

To: General Distribution

From: Elliott H. Berger

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Re: Custom Earplugs - Frequently Asked Questions (FAQs)

The following discussion addresses questions about custom earplugs and the features they provide, as well as their place in the overall mix of available products.

What is a custom-molded earplug?

As the name implies, custom-molded earplugs are specifically molded to fit an individual's earcanals. This has classically been accomplished using silicone or vinyl materials that form soft earplugs, or acrylics that form hard molds (primarily in the case of custom molds for hearing aids). The earcanal impressions are made using a viscous material with a consistency varying from that of thick syrup to soft putty. The material is mixed with a curing agent and then injected into the earcanal using a large syringe, or in a less preferable technique, formed into a cone and manually packed into the canal. When using the injection technique, a cotton or preferably foam block (eardam) is inserted deep into the earcanal to prevent the impression material from reaching the eardrum. After about a 10-minute curing time, the ear impression is removed from the ear and is either modified on-site for immediate use (instant earmolds) or shipped to an earmold laboratory for production of manufactured custom earplugs.

In the case of conventional instant earmolds, the ear impression itself becomes the hearing protection device after it is trimmed and coated by the technician. The coating improves its durability and increases the tightness of the fit. Extra coatings can be used to increase attenuation, but at the expense of comfort. With custom earplugs that are manufactured in a laboratory, the impressions are used to make subsequent negative and positive molds in order to create the final custom earplug. The ear impression is also trimmed and coated in this process in order to remove imperfections and to make the finished earplug larger for a secure fit.

An alternative type of custom earplug consists of a thin expandable bladder filled with a silicone gel that is formed for each ear. The result is a custom-molded earplug with a smooth, durable finish that can be worn immediately after it is molded. Advantages of the bladder design include added safety during the initial molding process since the syrupy material is



Figure 1 – E•A•R™custom (left) and conventional custom earmold.

contained, and the ability to incorporate a channel through the plug that can be used for temporary insertion of a microphone to measure the in-the-ear attenuation using a fit test system, such as the E•A•Rfit™ validation system. Figure 1 illustrates a conventional custom earplug of the type described in the prior paragraph, as well as a bladder-style earplug, available as an E•A•R™ custom earmold.

Are custom earplugs a “new technology?”

Conventional custom earplugs have been in use for at least 40 years. Although it is true that their materials and means of manufacture have seen improvements, and the ability to provide in-the-ear fit testing has been incorporated in some products, their fundamental form and function have remained the same.

What are the benefits of custom earplugs?

Perhaps the most substantial benefit of custom earplugs is that, because of the “made-just-for-me” attribute, the customization process/feature can provide inherent motivation to the user to wear the products consistently and properly. Custom earplugs are a worthwhile option to consider for employees who do not respond well, or cannot adapt to other devices such as foam or premolded earplugs, semi-inserts (canal caps), or earmuffs, or who may benefit from an earplug with an individually adjusted (certain custom earmolds allow insertion of filters with varying levels of protection) and validated level of protection. However, as with all hearing protectors not any one product is best for, and appreciated by everyone, and thus a variety of products should be offered. Despite the widely held notion that custom earplugs provide greater protection when maximum noise reduction with a single hearing protector is required, deeply inserted foam earplugs typically provide equivalent or greater noise reduction than custom earplugs.¹

Since conventional custom earplugs are “customized” don’t they provide the best possible fit and highest levels of protection?

For all types of earplugs, sound is blocked by creating virtually an airtight acoustical seal within the earcanal. With foam earplugs this is achieved by the constant uniform pressure provided against the canal walls by the foam; with premolded earplugs it is the pressure exerted by their flexible flanges. With custom plugs the seal is created by a precise fit, to the extent possible, within the earcanal, much like a ground glass stopper would seal a glass jar. Any small imperfections or movement of the glass stopper will impair its seal. The same holds true for the acoustical seal of a custom earplug. It must closely match the shape of the earcanal to provide the acoustic seal. This can be offset somewhat by “inflating” the earcanal when the impression material is injected (to make the impression slightly oversized), or by dipping and coating the ear impression to uniformly increase its size. Both of these processes tend to cause a tighter and less comfortable fit, which offsets the principal advantage of the custom earmold, namely comfort.

¹ EARLog 20 and the entire EARLog series is available at www.e-a-r.com/hearingconservation/earlog_main.cfm

Considerable skill is required to take accurate impressions of each ear. Occupational hearing conservationists, technicians, or others who make such impressions should receive special one-on-one training from an audiologist or other professional specifically skilled in such procedures.

The fact that custom earplugs are user-specific and intended to fit only the canal for which they are manufactured does not assure that they will provide better protection than other well-fitted earplugs. In fact, the opposite has been reported as can be noted by looking at the data summarized in Figure 1 of EARLog 20.¹ The low attenuation may be partially explained by reference to Figure 2 (below) that depicts five different earmolds, all of which were made for the right ear of the same individual, and all of which were obtained by "experienced" fitters. Note the significant differences in the canal portion of the impressions, the part of the earplug that is responsible for sealing the ear and blocking sound.

The low-attenuation problem for custom earplugs can be addressed by better training of impression takers and greater care in fitting, as well as by fit-testing the impressions using a system such as the E•A•Rfit validation process (for those earplugs that allow such measurements).

Does the fact that a conventional custom earplug fills so much of the external ear (the concha and some of the folds of the pinna) cause it to provide more protection than plugs that only seat in the earcanal?

The “business portion” of the custom earplug is only the portion that seals within the earcanal. This is the part that actually blocks sound. In Figure 2, that portion is highlighted by the arrows. The remainder of the plug primarily helps to retain it in position within the canal.

Does it make sense to label custom earplugs with NRRs since the molds are custom fit to each individual?

Some manufacturers of custom earplugs argue that an NRR based upon laboratory test data for a group of 10 subjects makes no sense for customized devices that are essentially unique for each wearer. But the same can be said for a foam or premolded earplug – the shape that the plug takes on in the earcanal is unique for that wearer and application. When any plug is measured in the laboratory with the best-fit procedures of the currently required Environmental Protection Agency (EPA) hearing protector labeling regulation, the

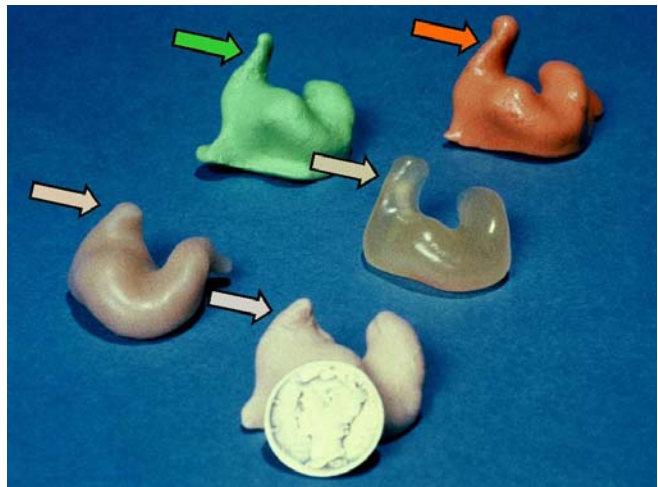


Figure 2 - Five custom earmolds, all in the same orientation, for one person's right earcanal. Arrows indicate canal portion of earmold and Liberty dime indicates size.

results are optimistic and in essence apply only to the 10 subjects involved in the study. This also holds true for conventional custom earplugs.

It should be noted, however, that use of earplugs that can be validated via individual fit testing, provides a degree of assurance that the NRR can be relied upon as an indicator of the product's performance. Additionally, when fit testing is part of the process, each earplug user will have individually measured attenuation values that provide a more valid estimate of their protection than noise reduction values generated on groups of subjects in a laboratory setting.

“Real-world” data vs. E•A•Rfit™ data.

The term real-world data, as it has come to be used in the literature, suggests a grab sample of employees taken from their place of work, without warning, wearing the devices as they usually wear them. The devices may have been worn for a period of weeks or months so that any degradation in the product or any changes in the wearer's anatomy (see question below on durability) will also affect the measurements. Although the E•A•Rfit procedure does include a test on the product as manufactured and delivered, the test is on an earplug that was molded only moments before and fitted by the employee under supervision. Even though it is a custom plug, there are differences in how the plug may be fit in practice, especially if the earmold is not a perfect match to the earcanal.

Though the E•A•Rfit data are a much better estimate of real-world values for that individual user than labeled NRRs, the actual real-world attenuation may still be less than the E•A•Rfit predictions.

Do custom earplugs provide the highest levels of comfort?

Custom earplugs can be very comfortable, but as the plugs more fully and tightly fill the canal and therefore more effectively attenuate sound, comfort deteriorates. This can sometimes lead users to cut down the canal-portion of a conventional custom earplug to enhance comfort. Although it is true that for many employees, custom earplugs will provide a high level of comfort, in practice, there is a limit to how snugly they can be fit. Wearers of custom plugs who experience discomfort should be cautioned not to modify their earplugs, but to instead contact their fitter to discuss if the product should be remade or if there are other means to improve the fit and comfort.

Since custom earplugs are so durable, won't they reduce costs and simplify a hearing conservation program?

In spite of the longevity claims made by some manufacturers for their "permanent" earplugs, these devices, like other earplugs, are susceptible to shrinkage, hardening, and cracking with time, and must be periodically reexamined to assure they are still soft, flexible, and wearable. Although there are scant data on actual use life of earplugs in occupational programs, it is reasonable to estimate a use life of up to

three years for a properly maintained product.² However, changes in body weight of 9 kg (20 lbs.) can affect the fit of a custom earplug sufficiently to require a remake.³ Additionally, since they may be lost or misplaced, as can all hearing protectors, administrative issues may arise regarding allowance of time to remanufacture them on an as-needed basis. Employees should be issued alternative backup devices to use in the interim.

Another factor that can affect the computation of relative costs is lost productivity due to time away from work because of the additional effort that is required in taking ear impressions, over and above the normal dispensing and training involved in properly issuing all types of hearing protection. Whether that time will be spent every other year or more often depends on the factors mentioned in the paragraph above.

Are there disadvantages to custom earplugs or risks in taking earcanal impressions?

As discussed above, taking a good ear impression requires skill and care. Even when impressions are well made, for certain users the custom earplugs made from those impressions may not seal well or consistently. Like other types of hearing protectors, no one variety is best for all earcanals. On occasion, the worker will experience minor discomfort or slight trauma to the earcanal, and, in rare instances, there have been reported cases of significant earcanal and middle ear trauma as earcanal impressions were being made.⁴

Do earplugs cause ear infection, and cannot custom earplugs reduce this problem?

The issues of hygiene are often overblown and misreported. See EARLog 17⁵ for a factual review. There is no evidence that earplugs in general cause problems, no evidence that foam earplugs are more of a problem than others, and neither is there evidence that the use of custom earmolds differentially affects the incidence of this problem.

Should I use custom earplugs of either conventional or the E•A•R™ custom variety in my hearing conservation program?

Custom earplugs can provide benefits in a hearing conservation program where the motivation provided by a customized/individualized product may be the key to getting buy-in from the worker, or for individuals who have not been able to find a suitable and comfortable earplug or earmuff, or those who may have unusual shapes to their earcanals. However for many, the wide array of non-custom products will be

² Briskey, RJ (1984). "NAEL: Fitting facts, Part VII: Hearing aid fitting: Outer ear and canal," Hearing Inst. 35(9), 30-32.

³ Royster, LH, and Royster, JD (1984). "Hearing protection utilization: Survey results across the USA," J. Acoust. Soc. Am. Suppl. 1, 76, S43.

⁴ Wynne, MK, Kahn, JM, Abel, DJ, and Allen, RL (2000). "External and middle ear trauma resulting from ear impressions," J. Am. Acad. Audiol. 11, 351-360.

⁵ EARLog 17 and the entire EARLog series is available at www.e-a-r.com/hearingconservation/earlog_main.cfm

appropriate and often provide equivalent or better comfort and attenuation than a custom device. Custom earplugs are not a panacea and should not be specified as the only product in a plant or the required hearing protector for all employees. One of the keys to the success of any hearing conservation program is to offer employees a variety of hearing protector types and sizes. Within that context, custom-molded earplugs can play a useful role in helping the employer assure that each worker who wears hearing protection is able to select the hearing protector that best matches his/her needs.