

[54] **IMPLANTABLE SUBSTITUTE STRUCTURE
FOR AT LEAST PART OF THE MIDDLE
EAR BONY CHAIN**

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[58] Field of Search **3/1, 1.9; 128/350, 92 C,
128/92 R, DIG. 14**

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Primary Examiner—Ronald L. Frinks

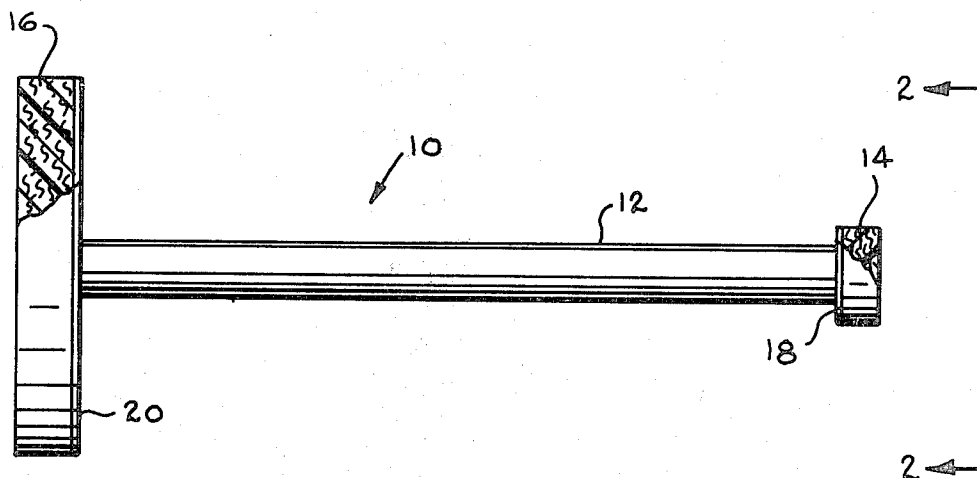
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[57]

ABSTRACT

A structure for in vivo implantation in place of the
bony chain between the ear drum and the vestibule
which includes a biocompatible columella having a
suitable length and biocompatible porous pads se-
cured to the ends of the columella which have the
characteristics of promoting living tissue therein.

14 Claims, 2 Drawing Figures



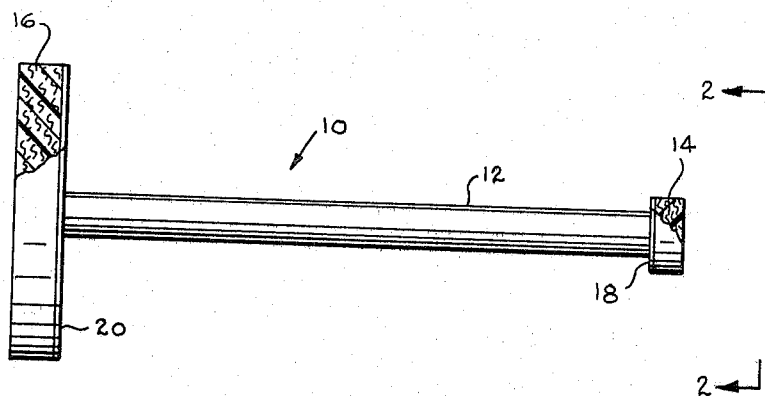


fig.1

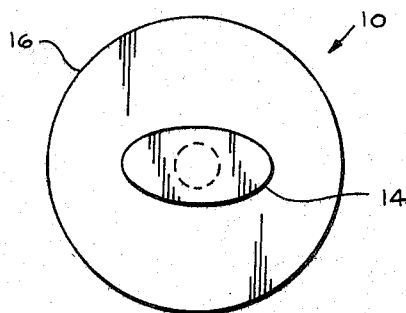


fig.2

IMPLANTABLE SUBSTITUTE STRUCTURE FOR AT LEAST PART OF THE MIDDLE EAR BONY CHAIN

BACKGROUND OF THE INVENTION

One of the reasons for deafness is the failure of the bony chain, i.e., the hammer, the anvil and the stirrup, to transmit the vibrations of the ear drum to the inner ear. Efforts have been made to repair the elements of the bony chain and to substitute components. With the substitution of components, one difficulty encountered is securing such components in the desired position.

SUMMARY

The present invention relates to an improved structure suitable for in vivo implantation as a substitute for the bony chain or parts thereof in the ear.

An object of the present invention is to provide an improved structure for implanting in the ear in substitution for the bony chain.

Another object is to provide an improved implantable structure which has an improved securing of the structure in its desired place within the ear.

A further object is to provide a structure suitable for implantation in substitution for the bony chain of the ear which has the capability of transmitting the ear drum vibrations to the oval window of the vestibule with adequate efficiency to provide acute hearing.

Still another object is to provide an improved vibration transmitting implant for the ear which is anchored in position by ingrowth of living tissue and is not hampered by excess tissue growth.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and advantages are hereinafter set forth and explained with respect to the drawings wherein:

FIG. 1 is a side view of the implantable structure of the present invention.

FIG. 2 is an end view of the implantable structure shown in FIG. 1 showing the end of the structure opposite to the end to be placed in engagement with the ear drum.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings the improved implantable structure 10 includes a columella 12 and end pads 14 and 16 secured to the ends of the columella 12. All of structure 10 is biocompatible and can be suitably sterilized preferably by steam autoclave or by gas sterilization.

Columella 12 is shown to be cylindrical in shape but may be of any suitable shape such as tubular or may have a square, rectangular or elliptical cross section. Also, the columella is made from a polymer such as a high molecular weight polyethylene, polytetrafluoroethylene such as sold by DuPont Company under the mark "Teflon TFE" or a perfluorinated ethylene propylene polymer such as sold by DuPont Company under the mark "Teflon FEP."

The columella is of a suitable length (usually about eight millimeters) to be implanted between the ear drum and the oval window of the vestibule of the inner ear with the pads 14 and 16 thereon or as a substitute for parts of the bony chain. In the preferred form the columella has a diameter of approximately six-tenths of

a millimeter. Normally, the columella will have transverse dimensions of less than 2 millimeters.

The pads 14 and 16 are of a material which is porous and which readily promotes the ingrowth of living tissue into the pores and voids within the material. A typical example of the preferred form of material is disclosed in my copending application Ser. No. 145,497, filed May 20, 1971. In such application a porous material of carbon fibers bonded by polytetrafluoroethylene is disclosed as the preferred growth promoting material. Other suitable growth promoting materials are disclosed in such application and the disclosure is herein incorporated by reference. Also a velour fabric made with a polyester such as sold by DuPont Company under the mark "Dacron" may be used as the growth promoting material for the pads 14 and 16.

As clearly shown in FIG. 2 the pad 14 which is to be placed against the oval window is elliptical in shape in its preferred form may have a major axis of approximately 2 millimeters and a minor axis of approximately 1 millimeter. The pad 16 which is to be placed against the eardrum may have a diameter of approximately 4 millimeters. Such dimensions of the pads 14 and 16 would be suitable with a columella having a diameter of approximately six-tenths of a millimeter and a length of approximately 8 millimeters. The thickness of the pads 14 and 16 may be approximately 1 millimeter.

The pads 14 and 16 are secured to the columella 12 by suitable bonding means. One suitable bonding means which is biocompatible and sterilizable is the perfluorinated high polymer such as sold by DuPont Company under the mark "Teflon FEP."

In the preferred form of pads 14 and 16 their sides facing columella 12 include a means for closing the pores on such side. The purpose of such pore closing means is to prevent growth of the tissue along the columella and between the pads since such tissue may interfere with the vibration transmission function of the structure 10. Such pore closing means can be layers 18 and 20 on the pads 14 and 16, respectively, of perfluorinated high polymer such as is sold by DuPont Company under the mark "Teflon FED." When this preferred material is bonded to the inner face or side of the pads 14 and 16 it also functions as the aforementioned bonding means.

The structure and materials therefor described above are the preferred form of the present invention but other materials as hereinafter set forth may be used. For example, if the structure is to be used in place of the stirrup of the bony chain, then the columella 12 may be a wire or wire coated element. With this structure the pad 14 would be secured to one end of the columella and the other end would be secured by connecting the wire around the stirrup end of the anvil. Other variations that may be used include a columella of the aforementioned perfluorinated high polymer with the same material being used as the means for closing the inner face of the pads and the bonding being accomplished with heat. The columella may be a silicone coated wire (or wire reinforced silicone) with a silicone material closing means provided by forcing the silicone material into the surface of the pads and the bonding being a silicone adhesive or a vulcanizing to secure the pads to the columella. When a polyethylene material is used for the columella a polyethylene material is used to close the inner face of the pads by heat bonding thereto and the columella is heat bonded to the closing

material. Similarly a polyester closing means is heat bonded to the pads and is heat bonded to the polyester columella.

It should be understood that all materials used in the implantable structure have to be biocompatible and suitable for some form of sterilization, preferably steam autoclaving.

From the foregoing it can be seen that the improved implantable structure is suitable for implantation between the ear drum and the oval window as a substitution for the bony chain or parts thereof. The use of the growth promoting insures a proper connection to the tissue so that the structure is mechanically stabilized and transmits the vibrations of the ear drum to the inner ear. Also by sealing the inner faces of the pads excessive growth of tissue which might interfere with the sound transmission function of the structure is prevented. When the structure is to be substituted for only a part of the bony chain the pad on one end of the columella would be omitted and a suitable connection provided for engaging the portion of the bony chain to be left in place.

What is claimed is:

1. A structure for in vivo implantation comprising a biocompatible columella having a suitable length and transverse dimensions for implantation as a substitute for at least a part of the bony chain of the middle ear,
a porous pad secured to both ends of said columella, said pads being biocompatible and having the characteristics of promoting ingrowth of living tissue therein when implanted,
one of said pads being of sufficient thickness so that when positioned against the eardrum the tissue of the eardrum becomes a part of said pad for efficient transmission of vibrations and without atrophy of said eardrum, and
the other of said pads being adapted to secure said columella in position to transmit vibrations to the oval window when implanted.

2. A structure according to claim 1, wherein the transverse dimensions of said columella are less than two millimeters.
3. A structure according to claim 1, wherein said columella is a cylinder having a diameter of less than one and one-half millimeter.
4. A structure according to claim 1, wherein the dimensions of said pads transverse to the length of said columella is substantially greater than said transverse dimensions of said columella.
5. A structure according to claim 1, wherein the side of each of said pads facing said columella includes means for closing the pores of said pads to prevent growth of living tissue therethrough.
6. A structure according to claim 5 wherein said pad closing means also functions to bond said pads to said columella.
7. A structure according to claim 5 wherein said pads are a porous material of carbon fibers bonded together by polytetrafluoroethylene.
8. A structure according to claim 5 wherein said pads are polyester velour material.
9. A structure according to claim 1 wherein said columella is a biocompatible polymer.
10. A structure according to claim 1, wherein said columella is a polytetrafluoroethylene.
11. A structure according to claim 1, wherein said columella is a high molecular weight polyethylene.
12. A structure according to claim 1, wherein said columella is a perfluorinated ethylene propylene polymer.
13. A structure according to claim 5, wherein said closing means is a perfluorinated high polymer bonded to said pads.
14. A structure according to claim 6, wherein said bonding and closing means is a perfluorinated high polymer bonded to said pads and bonding said pads to the ends of said columella.

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