



Towards a practical methodology for assessment of the objective occlusion effect induced by earplugs^{a)}

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ABSTRACT:

The occlusion effect (OE) occurs when the earcanal becomes occluded by an in-ear device, sometimes leading to discomforts experienced by the users due to the augmented perception of physiological noises, or to a distorted perception of one's own voice. The OE can be assessed objectively by measuring the amplification of the low-frequency sound pressure level (SPL) in the earcanal using in-ear microphones. However, as revealed by methodological discrepancies found in past studies, the measurement of this objective occlusion effect (OE_{obj}) is not standardized. With the goal of proposing a robust yet simple methodology adapted for field assessment, three experimental aspects are investigated: (i) stimulation source and the stimulus's characteristics to induce the phenomenon, (ii) measurement method of the SPL in earcanal, (iii) indicator to quantify the OE_{obj}. To do so, OE_{obj} is measured on human participants in laboratory conditions. Results obtained with a specific insert device suggest using the participant's own voice combined with simultaneous measurements of the SPLs based on the noise reduction method and using a single value indicator leads to a simple yet robust methodology to assess OEobj. Further research is necessary to validate the results with other devices and to generalize the methodology for field assessment. © 2022 Acoustical Society of America. https://doi.org/10.1121/10.0011696

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I. INTRODUCTION

The obstruction of the earcanal's entrance by an in-ear device (such as earplugs, hearing aids, or earbuds) results in a change in the auditory self-perception of the body's physiological noises. This phenomenon is commonly referred to as the occlusion effect (OE). This change is described as an augmented perception of bodily sounds such as mastication, heartbeats, and footsteps (Courtois et al., 1988; Hansen, 1997; Killion et al., 1988), and as a distorted perception of one's own voice, sound "hollow," "boomy," or "talking like in a barrel" (Berger, 2003; Courtois et al., 1988; Dillon, 2012). This can lead to dislike of one's own voice (Berger, 1986; Kiessling et al., 2005; Kuk et al., 2005; Suter, 2002) or even cause an inhibition to speak (Eriksson-Mangold and Erlandsson, 1984). For example, the experienced acoustical discomfort related to the OE strongly participates to the feeling of overall (dis)comfort induced by earplugs situations (Terroir et al., 2021) and thus should be reduced to avoid the in-ear device non-use or misuse, which can be critical for the wearers (Doutres et al., 2019, 2020). Historically, a baseline method to assess the OE has been done through bone conduction (BC) audiometry by measuring hearing thresholds with and without an occlusion device (Berger and Kerivan, 1983; Goldstein and Hayes, 1965; Huizing, 1960; Reinfeldt et al., 2013; Stenfelt and Reinfeldt, 2007). This leads to a subjective measure of the OE (referred to as OE_{subj}), described as improved lowfrequency hearing thresholds below 2 kHz (Berger and Kerivan, 1983; Reinfeldt et al., 2013). Although the assessment of OE_{subj} involves all BC pathways (through outer, middle, and inner ear), it does not necessarily correlate to the experienced discomforts associated with the OE (referred to as OE_{exp}), which are mostly assessed through questionnaires and interviews (Hansen, 1997; Kiessling et al., 2005; Kuk et al., 2005; Mueller, 2003; Terroir et al., 2021; Vasil-Dilaj and Cienkowski, 2011). An alternative method consists in measuring the sound pressure level (SPL) inside the earcanal with and without an in-ear device, which eliminates the need for a subjective response from a test subject. This leads to the assessment of an objective indicator of the OE (referred to as OEobj), typically described as the increased low-frequency SPL inside the occluded earcanal below 2 kHz (Berger and Kerivan, 1983; Hansen, 1998). From an engineering perspective, tools based on the assessment of OEobj combined with a known and understood correlation between OEobj and OEexp should be developed so that the latter can be estimated or anticipated. Indeed, such tools could be used by manufacturers to design and develop in-ear devices that generate less OE_{exp} and by occupational hygienists and audiologists to help the

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in-ear device users choosing the most adequate device and its fit that minimize the OE_{exp}. However, in the authors' opinion, the development of these tools is still facing two important issues. First, the methodology employed to conduct SPL measurements for the OE_{obj} assessment differs from one study to another and methodological choices are not always justified, highlighting the lack of consensus and standardization (see more details in Sec. II). There is thus a need for a robust yet simple methodology to assess this objective indicator. Second, few correlations between OE_{obi} and OE_{exp} have been found and the results are somehow limited. These correlations were mostly found with hearing aids and speech, but with limited speech content (i.e., short sentences or sustained phonemes) (Dillon, 2012; Kiessling et al., 2005; Kuk et al., 2005; Vasil-Dilaj and Cienkowski, 2011). Yet, none of or very few correlations were found with other types of in-ear devices (e.g., earplugs) or with other types of user-generated noises, such as mastication, footsteps, or physiological noise, albeit they are associated with OE_{exp} as abovementioned. Consequently, clinical and field trials are still necessary to further investigate the correlation between OE_{obj} and OE_{exp} .

This paper focuses on the first of the two aforementioned issues. The aim is to compare different existing approaches to measure OEobj and to propose a simple, yet robust (i.e., practical) methodology to assess the OEobi induced by earplugs, and which could be ultimately for field assessment. The different experimental aspects found in the literature (stimulation sources, measurement methods, SVIs) are first presented in Sec. II. Then, they are investigated and compared one against another in the rest of the paper. Measurements are conducted in a controlled environment, i.e., laboratory conditions, to gather data with human participants. This study focuses on a single type of occlusion device thus the data collected is for earplugs only. These data are then analyzed to identify the experimental aspects that provide a simple, precise, and reliable measurement of OE_{obi}. The rest of the paper is organized as follows. The methodology and material are presented in Sec. III. Then, results are shown and discussed in Sec. IV. In addition, the limitations encountered in the study are also summarized.

II. LITERATURE REVIEW OF THE MEASUREMENT OF THE OBJECTIVE OE

In order to propose a methodology to obtain OE_{obj} , three experimental aspects must be analyzed: (i) the stimulation sources to induce the OE and their characteristics; (ii) the measurement methods used to obtain OE_{obj} ; (iii) the objective indicator to quantify OE_{obj} . An overview of the three abovementioned experimental aspects found in the literature is presented below.

A. Stimulation sources

The first experimental aspect deals with the stimulation source used to induce the OE. In laboratory conditions, bone transducers are often used to generate the BC stimulation

(Reinfeldt et al., 2013; Stenfelt and Reinfeldt, 2007). In most cases, the bone transducer is placed on either the mastoid process or on the forehead and is held in place with a headband. To measure OEobj with the bone transducer, the SPLs in the earcanal with and without the occlusion device are assessed. This is similar to the evaluation of the sound attenuation of the HPD through measurement of the objective insertion loss (IL) (Berger, 2003), but by using a supraliminal BC stimulation rather than a noise field. Alternatively, the bone transducer can be used to assess OE_{subi} with an approach analogous to the real-ear attenuation at threshold (REAT) method used to evaluate the sound attenuation provided by an HPD (ANSI and ASA, 2016; Berger, 2003). Although bone transducers provide a relatively precise and repeatable stimulation, limitations can be encountered during measurements. The bone transducer's position on the skull influences the magnitude and repeatability of the OE because of the transcranial attenuation and the excitation of soft tissues surrounding the ear when placed on the mastoid process compared to the forehead (Klodd and Edgerton, 1977; Reinfeldt et al., 2013). The bone transducer's operation limits in the low- and high frequencies can also result in measurement artefacts due to acoustic radiation by the outer casing of the bone transducer (Reinfeldt et al., 2013; Shipton, 1980), which could contribute to the unoccluded ear SPL or to the unoccluded BC hearing threshold (Berger and Kerivan, 1983). Furthermore, given the cumbersome procedure and required equipment (i.e., audiometer, bone transducer), measuring the OE with a bone transducer is not very well adapted for field measurements and is mostly utilized in laboratory conditions. A simpler way to induce the OE is by using the subject's own physiological noises; these stimulations are hereby designated as wearer-induced stimulations (WIS). As with a bone transducer, OEobi can be obtained by measuring the SPL in the earcanal with and without the occlusion device when a WIS is produced. A common WIS is speech, i.e., the subject's own voice (Courtois et al., 1988; Hansen, 1997, 1998; Killion et al., 1988; Lundh, 1986; Sgard et al., 2016; Vasil-Dilaj and Cienkowski, 2011). As speech is controllable by the user, it is possible to induce the BC stimulation using two types of speech content, namely producing continuous speech by reading a text aloud or enumerating numbers (Hansen, 1998; Sgard et al., 2016), or vocalizing a phoneme, more than often one of the cardinal vowels, i.e., /i/, /æ/ or /u/ (Killion et al., 1988; Stender and Appleby, 2009; Vasil-Dilaj and Cienkowski, 2011). In some cases, speech is monitored with a feedback system for the subject, e.g., sound level meter, to ensure that speech is produced at the same intensity during open and occluded ear measurements or to a specific intensity (Hansen, 1998; Sgard et al., 2016; Stender and Appleby, 2009; Vasil-Dilaj and Cienkowski, 2011), at the cost of complexifying the procedure. In contrast with a bone transducer, using speech is more accessible as no specialized equipment is required other than a simple feedback system (e.g., screen of a sound level meter) if the vocal effort is to be monitored. Additionally, it is deemed relevant to use speech as a stimulation source since it is often associated with discomforts in real life situations (Dillon, 2012; Doutres et al., 2019; Kochkin, 2010; Terroir et al., 2021). Using one's own voice as a stimulation source is, however, associated with some limitations. Vocalizing a vowel introduces more variability compared to using continuous speech; because the OE affects one's self-perception, reproducing a vowel twice with the same spectral content and at the same level can be challenging (Hansen, 1998). The sound chosen to be vocalized also influences the magnitude of the measured OE as the ratio between the airborne conduction (AC) and BC component produced in the vocal organs depends on the phoneme (Hansen, 1998; Reinfeldt et al., 2010). Using continuous speech allows one to obtain a more repeatable stimulus as the long-term average speech spectra is fairly constant, but at the cost of a longer measurement time (Byrne et al., 1994). OEobi has also been measured using other WIS, namely, mastication, heart beats, blood flow, swallowing, and footsteps (Courtois et al., 1988; Hansen, 1997, 1998; Killion et al., 1988; Stone et al., 2014). Because of their nature, producing these WIS twice the same can be quite difficult, if not impossible. With mastication, the magnitude and the variability of OE_{obj} value greatly depend on the nature of the food masticated, i.e., crispy vs soft food (Courtois et al., 1988; Hansen, 1997, 1998; Killion, 1988; Killion et al., 1988). Heart beats were found to produce a large OE_{obj} below 125 Hz, but OE_{obj} was challenging to measure as the SPL in the unoccluded ear is low due to the low energy of the stimulus (Stone *et al.*, 2014).

B. Measurement methods

The second experimental aspect, hereby designated as the measurement method, refers to how OEobj is obtained. More specifically, it refers to which ears are used to conduct the measurements, whether one or two separate stimuli are required to excite the ear(s) via BC and the location of the microphones for SPLs measurement. In the literature, three distinct measurement methods can be found. A first one consists in conducting successive SPL measurements inside the earcanal of a single ear first occluded and then unoccluded to obtain OE_{obi}. This method is the most commonly found in the literature and is designated as the "standard method" in this paper. As two separate measurements are needed (and thus two separate stimulations), assessing the OE_{obi} with the standard method is sensitive to stimulation sources that have a low repeatability (Hansen, 1998). A second measurement method consists in using both ears simultaneously to obtain OE_{obi}, here designated as the "real-time method." To do so, one ear is occluded while the other is unoccluded and SPLs in both ears are measured simultaneously (in "real-time") with a single stimulation (Hansen, 1998; Killion et al., 1988). This method offers the advantage over the standard method that measurements are more reliable with short and variable stimulations such as the vocalization of a phoneme since it has to be produced only once (Hansen, 1998). However, this method requires the stimulation sources to be centered on the sagittal plane of the body so that both ears are equally stimulated and both ears to have similar anatomies (Hansen, 1998). Because this method has only rarely been used and studied, its reliability must be further investigated. A third method is also based on simultaneous measurements of the occluded and unoccluded SPLs to obtain OEobj, but using a single ear only (Bernier, 2016; Bouserhal et al., 2019; Mejia et al., 2008). This method has also been integrated in commercially available devices, such as the Audioscan Verifit 2 for the OE test (Audioscan®, Dorchester, Ontario, Canada) and the Etymotic Research ER-33 Occlusion meter (Etymotic Research®, Elk Grove Village, IL) (Audioscan, 2021; Killion, 1996). In this approach, the SPL in the unoccluded ear condition is approximated by the SPL measured just outside the occlusion device, in the occluded ear condition. This approach is analogous to the evaluation of the sound attenuation of an HPD using the noise reduction (NR) (Berger, 2003; Voix et al., 2022), but by using BC stimulations in order to obtain the OE. Thus, this method is here designated as the "NR-based method." While it does not provide a measurement of OEobj as defined in most studies, it allows one to obtain simultaneous measurements in both ears using only a single stimulation. However, discussions on the limitations and constraints associated with this method and comparisons with the other two are scarce in the literature.

Still regarding the measurement method, two approaches are used to measure the SPL inside the occluded earcanal. A first approach consists in using a probe tube microphone inside the earcanal. Although this approach provides an SPL measurement near the tympanic membrane by placing the probe tube's opening near to it, special care must be taken to ensure that the tympanic membrane is not touched to avoid causing discomfort or harm to the test subject. Often, this manipulation (i.e., the placement of the probe tube into the earcanal) must be performed by an audiologist or by a person trained by an audiologist. Additionally, special care must be taken to ensure that the tube positioned between the in-ear device and the earcanal walls does not cause any acoustic leaks, in particular with earplug-type hearing protectors for which a good seal is needed to maintain good attenuation performance. A second approach consists instead in measuring the SPL at the medial face of the in-ear device which allows to keep a safe distance from the tympanic membrane. This is achieved by using in-ear devices equipped with a designated probe tube for this purpose, such as the 3M E-A-RLink earplugs (3M, St. Paul, MN). Although the SPL is measured farther from the tympanic membrane, both approaches yield similar results when measuring OE_{obj} (MacKenzie et al., 2004) as the OE is the largest at frequencies below 2000 Hz, frequencies for which the microphone location in the earcanal only slightly influences the measured SPL (Berger and Kerivan, 1983; Bonnet et al., 2018).

C. Indicators

The third experimental aspect deals with the indicator used to quantify the OE. OE_{obj} values are typically

presented as a spectrum at various frequencies in octave, third octave or twelfth octave bands (Lundh, 1986; Reinfeldt et al., 2013; Sgard et al., 2016; Stenfelt and Reinfeldt, 2007). An indicator that is a function of frequency provides the most information about the phenomenon, but at the cost of making the analyses frequency-dependent, hence more complex and more time consuming. Some authors have instead quantified OEobi using different single value indicators (SVI), as they offer the simplicity of having only a single number to characterize the phenomenon, making comparisons and analyses simpler. However, as these indicators are not standardized, the choice of the indicator varies from one study to another. These indicators are either based on the magnitude of OEobj at a specific frequency, e.g., at 250 Hz (Killion et al., 1988; Lee and Casali, 2011; Valentin and Laville, 2017); on the magnitude averaged over a specific frequency range, e.g., between 125 and 500 Hz (Biering-Sørensen et al., 1994; Hansen, 1997; Kiessling et al., 2005); or based on the maximum value of the OE in the measured frequency range (May and Dillon, 1992) cited in (Hansen, 1997). Some authors have also quantified the magnitude using occluded/unoccluded squared root mean square (rms) sound pressure integrated over a specific frequency range (Audioscan, 2021; Hansen, 1997; Mueller, 2003; Stender and Appleby, 2009). In most cases, the selection of a SVI over another is not much discussed, which contributes to the lack of consensus in the literature on how to represent OE_{obi}.

III. MATERIAL AND METHODS

In order to propose a practical methodology to obtain OE_{obi} induced by earplugs, the investigation of the three experimental aspects abovementioned was conducted through measurements with human participants in laboratory conditions. The experimental approach employed to conduct these measurements is described below.

A. Participant selection

Thirty participants (26 males, 4 females, age: 25.1 ± 4.4 years) volunteered to participate in the study. Most were university students with no prior experience in OE measurements and not used to wear earplugs on a daily basis. Each participant was met during two separate sessions, the first to assess their eligibility to participate and the second to conduct the experiments. To be eligible, the participants had to meet the following criteria: (i) Have AC and BC hearing thresholds equal or better than 20 dB hearing level (HL) in the frequency range from 125 to 8000 Hz; (ii) Have both ears free of anomalies following an otoscopic inspection and not have had ear surgeries. Hearing thresholds were assessed with a Shoebox Pro Audiometer (Shoebox Ltd., Ottawa, Ontario, Canada) paired with a RadioEar B-81 bone transducer (RadioEar Corporation, New Eagle, PA) for BC hearing thresholds and with 3MTM E-A-RTone insert earphones for AC hearing thresholds. A RadioEar P-3333 headband was used to secure the bone transducer on the skull of the participant. All criteria were evaluated by the experimenter who was trained by a registered audiologist. Prior to taking part in the study, participants were required to read the project's general information and sign a consent form, as approved by the IRSST and the ETS Research Ethics Committee (Certificate #H20180402). Although participants were free to terminate their participation in the trial at any time for any given reason, all sessions were completed. Participants received a \$30 compensation for their participation in the trial.

During the first session, the better ear (i.e., lowest AC hearing threshold) of each participant was identified. Because some stimulation sources used in the study were off-centered relative to the sagittal plane of the body, one ear was closer to the stimulation than the other. This ear is designated as the ipsilateral ear while the other one is referred to as the contralateral ear in the rest of the document.

B. Material

During the second session, two types of measurements were conducted: (1) microphonic measurements to assess OE_{obj} with multiple stimulation sources and (2) hearing threshold measurements to assess OE_{subj} with a bone transducer.

All measurements were conducted in a 20 m³ audiometric booth (Industrial Acoustics Company Inc., Naperville, IL) located in the ICAR laboratory at the École de technologie supérieure (ÉTS) in Montreal (Canada) as shown in Fig. 1. The room was equipped with four decorrelated KlipschTM speakers (Klipsch LLC., Indianapolis, IN) placed in each corner. Participants were comfortably seated in a chair, facing a ceiling-mounted computer screen used as a communication and feedback system. Two microphones were placed 1.2 m above the floor and approximately 0.6 m from the participants' mouth. A 1 in. G.R.A.S type 26 HF microphone with a type 12HF amplifier (G.R.A.S., Holte, Denmark) and a ½ in. B&K type 2669 microphone with a type 2829 amplifier (Brüel & Kjaer, Nærum, Denmark) were used as reference

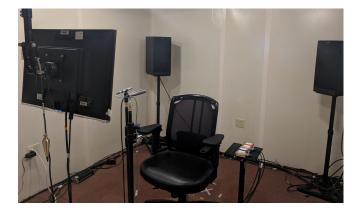


FIG. 1. (Color online) Experimental setup consisting of the participant's chair, four decorrelated speakers (only two shown), two reference microphones and a screen displaying the real-time feedback system.

microphones. The 1 in. microphone was connected to a real-time sound level meter developed in LabVIEW (National Instruments, Austin, TX), displayed on both the experimenter's and the participant's screens. It allowed for monitoring the A-weighted equivalent continuous SPL with a 500 milliseconds integration time [$L_{eq(A)500ms}$]. The ¹/₂ in. microphone was connected to a MATLAB program (MathWorks, Natick, MA) for the data acquisition. Both microphones and the four speakers were connected to two NI PXI 4461 and two PXI 4462 cards mounted on a NI PXI 1033 chassis located outside the room and connected to the experimenter's computer. The measurements conducted with the bone transducer used the RadioEar B-81 bone transducer, the RadioEar P-3333 headband, and the 3M E-A-RTone. The bone transducer and the insert earphones were both connected to the Shoebox Audiometer located outside the room and controlled by the experimenter.

C. Microphonic earpieces

SPLs in earcanals were measured using two pairs of custom-made microphonic earpieces (Bonnet *et al.*, 2019; Coser Nogarolli, 2019) as shown in Fig. 2. The first pair consisted of protecting earpieces [Figs. 2(a) and 2(b)], used for the occluded ear condition. It was designed to fit three sizes of Comply T-400 Isolation ear tips (Comply, St. Paul, MN); small, medium, and large. The size of the ear tips was chosen according to the participant's earcanal size and to the ability to obtain an adequate acoustic seal, verified with a sound attenuation measurement. The second pair consisted of open earpieces [Figs. 2(c) and 2(d)], used for unoccluded ear measurements. Each earpiece was equipped with two miniature microphones: an inner microphone (IEM) connected to a

probe tube to measure the SPL approximately 15 mm into the earcanal relative to the tragus and an outer microphone (OEM) to measure the SPL at the earcanal's entrance. Each probe tube microphone was calibrated by placing its opening next to the calibrated $^{1}/_{2}$ in. reference microphone inside the audiometric booth and by generating a 90 dB(A) uncorrelated Gaussian white noise with the four speakers, which allowed the calculation of a frequency-dependent calibration factor. A stopper integrated into the earpieces ensured an identical positioning of the inner probe tube microphone opening in the earcanal for the occluded and unoccluded conditions.

D. Experimental protocol and stimulation sources

The second session with each participant was divided into seven parts during which OE_{obj} and OE_{subj} were measured with various stimulation sources, namely, a bone transducer, speech, and mastication. Before proceeding to the measurements, the participant was given time to understand and practice the different tasks. The tasks, described below, were conducted with the protecting earpiece (occluded ear) and with the open earpiece (unoccluded ear).

To measure OE_{obj} with the bone transducer, a 25 dB HL pure-tone signal centered at the 250, 500, 750, 1000, 1500, and 2000 Hz audiometric frequencies for a 20 s duration was used. The signal intensity was chosen to ensure that the noise generated in the earcanal was supraliminal and above the noise floor levels, but low enough to avoid any measurement artefacts due to the bone transducer's operation limit and acoustic radiation.

To measure OE_{subj} with the bone transducer, BC hearing thresholds were assessed using the modified Hughson-Westlake procedure at the 250, 500, 750, 1500, and 2000 Hz

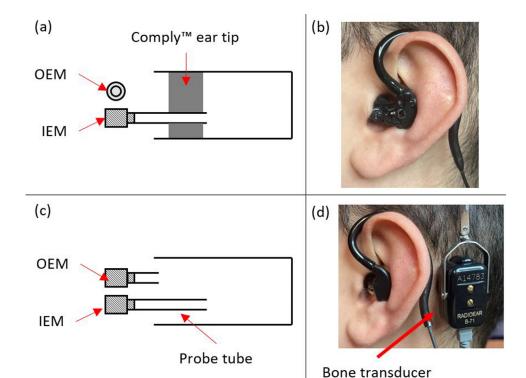


FIG. 2. (Color online) Schematics and pictures of the custom-made earpieces (Bonnet et al., 2019; Coser Nogarolli, 2019). (a) Schematic of the protecting earpiece. The OEM measures the SPL at the earcanal's entrance, and the IEM measures the SPL inside the earcanal with a probe tube passing through the Comply T-400 ear tip. (b) Protecting earpiece installed in the ear. (c) Schematic of the open earpiece. The OEM measures the SPL at the earcanal's entrance with a probe tube and the IEM measures the SPL inside the earcanal with a probe tube. (d) Open earpiece installed in the ear with the bone transducer placed on the temporal bone.

audiometric frequencies (Raymond and Jerger, 1959). To ensure the measured hearing thresholds were those of the chosen ear, the opposite ear was masked with a broadband white noise controlled and generated by the audiometer at 60 dB HL, delivered to the participant through a 3M E-A-RTone earphone. The 60 dB HL level was chosen to ensure the level of masking would be adequate without leaking to the other ear by transcranial transmission. As a great deal of concentration is needed by the participant for the BC audiometry, hearing thresholds were only obtained for the ipsilateral ear for all the participants.

To reduce the variability associated with the fit of the earplug, all measurements were done for a single fit of the earpiece; measurements were conducted in a specific sequence to eliminate the need to install the bone transducer and fit the protecting earpieces multiple times. Before proceeding to the measurements, a verification was made to ensure that the earplug was correctly positioned and fitted in the participant's earcanals. To do so, a broadband AC noise field was generated using the four decorrelated speakers and the sound attenuation provided by the earplug was verified. A NR of a least 10 dB at 160 Hz was considered as a sufficient fit for the study. If an inadequate sound attenuation was measured, the earplug was removed and re-fitted, and the verification process was repeated. When the earplug was properly fitted, measurements were conducted according to the sequence shown in Table I. The multiple parts of the sequence differ by the ear configurations (open or closed), the type of stimulation and the stimulus level. In parts 1, 2, 3, and 4, the bone transducer was used to induce the OE. When the experimenter installed the bone transducer on the temporal bone of the participant as shown in Fig. 2(d), a verification was done to ensure that there was no contact with the pinna or the pinna hook of the earpieces, and that the positioning was stable. If at any point during the measurement some slippage occurred, the bone transducer was removed and replaced, and all preceding measurements were ignored. In parts 5, 6, and 7, the stimulations used to induce the OE were produced by the participants, i.e., by using their own voice (speech) and by masticating a chewing gum (mastication). In these three parts, multiple speech contents were produced, namely enumerating numbers and

TABLE I. Sequence divided into seven different parts.

Part	Ipsi. ear configuration	Contra. ear configuration	Stimulation source	Stimulation level
1	Open	Open	Bone transducer	Supraliminal
2	Open	Masked	Bone transducer	Threshold
3	Protected	Masked	Bone transducer	Threshold
4	Protected	Protected	Bone transducer	Supraliminal
5	Protected	Protected	Speech, mastication	Supraliminal (user generated)
6	Protected	Open	Speech, mastication	Supraliminal (user generated)
7	Open	Open	Speech, mastication	Supraliminal (user generated)

vocalizing the vowels /i/ and /ə/. The speech-based stimulations were produced at three distinct vocal efforts: 60, 70, and 80 dB(A), as measured by the reference microphone. To help the participants, a list of randomly generated numbers and a sound level meter were displayed on the screen facing them to ensure they spoke with a continuous flow and at the designated target noise level. For the mastication, participants were given four instructions on how to masticate the chewing gum: (1) masticate only on the side of the ipsilateral ear, (2) masticate while keeping the lips shut, (3) masticate at a normal rate, (4) masticate without exaggerating the movement. The instructions were given to ensure that mastication would be done in a similar manner by all the participants. A summary of the different stimulations within each part is shown in Table II. The order in which the stimulations were produced was randomized for each configuration and for each participant to reduce the order effect.

The sequence used during the tests allowed one to objectively measure the OE with the three measurement methods found in the literature: (1) the standard method, (2) the realtime method, (3) the NR-based method. As previously mentioned, the three methods differ by when and where the occluded and unoccluded sound pressures are measured. The positions where the SPLs are measured of the three methods are depicted in Fig. 3. Measurements conducted in part 1 and part 4 were used to compute OE_{obi} using the standard method for a stimulation with the bone transducer, while measurements in parts 5 and 7 were used for a stimulation with speech and mastication. Measurements conducted in part 6 were used to compute OE_{obi} with the real-time method for a stimulation with speech and mastication. This was accomplished by equipping the ipsilateral ear with the protecting earpiece (occluded SPL) and the contralateral one with the open earpiece (unoccluded SPL) and measuring the sound pressure in the earcanal with the IEM of both earpieces simultaneously. Finally, measurements done in part 6 were also used to compute OE_{obj} using the NR-based method. Measurements with this method were carried out with the protecting earpiece only; the occluded SPL was measured with the earpiece's IEM and the unoccluded SPL was estimated by measuring the SPL outside the earcanal with the earpiece's OEM. Only the measurements done in part 6 were used to compute the OE_{obi} using the NR-based method to do a direct comparison with the real-time method, although other parts listed in Table I could also have been used to perform such comparison. For the OE_{subj}, only the standard method was used as it is based on hearing threshold measurements. The OE_{subi} was computed with measurements conducted in

TABLE II. Stimuli produced by the participants in part 5, 6, and 7, in a randomized order.

Stimulation	Effort	Duration
Enumeration of random numbers	60, 70, 80 dB(A)	20 s
Vocalization of the vowel /i/	60, 70, 80 dB(A)	5 s
Vocalization of the vowel /ə/	60, 70, 80 dB(A)	5 s
Mastication of a chewing gum	_	20 s

FIG. 3. (Color online) Positions of the sound pressure measurements used to compute the OE_{obj} with the three measurement methods: (a) the standard method, (b) the real-time method, (c) the NR-based method. p_{EC} and p'_{EC} are respectively measured with the IEM of the open and protected earpieces. p'_{OUT} is respectively measured with the OEM of the protected earpiece.

parts 2 and 3 and was carried out for the ipsilateral ear only as mentioned previously.

E. Sample sizes

While the same procedure was used with every participant, few data could not be recorded or were considered invalid. These missing data can be explained by methodological problems, the inability of some participants to produce some of the stimulations, or the presence of artefacts during the measurements. For these reasons, the sample sizes of the data used in the analyses are variable. In most cases, they vary between n=26 and n=30 for the different stimulation sources and for the different frequency bands. The exception is for OE_{subj} data obtained with the bone transducer, with which the sample sizes at the different frequency bands are smaller, varying between n=6 and n=26. The reduced sample sizes are attributed to a methodological limitation encountered with the audiometer; this limitation is further discussed in Secs, IV B and IV E.

F. OE indicators

Two types of indicators are used for the analyses: spectral and single value. Hearing threshold levels (HTL) measured at the different audiometric frequencies are used to compute the OE_{subi} , as shown in Eq. (1),

$$OE_{subj} = HTL_{unoccluded} - HTL_{occluded}.$$
 (1)

For the OE_{obj} , the rms sound pressure (p_{rms}) is measured with the microphonic earpieces to compute equivalent continuous SPL $(L_{eq,t})$ measured with the different microphones, as shown in Eq. (2),

$$L_{p,eqT} = 10 \log_{10} \left(\frac{1}{T} \int \left(\frac{p(t)}{p_0} \right)^2 dt \right),$$

with
$$p_0 = 20 \,\mu Pa$$
. (2)

The OE_{obj} can be obtained using the three distinct measurement methods. OE_{obj} measured with the standard, the

real-time, and the NR-based methods, are respectively given by Eqs. (3)–(5),

$$OE_{obj}^{STD} = L_{p'_{EC(1)}} - L_{p_{EC(1)}},$$
 (3)

$$OE_{obj}^{RT} = L_{p'_{EC(1)}} - L_{p_{EC(2)}},$$
 (4)

$$OE_{obj}^{NR} = L_{p'_{EC(1)}} - L_{p'_{OUT(1)}}.$$
 (5)

Based on these frequency-dependent OE_{obj} (and OE_{subj}), SVIs are computed in order to quantify the OE with a single number, hence making comparisons and analyses simpler as previously discussed. Multiple SVIs were computed, as shown in Table III. The SVIs are based on the ones found in the literature to compare them one against another. As both OE_{obj} and OE_{subj} typically exhibit a maximum at low-frequency, the $160{-}500\,\mathrm{Hz}$ range was chosen to compute the different SVIs. Following the comparison between the different SVIs, the most robust, as defined by the smallest variability and the lowest numbers of outliers, is identified as the occlusion effect index (OEI).

IV. RESULTS AND DISCUSSION

A. OE indicators

 $OE_{obj}^{\ \ STD}$ measured using the standard method is plotted as a function of frequency in Fig. 4 for the five stimulations (numbers, vowel /i/, vowel /ə/, mastication, and the bone transducer), as well as OE_{subj} measured with the bone

TABLE III. List and description of the different SVIs computed.

SVI	Description		
OE _{160 Hz}	OE magnitude at 160 Hz.		
$OE_{250~Hz}$	OE magnitude at 250 Hz.		
$OE_{500~Hz}$	OE magnitude at 500 Hz.		
OE_{max}	Maximum OE in the 160–500 Hz range.		
OE_{AVG}	Arithmetic mean of the OE in the 160–500 Hz range.		
OE_{B-L}	Occluded/unoccluded level difference		
	of the band-integrated square rms sound pressure in the limited bandwidth 160–500 Hz		

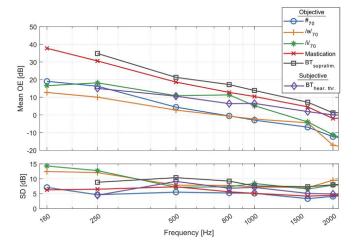


FIG. 4. (Color online) $OE_{obj}^{\ \ STD}$ and OE_{subj} as a function of frequency for five stimulation sources. The # symbol indicates the enumeration of random numbers. $BT_{supramllim.}$ and $BT_{hear.\ thr.}$ indicates the bone transducer used at a supraliminal level and at hearing thresholds, respectively.

transducer. The upper panel shows the average value measured for each stimulation while the lower panel shows the standard deviation. For all stimulations, only the data measured in the ipsilateral ear are plotted. Additionally, only the data measured for the $70\,\mathrm{dB}(A)$ vocal effort is plotted for speech-based stimulation (the effect of the vocal effort is presented in Sec. IV C 1). The magnitude and the variability of $\mathrm{OE_{obj}}^{STD}$ depends on the stimulation type (speech-based vs BC) as well as on the speech content (numbers vs vowel /i/ vs vowel /ə/). In accordance with the literature, $\mathrm{OE_{obj}}^{STD}$ (and $\mathrm{OE_{subj}}$) presents a maximum at low-frequency and gradually decreases with increasing frequency (Berger and Kerivan, 1983; Hansen, 1998; Reinfeldt *et al.*, 2013).

The data used to calculate $OE_{obj}^{\ \ STD}$ and OE_{subj} as a function of frequency in Fig. 4 lead to the six SVIs presented in Sec. IIIF. To compare the six SVIs computed for each of the five stimulations, results are presented as clustered boxplots in Fig. 5. The comparison between the different SVIs highlights that the variability, described here by the interquartile range, depends on the stimulation source (as previously discussed) and the SVI used. Unsurprisingly, indicators that are average-based (OEAVG, OEB-L) typically exhibit a smaller interquartile range and fewer outliers than the indicators based on the value in a specific octave band $(OE_{160Hz}, OE_{250Hz}, OE_{500Hz}, OE_{MAX})$. It can also be noted that SVI values differ from one another for each stimulation source since they are computed differently. When considering the relative order between the SVI for each stimulation, e.g., the ascending order, the lowest magnitude is obtained for OE_{500Hz} while the highest is for OE_{MAX}. For the other indicators that are in between (i.e., OE_{160Hz}, OE_{250Hz}, OEAVG, OEB-L), their relative order only slightly differs from one stimulation source to another, and their medians are typically close to one another. It suggests that choosing arbitrarily one of those four SVIs would not change the interpretation of the results. Moreover, this comforts that the conclusions drawn in a given study should remain the same

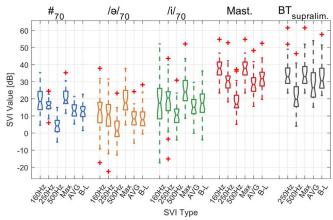


FIG. 5. (Color online) SVI Value as a function of different types of SVIs. The label above each boxplot cluster indicates the stimulation source used to induce the OE. The # symbol indicates the enumeration of random numbers and $BT_{supralim.}$ indicates the bone transducer at a supraliminal level. In the boxplot representation, the height of the box represents the interquartile range $(Q_{75\%}_Q_{25\%})$. The horizontal bar dividing the box represents the median and the tapered sections on both sides represent the 95% confidence interval around the median. The whiskers represent the minimum and the maximum values of the sample while the crosses represent values determined as outliers.

even if the analyses were conducted with another indicator, e.g., using OEAVG rather than OE250Hz. However, great care must be taken when comparing the results from two studies that do not employ the same indicator as a difference between the results could be attributed to how the two indicators are computed. Although these findings (variability unchanged relative order) help to better understand the influence of an SVI on the results that are drawn from the analysis of a data set, computing and analyzing the results obtained with every indicator is cumbersome and time consuming. Thus, a single SVI is used for the remainder of the subsequent analyses. In the context of this work, which aims at investigating the methodology to assess OE_{obi}, OE_{AVG} is chosen arbitrarily based on the low variability it exhibits. Other factors could also be used to justify the choice of an SVI over another one. For example, one such factor could be the correlation between the SVI and OE_{exp}. However, this falls outside this work as the correlation between OE_{obj} and OE_{exp} must be further investigated, as discussed in Sec. I.

Because of the fluctuating nature of the voice, $OE_{obj}^{\ \ STD}$ was also computed using the percentile sound levels (L_n) (Corthals, 2004), a metric typically used for environmental noise, instead of the continuous equivalent sound level $(L_{eq,T})$. The results, not shown here, indicate that in the frequency range where the OE is maximal (<500 Hz), L_n and $L_{eq,T}$ both lead to similar $OE_{obj}^{\ \ STD}$ values for a wide range of percentile n (from 10 to 90). This finding confirms that using the $L_{eq,T}$ is a valid type of metric to characterize the $OE_{obj}^{\ \ STD}$ induced by speech.

B. Objective vs subjective OE with a bone transducer stimulation

Large differences can be seen in Fig. 4 between the OE_{obj}^{STD} and the OE_{subj} with the bone transducer at low-

frequency (see gray/square and purple/diamond curves), approximately 21 and 12 dB at 250 and 500 Hz, respectively. These differences, already reported in the literature (Huizing, 1960; Reinfeldt et al., 2013; Stenfelt and Reinfeldt, 2007), can be attributed to the different BC mechanisms involved when measuring the occluded and unoccluded low-frequency SPL and HTL, respectively. When the ear is occluded, the outer ear BC mechanisms are the main contributors to both BC hearing and earcanal SPL (Carillo et al., 2020; Stenfelt et al., 2003; Stenfelt and Goode, 2005). When the ear is unoccluded, the outer ear BC mechanisms are the main contributors to the earcanal SPL while the inner and middle ear BC mechanisms are the main contributors to BC hearing (Stenfelt et al., 2003; Stenfelt and Goode, 2005). This leads to a smaller earcanal SPL in comparison with the equivalent BC hearing threshold, thus causing an overestimation of OE_{obj}^{STD} compared to OE_{subj} . To further analyze the relationship between the two indicators, their correlation is investigated. To do so, OE_{obj}^{STD} is plotted against OE_{subi} in the scatterplot shown in Fig. 6. Each point represents the data of one participant in a specific frequency band; the horizontal axis represents $OE_{subj,}$ and the vertical axis represents $OE_{obj}^{\ \ STD}$. Data of the frequency bands of 250, 500, 800, and 1000 Hz are pooled together. Based on the Pearson's correlation coefficient, rho (ρ) , and the associated p-value, the correlation between OE_{obi} and OE_{subi} is deemed significant ($\rho = 0.57$, p-value = < 0.001) and is in accordance with results from previous studies (Fagelson and Martin, 1998; Goldstein and Hayes, 1965). This suggests that measuring OE_{obj} STD with the bone transducer driven at a supraliminal level could allow one to assess OE_{subj}, but without the need to conduct cumbersome hearing threshold measurements, which could allow one to simplify future studies on the OE. Additional research is however necessary to further investigate the correlation between $OE_{obj}^{\ \ STD}$ and OE_{subj} as the data that could be analyzed in this study is limited. This limitation originates from a methodological problem that was encountered with the audiometer, mostly at low-frequency. To ensure the data

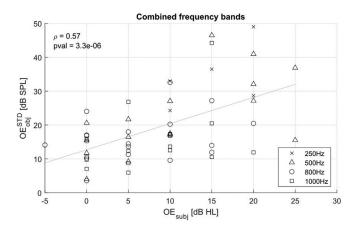


FIG. 6. Scatter plots of the OE_{subj} against the OE_{obj}^{STD} both obtained with the bone transducer for each participant, at 250–500–800–1000 Hz combined. The Pearson's correlation coefficient (ρ) and the associated p-value is shown in the top left-hand side corner.

were reliable, a rejection procedure was applied to remove data points that could potentially underestimate OE_{subj} , but at the cost of significantly reducing the sample sizes. In the 250 Hz and 500 Hz frequency bands, the data of only 6 and 16 out of the 30 participants could be used. The methodological problems and the data filtering are further discussed in Sec. IV E.

C. Influence of the stimulation on the OE

The OEI defined as the average $OE_{obj}^{\ \ STD}$ in the 160–500 Hz bandwidth obtained with the two types of stimulations (speech-based, BC) as well as the three vocal efforts for speech-based stimulations [60, 70, 80 dB(A)] are shown in Fig. 7 in clustered boxplots. Considering that the stimulation produced by the mastication and the bone transducer is asymmetrical, the results are shown in two clusters of boxplots, one for each measurement location (ipsilateral ear, contralateral ear). The differences in speech-based stimulations, BC stimulations as well as the differences between speech-based and BC stimulations are discussed below.

1. Differences between speech-based stimulations

As shown in Fig. 7 for OE_{obj}^{STD} , the magnitude and variability of the OEI depends on the nature of the sounds produced by the participants when speaking, i.e., continuous speech (random numbers) vs sustained vowels (/i/, /ə/). This result was somehow expected given their different characteristics and how they are produced in the speech organs, thus resulting in different AC and BC stimulations (Hansen, 1998). The OEI shown in Fig. 7 exhibits more variability with vowels than with numbers at a vocal effort of 70 dB(A). Using the interquartile range ($Q_{75\%}$ – $Q_{25\%}$) to

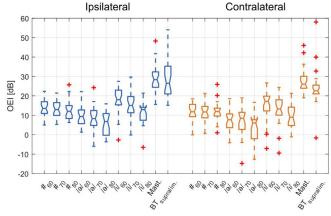


FIG. 7. (Color online) OEI, defined as the average $OE_{obj}^{\ \ \ \ \ \ }^{STD}$ in the 160–500 Hz bandwidth, as a function of the ipsi- and contralateral ears, BC stimulations and speech-based stimulations at the three vocal efforts. The # symbol indicates the enumeration of random numbers and BT_{supralim}. indicates the bone transducer at a supraliminal level. In the boxplot representation, the height of the box represents the interquartile range (Q75%–Q25%). The horizontal bar dividing the box represents the median and the tapered sections on both sides represent the 95% confidence interval around the median. The whiskers represent the minimum and the maximum values of the sample while the crosses represent values determined as outliers.

quantify variability associated with the stimulation, it was found to be smaller when numbers were used, ranging from 4 to 6.6 dB, in comparison to the vowels, ranging from 6.6 to 11 dB. Additionally, using vowels caused outliers to be detected whereas none were when using numbers. This difference in variability was also found with the vocal efforts of 60 and 80 dB(A). The larger variability obtained with vowels is attributed to the difficulty of producing a similar stimulus twice, both in terms of the produced vocal effort amplitude and speech spectrum (Hansen, 1998). Although the vocal effort amplitude was monitored with the feedback system, a shift in the voice pitch occurred for most participants when occluding the ear. The magnitude of the shift varied from a participant to another, e.g., ranging from less than 5 up to 90 Hz when considering the first formant during the vocalization of the vowel /i/ at a vocal effort of 70 dB(A). In contrast, enumerating numbers instead allows one to measure the signal on longer periods of time (20 vs 5 s) as the participants can breathe throughout the recording. In addition, the signal integration over the recording time to compute the $L_{eq,T}$ averages a large number of vowels and consonants which leads to a more stable, broadband, and more realistic stimulation. Considering these results, numbers are considered more robust to measure OE_{obj}^{STD} and OEI. The results shown in Fig. 7 also suggest that the effect of the vocal effort on the measured OEI is small. Using a repeated measure analysis of variance (ANOVA) statistical analysis, the three vocal efforts were

compared to one another for each stimulation. Statistical results indicate that vocal effort does not statistically influence the OEI obtained with random numbers. With vowels, a 10 dB change in the vocal effort [e.g., 60 vs 70 dB(A), 70 vs 80 dB(A)] does not lead to a statistically different OEI, but the larger 20 dB change does [e.g., 60 vs 80 dB(A)]. This suggests that the measurement methodology of the OE using one's own voice could be simplified: as the influence of the vocal effort is only small, repeated measures at multiple speech intensities seem unnecessary, provided a feedback system is used. Further investigations should be conducted to investigate the influence of speech content on the OE, e.g., numbers vs words. Using numbers to obtain the OEI is, however, in accordance with some procedures used with certain hearing aids to control the OE to improve users' comfort (Høydal, 2017).

2. Differences between BC stimulations

For the two BC stimulations (i.e., mastication and bone transducer driven at a supraliminal level), $OE_{obj}^{\ STD}$ results obtained were typically similar. In Fig. 4, $OE_{obj}^{\ STD}$ measured with mastication was typically 2.5 dB lower than with the bone transducer between 250 and 2000 Hz. The larger variability of $OE_{obj}^{\ STD}$ can be attributed to the more extreme values the bone transducer produces in some instances. For a closer inspection of the data, $OE_{obj}^{\ STD}$ obtained with both stimulation source is plotted as a function of frequency for each individual participant in Fig. 8. The identification

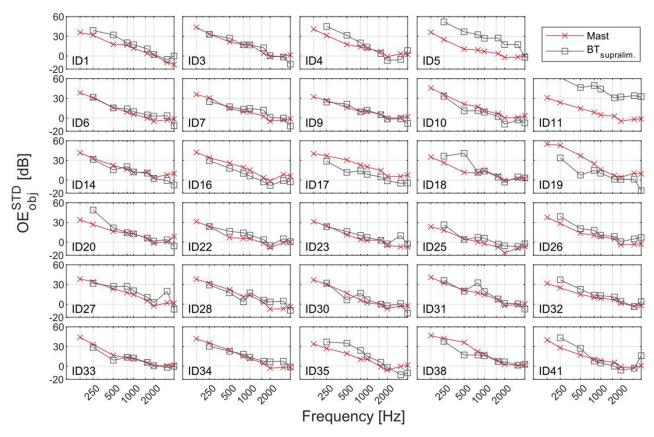


FIG. 8. (Color online) Individual comparison between the OE_{obj}^{STD} obtained with mastication and the bone transducer driven at a supraliminal level (BT_{supralim.}).

number (ID) of each participant is indicated in the bottom left-hand side of each panel. Typically, both OE_{obi} STD are in good accordance, but there are instances where differences are present. These differences can be in specific third octave bands, such as for participants ID18 and ID19, but can also be present over the entire studied bandwidth, such as for participants ID5 and ID11. The OE_{obi} STD difference between mastication and the bone transducer are also observed with an SVI. When considering the OEI shown in Fig. 7, the difference between the two median is less than 2.5 dB in the ipsilateral ear, and less than 5 dB in the contralateral ear. When considering the variability of the OEI, both stimulation sources yield different results in each ear. In the ipsilateral ear, the standard deviation of $OE_{obj}^{\ \ STD}$ is smaller with mastication than with the bone transducer (see Fig. 4), as previously discussed. When considering the OEI (see Fig. 7), the interquartile range associated with mastication is smaller than with the bone transducer (respectively 8.0 and 14.3 dB). In the contralateral ear, the interquartile ranges are smaller than in the ipsilateral ear, and the interquartile range obtained with the bone transducer is smaller than with mastication (respectively 4.5 and 6.2 dB). With the bone transducer, the smaller interquartile range measured in the contralateral ear compared to the ipsilateral ear are in accordance with results from Reinfeldt et al. (2013). As speculated by Reinfeldt et al., the OE_{obi} STD measured in the ipsilateral ear compared to the contralateral could be more variable due to the soft tissues' proximity to the stimulation position at the ipsilateral mastoid (Reinfeldt et al., 2013). In contrast, the contralateral ear's soft tissues are excited via the skull and not directly by the bone transducer. With the mastication of a chewing gum, the variability obtained in both ears are comparable. Using the mastication as a BC stimulation source must be investigated further to understand the influence of mastication's characteristics on OE_{obj} STD: jaw movement, intensity, duration, food being masticated, background noise, etc. In addition, although the average OE_{obj} STD obtained with both stimulations are similar, their characteristics are very different. Mastication produces the excitation of the teeth, bones, muscles, and soft tissues of the head, whereas the bone transducer excites the soft tissues and the skull near the site of the stimulation, i.e., in this study, the mastoid process. Nevertheless, these findings suggest that mastication could be used as a quick alternative to the bone transducer to measure $OE_{obj}^{\ \ STD}$, notably because of its compatibility with earmuffs (no physical interference with the headbands), the broadband stimulation it produces, and the lower variability achieved when compared to the bone transducer. Moreover, mastication is simple, straightforward and does not require additional equipment (bone transducer, audiometer), which makes it adapted for a field measurement methodology of the OE_{obj} STD, provided that a quiet environment is used to perform the tests. A more thorough investigation is however required to validate this approach.

3. Differences between speech-based and BC stimulations

The difference between the OE measured with speechbased stimulations and BC stimulations is now highlighted. In Fig. 7, the median of the OEI obtained with random numbers is 15 to 22 dB less than with the mastication and the bone transducer. This difference can be explained by the AC component of the voice, i.e., the sounds radiated through the lips and nostrils that reaches the ears (Porschmann, 2000), that is more important in the unoccluded ear configuration (open ear). When the ear is unoccluded, the airborne component contributes to the measured SPL in the earcanal. When the ear becomes occluded, this contribution is partly blocked by the occlusion device (Hansen and Stinson, 1998). As the AC contribution is diminished in the occluded ear configuration, the resulting OE_{obj} STD is lower in comparison to the bone transducer. With the latter, the airborne component due to the acoustic radiation of the casing is small; even more in this study as special care was taken to ensure it was minimal. As of now, measuring the OE_{obj} STD with both stimulations (speech, BC stimulation) allows one to characterize the OE. Using both stimulations provides a method to obtain different values of OE_{obj} STD (or OEI) when using a specific HPD in different situations during a workday. Speech could allow one to measure an OE_{obj}^{STD} representative of when a worker is at their workstation and when verbal communication is needed with colleagues around. A BC stimulation, such as mastication, could allow one to measure an OE_{obi} STD representative of other events occurring during the day while the HPD is worn in a quiet environment, such as in a break room or an office. For the scope of this work, which focuses on earplugs, an approach based on using one's own voice to measure OEobj is preferred over BC stimulation sources (mastication, bone transducer) as speech is more often reported as the main source of OE_{exp} when workers are using HPDs. Moreover, because the AC component of the voice is measured by the microphone in the assessed in a test room with moderate ambient noise level (levels yet to be defined) provided the AC component of the voice dominates the SPL measured in the earcanal. By eliminating the need for a quiet or controlled environment, such approach would be adapted for field assessment of OEobi. Nonetheless, the results obtained with BC stimulations are deemed relevant as they could benefit studies on hearing aids or even future studies on HPDs if BC stimulation sources are identified as an important source of OE_{exp}. Nevertheless, further investigation would be necessary to study the influence of background noise on the magnitude of the OE_{obi} STD as all measurements were conducted in a quiet and controlled environment during this study.

D. Comparison between measurement methods

The results presented up to this section were obtained using the "standard" method [see Fig. 3(a)]. This method is now compared with the two other methods introduced

earlier, i.e., the real-time method [see Fig. 3(b)] and the NRbased method [see Fig. 3(c)]. To compare them one against another, the OE_{obj} obtained with the three methods is shown individually as a function of frequency in Fig. 9 for the speech-based stimulations at the 70 dB(A) vocal effort and mastication. Only the data obtained in the ipsilateral ear is shown for all stimulation sources. The upper panels display the average values while the lower panels show the standard deviation to evaluate the variability associated with each method. For all stimulation sources, the average OE_{obj}^{STD} and OE_{obj}^{RT} are very similar between 160 and 2000 Hz; the difference is at the most 3.5 dB, but typically less than 2 dB. In addition to providing similar results, measuring the ${\rm OE_{obj}}^{RT}$ significantly reduces the variability. With random numbers, the standard deviation is slightly less with ${\rm OE_{obj}}^{RT}$ than with OE_{obj}^{STD} , but this improvement is more significant when vowels are used. It corroborates the hypothesis that a part of the variability when measuring the OE_{obi} STD with vowels can be associated with the difficulty of reproducing the same vowels twice (Hansen, 1998). With mastication, the variability obtained with OE_{obj}^{RT} is however

slightly larger below 500 Hz compared with OE_{obj} STD.

When considering OE_{obj} NR, the NR-based method overestimates the magnitude of OE_{obj} compared to the other two methods. Since the occluded SPL is measured similarly for the three methods (i.e., Lp'_{EC} (1) in Fig. 3), the overestimation is mostly attributed to a difference in the estimation of the unoccluded SPL. By construction, there is no unoccluded condition with the NR-based method. In this method, the unoccluded SPL is rather approximated by the SPL measured at the entrance of the earcanal, just outside of the protected earpiece, using the OEM [see. Lp'_{OUT} (1) in Fig. 3]. However, by approximating the unoccluded SPL by Lp'_{OUT} (1), the contribution of certain AC and BC paths and

mechanisms are either blocked or significantly modified by the presence of the protected earpiece. This can lead to an SPL that is lower compared to the SPL measured inside the unoccluded earcanal, thus leading to the overestimation of OE_{obj} NR. This overestimation depends on both the frequency and the stimulation source that is used. With speech, the AC component of the voice is the main contributor below 800 Hz for both the SPL measured by the OEM in the protected condition and for the SPL in the unoccluded ear, which leads to similar OEobj values with the three measurement methods. Above 800 Hz, OE_{obj} NR overestimates the OE with speech. In this case, approximating the unoccluded SPL with Lp'_{OUT (1)} fails to capture (1) the earcanal's quarter wavelength resonance (Hammershoi and Moller, 1996), (2) the diffraction of the head, torso and pinna (Hammershoi and Moller, 1996) (3) the acoustic radiation of the earcanal's walls (Stenfelt et al., 2003), and (4) the acoustic radiation of the tympanic membrane (Stenfelt et al., 2003) that are not seen by the OEM due to the presence of the protected earpiece. In the case of mastication, the overestimation is larger and is present over the whole studied frequency range. This is attributed to the fact that the low noise level measured just outside the earpiece is a poor approximation of the unoccluded ear SPL. Indeed, with a BC dominated excitation such as mastication, the main contributions to the unoccluded SPL come from four above-mentioned paths and mechanisms, which are clearly missed when using Lp'_{OUT (1)} as an approximation. Moreover, the AC component is minimal (or even inexistent) as the participants kept their mouth shut while chewing. Therefore, using Lp'OUT (1) to approximate the unoccluded SPL with BC stimulations is unadvised and limits the usability of the NR-based method for such stimulations.

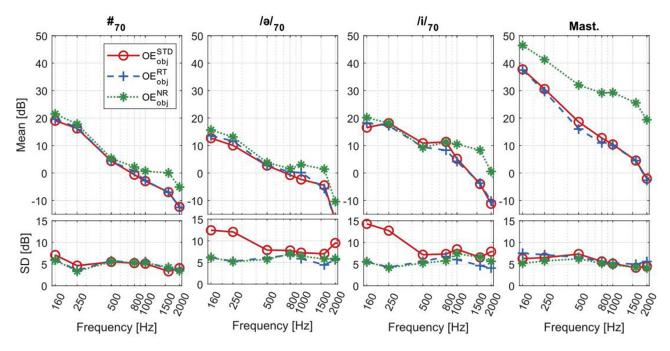


FIG. 9. (Color online) OE_{obj} as a function of frequency and measurement method for speech-based stimulations and mastication.

These findings suggest that measuring OE_{obj} with the real-time and the NR-based methods provides advantages over the widely used standard method. The real-time and the NR-based methods allow one to measure OE_{obi} faster, i.e., both the occluded and unoccluded SPL are measured simultaneously and subject to less variability as the stimulation is produced once. Furthermore, both methods could lead to an even more simplified measurement methodology when speech is used as a feedback system is not necessary because of the small effect of vocal effort on OEobj (as previously discussed). Therefore, the participant only needs to speak once. This reduces the cognitive workload, i.e., not having to focus on monitoring the feedback system, and therefore makes it possible to use more realistic and complex speech contents, such as a list of words or sentences. When comparing the real-time method to the NR-based method, each offer advantages and disadvantages over the other. On the one hand, the real-time method is more flexible as it can be used with every type of stimulation without overestimating the OE_{obj}, but at the cost of having both ears instrumented and in opposite configuration, i.e., one occluded and the other unoccluded. On the other hand, the NR-based method provides the advantages of requiring a single ear to estimate OE_{obi}, but is not reliable with BC stimulation sources. Moreover, as a single ear is required, this approach allows computing OEobi in both ears simultaneously and independently, thus leading to a more robust OEobi as it is not affected by possible anatomical differences between both ears. Although systems using the NR-based method have already been used (Bernier and Voix, 2013; Bouserhal et al., 2019; Mejia et al., 2008), patented (Killion, 1996, 2019) and commercialized (Audioscan, 2021), the findings in the present study confirm the accuracy and robustness of this method against the standard and real-time methods when speech is used. Moreover, as the scope of this work focuses on the OE induced by earplugs, these results suggest the NR method is the most adapted and the most practical to measure OE_{obi} generated by one's own voice as speech is often reported as the main OE_{exp} by HPD users.

E. Limits of the study

Measuring OE_{obi} requires miniature or probe microphones to obtain the SPL in the open and occluded ear canal. To control the insertion depth and to simplify the procedure, prototypes of microphonic earpieces equipped with Comply T-400 ear tips were used in this study which ensure a safe and consistent positioning of the microphones in the earcanal. However, this occlusion device differs from commercially available HPD; thus, the results obtained in this study are valid for this specific occlusion device. Nonetheless, it is expected that similar conclusions about OE measurement methods would be drawn using other earplug-type HPDs. These results could be further validated by conducting additional measurements with other earplugs, earmuffs as well as HPD and hearing aids equipped with various components (acoustic filters, electronic filters,

speakers, microphones) to investigate their respective influence on the OE.

As mentioned in Sec. IVB, technical limitations were encountered with the clinical equipment, i.e., commercially available audiometer and bone transducer, as they are not designed for research purposes. Some measurement artefacts were encountered and induced a possible underestimation of the OE_{subj} at low-frequency for many participants. The combination of the audiometer's minimal operation limit, i.e., lowest signal intensity of $-10 \, dB$ HL, with the specific population recruited for this study, i.e., hearing thresholds equal or better than 20 dB HL, limited the OE_{subi} that could be measured to 30 dB HL. In reality, however, most participants had low-frequency HTLs between 0 and 5 dB HL, which limited the measurable OE_{subj} even more. However, the measurement artefact mostly occurred when measuring the occluded hearing thresholds; as the OE phenomenon improves (decreases) the hearing thresholds, most participants detected the signal generated by the bone transducer at the audiometer's operation limit quickly and without hesitation. Because of this, hearing thresholds measured at $-10 \, dB \, HL$ were not deemed reliable as they could have been lower in reality. To address this measurement artifact in the analysis, the data were filtered to remove any pair of hearing thresholds in a specific frequency band (occluded and unoccluded) if one or the other was measured at $-10 \, dB$ HL. This made it possible to conduct analyses with the OE_{subi} data, but at the cost of significantly reducing the sample size in the low-frequency range (see Sec. IV B), thus limiting the interpretation of the results. To the authors' knowledge, this problem was not encountered nor mentioned in previous studies. These results have been deemed interesting to be included in the paper to highlight the limitations encountered when using a commercially available equipment that is not specifically designed to perform the type of measurements presented in this study.

The results obtained in this study show how difficult it is to carry out OE_{obj} and OE_{subj} measurement with low variability. Although the insertion depth was controlled relative to the tragus by the microphonic earpieces, the inter-subject differences in the earcanal lengths and anatomies contribute to the measurement uncertainties. In future works, the insertion depth should be controlled relative to the tympanic membrane, although doing so can be cumbersome as the insertion of an instrument near the tympanic membrane (i.e., to determine the earcanal's length) is a procedure often reserved to audiologists or trained professionals. While some stimulation sources resulted in less variability than others, i.e., random numbers vs vowels, the inter-subject differences in the speech organ and how each participant produces their voice also contributes to the measurement uncertainties. With mastication, uncertainties were associated with the mastication itself; the jaw movements, the food masticated, the duration of the mastication are elements that should be further investigated. Although it is deemed simple to examine, it was not possible to conduct additional measurements considering that the measurements

sessions were already long and tiring for the participants (close to three hours). Thus, it is without a surprise that the standard deviations obtained for OE_{obj} (and OE_{subj}) are of the same order of magnitude as those obtained in studies on sound attenuation [microphone in real ear (MIRE) and REAT] (Berger and Kerivan, 1983) as well as on OE_{obj} (Reinfeldt *et al.*, 2013; Stenfelt and Reinfeldt, 2007). Because of these large standard deviations, data analysis and results interpretation are somewhat limited.

The results presented in this study were obtained in a laboratory with a specific population; most were young adults with normal hearing and non-abnormal ears that were mostly unfamiliar with using HPDs. During the measurements, the participants were in an audiometric booth with a low-level background noise, mostly still. The earpieces were fitted by the experimenter and most participants had limited experience with HPDs. In contrast, a typical work-place environment greatly differs; workers move and interact with their work environment, communicate with their colleagues, may remove and reinstall their HPD, and may be subjected to high-level background noise. For these reasons, the OE_{obj} measured on workers in a workplace environment might be different than when measured on participants in a controlled environment.

V. CONCLUSION

As there is no consensus nor a standardization on how to measure the objective OE (OE_{obi}) induced by in-ear devices, different approaches to measure OEobi were investigated in this study with the intention of finding a simple and robust methodology adapted for clinical and field assessments. Using microphonic earpieces, OEobj was measured on human participants in laboratory conditions. Based on the three experimental aspects investigated (i.e., stimulation source to induce the OE, measurement method of OE_{obi}, indicator to quantify OE_{obj}), it is suggested to assess OE_{obj} by (i) using the participant's own voice, (ii) measuring SPLs using the NR-based method (i.e., using the protected earpiece's inner ear microphone to measure the occluded SPL and the outer ear microphone to estimate the unoccluded SPL), (iii) quantifying OE_{obj} with the single value indicator SVI of the average value in the 160 Hz to 500 Hz frequency range. Using the participant's voice is a simple stimulation source to induce the OE that is also associated with a common complaint made by in-ear device users. When paired with the NR-based method, the choice of speech content as well as the vocal effort is at the discretion of the experimenter and does not affect the reliability of the results (i.e., variability). The NR-based method was found to be a versatile approach to measure OE_{obj} as reliable results (with speech) can be obtained for both ears independently and a feedback system for the participant is not needed. However, the reliability of this approach is limited to the frequency range below 1000 Hz as OE_{obi} tends to be significantly overestimated above 1000 Hz. Finally, using the average OEobi value in the 160 Hz to 500 Hz frequency range provides a

simple and useful SVI. This indicator is easy to comprehend, even for a non-specialist, and is adapted for quick comparisons with other values (e.g., when comparing different in-ear devices or stimulation sources). With the proposed methodology, future works should aim at conducting clinical and field trials to validate the methodology with other in-ear devices and to investigate the correlation between OE_{obj} and the discomforts they generate, so that the OE can be reduced when designing and fitting in-ear devices.

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