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SUTURES

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This invention relates to surgical sutures, and particularly to the composition of the liquid in which sutures are usually packed and stored. It results from our discovery that sutures formed of absorbable protein such as animal tissue when stored in solutions of critical proportions of the propyl alcohols have unexpected properties and marked advantages over sutures heretofore known.

In order to provide surgeons with sutures which are both sterile and soft and therefore ready to use, it has been the practice to pack the suture in a glass tube containing a preserving or conditioning liquid, called tubing fluid, the tube being sealed hermetically either before or after sterilizing the suture, depending on the nature of the suture and the particular tubing fluid used. Tubing fluids fall into two recognized classes called boilable and non-boilable. The boilable tubing fluids are inert to the suture at temperatures considerably above that of boiling water, and so permit the tubed suture to be boiled either to sterilize the suture within the tube or to sterilize the suture within the tube or to sterilize the outside of the tube without damaging the suture. The non-boilable fluids are those which cannot be boiled because at the temperature of boiling water they damage the suture.

The most extensively used sutures are of proteinaceous material which is absorbable in the human body, such as animal tissues. The submucosa of the small intestines of sheep is commonly used and is called surgical gut. When these have been prepared in the form of threads or strands and sterilized they are undesirably stiff and must be rendered pliable before use. When such sutures have been tubed in boilable tubing fluids (which, as so far known, retain the stiffness of the gut) the softening has been accomplished customarily by soaking the suture in a softening liquid, usually water, after removal from the tube. This causes delay and exposes the suture to risk of contamination.

In order to avoid this risk and to provide the surgeon with a pliable, instantly usable suture, it has been the practice to tube gut sutures in liquids which render them pliable. Of the known softening solutions, examples are mixtures or solutions of ethanol or methanol and water such as 95% ethanol and 5% water, or a mixture of 76% ethanol, 20% isopropanol and about 4% of water, with or without small quantities (e g., .025%) of a germicide such as phenyl mercuric benzoate. In such mixtures water, ethanol and methanol are recognized softening agents. Su-

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tures tubed in these mixtures are not boilable.

While known softening tubing fluids satisfactorily preserve the sterility and pliability of sterilized animal tissue sutures, they have recognized disadvantages. Sutures tubed in them swell, losing specific tensile strength (that is, tensile strength per unit of cross-sectional area), lose total tensile strength, and are apt to fray. A given suture swells when tubed in standard softening fluids, frequently as much as 20%. Therefore if the total tensile strength of the strand should remain the same, this strength would be distributed over a larger area of gut, resulting in a corresponding loss of tensile strength per unit of cross-sectional area. In addition, a given suture, tubed in standard softening solutions loses total tensile strength. These two phenomena combine to reduce materially the total or effective tensile strength of sutures having a given final size when tubed in softening fluids heretofore known.

We have also discovered that where gut is a type, or from a batch, which is susceptible to fraying, the frayability is materially increased by tubing in heretofore known softening solutions. A frayed suture is one in which small fragments of gut break and stand out from the string like whiskers. One kind of fraying occurs in frayable gut when the string is pulled to somewhere near its normal tensile capacity, then relaxed. Another kind of fraying results from abrasion, such as occurs when a suture is threaded through a needle, or is drawn between the tightly pressed fingers of a hand wearing rubber gloves. A frayed suture is apt to be weak and break at the knot, but in addition to whiskers are objectionable because they may aggravate the wound made by the needle in sewing them through tissue of the body.

The disadvantages of absorbable sutures tubed in known softening tubing fluids are related to their water-absorbing characteristics. Protein in general, and especially animal gut, is very reactive and has a high affinity for water. While absorbable suture material, particularly animal gut, has properties with respect to ethanol and methanol similar to its hydrophilic properties, we have found that its characteristics with respect to the propyl alcohols are quite different. Thus we have discovered that gut sutures tubed in solutions containing critical proportions of a propyl alcohol have the unexpected property of marked increase in total tensile strength of a given strand over sutures tubed in known non-boilable tubing fluids, and that they swell much

less while acquiring a pliability comparable with that imparted by usual softening solutions. The causes of fraying are not well understood, but we have discovered that gut sutures tubed in the propyl alcohols are less apt to fray than when tubed in known softening liquids. We have also discovered that when gut which is of a type or from a batch which is susceptible to fraying is tubed in propyl alcohol solutions of proper concentrations, fraying can be completely prevented.

In accordance with our invention sutures are prepared in the usual manner including drying and polishing and placing in open glass tubes. The tubes are then filled with an anhydrous hydrocarbon of high boiling point, such as high-flash naphtha, sufficiently to cover the sutures and the tubes are heated to sterilize the gut. The hydrocarbon is then poured off, the tube is partially filled with our novel tubing fluid, and sealed. We use as a tubing fluid a mixture or solution of a propyl alcohol and water, the proportion of the propyl alcohol varying between about 70% and about 95% of the liquid poured in. The water is the softening agent. If desired, we can include in the tubing fluid the usual quantity of a suitable germicide (e. g., .025% phenyl mercuric benzoate) without departing from our invention. The advantages of our invention are most marked when the concentration of the propyl alcohol is about 90%.

We have observed that gut sutures in 90% isopropanol swell only about 50% as much as sutures tubed in standard non-boilable tubing fluids. An example of a standard non-boilable fluid used herein for control or comparison is 76% ethanol, 20% isopropanol, and 4% water. In extensive tests of large batches of commercial gut, we have observed that sutures tubed in the control standard non-boilable tubing fluid swell on an average of 18.8%. This means that a dry suture, whose diameter was 17 mils (.017 inch) will swell to a final diameter of about 20.2 mils. Sutures from the same commercial production, when tubed in 90% isopropanol, swelled on an average of only about 9.8% to a final diameter of about 18.7 mils. It is evident that if a given suture retains its total tensile strength after swelling, then the specific tensile strength of the enlarged suture will be less than the specific tensile strength of the suture before swelling. Consequently, the less a suture swells, the greater will be its specific tensile strength, or tensile strength per unit of cross-sectional area, and the greater will be to the total tensile strength of a suture of a given size. For example, neglecting any change in total tensile strength due to the tubing fluid, if the tensile strength of the strands mentioned above were each ten pounds when tubed in the control standard non-boilable solution, the specific tensile strength of the suture will be about 31,200 pounds per square inch, while the specific tensile strength when tubed in 90% isopropanol will be about 36,360 pounds per square inch, a gain of about 16.4%.

The United States Pharmacopoeia sets standards of strength on straight pull and over a surgeon's knot for various nominal sizes, and sets definite dimensional limits for the sizes. Thus a No. 1 suture must have a tensile strength of ten pounds on straight pull and seven pounds over a surgeon's knot, while a No. 0 suture need have a tensile strength of only seven pounds on straight pull and five pounds over a knot. A No. 1 suture tubed in non-boilable fluid must be

between 19.5 and 23 mils in diameter. A No. 0 suture must be between 16 and 19.5 mils in diameter. Thus, a dry suture having an original diameter of 17 mils when tubed in the control standard non-boilable fluid will have a final diameter of 20.1 mils, must be classed as a size 1, and must have a knot tensile strength of seven pounds. If this same suture were tubed in 90% isopropanol, it would have a final diameter of 18.7 and could be classified as a No. 0. Thus, the suture classified as No. 1 when tubed in the control tubing fluid, if it had the requisite tensile strength of ten pounds, would have a tensile strength of at least ten pounds when tubed in 90% isopropanol, but would be classified one size smaller, and would have an excess of three pounds over the tensile strength required for the smaller size. Since surgeons desire to select the minimum size having the requisite tensile strength, the advantage of tubing the suture in 90% isopropanol is evident.

The above considerations, based on assumed minimum straight tensile strength for United States Pharmacopoeia standards, have been borne out in actual experience with our invention. For example, we have found a given lot of sutures having a specific tensile strength of 70,500 pounds per square inch of cross-section when dried before tubing, has a specific tensile strength of 48,500 pounds per square inch when tubed in the control standard solutions, whereas the same gut has a specific tensile strength of 53,500 pounds per square inch when tubed in 90% isopropanol. This represents a gain of 5,000 pounds per square inch, or approximate 10% over sutures tubed in standard ethanol mixtures.

The above figures represent the specific tensile strength on straight pull. The advantage of our invention in the tensile strength over surgeon's knots is even more marked. Any strand, particularly a suture, breaks more easily over a knot than on a straight pull, and the strength over a knot is the determining factor in the usable strength of the suture. A lot of the same gut (original dry tensile strength, 70,500 pounds per square inch) showed a specific knot tensile strength of 36,200 pounds per square inch when dried before tubing. Upon being tubed in the control solutions, it showed a knot tensile strength of 21,400, but 27,200 pounds per square inch knot strength when tubed in 90% isopropanol, a gain of 5,800 pounds per square inch, or approximately 27% over known practice.

The above holds true even though the total tensile strengths of a given size of sutures are the same when tubed in 90% isopropanol and in the control tubing fluid. We have found, however, that tubing a gut suture in 90% isopropanol increases the total tensile strength over the tensile strength obtained by tubing in the control solution. This is in addition to the observed decrease in swelling and results in a suture of even greater total tensile strength, both straight and over knots. The increase of total tensile strength varies in accordance with conditions which we do not fully understand. For example, in a batch of No. 0000 gut (U. S. P. diameter 7.0 to 9.5 mils) the average total tensile strength of each strand was 3.75 pounds dry, 2.87 pounds tubed in the control softening solution, and 3.06 pounds tubed in 90% isopropanol, showing an improvement (without regard to swelling) of 6.5%; while in a batch of No. 00 gut (U. S. P. diameter 12.5 to 16 mils) the average total tensile strength of each strand

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was 10.4 pounds when dry, 7.2 pounds when tubed in standard softening solution, and 8.0 pounds when tubed in 90% isopropanol, an improvement of 11%. Similarly in a batch of No. 1 gut (U. S. P. diameter 19.5 to 23 mils) the average knot tensile strength of each strand was 9.4 pounds dry, 7.5 pounds tubed in the control standard softening solution, and 8.0 pounds tubed in 90% isopropanol, an improvement of about 6.5%; while in a batch of No. 00 gut the average knot tensile strength of each strand was 4.9 pounds dry, 3.9 pounds in the control standard softening solution, and 4.4 pounds in 90% isopropanol, an improvement of about 12.8%.

An additional advantage of our invention is the marked reduction or complete elimination of fraying. The causes of fraying are not well understood, but it is known that some batches of gut are susceptible of fraying where others are not, and that the incidence of fraying or percentage of strands that fray varies widely. As a general rule, the percentage of fraying of dried gut is increased when the gut is tubed in the control softening solution. In testing a large number of batches known to be susceptible to fraying, we have discovered that tubing in critical proportions of the propyl alcohols sharply reduces the frequency or percentage of fraying from that encountered in the control solution, in many cases reduces the frayability below that of dried gut, and in some instances eliminates fraying completely. For example, in one batch of frayable gut, which in the raw showed a fraying incidence of 3.3%, was 10.0% frayable when tubed in the control solution, but only 3.3% when tubed in 90% isopropanol. Another frayable gut showing a fraying incidence of 40% in the raw, showed 46.6% in the control solution, but only 26.6% in 90% isopropanol. Still other tests showed gut having a fray incidence of 44% in the raw to have a fray incidence of 56% in the control solution. Fraying was reduced to 4% when tubed in 95% isopropanol and completely eliminated by tubing in 100% isopropanol.

We have found that the advantages enumerated, namely increase in specific tensile strength, reduction of swelling, and reduction of fraying, gradually increase with isopropanol concentrations above 90%, and decrease gradually below 90% until at about 65% the advantages of isopropanol over the control non-boilable tubing fluid disappear. At 70% concentration, however, the advantage of isopropanol is still apparent. Above 90% the advantages are limited by increasing stiffness of the suture, which when tubed in concentrations above about 95% becomes too stiff to be used without conditioning. The optimum combination of advantages with acceptable pliability occurs when the suture is tubed in about 90% propyl alcohol, and we prefer this concentration.

The various advantages of the invention can be derived from using normal propyl alcohol in concentrations corresponding to those given for isopropanol. These advantages may in some instances be somewhat less marked than those of isopropanol. For example, in one batch of sutures tested after tubing in normal propanol, the knot tensile strength obtained was approximately the same as obtained with isopropanol in concentrations ranging from 75% to 96%, but the straight tensile strengths were less in the lower ranges of concentration. In general, however, the properties of normal propyl alcohol alcohol correspond to those of isopropyl alcohol with re-

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spect to gut sutures, and our invention includes sutures tubed in normal propyl alcohol in proportions corresponding to the concentrations of isopropyl alcohol herein stated.

We claim:

1. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising material selected from the group of propyl alcohols and a softening agent for the suture, said mixture including, when placed in the container, a minimum of about 70% of said propyl alcohol material and a minimum of about 5% of said softening agent.

2. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising isopropyl alcohol and water, said mixture including, when placed in the container, about 90% of isopropyl alcohol and about 10% of water.

3. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising material selected from the group of propyl alcohols and water, said mixture including, when placed in the container, about 90% of said propyl alcohol material and about 10% of said water.

4. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising material selected from the group of propyl alcohols and water, said mixture including, when placed in the container, a minimum of about 70% of said propyl alcohol material and a minimum of about 5% water.

5. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising material selected from the group of propyl alcohols and water, said mixture including, when placed in the container, a minimum of about 70% of said propyl alcohol material and a minimum of about 10% water.

6. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising isopropanol and a softening agent for the suture, said mixture including, when placed in the container, a minimum of about 70% isopropanol and a minimum of about 5% of the softening agent.

7. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising isopropanol and water, said mixture including, when placed in the container, a minimum of about 70% isopropanol and a minimum of about 5% water.

8. As an article of manufacture, a sealed container having therein in combination a proteinaceous suture absorbable by the human body and a homogeneous liquid mixture comprising isopropanol and water, said mixture including, when placed in the container, a minimum of about 70% isopropanol and a minimum of about 10% water.

9. The method of reducing the frayability of animal gut sutures which comprises immersing the gut at room temperature in a water solution of one of the propyl alcohols, said solution including a propyl alcohol in proportion between 70%

and 95% of the total liquid and subsequently sealing the solution and the suture in a container.

10. The method of reducing the frayability of animal gut sutures which consists in storing the suture at room temperature in a water solution of isopropanol between 70% and 95% of the total liquid and subsequently sealing the solution and the suture in a container.

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