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Reliability of an extended version of the 3M™ Eargage Tool to assess earcanal size and assist earplug selection

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Reliability of an extended version of the 3M™ Eargage to Assess Earcanal Size and Assist the Earplugs Selection

Abstract

Objective

Evaluate the ability of an extended version of the 3M™ Eargage to estimate the earcanal size and assess the likelihood that a particular earplug can fit an individual's earcanal, ultimately serving as a tool for selecting earplugs in the field.

Design

Earcanal morphology, assessed through earcanal earmolds scans, is compared to earcanal size assessed with the extended eargage (EE) via box plots and Pearson linear correlations coefficients. Relations between attenuation measured on participants (for 6 different earplugs) and their earcanal size assessed with the EE are established via comparison tests.

Study sample

121 participants exposed to occupational noise (103 men, 18 women, mean age 47 years).

Results

The earcanal size assessed with the EE allows for estimating the area of the earcanal's first bend cross-section (correlation coefficient r = 0.533, p<0.001). Extremely large earcanals (12.7 % of earcanals in our sample) lead to significantly lower earplug attenuation (potentially inadequate) than smaller earcanals.

Conclusions

The EE is a simple and inexpensive tool easily deployable in the field to assist earplugs selection. When extended with sizes larger than the maximum size of the commercial tool, it allows for detecting individuals with extremely large earcanals who are most likely to be under-protected.

Keywords: Earplugs, hearing protection device, earcanal sizing tool, personal attenuation rating, morphology

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1. Introduction

Occupational exposure to hazardous noise ranks among the most prevalent and widespread risks faced by workers worldwide. In regions such as Quebec (Canada), noise-induced hearing loss (NHIL) stands as a prominent and financially burdensome occupational disease (Lebeau 2014). To mitigate these risks, disposable and reusable earplugs have become indispensable tools for curtailing the transmission of noise to the tympanic membrane and averting NHIL. These earplugs come in diverse configurations, encompassing an array of shapes, sizes, and materials. Typically, earplug selection hinges upon their primary function: noise attenuation, frequently quantified by the Noise Reduction Rating (NRR) – a lab-measured metric (ASA/ANSI S12.6– 2016) known to often overestimate real-world attenuation (Berger and Voix 2022). To address this disparity, derating schemes, such as reducing the NRR by a specific percentage (e.g., 50%), contingent on the type of hearing protectors (disposable or reusable earplugs, earmuffs, dual protection), have been proposed (CSA Z1007 2022; CSA Z94.2-14. 2014; NIOSH 1998). Nevertheless, these derating schemes pertain to user groups and do not account for individual-specific physical characteristics.

In contrast to other protective equipment, like shoes or gloves, which are available in distinct sizes clearly indicated on the packaging, earplugs are typically marketed as "one-size-fits-most." Nevertheless, earcanal size plays a pivotal role in attenuation (Abel et al. 1990; Poissenot-Arrigoni et al. 2022) and must be considered during the earplug selection process. Recent research assessed the earcanals of 121 workers, employing earmold scans to capture various morphological indicators, including girth, ellipticity (referred to as ovality in Poissenot-Arrigoni et al. 2022), cross-sectional characteristics, length, tortuosity, and conicity. The results underscored the crucial relationship between earplug attenuation and earcanal morphology. Specifically, the girth (circumference and area) of the cross-section at the first bend (FB) of the earcanal exhibited a noteworthy, negative correlation with earplug attenuation: a wider FB cross-section correlated with lower attenuation (Poissenot-Arrigoni et al. 2022). This underscores the need to consider earcanal morphologies, especially the girth near the FB region, during earplug selection.

While employers may be obligated to provide a variety of hearing protectors (OSHA 1983), no consensus or established method exists for selecting earplugs that ensure adequate attenuation for individual workers, especially when multiple sizes are available. For example, certain roll-down foam earplugs come in regular and small sizes, but target user groups for each size are often not clearly identified on the packaging. Furthermore, there's a lack of guidance in the standards regarding the selection of earplugs based on earcanal shapes and sizes.

One promising development to improve the earplug selection process is the advancement of fit testing and the adoption of field attenuation estimation systems (FAES) to measure individual attenuation (Voix et al. 2022) A FAES, is a tool used to assess the effectiveness of hearing protection devices, such as earplugs, in real-world work environments. It measures the noise attenuation achieved by these earplugs on an individual basis, helping to ensure proper hearing protection for workers in various noise-exposed settings. However, FAES adoption in hearing conservation programs is far from widespread and FAES-based selection methods would benefit from a pre-selection of earplugs based on the user's earcanal size, reducing the number of earplugs to test and allowing more time for user training and motivation in proper earplug use, a critical aspect of hearing conservation programs.

To determine efficiently the most appropriate earplugs for different earcanal types, it is useful to assess the earcanal size. Intra-aural 3D scanning devices offer the capability to fully digitize both the earcanal and the pinna. However, their use is limited in practical settings due to proprietary technologies primarily employed in the production of hearing aids and protectors. An alternative approach, frequently utilized by manufacturers of custom earplugs and hearing aids, as well as in studies of earcanal morphology (Lee et al. 2018; Voss et al. 2020), involves the creation of earmolds for earcanals. These earmolds are typically crafted using a soft silicone material that solidifies after insertion into the earcanal. Once removed, these earmolds can be scanned to digitally capture a section of the pinna, including the concha, and the accessible portion of the earcanal, extending a few millimeters beyond the second bend region but not reaching too close to the tympanic membrane for safety considerations. However, merely digitizing earcanal morphology falls short of determining its size. Essential indicators, such as circumference, which correlates with earplug attenuation, must be extracted from the digital representations of the earcanal. Quantifying earcanal size requires complex computations. The latter method presents challenges, especially in terms of identifying consistent landmarks on the molds for measurement, making it impractical as a dedicated field tool for the earplug selection phase.

To date, the most expeditious and straightforward method for assessing earcanal size relies on the 3M™ Eargage (ASA/ANSI S12.6– 2016; Berger 2013; Thomas, Wright, and Casali 1994). This tool facilitates rapid evaluation of the "earcanal opening," a term used in the (ASA/ANSI S12.6–2016) standard to describe the sized area of the earcanal. The 3M™ Eargage includes five plastic spheres, designated as extra-small (XS), small (S), medium (M), large (L), and extra-large (XL), each with specified dimensions. The procedure involves sequentially inserting the spheres into the earcanal, starting with one appearing slightly smaller than the earcanal opening, and selecting the one that fits best (this process is applied to both the right and left earcanals). The simplicity and field-applicability of the 3M™ Eargage makes it an attractive choice for assessing earcanal diameter. However, few studies have evaluated the precision of 3M™ Eargage for sizing earcanals.

Actually, the commercial 3M™ Eargage described previously represents the contemporary version of the original "American Optical Corporation Eargage" (referred to as "AO Eargage"): a device consisting of five plastic spheres with diameters ranging from 7.6 to 11.4 mm. The primary function of the AO Eargage was to ensure proper fitting of AO V-51R earplugs (a 5-sized premolded earplug with a single flange that doesn't insert deeply into the earcanal) in an individual's earcanals (Mears 1996). While the AO Eargage was specifically designed for AO V-51R earplugs, it has come to be used for sizing earcanals for other earplug types. However, its design and accuracy may have been better suited for AO V-51R earplugs.

Thomas et al. (1994) compared earcanal sizes of 552 participants assessed using the 3M™ eargage (measurements independently conducted by two experimenters) and caliper measurements on earmolds of participants' earcanals. Comparisons between the 3M™ eargage measurements from the two experimenters revealed that the 3M™ eargage provided repeatable measurements. Nevertheless, they found significant differences between the earcanal opening measured with the 3M™ eargage and the elliptical cross-sectional area obtained from caliper measurements at the base of the concha (near the earcanal entrance) and at a depth of 4.8 mm inside the earcanal (around the FB region). They concluded that the 3M™ eargage, with its spherical tip, distorts the elliptical earcanal cross-section and is inadequate for anthropometric classification applications. Samelli and his coworkers (Samelli et al. 2018) employed an earcanal sizing tool to assess earcanal size and compared it to a tympanometer, which measures earcanal volume. They observed that earcanal volume is not directly related to the earcanal opening, suggesting that an earcanal with a narrow, small diameter could be deep and have a larger volume. In particular, the definition of the earcanal opening, as measured with the commercial 3M™ Eargage, remains ambiguous.

In a field campaign aimed at collecting data on the usage and comfort of earplugs, a cohort of Canadian workers underwent earcanal morphology assessment (Poissenot-Arrigoni et al. 2023). The cohort consisted mainly of males who had been regular earplug users for several years and exhibited notably large earcanals. Consequently, three supplementary spheres labeled XXL, XXXL, and XXXXL were integrated into the tool to accommodate extremely large earcanals, surpassing the size of XL. This extended 3M™ Eargage was primarily utilized to determine any potential correlation between discomfort induced by earplugs and earcanal morphology. However, no investigation was undertaken to explore the connection between earcanal morphology assessed with the extended 3M™ Eargage and the fit of the earplugs. Throughout the remainder of the manuscript, the 3M™ Eargage, which underwent augmentation with three additional spheres, is referenced as the extended eargage (EE). The initial commercial tool manufactured by 3M is designated as the commercial 3M™ Eargage within the context of this study.

The objective of this study is to evaluate the ability of the EE to estimate the earcanal size and assess the likelihood that a particular earplug can fit an individual's earcanal, ultimately serving as a tool for selecting earplugs in the field. As such, this research addresses the following questions: (i) Which zone of the earcanal is effectively sized by the EE and with what level of accuracy? (ii) What is the relationship between the earcanal dimensions sized with the EE and the personal attenuation rating of various commercial earplugs, typically labeled as "one-size-fits-most," and constructed from different materials and shapes? (iii) Can the EE identify any asymmetry between the left and right earcanals, necessitating different-sized earplugs for each ear?

The subsequent sections outline the methodology, including procedures for earcanal sizing through earmold scans, the use of the EE, and attenuation measurements for six disposable and reusable earplugs. Statistical tests for comparing earcanal sizing methods (EE vs. earmold scans), calculating correlations between earplug attenuation and EE sizing measurements, and assessing earcanal asymmetry are also detailed. The results section systematically addresses the aforementioned research questions before concluding on the applicability of the EE in the earplug selection phase.

2. Methodology

a. Participants

The study presented here uses the secondary data of morphologic and attenuation data collected during a field survey on earplugs comfort carried out from 2018 to 2020 [Grant IRSST #2015-0014] approved by the ethical committee of the École de technologie supérieure (ÉTS) (ethic certificate H20171101). The study's sample comprised 121 participants, predominantly male (n=103; 85%), employed across three distinct Canadian organizations. The participants ages ranged from 21 to 64 years (M=46.5, SD=10). All participants reported occupational noise exposure and the use of earplugs before their involvement in the study.

b. Morphologic data acquisition

i. Earmolds scans method

A comprehensive morphologic and attenuation data acquisition has been described in Poissenot-Arrigoni et al. (2022). In this paper, only the computation and indicators relevant to the present study are presented.

The morphological characteristics of both the left and right earcanals for each participant were obtained through the scanning of earcanal earmolds. These earmolds were molded by various custom earplug manufacturers and were scanned either by the manufacturers themselves or in our laboratory using an Einscan-SP 3D scanner (Hangzhou Shining 3D Tech Co., China). For a more detailed account of the earmold molding and scanning process, refer to (Poissenot-Arrigoni et al. 2022). It was assumed that the resulting earcanal scans accurately represented the earcanal morphology of the participants. Any alterations in earcanal morphology due to the acquisition process such as the variation arising from the molding of the earcanal by different earplug manufacturers and the scanning of the earmolds were considered negligible. The differences observed between the scans were attributed solely to disparities in the earcanal morphologies of the participants.

The earcanal takes on an "S-shaped" configuration, extending from the lateral concha to the medial tympanic membrane (refer to Figure 1). The shape and size of the cross-sections within the earcanal vary along its curvilinear axis, the axis passing through the centroid of the earcanal cross-sections. To standardize the placement of these cross-sections in an objective and repeatable manner, the curvilinear axis of each earcanal was extracted utilizing the method developed by (Stinson and Lawton 1989). Subsequently, the cross-sections were positioned perpendicular to this curvilinear axis.

The cross-section entrance (E) was defined at the base of the concha, utilizing a landmark established in (Lee et al. 2018). The first bend (FB) was situated at the initial point of maximum curvature along the curvilinear axis and positioned perpendicular to it, typically located a few millimeters beyond the entrance within the cartilaginous portion of the earcanal. The second bend was situated deeper within the earcanal, corresponding to the second point of maximum curvature along the curvilinear axis and usually in close proximity to the cartilaginous-bony junction.

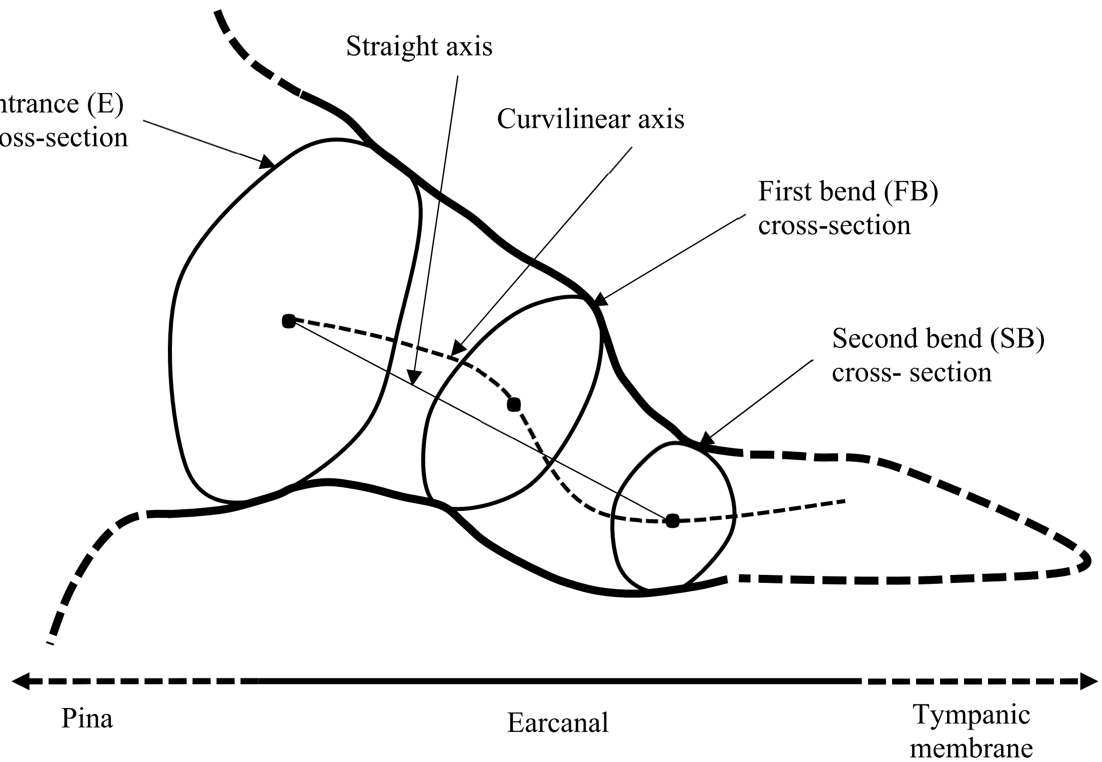

Figure 1 : Earcanal description. Dark thick solid lines represent earcanal walls in the region of interest for this study. Dark thick dotted lines represent earcanal regions that are ignored. Dark thin solid lines represent reference cross-sections of earcanal. Dark thin dotted line represents the curvilinear axis of the earcanal.

In this study, several morphological indicators of earcanals previously employed by Poissenot-Arrigoni et al. (2022) have been considered. These indicators were selected due to their established correlations with earplug attenuation and their potential to identify the area of the earcanal that corresponds to the sizing performed with the EE. Specifically, three indicators related to earcanal circumference, encompassing the areas of the E, FB, and SB cross-sections, have been extracted. Additionally, indicators pertaining to the length of the curvilinear axis of the earcanal between cross-sections E and FB, as well as between cross-sections E and SB, have been calculated by the authors.

Following a data inspection, the authors excluded two earcanals from the database as the computation of the curvilinear axis was not feasible using Stinson and Lawton's method. Additionally, three more earcanals were removed by the authors because the proposed method for determining their cross-section FB resulted in intersections with the concha, leading to highly unusual shapes and significantly enlarged circumferences (resulting as outliers to the statistical analysis).

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ii. Earcanal sizing tool measurement

The commercial 3M™ Eargage comprises a plastic sphere and a tab both affixed to a stem, as depicted in Figure 2. The stem allows the operator to hold the tool and insert the sphere inside the earcanal until the tab makes contact with the concha. This 3M™ eargage is commercially available in five sizes designated as extra-small (XS), small (S), medium (M), large (L), and extra-large (XL). In this study, an "extended" version of the tool (the EE), incorporating three additional larger spheres named XXL, XXXL, and XXXXL, has been considered to size all participants' earcanals. These extended spheres were 3D printed, and their respective diameters are summarized in table 1. Both the right and left earcanals of all workers are sized following the ASA/ANSI S12.6-2016 annex B procedure. The instructions for this procedure are as follows: “choose a sphere that appears to be a little small for the earcanal being measured. Pull the pinna outward and upward to assist in placing the gauge in the earcanal opening until the tab of the gauge touches the floor of the concha. Release the pinna and observe if the entire earcanal opening conforms to the sphere. Then pump the gauge in the earcanal with a slight, gentle movement of about 1–2 mm. Ask the subject if s/he feels a suction or pressure. Move up in gauge size until the subject feels suction, the earcanal opening appears to conform to the sphere, and the gauge tab still lies on the concha floor, indicating a fully inserted sphere. The sphere accommodating these requirements represents the size of the earcanal. If suction can only be achieved with a partial insertion, recheck the next smaller size to confirm. The assigned size will be the size that achieves suction”.

Nitrile finger cots were employed to encapsulate the EE, and were replaced for each worker. Although the application of single-use Nitrile finger cots is not explicitly delineated in the ASA/ANSI S12.6-2016 annex B procedure, the Canadian protocol “Infection prevention and control guidelines for audiology” established by the Interorganizational Group for Speech-Language Pathology and Audiology (2010) advocates for the preference of disposable or single-use alternatives when handling "semi-critical" tools. Audiologists conducting field measurements have attested that the Nitrile finger cots did not impede the visual confirmation of the gage tab resting on the concha during measurements, as mandated by the ASA/ANSI S12.6-2016 annex B procedure).

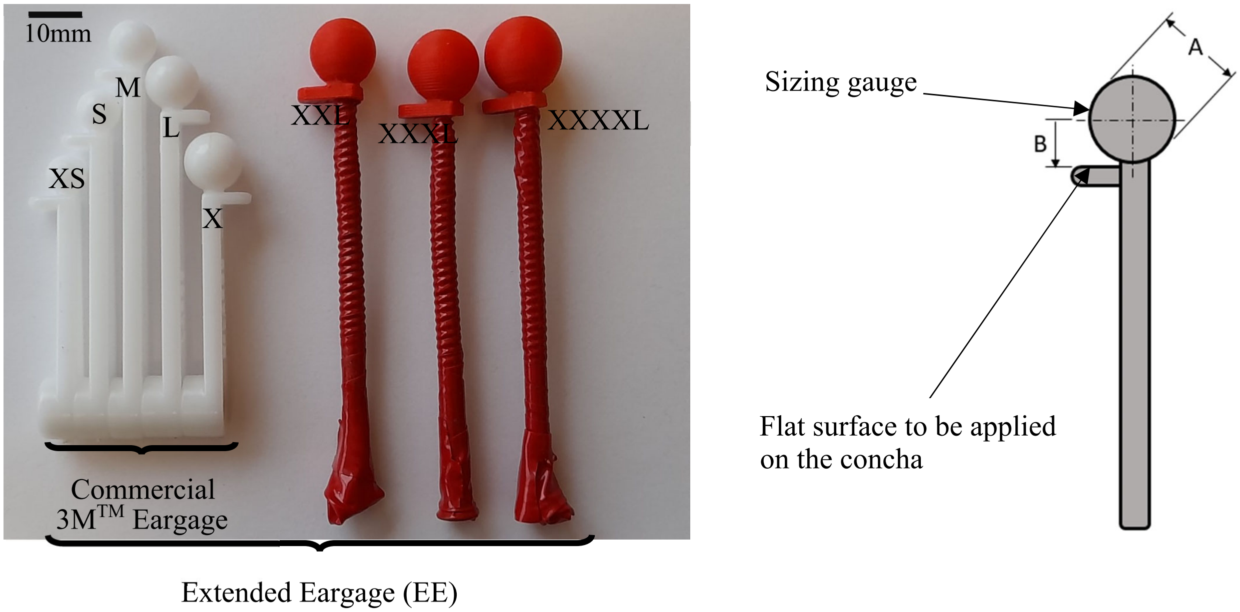

Figure 2 : a) Commercial 3M Eargage™ earplug sizing tool on left and gages for extended eargage (EE) on right. b) Illustration of dimensions A and B for the EE.

c. Attenuation data acquisition

In terms of attenuation data acquisition, this study relies on the secondary data of attenuation measurements gathered during a field survey focused on earplug comfort. In this study, participants tested an earplug from each of the families: roll-down-foam, premolded, push-to-fit-foam. An earplug from the roll-down foam family was offered in two sizes: regular and small. During a fit training session, both the audiologist and the participant selected the size based on functional comfort criteria. If the regular size was found to be too large, deep insertion of the earplug posed challenges and it felt as though it might almost slip out of the earcanal. In such cases, a smaller-sized earplug was suggested to the participant, who then made several attempts to insert it into the earcanal. Note that since the multi-flange elastomeric polymer earplug was the only one in the premolded earplugs family in this study, it was tested by all participants. Not all participants finished the 7-week field study. The participants, the same individuals who had their earcanals cast, engaged in one-on-one sessions with an audiologist who provided them with training on the specific model of earplugs to be tested. The FAES 3M™ E-A-Rfit™ Dual-Ear Validation System served as the training tool for this purpose. This system employs surrogate earplugs and allows for the calculation and export of a personal attenuation rating (PAR) for each ear. The reference names of the six earplugs considered in this study can be found in table 2. The surrogate earplugs are identical to the actual earplugs (see manufacturer names of the earplugs in the table 2) except for the hole that penetrates the earplug with a thin flexible tube connected to a measurement microphone.

Detailed information regarding the training procedure can be found in (Martin et al. 2019) and (Poissenot-Arrigoni et al. 2022). In brief, the audiologist initially instructed the worker on how to correctly insert the earplugs, when to replace them, and how to verify proper fit. Subsequently, the worker independently inserted the surrogate earplugs for an initial PAR trial. If both ears achieved an initial $PAR_{84\%}$ of at least 50% of the manufacturer's NRR value (which is considered to be the first threshold value), the training was considered complete. However, if this threshold was not met, the worker was instructed to readjust the earplugs for a second PAR trial, with the same goal of achieving 50% of the NRR. Given that most of the workers in the study had an average daily sound exposure level for 8 hours less than 95 dBA, a second threshold value of $PAR_{84\%}$ = 10 dB was accepted. If the second trial reached or exceeded this second threshold value of $PAR_{84\%}$ = 10 dB for each ear, the training concluded. In cases where this threshold value couldn't be achieved, the audiologist attempted a third placement. If this third PAR trial proved to be adequate, the worker was then asked to replicate the correct placement, ensuring they could do it themselves (a third trial, and more if needed). Finally, if both ears failed to reach a $PAR_{84\%}$ of 10 dB for all trials, based on the worker's efforts, the earplug model was deemed unsuitable for that participant. Most workers required between one and three trials per session to properly fit their earplugs, although for roll-down-foam earplugs, six trials (for one ear) were sometimes necessary. In a few cases, more than 10 trials were needed to attain the safe-threshold attenuation values during training. While the $PAR_{84\%}$ was employed during training to adopt a conservative approach in an insertion training scenario, this study utilizes the $PAR_{50\%}$ as the attenuation data. The term "PAR" in the remainder of the paper refers to the $PAR_{50\%}$ for ease of reference. Note that unlike the NRR, the PARs are not a description of group data, but rather specific to an individual.

For each ear of every worker and for each specific earplug, the test data that resulted in the highest PAR was retained, and the research team extracted this PAR value as the attenuation data. The training process leading to the PAR values considered in this study represents a standard training that individuals may receive as part of a hearing conservation program employing FAES.

d. Statistical analyses

Various levels of statistical analyses were conducted using IBM® SPSS® Statistics 27 (IBM Corp., 2020). Initially, descriptive statistics such as means and frequencies were computed to understand the characteristics of the sample. Next, to determine which region of the earcanal was accurately sized with the EE and the degree of accuracy, Pearson linear correlation coefficients were calculated between variables measuring the earcanal size assessed with the EE and the circumference of the three characteristic sections of earcanals evaluated with the earmold scan method.

To investigate the relationship between the earcanal dimensions sized with the EE and the attenuation of 5 one-size-fits-most commercial earplugs and one two-size commercial earplug made from various materials and shapes, correlations between earcanal size evaluated with the EE (diameter A in Figure 2) and earplug attenuation were examined. Mann Whitney U non-parametric comparison tests were also conducted to assess whether there were significant differences in earplug attenuation among earcanals categorized into different EE size groups. This non-parametric test was employed to compare two groups with unequal sample sizes, as few earcanals were sized in extreme categories (XS and XXXL), resulting in uneven group sizes.

Lastly, to determine if the EE can be used to identify an asymmetry between the left and right earcanals, potentially necessitating earplugs of different sizes for each ear, paired T-tests were performed between the right and left ears of each participant for all morphological indicators computed with the scan method (i.e., cross-sections E, FB, and SB areas), the EE measurements, and PARs.

3. Results and discussion

a. Ability of the EE to measure earcanal size

The results of EE measurements are presented in Table 1. The first two columns provide the EE size and the sphere diameter measured with a caliper (with a resolution of 0.01 mm). The subsequent columns present the number and percentage of earcanals assigned to each size, ranging from XS to XXXXL, considering all earcanals in the dataset and separately for male and female earcanals.

In general, the majority of earcanals (82.7%) fall into the M, L, or XL size groups. Only a small proportion, 4.6%, are categorized as S or XS earcanals, while 12.7% of earcanals belong to the XXL or XXXL categories. Notably, there are no earcanals sized in the XXXXL group. It's worth mentioning that there are very few workers classified in the {XS + S} category. This trend can likely be attributed to the composition of the participant sample, which predominantly consists of males. As previous research has shown, female earcanals are generally smaller in girth than male earcanals (Chiou, Huang, and Chen 2016; Fan et al. 2021; Lee et al. 2018). This trend is reaffirmed in this study, where 0% and 1.5% of male earcanals fall into the XS and S size groups, respectively, whereas 11.4% of female earcanals are categorized as XS, and another 11.4% as S. In contrast, XXL and XXXL sizes account for 8.9% and 5.9% of male earcanals, with no female earcanals sized in these categories.

The finger cots utilized for EE coverage were exceedingly thin; however, it cannot be ruled out that this might have influenced the measurements, in particular because they could have changed the texture of the spheres.

Audiologists administering the measurements with the EE also noted instances where there was a gap of the order of the millimeter around the XL gauge in numerous ears, indicating no contact with the earcanal wall, even when the gauge tab adhered to the concha, following the specifications outlined in the ASA/ANSI S12.6 standard procedure. It is noteworthy that the XL gauge represents the largest size within the commercial 3M™ tool. Consequently, it is plausible that male participants in this study exhibited particularly large earcanals. A reason could be the age of participants: 70 % of participants were more than 40 years old at the time of the study and the earcanal first-bend cross-section area enlarges with age (Balouch et al. 2023). Another hypothesis is that the prolonged use of earplugs at their workplace over several years (participants were accustomed to wearing earplugs at work), might have led to an enlargement of the cartilaginous segment of their earcanals.

The relationship between earcanal size assessed with the EE vs the earmold scan method was assessed using a Pearson linear correlation method and found to be statistically significant ($p<0.001$). Specifically, there is a weak but significant correlation between the area of cross-section E and the earcanal size assessed with the EE (correlation coefficient $r = 0.30$). Moderate correlations were observed between the earcanal size evaluated with the EE and the areas of cross-sections FB ($r = 0.53$) and SB ($r = 0.50$). Subsequent analyses (details not provided here) revealed that the correlations between the two measurement methods (earmold scans and EE) were consistent for both men and women when analyzed separately.

To provide additional insights into the location of the earcanal area sized with the EE, the earcanal length were compared to dimension B (as seen in Figure 2) of the EE, which determines the depth of the measurement. In this dataset, the length of the curvilinear axis of the earcanal between cross-sections E and FB averaged 4.9 mm (STD = 1.8 mm). The distance between the tab of the EE, which is applied to the concha during earcanal sizing, and the center of the EE's sphere (see distance B in Figure 2) varies between 4.19 mm (XS) and 6.10 mm (XL), as specified in the ASA/ANSI

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S12.6 standard. Given this information, it can be concluded that the EE assesses the diameter of the earcanal's cross-section area at a position located near the FB region. This finding aligns with the strongest correlation observed between the earcanal size evaluated with the EE and the cross-section FB area. Consequently, the "earcanal opening" sized with the EE corresponds to the diameter of the earcanal near the FB zone.

The area of cross-section FB for each earcanal, grouped by size as evaluated with the EE, is plotted in Figure 3.

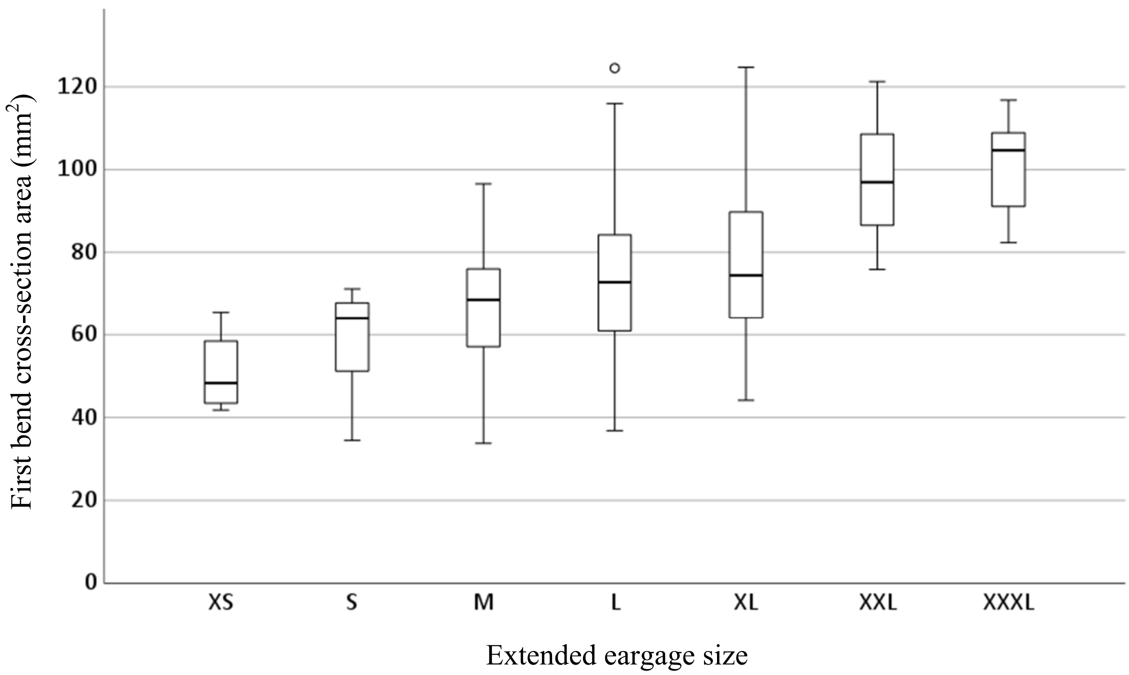

Figure 3 : Box plots of the earcanal cross-sectional area at the first bend (region FB) as a function of the estimated earcanal size measured using the EE.

By examining these box plots, it becomes evident that there is a positive correlation between the earcanal size assessed with the EE and the area of the cross-section FB. In general, the smaller the EE size, the smaller the median of the distribution of earcanal cross-section FB area. However, it's important to note that there is a substantial amount of variability in the areas of the cross-section FB within the M, L, and XL size groups. This variability leads to a significant overlap between these size categories and others. As a result, the EE does not provide accurate measurements for precisely assessing the cross-sectional area of the earcanal at the first bend, and it cannot be used for morphological classification of earcanals, which aligns with the findings of Thomas et al. (1994).

Nevertheless, there is no overlap in the cross-section FB areas between the categories (XS and S) and the categories (XXL and XXXL) in our dataset. This means that an earcanal classified as XS or S consistently has a smaller cross-section FB than a XXL or XXXL earcanal. Consequently, the EE can be a valuable tool for distinguishing the smallest earcanals from the largest ones. Given the correlation between earplug attenuation and the cross-sectional area of the earcanal at the first bend FB (as previously noted in Poissenot-Arrigoni et al., 2022, and Table 3 of this paper), the EE can aid in identifying some extremely large earcanals (i.e. earcanals that are XXL or XXXL) that are more likely to be under-protected.

b. Ability of the EE to inform about earplugs sound attenuation

In this section, the findings regarding the relationships between earcanal morphologies, assessed using both the EE and earmold scan methods, and PARs obtained after insertion training are presented. The Pearson linear correlation coefficients between earplugs' PARs and cross-section FB area, evaluated through earmold scans, as well as the earcanal size assessed with the EE, are shown in Table 3.

Overall, all significant correlations between earcanal size, as assessed by both methods presented in this study, and earplug attenuation were negative for most of the earplug types evaluated. This indicates that the larger the earcanal in terms of circumference, the lower the attenuation. The two possible causes are acoustic leakage and the lower compression of the tissues. The second possible cause aligns with the findings reported by Poissenot-Arrigoni et al. (2022), suggesting that a larger earcanal results in less compression of the earplug and surrounding tissue. At lower frequencies, the vibro-acoustic behavior of the earplug coupled to the earcanal is influenced by the equivalent stiffness of the combined earplug and earcanal skin system. Lower compression of the earplug and skin leads to lower equivalent stiffness and lower sound attenuation.

Table 3 indicates that the FB cross-section area and the earcanal size assessed with the EE are not correlated with the PARs of cylindrical roll-down foam earplugs (both regular size and small size). The PAR of the bullet-shaped roll-down foam earplug has a weak negative correlation with the FB cross-sectional area assessed using the earmold scanning method but is not correlated with the earcanal size assessed with the EE. However, weak negative correlations were found between the bell-shaped roll-down foam, multi-flange elastomeric polymer, push-to-fit pod foam, and push-to-fit sheath foam earplugs PARs and the FB section area, as well as earcanal size assessed with the EE. For each of these earplugs, the correlation coefficients are similar for the earcanal sizes assessed with the earmold scans and EE methods. In essence, with the exception of the cylindrical and bullet-shaped foam earplug, the earcanal circumference assessed with the EE correlates with the attenuation of the earplugs, at least in a manner similar to that of the earmold scan method, which provides a more accurate estimate of the area of the FB cross-section.

Box plots of earplugs' PARs categorized by EE sizes are shown in Figure 4. Due to the limited number of earcanals in categories XS, S, XXL, and XXXL, earcanals are grouped into three categories: {XS + S}, {M + L + XL}, and {XXL + XXXL} earcanals.

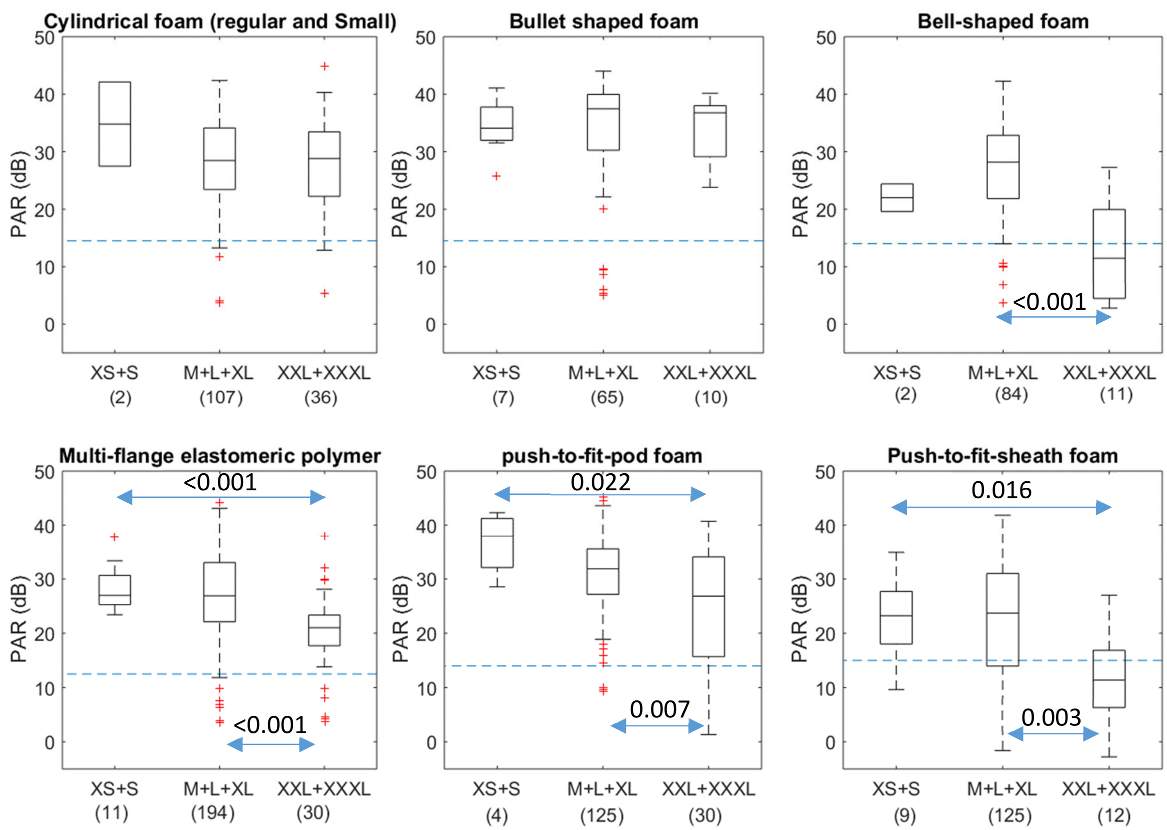

Figure 4 : Box plots of $PAR_{50\%}$ of six commercial earplugs grouped into the three proposed EE categories: {XS + S}, {M+L+XL} and {XXL+XXXL}. Numbers in brackets indicate the number of subjects in each category. One-half of the manufacturer's labeled NRR of each earplug (which is a typical derating score and the first threshold of the training) is represented with a blue dashed horizontal line. P-values of Mann Whitney U comparison test are plotted between each pair of groups that are significantly different at the level 0.05.

Figure 4 illustrates that except for the cylindrical and bullet-shaped roll-down foam earplugs, earcanals categorized in the {XXL + XXXL} category consistently exhibit significantly lower attenuation compared to other categories. This suggests that bell-shaped foam, multi-flange elastomeric polymer, push-to-fit-pod foam, and push-to-fit-sheath foam earplugs may be less effective on extremely large earcanals. Furthermore, for the three earplug types (bell-shaped foam, push-to-fit-pod foam, and push-to-fit-sheath foam), a notable number of earcanals did not achieve at least 50% of the NRR attenuation value. This indicates that some "one-size-fits-most" earplugs are not suitable for certain extremely large earcanals and Figure 4 highlights the potential of the EE in identifying such earcanals.

The purpose of Table 4 is to present the range of EE sizes suitable for each earplug under investigation in this study, ensuring both a proper fit and sufficient protection efficiency. This type of information has the potential to streamline earplug selection through the utilization of a straightforward tool. Table 4 provides the proportion of earcanals in each of the three categories ({XS + S}, {M + L + XL}, {XXL + XXXL}) that meet the NRR/2 dB threshold. This threshold corresponds to a typical 50 % derating score applied to the manufacturer's labeled NRR.

The results clearly demonstrate that nearly all participants achieved the NRR/2 attenuation threshold with cylindrical and bullet-shaped roll-down foam earplugs. In the case of bell-shaped foam, multi-flanged elastomeric polymer, and push-to-fit-pod foam earplugs, a significant majority of participants in the {XS + S} and {M + L + XL} groups successfully reached the safe attenuation threshold. However, not all earcanals classified in the {XXL + XXXL} category managed to attain the NRR/2 for multi-flanges elastomeric polymer and push-to-fit-pod foam earplugs. For these two earplugs, respectively 80% and 77% of participants managed to obtain the NRR/2 criterion. For the bell-shaped foam earplugs, only 45% of earcanals in the {XXL + XXXL} category achieved the NRR/2, and for the push-to-fit-sheath foam earplug, this percentage dropped to just 33%.

In the context of earplug selection in the field, the EE can serve as a straightforward tool to identify earcanals for which specific earplugs are not suitable. For instance, based on this dataset, individuals with {XXL + XXXL} earcanals should prioritize cylindrical foam and bullet-shaped foam earplugs, if available. On the other hand, individuals with {XS + S} earcanals may have more flexibility in choosing earplugs based on factors attenuation and NRR. It is important to recall that factors beyond attenuation such as comfort shall be taken into account when selecting earplugs.

These results also raise questions about the safety of derating scales applied to the NRR, particularly for earplugs used in extremely large earcanals. The (CSA Z94.2-14. 2014), for example, recommends applying a derating factor of 50% to the NRR of earplugs. The first threshold of the insertion training was set to 50 % of the NRR and results show that only 45 % of workers with XXL and XXXL earcanals would achieve a $PAR_{50\%}$ of 50 % of the NRR for the bell-shaped foam earplug presented in this study. This may be due to the fact that the bell-shaped foam earplug has a flared back end that limits the depth of insertion into the ear (Leight, 1988). For multi-flange elastomeric polymer and push-to-fit-pod foam earplugs, the 50% NRR criterion would be met for

80% and 77% of workers with XXL and XXXL earcanals, respectively. However, for push-to-fit-sheath foam earplugs, only 33% of workers with XXL and XXXL earcanals achieved adequate protection.

In situations where a FAES is not available for earplug selection, certain earplug designs, such as cylindrical roll-down foam earplugs, should be preferred over other designs like premolded or push-to-fit earplugs for individuals with large earcanals. It's important to note that roll-down foam earplugs may not be the best choice, when HPDs must be removed or reinserted in work environments where workers' hands may be contaminated with caustic or irritating substances or abrasive materials (Voix et al. 2022) .

These findings underscore the value of using the EE in the earplug selection phase when an FAES is unavailable. Such a tool can assist in identifying individuals with extremely large earcanals that may not be compatible with certain earplug models. Furthermore, it may be beneficial for earplug manufacturers to indicate which EE sizes are compatible with each of the earplug models they produce, potentially on the earplug packaging, to aid hearing conservationists in selecting the most suitable earplugs for workers.

c. Earcanals bilateral asymmetry

To examine potential differences in earcanal morphology between the left and right ears that could influence earplug selection, paired t-tests were conducted on various morphological indicators for the participants. The results revealed significant differences between the right and left ears in terms of the areas of the cross-sections E ($p = 0.034$) and FB ($p < 0.001$), as assessed by the earmold scan method. Notably, there were no significant differences between the areas of the cross-section SB, which is located near the bony part of the earcanal. This suggests that the asymmetry in earcanal morphology is primarily related to the cartilaginous portion, with the bony part being more symmetrical. These trends held true when the analyses were performed separately for men and women.

Furthermore, when using the EE to measure earcanal size (near the cross-section FB location), different results were observed between the left and right ears for 28% of the participants. In most cases, the difference was one size, such as size XL for the right ear and size L for the left ear. However, a few participants had differences of two sizes between their ears, for example, XXL for the right ear and L for the left ear. Similar findings were reported in (Copelli et al. 2021), where 38% of participants had different EE measurements between their left and right ears.

In general, the variations in earcanal morphology between the right and left ears are minor, and paired t-tests showed no significant differences in attenuation between the right and left earcanals for the six earplugs studied. This suggests that, overall, the degree of asymmetry in earcanal morphology is not substantial enough to result in significant differences in PARs. However, this conclusion is drawn from global paired comparisons. In cases where a participant exhibits a pronounced asymmetry, it is advisable to adopt a conservative approach and recommend an earplug model based on the larger earcanal, considering that larger earcanals tend to have lower attenuation (as discussed in Section 3.b). Alternatively, when earplug models are available in various sizes, offering different sizes for each ear may be beneficial, in accordance with the CSA Z94 (2014, R2019) standard recommendation.

4. Conclusion

The selection of earplugs is a critical step in any hearing conservation program. In particular, the earplug must be adapted to the earcanal morphology of the person to be protected. The use of the commercial 3M™ Eargage earcanal sizing tool is the quickest, cost-effective, and straightforward method to assess earcanal size (XS, S, M, L, or XL). In the paper presented here, the relevance of the use of an extended version of this tool (extended with sizes larger than the maximum size of the commercial tool) to help in the preselection of earplugs by quickly assessing earcanal diameters in the zone where the earplugs are fitted was evaluated.

Results show that the 3M™ Eargage, including its extended version, enables estimation of the size of the earcanal near the first bend region. This tool is not accurate enough to perform a precise morphologic classification of earcanals; however, the proposed extended version could help identify some extremely large earcanals. Extremely large earcanals were shown to have a significantly lower attenuation than other earcanals for some specific models of earplugs. Moreover, classic derating scales applied to the noise reduction rating were shown to be unsafe for these extremely large earcanals. This finding could be used to recommend specific models of earplugs for persons with extremely large earcanals and improve the selection of earplugs based on the derating of single number ratings. The results of this study also suggest that it may be beneficial to indicate on earplug packaging, in addition to the single numbers attenuation ratings, the earcanal sizes for which the earplugs are most suitable.

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Informed consent

Informed written consent to take part in the study has been obtained by all participants

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used GPT-3.5 (OpenAI, 2021), retrieved from https://openai.com, in order to enhance the text's coherence, grammar, and syntax. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Table 1: Statistics of the EE measurement results in terms of number of earcanals (first number) and percentages (number in parenthesis) in each category. Data are presented for the entire sample and are further delineated by sex, specifically male and female subsets. Please note that not all participants' earcanals are included in this table; five were excluded from the study (see methodology section 2.b.i).

EE Dimensions			Number of earcanals and percentage N (%)			Earcanal length between entrance and first bend (mm)		
Size	diameter (mm)	Length B (mm) (see figure 2)	Overall	Males	Females	Overall	Males	Females
XS	7.6	4,1	4 (1.7)	0 (0)	4 (11.4)	4,2		4,2
S	8.4	4,7	7 (3.0)	3 (1.5)	4 (11.4)	6,2	6,3	6,1
M	9.3	5,1	61 (25.7)	41 (20.3)	20 (57.1)	4,6	4,4	5,0
L	10.4	5,7	75 (31.6)	70 (34.7)	5 (14.3)	5,1	5,1	4,9
XL	11.4	6,1	60 (25.3)	58 (28.7)	2 (5.7)	4,9	4,9	5,7
XXL	12.9	6,7	18 (7.6)	18 (8.9)	0 (0)	4,7	4,7	
XXXL	14.0	7,4	12 (5.1)	12 (5.9)	0 (0)	3,9	3,9	
XXXXL	14.9	8,1	0 (0)	0 (0)	0 (0)			
Total			237	202	35			

Table 2: The six surrogate earplugs evaluated in this study along with the manufacturer's names and designations used in this study. Note that the 3MTM E-A-R^{TM} Classic uncorded was available in regular and small size.

Earplug family	Roll-down-foam			Multi-flange elastomeric polymer	Push-to-fit	
Surrogate earplugs pictures						
Earplug manufacturer's name	3M^{TM} E-A-R ^{TM} Classic uncorded (Regular and small)	3M™ 1100 Earplug	3M™ E-A-R™ E-Z-Fit™	3M™ E-A-R™ UltraFit™	3M™ E-A-R™ Push-Ins	3M™ E-A-R™ Push-Ins earplugs, with grip rings
Simplified name in this study	Cylindrical foam	Bullet shaped foam	Bell-shaped foam	Multi-flange elastomeric polymer	Push-to-fit-pod foam	Push-to-fit-sheath foam

Table 3: Pearson linear correlation coefficients between PAR and either earcanal cross sectional area at the first bend, or between PAR and earcanal size per the EE measurements. Empty boxes indicate that the correlation is not significant. All printed correlations are significant at the level 0.01

	Earplugs PARs						
	Cylindrical foam Regular	Cylindrical foam small	Bullet shaped foam	Bell-shaped foam	Multi-flange elastomeric polymer	Push-to-fit-pod foam	Push-to-fit-sheath foam
N	107	40	82	97	235	159	146
FB area (earmold method)			-0.28	-0.26	-0.41	-0.33	-0.34
Earcanal size (EE method)				-0.38	-0.29	-0.29	-0.24

NRR /2 (dB)	Cylindrical foam	Bullet shaped foam	Bell-shaped foam	Multi-flange elastomeric polymer	Push-to-fit-pod foam	Push-to-fit-sheath foam
XS + S	100 %	100 %	100 %	100 %	100 %	78 %
M + L + XL	95 %	91 %	92 %	96 %	98 %	74 %
XXL + XXXL	95 %	100 %	45 %	80 %	77 %	33 %

Table 4: percentage of earcanals in each group identified using the EE ({XS+S}, {M+L+XL}, {XXL+XXXL}) that obtained a PAR superior to: the NRR/2 first threshold of the training (and typical derating score of the NRR). Grey boxes indicate that there are less than five participants in the group that tested the earplug.