Attenuation variables in earmolds for hearing protection devices

By Chester Pirzanski, Marshall Chasin, Mary Klenk, Vince Maye, and Julie Purdy

In addition to serving as acoustic couplers for hearing instruments, custom earmolds are also commonly used as hearing protection devices. Individually manufactured earplugs offer several advantages, including comfort, customized acoustic seal, and a lightweight and appealing cosmetic appearance. Incorrect insertions are also easily detected and the molds, if properly manufactured, have little chance of working loose with time.[1]

However, for a variety of reasons, these benefits may not always be achieved. Some custom earplugs leak acoustically and provide inadequate attenuation, particularly with the user's head and mandibular movements. In the wake of recent studies on ear canal dynamics, the need arose for identifying and investigating a variety of factors involved in custom earplugs manufacturing.[2-7]

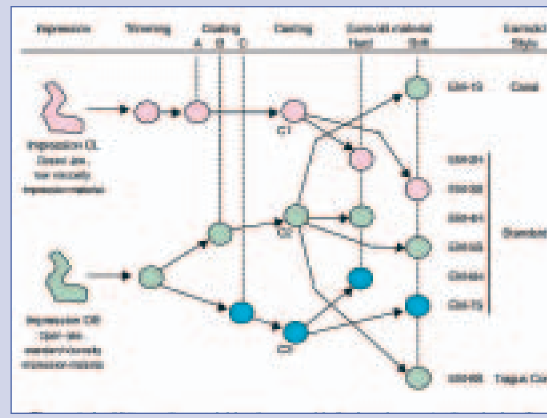

Figure 1. *Earmold manufacturing conditions.*

PURPOSE OF STUDY

The purpose of our study was to investigate the relationship between earmold attenuation and the earmold manufacturing process. In particular, we examined the following factors:

- Ear impression-taking technique
- Ear impression material viscosity
- Thickness of in-lab impression coating
- Earmold style
- Earmold material.

In our research, we also attempted to determine how mandibular movements affect earmold attenuation.

To limit the number of earmolds made and tests conducted, we selected for study only the most interesting combinations of ear impression taking and earmold manufacturing. Figure 1 illustrates the conditions under which the earmolds were made.

METHOD

Subjects

Ten subjects were selected for the study: five males and five females, with no experience in hearing aid use. No ear tissue abnormalities or eardrum perforations were found during otoscopic examination. The subjects' ear canals, including the eardrum, were all within normal limits.

Ear impressions

Two ear impressions were taken from each subject's left ear. We took the first impression with the subject's jaw closed using a low-viscosity silicone impression material (impression CL). This material was introduced into the ear canal via an injection gun. For the second impression, we used an open-jaw impression-taking technique and a standard-viscosity silicone impression material (impression OS). We introduced the material into the ear canal with a standard impression syringe. Both impressions were taken as deep-ear imprints. We used an otoblock to protect the eardrum from the injected silicone.

All finished impressions were trimmed. This included trimming the canal length to 2 mm past the second anatomical bend and a slight tapering of the canal tip. The purpose of these modifications was to ensure comfort and ease of insertion for the resulting earmold.

Earmolds

We made eight earmolds for each subject using three types of impression coatings: types A, B, and C. Coating type B was thicker than A, but thinner than C. We used the thinly coated impression, CL, to manufacture earmolds EM-2H (hard) and EM-3S (soft), both in standard style. Impression OS waxed with type B coating was used to make a hard earmold EM-4H (standard) and soft molds EM-1S (canal), EM-5S (standard), and EM-8S (tragal configuration). Impression OS, coated with the type C coating, was then used again to make two standard-style earmolds: EM-6H (hard) and EM-7S (soft).

The canal mold was a small earmold that fitted only in the subject's ear canal and ear canal aperture. The standard earmold was a full-concha mold. The tragal-configuration earmold had the tragal area raised to provide a better seal at the tragal area.[8] All earmolds made for a given subject had the same canal lengths.

Each earmold had a microphone probe tube inserted through a channel drilled throughout the mold's body and cemented in place. The end of the tube protruded 1.5 mm beyond the tip of the earmold. The earmold material was either a soft 30-shore medical grade silicone or a rigid ultraviolet resin.

Instrumentation and procedures

We made all measurements in a quiet room, with ambient noise not exceeding 30 dB SPL. We performed otoscopy prior to probe-tube or earmold insertion to ensure a cerumen-free canal. Non-occluded responses used an equal insertion depth. The tester inserted all earmolds. Those earmolds judged as having a looser fit (UV molds) were tested first, followed by those judged to have a tighter fit (silicone molds) to minimize irritation of the ear canal. Lubrication was applied only when necessary for subject comfort.

We used the Starkey PFS 6000 real-ear measurement system to measure all real-ear unaided response (REUR), occluded, and real-ear attenuation threshold (REAT) transforms. The test stimulus used for all test conditions was an 80-dB-SPL, speech-weighted, broad-band noise. The probe-tube apparatus for this system was calibrated according to the manufacturer's specifications prior to each test session.

We measured the REUR before inserting the earmold. Then we performed REAT measurements for each earmold in two test conditions: the closed-jaw condition and the open-jaw condition, using a mouth prop to stabilize the subject's jaw position. Measurements were made in 1/24-octave steps and exported to a desktop computer for storage and analysis. All measurements were taken twice, with the probe tube and/or earmold removed and replaced between measures. All measures were repeated again after approximately a 1-week interval to verify the accuracy of the data collected. Thus, measurements were taken four times in each occluded and each non-occluded condition. The four recordings of each response were averaged to compute a mean spectral response. A total of 68 measures were obtained for each subject.

RESULTS

The research results are presented in Figures 2 to 7. Figures 2 to 5 show data in seven one-third-octave bands from 125 Hz to 8000 Hz. Figures 6 and 7 show data in 1/24-octave steps. Following are the major findings from this research:

Ear impressions

The impressions taken with a low-viscosity impression material and with the subject's jaw closed (impressions CL) often had smaller canal diameters than impressions taken with a standard-viscosity impression material and the subject's jaw open (impressions OS). The measurements were taken between the first and second bends on the impression canal in the anterior-posterior direction. The magnitude of the stretching varied among subjects and was measured up to 1.17 mm, with the mean value of approximately 0.53 mm. Ear canals in three subjects did not change their diameters. Other researchers have reported similar findings.[3-7,9-10]

Attenuation

In most cases, more snugly fitting earmolds were found to provide greater attenuation than loosely fitting earmolds (Figures 2 and 3). For hard earmolds, the impression-taking technique/material proved to be more critical than the thickness of the impression coating. In the most snugly fitting soft earmolds (EM-7S), proper insertion seemed to dominate over other issues.

Standard soft-body earmolds attenuated the noise more effectively than did standard hard-body earmolds (compare Figures 2 and 3). The difference within a pair ranged from 4 dB to 8.8 dB in the 125-Hz to 2000-Hz range, depending on the pair.

The style of the earmold (canal, standard, or tragal configuration) was practically irrelevant for the level of attenuation. As shown in Figure 4, all three curves are rather close, with the canal and tragal earmolds exhibiting the best sealing properties.

As expected, the physical activity of a subject's mouth—the opening of the jaw—introduced sound leakage that adversely affected the level of earmold attenuation. Figure 5 shows the change in the attenuation computed separately for all hard and all soft molds.

Subjects' ears varied greatly in their ability to attenuate noise. In some subjects the range of attenuation was approximately 20 dB, whereas in other subjects it was extended to about 38 dB in the range from 125 Hz to 2000 Hz, as demonstrated in Figures 6 and 7. Such variations were common and observed in both male and female subjects.

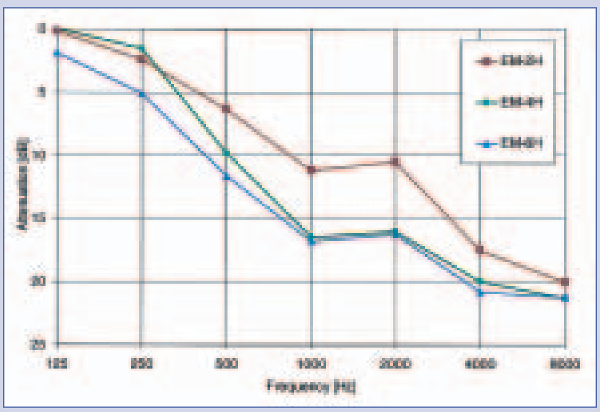

Figure 2. *Attenuation in hard, standard-style earmolds. Earmolds made from closed-jaw, low-viscosity, lightly coated impressions (CL) provided the lowest attenuation thresholds.*

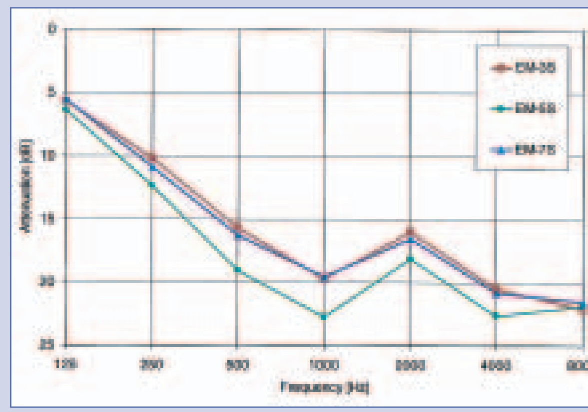

Figure 3. *Attenuation in soft, standard-style earmolds. The lower attenuation thresholds for earmolds EM-3S and EM-7S most likely arose from different causes. For EM-3S it could have been the use of the closed-jaw, low-viscosity, lightly coated impression (CL), while for the snugly fitting EM-7S it could have been improper (too shallow) insertion.*

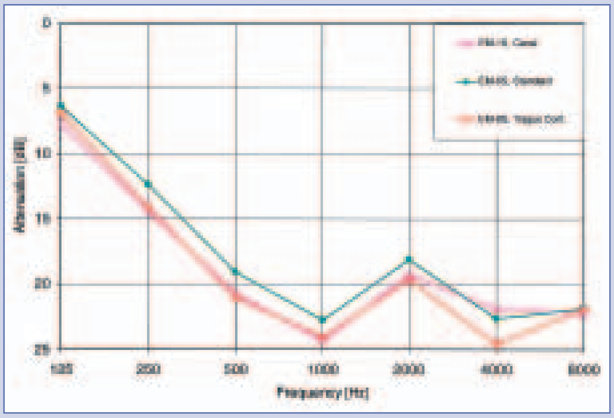

Figure 4. *Attenuation in soft earmolds made in different styles. Earmolds EM-1S, EM-5S, and EM-7S cast from the same investment offered similar attenuation thresholds.*

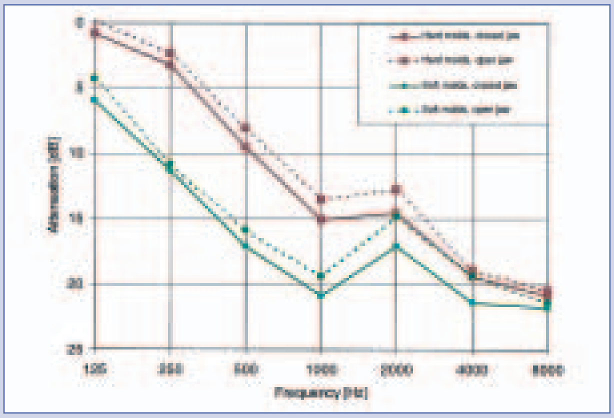

Figure 5. *The physical activity of subjects' jaw opening reduced attenuation thresholds for both hard and soft standard-style earmolds.*

Comfort

Subjects reported that all earmolds were comfortable. Soft earmolds made from impressions having coating C were typically more difficult to insert, and, in some cases, earmold lubrication was necessary. In contrast, hard earmolds were easier to insert but, for some subjects, more challenging to remove from the ear.

DISCUSSION

Two findings of this research raise questions that require a more detailed explanation. The first question is why did standard soft earmolds attenuate noise better than standard hard earmolds, which were poured from the same casting as the soft earmolds? The second is, why did canal-style earmolds provide as good attenuation as tragal-configuration soft molds?

Soft vs. hard earmold materials

For the purpose of this research, we used three casting investments (C1, C2, and C3) to make three pairs of earmolds in the standard style. One earmold in each pair was made from a hard UV resin, the other from a soft silicone.

We used the same casting for each to ensure the same accuracy of the earmold's physical fit in the subject's ear. However, because different earmold materials were used, the expected accuracy was not achieved. The UV resin contracted more during polymerization than the silicone did. In addition, finished UV earmolds required surface buffing and polishing to make them cosmetically appealing. Silicone earmolds did not require such treatment.

These differences in earmold manufacturing caused hard earmolds to have canal diameters approximately 0.32 mm smaller than those of the soft earmolds. As a result, hard molds provided a poorer acoustic seal. The silicone earmolds fitted more snugly and therefore attenuated noise more effectively.

It must be stressed, however, that the earmold manufacturing technique described here was employed for this study only. All soft and hard body earmolds made by our lab have equal sealing properties. The contraction ratio of a given earmold material and the earmold-finishing technique are incorporated in the manufacturing process.[11]

Earmold style vs. acoustic seal

Since soft earmolds made in the canal, standard, and tragal configurations were poured from the same casting (C2), made of the same material, and did not require any surface treatment, they provided the same quality of fit in the canal area of the subject's ear. As a result, these earmolds were measured as providing remarkably similar attenuation levels, regardless of the size of their conchal area. These results supported our opinion that acoustic seal in most hearing instrument fittings occurs at the ear canal, not the concha.

These research results were consistent with findings established in studies by Kieper et al.,[3] Chasin et al.,[2] and Macrae.[10]

The results of our study also indicate that neither the style nor the material of an earmold can be used to predict what level of attenuation will be achieved in the patient's ear. For example, as shown in Figures 6 and 7, earmold EM-1S made for Subject 9 attenuated the noise at 35 dB at 1000 Hz, whereas another EM-1S mold made for Subject 5 reached only a level of 10 dB at the same frequency, even though both earmolds were made in the same style and from the same material.

We attempted to determine if this discrepancy resulted from the loose fits of the earmolds or from the ear tissue's low impedance to noise. Subjects were asked to close their ear canal by pressing snugly, but comfortably, on the ear tragus. A curve marked FA5 (finger attenuation) in Figure 6 shows the test results. Because the levels of attenuation of all earmolds fitted on Subject 5 were greater than the FA5 response, low impedance of the subject's ear tissue was the likely cause of low attenuation thresholds.

The above findings are quite important in fitting custom hearing protection devices. The earmold style and/or material give no indication of what level of attenuation can be expected. Only a REAT test can establish the level of attenuation that a given earmold will provide. Without the REAT, the patient can be greatly over- or under-attenuated.

For example, a Musician's Earplug with the ER 25 attenuator made for Subject 5 would fall short of expectations, even if the mold had a very snug fit. On the other hand, if Subject 9 was fitted with a solid earmold, he could be over-attenuated and therefore unable either

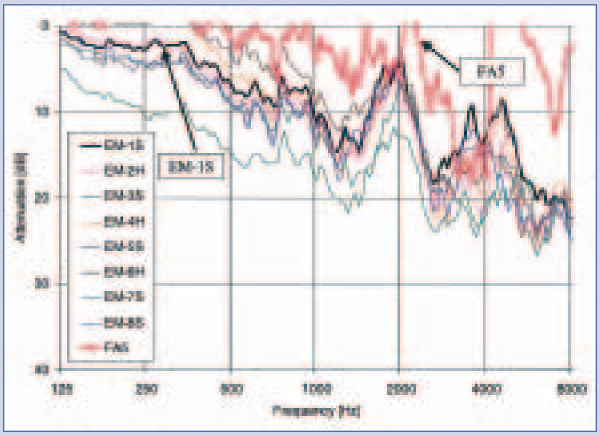

Figure 6. *Earmold attenuation thresholds obtained from Subject 5.*

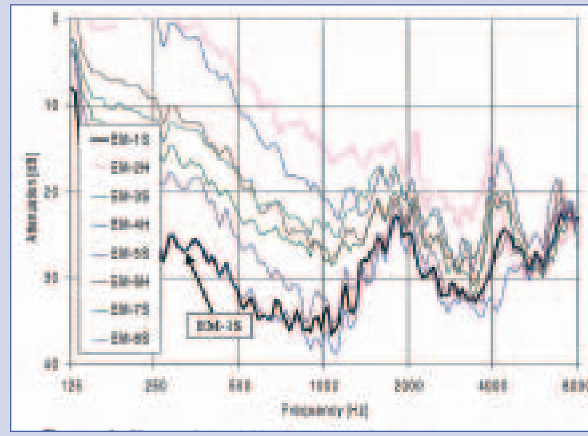

Figure 7. *Earmold attenuation thresholds obtained from Subject 9.*

to communicate or hear warning signals.

SUMMARY

This study found that the ability of an earmold to attenuate acoustic noise depended on more factors than the thickness of impression in-lab coating and the earmold style and material. The impression-taking technique and impression material proved to be equally important factors. Interestingly, the earmold style was determined to be of much lower importance than has been commonly believed. In fact, we found no direct relationship between the earmold style and the level of attenuation. Subjects' jaw movements typically introduced sound leakage and caused a reduction in the level of earmold attenuation.

Earmolds that require an enhanced acoustic seal should be made from open-jaw impressions taken with a standard-viscosity ear impression material. It is also advisable to indicate the importance of a snug fit on the order form so the manufacturer can employ a proper impression-coating technique. HJ

Chester Pirzanski, BSc, is a Process Engineer, **Mary Klenk**, MSc, and **Julie Purdy**, PhD are Audiologists, and **Vince Maye** is Director of Manufacturing, all at Starkey Canada, Mississauga, ON. **Marshall Chasin**, MSc, is an Audiologist and Coordinator for the Canadian Hearing Society in Toronto.

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