

AWARD NUMBER: W81XWH-14-1-0254

TITLE: Evaluation of Extended-wear Hearing Aid Technology
for Operational Military Use

PRINCIPAL INVESTIGATOR: Dr. Douglas Brungart

CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation for the Advancement of Military
Medicine
Bethesda, MD 20817

REPORT DATE: July 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE July 2016		2. REPORT TYPE Annual		3. DATES COVERED 01 July 2015 – 30 June 2016	
4. TITLE AND SUBTITLE Evaluation of Extended-wear Hearing Aid Technology for Operational Military Use				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-1-0254	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Douglas Brungart, LaGuinn Sherlock & Nandini Iyer E-Mail: douglas.s.brungart.civ@mail.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720A Rockledge Drive, Bethesda MD Walter Reed Military Medicine Center; Air Force Research Laboratory				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The primary goal of this research effort is to determine the potential viability of the Lyric device both as a deployable hearing aid for Service Members with existing hearing loss and, in the future, as a possible form factor for a transparent hearing protection device that could protect the hearing of normal-hearing listeners without degrading auditory situational awareness. To this point, significant progress has been made in this evaluation process. The devices have been electroacoustically tested for impulse noise protection, both with C4 and with a blast tube, and they have been found to provide impulse noise protection comparable to commonly-used passive protection earplug devices. Electroacoustic tests in continuous noise, as well as preliminary behavioral tests, suggest that continuous noise protection is also comparable to conventional earplug devices. Preliminary behavioral testing suggests that, in the active mode, the devices allow external sounds to pass through at frequencies up to 12 kHz, which provides excellent preservation of situational awareness and localization accuracy comparable to the open ear. An individual who has worn the devices in two combat deployments was identified, and his testimonial appears to provide support for the suitability of the devices for use in military environments. Full-scale testing of normal hearing subjects is underway at WPAFB and a field-test for active duty hearing aid users is under review at the Walter Reed IRB.					
15. SUBJECT TERMS Lyric, hearing aid, localization, attenuation					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

1. Cover Page.....	1
2. SF 298.....	2
3. Table of Contents.....	3
4. Introduction.....	4
5. Keywords.....	4
6. Accomplishments.....	4
7. Impact.....	9
8. Changes/Problems.....	9
9. Products.....	9
10. Participants & Other Collaborating Organizations.....	9
11. Special Reporting Requirements.....	10

Introduction: The purpose of the proposed study is to assess the potential military utility of a new hearing aid technology called “extended-wear” that allows a hearing aid to be inserted deeply in the ear canal and left in place continuously for up to 120 days before requiring removal and replacement. We hypothesize that this new extended-wear hearing device can, with little or no modification, be adapted to provide a treatment option for hearing loss that will allow soldiers with mild-to-moderate hearing loss to return to full duty in military environments where standard hearing aid use is not practical. We also hypothesize that, in the longer term, the technologies associated with the extended-wear hearing aid could be adapted to provide long-term hearing protection for listeners with normal hearing with minimal impact on auditory situational awareness and minimal annoyance due to factors related to occlusion, comfort, and device maintenance. We believe that such a system, if it could be achieved, could largely eliminate noise induced hearing loss in battlefield military operations.

Keywords: Hearing aid, situational awareness, Lyric, attenuation, protection, auditory localization, communication, hearing protection, hearing loss, noise exposure, occlusion

Accomplishments:

What were the major goals of the project?

The purpose of this project is to evaluate the potential military utility of the technologies embodied in the revolutionary new “extended-wear” hearing aid. A total of six different types of evaluations will be performed as part of this effort:

- 1) Evaluate the impact of the devices on sound localization accuracy
- 2) Evaluate the effect of the devices on occlusion and speech communication in noise
- 3) Evaluate how well the devices can protect the ear from blast exposure
- 4) Evaluate how well the devices can protect the ear from noise exposure
- 5) Evaluate device compatibility with existing military communication systems
- 6) Evaluate user acceptability of the devices in the hearing-impaired military population

What was accomplished under these goals?

Human Research Protocol: An existing protocol used in the routine evaluation of hearing protection devices at the Air Force Research Laboratory (AFRL), Battlespace Acoustics Branch was updated and approved to include the Lyric device. The AFRL protocol was sent to the Human Research Protection Office (HRPO) at the US Army Medical Research & Materiel Command (USAMRMC) and received final approval. Subject recruitment has been initiated. As of June 30, 2016, data collection was completed on two participants. Eight more participants are expected to be tested before the end of FY16.

Test Plan: A comprehensive test plan is complete for the measurements at AFRL, which will incorporate goals 1-2 and 4-5 above using a normal hearing population; see Table 1 for details. All components of the test plan are ready to start human testing

Preliminary Results: Two participants were fitted with the Lyric devices and data was collected according to the test plan.

Attenuation is measured for hearing protection devices using the standards developed by the American National Standards Institute (ANSI) published in 2008 and 2012, Methods for Measuring the Real-Ear Attenuation of Hearing Protectors, and Methods of Estimating Effective A-Weighted Sound Pressure Levels When Hearing Protectors Are Worn, respectively.

The Real-Ear Attenuation at Threshold (REAT) measurement is completed in a sound booth (Figure 1) using Bekesy audiometry. The subject listens to 1/3rd octave-band noise presented from speakers and responds behaviorally by pressing a button when the noise is heard and releasing the button when the noise is not heard. The hearing thresholds, gathered in this manner, for an open ear condition and a closed ear condition (hearing protector) result in the amount of attenuation for a given hearing protection device. Devices are measured with electronics “off” to measure the amount of passive protection (attenuation).



Session:	Measurements
1	Ear exam/cleaning
	Hearing Tests
	REAT training
	Localization training
	VOCRES training
2	Open ear audiometric data
	Open ear REAT thresholds
	Device programming & fitting
	Closed ear REAT thresholds
	Occlusion, aided audiometric data
	Localization/detection
	Communications (listener/talker conditions)
	BREAK
	Closed ear REAT thresholds
	Device removal
	Open ear REAT thresholds
	Questionnaires

Table 1: Test plan overview

Figure 1: Real-Ear-At-Threshold Test Chamber, Air Force Research Laboratory

Figure 2 demonstrates the attenuation for three subjects (1 pilot and 2 enrolled subjects). The subjects received on average 10-30 dB of attenuation across the frequency range tested. By comparison, average attenuation ranged from 7 to 27 dB for the CAE in the open position and 20 to 34 dB for the CAE in the closed position. Based on these subjects, the Lyric device appears comparable to traditional hearing protection devices when used in the passive mode (off). Test results comparing attenuation provided by the Lyric alone compared to the addition of hearing protection devices, presented last year, indicate that if needed, additional attenuation could be obtained by combining the Lyric with a second protector. In fact, it appears that it may be possible to achieve attenuation close to the bone conduction limit (traditional “double hearing protection” limit) simply by combining the Lyric devices with a second set of earplugs (Figure 3, Lyric with Earbuds and Earmuff condition). However, no additional attenuation is obtained by adding earmuffs to the “double hearing protection” condition of Lyric plus earbuds.

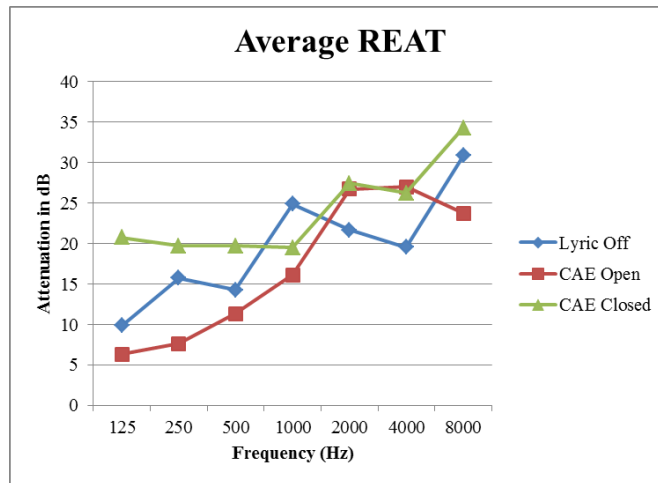


Figure 2: Comparison of REAT attenuation with Lyric vs. Combat Arms Earplug (CAE).

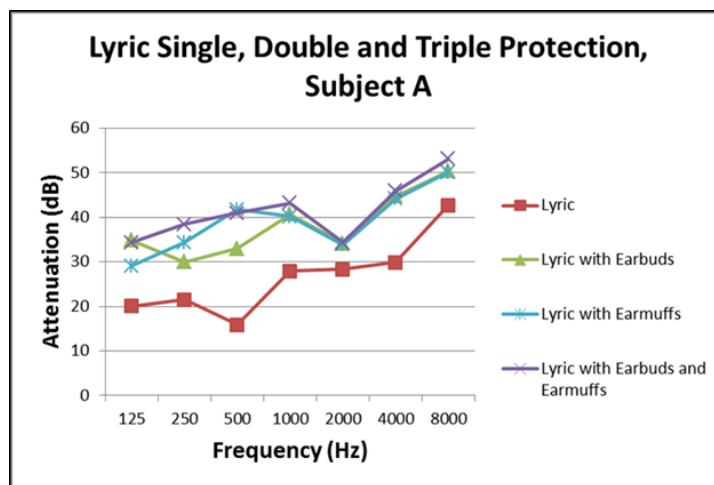


Figure 3: “Double” and “Triple protection on pilot subject.

Figure 4 demonstrates the hearing thresholds and aided hearing thresholds for two subjects. Both subjects have essentially normal hearing in both ears in the standard audiometric range (250 – 8000 Hz). The “sleep” mode provides approximately 10 dB less gain overall compared to the “on” mode. The prescribed gain with the Lyric device “on” shows that the device appears to allow the detection of 8-12 kHz when worn under headphones, suggesting that the device does pass through sufficient bandwidth to restore normal localization accuracy in normal hearing listeners.

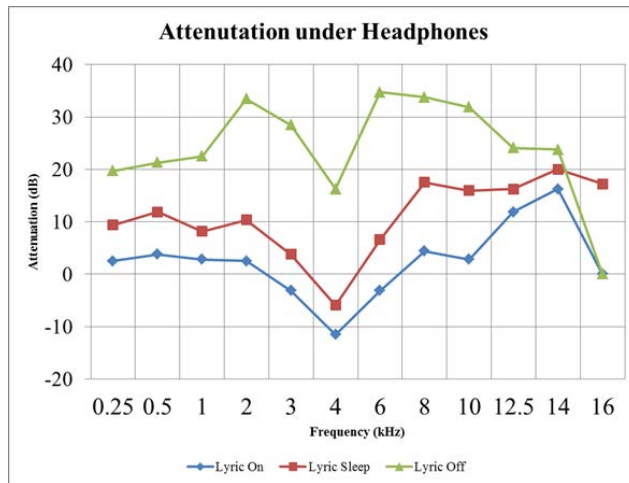


Figure 4: Audiometric thresholds with the Lyric device for two subjects (1600 and 1629)

Localization errors and aurally guided visual search tasks were completed on two subjects in the Spatial Hearing Auditory Research Chamber (SHARC) (Figure 5) at AFRL. The chamber consists of a 32 speaker array in an anechoic chamber. Four light-emitting diodes (LEDs) are located on each speaker. The SHARC is housed within an anechoic chamber. Subjects sit in the center of the array of speakers, and identify the correct speaker either by head pointing or by selecting the speakers by number.



Figure 5: Spatial Hearing Auditory Research Chamber (SHARC)

In a pilot study conducted in the AFRL Auditory Localization Facility (ALF) (a three-dimensional sphere of speakers requiring accurate localization in both azimuth and elevation) a subject who wore the Lyric device in “on” mode was able to localize short duration (250 ms) sounds within 16 degrees and long duration (4s) sounds within 3 degrees; this was essentially equivalent to localization ability without the devices in the ears (open ear). Due to a problem with the ALF, the localization paradigm was switched to the 2-dimensional SHARC speaker array. Results from two subjects in this new paradigm are shown in Figure 6. Although performance was slightly worse with the devices in active mode than it was in the open ear condition, performance was substantially better than was obtained with conventional earplug or earmuff Tactical Communication and Protection (TCAP) devices.

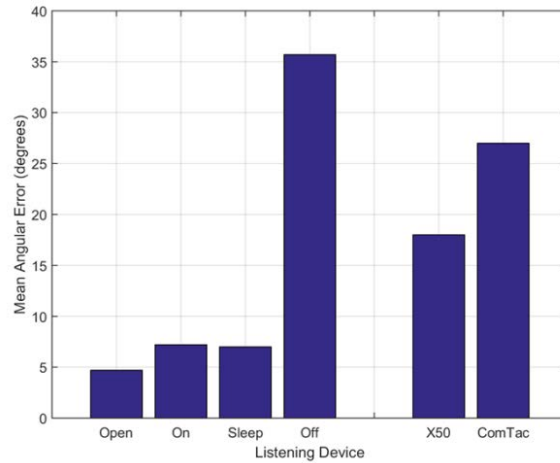


Figure 6: Auditory localization angular error; two subjects

For the aurally guided visual search task, response time to aurally locate and visually identify the sound source location was collected for one pilot subject. For this task, the target stimulus was a cluster of LEDs in which either two or four LEDs were illuminated. The distracter stimuli were clusters of LEDs with either one or three illuminated LEDs. In addition, a 250 ms burst of broadband (200 Hz - 16 kHz) pink noise was played from the speaker at the target location at predetermined sound levels of 15, 25 and 40 dB SPL for aided and open ear conditions, and 45 and 65 dB SPL for aided-passive device condition. Results are shown in Figure 10. These results show that the “Lyric On” condition (open circles) was comparable to the open-ear condition at all stimulus levels tested. In comparison, all of the other active protectors tested, including the current US Army TCAPs system (Invisio X50, pink triangles) resulted in a 2-4 substantial increase in visual target acquisition time at 15 dB. At this highest signal level (65 dB), the Lyric in passive (off) mode (blue diamonds) was close to open-ear performance, which was not true for any other protection device. While preliminary, these data suggest that the unique design of the Lyric, which uses an analog amplification circuit that preserves relatively high bandwidth and is inserted deeply in the ear canal where it minimizes the disruption of localization cues, could someday be used to produce a hearing protection system that preserves substantially more situational awareness than any other active or passive hearing protection system currently on the market.

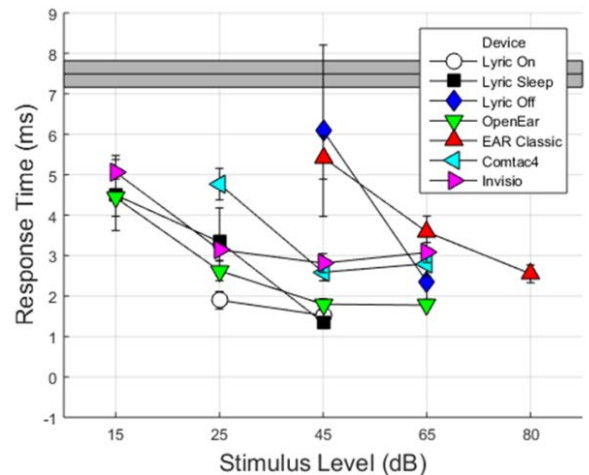


Figure 7: Aurally guided visual search task, two subjects.

Case Study:

A retired service member who used the Lyric hearing aids during two deployments was seen for evaluation at Walter Reed National Military Medical Center in February 2016. The SM had a bilateral sensorineural hearing loss sloping from moderate to severe degree. A series of measures were made, including functional gain, attenuation provided by the hearing aids when turned off, localization ability, and speech understanding in noise. The results did not indicate that performance with the Lyric was substantially better than performance with a standard hearing aid. Although the SM's hearing loss was outside the range of the target population, his experience indicates that the Lyric could function in deployment.

What opportunities for training and professional development has the project provided?

The Lyric device is commercially available through Phonak, LLC. Phonak provides regional training for audiologists who fit the Lyric device. Training was provided at AFRL for several audiologists through Phonak's regional consulting audiologist 26-28 May 2015 and again in June 2016.

How were the results disseminated to communities of interest? Nothing to report.

Impacts: Nothing to report

Changes/Problems: Nothing to report

Products: Nothing to report

**Participants & Other Collaborating Organizations:
What individuals have worked on the project?**

Name: Douglas Brungart
Project Role: Principal Investigator
Nearest person month worked: 1
Contribution to Project: PI
Funding Support: Government employee

Name: Elizabeth McKenna
Project Role: Associate Investigator
Nearest person month worked: 9
Contribution to Project: AFRL lead researcher for project
Funding Support: Funded by award

Name: Nina Pryor
Project Role: Associate Investigator
Nearest person month worked: 1
Contribution to Project: AFRL lead researcher for project
Funding Support: Funded by award

Name: Nandini Iyer
Project Role: Associate Investigator
Nearest person month worked: N/A
Contribution to Project: Consultation support
Funding Support: Government employee

Name: LaGuinn Sherlock
Project Role: Associate Investigator
Nearest person month worked: N/A 9

Contribution to Project: Consultation support
Funding Support: Government employee

Name: Ashley Zaleski
Project Role: Doctoral student
Nearest person month worked: N/A
Contribution to Project: Consultation support
Funding Support: Army Hearing Program

Has there been a change in the active or other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Elizabeth McKenna left the project in March 2016. She has been replaced by Nina Pryor.

What other organizations were involved as partners?

Organization Name: Integrated Demonstrations and Applications Laboratory, Electromagnetic Interference Research Laboratory, Wright-Patterson Air Force Base, OH
Partner's Contribution: Facilities and personnel exchanges; completed Electromagnetic Interference laboratory measurements on Lyric device prior to human testing in accordance with MIL-STD 461F.

Organization Name: Phonak, LLC
Partner's Contribution: In-kind support; provided on-site training, software and equipment for fitting of Lyric device.

Special Reporting Requirements: N/A