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[54] **TUBE FOR CONNECTING BLOOD VESSELS**

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[58] Field of Search ... **128/334 R, 334 C, 335.5, 348; 3/1; 424/35; 99/138**

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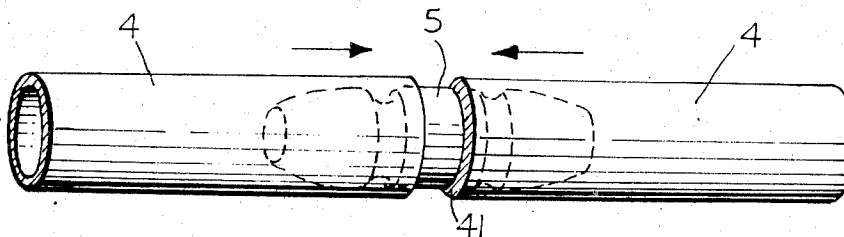
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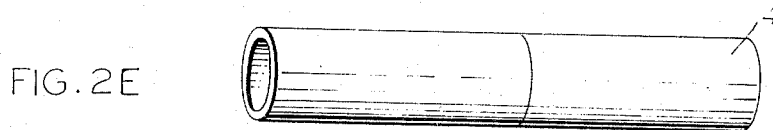
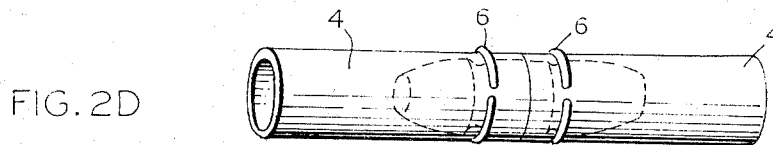
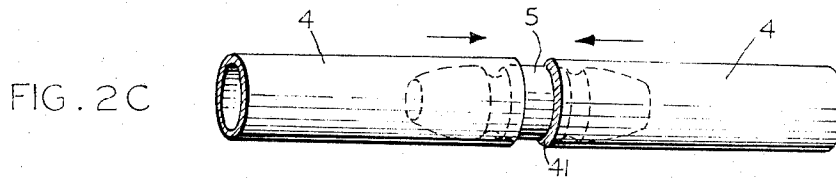
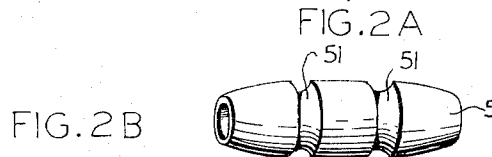
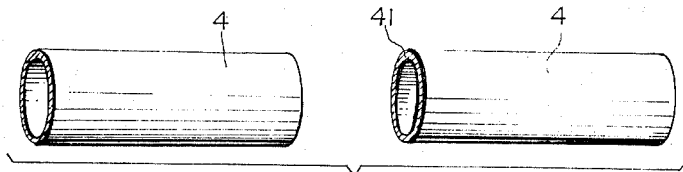
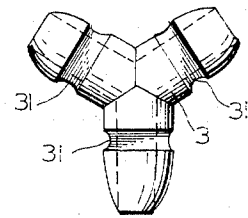
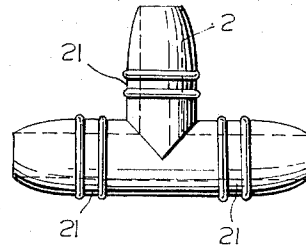
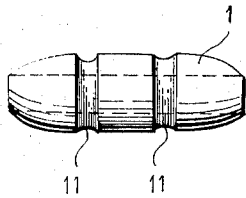
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[57] **ABSTRACT**

A tube readily soluble into blood and useful as the support for connecting blood vessels, which is made of a composition comprising 70 to 90 percent by weight of sucrose, 6 to 25 percent by weight of a crystallization inhibitor therefor and 2 to 10 percent by weight of an elasticizer, shaped in a cylinder, T-letter or Y-letter form, tapered at both ends and provided grooves or protuberances circumferentially on the outer surface.

10 Claims, 8 Drawing Figures





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TUBE FOR CONNECTING BLOOD VESSELS

The present invention relates to a tube for connecting blood vessels. It also relates to a method for preparation of such tube. It further relates to a method for connecting blood vessels by the aid of such tube.

Suture technique of blood vessels was started by Hovoch early in 1800. Recently, further progress in small vascular surgery was made by Jacobson who introduced microstructure technique, and stapling technique has been developed with various new stapling instruments too. But, usual apparatuses of stapling or suture technique are not applicable to intracranial vascular surgery, because these apparatuses are too large to manipulate in very small operative fields. In addition, there is a danger of injuring to other surrounding important tissues such as cranial nerves, brain tissues and many small vessels.

In order to apply even to deeply located blood vessels as cerebral ones, attempts have been made on non-suture vascular anastomosis utilizing plastic adhesives, which is easy to manipulate and less time consuming and does not need any large supplementary instruments. In such non-suture vascular anastomosis, a support material shaped in, for instance, tube or rod is inserted to the lumens of both vascular ends, a plastic adhesive is applied to this anastomotic portion and blood flow is re-established so that, after a while, the support material dissolves into blood.

As understood from such technique, the support material should meet at least the following three requirements: (1) exerting no material toxicity on living bodies such as animals and human beings; (2) having such rigidity as can be readily inserted into vascular lumens; and (3) being soluble with ease into blood so as to recover smooth flow of blood as early as possible. Although various materials and shape have been proposed for such support, satisfaction has been not fully obtained on any proposal.

As the result of the study for a long time, it has now been found that a certain composition comprising sucrose as the main component meets the said requirements and is an ideal material for such support. On this finding, there has been produced a tube made of the said composition and shaped in such form as being easily inserted in and difficultly slipped out of vascular lumens, and it has been confirmed that the vascular anastomosis can be accomplished quite successfully in various blood vessels including diseased vessels like atherosclerotic arteries and deeply located vessels as cerebral ones. The present invention is based on these finding and confirmation.

Accordingly, a basic object of the present invention is to embody a tube useful as the support on non-suture vascular anastomosis. Another object of this invention is to embody a method for preparation of such tube. A further object of the invention is to embody a method for connecting vascular vessels by the aid of such tube. A still further object of the invention is to embody a composition suitable for preparation of such tube. These and other objects of the invention will be apparent to those conversant with the art to which the present invention pertains from the above and subsequent descriptions.

The following is a brief description of the drawings. FIG. 1 shows the front views of the tubes which are three typical embodiments of the invention. That is,

FIG. 1 (A) shows a cylindrical tube FIG. 1 (B) shows a T-letter shaped tube and FIG. 1 (C) shows a Y-letter shaped tube.

FIG. 2 illustrates the steps for connecting blood vessels according to the present invention. FIGS. 2 (A) and (B) show, respectively, two blood vessels to be connected each other at the section surface and a spindle tube (same as shown in FIG. 1 (A)) to be used as the connection between the blood vessels.

FIG. 2 (C) shows the intermediate state for connection wherein both ends of the tube are inserted into the lumens of the blood vessels. FIG. 2 (D) shows perfection of the insertion wherein two ring clips are placed on the outer surfaces of the blood vessels. FIG. 2 (E), shows the state after accomplishment of the connection where the tube dissolved and disappears into blood flow.

The tube of the present invention is made of a composition comprising sucrose as the main component, a crystallization inhibitor therefor and an elasticizer.

As the crystallization inhibitor, there are exemplified glucose, lactose, maltose, etc. Examples of the elasticizer are dextran, dextrin, etc.

The weight ratio of the components affects the solubility in blood flow and the mechanical strength of the resulting tube and may be varied with the place to which the tube is applied. Usually, the composition includes 70 to 90 percent 90 by weight of sucrose, 6 to 25 percent by weight of the crystallization inhibitor and 2 to 10 percent by weight of the elasticizer on the basis of the weight of the composition. The most preferable weight ratio at present is sucrose : the crystallization inhibitor : the elasticizer = 80 : 16 : 4.

In addition to the said essential components, the composition may include an antimicrobial agent, a blood coagulation inhibitor (e.g., mucopolysaccharides, heparin) and any other additive.

For preparation of the tube using such composition, the said essential components with or without the said optional components are first dissolved into water. The resultant solution is heated up to 150° to 170° C. Heating above 170° C is not favorable, because caramelization is caused and the caramelized product is not suitably used for the object of the invention. The heated solution is then cooled to about 60° C for obtaining a soft, glassy material, from which a long pipe is drawn in the same manner as adopted on the manufacture of a glass pipe. The pipe is then cut at a proper length to make numerous pieces of tubes, each of which is then preferably tapered at both ends so as to be easily inserted to vascular ends and also favorably provided with grooves or protuberances circumferentially on the outer surface for preventing from slipping out of vascular ends.

Alternatively, the soft, glassy material may be shaped directly into a tube by the use of a mold. In this case, the tapering and/or the formation of grooves or protuberances may be accomplished simultaneously.

The thus obtained tube is of hard, glassy quality and usually stored under the condition prevented from moisture.

Prior to storage or use, the tube may be dipped in a solution of the antimicrobial agent and/or the blood coagulation inhibitor and then dried to make a film of such agents on the surface.

A practical and presently-preferred embodiment of the invention is illustratively shown in the following Example.

EXAMPLE

A solution of 80 g of sucrose, 16 g of glucose and 4 g of dextrin in 200 g of water is gradually heated up to 160° C and then allowed to stand for cooling. After cooled to 80° C, the solution is kept in a warming room and gradually cooled to about 70° C. After removal of a hard film formed on the surface, an appropriate amount of the resultant soft, glassy material is attached uniformly around a cylindrical stick made of polytetrafluoroethylene ("Teflon") or glass (linoleic acid being applied previously on the surface in the latter case) so as to make a layer of 6 mm in thickness. When cooled to about 60° C, the stick is taken off, and the resultant hollow material is drawn to the directions of both ends while heating the central or trunk portion of the said material so as to make a pipe of 1 to 5 mm in outer diameter. The pipe is cut by alcoholic vapor without affording any change on the inner diameter into some pieces of tubes, each tube being 10 to 20 mm in length. A heated silver or platinum wire is contacted on the surface of the tube, and the tube is gradually rotated so that a groove is formed circumferentially on the surface. In the same manner, another groove is provided on the surface at a distance from and parallel to the said groove. The grooved tube is irradiated under ultraviolet sterilization lamp and stored in a desiccator. The tube is readily soluble in water, sparingly soluble in anhydrous ethanol and materially insoluble in benzene, toluene, ether, fats and oils.

Some of the experiments on the connection using the above prepared tube are shown below.

EXPERIMENT 1

The tube of the invention was inserted to each one end of two vinyl tubes to be connected each other and, after applying an adhesive to the section surface of the vinyl tubes, they were brought into contact each other by the section surface. Then, stored blood at 37° C was flowed to the connected vinyl tube at a pressure of 130 mmHg. The tube of the invention dissolved completely within 40 seconds.

EXPERIMENT 2

Common carotid arteries, femoral arteries and femoral veins of 2.0 to 4.0 mm in external diameter from 23 mongrel dogs weighing 4 to 11 kg were subjected to the experiment.

After transection of the artery occluded by two clamps, adventitia of vascular ends was stripped. The lumens of the vessels were irrigated with dilute heparinized saline solution. The tube of the invention having the same diameter as the internal diameter of the vessel was inserted to the both vascular ends. These ends were connected closely by the tube and two polyethylene sheathed clips were laid at the point of grooves of the tube from outside for fixation. Excessive blood and moisture at the anastomotic portion were removed by using a sponge and a very small amount of an adhesive ("Aron Alpha A" composed of 98 percent alpha-ethylcyanoacrylate monomer plus 2 percent

thickening agent and inhibitor) was applied directly by a polyethylene stick. After one minute for polymerization, the distal clamp was released first and, after confirmation of no occurrence of major bleeding, the proximal clamp was released. It was microscopically observed that anastomotic sites were covered smoothly by intimal proliferation within two weeks, and anastomosis was successfully accomplished.

Illustrating the present invention in reference to the attached drawings, FIG. 1 shows the front views of the tubes which are three typical embodiments of the invention. That is, FIG. 1 (A) shows a cylindrical tube (1) tapered at both ends and provided two grooves (11,11) circumferentially on the outer surface. FIG. 1 (B) shows a T-letter shaped tube (2) tapered at each end and provided three pairs of protuberances (21,21,21) circumferentially on the outer surface. FIG. 1 (C) shows a Y-letter shaped tube (3) tapered at each end and provided three grooves (31,31,31) circumferentially on the outer surface. The tapered portion is served for making it easy to insert into vascular lumens. The grooves and the protuberances are available for prevention of slipping out of vascular ends. If desired, ring clips may be placed on the groove or protuberance portion after insertion the tube in blood vessels.

FIG. 2 illustrates the steps for connecting blood vessels according to the present invention. FIGS. 2 (A) and (B) show respectively two blood vessels (4,4) to be connected each other at the section surface (41) and a spindle tube (5) (same as shown in FIG. 1 (A)) provided two grooves (51,51) before the connection. In FIG. 2 (C) showing the intermediate state for connection, both ends of the tube (5) are inserted into the lumens of the blood vessels (4,4). At this stage, an adhesive is applied to the section surface (41). In FIG. 2 (D) showing perfection of the insertion, two ring clips (6,6) are placed on the outer surfaces of the blood vessels at the places corresponding to the grooves of the tube now completely enclosed in the blood vessels for securing the connecting. In FIG. 2 (E), there is shown the state after accomplishment of the connection where the tube dissolved and disappeared into blood flow.

What is claimed is:

1. A tube for connecting blood vessels which is made of a composition comprising 70 to 90 percent by weight of sucrose, 6 to 25 percent by weight of a crystallization inhibitor selected from the group consisting of glucose, lactose and maltose, and 2 to 10 percent by weight of an elasticizer selected from the group consisting of dextran and dextrin on the basis of the total weight of the composition.
2. The tube according to claim 1, wherein the composition comprises an antimicrobial agent.
3. The tube according to claim 1, wherein the composition comprises a blood coagulation inhibitor.
4. The tube according to claim 1, wherein the blood coagulation inhibitor is mucopolysaccharide or heparin.
5. The tube according to claim 1, wherein the tube is shaped in a cylinder form.
6. The tube according to claim 1, wherein the tube is shaped in a T-letter form.
7. The tube according to claim 1, wherein the tube is shaped in a Y-letter form.
8. The tube according to claim 1, wherein the tube is tapered to the ends.

9. The tube according to claim 1, wherein grooves are provided circumferentially on the outer surface of the tube.

10. The tube according to claim 1, wherein protuberances are provided circumferentially on the outer surface of the tube. 5

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