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Title:

A Capacitive Cochlear Implant Electrode Array Sensing System to Discriminate Fold-over Pattern

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Capacitive CI Fold-over Pattern Discriminate

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Abstract and key terms

Purpose: During insertion of the cochlear implant electrode array, the tip of the array may fold back on itself and can cause serious complications to patients. This article presents a sensing system for cochlear implantation in a cochlear model. The electrode array fold-over behaviors can be detected by analyzing capacitive information from the array tip.

Method: Depending on the angle of the array tip against the cochlear inner wall when it enters the cochlear model, different insertion patterns of the electrode array could occur, including smooth insertion, buckling, and fold-over. The insertion force simulating the haptic feedback for surgeons and bipolar capacitance signals during the insertion progress were collected and compared. The Pearson Correlation Coefficient (PCC) was applied to the collected capacitive signals to discriminate the fold-over pattern.

Results: Forty-six electrode array insertions were conducted and the deviation of the measured insertion force varies between a range of 20% and 30%. The capacitance values from electrode pair (1, 2) were recorded for analyzing. A threshold for the PCC is set to be 0.94 that can successfully discriminate the fold over insertions from the other two types of insertions, with a success rate of 97.83%.

Conclusions: Capacitive measurement is an effective method for the detection of faulty insertions and the maximization of the outcome of cochlear implantation. The proposed capacitive sensing system can be used in other tissue implants in vessels, spinal cord or heart.

Keywords-Hearing Preservation, Medical Robotics, Surgical Assistance, Capacitive sensing, K-Nearest Neighbors analysis (KNN)

1. Introduction

To date, the insertion of a cochlear implant electrode array is performed by hand, and the tools used by surgeons do not provide any force feedback or other means of sensing to avoid insertion trauma (Nguyen et al., 2014). As the electrode array is inserted into the cochlea, care must be exercised to avoid any traumatic events to any of the intracochlear surrounding structures (David Edelstein, 2014). Ideally, an electrode array should not touch the cochlear walls during insertion to prevent any intracochlear trauma (Dhanasingh & Jolly, 2017), but in practice damage does sometimes occur.

To prevent intracochlear trauma, several mechanical properties, such as electrode array insertion speed, stiffness, use of lubricants, electrode array types, and different insertion tools, are reviewed (De Seta et al., 2017). Among them, insertion force directly applied to the intracochlear structures is considered as a key element of intracochlear trauma and residual hearing loss (Roland, 2005). Electrode array insertion force as low as 26mN to 35mN may result in a rupture of the basilar membrane (Ishii et al., 1995). Consequently, the assessment of array insertion force is necessary to evaluate the electrode array's design and its mechanical behavior. A summary of previously published insertion force investigations is listed in Table 1.

Variations in the structure and/or position of the electrode array may result in drastically varied outcomes, potentially including trauma (Dhanasingh & Jolly, 2017). One example of this is a particular complication that may arise during implantation: the tip of the electrode may fold back on itself at the time of insertion (Zuniga et al., 2017). This problem, referred to as tip fold-over or roll-over, occurs when the tip of the electrode array impinges the modiolar wall or other structure and is temporarily held stationary. In such a situation, further pushing of the array results in more electrodes advancing past it (Dhanasingh & Jolly, 2019),(Ramos-Macias et al., 2017). It can cause the patient to suffer from various post-operative complications, including reduced speech comprehension (Wanna et al., 2014), vertigo, pitch confusion and tinnitus (Dhanasingh & Jolly, 2019), and even cause injury to important adjacent neurovascular structures (Ying et al., 2013). Tip fold-over poses a serious challenge to the scientific community since it has been reported that in many cases it goes unnoticed by the surgeon performing the procedure. The literature reports such mispositioning of the electrodes, and specifically states that tip fold-over in the electrodes has an incidence rate that varies from 0.2% to 5.8%, with an average of 1.02% (Ying et al., 2013), (Dhanasingh & Jolly, 2019). Additionally, the design of the electrodes and the surgical procedures used are both deemed important factors for correct positioning (O'Connell et al., 2016). For example, perimodiolar (pre-curved) electrodes have shown better performance compared to straight electrode array. This is due to their placement close to the modiolus, which gives them an advantage in stimulating neurons. However, perimodiolar electrodes have a higher rate of tip fold-over when they are inserted through the round window (Zuniga et al., 2017). There is currently no universally agreed-upon protocol for intraoperative monitoring during cochlear implantation to ensure proper electrode array positioning within the cochlea.

There are different methods to correct the tip folding issue. Correction can either be performed within the same surgery, using an intraoperative method to rectify the problem, or, if the evaluation criterion of choice is postoperative, correction can take place using revision surgery.

In the past, several imaging methodologies, such as high-resolution computed tomography (HR-CT) and digital volume tomography, have been used to reliably identify the position of the electrode array intra- or post-operatively (Carelsen et al., 2007), (Trakimas et al., 2018). One of the methods used to correct positioning is rotational X-ray imaging, which acquires 3D images of the cochlea and the electrode array during implantation(Rau et al., 2010). However, this technique does not prevent foldover; indeed, it only detects fold-over immediately after the electrode array has been placed (Carelsen et al., 2007). Furthermore, image acquisition may take time. However, these techniques require the patient to be exposed to radiation and may not be suitable for all patients.

The intra-cochlear electrode positioning can also be evaluated through post-operative fluoroscopy (Zuniga et al., 2017) but may not be adopted widely owing to its prohibitive procedural cost and resolution limits.

Another method, recently utilized, is the multivariate analysis of telemetry signals; this includes the spread of excitation (SOE) and the Neural Response Telemetry Ratio (NTR)(Grolman et al., 2009),(Mittmann et al., 2015). The SOE can be used to detect the tip fold by observing the excitation fields around different electrodes. This method has the advantage of not requiring expensive additional equipment and the acquisition takes 1.5 to 2 minutes. However, it has some limitations as it assumes that the cochlea is a homogeneous conductor. Similarly, the NTR is not suitable for patients suffering from neural degeneration or long-term deafness. Finally, all of these electrophysiological testing methods mainly aim at studying the function on the implant rather than focusing on the positioning of the array.

A method under investigation uses an automatic insertion tool that inserts the electrode array in steps of less than one millimeter while monitoring the insertion force. The tests were conducted in an experimental model using an artificial acrylic cochlea(Rau et al., 2010). Another of the studies has been reported with experimental models by Pile et al. who investigated the efficiency of implantation using a highprecision robot coupled with machine learning classification of force signals and insertion speed. The contribution of this work is the use of temporal bone specimens with a simplified model of the human ear (Pile & Simaan, 2013).

The goal of the present study is to investigate a sensing system for cochlear implantationthat discriminates the fold-over signal pattern among certain patterns. This is achieved by analyzing the capacitance signals from the array. Using this method, the surgeons will be notified once the faulty pattern occurs during the robotic insertion process.

[Table 1]

2. Materials and Methods

a. Electrode array feed and sensing system

The feed and sensing system was significantly improved based on the research presented in our previously published papers (HOU et al., 2018),(Hou et al., 2021). The electrode array that was utilized in the paper was a clinical CI electrode array supplied by OTICON with a length of 26 mm. As shown in Figure 1 (a), the electrode array held 20 electrodes that were numbered from the apex to the bottom. Among them, capacitance was measured between the top two electrodes. These electrodes were located at the electrode array tip, which was the most sensitive part of the array folding-over phenomenon. The two electrodes are circled in Figure 1 (a).

[Figure 1]

A robotic automated electrode array feed system was developed to insert a clinical used CI electrode array into a 3D printed cochlear implant model. The feed system was described in detail in our previously published papers (Hou et al., 2018),(HOU et al., 2018). The device, as shown in Figure 1 (b), comprised one rotational stage, two translation stages (Physik Instrumente (PI), 2017), one 3D printed array holder, an LCR meter, and a force sensor (ATI Industrial, 2016).

In addition to our previously published papers(HOU et al., 2018),(Hou et al., 2021), a three-axis force sensor (ATI Industrial, 2016) was integrated into the system in order to collect force data. The force sensor, as shown in Figure 1 (d), was screwed with the array holder onto the rotational stage. The transducer was driven by data acquisition modules (DAQ) (Instruments, 2007), which were formed with a data acquisition device (ATI Industrial, 2016) and a multi-functional input/output device (National Instruments, n.d.). A built-in handling software with a sampling rate of 10Hz was programmed. Before each measurement, a calibration procedure of the force sensor was conducted to convert the input signals into forces.

A translucent cochlear model was glued on a supporter and placed onto the bottom of a glass. The cochlear model and supporter used non-conductive materials (Veroclear and Accura 60). The glass was filled with a saline solution with a 0.9% concentration to simulate the environment of a human's inner cochlea. Before each insertion, the tip of the array was placed at the entry of the cochlear implant model. The special cochlear model was formed by the first 90-degree track, which was the most common place for the tip fold-over feature (Pile & Simaan, 2013). By adjusting the entry angle to approximately 40 degrees against the cochlear inner wall, the tip of the array would come into contact with the inner wall and fold over.

The capacitance of the electrode pair (1, 2) was recorded in real-time by the LCR meter(ISO-TECH, 2014) with a sampling rate of two measurements per second and a resolution of 0.1pF. The recorded data was stored in software WINDMM700 as a txt file. An insertion speed of 0.1 mm/s was set for every experiment.

b. Application of the Pearson Correlation Coefficient (PCC)

The k-Nearest Neighbor analysis (K-NN) with a pre-processing algorithm, which was the PCC, was subsequently applied to the capacitance measurements. The k-NN is a non-parametric algorithm that is widely used for classification and regression (Altman, 1992). As k-NN is based on feature similarity, classification can be conducted using the k-NN classifier. The k-NN algorithm stores all available cases in a feature set and classifies new cases in a test set, which is based on a similarity measure (Ali et al., 2019). The PCC is a distance measure of the linear correlation between two samples (Pearson, 1895). The coefficient was represented by *r* with a range between -1 to 1 (Galton, 1886).

This pattern classification can help to distinguish between a fold-over insertion and smooth insertions or insertions with a buckling feature.

Two sets of measurements, the reference set and the test set were used in the experiments. The reference set (Γ_i^r) was a set of vectors that had a pattern of a sharp drop curve and a flat curve. The set was applied for comparison with the test vectors to identify a similar pattern (drop and flat) in the test vectors. Therefore, the size of the reference dataset was the same as a test vector *(n).*

The test set (Γ_i^t) was a mix of capacitance measurements of smooth insertions and insertions with fold-over features and buckling features. In the test set, as the sequence of capacitance measurements was long, a sliding window method was applied. The method kept a window of specified length (n) and moved over the measurements, sample by sample to facilitate a comparison with the available reference vector. The PCC formula (Pearson, 1895) between the reference set $\Gamma_i^r = \{x_1, ..., x_n\}$ and a vector in the test dataset $\Gamma_i^t = \{y_1, ..., y_n\}$ was expressed as follows:

$$r = \frac{\sum_{i=1}^{n}(x_i - \overline{x})(y_i - \overline{y})}{\sqrt{\sum_{i=1}^{n}(x_i - \overline{x})^2}\sqrt{\sum_{i=1}^{n}(y_i - \overline{y})^2}} \quad (1)$$

where both of the two vectors contained *n* values and *n* was the feature size; x_i and y_i indicated the single sample data indexed with *i*; $\overline{x}$ and $\overline{y}$ represented the mean value of the vector; and *r* was the PCC result that represented the distance between two vectors.

When $r > 0$, the measured two vectors were positively correlated. When $r < 0$, the measured two vectors were negatively correlated. When $r = 0$, there were no linear correlations between the vectors. A value of $r = 1$ indicated that there was a perfect linear correlation between the vectors (Galton, 1886).

The final step was the recognition of the fold-over feature insertions. This could be achieved by applying a distance threshold to separate the maximum PCC values.

3. Results

[Figure 2]

Figure 2 (a) depicts how the electrode array is inserted into the model at an angle of 40°. Based on the low stiffness of the array, the tip of the array bends towards the inner wall, as seen in Figure 2 (b). Afterwards, the tip of the electrode array is obstructed by the wall, while the body of the array is still moving forward in Figure 2 (c). Electrodes 1–4 are squeezed together by the compressing force. In Figure 2 (d), the fold-over pattern arose if the obstruction was not removed. The electrode array tip stops advancing and repeatedly touches with the inner wall. At this stage, the electrode array will not be able to be recovered by itself. The insertion should be stopped immediately, and the array will have to be removed. During insertion, the circumstances of electrodes 1 and 2 change frequently, as such they are utilized to conduct the sensing measurements.

The number of force and capacitance measurements in each group is demonstrated in Table 2.

[Table 2]

a. Force and Capacitance Profiles

In Figure 3 (a–c), the insertion time is 220 seconds with a constant insertion speed of 0.1 mm/s for all insertions. The red curve indicates the average insertion force, and the grey area is the standard deviation of the force profiles.

[Figure 3]

Regarding the force profiles of the fold-over pattern in Figure 3 (a), the overall average force remains stable with minor fluctuations. The largest force value is apparent when the array tip first contacts the model wall. The figure reflects that a quick force increases from 0 to 0.14 N and occurs within 20 seconds. The largest force value is 6.6% higher than the overall average force of 0.127 N. The average force of the fold-over and buckling insertions in Figure 3 (a) and (b) increases dramatically up to 20 seconds, which is different from the smooth insertions in Figure 3 (c). This is because to create the fold-over and buckling patterns, the array tip's start position is slightly posterior to the smooth insertion's position. The alignment causes contact between the model wall and the tip at the start of the insertions, which leads to the maximum average force of 0.136 N (±0.028 N) for fold-over insertions and 0.093 N (±0.054 N) for buckling insertions.

Afterwards, the average force for the (a) fold-over and (b) buckling insertions remains relatively stable with small, frequent fluctuations. For (b) the buckling pattern insertions, the buckling phenomenon occurs at the end of the electrode array. The body of the electrode array deforms in the model track. However, from the force profiles, the buckling behavior only results in small rises from the insertion time of 100 seconds. For (c) smooth insertions, the average insertion force value rises continuously until it reaches the maximum force of 0.058 N (±0.02 N) is reached.

[Figure 4]

For Figure 4 (a–c), the average capacitance measured is marked by yellow triangles. The x-axis represents the insertion time up to 175 seconds, and the y-axis represents the normalized capacitance with a range between 0 and 1. The capacitance normalization procedure is achieved by dividing each capacitance value measured by the capacitance range. Each curve indicates individual insertion.

In Figure 4 (a), before the insertion time of 65 seconds, the overall trend of the capacitance measurement rises. This could be caused by the initial advancing activity.

The electrodes do not make contact with the wall, and the behavior matches the video screenshot in Figure 2 (a) and (b). Between 65 seconds and 80 seconds, the first electrode begins to make contact with the wall, and the distance between electrode 1 and 2 is squeezed. The complex operation results in capacitance measurement fluctuations. The behavior matches Figure 2 (c). Between the 80 seconds and 110 seconds, the first electrode in the array is firmly pressed onto the inner wall. This leads to a dramatic decrease in the capacitance, which matches Figure 4 (a). After that, the status of the electrode distances and their on-top pressures remain steady. As a result, the value of the capacitance fluctuates within a limited range.

In our analysis, the fold-over pattern occurs around the insertion time of 90 seconds. To recognize the fold-over pattern, it is essential to extract the falling capacitance and steady states afterwards.

Regarding Figure 4 (b) and (c), the overall results are the same. The only difference is the signals between 100 seconds and 160 seconds. The differences are caused by the electrode buckling feature. The buckling feature can be identified by the principal component analysis, which has been published in the previous paper(Hou et al., 2018),(HOU et al., 2018).

b. PCC Results

A sliding window method with a length of n = 50 is applied to convert the input experimental measurements into test vectors. The window length is identical to the reference dataset length. Based on the electrode array insertion patterns, the test vectors were divided into the following three subgroups: the fold-over group, the buckling group, and the smooth group. The normalized test vectors from each subgroup were compared with the normalized reference dataset by the PCC analysis. The similarity results of the comparisons are presented in Figure 5.

[Figure 5]

In all figures, the x-axis represents the insertion time in seconds, and the y-axis represents the PCC values. As each curve indicates an independent single electrode array insertion, the maximum PCC results for each insertion and its associated insertion time are detailed in Figure 6.

[Figure 6]

The maximum PCC value of the (a) fold-over group, (b) buckling group, and (c) smooth group are represented by triangles, circles and plus signs respectively. When the maximum PCC value becomes larger, the test vectors become more similar to the reference pattern. When PCC = 1, the test vector matches the reference pattern completely. In the analysis, a threshold can be applied to distinguish the fold-over pattern from the other two patterns.

The sum of the maximum PCC value in the fold-over group above the threshold and the maximum PCC in the buckling and smooth groups below the threshold are calculated.

The threshold value to separate the fold-over pattern from the other two patterns is examined from 0 to 1, with an increment of 0.01. As a result, a peak point with the location range of 0.89–0.94 has the largest maximum PCC calculation. Therefore, 0.94 is recognized as the threshold to separate the fold-over pattern from the buckling and smooth insertion groups.

To examine the threshold, the value will be applied to the three measurement groups. For the fold-over and buckling group, all 26 insertions meet the examination.

For the smooth insertion group, one out of 20 failed the examination, with a success rate of 95%. Overall, the threshold can successfully discriminate 45 out of 46 insertions, with a success rate of 97.83%.

4. Discussion

It is difficult to distinguish the fold-over pattern from the buckling pattern insertions and smooth insertions when comparing the average force profiles. The results reveal that the insertion force is useful in designing CI array properties and insertion strategies. It can record the contact force between the array and cochlear inner wall in the first turn. The CI array insertion force that was measured in the model proves that the assumption is reasonable by comparing it to other results in the literature review (Dhanasingh & Jolly, 2017),(Dhanasingh & Jolly, 2019),(Roland, 2005),(Todd et al., 2007),(Schurzig et al., 2010),(Rohani et al., 2014). The average force is similar in both the trending shape and magnitude. However, the force profiles vary significantly from individual insertions and are unlikely to detect the CI array behaviors inside the cochlea. As this problem is also mentioned by others in the literature review, further investigations can address the electrode array starting position and its stiffness.

Most importantly, the insertion force hardly identifies the position where the buckling or fold-over pattern occurs. The force measured that simulates the haptic feedback for surgeons is the overall insertion force applied at the entry point of the cochlear model. The insertion force is a complex force including advancing force, support force, friction force, viscous force, etc. Regardless of whether the insertion is smooth or the faulty patterns can be recognized, it is hard to identify where the error takes place. The process is like inserting an array into a black box whereby surgeons will know when errors happen but cannot identify the exact location of the errors. During the electrode array insertion process, the behavior of the array inside of the cochlea remains unknown for surgeons.

Furthermore, in all the force profiles, the force deviation is much larger than the standard value. The deviation value varies between a range of 20% and 30%. This suggests that there are significant differences between each insertion. The differences and deviations result in a lack of accuracy of the CI array insertion pattern discrimination from the insertion force.

Due to the unknown behavior and location information, small force variations and large deviations, the force sensing method is not sufficient to distinguish the faulty patterns. In order to fill the research gap, an electrodes bipolar capacitive sensing system is proposed. The method is highly sensitive at conducting solutions. It was found that electrode capacitive signals could be used to interpret the state of the electrode array without extra sensors. Based on the sensory signals, the control strategy could be applied to control the electrode array feed rate, position, and velocity of insertion devices.

In our experiments, there were only eight insertions with the fold-over pattern. The reason for the limited number of fold-over measurements is that the fold-over behavior damages the electrode array, particularly the wire between the first and second electrodes. After the fold-over experiments, the wire between them breaks due to the repetitive bending of the array. To maintain the consistency of the materials applied, only one electrode array was used for all the measurements. The authors will continue to collect more data on different models and materials to achieve higher accuracy.

However, the capacitive sensing method is easily affected by environment parameters, array materials and sensing methods. The reasons and modelling for the bipolar electrodes’ capacitance variations when filling with conducting solutions have been investigated previously. The results demonstrate that the measured capacitance value is formed not only by the electrodes’ capacitance but also by capacitance due to the liquid conductivity. While the environmental parameters have been carefully monitored and examined in experiments, other parameters such as solution pressure, oxygen content, air bubbles have to assumed to be constant. Lastly, all of the insertions were conducted by one electrode array. Although the electrode array is standard and for clinical use, materials and size of electrodes manufactured from different types of arrays would affect the capacitance signals.

In future work, the proposed method can be examined on different models and materials. The next stage of the investigation will be made on soft materials, animal tissues, fresh cadavers and further in the clinic. By activating and scanning different pairs of electrodes in sequence, the complete form of the CI electrode array and the locations of the faulty patterns inside the cochlear model can be further detected and analyzed. It is expected that the proposed method will be applied in discriminating wider failure patterns. In future experiments, this sensing system can be used to communicate with the array in real-time. Once the fold-over pattern appears during the insertion process, the array will be stopped to prevent further damage to the cochlea. The system would enable the signal discrimination process in real-time and demonstrate on a screen whether the array has been placed correctly during the insertion process. This will help to maximize the performance of cochlear implant and reduce the trauma of the insertion.

5. Conclusion

In this paper, a cochlear implant electrode array was robotically inserted into an artificial cochlear model. By adjusting the entry angle of the array against the cochlear inner wall, the array tip would touch the inner wall and fold over. The insertion force and bipolar capacitance signals during the progress were collected and analyzed. The results revealed that the insertion force is useful in designing CI array's properties and insertion strategies. The insertion force can be used to identify the contact force between the array and cochlear inner wall. However, the insertion force could not identify the position and the fold-over patterns of insertions. To identify fold-over patterns , the Pearson Correlation Coefficient (PCC) was used. Forty-six capacitance profiles from the electrode pair (1, 2) were analyzed and compared. The threshold distance was calculated to be 0.94. It demonstrated that for the fold-over and buckling groups, all 26 fold-over insertions met the examination criteria. For the smooth insertion group, 1 out of 20 failed the examination; with a success rate of 95%. Overall, the threshold can successfully discriminate 45 out of 46 insertions, with a success rate of 97.83%.

6. References

Ali, N., Neagu, D., & Trundle, P. (2019). Evaluation of k-nearest neighbour classifier performance for heterogeneous data sets. *SN Applied Sciences*, *1*(12), 1–15. https://doi.org/10.1007/s42452-019-1356-9

Altman, N. S. (1992). An introduction to kernel and nearest-neighbor nonparametric regression. *American Statistician*. https://doi.org/10.1080/00031305.1992.10475879

ATI Industrial. (2016). *Six-Axis Force/Torque Sensor System. Installation and Operation Manual. March*, 40–48. http://www.ati-ia.com/app_content/documents/9620-05-Transducer Section.pdf

Carelsen, B., Grolman, W., Tange, R., Streekstra, G. J., Van Kemenade, P., Jansen, R. J., Freling, N. J. M., White, M., Maat, B., & Fokkens, W. J. (2007). Cochlear implant electrode array insertion monitoring with intra-operative 3D rotational X-ray. *Clinical Otolaryngology*, *32*(1). https://doi.org/10.1111/j.1365-2273.2007.01319.x

De Seta, D., Torres, R., Russo, F. Y., Ferrary, E., Kazmitcheff, G., Heymann, D., Amiaud, J., Sterkers, O., Bernardeschi, D., & Nguyen, Y. (2017). Damage to inner ear structure during cochlear implantation: Correlation between insertion force and radio-histological findings in temporal bone specimens. *Hearing Research*, *344*, 90–97. https://doi.org/10.1016/j.heares.2016.11.002

Dhanasingh, A., & Jolly, C. (2017). An overview of cochlear implant electrode array designs. In *Hearing Research* (Vol. 356, pp. 93–103). https://doi.org/10.1016/j.heares.2017.10.005

Dhanasingh, A., & Jolly, C. (2019). Review on cochlear implant electrode array tip fold-over and scalar deviation. In *Journal of Otology* (Vol. 14, Issue 3). https://doi.org/10.1016/j.joto.2019.01.002

Galton, F. (1886). Regression Towards Mediocrity in Hereditary Stature. *The Journal of the Anthropological Institute of Great Britain and Ireland*, *15*, 246. https://doi.org/10.2307/2841583

Grolman, W., Maat, A., Verdam, F., Simis, Y., Carelsen, B., Freling, N., & Tange, R. A. (2009). Spread of excitation measurements for the detection of electrode array foldovers: A prospective study comparing 3-dimensional rotational x-ray and intraoperative spread of excitation measurements. *Otology and Neurotology*, *30*(1). https://doi.org/10.1097/MAO.0b013e31818f57ab

HOU, L., DU, X., & Boulgouris, N. . (2018). A Novel Sensing System for Robotic Cochlear Implants Electrode Array Placement. *2018 7th IEEE International Conference on Biomedical Robotics and Biomechatronics (Biorob)*, 1133–1137. https://doi.org/10.1109/BIOROB.2018.8487984

Hou, L., Du, X., Boulgouris, N., Coulson, C., Irving, R., Begg, P., & Brett, P. (2021). A Novel Capacitive Cochlear Implant Electrode Array Sensing System to Discriminate Failure Patterns. *Otology & Neurotology*, *Publish Ah*. https://doi.org/10.1097/MAO.0000000000003054

Hou, L., Du, X., & Boulgouris, N. V. (2018). Capacitance Measures During Cochlear Implants Electrode Array Positioning. *Proceedings of the 2018 10th International Conference on Bioinformatics and Biomedical Technology - ICBBT '18*, 78–82. https://doi.org/10.1145/3232059.3232069

Instruments, N. (2007). *DAQ M Series M Series User Manual NI 622x, NI 625x, and NI 628x Devices*. c:/pdflib/00021114.pdf

Ishii, T., Takayama, M., & Takahashi, Y. (1995). Mechanical properties of human round window, basilar and reissner's membranes. *Acta Oto-Laryngologica*, *115*(S519), 78–82. https://doi.org/10.3109/00016489509121875

ISO-TECH. (2014). *LCR1701/LCR1703 Digital Multi-meter Instruction Manual*.

Mittmann, P., Todt, I., Wesarg, T., Arndt, S., Ernst, A., & Hassepass, F. (2015). Electrophysiological Detection of Intracochlear Scalar Changing Perimodiolar Cochlear Implant Electrodes: A Blinded Study. *Otology and Neurotology*, *36*(7). https://doi.org/10.1097/MAO.0000000000000766

National Instruments. (n.d.). *USB-6211 Multifunction I/O Device*. https://www.ni.com/en-gb/shop/select/multifunction-io-device?modelId=124911

Nguyen, Y., Kazmitcheff, G., De Seta, D., Miroir, M., Ferrary, E., & Sterkers, O. (2014). Definition of metrics to evaluate cochlear array insertion forces performed with forceps, insertion tool, or motorized tool in temporal bone specimens. *BioMed Research International*, *2014*. https://doi.org/10.1155/2014/532570

O'Connell, B. P., Cakir, A., Hunter, J. B., Francis, D. O., Noble, J. H., Labadie, R. F., Zuniga, G., Dawant, B. M., Rivas, A., & Wanna, G. B. (2016). Electrode Location and Angular Insertion Depth Are Predictors of Audiologic Outcomes in Cochlear Implantation. *Otology and Neurotology*, *37*(8). https://doi.org/10.1097/MAO.0000000000001125

Pearson, K. (1895). Note on Regression and Inheritance in the Case of Two Parents. *Proceedings of the Royal Society of London (1854-1905)*, *58*(1), 240–242. https://doi.org/10.1098/rspl.1895.0041

Physik Instrumente (PI). (2017). *M-403 · M-404 Precision Translation Stage*.

Pile, J., & Simaan, N. (2013). Characterization of friction and speed effects and methods for detection of cochlear implant electrode tip fold-over. *Proceedings - IEEE International Conference on Robotics and Automation*, 4409–4414. https://doi.org/10.1109/ICRA.2013.6631202

Ramos-Macias, A., De Miguel, A. R., & Falcon-González, J. C. (2017). Mechanisms of electrode fold-over in cochlear implant surgery when using a flexible and slim perimodiolar electrode array. *Acta Oto-Laryngologica*, *137*(11), 1129–1135. https://doi.org/10.1080/00016489.2016.1271449

Rau, T. S., Hussong, A., Leinung, M., Lenarz, T., & Majdani, O. (2010). Automated insertion of preformed cochlear implant electrodes: Evaluation of curling behaviour and insertion forces on an artificial cochlear model. *International Journal of Computer Assisted Radiology and Surgery*, *5*(2), 173–181. https://doi.org/10.1007/s11548-009-0299-9

Rohani, P., Pile, J., Kahrs, L. A., Balachandran, R., Blachon, G. S., Simaan, N., & Labadie, R. F. (2014). Forces and trauma associated with minimally invasive image-guided cochlear implantation. *Otolaryngology - Head and Neck Surgery (United States)*, *150*(4), 638–645. https://doi.org/10.1177/0194599813519747

Roland, J. T. (2005). A model for cochlear implant electrode insertion and force evaluation: Results with a new electrode design and insertion technique. *Laryngoscope*, *115*(8). https://doi.org/10.1097/01.mlg.0000167993.05007.35

Schurzig, D., Webster, R. J., Dietrich, M. S., & Labadie, R. F. (2010). Force of cochlear implant electrode insertion performed by a robotic insertion tool: Comparison of traditional versus advance off-stylet techniques. *Otology and Neurotology*, *31*(8), 1207–1210.

https://doi.org/10.1097/MAO.0b013e3181f2ebc3

Todd, C. A., Naghdy, F., & Svehla, M. J. (2007). Force application during cochlear implant insertion: An analysis for improvement of surgeon technique. *IEEE Transactions on Biomedical Engineering*, *54*(7), 1247–1255. https://doi.org/10.1109/TBME.2007.891937

Trakimas, D. R., Kozin, E. D., Ghanad, I., Barber, S. R., Curtin, H., & Remenschneider, A. K. (2018). Precurved Cochlear Implants and Tip Foldover: A Cadaveric Imaging Study. *Otolaryngology - Head and Neck Surgery (United States)*, *158*(2). https://doi.org/10.1177/0194599817738978

Wanna, G. B., Noble, J. H., Carlson, M. L., Gifford, R. H., Dietrich, M. S., Haynes, D. S., Dawant, B. M., & Labadie, R. F. (2014). Impact of electrode design and surgical approach on scalar location and cochlear implant outcomes. *Laryngoscope*, *124*(S6). https://doi.org/10.1002/lary.24728

Ying, Y. L. M., Lin, J. W., Oghalai, J. S., & Williamson, R. A. (2013). Cochlear implant electrode misplacement: Incidence, evaluation, and management. *Laryngoscope*, *123*(3), 757–766. https://doi.org/10.1002/lary.23665

Zuniga, M. G., Rivas, A., Hedley-Williams, A., Gifford, R. H., Dwyer, R., Dawant, B. M., Sunderhaus, L. W., Hovis, K. L., Wanna, G. B., Noble, J. H., & Labadie, R. F. (2017). Tip fold-over in cochlear implantation: Case series. *Otology and Neurotology*, *38*(2). https://doi.org/10.1097/MAO.0000000000001283

Table 1: Published largest and average insertion forces for various electrode arrays and insertion methods. TB: temporal bone, AOS: advance off stylet, AIT: automated insertion tool, SIT: standard insertion technique.

Table 2. The number of force and capacitance measurements

Figure 1: The electrode array feed system

Figure 2. The insertion progress of the electrode array is inserted into the model. The four red dots represent the position of the front four electrodes to demonstrate the insertion and fold-over process, and the yellow triangle represents the array tip.

Figure 3. The force profiles of 105 electrode array insertions are depicted in Figure 3 (a–c). These insertions are separated into the three patterns: insertions with (a) fold-over feature, (b) buckling feature, and (c) smooth insertions. The red curve indicates the average insertion force, and the grey area is the standard deviation of the force profiles.

Figure 4. The capacitance profiles of 46 capacitance sensing results of the electrode pair (1, 2) are depicted in Figure 4 (a–c). These insertions are separated into the three patterns: insertions with (a) fold-over feature, (b) buckling feature, and (c) smooth insertions. The red square indicates the average measured capacitance, and each line demonstrates an individual insertion.

Figure 5. A sliding window method was applied to compare the normalized test vectors from each subgroup with the normalized reference dataset by the PCC analysis. Each dot indicates a PCC result with the length of 50 samples. The PCC results of the fold-over group, buckling group, and smooth group are shown in Figure 5 (a), (b), and (c), respectively.

Figure 6. The maximum PCC value of the (a) fold-over group, (b) buckling group, and (c) smooth group are represented by triangles, circles and plus signs respectively. A threshold of 0.94 is recognized to separate the fold-over pattern from the buckling and smooth insertion groups.