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Abstract

Highly invasive surgical procedures, such as the implantation of a prosthetic device, require correct force delivery to achieve desirable outcomes and minimize trauma induced during the operation. Improvement in surgeon technique can reduce the chances of excessive force application and lead to optimal placement of the electrode array. The fundamental factors that affect the degree of success for cochlear implant recipients are identified through empirical methods. Insertion studies are performed to assess force administration and electrode trajectories during implantations of the Nucleus^{reg} 24 Contourtrade and Nucleus^{reg} 24 Contour Advancetrade electrodes into a synthetic model of the human Scala Tympani, using associated methods. Results confirm that the advance off- stylet insertion of the soft-tipped contour advance electrode gives an overall reduction in insertion force. Analysis of force delivery and electrode positioning during cochlear implantation can help identify and control key factors for improvement of insertion method. Based on the findings, suggestions are made to enhance surgeon technique.

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Force Application During Cochlear Implant Insertion: An Analysis for Improvement of Surgeon Technique

Catherine A. Todd*, Fazel Naghdy, and Martin J. Svehla

Abstract—Highly invasive surgical procedures, such as the implantation of a prosthetic device, require correct force delivery to achieve desirable outcomes and minimize trauma induced during the operation. Improvement in surgeon technique can reduce the chances of excessive force application and lead to optimal placement of the electrode array. The fundamental factors that affect the degree of success for cochlear implant recipients are identified through empirical methods. Insertion studies are performed to assess force administration and electrode trajectories during implantations of the Nucleus® 24 Contour™ and Nucleus® 24 Contour Advance™ electrodes into a synthetic model of the human Scala Tympani, using associated methods. Results confirm that the Advance Off-Stylet insertion of the soft-tipped Contour Advance electrode gives an overall reduction in insertion force. Analysis of force delivery and electrode positioning during cochlear implantation can help identify and control key factors for improvement of insertion method. Based on the findings, suggestions are made to enhance surgeon technique.

Index Terms—Cochlear implant, force measurement, prosthetics, surgery.

I. INTRODUCTION

THE human cochlea is a tiny 3-D spiral with $2\frac{1}{2}$ – $2\frac{3}{4}$ turns [1]. It is located within the inner ear and is responsible for transducing mechanical motion to neural activity which the brain perceives as sound. Clusters of hair cells positioned from base to apex along its periphery oscillate at dedicated frequencies to stimulate the auditory nerve. Significant damage to this interface will result in profound hearing loss, as the nerve can no longer be excited. Cochlear implants are designed to overcome this deficiency and facilitate the perception of sound by replacing mechanical stimulus of the hair cells with electrical excitation of the auditory nerve. The prosthetic is a small implantable device that contains an electrode array embedded in a silicone carrier. It is designed to be inserted into the Scala Tympani (ST) of the human cochlea. The exposed electrodes assume a final position along the ST for individual stimulation of particular frequency bands.

The purpose of this work was to study force administration and electrode trajectories during cochlear implantation for the

Nucleus® 24 Contour™ and Nucleus® 24 Contour Advance™ electrodes, as well as examine surgical techniques for the minimization of contact pressures. The related literature did not report of any quantitative analysis on force administration during implantation of the Contour or Contour Practice electrodes using the Standard Insertion Technique (SIT) or partial stylet withdrawal method. Further, there is no existing work on force delivery during insertion of the Contour Advance electrode, which is uniquely implanted using the Advance Off-Stylet (AOS) technique.

In the paper, we review the existing work on the measurement of forces involved in cochlear implant insertion. Differences in the design of electrodes to be used in this work are evaluated. Experimental method and results are presented for the SIT, partial withdrawal, and AOS insertions. Force delivery and electrode trajectories for each process are assessed. Based on these findings, we will discuss the optimal technique to minimize force output during implantation.

Results that have been produced from this work, including insertion force profiles and coefficient of friction measurement, will be used to validate a haptic-rendered surgical simulator for cochlear implant insertion which has been developed by the authors [2]. The simulator will be used to train specialists in cochlear implantation with real-time force feedback and provide an objective assessment of surgeon technique during electrode advancement into a parametric model of the human ST [3].

A. Measurement of Insertion Forces

Insertion studies have been performed to quantify force delivery [4], [5] and evaluate electrode trajectories [4]–[7] during simulated cochlear implantation. These were carried out to assess force administration for different electrode designs, including the Clarion (Advanced Bionics Corporation) [4], [5], the Combi C40+ electrode (Med-El) [7], new prototypes such as the Flex EAS [7] and reduced-element electrodes (silicone housing without individual electrodes or wires) [4], [5]. Researchers have identified key elements that affected force output during electrode insertion, including implant design and insertion behavior [4], [5], restoration forces [4], carrier stiffness [4], [6], [8], contact pressure at the tip [6], as well as coefficient of friction between a lubricated model and silicone tip [5]. Synthetic models of the ST have been used for the purpose of insertion force measurement during cochlear implantation [4], [5], [7]. Existing studies have shown the importance of quantifying force components and the assessment of electrode trajectories for specific electrode designs, for the minimization of trauma [4], [5], [8]–[17], optimal electrode placement [1], [4], [9], [13], [14], [18]–[21], and to avoid damage to the electrode [8], [11], [12]. In this paper, we examine and compare

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Fig. 1. Nucleus® 24 Contour™ electrode. The Contour array is shown in its precurled state, following partial stylet withdrawal. Interrib spacing of 0.5 mm is shown on the diagram to provide an indication of electrode scale. Picture provided by Cochlear™.

force delivery, electrode positions and surgical techniques for implants not previously considered: the Contour and Contour Advance electrodes.

B. Insertion Techniques: the Nucleus® 24 Contour™ and Nucleus® 24 Contour Advance™ Electrodes

Specialist technique will vary depending on the type of implant that is chosen for insertion. In this study, we looked at trajectories and force delivery for implantation of the Nucleus® 24 Contour™ and Nucleus® 24 Contour Advance™ arrays with the insertion methods that are currently used by specialists. The SIT or partial withdrawal method is performed using the Nucleus® 24 Contour™ and an AOS insertion is uniquely associated with the Nucleus® 24 Contour Advance™. The electrodes are approximately 22 mm in length (from tip to first rib), tapering from a tip diameter of about 0.5 (0.4 mm Advance)–0.8 mm. The silicone-coated electrode is kept straight by a thin platinum wire (stylet). For both designs, stylet withdrawal will result in the arrays returning to their precurled state.

The Nucleus® 24 Contour™ was introduced by Cochlear™ in 1999 (Fig. 1). For this type of electrode, the surgeon uses either the SIT or partial withdrawal method. For the SIT, the electrode is advanced into the cochlea using tweezers, with the stylet in place. The electrode is fully inserted to the second rib of the carrier (Fig. 2, point 4) and the stylet is then withdrawn (Fig. 2, point 5). The surgeon may combine the SIT with a partial removal of the stylet around the Basal turn area, which would correspond with point 2 in Fig. 2. Using this approach, the electrode is inserted until the surgeon feels the point of first resistance and the stylet is partially removed (approximately 1–2 mm [14]). Continuation of advancement after this point without partial removal of the stylet may inflict trauma in this area [11], [12]. The electrode is then fully inserted (Fig. 2, point 4) and the stylet withdrawn (Fig. 2, point 5). The Contour is precurled prior to insertion and as the stylet is withdrawn, the array recoils. If positioned correctly, it is oriented towards and lies along the inner wall. Using this technique, the electrode does not touch the outer wall and is positioned closer to the modiolus, exerting restoration forces against this axis (Fig. 2, point 5).

Fig. 2. Electrode trajectories (SIT and AOS insertions) and force profiles for a typical SIT, partial stylet withdrawal and an AOS insertion. Diagram shows the different stages of insertion (numbered 1–5) for the Contour and Contour Advance electrodes, from left to right the array is inserted further into the cochlea. 1. The electrodes slide along the inner wall (this continues through points 2. to 5. for the AOS insertion). 2. For the SIT and partial withdrawal methods, the electrode touches the lateral outer wall at the Basal turn. 3. Using the SIT, the Contour electrode continues to slide along the outer wall until the stylet is removed at stage 5. For a partial stylet withdrawal, the stylet is withdrawn 1–2 mm at point 2, and the electrode progresses along the inner ST wall to approximately stage 4, where there is sliding against the outer wall. The stylet is fully withdrawn at stage 5. Spikes in the output force for the partial withdrawal method at 9.5 and 16 mm marks are due to the stylet withdrawals.

The Nucleus® 24 Contour Advance™ electrode was designed with a soft-tip, to enhance flexibility in this area. Developed in 2004, this electrode is similar in size and shape to the Contour array. The main difference is the soft-tip. It is a silicone structure of reduced hardness and different geometry compared to the Contour tip. As part of its design, the Contour Advance has a white line (marker) on the silicone housing, approximately 9 mm from its tip, to provide the surgeon with a visual aid during electrode advancement. A distinctive technique is used for insertion of the Contour Advance: the Advance Off-Stylet (AOS) insertion. Using this approach, the electrode is inserted with stylet in place until the white marker on the carrier is aligned with the cochleostomy site (Fig. 2, point 1). The surgeon clasps the carrier with tweezers using the dominant hand and holds the stylet loop with tweezers in the contra lateral hand. The stylet is held in place, while the electrode is advanced off it and into the cochlea. As it is inserted, the electrode assumes a precurled state and hugs the modiolus, with a final position along the ST inner wall (Fig. 2, point 5).

In this study, net insertion forces involved during implantation of the Contour and Contour Advance electrodes into a syn-

Fig. 3. A 2-D depiction of frictional force at point, *i*, along the ST inner wall. There is an additive effect of frictional forces during implantation causing an increase in total insertion force.

thetic replica of the ST were analyzed. Three techniques were applied: the SIT, partial withdrawal and AOS, using Contour electrodes for the former and Contour Advance arrays for AOS insertions. This information was used to evaluate force delivery and electrode trajectories for each process, to assist in the improvement of surgical technique and to minimize trauma caused by excessive force application. Studies were performed to identify factors that affect force output during an insertion.

II. MATERIALS AND METHOD

A. Preliminary Analysis of Force Contribution

During an electrode insertion, there are forces acting on the ST walls and electrode which contribute to the total insertion force. These force components include frictional force, F_f , input force from the user, F_{in} (Fig. 3), relaxation force of the electrode (due to the recoil properties of the precurled silicone) and adhesion forces. In this paper, we measured net insertion forces (along the longitudinal axis of insertion) and quantified frictional forces for the interfaces used in the experimentation. The former provides an overall measure of output force at different stages of electrode insertion, which will be compared against results produced from a haptic-rendered simulation of the procedure, in future work. By analyzing the net insertion force profile and electrode trajectories, we discuss how frictional force and contact pressure (including electrode strength) contributes to the total force output during implantation. A value for the coefficient of friction, as determined by experimentation, will be included as an input parameter to the virtual model of the surgical simulator.

B. Insertion Force Measurement

1) *Model of the Human Scala Tympani (ST)*: A 2-D synthetic model of the human ST, provided by Cochlear™, was used in this paper to carry out insertion studies. The dimensions of the model were taken from published data [10]. Inner and outer wall measurements taken from 11 silastic casts of the ST were plotted in two dimensions as a function of angular displacement about the modiolar axis [10]. The data was used by Cochlear™ to form the cavity of the ST model, which is approximately 9 mm (from cochleostomy to Basal turn area) by 6 mm (diam-

eter about modiolus), with a depth of 1.5 mm. In previous insertion studies, synthetic replicas have been created from human cadavers [4], [5], [7]. In this paper, the model used was machined from Polytetrafluoroethylene (Teflon). Teflon was assumed to have a very low coefficient of friction and with addition of a soap solution, sufficient for modeling the slippery endosteum lining of the ST. Whilst cadaver specimens would have been preferred and may be used in future work for comparison of results, the preparation, storage, handling and acquisition, considering ethics requirements, as well as cost prohibited use of the material. The Teflon model did enable viewing of the electrode trajectory during electrode insertion. At the site of the cochleostomy, the opening was widened (by about 0.1 mm) to minimize forces associated with electrode advancement in this area. This replicates the real procedure, where a 1.5-mm burr is used to create the cochleostomy and a 1-mm burr then used to trim its periphery [13]. This means there will be slight variation in cochleostomy size, as well as position [22].

2) *Experimental Procedure*: A series of experiments were carried out using a calibrated Instron 5543 force measurement device to advance the electrode into a stationary ST model (Fig. 4). The insertion studies were performed to evaluate force administration during cochlear implantation of three different electrode designs that have not been analyzed in other work. A load cell was attached to the Instron device to monitor insertion forces associated with cochlear implantation using the Contour Practice, Contour and Contour Advance electrodes (Fig. 4). Cochlear™ has developed the Contour Practice array for use in surgical training. It is of similar geometry and material composition to the Contour, but has fewer electrode wires and is constructed using a different process to reduce cost of manufacture. The SIT and partial withdrawal methods were applied for the Contour Practice and Contour electrodes. AOS insertions were performed exclusively for the Contour Advance.

The sensor was mounted above the upper clamp which held the tweezers and electrode, for the SIT and partial withdrawal methods, to capture forces imparted on the carrier by the ST wall. The forces should be equal and opposite to those imparted on the ST wall by the carrier, only if there is no interference with the carrier. This apparatus collectively moved downwards to insert the electrode into the ST model which was held securely in a lower clamp. Using this configuration, the sensor detected forces exerted onto the tweezers that gripped the electrode. For AOS insertions, the load cell was mounted below the lower clamp and did not move during electrode advancement (Fig. 4). In this case, the sensor was mounted below the model to capture forces imparted on the ST wall by the carrier. This eliminated the effect of additional forces imparted onto the carrier due to stylet removal during electrode advancement. The two scenarios for sensor mounting may be directly compared in terms of forces imparted during carrier and ST wall interactions, since the forces imparted on the carrier due to stylet removal are eliminated. The force sensor may be mounted below the model for any of the SIT, partial insertion or AOS techniques (only the withdrawal forces are expected to change due to the elimination of carrier and stylet interactions). The length of the electrode was aligned with the initial passage of the ST model, between its inner and outer walls [Fig. 4 (A)].

Fig. 4. Test rig for measurement of insertion force. An Instron device is used for insertion. The load cell is mounted in a clamp below the model for advancement of the Contour Advance electrode with an AOS insertion, as shown in the photograph, and is mounted above the model for insertion of the Contour electrode using either a SIT or partial stylet withdrawal. A close-up of the electrode insertion is shown at the bottom right-hand corner of the photograph, labeled 'A.', indicated by the white arrow. The magnified view shows the electrode held by tweezers being inserted into the ST model in an AOS insertion.

Each test was repeated several times, for each insertion technique, the SIT with Practice electrode (5 times) and Contour (11 times), partial stylet withdrawal for Practice (8 times) and Contour (26 times), and AOS (34 times). Between successive insertions, the stylet was carefully straightened by hand. A specialized tool was used to uncurl the carrier for insertion of the stylet with the aid of tweezers. The electrode was then transferred to a pair of bent-tip tweezers which secured grip at the third marker rib. This module was then attached to the Instron device. A 10 N load cell was used to measure insertion forces which were collected at 50-ms intervals on the PC by Instron data logging software. Prior to each insertion, the model cavity was lubricated with a soap solution of 10% Bathox and 90% distilled water in order to imitate the fluid-filled cavity inside live cochleae. It was expected to reduce friction between the carrier and ST walls.

For the SIT and partial withdrawal approach, the electrode was moved down until the tip was about 1–3 mm inside the ST

opening. This prevented large spikes in the force profile caused by the electrode tip catching at the entrance. The Contour Advance was inserted to the white marker on its silicone envelope, at a displacement of approximately 6.5–9 mm from the tip. It was then fed off the stylet and into the chamber at a constant speed of 120 mm/min, until the maximum extension was reached. This was 16–18 mm further into the cavity for the Contour and 8–10.5 mm for the Contour Advance. At full insertion, the second rib of the array was at the passage opening. Force profiles were generated from the data collected at the PC for each insertion method. An analysis of the results was carried out, to ascertain the effects of electrode design and insertion technique on force output during implantation.

C. Measurement of Force Due to Friction Between the Silicone/Teflon Interface

In this paper, frictional force was measured in a separate set of experiments, as it contributes to the overall force delivery during implantation. Since the electrode touches the ST inner wall, the outer wall, or both (depending on the insertion technique), there will be some degree of frictional force acting between the silicone carrier and ST walls. The impact of frictional force on final force delivery during electrode advancement was assessed.

A tribometer (CSM Instruments) was used in a pin-on-disc configuration to measure the coefficient of friction between Teflon and silicone samples, for varying degrees of surface roughness and lubrication. Circular Teflon discs of 25-mm diameter and 3-mm depth were precisely machined in a lathe and some samples finely polished for a smoother surface. Silicone specimens had either a rectangular surface area or a spherical geometry (of ball configuration, similar to the electrode tip, $\sim 1 \text{ mm}^2$ contact area). The silicone was mounted tightly in the tribometer and lowered onto the Teflon disc. Radii about the axis of revolution were changed between trials, measured from the center of the disc. Speed of rotation was set at 1 cm s^{-1} , load was varied from 1 N to 10 N and a sampling rate was set at 10 Hz. Experimentation was performed at room temperature. Trials were done with and without lubricant, on rough and smooth disc surfaces. This was done to determine the impact of lubrication and surface roughness on starting and dynamic coefficients of friction for this application. In this context, the starting friction is equal in magnitude and opposite in direction to the force required to set the disc into motion from its state of rest and the dynamic friction is a resistive force that opposes the disc surface whilst it is in motion, which is usually less than the starting friction.

The coefficient of friction, μ , can be calculated by application of (1)

$$\tilde{F}_f = \mu \tilde{F}_n \quad (1)$$

where F_f is the force due to friction, F_n is the normal force and μ is the coefficient of friction.

A force sensor that was mounted on the head of the tribometer measured frictional force, F_f . The normal force, F_n , is the downwards force applied at the head from a known load. Instantaneous values for μ were generated from the measurement of these two values. The Instron software calculated μ

Fig. 5. Summary of results: average insertion forces with first standard deviation for the Contour Practice (P), Contour 24 (C), and Contour Advance (CA) electrodes for the Standard Insertion Technique (SIT), Partial withdrawal (Partial), and Advance-Off Stylet (AOS) insertion methods. Also included are peak forces at the Basal Turn for the SIT with Contour array (F Bas), forces due to electrode (UP) removal for stylet (St) and no stylet (No St) with the Contour, and forces associated with stylet withdrawal (F S.W.) for the Partial withdrawal technique are also provided. Further, for the AOS insertions, the average peak force during initial electrode advancement, which occurs just prior to a change in direction (and hence reduction) of net forces against the inner wall (INI) and the average peak force generated when the first marker rib touches the cochleostomy site (R1) are documented.

over time and plotted this result. To get accurate measurements, the device was manually calibrated for each load.

In Section III, the results that were produced from the measurement of insertion forces during electrode advancement into the ST model and coefficients of friction (for varying degrees of surface roughness and lubrication) are presented. The significance of these results is then discussed, with an assessment of the parameters that directly affect force output.

III. RESULTS

Electrode trajectories and force data generated by insertion of the Contour and Contour Advance electrodes are presented in this paper, for the SIT, partial stylet withdrawal and AOS methods. Typical force profiles for the SIT, partial stylet withdrawal and AOS methods are shown in Fig. 2 for the Contour and Contour Advance electrodes, with electrode trajectories corresponding to specific stages of the insertions. Average output force values and first standard deviations that were calculated from the entire set of insertion forces, for each insertion method, are summarized in Fig. 5. Starting and dynamic coefficients of friction for the Teflon/silicone interface were quantified and averages are shown in Fig. 6. These results are intended for comparison of force delivery between the different insertion methods and to identify factors that directly affect force administration, at various stages of electrode advancement.

A. Force Output and Electrode Trajectories for the SIT, Partial Stylet Withdrawal and AOS Methods

1) *Standard Insertion Technique*: The SIT was performed for the Contour Practice and Contour arrays. Force profiles that were generated from insertion of the two types of electrodes appear similar in shape and magnitude. As the Contour electrode is inserted into the ST, the total force generally increases (Fig. 2). There is a small peak around the 4-mm mark which is due to

Fig. 6. Averages and first standard deviations for starting (start) and dynamic (dyn) coefficients of friction between silicone/Teflon interface, for different configurations: rough disc (R) or smooth disc (S), dry (D), or wet (W) conditions, with rectangular (C) or spherical (E) silicone geometries.

outer edge of the electrode hitting the cochleostomy site. Insertion force tends to drop off after the 5-mm mark, as the tip no longer touches the inner wall and the side slides along the outer wall as it progresses towards the Basal turn. A peak in insertion force is observed as the electrode tip touches the lateral wall of the Basal turn, averaging 0.095 N and 0.098 N for the Contour and Practice electrodes, respectively, around the 9–12 mm mark (Fig. 2, point 2). The net insertion force increases as the electrode array is fully advanced and reaches a peak value where the first marker rib touches the ST opening just before full insertion, where it drops off slightly (Fig. 2, point 5). Force profiles exhibit an overall increase to the average peak value of 0.113 N (Contour) and 0.090 N (Practice) just before the rib touches the cochleostomy site (Fig. 2, point 4). After this point, forces increase dramatically to 0.194 N (Contour) and 0.178 N (Practice). The stylet is then withdrawn. During electrode removal from the model, forces increase to 0.037 N (Contour) and 0.029 N (Practice) near the Basal Turn then decrease.

2) *Partial Withdrawal of the Stylet*: As in the SIT, a general increase in net insertion force is observed for the partial stylet withdrawal method. However these forces are reduced after the electrode touches the outer wall around the Basal turn area (Fig. 2, point 2). This is due to a decrease in strength near its tip and a change in electrode trajectory as it recoils to follow the ST inner wall, after the stylet is partially withdrawn. Slight peaks are again observed around the 4 and 9 mm marks, with an average peak force at the lateral wall of the Basal turn of 0.057 N (Contour) and 0.050 N (Practice). Insertion forces increase to 0.041 N (Contour) and 0.058 N (Practice) prior to the first rib contact. Near full electrode placement, during rib interaction with the model, peak values of 0.115 N (Contour) and 0.120 N (Practice) are reached, which are less than those produced from the SIT. Average forces associated with stylet removal at partial and full insertion depths are 0.247 and 0.261 N for the Contour (0.254 N total average).

3) *Advance Off- Stylet Insertions*: Notably lower insertion forces result from application of the AOS technique using the Contour Advance electrode. A slight increase occurs during initial insertion (Fig. 2, point 1) to an average value of 0.005 N. An increase in frictional force as the electrode slides along ST

the inner wall (due to an increase in contact surface area) may contribute to the rise in insertion forces during this period. The force then appears to reduce to a negative value (indicated by the trough in Fig. 2, between points 2. and 3). This corresponds to the change in direction of forces exerted on the inner wall as the electrode pushes against it in the opposite direction to the insertion. Frictional forces continue to increase the magnitude of the total force imparted on the model during this interval. An average peak force of 0.0082 N is reached just before the first rib touches the ST (Fig. 2, just before point 5). Contact between the marker rib and the model causes a significant increase in output force (represented by the spike in Fig. 2, point 5), for the AOS method at a distance of approximately 16 mm along the ST. Here, forces rise to an average value of 0.050 N.

Electrode trajectories appear to vary depending on the technique selected for insertion. Removal of the stylet causes the array to assume a position closer to the modiolus. In the AOS method, the electrode tends to follow the ST inner wall throughout the entire implantation, as shown in Fig. 2. Insertion studies are performed to see what effect early advancement of the Contour Advance would have on results for the AOS insertion. In these trials, the electrode is inserted 1–3 mm into the ST opening, as in the SIT, and the electrode advanced off the stylet. Out of 30 trials, in 40% of cases the silicone tip rolled back upon itself, precluding deep insertion into the model and prohibiting the tip from assuming a final position along the modiolus, the tip itself pushing the electrodes back towards the outer wall. This increases the chance of inducing trauma in this region, since the contact area is greater in the tip region and may lead to an increase in contact pressure upon collision with the ST wall. The Contour Advance is only meant to be used with an AOS insertion, where the array is inserted to the white marker on the silicone carrier, before the electrode is moved off the stylet.

B. Starting and Dynamic Coefficients of Friction for the Teflon/Silicone Interface

Results for starting and dynamic coefficient of friction measurements between the Teflon/Silicone interface are summarized in Fig. 6. The closest representation of the insertion scenario is the silicone tip against a lubricated, rough disc (a Teflon disc that has been cut via rotational machining and its surface remains unpolished). This gives an average starting coefficient of 0.061 and a dynamic coefficient of 0.040, for a time period 1s to 8.5 s which is the average time for an electrode insertion (based on the SIT).

Insertion force and coefficient of friction data produced in this paper are compared with previously published results for different electrode designs and insertion methods. This is done to validate the results and for comparison of force output and electrode trajectories of the available techniques. The importance of these results is discussed and the key factors that affect force output during electrode insertion are identified.

IV. VALIDATION OF RESULTS

In this section, a critical analysis of the results produced in this paper is carried out by comparing them with the previously published data. Force profiles generated from electrode insertion in [4] and [7] are of similar shape to those produced

in this paper for the SIT, with insertion forces increasing to a peak value near maximum insertion depth. The Clarion electrode reaches a peak value of approximately 32.5 g (0.320 N) and the prototype electrode of about 34 g (0.340 N) [4]. The authors attribute the rise in insertion force to frictional forces associated with electrode carrier positioning. Depending on electrode location (hence proportion of contact surface area between the carrier and ST walls), frictional force will vary. Similar force profiles are generated for the C40+ and C40+ FLEX electrodes [7], reaching average peak values of ~ 0.036 N and ~ 0.023 N, respectively. Insertion forces in this paper also increase to a peak value before the first rib touches the model. These values are 0.113 N (Contour) and 0.090 N (Practice Contour). Removal of the platinum stylet reduces peak values at the same distance to 0.041 N (Contour) and 0.058 N (Practice Contour). The peak insertion force for the AOS insertion is lowest at 0.008 N (Contour Advance), yet the force increase is not as steep (Fig. 2).

Insertion forces for all three techniques produce lower insertion forces (both before and after contact with the first marker rib) than those in [4]. However, insertion forces produced in this paper are higher than those presented by Adunka *et al.* [7], for the SIT and partial withdrawal methods. This is most likely due to differences in electrode design and insertion technique. Using the SIT and partial withdrawal method, the presence of the stylet increases the rigidity of the electrode. It does not appear that the carrier used by Adunka *et al.* [7] houses a stylet. This reduction in strength may account for lower force output.

Insertion forces are lowest for the AOS technique in comparison with results produced by other methods [4], [7]. The force exerted onto the model is 0.008 N prior to interaction with the first rib, whilst insertion of the FLEX electrode gives a peak insertion force of 0.023 N [7]. Again, this may be due to differences in electrode properties and methods for insertion. In the AOS insertion, the electrode does not make contact with the outer wall, has a soft-tip to create a softer region in this area and the stylet is not inserted with the carrier which decreases its overall strength. In this paper, we consider peak forces prior to the point of contact between the first rib and ST. Interaction between the rib and ST opening dominates force output, which does not provide a true representation of force delivery inside the model.

For the SIT, electrode trajectories primarily follow the ST outer wall to full insertion depth, as for the Clarion electrode [4] and as is simulated for the Nucleus Straight electrode [6]. The electrode tip similarly contacts the lateral outer wall in the Basal turn area [4]–[6]. A more medial position is achieved by a new prototype developed by Adunka *et al.* [4]. For an AOS insertion, the implant follows the ST inner wall and assumes a perimodiolar position at full insertion depth.

Similar work carried out by Rebscher *et al.* [5] for silicone on epoxy with a 25% soap solution have resulted in a coefficient of friction of 0.600. In this paper, a silicone sample is rotated on a Teflon disc in the presence of a lubricant which simulates the surface interactions during electrode insertion into a ST model. The results produced for dynamic and starting coefficients of friction are 0.061 and 0.040, respectively, using silicone/Teflon interface with a 10% bathox soap solution. This difference in results may be due to the surface properties of the Teflon itself (including material composition and surface roughness), which

gives a lower coefficient than an epoxy surface for similar lubrication and sample size.

Results produced in this paper from insertion force measurements, electrode trajectory and coefficient of friction analysis are comparable with the outcomes of similar research [4]–[7]. The SIT is equivalent to insertion methods applied by Rebscher *et al.* [4] and Adunka *et al.* [7]. The partial withdrawal method is a modified version of this and the AOS insertion is a newly evaluated technique.

V. DISCUSSION OF RESULTS

Measurement of insertion forces and coefficient of friction has revealed some critical factors that contribute to force delivery during insertion of the Contour and Contour Advance electrodes into a synthetic replica of the human ST. Analysis of the results reveals that carrier strength, contact pressure, frictional force, electrode trajectory and surgical technique each have an impact on insertion force output.

A. Effect of the Platinum Stylet On Insertion Force

In this section, the effect of carrier strength due to the stylet and contact pressure on force output during the insertion was examined. Strength of the Contour and Contour Advance electrodes is increased by the presence of the platinum stylet. Results indicate that the greater the stiffness properties of the carrier itself, the higher the total force imparted on the cochlea during implantation, as in [6]. Insertion forces associated with the SIT are the highest of all methods (Fig. 6). For the SIT, the stylet remains in place during electrode advancement. Partial withdrawal of the stylet in the region of the Basal Turn leads to a decrease in insertion force, as the carrier strength near the tip of the array is reduced. This is evident in Fig. 2. After withdrawal around the 9-mm mark insertion forces decrease following partial stylet removal after touching the lateral outer wall and then continue to increase. A lesser peak insertion force is reached by partial stylet removal than the SIT, both prior to and following introduction of the first rib. Contact pressure at the Basal turn is the same for both techniques, as the stylet remains in the carrier until after this point and contributes to a rise in insertion force at this stage (Fig. 2, point 2).

Insertion forces for the Practice and Contour electrodes are similar, indicating that the strength properties between designs do not vary significantly, hence the Practice electrodes provide a good representation of the true array, for specialist training. The AOS technique has minimal insertion forces, with the lowest average peak insertion force of all three methods analyzed in this paper. This method also results in the lowest variability of forces measured between trials. This indicates that the technique is more consistent than the SIT and partial withdrawal methods which have higher variability.

Advancing the electrode off the stylet greatly reduces its overall strength since the stylet does not provide additional support as the carrier progresses along the cavity. The addition of a soft-tip on the Contour Advance creates a softer region in this area, in comparison to the Contour array tip. Since the electrode does not touch the Basal Turn area for the AOS insertion, there is no peak in insertion force in this region (Fig. 2). Therefore, there is no contact pressure from input force exerted in this region. To summarize the effect of implant strength on

force application: generally, the greater the electrode carrier rigidity coupled with contact pressure at the tip, the higher the force output during an insertion.

B. Contribution of Frictional Force to Insertion Force

The contribution of force due to friction to the overall force delivery is examined. For all techniques applied in this paper it was evident that as the silicone carrier was inserted into the model, the contact area between the carrier and ST increased (as more of it touched the outer and/or inner walls). This led to an accumulation in force due to friction (2)

$$\tilde{F}_{F\_TOT} = \sum_{i=1}^N \tilde{F}_{Fi} \quad (2)$$

where F_{F_TOT} is the total force due to friction, F_F is the force due to friction at point i at the cochlea wall and N is the total number of contact points between the silicone and wall.

Frictional force is proportional to the normal force exerted during insertion (1), where the latter is resolved from the total input force by application of (3)

$$\tilde{F}_n = \tilde{F}_{in} \sin \alpha \quad (3)$$

where F_n is the normal force, F_{in} is the input force and α is the angle between the input force vector and through the point of contact (Fig. 3).

As the electrode was advanced into the ST using the SIT, partial withdrawal and AOS methods, the increasing component of frictional force contributed to the rise in insertion force magnitude (Fig. 3). The input force, F_{in} , is greater for the SIT and partial withdrawal methods than the AOS technique. Whilst there is a restoration force exerted onto the ST inner wall as the electrode is advanced using an AOS approach, this is expected to be much smaller than F_{in} exerted by the user. F_{in} can be resolved into two forces: a reaction or normal force, F_n acting against the ST walls and the force that advances the carrier along the ST. F_{in} appeared to provide significant contribution in contact pressure at the Basal turn upon first impact with the outer wall, as reflected by the peak in output force (Fig. 2, point 2).

Whilst the coefficient of friction is assumed to be relatively constant during insertion, tests revealed that starting and dynamic coefficients will vary depending on surface roughness, contact geometry and lubrication (Fig. 5). For the Teflon/silicone interface, μ increases with surface roughness in dry conditions. However, addition of lubricant (bathox solution) reduces μ and the effect of surface roughness becomes negligible. Rectangular geometry for the silicone sample results in a higher value of μ than the point contact area of the sphere, suggesting that μ may depend on surface contact area (most likely due to adhesion [23]). The value of μ at the start of testing is consistently higher than dynamic μ for all cases. The most applicable representation for the environment inside the model is the silicone sphere geometry, on the rough (not polished) disc in the presence of lubricant, for a dynamic friction coefficient measured from 1 s to 8.5 s. This is because the sphere geometry most closely matches the silicone tip of the electrode in size and shape, the rough disc was machined in the same way as the model surface (unfinished) and the soap solution is a substitute for the endosteum lining of the ST. An average insertion took

approximately 8.5 s. Although the values for μ are small for this scenario, the additive effect of frictional force during an insertion is apparent and does contribute to the final force delivery. The magnitude of frictional force during electrode insertion has not been determined, but could be obtained by using a two-degree-of-freedom (2DoF) load cell to measure F_n during initial electrode advancement and then calculate F_F based on the value of μ (dynamic) as determined in this paper. The exact contribution of F_F to the total insertion force could then be established.

C. Electrode Trajectories and Positioning During Insertion

Electrode trajectory will vary depending on surgeon technique (Fig. 2). For the SIT, the electrode primarily followed the ST outer wall during the entire insertion. Partial stylet withdrawal around the Basal turn area resulted in the electrode recoiling towards the inner wall and following it until insertion forced the electrode back to the outer wall near its final position. Withdrawal of the stylet at full insertion depth caused the array to be positioned along the inner wall, with electrode orientation towards the modiolus. The Contour Advance followed the inner wall of the cochlea for AOS insertions, as restoration forces caused the silicone to curl towards it. This eliminated contact pressure between the electrode tip and ST outer lateral wall, which caused a significant peak in insertion forces for both the SIT and Partial withdrawal methods (Fig. 2, point 2). It also reduces the chance of the electrode deflecting upwards and into the delicate BM during an *in vivo* implantation. This may occur in the SIT and Partial withdrawal after the tip contacts the outer wall at the Basal Turn [11]. Final removal of the stylet at full insertion depth caused the electrode to advance slightly, providing a deeper insertion.

It is worth noting that if the electrode orientation is correctly pointed towards the modiolus, there will be a reduced contact surface area between the carrier/wall interface for the AOS insertion as opposed to the SIT and Partial withdrawal methods. Exposure of the electrodes for the Contour and Contour Advance means that they do not come into contact with the cochlea walls and so the total contact surface area on this face is reduced. Since the electrode followed the inner wall only for the AOS and primarily the outer wall for the SIT, $F_{F_{TOT}}$ was reduced (2), which caused a decrease in insertion force.

D. Recommendation of Insertion Technique

Surgeon technique and selection of electrode type will vary between specialists, however insertion studies performed in this paper reveal that this decision will affect force administration and electrode trajectory. The Contour Advance is designed for use with an AOS insertion, which collectively achieved a more desirable outcome than the Contour electrode inserted in a SIT or combined with partial withdrawal of the stylet. An overall reduction in the rigidity of the electrode as it was inserted into the ST, combined with improvement in trajectory as it traced a path along the inner wall, lead to a marked reduction in force application, particularly at the Basal turn where previous designs and administration have caused damage or trauma in this area [4], [5], [11], [12].

The authors recommend that the Contour Advance is inserted to the white marker on the carrier, as intended by the manufacturer, in order to achieve optimal placement of the electrode

array as well as preventing its damage. Results indicate that early advancement of the carrier off the stylet may result in the tip rolling back upon itself. At worse case this prohibited insertion during trials, causing the array to buckle and in practice it would be discarded. In most instances, bending of the tip results in a continued insertion, yet at final position the tip remains bent at 180° and pushes the electrode array further away from the inner wall. This would result in an electrode position that is closer to the delicate structures residing along the lateral wall. As a larger tip cross-section is advanced in this region (due to bending of the tip), there is an increased risk of inducing trauma in this area caused by incorrect force application and/or undesirable electrode trajectory.

VI. CONCLUSION

For any prosthetic implantation it is important to evaluate the products and associated procedures that the surgeon has available for use. Appropriate selection of design and technique can reduce force administration during surgery, minimize trauma and lead to an improved outcome. In this paper, force application is evaluated for implantation of the Practice, Contour and Contour Advance electrodes into a synthetic model of the human ST, using the SIT, Partial withdrawal and AOS methods. This paper was undertaken to assess insertion forces for these techniques and identify factors which affect force administration for the reduction of force output. Previous studies have examined electrode trajectories and insertion forces for the Med-El Combi 40+, C40+ FLEX, Clarion and custom designs.

Results produced in this paper indicate that forces imparted on the ST during insertion are dependent on electrode strength, trajectory and frictional forces between the silicone/wall interface. Higher electrode strength combined with contact pressure between the tip at the Basal turn and accumulation of force due to friction increases total forces associated with cochlear implantation. Minimal force application was achieved using the Contour Advance electrode in an AOS insertion. This method prevents the electrode from touching the ST lateral outer wall in the Basal Turn area, which is expected to eliminate contact pressure and minimize trauma in this region. This is a significant finding of the work. In order to avoid buckling of the silicone soft-tip, the Contour Advance should be inserted to the white marker, as intended by the manufacturer. Early advance of the electrode may prohibit both its optimal placement along the ST inner wall as well as a deeper insertion.

VII. FUTURE WORK

For future studies, the authors suggest the use of a 3-D model of the ST from Teflon and cadaver material for comparison of results obtained using the 2-D replica. To date, force measurement studies have used synthetic models of the ST as technology enabling *in vivo* measurement is presently not available for this surgical application. It is difficult to replicate tissue properties and quantify insertion forces that directly inflict trauma in a plastic model of the ST, which is not a true scenario of the actual procedure. The Teflon model is of different material composition and physical behavior than a live human cochlea. In this paper, a 1 degree-of-freedom (DoF) Instron device is used for measurement of insertion force, which does not capture all force

components contributing to the total insertion force. Specifically, measurement of F_n would enable the quantification of F_F . Ideally, a 6 DoF device should be used. This work was performed to investigate force delivery during insertion of the Nucleus® 24 Contour™ and Nucleus® 24 Contour Advance™ arrays. Results from this study will be used to validate a surgical simulator with force-feedback for training surgeons in cochlear implantation. Research of this kind will assist in improvement of administration techniques for cochlear implantation.

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