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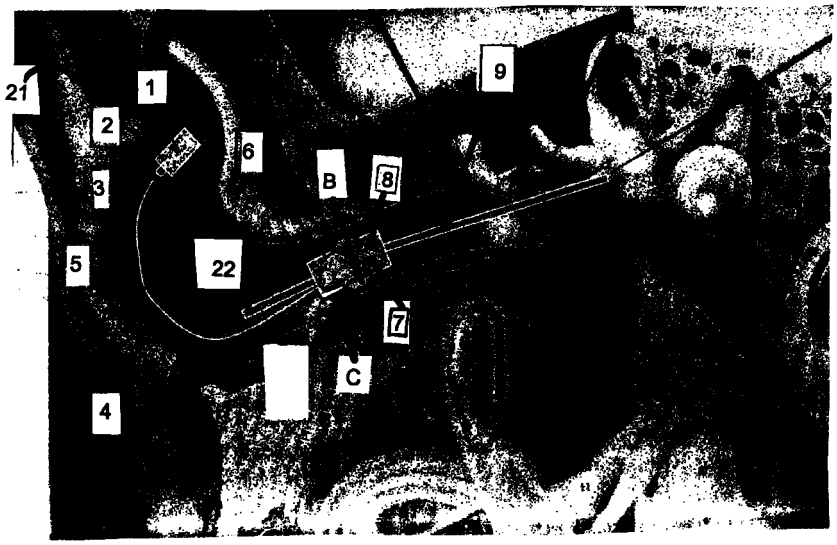
(54) Implantable acoustic device

(57) An acoustic device implantable into the middle ear is described, having a sound conveyor (9) or (5'), inserted in the middle ear, which sends acoustic waves directly to the organs of the middle ear, which direct the sounds towards the brain; the device not obstructing the canal (22) and cooperating with the external parts of the ear: auricle (21) and canal (22).

Fig. 6



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Description

Field of the invention

[0001] The present invention concerns an implantable acoustic device, acting on and over the middle ear.

Background art

[0002] The ear is an organ which transfers the external sounds to the brain. For a description of the ear functionality see for example G. Von Bekèsi "The ear" Scientific American 197 (1957) or "Mechanics of hearing" Surgery of the ear - Shambough ed. 1967, page 379.

[0003] When the mechanism of transmission of the sounds is altered, it's used to talk about uni or bilateral hypoacusia, or about neurosensorial loss hypoacusia when the sensorial receptors located into the choclea (organ of Corti) or the same fibers which constitute the nerve are affected.

[0004] It's used to talk about transmission hypoacusia when there is an alteration of the external acoustic canal or tympanic membrane or the ossicles (malleus, incus, stapes) or Eustachian tube.

[0005] In the present description the acoustic external canal will be named simply as canal or conduct. The hearing aids for the neurosensorial hypoacusia nowadays available on the market are external (retroauricolar or pretympanic) and are constituted of a plastic ear mold (obturator or plug) which is inserted into the canal in such a way to plug it and which carries connected elements which have the purpose to amplify the sound waves.

[0006] Such hearing aids have noticeable disadvantages, first of all due to the difficulty to adapt the plug on the canal because of the elasticity of the skin especially in subjects who have copious hairs in the canal.

[0007] Furthermore in case of alteration of the canal consequently to radical or modified radical mastoidectomies, recurrent external otitis, bacterial or mycotic dermatoses, there are often infections, which are perpetuated by the infected plug, and therefore a constant, continuos cleaning of the canal and of the plug itself is requested.

[0008] Such kind of hearing aids produce aesthetic alterations and embarrassing situations as, for instance, for swimming, during the night, during sexual relationships, gymnastic exercises and in some particular kind of professions.

[0009] They, furthermore, present difficulties in maneuverability, as, for instance, in subjects with tremors.

[0010] The plugs produce feeling of compression into the ears.

[0011] Another disadvantage of those conventional hearing aids is the impossibility of knowing in advance the amplification value of which the patient will benefit; in fact, hearing aids with same adjustment, fitted by different subjects, will produce different amplification because different are the canals in which the prostheses are inserted.

[0012] Furthermore, in case of bilateral prosthesization of both ears with conventional hearing aids, "the gain of insertion" (see below for the definition) is different from one ear to the other, because even in the same individual the canals are dissimilar among themselves, and so a different perception happens on which nothing can be done and which turns to be very annoying for the patient.

[0013] Finally, by applying very tightly the mold (plug) in the canal, it is shut off a natural resounding and amplification effect given by the ensemble of the external auricle and the canal.

[0014] The "gain of insertion" is defined as result of the global effect given by the amplification of the hearing aid and the effect of the attenuation due to the occlusion of the canal by the mold (plug) of the aid.

[0015] The current prostheses are conceived in such a way that they have to correct not only the preexisting hypoacusia, but also a superimposed hypoacusia produced by the occlusion of the canal in which the mold is inserted.

[0016] Such obstruction, causing also the presence of humid squamous debris or cerumen (interposed between the hearing aid and the tympanic membrane) produces an increase of the superimposed hypoacusia.

[0017] Therefore, the conventional prosthesis, besides creating a distortion of received sounds, must act with a volume and a potency much higher with respect to those which should be actually requested to treat the real hypoacusia.

[0018] Another drawback of external or pretympanic prostheses is that they "whistle".

[0019] Especially when the potency is to be set to the maximum level, if the hearing aid doesn't adhere properly to the canal, it starts to whistle with great embarrassment for the patient (Larsen phenomenon).

[0020] Moreover, the external prostheses do not decrease but even amplify (because of the pressure of the mold on the canal) the tinnitus and all the annoying problems given by the temporo-mandibular joint (T.M.J.) arthritis malocclusion (periauricular pins → feeling of ear occlusion → tinnitus), and the more the plugs are pushed into the canal, the more those symptoms increase with unbearable situation, especially in elderly people, with unappropriated dental plates.

[0021] The Authors believe to be wrong the principle on which the traditional hearing aids (by air conduction type) are based. In that, in order to increase the intensity of the mechanical vibration on the tympanic membrane, and so over the ossicular chain and oval window, necessarily the ear canal has to be plugged, thus excluding one of the best systems of natural amplification known in nature: auricle and ear canal.

[0022] Plugging the ear canal is unnatural. Several

people know by experience that if the canal is obstructed, for instance, by a plug of earwax, they do every thing to have it be removed, because they are afflicted from the annoying phenomenon of echo sound of their own or others' voice, at times feeling of vertigo and diminution in the hearing acuity and, when the plug comes removed, they have a sense of relief and comfort.

[0023] As far as the eyeglass acoustic prostheses (in case of transmission hypoacusia) are concerned, it's to be said that also such kind of hearing aid request a very strong potency, because the vibration wave starting from the frame must pass through several layers, i.e. skin, subcutaneous fascia, temporal muscles periostium, temporal spongy bone, all mediums of different nature, aggregation and constitution density, before reaching the neural endorgans of the cochlea, giving raise during this long way to refraction and diffraction phenomenons. This process involves an enormous dispersion and distortion of the acoustic wave.

Summary of the invention

[0024] The present invention has the aim to obviate to all the inconveniences of the conventional hearing aids and it is an object of the invention an acoustic implantable device acting directly on and over the middle ear, anchored in the canal in such a way of not obstructing it. The invented hearing aid requires a minimal potency to cure a patients hypoacusia, in that the resistances of refraction and diffraction of the acoustic waves must not be overcome, like in the case of conventional hearing aids acting over the tympanic membrane and over the ossicular lever mechanism, and, at the same time, ifs not excluded the action of one of the best systems of natural amplification known in nature: auricle and canal. As the potency of the invented device has to be set to the minimum, an increased battery duration and an almost irrelevant sound distortion are obtained. Further objects of the invention will be evidenced by the detailed description of the invention itself.

Brief description of the figures

[0025]

Fig. 1 schematically illustrates in section the conformation of the external and middle ear and part of the internal ear.

Fig. 2 schematically illustrates a first embodiment of the prosthesis according to the invention.

Fig. 3 schematically illustrates a second embodiment of the prosthesis according to the invention.

Fig. 4 schematically illustrates a third embodiment of the prosthesis according to the invention.

Fig. 5 schematically illustrates a feeding battery and corresponding needle for the prosthesis according to the invention.

Fig. 6 schematically illustrates a section of the ear (as in fig. 1) into which an embodiment of the invented hearing aid is inserted.

Fig. 7, as in fig. 6, illustrates another embodiment of the hearing aid as invented, with the microphone beyond the tympanic membrane.

Fig. 8, as in fig. 6, illustrates a further embodiment of the hearing aid as invented with direct action over the promontory of the middle ear in case of transmission hypoacusia.

Fig. 9, as in fig. 6, illustrates another embodiment of the invention, acting over the middle ear but with the whole electronic apparatus located in the auricle.

Fig. 10 is a diagram of an amplifier.

Fig. 11 is an audiogram (calibration).

Fig. 12 is an audiogram (calibration).

Detailed description of the invention

[0026] The invented device, even if it cannot re-establish the natural function of the organ, eliminates the inconveniences of conventional and pretympanic hearing aids; and, as in the case of the intraocular lenses which substitute the crystalline, gives back to the patient the continuity of the function without contraindications for any kind of activity the patient himself wants to perform.

[0027] The fundamental characteristics of the invented prosthesis is that it is implantable and acts amplifying the sound waves directly over the middle ear without obstructing the canal, maintaining the natural amplification of the auricle and canal and being provided with an element (conveyor element) placed in the middle ear which conveys the acoustic wave in the proximity of the oval window or round window or over the petrosa as clearly specified in the following pages.

[0028] Regarding the kind of hypoacusia (transmission or perceptive type) and the positioning of the conveyor element of the device inside the middle ear, the acoustic wave will reach directly contact the bony petrosal portion of cochlea (promontory) (transmission hypoacusia), or the oval window (perceptive hypoacusia), hitting the stapes footplate as it happens naturally in a safe ear, or can be addressed over the round window when the ossicles are missing and the suprastructure of the stapes and around it there should be fibrous tissue obstructing the oval window.

[0029] For a better understanding of the positioning of the device it is wise to recall the fig.1 which represents the basic for perceiving the illustrated prosthesis.

[0030] The elements composing the ear and useful to the present description are the following: auricle (21), canal (22), cartilagineous portion of the canal (23), skin of the canal (24), bony canal (25), anulus (26), tympanic membrane (27), ossicular chain (malleus (28), incus (29), stapes (30)), oval window (31), round window (32), promontory (33), Eustachian tube (34), perforation area (35) for the passage of the sound conveying element,

cochlea (36), acoustic nerve (37), vestibular nerve (38).

[0031] The invented prosthesis will be described now with reference to some schematic examples of realization shown in the enclosed figures, which, therefore, must not be considered of any limitation of the scope of the invention.

[0032] In the figures equal numbers correspond to elements similar or having the same function.

[0033] With reference to the submitted figures, the invented device contains the following components in relationship of cooperation among themselves: an electrical feeding battery (1) or (6'), an element with the aim to control the volume of the device (2), a battery detachable connector (3), removable in order to change the battery itself a wire (4) or (7') connecting the battery case and the device, a microphone (5) or (1'), an electronic power station (6) or (3'), an amplifier (7) or (2'), a loudspeaker (8) or (4'), a sound wave conveying element (9) or (5').

[0034] The invented device way of functioning is the following: the acoustic stimulus amplified by the auricle (21) and canal (22), reaches the microphone (5) or (1') and is amplified by the amplifier (7) or (2').

[0035] In case of uni or bilateral perceptive type hypoacusia, the following invented prostheses are applied, according to figures 2, 3, 6; 7, 9, the amplified acoustic wave, through the loudspeaker (8) or (4'), is pushed into the conveyor (9) or (5') and, from this, directly over the oval window (31) or round window (32).

[0036] In case of uni or bilateral transmission type hypoacusia and only in case of surgical inoperativeness or after unsuccessful surgical approach, the device can be applied according to figures 4, 8, 9. In this case the amplified acoustic wave, as said before, is addressed directly by the conveyor element (9) or (5') which is almost at immediate contact with the promontory (33), which constitutes the bony portion of the cochlea (36).

[0037] In fig. 2 it is illustrated a first embodiment of the invented hearing aid. It contains the following elements all in cooperation relationship among themselves: a hearing aid "body" (A) having a shape such to be implanted in the middle ear and containing a microphone (1') connected to an amplifier (2'), that is connected to an electrical station (3') and to a loudspeaker (4'). All the functions of the above mentioned elements are well known by any expert of the specific matter. The loudspeaker is directly connected to a sound conveying element, which, in this case, has the shape of a tube (5'), with preferably an external diameter of about 1.5 mm. Its opened extremity (5') is positioned inside the middle ear, preferably in proximity of the oval window.

[0038] On the hearing aid body (A) some fixing elements are present, elements which have the aim to block the prosthesis in the ear canal. It's wise remember that the new invented hearing aid doesn't obstruct the canal. Preferably, such fixing elements (8') are in the shape of steel springs. The electrical feeding of the system is provided by a battery (6') that, properly connected to the elements (1'), (2'), (3') and (4') inside the hearing aid body (A) through a specific electric wire (7'), is placed in a remote position with respect to the above mentioned "body" (A).

[0039] In order to make the hearing aid as small as possible, the battery (6') is preferably positioned outside the hearing aid itself, preferably behind the ear lobe. An advantage of such solution is that it is easy to replace the exhausted battery, without removing the prosthesis at all.

[0040] The hearing aid is preferably covered with biocompatible materials, well known to the field experts, such as Teflon ® or Sealastic ®, which don't make any obstacle to the prosthesis implantability.

[0041] In fig. 3 it is illustrated a second embodiment of the invented hearing aid, which differs from the previous one, because the conveying element has a sort of hook (10'), which has the aim to fix the prosthesis directly on the handle of the malleus.

[0042] It's to be noted that the middle portion (9') of the hook (10') is shaped in such a way to facilitate instead of being an obstacle to the malleus vibrations (for the malleus (28) functionality see fig. 1).

[0043] A third embodiment of the invented hearing aid, consisting in a transduction type prosthesis for recovering transmission type hypoacusia, is represented in fig. 4.

[0044] In this case, the loudspeaker (4') has been substituted by a transductor (12'), to which has been connected a sound conveying element, that is in the shape of a transmission wire (11'), placed inside the tube (5'); said wire (11') is in almost direct contact with the cochlea bony wall and has the aim to transmit the mechanical vibrations of the sounds. For example, the transmission wire (11') can be made in ivory or in a high mechanically conducting metal and can be terminated at the opened extremity (5") of the tube (5').

[0045] For this embodiment too, the tube (5'), in which the transmission wire (11') is located, can have a middle portion (9') and a hook (10') (not shown in fig. 4 and similar to what illustrated in fig. 3), if the hearing aid has to be hanged to the handle of the malleus.

[0046] In fig. 5 it is schematically represented an embodiment of the battery elements comprising, for instance, a battery case (13'"), which can be implemented in well known shapes and materials, such as waterproof materials, in order to be water resistant and esthetically accepted by the patients.

[0047] In a zone (13") of the case (13'"), it is located the electrical connection between battery (6') and wire (7'), for instance a female threading can be screwed to a male threading (7"), existing at one end of the wire (7'), preferably interposing a further tightening waterproof element (7'").

[0048] According to a preferred embodiment, the wire (7') is made to pass from the external ear canal up to the zone behind the auricle by means of a curved needle (15'), having at one end, a female threading

(15"), on which it is screwed the corresponding male threading (7") of the above mentioned wire (7'), when such wire is still inside the ear, in order to put out together the wire (7') and the needle (15') behind the auricle in a designated point.

[0049] Fig. 6 illustrates another embodiment of the invented device. As it can be seen, the hearing aid is inserted into the external and middle ear. The electrical feeding battery (1) and the hearing aid volume control (2) are inserted, for a better understanding of the representation, in the auricle (21), but the position of those elements is preferably in a not visible location, behind the ear lobe, connected through a removable connector (3) to change the battery itself, with a feeding and programming wire (4), which is passed (like an ear ring) piercing the cartilage of the canal behind the ear lobe or, if the patient doesn't want to have the cartilagineous canal pierced, into the fold of the auricle. The battery can be easily changed removing the battery case from the wire.

[0050] The wire (4) is connected to a: microphone (5), electronic power station (6), amplifier (7), loudspeaker (8). All of those elements are inserted into an hermetic container (C), realized in bio-compatible material and with such physical dimensions so small as to be inserted into a canal without obstructing it.

[0051] The container (C) is provided of suitable blocking and anchoring systems to the walls of the canal. Those blocking systems (B) can be made in a shape of a opportunely dimensioned steel spring. The container (C) is connected to a sound conveyor element (9) in the shape of a tube preferably of the diameter of 1.5 mm and the length of preferably about 2 cm, which can be made opportunely shorter by the surgeon, when the hearing aid has been implanted. That tube is realized with already known and implanted plastic bio-compatible material such as bio-compatible Teflon® or Sealastic®, or made bio-compatible via surface treatment processes, like heparinization, well known to the field experts.

[0052] All the above mentioned device components can be found on the market and all over the countries.

[0053] The microphone (5) can be a microphone of the series EG-EM or EG 3000, Eg 3001, EM 3046, EM 3047, EM 3056, produced by Knowles Electronics, with physical dimensions of about 4 mm.

[0054] As amplifier (7), it can be used the one illustrated in the block diagram of fig. 10, hybrid circuit GS3026 produced by Genum, having the following characteristics: compression ratio 8:1, maximum gain 38 dB (decibels) adjustable over the range of 38 dB, output compression level adjustable over the range of 38 dB, physical dimensions 4.11 x 2.39 x 1.178 mm.

[0055] The volume control element (2) can be a variable resistor (trimmer) as, for instance, PJ63 produced by Microtronix.

[0056] The loudspeaker (8) can be a receiver of series EH, produced by Knowles Electronics, as for instance EH 3030 or EH3043, both with nominal impedance of 1000 Ω at 1000 Hz and nominal resistance of 400 Ω and with dimensions of about 3-5.5 mm.

[0057] The length of the wire (4) between the device and the battery case (1) can be changed according to the morphology of the ear canal. The electric power source can be a zinc-air battery.

[0058] As it is shown in fig. 6, the container (C) is positioned inside the canal (22), i.e. in the external ear, while the conveyor (9) passes through a hole performed in the tympanic membrane (world wide diffused technique for ventilation tube application) or under the tympanic anulus (so leaving intact the tympanic membrane) up to reach the proximity of the oval or round window.

[0059] In the fig. 7 it is shown another embodiment of the invented hearing aid. In that case, the loudspeaker is distant from the container (C) and it's implanted beyond the tympanic membrane into a sealed container (C') through a hole in the tympanic membrane itself or under the anulus. The connection between the amplifier (7) and the loudspeaker (8) is done through two tiny wires isolated by means of bio-compatible plastic material. The described embodiment has the advantage that, being the loudspeaker far way from the amplifier and inserted behind the tympanic membrane, any form of feedback (whistling) is cut off and being the loudspeaker in contact with the oval or round windows, the sound doesn't present any distortion and the discrimination of spoken voice is almost perfect.

[0060] In fig. 8 it is illustrated another embodiment of the invented hearing aid, which can be used for recovering transmission type hypoacusia. In this case, the sound conveyor element is in the shape of a tube and it is placed in almost direct contact with the bony portion of cochlea (petrosa) Such tube is made of a stiff material (plastic or metal). The material is stiff enough to maintain its position even during head movements. The aim if the tube is to directly convey and concentrate the sounds over the petrosa.

[0061] In fig. 8 the loudspeaker is beyond the tympanic membrane, however any other location can be suitable.

[0062] Fig. 9 represents an embodiment which has all the elements above mentioned in fig.s 6 or 9, but all inserted into the folds of the auricle and with the conveyor (9) which is prolonged for the whole length of the canal (22) until to pass through the tympanic membrane and positioned in the middle ear. That kind of hearing aid is suitable for both transmission hypoacusia and perceptive hearing loss and it is easily applicable in old patient or poor surgical patients or patients who are not interested in aesthetic problems. That kind of device can be applied easily also in small children, doing a simple myringotomy, applying a long tube connecting this inserted tube with the conveyor tube of the prosthesis.

[0063] It's to be pointed out that the above described device, having the microphone outside the canal, doesn't take any advantage of the natural ampli-

fication of the auricle and canal itself.

[0064] The invented prosthesis has a very easy surgical applicability under local anaesthesia as office procedure or as half-day hospital procedure. The invented hearing aid is much smaller than the existing conventional pretympanic prostheses and, not adhering to the ear canal (22), will be preferably fixed in 3 different points:

- middle ear, through several kinds of surgical techniques world wide diffused and known by any otosurgeon (a surgical technique is known as Helbert Silverstein method, described by the same athor in "Surgical treatment of the temporal bone and skull base" pages 109-112, Lea and Febiger, 1992);
- in the canal, e.g. through steel spring (B);
- outside, e.g. behind the ear lobe (piercing the canal), or in the fold of the auricle, via the elements (1) or (6') (electric power station) and (4) or (7') (wire).

[0065] The blockage of the conveyor (9) or (5') is such that it cannot move with the head and body movements.

[0066] The advantages of the invented prostheses are:

- the hearing function is always present, even at night time,
- they are not visible,
- they are impermeable to the water (patient can swim),
- according to clinical experiments performed, they have better functionality with respect to the conventional ones,
- they are easily tolerable,
- absence of feedback (Larsen's phenomenon),
- they are very useful in chronic operated ears.

[0067] Various surgical techniques can be used to implant the invented hearing aids, all of them well known and described by the inventors in a detailed publication with ample references to well known books for the eventual surgeons and well illustrated with various photographs, very easily understandable also by eventual patients, who can easily judge for eventual informed consent.

[0068] The hearing aid object of the present invention, as already said in the above, on the contrary of the other hearing aids currently available on the market, does not require a notable amplification power, moreover the patient does not loose those acoustic frequencies naturally transmitted through the ear canal. A small employed power involves a small consumption of the batteries, a small distorsion of the sounds (therefore small inconveniences for the patient who wears the prosthesis) which are much similar faithful to the normal ones.

[0069] The new conceived prosthesis is particularly advantageous in case of patients who have a vertical type auditory drop in some intervals of frequencies, that is a sonorous perception falling curve in the range of frequencies of 2000-8000 Hz. In fact, in the case of the conventional external hearing aids, in order to "carry up" the high frequencies, because of plugging of ear canal, also low and middle frequencies are "carried up", inducing a serious, easily understandable, trouble for the patient. On the contrary, the new conceived hearing aid, as it doesn't plug the ear canal, could be programmed for amplifying only the frequencies of interest, for instance, typically those from 2000 to 8000 Hz. On the other side, the low frequencies, typically from 125 to 2000 Hz, will pass unchanged through the ear canal without any necessity to be amplified by the hearing aid, being perceived by the ear in a normal way and so giving the patient a "normalized" restoration of the auditory ability. In this context, the hearing aids come also advantageous as far as the phenomenons of the secondary fitting (adaptability), acclimatization and deprivation are concerned. In fact Neuro Central System (N.C.S.) must get used again to the reintroduction of the vanished or diminished sounds, when they are reinserted into the auditory circuit by the amplification of the hearing aid.

[0070] In case of neurosensorial hypoacusia, there is a decreased auditory input from the periphery to the N.C.S. with consequent alteration of the last one.

[0071] So the reintroduction of the sounds through the amplification done by the hearing aid, might produce an impact at level of the N.C.S. with a possible adaptation which follows to a period of acclimatization or a negative reaction. Therefore, the aerial conduction type hearing aid can stimulate only those auditory cells which are responsible of reintroducing into the N.C.S. vanished or diminished frequencies, without stimulating at the same time the normally functioning auditory cells.

[0072] Further advantages of the invented hearing aid are the following:

- Pre-programming by the otology surgeon, thus requiring no intervention of an audioprosthesis for a tuning of the device;
- Negligible or nonexistent aesthetic alteration (only a small remotely applied battery);
- Complete safety of the electric apparatus (isolation, absence of damages for possible explosions of the battery);
- Only partial occupation of the external auricular canal so preserving the functionality for the amplification of sounds performed by the auricle and the ear canal;
- Constant presence and, therefore, ability to substitute the lacking hearing function;
- Easy surgical applicability;
- Lack of irritation of auricular canal in cases of temporo-mandibular joint arthrosis due to dental

malocclusion (especially in the elderly people);

- Lack of worsening of tinnitus extrauricolar type in case of T.M.J. syndrome (47% of the cases), while with conventional hearing aid pressing with plug in the already painful canal there could be an increasing of tinnitus;
- Lack of irritation of the skin in the canal (which, not properly oxygenated, has tendency to become altered, giving rise to the production of acid substances well known to the audioprosthesists for the erosion of the loudspeaker of the hearing aids);
- Possibility of fining this kind of hearing aid even in an ear with perforated tympanic membrane;
- Lack of the phenomenon known as "gain of fitting" or "gain of insertion".

[0073] The bony conduction hearing aid amplifies in the best of the ways, acting directly over the petrosa, which like the ivory conducts the acoustic waves at the highest speed 3013 m/sec (as comparison the sound propagation speed is 344 m/sec in the air and 1437 mt/sec in the water).

[0074] Therefore there is a noticeable difference with the eye glasses hearing aids, in which the vibrations are muffled by the cutaneous, subcutaneous and muscular layers, or with trasductors implanted in the mastoid cavity, whose bone is spongy with several phenomenons of refraction and diffraction. If the nerve is intact or almost intact, the vibrations, acting over the cochlea, reach the nerve in the best way.

[0075] In case of C.R.O.S. hearing aid, the vibrations over the petrosa of the dead ear are in the best position to reach the petrosa of the opposite side through the base of skull better than through the temporo-parietal bone.

[0076] However, the most important thing is that of giving safety to the patient and, above all, to save him from all the inconveniences caused by conventional hearing aids.

[0077] In fact, even with the new hearing aid implanted the ears can be cleaned out of ear wax or cured as in any other patient, while the auditory controls can be simply done disconnecting the external battery.

[0078] In case of a possible infection of outer or middle ear, the therapy will be the usual one.

[0079] In case of substitution of the hearing aid, the procedure will require only few minutes under local anaesthesia.

Claims

1. Implantable acoustic device in the middle ear, characterized in that it has a sound conveyor (9) or (5'), inserted in the middle ear, which sends acoustic waves directly to the organs of the middle ear, which direct the sounds towards the brain; the device not obstructing the canal (22) and cooperating with the external parts of the ear: auricle (21) and canal (22).

2. Implantable acoustic device according to claim 1 in which, in case of transmission hypoacusia, the conveyor (9) or (5') of the sound carries the acoustic wave directly almost over the bony wall of the cochlea.

3. Implantable acoustic device according to claim 1 in which, in case of perceptive hearing loss, the sound conveyor sends the acoustic wave directly towards the oval (31) or round window (32).

4. Implantable acoustic device according to claim 1, including the following elements in relation and cooperation among themselves: an implantable "body" (A) prosthesis (device), a microphone (5) or (1') connected with a control station (6) or (3'), a loudspeaker (8) or (4') connected with the conveyor (9) or (5') of the sounds which has the shape of a small tube, whose extremity (5'') is open and is positioned inside the middle ear being the "body" (A) provided with elements (8') or (B) to fix it up inside the canal (22), an electrical power source (1) or (6') feeding the device.

5. Implantable acoustic device according to claim 4 in which the tube (9) or (5') has an external diameter of about 1.5 mm.

6. Implantable acoustic device according to claim 4 in which an open end (5'') of the tube (9) or (5') is positioned inside the middle ear in proximity of the round (32) or oval (31) window.

7. Implantable acoustic device according to claim 4 in which the fixing elements (8') or (B) are steel springs.

8. Implantable acoustic device according to claim 4 in which the power source (1) or (6') is positioned externally with respect to the prosthesis.

9. Implantable acoustic device according to claim 4 in which the power source (1) or (6') is positioned behind the auricle.

10. Implantable acoustic device according to claim 4 in which the loudspeaker (8) or (4') is connected to the promontory of the middle ear through a small stiff tube.

11. Implantable acoustic device according to claim 4 in which the loudspeaker is connected to the wall of the promontory through a tube (9) made of a stiff material directly conveying concentrated waves against the promontory (33).

12. Implantable acoustic device according to claim 4 in which the conveyor (5') is provided with a wire (11') which can be passed around and fixed at the handle of malleus (28).

13. Implantable acoustic device according to claim 4 in which the power source (1) or (6') is contained in a waterproof external container (13'''), connected via an insulated wire (4) or (7') to the "body" (A).

14. Implantable acoustic device according to claim 4 in which the body (A) is fixed in the canal (22) of the patient in at least one of the following three different points:

a) in the middle ear according either through the tympanic membrane (27), or under the anulus tympanicus (26), attached to the promontory (33);
b) in the auricular canal (22) through steel spring;
c) outside, behind the ear lobes or into a fold of the auricle (21).

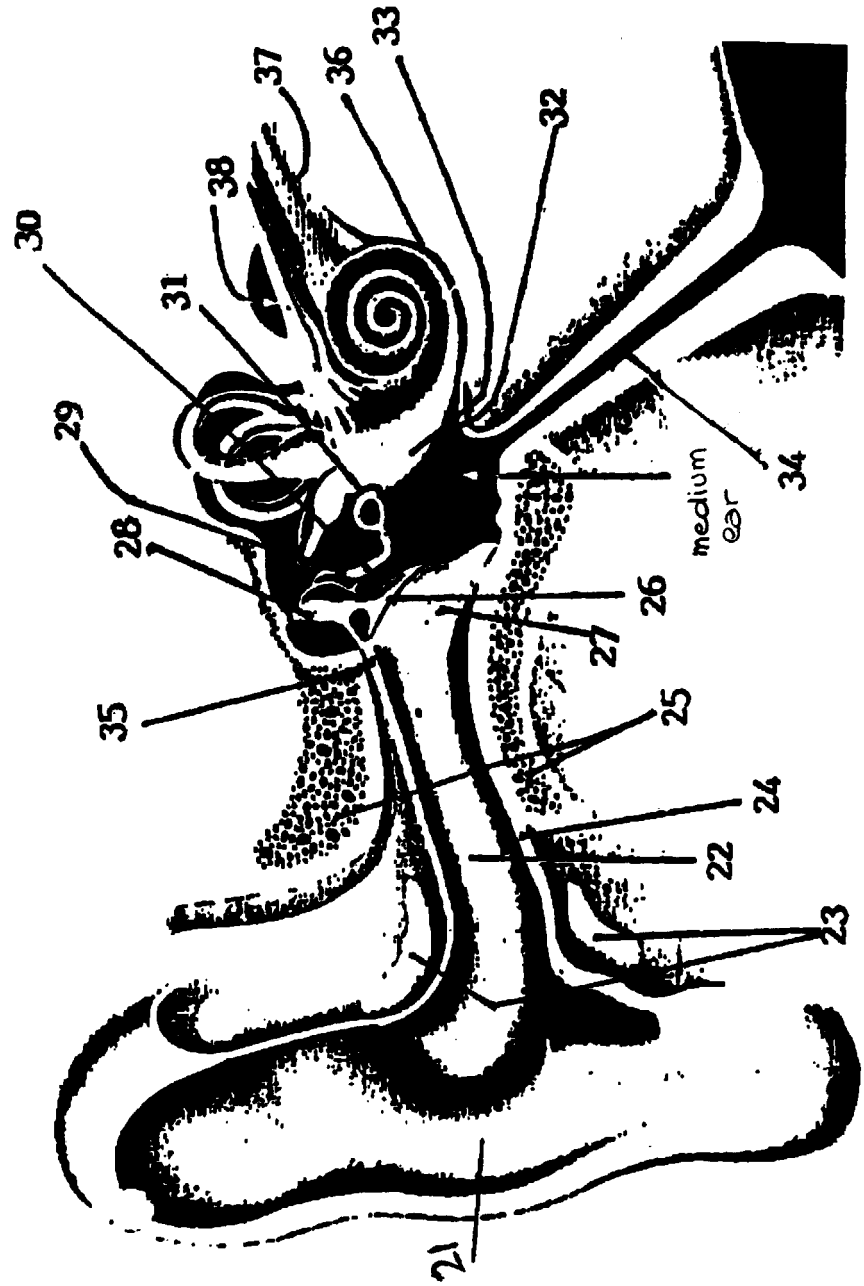


Fig. 1

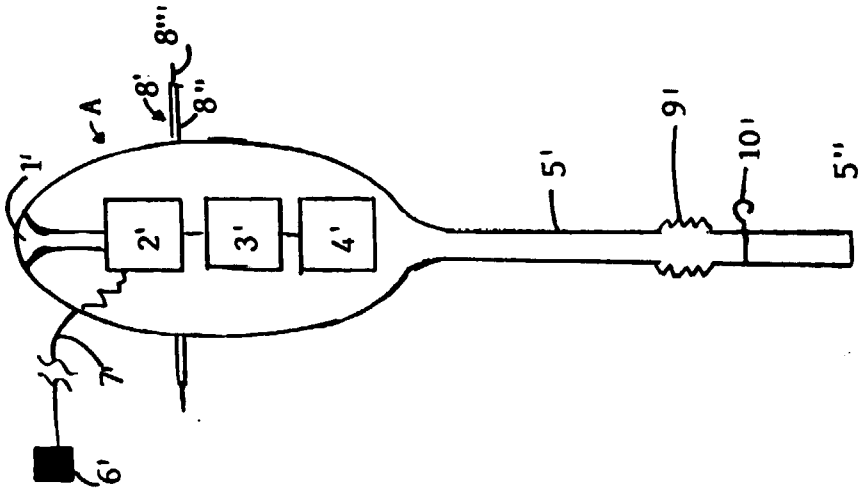


Fig. 3

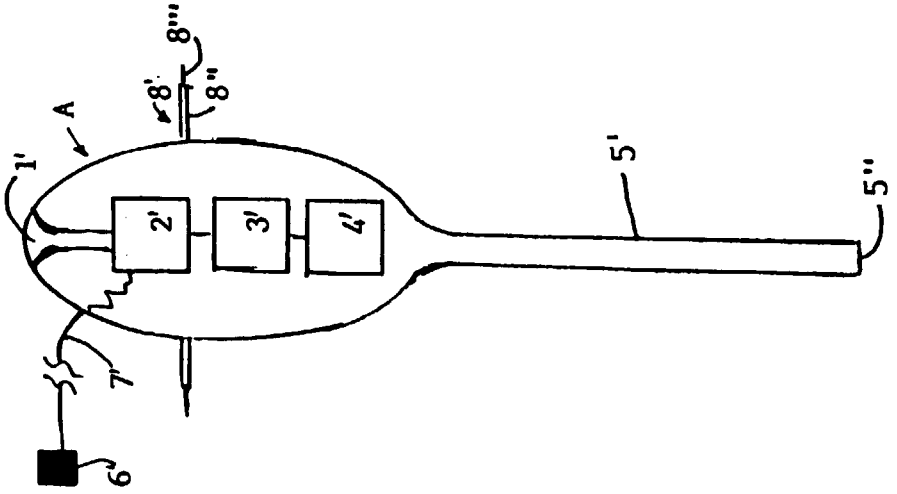


Fig. 2

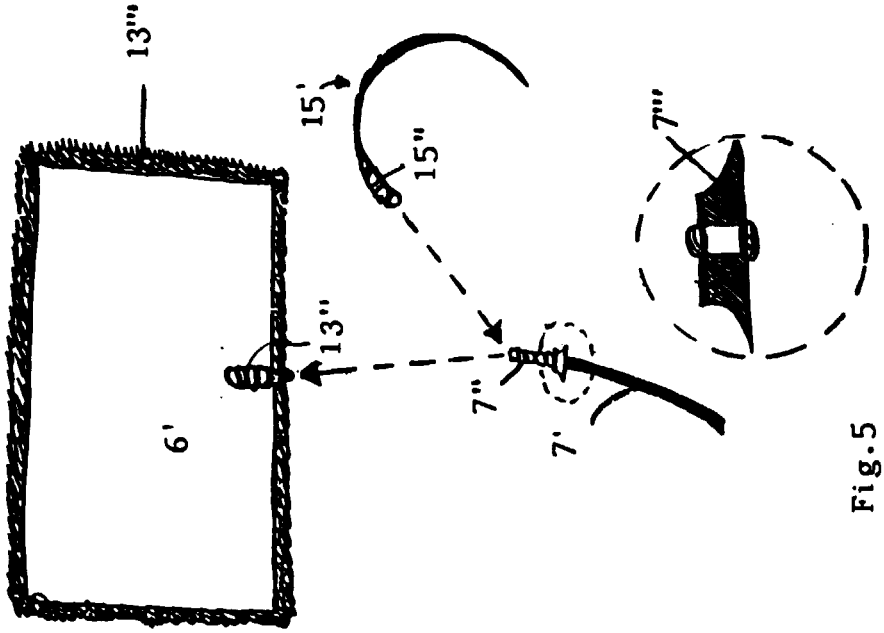


Fig.5

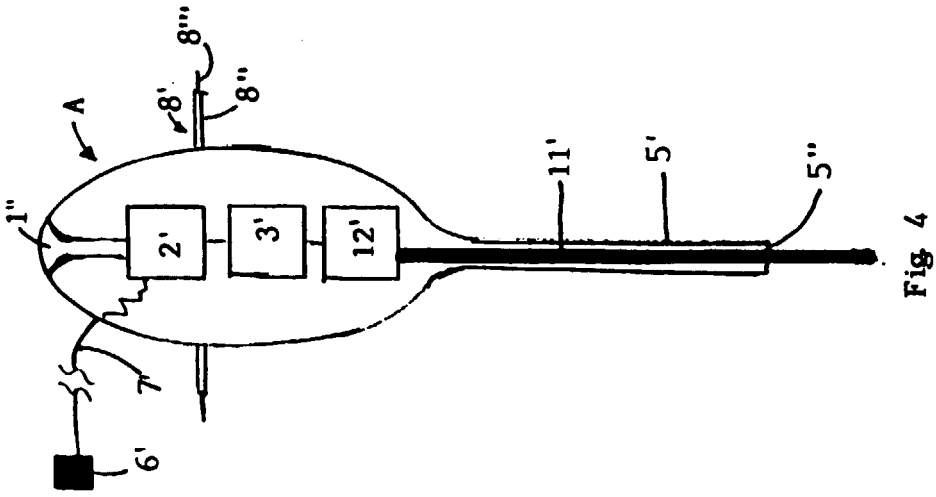


Fig 4

Fig. 6

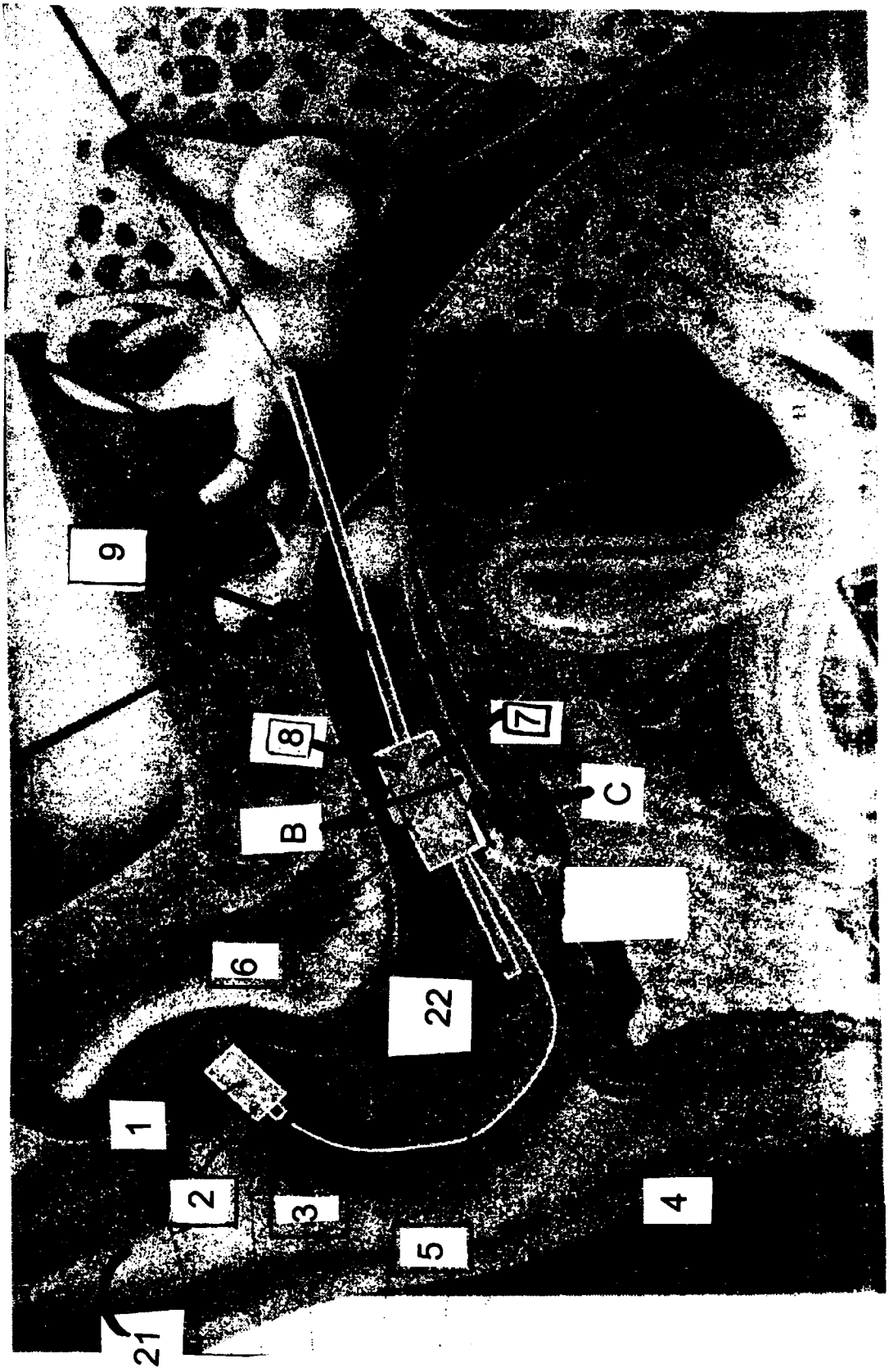


Fig. 7

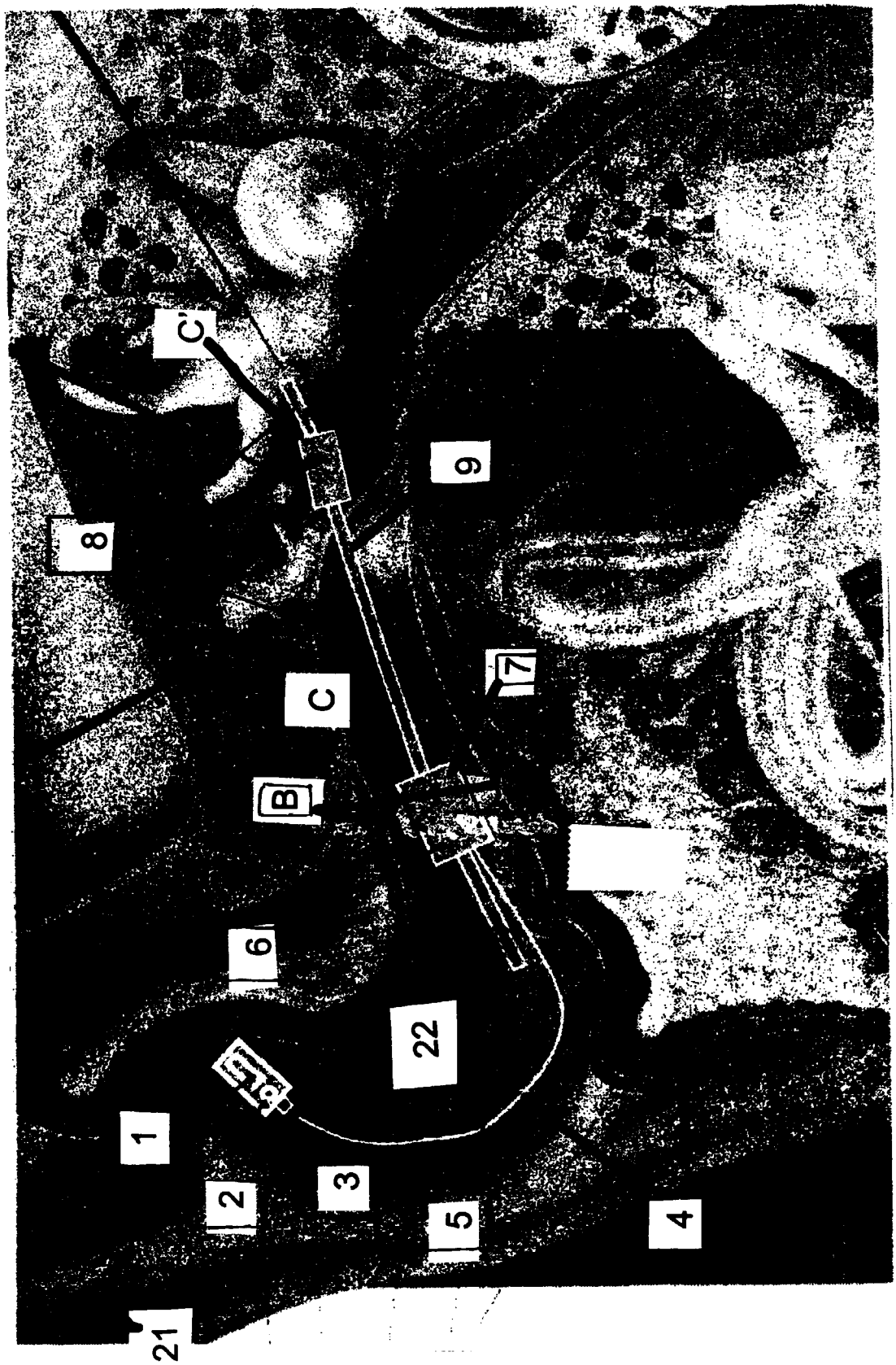


Fig. 8

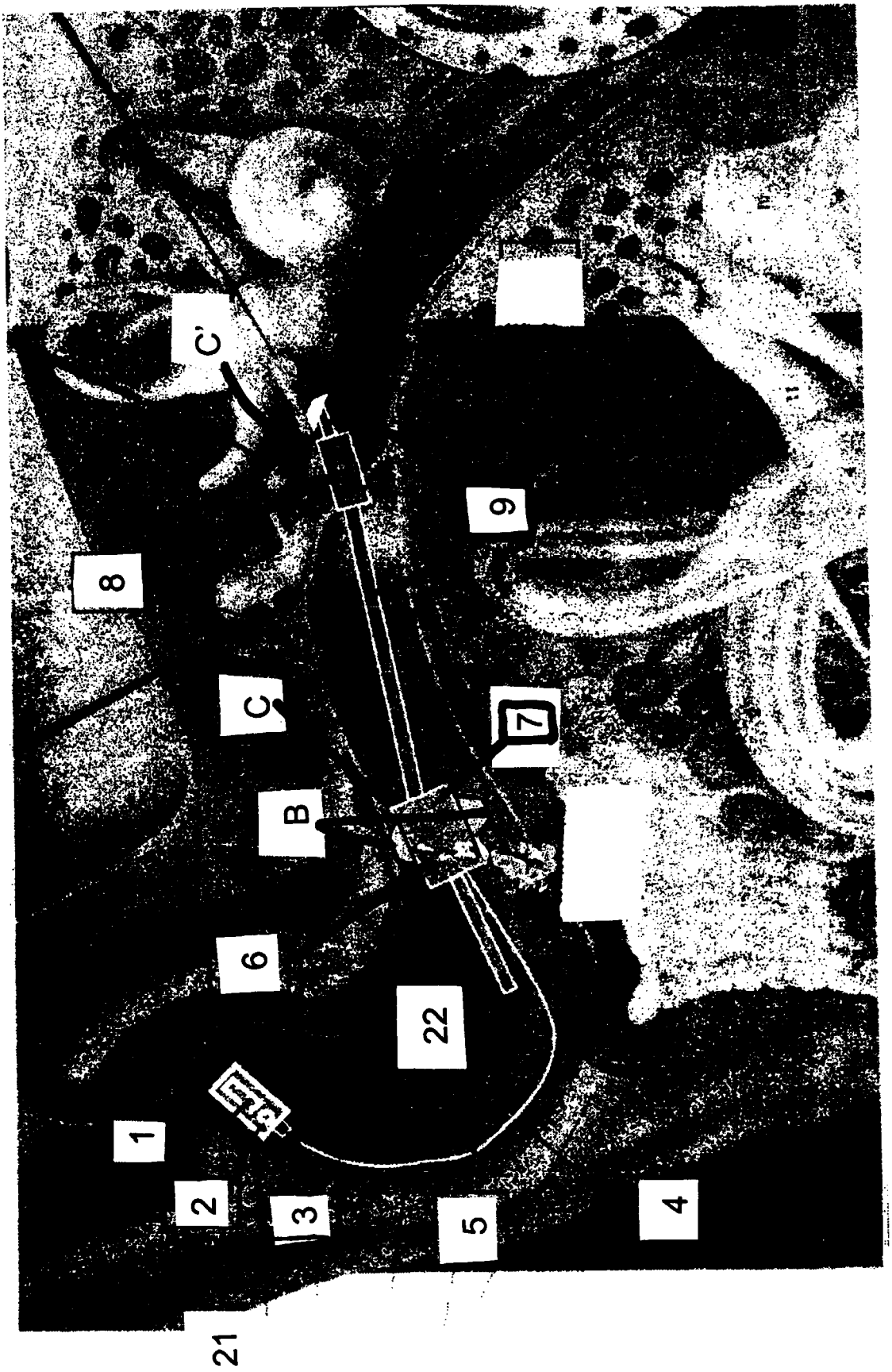


Fig. 9

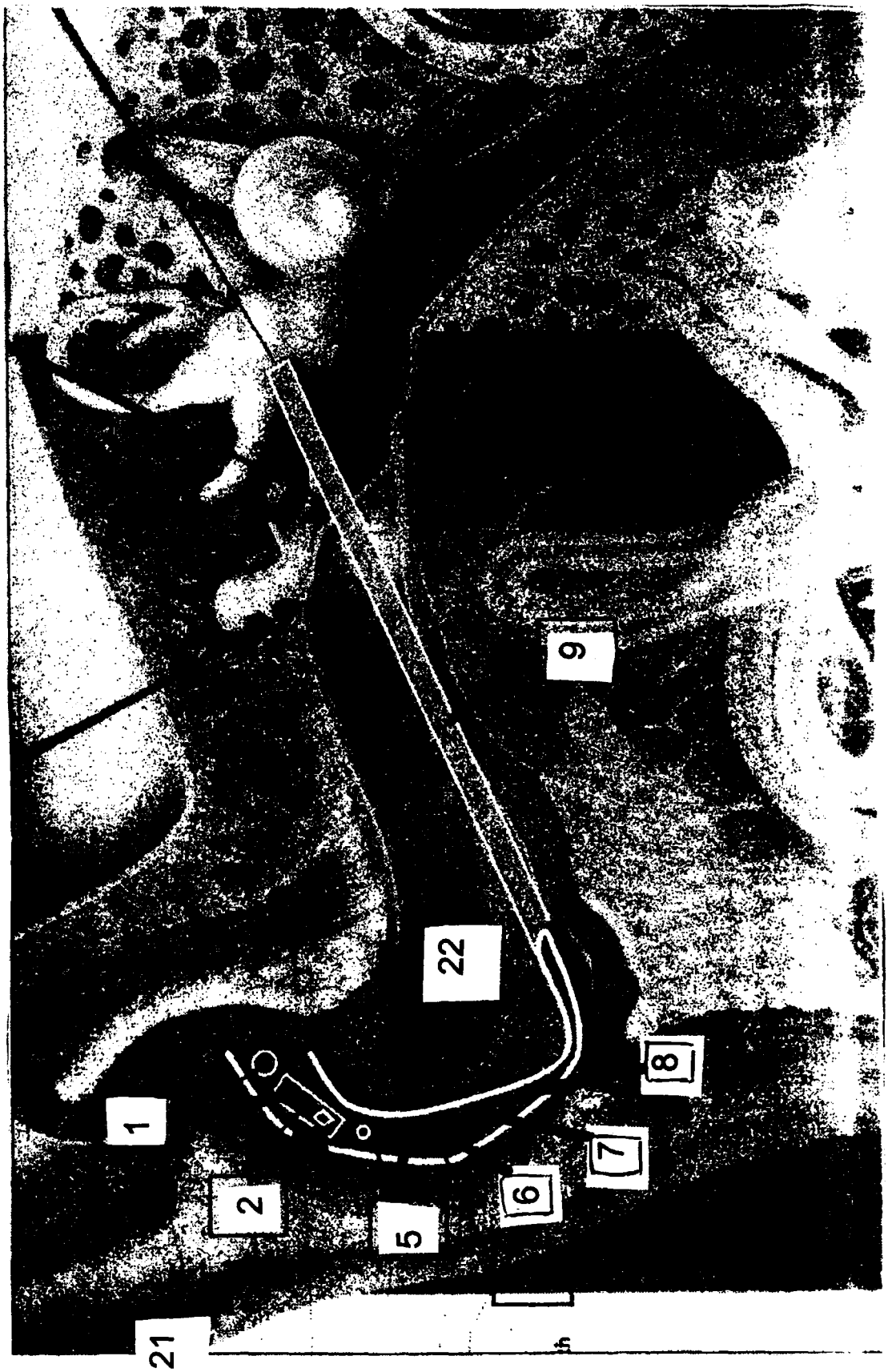
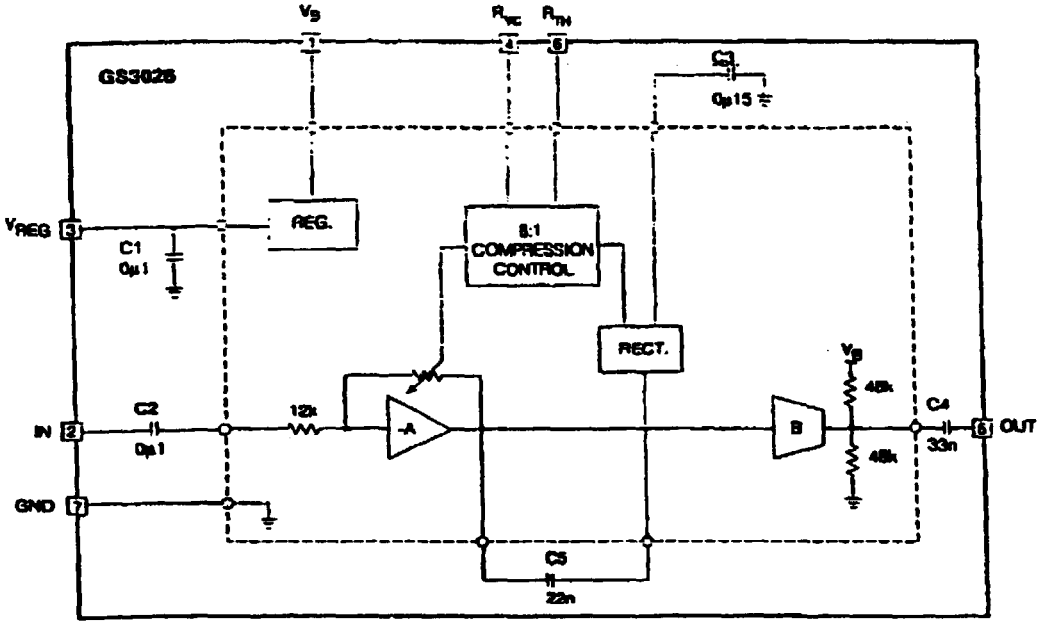


Fig. 10



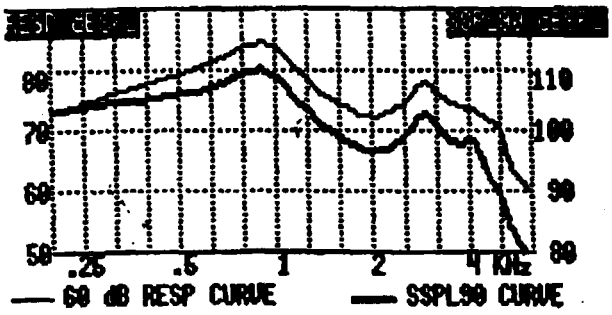
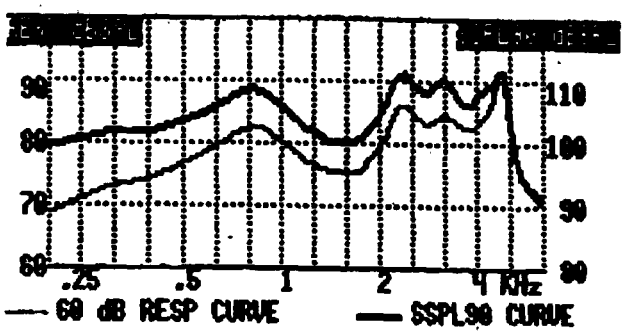


Fig. 11

Fig. 12



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EUROPEAN SEARCH REPORT

Application Number
EP 99 10 4444

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 318 502 A (GILMAN) 7 June 1994 (1994-06-07)	1-5,8,14	H04R25/00
A	* column 1, line 19 - line 46 * * column 2, line 59 - column 3, line 24; figures 1-3U *	6,7,9-13	
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A	* column 3, line 42 - column 5, line 52; figures *	6,7,9-13	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	25 August 1999	Gastaldi, G

CATEGORY OF CITED DOCUMENTS

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