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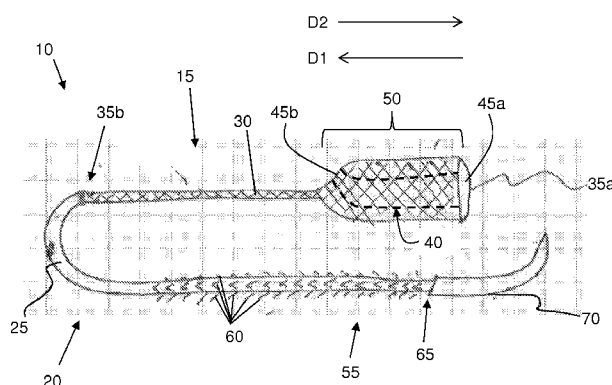
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(54) Title: COLLAPSIBLE LOCKING SUTURE

**FIG. 1**

(57) **Abstract:** A device including a self-locking suture including both a braided section and a monofilament section is provided. The monofilament includes a single strand. The braided section includes three or more strands that are intertwined or woven together. The terminal end of the braid is compressible to take on a radially expanded configuration. The braided structure is temporarily fixable in the open configuration providing a wide berth opening. A needle at the terminal end of the monofilament is insertable through the wide berth opening and pushed out through the back wall of the expanded braid, after which the braid can be pulled on to collapse it down onto the barbed monofilament. The construct may then be tightened onto the tissues to be joined, and the one-way locking mechanism between the braided trap and the directionally biased suture automatically engages. Another aspect includes a method of fastening tissue using the device.

COLLAPSIBLE LOCKING SUTURE

CROSS REFERENCE

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/774,867, filed March 8, 2013, the contents of which are incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] The invention generally relates to medical devices, and more particularly to sutures and associated methods of manufacture and use.

BACKGROUND

[0003] Surgical suture is commonly used to join various tissues to each other. Suture commonly consists of a needle attached to a length of thread. The suture is passed through the tissues to be joined and a knot is typically tied to secure the final construct.

[0004] The ability to use a self-locking knotless suture may provide a number of advantages over conventional sutures. A knotless suture may provide the security of a knot while eliminating the bulk of a knot. Additionally, the ease of the procedure does not require the surgeon to learn new techniques. Further, the elimination of knot tying may increase the speed of the procedure potentially decreasing the time the patient is under anesthesia.

SUMMARY

[0005] In a first aspect of the invention, there is a device comprising a self-locking suture comprising both a braided section and a monofilament section. The monofilament comprises a single strand of a material. The braided section comprises three or more strands of material that are intertwined or woven together. The terminal end of the braid may be compressed such that it takes on a radially expanded configuration. The braided structure may be temporarily fixed in the open configuration that provides a wide berth opening. A needle at the terminal end of the monofilament may be inserted through the wide berth opening and pushed out through the back wall of the expanded braid. Once the needle is passed through the open braid, the braid can be pulled on to collapse it down onto the barbed monofilament. The construct may then be tightened onto the tissues to be joined, and the one-way locking

mechanism between the braided trap and the directionally biased suture should automatically engage. Another aspect of the invention includes a method of fastening tissue using the device comprising the self-locking suture comprising both the braided section and the monofilament section.

[0006] In a another aspect of the invention, there is a method comprising: passing the needle of the device through the two sections of tissue to be joined together; introducing the tip of the needle into the temporarily fixed open braided trap section; and pushing the needle out through the back wall of the trap section, and feed the remaining portion of the needle through the trap. At this point the terminal end of the braided trap can be pulled on in order to lengthen and collapse the braided trap section down onto the monofilament. The method also comprises, with a counterforce being placed on the braided trap section, pulling on the needle end of the monofilament to tighten the suture loop onto the tissues. The one-way locking mechanism will automatically engage, thus no additional locking steps are required. The method further comprises cutting the free end of the monofilament near the point it exits the braided trap.

[0007] Implementations of the invention as described herein may be applicable in a manner similar to a suture, where various tissues may need to be joined together.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0008] The present invention is described in the detailed description which follows, in reference to the noted plurality of drawings by way of non-limiting examples of exemplary embodiments of the present invention.

[0009] FIGS. 1, 2, 3a, 3b, and 4 show aspects of a collapsible locking suture and method of use in accordance with aspects of the invention.

DETAILED DESCRIPTION

[0010] The particulars shown herein are by way of example and for purposes of illustrative discussion of the embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the present invention. In this regard, no attempt is made to show structural details of the present invention in more detail than is necessary for the

fundamental understanding of the present invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the present invention may be embodied in practice.

[0011] FIG. 1 depicts a combination, self-locking suture 10. In embodiments, the self-locking suture 10 consists of both a braided section 15 and a monofilament section 20. In embodiments, the monofilament section 20 consists of a single strand of a material 25, while the braided section 15 consists of three or more strands of material 30 that are intertwined or woven together, e.g., in a helically wound braid. The braided material 30 may form a sheath of material strands with a hollow core. The braided material 30 and monofilament material 25 may or may not be the same material. Materials for the braided material 30 and monofilament material 25 may include but not limited to: non-resorbable polymers such as polyethylene, polyester, polypropylene or nylon; resorbable polymers such as polyglycolic acid, polylactic acid, or polydioxanone; biological materials such as catgut or silk; metals and any combination thereof.

[0012] The braided section 15 may be configured such that it can convert between two different states. The braided section 15 may change to a “collapsed” configuration as the ends 35a, 35b of the helically wound braid are pulled apart. This occurs as part of the normal behavior of a helically wound braid whereby the length of the helically wound braid increases as the diameter decreases when the ends are pulled. This occurs as the angles between the adjacent strands decreases at the crossing points, while simultaneously reducing the radial distance across the walls of the helically wound braid. The braided section 15 may also change to an “open” configuration as the two ends 35a, 35b of the helically wound braid are pushed towards each other, causing the length of the helically wound braid to decrease and the diameter to increase.

[0013] The terminal end 35a of the braided section 15 may have a passageway (e.g., tunnel) 40 created in it. The tunnel 40 begins at a first opening 45a in the hollow core at the end 35a of the braided section 15, and ends at a second opening 45b some distance from the first opening 45a and through the wall of the braided section 15. The first opening 45a may be created by fixing a portion of the braided section 15 in the “open” configuration, utilizing melting, gluing, welding or other similar operations. This process may help create a smooth entry point for the monofilament section 20 into the braided section 15 while eliminating any

fraying that may occur from the ends of the fibers in the braid. The second opening 45b may be created by pushing aside the woven fibers of the braided material without cutting or disturbing the integrity of any of the fibers of the braided section 15. The second opening 45b may optionally be fixed in this “open” configuration using previously described techniques. Alternatively, the second opening 45b is not fixed in the open configuration. Between these two openings 45a, 45b is a free section 50 (also referred to as a braided trap) of the braided section 15 that can alter between the “open” and “collapsed” configurations as the braided section 15 is pushed together or pulled apart, respectively.

[0014] The free end 55 of the monofilament section 20 may have a number of directionally biased protrusions 60 (e.g., barbs) that extend axially and radially along the length of the free end 55 of the monofilament section 20. The directionally biased nature of the protrusions 60 allows for the monofilament section 20 to be inserted into the tunnel 40 of the braided section 15 in one direction D1, but engage the braided section 15 when the monofilament section 20 is pulled in the opposing direction D2. In embodiments, D1 and D2 are opposed axial directions. The tip 65 of the free end 55 of the monofilament section 20 may also be tapered or angled to facilitate the initial insertion through the tunnel of the braid. This tip 65 of the free end 55 may also have a needle 70 or other sharp tipped object that can easily penetrate tissue material.

[0015] Once the free end 55 of the monofilament section 20 has been passed through the tissue(s) to be joined, the tip 65 of the monofilament is passed through the tunnel 40 of the braided trap 50, e.g., as depicted in FIG. 2. The resultant loop is shortened by pulling the free end 55 of the monofilament section 20 thereby tightening the tissues 85a, 85b together, e.g., as depicted in FIGS. 3a, 3b, and 4. A knot pusher or other instrument may be necessary to facilitate this tightening process. Once the desired level of tension is created in the loop, the remaining free end 55 of the monofilament section 20 may be cut off near the braided trap 50, e.g., as depicted at cut 90, as shown at FIG. 4.

[0016] In embodiments, the braided section 15 includes the braided trap 50 that may be temporarily fixed in the open configuration that provides a wide berth opening 45a, as shown in FIG. 1. A needle 70 at the terminal end of the monofilament section 20 may be inserted through the wide berth opening 45a and pushed out of opening 45b through the back wall of the expanded braided trap 50. Once the needle 70 is passed through the open braided trap 50,

the braided section 15 can be pulled on (e.g., pulling end 35a in direction D2 and end 35b in direction D1) to collapse the braided trap 50 down onto the barbed monofilament 25, such that an inner surface of the braided trap 50 contacts an outer surface of the monofilament 25 at plural locations. The construct may then be tightened onto the tissues to be joined, and the one-way locking mechanism between the braided trap 50 and the directionally biased suture automatically engages.

[0017] The terminal end 35a of the braided section 15 may be compressed such that it takes on a radially expanded configuration, as shown in FIG. 1. This radially expanded configuration may be 2 times to 10 times the size (e.g., diameter) of the collapsed configuration (e.g., as shown in FIGS. 3b and 4), or more. This expansion may be accomplished by inserting a dowel pin inside the hollow core of the braided section 15. The dowel pin may have a tapered tip to facilitate insertion into the core of the braided section 15. While the braided section 15 is held in the open configuration over the dowel pin, a binding material may be placed onto the expanded braided section 15. This binding material may comprise an adhesive or more specifically an elastic adhesive (such as a latex-based material). The adhesive may provide a temporary adhesion of the braid fibers in the open configuration, but the bonds may easily be broken by pulling on the braided section 15 (e.g., when collapsing the braided trap 50 onto the monofilament 20) without damaging or disrupting the fibers of the braid. Additionally the braided section 15 can be held in the expanded position by another specific radial braid or strand woven into the open braid. This may hold the receptacle braid open or otherwise influence the shape the that braid to accept a needle or male end of the suture.

[0018] The terminal end 35a of the open braided section 15 may further be fixed with a permanent adhesive that creates a stiff ring at the end of the braided section 15. This may be beneficial in that it provides a firm location that can be pulled on to break or stretch the elastic adhesive, allowing the braided trap 50 to collapse down to the collapsed configuration. Additionally, this stiff ring may be used to push the terminal end of the braided section 15 when cinching the suture onto the tissue. A secondary instrument such as a knot pusher may also be used to push against the stiff ring and extend the trap while cinching the device.

[0019] In aspects described herein, the exit portal 45b need not be fixedly formed. Instead, as the needle 70 is inserted into the expanded braided trap 50, the needle may be pushed out

through the back end of the braided trap 50, e.g., between strands in the sidewall of the braid. This may help ease the manufacturing of the braided trap, as only an entry portal is provided.

[0020] Temporarily fixing the braid in this open configuration may help accomplish two different goals: (1) to provide a large target for insertion of the needle or free end of suture, (2) to shorten the length of the braided trap 50 to be initially threaded.

[0021] By significantly increasing the size of the expanded configuration, a larger target is created for which the needle or the terminal end of the monofilament can easily be inserted into. For instance, a Size 0 suture is approximately 0.35 mm in diameter, however, the braid may be expanded open to 2.0 mm or greater. This opening should be easily located by the tip of a typical needle used with suture, without the use of a microscope, loupe or supplemental visualization means. The large opening should not require enhanced dexterity that may be required for smaller openings.

[0022] Furthermore when the braided trap 50 is compressed into the open configuration, the overall length of the braided trap 50 is reduced. This reduced length may also increase the ease of which the needle or terminal end of the monofilament 20 can be inserted into the braided trap 50. For example, when the braided trap 50 is expanded to an open diameter of 2.0 mm, the length of the braided trap 50 may be 5 mm long; however when the braided trap 50 is collapsed down to a diameter of 0.35 mm, the length of the braided trap 50 may double or triple to 10-15 mm. The shortened length during the initial threading provides for ease of use, while the increased length may provide increased fixation strength of the construct by increasing the length of engagement of the trap to the monofilament 20.

[0023] FIGS. 2, 3a, 3b, and 4 show exemplary steps for using the collapsible locking suture 10 in accordance with aspects of the invention. Specifically, FIG. 2 depicts the needle 70 is pushed out the back wall of the braided trap 50. FIG. 3a depicts the braided trap 50 in its initial (expanded) configuration and FIG. 3b depicts the braided trap 50 in its extended (collapsed) configuration. FIG. 4 depicts the free end of the monofilament 20 is cut off to form the final construct across the adjoined tissue. In embodiments, a method of using the suture 10 includes the following steps.

[0024] 1) Pass the needle 70 through the two sections of tissue 85a, 85b to be joined together.

[0025] 2) Introduce the tip of the needle 70 into the temporarily fixed-open braided trap 50, e.g., at opening 45a.

[0026] 3) Push the needle 70 out through the back wall of the braided trap 50, e.g., at opening 45b, and feed the remaining portion of the needle 70 through the braided trap 50, as shown in Fig. 2

[0027] 4) At this point the terminal end 35a of the braided trap 50 is pulled in direction D2 in order to lengthen and collapse the braided trap 50 down onto the monofilament 20, as shown in FIGS. 3a and 4.

[0028] 5) With a counterforce being placed on the braided trap 50, pull the needle end of the monofilament 20 to tighten the suture loop onto the tissues 85a, 85b, as shown in FIG. 4. The one-way locking mechanism will automatically engage, thus no additional locking steps are required.

[0029] 6) Cut the free end of the monofilament 20 near the point it exits the braided trap 50, as shown in FIG. 4.

[0030] Alternatively, the collapsible braided trap may be provided as a separate entity from the barbed monofilament suture. A fully braided implant may be constructed with a collapsible trap arranged at each of the free ends.

[0031] Additional aspects of the invention include manufacturing the self-locking suture 10. The method of manufacturing may include: providing a suture including the braided section 15 and the monofilament section 20, and applying a binding material onto the expanded braided section 15 to temporarily retain the braided section 15 in the expanded configuration.

[0032] Even further aspects of the invention include providing instructions for using the self-locking suture 10, e.g., instructions for how to use the self-locking suture 10 in a method of attaching tissue as described herein. The instructions may be at least one of printed and video.

[0033] It is noted that the foregoing examples have been provided merely for the purpose of explanation and are in no way to be construed as limiting of the present invention. While the present invention has been described with reference to an exemplary embodiment, it is understood that the words which have been used herein are words of description and

illustration, rather than words of limitation. Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present invention in its aspects. Although the present invention has been described herein with reference to particular means, materials and embodiments, the present invention is not intended to be limited to the particulars disclosed herein; rather, the present invention extends to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.

CLAIMS

What is claimed:

1. A device, comprising:

a self-locking suture comprising both a braided section and a monofilament section,

wherein:

the monofilament section comprises a single strand of a material;

the braided section comprises three or more strands of material that are intertwined or woven together;

a terminal end of the braided section is compressible such that it takes on a radially expanded configuration;

the braided section is temporarily fixable in the expanded configuration that provides a wide berth opening;

a needle at a terminal end of the monofilament section is insertable through the wide berth opening and configured to be pushed out through a back wall of the braided section; and

the braided section is collapsible onto the monofilament section after the monofilament section has been passed through the braided section.

2. The device of claim 1, wherein the monofilament section includes protrusions.

3. The device of claim 2, wherein the protrusions are directionally biased.

4. The device of claim 3, wherein the protrusions permit the monofilament section to be inserted into a tunnel of the braided section in a first direction, and engage the braided

section when the monofilament section is pulled in a second direction opposing the first direction.

5. The device of claim 1, wherein the braided section is collapsible onto the monofilament section by pulling on the braided section.

6. The device of claim 1, further comprising a binding material that temporarily fixes the braided section in the expanded configuration.

7. The device of claim 6, wherein the binding material comprises an elastic adhesive.

8. The device of claim 1, wherein:
in the expanded configuration, the braided section has a first length and a first open diameter;
in a collapsed configuration, the braided section has a second length and a second open diameter;
the first length is less than the second length; and
the first diameter is greater than the second diameter.

9. A method, comprising:
passing a needle of a suture device through the two sections of tissue to be joined together;
introducing a tip of the needle into a temporarily fixed open braided trap of the suture device;

pushing the needle out through a back wall of the braided trap, and feeding a remaining portion of the needle through the braided trap;

pulling on a terminal end of the braided trap in order to lengthen and collapse the braided trap down onto a monofilament of the suture device;

placing a counterforce on the braided trap and pulling the monofilament to tighten a loop of the suture device; and

cutting a free end of the monofilament near a point where the monofilament exits the braided trap.

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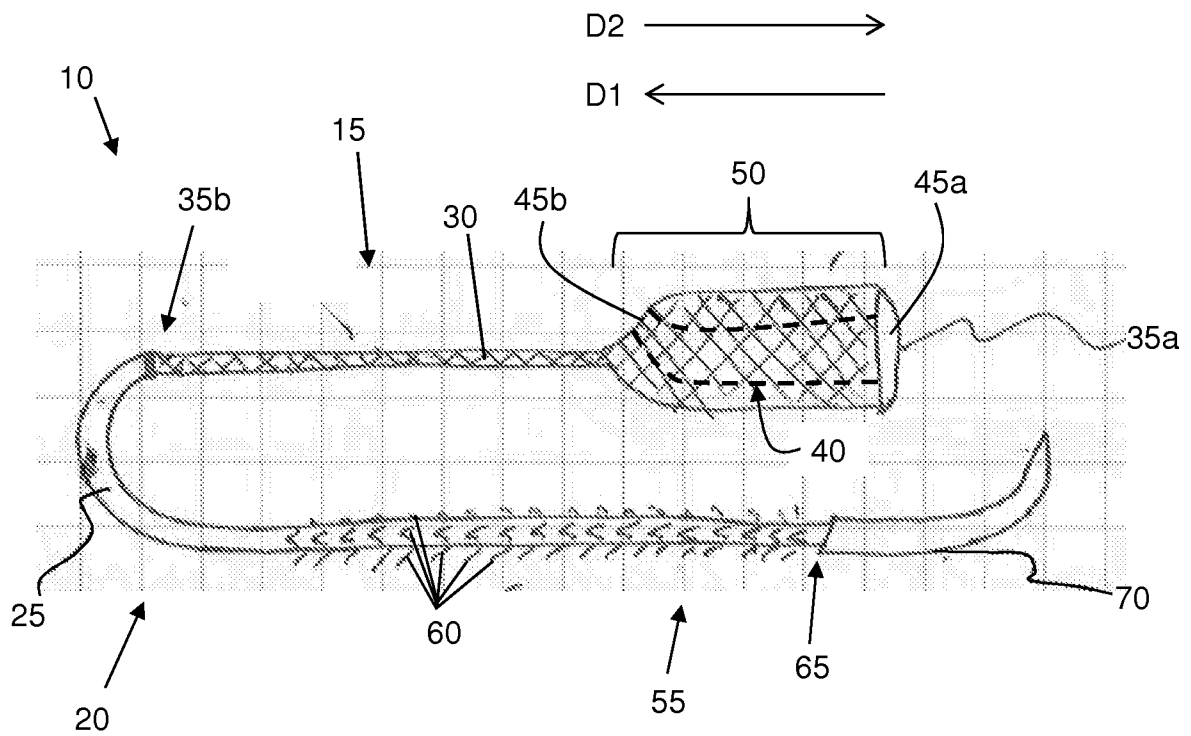


FIG. 1

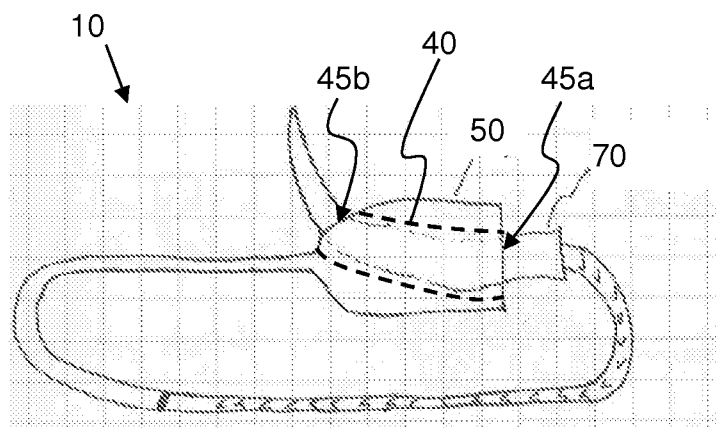


FIG. 2

FIG. 3a

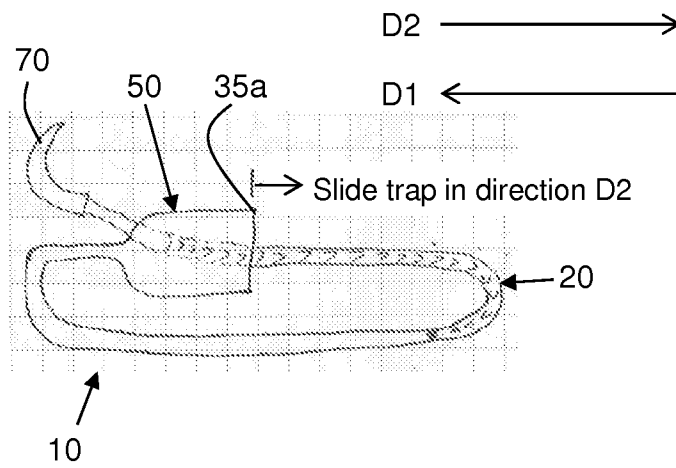


FIG. 3b

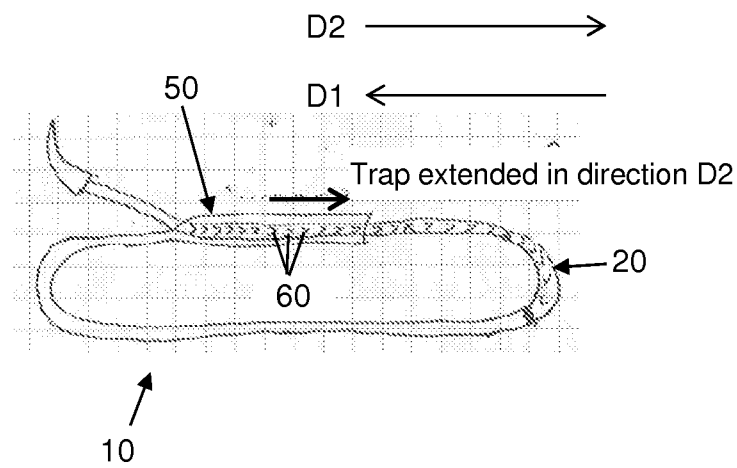


FIG. 4

