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Insertion trauma of a cochlear implant electrode array with Nitinol inlay

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1 Introduction

Preservation of residual hearing is an important and growing consideration in the treatment of sensorineural hearing loss with cochlear implants (CI) (Incerti et al., 2013; Irving et al., 2014; Lenarz et al., 2009; Von Ilberg et al., 2011). CI systems designed for patients with high frequency sensorineural hearing loss, but with functional low frequency hearing present electrical stimulation and acoustic amplification in the same ear (electro-acoustic stimulation, EAS). EAS implants, such as the Nucleus Hybrid L24, feature a relatively short straight electrode array designed for atraumatic, relatively shallow insertion into the inner ear (cochlea): that is, they are designed to provide electrical stimulation to the basal high frequency region of the cochlea while leaving the structures required for low frequency hearing in the apical region undisturbed. A limitation of such designs is that if residual hearing is lost, either directly or at some time after implantation, the short electrode is not able to deliver electrical stimulation at lower frequencies like a conventional CI.

One idea to address this limitation is to functionalize an existing EAS electrode array using an actuator made of a shape memory alloy, and to teach it the final spiral shape of the cochlea (Chen et al., 2007; Majdani et al., 2013; Min et al., 2013). In response to temperature change—either by body temperature or additional (electrical) heating— the implant will remember its final shape during or after the insertion process and move from the outer wall toward the inner wall of the inner ear. This would have the dual effect of increasing the angular depth of insertion, and bringing the electrode closer to the target neurons.

Indeed, this is not a new idea but has already been described at least since the mid 1990's in some patent applications (Corbett et al., 1997; Gibson et al., 2011; Kuzma, 2000; Spelman et al., 1998). Apart from those more theoretical considerations there are only few experimental approaches dealing with the integration of a shape memory effect into a CI electrode array (Chen et al., 2007; Majdani et al., 2013; Min et al., 2013). Up to now, none of these ideas and suggestions reached a clinical or even pre-clinical level of development and testing. In contrast to the noteworthy work by Min et al. (2013) which used a custom-made eight-channel ball-type electrode array, the main objective of our research is to modify a clinically well-established electrode array for residual hearing preservation in such a way that it keeps its gentle insertion characteristic but will achieve a

deeper insertion with more complete coverage of the cochlea frequency range in combination with a more perimodiolar position.

For the development of a laboratory sample of an actively curling cochlear implant electrode array Hybrid-L electrodes (Cochlear Ltd., Sydney, Australia) were modified and equipped with an additional wire made of Nitinol (Majdani et al., 2014b, 2013). Nitinol is a well-established shape memory alloy made from nickel and titanium with numerous biomedical applications and has been successfully used as implant material (Barras and Myers, 2010; Duerig et al., 1999; Petrini and Migliavacca, 2011). The term shape memory effect describes a phenomenon of some materials to return from one shape into a second one in response to temperature change. The temperature at which the material starts to transform is referred to as austenite start temperature (A_S) while the transformation is finished at austenite finish temperature (A_F). These transformation temperatures can be adjusted according to the application and the specific requirements. A rough adjustment can be achieved by changing the atomic composition in percentage of nickel and titanium (Pelton et al., 2003). For additional fine tuning of the transformation temperatures several steps of heat treatment are used (Pelton et al., 2000). Doing that, it is possible to set a desired temperature for the beginning of the shape memory effect, without affecting the geometry and only slightly altering the stiffness properties of the Nitinol wire.

This wire, made of Nitinol, is referred to as "inlay" in the following as it is mounted inside the silicone body of the electrode array. Later, it should serve as an actuator, enabling the temperature dependent curling of the electrode. The Nitinol inlay extended from the electrode handle to near the distal tip of the array. It replaced the platinum element that stiffens the proximal region of the array in the conventional Hybrid L electrode.

Insertion of the straight electrode into the cochlea followed by recovery of a trained spiral shape by activation of the shape memory effect by the body temperature would result in extended angular insertion depth if compared to the lateral wall position of the electrode array while not changing its total length. As a second effect a position within the scala tympani closer to the modiolus will be achieved bringing the stimulation contacts closer to the cochlear nerve inside the modiolus. Due to this new feature of a shape memory and also the desired final position close to the modiolus, the prototypes are referred to as Hybrid-M.

The aim of this study was to investigate whether the higher stiffness of the Hybrid-M compared to the original design of Hybrid-L due to the integration of an additional thin wire made of Nitinol will affect the insertion behaviour and especially increase the risk of insertion trauma. This is an essential question and needs to be answered at the beginning of the development of a new electrode array as residual hearing preservation has a decisive role for the acceptance. Investigations on the stiffness-dependent insertion behaviour are therefore of particular importance as also the Hybrid-M should be inserted initially as a straight electrode array before it starts moving from the lateral wall toward the modiolus due to the shape memory effect. Therefore, this first part of the insertion is especially crucial regarding insertion trauma and the presented study on it is an important preliminary investigation to decide whether further research on an active cochlear electrode array featuring a Nitinol-based shape memory effect is justified and worthwhile. If it is not possible to perform this initial part of the insertion process in an atraumatic manner, an electrode array with Nitinol inlay inside won't be usable for

hearing preservation and therefore the potential advantage of the shape memory effect and the related perimodiolar positioning disappears.

These considerations and concerns regarding insertion trauma of an inlay loaded electrode array leads to the following hypothesis: histologically detectable insertion trauma of Hybrid-L electrode arrays with integrated Nitinol inlay is not higher than using conventional Hybrid-L samples. For testing this hypothesis temporal bone studies needs to be performed. To enable the desired isolated investigation of the influence of the stiffening effect of the additional Nitinol wire on histological trauma a special version of the Hybrid-M electrode was design with disabled shape memory effect. This was done be setting Austenite start temperature sufficiently above body temperature to get "non-functional" Nitinol inlays. Non-functional in terms of this study means that the shape memory effect will not be activated in the range of body temperature. A secondary aim of this study was to test suitability and usability of the developed experimental setup with heated temporal bone specimens in order to mimic physiological conditions during insertion trials. This complex setting was not mandatory for this type of study, but it was an essential trial run for future experiments with full functional shape memory electrode arrays.

These modified Hybrid-M samples are sufficient to test the aforementioned hypothesis. Consequently, this also means that several aspects of a shape memory cochlear implant electrode array cannot be investigated using this study design. For example the temporal bone trial will not provide results regarding the extension of angular insertion depth due to moving from the lateral wall toward the modiolus as well as assessment of the perimodiolar final position won't be possible. Also it is not the intention of this study to broadly prove safety and usability of shape memory cochlear electrode arrays.

Regardless, it is important to establish that the chosen inlays are strong—which consequently means that they are thick enough—to bend the electrode array. That's why the temporal bone trial was preceded by thermal characterization of these inlays in a transparent artificial cochlear model heated in a water bath.

Testing the hypothesis requires in principle a control group of Hybrid-L electrode arrays inserted in temporal bone specimens. However, the Hybrid-L electrode is an already extensively investigated electrode array with several published experimental studies dealing with insertion trauma. That's why published studies were considered as sufficient control groups. Details about these published results as well as its comparison with our findings is provided in the discussion section.

2 Materials and Methods

2.1 Hybrid-M electrode arrays

For the development of laboratory prototypes of an active curling cochlear implant electrode array the Hybrid-L electrode (Cochlear Ltd., Sydney, Australia) was modified and equipped with an additional wire made of Nitinol. Originally the Hybrid-L includes a malleable platinum stiffener in the basal section to prevent the electrode from buckling or kinking during the insertion process. The Nitinol inlay removes the need for this stiffener. Therefore, it was omitted in the design of the Hybrid-M.

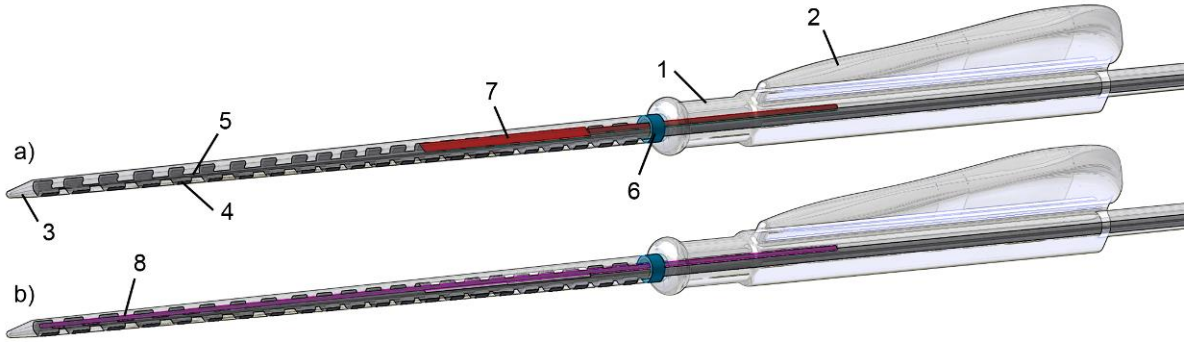

Figure 1: Electrode Carriers. **(a)** Schematic drawing of Hybrid-L electrode array showing silicone body (1) with extracochlear wing (2) and softip (3), 22 contact electrodes (4) and their conductors (5), marker ring (6) and stiffener (7). **(b)** Schematic drawing of Hybrid-M electrode array with Nitinol inlay (8) but without stiffener.

2.1.1 Design and fabrication of the shape memory inlays

The spiral shape of the Nitinol inlays is based on the geometry of an artificial cochlear model (Cochlear Ltd.), which represents an average human cochlea. This model was already used in previous studies (Majdani et al., 2013). It was reused for simplified comparability. Using a CAD program (Inventor Professional, Autodesk Inc., San Rafael, USA) the inlay was designed so that the final spiral shape fits to the inner wall of the cochlea model and therefore to the inner wall of an average sized cochlea. The diameter of the wires was chosen to be 100 µm. Additionally, a tapered region was added. Austenite start temperature was deliberately set to be higher than 42°C to prevent premature curling at body temperature before entering the cochlea, as the aim of this initial study was to assess trauma only.

The Nitinol inlays were fabricated by G.RAU GmbH & Co. KG (Pforzheim, Germany). To create the Hybrid-M samples the inlays were cut off in two different ways: For type A the inlay was trimmed at approximately 360° for an optimal fitting to the average cochlear model. Thus, the tapered region begins approx. 7 mm behind the tip with the diameter being reduced from 100 µm to 80 µm. For type B, only the very end of the inlay was trimmed in order to cut off the sharp tip to prevent the inlay from piercing through the silicone body. In that case, most of the tapered region was preserved. However, this leads to a longer inlay which also results in a more tightly curled shape than with type A. Tapering in type B inlays reduced the diameter from 100µm to 40µm.

2.1.2 Assembling the Hybrid-M laboratory samples

A laboratory prototype of a Hybrid-M used in this study is shown in Figure 2. The silicone carrier of a standard Hybrid-L electrode was cut open and the platinum stiffener was removed. Afterwards, the back side of the electrode carrier was remodelled using silicone to create a lumen of 125µm diameter to accommodate the Nitinol inlay. The inlay was straightened, inserted into the lumen, and fixed by gluing only the proximal portion at the handle, so that the tip of the inlay was able to move relative to the silicone carrier.

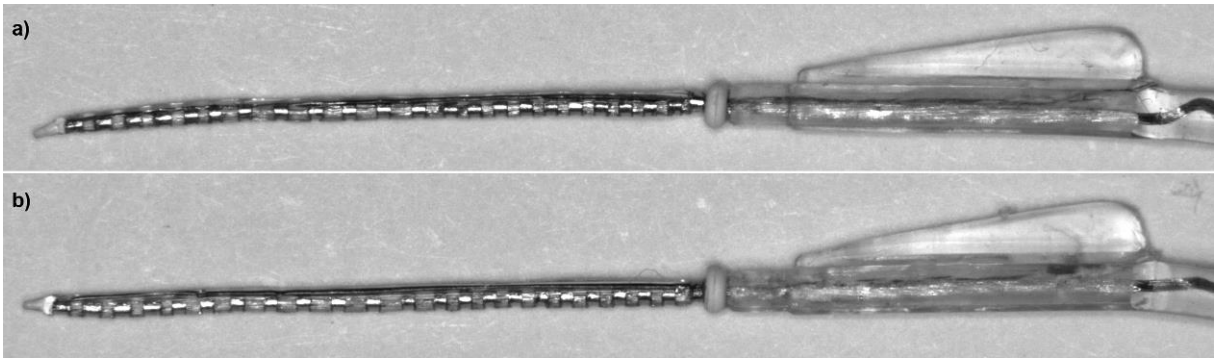

Figure 2: Hybrid-M laboratory sample. **(a)** Type A. The Hybrid-M shows an almost straight configuration at room temperature. **(b)** Type B.

2.2 Thermal characterization

Prior to the temporal bone insertion a part of the Hybrid-M samples underwent thermomechanical characterization. This was done to verify the shape memory effect and measure the temperature dependant shape change of the laboratory samples. For this attempt a modified "bend and free recovery" (BFR) test (ASTM 2082, 2006) was performed. This type of test was chosen because it is a simple approach for thermomechanical characterisation of shape memory devices (Pelton et al., 2000). Furthermore, this setting, which is close to the real application, allows the investigation of the impact of the electrode carrier on the shape memory effect.

The setup for the free recovery test consisted of a small water bath with a thermostat (Thermoxmix 1419, B. Braun Melsungen AG, Germany) which allows manual adjustment of the target water temperature. Temperature was confirmed with a temperature sensor (handheld thermometer HH806AWE with thermocouple probe type HTMQSS-IM050G-150, both Omega Engineering Ltd., Stamford, CT, USA). An artificial cochlear model made of Teflon was clamped to theinside of the water bath. The transparent bowl allowed photo documentation of the shape change of the Hybrid-M samples inside the cochlear model. The cochlear model was chosen for its similarity with the real setting. However, it is the major difference from the ASTM standard for BFR tests, as the recovery is not completely free but limited by the walls of the cochlear model.

After fixing the electrode inside the model using a small clip, the temperature of the water bath was increased stepwise from 29°C and 57°C in steps of 2°K. The temperature of the water bath and the shape of the electrode were allowed to stabilise at each step before proceeding to the next. Then a photo of the Hybrid-M samples was captured using a USB camera (9.0 MP, Conrad Electronic SE, Hirschau, Germany) which was mounted in front of the cochlear model (outside the water bath). For a rough estimation of the temperature range of the shape

memory effect two temperatures were determined: T_1 was defined as the temperature at which each sample just begins to curl (therefore T_1 is in the range of A_S). T_2 is defined as the temperature at which the shape memory effect is either finished due to reaching A_F temperature or an observable shape change is prohibited due to contact of the electrode array with the inner wall of the cochlea model.

One electrode of both types (HM-A03 and HM-B03; see table 1) was not used for thermal characterisation. These were reserved to later attempt insertion of never activated electrodes.

2.3 Specimens and specimen preparation

Six temporal bone specimens were harvested within 24 hours after death of the body donors and were immediately frozen. The specimens were kept frozen until shortly before beginning the experiments to avoid any damage to the intracochlear soft tissue structures. After slowly thawing overnight in the refrigerator, the standard surgical procedure for Hybrid-L insertion including mastoidectomy and posterior tympanotomy approach (Gantz et al., 2005; Lenarz et al., 2006) was performed by an experienced CI surgeon. In all specimens the electrode array was inserted through the round window. Therefore, the bony overhang was carefully removed to enable free access to the round window. The round window membrane, however, was initially kept intact to preserve the intracochlear structures until the specimen was put into the test bench and all other preparations of the insertion experiment were finished. In the meantime, the specimens were stored in physiologic salt solution at 4°C.

2.4 Experimental Setup and Procedure

A water tank, equipped with a heating thermostat (Lauda ET 20 G, Lauda Dr. R. Wobser GmbH & Co. KG, Lauda-Königshofen, Germany) was used to replicate realistic thermal conditions during the temporal bone insertion trial. An integrated temperature probe enabled automated controlling of a specific bath temperature using the digital heating thermostat. A pressure pump constantly circulated the water in the tank. Decalcified water was used as heat transfer liquid. To fixate the temporal bone specimens inside the water bath a custom-made temporal bone holder was used (see Figure 3). The device consists of a half shell made of stainless-steel with numerous holes to allow good circulation of the heating liquid around the specimen. Additionally, the half shell is equipped with fixation screws for clamping the irregularly shaped temporal bone specimen. The shell is supported by a ring frame with an intermediate silicone ring. Thus, the orientation of the temporal bone specimen can easily be adapted in all three rotatory degrees of freedom. The entire mounting bracket is situated on a lifting plate that can be adjusted in height.

Before putting the temporal bone specimens into the water bath they were wrapped in a plastic bag. This was done to protect the decalcified water in the tank from contamination with liquids from the temporal bone specimen on the one hand, on the other one this created an extra reservoir around the specimen which was filled with saline solution to mimic physiological conditions during the experiments. Additionally, the water level inside the plastic bag could be adjusted independently of the filling level of the surrounding water bath to enable an air filled mastoid cavity.

The temperature of the temporal bone specimen was controlled by use of an additional temperature probe (handheld thermometer HH806AWE with thermocouple probe type HTMQSS-IM050G-150, both Omega Engineering Ltd., Stamford, CT, USA). The bones were heated to approximately body temperature. Shortly before insertion the round window membrane was incised using a thin hypodermic needle to prepare electrode insertion.

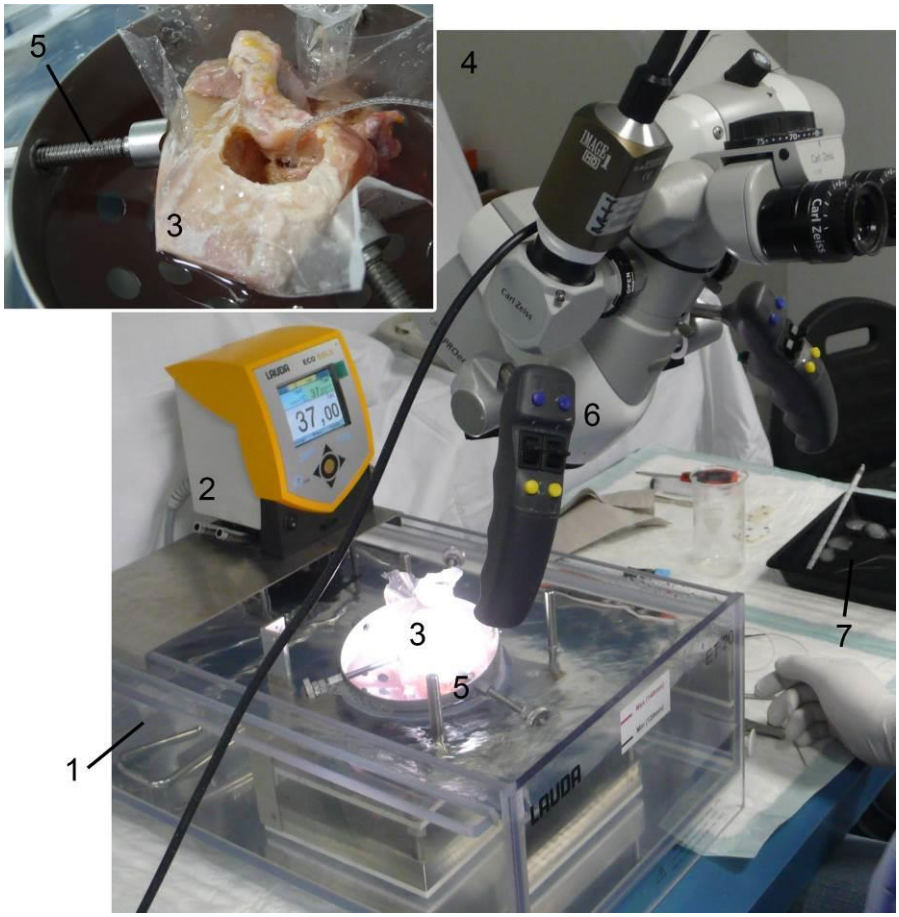

Figure 3: Experimental setup. A water bath (1) with digital thermostat (2) was used to heat up a temporal bone specimen (3) in order to mimic body temperature during insertion. The temporal bone specimen was wrapped in a plastic bag (4) and therefore surrounded by physiologic salt solution before it was put into a custom-made specimen holder (5). A standard OR microscope (6) as well as standard instruments were used for the insertion trials. Prior to insertion Hybrid-M samples were put into ice water (7) for cooling down.

Before insertion the electrode array was inserted into the straightening tool (see Figure 4) and both were put into ice water for several minutes to reach the low temperature phase of the Nitinol inlay. Finally, the electrode array was straightened inside the ice water bath by pushing the slider of the straightening tool. In the next step, the electrode array was grasped with common surgical forceps at the lateral part of the silicone body, taken out of the straightening tool and moved quickly to the temporal bone specimen until the tip of the implant reached the opening of the cochlea. Insertion of the electrode array was done slowly and carefully as done in routine hearing preservation surgery with the conventional Hybrid-L electrode array. After straightening the electrode with the

straightening tool under water, it was not touched by the surgeon's finger to avoid warming of the device due to the surgeon's body temperature.

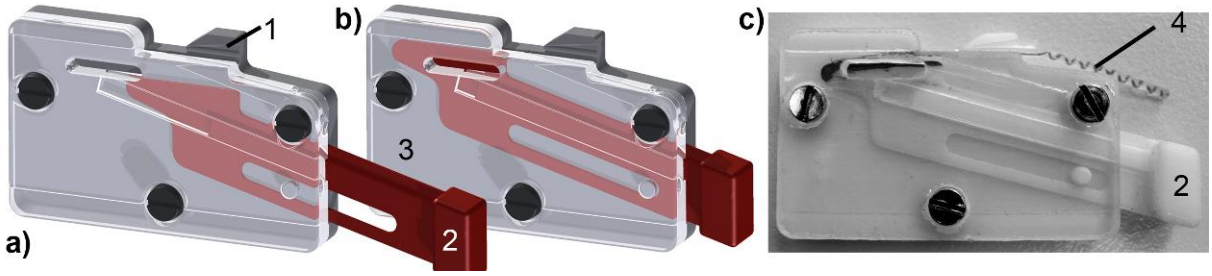

Figure 4: Straightening Tool. **(a, b)** Rendered CAD drawing of the straightening tool with housing (1) including a form-locking interface for grabbing the Hybrid-M electrode carrier. A movable slider (2) allows straightening of the curved electrode array. The transparent cover plate (3) enables visual control. (c) Prototype of the Straigthening Tool with Hybrid-M (4) inside.

The insertion was done by an experienced CI surgeon using a common OR microscope. After insertion, the lead wire was attached to the bone by super-glue to fix the intracochlear position of the electrode and avoid intracochlear movements during the following specimen preparation and epoxy embedding.

For each type of inlays, in total three insertions were performed. For two of these insertions, electrodes had undergone previous thermal characterization. For each type the third electrode array was inserted without previous investigation to inserted at least one completely unused (out of the box) electrode array. Table 1 shows the sequence of insertion trials and the type of the used electrode arrays.

Table 1. Overview of samples used for thermal characterization and temporal bone insertion trials.

# of insertion	temporal bone specimen	type of inlay	prior thermal characterisation	used label
1	TB01	A	yes	HM-A01
2	TB02	A	yes	HM-A02
3	TB03	B	yes	HM-B01
4	TB04	B	yes	HM-B02
5	TB05	A	no	HM-A03
6	TB06	B	no	HM-B03

2.5 Histological Evaluation

After insertion of the electrode array each specimen was put in 4% Paraformaldehyd (PFA) solution for fixation for approximately 18 hours. Afterwards, fixation solution was washed out using phosphate buffered saline (PBS) for approximately 1h at room temperature. Next, the specimens were dehydrated in increasing ethanol series

(50%, 70%, 90%, 100%). Each step took 1 day at room temperature. This series was completed with 100% methanol for another day. The dehydrated specimens were fixed in epoxy resin (SpeziFix 40, Struers GmbH, Willich, Germany). The epoxy resin hardened overnight at room temperature for a minimum of 8 hours. This procedure of tissue fixation and epoxy embedding was chosen to ensure that none of the preparation steps exceeds a temperature of 45°C.

The embedded specimens were ground with a grinder (Power Pro 4000, Buehler GmbH, Düsseldorf, Germany) with a distance of 250µm between two grinding layers. The polished surface was stained with Kallichrom for 90 seconds which was afterwards removed using rinsing water. Each surface was photographed (VHX 600, Keyence International, Mechelen, Belgium) at magnifications of 20x and 60x. All histological images were assessed for intracochlear trauma (Eshraghi et al., 2003) related to the insertion of the Hybrid-M electrode array.

3 Results

3.1 General results

Insertion of the Hybrid-M prototypes was successfully performed in all six temporal bone specimens. Insertion could be done smoothly and easily and no difficulties were observed. The surgeon reported the procedure as routine and unremarkable. The handling of the electrode after removing from the straightening tool was comparable to that of the conventional Hybrid-L electrode. Also based on the haptic feedback, the surgeon reported no differences regarding resistance during the insertion. No noticeable insertion forces were observed.

3.2 Thermal characterization

Experimental evaluation of the laboratory samples was carried out using the experimental setup described in section 2.2. Figure 5 shows individual photographs of the intracochlear curling behavior caused by warming and thus activation of the shape memory effect. Table 2 summarizes the results. T_1 was defined as the temperature at which observable shape change starts. As images were captured in steps of 2°C the interval indicates the temperature values of the images before and after the first notable change in shape occurred. To enable measurement of T_1, 3 of 4 samples (except HM-A02) were only partially inserted to keep the straight configuration at low temperature. A_S temperature is in the range of 47°C to 49°C. T_2 was defined as the temperature at which the electrode is curled toward the inner wall of the cochlear model and reaches its final placement. Therefore T_2 is not equal to but in the range of A_F temperature. However, exact determination of T_2 was difficult due to the limited temperature range of the water bath. In 3 of 4 cases shape change could be observed up to the last image at 57°C. That is why it is not possible to state T_2 precisely as the shape memory effect may have continued beyound 57°C. Only for sample HM-B02 there are images at temperatures higher than 55°C which show no further change in shape. Thus, T_2 was determined to be approximately 55°C in that case. The imperfect final location with a gap toward the inner wall could be a hint that tapering the Nitinol wire down to 40µm leads to a too thin and therefore too weak inlay to bend the electrode carrier sufficiently.
In contrast to the other samples the electrode HM-A02 was fully inserted at the beginning. This corresponds to the typical lateral wall position of the conventional Hybrid-L electrode array. Doing this, measuring the angular

insertion depth before and after activation of the shape memory effect was possible (see Figure 6). Due to the shape change and positioning toward the modiolus the angular insertion depth increases from 255° to 350°. This is a deeper insertion of 95° or approximately one quarter turn of the cochlea.

Table 2: Transformation temperatures.

sample	T_1 [°C]	T_2 [°C]
HM-A01	[47,49]	≥ 57
HM-A02	≤ 50	≥ 57
HM-B01	[47,49]	≥ 57
HM-B02	[47,49]	~ 55

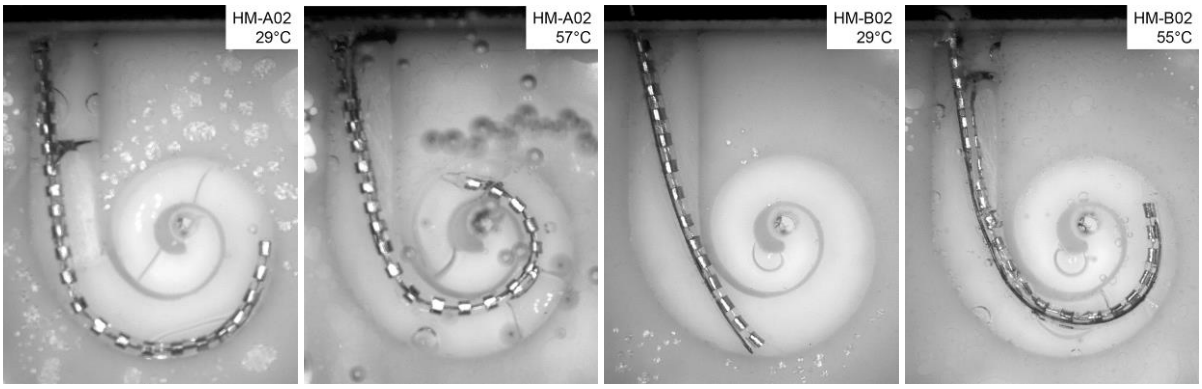

Figure 5: Results of thermal characterization. Sample HM-A02 shows the desired movement from the lateral wall toward the inner wall of the cochlea model in response to temperature change. Sample HM-B02 was inserted incompletely at the beginning to preserve the straight configuration for the determination of T_1. Final shape is reached at T_2 = 55°C.

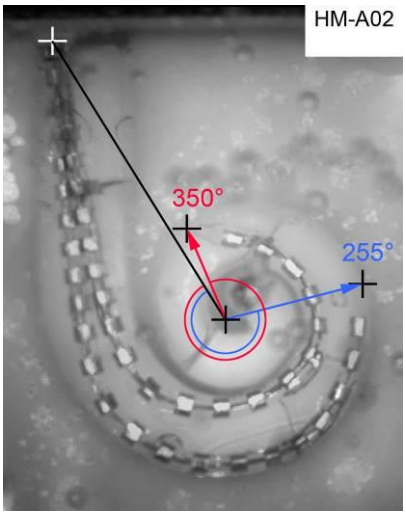

Figure 6: Increasing angular insertion depth due to the activation of the shape memory effect and moving of the electrode array from lateral wall position to a perimodiolar one.

3.3 Histological results

In all cases, an atraumatic insertion of the Hybrid-M electrode array was shown histologically. No displacement into another scala and also no tip fold-over were observed. No damage to any soft tissue or bony intracochlear structure occurred in the experiments. Therefore all six insertions were rated with insertion trauma 0 on the insertion trauma scala proposed by Eshraghi et al. (2003). Figure 7 shows selected histological slides. All Hybrid-M samples showed basally a midscalar to perimodiolar positioning and apically a lateral position without lifting the basilar membrane. The distance to the lateral wall in the basal turn of the cochlea is related to the round window access and is not caused by the shape memory effect (which was not activated due to the high A_S temperature). The observed location of these Hybrid-M samples in the basal turn is in accordance with the findings in literature about the Hybrid-L electrode (Briggs et al., 2006; Driscoll et al., 2011; Lenarz et al., 2006; Shepherd et al., 2011).

Table 3: Summary of histological evaluation

temporal bone (TB) specimen	electrode array	tip fold-over	rupture of basilar membrane	scala dislocation	severe trauma	trauma rating†
TB01	HM-A01	no	no	no	no	0
TB02	HM-A02	no	no	no	no	0
TB03	HM-B01	no	no	no	no	0
TB04	HM-B01	no	no	no	no	0
TB05	HM-A03	no	no	no	no	0
TB06	HM-B03	no	no	no	no	0

† according to Eshraghi et al. (2003)

In TB06 super-glue entered the opening of the cochlea. Therefore, epoxy resin insufficiently infiltrated the inner ear which revealed itself through numerous air bubbles inside the scala vestibule. However, all relevant intracochlear structures— including electrode array and basilar membrane—were sufficiently fixated and embedded in epoxy resin so that histological evaluation was possible.

In most cases, the histological evaluation disclosed problems regarding the intracochlear orientation of the platinum contacts of the electrode array. As it is shown in Figure 7 the inlay is not always located laterally to the electrode contacts which should normally face toward the modiolus. Instead the electrode arrays tend to twist resulting in electrode contacts facing down- or upwards (see Figure 7 a2 and b2).

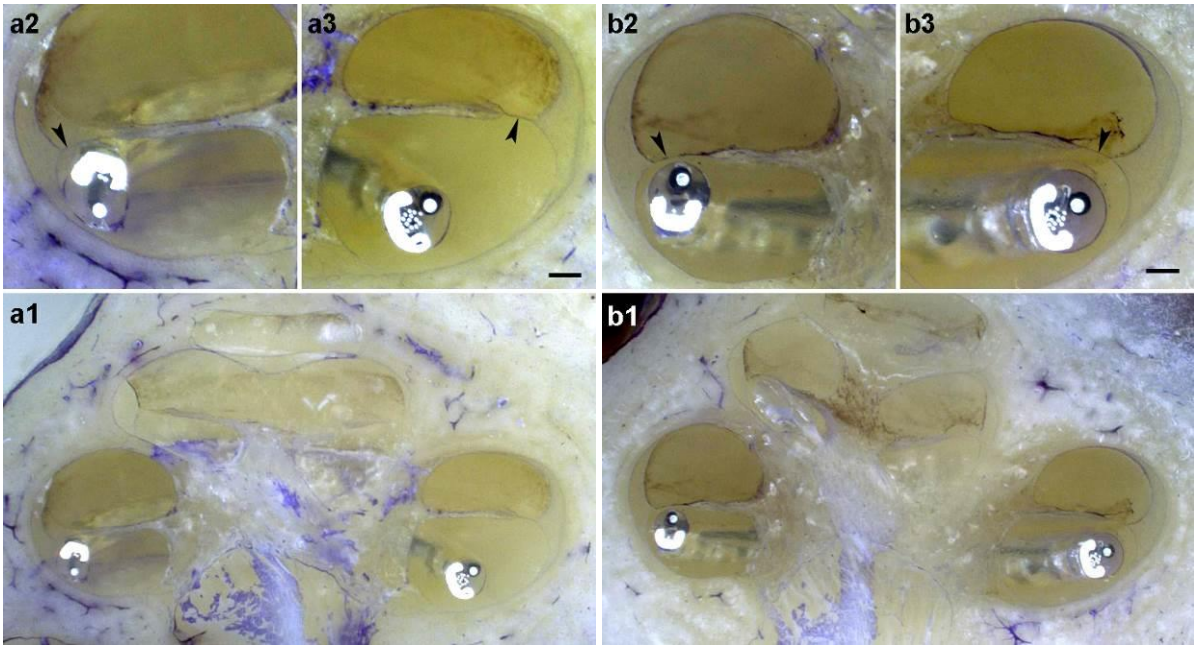

Figure 7: Histological results. **(a)** Specimen TB01 (HM-A01). **(b)** Specimen TB03 (HM-B01). Black arrows indicate the preserved basilar membrane. Bar scale is 250µm. Midscalar location of the electrode array in the basal turn of the cochlea (a3) is due to the round window access and not caused by the shape memory effect.

4 Discussion

Existing electrode arrays designed to minimise insertion trauma are straight, thin and flexible, in order to reduce insertion forces (Hochmair et al., 2006; Jurawitz et al., 2014; Lenarz et al., 2009; Von Ilberg et al., 2011) and therefore decrease risk of harming intracochlear structures (e.g. basilar membrane) to preserve residual hearing. Additionally, a common design feature is the limited length of these EAS electrodes. Studies have shown that a shorter electrodes enable preservation of residual hearing (Gantz et al., 2005; Hochmair et al., 2006; Kiefer et al., 2005; Lenarz et al., 2009; Von Ilberg et al., 2011; Woodson et al., 2010). The Hybrid-L electrode (Cochlear Ltd., Sydney, Australia) is such an electrode array which was developed for hearing preservation surgery. In temporal bone trials it was shown that, in most cases, it can be inserted in an atraumatic manner (Briggs et al., 2006; Lenarz et al., 2006). Additionally, its ability to preserve low frequency residual hearing has been demonstrated in several clinical studies (Friedmann et al., 2015; Jurawitz et al., 2014; Lenarz et al., 2013, 2009; Szyfter et al., 2013), including a European multicentre study (Lenarz et al., 2013) and a multicentre study in the United States (Roland et al., 2015). Based on the last-mentioned investigation, the CI24REH implant with Hybrid-L electrode has been approved as an EAS device by the FDA.

However, no current electrode array, regardless of design and CI manufacturer, has 100% success in preserving hearing. While in the European multicentre study (Lenarz et al., 2013) hearing preservation could be achieved in 74% of 61 patients (≤ 30 dB threshold change at 500 Hz after one year), the remaining 16 patients (26%) could not benefit from the hybrid stimulation. Comparable results are reported by (Jurawitz et al., 2014): although hearing was preserved in the majority of cases, total hearing loss was reported in 23 of 51 patients (23.3%) measured after 24 month. Hearing preservation in the U.S. study was slightly less successful where after 6

months 17 of 50 patients (34%) did not retain functional acoustic sensitivity. On the other side, total hearing loss does not implies in all cases that the implanted device become useless and needs to be substituted by a longer standard cochlear implant. Using the Hybrid-L performance in the electric-only condition is better than preoperatively with hearing aids (Friedmann et al., 2015; Lenarz et al., 2013; Roland et al., 2015; Szyfter et al., 2013). For example in the study reported by (Roland et al., 2015) only 5 of 17 patients decided on reimplantation of a standard CI.

Even if using state of the art EAS electrodes, there is a residual risk of immediate or delayed hearing loss. In these cases electric-acoustic stimulation is no longer feasible, and a deeper electrode insertion is desirable for electric-only stimulation. Therefore our motivation is to combine the atraumatic insertion behaviour of the Hybrid-L electrode with perimodiolar placement as this results in a more complete coverage of the cochlea frequency range. It would be desirable, therefore, to insert a sufficiently thin and flexible electrode array atraumatically along the outer wall and then to achieve a position shift towards the inner wall with the integrated shape memory actuator after its activation by body temperature. However, such an electrode would only be beneficial, if the additional Nitinol wire did not compromise the good insertion behaviour in terms of preserving intracochlear structures.

That's why , we investigated whether the insertion of the Hybrid-L electrode carrier with an additional Nitinol wire inside (as a precursor for a Nitinol based shape memory actuator) is still atraumatic. There are two main ways how such a shape memory actuator may change the insertion behaviour in comparison to a conventional electrode array. A first potential source of errors is the shape change itself and the resulting intrinsic curling of the implant. Currently, a straight electrode array is indirectly forced into a curled shape through contact with the spirally shaped inner ear (Roland and Wright, 2006). Using an active component, an electrode would recover that spiral shape by "itself"—triggered by its increasing temperature. If that shape recovery occurs too early during the insertion process the entire procedure can be impeded (increasing risk of insertion trauma), or even needs to be aborted. If the curling starts while passing the mastoid and the middle ear before reaching the opening of the cochlea, the already curved electrode array cannot be inserted into the inner ear. If the curling occurs after passing the round window membrane or the cochleostomy but too early in the basal part of the inner ear, risk of tip fold-over and risk of insertion trauma in general may increase.

The second aspect with relevance to insertion behaviour and trauma is an increase in the stiffness of the electrode array caused by the additional Nitinol wire which is embedded inside the silicone body. This is especially crucial when the wire runs up to the critical tip region of the electrode. The principal aim of the study was an isolated examination of the influence of this stiffening effect of the Nitinol inlay. Therefore, transformation temperature was chosen considerably above body temperature to avoid premature curling of the electrode array and insertion trauma related to the shape memory effect itself. As stiffness of a Nitinol wire primary depends on the diameter and is comparability less altered by changing the transformation temperature, these findings based on experiments with inlays having a transformation temperature significantly above body temperature seems to be transferable to future samples with transformation temperature at the level of body temperature. This is valid as long as wire diameter will not be significantly increased in future versions of the Hybrid-M.

As in previous studies (Majdani et al., 2014b, 2013) inlays were made of a thin Nitinol wire (100µm in diameter) which underwent thermomechanical processing for shape setting. Finally, the tip region of the Nitinol inlays was tapered. Inlays were fabricated by G.RAU GmbH & Co. KG (Pforzheim, Germany), a company, specialized in processing metals and metal alloys into semi-finished products.

For a first set of laboratory samples most of the tapered region was trimmed off to provide a spiral shape which best fits to the CAD data of the average human cochlea. This set was called type A during this study. For a second set, the complete tapered region was preserved to investigate using the thinnest possible wires as well (type B in this study). This could be advantageous for the insertion as reduced stiffness is associated with reduced trauma. In contrast, the final curling of type B wires is much tighter than necessary for an average human cochlea. This could be disadvantageous regarding insertion trauma. Furthermore, the thickness of type B inlays at the tip region is much smaller than covered by previous investigations. Therefore, it is unknown whether an inlay of such low thickness is still strong enough to bend the electrode array and to ensure the desired movement toward the modiolus. The imperfect final location in both type B wires which underwent thermal characterization suggests that tapering the Nitinol wire down to 40µm leads to a too thin and therefore too weak inlay to bend the electrode carrier sufficiently. However, it is also possible that the Hybrid-M samples were slightly damaged during handling, leading to plastic deformation of the Nitinol wire resulting in an impaired shape memory effect. This needs to be investigated with a larger samples size if thickness down to 40µm is favoured. However, adequate perimodiolar position was not in the focus of this study and therefore reserved to further investigations.

The Hybrid-M samples were inserted into the temporal bone using the same surgical technique as usually used for the Hybrid electrode in previous temporal bone studies (Briggs et al., 2006; Gantz et al., 2005; Lenarz et al., 2006) and clinical trials (Jurawitz et al., 2014; Lenarz et al., 2013, 2009) including mastoidectomy and the access through the facial recess. The cochlea was opened by slitting the round window membrane as described by (Lenarz et al., 2006). This was done to make sure that the histological results are not influenced by a differing surgical technique.

For histological evaluation a well-established specimen fixation technique was used. Its applicability for evaluation of cochlear implant electrodes after insertion in cochlear specimens has been proven in several previous studies and publications (Burghard et al., 2014; Lenarz et al., 2006; Rau et al., 2013; Stöver et al., 2005). Although dehydration in increasing ethanol series is known in principle to cause volume shrinkage in soft tissues (like muscles or nerves [Buytaert2014]) all histological images acquired in this study do not show shrinkage artefacts. Therefore, it is assumed that the used specimen fixation technique provides reliable and sound histological results.

A general finding of histological evaluation was a false orientation of the platinum contact electrodes which do not face towards the modiolus in most cases. Instead an internal twisting of the silicone body was observed. This could be related to general changes in bending behavior of the electrode array due to the additional Nitinol wire.

From a technological point of view this undesired twisting of the contact electrodes is related to fabrication processes and details of electrode design. Currently the experimental fabrication process results in a very lateral position of the inlay inside the silicone body. This may promote internal torsion moments when the shape memory actuator works against the straight platinum wires. Moving the actuator closer to the internal wire bundle and the contact electrodes may reduce this effect.

Aside from these details regarding insufficient orientation of the electrode pads, the change in overall stiffness due to incorporating a Nitinol wire into the electrode array did not cause a detectable insertion trauma in this study. In all six temporal bones, histological evaluation of the Hybrid-M laboratory samples provides no indication of damage to intracochlear structures. Comparing the results of type A and type B inlays, this study did not disclose any differences regarding insertion trauma.

This study was done without an explicit control group of an additional temporal bone trial. This was done because the Hybrid-L electrode is a well-known, widely used and extensively investigated electrode array with several published experimental studies dealing with insertion trauma. Therefore an additional temporal bone trial only for the reason to provide reference values was not necessary from our point of view. The two most relevant studies were published by (Briggs et al., 2006) and (Lenarz et al., 2006). In total 22 Hybrid-L electrodes were inserted in temporal bones. In 21 of the insertion no sign for intracochlear trauma was observed; in the remaining samples the authors reported “slight damage to the lateral wall of the scala tympani” (Lenarz et al., 2006, p. 36). Aside from these two references which were consulted in terms of the control group, there are additional studies published, dealing with the Hybrid-L electrode (Driscoll et al., 2011; Roland et al., 2008; Shepherd et al., 2011). However, they are of limited value regarding consideration as reference values for insertion trauma as the evaluation was either based on micro-computed tomography (µCT) images instead of histological evaluation (Driscoll et al., 2011), or shorter predecessor of the Hybrid-L was used with 10mm length instead of 16mm (Roland et al., 2008), or histological evaluation was done using cats instead of human temporal bone specimens (Shepherd et al., 2011). Nevertheless, also these experimental investigations on the Hybrid-L confirm its gentle and less traumatic insertion and make a supplemental control group within this preliminary study dispensable. With respect to these findings from literature we concluded that the risk of insertion trauma for the investigated Hybrid-M laboratory samples is comparable low to the conventional Hybrid-L electrode array.

Finally, the result obtained in this study of no histologically detectable trauma or scala dislocation makes a control group somewhat redundant. It was never supposed that the Hybrid-M electrode design with its Nitinol inlay would be *less* traumatic than the existing Hybrid-L electrode. Therefore, no matter what the outcome of the Hybrid L control group in the present study had been, it would not have changed the conclusion that there is no evidence to suggest that the Hybrid-M design is more traumatic during initial insertion. Therefore, outcomes achieved in this study are considered as an encouraging preliminary result which justifies further developments of Nitinol-actuated cochlear implant electrode arrays.

Potential advantages of shape memory electrode array are: First, the insertion depth increases, which is advantageous for purely electrical stimulation, should residual hearing be progressively lost in the years after CI implantation. The patient would be spared the necessity of having to undergo reimplantation of a longer

conventional electrode array. In one case, the experimental characterization of the Hybrid-M samples inside the heatable water bath was used for a first estimation of how angular insertion depth will change due to an activation of the shape memory effect. In lateral wall position the angular insertion depth of the electrode array inside the artificial cochlear model was 255° (see Figure 6). This is in good agreement with published data about Hybrid-L. (Briggs et al., 2006) reported a mean insertion angle of 255° when using a cochleostomy (12 temporal bone specimens) and a mean value of 240° for the group with round window access (n=6). Comparable findings in the temporal bone study of (Driscoll et al., 2011): 250° in average for the insertion through the cochloestomy (n=5) and 254° for the round window access (n=5). This agreement of our measurement with published data indicates that the used model has a suitable geometry for this type of evaluation. After heating up the water bath and reaching the perimodiolar configuration an angular insertion depth of 350° was measured. This means an increment on angular insertion depth of 95°. Future temporal bone trials have to show in detail in which range the insertion of the Hybrid-M, due to the activation of the shape memory effect and its movement toward the modiolus, will be deeper than of Hybrid-L. However, the specific value strongly depends on the individual anatomy of the patients, which is known to show considerable interindividual variability (Avci et al., 2014; Skarzynski et al., 2012; Würfel et al., 2014). If comparing the Hybrid-M with other available EAS electrodes with respect to insertion depth it should be kept in mind that insertion depth does not only depends on anatomical variations and the availability of a shape memory effect but also depends on general design considerations like initial insertion length. For the CI422 (also known as SRA electrode) an average angular insertion depth of about 360° (range between 250° and 380°) is reported (Skarzynski and Podskarbi-Fayette, 2010) if insertion was stopped at the 20mm marker as it is recommended for residual hearing preservation surgery. Our Hybrid-M samples are within this range. In contrast, the CI422 can be inserted much deeper, up to 450°, if the electrode array is forwarded up to the second (25mm) marker. Such a deep insertion cannot be achieved with the current design of the Hybrid-M. Although it is in principle possible to increase the initial straight length of the Hybrid-M (currently 16 mm) to 20 mm or even 25 mm as for the SRA, this is not in the scope of our current research, as increased insertion depth goes along with higher risk of insertion trauma and more likely loss of residual hearing (Friedmann et al., 2015; Jurawitz et al., 2014).

A second advantage of shape memory electrode array may be the immediate proximity of the stimulation electrodes to the nerve tissue to be stimulated. Although this is an ongoing, controversial discussion there are several studies published which suggest that there is a positive effect on electric stimulation if the electrode array is located close to the modiolus like a more focussed spread-of-excitation (Todt et al., 2008; van Weert et al., 2005) or reduced thresholds (Seidman et al., 2005; Shepherd et al., 1993). However, these are up to now theoretical benefits, as significant improvements in terms of speech perception of patients with perimodiolar electrodes could not yet been shown (Hughes and Abbas, 2006).

Finally, there is evidence from literature that a complete insertion into the scala tympani can be successfully achieved more frequently with straight electrode arrays than with traditional perimodiolar electrode arrays (Wanna et al., 2014). This leads to the hypothesis that it may be an advantage to insert the electrode array using a straight but flexible configuration to prevent dislocation into the scala vestibuli and only afterwards—after successful insertion—change to a perimodiolar configuration. It requires further research including extensive temporal bone trials to test this hypothesis though.

However, additional insertion trials using temporal bones are indispensable as the influence of the active bending process on the insertion process was not included in this investigation. For a practicable surgical procedure implants are necessary which keep a straight configuration until they are inserted into the inner ear. Only during the later stage of the insertion (or after reaching the final placement at the lateral wall) the shape memory effect should cause the desired perimodiolar placement. Based on past experiences (Majdani et al., 2014b, 2013) considerable very fine tuning and optimization of both material properties as well as process parameters of the thermal treatment seem to be necessary to meet these goals. One strategy to overcome the problem of premature curling could be actively heating of the Nitinol wire above body temperature as previously investigated by Min et al. (2013) and Majdani et al. (2014b) using direct resistance heating. However, using this method requires ensuring that heating is limited to the inlay inside the silicone body and to not damage the cochlea by heating it beyond its physiological limitations. Current regulatory requirements for clinical application limit the tolerable heating of the device to 2°C above body temperature. In contrast to the statement in Min et al. (2013), our experience suggests that the silicone body does not provide a strong insulating effect.

The opposite approach focuses on cooling the device to delay the activation of the shape memory effect during the insertion process. In this study, we already included the cooling of the electrode array using ice water and a special straightening device. This was not necessary for the insertion as the transformation temperature was chosen far above body temperature. This step was included to gain experience regarding the handling and usability of such a procedure. Cooling the electrode array in sterile ice water would represent a conceivable and acceptable process for later clinical application. If cooling the implant itself is not sufficient for save clinical use, cooling the complete mastoid for a "under water" insertion strategy could be a feasible alternative (Majdani et al., 2014a).

5 Conclusion

In this study, a CI electrode array with Nitinol inlay was evaluated for insertion trauma. The basic concept of an active bending mechanism fundamentally combines the advantages of residual hearing-preserving insertion and positioning the electrode array in close proximity to the modiolus, which to date no available cochlear implant has been able to provide. The findings of this study do not indicate a higher risk of insertion trauma due to the additional stiffness of the integrated Nitinol inlay. Rather the tested Hybrid-M samples with inactive shape memory effect were at least as atraumatic as conventional Hybrid-L electrodes during initial insertion. These promising results support further research on shape memory cochlear electrode arrays featuring thin wire Nitinol actuators.

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