DE GRUYTER Current Directions in Biomedical Engineering 2017; 3(2): 765–769

Thomas S. Rau*, Silke Hügl, Thomas Lenarz and Omid Majdani

Toward steerable electrodes. An overview of concepts and current research.

Abstract: Restoration of hearing is a demanding surgical task which requires the insertion of a cochlear implant electrode array into the inner ear while preserving the delicate basilar membrane inside the cochlea for an atraumatic insertion. Already shortly after the first clinical success with early versions of cochlear implants the desire for a controlled insertion of the electrode array arose. Such a steerable electrode should be in its shape adaptable to the individual path of the helical inner ear in order to avoid any contact between the implant and the surrounding tissue. This article provides a short overview of concepts and actuator mechanisms investigated in the past and present with the objective of developing a steerable electrode array for an individualized insertion process. Although none of these concepts has reached clinical implementation, there are promising experimental results indicating that insertion forces can be reduced up to 60% compared to straight and not steerable electrodes. Finally, related research topics are listed which require considerable further improvements until steerable electrodes will reach clinical applicability.

Keywords: cochlear implant, controlled insertion, actuator mechanism, navigation, individualized implants

https://doi.org/10.1515/cdbme-2017-0161

1 Introduction

Restoration of hearing by means of a cochlear implant (CI) is a demanding surgical task. It requires the insertion of an electrode array (EA) into the narrow cavity of the inner ear (cochlea) for an electrical stimulation of the auditory nerve. This procedure is particularly challenging in the case of patients with residual hearing as there is a delicate membrane inside the cochlea, called basilar membrane (BM), which is an essential structure for the transformation of acoustic vibrations into neural stimuli. The BM needs to be preserved during insertion of the electrode array; otherwise residual hearing could be lost.

That's why contact forces between the electrode array and the intracochlear soft tissue structures, especially the BM, need to be as low as possible. In our days, the dominant strategy of all CI manufacturers is to provide very thin and flexible electrodes arrays in order to reduce resulting insertion forces [1]. This goes along with a straight design of the EA without any additional components (beside the silicone body and the contact array) which may adversely alter the stiffness properties. Due to the straight design, the EA is in contact with the lateral wall of the inner ear during the entire insertion process and forced into the spiral configuration by the shape of the cochlea. Hence, insertion forces can never be avoided completely and the laterally located electrode array is far away from the auditory nerve.

In contrast, there is the vision of atraumatic electrode arrays which hug the inner wall of the cochlea (called perimodiolar EA) in order to place the stimulating contacts in close proximity to the auditory nerve, enable deeper insertion due to the perimodiolar course inside the cochlea and allow for a controllable end position [2]. The shape of such an "active" or "steerable" electrode array could be adapted to the individual geometry of the spiral inner ear in order to avoid any contact between the EA and the surrounding tissue—resulting in a contactless, and therefore, truly atraumatic insertion.

In the following, this article provides an overview of concepts and actuator mechanisms investigated in terms of developing a steerable electrode array for an individualized insertion process. It covers published investigations found in patents and journal articles of other researchers as well as own research projects in recent years.

***Corresponding author: Thomas S. Rau:** Department of Otolaryngology, Hannover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover, Germany, e-mail: rau.thomas@mh-hannover.de
Silke Hügl, Thomas Lenarz, Omid Majdani: Department of Otolaryngology and Cluster of Excellence "Hearing4all", Hannover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover, Germany, e-mail: huegl.silke@mh-hannover.de, lenarz.thomas@mh-hannover.de, majdani.omid@mh-hannover.de

Open Access. © 2017 Thomas S. Rau et al., published by De Gruyter. BY-NC-ND This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 License.

Bereitgestellt von | Technische Universität Ilmenau
Angemeldet
Heruntergeladen am | 22.03.19 07:54

2 Actuator mechanisms for steerable CI electrode arrays

2.1 Pulling a steering wire

An early idea for providing an electrode array that hugs the modiolus was building it in a spiral shape with a thin cord embedded in a lumen or groove at the lateral side of the EA. By gradually pulling that cord the shape of the EA can be modified between a temporary straight configuration and the spiral, its permanent shape [3–5].

This mechanism was used for one of the most advanced developments toward steerable electrodes by Zhang *et al.* A first pilot study was published in 2006 [5] using scaled up (3:1) demonstrators which were actuated by a 100 µm Kevlar thread. Today, there are prototypes adapted to the true size of the human cochlea [6]. Their development of steerable electrodes goes along with the development of a robot system for automated insertion. Using an artificial planar model of the human scala tympani insertion forces could be reduced by approx. 60% using the 3:1 scaled up electrode prototype compared with straight and unactuated electrodes.

2.2 Magnetic guidance

In 2011, a magnetic steering concept was proposed by Clark *et al.* [7]. Using an external permanent magnet the magnetic tip of a CI electrode array could be bent during insertion in order to reduce contact with the inner ear. Scaled-up (3:1) magnetically tipped implant prototypes were built and non-guided and magnetically guided insertion experiments have been compared regarding insertion forces. The authors reported reduction of the mean force magnitude up to 50%.

2.3 Shape memory alloy actuators

The ability of some materials to change between two different shapes as a result of heating (known as shape memory alloys, SMA) is another strategy to control the shape of the EA during insertion. In one embodiment there is a single SMA actuator in terms of a wire [8,9] which covers almost the entire length of the EA. Alternatively, the integration of multiple, separately controllable SMA actuators have been described [10,11]. Heating can be achieved either by body temperature [8] or by electrical resistance heating [9–11].

2.4 Tubular manipulators

Another concept for intracochlear positioning of the electrode array uses active cannulas—the smallest type of continuum manipulators developed so far—and was proposed and investigated by the authors of this article together with the Laboratory for Continuum Robotics (Leibniz Universität Hannover, head: J. Burgner-Kahrs) [12,13]. This actuator, also known as tubular manipulator, is composed of multiple precurved, elastic tubes which are nested inside each other. Its shape can be adjusted by translating and rotating the base of each tube. In our vision the tubular manipulator is moving within a lumen inside the silicone body and consists of an outer tube and an inner wire; both made of superelastic Nitinol and produced in a helical shapes.

The feasibility of the concept was investigated by use of an optimization algorithm, which automatically determined tube set parameters for an individual final position and an insertion movement close to the centreline of the given scala tympani. The maximum deviation from the optimal path (follow-the-leader error) was set to be less than 1 mm. In this initial study sufficient tube sets could be determined for 19 out of 22 human cochlea datasets.

As individual fabrication of tubular manipulators is not cost efficient it was investigated whether a reduced number of tube sets is sufficient for all cochleae too. This was possible with only 4 different tube sets. This motivating result indicates that this actuation concept enables individualization of the insertion process by individual process parameters rather than by patient-specific fabrication of the devices [13].

2.5 Fluid-mechanical actuator

Actuation of the CI's electrode can also be realized by modification of fluidic pressure inside a lumen of the silicone carrier. That idea was first mentioned by Hansen *et al.* in 1981 [3]. They considered an oval cross-section of the lumen to straighten the spiral shaped silicone tube by increasing the internal pressure. Thus, the device will have an implanted shape hugging the modiolus, but that curling can be temporarily supressed to allow for surgical insertion through the mastoid cavity and the posterior tympanotomy approach.

However, a first prototype using that concept has not been realized until more than 20 years later by Arcand *et al.* [14]. Their prototype featured three separate fluidic actuator chambers; a number of tubes which they found to provide optimal curvature control in case of a guinea pig cochlea [15]. Using these separate chambers the local curling radius

Bereitgestellt von | Technische Universität Ilmenau
Angemeldet
Heruntergeladen am | 22.03.19 07:54

of the implant can be controlled and adapted to the cochlear shape throughout the insertion process.

A comparable curling using internal fluidic pressure can be achieved by combining a lumen with circular cross-section with a non-stretchable thin fibre embedded in the wall of the silicone tube. Through modification of geometric parameters like position of the fibre and wall thickness the spiral shape of the silicone tube can be adjusted in a patient-specific manner. This idea was first presented by Zentner *et al.* in 2006 [16] and in the meantime further investigated within a joint project of the authors with the Department of Mechanism Technology (Technische Universität Ilmenau, head: L. Zentner). A model-based synthesis was developed which combines finite element method with an analytical model and allows for synthesising of individually fitted electrode carrier geometry based on the patient's shape of the inner ear [17,18]. Using finite element analysis the shape change of the implant due to pressurizing of the inner hollow will be further analysed in order to investigate whether an individual insertion process can be realized by varying the pressure instead of building a specific silicone carrier for each patient.

2.6 Summary

Most of the presented the mechanisms are integrated in the electrode array. As a consequence the overall stiffness increases in comparison to straight and flexible electrodes due to the additional components and structures required for the controlled bending. This, in turn, reinforces the necessity of a controlled movement inside the cochlear lumen to compensate the drawback of increased stiffness regarding in terms of atraumatic insertion and hearing preservation. Magnetic guidance is the only known exception, where an external magnetic field is used to bend the tip of the electrode array according to the shape of the inner ear. Although none of these concepts has reached clinical implementation, there are promising experimental results indicating that insertion forces can be halved compared to insertions with straight and not steerable electrodes.

3 Outlook on further research

Aside from the actuation mechanism there is a considerable need for further research until steerable electrodes will reach clinical applicability. First, imaging needs to be improved for individual planning of the anatomically adapted insertion process as the modalities available in clinical practices—such as computed tomography (CT), digital volume tomography (DVT), and magnetic resonance imaging (MRI)—do not provide the necessary high-resolution visualization of soft tissues. Alternatively, model-based segmentation methods may be used to supplement the insufficient clinical image data with additional information from a database containing anatomical models of the missing soft tissue structures [19,20].

Secondly, (semi-)automated planning methods need to be developed which are fast, reliable and of course adapted to the specific actuator mechanism. As time is a crucial factor for clinical implementation, there is only a small time slot of a few minutes within clinical routine for the complete process; including loading of the patient's image data, calculation of the ideal path and the actuation parameters, and finally the verification by the surgeon (and if necessary manual adjustment). The corresponding graphical user interface of the planning software needs to be easy and intuitive to use, requires a pleasing design and should allow the physician to carry out the planning efficiently and effectively.

Thirdly, highly accurate intracochlear movement of the electrode array is only expedient and feasible if a just as accurate positioning device is incorporated in the surgical workflow which carries the corresponding tools for an automated insertion procedure. Microstereotactic frames [21] as well as surgical robot systems [22]—which could fulfil that task—are currently under development; however they still have to prove their clinical suitability.

Fourthly, preoperative planning of the insertion process requires high reproducibility of the pre-planned movement of the electrode array. So far, fabrication of the intracochlear devices includes a large amount of handmade production techniques. These cause remarkable variability in the mechanical properties of the electrode arrays, especially regarding the curling behaviour [23,2] making it less predictable. This is contradictorily to an accurate precursory planning and may be overcome by a higher degree of automated fabrication methods like batch-processing using thin-film techniques.

Fifthly, more fundamental research is necessary for a deeper understanding of the trauma mechanisms and the strength properties of the intracochlear tissues. This is required to estimate tolerable contact forces and therefore tolerable deviations from the ideal path. The latter enables the assessment of the safety of a new concept for steerable electrode insertion if a contactless movement of the implant inside the cochlear lumen cannot be guaranteed for all patients.

Bereitgestellt von | Technische Universität Ilmenau
Angemeldet
Heruntergeladen am | 22.03.19 07:54

Sixthly, to enable a high safety level for the patient, the intracochlear movement of an active electrode array should be controlled by at least one sensory system. Therefore, there is a demand for the development of suitable force or position sensors small enough to be integrated into the electrode array without adverse alteration of their mechanical properties. These sensors may allow for an implementation of a closed loop control in case of an automated insertion process or for providing force feedback in case of semi-automated approaches.

4 Conclusion

Although multiple concepts have been described and motivating results with first prototypes have been achieved, there is still a long way to go until steerable EA for cochlear implants may reach clinical implementation. Beside further improvements on the actuator mechanism itself, there is a considerable need for further research in associated topics until a fully automated and controlled insertion of the EA into the cochlea in a patient-specific manner leads to improvement in hearing preservation and better outcome for the CI patient.

Acknowledgment
We gratefully acknowledge our collaborators: J. Burgner-Kahrs and J. Granna (both Laboratory for Continuum Robotics at Leibniz Universität Hannover, Germany); L. Zentner and S. Griebel (both Department of Mechanism Technology at Technische Universität Ilmenau, Germany); N. Pawsey (Cochlear Ltd., Sydney, Australia); G. Sedlmayr (G.RAU GmbH & Co. KG, Pforzheim, Germany); S. Dudziak and R. Hagemann (both Laser Zentrum Hannover e.V., Germany).

Author's Statement
Research funding: The presented work was supported by the German Federal Ministry of Education and Research (award numbers 01 EZ 0832, 16SV3943) and the German Research Foundation (MA 4038/9-1, RA 2751/1-1, Cluster of Excellence "Hearing4All"). Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent is not applicable.Ethical approval: The conducted research is not related to either human or animals use.

References

[1] Von Ilberg C a., Baumann U, Kiefer J, Tillein J, Adunka OF. Electric-acoustic stimulation of the auditory system: A review of the first decade. Audiol Neurotol 2011;16:1–30.

[2] Rau TS, Lenarz T, Majdani O. Individual Optimization of the Insertion of a Preformed Cochlear Implant Electrode Array. Int J Otolaryngol 2015;Vol. 2015:1–22.

[3] Hansen CC, Lauridsen OM. Electrode for implantation into the cochlea. US Patent 4,284,085, 1981.

[4] Kuzma JA. Cochlear Electrode Array With Positioning Stylet. US 6,119,044, 2000.

[5] Zhang J, Xu K, Simaan N, Manolidis S. A Pilot Study of Robot-Assisted Cochlear Implant Surgery Using Steerable Electrode Arrays. MICCAI 2006;9:33–40.

[6] Zhang J, Simaan N. Design of Underactuated Steerable Electrode Arrays for Optimal Insertions. J Mech Robot 2013;5:11008.

[7] Clark JR, Leon L, Warren FM, Abbott JJ. Investigation of magnetic guidance of cochlear implants. IEEE Int Conf Intell Robot Syst 2011:1321–6.

[8] Rau TS, Harbach L, Pawsey N, Kluge M, Erfurt P, Lenarz T, et al. Insertion trauma of a cochlear implant electrode array with Nitinol inlay. Eur Arch Oto-Rhino-Laryngology 2016;273:3573–85.

[9] Min KS, Jun SB, Lim YS, Park S-I, Kim SJ. Modiolus-hugging intracochlear electrode array with shape memory alloy. Comput Math Methods Med 2013;2013:250915.

[10] Chen B, Kha H, Clark G. Development of a steerable cochlear implant electrode array. 3rd Kuala Lumpur Int Conf Biomed Eng 2007;15:607–10.

[11] Hagemann R, Noelke C, Rau T, Kaierle S, Overmeyer L, Wesling V, et al. Design , processing , and characterization of nickel titanium micro-actuators for medical implants. J Laser Appl 2015;27:S29203.

[12] Rau TS, Granna J, Lenarz T, Majdani O, Burgner-Kahrs J. Tubular manipulators: a new concept for intracochlear positioning of an auditory prosthesis. Curr Dir Biomed Eng 2015;1:515–8.

[13] Granna J, Rau TS, Nguyen T-D, Lenarz T, Majdani O, Burgner-Kahrs J. Toward automated cochlear implant insertion using tubular manipulators. Proc SPIE Med Imaging 2016:8.

[14] Arcand BY, Bhatti PT, Butala N V., Wang J, Friedrich CR, Wise KD. Active positioning device for a perimodiolar cochlear electrode array. Microsyst Techn 2004;10:478–83.

[15] Arcand B, Shyamsunder S, Friedrich C. A Fluid Actuator for Thin-Film Electrodes. J Med Device 2007;1:70.

[16] Zentner L, Keskeny J, Westhofen M, Huba A. Hydraulic actuation for the navigation of a cochlear implant. 10th Int. Conf. New Actuators, Bremen, 2006.

[17] Hügl S, Griebel S, Zentner L, Lenarz T, Majdani O, Rau TS. Analysis of Fluid-Actuated Cochlear Implant Electrode-Carrier. Comput Aided Med Eng 2016;7:23–6.

[18] Zentner L, Griebel S, Wystup C, Hügl S, Rau TS, Majdani O. Synthesis process of a compliant fluidmechanical actuator for use as an adaptive electrode carrier for cochlear implants. Mech Mach Theory 2017;112:155–71.

[19] Noble JH, Rutherford RB, Labadie RF, Majdani O, Dawant BM. Modeling and segmentation of intra-cochlear anatomy in conventional CT. Proc SPIE 7623, Med Imaging 2010 Image Process 762302 2010;7623:762302.

[20] Sarvazyan A. Model-based imaging. Ultrasound Med Biol 2006;32:1713–20. doi:10.1016/j.ultrasmedbio.2006.05.016.

[21] Labadie RF, Balachandran R, Noble JH, Blachon GS, Mitchell JE, Reda F a., et al. Minimally invasive image-

Bereitgestellt von | Technische Universität Ilmenau
Angemeldet
Heruntergeladen am | 22.03.19 07:54

guided cochlear implantation surgery: First report of clinical implementation. Laryngoscope 2014;124:1915–22.

[22] Weber S, Gavaghan K, Wimmer W, Williamson T, Gerber N, Anso J, et al. Instrument flight to the inner ear. Sci Robot 2017;2:eaal4916.

[23] Rau TS, Majdani O, Hussong A, Lenarz T, Leinung M. Determination of the curling behavior of a preformed cochlear implant electrode array. Int J Comput Assist Radiol Surg 2011;6:421–33.

Bereitgestellt von | Technische Universität Ilmenau
Angemeldet
Heruntergeladen am | 22.03.19 07:54