United States Patent [19]

Tascon-Alonso et al.

[11] **3,805,300**

[45] **Apr. 23, 1974**

[54] **TENDON PROSTHESIS**

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[52] **U.S. Cl.** ..... **3/1**, 128/334 R, 128/DIG. 14, 128/DIG. 21

[51] **Int. Cl.** **A61f 1/24**

[58] **Field of Search** ..... 3/1; 128/334 R, DIG. 14, 128/DIG. 21

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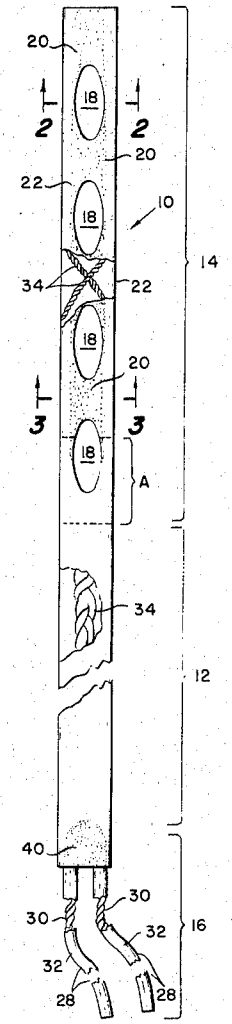
Assistant Examiner—Ronald L. Frinks
Attorney, Agent, or Firm—Gardiner, Sixbey, Bradford & Carlson

[57] **ABSTRACT**

A tendon prosthesis for repair or replacement of a damaged or diseased natural tendon which comprises an elongated member made of biocompatible material having a central portion and two end sections at least one of which has a plurality of longitudinally arranged fenestrations for interweaving with a resected tendon to provide a strong, functional anastomosis. In one embodiment, the second end section of the prosthesis is formed of a pair of flexible cord-like members adapted to anchor the prosthesis to bone structure. In a second embodiment, both end sections include fenestrations allowing each end section to be secured to interwoven segments of a resected tendon.

26 Claims, 6 Drawing Figures



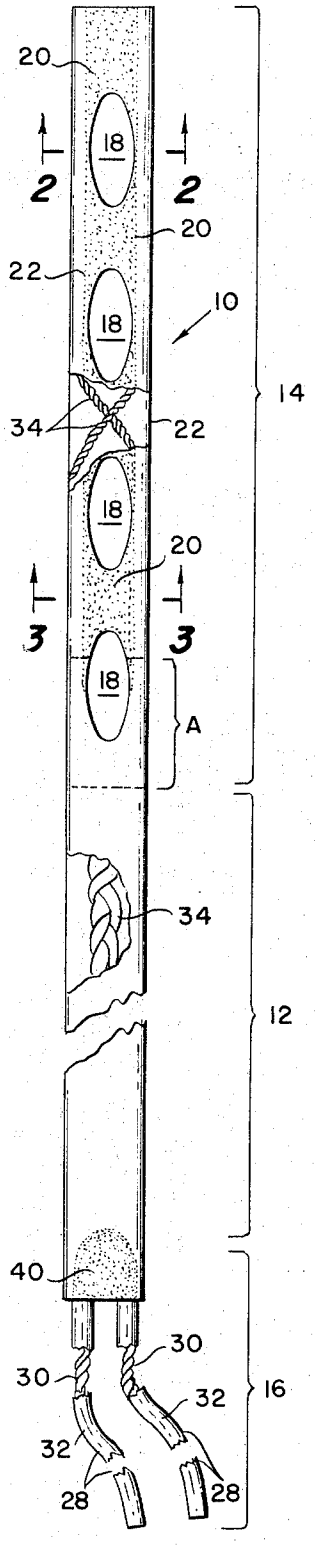
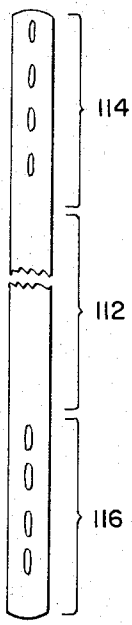


Fig. 1

Fig. 5



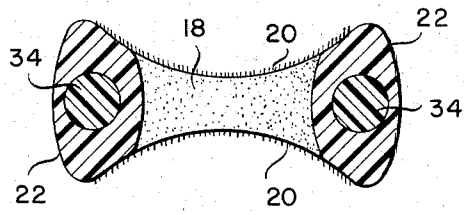


Fig. 2

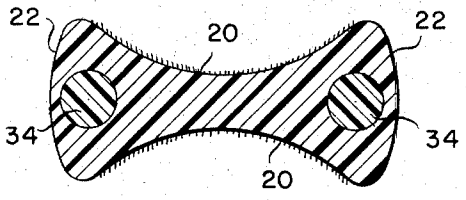


Fig. 3

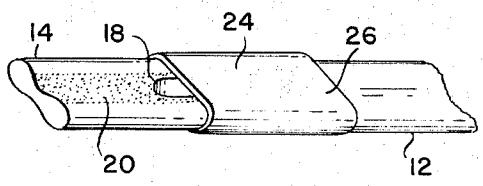


Fig. 4

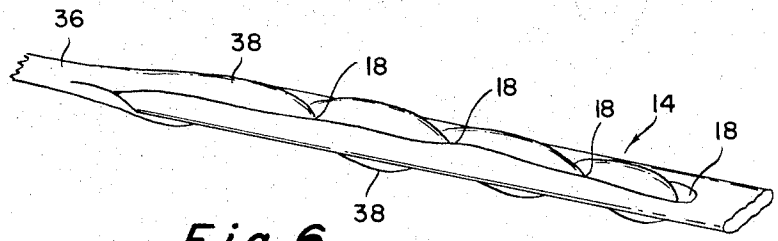


Fig. 6

TENDON PROSTHESIS

BACKGROUND OF THE INVENTION

This invention relates to an improvement in an artificial tendon for replacement of natural tendon damaged or destroyed by such events as injury, infection, burns, disease and surgical resection.

Numerous techniques designed to restore the function of a damaged or diseased tendon by reconstruction or replacement of the affected member are known to the prior art. One of the most frequently affected and yet often the most difficult to repair successfully are the flexor tendons of the hand. Approaches toward surgical repair by suturing severed ends of tendon or replacement of a damaged segment with an autologous tendon graft often result in failure to establish motion of the tendon since post-operative adhesions in the area of the sutured ends with surrounding tissue almost always occur with concommitant immobilization of the tendon. A recent advance in graft repair involves an initial surgery in which a silicone rod is implanted in the area where the graft is to be installed. After a natural non-adherent sheath has developed around the rod for several weeks or months, the rod is removed and an autologous tendon graft is made within the tunnel of the sheath. Although reasonably good tendon function is restored in some few cases, the problem of subsequent adhesion still remains in many instances. This approach leaves much to be desired since two surgical procedures are required and the hand must be immobilized for a good portion of time following both surgeries.

A great many artificial tendons have been devised in an attempt to improve tendon restoration. Generally, they all have an elongated flexible central section for bridging the gap between resected tendon ends. This central position is made of biocompatible material which inhibits or resists tissue ingrowth. The means for attachment of the ends of the artificial tendons to the ends of tendon or bone have been the principal area of investigation. Some prostheses have a loop at one (or both ends) around which the end of the natural tendon is looped and sutured. Other prostheses have a tubular cloth end into which the end of the resected tendon is placed and sutured. Still another prosthesis has two flaps at each end with tissue ingrowth material on the inside of the flaps. Tendon ends are layered between the flaps and are retained by sutures running through the flaps. Both the tubular and flap ended types are designed to permit tendon tissue ingrowth to occur into the receptive surface of the prosthesis encasing the tendon and provide strength to the attachment.

An artificial tendon should have the capability for being connected to natural tendon so as to create a strong attachment which will withstand both normal stress over a prolonged period and intense stress for shorter periods without breaking the attachment or causing injury to the natural tendon. Preferably, the means for attachment should be such that immediate mobility of the repaired tendon is possible following surgery so as to minimize or avoid the formation of restricting adhesions. There should also be means for attachment such that the blood supply to the natural tendon may be maintained and means for positioning the ends of the natural tendon so as to minimize the possibility for formation of adhesions to surrounding tissue. Each of the prior artificial tendons fails to provide

means to accomplish one or more of the above requirements. Those with looped ends cannot prevent the formation of adhesions and the high concentration of stresses on the small portion of tendon in contact with the loop produces trauma to that portion of the tendon. Those prosthetic tendons with tubular ends or flaps on the ends cannot envelop the resected end of the tendon for much more than one centimeter without interferring seriously with the blood supply to the tendon. Such limited area for subsequent firmer attachment by tissue ingrowth would be inadequately strong both to achieve the desired goals of immediate mobility and to withstand intense stress imposed on the area of attachment. Furthermore, the flap and the loop designs in particular create bulkiness at the attachment site tending to comprise motion within the sheath.

SUMMARY OF THE INVENTION

This invention relates to improvements of artificial tendons having as a primary object a tendon prosthesis which provides an immediate and long lasting strong functional union between the prosthesis and tendon. A further object is a tendon prosthesis which permits immediate mobility following surgery and essentially eliminates adhesions. Another object is a tendon prosthesis which permits extensive anastomotic union without compromising the nutrient supply to the tendon. Another object is a tendon prosthesis which provides minimal bulk at the anastomotic site.

The present invention which accomplishes these objects comprises a somewhat narrow, rather flat, tape-like structure made of bicompatible material capable of withstanding functionally physiological forces exerted at each end without breaking or stretching significantly. The internal strength-imparting framework of the prosthesis may be made of non-stretching material such as braided, woven or standard fabric cords, metal wire, or other strong flexible filaments. The framework is coated with a biocompatible material, such as Teflon, silicone, polyurethane or other suitable flexible polymer, over the entire central portion and a part of the end sections so as to prevent ingrowth of tissue into the prosthesis except at certain desired areas at the end portions. At least in one end section there are a series of holes or fenestrations centrally located and running longitudinally on the flatter side of the end section. The surfaces lying centrally between the holes are of such material and/or structure that they allow ingrowth of tissue to occur. The other end section may also be similarly constructed or it may have means, such as cords or small tapes extending beyond that end for tying or otherwise securing that end to bone. A resected end of a tendon, preferably one which is first split down the middle, is interwoven through the fenestrations at the end section of the prosthetic tendon and secured by several sutures. The other end of the prosthesis may be similarly anastomosed to a resected tendon when a tendon prosthesis is used which has both end sections fenestrated. The attachment of the natural tendon to the prosthetic tendon by this means gives immediate strength and security to the attachment somewhat in the manner of a spliced rope. This means of attachment also permits the natural tendon in the area of attachment to externally envelop the prosthesis so that the tendon can continue to be nourished by the surrounding tissues and necrosis of the tendon is avoided. The resected end (or ends of the split tendon as the case

may be) may be readily contained within the prosthesis and thus the problem of adhesion to surrounding tissue is essentially avoided.

The advantages of the prosthetic tendon of this invention will be more readily understood from a consideration of the following specification and claims in light of a detailed description of an embodiment and of the accompanying drawings in which:

FIG. 1 is a top plan view of a tendon prosthesis in accordance with a first embodiment of this invention, partly broken away;

FIG. 2 is an enlarged cross-sectional view of the prosthesis of FIG. 1, taken on line 2—2;

FIG. 3 is an enlarged cross-sectonal view of the prosthesis of FIG. 1, taken on line 3—3;

FIG. 4 is a view of a modified portion of the prosthesis of FIG. 1, showing an integrally attached sleeve at position A of the prosthesis;

FIG. 5 is top elevational view of a second embodiment of the invention; and

FIG. 6 is a perspective view showing the interweaving of a tendon into the end portion of a prosthesis formed in accordance with this invention.

DETAILED DESCRIPTION OF THE INVENTION

In an embodiment of this invention, a tendon prosthesis **10** as shown in FIGS. **1** through **4** comprises a central portion **12** and two end portions **14** and **16.** The entire prosthesis **10** is made of biocompatible material and may be constructed by the same material or a combination of materials. The central portion **12** is a somewhat flat or tape-like structure as shown in this embodiment or it may be ovoid in cross-section or it may be more circular. A variety of shapes may be manufactured to conform more or less to the cross-sectional shape of the natural tendon to which the artificial tendon is to be attached. The length of the central portion **12** may vary, depending upon the length of damaged or diseased tendon to be replaced.

The end section **14** is integral with the central portion **12** and has essentially the same cross-sectional dimensions as the central portion **12.** Located centrally and arranged longitudinally in end **14** are a series of openings or fenestrations **18,** at least two and preferably three or four in number. These openings **18** may take a variety of shapes, preferably somewhat oval, and are more or less uniformly spaced apart to provide surfaces **20** in between each opening **18.** These surfaces **20** have structure which is receptive to ingrowth of tissue. For example, when the body of the prosthesis is made of silicone, tissue ingrowth surfaces **20** may comprise a favric such as Dacron velour or woven mesh which may fabric secured to the desired areas by applying an adhesive such as silicone adhesive between the body of the prosthesis and the fabric and by vulcanizing the resulting structure to achieve a firm bond. Alternatively, the velour or mesh with an unvulcanized silicone backing may be compressed onto the silicone body and vulcanized. The ingrowth surface also extends inwardly on the surfaces within the openings **18** as shown in FIG. **2.** When the body of the prosthesis is made of polyurethane, for example, the ingrowth surface **20** may also be of polyurethane having an open pore structure. The polyurethane may be molded into the desired shape to form the body with its fenestrations and then an overlayer of polyurethane having open pore structure may be secured to those areas where tissue ingrowth is desired. The prosthesis may be made of metal, and if made from woven or twisted strands of metal wire, such as titanium wire, the woven or twisted structure has crevices into which tissue may grow and one needs only to coat the central portion **12** and outer edges **22** of the end section **14** with a suitable material, for example, silicone, to provide a surface which prevents tissue ingrowth as may be required.

Although the surfaces **20** may be more or less flat, it is preferable that these surfaces be somewhat depressed, resulting in the dumbell cross sectional configuration illustrated in FIGS. **2** and **3.** Providing depressions in these areas of the end section **14** serves to decrease further the bulkiness of the anastomotic union between the natural tendon and the prosthetic tendon as will be discussed later in greater detail.

A cuff **24** illustrated in FIG. **4** may be included at the junction between the central portion **12** and the end section **14** as indicated at position A of FIG. **1.** When provided, cuff **24** fits snugly around the peripheral surface of the prosthesis. Cuff **24** is secured to the prosthesis, by sutures and/or adhesive applied near edge **26** of the cuff closest to the central portion, and is capable of being rolled back prior to the installation of the natural tendon. The cuff **24** is made of cloth, preferably Dacron velour and its exterior surface is coated with material, such as silicone, which resists ingrowth of tissue. The length of cuff **24** is usually of sufficient length to extend over a good portion of the innermost fenestration **18** in the end section **14.**

In the embodiment shown in FIG. **1,** end section **16** is different from end section **14** and is designed to be used to anchor end section **16** of the prosthesis to other more rigid tissue such as bone. End section **16** in this embodiment comprises a cord-like extension **18,** preferably two in number, although one or more than two may provide the function for which the extension **28** is intended. The extension **28** may be made of fabric preferably in the shape of a cord. The extension **28** may be made of metal wire, advantageously several small strands of wire twisted together, and is particularly useful when the body of the prosthesis is made of flexible metal. In the embodiment shown in FIG. **1,** the extension **28** comprises several strands of cord **30,** preferably braided, snugly covered by a woven cloth tube **32.** Both cord **30** and tube **32** are made of material receptive to ingrowth of tissue, such as Dacron. Although it is not essential for cord **30** to be covered by tube **32,** the tube helps to preserve cord **30** from abrasion on sharp edges which may be present at the point where extension **28** enters and leaves bone as will be explained below. For a short distance on the surface of both sides of the central portion **12** adjacent to extensions **28,** pads **40** may be present. These pads **40** are of such material or structure, such as Dacron velour, as to permit ingrowth of tissue.

When the prosthesis **10** is made of plastic, for example, silicone, it is preferable to have internal reinforcement to add strength to the prosthesis. Reinforcing cords **34,** preferably of braided non-extensible strands of suitable material such as Dacron strands may be incorporated at the time of molding. The cords **34** are integral with the extensions **28** of end section **16** and run through the entire length of the prosthesis. The cords **34** may run through any part of the central portion **12** and near the outer edges **22** of end section **14** or they may extend more or less in the middle of central por-

tion **12** and criss-cross between fenestrations **18** as shown in FIG. **1.**

Prosthesis **10** may be made in various lengths depending on where the prosthesis is to be used to effect a repair or replacement. Generally the length can be varied merely by making the central portion **12** longer or shorter at the time of manufacture to provide a variety of sizes for a particular use. The width of prosthesis **10** also may vary depending on which particular tendon is to be replaced. The width selected should generally be slightly smaller than the width of the natural tendon.

As an example of how the prosthesis is made, the reinforcement in combination with the end extensions **28** is first formed by braiding two separate groups of three strands of Dacron for a length of about 3 inches for the formation of the two extensions **28.** The six strands are then divided into three groups of two and braided into a single tape-like structure for a length corresponding to the central portion **12.** The six strands are finally divided into two groups of three as before and braided to form the two reinforcing cords for end section **14.** The fenestrated section **14** is usually about 2 to 3 inches in length. Woven Dacron tubing is next slipped over the two extensions **28** and secured at each end by stitching.

The assembly is coated with a silicone primer, arranged on an appropriate mold piece and sandwiched between two layers of unvulcanized silicone sheets. A mating mold piece is placed on top and the sandwich is hydraulically compressed. The article, while still in the clamped mold, is vulcanized above 100 C. then removed from the mold and trimmed of any flashing. A strip of Dacron velour with unvulcanized silicone backing and having fenestrations approximating those of the molded piece is placed on each side of the fenestrated end section and vulcanized to this section. The velour pads **40** are likewise incorporated at this stage. The prosthesis is washed, sterilized and is ready for use.

As illustrated in FIG. **5,** a prosthesis formed in accordance with this invention may include a pair of fenestrated end sections **114** and **116** attached at one end, respectively, to a central portion **112.** This embodiment, identical in all other respects with the embodiment illustrated in FIGS. **1–4,** is adapted to bridge the gap between two resected ends of a tendon.

In the clinical application of the prosthesis **10,** to make the anastomotic union between a resected tendon and the prosthetic tendon of this invention, as for example in the repair of a flexor tendon in the hand, the prosthesis **10** is first anchored to either the distal or middle phalanx. This may be done by drilling two small holes into that member, running extensions **28** through the holes and tying on the dorsal, or medial side of the bone. In addition, a short stub of the natural tendon where the tendon joins the phalanx may be retained and sutured to the velour pad **40** portion of the prosthesis. The prosthesis is then led through or placed within the natural tendon sheath for joining in the palm to the resected end of the flexor tendon of the appropriate digit. The primary object is to reconstruct the long flexor or profundus tendon. (The surgeon may at his option elect to also join the sublimis tendon with the profundus into a common anastomosis with the end section **14** of the prosthesis). As illustrated in FIG. **6,** the other end of the prosthesis is attached to a tendon **36** in this case the profundus tendon which is resected just proximially of the tendon sheath near the metacarpal head and the end is divided by scalpel into two tendon segments **38** over a distance of approximately 2 inches up to the entrance of the carpal tunnel or sheath. The two tendon segments **38** are then interwoven through the series of fenestrations **18** provided in end section **14** of the prosthesis taking care to lay the split surfaces of the tendon against the ingrowth surfaces **20.** The wrist and finger are placed in full extension and the tendon interweaving is adjusted to provide light tension. Care is taken to insure that the anastomosed portion lies in the more open zone of the palm and does not enter or come too close to the more restricted sheathed areas. The resected end of the two tendon segments **38** are then abutted and sutured within the distal fenestration. The tendon may be additionally sutured at several points along the anastomosis. The surgeon has the option of choosing an alternative anastomotic site just proximal of the carpal tunnel at the flexion crease of the wrist. In this situation the prosthesis **10** has a suitably longer central portion **12.** To make use of the cuff **24** when provided, the individual tendon segments **38** are abutted and sutured within the distal fenestration as previously described. The cuff **24** is then rolled over that portion of the sutured tendon ends and the cuff optionally secured by sutures. With either procedure, the problem of adhesion between the resected end of the tendon and the surrounding tissues is greatly reduced.

Whereas the fenestrated end section **14** is generally intended to be interwoven with a tendon alone, in certain cases it may be desirable to incorporate the muscle adjacent the musculotendon junction along with the tendon into the interweaving with the prosthesis. In this situation, the outer end of the end section **14** is generally broader and the outermost fenestrations are somewhat larger so as to accommodate to the larger cross-sectional size of the muscle.

Immediate mobility of the tendon is thus achieved by the use of the prosthetic tendon of this invention. In addition, it can be readily seen that the anastomotic union is not bulky so that motion may be maintained even within the restricted fibrotic sheath which develops later around the repaired tendon and prosthesis. Furthermore, the prosthesis of this invention allows the natural tendon at the anastomotic site to be exteriorized, i.e., to lie outside of the prosthetic member so that the nutrient supply to the tendon in this area is readily available for maintaining the integrity of the natural tendon.

While preferred embodiments of the invention have been shown and described, other variations and modifications may be made in the structures without departing from underlying principles of the invention.

We claim:

1. A tendon prosthesis for repair of a resected tendon within a living organism wherein the tendon is characterized by an elongated segment having a free end, comprising

a. an elongated central portion formed of flexible, biocompatible material;

b. a first end portion connected with one end of said elongated central portion, said first end portion including first connective means for securing said first end portion within the living organism; and

c. a second end portion connected with the other end of said elongated central portion, said second end

portion including second connective means for connecting the second end portion with the resected tendon by permitting the elongated segment of the resected tendon to be interwoven through said second end portion, said second connective means including a plurality of longitudinally spaced fenestrations formed in said second end portion, each said fenestration passing completely through said second end portion from one side to the other, each said fenestration further being of sufficient size to permit the elongated segment of the resected tendon to pass therethrough, whereby the free end of the elongated segment may be interwoven with said second connective means by being passed back and forth through said longitudinally spaced fenestrations of said second end portion.

2. A tendon prosthesis as defined in claim **1** wherein the surface of said elongated central portion includes means resistant to living tissue ingrowth.

3. A tendon prosthesis as defined in claim **1** including reinforcement means for reinforcing said elongated central portion and said first and second end portions.

4. A tendon prosthesis as defined in claim **3,** wherein said reinforcement means includes fibers within said central portion and said first and second end portions.

5. A tendon prosthesis as defined in claim **4,** wherein said fibers are formed of polyethylene terephthalate cord extending substantially the entire longitudinal length of said central portion and said first and second end portions.

6. A tendon prosthesis for repair or replacement of a natural tendon comprising an elongated central portion formed of flexible, biocompatible material, a first end portion integral with a first end of said central portion, said first end portion including first connective means for securing said first end portion, and a second end portion integral with a second end of said central portion, said second end portion including second connective means for securing said second end to a segment of a natural tendon, said second connective means including a plurality of longitudinally spaced fenestrations formed in said second end portion for receiving the tendon segment, wherein the surface of said second end portion extending longitudinally between said fenestrations includes means receptive to tissue ingrowth.

7. A tendon prosthesis as defined in claim **4,** wherein said first connective means is formed by an extension of said fibers beyond said first end portion.

8. A tendon prosthesis as defined in claim **7,** wherein the portions of said fibers forming said extension are formed into at least one cord-like member.

9. A tendon prosthesis as defined in claim **8,** wherein at least a portion of the surface of said cord-like member is receptive to tissue ingrowth.

10. A tendon prosthesis as defined in claim **7,** wherein said fibers are separated into groups, said groups being combined to form a pair of cord-like extensions extending from said first end portion, a single reinforcing strand extending through said central portion and a pair of reinforcing strands extending through said second end portion.

11. A tendon prosthesis as defined in claim **1,** wherein said first connective means includes a plurality of longitudinally spaced fenestrations formed in said first end portion for receiving a segment of natural tendon.

12. A tendon prosthesis as defined in claim **1,** wherein said first connective means includes at least one cord-like extension secured at one end to said first end portion.

13. A tendon prosthesis as defined in claim **12,** wherein said cord-like extension includes a plurality of strands and a woven cloth tube surrounding at least a portion of said strands, said woven cloth tube being receptive to tissue ingrowth.

14. A tendon prosthesis as defined in claim **13,** including at least one pad secured to said first end portion adjacent the terminal end thereof, said pad being formed of material receptive to tissue ingrowth.

15. A tendon prosthesis for repair or replacement of a natural tendon comprising an elongated central portion formed of flexible biocompatible material, a first end portion integral with a first end of said central portion, said first end portion including first connective means for securing said first end portion; a second end portion integral with a second end of said central portion, said second end portion including second connective means for securing said second end to a segment of a natural tendon, said second connective means including a plurality of longitudinally spaced fenestrations formed in said second end portion for receiving the tendon segment; and a cuff member surrounding the adjacent outer surfaces of said central portion and said second end portion, said cuff member being secured to said central portion and extending a sufficient distance over said second end portion to cover at least a substantial portion of the innermost fenestration formed therein, said cuff member having an outer surface which includes means resistant to tissue ingrowth.

16. A tendon prosthesis as defined in claim **2** wherein said first and second end portions include surfaces which includes means receptive to the ingrowth of tissue.

17. A tendon prosthesis as defined in claim **16** wherein said fenestrations are centrally located with respect to the side edges of said second end portion, said fenestrations being oval in shape.

18. A tendon prosthesis as defined in claim **17** wherein said central and first and second end portions form a unitary molded body of plastic material and fiber reinforcing means are provided which extend essentially longitudinally within said molded body.

19. A tendon prosthesis as defined in claim **18** wherein said first connective means is formed by an extension of said fiber reinforcing means beyond said first end portion.

20. A tendon prosthesis as defined in claim **18** wherein said first connective means is formed by oval shaped fenestrations formed in said first end portion and centrally located with respect to the side edges thereof, said means receptive to tissue ingrowth being positioned to extend between said fenestrations.

21. A tendon prosthesis as defined in claim **19** which includes a cuff member surrounding the adjacent outer surfaces of said central portion and said second end portion, said cuff member being secured at one end to said central portion and extending a sufficient distance over said second end portion to cover at least a substantial portion of the innermost fenestration formed

therein, said cuff member having an outer surface which includes means resistant to tissue ingrowth.

22. A tendon prosthesis as defined in claim **18** wherein said second end section has a dumbell cross sectional configuration with edge sections extending on either side of a center section, said edge sections being of greater thickness than said center section.

23. A method for repairing a natural tendon within a living organism comprising the steps of

1. forming an elongated tendon prosthesis of biocompatible material;
2. forming a plurality of longitudinally spaced fenestrations within one end portion of the prosthesis;
3. anchoring the other end portion of the prosthesis within the living organism;
4. preparing the remaining portion of natural tendon by forming at least one elongated end segment of natural tendon having a free end with a cross section sufficiently small to pass through each fenestration; and
5. interweaving the elongated end segment with the one end portion of the prosthesis by passing the free end of the elongated end segment back and forth through the fenestrations.

24. The method as claimed in claim **23** wherein step 4 further includes the step of forming at least one additional elongated segment of natural tendon having a free end with a cross section sufficiently small to pass through each fenestration and wherein step 5 includes the step of interweaving the additional elongated segment of natural tendon with the one end portion of the prosthesis by passing the free end of the additional elongated end segment back and forth through the fenestrations.

25. The method of claim **24** wherein elongated segments of natural tendon are formed by splitting the natural tendon longitudinally.

26. The method of claim **25** further including the step of forming surfaces receptive to tissue ingrowth between the fenestrations and wherein the step of interweaving the elongated segments of natural tendon with the one end portion of the prosthesis includes the step of placing the split surfaces of the elongated segments in contact with the surfaces receptive to tissue ingrowth.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,805,300 Dated April 23, 1974

Inventor(s) Manuel Tascon-Alonso et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 2, line 15, "comprise" should read -- compromise --; line 32, "bicompatible" should read -- biocompatible --; line 37, "standard" should read -- stranded --. Column 3, line 51, "favric" should read -- fabric --; line 53, "fabric" should read -- be --.

Signed and sealed this 24th day of September 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents

FORM PO-1050 (10-69)

USCOMM-DC 60376-P69
* U.S. GOVERNMENT PRINTING OFFICE : 1969 O—366-334.