The Potential Use of Curved Nitinol Stylets for Optimized Robotic Insertion of Perimodiolar Electrode Arrays

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KEYWORDS. Nitinol, cochlea, electrode array, robot

BRIEF. The purpose of this study is to assess whether custom-designed Nitinol stylets could better fit the human cochlea than those currently used in cochlear implant surgery.

ABSTRACT. During cochlear implant surgery, a perimodiolar electrode array (PEA) is inserted into the cochlea to partially restore hearing sensation. The PEA coils to the shape of the cochlea via retraction of a straight internal stylet. Yet, previous studies have shown that much risk is associated with the insertion of the PEA. This study evaluates the potential to reduce that risk by using pre-curved stylets to change the equilibrium shape of commercial electrode arrays. First, a protocol is established for creating curved stylets from superelastic Nitinol. Image processing algorithms are presented to model and characterize how different types of stylets affect PEA equilibrium shapes. Results suggest that the extent of curvature used in the stylet shape is limited by the stability of the assembled stylet-electrode pair. Custom stylets with smoother shape curvatures were discovered to cause the electrode array to better match the curve in the cochlea than did straight stylets. A custom stylet with two inverted curves was observed to minimize premature curling of the PEA during insertion. Insight into these behaviors of the electrode array system may lead to an improved PEA setup during cochlear implant surgery assisted by medical robotics.

INTRODUCTION.

Background.

Hearing loss is prevalent within modern society. Sound from the environment travels through the auditory system, is converted into nerve pulses, and is finally sent to the brain for interpretation [1]. In a sense, cochlear implants can be called "bionic ears" – they provide greater benefits to their users than do conventional hearing aids. Hearing aids only amplify sounds to damaged portions of the ear [2]. Those fitted with hearing aids still have functioning inner ear hair cells to relay those amplified sounds to the brain. Individuals with damaged hair cells in the inner ear can often have a degree of hearing restored by cochlear implants.

A cochlear implant has five main components. External parts consist of a speech processor, electromagnetic transmitter, and microphone, as seen in Figure 1. Internal pieces include an electromagnetic receiver and an electrode system [3]. This electrode system comprises platinum electrode contacts embedded in a silicone tube, designed to fit inside the cochlea. A perimodiolar electrode array (PEA) is one type of electrode array with a pre-manufactured curve. During surgery, a PEA is inserted and curls into the shape of the cochlea wall after retraction of the internal stylet [4]. To provide hearing, the PEA makes contact with and electrically stimulates the neural system.

Pertinent Literature.

Electrical stimulation of human hearing has spanned over a few centuries, beginning with Alessandro Volta in the late 18th century [5]. In recent years, robotically assisted cochlear implant surgery came into play when in 2011, Pile et al. analyzed the Contour Advance array for repeatability between consecutive stylet re-insertions [6].

Nitinol, or NiTi, is used in this study to create various curved stylets and is an alloy of Nickel and Titanium [7]. It exhibits shape memory qualities that allow it to switch between two crystallographic states at respective temperatures [8].

Purpose.

Currently, the commercial stylets accompanying the Contour Advance PEA are made of Platinum. This report presents an investigation of the potential use of custom made pre-curved NiTi stylets, with various curvatures, in order to change the equilibrium shape of the electrode array during insertion.

Rationale.

Previous works have shown that the standard, straight stylet had a tendency of causing premature curling of the PEA [6]. This in turn leads to an increased risk of insertion trauma due to unintentional puncturing of the cochlear wall. By creating stylets of different curvatures in order to change the shape of commercially available electrode arrays, this study hopes to discover a variation that will resolve premature curling of the PEA.

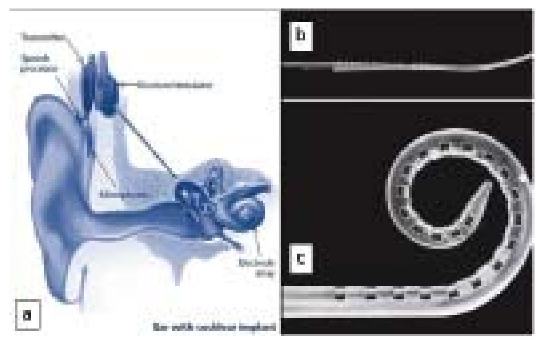

Figure 1. The common (**A**) setup of a cochlear implant. Photo credit: NIH Medical Arts. (**B**) Contour Advance perimodiolar electrode array (PEA) with the stylet fully inserted; (**C**) curled PEA with stylet removed. Photo credit: Cochlea Americas, Inc.

MATERIALS AND METHODS.

Shaping the stylets.

In order to test the effect of curved stylets, straight Nitinol wire was first shaped to different curves. Since superelastic Nitinol can only be shape set after reaching a specific temperature, usually in the range of 500 – 550 °C, it was critical to obtain a furnace to heat the Nitinol wire. The "furnace" was made of the following: a commercial hot plate capable of obtaining temperatures of up to 540 °C, 3 alumina silicate ceramic plates, and high viscosity ceramic adhesive. The assembly was heated at 50 °C for 2 hours in a commercial environmental chamber to cure the adhesive. The completed "furnace" setup consisted of the hot plate covered by the ceramic chamber.

A program was written in MATLAB to calculate the three different points – two that determined the straight length before the curve, and the third which determined where the curve would end – that defined the curved stylet. A four flute, 0.05 mm carbide mill was used to make the curves in the copper plate. An optimal time was calculated for the copper plate, which contained the grooves the wire was to be constrained, to reach the desired temperature of 540 °C.

After the copper plate was removed from the furnace, it was immediately quenched in cold water to induce rapid cooling.

Image capture for characterizing electrode arrays.

The experimental setup for capturing and processing the images of how the various shaped stylets performed comprised the following: a high-resolution digital boom microscope, a linear slider, an adjustable light source, and a laptop computer that processed the photos taken. The high definition microscope was placed above the linear slider. 1mm by 1mm graph paper was taped onto the platform where the electrode array would remain while images were taken.

For consistency, the linear slider's platform for the electrode array was set up so that the array curled into the image plane. Four trials of 14 images each were conducted for each of the various curved stylets, as well as for the baseline – the straight stylet. For each image, shot at 10 megapixel resolutions, a specific process followed. The electrode array, with the stylet fully inserted, was placed onto the platform of the linear slider. The slider was manually turned, each time retracting 1.27mm of the stylet from the electrode array via the circumference of the retracting screw. After each complete turn, an image was taken, assuming any noticeable change in the electrode array had occurred. A total of 14 turns of the knob from the initial image were completed; further removal of the stylet would have no effect on the final, curved shape. As result, 14 images were captured and processed for each trial.

A program was written in MATLAB to compare equilibrium PEA shape results. First, it loaded the initial data file for each of the 4 trials of the stylet variations. This data contained the angles, arc lengths, and kinematics based on calibration matrices from the experiment's data [6]. After averaging the data, it was able to produce a PEA shape that most represented a specific stylet shape.

RESULTS.

Electrode array with straight stylet (S100).

The results obtained with this stylet served as the baseline. As shown in Figure 2, the straight stylet produced relatively consistent errors between the 4 trials. There were a total of 24 total manually digitized points – 22 electrode contacts, the starting and ending points of the PEA. Variation between the trials increased towards the tip, as indicated by a slight jump in error after segment number 20.

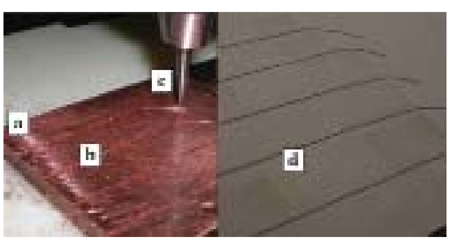

Figure 2. Deviation from the reference trial of the current, commercially available straight stylet. The error is represented qualitatively on the left and quantitatively on the right.

Electrode array with curved stylet 1 (S70c).

Stylet S70c produced a wider range of error from its reference trial than did S100.

Electrode array with curved stylet 2 (DS4c).

Stylet DS4c produced more consistent, decreased errors from the reference than did S100. However, it did begin to peak in variation at about segment 22.

S100 vs. S70c vs. DS4c.

The three stylet variations were superimposed on top of each other at various intervals. The average electrode array shapes are displayed for each of the three different types of stylets. Thus, as detailed in Figure 3, the equilibrium shape for each stylet-PEA-variation was compared.

Stylet S70c produced an electrode array with an initial position vastly different from the baseline straight stylet S100. At pull #1, the first half of the S70c array was almost perpendicular to the x-axis, whereas that of S100 was slanted at around a 30 angle. During the initial pulls, S70c demonstrated more erratic shape change than did S100. For instance, the tip of S100 begins curling inwards gradually; however, the tip and midsection of S70c both curl as seen in the transition between pull #1 and pull #6, greatly changing the initial shape. At stylet pull #6, S70c is bent and above S100 by roughly 1 mm.

On the other hand, DS4c created a balance between the shape changes between pulls of S100 and S70c. DS4c displayed increased curling relative to S100 during the initial stages of stylet pull but decreased curling relative to S100 during the final stages of stylet pull. After the stylet was fully retracted, DS4c did not curve towards the y-axis as much as S100 did. As seen at pull #14, S100 curled almost .75 mm more inward than did DS4c.

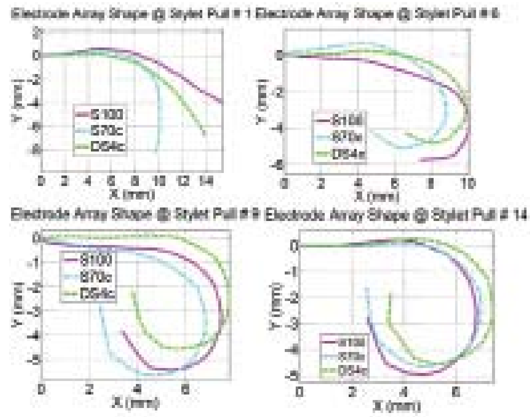

Figure 3. Selected outputs, from the program written based on Pile's algorithms, to display graphical results of the average shapes produced by the three different stylets. The equilibrium shapes are superimposed on top of each other for comparison.

DISCUSSION.

Quality of Produced Stylets.

For the initial set of curved stylets, the Nitinol was left in the furnace for thirty minutes to make sure that the critical temperature at which the Nitinol began to shape set would take place. However, after observing the finished stylets, the wire exhibited degraded superelasticity. Thus, a shorter heating time was determined as described in section 2.1. Stylets made from the shorter heating time retained the superelasticity initially desired.

Observations on Behavior of Stylets.

A few interesting observations of S70 were made while inserting it into the electrode array. When inserting the standard stylet into the electrode array, the rotation angle perpendicular to the insertion path did not influence the insertion process. For instance, if a straight stylet was already halfway inserted into the electrode array, the stylet could be rotated about itself and nothing significant will happen to alter the insertion path. However, if a curved stylet had accidentally rotated halfway inserted, then the curve would no longer have faced the desired direction.

As a result, a new S70 was made; this time with a modification on the end tips. An extra screw was attached to the copper plate near the end of the S70 groove. Before heating, the Nitinol wire in the groove, once constrained in shape, was tied around the end screw in a fashion that followed the direction the curve of S70 was pointing in. When the finished stylet came out of the shape setting process, the coiled Nitinol wire at the end of the stylet served as guide for insertion. Yet, after taking the electrode out of the stylet replacement tool with S70c fully inserted, the curve of S70c would still automatically curve back to the natural shape of the electrode array. The elastic energy exerted by S70c overcame the friction within the electrode array and allowed the stylet to change its intended insertion path. Thus, a double curved stylet was designed. The idea behind this concept was that a double curved stylet would be less resistant to curving back to the natural shape of the electrode array.

Comparison of the Results between Curved Stylets and Straight Stylets.

The self-fabricated Nitinol stylets indeed had a significant influence on the equilibrium shape of the PEA. The increased amount of error produced by S70c was most likely due to the heavy curve within the top half of the array, since pulling the curve though a relatively straight body would cause more erratic behavior than a straight stylet through a relatively straight body of silicone. Compared to the straight stylet, DS4c also was more consistent than S70c, mainly because its double curve did not deviate from the standard straight S100 stylet as much. As a result, DS4c served as a balance between the single curved and non-curved stylet.

The results obtained by stylet DS4c on the equilibrium shape of the PEA are significant because its equilibrium shape did not curl prematurely as did the straight stylet. In addition, given that the width of the wall that the PEA is being inserted into ranges from 3.0 mm to 1.5 mm, the .75 mm equilibrium shape difference between S100 and DS4c is noteworthy. Such a difference could resolve the premature curling, as Pile et al. pointed out, exhibited by the commercial straight stylet, thereby lowering insertion trauma risk. It is this risk that this study aims at reducing -- thus far, the custom made DS4c stylet displays potential in doing so.

CONCLUSION.

This study was able to fill in some gaps in the literature regarding the use of Nitinol in cochlear implant surgery. In order to add to the understanding of the different properties of PEAs, this paper has presented an in depth analysis of the role the stylet plays during insertion of the array. Nitinol, commonly used in medical stents with eye surgery, as well as other applications requiring the shape memory alloy, was employed for the first time in shaping various PEA stylet designs. Future work will focus on developing stylets with more than a double curve – perhaps a triple or quintuple curve and address how to prevent stylets from twisting inside the electrode array. In addition, future work will attempt to combine a curved stylet design with robotic insertion of the PEA to further reduce insertion risk associated with cochlear implant surgery. Regardless, the current results suggest a more favorable PEA setup, consisting of a double inverted curved stylet, rather than the current straight stylet. This could possibly impact the field of this inner ear surgery, allowing surgeons and robots alike to perform cochlear implant surgery with a PEA that molds more closely to the actual shape of the human cochlea. Doing so would pave the way for safer and more precise surgeries for those in need of cochlear implants.

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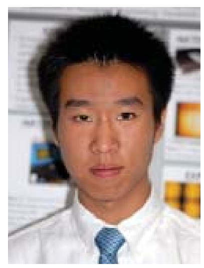

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