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ORIGINAL ARTICLE

Automated insertion of preformed cochlear implant electrodes: evaluation of curling behaviour and insertion forces on an artificial cochlear model

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Abstract

Purpose As a substantial part of our concept of a minimally invasive cochlear implant (CI) surgery, we developed an automated insertion tool. Studies on an artificial scala tympani model were performed in order to evaluate force application when using the insertion tool.

Methods Contour electrodes were automatically inserted into a transparent cochlea model in Advance Off-Stylet technique. Occurring forces were measured by the use of a load cell and correlated with observed intracochlear movement of the electrode carriers.

Results Mean insertion forces were measured up to 20 mN comparable to previous studies on temporal bones. The most influencing factor is the implant's 2D curling behaviour in comparison to the 3D helical shape of the cochlea.

Conclusion The study confirms the functionality and reliability of the automated insertion tool for insertion of preformed CI. Improved insertion strategies considering patient-specific anatomy become possible.

Keywords Cochlear implant · Automated insertion tool · Minimally invasive surgery · Intracochlear force · Force measurement

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Introduction

Cochlear implants (CI) are electronic devices which are implanted into the inner ear (cochlea) to bypass the missing or defect sensory receptors by directly stimulating the auditory nerve. The complete cochlear implant system consists of a microphone, a speech processor, and an external transmitter as well as the implanted receiver and electrode array. The latter is inserted into the scala tympani, one of three fluid-filled compartments inside the cochlea separated from the others only by a fine membranous layer. In normal hearing the sound correlated motion of this layer, called basilar membrane, is sensed by the inner hair cells which are located at the top of this membrane and generate neural activities. Damage to or missing of these fragile hair cells causes hearing loss or deafness.

In the mid-1960s, clinical research on these devices began, motivated by the reserved hope to help a couple of patients to achieve an auditory impression of environmental sounds [1]. Due to technical and surgical improvements to preserve the patients' residual hearing during implantation, the use of cochlear implants recently has been introduced even for patients with severe hearing loss and some residual hearing. In contrast, only marginal increases in word discrimination could be achieved at these patients through conventional hearing aids [2,3]. New technology of combined electrical and acoustic stimulation (EAS) allows amplifying the residual hearing using a hearing aid and simultaneously providing electrical stimulation of the cochlear nerve. This strategy is mainly applicable to patients having only moderate-to-severe loss in the low frequencies [4–9]. For this strategy it is essential not to harm the intracochlear anatomical substructures during the insertion process to preserve the residual hearing.

Unfortunately, conventional cochlear implant surgery often results in the loss of all natural residual hearing in the implanted ear. Mechanisms operatively caused traumas are extensively described in literature [2,3,10–17]. They can be subdivided into two main categories: Traumas caused by (a) cochleostomy (the opening of the cochlea) and (b) by the insertion of the electrode into the scala tympani.

Therefore, a first step towards atraumatic CI surgery is the accurate positioning of the cochleostomy [3,11–14,18] located anterior inferior to the round window to avoid damages to the basilar membrane and to provide a tangential insertion path for the electrode carrier. A second step is to avoid harmful contact of the electrode to the limitative, membranous structures while inserting the electrode into the scala tympani. Since position and orientation of the most part of the cochlea as well as the position of the advanced electrode are not exposed to the surgeon during the operation the insertion of the implant is performed without any visual feedback. To receive more reliable information on the intraoperative position of the cochlea image-guided surgery technique (IGS, navigation system) and robot assistance were proven and tested in recent years.

The aim of several studies recently published was to decrease the overall surgical trauma by applying minimally invasive approaches [19–23] particularly based on robot-assisted devices [24–27] or bone-mounted customized drill guides [28,29] to perform a percutaneous access to the cochlea. Both concepts are based on drilling a canal from the surface of the skull (mastoid) to the cochlea. Once the small access to the cochlea is drilled a special insertion tool is necessary to insert the electrode into the scala tympani. To overcome this technical limitation our group developed a mechatronical insertion tool [30] for a controlled implantation of the electrode array. To analyze the insertion process and the occurring forces while using the insertion tool we performed studies on a cochlear model with Contour Advance electrodes (Cochlear Ltd., Sydney, Australia). This type of cochlear implant electrode is precurled for an optimised insertion in the scala tympani and for perimodiolar positioning.

Perimodiolar positioning of the CI electrode shall provide the shortest distance between the active electrodes of the array and the cochlear nerve in the central axis of the cochlea (modiolus). The hearing results of patients having a perimodiolar electrode array are shown to be better than those of patients with straight electrodes [31]. Together with the finding that straight electrodes cause trauma by force against the outer wall the aim of current research is the reliable perimodiolar and atraumatic insertion [32].

In recent years, numerous studies were carried out on the insertion behaviour of cochlear implant electrodes to characterise the advantages and disadvantages of different concepts. Besides preformed electrode carriers as e.g. the Contour Advance electrode (Cochlear Ltd.) or the C40+ array (MED-EL, Innsbruck, Austria) also new more flexible implants were used which should reduce the risk of intraoperative hearing loss by a lower stiffness and thus decrease insertion trauma. However, because of their straight design these implants do not achieve a perimodiolar position. Electrode carriers which combine the advantages of high flexibility and perimodiolar placement are not yet available.

Fig. 1 Contour Advance electrode (Cochlear Ltd.) with soft tip is a preformed electrode carrier pre-operatively straightened by a platinum wire (stylet). A white marker (*white arrow*) and ribs at the end of the electrode carrier (*black arrow*) give orientation for the surgeon during insertion. A loop at the end of stylet allows coupling to the insertion tool

The design of our insertion tool was exemplarily adapted for the Contour Advance electrode (see Fig. 1). The electrode carrier is fabricated in a precurled configuration based on size and shape of an average scala tympani and is equipped with a special soft tip to minimize risk of tip foldover. It is held in straight position prior to the insertion with a platinum wire stylet. By withdrawing the stylet the electrode returns to its precurled state. For implantation the electrode carrier with the stylet inside is inserted until its tip reaches near the back of the basal turn. This position is visualised by a white marker on the silicone carrier which delineates the starting point of stylet retraction when the marker is aligned with cochleostomy site. Then the stylet is held in place and the silicone electrode carrier is pushed off the stylet further into the cochlea. Hence, the distal part of the electrode will follow the round curvature of the inner wall due to its precurled shape. This method is called Advance Off-Stylet (AOS) technique [33]. The insertion tool presented here was designed to realize this technique which is usually performed by an experienced surgeon (Fig. 2).

Materials and methods

Artificial cochlear model and electrodes

A transparent, artificial model of the scala tympani (MED-EL, Innsbruck, Austria) was utilised in this study to achieve standardised conditions of the experimental setup with equal frictional and geometrical conditions for all tests. The scala tympani phantom is made of acrylic glass which facilitates the monitoring and documentation of the coiling behaviour of the electrodes during insertion (see Fig. 3).

The geometrical shape of the scala tympani as well as the position and size of the cochleostomy in the model are based

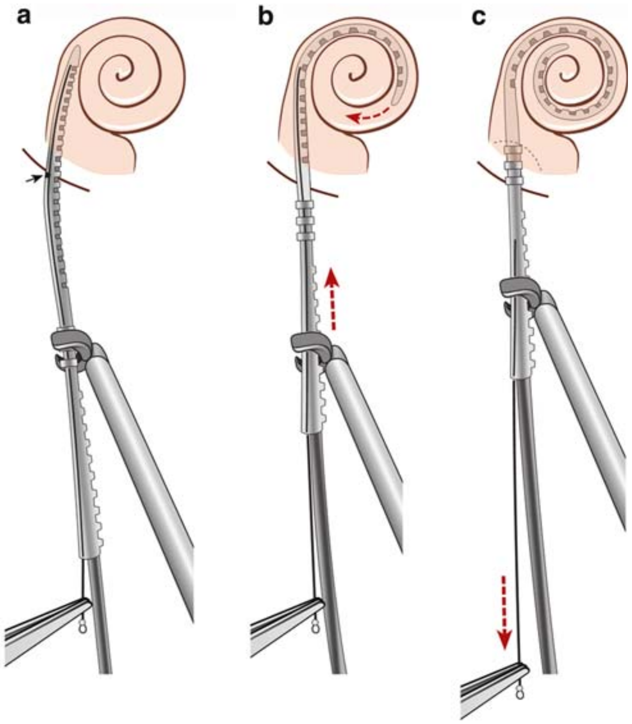


Fig. 2 Advance Off-Stylet (AOS) insertion technique for Contour Advance electrode array. Step one (**a**) is the insertion of the electrode until a white marker (*black arrow*) reaches cochleostomy site. **b** AOS insertion by holding the stylet stationary while advancing the electrode carrier off the stylet until the ribs are at the cochleostomy (image provided by courtesy of Karl STORZ, Tuttlingen, Germany)

on the average size of an adult human cochlea. To achieve a good approximation of the frictional conditions within the cochlea by lubrication and a reduced friction coefficient, the cavity of the model was filled with glycerine.

Five Contour Advance electrodes were used for this study. Following each insertion the silicone carrier was uncurled using a special tool offered by Cochlear Ltd. to replace the stylet with the aid of tweezers. Afterwards, the implant was carefully straightened manually. Each electrode was used for up to five insertion studies.

Insertion tool

The automated insertion tool consists of two separately controllable gearless piezoelectrical linear drives with a travel range of 45 mm, a maximum velocity of 5 mm/s and a position accuracy of 1 µm (SmarAct GmbH, Oldenburg, Germany). The first drive is directly connected to a forceps for the grabbing of the electrode carrier. A protective shielding in the form of a u-tube is placed around this forceps to protect electrode and grasping mechanism during the insertion process. An additional motor is attached to a long hook connected to the stylet which thus can be withdrawn or kept in the desired position [30].

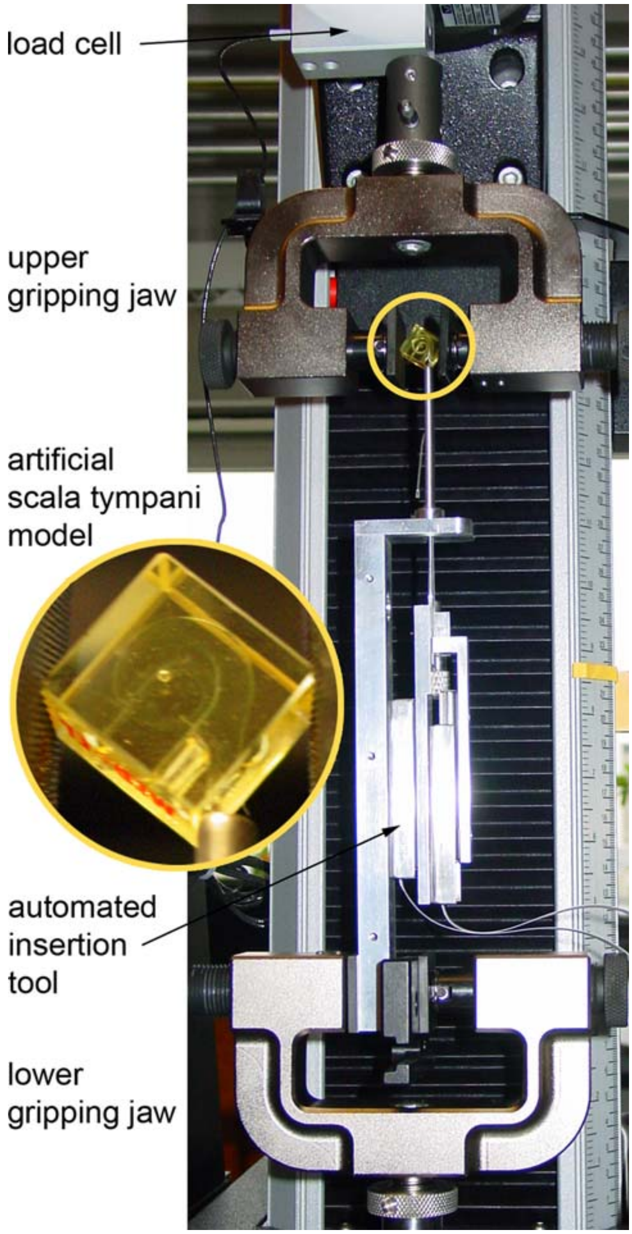


Fig. 3 Experimental setup. An Instron System was used to measure insertion forces. Implant motion and withdrawing of the stylet were realized by the automated insertion tool fixed in the lower jaw. Above, the artificial scala tympani model (see embedded close-up) was fixed in the second jaw connected to the load cell

Force measurement device

During the insertion process the force applied on the model was recorded by a calibrated Instron 5542 Force Measurement System (Instron Deutschland GmbH, Pfungstadt, Germany) equipped with a 10 N load cell. The device was connected to a computer running the measurement software Bluehill Version 2.9 (Instron). The artificial cochlear model was fixed in the upper gripping jaw which was connected to the load cell. Instead of a linear movement of the traverse

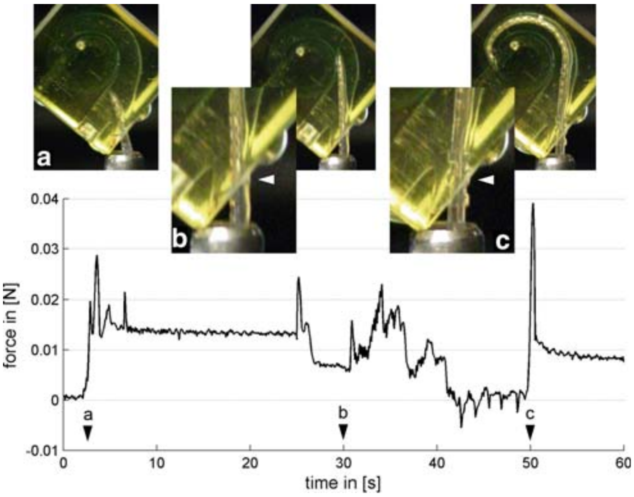


Fig. 4 According to the Advance Off-Stylet insertion technique implant and stylet were moved and corresponding forces were recorded. The force chart is highlighted with the appropriate images of the intracochlear electrode position. Position (**b**) indicates the point where the electrode begins to advance off the stylet. Insertion was finished after 10 mm (20 s if inserted with 0.5 mm/s), which conforms to the recommended insertion depth marked by the ribs (*white arrow* in **c**)

the feed motion of the implant was realised by the insertion tool. Thus, the load cell was immobile and measurement was not influenced by dynamic forces and vibrations. The insertion tool was fixed in the lower gripping jaw (see Fig. 3) according to the direction of the basal turn of the scala tympani model to allow a tangential advance of the electrode. The custom-made control software for the insertion tool was running on a second computer.

Insertion process

The first step of the insertion process was positioning the tip of the electrode right underneath the cochleostomy site and adjusting the electrode tangentially to the basal turn of the scala tympani model with high accuracy. As recommended for the Advance Off-Stylet insertion technique the implant was inserted until the white marker was aligned with the cochleostomy site of the cochlear model. This motion was realized by 1 mm steps at the beginning and by 0.1 mm steps with increasing insertion depth. During the following AOS mode a synchronous implant feed and a stylet withdrawal were applied for keeping the stylet stationary while the electrode was inserted by advancing it off the stylet. Thus, the implant started curling from the tip according to the preformed shape. The AOS technique was realized by the controlled actuation of both linear drivers at a velocity between 0.3 and 0.5 mm/s. The electrode was inserted additional 10 mm with this technique.

Applied forces during insertion were recorded at 100 Hz (10-ms interval) by the load cell. The insertion was permanently visually observed and digital photographs were taken.

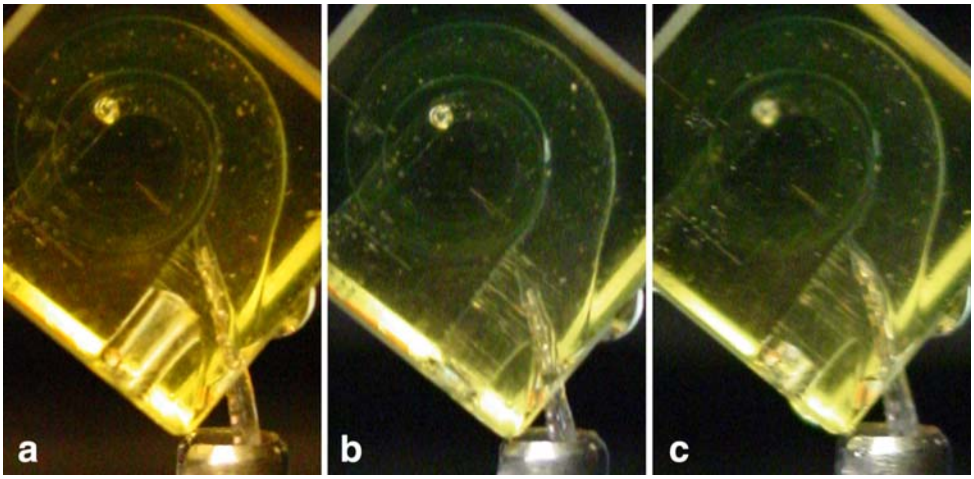
Results

In total, 20 insertions were performed with five Contour Advance electrodes. In 19 cases, the insertion forces applied on the model were successfully recorded, as represented in Fig. 4. In one case, data were not saved because of a failure in the recording software although the insertion was visually rated as normal. Six insertions were performed with 0.3 mm/s, further two with 0.4 mm/s feed rate, and most of them (11 insertions) were run at 0.5 mm/s. To allow comparison of the different feed rate results, the applied forces were plotted against insertion depth.

Insertion trajectory and electrode behaviour

During the first phase of insertion (prior to AOS) all implants touched the inner wall of the basal turn shortly after entering the cochlear lumen (see Fig. 5), which resulted in measur-

Fig. 5 First contact of the soft tip with the medial wall shortly after passing the cochleostomy site. **a** and **b** show the initial configuration of brand new implants. **c** displays the third insertion of the same electrode as in **b**



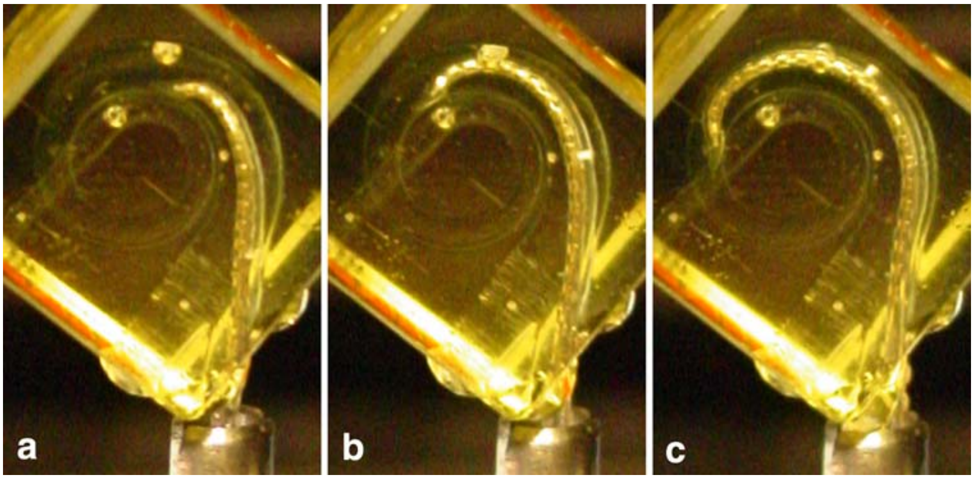


Fig. 6 Stepwise movement of the tip along the inner wall. Due to the sharp bend behind the soft tip it apparently gets stuck and causes a buckling of more proximal parts of the electrode carrier toward the outer wall. With increasing tension inside the silicone body the electrode pushes forward

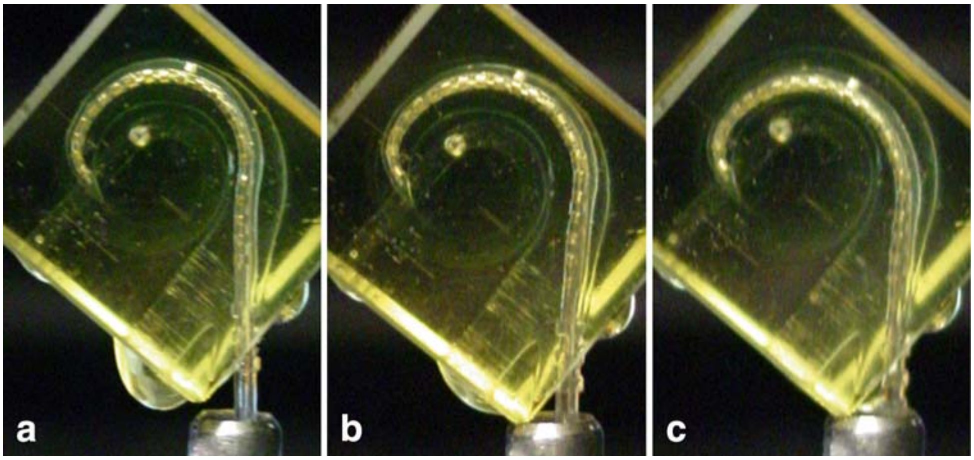


Fig. 7 End position of electrode carriers. **a** Proximal part of electrode carrier next to the modiolar wall of cochlea but more distal part with lateral position. **b** Completely lateral position of the implant. Pullback of the same electrode of approximately one rib causes modiolar end position (**c**)

able force values between implant and cochlear model. This is due to the inadequate straightening of the implants in the starting configuration with stylet inside and can be observed in all trails regardless of whether the stylet was withdrawn for the first time or was already reloaded and the electrode carrier straightened by hand. It was not possible to avoid the contact between implant tip and inner wall by repositioning the electrode or phantom due to the restricted size of the cochleostomy. Otherwise, high friction forces between the edge of the cochleostomy and the silicone carrier would appear.

During the second phase of insertion (AOS) the tip of the electrode continued to have further contact with the modiolar wall of the scala tympani whereas the more proximal part of the electrode veered toward the outer wall (see Fig. 6). The reason for this seems to be the sharp bend in the progress of the electrode bending behind the tip after partial withdrawal of the stylet. Observing the insertion process it became obvious that the electrode's movement in the cochlea model was not smooth in any case. Instead, the tip moved step-by-step along the inner wall.

The lateral position of the electrode carrier remained during the whole insertion process, even in its final position. After finishing the AOS technique most electrodes were positioned at the outer wall of the scala model. In 17 cases, digital images of the final position are available (Fig. 7). 11 (65 %) showed a completely lateral position of the electrode carrier. After 6 insertions (35%) at least the basal part of the electrode carrier was located near the inner wall. Pulling the electrode back for approximately 1 mm produces a more general modiolar end position.

In 5 out of the 19 cases tip foldovers were encountered in the first phase of insertion (prior to the AOS movement). In one case the tip foldover persisted and the measurement had to be aborted. In four cases the implant's soft tip automatically returned to its regular position during further progress of the feed motion without any intervention (see Fig. 8). During the second phase of insertion (AOS movement) no tip foldover was recorded. Our data gave no evidence that the foldover is caused by reloading the implant since the irreversible foldover appeared in a test with an unused silicone carrier.

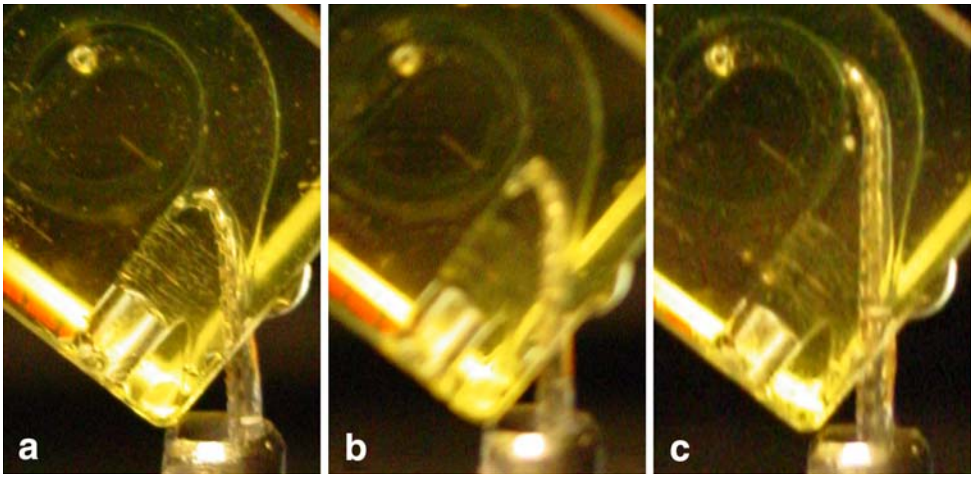


Fig. 8 Temporary soft tip foldover in the basal turn of the cochlear lumen. In the observed cases the electrode automatically returned to its regular configuration without any necessary intervention

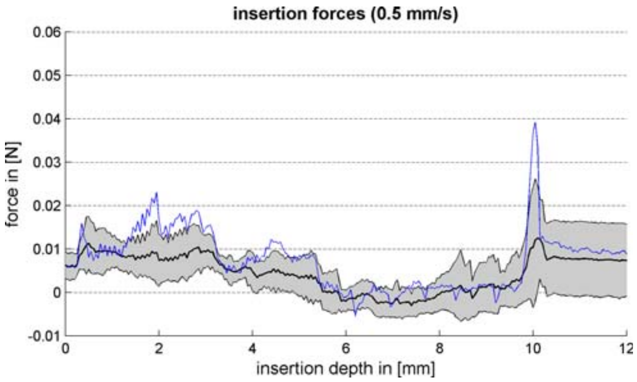


Fig. 9 Mean value (*bold black line*) and standard deviation (*grey range*) of applied forces against insertion depth measured from the beginning of the AOS technique if inserted with 0.5 mm/s. Additionally, the force profile with the highest peak value is plotted (*thin blue line*)

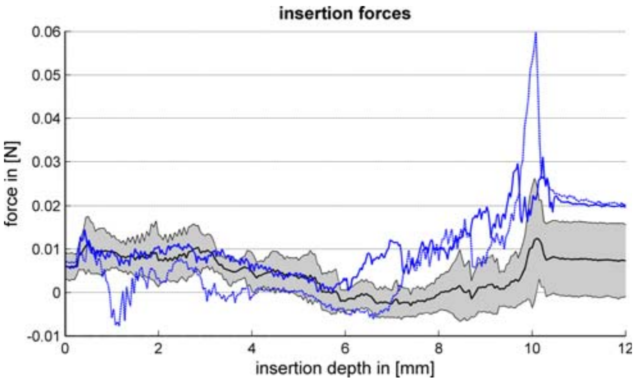


Fig. 10 Mean force profiles for an insertion with 0.3 mm/s (*blue solid line*) and 0.4 mm/s (*blue dashed line*) in comparison with insertion force values of 0.5 mm/s feed speed of implant advancement (*black line* mean value, *grey range* standard deviation)

Insertion force

All insertions showed a typical pattern of the force against insertion depth diagram, clearly indicating the different steps of insertion (see Fig. 4). Peaks during the first phase of insertion correlate with the observed contact of the electrode tip with the inner wall and its erratic non-uniform advancement.

During the second phase (AOS) the plots also reflect the observed stepwise advancement of the electrode caused by the contact of the soft tip with the inner wall and the resulting friction forces. A closer look on the AOS-technique (Fig. 9) shows well the repeatability of insertion behaviour and similar values for the applied forces. Absolute values of measured insertion forces of the cases driven with 0.5 mm/s insertion velocity ranged up to 23 mN. Additionally, peak forces up to 40 mN were measured at the end of the AOS movement. These forces even remained after the end of the electrode movement.

In comparison to the mean value of insertion progress with 0.5 mm/s velocity the measured insertion forces showed higher values if the implants were inserted with lower velocity (see Fig. 10). Admittedly, these data are based on only few series because two of the insertions with 0.3 mm/s were excluded from the study. This is due to the dramatically changing results if an irreversible soft tip foldover appears. In this case the measured forces increase over 200 mN which prompted us to stop the further advancement of the implant. Two further insertions with the same implant after reloading also showed high values of insertion forces up to 92 mN. Owing to the obvious deterioration of the electrode carrier these data were excluded from the study.

In four cases a temporary foldover of the electrode's tip occurred during the initial phase of insertion. In these cases the measured insertion forces rose up to 117 mN (mean 60 mN, SD 35 mN). In the further progress of these insertions applied insertion forces (period of AOS technique) showed comparable values to a normally proceeded implant forwarding. However these data suggest that temporary soft tip foldover leads to higher stress peaks (Fig. 11).

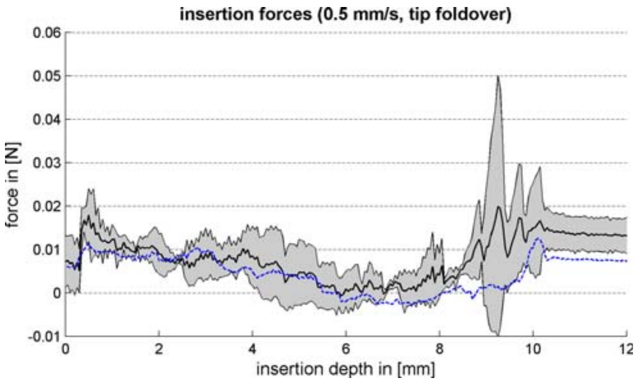


Fig. 11 Mean value (*bold black line*) and standard deviation (*grey range*) of applied forces against insertion depth measured from the beginning of AOS technique if soft tip foldover happened previously. Additionally, the mean value of the insertions without previous soft tip foldover is plotted (*dashed line*)

Discussion

During the past two decades many advances in the development of cochlear implants were achieved resulting in continuously improving treatment of deafness and severe to profound hearing loss. Thus, patients treated with modern implants can achieve speech understanding as the most important step to social reintegration. For many years the residual hearing of these patients was not considered worth preserving because the results of those patients treated with CI were much better than any amplification of their residual hearing capacity with conventional hearing aids. Furthermore, hybrid speech processors for simultaneous stimulation of the cochlear nerve via CI in combination with conventional hearing aids were not available. Recent outcomes in the context of "soft surgery technique" [2,34,35] motivate further investigations towards the combined electrical and acoustic stimulation [4,6,9].

However, it should not be concluded from these motivating results that current "soft surgery" safely assures the preservation of residual hearing. These surgical challenges were investigated in numerous studies [34,36–38] showing a strong fluctuation in the success rate. The range of reported complete preservation of residual hearing varies from 26% [34] to 39% [38]. This underlines the importance of further improvement of the surgical procedure.

The surgical clue for preservation of residual hearing is minimizing intraoperatively caused trauma to the cochlea. Therefore, the cochleostomy needs to be placed correctly to avoid damage to the membranous structures inside the cochlea by the drilling process. Additionally, lesions during insertion of the electrode carrier should be prevented. To achieve the latter we developed an automated insertion tool for a controlled insertion of the electrode array into the scala tympani. Using intraoperative image-guided systems (also called intraoperative navigation) either exclusively or in combination with a robot-assisted device the tool can be placed in the correct position according to the patient-specific location and orientation of the cochlea. Therefore, the curling behaviour of the electrode array can be adapted to the individual shape of the cochlear and thus trauma to the functional inner ear structures can be minimized. This aspect was taken into account during this study by using a translucent model in which the orientation and dimension of the scala tympani was visible. The alignment of the insertion tool to the basal turn of the cochlea could be performed manually based on visual observation. In a surgical setup image guidance or mechatronical assistance would be recommended.

Albeit temporal bone studies are closer to surgical reality, studies on transparent models allow investigations which otherwise would not be easy to implement. Using a transparent model of the scala tymani it was possible to observe the coiling behaviour of the electrode while withdrawing the stylet. Since additionally the insertion forces were recorded both aspects could be correlated. Furthermore, the now available automated insertion tool allows the repeatable testing of arbitrary insertion techniques under constant conditions irrespective of the dexterity of the surgeon. These steps toward standardisation of test conditions in our laboratory allow comparing future experimental results with different electrode designs and insertion strategies.

Force measurements were performed during the insertion of the electrode into the cochlea model to identify the critical steps of the insertion process. The results of our force measurement correlate well with the current literature including both studies on artificial cochlear models and studies performed on temporal bones. Beside investigations on new prototype electrode arrays of MED-EL implants in comparison to the regular C40+ carrier [10,39] two other published studies deal with Contour Advance electrodes. Roland et al. [32] evaluated the applied forces while inserting the Contour Advance electrode with the Advance Off-Stylet technique versus the standard insertion techniques. Thereby insertion forces were measured in a standard PTFE cochlear model as well as in fresh formalin-fixed temporal bone using Instron 5543 Universal Force Measurement System equipped with a 50 N load cell. Soap solution was used as a lubricant to approximate the frictional behaviour of the intracochlear environment. This study revealed that the AOS technique constitutes a significant improvement in insertion concepts. Measured forces varied between 5 and 20 mN both on cochlear model and temporal bone.

Todd et al. [40] published a study dealing with the assessment of insertion forces and electrode trajectory of Contour and Contour Advance electrodes. They also used a calibrated Instron 5543 force measurement device with a 10 N load cell to insert the electrode into a two dimensional artificial model of the human scala tympani. This model enabled monitoring the electrode trajectory during electrode insertion. As results of their study they also revealed that lowest insertion forces can be achieved when the Contour Advance electrode is inserted applying the AOS technique. Insertion forces were reported to be between 5 and 50 mN.

One reason for the appearance of intracochlear forces during electrode insertion pointed out by our study is the inadequate straightening of the implant in its starting configuration. The out of the box electrodes straightened by the stylet show some slight curvature. This effect did not change much after reinserting the stylet for the subsequent tests as underlined by previous studies on the curling behaviour of Contour Advance electrodes [41]. It seems to be a plausible explanation for the observation that during the first phase of insertion (prior to AOS) all implants touched the medial wall of the basal turn shortly after entering the cochlear lumen. The recorded forces suggest that the occurrence of tip foldover can be detected by suitable force sensors integrated into the insertion tool. Especially in the case of an irreversible soft tip foldover insertion force increases dramatically. To what extent a temporary foldover is detectable by these means needs to be investigated by closer examinations, particularly with regard to the still missing quantitative correlation of applied forces and soft tissue damage.

One possibility to avoid the basal contact of the imperfectly straightened electrode with the medial wall is to adapt the angle between adjustment of the insertion tool and the basal turn of the cochlea as it becomes possible when using intraoperative image-guided systems in combination with the tool. However, such a non-tangential entry to the cochlear lumen is limited by the location and size of cochleostomy. Additionally a rotation around the electrode axis can be realized by this way to reduce forces, especially resulting from the three-dimensional curling of the cochlea. As the current insertion tool does not allow the realization of such a rotation, especially if mounted stationary in the measurement device, this was not considered in this study.

In the further progress of insertion applied forces to the intracochlear structures could also be constituted in an inadequate curling behaviour in comparison to the helical shape of the human cochlea. Apart from that the preformed electrode carriers only feature a curling in a plane but not in the three dimensions of the cochlear anatomy, the sharp bending of the soft tip shortly after starting to withdraw the stylet results in considerable contacts of implant and cochlea. One consequence is that the pressure of the soft tip against the inner wall forces the more proximal parts of the implant's silicone body to bow away from the modiolus against the outer wall which leads to an increase of contact surface between cochlea and electrode. Therefore, additional friction forces immeasurable to the one-dimensional force measurement equipment cannot be excluded.

Finally, in our studies on the transparent cochlear model this curling behaviour results in a lateral position of the electrode carrier after finishing the AOS insertion technique. This bowing of the electrode could be relieved when retracting it by one more distal ribs. This finding is in agreement with the fluoroscopic evaluation of Roland at al. [32] who also showed that the electrode regained perimodiolar position when withdrawing it about 1 mm.

Conclusions

Using our automated insertion tool the force during the insertion of Nucleus Contour Advance electrodes into an artificial model of the human scala tympani was measured. This database of insertion force characteristics can be used to compare investigations of further developed electrodes and improved insertion strategies. These may include the future usage of information about patient-specific anatomy. The automated insertion by the flexible programmable insertion tool offers the advantage that further studies become comparable to the presented results since the insertion process and consequently the measurable forces no longer depend on the surgeons or experimenters skill.

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