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ANALYSIS OF THE CUSTOMIZED IMPLANTATION PROCESS OF A COMPLIANT MECHANISM WITH FLUIDIC ACTUATION USED FOR COCHLEAR IMPLANT ELECTRODE CARRIERS

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ABSTRACT

Patients suffering from severe to profound hearing loss, can be treated with a cochlea implant to restore hearing due to direct electrical stimulation of neurons. Hence, a silicone electrode carrier has to be implanted into the spiral-shaped organ of the cochlea (inner ear). The here presented fluid actuation by use of a compliant mechanism within the electrode carrier is designed to enable an active steering of the implant and its bending in order to achieve contactless insertion into the cochlea and a preset final position under a certain pressurization. An averaged small, middle and large spiral cochlea path has been defined based on the segmentation of 23 3D-datasets of human cochleae in order to enable the synthesis of individual implants. The fit of these implants within all three sizes of cochleae was adapted by variation of the pressure load which induces the bending of the implant.

Index Terms – Cochlea Implant, compliant mechanism, individual implant

1. INTRODUCTION

Cochlear implants (CI) are neuroprostheses designed to induce a hearing impression for patients who suffer from severe to profound hearing loss or deafness. Since the therapy of patients with residual hearing comes more into focus, the preservation of this residual hearing becomes a crucial demand for the development of new cochlear implant electrode carriers. The preservation of residual hearing requires an atraumatic insertion of the electrode carrier into the scala tympani, a compartment of the inner ear (cochlea) in which the electrode carrier needs to be inserted in order to electrically stimulate the auditory nerve. In this context "atraumatic" is defined as an insertion with low or ideally no insertion forces to avoid any damage to the delicate intracochlear soft tissue structures, which are essential for the preservation of residual hearing. To achieve a contactless, and therefore atraumatic, insertion, the here presented electrode carrier is under development to add an actuator, which can actively steer and define the bending of the implant.
In this contribution, the functionalization of the electrode carrier with a compliant mechanism with fluidic actuation is described, in order to address these demands for defined actuation. This compliant mechanism comprises a silicone body with an inner hollow and a non-stretchable fiber embedded in the silicone wall. Using this mechanism, a conical implant would bend into a spiral form, like the cochlea, if pressurizing the inner hollow. The actual shape is then depending on the pressure. The basis for an individualized design of the implant is the segmentation of the spiral-shaped path of the inner wall of the cochlea (perimodiolar path), which is done based on histologic or radiologic imaging.

2. SEGMENTATION

A customized tool (*G.J. Lexow, Medical School Hannover, [1]*) has been used for the visualization of radial slices every 22.5 ° around the spiral axis of the cochlea, the modiolar axis. Within these slices the cross section of the scala tympani, has been segmented (see Fig. 1a). The segmentation allows for the generation of a 3D model (Fig. 1c) using CAD-software (*Autodesk Inventor Professional 2015, Autodesk, San Rafael, CA, USA*). For each slice, the point nearest to the modiolar axis is extracted from the segmentation, defining the perimodiolar path of the scala tympani (see Fig. 1b).

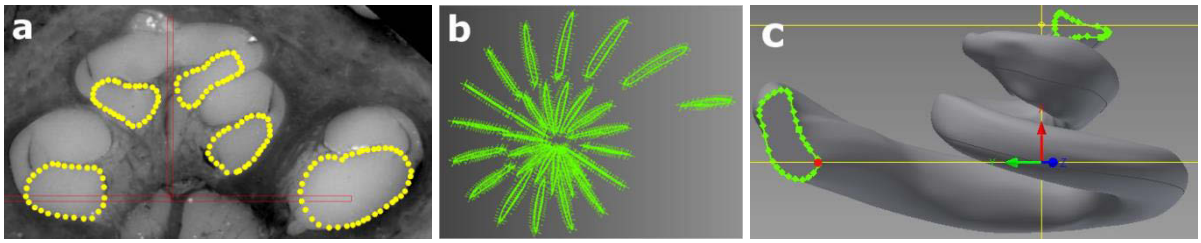

Fig. 1: *(a)* Midmodiolar cross section image through a human cochlea sample, derived by microgrinding [2], which is a serial cross sectioning technique of epoxy embedded samples for the generation of morphological images. The dataset of so derived images can be rotated around the modiolar axis (vertical, red axis) to segment the scala tympani (yellow dots). *(b)* Top view onto the segmentation of the scala tympani in steps of 22.5 ° around the modiolar axis. *(c)* Generation of a CAD-model (Autodesk Inventor) of the scala tymani of this one human cochlea sample. The most modiolar point of the scala tympani in this slice plane is segmented (see red point). The perimodiolar path is made of these points in each slice plane.

After projection of these points onto a plane, the resulting path can be evaluated in 2D, according to the physical models of the cochlea made of Polytetrafluoroethylene (PTFE) already used for insertion studies which represent the path in 2D too. The segmentation of n = 23 human cochlea samples, following the process previously described, provide the basis for the definition of an averaged small (S), medium (M) and large (L) cochlea shape (see Fig. 2). The separation of the three averaged groups was done on behalf of the calculated path length of the segmented spiral form in 2D.

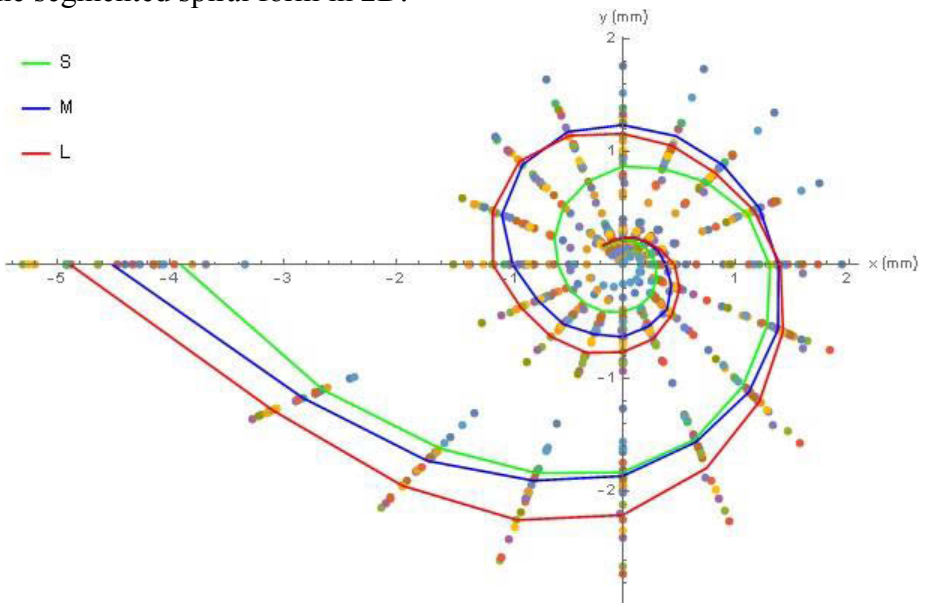

Fig. 2: Visualization of all n = 23 segmented human cochlea samples. The segmentations show the position of the most modiolar point (see Fig. 1c) of the scala tympani for all samples in each segmented slice plane until 675 °. The segmentations of each cochlea dataset were registered along the modiolar axis and for the first segmented plane.

3. SYNTHESIS OF INDIVIDUALIZED IMPLANTS

An analytical synthesis (*Mathematica 10.4, Wolfram Research Inc., Champaign, IL, USA*) has been developed to define the geometrical measures of an implant which would fit such a given cochlea form with a pressurization of 6 bar [3]. The method starts with the numerical Finite-Element-Analysis (FEA) (*Ansys Workbench V.17.2, ANSYS Inc., Canonsburg, PA, USA*) of a cylindrical demonstrator using the previously analysed non-linear material description [4] for the used silicone rubber. Based on this shape under pressurization, a deformation-dependent, local modulus of elasticity can be calculated for the use in the subsequent analytical synthesis, which needs a linear material description. Thus, the synthesis enables the design of individualized implants which would fit to the given cochlear shape at the predefined pressurization of 6 bar (see Fig.3).

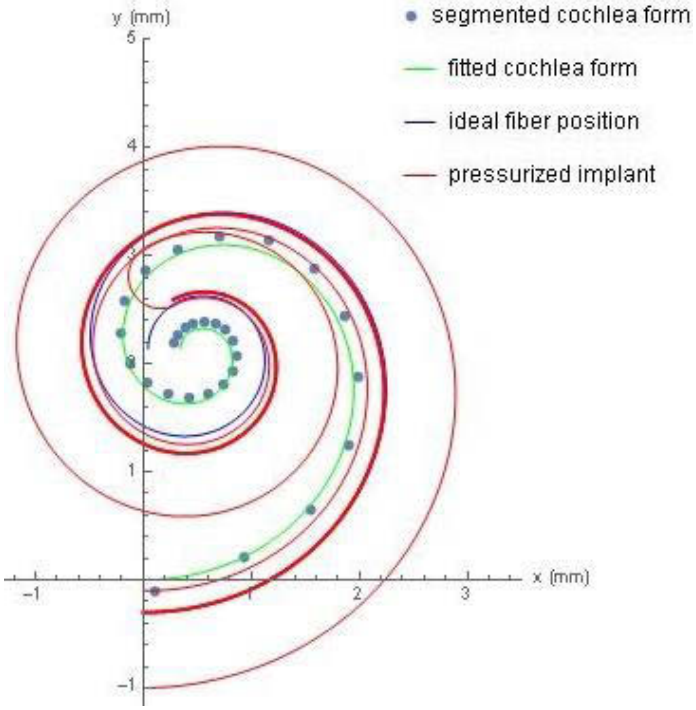

Fig.3: The image shows the contour of the inner wall of an averaged small cochlea with blue dots. Based on this segmentation a path fitting was conducted (green line). In a distance of 0.3 mm to this fitted path the ideal location the fiber within the electrode carrier under pressurization of 6 bar was defined (blue line). Based on this fiber location the synthesis was conducted providing as results the length, the basal and the apical diameter of an implant which would fit this path under pressurization of 6 bar (red lines). Further analysis (see Fig.4) will only show the segmentation and the path of the fiber after pressurization (thick red line) for easier visibility.
The shown overlap of the implant with itself is due to the projection into the plane and will not take place in patients, because of the three-dimensional spiral shape of the cochlea.

Another option for customization is to individualize the implantation process using variable pressurization of the fluidic actuator within an implant which ideally fits all cochlea sizes. The synthesis based on the averaged cochleae forms (S, M and L) was conducted after the first 45 ° of the paths had been cut because these parts are nearly linear (see Fig. 2). Each implant geometry, comprising apical and basal diameter and length of the implant, derived from the synthesis for the short, middle and long averaged cochlea path, was tested for the implantation in all three averaged cochlea forms (see Tab. 1).

Tab. 1: Geometrical measures for the implants, after synthesis

	outer radius, basal (mm)	outer radius, apical (mm)	length (mm)
Implant Size S	0.45	0.3	12
Implant Size M	0.45	0.3	14
Implant Size L	0.45	0.3	15

The spiral form of the implant and thereby the fit of the implant to the cochlea was optimized by variation of the pressure within the inner hollow. The distance of the implant to the cochlea along its length was evaluated to assess the fit and to find the sufficient pressure load (see

Fig. 4). The resulting geometry of the implants for the three different cochlea sizes showed only marginal variations for the radii, which were eliminated due to rounding of the values. The stronger influence of the cochlea size applied to the length of the implant and thereby the gradient of the conical implant even with identical radii (see Tab. 1).

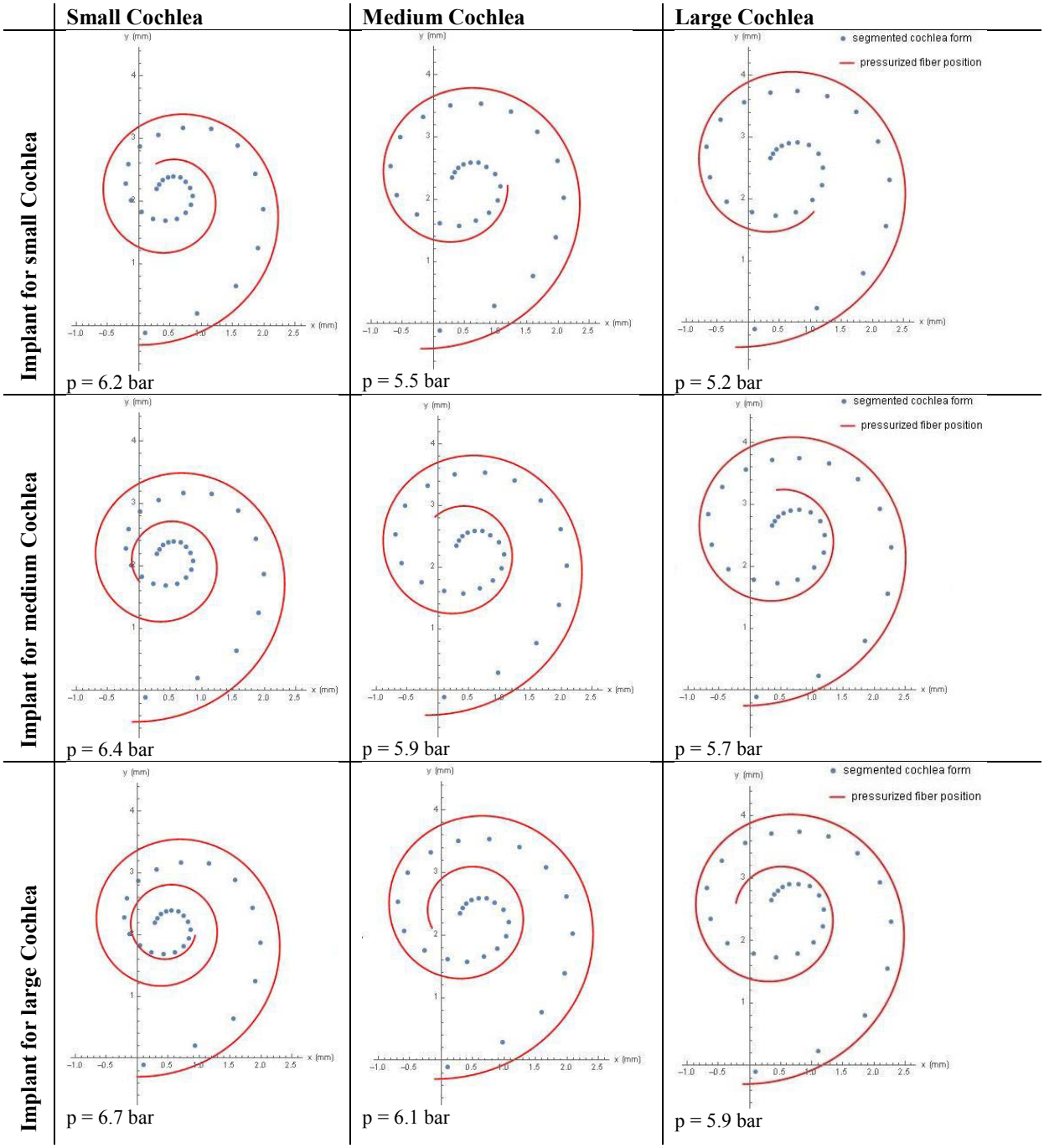

Fig.4: After synthesis of an implant fitting the one averaged cochlear path, the pressure needed to adjust this implant for additional use within the other two cochlear sizes was assessed. The comparison of each row shows that the adjustment of one implant for different cochlea sizes is possible due to variable pressurization and thereof resulting curvature.

In general, a higher pressure within the inner hollow corresponds to a stronger bending of the implant, fitting to the tighter spiral cochlea shape of a comparatively small cochlea. Besides that, the insertion depth angle decreases from the small cochlea to the large cochlear path for all implant sizes. Because of that, an implant defined based on the large averaged cochlea

form, has to be applied with a higher pressure than the predefined 6 bar to fit into a small averaged cochlea form (see Fig. 4).
In order to reduce the needed pressure for a sufficient curvature, the implant derived from the small cochlea form would be beneficial for additional use within the medium and large size averaged forms. This confirms the previously stated hypothesis that individualization for each patient is possible by variation of the applied pressure using one standardized implant form. The synthesis as an analytical calculation uses a linearized material definition and does not represent the radial dilatation of the silicone implant which occurs due to pressurization of the inner hollow. That means assessing of the fit of the implant position along the perimodiolar wall of the scala tympani has to be completed by the assessing of the implant thickness after pressurization. In order to address the question of radial dilatation 3:1 up-scaled models of an implant with a cylindrical and a conical outer shape were evaluated using numerical FE-Analysis (*Ansys Workbench V.17.2*) (see Fig. 5). The results are in congruence to the Long Term Hydrostatic Pressure Resistance Formula (or Boiler Formula) *(1)*, which describes the linear influence of the wall thickness (t) on the tangential stress (σ_{tan}).

$$\sigma_{tan} = p * \frac{r}{t} \qquad (1)$$

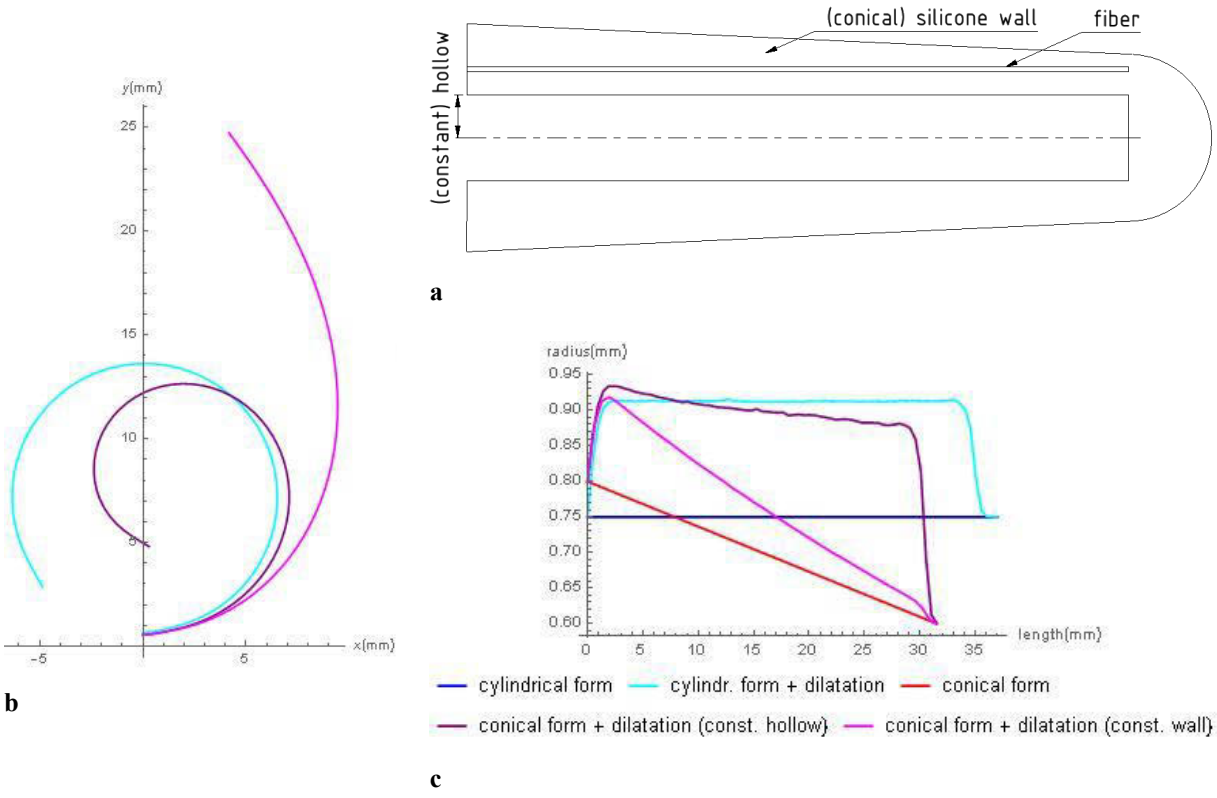

Fig.5: *(a)* Cross section of a conical demonstrator with a constant hollow, a conical silicone wall and the non-stretchable fiber. For better visibility of the individual parts, the aspect ratio of length to thickness of the demonstrator is neglected. *(b)* Position of the fiber of a cylindrical demonstrator and a conical demonstrator (once with constant hollow and once with a constant silicone wall) under pressurization with 6 bar. *(c)* Outer radius of the cylindrical and the conical demonstrators before (without radial dilatation) and after pressurization (with radial dilatation). All demonstrators are 3:1 scaled.

From this follows, that a decreasing wall thickness of the silicone implant from base to tip is needed to induce an increasing curvature under pressurization (p) leading to a spiral shape of the whole structure, which correlates to the one of the cochlea.

4. SUMMARY

The combination of analytical and numerical calculation was used to evaluate whether a silicone implant equipped with a fluidically actuated compliant mechanism would fit to the perimodiolar path of three different cochlea sizes by adapting the pressurization of the inner hollow as source for the resulting curvature.
A tight cochlea path, as shown in the small cochlea, required an increased pressurization of the implant compared to the larger paths. Thus, an implant which was designed to fit a small cochlear path at a previously set pressure load would be beneficial for the extended use with larger cochleae, since the adaption requires a decrease of the needed pressure load to achieve a suitable curvature fit. However, the insertion depth of the implant measured in degree or cochlear coverage would decrease, which affects the frequencies which would be stimulated through the implant. Especially for patients with residual hearing, manufacturers of cochlear implants already introduced shortened electrode carrier [e.g. Hybrid L, Cochlear Ltd., Sydney, Australia], for a shorter insertion depth which is expected to be less traumatic and therefore preserving residual hearing while enabling electrical stimulation for the frequencies where hearing loss already occurred.

5. ACKNOWLEDGMENTS

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