Study measures openness of custom earpieces for open-canal mini-BTE fittings

By Richard Anesko

Since the introduction of the GN ReSound AIR 60 in 2003 and the flood of open-fitting, behind-the-ear (BTE) devices that followed it, the way we fit hearing instruments has changed dramatically. These devices, which offer the cosmetic advantages of a mini-BTE with thin, pre-formed tubing, as well as a dynamic feedback algorithm, have given audiologists and hearing instrument specialists a solution they can offer patients with mild or sloping hearing losses without fear of occlusion. What's more, this new type of instrument has the potential to be fitted "off the shelf" on a patient's initial office visit.

Soon after open instruments came to market, the need for custom-fitted earpieces (or earmolds) became apparent. Dispensing professionals were looking for better earpiece retention, easier insertion, and, if possible, more available gain. They also were asking for a more comfortable fit in the ear canal, since patients often complained that stock silicone domes itched or tickled their ears.

Rose noted several limitations of open-fit devices used with stock silicone domes.[1] Specifically, he discussed the impossibility of altering the "plumbing" of stock eartips (apparently a reference to their venting characteristics), their reduced directionality compared with more occluding earpieces, and their potential for feedback.

In response to industry demand, Westone Laboratories created a variety of custom-fit earpieces specifically for thin-tube/open-canal fittings. Its flagship open earpiece is style #4VH, a clear acrylic, hollow CIC earpiece designed to accept the tight friction fit of a stock thin tube. No tubing cement is required, which makes re-tubing easy. The 4VH is suitable for patients with normal hearing or mild losses in the low frequencies and up to a moderately severe loss in the highs.

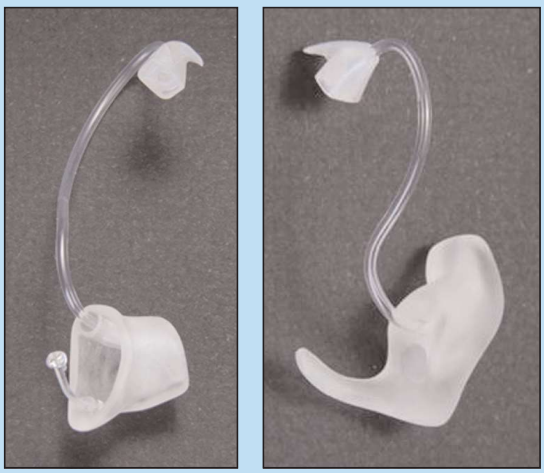

Figure 1. *Left panel shows a 4VH earpiece for the left ear and the right panel shows a 5-Air earpiece for the right ear.*

Westone also designed a series of "open-air" earpieces that essentially look like the traditional earpiece styles that have been around for years. However, they have a few significant differences. These "open-air" earpieces come standard with the largest vent apertures possible and a sound bore sized for stock thin tubes. Also, we remove ½ to ⅔ of the lower/inner canal, creating a step vent. The thinking is that less earpiece mass in the canal and a short vent should result in less occlusion.

Subjective, anecdotal reports about both these types of open earpieces have been very positive. However, Westone's goal has been to create multiple styles of earpieces that can be verified as truly non-occluding, that is, producing no own-voice ("head-in-a-barrel) effects, while at the same time allowing for the added benefits that a custom-fit earpiece provides, namely: (1) a comfortable and repeatable fit, (2) easy insertion and removal, and (3) good in-ear retention.

Therefore, Westone conducted a study to examine the acoustic effects that the 4VH and the 5-Air models of earpiece have in subjects' ears as compared with normal open-ear canal resonance.

SUBJECTS

We conducted the study with a test group of 10 people with essentially normal hearing, all Westone Laboratories employees. They consisted of 5 male and 5 female subjects ranging in age from 22 to 47 years, with a mean of 35 years. None of the subjects reported any history of hearing loss or any communication difficulties, nor had any of them ever used amplification (hearing aids). Audiograms were not deemed necessary as this study did not include any subjective occlusion measures (own voice naturalness), but rather looked at the objective, measurable occluding properties of two types of custom earpieces and compared them with non-occluded ears.

METHODS

Otoscopy revealed essentially clear ear canals on most subjects. A small amount of cerumen was removed from a few ears to allow for accurate ear impression taking. No abnormalities of any ears were noted.

We took impressions of each subject's ears to at least the second bend, using a two-part cartridge-type silicone

(Westone's Siliclone™) and employing a manual impression gun with mixing tips. The same pair of ear impressions was used to manufacture both sets of custom earpieces being evaluated—the open-fit style #4VH earpieces and the 5-Air earpieces.

The 4VH earpieces are designed to sit fairly deep in the ear canal, with the largest vents possible. They are made on a stereolithography machine using acrylic material.

The 5-Air is a canal-style earpiece incorporating a lower concha bowl lock for retention. It uses a semi-IROS vent stepped back approximately ½ to ⅔ of the way from the canal tip, and has the largest vent aperture possible. It is also made on a stereolithography machine using acrylic material.

The 5-Air style is one of many less occluding earpieces manufactured by Westone for thin-tube fittings. Unlike the 4VH, the "open-air" earpieces can be manufactured with various venting characteristics, allowing for anything from essentially open-fit to fully occluding, depending on the patient's hearing loss and dispenser preferences.

We saw the subjects again approximately a week later to allow for manufacture and inspection of the two sets of custom earpieces. Otoscopy was repeated to verify clear ear canals. A proper fit of both the 4VH and 5-Air earpieces was verified in each ear.

We placed probe tubes approximately 4-5 mm from the tympanic membrane, per manufacturer's instructions, and marked them for insertion depth. Open-ear (unoccluded) responses were obtained with an Audioscan Verifit Real-Ear test system.

Next, we placed the 4VH earpieces in the subjects' ears, taking care to maintain probe-tube insertion depth. Occluded responses were obtained. The same procedure was repeated for the 5-Air earpieces. All results were recorded graphically and in numerical chart format.

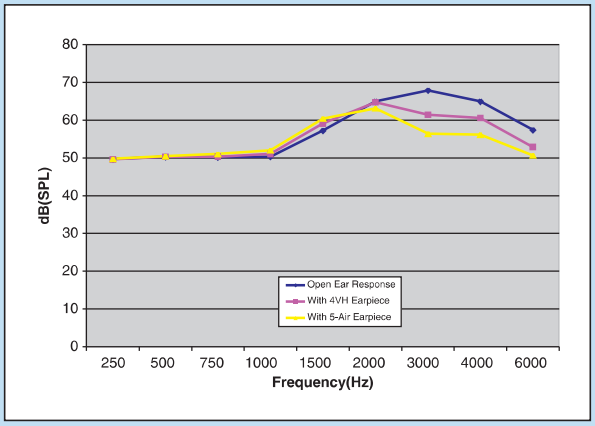

Figure 2. *Combined real-ear data with 65-dB pink noise (n=20 ears).*

Later we used the occlusion meter to objectively measure occlusion with both types of earpiece in place. Subjects were instructed to vocalize the closed vowel "ee" at a sustained level of approximately 75 to 80 dB SPL. Results were recorded.

RESULTS

Probe-microphone insertion gain measures showed that neither the 4VH nor

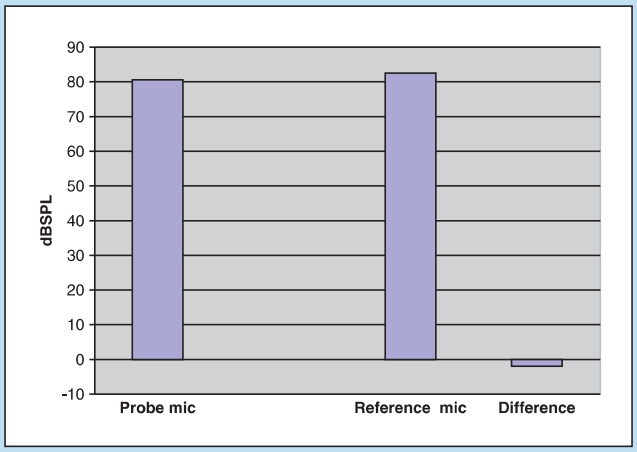

Figure 3. *4VH mean occlusion (n=20 ears).*

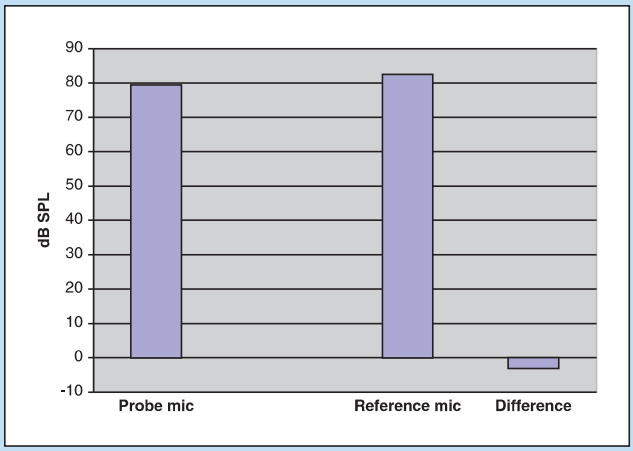

Figure 4. *5-Air mean occlusion (n=20 ears).*

the 5-Air earpiece was occluding at all (see Figure 2). Neither produced any significant differences in frequency response from 250 through 1000 Hz, where occlusion complaints are known to originate.

Occlusion meter results revealed no occlusion issues (Figures 3 and 4). In fact, only 2 of the 40 ears tested with earpieces in place showed probe-microphone recordings even slightly greater than reference microphone recordings. Most showed either no change or *less* sound pressure measured in the ear canals with the earpieces inserted. According to Audioscan, *possible* occlusion issues are indicated by sound pressure levels approximately 8 to 11 dB greater in the occluded ear canals than with the reference microphone; *definite* occlusion complaints occur when sound pressure levels are 12 dB or more higher in occluded ears.

DISCUSSION

These results clearly indicate that the 4VH and 5-Air style earpieces are non-occluding. In fact, the frequency response in the 20 ears of the 10 subjects is essentially identical to the open-ear condition from 250 to 1000 Hz, indicating effective vent-

ing/bleed-off of low-frequency sound energy. Differences in frequency response are seen only in the higher frequencies, where custom earpieces will tend to shift the ear's natural resonance peak downward slightly and reduce its amplitude beyond approximately 2000 Hz. It may be possible to address these changes by making gain adjustments as needed in the hearing aid's fitting software.

From the vocalized occlusion meter test we can verify that both styles of earpieces are non-occluding. It is interesting, however, to see consistently lower SPL values from probe-microphone measurements as compared to those obtained from the reference microphones. One possible explanation is that these open-canal earpieces provide stability within the ear canal, thus reducing the canal's soft tissue vibration. This vibration is thought to contribute to greater SPL at the eardrum and, as such, more occlusion complaints. Or it may be because the occlusion meter test is not frequency-specific and simply averages out speech energy. As these earpieces may marginally reduce the ear canals' resonance peaks, the probe microphones are recording slightly less high-frequency energy in the subjects' ear canals as compared to the reference microphones. This might account for the overall lower SPL recorded by the probe microphones as compared to the reference microphones.

Research in this area is continuing. Future inquiries may include another objective measurement of occlusion in which the subjects vocalize while using the Live Speech Mapping feature in the Verifit system. This may provide more frequency-specific data during vocalization and allow a better comparison to the findings of a previous study by MacKenzie.[2] Also, measurement and comparison with manufacturer's stock eartips may be done, although similar data are currently available.[2,3]

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