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PRINCIPAL INVESTIGATOR:	Dr. Douglas Brungart
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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 tested electro-acoustically 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 nearing completion at WPAFB and afield-test for active duty hearing aid users is underway at the Walter Reed National Military Medical Center.					
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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 was initiated during the previous reporting period. As of June 30, 2018, data collection has been completed on most of the Specific Aims.

Test Plan: A comprehensive test plan is complete for the measurements at AFRL, which incorporate goals 1-2 and 4-5 above using a normal hearing population; see Table 1 for details.

Preliminary Results:

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A group of NH listeners were fitted with the Lyric devices and data was collected according to the test plan outlined in Table 1.

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

Pure tone audiometric thresholds, both aided and un-aided, were measured at various frequencies for normal-hearing listeners using standard audiometer techniques. Figure 1 demonstrates the mean and standard deviation aided and un-aided hearing thresholds across ears and across 10 subjects. The average subject had essentially normal hearing in the standard audiometric range (250 – 8000 Hz) in the “open ear” condition. 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 passes through sufficient bandwidth to allow normal localization accuracy in normal hearing listeners. The “sleep” mode provides approximately 10 dB less gain overall compared to the “on” mode. The “off” mode provides about 20-35 dB of attenuation, depending on the frequency-band.

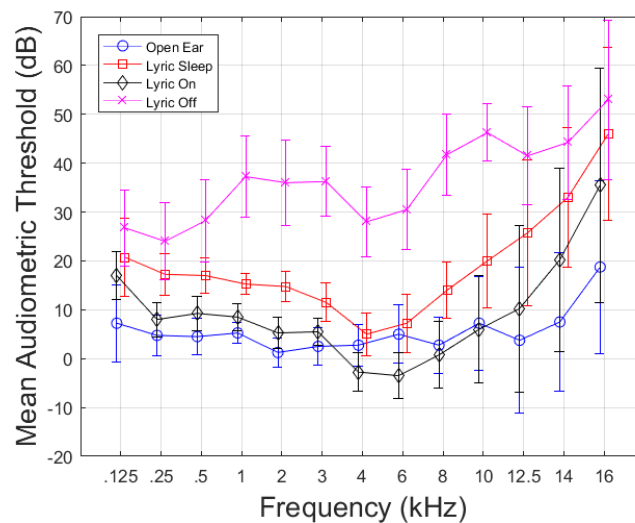


Figure 1: Mean audiometric thresholds across the left and right ears with the Lyric devices, across ten subjects.

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 2) 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).



Figure 2: Real-Ear-At-Threshold Test Chamber, Air Force Research Laboratory

Figure 3 demonstrates REAT attenuation for the Lyric off condition, for 10 subjects. The average attenuation was 10-30 dB, the specific amount depending on the frequency. Figure 3 also compares attenuation data for the Lyric off condition to attenuation data collected at AFRL for the Combat Arms Earplugs (CAEs) ear plugs. About 7 to 27 dB of attenuation was measured for the CAE in the open position and 20 to 34 dB for the CAE in the closed position (Gallagher et al, 2016). Based on these data, the Lyric device appears comparable to traditional hearing protection devices in terms of attenuation provided when used in the passive mode (off).

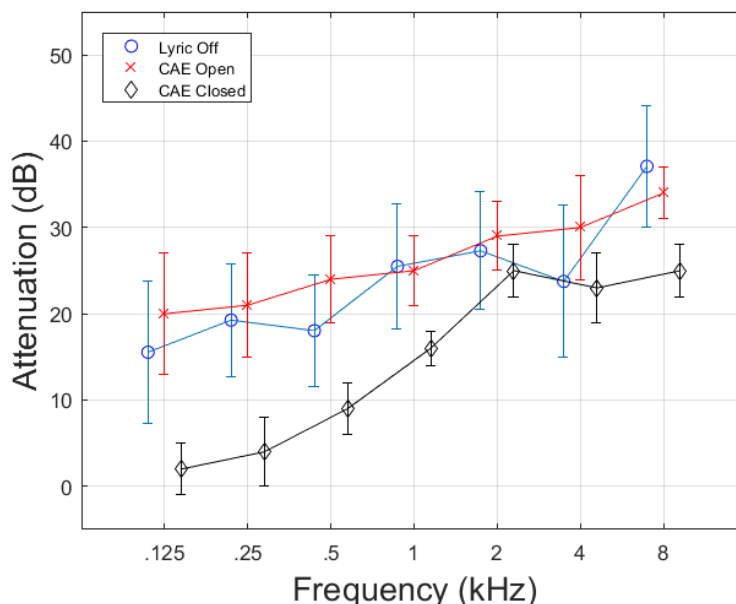


Figure 3: Comparison of REAT attenuation with Lyric vs. Combat Arms Earplug (CAE). CAE data re-plotted from Gallagher et al (2016) (“Performance assessment of the 3M Combat Arms Generation 4.0 Tactical Military Shooter’s Ear Plug”).

Figure 4 compares attenuation data for the Lyric devices alone to those for the Lyrics in conjunction with a second, or second and third type of hearing protector. These data indicate that, if needed, additional attenuation can 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 protection (Figure 4, Lyric with Earbuds condition; Figure 4, Lyric with Earmuff condition). However, no additional attenuation is obtained by adding earmuffs to the “double hearing protection” condition of Lyric plus earbuds.

It is also worth noting that there are some types of existing military hearing protectors which can be switched on to provide gain (for communication), or off to provide attenuation, like the Lyric hearing aids.

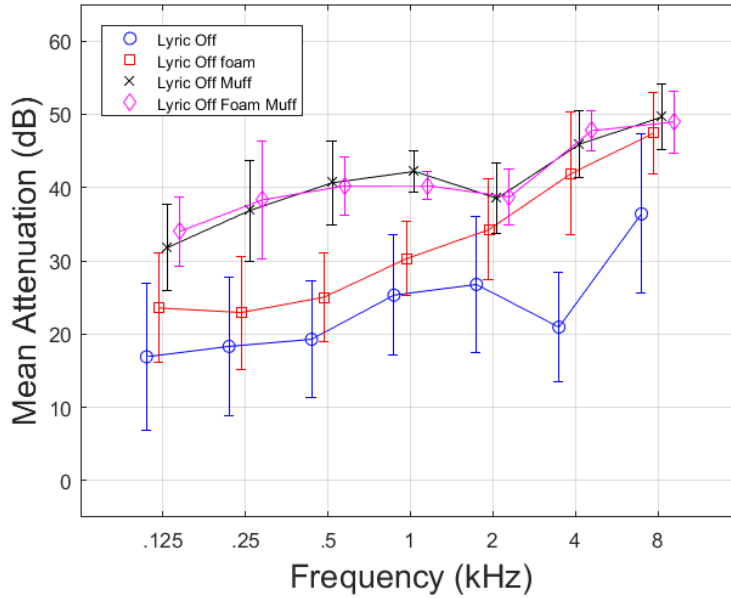


Figure 4: Average and standard deviation REAT attenuation for Lyric with and without “Double” and “Triple” protection for seven subjects.

Note that these data are for a different set of subjects as used to generate the data in Figure 2. 3M Ear classic foam plugs were used as the “foams”, Peltor X5a muffs as the “muffs”.

Sound localization errors were measured in the Auditory Localization Facility (ALF) (Fig. 5) at AFRL. The ALF consists of a geodesic sphere (4.3m in diameter) with 277 Bose 11 cm, full-range loudspeakers mounted on its surface, and a small cluster of 4 LEDs mounted on the front of each loudspeaker. The sphere contains a platform in its center, upon which the subjects stand. The sphere is housed within an anechoic chamber, the walls, floor and ceiling covered in 1.1m fiberglass wedges. Only 237 of the loudspeakers were used for the current study; those -45° and lower were excluded. The errors were measured for less impulsive (“burst noise” and “continuous noise”) and more impulsive (“burst click”) stimuli.

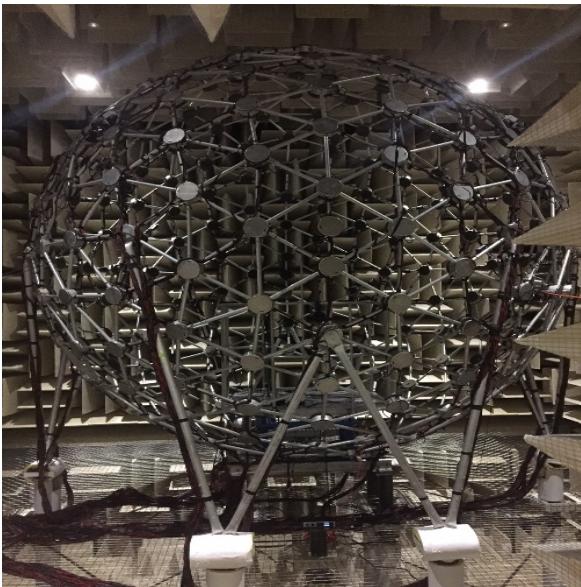


Figure 5: The auditory localization facility (ALF), Air Force Research Laboratory

In a pilot study conducted in the AFRL Auditory Localization Facility (ALF) 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 (Figure 6). Results from two subjects in this new paradigm are shown in Figure 7. 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: Spatial Hearing Auditory Research Chamber (SHARC)

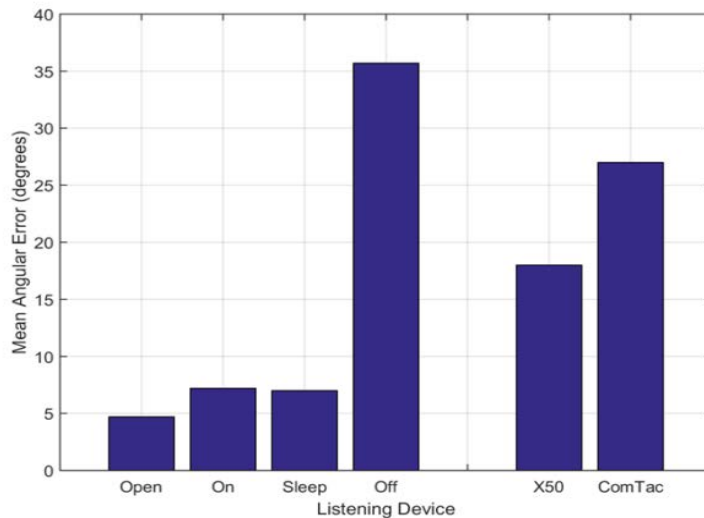


Figure 7: Auditory localization angular error; two subjects.

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 8. 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.

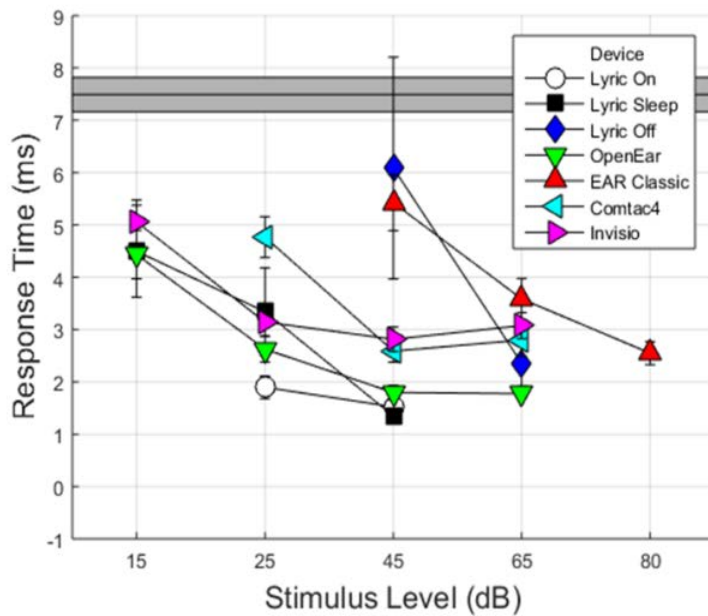


Figure 8: Aurally guided visual search task, two subjects.

Sound localization errors were measured on N=8 subjects with the subjects standing on the platform in the center of the ALF, their ears in line with the center of the front loudspeaker, height-wise. The subjects faced the front loudspeaker location, heard the target stimuli, elected their response and received correct answer feedback. There were 55 trials per condition.

Figure 9 shows the sound localization overall angular errors as a function of the condition. The angular errors were relatively low, those for the burst clicks increasing with level in the open ear condition. The angular errors were slightly poorer in the Lyric on than open ear condition, albeit moderately poorer when the stimulus level was high. The angular errors were higher in the Lyric off condition, especially when the stimulus level was low.

Figure 9 also compares open ear data between the current study and previous studies, capturing localization errors for stock devices used in the military. There were minor differences between the current and previous studies (pink noise used in the previous studies, white noise with no pink filter in the current study). Note however that the localization errors for the Lyric on and off conditions were always lower than (sometimes substantially so) or about equal to those for one of the other stock devices, for a given stimulus type and the approximate stimulus level. [Note: When comparing the results to previous protectors, be sure to make the comparison “diamonds-to-diamonds” (continuous noise) or “squares-to-squares” (burst noise). The “Burst-Click” is a special, difficult to localize condition that was only tested on the Lyric”. Thus, for a 250 ms noise burst at 70 dB, the Lyric produced an error of roughly 15 degrees, whereas the Invisio X5, which was the second best protector tested, produced an error of 25 degrees. For a continuous noise at 70 dB, the Lyric produced an error of < 5 degrees, compared to 10 degrees for the X5.].

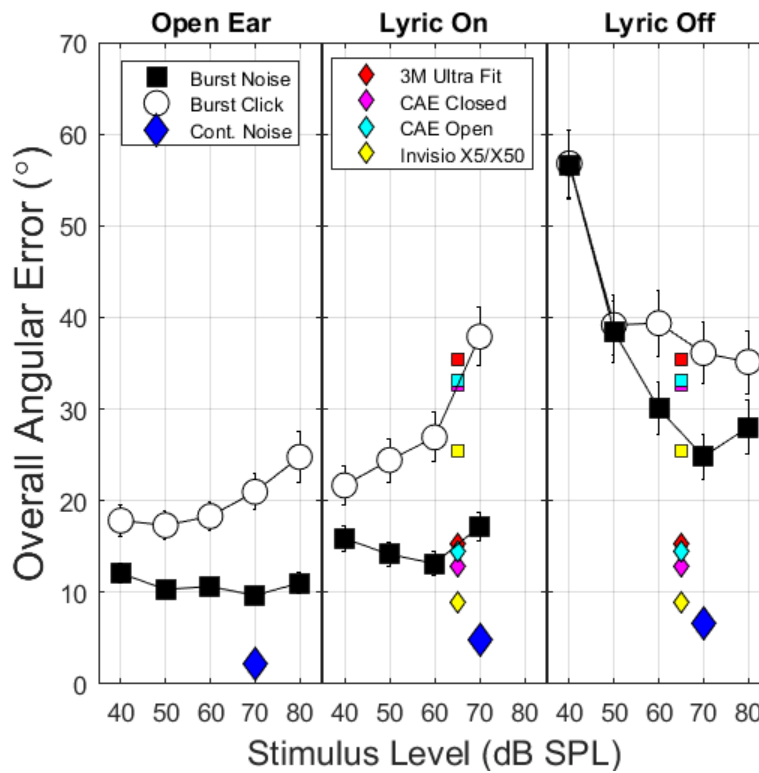


Figure 5: ALF overall angular error data for 250 ms noise burst, 250 burst click and continuous noise stimuli, and comparison with re-plotted previous study data.

Note that the previous-study were all collected at AFRL. Previous study data collected from the following studies: Gallagher et al (2014), "Performance assessment of passive hearing protection devices", Gallagher et al (2016), "Performance assessment of the 3M Combat Arms Generation 4.0 Tactical Military Shooter's Ear Plug", Swayne and Gallagher (2018), "Tactical hearing protection and communication device performance assessment for the United States Marine Corps" (In process). The "Invisio X5/X50" data were measured using the Invisio X5 Generation II.

There are a variety of different types of errors that subjects can make in the ALF sound localization set-up which contribute to overall angular error. It is important, for example, to differentiate between errors made in the left/right dimension from those in the vertical polar dimension.

Figure 10 illustrates left/right errors and vertical polar errors as a function of stimulus level and stimulus type, for the same experiment and stimuli used in Fig. 9. Note the difference in y-axis scales between the plots. With this difference in mind, the most important finding was that the vertical polar errors were always larger, sometimes substantially so, for a stimulus type, level and device setting. Both types of errors showed a similar stimulus level dependence as the angular errors, for a given stimulus type and device.

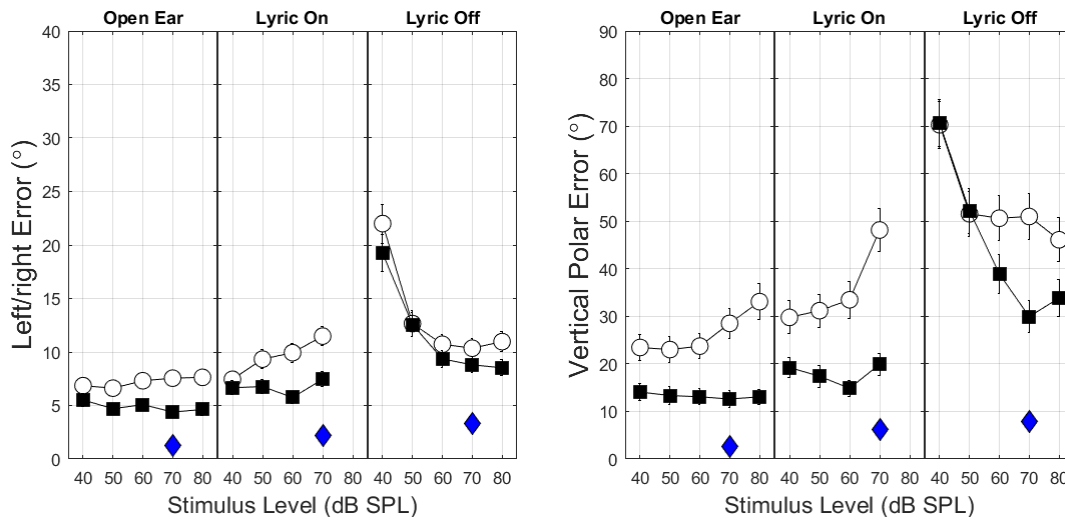


Figure 6: ALF left/right and vertical polar error data for 250 ms noise burst, 250 burst click and continuous noise stimuli.

As a part of our efforts to evaluate device compatibility with existing military communication systems, sound localization errors were measured on subjects who were either wearing Comtac III military headsets or a combination of the Comtac IIIs and Lyric hearing aids. The Comtac IIIs were either turned on, to a minimum or maximum gain setting, or turned off. The Lyric hearing aids were always turned on. The Comtac III and the Comtac III/Lyric On conditions were run on separate days. Performance was measured on N=4 subjects in the Comtac III alone conditions, and N=2 for the Lyric On/Comtac III conditions (both of whom were also tested in the Comtac III alone conditions). The localization data collection methods were the same for these conditions as for the various lyric conditions.

Figure 11 shows the overall angular errors as a function of the stimulus level and stimulus type for the Comtac III and the Comtac III/Lyric On conditions. These data are only shown for N=2 or 4 subjects, but some of the same patterns, which were also found in the Lyric conditions, are emerging. The angular errors were smaller for the continuous noise and burst noise conditions than for the burst clicks, and level-dependent in some cases for the burst clicks in some cases, as well.

The angular errors only increased slightly on average for the Lyric On/Comtac III conditions when compared to the Comtac III alone conditions. This suggests that Lyric/Comtac III compatibility was high.

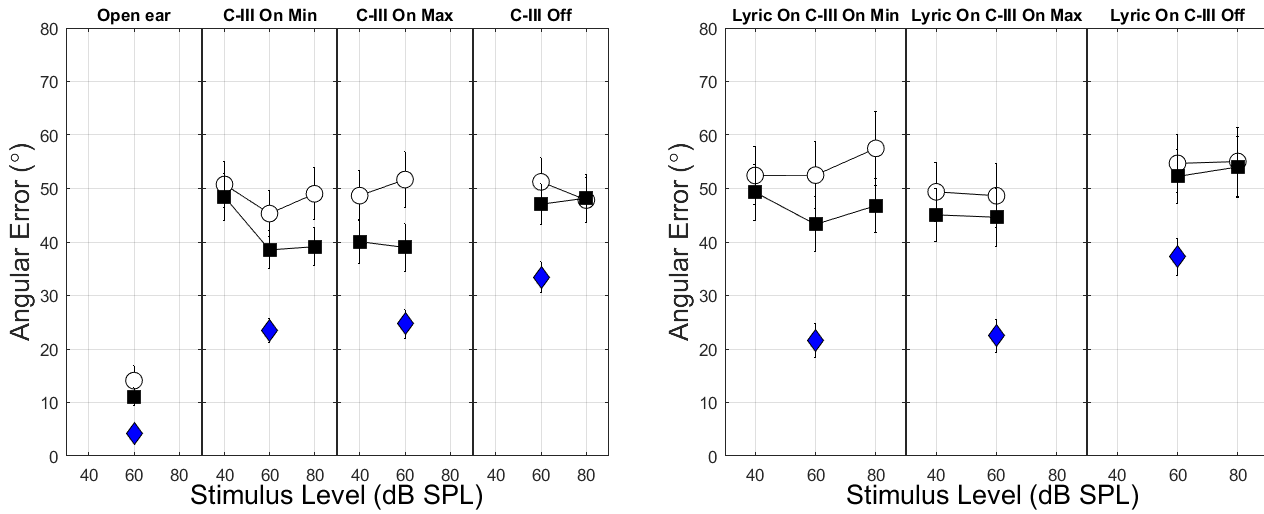


Figure 11: ALF angular error data for Comtac III On and Lyric On/Comtac III On. 250 ms burst noise, 250 ms burst click and continuous noise stimuli, and comparison with re-plotted previous study data.

Electro-acoustic measurements were made with a Knowles Electronics Manikin for Acoustic Research (KEMAR) that was equipped with GRAS IEC 711 Ear Simulators. The KEMAR was placed on the center of the platform in the center of ALF, facing forward and ears equalized height-wise with respect to the center of the front loudspeaker. Measurements were made with three different types of stimuli: burst noises, burst clicks and logarithmic sweeps. Burst noises (more steady-state) and burst clicks (more impulsive) were used in localization experiments.

It is important to plot the input/output gain characteristics of a device, as a general descriptor of device behavior. Figure 12 plots the signal level as a function of the device condition for stimuli presented through the front loudspeaker in ALF. A small amount of gain is found in the open ear condition due to the outer ear resonance effect. The maximum levels are higher than the RMS levels, especially for peaky burst click stimuli. Non-linearities are found in the RMS and maximum gain functions for the Lyric on condition, due to compression. The peak/RMS ratio drops at high levels for the burst clicks in the Lyric on condition, due to compression. Attenuation is provided by the Lyrics when turned off. The signal levels and peak/RMS ratios are affected by the noise floor for levels of ~50 dB SPL and lower.

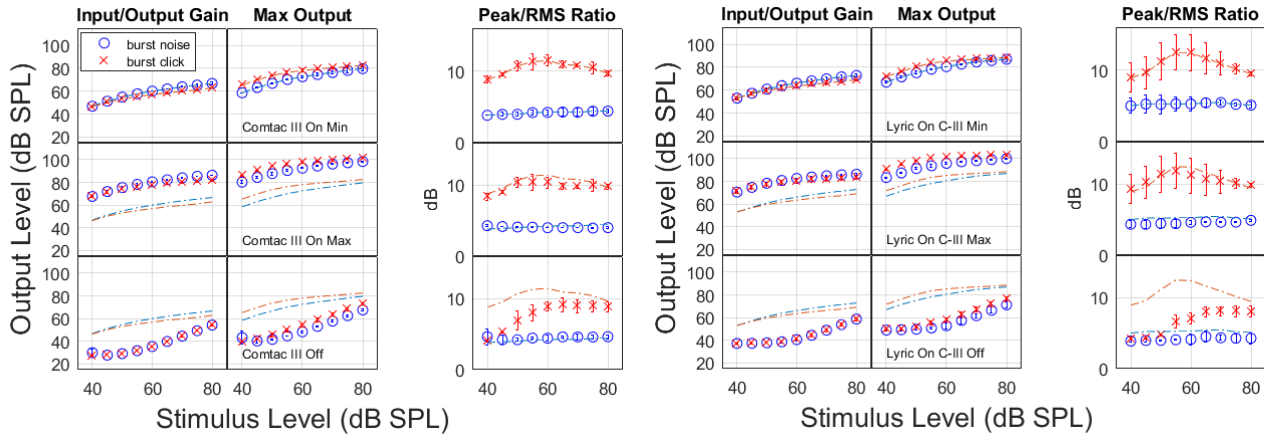


Figure 72: The effect of the device condition on the RMS and peak output ratios, measured as a function of stimulus level and stimulus type, for stimuli presented from the front loudspeaker in the ALF. RMS levels are shown on the left, max output levels in the middle and peak/RMS ratio on the right. Dashed data are for the Comtac III On Min or the Lyric On Comtac III On Min conditions.

The frequency-dependent magnitude spectrum is thought to be important for a number of functions, sound localization in the vertical plane one of them in particular. The left panels of Figure 13 show magnitude responses as a function of the device setting for the front loudspeaker location. The Lyric on condition provided more gain in some frequencies, less than others relative to the open ear condition. The Lyric off condition provided a relatively-large amount of attenuation relative to the open ear and Lyric on conditions, especially in the high frequencies.

The right panels of Figure 13 show magnitude responses as function of the target vertical angle, for front loudspeaker locations. Note that some of the elevation-dependent patterns that listeners might use to localize (i.e., elevation dependent changes at 10 kHz) are preserved, between the Lyric conditions.

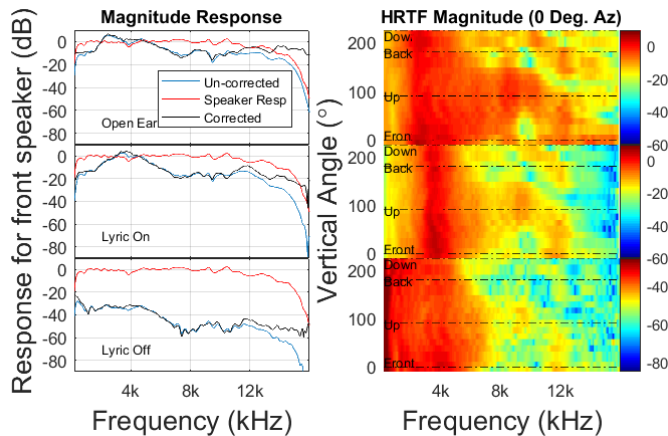


Figure 83: Magnitude responses as a function of device setting for an 80 dB SPL stimulus presented from the front loudspeaker location, using a standard logarithmic sweep method

Interaural signal statistics are thought to be important for a wide variety of functions, including sound localization in the plane-of-azimuth, and speech intelligibility in the presence of maskers. Interaural coherence is a measure of left/right signal similarity. Interaural time differences (ITDs) and interaural level differences (ILDs) are used to localize in the plane of azimuth. Figure 14 plots interaural signal statistics as a function of the stimulus azimuth, the stimulus elevation always zero. The broadband interaural coherence function varies with the stimulus azimuth for the open ear condition. The function peaks at near 1 at an azimuth of 0 and reaching a minimum when the azimuth is 90 degrees. The broadband ITD function varies with azimuth, reaching a positive peak for a 90 degree azimuth and a negative peak for a -90 degree azimuth.

The ITD function is not affected for the Lyric on condition, but the ILD (especially) and interaural coherence functions is affected for high-SPL signals, due to compression. The interaural difference signal statistics are relatively-similar between the open ear and Lyric off conditions.

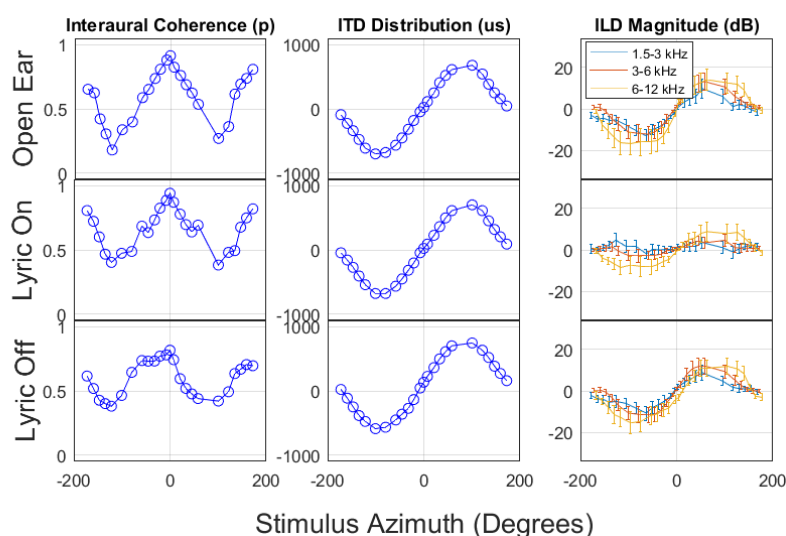


Figure 94: Interaural difference statistics as a function of the stimulus azimuth, for an 80 dB SPL signal presented at an elevation of 0.

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.

FIELD TRIAL / WALTER REED:

Fifteen hearing-impaired participants have been enrolled. The test protocol and field trial have been completed by 6 participants. Partial data sets have been obtained from an additional 6 participants. One participant withdrew before the Lyric device was fit. Two participants were recently enrolled. Participants are scheduled for five test sessions to compare performance between unaided, aided with the participants' standard hearing aids, and aided with the Lyric hearing aids. The test sessions include measurements of functional gain and attenuation, localization ability, speech

recognition in quiet and in noise and subjective evaluation of aided benefit and user acceptability between the aided conditions. Participants are fit with the Lyric devices following unaided testing and are scheduled to use the devices for a period of 12 weeks.

Functional gain and attenuation were measured in the sound field test condition for the frequency region 2000-8000 Hz. Figure 15 displays the results for 13 participants. Average gain was better in the 3-4 kHz frequency region with the Lyric devices than the participants' standard hearing aids; differences in the frequency region 6-8 kHz were negligible. Gain was boosted an additional 5 dB when participants had the TCAPs over the Lyric devices. When the Lyric devices were turned off, attenuation of 20-27 dB was achieved.

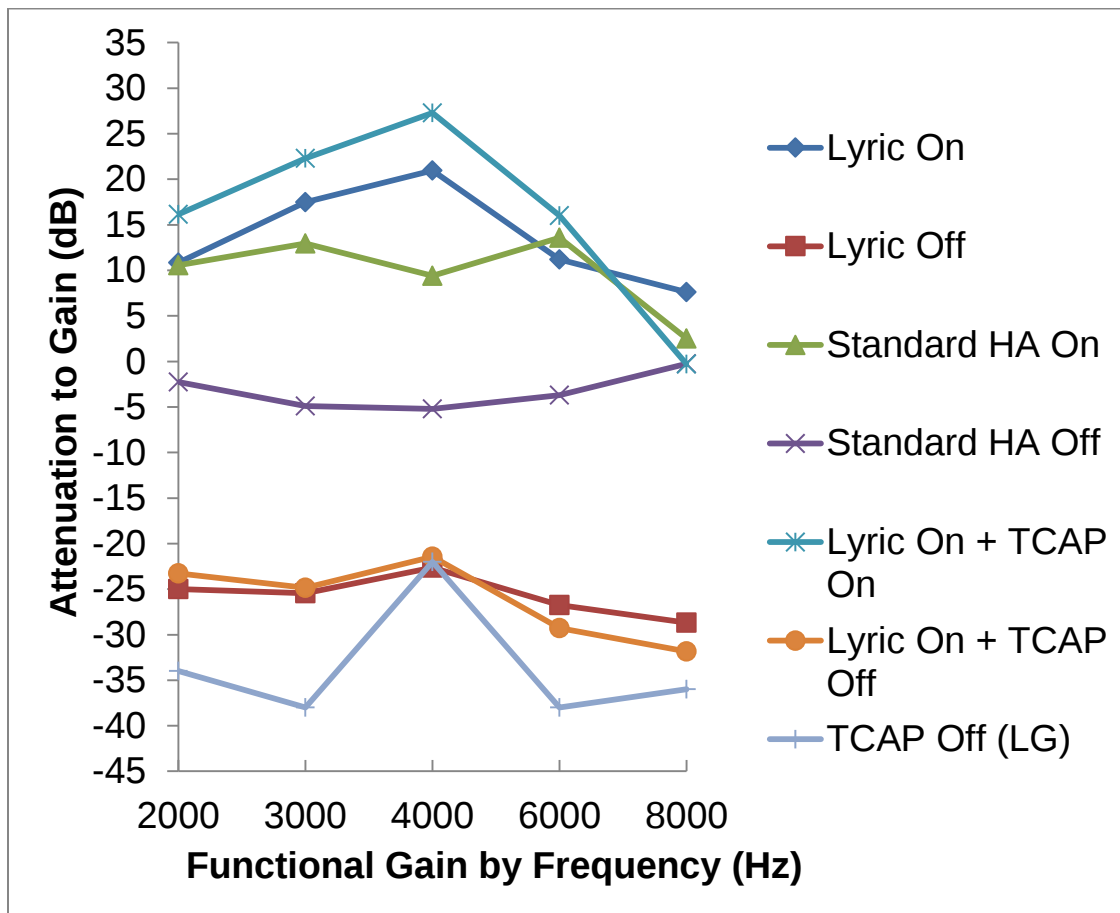


Figure 105: Functional gain for 13 participants.

Localization was evaluated in the Spatial Hearing Laboratory, which consists of a loudspeaker array with 27 loudspeakers arranged at three elevation levels in an arc covering an angle of roughly 270 degrees. Target sounds of varying durations (250, 1000 and 4000 ms) were presented from a single speaker in the array and listeners identified the location of the target sound using a handheld wand. Figure 16 displays localization error as a function of listening condition for 13 experimental group participants. Data from the control group for open ear listening is plotted for reference. Localization accuracy for the experimental group was poorer for the Lyric condition, followed by the standard hearing aid condition, and was best for unaided listening.

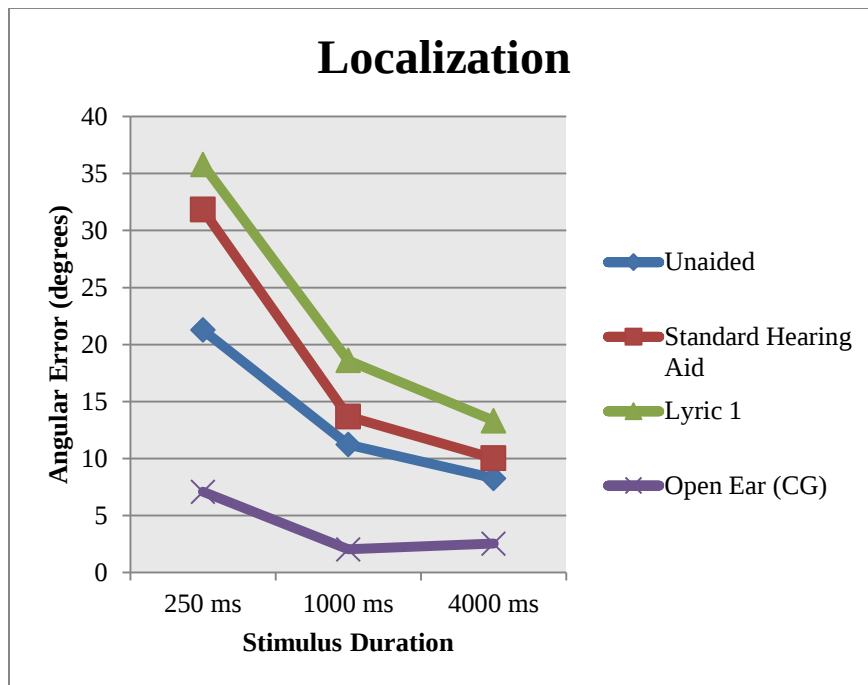


Figure 116: Localization accuracy for 13 participants.

Test/retest localization accuracy is plotted in Figure 17. The results indicate a minimal learning effect between testing with Lyric the first time and testing a second time after approximately 6 weeks of Lyric use.

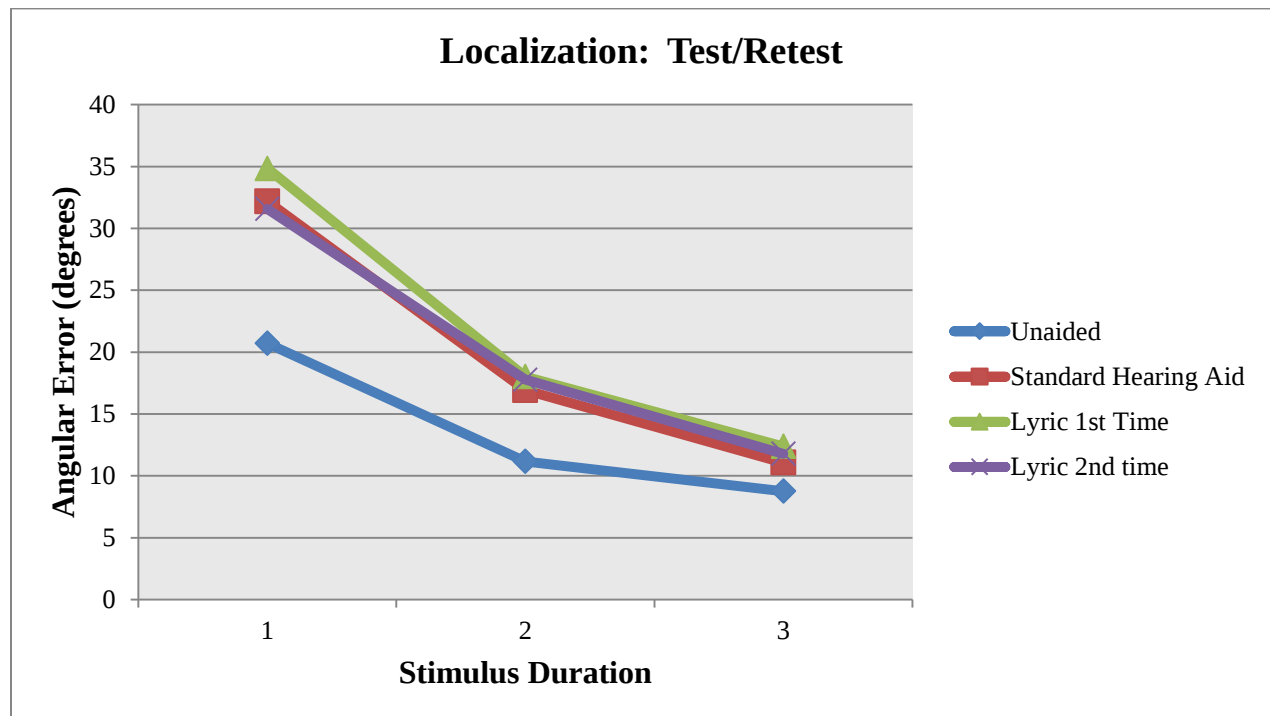


Figure 127: Localization Test-Retest for 7 participants.

Speech recognition was evaluated in quiet at a presentation level approximating soft conversational speech (45 dB HL) under the following conditions: unaided, aided with listeners' hearing aids, Lyric turned on and Lyric turned off. On average, speech recognition performance is slightly better when listeners are aided with Lyric as compared to their own hearing aids. There is good test-retest reliability, as indicated by the similarity in performance between the first test with Lyric (Lyric On 1) and the second test with Lyric (Lyric On 2). Testing with the Lyric turned off confirmed a significant reduction in speech understanding ability for soft speech.

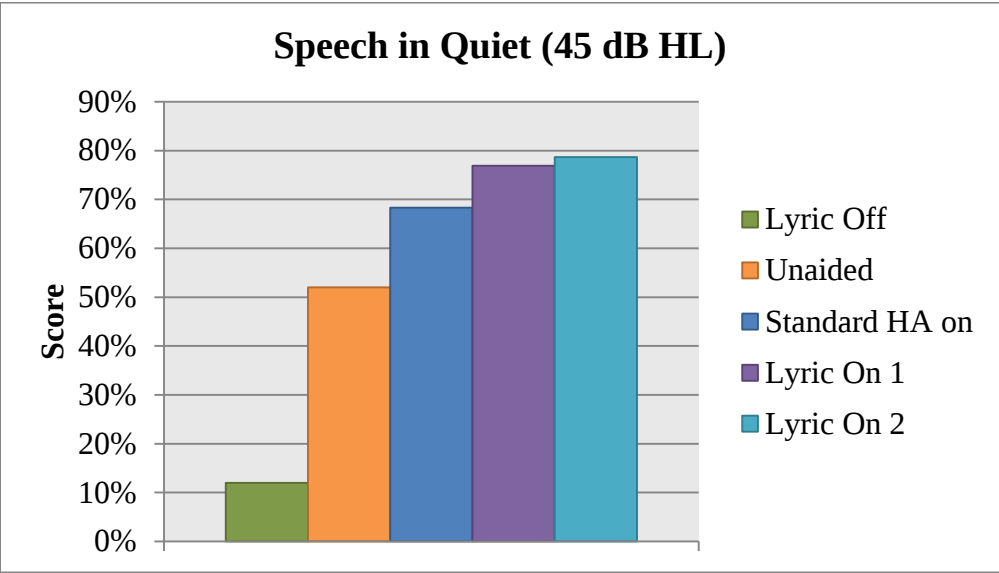


Figure 138: Speech Recognition in Quiet

Speech recognition also was evaluated in the presence of multi-talker noise using the Hearing in Noise Test. The results indicate comparable performance between unaided listening and listening with the participants' standard hearing aids. Performance was slightly better when the listeners were using the Lyric hearing aids.

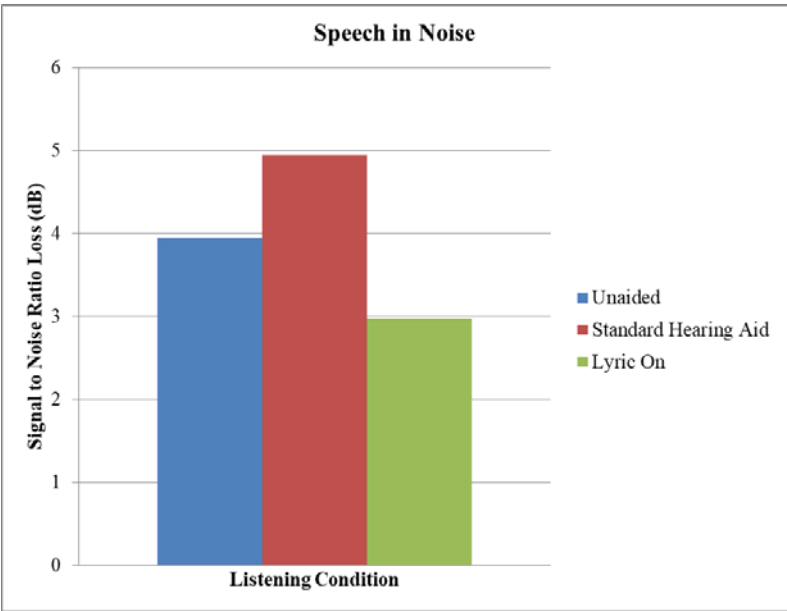


Figure 149: Speech Recognition in Noise.

Subjective evaluation is being done with three questionnaires: the Abbreviated Profile of Hearing Aid Benefit (APHAB), the Speech, Spatial and Qualities of Hearing (SSQ) and the Hearing Aid Acceptance Questionnaire (HAAQ). Subjective outcome data for unaided, standard hearing aid and Lyric hearing aid conditions has been obtained from nine participants. The APHAB is a 24-item self-assessment to determine the amount of difficulty patients have with communication in a variety of everyday listening situations and data from this questionnaire is displayed in Figure 20. The results indicate that the percentage of perceived difficulty declines significantly with amplification, but the difference between standard amplification and Lyric extended-wear amplification is not clinically significant. The SSQ provides a measure of self-perceived localization ability, speech understanding ability and sound quality. Figure 21 displays the average SSQ across listening conditions. The results indicate improvement for both conditions of amplification relative to unaided listening. The HAAQ is a questionnaire developed at Walter Reed for use in a previous hearing aid field trial study to evaluate overall acceptance of a given hearing aid fitting. The results suggest no difference in acceptability between the participants' standard hearing aid and the Lyric. Hearing aid acceptance is comparable between participants' own hearing aids (27%) and Lyric hearing aids (21%).

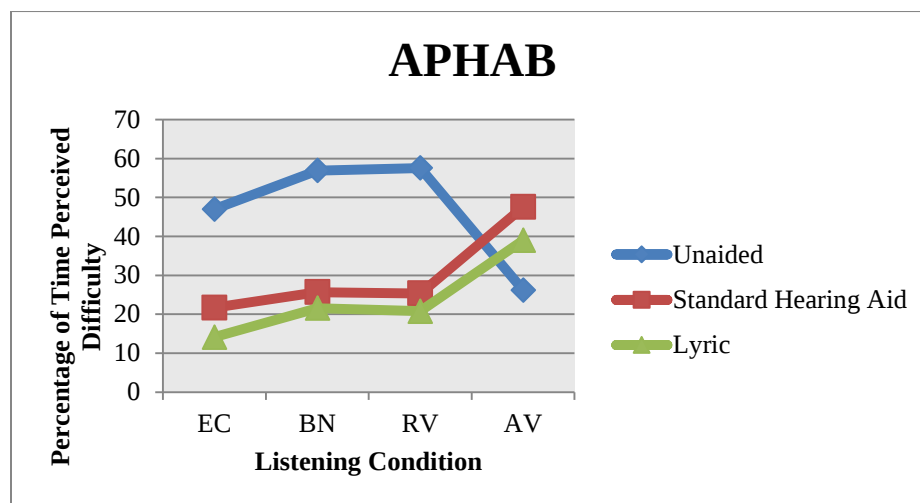


Figure 20: Abbreviated Profile of Hearing Aid Benefit for unaided and aided listening.

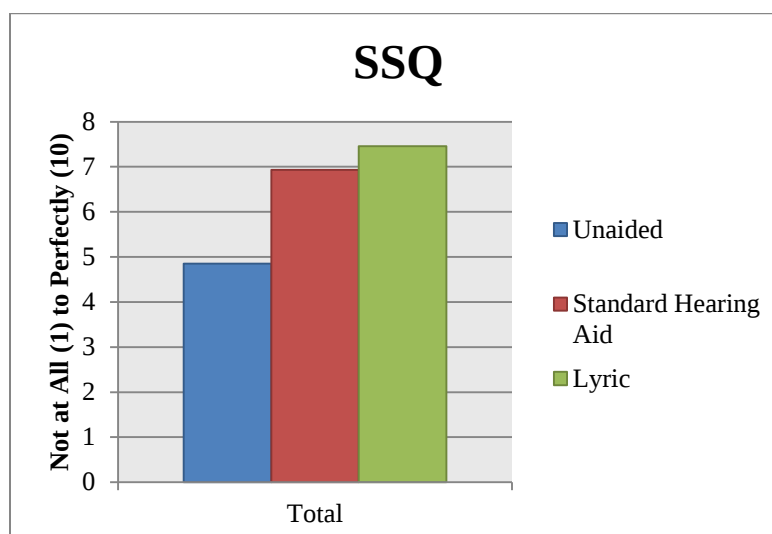


Figure 21: Speech, Spatial and Qualities of Hearing questionnaire responses as a function of listening condition.

SUMMARY OF PROGRESS TO DATE:

The results of this study to this point are promising, but there are also a few surprising findings. On normal-hearing listeners, the Lyric without question achieves the expected goal of providing protection from blast exposure while maintaining situational awareness levels that approach the pen ear. We are not aware of any other devices that are currently available or under development that can achieve this objective.

Somewhat surprisingly, the Lyric does *not* appear to preserve open-ear performance in hearing impaired listeners. These listeners consistently localized less accurately with the lyric than with the open ear (and marginally less accurately than with their own hearing aids). On the surface, this result is somewhat puzzling. Our current working hypothesis for this difference is that the hearing-impaired listeners were generally receiving slightly different gain profiles in their two ears to accommodate small differences in their hearing losses, and this may have introduced a level-dependent interaural level difference into the head-related transfer function. The normal-hearing listeners all received symmetrical lyric fittings, which would not introduce an ILD. We are planning some pilot testing with symmetrical fittings on hearing impaired listeners to explore this hypothesis.

For hearing impaired listeners, it is clear that the Lyric provides speech intelligibility and gain that is at least as good as a conventional hearing aid, with the added benefit that it can potentially be worn during exposure to impulse noise without additional hearing protection.

In order to progress the advancement of the Lyric as an option for the military population, we propose the following next steps:

- 1) Conducting a walk-up study to verify the safety and comfort of wearing the Lyric during exposure to impulse noises, like firearms
- 2) Exploring the requirements and limitations of providing a "user-refit" option for the Lyric that would allow an individual to remove or replace the devices as needed. Many users report doing this, but it is not officially sanctioned by the manufacturer.
- 3) Exploring the possibility of developing a "passive" version of the Lyric that would protect from blast with minimum attenuation.

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. Training was provided at WRNMMC for the AI audiologists in June 2017.

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

Impacts: A substantial impact resulting from this research was the discovering of a manufacturing flaw in the 3M COMTAC III Hearing Defender that resulted in the company issuing a safety recall on all of these devices on July 12th, 2018. This recall was discovered as part of the Lyric Field Study, which included a condition that was intended to combine the Lyric with a COMTAC III device in hearing impaired listeners. The hearing-impaired listeners were performing extremely poorly in that condition, so a follow-up test on normal hearing listeners was conducted. This testing revealed that the COMTAC III we were using (Bad in the following table) produced localization errors that were 30-140% worse than the other COMTAC III devices we had available at Walter Reed. Consequently, we

sent the manufacture (on March 14th, 2018) an email asking them if they knew what might cause such a problem. They did not have an answer, so on the assumption we had a defective unit, we asked them to send two replacement COMTAC IIIs that were known to be functioning properly. These two devices (#856 and #859) also exhibited very poor localization. We were able to identify that the problem was limited to the devices that did not have a radio connection. After several more back-and-forth discussion on the problem, including some measurements we sent to the manufacturer, we received a call from 3M where they revealed that all of the -09 (non-radio-enabled) COMTAC IIIs were manufactured with the polarity of one earcup reversed, which was the cause of the very poor localization. They then issued a recall letter to replace or repair all units, identifying that the current configuration is unsafe for use in tactical environments. We were informed by the manufacturer that this recall may effect up to 12,000 units, including 2,000 as yet unsold in the warehouse and 10,000 that have been sold, largely to DoD customers are directly to service members. Note that previous studies at West Point showed that the decrease in continuous localization accuracy caused by this defect (i.e. 20 vs 45 degrees of localization accuracy) resulted in nearly a 50% reduction in the probability of a successful outcome in a force-on-force exercise. Thus, we believe that the identification and correction of this problem will substantially reduce the probability that a service member wearing an affected headset would have a negative outcome in a future combat situation.

	250 ms	1000 ms	4000 ms
Bad	54.3	48.7	46.2
#856	55.9	50.8	42.8
#859	57.2	50.3	42.6
Good	41.1	29.2	19.3

Table of Localization Results for COMTAC used to identify manufacturing problem

Changes/Problems: Enrollment in the field trial has not been as rapid as hoped, in part because as many as 50% of the enrollees in the project have had to withdraw as a result of varying issues related to the Lyric fitting. This may be in line with commercial finding on the Lyric device, which have shown that the extended-wear use of the Lyric does not pan out for all users. In a military setting, with more sophisticated users and the availability of additional training, it may be possible to coneract these problems by developing tools and training to allow users to self-fit the Lyric devices.

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: Nina Pryor
Project Role: Associate Investigator
Nearest person month worked: 12
Contribution to Project: AFRL lead researcher for project
Funding Support: Funded by award

Name: Nathan Spencer
Project Role: Associate Investigator
Nearest person month worked:
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:
Contribution to Project: WRNMMC lead researcher for the project
Funding Support: Government employee

Name: Marge Jylkka
Project Role: Associate Investigator
Nearest person month worked:
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?

Marge Jylkka joined the team as an associate investigator, replacing Ashley Zaleski.

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

Appendices: N/A

Evaluation of extended-wear hearing aid technology for operational military use

Polytrauma and Blast Injury – Diagnostics, metrics & therapeutics for Hearing Protection



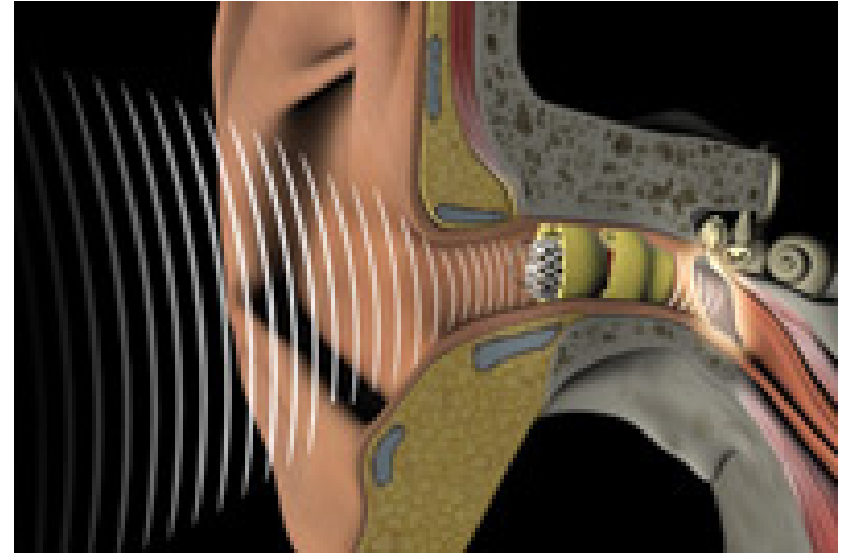
PI: Douglas Brungart

W81XWH-14-1-0254

Org: Henry M. Jackson Foundation

Problem, Hypothesis and Military Relevance

- **Problem:** Hearing loss is the most common injury in the military, in part because current hearing protection systems cannot be worn comfortably for the long periods needed for adequate protection. Also, current hearing aids are incompatible with military operations.
- **Hypothesis:** Extended-wear hearing aid technology may serve as a long-term solution to both of these problems.
- **Military Relevance:** The ability to adequately protect military personnel from noise-induced hearing loss, and to restore functional hearing performance to those who already have hearing loss, is a problem of extreme importance within the US military.



Progress to Date

Data has now been collected on 10 normal hearing subjects at AFRL. The results are promising:

- 1) Blast and attenuation testing confirms that the device provides passive attenuation comparable to that provided by a standard hearing aid
- 2) Localization testing indicates that the device produces localization errors comparable to the open ear and *substantially better* than any other active hearing protection device ever tests
- 3) EFI testing, speech-in-noise testing, and an interview with someone who has used the Lyric in theater appear to confirm feasibility of Lyric for military use and compatibility with other military communication systems and PPE
- 4) Field testing completed for 6, partial for 6, 2 in progress.

Timeline and Total Cost (direct and indirect)

Activities	FY 15	FY 16	FY 17	FY 18
Evaluate occlusion, localization, and speech-in-noise perception with device	■		■	
Evaluate Noise Protection of Devices by conducting REAT test with devices off		■		
Evaluate blast protection of devices with deep-in-the-canal test fixture		■		
Conduct field test of devices in military population			■	
Estimated Total Budget (\$K)	544	419	410	