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A method to determine the accuracy of shape setting thin, spirally shaped Nitinol wires

Abstract: Electric stimulation of the auditory nerve using a cochlear implant (CI) is presumed to be superior when the electrode array (EA) is placed close to the inner wall of the cochlea. Nitinol is investigated as an actuator that enables an intracochlear shape change of the EA from a straight configuration (also necessary for the insertion) to a spiral shape fitting to the inner wall. As shape setting of the thin Nitinol wires is crucial, a method to quantify the accuracy of the shape setting is presented.

To measure the trained shape of thin Nitinol wires ($\varnothing$ 100 μ m) a contactless, optical method was developed. For each wire, a photomicrograph was captured and processed using a custom Matlab algorithm. Threshold based segmentation followed by morphological operations to remove artefacts were applied to extract the wire's shape. Utilizing an iterative closest point (ICP) algorithm the actual shape was registered to the desired spiral path. Finally, the root mean squared error describing the deviation between both spirals was calculated as a measure for the "shape error" (ϵ_{shape}). In total 147 Nitinol wires of 16 batches were analyzed to quantify the reliability of the shape setting procedure.

The proposed method was successfully applied in all samples. On average ϵ_{shape} was 0.06 ± 0.02 mm. Deviation from the desired shape was < 0.1 mm (< 0.15 mm) in 95% (99%) of the samples. In summary, the presented method is suitable to control the trained shape of thin Nitinol wires. Furthermore, our results confirm a high reliability of the shape setting procedure used for our thin Nitinol actuators intended for future applications in CI EAs.

Keywords: Shape memory alloy, Nitinol, NiTi, cochlea implant, shape setting, memory effect

<https://doi.org/10.1515/cdbme-2021-2024>

1 Motivation

A cochlear implant (CI) is an auditory neuroprosthesis used in therapy for patients with profound hearing loss or deafness. The CI electrically stimulates the auditory nerve using an electrode array (EA), which is inserted into the inner ear (cochlea). Due to the location of the auditory nerve in the central axis of the cochlea, a final position of the EA close to the inner wall of the cochlea (also known as "perimodiolar") is assumed to be more beneficial for stimulation [1]. However, literature reports higher rates of atraumatic insertions (less translocations) when using EAs designed to rest against the outer wall of the cochlea. In addition, to insert the EA into the cochlea a temporary straight shape is required at the beginning of the surgical procedure. Therefore, the beneficial perimodiolar position could be facilitated with an intracochlear shape change of the EA. Given current requirements for thin and flexible EAs, the use of small or thin actuators that could facilitate this intracochlear position shift has been limited.

A single wire of Nitinol, a commonly used shape memory alloy (SMA) known for its temperature-induced shape change, can act as a thin and mechanically simple actuator if embedded inside the EA. The main characteristic of SMAs, such as Nitinol, is their ability to be pseudo-plastically deformed followed by a transformation to the starting geometry. Simply put, the alloy remembers a trained shape after being temporarily deformed. When subjected to temperatures above a characteristic value, the shape memory effect is activated. Above the austenite finish temperature (A_f) the material is fully transformed. The desired shape of the SMA wires, which for our purposes is a spiral-shape, can be implemented using thermal treatment. This process is known as "shape setting" or "shape training".

For the development of CI prototypes that reach the perimodiolar position with an integrated Nitinol wire serving as an actuator we developed a method to first fabricate thin Nitinol wires and then train them to a spiral-shape adapted to the anatomy of the human cochlea together with our industrial partner G.RAU GmbH & Co. KG (Pforzheim, Germany) [2]. Accurate shape setting plays a crucial role in the preservation

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of delicate intra-cochlear structures by minimizing the trauma from intracochlear position shift. Therefore, a method to evaluate the accuracy of the shape setting procedure is necessary. The present work presents a measurement method to determine this accuracy on a large set of Nitinol wires.

2 Material and methods

To determine the accuracy of the shape setting procedure, the geometry of trained Nitinol wires were compared to their target geometry based on the following method. Initially, a trained wire is dipped in hot water (water temperature $\gg A_f$) to ensure that the final (for our purpose spiral shape) shape is captured. Subsequently, an image of the wire is taken with a microscopic camera. The captured image is first binarized and further processed with morphological operations to enable segmentation of the wire using the Image Processing Toolbox in Matlab (release 2020b, The MathWorks, Inc., Natick). The program flow chart of the Matlab application is shown in Figure 1.

Figure 1: Program flow chart of the developed Matlab application to calculate the shape error ϵ_{shape} and the length error ϵ_{length} using the Iterative Closest Point algorithm (ICP).

To compare the obtained wire geometry to the reference the Iterative Closest Point algorithm (ICP) is executed. The reference geometry is equal to the geometry used to train the wires. The geometry in Matlab was obtained from CAD data using six circular arcs (Figure 2). The six arcs represent the centreline of the target wire geometry. To evaluate the shape error ϵ_{shape} quantifying the average shape deviation from the reference along the measured wire, the root mean square error (RMSE) of the distance between the two aligned geometries

was calculated by the ICP. A second value referred to as length error ϵ_{length} quantifies the accuracy of the total length of the produced wires and is calculated from the distance between the tip of the reference and the obtained geometry. Each value evaluates the quality of one separate fabrication process performed by the supplier. On the one hand, the result of the shape setting includes the training of the wire represented by ϵ_{shape} . On the other hand, the accuracy of the wire cutting process is quantified by ϵ_{length} .

In order to test the usability of the proposed method and to quantify the accuracy of the shape setting procedure, a

Figure 2: The reference geometry consisting of six circular arcs defined by the radius R in mm and the angle. The values were obtained from CAD data of the target wire geometry.

retrospective analysis of 147 Nitinol wires was performed. The wires were fabricated with a diameter of $100 \mu\text{m}$, a Nickel content of 50.8 at.% and belong to 16 batches with different parameters for the annealing processes. The desired spiral-shape was derived from a specific average sized human cochlea specimen that has been segmented from cross sectional images [3-4]. Photomicrographs of 147 unused wires were taken directly upon their acquisition, before any unintended deformation could take place. Limit values were defined at 0.1 mm for ϵ_{shape} and 0.5 mm for ϵ_{length} . These values were estimated based on constructive dimensions of the current developed CI EA prototype. Based on the two investigated parameters the wire is then classified as conforming when satisfactorily complying with both limit values, or sorted out when deemed noncompliant. If possible, the rejected wire could be reworked (correcting the length),

otherwise this is neither examined in following experiments nor used to fabricate CI prototypes.

3 Results

The microscopic images taken from the 147 Nitinol wires were successfully evaluated. In Figure 3 an exemplary photomicrograph of a trained wire in final shape setting with the corresponding registered and reference geometry is depicted. The mean measured values for ϵ_{shape} and ϵ_{length} are summarized in Table 1. The resulting total mean value is 0.06 ± 0.02 mm for ϵ_{shape} and 0.31 ± 0.26 mm for ϵ_{length} . A normalized cumulative histogram for ϵ_{shape} and ϵ_{length} is shown in Figure 4. The shape deviation ϵ_{shape} was smaller than the desired limit of 0.1 mm for 95% of the wires. For the length error at the tip ϵ_{length} , 82% of the wires showed a deviation smaller than the limit value of 0.5 mm. Seven wires did not fulfil the requirements for ϵ_{shape} and were thus rejected. Out of these, six wires did not satisfy the pre-defined threshold for ϵ_{length} either. Of the remaining 140, another 20 also exceeded the limit for ϵ_{length} . None of these wires could be reworked, as they all were classified as too short. Therefore, 120 of 147 wires (82%) were identified to be suitable for further experiments.

Figure 3: Image of a trained Nitinol wire in final shape setting with the registered geometry shown with a superimposed red line and the reference shown as a superimposed blue line. ($\epsilon_{\text{shape}} = 0.05$ mm, $\epsilon_{\text{length}} = 0.22$ mm)

Table 1: Mean measured values for ϵ_{shape} and ϵ_{length} . Samples subdivided in 16 different batches.

Batches		ϵ_{shape} [mm]	ϵ_{length} [mm]
#01	(n = 5)	0.06 ± 0.02	0.24 ± 0.12
#02	(n = 5)	0.05 ± 0.02	0.24 ± 0.11
#03	(n = 10)	0.06 ± 0.03	0.41 ± 0.26
#04	(n = 10)	0.07 ± 0.02	0.22 ± 0.14
#05	(n = 10)	0.05 ± 0.01	0.30 ± 0.11
#06	(n = 10)	0.06 ± 0.01	0.22 ± 0.18
#07	(n = 10)	0.06 ± 0.01	0.22 ± 0.17
#08	(n = 9)	0.07 ± 0.02	0.19 ± 0.17
#09	(n = 10)	0.06 ± 0.02	0.21 ± 0.16
#10	(n = 9)	0.06 ± 0.02	0.34 ± 0.26
#11	(n = 9)	0.08 ± 0.02	0.69 ± 0.39
#12	(n = 10)	0.07 ± 0.03	0.32 ± 0.16
#13	(n = 10)	0.05 ± 0.01	0.18 ± 0.09
#14	(n = 10)	0.05 ± 0.02	0.38 ± 0.27
#15	(n = 10)	0.08 ± 0.03	0.44 ± 0.35
#16	(n = 10)	0.07 ± 0.04	0.32 ± 0.32
total	(n = 147)	0.06 ± 0.02	0.31 ± 0.26

4 Discussion

The proposed method was successfully used to evaluate trained Nitinol wires with respect to their deviation from a target geometry.

The two investigated parameters ϵ_{shape} and ϵ_{length} can be correlated to two different fabrication steps. The shape setting process linked to ϵ_{shape} showed a high accuracy, as 95 % (140 of 147) of the wires deviated less than the limit value. The corresponding procedure can therefore be regarded as suitable for the fabrication of thin Nitinol actuators for CI prototypes.

With 82 % (121 of 147) of the wires satisfying the requirement for ϵ_{length} , the correlated wire cutting process showed a larger error. While the cause for this error is unknown, optimizing this step could further increase the outcome of the fabrication process.

The pre-defined limit values for ϵ_{shape} and ϵ_{length} used in this study are based on constructive dimensions. However, the limits can be adjusted for other purposes or future CI prototypes.

An unknown set of parameters in the performed measurements are the environmental conditions. In CI surgery, the wire would be subjected to an external (i.e. body) temperature of around 37° C. The measurements in this study were however recorded at room temperature due to the

Figure 4: Normalized cumulative histogram of the measured values for ϵ_{shape} (a) and ϵ_{length} (b).

microscopic setup. Measurements with the desired temperature could have resulted in a slightly different outcome. As the magnitude of this influence is yet unknown, future experiments can further investigate this property.

The method of inferring the shape of the wire from image segmentation showed reliable results. However, in singular cases, small deviations between the straight parts in the reference and the registered geometry were visible. This is due to the fact that the ICP allows deviations in the straight part if it leads to a more optimal fit in the curved sections. For a more realistic result, the algorithm could be forced to align the straight wire parts of the image and the reference completely. To this end, the straight section of the wire should be considered as a fixed constraint, due to the fact that it does not belong to the trained shape.

Author Statement

Research funding: This work was funded by the German Research Foundation (DFG, RA 2751/1-1 and under Germany's Excellence Strategy – EXC 2177/1 - Project ID 390895286).

Conflict of interest: Authors state no conflict of interest.

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