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(54) **AWL-TIPPED PEDICLE SCREW AND METHOD OF IMPLANTING SAME**

(71) Applicant: **Jean-Pierre Mobasser**, Indianapolis, IN (US)

(72) Inventor: **Jean-Pierre Mobasser**, Indianapolis, IN (US)

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Related U.S. Application Data

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(60) Provisional application No. 61/396,564, filed on May 28, 2010.

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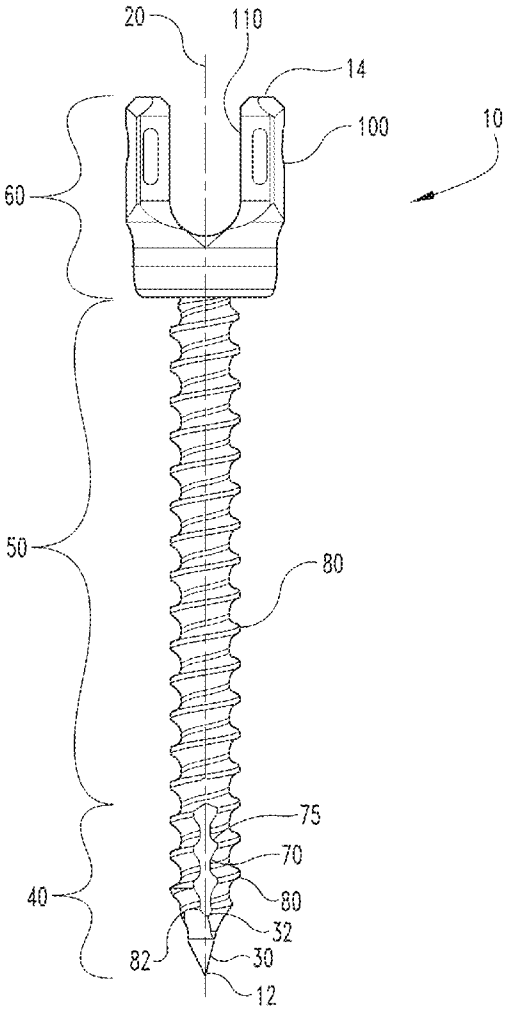
(57) **ABSTRACT**

A bone screw and method of inserting the same is disclosed. In one example, the bone screw includes an awl tip for creating a pilot hole in the pedicle of a vertebra without having to predrill a starter hole. One or more threads located adjacent to the awl tip engage the wall of the pilot hole and draw the screw into the bone, thereby eliminating the need to drill and tap a hole in the bone prior to implantation of the screw.



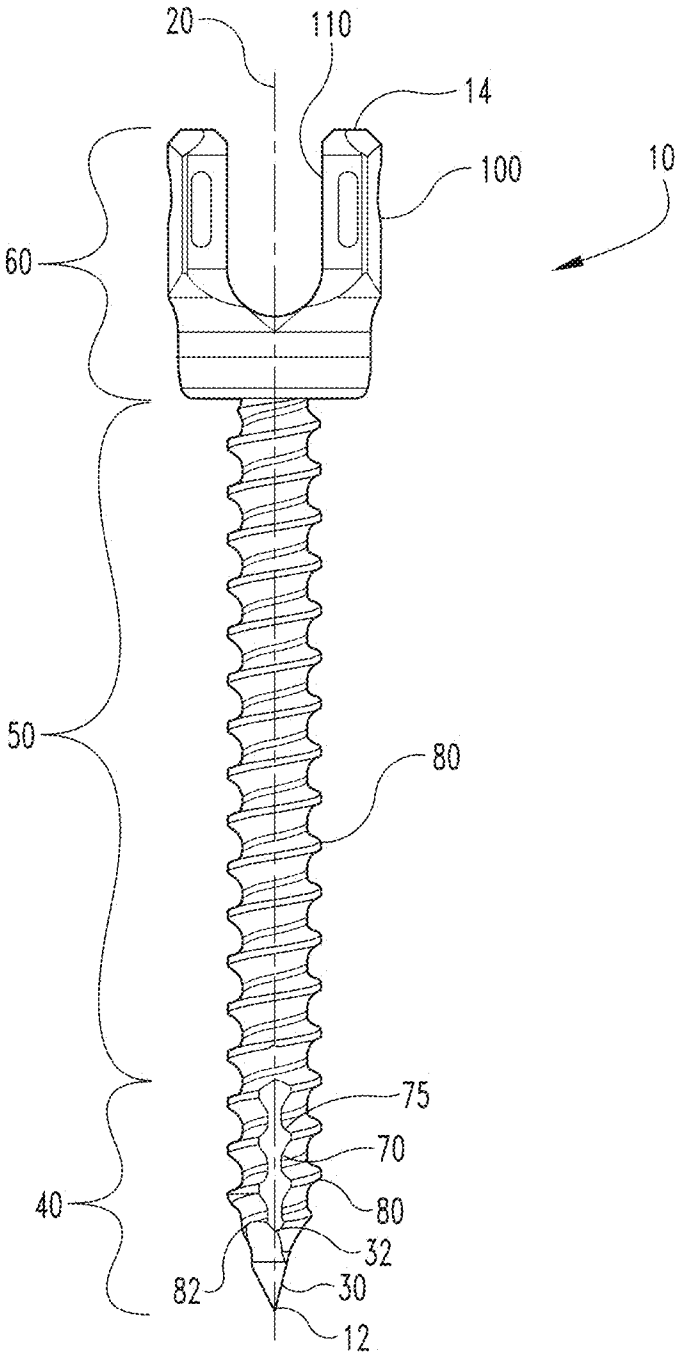


Fig. 1

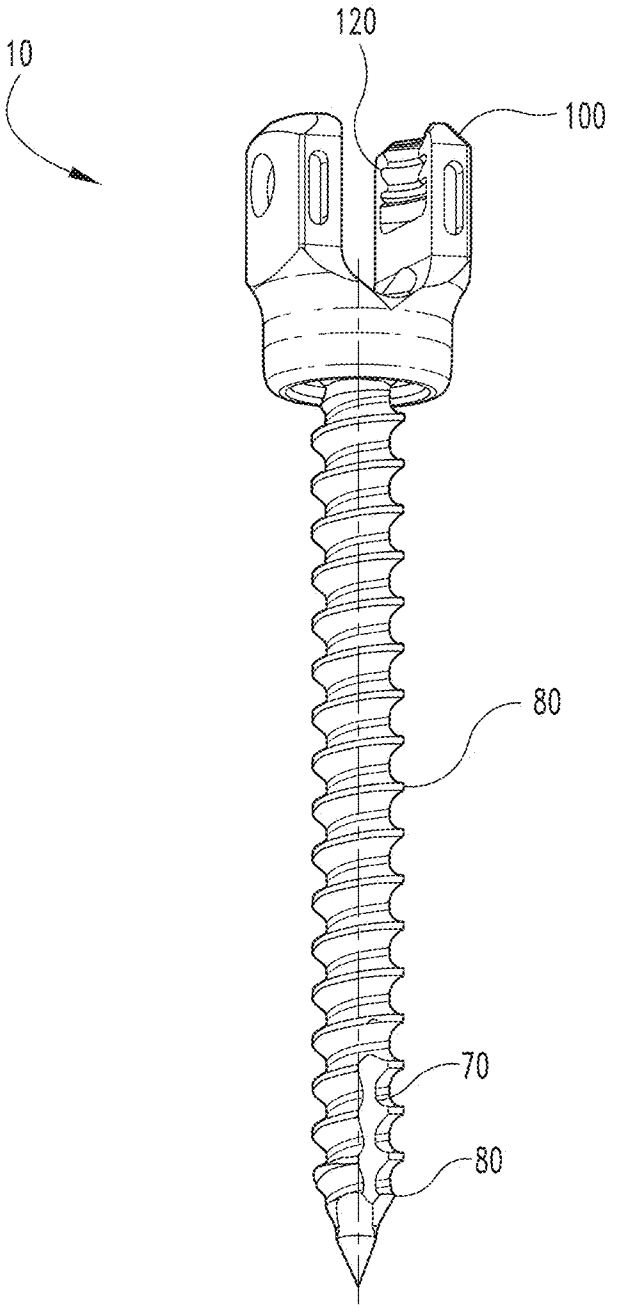


Fig. 2

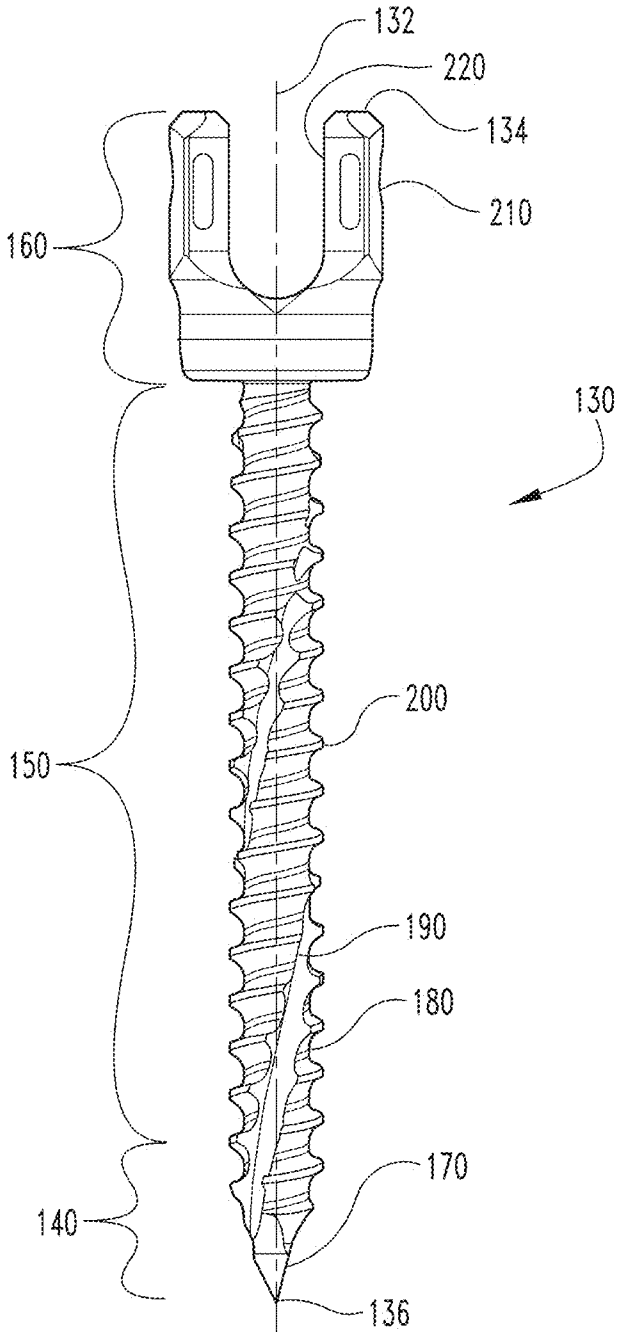


Fig. 3

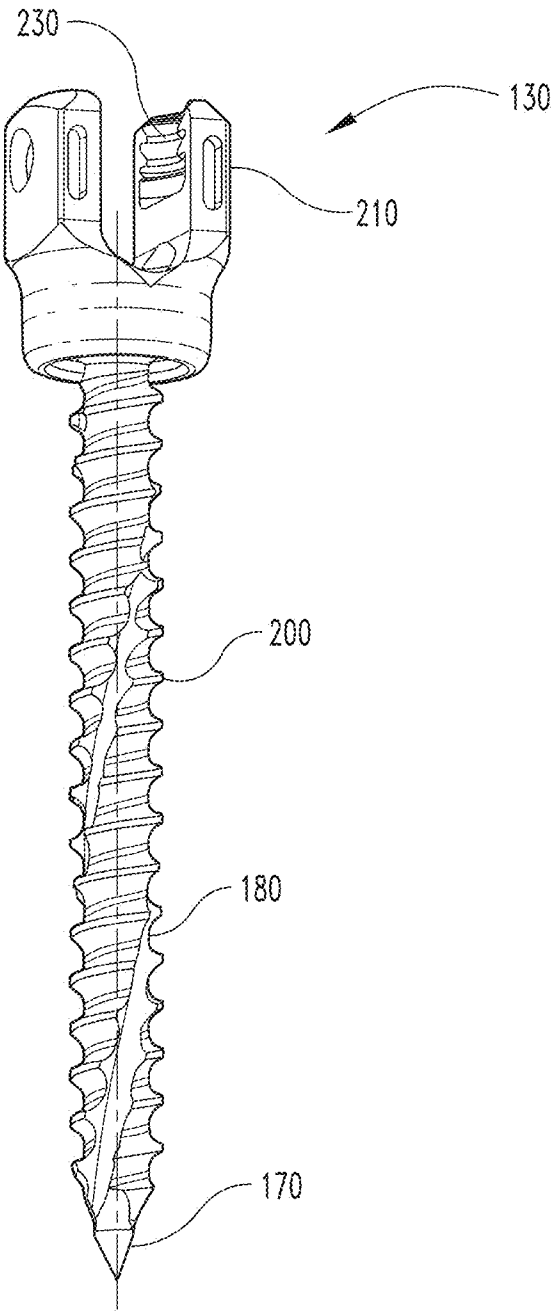


Fig. 4

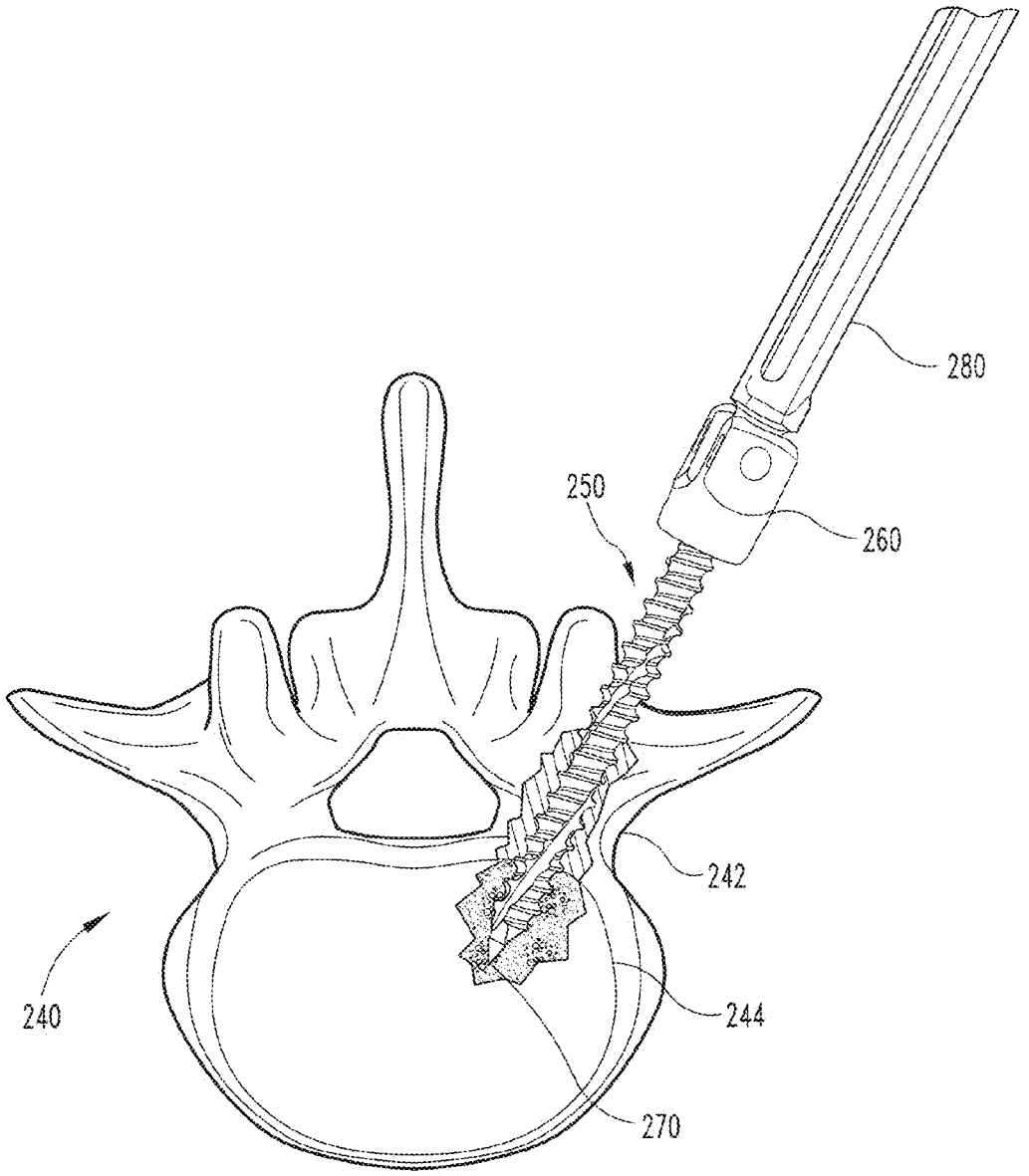
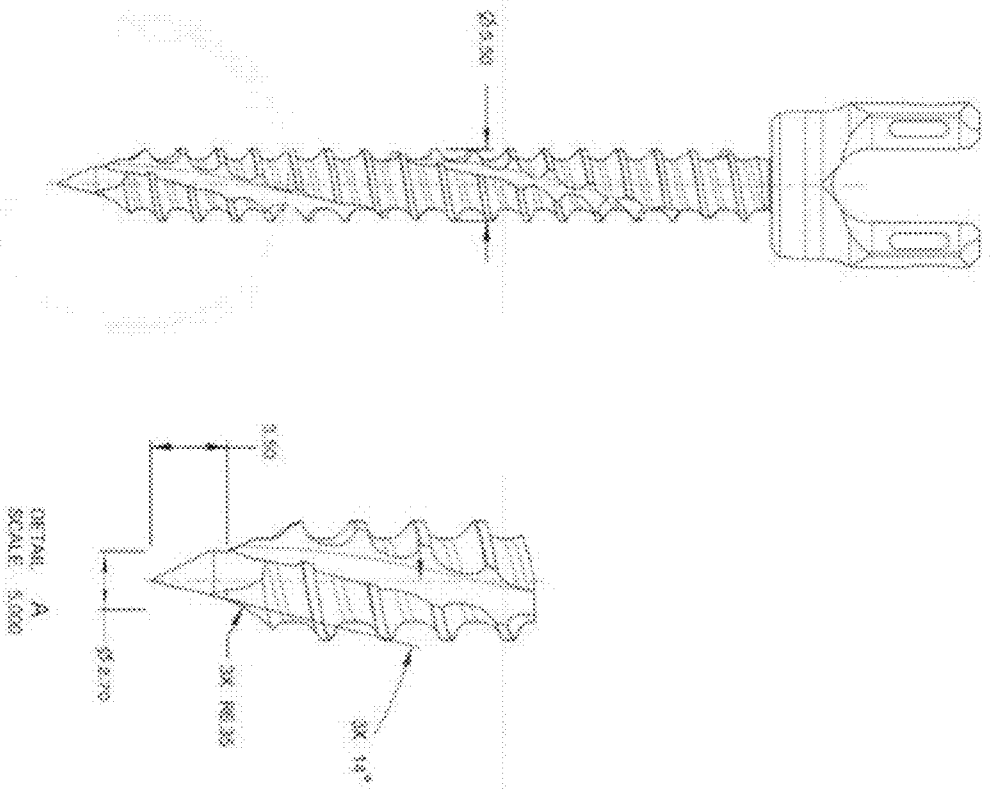


Fig. 5



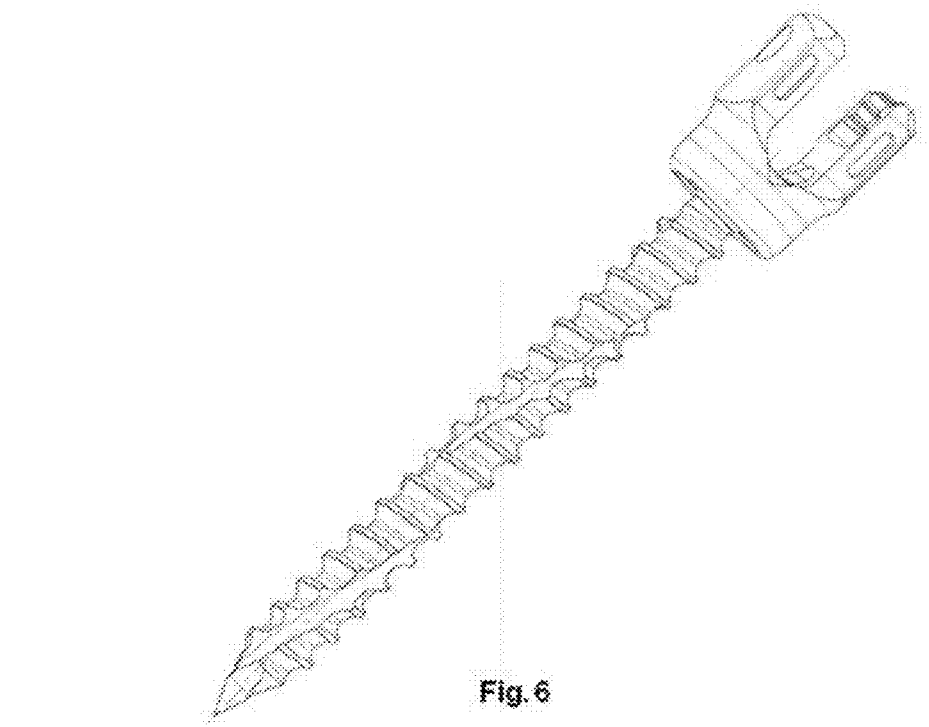


Fig. 6

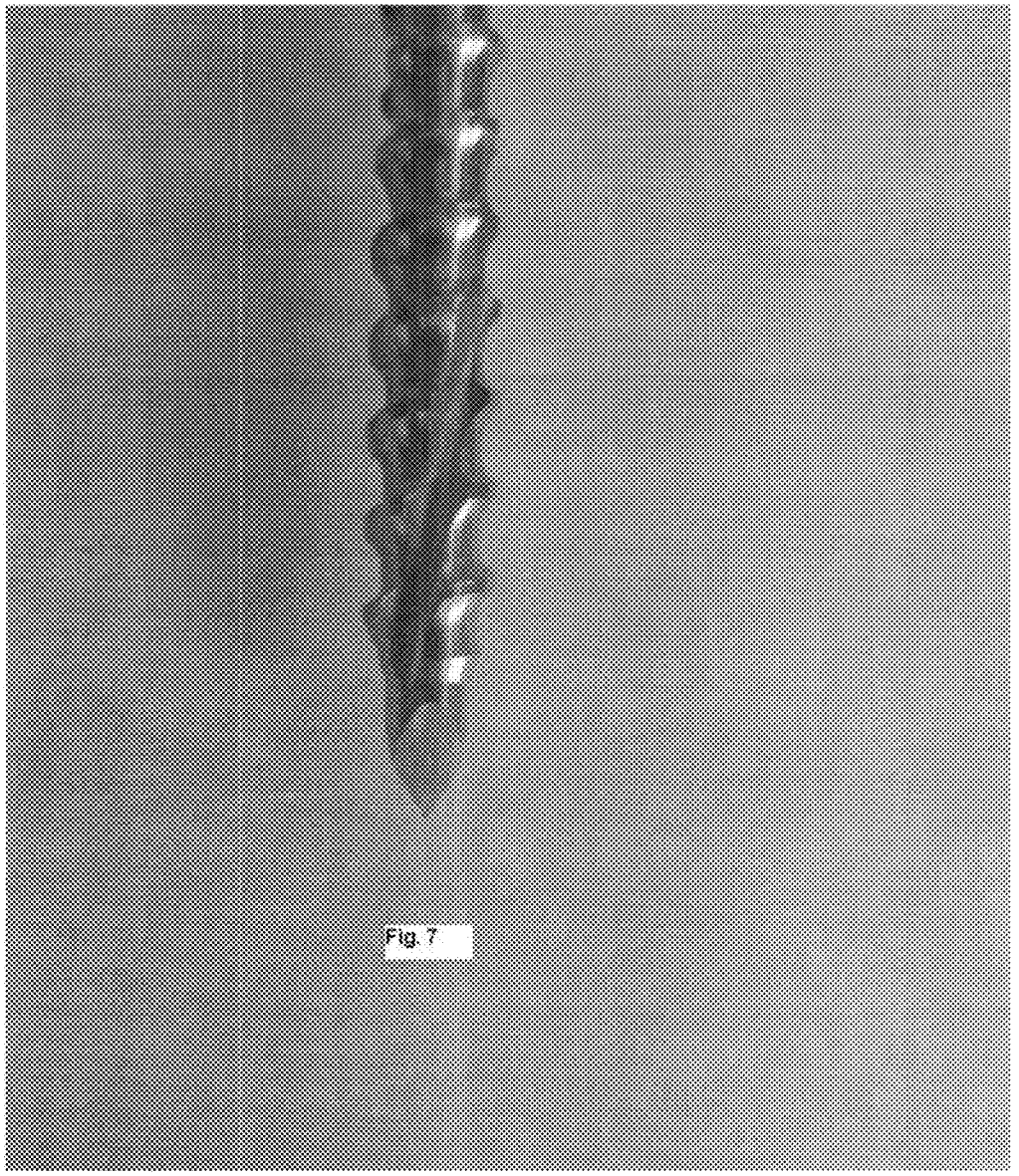
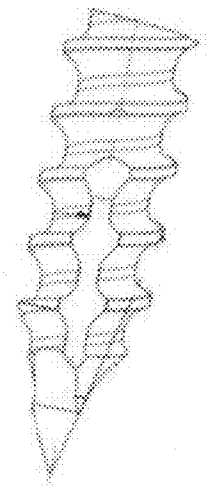


Fig. 7



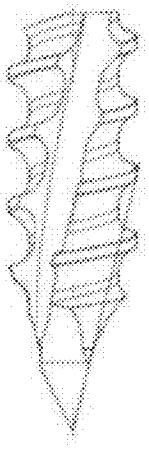


Fig. 8

AWL-TIPPED PEDICLE SCREW AND METHOD OF IMPLANTING SAME

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of and claims priority to co-pending U.S. patent application Ser. No. 13/117,669 filed on May 27, 2011, which claims priority to U.S. Provisional Pat. No. 61/396,564 filed on May 28, 2010.

FIELD

[0002] The claimed technology relates generally to medical devices and more particularly to bone screws and methods of implanting the same.

BACKGROUND

[0003] A variety of threaded fasteners have been developed for use in orthopedic surgical procedures to secure bone fragments, reattach ligaments or soft tissue to bones, or to hold bones in relative position to one another. One variety of bone screws used in the vertebrae of the spine are called pedicle screws, so named because they are inserted into the pedicle of the vertebral body. Pedicle screws are commonly used along with rods and screws to immobilize a portion of the spinal column. In other applications, pedicle screws are inserted into a series of vertebrae and one or more metal rods are secured to the heads of the screws, typically using set screws or some other securing means.

[0004] Current pedicle screw designs require multiple steps to insure proper implantation into the vertebral body. Typically, an entry point is made into the pedicle using a high speed drill bit or an awl to create a pilot hole. In some instances, the pilot hole is enlarged using larger diameter drill bits. The pilot hole may then be probed with an instrument to detect any breaches in the pedicle wall. After the integrity of the pilot hole wall is confirmed, the pilot is then tapped to create a track in the hole wall for the screw to follow using a tap. Finally, the screw may be implanted into the prepared hole.

[0005] Every surgical procedure carries with it a risk of complications. Procedures which require multiple steps such as pedicle screw implantation create the potential for the patient to experience complications with each step. Additionally, the chances for a surgeon to make a mistake due to fatigue during long procedures involving multiple screws increases with the number of steps required for placement of each screw. Thus there is a need for an improved bone screw which reduces the number of steps required for implantation of the screw into bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. **1** is a side view of a bone screw according to one embodiment of the disclosed invention.

[0007] FIG. **2** is a perspective view of the bone screw shown in FIG. **1**.

[0008] FIG. **3** is a side view of a bone screw according to another embodiment of the disclosed invention.

[0009] FIG. **4** is a perspective view of the bone screw shown in FIG. **3**.

[0010] FIG. **5** is a side, cross sectional view of a bone screw being inserted into the pedicle of a spine according to one embodiment of the disclosed invention.

[0011] FIG. **6** is a side and perspective view of another embodiment of the disclosed invention.

[0012] FIG. **7** is a side view of yet another embodiment of the disclosed invention.

[0013] FIG. **8** is a partial view of tips according to other embodiments of the disclosed invention.

DESCRIPTION

[0014] For the purposes of promoting an understanding of the principles of the claimed technology and presenting its currently understood best mode of operation, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the claimed technology is thereby intended, with such alterations and further modifications in the illustrated device and such further applications of the principles of the claimed technology as illustrated therein being contemplated as would normally occur to one skilled in the art to which the claimed technology relates.

[0015] A bone screw **10** according to one embodiment of the disclosed invention is shown in FIG. **1**. In the following description, the term "distal" will refer to the direction towards which a screw is designed to be advanced as the screw is engaged to bone and "proximal" will refer to the opposite direction. Bone screw **10** comprises several segments or portions which begin at a distal end **12** and extend along a longitudinal axis **20** to a proximal end **14**. Located at distal end **12** of bone screw **10** is a tip portion **40** comprising an awl tip **30** and a helical, radially outward-extending thread **80**. The awl tip is sized and configured so as to be capable of cutting, boring, or otherwise creating a pilot hole when placed against bone and torsional and/or downward force is applied to the screw, thereby eliminating the need for the separate steps for placing a pilot hole, drilling, probing, and tapping the hole during implantation. In some examples, the leading or distal edge **82** of the thread **80** begins at the proximal edge **32** of the awl tip **30**. In other examples, the thread actually overlaps a portion of the awl tip. Typically, the leading edge of the thread is positioned such that as the awl tip excavates a hole in the bone, the leading edge engages the walls of the hole and draws the screw body into the bone. A variety of different thread styles and patterns may be used, including self-tapping threads, dual threads, and other suitable thread designs known in the industry. Optionally, tip portion **40** further includes one or more flutes **70** for conveying bone material away from the awl tip **30** and/or thread **80** during insertion of the screw into bone. In some examples, the flute **70** may also include a cutting edge **75** for engaging and removing bone material. The flute show in FIG. **1** is longitudinally disposed in the surface of the screw along axis **20**, however other shapes, styles, and configurations of fluting may be used.

[0016] Adjacent to the proximal end of tip portion **40** is the distal end of a shank portion **50**. The thread **80** from tip portion **40** continues through shank portion **50** to approximately the head portion **60** in this particular example. In other examples, a part of shank portion **50** may be unthreaded. Optionally, flute **70** which begins in tip portion **40** may continue or extend through a portion or all of shank portion **50**. Adjacent to the proximal end of shank portion **50** and is the distal end of a head portion **60**. In this particular embodiment, head portion **60** is shown comprising a U-shaped rod fixation element having a cradle **100** for receiving and securing rods

(not shown) such as those commonly used in spinal procedures. Cradle **100** may further include a locking portion **120** (as shown in FIG. **2**) for receiving and securing a locking member (not shown), such as a set screw, using a variety of locking means such as threads, bayonet style closure, and the like. Even though a fixed, U-shaped head assembly is shown in the present example, it is understood that other types and styles of head assemblies may also be used with the disclosed invention such as a polyaxial head assembly, a hex head assembly, and any other mono-axial, mutli-axial, or fixed head design as known in the art.

[0017] A bone screw **130** according to another embodiment of the disclosed invention is shown in FIG. **3**. Bone screw **130** comprises several segments or portions which begin at a distal end **136** and extend along a longitudinal axis **132** to a proximal end **134**. Located at distal end **136** of bone screw **130** is a tip portion **140** comprising an awl tip **170** and a helical, radially outward-extending thread **200**. A variety of different thread styles and patterns may be used, including self-tapping threads, dual threads, and other suitable thread designs known in the industry. Optionally, tip portion **140** further includes one or more flutes **180** for conveying bone material away from the awl tip **170** and/or thread **200** during insertion of the screw into bone. In some examples, the flute **180** may also include a cutting edge **190** for engaging and removing bone material. The flute show in FIG. **3** is an axially wound or spiral flute about the central body of screw **130** disposed along axis **132**.

[0018] Adjacent to tip portion **140** is a shank portion **150**. The thread **200** from tip portion **140** continues through shank portion **150** to approximately the head portion **160** in this particular example. In other examples, a part of shank portion **150** may be unthreaded. Flute **180** which begins in tip portion **140** continues through a portion of shank portion **150**. Adjacent to shank portion **150** and continuing to the proximal end **134** of screw **130** is a head portion **210**. In this particular embodiment, head portion **210** is shown comprising a U-shaped rod fixation element having a cradle **220** for receiving and securing rods (not shown) such as those commonly used in spinal procedures. Cradle **220** may further include a locking portion **230** (as shown in FIG. **4**) for receiving and securing a locking member (not shown) using a variety of locking means such as threads, bayonet style closure, and the like. Even though only a U-shaped head assembly is shown in the present example, it is understood that other types and styles of head assemblies may also be used with the disclosed invention such as a polyaxial head assembly, hex head assembly, and the like.

Screw Implantation

[0019] Placement of a bone screw according to the presently disclosed invention does not require the multi-step procedure commonly used in the industry and previously described. One method of implanting a bone screw according to the presently disclosed invention comprises placing the awl tip against the vertebra at the desired entry point, typically at the surface of a pedicle. Torsional force is applied to the bone screw using a driving tool engaged with the head of the screw. Typically the driving tool will be an image guided and navigated tool, such as a screw driver, to allow the surgeon to confirm the correct trajectory of the screw through the bone. In other examples, guidance techniques such as anatomic landmarks or fluoroscopy may also be used to insure proper screw placement. As torsional force is applied to the screw, the awl tip engages and begins to carve a hole into the bone. Once the awl has carved a hole of sufficient depth the threads will engage the bone. Typically, the thread (or threads if a multi-thread design is used) of the screw begin immediately adjacent to the awl tip so as to reduce the depth to which the screw must be driven before the screw engages the bone.

[0020] Once the screw threads have engaged the bone, the threads act to draw the screw down into the vertebra while the awl tip continues to carve out bone at the tip of the screw. If the screw also includes one or more flutes, the flutes act to channel bone material away from the tip and thread so as to increase performance of the screw. As the threads act to pull the screw down into the bone less force will need to be applied by the surgeon. Proper placement of the screw can be confirmed using imaging. Additional confirmation may be provided using neuromonitoring to insure there is no nerve irritation. Once the desired implantation depth is reached, additional elements such as rods, plates, and the like, may be secured to the screw using appropriate means.

[0021] FIG. **5** shows the implantation of a bone screw in a vertebra according to one embodiment of the disclosed invention. In this particular example, a bone screw **250** such as those previously described is implanted in vertebra **240**. An awl tip **270** allows the screw **250** to be driven into the bone of the vertebra, specifically through the body of a pedicle **242** and into the vertebral body **244**. Bone screw **250** includes a head portion **260** which is configured and adapted to engage a suitable driving tool **280** which allows for implantation of the screw. Optionally, driving tool **280** is an image guided and navigated tool, such as a screw driver, to allow for confirmation of the trajectory of the screw through the pedicle. Image guided navigation allows a surgeon to confirm proper placement of the screw in the bone. Additionally, the harder cortical bone walls of the pedicle will encourage the screw to follow a trajectory through the softer, cancellous bone found in the center of the pedicle. Imaging may be used to confirm proper screw placement. Additionally, neuromonitoring may be used to confirm there is no nerve root irritation while the screw is being placed. Once placed, additional elements such as rods, plates, and the like, may be secured to the screw using appropriate means.

[0022] Reducing the number of steps in the implantation procedure using the devices and methods previously described decreases the time required for a procedure. Less time in the operating room means less blood loss, decreased risk of infection and the patient spends less time sedated, thereby reducing the possibility of anesthesia-related complications. Elimination of preparatory steps required for the placement of current bone screw designs also decreases the opportunities for mistakes during implantation, especially during long procedures involving the implantation of multiple screws where surgeon fatigue can become a factor.

[0023] While the claimed technology has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. It is understood that the embodiments have been shown and described in the foregoing specification in satisfaction of the best mode and enablement requirements. It is understood that one of ordinary skill in the art could readily make a nigh-infinite number of insubstantial changes and modifications to the above-described embodiments and that it would be impractical to attempt to describe all such embodiment variations in the present specification. Accord-

ingly, it is understood that all changes and modifications that come within the spirit of the claimed technology are desired to be protected.

What is claimed is:

1. A bone screw, comprising:

a tip portion, comprising an awl tip capable of creating a hole in bone;

a shank portion proximate to said tip portion;

a head portion proximate to said shank portion; and

at least one helical thread which begins at said tip portion and continues through said shank portion.

2. The bone screw of claim **1**, wherein said tip portion further comprises at least one flute.

3. The bone screw of claim **2**, wherein said flute extends into said shank portion.

4. The bone screw of claim **3**, wherein said flute is a spiral flute.

5. The bone screw of claim **2**, wherein said flute further comprises a cutting edge.

6. The bone screw of claim **1**, wherein said head portion is adapted and configured to receive an image guided drive tool.

7. A pedicle screw, comprising:

a tip portion located at the distal end of said pedicle screw, comprising a tip capable of starting a hole in bone;

a head portion located at the proximate end of said pedicle screw;

a shank portion disposed between said tip portion and said head portion; and

at least one thread beginning on said tip portion and continuing in said shank portion.

8. The pedicle screw of claim **7**, wherein said tip portion further comprises at least one flute.

9. The pedicle screw of claim **8**, wherein said flute extends into said shank portion.

10. The pedicle screw of claim **9**, wherein said flute is a spiral flute.

11. The pedicle screw of claim **8**, wherein said flute further comprises a cutting edge.

12. The pedicle screw of claim **7**, wherein said head portion is adapted and configured to receive an image guided drive tool.

13. A bone screw, comprising:

a tip portion, comprising an awl tip and at least one thread;

a shank portion, located proximate to said tip portion and comprising part of the at least one thread of the tip portion; and

a head portion proximate to said shank portion and adapted to receive a driving tool;

wherein said awl tip creates a hole in bone when torsional force is applied to the screw;

wherein said at least one thread is disposed on said tip portion such that said thread engages the walls of the hole created by said awl tip and draws the screw into bone.

14. The bone screw of claim **13**, wherein said tip portion further comprises at least one flute.

15. The bone screw of claim **14**, wherein said flute extends into said shank portion.

16. The bone screw of claim **15**, wherein said flute is a spiral flute.

17. The bone screw of claim **13**, wherein said at least one thread begins on said awl tip.

18. The bone screw of claim **13**, wherein said at least one thread begins adjacent to the proximal end of said awl tip.

* * * * *