US Patent & Trademark Office
Patent Public Search | Text View

United States Patent	12383322
Kind Code	B2
Date of Patent	August 12, 2025
Inventor(s)	Kent; Todd et al.

Methods and devices for syndesmosis tensioning

Abstract

A system is provided for the approximation of two bones. The system may include an implant having a first anchor, a flexible segment, and a second anchor. The first anchor may be configured for insertion into a first bone. The second anchor may be configured to engage with a second bone. The flexible segment may extend between the first and second anchors. The system may include a delivery device which may include a removable driver configured to facilitate insertion of the first anchor into the first bone, and a first handle configured to engage the removeable driver. The delivery device may include a second handle configured to increase tension on the flexible segment. The delivery device may include a third handle configured to engage the second anchor with the second bone and to attach the flexible segment to the second anchor.

Inventors: **Kent; Todd (Raynham, MA), Sayger; Daniel (Memphis, TN)**

Applicant: **DePuy Synthes Products, Inc.** (Raynham, MA)

Family ID: **1000008750800**

Assignee: **DePuy Synthes Products, Inc. (Raynham, MA)**

Appl. No.: **18/453784**

Filed: **August 22, 2023**

Prior Publication Data

Document Identifier	Publication Date
US 20250064496 A1	Feb. 27, 2025

Publication Classification

Int. Cl.: **A61B17/88** (20060101)

U.S. Cl.:

CPC **A61B17/8866** (20130101);

Field of Classification Search

CPC: A61B (17/8866); A61B (17/8875); A61B (2017/0409); A61B (2017/0496)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
5306290	12/1993	Martins et al.	N/A	N/A
6187008	12/2000	Hamman	606/232	A61B 17/8888
7029490	12/2005	Grafton et al.	N/A	N/A
7235091	12/2006	Thornes	N/A	N/A
7608098	12/2008	Stone	606/304	A61F 2/0805
7611521	12/2008	Lubbers et al.	N/A	N/A
7955388	12/2010	Jensen	623/13.14	A61B 17/8685
8298247	12/2011	Sterrett et al.	N/A	N/A
8398678	12/2012	Baker et al.	N/A	N/A
8460379	12/2012	Albertorio et al.	N/A	N/A
8888779	12/2013	Senn et al.	N/A	N/A
D740417	12/2014	Chavan	N/A	N/A
D740418	12/2014	Chavan et al.	N/A	N/A
D740419	12/2014	Chavan et al.	N/A	N/A
D740480	12/2014	Thompson	N/A	N/A
9179950	12/2014	Zajac et al.	N/A	N/A
9421049	12/2015	Rogachefsky	N/A	N/A
9737347	12/2016	Schlienger et al.	N/A	N/A
9788876	12/2016	Stone	N/A	A61B 17/0401
9826969	12/2016	Larsen	N/A	N/A
9888916	12/2017	Bonutti et al.	N/A	N/A
9943304	12/2017	Branthover et al.	N/A	N/A
10130377	12/2017	Hollis et al.	N/A	N/A
10206670	12/2018	Thornes	N/A	N/A
10251686	12/2018	Zajac et al.	N/A	N/A
10327826	12/2018	Horrell et al.	N/A	N/A
10390816	12/2018	Thornes	N/A	N/A
10405847	12/2018	Petry et al.	N/A	N/A
10413341	12/2018	Chaudot et al.	N/A	N/A
10492774	12/2018	Larsen	N/A	N/A
10499900	12/2018	Wade	N/A	N/A
10499972	12/2018	Bosshard et al.	N/A	N/A
10582957	12/2019	Hollis et al.	N/A	N/A
10682131	12/2019	Fallin et al.	N/A	N/A
10695049	12/2019	Thornes	N/A	N/A
10722229	12/2019	O'Donnell et al.	N/A	N/A
10736622	12/2019	Thornes	N/A	N/A
10799250	12/2019	Hollis et al.	N/A	N/A
10864028	12/2019	Zajac et al.	N/A	N/A

10918375	12/2020	Thornes	N/A	N/A
11109855	12/2020	Shoshtaev et al.	N/A	N/A
11129654	12/2020	Zajac et al.	N/A	N/A
11234688	12/2021	Taber et al.	N/A	N/A
11253301	12/2021	Larsen et al.	N/A	N/A
11471146	12/2021	Petry et al.	N/A	N/A
11534157	12/2021	Norton	N/A	N/A
2006/0100627	12/2005	Stone	606/907	A61F 2/0805
2011/0112576	12/2010	Nguyen	606/232	A61B 17/0401
2011/0282361	12/2010	Miller	606/139	A61B 17/0401
2012/0172936	12/2011	Horrell	606/104	A61B 17/0401
2013/0331897	12/2012	Holt	606/328	A61B 17/1684
2014/0194907	12/2013	Bonutti	606/151	A61B 17/0401
2016/0038186	12/2015	Herzog	606/328	A61B 17/686
2016/0287302	12/2015	Horrell	N/A	A61B 17/84
2017/0035552	12/2016	Fallin	N/A	A61B 17/06133
2017/0128061	12/2016	Stone et al.	N/A	N/A
2018/0049784	12/2017	Gault et al.	N/A	N/A
2018/0098762	12/2017	Borden	N/A	A61B 17/0401
2020/0245997	12/2019	Balboa	N/A	A61B 17/0401
2021/0059729	12/2020	Zajac et al.	N/A	N/A
2021/0161518	12/2020	Thornes	N/A	N/A
2021/0219972	12/2020	Zakhary	N/A	N/A
2022/0000470	12/2021	Fallin	N/A	A61B 17/0401
2022/0071676	12/2021	Horrell	N/A	G06Q 20/3678
2022/0142635	12/2021	Bachmaier et al.	N/A	N/A
2022/0151604	12/2021	Fallin	N/A	A61B 17/1604
2022/0192817	12/2021	Gill	N/A	A61B 17/72
2022/0226100	12/2021	Feuer	N/A	A61B 17/8645
2022/0323058	12/2021	Zenz-Olson et al.	N/A	N/A
2023/0248351	12/2022	Khalil	606/232	A61B 17/0401
2023/0320838	12/2022	Duquesnel	623/13.12	A61B 17/0401
2024/0315830	12/2023	Johnson	N/A	A61F 2/0811
2024/0415545	12/2023	Colwell	N/A	A61B 17/0401

FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
108186096	12/2017	CN	N/A
3206607	12/2017	EP	N/A
2461366	12/2011	RU	N/A

OTHER PUBLICATIONS

International Search Report and Written Opinion dated Nov. 19, 2024, from corresponding International Application No. PCT/IB2024/057626. cited by applicant

---

Primary Examiner: Sipp; Amy R

Background/Summary

FIELD

(1) The present invention generally relates to methods and devices for syndesmosis tensioning. More specifically, certain embodiments relate to methods and devices for tensioning of the tibia and fibula following an injury to the corresponding syndesmotic joint.

BACKGROUND

(2) A syndesmotic injury results when a traumatic injury damages the ligaments that span the gap between the distal tibia and fibula. This can be the result of a high ankle sprain, with no fracture of the fibula, or can also accompany a fibular fracture in a Weber B or Weber C fracture.

(3) A surgeon can determine the presence of a syndesmotic injury by direct visualization of the joint or through radiographic imaging while positioning the ankle in a mortise view orientation. In either case, loads are applied to the joint in either a direct lateral load applied to the fibula or by applying an external rotation load to the foot. While the load is being applied, the relative distance between the fibula and the tibia, the fibula and the talus, and the tibia and the talus are observed to determine the level of damage sustained by the ligaments that typically hold the syndesmotic joint together.

(4) If a syndesmotic injury is found to be present, the typical treatment involves stabilizing the fibula and tibia with respect to each other in the proper orientation and holding them there throughout the soft tissue healing period to allow the ligaments to re-attach and heal. In the event of a syndesmotic injury with a corresponding fibula fracture, this is done while also stabilizing the fibular fracture, which is usually accomplished with a small fracture plate on the lateral side of the fibula. Traditionally the method of stabilization has been to place one or more cortical screws across the syndesmosis, with the head against the lateral face of the fibula and the tip of the screw being in the middle of the tibia or in the medial cortex of the tibia.

(5) This form of treatment provides very rigid fixation, allowing the ligaments to heal, but makes return to weight-bearing more difficult. During a standard gait, the ligaments hold the distance between the tibia and fibula fairly constant, but allow a small amount of shear motion and rotation of the fibula with respect to the tibia. The presence of the fixation screws prevents this motion and can cause discomfort and limited flexibility of the ankle joint. Typically, the surgeon prescribes a secondary surgery to remove the screws once the ligaments have healed. In some cases, a surgeon may simply recommend a return to weight-bearing when the ligaments have healed and, after a period of time of loading the screws, they will experience a fatigue failure and normal anatomical motion will be restored.

(6) To address these rigidity issues, some methods of stabilization have been developed to include a flexible internal segment connected by a first anchor on the lateral side of the fibula and a second anchor on the medial side of the tibia. These methods, however, typically present challenges in achieving an appropriate degree of tension between the two bones for sufficient healing and recovery.

(7) Accordingly, alternative devices and methods for providing syndesmosis tensioning would be useful.

SUMMARY

(8) The present invention is directed to methods and devices for providing syndesmosis tensioning while stabilizing a joint between two bones, e.g., the tibia and fibula, during a healing period following a traumatic injury.

(9) An example system is provided for the approximation of two bones. The system may include an implant having a first anchor, a flexible segment, and a second anchor. The first anchor may include a distal end configured for insertion into a first hole in a first bone. The second anchor may

be configured to engage with a second bone. The flexible segment may extend between the first and second anchors. The system may further include a delivery device configured to engage the implant with the first and second bones. The delivery device may include a removable driver configured to engage the first anchor to facilitate insertion of the first anchor into the first hole. The delivery device may include a first handle configured to engage the removeable driver to facilitate insertion of the first anchor into the first hole by the removable driver. The delivery device may include a second handle coupled to the first handle and configured, with the removable driver disengaged from the first handle and first anchor, to increase tension on the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction. The delivery device may include a third handle configured to engage the second anchor with the second bone and to attach the flexible segment to the second anchor.
(10) An example method is provided for the approximation of two bones. The method may include delivering, via a first handle and a removeable driver of a delivery device, a first anchor into a first bone, wherein the first anchor engages with a distal end of a flexible segment. The method may include disengaging the removeable driver from the delivery device, thereby exposing the flexible segment. The method may include adjusting, via a second handle of the delivery device, tension of the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction. The method may include delivering, via a third handle of the delivery device, a second anchor into a second bone. The method may include attaching, via the third handle of the delivery device, the flexible segment to the second anchor.
(11) An example method is provided for constructing a system for the approximation of two bones. The method may include coupling a locking component to a third handle of a delivery device. The method may include feeding a flexible segment through a second anchor of an implant. The method may include configuring the delivery device such that rotation of the third handle couples the locking component to the flexible segment and the second anchor. The method may include coupling a proximal end of a flexible segment to a second handle of the delivery device such that a distal end of the flexible segment is coupled to a first anchor of the implant. The method may include configuring the delivery device such that rotation of the second handle adjusts tension in the flexible segment. The method may include engaging a distal end of a removable driver to a proximal end of the first anchor and engaging a proximal end of the removable driver to a first handle of the delivery device such that the flexible segment extends along the removable driver. The method may include configuring the delivery device such that rotation of the first handle rotates the removable driver and thereby the first anchor. The method may include configuring the delivery device such that the removable driver is configured to be disengaged from the first handle and the first anchor while the flexible segment remains coupled to the second handle and the first anchor.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) The above and further aspects of this invention are further discussed with reference to the following description in conjunction with the accompanying drawings, in which like numerals indicate like structural elements and features in various figures. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating principles of the invention. The figures depict one or more implementations of the inventive devices, by way of example only, not by way of limitation.
(2) FIG. **1** is an illustration of an example implant used for syndesmosis tensioning, according to aspects of the present invention.
(3) FIG. **2** is a cross-sectional view of a first anchor of the example implant of FIG. **1**, according to

aspects of the present invention.
(4) FIG. **3** is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(5) FIG. **4** is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(6) FIG. **4**A is a perspective view of an example delivery device used for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(7) FIG. **5** is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(8) FIG. **6** is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(9) FIG. **7**A is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(10) FIG. **7**B is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(11) FIG. **7**C is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(12) FIG. **7**D is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(13) FIG. **7**E is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(14) FIG. **7**F is a perspective view of an engagement between a component of a delivery device and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(15) FIG. **7**G is a perspective view of an engagement between a component of a delivery device and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(16) FIG. **8**A is a perspective view of an example delivery device used for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(17) FIG. **8**B is a cross-sectional view of components of the example delivery device of FIG. **8**A, according to aspects of the present invention.
(18) FIG. **9**A is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(19) FIG. **9**B is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(20) FIG. **9**C is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.
(21) FIG. **9**D is a cross-sectional view of a tibia and fibula showing an example step of an example

method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.

(22) FIG. **9**E is a cross-sectional view of a tibia and fibula showing an example step of an example method for installing an implant, such as that shown in FIG. **1**, according to aspects of the present invention.

(23) FIG. **10** is a cross-sectional view of an engagement between a second anchor and a flexible segment of an example implant, such as that shown in FIG. **1**, according to aspects of the present invention.

(24) FIG. **11** is a flowchart of an example method for providing syndesmosis tensioning, according to aspects of the present invention.

(25) FIG. **12** is a flowchart of an example method for providing syndesmosis tensioning, according to aspects of the present invention.

DETAILED DESCRIPTION

(26) As used herein, the terms "about" or "approximately" for any numerical values or ranges indicate a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. More specifically, "about" or "approximately" may refer to the range of values ±20% of the recited value, e.g., "about 80%" may refer to the range of values from 60% to 100%.

(27) The example devices and methods of treatment described herein generally involve providing syndesmosis tensioning and repair of two bones, such as the tibia and fibula bones. That is, a delivery device having one or more handles may be used to install an implant into two bones, such as the tibia and fibula bones, to provide an appropriate degree of tensioning between the two bones for injury treatment and repair.

(28) Various example systems and methods are presented herein. Features from each example are combinable with other examples as understood by persons skilled in the pertinent art.

(29) FIG. **1** is an illustration of an example implant **102** for the approximation of two bones. The implant **102** may include a first anchor **104**, which may include a proximal end **104***a* and a distal end **104***b*. The first anchor **104** may be configured to be inserted into a first bone **112** (e.g., a tibia bone) through a first bone hole **110**. In some embodiments, the implant **102** may further include a second anchor **108** configured to engage a second bone **114** (e.g., a fibula bone). The second anchor **108** may include a proximal end **108***a* and a distal end **108***b*, and may be configured to be inserted into the second bone **114**. The second anchor **108** may include a threaded screw, a barbed fastener, a button, and/or a cap.

(30) The first and/or second anchors **104**, **108** can include any type of suture anchor, and can be manufactured from a surgical stainless steel or other suitable biocompatible material, such as 316 LVM stainless steel, titanium, and other suitable materials, such as nitinol, bio-absorbables, or non-absorbables. First and/or second anchors **104**, **108** can also include an "all-textile" anchor.

(31) As particularly shown in FIG. **2**, the first anchor **104** may include a bore **202** extending from the proximal end **104***a* at least partially towards the distal end **104***b*, generally along a longitudinal axis **14** of the implant **102**. The bore **202** can include a proximal region **202***a*, an intermediate region **202***b* distal to the proximate region **202***a* including a first support structure **204** therein, and a distal region **202***c* extending distally from the intermediate region **202***b* to a recess **202***d* in the distal tip **104***c*. The intermediate region **202***b* and distal region **202***c* may have a circular or other desired cross-sectional shape, with the distal region **202***c* having a diameter or other maximum cross-section smaller than the intermediate region **202***b*. The recess **202***d* may have a diameter or other cross-section larger than the distal region **202***c*, e.g., to receive a knot **106***c* or otherwise fixed distal ends **106***b* (e.g., a crimp eyelet pin, etc.) of the flexible segment **106**, as described elsewhere herein.

(32) A first support structure **204** may be provided within the bore **202**, e.g., across the intermediate region **202***b* substantially perpendicular to the longitudinal axis **14**. In one example first anchor

104, holes may be provided through opposite side walls of the first anchor **104** into the intermediate region **202***b* and a first support structure **204**, e.g., a pin, may be inserted into the holes such that the first support structure **204** extends across the intermediate region **202***b* and substantially permanently attached thereto, e.g., by one or more of press-fit or other interference fit, bonding with adhesive, sonic welding, soldering, and the like. In an alternative example first anchor **104**, the holes may be omitted and a first support structure **204** may be inserted through the intermediate region **202***b* and positioned and fixed across the intermediate region **202***b*, e.g., by one or more of interference fit, bonding with adhesive, sonic welding, soldering, and the like. In another example first anchor **104**, a support structure may be integrally formed with the first anchor **104**, e.g., machined, cast, molded, and the like from the same piece of material as the rest of the first anchor **104**. The pin or other first support structure **204** generally has a diameter or other cross-section smaller than the intermediate region **202***b* such that a flexible segment **116** may be wrapped at least partially around the first support structure **204**, as described further elsewhere herein.
(33) Turning back to FIG. **1**, in some embodiments, the implant **102** may include a flexible segment **106** configured to extend between the first and second anchors, **104**, **108**, as further discussed below. The flexible segment **106** may be configured to adjust a distance L**1** between the first and second bones **112**, **114**.
(34) The flexible segment **106** can be manufactured out of a variety of fibers or filaments including but not limited to polymer filaments, metallic filaments, or organic filaments, or other filaments such as carbon fiber or carbon nanotubes, etc., and can be made of resorbable and/or biologic materials. Flexible segment **106** can include, but is not limited to, a coreless suture, a suture with a jacket and a central core, a tape, or any other tension member available or contemplated, can be poly-coated or uncoated, and can include collagen.
(35) FIGS. **3-6** provide an example system **100** for the approximation and tensioning of two bones, such as the tibia and fibula bones, and an example method for delivering an implant **102**, such as that shown in FIG. **1**, into the two bones. It will be appreciated that the apparatus, systems, and methods described herein may also be used in other locations and/or procedures, e.g., to provide approximation between two bones other than the tibia and fibula.
(36) The system **100** may include an implant **102**, such as that shown in FIG. **1**, and a delivery device **120**. The delivery device **120** may include a removeable driver **124** (FIGS. **3-4**) configured to facilitate insertion of the first anchor **104** into the first hole **110** of the first bone **112**. The delivery device **120** may further include a first handle **122** configured to engage the removeable driver **124** to facilitate insertion of the first anchor **104** into the first hole **110** by the removable driver **124**. For example, as shown in FIGS. **3-4**, the removeable driver **124** may first be used to facilitate insertion of the first anchor **104** into the first bone **112**, such as by rotating the first handle **122** thereby rotating the removable driver **124** and the first anchor **104**. The first anchor **104** may then be inserted into, e.g., screwed into, the first bone **112**.
(37) As shown in FIG. **4**, once the first anchor **104** has been inserted into and anchored in the first bone **112**, the removeable driver **124** may be removed from the delivery device **120**, thereby exposing the flexible segment **106** extending between the first anchor **104** and the second anchor **108**, which itself is engaged with the delivery device **120**. In some embodiments, as shown in FIG. **4**A, the delivery device **120** may include a slider **132** configured to slide along a length of the removeable driver **124** thereby enabling the removable driver **124** to disengage from the delivery device **120**.
(38) As particularly shown in FIGS. **5-6**, the delivery device **120** may further include a second handle **126** coupled to the first handle **122**. In some embodiments, the second handle **126** may be rotatable independent of the first handle **122**. In some embodiments, the second handle **126** may be configured, with the removable driver **124** disengaged from the first handle **122** and first anchor **104**, to increase tension on the flexible segment **106** by pulling one or more proximal ends **106***a* of the flexible segment **106** in a proximal direction **10**. In some embodiments, the delivery device **120**

may include one or more extensions **130** configured to engage with the proximal ends **106***a* of the flexible segment **106**, whereby rotation of the second handle **126** is configured to move the extensions **130** proximally along a length of the delivery device **120** thereby increasing the tension on the flexible segment **106**, as shown in FIG. **6**.

(39) In some embodiments, the delivery device **120** may include a force gauge **134** (FIG. **3**) that may provide an indication of the tensile force placed on the flexible segment **106** as the second handle **126** is rotated and the tension of the flexible segment **106** is adjusted.

(40) As particularly shown in FIG. **6**, the delivery device **120** may further include a third handle **128** configured to engage the second anchor **108** with the second bone **114** and to attach the flexible segment **106** to the second anchor **108**. For example, rotation of the third handle **128** (e.g., independent of the first handle **122** and second handle **126**) may provide for the second anchor **108** being locked or fitted into place within the second bone **114**, and the proximal ends **106***a* of the flexible segment **106** being attached to the second anchor **108** with a desired amount of tension.

(41) FIGS. **7**A-**7**G provide examples of engagements between the second anchor **108** and the flexible segment **106**. As shown, the third handle **128** may include an internal shaft **128***a* and a locking component **128***b*. As the third handle **128** is rotated, as discussed above and particularly shown in FIGS. **7**A-**7**B, the internal shaft **128***a* may be rotated thereby moving the locking component **128***b* in a distal direction **12** and engaging the locking component **128***b* with the flexible segment **106** and the second anchor **108**, and thereby attaching the flexible segment **106** to the second anchor **108**. As shown, the flexible segment **106** may be configured in one of many different shapes, arrangements, configurations, etc., depending on the selected shape and/or configuration of the second anchor **108** and/or the delivery device **120**. For example, FIG. **7**F illustrates a flexible segment **106** having four individual suture strands, while FIG. **7**G (FIG. **7**E showing a cross-sectional view thereof) illustrates a flexible segment **106** having a single and flatter suture strand. FIG. **7**D shows a cross-sectional and perspective view of how, for example, the flexible segment **106**, internal shaft **128***a*, and locking component **128***b* of FIG. **7**F might engage with second anchor **108**.

(42) FIGS. **8**A-**8**B provide an example of another system **200** for the approximation and tensioning of two bones, such as the tibia and fibula bones. As with system **100**, discussed above, system **200** may include an implant **102**, such as that shown in FIG. **1**, and a delivery device **220**. Delivery device **220** may include a first handle **222**, a second handle **226**, and a third handle **224**.

(43) As particularly shown in FIG. **8**B, and further discussed below, the second handle **226** may include a suture carriage **226***a* disposed within the delivery device **220** and configured to rotate and move along the longitudinal axis of the delivery device **220** as the second handle **226** is rotated. As such, the suture carriage **226***a* may aid in adjusting the tension of the flexible segment **106**, as further discussed below.

(44) As also particularly shown in FIG. **8**B, the third handle **224** may include an internal shaft **224***a*, whereby rotation of the third handle **224** is configured to rotate the internal shaft **224***a* to engage the locking component **228** (FIG. **9**D) with the second anchor **108** and the flexible segment **106**, as further discussed below.

(45) FIGS. **9**A-**9**E provide an example method for delivering an implant **102** into two bones, such as the tibia and fibula bones, using delivery device **220**.

(46) As shown in FIG. **9**A, the first, second, and third handles **222**, **226**, **224** may be simultaneously rotated, thereby facilitating the insertion of the first anchor **104** into the first hole **110** of the first bone **112**.

(47) As shown in FIG. **9**B, once the first anchor **104** has been inserted into and anchored in the first bone **112**, the third handle **224** may be removed from the delivery device **220**, thereby enabling the second handle **226** to be independently rotated to thereby increase tension on the flexible segment **106** by pulling one or more proximal ends **106***a* of the flexible segment **106** in a proximal direction **10**. As discussed above with respect to FIG. **8**B, as the second handle **226** is rotated, the internal

suture carriage **226***a* may move along the longitudinal axis of the delivery device **220**, thereby aiding in adjusting the tension on the flexible segment **106**.
(48) As shown in FIGS. **9**C-**9**E, the third handle **224** may then be re-attached to the delivery device **220**. The third handle **224** may include an internal shaft **224***a* (FIGS. **8**B and **10**) and a locking component **228** (FIGS. **9**D and **10**). Rotation of the third handle **224** (FIG. **9**E) may be configured to rotate the internal shaft **224***a* to engage the locking component **228** with the flexible segment **106** and the second anchor **108**, thereby attaching the flexible segment **106** to the second anchor **108**, as particularly shown in FIG. **10**.
(49) FIG. **11** provides a flowchart of an example method **300** for syndesmosis tensioning.
(50) In block **302**, the method may include delivering, via a first handle (e.g., **122**, **222**) and a removeable driver (e.g., **124**, **224**) of a delivery device (e.g., **120**, **220**), a first anchor (e.g., **104**) into a first bone (e.g., **112**), wherein the first anchor engages with a distal end of a flexible segment (e.g., **106**).
(51) In block **304**, the method may include disengaging the removeable driver from the delivery device, thereby exposing the flexible segment, for example, as discussed with respect to FIGS. **4** and **9**B.
(52) In block **306**, the method may include adjusting, via a second handle (e.g., **126**, **226**) of the delivery device, tension of the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction.
(53) In block **308**, the method may include delivering, via a third handle (e.g., **128**, **224**) of the delivery device, a second anchor (e.g., **108**) into a second bone (e.g., **114**).
(54) In block **310**, the method may include attaching, via the third handle (e.g., **128**, **224**) of the delivery device, the flexible segment to the second anchor.
(55) FIG. **12** provides a flowchart of an example method **400** for constructing a system for syndesmosis tensioning.
(56) In block **402**, the method may include coupling a locking component (e.g., **128***a*) to a third handle (e.g., **128**) of a delivery device (e.g., **120**). For example, as shown in FIG. **7**A, locking component **128***a* may be coupled or attached to the internal shaft **128***a* of the third handle **128**.
(57) In block **404**, the method may include feeding a flexible segment through a second anchor of an implant. For example, as discussed herein, one or more proximal ends of the flexible segment may extend from a proximal end of a first anchor, through a second anchor, and past the proximal end of the second anchor such that the delivery device can adjust tension of the flexible segment by moving the proximal ends in a proximal direction.
(58) In block **406**, the method may include configuring the delivery device such that rotation of the third handle couples the locking component to the flexible segment and the second anchor, such as discussed above with respect to FIG. **6**.
(59) In block **408**, the method may include coupling a proximal end of a flexible segment to a second handle of the delivery device such that a distal end of the flexible segment is coupled to a first anchor of the implant. For example, a distal end **106***b* of flexible segment **106** may be coupled to the first anchor **104**, e.g., as discussed with respect to FIG. **2**, while a proximal end **106***a* of flexible segment **106** may be coupled to a second handle **126**, e.g., via extensions **130**.
(60) In block **410**, the method may include configuring the delivery device such that rotation of the second handle adjusts tension in the flexible segment, such as discussed above with respect to FIG. **5**.
(61) In block **412**, the method may include engaging a distal end of a removable driver to a proximal end of the first anchor and engaging a proximal end of the removable driver to a first handle of the delivery device such that the flexible segment extends along the removable driver. For example, as shown in FIG. **3**, a distal end of removeable driver **124** may be engaged with a proximal end of first anchor **104**, while a proximal end of removeable driver **124** is engaged with first handle **122**. As shown in FIG. **4**, once the removeable driver **124** is disengaged, flexible

segment **106** is exposed, extending between the first and second anchors **104**, **108**.
(62) In block **414**, the method may include configuring the delivery device such that rotation of the first handle rotates the removable driver and thereby the first anchor, for example as discussed above with respect to FIG. **3**.
(63) In block **416**, the method may include configuring the delivery device such that the removable driver is configured to be disengaged from the first handle and the first anchor while the flexible segment remains coupled to the second handle and the first anchor, for example as discussed above with respect to FIG. **4**.
(64) The descriptions contained herein are examples of embodiments of the invention and are not intended in any way to limit the scope of the invention. As described herein, the invention contemplates many variations and modifications of structures and methods, including alternative materials, alternative configurations of component parts, and alternative method steps. Modifications and variations apparent to those having skill in the pertinent art according to the teachings of this disclosure are intended to be within the scope of the claims which follow.
(65) The disclosed technology described herein can be further understood according to the following clauses.
(66) Clause 1. A system for the approximation of two bones, the system comprising: an implant comprising a first anchor, a flexible segment, and a second anchor, the first anchor comprising a distal end configured for insertion into a first hole in a first bone, the second anchor being configured to engage with a second bone, and the flexible segment extending between the first and second anchors; and a delivery device configured to engage the implant with the first and second bones, the delivery device comprising: a removable driver configured to engage the first anchor to facilitate insertion of the first anchor into the first hole; a first handle configured to engage the removeable driver to facilitate insertion of the first anchor into the first hole by the removable driver; a second handle coupled to the first handle and configured, with the removable driver disengaged from the first handle and first anchor, to increase tension on the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction; and a third handle configured to engage the second anchor with the second bone and to attach the flexible segment to the second anchor.
(67) Clause 2. The system of clause 1, wherein the third handle is the removable driver.
(68) Clause 3. The system of clause 1, wherein the delivery device further comprises one or more extensions configured to engage with the one or more proximal ends of the flexible segment, and wherein rotation of the second handle is configured to move the one or more extensions proximally along a length of the delivery device thereby increasing the tension on the flexible segment.
(69) Clause 4. The system of clause 1, wherein the second handle is rotatable independent of the first handle.
(70) Clause 5. The system of clause 1, wherein the delivery device further comprises a slider configured to slide along a length of the removeable driver thereby enabling the removeable driver to disengage from the delivery device
(71) Clause 6. The system of clause 1, wherein rotation of the first handle is configured to cause rotation of the removable driver and the first anchor, with the removable driver engaged to the first handle and first anchor.
(72) Clause 7. The system of clause 1, wherein the third handle comprises an internal shaft and a locking component.
(73) Clause 8. The system of clause 7, wherein rotation of the third handle is configured to rotate the internal shaft to engage the locking component with the flexible segment and the second anchor, thereby attaching the flexible segment to the second anchor.
(74) Clause 9. A method for the approximation of two bones, the method comprising: delivering, via a first handle and a removeable driver of a delivery device, a first anchor into a first bone, wherein the first anchor engages with a distal end of a flexible segment; disengaging the

removeable driver from the delivery device, thereby exposing the flexible segment; adjusting, via a second handle of the delivery device, tension of the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction; delivering, via a third handle of the delivery device, a second anchor into a second bone; and attaching, via the third handle of the delivery device, the flexible segment to the second anchor.
(75) Clause 10. The method of clause 9, wherein the third handle is the removable driver.
(76) Clause 11. The method of clause 9, wherein the one or more proximal ends of the flexible segment are attached to one or more extensions disposed on the delivery device, and wherein adjusting the tension of the flexible segment is conducted by moving the one or more extensions proximally along a length of the delivery device.
(77) Clause 12. The method of clause 9, wherein disengaging the removeable driver from the delivery device comprises moving a slider along a length of the removeable driver.
(78) Clause 13. The method of clause 9, wherein the third handle comprises an internal shaft and a locking component.
(79) Clause 14. The method of clause 13, wherein rotation of the third handle is configured to rotate the internal shaft to engage the locking component with the flexible segment and the second anchor, thereby attaching the flexible segment to the second anchor.
(80) Clause 15. The method of clause 9, wherein the delivery device comprises a force gauge, and wherein adjusting the tension of the flexible segment comprises rotating the second handle of the delivery device thereby providing, via the force gauge, an indication of the tensile force placed on the flexible segment.
(81) Clause 16. A method of constructing a system for approximation of two bones, the method comprising: coupling a locking component to a third handle of a delivery device; feeding a flexible segment through a second anchor of an implant; configuring the delivery device such that rotation of the third handle couples the locking component to the flexible segment and the second anchor; coupling a proximal end of a flexible segment to a second handle of the delivery device such that a distal end of the flexible segment is coupled to a first anchor of the implant; configuring the delivery device such that rotation of the second handle adjusts tension in the flexible segment; engaging a distal end of a removable driver to a proximal end of the first anchor and engaging a proximal end of the removable driver to a first handle of the delivery device such that the flexible segment extends along the removable driver; configuring the delivery device such that rotation of the first handle rotates the removable driver and thereby the first anchor; and configuring the delivery device such that the removable driver is configured to be disengaged from the first handle and the first anchor while the flexible segment remains coupled to the second handle and the first anchor.
(82) Clause 17. The method of clause 16, wherein coupling the proximal end of the flexible segment to the second handle comprises attaching the proximal end to one or more extensions disposed on the delivery device.
(83) Clause 18. The method of clause 17, wherein adjusting the tension in the flexible segment is conducted by moving the one or more extensions proximally along a length of the delivery device.
(84) Clause 19. The method of clause 16, wherein the removeable driver is configured to be disengaged from the first handle by moving a slider along a length of the removeable driver.
(85) Clause 20. The method of clause 16, wherein the third handle comprises an internal shaft, and wherein rotation of the third handle rotates the internal shaft to couple the locking component to the flexible segment and the second anchor.
(86) Clause 21. A method of constructing a system for approximation of two bones, the method comprising: coupling a locking component to a third handle of a delivery device; feeding a flexible segment through a second anchor of an implant; configuring the delivery device such that rotation of the third handle couples the locking component to the flexible segment and the second anchor; coupling a proximal end of a flexible segment to a second handle of the delivery device such that a

distal end of the flexible segment is coupled to a first anchor of the implant; configuring the delivery device such that rotation of the second handle adjusts tension in the flexible segment; engaging a distal end of the third handle to a proximal end of the first anchor and engaging the third handle to the second handle and a first handle of the delivery device such that the flexible segment extends along the third handle; configuring the delivery device such that rotation of the third handle rotates the first anchor; and configuring the delivery device such that the third handle is configured to be disengaged from the delivery device and the first anchor while the flexible segment remains coupled to the second handle and the first anchor.

Claims

1. A system for approximation of two bones, the system comprising: an implant comprising a first anchor, a flexible segment, and a second anchor, the first anchor comprising a distal end configured for insertion into a first hole in a first bone, the second anchor being configured to engage with a second bone, and the flexible segment extending between the first and second anchors; and a delivery device configured to engage the implant with the first and second bones, the delivery device comprising: a removable driver configured to engage the first anchor to facilitate insertion of the first anchor into the first hole; a first handle configured to engage the removeable driver to facilitate insertion of the first anchor into the first hole by the removable driver; a second handle coupled to the first handle and configured, with the removable driver disengaged from the first handle and first anchor, to increase tension on the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction; and a third handle configured to engage the second anchor with the second bone and to attach the flexible segment to the second anchor.
2. The system of claim 1, wherein the delivery device further comprises one or more extensions configured to engage with the one or more proximal ends of the flexible segment, and wherein rotation of the second handle is configured to move the one or more extensions proximally along a length of the delivery device thereby increasing the tension on the flexible segment.
3. The system of claim 1, wherein the second handle is rotatable independent of the first handle.
4. The system of claim 1, wherein the delivery device further comprises a slider configured to slide along a length of the removeable driver thereby enabling the removeable driver to disengage from the delivery device.
5. The system of claim 1, wherein rotation of the first handle is configured to cause rotation of the removable driver and the first anchor, with the removable driver engaged to the first handle and first anchor.
6. The system of claim 1, wherein the third handle comprises an internal shaft and a locking component.
7. The system of claim 6, wherein rotation of the third handle is configured to rotate the internal shaft to engage the locking component with the flexible segment and the second anchor, thereby attaching the flexible segment to the second anchor.
8. A method for approximation of two bones, the method comprising: delivering, via a first handle and a removeable driver of a delivery device, a first anchor into a first bone, wherein the first anchor engages with a distal end of a flexible segment; disengaging the removeable driver from the delivery device, thereby exposing the flexible segment; adjusting, via a second handle of the delivery device, tension of the flexible segment by pulling one or more proximal ends of the flexible segment in a proximal direction; delivering, via a third handle of the delivery device, a second anchor into a second bone; and attaching, via the third handle of the delivery device, the flexible segment to the second anchor.
9. The method of claim 8, wherein the one or more proximal ends of the flexible segment are attached to one or more extensions disposed on the delivery device, and wherein adjusting the

tension of the flexible segment is conducted by moving the one or more extensions proximally along a length of the delivery device.

10. The method of claim 8, wherein disengaging the removeable driver from the delivery device comprises moving a slider along a length of the removeable driver.

11. The method of claim 8, wherein the third handle comprises an internal shaft and a locking component.

12. The method of claim 11, wherein rotation of the third handle is configured to rotate the internal shaft to engage the locking component with the flexible segment and the second anchor, thereby attaching the flexible segment to the second anchor.

13. The method of claim 8, wherein the delivery device comprises a force gauge, and wherein adjusting the tension of the flexible segment comprises rotating the second handle of the delivery device thereby providing, via the force gauge, an indication of the tensile force placed on the flexible segment.

14. A method of constructing a system for approximation of two bones, the method comprising: coupling a locking component to a third handle of a delivery device; feeding a flexible segment through a second anchor of an implant; configuring the delivery device such that rotation of the third handle couples the locking component to the flexible segment and the second anchor; coupling a proximal end of the flexible segment to a second handle of the delivery device such that a distal end of the flexible segment is coupled to a first anchor of the implant; configuring the delivery device such that rotation of the second handle adjusts tension in the flexible segment; engaging a distal end of a removable driver to a proximal end of the first anchor and engaging a proximal end of the removable driver to a first handle of the delivery device such that the flexible segment extends along the removable driver; configuring the delivery device such that rotation of the first handle rotates the removable driver and thereby the first anchor; and configuring the delivery device such that the removable driver is configured to be disengaged from the first handle and the first anchor while the flexible segment remains coupled to the second handle and the first anchor.

15. The method of claim 14, wherein coupling the proximal end of the flexible segment to the second handle comprises attaching the proximal end to one or more extensions disposed on the delivery device.

16. The method of claim 15, wherein adjusting the tension in the flexible segment is conducted by moving the one or more extensions proximally along a length of the delivery device.

17. The method of claim 14, wherein the removeable driver is configured to be disengaged from the first handle by moving a slider along a length of the removeable driver.

18. The method of claim 14, wherein the third handle comprises an internal shaft, and wherein rotation of the third handle rotates the internal shaft to couple the locking component to the flexible segment and the second anchor.