July 8, 1969 M. WAGNER 3,454,011

SUTURES AND PROSTHETIC PATCHES

Filed Dec. 28, 1966

Fig. 1

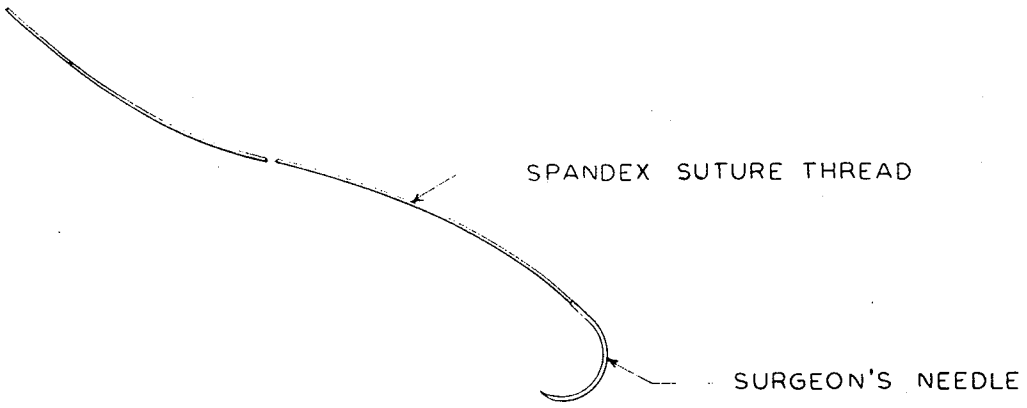
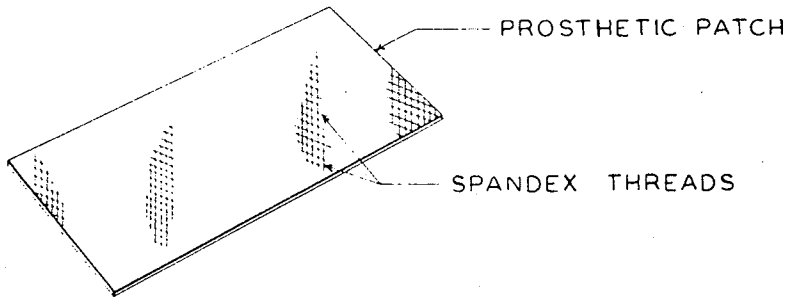


Fig. 2



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SUTURES AND PROSTHETIC PATCHES

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ABSTRACT OF THE DISCLOSURE

This invention relates to materials generically identified as spandex materials. More specifically, this invention relates to the efficacy of spandex as suture and prosthetic patch material. Disclosed herein is a suture thread attached at one end of a surgeon's needle and comprising at least one thread formed of elastomeric spandex material consisting of a long chain synthetic fiber-forming polymer comprised of at least 85% of a segmented polyurethane.

This invention relates to sutures and prosthetic patches for use by surgeons in closing wounds, repairing tissue and organs, etc. More specifically, this invention relates to the utilization of a material as sutures and prosthetic patches which has not heretofore been employed in such use.

PRIOR ART

The typical prior art materials used or tried as sutures and prosthetic patches include: natural fibers such as cotton, silk and linen; animal materials such as "cat" and/or intestinal gut of various types and sheep gut; various metal wires; and synthetic materials such as nylon, polyester fibers such as polyethylene terephthalate, fluorocarbon polymers and polyacrylic materials. These widely-dissimilar materials have a common feature in that all of them are relatively rigid or inelastic. When used in thread or fiber form as a suture, such materials will commonly exhibit an elongation at break of around fifty or sixty percent at the most, and much less in most cases. Thus, fibers of nylon, fluorocarbons such as "Teflon," polyester fibers such as "Dacron," cotton and silk all have rupture elongations in the range of ten to fifty or sixty percent. These figures are the elongation at break and are generally measured on a tenacity scale ranging from one to eight grams per denier, with most of the listed materials showing the stated elongation at rupture at a tenacity of between 1.5 and 8 grams per denier. When threads of such materials have been used as sutures in the sewing of a wound or incision, it has been noted that as the tissue heals it will swell and displace itself but the suture material will not displace along with the tissue so that it may lacerate or tear the tissue and fairly large lacerations can occur where the thread traverses the opposed tissue. Some of these relatively rigid suture materials are difficult to sew in many tissues, as for example the liver, which are friable or easily lacerate or separate. In the field of plastic surgery this can be a special problem since the plastic surgeon usually wants a facial wound to heal with a smooth unmarked surface for cosmetic purposes. Thus these known suture materials still present problems to the surgeon who desires to obtain the best possible healing of a wound.

PRESENT INVENTION

This invention is based upon the discovery that a certain class of highly elastic materials can be utilized as sutures and prosthetic patches and produce results not attainable with the prior art materials described above. The particular materials to which this invention relates are those identified as spandex materials which are

generically defined under regulations issued by the Federal Trade Commission. The spandex materials have a high degree of elasticity and, for example, a typical spandex fiber will show an elongation at rupture of 500 to 600% under a tenacity of about 0.7 gram per denier. It has been found that a spandex material of the foregoing type, when used as a suture, can expand and contract with the swelling of the tissue which it is used to sew together and thereby eliminate the ripping, tearing or cutting of the tissue which would otherwise take place with the use of a rigid, inelastic prior art suture material and, that at the same time, it has sufficient strength and retention properties to hold in apposition the tissues being joined together tightly against one another for proper healing. It has further been found that spandex materials of the described type are inert and can be present in animal tissue for extended periods of time without any adverse reaction, unlike other elastomeric materials such as rubber. It has further been found that spandex materials have satisfactory tensile strength properties for use as suture materials and retain a sufficient degree of the strength during the time they would normally be used as a suture. Furthermore, the spandex fibers have a low coefficient of friction which enables the surgeon to easily draw the material through a tissue. Spandex fibers have also been found to possess excelent knot properties such as ease of formation, small size, and knot-holding capability not found in other known suture materials, especially among the synthetic fibers. Another important facet of the present discovery is that the spandex materials can be sterilized by known techniques and although most sterilization methods affect some of the physical properties of the spandex, they do not cause deleterious effects which would inhibit the use of the spandex fibers as suture materials. The suture and prosthetic patch materials of this invention are useful for closing wounds in mammalian tissue and organs.

Among the principal objects of this present invention are to utilize a material as a suture or prosthetic patch which has not heretofore been used in such environments, to provide a suture material which has important advantages over the prior art materials, and to provide devices for use in suturing wounds which include spandex fiber of high elasticity. A more specific object is to provide the new or improved details of structure and/or method herein claimed. These and other objects will appear in the description which follows.

The ensuing description is made with reference to the accompanying drawings that form a part hereof and show, by way of illustration and not of limitation, two specific forms in which this invention can be practiced. These will be described in detail and a number of examples will be set forth which demonstrate the utility of the suture and prosthetic patch materials according to this invention. It is to be understood that other embodiments of this invention may be used and changes may be made in the embodiments described without departing from the scope of the present invention. In the drawings:

FIG. 1 is a view of a surgical needle with a suture attached in accordance with this invention; and

FIG. 2 is a perspective view of a prosthetic patch material also according to this invention.

FIGS. 1–2

The first drawing, FIG. 1, illustrates a surgeon's needle to which is attached a suture which, in accordance with this invention, consists of a thread of spandex material. In the form illustrated, the spandex suture is inserted in a hollow portion at the end of the needle, and the needle is swaged in order to hold the suture. It has been found that any of the usual methods of joining suture threads to surgeons' needles can be used with the present inven-

tion, including swaged and flanged connections. Although a surgeon's needle with a single strand is shown in FIG. 1, the present sutures may also be used with a needle that has an eye in it so that there will be two strands. FIG. 2 shows a prosthetic patch which is formed from a section of woven material having spandex threads for both the warp and the weft threads. The threads of the patch of FIG. 2 are of the same composition as the suture shown in FIG. 1. In either case, the spandex threads may be in the form of a monofilament, a plurality of monofilaments combined to form a thread or a plurality of monofilaments fused together, and may be of any desired cross-sectional shape, such as round, rectangular, etc. Thus the term thread as used in this description and in the claims is employed in a generic sense.

DESCRIPTION OF MATERIALS

As mentioned above, the Federal Trade Commission has established the following generic definition for the term spandex, which definition is adopted herein wherever spandex is used in the specification or the claims:

> "a manufactured fiber in which the fiber-forming substance is a long chain synthetic polymer comprised of at least 85% of a segmented polyurethane."

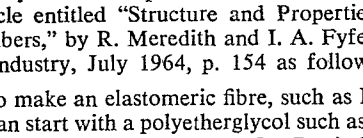
The preceding definition is contained in FTC Rule 7(*k*) issued under the Textile Fiber Products Identification Act, 15 U.S.C. §70, in the Rules and Regulations amended to Mar. 13, 1966. Some spandex fibers within this definition that are commercially available from several sources under various trademarks or trade names are:

(1) Lycra.—E. I. du Pont de Nemours
(2) Interspan.—Interspan, Inc.
(3) Blue C.—Polythane Corporation (Chemstrand)
(4) Vyrene.—United States Rubber Co.
(5) Glospan.—Globe Manufacturing Co.
(6) Duraspan.—Carr-Fulflex, Inc.

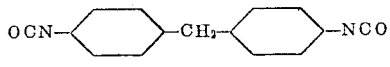
The manufacturers of these spandex materials would not disclose the chemical composition of their materials to the applicant and such information is maintained by them as confidential proprietary information.

However, it can be said that spandex elastomeric fibers are the reaction products of polyether or polyester glycols containing alcoholic hydroxyl groups, diisocyanates, and diamines. More than one polyester glycol or more than one polyether glycol or a physical combination of polyester and polyether glycols can be used to form the polymer, and it is also possible to employ poly-ether-ester glycols which are formed from the chemical combination of a polyester and a polyether. The preparation of one commercially available spandex fiber has been described in an article entitled "Structure and Properties of Elastomeric Fibers," by R. Meredith and I. A. Fyfe in Textile Institute Industry, July 1964, p. 154 as follows:

> "To make an elastomeric fibre, such as Lycra, one can start with a polyetherglycol such as polytetrahydrofuran, $H(—O—R—O—R—)_nOH$ of molecular weight about 1,000 which is reacted with toluene diisocyanate



> to form a long molecule with hydroxyl groups at its ends.
>
> This is further reacted at 100° C. with diphenylmethane diisocyanate,



> to form a macrodiisocyanate which is dissolved in anhydrous dimethyl formamide, and after a determination of free diisocyanate groups, a calculated quanity of a diamine, $H_2N \cdot R'' \cdot NH_2$ is added to produce the elastomeric polyurethane. If we denote the polyetherglycol by A, the diisocyanates by B and B' and the diamine by C, the polyurethane takes the form
>
> $$[—CB'ABAB'—]_n$$
>
> where A contains many flexible ether linkages, the AB or AB' bond it a urethane linkage and the CB' bond is a urea linkage. The object is to produce an essentially linear polymer that can be dissolved in a suitable solvent and spun into fine filaments.
>
> The fibre contains a large fraction of polyether chain molecules of softening point around 30° C. which are held at intervals by strong inter-molecular forces between isocyanate groups in neighbouring molecules. These act as pseudo cross-links and represent stiff regions of high softening point. This combination of flexible molecules and limited number of cross-links produces a rubbery material."

Polyester glycols used in spandex fiber production typically have a molecular weight of 300 to 5,000, preferably 1,500 to 3,000, and may be a chain extended polyester made from a glycol, often a mixture of ethylene and propylene glycols, and a saturated organic dicarboxylic acid, often adipic acid. Usually the glycol contains from 4 to 20 carbon atoms, and the acid contains from 4 to 20 carbon atoms. An excess of the glycol over the acid is used in preparing the polyester, so that the resulting polyester contains terminal hydroxyl groups. Usually an amount of glycol is used to give a polyester having a hydroxyl number of 20 to 225, and preferably 36 to 75, and a low acid value less than 6 and preferably less than 1. In general the most suitable polyesters are chiefly linear in type with melting point levels of 90° C. or lower. Other examples of suitable polyesters for use in preparing the prepolymer are polyethylene adipate, polyethylene adipate-phthalate, polyneopentyl sebacate, etc. If desired, small amounts of tri-alcohols such as trimethylolpropane or trimethylolethane may be included in the preparation of the glycoldicarboxylic acid polyester, and such modified forms of polyester are included within the term polyester as used herein.

Polyether glycols used in producing spandex fiber may be homopolymers or copolymers. Their essential features are that they be difunctional and have a melting point below 50° C. The polyethers are primarily poly (alkylene oxide) glycols but some of the oxygens may be replaced with sulfur atoms and/or some of the alkylene groups may be replaced with arylene or cycloaliphatic radicals. Even where the linkages and types of organic radicals are the same, the compositions may still be copolymers, such as a copolyether derived from more than one glycol. Copolymer formation is useful when a macromolecular homopolymer melts too high to be useful in the process. Copolymers usually melt lower and show less tendency to produce undesirable crystallization in this segment of the final copolymer. These macrointermediates may have hydroxyl or chloroformate end groups, as long as they are capable of reacting with one of the monomeric constituents of the higher melting segment to form a urethane linkage. Representative polyether glycols which may be used include polyoxathiaalkylene glycols, such as poly(1,4-dioxa-7-thianonane), poly(1-oxa-4-thiahexane), and poly(1,6-dioxa - 9 - thiahendecane); poly(alkylene oxide) glycols, such as poly(ethylene oxide) glycol, poly(propylene oxide) glycol, poly(tetramethylene oxide) glycol, and poly(decamethylene oxide) glycol; polydioxolane and polyformals prepared by reacting formaldehyde with other glycols or mixtures of glycols, such as tetramethylene glycol and pentamethylene glycol. Some of the alkylene radicals in these compositions may be replaced with arylene or cycloaliphatic

radicals. The preferred polyether macrointermediate of this type appears to be poly(tetramethylene oxide) glycol and/or its derivatives. Particularly useful are copolymers formed when a mol of this glycol is reacted with 2 mols of p,p'-methylenediphenylisocyanate and this derivaive with isocyanate ends is reacted with ethylenediamine. "Dimers" prepared by linking 2 mols of these glycols with 1 mol of a diisocyanate are reported to be particularly useful in preparing desirable copolymers. The corresponding "trimers" have also found many uses. The "dimers" and "trimers" prepared by reacting poly(tetramethylene oxide) glycol with 4-methyl-m-phenylene diisocyanate or p,p'-methylenediphenylisocyanate are said to be particularly useful when these products with hydroxyl ends are reacted with 2 mols of p,p'-methylenediphenylisocyanate and then reacted subsequently with a diamine, particularly ethylenediamine.

Representative aromatic diisocyanates used in producing spandex fiber are m- and p- phenylene diisocyanate, toluene diisocyanate, p,p'-diphenyl diisocyanate, 1,5-naphthalene diisocyanate, and aromaticaliphatic diisocyanates such as p,p'-methylenediphenylisocyanate. Many other isocyanates are suitable for production of spandex elastomer fibers and are known to those skilled in the art of producing such polymers.

The primary diamines used to prepare the spandex polymers may be aliphatic, alicyclic, aromatic, or heterocyclic diamines. Suitable diamines include ethylenediamine, tetramethylenediamine, heptamethylenediamine, octamethyelnediamine, p-xylylenediamine, 1,4-diaminocyclohexane, p-phenylenediamine, 1-methyl-2,4-diaminobenzene, bis(p-aminocyclohexyl) methane, and many others. Derivatives of these diamines may also be used as long as the substituents do not interfere with the polymerization. For example, they may have hydrocarbon side chains or be substituted with halogens or nitro groups which are inert under the polymerization conditions. The diamines may be used in the form of their bis(carbamyl halides), which can be reacted with diamines to form ureas.

The reactants can be fed simultaneously to a reaction zone or intermediates may be formed and condensed in various sequences. The polymers may be prepared by melt, interfacial or solution polymerization techniques, although melt polymerization may result in unsatisfactory gel formation and cross linking. More definite methods for production of the polymers and forming spandex fibers from them and suitable materials are contained in United States Patent 2,929,804 (believed to pertain to the Lycra brand of spandex fibers) and United States Patent 3,009,762 (believed to relate to the Vyrene brand of spandex fibers).

Thus, the spandex fibers are segmented polyurethanes which have segments derived from polyether or polyester glycols often referred to as the "soft" segments and are relatively flexible, connected through urethane linkages

to segments derived from diamine compounds, generally referred to as the "hard" segments and are relatively inflexible. They may be designated by the type formula $(—CBAB—)_n$ wherein A is the residue from after removal of the terminal hydroxyl groups from a hydroxyl-terminated polyether gylcol or polyester glycol, B and B' are residues from the diisocyanate compounds reacted with the terminal hydroxyl groups of the A precursor, and C is the segment resulting from the diamine reactant, with urethane linkages

contained in the AB bond and urea linkages in the CB bond. The polymers thusly defined can be dissolved in a suitable solvent and spun into filaments. For the purposes of this invention the spandex may be used as monofilaments or monofilaments twisted into threads or as fused multifilaments.

The spandex threads and fibers as used in this invention are elastomeric in that they can be stretched several times their original length and recover their original size upon release of the stress. Thus, they commonly have a breaking elongation at least about 400–700% (dry) and an elastic recovery over 90% at high elongations such as over 50%. They exhibit viscoelastic behavior in their load-elongation properties. As compared to other materials used as sutures, spandex fibers will usually have a fiber breaking strength, or fiber tenacity, under 1.0 grams per denier, generally in the range of 0.5 to 0.8 g.p.d., whereas the prior materials have a fiber tenacity over 1.0 g.p.d. Thus the Lycra spandex used in the following examples has a fiber breaking strength of about 0.6 to 0.8 g.p.d. and the Vyrene spandex 0.5 to 0.6 g.p.d.; in contrast, synthetic materials used as sutures have a fiber breaking strength as follows: nylons 4.5 to 9.2 g.p.d., polyesters (such as Dacron) 4.4 to 7.8 g.p.d., fluorocarbons (such as Teflon) 1.7 g.p.d., and acrylic polymers 2.0 to 3.5 g.p.d. Cotton and silk are in the range of 2.4 to 5.1. All of the foregoing are dry tenacities. As suggested previously, the spandex fibers also have a markedly higher rupture elongation when compared to prior art sutures as is shown in the following list of percentage ranges, although specific materials may vary somewhat from the numerical values listed for their class of fibers:

	Percent
Cotton	<10
Silk	10–25
Polyester fibers	10–45
Fluorocarbon fibers (Teflon)	<15
Nylon	15–40
Acrylic fibers	20–40
Spandex fibers (Lycra, Vyrene)	510–700

EXAMPLES

This invention will be more fully understood by reference to the following examples, which are set forth to illustrate this invention but not to limit its scope. Examples 1–7 demonstrate the efficacy of spandex as suture and prosthetic patch material, with experimental work based upon testing performed in suturing the skin, internal organs and intestinal tract in rabbits and dogs.

EXAMPLE 1

Fifty rabbits were used for evaluation of spandex fiber as a skin suture. The rabbits were anesthetized by intravenous Nembutal and 2 parallel incisions were made on the backs of each animal; one incision was sutured with No. 560 denier spandex fiber and the other was sutured with either cotton, silk, Mersilene or Dermalene. The animals were sacrificed at two week and four week intervals and comparative histologic studies were made. Photomicrographs of tissue sections showed that the tissue reaction to the spandex suture was characterized by a well defined hyaline fibrosis with little or no foreign body granulomatous reaction. In comparison, observations of tissue sections with the other suture materials showed substantial foreign body reaction.

EXAMPLE 2

In this example, spandex fiber was utilized as a suture material for the repair or suture of fractured or lacerated solid organs. Twenty-five rabbits were anesthetized with intravenous Nembutal and their livers were either completely lacerated or fractured through three quarters of the substance of an entire lobe. These were then sutured in an interrupted manner with No. 560 denier spandex fiber. The results were gratifying for in the apposition of the tissues as fragile as the liver substance in a rabbit, the spandex suture could be snugged up and approximate the lacerated surfaces without lacerating the host tissue. This latter condition could not be obtained with the usual

prior art suture materials. Histological studies were made of the tissues after two, four and eight week intervals. There was no obvious cellular reaction in the parenchyma to the spandex suture. On the surface of the liver the reaction was similar to that observed in skin as reported in Example 1.

EXAMPLE 3

To assay the use of spandex as an intestinal suture, twenty mongrel dogs were used and, under intravenous Nembutal anesthesia, the small bowel was transected in some animals at one site, usually the ileum, and in others at two sites, the ileum and jejunum. No. 560 denier spandex fiber was used as the intestinal suture with a two layer closure. The animals were sacrificed at two, four, and eight week intervals for histological study. There was no evidence of dehiscence or leak at the suture line in any of the animals of the series. The suture material maintained its elasticity throughout the time it was in the host animal as, in each instance, material still manifested its elastic quality at the time of sacrifice. The histological study showed no foreign body reaction to the spandex in the suture line of the intestine.

EXAMPLE 4

In this example, spandex fiber kitted into a fabric was used as a patch graft. Thirty-five mongrel dogs were used and defects were created in the abdominal aortas which were 2.5 to 3.0 cm. in length and at least one-third to one-half the circumference of the host vessel. Patches of the knitted spandex material were applied to these defects; all of the animals survived. Aortograms, flow studies, and histologic studies were performed on twenty-four of the animals. (See Example 5.) The histologic studies showed a pseudo-intimal layer covering the spandex material, which was surrounded by a reactive fibrosis and minimal inflammatory reaction on the contiguous margin of the host vessel. Eleven of the animals were kept for prolonged survival studies.

EXAMPLE 5

The long term effects of spandex suture and patch materials were assessed using twenty-four dogs as the host animal. Spandex fibers were applied as skin sutures, and as sutures in the intestinal tract. Patches of spandex fabric (see Example 4) were applied to the abdominal aorta. Nine of the dogs were sacrificed at the end of twelve months, twelve at the end of fourteen months, and three at the end of sixteen months. Histological studies showed the same results as in the preceding examples, indicating no adverse long-term effects of the spandex sutures and patches. Eight of the animals were sacrificed at the end of twenty months, and the histologic studies showed the same findings as were noted at three months and twelve months.

Examples 1–5 utilized one type of commercial spandex, "Lycra," spandex No. 1 as listed previously, and the following two examples were initiated to determine whether all six of the spandex fibers previously cited behaved in the same manner for the purposes of this invention.

EXAMPLE 6

Using twenty-four rabbits, each of the six spandex fibers listed above ("Lycra," "Interspan," "Blue C," "Vyrene," "Glospan," and "Duraspan") were implanted as skin sutures on islands of the abdominal wall of each animal. Six 2 cm. incisions were cut on the abdonimal wall of each animal and each incision was sutured with a different one of the six enumerated spandex fibers so that every fiber was used on the same animal at the same time. Twelve animals were sacrificed at the end of fourteen days and examined in gross and histologically, and the remaining twelve animals were sacrificed after twenty-one days and examined in gross and histologically. The findings of such examinations were essentially the same as the preceding examples and there was a minimal local reaction histologically by the host animal to the six spandex fibers, thereby demonstrating that they are all useful for the practice of this invention. There was no evidence of any abnormal cells near the implanted suture materials.

EXAMPLE 7

The six spandex fibers used as skin sutures in Example 6 were tried as vascular sutures on the vein and artery of the kidney, namely the renal artery and renal vein. Twelve medium-sized mongrel dogs were used as the host animals. The renal artery and renal vein of each animal was transected and then sutured with the various spandex fibers. After reestablishing the continuity of the vessel, the vascular clamps were removed proximal to the suture line and there was complete integrity of the suture line. Some of the animals were sacrificed after seven days and some after twenty-one days and it was noted that there was no evidence of any thrombosis, except in the renal vein of one animal; there was complete healing, and there was no evidence of tear of the respective vessels. Histologic study of the renal vein and renal arteries after sacrifice showed that there was a good intimal covering over the suture line with no evidence of any local histological reaction by the host in either the artery or the vein.

In the preceding examples, the spandex threads were of various sizes, as follows: spandex No. 1, 560 denier; spandex No. 2, 104 gauge (about 500 denier); spandex No. 3, 420 denier; spandex No. 4, 110 denier; spandex No. 5, 560 denier; and spandex No. 6, 95–S (a flat form that had to be slit into thread form).

EXAMPLE 8

In this example, tests were made on most of the spandex materials listed above to determine whether they could be sterilized without losing their desirable properties for suture materials as disclosed herein. Examples of spandexes Nos. 1–5 were subjected to sterilization by exposure to ethylene oxide and to sterilization by irradiation and two physical properties were measured as an indication of the effects of sterilization on the materials. In the ethylene oxide sterilization, the samples were exposed to a mixture of 20% ethylene oxide and 80% "Gentron" for two hours and then aerated for at least 24 hours. In the irradiation sterilization, the samples were radiated with a cobalt source to a dosage of 2.5 megarads. Random samples of each material were selected for the tests.

One test involved a measurement of the "holding power" of sterilized and unsterilized spandexes, on the basis this would be a useful index since the main purpose of a suture is to hold tissues in a required position. For this characteristic, the samples were fastened into the serrated jaws of an Instron tensiometer. An unstretched sample one inch in length was stretched to five inches and then held at five inches for two minutes. The tensile force required to stretch the material to five inches was measured at the beginning and at the end of the holding period, and the ratio of the tensile force after two minutes holding to the tensile force when the material was initially stretched to five inches is referred to herein as "holding power." Ten samples of each spandex were measured, except that twenty samples were used for spandex No. 1. The results are reported in Table I below.

After each sample was held at five inches elongation for two minutes as specified above, it was cycled between four and five inches three times. The Young's modulus of elasticity over the last 20 grams of force of the final cycle was computed and the results are reported in Table II below.

The data indicate that the holding power of all samples was effected little if any by either method of sterilization. Further, the tests did not show that Young's modulus as determined herein was altered by either method of sterilization, but the variation within samples was great

enough that changes of 20% or less in the modulus would have been masked by the variation. It is therefore believed that these tests, in conjunction with Examples 1–7, indicate that sterilization does not impair the ability of spandex materials to provide an elastic suture material in accordance with this invention. In the foregoing tests, spandex No. 1 was 560 denier; No. 2 about 500 denier; No. 3 840 denier; No. 4 about 1330 denier; and No. 5 420 denier. While suitable samples of spandex No. 6 were not available for the above tests, its action in Examples 6 and 7 when it was sterilized and used as a suture indicate it would behave similarly.

The effects of a variety of sterilization methods were tested with samples of spandex No. 1. Seventy samples of 560 denier fiber were randomly selected and randomly placed into seven groups and treated as follows: group No. 1, left unsterilized; group No. 2, sterilized with steam; group No. 3 sterilized with ethylene oxide (2 hours, mixed with inert gas); group No. 4 sterilized with Bard-Parker solution; group No. 5 sterilized with Amphyl solution; group No. 6 sterilized by flash autoclave (280° F., 3 min.); and group No. 7 soaked in Tis-U-Sol solution for thirteen days at 36° C. Sterilization was done by standard hospital procedures. For the testing, each sample was fastened in an Instron tensiometer with serrated jaws and stretched at a rate of five inches per minute. The elongations at 30 grams and at 60 grams tensions were recorded. At 60 grams tension, the cross-head of the instrument was stopped and after two minutes relaxation the tension recorded. The crosshead was then moved back until all tension was removed and the sample allowed to recover for one minute; permanent stretch after one minute after removal of tension was then recorded. It was found that, in varying degrees, all methods of sterilization altered the physical characteristics of the material. These tests indicated that ethylene oxide sterilization, flash sterilization and steam sterilization reduced the measured properties to a lesser degree than the others and that the results of these three methods correlated closely with the untreated material; thus there was small enough departure from the unsterilized characteristics than the properties of relaxation, permanent stretch and elongation to indicate they each would be satisfactory. It is believed at this time that similar results would apply to the other spandex fibers with respect to a qualitative assessment of these various sterilization methods.

TABLE I

Material (spandex)	Holding power, untreated material [1]	Tensile force, after 2 min. holding/tensile force, initial: Ethylene oxide sterilization [1]	Tensile force, after 2 min. holding/tensile force, initial: Irradiation sterilization [1]
No. 1	0.503	0.515	0.508
No. 2	0.568	0.576	0.559
No. 3	0.445	0.470	0.418
No. 4	0.654	0.687	0.680
No. 5	0.613	0.632	0.596

[1] Each ratio is the mean of 10 samples for spandex Nos. 2–5 and 20 samples for spandex No. 1

TABLE II

[Young's modulus [1] (change of force in gms.÷elongation in in./in.)]

Material (spandex)	Untreated	Ethylene oxide sterilization	Irradiation sterilization
No. 1	718	592	586
No. 2	639	574	710
No. 3	567	562	533
No. 4	688	505	558
No. 5	989	891	1,117

[1] Calculated as the slope of the stress-strain curve of a sample 1 inch long stretched to five inches measured over the last 20 grams of stress; mean of 10 samples for spandex Nos. 2–5 and 20 samples for spandex No. 1.

There has thus been described the use of spandex materials for sutures and prosthetic patches which, it is believed, have not heretofore been employed for such purposes. It has been found that the suture and patch materials of this discovery possess important and useful advantages not found in typical prior art materials. In comparison to other synthetic plastic suture materials, such as polyethylene and polyester fibers, spandex fibers are much more elastic and pliable; these features enhance the use of spandex as a suture material since they allow the approximation of tissues without tension and maintain comfortable apposition of the tissues, both characteristics being ideal attributes of suture material.

Further, the spandex fibers did not lacerate tissue when snugged up and the spandex sutures would give or stretch with the swelling or edema of host tissues at the suture line, if and when it occurs.

Rigid, as opposed to elastic suture materials, are difficult to sew in many tissues, such as the friable organs such as the liver and the commonly-used suture materials characteristically readily cut such friable tissues when used therein. This may occur, for example, after the wound is sutured when the tissue might swell and displace itself; the suture materials of the rigid type would not be displaced together with the swelling of the tissue so they would thereby cut the tissue and fairly large lacerations could sometimes be developed. However, this type of problem does not exist with the elastomeric spandex suture materials as disclosed herein. At the same time, the spandex sutures have sufficient strength and tension properties to hold the tissues being joined tightly against one another to allow proper healing of the wound.

It was further noted that knot technic was facilitated because of the softness and elasticity of the spandex material in that the "throws" could be snugged up and locked in place whereas with polyester sutures such as Dacron and with polyethylene sutures the first throw has a marked tendency to open because of the inherent stiffness of the respective fibers. In comparison to silk, cotton and other synthetic sutures now available, it was noted that the spandex fibers or sutures of this invention had a soft-locking property which was comparatively better. Particularly in the case of monofilaments or a plurality of filaments fused or otherwise combined to form essentially a thread of monofilament construction, it was noted that the sutures easily glided through tissues.

The spandex materials were found to be superior for sutures because of the almost complete inertness they exhibited with respect to tissue reaction. As the preceding examples demonstrate, spandex fibers have been left in test animals for extended periods of time without any adverse chemical reaction to the host tissue. This is in contradistinction to chemical reactivity of elastomeric materials such as rubber which are quite reactive chemically and can cause an inflammation with body tissue. The spandex sutures also showed excellent knot-holding characteristics in that the knots do not slip and become untied; this can sometimes occur with other synthetic materials such as nylon.

It is pointed out that it is to be expected that others may devise spandex materials of different composition from those specifically exemplified herein and still remain within the precepts of the present invention. It is to be understood that it is intended to cover all changes and modifications of the examples of this invention herein shown for the purpose of illustration which do not constitute a departure from the spirit and scope of this invention.

I claim:

1. As an article of manufacture, a medical suture comprising:

(1) a surgeon's needle, and

(2) a suture thread attached at one end of the needle and comprising at least one thread formed of elastomeric spandex material consisting of a long chain synthetic fiber-forming polymer comprised of at least 85% of a segmented polyurethane.

2. An article of manufacture according to claim 1 wherein:

each suture is a monofilament thread.

3. An article of manufacture according to claim 1 wherein:

each thread comprises a plurality of monofilaments.

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