Laryngoscope Investigative Otolaryngology

Intracochlear Pressure Changes After Cochlea Implant Electrode Pullback—Reduction of Intracochlear Trauma

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Objective: Different aspects should be considered to achieve an atraumatic insertion of cochlear implant electrode arrays as an important surgical goal. Intracochlear pressure changes are known to influence the preservation of residual hearing. By using the intraoperative "pullback technique," an electrode position closer to the modiolus can be achieved than without the pullback. The aim of the present study was therefore to investigate to what extent the pullback technique can influence intracochlear pressure changes.

Methods: Insertions of cochlear implant electrodes were performed in an artificial cochlear model with two different perimodiolar arrays. Intracochlear pressure changes were recorded with a micro-optical pressure sensor positioned in the apical part of the cochlear. After complete insertion of the electrode array, a so-called pullback of the electrode was performed.

Results: Statistically significant pressure differences were measured if the electrode array was wet (ie, moisturized) during the pullback. Relative pressure changes in electrodes with smaller total volume are lower than pressure changes in larger electrodes.

Conclusion: The preservation of residual hearing and, thus, the resulting postoperative audiological outcome has a major impact on the quality of life of the patients and has become of utmost importance. Intracochlear pressure changes during the pullback manoeuver are small in absolute terms, but can even be still reduced statistically significantly by a moistening the electrode before insertion. Using the pullback technique in cases with residual hearing does not affect the probability of preservation of residual hearing but could lead to a better audiological outcome.

Key Words: Cochlear implant, preservation of residual hearing, pullback.

Level of Evidence: NA

INTRODUCTION

Cochlear implantation (CI) has evolved over the last 20 years as the standard therapy for patients with severe to profound sensorineural hearing loss, apart from the undisputed paedaudiological indications. As the indication criteria for CI were extended, for example, now including very young children, patients with ossifying otosclerosis or those with substantial residual hearing, the perioperative management and surgical techniques used for this procedure must also adapt to these trends. Minimizating of the insertion trauma and, thus, reliable preservation of residual hearing is a crucial factor in modern CI surgery. To preserve those delicate intracochlear parts, the insertion trauma should be minimized and a selective and specific scala tympani insertion should be achieved.[1–6] An electrode positioned within the scala tympani and close to the modiolus is preferable and demonstrates an advantage in terms of frequency discrimination outcome postoperatively in comparison to lateral wall electrodes.[7] The closer approximation of a perimodiolar electrode to the modiolus by surgical modification is called the "pullback technique." This technique was first described by Todt et al in 2005, and is characterized by a full insertion followed by a controlled pullback of the CI electrode array (for about 1–2 mm in total) to gain a position closer to the modiolus.[8]

As a surgical technique aimed at improving the CI outcome, the pullback technique is not very common. Little is known about possible intracochlear alterations and /or intracochlear pressure changes that occur during the pullback. Intracochlear pressure changes should be kept at a very low level before, during, and after the implantation.[9–12] The cochlea has a dynamic fluid system,[13] and as such, pressure applied to any part of the cochlea or to the electrode array itself is transferred through the cochlear partitions and can possibly interfere with the cellular structures. Pressure changes in the intracochlear fluid can be minimized by ensuring a large and/or laser supported opening of the round window membrane and a reduced insertion speed of the CI electrode array.[9,14,15] Lubrication of the round window membrane and lubricated insertion of the electrode array is part of the "soft surgery" principle[16] which reduces intracochlear fluid pressure changes during opening of the cochlea and insertion of the electrode array.[10,17]

The aim of this study was therefore to investigate whether the pullback of a perimodiolar electrode would possibly increase intracochlear pressure and, thus, the risk of intracochlear damage.

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Funding: None.

Conflict of Interest: There are no conflicts of interest from the authors.

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DOI: 10.1002/lio2.295

MATERIAL AND METHODS

Pressure Sensor

The fiber-optic pressure sensor, used in this study, was developed by Olson[18] and is commercially available from FISO Technology, Inc. (Quebec, Canada). The tip is a thin, quadratic hollow glass tube covered with a thin plastic film diaphragm coated with a reflective surface of evaporated gold.[18] A small distance (50–100 μm) optical fiber is contained within the glass tube, attached to the diaphragm tip, a light-emitting diode light source and a photodiode sensor. The fiber emits light, which is reflected by the gold-covered flexible diaphragm in a manner subject to a pressure-sensitive distance shift. The reflected light is sensed by the photodiode and the recording frequency is 5,000 measurements per second.

Preparation of the Cochlear Model

Experiments were performed using a synthetic transparent artificial full-scale cochlear model with a total volume of 87 mm^3. This is slightly above the physiological volume.[19] The round window is a circular opening with a diameter of roughly 1.5 mm, which is slightly greater than the human round window (1.23 mm)[20] and is rather plain than shaped. The cochlea was filled with pure water, and the pressure sensor was then positioned in the apical part of the cochlea and fixed with fibrin glue to avoid fluid loss. Neither the edge nor the bottom of the channel was in contact with the sensitive tip of the sensor.

Electrode Insertion and Pullback

All experiments were performed in a series of five trials under each condition with the perimodiolar Nucleus Contour Advance (512) and perimodiolar Nucleus Slim Modiolar (532) electrodes from the Cochlear Corporation (Sydney, Australia). The perimodiolar 512 electrode has a total volume of 9 mm^3 with a total intracochlear volume of 4.8 mm^3, and a apical diameter of 0.5 mm and basal area of 0.8 mm. Full insertion of the 512 using the advanced off-stylet technique was performed until the third rib was positioned at the level of the round window. The 532 electrode is 18.4 mm long and has a volume of 3.11 mm^3, with an apical diameter of 0.4×0.35 mm and basal diameter of 0.475×0.5 mm (data were provided by Cochlear Corp., Sydney) (Table I). Both electrodes have three markers which should be positioned within the round window or cochleostomy after insertion. Full insertion up to the third marker was performed using the insertion sheath provided by Cochlear Corporation. Under microscopic control, a pullback was performed until the mid-marker was at the level of the round window. In the first setup, a pullback was performed under dry conditions just after full insertion of the electrode array. In the second setup, a drop of water was placed within the round window before the pullback. To standardize the conditions, the senior author performed all insertions and pullbacks. The sensor was set to zero before each measurement. A measurement was considered to be valid if the pressure value measured close to zero after the pullback. Five pullbacks with every electrode array were performed under these conditions. After each pullback, the model was refilled with water and checked microscopically for any enclosed air bubbles before the electrode array was reinserted.

TABLE I.
Electrode Dimension

Electrode	Intracochlear Volume (mm^3)	Diameter Apical (mm)	Diameter Basal (mm)
512	4.8	0.5	0.8
532	3.11	0.4×0.35	0.475×0.5

RESULTS

Full insertion and complete pullback were achieved with every electrode, with five dry (532 dry/512 dry) and five moisturized (532 wet/512 wet) pullbacks performed each. Changes of the intracochlear pressure were measured in mmHg and were found to be unidirectional (Fig. 1a–d).

To compare differences between groups, a one-way analysis of variance (ANOVA) was performed. There were no outliers, and the data were normally distributed for each group as assessed by boxplot and the Shapiro–Wilk test ($P > .05$). Variances between groups were not homogeneous, as assessed by Levene's test ($P < .005$). Intracochlear pressure values had statistically significance differences in terms of both differing electrodes and conditions, with Welch's F test (3, 14.366) = 54.593, $P < .0005$. Increasing intracochlear pressure values were observed with the lowest in the 512 dry group (−2.98 ± 1.13 mmHg), followed by the 532 dry (−0.85 ± 0.18 mmHg), 512 wet (−0.17 ± 0.07 mmHg), and 532 wet (−0.09 ± 0.07 mmHg) groups. A Games-Howell post hoc analysis revealed that the 0.8 mmHg increase from 532 wet to 532 dry (95% confidence interval (CI), 0.5–1.0 mmHg) was statistically significant ($P < .005$), similar to the 2.9 mmHg increase from 532 wet to 512 dry (95% CI, 1.6–4.2 mmHg), ($P = .001$), the 0.7 mmHg increase from 512 wet to 532 dry (95% CI, 0.5–-0.9 mmHg), ($P < .005$), the 2.8 mmHg increase from 512 wet to 512 dry (95% CI, 1.5–4.1 mmHg), ($P = .001$), and the 2.1 mmHg increase from 532 dry to 512 dry (95% CI, 0.8–3.5 mmHg), ($P = .004$). Differences between the 532 wet and 512 wet groups were not significant (Fig. 2).

DISCUSSION

Preservation of residual hearing is one of the goals of modern CI surgery.[1,4,21–23] An atraumatic and selective CI electrode insertion and careful opening of the cochlea are known predictors of preservation of residual acoustic hearing.[1,24] The round window approach is widely used for atraumatic CI electrode insertion[3,5,25] and is associated with an increased likelihood of successful scala tympani placement and superior audiological outcomes.[26]

To our knowledge, there are no studies including the pullback technique for use in patients with residual hearing. The pullback technique is limited to perimodiolar electrode arrays. These are known to be more traumatic than straight electrode arrays and impose distinct intracochlear pressure

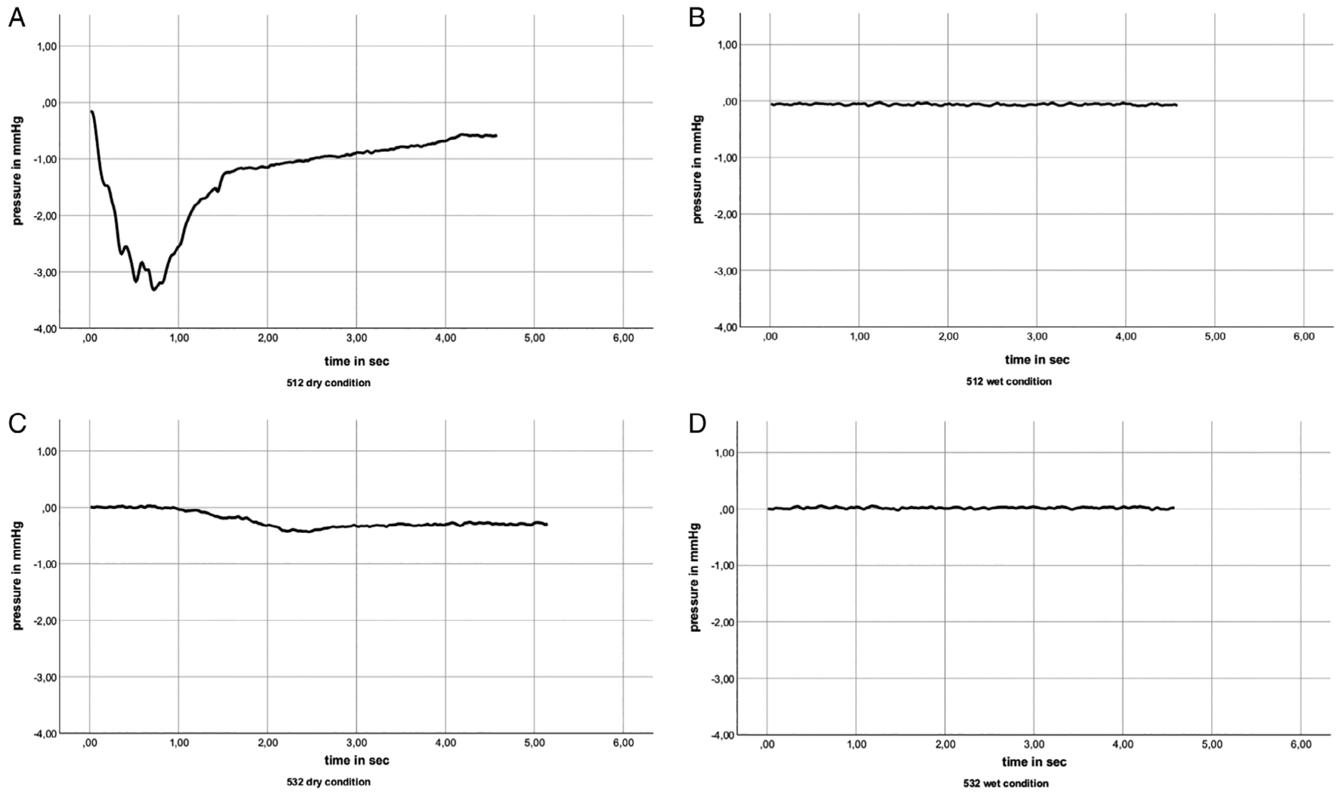

Fig. 1. (a) Exemplary course of unidirectional pressure change during the pullback of the 512 electrode under dry conditions. (b) Exemplary course of unidirectional pressure change during the pullback of the 512 electrode under wet conditions. (c) Exemplary course of unidirectional pressure change during the pullback of the 532 electrode under dry conditions. (d) Exemplary course of unidirectional pressure change during the pullback of the 532 electrode under wet conditions.

changes.[11,27] The newly designed 532 electrode has a 60% reduction in volume in comparison to the 512 electrode. With this smaller electrode array, decreased intracochlear pressure changes could be expected, in conjunction with only small pressure changes during pullback. In general, differences in intracochlear pressure changes due to pullback were marginal but statistically significant between the electrode arrays, with the 532 having more favorable results with decreased pressure changes as compared to the 512 under dry conditions. Similar to previous observations,[9,10] moistening of

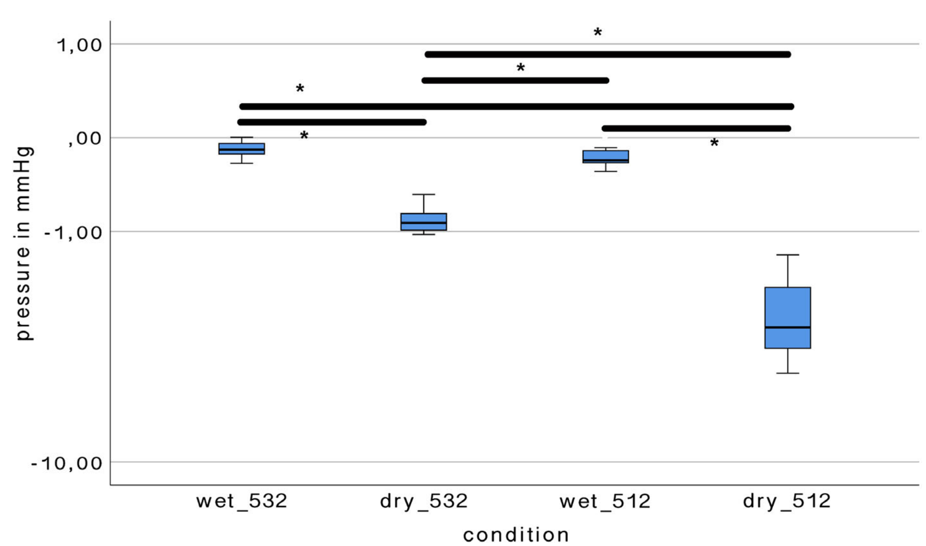

Fig. 2. Mean pressure values for electrode pullback under different conditions. The asterisk marks significant differences between the different conditions (*$P < .05$).

the electrode array significantly decreased the intracochlear pressure changes ($P < .005$). However, intracochlear pressure changes during pullback were not significantly different ($P > .05$) if an extra drop of water was placed on the electrode. This is in line with the observed reduction of intracochlear pressure due to opening of the round window membrane under wet conditions and subsequent insertion of the moisturized electrode array.[9,10] Indeed, earlier studies demonstrated that moisturized electrode insertion offers a reliable non-traumatic method for electrode array insertion during CI.[28,29] Negative pressure changes described here are known from previous studies.[12,15] The opening of the round window membrane with the carbon dioxide laser or any electrode movements after implantation can cause those negative pressure shifts.[12,15] The real impact of those pressure changes, however, on the preservation of residual hearing remains a matter of discussion.

Besides intracochlear pressure changes, the extent of the pullback has to be watched carefully. Based on the recommendations by Todt et al,[30] the pullback should be between 1.37 and 1.5 mm. In this study, all electrode arrays were inserted completely, until the third marker was completely inside the round window. After the subsequent pullback, the midmarker was at the level of the round window, which measured as a pullback of roughly 1.33 mm. A complete extrusion of the electrode was not observed in any of our experiments.

Our results show that electrode pullback in CI surgery leads to minimal intracochlear pressure variation. Lubrication of the electrode before the pullback seems to reduce frictional forces and surface tension, which leads to reduced intracochlear pressure changes.[29] For surgeons, main goals during this surgery are to minimize intracochlear trauma and achieve an optimal intracochlear electrode position. In comparison to intracochlear pressure changes during electrode insertion,[31] the pullback under wet condition is clearly associated with less pressure changes. The total influence of intracochlear pressure changes on intracochlear trauma remains unclear. Since the level of pressure change is less clearly understood and clinical significance of pressure changes remains unknown, it can be only be presumed that fewer intracochlear pressure changes lead to less intracochlear trauma. With the small voluminous electrode array, the pullback had only a minimal influence on intracochlear pressure. In regards to the probability of intracochlear trauma related to pressure change, general changes in fluid pressure must be separated from fast sound-related pressure. The current literature related to this topic is limited and does not offer clear answers.[32,33]

The effect of pullback of perimodiolar electrodes is primarily electrophysiological. A focusing of the spread of excitation[8,34,35] and an increase in frequency discrimination was demonstrated after pullback in completely deaf patients.[36] To date, clinical results in pullback studies have not demonstrated any performance benefit for patients. Therefore, clearly more clinical studies with increased numbers of patients are needed.

Although the risk of intracochlear trauma increases with postinsertional movements of the electrode,[12] our results indicate that the pullback bears minor risk for intracochlear trauma due to minor intracochlear pressure changes. However, the direct influence of the pullback on subsequent electrophysiological benefits and preservation of residual hearing in these patients remains unknown and needs to be investigated in further studies.

The design of this study has some limitations regarding its similarity to the human cochlea. Intracochlear hydrostatic pressure changes in vivo and in temporal bones are influenced by natural drainage systems. In our model, fluid sealed in the apical portion can only evacuate through the round window. In contrast, the human cochlea and the vestibule are a functional unit. Fluid pressure transfer between the different labyrinthine compartments is widely described[13,37,38] and should be considered when assessing these systems in vivo.[39]

Since actual human intracochlear pressure data are currently not available, transference of our measured model values into an in vivo setting is problematic. Knowledge from cadaveric studies emphasizes the transferability into the human temporal bone.[40,41] Nevertheless, the observed pressure differences after pullback underline the importance of every specific substep of electrode implantation, as well as the impact that the type of electrode array and the moistening condition have on intracochlear pressure. Further understanding of the pattern and principles of fluid pressure changes related to manual or mechanical handling in terms CI is essential for the establishment of reproducible, atraumatic CI.

CONCLUSION

We here provided for the first time an analysis of intracochlear pressure changes due to electrode pullback. More experiments are needed to transfer these results to the actual human cochlear temporal bone. The differences found in this study underline the importance of every specific substep of electrode implantation.

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