SPECIFIC CURVATURE BEHAVIOR OF COMPLIANT MECHANISM WITH HYDRAULIC ACTIVATION USED FOR MEDICAL INSTRUMENTS OR IMPLANTS

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ABSTRACT

In recent years, there are ever increasing demands on the accuracy of surgical procedures besides the gentle, minimally-invasive surgery. Due to the complexity of patient-specific anatomy and the need to preserve crucial structures that may lie on the linear pathway from the access to the target area, analyzing of non-linear access paths is preferred. This method requires specific design of the instruments (e.g. flexible endoscopes) or the implants (e.g. Cochlea implant). The existing systems used in this field are developed using smaller dimensions, increased operative possibilities, easier and faster handling resulting in a reduction of potential trauma. In this paper, a new compliant mechanism, which allows for a specific curvature by external activation, is presented. The curvature behavior of the compliant mechanism by hydraulic actuation is considered. The curvature behavior of the compliant mechanism by hydraulic actuation is of interest to facilitate the insertion of the implant or the instrument used in the non-linear access paths to the target area, and to avoid any damage, which could occur during the surgical procedure. With the help of the simulations, a specific curvature behavior of the compliant mechanism executed by hydraulic actuation is demonstrated in this paper. For simulation purposes the Finite Element (FE) model was used.

Index Terms - Cochlear implant, curvature, electrode carrier, active bending, hydraulic activation

1. INTRODUCTION

Current medical research and development has to meet the challenging demands for decreasing the invasiveness of surgical approaches, more conservative surgery and increasing the accuracy of surgical procedures.
Due to the complexity of patient-specific anatomy and the use of minimally-invasive approaches, instead of large-volume approaches, the analysis and realisation of non-linear access paths is crucial. That in turn places special requirements on the instruments (e.g. flexible endoscopes) or the implants (e.g. cochlea implants), these requirements must be met.
An exemplary requirement is the mechanical characteristic of the instruments or implants. There are two general methods, passive and active, to preserve delicate structures of the inner ear, especially if they show a non-linear shape. Firstly, soft and flexible design of the instruments can be used to allow gentle insertion and passively follow through non-linear

pathways. Unfortunately that often conflicts with the purpose and function of such instruments (e.g. biopsy forceps), making it an inadequate method in that case. Secondly, the instruments could actively follow the non-linear shape of the target structure using designed actuators, thereby minimizing the amount of contact and the contact force, resulting in a gentle surgery.

The requirements of instrumentation for non-linear pathways can be applied to other areas of medical science for instruments such as, cardiac catheters, flexible endoscopes or implants e.g. cochlear implants.

Although all clinical instruments have to meet the requirement of minimization, the most challenging task is the implantation of cochlear implant electrodes into the fluid-filled spiral shape of the cochlea, which comprises between two and three turns in humans. Due to the geometrical constraints of the cochlea, the outer diameter of such an implant is restricted to approximately 1 mm (at the larger end of the implant). The compliant actuator, which is under development needs to be included in the implant and must maintain all functional components required for the electrical stimulation as the main function of the implant.

This paper presents an implant with hydraulic actuation, with the capability to bend itself during the operation and is able to suit the shape of the cochlear duct resulting in simplification of the insertion.

2. STATE OF THE ART // STATE OF TECHNOLOGY

A Cochlear implant is an auditory neuroprosthesis, developed to directly stimulate the auditory nerve in order to create an auditory impression in deaf patients, or patients with severe to profound hearing loss (see Figure 1).
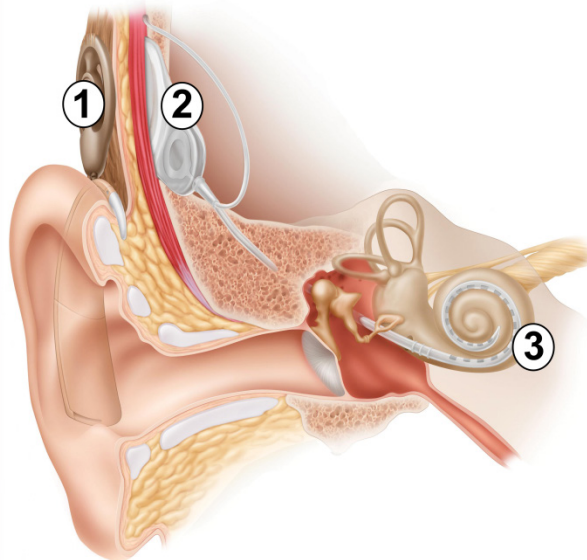

Figure 1. Illustration of the whole cochlear implant system. A microphone detects sound signals, which then are filtered by a speech processor worn behind the ear conch. A wireless connection transmits the signals from sender coil (1) to receptor coil (2). The receptor coil sends the electrical signal to the implant electrode (3) located inside the cochlea. Platinum contacts of the implant electrode stimulate the neurons to generate a sound impression. Microphone, speech processor and sender coil are the external parts of the system. The receptor coil and the implant electrode are implanted.
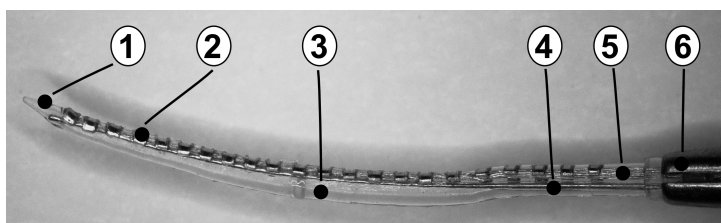*By courtesy of Cochlear Ltd., Sydney, Australia*

Figure 2. Detailed view on a cochlear implant electrode, showing the tip of the electrode (1), platinum contact electrodes used for stimulation (2) which are embedded in a silicone body (3), the stylet (4) which straightens the preshaped implant electrode and contact wires (5) to every contact electrode. The implant electrode is held with a forcep (6).

Currently, nearly all commercially available cochlear implant electrodes can be classified into two groups. On the one hand there are electrodes which are characterised by a small outer diameter and a very flexible design, e.g. the Hybrid L (Cochlear Ltd.) and Flex 28 (MED-EL Elektromedizinische Geräte Gesellschaft m.b.H.). These implant electrodes lie at the outer wall of the cochlea after they have been successfully implanted (see Figure 3A). Since the auditory nerve lies in the central axis of the spiral shaped cochlea, a positioning of the implant at the outer wall of the cochlea implies the largest possible distance between the contact electrodes of the implant and the auditory nerve as the target of stimulation.

The second group of available implants are characterised by a final position at the inner wall of the cochlea, called perimodiolar position (see Figure 3B). There are different approaches to achieve that final positioning, especially noted in numerous patents but only a few of them were realised in commercial implant electrodes: At first the use of an additional positioner which enables the surgeon to move the implant from the outer to the inner wall; secondly, the use of an integrated stylet which works as a stiffener to straighten the pre-shaped electrode during the first part of implantation and later being removed; and finally, an insertion tool into which the pre-shaped implant electrode can be loaded and straightened in preparation for insertion.

Since the implantation occurs in a confined area with very small and delicate hard and soft tissue structures, all of the aforementioned methods can lead to problems with the use of auxiliary tools, as they too, require additional space either inside the implant or around it.

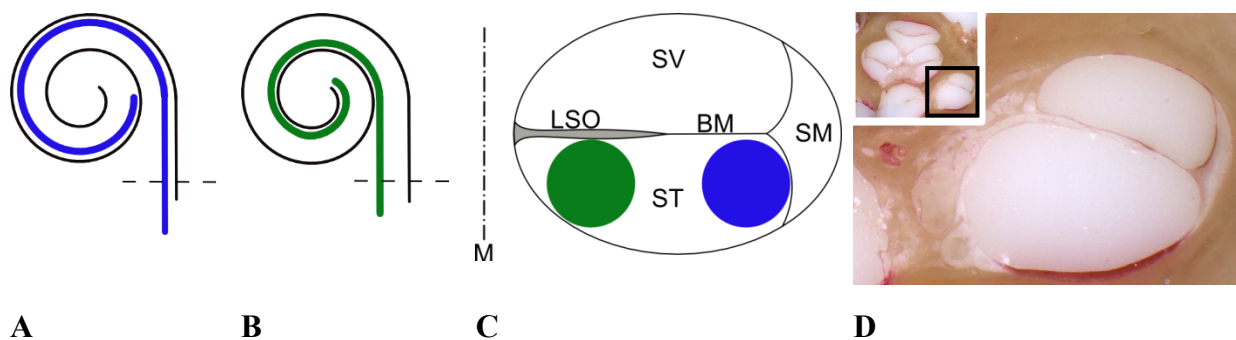**A**   **B**   **C**   **D**

Figure 3. Schematic representation of a cochlear implant showing different final positions within the cochlea. Image A shows the lateral final position of the implant (blue), whereas Image B shows the perimodiolar final position of the implant (green). That comparison illustrates that the implant electrode reaches deeper into the cochlea combined with a smaller distance to the central axis if it is placed perimodiolar. The dashed line shows the position of the cross section shown in Image C. Image C illustrates a cross section through the basal turn of the cochlea, showing main anatomical structures and the position of a lateral (blue) and a perimodiolar (green) implant. The dash-dotted line (M) represents the central axis of the spiral shaped cochlea, called modiolus. The fluid-filled cochlea is separated into different compartments, called scala vestibuli (SV), scala tympani (ST) and scala media (SM). SV and ST are separated through a delicate bony disk called lamina spiralis ossea (LSO) and the basilar membrane (BM). Image D shows a morphological cross section of a human cochlea derived from the so-called microgrinding procedure described by Rau et al. (2013) [4]. The image is provided in the same orientation as the Image C but without the implant. The upper left corner shows the overall view as a cross section of the cochlea, whereas the main image provides the cross section of the basal turn of the cochlea.

3. ANATOMY OF THE COCHLEA

Morphology and geometrical measurements of the cochlea have been investigated by several groups using radiological and histological methods.

Erixon et al. (2009) performed measurements concerning geometrical details on plastic corrosion casts of adult human inner ear specimens [2]. Based on the variations in coiling characteristics, geometrical measurements and the individual design of each cochlea the

authors found it to be like a "fingerprint". The mean length of the outer wall of a cochlea was found to be 42.0 mm (range: 38.6 – 45.6), comprising a mean number of turns of 2.6 while the first turn represents already 53% of the total length. Biedron et al. (2006) found that 65% of their studied cochleae had more than 2.5 turns (157 cochleae from 101 individuals) [1]. Cochleae with up to three completely developed turns were reported by Tian et al. (2006), which in literature is accepted to be the upper limit in humans [5]. The modiolus is defined as the central axis of the three-dimensional spiral shaped cochlea. By defining a plane for each cochlear turn, Erixon et al. (2006) showed how these turns may vary concerning the angle between the planes, this results in the impression of tilted turns. That again made the definition of one central axis difficult [2].

Another method of studying morphology of cochleae is to measure the semi-major and the semi-minor axis, as used in the definition of ellipses.
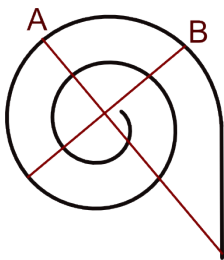

Figure 4. Definition of the semi-major axis (A) and the semi-minor axis (B). A is the largest distance from the round window to the lateral wall of the cochlea, whereas B is the perpendicular distance.

Escudé et al. (2006) used computed tomography to measure these distances shown in Figure (4) [3]. The differences of the mean distances A and B between left and right cochlea of one individual were below the resolution of the high resolution computed tomography (0.25 – 0.3 mm). Since the authors found a mean difference between male and female for both axes (A: male 9.43 mm, female 9.05 mm; B: male 7.15 mm, female 6.86 mm), but no difference for the ratio A/B (mean 1.32), no difference in the overall morphology between male and female is to be expected.

Knowledge of the geometry of the scala tympani is important since the cochlear implants are inserted into that compartment. Wysocki (1999) studied the cross section area of scala tympani, measuring the width and height along the turns of the cochlea from bottom to top [6]. The mean height of scala tympani starts at the bottom with 1.2 mm and decreases to 0.3 mm. The mean width of scala tympani shows a smaller decrease from 2 mm to approximately 1.2 mm at the smallest point.

The aforementioned measurements are generally the basis of development of new implant electrodes to meet the geometrical restriction, such as, decreasing the outer diameter of the implant to fit into scala tympani. Although the human cochlea shows a three-dimensional spiral, pre-shaped implant electrodes are bending in the plane. That simplification to a two-dimensional spiral is due to the fact that implant electrodes should be useable in left and right cochleae. Implants with a three-dimensional spiral would have to be produced with different coiling directions to fit in left and right cochleae.

4. ACTIVE BENDING OF THE IMPLANT

By insertion of the electrode carrier into the cochlea, the tissue can be damaged, which can destroy the residual hearing. An electrode carrier, which can bend itself to suit the shape of cochlear duct during the operation can not only prevent insertion trauma but also simplifies the implanting procedure. The curvature of the electrode carrier can be attained by using a special structure of the electrode carrier [7] [8]. The proposed implant is a hydraulically actuated compliant structure with an internal hollow core. The bending of the electrode carrier can be achieved under inner pressure by the following two options; (a) silicone body

embedded with a non-stretchable thin fibre in the wall and a hollow symmetrical centre core or (b) an asymmetrical hollow core in the silicone carrier. Figure (5) illustrates the principles described above.

Figure 5. Schematic of bending under inner pressure. The left Image shows a silicone body embedded with a non-stretchable thin fibre in the wall and a hollow symmetrical centre core, the right Image shows an asymmetrical hollow core in the silicone carrier.

In an unloaded or non-pressurized state, there are two options for the structure; (a) straight or (b) a pre-curved structure, as shown in Figure (6). The straight electrode carrier will bend itself by the internal pressure with respect to the end position. An electrode carrier manufactured in a pre-curved state is held straight by the pressure at the beginning of the insertion. Its stiffness will be changed continuously over the total length by releasing the pressure so that the electrode carrier turns to a curved shape.
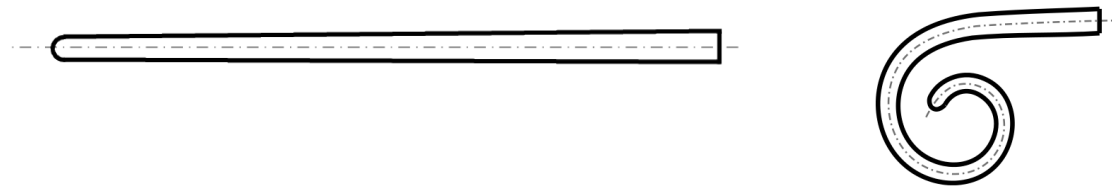

Figure 6. Possible structures of the unloaded electrode carrier. The left Image shows the straight structure, the right Image shows the pre-curved structure.

For production reasons, it was decided to fabricate a straight electrode carrier. The asymmetrical variation is less effective than the symmetrical variation with respect to the change of curvature, since this permits the total change in length of the electrode carrier. Therefore, the silicone body embedded with a non-stretchable thin fibre in the wall and a hollow symmetrical centre core will be taken into consideration.

5.   FE-MODEL OF THE IMPLANT

In this paragraph, a three-dimensional parametric model is presented. This model is designed and examined with the help of "ansys mechanical APDL 14.5" and will be used to compare the simulated curvature with the real curvature behavior of the proposed cochlear implant. The results of the simulation could simplify the insertion of the implant in the cochlear model by giving suitable pressure to achieve a certain curvature of the implant.

The cochlear implant has a conical form with a minimal radius r_{min} of 0.25 mm at the front and a maximal radius r_{max} of 0.4 mm at the end of it. The length of the implant is 18 mm without the tip. The part of the CAD-model of the cochlea, where the end of the implant will be established, is virtually straight; the curvature is very small. The length of this part is approximately 6 mm. This part will be neglected in the model of the implant because it will not bend.

The production of the first physical model of the cochlear implant will be created on a scale of 1:3 and constructed in the laboratory of the Mechanism Technology Groupat Technische Universität Ilmenau. In order to be able to use the results of the simulation, the model for the simulation is also designed on the same scale of 1:3.

The structure of the implant is shown in Figure (7). It has a conical form with a minimal radius r_{min} of 0.75 mm at the front of the implant and a maximal radius r_{max} of 1.05 mm at the end of the implant. The length of the implant L shown in figure (7) is 36 mm without the tip; the tip is a half of a sphere and has the radius r_{min} of 0.75 mm. The implant includes a cylindrical hollow with radius r_i of 0.3 mm. This hollow is extended along 35 mm of the implant and it is closed on one side at the front forming a fluidic channel, which will be used to apply an internal pressure to the implant. A non-stretchable thin fibre of length L_f 35 mm is embedded in the wall of the conical structure with a constant distance h of 0.6625 mm from the symmetry axis of the implant (see diagram A-A below). Once the pressure is applied to the hollow, the implant structure will bend toward the thin fibre. In order to prevent the large radial deformation and thus facilitate larger bending of the structure the model was also reinforced using ring-fibres (see diagram A-A and B-B below).
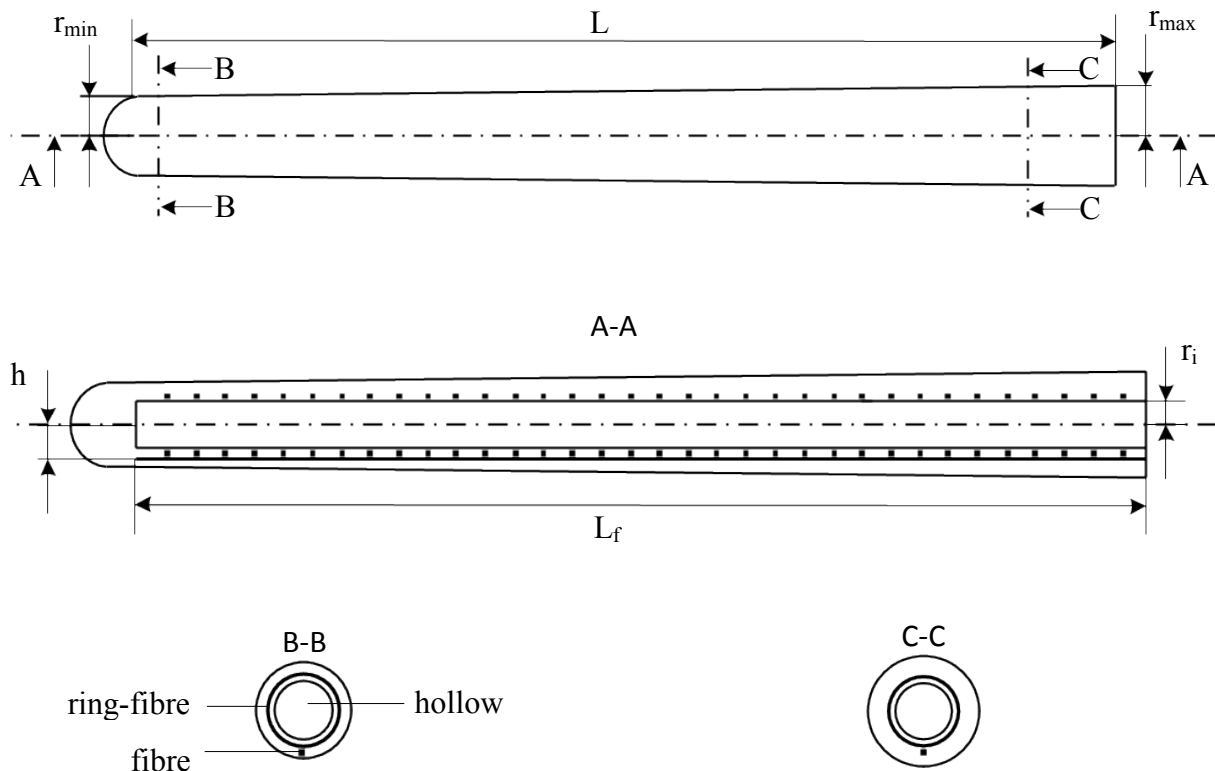

Figure 7. Schematic representation of the proposed cochlear implant.

The model is symmetrical, therefore only half of the model was simulated, lengthwise, in order to minimize the number of the elements and hence the simulation time. The model is meshed with hexahedral elements solid186. The mechanical properties of the silicone rubber "Elastosil® M 4644 A/B, Hardness Shore A 40", were determined in the laboratory of the Mechanism Technology Group at Technische Universität Ilmenau. In addition to the silicone material for the electrode carrier, a copper material was used for the non-stretchable thin fibre to simulate the implant. The above-mentioned materials are only for the use in the laboratory.

As a boundary condition, a fixed support of the selected nodes at the end of the implant was selected and normal displacement of all surfaces at the interface of the half model was not allowed. All internal surfaces of the hollow were subjected to a pressure P up to 9 bar. Figure (8) shows the deformed shape (total deformation vector) of the cochlear implant under pressure of 9 bar applied to the hollow. It can be seen that the shape of the deformed implant is similar to the cochlear model.
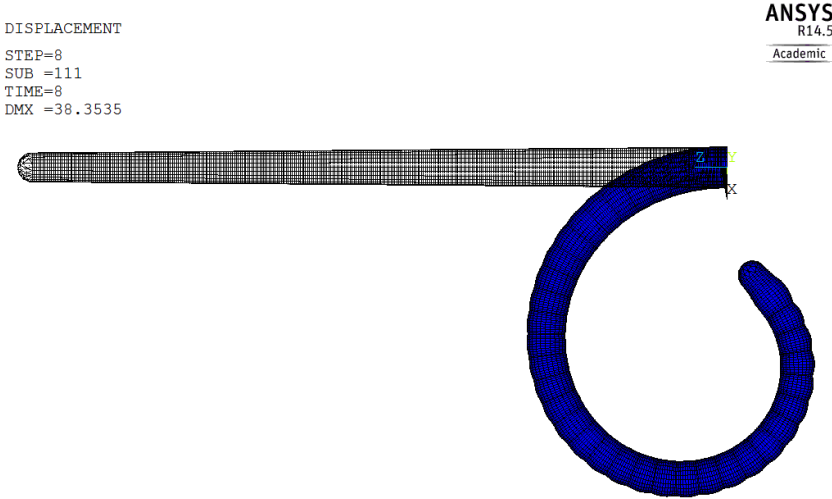

Figure 8. Undeformed and deformed implant under pressure of 9 bar.

In order to compare the results of FE simulation with the cochlear model, the shape of the fibre was documented under different levels of the pressure and compared with the internal and external side of the cochlear model, as illustrated in Figure (9).
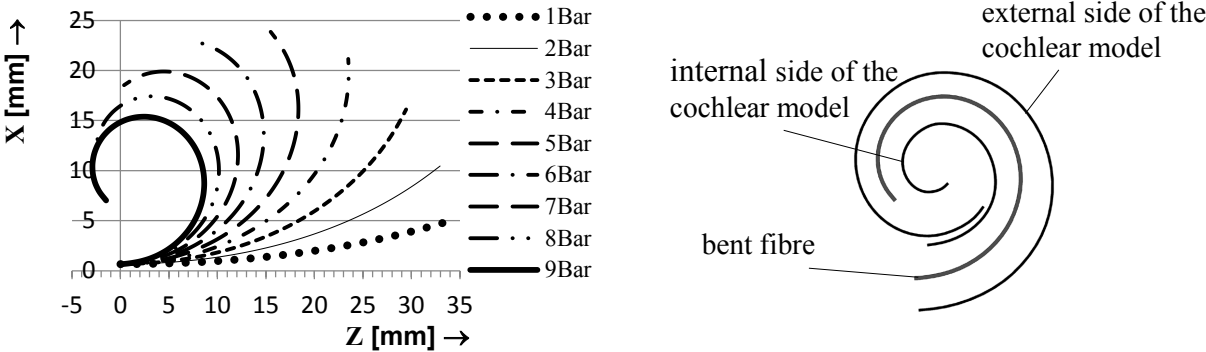

Figure 9. Curvature of the fibre under pressure. The left Image shows the bent fibre under different steps of pressure, the right Image shows the comparison between the bent fibre under pressure of 9bar and the external and internal sides of the cochlear model.

The comparison between the cochlear model and the bent fibre establishes that the implant can bend itself under pressure to approximate the spiral form of the cochlear model.

6. SUMMARY

The findings outlined in this paper confirms that it is possible to utilize the bending of the electrode carrier by using a structure with a silicone body embedded with a non-stretchable thin fibre in the wall and a hollow symmetrical centre core. The aim of FEM investigations is to verify the bending of the electrode structure. The first results of FEM simulation confirms that the bending of the implant with non-linear material properties produces the required shape, which is similar to the cochlear model.

7. ACKNOWLEDGMENTS

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