United States Patent

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[54] SUTURE PROVIDED WITH WOUND HEALING COATING 14 Claims, 7 Drawing Figs.

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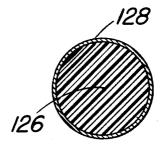
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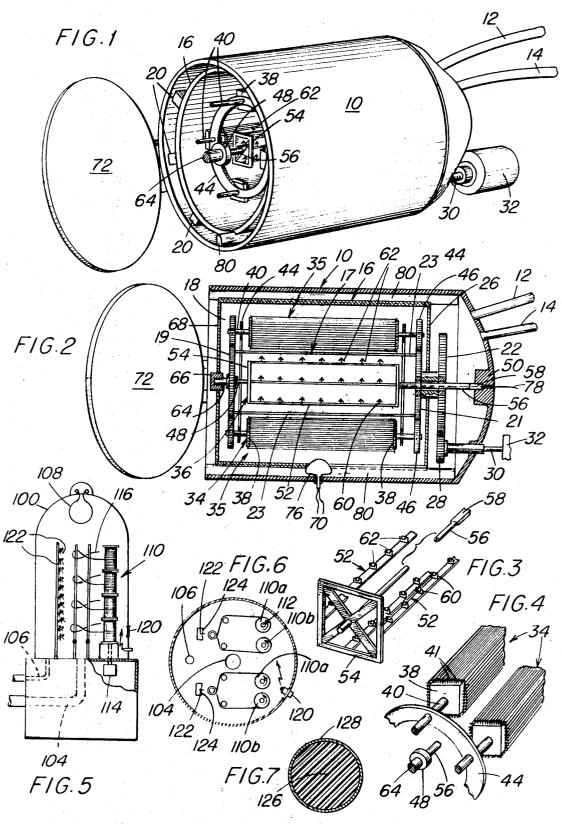
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ABSTRACT: Sutures coated with a wound-healing, nontoxic metal, such as aluminum or magnesium, are described as are methods for coating sutures with such material.



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SUTURE PROVIDED WITH WOUND HEALING COATING

CROSS REFERENCES

This is a continuation-in-part of application Ser. No. 531,768 filed Mar. 4, 1966, for SUTURES AND LIGA-TURES ADAPTED FOR THE ACCELERATION OF WOUND HEALING, and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to absorbable and nonabsorbable sutures for closing wounds. In order for a material to be satisfactory as a suture, it must be nontoxic and noncarcinogenic, have tissue acceptance and be flexible yet strong enough to 15 meet United States Pharmacopeia (USP) standards even when tied in a surgical knot. Naturally, it must also be sterilizable, be able to hold surgical knots without slipping and have only a limited stretchability so that under tension it does not exceed the stretch prescribed by USP standards. In addition, it is 20 desirable to have the suture add something to the compendium of surgical materials already available for use as sutures. Finally, it is desirable to have the suture somehow contribute to the healing of the wound in which it is used.

These last characteristics are the ones to which this inven- 25 tion pertains. It has recently been discovered that pure aluminum (i.e., aluminum that is 99.9999 percent pure) accelerates wound healing by an electrochemical reaction between the metal and the surrounding tissues. The same effect is also achieved with pure magnesium, although magnesi- 30 um's wound-healing ability is not as great. Monofilament sutures of either of these materials are not practical, however, because they are too brittle and cannot meet the knot-pull tensile strength requirements of the USP specifications for monofilament sutures. In the second place, since both alu- 35 minum and magnesium react with the surrounding tissues, they undergo a chemical transformation and dissipate during the wound-healing process and thus weaken the suture and lessen its ability to keep the wound closed.

SUMMARY OF THE INVENTION

I have discovered that both these undesirable characteristics can be overcome by providing a suture which is coated with a wound-healing metal such as aluminum or mag- 45 nesium. The core os such a suture is preferably Dacron, nylon, polyester fiber or stainless steel, though any other suitable suture material such as cotton, silk, catgut (plain or chromicized), collagen (plain or chromicized) or any other organic, inorganic, metallic or synthetic material which lends 50 itself to usage as a suture can also be used. The core can be a standard monofilament suture or it can be a twisted or braided suture made of any of these materials. Using aluminum as a coating not only helps heal the wound faster, it gives the advantage that the strength of the suture is not lessened as the 55 aluminum dissipates in the wound. On an absorbable suture the aluminum or magnesium coating also acts as a temporary barrier between the tissue cells and the absorbable material, thus increasing the suture's useful life in the wound. The coating should be as pure as possible because its wound-healing 60 ability diminishes with the number and amount of alloying materials in the metal as well as with the number and amount of contaminants it contains. Neither of these materials should comprise over 5 percent impurities. Aluminum that is 99.9999 percent pure is preferred, though if it contains 0.76 percent 65 magnesium and less than 0.0009 percent of any other component, the coating is quite satisfactory. Oxidation of the coating also reduces its activity and its wound-healing ability. To give a suture the desired wound-healing characteristic, the coating should be of the appropriate thickness. A principal ad- 70 vantage of using either of these materials, and this is particularly true of aluminum, is that it enables the fibrotic reaction in wound healing to proceed at a controlled, faster-than-ordinary rate. Thus, by controlling the thickness of the coating, it is possible to insure that when it is healed there will be no 75 manner using other known temperatures and tensions.

residual fibrotic reaction in the wound due to the presence of the coating material. I have found that a thickness from between about 6 to 40 microns is useful in achieving this result with the range of about 10 to 20 microns being preferred in order that the reactive coating material be substantially completely dissipated from the suture core by the time the wound is healed.

The coating process includes cleaning the suture core by any known chemical or other process. When Dacron, nylon, 10 silk or certain other suture materials are used, it is also necessary to render them dimensionally stable by thermosetting them in a known manner at a temperature which is at least 10° F. higher than any temperature at which they are likely to be subjected later. Then all suture materials are bombarded over their entire surface with negatively charged particles under high vacuum with the result that they become negatively charged. This should be done in a thin atmosphere of pure nitrogen or one of the inert gases to prevent oxidation. By then vaporizing the aluminum, the vapor is attracted to and condensed on the suture material with a strong bond. Vaporization of the aluminum can be accomplished by any convenient known technique, such as by heating tungsten filaments over which strips of aluminum are twisted or hung, or by using a laser beam or by induction heating. If the filament method is used, the vaporization should take place at as low a temperature as possible to avoid vaporizing tungsten particles which would also be deposited on the suture material and which are toxic to the tissues. When sufficient aluminum has been vaporized and deposited on the core material, the vacuum is broken and the coating process is over. I have also discovered that (whether the core material is bombarded before deposition or not) all the aluminum or magnesium must be deposited

on the core in a single session without breaking the vacuum. Once the vacuum is broken, even if more wound-healing metal is later deposited on the suture using a second vacuum, for some reason the first or undercoating material appears to have lost most of its wound-healing or reactive ability. Thus, the suture's wound-healing ability will depend almost entirely 40 on the thickness of its second or last coating. To improve the

adherence of the wound-healing coating on metallic sutures, it is useful to minutely etch the surface of the suture before subjecting it to the bombardment treatment.

Further, other and additional aspects of the invention will appear from the following description, the novel features of which will be particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWING VIEWS

FIG. 1 is a schematic perspective view of a vacuum chamber which can be used to coat a suture in accordance with the invention.

FIG. 2 is a vertical elevation in cross section of the chamber of FIG. 1.

FIG. 3 is a perspective view of a portion of the tungsten heating element frame shown in FIG. 2.

FIG. 4 is a perspective view of a portion of the rotatable suture rack frame shown in FIG. 2.

FIG. 5 is a vertical elevation view in cross section of another

kind of vacuum chamber usable in coating the suture core.

FIG. 6 is a plan view of the vacuum chamber of FIG. 5.

FIG. 7 is a cross section view of a coated Dacron suture according to the invention.

DETAILED DESCRIPTION

Referring now more particularly to the drawings, the process of coating Dacron core material with aluminum is begun by thermosetting or dimensionally stabilizing the material in a known manner by bringing it up to a temperature of between 300°-360° F. under a tension which can vary from 5-25 percent of its breaking tension depending on the residual stretch to be left in the material. Certain other materials, such as nylon or silk, must also be thermally set in this

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Then the suture must be cleaned to remove all reactive constituents or substances from its surface. This can be done using standard ultrasonic cleaning techniques for sutures or by subjecting it to multiple washings in neutral nonreactive clean (USP) water. Stainless steel sutures are usually cleaned in toluene. When the material is clean, it is placed in a vacuum chamber 10 having one open line 12 connected to a source of vacuum (not shown) and another open line 14 connected to a source of nitrogen (not shown). In operation the chamber is preferably drawn down to a high vacuum of about 4×10^{-8} 10 microns and is then filled with nitrogen after which the vacuum is again drawn down to about 4×10^{-8} microns. Lower vacuums down to 3×10^{-4} microns can also be used, but the higher the vacuum the better the deposition and the lower the vaporizing temperature will be. By refilling the chamber this way, it is purged of air and all its contaminants and contaminating influences and is filled with a thin atmosphere which inhibits oxidation so the deposition process can be carried out effectively and easily. When a stainless steel 20 suture is being coated, it is helpful if it can be heated while the deposition is taking place because I have found that such heating improves the bond between the coating and the suture.

In carrying out the process, with all suture materials it is important that to the extent possible the entire surface of the 25 material be exposed not only to the conditioning step in which the surface is treated to insure adequate bonding of the coating but also that it face directly and be exposed on all sides to the source of the metal being deposited on it. This can be accomplished by rotating the material in the chamber 10. As 30 seen in FIGS. 1-4, chamber 10 includes a fixed cylinder 16 separated from the cylindrical wall 18 of the chamber by a plurality of mounts 20. Inside cylinder 16 is a cage 17 which can be rotated by a gear 22 rigidly connected to it about its central axis by means of a collar 24. A spider bearing 26 35 rotatably supports the collar along the axis of the cylinder. Cage 17 includes an idler gear 19 at one end and a driven gear 21 at its opposite end and the two gears are connected to each other by a plurality of rods 23. Gear 21 is releasably fixed to collar 24. A pinion gear 28 powered by shaft 30 driven by a 40motor 32 drives gear 22 to rotate collar 24 and thus gear 21. Motor 32 is shown schematically outside the chamber in FIG. 1.

Surrounding cage 17 there is a frame assembly 34 for carrying and rotating the Dacron or other material to be coated. In- 45 side the cage is a nonrotating framework 36 for carrying and vaporizing the aluminum to be deposited on the material.

Assembly 34 preferably includes four rack units 35 each of which includes two frames 38 separated from each other but 50 rigidly mounted coaxially on a rotatable shaft 40. Each frame has a plurality of fingers 41 protruding from its edges to enable the Dacron 42 to be strung back and forth between opposing fingers on the other frame on the shaft. The racks are independent but lie parallel and 90° apart from each other in a pair of 55 rims 44 in which each shaft 40 is rotatably mounted (see FIG. 2). Mounted on opposite ends of each shaft 40 beyond rims 44 is a gear 46 which meshes either with idler gear 19 or driven gear 21 so that when the cage rotates each rack unit 35 rotates about its shaft 40 in the same direction. At the same time the 60whole assembly 34 rotates about the central axis of the cylinder. Thus, when the cage rotates, each of the racks 35 moves around the cylinder in addition to rotating about the axis of its shaft 40.

The aluminum is supplied to the Dacron or other material 65 on these racks by a heater framework 36 mounted inside cage 17 between a cup 48 at one end and a mounting block 50 at the other. Framework 36 includes four heater racks 52 each of which includes four or more tungsten filaments 60 on which are placed or twisted the strips of aluminum 62 which are to 70 be vaporized. These racks are mounted parallel each other and 90° part on a pair of frames 54 at opposite ends of each rack and frames 54 are rigidly mounted coaxially on a shaft 56. One end of the shaft is mounted in cup 48 and the other end extends through gears 21 and 22 and collar 24 to mount-75

ing block 50 in the rear of the chamber. The end of the shaft in the mounting block has a rectangular cross section 58 to prevent the shaft and the framework from rotating. Cup 48 is mounted coaxial with assembly 34 on one side of gear 19 which has one end of a stub shaft 64 fixedly mounted on its opposite side. The other end of stub shaft 64 is journaled in a spider 68, the radial tips of which are releasably attached to the forward end of cylinder 16. In operation, cage 17 rotates at one speed, suture racks 35 rotate around their shafts 40 driving assembly 34 around the cylinder in the same direction but at a slower speed than the cage. Heater racks 52, framework 36 and spider 68 remain stationary. In this way all the surfaces of the Dacron or other material are brought close to the source of the aluminum vapor.

15 A door 72 is provided to close the open front end of the chamber and is equipped with conventional means for sealing the chamber against air leaks when a vacuum is drawn. A conventional spark gap unit 74 is also provided in the chamber to detect the presence of substantial amounts of free metal in the chamber during deposition of the metal. The chamber also includes a known device 76 for bombarding the material mounted on racks 35 with negatively charged particles such as electrons. The device is shown schematically in FIG. 2 and is connected to a control (not shown) outside the chamber by wires 70. Preferably the device produces a stream of electrons accelerated through a potential of 25,000-30,000 volts for at least 5 minutes, while the racks 35 are rotating to insure that all the surfaces of the Dacron have been bombarded and become negatively charged.

After the Dacron has undergone this conditioning treatment, the aluminum deposition begins. In the device shown in FIGS. 1-4 in the drawings, this is accomplished by energizing one of the tungsten filaments on each rack 52 at a time. Under a vacuum, aluminum vaporizes into positively charged particles at temperatures ranging from 800° to 1500° F. The precise temperature depends on the purity of the aluminum and the extent of the vacuum. Electrical controls (not shown) are provided outside the chamber to insure that the temperature of the filaments doesn't get too hot. As soon as all the aluminum that will vaporize from these filaments at the desired temperature has been given off, the filaments are turned off. The existence of this condition is detected by observing the spark gap unit to see when the residual amount of free aluminum in the atmosphere within the chamber is not sufficiently concentrated to conduct electricity across the gap of the unit. When this occurs, the condition has been reached, and after the first set has been turned off, another set of filaments is energized to vaporize additional aluminum. This sequence is followed again and again until all the filaments in the chamber have been energized and no more aluminum can be vaporized at the desired temperature. The aluminum particles are initially attracted to the suture because of the potential difference between them; and while the deposition process is going on, the cage, racks, gears, frames and assemblies are rotating to expose as much of the surface of the suture material as possible and to get it as close as possible to the vaporized aluminum source. Wiring 78, shown schematically in FIGS. 1 and 2, connects the filaments with the controls (not shown) and permits them to be selectively energized.

When the deposition is finished, the vacuum is released and the coated suture is removed from the chamber by removing cylinder 16 along guide tracks 80 (see FIG. 1).

As seen in FIGS. 5 and 6, the Dacron or other suitable suture core material need not be wound between fingers on spaced apart frames, as in FIGS. 2 and 4, but can be stored on spools 110 which can be stacked one on top of the other and fixed to a rotating shaft 112 driven by a motor 114 in the base 102 of a different kind of vacuum chamber. This type of chamber comprises a metal bell jar 100 which is releasably sealable to the base which has a vacuum line 104 and a nitrogen-purging line 106 opening within the jar. The chamber also includes a known electron bombardment device 108 shown schematically, a known spark gap unit 120 and a supply

of aluminum for vaporization as in the first type chamber. Though the aluminum supply shown in FIGS. 5 and 6 comprises strips 122 of aluminum placed or twisted on tungsten filaments 124, it should be realized that the supply could comprise an aluminum bar which is vaporizable by a laser beam or by induction heating. The essential difference between this type chamber and that shown in FIGS. 1-4 is that here there has to be at least one takeup spool and one feed spool in the chamber. As shown in FIG. 6, there are two stacks of each type, reference character 110a referring to the feed spools and 110b to the takeup spools. The suture material 116 is threaded from spools 110a over and through a set of three idler rollers 118 to spools 110b in such a way that all surfaces of the material can be directly exposed to the source of vaporized aluminum by rotating the spools so as to transfer the material from one spool to another. Then, by rotating the spools, all the suture material may be bombarded and coated with aluminum. The finished product has a cross section like that shown in FIG. 7 in which 126 is the suture core and 128 the 20 coating.

If desired, a nonabsorbable coated suture according to this invention can be left in the body as a supporting element even after the coating has been dissipated. It is still useful in strengthening the tissues around the location of the healed 25 wound even after the coating is gone.

It will be understood that various changes in the details, materials, steps and arrangements of parts, which have been herein described and illustrated in order to explain the nature of the invention, may be made by those skilled in the art within the principle and scope of the invention as expressed in the 30 coating comprises pure aluminum. claims

I claim:

1. A surgical suture useful for accelerating the healing of wounds by beneficial fibrotic reaction with the tissues surrounding such wounds, said suture comprising:

an elongated core of surgical suture material; and

a coating on said core of a different material, said coating extending over a substantial portion of the surface of said core, said coating material being selected from the group consisting of substantially pure aluminum and substan- 40 tially pure magnesium.

2. A suture material according to claim 1 wherein said coating has a thickness of between about 6 and 40 microns.

3. A suture material according to claim 2 wherein said coating comprises aluminum.

4. A suture material according to claim 2 wherein said coating comprises magnesium.

5. A suture component according to claim 3 wherein said suture component comprises a nonabsorbable suture.

6. A suture material according to claim 5 wherein said nonabsorbable suture component comprises Dacron and said aluminum coating has a thickness of between 10 to 20 microns.

7. A suture material according to claim 2 wherein said suture component comprises an absorbable suture and said coating comprises aluminum.

8. A suture material according to claim 5 wherein said nonabsorbable suture component comprises stainless steel.

9. A surgical material for use in a patient as ligatures and as 15 sutures for closing wounds, said surgical material comprising:

- an elongated core of surgical suture material; and a coating on said core of a different material, said coating
- extending over a substantial portion of the surface of said core, said coating material being selected from the group consisting of substantially pure aluminum and substantially pure magnesium; said coating being adapted to beneficially chemically react with the tissues in the vicinity of said surgical material, said coating being of such thickness as to increase the rate of fibrosis in said tissues at a controlled rate, said coating being dissipated by said chemical reaction and the residual fibrotic reaction due to said coating materials ceasing when said coating has

been completely dissipated. 10. The combination according to claim 9 wherein said

11. The combination according to claim 10 wherein said suture component comprises a nonabsorbable material which can be left as a supporting element for the wound tissues after said coating has been completely dissipated.

35 12. The combination according to claim 11 wherein said aluminum coating has a thickness of between about 6 to 40 microns.

13. A suture component and coating according to claim 7 wherein said suture component is resorbable in the wound and said coating protects said component against resorption until said coating has been dissipated.

14. A suture component and coating according to claim 11 wherein said coating comprises pure aluminum between about 10 to 20 microns in thickness.

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