Nov. 8, 1949 J. O. BOWER ET AL 2,487,041

WOUND BINDING ELEMENT AND METHOD OF MANUFACTURE

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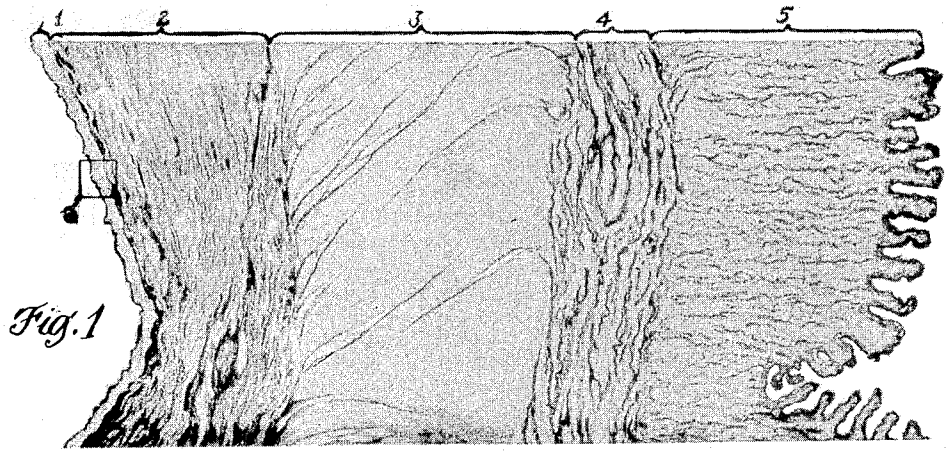


Fig. 1

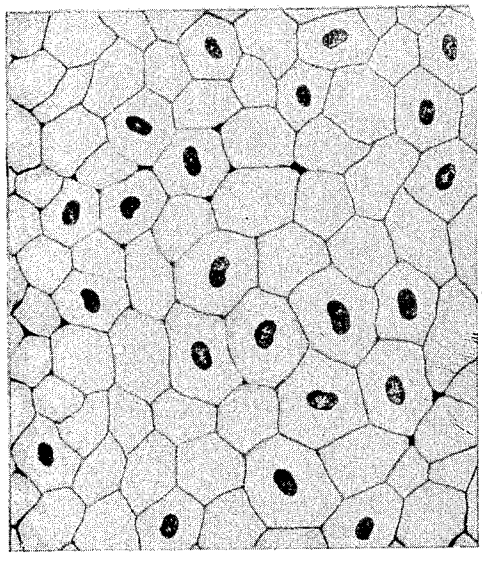


Fig. 2

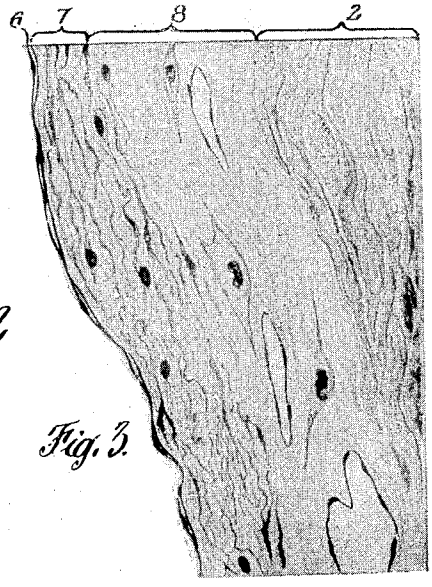


Fig. 3

Fig. 5.

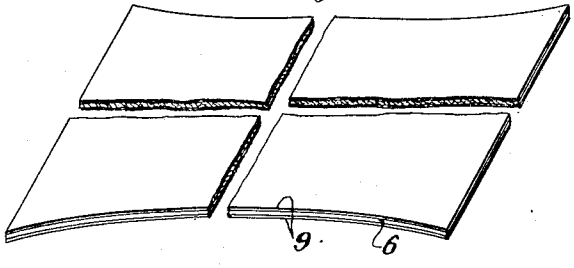
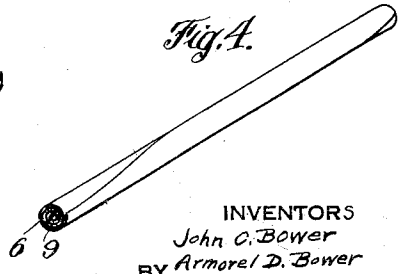


Fig. 4.



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WOUND BINDING ELEMENT AND METHOD OF MANUFACTURE

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12 Claims. (Cl. 128—335.5)

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Our invention is a wound binding element having phenomenal wound healing properties and a method of making it. Outstandingly our wound binding element takes the form of a surgical suture, but it may also have the form of a wound binding patch or filler.

Our outstanding object is to achieve a wound binding element which carries uniformly throughout its cross-section a wound healing compound. Synthetic sutures have been proposed by one of us, the strength-affording main body of the suture itself being comprised of a wound healing substance (e. g., see Bower application Serial No. 502,503, filed September 15, 1943). In this instance we seek to attain uniformity of wound healing character throughout the cross-section of sutures the main body of which derives its principal strength from a substance other than the wound healing substance. Thus we would seek to attain this uniformity of wound healing character throughout the cross-section of a suture having characteristics of catgut.

Sutures have been commonly made of catgut, but we have discovered that the peritoneal tissue of mammalians also can be effectively utilized in the attainment of our invention, and that when the main body of the suture is made of peritoneal tissue the strength per unit cross-section is greater than that of catgut in a catgut suture. We have discovered further that the peritoneal tissue can readily be given healing character throughout its cross-section by us.

Our method consists in deriving from within the abdominal cavity of an animal, particularly a mammalian animal, an elongated strip of peritoneal tissue deriving it cured and dried, impregnating it uniformly throughout its thickness and area while it is yet in strip form with an hemoglobin or other solution which affords it wound healing character, and thereafter consolidating the strip into filamentary cross-section. Preferably the consolidation is achieved by stretching the strip while it is still wet with the hemoglobin solution to convert its strip width cross-section into filamentary cross-section.

Wound binding elements in the form of ligatures or patches are manufactured by the same method, but while the step of stretching is used, it is used in a manner to maintain, not to convert, the cross-section.

The article of manufacture in which our method results is characterized as comprising this strip of wall structure derived from the abdominal cavity, uniformly impregnated throughout its cross-section with the wound healing hemoglobin

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solution, a characterization which is likely to be absent from sutures which are impregnated with an hemoglobin solution after they have been given final filamentary cross-section.

Peritoneal tissue is an outstanding form of the invention. Constituting the strength affording main body of peritoneal tissue affords it hitherto unrealized strength per unit of cross-section at the same time that it heightens the facility with which uniformity of impregnation may be attained. So far as we are aware, no one has ever before utilized peritoneal tissue in the manufacture of wound binding elements for use in surgery.

In the accompanying drawings:

Fig. 1 is a drawing of a microsopic section through one wall of an intestine.

Fig. 2 is an elevational view, so to speak, showing the appearance of the pavement-like epithelial cells which constitute the peritoneal membrane. This view is taken at a much higher magnification than Fig. 1.

Fig. 3 is an enlargement of the section outlined at "a" in Fig. 1, to the same scale as Fig. 2.

Fig. 4 is a sketch, on a grossly exaggerated scale, of an extremely short piece of a suture produced in accordance with our invention.

Fig. 5 is a grossly exaggerated view of a wound patch, produced in accordance with our invention, the illustration having been broken away in both directions, because if the area of the wound patch were in true proportion to the thickness illustrated, the patch would be many square yards in area.

Referring now to Fig. 1, it will be seen that the reference number 1 indicates the entire serous coating which is found on the outside of the intestine. The longitudinal muscular layer is indicated by the reference number 2. Within this is found the circular muscular layer identified by the reference numeral 3. This is joined to the mucosa or innermost layer 5 by the submucosal layer, marked 4. The drawing represents an enlargement of approximately 60 diameters.

A very small part of the longitudinal muscle indicated at 2 in Fig. 1 is indicated by the reference numeral 2 in Fig. 3. This is joined by a layer of connective tissue 8 and a mass of elastic fibers 7 to the peritoneal membrane 6.

This membrane, shown in face view in Fig. 2 (which is on the same scale as Fig. 3), comprises a layer of cells not more than two cells thick. It is this membrane which we prefer to use in forming the sutures and wound patches of our invention.

This membrane is indicated at 6 in Figs. 4

and 5. An attempt has been made to show the presence of a coating, identified by the reference numeral 9. Actually, this coating would be of microscopic thickness. Since the membrane itself is thinner than the finest tissue paper, the extent of exaggeration necessary in order to suggest the structure of the completed article may be appreciated. Furthermore, the spiral line in Fig. 4 which is intended to indicate the longitudinal edge of the strip of peritoneal tissue after it has been twisted and consolidated to form a suture is inaccurate. Actually, the impregnating fluid will fill out the contour of the suture to such an extent that its external surface will seem to be perfectly smooth.

The tissue known as peritoneum of all mammalians, whether it be of man, of steer or other mammals, is identical in structure and function. In structure it is approximately the thickness of the membrane beneath the hen's egg shell, from four to eight microns. It is composed of a thin layer of fibrous tissue covered with a single layer of endothelial cells. In extent it closely approximates the skin surface in man and the epidermal covering of the other species of the mammal group. Specifically in both, it is the innermost covering of the abdominal cavity and the external-most covering of all the organs therein contained with slight exception. When removed from these organs and dried, it resembles on inspection tissue paper. It is translucent, oily to touch, and when tested for tissue strength it is surprisingly strong.

The following is one example of the practice of our method, utilizing peritoneal tissue.

A large area of the wall is cleaned and cured after removal by any known processing. Then either dry or wet, it is cut in strips varying in length and width according to the indications for its use. For the average size suture "0" having a diameter of approximately 0.5 mm., strips of peritoneum 1 cm. wide and 37.5 cm. in length are cut. Each such strip is then placed in an hemoglobin, electrolyte stroma solution and permitted to remain varying periods of time, from a few minutes to as long as 48 or 60 hours. Such a solution is the subject of the copending application of John O. Bower, Serial No. 519,686, filed January 25, 1944. As there described, the solution comprises, essentially, the product resulting from deep-freezing animal blood, particularly after extraction of serum or plasma, the freezing being effected practically instantaneously, and the frozen material being thereafter thawed gradually. The hemoglobin constituent is the content of the red blood cells, the stroma is the cell wall or framework, and the electrolyte constituent is the inorganic residue of calcium, magnesium, sodium and potassium. Wound healing solutions other than this particular hemoglobin solution may be used, e. g., the sodium sulphide solution also described in our application Serial No. 519 686. However, a "pure" blood solution of the character first mentioned enters intimately into the achievement of our invention. The time that the strip is left in the solution is varied with variation in the degree of rapidity of absorption of the strip that is being treated. Usually within a minute or two after the 1 cm. strip is immersed in the hemoglobin solution it is completely coated externally and at least partly impregnated. It is then removed and stretched either by hand or in a stretching apparatus. The strip begins to assume a uniformly rounded shape as soon as it is drawn taut. It is stretched to a point where it is substantially circular in cross-section. It may then be permitted to dry. During the stretching and drying the coating completes its impregnation. By reducing the time of immersion and the time of drying, partial impregnation may be accomplished if desired. The coating and impregnation pervade uniformly all parts of the circular cross-section into which the width of the strip has been consolidated.

If instead of simply coating the thin tissue strip, the strip is alternately immersed in the hemoglobin solution and partially stretched by hand, it will become uniformly infiltrated through and through, and at the end of several of these cycles a strip of the initial dimensions given will measure about 0.4 mm. in diameter and will have increased in length approximately 20%. During the process of immersion and stretching, the excess fluid which collects on the strip is removed by running over it gently with the thumb and forefinger. It is then placed on a stretching apparatus and stretched to the maximum degree desired where set screws hold it so stretched until it is thoroughly dry.

The perfection of the circular cross-section may be aided if desired by twisting to a greater or lesser degree. Stiffness is relieved and excess dried particles of the hemoglobin solution removed by running it through the fingers in a limbering up process, after which it is placed in xylol and sterilized at a temperature of 160° C. for one hour.

In the manufacture of patches, pieces of peritoneal tissue of appropriate width and length are similarly coated or impregnated as may be desired, but instead of stretching to consolidate the cross-section, the piece is stretched flat or otherwise maintained flat until it dries, in order to further impregnation, to prevent curling, and in order further to permit appropriate removal of excess hemoglobin solution and appropriate cleaning up when dry. The degree to which adherence of excess of the hemoglobin solution to the surface of the body material is controlled during the coating or impregnation step of course controls the amount of cleaning up during or after the stretching and drying steps. In some cases a considerable coating of the hemoglobin solution may be permitted to remain upon the surface of the ultimate cross-section. In patches (and sutures, too) we contemplate that the surface may retain such a thickness of coating of the solution as will reduce to a minimal amount the initial irritation of the wound which is bound.

Sutures of peritoneal tissue have been tested for reaction in animals by the following procedures.

Using rabbits of 2 kilos weight or over, anesthesia is induced by intravenous sodium pentobarbital. The abdomen is prepared aseptically. A vertical incision is made and the stomach exposed. Three to four centimeters of each suture is embedded beneath the outermost covering, the peritoneum. Black silk sutures are placed at both ends of each suture to identify the exact embedding site. The abdomen is closed using aseptic technique. The rabbits are sacrificed at 1, 3, 5, 10, 15, 20 and 30 day intervals, occasionally longer, when sections containing the sutures are removed for microscopic examination.

These sections show that the tissues accept such sutures without any evidence of the irritation which is constantly present around ordinary sutures. This absence of irritation is due combinedly to the fitness of the mammalian per-

itoneum to be accepted by the tissues, and to the uniformity of the coating and infiltration of the hemoglobin solution.

The evidence of irritation referred to is the immediate mobilization of the white cells, the leucocytes which attempt to digest and absorb ordinary catgut, silk or cotton sutures. In other words, the tissue reaction against these foreign materials is the same as if they were composed of wood, steel or lead. Nature isolates them by first surrounding them with leucocytes which are later replaced by a capsule of scar tissue known as fibro-connective tissue.

It is to be borne in mind that it is peculiar to wounds in the abdominal cavity that they are wounds in the peritoneum, and the suture of peritoneal tissue is at home in this surrounding. When the sterile peritoneal strip impregnated with the hemoglobin-electrolyte-stroma solution is there imbedded under aseptic conditions, there is no attempt on the part of the tissues to treat it as a foreign body. It is immediately accepted as a part of the tissue in which it is implanted. The blending of the suture with the tissue in which it is implanted is so perfect that the differentiation of the two is at times only possible by using special stains. In contrast to this, the microscopic picture of the cross-section of the ordinary catgut, silk and cotton sutures not only show heavy leucocytic infiltration, but between the strand and the tissue in which it is imbedded is a space the width of which is frequently as great and at times greater than one-third the diameter of the suture.

The function of the suture material used in the uniting of divided tissue need be only temporary. Directly after apposition, the edges are cemented together with plasma and red blood cells. Across this bridge at the end of three or four days, capillaries (small blood vessels) begin to cross in both directions. The wound soon develops a strength of its own which increases each day until at the end of 10 to 14 days the suture is unnecessary. The ideal suture material maintains approximation of the wound walls until healing is complete and nature again takes over. It should be composed of materials similar in character to those normally present in man. The suture here described is just such a suture.

Patches or ligatures of similar characteristics and constructed by the same method have been made by us and tested in animals with advantageous results.

An expansive rather than a greatly elongated area of the peritoneum wall was prepared, the steps of the preparation being substantially those outlined above excepting that the stretching we achieved was in all directions rather than in the one direction of length as in the case of the preparation of the suture, whereby the expansive character of the area was maintained instead of being consolidated into suture cross-section.

More specifically, using aseptic technique, sterile prepared peritoneum is first cut to the desired size. The quantity of sterile hemoglobin, electrolyte, stroma solution is placed in a flat glass container and the prepared piece of peritoneum membrane placed flat upon it. The solution begins to penetrate the tissue immediately and it gradually becomes submerged. After a few minutes only isolated areas will appear above the surface. These are pressed down and the entire surface becomes covered by the solution. The membrane is permitted to remain as before

for varying periods of time depending upon the degree of impregnation desired; periods of time from 2 to 48 or 60 hours may be used, although impregnation becomes substantially entirely complete in a relatively short time.

We propose using these patches or ligatures for closing tissue defects in the outside coverings of the various organs of the human body—brain, stomach, intestines—and even for covering of nerves, tendons and ligaments. We propose using them fresh from the impregnating solution, placing them upon or about the organ in the locus of the defect and suturing them in place, preferably, but not necessarily employing the suture described above.

We have tested the use of these patches or ligatures by removing limited areas of the peritoneum of rabbits during anesthesia and replacing it with a patch or ligature of corresponding area prepared according to our invention. The area of peritoneum removed was from the anterior wall of the animal's stomach, the extent being from the junction of the proximal and middle thirds to the duodenum. The peritoneum was raised from the external muscular coat by blunt dissection. Bleeding was controlled. The patch or ligature having been cut to fit the defect, was affixed to the edges of the defect by using interrupted sutures. The rabbits so treated are living and thriving. Examinations indicate rapid and excellent healing.

The peritoneal tissue with which we have conducted our experiments has been derived from animals other than man and is of the kind commonly known as "gold beater's skin." We contemplate that peritoneal tissues derived from man may also be used, and, used in the body of man, this human tissue we believe will prove even more acceptable to the human system than other animal tissue.

We have described several different forms of our invention. It is susceptible of embodiment in a number of different forms and of modification in various ways, all without destruction of its generic spirit. In view of our present limited knowledge of such forms and modifications, and of the fact that utter novelty and lack of prior art may be responsible for shortcomings in our attempted definition of the invention, there should be imparted to the annexed claims and those which may follow them in the prosecution of the case, irrespective of their circumstantial terminology, every fullness of scope of the generic spirit.

What is claimed is:

1. The method of making surgical sutures which consists in deriving from within the abdominal cavity of an animal a cured relatively long strip of the membranous envelope, impregnating said strip before its consolidation into ultimate suture cross-section with a solution comprising at least one of the following constituent substances of animal blood, namely, hemoglobin and stroma, and thereafter consolidating it into suture cross-section.

2. The method of making surgical sutures of the peritoneal tissue of animals which consists in first deriving a narrow but long strip of material in cured condition, then impregnating the strip with an hemoglobin solution, and while it is still wet with the solution stretching it until its width is consolidated into a filamentary form.

3. A surgical wound binding element consisting of peritoneal tissue impregnated with the solution resulting from instantaneous freezing and

gradual thawing of the constituents of animal blood remaining after plasma extraction.

4. A surgical suture consisting of a strip of peritoneal tissue stretched lengthwise and impregnated with constituents of blood comprising at least hemoglobin and transversely rolled upon itself to the form of a thread.

5. The method of making a wound-binding element which comprises the steps of immersing in an impregnating solution a continuous web of peritoneal tissue, which tissue has been previously cured and stretched, until the solution has thoroughly impregnated the web, stretching the web while wet to effect a further extension thereof of the order of 20%, and drying it in stretched condition, the impregnating solution employed being a solution of blood constituents which includes hemoglobin in substantial quantity.

6. A surgical wound binding element the structural basis of which consists of a stretched and elongated web of peritoneal tissue and which has, uniformly distributed throughout its structure, the nonvolatile residue of a solution comprising at least one of the following components of blood, namely, hemoglobin and stroma.

7. The wound binding element of claim 6, consolidated into filamentary form for use as a surgical suture.

8. The wound binding element of claim 6, in which the solution also includes at least one of the remaining components of blood, namely, blood electrolytes and serum.

9. The method of making a surgical wound binding element which consists in deriving a cured continuous web of peritoneal tissue from within the abdominal cavity of an animal, and thoroughly impregnating the web with a solution comprising at least one of the following components of blood, namely, hemoglobin and stroma, while in flat form.

10. The method of claim 9, in which the impregnated web is stretched wet and is permitted to dry in stretched condition while still in flat form.

11. The method of claim 9, in which a relatively long strip of the impregnated tissue is stretched lengthwise and consolidated into the form of a surgical suture, and is permitted to dry in stretched condition.

12. The method of claim 9, in which the web of impregnated tissue is stretched flat to an elongation of at least 20%.

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