United States Patent

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[54] METHOD AND APPARATUS FOR INSERTING A TUBE THROUGH THE EAR DRUM

15 Claims, 7 Drawing Figs.

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[51] Int. Cl. A61b 17/34, A61m 27/00
[50] Field of Search ..... 128/303, 305, 321, 329, 330, 348, 350, 351, 343, 9, 214, 214.4 (Index Medicus)

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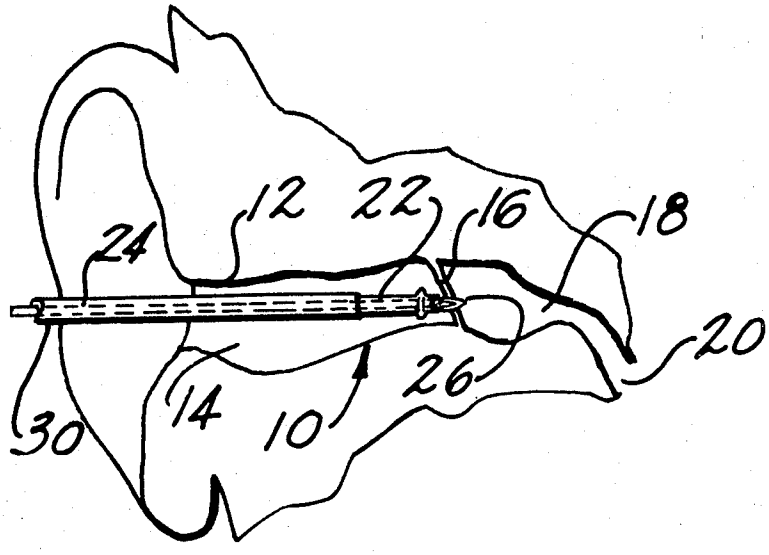
ABSTRACT: A method for inserting a tube, such as a small plastic drain tube, through the ear drum into the middle ear, which comprises supporting the drain tube on an elongated instrument member with the tube tightly fitting the end of the instrument, the tip of which protrudes beyond the outer end of the tube, inserting the tip of the instrument through the ear drum, making an opening smaller than the drain tube by making an incision with the tip of the instrument, and then in the same motion inserting the tip of the tube through the incision and, while the tube is in position through the incision in the ear drum, bringing a second member into engagement with the tube to push same from the first instrument member. One form of the instrument apparatus comprises a scissors having an elongated, rigid first instrument incision member attached to one leg of the scissors and the other leg of the scissors in the form of a crank which has an elongated tubular sleeve attached thereto and slidably fitting over and sliding on the first member whereby operating the scissors causes relative motion between the outer tubular sleeve and the end of the inner insertion instrument member, the tip of which serves to make the small incision in the ear drum.



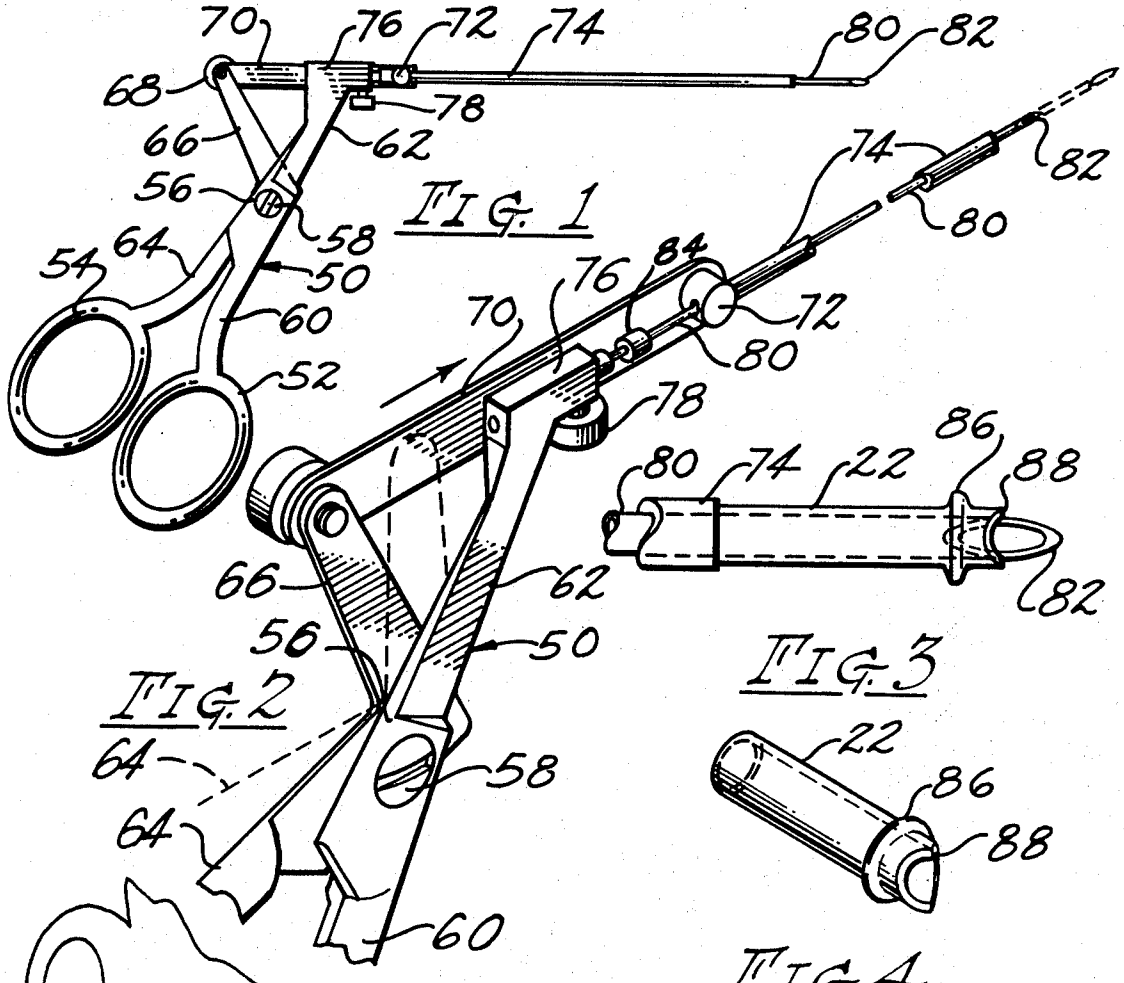


FIG. 1

FIG. 2

FIG. 3

FIG. 4

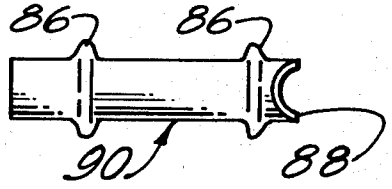


FIG. 5

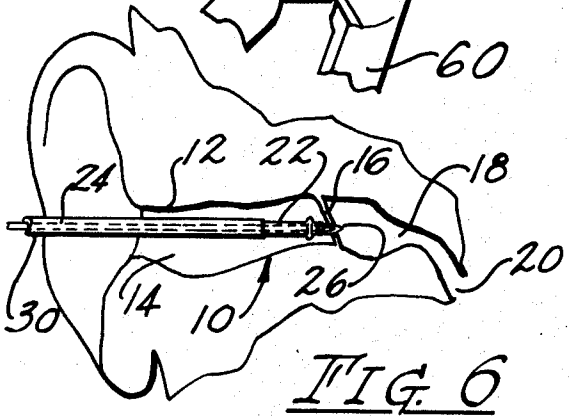


FIG. 6

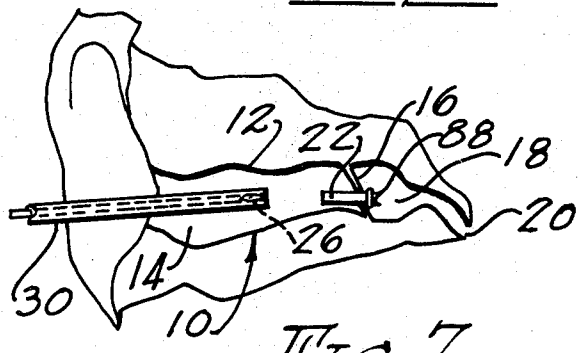


FIG. 7

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METHOD AND APPARATUS FOR INSERTING A TUBE THROUGH THE EAR DRUM

A myringotomy is the procedure for making an incision in the ear drum for any reason such as to receive a small plastic drain tube which prevents the incision from closing and aids in the drainage. This procedure is well known. This has been done by inserting a small knife into the ear and making the incision. This is not satisfactory because there is limited vision and the opening is usually much larger than needed and since the ear drum does not respond well to topical anesthesia there is noticeable pain which can cause much difficulty especially in children. Some attempts to facilitate this operation have resulted in bulky, oversized instruments which obstruct the vision or interfere with the dexterity of the hands. The present method presents a procedure for the incision through the ear drum and the placement of the tube in one continuous stroke almost simultaneously and with much better vision than heretofore possible.

The present method of inserting a drain tube with a myringotomy includes the advantage of making the incision and inserting the drain tube through the opening made by the incision almost simultaneously and immediately thereafter without delay. This reduces the length of time of pain and should result in a smaller incision in which the drain tube is tightly fitted.

The present instrument provides excellent visibility of the ear drum during the entire procedure and facilitates the placement of the incision opening and the drain tube in the proper location.

The present procedure also employs the method for supporting and positioning the drain tube which virtually eliminates fumbling or tedious pre-positioning of the drain tube which is the case when the tube is placed in the ear after the incision has been made.

A further advantage of the present invention is that the instrument support member which securely and temporarily supports the drain tube for insertion also makes the incision in the ear drum thereby eliminating two or more instruments such as forceps or the like to serve this purpose.

Another advantage of this invention resides in the particular drain tube which may be used with the present instrument and procedure and which includes a tube or tip that is cut back to reduce clogging and also may include one or more protrusions on a tube to prevent the tube from being displaced in either direction after it is positioned in the incision.

Another advantage of the present instrument resides in the offset construction which places the instrument tube positioning and insertion member away from the hand and the scissors actuating members to provide maximum vision inside the ear.

Still another feature of the instrument resides in the construction of the tube supporting instrument member having a tube insertion member relatively movable therewith.

Other and further objects and advantages of my invention will become apparent upon reading the following specification taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a side elevation view of the instrument;

FIG. 2 is a partial perspective view of the instrument shown in FIG. 1 and with dotted lines to illustrate relative motion;

FIG. 3 is a plan view of the tip of the instrument shown in FIGS. 1 and 2 with the plastic tube inserted thereon;

FIG. 4 is a perspective view of the plastic tube shown in FIG. 3;

FIG. 5 is a plan view of a modified form of the plastic tube shown in FIGS. 3 and 4;

FIG. 6 is the first of two sequential diagrams showing the procedure employing the present method for inserting a tube into and through the ear drum into the middle ear; and

FIG. 7 is the second diagram showing the tube inserted and the instrument being removed.

As stated previously, a myringotomy is performing an incision in the ear drum and which incision may be prevented from closing by means of a singular tube inserted therein. The present method and instrument may be used to perform both the myringotomy and the insertion of the tube all in one procedure involving primarily only one single motion supplemented by manipulation of the instrument to disengage and withdraw from the ear.

Referring initially to FIGS. 6 and 7, for an understanding of the procedure, the entire ear is designated generally by reference numeral 10 and has a superior canal wall 12 defining the external auditory canal 14 leading to the ear drum or malleus 16 which is covered by a tympanic membrane also commonly referred to as the ear drum. The middle ear is designated generally by reference numeral 18 and leads to the Eustachian tube 20. The present invention is concerned primarily with making an incision or an opening through the tympanic membrane 16 for any medical reason where such an opening is indicated as for example when there is fluid in the middle ear 18 which should drain for a period of time through the ear drum tympanic membrane 16 and from the external auditory canal 14. If the middle ear 18 is to drain for a period of time it is necessary to place something in the incision or opening made in the ear drum 16 in order to prevent the opening from closing and customarily this would be a small tube which does not necessarily have to be perfectly cylindrical or circular but has a body portion long enough to go through the membrane of the ear drum 16 and to remain therein and to have an opening therethrough through which the fluid can drain. According to the present procedure, a small tube 22 which may be manufactured from metal or plastic such as polyethylene, or "Teflon" or any other material which typically is approximately 11 mm. long and with a slight bevel approximately 1.5 mm. from the tip. An elongated instrument member 24, which may be a rigid stainless steel tube, is approximately the size of the internal bore of the tube 22 but preferably slightly larger than the tube 22 when the tube 22 is in normal condition so that the tube 22 is stretched slightly and forced onto the instrument member 24 a distance from the end or tip 26 of the tube 22 which has been provided with a sharp edge capable of making a clean and quick incision in the ear drum 16. The instrument member 24 may be approximately 9 cm. long and the tip 26 extends approximately 1.4 cm. beyond the tube 22 which also may be called a tubular sheath. The length of 1.4 cm. corresponds approximately with the length of the plastic tube to be inserted through the ear drum or tympanic membrane 16 during the procedure. Therefore, it is possible to insert the tip 26 of instrument member 24 a distance corresponding approximately to the amount of the tube 22 inserted through the ear drum 16 facilitating the insertion and keeping the travel of the instrument to a minimum. As seen in FIG. 6, the instrument member 24 is inserted through the external auditory canal and pushed to force the tip 26 through the membrane 16 at which time a second instrument member, which may be the sleeve 30, is inserted and moved relatively with respect to the instrument member 24 to push the tube 22 through the incision made in the ear drum 16 and at the same time to dislodge the tube 22 from the member 24.

As seen in FIG. 7, the member 24 and the sleeve 30 may be withdrawn simultaneously from the external auditory canal 14 leaving the tube 22 in place. It should be noted that the insertion of the plastic tube and the performance of the incision was done with one single motion accompanied by almost instantaneous and simultaneous motion of the dislodgement of the tube 22 from the end of the member 24 into the ear drum 16.

Referring to FIG. 1, a scissors designated by reference numeral 50, which may be made from surgical stainless steel, comprises a pair of finger loops 52, 54 and a common junction at 56 connected by a pivot pin 58. Finger loop 52 is connected by the stainless steel portion 60 beyond pivot 58 with a support portion 62 and finger loop 54 is connected by a stainless steel connecting portion 64 through the pivot 58 to a crank member 66 which is pivotally attached by removable pivot screw 68 with a link 70 carrying a small size block 72 on its outer end which has an elongated, rigid surgical stainless steel

outer sleeve or tube 74 connected thereto and extending therefrom. Member 74 serves as a means for removing the small plastic tube 22 as will appear hereinafter.

The portion 62 of the scissors 50 has an attachment block 76 thereon in which is inserted and securely locked by a set screw 78, the surgical instrument member 80 which serves to support temporarily the small plastic tube 22 and which is provided with a beveled end 82 that may be sharpened quite sharp to perform the function of a small knife to puncture and make an incision in the ear drum 16. When the instrument is in a normal, retracted position shown in FIG. 1, at which time it is in condition and position to receive the plastic tube 22, a portion of the tip 82 of the instrument member 80 extends beyond the outer sleeve 74 to receive the small plastic sleeve 22 mentioned previously. A resilient stop member 84 is slidably mounted on member 80 and engaged by block 72.

In one form of the plastic tube, shown in place in FIG. 3, the tube 22 is provided with a circumferential annular flange 86 which prevents the tube from being backdrawn or withdrawn from the opening or from accidentally dislodging therefrom and also the end of the tube may be provided with a beveled tip 88 which tends to reduce clogging and to prevent the end or tip of the tube 88 from becoming closed due to engagement against one of the walls inside of the ear. An alternative form of the sleeve 22 is designated by reference numeral 90 in FIG. 5 and comprises two annular flanges 86, one of which as mentioned previously prevents the backdrawing or withdrawing of the tube from the ear after insertion and the other of which spaced therefrom prevents the tube from accidentally dropping in the other direction through the drum 16 from the external auditory canal and the entire tube thereby going into the middle ear requiring that the ear drum 16 be opened to remove it from the middle ear.

In the operation of the instrument shown in FIGS. 1 and 2, which may be employed to perform the method described in conjunction with FIGS. 6 and 7, one of the small polyethylene or "Teflon", or other plastic or metal, tubes 22, or the tube 90 shown in FIG. 5, is inserted on the instrument 50 in the retracted position shown in FIG. 1 to the approximate position shown in FIG. 3 which leaves the beveled tip 82 of the instrument member 80 extending beyond the tube 22 in a manner, as mentioned before, approximately equal to the amount of the tube 22 which will be inside the ear drum 16. As mentioned previously, a typical tube 22 is approximately 11 mm. long and the bevel 88 may be approximately 1.5 mm. from the tip.

After the tube is in position as shown in FIG. 3, the instrument is inserted through the external auditory canal and in one single motion the instrument 50 is pushed to bring the tip 82 against the ear drum 16 and on through the ear drum 16 carrying the end 88 and the circumferential flange 86 with the tube 22 inside the ear drum 16, at which time the plastic tube 22 having been inserted in one single uninterrupted motion, the scissors are actuated by separating the steel loops 52, 54 which causes the outer tube or sleeve 74 to be driven in the direction of the arrow shown in FIG. 2 which brings the tip of the outer sleeve 74 against the inner tip of the plastic sleeve 22 and pushes the plastic sleeve from the end of the instrument member 80 and at the same time, if desired, the entire instrument may be withdrawn from the external auditory canal 14 leaving the tube 22 in position.

Therefore, the instrument serves two purposes —one, to do a myringotomy, and the other, to insert simultaneously or almost simultaneously a plastic tube 22 through the incision opening into the middle ear. It is significant to note that besides accomplishing both the myringotomy and the insertion of the plastic tube 22 with one single motion, the instrument 50 is angled so that the operator's hand does not cover up the vision during the procedure and the incision made by the tip 82 is significantly smaller than some of the incisions made by a knife performing the myringotomy in one of the other methods and also the incision being smaller than the tube 22 itself results in the stretching of the fibers of the drum 16 when the tube is inserted thereby holding the tube 22 snugly in place.

The instrument 50 provides the excellent visibility of the drum 16 during the procedure and it facilitates the placement of the opening and the tube 22 in the proper location. Since the drum 16 does not respond well to topical anesthesia the use of instrument 50 and the procedure lessens the pain and discomfort by decreasing the amount of time between the incision and the insertion as well as performing the procedure substantially simultaneous in one single motion which gives the operator an opportunity to get the operation performed rapidly before the patient has a chance to respond to the pain particularly in the case of children who tolerate the instrument much better than other procedures.

In the FIG. 1 embodiment, tube 22 is removed by opening the scissors 50. This may be modified and easily reversed to remove tube 22 when the scissors is closed. Therefore, while I have shown and described a particular instrument which may be used to perform a method, and in addition I have illustrated and described one type of plastic tube 22 and alternative form, this is by way of illustration only and does not form or constitute any sort of limitation on the scope of my invention since various alterations, changes, deviations, eliminations, substitutions, revisions, additions, omissions and ramifications may be made in the manner described.

I claim:

1. In a method for performing a myringotomy and substantially simultaneously thereafter inserting a hollow member such as a plastic drain tube and in one continuous, substantially uninterrupted procedure, the procedure comprising:

a. making an incision in the ear drum by inserting a cutting instrument from the outside through the passage to the ear drum;

b. inserting the cutting instrument in one stroke as the incision is made through the ear drum for a distance sufficiently to extend inside the middle ear and beyond the ear drum so as subsequently to get the hollow member through the drum into the inner ear;

c. supporting the hollow member on the cutting instrument and when the instrument is in position inserting the hollow member through the incision into the inner ear, and moving the instrument and the hollow member relative to one another; and

d. resisting movement of the hollow member while withdrawing the cutting instrument leaving the hollow member in place.

2. The method claimed in claim 1, wherein: the cutting instrument is inserted through the incision an amount approximately equal to the distance the hollow member is subsequently inserted.

3. The method claimed in claim 1, wherein: the hollow member is inserted on the cutting instrument from the tip and moved a distance from the tip prior to the incision.

4. The method claimed in claim 1, wherein: the hollow member is resisted by inserting a second member on the cutting instrument and moving the cutting instrument and second member relative to each other while the second member engages the hollow member.

5. In an instrument for performing a myringotomy and almost simultaneously and immediately thereafter inserting a small hollow member such as a plastic drain tube through the incision in the ear drum and into the middle ear:

a. an insertion member having a cutting tip that is pushed through the ear drum to make an incision therein, said tip initially extending through said hollow member and receiving and temporarily retaining the hollow member with the tip protruding therefrom an amount sufficient to cut;

b. engagement means having a hollow member engagement portion supported for movement on the outside of said insertion member and on the other side of said hollow member from said tip, and responsive to manual manipulation to cause temporary engagement with the hollow member that is to be removed; and

c. other means on said instrument manually manipulated to cause relative motion between said engagement means and said insertion member when said hollow member is engaged by said engagement portion to push said hollow member from said tip and cause it to remain in place in the incision in the ear drum as said instrument is withdrawn.

6. The instrument recited in claim **5**, wherein said engagement means is a second member mounted for movement with said insertion member.

7. The instrument in claim **6**, wherein said instrument has a handle with a manually operated actuating member movably connected for motion, and said actuating member is connected to drive one of said insertion member and said engagement member to cause the relative motion therebetween.

8. The instrument in claim **7**, wherein said handle includes a pair of opposed, spaced finger gripping members one of which is connected with said actuating member, said finger gripping members being pivotally related to be held by the hand in a respective finger for manipulation to disengage the hollow member when in position in the ear drum.

9. The instrument in claim **8**, wherein said handle and finger gripping, pivotally related members define a scissors action, and said insertion member is an elongated, rigid member having a cutting tip, said engagement means being carried by said insertion member and slidable thereon.

10. In an article positioned about an instrument which makes an incision for insertion through the ear drum (tympanic membrane) to follow and provide a temporary opening from the middle ear and in which opening said article is left by the detachment from said instrument, said article comprising:

a. An elongated, self-supporting, hollow member constructed from plastic, metal or the like having a tip on one end following the instrument through the opening in the ear drum and having an annular protrusion extending from the outer surface thereof outwardly and spaced inwardly from the tip thereof, said tip being beveled to diverge from opposite apexes to follow the instrument in one direction of insertion without requiring incision other than that made by said instrument leading the article in the initial penetration through the ear drum and without requiring separate enlargement of the opening, said annular protrusion also following the tip thru the incision and thereafter assisting in preventing dislodgement of the article from the ear drum.

11. The article claimed in claim **10**, wherein said member has at least two protrusions spaced from each other and from the respective ends of the member to help prevent the dislodgement in either direction.

12. The article in claim **10**, wherein said member is a hollow tube and said protrusion is an annular flange.

13. The article claimed in claim **12**, wherein said tube is made from a flexible, resilient plastic or similar material and said annular flange is molded thereon.

14. The article claimed in claim **11**, wherein said article is a tube made from plastic or similar material, and said protrusions are annular flanges molded on the surface of the article, said flanges being located each closer to a respective end than the middle of the tube.

15. The device claimed in claim **10**, wherein said hollow member has part of the opening of the tip that is inserted through the ear drum recessed from the terminal end of the tip to reduce the clogging which might result from contact with the inside surface of the ear.