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(54) **TENDON REPAIR USING INTERNAL REINFORCING MEMBER**

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(63) Continuation of application No. 10/112,597, filed on Mar. 28, 2002, now Pat. No. 6,740,100, which is a continuation of application No. PCT/US00/35261, filed on Dec. 22, 2000.

(60) Provisional application No. 60/171,963, filed on Dec. 23, 1999.

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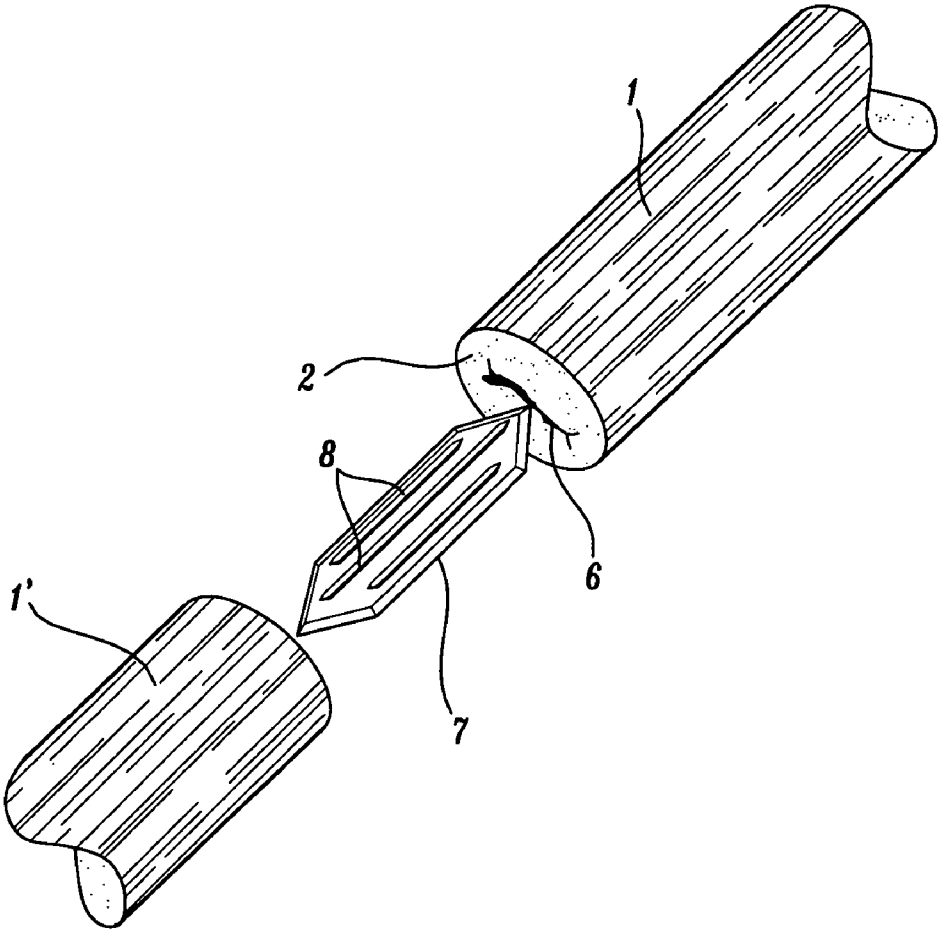
(57) **ABSTRACT**

A reinforcing member or stent (**7**) is inserted into opposite end portions (**1, 1'**) of a lacerated tendon and fixed within the tendon so that tension applied to the tendon is transmitted across the laceration by way of the reinforcing member (**7**).



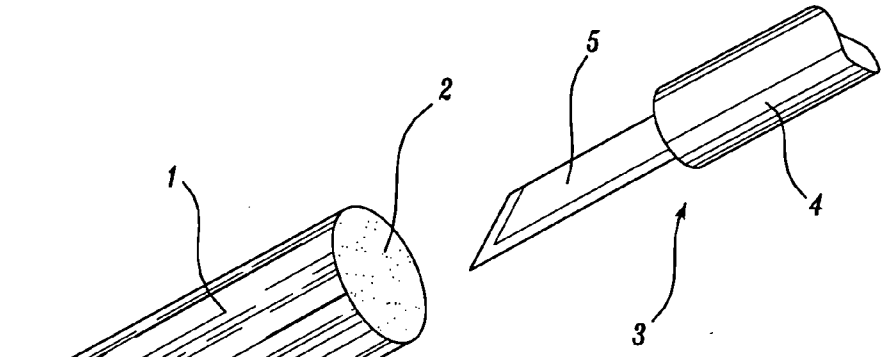


Fig. 1.

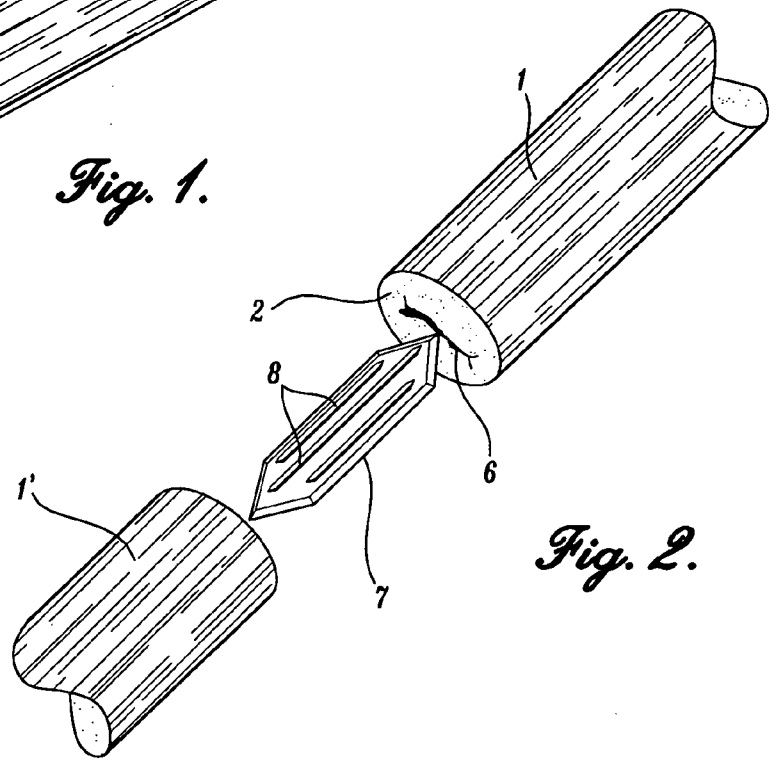
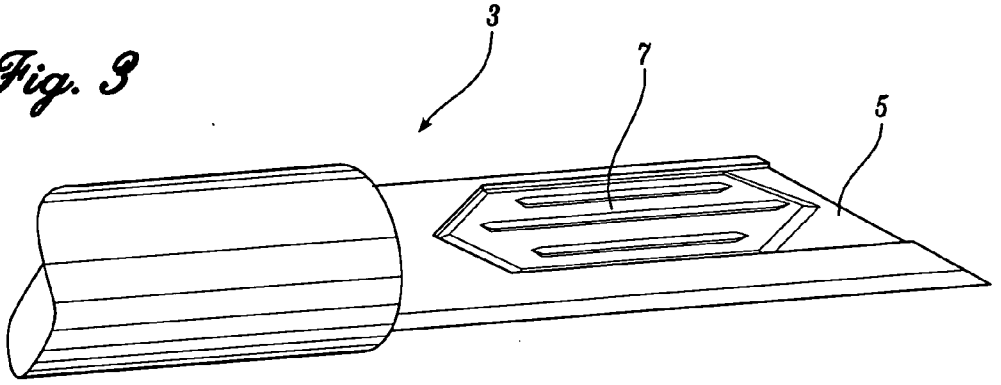


Fig. 2.

Fig. 3



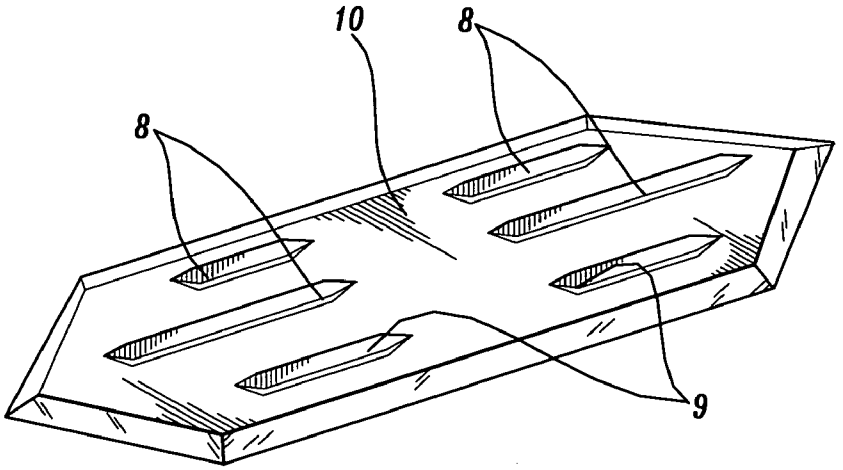


Fig. 4.

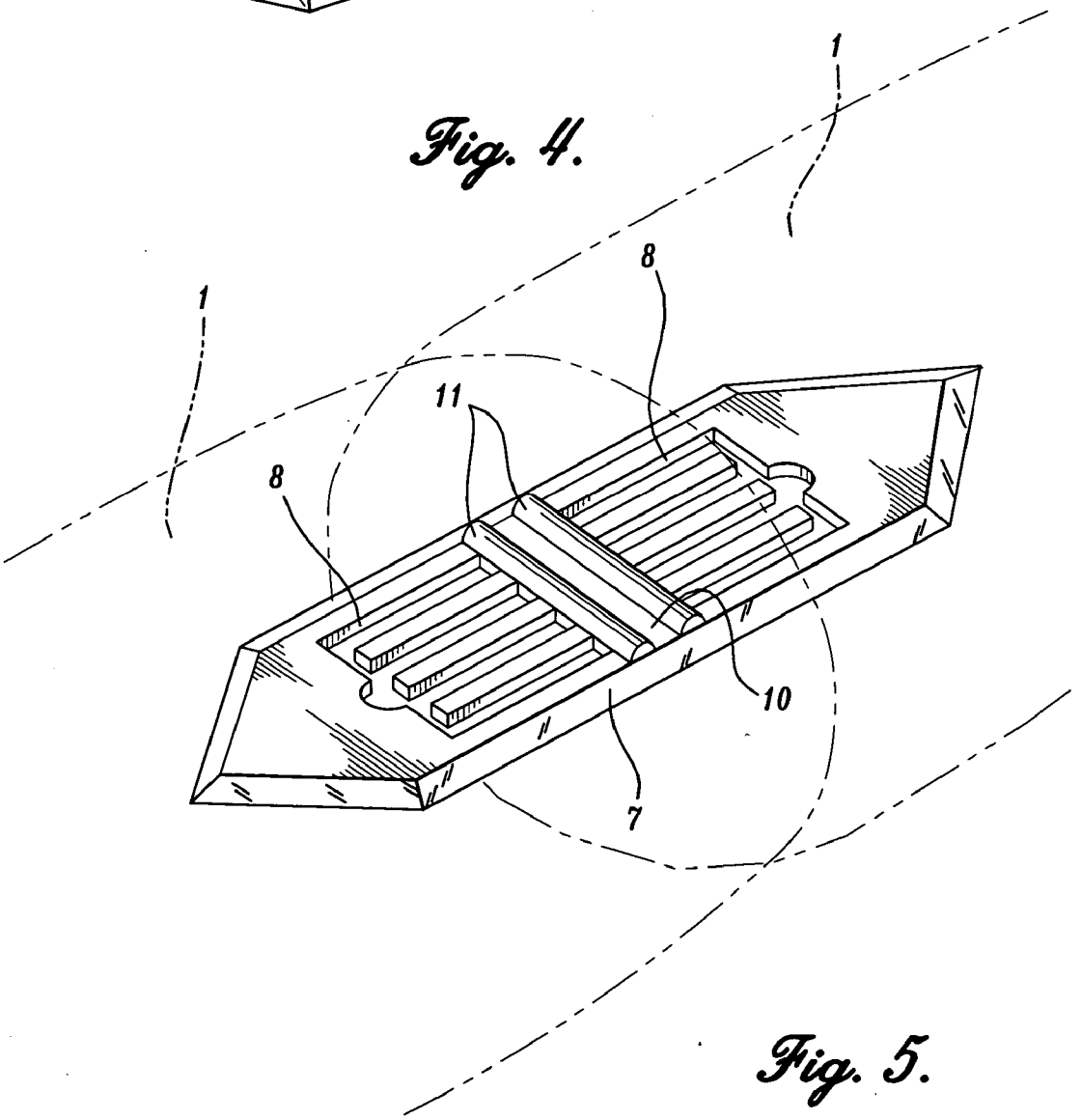


Fig. 5.

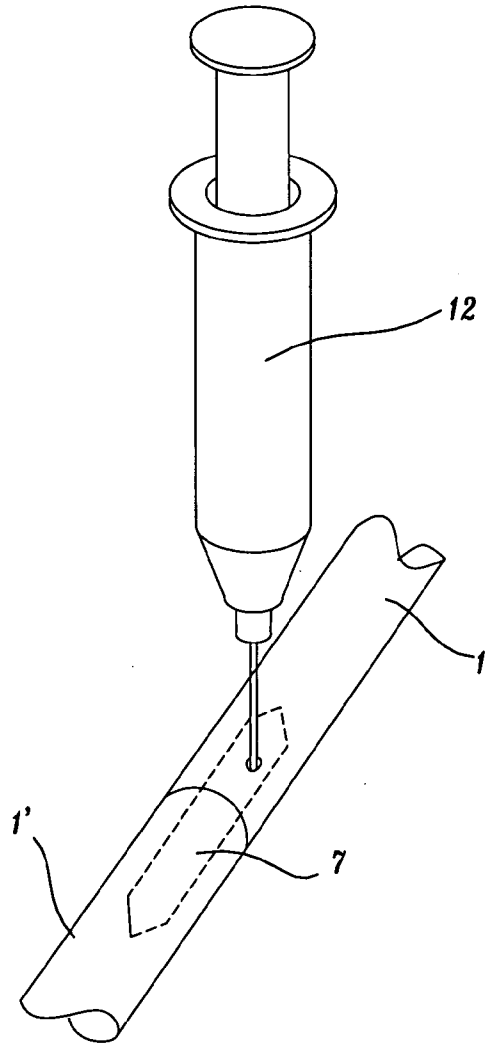


Fig. 6.

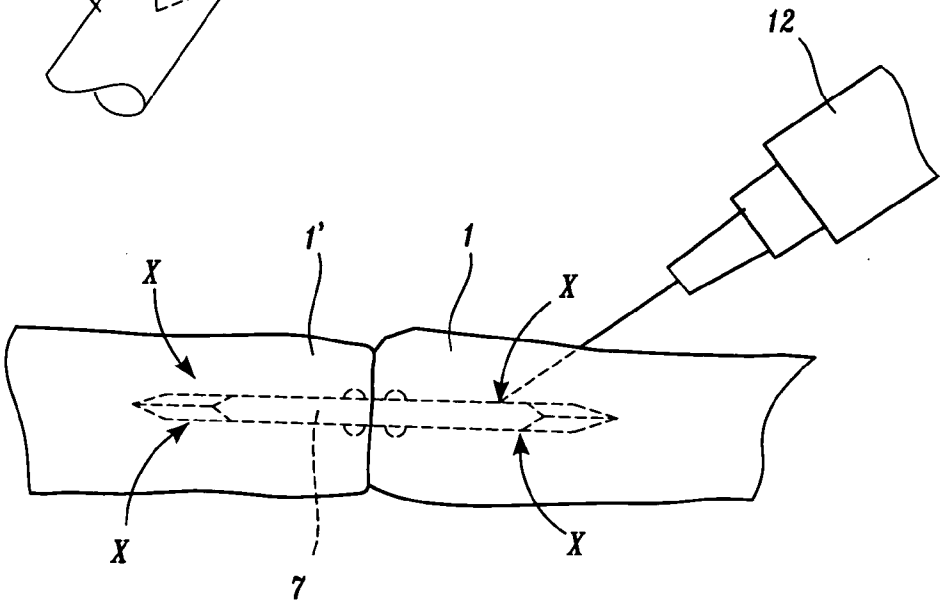


Fig. 7.

TENDON REPAIR USING INTERNAL REINFORCING MEMBER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. patent application Ser. No. 10/112,597, filed Mar. 28, 2002, to issue May 25, 2004, as U.S. Pat. No. 6,740,100, which is a continuation of International Application PCT/US00/35261 filed Dec. 22, 2000 designating the United States, which claims the benefit of the filing date of U.S. Provisional Application Ser. No. 60/171,963 filed Dec. 23, 1999.

FIELD OF THE INVENTION

[0002] The present invention relates to a system for repairing lacerated or severed soft tissue structures of the body, particularly connective cords such as tendons.

BACKGROUND OF THE INVENTION

[0003] Repair techniques for lacerated or severed tendons vary widely depending on the nature of the injury and the particular tendon affected. There are large differences in the extent to which access can be obtained in the least obtrusive manner, in the amount of tendon excursion, in the surrounding environment, in the stresses to which different tendons are normally subjected, and in the healing characteristics of different tendons. In addition, often there is no consensus of the overall best way to repair a given tendon.

[0004] For example, repair of a long flexor tendon in the hand that has been severed is typically achieved by suturing the severed tendon ends face-to-face. Historically, the joints across which the tendon acts were immobilized for from three to eight weeks to protect the tendon while it healed, because a freshly sutured tendon can withstand only a fraction of the tensile force to which a healthy tendon is subjected during normal use. Immobilization results in scarring and adhesion formation along the length of the tendon. Range of motion is adversely affected, particularly in the case of flexor tendons which normally glide smoothly through and over the unique system of tendon tunnels and pulleys of the hand. Nevertheless, it was thought that fibroblastic ingrowth was required in order for the tendon to heal, such that immobilization and the resulting decreased range of motion were considered necessary evils in order for effective healing to take place. More recently it has been discovered that flexor tendons have an intrinsic capacity to heal and that early motion may actually expedite healing. Still, exercises must be carefully planned and carried out due to the weakness of the sutured repair. In early stages of healing, protected passive and/or restricted active exercises may be used, followed by tendon gliding and active strengthening exercises in later stages. The affected joints are most often partially immobilized to prevent inadvertent application of excess force.

SUMMARY OF THE INVENTION

[0005] The present invention is concerned with a system for repair of injured soft tissue structures, particularly connective cords such as tendons, by use of adhesive and, preferably, reinforcing members or stents which can be made of substantially rigid or semi-rigid material. Such stents are adapted for extending longitudinally between severed end portions of a tendon with the severed end portions in abutting relationship. The tendon is secured to the stent by the adhesive such that tension applied to the tendon is transmitted through the stent. The stent and adhesive maintain the severed tendon ends abutting as tension is applied to the tendon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

[0007] **FIG. 1** is a diagrammatic top perspective of a severed end of a tendon and a cutting tool that can be used to prepare a tendon for repair using the present invention;

[0008] **FIG. 2** is a top perspective corresponding to **FIG. 1** showing a severed tendon is the process of repair in accordance with the present invention;

[0009] **FIG. 3** is a top perspective of another tool that can be used when repairing a tendon in accordance with the present invention;

[0010] **FIG. 4** is a top perspective of a first embodiment of a stent usable in the present invention;

[0011] **FIG. 5** is an enlarged top perspective of a second embodiment of a stent usable in the present invention;

[0012] **FIG. 6** is a diagrammatic top perspective of a severed tendon in the process of repair in accordance with the present invention; and

[0013] **FIG. 7** is side elevation of the repair of **FIG. 6**, with parts broken away.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0014] The present invention provides a splice for soft tissue structure having a laceration. **FIG. 1** shows a tendon **1** severed at a lacerated "end" face **2**. In preparation for insertion of a reinforcing member or stent, a cutting tool **3** having a handle **4** and distally projecting blade **5** can be used to cut a slit **6** (**FIG. 2**) in the end face **2** of the tendon **1**. Preferably the slit does not extend the full width of the tendon, so that the external sheath of the tendon is not weakened. The same procedure can be used for forming a slit in the mating tendon end portion **1'** (see **FIG. 2**).

[0015] Next, a reinforcing member or stent **7** is inserted into first one then the other slit **6**, and the end faces of the severed tendon **1**, **1'** are brought together to an abutting relationship. The stent **7** shown in **FIG. 2** is much longer than it is wide and much wider than it is thick, having opposite broad surfaces at the top and bottom. More specifically, the width of the stent is approximately equal to the width of the preformed slits **6**, and the length of the stent is approximately equal to the depth of the slits measured axially or lengthwise of each tendon portion **1**, **1'**. The stent may be inserted by use of a suitable grasping tool, eased by forming the stent with pointed and/or sharpened ends. Alternatively, as represented diagrammatically in **FIG. 3**, the blade **5** of the cutting tool **3** can be formed with a depression for receiving the stent **7**. By careful manipulation of the

cutting tool, the stent may be automatically deposited in a first end portion **1**, **1'** of the tendon as the cutting tool is removed following formation of the slit **6**. Another alternative is to form the slit with one tool, and deposit the stent with another tool similar to that shown in **FIG. 3**.

[0016] Ultimately, the stent will be held in place within the slits **6** by adhesive. To increase the surface area between the stent, the adhesive and the tendon, and to form channels for receiving the adhesive, the stent **7** of **FIG. 2** may have longitudinally extending grooves **8** or other surface modifications to expand surface area in both its upper and lower surfaces. These grooves may extend all the way through the stent, but preferably extend only partway into the stent to isolate the top surface from the bottom.

[0017] With reference to **FIG. 4**, it may be desirable to prevent the adhesive from flowing between the abutting faces of the severed tendon. Consequently, the grooves **8** can have inner ends **9** which are spaced apart, such that an ungrooved area **10** is formed at the center of the stent, both in the top and bottom surfaces, in the area where the stent bridges between the abutting faces of the severed tendon.

[0018] **FIG. 5** shows another construction in more detail, including a pattern of grooves **8** at the opposite end portions of the stent **7**. At each end the grooves are in communication with each other, but the grooves at one end are not in communication with the grooves at the other. Short bumps **11** can be formed at the inner ends of the grooves **8** at each end, to further isolate the central portion **10** from the grooves and, preferably, prevent adhesive from flowing to the abutting faces of the severed tendon. While the grooves **8** can be formed in only one or the other of the flat surfaces of the stent **7**, preferably the grooves are formed both at the top and at the bottom.

[0019] With reference to **FIG. 6** and **FIG. 7**, a settable liquid adhesive is used to fix the stent within the slits of the severed tendon end portions **1**, **1'**. One way this can be done is by use of a syringe **12**. For consistent results, the amount of adhesive is predetermined, i.e., a "metered" amount of injected adhesive is used. As illustrated diagrammatically in **FIG. 7**, the adhesive can be injected by use of the syringe at a plurality of sites along the stent (e.g., four locations designated "x", two at each end, one of which is at the top surface and the other of which is at the bottom surface). In addition, to provide additional strength of the repair and a smooth outer profile of the repaired tendon, a metered quantity of an adhesive can be carefully applied externally around the area of the abutting faces of the severed tendon, preferably without injecting or disbursing that adhesive between the severed ends which could interfere with healing.

[0020] Preferably the stent will be dimensionally stable so that once it is secured in place it will not elongate or stretch which could alter the abutting relationship of the severed tendon ends and interfere with healing. Nevertheless, the stent should be reasonably flexible, possibly approaching the flexibility of the tendon itself, so as not to interfere with excursion of the tendon during normal motion. This may require that the stent be very thin. Widthwise and lengthwise, the stent has substantial dimensions for increasing the effective surface area for bonding the stent internally of the tendon by use of the adhesive.

[0021] It is envisioned that the adhesive can be of the general type described in U.S. Pat. No. 5,350,798 of Linden et al. or a variant. Such an adhesive is, in general, a polymer gel and, more specifically, a cyanoacrylate polymer. Modified gels are described in U.S. Pat. Nos. 5,714,159 and 5,612,052 of Shalaby.

[0022] At the time of injection, preferably the adhesive flows freely without high adhesive properties relative to the tendon, but will thereafter set quickly and secure the severed tendon ends in the desired abutting relationship. The adhesive preferably will have a high sheer strength and approximately the same bending and deflection characteristics as the stent, i.e., the adhesive, once set, will not stretch substantially and also will not be so rigid as to crack if the repaired tendon undergoes normal deflection. The adhesive may inherently have disinfectant characteristics and/or may be coated or impregnated with a compound having disinfectant characteristics. Alternatively or additionally, the adhesive may serve as a delivery system for drugs and/or agents and/or factors to promote healing and/or growth. Both the stent and the adhesive preferably are bioabsorbable, but over a sufficiently long length of time that full healing of the tendon occurs. Materials currently under consideration for the stent are E-caprolactone and poly-L-lactide, or a blend or co-polymer of E-caprolactone and/or trimethylene carbonate and poly-L-lactide, preferably with an inherent viscosity in the range of 1.0 to 2.8 dL/gm at 20° C. These polymers also may be optimized to meet the physical requirements of a successful tendon repair, such as by controlling the degree of crystallinity via primary and/or secondary processing conditions. In general, it is preferred that the strength of the stent-adhesive repair plus the strength of the healed or partially healed tendon be equal or greater to that necessary for full active motion of the tendon. For example, in the case of a flexor tendon of the hand, the stent-adhesive repair may provide "full" strength for approximately three weeks and at least about 50% strength at six weeks when the partially healed tendon itself has 50% or more of its normal tensile strength.

[0023] For a typical repair of a flexor tendon of the hand, the width of the stent could be about 3 mm, the length about 2 to 3 cm and the thickness about 0.7 mm in order to withstand a force of 5000 to 6500 grams without substantial stretching or elongation. This results in a bonding area at each side of at least about 3 mm by 10 mm at both the top surface and the bottom surface, although the actual size of the bonding area will depend on the design of the stent. The bond strength at each of the four bonding areas (top and bottom at each side of the tendon laceration) is preferably at least about 2500 to about 3250 grams.

[0024] While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting rela-

tionship, the reinforcing member being adapted for insertion into the lacerated end portions without compromising the integrity of the cord sheath during installation; and

internal fixing means for fixing the reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

2. The device of claim 1, wherein the reinforcing member is formed from rigid or semi-rigid material.

3. The device of claim 1, wherein the reinforcing member is formed from a dimensionally stable material so as to not elongate after fixation within the cord.

4. The device of claim 1, wherein the reinforcing member is longer than wide and wider than thick, defining opposite broad surfaces.

5. The device of claim 1, wherein the reinforcing member defines pointed or sharpened ends.

6. The device of claim 1, wherein the internal fixing means comprises an adhesive.

7. The device of claim 6, wherein the adhesive further comprises at least one drug, agent and/or factor to promote healing and growth of the cord tissue.

8. The device of claim 1, wherein the reinforcing member defines channels, grooves or surface modifications that increase the surface area of the reinforcing member.

9. The device of claim 1, wherein the reinforcing member and internal fixing means are bioabsorbable.

10. The device of claim 9, wherein the strength of the fixed reinforcing member and the healing cord in which it is fixed are equal to or greater than the strength necessary for active motion of the cord during healing.

11. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship, the reinforcing member being adapted for insertion into the lacerated cord end portions without compromising the integrity of the cord sheath during installation and the reinforcing member defining a surface that is adapted to be internally fixed to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

12. The device of claim 11, wherein the reinforcing member defines channels, grooves or surface modifications that increase the surface area of the reinforcing member.

13. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship, the reinforcing member being adapted for insertion into the lacerated end portions without passing through the cord sheath; and

internal fixing means contained completely within the cord for fixing the reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

14. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship, the reinforcing member being adapted for insertion into the lacerated end portions without passing through the cord sheath and the reinforcing member defining a surface that is adapted to be internally fixed to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

15. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship; and

internal fixing means for fixing the reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member, wherein the reinforcing member and the internal fixing means are adapted to remain within the cord sheath during repair of the connective cord.

16. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship; and

internal non-suture means for securing the reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

17. A device for repair of a connective cord normally tensioned in the body during joint movement, the cord including a sheath and having a laceration forming opposing lacerated end portions, the device comprising:

an elongated internal reinforcing member insertable into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the opposing lacerated end portions in abutting relationship, the reinforcing member being formed from rigid or semi-rigid material; and

internal non-suture means for securing the reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

18. A method for repair of a connective cord normally tensioned in the body during joint movement, the cord

having a sheath and having a laceration forming opposing lacerated end portions, comprising:

inserting opposing ends of an elongated reinforcing member into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the lacerated cord end portions positioned in abutting relationship, wherein the insertion of the reinforcing member is carried out without compromising the integrity of the cord sheath; and

internally fixing the inserted reinforcing member to internal tissues of the cord such that tension applied to the cord is transmitted through the reinforcing member.

19. The method of claim 13, further comprising cutting a slit into each face of the lacerated cord end portion prior to insertion of the reinforcing member.

20. The method of claim 13, further comprising cutting a slit into a face of each lacerated cord end portion during insertion of the reinforcing member.

21. The method of claim 13, wherein internally fixing the reinforcing member comprises applying adhesive to the reinforcing member.

22. A method for repair of a connective cord normally tensioned in the body during joint movement, the cord having a sheath and having a laceration forming opposing lacerated end portions, comprising:

inserting opposing ends of an elongated reinforcing member into the opposing lacerated end portions of the cord such that the reinforcing member bridges the laceration with the lacerated cord end portions positioned in abutting relationship, wherein the insertion of the reinforcing member is carried out without passing the reinforcing member through the cord sheath; and

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