US 20160000554A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2016/0000554 A1

(43) Pub. Date: Jan. 7, 2016

Woo et al.

(54) **APPARATUS AND METHOD FOR REGENERATION OF LIGAMENTS AND TENDONS**

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(21) Appl. No.: **14/772,670**

(22) PCT Filed: **Mar. 6, 2014**

(86) PCT No.: **PCT/US2014/021377**

§ 371 (c)(1),
(2) Date: **Sep. 3, 2015**

Related U.S. Application Data

(60) Provisional application No. 61/773,435, filed on Mar. 6, 2013.

Publication Classification

(51) **Int. Cl.**

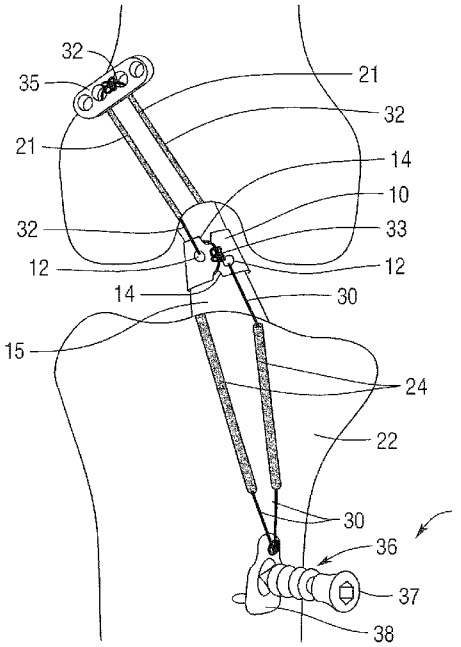
A61F 2/08	(2006.01)
A61B 17/11	(2006.01)
A61B 17/04	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/0811*** (2013.01); ***A61B 17/0401*** (2013.01); ***A61B 17/1146*** (2013.01); *A61F 2002/0882* (2013.01); *A61F 2002/0847* (2013.01); *A61F 2002/0817* (2013.01); *A61F 2210/0004* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2230/0067* (2013.01); *A61F 2230/0069* (2013.01); *A61B 2017/0414* (2013.01); *A61B 2017/0464* (2013.01); *A61B 2017/00004* (2013.01)

(57) **ABSTRACT**

A method for repairing a ligament or tendon, the method comprising: passing one or more sutures through and/or around each respective end of a completely or partially torn ligament or tendon; placing a generally cylindrical hollow body or ring over the respective ends of the completely or partially torn ligament or tendon; passing the one or more sutures through the generally cylindrical hollow body or ring; and tying the one or more sutures around or through the generally cylindrical hollow body or ring wherein the sutures are secured in place around or through the generally cylindrical hollow body or ring via one or more notches or holes defined by the generally cylindrical hollow body or ring. The method may further comprise tensioning the one or more sutures while tying them around or through the generally cylindrical hollow body or ring so that the respective ends of the completely or partially torn ligament or tendon are brought into and stay in contact with each other inside the generally cylindrical hollow body or ring after the tying is complete. The generally cylindrical hollow body or ring preferably is biodegradable and may be coated with an ECM.



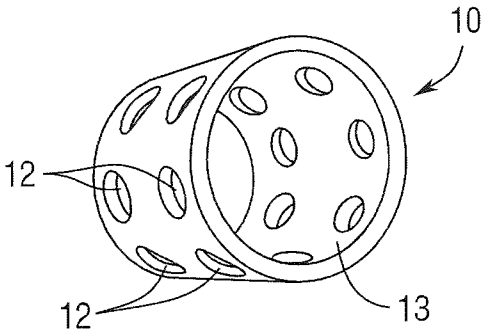


Fig.1

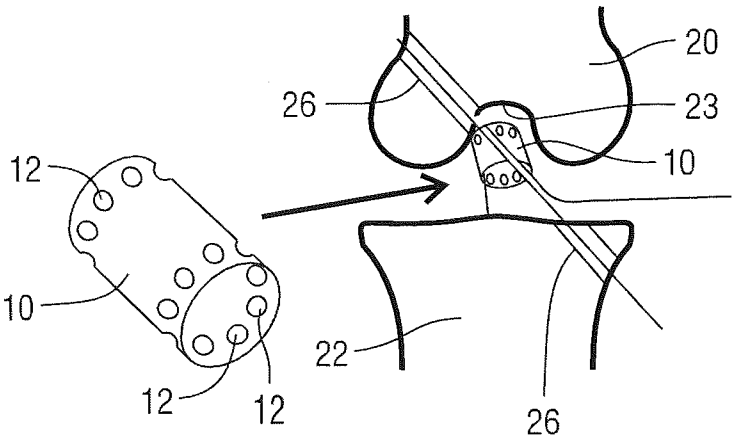


Fig.2

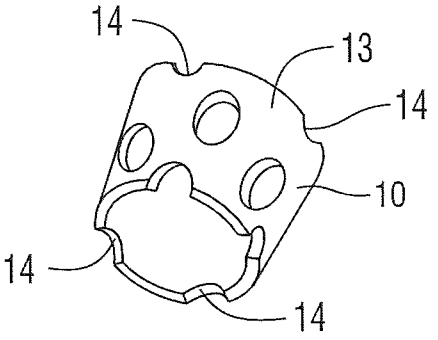


Fig.3

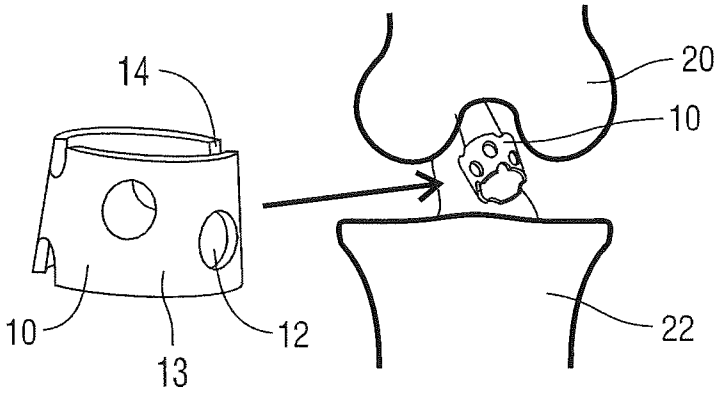


Fig.4

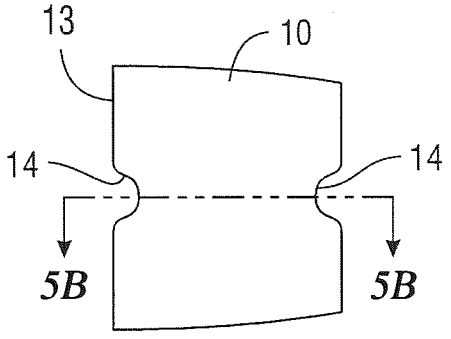


Fig.5A

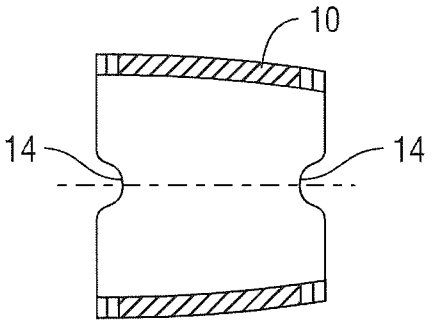


Fig.5B

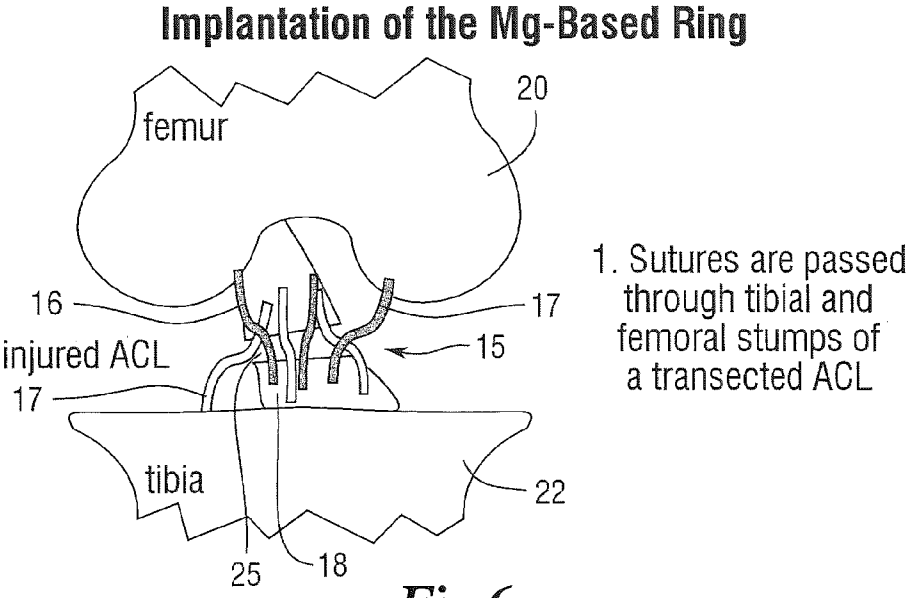

Implantation of the Mg-Based Ring
femur
20
16
17
injured ACL
15
17
tibia
22
25
18
1. Sutures are passed through tibial and femoral stumps of a transected ACL

Fig.6

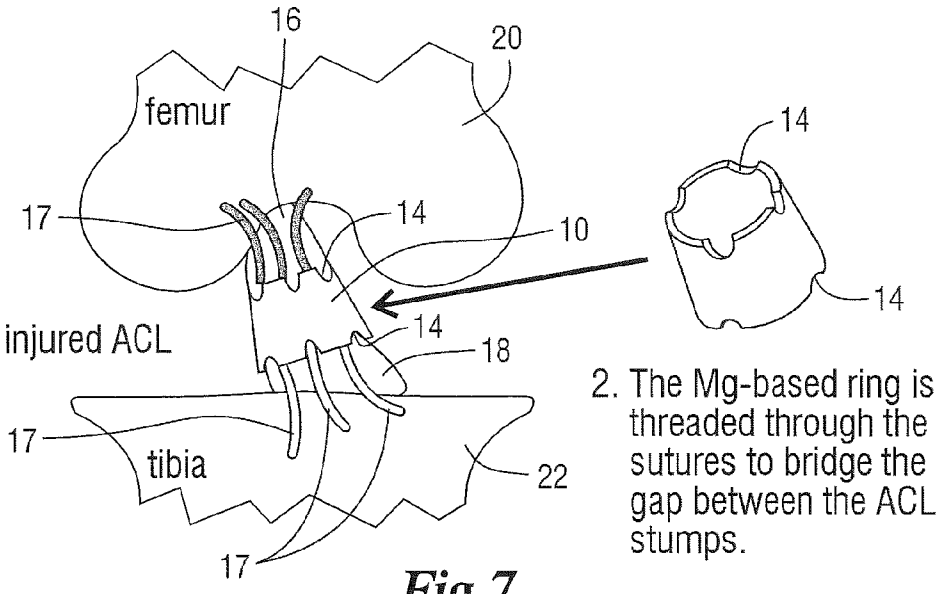

16
femur
20
14
17
14
10
14
injured ACL
14
18
17
tibia
22
17
2. The Mg-based ring is threaded through the sutures to bridge the gap between the ACL stumps.

Fig.7

3. The sutures are tied around the ring, secured in place by 4 equally-spaced notches around the circumference of the top and bottom.

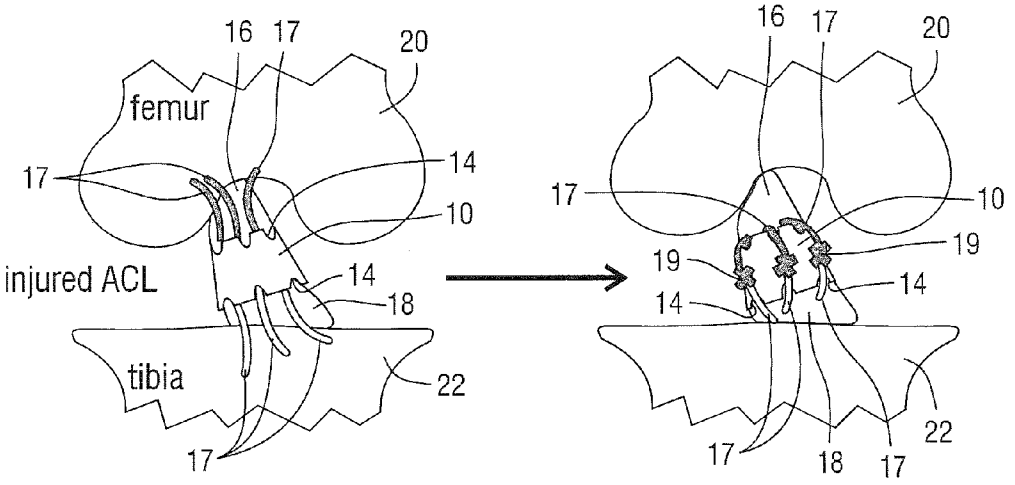


Fig.8A *Fig.8B*

4. By applying tension to the sutures while tying, the gap between the ACL stumps is closed as they are brought together.

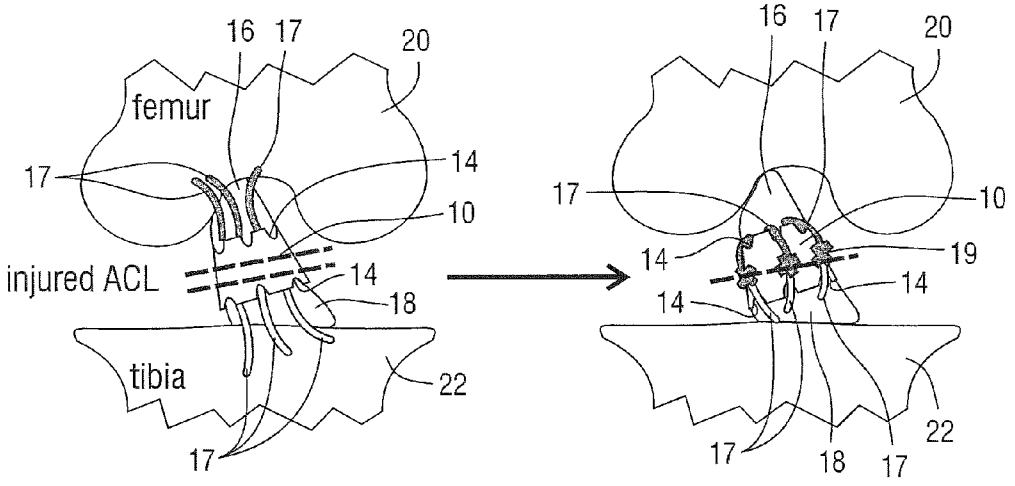


Fig.9A *Fig.9B*

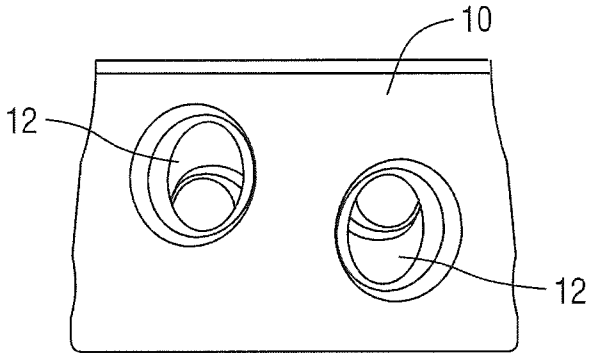


Fig.10A

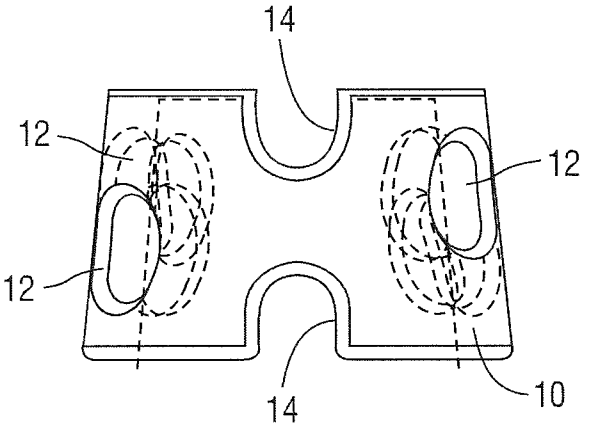


Fig.10B

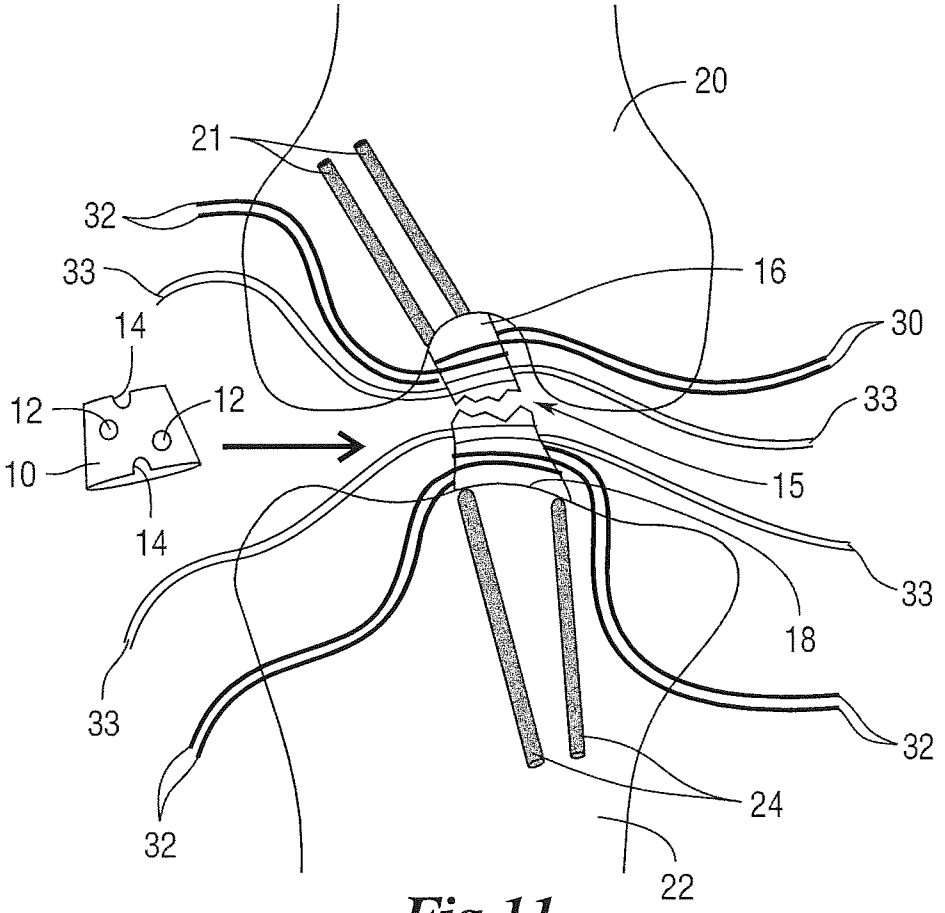


Fig.11

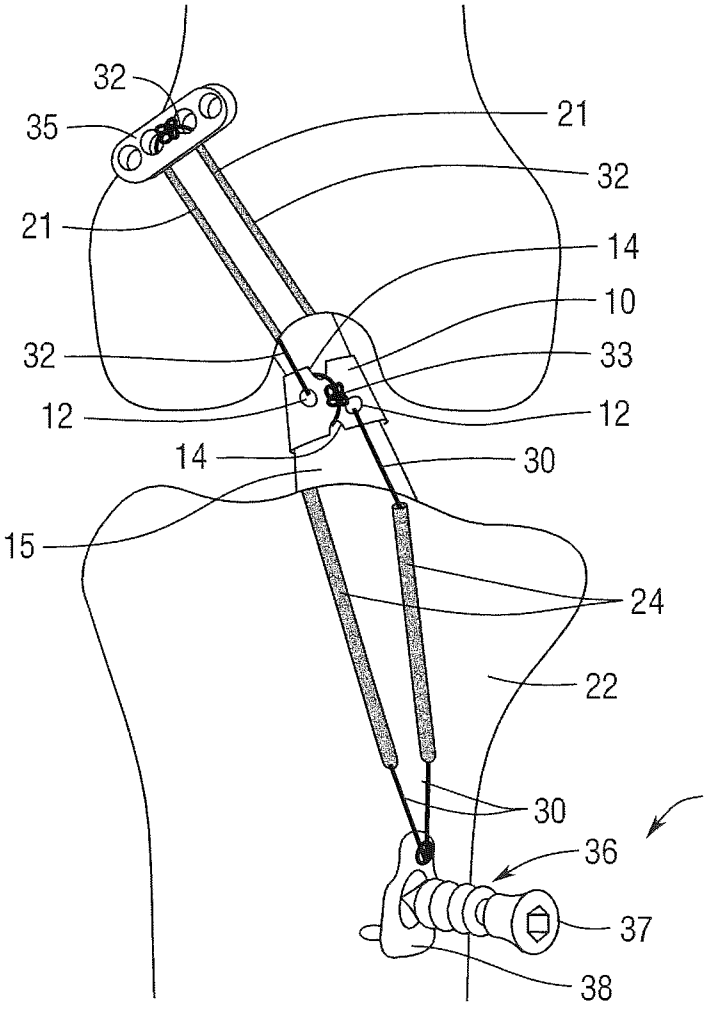


Fig.12

APPARATUS AND METHOD FOR REGENERATION OF LIGAMENTS AND TENDONS

RELATED APPLICATIONS

[0001] This application claims priority benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 61/773,435, filed Mar. 6, 2013, entitled Metallic and Extracellular Matrix Bioscaffolds for Regeneration of the Anterior Cruciate Ligament, the contents of which are herein incorporated by reference.

GOVERNMENTAL RIGHTS

[0002] This invention was made with government support under Grant Number 0812348 awarded by the United States National Science Foundation. The government has certain rights in the invention.

FIELD

[0003] The present disclosure relates to devices, systems and methods for repair of ligaments and tendons such as the anterior cruciate ligament (ACL).

BACKGROUND INFORMATION

[0004] The ACL is the most frequently injured knee ligament with tears occurring in well over 200,000 people in the U.S. each year. Midsubstance ACL ruptures have a limited capacity for healing, so ACL reconstruction using soft tissue autografts has become the clinical gold standard of treatment. However, though this treatment relieves pain and can help maintain knee stability in the short-term, long-term follow-up studies (10+ years) of these patients showed up to 25% unsatisfactory results, including osteoarthritis, residual pain, and donor site morbidity.

[0005] These complications have led to alternative clinical and experimental approaches to heal the ACL. A successfully regenerated ACL would have many advantages over surgical reconstruction as its complex anatomical features can be preserved, while complications, including graft donor site morbidity and procedural complexity, could be reduced or eliminated.

[0006] Laboratory research has shown that healing of partial ACL tears can be stimulated in animal models through the use of scaffolds and/or growth factors, e.g. bFGF, hyaluronic acid, bone marrow-derived mesenchymal stem cells, and platelet-rich plasma. However, all treated ACLs remained quite abnormal in terms of their morphology and biomechanical properties.

[0007] A bioscaffold small intestinal submucosa (SIS) and an Extracellular Matrix (ECM) sheet in combination with its 3-D hydrogel form was used to promote ACL healing following suture repair in a goat model. To reduce joint instability, a bone-to-bone fixation method (suture augmentation) was used to restore initial joint stability. Both SIS treatment and augmentation techniques showed improvements in healing over suture repair alone, but structural properties of the femur-ACL-tibia complex and joint stability remained inferior to the normal ACL. Preferably, healing would be improved by partial loading of the ACL at time zero to avoid disuse atrophy and degradation of the insertion sites.

[0008] Thus, there remains a considerable need for an apparatus and method for repairing a ligament or tendon, such as the ACL, that allows for partial loading of the ligament or tendon at time zero to avoid disuse atrophy and degradation of the insertion sites to produce a regenerated ligament or tendon that functions virtually as well as the normal ligament or tendon.

SUMMARY OF THE DISCLOSURE

[0009] In a preferred aspect, the present disclosure is directed to a method for repairing a ligament or tendon, the method comprising: passing one or more sutures through and/or around each respective end of a completely or partially torn ligament or tendon; placing a generally cylindrical hollow body or ring over the respective ends of the completely or partially torn ligament or tendon; passing the one or more sutures through the generally cylindrical hollow body or ring; and tying the one or more sutures around or through the generally cylindrical hollow body or ring wherein the sutures are secured in place around or through the generally cylindrical hollow body or ring via one or more notches or holes defined by the generally cylindrical hollow body or ring.

[0010] In another preferred aspect, the method may further comprise tensioning the one or more sutures while tying them around or through the generally cylindrical hollow body or ring.

[0011] In a further preferred aspect, the method may further comprise tensioning the one or more sutures while tying them around or through the generally cylindrical hollow body or ring so that the respective ends of the completely or partially torn ligament or tendon are brought into and stay in contact with each other inside the generally cylindrical hollow body or ring after the tying is complete.

[0012] In another preferred aspect, the method may further comprise applying an ECM to the generally cylindrical hollow body or ring.

[0013] In a further preferred aspect, the generally cylindrical hollow body or ring may comprise a biodegradable material.

[0014] In another preferred aspect, the generally cylindrical hollow body or ring may comprise a biodegradable material having an in-situ degradation rate consistent with a healing time of the ligament or tendon.

[0015] In a further preferred aspect, the generally cylindrical hollow body or ring may comprise magnesium or a magnesium alloy.

[0016] In another preferred aspect, the completely or partially torn ligament may comprise an ACL.

[0017] In an additional preferred aspect, the method may further comprise providing suture augmentation to a joint which the ACL is a part of by passing one or more sutures through each of tibial and femoral bone tunnels disposed adjacent to the joint and securing the sutures to the joint under tension.

[0018] In another preferred aspect, the generally cylindrical hollow body or ring may have a first end diameter smaller than a second end diameter and is tapered therebetween.

[0019] In another preferred aspect, the present disclosure is directed to an implant device for use in surgically repairing a ligament or tendon, comprising: a generally cylindrical hollow body, wherein the generally cylindrical hollow body defines a plurality of holes and/or notches for tensioning or tying sutures around or through the generally cylindrical hollow body. Such implant device may further comprise an ECM.

[0020] In another preferred aspect, the generally cylindrical hollow body of the implant device may comprise a biodegradable material.

[0021] In a further preferred aspect, the generally cylindrical hollow body of the implant device may comprise a biodegradable material having an in-situ degradation rate consistent with a healing time of the ligament or tendon.

[0022] In another preferred aspect, the generally cylindrical hollow body of the implant device may comprise magnesium or a magnesium alloy.

[0023] In a further preferred aspect, the generally cylindrical hollow body of the implant device may have a first end diameter smaller than a second end diameter and is tapered therebetween.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] For the present disclosure to be easily understood and readily practiced, the disclosure will now be described, for the purposes of illustration and not limitation, in conjunction with the following figures, wherein:

[0025] FIG. **1** is a perspective view of a preferred embodiment of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure;

[0026] FIG. **2** is a perspective view of another preferred embodiment of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure;

[0027] FIG. **3** is a perspective view of yet a further preferred embodiment of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure;

[0028] FIG. **4** is a perspective view of another preferred embodiment of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure;

[0029] FIG. **5** is a perspective view of yet a further preferred embodiment of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure;

[0030] FIGS. **6-9** are schematic views of a preferred method for repairing a ligament or tendon such as an ACL according to the present disclosure;

[0031] FIGS. **10**A-**10**B show additional side plan views of the preferred embodiment shown in FIG. **4** of an implantable cylinder or ring for use in accordance with a preferred method for repairing a ligament or tendon according to the present disclosure; and

[0032] FIGS. **11-12** are schematic views of another preferred method for repairing a ligament or tendon such as an ACL according to the present disclosure.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0033] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about", even if the term does not expressly appear. Also, any numerical range recited herein is intended to include all sub-ranges subsumed therein.

[0034] Despite its low healing capacity, it has recently been shown that ACL healing can be stimulated by biological augmentation. An ECM bioscaffold with suture repair according to preferred embodiments and methods of the present disclosure preferably can promote healing of an injured ACL or other ligament or tendon.

[0035] Because the process of ACL healing is slow, mechanical augmentation is desirable to restore initial joint stability and allow immediate loading of the joint at time zero to prevent disuse atrophy and degradation of the insertion sites due to a lack of stress. Preferably, a magnesium (Mg)-based ring **10** and suture implantation technique can be used for mechanical augmentation of an injured ACL or other ligament or tendon to promote better healing and improved results.

[0036] The present disclosure is directed to using a biodegradable metallic device **10** to partially load the ACL at time zero or other ligament or tendon.

[0037] Preferably, the Mg-based ring **10** will bridge the gap **25** between the two torn ends **16** and **18** of a completely or partially ruptured ACL **15**. In addition, a preferred suture augmentation technique is employed to restore joint stability while allowing some loading of the healing ligament at time zero to prevent disuse atrophy of the insertion sites.

[0038] In a first preferred embodiment shown in FIGS. **1** and **2**, generally cylindrical hollow body or ring **10** defines one or more suture holes **12** for sutures **17** to pass through in accordance with preferred aspects of the present disclosure. Preferably, suture holes **12** are disposed around the upper and lower circumference as shown. Also, the ring **10** may preferably define a flared tibial end **13**. Ring **10** preferably may come in various sizes produced to reflect interspecimen variation and is made of commercial alloy AZ31 which may be specifically designed to have an in-situ degradation rate consistent with ACL healing.

[0039] In a second preferred embodiment shown in FIGS. **3** and **5**, ring **10** is generally cylindrically shaped and defines one or more suture notches **14** to allow sutures **17** from femoral and tibial stumps **16** and **18**, respectively, to be tied around and traverse the length of ring **10** in accordance with preferred aspects of the present disclosure. Preferably, suture notches **14** are disposed around the upper and lower circumference as shown. Also, the ring **10** may preferably define a flared tibial end **13**. Ring **10** of this preferred embodiment may come in various sizes produced to reflect interspecimen variation and is made of commercial alloy AZ31 which may be specifically designed to have an in-situ degradation rate consistent with ACL healing.

[0040] In a third preferred embodiment shown in FIGS. **4** and **10**A-**10**B, ring **10** is generally cylindrically shaped and defines one or more suture holes **12** and suture notches **14** to allow sutures **17** from femoral and tibial stumps **16** and **18**, respectively, to be tied through and/or around ring **10** and traverse the length of ring **10** in accordance with preferred aspects of the present disclosure. Preferably, suture notches **14** are disposed around the upper and lower circumference, while suture holes **12** are disposed intermediate thereto as shown. As shown in FIG. **10**B, alternate placements of suture holes **12***a* (shown in dashed lines) preferably may be used depending upon the application. Also, the ring **10** may preferably define a flared tibial end **13**. Ring or cylinder **10** of this preferred embodiment may come in various sizes produced to reflect interspecimen variation and is preferably may be made of magnesium or a commercial alloy AZ31 or a single crystal Mg material either of which preferably may be specifically designed to have an in-situ degradation rate consistent with ACL healing. Ring **10** preferably may also be hinged on one

longitudinal side and have a clasping or other closure mechanism on an opposite side to accommodate placing the ring over a partially torn ligament or tendon such as an ACL.

[0041] Ring **10** preferably has a slightly larger diameter on one end (tibial end **13**) and has a geometry and dimensions chosen based on the geometry of the ligament or tendon to be repaired. Along both the top and bottom edges of the ring **10**, notches **14** are present in order to hold sutures **17** in place as they are tied from the ligament ends around the Mg-based ring **10** and tied under tension.

[0042] Preferably, the surface of the Mg-based alloy ring **10** and/or the ligament or tendon **15** could also be treated with an ECM with or without its 3-D hydrogel form, such as an SIS or a urinary bladder matrix (UBM) applied as a coating or sheet wrapper, to accelerate healing of the ligament or tendon **15**. In addition, the hydrogel preferably may be injected into the ligament or tendon **15** instead of being used in a sheet wrapper form. Thus, the system of the present disclosure can serve as a smart, biodegradable complex, capable of integrating with healing tissues and enabling regeneration while the porous metallic scaffold or ring **10** degrades.

[0043] Though rings **10** and the preferred methods of the present disclosure maybe used for ACL repair, the application thereof could also be used to bridge the gap **25** between the torn ends of other ligaments and/or tendons for improved healing. The rings **10** and the preferred methods of the present disclosure can provide structural support and limit hypertrophy of healing tissue, leading to better tissue quality in such other ligaments or tendons, where again ring **10** may preferably be used as a scaffold for biological augmentation to accelerate tissue healing, such as in combination with an SIS.

[0044] Preferably, ligament repair using Mg-based implant **10** of the present disclosure will be able to restore initial anterior-posterior joint stability and in-situ force in the ACL **15** or other ligament close to normal and better than previously-used suture repair techniques.

[0045] Testing has shown that use of the ring **10** and methods of the present disclosure has restored Anterior Tibial Translation (ATT) to within 2-8 mm of an intact joint which represents a reduction of ATT of 50% compared to traditional suture repair.

[0046] Testing has also shown that In-situ force in the ACL repaired in accordance with the present disclosure is close to normal. Increased in-situ forces can be handled in the ACL with the Mg-based ring compared to suture repair. Also, repairs made according to the present disclosure provide better anterior-posterior joint stability and in-situ force resistance than in ACLs repaired by traditional suturing.

[0047] Ring **10** preferably provides mechanical support to ACL by transmitting load between torn ACL stumps **16** and **18** (reduce stress-shielding) for 12-18 weeks. Ring **10** preferably degrades over such time to let the healing ACL tissue take over. Ring **10** preferably is used as "sheath" to protect injury site during healing.

[0048] As shown in FIGS. **6-9**, in a preferred repair method for a ligament or tendon of the present disclosure, sutures **17** are passed through femoral and femoral stumps, **16** and **18**, respectively of a transected ACL **15**. As shown in FIG. **6**, a preferred Mg-based ring **10** is threaded through the sutures **17** to bridge the gap **25** between the ACL stumps **16** and **18**. FIG. **7** shows that preferably, sutures **17** are tied around ring **10** and secured in place around the four equally-spaced notches **14** disposed around the circumference of the top and bottom of ring **10**. By applying tension to the sutures **17** while tying, the gap **25** between the ACL stumps **16** and **18** preferably may be closed as shown in FIG. **8**. Additionally, the surface of the ring **10** and/or the ligament or tendon **15** preferably may be treated with an ECM such as an SIS or a UBM applied as a coating or sheet wrapper, with or without the ECM's 3-D hydrogel form, to accelerate healing of the ligament or tendon **15**. In addition, the hydrogel preferably may be injected into the ligament or tendon **15** instead of being used in a sheet wrapper form. This preferred repair method of the present disclosure using ring **10** with ECM bioscaffolds, hydrogel and/or a preferred suture augmentation technique as shown in FIGS. **6-9** provides for synergistic effects on the healing of ACL **15** or other ligaments or tendons. As shown in FIG. **2**, additional suture augmentation preferably may also be employed comprising passing two sutures **23** through tibial and femoral bone tunnels **26** drilled adjacent to the insertion sites and fixing them under manual tension with a titanium button (not shown).

[0049] As shown in FIGS. **11-12**, in another preferred repair method for a ligament or tendon of the present disclosure, repair sutures **33** and fixation sutures **30**, **32** are attached to each respective end of the transected ACL **15**. Ring **10** is then threaded onto ACL **15** and repair sutures **33** are tied around notches **14** of ring **10**. By applying tension to repair sutures **33** while tying them around notches **14** of ring **10**, the gap **25** between the ACL stumps **16** and **18** preferably may be closed such that stumps **16** and **18** contact each other within ring **10**.

[0050] Preferably, fixation sutures **32** passing through femoral bone tunnels **21** are passed first through and/or around the tibial stump **18**, then through the inside of ring **10**, then out of ring **10** through holes **12** before going through bone tunnels **21** and being secured to endobutton **35** on femur **20**. Fixation sutures **30** passing through tibial bone tunnels **24** are preferably passed first through and/or around femoral stump **16**, then through the inside of ring **10**, then out of ring **10** through holes **12** before going through bone tunnels **24** and being secured to tibia **22** with a fixation post **37** and double-spiked plate **38**.

[0051] Additionally, as part of the preferred method shown in FIGS. **11-12**, the surface of ring **10** and/or the ligament or tendon **15** preferably may be treated with an ECM such as an SIS or a UBM applied as a coating or sheet wrapper, with or without the ECM's 3-D hydrogel form, to accelerate healing of the ligament or tendon **15**. In addition, the hydrogel preferably may be injected into the ligament or tendon **15** instead of being used in a sheet wrapper form. This preferred repair technique of the present disclosure using ring **10** with ECM bioscaffolds, hydrogel and/or a preferred suture augmentation comprising repair sutures **33** and fixation sutures **30**, **32** as shown in FIGS. **11-12** provides for synergistic effects on the healing of ACL **15** or other ligaments or tendons.

[0052] While the present disclosure has been described in detail and with reference to specific embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope of the embodiments. Thus, it is intended that the present disclosure cover any such modifications and/or variations provided they come within the scope of the appended claims and their equivalents.

What is claimed is:

1. A method for repairing a ligament or tendon, the method comprising:

passing one or more sutures through and/or around each respective end of a completely or partially torn ligament or tendon;

placing a generally cylindrical hollow body or ring over the respective ends of the completely or partially torn ligament or tendon;

passing the one or more sutures through the generally cylindrical hollow body or ring; and

tying the one or more sutures around or through the generally cylindrical hollow body or ring wherein the sutures are secured in place around or through the generally cylindrical hollow body or ring via one or more notches or holes defined by the generally cylindrical hollow body or ring.

2. The method of claim **1** further comprising tensioning the one or more sutures while tying them around or through the generally cylindrical hollow body or ring.

3. The method of claim **1** further comprising tensioning the one or more sutures while tying them around or through the generally cylindrical hollow body or ring so that the respective ends of the completely or partially torn ligament or tendon are brought into and stay in contact with each other inside the generally cylindrical hollow body or ring after the tying is complete.

4. The method of claim **1** further comprising applying an ECM to the generally cylindrical hollow body or ring.

5. The method of claim **1** wherein the generally cylindrical hollow body or ring comprises a biodegradable material.

6. The method of claim **1** wherein the generally cylindrical hollow body or ring comprises a biodegradable material having an in-situ degradation rate consistent with a healing time of the ligament or tendon.

7. The method of claim **1** wherein the generally cylindrical hollow body or ring comprises magnesium or a magnesium alloy.

8. The method of claim **1** wherein the completely or partially torn ligament comprises an ACL.

9. The method of claim **8** further comprising providing suture augmentation to a joint which the ACL is a part of by passing one or more sutures through each of tibial and femoral bone tunnels disposed adjacent to the joint and securing the sutures to the joint under tension.

10. The method of claim **1** wherein the generally cylindrical hollow body or ring has a first end diameter smaller than a second end diameter and is tapered therebetween.

11. An implant device for use in surgically repairing a ligament or tendon, comprising: a generally cylindrical hollow body, wherein the generally cylindrical hollow body defines a plurality of holes and/or notches for tensioning or tying sutures around or through the generally cylindrical hollow body.

12. The implant device of claim **11** further comprising an ECM.

13. The implant device of claim **11** wherein the generally cylindrical hollow body comprises a biodegradable material.

14. The implant device of claim **11** wherein the generally cylindrical hollow body comprises a biodegradable material having an in-situ degradation rate consistent with a healing time of the ligament or tendon.

15. The implant device of claim **11** wherein the generally cylindrical hollow body comprises magnesium or a magnesium alloy.

16. The implant device of claim **11** wherein the generally cylindrical hollow body has a first end diameter smaller than a second end diameter and is tapered therebetween.

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