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# SYNTHETIC SURGICAL SUTURES

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This invention relates to a sterile surgical suture of high-strength, heat-resistant, high density, oriented lower alkylene polymers of linear polyethylene or isotactic polypropylene of sufficient stereospecific orientation to have the characteristics described in more detail below, of monofilament or twisted or braided multifilament structure, a package containing the same, and the use thereof.

This application is a continuation-in-part of application Ser. No. 804,588, filed Apr. 7, 1959, and of application Ser. No. 817,734, filed June 3, 1959, both now abandoned.

The medical profession has for a long time been looking for more satisfactory sutures to be used in closing wounds whether such wounds are incisions from operations, or tears, cuts or abrasions from accidental or other causes. Many materials have been suggested for use as sutures. Sutures are divided into two broad classes, the adsorbable sutures such as catgut sutures which are absorbed by the body tissues, and non-absorbable sutures which either remain in the tissues in substantially their original form for prolonged periods or are removed from the skin surfaces after the underlying tissues have been healed. For non-absorbable sutures many materials have been suggested which range from cotton and silk through various synthetic filaments such as nylon to stainless steel or nickel or other metallic filaments. While each of these has certain advantages there are corresponding disadvantages and the search for sutures with more suitable properties continues.

Sterility is a most important characteristic of a suture. Any material to be used as a suture must have such physical characteristics that the suture can be sterilized. The most convenient method of sterilizing is by heat in which the suture is heated under such conditions that any microorganisms or deleterious materials are rendered inactive. A second common method is to sterilize using a gaseous sterilizing agent such as ethylene oxide. Other methods of sterilizing include radiation by X-rays, gamma rays, neutrons, electrons, etc., or high intensity ultra-sonic vibrational energy or combinations of these methods. Preferably a suture should have such physical characteristics that it may be sterilized by any of these methods. The present linear polyethylene and isotactic polypropylene sutures may be sterilized by any of these methods.

Other things being equal, the surgeon usually prefers the suture which is strongest. In spite of many disadvantages stainless steel has met with considerable acceptance because of its extremely high tensile strength. Such plastic materials as nylon are meeting currently with considerable commercial acceptance because of comparatively high tensile strength. Additionally, the suture material needs high knot strength and knot security. That is, the suture strand must have such characteristics that a knot can be tied in the suture. Some materials are so brittle that if a suture made from them is knotted, the strength of the suture is markedly reduced. For some materials an overhand knot in a strand can reduce the strength of the strand by a factor of two or more. In addition to knot strength, the suture should have such characteristics that the knot when tied remains in position. For example, even though nylon is used to a considerable extent as a suture material, special knots are required and even then the knot security of nylon sutures is not all that is desired.



Additionally, a suture should have good handling qualities. Such qualities are extremely hard to characterize, but nonetheless are very obvious to those using a suture. For example, the suture should be "throwable" so that when the free end is placed in position by the surgeon it will remain in that position until moved. Similarly, the suture should have such characteristics that it can be thrown or moved from side to side and yet retain the position into which it is thrown.

The suture should be comparatively impermeable by body fluids. Such materials as silk and cotton usually require special treatment to cut down on capillarity so that body fluids, and micro-organisms, cannot travel along the suture. The migration of micro-organisms along the suture is particularly undesirable.

It is desirable that the suture be one that can be colored so that it contrasts with tissues and can be easily located in the operating field even though it is of small diameter.

Additionally, the suture material must be such that there are no undesirable interactions with body tissues. Some materials which would otherwise be satisfactory for sutures are irritating to body tissues and may even be responsible for neoplastic growth. The reaction of the various body tissues in which the suture is used to the suture material must be of an acceptable nature, for periods at least as long as the maximum period of implantation of the suture.

It has now been found that a high-strength, heat-resistant, high density linear polyethylene or isotactic polypropylene as either a monofilament suture or as a braided or woven suture constructed from a plurality of smaller filaments, which filaments may be round, elliptical, flat or other cross-sections, meets these requirements and gives a suture which is unexpectedly and uniquely useful to the surgeon.

*Linear polyethylene*

The present linear polyethylene has sufficient orientation to have a higher density and a higher strength than conventional polyethylene. The characteristics as compared with ordinary polyethylene are as set forth in the following table:

| | Ordinary Polyethylene | Linear Polyethylene |
|---|---|---|
| Melting Range, °F | 240–255 | 260–280 |
| Softening Range, °F | 225–240 | 250–260 |
| Decomposition, °F | Above 600 | Above 600 |
| Odor | None | None |
| Plasticizer | None | None |
| Burning | Slow | Slow |
| Specific Gravity | 0.92 | 0.95–0.96 |
| Tenacity, gr./den | 2.1–2.3 | 6–9 |
| Ultimate Elongation, percent | 25–50 | 10–25 |
| Strength: | | |
| P.s.i. "as is" | 25,000–27,000 | 70,000–120,000 |
| P.s.i. "at rupture" | 33,000–37,000 | 80,000–140,000 |
| Diam.—Single Strand Break in Pounds (mean values): | | |
| .008" | 1.4 | 4.3 |
| .010" | 2.2 | 7.0 |
| .012" | 3.2 | 9.2 |
| Dimensional Stability (percent): | | |
| Shrinkage at 165° F | 5–8 | 1–5 |
| Shrinkage at 212° F | 30–50 | 5–10 |

The strength in pounds per square inch at rupture is the strength calculated on the cross-section of the stretched material rather than that of the original strand. The dimensional stability and ultimate elongation may be controlled to a considerable extent during manufacture by the stretching of the fiber during the orientation process and by subsequent annealing processes. As is known to those skilled in the art, polyethylene is cast or extruded as a filament, which filament is stretched to several times its original length which orients the fiber giving it a characteristic X-ray diffraction pattern and greatly increases

its strength and reduces its elongation. By tempering, that is, heating the filament up to temperatures of about 212° F. or slightly higher, any shrinking or shape change takes place before use, so that the filament has the desired characteristics.

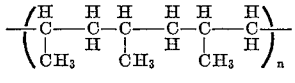
For a filament 0.008" in diameter, the U.S. Pharmacopoeia strength requirement is 2.0 lbs. pull. Ordinary polyethylene filament does not meet this minimum. As can be seen from the above table, linear polyethylene exceeds such a minimum by a factor of more than 2.

The linear polyethylene having a specific gravity of at least about 0.95 has the desired characteristics and can be readily identified by specific gravity as well as melting range. Linear polyethylene can have a specific gravity as high as at least about 0.96 or slightly more.

Linear polyethylenes may be purchased on the commercial market either as the resin suitable for extrusion into a filament or as a filament. Such polyethylenes are frequently manufactured by passing ethylene under pressure at an elevated temperature over an insoluble solid chromic oxide type catalyst. From about 0.05 to 0.1% of a dialkylphenol sulfide is preferably used as an antioxidant. Such materials may be purchased under the trade name "Santo-Nox."

*Isotactic polypropylene*

The physical characteristics of polymers of alpha-olefins, that is those olefins where the double bond occurs between the terminal carbon atom and the carbon atom adjacent to it, are determined to a great extent by the relative position in space of the pendant alkyl groups. For example, in the case of polypropylene, the pendant —$CH_3$ groups may be randomly distributed sterically along the polymethylene backbone chain or they may be oriented according to a definite spatial pattern. In the first case in which the —$CH_3$ groups have no systematic distribution in space the polymer is termed "atactic" and shows none of the properties desired in a fibrous suture material. At room temperature, this form of polypropylene is a rubbery gummy solid with no crystallinity and of very poor strength properties. With the second type of polypropylene, the pendant —$CM_3$ groups are uniformly arranged with respect to the backbone chain. If the normally zigzag pattern of the polymethylene chain of polypropylene is projected to a two dimensional representation, the methyl side groups then appear as uniformly distributed in space along the main chain according to the following formula:



Such polymers have been termed by Giulio Natta as "isotactic." This term has become accepted in the industry. Because of the regularity of configuration, this type of polypropylene is highly crystalline, has a high melting point and very good strength properties—all qualities desired in a satisfactory material for sutures.

Actually, in practice the synthesis of an entirely isotactic polymer is rarely if ever achieved. And it is doubtful if the 100% isotactic configuration would be as useful as those of a somewhat lower degree of isotacticity as are produced commercially, as will be explained later. The polymers produced by the new stereospecific catalysts such as those described by Karl Ziegler and Giulio Natta can be considered as being composed of several different types of macromolecules: (1) completely isotactic molecules, (2) completely atactic molecules and (3) molecules in which both isotactic and atactic portions occur along the same chain. Ordinary, so-called isotactic polymers are probably predominantly of the third type, that is, molecular backbone chains that are made up of stretches of polymer of atactic configuration between the segments that are completely isotactic. Such types show a lower degree of crystallinity than the totally isotactic variety. The presence of the minor amounts of atactic groupings, either occurring as atactic chains or atactic portions of otherwise isotactic molecules, is believed to lead to greater flexibility than would otherwise be realized if they were not present. Polypropylenes of lower than the maximum isotacticity or crystallinity are preferred for the most desirable fiber characteristics.

The term "isotactic polypropylene" is here used to designate those polymers which contain a majority of molecules in the essentially isotactic configuration but also are composed of some atactic segments or molecules.

*Preparation of crystalline polypropylene*

Crystalline polypropylene polymers are prepared by carrying out the polymerization, generally in a hydrocarbon diluent, under conditions where moisture and oxygen are rigorously excluded or closely controlled. As catalysts, several types may be employed. A preferred type consists of the reaction product of a compound of a transition metal of Groups IV–B to VI–B and metal alkyls of metals selected from Groups I to III of the periodic table. For example, a titanium halide together with an aluminum alkyl are satisfactory for polymerizing propylene to products of varying degrees of crystallinity. To a considerable extent, the degree of isotacticity and the resulting crystallinity can be controlled over a wide range depending upon the particular catalyst used. Titanium tetrachloride and aluminum triethyl yields polymers of a lower isotactic content than when the trichloride of titanium is used together with the same aluminum triethyl. Following the polymerization that is carried out at temperatures near or somewhat above room temperature, the product is freed of contaminating catalyst residues by suitable treatments, dried and melt extruded in fiber form. Much improved strength properties are imparted by elongating the resin during the drawing operation which results in alignment of the polymer molecules.

In addition to the metal-organic complexes mentioned above as catalysts, certain metal oxides such as chromia on silica-alumina and molybdena on alumina have been reported as being applicable for the production of isotactic polyolefins.

A typical suitable isotactic polypropylene has the following properties:

| | |
|---|---|
| Melting range | 325° to 335° F. |
| Softening range | 280° to 300° F. |
| Decomposition | Above 550° F. |
| Odor | None. |
| Plasticizer | None. |
| Burning | Slow. |
| Specific gravity | 0.87 to 0.94. |
| Tenacity | 5 to 10 grams per denier. |
| Ultimate elongation | 15 to 25%. |
| Molecular weight | 300,000 to 450,000. |

The isotactic polypropylene is cast or extruded as filament, which filament is stretched to several times its original length which orients the fiber giving it a characteristics X-ray diffraction pattern and greatly increases its strength and reduces its elongation.

The linear polyethylene or isotactic polypropylene can be colored by mechanically blending with a pigment. About 1% or less of pigment can give a desired color. Pigments such as titanium dioxide, iron oxide or carbon black give identifiable colors. Other colored pigments which do not cause deleterious tissue reactions may also be used to impart color to the strands.

A single strand or monofilament is a very useful suture. The strands of the suture can be round or oval, flat, square, triangular or other configuration. Greater flexibility may be obtained by using twisted or braided constructions in which a plurality of filaments or "ends" are constructed in a fashion similar to those used with silk

sutures. Inasmuch as linear polyethylene and isotactic polypropylene are comparatively resistant to the action of water, special treatments are not normally required to prevent capillarity in multiple strand sutures. The sutures preferably have a needle attached to one end thereof so that the operation of threading is obviated. The sutures are packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred. As is well known, such needles cause less tissue damage. Conveniently, monofilament or multifilament strands are formed, cut to convenient lengths, then attached to eyeless needles, wound on reels if desired and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other gaseous sterilizing agent and sealed in accordance with known practices; or the suture may be sealed in the envelope and then sterilized by using heat or radiation including X-rays, gamma rays, electrons, neutrons, etc. or the package may be one which is permeable to a gaseous sterilizing agent. Each of these processes gives a satisfactory product and the present invention is not limited to a single method of sterilization.

The choice of size of the suture depends on the surgeon's choice for a particular operative or repair technique.

A group of sutures of linear high density polyethylene were sterilized. A group of thirty rabbits had their abdomens shaved, the skin sterilized and the sterile sutures were then placed laterally through the muscles of the ventral wall just below the skin. The suture ends were cut short so that no suture material protruded through the skin and the animals were returned to their cages. Rabbits were sacrificed at intervals of 3 to 40 days and both gross and miscroscopic examination of the implanted sutures were made. The short term results showed a minimal reaction. There was practically no exudation and no evidence of irritation. On microscopic examination it was found that fibroblasts did not develop until 20 days postimplantation but after 40 days a small, dense fibrous capsule was produced. This is a normal and desirable end reaction and is the usual response of animal tissue to the presence of an inert foreign body.

On similar tests in mice over a period of from 20 days to 9 months before sacrificing the animals, microscopic examination showed some evidence of inflammatory cells after 20 days but these had disappeared by 3 months. During the entire period of observation for 12 months no abnormal cells or cell structures were observed and regular tissue architecture was found to exist in the vicinity of the suture. Dense fibrous capsules of moderate size were present which is the normal and desired reaction.

Similar results are obtained using isotactic polypropylene sutures.

The reactions observed were comparably less than is usually obtained with silk or cotton sutures. It was similar to that obtained with monofilament nylon. The linear polyethylene is more flexible and easier to handle and shows better knot characteristics and less elongation than does monofilament nylon.

The isotactic polypropylene sutures have superior knot holding strength. For example, in a standard inclined plane tensile tester, a surgeon's knot was tied around a ½" diameter rod, the loop slipped off the rod, and placed over two hooks, which were pulled apart. The knot was tested both dry, and after soaking in water. For a 0.0083" monofilament isotactic polypropylene, of 6 samples, 4 broke, and 2 slipped. The average failure was at 6.3 pounds. When repeated wet, 3 broke, and 3 slipped, at an average failure of 4.8 pounds.

For linear polyethylene, with a 0.0081" monofilament suture, 6 of 6 slipped at an average of 1.9 pounds dry; and 6 of 6 slipped with an average of 1.8 pounds wet.

Isotactic polyproplene in braided form is an excellent suture. It can be used either in the undyed or white form, or in dyed form, depending on the color preference of the using surgeon. Carbon black is an innocuous pigment suitable for the purpose. In describing the filaments used, the industry abbreviation can be used as for example, a 60/20 multifilament designates a total of 60 denier, and 20 filaments per strand. Good results are obtained using such 60/20 strands at:

| Size (U.S.P.) | Sleeve (denier) | Carriers | Core | Total | Pick/inch |
|---|---|---|---|---|---|
| 3/0 | 60 | 8 | 0 | 480 | 40 |
| 4/0 | 60 | 4 | 60 | 300 | 40 |
| 5/0 | 60 | 4 | 0 | 240 | 40 |
| 6/0 | 60 | 3 | 0 | 180 | 40 |

The sutures are stretched slightly while heated between 109° C. and 125° C.

Either raw, ethylene oxide sterilized or heat sterilized (15 pounds steam, 30 minutes), the size and strength were satisfactory. The knot pull, that is the pull over a surgeon's knot, was slightly superior in the heat sterilized product. This is about:

| | Pounds |
|---|---|
| 3/0 | 3.5 |
| 4/0 | 1.9 |
| 5/0 | 1.6 |
| 6/0 | 1.2 |

Dry or wet, the suture usually breaks before the knot slips.

The appearance and hand are similar to silicone coated silk. If any evidence of capillarity appears in any sample or construction, silicone coating can be used to completely prevent any capillarity, however slight.

The braided construction is well tolerated in both experimental animals and in human use.

Both monofilament and multifilament braided sutures are used in normal operating room procedures on humans in procedures which require non-absorbable sutures. The sutures can be withdrawn when used as a skin suture and are left embedded when used as a buried suture. The suture of either linear polyethylene, or isotactic polypropylene, as specified, are found to have satisfactory characteristics from the standpoint of tissue reaction insofar as can be observed. Naturally, the human subjects could not be sacrificed for autopsy.

I claim:

1. A needled surgical suture comprising a linear polyethylene suture attached to a surgical needle, said needle and said suture being sterile, said linear polyethylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 260 to 280 |
| Softening range, ° F. | 250 to 260 |
| Decomposition point, ° F. | Above 600 |
| Odor | None |
| Plasticizer | None |
| Specific gravity | 0.95 to 0.96 |
| Tenacity, grams per denier | 6 to 9 |
| Ultimate elongation, percent | 10 to 25 |
| Strength, on original diameter, pounds per square inch | 70,000 to 120,000 |

2. A surgical suture package comprising a sterile enclosure and therein a sterile needled surgical suture comprising a linear polyethylene suture attached to a surgical needle, said linear polyethylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 260 to 280 |
| Softening range, ° F. | 250 to 260 |
| Decomposition point, ° F. | Above 600 |
| Odor | None |

| | |
|---|---|
| Plasticizer | None |
| Specific gravity | 0.95 to 0.96 |
| Tenacity, grams per denier | 6 to 9 |
| Ultimate elongation, percent | 10 to 25 |
| Strength, on original diameter, pounds per square inch | 70,000 to 120,000 |

3. A method of closing a wound in living tissue which consists of sewing the edges of the wound with a suture consisting of a linear polyethylene filament, leaving the linear polyethylene in the tissue until the wound is substantially healed and self-supporting, and removing the linear polyethylene suture, said linear polyethylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 260 to 280 |
| Softening range, ° F. | 250 to 260 |
| Decomposition point, ° F. | Above 600 |
| Odor | None |
| Plasticizer | None |
| Specific gravity | 0.95 to 0.96 |
| Tenacity, grams per denier | 6 to 9 |
| Ultimate elongation, percent | 10 to 25 |
| Strength, on original diameter, pounds per square inch | 70,000 to 120,000 |

4. A method of repairing a wound in living tissue which consists of approximating living tissue with a buried suture of linear polyethylene, and leaving the linear polyethylene in the tissue, said linear polyethylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 260 to 280 |
| Softening range, ° F. | 250 to 260 |
| Decomposition point, ° F. | Above 600 |
| Odor | None |
| Plasticizer | None |
| Specific gravity | 0.95 to 0.96 |
| Tenacity, grams per denier | 6 to 9 |
| Ultimate elongation, percent | 10 to 25 |
| Strength, on original diameter, pounds per square inch | 70,000 to 120,000 |

5. A needled surgical suture comprising an isotactic polypropylene suture attached to a surgical needle, said needle and said suture being sterile, said isotactic polypropylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 325 to 335 |
| Softening range, ° F. | 280 to 300 |
| Decomposition, ° F. | Above 550 |
| Odor | None |
| Plasticizer | None |
| Burning | Slow |
| Specific gravity | 0.87 to 0.94 |
| Tenacity, grams per denier | 5 to 10 |
| Ultimate elongation, percent | 15 to 25 |
| Molecular weight | 300,000 to 450,000 |

6. A surgical suture package comprising a sterile enclosure and therein a sterile needled surgical suture comprising an isotactic polypropylene suture attached to the surgical needle, said isotactic polypropylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 325 to 335 |
| Softening range, ° F. | 280 to 300 |
| Decomposition, ° F. | Above 550 |
| Odor | None |
| Plasticizer | None |
| Burning | Slow |
| Specific gravity | 0.87 to 0.94 |
| Tenacity, grams per denier | 5 to 10 |
| Ultimate elongation, percent | 15 to 25 |
| Molecular weight | 300,000 to 450,000 |

7. A method of closing a wound in living tissue which consists of sewing the edges of the wound with a suture consisting of an isotactic polypropylene filament, leaving the isotactic polypropylene in the tissue until the wound is substantially healed and self-supporting, and removing the isotactic polypropylene suture, said isotactic polypropylene having approximately the following characteristics:



| | |
|---|---|
| Melting range, ° F. | 325 to 335 |
| Softening range, ° F. | 280 to 300 |
| Decomposition, ° F. | Above 550 |
| Odor | None |
| Plasticizer | None |
| Burning | Slow |
| Specific gravity | 0.87 to 0.94 |
| Tenacity, grams per denier | 5 to 10 |
| Ultimate elongation, percent | 15 to 25 |
| Molecular weight | 300,000 to 450,000 |

8. A method of repairing a wound in living tissue which consists of approximating living tissue with a buried suture of isotactic polypropylene, and leaving the isotactic polypropylene in the tissue, said isotactic polypropylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 325 to 335 |
| Softening range, ° F. | 280 to 300 |
| Decomposition, ° F. | Above 550 |
| Odor | None |
| Plasticizer | None |
| Burning | Slow |
| Specific gravity | 0.87 to 0.94 |
| Tenacity, grams per denier | 5 to 10 |
| Ultimate elongation, percent | 15 to 25 |
| Molecular weight | 300,000 to 450,000 |

9. A surgical suture package comprising a sterile enclosure and therein a sterile needled surgical suture comprising an oriented lower alkylene polymer suture attached to a surgical needle, said polymer of the suture being selected from the group consisting of linear polyethylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 260 to 280 |
| Softening range, ° F. | 250 to 260 |
| Decomposition point, ° F. | Above 600 |
| Odor | None |
| Plasticizer | None |
| Specific gravity | 0.95 to 0.96 |
| Tenacity, grams per denier | 6 to 9 |
| Ultimate elongation, percent | 10 to 25 |
| Strength, on original diameter, pounds per square inch | 70,000 to 120,000 |

and isotactic polypropylene having approximately the following characteristics:

| | |
|---|---|
| Melting range, ° F. | 325 to 335 |
| Softening range, ° F. | 280 to 300 |
| Decomposition, ° F. | Above 550 |
| Odor | None |
| Plasticizer | None |
| Burning | Slow |
| Specific gravity | 0.87 to 0.94 |
| Tenacity, grams per denier | 5 to 10 |
| Ultimate elongation, percent | 15 to 25 |
| Molecular weight | 300,000 to 450,000 |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