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Assessing the comfort of earplugs: development and validation of the French version of the COPROD questionnaire

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Abstract

Earplugs are a common form of protection for workers exposed to hazardous noise levels. Their comfort directly impacts the effective protection by influencing their consistent and correct use. Nevertheless, comfort definition may vary according to the studies. Thus, a previous review of the literature has shown that to improve our understanding of perceived comfort and to reduce measurement variability, it is advisable to consider comfort through a multidimensional construct (physical, acoustical, functional and psychological). On this basis, the COPROD questionnaire was developed. It is intended for people working in noisy environments. Nine earplug models were evaluated by 118 participants over a six-week period. This paper presents the successive analyses that were used to validate the structure of the questionnaire and confirm the relevance of the proposed dimensions and of the addressed items. First results suggest a preference for custom molded earplugs.

Keywords

Ergonomics tools and methods; earplugs; comfort; questionnaire; sound and noise

Practitioner summary

Earplugs comfort conditions the hearing protection of the users. As the definition of comfort can vary between studies, the COPROD questionnaire was developed to jointly evaluate all its dimensions. Nine earplugs models were evaluated by 118 participants during six weeks. This paper presents the validation process of the questionnaire.

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1. Introduction

Many workers are exposed to noise levels that are potentially dangerous for their hearing. The risk of hearing loss depends on the level and on the duration of the exposure. In addition to collective protective solutions, hearing protection devices (HPD), and more specifically earplugs, remains in very widespread use. Currently, because of their protective function, earplugs are still exclusively characterized by the acoustic attenuation they provide. However, comfort preconditions the effectiveness of the protection, through the continuity and quality of its use. Thus, the choice of a model should be conditioned as much by economic, practical, and qualitative parameters as by the comfort it provides.

As formulated in [DeLooze:2003], comfort is "a construct of a subjectively defined personal nature". Recent literature reviews [Terroir:2017] [Doutres:2019] [Doutres:2020] showed that this complex and multidimensional construct can vary from one study to another. Consequently, while questionnaires dedicated to the evaluation of comfort have been developed for decades (e.g. [Sweetland:1983] [Epps:1985] [Park:1991] [Davis:2016]), the lack of a consensus definition of comfort implies that most studies consider comfort within a limited and variable set of parameters. This raises two problems: (a) it makes it difficult to compare the results of different studies; (b) the results depend on the initial assumptions about the concept of comfort. In fact, only a few studies consider HPD comfort in a more global perspective ([Lhuede:1980] [Brown-Rothwell:1986] [Hsu:2004] [Arezes:2008] [Goncalves:2015]). However, even these studies do not address every parameters that could have an impact on comfort. In order to improve knowledge about comfort of earplugs, to help in the selection of protection and to progress towards a definitive definition, it is therefore necessary "to use exhaustive and valid questionnaires in order to grasp the complexity of this multidimensional construct" [Doutres:2020]. The proposal of such a questionnaire would constitute an interesting step forward in this field of research. Indeed, even the few studies that consider HPD comfort in a more global perspective do not address every parameters that could have a more or less important impact on comfort [Doutres:2019].

Based on the previous observations, an international collaboration was initiated in 2017 [Doutres:2018] to address the issue of earplug comfort through a novel comprehensive approach [Terroir:2017] [Doutres:2019] [Doutres:2020]. Following this preliminary work, different parameters of comfort were identified and classified according to several dimensions. The COPROD (**CO**nfort des **PRO**tections au**D**itives / **CO**mfort of hearing **PRO**tection **D**evices) questionnaire was then designed to collect participants' feelings in real condition of use. The aim of this paper is to present the French version of this questionnaire (translated into English for this paper) and the successive validation steps.

2. Definition of comfort

There is considerable variability in the literature regarding the definition of earplug comfort and the parameters involved in its assessment [Doutres:2020]. To decrease comfort measurement variability and encompass the complexity of such construct, the multidimensional definition of comfort described in [Terroir:2017] [Doutres:2019] is used. The four dimensions are briefly recalled.

"Physical comfort" is related to physical annoyance and pain. It is associated with mechanical and thermal interactions between the earcanal and the earplug (e.g. sensations of irritation in the earcanal, earplug mechanical pressure against the earcanal walls, heat, etc.).

“Functional comfort” addresses the feelings of protection and overprotection, intuitiveness, ease, speed of use and number of gestures required to fit and remove earplugs, as well as the ease of cleaning, maintaining in position and utility. It has been broken down into several criteria based on the concept of acceptability developed by Nielsen [Nielsen:1993]: usability (“the question of how well users can use that functionality”) and utility (“the question of whether the functionality of the system in principle can do what is needed”) . Items related to the perceived impact of the earplug use on work have also been included.

“Acoustic comfort” is related on the one hand to the good perception of useful sounds (e.g. voice, alarms, machines) and to their localization, and on the other hand to the annoyance related to the occlusion effect. The latter can lead to unpleasant sensations through the distortion of the user's own voice and an increased perception of physiological noises. Moreover, both can be affected by the annoyance due to the acoustic reduction of noise.

“Psychological comfort” reflects the well-being related to the use of earplugs. Although rarely addressed in studies dedicated to the comfort of earplugs, it cannot a priori be ignored. It is linked to the various feelings associated with the earplugs use (trust, habituation, feeling of isolation...).

3. Methods

3.1 Designing the French COPROD questionnaire

The questionnaire was designed by a multidisciplinary working group of ergonomists, engineers, psychologists and acousticians. In order to overcome the problem of the variability of the parameters considered in the comfort assessment (cf. paragraph 1), this questionnaire brings together, for the very first time, all the items of the previous questionnaires dedicated to the comfort of earplugs or earmuffs (e.g. [Casali:1987] [Hsu:2004] [Brangier:2003] [Lusk:1994] [Arezes:2008] [Ivergård:1976] [Epps:1985] [Sviech:2013] [Park:1992] [Brown-Rothwell:1986]) (for more details, see [Doutres:2019]). Moreover, new items were added (mainly for the psychological comfort dimension) to cover all comfort attributes and meet the specific objectives of this research project. The questionnaire was divided into sections corresponding to the proposed four dimensions of comfort. It mostly includes 5-point *Likert*-type response scales (i.e. *strongly disagree (1); disagree (2); moderately agree (3); agree (4); strongly agree (5)*) [Likert:1932]. Differential semantic scales [Osgood:1962] were considered too. The questionnaire was constructed to be suitable for workers using earplugs in any noisy work environment, regardless of the sound level. As far as possible, the items were written in an affirmative and positive way to measure the comfort, and not the discomfort. Nevertheless, some aspects, such as annoyances or pain, contributing to comfort by their absence were assessed using negative wordings referring to the “discomfort”.

3.2 Research protocol

Nine models of earplugs belonging to three different families were tested: roll-down foam (A_1, A_2, A_3), premolded (B_1, B_2, B_3) and custom molded (C_1, C_2, C_3). Roll-down foam earplugs are made of compressible foam. They are generally cylindrical. The earplug is compressed between the user's fingers and inserted into the earcanal. It then gradually returns to its original shape, providing acoustic sealing. Premolded earplugs are made of elastic materials that deform much less than those used in the previous family. These earplugs consist of a flexible stem covered with one or more flanges of various shapes, which provide acoustic sealing. Custom molded earplugs are made of silicone or acrylic and based on the impression of the person's earcanal.

For 6 weeks, the participants tested, under real working conditions, one model per family according to a X_i-Y_j-Z_k-X_i-Y_j-Z_k sequence (where [X; Y; Z] ∈ [A; B; C] and [i; j; k] ∈ [1; 2; 3]). In order to be able to consider an overall ranking and to conduct inter-family and intra-family analyses, the experimental design presented in Table 1 was chosen, with each participant testing one configuration. The following constraints were taken into consideration: random distribution among participants; the model tested during the first week could not be of the same family as the model usually worn (in order to limit the bias related to usage habits); for each participant, the earplugs were tested in a random order (after taking into account the previous constraint).

Table 1

Prior to the test campaign, participants were reminded of the study objectives, protocol, and good practices. To remain in a realistic context of use, the fit was performed by the user (after prior training) and a single fit check was performed before the tests began. The questionnaire was completed on a weekly basis. Questions about socio-demographic characteristics, attitude and beliefs regarding earplugs, and working environment were included in a preliminary *User profile* questionnaire and asked before the first week. In addition to the Likert and semantic scales (cf. paragraph 3.1), multiple-choice scales were used for this questionnaire. A pre-test was conducted using a protocol similar to the one later deployed on a larger scale, but only for configuration 1 of Table 1. The inclusion criteria for participants were that they were volunteers, did not have hearing problems and were exposed to noise at work.

3.3 Validation protocol

A validation protocol was defined [DeKetele:1993] [Pierrette:2015] [Bouletreau:1999] [Caron:1999] [Corbière:2016]. Apparent validity and content validity of the questionnaire were first assessed through the review by an expert group of ergonomists and occupational psychologists external to the study. After updating the questionnaire, an in-situ pretest was conducted with a small number of participants to assess the internal consistency of the questionnaire and to highlight any imperfections of the protocol in real-life situation. The internal consistency was checked through Cronbach's alpha calculations ($\alpha > 0.9$: very high consistency; $\alpha > 0.8$: high; $\alpha > 0.7$: acceptable) [Cronbach:1951] [Moret:1993]. The questionnaire was again updated considering the previous observations and in situ tests were carried out to collect data. The internal consistency and the construct validity were then jointly achieved. The construct validity was checked through Spearman correlations [Corder:2014] or structural equation modeling (SEM). Indeed, the questionnaire is based on assumptions that indicators would fit into certain latent variables. Latent variables are predictive (this predictive quality will next be identified by the *PRED_* prefix) and consist of a combination of several observed items. A Confirmatory Factor Analysis (CFA within SEM) was undertaken to test whether the collected data fitted to the hypothesized questionnaire structure. SEM analysis was done following a process like the one applied in [Cohidon:2019]. The goodness of fit (GOF) of the CFA was assessed using three parameters: the root mean square error of approximation (RMSEA - values greater than 0.10 indicate a poor model [Hu:1999]); the comparison fit index (CFI - values greater than 0.90 suggest a reasonably good fit and greater than 0.95 suggest a good fit); the standardized root mean square residual (SRMR - values lower than 0.08 suggests an acceptable model [Hu:1999]). In addition to the statistical significance of the parameters, the estimated standardized coefficients associated with each item or covariance indicate the sign and the strength of the relationships (weak (<0.2); moderate (0.2 - 0.5); strong (>0.5)). The sensitivity of the questionnaire was next analyzed through descriptive analyses and ordered logistic regressions to estimate the ability of the questionnaire to discriminate earplug models based on reported overall comfort. Finally, the test-retest reliability was checked through correlation calculation to verify the stability of the results over time (for similar conditions).

4. Results

4.1 Apparent validity, content validity and protocol pre-test

Following the review of the first version (v1) of the COPROD questionnaire (40 items) by the group of experts, some items were removed or added, and some rephrasing was undertaken. Examples were also included to facilitate understanding, reminders about the response scales were added throughout the questionnaire and some important words were underlined or capitalized to help distinguish between related items.

Based on the previous observations, a second version (v2) of the questionnaire (40 items) was developed and pre-tested (see section 3.1). Seventeen men working in the same French engine manufacturing company participated. The median age was 31 years (SD = 9.3). Seniority in the company was more than five years for ten participants and less than one year for one participant. Occupational activities required verbal communication. Most of the volunteers (13) were used to wear earplugs for several years. Except for the psychological dimension, high or very high internal consistency was found for each dimension ($0.81 \leq \alpha \leq 0.97$). Internal consistency for the psychological dimension was just acceptable (α = 0.71). Consequently, the section was restructured (an item was deleted and a reorganization was undertaken). The internal consistency was then conclusive (α = 0.91). Following discussions with the participants and the analysis of their responses, one item related to the trust was added. Concerning acoustic comfort, the analyses showed that it was more relevant to distinguish items according to two groups: the first was associated with good perception of useful signals, the second was associated with annoyance due to the occlusion effect. No problem was identified concerning completion time, format or difficulty of interpretation, and the content, wording, structure, and response scales were approved.

Finally, the updated questionnaire (v3) consists of 31 items, grouped into sections corresponding to the proposed dimensions of comfort. The structure and content of the questionnaire are displayed in Table 2. Each section opens with one or two *general* items representative of the dimension. These items are followed by sub-dimensions or by *explanatory* items detailing this dimension. Depending on the content, the sub-dimensions are described by one general sub-item followed by explanatory sub-items or by a group of explanatory sub-items. In the following, unless otherwise indicated, the response scales are 5-point *Likert*-scales.

Table 2

4.2 In situ tests and COPROD v3 data analyses

4.2.1 Characteristics of the sample

118 workers from four French companies (agri-food sector, automobile assembly plant, construction and public work, tires and car maintenance services) took part in this study. Information from the *User profile* preliminary questionnaire (see section 3.2) is given in Table 3 to Table 5. The imbalance between the number of male and female participants is due to the company sectors that agreed to participate in the study. All occupations exposed to noise were included in the selection of participants. Most respondents (92%) are experienced earplugs users (from several months to several years). The noise exposure appears to be due to various types of sound sources (continuous, discontinuous, impact noise). Activities require the need to speak, to hear warning signals, to rely on certain sounds to carry out the work or to make repeated head movements.

Table 3

Table 4

Table 5

4.2.2 Construct validity and internal consistency

In order to check the construct validity of the questionnaire and to propose a latent variable which will enable to predict the overall comfort, a SEM is undertaken (cf. section 3.3). For each dimension, a CFA is carried out and a corresponding factor score is generated in order to be subsequently integrated into the final SEM. Internal consistency is addressed in parallel in order to check the homogeneity of the explanatory items. Due to the structure of the questionnaire and to the nature of the analyses, for sub-dimensions hierarchically structured via a general sub-item followed by at least two relevant explanatory sub-items, a SEM is considered. In other cases, correlations are performed. Analyses are detailed only for the functional dimension of comfort. The results for the other dimensions are summarized next.

Functional comfort

Functional comfort is described according to several sub-dimensions: effectiveness, ease of use, utility, and impact on work. Within the questionnaire, the first two are considered through one general sub-item followed by several explanatory sub-items, the next two are considered via a group of items (cf. Table 2).

Effectiveness

Effectiveness is first addressed through the general sub-item 8. Explanatory sub-items 9a and 9b consider feelings of protection and overprotection. A preliminary analysis shows a low correlation (and consequently low internal consistency) between items 9a and 9b (r_s = -0.48; $P < 10^{-3}$). Thus, while effectiveness is highly correlated to the feeling of protection (r_s = 0.76; P

< 10^{-3}), the correlation with the feeling of overprotection is much lower (r_s = -0.39; $P < 10^{-3}$). Consequently, item 9b appears inconsistent and effectiveness can only be described by items 8 or 9a.

Ease of use

Following the general sub-item 10, explanatory sub-items deal with fit (item 11), maintaining in position (item 12), removal (item 13), and cleaning (item 14). The very high internal consistency (α = 0.91) shows that these explanatory sub-items describe a same notion. A CFA shows that all explanatory sub-items are statistically significantly ($P < 10^{-3}$) related to the representative latent variable *PRED_EaseOfUSe*. Nevertheless, the fit of this model is unsatisfactory and very high covariance values are observed between some items. On this basis, maintaining in position and cleaning items are excluded and the four items related to the removal are regrouped using a factor analysis (*Removal*), as well as the two items related to the ease and speed of fit (*FitEase&Speed*). A CFA involving the new set of items (11a, *FitEase&Speed*, 11d, *Removal*) is then done. The GOF is conclusive and coefficients range from 0.55 to 0.96 (see Table 6). Consequently, the *EaseOfUse* factor score representative of the ease of use is generated. The strong correlation (0.82) existing between the latter and the general sub-item 10 confirms the relevance of this score.

Table 6

Utility

The two items 15a and 15b describing the feeling of utility are highly correlated (r_s = 0.90; $P < 10^{-3}$). They therefore describe the same notion and a representative factor score *Utility* is generated.

Impact on work

The impact of earplugs on work performance is addressed through items 16a to 16c (5-point differential semantic scale). Items have a very high internal consistency (α = 0.94), as well as high correlation values ($0.77 \le r_s \le 0.91$; $P < 10^{-3}$). They therefore describe the same dimension and a representative factor score *ImpactOnWork* is generated.

Overall functional comfort

Since functional comfort is considered through four sub-dimensions, internal consistency is calculated for items or factor scores representative of each sub-dimension: item 8, *EaseOfUse*, *Utility* and *ImpactOnWork*. The high internal consistency (α = 0.82) confirms that they describe a similar notion. The CFA shows that these items are statistically significantly related to the latent variable *PRED_Functional_Comfort,* with a conclusive GOF (see Table 7). The correlation between the representative factor score *Functional_Comfort* and the general item 7 being high (0.80), this score seems relevant.

Table 7

Physical, acoustic and psychological comfort

According to a process similar to the one detailed for functional comfort, the other comfort dimensions are analyzed. High to very high internal consistency (0.81 ≤ α ≤ 0.94) is systematically found for groups of explanatory items (see Table 2). In order to obtain conclusive GOF, exclusions or groupings of items were performed. Since for the physical dimension, the two general items (related to physical annoyance and pain) are described by the same explanatory items (cf. Table 2), only one factor score is generated to represent this dimension. Moreover, because of the structure of the questionnaire and of the pretest observations, the acoustic dimension is considered through two factor scores. Finally, successive CFA enable to generate factor scores representative of each dimension (*Physical_Comfort*, *Acoustic_Comfort_Perception*, *Acoustic_Comfort_Occlusion, Psychological_Comfort*). Results are summarized in Table 8 to Table 10.

Table 8

Table 9

Table 10

Overall comfort & structural equation final model

Since the notion of comfort has been considered through four dimensions, internal consistency is calculated for the factor scores representative of each dimension of comfort (*Physical_Comfort*, *Functional_Comfort*, *Acoustic_Comfort_Perception*, *Acoustic_Comfort_Occlusion* and *Psychological_Comfort*). The value being high (α = 0.84), these factor scores describe a similar notion. In order to define the latent variable representative of the overall comfort, a CFA is performed. All factor scores are statistically significantly related to the latent variable *PRED_Overall_Comfort* ($P < 10^{-3}$). In addition, the covariances between the *Functional_Comfort* and *Psychological_Comfort* scores, as well as between the *Acoustic_Comfort_Perception* and *Acoustic_Comfort_Occlusion* ones are strong. The high correlation value (r_s = 0.88; $P < 10^{-3}$) existing between the latent variable *PRED_Overall_Comfort* and item 31 confirms the relevance of this variable for predicting the overall comfort on the basis of assessments of the different dimensions of comfort.

Univariate analyses are next conducted for each of the predictive items described in Table 3 to Table 5. Items for which statistically significant ($P < 0.05$) relationships are observed (daily duration of use, level of education, earplugs use experience, reason of earplugs use and earplugs family) are then incorporated into the final SEM shown in Figure 1. Adequate GOF values (RMSEA = 0.087; CFI = 0.927; SRMR = 0.049) are found for this model.

Figure 1

4.2.3 Sensitivity in relation to overall comfort

Overall comfort ratings are analyzed using descriptive analyses and ordered logistic regressions. The earplug models are thus ranked (in descending order of comfort) according to the typologies described in Table 11 (the distribution of responses is also included). Earplugs within a given typology do not exhibit statistically significant differences at a 95% confidence level.

Table 11

4.2.4 Test-retest reliability

As the test protocol involves two successive series of X-Y-Z tests spaced three weeks apart (cf. section 3.2), the test-retest reliability is considered by assessing the impact of these series on the evaluations. For each participant, the overall comfort is averaged per series. The strong correlation (0.74) between the two series shows a satisfying reliability in the assessment of the overall comfort. Similar analyses are carried out for each dimension of comfort. Correlations values between 0.63 and 0.79 show satisfying reliability for each dimension.

5. Discussion and conclusions

The process described above demonstrates the validity of the French COPROD questionnaire for assessing the comfort of earplugs. Apparent validity and content validity have been successfully verified through the review by ergonomists and occupational psychologists external to the study. Following an in situ pre-test step, the questionnaire was deployed on site to collect data. Sensitivity analyses showed that the questionnaire makes it possible to discriminate different models of earplugs according to their overall comfort. Reliability is also found satisfying for the overall comfort, as well as for each comfort dimension. SEM analyses showed the validity of the questionnaire to predict the feeling of comfort via a single latent variable *PRED_Overall_Comfort*. This suggests a homogeneity of the results independently of the participants or of the tested models of earplugs. Moreover, internal consistency is found to be high to very high for every groups of explanatory items related to a given dimension or sub-dimension. This proves a high degree of homogeneity for these items and suggests that the questionnaire is structured in a relevant way. Finally, the high correlation between the latent variable *PRED_Overall_Comfort* and the final item 31 (rating of the overall comfort) highlights the relevance of this latent variable in predicting overall comfort on the basis of other measured items and predictors.

The latent variable representing the overall comfort *PRED_Overall_Comfort* is statistically significantly related to the factor scores describing physical, functional, acoustic and psychological dimensions. Nevertheless, the final SEM (Figure 1) suggests a strong link of the functional and psychological dimensions with the overall comfort (coefficient values of 0.81 and 0.96), compared to the physical and acoustic ones (coefficient values ranging from 0.49 to 0.57). Moreover, there is a statistically significant covariance value between the latent variables associated with the occlusion effect and with the perception of useful sounds. Although these concepts are distinct, this highlights that they do represent both sides of the same dimension or that they are not clearly distinguished by the participants. These results may be specific to the present data. However, this seems unlikely given the reasonably high number of participants included with a wide range of characteristics. Nevertheless, while in past studies, acoustical and psychological dimensions have often been neglected in comparison to the physical and functional ones, their inclusion within a global consideration of comfort highlights their impact on perceived comfort. Particularly, functional and psychological dimensions appear necessary for a better estimation of comfort, to help in the selection of earplug models in the workplace and to guide the development of future earplugs. This obviously does not imply ignoring the acoustic and physical dimensions, but emphasizes the importance of these dimensions on the prediction of the overall feeling.

As with the overall comfort, the relevance of the items was checked for each dimension. While both irritation and mechanical pressure are significantly related to physical comfort, there is a predominance of irritation-related items over the feeling of physical comfort. Friction therefore seems to play an important role in physical comfort. Although the hypothesis of a parallel between physical sensation and the characteristics of the earplugs was made during the development of the questionnaires by including items related to the size, roughness and softness, this is not confirmed by the evaluations. Given the disparities in the earplug models tested, this suggests that these characteristics are not relevant or that people have difficulty assessing them. Therefore, these items may not be relevant to a subjective assessment of comfort. Nevertheless, this information may be useful for manufacturers to compare subjective and objective data representative of the physical properties of the earplugs and to improve their product quality.

The functional comfort is well described through the notions of effectiveness, ease of use, utility and impact on work. While overprotection does not seem relevant, both effectiveness and the feeling of protection are representative of the same characteristic. The ease of use is very strongly associated with the fit items, those associated with removal being secondary. In addition, the participants do not seem to distinguish the utility of the earplugs either because of their work environment (item 15a) or their activities (item 15b). This is consistent with the fact that environment and activities are necessarily linked. A similar observation applies to the items dedicated to the impact of earplugs on concentration, productivity and quality of work. If a distinction between these items was initially made, it may not be justified in the context of the present questionnaire.

Acoustic comfort is considered according to two aspects: good perception of useful sounds and annoyance related to the occlusion effect. For both notions, explanatory items are statistically significantly related to the associated general item. Nevertheless, the grouping of items dedicated to the perception of sounds other than speech was necessary to improve the GOF of the model. Even though the items do not have significant covariance values, the grouping was performed on a conceptual basis. Thus, even if the participants distinguish the feelings associated with each type of sound, a grouped score appears more relevant in the predictive framework of the analyses presented in this paper. The occlusion effect is also well represented by the items included in the questionnaire.

Psychological comfort is described in a relevant manner by all the explanatory items. Nevertheless, the four items associated with semantic scales representative of emotions (*angry vs. calm*; *worried vs. confident*; *tense vs. relaxed*; *oppressed vs. free*) show large covariance values. Either the differences in meaning are not well perceived, or these emotions are all moving in the same direction. In either case, a single item may be able to represent these emotions. All other aspects (satisfaction, isolation, trust, habituation, response to needs and possible reuse) appear to be strongly related to the latent variable representing the psychological dimension of comfort. This makes it possible to describe and predict the well-being associated with the use of earplugs.

For each dimension, groupings or exclusions of items were necessary to improve the GOF of the SEM. Some items therefore seem irrelevant, redundant or, from the participants' point of view, correspond to the same concept. Thus, a simplification of the questionnaire could lighten the protocol without reducing the collected information.

Additionally, the use of custom molded earplugs appears to be the first positive predictor of comfort, associated with greater overall comfort. This is consistent with past studies that have found custom molded earplugs to be preferred to roll-down foam ones [Marshall:2016] [Neitzel:2006]. Their use should therefore be favored when conditions allow it. These conclusions apply to a lesser extent to premolded models. This suggests a hierarchy of custom molded, premolded and roll-down foam earplug families in descending order of comfort. This is consistent with the hierarchy found for the sensitivity analyses. The second positive predictor of comfort is the daily duration of use. A continuous use of the earplugs implies a greater perceived comfort. This is consistent with the behavioral phenomenon of acclimatization that is sometimes found in the literature and which parallels the rate of use and a higher comfort [Doutres:2020]. Conversely, the level of education emerges as a negative predictor of comfort. Thus, a higher education level is associated with a lower feeling of comfort. Several hypotheses can be raised: a demand correlated to the level of education, a different understanding of the questionnaires, or requirements according to the activities required with the position. Within the final model, overall comfort is not statistically significantly correlated with experience (P = 0.13) or reason for using earplugs (P = 0.06). Nevertheless, the fact that less comfort may be associated with more experience could be due to higher expectations or demands. In addition, voluntary use could be associated with a higher feeling of comfort (inversely to a use imposed by hierarchy).

From a practical point of view, this questionnaire will be useful for both companies to help them choose the most suitable earplugs for their employees and earplugs manufacturers to evaluate and improve their products. At this point, it remains necessary to keep in mind that the purpose of the questionnaire is to assess comfort and not to predict usage patterns. Indeed, comfort is only one of the elements allowing to predict and favor the use and therefore the effective protection of the users. Thus, in the future, the notion of comfort should be integrated into a more global concept of earplug use. It might also have been interesting to compare these results with those of previously developed questionnaires. Nevertheless, the questionnaire presented in this document, although based on an exhaustive review of the literature, is not a compilation of several pre-existing questionnaires but a design based on a new architecture. Therefore, the comparison with previous questionnaires could be irrelevant.

One of the limitations of the previous analyses is related to the protocol. Even though the reliability of the questionnaire was found satisfying, it is impossible to know whether, in the long term, comfort evolves or not. A second limitation is related to the collected data. These are based on a given corpus of earplugs for a specific panel of participants, corresponding to only a small sample of the type of activities/environments requiring the use of earplugs. Moreover, most participants (59%) usually use custom molded earplugs. A habit effect could therefore affect the evaluations and the observed hierarchy by family. Thus, now that the questionnaire is validated, it would be relevant to continue this survey with more models of earplugs and more types of companies in order to deepen our knowledge of the processes involved in the feeling of comfort.

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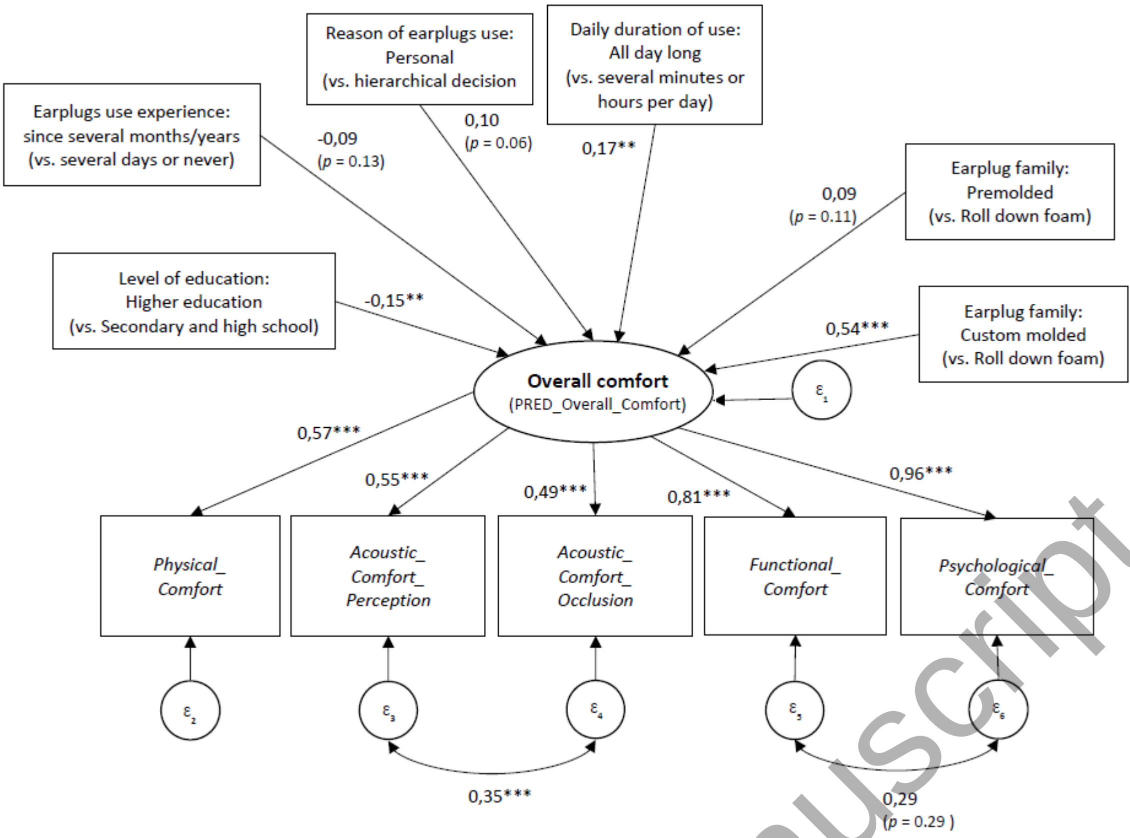

Figure 1 caption: Structural equation model for the PRED_Overall_Comfort*.*
Coefficient: < 0.2: weak association; 0.2-0.5: moderate association; > 0.5: strong association.
**: 0.05 < P < 0.01 / **: 0.01 < P < 0.001 / ***: P ≤ 0.001.*

Figure 1 Alt-text: Diagram of the relationship between the latent variable PRED_Overall_Comfort*, the factor scores representative of each dimension of comfort and the following predictive items : daily duration of use, level of education, earplugs use experience, reason of earplugs use and earplugs family.*

Table 1. Selected test configurations regarding the distribution of earplugs among participants.

	Roll-down foam			Premolded			Custom molded		
	A_1	A_2	A_3	B_1	B_2	B_3	C_1	C_2	C_3
Configuration 1	X			X			X		
Configuration 2			X		X		X		
Configuration 3		X				X	X		
Configuration 4			X	X				X	
Configuration 5		X			X			X	
Configuration 6	X					X		X	
Configuration 7		X		X					X
Configuration 8	X				X				X
Configuration 9			X			X			X

Table 2. Structure and items of the COPROD questionnaire. Differential semantic scales are used for items 6a, 6b, 6c, 16a, 16b, 16c, 27a, 27b, 27c, 27d and 31. For all other items, the response scales are 5-point Likert-*scales.*

PHYSICAL COMFORT		
General items	**Explanatory items**	
1a. Overall, these earplugs generate physical annoyance. **1b.** Overall, these earplugs generate pain.	**2.** You get the feeling that these earplugs are pressing on your earcanal. You feel a sensation of irritation: **3.** when you INSERT these earplugs; **4.** WHILE you are wearing these earplugs; **5.** when you REMOVE these earplugs. **6.** These earplugs seem to you: **a.** from *Too soft* (1) to *Too hard* (5); **b.** from *Too smooth* (1) to *Too rough* (5); **c.** from *Too small* (1) to *Too large* (5).	
FUNCTIONAL COMFORT		
General item		
	EFFECTIVENESS	
7. Overall, these earplugs are functional (effectiveness, intuitive fit…).	**General sub-item** **8.** These earplugs are efficient.	**Explanatory sub-items** **9a.** When you wear these earplugs, you feel protected. **9b.** When you wear these earplugs, you feel overprotected.
	EASE OF USE	
	General sub-item **10.** These earplugs are easy to use.	**Explanatory sub-items** **11.** The fit is: **a.** intuitive; **b.** easy; **c.** quick; **d.** requires few gestures. **12.** Once fit, these earplugs stay in position. **13.** The removal is: **a.** intuitive; **b.** easy; **c.** quick; **d.** requires few gestures. **14.** Cleaning these earplugs is easy.
	UTILITY **15a.** These earplugs are useful given your work environment. **15b.** These earplugs are useful given your work activities.	
	IMPACT ON WORK **16a.** When you wear earplugs, your concentration is: from *really worse* (1) to *really better* (5). **16b.** When you wear earplugs, the quality of your work is: from *really worse* (1) to *really better* (5). **16c.** When you wear earplugs, your productivity is: from *really worse* (1) to *really better* (5).	
ACOUSTIC COMFORT		
General items	**Explanatory items**	

<u>17a.</u> These earplugs allow you to hear useful sounds coming from your work environment (conversations, machines, warning signals, arrival of vehicles...).	**<u>18.</u>** When you wear these earplugs, you do not hear what others are saying to you. **<u>19.</u>** When you wear these earplugs, you have difficulty perceiving the following sounds: **<u>a.</u>** sounds of machines useful for doing your work; **<u>b.</u>** warning signals; **<u>c.</u>** company communication messages; **<u>d.</u>** arrival of vehicles. **<u>20.</u>** When you wear these earplugs, you can clearly hear where these sounds come from.
	<u>21.</u> The noise reduction induced by these earplugs is annoying.
<u>17b.</u> These earplugs allow you not to be disturbed by the sounds of your body (voice, chewing, swallowing, heartbeat, breathing...).	**<u>22.</u>** When you wear these earplugs, you are annoyed by: **<u>a.</u>** your own voice when you speak; **<u>b.</u>** chewing noises when you chew; **<u>c.</u>** sounds from your body (swallowing, stomach, heartbeat, breathing...).
PSYCHOLOGICAL COMFORT	
General item **<u>23.</u>** You feel good when you use these earplugs.	**Explanatory items** **<u>24.</u>** You trust these earplugs. **<u>25.</u>** You get used to their presence (followed, if applicable, by the multiple-choice item: You become accustomed to their presence after: a few seconds; a few minutes; a few hours; a few days). **<u>26.</u>** This isolation bothers you. **<u>27.</u>** When you use these earplugs, you feel: **<u>a.</u>** from *angry* (1) to *calm* (5); **<u>b.</u>** from *worried* (1) to *confident* (5); **<u>c.</u>** from *tense* (1) to *relaxed* (5); **<u>d.</u>** from *oppressed* (1) to *free* (5). **<u>28.</u>** You are satisfied with these earplugs. **<u>29.</u>** These earplugs meet your needs. **<u>30.</u>** If you had a choice, you would use these earplugs again.
OVERALL COMFORT	
<u>31.</u> Overall, how would you rate this model of earplugs (knowing that 1 equals *very bad* and 5 equals *very good*)?	

Table 3. User profile *questionnaire: socio-demographic characteristics of the sample.*

Characteristics	Conditions	N = 118	Frequency (%) or median[(m)]
Company	A	34	28,8
	B	39	33,1
	C	27	22,9
	D	18	15,3
Sex	Male	96	81,3
Age	All participants	112	39[(m)]
	< 40 years	57	32[(m)]
	≥ 40 years	55	48[(m)]
Level of education	Secondary school	32	26,9
	High school	53	44,9
	Higher education	33	28,2
Seniority in the company	< 1 year	4	3,8
	Between 1 and 5 years	20	16,7
	> 5 years	94	79,5
Seniority in the position	< 1 year	4	3,8
	Between 1 and 5 years	33	28,2
	> 5 years	80	67,9
Fixed or rotating position	Fixed	59	50
	Rotating	59	50
Solo or collaborative work	Solo	36	30,8
	Collaborative	82	69,2
Working shifts (multiple answers possible)	Morning	106	89,8
	Afternoon	2	1,7
	Night	48	40,7
	Other	10	8,5

Table 4. User profile *questionnaire: attitude and beliefs regarding earplugs.*

Characteristics	**Conditions**	**N = 118**	**Frequency (%)**
Wearing earplugs helps to control hearing problems	Strongly disagree	0	0
	Disagree	3	2,6
	Neither agree nor disagree	6	5,1
	Agree	24	20,5
	Totally agree	85	71,8
Use of earplugs at work since	Some days	9	7,7
	Some months	11	8,9
	Some years	98	83,3
	I don't use HPD	0	0
Reason of earplugs use (multiple answers possible)	Hierarchy	72	61
	Personal choice	75	63,6
	Other	3	2,5
Earplug family(s) usually worn (multiple answers possible)	Custom molded	69	58,5
	Roll-down foam	32	27,1
	Premolded	25	21,2
Reason for use of this(these) family(s) (multiple answers possible)	Hierarchy	50	42,4
	Personal choice	78	66,1
	Other	3	2,5
Daily duration of use	A few minutes	15	12,8
	A few hours	48	41
	All day long	55	46,2
Noise hazard awareness training	Yes	71	60,3
	No	47	39,7
Operating instructions : useful	Strongly disagree	2	1,3
	Disagree	4	3,8
	Neither agree nor disagree	15	12,8
	Agree	53	44,9
	Totally agree	44	37,2
Operating instructions: understandable	Strongly disagree	2	1,3
	Disagree	6	5,1
	Neither agree nor disagree	14	11,5
	Agree	51	43,5
	Totally agree	45	38,5
What type(s) of HPD is used off the job (multiple answers possible)	Earmuffs	11	9,3
	Custom molded earplugs	7	5,9
	Roll-down foam earplugs	6	5,1
	Premolded earplugs	6	5,1
	None	12	10,2

Table 5. User profile *questionnaire: working environment.*

Characteristics	Conditions	N = 118	Frequency (%)
Noise exposure level	Very quiet	2	1,3
	Quiet	4	3,8
	Neither quiet nor noisy	35	29,5
	Noisy	47	39,7
	Very noisy	30	25,6
Origin of noises (multiple answers possible)	Your workstation	87	73,7
	Other workstations	83	70,3
	Other	14	11,9
Type of noises (multiple answers possible)	Continuous noises	75	63,6
	Discontinuous noises	88	74,6
	Impact noise	69	58,5
	Other	10	8,5
Annoyance due to continuous noises	Strongly disagree	8	6,4
	Disagree	17	14,1
	Neither agree nor disagree	29	24,4
	Agree	39	33,3
	Totally agree	26	21,8
Annoyance due to discontinuous noises	Strongly disagree	2	1,3
	Disagree	6	5,1
	Neither agree nor disagree	30	25,6
	Agree	47	39,7
	Totally agree	33	28,2
Annoyance due to impact noise	Strongly disagree	3	2,6
	Disagree	9	7,7
	Neither agree nor disagree	35	29,4
	Agree	36	30,7
	Totally agree	35	29,5
These noises affect your health	Strongly disagree	3	2,6
	Disagree	11	8,9
	Neither agree nor disagree	19	16,2
	Agree	41	34,6
	Totally agree	41	34,6
Work requirements (multiple answers possible)	Talk	102	86,4
	Repeated head movements	47	39,8
	Hearing warning signals	67	56,8
	Relying on certain sounds	59	50
Environment (multiple answers possible)	Hot	78	66,1
	Cold	63	53,4
	Wet	50	42,4
	Dirty	58	49,2
	Other	14	11,9

Table 6. CFA for the latent variable PRED_EaseOfUSe *related to ease of use.*

FUNCTIONAL COMFORT – EASE OF USE: CFA			
Items	**Items loading on the latent variable *PRED_EaseOfUse***		
	Coefficient	95% confidence interval	*P* value
11a	0.87	[0.84; 0.89]	$< 10^{-3}$
FitEase&Speed (factor score representative of item 11b and 11c)	0.96	[0.94; 0.98]	$< 10^{-3}$
11d	0.80	[0.76; 0.83]	$< 10^{-3}$
Removal (factor score representative of item 13a to 13d)	0.55	[0.49; 0.62]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.056	0.997	0.011

Table 7. CFA for the latent variable PRED_Functional_Comfort *related to functional comfort.*

FUNCTIONAL COMFORT - OVERALL FUNCTIONAL COMFORT: CFA			
Items	**Items loading on the latent variable *PRED_Functional_Comfort***		
	Coefficient	95% confidence interval	*P* value
8	0.77	[0.72; 0.82]	$< 10^{-3}$
EaseOfUse	0.68	[0.62; 0.74]	$< 10^{-3}$
Utility	0.82	[0.77; 0.86]	$< 10^{-3}$
ImpactOnWork	0.62	[0.56; 0.69]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.063	0.994	0.018

Table 8. CFA for the latent variable PRED_Physical_Comfort *related to physical comfort.*

PHYSICAL COMFORT: CFA			
Items	**Items loading on the latent variable *PRED_Physical_Comfort***		
	Coefficient	95% confidence interval	*P* value
2	0.64	[0.59; 0.69]	$< 10^{-3}$
3	0.83	[0.79; 0.86]	$< 10^{-3}$
4	0.88	[0.86; 0.92]	$< 10^{-3}$
5	0.83	[0.80; 0.87]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.098	0.991	0.018

Table 9. CFA for the latent variables PRED_Acoustic_Comfort_Perception *related to the good perception of useful sounds and* PRED_Acoustic_Comfort_Occlusion *related to the occlusion effect.*

ACOUSTIC COMFORT- GOOD PERCEPTION OF SOUNDS: CFA			
Items	**Items loading on the latent variable *PRED_ Acoustic_Comfort_Perception***		
	Coefficient	95% confidence interval	*P* value
21	0.71	[0.65; 0.76]	$< 10^{-3}$
18	0.78	[0.72; 0.83]	$< 10^{-3}$
UsefulSounds (factor score representative of items 19a to 19d)	0.66	[0.60; 0.72]	$< 10^{-3}$
20	0.71	[0.65; 0.77]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.049	0.996	0.015

ACOUSTIC COMFORT - ANNOYANCE DUE TO OCCLUSION EFFECT: CFA			
Items	**Items loading on the latent variable *PRED_Acoustic_Comfort_Occlusion***		
	Coefficient	95% confidence interval	*P* value
21	0.55	[0.48; 0.91]	$< 10^{-3}$
22a	0.81	[0.78; 0.85]	$< 10^{-3}$
22b	0.89	[0.87; 0.92]	$< 10^{-3}$
22c	0.91	[0.89; 0.93]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.000	1.000	0.007

Table 10. CFA for the latent variable PRED_Psychological_Comfort *related to the psychological comfort.*

PSYCHOLOGICAL COMFORT: CFA			
Items	**Items loading on the latent variable *PRED_Psychological_Comfort***		
	Coefficient	95% confidence interval	*P* value
24	0.78	[0.74; 0.82]	$< 10^{-3}$
25	0.77	[0.73; 0.82]	$< 10^{-3}$
26	0.57	[0.50; 0.64]	$< 10^{-3}$
Emotions (factor score representative of items 27a to 27d)	0.55	[0.47; 0.62]	$< 10^{-3}$
28	0.96	[0.95; 0.97]	$< 10^{-3}$
29	0.96	[0.95; 0.97]	$< 10^{-3}$
30	0.91	[0.89; 0.93]	$< 10^{-3}$
GOF	**RMSEA**	**CFI**	**SRMR**
	0.088	0.982	0.031

Table 11. Typologies identified based on the statistical modelling of the evaluations of overall comfort. For each earplug model, the distribution of responses is shown in brackets ranging from very good (left) to very poor (right).

<table>
<tr><th>Typology 1</th><th>Typology 2</th><th>Typology 3</th><th>Typology 4</th><th>Typology 5</th></tr>
<tr><td rowspan="5">Custom molded C_1
(49%-41%-6%-3%-1%)</td><td rowspan="5">Custom molded C_2
(31%-45%-17%-7%-1%)
Custom molded C_3
(33%-43%-16%-5%-3%)</td><td rowspan="5">Premolded B_1
(11%-38%-27%-18%-6%)</td><td>Premolded B_2
(4%-33%-32%-22%-9%)</td><td></td></tr>
<tr><td colspan="2">Roll-down foam A_2 *(3%-23%-40%-27%-7%)*</td></tr>
<tr><td colspan="2">Roll-down foam A_3 *(9%-23%-27%-35%-6%)*</td></tr>
<tr><td colspan="2">Premolded B_3 *(2%-15%-38%-33%-12%)*</td></tr>
<tr><td></td><td>Roll-down foam A_1
(5%-20%-28%-32%-15%)</td></tr>
</table>