



## Research paper

# Synthesis process of a compliant fluidmechanical actuator for use as an adaptive electrode carrier for cochlear implants



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## ABSTRACT

The cochlear implant, consisting of an electrode carrier and embedded electrodes, is an auditory neuroprosthesis surgically inserted into the cochlea in order to create an auditory impression in deaf or profoundly hearing-impaired patients. This contribution presents a fluidically actuated electrode carrier with a changeable curvature to simplify insertion. Targeted deformation of the carrier is accomplished by applying pressure internally as well as using a non-stretchable thin fibre embedded in its wall. An analytical examination of the scaled model shows that enlarged geometrically similar systems can be studied in place of actual systems, reducing the effort required for measurements. The geometry of the electrode carrier was determined using model-based synthesis combining the finite element method with an analytical model. The material parameters for the finite element model were found experimentally and fitted by using a third-order Ogden material model. The result of the synthesis yielded a conical shape for the carrier. Synthesis of other forms is also possible and one form is shown which was calculated using a polynomial approach. Demonstrators (3:1-scale) were manufactured and measured. The difference between the measured and calculated pressures was less than 0.6 bar for the cylindrical form and less than 0.78 bar for the conical form.

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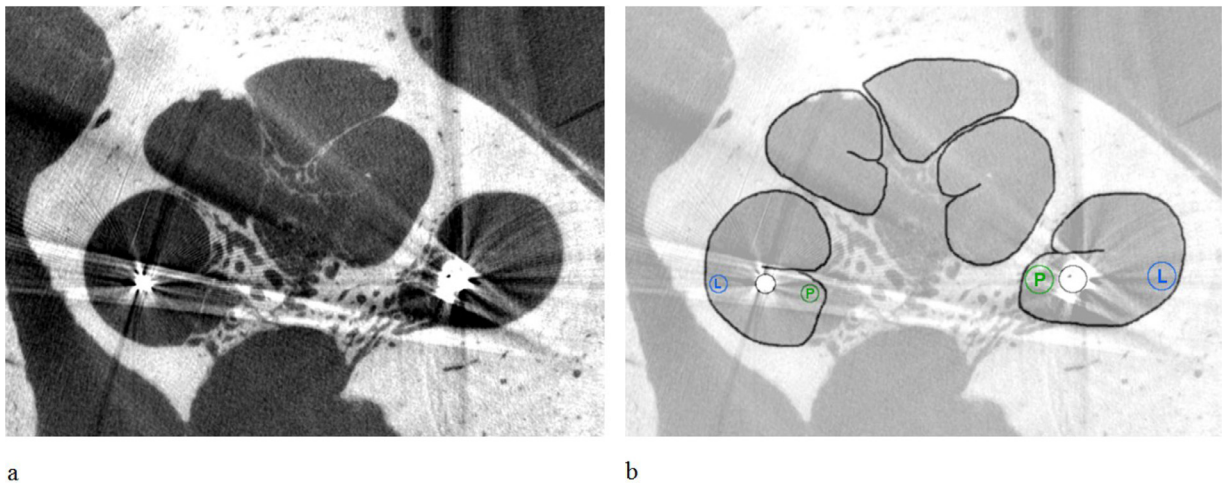
## 1. Introduction

Severe to profound sensorineural hearing loss is usually caused by deficient, damaged or missing hair cells in the inner ear (cochlea). A primary method of treatment involves the insertion of an auditory neuroprosthesis, called a cochlear implant (CI). The CI is surgically implanted into the cochlea, where it electrically stimulates the auditory nerve [1,2]. This allows the patient to receive auditory stimuli.

A cochlear implant system consists of two parts: one component worn behind the ear containing a microphone and a speech processor as well as one component implanted in the body. The implanted part contains a processor housing with an integrated coil and an electrode carrier, made of a silicone body in which multiple contact electrodes (platinum alloy) are embedded to stimulate the auditory nerve. This electrode carrier is surgically inserted into the cochlea (Fig. 1a).

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**Fig. 1.** Micro-computer tomographic image of a human cochlea with an implanted electrode carrier. a: Image artefacts arise through platinum stimulation contacts of the electrode carrier; b: A sketch shows the actual position of the electrode carrier (empty circle) and the ideal positions for a lateral (L) or perimodiolar (P) placement within the first cochlear winding.

**Table 1**

Properties of electrode carrier (exemplarily two types for each manufacturing company).

Company	Electrode carrier	Form	Diameter [mm] (tip – basal end)	Active length [mm]	Embedded contact electrodes
Cochlear Ltd Sydney, Australia	Contour Advance	curved	0.5 – 0.8	15.5	22
	Slim Straight (SRA)	straight	0.3 – 0.6	19.1	22
MedEl Innsbruck, Austria	Flex Soft	straight	(0.4 × 0.5) – 1.3	26.4	19
	Flex 20	straight	(0.3 × 0.5) – 0.8	15.4	19
Advanced Bionics Valencia, CA, USA	HiFocus Helix	curved	(0.6 × 0.7) – 1.1	13.3	16
	HiFocus 1j	straight	0.4 – 0.8	17.0	16
Oticon Medical Vallauris, France	Evo	straight	0.4 – 0.5	24.0	20
	Classic	straight	0.5 – 1.1	25.0	20

Commercially available electrode carriers have either a straight or curved form. Besides that, other characteristics like the number of embedded contact electrodes, the length and diameter varies among different types of electrode carriers and depending on the company (see Table 1).

After insertion into the cochlea, straight electrode carriers rest along the outer wall whereas curved carriers remain along the inner wall (see Fig. 1b). These end positions are referred to as lateral and perimodiolar, respectively. The auditory nerve, which is stimulated by the implant, emanates from the axis (modiolus) of the spiral-shaped cochlea. For this reason, a perimodiolar resting position reduces the distance between the stimulation electrodes and the nerve cells to be stimulated, which leads to a decrease in the energy necessary for stimulation and improved frequency selectivity [3]. For suitable comparison of the insertion depth achieved by lateral and perimodiolar electrode carrier the insertion angle is used instead of measuring absolute length. Various approaches have been shown in the literature for achieving a perimodiolar placement, for example using hydrogels [4], shape memory actuators [3] or magnetic guiding of the implant during insertion [5].

The general operative procedure already represents a well-established clinical routine, especially with respect to completely deaf patients. In contrast, patients with severe hearing loss, for whom a hearing aid cannot provide adequate speech intelligibility, can only be treated in specialised centres by experienced surgeons in order to minimise the risk of further hearing degradation resulting from surgery (iatrogenic). Introduction of the CI into the spiral shape of the cochlea [3,6] may cause damage to the basilar membrane and the still intact sensory hair cells, leading to complete deafness post-surgically. Afterwards, these patients can then no longer profit from the simultaneous use of the cochlea implant along with residual hearing capability (electro-acoustic stimulation or EAS). Nevertheless, in recent literatures there have been published several studies which achieved in 90–95% of patients hearing preservation using electrode carrier of different length [8]. Additionally deeper insertion is related to improved music perception, which was displayed in 25 patients with an insertion angle of  $521.6 \pm 117.9^\circ$  [9]. The variation of observed insertion angles varies greatly: Boyd [10] reports the general insertion depth to be 1–1.5 turns ( $360^\circ$ – $540^\circ$ ) and Buchmann [11] evaluated the insertion depth in 13 subjects to be  $549.2 \pm 130.7^\circ$ . The insertion angle does not only depend on the absolute length of the electrode carrier but as well on the size of the cochlea [12]. Based on a study on 10 only male human temporal bones using lateral electrode carrier of different length (20, 24, 28 and 31 mm) the insertion angle was found to be  $341 \pm 22^\circ$ ,  $477 \pm 36^\circ$ ,  $587 \pm 42^\circ$ , and  $673 \pm 38^\circ$  respectively [12]. On the other hand, the risk of loss of residual hearing during implantation is reported to increase with longer electrode carrier

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