

[54] **IMPLANTABLE PROSTHETIC PASS-THROUGH DEVICE**

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Primary Examiner—Dalton L. Truluck

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Attorney—Burd, Braddock & Bartz

[52] U.S. Cl.128/214 R, 128/348, 138/177

[57] **ABSTRACT**

[51] Int. Cl.A61m 05/00, A61m 25/00

An implantable through-the-skin prosthetic device for the permanent entry into the body for passage of liquid, conductors or the like. The device includes a roughened synthetic resinous member that courses through the skin and subcutaneous tissues and into the body. This special roughening promotes tissue ingrowth and thus effects a firm mechanical seal. Animal experimentation and clinical success imply that the seal is also dry and germproof. One form of such a device is an arteriovenous shunt for use in artificial dialysis. A roughened plastic cannula passes through the skin into the blood vessel itself. A ball joint fitting for connection to the external circuits allows for one-handed operation by a trained patient. A special reamer is provided for use with the shunt.

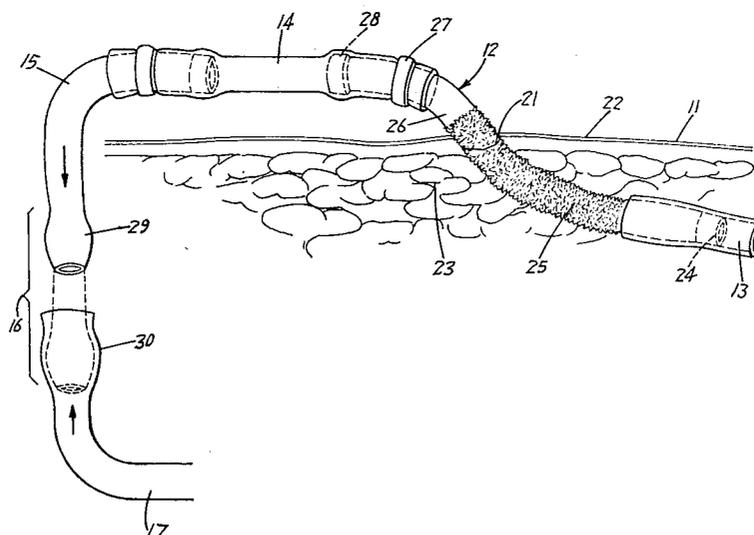
[58] Field of Search128/348-351, 214, 128/214.4; 138/177, 178; 15/104.3

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11 Claims, 4 Drawing Figures



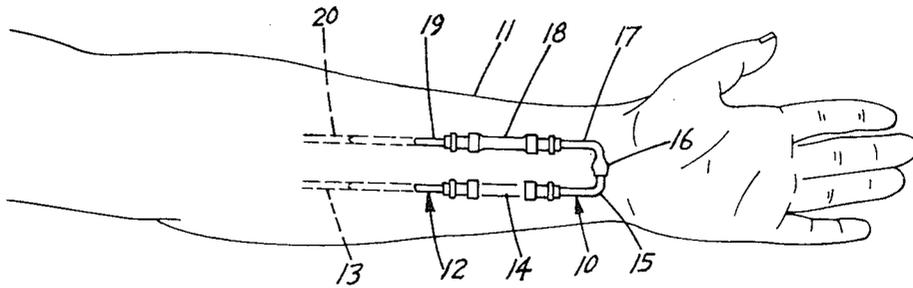


FIG. 1

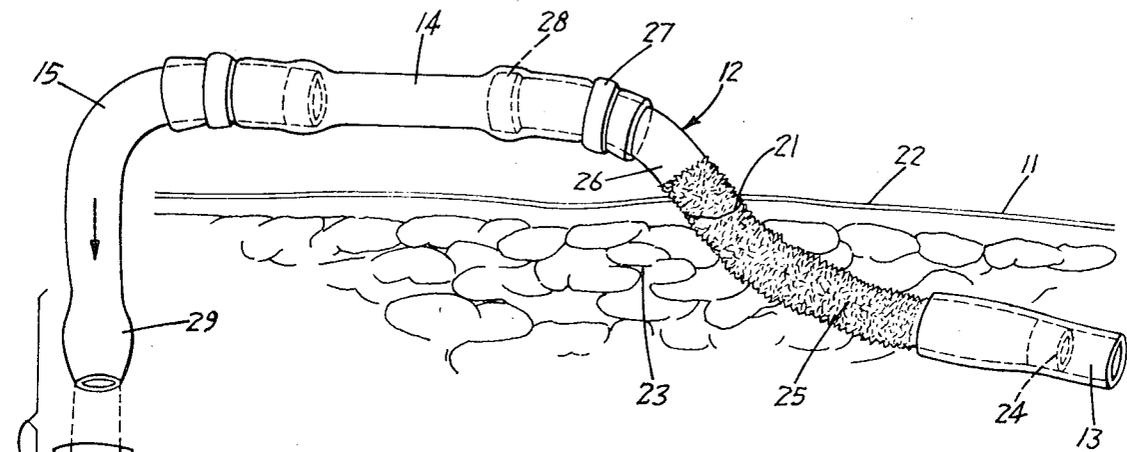


FIG. 2

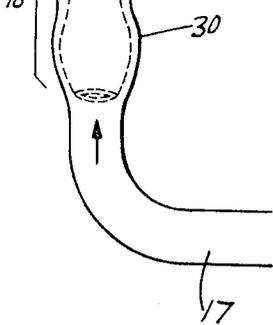


FIG. 3

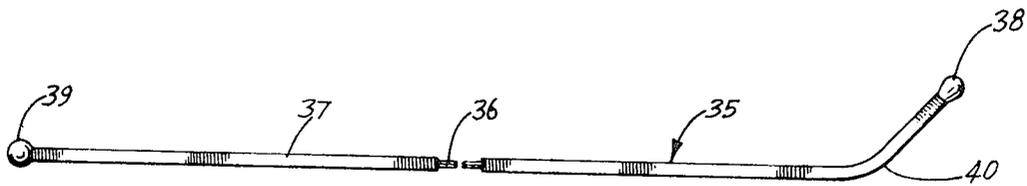
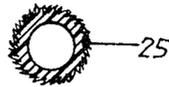


FIG. 4

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IMPLANTABLE PROSTHETIC PASS-THROUGH DEVICE

This invention relates to device for the permanent entry into the body for passage of liquids, conductors, or the like where a permanent firm mechanical dry and germproof seal with the skin and subcutaneous tissues is desired. Such devices are useful, for example, in artificial dialysis where a shunt is inserted into a vein in the arm or leg of the patient and maintained for long periods of time. Other devices such as heart pacemakers, bladder stimulators, blood pumps, and the like, which are externally powered require conducting cables or wires to extend through the skin. These have been a source of irritation and infection since, prior to the present invention, no safe dry and germproof mechanical seal through the skin was possible. The invention is described with particular reference to an implantable tubular arteriovenous shunt for use by patients suffering from renal failure and undergoing artificial dialysis, although it must be understood that the invention is not so limited.

There are approximately 50,000 Americans contracting renal failure each year. Of these, some 10,000 are qualified for dialysis or transplantation. Each year as patients are saved by these modalities, additional facilities are needed to accommodate the new patients as well as those previously helped. Thus, there is an expanding need for improvement in the treatment of renal failure.

Since the demonstration of the feasibility of artificial dialysis by Kolff, in the mid 1940's, great efforts have been directed to the improvement of methods for gaining access to the bloodstream. In 1960, Quinton and Scribner (Quinton, W., Dillard, D. H. and Scribner, B. H., *Cannulation of blood vessels for prolonged hemodialysis. Trans. Am. Soc. for Artif. Int. Organs*, 6: 104, 1960.) described a Teflon shunt system that allowed long term implantation and repeated dialysis. Although many minor variations have been brought forth, the basic device remains similar to the original design except that silicone rubber tubing is used for the subcutaneous and exterior sections. Successful cannulations have been reported for as long as 5 years.

In 1961, Quinton and Scribner (Quinton, W. E., Dillard, D. d., Cole, J. J. and Scribner, B. H. Possible improvements in the technique of long term cannulation of blood vessels. *Trans. Am. Soc. for Artif. Int. Organs*, 7: 60, 1960.) defined the ideal cannula as having 10 major properties. They are: (1) The inner surface should minimize clotting; (2) The exterior surface should give minimal tissue reaction; (3) The exterior surface should allow some attachment to the tissues in order to anchor the cannula firmly in place; (4) The skin at the exit site should surround the cannula so that a seal is formed and weeping and granulation tissue are absent.; (5) Cannula material should be elastic and move freely with the tissue as the arm is rotated; (6) Cannula should be able to withstand extended trauma without permanent damage.; (7) Cannula should not occlude vessels at the cannulation site; (8) Cannula should have an easily replaceable tip to facilitate fitting any size vessel; (9) A simple clamp or method of attachment to the external circuit is needed; and (10) The cannula should lie close to the skin.

In spite of many refinements, several problems have remained unsolved in the prior art shunts. The exit sites of the silicone rubber cannula are usually long sinus tracts that must be meticulously cleaned and are a constant septic threat to the patient. The junction means for connection to the external circuits are cumbersome, undependable, and require at least two hands to manipulate. The many turned lumen prevents easy reaming of those shunts should an occlusion occur. The newly developed shunt which is the subject of the present invention is directed toward solving these problems.

The arteriovenous shunt, according to the present invention, is illustrated in the accompanying drawings in which:

FIG. 1 is a schematic plan view showing the shunt in place in the arm of a patient;

FIG. 2 is an enlarged schematic illustration of the arterial portion of the shunt showing details of construction and showing the arterial cannula implanted in the body tissue;

FIG. 3 is a section on a somewhat enlarged scale on the line 3—3 of FIG. 2; and

FIG. 4 is an illustration of the reaming device used with the shunt.

Referring now to the drawings, the shunt, including an implantable through-the-skin seal device, according to the present invention, indicated generally at 10 in FIG. 1 and shown in place in a forearm 11, comprises an arterial cannula 12 extending into the artery 13, a flexible occlusion member 14, a distal arterial segment 15 connected through a disengageable junction means 16 to a distal venous segment 17 connected by means of an occlusion member 18 to a venous cannula 19 inserted through the skin into a vein 20. As is well understood, the shunt remains in place in the arm (or leg) of the patient between treatments, the blood flowing from the artery through one cannula through the shunt to the other cannula and back into the vein. During his periodic dialysis treatments, the junction means 16 is disengaged and the distal arterial segment 15 and distal venous segment 17 of the shunt are connected to the dialysis apparatus, the so-called "artificial kidney."

As best seen in FIG. 2, the semirigid arterial cannula 12 extends through an opening 21 in the skin 22 through the subcutaneous tissue 23 and into the end of severed artery 13. The interior of the cannula is smooth throughout. The intravascular tip portion 24 of the cannula is smooth and slightly tapered to facilitate insertion into the vessel. The intermediate portion 25 of the cannula from adjacent the tapered smooth tip 24 to beyond its point of exit through the skin is roughened to create a myriad of hairy projections to enable an attachment to be achieved between the body tissue and the cannula. A portion of the roughened surface extends into the vessel 13 to anchor the cannula and keep the vessel sealed around it.

After the cannula exits the skin, it is again smooth and is fitted to a collapsibly deformable tubular occlusion member 14 which can be squeezed closed by any suitable clamp during attachment of the shunt device to and release from the dialysis apparatus. The cannula-occlusion member junction can be made in the standard fashion using a steel crimp ring 27, or a suture, or similar means. Desirably, however, the smooth end 26 of the cannula is provided with a cuff 28 in the form of an externally thickened ring in order to assure a positive strong grip between the cannula and occlusion tubing. The distal arterial segment 15 is similarly connected to the opposite end of the occlusion tubing 14. The junctions are permanent, leak-proof and pressureproof.

The disengageable junction means 16 connecting the distal arterial and venous segments 15 and 16, respectively, is in the form of a ball joint. One of the distal segments has a bulbous male end 29. The other segment is provided with mating bulbous socket 30 having a slightly outwardly flaring mouth forming the female end of the ball joint. This ball joint junction means allows rapid and certain engagement and disengagement. The ball joint junction members are relatively thin walled such that they may be deformed slightly when fit together so that the narrowest part of the mouth of the socket may have a slightly lesser diameter than the greatest diameter of the male member. Any pressure within the lumen tends to force the outer walls of the smaller male fitting 29 against the inner walls of the slightly larger female fitting 30, thus increasing the leakproofness and better seating the seal. The inner blood path remains nearly uniform through such a connection. It is possible to disengage and reengage the ball joint with just one hand, allowing for self-dialysis by a trained patient. Apart from the male-female ball joint members, the venous portion of the shunt essentially duplicates the arterial portion already described in detail.

The cannula segments and distal segments of the shunt are preferably formed from polytetrafluoroethylene (Teflon) which has the requisite properties of inertness, chemical resistance, compatibility with body tissues, workability, strength, and the like. Other suitable materials, though less desirable, include nylon, acetal resin (Delrin), polycarbonate

resin (Leaxan), polyvinylchloride, polyvinylidenechloride, and the like, compounded so as to have the requisite semirigidity to form a noncollapsible tube. Similarly, medical grade silicone rubber (Siliastic) is the preferred material for the occlusion members although other flexible natural and synthetic rubber or rubberlike materials having the required properties of inertness chemical resistance, etc., may be used.

The desired roughness of the intermediate portion of the cannula segments which transverse the blood vessel lumen and the subcutaneous tract was achieved by turning the tubing on a lathe and applying a roughening tool. The tube is inserted over a steel mandrel to prevent deformation of the tubing, the lathe was rotated at about 600 r.p.m. and the machining tool was made from a hacksaw blade and piece of brass stock. The teeth of the hacksaw blade are allowed to very carefully gouge just the outer few thousandths of an inch of the tubing. As the tubing spins in contact with the roughening tool, thousands of roughened hairy projections are created. As is apparent, the hairy projections are integral with the body of the tubing. Great care, of course, is exercised in order that the lumen is not entered or the tubing deformed.

The cuff 28 at the ends of the cannula and distal segments can be formed by forcing the tubing back on itself while being heated and placed within a forming jig.

The shunt may be reamed by use of a flexible elongated wire, as shown in FIG. 4. The reamer 35 comprises an elongated central flexible wire core 36, which may be a single-strand or a multiple-strand cable. The core 36 is wrapped along its length by a coil spring 37 of small diameter. The reamer has a smooth bulbous termination 38 at one end and a manipulative device in the form of a small ball configuration 39 at the other end. The first end has a permanent slightly angled bend 40 deviating by about 40° to 50° from the longitudinal axis of the cable and spaced inwardly about 1 to 3 inches from the bulbous end. The reamer ranges in length from about 2 to 3 feet. The remotely angled bend can be controlled from the opposite end by manipulation of the ball element 39. By pushing the reamer into the lumen of the shunt and flexing and straightening the ball end, any turns can be followed and the smooth finish of the reamer protects the inner lumen from scratches.

In order to assess the efficacy of the pass through design, animal experiments were conducted to determine if the connective tissue would grow into and become attached to the roughened cannula (Teflon) surface, if sepsis could be avoided, and if strength could be expected from such a seal. In the initial series, a single U-shaped piece of Teflon tubing with one limb of the U roughened and the other smooth, was implanted beneath the skin of two dogs. The skin was completely closed over the tubing, since previous tests were thwarted by the dogs removing the device, no matter what steps were taken to restrain them. A single U-shaped piece of Teflon was employed in order that the very same piece of stock would be used and thus serve as its own control, and so that photomicrographs could be taken of the two limbs of the U.

When the skin and subcutaneous tissue containing the tubes were removed, a firm grip of the roughened segment was noted and no grip of the smooth area was seen. Photomicrographs of the two ends of the same U-shaped piece of tubing show connective tissue tenaciously involved with the roughened portion and the smooth portion remaining discretely uninvolved.

In a second series of experiments 10 guinea pigs were used and a roughened and a smooth Teflon tube was implanted into the dorsal surface thereof through a small skin puncture into the underlying tissue. Two percent Xylocaine was infiltrated into the area for anesthesia and each animal received five drops of a mixture of 1 million units penicillin and 1 gram streptomycin orally. These devices were then removed after 14 to 20 days for inspection. The skin and underlying connective tissue grew into the roughened tube but all smooth segments fell out spontaneously, even though a circumferential bandage was applied in order to prevent the dislodgment by

the guinea pigs, and the roughened tubes just a few millimeters away remained intact.

In other experiments 10 guinea pigs received a roughened Teflon tube but herein were allowed 21 days to become embedded and a 2 by 4 inch circle of skin was removed and pressure applied by pneumatic piston to determine what force was needed to disrupt the skin-Teflon seal. The 21-day implanted rough Teflon segments were disrupted by pressure calculated at 720 mm. Hg. The skin Teflon seal was watertight until the bursting pressure was attained.

Shunts incorporating the roughened Teflon cannula were then implanted in three uremic patients. The shunt in one patient remained clot free for more than 8 weeks. In the first case the shunt clotted several times after 1 day and 1 night, and was replaced by a prior art shunt, which also clotted several times. The patient went on to recovery of his acute tubular necrosis in 24 days. The second patient, a 45-year-old white female with acute tubular necrosis following pancreatitis was placed on dialysis acutely and after 4 weeks began to have urine output and her uremia slowly receded. Her shunt remained patent through this course and the skin and subcutaneous tissue became well involved within the roughened surface of the shunt. Photomicrographs show that a good junction was formed between the epithelial layers of the skin and the exit site of the cannula. There was never any pain associated with this shunt and the patient remained afebrile with a dry exit site throughout her hospital course. No infection was noted in either of these two, even though the second patient forgot about her shunt and completely submerged the arm in her bath water during the sixth week.

The leak pressure of the ball joint was tested by placing a closed ball joint seal in series with a mercury manometer and pumping the system full of fluid and measuring the pressure on the mercury manometer. Five ball joints were subjected to 300 mm. HG pressure without leak or bursting.

The use of all Teflon members to transverse the vessel lumen and the subcutaneous tract enables an attachment to be achieved between the tissue and the prosthesis if the Teflon has been roughened. The seal obtained appears to be a mechanical seal but a tight one, as evidenced by the tests. This is a logical result if we examine the basic processes of wound healing by secondary intention whereby new cells are added to the advancing wound edge, thus the roughened surface presents many facets, angles and geometric projections for the advancing connective tissue cells to become entangled in and mechanically intertwined.

As the cells multiply at the circular wound edge, the potential defect herein occupied by the prosthesis becomes smaller and smaller, until pressure exerted by advancing cells exceeds that pressure under which they can continue to proliferate. By that time a firm mechanical seal is effected. The strength of the seal is related to the number of surface grooves and projections on the rough Teflon surface and the strength of the fibrous tissue that embraces them. The guinea pig skin accepting the roughened tube is a measure of the affinity for implantation, since all the smooth tubes fell out of the guinea pig's skin. To withstand pressures without leaks points out the intimacy of the seal as is further implied in photomicrographs where a close juxtaposition of the tissues and the Teflon is shown.

The slight taper and smooth leading edge of the intravascular portion of the cannula facilitates its insertion, since the roughened surface requires some force for sliding but follows the few smooth millimeter at its tip with ease. The skin itself grows into the roughened surface and forms a seal. Study of the photomicrographs, in addition to showing the mechanical interdigitation between the tissue and the Teflon, points out the germproof nature of this seal since the cells adjacent to the Teflon seem to be mostly fibroblasts without significant inflammation or foreign body reaction. The short (2 to 3 cm.) subcutaneous path and gentle turns of this shunt decrease the tissue damage and scar formation at a given shunt site, and hence allows greater number of shunt sites per limb. This is

especially important in the chronic uremic whose life is dependent on the availability of shunt sites.

The new arteriovenous shunt, according to this invention, meets the 10-point criteria outlined by Scribner as well as current materials will allow. Since there are fewer parts than other designs, and since mass production can be simple, significant cost reduction can be effected.

In the case of a lead-through for electrical conductors, as for a cardiac pacemaker or the like, the prosthetic device may be made in tubular form, as a cannula. Then, after implantation of the roughened tubular member through the skin and subcutaneous tract, the conductors may be mechanically sealed within the tubular passage. The device may be utilized whenever a permanent or semipermanent sealed passage through the skin is desirable or necessary.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An implantable through-the-skin prosthetic cannula device for making a firm dry germproof mechanical seal, said device comprising:

- A. a flexible inert nontoxic synthetic resinous tube of length and subcutaneous tissue of a living being,
- B. at least a portion of the length of said tube at least sufficient to extend through said cutaneous and subcutaneous tissue having a roughened outer surface,
- C. said roughened surface consisting of a plurality of integral closely spaced hairlike projecting fibers whereby tissue ingrowth into and among said projecting fibers is promoted when said tube is implanted into living body tissue.

2. A device according to claim 1 further characterized in that said synthetic resinous tube is formed from polytetrafluoroethylene resin.

3. A method of making a firm dry germproof mechanically sealed passage through the skin of a living being which comprises implanting a tubular device according to claim 1 extending through the cutaneous and subcutaneous tissue of a living being and maintaining therein by means of attachment between the body tissues and roughened surface of the tube.

4. An arteriovenous shunt comprising:

- A. a pair of cannula segments according to claim 1, each having a roughened outer surface intermediate of their ends,
- B. a distal arterial segment and a distal venous segment,
- C. occlusion means connecting each of said distal segments with a cannula segment, and
- D. disengageable junction means between said distal segments.

5. An arteriovenous shunt according to claim 4 further characterized in that said junction means comprises a bulbous male member on one of said distal segments and a mating

female socket member on the other of said distal segments.

6. An arteriovenous shunt according to claim 4 further characterized in that the outer surface of the tip of each of said cannula segments opposite from said occlusion means is smooth and tapered.

7. An arteriovenous shunt according to claim 4 further characterized in that:

- A. said occlusion means comprises a length of flexible tubing extending telescopically over the ends of the cannula segments and distal segments connected thereby,
- B. the ends of said cannula segments and distal segments telescoped within the ends of the occlusion means are provided with a cuff of enlarged exterior diameter, and
- C. means are provided to secure the ends of said occlusion means to the ends of said cannula segments and distal segments spaced inwardly from said cuffs.

8. An arteriovenous shunt according to claim 4 further characterized in that said cannula segments and said distal segments are formed from polytetrafluoroethylene resin.

9. An arteriovenous shunt according to claim 4 further characterized in that said occlusion means is formed from silicone rubber tubing.

10. An arteriovenous shunt according to claim 5 further characterized in that:

- A. said mating male and female members are relatively thin walled,
- B. said male member mates with a close sealing fit in said female member, and
- C. the open end of said female member is of diameter less than the outer diameter of the bulbous male member such that slight deformation of said members occurs during engagement and disengagement of the members.

11. An arteriovenous shunt comprising:

- A. a semirigid tubular arterial cannula segment and a semirigid tubular venous cannula segment formed from polytetrafluoroethylene resin,
- B. a roughened outer surface composed of a plurality of closely spaced hairlike projecting fibers intermediate of the ends of each of said cannula segments,
- C. a smooth and tapered outer surface intravascular tip on each of said cannula segments,
- D. a distal arterial segment and a distal venous segment formed from polytetrafluoroethylene resin,
- E. tubular silicone rubber occlusion means extending telescopically over the ends of each of said respective cannula segments and distal segments connecting the same, and
- F. disengageable junction means between said distal segments comprising a bulbous male member on one of said segments and a mating female socket member on the other of said segments.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,638,649 Dated February 1, 1972

Inventor(s) Robert A. Ersek

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, line 1, after "to", --an implantable through-the-skin prosthetic-- is omitted.

Column 1, lines 39-40, "Dillard, D. d." should be --Dillard, D. H.--

Column 3, line 40, "he" should be --the--

Column 4, line 22, "ans" should be --and--

Column 5, line 21, after "length", --at least sufficient to extend through the cutaneous-- is omitted.

Signed and sealed this 13th day of June 1972.

(SEAL)

Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents