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(54) SYNTHETIC ABSORBABLE SURGICAL DEVICES
 OF POLY(ALKYLENE OXALATES)

(71) We, ETHICON INC., a Corporation organised under the laws of the State of New Jersey, United States of America, of Somerville, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to synthetic absorbable devices, and more particularly, to synthetic absorbable sutures and prostheses comprising sterile fibers of certain poly(alkylene oxalates).

Absorbable filamentary materials have traditionally been comprised of natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable fibers from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable products are described in U.S. Patents, Nos. 3,636,956 and 3,297,033, and elsewhere in the literature. Polyesters of succinic acid have also been suggested for at least partially bioresorbable surgical articles as disclosed, for example, in U.S. Patent No. 3,883,901.

In the case of the present invention, we contemplate the melt-extrusion of certain poly(alkylene oxalates) to provide pliable, monofilament fibers which have a high level of softness and flexibility and which are absorbable in animal tissue without significant adverse tissue reaction. The fibers have good initial tensile and knot strength and can be sterilized with cobalt-60 without serious loss of these properties. The higher alkylene oxalate polymers have good *in vivo* strength retention and are absorbed slowly, while the lower alkylene oxalate polymers are characterized by rapid absorption.

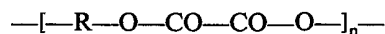
Poly(alkylene oxalates) and the preparation thereof are described in the art.

Carothers et al, J. Amer. Chem. Soc. 52, 3292 (1930), for example describes the ester interchange reaction of diols such as ethylene glycol, 1,3-propanediol, or 1,4-butanediol with diethyl oxalate to yield a mixture of monomer, soluble polymer and insoluble polymer. The reaction of oxalic acid and an alkylene glycol to form polyester resins is described in U.S. Patent No. 2,111,762, while the preparation of polyesters of fiber-forming quality from dicarboxylic acids and diols is described in U.S. Patent No. 2,952,652. Superpolyesters of fiber-forming quality and derived from dibasic acids plus glycols are described in U.S. Patents Nos. 2,071,250 and 2,071,251. Linear polyesters of oxalic acid have been reported as having high melting points, being soluble in many solvents, capable of forming films, and readily hydrolyzed [Savinov et al, Polymer Science USSR 6, 1475 (1964)].

The absorbability of poly(alkylene oxalates) in animal tissue has not been known prior to the present invention, and there has been no suggestion in the art for the use of poly(alkylene oxalates) in surgical applications. In particular, there has been no suggestion in the art that absorbable fibers having good tensile properties could be prepared from poly(alkylene oxalates) or that such fibers would have any useful application in the fabrication of surgical devices.

It is accordingly an object of the present invention to provide absorbable sutures and prostheses of poly(alkylene oxalates).

According to the present invention we provide a synthetic absorbable suture comprising a sterile fiber of a polymer of an alkylene oxalate having a major proportion of units of the formula



wherein R is a C₃ to C₁₆ alkylene group and n is the degree of polymerization resulting in a fiber-forming polymer having an inherent

viscosity (as hereinafter defined) of at least 0.4. The invention also includes a surgical prosthesis comprising a fabric manufactured at least in part from fibers as just specified.

Polymers as just specified can be prepared by the transesterification reaction of an alkylene diol and e.g. diethyl oxalate are melt-extruded into filaments suitable for use as or in the sutures and surgical prostheses. The filaments are characterized by high tensile and knot strength with a high degree of softness and flexibility as characterized by a Young's modulus of e.g. less than 600,000.

In the foregoing formula; R is most preferably a C₄ to C₁₀ alkylene group. The above-mentioned inherent viscosity is that determined at 25°C on a 0.1 percent solution of polymer in chloroform or hexafluoroisopropanol (HFIP).

Alkylene oxalate polymers for use as or in the sutures and surgical prostheses of the present invention are conveniently prepared by an ester interchange reaction between an alkylene diol and a lower ester of oxalic acid in the presence of an ester interchange catalyst. The diol is a C₃ to C₁₆ alkylene diol, and the ester of oxalic acid preferably diethyl oxalate. The ester interchange is preferably conducted in two stages wherein the reactants are first heated with stirring under a nitrogen atmosphere to form a prepolymer with the removal of ethanol, followed by postpolymerization under heat and reduced pressure to obtain a final polymer of the required molecular weight.

The polymer may be melt-extruded through a spinnerett in a conventional manner to form one or more filaments which are subsequently drawn about 4X to 6X in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments are characterized by a straight tensile strength of at least 30,000 psi and a crystallinity of at least about 15 percent.

To further improve dimensional stability and *in vivo* strength retention, the oriented filaments may be subjected to an annealing treatment. This optional annealing treating consists of heating the filaments to a temperature of from about 40° to 80°C, most preferably from about 40° to 60°C while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 40° to 60°C for up to about 24 hours is satisfactory for poly(alkylene oxalate). Optimum annealing time and temperature for maximum improvement in fiber *in vivo*

strength retention and dimensional stability are readily determined by simple experimentation for each particular fiber composition.

The preparation of high molecular weight oriented filaments of poly(alkylene oxalate) is further illustrated by the following examples where all percentages are by weight unless otherwise noted. The following analytical methods were used to obtain the data reported in the examples. Inherent viscosity (N_{inh}) was determined at 25°C on a 0.1 percent solution of polymer in chloroform or hexafluoroisopropanol (HFIP). The infrared spectra of polymer films (cast from CHCl₃ or HFIP) were recorded on a Beckman Acculab 1 spectrophotometer. The NMR spectra of the polymer solutions in CDCl₃ were recorded on an MH-100 or CFT-20 spectrometer. A DuPont 990 DSC apparatus was used to record the glass transition (T_g), crystallization (T_c) and melting temperatures (T_m) of the polymers in nitrogen, using 4 mg samples and a heating rate of 10°C/min or as otherwise specified. The thermo-gravimetric analysis (TGA) data of the polymers were recorded in nitrogen using a DuPont 950 TGA apparatus at a heating rate of 10°C/min and with 10 mg samples. A Philips vertical goniometer with graphite crystal monochromatized copper K α -radiation was used to obtain the X-ray powder and fiber diffraction patterns of the polymers. Crystallinity was determined by the method of Hermans and Weidinger and the diffractometer patterns were resolved with a DuPont 310 curve analyzer.

In vitro hydrolyses of polymer discs (about 1.2 g, 2.2 cm diameter) and monofilaments (8–25 mil) were conducted in a phosphate buffer of pH 7.25 at 37°C.

In vivo absorption (muscle) was determined by implanting two 2 cm segments of monofilament fiber into the left gluteal muscles of female Long-Evans rats. The implant sites were recovered after periods of 60, 90, and 120 and 180 days and examined microscopically to determine the extent of absorption. *In vivo* absorption (subcutaneous) is a nonhistological technique in which continuous observations of the biological degradation of segments of the filament were made by implanting two filaments, 2 cm long, into the abdominal subcutis of young female rats. The implants are readily visible when the skin is wetted with propylene glycol and extent of absorption can be determined by subjective visual examination.

In vivo strength retention was determined by implanting segments of filaments in the posterior dorsal subcutis of female Long-Evans rats for a period of 5 to 30 days. The

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samples were recovered at the designated periods and pull-tested for straight tensile strength.

EXAMPLES

5 General Polymerization Procedure

Diethyl oxalate was heated with a selected diol in a stirred reactor using a stannous alkanoate or oxalate or an organic titanate as a catalyst. The reaction was
10 conducted under a nitrogen atmosphere at suitable temperatures until a substantial portion of the calculated amount of ethanol was obtained. Postpolymerization of the resulting prepolymer was then continued
15 under reduced pressure using a suitable heating scheme. At the end of the postpolymerization period, the molten polymer was allowed to cool slowly at room temperature, isolated, ground and redried
20 at 25° to 80°C (depending on the polymer T_m) *in vacuo* for at least one day. Detailed experimental conditions for the preparation of representative samples of linear polyalkylene oxalates and important properties
25 of the resulting polymers are presented below.

EXAMPLE 1

Poly(trimethylene oxalate)

Distilled 1,3-propanediol (17.48 g, 0.23
30 mole) and diethyl oxalate (29.2 g, 0.2 mole) were mixed with a catalytic amount of stannous oxalate (4.1 mg, 0.02 mmole) under nitrogen. The mixture was heated with stirring while allowing the resulting
35 ethanol to distill at 150°, 120° and 150°C for 0.5, 2 and 4 hours, respectively. The resulting polymer was then cooled to about 100°C and the pressure was reduced to 0.1 mm. The polymerization was continued *in vacuo*
40 at 150°, 160°, 180° and 200°C for 1, 3, 1 and 2 hours, respectively. The polymeric product was recovered as a clear, soft material.

Polymer Characterization

45 N_{inh} in $CHCl_3$ =0.57;
DSC (20°C/min): T_g =-1°C

EXAMPLE 2

Poly(tetramethylene oxalate)

Diethyl oxalate (36.5 g, 0.25 mole) was
50 mixed with 1,4-butanediol (45 g, 0.5 mole) and a 1 percent solution of tetrakis(2-ethylhexyl) titanate (TOT) catalyst (1 ml, 0.012 mmole) and transferred to a resin kettle under a dry nitrogen atmosphere. A
55 prepolymer was formed by heating the reaction mixture under a nitrogen atmosphere for 2 hours each at 140° and 160°C while allowing the formed ethanol to distill. The mixture was then heated under
60 reduced pressure (2-3 mm Hg) at 160° and 180°C for 20 and 2 hours, respectively. The

polymer melt was slow-cooled, quenched in liquid nitrogen, isolated and ground. The ground polymer was redried at room temperature, *in vacuo*.

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Polymer Characterization

N_{inh} in HFIP=0.95

DSC (20°C/min):

T_g =4.5; T_c =22; T_m =105°C

Polymer Melt-Spinning and Fiber Properties

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The polymer was spun using an Instron Rheometer at 110°C with a 30 mil die and a shear rate of 841 sec⁻¹. The extrudates were quenched in ice water, wound and dried *in vacuo* at 25°C. The fibers were drawn 5X at 32°C and the properties of the drawn fibers were as follows:

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Inherent viscosity in HFIP: 0.79

DSC data (10°C/min): T_g =15; T_m =103°C

X-ray data: 50% crystallinity

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Physical Properties:

Fiber diameter=12.9 mil

Straight tensile strength=34,500 psi

Elongation=39%

Modulus=2.19×10⁹ psi

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In Vivo Properties:

After 5 days of implantation in rat muscle, the initial tensile strength of the fiber was reduced from 4.0 lbs to zero. Subcutaneous implantation of the fibers in rats indicated that 50 percent of their apparent mass was absorbed in the first 9 days, and 10 percent remained after 15 days, and absorption was substantially complete
95 after 28 days.

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In Vitro Hydrolysis Data:

Drawn fibers lost 67 percent of their initial mass in 7 days.

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EXAMPLE 3

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Poly(hexamethylene oxalate)

Distilled diethyl oxalate (73.1 g, 0.500 mole) was mixed with 1,6-hexanediol (61.2 g, 0.519 mole) and stannous octoate catalyst (0.33 M in toluene; 0.3 ml, 0.1 mmole)
105 under a dry nitrogen atmosphere in a glass reactor equipped with a mechanical stirrer. A prepolymer was formed by heating the mixture at 120°C for 2 hours and then at 160°C for 3 hours under nitrogen at 1
110 atmosphere while allowing the formed ethanol to distill. The prepolymer was then heated for one hour *in vacuo* (0.1 mm Hg) at 80° and then 90°C. The postpolymerization of the polymer melt was completed by
115 heating at 100°, 115°, 135°, 150°, 170°, 190° and 200°C for 2, 1, 1.5, 4, 6, 1 and 6.5 hours, respectively. The polymer was allowed to cool at room temperature, quenched in

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liquid nitrogen, isolated and ground. The ground polymer was dried *in vacuo* at room temperature.

- 5 Polymer Characterization
 N_{inh} in $CHCl_3=0.83$
 DSC ($10^\circ C/min$): $T_m=70^\circ C$

Polymer Melt-Spinning and Fiber Properties

- 10 The polymer was spun using an Instron Rheometer at $105^\circ C$ with a 40 mil die. The extrudates were quenched in ice water, wound and dried *in vacuo*. The fibers were drawn 5X at room temperature and the properties of the drawn fibers were as follows:

X-ray data: 47% crystallinity

Physical Properties:

- 20 Fiber diameter=8.7 mils
 Straight tensile strength= 5.22×10^4 psi
 Knot strength= 3.70×10^4 psi
 Elongation=33%
 Modulus= 1.89×10^5 psi

In Vivo Evaluation:

- 25 After 3 days of implantation in the rat muscle, drawn fibers retained 35 percent of their original strength. No measurable strength was recorded after 7 days of implantation. After 42 days, absorption of the fiber was about 20 percent complete and
- 30 after 121 days absorption was substantially complete.

In Vitro Hydrolysis Data:

Drawn fibers lost 83 percent of their initial mass in 31 days.

35 EXAMPLE 4

Poly(octamethylene oxalate)

- Using a similar system to that of Example 3, distilled diethyl oxalate (109.6 g, 0.750 mole), distilled 1,8-octanediol (113.6 g, 0.777 mole) and stannous octoate catalyst (0.33 M in toluene-0.455 ml, 0.150 mmole) were mixed under a dry nitrogen atmosphere in a glass reactor equipped with a mechanical stirrer. A prepolymer was formed by heating the mixture at $120^\circ C$ for 12 hours under nitrogen while allowing the formed ethanol to distill. Prior to postpolymerization, the product was heated for 1 hour at $90^\circ C$ and 0.1 mm Hg. The postpolymerization of the stirred polymer melt was completed by heating at 110° , 135° , 150° , 170° and $200^\circ C$ for 3.5, 2.5, 4.5, 0.5 and 5 hours, respectively at 0.1 mm Hg. The polymer was cooled, quenched in liquid nitrogen, isolated, ground and dried *in vacuo* at room temperature. The polymer was then heated at $60^\circ C$ *in vacuo* for one hour and finally at $200^\circ C$ for 6 hours to yield the final product.

Polymer Characterization

N_{inh} in $CHCl_3=0.88$
 DSC ($10^\circ C/min$): $T_m=75^\circ C$

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Polymer Melt-Spinning and Fiber Properties

The polymer was spun according to the procedure described in Example 3. The extrudates were quenched in an ice water bath and subsequently drawn 6X at $64^\circ C$. The properties of the drawn fibers were as follows:

Inherent viscosity in $CHCl_3$: 0.8
 X-ray data: 54% crystallinity

Physical Properties:

Fiber diameter=8.8 mil
 Straight tensile strength= 4.99×10^4 psi
 Knot tensile strength= 3.95×10^4 psi
 Elongation=32%
 Modulus= 1.81×10^5 psi

DSC ($10^\circ C/min$): $T_m=75^\circ C$

In Vitro Hydrolysis Data:

The drawn monofilaments lost 15, 66 and 96 percent of their original weight after 18, 122 and 199 days respectively.

In Vivo Evaluation:

Drawn monofilaments implanted in the posterior dorsal subcutis retained 79, 19 and 0 percent of their original breaking strength (3.16 lbs) after 3, 7 and 14 days, respectively. Fibers implanted into the gluteal muscles of rats to determine their absorption and tissue response characteristics at 3, 21, 42 and 119 days post-implantation showed no absorption up to the 42-day period. At the 119-day period, there was evidence of minimal absorption of some of the fibers.

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EXAMPLE 5

Poly(decamethylene oxalate)

1,10-Decanediol (87.1 g, 0.5 mole) was mixed with diethyl oxalate (58.4 g, 0.4 mole) and a solution of TOT catalyst in toluene (0.012 mmole) under a nitrogen atmosphere. The reaction mixture was heated with stirring while allowing the resulting ethanol to distill at 120° , 130° and $140^\circ C$ for 4, 2.5 and 2 hours respectively. The pressure was then reduced to 0.5 mm while heating to $190^\circ C$ for 20 minutes. The polymerization was continued *in vacuo* at 190° and $210^\circ C$ for 4 and 13 hours, respectively. The polymer was recovered and characterized as follows:

Polymer Characterization

N_{inh} in $CHCl_3=0.45$
 DSC ($10^\circ C/min$): $T_m=77.5^\circ C$

Polymer Extrusion and Fiber Properties

The polymer was extruded at $84^\circ C$ using a 40 mil die. The resulting undrawn

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monofilament had an average diameter of 19 mil.

In Vitro Hydrolysis Data:

The undrawn monofilaments had a weight loss of 1, 11, 38 and 62 percent after 6, 17, 44 and 177 days, respectively.

EXAMPLE 6

Poly(dodecamethylene oxalate)

Distilled diethyl oxalate (14.6 g, 0.100 mole) was mixed with 1,12-dodecanediol (20.8 g, 0.103 mole) and stannous octoate catalyst (0.33 M in toluene—0.061 ml, 0.02 mmole) under a dry nitrogen atmosphere in a glass reactor equipped for magnetic stirring. The prepolymer was formed after heating the mixture at 120°C for 3 hours and 160°C for 2 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill. The mixture was then heated for 6 hours *in vacuo* (0.1 mm Hg) at 200°C and then 210°C for 2 hours. The postpolymerization of the polymer melt was completed after heating at 200°C for 5 additional hours. The polymer was cooled at room temperature and recovered.

Polymer Characterization

N_{inh} in $CHCl_3$ =0.57

DSC (20°C/min): T_m =91°C

EXAMPLE 7

Poly(hexadecamethylene oxalate)

Using a similar system to that used for Example 6, diethyl oxalate (8.0 g, 0.055 mole), 1,16-hexadecanediol (14.6 g, 0.057 mole) and stannous octoate catalyst (0.33 M in toluene—0.033 ml, 0.01 mmole) were mixed under an atmosphere of dry nitrogen in a glass reactor equipped for magnetic stirring. The prepolymer was formed after heating the mixture at 120°C for 3 hours and then at 160°C for 2 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill. The mixture was then heated *in vacuo* at 0.1 mm Hg and at 200°, 210° and 230°C for 2, 2 and 3 hours, respectively. The postpolymerization of the stirred polymer melt was completed after heating at 200°C for 4 additional hours. The polymer was cooled and recovered.

Polymer Characterization

N_{inh} in $CHCl_3$ =0.45

DSC (20°C/min): T_m =95°C, T_g =40°C

The preceding examples refer to the preparation of specific alkylene oxalate homopolymers. However, use may also be made of copolymers of C_3 to C_{16} alkylene oxalates with a minor proportion of one or more other compatible monomers which produce nontoxic and absorbable polymers, and of physical mixtures of the homopolymers and copolymers mentioned.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the polymers employed for the purposes of the present invention. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis-2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments even more pliable, but it also serves as a processing aid in extrusion and thread preparation. As used herein, the term "inert" means materials that are chemically inert to the polymer, and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed.

Filaments employed for the purposes of the present invention are adversely affected by moisture and are accordingly preferably packaged dry in a substantially moisture-free environment within a hermetically sealed package. A suitable package is fabricated of two sheets of aluminum foil or an aluminum foil-plastics laminate heat-sealed or bonded with adhesive around the border of the package to hermetically seal the cavity and isolate the contents of the package from the external atmosphere. The package may be evacuated or filled with a dry, inert gas such as air or nitrogen. Such packages are conventionally used for storing hydrolytically sensitive materials comprised of polymers of glycolide and/or lactide as illustrated, for example, in U.S. Patent No. 3,636,956.

Filaments as specified in respect of the present invention may be used as monofilaments or multifilaments and may be woven, braided, or knitted alone or in combination with other absorbable fibers such as polyglycolide or poly(lactide-co-glycolide), or in combination with nonabsorbable fibers such as nylon, polypropylene, polyethylene-terephthalate, or polytetrafluoroethylene to form fabrics having use as surgical prostheses, e.g. in the repair of arteries, veins, ducts and esophagi. Those filaments which have an initial straight tensile strength and knot strength of at least 40,000 psi and 30,000 psi respectively, retain a substantial portion of their initial tensile strength after 21 days *in vivo*, and are substantially completely absorbed *in vivo* within about 6 months, are also useful as synthetic absorbable sutures.

Multifilament yarns constructed of the poly(alkylene oxalate) filaments specified in respect of the present invention together with nonabsorbable filaments are useful in the fabrication of surgical fabrics which are only partially absorbable for applications

where long-term fabric strength retention is desirable even after the absorbable components have been replaced by natural tissue growth into the fabric. The relative proportions of absorbable filaments and nonabsorbable filaments may be varied to obtain the absorption and strength retention characteristics desired in the particular prosthesis concerned.

Composite fabrics of absorbable and nonabsorbable materials may be fabricated by conventional textile processes such as weaving, knitting and nonwoven felting as described in U.S. Patents Nos. 3,108,357 and 3,463,158. Methods of weaving and crimping tubular vascular prostheses are described in U.S. Patent No. 3,096,560. In addition, surgical aids may be composed of "bi-component filaments" of absorbable and nonabsorbable components as described in U.S. Patent No. 3,463,158, the teaching of which is incorporated herein by reference.

Fabrics containing filaments as specified in respect of the present invention are useful in surgical applications where an absorbable aid or support is required, as for example, in hernia repair and in supporting damaged liver, kidney and other internal organs where a temporary aid during healing is needed.

WHAT WE CLAIM IS:—

1. A synthetic absorbable suture comprising a sterile fiber of a polymer of an alkylene oxalate having a major proportion of units of the formula



wherein R is a C₃ to C₁₆ alkylene group and n is the degree of polymerization resulting in a fiber-forming polymer having an inherent viscosity of at least 0.4 as determined at 25°C on a 0.1 percent solution of polymer in chloroform or hexafluoroisopropanol.

2. A suture of Claim 1 further characterized by a straight tensile strength of at least 30,000 psi and a Young's modulus of less than 600,000 psi.

3. A suture of Claim 2 wherein R is a C₄ to C₁₀ alkylene group.

4. A suture of Claim 1 wherein said polymer is a copolymer of a C₃ to C₁₆ alkylene oxalate with a minor proportion of at least one other monomer

copolymerizable therewith to form an absorbable polymer.

5. A suture of Claim 4 wherein said other monomer is lactide, glycolide or a mixture thereof.

6. A suture of Claim 1 comprising poly(tetramethylene oxalate).

7. a suture of Claim 1 comprising poly(hexamethylene oxalate).

8. A suture of Claim 1 comprising poly(octamethylene oxalate).

9. A suture of Claim 1 comprising poly(decamethylene oxalate).

10. A suture of Claim 1 comprising a major proportion of said polymer and a minor proportion of at least one other synthetic absorbable polymer.

11. A suture of Claim 10 wherein said other synthetic absorbable polymer is selected from homopolymers and copolymers of lactide and glycolide.

12. A suture of Claim 1 packaged in a sterile and moisture-free environment within a hermetically sealed and substantially moisture impervious container.

13. A suture of Claim 4 packaged in a sterile and moisture-free environment within a hermetically sealed and substantially moisture impervious container.

14. A surgical prosthesis comprising a fabric manufactured at least in part from fibers as specified in claim 1.

15. A surgical prosthesis of Claim 14 wherein said fibers are further characterized by a straight tensile strength of at least 30,000 psi and a Young's modulus of less than 600,000 psi.

16. A surgical prosthesis of Claim 15 wherein said polymer is a homopolymer of poly(alkylene oxalate) or a copolymer of a C₃ to C₁₆ alkylene oxalate with a minor proportion of at least one other monomer copolymerizable therewith to form an absorbable polymer.

17. Synthetic absorbable sutures and prostheses according to claim 1 or 14, comprising fibers substantially as described in the foregoing Examples.

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