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STRAND FOR SUTURE AND OTHER PURPOSES AND METHOD OF MAKING THE SAME

George Aaron Sharp, Los Angeles, Calif., assignor to Davis & Sharp, a corporation of California

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This invention relates to sutures, ligatures, cords and the like, and to methods of manufacturing the same.

It has been common practice to make sutures, such as are ordinarily used in surgical work, of catgut, which is most frequently produced from sheep intestines.

Such catgut sutures are relatively expensive, because of the expert and laborious hand work required in their manufacture and because of the relatively high prices of the sheep intestines caused by great demand for other purposes. In addition, catgut, while extensively used because of the absence of something better, is not entirely satisfactory, due to the difficulty of obtaining catgut sutures of uniform size, of sufficient strength and flexibility to permit most efficiently of the stitching and tying necessitated in surgical work, and because of the difficulty of rendering them sterile and capable of being treated at adequate sterilizing temperatures without deterioration.

Intestinal tissues, forming the basis of catgut, are porous and are almost always infected and contaminated with harmful pathogenic bacteria, particularly of tetanus or lockjaw variety, and in many cases of the anthrax type. These bacteria withstand relatively high sterilizing temperatures. Sheep catgut also usually contains fats, mucosa, irritating fatty acids and other impurities, which are not altogether eliminated by the many purifying and scraping operations to which the catgut is subjected. These last-mentioned impurities cause the catgut to become harsh and brittle, and to decrease in strength and flexibility, particularly when it is subjected to sterilizing temperatures.

Among the objects of the present invention are to provide sutures which will be free from these defects, which may be easily and readily manufactured from inexpensive raw materials, and by automatic machinery of the type usually employed in the textile industries; which will be normally sterile or which may be readily sterilized at high temperatures without substantial deterioration, which will have sufficient strength and flexibility to be efficiently and facily stitched and tied in surgical operations, even after treatment or effective sterilizing temperatures, and which may be made of controlled and uniform sizes for any desired purpose.

In accomplishing these objects it has been found satisfactory to employ animal tendons. In preparing sutures from animal tendons experiments have demonstrated that it is not satisfac-

tory to employ long coarse tendon fibers, such as those obtained from the tendon fascia lata derived from the thighs or quarters of steers or beeves. It has been attempted heretofore to make sutures from such tendons, but as far as I am aware, they have never been produced commercially, for a number of good reasons.

It is difficult to obtain twisted strings or cords from such tendon material by approved textile processes and machinery, and it has been proposed, but without success, to utilize relatively less satisfactory braided cords or strings, the constituent fibers of which are caused to adhere together by glue or other adhesive; or to form the material into thin sheets, by overlapping and pressure, which sheets were to be slit into ribbons. Sutures prepared of a plurality of braided fibers glued together have been suggested for surgical work, but did not prove satisfactory because they do not remain homogeneous in the tissues. The lytic substance such as the lymph in the tissues will dissolve the adhesive, with the result that within a relatively short time the constituent fibers will fall apart, permitting the sutures to disintegrate.

Among the particular objects of the present invention are, therefore, to prepare substantially pure collagen sutures from the fibers of animal tendons, which may be readily spun or twisted into a cord, strand, suture or ligature by approved textile processes, and which may be formed into a homogeneous and unitary cord or string without an added adhesive and of such structure as to withstand the action of tissue solvents and sterilizing temperatures without any substantial disintegration or impairment.

In one embodiment of my invention, the pure white connective tissues contained in the leg tendons of year-old veal, or calves, or of sheep, and preferably the tendo Achillis derived from the hind legs of such calves or veals are utilized, as preferred tendon materials.

As a specific example of one method of preparing the sutures of the present invention, the following is given: The muscular, fatty and other tissues adhering to these tendons are removed, and the tendons are then dried. These tendons are usually about 2 to 2½ inches long, and as slender as perhaps one-eighth of an inch, with about 300 of them producing one pound of fiber, 30,000 tendons being approximately equivalent to a one hundred pound run of fiber.

After drying the tendons, they are run through a machine, which will crack off the capsule or tendon sheath, and also open up the interior fiber

structure so that the shredder teeth can get in between them and tear the fibers apart.

The shredder, which is next employed, will separate the fibers so as to prepare them for carding. In the carding machine the material is carded and combed down to very fine fibers and thereafter is passed into a roving machine, which forms the fibers into a very small roving, so delicate that it is just able to hold together.

These rovings are passed into a spinning machine, from which they are obtained in the form of fine yarn, and this yarn is passed into a twisting machine which takes several strands of the yarn and twists them into what is, after further treatment, to become the final substantially transparent or glossy cord of very attractive appearance and external smoothness.

These spun cords or strands thus formed are then treated with carbon tetrachloride or with some other suitable fat solvent in a Soxhlette apparatus. The fibers are also subjected to the selective digestive action of enzymes, such as lipase and trypsin which will dissolve out or remove the other impurities from the animal materials namely, the mucin and elastin with the ultimate object of producing fibers of pure collagen. The selective enzymes are present in an alkaline bath or baths and have a selective digestive action on the fat, mucin and elastin present in the fibers, but do not have any digestive action on the collagen. The cords or strands or their fibers are allowed to remain in the bath or baths for a sufficient time to properly digest the impurities mentioned. By removing the non-essential impurities, namely, the elastin, mucin and fats, which is accomplished by the selective digestive enzyme step or steps of the method, the bulk or size of the cord or strand is reduced and elasticity properties are greatly improved. To neutralize any fatty acids which may be present in the fibers at this stage, a neutralizing agent, or an alkali, such as sodium carbonate, may be employed. After these solvent treatments, the cords or strands are washed in distilled running water for about three hours to remove from their fibers all traces of the treating chemicals and other objectionable substances. Then they are dried in a vacuum chamber at a temperature gradually increasing to 65° C.

The cord thus prepared is then treated to unite to each other the adjacent surfaces of the constituent separated fibers or materials, as by a suitable combination of chemical acid and/or alkaline baths, with the result that a homogeneous or unitary strand or cord of fibrous material of substantially pure collagen tissue is obtained. The chemical utilized in this fiber surface union treatment may be selected so as not to cause substantial deterioration of the collagen base, and should be of such a nature that it will not have any disadvantageous effect in subsequent surgical utilization. In any case, the chemical substance should be removed as far as possible from the resultant homogeneous cord or ligature material.

One method of forming the unitary strand or homogeneous cord which may be employed under suitable circumstances is as follows:—

The cord, after the twisting operation, and the treatment described, is wound on a drum or reel with spokes about 60 inches apart, so that it will be substantially free and without contact with the drum or reel throughout the length into which it is to be cut for putting up into tubes as surgical

sutures. Sutures are customarily cut into 5 foot lengths and put into glass tubes, the surgeons later cutting them into shorter lengths as required. The cord is also wound on the drums so that no two laps of the cord will touch one another, which permits of perfect processing and prevents adhesion between the different laps of cord. The drum with the cord wound upon it now is put into a substantially constructed vacuum chamber, and there every vestige of moisture is extracted under high vacuum and at a temperature of about 52° C., for a period of about 75 minutes.

At the completion of the seventy-five minute drying period, a caustic solution, preferably of the same temperature as the inside of the vacuum chamber, is passed into the vacuum chamber to submerge the drum with the cord thereupon. A satisfactory caustic or alkaline solution for this purpose may consist of a 0.235% sodium carbonate solution in distilled water.

After addition of the caustic solution the same high vacuum is reestablished, but the temperature is gradually allowed to decline to 45° C., and this temperature is maintained for eighteen hours.

After eighteen hours the drum with the strand thereon is removed from the vacuum chamber and for several hours is subjected to a washing operation in running distilled water. The drum and strand next is placed in a bath of hydrochloric acid solution for neutralizing the caustic, and then it is placed in a weak solution of sodium carbonate to neutralize any acid. Then it is again washed in running water, and this time for about twelve hours.

After this washing operation the drum of cord is air dried for about twenty-four hours in a normal atmosphere, and after that is dried in a vacuum chamber under a relatively high vacuum at 52° C.

The thoroughly dried cord is then subjected to a treatment of formalin to coagulate or harden it and to render it more slowly absorbed in the tissues for definitely predetermined lengths of time, such as 10 days, 20 days, 30 days, etc., as variously required by surgeons.

Finally after the formalin treatment, it is put through a surface treatment machine which gives it a smooth highly polished surface, whereupon it is ready to be cut into proper lengths, put into glass tubes and sterilized. This surface treatment may include the application of a coagulable coating applied to the strand. If applied, this coating should be of a character that is insoluble in water. In practice, I have found that a strand coated with coagulated albumen will properly resist absorption when in the tissues. That is to say, a coating of the kind stated is slowly digestible by the enzymes of the body tissues, is non-irritating when the coated strand is used as a suture, and is insoluble in water. Blood albumen, which may be coagulated by heat or a chemical coagulant, has been found to be especially adapted for the purpose although others may be employed.

The above example describes a very complete process, and it is to be understood that some of the steps thereof may be omitted or modified to produce a cord or suture of satisfactory property. Also many other fiber uniting and homogenizing steps or processes may be employed, involving either physical or chemical treatments, or both.

The resultant surface united or homogenized fibers constitute a substantially unitary cord,

thread, suture or ligature formed of highly pure collagen. Although it still retains its longitudinal or grained structure, the individual fibrous character has been eliminated only to the extent that the fibers are surface united by their own inherent adhesive properties, and the many individual small fibers of which the strand is composed are no longer free as such. The homogeneity of the cord or fiber formed is particularly advantageous in the case of sutures in surgical work as it is unaffected by the lytic substances such as the lymph in the tissues and will not disintegrate into the constituent fibers, though it remains in the tissues for relatively long periods of time. Sutures made in accordance with my invention have been used extensively in animal experimentation and also in the human body, and it has proven beyond doubt that they do withstand permeation by the body fluids and retain their strength fully as long if not longer than the best grades of catgut made from sheep's intestines, and furthermore they are superior to catgut in many fundamental ways as herein described.

Moreover, and of prime importance in the case of sutures, the resulting strings or cords will endure sufficiently high sterilizing temperatures to kill all micro-organisms including the highly resistant spores of tetanus and anthrax. Pathogenic micro-organisms, and especially the spores of tetanus and anthrax, are not always killed at the temperature generally used for sterilizing catgut sutures, which is dry heat at 275 degrees F., whereas catgut cannot stand a higher temperature than 275 degrees F. without severe deterioration. This, obviously, is not a sufficient margin of safety. Indeed, the fact that it is not a sufficient margin of safety has been evidenced in two ways: by bacteriological tests, and by the incidence of infected wounds, following surgical operations, where the source of the infections has been traced to the catgut sutures used, and which sutures were sterilized in the manner described. The suture material of the present invention withstands a sterilizing temperature in excess of 330 degrees F., without impairment, thus affording a margin of safety of fully 55 degrees F. This is a tremendous advantage, as it eliminates one of the most serious hazards which still beset surgery, and enables the prevention of countless cases of post-operative infections and many deaths. In addition, the suture of the present invention is more flexible and of greater strength after sterilization than catgut, and this facilitates the surgeon's work and brings about a shorter operation time, the latter a feature of importance from every viewpoint, especially in curtailing the periods of anesthesia and of surgical shock.

Another advantage which the suture of the present invention has over catgut is that when suture material becomes absorbed, the tract or hole which it makes through the tissues becomes grown full of scar tissue, thereby providing additional strength for the continued support or holding together of the tissues even after the wounds have healed. On the other hand, with catgut the tracts or holes become filled with merely the muscle, the fascia or other tissue surrounding it. The advantage of providing scar tissue (beneath surface, not on the skin) is of great importance in surgery, and to obtain this advantage surgeons sometimes use strips of living fascia lata so that strong supporting ligaments or bands of scar tissue are formed, to give additional support to the wound. The suture of the

present invention achieves this same desirable result without necessitating the utilization of strips of living fascia. For this reason sutures of the present invention are of particular and outstanding value in operations for hernia as well as for various abdominal and other operations.

Furthermore, the suture material prepared in accordance with the processes of the present invention, may be cut or separated into sections to provide elements of desired length, and it will be obvious that by this method the fibers may be formed into a continuous uniform strand, and which in turn may be cut into predetermined lengths, whereby sutures of uniform thickness and length may be obtained.

Another advantage incident to the manufacture of the suture of the present invention in continuous lengths resides in the fact that the strands may be wound upon large spools, as in the manufacture of cotton, flax, hemp and jute cord. Such continuous lengths render it possible to employ machines for winding sutures into small loops for insertion into glass tubes. This is work that is now necessarily done entirely by hand because of the fact that catgut strands cannot be made in continuous lengths, and cannot therefore be fed into automatic machines to wind them into small loops to be inserted in glass tubes.

Although the suture or ligature material of the present invention is particularly advantageous in surgical work, cords, strings and the like prepared in accordance with the present invention may also be used for a variety of other purposes, such as the stringing of tennis rackets, musical instruments and other articles or devices.

In the practice of my invention, the strands or cords may be made of various thicknesses and strength to be utilized for such purposes, and where for example the strand is intended to be utilized as a string for a musical instrument, this uniformity of size is a distinct advantage in giving more perfect tonal effects, because of the uniform diameter of the string, as opposed to the inaccurately hand-made catgut strings, which latter are unavoidably of uneven or varying diameters. On the other hand, in the stringing of tennis rackets, the greater the strength and the better the resistance to moisture, coupled with greater economy, makes them far more desirable for such purpose than the expensive catgut strings now employed.

While I have herein shown and described one particular embodiment of my invention, it is to be understood that I do not confine myself to all the precise details of the construction herein set forth by way of illustration, as modifications and variations may be made without departing from the spirit of the invention, or exceeding the scope of the appended claims.

What is claimed is:

1. A strand for use as a suture and for other purposes, composed of substantially pure collagen fibers, the contacting surfaces of which are intimately united into an homogeneous structure by their own inherent adhesive properties, said strand having a smooth outer surface.

2. A strand for use as a suture and for other purposes, composed of substantially pure collagen fibers derived from the leg tendons of young animals, said fibers being formed into a roving and spun into a strand and the contacting surfaces of which are intimately united into an homogeneous structure by the inherent adhesive properties only of the fibers.

3. A strand for use as a suture and for other

purposes, composed of substantially pure collagen fibers, the contacting surfaces of which are intimately united into an homogeneous structure by the inherent adhesive properties of the fibers, said strand having a coating of a water insoluble substance.

4. A strand for use as a suture and for other purposes, composed of substantially pure collagen fibers spun into a strand, said fibers being intimately united into an homogeneous structure by their own inherent adhesive properties, and the strand having a coagulated coating of a water insoluble substance.

5. A strand for use as a suture and for other purposes, formed from a plurality of intertwisted spun strands composed of substantially pure collagen fibers derived from the leg tendons of young animals, the fibers of the separate strands being surface-united into an homogeneous structure by their own inherent adhesive properties.

6. A strand for use as a suture and for other purposes, formed from a plurality of intertwisted spun strands of pure collagen fibers derived from the tendons of young animals, the said fibers being surface-united into an homogeneous structure by their own inherent adhesive properties, and the said strand having a suitable albumen coating to render it smooth.

7. A strand for use as a suture and for other purposes, formed from substantially pure collagen fibers derived from the pure white connective tissues in the leg tendons of veal, calves and sheep, said fibers being carded, formed into a roving and spun into a strand and intimately united into an homogeneous structure by the inherent adhesive properties of the fibers.

8. A strand for use as a suture and for other purposes, formed from substantially pure collagen fibers derived from the tendo "Achillis" of veal and calves, said fibers being formed into a roving and spun into a strand and the contacting surfaces of which are united into an homogeneous structure by the inherent adhesive properties only in the fibers.

9. A strand for use as a suture and for other purposes, formed from substantially pure collagen fibers derived from the tendons of young animals, and comprising a relatively large number of said fibers spun and twisted together and surface-united into an homogeneous structure by their own inherent adhesive properties.

10. A strand for use as a suture and for other purposes, formed from substantially pure collagen fibers derived from the smaller tendons of animals, the contacting surfaces of the fibers being intimately united into an homogeneous structure by their own inherent adhesive properties rendered adhesive by the softening action of chemicals.

11. A strand for use as a suture and for other purposes, formed from substantially pure collagen fibers derived from animal tendons, said fibers being purified by treatment with fat solvents and tissue-digestives, the contacting surfaces of the fibers being intimately united into an homogeneous structure by their own inherent adhesive properties.

12. A strand for use as a suture and for other purposes, composed of substantially pure collagen fibers derived from the smaller tendons of animals, the contacting surfaces of the fibers being intimately united into an homogeneous structure by their own inherent adhesive properties, and said strand having an homogenized and polished surface.

13. The hereindescribed method of producing sutures and similar cord-like structures, which comprises treating animal tendons to separate the fibers from the flesh, mechanically segregating the fibers into single fibers, purifying the fibers to remove the fats, mucin and elastin to convert them into substantially pure collagen, forming the fibers into a roving, spinning the roving into a single strand and then softening the strand to surface-unite and homogenize the fibers by their own inherent adhesive properties to form a unitary strand.

14. The hereindescribed method of producing sutures and similar cord-like structures, which comprises treating animal tendons to separate the fibers from the flesh, mechanically segregating the fibers into single fibers, forming the fibers into rovings, twisting the rovings into a single strand, treating the strand with tissue digestives to remove the impurities including the fats, mucin and elastin and without affecting the collagen, and then chemically softening the strand to homogenize and surface-unite the fibers into a unitary strand by the inherent adhesive properties of the fibers.

15. The hereindescribed method which consists in selecting animal tendons derived from the pure white connective tissues of the class defined in the tendo "Achillis" of young animals, combing the tendons into a fibrous mass, mechanically segregating the mass into single fibers, forming the fibers into rovings, spinning and twisting the rovings into a single strand, purifying the fibers to remove all impurities and thus reduce them to substantially pure collagen, then chemically softening said strand with an acid and an alkali to surface-unite and homogenize the fibers by their own inherent adhesive properties, and then drying the strand.

16. The hereindescribed process, which comprises selecting the leg tendons of young animals, drying the tendons and reducing them to fiber form, carding the fibers and forming them into small rovings, spinning the rovings into fine strands, twisting several strands to form a cord, subjecting the cord to the action of selective tissue digestive enzymes to purify it by removing the fats, mucin and elastin and thus convert the fibers into substantially pure collagen, and then chemically softening the fibers to surface-unite and homogenize them by their inherent adhesive properties, then drying the cord to form a unitary and homogeneous structure.

17. A spun strand for use as a suture and for other purposes, composed of substantially pure collagen fibers derived from the tendons of animals, said strand being purified by treatment with selective tissue digestive enzymes to remove the fats, mucin and elastin, and the fibers being surface-united by their own inherent adhesive properties.

18. A surgical suture composed of animal tendon fibers derived from the leg tendons of young animals, said fibers being treated with selective tissue digestive enzymes to remove the undesirable impurities such as fats, mucin and elastin, and spun into a strand, said fibers being surface-united by their own inherent adhesive properties and the strand having a lymph-resistant coating.

19. A surgical suture consisting of a spun strand composed of substantially pure collagen fibers derived from the leg tendons of young animals, the surfaces of which are intimately united into an homogeneous structure by their own inherent

adhesive properties, and said strand having a coagulated coating consisting of a substance resistant to body fluids.

20. A strand for sutures and other purposes, 5 composed of spun animal tendon fibers surface-united and homogeneized by their inherent adhesive properties and having a moisture-resistant coating.

21. A strand for suture and other purposes com- 10 posed of spun animal tendon fibers derived from the tendons of young animals, said fibers being homogeneized and having a coating of a lymph-resistant substance capable of digestion by the enzymes of the body tissues.

22. The method of surface-uniting and homogeneizing the constituents of a cord composed of spun collagen fibers derived from animal tendons, which consists in winding the cord upon supports, removing moisture therefrom, submerging the 5 supported cord in a caustic solution, washing and then drying the cord and finally subjecting the supported cord to an acid treatment to soften and thus surface-unite the individual fibers into an homogeneous structure by the inherent adhesive 10 properties only of the fibers.

GEORGE AARON SHARP.