Feasibility of High-Resolution Computed Tomography Imaging for Obtaining Ear Impressions for Hearing Aid Fitting

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. This study investigated the feasibility of obtaining ear impressions for hearing aids by using 3-dimensional high-resolution computed tomography (HRCT) images.

Study Design. Case series.

Setting. One referral tertiary center.

Subjects and Methods. Hearing-impaired adults who were fitted with 1 or 2 behind-the-ear hearing aid(s) and had undergone temporal bone HRCT for various ear pathologies were enrolled in this study. Earmolds were fabricated from the impressions obtained using the conventional ear canal silicone injection technique and the HRCT reconstructed technique. Outer ear canal resonance frequencies and amplitude in open ears and those measured with silicon and HRCT reconstructed earmolds were determined through real-ear gain measurements, including real-ear unaided gain (REUG) and real-ear occluded gain (REOG), for comparison.

Results. A total of 50 HRCT reconstructed earmolds were compared with 50 conventional silicon injection earmolds. The average value of open ear canal resonance amplitude (REUG) for each ear was 0.41 to 16.76 dB. No statistically significant difference in resonance amplitude (REOG) was observed between silicon and reconstructed earmolds (paired t test, P > .05). The mean insertion loss (REOG-REUG) at all frequencies also did not differ significantly between the two earmolds (paired t test, P > .05).

Conclusion. According to our real-ear measurements, acoustic characteristics of the HRCT reconstructed earmolds were compatible with those of the silicone injection earmolds. Despite concerns about increased cost and radiation exposure, the HRCT reconstructed technique is a clinically useful and applicable method and can reduce potential safety complications for difficult cases.

Keywords

HRCT, reconstructed earmold, hearing aid, real-ear measurement

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The advent of imaging techniques, such as computed tomography (CT) and magnetic resonance imaging, since 1970s has engendered a considerable change in the visualization of the entire human body from a 2-dimensional (2D) view to a 3-dimensional (3D) view. Thus, researchers are motivated to further explore imaging modalities in areas of reverse engineering or 3D reconstruction of human anatomical structures. Although such applications in reconstruction implants of human orbital floor or wall fractures,1 cranial-facial defects,2 and bones and cartilages3 have been reported, few studies on 3D imaging reconstruction have obtained ear impressions for customized hearing aids.

The fitting of a custom hearing aid specifically requires either a custom earmold coupled with a behind-the-ear (BTE) style instrument or a custom ear shell that encases the amplifier circuitry in an in-the-ear style instrument and its more recessed versions, such as in-the-canal and completely-in-the-canal hearing aids. Such an earmold or ear shell is fabricated from an ear impression that mimics the surface of the outer ear and the ear canal in 3 dimensions. A high-quality ear impression facilitates the fabrication of a physically fitted
An ear mold or shell with improved target acoustics and comfort of wearing. Given the increasing demands of hearing aids to improve the quality of life of the growing elderly population, more comfortable and less complicated procedures of hearing aid fitting are developing.

Several techniques have been used for obtaining ear impressions. Most conventional methods entail obtaining a solid silicone impression by injecting silicone materials into the external auditory canal (EAC). However, this procedure has some disadvantages. First, patients may experience otalgia, aural fullness, and ear itching during the injection procedure. Second, earmold fitting for patients with a narrow and curved canal, congenital or acquired deformities of the EAC, a perforated tympanic membrane, or a canal wall-down defect following tympanomastoidectomy is challenging and laborious. Some studies have reported the middle ear or mastoid foreign body after ear impression taking with silicon, and some patients may develop serious complications, such as severe sensorineural hearing loss (SNHL) and vertigo, and may require further surgical intervention.

Under the aforementioned conditions, a temporal bone CT scan is a useful tool for exploring the external ear, middle ear, and mastoid pathology. Because CT is sensitive to soft tissues and bony structures, the shape and geometric structure of the entire EAC up to the tympanic membrane are easily defined. To evaluate and avoid the complications of silicone injection procedures in patients with ear-related diseases, high-resolution computed tomography (HRCT) imaging techniques are warranted. Recently, digital technology and rapid prototyping (RP) provide a novel approach for designing customized shells or earmolds for hearing aids by using 3D reconstructions of CT. In this study, we investigated the acoustic characteristics of HRCT reconstructed earmolds in comparison with those of silicon injection earmolds. To assess the feasibility of the HRCT reconstructed earmolds, we performed real-ear measurements (REMs) on each patient to obtain open ear canal resonance amplitude: real-ear unaided gain (REUG) and real-ear occluded gain (REOG) with the earmolds fabricated using the conventional ear canal silicone injection technique and the proposed HRCT reconstructed technique.

**Materials and Methods**

**Patients**

Hearing-impaired adults who had undergone temporal bone HRCT for various auditory pathologies and who were fitted with a BTE hearing aid were recruited in this study. Ethical approval for the experiment was obtained from the Institutional Review Board of Chang Gung Memorial Hospital. Informed consent was also obtained from all patients prior to conducting the study.

**HRCT Reconstructed Ear Impressions**

Obtaining hearing aid ear impressions using HRCT involves the following 5 stages: (1) data acquisition and image segmentation of the external ear scanned through HRCT, (2) 3D image processing using Avizo software (Mercury Computer Systems, Chelmsford, Massachusetts), (3) noninvasive ear impression reconstruction through HRCT, (4) 3D RP, and (5) earmold or hearing aid shell fabrication. Details of the complete procedure are given as follows.

**Data acquisition and image segmentation of the external ear.** HRCT of the temporal bone was conducted using a 16-slice CT scanner (Somatom Sensation 16; Siemens, Erlangen, Germany). Using the CT scanner, 2D images of 100 EACs were obtained (Figure 1). Scanning was performed using simultaneous acquisition of 16 sections with a collimated slice thickness of 0.7 mm. Axial projection were obtained by serial 0.7-mm-thin sections of the temporal bone with the line joining the infraorbital rim and external auditory meatus perpendicular to the table. The helical pitch was 0.562, the rotation time was 1 second, the tube voltage was 140 kV at 200 mA, and the matrix size was 512 × 512 pixels. Images were reconstructed using the kernel H20 smoothing algorithm at overlapping intervals (0.3 mm) to improve the through-plane spatial resolution, and the reconstructed field of view (9.6 cm) was placed separately for each ear to maximize the in-plane resolution. Then, all the images were transferred to an Avizo visualization system (Mercury Computer Systems) for 3D reconstruction.

**Three-dimensional image processing using Avizo software.** Avizo software was used for 3D image processing. The range and orientation of the EAC were established on the CT scans by first locating the external ear and temporal bone. The settings for the grayscale threshold in the data window were –1600 for the minimum, 1600 for the maximum, and 100 for the opacity to highlight the EAC boundary and the interface between the EAC and tympanic membrane.

**Noninvasive ear impression reconstruction through HRCT.** The areas covered by a BTE hearing aid—namely, the cavum concha and the first bend of the EAC—were encircled in the 2D HRCT scans to acquire a 2D outline for the ear impression. The 2D outline was then used to reconstruct a 3D ear impression (Figure 1).
Using computer-aided design (CAD) software (Avizo visualization system), these images were then easily converted to stereolithographic files. The ProJet HD3000 (3D Systems, Valencia, California) was subsequently used to build 3D ear impressions from various cross sections of the CAD model. The details about earmold fabrication using this laser technology were described in previous studies.\textsuperscript{12,13}

**Earmold or hearing aid shell fabrication.** In the silicone injection method, an ear impression was obtained by injecting silicone materials directly into the ear canal, whereas in the proposed method, 3D HRCT imaging was used for reconstructing the impression. After obtaining the ear impressions by both methods, the actual earmolds of hearing aids were fabricated with the same procedures and materials. Then we compared the real-ear acoustic performance of the 2 types of earmolds fabricated using the conventional invasive silicone injection method and the noninvasive 3D reconstructed method.

**REMs**

REMs were performed using Audioscan Verifit (Etymonic Design, Ontario, Canada) in an audiometric test booth. A loudspeaker was placed in front of each patient at a distance of 50 cm, which set the test ear at 45° azimuth. Prior to conducting any REM, an otoscopic examination was performed to clear the path for probe tube insertion. Then, the probe tube was inserted 30 mm past the intertragal notch. Based on the report by Zemplenyi et al,\textsuperscript{14} with an average ear canal length of 24 mm and the typical distance from the ear canal opening to the intertragal notch being 10 mm, an insertion depth of 30 mm past the tragus should result in the placement of the probe tip within 5 mm of the tympanic membrane.\textsuperscript{15,16} Then, the hearing aid mold is placed laterally to the probe tube in the canal.

REUG and REOG were measured using a 70-dB sound pressure level (SPL) swept-tone stimulus at a frequency range of 250 to 6000 Hz in accordance with the official definition by American National Standards Institute S3.46-1997 (R2007).\textsuperscript{15} Insertion loss was calculated as REOG – REUG. Statistical analysis was performed using Statistical Package for Social Science version 16 for Windows (SPSS, Inc, an IBM Company, Chicago, Illinois). We compared the data through paired sample \( t \) tests. The differences were considered significant at \( P < .05 \).

Using G power, the effect size and sample size of each frequency were calculated, with an \( \alpha \) level of \( P = .05 \) and a power of 0.80. The sample size at 1, 4, and 6 kHz appeared to be 339, 1298, and 4122, respectively. These implied that it would be more difficult to have significant results in these 3 frequencies, even by increasing the sample size. Therefore, only the other 4 frequencies were included for the estimation of the population size. The sample size at 0.25, 0.5, 2, and 3 kHz appeared to be 18, 22, 41, and 21, respectively. Finally, we chose 50 ears as the total number for this study. The effect size was calculated as moderate to high at 0.25, 0.5, 2, and 3 kHz.

**Results**

All the patients who had undergone temporal bone HRCT for clinical evaluations of the etiology of hearing loss and who were fitted with 1 or 2 BTE hearing aid(s) later were included. A total of 40 hearing-impaired adults (23 women and 17 men) were enrolled in this study. Their ages ranged from 22 to 75 years, with the median age being 58 years. Diagnoses of all the patients included sudden SNHL, conductive hearing loss, otosclerosis, asymmetric hearing loss, chronic otitis media (COM), revised COM, and bilateral SNHL. In total, 10 patients were fitted with bilateral-sided, 17 right-sided, and 13 left-sided hearing aids; 50 corresponding HRCT reconstructed earmolds were compared with 50 conventional silicone injection earmolds.

Two ear impressions of the same patient obtained using the HRCT reconstruction method and the silicone injection method are depicted in Figure 2. The cavum, cymba, and first bend of the EAC could be easily identified in both molds. As observed in our previous study in 2012,\textsuperscript{11} the HRCT impression molds were slightly smaller than the silicone impression molds, but their volumes were strongly linearly correlated with the volumes of the silicone impression molds. In this study, we verified the acoustic properties of the HRCT reconstructed earmolds and compared them with those of the conventional silicone injection earmolds.
The mean REUG measured at each frequency is illustrated in Figure 3A. The mean REUG revealed a peak at 3 kHz, representing the maximum value of 16.76 dB at 3 kHz.

REOG values and insertion loss measured for both the reconstructed and silicon injection molds coincide at each frequency (Figure 3B,C). The lowest mean REOG values for the 2 molds were 11.47 and 12.4 dB at 3 kHz. Differences in the mean REOG values for the 2 molds were less than 1 dB from 250 to 6 kHz (Figure 3B). No significant differences in REOG values were observed between the 2 molds (paired t test; P > .05). The insertion loss (REUG – REOG) of both earmolds and P value at each frequency are shown in Table 1. Maximum insertion losses for the 2 molds were 27.81 and 29.16 dB at 3 kHz, respectively. No significant differences in insertion loss were observed between the 2 molds at 250 to 6 kHz.

During hearing aid impression fitting through the traditional injection method, some complaints were acquired at the time of the fitting through open questions in a questionnaire, including otalgia in 3 patients (3/40), ear itchiness in 5 patients, fullness sensation in 18 patients, cough in 10 patients, anxiety in 8 patients, and 1 residue of foreign body (cotton) in the ear canal. No serious and irreversible complications, such as drum perforation and worsening of hearing, were observed.

**Discussion**

In our previous study, we had designed and created an ear impression using 3D HRCT image reconstruction and RP technology. In this study, we further verified the acoustic performance of the HRCT reconstructed earmolds through REMs and compared the acoustic characteristics of the earmolds generated using the traditional silicon injection impression technique with those of the earmolds generated using the HRCT reconstructed impression technique. The insertion losses of reconstructed ear impressions were similar to those of the ear impressions obtained using the conventional method. This verified the applicability of the proposed HRCT reconstructed earmolds. Thus, these reconstructed earmolds can serve as a clinical alternative to those generated using the conventional silicon injection procedure and can reduce potential complications in obtaining ear impressions for difficult cases.

Given individual anatomical variation in the EACs observed through REMs, the REUG values for each subject measured in our study (Figure 3A) were compared with those published by Dillon in 2001. The mean REUGs of our study and Dillon’s results were similar. Insertion loss was calculated by subtracting REUG from REOG at each frequency, thereby factoring out patient-specific resonance differences in each ear canal. The maximum insertion loss was observed at 3 kHz, −24.45 to −31.17 dB (mean ± 2 SD), which was very similar to the result of the −30 dB gain reported in a previous study. Furthermore, REOG and insertion loss at each frequency for both types of earmolds did not differ significantly (P > .05). This result indicates that the HRCT reconstructed earmold had a similar acoustic effect as the conventional silicon earmold and could be considered an alternative for hearing aid fitting.

**Table 1. Mean Difference of Insertion Loss (REOG – REUG), in Decibels, of both Earmolds as a Function of Frequency.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency, kHz</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>0.25</td>
</tr>
<tr>
<td>Reconstruction mold</td>
<td>−6.26 ± 1.43</td>
</tr>
<tr>
<td>Silicon injection mold</td>
<td>−5.14 ± 1.13</td>
</tr>
<tr>
<td>P value</td>
<td>.37</td>
</tr>
</tbody>
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Abbreviations: REOG, real-ear occluded gain; REUG, real-ear unaided gain.

*Values are expressed as mean ± standard deviation. There were no significant differences at each frequency (P > .05).*

Figure 3. (A) Mean real-ear unaided gain, (B) mean real-ear occluded gain, and (C) mean insertion loss, in decibels, as a function of frequency for all patients. Data are presented as mean ± standard error.
If patients have underlying ear diseases or hearing impairment, they may be subjected to temporal bone CT for evaluating the severity of the disease beforehand. When they need a hearing aid, a previous HRCT film can be downloaded and EAC images can be used for ear impression reconstruction without unnecessary exposure to radiation. The patients would then be able to use their individualized reconstructed EAC ear impressions for fabricating custom hearing aids, if required. Furthermore, technologies and techniques to reduce CT radiation doses have been developed in recent years. In this study, we use the 16-slice CT protocols. The radiation dose is often expressed as an equivalent dose in millisieverts (mSv). The radiation dose of a chest X-ray and a temporal bone CT is around 0.1 and 1 mSv, respectively. However, a low-dose 64-slice CT protocol is available, and the radiation dose is lower than that of the 16-slice CT protocol.\textsuperscript{18}

Obtaining ear impressions is a challenge under some conditions, such as a small curved ear canal, eardrum perforation, a defect following tympanomastoidectomy, and a congenital or an acquired ear deformity.\textsuperscript{6-8} Complications have been reported with the use of the conventional silicone injection method for obtaining ear impressions, particularly in such cases.\textsuperscript{5} Therefore, the HRCT reconstructed technique is useful and appreciable in these difficult cases. Besides, the advantage of the HRCT reconstructed earmold is that creating impressions of the auditory canal, which is a laborious and unpleasant procedure for patients, is not necessary.

Despite the feasibility of the proposed 3D HRCT imaging technique, some disadvantages still exist. For example, the procedure and equipment costs are higher than those for the conventional silicone injection technique. The cost for temporal bone CT is around 160 USD in Taiwan. In this study, all patients underwent a CT scan for clinical purposes. No financial burden was incurred on them. In addition, the costs of the equipment for image processing and the 3D printer are higher. The cost of an injection earmold is around 40 USD. Therefore, the actual total cost of a reconstructed HRCT earmold is higher than that of injection method. The time required for temporal bone CT and 3D processing is around 30 minutes, while obtaining an ear impression of a silicon injection needs only 10 minutes. Therefore, the proposed technique is also more time-consuming than the traditional silicon injection method. The imaging procedure may also increase the risk of exposure to radiation.

There were some limitations in this study. First, we did not assess patient comfort, quality of life, or speech perception scores with either mold. Second, all the patients in this study had “normal ear canals.” They had no congenital ear anomaly and did not receive canalplasty or canal wall-down surgeries that would lead them to have more tortuous or abnormal ear canals compared to the “normal” population. Third, the sample size of this study was limited and not enough at 1, 4, and 6 kHz to meet the moderate to high effect size according to G power statistics. Furthermore, 3D ultrasonography has no ionizing radiation exposure and is less invasive, which may provide an opportunity for imaging reconstruction in the future.\textsuperscript{19-21}

**Conclusion**

Compared with the traditional silicone injection technique, the precision of the HRCT reconstructed technique was compatible according to our REMs and verified its clinical application. It can reduce potential complications in congenital or acquired ear diseases compared with the conventional silicon injection method. Despite concerns about increased radiation exposure and cost, the HRCT reconstructed ear impression technique is a clinically useful and applicable method for hearing aid fitting.

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**Author Contributions**

Chin-Kuo Chen, designed the study, analyzed the data, wrote the draft, and revised the article; Li-Chun Hsieh, interpreted the data, wrote the draft, and revised the article; Yuan-Chuan Chiang, designed the study, analyzed the data, provided techniques and consultation, and drafted the work; Wei-De Cheng, collected data and wrote the article.

**Disclosures**

Competing interests: None.

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