BACTERIA-RESISTANT PERCUTANEOUS CONDUIT DEVICE

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UNITED STATES PATENTS
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1,810,466 6/1931 Deutsch..........................128/348
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ABSTRACT

A percutaneous device for facilitating passage of wires, tubes, and other electrical or fluid conductors through the skin of an animal, in a manner such that the wires, tubes, or other conductors are immobilized with respect to the skin and a fluid and bacterial seal is obtained. The device comprises a generally cylindrical, elongated percutaneous conduit element having a central passageway therethrough and a subcutaneous fenestrated flange disposed in generally surrounding relationship to the conduit element. The subcutaneous flange is provided with a series of holes suitably spaced and sized to facilitate growth of tissue therethrough. The conduit element and the flange are contoured to facilitate the proliferation of the external epidermis down along the outer surfaces of the conduit, out, over and under the surfaces of the subcutaneous flange, through the holes in the flange, and up the passageway in the conduit element. Thus, the epidermis provides, in effect, an exteriorization of the flange and a sphincter around the passageway to immobilize wires, tubes and other electrical or fluid conductors extending through the passageway.

5 Claims, 3 Drawing Figures
BACTERIA-RESISTANT PERCUTANEOUS CONDUIT DEVICE

The invention described herein was made in the course of work under a grant or award from the Department of Health, Education and Welfare.

BACKGROUND OF THE INVENTION:

1. Field of the Invention

The present invention relates to percutaneous conduit devices and particularly to percutaneous connectors adapted to provide repeated access to internal regions of the body to facilitate such operations, for example, as hemodialysis.

2. Description of the Prior Art

The prior art is replete with examples of percutaneous devices. In particular, percutaneous devices have been utilized to provide artificial corneal implants. Examples of these devices are illustrated in U.S. Pat. Nos. 2,714,221 and 3,458,870. These devices, of course, are not conduit devices.

Prior art percutaneous conduit devices are exemplified in U.S. Pat. Nos. 3,447,161; 3,452,366; and 3,461,869. These devices provide, for example, access for pressure and electrical connections for heart pump systems and access to blood vessels for procedures such as peritoneal dialysis, lymph dialysis, and hemodialysis.

The prior art conduit devices commonly have failed to provide adequate sealing from the standpoint of preventing ingress of bacteria and egress of body fluids through and around the percutaneous device. Of course, inadequate sealing presents the potential problem of sinus tract infection from the skin surface downward along the cannulae into the blood, itself, causing septicemia. Such infections, in addition to complicating medical management, necessitate repositioning of the cannulae thereby presenting increased surgical difficulties as the supply of suitable vessels is progressively diminished.

Prior art devices also have been noted for their relatively short life expectancy resulting from trauma applied to vascular walls by movement of the cannulae tips positioned within them. The traumatized vessel walls are active sites for the formation of blood clots and phlebitis, and with time, such complications will also require repositioning of shunts and the like.

The most severe problem encountered in the use of prior art percutaneous devices has been the failure of such devices to resist extrusion from the body. Typically, this phenomena has been encountered because the geometrical configuration of prior art devices has been inadequate to properly anchor the devices within the epidermal epithelium.

SUMMARY OF THE INVENTION

The object of the present invention is to avoid the shortcomings of the prior art, and in particular, those which have been discussed above. Primarily, this result has been accomplished by providing a percutaneous device having a configuration suitable for being securely anchored within the epidermal epithelium while maintaining a seal adequate to prevent ingress of bacteria and egress of body fluids and without causing severe trauma to tissues adjacent to the device.

According to the present invention, there is provided a percutaneous conduit device for facilitating passage of information, energy or material to or from the interior of an animal while preventing substantial ingress of bacteria and egress of body fluids. The percutaneous device of this invention comprises an elongated, generally cylindrical percutaneous conduit element having a central passageway therethrough. The device further comprises a subcutaneous fenestrated flange mounted on the conduit element, in surrounding relationship to the passageway. The fenestrations or holes in the flange are spaced and sized to facilitate growth of skin tissue therethrough. The outer surfaces of the conduit element and the flange are contoured to facilitate and guide the proliferation of the external epidermis of an animal in which said device has been implanted in a direction down along the conduit, out, over and under the flange, through the fenestrations in the flange, and up to said passageway for immobilizing a tube, wire or other electrical or fluid conductor extending through the passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a percutaneous conduit device constructed in accordance with the concepts and principles of the instant invention;

FIG. 2 is a cross-sectional view of the device in position in the skin after surgical implantation; and

FIG. 3 is a top plan view of a preferred embodiment of the device illustrating the manner in which the holes in the fenestrated flange are arranged to achieve a constant ratio of open area to total flange area.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The device described herein allows the passage of wires and tubes through the skin of a living animal while precluding egress of body fluids and ingress of bacteria through and around the device.

The puncture sealing skin conduit device may comprise a plurality of component parts which may be constructed individually and later assembled. Conversely, the device may comprise an integral assembly or a plurality of subassemblies.

A preferred form of the device, wherein the components are integral, is shown in FIG. 1.

In FIG. 2, it can be seen that the device has a subcutaneous flange 1 implantable beneath the skin of an animal. Flange 1 is contiguous with the internal portion 2a of a percutaneous conduit 2. Percutaneous conduit 2 also has a central portion 2b disposed to be located in the subcutaneous tissue and to extend therethrough, and an external portion 2c adapted to be disposed outside the skin of the animal. The device may also include an extracutaneous flange 3 contiguous with external portion 2c of percutaneous conduit 2.

A connecting element 4 is provided for carrying information, energy and/or material to or from the interior of the animal. For this purpose, connecting element 4 extends through conduit 2 as illustrated. Passage of body fluids from within the animal to its exterior and passage of bacteria from the exterior to the interior of the animal, by way of the path between the exterior surface of the connecting element 4 and the interior surface of the conduit 2, is prevented by compression of the conduit 2 around the connecting element 4, and/or by the application of a sealing adhesive at the junction of the connecting element 4 and the extracutaneous flange 3.

Subcutaneous flange 1 is fenestrated to present a plurality of circular holes 6 therethrough. Holes 6 preferably have transversely rounded edges 6a as can best be seen in FIG. 2. The peripheral edge 7 of subcutaneous flange 1 is also preferably rounded with a radius equal to approximately one half of the thickness of the subcutaneous flange 1. The junction 8 between percutaneous conduit 2 and subcutaneous flange 1 is also preferably rounded to provide a smoothly contoured fillet radius at junction 8.

FIG. 2 illustrates a cross section of the puncture sealing skin conduit as it appears in the skin after surgical implantation. The epidermal epithelium (stratum corneum to stratum germinatium 9), has been surgically punctured or otherwise modified to implant the device. Because of the novel configuration of the device of this invention, the epidermal epithelium heals by growing inwardly along the exterior cylindrical surface of conduit 2, then along the rounded surface of junction 8 between percutaneous conduit 2 and subcutaneous flange 1, thereafter through the holes 6 in subcutaneous flange 1 nearest the conduit 2 and finally along the lower surface 1a of subcutaneous flange 1 until connecting element 4 is completely surrounded thereby. Note that the epithelium, in effect, forms a sphincter 11 around element 4 to substantially immobilize the latter against movement internally of the host. The epithelium 9 proliferates across both the upper 1b and lower
subcutaneous flange 1. These holes 6 also facilitate proper removal of waste products of skin metabolism from tissues 10.

Devices embodying the concepts of this invention may be fabricated from a variety of materials matching the physical characteristics of each device to any one of a variety of applications. The materials found best suited for device fabrication are TFE Teflon (R), silicone rubber, polypropylene, polyurethane, epoxy, and various forms of pyrolyzed carbon. Materials with higher elastic moduli may preferably be used for the subcutaneous flange 1 where the device is to be planted at a location on the animal where the mobility of the skin is minimal. On the other hand, where the mobility of the skin is high, materials having a lower elastic moduli are preferred for the subcutaneous flange 1 so that erosion of tissues adjacent to the edge 7 of the subcutaneous flange 1 is minimized by the higher compliance of the latter.

After the device has been implanted, final growth and cessation of the healing process will be characterized by the complete coverage of all of the subcutaneous and percutaneous surfaces of the device with epithelium. Also, in the absence of severe mechanical trauma, the appearance of the tissues adjacent to the device will return to normal, when examined by standard histological techniques, that is by: (a) excision of the device and adjacent skin; (b) sectioning with a microtome; (c) slide preparation; (d) staining with suitable preferential coloring stains; and finally (e) examination of the slides through a microscope.

The epithelium, having covered all subcutaneous and percutaneous surfaces of the device, completely isolates subcutaneous tissues from the foreign material of the device itself and thereby reduces foreign body reactions of the subcutaneous tissues.

In the absence of severe mechanical trauma, the rounded, smooth contour of the surface of the device at the junction 8 between the percutaneous conduit 2 and the subcutaneous flange 1, being completely covered by the epithelium, provides a long, tortuous, labyrinth type path through which bacteria are required to pass before entering the subcutaneous regions. Thus, such bacteria will be subjected to the naturally occurring bacteriostatic and bactericidal agents of the epithelium to thereby minimize the possibility that a multiplying colony of bacteria will be established in the subcutaneous tissues adjacent to the device.

The growth of subcutaneous connective tissue through the holes 6 in subcutaneous flange 1, during the latter stages of the healing process, results in the firm emmeshing of the device in the tissue. Accordingly, the device and the adjacent tissues are capable of resisting considerable mechanical force without dislodging the device or otherwise disrupting the adjacent tissues.

The holes 6 in the subcutaneous flange 1 permit free passage of normal body electrolytes and fluids, thereby providing for nutrition of subcutaneous tissues 10 lying between the surface of the skin and the upper surface 1b of the subcutaneous flange 1. These holes 6 also facilitate proper removal of waste products of skin metabolism from tissues.
The percutaneous conduit 2 of this invention provides for the passage of connecting element(s), such as 4, from the interior of an animal to its exterior while precluding entrance of bacteria into the animal and passage of fluids from within the animal to its exterior.

Mechanical forces applied to the connecting element 4 are transferred through the percutaneous conduit 2 to the subcutaneous flange 1. Thus, such forces are distributed to the epithelial and subcutaneous connective tissues lying in the holes 6 of the subcutaneous flange 1 to thereby minimize the deleterious effects of the mechanical forces on the tissues adjacent to the junction of the skin and the percutaneous conduit 2. This minimizes the possibility that the tissues will be disrupted sufficiently to cause distension of the tissues with the consequent allowance of entrance of bacteria or escape of body fluids.

The extracutaneous flange 3 is disposed to prevent the epithelium 9 of the skin from proliferating such that the exterior portion of the device becomes covered, when, during the initial healing of the skin puncture, the skin adjacent to the percutaneous conduit 2 is swollen because of edema due to subclinical infection, post operative mechanical trauma, surgical trauma, or other causes. Manifestly, such swelling could elevate the epithelial layer 9 to a position above the device and, in the absence of the extracutaneous flange 3, a path would be provided along which epithelial proliferation could occur with great rapidity. This would interfere with proper epithelial proliferation in the desired downward direction along the exterior cylindrical surfaces of the subcutaneous portions 2a and 2b of the percutaneous conduit 2.

The characteristics discussed above will be achieved with the puncture sealing skin conduit in the living animal if proper surgical and clinical techniques are utilized. These techniques include, inter alia, the following:

A. Implantation of the device using adequate surgical technique and sterile implements;
B. Implantation of the device using sharp and well controlled cutting instruments so that trauma to the skin of the animal is minimized;
C. Isolation of the device and adjacent tissues from interior and exterior mechanical, chemical, and bacteriological trauma until the aforementioned functional characteristics are observed to have occurred; and
D. Protection of the device and adjacent tissues from mechanical, chemical, and bacteriological trauma even after the aforementioned functional characteristics have been fully developed if the level of such trauma is as great as or greater than that which can be sustained without damage by the normal, intact skin.

The bacteria-resistant percutaneous conduit device of this invention may be used whenever it is desirable to pass electric, hydraulic, thermal, or pneumatic energy through the skin of a living organism, or to gain, for any other reason, access to the organism, without the escape of material from within the organism, or invasion of the organism by foreign matter, be it either animate or inanimate.

The device is usable as a container and conduit for single and multi-conductor electrical, pneumatic, hydraulic, optical or thermal circuit connectors. Such connectors may be positioned in the device before or after fabrication, or before or after surgical implantation of the device in the animal. Alternatively, the device may have a removable plug, appropriately designed for the necessary bacterial and fluid seal, so that periodic access to the interior of the organism is possible without disrupting the tissues adjacent to the device, or without resorting to additional surgical trauma to the organism to achieve said access. Visual access may be attained through the use of a device having a suitable window fabricated therein as an integral part of the assembly or as a replacement of the previously mentioned plug.

Specifically, providing access for powering a heart assist device or a total mechanical heart replacement, or for the leads of a pacemaker are among the specific uses of the device. As a circulatory access device the percutaneous conduit device is useful for the admission and exit of blood cannulae to allow the connection of the circulatory system to an artificial kidney or an artificial lung or both. Access to the peritoneal cavity may be provided by the percutaneous conduit device for the periodic administration of the peritoneal dialysis. The percutaneous conduit may also be used for the exteriorization of brain electrodes, nerve electrodes, blood pressure, flow, pH, pCO₂, pO₂, and temperature transducers, which may be used to provide information for the control systems of various external adrena or prosthetic organs.

We claim:

1. A percutaneous conduit device for facilitating passage of information, energy or material to or from the interior of an animal while preventing substantial ingress of bacteria and egress of body fluids, said device comprising:
   an elongated, generally cylindrical percutaneous conduit element having a central passageway therethrough; and
   a subcutaneous fenestrated flange mounted on the conduit element, in surrounding relationship to said passageway, the holes being dispersed throughout the flange area, being generally circular and having diameters approximately equal to the thickness of the flange and being spaced equidistant along a series of equally angularly spaced involute spirals;
   the junction between the outer surfaces of said conduit element and said flange being rounded to provide a smoothly contoured fillet radius to facilitate and guide the proliferation of the external epidermis of an animal in which said device has been implanted in a direction down along the conduit, out, over and under the flange, through the fenestrations in the flange, and up to said passageway whereby said epidermis provides an exteriorization of the flange and a sphincter around said passageway.

2. A percutaneous device as set forth in claim 1 wherein the total open area of the holes is approximately equal to the remaining area of the flange.

3. A percutaneous device as set forth in claim 1 wherein the lateral edges of the holes and of the flange are rounded.

4. A percutaneous device as set forth in claim 1 wherein said conduit element and said flange are integral.

5. A percutaneous device as set forth in claim 1 wherein is included an external flange disposed at the opposite end of the conduit element from said subcutaneous flange.