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AN ARTIFICIAL EAR TO ASSESS OBJECTIVE INDICATORS RELATED TO THE ACOUSTICAL COMFORT DIMENSION OF EARPLUGS: COMPARISON WITH ATTENUATION AND OCCUSION EFFECT MEASURED ON SUBJECT

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Hearing protection devices (HPD) are widely used to prevent noise-induced hearing loss (NIHL). In a noisy environment, wearing a correctly fitted HPD during all the time exposure is the sine qua non condition to prevent NIHL. However, this condition is often unfulfilled due to the discomforts induced by HPDs. Although this is a well-known fact, it remains challenging to quantify HPD comfort since it is a multidimensional concept related to subjective feelings of the users. Thus, it seems necessary to use objective indicators correlated to subjective attributes of HPD comfort to help manufacturers to design efficient protectors. Those indicators would also help an adequate HPD selection by users. For earplugs, the insertion loss (IL), attenuation and occlusion effect (OE) are good candidates to objectively describe attributes belonging to the acoustical dimension of comfort. However, most of the current ear simulators are not adapted to evaluate the physical variables related to these indicators since they do not consider important features of the external ear such as the earcanal geometry or the tissues surrounding it. As part of an ongoing project aiming at developing augmented artificial heads for measuring indicators of the acoustical comfort dimension induced by earplugs, this study presents an artificial ear to assess objective indicators related to attributes of the acoustical comfort dimension of earplugs. This testing device has a realistic geometry and includes synthetic tissues mimicking the real human ear's bone, cartilage and soft tissues. Its design and fabrication steps are presented. The ability of the device to assess objective indicators related to comfort attributes of earplugs is investigated by comparing attenuation and occlusion effect measurements performed on the artificial ear, a subject and an acoustic test fixture. Limits of the device such as its material properties, the absence of tympanic membrane and boundary conditions are discussed.

Keywords: earplug, comfort, artificial ear, attenuation, occlusion effect

1. Introduction

Noise-induced hearing loss is one of the major worldwide workplace-related health issues [1]. Currently, the most widespread solution to prevent occupational deafness is the use of hearing protection devices such as earplugs (EPs). However, EPs are not as efficient as expected on the field. Indeed, the discomfort caused by EPs prevents workers to wear them properly and during the full exposure time causing drastic reduction in protection. The design of comfortable EPs remains a challenge since no tool are available on the market which allows for taking the acoustical comfort into account right from the design phase. Main attributes of the acoustical comfort are sound attenuation, intelligibility and occlusion effect (OE) [2-5]. The intelligibility and the attenuation are related to the sound pressure in the earcanal of the open and occluded ear created by an acoustical excitation. The objective OE can be obtained from the difference of sound pressure levels in the earcanal of the occluded and open ear created by a mechanical excitation (e.g. vibrations induced by the voice or a bone-transducer). Methods such as microphone in real ear (MIRE) make it possible to measure these variables directly on subjects in laboratory [6] or in the field (F-MIRE), but they are invasive and very cumbersome to implement, and thus, unsuitable to be used as a design tool.

A common alternative is the use of acoustical test fixtures (ATFs) that allow for quick and repeatable measurements [6-8]. However, most ATFs on the market have been designed to test devices such as hearing aids or headphones and are not suitable for the development of EPs. Testing the attenuation of hearing protection devices is possible using ATF but involves strict specifications regarding their characteristics such as dimensions, degree of realism or self-insertion loss [7]. For example, artificial earcanal must be layered by artificial flesh mimicking the human soft tissues and be heated at a realistic temperature. Even with these specific characteristics, some features of ATFs are missing to properly evaluate all the acoustic comfort attributes of earplugs [6,9]. The most obvious one is the lack of realistic tissues surrounding the earcanal such as temporal bone and cartilage which are responsible for the propagation of mechanical vibrations when studying the occlusion effect. Another limitation of current ATFs is related to the depth an earplug can be inserted in the earcanal. Acoustic couplers used to simulate the impedance of the tympanic membrane and located at the end of the artificial earcanal include a protected section where no earplug can be inserted. Thus, even if the total length of the artificial earcanal is approximately 24 mm, the length dedicated to earplug insertion is only about 12 mm [10]. This inaccessible section of the acoustic coupler also leads to limitation regarding the realism of the earcanal since it is not covered by artificial flesh [10]. Moreover, the entrance of the earcanal is not directly connected with the artificial pinna of the ATF. These discontinuities in the artificial flesh layer make difficult the proper investigation of the sound and vibration transmission from the outer to the inner part of the occluded earcanal [6]. The earcanal geometry is also an important feature to take into account if one wants to proper investigate the intra- and inter-subject variability of attenuation [11-13]. Indeed, the facts that the earcanal does not follow a straight line and that its cross section is not constant along its center axis can affect both the fit quality and the radial compression of earplugs. Since these two characteristics are respectively responsible for acoustic leaks and earplug sound transmission properties, they also affect the attenuation of EPs [11,14]. However, most of the current ATFs include a straight earcanal with a fixed diameter even if commercial products recently started to embed a more realistic earcanal geometry (e.g. head and torso simulator type 5128-C from Brüel & Kjær (Nærum, Danemark)). Given these limitations, there is a need to develop more realistic ATFs that mimic properly the earcanal/EP system for both acoustical and mechanical excitations. For this purpose, an artificial ear with a complex geometry and including surrounding soft tissues, cartilage and bone has been developed [15]. However, the acoustic performances and realism of this artificial ear are not fully understood at the moment.

This paper aims to present and evaluate this artificial outer ear designed to assess objective indicators related to attributes of the acoustical comfort of earplugs. This device has a realistic geometry reconstructed from magnetic resonance images of a human subject (called the reference subject) and is made

of synthetic materials mimicking the real human ear bone, cartilage and soft tissues. Earplug attenuation and occlusion effect measurements are used to evaluate its ability to mimic the acoustical behaviour of a real human outer ear. For the attenuation, measurements are compared to results obtain on the reference subject and on an ATF. Various insertions of a roll-down foam and push-to-fit earplugs are tested to evaluate the ability of the artificial ear to capture the intra-subject variability. For the occlusion effect, measurements are performed only on the artificial ear and reference subject since ATFs are not designed for this kind of measurements. In this case, a single insertion depth is tested using an in-house earpiece. In addition, a numerical investigation of the acoustical behaviour of the artificial ear is also presented in a companion paper [16].

The paper is organized as follows. The human subject and artificial devices are presented. The design and fabrication steps of the artificial ear are detailed. Objective attenuation and occlusion effect measurement methodologies are described. Then, the attenuation measured on the artificial ear, the subject and the ATF are compared. The occlusion effect measurements are compared only for the artificial ear and the subject. Finally, the ability of each artificial device to catch acoustical features such as intrasubject variability and limits of the artificial ear such as the absence of a realistic tympanic membrane or its boundary conditions are discussed.

2. Materials and Methods

2.1 Reference subject and artificial devices

In order to investigate the ability of an in-house designed artificial outer ear to capture realistic earplug attenuation and occlusion effect, results obtained on this device are compared with those measured on the human subject used to design it and called the "reference subject" in this paper. These results are also confronted to measurements achieved on a GRAS (Holte, Denmark) 45CB ATF commonly used to assess earplugs sound attenuation. Since no artificial head is currently adapted to the occlusion effect investigation, the ATF is only used to study the attenuation.

2.1.1 Reference subject

The reference subject chosen as participant for the design of the artificial ear is a 28 years old volunteer and healthy male. He was selected in accordance with the criteria described in the ethic protocol 16.400/H20161101 approved respectively by the CHUM and ETS ethic comities.

2.1.2 Artificial ear

The artificial ear was designed with the specific objective to mimic the acoustical behaviour of a real human ear when occluded by an earplug. The outer ear of the reference subject was used as model for the artificial ear whose design and fabrication steps are described here.

Firstly, the reference subject left ear was imaged using an MRI system to obtain a realistic ear geometry. This step was performed with the collaboration of the CRMBM/CEMEREM from Marseille. An MR sequence was adapted to obtain a contrast and resolution good enough to observe the geometry of the earcanal but also the tissues surrounding it. Details about the MR system and sequence are given in [15]. Since MR system is a noisy environment, the subject was protected with silicone custom molded earplugs during the acquisition. Thus, the geometry of the open earcanal of the artificial ear corresponds to the shape of the reference subject occluded earcanal. It is noteworthy that the latter is certainly slightly different from the open earcanal shape of the subject [17]. An example of an axial view obtained with the MR sequence is shown in Figure 1(a).

Then, MR images were segmented according to the different tissues surrounding the earcanal of the subject. Figure 1(b) shows the different parts considered for the segmentation with (1) the silicone custom molded earplug, (2) the bony part surrounding the end of the earcanal, (3) the cartilage surrounding its entrance, (4) the soft tissues and (5) the air inside the earcanal. It is noteworthy that the soft tissue part

includes the skin, the fat, the muscles and all other tissues which are not bone or cartilage. This simplification was considered since it seemed difficult to discriminate every soft tissue. The masks obtained thanks to the segmentation were used to reconstruct a 3-dimensional (3D) numerical model of the ear of the subject shown in Figure 1(b). This 3D model was adapted to reduce the size of the artificial ear and to optimize its outer geometry for manipulations as shown in Figure 1(c).

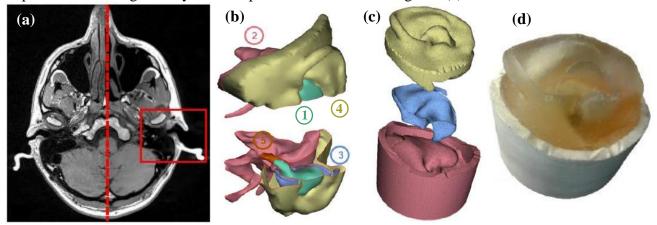


Figure 1: (a) MR image axial view of the reference subject's head. (b) Numerical reconstruction of the subject's ear and (c) numerical model of the artificial ear. Each part corresponds to a segmented region with (1) the earplug, (2) bony part, (3) cartilage, (4) soft tissues and (5) air. (d) Artificial ear.

Finally, the artificial ear was manufactured by True Phantom solutions (Windsor, Canada), a company specialized in anatomical phantom manufacturing. The 3D model of the artificial ear was used to print molds for the fabrication of the ear phantom presented in Figure 1(d). Materials used for the different parts of the artificial ear are an epoxy based ceramic material for the bony part, a polyurethane based material (65 shore A) for the cartilage and a polyurethane based material with a lower stiffness (35 shore 00) for the soft tissues.

2.1.3 Acoustic test fixture

The ATF used in this study is a GRAS 45CB Acoustic Test Fixture which has a realistic head and torso shape according to [7]. The part of its artificial earcanals dedicated to earplug insertion consist of a cylindrical tube covered by a 1.7 mm artificial flesh layer. Its length is about 12 mm and its diameter is equal to 7.5 mm. The ATF is also equipped with two artificial soft pinnae with realistic shapes.

2.2 Measurement methods

It is worth mentioning that measurements are performed using objective methods since attenuation and occlusion effect are assessed both on the reference subject and on artificial devices.

2.2.1 Attenuation

The attenuation was measured using the commercial E-A-Rfit^(TM) system from 3M (Mapplewood, USA) between 250 and 8000 Hz. 3M^(TM) E-A-R^(TM) Classic roll-down foam (referred to as "roll-down foam" in this paper) and 3M^(TM) E-A-R^(TM) Push-ins push-to-fit (referred to as "push-to-fit" in this paper) earplugs were used as occluding devices. For the reference subject, measurements were performed in a quiet room following the ethic protocol H20171101 approved by the ETS ethic committee. Measurements making use of the artificial ear and the ATF were performed in a hemi-anechoic chamber. It is noteworthy that at the moment, the artificial ear is not embedded in a whole head and is rather hung up using a low-stiffness spring. In each case, the E-A-Rfit^(TM) system was placed 50 cm in front of the subject or devices. For the roll-down foam earplug, three different insertion depths defined according to Berger [14] were investigated. They corresponded to: "partial (PI, about 15-20% of the plug in the

earcanal), standard (SI, about 50-60% of the plug in the canal), which is representative of a well-fitted plug [...], and deep (DI, about 80-100% in the canal), which was the maximum depth of insertion a subject could achieve before s/he experienced significant discomfort." Due to its complex shape (a spherical foam tip at the end of a plastic stem), the precise definition of three insertions for the push-to-fit earplug was more complex. The deep insertion was considered as the maximum depth the reference subject could achieve before experiencing a significant physical discomfort. Partial insertion was considered when the tip of the push-to-fit earplug was inserted just at the entrance of the earcanal of the reference subject. Standard insertion was considered as the half-way position between deep and partial insertions. For each insertion, the attenuation measurement was performed at least three times.

2.2.2 Occlusion effect

The occlusion effect was measured objectively during a laboratory measurement campaign using the sound pressure inside both non-occluded and occluded earcanal [18]. All measurements were performed in an audiometric chamber where the artificial ear was hung up using a low-stiffness spring. Two inhouse earpieces equipped with microphones were used to measure the sound pressure inside the earcanal [19]. The first one is a hollow earpiece which ensures a fixed positioning of the microphone inside the open earcanal. The second one is equipped with a Comply (St Paul, USA) Isolation T-400 ear tip to measure the pressure in the occluded earcanal at the same position as for the open earcanal. Due to the specific design of these earpieces, only one earplug and one insertion were tested. A mechanical excitation was applied on the mastoid of both subject and artificial ear using a bone oscillator B-81 from Radioear Corporation (New Eagle, USA). Since measurement of occlusion effect is known to be relevant up to 2 kHz and because of the limitation of the bone oscillator, only six frequencies were investigated: 250, 500, 750, 1000, 1500 and 2000 Hz. Measurements were repeated at least three times. Measurements performed on the reference subject were conducted following the ethic protocol H20180402 approved by the IRSST ethic committee.

3. Results and discussions

3.1 Attenuation

Figure 2 shows the attenuation measured on (a) the reference subject, (b) the artificial ear and (c) the ATF for (1) the roll-down foam and (2) the push-to-fit earplugs. The blue, green and red lines correspond respectively to the deep, standard and partial earplug insertions described in section 2.2.1.

The attenuation measured on the reference subject for the different insertions of earplugs represents the variability due to the various way an earplug can be inserted into an earcanal. This variability is one contribution (but not the only one) to the intra-subject attenuation variability. Figure 2(a.1) and 2(a.2) show that the intra-subject variability, given by the gap between the deep and partial insertion curves, is large at low frequency and decreases with frequency for both roll-down foam and push-to-fit earplugs. The attenuations presented in Figure 2(a.1) and obtained for the different insertions of the roll-down foam earplug are very similar to the results obtained in [14] for 10 subjects.

For the roll-down foam earplug, the trend of the attenuation measured on the artificial ear (see Figure 2(b.1)) is very close to the results obtained for the reference subject (see Figure 2(a.1)). Figure 2(c.1) indicates that the attenuation measured on the ATF is much larger than the attenuation measured on the reference subject. The variability due to insertions measured on the ATF is also much smaller than the intra-subject variability measured on the reference subject. This might be explained by the fact that (i) the self-insertion loss of the ATF is higher than the subject and artificial ear ones and (ii) the complex shape that a roll-down foam earplug has when inserted in an earcanal is an important factor when measuring the attenuation. The first point is related to the sound transmission through the tissues surrounding the earcanal which are partially taken into account in current ATFs through a single thin layer of artificial skin. This transmission is demonstrated to be important in the artificial ear when occluded [16]. The

second point is associated with the shape of the roll-down foam earplug once inserted in an earcanal of complex geometry. The fact that the earcanal of the ATF is a cylindrical tube avoids complex phenomena related to a realistic insertion such as non-uniform radial compression of the earplug or the creation of acoustic leaks. Thus, the geometry and the materials of the artificial ear play an important role in the attenuation measurements.

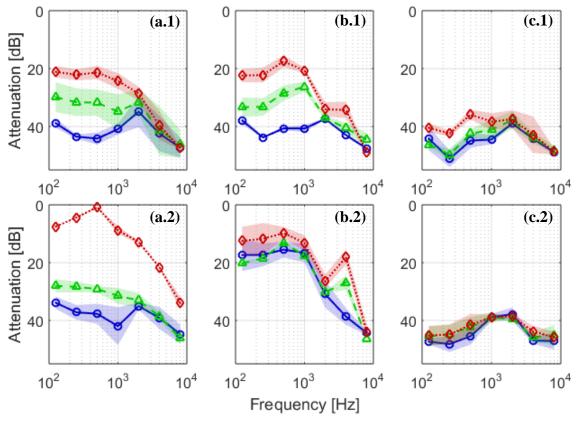


Figure 2: Average and standard deviation of the attenuation measured on (a) the reference subject, (b) the artificial ear and (c) the ATF for a (— o —) deep, (– A –) standard and (····· o ·····) partial insertion of (1) the roll-down foam and (2) push-to-fit earplugs.

For the push-to-fit earplug, the ATF still over-estimates the attenuation compared to the subject (see Figure 2(c.2)) and this might also be explained by the aforementioned points (i) and (ii). Figure 2(a.2) and 2(b.2) show that the artificial ear does not properly mimic the attenuation measured on the reference subject anymore. Except for the partial insertion and particularly up to 1 kHz, the measured attenuation is much lower for the artificial ear than for the reference subject. This might be explained by the fact that the artificial ear corresponds to the ear canal of the reference subject occluded by a custom molded earplug, not to the open ear. Thus, the ear canal of the artificial ear is slightly larger than the subject one [17] and the acoustic seal is weaker. It is also possible that the walls of the artificial earcanal were damaged due to the numerous measurements performed on it, thereby creating acoustic leaks. These two defaults are not an issue in the case of the roll-down foam earplug since it is longer and larger than the push-to-fit earplug and greatly expands in the ear canal creating an airtight acoustic joint with the earcanal walls. These assumptions must be investigated on a clean artificial ear based on images of the open earcanal of the reference subject.

3.2 Occlusion effect

Figure 3 presents the occlusion effect average and standard deviation measured on (green) the reference subject and (red) the artificial ear following the methodology described in section 2.2.2. Note that results are slightly shifted from the measured frequency to avoid superposition.

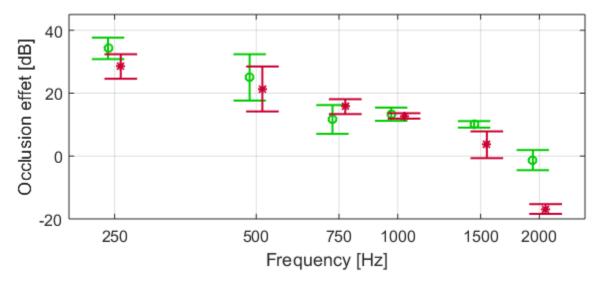


Figure 3: Average and standard deviation of the occlusion effect measured on (ϕ) the reference subject and (*) the artificial ear.

The variability measured on the reference subject and the artificial ear is related to the repeatability of measurements since only one insertion is possible with the in-house earpieces used for measurements. The occlusion effect measured on the artificial ear is close to the subject one except at 250 Hz and 2000 Hz where it is lower. For both the subject and the artificial ear, the intra-subject variability is unexpectedly large at 500 Hz.

4. Conclusion

This paper presented an outer artificial ear designed to assess objective indicators related to acoustical comfort of earplugs. After a description of the design and fabrication steps of this device, attenuation and occlusion effect measurements were performed. The obtained results have been compared with measurements performed on a reference subject in order to evaluate the ability of the artificial ear to mimic the acoustical behaviour of a real human ear. When possible, the results were also compared to measurements performed on an ATF and to results available from the literature.

The main result of this study is that the artificial ear is able to properly mimic some of the acoustical feature of a real human. Compared to the ATF, the artificial ear enables a proper measurement of the occlusion effect (which is not possible with the ATF) and gives a much more precise measurement of the attenuation due to roll-down foam earplug. The measurement of the attenuation due to a push-to-fit earplug remains hardly capturable by both the ATF and the current artificial ear. For the occlusion effect, a restricted size of tissues surrounding the earcanal (bone, cartilage and soft tissues) seems sufficient to properly measure this indicator. However, some differences were observed between the artificial ear and the reference subject. Further studies have to be conducted to improve the realism of the device and particularly regarding its tympanic impedance, its self-insertion loss and its temperature. The variability due to earplugs themselves must also be quantified and controlled. Nevertheless, the proposed artificial ear is already a first step toward ATF enhancement and is a promising tool to help manufacturers to improve earplug comfort.

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