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BONE FIXATION SYSTEM AND METHODS OF USE

Abstract

A bone fixation system including a first fastener, a second fastener, and a set screw. The first fastener may include a first shaft and a first head. The first head may define a passageway and may have a passageway axis. The first head may include an interior surface defining a curved seat, a front surface, and a U-shaped surface connecting each side of the front surface. The second fastener of the bone fixation system may include a second shaft and a second head shaped for disposal within the passageway such that the curved surface of the second head may contact the seat of the first head and may be pivotable about the curved surface. The set screw of the bone fixation system may secure the second head to lock the second fastener in a fixed, non-pivotable position.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION [0001] This application is a continuation of International Application No. PCT/US2023/079466 filed Nov. 13, 2023, which claims benefit of priority of U.S. Provisional Patent Application No. 63/424,367, filed Nov. 10, 2022, and entitled “Bone Fixation System and Methods of Use,” the disclosure of which is hereby incorporated herein by reference in its entirety.

FIELD OF INVENTION

[0002] The present disclosure relates generally to general surgery, orthopedic and neurosurgical implants used for insertion within a patient's vertebrae. More specifically, but not exclusively, the present disclosure concerns bone fixation systems for implantation into a patent's spine to maintain or re-establish proper spacing and alignment of the spine.

BACKGROUND

[0003] Spinal deformities may result from disease, age or trauma causing destabilization of the spine. To correct destabilization of a patent's spine, posterior fusion device systems may be used. The posterior fusion device systems that are currently available are designed to be applicable to single and multiple level stabilizations using a rod extending between adjacent bone screws for strength. These posterior fusion device systems and the instrumentation used for insertion into a patient's spine are extensive, complicated and expensive and susceptible to loosening of the rods and screws.

SUMMARY

[0004] Aspects of the present disclosure provide bone fixation systems, including at a single level or multiple levels, and methods that can maintain or re-establish anatomic spacing within a patent's spine.

[0005] Some embodiments of the present disclosure may include a bone fixation system including a first fastener, a second fastener, and a set screw. The first fastener may include a first shaft and a first head. The first shaft may include a distal end, a proximal end, a first longitudinal axis, and a first neck disposed at the proximal end. The first neck may be unthreaded. The first head may be disposed at the proximal end of the first shaft and may define a passageway extending from a first end to a second end and having a passageway axis. The first head may also include an interior surface along the passageway, wherein the interior surface defines a curved seat, a front surface disposed between the first neck of the first shaft and the first end of the first head, and a U-shaped surface connecting each side of the front surface. The U-shaped surface may comprise a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces. The first and second side surfaces may be generally planar and are generally aligned with the passageway axis. The front surface may be generally aligned with the first longitudinal axis. The first longitudinal axis and the passageway axis may be obliquely angled. The second fastener of the bone fixation system may include a second shaft and a second head. The second shaft may include a distal end, a proximal end, a second longitudinal axis, and a second neck disposed at the proximal end. The second neck may be unthreaded. The second head may be disposed at the proximal end of the second shaft and may be bulbous and have a curved surface. The second head may be shaped for disposal within the passageway such that the curved surface of the second head may contact the seat of the first head and may be pivotable about the curved surface. The set screw of the bone fixation system may be introducible into the passageway along the passageway axis to secure the second head of the second fastener in the passageway between the seat and the set screw and to

lock the second fastener in a fixed, non-pivotable position.
[0006] In some embodiments, a first edge between the first side surface and the front surface may be rounded and a second edge between the second side surface and the front surface may be rounded. In some embodiments, the first fastener may be threaded between the unthreaded first neck and the distal end. In some embodiments, the threading of the first fastener may comprise a first portion and a second portion, wherein the first portion has a higher thread pitch than the second portion. In some embodiments, an intersection between the first neck and the threading on the first shaft may be at least one of rounded or tapered. In some embodiments, the second fastener may be threaded between the unthreaded second neck and the distal end. In some embodiments, the second longitudinal axis may be parallel to the passageway axis and, in other embodiments, the second longitudinal axis may be obliquely angled relative to the passageway axis. In some embodiments, the second fastener may be pivotable such that the second longitudinal axis can be angled in a range of 0 degrees to 15 degrees relative to the passageway axis.
[0007] Some embodiments of the present disclosure may include a bone fixation system including a first fastener, a second fastener, and a set screw. In some embodiments, the first fastener may include a first shaft and a first head. The first shaft may include a threaded distal end, a proximal end, a first longitudinal axis, and a first neck disposed at the proximal end. The first neck maybe e unthreaded. The first head may be disposed proximal to the neck, may define a passageway extending between a first passage end and a second passage end, and may have a passageway axis obliquely angled relative to the first longitudinal axis. The first head may comprise a seat disposed along the passageway. An outer profile of the first head may not match an inner profile of the first head. The inner profile may be cylindrical and the outer profile may comprise at least one flat surface. The second fastener of the bone fixation system may include a second shaft and a second head. The second shaft may include a distal end, a proximal end, a second longitudinal axis, and a second neck disposed at the proximal end. The second neck may be unthreaded. The second head may be disposed proximal to the second neck, may be bulbous, and may have a curved surface. The second head may be shaped for disposal within the passageway such that the curved surface of the second head contacts the seat of the first head and is pivotable about the curved surface. The set screw of the bone fixation system may be introducible into the passageway along the passageway axis to secure the second head of the second fastener in the passageway between the seat and the set screw and to lock the second fastener in a fixed, non-pivotable position.
[0008] In some embodiments, the outer profile may comprise a front surface disposed between the first neck of the first shaft and a top surface of the first head and a U-shaped surface connecting each side of the front surface. The U-shaped surface may comprise a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces, and at least one of the front surface, the first side surface, and the second side surface may be the at least one flat surface. In some embodiments, a first edge between the first side surface and the front surface may be rounded and a second edge between the second side surface and the front surface may be rounded. In some embodiments, the first fastener may be threaded between the unthreaded first neck and the distal end. In some embodiments, an intersection between the first neck and the threading on the first shaft may be at least one of rounded or tapered. In some embodiments, the second longitudinal axis may be parallel to the passageway axis and, in other embodiments, the second longitudinal axis may be obliquely angled relative to the passageway axis. In some embodiments, the second fastener may be pivotable such that the second longitudinal axis is angled in a range of 0 degrees to 15 degrees relative to the passageway axis.
[0009] Some embodiments of the present disclosure may include a method of implanting a bone fixation system. The method may include the steps of: introducing a first fastener into a first bone; introducing a second fastener into a second bone; implanting the first fastener; implanting the second fastener through the passageway at a first angle, such that the first angle is one of parallel to the passageway axis or obliquely angled relative to the passageway axis; and, securing the second

head of the second fastener in the passageway using a set screw to lock the second fastener in a fixed, non-pivotable position. In some embodiments, the first fastener may include a first shaft and a first head. The first shaft may include a distal end, a proximal end, a first longitudinal axis, and a first neck disposed at the proximal end. The first neck may be unthreaded. The first head may be disposed at the proximal end of the first shaft, may define a passageway extending from a first end to a second end, and may have a passageway axis. The first head may include an interior surface along the passageway, such that the interior surface defines a curved seat, a front surface disposed between the first neck of the first shaft and the first end of the first head, and a U-shaped surface connecting each side of the front surface. The U-shaped surface may include a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces. The first and second side surfaces may be generally planar and may be generally aligned with the passageway axis. The front surface may be generally aligned with the first longitudinal axis. The first longitudinal axis and the passageway axis may be obliquely angled. In some embodiments, the second fastener may include a second shaft and a second head. The second shaft may include a distal end, a proximal end, a second longitudinal axis, and a second neck disposed at the proximal end. The second neck may be unthreaded. The second head may be disposed at the proximal end of the second shaft, and may be a bulbous head having a curved surface. The second head may be shaped for disposal within the passageway such that the curved surface of the second head contacts the seat of the first head and is pivotable about the curved surface.

[0010] In some embodiments, a first edge between the first side surface and the front surface may be rounded and a second edge between the second side surface and the front surface may rounded. In some embodiments, the first fastener may also include a threaded portion between the unthreaded first neck and the distal end and an intersection between the first neck and the threaded portion. The intersection may be at least one of rounded or tapered.

[0011] These and other objects, features and advantages of this disclosure will become apparent from the following detailed description of the various aspects and principles of the disclosure taken in conjunction with the accompanying drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate embodiments of the disclosure and, together with the detailed description herein, serve to explain the principles of the disclosure. The drawings are only for purposes of illustrating examples and are not to be construed as limiting the disclosure. It is emphasized that, in accordance with the standard practice in the industry, various features are not drawn to scale. In fact, the dimensions of the various features may be arbitrarily increased or reduced for clarity of discussion.

[0013] FIG. **1** illustrates a side view of one embodiment of a bone fixation system implanted in a spine, in accordance with one or more aspects of the present disclosure;

[0014] FIG. **2** illustrates a perspective view of one embodiment of a bone fixation system, in accordance with one or more aspects of the present disclosure;

[0015] FIG. **3**A illustrates a cross-sectional view of the assembled bone fixation system shown in FIG. **2**, in accordance with one or more aspects of the present disclosure;

[0016] FIG. **3**B illustrates an exploded, cross-sectional view of the bone fixation system shown in FIG. **2**;

[0017] FIG. **4**A illustrates a perspective view of one embodiment of a first fastener of the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure;

[0018] FIG. **4**B illustrates a side view of the first fastener of FIG. **4**A, in accordance with one or

more aspects of the present disclosure;
[0019] FIG. **4**C illustrates a partial cross-sectional view of the first fastener of FIG. **4**A, in accordance with one or more aspects of the present disclosure;
[0020] FIG. **4**D illustrates a top view of the first fastener of FIG. **4**A, in accordance with one or more aspects of the present disclosure;
[0021] FIG. **5** illustrates a side view of one embodiment of a second fastener of the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure;
[0022] FIG. **6**A illustrates a perspective view of one embodiment of a set screw of the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure;
[0023] FIG. **6**B illustrates a cross-sectional view of the set screw of FIG. **6**A, in accordance with one or more aspects of the present disclosure;
[0024] FIG. **7**A illustrates a perspective view of one embodiment of an inserter instrument coupled to the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure;
[0025] FIG. **7**B illustrates a perspective view of the inserter instrument of FIG. **7**A, in accordance with one or more aspects of the present disclosure;
[0026] FIG. **8** is a flow chart that illustrates a surgical method for implanting the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure; and
[0027] FIG. **9** illustrates an enlarged cross-sectional view of the head of the primary fastener of the bone fixation system of FIG. **2**, in accordance with one or more aspects of the present disclosure.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Generally stated, disclosed herein are different embodiments and examples of a bone fixation system. The embodiments and examples described herein of a bone fixation system constructed in accordance with one or more aspects of the present disclosure avoid the need for using a rod to connect adjacent pedicle screws typically used in back surgery. Without use of a connecting rod, there are less parts involved and less movable parts and less chance of movement of the fusion system or loosening of its components after surgery with a bone fixation system constructed in accordance with one or more principles or aspects of the present disclosure. A bone fixation system constructed in accordance with one or more principles or aspects of the present disclosure also does not rely on a connecting rod for strength. Further, surgical methods for inserting the bone fixation systems are discussed.
[0029] In this detailed description and the following claims, the words proximal, distal, anterior, posterior, medial, lateral, superior, inferior, cephalad and caudally are defined by their standard usage for indicating a particular part of a bone or implant according to the relative disposition of the natural bone or directional terms of reference. For example, “proximal” means the portion of an implant nearest the insertion instrument, while “distal” indicates the portion of the implant farthest from the insertion instrument. As for directional terms, “anterior” is a direction towards the front side of the body, “posterior” means a direction towards the back side of the body, “medial” means towards the midline of the body, “lateral” is a direction towards the sides or away from the midline of the body, “superior” means a direction above and “inferior” means a direction below another object or structure, “cephalad” means a direction toward the head and “caudally” means a direction toward the inferior part of the body.
[0030] In general, the embodiments and examples described herein of a bone fixation system constructed in accordance with one or more principles or aspects of the present disclosure include a primary screw or fastener and a secondary screw or fastener. The primary fastener may include a shaft and a head angled relative to the shaft. In some embodiments, a set screw is used to retain the second fastener within the head of the primary fastener. The head of the primary fastener provides a seat for the second fastener to enable variable angulations of the secondary fastener relative to the primary fastener.
[0031] In general, the head of the primary fastener is shaped and angled relative to the shaft to

enable insertion of the secondary fastener through it and into an adjacent pedicle, thereby eliminating the need for a rod or plate. In some embodiments, the head of the primary fastener is shaped to accommodate the physiology of the spine. In some embodiments, the head of the primary fastener may be shaped to minimize contact or interference with bone including, for example, the spinous process or transverse process. In some embodiments, the shape of the head of the primary fastener provides a low profile and less trauma to soft tissues when inserted, for example, via minimally invasive techniques.

[0032] In some embodiments, the head of the primary fastener is enlarged with respect to the shaft of the primary fastener. For example, the cross-sectional width of the enlarged head, taken normal to the longitudinal axis of the head, may be greater than the cross-sectional width of the shaft, taken normal to the longitudinal axis of the shaft. In some embodiments, the head may be shaped and manufactured to provide support for the bone fixation system. For example, the head may be shaped to provide additional strength and stress resistance to the bone fixation system. The head may also be shaped to withstand the cyclical loading that a patient's spine generally undergoes in daily life.

[0033] Moreover, the head may be angled relative to the shaft of the primary fastener. The position of the head of the primary fastener ensures closest proximity of the head to bone, thereby maximizing strength of the system. The angulation of the head relative to the shaft of the primary fastener enables appropriate direction of the secondary fastener to engage a second vertebra or pedicle, thus eliminating the need for a rod or plate. A set screw may be inserted into the head of the primary fastener to secure the secondary fastener to the primary fastener in a particular angular relationship. By minimizing the number of parts, the risk of failure through, for example, loosening of set screws to tulip heads in conventional bone fixation systems is reduced.

[0034] In general, the head of the primary fastener and a portion of the second fastener are configured to reside outside bone to allow for trajectory of the secondary fastener to engage an adjacent pedicle or span multiple adjacent vertebrae levels. The head of the primary fastener is incorporated partially into the longitudinal axis of the shaft of the primary fastener to minimize the overall size of the head, thereby decreasing soft tissue trauma on insertion and long-term irritation of adjacent muscle. The angulated head of the primary fastener enables, for example, in line insertion of a primary fastener screwdriver, and insertion of a secondary fastener and screwdriver through the same external entrance of the primary fastener during insertion. Moreover, part or all of the exposed shaft of the primary and/or secondary fastener may be unthreaded to minimize soft tissue trauma and long-term irritation of adjacent muscle.

[0035] The bone fixation system described herein may also include a tapering or a gradually increasing thickness of the shaft of the primary fastener as it approaches the head. This tapering or increased thickness at a region of greatest stress on the primary fastener reduces failure through fracture of the primary fastener and enhances the fastener to bone interface thereby providing enhanced stability by increasing compressive load.

[0036] The combination of the primary fastener and secondary fastener described by the examples herein enables insertion of the bone fixation system via either an MIS or OPEN technique without the need for additional instrumentation. The system design relies on angulation of two fasteners relative to each other for stability and minimizes the need for additional instrumentation or components, such as, for example, rods and multiple screw lengths and thicknesses. The design of the bone fixation system described herein combines the resistance to “pull out” imparted by the threads of the fasteners with that created by the angulation of the fasteners relative to each other, thereby making pull out virtually impossible.

[0037] Referring to the drawings, FIG. **1** illustrates an exemplary embodiment of a bone fixation system **100** implanted into the spine **50**. In the illustrated example, the bone fixation system **100** is implanted into one level of the spine **50**. The bone fixation system **100** may include a primary fastener **200** and a secondary fastener **300**. The primary fastener **200** may be implanted into a first

vertebra **52** and the secondary fastener **300** may be implanted into a second vertebra **54** (where the first vertebra **52** and the second vertebra **54** are shown as partially transparent in FIG. **1**). The first vertebra **52** and second vertebra **54** may be neighboring vertebra.

[0038] The primary fastener **200** may comprise a shaft **210** and a head **250**. The shaft **210** may have a threaded portion **212** and an unthreaded portion or neck **214**. The threaded portion **212** may be implanted into the first vertebra **52** such that part or all of the threaded portion **212** is implanted in the bone. The unthreaded neck **214** may not be implanted in the first vertebra **52** and may be disposed above the first vertebra **52**. In some embodiments, part or all of the unthreaded neck **214** may be implanted into bone.

[0039] The secondary fastener **300** may comprise a shaft **310** and a head **350** (not shown in FIG. **1**; shown in FIG. **5**). The shaft **210** may have a threaded portion **312** and an unthreaded portion or neck **314**. The secondary fastener **300** may be inserted through the head **250** of the primary fastener **200** such that the head **350** of the secondary fastener **300** is seated in the head **250** of the primary fastener **200**, as described in more detail below. The threaded portion **312** of the secondary fastener **300** may be implanted in the second vertebra **54** such that part or all of the threaded portion **312** is implanted in the bone. The unthreaded neck **314** may not be implanted in the second vertebra **54** and may be disposed above the second vertebra **54**. In some embodiments, part or all of the unthreaded neck **314** may be implanted into bone. In some embodiments, the threading **212**, **312** and the angling of the fasteners **200**, **300** relative to each other may prevent the bone fixation system **100** from backing out of the bone.

[0040] FIGS. **2**, **3**A, and **3**B illustrate the bone fixation member **100** according to some embodiments of the present disclosure. FIG. **2** illustrates a perspective view of the bone fixation member **100** according to some embodiments. FIGS. **3**A and **3**B illustrate a cross-sectional view of the bone fixation member shown in FIG. **2** in an assembled and exploded configuration, respectively. The primary fastener **200**, which may also be referred to as a first fastener, a primary bone anchor, or a first bone anchor, may include a shaft **210**, a head **250**, and a longitudinal axis **202**. The shaft **210** may have a distal end **224** and a proximal end **226**. The shaft **210** may be aligned with the longitudinal axis **202** and may have a threaded portion **212** and an unthreaded portion or neck **214**. The head **250** may be enlarged relative to the shaft **210** and may have a passageway **252** or opening that passes through it. The head **250** may include at least two planar outer side surfaces **278**, **280** to facilitate coupling with an insertion instrument. The at least two planar side surfaces **278**, **280** may be positioned on opposite sides of the head **250**. An arcuate outer surface **282** may be present to connect the two planar side surfaces **278**, **280** on the periphery of the head **250**. The arcuate surface **282** may be positioned opposite from the neck **214** of the head **250**. The passageway **252** may have a passageway axis **254**. In some embodiments, the passageway axis **254** may be obliquely angled with respect to the longitudinal axis **202** of the primary fastener **200**. For example, in some embodiments, the angle between the longitudinal axis **202** and the passageway axis **254** may be 5°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60°, 65°, 70°, 75°, 80°, 85°, or 90°. In some embodiments, the angle may preferably be in a range of about 40° to 60°, and in some implementations, at approximately 50°. The passageway **252** defines an interior cavity or space having an inner surface **262** extending from a first end **256** to a second end **258**. The passageway **252** may be sized and configured to receive and allow pass through of at least a portion of second fastener **300** or other spinal connection element to anchor the system **100** to, for example, a second bone or vertebrae **54**. The passageway **252** may also be sized and configured to retain or secure at least a portion of head **350** of second fastener **300**.

[0041] The second fastener **300**, which also may be referred to as a second fastener, a secondary bone anchor, or a second bone anchor, may include a shaft **310**, a head **350** (not shown in FIG. **2**), and a longitudinal axis **302**. The shaft **310** of the secondary fastener **300** may have a distal end **320** and a proximal end **322**. The shaft **310** of the secondary fastener **300** may include a threaded portion **312** and an unthreaded portion or neck **314**. The secondary fastener **300** may be inserted

through the passageway **252** of the head **250** of the primary fastener **200** such that the head **350** may be seated in the head **250** of the primary fastener **200**. A set screw **400** may be introduced into the passageway **252** of head **250** of the primary fastener **200** to secure the head **350** of the secondary fastener **300** into the head **252** of the primary fastener **200**. In some embodiments, as shown in the illustrated embodiment, the longitudinal axis **302** of the secondary fastener **300** may be coaxial with the passageway axis **254**. However, in other embodiments, the longitudinal axis **302** may be obliquely angled with respect to the passageway axis **254**, as described in more detail below.

[0042] In some embodiments, as shown the illustrated embodiment, the primary fastener **200** may include a cannula **204** through the shaft **210**. The cannula **204** may intersect with the passageway **252** of the head **250**. There may be a tool engagement feature **206** at the top of the cannula **204**. Additionally, in some embodiments, as shown in the illustrated embodiment, the secondary fastener **300** may have a cannula **304** that passes from the top of the head **350** through the distal end **320** of the shaft **310**. There may be a tool engagement feature **306** at the top of the cannula **304**.

[0043] The passageway **252** has a first end **256** and a second end **258** opposite the first end **256**. There may be a seat **260** formed in the interior surface **262** of the passageway **252** proximate the second end **258** of the passageway **252**. The seat **260** may be shaped to contact the bottom of the head **350** of the secondary fastener **300**. The seat **260** may extend along at least another portion of interior surface **262** towards second end **258**. In one example, seat **260** may be formed by interior surface **262** tapering inward towards longitudinal axis **302** as it approaches second end **258**.

[0044] The head **350** of the secondary fastener **300** may be enlarged with respect to the shaft **310**. The head **350** may be bulbous, spherical, semi-spherical or otherwise rounded. The head **350** may have a curved bottom **352** that curves to a flat top surface **354**. In some embodiments, the seat **260** of the passageway **252** is shaped to match the curved bottom surface **352** of the head **350** of the secondary fastener **300**. When the curved bottom surface **352** rests on the seat **260**, the secondary fastener **300** may pivot about the curved bottom surface **352** on the seat **260**. Thus, the secondary fastener **300** may pivot, spin, slide, rotate, or otherwise move through a variety of positions against the seat **260**. In some embodiments, the longitudinal axis **302** of the secondary fastener **300** may be obliquely angled with respect to the passageway axis **254**. This configuration allows a range of motion along several different axes, e.g. multi-directional movement or rotation or angulation, of secondary fastener **300** relative to the passageway axis **254**. For example, a curved bottom surface **352** of secondary fastener **300** mating with a mating concave-shaped seat **260** enables a variation of angulation to accommodate pedicle screw insertion in variable anatomy. For example, the secondary fastener **300** may pivot through a variety of angles in a range of 0° to 5°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60° relative to the passageway axis **254**. In some embodiments, the secondary fastener **300** may pivot through a variety of angles in a range of 0° to 15° relative to the passageway axis **254**.

[0045] In some embodiments, the secondary fastener **300** may be coaxial with the passageway axis **254**. In other embodiments, the secondary fastener **300** may be obliquely angled with respect to the passageway axis **254**. Moreover, in some embodiments, the secondary fastener **300** may be obliquely angled relative to the longitudinal axis **202** of the primary fastener **200**. In other embodiments, the secondary fastener **300** may be parallel to the longitudinal axis **202** of the primary fastener **200**.

[0046] FIGS. **4**A-**4**D illustrate various views of the primary fastener **200** in FIG. **2**. FIG. **4**A is a perspective view, FIG. **4**B is a side view, FIG. **4**C is a partial cross-sectional side view, and FIG. **4**D is a top view of the primary fastener **200**. In the illustrated embodiment, the shaft **210** of the primary fastener **200** includes a threaded portion **212** and an unthreaded portion or neck **214**.

[0047] The threaded portion **212** may have any appropriate profile. In the illustrated embodiment, the threaded portion **212** has a first portion **216** and a second portion **218**. The first portion **216** may have a lower thread pitch than the second portion **218**. In some aspects, the lower thread pitch may

make the first portion **216** better suited for cortical bone and the higher thread pitch may make the second portion **218** better suited for cancellous bone. In other embodiments, the threaded portion **212** may have more than two portions, which may each have different thread pitches or one or more portions may have the same thread pitch. In other embodiments, the threaded portion **212** may not have more than one portion and may instead have one portion of the same thread pitch. In some embodiments, the threaded portion **212** may be single lead or dual lead. In other embodiments, the shaft **210** may be threaded along its entire length and may have no unthreaded portion.

[0048] The shaft **210** may also have an intersection **220** between the threaded portion **212** and the unthreaded neck **214**. The intersection **220** may be the thread runout of the threaded portion **212**. In some embodiments, the thread runout **220** may be gradual. The thread runout **220** may be gradual over a range of about 0.5 to 6 full rotations. In some implementations, the thread runout is in a range of about 0.5 to 2 full rotations. In some implementations, the thread runout includes a taper angle in a range of about 3 to 30 degrees. In some implementations, the thread runout includes a taper angle in a range of about 5-10 degrees.

[0049] The shaft **210** may be tapered from the proximal end **226** to the distal end **224** and may come to a point **222** at the distal end **224**. In some embodiments, only the threaded portion **212** or unthreaded neck **214** may be tapered. In other embodiments, the shaft **210** may not be tapered, but may have discrete sections or steps where the width narrows.

[0050] The head **250** of the primary fastener **200** may be disposed at the proximal end **226** of the unthreaded neck **214**. The passageway **252** or interior surface **262** of the head **250** may be generally cylindrically shaped as in the illustrated embodiment. There may be a seat **260** formed in the interior surface **262**. The seat **260** may be curved to match the shape of the head **350** of the secondary fastener **300**. There may also be a skirt **261** extending outward from the seat **260** to the second end **258** of the passageway **252**. In some embodiments, the skirt **261** may be curved or flat. The skirt **261** may provide additional space for the unthreaded neck **314** of the secondary fastener **300** to move or rotate as the secondary fastener **300** pivots about the seat **260**. Thus, the skirt **261** may provide an added pivoting range of motion.

[0051] As shown in FIG. **9**, the pivoting range of motion (See A in FIG. **9**) relative to the passageway axis **254** in one direction may be 10° to 15° or preferably 13° with a full range of motion from 20° to 30° with a preferable total range of motion of 26° relative to the passageway axis **254**. In other embodiments, the skirt **261** may not extend outward, but may extend further inward or may extend straight down from the bottom of the seat **260** to the second end **258** of the passageway **250**. In some embodiments, there is no skirt **261** and the seat **260** is disposed along the second end **258** of the passageway **252**.

[0052] The head **250** may have an exterior or outer surface **264**. In some embodiments, the exterior surface **264** of the head **250** does not match the interior surface **262**. In the illustrated embodiments, the exterior surface **264** is comprised of a front surface **266** and a back region **268**. The front surface **266** extends from the proximal end **226** of the unthreaded neck **214** to the top surface **270** of the head **250**. The back region **268** may be generally U-shaped and may connect a first side edge **274** of the front surface **266** with a second side edge **276** of the front surface **266**. The back region **268** may have a first side surface **278** and a second side surface **280** connected by a curved surface **282**. In some embodiments, the first side surface **278** and second side surface **280** may be connected by a flat surface.

[0053] In some embodiments, the first side surface **278** and the second side surface **280** are generally planar and parallel to each other. In some embodiments, the edges between the front surface **266** and the back region **268** are rounded or curved. In other embodiments, the edges come to a pointed corner or are flat and angled at a chamfer. In some embodiments, the front surface **266** may extend from the side edges **274**, **276** and come to a point **284** at the bottom along the proximal end **226** of the unthreaded neck **214**.

[0054] In some embodiments, the front surface **266** is arranged so that it is generally aligned with the longitudinal axis **202** of the primary fastener **200** such that the longitudinal axis **202** and the plane of the front surface **266** are parallel to each other. In some embodiments, the back region **268** is generally aligned with the passageway axis **254** such that the surfaces **278**, **280**, **282** are generally parallel to the passageway axis **254**. Thus, a line or boundary along the front surface **266** and a line or boundary along the back region **268** may be angled relative to each other, as shown in FIG. **4**B at angle a. More specifically, FIG. **4**B shows a boundary line along the curved surface **282** that intersects a boundary line along the front surface **266** and forms the angle α. In some embodiments, the angle a may be about 5°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60° 65°, 70°, 75°, 80°, 85°, or 90°. In some embodiments, the angle may preferably be in a range of about 45° to 55°, and in some implementations, at approximately 50°. In other embodiments, the front surface **266** may be angled with respect to the longitudinal axis **202**. In some embodiments, the back region **268** may be angled away from the passageway axis **254** from the top surface **270** to the bottom surface **272** of the head **250**. In other embodiments, the back region **268** may be angled towards the passageway axis **254** from the top surface **270** to the bottom surface **272** of the head **250**.

[0055] The head **250** may be shaped to improve the strength of the primary fastener **200**. In some embodiments, the front **266** and back **268** surfaces are shaped to add support for the head **250** and unthreaded neck **214**. The head **250** may also be shaped to accommodate the physiology of the spine including, for example, to minimize contact or interference with bone such as, for example, the spinous process or transverse process. The head **250** may also provide a low profile and less trauma to soft tissues when inserted. In some embodiments, the head **250** may be shaped to provide additional strength and stress resistance. For example, the head **250** may be shaped to withstand the cyclical loading that a patient's spine generally undergoes in daily life.

[0056] The interior surface **262** along the passageway **252** may have a threaded portion **286**. The threaded portion **286** may extend partially or completely down the passageway **252**. In some embodiments, the threaded portion **286** may be proximate the first end **256** of the passageway **252**. The threaded portion **286** may engage threading on the set screw **400**, as described in more detail below.

[0057] There may be a cannula **204** that passes through the shaft **210** of the primary fastener **200**. The cannula **204** may open into and intersect the passageway **252** along the interior surface **262**. The top of the cannula **204** may include a tool engagement feature **218**. The cannula **204** and tool engagement feature **206** may be accessible through the first end **256** of the passageway **252**. Thus, a guidewire may be inserted from the first end **256** of the passageway **256** through the cannula **204**. Moreover, a tool, like for example a screwdriver, may be able to engage the tool engagement feature **206** through the first end **256** of the passageway **252** to implant, or screw, the primary fastener **200** into the bone. In some embodiments, the guidewire may be inserted through the cannula **204** of the primary fastener **200** and inserted into the desired location in the vertebra. Then, the shaft **210** of the primary fastener **200** may be implanted around the guidewire using a tool that engages the tool engagement feature **206**. In some embodiments, the tool engagement feature **206** may be hexagonally or hexalobe shaped. However, in other embodiments, the tool engagement feature **206** may be any other appropriate shape including, triangular, square, rectangular, ovular, or pentagonal.

[0058] FIG. **5** illustrates a side view of the secondary fastener **300** of the bone fixation system **100** shown in FIG. **2**. In the illustrated embodiment, the shaft **310** of the secondary fastener **300** includes a threaded portion **312** and an unthreaded portion or neck **314**.

[0059] The threaded portion **312** may have any appropriate profile. In the illustrated embodiment, the threaded portion **312** has a single thread pitch. In some embodiments, the thread pitch of the threaded portion **312** of the secondary fastener **300** may be higher than the thread pitch of both threaded portions **216**, **218** of the primary fastener **200**. In other embodiments, the thread pitch of

the threaded portion **312** of the secondary fastener **300** may be lower than the thread pitch of both threaded portions **216**, **218** of the primary fastener **200** or may the same as the thread pitch of one of the threaded portions **216**, **218**. In some embodiments, the threaded portion **312** of the secondary fastener **300** may have more than one portion that may have the same or different thread pitches. In some embodiments, the threaded portion **312** of the secondary fastener **300** may be single lead or dual lead. In other embodiments, the shaft **310** may be threaded along its entire length and may have no unthreaded portion.

[0060] The shaft **310** may also have an intersection **316** between the threaded portion **312** and the unthreaded neck **314**. The intersection **316** may be the thread runout of the threaded portion **312**. In some embodiments, the thread runout **316** may be gradual. The thread runout **316** may be gradual over a range of about 0.5 to 6 full rotations. In some implementations, the thread runout is in a range of about 0.5 to 2 full rotations. In some implementations, the thread runout includes a taper angle in a range of about 3 to 30 degrees. In some implementations, the thread runout includes a taper angle in a range of about 5-10 degrees.

[0061] The shaft **310** may be tapered from the proximal end **322** to the distal end **320** and may come to a point **318** at the distal end **320**. In some embodiments, only the threaded portion **312** or unthreaded neck **314** may be tapered. In other embodiments, the shaft **310** may not be tapered, but may have discrete sections where the width narrows.

[0062] The secondary fastener **300** may have a bulbous, spherical, or semispherical head **350**. The head **350** may have a curved bottom surface **352** and a flat top surface **354**.

[0063] The secondary fastener **300** may have a cannula **304** that passes from the top of the head **350** through the distal end **320** of the shaft **310**. There may be a tool engagement feature **306** at the top of the cannula **304** along the flat top surface **354** of the head **350**. When the secondary fastener **300** is disposed in the head **250** of the primary fastener **300**, the cannula **304** and the tool engagement feature **306** may be accessible through the first end **256** of the passageway **252**. Thus, a guidewire may be inserted from the first end **256** of the passageway **252** through the cannula **306** of the secondary fastener **300**. Moreover, a tool, like for example a screwdriver, may be able to engage the tool engagement feature **306** of the secondary fastener **300** through the first end **256** of the passageway **252** to implant, or screw, the secondary fastener **300** into the bone. In some embodiments, the guidewire may be inserted through the cannula **304** of the secondary fastener **300** and inserted into the desired location in the vertebra. Then, the shaft **310** of the secondary fastener **300** may be implanted around the guidewire using a tool that engages the tool engagement feature **306**. In some embodiments, the tool engagement feature **306** may be hexagonally or hexalobe shaped. However, in other embodiments, the tool engagement feature **306** may be any other appropriate shape including, triangular, square, rectangular, ovular, or pentagonal.

[0064] FIGS. **6**A and **6**B illustrate a perspective view and a cross-sectional view, respectively, of the set screw **400** of the bone fixation system **100** shown in FIG. **2**. After secondary fastener **300** is positioned into bone in a selected direction and orientation relative to the primary fastener **200**, set screw **400** may lock the orientation of secondary fastener **300** relative to the primary fastener **200**. Set screw **400** may have any suitable size, configuration and means for securing the head **350** of the secondary fastener **300** to seat **260** in the passageway **252** of the primary fastener **200**. The set screw **400** may include a top surface **402**, side surface **404** and a bottom surface **406**. Set screw **400** may also include a tool engagement feature **408** along the top surface **402**. In some embodiments, the tool engagement feature **408** may be hexagonally or hexalobe shaped. However, in other embodiments, the tool engagement feature **408** may be any other appropriate shape including, triangular, square, rectangular, ovular, or pentagonal. In some embodiments, set screw **400** may be cannulated and in other embodiments, it may not be cannulated. The set screw **400** may include threads **410** on side surface **404** extending partially or entirely from the top surface **402** to the bottom surface **406**.

[0065] The bottom surface **406** may be sized and shaped to retain the head **350** of the secondary

fastener **300** against the seat **260** of the passageway **252**. In some embodiments, the shape of the bottom surface **406** may be curved to match the shape of the head **350** of the secondary fastener **300**. In some aspects, the shape of the bottom surface **406** may maximize surface contact and, therefore, maximize the rigidity of the system. In some other embodiments, the radius of curvature of the bottom surface **406** may be smaller than the spherical radius of curvature of the head **350** of the secondary fastener **300**. In the scenario where the geometry of the bottom surface **406** of the set screw **400** is smaller than the surface geometry of the head **350** of the secondary fastener **300**, such a difference may result a secure engagement between the head **350** and the bottom surface **406** by the engagement (e.g., cutting into) of the lower circumferential break edges **407** of the set screw **400** with the surface of the head **350** when the set screw **400** is threaded into the head **250** of the primary fastener **200**. In another embodiment, the bottom surface **406** may include a surface treatment, such as, for example, surface etching, which engages and/or interacts with head **350** of second fastener **300** to provide, for example, enhanced rigidity through a friction fit that prevents shifting of second fastener **300** once secured. In one example, head **350** may also include a surface treatment or similar surface etching that engages and/or interacts with bottom surface **406** of the set screw **400**.

[0066] FIGS. **7**A and **7**B illustrate an inserter instrument **500** for implanting the bone fixation system **100** into bone. The inserter instrument **500** may have a handle **502** and a shaft **504** that extends from the handle **502**. In some embodiments, the handle **502** may have grips **506** that allow a surgeon to hold and maneuver the inserter instrument **500** more easily. The bottom of the shaft **504** may have an attachment feature **508** for coupling to the bone fixation system **100**. The attachment feature may have an opening or cutout **510** with a U-shaped or C-shaped interior surface **512**. The interior surface **512** may have a ridge **514** spaced from the bottom end of the shaft. The interior surface **512** may have a first side surface **516** and a second side surface **518** connected by a curved surface **520**. The side surfaces **516**, **518** of the attachment feature **508** may contact and hold the side surfaces **278**, **280** of the exterior surface **264** of the head **250** of the primary fastener **200**. In some embodiments, the top surface **270** of the head **250** may contact the bottom of the ridge **514** of the attachment feature **508** of the inserter instrument **500**. In this way, the surgeon may use the inserter instrument **500** to hold the primary fastener **200** steady as other instruments are used to implant the bone fixation system **100** into bone. For example, a screwdriver instrument **600** may be inserted along the opening **510** to contact the tool engagement feature **206** of the primary fastener **200** or the tool engagement feature **306** of the secondary fastener **300** to implant the respective fastener into bone.

[0067] In some embodiments, the bone fixation system **100** may be provided as a kit with one or more primary fastener **200** sizes and one or more secondary fastener sizes **300**. In some embodiments, the primary fastener **200** and the secondary fastener **300** may be the same size. In other embodiments, the primary fastener **200** and the secondary fastener **300** may be different sizes. The surgeon may choose the primary fastener **200** and the secondary fastener **300** based on the patent's physiology or the surgeon's preference.

[0068] FIG. **8** illustrates a flow chart of a method **800** for implanting a bone fixation system **100** into a spine of a patient, according to some embodiments of the present disclosure. In some embodiments, the bone fixation system **100** may be implanted into the spine **50** of a patient to stabilize one or more levels of the spine **50**. The method may include choosing a primary fastener **200** from a kit.

[0069] Step **802** of the method **800** may optionally include inserting a guidewire into a first vertebra **52** to a desired location. The guidewire may then be threaded through the cannula **204** of the primary fastener **200**.

[0070] Step **804** of the method **800** may include implanting the primary fastener **200** into the first vertebra **52**. If a guidewire is used, the primary fastener **200** may be implanted around the guidewire. A screwdriver may be used to screw the primary fastener **200** into the first vertebra **52**.

In some embodiments, the screwdriver may engage the tool engagement feature **206** through the first end **256** of the passageway **252** to implant the primary fastener **200** into bone. In some embodiments, the screwdriver is cannulated so that a guidewire may be inserted through the primary fastener **200** and through the screwdriver. Once the primary fastener **200** is implanted, the guidewire may be removed.

[0071] Step **806** of the method **800** may optionally include inserting a guidewire into a second vertebra **54** to a desired location. The guidewire may then be threaded through the cannula **304** of the secondary fastener **300**.

[0072] Step **808** of the method **800** may include inserting the secondary fastener **300** through the passageway **252** of the head **250** of the primary fastener **200**. The shaft **310** of the secondary fastener **300** may be inserted first through the passageway **252** until the head **350** is seated within the passageway **252**. In some embodiments, the curved surface **352** of the secondary fastener **300** will contact the seat **260** in the passageway **252**. The secondary fastener **300** may pivot about the seat **260** to the desired angle.

[0073] In some embodiments, an angle guide may optionally be used to determine the appropriate trajectory of the secondary fastener **300**. The angle guide may have a curved end or a spherical ball shape that matches or is smaller than the curved bottom surface **352** of the head **350** of the secondary fastener **300**. The angle guide may have an inner lumen that passes through the curved end of the angle guide. The angle guide may fit through the first end **256** of the passageway **252** of the head **250** of the primary fastener **200** and may contact the seat **260**. The curved surface or ball end of the angle guide may pivot about the seat **260** similar to the way the secondary fastener **300** pivots about the seat **260**. Thus, the surgeon may use the angle guide to determine the desired angle of the secondary fastener **300** using the angle guide. Once the desired angle is determined, the surgeon may insert a guidewire through the lumen of the angle guide and insert the guidewire into the second vertebra **54** at the desired angle. The angle guide may then be removed. In some embodiments, the secondary fastener **300** is implanted without the use of an angle guide.

[0074] Step **810** of the method **800** may include implanting the secondary fastener **300** into the second vertebra **54**. A screwdriver may be used to implant the secondary fastener **300** into the bone. The screwdriver may engage the tool engagement feature **306** on the head **350** of the secondary fastener **300** through the first end **256** of the passageway **252** of the primary fastener **200** to screw the secondary fastener **300** into the bone around the guidewire. In some embodiments, the screwdriver is cannulated so that a guidewire may be inserted through the secondary fastener **300** and through the screwdriver. Once the secondary fastener **300** is implanted, the guidewire may be removed.

[0075] In some embodiments, an inserter instrument **500** may be used to aid in implanting the secondary fastener **300** into the bone. The head **250** of the primary fastener **200** may be inserted into the attachment feature **508** of the inserter instrument **500**. The opening **510** of the attachment feature **508** of the inserter instrument **500** may be placed around the head **250** of the primary fastener **200** such that the ridge **514** rests on the top surface **270** of the head **250**. A screwdriver instrument **600** may then be inserted into the first end **256** of the passageway **252** of the primary fastener **200** to contact the tool engagement feature **306** on the head **350** of the secondary fastener **300**. The inserter instrument **500** may then be held steady as the screwdriver instrument **600** is used to implant or screw in the secondary fastener **300**.

[0076] Step **812** of the method **800** may also include securing the head of the secondary fastener **300** in the head **250** of the primary fastener **200** using a set screw **400**. In some embodiments, the set screw **400** may have threading along the side surface **404** that may engage a threaded portion **286** of the passageway **252**. The set screw **400** may be inserted into the first end **256** of the passageway **252** of the primary fastener **200**. In some embodiments, a screwdriver may be used to screw the set screw **400** into the passageway **252** by engaging the tool engagement feature **408** on the top of the set screw **400**. The set screw **400** may contact the head **350** of the secondary fastener

300 and secure it against the seat **260** of the passageway **252**. Thus, the set screw **400** may be tightened until it retains the secondary fastener **300** in the same angular position relative to the primary fastener **200** and prevents the secondary fastener **300** from moving.

[0077] In some embodiments, the inserter instrument **500** may be used to aid in inserting and tightening the set screw **400** into the passageway **252** of the primary fastener **200**. The head **250** of the primary fastener **200** may be inserted into the attachment feature **508** of the inserter instrument **500** as described above. A screwdriver instrument **600** may then be inserted into the tool engagement feature **408** of the set screw **400**. The inserter instrument **500** may then be held steady as the screwdriver instrument **600** is used to insert and tighten the set screw **400** in the passageway **252**.

[0078] In some embodiments, a drill instrument may be used to drill a hole before the fasteners **200**, **300** are implanted. This may make it easier for the surgeon to implant the fasteners **200**, **300**. In some embodiments, alternative methods may be employed to install the bone fixation system **100** described herein. For example, a surgical robot or an image guidance system may be used to perform or aid in performing all or portions of the various steps required to properly install a system constructed in accordance with one or more aspects within a patient.

[0079] Although the fasteners shown and described through the present description, such as fasteners **200** and **300** are shown as being straight, it is also contemplated that one or more of these fasteners may have curved shafts that may be driven into the patient's vertebrae rather than screwed, or the shafts of these fasteners may also be slightly curved.

[0080] As may be recognized by those of ordinary skill in the art based on the teachings herein, numerous changes and modifications may be made to the above-described and other embodiments of the present disclosure without departing from the scope of the disclosure. The fasteners, elongate members, and other components of the devices and/or systems as disclosed in the specification, including the accompanying abstract and drawings, may be replaced by alternative component(s) or feature(s), such as those disclosed in another embodiment, which serve the same, equivalent or similar purpose as known by those skilled in the art to achieve the same, equivalent or similar results by such alternative component(s) or feature(s) to provide a similar function for the intended purpose. In addition, the devices and systems may include more or fewer components or features than the embodiments as described and illustrated herein. For example, the components and features of FIGS. **1**-**7**B and FIG. **9** may all be used interchangeably and in alternative combinations as would be modified or altered by one of skill in the art. Accordingly, this detailed description of the currently-preferred embodiments is to be taken as illustrative, as opposed to limiting the disclosure.

[0081] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. 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. It will be further understood that the terms “comprise” (and any form of comprise, such as “comprises” and “comprising”), “have” (and any form of have, such as “has”, and “having”), “include” (and any form of include, such as “includes” and “including”), and “contain” (and any form of contain, such as “contains” and “containing”) are open-ended linking verbs. As a result, a method or device that “comprises,” “has,” “includes,” or “contains” one or more steps or elements possesses those one or more steps or elements, but is not limited to possessing only those one or more steps or elements. Likewise, a step of a method or an element of a device that “comprises,” “has,” “includes,” or “contains” one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

[0082] The disclosure has been described with reference to the preferred embodiments. It will be understood that the architectural and operational embodiments described herein are exemplary of a

plurality of possible arrangements to provide the same general features, characteristics, and general system operation. Modifications and alterations will occur to others upon a reading and understanding of the preceding detailed description. It is intended that the disclosure be construed as including all such modifications and alterations.

Claims

1. A bone fixation system, comprising: a first fastener comprising: a first shaft comprising a distal end, a proximal end, a first longitudinal axis, and a first neck disposed at the proximal end, wherein the first neck is unthreaded; a first head disposed at the proximal end of the first shaft and defining a passageway extending from a first end to a second end and having a passageway axis, the first head comprising: an interior surface along the passageway having a passageway axis and having a curved seat, the first longitudinal axis and the passageway axis being obliquely angled; a front surface disposed between the first neck of the first shaft and the first end of the first head, wherein the front surface is generally parallel to the first longitudinal axis; a U-shaped back portion intersecting a first edge and a second edge of the front surface, wherein the U-shaped back portion comprising a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces, wherein the first and second side surfaces are generally planar and are generally aligned with the passageway axis, a second fastener comprising: a second shaft comprising a distal end, a proximal end, a second longitudinal axis, and a second neck disposed at the proximal end, wherein the second neck is unthreaded; a second head disposed at the proximal end of the second shaft, the second head having a curved surface sized and shaped to contact the seat of the first head and pivot about the curved surface; and a set screw introducible into the passageway along the passageway axis to secure the second head of the second fastener in the passageway between the seat and the set screw and to lock the second fastener in a fixed, non-pivotable position.
2. The bone fixation system of claim 1, wherein the first edge between the first side surface and the front surface is rounded and wherein the second edge between the second side surface and the front surface is rounded.
3. The bone fixation system of claim 1, wherein the first fastener comprises threads between the unthreaded first neck and the distal end.
4. The bone fixation system of claim 3, wherein the threads of the first fastener comprise a first portion and a second portion, wherein the first portion has a higher thread pitch than the second portion.
5. The bone fixation system of claim 3, wherein an intersection between the first neck and the threading on the first shaft is at least one of rounded or tapered.
6. The bone fixation system of claim 1, wherein the second fastener is threaded between the unthreaded second neck and the distal end.
7. The bone fixation system of claim 1, wherein the second longitudinal axis is parallel to the passageway axis.
8. The bone fixation system of claim 1, wherein the second longitudinal axis is obliquely angled relative to the passageway axis.
9. The bone fixation system of claim 1, wherein the second fastener is pivotable such that the second longitudinal axis is angled in a range of **0** degrees to **15** degrees relative to the passageway axis.
10. A bone fixation system, comprising: a first fastener comprising: a first shaft comprising: a threaded distal end; a proximal end; a first longitudinal axis; and, a first neck disposed at the proximal end, wherein the first neck is unthreaded; a first head disposed proximal the neck and defining a passageway extending between a first passage end and a second passage end and having a passageway axis obliquely angled relative to the first longitudinal axis, the first head comprising

a seat disposed along the passageway, wherein an outer profile of the first head does not match an inner profile of the first head, and wherein the inner profile is cylindrical and the outer profile comprises at least one flat surface; a second fastener comprising: a second shaft comprising: a distal end; a proximal end; a second longitudinal axis; and, a second neck disposed at the proximal end, wherein the second neck is unthreaded; a second head disposed proximal the second neck, the second head being bulbous and having a curved surface, wherein the second head is shaped for disposal within the passageway such that the curved surface of the second head contacts the seat of the first head and is pivotable about the curved surface; and a set screw introducible into the passageway along the passageway axis to secure the second head of the second fastener in the passageway between the seat and the set screw and to lock the second fastener in a fixed, non-pivotable position.

11. The bone fixation system of claim 10, wherein the outer profile comprises a a front surface disposed between the first neck of the first shaft and a top surface of the first head; and, a U-shaped surface connecting each side of the front surface, wherein the U-shaped surface comprises a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces, wherein at least one of the front surface, the first side surface, and the second side surface is the at least one flat surface.

12. The bone fixation system of claim 11, wherein a first edge between the first side surface and the front surface is rounded and wherein a second edge between the second side surface and the front surface is rounded.

13. The bone fixation system of claim 10, wherein the first fastener is threaded between the unthreaded first neck and the distal end.

14. The bone fixation system of claim 13, wherein an intersection between the first neck and the threading on the first shaft is at least one of rounded or tapered.

15. The bone fixation system of claim 10, wherein the second longitudinal axis is parallel to the passageway axis.

16. The bone fixation system of claim 10, wherein the second longitudinal axis is obliquely angled relative to the passageway axis.

17. The bone fixation system of claim 10, wherein the second fastener is pivotable such that the second longitudinal axis is angled in a range of **0** degrees to **15** degrees relative to the passageway axis.

18. A method of implanting a bone fixation system, comprising the steps of: introducing a first fastener into a first bone, the first fastener comprising: a first shaft comprising: a distal end; a proximal end; a first longitudinal axis; and a first neck disposed at the proximal end, wherein the first neck is unthreaded; a first head disposed at the proximal end of the first shaft and defining a passageway extending from a first end to a second end and having a passageway axis, the first head comprising: an interior surface along the passageway, wherein the interior surface defines a curved seat; a front surface disposed between the first neck of the first shaft and the first end of the first head, wherein the front surface is generally aligned with the first longitudinal axis; a U-shaped surface connecting each side of the front surface, wherein the U-shaped surface comprises a first side surface, a second side surface, and a curved surface connecting the first and second side surfaces, wherein the first and second side surfaces are generally planar and are generally aligned with the passageway axis, wherein the first longitudinal axis and the passageway axis are obliquely angled; introducing a second fastener into a second bone, second fastener comprising: a second shaft comprising: a distal end; a proximal end; a second longitudinal axis; and a second neck disposed at the proximal end, wherein the second neck is unthreaded; a second head disposed at the proximal end of the second shaft, the second head being a bulbous head and having a curved surface, wherein the second head is shaped for disposal within the passageway such that the curved surface of the second head contacts the seat of the first head and is pivotable about the curved surface; implanting the first fastener; implanting the second fastener through the passageway at a

first angle, wherein the first angle is one of: parallel to the passageway axis or obliquely angled relative to the passageway axis; and, securing the second head of the second fastener in the passageway using a set screw to lock the second fastener in a fixed, non-pivotable position.

19. The method of claim 18, wherein a first edge between the first side surface and the front surface is rounded and wherein a second edge between the second side surface and the front surface is rounded.

20. The bone fixation system of claim 1, wherein the first fastener further comprises: a threaded portion between the unthreaded first neck and the distal end; and, an intersection between the first neck and the threaded portion, wherein the intersection is at least one of rounded or tapered.

21. A bone fixation system, comprising: a first fastener having a proximal end and a distal end, the first fastener comprising: a first shaft defining a first longitudinal axis; and a first head disposed at the proximal end of the first shaft, the first head comprising: a passageway sized to receive a second fastener, the passageway having a passageway axis obliquely angled relative to the first longitudinal axis, the passageway having an interior surface defining a curved seat shaped to interface with the second fastener; a front surface forming a plane generally parallel to the first longitudinal axis; a U-shaped back portion extending from opposing sides of the front surface, wherein the U-shaped back portion comprises a first planar side surface, a second planar side surface, and a curved surface connecting the first and the second side surfaces, the first side surface and the second side surface being generally planar and generally parallel to the passageway axis, the curved surface defining a reference line angled relative to and intersecting a reference line along the front surface.

22. The bone fixation system of claim 1, wherein a first edge between the first side surface and the front surface is rounded and wherein a second edge between the second side surface and the front surface is rounded.