

July 27, 1965

M. ROBINSON

3,196,462

STAPEDIAL PROSTHESIS

Filed Sept. 5, 1961

Fig. 1.

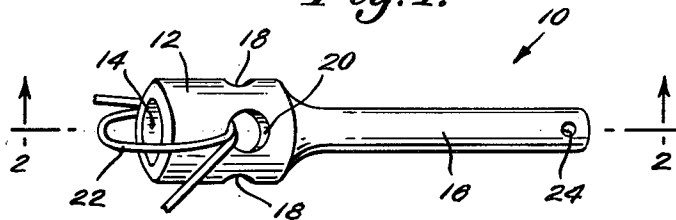


Fig. 2.

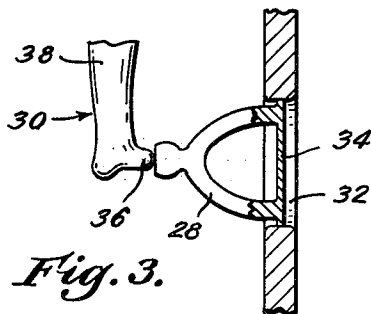
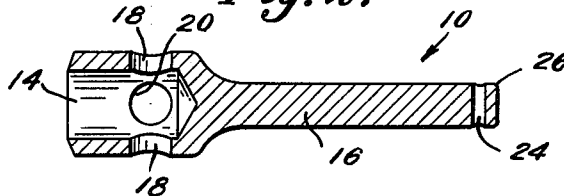


Fig. 3.

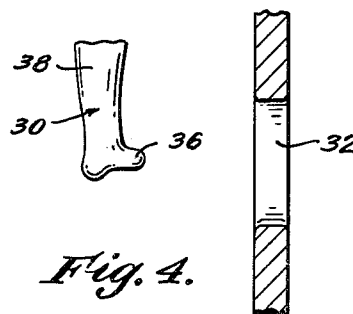


Fig. 4.

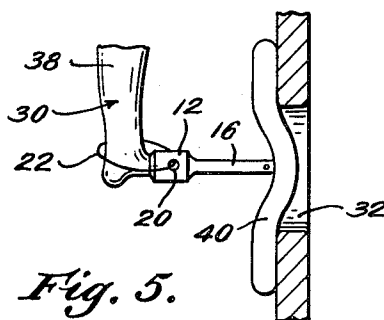


Fig. 5.

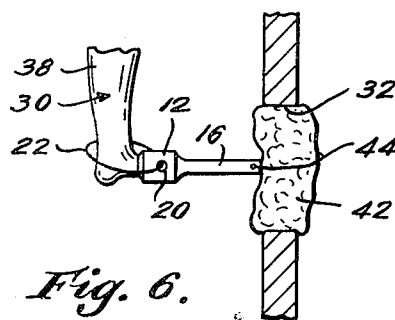


Fig. 6.

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3,196,462

STAPEDIAL PROSTHESIS

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Filed Sept. 5, 1961, Ser. No. 135,843

3 Claims. (Cl. 3—1)

The present invention relates to a novel and improved stapedial prosthesis for use in middle ear surgery.

In the healthy and normal ear, the stapes extends from the incus to the oval window, the foot plate of the stapes sitting in the oval window and covering same. As is well known, the function of the stapes is to carry sound vibrations from the incus to the oval window and inner ear. When a patient becomes affected with otosclerosis, a bony overgrowth of spongy vascular bone, peculiar to the temporal bone, causes the stapes to be rigid, whereupon it is unable to vibrate. This condition has long been one of the contributory causes of deafness.

In recent years, a technique has been developed wherein the diseased stapes is removed from the ear and a polyethylene stapedial prosthesis substituted in lieu thereof. This technique is known as the Shea stapedectomy-vein graft procedure. Briefly described, this procedure involves the use of a cone-shaped hollow polyethylene strut, the larger end of which is positioned on the lenticular process of the incus, while the smaller pointed end of the strut bears against a vein graft that is positioned over the oval window. This technique has resulted in a high percentage of rehabilitation of patients afflicted with otosclerotic deafness.

Although the Shea procedure as broadly described above has proven to be tremendously beneficial in curing otosclerosis, it has nevertheless been found that certain disadvantages exist as a result of the polyethylene strut which is used in that technique. First of all, there exists the possibility that polyethylene may be irritating to both animals and humans, since it has never been definitely proven that this material is completely inert. Although clinical tests have never shown polyethylene as having an undesirable reaction with the human body, the fact still remains that tests have shown that this material can be irritating when implanted in certain animals, and hence the possibility does exist that over extended periods of time it may turn out that polyethylene does have a reaction when implanted in the human body. In addition, should the polyethylene strut become detached from the incus, there would be no way of determining this dislocation without surgical re-exploration of the middle ear since polyethylene is not radiopaque. Also, polyethylene cannot be autoclaved but rather can only be sterilized by a rather complicated and expensive atomic process. Lastly, polyethylene does not have maximum vibratory characteristics.

It is therefore a primary object of this invention to provide a novel and improved stapedial prosthesis which may be used in place of the polyethylene strut used in the above described Shea stapedectomy-vein graft procedure.

It is a further object of my invention to provide a novel and improved stapedial prosthesis which is constructed of a material that has minimal tissue reaction to the human body.

Another object of my invention is the provision of a novel and improved stapedial prosthesis that has greater vibratory quality than the polyethylene strut heretofore used.

A further object is the provision of a stapedial prosthesis that is constructed of radiopaque material and hence may be inspected and examined by X-ray without the necessity of surgical exploration of the middle ear.

Still another object of my invention is the provision of a novel and improved stapedial prosthesis that can be autoclaved without difficulty, whereupon absolute sterility of the prosthesis can be maintained.

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A further objects of my invention is the provision of a stapedial prosthesis having means which function to maintain the prosthesis properly positioned between the incus and the oval window.

Other objects, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

In the drawings which illustrate the best mode presently contemplated by me for carrying out my invention:

FIG. 1 is a perspective view of a stapedial prosthesis constructed in accordance with my invention;

FIG. 2 is a section taken on line 2—2 of FIG. 1, with the wire omitted;

FIG. 3 is a diagrammatic view showing the relationship between the incus, the stapes and the oval window in a normal and healthy ear;

FIG. 4 is a diagrammatic view showing an ear after the stapes has been removed;

FIG. 5 is a diagrammatic view showing my stapedial prosthesis in operative position in the ear; and

FIG. 6 is a diagrammatic view illustrating a slightly modified technique with which my stapedial prosthesis may be utilized.

Referring now to the drawings, there is shown generally at 10 a stapedial prosthesis constructed in accordance with my invention. The prosthesis 10 comprises an enlarged proximal portion 12 which is hollow, as shown most clearly in FIG. 2, and which is open at its outer end, as at 14. A reduced shank portion 16 extends axially and centrally from proximal portion 12, said shank portion being preferably solid. The prosthesis 10 is preferably of integral, one-piece construction, and it may be a screw machine part. For reasons which will hereinafter become apparent, I prefer to make the prosthesis 10 of stainless steel.

As will be seen most clearly in FIGS. 1 and 2, the proximal portion 12 is provided with a pair of openings 18 and 20, said openings extending laterally through the proximal portion and being substantially perpendicular with respect to each other. A stainless steel wire 22 is looped through one of the aforementioned openings so as to provide a pivotal bail which is in spaced relation to the open end 14. At the opposite end of the prosthesis 10, an opening 24 extends laterally through the shank portion 16, adjacent the outer end thereof. It is important to note that the outer end of shank portion 16 is rounded at its edges, as at 26, so as to eliminate any sharp corners.

Turning now to FIGS. 3 through 6, there is shown in FIG. 3 in diagrammatic form a normal and healthy ear in which the stapes 28 extends from the incus 30 to the oval window 32, it being noted that the foot portion 34 of stapes 28 sits in and blocks said oval window. Thus, the stapes functions as a link for imparting vibrations from the incus to the oval window and inner ear. When, however, the stapes loses its vibratory characteristics due to the effects of otosclerosis, for example, the diseased stapes is removed, as illustrated in FIG. 4, and my prosthesis 10 is substituted in lieu thereof. More specifically, referring to FIG. 5, it will be seen that the hollow open end 14 of the enlarged proximal portion 12 functions as a socket for receiving the lenticular process 36 of the incus so as to form, in effect, a ball and socket joint therebetween. The wire bail 22 is loosely looped over the long process 38 of the incus and then may be subsequently tightened to the desired degree, whereupon the wire functions as a ligament and acts as an anchor to reinforce the attachment of the prosthesis to the incus. The cross openings 18 and 20 enable mucus membrane to grow into the prosthesis so as to securely anchor it to the incus. In fact, it has been found that the wire 22 is not an absolute necessity in view of the anchor that is eventually obtained

by membrane growing into the openings 18 and 20. However, the wire 22 does function to maintain the prosthesis properly positioned on the incus before the membrane has had a chance to form a secure bond, and hence I prefer to utilize the wire bail. At the opposite extremity of the prosthesis 10, a vein graft 40 is positioned over the oval window 32 and is maintained in position thereover by the pressure exerted by the prosthesis 10. The rounded edges 26 at the end of shank portion 10 function to prevent perforation of the oval window by sharp corners and at the same time minimize tissue reaction around the vein graft. The lateral opening 24 facilitates a fibrous attachment from the prosthesis to the vein graft.

In FIG. 6, a slightly modified technique is illustrated, wherein instead of a vein graft being used, a fat graft 42 is employed for blocking the oval window. Since the fat graft actually sits within the window, a wire 44 is preferably looped through the opening 24 and around the fat graft to maintain the latter in proper position. Otherwise, the construction and use of the prosthesis shown in FIG. 6 is identical to that which has been aforedescribed.

As has hereinbefore been set forth, my prosthesis 10 is preferably constructed of stainless steel since this material has been shown to have minimal tissue reaction in the body. It is conceivable, however, that other inert metallic materials, such as platinum, gold, vitalium and the like could also be used, although for economic reasons stainless steel is preferable. Also, since stainless steel, or any other suitable inert metallic material, is radiopaque, the prosthesis can be inspected externally by X-ray. Hence, any dislocation that might inadvertently develop between the prosthesis and the incus, for example, can be discovered without the necessity of surgery. Stainless steel also possesses good vibratory characteristics, better than polyethylene, for example, and additionally can be autoclaved, which is not possible with plastic. It will be understood that my prosthesis 10 is passivated, electropolished and ultrasonically cleaned, whereupon it is ready for use after sterilization by autoclaving.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without de-

parting from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

5 What is claimed is:

1. A stapedial prosthesis comprising an integral, one-piece body member, said body member having an enlarged open-ended tubular proximal portion, and a reduced solid shank portion extending axially from said proximal portion and centrally disposed with respect thereto, and a pair of apertures extending laterally through said proximal portion, the axes of said apertures being angularly disposed with respect to each other.

2. A stapedial prosthesis comprising an integral, one-piece body member, said body member having an enlarged open-ended tubular proximal portion, and a reduced solid shank portion extending axially from said proximal portion and centrally disposed with respect thereto, an opening extending laterally through said shank portion adjacent the outer end thereof, said outer end being rounded at its edges so as to eliminate any sharp corners, and a pair of openings extending laterally through said proximal portion, said last-mentioned openings being substantially perpendicular with respect to each other.

3. The stapedial prosthesis of claim 2 further characterized in that a wire loop extends through one of said last-mentioned lateral openings so as to provide a pivotal bail in spaced relation to the open end of said proximal portion.

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