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- (54) Benævnelse: **Fremgangsmåde og system til dannelse af ikke-okkluderende ørestykker**
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WO-A-02/30157
WO-A-02/071794
WO-A-2004/057916
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DESCRIPTION

Field of invention

[0001] The present invention relates to a method for computer-controlled modelling of customized earpieces that can be used as part of communication devices, and more particularly, the invention relates to a method for creating non-occluding earpieces with tube bore.

Background of invention

[0002] Non-occluding ear moulds are the new trend in the market for behind-the-ear (BTE) hearing aids and personal communication devices. Instead of filling the auditory canal of the user's ear, an alternative shape is created that allows air to flow freely in and out of the inner ear. Many users of ear molds complain that an occluded ear mold causes discomfort when chewing or that they feel secluded from their surroundings. Also non-occlusion improves wearability as there is nothing to irritate the canal of the ear.

[0003] Existing methods to model and manufacture customized non-occluding earpieces are manual, time consuming, and tedious. This form of manual work also introduces a great deal of uncertainty of the finished product. The process typically begins with an impression of the user's ear canal and helix area. Through computer-assisted methods an occluding ear mould is produced which is then grinded to a non-occluded type by hand. This method is a waste of materials, the result often vary between each produced mould and the risk of grinding too close to the inner bore is high - causing the whole work process to be iterated all over.

[0004] In WO 02/30157, a 3D digital model that describes shape of an ear canal, is automatically generated as a two manifold surface having zero or non-zero functional boundary using input 3D data. Another 3D digital model is generated from previous model by surface triangulation and is printed. The quality assurance is performed by comparing generated 3D digital models and 3D digital model derived from printed hearing-aid shell.

[0005] In WO 2004/057916, the data from left and right ear shells are loaded into a CPU and the loaded data are registered using a feature-based, point-based, model based or global similarity registration. The left and right ear shells are processed such that processing e.g. line cut, canal tapering or local relaxing on left ear shell is automatically performed in synchronized fashion on the right ear shell.

Summary of invention

[0006] The present invention relates to a method for creating non-occluding earpieces with a tube bore. The produced earpiece models have a non-occluding canal area, wherein the canal area is the part of the earpiece positioned in the entrance to the auditory canal. These earpieces could include housings for hearing aids, wireless or connected communication devices (headphones, mobile phones, behind-the-ear (BTE) hearing aids, personal agents), loud speakers, tinnitus masking devices, devices recording vibrations in the skull and transforming these into audio signals, voice recognition devices, Man Machine Interface (MMI) products or related to wireless Internet applications. All of these devices may be worn in the user's meatus and/or auditory canal.

[0007] Thus, in one aspect the present invention relates to a method for producing a computer model of a non-occluding earpiece according to claim 1. In the present context the term "occlusive" means that an earpiece based on the occlusive model would be occluding at least a part of the auditory canal.

[0008] In another aspect the present invention relates to a computer program capable of executing program code conducting the method for creating non-occluding earpieces. In a further aspect the invention relates to a system and a method for producing a non-occluding earpiece, wherein the system comprises means for conducting the method for producing a non-occluding earpiece model, as well as means for producing a non-occluding earpiece from said non-occluding earpiece model.

Description of Drawings

[0009]

Figure 1 shows arrangement of a conventional occluding earpiece in the ear.

Figure 2 shows arrangement of a non-occluding earpiece with a tube bore in the ear.

Figure 3 shows an occlusive model of at least a part of the outer ear and at least a part of the auditory canal.

Figure 4 shows the model of Figure 1 wherein a cutting surface is provided.

Figure 5 shows various steps in selecting an area of interest.

Figure 6 shows an example of a non-occluding shape.

Figure 7 shows a shape from a CAD model merged with the earpiece model.

Figure 8 shows construction of control path in the canal part of the occlusive model.

Figure 9 shows a non-occluding earpiece with a tube bore.

Figure 10 shows production of a tube bore using a combination of techniques.

Figure 11 shows manipulation of an optional component.

Detailed description of the invention

[0010] All three-dimensional models of the present invention may be obtained by scanning an impression or by direct scanning of the outer ear and the auditory canal, wherein the scanning may be performed using any suitable method, such as laser scanning, white light, in the ear scanning, ultrasound scanning, MR scanning or CT scanning.

[0011] In the following the invention is described in relation to the drawings by following a series of steps conducted.

Step 1: Cut the canal

[0012] In one embodiment the canal (301) of the impression is cut with a cutting surface (401) creating a trimmed surface (402). Said cutting surface may be a simple plane, a bicubic surface, or another parametric surface. The edges of the cut may be pre or post processed to avoid sharp bends. Otherwise the sharp edges may cause irritation to the user of the ear mould. The cut determines the depth of the ear mould into the canal, and may be cut at any suitable distance from the canal area.

Step 2: Create non-occluding shape

[0013] Define the shape of the ear mould by selecting the area of interest of the three-dimensional model resulting in an earpiece model having a non-occluding outer ear area. It could be achieved by painting on the impression or using splines (501) to define what needs to be cut away. Placing splines on the newly created surface from step 1, results in a non-occluding ear mould when constructing the shape (502). An example of a non-occluding shape can be seen on figure 6. When used with BTEs, the ear mould should fixate a tube coming from the hearing aid device placed behind the ear. The fixation can be achieved by gluing the tube to the ear mould, drilling a hole in the ear mould, or simply leaving a hole in the area of interest when constructing it.

[0014] These methods provide the crudest implementations of non-occluding ear moulds but often these are not enough to satisfy the needs of the user. To improve perceived sound quality, the sound should be shielded as far as possible into the canal - still without blocking the free passage of air. This could be achieved by extending the tube into the canal (301). It is preferred that such a tube is a rigid body, whereby it can be prevented by determining the

shape, that the tube cannot touch the sides of the canal (301). As a rigid body extension needs to be fixed to the ear mould to fulfil its purpose, it may be seen as a part of the ear mould. Such an extension will henceforth be referred to as a tube bore.

Step 3a: Create tube bore from a fixed shape

[0015] To direct the sound towards the eardrum at the end of the canal (301) a tube model can be applied to the canal area of the ear mould (601) creating a tube bore in the non-occluding earpiece model. A simple way to produce such a tube is to apply a fixed shape, e.g. a CAD model, to the canal area (601). The shape will be merged with the ear mould through a Boolean OR operation on the two solids. A shape derived from a CAD model (701) can be seen merged with the ear mould on figure 7. Subsequently, another fixed shape may be Boolean subtracted from the ear mould to produce the bore through which the sound will pass. Alternatively, the tube from the BTE may be glued to the canal extension of the ear mould or the fixed shape (701) may include fixation points.

Step 3b: Create tube bore from control path

[0016] Using a fixed shape for the tube bore can be disadvantageous as no ears are similar. A fixed shape may collide with the ear of the user and thus alleviate the benefits of a non-occluding ear mould. Instead the tube bore can be generated from the canal part of the occlusive model. In practice the tube bore can be created by defining a control path through the canal (301) from which the tube bore shape can be generated.

[0017] The control path may be a curve such as a spline with control points that enables manipulation. In the preferred embodiment, a spline is used with an end point (801) at the canal area (601) and a point at the tip of the canal (802) and at least one control point in between (803). The control points (801, 802, 803) may be applied manually, using template based placement, morphologic, or topologic criteria based placements. One possibility to manipulate the at least one control point (803) is by using a plane (804) to which the control point (803) is restrained. The control point (803) can be moved in the plane (804) and the plane (804) itself can be tilted and slit up and down along its normal. Thus, the control point (803) can be positioned at any 3D coordinate. Using a plane (804) also enables the user to manipulate the length of the tube bore and the angle at which the tube bore is cut off by letting the plane of the at least one planes closest to the tip of the canal (301) be the stop point for the generated shape.

[0018] Constructing the shape can be done by producing a cylinder around the control path or by defining a 2D template shape that is extruded along the control path. It should be understood that the cylinder is simply a circle template extruded along the control path. Several different templates could be used for the generation of the shape. Either by interpolating

between two templates associated with the end points (801, 802) or associating templates with each control point (803).

[0019] The shape generated from the control path defined by the spline can be used for merging with the non-occluded part (601) similar to the process described in 3a as either the additive or subtractive shape described in step 3a. Producing the other shape, additive or subtractive respectively, can be done as an offset from the first shape - outwards to produce an additive shape and inwards to produce a subtractive shape. Alternatively, the tube from the BTE may be glued to the produced shape. An example of a non-occluding ear mould with a tube bore constructed using a control path can be seen on figure 9.

Step 4: Optional components at the tube bore

[0020] In order to design more advanced ear moulds a fixed shape could be applied to the non-occluding earpiece, such as a fixed shape for fixation means for fixing a tube from a hearing aid device.. The fixed shape or optional component is a post application of at least one fixed shape to the ear mould by a Boolean operation. Such shapes could also produce hooks, interfaces, wax guards, transmitters, etc. The optional component will initially be placed at either of the control points (801,802,803) and can then be manipulated in relation to this point. This manipulation includes tilting, rotation, panning and relocation. An example of such manipulation can be seen on figure 10.

Step 5: Using subtraction for creation of tube bore

[0021] In a different embodiment of the invention the tube bore is produced by exchanging step 1 with a Boolean subtractive operation in which the canal (301) is reduced to the tube bore by a shape that can be defined as in step 3 or 4, but is instead composed of the complementary shape to the one generated in those steps. Subtracting this from the impression produces the same result as achieved by step 3 or 4.

Composite construction possibilities

[0022] Producing a non-occluding ear mould is not restricted to using either step 3a, 3b, or 5. They can be combined to produce ear moulds with specific features. E.g. a fixed shape could be applied first and afterwards a shape derived from a control path could be applied. In figure 11, this approach is depicted. Also, using the control points (801,802,803) to signify sections of the canal (301) and either step or a combination of them could be applied separately to each section.

[0023] Furthermore according to the present invention, there is provided a method for

modelling the complete 3D earpiece with all its surfaces. The fact that the complete earpiece can be modelled also makes it possible to rapid prototype the whole piece in one operation.

[0024] Thus, the present invention also relates to a system comprising a computer and a rapid prototype machine. In a preferred embodiment the system further comprises a three-dimensional scanning device for providing the three-dimensional occluding earpiece model.

[0025] Thereby the physical version of the final non-occluding three-dimensional model may be produced using a rapid prototyping set-up such as Milling, stereo lithography/SLA, solid ground curing, selective laser sintering, direct shell production casting, 3D-printing, topographic shell fabrication, fused deposition modelling, inkjet modelling, laminated object manufacturing, nano-printing or any other system that produces real models from 3D computer models.

REFERENCES CITED IN THE DESCRIPTION

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- [WO2004057916A](#) **[0005]**

Fremgangsmåde og system til dannelse af ikke-okkluderende ørestykker

P a t e n t k r a v

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1. Fremgangsmåde til fremstilling af en computermode af et ikke-okkluderende ørestykke omfattende en rørboring, hvilken fremgangsmåde omfatter trinnene med at:

10 - opnå en tredimensionel okklusiv computermode af mindst en del af det ydre øre og mindst en del af øregangen, hvilken mode omfatter en ydre øredel og en gangdel,

- at vælge et interesseområde af den tredimensionelle computermode;
- at danne en rørboring i gangdelen af den tredimensionelle computermode ved at:

15 - definere en styrebane gennem gangdelen af den tredimensionelle computermode;

- generere en rørboringsform ud fra styrebanen, således at rørboringen ikke kan berøre siderne af gangdelen;

20 hvorved der opnås en ørestykkecomputermode med et ikke-okkluderende gangområde.

2. Fremgangsmåde ifølge krav 1, hvor rørboringen tilvejebringes ved at påføre en mode af et rør på det ikke-okkluderende gangområde.

25 **3.** Fremgangsmåde ifølge krav 1, hvor rørboringen genereres ved boolesk addition og/eller subtraktion fra gangdelen af den tredimensionelle computermode for at opnå rørboringen.

30 **4.** Fremgangsmåde ifølge et hvilket som helst af de foregående krav, hvor der tilvejebringes en boring i rørboringen ved subtraktion af en fikseret form fra modellen af røret.

35 **5.** Fremgangsmåde ifølge et hvilket som helst af de foregående krav, hvilken fremgangsmåde yderligere omfatter definering af en fikseret form, som skal påføres den ikke-okkluderende ørestykkemode såsom en fikseret form til

fikseringsmidler til fiksering af et rør fra en høreapparatindretning.

- 5 **6.** Fremgangsmåde ifølge et hvilket som helst af de foregående krav, hvor trinnet, hvori der vælges et interesseområde af den tredimensionelle model, også resulterer i en ørestykkemodel med et ikke-okkluderende ydre øreområde.
- 10 **7.** Computerprogramprodukt, som indeholder et computerlæsbart medium, hvor det computerlæsbare medium har et computerprogram, som er lagret deri, hvor programmet til fremstilling af en ikke-okkluderende ørestykkemodel omfatter en programkode til udførelse af trinnene i fremgangsmåden som defineret i et hvilket som helst af kravene 1-6.
- 15 **8.** System til fremstilling af et ikke-okkluderende ørestykke, hvilket system indeholder en computerlæsbar hukommelse, som har en eller flere computerinstruktioner, som er lagret deri, hvilke instruktioner omfatter instruktioner til udførelse af trinnene i fremgangsmåden som defineret i et hvilket som helst af kravene 1-6, og hvilket system omfatter en computerstyrbar prototypefremstillingsmaskine, hvilken prototypefremstillingsmaskine er forbundet med
- 20 systemet til udformning af et ørestykke ud fra den ikke-okkluderende ørestykkemodel, som genereres ved hjælp af systemet.
- 25 **9.** System ifølge krav 8, hvor prototypefremstillingsmaskinen kan udføre 3D-fræsning og/eller stereolitografi/SLA og/eller solid ground curing og/eller selektiv lasersintring og/eller direkte ørestykkeproduktionsstøbning og/eller 3D-printning og/eller topografisk ørestykkefremstilling og/eller fused deposition-modellering og/eller inkjet-modellering og/eller fremstilling af laminerede genstande og/eller nanoprintning.
- 30 **10.** Fremgangsmåde til fremstilling af et ikke-okkluderende ørestykke, hvilken fremgangsmåde omfatter tilvejebringelse af en prototypefremstillingsmaskine og tilvejebringelse af en ikke-okkluderende ørestykkemodel som fremstillet ifølge et hvilket som helst af kravene 1-6 og fremstilling af et ikke-okkluderende ørestykke på prototypefremstillingsmaskinen ud fra den ikke-okkluderende ørestykkemodel.
- 35

DRAWINGS

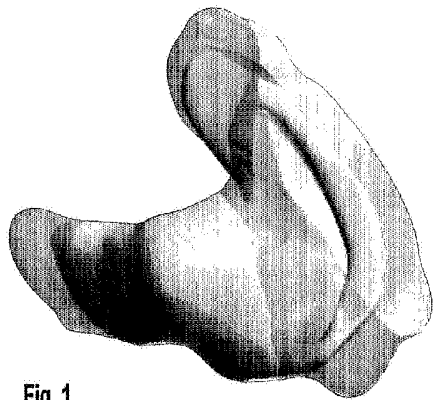


Fig. 1

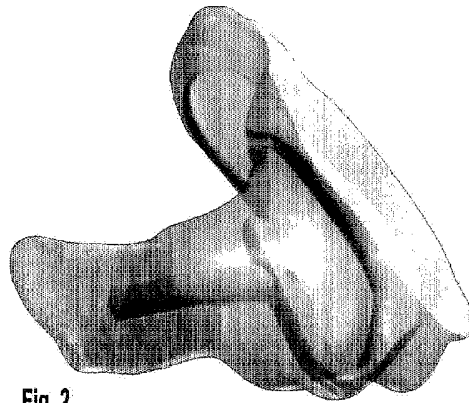


Fig. 2

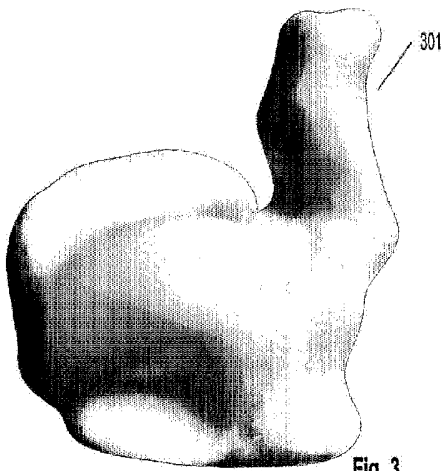


Fig. 3

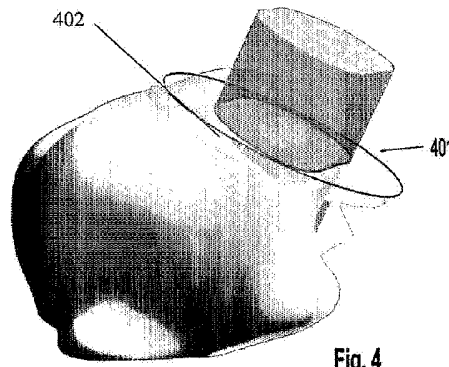


Fig. 4

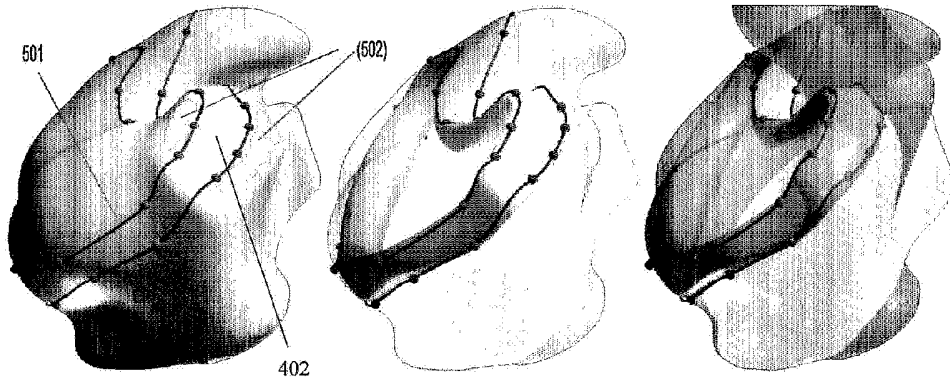


Fig. 5

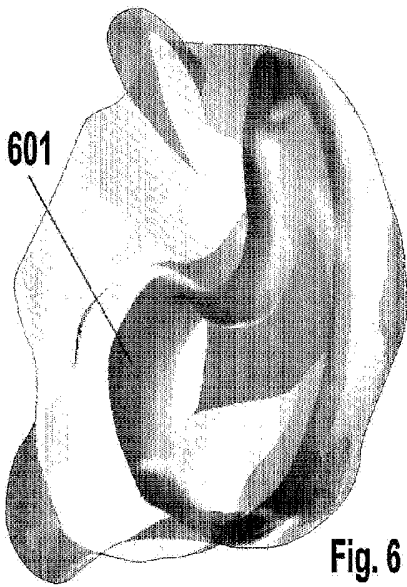


Fig. 6

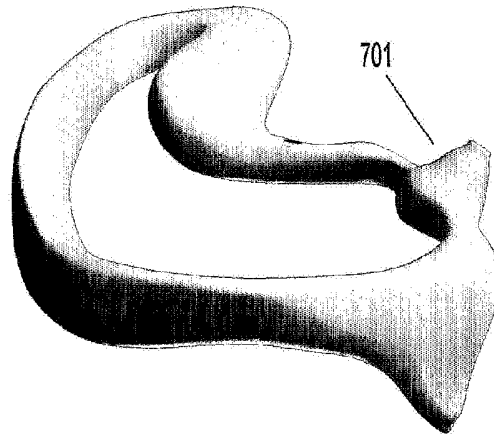


Fig. 7

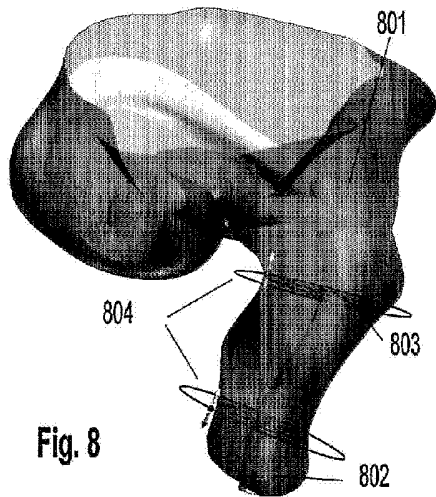


Fig. 8

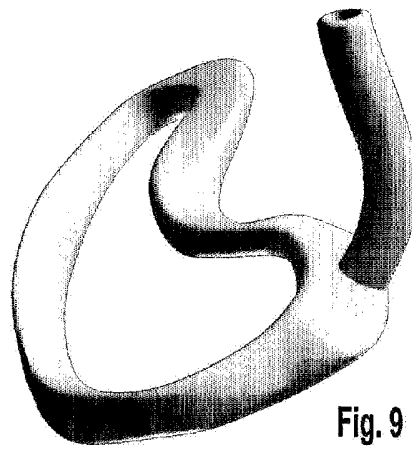


Fig. 9

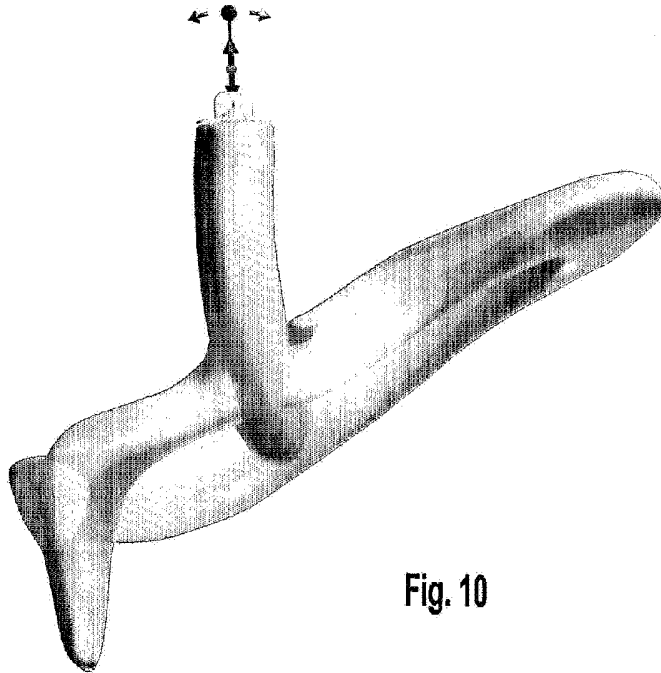


Fig. 10

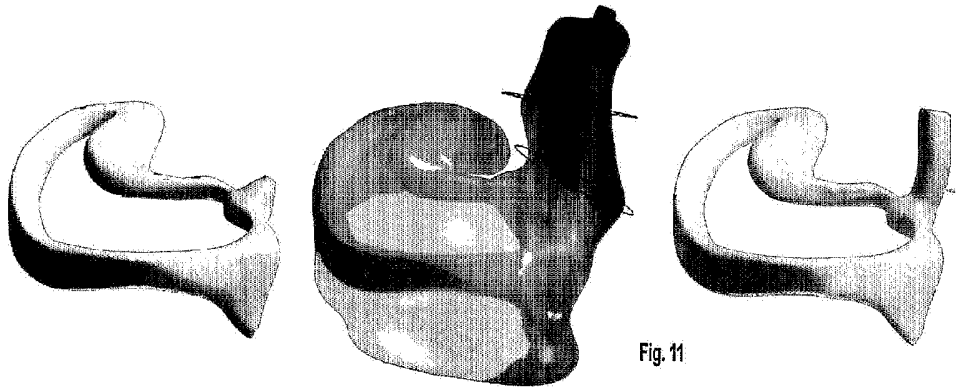


Fig. 11