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## [54] IMPREGNATION OF POLYFILAMENTOUS SUTURES WITH SYNTHETIC POLYMER PARTICLES


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[52] **U.S. Cl.** .....**128/335.5,** 117/101, 117/141, 117/161 R

[51] **Int. Cl.** .....**A61l 17/00**

[58] **Field of Search** .....117/101, 141, 145, 161 R, 169; 128/335.5



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[57] **ABSTRACT**

Polyfilamentous sutures having the attributes of a monofilamentous suture are prepared by impregnating the sutures with an aqueous dispersion of inert, synthetic polymeric particles and then subjecting the impregnated suture to centrifugal force to simultaneously extract water and dry the suture.


**6 Claims, No Drawings**

# IMPREGNATION OF POLYFILAMENTOUS SUTURES WITH SYNTHETIC POLYMER PARTICLES

This invention relates to surgical sutures. More particularly, the invention relates to sutures having decreased reactivity with tissue and to a method for their preparation.

Sutures are classified either as absorbable or nonabsorbable and may be polyfilamentous or monofilamentous. Polyfilament sutures are preferred by surgeons because they have superior knotting characteristics relative to monofilament materials. On the other hand, monofilament sutures are preferable for the patient as there is less trouble in cases of infection.

It is generally accepted that monofilaments, such as monofilament stainless steel, monofilament nylon, monofilament polyethylene and monofilament polypropylene are the most inert of the nonabsorbable sutures. When implanted in an area where infection occurs, as a rule, they are not "spit" spontaneously by the wound, nor do they require surgical removal. On cross section, all of these monofilaments have one thing in common. They are solid with no "dead spaces" or interstices.

On the other hand, braided and twisted sutures when implanted where infection occurs, will, as a rule, be "spit" spontaneously by the wound, or require surgical removal in order for healing to occur. On cross section, the braided and twisted sutures consist of many filaments and dead spaces. For example, on cross section, braided silk has 40 to 50 percent dead space.

On the basis of the above facts, it seems possible that there is a direct relationship between dead spaces in a suture and the incidence of spontaneous spitting or the necessity for surgical removal of the suture when infection occurs. If this hypothesis is correct, monofilaments should be the sutures of choice for the patient undergoing surgery. However, surgeons have a great deal of difficulty in their use. All of them are stiff, difficult to knot, and have a tendency to open spontaneously. Some, in addition, have sharp ends, kink, or are too elastic. All monofilaments apparently pose difficulties in surgical techniques. Many surgeons continue to use the monofilaments despite their problems because of the excellent patient response. However, obviously, monofilaments cannot be used if the surgical knotting technique becomes inadequate.

It is an object of the present invention to provide a method whereby polyfilament sutures can be imbued with monofilament characteristics.

These and other objects, which will become apparent in light of the description which includes a preferred embodiment, are achieved according to the invention by substantially eliminating the dead air spaces in a polyfilamentous suture by filling the interstices of the silk suture with a plurality of solid particles of synthetic polymeric materials. It has been discovered that the reactivity of the polyfilamentous suture can be reduced to such an extent that reactivity of the suture is as low as reactivity of a monofilament when these solid particles are incorporated therein.

The inert material used to fill the sutures may be any suitable inert, insoluble, synthetic polymeric material small enough to penetrate the interstices of the silk suture. Tetrafluroethylene polymers such as Teflon(polytetrafluoroethylene) are particularly suitable as particles. Other inert, insoluble synthetic resins which can be used include polyolefins such as polyethylene, polypropylene and the like; polydiolefins such as polymers of butadiene and isoprene; polystyrene; polyesters, polyamides and like materials. Aqueous dispersions of these materials such as the aqueous dispersions of Teflon described in Berry, U.S. Pat. No. 2,478,229 are suitable to incorporate the particles into the suture. Saturated aqueous dispersions are particularly suitable. Ordinarily, the inert particles employed will have a particle size of up to 1 micron.

The sutures which can be improved according to this invention include all nonabsorbable sutures. Illustrative of such sutures are polyfilament sutures made from silk; hydrophobic synthetic materials such as polyesters (e.g. "Dacron"), polyolefins (e.g. polypropylene), polyamides (e.g. nylon and polyacrylonitrile), and like materials; cotton and linen.



It is believed that by filling the dead space within the interstices of the silk suture, the pockets which are conducive to harboring invading organisms are eliminated or at least reduced to an extent that clinical results indicate that the suture is monofilamentous. In other words, while it is not certain that the voids are eliminated, the sutures produced in accordance with this invention behave like a monofilament. In any event, the amount of the particles introduced into the suture should be an amount sufficient to render the suture substantially monofilamenteous. It is preferred, however, that the particles substantially fill the dead space within the interstices of the suture. The exact amount of particles necessary to fill the dead spaces within the suture varies with the nature and configuration of the suture and, of course, on the density of the particulate matter employed. For instance, a minimum of about 6 percent by weight of polytetrafluoroethylene based on the weight of the suture up to as much as may be impregnated into the suture and which will remain there is generally used to render the suture substantially monofilamentous. The maximum will depend upon techniques as well as materials and pressurized impregnations that may be used. It should be noted, however, that a suture exhibiting monofilamentous characteristics can be obtained without entirely filling the dead spaces in the suture.

Impregnation of the suture is accomplished in accordance with the present invention by immersing the suture in an aqueous dispersion of the solid polymeric particles for a time sufficient to introduce said polymeric particles into the suture. After the immersion, the impregnated suture is subjected to centrifugal force to extract the water carrier and simultaneously dry the suture. This extraction-drying step has been found to provide a suture having the polymeric particles distributed and set uniformly and homogeneously throughout the entire suture. Thus, the method of the invention prevents the dripping and exuding of the aqueous dispersions from the impregnated suture which causes nonuniform distribution and loss of impregnated particulate matter.

Any suitable centrifuge or spinning means capable of providing a centrifugal force sufficient to remove the water carrier and dry the suture while spinning can be used. It is preferred, however, that a relatively slow extractor be employed in order to avoid the throwing off of impregnated solid particles that is likely to occur with excessively fast extractors. Although fast extractors, for example, extractors having a spinning rate of 1600 to 1750 or more r.p.m., can be employed for the extraction-drying operation, they frequently necessitate repeated impregnation-spinning cycles to provide the desired final product. Use of slower extractors for the extraction-spinning operation such as an extractor having a spinning rate of about 700 r.p.m., for example, provides the desired impregnated suture in a single cycle. The spin time will vary, of course, with the centrifugal force to which the impregnated suture is subject. With the slower extractors, the spin time is usually at least 1 minute. If desired, heat may be provided the spinning means to reduce the spinning time.

Wax, of course, has been used for treating polyfilament silk sutures for years. Likewise, silicones have also been proposed to treat "Dacron" and silk polyfilament sutures for various reasons. In these and all analogous instances, however, the sutures when used clinically have behaved like polyfilaments and not like monofilaments. If is believed that the monofilament characteristics achieved by the present invention are due primarily to the use of dispersions of the solid particles to load the suture with the particulate matter. The old wax-type and silicone treatments have been strictly concerned with the use of liquid solutions of the was or silicon material.

The following examples are included to further illustrate the present invention.

## EXAMPLE I

A silk suture is immersed in a suspension of colloidal size Teflon (polytetrafluoroethylene) particles available from Dupont as Teflon Te 3170, and having an average particle size of about 0.2 micron. The suspension described by Berry, U.S. Pat. No. 2,478,229 is also suitable for this purpose. The suture has a core of 3 ends of 2 threads and a braided cover of 12 ends of 2 threads. The total denier of the suture is 420. The impregnation is continued for 5 minutes after which it is subjected to spinning and drying for 10 minutes in a spin-extractor at a spinning rate of 700 r.p.m. The resulting suture exhibits a weight gain of about 9 percent and behaves substantially like a monofilament. The particles of Teflon remain tenaciously imbedded in the body of the suture and repeated wash cycles will not dislodge a detectable amount thereof.

The sutures can be sterilized in the usual manner and at any stage of manufacture or may be sterilized by the user. Since silk sutures tend to swell in water or steam, it is preferred to sterilize them by electromagnetic radiation techniques or with ethylene oxide. The sutures may, of course, be attached to surgical needles.

## EXAMPLES II–III

Polyfilamentous silk sutures exhibiting monofilament characteristics can be prepared by substituting the following synthetic particles in the process described in Example I:
Example II—polyethylene; Example III—polystyrene in latex

## EXAMPLE IV

A 4–0 polyfilamentous suture made from Dupont type 55 Dacron and having a 4 thread core of 56 denier and a braided cover with two threads of 13–15 denier per carrier is provided with monofilamentous characteristics by impregnating the suture by the method described in Example I above.

It is claimed:

1. A method for imparting attributes of a monofilament to a polyfilament suture comprising the steps of immersing a polyfilamentary suture in an aqueous dispersion of insoluble, inert synthetic polymeric particles, the particles being of a size sufficiently small to enter within the interstices of the suture, maintaining the immersion to introduce said polymeric particles into said suture in an amount sufficient to imbue the polyfilament suture with substantially monofilamentous properties and subjecting said impregnated suture to centrifugal force to simultaneously extract water and dry said suture.

2. A method according to claim 1 wherein the suture is polyfilament silk and the synthetic polymeric particles are particles of tetrafluoroethylene polymer.

3. A method according to claim 2 wherein the tetrafluoroethylene particles are polytetrafluoroethylene particles having an average size of up to 1 micron.

4. A method according to claim 3 wherein the suture is filled with at least 6 percent by weight said particles based on the weight of the suture.

5. A suture comprising a polyfilamentary silk suture having a plurality of fine, solid particles of inert, insoluble, synthetic polymeric material incorporated in the interstices thereof in an amount sufficient to imbue the polyfilament silk suture with substantially the properties of a monofilament.

6. The suture of claim 5 wherein the solid particles are of tetrafluoroethylene polymer.

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