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Identification of factors influencing insertion characteristics of cochlear implant electrode carriers

Abstract: Insertion studies in artificial cochlea models (aCM) are used for the analysis of insertion characteristics of different cochlear implant electrode carrier (EC) designs by measuring insertion forces. These forces are summed forces due to the measuring position which is directly underneath the aCM. The current hypothesis is that they include dynamic friction forces during the insertion process and the forces needed to bend an initially straight EC into the curved form of the aCM.

For the purposes of the present study, straight EC substitutes with a constant diameter of 0.7 mm and 20.5 mm intra-cochlear length were fabricated out of silicone in two versions with different stiffness by varying the number of embedded wires. The EC substitutes were inserted into three different models made of polytetrafluoroethylene (PTFE), each model showing only one constant radius. Three different insertion speeds were used (0.11 / 0.4 / 1.6 mm/s) with an automated insertion test bench. For each parameter combination (curvature, speed, stiffness) twelve insertions were conducted. Measurements included six full insertions and six paused insertions. Paused insertions include a ten second paused time interval without further insertion movement each five millimetres.

Measurements showed that dynamic and static components of the measured summed forces can be identified. Dynamic force components increase with increased insertion speeds and also with increased stiffness of the EC substitutes. Both force components decrease with larger radius of the PTFE model. After the insertion, the EC substitutes showed a curved shape, which indicates a plastic deformation of the embedded wires due to the insertion into the curved models.

The results can be used for further research on an analytical model to predict the insertions forces of a specific combination of selected parameters as insertion speed and type of EC, combined with given factors such as cochlear geometry.

Keywords: insertion force, insertion speed, cochlear model.

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1 Motivation

Cochlear implant (CI) systems are the standard therapy for patients with severe to profound hearing loss. A CI system comprises the external part, worn behind the ear, and the internal part, which has to be implanted. During that surgery the silicone electrode carrier (EC) has to be inserted into the spiral organ of the cochlea. In order to preserve the delicate soft and bony tissue structures of the inner ear the insertion needs to be conducted very carefully.

In-vitro test bench setups are used to identify different factors that influence the insertion characteristics [1-3]. In order to compare different parameters the insertion force, measured as a summed force profile directly underneath a cochlear model mounted within the test bench serves as the characteristic value. Post-experimental evaluation of measured insertion force profiles is used to evaluate different designs or insertion techniques. One of the next research aims is to provide pre-experimental predictions of these profiles using analytical models based on an improved knowledge about factors impacting the insertion forces.

The aim of the presented study was to provide more insight into the influences on insertion forces by reducing the complexity of the components used: samples (EC substitutes) with a constant diameter and cochlear models with a constant radius.

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2 Material and methods

2.1 Sample preparation

For the purposes of the present study, samples to substitute a commercial EC were fabricated. In order to provide a constant stiffness of the sample from base to tip over the whole sample length of 20.5 mm, the diameter was set to a constant value of 0.7 mm (see Figure 1). The variation of the stiffness of the sample was implemented due to different numbers of embedded bare copper wires of each 0.07 mm diameter (four / six wires). A two-component silicone for room temperature cure was used (Sylgard 184, Dow, Barry, UK). The preparation protocol, including mixing of the silicone, degassing, preparing the mould, injection of the silicone and curing, was previously described in detail [1-2].

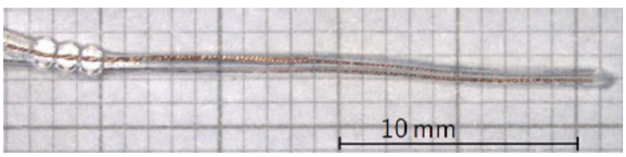

Figure 1: Fabricated straight EA substitutes.

2.2 Cochlear model preparation

The models, into which the samples were inserted, were manufactured from PTFE. In order to provide a constant model geometry the fabricated models were simplified compared to previously used planar cochlear models [1-2]. Each model was designed with another radius (r = 6.4 / 8.5 / 12.7 mm, see Figure 2), which corresponds ideally to an insertion of 180 °, 135 ° and 90 ° with the fabricated EC substitutes.

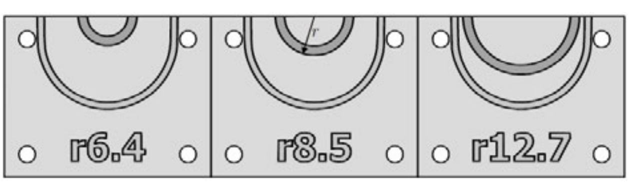

Figure 2: Fabricated models, each with another radius (r). The second path, which is identical for each model, is a narrow notch to apply a sealing material.

2.3 Test bench setup

The used test bench setup comprised a motorized linear actuator (LTM-80M-270, Owis GmbH, Staufen, Germany) for smooth insertion of the samples and for the possibility to set a certain insertion speed (0.11 / 0.4 / 1.6 mm/s). The models were mounted on top of a force sensor (K3D35, ME-Meßsysteme GmbH, Hennigsdorf, Germany; 0.5 N nominal force, accuracy class 2%) [1-2]. Each insertion was documented by a microscopic camera (DINO-Lite).

2.4 Insertion protocol

Each model was filled with saline solution (NaCl 0.9%) and supplied with a sealing between the PTFE model and the acrylic glass disk to decrease fluid loss during insertion. Measurements included six full insertions and six paused insertions (see Table 1). Paused insertions included a ten second time interval without further insertion movement each five millimetres of progressing insertion depth. The insertion depth for a full insertion was 20 mm.

Table 1: Insertion protocol for six EC substitutes (EC subst.) showing the insertion (ins.) order for models and continuous (cont.) and paused insertions. This protocol was conducted three times (each with another speed) for both stiffness variations (four / six wires).

EC subst.	model 1 cont. / paused		model 2 cont. / paused		model 3 cont. / paused	
1	ins. 1	2	3	4	5	6
2	6	1	2	3	4	5
3	5	6	1	2	3	4
4	4	5	6	1	2	3
5	3	4	5	6	1	2
6	2	3	4	5	6	1

3 Results

In total, 216 insertions using 36 EC substitutes (each 18 samples per stiffness) were successfully conducted.

Measurements showed that, based on theory, the pre-experimentally expected dynamic and static components of the measured summed forces can be differentiated based on the measured insertion force profile. Dynamic force components increase with increased insertion speeds and also with increased stiffness of the EC substitutes. Furthermore, dynamic force components decrease with larger radius of the PTFE model.

After the insertion, the EC substitutes showed a curved shape, which indicates a plastic deformation of the embedded wires through the insertion into the curved models. That is in congruence to the analysis of insertion forces in paused and continuous insertion mode. The insertion forces measured during paused time intervals showed no clear dependence on the sample stiffness, which, in turn, would have been expected in the case of mostly elastic deformation.

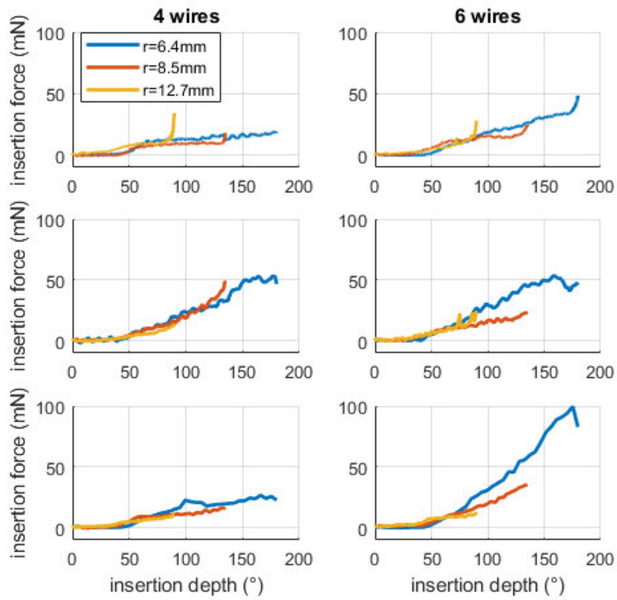

Figure 3: Insertion forces measured with sample comprising 4 (left column) and 6 wires (right column) inserted with insertion speeds of 0.11, 0.4 and 1.6 mm/s (corresponding to first, second and third row). The shown insertion forces are mean values of n=6 insertions each.

Apart from that, the measured insertion forces during paused time intervals showed a clear (negative) dependence on the model radius. These force components decrease with larger radius of the PTFE model.

Comparing all force profiles along the angular insertion depth (see Figure 3) the single force profiles start to differ from each other upon 90 ° insertion depth. That corresponds to the point from which on the sample finally moved with a full surface contact deeper into the model, which was analysed within the video documentation of each insertion. In the first part of insertion, between 0 ° and 90 °, the samples only had point contacts with the wall of the models.

4 Discussion

Based on the results, further insight into the formation of insertion forces might be identifiable by a place-dependent measurement of insertion forces. It is observed that the contact mode of the sample within the model is an important factor. These results would need to be considered within a future analytical model. Such a model could provide pre-experimental predictions of insertion force profiles, based on input parameters like EC design, geometry of the cochlear model and its fluid filling. Further mechanical parameters, e.g. the friction coefficient of silicone and PTFE lubricated by the fluids used for the filling of the model, need to be determined within further experiments.

Author Statement

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Conflict of interest: Authors state no conflict of interest.

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