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The Acoustics of Instant Ear Tips and Their Implications for Hearing-Aid Fitting

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Objectives: Today, approximately 70 to 80% of hearing aid fittings are made with silicone instant ear tips rather than custom earmolds. Nevertheless, little is known about the impact of instant ear tips on the acoustic coupling between the hearing aid receiver and the individual ear canal, even though it can have a major impact on the overall sound of the hearing aids. This study aimed to investigate the acoustic properties of different instant ear tip types and their across-subject variability, the within-subject reliability of those properties, and the influence of the users' level of experience with ear-tip insertion on the acoustics. Furthermore, subjective ratings of occlusion produced by the ear tips were considered.

Design: Five types of instant ear tips (Open, Tulip, Round [2-vent], Round [1-vent], Double Domes) provided by the hearing aid manufacturer Widex were considered in this study. Probe-microphone measurements were performed at the eardrums of 30 participants (60 ears). In the first experiment, the real ear occluded insertion gain and the vent effect (VE) were measured, and the listeners rated the subjective occlusion experienced with each ear tip. In the second experiment, the same measurements were repeated six times per participant. The within-subject variability of the acoustic ear tip properties was investigated as well as the impact of the degree of users' experience with ear tip insertion on the resulting real ear measurements.

Results: All tested ear tips were, on average, acoustically transparent up to 1 kHz except Double Domes, which were only transparent up to 600 Hz. Distinct VE profiles were found for each ear tip type, but a large across-subject variability was observed for both real ear occluded insertion gain and VE. However, the within-subject reliability was high. The measured VE was highly correlated with the perceived occlusion. Finally, no significant effect of the level of experience in ear tip insertion on the acoustic properties of the ear tips was found, but the within-subject variability was larger in the less experienced group.

Conclusions: These results suggest that the acoustic properties of instant ear tips and their coupling to the individual ear canal impact the resulting hearing aid fitting and should be considered by the hearing care professionals and reflected in the fitting software. The high within-subject reliability indicates that the ear tip acoustics remain stable for the individual in daily use. Finally, real ear measurements should be considered an essential part of the hearing aid fitting process in clinical practice to ensure an optimal fit for the individual hearing aid user.

Key words: Acoustics, Ear Canal, Hearing Aids, Instant Ear Tips, Occlusion, Real Ear Measurements, Vent Effect.

Abbreviations: HA = hearing aid; ICC = intra-class correlation; RECD = real ear to coupler difference; REIG = real ear insertion gain; REM = real ear measurement; REOG = real ear occluded gain; REOIG = real ear occluded insertion gain; REOR = real ear occluded response; REUG = real ear unaided gain; REUR = real ear unaided response; RIC = receiver in the canal; SNR = signal-to-noise ratio; VE = vent effect.

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INTRODUCTION

Whenever a hearing aid (HA) is worn by a user, an earpiece is needed to ensure efficient acoustic coupling between the HA loudspeaker (generally referred to as the receiver) and the user's ear canal. For behind-the-ear HAs, this has traditionally been accomplished with a custom-made earmold, manufactured after an impression made during the first visit to the hearing care professional. While such earmolds provide very efficient acoustic coupling and high resistance to feedback, they also create some issues. Prime among those is the occlusion effect, that is, the increase in sound pressure at the eardrum at frequencies below 1000 Hz that occurs when the ear canal is covered or blocked (Dillon 2012; Pohlman & Kranz 1926; Stenfelt et al. 2003). Dillon (2012) and Mejia et al. (2008) showed that the occlusion effect was most pronounced in the octave band centered around 315 Hz, which roughly coincides with the frequency of the first formant of the vowels /e:/ and /i:/ (Zurbrügg et al. 2014). The occlusion effect can impact the user's perception of their own voice, which they describe as sounding unnatural, boomy, hollow or echoing (Carle et al. 2002). A common measure to reduce the occlusion effect is to drill a venting hole through the earmold, thereby opening up the ear canal to the environment. However, this not only reduces the occlusion effect experienced by the user, but it also changes the properties of the acoustic coupling provided by the earmold.

The overall sound at the HA user's eardrum is the result of the superposition of two components: the direct sound generated outside the ear canal and transmitted to the eardrum through the vent, and the sound amplified by the HA. The transmitted direct sound component is shaped by the real ear occluded insertion gain (REOIG). This term is also often referred to as the insertion loss. However, that term is ambiguously defined in different places. Therefore, we chose to use the term REOIG instead, as described in Dillon (2012). The REOIG is calculated as the difference between the real ear occluded response (REOR; ANSI-S3.46-1997, 2011), measured with the turned off HA and the ear tip placed inside the ear canal and the real ear unaided response (REUR; Dillon 2012). This measure describes how efficiently the ear tip works as an earplug and how much it affects the level of the incoming sound. The HA-amplified sound is affected by the vent effect (VE), which describes the difference between the response level of the amplified sound at the eardrum compared to that in a fully occluded ear canal

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(Dillon 2012; Kuk & Nordahn 2006; Studebaker et al. 1978). Increasing the size of the vent results in a level decrease at low frequencies, which is inversely proportional to the acoustic mass of the vent (Kuk et al. 2005, 2009).

For custom earmolds, the relationship between the vent size and their acoustic properties is well documented (Dillon 2012; Kiessling et al. 2005; Kuk et al. 2005, 2009), but over the last 15 years, instant ear tips made of silicone have increasingly replaced traditional custom earmolds in HA fittings. Instant ear tips are now used in about 70% of all HA fittings (Smith et al. 2008; Sullivan 2018). Although instant ear tips can be used with behind-the-ear hearing aids with thin tubes, the increased number of receiver-in-canal (RIC) HAs being sold has contributed strongly to this trend. In the United States, for example, RIC-style HAs constituted a total of 81.7% of all HAs dispensed in the first half of 2019 (Hearing Review 2019). There are many reasons for the high market share of open-fit instant ear tips. They do not require impressions, offer improved wearing comfort and cosmetics, and result in high customer satisfaction (Johnson 2006; Kuk et al. 2005; Mueller & Ricketts 2006; Winkler et al. 2016).

Instant ear tips range from types that aim to provide an open fit to those that aim to completely occlude the ear canal. Occluded fittings have no vents, but leakage due to the imprecise fitting of the ear tip will commonly allow sound to pass into or out of the ear canal (Winkler et al. 2016). While the underlying acoustic principles are identical for custom earmolds and instant ear tips, the slit leak venting of instant ear tips might dominate their acoustic behavior, which in turn may be more variable and less well defined than for custom earmolds due to the softness of the ear tips.

Some studies have investigated the properties of open ear tips [see Winkler et al. (2016) for an overview]. Taylor (2006) reported better satisfaction in daily life with open fit HAs with respect to sound quality of the user's voice, appearance, localization, wind noise, and the sound of chewing or swallowing. Furthermore, instant ear tips generally reduce the occlusion effect (Kiessling et al. 2005). However, the opening of the ear canal can also introduce some challenges to the signal processing of the HAs compared with conventional closed earmolds. Blau et al. (2008) and Borges et al. (2014) reported lower gain before feedback, while Ricketts (2000), Keidser et al. (2007), and Magnusson et al. (2013) have shown reduced benefit of directional microphones and noise reduction. Nonetheless, for people with relatively normal hearing at lower frequencies open fits may still be the better option (Mueller & Ricketts 2006).

For instant ear tip types other than open, the literature is relatively sparse. Blau et al. (2008) examined the real ear to coupler difference (RECD) and the REOG-REUG (here called REOIG) of custom earmolds with and without vent and of three types of instant tips (Open Domes, Closed Domes and Power Domes) on 20 test subjects. They found differences in the acoustic properties of the tested ear tips and considerable variability across subjects on both measures. Coburn et al. (2014) found significant differences between three tips (Open, Occluded, and Power) in terms of VE as well as large variability between subjects, indicating that ear tips can have different acoustic properties depending on individual ear canal characteristics. However, the sample size in this study was very small (7 participants). Jespersen & Møller (2013) investigated the test-retest reliability of real ear insertion gain (REIG) measurements for 10 normal hearing listeners for a moderate hearing loss (N3, IEC 60118-15, 2008) for three types of instant ear tips and for custom earmolds for both receiver-in-the-aid and receiver-in-the-ear HAs. They found a high reliability across measurement conditions, between tests and across two examiners, despite their initial expectation to find greater variability for instant ear tips than for traditional behind-the-ear HAs with custom earmolds. Unfortunately, they only presented data for the difference between measures, not actual REIG data.

To the authors' knowledge, there are no published data about the within-subject variability of the acoustic characteristics due to repeated insertion, and due to insertion by either the hearing care professional or the HA user. Typically, in the initial fitting session, the ear tip is inserted by the hearing care professional, but in daily use, the HA users insert the ear tips themselves. If the acoustics change between these two situations, this too might impact the sound experienced by the HA user.

The initial fitting of a HA to the individual HA user is usually based on a gain prescription or desired response level at the patient's eardrum from a fitting rule based on their audiogram. Hence, the overall gain or sound pressure at the HA user's eardrum needs to be computed and the acoustic effects of the earmold or ear tip must be known and considered to match the fitting target (Aazh et al. 2012). If the acoustic properties of the coupling are unknown, a good match to target can also be achieved if hearing care professionals perform real ear verification measurements to evaluate the initial fitting. However, this is routinely done by only 40% of hearing care professionals (Mueller & Picou 2010), whereas the remaining hearing care professionals rely on the estimated gain or response curves provided by the manufacturers' software (Amlani et al. 2016).

This study investigated the acoustic properties (REOIG, VE) and the perception of occlusion for five types of instant ear tips ranging from open to closed, as well as the within- and across-subject variability of those measures across ear tips. Additionally, the impact of the difference in ear-tip insertion experience between test leader and test subjects on repeated measures of REOIG and VE for different ear tips was investigated.

METHODS

The study was conducted at the laboratories at the Widex headquarters in Lynge, Denmark. Ethical clearance for conducting the study was obtained from the Research Ethics Committee of the Capital Region of Denmark (case no. H-18056647). The study included two experiments. Experiment 1 focused on the REOIG, VE, and occlusion ratings and their variability across test subjects. Experiment 2 investigated the within-subject variability of the REOIG and VE and the impact of experience with ear tip insertion. Each of the two experiments lasted between 1.5 and 2 hours per subject.

Test Subjects

Thirty normal-hearing subjects (10 female) who did not suffer from hyperacusis participated in the experiment. The average age was 45 years (min. 19, max 67). All participants were Widex employees, and they were not paid any additional compensation for their participation. Eighty percent of the participants reported no or very little previous practical experience with HAs and the insertion of ear tips in the ears. Normal hearing was required because this made communication between test subject and test leader possible, also in conditions where the HAs were turned off or where the ears were occluded with impression material. The test subjects were screened before the experiment to determine the ear tip size and wire length required for their ears. The resulting overall distribution of ear tip sizes was compared with the internal worldwide sales numbers for Widex ear tips. The size distributions matched well, except for Open, where large tips were over-represented in the study and for Double Domes, where large tips were under-represented. Before the experiment, the test subjects received written information about the experiment and gave written informed consent to their participation and to the use of the resulting anonymized data for publication.

Procedure and Apparatus

The test subjects were seated in a chair facing the real ear measurement (REM) system, at 1 m distance and an azimuth of 0 degrees. The loudspeaker was placed at a height of 1.2 m in an acoustically dampened, double-walled audiometry room. A pair of Widex Evoke 440 Passion RIC HAs with 'S' receivers was used for all measurements. No retention tools (anchors) were used with the receivers. The five instant ear tips under investigation were the following: Widex Open, Tulip, Round (2-vent), Round (1-vent), and Double Domes (see Fig. 1). The testing order of the ear tips was counterbalanced across test subjects to avoid order effects.

All REMs were performed with the Affinity 2.0 measurement system (Interacoustics A/S, Middelfart, Denmark). The analysis inside the system is based on an FFT length of 1024 samples at a sampling frequency of 44100 Hz with a Blackman-Harris window and no overlap, resulting in a spectral density with a frequency resolution of 43 Hz and 231 values within the measurement range from 100 Hz to 10 kHz. All measurements were averaged over 10 s.

Experiment 1

Measurement of REOIG • After an initial otoscopic examination of the ear canal and the calibration of the probe microphones relative to the reference microphone of the REM equipment, the probe tubes were placed inside the ear canals, and it was checked through the otoscope that the end of the tube was placed close to the eardrum. A first frequency spectrum was measured without a measurement signal to estimate the level of the background noise inside the room. Then, REURs were measured using pink noise played back from the Affinity system at a level of 65 dB SPL measured at the field reference point microphone of the REM probe. If the first REUR measurement showed an unexpected drop in level at high frequencies, the probe tubes were repositioned closer to the eardrum and the measurement was repeated. Then, the HAs were placed on the ears, and the ear tips were inserted into the ear canal with the probe tubes still in place. Subsequently, real ear occluded responses (REORs) were measured with the HAs switched off. The REOIG was computed as the difference between the two measurements in dB (REOIG = REOR – REUR). This procedure was repeated for all five instant ear tips.

Measurement of the VE • As the VE is mainly a low-frequency phenomenon, brown noise was used as the measurement signal, because its spectral emphasis at low frequencies allows for a better signal-to-noise ratio (SNR) in the region of interest (cf. Fig. 2, dash-dotted line). All measurements were based on the same noise file with a length of 60 s and an RMS level of −14.5 dB FS. The playback was controlled via a graphical user interface in MATLAB (The MathWorks, Inc, Natick, Massachusetts). The audio signal was played through an RME Audio Fireface UCX audio interface and streamed to the HAs via a Widex TV-DEX streaming device, which was connected to a stereo analog output of the audio interface. The level of the TV-DEX was adjusted to 20 steps below the maximum setting, which corresponds to the middle of the adjustment range and, with the given audio signal, falls within its linear transmission range. The HAs were programmed to provide 10 dB of linear gain in all 15 frequency bands, and all adaptive processing was deactivated. Linearity of TV-DEX and HAs was verified by measuring an input/output curve for a 1 kHz signal played via the audio interface. The acoustic HA output signal was measured using a Brüel & Kjær Pulse system 4. The HA gain value of 10 dB was chosen 'by ear' to achieve an overall HA output signal that was loud for the test subjects but not disturbingly so to maximize the measurement SNR. With these settings, the overall signal chain resulted in a sound pressure level of 84 dB(A) in a G.R.A.S. RA0045 ("711") ear simulator. For an estimated overall measurement time of 10 min throughout the experiment, this corresponds to a noise exposure level normalized to a nominal 8 h working day of 67 dB(A). Even allowing for some variability of the actual level at the eardrums of the individual test subjects due to differences in the residual ear canal volume, this value was well below the critical level of 85 dB(A) specified in ISO 1999:2013 and did not pose a risk for causing a permanent hearing threshold shift. The speech mapping feature in the Affinity system was used in combination with the Live Voice option to measure the frequency spectrum of the noise at the eardrum when the ear tip was inserted in the ear.

The first measurement was performed in a "Normal" fitting mode, that is, with regular placement of the ear tip like in daily use (see Fig. 2, left image). Subsequently, the ear canal and the concha were completely filled with impression material all the

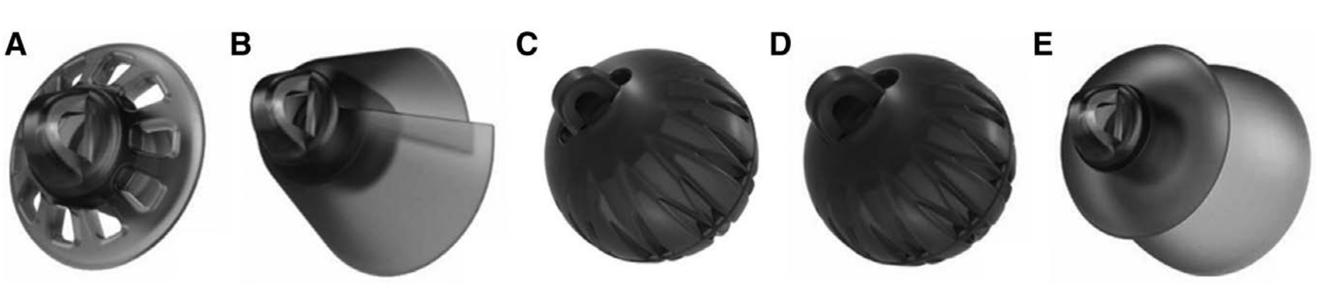

Fig. 1. Instant ear tips used in this study: Open (A), Tulip (B), Round (2-vent, C), Round (1-vent, D), Double Domes (E).

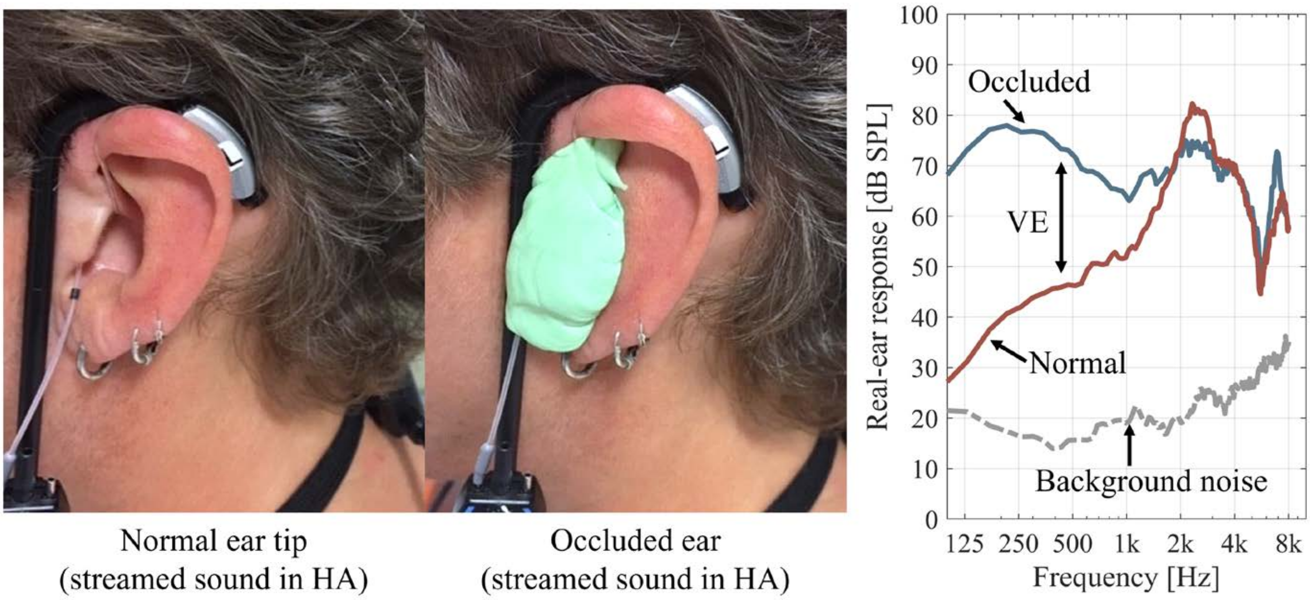

Fig. 2. VE estimation method. Responses were measured with brown noise streamed to the HAs both normally and with the ear occluded with impression material. The VE was computed as the difference between the two responses (normal – occluded). The dash-dotted line in the right panel represents the background noise inside the room as measured by the probe microphone inside the ear canal. HA indicates hearing aid; VE, vent effect.

way to the ear tip with the receiver, ear tip, and probe tube still in place. This allowed for a reference measurement of a fully occluded response with no leakage. This fitting mode is referred to as "Occluded" (see Fig. 2, right image). The occluded response was also used by the test leader as a verification tool to spot and correct potential errors in the measurement like an obstructed or squeezed probe tube. The VE was computed as the difference between the spectra measured in the Normal fitting mode and in the Occluded fitting mode in dB. The difference between the Normal spectrum and the background noise spectrum in dB was used to estimate an SNR for each frequency bin. It was assumed that each bin with an SNR of at least 10 dB could be considered reliable. This SNR was nearly always achieved, except in some cases in the lowest frequency bins in measurements with the more open ear tips.

REOIG and VE measurements were done sequentially in the data collection, that is, the probe tube and the ear tip remained in the exact same position throughout these measurements.

Subjective Occlusion Ratings • The test subjects were asked to utter the names of the months of the year in Danish and rate the perceived occlusion based on the sound of their own voice on a scale ranging from 0 (no occlusion, "like normal listening") to 10 (complete occlusion, "as if they stuck their fingers in their ears"). These scale references were established with the subjects in a training run before the actual experiment. The familiar words allowed participants to concentrate on the perceived occlusion while speaking. Vowel statistics of the words revealed that 14 of the 33 vowels were either /e:/ or /i:/, whose first formants F1 fall around 300 Hz and cause a strong occlusion effect. The subjects were instructed to report whether the occlusion was equally strong on both ears. In case of unequal occlusion, they were instructed to rate the ear with the higher perceived occlusion and to indicate which ear they rated. The occlusion ratings were done with the HAs turned off and the subjects rated the occlusion with ear tips inserted in both the Normal and the Occluded fitting mode.

In addition, all measurements were performed in 2 conditions (1) "Normal": after the insertion of the ear tip and (2) "Movement": the test subjects were asked to open and close their mouth as if they were eating a big apple, that is, doing exaggerated jaw movements while wearing the HAs. After the jaw movements, the same REMs were repeated. This condition was added to investigate whether changes in the REOIG/VE are to be expected when wearing the HAs throughout the day, where jaw movements might cause lateral migration of the ear tips.

Experiment 2

The Reliability Experiment • The second experiment focused on the reliability of the REOIG and the VE results when ear tips are inserted repeatedly on the same person. The test was conducted with the same five instant ear tip types (Open, Tulip, Round 2, Round 1, Double Domes) and same test participants as in Experiment 1. To keep the experiment duration within reasonable limits, each test subject was only tested with two of the five ear tips during the second experiment and the frequency spectra from the Occluded fitting mode measured with impression material were re-used from Experiment 1. Each ear tip type was tested by 10 test participants and the REOIG, and VE measurements were repeated 6 times per ear tip. In the first three measurements, the ear tip was inserted by the test leader, and in the remaining three measurements the ear tips were inserted by the test subject themselves. The repetition of the insertion by both test subject and test leader was performed to investigate whether the level of experience in tip insertion would lead to differences in the resulting VE and REOIG curves or in the variability between repetitions. Such differences between test subject and test leader might be problematic. This would indicate differences between the fitting session in the clinic with the hearing care professional inserting the ear tip and at home, where the user inserts the ear tip.

Before the experimental session, the test subjects were trained in inserting the ear tips into their ears, and the experiment commenced once the test subjects were able to correctly place the tips. The probe tube was kept inside the ear canal, whereas the ear tip was removed and placed again between measurements. The probe tube was only re-positioned if it slipped out of the ear canal in the process. A new REUR measurement was performed before every insertion of the ear tip, which was then used to calculate the REOIG. This was done to account for such changes between the individual REORs as might be attributed to slight changes in probe tube placement.

Statistical Analysis

For the statistical analysis, the powers of the REOIG and VE results were averaged in 1/3 octave bands, and then the dB values were further averaged into five frequency bands (200 to 400; 500 to 1000; 1250 to 2000; 2500 to 3150; 4000 to 8000 Hz). This was done to reduce the data from 17 to 5 frequency bands and hence to reduce the number of statistical tests to be conducted. A two-way repeated measures ANOVA was conducted to examine the effect of ear tip type (Open, Tulip, Round 2, Round 1, Double), and condition (Normal, Movement) on REOIG and VE. If overall significance was observed, post-hoc analysis was performed using Bonferroni adjustment for all pairwise comparisons. To assess how closely related the subjective occlusion ratings were to the measured VE, Spearman's correlation coefficient was calculated between the absolute value of the VE in the 315-Hz 1/3-octave band and the corresponding occlusion rating. This frequency band was selected as a representative single-number predictor for occlusion. Spearman's correlation was computed because subjective occlusion ratings were skewed (most values were <5). One-way repeated measures ANOVA was conducted to examine the effect of experience in ear tip insertion (test leader/test subject) on REOIG and VE. To compare the variability in VE between the two groups, ANOVA was conducted with the standard deviation of the VE across the repetitions as the dependent variable. Prior to the ANOVA, the data were inspected for approximate normal distribution by looking at histograms with overlaid normal density curves. In order to account for potential violation of the sphericity assumption, p values were Huynh-Feldt (if $\varepsilon > 0.75$) or Greenhouse-Geisser (if $\varepsilon < 0.75$) corrected. These statistical analyses were performed in STATA (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC). Within-subject reliability in Experiment 2 was assessed using Bland-Altman analysis and intraclass correlation (ICC). These analyses were performed in Matlab.

RESULTS

The data for one test subject in Experiment 1 were excluded from the analysis due to issues with cerumen occluding the probe tube during some measurements.

Real Ear Occluded Insertion Gain

Figure 3A shows the average and individual REOIG across 58 ears for the five different ear tips. The average results roughly fall into three categories: Open ear tips are mostly transparent for sound generated outside the ear canal, apart from a slight attenuation of about 2 dB at mid- and high frequencies above about 22 kHz. Tulip, Round 1 and Round 2 tips show similar attenuation patterns with a transparent response up to about 1 kHz and a maximum attenuation of about 9 dB (Tulip), 10 dB (Round 2), and 12 dB (Round 1) at frequencies between 2.6 and 2.8 kHz. Double Domes are, on average, only transparent up to about 600 Hz, and they show the highest attenuation of 16 dB at 3 kHz. The data also show high variability between subjects across ear tips, especially for Double Domes. There was an overall significant difference between ear tips for the frequencies 500 to 1000 Hz ($F_{4,519} = 5.71$; $p = 0.02$), 1250 to 2000 Hz ($F_{4,519} = 21.5$; $p < 0.0001$), 2500 to 3150 Hz ($F_{4,519} = 35.37$; $p < 0.0001$), and 4000 to 8000 Hz ($F_{4,519} = 18.59$; $p < 0.0001$). Post-hoc analysis revealed that there were differences in REOIG between most instant ear tips (see Table in Supplemental Digital Content 1, http://links.lww.com/EANDH/B19, for detailed statistics). No significant differences were found between the Normal and the Movement condition or for the interaction between ear tip and condition (all $p > 0.05$), indicating that the REOIG does not change systematically over time despite the excessive jaw movements.

Vent Effect

Figure 3B shows the average and individual VE across 58 ears for each of the ear tips. On average, the largest VE was found for Open ear tips. Here, the VE starts just below 2 kHz and reaches a maximum of about 40 dB around 125 Hz. The response level has a peak between approximately 2 and 6 kHz. This peak is caused by the difference between the two underlying measurements. Subtracting the Occluded response level from the Normal response level obtained with an Open ear tip results in the peak seen in the VE curve. With the Open tip, the natural free-field-to-eardrum response with its prominent resonance between 2 and 4 kHz (cf. Fig. 2, "Normal") is hardly affected. Occluding the ear canal with impression material changes the ear canal from a tube that is open at one end to one that is closed at both ends, which results in a shift of the ear canal resonance to much higher frequencies and consequently a much lower response between 2 and 4 kHz. A similar effect can be observed for the other ear tips that provide a termination of the ear canal that falls somewhere between completely open and completely closed. Tulip, Round 2, and Round 1 show similar responses with a vent loss starting between 1 and 1.5 kHz and a maximum average attenuation between 28 and 30 dB at the lowest frequencies. Double Domes show the least pronounced VE with an average cut-off frequency of about 1150 Hz and an average VE of 24 dB around 125 Hz. There is some variability in the VE measurements between subjects for each ear tip. Open shows the lowest and Double Domes show the highest variability, which was also the case for the REOIG. At the lowest frequencies, the VE with Double Domes varied from as low as 6 dB (nearly fully closed) to as high as 38 dB (nearly completely open).

ANOVA revealed a statistically significant difference between ear tips in the first four frequency bands: 200 and 400 Hz ($F_{4,519} = 25.83$; $p < 0.0001$), 500 to 1000 Hz ($F_{4,519} = 38.91$; $p < 0.0001$), 1250 to 2000 Hz ($F_{4,519} = 42.97$; $p < 0.0001$), 2500 to 3150 ($F_{4,519} = 6.24$; $p < 0.001$). The post-hoc analysis revealed a significant difference between the ear tips for most frequencies (see Table in Supplemental Digital Content 2, http://links.lww.com/EANDH/B42, for detailed statistics), suggesting that all ear tips differ in their resulting VE. The differences are most pronounced in the two lowest frequency bands, which is not

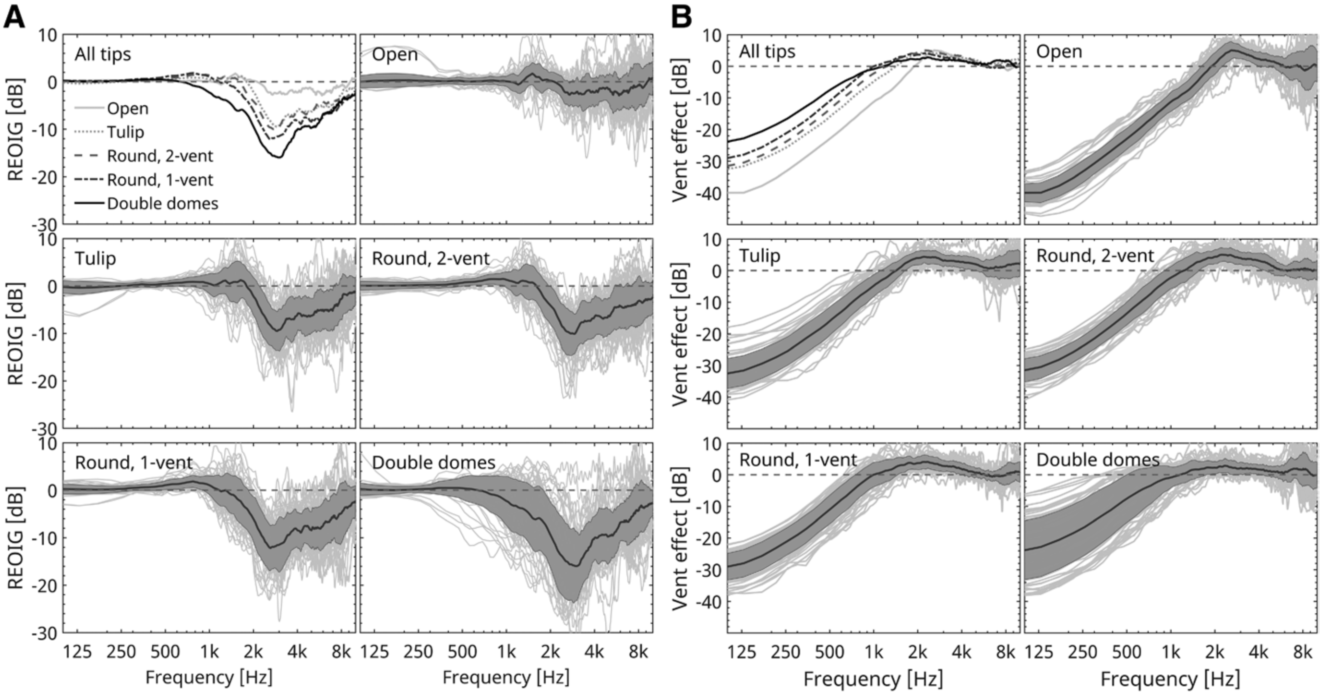

Fig. 3. A, Average REOIG across 58 ears for the five ear tips (top left) and (B) average VE across 58 ears for each ear tip (top left). The remaining panels in each sub-figure show the average REOIG or VE per tip (thick line) +/− one standard deviation (shaded area). The light gray lines represent individual measurements. REOIG indicates real ear occluded insertion gain.

surprising, as the VE mostly affects low frequencies. No significant differences were found for the main effect condition (Normal versus Movement) or for the interaction between ear tip and condition (all $p > 0.05$).

Occlusion Ratings

Figure 4 shows the average occlusion ratings for the different ear tips and for the condition with impression material. On average, open ear tips were perceived as least occluding with an average rating of 0.82, followed by Tulip (2.31), Round 2 (2.87), Round 1 (3.23), and Double Domes (3.74). Most subjects indicated the occlusion to be equal on both ears. The individual ratings showed a trend toward increased variability with increased average occlusion rating. Whereas all ratings for Open tips were between 0 and 4, the occlusion ratings for Double Domes spread between 0 and 8. All average ratings for the Occluded conditions with impression material for the five ear tips were above 9.3. Correlation analysis of the occlusion ratings and the VE showed a significant negative correlation [Spearman's rank correlation coefficient (rho): −0.61, $p < 0.0001$], that is, a larger VE generally results in lower occlusion ratings (cf. Fig. 5).

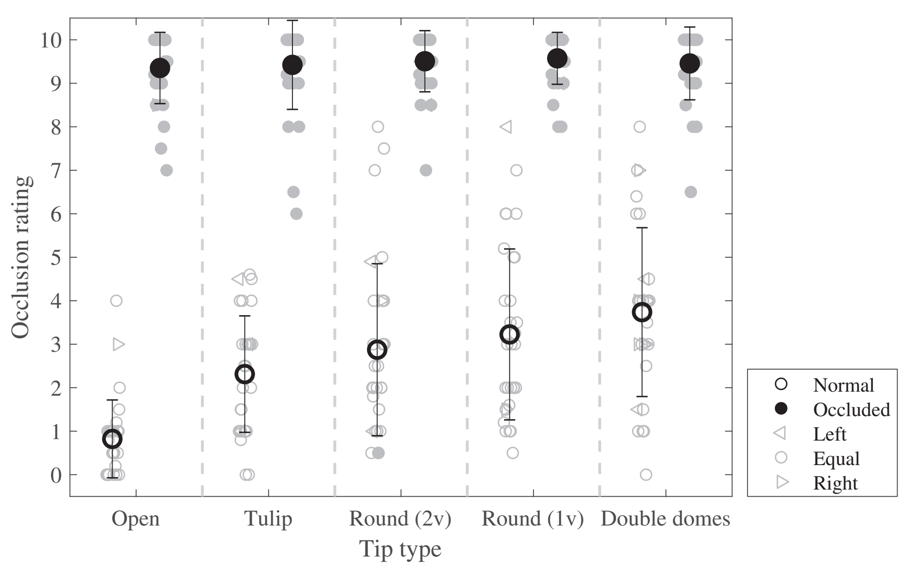

Fig. 4. Individual occlusion ratings (gray) and mean ± 1 SD (black). Circles indicate equal amounts of occlusion on both ears, triangles point in the direction of stronger occlusion.

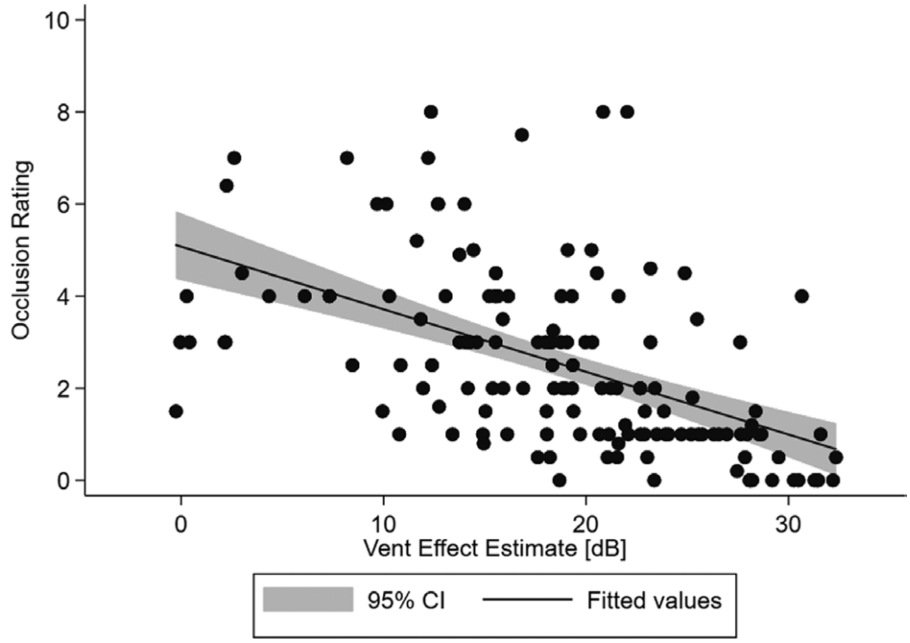

Fig. 5. Correlation between the VE estimate in the 315-Hz 1/3-octave band and the perceived occlusion. The two measures showed a significant correlation ($p < 0.0001$) with a Spearman's rho of −0.61.

REOIG Reliability

ICC and Bland-Altman results are shown in Table 1. The ICC coefficients show agreement or consistency between two measurements, whereas Bland-Altman analyses show the absolute difference between measurements. ICC considers both within- and across-subject variability. If the across-subject variability is small, the ICC can be low, even if the within-subject variability is relatively low as well. In cases where the within-subject variability is higher than the across-subject variability, the ICC coefficient even becomes negative. In such cases, additional Bland-Altman results can be used to assess reliability. The Bland-Altman measure shows the mean of all within-subject differences (termed *bias*) and 95% *limits of agreement* of the bias (±1.96 SD).

The Bland-Altman bias was 0 in all cases, indicating no systematic differences between the six responses. Table 1 shows lower or negative ICC values for Open ear tips at all frequencies and for most ear tips in the 200 to 1000 Hz frequencies. The corresponding Bland-Altman values, however, show that the limits of agreement are in most of these cases lower than 2 dB, indicating that the difference between measurements is generally lower than 2dB, and hence the low ICC values can be attributed to low across-subject variability. In all other cases, the ICC values (0.75 to 0.92) fall within the range of good to excellent reliability.

VE Reliability

Table 2 shows the ICC and Bland-Altman results for the five ear tips across the five frequency bands. The ICC coefficients were larger than 0.8 and, in most cases, larger than 0.9. This indicates good to excellent within-subject reliability across repetitions in all frequency bands for all ear tips. The Bland-Altman bias was 0 in all the cases, indicating no systematic differences between measurements.

Impact of Experience in Ear Tip Insertion • There were no statistically significant differences in the measured response levels between the test leader and test subjects in any of the frequency bands or for any of the ear tips (all $p > 0.05$). The boxplots in Figure 6 show the VE in the five frequency bands for the five ear tips both for test leader (dark gray) and test subject insertion (light gray). ANOVA on the overall standard deviation of the VE revealed significant differences between the two groups for Open ($F_{1, 99} = 12.59$; $p < 0.001$), Round 1 ($F_{1, 99} = 11.78$; $p < 0.001$), Round 2 ($F_{1,89} = 11.58$; $p = 0.001$), and Double ($F_{1, 99} = 6.22$; $p = 0.01$). These differences indicate more variability across repetitions after insertion by the test subject than after insertion by the test leader. Although, the overall standard deviation was on average very low (<2 dB) for both groups within each ear tip. There was no difference in SDs for Tulip between the two groups ($F_{1, 99} = 1.39$; $p = 0.24$).

DISCUSSION

REOIG, VE, Occlusion Across Subjects

The measured REOIG results indicate that all tested instant ear tips were, on average, acoustically transparent up to at least 1 kHz except Double Domes, which were transparent only up to 600 Hz. This agrees with the findings shown in Blau et al. (2008) for instant ear tips from another manufacturer. Mueller et al. (2017) showed similar data but only for a single patient. Statistical analysis revealed that the 5 different ear tips have different REOIGs between 400 and 8000 Hz. For the sound mixture at the eardrum, the REOIG in the frequency range from 200 to 1250 Hz is particularly relevant, because typical users of instant ear tips have close to normal hearing at low frequencies and will get very little or no amplification from their HA in this frequency range. A transparent tip allows such users to exploit uncoloured acoustic cues from their environment and may have a positive influence on the perceived sound quality. However, care must be taken for users who need amplification at low frequencies, because the superposition of the direct sound transmitted through the ear tip and the slightly delayed amplified sound from

TABLE 1. ICC and Bland-Altman results across six repetitions of the REOIG

	Real Ear Occluded Insertion Gain—ICC Coefficients					Real Ear Occluded Insertion Gain—Bland-Altman Bias ± Limits of Agreement				
	200–400 Hz	500–1000 Hz	1250–2000 Hz	2500–3150 Hz	4000–8000 Hz	200–400 Hz	500–1000 Hz	1250–2000 Hz	2500–3150 Hz	4000–8000 Hz
Open	–0.56	0.12	0.48	0.71	0.02	0 ± 1.66	0 ± 1.66	0 ± 2.03	0 ± 3.37	0 ± 5.18
Tulip	0.40	0.75	0.78	0.85	0.75	0 ± 1.30	0 ± 1.23	0 ± 4.27	0 ± 5.18	0 ± 5.16
Round, 2-vent	–0.64	0.74	0.85	0.90	0.80	0 ± 1.86	0 ± 1.50	0 ± 3.26	0 ± 4.79	0 ± 4.42
Round, 1-vent	0.49	0.80	0.92	0.91	0.82	0 ± 1.72	0 ± 2.52	0 ± 5.25	0 ± 5.58	0 ± 5.22
Double Domes	0.33	0.41	0.82	0.90	0.75	0 ± 1.92	0 ± 5.48	0 ± 8.90	0 ± 8.24	0 ± 6.98

ICC interpretation: <0.5 is poor; 0.50 ≤ ICC ≤ 0.75 is moderate; 0.76 ≤ ICC ≤ 0.90 is good; and ICC > 90 is excellent (Koo & Li 2016). The Bland-Altman limits of agreement are reported as bias ± 95% random error component.

the HA can cause sound coloration due to the resulting comb filter effect (Dillon 2012; Stiefenhofer 2022; Stone et al. 2008). If the REOIG is known and compared with the individual gain requirement for each frequency, such comb filter effects can be limited by reducing the amplification in frequency bands where the levels of the two sound components are too similar.

The REOIG data show substantial across-subject variability. This can most likely be attributed to differences in the tightness of fit of the ear tip in the individual's ear canal, combined with the tip size used. Another effect to consider is the pronounced Helmholtz resonance (positive REOIG at certain frequencies) found for some ear tips in individual ears. Such a resonance can provide additional gain of up to 10 dB in narrow frequency bands at mid frequencies in some listeners, which could easily have an impact on the sound quality perceived by the user, depending on the hearing loss and amplification applied in the respective frequency range.

All tested instant tips showed a pronounced VE. Although significant differences were found between the response levels for all five ear tips, the resulting average VEs can be roughly grouped into three distinct acoustic categories: open (Open), semi-open (Tulip, Round 1, Round 2), and semi-closed (Double). Comparison of these results to traditional custom moulds shows that the VE measured with Round 1 tips is similar to the VE of a custom earmold with a 3.5 mm vent at 250 Hz (Dillon 2012). The average VE for Double Domes, that is, the most occluding instant ear tip in the present study, roughly compares to the VE of a custom earmold with a 3 mm vent. It should be noted that the VE in custom earmolds is also highly dependent on the length of the vent. A long vent in a solid mould results in a much smaller VE than the same vent diameter in the much shorter vent of a hollow earmold (Kuk et al. 2009).

Blau et al. (2008) reported RECDs for instant tips and a vented custom earmold from a different manufacturer. The data are presented as the RECD for a fully closed ear tip and the deviation of the results for each ear tip type from that RECD. This deviation is directly comparable with the VE results presented here. They found a very similar response to the VE reported here for Open ear tips. Their responses for the Closed Domes are very similar to Tulip and Round 2 in the present study, and their average Power Dome response is comparable to Round 1. Coburn et al. (2014) showed data on acoustic leakage for ear tips referred to as Open, Occluded Domes, and Power Domes from yet another manufacturer. Their sample size is small (seven test subjects), and their data are quite variable, which makes a direct comparison problematic. However, they also report a general tendency of three acoustically distinct types of ear tips. In their study, Open ear tips show the largest VE, the Occluded tips show an intermediate VE, and the Power tips show the smallest VE, which agrees with Blau et al. (2008) and the present study.

The across-subject variability of the VE was large in the present study, again probably due to differences in coupling between the ear tip and the individual ear canal. Especially Double Domes show VEs ranging from completely open for some subjects to completely closed for others. This result could be related to the complex shape of this ear tip type with its two domes. In individual ear canals, a complete seal might not always be achieved with both domes, resulting in varying degrees of leakage.

The large across-subject variability found for both REOIG and VE for the different ear tips highlights the importance of performing real ear verification when fitting HAs in the clinic in order to ensure that the target gain prescribed by the fitting rationale is matched for the hearing-impaired listener (Aazh et al. 2012; Ching et al. 2010) and to achieve maximum benefit from directional microphones and noise reduction algorithms (Kuk & Keenan 2006; Magnusson et al. 2013). This is particularly important in cases where the HA fitting software does not take the individual ear tip acoustics into account.

On the other hand, comparison of the measured VE in the Normal condition and the Movement condition, in which the

TABLE 2. ICC and Bland-Altman results across six repetitions of the VE

	Vent Effect—ICC Coefficients					Vent Effect—Bland Altman Bias ± Limits of Agreement				
Open	0.96	0.96	0.97	0.94	0.85	0 ± 2.52	0 ± 2.62	0 ± 2.18	0 ± 2.26	0 ± 3.70
Tulip	0.95	0.95	0.88	0.89	0.91	0 ± 5.39	0 ± 4.79	0 ± 3.10	0 ± 3.35	0 ± 4.26
Round, 2-vent	0.89	0.88	0.96	0.95	0.94	0 ± 5.01	0 ± 5.36	0 ± 2.06	0 ± 2.45	0 ± 2.96
Round, 1-vent	0.94	0.94	0.94	0.97	0.97	0 ± 6.96	0 ± 5.75	0 ± 2.38	0 ± 1.85	0 ± 2.37
Double Domes	0.89	0.91	0.81	0.93	0.97	0 ± 11.00	0 ± 7.43	0 ± 5.20	0 ± 3.03	0 ± 2.63

ICC interpretation: <0.5 is poor; 0.50 ≤ ICC ≤ 0.75 is moderate; 0.76 ≤ ICC ≤ 0.90 is good; and ICC > 90 is excellent (Koo & Li 2016). The Bland-Altman limits of agreement are reported as bias ± 95% random error component.

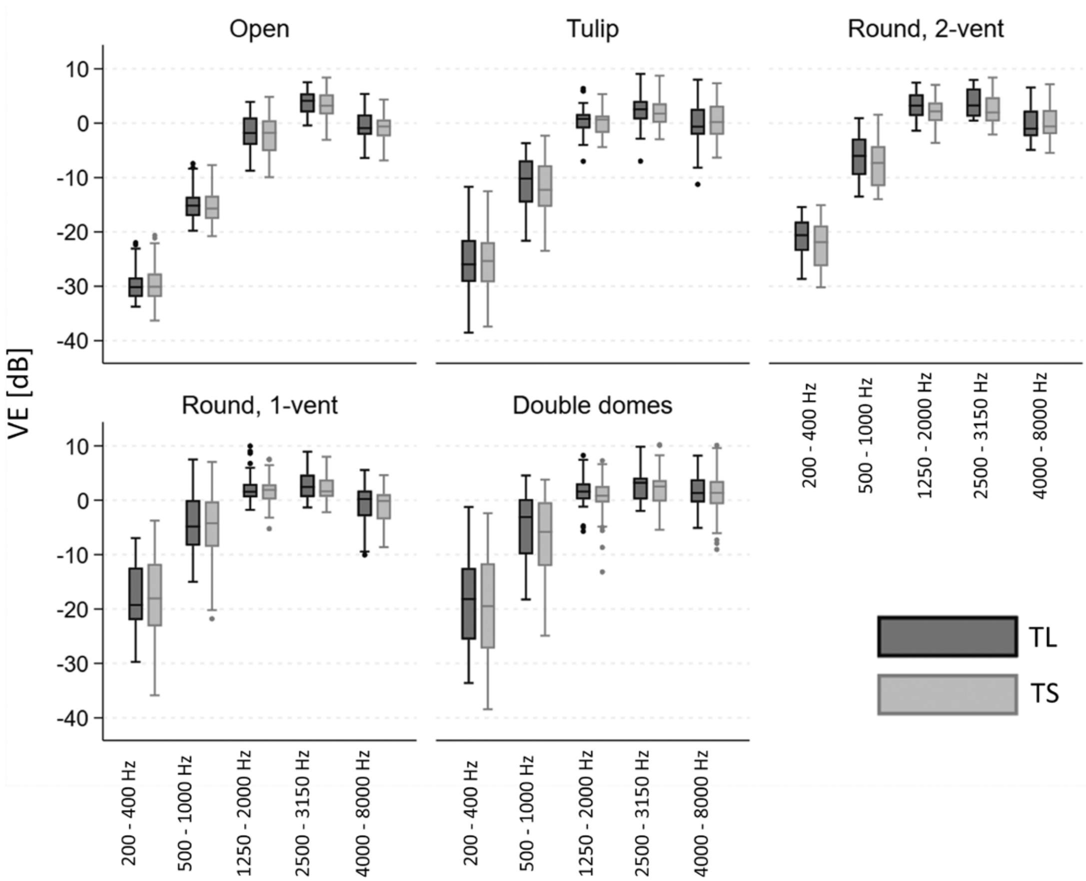

Fig. 6. Box plots for the VE after tip insertion by the test leader (TL, dark gray) and the test subject (TS, light gray). For clarity and statistical analysis, the measured VE spectra were averaged in five frequency bands. VE indicates vent effect.

subjects were asked to move their jaws, showed no differences, which suggests that the VE does not change over time and that the acoustics of the ear tip are likely to be stable in the individual ear after the insertion of the ear tip. This stability of the ear tip across conditions also reflects good retention of the ear tip-receiver combination, consistent with Sweetow et al. (2014).

The relatively low average occlusion ratings indicate that all tested ear tips were still perceived as not very occluding. Correlation analysis was applied between the occlusion ratings and the corresponding physical VE. These two measures relate to different excitation mechanisms. The VE relates to the sound provided by a hearing aid loudspeaker, whereas the occlusion ratings were based on own voice production and sound radiation from the cartilaginous part of the ear canal. Nonetheless, the correlation analysis is meaningful, as both mechanisms cause air-borne sound in the ear canal, which has been shown to be the primary cause for occlusion (Zurbrügg et al. 2014). The occlusion ratings correlate well with the measured VE, which is consistent with findings from Kiessling et al. (2005). Although the correlation is significant, there is still some variability in the subjective occlusion ratings for a given VE. Apart from the acoustic properties, other factors might influence the subjective perception of occlusion, such as the shape of the ear tip, its size, and the individual ear canal shape (Zurbrügg et al. 2014). A tighter fitting ear tip, which exerts more pressure on the ear canal walls might increase the perception of occlusion not only acoustically, but also due to stronger tactile stimulation. Since no sound was provided by the HAs, pronounced Helmholtz resonances in the lower mid-frequency range could also have contributed to higher occlusion ratings.

Within-Subject Reliability

The REOIG and VE measurements in this study were generally highly consistent across the six repetitions. To our knowledge, no previous study has investigated the test-retest reliability of the REOIG of different ear tips. However, for REMs, in general, it has previously been shown that the test-retest reliability is high if the measurements are performed according to clinical practice (Denys et al. 2019; Dirks & Kincaid 1987; Hawkins & Mueller 1986; Kim & Ricketts 2013; Valente et al. 1990).

Jespersen & Møller (2013) also reported high repeatability across conditions and examiners. However, a direct comparison between the two studies is difficult, because Jespersen & Møller (2013) measured the REIG, which reflects a combination of both direct sound and amplified sound, whereas the present study measured the REOIG, where no amplified sound is provided by the HA. Furthermore, Jespersen & Møller (2013) only reported differences between measures, but did not show actual measurement data.

In the case of the REOIG investigated in this study, only frequencies up to about 1500 Hz are likely to have an impact on the sound at the listener's eardrum during HA use, because the combination of the direct sound and the amplified sound will be dominated by the amplified sound at higher frequencies. If the ear tips are consistently transparent at low frequencies in a test-retest set up, we can expect the sound at the eardrum for a given ear tip to be the same, independent of how many times the ear tips are re-inserted into the ear canals, given that the HAs provide gain at high frequencies.

Excellent within-subject reliability of the VE indicates that the acoustic properties of the ear tips are stable across insertions. This agrees with findings from Coburn et al. (2014), who found no significant differences in acoustic leakage between trials (test-retest). However, in their experiment, only a single re-test was performed for a subset of five test subjects, resulting in a very small sample size. With six test-retest measures for ten participants per ear tip (20 ears), we consider the results of the present study more robust and more likely to be representative for the acoustic properties across insertions observed in daily life. It should be noted though that some individuals in the present study showed a large variability across repetitions. This could be due to the particular combination of ear tip type and size, ear canal shape and length, the amount of earwax, etc (Kuk et al. 2009).

The fact that the REOIG and VE of an individual were stable over time and from insertion to insertion in our study is encouraging for clinical practice. This means that the "acoustic fingerprint", that is, the interaction of the physical and acoustic properties of a specific combination of ear tip and individual ear canal can be expected to persist, and thus to be representative for what the HA user can expect to experience in their daily life. This result also implies that any vent compensation applied during the first fitting in the clinic is still likely to be appropriate in daily use.

The comparison between the first three measurements (ear tip inserted by test leader) with the last three measurements (ear tip inserted by test subject) attempted to reproduce the difference between hearing care professional and HA-user insertion of the ear tip. The results did not show any significant differences, neither in terms of REOIG nor VE. This agrees with Jespersen & Møller (2013) who did not find significant differences in REIG measurements obtained by two examiners, although they did not investigate the difference between hearing care professional and HA user ear tip insertion. This is again promising for clinical practice, because it indicates that the "acoustic fingerprint" of the ear tip measured in the clinic by the hearing care professional is likely to be similar to that experienced by the patient in daily use after they inserted the ear tips themselves.

No significant difference in VE and REOIG was found between the two groups, but the standard deviation was larger for the test subject group than for the test leader group for Open, Round 1, Round 2, and Double Domes. This larger standard deviation in the test subject group is likely due to lack of previous experience and an increase in experience may lead to more stable insertions. As indicated in the results, these differences were statistically significant, but they are probably not clinically relevant, because (1) there was no difference in overall acoustics between two groups and (2) the standard deviation itself is very small.

Study Considerations

In the present study, only ear tips from one manufacturer (Widex A/S) have been tested. Since most instant tips on the market are conceptually very similar and the acoustic properties are ultimately determined by the coupling between the ear tip and the individual ear canal, which in turn depends on the tip shape and size and on the individual ear canal configuration, we would expect to find similar results for ear tips from other manufacturers.

The new REM procedure to investigate the VE applied in this study generally resulted in very robust data. Minor errors have been observed because of some variability in the tightness of the seal achieved in the impression fitting mode. In rare cases, a perfect seal has not been achieved despite the impression material. To control for this, the five occluded responses obtained during the measurement of the five tip types in Experiment 1 were compared for each listener. In most cases, the impression measurements with different ear tips were highly similar in the frequency range of interest. Also, the generally high repeatability suggests a reliable measurement method.

All measurements in Experiment 2 were obtained within one experimental session, which means that the physical properties of the ear canal can be considered mostly constant. However, in real life, changes of the ear canal properties can occur, for instance due to buildup of earwax, middle ear conditions, or changes in the amount of sweat inside the ear canal, which might change the degree of sealing between tip and ear canal and thus the VE.

Finally, it could be argued that the test subject selection biased the findings of this study. All test subjects were Widex employees, but most of the participants do not work in R&D and did not have previous experience with ear tip placement. The test subjects were normal-hearing listeners, but we still consider their perception of occlusion representative for hearing-impaired listeners, as Carle et al. (2002) found no correlation between the subjective annoyance caused by occlusion and the degree of hearing loss, at least for mild to moderate losses. Typical users of instant ear tips also tend to have some degree of residual hearing at low frequencies. The participants in this study were also relatively young compared with typical HA users. Stenklev et al. (2004) found no significant change of the ear canal volume, middle ear pressure and tympanic membrane compliance on aging compared with young adults. However, the study suggested that the older male population typically has larger ear canals than females. To test whether age impacted our results, we incorporated age as a factor into a mixed-effects linear regression model and found no significant effect on the REOIG or VE standard deviation between the three insertions done by test participants (data not shown). Overall, the test subject selection does not appear to have impacted the representativeness of our results.

Implications for Clinical Practice

Each of the five ear tip types in the current experiment has a distinct "acoustic fingerprint". In the clinic, the task of the hearing care professional is to find the ear tip that best matches both the individual gain requirement and the individual ear canal shape and size of the HA user. Generally, a higher demand for gain at lower frequencies calls for an acoustically more closed ear tip. However, a closed tip will likely also cause more occlusion. The challenge is to find the best compromise between comfort and available gain for each patient. If the prescribed gain cannot be matched with instant ear tips, a custom earmold should be considered, and an appropriate vent size should be selected to allow for maximum comfort while still providing enough gain to improve audibility.

Our data show that the acoustic properties of the same ear tip can vary considerably in different ears. This will impact the combination of direct sound and amplified sound at the eardrum of the HA user. Here, the hearing care professional can optimize the sound for the patient by selecting the most appropriate ear tip shape and size for the specific ear. Choosing a tip that is too small will increase the leakage and thus the VE, because the ear tip loses contact with the ear canal walls. Choosing a tip that is too large may result in the same effect, because the ear tip can develop folds or creases through which sound can leak out.

Different HA manufacturers follow one of three different strategies to account for the ear tip acoustics. Some manufacturers do not consider the acoustic properties of the ear tips in the initial fitting, some use generic VE compensation for each ear tip type, and some estimate the individual acoustics to provide appropriate gain adjustment. No compensation potentially results in underamplification at mid- and low frequencies and a thin overall HA sound. Applying generic compensation can result in a "boomy" sound if too much gain compensation for the individual case is applied and a "tinny" sound if the compensation is not sufficient for the individual ear and thus impact the overall sound quality perceived by the user. Applying individualized gain compensation in the fitting software allows for appropriate gain compensation and sound quality optimization. Based on the individual gain requirement and ear tip acoustics, a good compromise can be found between matching the prescribed gain and reducing the comb filter effect by not applying any gain in bands in which the direct and amplified sound components are too similar in level.

Ultimately, only by performing real ear verification the clinician can ensure that an accurate matching of the prescribed gain target has been achieved at the listener's eardrum. This again will provide the best basis for maximum benefit from audibility and advanced HA features.

CONCLUSIONS

In general, instant ear tips seal the ear canal less effectively than custom earmolds, resulting in more transparency for sounds from outside the ear canal and in a more pronounced VE, even if no venting is intended. The increased transparency is desirable for mild to moderate sloping hearing losses because the direct sound at low and mid frequencies is not coloured and can be fully utilized by the user. The larger VE helps reduce the perceived occlusion. However, instant ear tips may not be the best option for flatter, more severe hearing losses that require gain also at low frequencies. In such cases, much more than the prescribed gain needs to be provided by the HA to overcome the VE, especially at low frequencies, which could lead to distortion. Knowing and understanding the acoustic properties of the available ear tip options allows the hearing care professional to select an ear tip that is open enough to avoid excessive occlusion yet closed enough to allow for sufficient gain to successfully match the fitting target to achieve the best possible sound experience for their patient. The large across-subject differences for different ear tips found in this study highlight the benefit of considering the individual VE and REOIG within the fitting software. The low within-subject variability suggests that the resulting fitting is stable over time. Ultimately, our results also show that real ear verification is crucial in clinical practice to verify that the prescribed gain has been matched at the individual listener's eardrum. Without this step, differences between different fitting rules could easily be levelled out by the individual differences in VE, especially at low frequencies.

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