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Histological evaluation of a cochlear implant electrode array with electrically activated shape change for perimodiolar positioning

Abstract: For the treatment of deafness or severe hearing loss cochlear implants (CI) are used to stimulate the auditory nerve of the inner ear. In order to produce an electrode array which is both atraumatic and reaches a perimodiolar final position a design featuring shape memory effect was proposed. A Nitinol wire with a diameter of 100 µm was integrated in a state of the art lateral wall electrode array. The wire serves as an actuator after it has been 'trained' to adopt the spiral shape of an average human cochlea. Three small diameter platinum-iridium wires (each 20 µm) were crimped to the Nitinol wire in order to produce thermal energy. An insertion test was pursued using a human temporal bone specimen. The prototype electrode array was cooled down by means of immersion in ice water and freeze spray to enable sufficient straightening. Thereafter, insertion into the cochlea through the round window as performed. Insertion was feasible but difficult as premature curling of the electrode occurred during the movement towards the inner ear while passing the middle ear cavity. Therefore, the insertion had to be performed faster than usual. The shape memory actuator was subsequently activated with 450mA current at 5V for 3 seconds. After insertion the specimen was embedded in epoxy resin, microgrinded and all histological slices were assessed for trauma. Perimodiolar position was achieved. No insertion trauma was observed and there were no indications of thermal damage caused by the electrical heating. To the best of our knowledge, this is the first histological evaluation of the insertion trauma caused by an electrically activated shape memory electrode array. These promising results support further research on shape memory CI electrode arrays.

Keywords: shape memory allow, Nitinol, NiTi, insertion trauma, inner ear, electrical heating, electrical activation

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1 Introduction

For the treatment of deafness or severe hearing loss cochlear implants (CI) are available which are used for an artificial stimulation of the auditory nerve within the inner ear (cochlea) [1]. Trauma to the tissue within the cochlea during the electrode insertion are known to cause loss of residual hearing [2] which limits the patient's benefit in speech recognition using the CI [3]. Therefore, minimising trauma during electrode insertion is an important goal. Furthermore, it is reported, that perimodiolar positioning of the electrode array—which means close to the inner wall (modiolus) of the inner ear—improves the performance of the devices [4].

In order to produce electrode arrays which are both atraumatic and perimodiolar several designs and curling mechanisms have been proposed such as using a pre-curved electrode with a straightening sheath [5], fluid-mechanical actuators [6], hydrogel-swelling [7], or the shape memory effect [8–10]. An electrode array featuring shape memory effect can be achieved by integration of a wire made of a nickel-titanium alloy (also known as Nitinol or NiTi) which serves as an actuator after it has been 'trained' to adopt the spiral shape of the cochlea. In response to temperature change the implant will remember that shape during or after the insertion process. This has the dual effect of bringing the stimulation electrodes of the implant closer to the auditory nerve, and increasing the angular depth of insertion [10]. Change in temperature can result from the patient's body heat [10] or can be caused by an external, switchable energy source, e.g. electrical heating [8,9], which makes the insertion process independent from the environmental conditions. To the best of our knowledge, in this study the first histological investigation of the insertion trauma caused by an electrically activated shape memory electrode array is presented.

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2 Materials and Methods

2.1 Design of the electrode array

The development of a cochlear implant electrode array prototype with shape change capability, which can be "actively" activated by input of electrical energy, was based on the Cochlear Nucleus Hybrid™ L24 electrode (Cochlear Ltd., Sydney, Australia), an established, commercial, lateral wall cochlear implant electrode array. It consists of 22 half-band platinum electrodes embedded in a silicone carrier [11]. For this study the silicone carrier was modified by integrating an additional lumen of 125µm diameter to accommodate a Nitinol wire, which acts as an actuator that curls the electrode array to a specified shape. This prototype was referred to as 'Hybrid-M' [10]. The thin Nitinol wire (hereinafter referred to as 'NiTi inlay') was manufactured (by G.RAU GmbH & Co. KG, Pforzheim, Germany) with a diameter of 100µm and specified shape adapted to the spiral geometry of an average human cochlea [10]. Three platinum-iridium wires (each ∅ 20µm) with insulating coating were crimped to the apical tip of the NiTi inlay and inserted in parallel to the shape memory wire in the lumen of the silicone carrier. Two copper wires—one crimped to the other end of the NiTi inlay and the second one to extend the three platinum-iridium wires before they leave the silicone carrier—serve as conductors to a power supply (Fig. 1). Three small diameter platinum-iridium wires were used to conduct the current to minimise bending stiffness and at the same time electrical resistance, to ensure the majority of thermal energy was produced within the inlay.

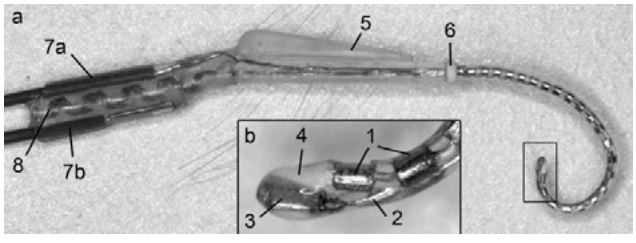

Figure 1: Hybrid-M prototype featuring a shape memory effect activated by electrical heating using an integrated Nitinol wire. 1: platinum contact electrodes; 2: Nitinol wire (NiTi inlay); 3: crimp connection between the NiTi inlay and three platinum-iridium wires; 4: silicone carrier; 5: wing for proper handling of the electrode array during insertion; 6: stopper indicating full insertion; 7: copper wires; 8: lead portion of the electrode array.

2.2 Experimental setup and procedure

Prior to the temporal bone experiment, the prototype underwent thermomechanical characterisation in order to verify the proper shape memory effect and to determine the transformation temperatures. Therefore, a modified 'bend and free recovery' (BFR) test [10,12] was performed.

Following this, a temporal bone insertion trial was pursued. The temporal bone specimen was prepared in accordance with the standard surgical procedure for the Hybrid-L [11] including the facial recess approach and round window insertion. After preparation the specimen was mounted to a water bath setup which was equipped with a digital heating thermostat (Lauda ET 20 G, Lauda Dr. R. Wobser GmbH & Co. KG, Lauda-Königshofen, Germany) enabling a temperature-controlled environment set at 37°C to simulate the normal body temperature [10].

The prototype electrode array was cooled down by means of immersion in ice water and freeze spray to enable sufficient straightening. Thereafter, insertion into the cochlea through the round window was performed. A surgical microscope was used throughout the electrode insertion and the procedure was recorded with a digital video camera.

Afterwards, the copper wires crimped to the NiTi inlay were connected to a power source. The electrical current was controlled using a digital multimeter. The Hybrid-M electrode carrier was subsequently activated with 450mA current at 5V for 3 seconds [9]. The lead was then fixated to the bone using superglue to secure the intracochlear position during the subsequent specimen preparation procedure.

2.3 Histological evaluation

After insertion the temporal bone specimen was fixed in 4% paraformaldehyde (PFA) solution. Following this, a dehydration process with increasing ethanol series (50, 70, 90, 100%) was performed. The dehydrated specimen was then fixed in epoxy resin (Spezifix 40, Struers GmbH, Willich, Germany) with the help of a vacuum cabinet, and hardened overnight at room temperature. The embedded specimen was further processed according to the previously described microgrinding procedure with image fusion [13,14] resulting in a three-dimensional image stack with approx. 100µm distance between consecutive slices. All histological slides were assessed for intracochlear trauma related to the insertion of the Hybrid-M prototype electrode array and evaluated according to the trauma scale introduced by Eshraghi *et al.* [15].

3 Results

The prototype electrode array with NiTi inlay inside showed a stable shape at temperatures below 23°C. Perfect straightening was not possible; however, the banana-shaped configu-

ration (Figure 2) was considered suitable to perform the insertion. In the BFR test, the shape memory effect was activated with increasing temperature. At 53°C the final spiral shape, to which the inlay had been trained, was reached.

Figure 2: (a) Banana-shaped configuration of the electrode array at 23°C. **(b)** Final shape.

Insertion of the prototype in the temporal bone specimen was feasible. However, several attempts were needed to achieve a successful insertion due to the onset of the shape memory effect during approach to the round window, resulting in a premature curling of the electrode's tip. Challenges during insertion of the prototype were experienced due to difficulties in maintaining the prototype straight before entering it into the inner ear. Premature curling of the electrode array occurred during the movement through the facial recess down to the inner ear. Therefore, the insertion had to be performed faster than usual. Figure 3 depicts the final position of the prototype inside the facial recess entering the cochlea through the round window.

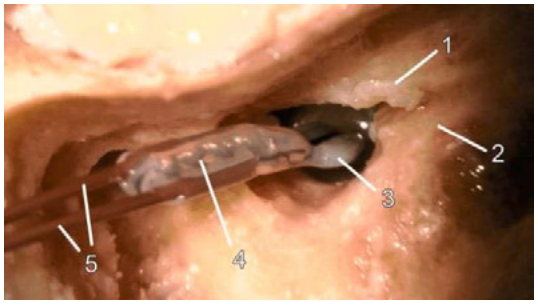

Figure 3: Facial recess and round window approach with inserted electrode array. 1: Chorda tympani; 2: facial nerve; 3: wing of the electrode array; 4: lead of the electrode array (cut off); 5: conductors for electrical heating of the embedded NiTi inlay.

The angular insertion depth of the prototype in its final position after activation of the shape memory effect, according to the histological evaluation is 360°. No tip fold-over was observed and no damage to any soft tissue was revealed (Fig. 4, 5). Due to several embedding artefacts such as air bubbles and cracks inside the epoxy resin, histological evaluation was impeded. At one position, elevation of the basilar membrane was observed (see Fig. 5a) which is equal to trauma grade 1 in Eshraghi's trauma scale. However, it cannot be distinguished whether this elevation is caused by the electrode insertion or by an air bubble close to the prototype which could have pushed the implant against the basilar membrane during insufficient vacuum degassing of the epoxy resin. Aside from this finding, all other slides were rated with grade 0 (no visible trauma). There were no indications of thermal damage of the soft tissue structures caused by the electrical heating of the NiTi inlay inside the inner ear visible.

Perimodiolar position was achieved. The histological evaluation showed a twisting of the electrode array around its longitudinal axis resulting in electrode contacts not facing the modiolus in the apical region (Fig. 5).

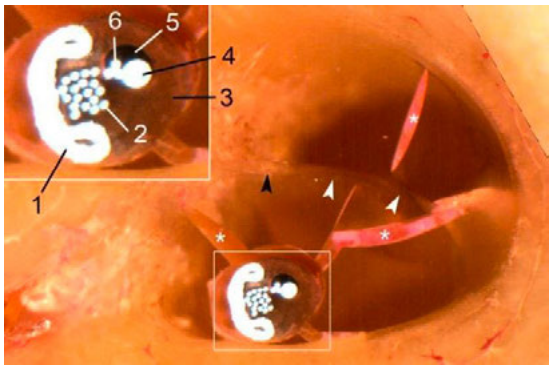

Figure 4: Histological slide of the cochlear specimen showing the prototype electrode array inside the scala tympani at the basal turn. Perimodiolar positioning was achieved. Lamina spiralis ossea (black arrow) as well as basilar membrane (white arrows) are preserved. 1: half-band platinum contact electrode; 2: wire bundle connecting the contact electrodes; 3: silicone carrier; 4: NiTi inlay; 5: lumen inside the silicone carrier housing the NiTi inlay; 6: three platinum wires of the closed electric circuit. White asterisks (*) indicate cracks in the epoxy resin.

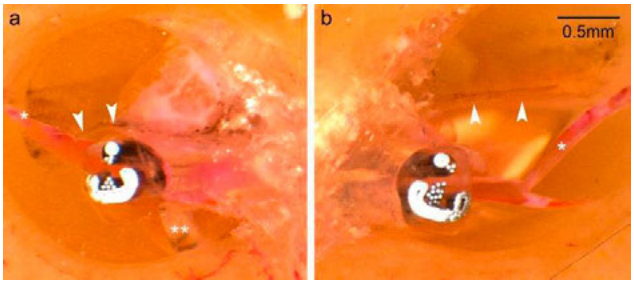

Figure 5: Midmodiolar cross section. Histological findings confirm preservation of intracochlear soft tissue structures including basilar membrane (white arrows). In (a) elevation of the basilar membrane cannot be excluded. However, it could be caused by the visible air bubble (**) which is an embedding artifact. White asterisks (*) indicate cracks in the epoxy resin.

4 Discussion

In order to position the stimulating contacts close to the modiolus, a cochlear implant electrode array with electrically activated shape change capability was introduced. After insertion, the shape memory effect can be activated by electrically heating the integrated NiTi inlay, which—in theory—makes the insertion process independent from the ambient and body temperatures in contrast to a 'passive' activation strategy [10]. This study showed that both insertion of the

electrode array and intracochlear shape change due to the activation of the shape memory effect with its resultant movement toward the modiolus do not cause visible intracochlear trauma. There is also no indication of thermal damage to the soft tissue structures caused by the electrical heating of the inlay. However, functional and metabolic effects on the organ of Corti due to heat stress or even cell death of the hair cells could not be assessed through this type of histological evaluation.

The insertion process using that first prototype was still substantially affected by the thermal conditions inside the temporal bone. The cooling effect of the ice water—and even of the freeze spray—was only effective for a few seconds. Reasons may be: the low insulation effect of the thin silicone body surrounding the NiTi inlay, the low heat capacity of the thin inlay, and the increasing temperature inside the mastoid cavity and in particular inside the middle ear space after passing the facial recess. The latter causes a substantial heat transfer resulting in the premature start of the shape transformation. This makes the insertion into the small opening of the cochlear more difficult and requires faster execution of the insertion which is undesirable with respect to an atraumatic insertion and preservation of residual hearing. One way to address this may be to use a grade of Nitinol with higher transformation temperatures to ensure that shape change only occurs above 37°C. However, this would require more electrical energy be delivered to heat the inlay to a higher temperature within the cochlea to achieve the final shape, increasing the risk of thermal tissue damage. Alternatively, insertion tools, e.g. a steel tube surrounding the electrode array, to increase the shielding against ambient temperatures during the facial recess approach might be explored.

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