Occlusion and coupling effects with different earmold designs – all a matter of opening the ear canal?

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Occlusion and coupling effects with different earmold designs – all a matter of opening the ear canal?

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ABSTRACT

Objective: Ear canal occlusion by a hearing aid leads to an unnatural sound of the own voice due to a level increase of bone-conducted low-frequency components of the ear canal. Opening the ear through vents or domes reduces this so-called occlusion effect, however at the cost of reduced hearing aid performance. For individual earmolds, several other design options to reduce the occlusion effect have been proposed but not reliably evaluated.

Design: The occlusion effect and coupling parameters were assessed through subjective ratings and real-ear measurements.

Study sample: Six individual earmold designs, each with different venting options, were tested in 10 subjects.

Results: In line with previous studies, our data show that the opening of the ear as described by the acoustic mass of the vent is the prime parameter that predicts both the occlusion effect and coupling parameters. However, the design of the earmold, most importantly the location where sealing of the ear canal is achieved, is another important factor for occlusion and coupling effects.

Conclusions: Although no reduction of the occlusion effect seems possible without additional opening of the ear canal, some earmold modifications seem to aggravate the occlusion effect as compared to a standard earmold with equivalent vent.

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Hearing aids; own voice; sound quality; real-ear measurements

Introduction

A frequent complaint of many hearing aid users is an unnatural, boomy sound of their own voice (Jenstad, Van Tasell, and Ewert 2003; McCormack and Fortnum 2013). This issue is mainly caused by the occlusion effect, i.e. a level increase of low-frequency components in the ear canal originating from bone-conducted sound, due to the occlusion of the ear canal by a hearing aid or other ear-worn device (Carillo, Doutres, and Sgard 2020; Dillon 2012; Hansen 1998). In addition, the air-conducted part of the own voice is altered through amplification by the hearing aid (Laugesen et al. 2011). While signal processing techniques can largely reduce the effects of the hearing aid amplification on the own voice (Powers et al. 2018), the problem of the occlusion effect is far from being solved even after decades of technological progress. In the present study, we investigate the effect of venting and other more elaborate design options for individual earmolds on the experienced occlusion effect as well as acoustic coupling parameters that determine the performance of the hearing aid. Although this work is centred around hearing aid applications, the results on earmold design options can be transferred to other ear-worn acoustic devices where occlusion and coupling effects are critical for the performance and wearing comfort, such as hearing protectors or hearables.

The occlusion effect is commonly tackled by partly opening up the earmold or other coupling element to the ear canal by vents. The opening of the ear canal reduces the termination impedance at the lateral side of the ear canal, allowing for bone-conducted sounds to "flow out" of the ear canal. This leads to a reduction of the level increase in the ear canal, as well as a reduction of the perceived occlusion effect. To describe the effect of the ear canal opening, the acoustic mass of a vent has long been established as a well-suited metric (Dillon 2012; Goldberg 1980; Kiessling et al. 2005). The acoustic mass of a vent is proportional to its length and inversely proportional to its cross-sectional area. Thus, the acoustic opening of the ear canal can be increased by increasing the vent diameter or decreasing the vent length, or both. While the diameter of the vent is quite constrained by the space available in the ear canal, reduction of the vent length allows for more flexible venting options. Reduction of the vent length can be achieved, for example, by making the earmold hollow (Kiessling et al. 2005; Kuk, Keenan, and Lau 2009), or removing material at either side of the earmold, also during the fine-tuning process.

However, reduction of the occlusion effect by means of opening the ear canal comes at the cost of several negative effects regarding the coupling of the hearing aid. First, the output of the hearing aid leaks out of the ear canal similarly to the bone conducted sound. This leads to a reduction of sound pressure level

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generated at the eardrum in low frequencies, as well as an increased risk of feedback in the high frequencies (Gatehouse 1989; Kuk, Keenan, and Lau 2009). These effects are often summarised as *vent-out* effects. Second, sounds from the environment leak into the ear canal without being processed by the hearing aid, referred to *vent-in* effect. This effect can be measured as an increased Real-Ear Occluded Gain (REOG), and may lead to an increased disturbance due comb filtering effects originating from an interaction with the delayed hearing aid output (Denk, Ohlmann, and Kollmeier 2021; Groth and Søndergaard 2004; Stone et al. 2008). Combined with the lowered hearing aid output at low frequencies, the vent-in effect also reduces the effectivity of signal processing features like noise reduction and directional microphones (Keidser et al. 2007). In summary, opening the ear canal is a simple option to reduce the occlusion effect but comes at the cost of reduced hearing aid performance. Therefore, an individually optimal compromise has to be found for each patient. Alternative approaches to opening the ear canal in for reducing the occlusion effect in closed-fit devices based on active feedback loops (so-called Active Occlusion Cancellation) have been demonstrated in prototype devices (Mejia, Dillon, and Fisher 2008; Zurbrügg et al. 2015) but are, to the authors' best knowledge, not available in today's hearing aids.

Besides earmolds, the hearing aids can be coupled to the ear using non-individualised domes with or without included openings. The use of domes has gained increased popularity in the past decade, and makes up a large portion of hearing aid fittings in many countries today. The benefit of domes is reduced cost, and the possibility to provide instant fittings. However, domes are not suitable for achieving rather closed fits, and their coupling properties tend to vary strongly between subjects and also between insertions (Caporali et al. 2019; Kühnel 2021). Further, the non-individualised shape can usually not provide a secure fit in the ear, although it is based on potentially inconvenient pressure on the sensitive ear canal walls. Therefore, in the authors' opinion individual earmolds are still the best and most flexible option for achieving individually optimised coupling of hearing aids to the ear.

With individual earmolds, other options than vents to reduce the occlusion effect are available. As predicted by early considerations of von Békésy (1941) and Zwislocki (1953), and Killion, Wilber, and Gudmundsen (1988) showed that the occlusion effect can be virtually cancelled if the earmold is fitted deep enough to provide a seal within the bony part of the ear canal. Several further studies showed that the deeper an earmold is fitted, the smaller is the occlusion effect (Blau et al. 2008; Lee and Casali 2011; Stenfelt and Reinfeldt 2007). However, deep fitted earmolds are hard to manufacture and usually not very comfortable to wear over long periods (Dillon 2012). Other designs propose material removal at the canal stalk to reduce the transduction of body-generated sounds to the residual ear canal volume, and at the same time improve the wearing comfort as compared to standard deep-fitted earmolds. For example, a recess around the mandibular condyle can improve the wearing comfort by allowing free ear canal movements while speaking and chewing (Voogt 2013). Further, such a recess is believed to reduce the occlusion effect by minimising contact between the earmold and this region of the ear canal, where the transduction of bone-conducted sound is thought to be maximal (Bayer 2010; Saile 2010). Similar designs propose removing other parts of the canal stalk that are in contact with the ear canal walls (Dillon 2012). Such modifications inherently include an effective shortening of the canal stalk and thus the potential vent length, which allows for more open configurations as compared to standard earmolds. Further, feedback might be reduced by the jumps of cross-section in the vent that could lead to a reflection of high-frequency components back into the ear canal. Special earmold designs might thus give large benefits to the user in terms of wearing comfort and the occlusion effect without reducing the performance of the hearing aid by largely opening the ear canal. However, reliable data on the effect of such designs on the occlusion effect and especially other coupling parameters is very limited.

In the present study, we therefore quantify the occlusion effect and further coupling effects in six earmold designs, each with different vent configurations. Measurements included the subjective and objective occlusion effects, the hearing aid response at eardrum, the feedback path, and the attenuation of external sounds. The rich data allows a conclusive comparison of earmold designs and venting parameters. In particular, we want to tackle the following open questions:

- Is the opening of the ear canal, as described by the acoustic mass, sufficient to predict both the occlusion effect as well as other coupling parameters of the hearing earmold also with special earmold designs?
- Are there earmold design options that allow for reducing the occlusion effect without introducing the same negative effects for coupling parameters as observed with vents?

Methods

Subjects and earmold designs

Earmolds for coupling a Behind-the-Ear (BTE) hearing aid were manufactured for ten adult subjects (each five male and female, age 22–44) who participated in the experiment. While one subject had a retro-cochlear hearing loss and wore hearing aids since childhood, the others were normal-hearing young adults. Since previous data (Kiessling et al. 2005) suggests that hearing loss does not lead to different ratings of the occlusion effect, the data from all subject were further evaluated. All subjects had prior knowledge regarding hearing aid technology and the occlusion effect.

Two sets of ear impressions were taken from each subject, with the mouth either wide open or closed, in order to be able to later identify the location of the mandibular condyle within the cartilaginous part of the auditory canal (Voogt 2013). All impressions exceeded the second bend of the ear canal. The impressions were then 3 D-scanned, and individual earmolds designed using the Software SecretEarDesigner 5.1 (Cyfex, Zurich, Switzerland). Although the earmolds were designed for coupling a standard sound tube (outer diameter: 3.1 mm, inner diameter: 2 mm), the designs and results from this study are transferable to other earmolds or In-Ear hearing device styles as well. Besides the 3.1 mm bore for the sound tube and the vent, the earmolds included an additional bore of 1.2 mm in diameter for later insertion of a probe tube. This bore was included to avoid additional leaks between skin and earmold by guiding the probe tube along the ear canal wall (Dillon 2012). Its diameter was chosen minimal, while still allowing smooth insertion of the probe tube. The bores for the probe tube and sound tube were placed identically in all earmolds of one subject. The earmolds were designed in the order given below by subsequent "removal" of material. Samples of all earmold designs are shown for one male subject in Figure 1, and STL files of all earmolds and ear

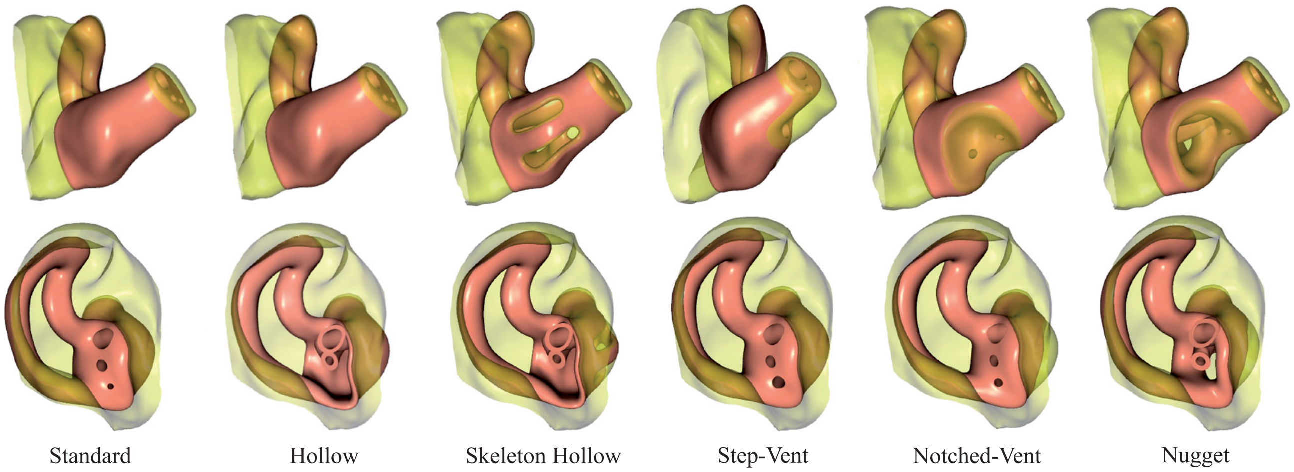


Figure 1. Sample earmolds for one male subjects, with shade of ear impression. Identical earmolds are shown below each other from two different angles.

canal scans are provided as supplementary material (see Data Availability Statement).

Standard earmold: A standard ring earmold, i.e. material in the concha was removed except for a ring-shaped Concha lock. The ear canal was filled with solid material up to the second bend of the ear canal.

Hollow earmold: Same outer shape as the *Standard* earmold, but the canal stalk hollowed out up to a 1.3 mm thick layer in contact with the ear canal walls. This allows for very short vents and thus acoustically very open properties.

Skeleton hollow earmold: Same as the *Hollow* earmold, but with three slits introduced into the earmold material parallel to the ear canal axis, within the area touching the ear canal walls. These slits are intended to leave parts of the ear canal walls open, such that body-generated sound is ducted into the hollow part of the canal stalk and out of the ear canal, rather than coupled into the earmold.

Step-Vent earmold: Same as the *Standard* earmold, but with material at the lower part of the ear canal removed from the medial termination up to approx. half the length covering the ear canal. This resulted in reducing the length of the vent within the earmold by approx. one third, and the creation of a second part of the vent that is made up of the residual ear canal volume below the residual earmold. Note that for the computation of the acoustic mass of the vent of this design, only the part of the vent within the earmold is considered. This design option is a popular practical method to reduce the vent length during the fine-tuning process (Voogt 2013).

Notched-Vent earmold: Same as the *Standard* Earmold, but with material removed where the mandibular condyle was detected by comparing the two ear impressions with different mouth opening (Bayer 2010). This created a notch at the lower half of the earmold, which was designed such that it separates the vent into two equally long parts. This design is sometimes referred to as Shark-Bite (Winkler, Latzel, and Holube 2016) and aims at improving the wearing comfort and reducing the occlusion effect by isolating the region of the ear canal close to the mandibular condyle from the residual ear canal, while avoiding contact with the earmold. Note that for the computation of the acoustic mass, the masses of the two vent parts were added.

Nugget earmold: Based on the *Notched-Vent* Earmold, but with the earmold hollowed out from the notch outwards, such that the ear canal is only occluded further medial of to the mandibular condyle, and the vent is shortened appropriately (Saile 2010; Winkler, Latzel, and Holube 2016). In this design, all sounds generated by ear canal wall vibrations at the mandibular condyle and further lateral are ducted towards the outside to reduce the occlusion effect. Additionally, the reduced contact to the ear canal walls aims at improving the wearing comfort.

For all designs, one closed and at least one vented earmold was designed. An exception was the *Hollow* earmold, where no closed version was manufactured due to the suspected similarity to the *Skeleton Hollow* earmold. Target vent diameters and average nominal acoustic masses of the vents as provided by the earmold modelling software are listed in Table 1. The diameter, length and nominal acoustic mass of the vent in each earmold were taken from the modelling software, and are provided as Supplementary material. Finally, the earmolds were 3 D printed in hard acrylic material (Medicalprint clear, Detax, Ettlingen, Germany) using a Digital Light Processing machine (Freeform Pro 2 UV385, ASIGA, Sydney, Australia), cleaned, and all surfaces with skin contact coated with biocompatible transparent paint. Finally, sound tubes were glued into the appropriate bores, flush with the inner surface of the earmold.

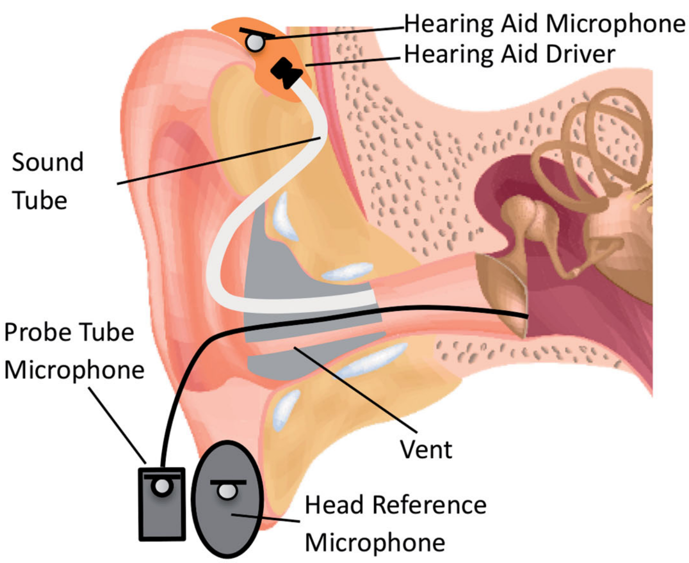
Please note that for three ears in two subjects (17-L, 17-R and 18-L), the acoustic masses of the vented *Hollow* and *Skeleton Hollow* earmolds were much larger than in the rest of the subjects due to the shape of the ear canals. These data were therefore excluded from analyses.

Measurement setup

Real-ear measurements were performed with a setup shown in Figure 2, built up in a double-walled and acoustically treated room ($2.5 \times 3.6 \times 2{,}3$ m, T30 < 0.1 s). The earmold under test was coupled to a BTE hearing aid shell (risa S, Audifon, Kölleda, Germany) with wired drivers and microphones, which were

Table 1. Vent diameters, and acoustic masses for the used earmolds. Nominal acoustic masses were provided by the earmold fitting software. Equivalent acoustic masses were derived from the linear regression between acoustic mass and the bass response and subjective occlusion effect (subj. OE) shown in Figure 4 (see Importance of the opening of the ear canal). The values given are the averages across subjects calculated with the logarithmic values.

Earmold Design	Vent diameter	Nominal ac. mass [kg/m^4]	Equivalent ac. mass [kg/m^4] (for Bass Resp)	Equivalent ac. mass [kg/m^4] (for subj. OE)
Standard	Closed	n.a.	27 714	61 858
	mm	28 490	28 270	34 054
	mm	8 160	9 100	7 657
Hollow	1 mm	2 080	5 401	10 298
Skeleton Hollow	Closed	n.a.	13 207	15 557
	mm	2 080	2 081	2 528
Step-Vent	Closed	n.a.	11 687	29 333
	mm	5 440	6 074	11 120
Notched-Vent	Closed	n.a.	16 963	41 037
	2 mm	14 400	14 298	14 438
Nugget	Closed	n.a.	13 894	17 399
	2 mm	7 200	6 557	5 273



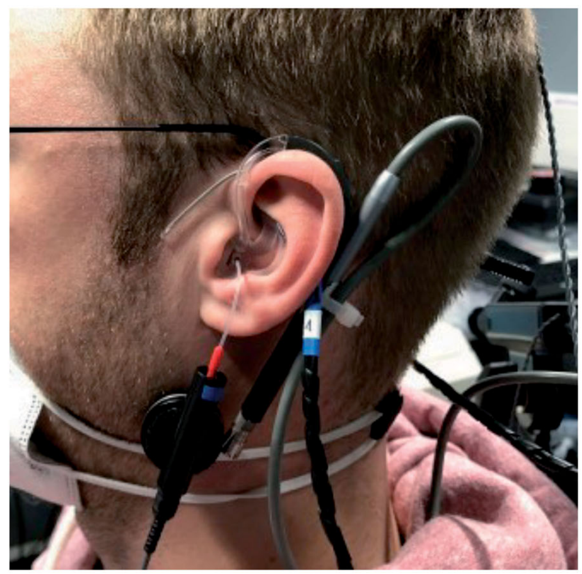


Figure 2. Schematical (left) and photograph (right) of the measurement setup.

connected to customised pre-amplifiers and a soundcard (Fireface 802, RME, Haimhausen, Germany). No real-time processing was active on the hearing aid shells, i.e. all sounds played back from the hearing aid driver were measurement signals solely originating from the soundcard. Although the hearing aid contained two microphones, only the frontal one is considered in further analyses. In case of measurements with the open ear, the hearing aid shells remained in place, but were not coupled to a sound tube or earmold. Further, a coaxial loudspeaker (8351, Genelec, Iisalmi, Finland) was mounted at a distance of 1 m in front of the subject.

A probe tube microphone (ER7C Series B, Etymotic Research, Elk Grove Village, IL) was conducted through the appropriate bore of the earmold and placed close to the eardrum. Placement close to the eardrum was achieved by carefully inserting it until the subject reported contact with the eardrum. Afterwards, it was pulled back by a maximum of 1–2 mm, and the location of the probe tube at the outer end of the earmold marked. Since the outer end of the earmold was identical in all designs, contact with the eardrum only had to be established with the open ear and when measuring the first earmold; for all subsequent earmolds, the probe tube was inserted only up until a marked depth. It was occasionally verified that the probe tube tip was indeed placed close to the eardrum by carefully inserting it slightly deeper. The probe tube bore was designed such that the probe tube tip reached the eardrum at the lower anterior corner, i.e., close to the umbo, to capture the maximum sound pressure levels across the eardrum (Hudde and Schmidt 2009).

Another measurement microphone referred to as head reference microphone was placed below the ear lobe. This is the typical location of the reference microphone in real-ear measurement systems (Dillon 2012). This was realised by taping it to a hook that was placed around the ear, together with the body of the probe tube microphone. Here, a ¼" pressure microphone (4939 with 2670 preamplifier, Brüel&Kjaer, Naerum, Denmark) was used to provide a mostly direction-independent sensitivity in the frequency range of interest up to 10 kHz. Another free-field microphone (Brüel&Kjaer 4190 with 2669 preamplifier) was placed in 1 m distance to and pointed in the direction of the subject, next to the loudspeaker, to monitor the subjects' vocalisation.

Procedure

Measurements were conducted for one side at a time; and each subject attended two experimental sessions for measurements in both ears. However, earmolds and hearing aid shells were always inserted in both ears to facilitate a subjective rating of the occlusion effect (see below). The bore for the probe tube on the side where no measurements were performed was occluded by putty to avoid additional ventilation effects. All measurements were conducted with the open ear first, followed by the earmolds in a Latin square-balanced order. Three types of measurements were performed for each condition (earmolds, open ear) sequentially: First, general coupling effects of the earmolds were assessed by analysing transfer functions from the hearing aid driver and the loudspeaker to the microphones in and around the ear (see Transfer function measurement). Second, the objective occlusion effect was assessed through recordings of the subjects' own voice as well as through transfer functions measurements from a bone conduction driver. However, the results regarding the objective occlusion effect are not assessed in the scope of this paper. Third, the subjects gave subjective ratings on the naturalness of their own voice on a scale from 1 (very unnatural, like an earplug) to 10 (very natural, like open ear). For this purpose, they were provided with a text describing general experimental instructions in German, which they read out loud until they came to a rating. At the beginning of the experimental session, they were asked to insert foam earplugs and speak, to give an internal reference of a fully occluded ear that is created with the typical shallow insertion of such earplugs.

Since the study was conducted during the COVID-19 pandemic, rigorous hygiene was pursued, and the experimenter as well as the subject wore appropriate personal protection equipment (FFP2 face masks, medical gloves). The experimenter was only in the room with the subjects for inserting the earmolds and conducting the transfer function measurements. For measurements involving vocalisation, the experimenter left the room and communicated with the subject via audio transmission. This allowed the subject to remove their face masks during these measurements. Active ventilation of the room exchanged the air in the room approx. eight times per hour. The study was approved by the ethics council of the Technische Hochschule Lübeck, and no case of COVID-19 infection or transmission has occurred during the study.

Transfer function measurement

The transfer functions from the hearing aid driver and loudspeaker to all available microphones were measured using the swept-sine technique (Farina 2000; Müller and Massarani 2001). The sweeps ranged from 30 Hz to 22050 Hz (half sampling frequency of 44100 Hz), had a duration of 10 s. The playback level of sound sources was 80 dB referenced to the free field, measured at 1 kHz. To speed up the measurements, the sweeps were interleaved, i.e. partly overlapped during playback in a way that the impulse responses from the different sound sources could be separated by windowing (Majdak, Balazs, and Laback 2007). The impulse responses were windowed to include only a minimum of noise floor (hearing aid driver: 10 ms, loudspeaker: 100 ms), and the corresponding transfer functions were calculated using a Discrete Fourier Transform of length 4096.

The following responses are further analysed in this work:

- Hearing aid response: Response of the hearing aid driver at the eardrum, measured using the probe tube microphone.
- Feedback path: Response of the hearing aid driver at the frontal hearing aid microphone.
- Insertion loss: Response of the loudspeaker at the eardrum with earmold inserted, divided by the same response measured with open ear. Both responses were smoothed by a 1/6 octave sliding average window (Hatziantoniou and Mourjopoulos 2000) before division.

Results and analysis

Occlusion and coupling effects

Figure 3 shows the results of all gathered metrics as denoted in the panel title, averaged across all subjects and ear sides. Data of individual subjects is given in the Supplementary material. Frequency regions where the data are unreliable due to measurement noise is marked by shaded areas in the panels of Figure 3.

The top left panel of Figure 3 shows the subjective occlusion rating on a scale from 1 to 10, together with the standard deviation across subjects, which lies around two subjective points for all earmolds. Note that the depicted scores were calculated by subtracting the original ratings of naturalness of the own voice from 11. Differences are visible both between earmold designs, as well as between different vents. The occlusion effect with the vented version of an earmold is generally perceived as lower than with the closed version, on average by approx. two subjective points. The largest subjective occlusion effect is observed with the closed *Standard* earmold, and the lowest with the vented *Skeleton Hollow* earmold.

The top right panel of Figure 3 shows the insertion loss with the different earmolds across frequency. The largest attenuation is observed with the closed *Standard* earmold. With the other closed earmolds, a lower attenuation is seen, which is the lowest in the *Skeleton Hollow* earmold. In all vented earmolds, an amplification of external sounds is seen in the low frequencies with a peak varying between approx. 200 Hz (Standard earmold, 1 mm vent) and 700 Hz (Skeleton Hollow Earmold, 1 mm vent). This amplification is caused by a Helmholtz resonance of the residual ear canal and the vent. Only above this peak, attenuation is achieved, which is always lower than in the corresponding closed earmold.

The lower left panel of Figure 3 shows the driver responses at eardrum. For frequencies above 2000 Hz, no considerable difference is seen between the earmolds. Between 500 Hz and 2000 Hz, the closed and vented earmolds behave very similarly as groups, where slightly (1.2 dB) higher responses are seen with the vented earmolds, which is probably again caused by Helmholtz resonances. At frequencies below 500 Hz, larger differences between earmolds become obvious and reach up to approx. 25 dB at 100 Hz. Whereas in all vented earmolds except the *Standard* earmold with 1 mm vent, a rather similar high-pass behaviour is observed, the response in this frequency regime is larger with the closed earmolds but varies with the designs. Again, the highest low-frequency response is noted with the closed standard earmold, while the other closed earmolds lie approx. 7 dB below at a very similar level.

The lower right panel of Figure 3 shows the feedback paths to the frontal microphone. Below approx. 700 Hz, the feedback paths approach the noise floor of the microphone, which masks any differences between earmolds. At higher frequencies, the feedback paths look generally similar in all earmolds and show peaks corresponding to those of the driver response at eardrum. The levels of the feedback paths are shifted between earmolds with maximum differences up to 15 dB. Lower feedback paths are generally observed in closed versus

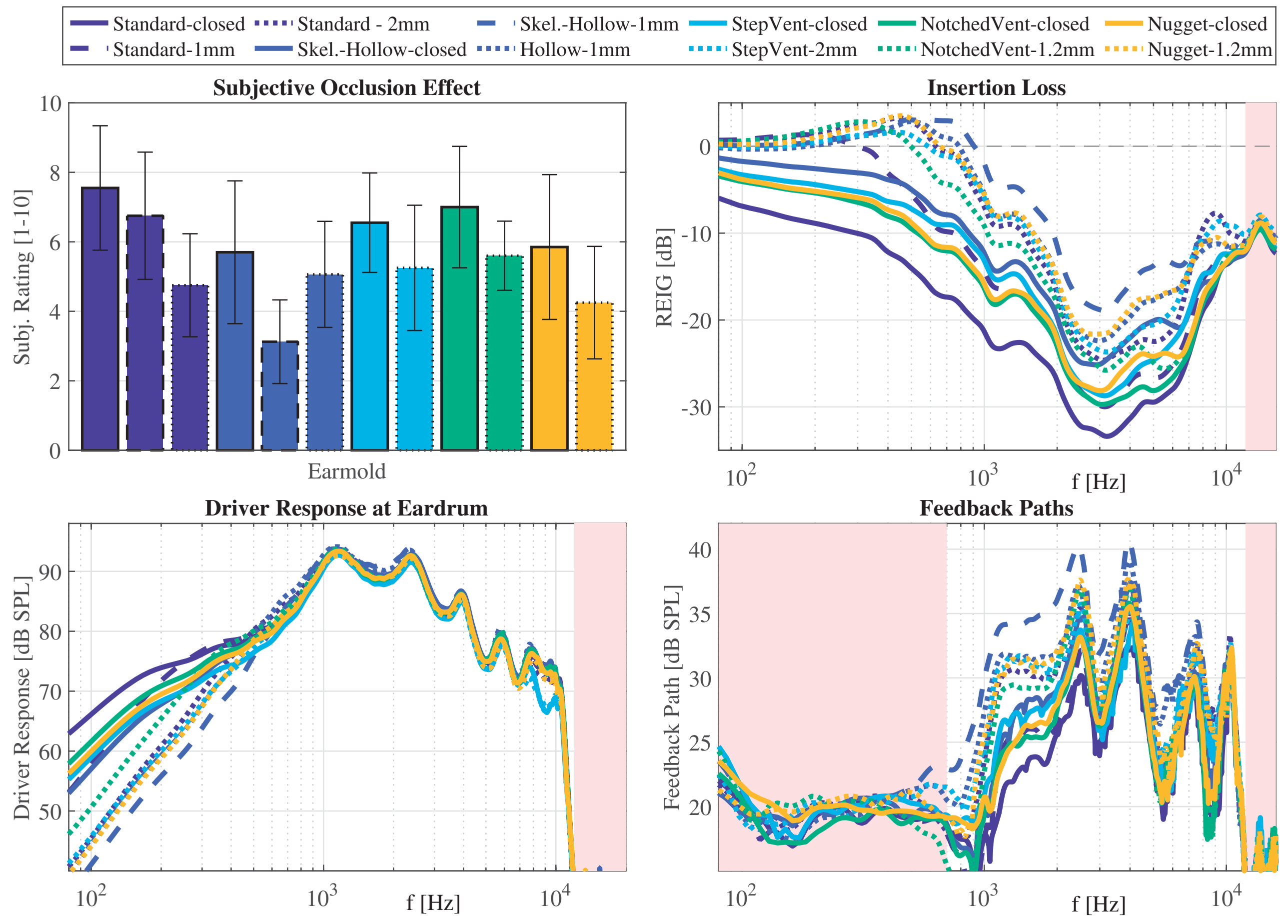


Figure 3. Subjective occlusion effect, insertion loss, hearing aid response and feedback paths, averages across subjects shown for each earmould. Line colours indicate the earmold design as per legend; solid lines denote closed earmolds, dashed and dotted lines vented earmolds. Red shaded ares denote frequency regions with unreliable data.

vented earmolds (except for the *Standard* earmold with 1 mm vent). The lowest feedback path is seen in the closed *Standard* earmold, while the largest is observed in the vented *Skeleton Hollow* earmold.

Correlations between earmold parameters

For further assessment, single numbers representing each of the frequency-dependent metrics have been computed as follows:

- Insertion loss: average attenuation at frequencies 250 Hz, 500 Hz and 750 Hz.
- Driver response: Average level at frequencies 250 Hz, 500 Hz and 750 Hz relative to the level at 1000 Hz.
- Feedback path: Maximum level in a frequency range between 1000 and 8000 Hz.

All quantities were calculated per subject and afterwards averaged across subjects. The selection of frequencies was made to represent the most relevant range of vent effects from an audiological perspective.

Figure 4 shows the correlations between all quantities shown in Figure 3, as well as with the decadic logarithm of the nominal acoustic mass of the vent. Generally, most metrics show strong and significant correlations with typical correlation coefficients above 0.9. The exception are correlations including the insertion loss, as well as the correlation between the acoustic mass and the subjective occlusion effect. As further discussed below, a high correlation between two metrics probably represents that they are different effects of a single cause, namely opening the ear canal. Low correlations, or single points that differ significantly from a linear relationship, would indicate a deviation from a behaviour that is governed by the ear canal opening.

The insertion loss varies between designs with closed earmolds and between vented and closed earmolds, but less between the vented earmolds. This is consistent with the observations above (c.f. Figure 3) especially for the low-frequency regime that was chosen for the calculation of the average. For the vented earmolds, the insertion loss reaches a saturation towards high values slightly above 0 dB, leading to a broken-stick like relationship between the insertion loss and most other parameters. In turn, correlation coefficients are decreased. If the vented earmolds are left out of the picture, higher correlation coefficients with the insertion loss are be observed for the bass response: ($r = -0.93^*$) and feedback path: ($r = 0.90^*$), but not for the subjective occlusion effect ($r = 0.83$ (n.s.)).

Correlations with the nominal acoustic mass are only given for the vented earmolds, since it is not defined for the closed ones. High correlations ($r > 0.9$) are seen between the acoustic mass and the bass response as well as the feedback path, whereas it is lower for the insertion loss (see also above) and the subjective occlusion effect. Note that the *Hollow* Earmold and the *StepVent* earmold deviate from the general behaviour of the other

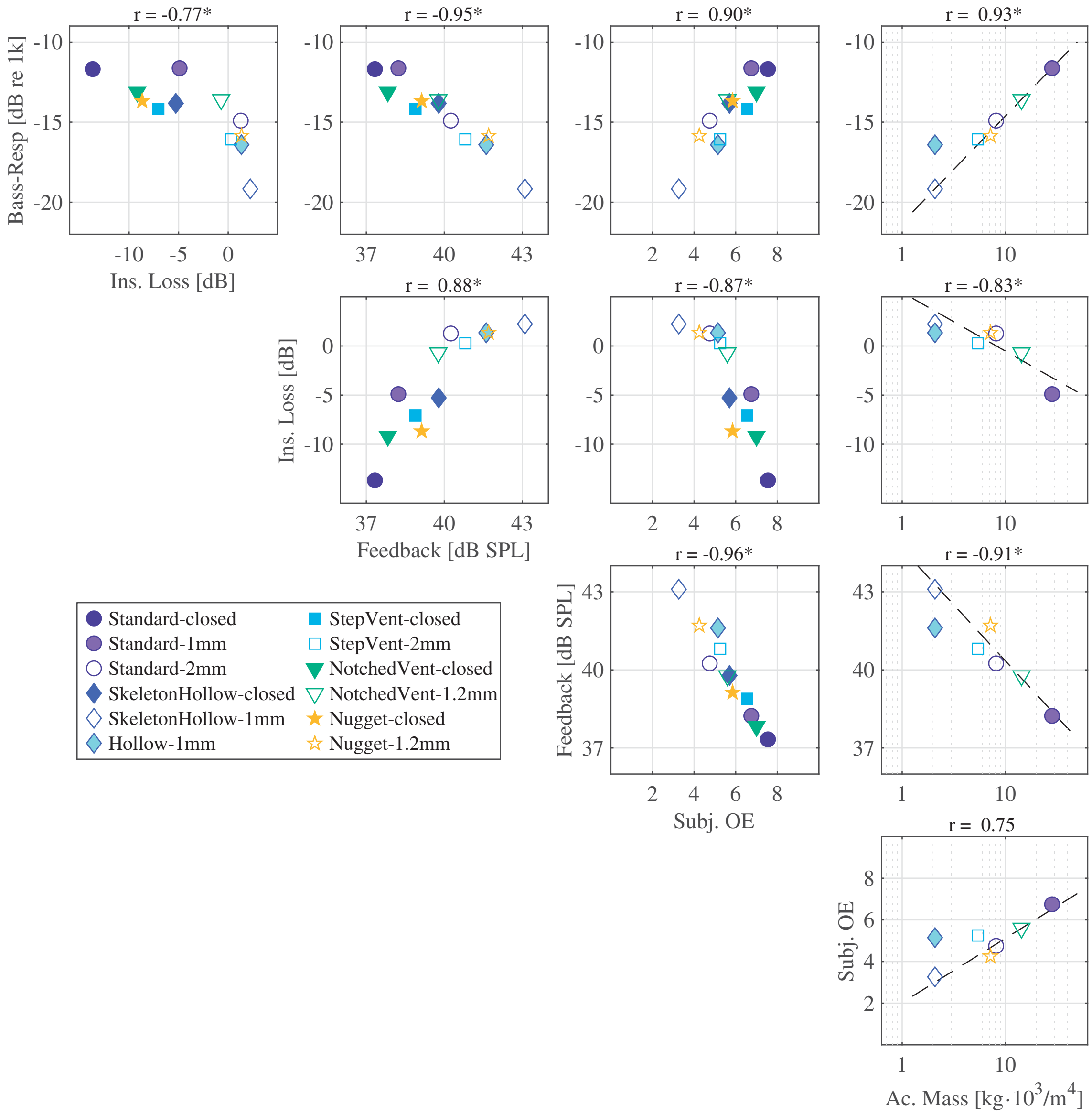


Figure 4. Correlations between parameters as given on the x and y axes. Each symbol denotes the average across subjects for the earmold as specified by the symbol. Panel titles denote separate Pearson's correlation coefficients between quantities on the x and y axes, stars behind values indicate statistically significant correlations.

designs (see below). To illustrate this, the dashed lines in the rightmost panels of Figure 4 show the regression line between acoustic mass and the appropriate quantity computed with results from the *Standard*, *Notched Vent*, *Nugget*, and *Skeleton Hollow* earmolds. For all metrics, the result for the *Hollow* earmold deviates from the other designs, namely it has a higher bass response, a lower feedback path and a higher subjective occlusion effect as compared to the other designs. Also, the subjective occlusion effect with the *Step-Vent* earmold is shifted up from the regression line, i.e. it is higher than expectable from the acoustic mass of the vent. Leaving the *Hollow* and *Step-Vent* earmolds out of the calculation, i.e. only considering vented earmolds with identical inner fitting zone, the correlation coefficient between acoustic mass and subjective occlusion effect is 0.97.

Comparison of earmold designs

Figure 5 shows a further condensed version of the performance metrics for each earmold, summarising the own-voice perception and coupling quality as trade-off parameters. To this end, scores on a scale from 1 to 10 were computed, where the best earmold received 10, the worst earmold a 1, and the remaining earmolds were linearly rated based on the underlying metric. For the own-voice perception, the average of the original ratings of the subjects judging the naturalness of the own voice were taken. To summarise the coupling effects, a rating as described above was computed both for the driver response (high values as best rating) and the insertion loss (low values as best rating), and the rating scores averaged. The resulting number contains both vent-in and vent-out effects. Due to the high correlation between the driver response and the feedback path (see above), the driver response was taken as the sole descriptor of vent-out effects. As a single rating score, the sum of the rating scores for the own-voice and coupling effects is shown above each column group.

Figure 5 clearly illustrates the trade-off between own-voice quality and coupling effects: The earmold with the highest own-voice quality (vented *Skeleton Hollow* earmold) showed the worst coupling parameters, while the closed *Standard* earmold, which showed the best coupling performance, received the worst

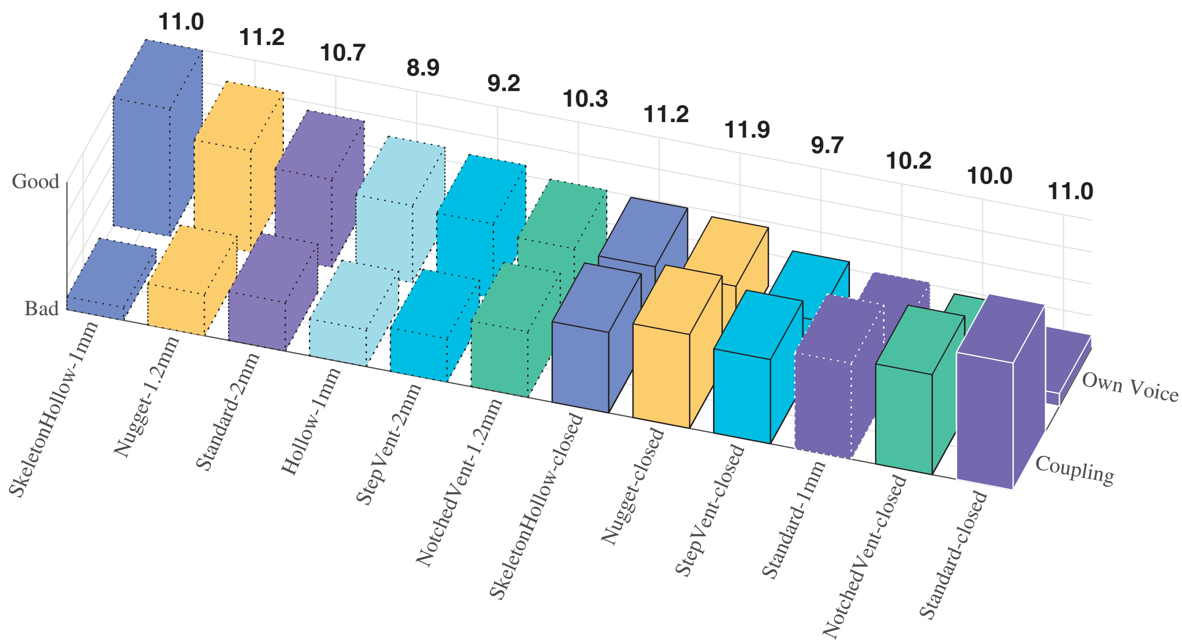


Figure 5. Comparison of average coupling (front row) and own-voice quality (rear row) of earmolds, each transformed to a scale from 1 (worst in dataset) to 10 (best in dataset). Higher bars indicate better performance. Numbers above column groups indicate the sum of both scores, indicating an overall ranking score. Earmolds are sorted from left to right with descending own-voice quality.

own-voice ratings. In between, the ownvoice quality decreases as the coupling quality increases, but not in a strictly monotonic manner. Among the vented earmolds, especially the *Nugget*, *Standard* (2 mm vent), *Hollow* and *Step-Vent*, the coupling quality is very similar, while the best own-voice quality is seen with the *Nugget* earmold. The *Nugget* earmold also achieved the highest overall score. Similarly, the vented *Notched-Vent* received only slightly poorer own-voice ratings than the vented *Hollow* and *Step-Vent* earmolds, while its coupling performance is notably better. In agreement with these observations, the *Hollow* and *Step-Vent* earmolds achieved the poorest overall ratings.

A similar trend can also be seen in the closed earmolds: With increasing own-voice quality, coupling effects generally get poorer. With the *Skeleton Hollow* earmold, the highest own-voice quality among the closed earmolds is achieved, followed with a small difference by the *Nugget* earmold, which in turn shows better coupling performance. The best overall rating score is also seen in the closed *Nugget* earmold.

Discussion

Importance of the opening of the ear canal

Overall, the high correlations between metrics (Figure 4) and the general trade-off between coupling and own voice quality (Figure 5) showed that the opening of the ear canal is the underlying mechanism that determines most of all assessed parameters. However, the present investigation revealed some interesting deviations to this dependence in some earmold designs, namely the *Hollow* and the *Step-Vent* earmolds. Common to the remaining earmolds was the identical medial sealing zone, i.e. the innermost zone where they are in full contact with the ear canal walls, lies at the same location. In these earmolds, when they included a vent, the measured parameters were well predicted by its acoustic mass. The strong correlation between the logarithm of the acoustic mass and the subjective occlusion effect ($r = 0.97$ without *Hollow* and *Step-Vent* earmold) is in excellent agreement with the results reported by Kiessling et al. (2005), who only used standard and a different realisation of hollow earmolds. These results are also in line with results by Kuk et al. (2009) showing that vent effects between solid and hollow earmolds can be seen as equivalent if adjusted for the acoustic mass. To summarise, based on our data we agree with previous studies that the acoustic mass of the vent predicts the behaviour of an earmold very well, with the constraint that this holds only for earmolds with identical inner sealing zone.

The only quantity that showed a weaker dependence on the acoustic mass is the insertion loss. This can be probably attributed to the fact that it cannot be larger than some dB above zero, resulting in an upper boundary that is already reached at intermediate acoustic vent masses around 10 000 kg/m^4. If the full frequency range would be considered for the average, the larger differences between vented earmolds above approx. 1 kHz as shown in Figure 3 would probably lead to a better correlation with the acoustic mass. However, the insertion loss in a hearing aid context is only audiologically relevant at low frequencies below 1 kHz, since at higher frequencies the hearing aid output dominates the leakage sound in virtually all cases.

With closed earmolds, factors other than a vent dominate the opening of the ear canal. Although no opening is actually intended here, acoustics leaks are generated by reducing contact areas between the earmold and skin that usually lead to a tight fit (*Nugget*, *Notched-Vent* and *Step-Vent* earmolds), removing material inside the earmold which reduces its mass (*Hollow* earmold), or both (*Skeleton Hollow* earmold). Similar to the vented earmolds, a trade-off between own-voice perception and coupling parameters is seen in the different earmold designs, where some designs seem to be advantageous to others (as discussed below). These observations demonstrate that appropriate modification of the earmold shape can be an alternative means to partially open the ear canal that may lead to similar effects as vents. For illustration, Table 1 also shows the acoustic mass (average across subjects taken on log-values) that can be assigned to the each earmold based on the linear regression for bass response and subjective own-voice occlusion effect shown in Figure 4. Note that the equivalent acoustic masses deviate between the different metrics it was derived from, which is a consequence of the imperfect linear regression, as well as differences between earmolds as discussed below. The best correspondence to the nominal acoustic mass of the vented earmolds is seen for the equivalent acoustic mass obtained from the bass response, whereas the difference between earmolds is more pronounced for the equivalent acoustic mass derived from the subjective occlusion effect. The *Skeleton Hollow*, *Step-Vent* and *Nugget* earmolds show equivalent acoustic masses that are in the range of the other vented earmolds (below 15.000 kg/m^4), which is in line with the coupling parameters and occlusion effects (c.f. Figure 5).

It should be noted that with closed earmolds, very small changes in the fit may dramatically change the acoustic behaviour. In our data, this is verified by a much larger between-subject variation in the closed versus vented earmolds (see Supplementary material). Although effects of a vent are well controllable, the effects of small changes in fit could not be controlled even in the well-supervised present study. In turn, an imperfect seal might be detected by the user and corrected on the fly.

Earmold designs options and coupling effects

Earmold designs where a deviation from the predictive properties of the acoustic mass was observed included the *Hollow* and the *Step-Vent* earmolds. The reason for the discrepancy to the results with other earmolds probably have different reasons and are discussed separately.

The *Step-Vent* earmold includes a shortening of the vent by removal of material at the medial lower part of the earmold, such that the vent is largely increased to the residual ear canal diameter in this region (c.f. Figure 2). This decreases the acoustic mass of the vent and leads to a desired larger opening of the ear canal (see also Table 1). In comparison to the *Standard* earmold with equivalent vent diameter, in the present data the *Step-Vent* showed an increase in feedback path and reduced bass response that were in line with the change in acoustic mass (Figures 3–5). However, in spite of the larger ventilation of the ear canal, the subjective occlusion effect with the vented *Step-Vent* earmold was approx. 1.5 rating points larger than appropriate for its acoustic mass (Figure 4). This is probably due to the fact that in the *Step-Vent* design, the sealing zone is effectively moved outwards. In consequence, a larger area of the cartilaginous part of the ear canal walls is exposed to the residual ear canal volume. More sound flux generated by bone-conducted parts of the own voice is thus directed into the residual ear canal volume, leading to higher low-frequency levels and thus a higher subjective occlusion effect. This interpretation is generally consistent with previous studies reporting a higher occlusion effect for shallower inserted earmolds/earplugs (Blau et al. 2008; Carillo, Doutres, and Sgard 2020; Stenfelt and Reinfeldt 2007). In the present data, the occlusion effect with the *Step-Vent* design was higher than observed with a standard earmold of equal diameter, i.e. higher acoustic mass. In conclusion, according to our data a *Step-Vent* is not helpful, but even detrimental in reducing the occlusion effect – while coupling performance is reduced according to the reduction of acoustic mass of the vent, the occlusion effect is not reduced or even increased due to the altered sealing zone.

The other earmold design that showed a significant deviation from the behaviour expected due to the acoustic mass of the vent was the *Hollow* earmold. This behaviour is unexpected given previous results (Kiessling et al. 2005; Kuk, Keenan, and Lau 2009), which showed an equivalence of venting behaviour between *Hollow* and *Standard* earmolds. In turn, in the present data the *Skeleton Hollow* earmold showed a behaviour that was well in line with its acoustic mass. It should be added that the hollow earmolds in the previous studies (Kiessling et al. 2005; Kuk, Keenan, and Lau 2009) were restricted to the ear canal. While the hollow earmolds of Kuk et al. (2009) hat a thickness of 0.7 mm, Kiessling et al. (2005) provided no information on this issue. Both design differences may have influenced the behaviour of the hollow earmolds in the three studies. In the present data, the *Hollow* and *Skeleton Hollow* earmolds had an identical vent, and the only difference between the two were the slits at ear canal walls in the *Skeleton* version. Comparing the performance of the two designs, the *Hollow* earmold showed a higher occlusion effect and bass response, and a lower feedback path and insertion loss, i.e. it generally behaved more closed regarding all measured quantities. This behaviour is understandable given the reduction in fitting zones with the *Skeleton Hollow* earmold, which introduce additional small leaks around the earmold and further reduce its mass. However, our initial expectation was that the *Hollow* earmold would behave like a *Standard* earmold with equivalent vent size, while the *Skeleton Hollow* earmold would introduce another opening. We cannot provide a solid explanation for this discrepancy based on the present results. It is unlikely that the reason is a biased estimation of the acoustic mass of the vent, e.g. due to the geometry of the remaining earmold that effectively increases the vent length, since the vent length appropriate for the behaviour of the *Hollow* earmold is simply too large (increase to approx. 5 mm length). One possible explanation for the unexpected behaviour is the low mass of the *Hollow* earmold, which may lead to vibration resonances that affects its behaviour, e.g. conduct vibrations from the ear canal walls to the residual ear canal volume (Hansen 1998).

The remaining earmold designs, i.e. *Nugget* and *Notched-Vent*, showed no significant difference in behaviour to the *Standard* earmold after the effect of the acoustic mass is accounted for. In turn, this means that the initial motivation that removal of material around the location of the mandibular condyle reduces the occlusion effect by reducing the coupling of body-conducted sound in this region, cannot be supported. Also, no notable effect of multiple jumps in cross-section in the *Notched-Vent* design on the feedback path could be observed. However, the data showed that such material removal is not detrimental from an acoustic point of view, such that there is no reason against such design options due to reasons of wearing comfort, as long as the medial sealing zone is kept intact. Wearing comfort was not explicitly assessed in the present study, and a formal assessment in future studies may yield an additional important quality criterion. Shortening the vent by removing material along the ear canal walls from the lateral side of the earmold seems like a good design option, and an alternative to *Hollow* earmolds that may bear drawbacks in acoustic behaviour and wearing comfort. Especially designs similar to the *Nugget* earmold included here seem promising, since short vents are possible and a large wearing comfort is expectable in spite of a deep fit, since the ear canal is free in regions where dynamic movements during speaking and chewing are present (Voogt 2013). Also, body sounds generated around the mandibular condyle and further lateral are effectively conducted outwards. Although a significant benefit against standard earmolds after correction for the acoustic mass could not be shown, it should be noted that the *Nugget* earmold achieved the highest overall ratings as shown in Figure 5.

Conclusions

The opening of the ear canal as described by the acoustic mass of the vent is the dominating factor for the perceived occlusion effect and coupling quality of an earmold. The acoustic mass of the vent is highly predictive for the occlusion effect and all acoustic performance metrics, however, comparison between earmolds by means of the acoustic mass of the vent can only be made if they provide an identical innermost sealing zone in the ear canal. Similar effects as a vent can be created by earmold modifications, in particular material removal in the canal stalk that reduce the seal. An innermost sealing zone that is as deep as possible is key for a low occlusion effect. Shortening of the vent to reduce its acoustic mass as well as reducing contact zones with the ear canal walls to improve the waring comfort should thus be implemented by removing material from the lateral, not medial end of the earmold. While doing so, reducing contact of the canal stalk with the dynamic parts of the ear canal may give an additional benefit.

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Ethical approval

The study was performed in accordance with the Declaration of Helsinki. All subjects signed a written informed consent before participating voluntarily. The study was approved by the Ethics council of the Technical University of Applied Sciences (Technische Hochschule) Lübeck.

Disclosure statement

The authors declare no conflict of interests.

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Data availability statement

3D models of the earmolds and ear impressions are available at https://doi.org/10.5281/zenodo.5569300. Plots of single-subject data and vent parameters for each earmold are provided as Supplementary material. Further data are available from the corresponding author upon reasonable request.

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