

[54] **PROSTHESIS FOR THE INNER EAR**

[75] Inventor: John J. Shea, Jr., Memphis, Tenn.
[73] Assignee: Richards Manufacturing Company, Inc., Memphis, Tenn.
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[58] Field of Search 3/1; 128/350

[56] **References Cited**

FOREIGN PATENTS OR APPLICATIONS

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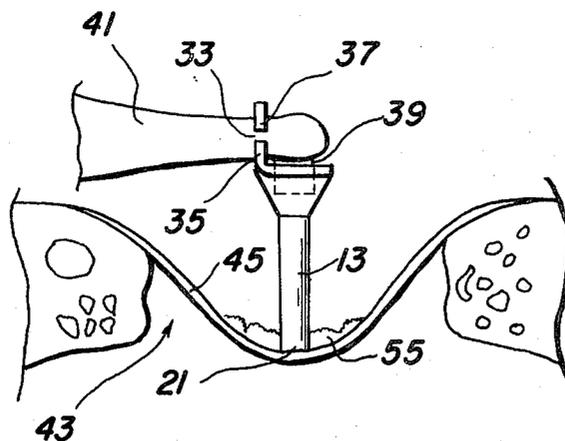
Richards Micro-Surgery Instruments and Implants Catalog, Richards Mfg. Co., Memphis, Tenn., Copyright 1965, page 34 Relied upon (Teflon Piston).

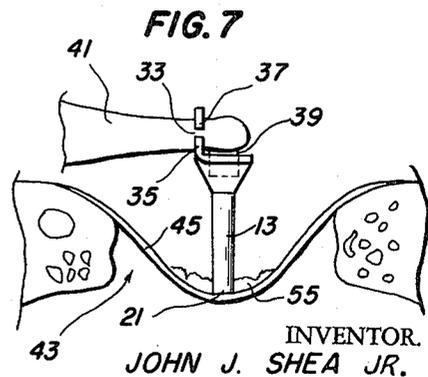
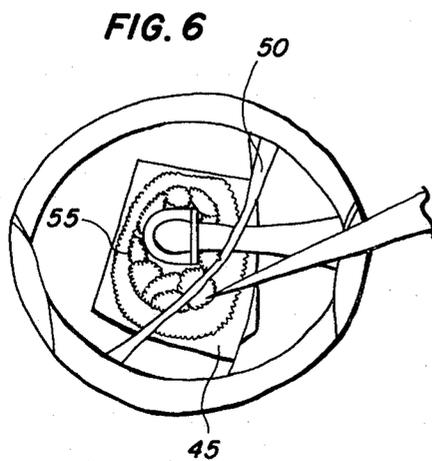
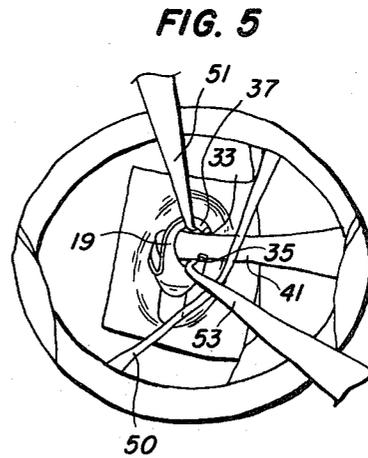
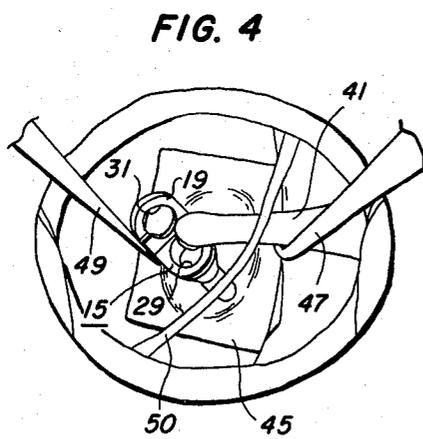
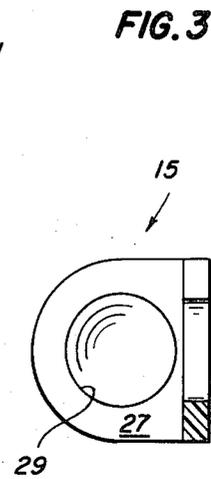
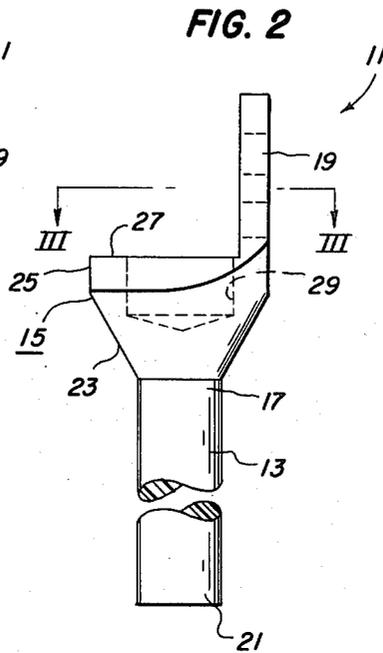
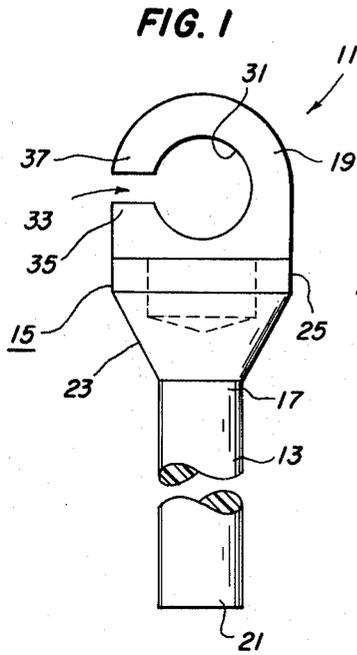
Primary Examiner—William E. Kamm
Assistant Examiner—Ronald L. Frinks
Attorney—John R. Walker, III

[57] **ABSTRACT**

Prosthesis for use in otologic surgery in the middle ear to replace the stapes and attach to the undersurface of the lenticular process of the incus. The prosthesis is formed from "Teflon" and includes an elongated piston member, a head fixedly attached to the piston member having a socket therein adapted to receive the lenticular process of the incus, and a loop fixedly attached to the head for extending over the incus to hold the prosthesis in place.

7 Claims, 7 Drawing Figures





INVENTOR.
JOHN J. SHEA JR.

BY *John R. Walker, III*
Attorney

PROSTHESIS FOR THE INNER EAR**BACKGROUND OF THE INVENTION****1. Field of the Invention**

This invention relates to prostheses and, more particularly, to a prosthesis for use in otologic surgery in the middle ear.

2. Description of the Prior Art

One of the prior prostheses, known as the Robinson prosthesis, (U.S. Pat. No. 3,196,462) is formed of stainless steel and includes a piston-like member with a cuplike member affixed to one end thereof. The Robinson prosthesis utilizes a metal wire for holding the device onto the incus. In this type of prosthesis, there is the possibility of pressure necrosis (deading or killing of bone cells) when the wire is applied too tightly. Conversely, if the wire is applied too loosely, the prosthesis will not be properly adhered to the incus. Also, with the use of stainless steel, the prosthesis does not have the same natural resonating frequency as the replaced stapes.

The Mercandino et al. U.S. Pat. No. 3,191,188 utilizes a hollow tubular strut made of polyethylene, with at one end receives the lenticular process of the incus. However, there is no means for insuring that the tubular strut maintains a proper angle relative to the incus.

The Haase et al. U.S. Pat. No. 3,473,170 discloses an arcuate frame member having a film extending across the frame member and adapted to be in contact with the tympanic membrane, and an elongated member extending from the film of sufficient length to contact the area of the oval window.

In addition, a prior device of applicant's utilized a "Teflon" cylindrical prosthesis which has a ring adjacent one end of the cylinder defining a hole and the ring was slit from the hole towards the proximal end of the cylinder, whereby the ring was adapted to fit over the incus with the incus extending through the hole. However, this prior device had no means for firmly establishing the right angular relationship between the incus and the cylindrical member.

SUMMARY OF THE INVENTION

The present invention is directed towards overcoming the heretofore mentioned and other disadvantages in prostheses for replacing the stapes.

It is a concept of the present invention to provide a prosthesis which will have substantially the same resonating frequency as the stapes and which efficiently and firmly attaches to the incus. It is a further concept to provide such a prosthesis which is easy to be put in place by the surgeon, and which does not cause pressure necrosis.

The means by which the applicant accomplishes the above is by providing a prosthesis which comprises a piston member; a head attached to the piston member having a socket therein adapted to receive the lenticular process of the incus; and a loop fixedly attached to the head, with the loop having a hole therein for receiving the incus. The loop is provided with a slot therethrough extending from the exterior of the loop to the hole therein which establishes at least one free end portion of the loop. The slot is narrower than and the is greater than the incus with which the prosthesis is adapted to be used. The loop has a substantial elastic recovery capacity whereby the free end portion is

adapted to be moved from its original disposition to widen the slot for insertion of the incus therethrough and into the hole and subsequently, said free end is adapted to be released for return to its original disposition to form a firm attachment to the incus. Preferably, the entire prosthesis is formed integrally and from the same material, which is a plastic having a substantial elastic recovery capacity, such as "Teflon." "Teflon" is the registered trademark of the DuPont Company for its product, which is a tetrafluoroethylene-hexa-fluoropropylene copolymer. By the use of such a material, the prosthesis will have substantially the same natural resonating frequency as the replaced stapes. In addition, by having the piston member formed from "Teflon," the length thereof can be cut by a surgeon or nurse to the exact length to fit patients with different length requirements, which was not possible with the types made of metal.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a front elevational view on an enlarged scale of the prosthesis of the present invention.

FIG. 2 is a side elevational view thereof.

FIG. 3 is a sectional view taken as on the line III—III of FIG. 2.

FIGS. 4-6 are views looking down into the inner ear and showing some of the steps taken during the surgery in which the prosthesis of the present invention is utilized.

FIG. 7 is a fragmentary side elevational view showing the prosthesis of the present invention in place after the surgery has been completed.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The prosthesis 11 of the present invention comprises in general an elongated piston member 13, a head 15 fixedly attached to piston member 13 at the proximal end 17 of piston member 13, and a loop 19 fixedly attached to head 15. Prosthesis 11 is preferably integrally formed from a material that has a substantial elastic recovery capacity for reasons which will be more apparent in the discussion to follow later in the specification. It has been found that a suitable material having the characteristics desired is "Teflon," which is a tetrafluoroethylene-hexa-fluoropropylene copolymer. This material is somewhat flexible and has substantially the same natural resonating frequency as the replaced stapes. In addition, as heretofore mentioned, it has a substantial elastic recovery capacity or plastic memory, that is, when it is displaced from its original disposition and subsequently released, it will within a certain period of time, as for example, twenty minutes, return to its original disposition. The importance of this will be brought out later in the specification.

Referring now in more detail to prosthesis 11, piston member 13 is preferably solid and cylindrically shaped, extending from its distal end 21 to its proximal end 17, where the prosthesis 11 flares outwardly into the substantially frusto-conical portion 23 of head 15. Head 15 preferably has a rim portion 25 extending from frusto-conical portion 23 to a flat surface 27 which is substantially perpendicular to the axis of piston member 13. A socket 29 is provided in head 15. Socket 29 is preferably cylindrical with its axis being in alignment

with the axis of piston member 13 and with the socket opening remotely from piston member 13 through surface 27.

Loop 19 is preferably integrally formed with head 15 along one edge thereof and extends from head 15 in the opposite direction from the extension of piston member 13 from the head. In other words, loop 19 is in parallel relationship with piston member 13 but offset to one side of the axis thereof and extends perpendicular relative to surface 27. A hole 31, which is preferably circular, extends through loop 19 centrally thereof with the axis of hole 31 extending substantially perpendicular to the axis of socket 29. A slot 33 extends from the exterior of loop 19 along one side thereof laterally through the loop to hole 31 with the slot 33 establishing free end portions 35, 37 of loop 19.

The size of socket 29, hole 31 and slot 33 depends upon the size of the incus and lenticular process with which prosthesis 11 is adapted to be used. For a better understanding of the comparative sizes, in relation to the incus and lenticular process, the following background is submitted:

The prosthesis 11 is adapted to replace the stapes in the middle ear, as for example, to correct otosclerosis. The middle ear is prepared for the reception of prosthesis 11 by the procedure well known to those skilled in the art wherein the arch of the stapes (not shown) is fractured away from the footplate (not shown) and the lenticular process leaving a portion 39 of the lenticular process which extends substantially perpendicular from the incus 41 (see FIG. 7). The socket 29 should be just large enough to closely receive the portion 39 of the lenticular process and the hole 31 should be slightly greater than the incus 41. However, the slot 33 should be narrower than the incus 41 so that when the prosthesis 11 is in place, as shown in FIG. 7, the incus 41 cannot pass through the slot 33 and the prosthesis is held firmly in place on the incus with the portion 39 extending into the socket 29 to hold the prosthesis 11 in a correct right angular relationship to the incus 41. This is an important feature of the present invention, and is particularly an advance over the previous prostheses, such as applicant's device heretofore mentioned, which could move relative to the incus, and the heretofore mentioned Robinson device, which could move if the wire was not tight enough and would cause pressure necrosis if it were too tight.

In describing the procedure in putting prosthesis 11 in place, it is assumed that the stapes has been removed as heretofore described and the oval window 43 from which the foot of the stapes was removed, is covered with a rectangular vein graft 45 which has been previously removed from the back of the hand. The vein 45 is invaginated into the oval window and held in place with "Gelfoam," a product of the DuPont Co. The lining membrane, not shown, of the middle ear, which was previously elevated from the circumference of the oval window 43 is replaced over the edge of the vein graft 45 to hold it in place. Now, starting with the step in the process after that above-described, the length of the piston 13 to be used is gauged, from the lower end of the portion 39 of the lenticular process to the center of the invaginated vein graft 45. In most ears three millimeters is correct, in some $3\frac{1}{4}$ millimeters, and in rare instances, $3\frac{1}{2}$ millimeters. The proper size prosthesis

11 is selected having the proper size socket 29, hole 31 and slot 33 and the piston member 13 is cut to give the proper length of piston which was gauged. It should be noted that it has been found that large and small sizes of the prostheses and one for the right and left ears are sufficient to cover the requirements for a correct prosthesis. These sizes are given below by way of illustration and not limitation:

	I. D. Loop	I. D. Socket	Lengths
Large	0.038"	0.044"	4mm, 4.5mm, 5mm, & 6mm
Small	0.033"	0.040"	4mm, 4.5mm, 5mm, & 6mm

The prosthesis 11 selected is inserted into the middle ear for a trial inspection of its length. The distal end 21 is put down on the center of the vein 45. The lower end of the incus 41 is elevated with a delicate right angle pick 47 in one hand and the head 15 is pushed into place with a straight pick 49 (see FIG. 4) beneath the lenticular process portion 39 until the portion 39 falls into place in the socket 29. It will be understood that the part shown as at 50 in FIGS. 4 - 6 is the chorda tympani nerve.

To get the loop 19 onto the incus 41, the end portion 37 is moved with a right angle hook 51 (see FIG. 5) to spread slot 33 and cause the loop to assume a relatively open disposition shown in FIG. 5. While pulling up with right angle hook 51, another right angle hook 53 is used to push down on end portion 35 and the opened loop 19 is pressed onto incus 41. There is no need to close loop 19 on incus 41 since it will do this automatically in about 20 minutes. The "memory" of the "Teflon" material causes it to gently close and revert to the closed position securely in place. The ease and efficiency of placement can be readily appreciated when it is compared with prior types utilizing wires, which had to be twisted in place and which in many cases caused necrosis of the bone. Finally, "Gelfoam" 55 is placed around the lower end of the piston member 13 to hold it in place on the center of the vein graft 45 during the healing process.

Although the invention has been described and illustrated with respect to a preferred embodiment thereof, it is not to be so limited since changes and modifications may be made therein which are within the full intended scope of this invention.

I claim:

1. A prosthesis for use in otologic surgery to replace the stapes and attach to the lenticular process of the incus, said prosthesis comprising an elongated piston member having a proximal end and a distal end, a head fixedly attached to said piston member at said proximal end, said head being provided with a socket opening remotely from said piston, said socket being just large enough to closely receive the lenticular process of the incus with which said prosthesis is to be used, a loop fixedly attached to said head, said loop defining a hole therethrough, said hole being of a size slightly greater than the incus with which said prosthesis is to be used, and said loop consisting of structure means having a substantial elastic recovery capacity for returning to its original disposition after being forced from its original disposition and subsequently released.

2. The prosthesis of claim 1 in which said loop is provided with a slot therethrough extending from the exterior of said loop to said hole therein for passage of the

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incus therethrough to said hole during placement of said prosthesis on the incus.

3. The prosthesis of claim 2 in which said slot is narrower than the incus with which said prosthesis is adapted to be used.

4. The prosthesis of claim 1 in which said structure means consists of tetrafluoroethylene-hexa-fluoropropylene copolymer.

5. The prosthesis of claim 1 in which said loop is disposed in offset relationship to said socket and extends substantially parallel with said piston member.

6. A prosthesis for use in otologic surgery to replace the stapes and attach to the undersurface of the lenticular process of the incus, said prosthesis comprising an elongated piston member having a proximal end and a distal end, a head integrally attached to said piston member at said proximal end, said head being provided with a socket opening remotely from said piston in axial alignment therewith, said socket being just large enough to closely receive the lenticular process of the incus with which said prosthesis is to be used, a narrow loop integrally attached to said head in offset relation-

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ship to said socket and extending substantially parallel with said piston member, said loop defining a hole therethrough having the axis thereof extending substantially perpendicular to the axis of said socket, said loop being provided with a slot therethrough extending from the exterior of said loop along one side thereof laterally through said loop to said hole therein, said slot establishing at least one free end portion of said loop, said slot being narrower than and said hole being larger in diameter than the incus with which said prosthesis is adapted to be used, and said loop having a substantial elastic recovery capacity whereby said free end portion is adapted to be moved from its original disposition to widen said slot for insertion of the incus therethrough and into said hole and subsequently said free end is adapted to be released for return to its original disposition in non-clamping relationship to the incus received therethrough.

7. The prosthesis of claim 6 which is made entirely of a tetrafluoroethylene-hexa-fluoropropylene copolymer.

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