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(54) Titre : PROCEDE DE FABRICATION D'APPAREILS AUDITIFS ET APPAREIL AUDITIF Y RELATIF
(54) Title: METHOD FOR PRODUCING IN-EAR HEARING AIDS AND IN-EAR HEARING AID

(57) Abrégé/Abstract:
The aim of the invention is to produce shells for in-ear hearing aids which are to be adapted very precisely to the individual auditory canal shape. To this end, a mould is made of the individual auditory canal and a hearing aid shell is created using an additive construction technique such as laser sintering, stereolithography or the thermojet technique, which is controlled with the mould data.

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(54) **Title:** METHOD FOR PRODUCING IN-EAR HEARING AIDS AND IN-EAR HEARING AID

(54) **Bezeichnung:** VERFAHREN ZUR HERSTELLUNG VON IM-OHR-HÖRGERÄTEN UND IM-OHR-HÖRGERÄT

(57) **Abstract:** The aim of the invention is to produce shells for in-ear hearing aids which are to be adapted very precisely to the individual auditory canal shape. To this end, a mould is made of the individual auditory canal and a hearing aid shell is created using an additive construction technique such as laser sintering, stereolithography or the thermojet technique, which is controlled with the mould data.

(57) **Zusammenfassung:** Für die Herstellung von Schalen für Im-Ohr-Hörgeräte, welche sehr exakt der individuellen Gehörgangform anzupassen sind, wird vom individuellen Gehörgang Form genommen, und eine Hörgeräteschale durch ein additives Aufbauverfahren erstellt, wie durch Lasersintern, Stereolithographie oder Termojetverfahren, das durch die Formdaten gesteuert wird.

METHOD FOR PRODUCING IN-EAR HEARING AIDS AND IN-EAR HEARING AID

The present invention relates to a method for producing in-the-ear hearing devices.

In the production of shells for in-the-ear hearing devices, the customary practice followed at present by the audiologist is to make a mold in the shape of the individual auditory canal, by taking an impression, usually of silicone.

This mold is subsequently sent to the producer of the hearing devices, where the hearing device shell is molded from a plastic on the basis of this mold.

This procedure is problematical from various aspects:

- In the production method based on the aforementioned impression of the outer ear, polymer materials which lead to relatively hard, dimensionally stable shells have to be used. This virtually always leads to the shell having to be re-worked on account of remaining pressure points when the finished in-the-ear hearing device is fitted into the individual ear. Since the trial fitting usually does not take place at the premises of the producer, a laborious procedure of sending the device back and forth is often required before the shell individually fits.

- The aforementioned procedure no doubt makes it possible for the resultant shell to correspond in its outer shape to the impression, but not for complex internal shapes to be formed, as would be desirable for functional parts of the hearing device to be received in an optimized way in terms of fitting. In this respect, we understand functional parts as meaning all units which are responsible for picking up, processing and reproducing the audio signals, that is of microphones, digital processors, loudspeakers and the associated auxiliary units, such as for remote control of binaural signal transmission, batteries etc. In this respect, it must be pointed out that optimum packing of these functional parts in a way which utilizes the space available can only be carried out on an individual basis, since the geometry of the auditory canal may vary greatly individually.

The procedure described is, on the one hand, highly labor-intensive, and the resultant hearing device usually remains less than optimum with respect to its wearing comfort and space utilization. The materials used in the case of said conventional production method also require a relatively great wall thickness of the shell of the in-the-ear hearing device, which reduces the space available for said functional parts move than is the case anyway.

The present invention has the purpose of overcoming these disadvantages mentioned.

According to the present invention, there is provided a method for producing in-the-ear hearing devices, comprising steps of:

making a mold in the shape of an individual auditory canal,

producing a hearing device shell corresponding to the mold,

installing functional parts of the hearing device, and

digitizing the shape in 3D, the hearing device shell being thus created by an additive construction method comprising a step of depositing one sectional layer after the other, on top of one another, characterized in that firstly sectional layers of a plurality of individual hearing device shells are respectively created virtually in parallel, before the following sectional layers of the individual hearing device shells are deposited on already created layers in the additive construction method.

Preferably, for this purpose, it is distinguished by the fact that the shape of the individual outer ear is digitized three-dimensionally (3D) and the device shell is created by an additive construction method. Additive construction methods are also known from "rapid prototyping".

Preferably, with respect to additive methods being used in rapid prototyping or those still under development, reference is made, for example, to Wohlers Report 2000, Rapid Prototyping & Tooling State of the Industry.

Preferably, of the additive processes known at present for rapid prototyping, it is found that laser sintering, laser lithography or stereolithography, or the thermojet method are particularly well suited for achieving the aforementioned object.

These and further additive construction methods from "rapid prototyping" are known per se. Therefore, specifications of the preferably used additive construction methods are only briefly summarized:

- Laser sintering:

  Hot-melt powder is applied in a thin layer from a powder bed, for example by means of a roller. The powder layer is solidified by means of a laser beam, said laser beam being guided according to a sectional layer of the hearing device shell by means of 3D shape information of the hearing device shell. A solidified sectional layer of the shell is obtained in the otherwise loose powder. This layer is lowered from the powder laying plane and a new layer of powder is applied over it, and this layer of powder is in turn solidified by laser according to a sectional layer, etc.

- Laser lithography or stereolithography:

  A first sectional contour according to a sectional layer of a hearing device shell is solidified by means of UV laser on the surface of liquid photopolymer. The solidified layer is lowered, is again covered by liquid polymer and the second sectional layer is solidified by means of UV laser.

- Thermojet method:

  The contour formation in accordance with a sectional layer is carried out in the same way as in an inkjet printer by liquid application according to the digitized 3D shape information. After that, the deposited sectional "picture" is solidified.

Once again, according to the principle of the additive construction methods, the device shell is built up by depositing layer after layer.

As regards additive construction methods, and the preferred ones mentioned above, reference may be made to the following further publications:

- "Selective Laser Sintering (SLS) of Ceramics", Muskesh Agarwala et al., presented at the Solid Freeform Fabrication Symposium, Austin, TX, August 1999, and

- Donald Klosterman et al., Direct Fabrication of Polymer Composite Structures with Curved LOM", Solid Freeform Fabrication Symposium, University of Texas at Austin, August 1999.

In principle, in additive construction methods a thin layer of material is in each case deposited on a surface, either over the whole surface as in laser sintering or stereolithography or, as in the thermojet method, already in the contour of a section of the shell under construction. The desired sectional shape is then stabilized and solidified.

Once a layer has been solidified, a new layer is deposited over this, as has been described, and this new layer is in turn solidified and connected to the already solidified layer lying below it. The hearing device shell is thus constructed layer by layer by additive layer-by-layer application.

For industrial production, it is preferable not just for the sectional layer of one hearing device shell to be deposited and solidified in each case, but for a plurality to be deposited and solidified simultaneously. In laser sintering, the laser, normally under mirror control, successively solidifies the sectional layers of a plurality of hearing device shells, before all the solidified sectional layers are lowered in unison. Then, after a new layer of powder has been deposited over all the already solidified and lowered sectional layers, the plurality of further sectional layers are formed in turn.

In order to solidify the sectional layers of the hearing device shells, either a single laser beam continues to be used, or several beams are operated in parallel.

In an alternative to this procedure, a sectional layer is in each case solidified with one laser, while at the same time the layer of powder is being deposited for the formation of a further hearing device shell. Thereafter, the prepared layer of powder is solidified according to the sectional layer for the next hearing device shell by the same laser, while the previously solidified layer is lowered and a new layer of powder is deposited there. The laser then operates intermittently between two or more hearing device shells under construction, and so the idle time of the laser occasioned by the deposition of powder for the formation of one of the shells is exploited for solidification of a sectional layer of another shell under construction.

In an analogous way, the productivity when using stereolithography is increased. When the thermojet method is used and an analogous increase in productivity is to be obtained, sectional layers of more than one hearing device shell are deposited at the same time.

It is thus possible by the method according to the invention to create extremely complex shapes on the shell produced according to the invention, to be precise both with respect to its outer shaping and with respect to its inner shaping. Overhangs, inward projections and outward projections can be readily created.

Furthermore, there are known materials for additive construction methods which lead to an elastomeric and nevertheless dimensionally stable shell, which if desired can be created differently locally, to the extent of producing an extremely thin wall which is nevertheless tear-resistant.

In an embodiment preferred at present, the mold in the shape of the individual auditory canal is made in the course of the production method according to the invention by taking an impression, for example of silicone, while not ruling out the possibility that in the near future the shape of the individual auditory canal will be scanned directly.

In a preferred embodiment of the production method according to the invention, furthermore, said digitization of the auditory canal is performed, whether by taking an impression or by directly scanning decentralized front centers, such as for example by the audiologist. The shape recorded there, as represented by digital 3D information, is transmitted to a production center, whether by sending a data carrier or by an Internet link etc. At the production center, the hearing device shell is individually shaped, in particular using the aforementioned methods. Final assembly of the hearing device with the functional modules is preferably also performed there.

On account of the fact that, as mentioned, the thermoplastic materials used generally lead to a relatively elastic, compliant shell, the shaping is far less critical in terms of pressure points than has previously been the case. In a way similar to an elastomeric plug, the shell of the finished in-the-ear hearing device will adapt itself optimally to the outer ear. The inclusion of one or more venting channels in the hearing device shell is readily possible and desired in this case, in order with the resultant relatively tight fit of the hearing device in the auditory canal to permit unimpaired ventilation of the ear drum. At the same time, with the individual 3D shape data, the interior space of the shell can also be optimally and individually shaped for optimum reception of the functional parts respectively to be provided in an individual case.

Furthermore, the central production of the shells also allows central storage and administration of the individual hearing device data to be performed, including the data which define the shape of the hearing device shells. If, for whatever reasons, a shell has to be replaced, it can consequently be readily reproduced by calling up the corresponding individual data records and renewed production.

On account of the fact that the methods used according to the invention for the production of hearing device shells are extremely widespread, albeit from prototyping, and described in the literature, there is no need at this point to reproduce all the technical details relating to these methods.

In any event, the adoption of this technology that is already known from prototyping for the industrial and commercially acceptable production of in-the-ear hearing device shells surprisingly gives rise to quite significant advantages, and does so for reasons which are not in fact important in prototyping, such as for example elasticity of the thermoplastic materials that can be used, the possibility of individual construction with extremely thin walls etc.

WHAT IS CLAIMED IS:

1. A method for producing in-the-ear hearing devices, comprising steps of:
making a mold in the shape of an individual auditory canal,
producing a hearing device shell corresponding to the mold,
installing functional parts of the hearing device, and
digitizing the shape in 3D, the hearing device shell being thus created by an additive construction method comprising a step of depositing one sectional layer after the other, on top of one another, characterized in that firstly sectional layers of a plurality of individual hearing device shells are respectively created virtually in parallel, before the following sectional layers of the individual hearing device shells are deposited on already created layers in the additive construction method.

2. The method as claimed in claim 1, comprising steps of taking an impression of the individual auditory canal, then scanning the impression to obtain a scanning signal, and digitizing the scanning signal.

3. The method as claimed in claim 1 or 2, characterized in that the step of digitizing is performed at distributed front centers, the data corresponding to the mold being transmitted to a production center, where at least the hearing device shell is created.

4. The method as claimed in any one of claims 1 to 3, characterized in that the additive construction method uses laser sintering, stereolithography or a thermojet method.