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MAIN ARTICLE

Electrode design and insertional depth-dependent intra-cochlear pressure changes: a model experiment

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Abstract

Background: Preservation of residual hearing is one of the major goals in modern cochlear implant surgery. Intra-cochlear fluid pressure changes influence residual hearing, and should be kept low before, during and after cochlear implant insertion.

Methods: Experiments were performed in an artificial cochlear model. A pressure sensor was inserted in the apical part. Five insertions were performed on two electrode arrays. Each insertion was divided into three parts, and statistically evaluated in terms of pressure peak frequency and pressure peak amplitude.

Results: The peak frequency over each third part of the electrode increased in both electrode arrays. A slight increase was seen in peak amplitude in the lateral wall electrode array, but not in the midscalar electrode array. Significant differences were found in the first third of both electrode arrays.

Conclusion: The midscalar and lateral wall electrode arrays have different intra-cochlear fluid pressure changes associated with intra-cochlear placement, electrode characteristics and insertion.

Key words: Cochlear Implants; Hearing Loss; Labyrinthine Fluids

Introduction

Cochlear implantation for the auditory rehabilitation of deaf patients (i.e. those with profound sensorineural hearing loss), and nowadays patients with substantial residual hearing, has become a worldwide-accepted procedure. As the number of implantations rises, the challenges and demands of modern surgery increase, and each sub-step of the surgical procedure is the focus of clinical research.

Recipients with preserved residual low-frequency hearing have significantly improved discrimination scores and hearing benefits in challenging listening surroundings.[1] Techniques have been developed to minimise the insertion trauma in surgery performed to preserve residual hearing.[2–5] In addition to surgical expertise, careful selection of the electrode array is an important sub-step of the procedure. Preservation of residual hearing can be achieved by implanting either short,[6,7] standard[8] or perimodiolar electrodes.[4,9] The latter are associated with an increased risk of intra-cochlear trauma,[10] and are hence less commonly chosen for hearing preservation. Nevertheless, these electrodes tend to be close to the modiolus, provide a good audiological outcome and have better electrophysiological abilities.

Lateral wall electrodes are known to cause less intra-cochlear trauma and are favourable for hearing preservation.[11] Midscalar electrodes have been designed to combine the electrophysiological benefits of perimodiolar electrodes and the atraumatic behaviour of lateral wall electrodes.

Important clinically evaluated factors for the preservation of residual hearing include: the design of the cochlear electrode,[12–14] peri- and post-operative medications,[15] sealing of the cochleostomy,[16] and electrode insertion speed.[17,18]

Reliable hearing preservation is a major goal in modern cochlear implant surgery. The intra-cochlear fluid pressure changes that occur during cochlear implantation are assumed to influence the intra-cochlear structures and can lower residual hearing. These intra-cochlear fluid pressure changes depend on different parameters during the cochlear implant surgery and should therefore be kept low in general.

As intra-cochlear fluid pressure changes occur in the pre- and post-insertion period, as well as during the insertion itself, each sub-step needs specific attention. In the pre-insertion period, the opening of the round window membrane can be associated with significant intra-cochlear fluid pressure changes.[19–21] In the

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post-insertion period, the sealing of the electrode array in the round window and the cable movements after complete insertion influence the intra-cochlear fluid pressure changes.[22] The intra-cochlear fluid pressure changes during electrode insertion are tremor dependent, but can be influenced by the insertion speed and stabilisation of the inserting hand.[18,23] Tremor is assumed to have an impact on the clinical outcome in cochlear implant surgery.[23] Electrode movements during the insertion can cause uncontrolled fast and static pressure changes that enhance intra-cochlear trauma.

Furthermore, electrodes with different designs, volumes, lengths and characteristics are associated with different absolute intra-cochlear fluid pressure changes and with a different course of intra-cochlear fluid pressure changes.[24] In high-volume lateral wall electrodes, the intra-cochlear fluid pressure changes decrease with progressive insertional depth.[25]

This study aimed to compare how the intra-cochlear pressure changes when increasing the cochlear implant electrode insertion depth in a midscalar electrode and a prototype, small-volume lateral wall electrode.

Materials and methods

An artificial and transparent full-scalar cochlear model, employed in former studies by the same research group,[18–21,23–25] was used in all experiments. The diameter of the round window in the model was 1.5 mm, which is slightly larger than that in the human temporal bone.[26] The total volume of the model was 87 mm^3. The sensor tip was inserted in an extra channel (about 800 µm) in the apex.

The model was filled with pure water, and the pressure sensor was sealed and fixed with fibrin glue within the channel. Neither the channel wall nor the floor was in direct contact with the sensor tip. The cochlear model was checked for enclosed air bubbles under the microscope. After every experiment, it was refilled and rechecked for enclosed bubbles. The experiments were performed with moisturised electrodes, and in series with the sensor in an unchanged position, in order to exclude sensor position-related bias and to allow inter-experimental comparability.

Pressure sensor

The 0.8 mm diameter micro-optical pressure sensor (FOP-M; FISO, Quebec City, Canada) was used to measure the intra-cochlear pressure changes. Details regarding the design, fabrication and capacity of the pressure sensor, designed by Olsen, can be found in the literature.[27] Generally, the pressure sensor is a hollow glass tube, which is tipped and sealed by a thin plastic diaphragm, coated with a reflective surface of gold on one side. An optical fibre delivers light from a light-emitting diode, which fans out and is reflected by the gold-coated diaphragm. The gold-coated membrane bends linearly with changes in the pressure and reflects the light. A photodetector senses the emitted light by taking 5000 measurements per second.[27]

Electrodes

The Advanced Bionics (Stäfa, Switzerland) HiFocus Midscalar electrode array and the prototype Lateral Wall 23 electrode array were used for all the experiments. The electrode insertions were made using the insertion tool recommended by Advanced Bionics for the HiFocus Midscalar electrode array and forceps for the Lateral Wall 23 electrode array.

The HiFocus Midscalar electrodes have a tip size of 0.5 mm and an end size of 0.7 mm, with a total insertion length of 18.5 mm. The total volume is 6.5 mm^3 and the mean volume per mm is 0.35 mm^3. The Lateral Wall 23 electrodes have a tip size of 0.22 mm × 0.55 mm and an end size of 0.6 mm × 0.8 mm, with a total insertion length of 23 mm. The total volume is 5.19 mm^3 and the mean volume per mm is 0.23 mm^3.

Insertions were performed using the one-point supported insertion technique, where only the elbow of the inserting arm is rested on the table.[23] The insertion speed was 0.5 mm/second for all measurements. The insertions took approximately 37 seconds and 46 seconds respectively, and were performed by the senior author.

Statistical analysis

GNOME™ Evolution software, Microsoft Excel (Santa Rosa, California, USA) and SPSS software, version 22.0 (SPSS, Chicago, Illinois, USA), were used to record and analyse the data.

Five complete insertions were performed with each electrode array. The individual measurements were split into thirds to further analyse the data. For each electrode third, the number of peaks was counted (pressure peak frequency) and the three greatest amplitudes were analysed (pressure peak amplitude).

Statistical evaluation was performed using one-way analysis of variance (ANOVA) and unpaired *t*-tests. The data are presented as means ± standard deviations (SDs). *P* values of less than 0.05 were considered statistically significant.

Results

Pressure peak frequency changes

In order to determine if there were differences in the number of peaks between the two electrode arrays, a one-way ANOVA was conducted for each array. Each electrode array was inserted five times. The data were normally distributed for both electrode arrays, as assessed by the Shapiro–Wilk test ($p > 0.05$). Homogeneity of variance was observed, as assessed by Levene's test of homogeneity of variances ($p > 0.05$).

There was no statistically significant difference in the mean number of peaks between each evaluated third for both the HiFocus Midscalar electrode array (F(2,12) =

0.369, $p > 0.05$) and the Lateral Wall 23 electrode array (F(2,12) = 0.092, $p > 0.05$). Post-hoc testing revealed no significant differences either. However, there was a slight increase in the number of peaks for the HiFocus Midscalar electrode array from the first third (mean number of peaks ± SD = 6 ± 1.87) to the second third (mean ± SD = 6.4 ± 1.14) to the last third (mean ± SD = 6.8 ± 1.3). For the Lateral Wall 23 electrode array, an increase from the first third (mean number of peaks ± SD = 8 ± 1) to the second third (mean ± SD = 8.4 ± 2.07) and a slight decrease to the last third (mean ± SD = 8.2 ± 1.1) was found (Table I).

An independent *t*-test was conducted to determine whether there was a significant difference between the peak frequency within the thirds between both electrode arrays. In all the thirds, a higher peak frequency was observed in the Lateral Wall 23 electrode array than in the HiFocus Midscalar electrode array, but the difference was not statistically significant (first third comparison, $p = 0.068$; second third comparison, $p = 0.095$; last third comparison, $p = 0.103$) (Table I).

Pressure peak amplitude changes

A one-way ANOVA was performed to determine whether there were any differences in the measured peak amplitudes between both electrode arrays. Each insertion was measured five times, similar to the peak frequency investigation.

Homogeneity of variance could not be assumed for the measured amplitudes in the last third of the Lateral Wall 23 electrode array group, as assessed by Levene's test of homogeneity of variance ($p = 0.003$). There was no statistically significant difference in the means of the peak amplitude between each evaluated third for both the HiFocus Midscalar electrode array (F(2,12) = 1.578, $p > 0.05$) and the Lateral Wall 23 electrode array (F(2,12) = 0.0225, $p > 0.05$). Post-hoc testing revealed no significant difference either. A slight decrease in peak amplitude was seen for the HiFocus Midscalar electrode array from the first third (0.13 ± 0.06 mmHg) to the second third (0.06 ± 0.02 mmHg) to the last third (0.12 ± 0.09 mmHg). For the Lateral Wall 23 electrode array, a smooth increase from the first third (0.05 ± 0.03 mmHg) to the second third (0.06 ± 0.02 mmHg) and to the last third (0.06 ± 0.01 mmHg) was found (Table I).

An independent *t*-test was conducted to determine whether there was a significant difference within the thirds between both electrode arrays, similar to peak frequency. Higher peak amplitudes were seen in the HiFocus Midscalar electrode array group in all the thirds. Regarding the first third, the difference of 0.08 mmHg was statistically significant (95 per cent confidence interval (CI) = 0.01 to 0.15, $p = 0.031$). In the second and last thirds, the difference was not statistically significant (second third comparison, $p = 0.768$; last third comparison, $p = 0.191$) (Table I, Figures 1 and 2).

Discussion

The value of cochlear implantation for the hearing rehabilitation of patients with severe to profound hearing loss has been established worldwide. The indication criteria have changed during the past few decades; nowadays, in many countries it includes patients with unilateral deafness as well as patients with sustainable residual hearing. Preservation of residual hearing has become one of the major goals in modern cochlear implant surgery.[1,4,5,28]

Insertion of the cochlear implant electrode arrays leads to intra-cochlear fluid pressure changes,[23–25] which may affect residual hearing preservation and hence the audiological outcome.[12] Therefore, the intra-cochlear fluid pressure changes should be minimised before, during and after cochlear implantation.[18,19,23,24]

The intra-cochlear fluid pressure changes during cochlear implant insertion are influenced by several factors. Significant reductions in terms of maximum pressure gain, peak frequency and peak amplitude can be achieved by inserting the electrode array with a supported technique[23] at a low insertional speed.[18]

Variations in the volume, tip size, shape, design and intra-cochlear position of the electrode array itself can influence the intra-cochlear fluid pressure. Usage of a stylet or sheath stabilises the electrodes, and reduces electrode-induced intra-cochlear fluid pressure changes by minimising intra-cochlear movement.[24] With increasing insertional depth, the lateral wall electrodes stabilise by increasing contact with the lateral wall. As a result, the intra-cochlear movement reduces, and the number of pressure peaks and the pressure amplitude decreases with progressive insertional depth.[25]

The Advanced Bionics HiFocus Midscalar® electrode array and the prototype Advanced Bionics Lateral Wall 23® electrode array were used in this study. The HiFocus Midscalar electrode array was inserted with the provided insertion tool that pushes the electrode off a stylet. The first third of the electrode is inserted manually into the cochlea; the tool then smoothly pushes the electrode off the stylet.

Regarding peak amplitude, there is a primary high peak amplitude in the first third (manually inserted electrode part), followed by a sudden decrease when the electrode is stabilised by the stylet. The natural tremor is reduced. For the final third, the electrode loses guidance from the tool and stylet; therefore, the peak amplitude rises.

The HiFocus Midscalar electrode array showed higher peak amplitudes than the Lateral Wall 23 electrode array in all the thirds, but the difference was significant only in the first third. The latter finding is assumed to be a result of the higher volume of the HiFocus Midscalar electrode array. The HiFocus Midscalar electrode array, inserted with the tool, is not guided by the lateral wall, which could increase

TABLE I
MEAN PEAK PRESSURE FREQUENCY AND AMPLITUDE FOR BOTH ELECTRODE ARRAYS

Electrode part	HiFocus Midscalar electrode array		Lateral Wall 23 electrode array	
	Peak frequency	Peak amplitude (mmHg)	Peak frequency	Peak amplitude (mmHg)
First third	6 ± 1.87	0.13 ± 0.06	8 ± 1	0.05 ± 0.03
Second third	6.4 ± 1.14	0.06 ± 0.02	8.4 ± 2.07	0.06 ± 0.02
Final third	6.8 ± 1.3	0.12 ± 0.09	8.2 ± 1.1	0.06 ± 0.01

Data represent means ± standard deviations.

the absolute movement within the cochlea. In contrast, the lateral wall stabilises the Lateral Wall 23 electrode array.

Compared with the Advanced Bionics IJ® electrode array,[25] for which the peak amplitude continuously decreases with ongoing insertional depth, the peak amplitude in the Lateral Wall 23 electrode array increases. Despite the fact that both are lateral wall electrode arrays, stiffness, volume and tip size appear to influence intra-cochlear fluid pressure changes; this is more distinct in smaller volume electrodes. This is in contrast to our previous study,[25] and we had expected to find an intra-cochlear fluid pressure reduction with increasing insertional depth, associated with the stabilisation of the electrodes by the cochlear wall. The Lateral Wall 23 electrode array has a smaller volume and is less stiff than the Advanced Bionics IJ electrode array, which might increase the intra-cochlear fluid pressure. Intra-cochlear fluid pressure changes are influenced by the insertion design (forceps *vs* Advanced Bionics IJ insertion tool), as well as the electrode array dimensions and characteristics.

Regarding peak frequency, the Lateral Wall 23 electrode array showed a greater number of peaks in every third than the HiFocus Midscalar electrode array. Although the differences between the thirds were not statistically significant, there was a visible tendency for reduced intra-cochlear pressure changes when using the HiFocus Midscalar electrode array. The peak frequency reflects the manual tremor. As the peak frequency is almost the same, a comparable manual tremor in all the insertions can be assumed. Compared with the Advanced Bionics IJ® electrode array,[25] the course of the number of peaks with progressive insertional depth of the Lateral Wall 23 electrode array was similar, but increased in the HiFocus Midscalar electrode array group.

Our study has some limitations associated with use of the artificial cochlear model. The comparisons between both electrode arrays is challenging as they differ in insertion design, as well as in volume, diameter and stiffness. Furthermore, the transformation of the rapid intra-cochlear fluid pressure changes in the human cochlea might be challenging to assess. The absolute intra-cochlear fluid pressure values *in vivo* might be different, as the relationship between the artificial model and the electrode array volume is different from the *in vivo* situation. The surface of the cochlear model is different from the human cochlea, which adds a certain resistance to the insertion. The resistance of the artificial model has to be overcome; it remains unknown how this resistance is comparable to that of the human cochlea.[29]

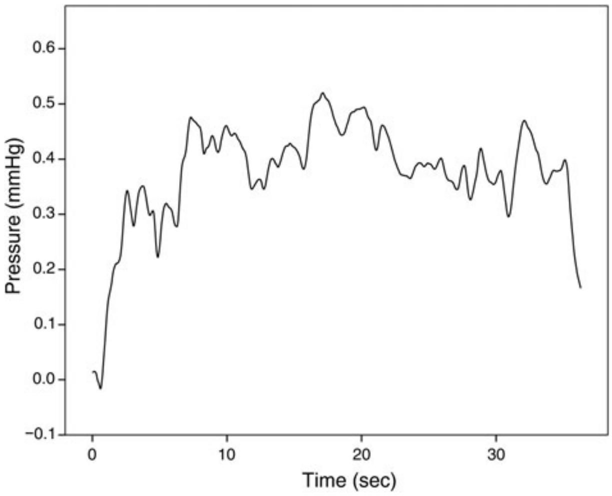

FIG. 1
Typical pressure course associated with insertion of the HiFocus Midscalar electrode array.

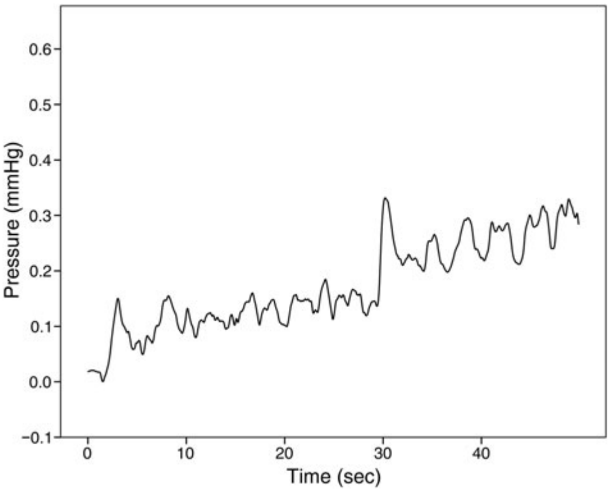

FIG. 2
Typical pressure course associated with insertion of the Lateral Wall 23 electrode array.

- **Preservation of residual hearing is a major goal in cochlear implant surgery**
- **Intra-cochlear fluid pressure changes influence residual hearing**
- **Intra-cochlear fluid pressure changes should be kept low before, during and after cochlear implant insertion**
- **The electrode array itself has an impact on intra-cochlear fluid pressure changes**
- **Perimodiolar and lateral cochlear implant electrode arrays have variable intra-cochlear fluid pressure effects**

Another aspect is the drain of the human cochlea. The model was sealed with fibrin glue in the apex; therefore, fluid loss was only observed through the round window. The relationship between the round window opening and the electrode array influences the amount of intra-cochlear fluid leakage and pressure, as it is slightly wider than the relationship *in vivo*. This smaller relationship might increase the *in vivo* intra-cochlear fluid pressure and this should be kept in mind. The natural main pathway for pressure equilibration is the cochlear aqueduct.[30] The intra-cochlear fluid pressure changes can be transferred between the different labyrinthine compartments.[31] However, the direct pressure transfer into these compartments has to be assumed to be limited *in vivo*.[32] Furthermore, our measurements consider only the intra-cochlear fluid pressure changes after the round window insertion, and were performed by one cochlear implantation surgeon only. These results may only be applicable to the surgeons who use the round window approach and who are familiar with these electrode arrays.

Conclusion

Intra-cochlear fluid pressure changes are assumed to affect residual hearing preservation and should be minimised. The midscalar and lateral wall electrode arrays have different intra-cochlear fluid pressure effects associated with intra-cochlear placement, electrode characteristics and insertion. Nevertheless, implant insertion into the human cochlea remains challenging and requires further investigation.

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