

[54] **MEDICAL VENTILATION TUBE**

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 [58] Field of Search **3/1, 13; 128/350 R**

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[57]

ABSTRACT

Medical ventilation tube one embodiment of which is specifically useful for surgical ventilation and drain for the middle ear. The prosthesis is constructed of silicone rubber in a tubular shape having an inner and outer flange, the inner flange of which is substantially larger than the outer flange. The inner flange is also characterized by having a V-shaped notch removed therefrom to assist in the insertion and removal of the drain prosthesis. In addition, the exterior flange has a special upstanding lip which assists in the grasping and removal of the prosthesis. The prosthesis comes in several sizes depending on the severity of the medical problem. Typical uses of the prosthesis is as a drain for otitis media and as a prosthetic airway or eustachian tube. The prosthesis for this invention may be useful generally as drains or ventilation tubes in medical situations.

6 Claims, 6 Drawing Figures

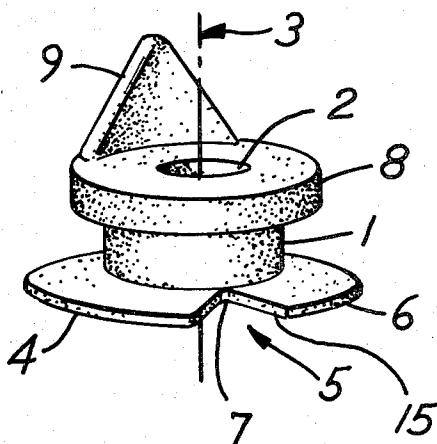


Fig. 1

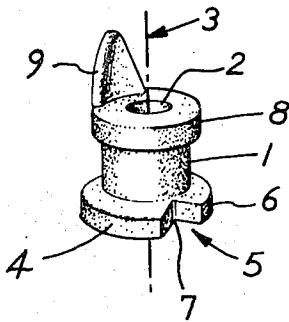


Fig. 2

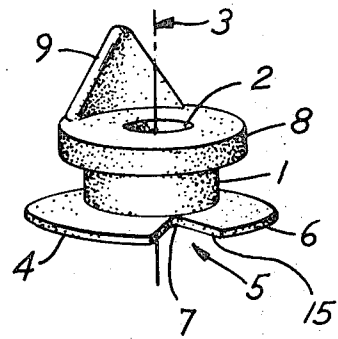


Fig. 3

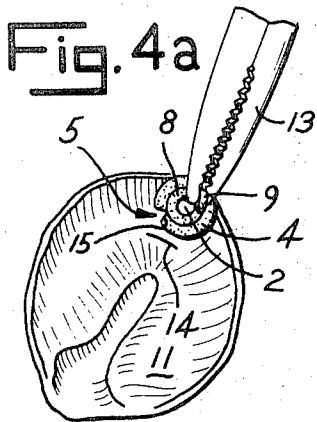
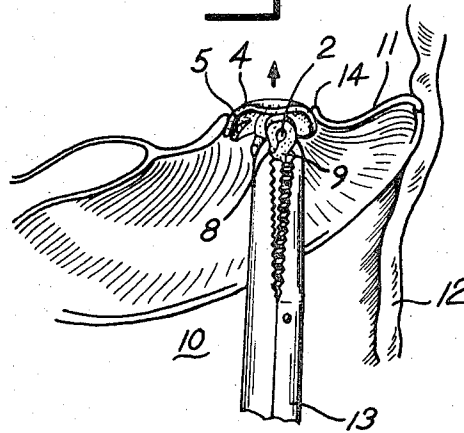


Fig. 4b

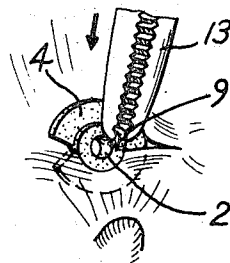
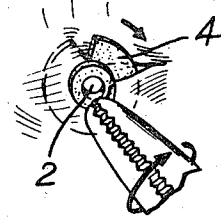


Fig. 4c



MEDICAL VENTILATION TUBE

FIELD OF THE INVENTION

The invention is directed to medical prostheses of the surgical drain or ventilation type. More specifically, the invention relates to surgical drains for the middle ear which are implanted into the tympanic membrane of the ear and functions as a drain for otitis media, and also as a prosthetic airway or eustachian tube. The prostheses of this invention are generally constructed of tissue-compatible silicone rubber.

BACKGROUND OF THE INVENTION

Armstrong in 1954 reported on middle ear ventilation tubes which were effective in treating middle ear effusions resistant to medical therapy; Armstrong, B. W.: A New Treatment for Chronic Secretory Otitis Media, Arch. Otolaryngol. 59: 6: 653-654, 1954. The elastomeric eustachian tubes which are commercially available and used in these cases are generally formed in the shape of a grommet with a small central tube section connected at each end with equal-sized flanges. A serious disadvantage of this design is that the internal fluid pressure extrudes the grommet out into the ear canal. This is called spontaneous extrusion of the ventilation tube. In many cases, the middle ear fluid reaccumulates shortly after the spontaneous extrusion of such ventilation tubes. In addition, the standard tubes usually remain only for four months or so before they are spontaneously extruded. Often this is insufficient time for the curing or alleviation of the condition which required the insertion of the ventilation tube in the first instance.

A second problem in the practical use of the elastomeric eustachian tubes presently commercially available is the difficulty associated with first implanting the drain into the tympanic membrane. This is complicated by the fact that the ear canal is a small, tortuous path which makes it difficult to both see and manipulate instruments within the confined space. In order to overcome these problems, a relatively large wound opening into the tympanic membrane is first incised, and then the grommet placed therein. Since the wound opening is usually oversized, the spontaneous extrusion of the ventilation tube is simpler than it would ordinarily be.

A third problem with the currently available elastomeric drains is the difficulty associated with removing the drain from the tympanic membrane in cases where the condition is cured prior to the spontaneous extrusion. The removal is normally occasioned by grasping the outer flange of the grommet with a very small forceps and pulling outwardly. Due, however, to the confined ear canal space, and the small size of the outer flange, this procedure is difficult, and it is not uncommon to injure the tympanic membrane while attempting to accomplish the removal.

Thus there is a need for an easily insertable and removable surgical drain for the middle ear which will not be spontaneously extruded within a short period of time after insertion, and which does not require oversized openings for their insertion.

THE INVENTION

OBJECTS

It is among the objects of this invention to provide a surgical prosthesis for draining body cavities or the like

or for providing ventilation thereinto as necessitated by medical conditions.

It is another object of this invention to provide a surgical drain prosthesis which is tissue compatible, relatively permanent, and is easy to insert and remove as desired.

It is another object of this invention to provide an improved middle ear ventilation tube of a soft, pliable silicone rubber which is simple to insert in, and remove from the tympanic membrane, and yet which resists spontaneous extrusion.

It is another object of this invention to provide a novel surgical drain design which may be adapted to numerous surgical and medical situations.

BRIEF DESCRIPTION OF THE FIGURES

These and other objects of this invention will be evident from the following description which makes reference to the drawing in which:

FIG. 1 is a perspective view of one embodiment of the tube prosthesis of this invention which is used routinely whenever a need for a tube is indicated.

FIG. 2 is a perspective view of a larger prosthetic tube of this invention where a permanent drum-head perforation is desired.

FIG. 3 shows one manner of inserting the prosthesis of this invention.

FIGS. 4a, 4b and 4c show, seriatim, another method of insertion and removal of the tube prosthesis of this invention.

SUMMARY OF THE INVENTION

We have solved all of the above problems with the prior art elastomeric eustachian tubes by providing a soft, silicone rubber tube of special flange design. We have found that by providing a large inner flange with a special V-shaped notch therein, we can obtain ease of insertion and withdrawal of the surgical drain of this invention yet prevent spontaneous extrusion of the ventilation tube. In one embodiment of this inner flange is disposed at substantially right angles to the central axis of the drain opening. In addition, we provide an exterior flange, also oriented at substantially 90° to the axis of the drain opening, which exterior flange may be of the same or smaller size as the interior flange. We also provide an upstanding tab mounted on the exterior flange, which is oriented generally parallel to, but radially spaced outwardly from, the central axis of the drain. This tab may be grasped with forceps or a special insertion tool for insertion or removal. The prosthesis tube is made of a tissue-compatible silicone rubber which is of a conventional type known to be inert and useful in the middle ear. Several tube types are employed for cases varying from routine to chronic difficult cases, and finally to rare cases wherein disease is so obstinate that a permanent drumhead perforation is desired.

DETAILED DESCRIPTION

The following detailed description is by way of illustration, and not by way of limitation, and has reference to the figures. FIGS. 1 and 2 illustrate generally two forms of the tube prosthesis of this invention. FIG. 1 illustrates the prosthesis tube which is used routinely whenever need for a tube is indicated. Not only is this tube useful for insertion directly into the tympanic membrane, but we have also shown successful medical

use in cases of insertion through an anterior drum-head remnant in patients having Type I tympanoplasty or myringoplasty. This is extremely significant since in such cases eustachian tubal difficulty exists. For tympanic membrane insertion, this tube generally remains in the tympanic membrane for four to eight months or more, as compared to typical extrusion on the order of four months. The tab on the tube, as well as being useful in insertion and removal, has also aided management and identification during the post-tympanoplasty healing period.

Referring to FIG. 1, the tube prosthesis of this invention comprises a main tube portion 1 having an opening 2 therethrough, the axis of the opening of which is identified by the line 3. Oriented at right angles to the axis 3 of the tube is an inner flange 4 having a V-shaped notch 5 cut therein along one margin, which V-shaped notch is substantially the depth of the flange from the exterior edge 6 to the outer wall 7 of the tube 1. Of course, the V-shaped notch may be of a greater or lesser depth, but we have found it preferable that the depth matches the radial thickness of the flange 4. The tube also has an outer flange 8 which is also oriented at right angles to the axis 3. Disposed along one edge of the flange is a tab 9 which is generally oriented parallel to, but spaced from the central axis 3 of the opening 2. Note that the tab is tapered and does not interfere with the opening 2.

FIG. 2 illustrates a similar shape, but in this case, the tube 1 and opening 2 are substantially larger to be useful in the rare case in which the disease is so obstinate that a permanent drum-head perforation is desired. Also note that the inner flange is substantially larger, thus overcoming the forces of spontaneous extrusion. The differential flange size is also more evident from FIG. 2, with the outer flange being substantially thicker and smaller in exterior radial diameter. The axial thickness of flange 8 has the added function of providing sufficient strength so that when the tab 9 is pulled, as upon removal, the tab 9 does not tear off the flange 8, leaving the prosthesis behind in the membrane. In contrast, the inner flange 4 is relatively wider and thinner providing for large surface area contact with the interior surface of the membrane thus preventing the spontaneous extrusion problem. The thinness of the interior membrane also has a function of permitting ease of insertion and removal which would not be possible were the inner flange excessively thick. Where the inner flange has a small radial diameter, it should be somewhat thicker, as in FIG. 1 to resist the extrusion.

An important observation which we have as a result of direct medical experience is that where the lumen is enlarged to provide for improved ventilation and drainage, the interior flange 4 must also be enlarged to permit the tube to remain in the tympanic membrane for a longer period of time in difficult cases.

In addition to these two sizes, there may be smaller, larger or intermediate sizes for varying uses. One particularly useful type is intermediate the two shown in FIGS. 1 and 2, which intermediate size is useful for chronic difficult cases. Such a tube has functioned in place after two years in several patients. Prior to the use of our tube, such patients had required numerous insertions of standard elastomeric middle ear ventilation tubes which were successively extruded. The length of time of tubes in accordance with our invention remain in place is approximately double that of the

prior art. These tubes generally start to extrude after one to two years, which time corresponds well with their actual need and the curing of the condition for which they were inserted.

FIG. 3 shows one mode of insertion of a tube prosthesis of this invention. FIG. 3 is a view partly in section and partly in perspective of an ear canal 10 and tympanic membrane 11. One wall of the ear canal is shown in section at the right as member 12. In the figure, the orientation is such that the exterior is downward and the interior is upward. As can be seen, forceps 13 grasps the outer flange 8 and tab 9 so that the tube prosthesis is securely held. The prosthesis is merely pushed inwardly through an incision 14 in the tympanic membrane 11 as shown by the arrow. The V-shaped notch 5 on the inner flange 4 permits that inner flange to bend easily so that it may be pushed through the incision 14 without injury.

FIGS. 4a through 4c show still another mode of insertion of the tube prosthesis of this invention. These views are from the exterior showing in plan view the tympanic membrane 11 and an incision 14 which has previously been made therein by a sharp surgical knife. As can be seen, the incision 14 is only slightly larger than the exterior diameter of the tube plus the radial width of the inner flange portion of the prosthesis. In prior elastomeric prosthesis use that incision would have to be larger than the outer diameter of the inner flange. The tube prosthesis is grasped by the tab 9 by forceps 13. By virtue of the incision 5 in the inner flange 4, there is a leading edge 15 which may be inserted into the small myringotomy incision 14. This is best shown in FIG. 4b which illustrates, in an enlarged view, the tube prosthesis partly inserted into the myringotomy incision. Thereafter, the tube prosthesis is simply twisted by means of the forceps 13 until the remainder of the inner flange is entirely below the drum-head, that is, until the inner flange is interior of the tympanic membrane 11. The rotational movement is shown in FIG. 4c. In FIGS. 4a through 4c, the forceps has been shown placed to one side for clarity of viewing. It should be understood that in actual practice the forceps will be aligned almost axially with the opening 2 of the tube prosthesis.

For removal, the reverse of either of the procedures shown in FIG. 3 or FIG. 4 may be used. Since the inner flange 4 is more flexible than the exterior flange, and there is, when in place, a tab for grasping by the forceps, the tube prosthesis can be easily removed. The tube may be pulled outwardly with the inner flange 4 flexing in just the opposite direction shown in FIG. 3. Likewise, removal of the drain can be accomplished by simple unscrewing process visualized by the sequence of FIGS. 4c, 4b and 4a in that order.

It is to be understood that various modifications within the scope of this invention can be made by one of ordinary skill in the art without departing from the spirit thereof. We therefore wish our invention to be defined by the scope of the dependent claims as broadly as the prior art will permit, and in view of this specification if need be.

We claim:

1. A medical prosthesis adapted for ventilation or drainage from the middle ear comprising in unitary combination;
 - a. a tube,
 - b. an inner circular flange secured to said tube,

- c. an outer circular flange secured to said tube,
 - d. said inner and outer flange being substantially parallel and spaced apart a distance sufficient to span the wall thickness of a tissue delimiting the space or area to be drained.
 - e. said inner flange having a radial width larger than said outer flange,
 - f. said inner flange having a portion of its circumference removed to provide a notch and to assist in the insertion or removal of said prosthesis,
 - g. said tubes and flanges being composed of pliable material compatible with body tissue,
 - h. said outer flange having a tab portion integrally combined to the flange and made of the same material as the tube and flanges adapted to be easily grasped by an insertion or removal instrument,
- thereby to provide a medical prosthesis resistant to spontaneous extrusion from the middle ear while being simple to insert and remove when needed.
2. A prosthesis as in claim 1 wherein said flanges are disposed at substantially right angles to the lumen in

said tube.

3. A prosthesis as in claim 1 wherein at least one of said flanges is disposed at the end of said tube.

4. A prosthesis as in claim 1 wherein said pliable material is a low durometer, physiologically acceptable silicone.

5. A prosthesis as in claim 1 wherein said flanges are disposed at opposite ends of said tube, said flanges being oriented substantially perpendicular to the lumen in said tube.

6. A prosthesis as in claim 1 wherein:

a. said outer flange is thicker than said inner flange and adapted to be grasped by insertion or removal instruments, and,

b. said inner flange is relatively thin and flexible for ease of insertion or removal, and is adapted to present a surface area greater than the area of the lumen in said tube to the inner surface of said tissue to resist spontaneous extrusion over long periods of time.

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