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Tubular manipulators: a new concept for intracochlear positioning of an auditory prosthesis

Abstract: The aim of this study was to investigate the applicability of tubular manipulators as an actuator mechanism for intracochlear positioning of the electrode array (EA) of a cochlear implant (CI). This is motivated by the vision of an atraumatic insertion of the EA into the inner ear (cochlea) without any damage to the intracochlear structures in combination with a well-defined final position. To realize this, an actuator mechanism is required which allows consideration of the patient-specific anatomy. We propose a tubular manipulator for this task. It consists of three concentric tubes: A straight outer tube serves as a guiding sleeve to enter the inner ear (cochlea) and two additional telescoping, superelastic, helically precurved tubes. By selecting helical tube parameters of both tubes prior insertion, a patient-specific curling behaviour of the tubular manipulator can be achieved. For preliminary investigation, segmentation and skeletonization of 5 human scala tympani were performed to determine their centrelines. These centrelines were considered as individual ideal insertion paths. An optimization algorithm was developed to identify suitable tube set parameters (curvature, diameter, length, torsion, stiffness) as well as configuration parameters (translation and rotation of the 2 inner tubes). Different error values describing the deviation of the shape of the tubes with respect to the insertion path were used to quantify the optimization results. In all cases tube set parameters for a final position within the cochlea were found, while keeping the maximum error below 1mm. These preliminary results are promising in terms of the potential applicability of tubular manipulators for positioning auditory prosthesis inside the scala tympani of the inner ear.

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1 Introduction

Cochlear implants have become the medical treatment of choice for patients suffering from deafness or severe hearing loss. To bypass the defect or highly ineffective organ of hearing, this neural prosthesis includes an electrode array (EA) which is inserted into the inner ear during a surgical procedure. This electrode array is used to apply electric fields which stimulate the hearing nerve, located in the central axis of the cochlea (referred to as the modiolus). Thereby, the cochlear implant allows for the perception of the sensation of sound [9]. The cochlea itself is a helical shaped hollow organ embedded in the temporal bone. It consists of three compartments separated by delicate membranous structures. The most important compartment for insertion of the CI electrode array is the scala tympani (ST), which is bounded by the basilar membrane (BM). The narrow dimensions of the ST (width: 1-2 mm [16]), its helical shape and the surrounding soft tissue structures make the electrode insertion an highly demanding surgical procedure.

Nowadays, research in the field of cochlear implants is dominated by the aim to improve preservation of these soft tissue structures for preservation of residual hearing [7]. Since v. Ilberg had described hearing preservation for the first time in 1999 [13] indication criteria have been extended to less severe hearing impairments [6]. Thus, atraumatic insertion of the electrode array into the scala tympani without harming the basilar membrane is required. One strategy is to develop very thin and flexible electrodes to reduce forces which occur while the—originally straight—implant is forwarded into the curved cochlea [14]. In contrast, there are some few research projects with the aim to manipulate the intracochlear movement of the electrode array to follow the spiral lumen of the scala tympani [2, 17]. This strategy necessitates that the patient-specific anatomy of the inner ear is taken into consideration as prerequisite for individualized CI electrode insertion. Initial results with steerable electrode arrays indicate a high potential for optimization of the insertion process: insertion forces could be reduced up to 70% compared to a not-optimized and not individualized insertion [17].

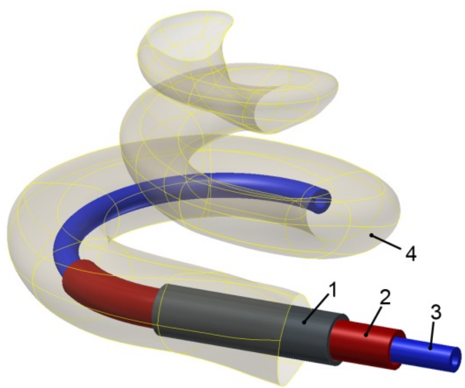

Figure 1: Schematic drawing of the tubular manipulator with straight guiding tube (1), helical outer (2) and inner tube (3) inside a model of a human scala tympani (4).

The main contribution of this paper is the proposal of a new concept for intracochlear positioning of the CI electrode array using tubular manipulators. We introduce design considerations and first results on the parameterization of the tubular manipulator. A preliminary study on 5 human datasets is presented to proof the concept.

2 Materials and methods

2.1 Concept

Our concept is motivated by the smallest among all continuum manipulators existent today: tubular manipulators (also referred to as concentric tube manipulators or active cannulas) [3, 15]. This needle sized manipulator is composed of multiple precurved, elastic, concentric tubes. By translating the tubes relative to one another and rotating them axially, the manipulator can achieve dexterous motion [1]. We propose to integrate a tubular manipulator into an EA such that the shape of the EA can be adjusted during insertion into the cochlea by manipulating the tubes until the optimal final pose of the EA is achieved.

2.2 Design considerations

As the ST exhibits a confined space and atraumatic insertion is desirable, it is indispensable that a follow-the-leader behaviour is achievable with the manipulator. Follow-the-leader behaviour means, that the manipulator's backbone follows the path of its tip. This is only possible under specific boundary conditions on the tube's parameters [4]. Actuation of the EA is realized by two tubes with helical precurvature and equal torsion. The requirements on the tube precurvature's and torsion [4] are favourable for our application as the ST exhibits a helical shape. The proposed concept is illustrated in Figure 1. A straight guiding tube (1) is used to access the ST (4) through the round window, e.g. after surgical access to the inner ear is achieved by masteoidectomy. The helical outer (2) and inner (3) tube control the curling behavior of the EA during insertion. For this preliminary study, the total insertion depth was chosen as 18 mm in regard of the length of existing electrode arrays.

2.3 Proof of concept

To proof the feasibility of the proposed concept, tube parameters for 5 human cochleae are determined. The scala tympani are segmented in 5 anonymised patient data sets using the auto-segmentation algorithm developed by Noble et al. [10]. Skeletonization [8] and postprocessing are then performed in order to extract the centreline of each scala tympani. Finally, each centreline is transformed into a common frame using the consensus coordinate system described in [12].

We then optimize helical tube parameters numerically for each cochlea, i.e. tube curvatures, tube torsions, tube lengths, tube stiffness', using sequential quadratic programming (SQP). The optimization process quantifies how well the resulting manipulator can conform to the centerline of the ST. Thus, the shape of the manipulator is determined using the kinematic model [4] and the mean and maximum deviation from the ST centreline as well as the tip error in the final pose is computed. Details on the optimization algorithms can be found in [5].

3 Results

We determined tube parameters for all 5 cochleae which allow for optimal conformance to the centreline of the ST. The tip error for all 5 cochleae was in the interval [0.16 mm; 0.63 mm], i.e. the Cartesian distance between the centre-

Table 1: Error values for 5 cochleae.

Cochlea	Maximum Path Accuracy Error [mm]	Mean Path Accuracy Error [mm]	Tip Position Error [mm]
1	0.52	0.29	0.39
2	0.60	0.38	0.16
3	0.63	0.31	0.63
4	0.50	0.29	0.50
5	0.62	0.46	0.57
max	0.63	0.46	0.63

Table 2: Individual tube parameters for all 5 cochleae which allow for optimal conformance to the centreline of the ST.

Cochlea	curvature [1/m]	torsion of both tubes [1/m]	length tube 1 [mm]	curvature tube 2 [1/m]	length tube 2 [mm]	inner diameter tube 1 [mm]	outer diameter tube 1 [mm]	inner diameter tube 2 [mm]	outer diameter tube 2 [mm]
1	552.10	24.20	15.80	40.07	7.60	0.22	0.36	0.45	0.59
2	450.11	11.65	16.10	19.16	8.10	0.22	0.40	0.49	0.63
3	537.91	24.05	16.50	47.49	7.90	0.22	0.40	0.49	0.63
4	533.16	32.66	16.20	52.95	9.70	0.22	0.40	0.49	0.63
5	482.79	16.62	16.80	52.29	0.01	0.22	0.40	0.49	0.63

line tip and the tip of the tubular manipulator in its final position. The mean path accuracy error, i.e. the deviation from the tubular manipulator shape from the centreline along the length, was in the interval [0.29 mm; 0.46 mm], with the maximum error in [0.5 mm; 0.63 mm] (see Table 1). Tube parameters are summarized in Table 2. Figure 2 shows example results of tubular manipulators for a final position close and the centreline. Figure 3 shows an example simulation of the insertion of a tubular manipulator following the centreline of the ST.

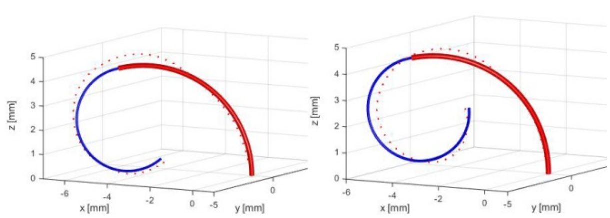

Figure 2: Final position of the tubular manipulator (left: Cochlea 2, right: Cochlea 3). Outer tube depicted in red, inner tube in blue. The centerline of ST is depicted as a red dotted line.

4 Discussion

Providing steerable electrode arrays is a challenging task in cochlear implant research. It requires both, accurate information about individual anatomy and a mechanism to manoeuvre the EA through the confined space of the ST following a predefined insertion path. Individual optimization of the insertion process has the potential to revolutionise the surgical treatment of patients with relevant residual hearing. A contact-less and therefore completely atraumatic insertion becomes feasible by the use of steerable electrode arrays—at least on a theoretical level as practical evidences in terms of temporal bone studies or clinical data are still missing.

To the best of our knowledge, this is the first investigation on the applicability of tubular manipulators as a mechanism for steerable CI electrode arrays. This initial feasibility study on 5 human cochleae datasets shows that this mechanism can in principle control the intracochlear movement of the electrode array. The deviations from the centreline of the cochleae are promising.

As a next step, this initial study needs to be extended to include more human cochleae datasets to cover a larger range of anatomical variations. Furthermore, it is essential to study the correlation between the deviation from the ideal insertion path and its impact regarding intracochlear trauma and clinical outcome. This requires building physical demonstrators and to perform insertion studies on artificial cochlear models [11] as well as temporal bone specimens.

An important aspect for getting this concept into clinical practice is the confirmation that the use of a limited number of tube sets is feasible [5]. This means that individualisation of the insertion process can be achieved by an individually optimized actuation of the tubular manipula-

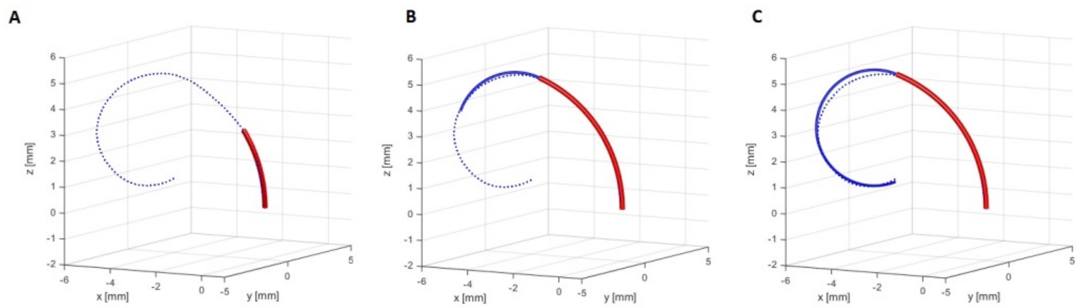

Figure 3: Insertion process for cochlea 1. ST centerline is depicted as a blue dotted line.
[Correction added after online publication 12 September 2015: Figure 3 was missing in the first online version]

tor and not by patient-specific fabrication of CI electrode arrays. This will be investigated as soon as the larger data base is available.

5 Conclusion

These preliminary results support the idea of using tubular manipulators for positioning auditory prosthesis inside the scala tympani of the inner ear.

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Author's Statement
Conflict of interest: Authors state no conflict of interest. Material and Methods: Informed consent: Informed consent is not applicable. Ethical approval: The conducted research is not related to either human or animals use.

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