Can fresh frozen heads be used to perform hydraulic pressure measurements during cochlear implant electrode insertion?

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ABSTRACT

Objective: Intracochlear hydraulic pressure change that occurs during cochlear implant surgery is thought to play a role in hearing preservation. Presence of intracochlear air might be a problem when performing pressure measurements in temporal bones. In this study, we aimed to examine if air could enter the cochlea due to decomposition through the opening of the labyrinth and through electrode insertion. Furthermore, the effect of a large amount of insufflated intracochlear air on peak hydraulic pressure during electrode insertion was also examined in fresh frozen heads (FFHs).

Methods: Three human FFHs were used. An electrode was inserted three consecutive times, while the peak hydraulic pressure was measured. Air was then insufflated, and a second series of electrode insertions was performed. Computed tomography scans were performed on each FFH before each experiment and after insufflation of air. Volume in mm$^3$ and location of air were reported.

Results: All FFHs had air, especially in the subarachnoid and intravascular space. One FFH had air in both cochleae (3–5 mm$^3$). All FFHs showed air near the stapes footplate (1–3 mm$^3$) after opening of the labyrinth. Air was present in the vestibule and scala vestibuli (1–23 mm$^3$) of all FFHs after the electrode insertions and removal of the pressure sensor. The mean peak hydraulic pressure during electrode insertion decreased with insufflation of air (from 0.68 mmHg (standard deviation [SD] 0.34) to 0.24 mmHg (SD 0.14)).

Conclusion: Future studies on FFH or temporal bones should consider intracochlear air when performing hydraulic pressure measurements.

Keywords: Cochlea, cochlear implants, fresh frozen head, hydraulic pressure, sensorineural hearing loss

Introduction

Cochlear implantation (CI) was first developed for patients with profound deafness. It has been shown to be a cost-effective intervention for patients with severe to profound sensorineural hearing loss (1). Because of continuous advances in CI technology and the subsequent improved outcomes in patients, the implantation criteria have expanded. Nowadays more patients with residual hearing in the low frequencies are being implanted. It is important to preserve the residual hearing in these patients. Therefore, hearing preservation during CI surgery is an important goal.

One of the factors that is thought to play a role in hearing preservation is the intracochlear hydraulic pressure change that occurs during CI surgery (2). Electrode insertion, among others, is one parameter that influences hydraulic pressure in an artificial cochlear model (3). Greene et al. (2) demonstrated that the intracochlear pressure changes during CI electrode insertion showed intensities that were predicted to be similar to those evoked by high-level sounds. These pressure changes may have the potential to cause hair cell loss and, therefore, have the potential to cause residual hearing loss during CI surgery (2). It seems to be important to have minimal intracochlear pressure change during CI surgery, which is why it is important to observe the hydraulic pressure during CI electrode insertion.

A problem related to current studies on hydraulic pressure during CI electrode insertion is that the majority of studies use artificial models of the cochlea (3-5). The problem with using...
an artificial model is that the volume of the artificial model is slightly above the physiological range of a human cochlea (6). Few studies exist that use temporal bones instead of an artificial model (2, 7). A good reason for using temporal bones instead of an artificial model of the cochlea is the correct physiology of the human cochlea. However, a problem that arises when using temporal bones is the possibility of intracochlear air, which could bias the results of intracochlear fluid pressure measurements (7). Air could theoretically enter the cochlea through opening of the round window and electrode insertion or it could be present due to decomposition (8). We found only one article on the effect of air in the cochlea on sound pressure measurements (7). It was found that intracochlear air bubbles could diminish the vestibule pressure (7). However, although studies on intracochlear pressure measurements during CI surgery exist, no studies that looked at the effects of possible intracochlear air on intracochlear pressure measurements during a CI electrode insertion have been found.

Therefore, in this study, we first aimed to show how air can enter the cochlea, and second, whether large air infiltration in the cochlea has an influence on intracochlear peak hydraulic pressure during a CI electrode insertion. Four hypotheses were tested:

- Intracochlear air can be generated through decomposition.
- Air can be introduced through the opening of the labyrinth.
- Air can be introduced through an electrode insertion.
- The mean hydraulic pressure will decrease when a large amount of insufflated air is present in the cochlea.

Methods

The medical ethics committee of the University Hospital Ghent, Belgium, approved this study (project number EC UZG 2017/1297).

Fresh frozen head preparation

Three human fresh frozen heads (FFHs) were used in this study. Postmortem time was not known. The FFHs were from anonymous donors who signed informed consent to donate their bodies to medical science after their death. All heads were vacuum sealed and stored in a freezer at approximately −20°C. Before each experiment, an FFH was defrosted over night. A post-auricular skin incision was performed, and the musculoperiostal flap was prepared. Subsequently, a cortical mastoidecomy and a posterior tympanotomy were performed to gain access to the stapes region. An experimental repeated measures study was conducted in three FFHs. Each experiment consisted of a series of consecutive measurements in one FFH on one day. First, the FFH was defrosted, and a classical mastoidecomy and posterior tympanotomy was performed to gain access to the stapes region and the round window. The FFH was then moved to the radiology department for measurements and CT scans. The first CT scan was performed to check for air in the cochlea. If air was present in the cochlea, the volume in mm³ and location were reported. After the first CT scan was performed, the fiberoptic pressure sensor was placed through a hole in the stapes footplate, and the lead was fixed with adhesive tape to the skull so as to prevent movement of the sensor. The round window membrane was then opened.

The electrode that was used for the experiments was the Cochlear™ Nucleus® slim straight electrode (Cochlear Ltd., Sydney, Australia). An electrode was manually inserted three consecutive times with the same speed (10 seconds) through a slit in the round window membrane. During each insertion, the peak hydraulic pressure was measured. After the three insertions, a second CT scan was performed, and the presence, volume, and location of air was reported. Then, 5 mL of air was manually insufflated into the cochlea through the round window. After filling the cochlea with air, a third CT scan was performed, and volume and location of air were reported to check whether air was correctly insufflated. Another three insertions were then performed while measuring the peak hydraulic pressure. A fourth and last CT scan was performed, and the volume and location of possible air was reported.

**Computed tomography scans**

A dual-source 128-slice CT scanner (Somatom Definition Flash, Siemens, Germany) was used for the experiments. A total of four CT scans were performed on each FFH. An experienced head and neck radiologist, blinded to the specific actions of the experiment, reported the presence and location of air bubbles and measured their volumes semi-automatically using image processing software (Olea Sphere 3.0, France).

**Hydraulic pressure measurement**

The hydraulic pressure was measured using a fiberoptic pressure sensor FOP-MA-NS-1094A and a FPI-HS_1-F2-SCAI-V signal conditioner with an EVO-SD-2 chassis (Fiso, Canada). The software acquisition rate was 1250 Hz, and the low pass filter was 5 Hz. The pressure sensor and the way it works has been previously described by Todt et al. The outcome measure was mean peak hydraulic pressure in mmHg. Although we could not compare our results with the literature, this outcome measure was chosen as it was the same as the outcome measure in studies on hydraulic pressure in an artificial model of the cochlea.

**Experiments**

An experimental repeated measures study was conducted in three FFHs. Each experiment consisted of a series of consecutive measurements in one FFH on one day. First, the FFH was defrosted, and a classical mastoidecomy and posterior tympanotomy was performed to gain access to the stapes region and the round window. The FFH was then moved to the radiology department for measurements and CT scans. The first CT scan was performed to check for air in the cochlea. If air was present in the cochlea, the volume in mm³ and location were reported. After the first CT scan was performed, the fiberoptic pressure sensor was placed through a hole in the stapes footplate, and the lead was fixed with adhesive tape to the skull so as to prevent movement of the sensor. The round window membrane was then opened.

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**Main Points:**

- It is inconclusive whether intracochlear air can be generated through decomposition.
- Air can be introduced through the opening of the labyrinth.
- Air might be introduced through an electrode insertion.
- Insufflated intracochlear air might decrease peak hydraulic pressure when performing intracochlear hydraulic pressure measurements in fresh frozen heads.
**Statistical analysis**

Evolution software version 2.1.8.0 (FISO Technologies Inc., Canada, 2016) and The Statistical Package for Social Sciences version 23.0 software (IBM Corp.; Armonk, NY, USA) were used to record and analyze the data (9). Owing to the small sample size, only descriptive statistics and graphs are presented.

**Results**

**Hypothesis 1: Intracochlear air through decomposition**
The contralateral cochleae (FFHc) of the three FFHs were evaluated for intracochlear air through decomposition before sensor placement. In FFH1c and FFH3c, no intracochlear air was found. However, in FFH2c, air was found in the scala tympani of the basal turn of the cochlea and a minimal air bubble in the scala vestibuli of the basal and middle turn of the cochlea (5 mm$^3$). Furthermore, air was found in the vestibule, in the crus commune of the superior and posterior semicircular canal, and a minimal air bubble was found cranially in the posterior and lateral semicircular canals (13 mm$^3$). However, it should be mentioned that a temporal bone fracture was also found, which did not seem to reach the labyrinth. In the ipsilateral side of FFH2, air was found in the scala tympani of the second half of the basal turn of the cochlea and two small air bubbles were found in the middle cochlear turn (total of 3 mm$^3$) (Figure 1). The first CT scans showed air present in all FFHs, especially in the intravascular and subarachnoid space.

**Hypothesis 2: Intracochlear air through opening of the labyrinth**
All three FFHs had CT scans after surgical preparation, in which the round window membrane was still intact, but an opening through the stapes footplate was created. In all FFHs, small air bubbles with a volume of 1 mm$^3$, 1 mm$^3$, and 3 mm$^3$ were found in the scala vestibuli, the vestibule, and anteriorly in the lateral and superior semicircular canal, respectively (Figure 2).

**Hypothesis 3: Intracochlear air through electrode insertion**
After three consecutive electrode insertions, a large air bubble of 23 mm$^3$ was present in the vestibule of FFH1, whereas only a small air bubble of 1 mm$^3$ was present in the scala vestibuli before the electrode insertions. FFH2 and FFH3 both showed a minimal increase of 1 mm$^3$ of air in the vestibule and in the lateral semicircular canal (Figure 3). This location of air suggests that it is more likely that the removal of the pressure sensor might, but not necessarily, have introduced extra air instead of the electrode insertions.

FFH2 that showed air in the second half of the basal turn of the cochlea and in the middle cochlear turn pre-insertion, showed approximately the same amount of air post insertion (2 mm$^3$ versus 3 mm$^3$ pre-insertions).

**Hypothesis 4: Peak hydraulic pressure change after insufflation of air**
After insufflating 5 mL of air manually, the volume and location of air were reported to check whether air was correctly insufflated. FFH1 had 36 mm$^3$ of air, FFH2 had 43 mm$^3$ of air, and FFH3 had 58 mm$^3$ of air. The location of air was in the vestibule and cochlea.

The intracochlear hydraulic pressure curve before and after air insufflation is shown in Figure 4. As the results of both FFHs showed a decline in peak hydraulic pressure, we pooled the data to calculate a mean peak hydraulic pressure. During the
Figure 3. Left: Vestibule without air before electrode/pressure sensor insertions. Right: Increase of air in the vestibule after electrode/pressure sensor insertions

Figure 4. The intracochlear hydraulic pressure curve before (above) and after (below) air insufflation
second series of three electrode insertions in FFH2, a resistance was felt during insertion. Therefore, we could not use that data for the evaluation of peak hydraulic pressure change during an electrode insertion. The mean peak hydraulic pressure during electrode insertion before the insufflation of air was 0.68 mmHg (n=6, standard deviation [SD]: 0.34 mmHg). The mean peak hydraulic pressure during electrode insertion after the insufflation of air was 0.24 mmHg (n=4, SD: 0.14 mmHg) (Figure 5).

Discussion

Intracochlear hydraulic pressure changes during electrode insertion might cause hair cell loss and are, therefore, thought to play a role in the preservation of residual hearing (2). Studies measuring hydraulic pressure in temporal bones might face the problem of intracochlear air, which could influence the results of intracochlear fluid pressure measurements (7). However, no studies that looked at the effects of possible intracochlear air on intracochlear pressure measurements during a CI electrode insertion have been found.

In this study, we aimed to show whether large air infiltration has an influence on intracochlear peak hydraulic pressure during a CI electrode insertion and to show how air could enter the cochlea. This is the first experiment that we know of that looked at different ways air could enter the cochlea and the influence insufflated air had on the intracochlear peak hydraulic pressure during an electrode insertion in an FFH.

Inconclusive whether intracochlear air can be generated through decomposition

Postmortem air because of decomposition has been reported before (8, 10, 11). Decomposition produces gas that begins in the intravascular space and proceeds to distend to all anatomical spaces in a symmetrical distribution (10, 11). The location of air in one FFH, namely in the scala tympani of the basal turn of the cochlea and in the middle cochlear turn, could suggest air through decomposition because the air was not located near the opening in the stapes footplate. Furthermore, the air was present symmetrically. However, a temporal bone fracture was found in the contralateral ear. Although the fracture did not seem to reach the labyrinth, air insertion through this pathway cannot be ruled out. All the first CT scans showed air present in all FFHs, especially in the subarachnoid and intravascular space. This means that air through decomposition was present in all FFHs, but not in all the cochleae. Moreover, it was found that FFHs exist without intracochlear air through decomposition.

It has been reported that freezing and thawing of a human temporal bone could result in some fluid leakage out of the inner ear, which then is replaced by air (12). However, this might be different in an FFH where the natural pathways of pressure equilibration are still present and intact, such as the cochlear aqueduct and the vestibular aqueduct, which terminates with the endolymphatic sac. In this study fresh frozen heads were used. The advantages of using fresh frozen material is their realistic appearance and their flexibility once thawed (13). Furthermore, studies on different human tissues showed that fresh frozen material has no effect on the biomechanical properties of the material even when they are frozen and stored for long periods (14, 15). Moreover, studies have also shown that one-time freezing of human tissue does not harm the integrity of the tissue, whereas repeated freezing and thawing leads to a diminished integrity (13). The FFHs in this study were not thawed before.

Air might be introduced through the opening of the labyrinth, through repeated electrode insertion and by removing the pressure sensor

All three FFHs showed air in the scala vestibuli, vestibule, and/or the semicircular canals after surgical preparation. This suggests that air might be introduced by opening the labyrinth through the stapes footplate. It was found that repeated electrode insertion may introduce air. However, in this study, a large amount of air was found in only one FFH, whereas only negligible air was found in the other two FFHs. Negligible air could be introduced when removing the pressure sensor. The literature reports that air infiltration into the cochlea could be prevented by opening the labyrinth or inserting pressure sensors under water (16, 17). Another method to prevent air infiltration is to cover the gaps between the pressure sensors and the bone with dental cement (17). Greene et al. (2) placed the pressure sensors by thinning the cochlear promontory and using a fine pick under a droplet of water instead of drilling a cochleostomy, to prevent air infiltration. However, they did not show whether this method was effective.

Influence of intracochlear air on peak hydraulic pressure

The results of the experiments in two FFHs showed a decreasing peak hydraulic pressure with a large amount of insufflated intracochlear air. This corresponds with the literature (7). To the best of our knowledge, no study has considered this phenomenon when inserting CI electrodes. When intracochlear air is not considered during intracochlear hydraulic pressure measurements, the results cannot be generalized. If the presence and amount of intracochlear air is known, then it could be considered during the analysis of the results, which would provide more generalized conclusions. However, in this study, we did not investigate whether the amount of air through decomposition, opening of the labyrinth, electrode insertion, or removal of the pressure sensor had a significant effect on the intracochlear hydraulic pressure.
Hydraulic pressure measurements in fresh frozen heads

B-ENT 2021; 17(2): 75-80

Our study had some limitations. Experiments were conducted in three FFHs, which made it difficult to draw general conclusions based on our results. Because of logistic reasons, we were obliged to drill a hole in the footplate before the first CT scan was taken. Only the contralateral cochleae could be used for evaluation of air through decomposition.

We have a couple of recommendations when performing intracochlear hydraulic pressure measurements in temporal bones or FFHs:

- Perform a CT scan before and during hydraulic pressure experiments to evaluate the intracochlear air.
- Take measures to prevent intracochlear air infiltration during hydraulic pressure experiments, such as:
  - Using an intact FFH without fractures
  - Placing pressure sensors by thinning the cochlear promontory and using a fine pick under a droplet of water
  - Covering the gaps between the pressure sensors and the bone with dental cement or something similar.

In conclusion, when performing hydraulic pressure measurements in temporal bones, one should be aware of the fact that there is a possibility of intracochlear air that can possibly influence the results of the measurement. Air through decomposition might be possible; however, FFHs do exist without intracochlear air through decomposition. We found that air could be introduced through opening of the labyrinth, repeated insertions of an electrode array, and when removing the pressure sensor. We also showed that insufflated intracochlear air might have an influence on the peak hydraulic pressure measurements. The peak hydraulic pressure decreases with an increase in insufflated intracochlear air. Whether the air introduced through decomposition, opening of the labyrinth, insertion of an electrode, and/or removal of a pressure sensor has a significant effect on the intracochlear hydraulic pressure should be investigated in future studies. Studies using FFHs or temporal bones should make allowances for intracochlear air when performing hydraulic pressure measurements. Our advice is to perform a CT scan of the temporal bone before and during hydraulic pressure experiments to evaluate the intracochlear air and to take measures to prevent air infiltration during the experiments.

**Conflict of Interest:** The authors have no conflict of interest to declare.

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