

[54] COVERED SUTURE
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[73] Assignee: Ethicon, Inc., Somerville, N.J.
[22] Filed: Sept. 22, 1971
[21] Appl. No.: 182,792

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Primary Examiner—Aldrich F. Medbery
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[52] U.S. Cl..... 128/335.5, 57/140, 260/340.2,
264/186
[51] Int. Cl..... A61I 17/00
[58] Field of Search 128/335.5; 161/175, 176 X;
57/140 X; 264/186 X; 260/340.2 X

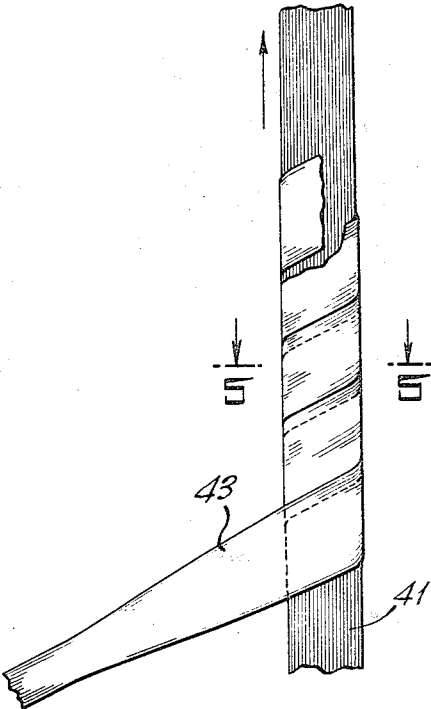
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[57] ABSTRACT

Surgical sutures having an improved knot strength are constructed with a central core of multifilament yarn that has been impregnated with an adhesive binder. The adhesive binder coated core yarn is covered with a ribbon-like helical winding of multifilament yarn and the composite structure is hot stretched whereby the binder secures the external winding to itself and the central core.

10 Claims, 5 Drawing Figures

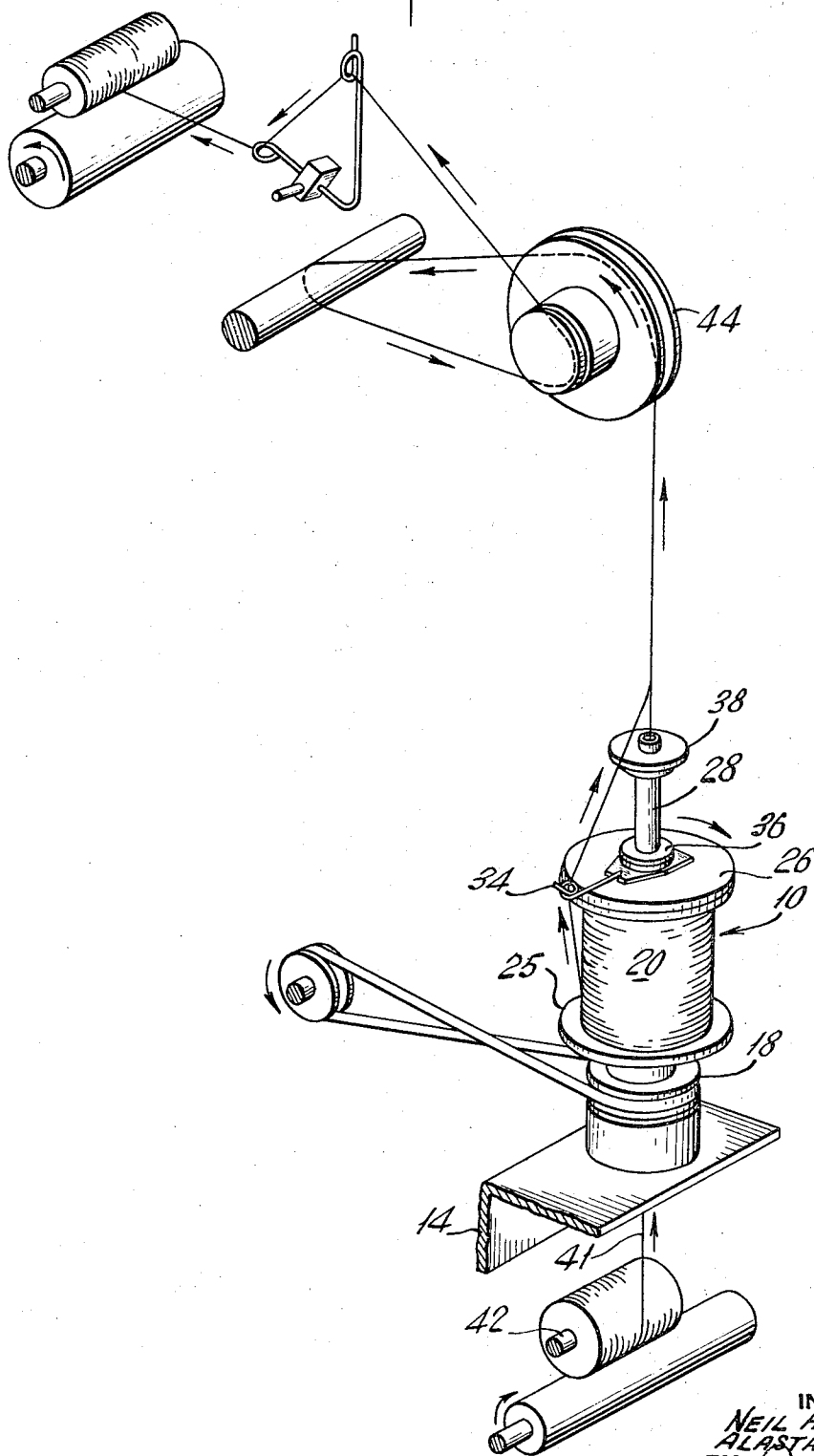


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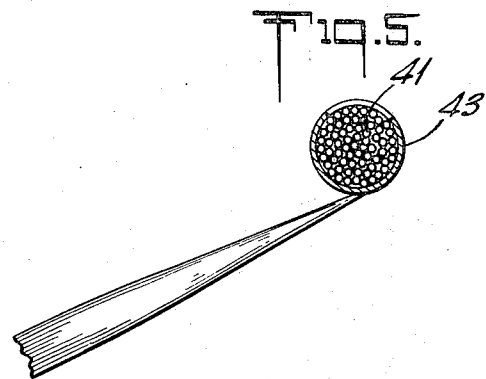
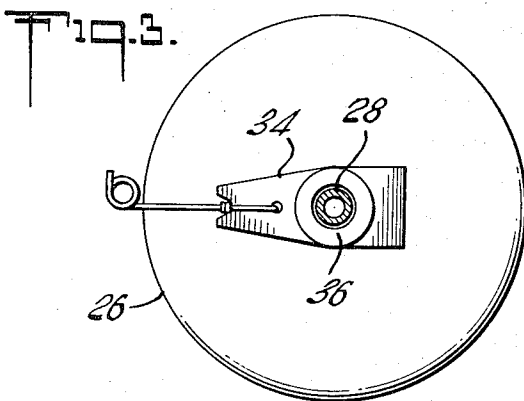
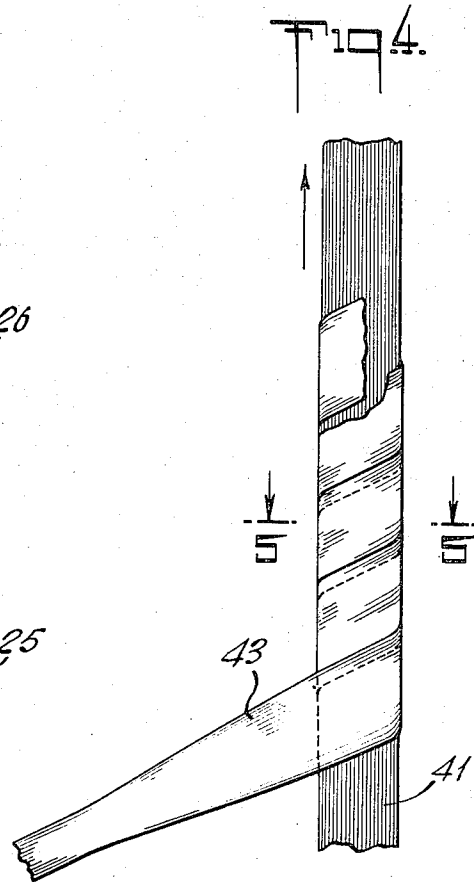
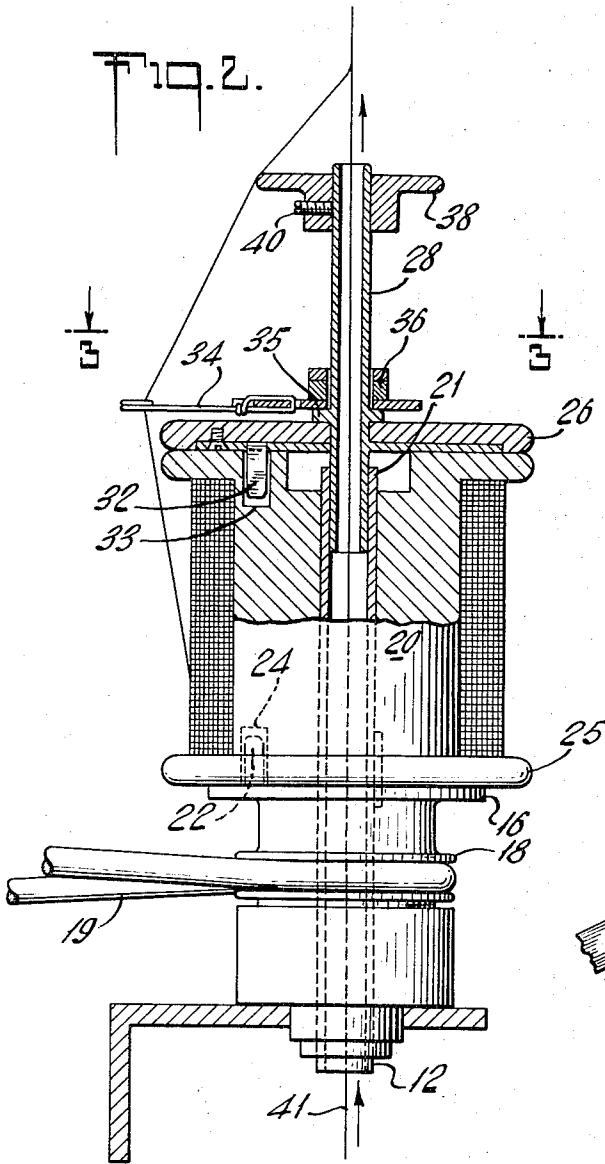
3,791,388

SHEET 1 OF 2

FIG. 1.



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1 COVERED SUTURE

BACKGROUND OF THE INVENTION

This invention applies to improved surgical sutures and more particularly to surgical sutures having an improved knot strength.

Braided multifilament sutures have found wide use in surgery because of their excellent flexibility and good handling properties. Such braided sutures tie down smoothly to form a secure knot. However, reduction of potential tensile strength is inherent in braided sutures consisting of continuous multifilaments or stable yarns. This is due to the deflection of the filaments required by the braided configuration from the straight or parallel directions. Braided suture production, furthermore, is extremely slow due to mechanical limitations of braider machine design.

The sutures of the present invention have flexibility and handling characteristics approaching a braided suture and tie down easily to form a knot of greatly improved strength. Inasmuch as the knot strength of a braided suture is generally only about 50 percent of the straight tensile strength, it is the knot strength that determines the actual retention of such a suture. It is an important advantage of the sutures of the present invention that they have a knot strength that is much greater than that of a braided suture of corresponding size.

SUMMARY OF THE INVENTION

The surgical sutures of the present invention are constructed with the central core of multifilament yarn that has been impregnated with an adhesive binder. The core yarn is covered with a helical winding of multifilament yarn the composite structure is not stretched whereby the binder secures the external winding to itself and the central core. Alternatively, the central core of multifilament yarn (no adhesive binder present) may be covered with a helical winding of multifilament yarn and an adhesive binder applied to the suture to secure the external winding to itself and to the central core.

Covered yarns are not new per se. Nylon-covered Spandex yarns have been used to make elastomeric stretch yarns for bathing suits. Such filaments would not be suitable for suture use, however, as the surgeon would find it difficult to control the tension of an elastic suture which could cause strangulation and necrosis of the tissue being sutured.

The sutures of the present invention differ from the covered yarns of the prior art in that they are not elastic. Preferably, the core and helical winding are constructed of filaments having the same composition. The covered sutures to be described are also characterized by a greatly improved knot strength.

The core yarn of the covered suture may be a multifilament of collagen, nylon, polyester, polypropylene, silk or cotton which is non-conductive electrically. Preferred polyesters for the manufacture of absorbable covered sutures are the homopolymers and copolymers of glycolide. The cover yarn may be a ribbon-like multifilament of collagen, nylon, polyester, polypropylene, silk or cotton. Again, in the construction of an absorbable suture, the preferred yarns for the helical winding around the core are the homopolymers and copolymers of L(-) lactide and glycolide.

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BRIEF DESCRIPTION OF THE DRAWINGS

The invention will appear more clearly from the following detailed description when taken in connection with the following drawings which show by way of example a preferred embodiment of the inventive idea.

In the drawings:

FIG. 1 is a perspective view of a covering machine;

FIG. 2 is an enlarged view partly in section of a hollow spindle on which is mounted a spool of cover yarn;

FIG. 3 is a plan view taken on the Line 3—3 of FIG. 2;

FIG. 4 is an enlarged perspective view of a covered multifilament yarn; and

FIG. 5 is a cross-sectional of a covered yarn on the Line 5—5 of FIG. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred method for preparing the flexible covered sutures of the present invention utilizes an H. H. ARNOLD Covering Machine (manufactured by H. H. Arnold, Rockland, Massachusetts) and illustrated in FIGS. 1, 2, and 3.

Referring now to the apparatus illustrated in FIGS. 1-3 and to the physical steps involved in preparing the covered sutures of the present invention, the covering machine 10 is constructed with a hollow spindle 12 mounted for rotation on the bracket 14. The hollow spindle is keyed to a spool platform 16, the lower end of which is constructed with a pulley 18. A belt 19 serves to drive the pulley rotating the spool platform and the hollow spindle.

The cover yarn is supplied from a spool 20 having a transverse central bore 21 to receive the hollow spindle. The spool rests upon the platform 16. A projection 22 extending upwardly from the spool platform engages a recess 24 in the bottom flange 25 of the spool.

To complete the description of the covering machine, a circular cover plate 26, the diameter of which is approximately the diameter of the spool, is provided with a concentric cylinder 28 extending above and below the cover plate when the machine is assembled. As shown in FIG. 2, the lower portion of this cylinder extends below the cover plate into the central bore of the spool and the hollow spindle 12. Projection on the lower surface of the cover plate engages a recess in the upper flange of the spool.

A flyer 34 rotates freely about the cylinder 28 and is supported on a bearing surface 35 which extends above the cover plate 26. The tension that is applied by the flyer to the cover yarn during rotation is controlled by weights 36 which may be slipped over the cylinder 28. After the desired number of weights have been added, a guide 38 is secured at the top of the cylinder 28 with a set screw 40.

In operation, a core yarn 41 that is to be covered is fed from a supply spool (not shown) to a feed star wheel 42 from which it passes upwardly through the hollow spindle 12, and cylinder 28 to the take-up star wheel 44. The core yarn is wrapped once around the feed and take-up star wheels to be sure that the core yarn is held under tension while the cover yarn is wound on in the "cover zone" (between the feed and take-up star wheels).

As the core yarn passes through the spool, the spool with its cover plate cylinder and guide are rotated at a rate that is determined by the speed of the pulley, that drives the spool platform, and hollow spindle. The amount of cover yarn 43 that is wound on the core yarn is determined by the rate at which the core passes through the cover zone.

The machine is preferably operated so that the take-up start wheel is rotating about 2 percent faster than the feed star wheel to keep the core yarn under tension. The flyer is loaded with a number of flyer weights (short of breaking the cover yarn) to provide high tension on the cover yarn. Under these conditions of operation, the machine produces a compact structure of good intrinsic strength. Preferably, for best appearance and handling characteristics of the final product, the core yarn, is ply twisted prior to applying the cover yarn 43.

The covered yarn from the take-up star wheel 44 is wound onto a spool 45 and may be stored pending subsequent treatment with an acceptable resin, wax or other suitable finish that may be applied to prevent unraveling, improve abrasion resistance, and tie down characteristics. Alternatively, the covered yarn may be passed directly into a finishing bath after it leaves the covering machine.

As indicated above, if the core yarn has not been coated with a resin binder before the helical cover yarn is applied thereto, it is necessary to treat the covered yarn with a resin or wax or other suitable finish to prevent unraveling and improve abrasion resistance. This may be done by passing the covered suture directly into a solution of the desired treating resin and then passing the coated yarn through a drying oven for removal of solvent as is well known in the textile art.

The present invention will be further illustrated by the following examples which described the manufacture of covered sutures of different sizes, all of which have excellent hand and flexibility and knot strength.

EXAMPLE I

Size 3/0 Polyester Covered Suture

A Size 3/0 covered polyester suture is prepared on the apparatus illustrated in FIGS. 1-3. The suture is constructed using a core having 2 ends of 220 denier, 50 filament polyester yarn plied together without twist. This yarn is a bright, high-tenacity multifilament that has been entangled for non-twist cohesion (Rotaset Industrial DACRON Type 2 available from E. I. DuPont de Nemours & Company, Wilmington, Delaware).

The core yarn prior to covering is coated with an adhesive binder by passing it through a solution containing seven parts of a linear saturated polyester polymer melting at about 280°F. (sold by the Industrial Chemicals Division, Eastman Chemical Products, Inc., Kingsport, Tennessee under the trade-name XFA-1); and 93 parts of methylene chloride. After the coating is applied, the core yarn is passed through a steel die to wipe off excess coating and form a smooth surface. The opening of this die is 18 mils. in diameter and the exit of the die is 12 mils. in diameter. The core yarn is next dried at room temperature in a counter-current of air, and collected on a drum. The coating thus applied to the core yarn amounts to 6.3 per cent of the weight of the uncoated core yarn.

The spool 20 of the covering machine is loaded with a 40 denier, 27 filament, bright, normal-tenacity yarn (Rotaset Industrial DACRON Type 56 available from the E. I. DuPont de Nemours & Company, Wilmington, Delaware). The flyer (E16) is loaded with five weights (total weights 50 grams) and the covering machine is operated with a spindle speed of 10,000 r.p.m. to obtain 70 turns per inch of the cover yarn (S twist direction).

The resin binder in the core of the covered yarn is activated by hot stretching the covered suture 2 per cent between two godets. The take-up godet has a diameter of 6 1/8 inches and is at a temperature of 430°F. The covered suture is wrapped around this heated godet 15 times; the dwell time on the godet at 430°F. is approximately 15 seconds.

After the binder resin present in the core has been activated to secure the helical winding of multifilament cover yarn to the core, the covered suture is cooled to room temperature under minimal tension, collected on a drum, cut to the proper length and sterilized with Cobalt 60 irradiation. The physical properties of the sterile covered sutures so obtained are compared with those of a braided suture of the same size in Table I.

Table I

Physical Properties:	Size 3/0 Covered Polyester Suture	Size 3/0 Braided Polyester Suture
Diameter, mils	9.6	9.5
Straight pull, lb.	7.8	8.4
Intrinsic straight pull, p.s.i.	107,600	118,400
Knot pull, lb.	5.5	4.3
Intrinsic knot pull	76,800	61,000

It will be noted from Table I that the covered polyester suture so obtained has a knot strength more than 25 per cent greater than that of a braided polyester suture of the same size.

EXAMPLE II

Size 2 Polyester Covered Suture

A Size 2 covered polyester suture is prepared on the apparatus illustrated in FIGS. 1-3. The suture is constructed using a core having nine ends of 220 denier, 50 filament polyester yarn plied together without twist. This yarn is a bright, high-tenacity multifilament that has been entangled for non-twist cohesion (Rotaset Industrial DACRON Type 52 available from E. I. DuPont de Nemours & Company, Wilmington, Delaware).

The spool 20 of the covering machine is loaded with a 70 denier, 34 filament, bright, normal-tenacity, yarn (Rotaset Industrial DACRON Type 56 available from E. I. DuPont de Nemours & Company, Wilmington, Delaware). The flyer (E20) is loaded with six weights (total weights 60 grams) and the covering machine is operated with a spindle speed of 8,500 r.p.m. to obtain 65 turns per inch of the cover yarn (Z twist direction).

The covered yarn is next coated by passing it through a solution containing 14.25 parts of a linear saturated polyester polymer (sold by the Good Year Tire & Rubber Company of Akron, Ohio, under the trade-name VITEL PE-207); and 0.75 parts of a modified isocyanate curing agent (sold by E. I. DuPont de Nemours & Company, Inc., Wilmington, Delaware under the trade-name RC-805); dissolved in 75 parts of methyl ethyl ketone. After the coating is applied, the covered suture is passed through a nine-foot horizontal drying tube

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(approximate dwell time 45 seconds). The suture is dried in the tube by a counter-current of warm air. The air at the entry of the drying tube is 197°C. and the exit air temperature is 140°C. After leaving the drying tube, the covered suture is cooled to room temperature under minimal tension and then collected on a drum, cut to the proper length and sterilized with Cobalt 60 irradiation. The physical properties of the sterile covered sutures so obtained are compared with those of a braided suture of the same size in Table II.

TABLE II

Physical Properties:	Size 2 Covered Coated Polyester Suture	Size 2 Braided Polyester Suture
Diameter, mils	21.6	21.1
Straight pull, lb.	34.6	21.2
Intrinsic straight pull, p.s.i.	94,000	60,600
Knot pull, lb.	20.0	13.6
Intrinsic knot pull, p.s.i.	54,500	38,900

It will be noted from Table II that the coated covered polyester suture so obtained has a knot strength more than 30 percent greater than that of a braided polyester suture of the same size.

EXAMPLE III

Nylon Covered Suture

A Size 4/0 covered nylon suture is prepared from a core yarn of 210 denier, 34 filament, Type 380 nylon with 0.7 turns per inch of S twist (available from E. I. DuPont de Nemours & Company, Wilmington, Delaware). Six turns per inch Z twist was inserted into this core yarn prior to covering. The spool 20 of the cover machine is loaded with a single covering yarn of 30 denier, 26 filament, 0.5 turns per inch Z twist (Type 280 semi-dull normal-tenacity nylon available from E. I. DuPont de Nemours & Company, Wilmington, Delaware). The flyer (E17) is weighted with 1 weight (5 grams) and the spool and spindle are rotated at 10,000 r.p.m. while the core yarn is taken up by the star wheel at a linear rate that produces a suture having 85 turns per inch of cover yarn (Z twist direction).

Skeins of the covered suture so obtained are dyed by immersing the skein in an aqueous bath containing 0.3 parts D & C Green No. 5 dye dissolved in 600 parts of glacial acetic acid and 5,400 parts water. The temperature of the bath is 212°F. and the dwell time in the bath is 20 minutes. The dried skein is next rinsed in cold water and allowed to air dry.

The suture is next coated by passing it at room temperature through a solution of 17.5 parts nylon 6 (available from Allied Chemical Plastics Division, Morristown, New Jersey as PLASKON 8202) dissolved in 82.5 parts of trifluoroethanol. The covered suture as it emerges from the coating solution passes through a steel die (entrance 0.012 inch, exit 0.006 inch) and travels under tension through a four-foot vertical drying tube. The approximate dwell time within the drying tube is about 11 seconds. The temperature at the bottom of the tube is about 75°C. and the temperature at the top of the tube is about 130°C. The weight of the coating resin applied in this step amounts to 14 per cent of the weight of the covered suture prior to coating. The finished suture is collected and sterilized as described in Example I above. The physical properties of the sterile covered suture obtained are compared with those of a braided suture of the same size in Table III.

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TABLE III

Physical Properties:	Size 4/0 Covered Nylon	Size 4/0 Black Braided Nylon
Diameter, mils	7.6	7.5
Straight pull, lb.	3.6	3.6
Intrinsic straight pull, p.s.i.	79,300	81,400
Knot pull, lb.	2.8	2.3
Intrinsic knot pull, p.s.i.	61,700	52,200

It will be noted from Table III that the coated covered nylon suture has a knot strength that is about 78 per cent of its straight tensile strength. By contrast, a braided nylon suture has a knot strength that is about 64 per cent of its straight tensile strength.

EXAMPLE IV

Nylon Covered Suture

A size 1/0 covered nylon suture is prepared using a core having three ends of 260 denier, 17 filament, bright, high-tenacity, Type 380 (available from E. I. DuPont de Nemours & Company, Wilmington, Delaware) nylon with one turn per inch of Z twist. The three core yarns are plied together with six turns per inch Z twist. The spool 20 of the covering machine is loaded with a single covering yarn of 70 denier, 34 filament, 0.5 turns per inch S twist, Type 380 nylon. The flyer (E20) is weighted with five weights (50 grams) and the spool and spindle are rotated at 10,000 r.p.m. while the core yarn is taken up by the star wheel at a linear rate that produces a covered suture having 45 turns per inch of covered yarn (Z twist direction).

The covered suture is next coated by passing it at room temperature through a solution of 17.3 parts nylon 6 (available from Allied Chemical Company Plastics Division, Morristown, New Jersey as OKASJIB 8202) dissolved in 82.7 parts of trifluoroethanol. The covered suture as it emerges from the coating solution passes through a steel die (entrance 0.030 inch, exit 0.018 inch) and travels under tension through a four-foot vertical drying tube. The approximate dwell time within the drying tube is about 11 seconds. The temperature at the bottom of the tube is about 75°C. and the temperature at the top of the tube is about 130°C. The weight of the coating resin applied in this step amounts to 11.2 per cent of the weight of the covered suture prior to coating. The finished suture is collected and sterilized as described in Example I above. The physical properties of the sterile covered suture obtained are compared with those of a braided suture of the same size in Table IV.

Table IV

Physical Properties:	Size 1/0 Covered Nylon	Size 1/0 Black Braided Nylon
Diameter, mils	13.8	15.2
Straight Pull, lbs.	11.0	11.5
Intrinsic straight pull, p.s.i.	73,500	63,300
Knot Pull, lb.	9.2	7.4
Intrinsic knot pull, p.s.i.	61,500	41,000

It will be noted from Table IV that the coated covered nylon suture has a knot strength that is about 83 per cent of its straight tensile strength. By contrast, a braided nylon suture has a knot strength that is about 65 per cent of its straight tensile strength. The tie down characteristics of this suture may be improved by applying a surface coating of tetrafluoroethylene as described in U.S. Pat. No. 3,527,650.

EXAMPLE V

Size 2/0, 65/35 L(-) Lactide/Glycolide Covered Suture

A Size 2/0 absorbable covered suture is prepared from a copolymer of 65 mol per cent L(-) lactide, 35 mol per cent glycolide utilizing the apparatus illustrated in FIGS. 1-3. The production of a copolymer from 65 mol per cent L(-) lactide and 35 mol per cent glycolide suitable for use in this example is described in Example XVIII of U.S. Application Ser. No. 36,797, filed May 13, 1970. The suture is constructed using a core having 9 ends of this copolymer yarn (66 denier, 34 filament copolymer multifilament having six turns per inch), plied together without twist.

The covering yarn is one end of 66 denier, 34 filament yarn of the copolymer composition described above having 36 turns per inch.

The flyer (E12) is weighted with three 5-gram weights (total weight 15 grams) and the covering machine is operated at a speed of 8,500 r.p.m. to cover the core yarn with a helical winding having 40 turns per inch (Z twist).

The covered suture is coated by passing it through a bath containing 10 parts of poly DL lactide homopolymer dissolved in 90 parts of toluene and dried by passing the coated suture through a nine-foot horizontal drying tube. The approximate dwell time of the suture within this tube is 40 seconds during which time the suture is dried by a counter-current of air at room temperature. The weight of the coating resin applied in this step amounts to 9.03 per cent of the weight of the covered suture prior to coating. The finished suture is collected on a drum, annealed at 65°C. for three days, and sterilized as described in Example I above. The physical properties of the sterile covered suture obtained are compared with those of a braided suture of the same size and composition in Table V.

TABLE V

	Size 2/0 Covered, Coated 65/35 L(-)lactide/ Glycolide Suture	Size 2/0 Braided 65/35 L(-)lactide/ Glycolide Suture
Physical Properties:		
Diameter, mils	12.2	13.0
Straight pull, lb.	4.7	8.9
Intrinsic straight pull, p.s.i.	40,200	67,000
Knot pull, lb.	3.3	4.8
Intrinsic knot pull, p.s.i.	28,200	36,100

It will be noted from Table V that the covered suture has a knot strength that is about 70 percent of its straight tensile strength. By contrast, the braided suture has a knot strength that is about 54 percent of its straight tensile strength.

EXAMPLE VI

Size 2/0 Polyglycolide Covered Suture

In accordance with the procedure described in Example V above, a Size 2/0 absorbable suture is pre-

pared substituting for the core yarn and covering yarn a polyglycolide homopolymer multifilament. The covered suture is coated by passing it through a solution of 10 parts of poly dl lactide homopolymer in () parts of toluene and dried, annealed, and sterilized as described in Example V above. The finished suture has excellent flexibility and knot strength.

The products of the invention are useful in surgery for suturing. If so desired, they may be treated with lubricants or other surface coating resins as described in U.S. Pat. No. 3,527,650 to improve tie down characteristics. It will be understood that with respect to the covered sutures made with core and cover yarns of an absorbable polymer or copolymer of L(-) lactide or glycolide, the proportions of L(-) lactide and glycolide in the polymer composition may be modified to obtain the esired in vivo absorption characteristics. The rate of absorption and tensile strength retention of such absorbable covered sutures may also be controlled by varying the copolymer composition of the binder resin that secures the external winding to itself and to the entral core.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

What is claimed is:

1. A sterile surgical suture constructed with an internal non-conductive multifilament core yarn that is covered by a ribbon-like helical winding of an external multifilament cover yarn; the adjacent edges of said external multifilament yarn being secured to each other and to the central core yarn by means of a binder composition; defining a suture having an intrinsic knot pull strength that is at least 65 percent of the intrinsic straight pull strength of the suture.

2. The suture of claim 1 wherein said suture, when bent into the shape of a knot, has a strength of not less than 65 percent of the tensile strength of said suture.

3. The suture of claim 1 wherein the core yarn and cover yarn are silk.

4. The suture of claim 1, wherein the core yarn and the cover yarn have the same composition.

5. The suture of claim 1, wherein the core yarn and the cover yarn are nylon.

6. The suture of claim 1, wherein the core yarn and the cover yarn are a polyester.

7. The suture of claim 1, wherein the core yarn and cover yarn are a polyglycolide multifilament.

8. The suture of claim 1, wherein the core yarn and cover yarn are a polymer of L(-) lactide.

9. The suture of claim 1, wherein the core yarn and cover yarn are multifilaments of a 65/35 L(-) lactide/-glycolide copolymer.

10. The suture of claim 9, wherein said binder composition is a polyester.

* * * * *

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,791,388 Dated February 12, 1974

Inventor(s) Alastair W. Hunter and Neil H. Rosen

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

On Page 1, Column 2, "Abstract" should read --- Abstract of the Disclosure ---.

In Column 1, line 64, "slik" should read --- silk ---.

In Column 2, line 15, "cross-sectional" should read --- cross-section ---.

In Column 2, line 31, "WThe" should read --- The ---.

In Column 2, line 48, "Projection on the..." should read --- A projection 32 ---.

In Column 2, line 49, "a recess in" should read --- a recess 33 ---.

In Column 3, line 9, "start" should read --- star ---.

In Column 3, line 11, "loadde" should read --- loaded ---.

In Column 3, line 11, "flyger" should read --- flyer weights ---.

In Column 3, line 42, Example 1, "Coverred" should read --- Covered ---.

In Column 3, line 51, "Type 2" should read --- Type 52 ---.

In Column 4, line 21, "sterilizeed" should read --- sterilized ---.

In Column 4, line 65, "75 parts" should read --- 85 parts ---.

In Column 5, line 3, "atthe" should read --- at the ---.

In Column 5, line 20, "Table 11 hat" should read --- Table 11 that ---.

In Column 5, line 29, "380 mylon" should read --- 380 nylon ---.

In Column 5, line 60, "ofthe" should read --- of the ---.

In Column 6, line 30, "hav ing" should read --- having ---.

In Column 6, line 36, "New Herset" should read --- New Jersey ---.

In Column 6, line 36, "OKASJIB" should read --- PLASKON ---.

In Column 6, line 37, "b 8202" should read --- 8202 ---.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,791,388

Dated February 12, 1974

Inventor(s) Alastair W. Hunter and Neil H. Rosen

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

In Column 6, line 38, "ext" should read --- exit ---.

In Column 6, line 40, "approxmate" should read --- approximate ---.

In Column 6, line 62, "tensil" should read ---tensile---.

In Column 8, line 4, "poly dl lactide" should read --- poly DL lactide---

In Column 8, line 4, "()" should read --- 90 parts ---.

In Column 8, line 17, "esired" should read --- desired ---.

In Column 8, lines 21-22, "entral" should read --- central ---.

Signed and sealed this 22nd day of October 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents