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(19)

(54) BONDED CONTROLLED RELEASE NEEDLE-SUTURE COMBINATIONS

(71) We, ETHICON INC., a Corporation organised and existing under the laws of the State of New Jersey, United States of America, located at Somerville, New Jersey, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

This invention relates to needle-suture combinations and a method of preparing them, and is an improvement in or modification of the invention described and claimed in our Patent Specification No. 1 562 927, referred to below as our "main" specification.

In our main specification, we have described and claimed a needle-suture combination comprising a needle having a pointed end and a blunt end with an axial opening in the blunt end, and a suture, wherein one end of the suture is secured in the internal axial opening in the needle solely by means of a bonding agent comprising a wax, as defined, having a melting point of at least 45°C and having a bonding affinity for the needle-suture combination which provides a needle pull-off value as defined of from substantially 3 to substantially 26 ounces.

In our main specification, we have also described and claimed a method of preparing a needle-suture combination wherein the needle has a pull-off value as defined of from substantially 3 to substantially 26 ounces which comprises:

(1) providing a needle having a sharp end and a blunt end and having an internal axial opening in the blunt end;

(2) charging the opening in said needle with a bonding agent comprising a wax, as defined, having a melting point of at least 45°C;

(3) inserting the end of a suture into the opening of the needle while the bonding agent contained in said opening is in a molten state; and

(4) cooling the needle to solidify the bonding agent in the opening while maintaining the end of the suture in said opening, whereby said suture is bonded to said needle in said needle opening by said solid bonding agent.

The present invention, like that of our main specification, is concerned more particularly with needle-suture combinations wherein the needle is attached to the suture in a nonpermanent manner which allows the needle to be deliberately pulled off the suture after completion of the suturing procedure.

In many surgical procedures, surgeons use an interrupted suturing technique which employs a suture thread and an eyed needle. The needle is threaded by the nurse and the surgeon takes one pass through the tissue using a needle holder. He slips the needle off the suture, returns the needle to the nurse, and is ready for another threaded needle from the nurse. An assistant follows behind and ties each suture.

Some surgeons find this technique preferable to using a needled suture which requires cutting the needle from the suture with a scissors after each pass. However, the time required for threading individual needles delays the suturing procedure, which is undesirable for the welfare of the patient and efficient utilization of expensive operating room time.

It has recently been suggested to use needle-suture combinations in which the needle and the suture are readily separable from each other after completion of the suturing procedure to provide the surgeon with the convenience of needled sutures without the inconvenience of requiring the needle to be cut off each suture. Several methods have been devised for preparing needle-suture combinations in which the pulloff value, which we define as the force required to separate the needle from the suture by a straight, steady pull is within the desired range. One approach to this problem is described in U.S. Patent 3,890,975, where the needle is attached to the suture by controlled swaging so that the force required to pull the needle off the suture is from about 3 to 26 ounces (0.085-0.736 kg). The needles are attached with

sufficient security to perform regular suturing procedures, and yet are readily removed by the deliberate action of the surgeon upon completion of the procedure.

Another approach to controlled release needle-suture combinations is described in U.S. Patent 3,799,169, where a suture is bonded in an open channel of a surgical needle with an adhesive composition which allows the suture to be peeled from the channel by a force of about 3 to 26 ounces when the suture is at an angle of 90° to the needle channel. Other issued U.S. patents describing needle-suture combinations having controlled release properties include U.S. Patents Nos. 3,875,946; 3,924,630; 3,926,194; 3,949,756; and 3,943,933.

Many of the prior-art controlled-release needle-suture combinations depend upon swaging to attach the needle to the suture. Controlled needle release values in the desired range are obtained either by controlling the degree of swaging, by partially withdrawing the suture from the swaged needle until the holding forces are reduced to the desired pulloff values, or by providing the securely swaged suture with a breakable segment adjacent the needle. Variations in suture composition or size, or in the size and finish of the needle barrel opening can affect needle attachment and make it difficult for the suture manufacturer to maintain pulloff values within the desired range.

U.S. Patent 3,799,169 *supra* depends upon adhesive forces rather than compression by mechanical swaging to obtain the desired release values, but is only effective with open channel needles which allow the suture to be peeled out of the channel.

Controlled release needle-suture combinations of the prior art have generally been characterized by a needle pulloff value within the range of 3 to 26 ounces. While this range is considered to be the preferred range for such needle-suture combinations, the *U.S. Pharmacopeia* has adopted a needle pulloff range of 0.028 to 1.59 kg (1 to 56 ounces) for sutures with "removable needles" and size 5-0 and larger as the standard for the suture industry.

It is an object of the present invention to provide another needle-suture combination having a removable needle within the specifications of the *U.S. Pharmacopeia*, i.e., with a needle pulloff value falling within the range of 1 to 56 ounces. It is a further object of the present invention to provide a controlled release needle-suture combination wherein the suture is secured within the axial opening of a surgical needle by means of a bonding composition which provides the needle with a pulloff value falling within the range of from about 1 to 56 ounces.

According to the present invention, we provide a needle-suture combination comprising a needle having a pointed end and a blunt end with an axial opening in the blunt end, and a suture, wherein one end of the suture is secured in the internal axial opening in the needle solely by means of a bonding agent comprising a wax (as herein defined) having a melting point of at least 45°C and having a bonding affinity for the needle-suture combination which provides a needle pulloff value (as herein defined), at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below.

The invention also includes a method of preparing a needle-suture combination wherein the needle has a pulloff value (as herein defined) at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below, which comprises: (1) providing a needle having a sharp end and a blunt end and having an internal axial opening in the blunt end; (2) charging the opening in said needle with a bonding agent comprising a wax (as herein defined) having a melting point of at least 45°C; (3) inserting the end of a suture into the opening of the needle while the bonding agent contained in said opening is in a molten state; and (4) cooling the needle to solidify the bonding agent in the opening while maintaining the end of the suture in said opening, whereby said suture is bonded to said needle in said needle opening by said solid bonding agent.

While adhesively bonded needle-suture combinations using drilled needles are known as described, for example, in U.S. Patents Nos. 2,928,395 and 3,394,704, conventional adhesives suggested in these references such as the polyepoxides, polyamides, polyesters, and urea resins do not reliably and consistently give needle pulloff values within the desired range for controlled release applications. These references are rather directed toward providing permanently attached needles having certain minimum, but no maximum, limits on needle attachment. The security of attachment of eyeless needles to absorbable surgical sutures or to nonabsorbable surgical sutures is prescribed in the *U.S. Pharmacopeia*, Vol. XVIII at page 944 (also see *U.S. Pharmacopeia*, Vol. XVII, p. 919). It has been the practice of suture manufacturers in the U.S. and abroad to securely attach the suture to the needle by swaging or with an adhesive so that the minimum pullout values recited in the *U.S. Pharmacopeia* are met or exceeded.

In the present needle-suture combination, as specified above, one end of the suture is secured in the internal axial opening of the needle solely by means of a bonding agent comprising a wax (as herein defined). The bonding agent may be any animal, vegetable,

mineral or synthetic wax (as herein defined) which has a melting point of at least 45°C and which provides a needle pulloff value (as herein defined), at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below. Needles are conveniently attached to the sutures by a method as specified above, wherein the needle opening is charged with molten wax (as herein defined), the top of the suture is inserted into the needle opening, and the needle is cooled to solidify the wax (as herein defined) surrounding the suture tip.

BRIEF DESCRIPTION OF DRAWINGS

In the accompanying drawings:

Figure 1 is an enlarged elevation, partially in cross section, of the blunt end of a drilled surgical needle having a surgical thread secured therein by a wax bonding agent.

Figure 2 is an enlarged elevation, partially in cross section, of the blunt end of a drilled surgical needle having a surgical thread secured therein by a wax bonding agent.

Figure 2 is an enlarged elevation, partially in cross section, of the blunt end of a preclosed channel surgical needle having a surgical thread secured therein by a wax bonding agent.

Figure 3 is a view of a bonded needle-suture combination in accordance with the present invention.

DESCRIPTION OF PREFERED EMBODIMENTS

The needle-suture combinations of the present invention comprise the elements of a surgical needle, a surgical suture, and a bonding agent comprising a wax (as herein defined).

The needles useful in the practice of the present invention are conventional surgical needles having a pointed end and a blunt end, and having an axial opening in the blunt end for receiving the suture. The needle may be fabricated of carbon steel or stainless steel. The pointed end may be a smooth tapered point or a shaped point with one or more cutting edges. The opening in the blunt end may be a drilled hole or a preclosed channel.

The suture may be any conventional multifilament surgical thread material such as braided silk, polyester or nylon, or twisted cotton or linen. Alternatively, the suture may be a monofilament material such as catgut or collagen. Synthetic monofilament sutures having very low surface friction characteristics such as conventional polyethylene or polypropylene may also be used, but care must be taken to ensure that the needle pulloff values do not fall below acceptable minimums. Since the release of needles from such sutures usually occurs by a separation between the suture and the bonding agent, improved bonding and higher needle pulloff values are obtained by simply roughening the tip of the suture prior to needle attachment to improve the security of the bond. Multifilament sutures which tend to fray when cut may be resin or wax coated to unify the tip for easier insertion into the needle, as described in U.S. Patent No. 3,890,975.

As used herein, the term "wax" includes true waxes and waxlike materials which, although not technically true waxes, nevertheless possess many of the attributes of waxes and are generally recognized as wax substitutes. We include in our broad definition of wax all such waxlike substances regardless of their sources, "since in the art of production or reproduction, we aim to have before us the whole field of waxes or waxlike substances from which we can select those which best suit our needs. Waxes are used in the arts because of their peculiar physical characteristics—seldom because of their chemical nature." (*The Chemistry and Technology of Waxes* by Albin H. Worth, 2nd Ed., 1956; p.3).

The term "wax" is defined according to *Hackh's Chemical Dictionary*, 4th Ed., to mean "a substance having the properties: (a) crystalline to microcrystalline structure; (b) capacity to acquire gloss when rubbed (distinction from greases); (c) capacity to produce pastes or gels with suitable solvents or when mixed with other waxes; (d) low viscosity at just above the melting point (distinction from resins and plastics); (e) low solubility in solvents for fats at room temperature." Waxes derived from animal, vegetable and mineral sources are included along with synthetic waxes which are primarily esters of high molecular weight fatty acids and high molecular weight alcohols.

In general, waxes may be classified as natural wax, fossil wax, earth wax, petroleum wax, or synthetic wax. Natural waxes include waxes from insects (beeswax), animals (woolwax) and plants (palm tree, candelilla, cotton and hemp wax). Fossil and earth waxes include montan wax and certain paraffin waxes. Petroleum waxes include rod wax, paraffin wax, and microcrystalline wax. Synthetic waxes include polyethylene wax, ethylene copolymer wax, carbowax and halogenated hydrocarbon waxes. All these and many other waxes which have application in the present invention are described in *The Chemistry and Technology of Waxes, supra.* However, not all waxes are useful in the present invention; we use, as already specified, only those waxes which have a melting point of at least 45°C and which have sufficient bonding power to secure the needle to the suture with

a pulloff value (as herein defined), at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below. Preferably, the melting point of the wax is between about 65°C and 200°C for ease and security of attachment. Wax melting point is determined by the "Standard Open End Capillary Tube" method of the American Wax Importers and Refiners Association, Inc., as described in *Wax Sampling and Test Methods,* Nov. 1960.

One particularly preferred wax is candelilla. Candelilla is a wax extracted from the coating of a shrub that grows in the arid regions of Mexico and the American Southwest. Candelilla is a relatively hard, brittle wax, having a Shore Durometer hardness value of 99-100 at 25°C. Official specifications for pure refined candelilla wax as published by the American Wax Importers and Refiners Association include: melting point 68.5° to 72.5°C, flash point 241°C, paraffinic hydrocarbons 45 percent minimum.

The "waxes" referred to herein include blends obtained by compounding candelilla and other waxes useful in the present invention with each other or with nonwax polymers, resins, rubbers, pigments, extenders and the like in order to control the melting point, hardness, color, viscosity or bonding strength of the wax. For example, a microcrystalline wax, e.g. candelilla, and/or a paraffin wax, may be formulated with an ethylene/vinylacetate copolymer, e.g. ELVAX, a wax-compatible ethylene/vinyl acetate copolymer which is a product of E. I. duPont de Nemours & Company. (The word "ELVAX" is a registered Trade Mark). ELVAX is reported to be a general-purpose resin designed for use with paraffin and microcrystalline waxes to provide good toughness and flexibility at moderate melt viscosity. Blending of ELVAX with petroleum waxes effectively improves the bonding strength of that wax. (DuPont Bulletin PL 14-171 "ELVAX Vinyl Resins").

The waxes employed in accordance with the present invention are distinguished from resins and plastic adhesives by having a low viscosity just above the melting point. A viscosity of less than about 20 centipoise at a temperature 10°C above the melting point of the wax (as herein defined) is particularly preferred, although higher viscosity values are not excluded. Low melt viscosities permit the suture to be readily inserted into the wax-charged hole of the needle, and allow the wax to flow uniformly around the suture as required to obtain uniform and cnsistent needle pulloff values.

The present invention is illustrated by the following examples where the waxes mentioned are used to secure needles to sutures of differing sizes and materials. In the preparation of these examples, conventional drilled needles were used. The opening in the needle was substantially filled with the selected wax. When ready for suture attachment, the needle barrel was heated to melt the wax, and the suture was inserted the full depth of the hole, allowing any excess wax to exude from the needle opening. The needle barrel was then chilled, e.g. by exposure to ambient air, to a temperature below the melting point of the wax to solidify the wax and secure the suture. Needle pulloff values were determined at room temperature (about 22°C).

The word "VICRYL" in the Examples is a Trade Mark of Johnson & Johnson or Subsidiary.

EXAMPLE 1

Size 0 VICRYL suture was attached to a needle having a bore diameter x depth of 0.55 x 1.84 mm using a 90/10 mixture of candelilla/ELVAX 310. For seven samples tested, the average pulloff value was 35 ounces with a range of pulloff values from 34 to 37 ounces.

EXAMPLE 2

Size 1 black braided silk was attached to a needle having a bore diameter x depth of 0.63 x 1.97 mm using the sealing wax of U.S. Patent No. 3,843,312. For 21 samples tested, the average pulloff value was 39 ounces with a range of pulloff values from 33 to 58 ounces. This example illustrates the preparation of a needle-suture combination having a removable needle in the upper range of the limits for needle pulloff values adopted by the *U.S. Pharmacopeia.*

In the preceding examples, the VICRYL and silk sutures were braided multifilament sutures, which were resin tipped, prior to needle attachment, to unify the strand.

As illustrated by the above examples, the suture materials may be attached to surgical needles with different wax compositions and formations to obtain desired needle pulloff values. The selection of a wax for any particular needle-suture combination is quickly and easily made on an experimental basis to obtain the desired needle pulloff characteristics.

In general, for any given needle-suture combination, needle pulloff values will increase as wax hardness is increased. For example, cendelilla wax is a hard, brittle wax which will provide higher needle pulloff values than paraffin wax. Using candelilla wax as a standard, needle pulloff values may be increased or decreased by formulating candelilla with other materials.

The surface characteristics of the suture also play a part in determining needle pulloff values. Smooth monofilament sutures such as polypropylene, for example, typic-

ally have significantly lower pullout values than comparably sized multifilament sutures. Surface coatings on multifilament sutures which tend to reduce surface irregularities and friction may also reduce suture pullout value compared to uncoated sutures.

Preferred needles for use in the present invention are drilled needles having a bore diameter of 1.05 to about 2.0 times the diameter of the suture. The needles bore should be as small as possible while permitting convenient insertion of the suture. Since it is desirable for surgical reasons to keep needle diameters small so that the puncture wound is small and filled by the suture, needle bore diameters in excess of 2.0 times the suture diameter are not recommended even though needle pulloff values in the desired range can be obtained with such larger bores.

With specific reference to the drawings,

Figure 1 illustrates needle 10 having drilled and chamfered hole 13. Suture 11 is bonded in hole 13 by a wax (as herein defined) shown at 12, which substantially fills hole 13.

Figure 2 illustrates needle 10 having axial opening 14 formed by a preclosed channel. Suture 11 is bonded in opening 14 by a wax (as herein defined) shown at 12.

Figure 3 illustrates a needle-suture combination of the present invention wherein suture 11 is bonded to needle 10 by means of a wax (as herein defined) which provides a needle pulloff value (as herein defined), at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below.

The inventive concept of the present invention resides in the use of waxes (as herein defined) for needle attachment to surgical sutures. Heretofore, waxes have been used as a suture coating to improve the lubricity thereof, and waxes have been suggested for use in combination with swaging to reduce the suture pullout value in order to obtain controlled release properties. Waxes, however, unlike adhesives, have not heretofore been suggested for use as the sole means of needle attachment. The discovery that waxes (as herein defined) not only provide a means for quickly and easily attaching needles to sutures, but that needles so attached have pulloff values within a narrow range desired for controlled release needle-suture combinations, and further that the variability of pulloff values for needles so attached is exceptionally low, represents a substantial advance in the art of constructing controlled release needle-suture combinations. Wax attachment is unique in providing a means for assembling controlled release needle-suture combinations in a variety of suture sizes, compositions and structures with a single attachment method and a simple technique.

In preparing a needle-suture combination by the method of the present invention, the opening in the needle, as specified earlier, is charged with the wax (as herein defined) prior to insertion of the suture, the wax (as herein defined) preferably being maintained at a temperature of from its melting point to about 200°C. The amount of wax charged to the needle opening is preferably just sufficient to fill the opening when the suture tip is inserted therein. If greater amounts of wax are used, the excess will simply exude from the needle opening when the suture is inserted, and be lost. If lesser amounts of wax are used, needle pulloff values will be correspondingly lower and variability of pulloff values may increase. The alternative procedure of dipping the tip of the suture in the wax prior to insertion into a preheated needle is not recommended since the entrapment of bubbles in the needle opening or incomplete bonding about the suture tip may result in variations in needle pulloff values.

Many variations of the present invention beyond those specifically disclosed herein will be apparent to those skilled in the art and it is to be understood that such variations are included within the scope of the present invention. In particular, there are very many waxes (as herein defined) which are useful in the practice of the present invention, and the present invention is accordingly not limited to any particular wax. There are also many steps which may be taken with regard to needle bore or suture-tip configurations in order to modify needle pulloff values. For example, the needle bore may be roughened, threaded, or otherwise modified to improve wax adhesion. Conversely, the needle bore may be polished to reduce wax adhesion. Likewise, the surface of the tip of the suture to be attached to the needle may be polished or roughened to decrease or increase wax adhesion. Yet other variations and embodiments of the present invention will be apparent to those skilled in the art and the invention is accordingly not limited except as set forth in the following claims.

WHAT WE CLAIM IS:

1. A needle-suture combination comprising a needle having a pointed end and a blunt end with an axial opening in the blunt end, and a suture, wherein one end of the suture is secured in the internal axial opening in the needle solely by means of a bonding agent comprising a wax (as herein defined) having a melting point of at least 45°C and having a bonding affinity for the needle-suture combination which provides a needle pulloff value (as herein defined), at room temperature, of up to substantially 56

ounces, excluding values of substantially 26 ounces and below.

2. A needle-suture combination of Claim 1, wherein the diameter of the axial opening is 1.05 to 2.0 times the diameter of the suture secured in said opening.

3. A needle-suture combination of Claim 1, wherein the axial opening in the needle is a drilled hole.

4. A needle-suture combination of Claim 1, wherein the axial opening in the needle is a closed channel.

5. A needle-suture combination of Claim 1, wherein the wax (as herein defined) has a melting point of from about 65°C to about 200°C.

6. A needle-suture combination of Claim 1, wherein the wax (as herein defined) comprises a wax having a microcrystalline structure.

7. A needle-suture combination of Claim 1, wherein the wax (as herein defined) has a viscosity of less than about 20 centipoise at a temperature 10°C above the melting point.

8. A needle-suture combination of Claim 1, wherein the wax (as herein defined) comprises a wax selected from the group consisting of natural wax, fossil wax, earth wax, petroleum wax, and synthetic wax.

9. A needle-suture combination of Claim 1, wherein the wax (as herein defined) is comprised of candelilla wax.

10. A needle-suture combination of Claim 1, wherein the wax (as herein defined) is comprised of a paraffin wax and/or a microcrystalline wax, and an ethylene/vinyl acetate copolymer.

11. A needle-suture combination of Claim 10, wherein the wax comprises a microcrystalline wax and this is constituted by candelilla.

12. A needle-suture combination of Claim 10, wherein the wax comprises a paraffin wax.

13. A needle-suture combination of Claim 10, wherein the wax comprises a mixture of a paraffin wax and a microcrystalline wax, and the latter is candelilla.

14. A method of preparing a needle-suture combination wherein the needle has a pulloff value (as herein defined), at room temperature, of up to substantially 56 ounces, excluding values of substantially 26 ounces and below, which comprises:

(1) providing a needle having a sharp end and a blunt end and having an internal axial opening in the blunt end;

(2) charging the opening in said needle with a bonding agent comprising a wax (as herein defined) having a melting point of at least 45°C;

(3) inserting the end of a suture into the opening of the needle while the bonding agent contained in said opening is in a molten state; and

(4) cooling the needle to solidify the bonding agent in the opening while maintaining the end of the suture in said opening,

whereby said suture is bonded to said needle in said needle opening by said solid bonding agent.

15. A method of Claim 14, wherein the axial opening in said needle is a drilled hole.

16. A method of Claim 14, wherein the axial opening in said needle is a closed channel.

17. A method of Claim 14, wherein the wax (as herein defined) is maintained at a temperature of from its melting point to about 200°C.

18. A method of Claim 14, wherein the needle is allowed to cool after insertion of the suture by exposure to ambient air.

19. The invention substantially as hereinbefore described.

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1587974 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

FIG. 1

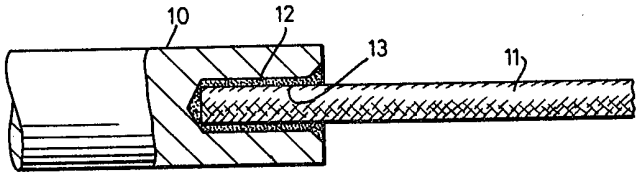

FIG. 2

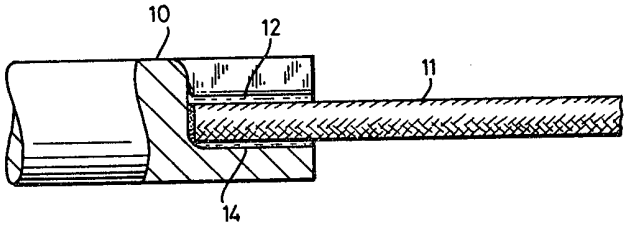

FIG. 3