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Perceived occlusion and comfort in receiver-in-the-ear hearing aids

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Perceived Occlusion and Comfort in Receiver-in-the-Ear Hearing Aids

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Dedication

To my husband, Colin, who has been a constant, unwavering source of encouragement.

To my parents, thank you for supporting me since the beginning. I could not have gotten here without you.

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Abstract

Purpose: In this study participants rated self-perceived occlusion and physical comfort for receiver-in-the-ear (RITE) hearing aids with different sizes of standard domes. Perceived occlusion was rated across listening and own voice conditions.

Method: Twenty-one older adults with hearing impairment were fitted with bilateral RITE hearing aids and tested with three dome size conditions: open, plus, and power domes, and one control condition: the participants' own aids. Participants ranked self-perceived occlusion across the dome size conditions as well as across listening and own voice conditions, and also ranked level of physical comfort across dome sizes.

Results: Self-perceived occlusion increased as dome size increased, with the open domes and participants' own aids causing the least amount of occlusion. The own voice condition yielded the most significant results, although significance was found across the listening condition as well. Perceived physical comfort decreased as dome size increased.

Conclusions: Self-perceived occlusion was greatest for the power domes, although average level of occlusion did not exceed moderate occlusion. Perceived physical comfort was highest with the open dome and participants' own aids. Plus and power domes were respectively ranked as more uncomfortable than the open domes, but overall were more comfortable than uncomfortable.

Chapter 1: Manuscript

Introduction

Of the approximately 35 million Americans with hearing loss, only about one out of five people currently wears hearing aids (American Speech-Language-Hearing Association, 2011). Common contributing factors include the stigma of hearing aid use, availability of services, financial burden, in addition to lack of comfort with hearing aids and poor sound quality (Kiessling, Brenner, Jesperson, Groth, & Jensen, 2005; Kochkin, 2007). Of those who do wear hearing aids, poor sound quality is one of the major complaints, particularly the way one's own voice and other self-generated sounds are perceived. These complaints are caused by blocking the ear canal using an earmold or in-the-ear hearing aid, and is the source of the occlusion effect (OE) (Brooks, 1994; Dempsey, 1990; French-Saint George & Barr-Hamilton, 1978; Kiessling et al., 2005; Warland & Tonning, 1993).

When there is a blockage in the ear canal, such as an ear mold or hearing aid, there is an augmentation of bone-conducted responses, which is referred to as the occlusion effect. An increase of sound enters the cochlea, because in addition to typical bone conducted vibrations that activate cochlear fluids, the walls of the ear canal additionally vibrate. This produces airborne vibrations in the ear canal. While talking or chewing, vibrations normally escape through an open ear canal, but while the canal is blocked, these vibrations are reflected back toward the eardrum (Kiessling et al., 2005). The occlusion effect can increase the low frequency sound pressure level by more than 25 dB, compared to a completely open ear canal (Goldstein & Hayes, 1965). When hearing aid users with normal hearing in the lower frequencies wear earmolds or in-the-ear hearing aids to aid a high frequency hearing loss, common complaints include that their voices sound "boomy", "hollow", or like they are "talking in a barrel" (Dillon, 2001).

The increase in SPL at low frequencies in the ear canal, or the perception of occlusion, is an important aspect of sound quality that is rated as poor when hearing aid users express frustration with their hearing aids. This can result in limited use of hearing aids or rejection of use. According to the MarkeTrak VII data by Kochkin (2005), sound quality is most important to a hearing aid patient. About 30% of patients were not satisfied with the quality of their own voice and believe their hearing aids were not natural sounding, and about 40% were not satisfied with the sound of chewing and swallowing with their hearing aids. While occlusion often contributes to hearing aid dissatisfaction, lack of physical comfort has also been identified as a factor that can lead to a person's dissatisfaction with hearing aids and resultant rejection. Approximately 15% of hearing aid users indicated that they were not satisfied with the fit and comfort of their aids (Kochkin, 2005).

For hearing aid users, the successful use of a vent is a popular method of decreasing occlusion. When a hearing aid creates a blockage in the ear canal, whether it is an earmold or hearing aid shell, low frequency energy is trapped in the canal. The use of a vent will decrease OE by allowing low frequency energy to escape from the ear canal. Through the use of real ear measures, it is shown that measured OE predictably decreases as vent size increases (Dillon, 2001; Kiessling et al., 2005; Tecca, 1991; Vasil-Dilaj & Cienkowski, 2011; Wimmer, 1986).

An open fit hearing aid, which has a vent diameter of greater than 3mm, reduces or even eliminates OE. This results in improved sound quality of one's own voice and other's voices, and can improve a user's localization ability (Berland, 1975; Cox & Alexander, 1983; Courtois, Johansen, Larsen, Christensen, & Bellin, 1988; Kuk, 1991; Kuk, Keenan, & Ludvigsen, 2005; Noble, Sinclair, & Byrne, 1998). In accordance with its definition, open fit devices should result in measured occlusion being nonexistent (Killion & Christensen, 2000). According to an open canal fitting questionnaire reviewed by Gnewikow and Moss (2006), those wearing open fit canal hearing aids rated the quality of their own voice as significantly better and the level of occlusion as significantly lower than those wearing closed canal hearing aids. Additionally, open fittings not only contribute to less occlusion, but also increased comfort, and therefore fewer hearing aids returned for credit based on studies with actual patients (Gnewikow & Moss, 2006; Taylor, 2006) and based on a dispenser report (Johnson, 2006).

Open fittings have evolved tremendously through the years. Traditionally, an open fitting may have been characterized using a custom earmold with an IROS (ipsilateral routing of signal) vent. However, this application was limited as increased vent diameter resulted in a greater risk of feedback (Sweetow & Mueller, 1991). However, current digital technology allows for improved feedback cancellation, and therefore receiver-in-the-aid (RITA) devices were made possible, which is a behind-the-ear (BTE) device utilizing slim tubes with small domes that leaves the ear canal unoccluded. Currently, receiver-in-the-ear (RITE) devices are gaining popularity in the hearing aid market. These devices house the receiver in the ear canal rather than in the aid. Like RITA, RITE devices act as open fit devices as they pair to soft ear tips or domes that permits retention, and allow sound waves to freely enter the ear canal without causing an unnecessary blockage of sound (Kiessling, Margolf-Hackl, Geller, & Olsen, 2003). When RITE or RITA hearing aids are used, measured occlusion via real ear is minimal, and research has shown that those using RITE or RITA devices report less occlusion than while wearing IROS earmolds, in-the-ear (ITE) hearing aids, or completely-in-the-canal (CIC) aids (Kiessling et al., 2003; Vasil & Cienkowski, 2006).

As discussed, the occlusion effect can be measured acoustically using real ear measures. Real ear occlusion effect (REOE) values can be obtained by subtracting the real ear unaided responses (REUR) from real ear occluded responses (REOR) during vocalizations (voc), and results in the formula: REORvoc - REURvoc = REOE. Acoustically, it is shown that as vent size increases, measured OE decreases (Vasil-Dilaj & Cienkowski, 2011). Although OE can be measured acoustically, the most important measures of OE may in fact be through the subjective measure of hearing aid user reports, as subjective measures have a greater impact on patient satisfaction with hearing aids (Kampe & Wynne, 1996; Vasil-Dilaj & Cienkowski, 2011). Previous studies have asked participants, while wearing an earmold or hearing aid, to rate how "hollow" or "boomy" their own voice sounds after reading aloud passages. Results have correlated with acoustic findings, and suggest that as vent size increases, the perception of OE decreases (Kampe & Wynne, 1996; Kiessling et al., 2005; Kuk, 1991; Kuk et al., 2005; Vasil-Dilaj & Cienkowski, 2011).

Although there are a multitude of studies highlighting the benefits of open fittings in terms of measured and self-perceived occlusion as well as comfort, a lack of substantial literature exists from independent or non-manufacturer-related sources. There is a particular lack of research highlighting self-perceived occlusion in RITE devices, as they have only been on the market for less than five years. Perceived OE measures often solely focus on the user's own voice, rather than others' voices as well. Also, currently there is no literature comparing the occlusion percept and level of comfort inherent across standard receiver tips or dome sizes, which work to create an open, closed, or partially closed fitting depending on the mass of the dome in the ear canal. There is additionally a lack of studies involving participants who are hearing-impaired, older adults.

Self-perceived occlusion and comfort across a manufacturer's standard dome lineup is a daily question for the dispensing clinician. Occlusion resulting from a more closed fitting may negatively affect the patient's hearing aid trial and result in a return-for-credit, as it has been shown that open fittings result in fewer hearing aids returned for credit. Therefore, clinicians may fit patients with RITE devices paired with small, open domes who have low frequency hearing losses that exceed a mild degree. In such cases, patients who may in fact benefit from additional low frequencies may not always receive adequate amplification since open fittings do not provide gain at frequencies below 1 kHz (Kuk, Peeters, Keenan, & Lau, 2007). Whether or not various standard domes in conjunction with RITE aids result in an intolerable degree of self-perceived occlusion and/or discomfort in hearing-impaired, older adults, has not been adequately answered in the literature thus far. Therefore, the purposes of this research were to establish the following:

1) Are there significant differences in self-perceived occlusion across various dome sizes in RITE hearing aids, in both listening and own voice conditions, measured by a self-rating scale?

2) Are there significant differences in self-perceived physical comfort across various dome sizes in RITE hearing aids, measured by a comfort self-rating scale?

Methods

Participants

Twenty-one hearing-impaired adult subjects (16 M, 5F), were recruited per the Institutional Review Board guidelines at James Madison University . Mean age of participants was 71.24 years (range 61-83, SD = 6.28). They were all native speakers of English. Upon otoscopic evaluation, all subjects had normal external auditory canals with no visible evidence of excessive cerumen. Tympanometry was performed using the Grason-Stadler Instruments (GSI) Tympstar to rule out middle ear pathology. Normal tympanograms were ensured for each participant using the following adult normative data: ear canal volume of 0.6 to 1.5 cc, peak compliance of 0.3 to 1.4 mmho, and pressure in the range of -150 to +25 daPa (Margolis & Heller, 1987). Thresholds were obtained using a Beltone Audio Scout portable audiometer with supra-aural headphones and the modified Hughson-Westlake technique (Carhart & Jerger, 1959) to measure degree of hearing loss between 500 and 8000 Hz. In order to be included in the study, the participants had bilateral, symmetrical sensory hearing loss. The participants were experienced hearing aid users with at least twelve months of experience.

Hearing-impaired participants were chosen for this study because there is a lack of self-perceived occlusion ratings for the hearing-impaired population, and this is a follow-up investigation to Vasil-Dilaj and Cienkowski's (2011) perceived occlusion study in which normal hearing participants were tested only. Participants had at least a mild hearing loss, but no more than a moderately-severe hearing loss between 500 and 4000 Hz, and configurations were gradually sloping. The hearing losses were within the guidelines for the hearing aids used in the study. Figure 1 displays the mean hearing threshold levels (HTLs) of the participants, from 500 to 8000 Hz bilaterally.

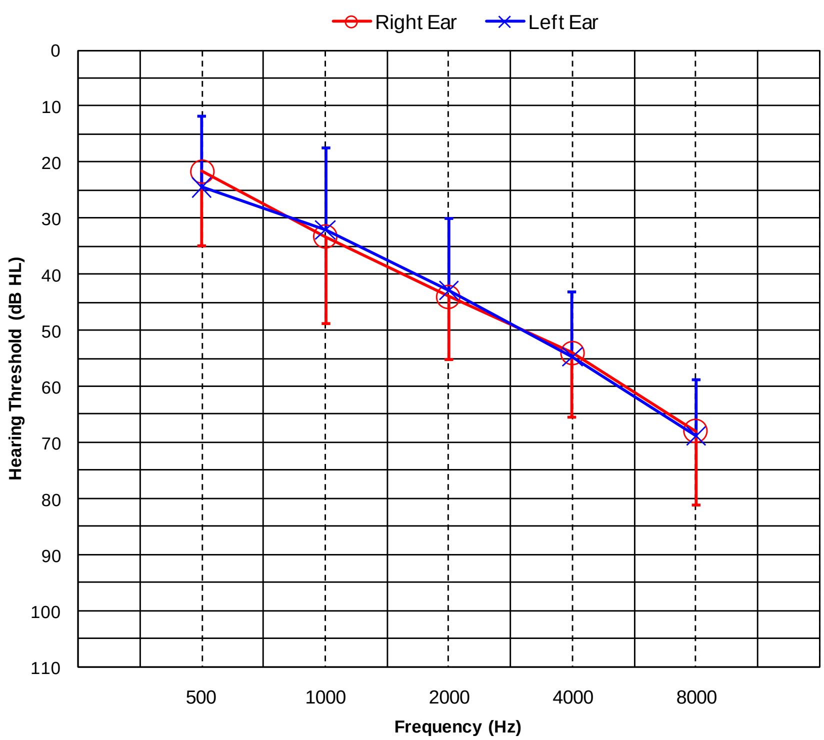

Figure 1: Mean HTLs for right and left ears of each participant for octave frequencies between 500-8000 Hz (n=21). Error bars represent ± 1 standard deviation.

Procedure

Testing was completed in one session, with total participation time ranging from 45 to 60 minutes. After the participants passed tympanometry and completed the audiometric screening, they were fit with bilateral Oticon Agil Pro Mini RITE hearing aids. Receiver length (1, 2, 3) was selected for each participant according to guidelines recommended by the manufacturer, and all were medium power. Hearing aids were programmed using a first fitting, with the Adaptation Manager set to 3, which provides full target gain. The three dome conditions included 1) open domes, 2) plus domes, and 3) power domes.

The fourth condition, participants' own aids, served as a control condition. It was expected that the physical fit and comfort of the participants' own hearing aid condition would be comparable to that of the open dome condition. However, the perceived sound quality from two different manufacturers could lead to different ratings of perceived occlusion. Therefore, the participants' own hearing aids were included as a control for each individual. Additionally, since 15 of the 21 participants wore open fit hearing aids with open domes similar in size to the open domes used in this study, and the other six participants wore custom aids with vents, from a physical standpoint these conditions are not notably different.

Figure 2 displays the side profiles of the silicone standard domes. The open dome has a single flange with large gaps within the tip which allows for acoustic leakage from the ear canal. The plus dome also has a single flange, however the material is more flush and lacks gaps. The power dome is a double flange tip and also lacks gaps, and is therefore the most occluding of the three standard domes. The sizes of the open and power domes (varying from 8 to 10 mm) were chosen individually for each participant, so that the domes were lightly touching the external ear canal. This was confirmed by use of otoscopy. The physical characteristics of the domes used in this study are similar in size, shape, and material (silicone) to other manufacturer's standard domes, even though the names of the domes may differ. Therefore, the results of this study can be inferred to other manufacturers' domes.

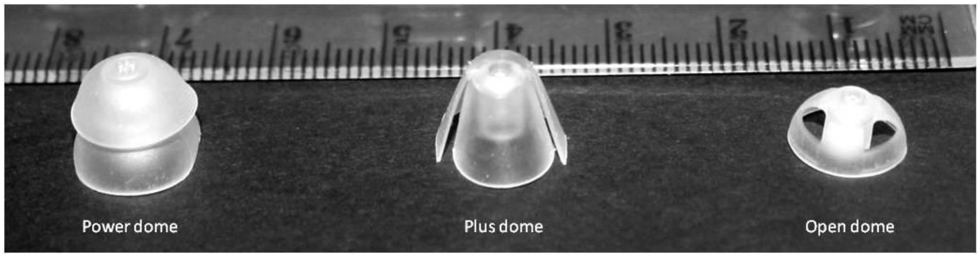

Figure 2: Side profile of the three types of standard domes used. Silicone domes depicted are 10 mm in diameter. Sizes shown from left to right: power, plus, open.

Real ear measures were performed for all participants under all four conditions to verify adequate amplification, using the Audio Scan RM500SL. REIG was recorded using NAL-NL1 prescriptive targets, as this was the prescriptive formula chosen in the manufacturer's software. Targets were considered met within ± 5dB SPL, and aids were reprogrammed using appropriate software if targets were not met. Since it was not appropriate for all subjects to use plus or power domes, namely those with low frequency thresholds within normal limits, amplification was provided appropriately below 1 kHz using guidelines set by the manufacturer's software and NAL-NL1 targets.

An instruction sheet was given to each participant to read prior to data collection, which described subjective terms that are commonly associated with occlusion, such as "hollow," "boomy," and "like talking in a barrel." Instructions were also verbally explained to the participant, and the participant was encouraged to ask for clarification of instructions. Rating scales were also given to the participant prior to data collection and thoroughly explained by the researcher.

During data collection, participants were seated 1 meter away from the speaker at 0 degree azimuth in a double walled sound booth (dimensions: 2.74m × 2.54 m × 2.0 m). For each of the four conditions, participants listened to a set of ten HINT sentences, recorded in quiet using the sound editing software Sound Forge, presented at 65 dBA.

HINT sentences were recorded from the standardized material, but were re-recorded using sound editing software so that there were longer pauses between the sentences. Longer pauses were helpful to the researcher to more easily control sentence playback since participants were allowed to listen to a sentence more than once.

Prior to data collection, daily calibration was performed. Recorded sentences were measured at 65 dBA. This level was ensured using a handheld sound level meter (RadioShack) using an A weighting scale, slow response, with a 1/2 inch microphone. The HINT sentences were streamed from the hard drive of a personal computer through a Russound R 1250MC power amplifier and delivered via a Tannoy System 600 loudspeaker. A touch screen was used on the participant side of the booth so that the researcher was able to sit next to the participant and ensure that tasks were properly followed, while at the same time controlling the order of conditions. Participants were blinded to all conditions, as they were not permitted to see which hearing aids they were currently wearing.

After listening to a recorded sentence, the participant was asked to rate the self-perceived level of occlusion of the male talker's voice using a 5-point rating scale which ranged from No Occlusion to Complete Occlusion (Vasil-Dilaj & Cienkowski, 2011). This rating scale is displayed in Table 1 as the Self-Perceived Occlusion Rating Scale. Participants recorded their responses with paper and pencil. They were instructed to use the entire range of the rating scale. Participants were encouraged to consider all possible choices for rating each sentence.

The participant was also asked to read aloud the sentences displayed on a display monitor and rate the perceived level of occlusion of his or her own voice using the same

5-point rating scale. They were asked to use their everyday speaking voices, although intensity of the participants' voices was not measured. There were ten sentences per condition. Subjects were allowed to listen to sentences repeatedly, and were allowed to repeat sentences aloud as many times as necessary before recording their responses.

Finally, the participant was asked to rate self-perceived level of physical comfort of the hearing aids worn in that condition. Table 2 depicts the Self-Perceived Physical Comfort Rating Scale. The rating scale used was a 7-point scale which ranged from Very Uncomfortable to Very Comfortable. This procedure was repeated for all four conditions, and the conditions were counterbalanced across all participants.

Conditions compared included self-perceived occlusion when listening to sentences, and also when speaking sentences aloud, across all four conditions. Self-perceived comfort across the four conditions was also compared. The four conditions include the three standard dome sizes, plus the control condition (own aids).

It should be noted that the number of data points are 50 less when the participants' own aids are compared. This is due to the fact that this was a condition added after the first five participants. Therefore, 16 participants completed four dome size conditions, and 5 participants completed only three dome size conditions (open, plus, and power). The control condition was added after commencement of the study to serve as a reference condition, since the participants were used to listening to their own aids for more than one year.

Following data collection, a carton of ten packs of batteries were provided to the participants as compensation.

Statistical analyses were performed utilizing the Statistical Package for the Social Sciences (SPSS) Version 18.

Table 1: Perceived Occlusion Rating Scale *(Vasil-Dilaj and Cienkowski, 2011)*

Rating Number	Rating Meaning
0	No Occlusion
1	Mild Occlusion
2	Moderate Occlusion
3	Severe Occlusion
4	Complete Occlusion

Table 2: Perceived Comfort Rating Scale

Rating Number	Rating Meaning
0	Very Uncomfortable
1	Uncomfortable
2	Slightly Uncomfortable
3	Neither Uncomfortable nor Comfortable
4	Slightly Comfortable
5	Comfortable
6	Very Comfortable

Results

Self-Perceived Occlusion

A repeated-measures analysis of variance (R-ANOVA) was performed to establish whether there was a significant difference across dome sizes in the perceived degree of occlusion. There was a significant main effect of dome size, $f(3, 474) = 22.45$, $p < 0.001$, indicating that the type of dome used affected the self-perceived degree of occlusion. In addition, the results showed that perceived occlusion was greater when the hearing aid user was listening to one's own voice as opposed to listening to the sentences delivered through the loud speaker [$f(1, 159) = 115.62$, $p < 0.001$]. The mean rating scores across dome size for self-perceived occlusion across listening and own voice conditions are shown in Figure 3.

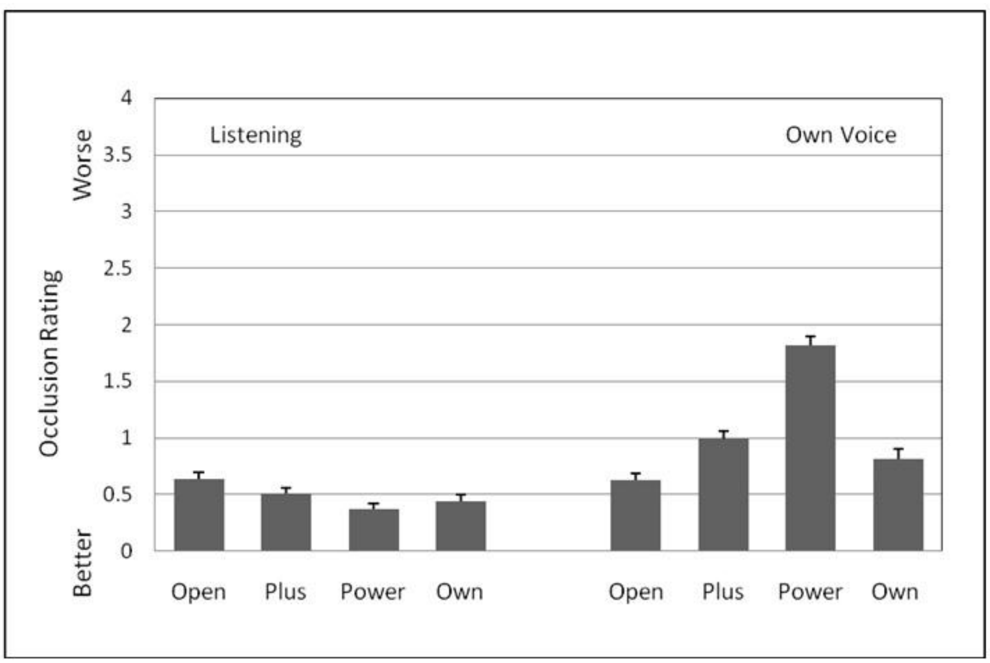

Figure 3: Mean rating scale scores across dome size and between listening and own voice conditions for Perceived Occlusion. Low scores represent less perceived occlusion than high scores. Error bars represent 1 SE.

A follow-up pairwise comparison between dome types indicated that both power and plus domes were perceived to be causing more occlusion ($p < 0.05$) than open domes and the participants' own hearing aids. There was no significant difference between the open dome and the participants' own aids. The statistical significance associated with each paired comparison is shown in Table 3.

Table 3: R-ANOVA measures for within subjects (Paired comparisons across dome size for Perceived Occlusion).

Source	*p*
Open × Plus	0.021*
Open × Power	0.000*
Open × Own Aids	0.477
Plus × Power	0.000*
Plus × Own Aids	0.208
Power × Own Aids	0.000*

* = significance reached at 0.05.

Another set of post-hoc pairwise comparisons were performed to evaluate differences between dome sizes while listening to own voice as well as another talker's voice (HINT sentences from the loud speaker). As shown in Table 4, while listening to one's own voice (reading aloud) there were pairwise significant differences ($p < 0.05$) across all combinations. While listening to another speaker, significant differences were observed between open, plus, and power domes.

Table 4: Two-tailed T-test measures for within-subjects (Paired comparisons across dome size and between listening and own voice conditions for Perceived Occlusion).

Condition	*Source*	*df*	*t*	*p*
Dome Size × Listening	Open × Plus	209	2.23	0.027*
	Open × Power	209	4.04	0.000*
	Open × Own Aids	159	1.08	0.281
	Plus × Power	209	2.49	0.014*
	Plus × Own Aids	159	-0.49	0.623
	Power × Own Aids	159	-0.92	0.361
Dome Size × Own Voice	Open × Plus	209	-5.65	0.000*
	Open × Power	209	-14.34	0.000*
	Open × Own Aids	159	-2.52	0.013*
	Plus × Power	209	-9.27	0.000*
	Plus × Own Aids	159	2.23	0.028*
	Power × Own Aids	159	9.08	0.000*

* = significance reached at 0.05.

Self-Perceived Comfort

A repeated-measures analysis of variance (R-ANOVA) was also performed to establish whether there was a significant difference between dome size in participants' rating of physical comfort. The summary of the results is shown in Table 5. Most notably, there was a significant difference ($p < 0.05$) between the power dome and the participants' own aids in self-perceived physical comfort, with the power dome causing the most discomfort. The mean rating scores across dome size for self-perceived comfort are shown in Figure 4.

Table 5: R-ANOVA measures for within-subjects (Paired comparisons across dome size for Perceived Comfort). * = significance reached at 0.05.

Source	*p*
Open × Plus	0.007*
Open × Power	0.000*
Open × Own Aids	0.523
Plus × Power	0.168
Plus × Own Aids	0.064
Power × Own Aids	0.008*

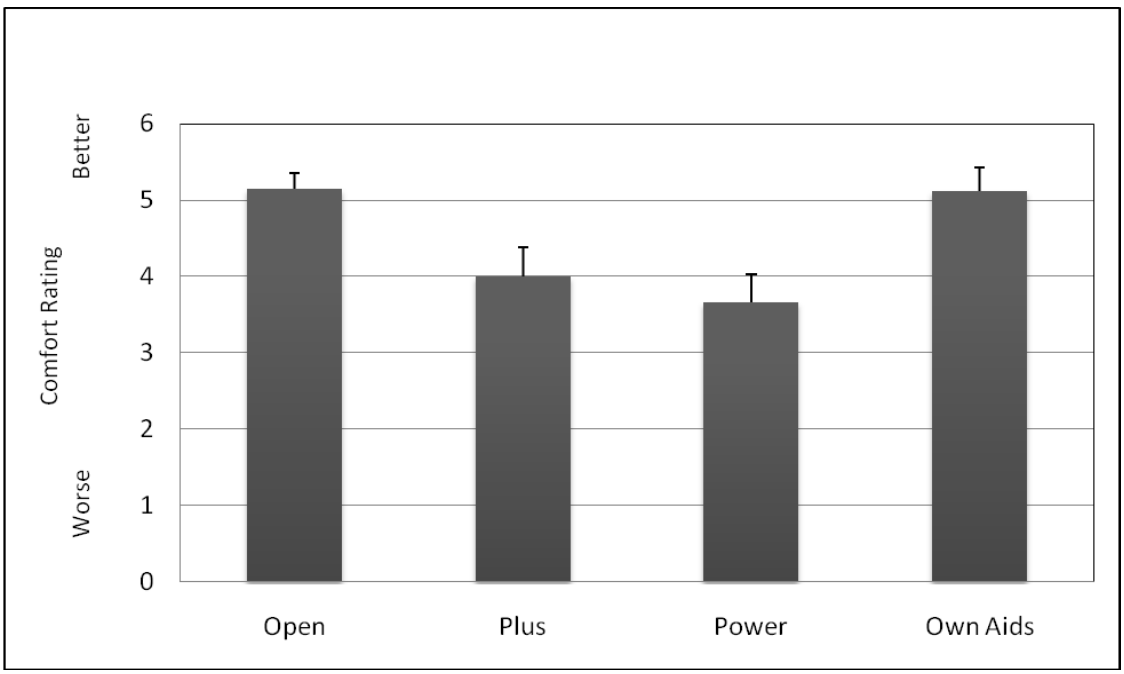

Figure 4: Mean rating scale scores across dome size for Perceived Comfort. Low scores represent less perceived comfort than high scores. Error bars represent 1 SE.

Discussion

Overall, results demonstrated that self-perceived occlusion increased as dome size increased. This finding is well-understood and is in agreement with previous literature. There is a decreased perception of occlusion as there is an increase in the diameter of the vent as well as a decrease in acoustic mass (Kamp & Wynne, 1996; Kiessling et al., 2005; Kuk et al., 2005; Vasil & Cienkowski, 2006; Vasil-Dilaj & Cienkowski, 2011). Although the domes used in this research have not been used in previous studies, the results of this study follow the same trend that the perception of occlusion is decreased when there is less mass and increased leakage of sound from the ear canal.

A significant difference was found between each paired comparison, with the exception of the open dome and the participants' own aids, as most of the participants already wore open domes. In the own voice condition, the power dome resulted in the most self-perceived occlusion. More specifically, the open dome was rated to cause the least amount of occlusion. This may be related to the fact that the majority of the participants wore open domes daily and were used to this method of fitting. The plus dome, which is in between the size of an open dome and power dome, resulted in comparatively low perceived occlusion.

Although statistically this trend was not apparent for the listening condition, perceived occlusion was rated as so low across all conditions (between no occlusion and mild occlusion), that significance was most likely found only due to the high number of data points analyzed. The results indicating that open domes cause greater self-perceived occlusion than plus or power domes is not consistent with literature. Significance is so negligible that we believe these inverse results are not clinically significant.

It should be well understood that although the power dome condition (while speaking) resulted in the greatest amount of self-perceived occlusion, mean values for the occlusion ratings frequently fell at a 1 or below, or no occlusion to mild occlusion. The power dome/own voice condition resulted in "mild occlusion or less" in seven participants, and all other conditions resulted in "mild occlusion or less" in 12 of the 21 participants. Mean values suggested severe to complete occlusion for the power dome/own voice conditions in only five participants, demonstrating that even though statistical significance was found between the domes and participants' own aids, no dome size consistently created a severe to complete perception of occlusion.

Although some participants rated the plus and power domes as causing severe to complete occlusion, this occurrence was rare, and it is possible that the participants were reacting more to the physical volume of the dome inside of the ear, rather than the perceived level of occlusion in terms of sound quality, even though the participants were blind to the conditions and were instructed to react only to sound quality, rather than physical fit during the self-perceived occlusion portion of the study.

Finally, comfort decreased with increasing dome size. This finding is expected, since increased comfort is reported with open canal fittings when compared to more closed canal fittings (Gnewikow & Moss, 2006; Kuk et al., 2005). However, the majority of research respective to comfort is completed by hearing aid manufacturers rather than independent researchers, therefore there is a need for further research to be completed on standard dome sizes coupled to RITE hearing aids as indicated in this study. Including self-perceived physical comfort measures should be repeated in future studies to ensure reliability. Physical fit of the device and associated comfort is strongly associated with greater satisfaction with hearing aids as indicated on IOI-HA scores, and is therefore related to lower rates of hearing aid rejection (Hickson, Clutterbuck, & Khan, 2010). However, it should be noted that participants only wore the domes in this study for a few minutes at a time, and it is possible that ratings may change with longer use.

Although the power dome was rated as the most uncomfortable of the four conditions, and the plus dome was rated as the second most uncomfortable of the dome conditions, mean values for the comfort ratings never fell below a 3 ("neither uncomfortable nor comfortable"), therefore there no dome size was ever consistently rated as "slightly uncomfortable, uncomfortable, or very uncomfortable." While the mean rating of the power dome fell between a 3 and 4 ("not uncomfortable or uncomfortable" and "slightly comfortable"), the plus dome was rated on average as a 4 or "slightly comfortable," and the open dome and participants' own aids were rated just above a 5, or "comfortable."

Comfort was included as a purpose of this study because in clinical practice, it is often easy to undermine the preferences of patients in order to ensure a precise hearing aid fitting. However, clinicians must remember that it is the patient who must wear the hearing devices every day, and unless the patient is comfortable with the hearing aid fitting, amplification may be unused due to discomfort and overall lack of satisfaction with the devices, rendering the audiologist's diligent work ineffectual.

Vasil-Dilaj and Cienkowski (2011) analyzed self-perceived occlusion of RITE devices across receiver size, using young normal hearing participants with an own voice condition only. The hearing aids used were Vivatone M44 RITE devices, as opposed to the Oticon Agil Pros used in the current study. Even though manufacturers differ, the receivers used with both types of aids are similar. They are designed to support an open fitting and are situated in the canal. Therefore, the type of hearing aid used in the current study is appropriate for use in a follow-up study of Vasil-Dilaj and Cienkowski's research. Receiver size conditions progressed similarly between studies, from an open fitting to a receiver size that provides more occlusion. Results of that study demonstrated that occlusion was perceived, on average, no more than mild across any condition.

This study employed the same rating scale, and although results were similar, mean results for the largest dome size differed. In this study, mean occlusion was rated closer to "moderate occlusion" than mild. This difference may be due to the difference in population, as this study focused on self-perceived occlusion of hearing-impaired, older adults. Vasil-Dilaj and Cienkowski's (2011) similar study with young, normal hearing participants noted that future research should include individuals with hearing loss to ensure that the perception of occlusion is minimal when RITE hearing aids with various dome sizes are used. The researchers also discussed replicating the study using older adults, since their ears differ from their younger counterparts in terms of aperture, volume, and cartilage compositions and differences in acoustic characteristics of the ear canal may alter the perception of occlusion. A follow-up study directly comparing self-perceived occlusion across age groups may be critical in better answering this question.

The results of this study may not apply to first time hearing aid users. The participants in this study had been wearing hearing aids for at least one year, and were therefore accustomed to the physical fit of a hearing aid. In addition, there may have been an internal bias favoring the open domes, since most participants wore RITE aids with open domes.

As a final note, statistical differences were found across dome sizes in all of the own voice conditions and much of the listening conditions. However, clinically, the differences may not be so great as to avoid larger domes such as the power dome. Only four of the 21 participants ever rated the power dome as causing "complete occlusion," the worst rating, and two of those participants only rated the dome as causing this degree of occlusion in one out of ten sentences. In terms of comfort, only one participant rated a dome, in this case the plus dome, as being "very uncomfortable," and only three of the participants rated a larger dome as being "uncomfortable." Thirteen of the 21 participants rated all of the standard dome sizes as being more comfortable than uncomfortable, or neither comfortable nor uncomfortable. Therefore, 62% of the participants found no discomfort in any of the domes used in this study.

Based on this study, clinicians should take into account a patient’s self-perceived observation of comfort, and attempt to achieve a balance of comfort and clarity, rather than only focusing on achieving improved sound quality. Progressive counseling on the advantages and disadvantages of various dome sizes used for RITE devices, including resultant comfort, occlusion, and audibility, will allow patients to optimally benefit from their RITE devices.

Conclusions

In summary, the results of this study demonstrated that as dome size increases, the self-perceived amount of occlusion also increases, and perceived comfort is decreased. Although outcomes from this study suggest that using a RITE device results in relatively low self-perceived occlusion, levels of occlusion were perceived as higher in this study than in previous literature. This may be due to the fact that this study involved hearing-impaired older adults, rather than young, normal hearing listeners. Therefore, this study suggests that audiologists should carefully consider the self-perceived observations of the older adult while choosing a dome size for RITE devices, so as to minimize hearing aid rejection and maximize hearing aid benefit and use.

Chapter 2: Extended Review of Literature

When there is a blockage in the ear canal, such as an ear mold or hearing aid, there is an augmentation of bone-conducted responses, which is referred to as the occlusion effect. An increase of sound enters the cochlea, because in addition to typical bone conducted vibrations that activate cochlear fluids, the walls of the ear canal additionally vibrate. This bone-conducted energy is produced through vocalizations, which subsequently causes the mandible and soft tissue proximal to the external ear canal to vibrate. This results in airborne vibrations in the trapped volume of air in the ear canal. While talking or chewing, vibrations normally escape through an open ear canal, but while the canal is blocked by the presence of an ear mold or hearing aid, these vibrations are reflected back toward the tympanic membrane (Kiessling et al., 2005; MacKenzie, 2006).

The occlusion effect can increase the low frequency sound pressure level by 25 to 30 dB compared to a completely open ear canal (Goldstein & Hayes, 1965). Typical values are between 12 to 16 dB (Mueller, Bright, & Northern, 1996). When hearing aid users with normal hearing in the lower frequencies wear ear molds or in-the-ear hearing aids to aid a high frequency hearing loss, common complaints include that their voices sound "boomy," "hollow," or like they are "talking in a barrel" (Dillon, 2001). Sweetow and Pirzanski (2003) reported occlusion effects in 28% to 65% of hearing aid users.

The increase in SPL at low frequencies in the ear canal, or the perception of occlusion, is an important aspect of sound quality that is rated as poor when hearing aid users express frustration with their hearing aids. This can result in limited use of hearing aids or rejection of use. According to the MarkeTrak VII data by Kochkin (2005), sound quality is most important to a hearing aid patient. About 30% of patients were not satisfied with the quality of their own voice and believe their hearing aids were not natural sounding, and about 40% were not satisfied with the sound of chewing and swallowing with their hearing aids. While occlusion often contributes to hearing aid dissatisfaction, lack of physical comfort has also been identified as a factor that can lead to a person's dissatisfaction with hearing aids and resultant rejection. Approximately 15% of hearing aid users indicated that they were not satisfied with the fit and comfort of their aids (Kochkin, 2005).

Before the advent of newer technology, such as open fit, receiver-in-the-ear (RITE) hearing aids, a common tool available to clinicians to resolve occlusion-related complaints included deep fittings, particularly completely-in-the-canal (CIC) devices. Throughout the 1980s and 1990s, researchers have reported on the effectiveness of deep fittings, in which the otoplastic seals in the bony portion of the ear canal (Kiessling et al., 2005; Killion et al., 1985; Killion et al., 1988; Staab and Finlay, 1991; Staab, 1997). Self-generated sound such as one's own voice and chewing mainly cause vibration in the cartilaginous portion of the ear canal, as the impedance mismatch between bone and air hinders efficient input into the bony portion. The deep seal works in minimizing occlusion effect because it reduces vibration of the cartilaginous ear canal walls caused by the bony-conducted sound. However, limitations to the approach include discomfort to the patient and space constraints for those with very small ear canals (Kiessling et al., 2005).

One of the most common methods of decreasing occlusion is the use of a vent. When a hearing aid creates a blockage in the ear canal, whether it is an ear mold or hearing aid shell, low frequency energy is trapped in the canal. Venting will decrease OE by allowing low frequency energy to escape from the ear canal. Through the use of real ear measures, it is shown that measured OE predictably decreases as vent size increases (Dillon, 2001; Kiessling et al., 2005; Tecca, 1991; Vasil-Dilaj & Cienkowski, 2011; Wimmer, 1986).

The effectiveness of a vent is determined by the inertia of the air column in the vent. The inertia can be described in terms of acoustic mass, which is proportional to the effective vent length. Effective vent length is geometric length plus a correction for the end of the vent. The inertia is also inversely proportional to the cross-sectional area of the vent. A vent should therefore be as short and as wide as possible to result in minimal occlusion effect. In addition to traditional parallel vents, cross-sectional vents can also be used to reduce occlusion, such as flexible vents (Kiessling et al., 2005).

The FlexVent is a 1 mm vent plate with a hole in the middle, and is attached to the canal portion of the ear mold. It consists of a 1 mm changeable vent insert carrying the sound tube. The sound tube is attached to the vent insert and is placed in the vent plate. The size of the insert can be selected in consideration of the necessary gain. The flexible vent has yielded significant improvements in subjective and measured occlusion compared to traditional vents. One group of researchers found that the average measured occlusion for traditional ear molds with 1.6 mm circular venting was about 12 dB compared to FlexVents resulting in only 5 dB of measured occlusion (Kiessling et al., 2005). For larger vents (2.4 mm), the average measured occlusion for traditional venting was about 10 dB compared to FlexVents resulting in only 3 dB of occlusion. On a scale of 1 to 10, from no occlusion to complete occlusion, across smaller vents, traditional vents resulted in a mean occlusion rating of about a 7, whereas flexible vents resulted in a mean occlusion rating of about a 4. Standard silicone eartips, resulting in an open fitting, yielded approximately a 1 for mean perceived occlusion, which is extremely low (Kiessling et al., 2005). In 2003, Jespersen and Asgaard found similar trends in measured and perceived occlusion across traditional venting systems and flexible vents.

Electronic venting is another method of reducing the occlusion effect. Using an active occlusion cancellation device, this strategy intends to reduce the level of one's own voice amplification in devices with minimal vents. Therefore, feedback is avoided while allowing optimal high-frequency gain in devices. Researchers created a prototype occlusion canceling system to test this hypothesis. In a study by Mejia, Dillon, and Fisher in 2008, they fit 12 normal hearing listeners with a hearing aid prototype which included this active occlusion cancellation technology and measured objective as well as subjective occlusion. On average, the prototype device allowed approximately 15 dB of occlusion reduction. Eleven of the 12 participants preferred this system compared to aids without electronic venting and 10 participants reported increased naturalness of their own voices and an increase in sound comfort.

The most extreme case of venting results in an open fit hearing aid, which has a vent diameter of greater than 3mm. Open fit hearing aids can reduce or even eliminate the occlusion effect. This improves sound quality of one's own voice and other's voices, and can improve a user's localization ability (Berland, 1975; Cox & Alexander, 1983; Courtois, Johansen, Larsen, Christensen, & Bellin, 1988; Kuk, 1991; Kuk, Keenan, & Ludvigsen, 2005; Noble, Sinclair, & Byrne, 1998). In accordance with its definition, open fit devices should result in measured occlusion being nonexistent (Killion & Christensen, 2000). According to an open canal fitting questionnaire reviewed by

Gnewikow and Moss (2006), those wearing open fit canal hearing aids rated the quality of their own voice as significantly better and the level of occlusion as significantly lower than those wearing closed canal hearing aids. Additionally, open fittings not only contribute to less occlusion, but also increased comfort, and therefore fewer hearing aids returned for credit based on studies with actual patients (Gnewikow & Moss, 2006; Taylor, 2006) and based on a dispenser report (Johnson, 2006).

According to the dispenser report by Johnson in 2006, reduced occlusion effect and improved sound quality of one's own voice were the two highest rated factors in fitting an open canal hearing aid. They were rated as significantly more influential than any of the other factors listed; however, the third most influential factor in fitting an open canal device was increased physical comfort. Dispensers enjoy fitting open canal devices due to the ease of fitting and delivery, reduced amount of hearing aids returned for credit, and reduced return visits for service, since common patient complaints such as occlusion are minimized.

Additionally, one clinical study reported a significantly lower return rate for open canal aids than for closed canal aids, or traditional aids with a vent less than 3 mm. The study reported a 1.8% rate of return for open fit hearing devices and an 11.3% rate of return for closed canal instruments at one specific clinic site. This data was gathered between participants with similar hearing losses fit during the same one year period in the same clinic using the same fitting protocol (Gnewikow & Moss, 2006). These researchers also found that 88.7% of closed-fitting participants experienced a degree of satisfaction with their hearing aids adequate enough to justify the cost of the aids. This is compared to participants who wore open fitting devices, in which 98.2% chose to purchase their hearing aids.

It should be well understood, however, that open canal fittings are not always the superior method of fitting patients with hearing loss. The effects of opening up the vent diameter on hearing aid performance include the loss of low-frequency output below 1000 Hz, reduction of maximum available gain before feedback in the mid- and high frequencies, increased contribution from direct sounds interacting with the amplified sounds to result in phase cancellation, and potential decrease in speech recognition of soft sounds in quiet from the loss of low-frequency output and the limitation in high frequency gain (Kuk & Keenan, 2006). Ideal candidates for open fittings include those with normal hearing below 1000 Hz with mild to moderately-severe hearing loss in the mid- to high frequencies. Those with severe-to-profound degrees of high frequency hearing loss may have cochlear dead regions, in that the hearing loss results from a complete loss of inner hair cells. In this case, the patient cannot use the amplified sounds for speech understanding. In fact, acoustic stimulation may actually distort sounds and lead to poorer speech understanding. Therefore, patients with this degree of hearing loss are also not ideal candidates for this type of fitting (Kuk, Peeters, Keenan, and Lau, 2007).

Open fittings have evolved tremendously through the years. Traditionally, an open fitting may have been characterized using a custom ear mold with an IROS (ipsilateral routing of signal) vent. However, this application was limited as increased vent diameter resulted in a greater risk of feedback (Sweetow & Mueller, 1991). However, current digital technology allows for improved feedback cancellation, and therefore receiver-in-the-aid (RITA) devices were made possible, which is a behind-the-ear (BTE) device utilizing slim tubes with small domes that leaves the ear canal unoccluded. Currently, receiver-in-the-ear (RITE) devices are gaining popularity in the hearing aid market. These devices house the receiver in the ear canal rather than in the aid. Like RITA, RITE devices act as open fit devices as they pair to soft ear tips or domes that permits retention, and allow sound waves to freely enter the ear canal without causing an unnecessary blockage of sound (Kiessling, Margolf-Hackl, Geller, & Olsen, 2003). When RITE or RITA hearing aids are used, measured occlusion via real ear is minimal, and research has shown that those using RITE or RITA devices report less occlusion than while wearing IROS ear molds, in-the-ear (ITE) hearing aids, or CIC devices (Kiessling et al., 2003; Vasil & Cienkowski, 2006).

MacKenzie (2006) conducted a study on objective and subjective occlusion using three different hearing aid manufacturers' RITA devices fitted to open domes. Participants were young, normal hearing adults. After using a probe-microphone to objectively measure the amount of occlusion present in each condition for all participants, they were asked to read aloud the Rainbow Passage, a commonly used test material by speech-language pathologists to evaluate speech skills. They rated the naturalness of their own voice on a 10-point scale. Results indicated virtually no measured or perceived occlusion using open domes on all three manufacturers' devices. Various dome sizes were not compared.

In another recent study, RITE and RITA aids were compared along objective and subjective measures including occlusion (Alworth, Plyler, Reber, & Johnstone, 2010). Twenty-five older adults with mild to moderately-severe sensorineural hearing loss completed two six-week trial periods for each device. Occlusion effect results were not significantly different between the RITE and RITA instruments objectively using probe microphone measures; however, overall sound quality was rated as significantly better using RITE devices compared to RITA instruments, which includes self-perceived occlusion. About 75% preferred RITE over RITA devices based on the subjective factors of sound quality, comfort, and clarity.

As discussed, the occlusion effect can be measured acoustically using real ear measures. Real ear occlusion effect (REOE) values can be obtained by subtracting the real ear unaided responses (REUR) from real ear occluded responses (REOR) during vocalizations (voc), and results in the formula: REORvoc - REURvoc = REOE. More specifically, this measurement is taken using a probe-tube microphone that is inserted in the ear canal. Sound pressure level within the cavity is measured with and without the hearing instrument while the participant vocalizes a vowel such as /i/. Acoustically, it is shown that as vent size increases, measured OE decreases (Vasil-Dilaj & Cienkowski, 2011).

Although OE can be measured acoustically, the most important measures of OE may in fact be through the subjective measure of hearing aid user reports, as subjective measures have a greater impact on patient satisfaction with hearing aids (Kampe & Wynne, 1996; Vasil-Dilaj & Cienkowski, 2011). Often in studies, even though occlusion may be measured to be negligible, the participant will claim that the perception of occlusion is pronounced. Therefore, it would be more clinically relevant to use the subjective rather than objective data on occlusion since such a negative percept could lead to rejection of amplification (Kampe & Wynne, 1996; Vasil-Dilaj & Cienkowski, 2011). Finally, previous studies have asked participants, while wearing an ear mold or hearing aid, to rate how "hollow" or "boomy" their own voice sounds after reading aloud passages. Results have correlated with acoustic findings, and suggest that as vent size increases, the perception of OE decreases (Kampe & Wynne, 1996; Kiessling et al., 2005; Kuk, 1991; Kuk et al., 2005; Vasil-Dilaj & Cienkowski, 2011).

Although there are a multitude of studies highlighting the benefits of open fittings in terms of measured and self-perceived occlusion as well as comfort, a lack of substantial literature exists from independent or non-manufacturer-related sources. There is a particular lack of research highlighting self-perceived occlusion in RITE devices, as they have only been on the market for less than five years. Perceived occlusion effect measures often solely focus on the user's own voice, rather than others' voices as well. Also, currently there is no literature comparing the occlusion percept and level of comfort inherent across standard receiver tips or dome sizes, which work to create an open, closed, or partially closed fitting depending on the mass of the dome in the ear canal. There is additionally a lack of studies involving participants who are hearing-impaired, older adults.

In 2005, Kuk, Keenan, and Lau examined the effect of vent diameters on objective and subjective occlusion using nine hearing-impaired, older adult participants. Each participant wore custom ear inserts resembling a CIC hearing aid shell, varying in vent size from 0 to 3 mm. They sustained the sound /i/ for 5 seconds while the real-ear occluded response (REOR) was measured for each condition, and repeated one phrase, "Baby Jeannie is teeny tiny," for each condition to measure subjective occlusion. As hypothesized, objective and subjective occlusion was increased with decreasing vent size.

Average occlusion effect was measured at approximately 17 dB in the 0 mm vent condition, 13 dB for the 1 mm vent, 10 dB for the 2 mm vent, and 5 dB for the 3 mm vent condition. On a scale of 1 to 10, varying from poorest to best quality of their own voice, median subjective scores were approximately a 6 during the 0mm condition, increasing to an 8 during the 3 mm vent condition. Only 2 of the 9 participants ever rated their own voice below a 5 in terms of sound quality.

Although this particular study used hearing impaired, older adults to study objective and subjective occlusion, amplification was not included in the study, and there was little data to compare for the subjective portion. Participants made a judgment on sound quality, not specifically occlusion, after repeating only one sentence. Therefore, the study is not a perfect example of self-perceived occlusion for those wearing hearing aids (Kuk, Keenan, & Lau, 2005).

Kiessling, Brenner, Jespersen, Groth, and Jensen (2005) quantified the occlusion effect with conventional ear molds, shell type ear molds with a novel vent design with equivalent cross-sectional vent areas, and non-occluding soft silicone ear tips. The silicone ear tips were manufacturer-standard, but did not differ in size. Only one standard ear tip was used in the study, which was small and allowed for an open fitting. Participants included nine normal hearing listeners and ten hearing impaired listeners. Ages were not specified. For all venting systems, the occlusion effect was measured using real-ear measures and subjective means. The occlusion effect associated with the standard silicone tip was comparable to the non-occluded ear, in that it did not result in measurable or perceived occlusion, while the other venting systems resulted in an increase in measured and self-perceived occlusion with smaller vents. Results suggested that the subjective judgment of occlusion is directly related to the acoustic mass of the air column in the vent. Therefore the amount of perceived occlusion can be predicted by the dimensions of the vent.

The current study is a follow-up study to Vasil-Dilaj and Cienkowski's research in 2011 which compared measured and perceived occlusion using RITE hearing aids. Five different sized receivers were compared, ranging from 0.149 to 0.230 inches, and a completely open condition was also included, for a total of six different conditions. Receiver sleeves were created for research purposes only and are therefore not readily available for everyday clinical use. Participants included 30 young, normal hearing listeners. After probe tube measurements were performed to objectively measure occlusion, subjective measures were obtained while participants vocalized /i/ at 70 dBC SPL for five seconds. Participants indicated how occluded or "boomy" their own voices sounded using a 5-point rating scale ranging from No Occlusion to Complete Occlusion. The current study used this exact rating scale so as to better compare perceived occlusion results.

The researchers found that objective and subjective occlusion measures were only weakly correlated, in that as receiver size increased, measured and perceived occlusion also increased, but not for all participants. On average, no more than mild occlusion was noted perceptually, and measured occlusion was no more than 5 dB. The lack of a strong significant relationship was attributed to the negligible REOE values measured in all conditions. Furthermore, some participants indicated the perception of severe to complete occlusion for the largest receiver size, even though acoustic measures were negligible. Therefore, the researchers indicated that from a clinical standpoint, it is best to rely on subjective measures of occlusion when choosing receiver size for a patient (Vasil-Dilaj & Cienkowski, 2011).

In summary, self-perceived occlusion and comfort across a manufacturer's standard dome lineup is a daily question for the dispensing clinician. Occlusion resulting from a more closed fitting may negatively affect the patient's hearing aid trial and result in a return-for-credit, as it has been shown that open fittings result in fewer hearing aids returned for credit. Therefore, clinicians may fit patients with RITE devices paired with small, open domes who have low frequency hearing losses that exceed a mild degree. In such cases, patients who may in fact benefit from additional low frequencies may not always receive adequate amplification since open fittings do not provide low frequency gain (Gnewikow & Moss, 2006; Kuk et al., 2007). Whether or not various standard domes in conjunction with RITE aids result in an intolerable degree of self-perceived occlusion and/or discomfort in hearing-impaired, older adults has not been adequately answered in the literature thus far.

Appendices

Appendix A: Lists of HINT sentences

List 1

1. A boy fell from the window.
2. The wife helped her husband.
3. Big dogs can be dangerous.
4. Her shoes were very dirty.
5. The player lost a shoe.
6. Somebody stole the money.
7. The fire is very hot.
8. She’s drinking from her own cup.
9. The picture came from a book.
10. The car is going too fast.

List 2

1. A boy ran down the path.
2. Flowers grow in the garden.
3. Strawberry jam is sweet.
4. The shop closes for lunch.
5. The police helped the driver.
6. She looked in her mirror.
7. The match fell on the floor.
8. The fruit came in a box.
9. He really scared his sister.
10. The tub faucet is leaking.

List 3

1. They heard a funny noise.
2. He found his brother hiding.
3. The dog played with a stick.
4. The book tells a story.
5. The matches are on the shelf.
6. The milk is by the front door.
7. The broom is in the corner.
8. The new road is on the map.
9. She lost her credit card.
10. The team is playing well.

List 4

1. The little boy left home.
2. They're going out tonight.
3. A cat jumped over the fence.
4. He wore his yellow shirt.
5. The lady sits in her chair.
6. He needs his vacation.
7. She's washing her new silk dress.
8. The cat drank from the saucer.
9. Mother opened the drawer.
10. The lady packed her bag.

<u>List 5</u>

1. The boy did a handstand.
2. They took some food outside.
3. The young people are dancing.
4. They waited for an hour.
5. The shirts are in the closet.
6. They watched a scary movie.
7. The milk is in the pitcher.
8. The truck drove up the road.
9. The tall man tied his shoes.
10. A letter fell on the floor.

<u>List 6</u>

1. The silly boy is hiding.
2. The dog growled at the neighbors.
3. A tree fell on the house.
4. Her husband brought some flowers.
5. The children washed the plates.
6. They went on vacation.
7. Mother tied the string too tight.
8. The mailman shut the gate.
9. A grocer sells butter.
10. The baby broke his cup.

Appendix B: Testing Instructions for Participants

The occlusion effect refers to a sound quality people may notice when wearing hearing aids. You may have experienced it before when you were first fit with your hearing aids. Some patients describe the quality as "hollow" or "booming," while others may describe it as "feeling plugged up" or "like talking in a barrel."

Today you will be fit with a few different types of hearing aids. While you are wearing each type of hearing aid, you will be asked to do two different things. First, you'll be listening to recorded sentences and rating how "occluded" the man's voice sounds. Think of "occluded" as how "hollow" he sounds, or how much he sounds like he is "talking in a barrel." Notice the rating scale. 0 means there is no occlusion, or the man's voice doesn't sound hollow at all, and 4 means he sounds very occluded, or his voice sounds extremely hollow or as if he is very much talking in a barrel. Circle the number that best describes how occluded or "boomy" his voice sounds. If you need the sentence repeated, please ask and you will be able to listen to his voice again.

Next, you will be asked to read sentences from a computer screen out loud while you are wearing the different types of hearing aids. Again, rate how occluded or hollow your own voice sounds by circling a number on the rating scale. Remember that 0 means your own voice does not sound blocked up at all, and 4 means you feel as if your voice is completely blocked up. If you need to repeat the sentence, you can do so until you feel comfortable with your rating. Do you have any questions?

Appendix C: Copy of Consent Form

Consent to Participate in Research

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Sara Conrad, Au.D. student, and Ayasakanta Rout, Assistant Professor and Advisor, from James Madison University. The purpose of this study is to determine whether or not there is a perceived occlusion effect while wearing hearing aids with closed fittings, versus an open fitting. The knowledge gained from this study will aid in choosing proper amplification for individuals with hearing loss. This study will also contribute to the student's completion of her doctoral dissertation (Au.D.).

Research Procedures

This study consists of an experiment that will be administered to individual participants in the Hearing Aid Research Laboratory in the Health and Human Services building at James Madison University. You will be asked to listen to sentences in quiet at a comfortable volume and rate sound quality using a paper form that will be supplied to you. You will then be asked to read sentences aloud and subsequently rate perceived "occlusion" using the same paper form. You will be fit with behind-the-ear hearing aids in both ears under three conditions: open, plus, and power domes. These concepts will be further explained to you prior to beginning the study and you will have the chance to manipulate all of the domes being used in the study. A signed consent form is required before beginning the study, as well as a hearing evaluation. In order to be eligible for the study, you must demonstrate at least a mild hearing loss, but no more than a moderately-severe sensory hearing loss, pass middle ear testing, and you must also have been wearing hearing aids for at least one month. If you are not eligible for the study, you will still receive a free hearing evaluation but will not receive the batteries since we will not be able to continue with data collection.

Time Required

Participation in this study will require 45-60 minutes of your time. One visit is required for participation.

Risks

The investigators perceive the following are possible risks arising from your involvement with this study: fatigue from listening to recorded sentences. To help minimize these risks, the sentences are presented at a comfortable listening level in a quiet environment. In addition, you will be given the opportunity to take a break from testing at any time.

Benefits

Potential benefits from participation in this study include aiding in the ability to help determine whether or not closed hearing aid fittings provide a significant difference in sound quality, particularly the occlusion effect. Knowledge gained from this study will help audiologists choose proper amplification for people who need hearing aids. Participants will directly benefit from this study by receiving a supply of free hearing aid batteries and a hearing evaluation. Batteries are provided only if you are eligible for the study and begin participation. If you leave the study during data collection, you will still receive the free batteries. If you are not eligible for the study, you will not receive the free batteries, but you will receive a free hearing evaluation and hearing aid check.

Confidentiality

The results of this research will be presented at the student's dissertation defense. Results may also be presented at a professional conference and may be submitted for publication in a professional journal. The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. The researcher retains the right to use and publish non-identifiable data.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

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Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
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Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigators provided me with a copy of this form. I certify that I am at least 18 years of age.

____

Name of Participant (Printed)

____ _______________

Name of Participant (Signed) Date

____ _______________

Name of Researcher (Signed) Date

Appendix D: Raw Data

Occlusion Data

		Open		Plus		Power		Own Aids	
Subject	Sentence	Listening	Own Voice	Listening	Own Voice	Listening	Own Voice	Listening	Own Voice
1	1	1	2	3	3	3	3	x	x
	2	2	2	2	3	2	2	x	x
	3	2	2	3	2	2	2	x	x
	4	3	3	3	2	1	3	x	x
	5	2	1	3	3	1	3	x	x
	6	2	2	3	2	1	2	x	x
	7	2	2	2	2	1	3	x	x
	8	2	2	2	2	0	3	x	x
	9	1	3	2	2	1	3	x	x
	10	2	2	1	3	2	2	x	x
2	1	1	1	0	1	0	1	x	x
	2	0	1	0	1	0	1	x	x
	3	0	0	0	1	0	1	x	x
	4	1	1	0	1	1	1	x	x
	5	0	1	1	1	0	1	x	x
	6	1	0	0	1	0	1	x	x
	7	0	0	0	1	0	1	x	x
	8	2	0	2	1	0	1	x	x
	9	1	1	0	1	0	1	x	x
	10	0	1	0	1	0	1	x	x
3	1	0	0	0	0	0	3	x	x
	2	0	0	0	0	0	3	x	x
	3	0	0	0	0	0	3	x	x
	4	0	0	0	0	0	3	x	x
	5	0	0	0	0	0	3	x	x
	6	0	0	0	0	0	3	x	x
	7	0	0	0	0	0	3	x	x
	8	0	0	0	0	0	3	x	x
	9	0	0	0	0	0	3	x	x
	10	0	0	0	0	0	3	x	x
4	1	2	0	3	0	0	3	x	x
	2	3	0	2	1	1	4	x	x
	3	3	0	2	1	1	3	x	x
	4	2	1	1	1	0	3	x	x
	5	2	1	1	2	1	4	x	x
	6	2	0	3	1	0	4	x	x
	7	2	0	2	1	0	4	x	x

	8	1	0	0	1	1	3	x	x
	9	3	0	1	2	1	3	x	x
	10	1	0	0	2	2	4	x	x
5	1	0	0	0	0	0	0	x	x
	2	0	0	0	0	0	0	x	x
	3	1	0	1	0	0	0	x	x
	4	1	0	0	0	0	0	x	x
	5	1	0	0	0	0	0	x	x
	6	1	0	0	0	0	0	x	x
	7	1	0	0	0	0	0	x	x
	8	1	0	0	0	0	0	x	x
	9	0	0	0	0	0	0	x	x
	10	0	0	0	0	0	0	x	x
6	1	0	2	0	2	0	2	0	2
	2	0	1	0	2	0	2	0	3
	3	0	0	0	1	0	2	0	2
	4	0	1	0	1	0	2	0	2
	5	0	2	0	1	0	2	0	2
	6	0	2	0	0	0	2	0	2
	7	0	1	0	1	0	1	0	2
	8	0	0	0	1	0	2	0	2
	9	1	1	0	1	0	2	0	3
	10	0	0	0	1	0	2	0	2
7	1	0	1	0	1	0	1	0	1
	2	0	0	0	1	0	2	0	0
	3	0	1	0	1	1	2	0	1
	4	0	0	0	1	0	2	0	0
	5	0	1	1	1	0	2	0	0
	6	0	0	0	2	0	2	0	0
	7	0	0	0	0	0	1	0	0
	8	0	0	0	0	0	2	0	0
	9	0	1	1	1	0	2	0	1
	10	0	0	0	1	0	2	0	0
8	1	0	0	0	2	0	0	0	0
	2	0	0	0	2	0	1	0	0
	3	0	0	0	2	0	1	0	0
	4	0	0	0	2	0	1	0	0
	5	0	0	0	2	0	1	0	0
	6	0	0	0	2	0	1	0	0
	7	0	0	0	2	0	1	0	0
	8	0	0	0	2	0	1	0	0
	9	0	0	0	2	0	1	0	0
	10	0	0	0	2	0	1	0	0
9	1	0	0	0	0	0	3	0	0
	2	0	0	0	0	0	3	0	0
	3	0	0	0	0	0	3	0	0
	4	0	0	0	0	0	3	0	0
	5	0	0	0	0	0	3	0	0

	6	0	0	0	1	0	3	0	0
	7	0	0	0	0	0	3	0	0
	8	0	0	0	0	0	3	0	0
	9	0	0	0	0	0	3	0	0
	10	0	0	0	0	0	3	0	0
10	1		3	0	2	1	3	3	3
	2	2	3	0	2	0	3	4	3
	3	1	2	0	2	0	2	3	4
	4	0	2	0	3	0	3	3	4
	5	0	2	0	3	1	3	3	4
	6	0	3	0	2	0	3	4	4
	7	0	3	1	2	0	3	3	3
	8	0	2	0	2	0	3	4	4
	9	0	2	0	4	0	3	3	4
	10	0	3	0	3	0	3	3	4
11	1	1	1	0	1	0	2	0	1
	2	0	0	0	1	0	2	0	0
	3	0	0	0	1	0	2	0	0
	4	0	0	0	0	0	1	0	0
	5	0	0	0	0	0	2	0	0
	6	0	1	0	0	0	1	0	0
	7	0	0	0	0	0	0	0	0
	8	0	1	0	0	0	2	0	0
	9	0	0	0	1	0	1	1	0
	10	0	1	0	1	0	0	0	1
12	1	3	1	0	0	0	4	1	1
	2	3	1	0	0	0	3	1	1
	3	2	2	0	0	0	4	1	1
	4	2	1	0	0	0	4	0	1
	5	1	2	0	0	0	3	0	1
	6	2	2	0	0	0	2	1	1
	7	1	1	0	0	0	3	0	1
	8	3	2	0	0	0	4	1	1
	9	1	2	0	0	0	2	0	1
	10	3	1	0	0	0	1	1	1
13	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	1	0	0
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	1	0	0
	7	0	0	0	0	0	0	0	0
	8	0	0	0	0	0	0	0	0
	9	0	0	0	0	0	1	0	0
	10	0	0	0	0	0	0	0	0
14	1	1	0	0	0	1	0	3	0
	2	1	0	1	0	0	0	2	0
	3	2	0	1	0	0	0	3	0

	4	0	0	0	0	0	1	2	0
	5	1	0	1	0	1	1	1	0
	6	0	0	0	0	1	2	1	0
	7	1	0	1	0	0	2	0	0
	8	2	0	0	0	0	1	0	0
	9	2	0	1	0	0	0	2	0
	10	1	0	1	0	0	1	1	1
15	1	1	0	0	0	0	1	0	0
	2	1	0	0	0	0	0	0	0
	3	1	0	0	0	0	0	0	0
	4	1	1	0	0	0	0	0	0
	5	1	0	0	1	0	0	0	0
	6	1	1	0	1	0	0	0	0
	7	1	0	0	0	0	0	0	0
	8	1	0	0	1	0	0	0	0
	9	1	0	0	0	0	0	0	0
	10	0	0	0	1	0	0	0	0
16	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	1	0	0	0
	5	0	0	0	1	1	0	0	0
	6	0	0	0	1	1	0	0	0
	7	0	0	0	1	1	1	0	0
	8	0	0	1	1	1	1	0	0
	9	0	0	1	1	1	1	0	0
	10	0	0	1	1	1	1	0	0
17	1	0	1	1	0	0	4	0	2
	2	0	1	1	0	1	2	0	2
	3	0	0	2	0	2	3	0	2
	4	0	0	0	1	2	1	0	2
	5	1	0	0	0	1	1	1	2
	6	0	0	0	0	1	1	0	2
	7	1	0	1	1	3	2	0	2
	8	0	0	2	0	2	1	0	2
	9	0	0	1	0	0	0	0	2
	10	1	0	0	1	0	0	0	2
18	1	1	0	0	2	1	3	0	0
	2	0	0	0	2	1	3	0	0
	3	0	0	0	1	1	3	1	0
	4	0	0	0	2	2	3	1	0
	5	1	0	0	2	2	3	0	0
	6	1	0	1	1	2	3	1	0
	7	1	0	1	1	2	3	0	0
	8	1	1	2	2	2	3	1	0
	9	1	0	2	1	2	2	1	0
	10	1	0	3	1	2	2	1	0
19	1	0	0	0	2	0	3	1	1

	2	0	1	1	2	0	3	0	1
	3	0	1	1	1	0	2	0	0
	4	0	1	1	0	0	0	0	1
	5	0	0	1	0	0	0	0	0
	6	0	0	1	0	0	1	0	0
	7	0	1	0	1	0	2	0	0
	8	0	1	0	2	0	1	0	1
	9	0	0	0	1	0	3	0	0
	10	0	1	1	0	0	1	0	1
20	1	2	1	1	3	0	3	1	2
	2	2	2	1	3	0	2	1	2
	3	2	1	1	3	1	2	0	2
	4	1	1	1	3	0	3	0	2
	5	1	2	1	3	0	3	0	3
	6	2	1	1	3	1	3	0	3
	7	1	1	1	3	1	4	1	3
	8	1	1	1	3	0	3	1	2
	9	1	2	1	3	0	2	0	2
	10	1	1	1	3	0	2	1	2
21	1	1	2	1	2	2	3	0	0
	2	1	2	2	2	1	3	0	1
	3	1	3	2	2	1	3	0	1
	4	1	2	2	2	1	3	0	1
	5	1	3	2	2	2	3	0	1
	6	1	2	2	2	1	3	0	1
	7	1	2	2	3	1	3	0	1
	8	2	2	2	3	1	3	1	0
	9	1	1	2	3	1	3	1	1
	10	1	1	1	3	1	3	0	0

Comfort Data

Subject	Open	Plus	Power	Own Aids
1	5	5	4	x
2	2	2	6	x
3	5	5	1	x
4	5	3	4	x
5	5	5	5	x
6	6	6	5	5
7	6	6	5	6
8	6	0	1	6
9	5	5	3	5
10	6	4	3	1
11	5	6	4	6
12	6	4	6	5
13	6	6	5	6
14	5	5	3	6
15	5	2	2	5
16	5	3	2	6
17	6	5	6	5
18	4	1	1	6
19	4	2	2	3
20	6	4	5	6
21	5	5	4	5

Participant Data

Subject	Sex	Hearing Aids	Hearing Loss Config 500-4kHz
1	M	Open	Normal to moderate
2	M	Ear mold	Mild to mod-severe
3	M	Open	Normal to mod-severe
4	M	Open	Normal to mod-severe
5	M	Open	Mild flat
6	M	Plus	Normal to mod-severe
7	M	Open	Normal to mod-severe
8	F	Open	Moderate flat
9	M	Plus	Mild to mod-severe
10	M	Plus	Normal to moderate
11	M	CIC	Normal to mod-severe
12	M	Open	Normal to mod-severe
13	M	Open	Mod to mod-severe
14	M	Open	Normal to moderate
15	F	Open	Mild to mod-severe
16	F	Open	Normal to moderate
17	M	CIC	Normal to moderate
18	F	Open	Normal to mod to mild
19	M	Open	Normal to mod-severe
20	F	Open	Mild to moderate
21	M	Open	Normal to moderate

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