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IMPREGNATION OF STRETCHED MULTI-FILAMENT POLYESTER SUTURE WITH POLYTETRAFLUOROETHYLENE

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4 Claims. (Cl. 117-7)

ABSTRACT OF THE DISCLOSURE

A process for modifying polyester threads, primarily surgical sutures comprising first hot stretching the polyester thread, impregnating the stretched thread with particles of polytetrafluoroethylene, and removing excess polytetrafluoroethylene. The knotting characteristics of thread in this manner are considerably improved.

This application is a continuation-in-part of co-pending applications Ser. Nos. 220,085 and 230,284, filed respectively Aug. 28, 1962 and Oct. 12, 1962, both applications being now abandoned.

The present invention relates to an improved thread and a process for preparing a thread. More particularly, the present invention relates to an improved surgical suture.

Silk, as a surgical suture, is well known. Although silk is widely used as a suture, other fibres which have certain superior properties have been suggested. Dacron, a terephthalic acid polyester braided fibre, has been suggested and is now widely used. Sutures made of this polyester fibre are stronger than silk, are waterproof, and have a very low degree of reaction within the body. Because the polyfilamentous polyester suture has greater strength than a silk suture of the same diameter, the surgeon could use the Dacron polyester suture and have a greater assurance against breakage in use. He also could use a finer size suture than could be employed using silk. These and other advantages accrue when polyester is substituted for silk.

However, there are certain definite disadvantages resulting from the use of Dacron sutures. The primary disadvantage lies in the knotting characteristics of the polyester fibre. The widely used silk suture is relatively "flaccid." When sharply flexed, as in a knot, it does not have a tendency to straighten. The knot, therefore, does not tend to become untied. Dacron, on the other hand, is quite wiry and does not easily take the sharp flexure resulting from the knotting process. In previous applications, it was noted that the use of a Teflon-impregnant decreased the tendency of the Dacron to become untied. It was postulated that the Dacron fibres became imbedded in the Teflon matrix in the process of knotting thus forming a restraining force opposing the tendency of the Dacron to straighten. In the actual use of the suture, we have advised surgeons to snug down securely on the last knot made. This would imbed the Dacron fibres in the Teflon wax and would prevent the Dacron from straightening and becoming untied. Clinically, this has been found to be most effective. As many as twelve Dacron knots have been used in the attempt to prevent the untying phenomenon. However, twelve would become eleven would become ten and so on until the knot was gone. With the Teflon-impregnated Dacron, however, there is no tendency to become untied with proper snugging. This is the reason for the widespread acceptance of the suture in valve replacement surgery. The knots have been found to hold securely when snugging was properly done.

Another disadvantage of Dacron is its relatively high coefficient of friction on its surface. A surgeon ordinarily forms a surgeon's knot or a simple knot above a tissue opening in the process of coapting the surface. In pulling the ends of the suture together, the knot slides down and draws the tissues together. Because of the stiffness of the Dacron, there is usually a considerable springback when the pressure of the pulling subsides and the surgeon must then push down the knot which has partly opened on forming of the succeeding knots. With Dacron, this is not easily accomplished. On sliding a second simple knot down onto the preceding knots, the preceding knot does not go back to its original position and coapting the tissues becomes clumsy or impossible. In the previous application, it was noted that the lubricity added to surface by the use of Teflon greatly simplified this process and enabled the surgeon to slide his knots downward even when his first knot had relaxed to some extent. This process, as previously noted, also occurs with silk. The surgeon is able to slide the original knot back to its original position if there has been some slipping upwards. Also, as previously mentioned, using Teflon impregnated Dacron enables the first simple or surgeon's knot to hold its line of coaptation better than the unmodified Dacron. As mentioned, the Teflon acts as a binder into which the Dacron fibrils are enmeshed. This tends to prevent the opening process. When Dacron alone is used, the springiness of the Dacron thread is unopposed and there is a greater tendency toward the opening process.

In the co-pending applications Nos. 220,085 and 230,284, the underlying problems are discussed and it is suggested that the Dacron suture be impregnated with Teflon (polytetrafluoroethylene). The Teflon impregnant has been found to vastly improve the knotting characteristics of Dacron. Because of this process, it was also noted that the deposition of Teflon on the surface resulted in a greatly increased lubricity which has the result of requiring more knots than would have been needed if the surface were not lubricated. Comparing the knots of Dacron, silk, and Teflon-impregnated Dacron, it was noted that two knots of Dacron has essentially the same security as three knots of silk which has essentially the same security of four knots of Teflon-impregnated Dacron. The additional knot required in the use of Teflon-impregnated Dacron has been a nuisance. The remaining characteristics of the thread have been so highly desirable that the use has increased enormously. However, it still has been most desirable to modify the thread, if possible, so that three knots of silk would equal three knots of Teflon-impregnated Dacron in security.

It is an object of the present invention to provide a method of coating threads with Teflon so that the thread has excellent knotting characteristics.

It is a further object of this invention to provide a thread having knotting characteristics desirable in surgical sutures.

These and other objects are achieved according to the present invention by stretching the thread, impregnating the stretched thread with Teflon, and removing the excess Teflon.

A method of modifying the thread, which involved recoating the coated Teflon-impregnated Dacron with Dacron, is described in my co-pending application Ser. No. 312,328 filed Sept. 30, 1963, now Patent. No. 3,307,971. This method, although eminently satisfactory in result, is cumbersome and requires the use of costly solvents which necessitates solvent recovery.

It is noted in the previous co-pending application, that it is desirable to restore some of the Dacron to the surface. Adding the Teflon impregnant increases the Teflon to Dacron ratio to such an extent that lubricity is excessive.

On reinvestigation of the process of manufacture, it is noted that the Dacron thread is impregnated with Teflon which is then run over a hot-stretch machine at temperatures of about 450° F. A series of rollers are used in this process. It seemed possible that the stretch under tension over a series of rollers might have the effect of spreading the Teflon over the surface of the Dacron thus decreasing the exposed Dacron surface. It would, therefore, seem desirable to impregnate the Dacron thread with Teflon and avoid any process which would tend to spread the Teflon over the surface of the Dacron.

It was, therefore, decided to reverse the process of manufacture and to hot-stretch the Dacron thread to the desired diameter and subsequently to impregnate with Teflon thus avoiding a hot-stretch after the Teflon impregnation process has been accomplished. It was hoped that the impregnation after hot-stretching would have the effect of placing particulate Teflon on the surface and would, therefore, avoid the spreading or "buttering over" that would occur with tension and heat.

The result has been successful. It is now possible, to knot Teflon-impregnated Dacron with the same number of knots as required with silk. This success involves all sizes. To the touch, the surface of the suture appears to be as highly lubricated in this new process as it was in the previous process. However, the result speaks for itself. There appears to be a definite increase in the surface of Dacron exposed which is probably the factor which can account for the equality of the knotting process noted at the present time.

Obviously, for use as a suture, the impregnation of the Dacron interstices to form an essentially monofilamentous structure is of major concern. With the present process of impregnation filling of the interstices has been found to be unchanged. Similarly, the stability of this Teflon-impregnated Dacron as compared to the stability of the Teflon-impregnated Dacron in the previous processes is of major importance. Once again, under torture methods involving washing machines used in 10 cycles, no discernible difference in weight could be found when the Dacron was impregnated after the hot-stretch or before the hot-stretch.

In summary, an excellently lubricated suture maintaining its essentially monofilamentous structure and requiring the same number of knots needed for security as with silk has been provided.

In my prior co-pending applications, a thread is coated with Teflon and then stretched. It has now been determined that, by performing the stretching step prior to coating, the knotting characteristics of the thread are markedly improved and the problems of excessive surface lubricity are overcome.

The invention will now be illustrated in the following examples:

Example I

Dacron polyester fibre was braided into a polyfilamentous suture on a New England Butt braider machine.

This machine is a well known braider and has 8 or 12 carriers in readily available models. Any type of braider will, of course, be suitable. Such machines, by varying the number of individual fibres and tensions, can provide a wide variety of sutures. A finished Dacron braid can be made having a weight of from about 1,700 yards per pound to about 28,000 yards per pound.

A braided polyester thread is then hot-stretched by pulling the thread, under tension, over a heated platen maintained at a temperature of about 450° F. This operation serves to substantially reduce elasticity and eliminate memory (that tendency of the fibre to return to its original length.) While elongation may vary from about 10 to 15 percent, a braid preferred for surgical use will usually be stretched about 40% during the process. Any suitable device providing the necessary tension and heat is suitable for this step.

The thread stretched about 40 to 50 percent is then gathered into a skein and immersed in a suspension of small Teflon particles in a dispersing medium. Agitation and/or a wetting agent may be employed to prevent settling of the Teflon particles. A preferred embodiment consists of a dispersion of Teflon particles in the size range of about 0.5 micron dispersed in water with the aid of a wetting agent. A suitable blend is readily available as duPont blend 2510 which contains about 58% Teflon particles by weight in water. Triton X-100 (Rohm and Haas) is a suitable wetting agent. The amount of Teflon in the suspension can vary widely but the commercially available blend of about 58% by weight solids is suitable.

A skein of thread is kept immersed in the Teflon dispersion for a time sufficient for the discrete particles to permeate into the interstices of the thread. If the skein is very large or tightly wound, a longer time should be allowed. For skeins weighing up to 50 lbs., an immersion time of 15 minutes has been found to be more than adequate. The weight pick up, measured after final processing, has been found to cease much prior to the 15 minutes allowed.

After immersion, a skein is placed in a wringer which comprises a pair of opposed rolls. The function of the wringer is to remove the excess Teflon from the thread and should be accomplished rapidly. If the process is not well controlled, considerable Teflon will deposit on the surface of the sutures. To prevent this excess deposition of Teflon on the sutures, the skein must be kept wet during the process of extraction and the extraction should be quickly accomplished. The skein of thread is then removed and wound as a final product. The thread is approximately 6% heavier than originally. In actual practice, for a given thread, weight increases of from 5 to 7 percent (approximately) are obtainable. Depending on the structural nature of the thread (number and tension of fibres) a weight increase of up to 20% is obtainable. The thread feels to the touch like a lubricated polyester thread, practically identical to the polyester thread surface noted when the process is reversed and the impregnation carried on before heat treating. It is only when a knot is actually tied that the vast difference becomes apparent. Using the surgeons technique of forming the surgeon's knot or simple knot and pulling it down, the knot forms smoothly and, most important, requires exactly the same number of knots as silk to give identical security. The lubricity of the surface is a highly desirable characteristic and is maintained to an equal extent, apparently, in this present suture construction.

Example II

The same thread and equipment employed in Example I were treated as in Example I except that the stretching step was carried out in two distinct operations. First, the thread was cold-stretched at room temperature to approximately 25% elongation. This step is conveniently carried out on a separate stretching device which has no provision for heating but may be performed on the machine described in Example I with the platens unheated. This cold stretch provides uniform fibers. The balance of stretching, to eliminate any remaining elasticity and to eliminate memory, is performed as in Example I, at a temperature of about 450° F. In both the single hot stretch and the two-phase stretch, the platens are preferably heated to about 450° F. but this temperature may be lower where the thread is kept on the platen for longer periods or higher if the thread is kept on the platens only long enough to heat the thread to a temperature below its melting point.

The thread produced according to this example has knotting characteristics like the thread in Example I.

Examples III and IV

Examples I and II were followed except that silk thread

was employed and the platens were heated to about 425° F. The resultant silk thread had knotting characteristics of surgical silk sutures, but the Teflon particles were very uniformly distributed throughout the thread and no excess material was present on the thread surface. Teflon could be accumulated in the silk up to 45% of the weight of the impregnated silk. As with polyester fibre, the Teflon was substantially within the interstices of the thread with none being visible on the surface under magnification. Undoubtedly, the Teflon is present on the surface to some extent. The suture appears to be well lubricated.

While a thread made according to this process has primary use as a suture, it should be apparent that the process generally relates to modifying the characteristics of thread. An analogy has been drawn to surgical silk only to show that certain properties of thread have been modified to compare with silk. In a general sense, the invention affords a means for producing a thread of modified characteristics useful wherever those characteristics are desirable. Further, the process of the invention is equally applicable to woven thread.

What I claim is:

1. A process of modifying a multifilament polyester thread comprising subjecting the polyester thread to an elevated temperature below the melting point thereof and stretching the thread up to 50% of the original length while at the elevated temperature, subsequently immersing the stretched thread in a liquid dispersion of small particles of polytetrafluoroethylene and removing excess polytetrafluoroethylene while the thread is wet with said liquid dispersion whereby a thread having an exposed surface of polyester and polytetrafluoroethylene is provided.

2. A process according to claim 1, wherein the poly-

ethylene thread is a multifilament polyester terephthalate suture.

3. A process according to claim 1, wherein the polyester thread is provided with up to about 20% by weight of polytetrafluoroethylene substantially wholly within the interstices thereof.

4. A process of modifying a polyethylene terephthalate multifilament suture to improve the knotting characteristics thereof, comprising the steps of hot stretching the suture at a temperature of about 450° F. to elongate the suture up to 50% of the original length, immersing the stretched suture in an aqueous dispersion of small particles of polytetrafluoroethylene, and removing excess polytetrafluoroethylene while the suture is wet so that the suture contains up to about 20% by weight of polytetrafluoroethylene with the exposed surface comprising both polyester terephthalate and polytetrafluoroethylene and with the interstices of the suture substantially filled with polytetrafluoroethylene.

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