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(54) SYSTEMS AND METHODS FOR THE FIXATION OR FUSION OF BONE

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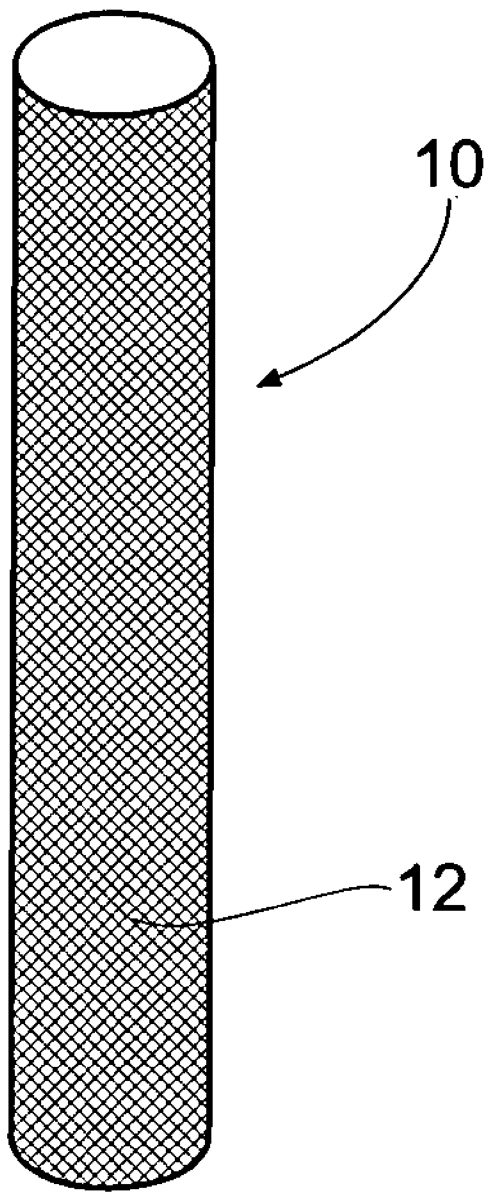
(57) **ABSTRACT**

A stem-like bone fixation device allows for bony in-growth on its surface and across fracture fragments or between bones that are to be fused.



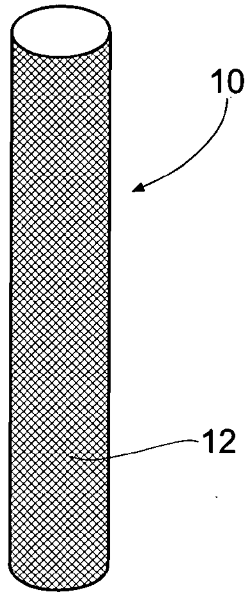


Fig. 1

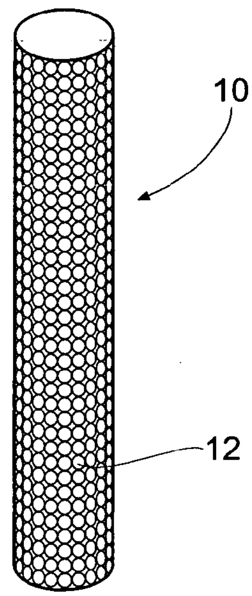


Fig. 2

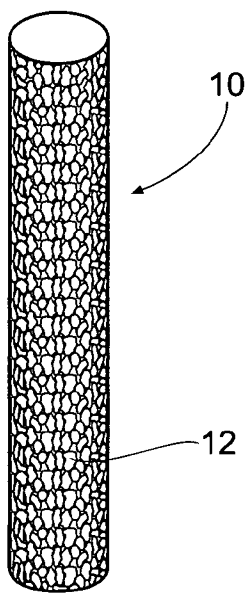


Fig. 3

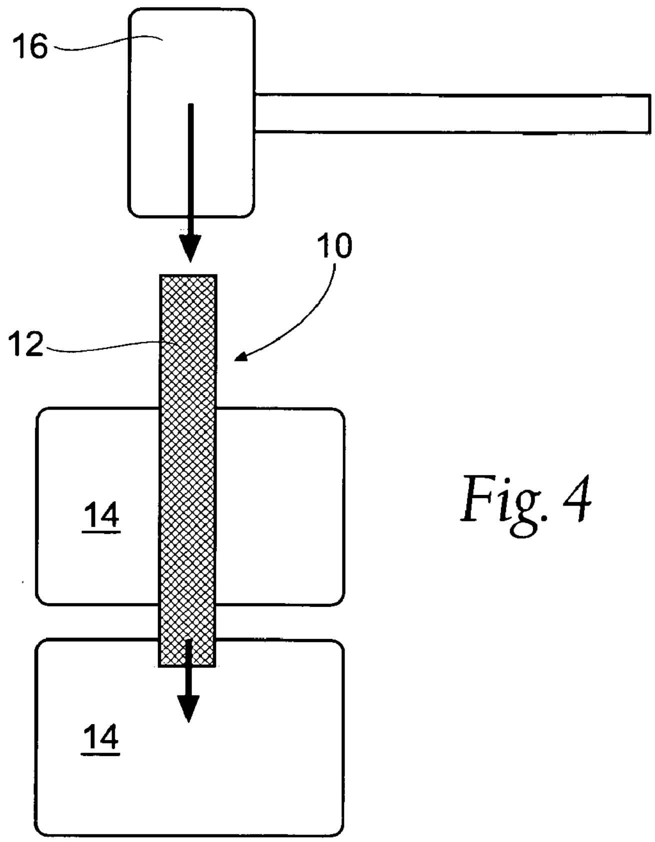


Fig. 4

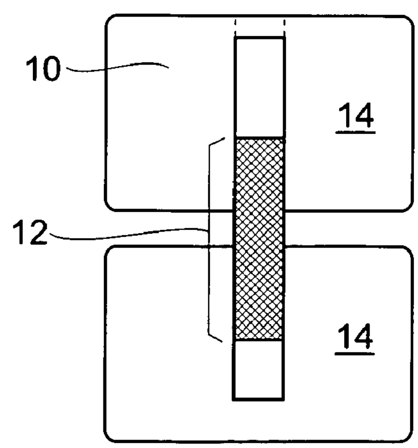


Fig. 5

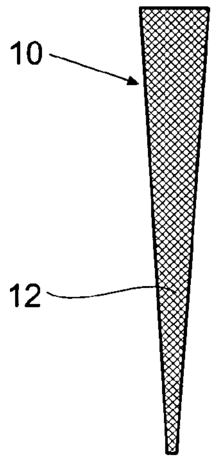


Fig. 6

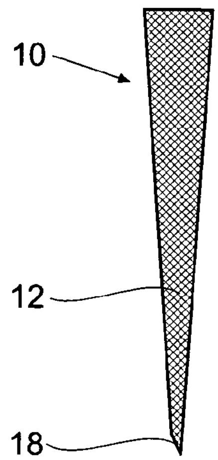


Fig. 7

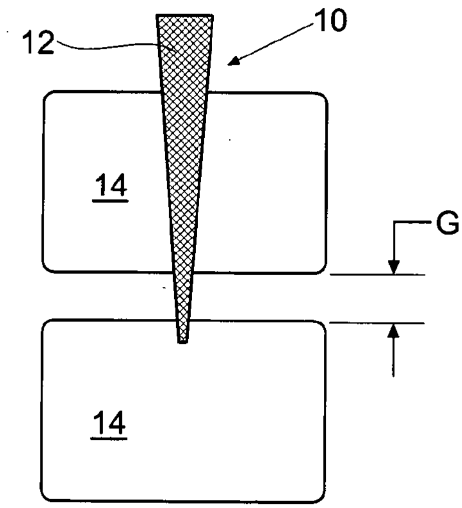


Fig. 8A

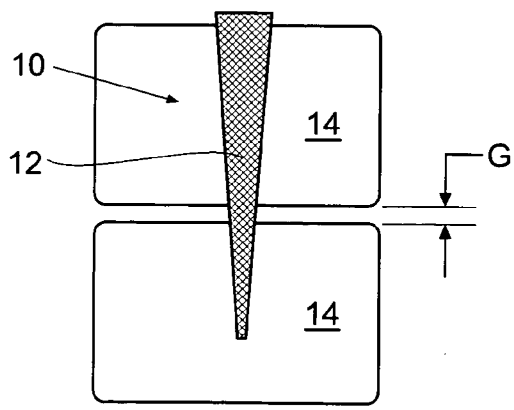


Fig. 8B

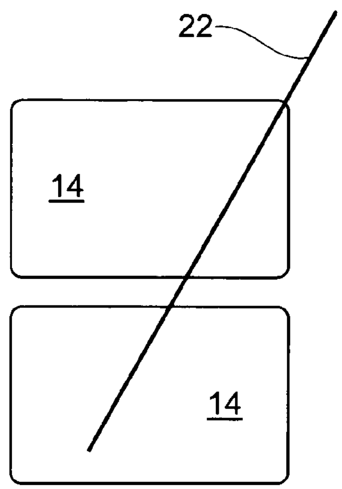


Fig. 9

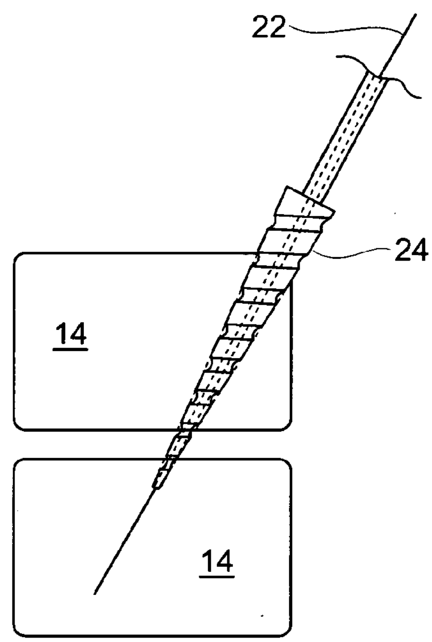


Fig. 10

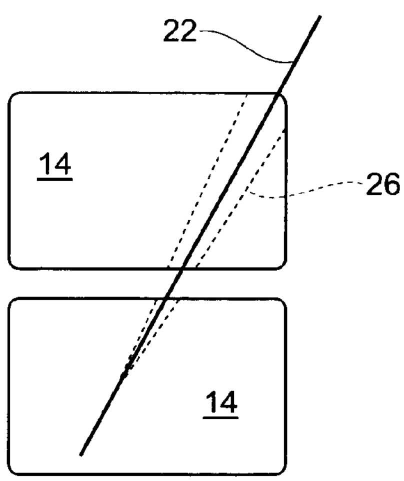


Fig. 11

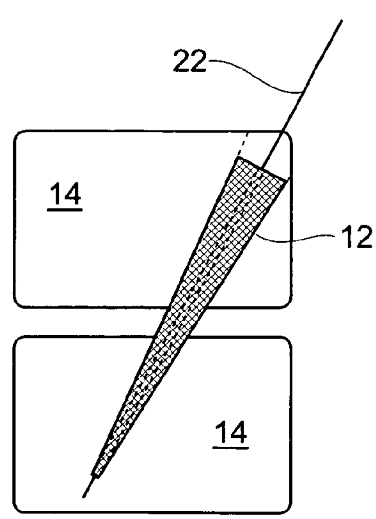


Fig. 12

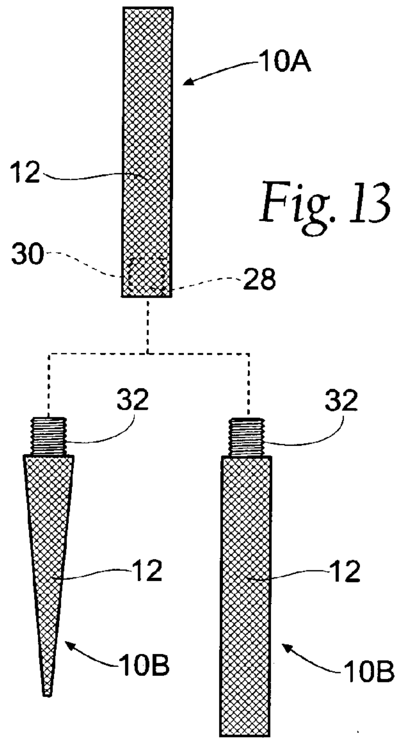


Fig. 13

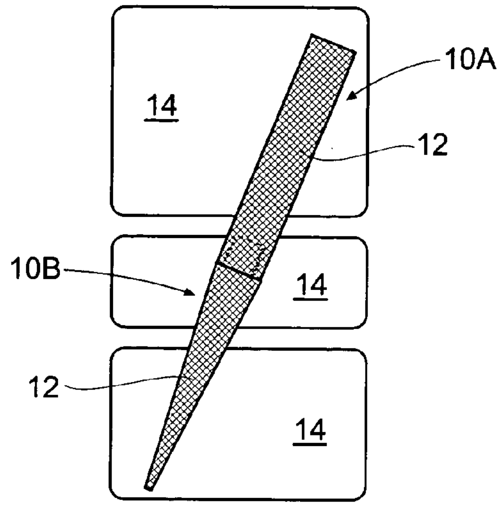


Fig. 14

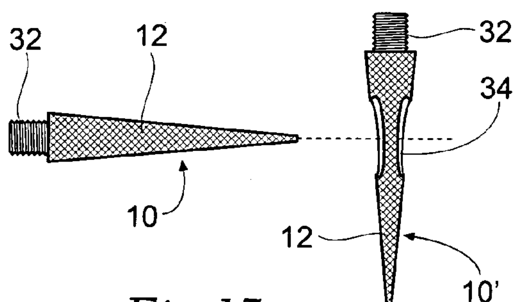


Fig. 15

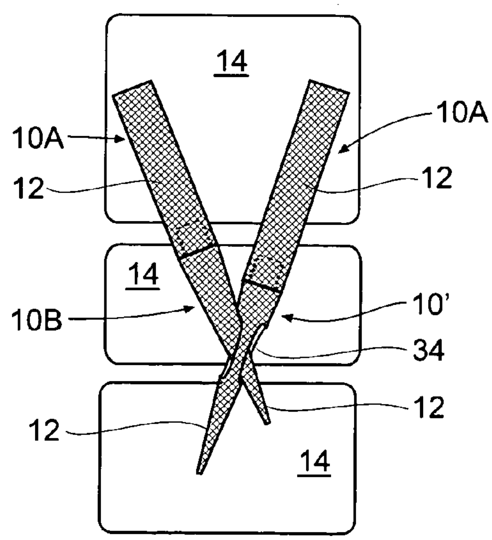


Fig. 16

SYSTEMS AND METHODS FOR THE FIXATION OR FUSION OF BONE

FIELD OF THE INVENTION

[0001] This application relates generally to the fixation of bone.

BACKGROUND OF THE INVENTION

[0002] Many types of hardware are available both for fracture fixation and for the fixation of bones that are to fused (arthrodesed).

[0003] Metal and absorbable screws are routinely used to fixate bone fractures and osteotomies. It is important to the successful outcome of the procedure that the screw is able to generate the compressive forces helpful in promoting bone healing.

SUMMARY OF THE INVENTION

[0004] The invention provides bone fixation devices and related methods for stabilizing bone segments. The systems and methods include a stem-like structure adapted for passage between adjacent bone segments. At least a portion of the stem-like structure includes a surface that enhances bony in-growth. Boney in-growth into the stem-like structure helps speed up the fusion process or fracture healing time.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] **FIG. 1** is a perspective view of a bone fixation stem having a boney in-growth surface of a mesh configuration.

[0006] **FIG. 2** is a perspective view of an alternative embodiment of a bone fixation stem having a boney in-growth surface of a beaded configuration.

[0007] **FIG. 3** is a perspective view of an alternative embodiment of a bone fixation stem having a boney in-growth surface of a trabecular configuration.

[0008] **FIG. 4** is a schematic view of a bone fixation stem of the type shown in Fig. being inserted into bone across a fracture line or bone joint.

[0009] **FIG. 5** is a schematic view of a bone fixation stem positioned within bone and illustrating a boney in-growth surface of the stem extending across a fracture line or bone joint.

[0010] **FIG. 6** is a front plan view of an alternative embodiment of a bone fixation stem having a boney in-growth surface in which the stem has a conical configuration.

[0011] **FIG. 7** is front plan view of an alternative embodiment of a bone fixation stem having a boney in-growth surface in which the stem has a beveled distal tip.

[0012] **FIGS. 8A and 8B** are schematics illustrating the insertion of a conical bone fixation stem of the type shown in **FIG. 6** to reduce the gap between bone segments.

[0013] **FIG. 9** is a schematic illustrating a guidewire being introduced into bone across bone segments.

[0014] **FIG. 10** is a schematic similar to **FIG. 9** and illustrating a drill bit being introduced over the guidewire.

[0015] **FIG. 11** is a schematic similar to **FIG. 10** and illustrating a bore formed in the bone remaining after withdrawal of the drill bit.

[0016] **FIG. 12** is a schematic similar to **FIG. 11** and illustrating insertion of a bone fixation stem into the pre-formed bore.

[0017] **FIG. 13** is an exploded front plan view illustrating the coupling of a pair of bone fixation stems by threaded engagement.

[0018] **FIG. 14** is a schematic illustrating a pair of bone fixation stems coupled together and inserted into bone across multiple bone segments.

[0019] **FIG. 15** is a front plan view illustrating passage of a bone fixation stem through a fenestration in another bone fixation stem.

[0020] **FIG. 16** is a schematic illustrating the placement of a series of bone fixation stems in bone.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0021] Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention that may be embodied in other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

[0022] **FIG. 1** shows a device **10** sized and configured for the fixation of bone fractures or for the fixation of bones which are to be fused (arthrodesed). The device **10** comprises an elongated, stem-like structure. The device **10** can be formed—e.g., by machining, molding, or extrusion—from a material usable in the prosthetic arts, including, but not limited to, titanium, titanium alloys, tantalum, chrome cobalt, surgical steel, or any other total joint replacement metal and/or ceramic, sintered glass, artificial bone, any uncemented metal or ceramic surface, or a combination thereof. Alternatively, the device **10** may be formed from a suitable durable biologic material or a combination of metal and biologic material, such as a biocompatible bone-filling material. The device **10** may be molded from a flowable biologic material, e.g., acrylic bone cement, that is cured, e.g., by UV light, to a non-flowable or solid material.

[0023] The device **10** can take various shapes and have various cross-sectional geometries. The device **10** can have, e.g., a generally curvilinear (i.e., round or oval) cross-section, or a generally rectilinear cross section (i.e., square or rectangular), or combinations thereof. As will be described in greater detail later, the device **10** can be conical or wedge shaped.

[0024] The structure **10** includes surface texturing **12** along at least a portion of its length to promote bony in-growth on its surface. The surface texturing **12** can comprise, e.g., through holes, and/or various surface patterns, and/or various surface textures, and/or pores, or combinations thereof. The device **10** can be coated or wrapped or surfaced treated to provide the surface texturing **12**, or it can be formed from a material that itself inherently possesses a surface conducing to bony in-growth, such as a porous mesh, hydroxyapetite, or other porous surface. The device **10** may further be covered with various other coatings such as antimicrobial, antithrombotic, and osteoinductive agents, or a combination thereof. The surface texturing **12** may be impregnated with such agents, if desired.

[0025] The configuration of the surface texturing **12** can, of course, vary. By way of examples, **FIG. 1** shows the surface **12** as an open mesh configuration; **FIG. 2** shows the surface **12** as beaded configuration; and **FIG. 3** shows the surface **12** as a trabecular configuration. Any configuration conducive to bony in-growth will suffice.

[0026] In use (see **FIGS. 4 and 5**), the device **10** is inserted into a space between two adjacent bone surfaces, e.g., into a fracture site or between two bones (e.g., adjacent vertebral bodies) which are to be fused together. In **FIG. 4**, the device **10** is shown being tapped into bone through bone segments **14** (i.e., across a fracture line or between adjacent bones to be fused) with a tap **16**. The bone may be drilled first to facilitate insertion of the device **10**. The bony in-growth surface **12** along the surface of the device **10** accelerates bony in-growth into the device **10**. Boney in-growth into the device **10** helps speed up the fusion process or fracture healing time.

[0027] The bony in-growth surface **12** may cover the entire outer surface of the device **10**, as shown in **FIG. 4**, or the bony in-growth surface **12** may cover just a specified distance on either side of the joint surface or fracture line, as shown in **FIG. 5**.

[0028] The size and configuration of the device **10** can be varied to accommodate the type and location of the bone to be treated as well as individual anatomy.

[0029] As **FIG. 6** shows, the device **10** can be angled or tapered in a conical configuration. The degree of angle can be varied to accommodate specific needs or individual anatomy. A lesser degree of angle (i.e., a more acute angle) decreases the risk of splitting the bone as the device **10** is tapped into the bone or the fracture segments **14**. The device **10** may also include a beveled distal tip **18** to further add in insertion of the device **10** into bone, as shown in **FIG. 7**. As shown in **FIGS. 8A** and BB, the conical shape also helps drive the joint surfaces or fracture fragments together, reducing the gap (G) between the bone segments **14**.

[0030] In FIGS. **9** to **12**, the device **10** is cannulated, having a central lumen or throughbore **20** extending through it, to assist in the placement of the device **10** within bone.

[0031] In use, the physician can insert a conventional guide pin **22** through the bone segments **14** by conventional methods, as **FIG. 9** shows. A cannulated drill bit **24** can then be introduced over the guide pin **22**, as seen in **FIG. 10**. A single or multiple drill bits **24** can be employed to drill through bone fragments or bone surfaces to create a bore **26** of the desired size and configuration. In the illustrated embodiment, the drill bit **24** is sized and configured to create a conical bore **26** similar in size and configuration to the device **10**. The bore **26** is desirably sized and configured to permit tight engagement of the device **10** within the bore **26** and thereby restrict movement of the device **10** within the bore **26**. The pre-formed bore **26** may be slightly smaller than the device **10**, while still allowing the device **10** to be secured into position within the bore **26** by tapping. As seen in **FIG. 11**, the drill bit **24** is then withdrawn. The device **10** is then inserted into the bore **26** over the guide pin **22**, as **FIG. 12** shows. The guide pin **22** is then withdrawn.

[0032] Alternatively, the device **10** itself can include screw-like threads along the body for screwing the device into place. In the arrangement, the device **10** be self-tapping. Also in this arrangement, the device **10** can be cannulated for use with a guide pin **22**, or it need not be cannulated.

[0033] Multiple devices **10** may be employed to provide additional stabilization. While the use of multiple devices **10** will now be described illustrating the use of multiple devices **10** of the same size and configuration, it is contemplated that the devices **10** may also be of different size and/or configuration, e.g., one device **10** is of a cylindrical configuration and a second device **10** is of a conical configuration.

[0034] In many cases, it may be desirable to couple a series of devices **10** together, e.g., to provide stabilization over a larger surface area. A series of devices **10** may be coupled together be any suitable means, e.g., by a snap fit engagement or a groove and tab key arrangement. In one embodiment, a series of devices **10** are coupled by threaded engagement. As illustrated in **FIG. 13**, a first device **10**A includes a recess **28** at one end providing a series of internal threads **30**. In the illustrated embodiment, the first device **10** is of a cylindrical configuration, but may be of any desired configuration. The internal threads **30** couple with a series of complementary external threads **32** on a second device **10**B of a similar or of a different configuration to couple the first and second devices **10**A and **10**B together.

[0035] The devices **10**A and **10**B are desirably coupled together prior to being inserted into the pre-formed bore **26**. The series of internal and external threads **30** and **32** provide an interlocking mechanism that permits a series of devices **10** to be stacked and connected to cover a larger area or multiple bone segments **14** (e.g., a bone having multiple fractures) and thereby provides additional stabilization, as seen in **FIG. 14**.

[0036] **FIG. 15** illustrates another embodiment in which a device **10'** includes an opening or fenestration **34** to allow another device **10** to pass through, thereby providing additional stabilization. The fenestration **34** can be sized and configured to permit another device **10** to be passed through the device **10'** at virtually any angle. The fenestration **34** can also be sized and configured to limit movement of the second device **10** relative to the second device **10'**.

[0037] In use, and as shown in **FIG. 16**, the physician taps a first device **10'** having a fenestration **34** through the bone segments. A second device **10** is then inserted (e.g., by tapping) through the fenestration **34** of the first device **10'** into place.

[0038] It is further contemplated that device **10'** may also be adapted for coupling with another device **10A** (e.g., by a series of external and internal threads), permitting the devices **10'** and **10A** to be additionally stacked and connected, as also shown in **FIG. 16**.

[0039] The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I claim:

1. A bone fixation device for stabilizing bone segments

comprising a stem adapted for passage between bone segments, at least a portion of the stem including a surface permitting bony in-growth.

2. A bone fixation device as in claim 1

wherein the stem structure is of a cylindrical configuration.

3. A bone fixation device as in claim 1

wherein the stem is of a conical configuration.

4. A bone fixation device as in claim 1

wherein the stem is cannulated.

5. A bone fixation device as in claim 1

wherein the stem includes a threaded end portion for coupling with another stem.

6. A bone fixation device as in claim 1

wherein the stem comprises a prosthetic material.

7. A bone fixation device as in claim 1

wherein the stem comprises a biologic material.

8. A bone fixation device as in claim 1

wherein the stem includes a fenestration permitting passage of another stem.

9. A bone fixation device as in claim 1

wherein the stem is cannulated.

10. A bone fixation device as in claim 1

wherein the stem is threaded.

11. A bone fixation device according to claim 1

further comprising a coupling to couple the stem with another stem:

12. A method for bone fracture fixation using the bone fixation device as defined in claim 1.

13. A method for bone fixation using the bone fixation device as defined in claim 1.

* * * * *