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Invited paper

Compliant Mechanism with Hydraulic Activation Used for Implants and Medical Instruments

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Abstract *- The hydraulic actuation of cochlear implant is considered in this research. The deformation 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. The described implant is a hydraulically actuated compliant structure with a symmetric internal hollow core and with a non-stretchable thin fibre embedded in the wall. Under inner pressure of 6 bar, the structure is bended, thus the insertion will facilitate during the operation. With the help of the simulations, a specific geometry of the compliant structure is determined for the target deformation executed by hydraulic actuation. In this paper a Finite Element (FE) model and an analytical model is demonstrated for simulation the deformation behavior of the fibre The maximum difference between both model results for simulated fibre curves is about 0.5 mm. This is 1.6% of the entire length of the implant.*

Key words: *Cochlear implant, curvature, active bending, hydraulic activation, compliant mechanism*

I. INTRODUCTION

Due to the complexity of patient-specific anatomy and the use of minimally-invasive approaches, instead of large-volume approaches, the analysis and realization of non-linear access paths is crucial in modern surgery. That in turn places special requirements, which must be met, on the instruments (e.g. flexible endoscopes) or the implants (e.g. cochlear implants).

Although all clinical instruments have to meet the requirement of minimization, the most challenging task is the inserting of cochlear implant 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 ([1]-[3]).

This paper presents a compliant mechanism with hydraulic actuation, which has the capability to bend actively during the operation and which has the ability to suit the shape of the cochlear lumen duct resulting in simplification of the insertion. The bending is carried out in plane. In addition, this simplification to a two-dimensional spiral is due to the fact that implants should be useable in left and right cochleae.

II. 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 Fig. 1-2).

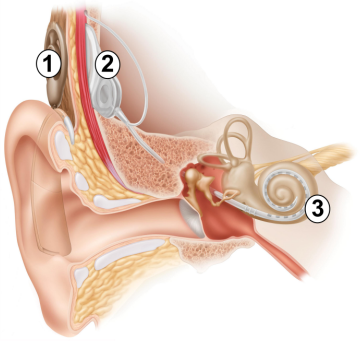


Fig. 1. Illustration of the whole cochlear implant system: A microphone detects sound signals. A wireless connection transmits the signals from sender coil (1) to receptor coil (2). The receptor coil leads the electrical signal to the implant electrodes (3) located inside the cochlea. Platinum contacts of the implant electrodes stimulate the auditory nerve to generate a sound impression. By courtesy of Cochlear Ltd., Sydney, Australia.

Currently, nearly all commercially available cochlear implants can be classified into two groups. On the one hand there are implants which are characterized 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 lie at the outer wall of the cochlea (lateral position) after it has been successfully implanted (see Fig. 3A, 4). 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. On the other hand available implants are characterized by a final position at the inner wall of the cochlea, called perimodiolar position (see Fig. 3B, 4).

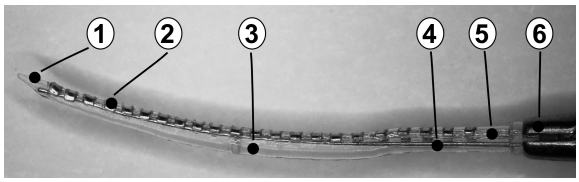
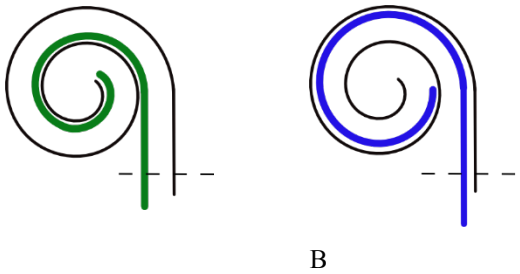


Fig. 2. Detailed view on a cochlear implant, showing the tip of the implant (1), platinum contact electrodes used for stimulation (2) which are embedded in a silicone body (3), the stylet (4) which straightens the preshaped implant and contact wires (5) to every contact electrode. The implant is held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

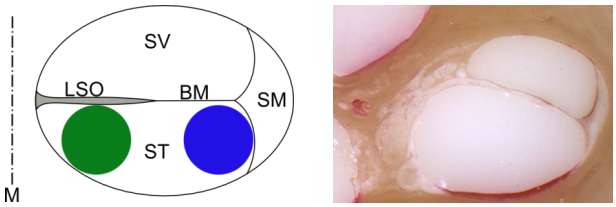
There are different approaches to achieve that final positioning, especially noted in numerous patents but only a few of them were realized in commercial implants: At first, the use of an additional positioner which enables the surgeon to move the implant from the outer to the inner wall; Secondly, the use of an integrated stylet which works as a stiffener to straighten the pre-shaped implant during the first part of implantation and later being removed; And finally, an insertion tool into which the pre-shaped implant can be loaded and straightened in preparation for insertion.



A B

Fig. 1. Schematic representation of different final cochlear implant positions within the cochlea. Image A shows the perimodiolar final position of the implant (green), whereas Image B shows the lateral final position of the implant (blue). That comparison illustrates that the implant 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 Figure 4A.

Fig. 4A 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).



A B

Fig. 4. A: 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; B: Morphological cross section of a human cochlea derived from the so-called micro-grinding procedure described by Rau et al. (2013) [4].

Fig. 4B shows a morphological cross section of a human cochlea derived from the so-called microgrinding procedure described by [4]. The image is provided in the same orientation as the Fig. 4A but without the implant and it shows the cross section of the basal turn of the cochlea (see also [5], [6]).

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, because they require additional space either inside the implant or around it.

IV. ACTUATED COMPLIANT MECHANISM

By insertion of the implant into the cochlea, the tissue can be damaged, which can destroy the residual hearing. An implant, which can bend actively to suit the shape of cochlea during the operation can not only prevent insertion trauma but also simplifies the implanting procedure. The deformation of the implant can be attained by using a special structure of the implant [7], [8]. The proposed implant is a hydraulically actuated compliant structure with an internal hollow core. The bending of the implant can be achieved under inner pressure by the following two options; (a) silicone body with a non-stretchable thin fibre embedded in the wall and a hollow symmetrical centre core or (b) an asymmetrical hollow core in the silicone carrier. Fig. (6) illustrates the principles described above.

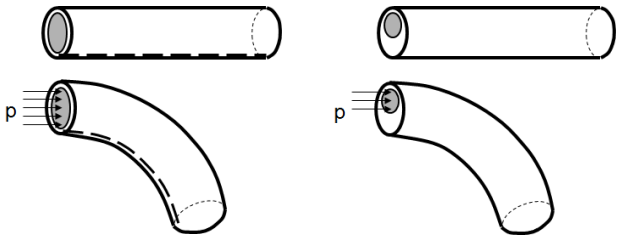


Fig. 6. Schematic of bending under inner pressure. The left image shows a silicone body with a non-stretchable thin fibre embedded in the wall and a hollow symmetrical centre core, the right image shows an asymmetrical hollow core in the silicone carrier.

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 Fig. (7). The straight implant will bend actively by the internal pressure with respect to the end position. An implant manufactured in a pre-curved state is held straight by the internal pressure at the beginning of the insertion. Its stiffness will be changed continuously over the total length by releasing the pressure so that the implant turns to a curved shape.

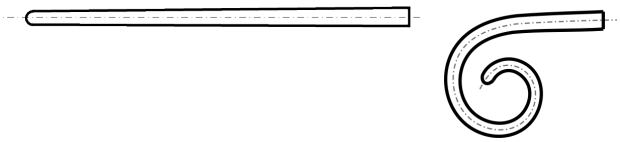


Fig. 7. Possible structures of the unloaded compliant mechanism. Left: straight structure; Right: pre-curved structure.

For production reasons, it was decided to fabricate a straight compliant mechanism. The asymmetrical variation (Fig. 6 right) is less effective than the symmetrical variation

(Fig. 6 left) with respect to the change of curvature, since this permits the total change in length of the implant. 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.

V. MODELING AND SYNTHESIS OF THE COMPLIANT STRUCTURE FOR THE IMPLANT

For modeling the bending of the compliant structure, analytical model and Finite Element (FE) model as combination will be used. The analytical model is based on the theory of curved beams described in [9]. Linear material law is supposed in this model. In fact, the material of the compliant mechanism is strong non-linear. The FE method can reflect this property very good, but the synthesis of the geometry for this problem cannot be realized by FE method easily. Therefore two models; analytical one for synthesis of geometry and FE method for the parameter identification and the analysis of optimized compliant mechanism were built.

At first, the material properties for the analytical model as a compliant beam must be identified. A simple model of a compliant beam with the length l=35 mm and radius r=0.75 mm is used. The beam has a hollow with a radius r_i=0.3 mm. In order to occur the bending of the compliant beam, an unstretchable thin fibre is embedded in the wall with a distance h=0.6625 mm from the symmetry axes of the beam (Fig. 8).

FE model is built with the same parameter to investigate the deformation behavior of the compliant mechanism by applying an inner pressure of p=6 bar, which is set to be the used pressure, on the hollow. The FE model is symmetrical structure, 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 compliant mechanism, a copper material was used for the thin fibre to simulate the deformation behavior of the structure. 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 structure was selected and normal displacement of all surfaces at the interface of the half model was not allowed. The first results of the simulation show that the modeled structure will bend towards the embedded fibre [9]. Fig. 9 shows the deformed shape of the fibre embedded in the wall of the structure as an orange curve. The shape of the deformed fibre is a circular arc. The arc is fitted by circle with radius R=6.54 mm (rounded). Corresponding to analytical model [9], Young's modulus is determined as follows:

$$E = \frac{4Rhpr_i^2}{r^4 - r_i^4 + 4h^2(r^2 - r_i^2)} \qquad (1)$$

E is calculated to 0.8 N/mm^2 (rounded). The modeled beam is a structure with distributed compliance and therefore the strain of the different parts of the structure differs not much to each other. Consequently, the modeling of this structure can be possible with linear material parameter by using the calculated Young's modulus E for given pressure.

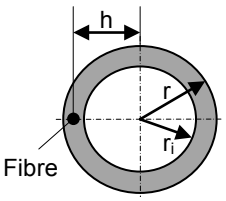


Fig. 8. Cross section of the model of the compliant beam to find the parameter E for analytical model [9].

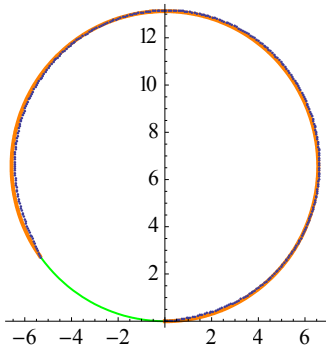


Fig. 9. Blue points: Deformed shape of the fibre embedded in the structure wall by FE method, as green circle: Fitted circle for the form of FE model; orange curve: Deformed shape of the beam by analytical model.

The inner wall of the cochlea, the form with a smaller distance to the central axis of the spiral shaped cochlea, and the desirable form of cochlea fibre, which has to be placed perimodiolar, are presented via several radiuses $R_{C,j}$ and corresponding radiuses $R_{F,j}$ for j=1,..,18 (Fig. 10). The length of the desirable fibre is 30.5 mm and the distance between this and the cochlea wall is 0.5 mm. By using the parameter E and according to $R_{F,j}$, the radiuses of desirable fibre $r_{F,j}$ will be detected by analytical model. The equations for the radiuses $r_{F,j}$ for j=1,..,18 of the bending implant are:

$$r_{F,j} = \left(\left(\frac{4h_{new} p R_{F,j} r_i^2}{E} + r_i^2 (r_i^2 + h_{new}^2) + 4h_{new}^4 \right)^{0.5} - 2h_{new}^2 \right)^{0.5} \qquad (2)$$

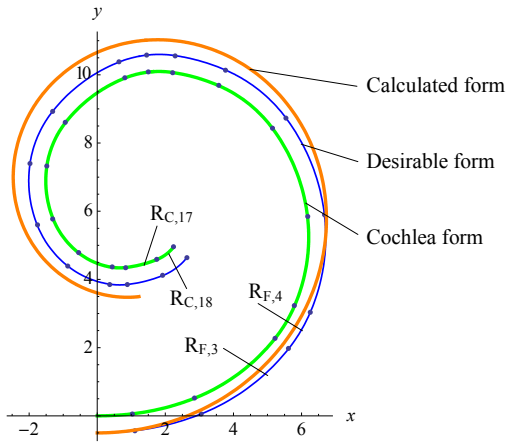


Fig. 10. Green curve: The inner wall of cochlea presented via 18 radiuses $R_{C,j}$; Blue curve: The desirable form of cochlea fibre built via corresponding radiuses $R_{F,j}$ for j=1,..,18, if it is placed perimodiolar. The distance between both curves is 0.5 mm; Orange curve: Calculated form of beam by analytical model.

In respect of the special parameter h_{new}=0.55 mm, which is defined for manufacturing reasons, the radiuses $r_{F,j}$ of modeled implant is obtained, as showed in Fig. 11. Such

design of cochlea implant (stepped form) is very difficult for manufacturing. Therefore, the stepped form is replaced with conical form represented by a fitted straight line (Fig. 11). The end of the modeled beam is at the location x=30.5 mm. Taking into account of the parameter h_{new} and that the fibre must be built completely in the wall, the parameter r_F is 0.6 mm (rounded) for the beam end.

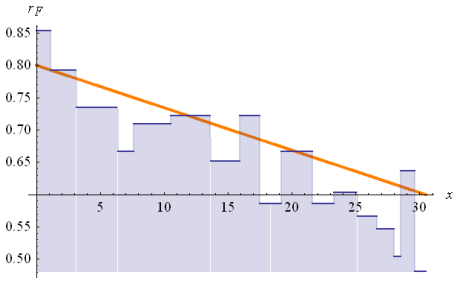


Fig. 11. Stepped form: Calculated radiuses $r_{F,j}$ of beam used equation (2); Straight line: A new conical form of the modeled beam represented by a fitted straight line, which goes through r_F=0.6 mm at the point presented the beam end.

The calculated conical form of the beam with maximal radius of 0.8 mm (rounded) and minimal radius of 0.6 mm is used for detecting the deformed implant under 6 bar. The form of the beam fibre is showed in Fig 10 (orange curve). The modeled beam with the calculated conical form repeats the cochlea shape very good. The maximum distance between both curves in the normal direction in relation to the curve of the cochlea form is about 0.55 mm. This is 1.8 % of the entire length of the implant.

VI. VALIDATION OF THE MODEL

FE model was used to proof the results obtained by the presented analytical model. Non-linear material parameters are used for the FE model. The FE model was adjusted to the same geometrical parameter of the final analytical model for the calculated conical form. The bending form (total deformation vector) of the FE model under pressure of 6 bar applied on the hollow is shown in Fig. 12.

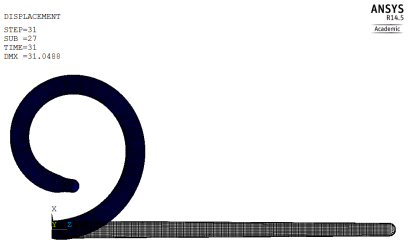


Fig. 12. Undeformed and deformed FE Model under pressure of 6 bar

The bent fibre of the modeled structure is presented as a set of points according to the FE model in Fig. 13. A comparison between the curvatures of the implant fibre resulted from the simulation by FE method and by analytical model is shown at the left side in Fig. 13. The maximum difference between both curves is about 0.5 mm. This is 1.6 % of the entire length of the implant. At the right site of Fig.13 the bent fibre resulted from the simulation by FE method (dark blue points), inner wall of the cochlea (green curve) and desirable form of fibre (blue curve) are illustrated. The curve simulated by FE method is demonstrated with offset of 0.5 mm downward in order to conform to the cochlea form with the minimal top difference between this curve and the desirable curve (under 0.5 mm).

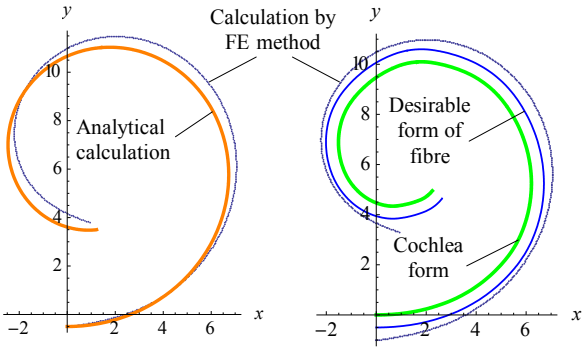


Fig. 13. On the left: Comparison between the curvatures of the fibre resulted from the simulation by FE method (dark blue points) and by analytical model (orange curve); On the right: The fibre form resulted from the simulation by FE method (dark blue points), the form of the inner wall of cochlea (green curve) and desirable form of the implant fibre (blue curve).

VII. SUMMARY

The results presented in this paper confirm that the synthesis of the cochlear implant geometry can be realized by the analytical model. The material parameter E for the analytical model obtains by FE model for given pressure. The comparison of the difference between both shapes and the desirable shape lies under 2 % of the entire length of the implant. Measurement setup is under development and will be used to verify the presented results.

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