Anatomical study of the human middle ear for the design of implantable hearing aids

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Abstract

Objective: To generate anatomical data on the human middle ear and adjacent structures to serve as a base for the development and optimization of new implantable hearing aid transducers. Implantable middle ear hearing aid transducers, i.e. the equivalent to the loudspeaker in conventional hearing aids, should ideally fit into the majority of adult middle ears and should utilize the limited space optimally to achieve sufficiently high maximal output levels. For several designs, more anatomical data are needed.

Methods: Twenty temporal bones of 10 formalin-fixed adult human heads were scanned by a computed tomography system (CT) using a slide thickness of 0.63 mm. Twelve landmarks were defined and 24 different distances were calculated for each temporal bone.

Results: A statistical description of 24 distances in the adult human middle ear which may limit or influence the design of middle ear transducers is presented. Significant inter-individual differences but no significant differences for gender, side, age or degree of pneumatization of the mastoid were found. Distances, which were not analyzed for the first time in this study, were found to be in good agreement with the results of earlier studies.

Conclusion: A data set describing the adult human middle ear anatomy quantitatively from the point of view of designers of new implantable hearing aid transducers has been generated. In principle, the method employed in this study using standard CT scans could also be used preoperatively to rule out exclusion criteria.

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1. Introduction

Extensive work on the anatomy of the human ear has been published [1–3]. Furthermore, the dimensions of the ossicles or parts of these, such as the superstructure of the stapes, have been studied in detail [4,5].

Nevertheless, data on the dimensions of the free space in the middle ear, especially quantitative data on distances which are not important in conventional middle ear surgery, are rare. The knowledge of such data is important when designing middle ear transducers for totally or partially implantable hearing aids.

Middle ear transducers, i.e. the equivalent of the loudspeaker of conventional hearing aids, are the most important part of implantable hearing aids [6]. Middle ear transducers are designed to be placed either partially or completely in the middle ear cavity and should ideally be implantable in any adult patient’s ear. However, this is not always the case. Maassen et al. [7] reported that for one specific design (TICA [8]), implantation was not possible in 11 out of 50 human temporal bones due to anatomical constraints. They proposed an X-ray and computed tomography (CT)-based method where the distance between...

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the sinus sigmoideus and the posterior wall of the external auditory canal was measured in order to evaluate implantability preoperatively. Similarly, Esselmann et al. [9] and Dammann et al. [10] proposed CT-based surgical planning and test fitting procedures for two different implantable hearing aids (TICA [8] and MET [6]) using 3D reconstruction. However, overall time for a single reconstruction amounted to 4–6 h [9] or 50 min [10], respectively. These studies indicate that a criterion for testing implantability preoperatively for implantable middle ear transducers is in demand. More importantly, they emphasize the importance of the availability of reliable anatomical data during the design phase of any new implantable hearing aid transducer.

The primary focus of this study was to determine a set of lengths and ranges of the most important distances in middle human ears, which influence the design of implantable middle ear transducers. In addition, the method for these measurements was chosen in a way that allows its application in vivo, so that it can be used to verify implantability before surgery in the future.

2. Materials and methods

Twenty temporal bones of 10 formalin-fixed human heads (4 females and 6 males) with an average age of 77.4 years (range, 69–88 years) were provided by our University’s Department of Anatomy. In this study, the bones were obtained from donors with no known otological problems. The heads were scanned axially with a multidetector row (8) CT (Light Speed Ultra, GE Medical Systems, Milwaukee, WI, USA). The following standard parameters for clinical temporal bone examination were applied: kilovoltage setting of 120 kV; tube current, 160 mA; collimation, 4 mm × 1.25 mm; table feed, 5 mm per rotation; rotation time, 600 ms. Secondly, the slice thickness and the increment from slice to slice were reduced to 0.625 mm. Each voxel measured 0.2 mm × 0.2 mm × 0.625 mm. Two volumes of 10 cm × 10 cm × 5 cm centered around the stapes of each ear were analyzed.

In order to reduce the actual complexity of the anatomy of the middle ear, we defined 12 landmarks, numbered 1–12, which are relevant for the design of middle ear transducers (Fig. 1).

The coordinates of each landmark were measured using the ImageJ Software, Version 1.30 (National Institutes of Health, USA, freeware). Nine of these landmarks were directly and unequivocally identifiable in the CT images (Fig. 2). Three landmarks, i.e. 4, 7 and 9 required each a selection out of multiple points (e.g. 4a and 4b) in such a way that a given distance (2–7 or 4–9, respectively) was minimized (Fig. 2).

Theoretically, 66 distances can be determined between any given 12 landmarks. We confined ourselves to a subset of 24 important distances, marked with capital letters A through X (Table 1), which may reasonably be expected to have an impact on the development of implantable middle ear transducers [11]. All distances were calculated automatically using Mathcat Software (Mathsoft Inc., Cambridge, MA, USA). Statistical analysis was performed with R: a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria) and SPSS (Version 13.0.1, Chicago, IL, USA). As normal distributions could not be assumed, unpaired Wilcoxon rank sum tests were used to find 95% confidence intervals of the median for differences between males and females. Paired Wilcoxon rank sum tests were used to analyze left-to-right differences. A scale with four degrees of pneumatization (DP1–4) [7] has been used to classify each temporal bone. DP1 denotes a mastoid with exclusively small cells, DP2 a mastoid with predominantly small cells, DP3 a mastoid with predominantly large cells and DP4 a mastoid with exclusively large cells [7]. Series of Jonckheere–Terpstra tests (SPSS, two-tailed Monte Carlo significance) were performed to quantify the dependency of each anatomical distance considered in this study with the degree of pneumatization. Ninety-five percent confidence intervals of the linear regression coefficients of the distances versus the age of the subjects were calculated. No Bonferroni correction was used for these statistical analyzes, as discussed below.

3. Results

All CT scans were reviewed by an experienced neuroradiologist and an experienced ENT surgeon and were found
to be of flawless quality and showed no abnormal anatomies of the temporal bone. Table 1 shows mean values, medians and 95% confidence intervals of the medians for all examined distances A–X.

Fig. 3 shows a graphical representation of the data, giving quartiles, minima and maxima for each of the distances. For most distances, the difference between the 1st and the 3rd quartile is in the order of magnitude of 1 mm, with most absolute lengths lying between 2 and 8 mm. However, for several distances (e.g. D, Q, V and X), the extreme values are considerably (more than a factor of 2) farther apart than the distance between the 1st and 3rd quartile.

For several contactless electromagnetic transducer designs employing a moving permanent magnet (e.g. [11,12]), probably the most important distances are B, E, F and G. Distance B, the minimal distance between the tip of

![Fig. 2. Typical subset of slices out of a right ear CT scan used for identification of landmarks 1–12. Slices are arranged in increasing order (inferior to superior) starting in the top left image. Landmarks 4, 7 and 9 required a selection of multiple points (i.e. a and b) to find the minimal distance between 2 and 7 or between 4 and 9.](image)

![Fig. 3. Distribution of all 24 distances A through X. Boxplots denote quartiles as well as minimal and maximal values.](image)

![Fig. 4. Median values and 95% confidence intervals. Top: Differences between male and female subjects. Bottom: Individual left-to-right differences.](image)
the manubrium mallei and the promontory, is considerably smaller than E, the distance between the promontory and the tip of the long process of the incus. This holds true for all quartiles. The smallest measured value was 1.3 mm for B and 2.7 mm for E. Likewise, distance F, i.e. the distance between the tip of manubrium mallei and the tip of long process of the incus is considerably smaller than G, the distance between the tip of the long process of the incus and the posterior border of the middle ear cavity for all quartiles. Minimal measured values were 2.0 mm for F and 3.7 mm for G.

Fig. 4 (top) shows the differences between males and females for each of the 24 distances; Fig. 4 (bottom) shows a similar representation for left-to-right differences. In both figures, a value of 0 mm denotes identical lengths across gender or side, respectively. The tick inside each bar indicates the difference of the median distances; the length of the bar corresponds to the 95% confidence interval of the differences.

In Fig. 4 (top), all 95% confidence intervals include the value 0 mm, showing no significant differences between genders. All medians are in the range of −0.4 to 0.5 mm and the length of the confidence intervals are in the range of 0.3–1.7 mm.

In Fig. 4 (bottom), two confidence intervals, H and S, exclude 0 mm. The differences are 0.7 mm for H and 0.9 mm for S. The lengths of the confidence intervals are in the range of 0.2–2.3 mm.

The degree of pneumatization (DP), as described by Maassen et al. [7], was determined for all temporal bones. One temporal bone was classified as DP1, seven temporal bones as DP2, nine temporal bones as DP3 and three temporal bones as DP4. Two-tailed Jonckheere–Terpstra test showed a significant (p < 0.05) trend only for the distance I and no significant trends for the other 23 distances. The single significant trend found was negative, i.e. distances I tend to decrease with increasing DPs (Fig. 5).

Regression correlation coefficients for each of the 24 distances A through X versus age was calculated and yielded values between −0.06 and +0.08. The 95% confidence interval for the largest correlation coefficient was −0.02 to 0.15, suggesting no relevant age dependency for the range of ages included in this investigation.

4. Discussion

The main purpose of this study was to describe the anatomy of the human middle ear quantitatively in such a way that it can serve as a sound basis for the development of novel middle ear transducers for implantable hearing aids.

The most restraining distances for several types of contactless electromagnetic transducer designs employing a moving permanent magnet (e.g. [11,12]) are the minimal distance between the tip of the manubrium mallei and the promontory B, between the promontory and the tip of the long process of the incus E, between the tip of the manubrium mallei and the tip of long process of the incus F, and between the tip of the long process of the incus and the posterior border of the middle ear cavity G. These distances...
directly limit the maximal volume of such transducers and therefore influence the maximal acoustic output.

As $B$ was smaller than $E$ through all quartiles, $B$, that is, the distance between the tip of the manubrium mallei and the promontory, limits the maximal height of this type of transducer. Our data suggest that this dimension should not exceed 1.3 mm if the transducer uses the entire space transducer. Our data suggest that this dimension should not exceed 1.3 mm if the transducer uses the entire space.

On the other hand, $F$, i.e. the distance between the tip of the manubrium mallei and the tip of the long process of the incus, is considerably smaller than $G$, the distance between the tip of the long process of the incus and the posterior border of the middle ear cavity. Therefore, $F$ rather than $G$ is the limiting distance for the design of a permanent magnet attached to the incus [11]. The minimum was found to be just below 2 mm, which led to a magnet radius of 1.7 mm for the design described in ref. [11].

However, these relations show only the application of the measured data to one specific type of transducer. Most of the other 22 distances are potentially useful for the design of other concepts of implantable hearing aids. Furthermore, our statistical analysis showed that the distances in middle ear are basically independent of gender, side, degree of pneumatization or age within the range considered. Our data suggest that there is a statistically significant left-to-right difference for the distances $H$ and $S$ (Fig. 4). However, when calculating 48 different 95% confidence intervals (cf. Fig. 4), statistically approximately two of them (5% of 48) can be expected to fall out of the interval, even if there is no statistically significant difference. Additionally, our data suggest decreasing distance $I$ for increasing degree of pneumatization. Again, such a result can be expected if tests with 24 variables are performed and no Bonferroni correction is made (Fig. 5).

Because formalin-fixed human temporal bones have been used in this study, CT images with a relatively high resolution could be obtained without any exposure to living human subjects. However, formalin shrinks some soft tissue considerably, e.g. by approximately 8% for the human brain compared to living tissue [13]. We could not find data on the influence of formalin on the distances of the middle ear. However, a limited comparison of our results with the results of in vivo measurements by Luntz et al. [14] is possible. The distance between the tip of the short process of the incus and the tympanic segment of the facial canal $W$ covers the range of 2.5–4.8 mm (average, 3.8 mm) in our study and is very similar to their data (range, 2.0–4.8 mm; average, 3.3 mm).

Our results found by CT are reasonably consistent with those found in quantitative anatomical studies using extraction of individual ossicles. The total height $A$ of the incus in our study (range, 5.2–7.1 mm; average, 6.3 mm) is similar to the findings by Olszewsky et al. [5] (average, 7.21 ± 0.19 mm standard deviation) and that found by Kikuchi [15] (range, 5.4–7.0 mm; average, 6.5 mm).

Sorensen et al. [16] presented a method to generate temporal bone data with a much better resolution (voxel size, 50 µm). However, such a high accuracy does not seem to be justified for the development of middle ear transducers and could not be reproduced in vivo to assess implantability preoperatively. As the ossicles in the middle ear move due to the static pressure in the order of 1 mm [17], the accuracy of our data of 0.68 mm, which corresponds to the length of the diagonal of one voxel, seems sufficient and reasonable. It should be noted that this accuracy has been obtained using standard CT-equipment and a standard CT-protocol, which could be directly adapted to a simple preoperative evaluation of patients. In contrast to computer-aided surgical planning tools, where still a manual segmentation is necessary [9,10], this method requires only the determination of a small number of points in the CT scans.

5. Conclusions

A data set describing the adult human middle ear anatomy quantitatively from the point of view of designers of new implantable hearing aid transducers has been generated. In principle, the method employed in this study using standard CT scans could also be used preoperatively to rule out exclusion criteria.

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