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Tactile Sensory Digit Feedback for Cochlear Implant Electrode Insertion

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***Abstract*—**Cochlear Implantation (CI) which became a routine procedure for the last decades is an electronic device that provides a sense of sound for patients who are severely and profoundly deaf. The optimal success of this implantation depends on the electrode technology and deep insertion techniques. However, this manual insertion procedure may cause mechanical trauma which can lead to severe destruction of the delicate intracochlear structure. Accordingly, future improvement of the cochlear electrode implant insertion needs reduction of the excessive force application during the cochlear implantation which causes tissue damage and trauma. This study is examined tool-tissue interaction of large prototype scale digit embedded with distributive tactile sensor based upon cochlear electrode and large prototype scale cochlea phantom for simulating the human cochlear which could lead to small scale digit requirements. The digit, distributive tactile sensors embedded with silicon-substrate was inserted into the cochlea phantom to measure any digit/phantom interaction and position of the digit in order to minimize tissue and trauma damage during the electrode cochlear insertion. The digit have provided tactile information from the digit-phantom insertion interaction such as contact status, tip penetration, obstacles, relative shape and location, contact orientation and multiple contacts. The tests demonstrated that even devices of such a relative simple design with low cost have potential to improve cochlear implant surgery and other lumen mapping applications by providing tactile sensory feedback information and thus controlling the insertion through sensing and control of the tip of the implant during the insertion. In that approach, the surgeon could minimize the tissue damage and potential damage to the delicate structures within the cochlear caused by current manual electrode insertion of the cochlear implantation. This approach also can be applied to other minimally invasive surgery applications as well as diagnosis and path navigation procedures.

***Keywords*—**Cochlear electrode insertion, distributive tactile sensory feedback information, flexible digit, minimally invasive surgery, tool/tissue interaction.

I. INTRODUCTION

COCHLEAR implantation aims to provide hearing technology for persons with sensorineural hearing loss. The technology of the cochlear implantation involves surgeons implanting a thin electrode array into the inner ear (cochlea) [1].

CI electrodes are manually inserted into the cochlea and this electrode insertion which requires atraumatic and complete insertion of the electrode array to the cochlea plays a major role in hearing preservation [2], [3].

The electrode insertion is stopped until further advancement of electrode array could not be made [3], [4]. The excessive resistance encountered by the electrode array which is required to insert or to reach sensitive regions of the cochlea wall may cause damage to the tissue or the walls of the cochlea [5]-[9].

Cochlear has delicate spiral lamina and outer wall which is filled with fluid (endolymph) and surrounded by fluid (perilymph). Electrode arrays (20-24 wires of 20µm diameter or less) interacts with auditory nerve during cochlear implant (size of 1.3mm diameter x 31.5mm length) during the cochlear implantation procedure. Electrode array insertion procedure without exerting force on these delicate tissues of the cochlea is needed [2], [3].

Significant efforts have been directed at minimizing trauma cochlear by suggesting different techniques such as perfusion-based method [2], position array sensor [providing flexible electrode [5], precurved electrodes [10], and automation insertion tool [11]. These attempts have tried to reach optimum insertion of the electrode cochlear insertion but did not produce the expected improvements of no trauma.

Small size which is not precluding small incision inside the human body and flexible of electrode arrays are needed to minimize exerted forces on the cochlea walls during electrode insertion [12]. Reducing forces on the cochlear outer walls, obtaining more consistent perimodiolar position should result in a favourable outcome. Furthermore, a flexible and steerable tool which can eliminate excessive force during the surgery has attracted considerable attention in recent decades due to its application in minimal access surgery procedures such as biopsies and cochlear implants [12], [13]. However, trauma and damage during insertion of electrode arrays is related to lack of tactile or haptic feedback of the interactions between cochlea and the electrode arrays. Consequently, to avoid damage to delicate tissue, it is crucial to have instruments which have haptic ability, measure small and delicate tissue contact, determine obstacles and what is happening inside the human body during surgery, and can be used for diagnoses and preoperative procedures which the surgeon does not have the ability to see [12]. Moreover, tactile tools/probes which provide feedback information from very soft tissues, such as inside a patient's body, to the surgeon during minimally invasive procedures are key components of current minimally invasive surgery including the cochlear implantation [14].

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In the present study, we have introduced development of a flexible digit with embedded sensitive touch feedback for CI electrode insertion. The aim of the new method is to minimize insertion related trauma and achieve more apical electrode insertion than possible by the contemporary techniques. The technique is still early stage, with the long-term goal of hearing preservation. The technique relies on sensory tactile feedback of the cochlear/electrode interaction information. This approach will provide tactile information feedback to the surgeon during cochlear implantation operations. That is, current existing flexible contour electrode arrays and insertion technique with tactile feedback approach could eliminate trauma and damage of the cochlea and can facilitate deeper insertion. Similarly, the risk of damaging the basilar membrane during insertion of the electrode array into the human cochlear is expected to be significantly reduced with the ability to redirect the tip of the electrode array at the critical hook region. The bending behaviour of the flexible electrode array and its trajectories during insertion into the scale tympani could be predicted and the final position of the EA can also be adjusted to lie beneath the basilar membrane inside the scala tympani.

II. MATERIALS AND METHODS

Besides the flexibility and contour shape of the digit, the fundamental principle behind this proposal is the sensor embedded on the digit. The prototype flexible sensory digit consists of a flexible silicone substrate that is bent to the required anatomical shape; stylet which will make it easy to advance the digit and keep the pre-curved shape of the digit during or after it has been released. Sensors were used to gather information about the interactions, and phantom which resembles human cochlea. Current electrode arrays of the cochlear may be classified based on their shapes such as straight, contour, curved and spiral electrode shapes. The contour electrode has flexibility as well as being pre-shaped to match the form of the cochlea to make it possible to reach a greater depth into the cochlea compared to a straight one and to reduce damage to the cochlear [15], [16]. It can therefore be assumed that the future development of cochlear implantation electrodes will be in the direction of flexible forms, and as such this study used prototype prosthesis similar in form to a conventional flexible cochlear electrode. The prototype will hitherto be referred to as a `digit'. Fig. 1 represents the flexible cochlear electrodes which are held in a straight configuration prior to insertion by inserting a stylet into the cochlea. This then relaxes to a shape matching the curvature of the cochlea when the stylet is removed (withdrawn). This action will be replicated in the digit enabling investigation of the effect of the stylet on the geometry of and loads exerted upon the digit. Also, the digit has a sensors on it which enable to investigate as well the interaction of the digit with the structure of the cochlea, or cochlear phantom, throughout the insertion process.

One of the key requirements of the digit's material is flexibility. A smaller size with flexibility will make the digit better designed to match any future designs. In that way, the material of the design should have high allowable strain, high stuffiness and high strength to match the functionality of the digit. Based on the required features (shape and flexibility) of the proposed digit, silicone was selected as the material of the substrate because of its high allowable strain, and its high stiffness and strength in comparison to rubber or plastic materials. The prototype digit is constructed from RTV C250 silicone.

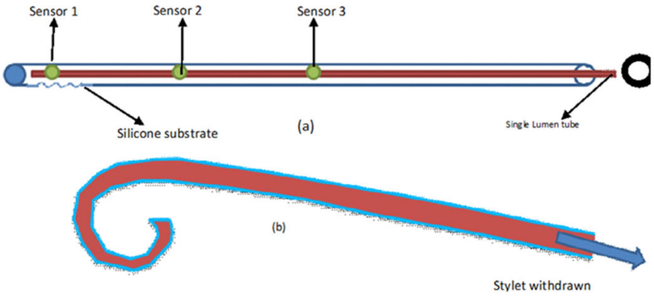

Fig.1 Main parts of the sensory digit: a) straightened through stylet during the insertion b) the digit with original pre-curved shape (stylet off) before the insertion

The flexible sensory digit has a single lumen that is 3 mm in diameter into which the stylet was inserted in order to control the digit curvature. To enhance the bending flexibility of the digit a serrated section shown on the end tip was added to make tip deflection easier as the digit was guided along with the basilar membrane wall of the cochlear phantom. In addition, the end tip should bend earlier than the other parts of the whole digit when stylet is removed to shape the curve shape of the cochlea. Sequential insertion of the flexible digit causes a curling trajectory of the flexible digit which conforms to the inside of the spiral shaped cochlear. For instance, the tip of the flexible digit should be able to detect the tissue contact of the CI as the electrode array goes deeper inside the cochlea in order to avoid any tissue damage. When the stylet is withdrawn, the deformation of the digit will be non-linear, however the curve shape and size of the tip are kept unchanged. This is the key point of the design as when the tip contacts with the basilar membrane wall, the sensors will feedback the status of the contact and the digit is expected to deform and bend as it slides around the wall by pushing back the stylet. Mathematically, the morphology of the digit prototype can be considered to be similar to a slender beam (aspect ratio > 25). As such, a relationship between the stresses, strains, radius of curvature and the material of the digit can be predicted using the Bernoulli-Euler bending moment-curvature relationship for a slender rectangular beam of uniform-section composed of a linear elastic material and this is expressed as [17]:

$$\kappa = \frac{1}{\rho} = \frac{\varepsilon_m}{c} = \frac{\sigma_m}{Ec} = \frac{1}{Ec}\frac{Mc}{I} = \frac{M}{EI} \tag{1}$$

where E is the Young's modulus of the material (N/M^2), M and κ are the bending moment and the curvature at any point of the beam respectively. (1/ρ) is the radius of curvature, σ is the stress, ε is the strain, *c* is the distance from the neutral axis of the beam and I is the moment of inertia (the second moment of area) of the beam cross-section about the neutral axis.

Besides contour shape and flexibility feature of the digit, the digit requires tactile sensing to feedback information about contacts between the digit's tip and the sidewalls of the cochlea phantom, as well as contact points along the digit and the sidewalls. A distributive tactile sensing system was selected for this research due its benefits of few sensors, small space and wiring requirements with larger covering area ability, and reduced data processing overhead. Strain gauge technology was selected for the tactile sensors as they require minimal space and are readily available in comparison with other technologies such as conductive elastomer and piezoelectric force sensors. Three strain gauge sensors are used as tactile sensors to collect information about the interaction between the digit and the phantom. Furthermore, strain gauges could be used to measure bending strains, which are proportional to curvature, allowing a distributive tactile sensing approach that can monitor both contact and shape through the bending strains induced by flexure. Fig. 2 shows the locations of the sensors of the sensory digit. Normally assuming 2 ¼, 2 ¾ or even one turn of the cochlear, there are three insertion stages: basal turn, second turn and the last turn. The optimal sensor locations were identified as being *0.12 L, 0.32 L* and *0.54 L* when measured from the fixed end, which are very close to 58%, 29% and 13% respectively of the anatomical measurements of the organ of Corti [18] as well as three stage locations which could cause contact with the electrode array insertions [19], [20]. These positions could show possibility of sensing the contacts along the digit during the digit insertion into the phantom through tactile sensing system feedback.

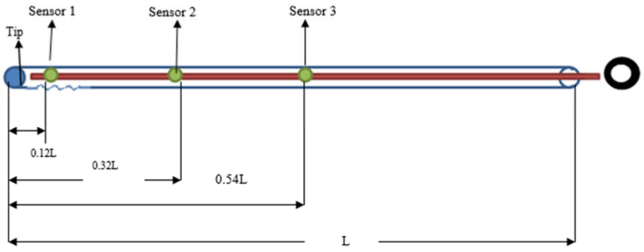

Fig. 2 Locations of the sensors along the digit

The overall digit as shown in Fig. 3 was manufactured using a 2 part split mould. The mould was constructed from Accura Si10 photocuring resin using a Viper Si2 Stereolithographic Apparatus from 3D Systems Inc. The instrumented lumen was located within the lower mould and then over moulded with RTV 250 silicone.

Geometric similarity exists between model (real or existing design) and prototype (proposed one) if the ratio of all corresponding dimensions in the model and prototype are equal. For the length (L) similarity, we have:

$$\frac{L_{\text{mod}\,el}}{L_{prototype}} = L_{raio} \qquad (2)$$

and the diameter similarity (D), we have;

$$\frac{D_{\text{mod}\,el}}{D_{prototype}} = D_{raio} \qquad (3)$$

The model geometry must be in the same proportions as the real or prototype condition.

$$\frac{L_m}{L_p} = \frac{D_m}{D_p} = L_r = D_r \qquad (4)$$

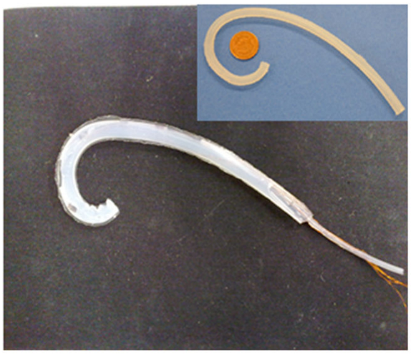

Fig. 3 Prototype of the sensory digit

Currently existing cochlear implants have different dimensions. For instance one cochlear [MED-EL standard] has the length of 31.5 mm with a diameter of 1.3 mm and another cochlear implant [MED-EL FLEX20] has length of 20 mm with diameter of 0.8 mm [5], [21]. In this study, the cochlear which has length of 20 mm with a diameter of 0.8 mm was considered as the dimensions of the model where the prototype has length of 250 mm and diameter of 10 mm. Using (1) the geometry similarity was calculated as:

$$L_r = D_r = \frac{L_m}{L_p} = \frac{D_m}{D_p} = \frac{20\,mm}{50\,mm} = \frac{0.8\,mm}{10\,mm} = 0.08$$

In that case, this prototype design has a geometric similarity with scale ratio of 0.08. In another way, the prototype is 12.5 times bigger than the actual (mode). The shape of the cochlea is one of the roots of the challenges of cochlear implantation operations. The cochlea (Fig. 4) is the auditory part of the inner ear and it is 'snail-shaped' structure which is roughly 2½ to 2¾ turns around its axis (the bony core of the cochlea). The shape of the cochlea affects the human hearing range, for instance, the basal affects high-frequency hearing frequency where the apex shows low-frequency range [22]. In CI insertion experiments, different phantom models are used such as making casts of human cadaver cochleae using epoxy and silicone elastomer and silicone only [22] to resemble the cochlea of the inner ear. In this research, it is focused the shape of the cochlear rather than the stiffness (or filled fluid) properties. The 1st turn of the cochlea was considered which can give us tool-tissue contact information of the cochlea phantom (Fig. 5) and the digit as shown in Fig. 5. The phantom cochlea was designed using Solidworks software and then manufactured using a Viper Si2 stereolithographic apparatus (SLA) from Accura Si10.

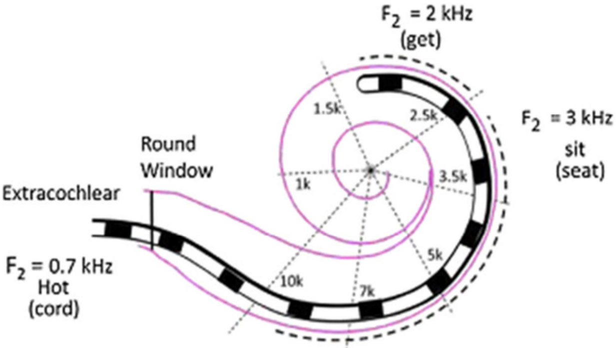

Fig. 4 Cochlea shape with human hearing ranges [22]

A 4.5:1 scale prototype which has a length of 158 mm, thickness of 1 mm and a varying diameter of 24.5 mm – 26 mm was used in this study where the human cochlea has the length of about 35 mm and diameter of 2mm [21], [22]. The phantom is large compared to the real size of the cochlea (4.5 times bigger) but it is only conceptual to investigate the interaction between the cochlea and the digit during the cochlear implant operation. The shape of this cochlea prototype resembles the human shape and this makes comparison analysis for the inserting electrodes into cochlea. Furthermore, since the behaviour of structure can be modelled, it can also be scaled up for ease of manufacture and manipulated whilst preserving geometric similitude.

Fig. 5 Cochlear Phantom

The experiments were performed using the apparatus shown in Fig. 6. The phantom was clamped in position and orientation using a retort stand and adjustable clamp. The fixed distal end of the flexible digit was connected to the end effector of a Kawasaki FS03N robot and its position with respect to the phantom was controlled using a computer linked to a D series controller. The root of the stylet was connected to a linear drive system supplied by Baldor (LMSS0602) comprising of a stepper motor on a linear etched platen which is mounted on the top of the Robot so that it moved dependently of the robot and NextMove ST controller using Mint ActiveX controls through MATLAB. All strain gauge signals were amplified using FE-MM4 FLYDE and recorded into MATLAB using and a National Instruments 6034E data acquisition board**.** *The flexible digit with tactile sensors* was 250 mm in overall axial length and the sensors were placed at 0.012L, 0.032L, and 0.054L as measured from the fixed (distal) end.

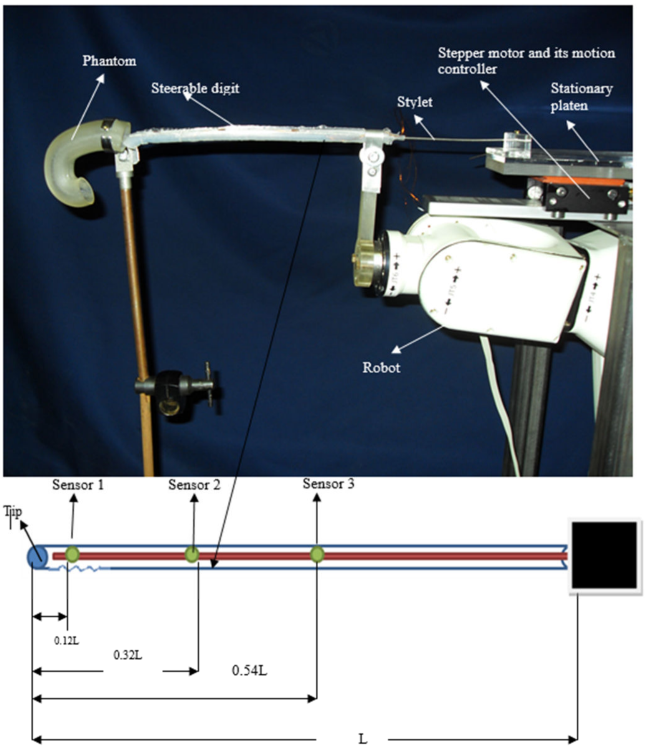

Fig. 6 Experimental set up

III. Results and Discussion

A. Digit Characteristics

Some experiments were done to verify basic characteristics of the digit. The first experiment aimed to detect any momentary contacts with the outer surface of the digit and establish directions of these contacts and manual tapping was selected as a contact method for simplicity. The experiment was repeated five times to test repeatability and the result was statistically significant ($p = 0.0703$) showing different contacts with their locations.

The three tap contacts were made in the sequence of L1, L2, and lastly L3. Ll and L2 were top contacts which caused bending strain, resulting from a linear force exerted in the vertical direction where L3 is bottom contact, and all contacts were made in a direction normal to the surface of the digit. It was expected that the strain at the top in bending (L1 and L2) or tensile side would have increase in resistance which produces positive signal of strain and stress, where

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compressive side (L3) will have negative signal of stress and stress due to decrease in resistance. In that way, the top contacts would result in a positive signal, a positive curvature of the digit (reporting a positive strain in the strain gauge sensors and a subsequent reduction in the output sensor voltages) and vice versa for bottom contacts due to the strain gauge deflection behaviour. The output responses of the digit are depicted in Fig. 7.

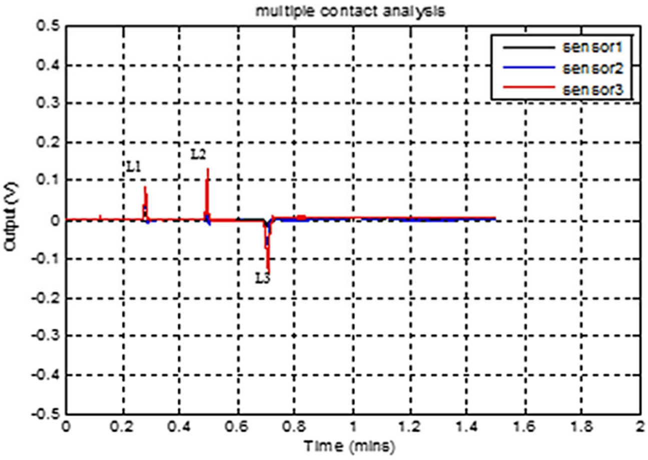

Fig. 7 Digit response with style in place (multiple contacts and their directions); L_i: tap contacts

L1 and L2 signals have positive (upward) direction while *L3* has a negative (downward) direction which coincides with the predicted directions of the contact. Positive spikes show top contacts whereas negative spikes indicate bottom contacts. The magnitudes and directions of the output signals depend on location of the sensors along the digit and force applied on the digit. In this case, contact L3 were applied higher force through tapping compare to other contacts. Further study of sensing algorithm is needed that can incorporate the magnitude of the applied forces and the location of the sensors with contact status and their directions

The second experiment was done without digit-phantom insertion to compare with insertion results. Initially, the digit was in straight condition with the stylet then the stylet was removed smoothly without insertion into the cochlea to observe its response. Fig. 8 shows only digit curl shape stages based on the sensor locations and there is no any digit/phantom interaction. The three spikes (a, b & c) indicate when the curvature stage has passed the position of the sensor respectively. There will be three curvature stages in this digit because of the three sensors. The final stage where all the three sensors settle into a value shows that the flexible digit has conformed to the shape of its unstressed curvature state where there was not any digit/phantom interaction; it matches the modiolus of the scala tympani. Later on, this response will be compared with digit/phantom insertion responses. Generally, positive signals indicate contacts with the top of the digit or naturally bending down (curvature) if there is no contact and vice versa, the negative signals indicate where the bottom of the digit made contact with the phantom.

B. Digit Insertion without Stylet

The aim of this experiment was to investigate the interaction between the digit and the cochlea phantom when a stylet was not used to aid insertion. In this experiment the sensory digit without stylet was inserted into the cochlea phantom; thus its bending was not controlled. Initially, the tip of the electrode was positioned at the beginning of the cochlea phantom before the electrode was pushed forward into the cochlea phantom. The digit was moved slowly forward into the cochlea a predetermined distance by the robot. As the digit moved into the cochlea, the digit slid along the inner wall and touched the lateral outer wall of the phantom. During the insertion, the geometrical curvature of the digit and the digit/phantom interaction can be recovered from the output signals of the sensors.

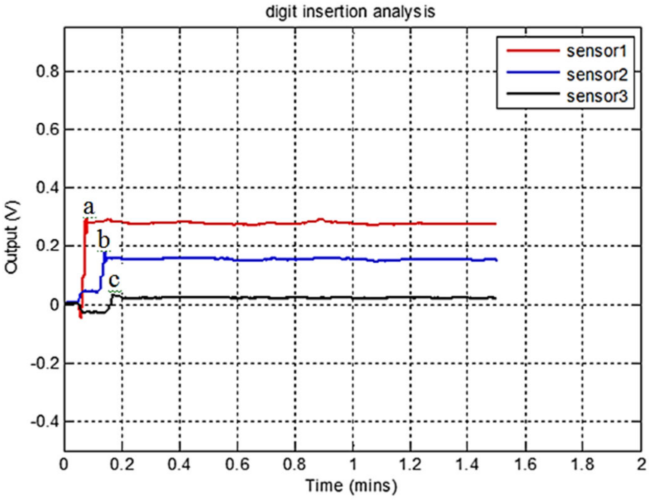

Fig. 8 Digit response during stylet withdrawal without phantom insertion

Fig. 9 depicts the contacts between the digit and the phantom during the digit insertion into the phantom. This response has pattern with previous result (Fig. 8) in terms of the spikes. Initial step (first 1 minute), the digit was moving forward and had no any contacts and no curling of its shape. This case, there was neither any contact nor any bending of the flexible digit; it may be considered to be in an “idle” state, where the digit was advancing into the cochlea without making any contact with the cochlea phantom. Next step, the digit started contacting with the phantom as shown by the positive and negative signals shown in the result. While the tip of the digit is bending, the digit has shown a bottom contact around the tip as shown on the sensor 1 signal as well as sensor 2 (negative signal shows bottom contact). Similarly, positive response of the sensor 3 indicates top contact of the digit with the phantom while the tip of the digit was bending (curving up).

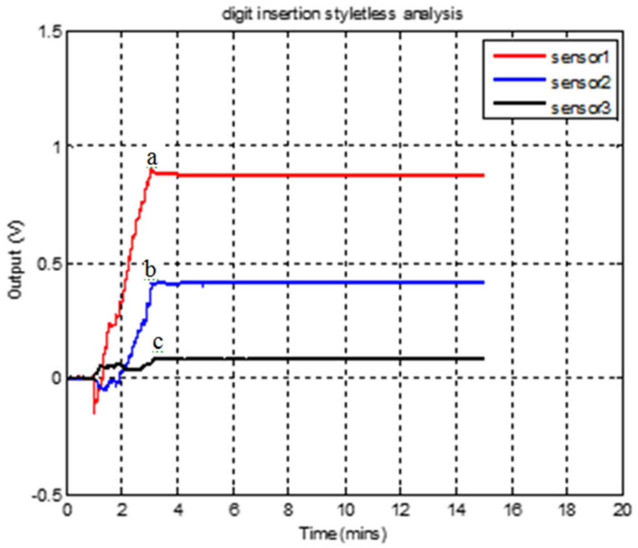

Fig. 9 Sensory digit response during the digit- phantom insertion (without stylet support insertion)

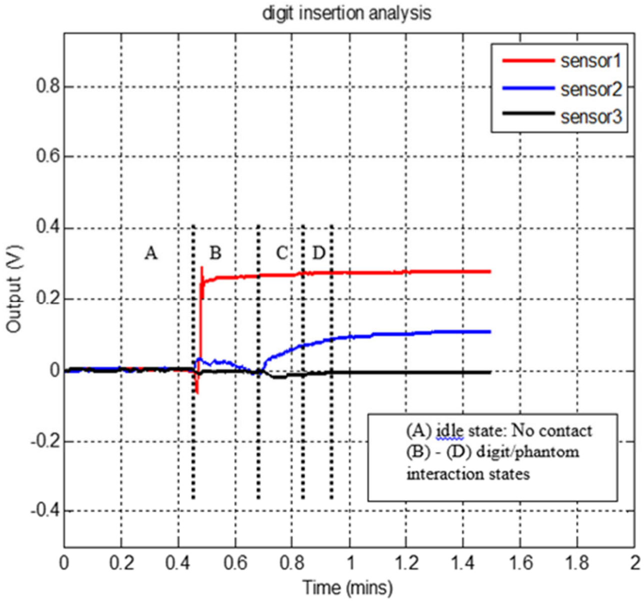

Fig. 10 Digit and phantom contact response during the insertion with stylet withdrawn

Final stage of the digit is shown by the flat response of the three sensors. This flat response of the three sensors indicates that the digit has reached final stage of hugging the modiolus of the scala tympani. This pattern matches the earlier result (Fig. 7) where the sensory digit has conformed to the shape of its unstressed curvature state where there was not any further digit/phantom interaction, it matches the modiolus of the scala tympani, and penetration has taken place. Fig. 7 has shown less magnitude for the final stage of the digit response because there was no any hugging or contact between the digit and the phantom whereas Fig. 8 has greater magnitude which shows contact between the digit and the phantom (the digit hugs on the walls of cochlear phantom). The sensor's spike response (i.e., a, b, & c) indicate relative position or the length of insertion of the digit as well as the bending (curling) stages of the sensory digit. For instance, the digit's relative position is about 3 mm at the time the digit passed 2 minutes. This could be deduced from the position of the sensor 1 which 0.013L where L (length of the digit) is 250 mm. Same procedure could be analyzed for the rest of the timeline of the digit insertion.

C. Digit Insertion with Stylet

This experiment has been conducted to observe the digit/phantom interaction. The stylet was withdrawn slowly stage by stage to control the insertion of the digit so as to hug the modulus of the phantom. As the digit was advanced further into the cochlea phantom, the stylet was slowly withdrawn further, and the digit allowed relaxing to its final insertion stage.

This experiment showed digit/phantom interaction depicted on Fig. 10. The sensory digit/phantom interactions could be summarized as: Section A: there was neither any contact nor any bending of the flexible digit as previous explained. Section B: First curvature of the digit is showed by sensor 1. Response signal of sensor 1 (Section B) of Fig. 10 is similar with response signal of sensor 1 in Fig. 9 (without insertion response). This similarity indicates that sensor 1 (tip of the digit) did not make significant contact except sliding or hugging the modulus of the digit. In addition, this section showed top contact which indicated by positive signal of sensor 2. Similarly, there was no contact between the phantom and location of sensor 3 which is far from the cochlea in this experiment. Section C: 2nd curvature of the digit has started as shown by the rising value of sensor 2. In addition, there is digit contact with the bottom side of the phantom (negative signal of the sensor 3). Section D: here the 3rd stage of curvature of the digit has started and is shown by rising signal of the sensor 3. Finally, the flexible digit has conformed to the shape of its unstressed curvature state where there was not any further digit/phantom interaction except sliding on the phantom walls smoothly (curving). There are different digit/phantom interaction states in this experiment. The bending of the digit was controlled by withdrawing the stylet smoothly according to the depth of penetration of the cochlea phantom. The pattern of the signals (signal spikes) had indication of the curvature shape of the digit. The signal's curvature also has clue of the insertion length of the digit into the cochlea phantom. The curvature signal can be inferred when the bending has passed a certain length depending on the location of the sensor. For instance, the first bending of this experiment occurred at 0.12 L = 30 mm. The location of the sensors has a great impact on the response and analysis of the digit and phantom interaction. Slight changes of the sensor locations could change the response signals pattern.

IV. CONCLUSION

The conceptual stage of this sensory digit has shown satisfactory tactile information about interaction between the digit and the cochlea phantom. The sensory digit has shown

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that the responses produced by the digit have displayed information about what was happening in this digit-phantom interaction. The digit has provided tactile feedback information such as digit- phantom contacts and their directions, information about the digit shape stages(curving), and relative position of the digit (depth insertion). These can be guidelines to assist in the improvement of the surgical technique and to minimize trauma caused by manual electrode insertion procedure. Furthermore, this digit can be used for other similar applications like surgical and diagnostic tools, which involve interaction of surgical tools with soft biological tissue in surgery. Finally, this is early stage and the digit can be improved by smaller sensing technologies and real-time clinical operations.

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