(54) Title: SLOTTED SCREW FOR USE WITH A VERTEBRAL MEMBER

(57) Abstract: A screw for use with vertebal members having one or more slots that extend along at least a section of the length. The slots are sized to contain bone growth material. A portion of the screw length may also include threads to assist in inserting and anchoring the screw into a vertebral member. In use, the bone growth material is loaded into one or more of the slots. Once loaded, the screw may be inserted into the vertebral member to a predetermined depth. At this depth, the slots deliver the bone growth material to a position to allow for bone growth to occur.
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— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(ii))

— as to the applicant’s entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
SLOTTED SCREW FOR USE WITH A VERTEBRAL MEMBER

Background

Screws are used in various settings for attachment to vertebral members. The screws may be used to attach together the vertebral member, or may be used to attach a support device, such as a vertebral rod. In one specific embodiment, screws are attached to the pedicle. One issue with previous screws is that the interface between the thread and the bone experiences stresses immediately following installation. This is especially seen in the thread-to-cancellous bone interface. The thread interface may tend to slip or move after installation, thus inhibiting bone adhesion and bone growth.

Bone growth materials have been used to promote bone growth. One application is the use of bone growth materials to facilitate attachment of a vertebral member to an intervertebral device, such as an intervertebral spacer. The bone growth material is delivered with the spacer and positioned in a manner to promote growth with the vertebral member. However, screws have been unable to adequately carry the bone growth material to the desired location within the vertebral member.

Summary

The present invention is directed to embodiments of a screw for use with vertebral members. The screw may include one or more slots that extend along at least a section of the length. The slots are sized to contain bone growth material. A portion of the screw length may also include threads to assist in inserting and anchoring the screw into a vertebral member.

One method of using the screw may include loading one or more of the slots with bone growth material prior to insertion. Once loaded, the screw can be inserted into the vertebral member. The threads assist in moving the screw into the vertebral member to a predetermined distance. At this predetermined position, the slots deliver the bone growth material to allow for bone growth to occur.
Brief Description of the Drawings

Figure 1 is a perspective view of a screw according to one embodiment of the present invention;

Figure 2 is a cross-section view of the screw cut along line 2—2 of Figure 1;

Figure 3 is a partial cross-section view of the slot according to one embodiment of the present invention;

Figure 4 is a partial cross-section view of the slot according to one embodiment of the present invention;

Figure 5 is a partial cross-section view of the slot according to one embodiment of the present invention;

Figure 6 is a partial cross-section view of the slot with a cap according to one embodiment of the present invention;

Figure 7 is a side view of a screw according to one embodiment of the present invention;

Figure 8 is a side view of a screw according to one embodiment of the present invention;

Figure 9 is a side view of the screw being inserted into a vertebral member according to one embodiment of the present invention; and

Figure 10 is a side view of the screw inserted into the vertebral member according to one embodiment of the present invention.

Detailed Description

The present invention is directed to embodiments of a screw for use with vertebral members. The bone screw 10 includes a body 20 that may be at least partially threaded for insertion into a vertebral member 99. One or more slots 30 are positioned along the body 20. The slots 30 may include a retaining feature sized to contain bone growth material 50. Once installed, the bone growth material 50 within the slots 30 is positioned to facilitate bone growth and securely attach the screw 10 within the vertebral member 99.

Figure 1 illustrates one embodiment of a screw body 20 having a head 22 at a proximal end and a tip 23 at a distal end. Threads 21 extend along at least a portion of the body between the head 22 and tip 23. In this embodiment, the threads 21 are positioned in
central and distal sections of the body 20. A plurality of slots 30 are positioned within the body 20 and sized to receive bone growth material 40. The slots 30 extend into the body 20 a distance from the threaded exterior.

In this embodiment, each slot 30 includes an interior wall 25 formed by a central section of the body 20. Each of the slots 30 further includes a pair of opposing sidewalls 26 spaced a predetermined distance apart and forming an exterior opening 27. The embodiment illustrated in Figures 1 and 2 illustrate four separate slots 30 evenly spaced around the periphery of the body 20. The body 20 may include various numbers of slots 30 which may be spaced at a variety of spacings and having a variety of orientations. The screw body 20 has an substantially circular cross-sectional shape.

Figure 3 illustrates a schematic view of one slot embodiment. The slot 30 includes an interior wall 25, and opposing sidewalls 26. An exterior opening 27 leads into the slot 30. The area of the slot 30 is sized to contain a predetermined amount of bone growth material 40. In this embodiment, each of the sidewalls 26 is substantially linear and sloped inward towards the exterior opening 27. The top sections of the sidewalls 26, adjacent to the opening 27, form retaining features 24 that hold the bone growth material 50 within the opening. A width W1 of the exterior opening 27 is smaller than the maximum extent of interior width W2. In this embodiment, the maximum width is at the interior wall 25. The reduced width at the exterior opening 27 maintains the bone growth material 40 within the slot 30 as the screw 10 is being inserted into the vertebral member 99. If the opening 27 were larger, bone growth material 40 may escape from the slot 30.

Figure 4 illustrates another embodiment of a slot 30 having arcuate sidewalls 26. The bottom of the slot 30 is formed by the interior wall 25 and an external opening 27 is positioned along the threaded surface 21. The arcuate surfaces of the sidewalls 26 result in the maximum width W2 being within a middle depth of the slot 30. The external opening 27 has a width W1 that is smaller than the maximum width W2. As with the embodiment of Figure 3, the top section of the sidewalls 26 adjacent to the opening 27 form retaining features for maintaining the bone growth material 50 within the slot 30.

Figure 5 illustrates another embodiment of the slot 30 having non-symmetrical first and second sidewalls 26a, 26b. The width W1 at the exterior opening 27 is less than the maximum width W2 that, in this embodiment, is at the maximum depth.
Figure 6 illustrates another embodiment of the slot 30 having a cap 40 forming a retaining feature to maintain the bone growth material 50 within the slot 30. The cap 40 is constructed of a material that allows for the bone growth material 50 to grow between the screw body 20 and vertebral member 99. The cap 40 may be positioned inward from an outer edge of the slot 30 to prevent inadvertent removal during screw insertion. Examples of cap materials include hydroxyapatite, bone morphogenic proteins, sponge, and porous metallic material.

Cap 40 may include a pair of extensions 41 that are placed within receivers 28 in the sidewalls 26. The cap 40 is flexible allowing for the extensions 41 to be moved inward to mount within the receivers 28. The natural outward bias of the extensions 41 is than adequate to maintain the cap 40 attached to the screw body. The bone growth material 50 is positioned within the slot 30 beneath the cap 40 during insertion into the vertebral member 50.

The slots 30 may be oriented on the screw body 20 in a manner of different orientations. As previously discussed in Figure 1, slots 30 are aligned in a vertical direction that extend substantially along a longitudinal axis A that runs the length of the screw body 20. Figure 7 illustrates another embodiment with a single slot 30 that helically winds about the screw body 20. The helical slot 30 may have a variety of pitches and helical directions, depending upon the application. Threaded sections 21 are positioned about the slot 30 to assist in anchoring the screw 10 to the vertebral member 99. Figure 8 illustrates an embodiment with a plurality of slots 30 arranged in a horizontal manner.

The spacing between the slots 30, and the number of slots 30 may again vary depending upon the application. Threaded sections 21 are again positioned between the slots 30. The slots 30 in Figures 7 and 8 each substantially encircle the longitudinal axis A, as opposed to the slot of Figure 1 that extends substantially along the axis.

Embodiments may also include combinations of different slot arrangements, such as both horizontal and vertical slots 30. In another embodiment, a first section of the screw includes a first slot arrangement, and a second section includes a different, second slot arrangement.

The threads 21 are positioned on the exterior of the screw body 20 to assist in inserting the screw into the vertebral member 99 and anchoring the screw 10. The threads
21 may be continuous along the exterior surface but for being interrupted by the slots 30.
In one specific embodiment such as that illustrated in Figure 1, a single thread 21 extends
around the screw body 20 as is interrupted by the slots 30. In another embodiment, each
threaded section may have a separate thread pitch. The thread 21 may extend the entire
length of the body 21 from the head 22 to the tip 23, or a distance less than the entire
length.

The slots 30 may have a variety of depths and widths depending upon the
application. The depth and width is adequate to contain a predetermined amount of bone
growth material 50. Further, the depths and widths of different slots 30 may vary. By
way of example using the Figure 8, a first slot 30a may have a first depth and width that
are different than the second slot 30b.

The term "bone growth material" used here means virtually any osteo-conductive
and/or osteo-inductive material that promotes bone growth or healing, including natural,
synthetic and recombinant proteins, hormones, and the like. The bone growth materials
used may comprise a therapeutically effective amount of a bone inductive factor such as a
bone morphogenic protein in a pharmaceutically acceptable carrier. Examples of factors
include recombinant human bone morphogenic proteins (rhBMPs) rhBMP-2, rhBMP-4
and heterodimers thereof. However, any bone morphogenic protein is contemplated,
including bone morphogenic proteins designated as BMP-1 through BMP-13, which are
available from Genetics Institute, Inc., Cambridge, Mass. Various osteoinductive factors
are contemplated whether obtained as above or isolated from bone.

The bone growth material 50 may include a demineralized bone matrix and,
optionally, a carrier, such as a gelatin substance. The demineralized bone matrix can be
provided in the form of a powder, paste or gel. When provided as a powder, the
osteogenic material can be reconstituted with sterile water, saline, glycerin or other
physiological solutions. The reconstituted material is molded and inserted into the slots
30. An osteogenic material can be applied to the screw 10 by the surgeon during surgery
or the screw 10 may be supplied with the composition pre-applied. In such cases, the
osteogenic composition may be stabilized for transport and storage. The osteogenic
material can be provided as a putty that can be retained in and about the implant assembly.

The osteogenic putty is a moldable, flowable material that sets up to a semi-rigid
form at about body temperature. The intervertebral spacer with the osteogenic material is then inserted into a prepared disc space. The osteogenic material can also include a reinforcement component such as bone chips, preferably cortical bone chips. Examples of bone growth material suitable for use with this invention include, but are not limited to: OSTEOFIL, which is commercially available from Regeneration Technologies, Inc. of Alachua, Fla.; GRAFTON CRUNCH available from Osteotech of Eatontown, N.J. and ALLOMATRIX, available from Allosource of Denver, Colo.

Figures 9 and 10 illustrate on embodiment of inserting the screw into a vertebral member 99. Prior to insertion, an amount of bone growth material 50 is inserted into the slots 30. Bone growth material 50 may be placed within each of the slots 30, or within a limited number of slots 30. The screw 10 is then inserted into the vertebral member 99 as illustrated in Figure 9. The pointed tip 23 and threads 21 ease the insertion through the hardened cortical section 91 and into the cancellous section 92 of the vertebral member 99.

The screw is inserted through rotations in the directions of arrow B. The retaining features of the slots 30 eliminate and/or reduce escape of the bone growth material 50 during rotation. Figure 10 illustrates the screw 10 fully inserted into the vertebral member 99. The slots 30 with bone growth material 50 are positioned within the vertebral member 99 to allow for bone growth to more fully attach the screw 10. To further facilitate bone growth, the slots 30 may have roughened surfaces. This facilitates the connection of the bone growth material 50 between the screw 10 and vertebral member 99.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. In one embodiment, the central section of the body 20 is solid. In another embodiment, a portion or all of the central section is porous. In the embodiments of Figures 3 and 4, each of the sidewalls 26 has a similar shape. Other embodiments may include one sidewall 26 having a first shape (e.g., linear), and the second sidewall 26 having a second shape (e.g., arcuate). The screw 10 may be constructed from a variety of materials, including titanium, surgical grade stainless steel, or other bio-compatible material using fabricating techniques known in the art. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.
What is claimed is:

1. A screw for use with a vertebral member comprising:
   an elongated body extending between a distal end and a proximal end and having
   an external thread; and
   a slot extending along the elongated body, the slot having an exterior opening with
   a first width, and having a maximum slot width within an interior section of the slot
   inward from the exterior opening.

2. The screw of claim 1, wherein the external thread extends between the distal end and
   the proximal end of the elongated body.

3. The screw of claim 1, wherein the slot is vertically positioned along the elongated
   body.

4. The screw of claim 1, wherein the slot is horizontally positioned along the elongated
   body.

5. The screw of claim 1, wherein the slot is helically positioned along the elongated body.

6. The screw of claim 1, wherein the slot is formed between symmetrical first and second
   sidewalls.

7. The screw of claim 1, further comprising a second slot extending along at least a
   portion of the elongated body.

8. The screw of claim 1, further comprising a cap that extends over the slot to contain a
   bone growth material within the slot.
9. A screw for use with a vertebral member comprising:
   an elongated body having an external thread; and
   at least one slot extending along the elongated body and having a first sidewall and a second sidewall, at least one of the sidewalls having a retaining feature that extends into the slot forming a reduced opening having a width that is less than an interior width of the slot.

10. The screw of claim 9, wherein a width at each interior depth of the slot is greater than at the retaining feature.

11. The screw of claim 9, wherein the first and second sidewalls are each substantially linear.

12. The screw of claim 9, wherein the slot extends along the body in a substantially vertical orientation.

13. The screw of claim 9, wherein the body has a longitudinal axis and the slot encircles the longitudinal axis.

14. The screw of claim 9, wherein the retaining feature is integral with the body.

15. The screw of claim 9, wherein one of the first and second sidewalls is substantially arcuate.

16. The screw of claim 9, further comprising a cap that extends over the slot and encloses the slot.

17. A screw for use with a vertebral member comprising:
   an elongated body having a longitudinal axis; and
a slot extending along the elongated body and having a first sidewall and a second sidewall, at least one of the sidewalls having a retaining feature that extends into the slot forming a reduced opening having a width that is less than an interior width of the slot.

18. The screw of claim 17, wherein the slot encircles the longitudinal axis.

19. A screw for use with a vertebral member comprising:
   an elongated body having an external thread; and
   a slot extending along the elongated body, the slot having an exterior opening; and
   a cap sized to attach to the elongated body and extend over the exterior opening to enclose an interior section of the slot.

20. The screw of claim 19, wherein the cap is positioned within the slot inward from an outer edge of the body to prevent inadvertent removal during insertion into the vertebral member.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/86 A61C8/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>US 2002/123752 A1 (SCHULTHEISS MARKUS ET AL) 5 September 2002 (2002-09-05) paragraph [0039]; figure 1 paragraph [0044]; figures 2,3</td>
<td>1,9,17, 19</td>
</tr>
<tr>
<td>A</td>
<td>EP 0 622 058 A (MEDEVELOP AKTIEBOLAG) 2 November 1994 (1994-11-02) abstract; figures 3,4</td>
<td>1,9,17, 19</td>
</tr>
<tr>
<td>A</td>
<td>US 4 872 840 A (BORI ET AL) 10 October 1989 (1989-10-10) column 9, line 26 – line 65; figures 2,5</td>
<td>1,9,17, 19</td>
</tr>
<tr>
<td>A</td>
<td>US 5 338 197 A (KWAN ET AL) 16 August 1994 (1994-08-16) figure 3</td>
<td>1,9,17, 19</td>
</tr>
</tbody>
</table>

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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL-2330 Rijswijk Tel (+31-70) 940-2040, Tx. 31 651 epo nl, Fax (+31-70) 940-3016

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<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DE 59906133 D1</td>
<td>31-07-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 0112088 A1</td>
<td>22-02-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 689462 B2</td>
<td>02-04-1998</td>
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<tr>
<td></td>
<td></td>
<td>AU 6073394 A</td>
<td>03-11-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BR 9401613 A</td>
<td>22-11-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2122192 A1</td>
<td>28-10-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 1094940 A</td>
<td>16-11-1994</td>
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<tr>
<td></td>
<td></td>
<td>CZ 9401005 A3</td>
<td>16-11-1994</td>
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<tr>
<td></td>
<td></td>
<td>DE 59408327 D1</td>
<td>08-07-1999</td>
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<tr>
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<td></td>
<td>DK 622058 T3</td>
<td>23-06-1999</td>
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<td></td>
<td></td>
<td>ES 2133524 T3</td>
<td>16-09-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FI 941934 A</td>
<td>28-10-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GR 3030398 T3</td>
<td>30-09-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HU 67974 A2</td>
<td>29-05-1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 6319759 A</td>
<td>22-11-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO 941524 A</td>
<td>28-10-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PL 174716 B1</td>
<td>30-09-1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZA 94022870 A</td>
<td>23-11-1995</td>
</tr>
<tr>
<td>US 4872840 A</td>
<td>10-10-1989</td>
<td>AU 2122888 A</td>
<td>13-02-1989</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 8900410 A1</td>
<td>26-01-1989</td>
</tr>
</tbody>
</table>

From: PCT/ISA/210 (patent family annex) (April 2005)