Custom Earplugs – Faster Delivery to the Warfighter

Kristen Semrud; Tyler Winningham

This column is coordinated and edited by Valerie E. Martindale, Ph.D. These articles are not peer-reviewed. The AsMA Science and Technology Committee provides the Watch as a forum to introduce and discuss a variety of topics involving all aspects of civil and military aerospace medicine. Please send your submissions and comments via email to: vemartindale@hotmail.com. Watch columns are available at www.asma.org through the "Read the Journal" link.

Hearing damage is the top service-connected disability for veterans receiving compensation, with an estimated annual cost of \$4.2B.[5] During flight operations, aircraft carrier flight deck personnel are exposed to sustained 150-dB noise—the same level as a gunshot from a high-powered firearm, but much longer duration. In this environment, personnel are at risk of noise overexposure even if hearing protection is worn perfectly. A 2006 study showed that flight deck personnel typically do not insert their universal fit (foam) earplugs correctly, resulting in very low noise attenuation and a high risk for noise-induced hearing damage.[1] It is thought that custom earplugs provide better real-world attenuation than universal fit earplugs because they conform to ear anatomy and thus are much easier to insert correctly.[3]

The challenge with fielding custom earplugs is the logistics footprint associated with procurement. The current method to produce custom earplugs requires an invasive silicone impression procedure to capture ear canal geometry. This procedure carries a risk of ear injury, e.g., a "blow-by," where impression material bonds with the eardrum or leaves scratches in the ear canal that can bleed. The physical impression is mailed to the vendor, who converts the physical impression to a digital file, completes some modeling modifications, creates custom earplug devices, and mails the completed product back to the user. This process can take weeks to months depending on the location of the user and the order volume at the manufacturer. At the Naval Air Warfare Center Aircraft Division (NAWCAD), this challenge was approached in two parts: the capture of ear canal geometry and the production of the custom earplugs.

In order to obtain physical impressions, members of the fleet are required to visit designated medically trained personnel, which is a barrier to many due to proximity to these specific personnel, deployments, etc. An alternative approach is made possible by the development of direct digital ear scanning technologies. Direct digital ear scanning technology enables real-time capture of ear canal and outer ear geometry. The output is a digital file that can be sent electronically to the manufacturer, thus shortening delivery time of ear geometry for earplug production. Additionally, the reduced risks associated with digital ear scanning enable a greater population within the fleet to obtain authorization to complete the scan.

The NAWCAD Auditory Performance Team investigated two different ear canal scanners as potential replacements for the physical impression method. The first study conducted in 2016 evaluated one scanner against physical impressions.[2] Earplugs from each ear canal geometry source were ordered from a single manufacturer for 20 subjects. All earplugs were tested using the ANSI S12.6 Method for Measuring Real Ear Attenuation of Hearing Protectors standard. In order to account for 98% of the population, this data was used to calculate the mean minus two standard deviation attenuation values. The results showed earplugs created by a given manufacturer from digital scans provided the same mean attenuation as earplugs created from physical impressions; however, the two methods had significantly different standard deviation values. Earplugs created from the physical impression method produced standard deviations ranging from 3.1–6.1 dB across the 125-Hz to 8-KHz frequency bands, whereas the earplugs created from the digital scan had standard deviations ranging from 5.8–10.5 dB. Therefore, earplugs created from a digital scan had lower mean minus two standard deviation attenuation than the physical impression counterparts.

The results of the 2016 study inspired a second study evaluating the variability in custom earplugs produced by a given

From the Naval Air Warfare Center Aircraft Division, Patuxent River, MD.

DOI: https://doi.org/10.3357/AMHP.5628.2020

manufacturer. The study compared two different digital ear-scanning technologies against the physical impression method.[4] Following the same ANSI S12.6 Real Ear Attenuation at Threshold (REAT) testing procedure, it was found that all earplugs, regardless of ear canal geometry source, performed worse than the earplugs used in the 2016 study. Relative to one another, the physical impression earplugs performed the best and Scanner A (also used in 2016) performed approximately 10 dB better than Scanner B (not previously evaluated). With regards to standard deviation, the earplugs created from physical impressions had the greatest standard deviation values, ranging from 4.9–9.9 dB across the 125-Hz to 8-kHz frequency bands. Scanner A and Scanner B had comparable standard deviation values, with Scanner A ranging from 3.8–7.6 dB and Scanner B ranging from 5.0–8.3 dB. It is thought that the results for Scanner B were heavily influenced by the manufacturer's lack of experience modeling the digital files produced by that scanner.

The second half of the logistics issue faced by fielding custom earplugs is the production and delivery of the completed product. To improve the timeline associated with this portion of the process, the Auditory Performance Team launched an effort in 2017 to develop the capability to 3D print custom earplugs on site using ear canal geometry captured by the digital ear scanning technologies.[4] This effort used scans from one digital ear scanner and a desktop 3D printer capable of printing with a biocompatible material. The material was a low viscosity liquid photopolymer that was certified for use in hearing aid products. Nine different modeling techniques were developed, and proof-of-concept solid custom earplugs and communications earplug ear tips were produced. The solid custom earplugs were evaluated against custom earplugs ordered from an outside manufacturer using an acoustic test fixture on which insertion loss measurements were taken using a procedure slightly modified from ANSI S12.42 Methods for the Measurement of Insertion Loss of Hearing Protection Devices in Continuous or Impulsive Noise Using Microphone-in-Real-Ear or Acoustic Test Fixture Procedures. The insertion loss performance and standard deviations of the 3D printed earplugs were comparable to the performance and standard deviations of manufactured silicone custom earplugs. One modeling technique was chosen to undergo ANSI S12.6 REAT testing. However, with human subjects, the proof-of-concept 3D printed earplugs did not perform quite as well as the manufactured silicone earplugs.

Further investigation continues into alternative materials for improved performance and comfort. In addition to alternative materials, the current effort is investigating the use of an alternative digital ear scanner, alternative printer, and new modeling techniques. Additional evaluation of earplugs created from digital scans by multiple manufacturers is also required to complete the digital scanning technology assessments. If successful, the time from ear geometry capture to hearing protection device in hand will be reduced from weeks/months to hours. The success of this effort would also increase the accessibility of custom hearing protection solutions.

REFERENCES

1. Bjorn VS, Albery CB, McKinley RLUS. Navy Flight Deck Hearing Protection Trends: Survey Results. Naval Air Warfare Center Aircraft Division Technical Report NAWCADPAX/TR-2006/73. Patuxent River (MD, USA): Naval Air Warfare Center, Aircraft Division; 2006.
2. Semrud K. Process for digital capture of ear canal geometry and rationale for use of custom earplugs. [Abstract.] Aerosp Med Hum Perform. 2017; 88(3):308.
3. Tufts JB, Jahn KN, Byram JP. Consistency of attenuation across multiple fittings of custom and noncustom earplugs. Ann Occup Hyg. 2013; 57(5): 571–580.
4. Winningham T. Evaluation of Custom Earplug Variation and Digital Ear Canal Scanning Technologies. Proceedings of the SAFE Association Annual Symposium; October 14–16, 2019; Reno, NV. Creswell (OR): SAFE Association; 2019.
5. U.S. Department of Veterans Affairs. Veterans Benefits Administration Annual Benefits Report Fiscal Year 2015. Washington (DC, USA): Department of Veterans Affairs; 2015.