Title: BONE TUNNER TISSUE INSERTER

Abstract: A tissue inserter (10) includes a shaft (12) with a proximal region (14) and a distal insertion region (16). The distal insertion region is configured for receipt in a bone tunnel. The distal insertion region includes a segment (18) having a non-circular cross - section and prongs (20) extending from the segment such that tissue can be wrapped about the insertion region between the prongs. The segment cross - section is, for example, rectangular.
BONE TUNNER TISSUE INserter

Cross-Reference to Related Applications

This application claims priority to and the full benefit of U.S. Provisional Application Serial Nos. 61/471,265 and 61/471,268, filed April 4, 2011, the entire contents of which are incorporated herein by reference. This application is related to U.S. Patent Application No. 12/725,686, the entire contents of which is incorporated herein by reference.

Background

During repair of soft tissue, such as biceps tenodesis repair, the biceps tendon is placed in a prepared hole in the humerus and temporarily secured in the hole prior to final fixation of the tendon via a fixation device.

Summary

In one aspect, a tissue inserter includes a shaft with a proximal region and a distal insertion region. The distal insertion region is configured for receipt in a bone tunnel. The distal insertion region includes a segment having a non-circular cross-section and prongs extending from the segment such that tissue can be wrapped about the insertion region between the prongs.

Embodiments of this aspect may include one or more of the following features. The segment cross-section may be rectangular, discontinuous, or variable. The distal segment has a width to thickness aspect ratio of greater than 1:1. The proximal region may have a non-circular cross-section or a circular cross-section.

The shaft may define a lumen extending from the proximal region towards and through the distal insertion region. The lumen may be configured to receive a pin such that a portion of the pin extends beyond the distal insertion region. The proximal region may be configured to be coupled to a vise. The vise may be configured to receive a proximal portion of the pin in one of at least two securable positions, each position resulting in the pin extending a different distance beyond the distal insertion region when the pin is received in the lumen.

According to another aspect, a method of placing soft tissue in a bone hole or tunnel includes wrapping the soft tissue over an end of a tissue inserter between prongs of the tissue
inserter, and advancing the tissue inserter into the bone hole or tunnel. The tissue inserter has an
insertion region with a non-circular cross-section that allows for placement of larger tendons
within a given diameter bone tunnel cross-sectional than obtainable with a complementary sized
inserter having a circular cross-section.

According to another aspect, a tissue pinning system includes a tissue inserter defining a
lumen, a pin configured for receipt in the lumen, and a vise configured to receive a proximal
region of the pin in one of at least two securable positions. Each of the securable positions
results in the pin extending a different distance out of the tissue inserter when the pin is received
in the lumen.

Embodiments of this aspect may include one or more of the following features. For
example, the vise may include a stepped channel having a proximal shelf and a distal shelf. The
proximal region of the pin may include a tang with an end surface. The end surface of the tang
may be placed against the proximal shelf when the proximal region of the pin is in a first of the
at least two securable positions and may be placed against the distal shelf when the proximal
region of the pin is in a second of the at least two securable positions.

According to another aspect, a method of performing biceps tenodesis repair includes
using a tissue inserter to place a tendon in a bone hole, securing a pin to a vise in one of two
predetermined positions, advancing the pin through a lumen of the tissue inserter to the surgical
site; and piercing the tendon and engaging the bone with the pin to temporarily secure the tendon
in place.

Embodiments of this aspect may include removing the vise and tissue inserter from the
surgical site leaving the pin in place.

The details of one or more embodiments are set forth in the accompanying drawings and
the description below. Other features, aspects, and advantages will become apparent from the
description, the drawings, and the claims.

Brief Description of the Drawings

Fig. 1 is an isometric view of tissue inserter.

Fig. 2 is an isometric view of a distal insertion region of the tissue inserter of Fig. 1.

Fig. 3 is a cross-section view of the tissue inserter of Fig. 1 taken along lines 3-3 in Fig. 2
shown with soft tissue in a bone hole or tunnel.
Fig. 4 is a side view of the tissue inserter of Fig. 1.
Fig. 5 illustrates a tissue insertion and pinning system.
Fig. 6 illustrates a distal region of the tissue insertion and pinning system of Fig. 5 with a pin of the system in a first position.
Fig. 7 illustrates a distal region of the tissue insertion and pinning system of Fig. 5 with a pin of the system in a second, extended position.
Fig. 8 is a cross-sectional view of a vise of the tissue insertion and pinning system of Fig. 5.
Fig. 9 is an isometric view of a proximal region of a pin of the tissue insertion and pinning system of Fig. 5.
Fig. 10 is a cross-sectional view of an alternative embodiment of a vise.
Fig. 11 is an isometric view of an alternative embodiment of the proximal region of a pin.
Fig. 12 illustrates an alternative embodiment of the tissue inserter with a segment that includes a discontinuous cross-section.
Figs. 13A-13C illustrate an alternative embodiment of the tissue inserter with a segment that includes a variable cross-section.

Detailed Description

Referring to Figs. 1 and 2, a tissue inserter 10 includes a shaft 12 with a proximal region 14 and a distal insertion region 16. The insertion region 16 includes a segment 18 having a non-circular cross-section and prongs 20 extending from the segment 18. The prongs define a space 22a therebetween for receiving tissue, for example, a soft tissue graft. The proximal region 14 includes a handle 22 and an intermediate shaft 24. In the illustrated embodiment, the segment 18 cross-section is rectangular and the cross-section of the proximal region 14, in particular, the intermediate shaft 24 of the proximal region 14, is circular. The intermediate shaft 24 and the distal insertion region 16 can be formed from stainless steel or an engineered plastic such as polycarbonate, and can be formed as a single or piece, or multiple pieces that are joined together. The handle 22 can be formed from stainless steel or plastics such as ABS or Radel.

Referring also to Figs. 3 and 4, the segment 18 has, for example, a width, W, of about 8mm, a thickness, T, of about 2mm, and a length, L1, of about 20-25mm. The prongs have a length of about 5mm such that the over length, L2, of the insertion region is about 25-30mm.
The shaft 12 can define a through lumen 26. Generally, various embodiments may employ a width, W, in the range of about 4-9mm, a thickness, T, in the range of about 1-8.9mm, and a width to thickness aspect ratio greater than 1:1.

In use, for example, a soft tissue graft 30 (Fig. 3) is wrapped over the end of the segment 18 between the prongs 20 in the space 22a. The tissue inserter 10 is then used to place the graft 30 in a bone hole or tunnel 32 by advancing distal insertion region 16 into the hole or tunnel 32, such as described in related U.S. Patent Application No. 12/725686.

The cross-section of segment 18 is selected to allow for placement of larger tendons within a given diameter bone tunnel cross-sectional area than has been previously known. The distal insertion region 16 is, in some embodiments, of sufficient length that the circular cross-sectional area of the instrument shaft 24 remains spaced from the bone tunnel even at the deepest penetration of the fork into the bone tunnel such that the cross-sectional diameter of the instrument shaft 24 does not limit the size of the tendon that can be placed in the bone tunnel. The prongs 20 act to cradle and control the tendon during placement of the tendon into the bone tunnel, while the segment 18 extends into the bone tunnel to insert the tendon while maximizing cross-sectional area for the tendon to reside in.

Other variations are possible. For example, the proximal region 14, in particular, the intermediate shaft 24 of the proximal region 14, can have a non-circular cross-section. The non-circular cross-section can be an extension of the rectangle shape of the distal insertion region 16. The distal insertion region 16 can have a thin cross-section other than a rectangular shape, for example any shape having a width to thickness aspect ratio of greater than 1:1. Figs. 12 and 13A-13C, below, show examples of embodiments that employ other cross-sectional shapes for segment 18.

Referring to Fig. 5, in a particular application, a tissue insertion and pinning system 38 is used during biceps proximal tenodesis surgery. The system 38 includes the tissue inserter 10, a pin 40 that is received in the lumen 26 of the tissue inserter 10, and a vise 42 that receives a proximal region 44 (Fig. 9) of the pin in one of at least two securable positions. Each securable position results in the pin extending a different distance out of the tissue inserter 10 when the pin is received in the lumen. The pin 40 can be formed from stainless steel or nitinol. The vise 42 can be formed from stainless steel or plastics such as polycarbonate or Radel.
In particular, the tissue inserter 10 is used to insert the biceps tendon in a prepared hole in the humerus. The biceps tendon may need to be temporarily secured in the hole prior to final fixation of the tendon via, for example, an interference screw. The pin 40, received within the lumen 26 of the tissue inserter 10, can be used to temporarily secure the biceps tendon in the hole. Depending on the chosen repair location (supra-pectoralis or sub-pectoralis) different amounts of pin penetration can be desirable. The pin 40 is coupled to the vise 42 such that different fixed amounts of pin penetration can be generated with a single set of instruments. In a first secured position (Fig. 6), the pin 40 extends about 8 mm out of the tissue inserter 10; and in a second secured position (Fig. 7), the pin 40 extends about 20 mm out of the tissue inserter.

Referring to Figs. 8 and 9, to provide system 38 with two securable positions, the vise 42 defines a stepped channel 46 for receiving the proximal region 44 of the pin 40. The stepped channel 46 is defined by a proximal shelf 48 and a distal shelf 50 of the vise 42. The pin 40 has, for example, a circular cross-section over the majority of its length, and has a corresponding stepped profile at the proximal region 44 forming a tang 52 defined between surfaces 54 and 56. The tang 52 is formed, for example, by slicing a cylindrical rod in half lengthwise. To position the pin 40 in the first position, the end surface 54 of the pin 40 is placed against the proximal shelf 48 of the vise 42. To position the pin 40 in the second position, the surface 54 of the pin is placed against the distal shelf 50 of the vise 42. The pin 40 can be secured in the first or second position using a set screw 54 (Fig. 5) that extends through the vise to the stepped channel 46 to engage the pin 40.

The pin and vise can be configured to have more than two levels of steps leading to more than two levels of penetration. For example, referring to Figs. 10 and 11, to provide system 38 with three securable positions, a stepped channel 46a of the vise 42 is defined by a proximal shelf 48a, a mid-shelf 49a, and a distal shelf 50a. The stepped profile of the pin 40 forms a tang 52a defined between surfaces 54a and 56a. Rather than being semi-circular, as illustrated in Fig. 9, the tang 52a is formed, for example, by slicing a cylindrical rod such that a third of the cross-section of the pin 40 remains. To position the pin 40 in a first position in which the pin 40 extends the least from the tissue inserter 10, the surface 54a of the pin 40 is placed against the proximal shelf 48a of the vise 42; to position the pin 40 in a second, mid-position, the surface 54a of the pin 40 is placed against the mid-shelf 49a of the vise 42; and to position the pin 40 in a
third position in which the pin 40 extends the most from the tissue inserter 10, the surface 54a of the pin 40 is placed against the distal shelf 50a of the vise 42.

In use, the tissue inserter 10 is used to place the tendon in the bone hole, the pin 40 is secured to the vise 42 in the desired position, and the pin 40 is advanced through the lumen 26 of the tissue inserter 10 to the surgical site to pierce the tendon and engage the bone to temporarily secure the tendon in place. The set screw 54 can then be loosened, and the vise 42 and tissue inserter 10 removed from the surgical site leaving the pin 40 in place.

The system 38 provides differing levels of penetration suited to different defined procedures, and compared with a variable pin vise, provides a set (controlled) amount of pin penetration. The system 38 also reduces or eliminates the need for stocking multiple kits for the supra-pectoralis or sub-pectoralis procedures.

The pin 40 and vise 42 can be used with other tissue inserters, such as described in related U.S. Patent Application No. 12/725686.

Fig. 12 illustrates an alternative embodiment of the tissue inserter 10 in which the segment 18 has a discontinuous cross-section. In this embodiment, segment 18 is rectangular in shape, but is not continuous from the proximal end 18a of segment 18 to the distal end 18b. Rather, the side edges 18c and 18d of segment 18 are connected by one or more struts 18e that define voids 18f along the length of segment 18. The edges 18c and 18d extend into prongs 20, which define a space 22a therebetween for receiving tissue.

Figs. 13A-13C illustrate an alternative embodiment of the tissue inserter 10 in which the segment 18 has a variable cross-section. In this embodiment, the segment 18 includes a proximal rectangular portion 18a that is coupled to a first tapering portion 18b. The first tapering portion tapers to a circular portion 18c. The taper of first tapering portion 18c increases towards the circular portion 18c along the top side 18d and the bottom side 18e of segment 18, and decreases toward the circular portion 18c along the sides 18f, 18g of the segment 18. The circular portion 18c has a diameter less than the width, W, of segment 18. A diameter of circular portion 18c less than the width, W, maintains a width to thickness ratio greater than 1:1. A second tapering portion 18h extends from the circular portion 18c and tapers to a distal rectangular portion 18i. The taper of second tapering portion 18c decreases towards the distal rectangular portion 18i along the top side 18d and the bottom side 18e of segment 18, and increases toward the distal rectangular portion 18i along the sides 18f, 18g of the segment 18.
Prongs 20 extend from the distal rectangular portion 18e and define a space 22a for receiving tissue.
What is claimed is:

1. A tissue inserter, comprising:
   a shaft with a proximal region and a distal insertion region, the distal insertion region configured for receipt in a bone tunnel;
   the distal insertion region including a segment having a non-circular cross-section and prongs extending from the segment such that tissue can be wrapped about the insertion region between the prongs.

2. The tissue inserter of claim 1 wherein the segment cross-section is rectangular.

3. The tissue inserter of claim 1 or 2 wherein the segment cross-section is discontinuous.

4. The tissue inserter of claim 1 wherein the segment cross-section is variable.

5. The tissue inserter of any of the preceding claims wherein the distal segment has a width to thickness aspect ratio of greater than 1:1.

6. The tissue inserter of any of the preceding claims wherein the shaft defines a lumen extending from the proximal region towards and through the distal insertion region.

7. The tissue inserter of claim 6 wherein the lumen is configured to receive a pin such that a portion of the pin extends beyond the distal insertion region.

8. The tissue inserter of claim 7 wherein the proximal region is configured to be coupled to a vise, wherein the vise is configured to receive a proximal portion of the pin in one of at least two securable positions, each position resulting in the pin extending a different distance beyond the distal insertion region when the pin is received in the lumen.

9. A tissue pinning system, comprising:
   a tissue inserter defining a lumen;
a pin configured for receipt in the lumen; and

a vise configured to receive a proximal region of the pin in one of at least two securable positions, each position resulting in the pin extending a different distance out of the tissue inserter when the pin is received in the lumen.

10. The tissue pinning system of claim 9 wherein the vise includes a stepped channel having a proximal shelf and a distal shelf.

11. The tissue pinning system of claim 10 wherein the proximal region of the pin includes a tang with an end surface, the end surface being placed against the proximal shelf when the proximal region of the pin is in a first of the at least two securable positions and being placed against the distal shelf when the proximal region of the pin is in a second of the at least two securable positions.
## INTERNATIONAL SEARCH REPORT

**PCT/US2012/032193**

### A. CLASSIFICATION OF SUBJECT MATTER

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### ADD.

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)

| A61F |

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

| EPO-Internal, WPI Data |

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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**X** Further documents are listed in the continuation of Box C.  
**X** See patent family annex.

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**Date of the actual completion of the international search**  
8 May 2012

**Date of mailing of the international search report**  
18/05/2012

**Name and mailing address of the ISA/ 
European Patent Office, P.B. 5818 Patentlaan 2 
NL - 2280 HV Rijswijk 
Tel. (+31-70) 340-2040, 
Fax: (+31-70) 340-3016**  

**Authorized officer**  
Storer, John
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