Tools and Methods Dedicated to the Design and Selection of Earplugs that Are Adapted to the User' Earcanal Morphology and Physically Comfortable

by

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Outils et méthodes dédiés à la conception et à la sélection de bouchons d'oreilles adaptés à la morphologie du conduit auditif de l'utilisateur et physiquement confortables

Bastien POISSENOT-ARRIGONI

RÉSUMÉ

Les bouchons d'oreille jetables et réutilisables sont largement utilisés pour prévenir la perte d'audition sur le lieu de travail. Pour protéger efficacement les utilisateurs, les bouchons d'oreilles doivent fournir une atténuation sonore adéquate et être portés de manière constante. L'atténuation des bouchons d'oreille dépend de nombreux facteurs, notamment de la morphologie du conduit auditif de l'utilisateur et des caractéristiques physiques du bouchon d'oreille, qui doit pouvoir s'adapter au conduit auditif et créer un joint acoustique. Même s'il est possible d'obtenir un fit correct, l'inconfort subit par le l'utilisateur peuvent l'amener à détériorer intentionnellement la qualité de l'ajustement ou à retirer le bouchon, ce qui entraîne une réduction drastique de la protection. Les têtes artificielles, dédiées à la mesure d'atténuation des bouchons d'oreille, sont équipées de conduits cylindriques droits de taille unique et sont donc incapables d'évaluer dans quelle mesure les bouchons d'oreille peuvent s'adapter à différentes morphologies de conduits auditifs. Une tête artificielle destinée à tester la façon dont les bouchons d'oreille peuvent s'adapter à différents utilisateurs (dans la phase de conception du bouchon d'oreille par exemple) devraient permettre une variété de formes de conduits auditifs. Il est donc nécessaire de disposer d'oreilles artificielles plus réalistes, disponibles dans une variété de tailles et de formes et morphologiquement représentatives des populations ciblées. En outre, les bouchons d'oreilles jetables et réutilisables sont disponibles dans une grande variété de formes et de matériaux, mais il n'existe pas de consensus sur une méthode de sélection simple et directe qui garantirait une atténuation suffisante pour un travailleur donné (il existe des systèmes d'estimation de l'atténuation sur le terrain, mais ils ne sont pas largement déployés sur le terrain). On ne sait pas quel modèle et quelle taille de bouchon d'oreille convient le mieux à chaque conduit auditif, et l'emballage des bouchons d'oreilles donne peu d'indications à ce sujet. Il est donc nécessaire de mettre au point des méthodes de sélection des bouchons à l'aide d'outils simples et adaptés au terrain. Enfin, même si un bouchon d'oreille fournit à l'utilisateur la bonne atténuation lorsqu'il est bien ajusté, son efficacité diminue considérablement s'il est porté de manière intermittente. L'une des principales causes de la mauvaise utilisation ou de la non-utilisation des bouchons d'oreilles est l'inconfort qu'ils provoquent chez l'utilisateur. L'inconfort résulte d'interactions entre diverses caractéristiques du bouchon (par exemple, sa forme ou sa souplesse), l'utilisateur (par exemple, la morphologie du conduit auditif) et l'environnement de travail (par exemple, la température, la durée du temps de travail), qui forment le concept de la triade. La connaissance de la relation entre les caractéristiques de la triade et le confort pourrait aider à la conception de bouchons d'oreille plus confortables. Cette thèse adresse les défis suivants : (i) concevoir des outils dédiés (oreilles artificielles) pour tester et concevoir des bouchons d'oreille qui offrent une bonne adaptation et une bonne atténuation à la plus large gamme de morphologies de l'oreille, (ii) sélectionner des bouchons d'oreilles adaptés aux morphologies des utilisateurs en utilisant des outils de dimensionnement du conduit auditif facilement accessibles sur le terrain, et (iii) comprendre l'inconfort physique des bouchons en identifiant les caractéristiques de la triade liées aux principaux attributs de cette dimension du confort et évaluées sur le terrain. Trois articles abordent successivement ces défis. Dans le premier article, une méthodologie permettant de regrouper les conduits auditifs en fonction de leur morphologie afin de concevoir des oreilles artificielles dédiées à la mesure de l'atténuation sonore a été développée et appliquée à un échantillon de conduits auditifs de travailleurs canadiens. Les indicateurs morphologiques des conduits auditifs qui sont en corrélation avec les atténuations de six modèles de bouchons d'oreille commerciaux ont d'abord été identifiés. Trois clusters de conduits auditifs ont ensuite été générés à l'aide d'une analyse statistique et d'un algorithme basé sur l'intelligence artificielle. Les clusters diffèrent par la longueur du conduit auditif et par la surface et l'ovalité de la section transversale du premier coude. Le cluster avec de petits conduits auditifs et une section transversale de la première courbure ronde présente une atténuation induite par le bouchon d'oreille significativement plus élevée que le cluster avec une section transversale du premier coude plus large et plus ovale. Dans le second article, la base de données morphologiques construite dans le premier article est comparée à la taille des conduits auditifs évaluée à l'aide de l'outil 3M^{TM} Eargage *earcanal sizing tool* (EST) (dimensionnement de conduit auditif) (qui est un outil simple et peu coûteux pouvant être déployé sur le terrain pour évaluer la taille des conduits auditifs). Les relations entre l'atténuation mesurée sur les participants pour 6 bouchons d'oreille différents et la taille du conduit auditif évaluée avec l'EST sont établies à l'aide de diagrammes en boîte et de tests de comparaison. Les résultats montrent que l'EST peut aider à sélectionner les bouchons d'oreilles en détectant les personnes dont les conduits auditifs sont très larges et qui sont le plus susceptibles d'être sous-protégées. Dans le troisième article, le confort de 7 modèles différents de bouchons jetables et réutilisables a été évalué sur le terrain avec 173 participants exposés quotidiennement au bruit sur leur lieu de travail à l'aide de questionnaires. Les caractéristiques de la triade (personne/bouchon/environnement) ont été évaluées à la fois par des questionnaires et en laboratoire par des mesures objectives. Des analyses à mesures répétées ont montré que la force radiale et le coefficient de frottement élevés des bouchons favorisent l'inconfort physique. En outre, les travailleurs ont trouvé leurs bouchons moins inconfortables physiquement s'ils avaient l'habitude de les porter avant de participer à l'étude. Les travailleurs dont la section d'entrée du conduit auditif est large et circulaire ont trouvé leurs bouchons d'oreille plus gênants et douloureux. Dans l'ensemble, cette thèse fournit des outils de conception et de sélection pour concevoir et sélectionner des bouchons d'oreille plus confortables physiquement et adaptés à la morphologie de l'utilisateur.

Mots Clefs : Bouchons d’oreilles, Confort physique, Morphologie, atténuation, sélection de bouchons

Tools and Methods Dedicated to the Design and Selection of Earplugs that Are Adapted to the User' Earcanal Morphology and Physically Comfortable

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ABSTRACT

Disposable and reusable earplugs are widely used to prevent hearing loss in the workplace. To effectively protect users, earplugs must provide adequate sound attenuation and be worn consistently. The attenuation of earplugs depends on many factors, including the morphology of the user's earcanal and the physical characteristics of the earplug, which must be able to fit the earcanal and create an acoustic seal. Even if a proper fit is feasible, discomforts experienced by the wearer can make him/her deteriorate intentionally the fit quality or remove the protector which causes a drastic reduction in protection. Acoustical test fixtures (ATFs), dedicated to earplugs attenuation testing, are equipped with straight cylindrical earcanals of a single size and are therefore unable to assess how well earplugs can fit different earcanal morphologies. An ATF intended to test how earplugs can fit different users (in the designing phase of the earplug for example) should allow for a variety of earcanals shapes. There is thus, a need for more realistic artificial ears available in a variety of sizes and shapes and morphologically representative of targeted populations. In addition, disposable and reusable earplugs are available in a wide variety of shapes and materials, but there is no consensus on a simple and straightforward selection method that will ensure sufficient attenuation for a given worker (field attenuation estimation systems exist but are not widely deployed in the field). It is not known which model and size of earplug is best suited for each unique earcanal, and the packaging of earplugs gives little indication on the subject. Thus, there is a need for methods to select earplugs using simple field-specific tools. Finally, even if an earplug provides the right amount of attenuation to the user when properly fitted, its effectiveness decreases significantly if worn intermittently. One of the main causes of misuse or non-use of earplugs is the discomfort they induce to the user. Discomfort results from interactions between various characteristics of the earplug (e.g., shape or softness), users (e.g., earcanal morphology), and the work environment (e.g., temperature, duration of work shift), which form the triad concept. Knowledge of the relationship between triad characteristics and comfort could help in the design of more comfortable earplugs. This thesis addresses the challenges of (i) designing dedicated tools (artificial ears) for testing and designing earplugs that provide good fit and attenuation to the widest range of earcanal morphologies, (ii) selecting earplugs that fit users' earcanal morphologies using earcanal sizing tools easily accessible in the field, and (iii), understanding the physical discomfort of earplugs by identifying the triad characteristics related to the main attributes of this comfort dimension and assessed in the field. Three papers successively address these challenges. In the first paper, a methodology to cluster earcanals according to their morphology in order to design artificial ears dedicated to the measurement of sound attenuation was developed and applied to a sample of earcanals from Canadian workers. Morphological indicators of earcanals that correlate with the attenuations of six commercial earplug models were first identified. Three clusters of earcanals were then generated using statistical analysis and an artificial intelligence-based algorithm. The clusters differ in the length of the earcanal and in the area and ovality of the cross-section of the first bend. The group with small earcanals and round first bend cross-section shows significantly higher earplug-induced attenuation than the cluster with larger, more oval first bend cross-section. In the second paper, the morphological database constructed in the first paper is compared to earcanal size assessed using the 3M^{TM} Eargage earcanal sizing tool (EST) (which is a simple and inexpensive tool that can be deployed in the field to assess earcanal size). Relationships between the attenuation measured on participants for 6 different earplugs and the earcanal size assessed with the EST are established using box plots and comparison tests. The results show that the EST can help in the selection of earplugs by detecting people with extra-large earcanals who are most likely to be under-protected. In the third paper, the comfort of 7 different models of disposable and reusable earplugs was evaluated in the field with 173 participants exposed daily to noise at their workplace using questionnaires. The characteristics of the triad (person/earplug/environment) were assessed both by questionnaires and in the laboratory by objective measurements. Linear mixed-effects modeling showed that high radial force and friction coefficient of the earplugs promote physical discomfort. In addition, workers found their earplugs less physically uncomfortable if they were accustomed to wearing them before participating in the study. Workers with a large circular earcanal entrance cross-section found their earplugs more physically annoying and painful. Overall, this thesis provides design and selection tools for designing and selecting more physically comfortable earplugs and that are adapted to the user's morphology.

Keywords: Earplugs, physical comfort, earcanal morphology, attenuation, earplugs selection

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LIST OF ABREVIATIONS

3D	Three-Dimensional
AIC	Akaike Information Criterion
ATF	Acoustical Test Fixture
E	Entrance
EST	Earcanal Sizing Tool
FAES	Field Attenuation Estimation Systems
FB	First Bend
IRSST	Institut de Recherche Robert-Sauvé en Santé et en Sécurité du Travail
L	Large
M	Medium
NHIL	Noise-Induced Hearing Loss
NRR	Noise Reduction Rating
PAR	Personal Attenuation Rating
PU	PolyUrethane

PVC	Polyvinyl Chloride
REAT	Real Ear Attenuation At Threshold
S	Small
SB	Second Bend
UPQ	User Profile Questionnaire
VIF	Variable Inflation Factors
WHO	World Health Organization
XL	Extra Large
XS	Extra Small

LIST OF SYMBOLS

μ	friction coefficient
°	arc degree
°C	degree Celsius
dB	decibel
g	Gram
Hz	hertz (with prefix k for kilo-)
m	meter (with prefix m for milli-)
min	minute
N	newton
S	second
SD	Standard Deviation

INTRODUCTION

0.1 Context

According to the World Health Organization (WHO), nearly 5% of the world population suffer from disabling hearing loss. The impact of hearing loss is particularly deleterious to quality of life and general health. Hearing loss increases the rate of depression, social isolation, functional disability, cognitive decline and even mortality (Genther et al., 2015; Meinke, Neitzel, Berger, Driscoll & Bright, 2022). Recent reports state that 16% of the disabling hearing loss is attributed to occupational noise (WHO, 2023).

Existing means to prevent occupational hearing loss include (i) controlling noise emitting sources, (ii) reducing the noise along propagation pathways and (iii) providing workers with individual hearing protectors, such as earplugs and earmuffs (Berger & Voix, 2022). This third method remains the most commonly used short-term solution and should be used in last resort when the first two cannot be achieved. According to the BCC Research report, "Hearing Protection: Global Market Data," (2021), intra-auricular hearing protectors (earplugs, uniform attenuation earplugs, hearing bands) account for over 85% of the total volume of hearing protection units on the market, and cover 75% of the total market. Disposable and reusable earplugs- type intra-auricular hearing protectors are the subject of this thesis. Their ability to prevent noise induced hearing loss to the wearer depends both on their attenuation and their wearing time.

The attenuation must be adapted to the sound environment, i.e., high enough to protect the user from hazardous noises, but not too high to avoid overprotection. In more than 90 % industries, all that is needed is 15 dB attenuation, what most of earplugs can easily provide if they are fitted correctly (Berger & Voix, 2022). It is therefore important to not over protect the user, which may prevent him/her to hear useful noises or communicate with colleagues. The attenuation of earplugs depends on many factors including their insertion depth (Berger, 2013), and fit (Berger, 1988) and earcanal morphology of the user (Abel, Rockley, Goldfarb &

Hawke, 1990). Attenuation also depends on the physical characteristics of the earplug (for example their shape and materials) which must be able to fit the earcanal and create an acoustic seal. One-size-fits-most earplugs must therefore adapt to the wide variability in human earcanal morphology ("each earcanal is unique" as stated in Franks, Stephenson & Merry, 1996). It is thus difficult for designers to achieve a universally acceptable product (Ferguson, Greene, Repetti, Lewis, & Behdad, 2015) , and tools to help in earplugs design are limited. As earplugs are mostly one-size-fits-most products, there is a need for designing earplugs adapted to the widest range of earcanal morphologies.

Acoustical test fixture (ATFs) provide a quick and reproducible way to measure earplugs attenuation. The ANSI S12.42 standard specifies the characteristics that an ATF must have to measure the attenuation of earplugs. This standard is intended for use in design, quality assurance, and verification of compliance with specifications for hearing protection devices. However, to the author's knowledge, existing ATFs that comply with ANSI S12.42 are equipped with straight cylindrical earcanals of one size. This makes it difficult for ATFs to capture, for a given earplug model to be tested, both the intra-individual variability in sound attenuation due to earplug fit (Benacchio et al., 2019), and the inter-individual variability due to the large difference between human earcanal morphology (e.g. extra-small, regular and extra-large earcanals). To take into account the large variability in human morphology, an ATF may include variable shapes and sizes (Berger, Kieper & Stergar,, 2011). There is thus a need for more realistic artificial ears available in multiple sizes and shapes, characteristic of targeted populations and instrumented to measure sound attenuations. This would allow for designing earplugs that better fit a wide range of earcanal sizes and shapes and better identifying the population for which the earplug is the most adapted, right from its designing phase.

In addition, selecting earplugs adapted to the users' morphology and work environment is essential to provide the right degree of attenuation. Indeed, earplugs come in many shapes and sizes, and although the employer may be required to make available a variety of different hearing protectors, there is no consensus on a strategy or method for selecting earplugs that will ensure sufficient attenuation for a given worker. The most suitable earcanals shapes and sizes for each model and size of earplug are not known and there are little indication on earplugs packaging about the earcanal morphologies for which they are the most adapted. The standards on the selection and use of hearing protection devices do not provide clear guidelines on this subject. A recent advance in earplug selection is the use of Field Attenuation Estimation Systems (FAES) that may allow for rapid measurement of individual attenuations. FAES are becoming more widespread but are still marginal. Thus, there is a lack of tools to simply measure the size of the earcanal, but also a lack of knowledge about the most suitable commercial earplugs for a given earcanal size (or morphology) (in terms of acoustic fit to avoid under protection) that would help to better choose earplugs, with simple tools adapted to the field.

To be efficient, the protector must also be worn consistently during all the exposure time. Indeed, removing the protector, even for short periods causes a drastic reduction in protection (Berger & Voix, 2022; CSA, 2014; Légis-Québec, 2022; Miles, 1983). The (dis)comfort induced by the earplug to the wearer is a strong factor influencing earplugs fit (and more generally misuse) and wearing time (Doutres, Terroir, et al., 2022). (Dis)comfort is multidimensional, and in the context of earplug use, the four dimensions characterizing earplug (dis)comfort are: physical, functional, acoustic and psychological (Doutres et al., 2019). The (dis)comfort results from the complex and mostly unknown interactions between the wearer, its earplug, and its work environment, which form the concept of triad. The triad components (person/earplug/environment) can be described by many physical and psychological characteristics (Doutres, Sgard, et al., 2022). Understanding all the characteristics of the triad that affect (dis)comfort, and their relative contribution, would allow for more effective protection of noise-exposed individuals. Indeed, knowing the influences of the psychosocial characteristics of the triad (e.g., past behavior, experience with HPD use) on comfort would allow for effective consideration of comfort in the earplug selection phase. Similarly, knowledge of the relationship between physical characteristics of earplugs (e.g., shape or softness) and comfort could aid in the design of more comfortable earplugs. In particular, the development of comfort models capable of objectifying comfort judgments with objective physical attributes of earplugs could provide essential tools for comfort-oriented design methods.

This thesis addresses challenges related to (i) developing dedicated tools (artificial ears) for testing and designing earplugs that provide good attenuation (i.e, good fit) to the widest range of earcanal morphologies, (ii) selecting earplugs that fit users' earcanal morphologies using earcanal sizing tools easily accessible in the field, and (iii), understanding the physical discomfort of earplugs by identifying the triad characteristics related to the main attributes of this comfort dimension and assessed in the field. The focus is on the physical dimension of comfort because, in many previous studies identified in the literature (Doutres et al., 2019), subjective perceptions related to mechanical contact between the earplug and the body have been shown to be a significant source of discomfort.

0.2 Objectives

The main objective of this work is to improve the effectiveness of earplugs by focusing on (1) the quality of the fit between the earplug and the earcanal to ensure proper attenuation and (2) the physical discomfort known as one of the main discomforts induced by earplugs and responsible of their misuse (and non-use).

Three sub-objectives associated with this main objective and with the above challenges are proposed here and are addressed in Chapters 2, 3 and 4.

Objective 1: Develop a methodology to cluster earcanals as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement and to apply this methodology to a sample of Canadian workers’ earcanals.

Objective 2: Evaluate the reliability of an existing earcanal sizing tool (simple and inexpensive tool easily deployable in the field) for estimating the fit quality of earplugs and ultimately for use as an earplug selection tool in the field.

Objective 3: Improve our understanding of the physical (dis)comfort induced by earplugs by identifying the physical and psychosocial characteristics of the triad, either determined objectively or subjectively, that significantly influence the main attributes of this comfort dimension.

0.3 Thesis Overview

The rest of the document is organised as follow. Chapter 1 presents a literature review identifying research issues associated with the three abovementioned challenges. Chapter 2 is an article published in the "Journal of the Acoustical Society of America" that provides tools for designing earplugs to fit the greatest number of earcanals. To this end, a methodology for grouping earcanals according to their morphology with the goal of designing artificial ears dedicated to measuring sound attenuation is developed and applied to a sample of Canadian workers' earcanals. In chapter 3, an article submitted to the "International Journal of Audiology" aims at evaluating the reliability of an earcanal sizing tool to guide the selection of commercial earplugs best suited to the morphology of the individual's earcanal. Finally, Chapter 4 is a paper submitted to the journal "International Journal of Industrial Ergonomics" that aims at understanding the physical discomfort of earplugs by identifying the triad characteristics related to the main attributes of this comfort dimension (i.e., physical annoyance, pain, feeling of pressure, irritation).

CHAPTER 1

LITTERATURE REVIEW

This chapter presents the existing literature relevant to study the three aforementioned objective of this thesis. In particular, section 1.1 addresses the challenges related to the design of tools dedicated to the design of earplugs that provide a good attenuation to the widest range of earcanals morphologies. Subsections 1.1.1 and 1.1.2 successively describe the disposable and reusable earplugs commonly used to protect workers from hazardous noises and the anatomy of the human ear. Subsection 1.1.3 review methods for ear morphologic data acquisition and anthropometric analysis. Subsection 1.1.4 focuses on the known relations between the attenuation provided by earplugs and the earcanal morphology. Subsection 1.1.5 gives an overview of existing ATFs dedicated to earplugs design and attenuation measurement. Section 1.2 lists the existing methods to select earplugs adapted to workers morphology. Section 1.3 describes previous studies focusing on the understanding of the relationships between some objective characteristics of the triad and attributes of physical comfort of the hearing protectors and in-ear devices, with the goal of improving the comfort-based design of the latter. Finally, section 1.4 provides a synthesis of the literature review and presents the overall research approach adopted in this thesis.

1.1 Tools dedicated to the design of earplugs that provide good attenuation to the widest range of earcanals morphologies

1.1.1 Briefs overview of disposable and reusable earplugs

This subsection recalls information (mostly taken from (Berger & Voix, 2022)) about earplug types and features. Reusable and disposable earplugs may be grouped into roll-down foam, premolded and push-to-fit foam families. Most of these earplugs are one-size-fits-most products but several premolded and some foam earplugs come in different sizes to fit a wider range of earcanal sizes.

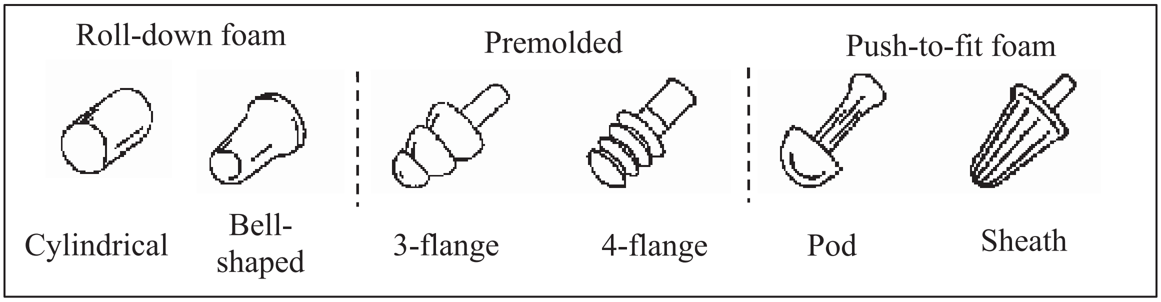

Figure 1.1 Disposable and reusable earplugs families
Adapted from Berger & Voix., (2022, p.259)

Roll-down foam earplugs must be rolled and compressed before insertion. The foam is usually slow-recovery polyvinyl chloride (PVC) or polyurethane (PU). These foams have similar acoustic properties, but PU is more sensitive to moisture absorption, which can alter its expansion time and make insertion of the earplug more difficult. They come in different shapes (cylindrical, bullet-shaped, bell-shaped) (see Fig 1.1). According to Berger and Voix, these shapes are more aesthetic than functional (Berger & Voix, 2022). PU earplugs are softer in the hand, but this does not necessarily translate into better physical comfort in the ear (Berger & Voix, 2022).

Premolded earplugs are formed from soft materials in generally conical shapes with flanges. In general, the more flanges, the fewer sizes needed to fit the population (Berger & Voix, 2022). Unlike roll-down foam earplugs, they require no preparation prior to insertion.

Push-to-fit foam earplugs are designed to combine the adaptability and comfort of foam earplugs with the ease of insertion of premolded earplugs (Berger & Voix, 2022). They consist of a foam dome attached to a flexible stem. The stem allows the foam to be pushed into the earcanal.

1.1.2 Briefs overview of ear anatomy

A comprehensive description of the anatomy and orientation of the human outer ear is given in (Alvord & Farmer, 1997). The outer ear is composed of the pinna (visible part of the ear succinctly described in the left part of the Fig 1.2) and the earcanal that expands between the pinna and the tympanic membrane. The entrance of the earcanal is generally defined at the base of the concha and it is closed medially by the tympanic membrane.

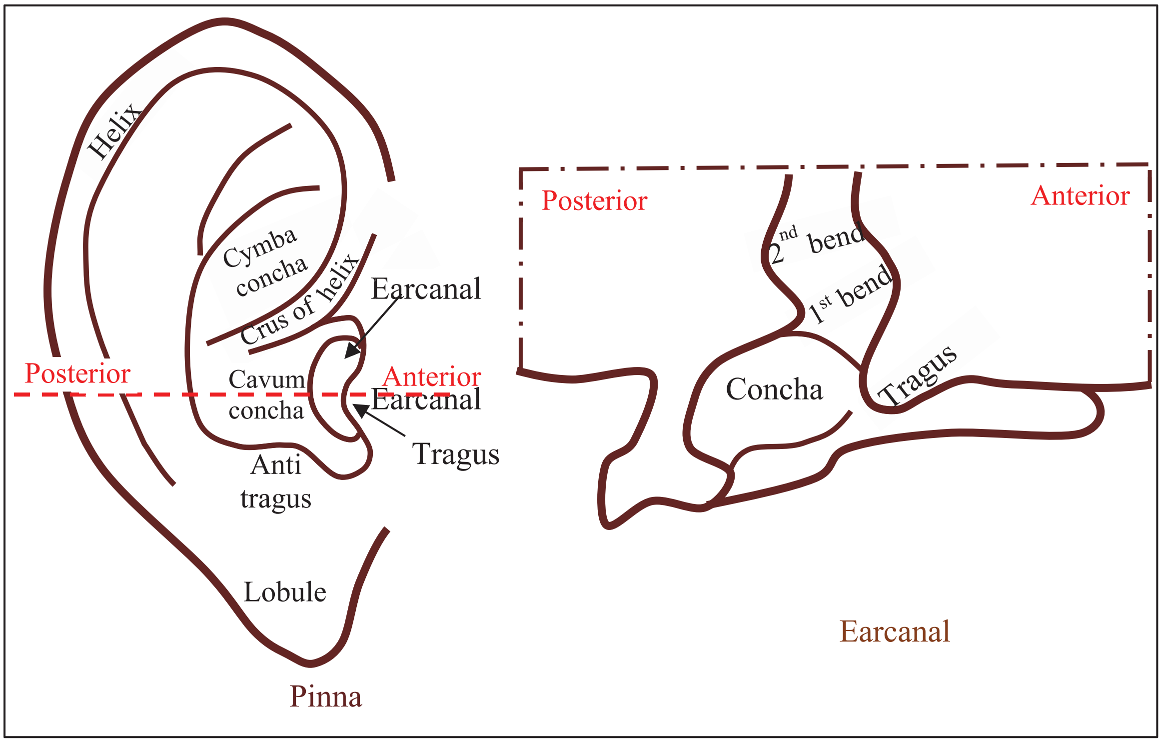

Figure 1.2 Anatomical structure of the ear
Adapted from Lee et al., (2028, p.1481)

The earcanal consists of an outer cartilaginous portion, which represents about one third of its length, and an inner bony portion. The junction of these two portions is called the osseo-cartilaginous junction. Two changes of directions of the earcanal occur in the antero-posterior plan. These changes of directions are usually called the first and second bend of the earcanal (see right part of the Fig. 1.2). The second bend corresponds approximately to the osseo-cartilaginous junction. The cross-section of the earcanal perpendicular to its curvilinear axis is oval shaped. The earcanal becomes more circular in the medial direction.

1.1.3 Methods of ear morphology acquisition and anthropometric analysis

Assessing the morphology of the outer ear is not straightforward (especially for the earcanal) and several methods are briefly discussed below. The quickest and more straightforward method to assess an earcanal opening diameter is based on the use of the 3M™ Eargage, referred to as the earcanal sizing tool (EST). It consists of 5 plastic spheres denoted as extra small (XS), small (S), medium (M), large (L), and extra-large (XL), with the dimensions specified (see Table 3.2). The procedure of the annex B of the ANSI/ASA S12.6 standard (2016), specifies how to size earcanals opening using this tool (ANSI/ASA S12.6, 2016). In short, it consists in inserting the spheres in the earcanal one by one starting from the smallest and select the one that better fits the earcanal opening (the procedure must be applied to both the right and left earcanal). Very few studies evaluated how precisely this EST can size an earcanal (Samelli et al., 2018; Thomas, Wright & Casali., 1994). Thomas et al., (1994) compared earcanals sizes of 552 participants assessed both with the EST (measurement were done independently by two experimenters) and caliper measurements on earmolds of participants earcanals. Comparison between the EST measurements performed by the two experimenters showed that the EST is a reliable tool that provide repeatable measurements. Thomas et al., (1994) found significant differences between the earcanal opening measured with the EST and the elliptical cross-section area obtained from caliper measurement at the base of the concha (near earcanal entrance) and at 4.8 mm depth inside the earcanal (around the first bend region). They conclude that the EST (that has a spherical tip) distorts the elliptical earcanal cross-section and is inadequate for anthropometric classification applications. Samelli et al., (2018) used the EST to assess the earcanal size and evaluated it in comparison with a tympanometer which provides the earcanal volume. They found that the earcanal volume is not directly related to the earcanal opening, possibly because an earcanal with narrow, small diameter, can be deep and have a larger volume. In particular, the definition of the earcanal opening supposedly measured with the EST remains unclear. The earcanal is an S-shaped conical duct (the earcanal narrows between the entrance and the tympanic membrane), and it is unclear at what depth from the earcanal entrance the EST sizes the earcanal diameter.

Methods which allow a more complete and more precise acquisition of the morphology of the ear exist. Intra-aural three-dimensional (3D) scanning devices or tomography scans obtained from medical images (Benacchio et al., 2018) enable a complete digitalisation of both the earcanal and the pinna. These methods require advanced technologies often patented by the owner and rather used for the manufacture of hearing aids and hearing protectors. Another method, commonly used by custom earplugs and hearing aids manufacturers and in studies about earcanal morphology (Lee et al., 2018; Voss et al., 2020) is to cast earmolds of earcanals usually using a soft silicone that hardens once injected inside the earcanal. The earmolds capture the geometry of a portion of the pinna (usually, cymba concha, cavum concha, crus of helix and a part of the tragus and anti-tragus). In addition, the earmolds can be cast inside the earcanal up to the second bend region or just a few millimeters beyond (the mold cannot reach the tympanic membrane for safety reasons). The earmolds can then be used to perform caliper measurement directly on the molds (Abel et al., 1990). Earmolds can also be digitalized which enables to perform more complex measurements via 3D computer aided design software (Chiou, Huang, & Chen, 2016; Fan, Yu, Wang, Li, Chu, et al., 2021; Fan, Yu, Wang, Li, Zhao, et al., 2021; Lee et al., 2018).

Several studies use earmolds scans to provide means and standard deviations of characteristic ear dimensions used in the design of in-ear devices. To this extent, the "landmarks method" is often utilized (Chiou et al., 2016; Fan, Yu, Wang, Li, Chu, et al., 2021; Fan, Yu, Wang, Li, Zhao, et al., 2021; Lee et al., 2018). This method consists in placing manually points on digitalized participants' ears (usually scans of earmolds of earcanals). Positions of the points are chosen as a function of the dimensions to be measured on the ear. For example, to measure the height of the concha (important dimensions to design earbuds), two points are placed: one at the intertragic incisure (i.e. the most inferior point of the ear notch located between the tragus and anti-tragus) and one at the superior cavum of the concha. The Euclidian distance between these two points is then defined as the height of the cavum concha. Distances such as concha height or earcanal entrance height are analyzed for the sample population and proposed for use in the design of ear products adapted to the ear morphology of a given population. The general conclusions of these studies are that: (i) female's ears are smaller than male's ears, (ii) there is an asymmetry between the right and left ear, and (iii) the ethnicity of the participant sample has an influence on ear size that is sufficiently important to be taken into account when designing in-ear devices. The main limit of these studies is that it is mostly the dimensions of the pinna that are comprehensively assessed. Dimensions related to the earcanal shape and size are left out because they are not relevant for the design of earbuds. However, the earcanal portion is of paramount importance for this thesis and very few studies focus on the links between the attenuation of in-ear devices that fit deep inside the earcanal and earcanal shape.

1.1.4 Relations between earplugs attenuation and earcanal morphology

Passive one-size-fits-most earplugs (that are the subject of this thesis) are inserted into the ears to form (in theory) a tight acoustic seal between the earcanal walls and the earplug. The short description of the earcanal morphology (see section 1.1.2) shows that the earplugs must adapt to the non-canonical shape of the earcanal to be efficient. On the one hand, each earcanal has a unique shape (Thomas et al., 1994) and on the other hand most of these one-size-fits-most earplugs have a unique design (e.g. material, shape). Having a comprehensive view of the earcanals morphology and its relation to earplugs sound attenuation is crucial, but the number of studies on this subject are limited.

Tufts et al., found in a pilot study that the attenuation of custom molded earplugs depend on their lengths (Tufts, Chen & Marshall, 2013). The study was conducted on four participants on which attenuation measurement of custom molded earplugs were made repeatedly shortening the earplug length by 2 mm between each measurement. For three of the four participants, the regions of the earcanal critical for attenuation were identified between the first and second bend and slightly medially to the second bend.

Abel et al., focused on disposable and reusable earplugs (Abel, Alberti & Rokas, 1988). They found significant differences between women and men in the attenuation of four commercially available earplugs: two foam earplugs and two premolded earplugs. The attenuations of earplugs available in a single size were lower when measured on females, whereas no gender effect was observed for earplugs available in multiple sizes. The gender differences in attenuation were therefore partially attributed to differences in earcanal morphology between men and women. Abel et al., examined the correlation between the real- ear attenuation at threshold (REAT) of three earplugs measured in 93 subjects and three morphological parameters of the earcanals estimated from the subjects' earmolds (Abel et al., 1990). These parameters were as follows (i) the areas of two cross-sections of the earcanal estimated at the conchomeatal angle (first bend region) and at the cartilaginous-bony junction (second bend region), (ii) the conicity (called degree of funneling in Abel's study) calculated as the ratio between these two cross-section areas and finally (iii) the tortuosity (which quantifies if the earcanal is more tortuous or straight), estimated visually. Results showed that a mismatch between the earcanal and the protector shapes could affect the attenuation. These earplug/earcanal mismatches were mainly attributed to the tortuosity and the conicity. Moreover, Abel et al. (1990) found that the attenuation is linearly related to the cross-sectional area of the earcanal at the cartilaginous-bony junction. A gender effect was observed since the correlation between the cross-sectional area of the earcanal at the cartilaginous-bony junction and the attenuation was found positive for women and negative for men. The effects of the morphology on sound attenuation were found higher at medium frequencies (3150 Hz) than at low frequencies (500 Hz). Viallet et al., found similar tendencies on the effects of morphology on sound attenuation (Viallet, Sgard, Laville & Nelisse, 2015). Using a numerical approach, Viallet et al., were able to investigate the effects of earcanal morphology and acoustic leakage between the earcanal and earplugs (Viallet et al., 2015). They showed that the important variability in the simulated sound attenuation of a foam and silicone earplugs was mainly due to acoustic leakage for frequencies below 1 kHz and by the inter-individual variability of the earcanal morphology between 1 and 5 kHz. More recently, Mououdi et al., measured 918 external ears dimensions of 153 operational workers and found that the design of molded-type earplugs should be improved to better match earcanal entrance shape and diameter to avoid inducing acoustic leaks (Mououdi, Akbari & Khoshoei, 2018).

The literature thus suggests that the inter-individual variability in earcanal morphology contributes significantly to the inter-individual variability in sound attenuation. However, none of these studies provides a comprehensive description of earcanals through morphologic indicators quantified objectively together with their relations with attenuations of earplugs from the three following one-size-fits-most earplugs family: roll-down-foam, premolded and push-to-fit.

1.1.5 Acoustical test fixtures dedicated to earplugs design and attenuation measurement

Berger specifies characteristics that ATFs dedicated to earplugs sound attenuation measurement should fulfill, to act as a proper surrogate (here only the characteristics related to the measurement of earplugs attenuation are listed, ATFs dedicated to earmuffs attenuation should fulfil different characteristics) (Berger, 2005). The ATF dimensions should correspond to the dimensions of human heads and earcanals and the ATF should match the impedance of the human eardrum. The ATF earcanal should include a simulation of the skin. This skin should match the coefficient of friction, and perhaps also the textural characteristics, of the earcanal flesh. To be able to compare the ATFs measurement with REAT measurements, the ATF should account for the occlusion effect and physiological-noise masking. It must also have a sufficient self-insertion loss. Finally, the ATF should allow for a variety of shapes of earcanals if the intent is to see how devices can fit different users. The ANSI S12.42 standard that specifies ATF methods for the measurement of the insertion loss of earplugs has identified these characteristics and standardized them (ANSI/ASA S12.42, 2010). At least two ATFs (shown in Fig. 1.3) are intended to meet requirement of this standard: the ISL *(L'Institut franco-allemand de recherches de Saint-Louis)* version 2 and the G.R.A.S 45CB. Both ATFs consist of a cylindrical artificial ear including an earcanal partially covered by a layer of silicone that mimics skin and terminated by an acoustic coupler that simulates the effect of the eardrum (plus a portion of the earcanal) on the sound waves that propagate through the earcanal. These earcanals are integrated into a head-shaped insulating structure.

Figure 1.3 Left, G.R.A.S 45CB without the circumaural flesh simulation
and the cylindrical earcanal with flesh simulation
Adapted from Viallet et al.,(2014, p.82)
Right, ISL version 2
Adapted from Berger et al., (2011, p.5)

Berger et al., compared earplug attenuations obtained with REAT method (conducted on a panel of 10 experimented subjects) and with both the ISL version 2 and the G.R.A.S 45CB (Berger et al., 2011). Five different earplugs of roll-down-foam and premolded type were tested. Their study clearly showed that the accuracy with which ATFs predict measured attenuation on subjects depends on the type of earplug. Participants of their study were experienced (they know how to properly fit an earplug) and a standard deviation sometimes close to 15 dB was observed on those measurements. This standard deviation, representative of the inter-individual variability in sound attenuation, is not captured by ATFs (both the G.R.A.S 45CB and the ISL version 2 in this study). A single artificial earcanal (see Fig. 1.3) is indeed unlikely to correctly capture the inter-individual variability of attenuation measured for different earplug types. The limited ATFs ability to capture the inter-individual variability in earplugs attenuation is at least partially due to the inter-individual human variability in earcanals geometry. In addition, a straight artificial earcanal does not allow to correctly capture the intra-individual variability of earplug sound attenuation. The intra-individual variability in sound attenuation corresponds to the variability in attenuation in a given earcanal resulting from the variability of earplugs insertion depth and fit. Benacchio et al., investigated the ability of the ATF G.R.A.S 45CB and an artificial ear of realistic geometry (obtained from MRI images of a participant) to capture the intra-individual variability (due to different earplug insertions) in attenuations objectively measured on the reference participant from which the artificial outer ear was designed (Benacchio et al., 2019). They found that the realistic artificial ear better captures the intra-individual variability than the ATF with a cylindrical earcanal. The ATF was shown inadequate to recreate the variations in attenuations due to earplugs insertion depth. Berger stated that large discrepancies, especially at low frequencies, of attenuations of numerous one-size-fits-most earplugs available on the market that have been reported in the literature are mainly due to the fit of earplug and its insertion depth (Berger, 2013).

In short, ATFs do not capture, for a given earplug model to be tested, both the intra-individual variability in sound attenuation due to earplug fit, and the inter-individual variability due to the large difference between human earcanal morphology (e.g. extra-small, regular and extra-large earcanals). This poses a problem when testing one-size-fits-most earplugs. ATFs do not allow for an assessment of the expected attenuation that these earplugs would provide over a wide spectrum of earcanal morphologies. In a design scenario, this could be a limitation of ATFs that would not help predict the attenuation of earplugs on a target population (with extra-small or extra-large earcanals, for example).

1.2 Earplugs selection

Selecting the right hearing protector is a critical step in any hearing conservation program (Berger & Voix, 2022). Guidelines to select earplugs are mostly written in standards, and therefore, the methods depend on the countries where the standard applies (and there is no legal obligation to apply these standards). Here, the focus is put on the North-American standards (some differences exist between requirements in Canada and United States). The employer may be obliged to make available one or several models of hearing protectors to the employees (CSA, 2014; Légis-Québec, 2022; Miles, 1983). Most of the time, the earplugs are selected based upon their primary function: the noise attenuation. To this extent, the noise exposure level is measured to determine the amount of attenuation required to protect the exposed workers (CSA, 2014). Then a protector that matches the required attenuation can be proposed to the exposed workers.

The easiest way to choose an earplug is to use the attenuation it is intended to provide according to the manufacturer's specifications. Usually, the earplug attenuation is quantified by the noise reduction rating (NRR). The NRR must be visible on the earplugs' packaging (CSA, 2014), which makes the earplug selection fast and convenient once the required amount of attenuation has been determined. The NRR, is measured in laboratory (ANSI/ASA S3.19, 1974), and is well known to provide false (often too high) estimates of field attenuation (Berger, 1993). To account for the discrepancy between the earplugs labelled and the real-world attenuation, derating scales have been proposed. They usually consist in reducing the NRR by a certain percentage (e.g., 50%) that depends on the types of products (disposable or reusable earplugs, earmuffs, dual protection) (CSA, 2014; NIOSH, 1998; CSA, 2022). The issue of derating schemes is that they only consider the hearing protection type and do not account directly for actual physical characteristics of the individual to be protected. Abel suggested that earplugs should be prescribed on an individual basis with special attention paid to earcanal morphology (and hearing loss and background noise) (Abel, 1986, p. 198).

A recent advance to help in the earplugs selection is the progress made in the field of fit testing and the popularization of field attenuation estimation systems (FAES) which make it possible to measure field individual attenuations (Voix, Smith & Berger, 2022). FAES are becoming more widespread but are still marginal.

Unlike other protective equipment sold in different sizes which are clearly identified on the packaging (e.g. shoes, gloves), earplugs are often one-size-fits-most type protections. But earcanals size plays a key role in the attenuation (Abel et al., 1990) and should be taken into account at the time of earplugs selection. Some earplugs are nevertheless available in multiple sizes but it is not clear to which population each size is addressed. This may be because assessing the earcanal morphology is not straightforward (see section 1.1.3).

In conclusion, the literature and standards do not provide clear guidelines or methods to select earplugs adapted to user's earcanals morphologies with limited available tools. There is thus a lack of tools to simply measure the size of the earcanals and to guide the selection of the most suitable earplugs.

1.3 Analysis of the physical (dis)comfort

1.3.1 Physical comfort of earmuffs

Few studies have attempted to link the physical (dis)comfort induced by the wearing of hearing protectors to their physical characteristics and most of them focus on the comfort of earmuffs and not earplugs. Tisserand and Krawsky measured several mechanical characteristics of earmuffs (e.g. mass or headband force) together with the subjective evaluation of the comfort they induce using questionnaires (Tisserand & Krawsky, 1972). They identified two main objective factors of comfort, which are a low stiffness of the headband and a weak pressure of earmuffs cushion on skin both related to sensations experienced by the subjects like tightening and compression of the temples. Gerges and Casali mention that the pressure applied by the earmuff on the skin is the most direct cause of discomfort (Gerges & Casali, 2007). Damongeot (1977) and Damongeot et al., (1982) found that, the mass of the protector does not affect physical comfort whereas the tightness of the headband and the "pressure of adaptation of the cushion to a contour" have an unfavorable influence on physical comfort (Damongeot, 1977; Damongeot, Tiserand, Krawsky & Grosdemange, 1982). Hsu et al., (2004) designed an experimental device (comfort tester) to objectively measure the characteristics related to the design parameters of earmuffs (headband clamping force, temperature inside the earmuff, weight). This comfort tester combined with subjective assessments of comfort makes it possible to obtain comfort indices corresponding to zones of indicator values for which subjects feel comfortable. In summary, these studies seem to emphasize that the static mechanical pressure between the protector and the skin is a key characteristic for earmuffs as it affects physical comfort. In a similar manner, the mechanical pressure applied by earplugs on the skin plays a role in earplugs physical discomfort (Doutres et al., 2019). However, few studies attempted to find relationships between physical comfort and characteristics of earplugs, most likely because the physical properties of earmuffs (like headband force) and coupled system earmuffs/skin (like static mechanical pressure) are easier to assess than those of earplugs

1.3.2 Analysis of the physical comfort of in-ear devices

Some studies aimed to analyze the physical comfort of in-ear devices such as earbuds, whose primary function is not to attenuate sound. These studies focused on the links between physical characteristics of the person or physical characteristics of in-ear devices with the physical comfort. Fu and Luximon examined the influences of in-ear devices sizes on human perception of physical and functional comfort (Fu & Luximon, 2022). In-ear devices (that fit in the cavum concha and cymba concha) of different sizes were customized for each individual ear to eliminate the influences of individual ear shape and size. Participant tested the devices in static and dynamic conditions and expressed their perceived comfort using Lickert scales (one about physical comfort and one about the device fit, which is related to the functional dimension of comfort). It was found that participant preferred (in terms of physical comfort) products that match the size of their concha or have a size slightly larger than their concha. These products were limited to the concha (cavum and cymba) and did not go inside the earcanal. Song et al., (2020) evaluated the effects of ear morphological dimensions (objective characteristic of the person component of the triad) and products attributes on the “wearing comfort” of wireless earphones (Song, Shin, Yoon & Bahn, 2020). Six ear morphological dimensions were measured on participants and classified into two groups using K-means clustering analysis.

Attributes “pain” and “pressure” (as referred to by the authors) related to physical comfort and attributes “comfort” and “fixation” (which refers to the holding in position in their study) related to physical and functional dimensions of comfort for four sample products were investigated. The results showed that pain in the earcanal is low for participants who have a deep cavum concha. It was hypothesized that a “deep concha” reduces the portion of the in-ear device that go inside the earcanal which enhances physical comfort. It was also found that kernel-type earphone (that fit the inside of the earcanal) induce more feeling of pressure than open-type earphone (that fit in the concha and do not reach the inside of the earcanal). All of these studies use physical characteristics of the individual or the in-ear device to objectify comfort. Another method of objectifying comfort is to use the objective physical properties of the coupled earplug/earcanal system. Indeed, earplug discomfort results (in part) from the "interaction" phase during which earplugs exert mechanical pressure on the contact surface with human tissue (Doutres, Terroir, et al., 2022). Characterization of the physical properties of the interaction between the earplug and the earcanal would therefore be useful in objectifying comfort.

1.3.3 Characterization of the physical properties describing the interaction between the earplug and the earcanal

Smith et al., measured the expansion force of foam earplugs inserted in a cylindrical earcanal cut in half lengthwise and mounted between two load cells (Smith, Broughton, Wilmoth & Borton 1982). Dalaq et al., used models of increasing complexity (from idealized axisymmetric model to full 3D-model) of an earcanal reconstructed from medical images of a human subject to compute the mechanical pressure distribution exerted by a foam earplug on earcanal walls (Dalaq, Melo, Sgard, Doutres & Wagnac, 2022). They found that the highest stress did not occur exactly at the minimum radius of the realistic 3D earcanal but in a region confined between the first and second bend where the earplug is pinched and twisted. Another objective physical characteristic of the system earplug/earcanal is the force required to extract the earplug from the earcanal. Kim and Kadam, used rigid cylindrical custom-made earcanals ranging from 7 mm to 11 mm diameter and different models of earplugs (foam, premolded) to measure the extraction force for different earplug-earcanal combinations (Kim & Kadam, 2004). The earplugs were inserted into the earcanals and the extraction force required to remove them was measured using a force gauge. The results of the study showed that the extraction force required to remove the earplugs varies depending on the material of the earplug, and the size of the earcanal.

1.3.4 Physical comfort objectification from the characteristics of the earcanal/earplug system

Finally, few studies actually linked objective characteristics of the earcanal/earplug system with the physical comfort. Wang et al., studied the impact of "outward degree of expansion of the tragus" induced by in-ear wearables (i.e. how much the tragus is pushed outward by the in-ear device) on physical (and functional) comfort (Wang et al., 2022). Ninety subjects tested successively between 20 and 30 prototypes of in-ear devices that pushed the tragus outward (starting with those who push the least the tragus outward) and assessed their physical discomfort via Lickert and Borg scales. The assessment was stopped when the prototype caused extreme discomfort. It was found that when the degree of expansion of the tragus increases, the physical discomfort in the concha and the earcanal entrance increases. Norris et al., used a finite element model for which the geometry was obtained from medical images to assess stresses and strains in the earcanal tissues compressed by earplugs (Norris, Chambers Kattamis, Davis & Bieszczad, 2011). Considering that a pressure of 4 kPa applied to capillaries may collapse them (internal body effects phase of the comfort model described in (Doutres, Terroir, et al., 2022), producing ischemic state and pain (Albin, 2007), Norris et al. planned to further develop the model to find the relationship between earplugs materials and comfort. However, few details are given about the models, probably because these works are funded by the US Navy. Baker et al., used the finite element method to predict the physical comfort of earplugs (Baker, Lee & Mayfield, 2010). The geometries of three participants' earcanals (supposedly small, medium and large) were reconstructed and modeled to simulate the insertion and stress relaxation of earplugs in earcanals. They found that the key characteristics of the earplug/earcanal system that correlate to physical comfort are the average contact pressure and total contact force (between the earplug and the earcanal). To build their model, the assumption was made that by ensuring that both the earplug penetration depth and penetration angle were accurately reproduced in the model the resulting earplug / ear deformation would also be reproduced. However, the model was not validated against in situ measurements.

This short literature review about earplugs comfort reveals that measuring objective characteristics of the coupled system earplug/earcanal is not straightforward. In addition, static contact mechanical pressure and total contact force are relevant metrics to objectify earplugs physical comfort. To the knowledge of authors, most of studies that attempted to objectify in-ear devices physical comfort focus on earbuds and very few dealt with earplugs. Finally, it is worth noting that most of the aforementioned studies focused most exclusively on the physical characteristics of the devices to explain the physical comfort and were carried out in the laboratory. However, psychosocial characteristics of the triad and physical characteristics of the wearer and of his/her work environment should not be ignored a priori since they may have a non-negligible influence on the experienced (dis)comfort and therefore on the wearing of hearing protectors (Doutres, 2022). It is therefore important to consider as many of the characteristics of the triad as possible in order to gain a more complete understanding of comfort and its influencing factors.

1.4 Synthesis and research approach

The key points and main research problems identified from the literature review in this chapter are the following. There is a need for tools dedicated to the testing and design of earplugs that provide a good fit (and thus attenuation) for the widest range of earcanals morphologies. Disposable and reusable earplugs come in a variety of shapes and materials, but the target population are not indicated on the earplugs packaging. Moreover, methods to select earplugs adapted to user’s earcanals morphologies are not always applicable in the field. Finally, there is a lack of knowledge about the relations between the various physical and psychosocial characteristics of the triad (person/earplug/environment) and their relations to earplugs physical discomfort.

In order to address the above-mentioned research issues, this thesis relies on a database from a project on earplugs comfort conducted in Québec between 2018 and 2022. More than 170 workers daily exposed to noise from 3 different companies participated in the study. Questionnaires and laboratory measurements were used to extract a multitude of characteristics from the triad. In particular, workers' earcanal morphologies were extracted both with the EST and via the earcanal scan method and an objective method developed to create a comprehensive database of earcanal morphologies. Earplug attenuations were also measured on these workers who were trained to use their earplugs correctly. Questionnaires enabled to collect a large amount of information on the comfort of earplugs tested directly in the field. Multiple statistical analyses conducted on this large database have made it possible to answer the research problems.

CHAPTER 2

MORPHOLOGIC CLUSTERING OF EARCANALS USING DEEP LEARNING ALGORITHM TO DESIGN ARTIFICIAL EARS DEDICATED TO EARPLUGS ATTENUATION MEASUREMENT

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2.1 Abstract

Designing earplugs adapted for the widest number of earcanals requires acoustical test fixtures (ATFs) geometrically representative of the population. Most of existing ATFs are equipped with unique sized straight cylindrical earcanals, considered representative of average human morphology, and are therefore unable to assess how earplugs can fit different earcanal morphologies. In this study, a methodology to cluster earcanals as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement is developed and applied to a sample of a Canadian workers' earcanals. The earcanals morphologic indicators that correlate with the attenuations of 6 models of commercial earplugs are first identified. Three clusters of earcanals are then produced using statistical analysis and artificial intelligence-based algorithm. On the sample of earcanals considered in this study, the identified clusters differ by the earcanals length, and surface and ovality of the first bend cross-section. The cluster that comprises earcanals with small girth

and round first bend cross-section shows earplugs induced attenuation significantly higher than the cluster that includes earcanals with bigger and more oval first bend cross-section.

2.2 Introduction

Commercial disposable and reusable earplugs are widely used to prevent noise-induced hearing loss by attenuating the surrounding noise. To efficiently attenuate noise, the shape and material of the earplugs must match the earcanal morphology and provide a tight seal. However, due to the wide variability in humans' morphology it is difficult for designers to achieve a universally acceptable product (Ferguson et al., 2015). Thus, designing efficient and adapted earplugs that fit the widest range of earcanals morphologies remains extremely challenging. The-one-size-fits-most approach has been used by manufacturer for many years to design earplugs. However, earplugs available in one size may provide either physical discomforts to extra-small earcanals due to a too-tight fit (e.g., pain inside the earcanal) or even functional discomfort (e.g., earplug falling out) and low attenuation to extra-large earcanals (Berger & Voix, 2022; Doutres, Sgard, et al., 2022). Today, more inclusive design approaches tend to be favored to ensure safety and comfort for all (not only in the hearing protection field, but also in clothing and architecture for example). To ensure the best fit for the widest variety of users, a common solution consists in providing some earplugs models in two or more sizes. For example, some models of foam earplugs are available in regular and small size. These sizes correspond to different earplug diameters, but targeted user groups of each size are not clearly identified on the packaging, making the selection and use of these earplugs much less convenient. As for premolded earplugs (usually made of flanges affixed to a stem), that may also be available in a range of sizes, it has been shown that the greater the number of flanges, the fewer the sizes required to fit the population (Berger & Voix, 2022). However, this is more a general trend than a practical designing rule. Designing for the outliers and introducing diversity into the design process requires inclusive methods and tools.

Acoustical test fixture (ATFs) (that comply with the (ANSI/ASA S12.42, 2010) standard) are good candidates for earplugs design tools because they allow for rapid and repeatable attenuation measurements. However, existing ATFs are equipped with unique sized straight cylindrical earcanals in which some earplugs (for example flangeless bullet-shaped earplug of small diameter) cannot be properly fitted (Berger, 1986; Smith, Borton, Patterson, Mozo & Camp 1980). Furthermore, for a given earplug model to be tested, artificial straight cylindrical earcanals poorly capture the intra-individual variability in sound attenuation due to earplug fit (Benacchio et al., 2019) and cannot capture the inter-individual variability caused by large differences between human earcanal morphology (e.g. extra-small, regular and extra-large earcanals). An ATF intended to test how earplugs can fit different users should therefore allow for a variety of shapes of earcanals (Berger, 2005). There is thus a need for more realistic artificial ears available in a variety of sizes and shapes, characteristic of targeted populations and instrumented to measure sound attenuation. It would allow for the design of earplugs that are better suited to a wide range of earcanal sizes and shapes or better identify the population for which the earplug is best suited.

The objective of this study is to develop a methodology to cluster earcanals as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement and apply it to a sample of a Canadian workers' earcanals. In this context, having a comprehensive view of the earcanals morphology and its relation to earplugs sound attenuation is crucial, but the number of studies on this subject are limited. In 1988, Abel et al., found significant differences between women and men in attenuation of four commercially available earplugs: two foam earplugs and two premolded earplugs (Abel et al., 1988). The attenuations of earplugs available in a single size were lower when measured on women, whereas no gender effect was observed for earplugs available in a range of sizes. Gender differences in attenuation were therefore partly attributed to earcanal morphology differences between men and women. Abel et al., examined the correlation between the real-ear attenuation at threshold (REAT) of three earplugs measured on 93 subjects and three morphologic parameters of earcanals estimated from the earmolds of these subjects (Abel et al., 1990). These parameters were: (i) the areas of two cross-sections of the earcanal estimated at the conchomeatal angle (first bend region) and at the cartilaginous-bony junction (second bend region), (ii) the conicity (called degree of funneling in the Abel study) calculated as the ratio between these two section areas and finally (iii) the tortuosity (which quantifies if the earcanal is more tortuous or straight), estimated visually. Results showed that a mismatch between the earcanal and the protector shapes could affect the attenuation. These earplug/earcanal mismatches were mainly attributed to the tortuosity and the conicity. Moreover, Abel et al., found that attenuation is linearly related to the cross-sectional area of the earcanal at the cartilaginous-bony junction (Abel et al., 1990). A gender effect was observed since the correlation between the cross-sectional area of the earcanal at the cartilaginous-bony junction and the attenuation was found positive for women and negative for men. The effects of the morphology on sound attenuation were found higher at medium frequencies (3150 Hz) than at low frequencies (500 Hz). Viallet et al., found similar tendencies on the effects of morphology on sound attenuation (Viallet et al., 2015). Using a numerical approach, Viallet et al., were able to investigate the effects of earcanal morphology and acoustic leakage between the earcanal and earplugs. They showed that the important variability in the simulated sound attenuation of a foam and silicone earplugs was mainly due to acoustic leakage for frequencies below 1 kHz and by the inter-individual variability of the earcanal morphology between 1 and 5 kHz. More recently, Mououdi et al., measured 918 external ears dimensions of 153 operational workers and found that the design of molded type earplugs should be improved to better match earcanal entrance shape and diameter to avoid inducing acoustic leaks (Mououdi et al., 2018). The literature thus suggests that the inter-individual variability in earcanal morphology contributes significantly to the inter-individual variability in sound attenuation. However, none of these studies provides a comprehensive description of earcanals through morphologic indicators quantified objectively together with their relations with attenuations of earplugs from the three earplugs family: roll-down-foam, premolded and push-to-fit. Thus, there is a lack of data and methods to design artificial ears representative of the wide variability in earcanals morphologies of a given population and able to mimic the sound attenuation measured on these earcanals.

In this work, a methodology to cluster earcanals as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement is developed and applied to a sample of Canadian workers' earcanals. The paper is organized as follows.

Section 2.3 presents the morphologic and attenuation data acquisition and details the proposed methodology. Section 2.4 discusses the results and presents the limitations of this study. Finally, some concluding remarks are given in Section 2.5.

2.3 Methodology

The general description of the methodology used to cluster earcanals is shown Fig. 2.2. In short, it starts with a verification of the main hypothesis of this work (step 0), followed by the clustering process (steps 1 and 2) and ends by the evaluation of the proposed clusters (steps 3 and 4).

Sections 2.3.1. to 2.3.3 describe the sample of participants and the acquisition of morphologic and attenuation data on which the clustering process is applied. Based on the literature, morphologic indicators supposedly correlated to attenuation are proposed and extracted from the sample of 242 earcanals. Attenuations of six different earplugs are objectively measured on these same earcanals. The clustering process is described in section 2.3.4. In step 0 (section 2.3.4.1), correlations between morphologic indicators and attenuation are evaluated to check that earcanals morphology is effectively related to inter-individual variability in sound attenuation. In step 1, a pre-processing of the morphologic dataset is performed: n combinations of morphologic indicators relevant for the clustering are selected following the rules detailed in section 2.3.4.2. These combinations are then set as input to the clustering algorithm (see section 2.3.4.3 about the k-means clustering algorithm) which is executed in step 2 to obtain $2n$ clustering proposals based on earcanal morphologies: n proposals of k=2 clusters and n proposals of k=3 clusters. The next two steps, aim at choosing the clustering proposal which is the most relevant to be used as a basis to the design of realistic artificial ears representative of a sample of earcanals and dedicated to sound attenuation measurement. To do so, statistical analyses are performed to check that morphologic indicators are significantly different from one cluster to another (step 3, referred to as internal validation) and that attenuation data are significantly different from one cluster to another (step 4, referred to as external validation).

2.3.1 Participants

A total of 121 persons (18 females, 103 males) working in three different Canadian companies participated in this study. Participants are aged between 21 and 64 years old (mean 46, standard deviation 10 years). They are exposed to noise at work and used to wear earplugs before being involved in the study. They did not have antecedents of ear or neurological pathologies and did not have an important amount of earwax in their earcanals. This study uses the secondary data of morphologic and attenuation data collected during a field survey on earplugs comfort (Doutres et al., 2018) [Grant IRSST #2015-0014, Principal Investigators: Doutres and Sgard] approved by the ethical committee of the École de technologie supérieure (ethic certificate H20171101).

2.3.2 Morphologic data acquisition

2.3.2.1 Earcanals morphology sampling and scanning

The left and right earcanal morphology of each participant was obtained by scanning earmolds of earcanals. Earmolds were casted by two different custom earplugs manufacturer: Laviolette auditory laboratory, QC, Canada (manufacturer #1) and Custom protect ear Inc, BC, Canada (manufacturer #2). The manufacturing process of custom earplugs involved remake of earmolds prior to the fabrication of custom earplugs. Among the 242 earmolds of this study (2 times 121 participants), 64 were cast and scanned by manufacturer #2 before being reworked. Manufacturer #2 casted and scanned 52 others after earmolds being remade. Remaking operations performed on these earmolds included cutting the lateral part of earmold to keep only the earcanal plus the concha and a portion of helix, chamfering the medial part of the mold and carrying out a hole to introduce acoustic filters. The remaining 126 earmolds casted by manufacturer #1 were slightly modified before being scanned in our laboratory using a 3D Scanner Einscan-SP (Hangzhou Shining 3D Tech Co., China). Scans were hole-filled and smoothed using the EinScan-S Series v2.6.0.8 software. Operations performed on these earmolds included cutting the lateral part of earmolds to keep only the earcanal plus the concha and a portion of helix. These simple operations did not modify the shape of the earcanal part of the mold.

The assumption is made that obtained earcanal scans accurately describes the participants' earcanals morphology: the modifications of the real earcanal morphology due to the acquisition process (i.e., the earmold casting process, the 3D scanner model, and the earmold reworking process) are considered negligible and the difference between scans is only attributed to the difference between participants' earcanal morphology.

2.3.2.2 Extraction of morphologic indicators of shape and size earcanals from scans

The earcanal is an "S-shaped" duct that extends between the concha on its lateral side and the tympanic membrane on its medial side. The cross-section shape and size vary along the duct curvilinear axis (axis that passes through the centroid earcanal cross-sections, as seen in Fig. 2.1). As an overall trend, cross-sections become smaller and more circular in the medial direction. Different characteristic sections are usually used to describe earcanal morphology (Abel et al., 1990; Fan, Yu, Wang, Li, Chu, et al., 2021; Lee et al., 2018). In this study, three characteristic cross-sections that cover all the earcanal portion accessible through the casting process are used: the entrance (E), the first bend (FB) and the second bend (SB). The entrance is usually defined at the base of the concha. The first bend is located a few millimeters after the entrance in the cartilaginous part of the earcanal. The second bend is positioned deeper in the earcanal and close to the cartilaginous-bony junction.

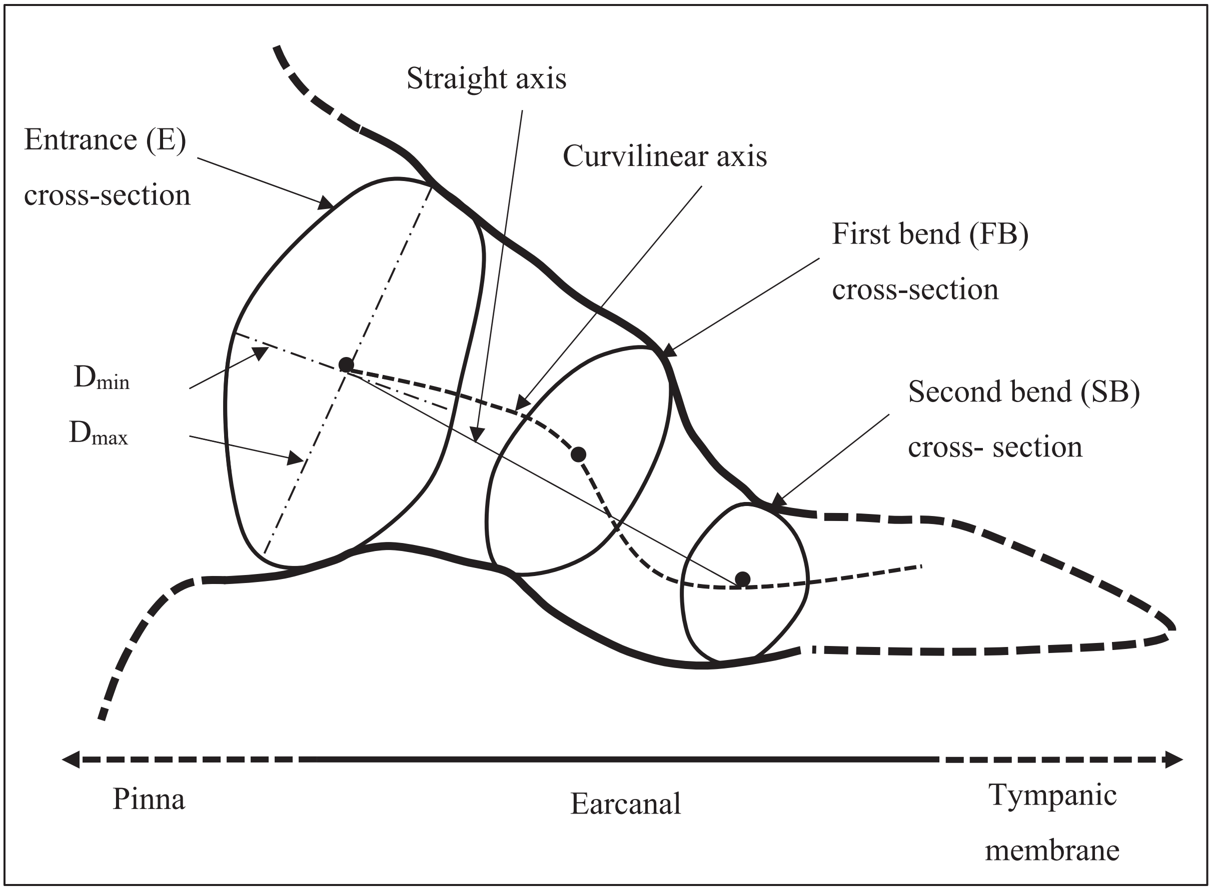

Figure 2.1 Earcanal description. Dark thick solid lines represent earcanal walls in the region of interest for this study
Dark thick dotted lines represent earcanal regions that are ignored. Dark thin solid lines represent reference cross-sections of earcanal. Dark thin dotted line represents the curvilinear axis of the earcanal. Thin mixed lines represent the longest and shortest diameters of entrance cross-section (used to calculate shape indicators as described below in this section)

Two dimensions can be used to describe the morphology of the earcanal: size and shape. In this work, five features are chosen to characterize these two dimensions either because they have been shown to be relevant to the ergonomic design of an ear product (Fan, Yu, Wang, Li, Chu, et al., 2021; Lee et al., 2018) or correlated with earplugs attenuation (Abel et al., 1990). Each feature is quantified with one or several indicator(s). The calculation of all indicators belonging to the two aforementioned dimensions is based on the determination of the three cross-sections E, FB and SB. It is worth noting that these 3 characteristic cross-sections may or may not be involved in the fit of the earplugs (since the earplug fit associated to the measured attenuation is unknown). For example, cross-section SB may not be involved in the fit of roll-down-foam earplugs for long earcanals, or if the earplug is not fitted deeply inside the earcanal. Similarly, cross-section E may not be involved in the fit of some push-to-fit-foam earplugs fitted deeply inside extra-large earcanals. The goal here is to describe the earcanal with morphologic indicators potentially related to earplugs attenuation (based on the limited literature on the subject). The relevance of these indicators will be discussed in section 2.4.2.

The position of each cross-section (E, FB and SB) in the earcanal is located using an objective methodology to avoid inducing any experimenter's bias. This objective methodology is based on both the landmarks method and an objective method described below based on the positioning of cross-sections perpendicular to the curvilinear axis of the earcanal. First, the curvilinear axis is extracted using the Stinson and Lawton's method (Stinson & Lawton, 1989). For each earcanal, the curvilinear axis has two local maxima of curvature. The first local maxima of curvature (the closest to cross-section E) and the second (the closest to the tympanic membrane) correspond to the position on the curvilinear axis of the FB and SB respectively. Cross-sections FB and SB are identified as the intersection between the earcanal walls and the planes perpendicular to the curvilinear axis at these two positions. Some earmolds are not casted deep enough in the earcanal to reach the SB. For these earmolds, the most medial section of the earmold is chosen as the section of the SB. To identify cross-section E with a good repeatability, Lee et al. methodology (also used by Fan et al.,) is adapted (Fan, Yu, Wang, Li, Chu, et al., 2021; Lee et al., 2018). This method is based on 4 different points (landmarks) to define the earcanal cross-section E. In the work presented here, cross-section E is defined as the intersection between the earcanal walls and a plane perpendicular to the curvilinear axis that passes through the most posterior point at cross-section E. This specific point defined in Lee et al., is chosen because it is the most easily identifiable one (Lee et al., 2018). Indeed, this point is located right at the junction between the concha and the earcanal so in this zone, the earcanal surface has a high curvature. Curvy areas such as bumps and valleys can easily be located on a surface with a good repeatability.

The features used to describe the earcanal size are the length and girth. The earcanal length is characterized by the length of its curvilinear axis (in mm) between cross-sections E and SB (because the bony portion of the earcanal was not accessible through the molding process). The girth of the three earcanal cross-sections (i.e. E, FB and SB) are described by two indicators that are either their area (in mm^2) or circumference (in mm).

The features used to describe the earcanal shape are the tortuosity, the conicity and the shape of cross-sections. The tortuosity measures if the earcanal is straight or crooked (i.e., being more "S-shaped"). It is computed as the ratio between the curvilinear and the Euclidean length of the earcanal between the E and SB cross-section centroids (see Fig. 2.1). A tortuosity equal to 1 indicates that the duct is perfectly straight whereas a tortuosity greater than 1 indicates that the duct has an "S" shape. Conicity measures how much the earcanal shrinks in the medial direction. It is computed similarly to Abel et al., as the ratio between the cross-sections E and SB areas (S_E / S_{SB}): A ratio close to 1 indicates that the earcanal is non-conical whereas a higher ratio indicates that the earcanal significantly shrinks in the medial direction (Abel et al., 1990). The indicator of conicity computed as a simple ratio between the cross-sections E and SB is an important simplification of the morphology of the earcanal. It simply describes the global diminution of earcanal cross-section surface between the cross-sections E and SB. A discussion about the relevance of this indicator can be found in section 2.4.1. Finally, the shape of a cross-section gives an information about its circularity. Usually, cross-sections between E and FB are triangular or elliptical whereas those close to the SB are more circular. The isoperimetric ratio is used to evaluate the circularity of these sections. It is defined as the ratio between the area and the squared perimeter multiplied by four times π and varies between 0 and 1 (the closer to 1, the more circular the section). The aspect ratio of these cross-sections is also computed to quantify their ovality. It is defined as the ratio between the longest and the shortest diameters of the cross-section. Here, a diameter refers to a segment joining two opposite points on the cross-section circumference and passing through its centroid. An example is shown in Fig. 2.1 where the aspect ratio of the cross-section E is calculated as D_{min}/D_{max}.

All indicators are determined using Polyworks (InnovMetric Logiciels Inc, Canada) and Matlab R2017b (MathWorks, Inc., USA). After a data inspection, two earcanals were discarded from the database because the curvilinear axis could not be computed with the Stinson and Lawton's method. Because cross-section FB determined with the proposed method intersects the concha leading to very unusual shapes and very large perimeters which yielded outliers for the statistical analysis, three more earcanals were removed.

2.3.3 Attenuation data acquisition

As mentioned previously, this study uses the secondary data of attenuation measurements collected during a field survey on earplugs comfort. The original project included nine earplugs of different families and different manufacturers but only 6 of them, for which attenuation measurements were carried out, are considered in this secondary study. Of these 6 earplugs, three belong to the "roll-down-foam" earplugs family, one to the "premolded" family and two to the "push-to-fit foam" family. References names of these earplugs can be found in Table 2.1. Participants of the original project tested 4 different earplugs models in their work environment for 7 weeks. At the beginning of each week, each worker had a one-on-one meeting with an audiologist to train him/her on the model of earplugs to be tested and to measure and verify the effective wearing of the earplugs. To this purpose, a field attenuation estimation system (FAES), the 3M™ E-A-Rfit™ Dual-Ear Validation System was used as a training tool and attenuation data measurement. This system uses surrogate earplugs (see pictures in Fig. 2.3 and Fig. 2.4) to instantly measure and display a Personal Attenuation Rating (PAR) compliant with the ANSI/ASA S12.71 standard (ANSI/ASA S12.71, 2018). The PAR is the overall average A-weighted attenuation of an earplug for a given fitting in a large ensemble of representative industrial noise spectra (NIOSH 100) (Berger, 2010). This FAES system was chosen because it allows for quick measurements which was an essential selection criterion since training sessions occurred during the participants work shift and had to be limited in time.

Two different PARs provided by the FAES are used in this study: the $PAR_{50\%}$ and the $PAR_{84\%}$. The $PAR_{50\%}$ is a median PAR that represents the most statistically probable value of the PAR

(Berger & Voix, 2022) and is used in the following to cluster the earcanals (see section 2.3.4). The $PAR_{84\%}$ is computed from the $PAR_{50\%}$ from which uncertainties are subtracted (such as the fit variability that accounts for the fact that the next time the person fits the hearing protector, he or she may do it differently) in order to give a more conservative estimate of the protection that is likely to be achieved on the field (Berger & Voix, 2022). It was therefore used by the audiologists during the training sessions as described in more details in the next paragraph.

Table 2.1 Earplugs references

Earplug family	Roll-down-foam			Premolded	Push-to-fit	
Earplug manufacturer's name	3M™ E-A-R ™ Classic uncorded	3M™ Foam Earplug 1100	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, 318-1008, with grip rings
Simplified name in this study	Classic foam	1100 foam	E-Z-Fit foam	Premolded	Push-ins	Push-ins-grip-rings

Details of the fit training procedure can be found in Martin et al., and are recalled here for completeness (Martin et al., 2019). The audiologist first reminded the worker how to put the earplugs in place, when to replace them and how to check if there was a proper fit. Then, the worker put the surrogate earplugs in place himself (or herself) for a first PAR trial. If both ears had an initial $PAR_{84\%}$ of minimally 50% of the manufacturer's NRR value (considered to as the first threshold value), the worker was considered adequately protected and the individual training was over. If not, the worker was asked to adjust the earplugs for a second PAR trial, still aiming for 50% of the NRR. Since, the $PAR_{84\%}$ data from the FAES takes into account uncertainties that act as a security factor (Berger, 2010), a second threshold value of $PAR_{84\%} = 10$ dB was accepted. This threshold was chosen because most of workers participating in the study had an average daily sound exposure level for 8 hours less than 95 dBA. If the second trial reached at least this second threshold value of $PAR_{84\%}$ = 10 dB for each ear, the training was over. If this threshold value could not be obtained, a third placement was attempted by the audiologist. If this PAR trial was adequate, the worker was asked to replicate the proper placement to ensure that he or she was able to put it back in place (third trial, and more if needed). This is similar to the method described by Federman & Duhon, where the participants learned successfully to reproduce the adequate placement (and similar PAR) after feeling the correct insertion by an expert (Federman & Duhon, 2016). Finally, if both ears did not reach a $PAR_{84\%} \geq 10$ dB for all trials (fitted by the worker), the earplug model was considered unsuitable for this participant's ear(s). Most workers needed between one to three trials per session to properly fit their earplugs. For the roll-down-foam earplugs, 6 trials (for one ear) were sometimes needed. For a few participants, more than 10 trials were required to reach the safe-threshold attenuation values of the training.

For each ear of each worker and for each earplug, the test data leading to the best $PAR_{84\%}$ is kept, and the research team exported the associated $PAR_{50\%}$ value as attenuation data to test the main underpinning hypothesis (see step 0 in Fig. 2.2) and to evaluate the clusters (see step 4 in Fig. 2.2). For the ease of reading, in the remainder of the paper, the acronym "PAR", refers to the $PAR_{50\%}$. The distributions of $PAR_{50\%}$ for each earplug are plotted in Fig. 2.3. By considering both the fitting training process (similar for all participants) and the relatively high PAR values displayed on Fig. 2.3 (i.e., usually greatly superior to NRR/2 , see section 2.4.1 for more details), the research team hypothesized that participants inserted their earplugs correctly so that the inter-individual variability in measured PARs can be mostly primarily attributed to differences in earcanals' morphology and not to other sources of variability related to the psychosocial characteristics of the participant and of his/her work environment (Doutres, Terroir, et al., 2022) (ex., education, gender, support from family /colleagues, type of work, type and frequency of training…). As mentioned previously, this hypothesis is checked in step 0 of the methodology presented in this paper (see sections 2.3.4.1 and 2.4.2).

2.3.4 Earcanals clustering

2.3.4.1 Steps 0: relations between earcanal morphology and sound attenuation

According to section 2.3.3, the research team hypothesized that the inter-individual variability observed in the measured PARs is mainly induced by the differences in earcanals morphology. To check if this hypothesis is relevant (from the sample to which the methodology is applied in this paper), it is first checked if correlations between morphologic data and attenuation data obtained during the training session exist. To do so, Pearson's correlation coefficients are computed between the morphologic indicators and PARs data using IBM® SPSS® Statistics 27.

2.3.4.2 Steps 1: choice of combinations of morphologic indicators relevant for the clustering

All relevant combinations of input morphologic indicators of the clustering algorithm to be tested are identified based on correlation between morphologic indicators. Accounting for correlations between morphologic data is crucial to avoid choosing a combination of morphologic indicators that are strongly correlated as an input to the clustering algorithm (Corbière & Larivière, 2020). Indeed, if two input morphologic indicators are strongly correlated, they would have a biggest weight in the clustering analysis than other morphologic indicators. To account for the correlations between morphologic indicators, Pearson's correlation coefficient is computed for each pair of morphologic indicators using IBM® SPSS® Statistics 27. Additionally, scatter plots of each pair of morphologic indicators are also drawn to visually check if non-linear correlations (not captured by the Pearson coefficient) between two morphologic indicators exist.

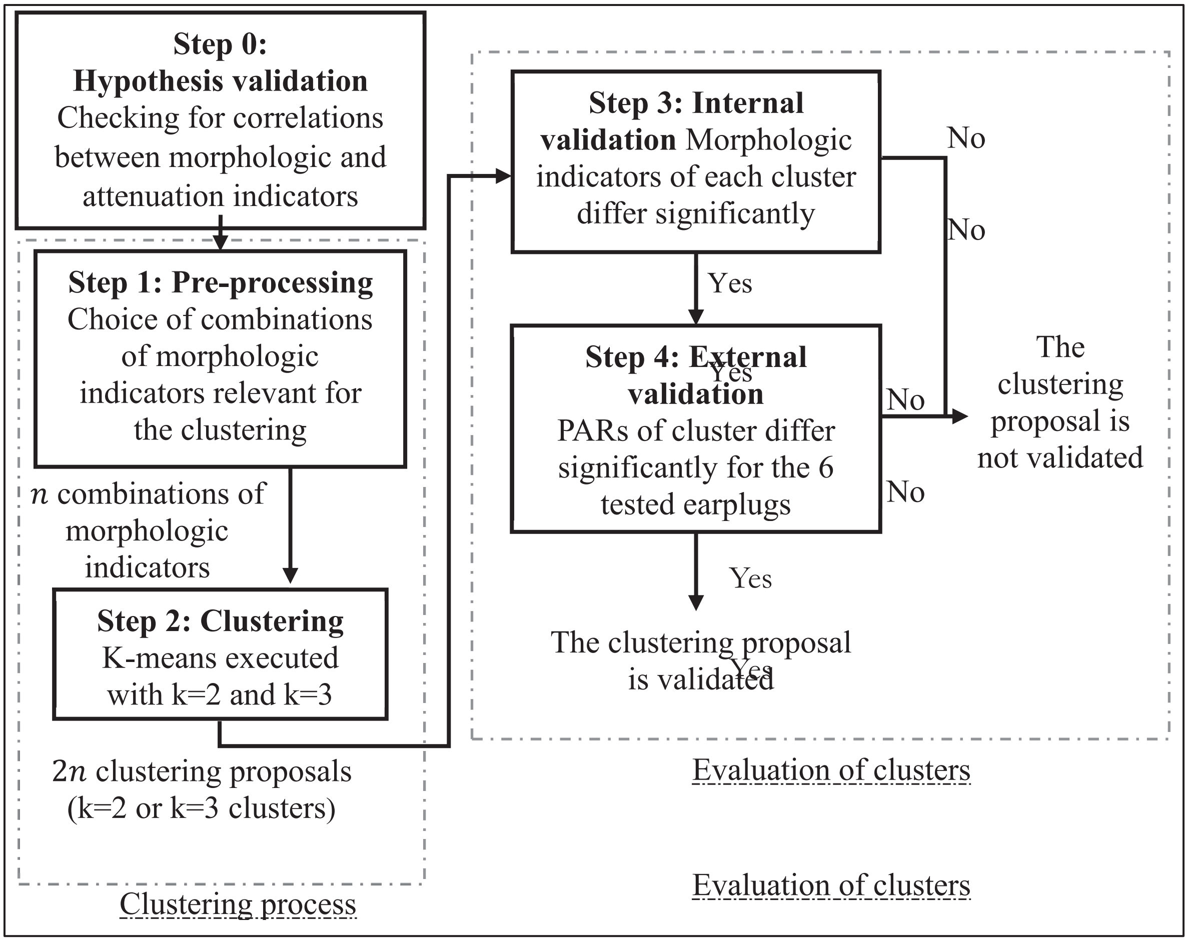

Figure 2.2 Description of the clustering process

Following the correlation analysis, the combination of morphologic indicators to cluster earcanals is performed and based on three considerations. Firstly, the correlation between two morphologic indicators in the same combination should not be higher than 0.8. Secondly, as some features (girth and cross-section shapes) are described by several indicators, each combination must not have more than one indicator per feature (not to overweight a feature over the others). Thirdly, each combination must include a girth indicator. This choice is motivated by the objective of building two or three artificial ears to test as much as earplugs as possible. As several commercial earplugs are available in two sizes that differ in diameter, artificial ears should have appropriate earcanal girth to make it possible to test these earplugs.

2.3.4.3 Steps 2: clustering algorithm

The k-means clustering algorithm is chosen to classify earcanals. K-means is a partitional algorithm that classifies a set of data points in two phases (Na, Xumin & Yong, 2010). The first phase selects k centers randomly, where the value k is fixed in advance. In this work k is forced to be less than 3 for practical and economical reasons associated with the objective of building artificial ears. The next phase is to take each data point to the nearest center. In this study, the Euclidean distance is used to determine the distance between each data point and the cluster centers. When all the data points are included in some clusters, the first step is completed, and an early grouping is done. This iterative process continues repeatedly until a goal function is minimal. Here, the goal function is the sum of the squared distances between each data point and its cluster center. An advantage of k-means over other clustering algorithms, is that it minimizes the dispersion of data points around the cluster centroid and allows for determining the centroid of each cluster (Jain, Murty & Fynn., 1999). Knowing the centroid of each cluster is essential to find earcanal morphologies representative of each cluster (for example, an existing earcanal with dimensions close to the centroid of the cluster).

The k-means algorithm is executed with all n selected morphologic indicators combinations (previously selected in step 1) as inputs with k=2 and k=3 clusters and provides $2n$ clustering proposals (n for k=2 plus n for k=3). All these proposals are then evaluated individually to choose the best clustering of earcanals.

2.3.4.4 Steps 3 and 4: clustering evaluation

The individual evaluation of each cluster is based on the following hypothesis: (i) it is possible to cluster 2 or 3 groups of workers' earcanals by combining relevant morphologic indicators; (ii) from these clusters, it is expected to observe significant differences in means showing that the level of PAR varies according to the morphologic indicators that characterize the groupings. The individual evaluation of each cluster proposal is therefore made using two consecutive validation procedures: (i) the internal validation (step 3) and (ii) the external validation (step 4). The internal validation is based on the following criterion: each morphologic indicator used to cluster earcanal must significantly differ from one cluster to another. This first criterion guarantees that artificial ears build based on these clusters will have significantly different morphologies. However, it does not guarantee that these artificial ears will enable to measure earplugs attenuations being different and representative of the inter-individual variability in sound attenuation. A second validation procedure, referred to as the external validation is therefore carried out. This validation is based on the following criterion: mean attenuations (PAR) of the 6 earplugs of this study must significantly differ from one cluster to another. This second criterion is relevant because PAR data are checked to be indeed correlated with earcanal morphology (in step 0), otherwise, significant differences in mean attenuation data of each cluster would not be expected.

Internal and external validations are performed using ANOVA and Bonferroni post-hoc test with a significance level set at 0.05.

2.4 Results and discussion

2.4.1 Data description

Descriptive statistics of morphologic data measured on the sample of a population of Canadian workers consisting of 237 earcanals are summarized in Table 2.2.

Table 2.2 Morphologic dimensions of earcanals and corresponding indicators names and descriptive values

Dimension	Features	Indicator (s)	Earcanal region	Symbol	Mean	Median	Std	Min	Max
Size	Length	Curvilinear length (mm)	Between E and SB	L_{E-SB}	13.3	13.3	2.3	7.8	19.6
	Girth	area (mm^2)	Cross-section E	S_E	104.3	102.7	22.3	43.3	203.2
			Cross-section FB	S_{FB}	75.6	73.2	19.0	33.8	124.8
			Cross-section SB	S_{SB}	62.3	60.5	19.5	21.6	117.5
		Circumference (mm)	Cross-section E	C_E	39.6	39.9	4.50	23.9	52.1
			Cross-section FB	C_{FB}	32.2	32.4	4.2	21.4	42.4
			Cross-section SB	C_{SB}	28.6	28.6	4.6	17.1	39.5

Table 2.2 Morphologic dimensions of earcanals and corresponding indicators names and descriptive values (cont'd)

Dimension	Features	Indicator (s)	Earcanal region	Symbol	Mean	Median	Std	Min	Max
Shape	Sections' shape	Isoperimetric ratio $4\pi\frac{Surface}{Circumference^2}$	Cross-section E	IR_E	0.83	0.84	0.07	0.62	0.96
			Cross-section FB	IR_{FB}	0.91	0.92	0.05	0.72	0.98
			Cross-section SB	IR_{SB}	0.93	0.94	0.04	0.79	0.99
		Aspect ratio D_{min}/D_{max}	Cross-section E	AR_E	0.64	0.62	0.12	0.32	0.96
			Cross-section FB	AR_{FB}	0.62	0.61	0.12	0.35	0.98
			Cross-section SB	AR_{SB}	0.72	0.71	0.11	0.45	0.99
	Tortuosity	Curvilinear length over Euclidian length	Between E and SB	T	1.06	1.06	0.03	1.01	1.19
	Conicity	area of E over area of SB $\frac{S_E}{S_{SB}}$	Between E and SB	$F_{E/SB}$	1.81	1.68	0.61	0.89	5.48

The earcanal size dimension is quantified through 2 features: the length and the earcanal girth. The length is comprised between 7.8 and 19.6 mm. The earcanal girth is quantified through 2 indicators that are the area and the circumference, both measured at the three cross-sections E, FB and SB. Their means (and standard deviations) circumferences are respectively C_E = 39.6 mm (*SD* = 4.5 mm), C_{FB} = 32.2 mm (*SD* = 4.2 mm) and C_{SB} = 28.6 mm (*SD* = 4.6 mm) and their areas are S_E = 104.3 mm2 (*SD* = 22.3 mm2), S_{FB} = 75.6 mm2 (*SD* = 19.0 mm2) and S_{SB} = 62.3 mm^2 (*SD* = 19.5 mm2). As expected, the earcanal shrinks in the medial direction ($C_E > C_{FB} > C_{SB}$), confirmed by the conicity indicator $F_{E/SB}$ that is larger than 1. Other shape dimension indicators indicate that the earcanal becomes more circular in the medial direction ($IR_E < IR_{FB} < IR_{SB}$). The aspect ratio of cross-sections E and FB are similar, whereas that of cross-section SB is larger. Cross-sections E and FB differ in terms of their iso-perimetric ratio but have similar aspect ratios. This is because cross-section E is shaped like a triangle whereas cross-section FB (and SB) is shaped like an ellipse. Consequently, the aspect ratio and the iso-perimetric ratio are complementary to describe cross-section E. Overall, this dataset confirms the general description of an earcanal given in Alvord and Farmer (Alvord & Farmer, 1997).

The medians of the distribution of the best PARs obtained during the fit training vary between 23 and 37 dB depending on the earplug. The histograms of PAR data are plotted in Fig. 2.3 and show that except for the push-ins grip-rings earplug, most workers were able to obtain a high PAR during the training session. Indeed, most of workers obtained PARs highly superior to 50% of the NRR values of the earplugs which is a typical derating factor applied to the earplugs NRR for estimating average protection levels for groups of users (see Table 2.2 of the CSA Z94.2-14 standard) (CSA, 2014). Considering that the workers received about 5 trainings in the insertion of disposable and reusable earplugs during the field study (see section 2.3.3), and that they obtained rather high PARs values after the training, it can be considered that the training sessions greatly reduced the inter-individual variability in sound attenuation related to psychosocial characteristics of the user and of his/her work environment (e.g., education, type and frequency of training…) (Doutres, Terroir, et al., 2022). It is therefore reasonable to hypothesize that the inter-individual variability observed in the PARs measured is mainly induced by the differences in the morphology of the earcanals (this hypothesis is checked during the step 0 presented in the next subsection).

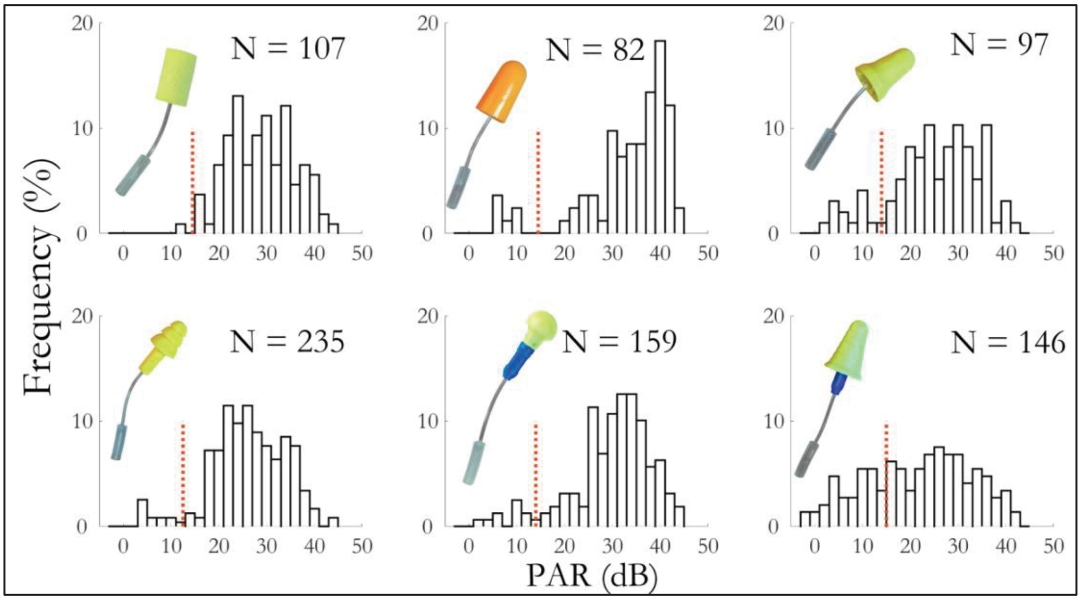

Figure 2.3 Distribution of the best PARs obtained during a fit training for the 6 earplugs (clockwise from top left): Classic foam, 1100 foam, E-Z-Fit foam, Push-Ins-Grip-Rings, Push-Ins and premolded Orange dotted lines show half of the NRR of each earplug

Low and negative PARs values observed on the push-ins-grip-rings earplug histogram suggest that a certain number of workers cannot fit properly the push-ins-grip-rings earplug resulting in leaks and a poor attenuation. Large leaks may indeed act as a Helmholtz resonator and provide a gain effect in the low to middle frequencies range (Berger, Brown & Smith, 2014). The fact that some workers were not able to obtain a safe PAR, even with a fit training, is consistent with the statement of Franks et al.,: “Not every person can wear every hearing protector. Some people may be unable to wear certain types of earplugs because of the shape or size of their earcanals” (Franks et al., 1996).

2.4.2 Step 0: relation between earcanal morphology and sound attenuation

Correlations between earcanals morphology and PARs are evaluated (Table 2.3) to confirm that the inter-individual variability in sound attenuation is related to the earcanal morphology and that the external validation described in section 2.3.4 is relevant on this dataset that characterizes a sample of Canadian worker' earcanals.

Table 2.3 suggests that the girth of FB and SB cross-sections are moderately but significantly correlated to the sound attenuation of the push-to-fit and premolded earplugs (Pearson correlations coefficients inferior to 0.05). A significant correlation between these sections' girths and attenuation of two malleable earplugs is also found. These correlations are negative, which means that the larger the earcanal, the lower the attenuation. It can be hypothesized that a large earcanal leads to a lower compression of the earplug and surrounding tissues. As at low frequencies, the vibro-acoustic behaviour of the earplug coupled to the earcanal is governed by the equivalent rigidity of the system {earplug + earcanal skin} (Sgard et al., 2011, p. 20), a lower earplug/skin compression induces a lower equivalent rigidity, and a lower sound attenuation. A lower mechanical pressure between earcanal skin and earplug may also introduce acoustic leakage.

Weak but significant correlations between the PAR and the cross-sections FB and SB shapes (IR_{FB}, IR_{SB} AR_{FB} and AR_{SB}) are also found especially with roll-down foam earplugs, except for IR_{SB} for which the correlation with the PAR of the 1100 foam earplug is fairly high (between 0.5 and 0.8). Correlations between sections shapes indicators and PAR are positive, meaning that the more circular the earcanal, the higher the PAR. It could be hypothesized that a circular earcanal allows for a better contact between earplug and earcanal walls, which avoids leaks between the earplug and the skin, leading to a higher attenuation. Lower but significant correlations between cross-section E size and shape and PAR of earplugs are observed.

Table 2.3 Pearson linear correlation between morphologic parameters of earcanals and maximum PAR obtained with trained participant fitting himself/herself its earplug
Dark gray boxes highlight a correlation higher than 0.4, gray boxes highlight a correlation between 0.3 and 0.4, white boxes highlight a correlation smaller than 0.3
Empty boxes indicate that the correlation between two variables is not significant at the level 0.05

Morphologic parameters		Personal attenuation rating					
		Malleable			Premolded	Push-to-fit	
Position in the earcanal	morphologic indicator	Classic foam	1100 foam	E-Z-Fit foam	Premolded	Push-ins	Push-ins-grip-rings
Entrance cross-section	C_E	-.195*		-.298**	-.359**	-.234**	-.285**
	S_E				-.302**	-.246**	-.257**
	AR_E		.273*				
	IR_E	.269**		.330**	.198**		
First bend cross-section	C_{FB}		-.355**	-.330**	-.418**	-.311**	-.362**
	S_{FB}		-.281*	-.261**	-.413**	-.332**	-.340**
	AR_{FB}	.235*					
	IR_{FB}	.228*	.292**	.327**			
Second bend cross-section	C_{SB}		-.335**	-.308**	-.478**	-.347**	-.410**
	S_{SB}		-.226*	-.270**	-.470**	-.352**	-.381**
	AR_{SB}			.304**			.182*
	IR_{SB}	.228*	.649**	.306**			.211*
Along earcanal	L_{E-SB}	.223*				.177*	
	$F_{E/SB}$				.260**		.221**
	T						-.209*
*. The correlation is significant at the level 0.05 (bilateral).							
**. The correlation is significant at the level 0.01 (bilateral).							

The conicity is only correlated to the attenuation of the premolded and the push-ins-grip-rings earplugs (the more conical the earcanal, the higher the PAR). These two earplugs have the most conical shapes of the 6 earplugs, and it can be hypothesized that they better match the geometry of conical earcanals than straight cylindrical earcanals (because the contact surface between the earplug and the earcanal would be higher in the first scenario). As described in the methodology section, the conicity computed as the ratio between the surfaces of the cross-sections E and SB is an important simplification of the morphology: it does not describe how the cross-sections area changes in the medial direction (linearly or exponentially for example), and it is computed between two cross-sections that are not necessarily involved in the earplugs fit (but correlated with earplugs attenuation). In a preliminary study not shown in this paper, the conicity has also been computed as the ratio between the cross-sections E – FB and FB – SB. These two additional indicators were however shown to be less relevant for this study because they were not or very poorly correlated to the earplug's attenuation. Finally, the conicity indicator computed between cross-sections E and SB seems relevant to be included in the clustering process of this study because it is significantly correlated to the attenuation of two conical earplugs.

As for the parameters of length and tortuosity, they are poorly but statistically correlated to the attenuation of the Classic foam and push-ins earplug (length indicator) and the push-ins-grip-rings earplug (tortuosity indicator). Conversely, Abel et al., found a high correlation between tortuosity and attenuation of earplugs (Abel et al., 1990). This could be due to the fact that Abel et al., evaluated the tortuosity subjectively and selected only the 17th most straight and the 18th most twisted earcanals (over the 186 of his study) to compute Pearson's coefficient. Taking extrema values favour high linear correlation coefficients.

Finally, correlations between morphologic indicators and attenuations of the six earplugs given in Table 2.3 show that a given morphologic indicator is not equally relevant for the attenuation of different earplugs models. This underlines the interest of choosing indicators that characterize the open earcanal (step 3, internal validation), and then, to study the correlation with the attenuation (step 4, external validation) in order to build artificial ears dedicated to the measurement of the attenuation of a multitude of earplugs. Overall, correlations suggest that the morphologic variability of the earcanals induces a variability in the sound attenuation of earplugs correctly inserted. Therefore, it seems relevant to use attenuation data to validate clustering proposal (step 4). It is reasonable to expect that mean attenuations of clusters classified using morphologic data will differ significantly.

2.4.3 Step 1: choice of combinations of morphologic indicators relevant for the clustering

To choose relevant combination of morphologic indicators as input for the k-means clustering algorithm, correlation coefficients are checked. Correlations between all morphologic indicators of this study are presented in Table 2.4.

Table 2.4 shows that the two indicators of girth (i.e., circumference C and area S) of a given cross-section have Pearson coefficients higher than 0.8 (see blue border boxes), indicating that they are highly correlated. Consequently, with the objective of choosing morphologic indicators combinations as input for the clustering algorithm, a given combination should include either the circumference or the area indicators but not both. Otherwise, the girth feature would have more weight that other features in a given combination. Correlations between the girths of SB and E cross-sections are between 0.45 and 0.5 (orange border boxes) and the correlations between the girths of couples {FB, E} on the one hand and {FB, SB} on the other hand are close to 0.6 (green border boxes). Consequently, the girth of all the earcanal can be fairly well described by the FB cross-section only. A similar conclusion can be drawn from the shape features of cross-sections E, FB and SB.

Table 2.4 Pearson linear correlation between different morphologic indicators of earcanals Dark gray boxes highlight a correlation higher than 0.5, gray boxes highlight a correlation between 0.3 and 0.5, while boxes highlight a correlation smaller than 0.3. Empty boxes indicate that the correlation between two variables is not significant at the level 0.05

S_E	AR_E	IR_E	C_{FB}	S_{FB}	AR_{FB}	IR_{FB}	C_{SB}	S_{SB}	AR_{SB}	IR_{SB}	L_{E-SB}	$F_{E/SB}$	T	
.92 **		-.35 **	.67 **	.65 **			.49 **	.48 **			.16 *		.25 **	C_E
	.15 *		.66 **	.69 **			.47 **	.46 **				.19 **	.18 **	S_E
		.26 **			.28 **	.17 **								AR_E
					.55 **	.50 **	-.14 *	-.13 *			-.23 **	.18 **	-.23 **	IR_E
				.97 **		-.19 **	.61 **	.58 **		-.18 **		-.14 *		C_{FB}
							.61 **	.59 **		-.13 *				S_{FB}
						.43 **								AR_{FB}
									.32 **	.20 **				IR_{FB}
								.98 **			-.15 *	-.72 **		C_{SB}
												-.71 **		S_{SB}
										.43 **				AR_{SB}
											.25 **	-.14 *		IR_{SB}
												.13 *	.21 **	L_{E-SB}
														$F_{E/SB}$

**. The correlation is significant at the level 0.01 (bilateral).

*. The correlation is significant at the level 0.05 (bilateral).

Considering that the earcanal girth is better represented by FB cross-section than E and SB ones, it is selected to calculate girth (S_{FB}, C_{FB}) and shape indicators (IR_{FB}, AR_{FB}). Either C_{FB} or S_{FB} are chosen as cross-section girth indicator and IR_{FB} or AR_{FB} as cross-section shape indicator. In the sample of earcanals used in this study, there are 48 combination of morphologic indicators that respect all criteria for the input combinations of the k-means algorithm. These 48 combinations of morphologic indicators are summarized in Table 2.5. To check that there is no multicollinearity between morphologic indicators of a same combination, variable inflation factors (VIFs) are computed between all morphologic indicators. It is found that no VIFs are higher than 5 if the surface and the circumference of the cross-section FB are not together in the list of morphologic indicators. As no combination includes these two morphologic indicators together, the research team concludes that there is no multicollinearity between morphologic indicators of a combination used as input for the clustering algorithm.

2.4.4 Step 3 and 4: cluster evaluation

As described in section 2.3.4.4, the evaluation of earcanals clustering is based on a two-step evaluation for each clustering proposal: the internal and external validations. This two-step evaluation is performed for both k = 2 and k = 3 earcanals clusters.

Table 2.5 summarizes the validation process for the 48 proposals of earcanals classifications in two different clusters (k = 2). The second column "combination of morphologic indicators" contains all the 48 combinations of morphologic data selected as inputs for the k-means clustering algorithm. The third column "Internally validated? T-test" indicates if the morphologic indicators of a given combination are statistically different from one cluster to another. If the answer is "Yes" the external validation is performed. The next 6 columns display the p-values of the ANOVAs performed on PAR of the 6 tested earplugs. If the 6 p-values are below the significance threshold of 0.05, the clustering proposal is considered validated according to the external validation procedure.

Table 2.5 Cluster evaluation for k=2 clusters
Gray boxes indicate that the p-value of the external validation ANOVA is significant at the level 0.05

N°	Combination of morphologic indicators					Internally validated? T-test	External validation p-value of the ANOVA on earplugs PAR					
							Classic foam	1100 foam	E-Z-Fit foam	premolded	Push-ins	Push-ins-grip-rings
1	C_{FB}					Yes	0.409	0.021	0.003	0.000	0.004	0.000
2	S_{FB}					Yes	0.823	0.031	0.011	0.000	0.005	0.000
3	C_{FB}	AR_{FB}				Yes	0.003	0.064	0.002	0.000	0.085	0.002
4	C_{FB}	$F_{E/SB}$				Yes	0.698	0.001	0.010	0.000	0.005	0.000
5	C_{FB}	T				No						
6	C_{FB}	L_{E-SB}				Yes	0.023	0.020	0.166	0.000	0.000	0.007
7	C_{FB}	IR_{FB}				Yes	0.001	0.017	0.000	0.000	0.061	0.042
8	S_{FB}	AR_{FB}				Yes	0.891	0.007	0.002	0.000	0.001	0.001
9	S_{FB}	$F_{E/SB}$				Yes	0.858	0.008	0.010	0.000	0.004	0.000
10	S_{FB}	T				Yes	0.972	0.025	0.009	0.000	0.006	0.000
11	S_{FB}	L_{E-SB}				No						
12	S_{FB}	IR_{FB}				No						
13	C_{FB}	AR_{FB}	$F_{E/SB}$			Yes	0.217	0.084	0.009	0.000	0.020	0.001
14	C_{FB}	AR_{FB}	T			Yes	0.002	0.055	0.022	0.000	0.190	0.001
15	C_{FB}	AR_{FB}	L_{E-SB}			No						

Table 2.5 Cluster evaluation for k=2 clusters
Gray boxes indicate that the p-value of the external validation
ANOVA is significant at the level 0.05 (cont'd)

N°	Combination of morphologic indicators					Internally validated? T-test	External validation p-value of the ANOVA on earplugs PAR					
							Classic foam	1100 foam	E-Z-Fit foam	premolded	Push-ins	Push-ins-grip -rings
16	C_{FB}	$F_{E/SB}$	T			No						
17	C_{FB}	$F_{E/SB}$	L_{E-SB}			Yes	0.199	0.018	0.108	0.000	0.002	0.002
18	C_{FB}	T	L_{E-SB}			Yes	0.285	0.800	0.789	0.659	0.000	0.727
19	C_{FB}	IR_{FB}	$F_{E/SB}$			Yes	0.197	0.004	0.012	0.000	0.006	0.007
20	C_{FB}	IR_{FB}	T			Yes	0.005	0.016	0.003	0.000	0.031	0.177
21	C_{FB}	IR_{FB}	L_{E-SB}			Yes	0.022	0.011	0.012	0.000	0.001	0.009
22	S_{FB}	AR_{FB}	$F_{E/SB}$			No						
23	S_{FB}	AR_{FB}	T			No						
24	S_{FB}	AR_{FB}	L_{E-SB}			Yes	0.156	0.262	0.475	0.258	0.018	0.743
25	S_{FB}	$F_{E/SB}$	T			No						
26	S_{FB}	$F_{E/SB}$	L_{E-SB}			Yes	0.307	0.038	0.139	0.000	0.004	0.000
27	S_{FB}	T	L_{E-SB}			Yes	0.274	0.802	0.429	0.809	0.001	0.508
28	S_{FB}	IR_{FB}	$F_{E/SB}$			No						
29	S_{FB}	IR_{FB}	T			Yes	0.847	0.347	0.286	0.000	0.032	0.000
30	S_{FB}	IR_{FB}	L_{E-SB}			No						
31	C_{FB}	AR_{FB}	$F_{E/SB}$	T		No						
32	C_{FB}	AR_{FB}	$F_{E/SB}$	L_{E-SB}		No						
33	C_{FB}	AR_{FB}	T	L_{E-SB}		No						

Table 2.5 Cluster evaluation for k=2 clusters
Gray boxes indicate that the p-value of the external validation ANOVA is significant at the level 0.05 (cont'd)

N°	Combination of morphologic indicators					Internally validated? T-test	External validation p-value of the ANOVA on earplugs PAR					
							Classic foam	1100 foam	E-Z-Fit foam	premolded	Push-ins	Push-ins-grip - rings
34	C_{FB}	$F_{E/SB}$	T	L		Yes	0.428	0.572	0.411	0.011	0.000	0.084
35	C_{FB}	IR_{FB}	$F_{E/SB}$	T		Yes	0.345	0.006	0.092	0.000	0.013	0.080
36	C_{FB}	IR_{FB}	$F_{E/SB}$	L_{E-SB}		Yes	0,011	0.019	0.010	0.000	0.000	0.010
37	C_{FB}	IR_{FB}	T	L_{E-SB}		Yes	0,005	0.041	0.093	0.002	0.000	0.143
38	S_{FB}	AR_{FB}	$F_{E/SB}$	T		Yes	0.580	0.003	0.056	0.000	0.002	0.000
39	S_{FB}	AR_{FB}	$F_{E/SB}$	L_{E-SB}		Yes	0,535	0.017	0.068	0.000	0.002	0.000
40	S_{FB}	AR_{FB}	T	L_{E-SB}		No						
41	S_{FB}	$F_{E/SB}$	T	L_{E-SB}		Yes	0,263	0.394	0.197	0.005	0.000	0.023
42	S_{FB}	IR_{FB}	$F_{E/SB}$	T		Yes	0.857	0.014	0.090	0.000	0.002	0.000
43	S_{FB}	IR_{FB}	$F_{E/SB}$	L_{E-SB}		No						
44	S_{FB}	IR_{FB}	T	L_{E-SB}		No						
45	C_{FB}	AR_{FB}	$F_{E/SB}$	T	L_{E-SB}	No						
46	C_{FB}	IR_{FB}	$F_{E/SB}$	T	L_{E-SB}	Yes	0.004	0.072	0.093	0.000	0.000	0.163
47	S_{FB}	AR_{FB}	$F_{E/SB}$	T	L_{E-SB}	No						
48	S_{FB}	IR_{FB}	$F_{E/SB}$	T	L_{E-SB}	No						

According to Table 2.5, 29 combinations of morphologic indicators passed the internal validation step. Each of these 29 combinations are then tested with the external validation procedure with the objective to select a clustering proposal for which attenuations significantly differ from one cluster to another. This external validation is much more restrictive. Looking at grey boxes in Table 2.5, it is worth noting that roll-down foam earplugs especially invalidate a lot of clustering proposals (this earplug is very restrictive for the external validation). The two push-to-fit and the premolded earplugs are much less restrictive. Indeed, the two push-to-fit earplugs invalidate only 9 clustering proposals over the 29 combinations internally validated whereas the Classic foam earplug invalidate 20 clustering proposals. Interestingly, earplugs for which PAR are poorly or not correlated to earcanals morphology invalidate more clustering proposals than earplugs for which PAR are moderately to highly correlated to earcanals morphology. Indeed, as the clustering is based upon morphologic classification, it is expected that earplugs PARs significantly correlated to earcanals morphology may have significantly different means between clusters. This supports the interest of an external validation based on attenuation data in the objective of building artificial ears for attenuation measurements.

Finally, only two clustering proposals lead to significantly different attenuations for all 6 earplugs. These two combinations are: $\{C_{FB} - IR_{FB} - L_{E-SB}\}$ (line 21 of Table 2.5) and $\{C_{FB} - IR_{FB} - L_{E-SB} - F_{E/FB}\}$ (line 36 of Table 2.5). These combinations are very close to each other, the only difference being the earcanal conicity which is present only in the second combination. As the objective is to design artificial ears representative and different between two clusters for a maximum of morphologic dimensions, it is the second proposal of clustering taking into account 4 morphologic dimensions that is retained (for k=2 clusters).

For this kept clustering proposal $\{C_{FB} - IR_{FB} - L_{E-SB} - F_{E/FB}\}$, Table 2.6 shows that the cluster 0 comprises the largest earcanals (leading to the lower attenuation as shown in Fig. 2.4) and the one with the lower iso-perimetric ratios (also leading to the lower attenuation as presented in Fig. 2.4). Therefore, there is a double effect of morphology on attenuation for this clustering proposal: the most circular and smallest earcanals have the best attenuation whereas the more oval and larger earcanals have the poorer sound attenuation. This double effect explains why attenuations of the cluster 0 and cluster 1 differ significantly.

It should be noted that for the sample of earcanals presented here, the cluster of largest earcanals also comprises the shortest earcanals. Finally, the most conical and straight cylindrical earcanals are grouped in cluster 1 and cluster 0 respectively.

Table 2.6 Comparison of means of morphologic indicators between the two clusters of the best clustering proposal with k = 2

Class	Earcanals number	C_{FB} (mm)	IR_{FB}	$F_{E/SB}$	L_{E-SB} (mm)	
0	83	35.2	.87	1.53	11.8	Mean
		3.2	.057	.42	2.0	std
1	154	30.5	.92	1.96	14.1	Mean
		3.6	.04	.64	2.03	std

For this clustering proposal, the PAR significantly differs from one cluster to another for the 6 earplugs as shown in Fig. 2.4.

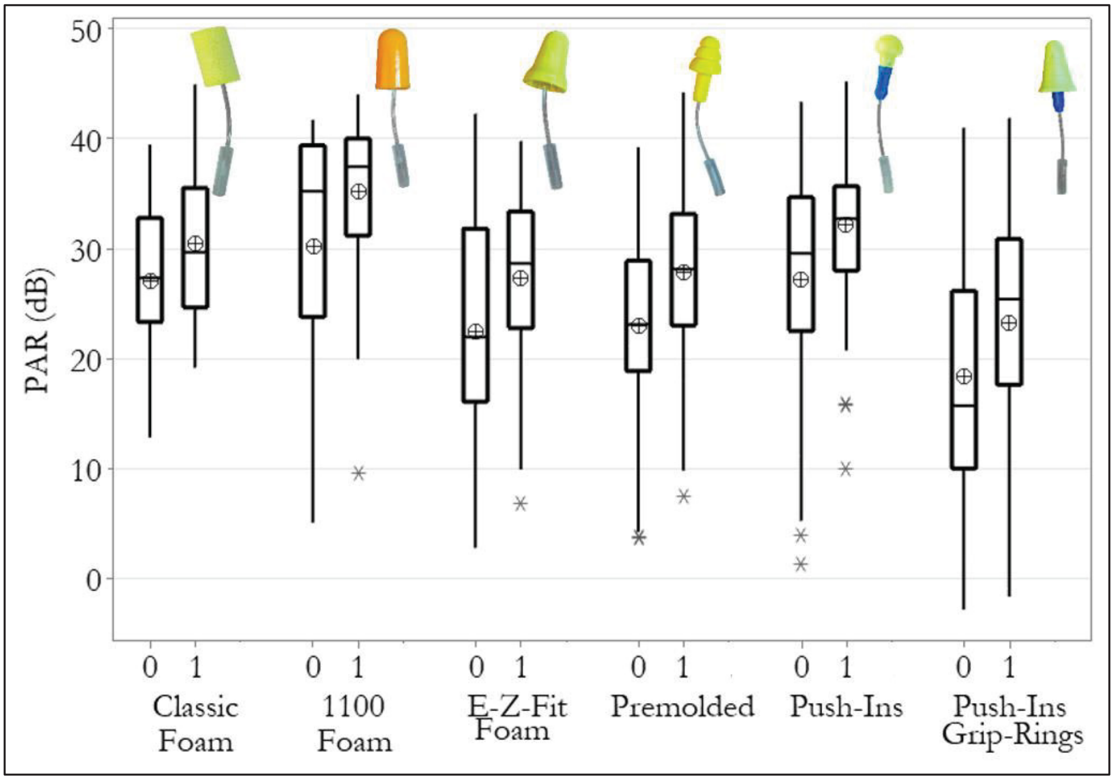

Figure 2.4 Box plot of the PAR of 6 earplugs for the two clusters of the best clustering proposal for k=2

Regarding the evaluation of clustering proposal for k=3: the same two-steps validation process as for k=2 is followed. The only difference is that the internal validation is based on the Bonferroni post-hoc test. This is motivated by the fact that there are now three clusters of earcanals. This post-hoc test allows a pairwise comparison of clusters. The results of the external validation for the 12 combinations that passed the internal validation are listed in Table 2.7.

Table 2.7 Cluster evaluation for k=3 clusters
Only clusters that satisfied the internal validation (Bonferroni post-hoc test) are plotted in this table. Gray boxes indicate that p-value of the external validation ANOVA is significant at the level 0.05

N°	**Combination of Morphologic indicators**				**External validation p-value of the ANOVA on earplugs PAR**					
					Classic foam	**1100 foam**	**E-Z-Fit foam**	**premolded**	**Push-ins**	**Push-ins-grip -rings**
1	C_{FB}				0.015	0.135	0.227	0.000	0.001	0,029
2	S_{FB}				0.907	0.001	0.009	0.000	0.000	0,000
3	C_{FB}	IR_{FB}			0.070	0.051	0.004	0.000	0.028	0,020
4	C_{FB}	$F_{E/SB}$			0.317	0.006	0.007	0.000	0.004	0,001
5	C_{FB}	T			0.586	0.061	0.001	0.000	0.015	0,000
6	C_{FB}	L_{E-SB}			0.192	0.023	0.003	0.000	0.009	0,002
10	S_{FB}	T			0.524	0.169	0.002	0.000	0.004	0,000
15	C_{FB}	AR_{FB}	L_{E-SB}		0.022	0.173	0.021	0.000	0.026	0,032
16	C_{FB}	$F_{E/SB}$	T		0.609	0.034	0.012	0.000	0.057	0,000
21	C_{FB}	IR_{FB}	L_{E-SB}		0.045	0.005	0.017	0.000	0.004	0,002
32	C_{FB}	AR_{FB}	$F_{E/SB}$	L_{E-SB}	0,344	0.159	0.027	0.000	0.030	0.003
33	C_{FB}	AR_{FB}	T	L_{E-SB}	0,006	0.754	0.019	0.000	0.003	0.064

As for the external validation, an ANOVA is performed on earplugs PARs. The same trends than for k=2 clusters are observed. The two push-to-fit earplugs PAR significantly differ for most of clustering proposals. All clustering proposal internally validated are also validated with the PAR for the premolded earplug. Foam earplugs, however invalidated several clustering proposals, especially the classic foam earplug which invalidate 8 out of the 12 internally validated clustering proposals.

Finally, only one combination of morphologic indicators provides clusters that meet both the external and the internal validation: $\{C_{FB} - IR_{FB} - L_{E-SB}\}$ (line 21 in Table 2.7). The unique combination of morphologic indicators ($\{C_{FB} - IR_{FB} - L_{E-SB}\}$) that satisfies both validation criteria for k=3 clusters also meets both criteria for k=2 clusters (see line 21 of Table 2.5).

As seen in Table 2.8, the number of earcanals per cluster is well balanced for this clustering proposal. Again, there is a double effect of morphology on attenuation. Cluster 0 includes the earcanals for which the girth is the smallest (higher attenuation as seen in Fig. 2.5) and earcanals with the highest iso-perimetric ratios (higher attenuation as seen in Fig. 2.5). Cluster 2 comprises the largest and most oval earcanals. Finally, cluster 1 is in the middle of these two clusters for these two indicators ($\{C_{FB} - IR_{FB} - L_{E-SB}\}$). This double effect explains why attenuations of clusters 0, 1 and cluster 2 differ significantly.

Table 2.8 Comparison of means of morphologic indicators between the three clusters of the best clustering proposal with k=3

Class	Earcanals number	C_{FB} (mm)	IR_{FB}	L_{E-SB} (mm)	
0	92	28.5	0.93	12,9	Mean
		28.2	0.93	13.0	Median
		2.6	0.03	1.6	std
1	69	33.4	0.91	15.7	Mean
		33.5	0.91	15.7	Median
		2.9	0.04	1.3	std
2	76	35.4	0.88	11.5	Mean
		35.1	0.88	11.7	Median
		3.0	0.06	1.6	std

Fig. 2.5, shows boxplots of the best PARs obtained during the fit training for the three clusters and each earplug. The sound attenuations of earplugs in cluster 0 are overall, higher (significantly at the level 0.05) than those in cluster 2. However, sound attenuations of earplugs in cluster 1 do not necessarily differ from those in other clusters. It is important to recall that attenuations have not been used as an input to cluster earcanals. The difference of attenuation of different clusters is just a consequence of the correlation between morphology and attenuation. A Bonferroni post-hoc test (not shown in this paper) has been conducted for sound attenuations of all earplugs. For the premolded earplug, attenuations in each cluster significantly differ from one another (at the level 0.032 between clusters 0 and 1, level 0.006 between clusters 1 and 2 and level <0.001 between clusters 0 and 2). Consequently, with the objective to build artificial ears for the measurement of attenuation on a maximum of earplug types, it seems relevant to use 3 different clusters of earcanals. Finally, it is this final clustering proposal, obtained with the k-means algorithm with morphologic indicators $\{C_{FB} - IR_{FB} - L_{E-SB}\}$ and k=3 different clusters of earcanals that seems the most relevant to help the design of realistic artificial ears dedicated to earplug measurement attenuation.

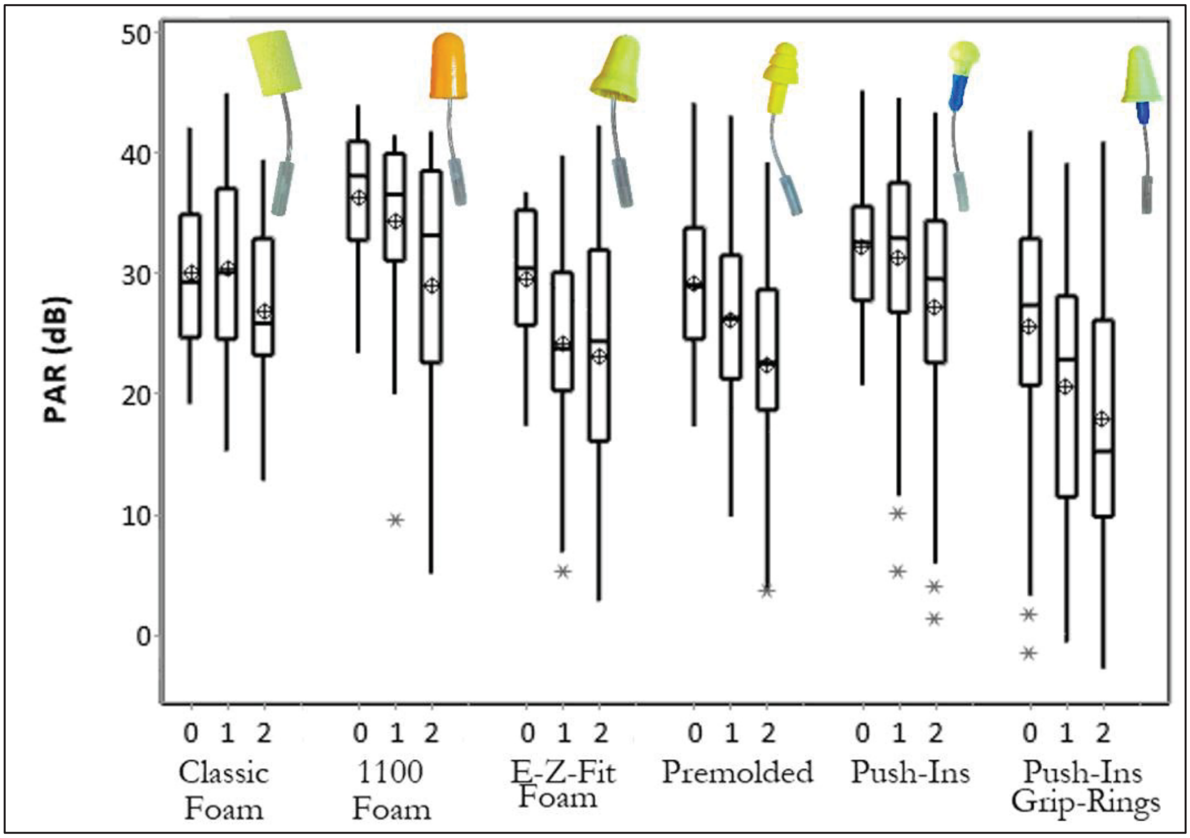

Figure 2.5 Box plot of the PAR of 6 earplugs for the three clusters of the best clustering proposal for k=3

In order to check that the final k value of 3 achieves an optimal solution, complementary analysis (not associated with the objective of building 2 or 3 artificial ears) have been conducted. The same clustering methodology as for k=2 and k=3 has been applied with k=4. For 4 clusters, only two combinations of morphologic indicators successfully passed the internal validation ($\{S_{FB}\}$ and $\{S_{FB}\ ;\ AR\}$). None of these two combinations successfully passed the external validation. This strongly suggests that the final clustering proposal obtained with k=3 clusters is an optimal solution.

2.5 Limits

Limitations of the clustering methodology and its application to a sample of earcanals are identified in this section.

The proposed methodology being applied on a limited number of earcanals, statistical limitations associated with generalizing results from a sample apply.

A single process of clustering and validation procedure is performed to cluster earcanals. Other clustering algorithms and/or statistical tests to validate clusters could have been used and may have led to another clustering structure of earcanals. The method presented here makes it possible to select a clustering of earcanals relevant as a basis for the design of artificial ears dedicated to sound attenuation measurement.

The description of earcanals' morphology is here limited to 15 morphologic indicators (7 size indicators and 8 shapes indicators), that describe the earcanal portion where the earplugs are supposed to be fitted (between the entrance and the second bend). It is therefore assumed that these indicators are sufficient to comprehensively describe the earcanal morphology. Other anatomical properties that may be also responsible for inter-individual variability in sound attenuation such as mechanical properties of ear tissues, the position of the cartilaginous/bony junction or eardrum impedance are not considered here (note that some of them can be difficult to determine in the field, or even impracticable).

Comparison of earcanal morphologic differences between studies is complicated because methods to extract morphologic indicators differ and are not always objective. In this paper, the proposed method to extract the morphologic indicators has been designed to be as objective as possible (i.e. reducing the number of manually placed landmarks to locate characteristic cross-sections of the earcanal). However, this method is based on the use of cross-sections perpendicular to the curvilinear axis, which may not be equally relevant for all earplugs considered in this study. For example, the radial axis about which the flanges of a premolded earplug extend might not be centered on the curvilinear axis.

The earplugs insertion depth is unknown and a better knowledge of the position of each earplug in each ear could have been helpful to identify the most relevant cross-sections to be correlated with the measured sound attenuation.

In addition, the type of training used in the original field study has led to a PAR value that was considered high enough to assume that that measured inter-individual variability in PAR could mainly be attributed to the morphologic differences between earcanals. However, it can be hypothesized that the correlations between morphologic indicators and PAR could have been higher if the training session was designed specifically for this study (or if an experimenter fitting was performed for PAR measurements) and thus would have targeted the maximum PAR achievable for a given earplug.

2.6 Conclusion

Most of existing ATFs dedicated to earplugs sound attenuation measurement are equipped with unique sized straight cylindrical earcanals, considered as representative averaged morphology of humans, and thus are unable to assess how earplugs can fit different earcanal morphologies.

In this paper, a methodology to cluster earcanal as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement is developed and applied to a sample of Canadian workers' earcanals. Morphologic indicators are measured/computed on earmolds of earcanals and attenuation of 6 different earplugs were measured on these same earcanals. An artificial intelligence-based algorithm and statistical analysis were used to assess earcanal clusters the most relevant to help the design of realistic artificial ears dedicated to earplug attenuation measurement. The morphologic data of the population sample considered in this study proved to be consistent with the literature and significant correlations between some morphologic indicators and attenuation of earplugs were found. Considering this population sample, the best clustering proposal was obtained using the three following morphologic indicators as input for the k-means algorithm: (i) circumference of the first bend cross-section (ii) isoperimetric ratio of the first bend cross-section and (iii) length between the entrance and the second bend. This clustering proposal consists of three different clusters of earcanals. It was found that the cluster that comprises earcanals of smallest girth and the most circular is also the cluster where measured PAR are the highest, whereas the cluster that includes the largest and most oval earcanals has low measured PAR. This observation is coherent with the correlation morphology/attenuation observed both in the literature and confirmed by this study.

2.7 Acknowledgments

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CHAPTER 3

RELIABILITY OF EARCANAL SIZING TOOLS TO ASSESS EARCANAL SIZE AND ASSIST THE EARPLUGS SELECTION

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3.1 Abstract

Objective: Choosing the right earplug is an essential step in any hearing conservation program to protect workers exposed to hazardous noises. The objective of this study is to evaluate the reliability of an earcanal sizing tool (EST) for estimating the fit quality of earplugs and ultimately for use as an earplug selection tool in the field.

Design: Earcanal morphology, comprehensively assessed through scans of earcanal earmolds, are compared to earcanal size assessed with the EST via box plots and Pearson linear correlations coefficients. Relations between personal attenuation rating (PAR) measured on participants (for 6 different earplugs) and their earcanal size assessed with the EST are established via box plots and comparison tests.

Study sample: 121 participants exposed to noise at work (103 men, mean age 47 years).

Results: The size of the earcanal assessed with the EST allows estimating the area of the earcanal first bend cross-section (correlation coefficient $r = 0.533$, p<0.001). Largest earcanals have significant lower PAR (often unsafe) than smaller earcanals.

Conclusions: The EST is a simple and inexpensive tool easily deployable in the field as an earplug selection tool, and primarily to detect and protect people with extra-large earcanals who are most likely to be under-protected.

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

3.2 Introduction

Exposure to hazardous noise is one of the most common occupational risks worldwide. In Quebec (Canada) for example, noise-induced hearing loss (NHIL) is one of the most prevalent and expensive occupational disease (Lebeau, 2014; Réseau de santé publique en santé au travail, 2022). Disposable and reusable earplugs are widely used to reduce the amount of noise that reach the tympanic membrane and prevent NHIL. They exist in multiple shapes, sizes, and materials. Most of the time, the earplugs are selected based upon their primary function: the noise attenuation usually quantified by the noise reduction rating (NRR). The NRR must be visible on the earplugs packaging (CSA, 2014), which makes the earplug selection fast and convenient once the required amount of attenuation has been determined (depending on the user noise exposure). However, the NRR, which is measured in laboratory (ANSI S3.19, 1974), is well known to provide false (often too high) estimates of field attenuation (Berger, 1993). To account for the discrepancy between the earplugs labelled and the real-world attenuation, derating scales have been proposed such as reducing the NRR by a certain percentage (e.g., 50%) that depends on the types of products (disposable or reusable earplugs, earmuffs, dual protection) (NIOSH, 1998; CSA, 2014; CSA 2022). The issue of derating schemes is that they only consider the hearing protection type and do not account directly for actual physical characteristics of the individual to be protected.

Unlike other protective equipment sold in different sizes which are clearly identified on the packaging (e.g. shoes, gloves), earplugs are often one-size-fits-most type protections. But earcanals size play a key role in the attenuation (Abel et al., 1990 ; Poissenot-Arrigoni, Law, Berbiche, Sgard & Doutres, 2022) and should be taken into account at the time of earplugs selection. In a recent paper, earcanals morphology of 121 workers was assessed with the earmolds scans methods and multiple morphologic indicators such as girth and ovality at characteristics earcanals cross-sections, length tortuosity and conicity were computed (Poissenot-Arrigoni et al., 2022). Authors found that the sound attenuation of a hearing protector correctly inserted inside an earcanal (by the wearer him/herself after receiving a typical fit training that can be given in the framework of a hearing conservation program), is correlated to the morphology of the earcanal. The girth (perimeter and area) of the cross-section located at the first bend of the earcanal is the morphologic dimension which was found the most (negatively) correlated with earplugs attenuation: the wider the first bend cross-section, the lower the attenuation (Poissenot-Arrigoni et al., 2022). This emphasizes the fact that earcanal morphologies and in particular its girth near the first bend region should be considered in the selection phase of earplugs. Although the employer may be obliged to make available a variety of different hearing protectors (OSHA, 1983b), there is no consensus on a strategy or method to choose earplugs that will ensure sufficient attenuation to a given worker (especially when it is offered in several sizes). Some roll-down foam earplugs of a given shape for example, are available in regular size and small size but targeted user groups of each size are not clearly identified on the packaging. Furthermore, the most suitable earplug model (characterized for example by the earplug’ shape, being cylindrical, bullet-shaped or spherical) and size for each earcanals shapes and sizes are not known. The standards on the selection and use of hearing protection devices do not provide clear guidelines on this subject.

A recent advance to help in the earplugs selection is the progress made in the field of fit testing and the popularization of field attenuation estimation systems (FAES) which enables to measure field individual attenuations (Voix et al., 2022). FAES are becoming more widespread but are still marginal. Moreover, FAES based selection methods would also be more effective if a pre-selection of earplugs was made beforehand, according to the size of the user's earcanals. A size-based pre-selection would reduce the number of earplugs to test, allowing more time to use the FAES to train and motivate the user in the use of earplugs (which is a critical step of any hearing conservation program).

In order to know which earplugs are best suited to which types of earcanals, it is necessary to be able to characterize the morphology of the earcanals. Intra-aural 3D scanning devices enable a complete digitalization of both the earcanal and the pinna but require advanced technologies that are not widespread on the field because often patented by the owner and rather used for the manufacturing of hearing aids and hearing protectors. Another method, commonly used by custom earplugs and hearing aids manufacturers and into studies about earcanal morphology (Lee et al., 2018; Voss et al., 2020) is to cast earmolds of earcanals (usually using a soft silicone that hardens once injected inside the earcanal). These earmolds can be scanned once removed from the earcanal which enables a digitalization of a part of the pinna (including the concha) and the entire earcanal portion that can be accessible through the molding process (i.e., a few millimeters after the second bend region and not too close to the tympanic membrane for safety reasons). Digitalizing the earcanal morphology is not sufficient to determine its size. Indicators such as diameter (related to earplugs attenuation) must be extracted from the digitalized earcanal and computed to quantify earcanal size. The latter method is cumbersome and therefore difficult to apply in the field as a dedicated tool for the earplug selection phase.

To the authors' knowledge, the quickest and more straightforward method to assess the earcanal size is based on the 3M™ Eargage (ANSI/ASA S12.6, 2016; Berger, 2013; Thomas et al., 1994). The 3M™ Eargage enables a quick evaluation of the "earcanal opening" (which is the term used in the ANSI/ASA S12.6 standard to describe the area of the earcanal which is sized with the EST). The EST consists of 5 plastic spheres denoted as extra-small (XS), small (S), medium (M), large (L), and extra-large (XL), with the dimensions specified. As described in the annex B of the ANSI/ASA S12.6 standard (2016), the procedure to size earcanals opening using this tool consists in inserting the spheres in the earcanal one by one starting from the smallest and select the one that better fits the earcanal opening (the procedure must be applied to both the right and left earcanal). This tool may be used to size earcanals and report their dimensions when measuring earplug attenuations (see Berger, 2013 for example). Because of its simplicity and great potential for field application, the 3M™ Eargage is used in this work to assess earcanal diameter and is referred to as the earcanal sizing tool (EST). However, very few studies evaluated how precisely this EST can size an earcanal (Thomas et al., 1994; Samelli, Gomes & Chammas, 2018). Thomas et al., (1994) compared earcanals sizes of 552 participants assessed both with the EST (measurement were done independently by two experimenters) and caliper measurements on earmolds of participants earcanals. Comparison between the EST measurements performed by the two experimenters showed that the EST is a reliable tool that provide repeatable measurements. Thomas et al., (1994) found significant differences between the earcanal opening measured with the EST and the elliptical cross-section area obtained from caliper measurement at the base of the concha (near earcanal entrance) and at 4.8 mm depth inside the earcanal (around the first bend region). They conclude that the EST (that has a spherical tip) distorts the elliptical earcanal cross-section and is inadequate for anthropometric classification applications. Samelli et al., (2018) used the EST to assess the earcanal size and evaluated it in comparison with a tympanometer which provides the earcanal volume. They found that the earcanal volume is not directly related to the earcanal opening, possibly because an earcanal with narrow, small diameter, can be deep and have a larger volume. In particular, the definition of the earcanal opening supposedly measured with the EST remains unclear. The earcanal is an S-shaped conical duct (the earcanal narrows between the entrance and the tympanic membrane), and it is unclear at what depth from the earcanal entrance the EST sizes the earcanal diameter. No study specifically concludes on the potential links between earplugs attenuation and the size of the earcanal assessed with the EST.

The objective of the study presented here is to evaluate the reliability of the EST for estimating the earcanal size and fit quality between a given earcanal and a given earplug model and thus to be used as a tool for the preselection of earplugs. For this purpose, the following research questions are addressed in this paper: (i) Which zone of the earcanal is effectively sized with the EST and with which accuracy? (ii) What is the link between the earcanal dimension sized with the EST and earplugs personal attenuation rating of multiple one-size-fits-most commercial earplugs of various materials and shapes? (iii) Can the EST be used to characterize a strong asymmetry between the left and right earcanals that would require one earplug of different size per earcanal?

The following part of the paper is organized as follows. The methodology section presents the procedures to size earcanals both with earmolds scans and the use of the EST. The attenuation measurement method for six disposable and reusable earplugs is also described. Statistical tests to compare earcanal sizing methods (EST vs scan of earmolds), compute correlations between earplugs attenuation and EST sizing measurement and assess the asymmetry of earcanals are detailed. The results section successively addresses the three abovementioned research questions prior to conclude on the relevance of using of the EST in the selection phase of earplugs.

3.3 Methodology

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

3.3.1 Participants

The sample of this study is composed of 121 participants, mostly men (n=103; 85%) working in three different Canadian organizations. They were aged between 21 and 64 years old (M=46,5, *SD*=10). They declared to be exposed to noise at work and to wear earplugs already before being involved in the study. 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).

3.3.2 Morphologic data acquisitions

3.3.2.1 Earmolds scans method

The morphology of the left and right earcanals of each participant was obtained by scanning the earcanal earmolds. The earmolds were molded by different custom earplug manufacturers and scanned either by the manufacturers or in our laboratory using an Einscan-SP 3D scanner (Hangzhou Shining 3D Tech Co., China) (see (Poissenot-Arrigoni et al., 2022) for more details on earmold molding and scanning). The assumption was made that the obtained earcanal scans accurately represent the earcanal morphology of the participants. Changes in the earcanal morphology due to the acquisition process are considered negligible and the difference between the scans is solely attributed to the difference between the earcanal morphologies of the participants.

The earcanal is an "S-shaped” duct that extends between the concha on its lateral side and the tympanic membrane on its medial side. The shape and size of the cross-section varies along the curvilinear axis of the canal (the axis that passes through the centroid of the earcanal cross-sections). To place the cross-sections in the most objective and repeatable way, the curvilinear axis of each earcanal is extracted using the method developed by Stinson and Lawton (Stinson & Lawton, 1989). The cross-sections are placed perpendicular to the curvilinear axis. The cross-section E is defined at the base of the concha (using a landmark defined in (Lee et al., 2018)). The first bend is located at the first maximum of curvature of the curvilinear axis and perpendicular to it (usually few millimeters after the entrance in the cartilaginous part of the earcanal). The second bend is positioned deeper in the earcanal at the second maximum of curvature of the curvilinear axis (usually close to the cartilaginous-bony junction).

Several morphological indicators of earcanals used by Poissenot-Arrigoni et al., are also used in this study, either because they have been shown to correlate with earplug attenuation or because they can help identify the area of the earcanal that is sized with the EST (Poissenot-Arrigoni et al., 2022). Three indicators of earcanal circumference are extracted, namely the areas of the E, FB, and SB cross-sections. Indicators of the curvilinear axis length of the earcanal between cross-sections E and FB and E and SB are also calculated.

3.3.2.2 Earcanal sizing tool measurement

The EST consists of a plastic sphere and a tab both affixed to a stem as shown in Fig. 3.1. The stem enables the operator to hold the tool and insert the sphere inside the earcanal until the tab touches the concha. This EST is commercially available in five sizes denoted as extra small (XS), small (S), medium (M), large (L), and extra-large (XL). An “extended” version of this tool using three additional larger spheres (named XXL, XXXL and XXXXL) is considered in this work to size all participants’ earcanals. The latter were 3D printed and their respective diameters are summarized in Table 3.2. To use the EST on all workers safely, Nitrile finger cots are used to cover the EST and are changed for each worker. All workers have both their right and left earcanal sized following the ANSI/ASA S12.6-2016 annex B procedure (ANSI/ASA S12.6, 2016). It consists in choosing a sphere that appears to be a little small for the earcanal being measured. Then the gauge is placed in the earcanal until the tab of the gauge touches the floor of the concha. If it is obvious that the gauge is loose (there is extra space all around it once inserted), the operator switches up one size. If the gauge seems to almost fit or fit, then the operator who sizes the earcanal must pump the gauge in the earcanal with a slight, gentle movement of about 1–2 mm and ask the subject if he/she feels a suction or pressure. The size of the smallest sphere for which the subject has a suction feeling represents the size of the earcanal. When the gauge size is right and causes this suction or pressure feeling for the subject, the effect is also usually felt by the experienced evaluator. When in doubt, the measurement is taken again.

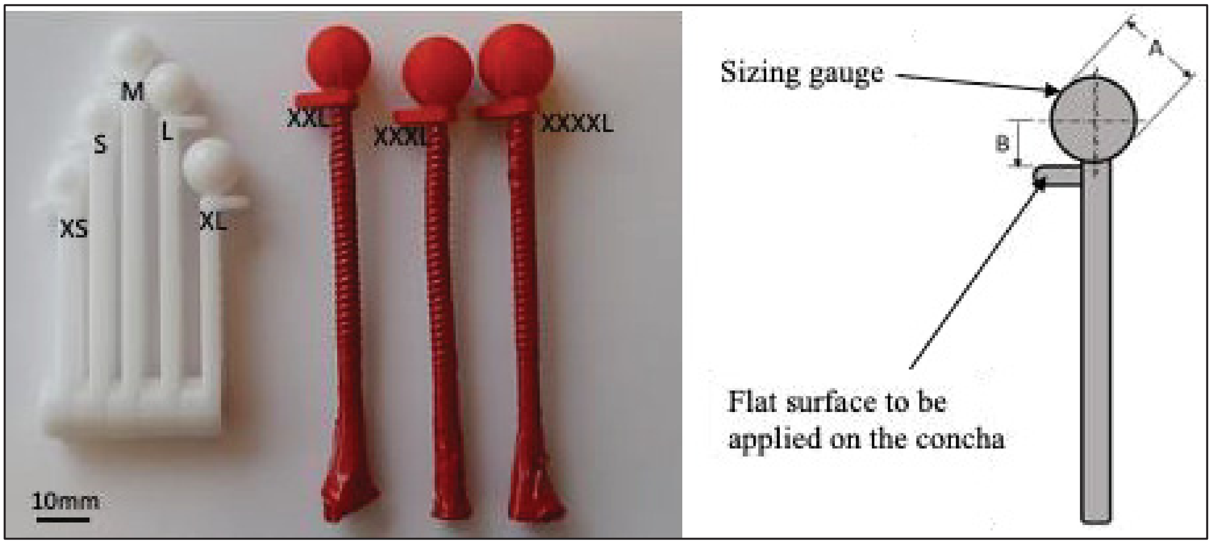

Figure 3.1 Extended EST
EST shape and main dimensions. The dimension A is the diameter of the sphere that sizes the earcanal. B is the distance between the flat surface of the EST to be applied on the concha during measurement and the parallel plan that passes through the center of the sizing sphere

3.3.3 Attenuation data acquisitions

As mentioned previously, this study uses the secondary data of attenuation measurements collected during a field survey on earplugs comfort. Participants (the same that had their earcanals casted) had a one-on-one meeting with an audiologist to train him/her on the model of earplugs to be tested. To this purpose, the FAES 3M™ E-A-Rfit™ Dual-Ear Validation System was used as a training tool. This FAES uses surrogates' earplugs and enables to compute and export a personal attenuation rating (PAR) for each ear. References names of the six earplugs considered in this study can be found in Table 3.1. Details of the training procedure can be found in Martin et al., and Poissenot-Arrigoni et al., (Martin et al., 2019; Poissenot-Arrigoni et al., 2022). In short, the audiologist first reminded the worker how to put the earplugs in place, when to replace them and how to check if there was a proper fit. Then, the worker put the surrogate earplugs in place himself/herself for a first PAR trial. If both ears had an initial PAR of minimally 50% of the manufacturer's NRR value (considered to be the first threshold value), the training was over. If not, the worker was asked to adjust the earplugs for a second PAR trial, still aiming for 50% of the NRR. Because most of workers participating in the study had an average daily sound exposure level for 8 hours less than 95 dBA, a second threshold value of PAR = 10 dB was accepted. If the second trial reached at least this second threshold value of PAR = 10 dB for each ear, the training was over. If this threshold value could not be obtained, the audiologist attempted a third placement. If this PAR trial was adequate, the worker was asked to replicate the proper placement to ensure that he or she was able to put it back in place (third trial, and more if needed). Finally, if both ears did not reach a PAR of 10 dB for all trials (fitted by the worker), the earplug model was considered unsuitable for this participant. Most workers needed between one to three trials per session to properly fit their earplugs. For the roll-down-foam earplugs, 6 trials (for one ear) were sometimes needed. For a few participants, more than 10 trials were required to reach the safe-threshold attenuation values of the training.

For each worker's ear and for each earplug, the test data leading to the best PAR was kept, and the research team exported the PAR value as attenuation data. The training leading to the PARs considered in this study is a typical training that may be given to individuals in the framework of a hearing conservation program using FAES.

Table 3.1 Earplugs references

Earplug family	Roll-down-foam			Multi-flange elastomeric polymer	Push-to-fit	
Surrogate earplugs pictures						
Earplug manufacturer's name	3M™ E-A-R ™ Classic uncorded	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

3.3.4 Statistical analyses

Different levels of statistical analyses were performed using IBM® SPSS® Statistics 27 (*IBM SPSS Statistics, Version 27.0.*, 2020). First of all, descriptive statistics (e.g., means and frequencies) were calculated to know the characteristics of the sample. Then, to know which zone of the earcanal is effectively sized with the EST and with which accuracy, the Pearson linear correlation coefficients were computed between variables measuring the earcanal size evaluated with the EST and the girth of the three characteristics sections of earcanals evaluated with the earmold scan method.

To know if there is a link between the earcanal dimension sized with the EST and earplugs PAR of multiple one-size-fits-most commercial earplugs of various materials and shapes, the correlation between earcanal size evaluated with the EST (diameter A in Fig. 3.1) and earplugs attenuation are evaluated. Mann Whitney U non-parametric comparison tests were also performed to see if there were statistical differences in earplugs attenuation between earcanals grouped in the different EST size categories. This non-parametric test allowed comparing two groups with no homogeneity of variances. In fact, in this sample, few earcanals are sized in extreme categories (XS and XXXL) leading to compare groups with unequal sample sizes.

Finally, to know if this EST can be used to characterize a strong asymmetry between the left and right earcanals that would requires one earplug different size per earcanal, paired T-tests were performed between the right and left ear of each participant for all morphologic indicators computed with the scan method (i.e. cross-sections E, FB and SB areas), the EST measurements, and PARs.

3.4 Results and discussion

3.4.1 Ability of the EST to measure earcanal size

Results of EST measurements are presented in Table 3.2. The first two columns give the EST size and sphere diameter measured with a caliper. The next columns present the number and percentage of earcanals assigned to each size (from XS to XXXXL) for all earcanals of the dataset and males and females earcanals taken separately.

Overall, most of earcanals (82.7%) are in the groups M, L or XL. Only 4.6% are S or XS earcanals, and 12.7% of earcanals are XXL or XXXL. No earcanal is sized in the XXXXL group. There are very few workers classified in the {XS + S} category. It may be hypothesized that this is due to the participants sample constituted by a large majority of males. Indeed, female earcanals are overall smaller (in girth) than men earcanals (Chiou et al., 2016; Fan, Yu, Wang, Li, Chu, et al., 2021; Lee et al., 2018). This trend is confirmed here: while 0% and 1.5% of males' earcanals are sized in the groups XS and S respectively, 11.4 % of females' earcanals are XS and 11.4 % are S size. XXL and XXXL sizes account for 8.9 % and 5.9 % of males earcanals whereas no female earcanals are sized in these categories.

Table 3.2 Descriptive statistics of the EST measurement results
Number of earcanals in each EST category (frequency)
Percentage of earcanals in each EST category (%)
Data are given for the entire earcanals sample (Overall), males earcanals and females earcanals

		N (%)		
EST size	EST diameter (mm)	Overall	Males	Females
XS	7.6	4 (1.7)	0 (0)	4 (11.4)
S	8.4	7 (3.0)	3 (1.5)	4 (11.4)
M	9.3	61 (25.7)	41 (20.3)	20 (57.1)
L	10.4	75 (31.6)	70 (34.7)	5 (14.3)
XL	11.4	60 (25.3)	58 (28.7)	2 (5.7)
XXL	12.9	18 (7.6)	18 (8.9)	0 (0)
XXXL	14.0	12 (5.1)	12 (5.9)	0 (0)
XXXXL	14.9	0 (0)	0 (0)	0 (0)

The Pearson linear correlation coefficients were statistically significant ($p < 0.001$), showing the significant relationship between the earcanal size evaluated with the EST and the earmold scan method. Specifically, there is a medium but significant correlation between the area of cross section E and the earcanal size evaluated with the EST (coefficient correlation $r = 0.297$). Stronger correlations were found between the earcanal size evaluated with the EST and the areas of cross-sections FB (r = 0.533) and SB (r = 0.504). Subsequent analyses (results are not detailed here) showed that correlations between the two measurement methods (earmold scans and EST) presented in this paragraph for all earcanals followed the same trend for men as for women when taken separately.

To provide more information about the position of the area of the earcanal sized with the EST, the dimensions of the earcanal length are compared to the dimension B (see Fig. 3.1) of the EST (the length which determines the depth of the measurement). In the dataset presented here, the length of the curvilinear axis of the earcanal between cross-sections E and FB is 4.9 mm (*SD* = 1.8 mm). The distance between the flat surface of the EST to be applied on the concha during earcanal sizing and the center of the sphere of the EST (see distance B in Fig. 3.1) is between 4.19 mm (XS) and 6.10 mm (XL) as specified in the ANSI S12.6-2016 standard. Considering this, the EST evaluates the diameter of the earcanal cross-section area at a position located near the FB region. This is consistent with the strongest correlation found between earcanal evaluated with the EST and the cross-section FB area. Finally, the “earcanal opening” that is sized with the EST, correspond to the diameter of the earcanal near the FB zone.

The area of cross-section FB of each earcanal grouped per size evaluated with the EST is plotted in Fig. 3.2.

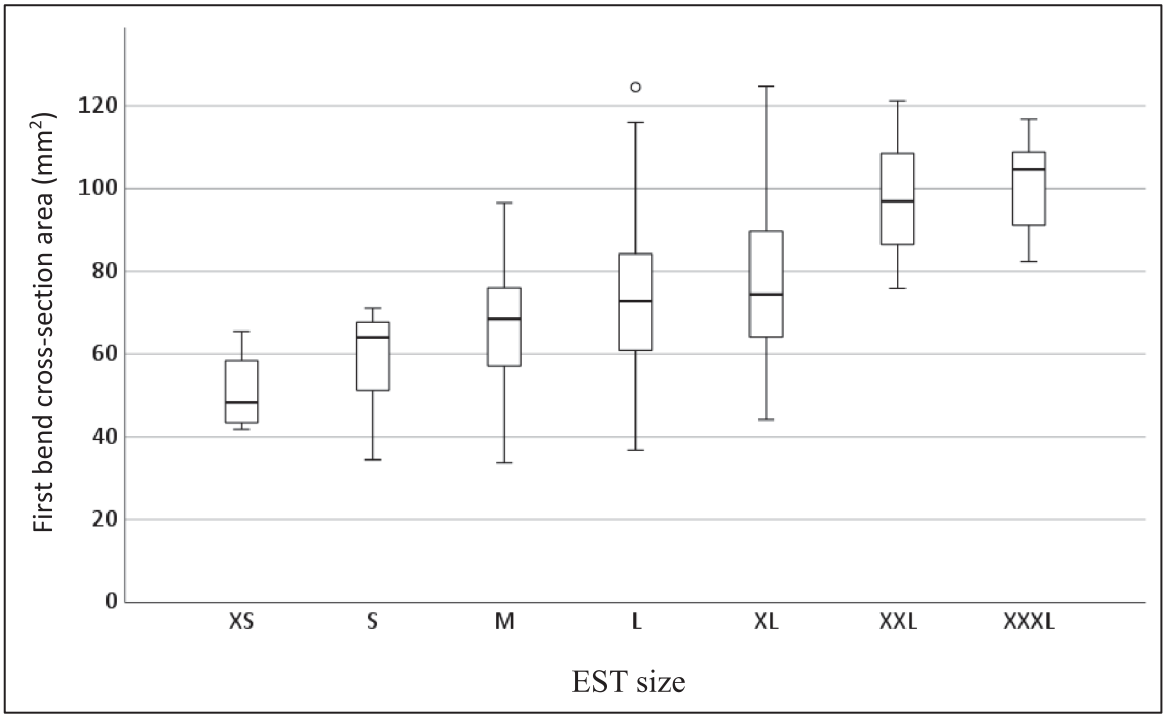

Figure 3.2 Box plots of earcanal cross-section FB area grouped per earcanal size evaluated with the EST

Observing these box plots, it is possible to confirm the positive correlation between the earcanal size evaluated with the EST and the area of the cross-section FB: overall, the smaller the size of the EST, the smaller the median of the distribution of earcanals cross-section FB area. There is a large variability in the areas of the cross-section FB classified in groups M, L and XL. This variability induces a considerable overlap between categories M, L, XL and others. Consequently, the EST is inaccurate for accurately assessing the cross-sectional area of the earcanal at the first bend and cannot be used for morphological classification of earcanals (which is consistent with the finding of (Thomas et al., 1994b)). However, there is no overlap in the cross-sections FB areas between categories (XS and S) and (XXL and XXXL): in our dataset, an earcanal classified in categories XS or S has a cross-section FB systematically smaller than a XXL or XXXL earcanal. Consequently, the EST can be useful in identifying the smallest earcanals from the largest ones. Because of the correlation between earplug attenuation and earcanal cross-section area at the first bend FB (see (Poissenot-Arrigoni et al., 2022); and Table 3.3 of this paper), the EST can help identify some extra-large earcanals who are most likely to be under-protected.

3.4.2 Ability of the EST to inform about earplugs sound attenuation

In this section, the results about the relations between earcanals morphologies (evaluated both with the EST and the earmold scans methods) and PARs obtained after an insertion training are presented. Pearson linear correlation coefficients between earplugs PARs and cross-section FB area evaluated through earmolds scans and earcanal size evaluated with the EST are plotted in Table 3.3.

Table 3.3 Pearson linear correlation coefficients between earcanal cross-section FB area and PARs of earplugs and earcanal size evaluated with the EST and PARs of earplugs Empty boxes indicates that the correlation is not significant. All printed coefficients 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
FB area (earmold scans method)	r			-0.28	-0.26	-0.41	-0.33	-0.34
	N	107	40	82	97	235	159	146
Earcanal size (EST method)	r				-0.38	-0.29	-0.29	-0.24
	N	107	40	82	97	235	159	146

Overall, all significant correlations between earcanal size (assessed with both methods presented in this study) and earplug attenuation were negative, showing that the larger the earcanal (in terms of circumference), the lower the attenuation. As indicated by Poissenot-Arrigoni et al., it can be assumed that a large earcanal results in less compression of the earplug and surrounding tissue (Poissenot-Arrigoni et al., 2022). As at low frequencies, the vibro-acoustic behavior of the earplug coupled to the earcanal is governed by the equivalent stiffness of the {earplug + earcanal skin} system (Sgard et al., 2011); lower compression of the earplug/skin induces lower equivalent stiffness and lower sound attenuation. Lower mechanical pressure between the earcanal skin and the earplug can also lead to sound leakage. According to the Table 3.3, the FB cross-section area and the earcanal size assessed with the EST are not correlated with the PARs of cylindrical roll-down foam earplugs (full size and small size). The PAR of the bullet-shaped roll-down foam earplug has a moderate negative correlation with the FB cross-sectional area assessed with the earmold scanning method, but is not correlated with the earcanal size assessed with the EST. Finally, small to moderate 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 and FB section area and earcanal size. For each of these earplugs, the correlation coefficients are similar for the earcanal sizes assessed with the earmold scans and EST methods. In short, with the exception of the bullet-shaped foam earplug, the earcanal circumference assessed with the EST 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.

Boxplots of earplugs PARs as a function of EST categories are plotted in Fig. 3.3. As few earcanals are classified into categories XS, S, XXL and XXXL, earcanals are grouped into the 3 following categories: {XS + S}, {M + L + XL} and {XXL + XXXL} earcanals.

Fig. 3.3 shows that except for the cylindrical and bullet shaped roll-down foam earplugs, earcanals classified in the {XXL +XXXL} category always have an attenuation significantly smaller than other categories. Bell-shaped foam, multi-flange elastomeric polymer, push-to-fit-pod foam and push-to-fit-sheath foam earplugs may be less efficient on large earcanals. It may also be seen that for the three bell-shaped foam, push-to-fit-pod foam and push-to-fit-sheath foam earplug, a non-negligible or even important number of earcanals did not reach the half of the NRR attenuation value. Some one-size-fits most earplugs are not adapted to some extra-large earcanals and Fig. 3.3 shows that some of these earcanals are identifiable with the EST.

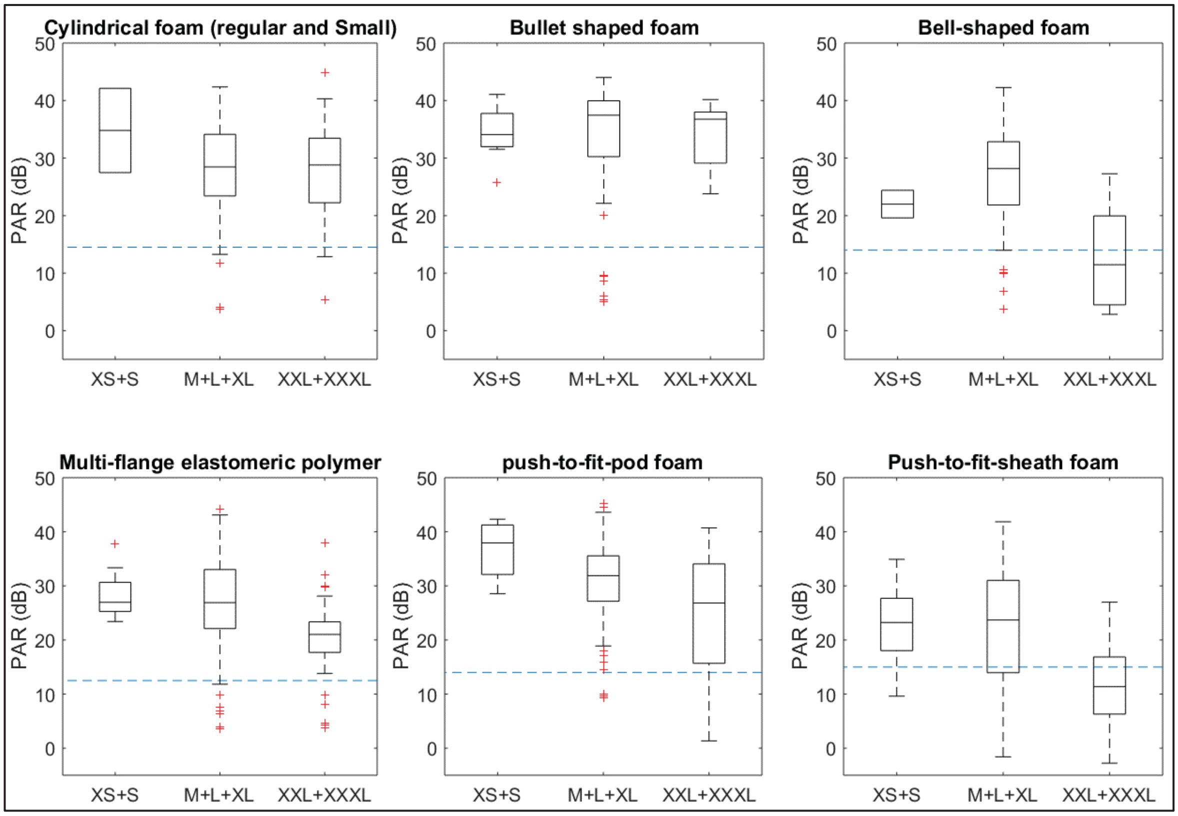

Figure 3.3 Boxplots of PARs of six commercial earplugs classified in function of the 3 proposed EST categories: {XS + S}, {M+L+XL} and {XXL+XXXL}
Numbers in brackets indicates the number of subjects in each category
Half of the NRR of each earplug (which is a typical derating score and the first threshold of the training) is represented with a blue dotted horizontal line
P-values of Mann Whitney U comparison test are plotted between each pair of groups for which the test is significant at the level 0.05

The next Table 3.4 aims to identify the range of EST sizes suitable for each earplug of interest in this study (i.e., ensuring a proper fit and sufficient protection efficiency) in the optic to aid in earplug selection with such a simple and straightforward tool. Table 3.4 presents the proportion of earcanals in each of the three categories ({XS+S}, {M+L+XL}, {XXL+XXXL}), that reaches the NRR/2 dB threshold which corresponds to a typical 50% derating score applied to the NRR as provided in the earplug packaging.

Table 3.4 Percentage of earcanals in each group ({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

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 %

Results show that almost all participants managed to reach the NRR/2 with the cylindrical and bullet shaped roll-down foam earplugs. As for the earplugs bell-shaped foam, multi-flanges elastomeric polymer and push-to-fit-pod foam, a large majority of participants classified in the groups {XS+S} and {M+L+XL} managed to reach the safe attenuation threshold. However, not all earcanals classified in the group {XXL+XXXL} managed to reach the safe attenuation value of NRR/2 for multi-flanges elastomeric polymer (80%) and push-to-fit-pod foam (77%) eaplugs. A small proportion of earcanals classified in the group {XXL+XXXL} managed to reach the NRR/2 for the bell-shaped foam earplugs (45%) and push-to-fit-sheath foam earplug (only 33%).

In the optic of selecting earplugs on the field, the EST may be a simple yet powerful tool to identify some earcanals for which certain earplugs are not adapted. For example, in this data set, earcanals in the {XXL+XXXL} group should prioritize cylindrical foam and bullet shaped foam earplugs, if possible, whereas earcanals in the {XS+S} group may have the choice to select earplugs based not only on attenuation and NRR but other selection factors such as comfort for example (CSA, 2014).

The results presented here also suggest that derating scales usually applied on the NRR may be unsafe for some large earcanals and some earplugs. The CSA Z94.2 standard for example recommends to apply a derating factor of 50 % to the NRR of earplugs (CSA, 2014). Although this approach may be relatively safe using the cylindrical and bullet-shaped foam earplugs presented in this study, the results show that only 45 % of workers with XXL and XXXL earcanals would be adequately protected by 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 the multi-flange elastomeric polymer and push-to-fit- pod foam, the 50 % NRR criterion would be met for 80% and 77% of workers with XXL and XXXL earcanals respectively. As for the push-to-fit-sheath foam, this proportion drop to only 33 % of workers with XXL and XXXL earcanals adequately protected. In the absence of FAES in the earplug selection phase, certain earplug designs such as cylindrical roll-down foam earplugs, shall be preferred over other earplugs such as premolded or push-to-fit ones for large earcanals. It should be noted, however, that roll-down foam earplugs are not always preferable to premolded or push-to-fit foam earplugs. Indeed, since roll-down foam earplugs require manual manipulation prior insertion, they are not suitable for work environment that may contaminate workers' hands with caustic or irritating substances or abrasive matter (Berger & Voix, 2022).

These results confirm the relevance of using the EST in the earplug selection phase if an FAES is not available. Such a tool can help identify extra-large earcanals that may be incompatible with certain earplug's models. In addition, it may be useful for earplug manufacturers to indicate which EST sizes are compatible with each of the earplug models they produce (on the earplug packaging, for example), to help preventionists select the best earplugs for workers.

3.4.3 Earcanals bilateral asymmetry

To see if there are significant differences between left and right earcanal morphologies that may be considered when selecting an earplug, paired t-tests were performed between morphologic indicators of the right and left ear of participants. Paired T-tests showed that the dimensions (assessed with the earmold scan method) that are significantly different between the right and left ear are the areas of the cross-sections E ($p = 0.034$) and FB ($p < 0.001$). As there are no significant differences between subject's left and right areas of the cross-section SB (located near the bony part of the earcanal), it may be hypothesized that this is the cartilaginous portion of the earcanal that is mostly asymmetric, whereas the bony portion of the earcanal is more symmetric. The same trends were found when performing these analyses for men and women separately.

The EST measurement (which sizes the earcanal near cross-section FB location, see sec. 3. a) gave different results between left and right ears for 28% of participants. The difference was of one size (e.g., size XL for the right ear and size L for the left ear) for most of these participants, except for three participants who had differences of two sizes between the ears (e.g., XXL for the right ear and L for the left ear). Similar results were also found in Copelli et al., were 12 over 32 (38%) participants obtained different EST measurement between left and right ear (Copelli, Behar, Le & Russo., 2021).

Overall, the differences of morphology between the right and left ear are small and paired t-tests exhibit no significant differences between the attenuations of right and left earcanals for the six earplugs of this study. This suggests that, overall, the asymmetry in earcanals morphology is not large enough to induce a difference in PARs. However, this conclusion is based on paired global comparison tests. In case of a strong asymmetry for a given participant, it would be safer to use a conservative approach and propose a model of earplug based on the largest earcanal (because the larger the earcanal, the lower the attenuation as seen in section 3. b.). Otherwise, if an earplug model available in several sizes can be offered to the user, it would be beneficial to test a different size per ear as recommended in the standard CSA Z94 (2014).

3.5 Conclusion

The earplug selection 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 3M™ Eargage earcanal sizing tool (EST) is the quickest, cost effective and more straightforward method to assess an earcanal size (XS, S, M, L or XL). In the paper presented here, the relevance of the use of this tool to help in the preselection of earplugs by quickly assess earcanals diameters in the zone where the earplugs are fitted was evaluated.

Results show that the EST enables to estimate the size of the earcanal near the first bend region. This earcanal sizing tool is not accurate enough to perform a precise morphologic classification of earcanals, however it could help identifying some extra-large earcanals. Extra-large earcanals identified with the EST 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 extra-large earcanals. This finding could be used to recommend specific models of earplugs for person with extra-large earcanals and improve the selection of earplugs based on the derating scales of single number ratings. The results of this study also suggest that it may be beneficial to indicate on earplugs packaging, in addition to the single numbers attenuation ratings, the earcanals sizes for which the earplugs are most suitable.

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CHAPTER 4

ANALYSIS OF THE PHYSICAL DISCOMFORT OF EARPLUGS EXPERIENCED BY A POPULATION OF CANADIAN WORKERS AND IDENTIFICATION OF THE INFLUENCING VARIABLES

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4.1 Abstract

Earplugs are widely used to prevent noise induced hearing loss. However, the discomforts they induce negatively impacts their effectiveness by influencing their consistent and correct use. The physical earplugs discomfort is related to the user perception resulting from biomechanical and thermal interactions between the earplug and the earcanal. Its main attributes are “physical annoyance”, “pain”, “pressure” and “irritation. The (dis)comfort results from the complex interactions between the wearer, his/her earplug, and his/her work environment, which form the concept of triad. This study aims at improving our understanding of the physical discomfort of earplugs by identifying the triad characteristics that have a significant influence on the main attributes of the physical discomfort. The (dis)comfort of earplugs was assessed in the field with 173 participants who tested 7 different earplugs models over 7 weeks and answered comprehensive comfort questionnaires. Triad characteristics were assessed both with questionnaires and in laboratory using comfort testers. Statistical analyses enabled to identify

main characteristics of the triad that influence physical comfort attribute including the earplug radial force, extraction force and friction coefficient. Characteristics of the work environment (work duration) and of the person (i.e., ear morphology, past experience with earplugs), were shown to influence physical discomfort. Results of this study could provide tools to manufacturers so that they can design earplugs taking into account comfort aspects and to preventionists so that they can propose to workers the earplugs that are the most adapted to them and to their work environment.

4.2 Introduction

In Quebec (Canada), noise-induced hearing loss is the most common and costly occupational disease. Disposable and reusable earplugs are widely used to reduce the amount of noise reaching the tympanic membrane and prevent hearing loss. Their effectiveness depends on both attenuation and wearing time, which are affected among other factors by the quality of the earplug fit and (dis)comfort aspects (Berger, 2013; Berger & Voix, 2022; CSA, 2014). Indeed, a mismatch between the earcanal morphology and the physical properties of the earplug (e.g., shape, softness) may result in a bad fit which greatly reduces the protection efficiency (Poissenot-Arrigoni et al., 2022). Discomforts experienced by the wearer can also make him/her deteriorate intentionally the fit quality or remove the protector which also causes a drastic reduction in protection even it is removed for short periods (Berger & Voix, 2022; Bockstael, Bruyne & Vinck, 2011; CSA, 2014; Doutres et al., 2019; Doutres, Terroir, et al., 2022).

The comfort is a multidimensional construct, and in the context of earplug use, four dimensions characterizing earplug (dis)comfort have been proposed by (Doutres et al., 2019). The ‘physical’ dimension, is related to the user perception resulting from biomechanical and thermal interactions between the earplug and the earcanal; the ‘acoustical’ dimension, is related to the modification of the perception of noises; the ‘functional’ dimension, corresponds to the practical acceptability of earplugs and refers to the usability, efficiency and usefulness concepts; finally, the ‘psychological’ dimension, refers to the well-being and the satisfaction of the user. The multidimensional (dis)comfort results from the complex interactions between the wearer, his/her earplug, and his/her work environment, which form the concept of triad. The triad components (person/earplug/environment) can be described by many physical and psychological characteristics which may have an impact on the experienced (dis)comfort (Doutres, Sgard, et al., 2022) and thus considered as inputs of a comfort model for hearing protectors recently proposed by (Doutres, Terroir, et al., 2022). As examples, physical characteristics of the earplug include its design parameters such as shape and its material properties. The person can be described by its physical characteristics (e.g, ear morphology, hand dominance) and its psychosocial characteristics (e.g., gender, previous experience with earplugs). The work environment is characterized by physical characteristics such as environmental and acoustical conditions, and its psychosocial characteristics include (but are not limited to), type of work (manual, non-manual, mixed) and physical activity (body, head or jaw movements). Knowledge of the physical and psychosocial characteristics of the triad affecting comfort is of utmost importance to be able to improve the effectiveness of this noise control strategy to prevent noise-induced hearing loss. This would make it possible to provide tools (i) to manufacturers so that they can design earplugs taking into account comfort aspects and (ii) to preventionists so that they can propose to workers the earplugs that are the most adapted to them and to their work environment. However, these tools should take into account characteristics of the triad that can be objectively determined either in the field (e.g., person' earcanal morphology) or during the earplug design process (e.g., earplug stiffness), which is a difficult task given the complexity of earcanals, earplugs and work environments.

The objective of this study is to identify the physical and psychosocial characteristics of the triad, either determined objectively or subjectively, that significantly influence the main attributes of physical comfort and evaluate the direction of these effects to better understand physical comfort. The focus is on the physical dimension of comfort because in many previous studies identified in the literature (Doutres et al., 2019), subjective perceptions related to mechanical contact between the earplug and the ear tissues have been shown to be a significant source of discomfort.

Studies that have sought to analyze the physical comfort of hearing protector (or in-ear devices) were primarily based on the study of objective variables that characterize their interaction with the earcanal. In particular, the contact pressure between a hearing protector and the skin seems to be a key variable that influences physical comfort (Doutres et al., 2019; Gerges & Casali, 2007). Norris et al., used a finite element model of an earcanal whose geometry was obtained from medical images to assess stresses and strains in the earcanal tissues compressed by custom-made earplugs (Norris et al., 2011). It was observed that a custom-made earplug of a girth of about 5% larger than the earcanal girth induces a pressure of 4 kPa on earcanal walls, which has been associated with the onset of pain (Albin, 2007). Baker et al., used participant's subjective evaluation and the finite element method to comprehensively evaluate the mechanical interaction between the earcanal and the earplug and to identify key parameters that correlate with the physical comfort of earplugs (Baker et al., 2010). The geometries of three participants' earcanals (supposedly small, medium and large) were reconstructed and modeled to simulate the insertion and stress relaxation resulting form the earplug/earcanal interaction. They found that the key characteristics of the earplug/earcanal system that correlate to comfort are not only the average contact pressure but also the total contact force (between the earplug and the earcanal). Wang et al., objectified an attribute of the physical comfort using the tragus expansion angle that characterizes how much the tragus is pushed outward by the in-ear device (Wang et al., 2022). They found that the physical discomfort at the concha and earcanal entrance increases when the tragus is pushed outward by the in-ear device. The above-mentioned studies elaborated links between physical quantities resulting from interaction between the hearing protector (or in-ear devices) and the outer ear. This enables to improve the understanding of physical comfort, but physical quantities resulting from the earplug/earcanal interaction can be difficult to assess (either experimentally or numerically), mostly because the earcanal is a confined space. Furthermore, this type of property is individual and can hardly be used by manufacturers for designing one-size-fits-most earplugs. The properties that are a priori more suitable for comfort-oriented design tools are indeed the physical characteristics of the decoupled components of the triad, which are also the inputs to the comfort model (Doutres, Terroir, et al., 2022).

Some studies directly linked objective physical characteristics of the earplug or of the earcanal to physical comfort. Fu and Luximon, for example, examined the influences of in-ear devices sizes on human perception of physical and functional comfort (Fu & Luximon, 2022). In-ear devices (that fit in the cavum concha and cymba concha) of different sizes were customized for each individual ear to eliminate the influences of individual ear shape and size. Participant tested the devices and expressed their perceived comfort using Lickert scales. It was found that participant preferred (in terms of physical comfort) products that have the size of their concha or larger than their concha. Song et al., observed that pain in the earcanal induced by in-ear devices was low for participants who had a deep cavum concha (Song et al., 2020). It was also found that kernel-type earphone (that fit the inside of the earcanal) induce more feeling pressure than open-type earphone (that fit in the concha and do not reach the inside of the earcanal). The benefit of these studies is that they provide clear guidelines for the design of comfortable in-ear devices.

To characterize physical characteristics of hearing protectors to be related to physical comfort, some authors designed comfort testers. Hsu et al., for example designed an experimental device to objectively measure the characteristics related to the design parameters of 28 commercial earmuffs (Hsu, Huang, Yo, Chen & Lien, 2004). The tester enabled to measure the headband force using a standard head frame of unique size, the mass of the protector and the temperature inside it. This comfort tester combined with subjective assessments of comfort, identified design factors that influence earmuff comfort and provided guidelines for earmuffs design. Tisserand and Krawsky measured several mechanical characteristics of earmuffs like headband force when the cushions are spaced at fixed distances representative of human heads width together with the subjective evaluation of the comfort they induce when tested on participants using questionnaires (Tisserand & Krawsky, 1972). They identified characteristics of earmuffs that influence physical comfort, including a low stiffness of the headband.

It is worth noting that most of the aforementioned studies focused most exclusively on the physical characteristics of the devices to explain the physical comfort and were carried out in the laboratory. However, psychosocial characteristics of the triad and physical characteristics of the wearer and of his/her work environment should not be ignored a priori since they may have a non-negligible influence on the experienced (dis)comfort and therefore on the wearing of hearing protectors (Doutres, Terroir, et al., 2022). It is therefore important to consider as many of the characteristics of the triad as possible in order to gain a more complete understanding of comfort and its influencing factors. Indeed, earplug manufacturers and preventionists need to know whether psychosocial characteristics of the triad should be considered in the design an selection phases of earplugs respectively.

This study aims at identifying the physical and psychosocial characteristics of the components of the triad that have a significant influence on the main attributes of physical (disc)comfort induced by earplugs. The main attributes of physical comfort considered here are “pain”, “physical annoyance”, “feeling of the earplug pushing in the ears” and “feeling of irritation”. The rest of the paper is organized as follows. The Methodology section describes the measurements of earplug comfort in the field and the assessment of the physical and psychosocial characteristics of the triad. The methodology to find relationships between the triad characteristics and the physical comfort of the earplugs is detailed at the end of this section. The results and discussion section presents the results of the field survey and the measured characteristics of the triad. Finally, the results of the analysis of triad characteristics effects on physical comfort attributes are presented and discussed.

4.3 Methodology

This study used data of morphologic descriptions of the participants' earcanals and field survey on earplug comfort approved by the ethical committee of the École de Technologie Supérieure (ETS) (ethics certificate H20171101).

The methodology section is organized into three main parts. The first part is devoted to the description of the measurements of earplug comfort in the field. It includes the description of the earplugs considered in this work and the conduct of the field study. The second part describes the assessment of the physical and psychosocial characteristics of the triad. The third part presents the statistical analyses conducted to identify the physical and psychosocial characteristics of the components of the triad that have a significant influence on the main attributes of physical (disc)comfort induced by earplugs.

4.3.1 Earplugs comfort assessment in the field

4.3.1.1 Earplugs

In this study, nine earplug models among the most used in North America were tested (see Table 4.1).

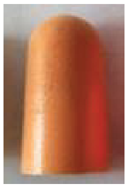
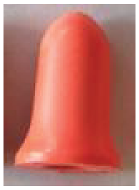
Of these earplugs, three were from the roll-down-foam earplugs families, and four were from the push-to-fit earplugs family (one premolded and 3 push-to-fit-foam). The last two earplugs were custom molded earplugs, which are not considered in this paper because their design issues are too different from reusable and disposable earplugs and thus are out of the scope of this paper

4.3.1.2 Test protocol

A total of 173 persons (27 females, 146 males) working in three different companies in Quebec (Canada) participated in this field study.

The field study was spread over eight weeks. During "Week 0", the research team (i.e., scientific professionals and audiologists) introduced the project and conducted eligibility interviews with workers of the participant companies interested in participating. The inclusion criteria were verified: i.e., being 18 years of age or older, having a good understanding of the French language, knowing the concept of hearing protection, being exposed to noise at work, not having antecedents of ear or neurological pathologies and not having a significant amount of earwax in the earcanals. The first "User Profile Questionnaire" (UPQ - see section 2.2.) was completed by the participants. Once the UPQ was completed, a custom earplugs manufacturer molded participants' earcanals. This step enabled to collect data about participant's earcanals morphologies (see section 2.2.1.1).

Table 4.1 Reference names of the disposable and reusable earplugs considered in this study

Earplug family	Roll-down-foam			Multi-flange elastomeric polymer	Push-to-fit		
							
Earplug model manufacturer's name	3M™ E-A-R™ Classic uncorded regular and small	3M™ 1100 Earplug	Honeywell - Howard Leight Max Regular and small	3M™ E-A-R™ UltraFit™	3M™ E-A-R™ Push-Ins	Honeywell - TrustFit® Pod	3M™ E-A-R™ Push-Ins with grip rings
Label used in this study	Cylindrical foam	Bullet shaped foam	Bell-shaped foam	Multi-flange elastomeric polymer	Push-to-fit foam pod 1	Push-to-fit foam pod 2	Push-to-fit foam sheath

Over the next seven weeks ("Weeks 1-7"), participants tested an earplug from each of the families (roll-down-foam, premolded, push-to-fit-foam and custom) in their workplace. For both the roll-down foam and push-to-fit foam earplugs, the participant wore the same earplug model for one week and then carried it over for another week, two weeks apart. A typical test week was as follows. At the beginning of the week, an individual training on earplugs insertion and use was offered to each participant by an audiologist. To this purpose, the field attenuation estimation system 3M^{TM} E-A-Rfit^{TM} Dual-Ear Validation System was used as a training tool. For the earplug models tested that were not compatible with this field attenuation estimation system, a surrogate model of closest shape and material was chosen. At the end of the individual training, if the earplug provided a safe attenuation for the participant, the test week could start. At the end of the week, participants completed the "Comfort of hearing protection devices – North America Questionnaire" (COPROD-NAQ) to express their opinion about the four dimensions of earplug comfort (i.e., physical, functional, acoustical and psychological). Each comfort dimension was measured with one or two general items. Several explanatory items were also used to measure specific comfort levels and help in the interpretation of general items. The physical dimension of comfort that is the subject of this paper was evaluated with two general items and 5 explanatory items (Table 4.2). The COPROD-NAQ and the UPQ questionnaires were developed in a larger and international study about earplugs comfort (Doutres et al., 2018). Specifically, the COPROD-NAQ is the North American companion of the "Comfort of hearing protection devices (COPROD) questionnaire" validated in France by Terroir et al., (2021). The North American validation process is in progress.

For each item, participants expressed their degree of agreement on a five points Likert scale (see "Results and discussion" section: Fig. 4.3 to 4.6). Note that the wording of the questions makes it possible to measure physical discomfort (and not physical comfort).

Table 4.2 Items assessing the physical discomfort of earplugs at the end of the test week

General items	Physical annoyance: Generally, these earplugs lead to physical annoyance
	Pain: Generally, these earplugs lead to pain
Explanatory items	Pressure: When you wear these earplugs, you get the feeling that they are pushing into your ears
	Irritation: -When you use these earplugs, you have the feeling that they irritate your earcanal. -You have a feeling of irritation when you insert these earplugs. -You feel an irritation while you wear these earplugs. -You have a feeling of irritation when you remove these earplugs.

4.3.2 Assessment of the triad characteristics

Several physical and psychosocial characteristics of the triad “Person/Environment/Earplug” potentially related to earplugs comfort and taken from Doutres et al. (2022b) were assessed on the field through the UPQ (see section 4.3.2.1) or objectively measured in laboratory and are listed in table 4.6.

The methodologies used to assess the characteristics of the triad are detailed in section 4.3.2

Table 4.3 Characteristics of the triad assessed in this study

Characteristics of the triad considered in this study		
Person	Work environment	Earplug
Ear characteristics: Morphology of the external earcanal (girth and shape of 3 characteristics cross-sections, length and conicity) **Hearing loss** **Hand dominance** **Gender** **Age** **Education** **Self-experienced** **Experience with HPD use**	**Company** **Situational and interpersonal influences**: Perception of exposition of high noise levels, possibility of changing departments, team work **Task and usage**: Time aspects (e.g., work duration, shift), physical activity (body, head or jaw movements)	**Design**: Shape (cylinder, bullet shape, conical) size (diameter), with stem/without **Weight** **Friction coefficient** **Softness**

4.3.2.1 “User ProfileQuestionnaire” (UPQ)

All data about the characteristics of the triad were collected at the “Week 0” through the UPQ and the eligibility interview. Questions were developed considering the three components of the triad.

Data was then entered into an SPSS file (IBM® SPSS® Statistics 27, IBM Corp., 2020) and different types of variables (i.e., continuous, dichotomous and categorical) were computed. Variables assessing triad characteristics were used to describe the sample of this study (Table 4.4) and to perform statistical analysis in order to find relationships between triad characteristics and main attributes of physical discomfort of earplugs, (see section 4.4.4).

4.3.2.2 Person (earplug user)

4.3.2.2.1 Physical characteristics

The physical characteristics of the person considered in this study are the following ones: persons earcanals morphologies, hearing condition, and hand dominance.

A comprehensive description of the process used to assess each participant’s earcanal morphology can be found in Poissenot-Arrigoni et al., (2022). The left and right earcanal morphology of each participant were obtained by scanning earmolds of earcanals (casted during the “Week 0”). The assumption was made that obtained earcanal scans accurately represent the participants’ earcanals morphology.

The earcanal is an “S-shaped” duct that extends between the concha on its lateral side and the tympanic membrane on its medial side. The cross-section shape and size vary along the duct curvilinear axis (axis that passes through the centroid earcanal cross-sections). In this study, three characteristic cross-sections are used: the entrance (E), the first bend (FB) and the second bend (SB). To place the cross-sections in the most objective and repeatable way, the curvilinear axis of each earcanal is extracted using the method developed by Stinson and Lawton (1989). The cross-sections are placed perpendicular to the curvilinear axis. The cross-section E is defined at the base of the concha (using a landmark defined in Lee et al., 2018). The FB is located at the first maximum of curvature of the curvilinear axis and perpendicular to it (usually few millimeters after the entrance in the cartilaginous part of the earcanal). The SB is positioned deeper in the earcanal at the second maximum of curvature of the curvilinear axis (usually close to the cartilaginous-bony junction). Several morphologic indicators of earcanals used in Poissenot-Arrigoni et al. (2022) are used in this study. Six indicators of the earcanal girth are extracted namely the right (R) and left (L) circumferences (C) of cross-sections E ($C_{E(L)}$ and $C_{E(R)}$), FB ($C_{FB(L)}$ and $C_{FB(R)}$) and SB ($CS_{B(L)}$ and $C_{SB(R)}$).

The ovality of each cross-section were quantified through their isoperimetric ratio (IR) which is computed for each right and left earcanal at each cross-sections E (IRE(L) and IRE(R)), FB ($IR_{FB(L)}$ and $IR_{FB(R)}$) and SB ($IR_{SB(L)}$ and $IR_{SB(R)}$). IR is defined as the ratio between the area and the squared perimeter multiplied by 4 times π and varies between 0 and 1 (the closer to 1, the more circular the section).

The lengths of the right ($L_{E\text{-}SB(R)}$) and left ($L_{E\text{-}SB(L)}$) earcanals are computed as the lengths of their curvilinear axis between the cross-sections E and SB. Conicity (or funneling) of each right $F_{E\text{-}SB(R)}$ and left $F_{E\text{-}SB(L)}$ earcanals measure how much the earcanal shrinks in the medial direction. The funneling is calculated as the ratio between the areas of the cross-sections E and SB.

Participants' earcanal sizes were also assessed with the 3M™ Eargage earcanal sizing tool (EST). This simple tool consists of a plastic sphere and a tab both affixed to a stem. This EST is commercially available for five sizes of spheres to categorize the earcanal into five different sizes: extra-small (XS), small (S), medium (M), large (L) and extra-large (XL). An “extended” home-made version of this tool using three additional larger spheres (named XXL, XXXL and XXXXL) is used in this work to measure the earcanals size of all participants. All workers had both their right and left earcanal sized following the ANSI/ASA S12.6-2016 annex B procedure. A short description of this procedure and a discussion about the reliability of ESTs to assess earcanal size and assist the earplugs selection can be found in chapter 3 of this thesis.

The hearing condition of the participant was assessed during the “Week 0” of the field study. Specifically, an audiologist of the research team performed a screening audiogram for each participant using a portable audiometer. The hearing screening was conducted in a quiet room at the company, with in-ear earphones covered by earmuffs. Each participant tested four frequencies (i.e., 500. 1000. 2000 and 4000 Hz). A dichotomous variable was created for each worker's ear ($HL_{(L)}$ and $HL_{(R)}$) to determine if the worker was hearing impaired or normal hearing (all tested hearing thresholds less than or equal to 25 dB).

The hand dominance (Laterality) of each participant (left, right or ambidextrous) was answered in the UPQ.

4.3.2.2.2 Psychosocial characteristics

Biological, demographic and sociocultural information about each participant was collected from the UPQ including age and educational degree (answer varied from 1 = no degree to 8 = master's degree). Participants' education was then grouped into three categories (group 1 No degree; group 2 Professional or collegial; group 3 University). The age of participants was also categorised in two groups: the 21 – 44 years old category and the 45 – 65 years old category. Previous experiences of workers with earplugs were measured through two variables. Participants indicated how long they had been wearing earplugs at work and were grouped in 4 categories (variable $\text{Expe}_{\text{Time}}$): from 0 to 5 years, from 6 to 15 years, from 16 to 25 years and more than 26 years. Participants also indicated which earplug family they were used to wearing (roll-down foam, push-to-fit-foam, premolded or custom). A dichotomous variable ($\text{Habit}_{\text{Fam}}$) was created and took the value “yes” if the worker tested an earplug classified in a family that he was used to wearing, or “no” if the participant never wore an earplug of this family.

Participants also indicated how long they used to wearing their earplugs during the workday (a few minutes, a few hours, or all day). Finally, their confidence in the effectiveness of earplugs was assessed by asking them how much they agreed (on a 5-point Likert scale) with the statement, "In general, wearing earplugs helps prevent hearing problems."

Table 4.4 Physical and psychosocial characteristics of the person

	Characteristic name	**Variable name**	**Variable type / values**
Physical characteristics	EST categorisation	$EST_{(R)}$; $EST_{(L)}$	Categorical: XS; S; M; L; XL; XXL; XXXL
	Earcanals cross-sections circumferences (left and right)	$C_{E(L)}$; $C_{FB(L)}$ $C_{SB(L)}$; $C_{E(R)}$ $C_{FB(R)}$; $C_{SB(R)}$	Continuous (mm)
	Earcanals cross-sections isoperimetric ratio (left and right)	$IR_{E(L)}$; $IR_{FB(L)}$ $IR_{SB(L)}$; $IR_{E(R)}$; $IR_{FB(R)}$; $IR_{SB(R)}$	Continuous, between 0 and 1
	Earcanals length	$L_{E\text{-}SB(L)}$ $L_{E\text{-}SB(R)}$;	Continuous (mm)
	Earcanals conicity	$F_{E\text{-}SB(L)}$; $F_{E\text{-}SB(R)}$	Continuous (surfaces ratio)
	Hearing loss	$HL_{(L)}$ $HL_{(R)}$	Dichotomous: Yes or no
	Hand dominance	Laterality	Categorical: Left-handed, Right-handed, or Ambidextrous
Psychosocial characteristics	Age	Age	Categorical: group 1 (21-44 y.o.) or group 2 (45-65 y.o.)
	Experience with HPD use (duration)	$Expe_{Time}$	Categorical: 0-5, 6-15, 16-25, or 26+ (years)
	Education	Edu	Categorical: group 1 No degree; group 2 Professional (or collegial); group 3 University
	Wearing time during day	$Wear_{Time}$	Categorical: Few minutes, Few hours, or All day
	Used to wear the earplug family	$Habit_{Fam}$	Dichotomous: Yes or no
	Confidence in earplugs efficiency	Trust	Likert scale: from 1 (totally disagree) to 5 (Totally agree)

4.3.2.3 Work environment

4.3.2.3.1 Physical characteristics

Physical characteristics of the work environment include, but are not limited to, air quality (presence of dust), air temperature, and humidity (Doutres et al., 2022b). Three different companies participated in the study. There was no constant monitoring of atmospheric conditions in the companies at each workstation. Therefore, the physical characteristics of the work environment were represented by the variable "Company." This categorical variable (which takes on values 1, 2, or 3) can be used in a statistical analysis to measure whether the company has an influence on the perceived comfort of earplugs. However, it does not make it possible to distinguish which physical (or psychosocial) characteristic(s) of the company influence physical comfort.

A "season" variable (which takes on the values "spring," "summer," "fall," and "winter") was measured during the field test campaign. It is used here to approximate an atmospheric condition score by making the assumption that the temperature in the work environment was higher in summer than in spring and fall, and that lower temperatures in the workspace occurred in winter. Indeed, in Quebec, the average daily temperature fluctuates between 22°C in July and -15°C in January (*source, climat.meteo.gc.ca*).

4.3.2.3.2 Psychosocial characteristics of the work environment

Regarding the “Task and usage” category of the work environment, participants were asked how many hours they worked per week and the continuous variable (W_{Dur}) was created to assess this characteristic (i.e. work duration). In addition, noise exposure time over the course of a week was also estimated by each worker and the two associated variables, hours of work exposure per day ($Expo_{Time}$) and percentage of time exposure per week ($Expo_{\%}$) were created. Their work schedule (week, week-end or both) was collected together with their work shift (day shift, or evening and night shifts). Three dichotomous variables also measured whether workers had to ("yes")" or not ("no") talk ($Must_{Speak}$), move their heads ($Must_{MoHead}$), or bend over ($Must_{Bend}$) to perform their tasks. Participants were also asked if any additional equipment interfered with their earplugs ($Equip_{Inter}$), and whether or not they worked in teams (dichotomous "Team" variable).

Table 4.5 Physical and psychosocial characteristics of the work environment

	Characteristic name	**Short form**	**Variable type / values**
Physical	Company	Company	Categorical: 1, 2, or 3
	Season of the completion of the UPQ	Season	Spring, Summer, Autumn, or Winter
Psychosocial	Work duration	W_{Dur}	Continuous (hours per week)
	Exposure time	$Expo_{Time}$	Continuous (hours per week)
	% of exposure time	$Expo_{\%}$	Continuous (%)
	Team work	Team	Dichotomous: Yes or no
	Noise level perception	$Noise_{Percep}$	Likert scale
	Possibility to change of position	$Change_{Dep}$	Categorical: Yes, No, Do not know, or Does not apply
	Necessity to: Speak, move head, bend	$Must_{Speak}$	Dichotomous: Yes or no
		$Must_{MoHead}$	Dichotomous: Yes or no
		$Must_{Bend}$	Dichotomous: Yes or no
	Earplug interference	$Equip_{Inter}$	Dichotomous: Yes or no
	Work shift	Shift	Dichotomous: Day shift, or Evening and night shifts
	Work schedule	Schedule	Categorical: Week, Week-end or Both

With regards to the "Situational influences" category of the work environment, participants were asked to indicate on a 5 points Lickert scale the extent to which they perceived the noise in their work environment to be "quiet" to "very noisy" ($Noise_{Percep}$). They were also asked to indicate if they were able to change of departments or teams in the company (variable $\text{Change}_{\text{Dep}}$).

4.3.2.4 Earplug

Psychosocial characteristics of earplugs (Doutres et al. 2022b), such as attractiveness, or aesthetic design, were not measured in the questionnaires. Only the physical characteristics of the earplug (listed in table 4.6) are considered in this study. These physical properties were measured in laboratory on new earplugs samples of the same models as those tested by participants.

The shape of earplugs was assessed with two categorical variables that measure if the earplug is conical/cylindrical (variable Con) and pod-shaped or not (variable Pod). The mass of each earplug was measured using a scale. Two diameters were measured on each earplug (using a caliper): one located near its lateral side (D_1) and one on its medial side (D_2). The positions of the diameter measurements correspond approximately to the position of the FB and a very few millimeters on the lateral side of the SB if the earplug is deeply inserted into the earcanal. Only the D_1 diameter was retained because the statistical analysis performed to analyze the relationships between earplug characteristics and physical comfort attributes did not allow to use both D_1 and D_2 diameters simultaneously (see section 4.4.4.4.1.3)

The three next characteristics of the earplugs (radial force, extraction force and friction coefficient) were measured using comfort testers (see Fig. 4.1(a) and Fig. 4.2).

The amount of radial force exerted by an earplug when it is inserted in a rigid cylindrical earcanal heated at 36°C is here used to assess the physical characteristics of the earplug that reflects the pressure it may exert on earcanal walls. Because the radial force depends on the compression applied to the earplug (again, related to the size of the earcanal), rigid earcanals with 3 different inner diameters that are supposed to be representative of the diameter of the FB section of the earcanal were used (based on morphological data from Poissenot-Arrigoni et al., 2022). The diameters are 11 mm, 9 mm, and 7 mm for all earplugs, except for the multi-flange elastomeric polymer one for which the compression diameters are 9 mm, 7.5 mm, and 6 mm (because it was too small for the larger diameter). The tests were performed on a J-Crimp station (©Blockwise, Tempe, Arizona, USA) by Blockwise operators (see Fig. 4.1 (a)). It consists in applying a radial displacement to the earplug and measuring the resulting radial force during 10 min. The iris of the machine (see Fig. 4.1 (a)) was heated to 36°C to match the temperature of the earcanal. The 10 min waiting time allowed the earplugs to reach thermal and mechanical equilibrium. The radial force obtained after 10 minutes of compression is called the radial force of the earplug. The radial force also depends on the depth of insertion of the earplug into the Blockwise machine. Because study participants were trained to properly insert their earplugs into their earcanals at the beginning of each week of testing, it was assumed that the workers were wearing their earplugs correctly inside their earcanals. Therefore, the insertion depth inside the “rigid earcanal” of the three roll-down foam earplugs, the multi-flange elastomeric polymer earplug, and the push-to-fit foam sheath was set at 70% of the earplug length. Only the two push-to-fit foam pod earplugs were completely inserted inside the "rigid earcanal" of the comfort tester.

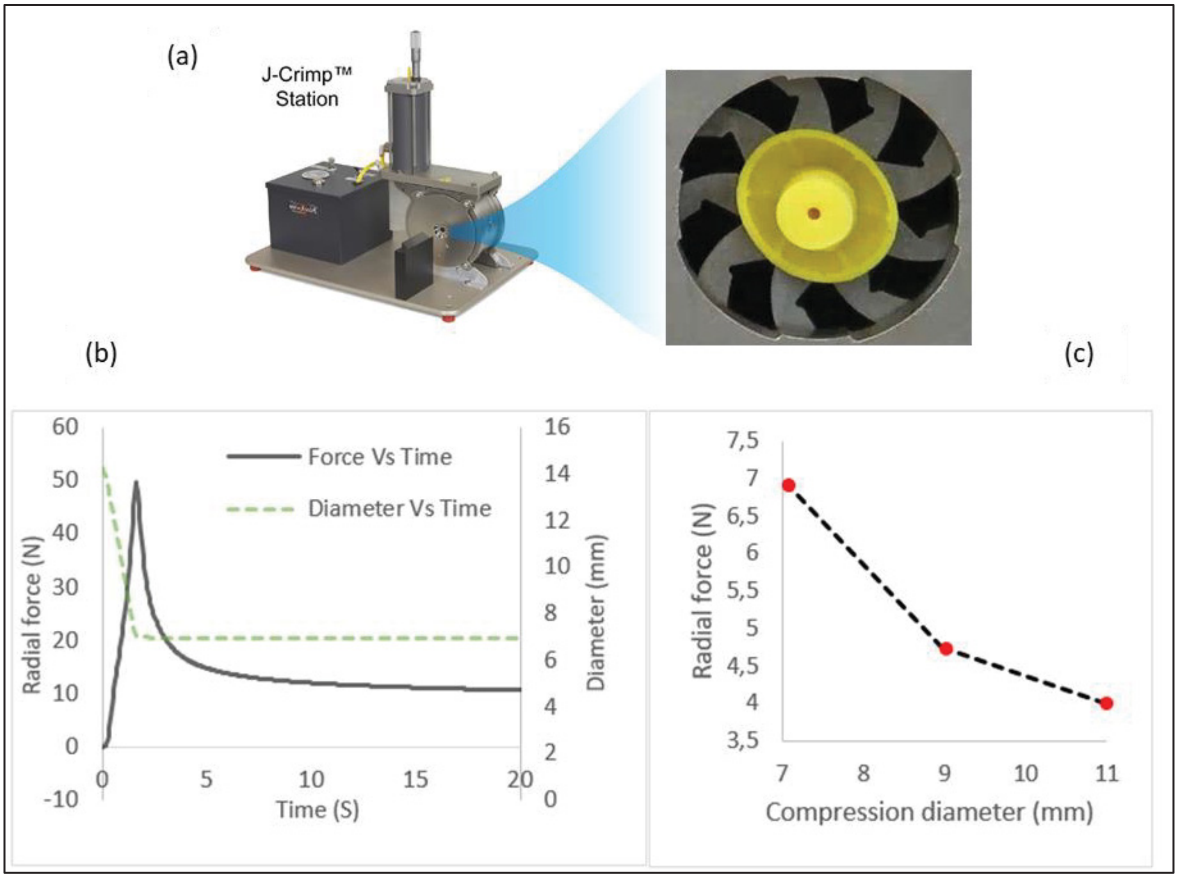


Figure 4.1 Comfort tester and procedure
(a) J-CrimpTM Station with crimp teeth applying displacement on a multi-flange elastomeric polymer earplug, (b) example of diameter and radial force Vs time (the 20 first seconds of the test) for the cylindrical foam (c) an example of experimental points of the cylindrical foam earplug (in red) and a linear interpolation curve (black dotted lines) and a linear interpolation curve (black dotted lines)

For example, the measured radial force versus diameter for the cylindrical foam earplug is shown in Fig. 4.1(c) as red dots. Measurements of the radial force was performed for all earplugs when compressed at 7 and 9 mm, except for the multi-flange elastomeric polymer for which linear regressions were performed to estimate the radial force compressed to these diameters. For each earplug, these two radial forces are considered as a mechanical characteristic of the earplug as defined in the triad proposed by Doutres et al., (2022b). Finally, only the radial force value at 9 mm compression will be used in the statistical analyses. Indeed, it will be shown in section 4.4.4.4.3.1 that the statistical analysis performed to analyze the relationships between earplug characteristics and attributes of the physical comfort did not allow the use of both the radial forces at 9 and 7 mm simultaneously.

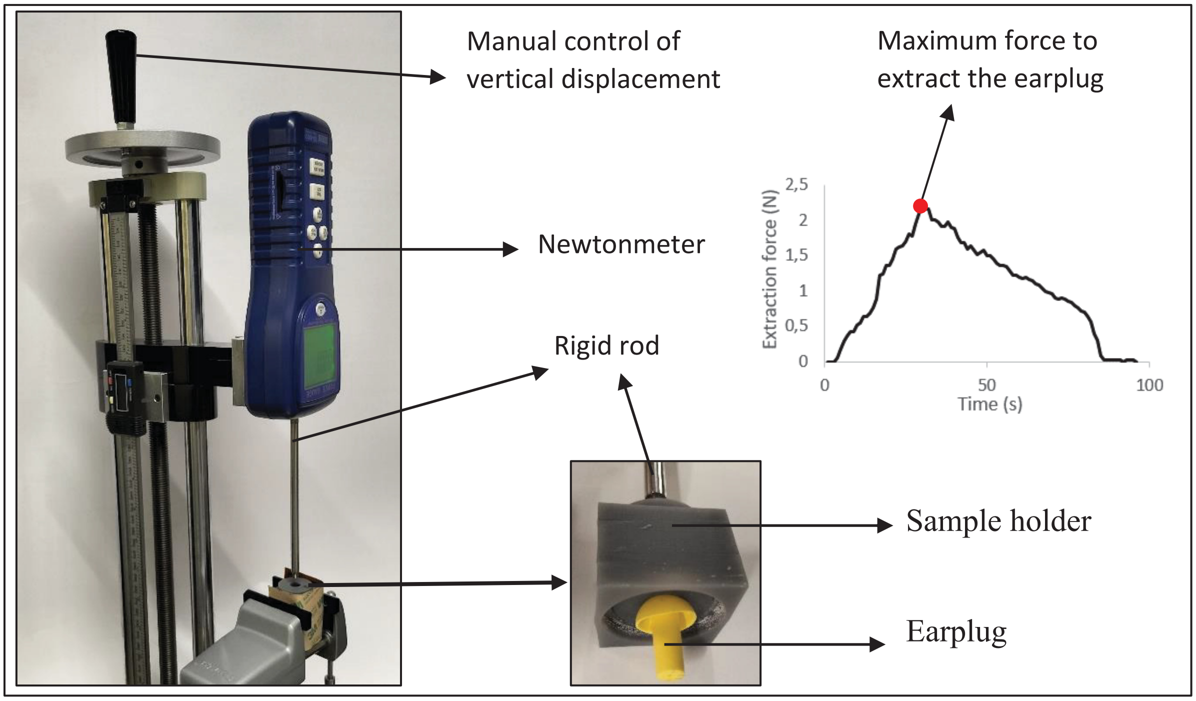


Figure 4.2 Comfort tester used to measure the extraction force of earplugs

The friction coefficient between the earplug and the earcanal is another physical property supposedly related to the irritation and physical discomfort induced by earplugs. This coefficient can be defined as the ratio between the tangential and normal force resulting from the earplug/skin interaction. To determine an approximation of this coefficient, the normal force at 9 mm compression was taken from the J-Crimp station (©Blockwise,Tempe, Arizona, USA) and the tangential force was assessed from another comfort tester shown in Fig. 4.2. It consisted of a rigid cylindrical sample holder of 9 mm diameter heated at 36°C, in which an earplug was inserted. A rigid rod was fixed to a newton meter mounted on a helical slide link. The rod enabled to push the earplugs out of the cylinder at a manually controlled rate and measure the force required to extract it from the cylinder. When the rod came in contact with the earplug, the later started to deform under the action of the rod (increasing part of the curve in Fig. 4.2). Then the earplug started to slide and the measured extraction force decreased (decreasing part of the curve in Fig. 4.2). The tangential force used in the friction coefficient calculation was assumed to be the maximum extraction force obtained. Note that each earplug model was tested three times using a new earplug for each test. The main limitations of this setup was that the cylindrical sample holder was rigid (no skin replica) and dry (no earwax replica).

4.3.3 Statistical analysis

Descriptive statistics were first performed with IBM® SPSS® Statistics 27 (IBM Corp., 2020) to explore responses to the four physical (dis)comfort attributes (see Table 4.2). A sequence of statistical analysis (see Fig. 4.3), was carried out for each physical comfort attribute. Statistical analyses sequences were carried out to identify the characteristics of the triad that significantly affected the physical discomfort attributes of interest in this work.

Because each participant tested different earplugs for seven weeks, these analysis sequences were based on the use of linear mixed-effects modeling. One of the strengths of these type of analysis is to take into account the measures related to an individual, even if some measurements are missing. These statistical analyses enable to identify the dependent variables that have a significant influence on a given independent variable and assess how they influence this independent variable. In the context of this study, independent variables were those that describe triad characteristics, and the dependent variables were the answers to the general and explanatory items of the COPROD-NAQ questionnaire for the physical dimension of comfort (i.e., physical annoyance, pain, pressure and irritation).

Because the number of independent variables considered in this work (see section 4.3.2) was too high to obtain robust results from the statistical analysis, a preliminary analysis (see the top part of Fig. 4.3) was therefore first carried out from the independent variables of each triad component, independently from each other. The advantage of this preliminary analysis was twofold, (i) it enabled to limit the number of variables considered and obtain more robust results from statistical analyses, and (ii) it enabled evaluating the effect of the characteristics of a triad component regardless of the characteristics of the two other components, which helped to interpret results and understand physical comfort. These preliminary analyses identified, for each component of the triad, the variables that influence physical comfort attributes. These variables were then grouped together to perform a global analysis (see lower part of Fig. 4.3) that takes into account variables from three components of the triad that were shown to influence comfort in the preliminary analyses. Note that because the person triad component was described by 27 characteristics (too many to obtain a robust results from statistical analysis given the number of participants), the preliminary analysis was first applied to two subcomponent of the person component namely the morphological and non-morphological subcomponents.

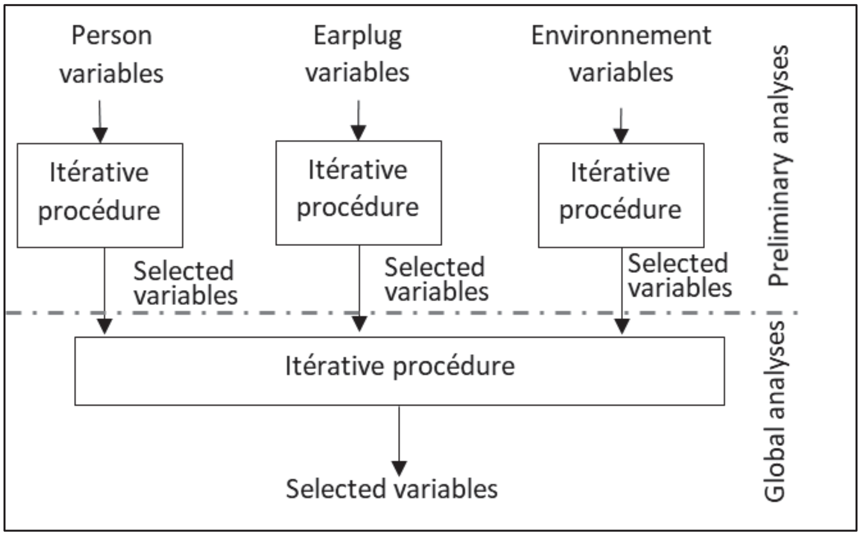


Figure 4.3 Conduct of the statistical analyses
This sequence is applied for each of the four comfort
attributes considered in this study

Preliminary and global analyses, consisted in applying the following iterative procedure to triad variables considered (e.g., variables that describe the earplug). The procedure consisted to conduct successively linear mixed-effects modeling and successively eliminate variables that do not influence physical comfort attribute. First, triad variables considered (e.g. variables that describe the earplug) were used as input to the linear mixed-effects modeling. The model results were examined to retain all independent variables that had a p-value inferior to 0.2. This first threshold was chosen to avoid eliminating variables that might have influenced discomfort attribute. Only the selected variables were used to perform a new linear mixed-effects modeling. This iterative procedure was repeated until all remaining independent variables had a p-value inferior to 0.2. Once this was the case, a new significance threshold was set at 0.1 to sort the variables. This was then repeated until all independent variables in the model had a p-value inferior to 0.1. The Akaike Information Criterion (AIC) was calculated at each step of the process. This criterion evaluates the relative quality of all the linear mixed-effects models tested during the iterative procedure, taking into account the parsimony criterion. It penalizes linear mixed-effects models with too many variables, thus avoiding overfitting and encouraging the selection of simple linear mixed-effects models (Cavanaugh, & Neath, 2019). At the end of the process, the linear mixed-effects model with the lowest AIC criterion was selected. For this selected linear mixed-effects model, the variables with the highest level of statistical significance were chosen to analyze their impact on the physical comfort attributes. Variables with p-values less than 0.05 were considered to have a statistically significant impact on comfort. Variables with p-values between 0.05 and 0.1 were not considered to have a statistically significant impact on comfort but were rather interpreted as trends. For significant continuous variables, the sign of the linear mixed-effects models beta-estimate indicates the direction of the variables influence on physical comfort attributes. For categorical variables, the estimated marginal means of the linear mixed-effects models indicate which categories generated the most physical discomfort (e.g., earplugs with stems generated more physical discomfort than roll-down foam earplugs).

4.4 Results and discussion

4.4.1 Descriptive analyses of the general items

The results of physical annoyance and pain induced by wearing earplugs are presented in Fig. 4.4 and 4.5, respectively. In these figures, each row shows the frequencies of distribution of responses (on a Likert scale) for each earplug expressed as a percentage of the total number of participants. Approximately 70% of the participants who tested the cylindrical and bullet-shaped foam earplugs totally disagreed or disagreed that these earplugs generate physical annoyance or pain, whereas approximately 15% agreed or totally agreed that these earplugs generate physical annoyance or pain. As for the bell-shaped foam, answers are more divided than for the two others roll-down foam earplugs. Forty percent of participants totally disagreed or disagreed that this earplug generates physical annoyance or pain and about 40% of participants agreed or totally agreed that this earplug generates physical annoyance or pain. The responses on the physical annoyance caused by the four stemmed earplugs show similar distributions. Between 40% and 65% of participants totally disagreed or disagreed that these earplugs generate physical annoyance or pain and between 20% and 40% of participants agreed or totally agreed that these earplugs generate physical annoyance or pain. It is worth noting that the answers (on the Likert scales), are very similar for the physical annoyance (Fig. 4.4) and pain (Fig. 4.5) attributes.

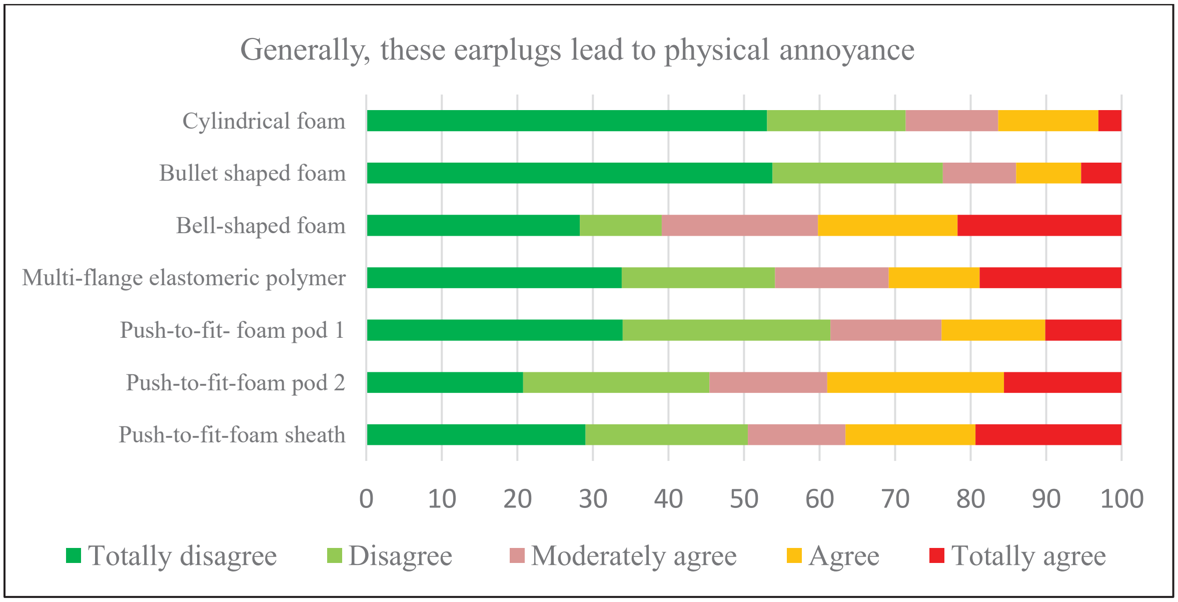


Figure 4.4 Distribution of evaluations and statistical typologies of answers to the question evaluating the physical annoyance attribute (in %)

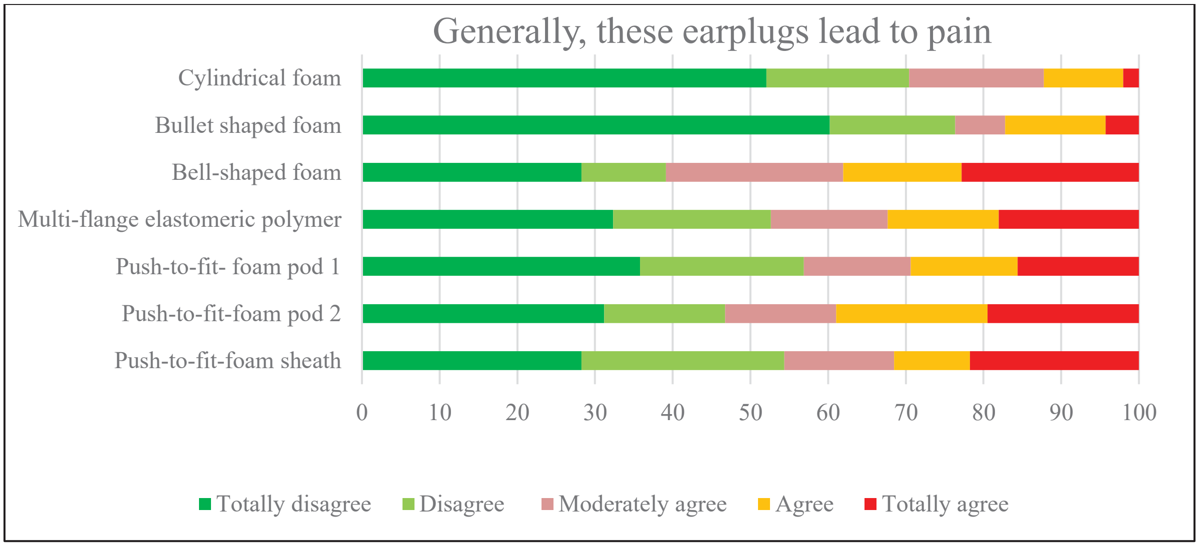


Figure 4.5 Distribution of evaluations and statistical typologies of answers to the question evaluating the pain attribute (in %)

4.4.2 Descriptive analyses of the explanatory items

Explanatory items presented in Fig. 4.6 and 4.7 address the feelings of pressure and irritation. Overall, the distribution of the answers about the feeling of pressure are quite balanced between the five Likert scales points. It is for the bell-shaped foam earplug that the most participants (almost 70%) agreed or totally agreed that this earplug generates a feeling of pressure. As similar proportion of participants (between 60 and 70%) moderately agreed, agreed or totally agreed that the stemmed earplugs pushed in their ears.

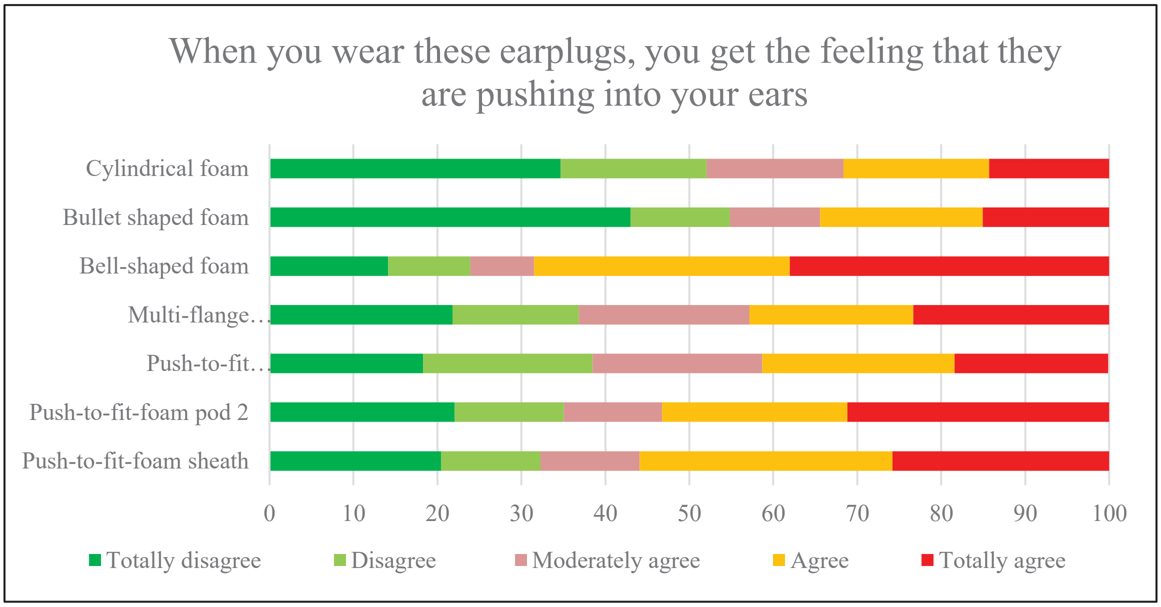


Figure 4.6 Distribution of evaluations and statistical typologies of answers to the question evaluating the attribute pushing in the ears (in %)

The distributions of the answers to the question about irritation show that the cylindrical foam and bullet-shaped foam earplugs are the ones for which the less participants (about 8%) totally agreed that these earplugs generated irritation. For the other earplugs of the study, between 15% and 25% of participants totally agreed that these earplugs generated irritation.

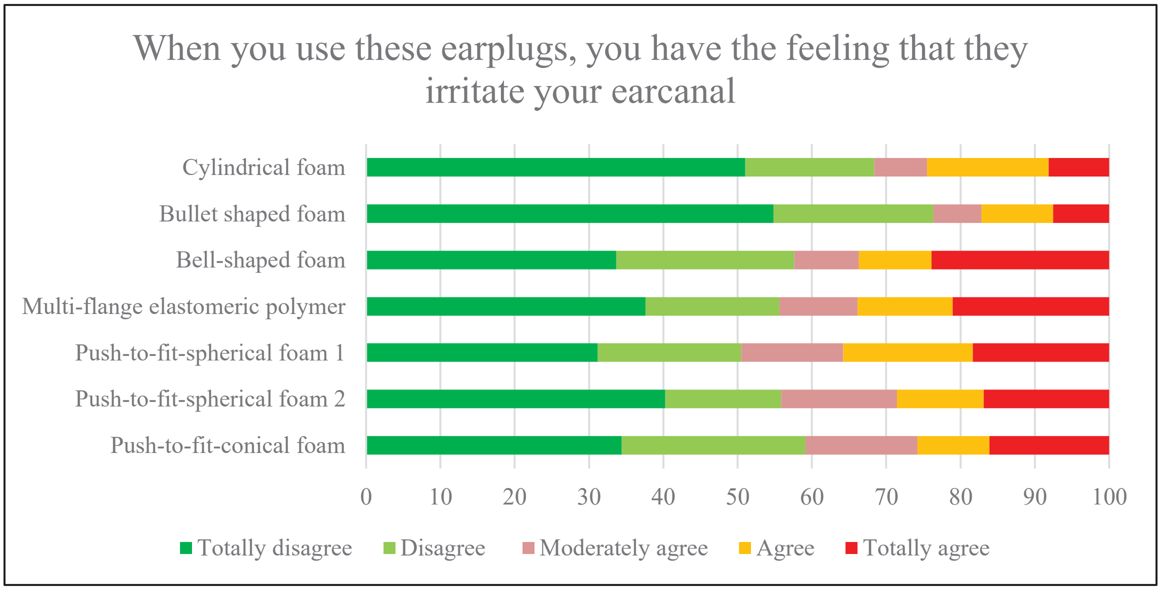


Figure 4.7 Distribution of evaluations and statistical typologies of answers to the question evaluating the attribute irritation (in %)

4.4.3 Characteristics of the triad

4.4.3.1 Person

A comprehensive description of the participants' earcanals morphology can be found in Poissenot-Arrigoni et al., (2022). In short, earcanals length is ranging between 7.8 mm and 19.6 mm. The mean circumferences of cross-sections E, FB and SB are respectively C_E = 39.6 mm (*SD* = 4.5 mm), C_{FB} = 32.2 mm (*SD* = 4.2 mm) and C_{SB} = 28.6 mm (*SD* = 4.6 mm). As expected, the earcanal shrinks in the medial direction ($C_E > C_{FB} > C_{SB}$). This is confirmed by the mean conicity indicator $F_{E/SB}$ that is equal to 1.81 (*SD* = 0.61) and therefore superior to 1. The ovality of the cross-sections is respectively IR_E = 0.83 (*SD* = 0.07), IR_{FB} = 0.91 (*SD* = 0.05) and IR_{SB} = 0.93 (*SD* = 0.04). It indicates that the earcanal becomes more circular in the medial direction ($IR_E < IR_{FB} < IR_{SB}$).

Regarding the classification of earcanal diameters with the EST, most earcanals (82,7%) belong to groups M, L or XL. Only 4.6% were S or XS earcanals, and 12,7% of earcanals were XXL or XXXL.

About 28% of participants were hearing impaired. Most of the participants (88%) were right-handed, 11% left-handed and 1% ambidextrous. Slightly more than half of the sample (55%) was between 45 – 65 years.

Previous experiences of workers with earplugs were the following: 23% of participants were used to wearing earplugs for less than 5 years, 27% from 6 to 15 years, 35% from 16 to 25 years and 15% had been wearing earplugs at work for more than 26 years. Almost a third of the participants (29%) tested an earplug family they used to wearing before entering the study. Most of participants (75%) had a professional or collegial degree at the time of the study, 10% did not had a degree and 15% had a university degree.

Regarding participants' past experiences with earplugs prior to participating in the study, the majority of participants were used to wearing earplugs during the entire work shift (75%). About 22% wore earplugs a few hours a day and 3% wore their earplugs a few minutes a day. Overall, participants had a good trust in earplugs efficiency, because 95% of them agree or totally agree that “wearing earplugs helps prevent hearing problems”.

4.4.3.2 Work environment

Eighty percent of participants perceive their work environment as noisy or very noisy. Fifty five percent of participants did not have the option of moving to another service or department at the time of the study.

With regard to the characteristics of the work environment related to the “task and use” category, 96% of workers had to speak during work, 47% had to move their head repeatedly and 67% had to bend their body during their workshift. Only 8% of participants found that their earplugs interfered with their equipment (before being involved in the study).

Overall, participants worked 41 hours per week (*SD* = 3.5 hours) and 42% of participants had evening or night work shifts and 44% of them had variable schedules (they worked either the week or the week-ends). On average, they perceived that they were exposed to noise at work 32 hours a week, which corresponds to 77% of the time of their work shift. Most of workers worked with colleagues or in teams (79%).

4.4.3.3 Earplug

The physical characteristics of earplugs are listed in Table 4.6. The first three characteristics are described by dichotomous variables that indicate whether the earplug is conical, pod-shaped, or has a stem. The two median (D_2) and lateral (D_1) diameters are also reported in Table 4.3. Because the stems of the three push-to-fit foam earplugs have a non-canonical shape (non-circular stem cross-section) and the stem is not intended to be in contact with the walls of the earcanal, the lateral diameters are set to 0 mm.

The radial forces at 7 mm and 9 mm diameter compression (RF_7 and RF_9), used in this work to characterize earplug stiffness, are also shown in Table 4.3. It can be seen that earplugs without stems have a small difference in radial force between the two compression diameters 7 and 9 mm, whereas this difference is much larger for earplugs with stems. The assumption is that the stems are much rigid than the foam. Therefore, when stemmed earplugs are compressed to 7 mm diameters, the foam is highly compressed between the cylinder of the comfort tester of Fig. 4.1(a) and the stem, resulting in a high radial force.

Table 4.6 Objective characteristics of the tested earplugs

Characteristic name	Conical?	Pod-Shaped	Stemmed	Mass (g)	Diameter (mm)	Friction coeff		Radial force (N)		Extraction force (N)
Variable symbol	**Con**	**Pod**	**Stem**	**Mass**	**D1**	**D2**	**μ**	**RF_7**	**RF_9**	**EF_9**
Cylindrical foam	No	No	No	0.31	13.5	13.5	0.48	7	4.7	2.27
Bullet shaped foam	Yes	No	No	0.38	12.9	12.4	0.61	6.9	4.45	2.7
Bell-shaped foam	Yes	No	No	0.63	12.3	11.7	0.55	9.9	6.5	3.57
Multi-flange elastomeric polymer	Yes	No	Yes	1	12.5	10.5	0.52	52	4	2.1
Push-to-fit foam pod 1	No	Yes	Yes	0.62	0	12.2	0.62	10.9	3.2	3.51
Push-to-fit foam pod 2	No	Yes	Yes	0.94	0	13	1.03	20.8	5.8	6
Push-to-fit foam sheath	Yes	No	Yes	1.18	13.4	11.5	0.52	29	4.5	2.33

4.4.4 Influence of the characteristics of the triad on the physical comfort

The statistical analysis of the physical annoyance and pain (the two general items) are presented in subsections 4.4.4.1 and 4.4.4.2. For each of these attributes of the physical comfort, the three preliminary analyses taking into account the characteristics of the person, the work environment and the earplug components (Fig. 4.3 top) are presented first, followed by the global analysis which takes into account the characteristics of the components of the triad previously selected (Fig. 4.3 bottom). The analyses of explanatory items are presented in section 4.4.4.3.

4.4.4.1 General items: “physical annoyance”

A summary of results of all the analyses can be found in Table 4.7.

4.4.4.1.1 Characteristics of the person

A preliminary analysis taking into account only the morphologic description of the person was first carried out. After the iterative procedure was completed, the circumferences of cross-section E of the right earcanal ($C_{E(R)}$), and of cross-section FB of the left earcanal ($C_{FB(L)}$) together with the isoperimetric ratios of the three characteristics cross-sections (E, FB and SB) of the right earcanal ($IR_{E(R)}$, $IR_{FB(R)}$ and $IR_{SB(L)}$) were found to have a significant impact on physical annoyance. Beta-estimates of the model suggest that the physical annoyance is higher when cross-section E circumference ($C_{E(R)}$) is larger and cross-section FB circumference ($C_{FB(L)}$) is smaller. The interpretation of these results is not straightforward. It could be hypothesized that a wide earcanal entrance would favor deep insertion, and therefore physical annoyance. A smaller cross-section FB would lead to a higher compression of the earplug and surrounding tissues leading to more physical annoyance.

The influence of the earcanal-cross sections ovality is as follows. If cross-sections E and SB have a more circular shape, the physical annoyance increases. On the contrary, if cross-section FB has a more oval shape, the physical annoyance increases. As the interpretation of the impact of earcanal ovality on earplugs physical annoyance is not straightforward, additional analysis has been carried out in order to evaluate the relative importance of each parameter on this attribute of comfort. The statistical analysis, has been computed again (using only variables selected after the iterative process was completed) but using the z-score of the continuous variables as input, which enabled to compare the beta-estimates. The “standardized” beta-estimates of the isoperimetric ratios of cross-sections FB and SB ($IR_{FB(R)}$ and $IR_{SB(R)}$) were about three times smaller than “standardized” beta-estimates of the two circumferences of cross-sections E and FB ($C_{E(R)}$ and $C_{FB(L)}$) and the isoperimetric ratio ($IR_{E(R)}$) of cross-section E. Consequently it can be hypothesized that the physical annoyance is mostly governed by the two circumferences of cross-sections E and FB ($C_{E(R)}$ and $C_{FB(L)}$) and the isoperimetric ratio of cross-section E ($IR_{E(R)}$) (when only the variables characterizing the person are taken into account to perform the statistical analyses).

Another analysis considering only the non-morphologic description of the person was then carried out. Two variables seem to have a statistically significant or close to significant impact on the physical annoyance: the earplugs wearing time ($Wear_{Time}$) and the habitude to wear earplugs from the same family as the tested earplug ($Habit_{Fam}$). Marginal estimated means suggest that the longer the wearing time, the higher the induced physical annoyance, which is intuitive because a prolonged wearing time could favour the appearance of the symptoms of the induced physical discomfort. As for the habituation, participant that were used to wear earplugs from the same family that the tested earplug found it less physically annoying than participants who never used earplugs from this family. In short, results suggest that habituation reduce physical annoyance. This is in line with the statement of Doutres et al., (2022a) that habituation, also referred to as acclimatization, is pointed out in the literature to improve the physical (and acoustical) comfort.

An analysis was then performed considering all the variables of the person component of the triad that were previously shown to have a significant impact on physical annoyance induced by the wearing of earplugs (7 in total). With the exception of the wearing time variable, all other variables were found to have significant impact on physical annoyance induced by earplugs.

In summary, the physical annoyance seems to be governed by the habituation of the person wearing some earplugs families ($Habit_{Fam}$) and morphologic variables: the physical annoyance is higher when cross-section E circumference ($C_{FB(L)}$) is larger and more circular and the FB cross-section ($C_{FB(L)}$) is smaller.

4.4.4.1.2 Characteristics of the work environment

After the iterative process described in the methodology section was completed, it was found that the necessity to bend to perform work tasks ($\text{Must}_{\text{Bend}}$) and the work shift (Shift) had a statistically significant influence on physical annoyance. Estimated marginal means show that overall, workers who had to bend during their work found that earplugs generate more physical annoyance than workers who did not. Estimated marginal means also suggest that participants who worked during the day found that their earplugs generated more physical annoyance than participants who worked during the evening and the night.

4.4.4.1.3 Characteristics of the earplug

Due to redundancy issues, input variables of the analysis had to be sorted before starting the iterative process. Variables characterising the conicity (Con) of the earplugs, the pod-shape (pod), the diameter (D_1) and the radial force at 7 mm compression (RF_7) were discarded. The first two variables were removed because the conicity and the "pod" variables together are redundant with the variable "Stem". It was decided to keep only one diameter and one radial force properties to avoid redundancy. To choose which one to remove (D_1 or D_2, or RF_7 or RF_9), linear mixed-effects modeling were performed with only these variables as input. The ones that had less impact on earplug physical annoyance were discarded; i.e., D_1 and RF_7. Once the redundancy issue was resolved and the sorting iterative procedure completed, three variables were found to have a statistically significant ($p\text{-value}<0.05$) or close to significant impact ($p\text{-value}<0.1$) on physical annoyance: the presence of stem on the earplug (Stem), the radial force at 9 mm diameter compression (RF_9) and the friction coefficient (μ). Marginal estimated means showed that non-stemmed earplugs (i.e., roll-down foam earplugs) generated less physical annoyance than stemmed earplugs. The beta-estimates showed that, the greater the radial force, the greater the physical annoyance. Similarly, the greater the friction coefficient, the greater the physical annoyance. These results seem consistent: a high radial force would induce a greater compression of soft tissues leading to physical annoyance, and a high friction coefficient would favor the earcanal skin irritation.

4.4.4.1.4 Characteristics of all triads components

Finally, all variables of each component of the triad that were shown to have a significant impact on physical annoyance were selected to perform the iterative procedure described in section 4.3.3. Five variables were shown to have a significant impact on physical annoyance: the presence of a stem (Stem), the radial force of the earplug compressed at 9 mm diameter (RF_9) and the three isoperimetric ratios of the three characteristics cross-sections of the right earcanal ($IR_{E(R)}$, $IR_{FB(R)}$ and $IR_{SB(R)}$). To study the relative importance of these characteristics, the z-scores of input variables were again used (except for the stem variable which is categorical). The beta-estimates of the variables Stem (beta=0.86), z-score of radial force (RF_9) (beta=0.48) and z-score of isoperimetric ratio of cross-section E ($IR_{E(R)}$) (beta=0.44) were higher than those of z-scores of isoperimetric ratios of the cross-sections FB ($IR_{FB(R)}$) (beta= -0.04) and SB ($IR_{SB(R)}$) (beta=0.29). Earplugs with stems and high radial forces generate more physical annoyance. As for the isoperimetric ratio, model beta-estimates suggest that a circular E cross-section and to a lesser extent circular SB cross-sections favor physical annoyance. The influence of the ovality of the cross-section FB seems negligible comparing to the ovality of cross-section E and SB.

Table 4.7 Summary table of the analyses of physical annoyance
Grey lines indicates that additional tests shown that these parameters have little impact on comfort compared to others

Variable	**p-value**	**Direction of the effect of the parameter**
Preliminary analysis accounting only for the "person" component of the triad		
circumferences of E and FB cross-sections	$C_{FB(L)}$ (0.008)	If $C_{FB(L)}$ increases the physical annoyance decreases
	$C_{E(R)}$(0.000)	If $C_{E(R)}$ increases the physical annoyance increases
isoperimetric ratios of the E, FB and SB cross-sections	$IR_{E(R)}$ (0.000)	If $IR_{E(R)}$ increases the physical annoyance increases
	$IR_{FB(R)}$ (0.012)	If $IR_{FB(R)}$ increases the physical annoyance diminish
	$IR_{SB(R)}$ (0.003)	If $IR_{SB(R)}$ increases the physical annoyance increases
Use to wear earplugs from the same family	$Habit_{Fam}$(0.000)	Being use to wear similar earplugs reduce physical annoyance
Preliminary analysis accounting only for the "work environment" component of the triad		
Necessity to bend during work	$Must_{Bend}$ (0.008)	Having to bend generate more physical annoyance than not having to bend
Workshift	Shift (0.017)	Working the day generate more physical annoyance than working the evening and the night
Preliminary analysis accounting only for the "earplug" component of the triad		
Stem	stem (0.001)	Earplugs with stem generate more physical annoyance than roll-down foam earplugs
Radial force	RF_9 (0.001)	If the RF_9 increases, the physical annoyance increases
Friction coefficient	μ (0.051)	If increases μ, the physical annoyance increases
Global analysis accounting for all triad components		
Stem	stem (0.000)	Earplugs with stem generate more physical annoyance than roll-down foam earplugs
Radial force	RF_9 (0.000)	If the RF_9 increases, the physical annoyance increases
isoperimetric ratios of the E, FB and SB cross-sections	$IR_{E(R)}$ (0.000)	If $IR_{E(R)}$ increases the physical annoyance increases
	$IR_{FB(R)}$ (0.002)	If $IR_{FB(R)}$ increases the physical annoyance diminish
	$IR_{SB(R)}$ (0.003)	If $IR_{SB(R)}$ increases the physical annoyance increases

4.4.4.2 General items: “Pain”

The statistical analyses of the pain attribute are described in subsections 4.4.4.2.1 to 4.4.4.2.4. The three preliminary analyses taking into account characteristics of components person, work environment and earplug are first presented followed by the global analysis (that takes into account characteristics of component of the triad previously selected). A summary of the pain analysis can be found in Table 4.8.

4.4.4.2.1 Characteristics of the person

The analysis taking into account morphologic variables allowed for the selection of the variables circumferences of cross-sections E (right earcanal) ($C_{E(R)}$), FB (left earcanal) ($C_{FB(L)}$) and isoperimetric ratio of cross-section E (right earcanal) ($IR_{E(R)}$) which all have the same direction effects on pain as on physical annoyance.

The analysis taking into account non-morphological variables showed that the wearing time ($Wear_{Time}$) and the habitude of wearing earplugs from the same family as the tested earplug ($Habit_{Fam}$) had an impact on earplugs pain in the same way as for the attribute physical annoyance.

The analysis that takes into account both morphological and non-morphological characteristics of the person for the attribute pain gave similar results as for the attribute physical annoyance. The cross-section E circumference ($C_{E(R)}$) has an impact on pain: the larger the earcanal E circumference, the higher the feeling of pain. As for the isoperimetric ratio ($IR_{E(R)}$), the more circular the E cross-section, the higher the pain. Workers who were used to wearing earplugs from the same family as the tested earplug found it less painful.

4.4.4.2.2 Characteristics of the work environment

The two following variables had a moderate impact (their p-value ranged between 0.05 and 0.1 which is not significant but gives tendencies) on the attribute “pain”: the necessity to speak ($Must_{Speak}$) and the possibility to change of service/department ($Change_{Dep}$). Surprisingly, estimated marginal means suggest that overall, workers who had to speak during their work found earplugs less painful than workers who did not. This result must be taken with caution since overall, the workers who tested the considered earplugs, only 7 did not have to speak during there work and 149 had to speak during their work. Estimated marginal means suggest that overall, workers who had the possibility to change of department found earplugs less painful than workers who did not.

4.4.4.2.3 Characteristics of the earplug

The same manipulations as for the analysis of the physical annoyance were done on the variables of the earplugs to avoid redundancy issues. After the iterative procedure, the four variables presence of a stem (stem), radial force of the earplug compressed at 9 mm diameter (RF_9), extraction force (EF_9) and friction coefficient (μ) were found to have a significant or close to significant impact on the pain attribute. The same trends as for the previous analysis (of physical annoyance) were observed. Regarding the extraction force, it was found that the higher the extraction force, the lower the induced pain. This may be due to the fact that a low extraction force would favor earplugs movements inside the earcanal which would induce irritation, and ultimately, pain. Care must be taken in interpreting these results, considering the limitations of the extraction force setup described in the methodology section (straight rigid earcanal, absence of skin replica, dry contact between the earplug and the earcanal).

4.4.4.2.4 Characteristics of all triad components

All variables of each component of the triad that were shown to have a significant impact on pain were grouped to perform the global analysis. The characteristics of the earplug were shown to strongly influence the perceived pain. Statistically significant variables were presence of a stem (stem), radial force of the earplug compressed at 9 mm diameter (RF_9), extraction force (EF_9) and friction coefficient (μ). Again, earplugs with stem were found more painful than roll-down-foam earplugs. Earplugs with the highest radial force and friction coefficient generated more pain, and the higher the extraction force, the less painful the earplug. A unique morphological variable (the isoperimetric ratio of the E cross-section ($IR_{E(R)}$) was shown to have a significant impact on pain: the more circular the E cross-section, the more painful the earplug. It can be hypothesized that a more circular earcanal entrance would favor deep insertion were the earcanal is more sensitive.

Finally, general physical comfort attributes analysis tend to show that the earcanal morphology and earplugs characteristics influence the most the perception of the two general items of the physical discomfort. High earplugs radial force and friction coefficient favour physical discomfort. In addition, two roll-down foam earplugs with radial forces (RF_9) of 4.45 N and 4.70 N were found less physically annoying and painful than stemmed earplugs (push-to-fit foam and premolded earplugs) and a roll-down foam earplug which has a radial force (RF_9) of 6.50 N. A precise mapping of earcanals sensitivity could be helpful to draw more conclusions from the results. Moreover, the insertion depth of earplugs on the field was unknown. Knowing if earplugs were deeply inserted or not in the earcanals could provide useful information to interpret the previous analysis of physical discomfort.

Table 4.8 Summary table of the analyses of pain

Variable	**p-value**	**Direction of the effect of the parameter**
Preliminary analysis accounting only for the "person" component of the triad		
circumference of the E cross-section	$C_{E(R)}$(0.087)	If $C_{E(R)}$ increases the pain increases
isoperimetric ratio of the E cross-section	$IR_{E(R)}$(0.026)	If $IR_{E(R)}$ increases the physical annoyance increases
Use to wear earplugs from the same family	$Habit_{Fam}$ (0.000)	Being use to wear similar earplugs reduces pain
Preliminary analysis accounting only for the "work environment" component of the triad		
Possibility to change of service/department	$Change_{Dep}$ (0.058)	Having the possibility to change of service reduces pain
Necessity to speak during work	$Must_{Speak}$ (0.077)	People who do not have to speak during work feel more pain
Preliminary analysis accounting only for the "earplug" component of the triad		
Stem	stem (0.001)	Earplugs with stem generate more pain than roll-down foam earplugs
Radial force	RF_9 (0.001)	If the RF_9 increases, the pain increases
Extraction force	EF_9 (0.051)	If EF_9 increases, the pain decreases
Friction coefficient	μ (0.016)	If increases μ, the pain increases
Global analysis accounting for all triad components		
Stem	stem (0.000)	Earplugs with stem generate more pain than roll-down foam earplugs
Radial force	RF_9 (0.000)	If the RF_9 increases, the pain increases
Extraction force	EF_9 (0.002)	If EF_9 increases, the pain decreases
Friction coefficient	μ (0.001)	If increases μ, the pain increases
isoperimetric ratio of the E cross-sections	$IR_{E(R)}$(0.03)	If $IR_{E(R)}$ increases the physical annoyance increases

4.4.4.3 Explanatory items

The next two subsections 4.4.4.3.1 and 4.4.4.3.2 give a short description of the analysis of the feeling of pushing in the ears and irritation. Since these two attributes correspond to explanatory items that are only intended to better interpret the two general items, the analysis description are more succinct than in the previous sections.

4.4.4.3.1 Pushing in the ears

The results of the analyses of the explanatory item pushing in the ears are summarized in table 4.9. Interestingly, the only physical property of the earplug that is related to the pushing sensation is its radial force (RF_9): the higher the radial force, the higher the pushing sensation.

The person variables related to the pushing feeling are the education level (Edu) and the variable characterising if the participant is used to wearing earplugs from the same family ($Habit_{Fam}$). The education level is not significant but close to be ($p=0.078$), the higher the education degree, the higher the feeling of the earplug pushing in the ear. The analysis taking into account only the morphological characteristics of the person had no variables that were statistically significant.

The season is close to significantly influences the pushing sensation. The pushing sensation is higher in the winter (suggested by marginal estimated means). It might be attributed to the fact that the temperature had an influence on earplugs foams properties. This hypothesis is to be confirmed since, the earplugs is supposed to reach a temperature close to the body temperature once inserted inside the earcanal. These interpretations must be taken with caution because the "season" variable may not be an accurate representation of the actual temperature inside the workshops. Here, it is assumed that the temperature was lower in the workshops in winter than in summer. In a future study, it may be interesting to continuously monitor the temperature near the participants.

The global analysis showed that perception of the pushing in the ears feeling is governed by the habituation ($Habit_{Fam}$) and the radial force (RF_9).

Table 4.9 Summary table of the analyses of the sensation of pushing in the ears

Variable	**p-value**	**Direction of the effect of the parameter**
Preliminary analysis accounting only for the "person" component of the triad		
Use to wear earplugs from the same family	$\text{Habit}_{\text{Fam}}$ (0.029)	Being use to wear similar earplugs reduces the feeling of pushing in the ears
Education	Edu (0.078)	Higher education degree leads to higher sensation of earplugs pushing in the ears
Preliminary analysis accounting only for the "work environment" component of the triad		
Season	Season (0.080)	Earplugs pushes more in the winter than in the summer
Workshift (0.054)	Shift (0.054)	Working the day generate more the sensation of pushing than working the evening and the night
Preliminary analysis accounting only for the "earplug" component of the triad		
Radial force	RF_9 (0.005)	If the RF_9 increases, the pushing sensation increases
Global analysis accounting for all triad components		
Use to wear earplugs from the same family	$\text{Habit}_{\text{Fam}}$ (0.002)	Being use to wear similar earplugs reduces the feeling of pushing in the ears
Radial force	RF_9 (0.000)	If the RF_9 increases, the pushing sensation increases

4.4.4.3.2 Irritation

Characteristics of the earplugs related to the feeling of irritation were the extraction force (EF_9) (the lower the extraction force, the higher the irritation), the friction coefficient (μ) (the higher the friction coefficient, the higher the irritation), the radial force (RF_9) and the presence of a stem (Stem) (see table 4.10). The influence of extraction force on irritation is similar to its influence on pain. It supports the assumption that a lower extraction force could lead the earplug to move more easily and generate irritation and ultimately, pain.

The season has an influence on the sensation of irritation, but in contrast with its influence on the pushing in the ears feeling, participants found earplugs more irritating in the summer than in the winter. This could be due to the sweating induced by high temperature. Another hypothesis could be that “warm” roll-down foam earplugs are softer and much more difficult to insert than “cold” earplugs. This would lead to higher degree of irritation in the tragus and entrance earcanal region.

The global analysis included showed that the season (Season), the radial force (RF_9) and the presence of a stem (stem) influence the irritation. It is worth noting that irritation is the only physical comfort attribute for which the global analysis showed that the work environment influences it.

Table 4.10 Summary table of the analyses of irritation

Variable	**p-value**	**Direction of the effect of the parameter**
Preliminary analysis accounting only for the “work environment” component of the triad		
Use to wear earplugs from the same family	$Habit_{Fam}$ (0.017)	Being use to wear similar earplugs reduces pain
Preliminary analysis accounting only for the “work environment” component of the triad		
Season	Season (0.030)	Earplugs irritate more in the summer than in the winter
Preliminary analysis accounting only for the “earplug” component of the triad		
Stem	Stem (0.028)	Earplugs with stem generate more irritation than roll-down foam earplugs
Radial force	RF_9 (0.001)	If the RF_9 increases, the irritation increases
Extraction force	EF_9 (0.002)	If EF_9 increases, the irritation decreases
Friction coefficient	μ (0.009)	If μ increases, the irritation increases
Global analysis accounting for all triad components		
Stem	stem (0.028)	Earplugs with stem generate more irritation than roll-down foam earplugs
Radial force	RF_9 (0.001)	If the RF_9 increases, the irritation increases
Season	Season (0.030)	Earplugs irritate more in the summer than in the winter

4.5 Limits

As there is no better method to determine the optimal number of independent variables, all potentially predictive variables (i.e., characteristics of the triad) were included in the preliminary linear mixed-effect models. In this work, the number of characteristics of the triad both assessed subjectively using questionnaires and objectively in the laboratory is large. Even if, the number of participants is quite high (173), and participants tested 7 times different earplugs (which significantly increases the number of comfort assessments of earplugs), a methodology was developed to sort out the triad characteristics that influenced significantly the physical comfort of earplugs. Statistical analyses based on the characteristics of a single component of the triad did not take into account the effects of the characteristics of the other components of the triad.

The lack of information on climatic conditions by task and workstation prevented us from making comprehensive statistical analysis based on work environment characteristics. Indeed, temperature, which can cause participants to sweat and change the material properties of the earplugs, is strongly suspected to influence physical comfort but could not be tested here.

4.6 Conclusion

The discomfort induced by earplugs to the user leads them to misuse their earplugs or remove them regularly, affecting their efficiency to protect from noise-induced hearing loss. Earplugs comfort results from complex interactions between the user, his/her earplugs and his/her work environment. In this study, characteristics of the triad person/earplug/environment are assessed through objective measurements and questionnaires. Earplug comfort was assessed in a field study with 173 workers of three different Canadian companies that tested nine models of disposable and reusable earplugs over seven weeks. Linear mixed-effect models enabled to identify characteristics of the triad that have an influence on four main attributes of the physical dimension of comfort: physical annoyance, pain, feeling of earplugs pushing in the ears and irritation. The statistical analyses showed that physical characteristics of the triad, measured objectively in this study, have an influence on physical comfort attributes. High earplugs radial force and friction coefficient favour physical discomfort. In addition, two roll-down foam earplugs with radial forces (RF_9) of 4.45 N and 4.70 N were found more comfortable than stemmed earplugs (push-to-fit foam and premolded earplugs) and a roll-down foam earplug which has a radial force (RF_9) of 6.50 N. Other characteristics of the triad were found to have an influence on earplugs comfort. In particular, workers found their earplugs less physically uncomfortable if they were used to wear them before being involved in the study. In addition, persons with large circular earcanal entrance cross-section found their earplugs more physically annoying and painful. The results presented in this article provide a better understanding of earplug-induced physical discomfort and the variables that influence it. Results could also help in the development of comfort-oriented design tools, since relations between objectively measurable characteristics of the triad (person/environment/earplug) and physical comfort attributes have been established.

4.7 Acknowledgement

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CHAPTER 5

CONCLUSION

This chapter summarizes the main results obtained in this thesis. The research problems and objectives are first briefly recalled (see Section 5.1). The summaries as well as, limitations and perspectives associated with each paper that constitute this thesis are presented in Sections. 5.2 to 5.4. A general conclusion is given in section 5.5.

5.1 Synthesis of research problems and objectives

The literature review presented in Chapter 1 showed that existing acoustical test fixtures (ATFs), dedicated to earplugs attenuation testing, are equipped with straight cylindrical earcanals of a single size and are therefore unable to assess how well earplugs can fit different earcanal morphologies. An ATF intended to test how earplugs can fit different users should allow for a variety of earcanals shapes. There is thus, a need for more realistic artificial ears of different morphologies characteristic of targeted populations. In addition, disposable and reusable earplugs are available in a wide variety of shapes and materials, but there is no consensus on a simple and straightforward selection method that would ensure for a given worker, a proper fit and thus sufficient attenuation (field attenuation estimation systems exist but are not widely deployed in the field). It is not known which model and size of earplug is best suited for each unique earcanal, and the packaging of earplugs gives little indication on the subject. Thus, there is a need for methods to select earplugs using simple field-specific tools. Finally, even if an earplug provides the right amount of attenuation to the user when properly fitted, its effectiveness decreases significantly if worn intermittently. One of the main causes of misuse or non-use of earplugs is the physical discomfort they induce to the user. However, the origins of this dimension of comfort are poorly understood and the relationships between the various characteristics of the user, his/her earplugs, his/her work environment (which form the concept of triad) and the main attributes of physical comfort remain to be established.

In this thesis three different papers with three specific objectives allowed us to propose solutions to the above-mentioned challenges.

Objective 1: Develop a methodology to cluster earcanals as a function of their morphologies with the objective of designing artificial ears dedicated to sound attenuation measurement and to apply this methodology to a sample of Canadian workers' earcanals.

Objective 2: Evaluate the reliability of an existing earcanal sizing tool (simple and inexpensive tool easily deployable in the field) for estimating the fit quality of earplugs and ultimately for use as an earplug selection tool in the field.

Objective 3: Model the main attributes of physical discomfort (i.e., pain, physical annoyance, feeling of the earplug pushing in the ears and feeling of irritation) based on physical and psychosocial characteristics of the triad in order to better understand physical comfort and the triad characteristics that influence it. Within the framework of this doctoral thesis, only the physical discomfort has been investigated but the other dimensions of comfort will be addressed in the near future.

5.2 Design of artificial ears dedicated to earplug attenuation measurement: summary, limitations and perspectives

Summary: In this first paper, a methodology to group earcanals according to their morphology for the purpose of designing artificial ears dedicated to the measurement of sound attenuation was developed and applied to a sample of Canadian workers earcanals. Morphological indicators of earcanals that correlate with the attenuations of six commercial earplug models were first identified. Three groups of earcanals were then generated using statistical analysis and an artificial intelligence-based algorithm. In the sample of earcanals considered in this study, the identified groups differed in the length of the earcanal and in the area and ovality of the first bend cross-section. Earplugs induced significantly higher attenuation in the cluster comprising small earcanals with a circular first bend cross-section than in the group comprising larger earcanals with a more oval first bend cross-section.

Limitations: A single clustering process and validation procedure was implemented to cluster earcanals. Other clustering algorithms and/or statistical tests to validate the clusters could have been used and could have led to a different clustering structure of earcanals.

The description of the earcanal morphology was limited to 15 morphological indicators (7 size indicators and 8 shape indicators), which describe the part of the earcanal where the earplugs are supposed to be fitted (between the entrance and the second bend). It is therefore assumed that these indicators were sufficient to comprehensively describe the morphology of the earcanal. Other anatomical properties that may also be responsible for inter-individual variability in sound attenuation, such as mechanical properties of the ear tissues, position of the cartilaginous/osseous junction, or impedance of the eardrum, were not considered (note that some of these may be difficult or impractical to determine in the field).

The depth of insertion of the earplugs was unknown during the attenuation measurements on the field, and better knowledge of the position of each earplug in each ear could have been useful in identifying the most relevant cross-sections to correlate with the measured sound attenuation.

In addition, the type of training used in the initial field study led to an attenuation that was considered high enough to assume that the measured inter-individual variability in attenuation could be primarily attributed to morphological differences between earcanals. However, it can be assumed that the correlations between morphological indicators and attenuation might have been higher if the training session had been designed specifically for this study.

The sample of participants was primarily male. Because there are significant differences between male and female ear morphologies, additional analyses should be conducted on a sample consisting of equal numbers of males and females. Ideally, artificial ears should be made separately for males and females.

Future work: Three artificial ears representative of the three aforementioned clusters are currently under fabrication in our laboratory. These artificial ears are intended to be able to mimic the attenuation that could be measured on earcanals of each clusters. A first prototype of these artificial ears has been 3D printed with materials with mechanical properties slightly softer than the human cartilage (the softest material that can be 3D printed in our laboratory) and has already shown encouraging results compared to the attenuations measured on the participants of each cluster (See appendix 1). In particular, the same trend as on the participants was observed on the 3 prototypes of artificial ears: the larger the cross section of the first bend, the lower the attenuation. A current project (which I am supervising) aims at making these ears more realistic by molding them in a soft silicone and integrating materials mimicking bones and cartilages.

An ongoing study carried out by another PhD student of our laboratory aims at investigating an important attribute of the acoustical comfort: the occlusion effect. A test campaign conducted in the laboratory measures both experienced (dis)comforts associated to the occlusion effect using questionnaires and objective indicators (objective occlusion effect using the NR-based method (Saint-Gaudens et al. 2022), sound attenuation) using miniature microphones in the ears of participants occluded by different commercial earplugs and for which the fit is carefully controlled. The results of this study (which includes the fabrication of the participants' earmolds) could be used to further investigate the correlations between earplug attenuation and earcanal morphologies but knowing precisely the earplugs insertion, which was not the case in the precedent study.

In addition, the methodology developed in this first paper to objectively assess earcanal morphologies could be automated to characterize a large number of earcanal morphologies in a reasonable amount of time (using databases of custom earplugs manufacturers, for example).

This could be used to feed artificial intelligence-based clustering algorithms and to design earcanal morphologies that are representative of a larger portion of a population.

Benefits for manufacturers and workplaces: The methods developed in this thesis for analyzing and cluster earcanals on the basis of the morphological characteristics of real earcanals represent a noteworthy advancement. These methods have been successfully validated, demonstrating significant differences in the attenuation of various earplugs depending on the determined earcanal clusters. Taking this research further could have a profound impact on the next generation of commercially available ATFs, making them even more valuable for rapid characterization of potential earplug designs. This would be particularly beneficial in assessing their ability to properly fit a diverse range of realistic earcanal shapes.

5.3 Reliability of earcanal sizing tools to assess earcanal size and assist the earplugs selection

Summary: This second paper evaluated the reliability of a straightforward earcanal sizing tool (EST) (3M™ Eargage) for estimating earplug fit quality and ultimately for use as an earplug selection tool in the field. To this purpose, the earcanal morphology of 121 participants exposed to noise at work (103 men, mean age 47 years) was comprehensively assessed through scans of earcanal earmolds. Different earcanal dimensions assessed in the first paper were compared to earcanal size assessed with the EST 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 EST were also established via box plots and comparison tests. It was found that the size of the earcanal assessed with the EST corresponds most to the area of the earcanal first bend cross-section (correlation coefficient $r = 0.533$, $p<0.001$). In addition, largest earcanals led to significant lower attenuation (often unsafe), than smaller earcanals for 4 of the 6 earplugs considered in the study. These results indicate that the EST (which is a simple and inexpensive tool easily deployable in the field) can be used as an earplug selection tool, and primarily to detect and protect people with extra-large earcanals who are most likely to be under-protected.

<u>Limitations:</u> The sample of participants is overwhelmingly male. The proportion of extra-large earcanals found in this sample may therefore not be representative of the actual proportion of extra-large earcanals in the Canadian population. In addition, there is a considerable variability in the cross-sectional areas of the first bend (FB) assessed with the earmold scanning method for the earcanals classified into groups M, L, and XL (with the EST). This variability induces an important overlap between the M, L, XL, and other categories, therefore, the EST does not identify all earcanals that are most likely to be underprotected.

The attenuation data in this study were obtained from a field attenuation estimation system during a training session. The actual field attenuation might lead to different results. In particular, earplugs are more difficult to insert into very small earcanals (Berger, 2001) and the field attenuation obtained for extra-small earcanals is likely to be lower than that for other earcanals due to insertion difficulties.

<u>Benefits for manufacturers and workplaces:</u> This paper evaluates how effectively a basic plastic ear gauge tool can determine the correct size of an earplug for a specific earcanal. It also aims to gather data for comparing the measurements obtained through the simple ear gauge method with a more accurate technique involving ear impressions. Moreover, the paper evaluates the ability of the simple ear gauge to estimate the likelihood that a particular earplug can fit an individual's earcanal based on the size of the canal. This could influence the worldwide standards and practices used to select earplugs and to train users of hearing protection. In particular the relationship between earplug attenuation and earcanal size assessed with the simple ear gauge could be used to recommend specific earplug designs for individuals with extra-large earcanals and to improve earplug selection based on single number attenuation derating scales. The results of this study also suggest that it may be useful to indicate on earplug packaging, in addition to the single number attenuation rating, the earcanal sizes for which the earplugs are best suited, such as it is commonly done already for other protective equipment (e.g. gloves, safety toe covers, and disposable respirator).

5.4 Analysis and objectification of the physical (dis)comfort of earplugs

Summary: This third paper aimed at identifying the physical and psychosocial characteristics of the components of the triad that have a significant influence on the main attributes of physical (dis)comfort induced by earplugs, in order to better understand physical comfort and the triad characteristics that influence it. To this purpose, the comfort of 7 different earplugs models was assessed in the field on 173 participants daily exposed to noise at work (27 females, 146 males) using questionnaires. Physical and psychosocial characteristics of the triad were assessed both using questionnaires and in laboratory via objective measurement of earplugs physical characteristics, and participants earcanals morphologies. Linear mixed-effects modeling enabled to identify characteristics of the triad that have an influence on the four main attributes of the physical dimension of comfort considered in the study. The statistical analyses showed that the following physical characteristics of the triad have an influence on the main physical discomfort attributes: the earplug radial force (force exerted by the earplug on a rigid cylindrical earcanal wall of 9 mm diameter), the extraction force (force required to extract the earplug inserted in a rigid cylindrical earcanal of 9 mm diameter) and the friction coefficient (ratio between the two earplug radial force and earplugs extraction force). As expected, high radial force and friction coefficient of earplugs are found to promote physical discomfort. More precisely, two roll-down foam earplugs with radial forces of 4.45 N and 4.70 N were found more comfortable than stemmed earplugs (push-to-fit foam and premolded earplugs) and a roll-down foam earplug characterized by a radial force of 6,50 N. Other characteristics of the triad were found to have an influence on earplugs physical discomfort. In particular, workers found their earplugs less physically uncomfortable if they were used to wear them before being involved in the study. In addition, persons with large circular earcanal entrance cross-section found their earplugs more physically annoying and painful. Analyses of the explanatory items showed that perception of the pushing in the ears feeling is governed by the habituation and the radial force and that irritation feeling is affected by the season (supposedly related to the work environment temperature), the radial force and the presence of a stem.

Limitations: As there is no better method to determine the optimal number of independent variables, all potentially predictive variables (i.e. characteristics of the triad) were included in the preliminary linear mixed-effect models. In this work, the number of characteristics of the triad both assessed subjectively using questionnaires and objectively in the laboratory is large. Even if, the number of participants is quite high (173), and participants tested 7 times different earplugs (which significantly increases the number of comfort assessments of earplugs), a methodology was developed to sort out the triad characteristics that influenced significantly the physical comfort of earplugs. Statistical analyses based on the characteristics of a single component of the triad did not take into account the effects of the characteristics of the other components of the triad.

The lack of information on climatic conditions by task and workstation prevented us from making comprehensive statistical analysis based on work environment characteristics. Indeed, temperature, which can cause participants to sweat and change the material properties of the earplugs, is strongly suspected to influence physical comfort but could not be tested here.

Future work: The (dis)comfort of earplugs is multidimensional. Acoustic, functional, and psychological dimensions of comfort were assessed in the field along with the physical dimensions of comfort, which is the focus of this paper. The same methodology used to analyze the physical dimension of comfort will be applied to other dimensions in order to gain a more complete picture of the characteristics of the triad that influence the multidimensional comfort of earplugs.

This work focused on disposable and reusable earplugs, but a similar methodology will be applied in a close future to the custom-molded earplugs that were also tested in the field in the framework of this project.

The physical properties of the earplug that significantly impact the physical discomfort of earplugs were objectively determined using preliminary "comfort testers" (in the study, comfort testers were the Blockwise machine and a setup to measure earplugs extraction force) that could be used by earplug manufacturers for comfort-based design. These comfort testers will be improved and become artificial earcanals with realistic mechanical properties and geometry representative of the clusters identified in the first paper. These earcanals may be instrumented to measure the radial force and extraction force of the prototype earplug. A test bench developed by a researcher at IRSST who is involved in the research team of our laboratory already allows for the measurement of the radial force of an earplug inserted into a rigid realistic synthetic earcanal in a localized region. At the same time, a master's student is working on developing a smart skin for ATF earcanal in order to sense the static mechanical pressure exerted by an earplug. However, the first prototypes are not yet mature enough to be used in this PhD project.

<u>Benefits for manufacturers and workplaces:</u> Relation between the characteristics of the person and environment components of the triad and the main attributes of physical comfort found in this study shall help occupational health preventionists to propose guidelines for the selection of comfortable earplugs adapted to the users and their work environment. As an example, when workers experience sensitivity to earplug-induced pain, preventionists may advise the use of earplugs with minimal radial force and a low friction coefficient. The results also offer valuable insights for manufacturers in designing earplugs with comfort in mind. Specifically, by utilizing innovative technologies like the Blockwise machine (originally designed for characterizing biomedical equipment) and comfort testers developed in our laboratory, manufacturers now have unprecedented opportunities to create comfort testers that can quickly assess the physical properties of earplugs. This assessment is crucial for predicting the level of physical discomfort that the earplugs may cause to the individuals they are intended to protect.

5.5 General conclusion

In this thesis, multiple studies were carried out to improve the effectiveness of passive earplugs by focusing on (1) the quality of the fit between the earplug and the earcanal to ensure proper attenuation and (2) the physical discomfort known as one of the main discomforts induced by earplugs and responsible of their misuse (and non-use).

More specifically, a method for clustering earcanals based on the attenuation provided by a variety of earplug designs was proposed. Clustering proposals will help in the design artificial ears that are representative of a given population. These artificial ears could be used to test and design earplugs adapted to a large portion of the population. In addition, the ability of a simple and inexpensive earcanal sizing tool (the 3M™ Eargage) to help in the earplugs selection was evaluated. It was demonstrated that this tool can detect individuals with extra-large earcanals who are most likely to be under protected. Finally, the characteristics of the triad (person/earplug/environment) that have a significant impact on the main attributes of physical (dis)comfort were identified. In particular, it was found that some physical characteristics of the earplugs (measured using dedicated "comfort testers") strongly influence earplugs physical discomfort. These results can be use to develop more realistic comfort testers dedicated to the design of comfortable earplugs.

Improved fit, comfort, and attenuation, potentially achieved through the methods developed in this thesis research, could benefit many who rely on earplugs to reduce their exposure to hazardous noise. For the future, we can hope that there will be earplugs adapted to everyone and to all work environments, generating comfort in all its complexity (physical, functional, acoustical and psychological) and that the earplugs selection will be made simple with dedicated tools and the target population identified on the packaging in addition to the attenuation performance indicator.

ANNEX I

PRELIMINARY ARTIFICIAL EARS

Earcanals clusters obtained in the first paper will be the base for the manufacturing of three artificial ears representative of each cluster. This work is in progress, and some preliminary results are briefly presented here. The 3 clusters barycenter were computed and the participant earcanal closest to each barycenter was chosen to be the earcanal representative of the cluster.

The geometries of each earcanal representative of the cluster were then numerically embedded inside a cylinder to be 3D printed (see figure A1.1). The shore hardness of the 3D-printed artificial ears was 40A. This is a little softer than the human cartilage and harder that the skin.

Attenuation measurements for all earplugs that were tested on participants were performed with these artificial ears prototypes using the 3M™ E-A-Rfit™ Dual-Ear Validation System. These attenuations were compared with the attenuations measured on participants. The ears were heated at 37°C during measurements.

Eight attenuation measurements were made for each given configuration of the artificial ear/earplug. As participants received a preliminary training, the insertion depth of earplugs were set between “deep” and “standard” during attenuation measurements on artificial ears (four measurements at a deep insertion and four measurements at a standard insertion).

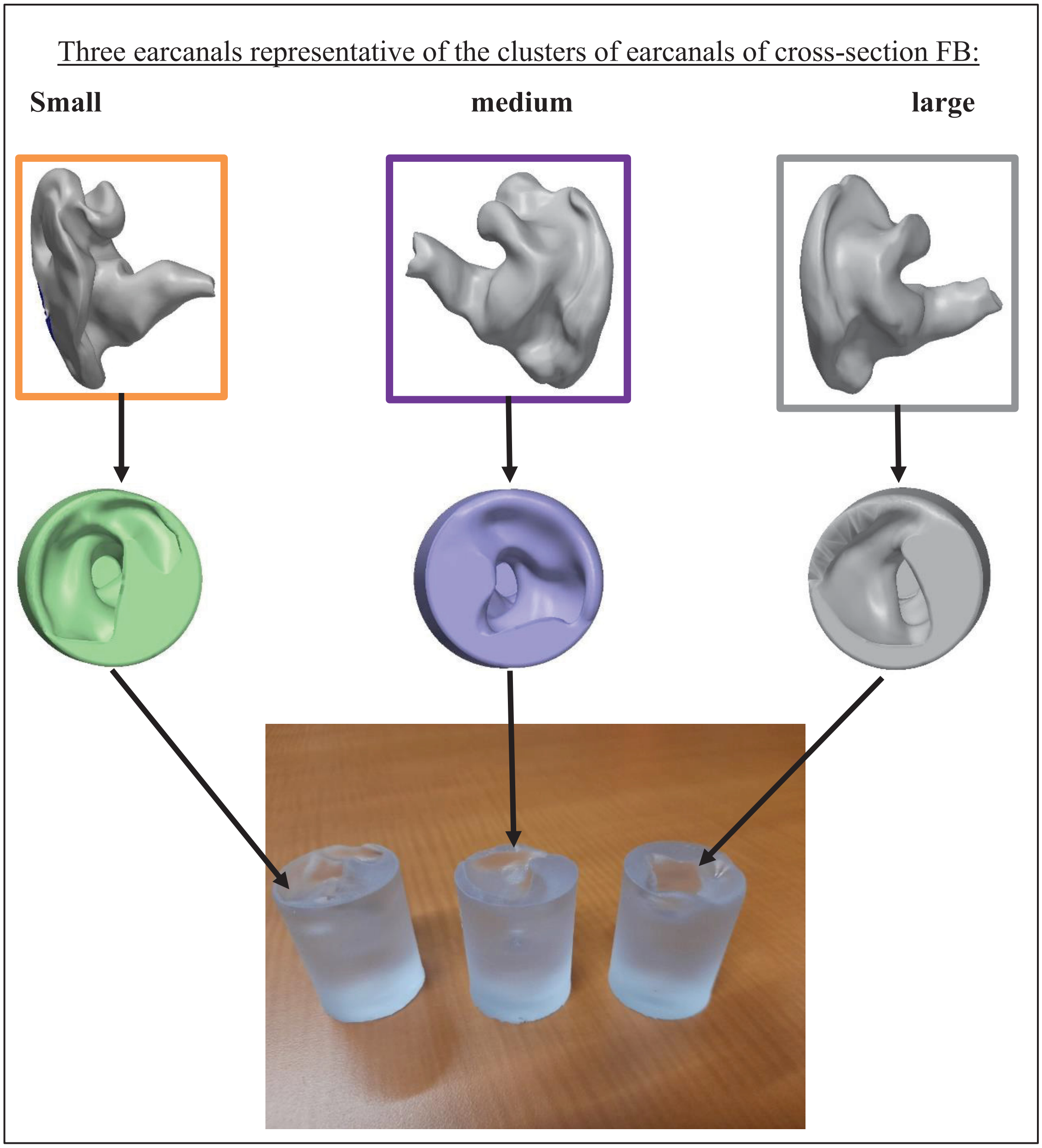

Figure-A I-1 Design of artificial ears representative of each cluster

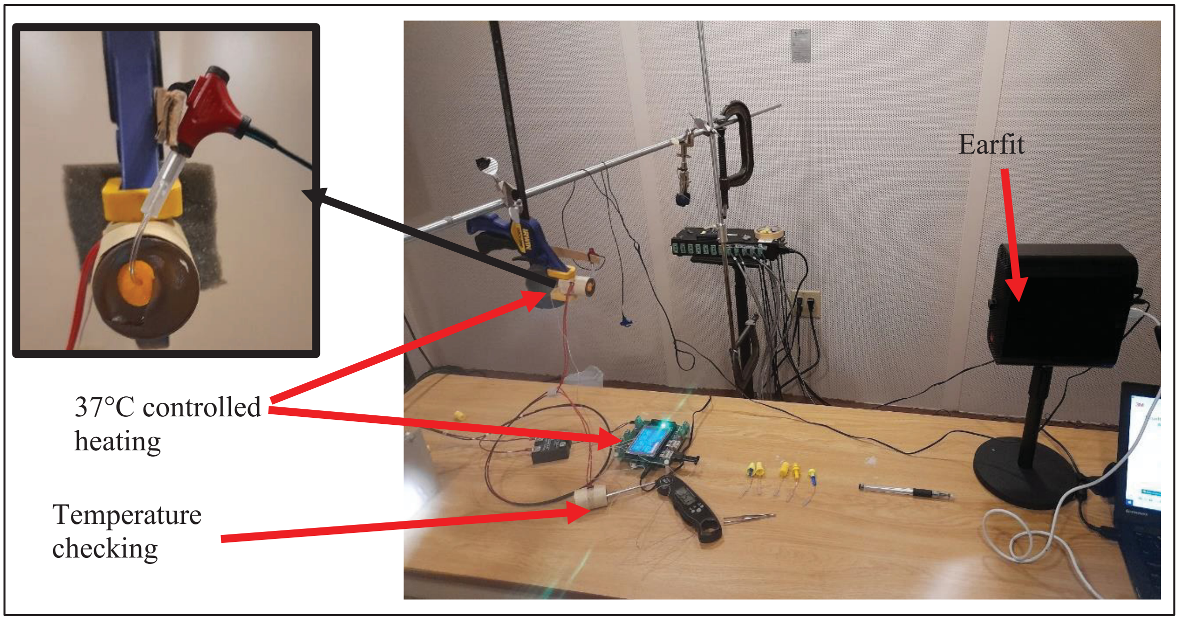

Figure-A I-2 Attenuation measurement setup

Measurement results are displayed in the Fig. A I-3 to A 1-8.

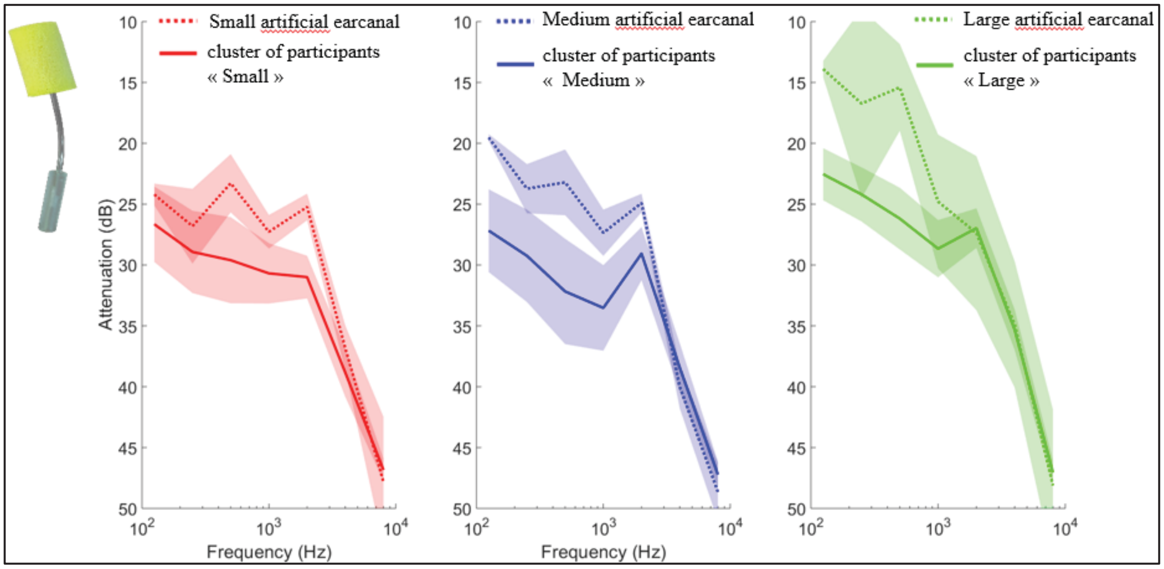

Figure-A I-3 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the classic foam earplug

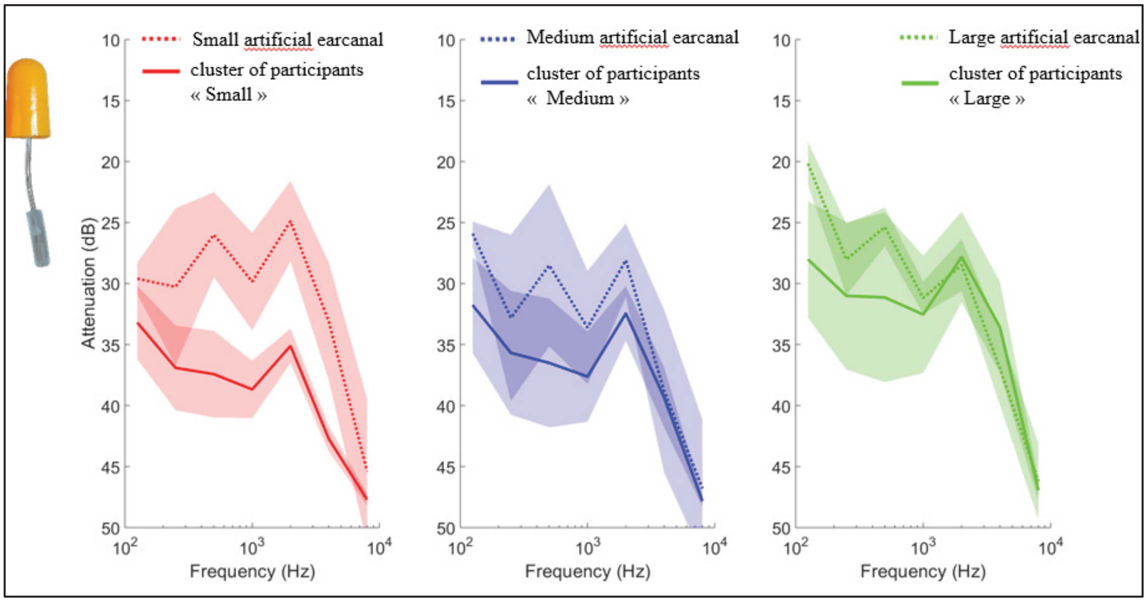

Figure-A I-4 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the 1100 foam earplug

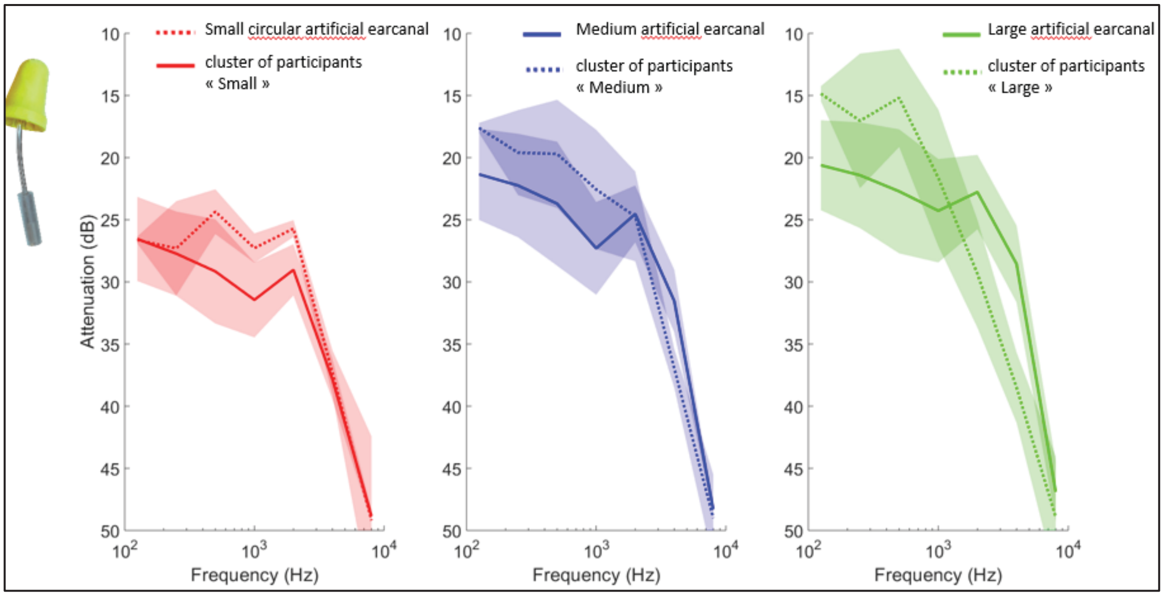

Figure-A I-5 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the E-Z-fit foam earplug

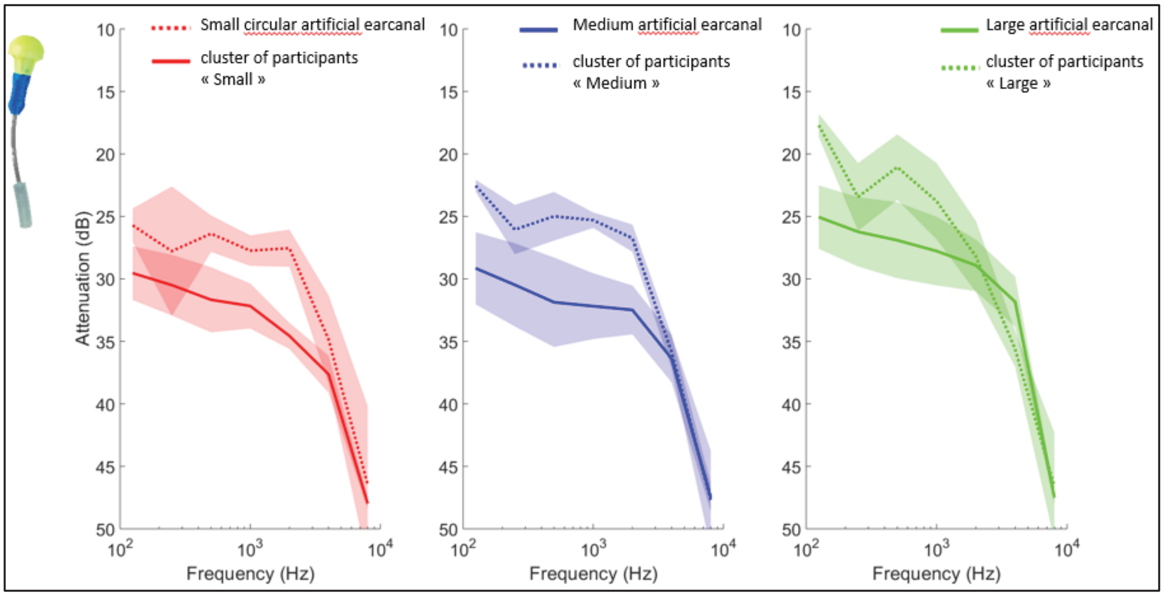

Figure-A I-6 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the push-ins earplug

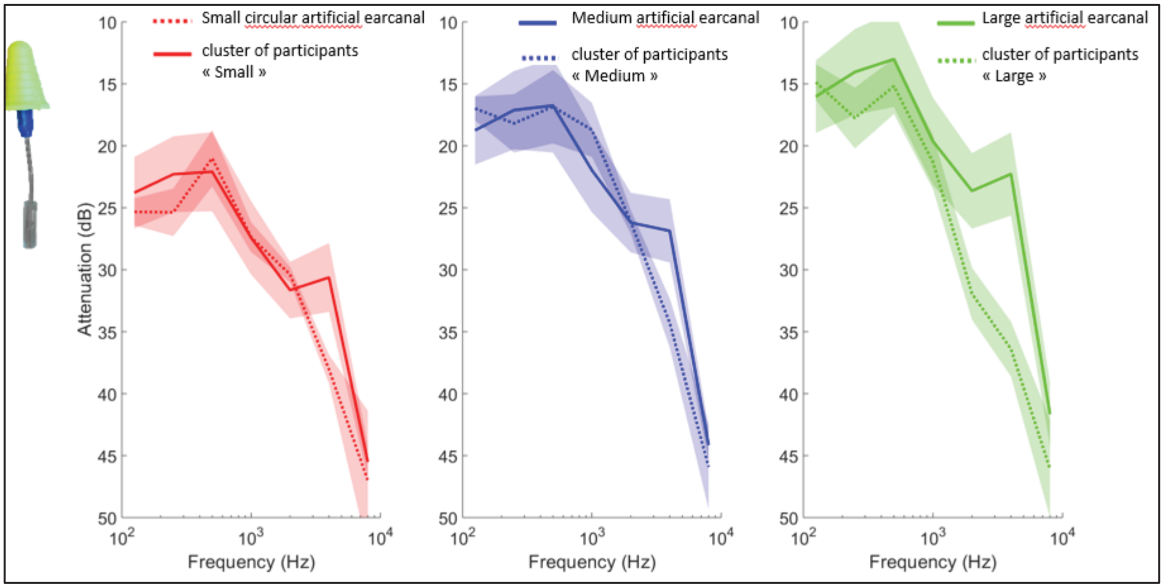

Figure-A I-7 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the push-ins-grip-rings

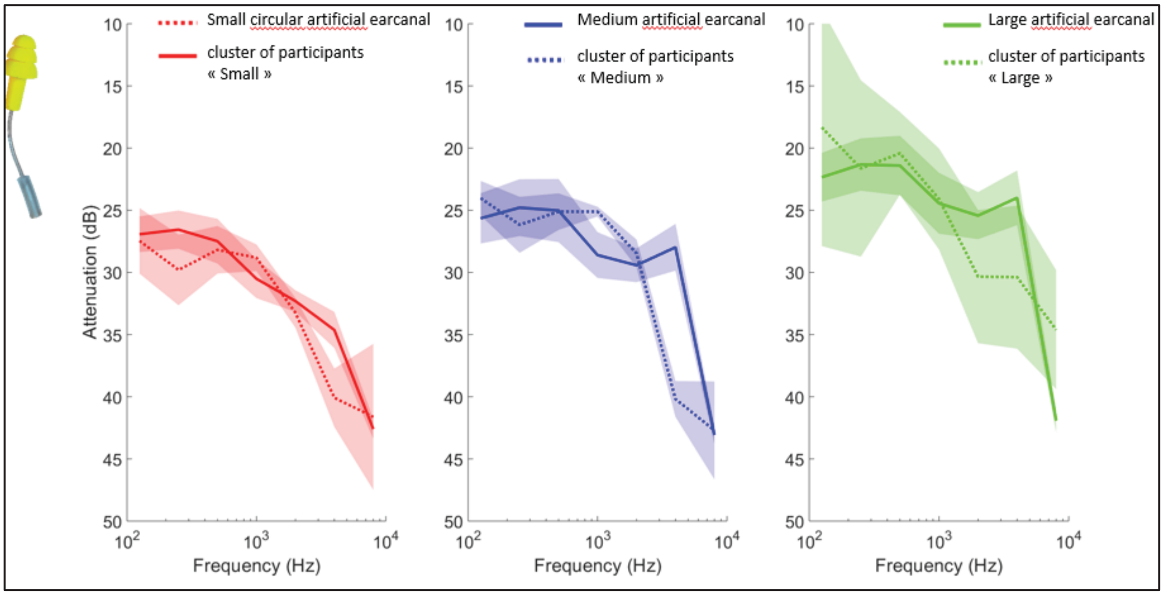

Figure-A I-8 Comparison of attenuation measurement between the three artificial ears and the three participant clusters for the premolded earplug

Attenuation measured on artificial ears does not fall in the 95% interval at all frequencies for all earplugs. Overall, the artificial ears underestimate the attenuation, probably because of their self-insertion loss, which is strongly suspected to be inferior to the self-insertion loss of the participant's heads. The artificial ears had a rigid eardrum which could also have induced differences between the measurements on participants and on the artificial ears

The participants head may have diffracted the soundwaves in a different manner that the artificial ears which are much smaller than a human head. This would have led to a difference in the measurement to the noise level measured by the external microphone.

Also, the experimental setup included a long rod (see Fig. A1.2) whose vibratory behavior could have perturbed the measurements.

Nevertheless, the attenuations measured on the artificial ears follow the same trend as on the participants: the larger the cross section of the first bend, the lower the attenuation. The comparisons between attenuation of participants and artificial ears are particularly encouraging for the E-Z-fit foam, push-ins-grip-rings and premolded earplugs (Fig. A I-.5, Fig. A I-.7, Fig. A I-8).

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