Geometrical analysis of temporal bones for bone conduction implants (BCI)

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Abstract: The study aims at assessing the feasibility of implanting a novel, transcutaneous, bone conduction implant (BCI) in the temporal bone of subjects with conductive or mixed hearing loss. A number of axial, high-resolution, computed-tomography (CT) images were acquired and categorized with reference to age, gender, and history of infection. Classification was implemented to avoid any undesirable impacts on the statistical analysis due to the diversity of human temporal bones. A reference plane was defined, decisive landmarks were designated, and critical distances and areas were measured at specified depths with respect to the reference plane. Virtual implantation of the BCI was performed in the mastoid bone based on statistically-attained data. Validation of the study was examined through 3D virtual implantation. It was found that, on average, the bottom surface of the transducer can be attached at a depth of 6 mm in the top portion of the mastoid bone and at a depth of 8 mm in the bottom portion in adult men, whereas the corresponding depths for women were 4 mm (top) and 6 mm (bottom), respectively. The results for children showed that, on average, the transducer can be implanted at a depth of 8 mm in the top site and at a depth of 6 mm depth in the bottom site. It was concluded that the method used to determine the size of temporal bone as a pre-operative investigation for BCI implantation was simple, effective, and provided results that were reproducible. The bottom site had more space, so it could be used in most patients with the present dimensions of the transducer. If the dimensions of the transducer were decreased, the top site also could be considered in most patients. The study should be performed on more subjects to attain more conclusive results by reducing ambiguities.
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1. Introduction

Hearing is one of the five senses, and it occurs when sound waves are perceived by the ear. Normal hearing consists of two parts, i.e., air conduction (AC) and bone conduction (BC). When sound waves propagate, they pass through the ear canals and the middle ear to reach the cochleae. This part of hearing is called AC. The sound waves can also be induced as vibrations in the skull bone, and these vibrations can be transmitted into the cochleae through different paths. This part of hearing is called BC. In short, it means that vibrations in the skull, teeth, and skin are transmitted through the skull bone to the cochlea, where the basilar membrane is located. Integrated in the basilar membrane is the organ of Corti. Here, sound vibrations are received and transmitted to the brain via the auditory nerve (1). Hearing losses are classified as conductive or sensorineural. There is also a case in which a mixture of these two types of hearing losses occurs, and this is called ‘mixed hearing loss.’

The conventional percutaneous, bone-anchored hearing aid (BAHA) is an important rehabilitative alternative for patients who have conductive or mixed hearing loss (2). Even though such percutaneous implants have a reasonably low rate of medical complications, some problems with them have been reported (3). Since the implants are percutaneous, meaning that they are permanently perforating the skin, a great deal of daily care and hygienic attention are required. Development of infections or thye formation of granulated tissue in some patients might necessitate surgical revision or re-implantation. Some patients have been known to refuse the BAHA for personal or esthetic reasons.

A novel bone conduction implant (BCI) system is being developed at Chalmers University of Technology as an alternative to BAHA, and this system is being designed to mitigate the adverse skin effects of BAHA, while offering comparable or even superior performance. In the BCI, the transducer will be implanted permanently into the temporal bone of the subject. The sound signal will be transferred through an induction loop system and, hence, the skin is left intact, preventing the adverse skin effects that BAHA patients have experienced. For pre-operative assessment of fit and mountability of such a transducer and to serve as the basis of its further development and optimization, detailed knowledge of the available space and pathways to access the middle ear and the inner ear is necessary.

The anatomy of the temporal bone has been studied extensively to facilitate surgical procedures (4). Axial, high-resolution CT with high-quality, multi-planar reformatting generally is accepted as the imaging standard to investigate the geometry of the temporal bone (5-7). Numerous studies have demonstrated that such CT imaging is of great value as the basis for computer-aided construction and surgical planning for implant surgeries (8-17). Our preliminary observation of the CT images indicated that there was a great deal of variation in the shape, dimensions, and appearance of the temporal bones of different subjects. The nature and extent of these variations have become the most significant challenges that must be overcome to ensure the viability of this surgical approach. Since we were studying groups of subjects and planned to conduct a statistical analysis of our observations, we had to verify that this diversity would not affect the analysis. The landmarks to be selected must be objective in order to perform consistent measurements. Objectivity of the landmarks ensures that the measurements will be reproducible, even when they are conducted by other researchers. This approach allowed us to plan and manage an unbiased, objective statistical analysis. The aim of this study was to investigate the geometry of human temporal bones and to assess the feasibility of implantation of the BCI in the temporal bone.

2. Material and Methods

Eighteen subjects were included in the study. We obtained images from four children (ranging from 4 to 13 years old) and from 14 adult males and females (ranging from 24 to 74 years old). Among them, there was one subject who had aural atresia and who had been treated as a case study for this condition. A set of supported CT images were studied to determine the important, anatomical landmarks. The subjects were grouped based on differences in age, gender, and history of middle ear disease with their right ears. The suggested method and measurements had to be technically simple, fast, and easy to learn so surgeons could use the method without too much difficulty. The main software that was utilized in this research was SurgiCase CMF (Materialise N.V., Leuven, Belgium). Statistical analyses were performed on the members of each group, and conclusions were derived. These conclusions allowed us to predict the geometrical shape of an average temporal bone and to determine where the transducer would fit best in the temporal bone. A pre-operative procedure for such an implantation was developed. Also, the number of subjects who are candidates for the current transducer design was determined, and the potential dimensions of a future transducer design to fit all studied subjects were estimated. Virtual fitting of the transducer was performed on the reconstructed, 3D mastoid cavities of two of the candidates to verify the results.

2.1. Landmarks

In the device itself, the height of the transducer was eight millimeters, so that was the maximum depth the transducer was expected to penetrate into the mastoid bone. Hence, the determination of the “penetration-depths” from a lateral perspective (Sagital plane) was the first step. A more recent transducer design indicated that the transducer may be developed to be considerably smaller, and, hence, it was concluded that it was reasonable to conduct measurements for sagital planes at depths of 4, 6, and 8 mm. If fewer penetration-depths were to be used, we might risk losing useful information due to the larger space left between the planes. If more frequent planes were decided, then the measurements will be more labor-intensive. Therefore, it was deemed an acceptable compromise to measure at every two millimeters of penetration. In addition, the first four millimeters were omitted since the mastoid retains an arched outer surface.

Since human temporal bones vary considerably among subjects (18), it was crucial to choose landmarks that were distinct and easily detectable in every subject. Laterally, the outermost (rightmost) point on the border of the right lateral semicircular canal (LSCC) was selected as the entry point. We set a reference point that was located on the outer surface of the right temporal bone, and it only disagrees with the entry point in the X coordinate (the X coordinate determines how deeply we have penetrated the bone laterally). A virtual sagital plane (YZ-plane) passing through this reference point was our reference plane. The penetration depths are sagital planes that are parallel to the reference plane at distances 4, 6, and 8 mm.

2.2. Measurements

2.2.1. Areas of interest

To indicate the areas of interest in any of the specified planes, the largest circle that could be drawn within the boundaries of the bone was decided, while some extent of bone thickness must be preserved as safety margins as follows:

- 1 mm for the inferior border of the mastoid process
- 3 mm for the anterior border of the mastoid process (posterior wall of the external auditory meatus)
- 1 mm for the inferior border of the dura
- 1 mm for the sigmoid sinus border

Normally the curve of the sigmoid sinus and its short distance from the posterior wall of the external acoustic canal results in a bottleneck (19). As a result, there were two possible sites for the placement of the transducer, i.e., a top circle or a bottom circle. The diameter and the relative position of the center of the circle would reveal how large the transducer can be and the location of the best site for the implantation at the specified plane.

2.2.2. Compact bone thickness

At the reference point on the outer surface of the mastoid, the bone is compact. As we penetrate into the bone, mastoid air cells emerge, a phenomenon known as mastoid pneumatization. It was interesting to know whether the bone was thick enough to house the transducer by itself and hence not intervene with the air cells.

2.3. Method validation

To assess intra-operator repeatability and inter-operator reproducibility, a cross measurement was undertaken. Four subjects were chosen randomly and crossed measured by two operators. Based on the outcome of these examinations, the degree of agreement and coherence between the two series of results was determined and described as mean absolute percentage error (MAPE).

3. Results

The results showed that the men, on average, had thicker compact bone than women. The averages were 2.2 mm and 1.6 mm for men and women, respectively. Children had even thicker compact bone than men, with an average of4.3 mm. The reason was probably due to the fact that the air cell system of the mastoid bone in children was not yet developed to the extent that it was in adults. In addition, the shape of the temporal bone was not as developed in children as it was in adults, e.g., the sigmoid sinus was not as distinct. Therefore, circular sites that were drawn in some children occasionally became one larger, single circle, as opposed to two separate top and bottom circles in adults. This was not an issue when determining whether the transducer would fit, but it explained the inconsistencies in the results from children and women/men.

The bottom site was larger than the top site in both genders, making it the preferred location for the transducer. The results showed that, for men, the transducer could fit into the 6-mm depth at the top site and in the 8-mm depth at the bottom site. Women could receive the transducer into the 4-mm depth at the top site and into the 6-mm depth at the bottom site. The results for the children proved that, on average, the transducer will fit into the 8-mm and 6-mm depths at the top and bottom sites, respectively.
From a surgical perspective, it is safer to use the bottom site to avoid sensitive structures. However, the top site is more adjacent to the inner ear, and, thus, most probably would provide a stronger vibration transmission (20). If the transducer had a diameter of 10 mm, the device would fit all the subjects in both top and bottom sites. It is important to mention that the method was considered to be the worst-case scenario in that it assumed that it would be impossible to place the device tilted at an angle. When surgeons perform the implantation procedure, there might be some capability to fit the transducer at higher success rates, simply by having the transducer rotated at some arbitrary angle.

The case study performed on a subject suffering from unilateral aural atresia, who was a very likely candidate for the BCI system, demonstrated that the method was absolutely feasible. Since the internal ear structures, including LSCC, were present, all the procedures were fully applicable to this subject. The absence of an external ear canal places no restrictions and sets no conditions on our protocol. It even removes the restrictions caused by the preservation of some bone thickness as a safety margin for the external auditory canal.

The reproducibility of the measurements was high according to the cross measurements which demonstrated that a measured distance of 10 mm would result in an uncertainty of ± 0.4 mm. Based on this relatively high accuracy, we assumed that the measurements could be performed sufficiently accurately, irrespective of the operator. The effects of errors caused by a tilted head during the CT scan were investigated, and, on average, the error in distance between the measured point and the anatomically correct point was1.5 mm. This implies that unintentional head movements during the scan runtime caused no significant errors in the measurements.

4. Discussions

The method developed and used in this study is applicable on any temporal bone where the lateral semicircular canal and the surface of the outer bone remain intact. The method is meant to be used in the further development of the BCI hearing device as well as in the pre-operative assessment of patients in healthcare centers. The method is simple, relatively fast, and easily performed by medical practitioners on ordinary computers and workstations. The virtual implantation on two random subjects resulted in the successful fit of the transducers as the measurements had predicted and, thus, proved the method to be valid. For more detailed research, we suggest that the study be performed in conjunction with some software that incorporates CAD/CAM capabilities, which would result in more advanced evaluation. However, performing surface representation with a relatively huge number of triangles and maintaining high frame rates would require costly, hardware-intensive workstations.

The classification of the subjects who participated in this study leaves questions to be answered. The age difference between the children seemed to be more influential than similar differences between adults. As a result, measurements from the children may be inconclusive. The classification of subjects was also planned to be based on a history of middle ear disease, but the subjects who had such a history were few, and they were not included in the study. If the number of subjects with a history of infection were large enough, it would be interesting to perform the study to verify the method on affected subjects.

Casselman et al. conducted a case study on a BAHA candidate to evaluate the amount of bone available for a successful implantation (17). They found the temporomandibular joint and the external auditory meatus to be important anatomical landmarks for pre-surgical assessments. Stieger et al. designated several landmarks and measured numerous distances to generate extensive quantitative, anatomical data (21). Contrary to us, they did not aim to evaluate the mountability of a specific transducer pre-operatively, but rather to serve as the basis for the development of future transducers. In an earlier study, they had found the maximal diameter of the transducer to be approximately 7 mm, if a cylindrical design were assumed for the transducer (22). The size is relatively large compared with our findings. Maassen et al. proposed to measure the distance between the sigmoid sinus and the posterior wall of the external auditory meatus on X-ray and CT data for pre-operative assessment of the implantability of hearing aids (23). They found broad inter-subject variations in the linear measurements. Therefore, it was concluded that evaluation of available space in the temporal bone of individual candidates for implantation must be considered. A sensitivity of 89.7% for volumetric assessment of successful implantation of a specific device was reported. In a more recent study, trial fittings in a virtual-reality (VR) environment were found to notably outperform implant surgery in cadaver temporal bones and in patients (24). Dammann et al. performed a similar feasibility assessment in the VR environment, in which they utilized CAD software to generate triangulated surfaces and fed them into the VR software in stereolithographic data format to implant the hearing aid modules virtually (25). The manual selection of landmarks and segmentation was performed in 45 minutes, whereas the corresponding time in our study was merely 20 minutes. Similarly, Esselman et al. proposed a lengthy, spiral, CT-based, 3D reconstruction procedure that amounted to four to six hours for each volumetric dataset. They validated their method on a human cadaver (12). Handzel et al. described a CT-based, three-dimensional reconstruction of a virtual canal wall up mastoidectomy, which took 45 minutes per reconstruction (26). They found that linear measurements did not correlate with volumetric assessment, so a virtual implantation was deemed necessary to predict the success of implantation. Their conclusion was in agreement with ours in that the measurements based on the CT scans of temporal bones had the advantage of being suitable for evaluation of future candidates for device implantation, while measurements on cadavers and on patients who had undergone mastoidectomy do not. Alternatively, they aimed to provide useful data on the shape of the mastoid cavity and its dimensions for use in the development of future transducers, whereas we tried to assess the mountability of a transducer with known dimensions.

The method used in this study was simple, precise, and effective, enabling it to be used pre-operatively at hospitals. It suggested that SurgiCase is an appropriate package for performing a simple, pre-operative implant fit and mountability assessment on medium-performance computers and workstations. The results demonstrated that some distinct, anatomical landmarks could be selected objectively to determine if the transducer would fit in the mastoid bone of candidate subjects. It was shown that the method was accurate, reliable, and that the results were reproducible objectively. According to the results, the bottom site was preferable for implantation based on the present dimensions of the transducer. If the transducer had a diameter of 10 mm, the device would fit all the adult subjects in the study at both sites. It is suggested that the transducer should be circular in shape for a more successful fit. Future work should include more subjects to reduce the ambiguity of the results.

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