United States Patent Office 3,322,125
Patented May 30, 1967

3,322,125

SUTURES AND METHOD OF MAKING SAME

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No Drawing. Filed Apr. 4, 1966, Ser. No. 539,619
4 Claims. (Cl. 128—335.5)

This application is a continuation in part of application Ser. No. 230,284 filed Oct. 12, 1962, now abandoned.

This invention relates to surgical sutures. More particularly, the invention relates to polyfilamentous sutures having decreased reactivity with tissue.

Sutures are classified either as absorbable or non-absorbable 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 non-absorbable sutures. When implanted in areas 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, all braided and all 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. All of these braided and twisted materials have one thing in common. On cross-section, they 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 these despite the 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 properties. It is a further object to provide polyfilament sutures having attributes of a monofilament suture.

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 substantially filling the interstices of a polyfilament suture with a plurality of particles of an inert material. It has been discovered that the reactivity of the polyfilament 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 sutures which can be improved according to this invention include all non-absorbable sutures. However, for reasons appearing hereinafter, polyfilament sutures made from materials which do not swell in water such as

the hydrophobic synthetics, polyesters, polyolefins, polyamides and the like are more suited to improvement by the present invention than those made from materials like silk which do swell in water.

The inert material used to fill the sutures may be particles of an inert material which are small enough to penetrate the interstices of the suture. Teflon (polytetrafluoroethylene) particles are particularly suitable as are particles of the other inert and insoluble synthetic resins such as those mentioned which can be used as sutures. Aqueous dispersions of these materials, such as the aqueous dispersions of Teflon described in Berry, U.S. Patent No. 2,478,229 are suitable to incorporate the particles into the suture. Saturated aqueous dispersions are particularly suitable.

Sutures made in accordance with the invention have been tried in hundreds of clinical cases and the results have been very successful. In the smaller sutures (sizes 3–0 and below) substantially all clinical results with the sutures tested were as good as with a monofilament suture. With larger sutures, results are improved with respect to untreated sutures but have not been as free from reaction within the suture as with monofilaments.

It is believed that by substantially filling the dead space within the interstices of the suture, the pockets which are conducive to harboring invading organisms are eliminated or at least reduced to an extent that the 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 clinically like a monofilament. 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. In general, however, with hydrophobic sutures which do not swell in water such as polyesters etc., a minimum of about 5 percent by weight up to as much as may be crammed into the suture and which will remain there can be used to render the suture substantially monofilamentous. The maximum will depend on techniques as well as materials and pressurized impregnations may be used. It should be noted, however, that substantial elimination of tissue reaction can be achieved without filling the suture to an extent equal to a theoretical maximum. For example, clinical results show that with from about 8 to 14 percent by weight of Teflon particles, a polyester suture can be rendered substantially non-reactive. The theoretical amount of Teflon which could be incorporated, however, is substantially higher. Since silk and the like swell in use, however, it is preferred to modify hydrophobic type sutures according to the invention.

Wax, of course, has been used for treating polyfilament silk sutures for years. Other materials, such as silicones, have also been proposed to treat 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. It is believed that this result is due primarily to the use of dispersions of particles to load the suture with particulate matter. The old wax-type treatments have been strictly concerned with the use of solutions of the wax material.

Example I

A 4–0 suture made from Du Pont type 55 Dacron is immersed in a suspension of colloidal size Teflon particles available from Du Pont as Teflon TE3170, and having an average particle size of about 0.2 micron. The suspension described by Berry, U.S. Patent No. 2,478,229 is also suitable for this purpose. The suture has a four thread core of 56 denier and a braided cover made with a twelve carrier braider with two threads of 13–15 denier

per carrier. Total denier of this conventional suture was 392. The polymer of the Dacron fiber is polyethylene terephthalate, a polyester wherein the ester linkage occurs in the polymer chain. The impregnation was continued for several minutes and water was removed and the suture dried. The weight gain was about 9 percent. The suture was then hot stretched at a platen temperature of 450° F. on a six-spindle hot stretching machine made by the W. M. Steel Company (model 115), 40 percent based on its original length.

The suture before treatment was naturally water proof and thus non-capillary. In clinical use the untreated suture caused a normal amount of tissue reaction. Clinical use of the treated suture, however, was essentially free of any reaction and the suture behaved as a monofilament. Hundreds of other sutures ranging in size from 3–0 to 6–0 were used and, of these, all but those of sizes above 3–0 behaved substantially like monofilaments. Some incidences of tissue reaction were reported with clinical use of the larger sutures but much less reaction occurred than would be normal with these sutures. In preparing these sutures, the length and nature of the impregnation treatment was such that from about 8 to 14 percent of Teflon particles by weight based on the polyester suture were incorporated into the suture. 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 combination of Teflon and polyester type sutures is particularly advantageous because the suture is rendered softer and thus more knottable as is fully described in my co-pending application Ser. No. 220,085, filed Aug. 28, 1962, now abandoned. The amount of Teflon necessary to render sutures non-reactive according to the present invention is higher than that necessary to impart improved knottability to the suture, but incorporation of such higher amounts within the interstices of the suture does not destroy the beneficial effect of incorporating lesser amounts therein. Teflon is thus preferred with other polyester sutures such as those made from the linear condensation products of terephthalic acids and diols such as Kodel and Tereylene.

Other solid particles can be similarly incorporated in polyester sutures and in other sutures by using dispersions of fine particles such as aqueous dispersions. In order to render hydrophobic, non-swelling sutures non-reactive, from about 5 to about 20 percent or perhaps 25 or 30 percent by weight of the particles may be incorporated into the suture. Of course the suture may be loosely braided in which case more particles may be necessary. In general, however, conventional sutures will be sufficiently loaded with the stated amount.

Hot stretching by ordinary means is employed with hot stretchable polyfilamentous sutures to reduce the elasticity thereof as is customary with such materials. This

procedure has the effect of reducing the diameter of the suture which is generally desirable but even more so in this case because the dead spaces are probably reduced even further.

The sutures can be sterilized in the usual manner and at any stage of manufacture or may be sterilized by the user. Sutures which tend to swell in water or steam may be sterilized by electromagnetic radiation techniques or ethylene oxide. The sutures may, of course, be attached to surgical needles which can either be eyed or eyeless.

I claim:

1. A method imparting attributes of a monofilament to a polyfilament suture comprising the steps of immersing a hydrophobic polyfilamentary polyester suture in an aqueous dispersion of solid polytetrafluoroethylene particles, the particles being of a size sufficiently small to enter within the interstices of the polyfilament suture, maintaining the immersion to impregnate the suture with the polytetrafluoroethylene particles to substantially fill the dead spaces of the polyfilament suture, drying the suture to remove the fluid carrier to provide a polyfilament suture having the dead spaces therein filled by said particles of polytetrafluoroethylene.

2. A method according to claim **1**, wherein the suture is polyethylene terephthalate and the particles of polytetrafluoroethylene have an average size of not more than 1 micron.

3. A method according to claim **1**, wherein the suture is polyethylene terephthalate and is filled with from 8 to 14 percent by weight of polytetrafluoroethylene particles based on the weight of said suture.

4. A suture comprising a polyfilamentary strand of polyethylene terephthalate having a plurality of fine solid particles of polytetrafluoroethylene incorporated in the interstices thereof to an extent sufficient to substantially fill the dead air spaces to imbue the polyfilament suture with the properties of a monofilament.

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