

Description

**Method for adapting an otoplastic of a hearing aid,
hearing aid, and hearing aid system**

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The invention relates to a method for adapting an otoplastic of a hearing aid, in particular an in-the-ear hearing aid, and such a hearing aid. Furthermore, the invention relates to a hearing aid system having such a hearing aid.

Hearing aids typically have a loudspeaker, also referred to as a "receiver", by means of which acoustic signals, i.e., sound, are provided to the sense of hearing of a user (also: wearer) of the hearing aid. In particular in the form of hearing aid devices, hearing aids are used to care for persons having hearing impairment (also: hardness of hearing). In this case, hearing aids usually comprise at least one microphone for acquiring ambient sound and a signal processor connected downstream thereof (also: signal processing unit) for typically frequency-specific processing (in particular filtering and/or amplification or damping) of the signals transmitted by the microphone. The signal processor passes on the processed signals to the loudspeaker for output to the sense of hearing. In the case of hearing aid devices, depending on the hearing impairment, the loudspeaker can also be replaced by another output transducer, for example, a bone vibrator or a cochlear implant for mechanical or electrical stimulation of the sense of hearing.

Hearing aids, in particular hearing aid devices, are typically designed in two basic embodiments, namely as so-called behind-the-ear ("BtE") hearing aids or as in-the-ear ("ItE") hearing aids. In the first basic embodiment, the at least one microphone - typically at least two microphones - and the signal processor and

normally an energy source are arranged in a housing to be worn behind the pinna. The sound output takes place via the loudspeaker, which is arranged in a typical design in this housing, via a sound tube to the ear.

5 Alternatively, the loudspeaker is moved outside this housing and is worn in the auditory canal. In the other embodiment, microphone, signal processor, and loudspeaker and an energy source are arranged in a housing to be worn in the auditory canal. The embodiment

10 as an ItE hearing aid has the advantage here that the sound can be best approximated to the natural sound impression of the ear.

In the case of an ItE hearing aid, an outer shell, also

15 referred to as a "shell", which typically forms the housing wall in contact with the auditory canal wall, is typically individually adapted to the specific auditory canal shape of the hearing aid user. Such an individual outer shell is also referred to as an otoplastic. An

20 impression of the auditory canal is generally taken and a negative mold for the outer shell to be manufactured is derived therefrom. An aid matched to the auditory canal of the wearer and a bonding material are introduced into the auditory canal of the wearer for this purpose

25 according to WO 02/067629 A2. After this material has cured, a negative is manufactured and after the processing of this negative, if necessary, and the insertion of the hearing aid or a hearing aid replacement therein, the support is produced. A similar method is

30 known from US 5,455,994 A, in which an auxiliary element, the cross section of which is larger than that of the auditory canal, is inserted into the auditory canal to produce an in-the-ear hearing aid. As a result thereof, the auditory canal is expanded. Subsequently, a hollow

35 ventilation tube is inserted into the auditory canal, after which the auditory canal is filled with a viscous material. After the viscous material has solidified, the mold is removed from the auditory canal. The ventilation

tube ensures that air is introduced into a space behind the mold. The mold thus formed has a cross section which is larger than the cross section of the auditory canal. Subsequently, a housing is produced for the hearing aid, wherein the mold is used as a template. The hearing aid thus fits tightly into the auditory canal, which improves the wearing comfort. The auxiliary element used in this method has a cylindrical wall which is provided with a plurality of openings to enable the passage of the viscous material into the spaces between the auxiliary element and the wall of the auditory canal. The auxiliary element furthermore comprises a sleeve for guiding the ventilation tube.

Forming a hearing aid by way of in situ molding of a material curing at room temperature around hearing aid components is known from WO 92/03894 A1. The in situ molding of the customer-specific hearing aid offers an acoustic and comfortable fit and minimizes the processing using multiple impression and casting methods. Comparable methods are known from US 5,131,411 A and US 5,333,622 A, in which an expanding foam material is used for negative molding of the auditory canal. A similar method is also known from DE 4 233 651 A1.

US 10,034,105 B describes articles and associated devices and methods for in situ assembly, which comprise a flexible sleeve, a housing arrangement fastened to the flexible sleeve, a light source arranged in the flexible sleeve, and a photo-curable resin contained in the flexible sleeve. The flexible envelope can consist of elastomer. A transducer can be arranged in the housing arrangement. A comparable invention is also known from US 10,284,975 B.

In the case of production by means of so-called "rapid manufacturing" methods, for example a 3D printing method, the impression is scanned and a CAD model is created

therefrom. This is linked in principle to a certain amount of effort. A BtE hearing aid can also have an otoplastic, by means of which a particularly good seat of the sound output of the sound tube or the loudspeaker worn in the auditory canal is to be achieved. For example, forming an auditory canal seal of a hearing aid at least partially from a moldable material which is not yet cured, and which can be molded thereon upon insertion into the auditory canal and subsequently cured, is known in US 9,936,314 B2.

An adaptable otoplastic for adaptation to the outer ear and/or the auditory canal of a user is described in US 2016/0317352 A1. The otoplastic has a body which is formed from a photocurable polymer and which is provided for insertion into the outer ear canal of the user. Moreover, the otoplastic has a light source which is positioned adjoining the body. With application of light radiation of the light source, the body can be cured so that it is applied in a fitted manner to the surface of the ear or the auditory canal of the user.

The invention is based on the object of enabling simplified adaptation of a hearing aid to the anatomy of a hearing aid wearer.

This object is achieved according to the invention by a method having the features of claim 1. Furthermore, this object is achieved according to the invention by a hearing aid having the features of claim 7. Moreover, the object is achieved according to the invention by a hearing aid system having the features of claim 10. Further advantageous embodiments and refinements of the invention, some of which are inventive per se, are described in more detail in the dependent claims and the following description.

The method according to the invention is used for adapting an otoplastic of a hearing aid, preferably to the shape of at least a part of an auditory canal of a hearing aid user.

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For this purpose, according to the method first a flexible outer shell formed from a material which is curable and not yet cured is provided. This outer shell forms an outer wall of the otoplastic and defines a housing interior of the hearing aid, or at least of the otoplastic. The housing interior is sealed both at its end facing toward the eardrum in the intended worn state in the auditory canal of the hearing aid wearer and also at the opposite end (also referred to as the auditory canal outlet side end). Moreover, the housing interior is connected via a pressure input opening to a pressure and curing facilitator. The outer shell is inserted into the auditory canal of the hearing aid wearer and also preferably aligned in an intended wearing position. Subsequently, an internal pressure value which is in particular increased in relation to the ambient pressure is applied to the housing interior via the pressure and curing facilitator, so that the outer shell presses against the auditory canal wall. The curing of the curable material is thereupon initiated via the pressure and curing facilitator while maintaining the internal pressure value.

The outer shell of the hearing aid is thus adapted "in situ" to the individual shape of the auditory canal of the hearing aid wearer. Measuring the auditory canal - for example by manufacturing an impression or optical methods - and subsequent separate manufacturing of the outer shell on the basis of the measurement and the effort linked thereto can thus be dispensed with. In particular, it is possible to adapt the otoplastic - thus the above-described outer shell - of the hearing aid directly (more or less without time delay which results for the separate

manufacturing of the outer shell) to the auditory canal of the hearing aid wearer.

5 In principle, the curing can be initiated here by means of elevated temperature, which is applied, for example, via a heating element integrated in the pressure and curing facilitator, or by injection of a reaction partner, for example, an accelerant, curing agent, or the like (optionally also gaseous) into the not yet cured
10 material.

However - while maintaining the internal pressure value - the outer shell is preferably subjected to radiation via the pressure and curing facilitator and the curing
15 of the curable material is thus initiated. In this case, pressure and curing facilitator thus preferably forms a pressure and radiation facilitator.

In one expedient method variant, to seal the housing
20 interior on the auditory canal outlet side, a terminus plate - for the case in which the housing interior is preferably used to accommodate electrical components, in particular in the form of a faceplate - and a loudspeaker on the eardrum side are installed on or in corresponding
25 openings of the outer shell. That is to say, the terminus plate or faceplate, which in particular in an in-the-ear hearing aid (abbreviated: "ItE hearing aid") terminates the housing interior in the direction of the ear outside in a known manner, is placed on the outer shell. The
30 outer shell preferably has a sound outlet opening on the eardrum side - i.e., at its end facing toward the eardrum in the intended worn state - into which the loudspeaker is inserted at least with a sound outlet nozzle in such a way that this sound outlet opening is closed and is
35 preferably sealed gas-tight. The gas-tight seal of the housing interior, in particular the sound outlet opening on the eardrum side, is also used in intended operation of the hearing aid to avoid feedback based on airborne

sound. For the adaptation of the hearing aid described here and hereinafter, the seal advantageously enables the elevated internal pressure value to be applied to the housing interior, so that the outer shell can be

5 "inflated" in the scope of its flexibility to press against the auditory canal. This process is advantageously suitable both for an ItE hearing aid and also for the otoplastic of a behind-the-ear hearing aid (abbreviated: "BtE hearing aid"), which has a loudspeaker

10 to be worn in the auditory canal. For a "classic" BtE hearing aid, in contrast, the sound outlet opening is preferably closed by means of a "blind plug", which is removed again after the adaptation.

15 The above-described terminus plate (in particular the faceplate) expediently has the pressure inlet opening here, into which the pressure and curing facilitator is inserted.

20 In one preferred refinement of the above-described method variant, the loudspeaker is preferably positioned in an intended alignment in relation to the terminus plate or faceplate by means of a holder (in particular a holding element). In particular, the loudspeaker is aligned here

25 in dependence on the individual auditory canal shape in relation to the terminus plate or faceplate. The holder is also used here as a spacer between the loudspeaker and the terminus plate or faceplate, so that expediently under action of the elevated internal pressure value, the

30 outer shell cannot expand in the direction of the longitudinal axis of the auditory canal - i.e., in the direction of the spacing between the terminus plate or faceplate and the loudspeaker. The above-described holder is preferably a (for example metallic) wire pin, which

35 can be bent accordingly to align the loudspeaker in relation to the terminus plate or faceplate, or a spacer formed in particular from a plastic or the like.

In a further expedient refinement of one of the two above-described method variants, the pressure and curing facilitator is inserted gas-tight into a battery opening of the faceplate forming the pressure inlet opening. In particular, for this purpose a battery compartment door reversibly closing the battery opening is initially removed ("uninstalled") from the faceplate. An opening generally present in any case in the faceplate can thus advantageously be used to apply the elevated internal pressure value to the housing interior and subsequently be able to apply the radiation to the inside of the outer shell. An additional opening which would subsequently have to be closed again can thus advantageously be omitted.

In a further expedient method variant, in particular UV light is emitted as radiation via the pressure and radiation facilitator. The pressure and radiation facilitator preferably has a UV lamp or a UV diode for this purpose at its end connected to the housing interior - preferably at the end by means of which it is inserted into the battery opening. Alternatively, an optical fiber configured for the transport of UV light ends at this end. This optical fiber optionally has a spherical tip end, which enables the most uniform possible light distribution in the housing interior.

In a further expedient method variant, a ventilation channel between the end on the eardrum side and the end on the auditory canal outlet side of the outer shell is molded into the latter by means of an insert. The ventilation channel preferably extends over the entire length through the outer shell, so that ventilation of the auditory canal residual space remaining in the intended worn state of the hearing aid between the eardrum and the hearing aid is enabled. In a simple embodiment, the insert is a type of cord, which molds a slot-shaped or trench-shaped channel (which is therefore

open toward the outside of the hearing aid) into the outer shell, in that the outer shell is pressed out around the insert under the effect of the elevated internal pressure value. Alternatively, the insert is a hose or a tube, so that a pressure equalization in the auditory canal residual space can also take place during the adaptation of the outer shell. As a further alternative, the insert is embedded in the form of a hose in the outer shell, wherein only the two ends of the hose at the end on the auditory canal outlet side or at the end on the eardrum side of the outer shell are open.

The hearing aid according to the invention has at least the above-described outer shell, i.e., the outer shell formed from the material which is curable (preferably radiation-induced), and is not yet cured in an intended intermediate manufacturing step (in particular in an intended delivery state). The outer shell forms the outer wall of the otoplastic here as described.

In addition, the otoplastic having the above-described outer shell also represents an independent invention.

The hearing aid is preferably an ItE hearing aid, in which the otoplastic forms the outer housing itself. Alternatively, the hearing aid is a BtE hearing aid, the otoplastic of which is used for positioning a sound outlet of a sound tube or the loudspeaker in the auditory canal. Specifically, the hearing aid according to the invention is the hearing aid, the otoplastic of which is adapted by means of the above-described method. Therefore, the above-described method and the hearing aid described here and hereinafter (or also the otoplastic) share the respective advantages and features in a corresponding manner.

Preferably - in particular in the case of the ItE hearing aid - the terminus plate, in particular the faceplate,

and the loudspeaker as described above are already preinstalled. All components required for the later intended operation of the ItE hearing aid are preferably already correspondingly installed. In other words, the hearing aid is also fundamentally ready for use with uncured outer shell. As described above, preferably only the battery compartment door is removed from the faceplate and the pressure and curing facilitator is inserted into the battery opening to adapt the otoplastic of the hearing aid in this case.

In one expedient embodiment, the outer shell has an outer membrane and an inner membrane, which are both preferably formed from a rubber-elastic material. The curable material is introduced here into a gap space arranged between the outer membrane and inner membrane. This is expedient in particular for the case in which the curable material in the not yet cured state is in liquid and/or at least in a comparatively sticky state. The outer membrane and the inner membrane therefore form partition layers here, which prevent the curable material from being able to stick to the auditory canal wall and/or to the electrical components of the hearing aid.

In one preferred refinement, the outer membrane and the inner membrane are preferably spaced apart from one another by spacers, which predefine a thickness of the gap space arranged between them. It is thus advantageously possible to prevent, upon pressure application to the housing interior, the wall thickness of the outer shell from thinning due to displacement of the curable material, which is in particular free-flowing. These spacers are arranged, for example, in the form of ribs, domes, or the like on the inside of the outer membrane and/or the outside of the inner membrane. For example, the inner membrane is inserted into the outer membrane and spaced apart therefrom by means of the spacers. Subsequently, the gap space predetermined by

means of the spacers is filled using the curable material. The gap space is optionally closed by a connection (for example, adhesive bonding, welding, or the like) of the loose ends of the inner membrane and the
5 outer membrane.

In an alternative embodiment, the curable material is in a gel-type state in the intended intermediate manufacturing step, in which the material preferably has
10 no surface stickiness and sufficient spatial cohesion. For example, this gel-type state is a partially cross-linked state in which the material still has a sufficiently high elasticity and/or plasticity. In this case, the outer shell is in particular formed by the gel-
15 type curable material while omitting the above-described outside and inside partition membrane in particular.

The curable material is preferably a UV-curable epoxy resin, a UV-curable silicone resin, or the like.
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The hearing aid system according to the invention comprises the above-described hearing aid and the above-described pressure and curing facilitator, which is configured and provided for connection to the pressure
25 inlet opening of the hearing aid.

This pressure and curing facilitator is preferably a type of pin having a tip complementary to the pressure inlet opening, through which a pressure channel is guided. In
30 one variant, the above-described UV lamp or diode or the above-described (tip) end of the optical fiber is seated at this tip.

The conjunction "and/or" is to be understood here and
35 hereinafter in particular to mean that the features linked by means of this conjunction can be formed both jointly and also as alternatives to one another.

An exemplary embodiment of the invention is explained in more detail hereinafter on the basis of a drawing. In the figures:

- 5 Figure 1 shows a hearing aid in a schematic perspective view,
 Figure 2 shows a hearing aid system having the hearing aid therein in a schematic partially sectional view II-II according to Figure 1, and
10 Figure 3 shows a method for adapting the hearing aid in a schematic flow chart.

Parts corresponding to one another are always provided with the same reference signs in all figures.

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A hearing aid, specifically in the design form of an ItE hearing aid, abbreviated as "ItE 1", is schematically shown in Figure 1. This ItE 1 has a faceplate 2 and an outer shell 4 connected thereto. The faceplate 2 and the
20 outer shell 4 define a housing interior 6 (see Figure 2), which is used to accommodate electronic components of the ItE 1. A microphone 8, a signal processor 10, and a loudspeaker 12 are arranged as electronic components in the housing interior 6. The microphone 8 is fluidically
25 coupled to a microphone opening 14 in the faceplate 2. The signal processor 10 is mounted just like the microphone 8 on the faceplate 2.

Since the ItE 1 is worn in an auditory canal of a hearing aid user or hearing aid wearer in an intended worn state, the outer shell 4 is adapted in a method described in greater detail hereinafter to the shape of the auditory canal and thus forms an outer wall of an otoplastics forming the housing of the ItE 1. In an intermediate
30 manufacturing state or delivery state, the outer shell 4 is not yet adapted to the auditory canal (see Figure 2). The outer shell 4 comprises material curable by means of UV light for the adaptation. This is introduced in a way
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not shown in greater detail between an outer membrane and an inner membrane, which each delimit the wall thickness of the outer shell 4 toward the outside or toward the housing interior 6, respectively. The faceplate 2 terminates the housing interior 6 - viewed in relation to the intended worn state in the auditory canal - on the auditory canal outlet side. For this purpose, the faceplate 2 is connected in a media-tight manner to a rigid section 16 of the outer shell 4. An end 18 on the eardrum side, specifically a sound outlet opening 20 of the outer shell 4 arranged there, is closed by means of the loudspeaker 12. The loudspeaker 12 is positioned and held here in relation to the faceplate 2 by means of a holder in the form of a wire pin 21.

To adapt the ItE 1, in a first method step S1 (see Figure 3), the above-described ItE 1 is provided in its delivery state, i.e., having not yet cured outer shell 4. In a second method step S2, a battery compartment door 22, which is used for holding and positioning a battery 24 (only indicated in Figure 2) in the housing interior 6 and for closing a corresponding battery opening 26, is removed from the faceplate 2. Subsequently, a pin 28 is inserted into the battery opening 26 and circumferentially sealed in relation to the battery opening 26 by means of a seal element 30. A pressure or air channel 32 and an optical fiber 34 extend in the pin 28. The pressure or air channel 32 therefore ends standing open on the tip side in the inserted state in the housing interior 6. The optical fiber 34 ends on the tip side in a spherical tip end 36, which is configured and provided for the purpose of homogeneously emitting UV radiation transported by means of the optical fiber 34 in the housing interior 6. The pin 28 is therefore used as a pressure and curing facilitator, specifically a radiation facilitator.

In a third method step S3, the ItE 1 is inserted by means of the pin 28 into the auditory canal of the hearing aid wearer and brought into its intended position in the auditory canal. In a further method step S4, air is pumped
5 into the housing interior 6 via the pressure or air channel 32, which therefore applies an elevated internal pressure value to the housing interior 6. The curable and not yet cured material of the outer shell 4 is thus expanded approximately radially toward the outside. The
10 wire pin 21 prevents lengthening of the outer shell 4 in the direction of the eardrum. The outer shell 4 is therefore inflated comparably to an air-filled balloon. The outer shell 4 thus presses against the auditory canal.

15 To enable venting of the auditory canal residual space remaining between the eardrum-side end 18 and the eardrum in the intended usage state or operating state of the ItE 1, a cord-shaped or tubular insert 40 is fastened on the
20 eardrum-side end 18, specifically on a holding ring 38 for the loudspeaker 12, which extends in the longitudinal direction 42 along the outer shell 4. Under the action of the elevated internal pressure value, the outer shell 4 partially flows around this insert 40, so that a
25 ventilation channel is formed in the outside of the outer shell 4. The rigid section 16 and the faceplate 2 have, in a form not shown in greater detail, a recess or the like, due to which the feedthrough of the insert 40 between the auditory canal wall and the rigid section 16
30 or the faceplate 2 past the latter is enabled. Notwithstanding the illustration, the faceplate 2 is smaller than the auditory canal diameter and the external diameter of the outer shell 4.

35 In a further method step S5, UV light is radiated into the housing interior 6 by means of the optical fiber 34 while maintaining the internal pressure value. Under the action of the UV light, the curing of the curable material

of the outer shell 4 is initiated, so that it cross links and fixes the outer shell 4 in its shape adapted to the auditory canal. Subsequently, the ItE 1 is removed from the auditory canal, the insert 40 is removed, the pin 28
5 is removed from the battery opening 26, and the battery compartment door 22 is inserted again. The ItE 1 is thereupon adapted for individual use.

The subject matter of the invention is not restricted to
10 the above-described exemplary embodiment. Rather, further embodiments of the invention can be derived by a person skilled in the art from the above description.

List of reference signs

1	ItE
2	faceplate
4	outer shell
6	housing interior
8	microphone
10	signal processor
12	loudspeaker
14	microphone opening
16	rigid section
18	end
20	sound outlet opening
21	wire pin
22	battery compartment door
24	battery
26	battery opening
28	pin
30	seal element
32	pressure or air channel
34	optical fiber
36	tip end
38	holding ring
40	insert
42	longitudinal direction
S1	method step
S2	method step
S3	method step
S4	method step
S5	method step

Claims

1. A method for adapting an otoplastic of a hearing aid
(1),
5 wherein according to the method
- a flexible outer shell (4) formed from a curable
and not yet cured material, which forms an outer
wall of the otoplastic and defines a housing
interior (6), is provided,
10 - the housing interior (6) is sealed both at its end
(18) facing toward the eardrum in the intended worn
state in an auditory canal of a hearing aid wearer
and also at the opposite end,
- the housing interior (6) is connected via a
15 pressure inlet opening (26) to a pressure and curing
facilitator (28),
- the outer shell (4) is inserted into the auditory
canal of the hearing aid wearer,
- an elevated internal pressure value is applied to
20 the housing interior (6) via the pressure and curing
facilitator (28), so that the outer shell (4)
presses against the auditory canal wall, and
- the curing of the curable material is initiated
via the pressure and curing facilitator (28) while
25 maintaining the internal pressure value.
2. The method as claimed in claim 1,
wherein radiation is applied to the outer shell (4)
via the pressure and curing facilitator (28) and the
30 curing of the curable material is thus initiated,
in particular wherein UV light is emitted as
radiation via the pressure and curing facilitator
(28).
- 35 3. The method as claimed in claim 1 or 2,
wherein the housing interior (6) is configured in
particular for accommodating electrical components,
and wherein to seal the housing interior (6), a

terminus plate, in particular a faceplate (2), is installed on the auditory canal outlet side, and a loudspeaker (12) is installed on the eardrum side, on or in corresponding openings of the outer shell (4).

4. The method as claimed in claim 3, wherein the loudspeaker (12) is positioned by means of a holder (21) in an intended alignment in relation to the terminus plate (2).
5. The method as claimed in claim 3 or 4, wherein the pressure and curing facilitator (28) is inserted in a gas-tight manner into a battery opening (26) of the terminus plate (2) forming the pressure inlet opening, in particular while temporarily omitting a battery compartment door (22) for closing the battery opening (26).
6. The method as claimed in any one of claims 1 to 5, wherein a ventilation channel between the end (18) on the eardrum side and the end on the auditory canal outlet side of the outer shell (4) is formed in this outer shell by means of an insert (40).
7. A hearing aid (1), having an outer shell (4), which forms an outer wall of an otoplastic and is formed from a curable material which is not yet cured in an intended intermediate manufacturing step.
8. The hearing aid (1) as claimed in claim 7, wherein the outer shell (4) has an outer membrane and an inner membrane, wherein the curable material is introduced into a gap space arranged between the outer membrane and the inner membrane.

9. The hearing aid (1) as claimed in claim 7,
wherein the curable material is provided in a gel-
type state, in particular without surface stickiness
and with spatial cohesion, in the intended
5 intermediate manufacturing step, and wherein the
outer shell (4) is formed by the curable material
while omitting outside and inside partition
membranes.
- 10 10. A hearing aid system,
having a hearing aid (1) as claimed in any one of
claims 7 to 9 and having a pressure and curing
facilitator (28) for connection to the pressure
inlet opening of the hearing aid (1).