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OBJECTIVE COMPARATIVE ANALYSIS OF LOCALIZATION PERFORMANCE USING PERSONAL SOUND AMPLIFICATION PRODUCTS (PSAPs) AND A TRADITIONAL HEARING AID

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THESIS APPROVAL PAGE

This is to certify that the thesis prepared by Tiffany Connatser, B.A. entitled "Objective Comparative Analysis of localization performance using Personal Sound Amplification Products (PSAPs) and a traditional hearing aid" has been approved by the thesis committee as satisfactorily completing the thesis requirement for the degree of Doctor of Audiology.

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ABSTRACT

OBJECTIVE COMPARATIVE ANALYSIS OF LOCALIZATION PERFORMANCE USING PERSONAL SOUND AMPLIFICATION PRODUCTS (PSAPs) AND A TRADITIONAL HEARING AID

Tiffany Connatser, B.A.

The purpose of this pilot study was to compare the objective benefit of a Personal Sound Amplification Product (PSAP) (Soundworld Solutions Sidekick) versus a traditional hearing aid (Oticon Nera miniRITE) in localization performance using an audiologist fit condition. Three participants with mild to moderate sensorineural hearing loss were evaluated with both PSAPs and traditional hearing aids. Electroacoustic analysis was performed for each PSAP and traditional hearing aid prior to each test session and compared to manufacturers' specifications to confirm proper functioning of the devices. Real-ear measurements were obtained and compared to NAL-NL2 targets. Each participant's speech-in-noise understanding was evaluated using the AzBio speech-in-noise test and speech identification ability was evaluated using speech-on-speech masking techniques. Lastly, localization ability was assessed in an unaided, PSAP, and traditional hearing aid condition.

The electroacoustic analysis measurements for both devices were in relatively good agreement with the manufacturers' specifications and indicate that the PSAP and hearing aid had relatively similar outputs. Both the PSAP and traditional hearing aid devices when fit in a gold-standard fitting protocol were able to meet NAL-NL2 targets relatively well.

Speech-in-noise testing with the AzBio sentence test revealed similar performance in all three test conditions (Unaided, PSAP, traditional hearing aid). Speech-on-speech masking revealed mixed speech identification abilities. Overall, all the participants performed better in the spatially separated condition compared to the co-located condition. On average the traditional hearing aid condition produced the highest spatial release from masking. However, statistical analysis was not completed due to the small sample size. When assessed for localization ability the participants were generally able to localize the low frequency stimulus (500 Hz) more accurately than the high frequency stimulus (3150 Hz). During localization tasks participant performance was variable based on hearing condition. On average participants performed better in the unaided conditions for both high and low frequency stimuli.

Collectively, the results of the pilot study are in good agreement with previous studies that suggest that advanced PSAPs have the ability to perform similarly to a traditional hearing aid for individuals with a mild to moderate sensorineural hearing loss. The localization results from this pilot study are generally in good agreement with previous hearing aid localization research, but further research is needed to draw conclusions based on device performance.

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KEY TO ABBREVIATIONS

ANSI: American National Standards Institute

ASHA: American Speech Language and Hearing Association

BTE: Behind the Ear

CDC: Center for Disease Control

CRM: Coordinate Response Measure

EAA: Electroacoustic Analysis

EIN: Equivalent Input Noise

FDA: Food and Drug Administration

FD&C: Food Drug and Cosmetic Act

fMRI: Function Magnetic Resonance Imaging

HA: Hearing aid

HL: Hearing Level

IOM: National Institute of Medicine

ITD: Interaural Time Difference

ITE: In the Ear

ILD: Interaural Level Difference

NAL: National Acoustics Laboratory

NAL-NL2: National Acoustic Laboratories Non-Linear version 2

NHANES III: National Health and Nutrition Examination Survey III

NIDCD: National Institute on Deafness and Other Communication Disorders

NIH: National Institute of Health

OTC: Over the Counter

OSPL90: Output Sound Pressure Level at 90 dB SPL

PCAST: President's Council of Advisors on Science and Technology

PTA: Pure Tone Average

PSAP: Personal Sound Amplification Product

REM: Real Ear Measurement

RMS: Root Mean Square

SNR: Signal to Noise Ratio

THD: Total Harmonic Distortion

TMR: Threshold to Masker Ratio

SPL: Sound Pressure Level

VA-SLUMS: Veteran's Affairs St. Louis University Mental Status

WHO: World Health Organization

WWH: Worldwide Hearing

CHAPTER 1

INTRODUCTION

Hearing loss is one of the most prevalent disabilities worldwide, affecting 642 million people (Worldwide Hearing (WWH), 2014). According to the NIDCD (2016), age is the strongest predictor for hearing loss. Hearing loss is ranked fourth in the U.S. among chronic conditions affecting adults 65 and older with this population expected to increase from 35 million to 71 million by 2030 (Lin & Bhattacharyya, 2011). As the U.S. population of older adults continues to increase hearing loss will become a greater concern among the general population, affecting communication abilities, overall health, and quality of life (MacDonald, 2011). Hearing loss can affect many aspects of an individual’s life including understanding speech, social relationships, and safety. Individuals with hearing loss may struggle to communicate with family and friends, leading to isolation and decreased quality of life, especially in older adults. The most common treatment approach to hearing loss is through amplification, such as hearing aids or personal sound amplification products (PSAPs).

While there are many individuals with hearing loss, many of these individuals do not wear hearing aids (Chien & Lin, 2012). There are many influencing factors or barriers that may be a cause of this disparity, including lack of awareness regarding the impact of age related hearing loss, lack of access to technology or a hearing healthcare professional, cost, and perceived stigma (Chien & Lin, 2012).

Previously PSAPs were a lower cost and more readily available alternative to hearing aids, but these devices were not meant to treat hearing loss, nor were they regulated by the FDA. The Senate and House of Representatives have recently passed the

Over the Counter Hearing Aid Act of 2017 that will regulate PSAPs and make them available for individuals with a mild to moderate hearing loss. Specifications and regulations for PSAPS are currently being developed and will become available in the coming months.

In this study, we compared the hearing-impaired participant's performance in simulated real-world difficult listening conditions using a PSAP and a traditional hearing aid fit using a "gold-standard" audiologist fitting protocol. Performance of the devices was evaluated through the use of several functional outcome measures which included electroacoustic analysis (EAA), and real-ear measurements (REMs). Participants completed an additional functional outcome measure which consisted of two speech-in-noise tests, the AzBio Sentence test and the coordinate response measure (CRM) test. Localization ability was assessed in a 13-speaker system. Participant performance was assessed while using a PSAP and a traditional hearing aid to evaluate the estimated performance of these devices in difficult real world listening environments.

In order to understand the impact of age-related hearing loss, the following literature review will discuss the prevalence of hearing loss, distinctions in the classification of hearing loss, consequences of untreated age-related hearing loss, potential barriers to hearing aid use, and the functional outcomes used to assess benefit from amplification.

CHAPTER 2

LITERATURE REVIEW

Hearing loss demographics

Hearing loss is one of the most prevalent disabilities worldwide, affecting 642 million people, including 181 million children (Worldwide Hearing (WWH), 2014). Eighty percent of the 642 million people worldwide live in low and middle-income countries (WWH, 2014; WHO, 2017). The World Health Organization (WHO, 2017) indicates 328 million adults and 32 million children around the world have disabling hearing loss. Disabling hearing loss is defined by the WHO as hearing loss of 40 decibels (dB) or greater in adults and hearing loss of 30 dB or greater in children. Hearing loss is the fifth leading cause of years lived with a disability worldwide (National Institute of Medicine (IOM), 2016).

The National Health and Nutrition Examination Survey III (NHANES III) study completed in 1988-1994 indicates that 14.9% of children had a slight hearing loss in one or both ears (Niskar et el., 1998). In the United States from 2005-2006 one out of every five children, aged 12-19 had at least a slight hearing loss and one in twenty had hearing loss that was recorded as 25 dB or greater (Shargorodsky, Curhan G., Curhan S., and Eavey, 2010). Since the NHANES III (1998) study, the national prevalence of adolescents with hearing loss has increased approximately 33% (Shargorodsky et al., 2010). In the United States, 2 out of every 100 children have a sensorineural hearing loss (IOM, 2014).

Fifteen percent (37.5 million) of American adults report some kind of hearing loss (NIDCD, 2016). In the U.S., hearing loss is ranked fourth in the prevalent chronic health conditions in those 65 years old or older (Fagan & Jacobs, 2009; Lin & Bhattacharyya, 2011). One in eight people in the U.S. (13% or 30 million) has documented hearing loss in both ears, based on standard hearing examinations (NIDCD, 2016; IOM, 2016; WHO, 2017). As the United States population of older adults increases, hearing loss will become a greater concern among the general population, as it affects communication, health, and quality of life. Hearing loss can cause difficulty understanding speech, hearing the phone, doorbells, alarms and make it difficult to talk to family and friends. This difficulty due to hearing loss can lead to isolation, especially in older adults (MacDonald, 2011).

What is hearing loss?

Hearing loss is defined as hearing thresholds of 25 dB HL (Hearing Level) or greater or hearing that is outside of the limits defined as normal (WHO, 2017). Hearing loss can range in severity from mild to profound and can be either unilateral or bilateral. There are three types of hearing loss: sensorineural, conductive and mixed. A hearing loss is defined as sensorineural when it is caused by damage to the sensory cells or nerves of the inner ear. Damage to the outer or middle ear can cause a conductive hearing loss, and a hearing loss is defined as mixed when there is damage to both the sensory cells or nerves of the inner ear as well as damage to the outer or middle ear (NIH, 2017).

Presbycusis is defined as hearing loss as the result of aging and the degenerative changes of aging and is one of the main causes of sensorineural hearing loss (Hain, 2012). Presbycusis can also be affected by genetic or environmental factors such as loud noise exposure, ototoxic substances, drugs, and diet (Liu & Yan, 2007). Common medical conditions such as stroke and diabetes can increase the risk of presbycusis (Bainbridge, Cheng, & Cowie, 2010; Maia & de Campos, 2005).

Prevalence of hearing loss as age increases

According to the NIDCD (2016), age is the strongest predictor for hearing loss and the largest group at risk for hearing loss are adults age 60-69 years old. An estimated 63.1% of the U.S. population aged 70 and older have hearing loss (Lin, Thorpe, Gordon-Salant, & Ferrucci, 2011). From 2001 to 2008, an estimated 12.7% of Americans over the age of twelve years old had bilateral hearing loss (Lin, Niparko, & Ferrucci, 2011). The prevalence of hearing loss increases with increasing age (Lin, Niparko, et al., 2011) as indicated in figure 1.

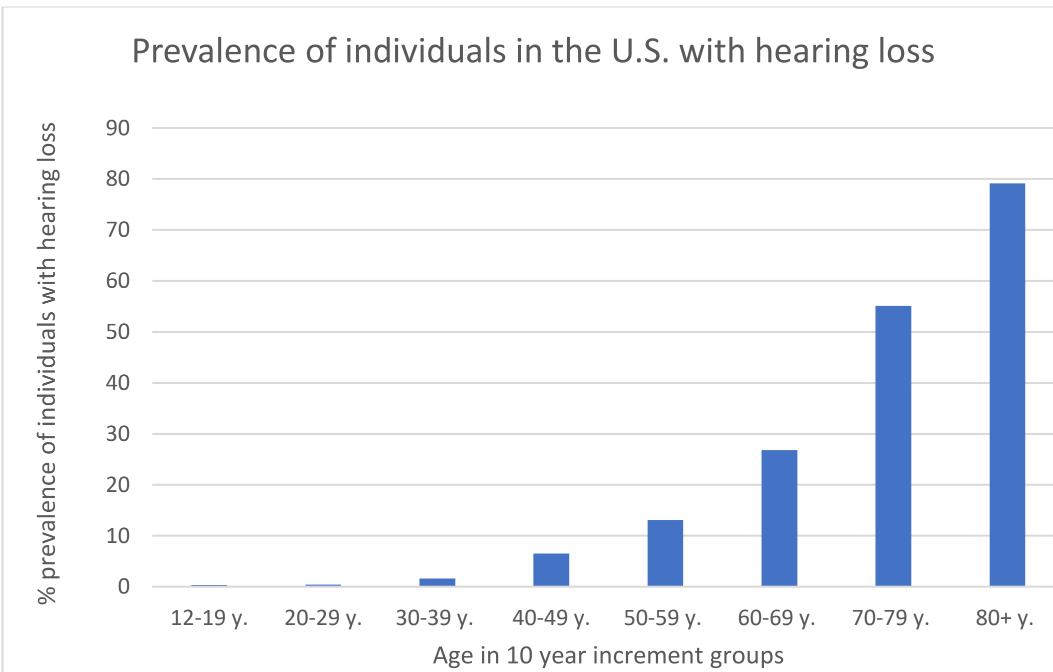

Figure 1. Prevalence of hearing loss ≥ 25 dB, unilateral or bilateral separated by gender and increasing age by 10-year grouping. Adapted from "Hearing loss prevalence in the United States". By Lin, Niparko, et al., 2011.

According to the NIDCD (2016), two percent (25 million) of Americans 45 to 54 years old have disabling hearing loss. As age increases to 55-64 years, the percentage of disabling hearing loss increases to 8.5% and older adults 65-74 years old have a 25% chance of disabling hearing loss. American adults age 75 years and older have approximately 50% chance of having disabling hearing loss. The WHO (2017) states that, globally, approximately one-third of people over 65 years old are impacted by disabling hearing loss, with most of these individuals located in South Asia, Asia Pacific, and Sub-Saharan Africa. According to Swanepoel (2010), one in four adults over the age of 45 years has a hearing loss around the world affecting 27% of males and 24% of females. There are approximately 63% of individuals aged 70 or older in the United States that have at least a mild hearing loss (Lin, Thorpe, et al., 2011). The population of American adults over the age of 65 years old is expected to increase from 35 million to 71 million by 2030 (Lin & Bhattacharyya, 2011). The most common treatment approach to a permanent hearing loss is through amplification.

Hearing Aids

A hearing aid is a device that turns an acoustic signal into an electronic signal to amplify the sound and then converts the electronic signal back into an acoustic signal and delivers it to the ear. Hearing aids are composed of a microphone, amplifier, and receiver. A hearing aid will increase the volume of the incoming signal and shape the signal to fit the hearing loss of an individual. A hearing aid can not only increase volume but can also reduce background noise and separate the determined noise from the speech input. While hearing aid technology has significantly improved in the past thirty years, the number of older adults using hearing aids is low and of concern (NIDCD, 2016). Ninety four percent of people that have hearing loss worldwide can he helped with amplification (WWH, 2014). According to Chien and Lin (2012), only 3.8 million (14.2%) adults in the United States with hearing loss own hearing aids. Among the American population over fifty years old, only one in seven adults with hearing loss are using hearing aids (Chien & Lin, 2012). The number of hearing aid users in the United States workforce, ages 50-59, decreases to less than one in twenty (Lin, Thorpe, et al., 2011). In 2012, around 10.7 million hearing aids were sold globally. IOM (2014) estimates that 20 percent of adults with hearing loss in the United States and Europe are wearing hearing aids. The number of individuals with hearing loss that use hearing aids drops to 11 percent in Japan, 6 percent in Russia, 2 percent in China, and less than 1 percent in India. (IOM, 2014). Prevalence of hearing aid use varies with gender, age, and degree of hearing loss. The incidence of hearing aid use increases with age and the degree of loss (Chien & Lin, 2012). As seen in figure 2 below, although the prevalence of hearing loss increases with age, the prevalence of hearing aid usage remains fairly low (Chien & Lin, 2012).

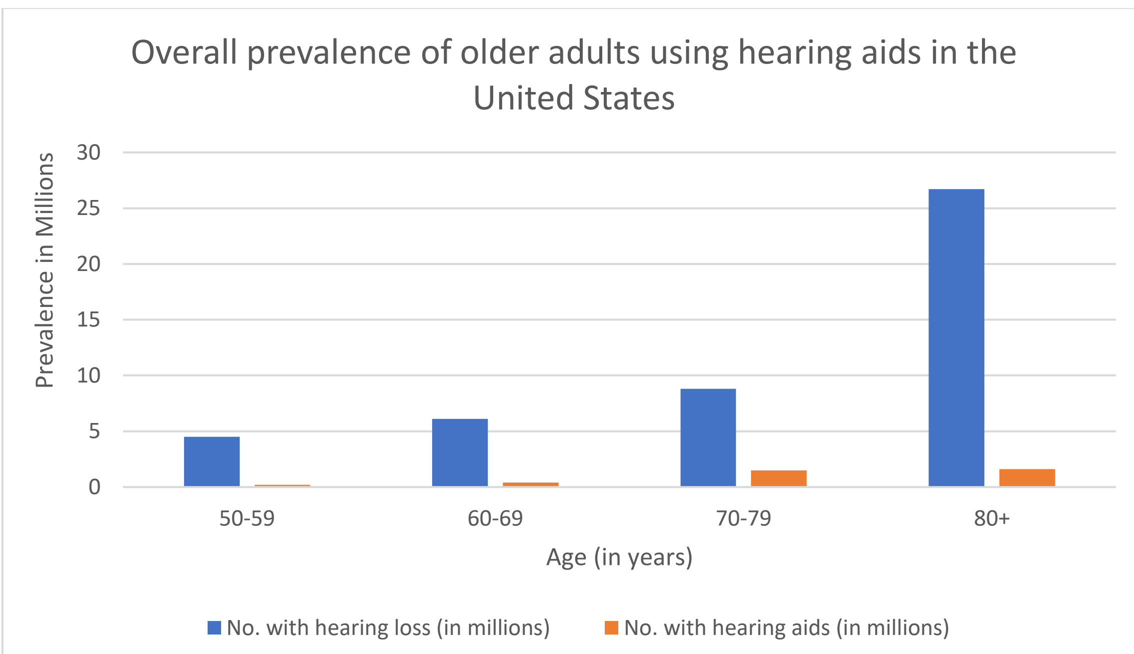

Figure 2. Prevalence of older adults with hearing loss ≥ 25 dB and hearing aid use. Adapted from “Hearing Loss in Older Adults: A Public Health Perspective.” by F. Lin, 2016. Data from Chien and Lin, 2012. For specific numerical data, see Table 1 below.

Table 1.
Prevalence of individuals 50 years and older with hearing loss using hearing aids.

Table. Prevalence and Number of Individuals 50 Years or Older With Hearing Loss[a] Using Hearing Aids in the United States[b]

Variable	Prevalence of Hearing Aid Use Among Adults With Hearing Loss[a] ≥25 dB, % (95% CI)[c]						No. With Hearing Loss[a] ≥25 dB (in Millions)
	Sex		Hearing Loss Severity[d]		Total		
	Male	Female	Mild (25-40 dB)	Moderate or Greater (>40 dB)	Overall Prevalence of Hearing Aid Use	No. With Hearing Aids (in Millions)	
Age, y							
50-59	4.3 (0-9.5)	4.5 (0-13.5)	2.7 (0-6.6)	11.8 (0-27.5)	4.3 (0-8.8)	0.2	4.5
60-69	7.3 (2.5-12.1)	7.2 (1.4-13.0)	2.6 (0-5.2)	23.9 (10.6-37.2)	7.3 (3.6-10.9)	0.4	6.1
70-79	21.1 (14.5-27.6)	12.7 (6.0-19.5)	3.4 (0.3-6.5)	47.8 (37.0-58.6)	17.0 (12.4-21.6)	1.5	8.8
≥80	28.1 (20.3-35.9)	17.9 (11.2-24.7)	3.4 (0-7.7)	35.7 (28.7-42.7)	22.1 (18.5-25.8)	1.6	7.3
Estimated total No. of individuals with hearing aids and with hearing loss (in millions)						3.8[d]	26.7

[a]Hearing loss was defined as a speech frequency pure tone average of hearing thresholds at 0.5-, 1-, 2-, and 4-kHz tones presented by air conduction in the better hearing ear of 25 dB or greater.
[b]Data were derived from the 1999-2006 National Health and Nutrition Examination Survey.
[c]All values represent prevalence percentage unless otherwise noted.
[d]Numbers do not sum to group total because of rounding.

Note. This table is adapted from “Hearing Loss in Older Adults: A Public Health Perspective.” by F. Lin, 2016. Data from Chien and Lin, 2012.

Consequences of Age-Related Hearing Loss

Age related hearing loss affects more than an individual’s auditory perception. Some consequences of age-related hearing loss are dementia and cognitive decline, an increased cognitive load, social isolation, physiological changes in the brain, vestibular declines and changes in quality of life (Lin & Ferrucci, 2012; Lin, Ferrucci, Metter, An, Zonderman, & Resnick, 2011; Lin, Metter, O’Brien, Resnick, Zonderman, & Ferrucci, 2011; Viljanen, Kaprio, Pyykkö, et al., 2009).

Hearing loss and communication

Hearing loss creates a breakdown in receptive communication abilities, which may impact expressive language by the hearing impaired individual responding inappropriately. Hearing loss acts as an “acoustic filter” that hinders an individual’s ability to communicate. The effect of this acoustic filter is increased difficulty in adverse listening environments. (Levey et al., 2012). Age-related hearing loss typically affects the higher frequency sounds first. In speech, the high frequency sounds include the consonant /s/ as well as other consonants that give meaning to the words in a sentence. An individual with age-related hearing loss may have problems discriminating these sounds, which results in an inappropriate response within a conversation (Helfer, 2015).

Dementia and Cognitive decline

Age related hearing loss has been associated with dementia and cognitive decline (Gallacher et al., 2012; Lin, Metter, et al., 2011). Issues rising from cognitive decline can lead to trouble remembering details and maintaining focus on the topic of conversation. Over a 12-year time span, 639 individuals were followed to determine the association between hearing loss and Alzheimer’s disease and dementia (Lin, Metter, et al., 2011). Individuals within this study were diagnosed with dementia by a multidisciplinary team using screeners based on age and standard measures for dementia and Alzheimer’s disease. Lin, Metter, et al., (2011) concluded that the risk of dementia was related to increased severity of hearing loss.

Lin and colleagues (2013) subsequently completed a follow up study over six years and found that age related hearing loss was independently associated with dementia. Specifically, the authors reported that individuals with hearing loss have a 24% greater risk for incident cognitive impairment and a 30-40% increased rate of cognitive decline when compared to individuals with normal hearing. Hearing loss was associated with dementia and cognitive decline in older adults. Specifically, hearing loss was found to be a determining factor in the overall time that it took for an individual display a significant change in cognitive function, 7.7 years in those with hearing loss compared to 10.9 years in those with normal hearing (Lin et al., 2013).

Collectively, the results of these studies indicate that age related hearing loss is associated with an increased risk of incident dementia and cognitive impairment when compared to age matched normal hearing individuals. The rate of cognitive decline is increased in individuals with age related hearing loss when compared to the normal aging process that occurs in individuals with normal hearing.

Increased cognitive load

Age related hearing loss can also increase the cognitive load experienced by older adults. According to Luigi Ferruccci from the National Council on Aging, 60 to 70% of the energy used each day is spent on natural bodily functions (IOM, 2014). When a bodily function or process is disabled, more energy is required to complete the tasks involving the disabled or diseased process. In older adults, additional energy is not readily available to devote to effortful listening. During communication tasks, older adults may need to allocate more cognitive resources to listening. As cognitive resources are allocated to listening as a result of a hearing loss, more cognitive energy is diverted from natural bodily functioning, and thus leads to more difficult listening.

As adults age, they experience a decline in their sensory abilities including their hearing sensitivity. The decline in hearing can be compensated for by using contextual information and increased cognitive effort. Compensating for the sensory decline comes at a cost to their overall cognitive energy that would otherwise be used in further processing (Wingfield, Tun, & McCoy, 2005).

Individuals with age related hearing loss have a greater cognitive load during communication. Gosselin and Gagne (2011) found that older adults used more effort to listen to and complete a speech in noise task than younger adults. Dawes and colleagues

(2015) found that hearing aid use was associated with better cognition when compared to those with untreated hearing loss.

Social isolation/ Quality of life

Age related hearing loss can lead to social isolation and therefore a reduced quality of life. MacDonald (2011) found a strong positive relationship between objectively measured hearing loss and depressive symptoms, such that individuals with severe hearing loss had greater depressive symptoms. A survey completed by The National Council on Aging documented responses from adults with hearing loss and their families regarding the effect of hearing loss and lack of treatment (IOM, 2014). The results of this survey revealed that individuals with untreated hearing loss were more likely to report sadness and depression, worry and anxiety, paranoia, less social activity, and insecurity in comparison to their normal hearing peers (IOM, 2014). In a longitudinal study, Pronk, Deeg, and Kramer (2013) found that individuals with hearing loss that did not use hearing aids were more socially lonely when compared to individuals that wore hearing aids. Dawes and colleagues (2015) found that treating hearing loss can significantly reduce the burden associated with cognitive decline and reduced quality of life.

Physiological changes of the brain

Age related hearing loss can not only affect an individual's social and emotional communication, but also age-related hearing loss can change the physical aspects of the brain (Peelle, Troiani, Grossman, & Wingfield (2011). Peelle, Troiani, Grossman, and Wingfield (2011) examined functional magnetic resonance imaging (fMRI) of individuals with hearing ranging from normal to a mild sensorineural hearing loss. These researchers found decreased language-related neural activity in individuals with hearing loss, as shown in figure 3, below. The volume of gray matter in the auditory cortex was reduced in individuals with hearing loss when compared to normal hearing listeners (Peele et al., 2011).

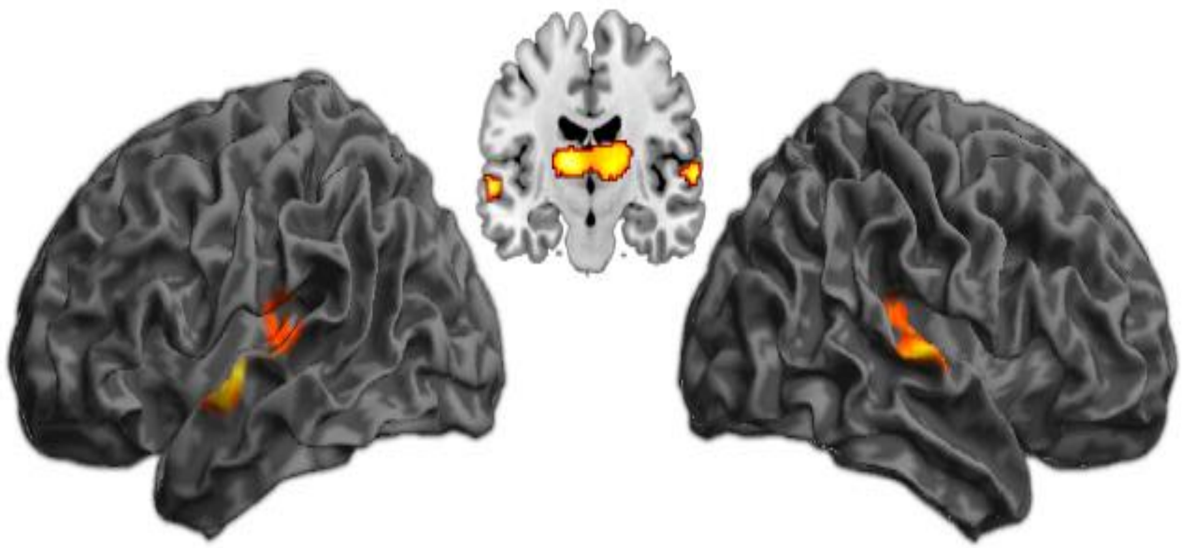

Figure 3. Decreased language-driven speech activity in individuals with poorer hearing. Highlighted regions indicate regions of decreased language-driven neural activity on fMRI in both superior temporal gyri. Adapted from "Hearing Loss in Older Adults Affects Neural Systems Supporting Speech Comprehension," by J.E. Peelle V. Troiani, M. Grossman, and A. Wingfield, 2011, *The Journal of Neuroscience*, *31*(35), 12638-12643.

Physiological changes of the brain are another consequence of age related hearing loss including reduced brain volume, especially the right temporal lobe and a decreased language-processing in complex speech tasks. Lin and colleagues (2014) evaluated magnetic resonance imaging (MRI) in participants with normal hearing and participants with sensorineural hearing loss ranging from mild to severe. The results of the Lin et al. (2014) study revealed that the participants with hearing loss had decreased total volume of the brain when compared to the normal hearing listeners. The decrease in volume was greatest in the right temporal lobe. The researchers speculated that the difference in brain volume was due to a greater amount of language processing in the left temporal lobe, which may help preserve brain volume in this part of the brain (Lin et al., 2014). These neuro-imaging studies indicate a strong relationship between hearing loss and cognitive dysfunction (Lin et al., 2013).

Vestibular declines

While hearing loss is one of the most common diagnoses in older adults, balance issues can co-occur in this population. Balance issues are one of the most common reasons that older adults seek treatment from a doctor (NIH Senior Health, 2014). As age increases, the incidence of balance issues also increases. Balance issues can increase the amount of fall related injuries in an aging population. According to the Center for Disease Control (CDC) (2017). one out of four adults aged 65 and older fall each year. Among older adults, falls are the leading cause of injury related death (CDC, 2017). Figure 4 depicts the increasing unintentional death rate from fall related injuries as age increases.

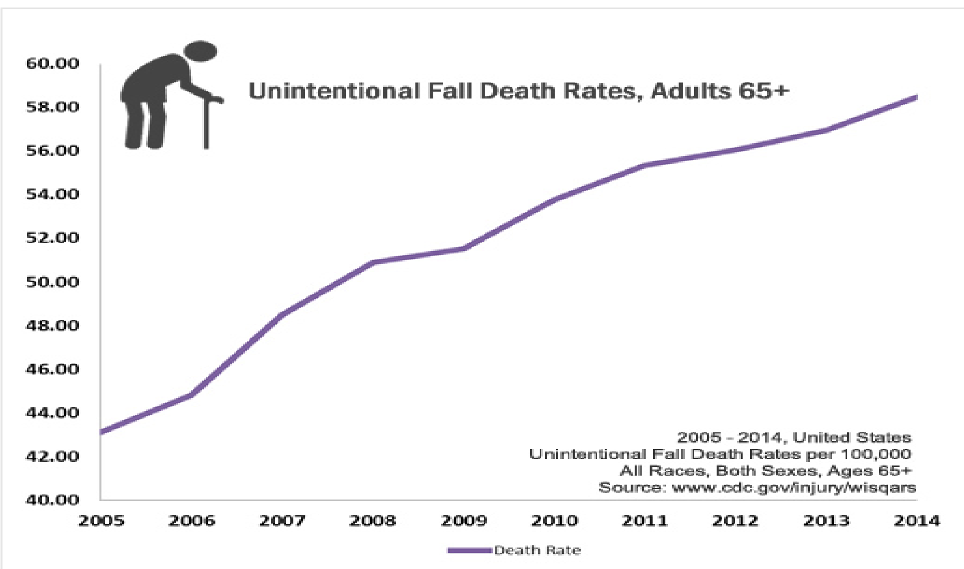

Figure 4. Death rate due to unintentional falls in adults 65 years and older per 100,000 from 2005-2014. Adapted from https://nihseniorhealth.gov/falls/aboutfalls/01.html. By Center for Disease Control and Prevention (2017).

Why are people with sensorineural hearing loss not using hearing aids?

While only a small amount of people with hearing loss own hearing aids, an even smaller amount of people regularly use their hearing aids. While hearing loss is affecting many lives, only 20 percent of individuals that could benefit from hearing aids use them (NIH, 2017). According to WWH (2014), 278 million people suffer from a hearing loss that makes participating in an average volume conversation difficult without a hearing aid, if not impossible. Among the reasons that people are not wearing hearing aids are lack of accessibility to an audiologist or healthcare associate, cost, and stigma associated with hearing aid use.

Access to technology and to hearing health care professionals.

Hearing aids are regulated by the Food and Drug Administration (FDA). An individual with hearing loss must visit an audiologist or hearing aid dispenser to obtain the devices. While in most metropolitan areas of the United States and developed countries access to technology and a hearing care professional is readily available, access is not as obtainable in developing regions, remote areas, or rural parts of the country (Fagan & Jacobs, 2009). In developing nations, approximately 80% of the people with hearing loss live in areas with little or no access to healthcare (Fagan & Jacobs, 2009). Goulios and Patuzzi (2008) collected information from 62 countries, which is representative of 78% of the global population and found a worldwide shortage of audiologists. Only 11% of countries indicated that they had enough audiologists. Lack of awareness regarding hearing loss and deafness was indicated by 60% of countries and lack of public awareness about the profession was indicated by 76% of countries (Goulios & Patuzzi, 2008). According Swanepoel et al. (2010) the ratio of audiologists to individuals ranges from one for every half a million people to one for every 6.25 million people in developing countries. Eighty percent of individuals that have hearing loss live in middle and low-income countries. Hearing healthcare is inaccessible to these individuals due to cost and insufficient hearing healthcare, with the result being that only in 1 in 40 individuals in developing countries that need a hearing aid have access to one (WWH, 2014). The ratio of audiologists to people in developed countries is only one for every 20,000 people (Goulios & Patuzzi, 2008). The limited access to technology and professional hearing healthcare is due to lack of professionals, lack of awareness, limited resources, as well as geographical and natural barriers (Swanepoel et al., 2010).

Costs

Age related hearing loss occurs gradually, over time and can be attributed as normal by the patient. The hearing loss is typically not a high priority and individuals tend to be very concerned about cost of amplification (IOM, 2014). Hearing aids can be one of the most expensive purchases in a person's lifetime. The average device costs $1500 per aid (Mamo, Reed, Nieman, Oh, Lin, 2016). While hearing aids can be an expensive purchase, most insurance plans do not cover hearing aids (NIH, 2016). According to the American Speech Language, and Hearing Association (ASHA) the typical lifespan of a hearing aid ranges from 4-6 years. This means that an individual diagnosed with hearing loss at a young age may go through several pairs of hearing aids, increasing the total cost of wearing hearing aids. In the United States, there are 26.7 million adults aged 50 years old and greater with hearing loss and 3.8 million use hearing aids, resulting in only a 14.2% overall rate of hearing aid usage (IOM, 2014).

The purchase price is not the only expense for an individual wearing hearing aids. Another expense that is associated with hearing loss is the cost of a trip to the physician to obtain the referral needed to see an audiologist, and then potentially back to the physician to obtain medical clearance (IOM, 2014). Additional costs of wearing hearing aids includes the cost of batteries, cleaning supplies, and repairs. If the individual decides to purchase an assistive listening device, this decision can add an additional cost of up to $800.00. Overall, the cost of purchasing bilateral hearing aids is much higher than the price of the devices themselves. The journey to pursuing amplification can be not only a financial investment but also a time investment for the individual. The combined number of visits to the otolaryngologist and audiologist occurs over several months for the individual and the whole process may take up to 4-6 months (IOM, 2014).

The Marketrak VII survey conducted by Kochkin (2007) found that 76% of the 3000 survey respondents indicated that they could not afford hearing aids and 52% of respondents reported that hearing aids are expensive to maintain. Hearing aids are not covered under many insurance policies and Kochkin (2009) reported that third party sources such as Medicare, union, insurance, health maintenance organizations, rebates, family members etc. commonly do not cover the entire purchase price of the hearing aid.

In the United Kingdom, where health care is provided at no cost to the patient. Interestingly the prevalence of hearing aid usage was not much higher than is seen in the United States (McCormack & Fortnum, 2013). Similarly, only 17% of adults with hearing loss in England and Wales own hearing aids even though the cost of hearing aids is covered under their national healthcare programs (IOM, 2014). Collectively this evidence shows that while cost is an important factor in an individual's decision to own a hearing aid, it is not the only deterrent that determines hearing aid use.

Stigma

Increased accessibility and increased visibility of hearing aids reduce the stigma around the devices (IOM, 2014). Those that are concerned with the perceived stigma of hearing aids are also less likely to get their hearing checked and purchase a pair of hearing aids (McCormack & Fortnum, 2013). Wallhagen (2010) found that self-perception, ageism, and vanity led to an altered hearing aid stigma. This self-perceived stigma was found to influence the individual's decision to seek out an audiologist or hearing aids (Meyer & Hickson, 2012). The attitude of family and friends is another important factor in the decision to pursue hearing aids. According to the MarkeTrak VII survey, participants considered the opinions of their spouse, other hearing aid wearers, friends, or children before adopting a hearing aid (Kochkin, 2007). Individuals that had friends and family that were positive regarding the adoption of hearing aids were more likely to own hearing aids, and individuals that had friends and family that were not supportive in the hearing aid process were less likely to own hearing aids (Kochkin, 2007).

What are PSAPs?

As previously mentioned, hearing aids are not a viable option for many people due to cost, stigma, and access to technology or an audiologist. However, a developing new market of personal sound amplification product (PSAP) is providing an alternative source of "do-it-yourself" amplification. PSAPs typically cost much less than hearing aids and can be purchased directly by the consumer (Smith, Wilber, & Cavitt, 2016).

According to Mamo and colleagues (2016), the newer generation of PSAPs are a higher cost amplification option that is sold directly-to consumer. The FDA has previously defined a PSAP as a wearable device that is intended to amplify environmental sounds for individuals without hearing loss. However, new regulations are currently being developed to define specifications for PSAP for use in individuals with hearing loss.

Difference between PSAPs and Hearing Aids

Both hearing aids and PSAPs are designed to amplify sound, but with separate classifications. Hearing aids are devices to help aid those with an impaired hearing diagnosis while PSAPS are defined as amplification devices to amplify environmental sounds that would be difficult to hear for a non-hearing impaired individual.

Appropriate Hearing Loss

The degree of sensorineural hearing loss can vary across individuals and must be considered when fitting amplification. Sensorineural hearing loss can range from a slight to profound hearing loss and the configuration of hearing loss can vary from sloping losses, to rising losses or even flat hearing losses. Hearing aids are able to amplify and fit all degrees of hearing loss and most, if not all configurations of hearing loss. Acoustic modifications and fitting strategies can be employed to fit a hearing aid to most losses (Taylor & Muller, 2016). In contrast, most PSAPs are meant for individuals with a lesser degree of hearing loss (Cheng & McPherson, 2000). According to Cheng and McPherson (2000), the over the counter devices were low-gain, suggesting they are only suitable for those with a mild to moderate degree of hearing loss. These researchers also reported that PSAPs provide very little useful gain above 3000 Hz, indicating that these devices were not a suitable fit for individuals with a high frequency hearing loss (Cheng

& McPherson, 2000). Typically, PSAPs are appropriate for those with a mild to moderate hearing loss. Certain PSAPs provide enough amplification to fit up to a moderately severe hearing loss, however acoustic feedback may occur if the device does not fit properly in the ear canal.

Styles

There are several styles of hearing aid options for an individual including a traditional behind-the-ear (BTE) device with either an earmold or a slimtube. Hearing aids can also be worn as a body aid (FDA, 2013). In addition, traditional hearing aids can be worn as an in-the-ear (ITE) style that fills the entire concha bowl (full-shell), half the concha bowl (half-shell), or part of the concha (ITE), or can be completely in the canal or invisible while in the canal (Cheng & McPherson, 2000). In contrast, PSAPs can be worn as a BTE or ITE style hearing aid and are typically worn unilaterally.

Earpieces

A key factor of how well a device amplifies sound is the fit of the hearing aid and its coupling apparatus. Both hearing aids and PSAPs can be coupled via rubber dome tips or custom earpieces made from either acrylic, vinyl, or silicone. The custom pieces are made to accommodate unique attributes of an individual's anatomy or severity hearing loss (Taylor & Muller, 2014). PSAPs typically only have rubber dome tips and may not have various sizes to fit different size ear canals (Cheng & McPherson, 2000). If the PSAP earpieces fit the individual incorrectly, sound may leak out causing insufficient amplification and/or feedback.

Cost

Hearing aids can be one of the largest purchases in an individual's lifetime with the average device costing on average $1500 per hearing aid (Mamo et al., 2016). PSAPs can be found in a wide range of prices, approximately $30 for a low-cost product to $500 for a single device (Callaway & Punch, 2008). Price has been cited in the literature as a primary concern of consumers considering amplification (Callaway & Punch, 2008). Cheng and McPherson (2000) found that over the counter hearing devices costing under $65.00 were only appropriate for a low-frequency hearing loss (Cheng & McPherson, 2000). When comparing self-perceived benefit a higher cost PSAP ($125.00) and a traditional hearing aid were found to provide essentially similar benefit, indicating that price was not directly associated with patient satisfaction (McPherson & Wong, 2005).

Internal components

Hearing aids and PSAPs contain the same basic internal components. The devices contain a microphone, amplifier, signal processor, and a receiver (Taylor & Muller, 2014). The microphone transforms the acoustic input into an electrical signal that is made louder by the amplifier. The receiver transforms the amplified signal back into an acoustic signal to be heard by the ear. Digital hearing aids also contain a signal processor that transform the signal to best fit the hearing loss or programmed settings of the aid (Taylor & Muller, 2014).

Acoustic features

Acoustic features are included in both hearing aids and PSAPs. Some of the technology included in hearing aids and PSAPs is similar, but PSAPs typically have fewer features and less functionality than hearing aids (FDA, 2013). Traditional hearing aids use features such as multichannel compression, digital noise reduction, directional microphones, and feedback cancellation to create the best fit for an individual in multiple listening environments (Taylor & Mueller, 2014). Lower level PSAPs provide less acoustic features, offering only a volume control with high volume capability that can potentially result in over amplification (Callaway & Punch, 2008; Cheng & McPherson, 2000). More advanced PSAPs offer multiple programming channels and acoustic features such as directional microphones, noise reduction, Bluetooth compatibility and frequency compression (Callaway & Punch, 2008; Mamo et al., 2016). Hearing aids and PSAPs may have a volume control and ability to switch between customized programs manually. Manual programs can be individually customized in traditional hearing aids but typically come pre-set in PSAPs. Most hearing aids and some PSAPs come with a telecoil feature to aid in phone usage while wearing the device. Some hearing aids are able to wirelessly connect to several sources, including TV, cell phones, and MP3 players etc., allowing the user to alter programs, volume, and answer and hang up the phone using the hearing aids (Edwards, 2007). Hearing aids can be coupled acoustically or wirelessly to the external electronic products (FDA, 2013). Hearing aids and PSAPs are able to wirelessly connect to a wide array of streaming devices (Edwards, 2007). Hearing aids may contain wireless ear-to-ear communication where the adjustments made to one hearing aid will be applied to hearing aids fit binaurally (Edwards, 2007). This ability improves binaural perception by preserving binaural auditory cues and processing the information simultaneously (Edwards, 2007). Wireless hearing aid ear to ear connectivity allows an individual that has been bilaterally fit to communicate to the right and left hearing aids at the same time (Edwards, 2007).

Hearing aid adjustments, such as adjusting volume or switching manual programs can occur to both ears at the same time, resulting in equal adjustments to the amplification the individual is receiving. The ear-to-ear connectivity allows the pair of aids to act as one unit rather than two individual devices. PSAPs are typically worn unilaterally. If an individual were to wear PSAPs bilaterally, they would operate the devices as individual independent devices. Individual adjustments and uneven amplification changes could potentially alter the timing cues the wearer is receiving.

Appropriate output

As defined earlier, presbycusis is most likely to affect high frequencies more than the low frequencies. Therefore, frequency specific complaints are the most common among the older population (Mamo et al., 2016). Age related hearing loss often results in difficulty understanding speech, and specifically speech including soft, high frequency sounds such as "/*th*/", "/*f*/", and "/*s*/". Lower frequency sounds remain intact with typical presbycusis, such as "/*ah*/". Previous complaints of PSAP users included too much low frequency amplification while under amplifying the higher frequency sounds (Mamo et al., 2016). The inappropriate output of earlier PSAPs enabled speech to be heard, but the speech lacked clarity. Hearing aids with multiple channels allow different amounts of amplification for different frequencies. This multi-channel processing allows the hearing loss to be fit appropriately and provide the correct amount of amplification. All hearing aids and some PSAPS function through multi-channel processing. Mamo et al. (2016) analyzed frequency-specific gain for five PSAPs and compared them to prescriptive targets that predict the best speech understanding. Four out of five of the PSAPs tested had a frequency output that fit prescribed targets and two PSAPs allowed further customization of the frequency output through smartphone programming to match hearing loss.

Signal processing

Hearing devices can process sound in either an analog or a digital manner. Hearing aid technology has progressed substantially in the past ten years with the development of digital signal progressing (Edwards, 2007). In 2005, 93% of hearing aids sold in the United States were digital programmable devices (Edwards, 2007). Developments in microphone directionality, background noise reduction, feedback cancellation, and multichannel compression have led to the success of digital hearing aids. According to Edwards (2007), 71% of hearing aid users expressed overall satisfaction with their hearing aids. The digital wireless technology employed in more modern hearing aids transmit a higher-fidelity signal than analog systems with greater consistency.

Devices employing a digital signal processing system have a greater ability to adjust parameters within the device and may have more accessible features. Both hearing aids and PSAPs can process sound in an analog or digital fashion. Typically, digital hearing aids have more acoustic features and functionality than PSAPs. (Taylor & Mueller, 2014)

FDA regulations

While traditional hearing aids and PSAPs are both intended to amplify sound, and compensate for difficulty hearing, the FDA currently only regulates traditional hearing aids. The requirements and labeling of the hearing aid including the model, serial number and other identifying features are regulated and must comply with FDA requirements.

The FDA also requires the instructional user manual be provided to each hearing aid user at time of the hearing aid issuance. All FDA regulations must be met prior to purchase. A medical evaluation by a licensed physician and a diagnostic hearing test must be completed within six months of the hearing aid issuance date. Individuals over the age of 18 years without any red flags of other medical issues may choose to sign a medical waiver, stating that they understand the risks of forgoing a medical evaluation. The paperwork including medical clearance or a waiver must be kept by the dispensing professional for three years after the purchase. An audiologist must program the hearing aids, maintain the devices, and make any necessary changes in an effort to improve speech intelligibility (FDA, 2013).

PSAPs were previously intended to amplify sounds in specific listening environments rather than for everyday use in multiple environments. They were not meant to treat hearing loss. PSAPs were developed to be used by hunters listening to prey, bird watching, or listening to a distant lecture or speaker (FDA, 2013). PSAPs were not intended to diagnose, treat, cure or mitigate disease, therefore they are not devices defined under the FD&C Act and they were not subject to regulatory classification. However, currently PSAPs are subject to the regulations of the Radiation Control for Health and Safety Act of 1968, under which the FDA regulates products that produce sonic vibrations. More recently the Senate and House of Representatives have passed a bill that will make over the counter hearing aids available for individuals with a perceived mild to moderate hearing loss. The bill known as the Over the Counter Hearing Aid Act of 2017 was signed into law by President Donald Trump in August 2017 as part of the Food and Drug Administration Reauthorization Act of 2017 designed to provide increased public accessibility and affordability with OTC hearing aids. The bill also requests the FDA to develop regulations and safety labeling on PSAP packaging. Currently PSAP manufacturers must report defects and comply with requirements defined regarding purchasing, repairing, or replacing the electronic devices (FDA, 2013).

The FDA distinguishes between hearing aids and PSAPs based on the intended use of each device, whether it is a medical device or an electronic product. The labeling of the product can establish the intended use of the device. Any labeling or advertising that promotes PSAPS for hearing impaired individuals would require the product to follow the regulations set forth by the FDA for a medical device. Examples of claims that would classify the amplifying device as a medical device would be any description of degree or severity of hearing loss, descriptions of situations associated with hearing loss, and wording that suggests the device is an alternative to a hearing aid. The President's Council of Advisors on Science and Technology (PCAST) (2015), suggest that "Americans would be better served if non-surgical air-conduction devices intended to address bilateral, gradual-onset, mild-to-moderate age-related hearing loss…were available over the counter" and advised the FDA to update the regulations for PSAPs and hearing aids. Once the current bill is signed into law, the regulations and requirements for PSAPs will change and should be available in the near future.

Signal to noise ratio improvement

Signal to noise ratio (SNR) is manipulated within a device to enhance speech understanding, separating the intended signal from the background noise. Directional microphones in hearing aids improve the SNR from front to back and in several different patterns that automatically adjust (Mamo et al., 2016). SNR can also be manipulated using a remote microphone separate from the hearing aids. The microphone is placed near the speaker or intended signal, increasing the SNR. The telecoil can also be used in a loop system to improve SNR in the intended environment. Mamo et al. (2016) found that two out of five PSAPs they evaluated had SNR improvement fully available and another two out of five had SNR improvement partially available, and one instrument had no SNR boost at all.

Listening comfort

A patient factor that is important to consider for a first-time amplification user is if the amplification be perceptually too loud for them? Hearing aids have different algorithms to determine how much to reduce different types of sounds to maintain audibility in noise. Reducing determined background noise can improve the ability to understand speech in background noise, but additionally improves the listeners comfort in noise (Mamo et al., 2016). Only some PSAPs have algorithms to address comfort in noise, and most only partially address the issue (Mamo et al., 2016).

Hearing Aid Functional Outcomes

Functional outcome measures are used to evaluate the proper functioning of hearing aids and PSAPs. Outcome measures can determine if the devices are providing an appropriate amount of amplification and benefiting the listener. Functional outcome measures include electroacoustic analysis, real ear measurements, and speech-in-noise testing.

Electroacoustic Analysis

Electroacoustic analysis can objectively measure the quality of a hearing device's output (Smith et al., 2016). The measurements are obtained by attaching a hearing aid to a 2cc coupler to the device that measures the calibrated signal delivered by the test box (Taylor & Mueller, 2014). The American National Standards Institute (ANSI) has developed standards originally developed to determine the characteristics of a hearing aid shipped from a manufacturer, known as ANSI S3.22 standards (ANSI, 2009). These standards have now been adapted into the FDA regulations. The most current update of the standard describes measurement techniques to assess quality of the devices and to provide tolerances for the quality assurance measures.

Output Sound Pressure Level 90

Output Sound Pressure Level 90 (OSPL90) is obtained by measuring the maximum output of the hearing device with a 90 dB input in sound pressure level. The measurement is obtained as a maximum point along the frequency range of the device. Smith et al. (2016) obtained OSPL90 values at 500 Hz and compared high-frequency average OSPL90 values to determine the difference in low and high frequency gain. Cheng and McPherson (2000) found that older PSAPs were providing too much low frequency gain and very little high frequency gain, which is an inappropriate configuration of gain for someone with age-related hearing loss. Smith et al. (2016) found that low-end PSAPs provided more low frequency gain and little high frequency gain. The hearing aids and high end PSAPs provided proportionate levels of both low and high frequency gain. In a comparison of eleven over the counter devices, six of the OSPL90 curves that were measured had narrow high frequency peaks ranging from 8-15 dB in magnitude, which can adversely affect speech intelligibility (Callaway & Punch, 2008).

Equivalent Input Noise

Equivalent Input Noise (EIN) is an electroacoustic measure of the noise generated by the internal components of the hearing device (Smith et al., 2016). EIN is measured when the hearing aid is programmed to the reference test setting, according to the ANSI S3 standards. Smith et al. (2016) found that low-end PSAPs had higher EIN and performed worse than high-end PSAPs and hearing aids, though all devices that were tested performed within ANSI specifications. Reed, Betz, Polyak, Grabowski, Korczak, Lin, & Mamo (2015) found that a group of high-end PSAPs had a similar amount of EIN compared to a traditional hearing aid. When comparing the performance of low, mid, and high-end PSAPs, the low-end PSAPs had high EIN as compared to the middle-end, high-end PSAPs, and traditional hearing aids (Polyak, 2016). Callaway and Punch (2008) found that ten out of the eleven devices tested in the study had high EIN, which was determined by a value greater than 28 dB.

Total Harmonic Distortion

Total Harmonic Distortion (THD) refers to the amount of unwanted harmonics in the output of the response that was not part of the input (Smith et al., 2016). THD is measured in the reference test setting position, according to the ANSI S3 standards. Smith et al. (2016) found that most devices tested measured within the appropriate range determined by ANSI standards, including low and high-end PSAPs. Similar performance was seen when comparing the THD of high end PSAPs and a traditional hearing aid (Reed et al., 2015). More recently, Polyak (2016) found that low end PSAPs had higher THD compared to middle, high-end PSAPs, and a traditional hearing aid. Callaway and

Punch (2008) found that ten out of the eleven devices tested in the study had acceptable THD values less than 3%.

Matching NAL-NL2 fitting targets

One of the most popular fitting formulas is NAL-NL2 which has been adapted from NAL-NL1 to provide more gain in the low and high frequencies and less gain for mid frequencies. NAL-NL2 prescribes gain respective of gender, degree of hearing loss, and age (Keidser, Dillon, Flax, Ching, & Brewer, 2011). An objective measure to assess the gain and output of amplification while on the listener's ear is through Real Ear Measures (REM). In REM the amplification is measured in the ear canal and compared to prescriptive NAL-NL2 targets for the individual's hearing loss. Smith et al. (2016) found that high end hearing aids matched NAL-NL2 prescriptive targets in individuals with variable audiometric configurations. High-end PSAPs were also able to match prescriptive targets for some hearing loss configurations. Three of the eleven devices including a low-end hearing aid and two low end PSAPs were not able to meet targets for all hearing loss configurations. When comparing a group of high-end PSAPs to traditional hearing aids in five subjects with hearing loss Reed et al. (2015) found that 44% of the high-end PSAPs met a majority of the NAL-NL2 targets within 10 dB.

Speech in Noise testing

One of the most common complaints of hearing aid users is difficulty in listening to speech in the presence of noise (Wilson & McArdle, 2007). These complaints have lead researchers to advocate for speech-in-noise testing as a hearing aid validation measure (Beck & Nilsson, 2013). Speech understanding in noise performance is be measured in a pre-treatment and a post-treatment condition to establish the benefit the amplification is providing. One of the most recent and well-validated speech-in-noise measure is the AzBio, which assesses a listener's ability to discriminate sentences in different levels of background noise (Spahr et al., 2012; Wilson & McArdle, 2007). Evaluating a listener's ability to understand in background noise cannot be predicted through conventional audiometric testing. A large portion of a conventional comprehensive hearing test is the individual's responses to beeps at different intensity levels. A conventional hearing test also tests an individual's responses to repeat words in the sound booth. Testing within the sound booth gives us an idea of an individuals' hearing status but does not give us much of an idea how they will function in the real world. Speech-in-noise testing, particularly the AzBio attempts to assess an individual's understanding in background noise and was used in this study.

Speech in noise testing is a method used to evaluate the benefit a person is receiving from hearing aids. The AzBio speech-in-noise test is a specific assessment of sentences used to evaluate the speech perception abilities of hearing impaired listeners and cochlear implant users (Spahr et al., 2012). In 2008, Gifford, Shallop, and Peterson found that AzBio sentence scores were highly correlated with monosyllabic word scores and did not have ceiling effects. The original AzBio speech-in-noise test consisted of 1000 sentences recorded with two male and two female voices. List equivalency and speech intelligibility were evaluated, reducing the sentence corpus to today's AzBio Sentence test that consists of 15 lists of 20 sentences (Spahr et al., 2012). The AzBio test provides a speech recognition score after calculating the number of words correctly identified in the sentence material (Spahr, 2012).

Binaural cues for Sound Localization

Listeners use cues from both ears in order to localize sound. Interaural level differences (ILDs) and interaural time differences (ITDs) combine to provide localization information. ILDs occur due to absorption and reflection of the sound resulting in acoustic attenuation (Stecker & Gallun, 2012). This attenuation of sound is referred to as the “head shadow effect”, where the magnitude of the ILD depends on head size, frequency and wavelength of the stimulus. The head is blocking the sound from reaching the far ear at an equivalent intensity or level as the nearer ear, resulting in a level difference between ears. The impact of ILD is influenced by both elevation and azimuth properties of the outer ear in relation to the sound source. A longer path to the ear results in a decreased sound level relative to the nearer ear. When listening to a sound source that originates from a farther distance the sound level will decrease by 6 dB with every doubling of distance. Sound level varies by 20-30 dB for nearer distances between 0.12-1.0 m, (Stecker & Gallun, 2012). The magnitude of ILDs varies on the frequency of the sound stimulus. ILD cues are more effective at higher frequencies and varies with a combination of absorption, reflection, and refraction (Stecker & Gallun, 2012). The dimensions of the human head and pinna are small compared to sound sources at or below 1500 Hz suggesting ILD as a more effective high frequency impacted phenomenon (Wightman & Kistler, 1997). Figure 5 depicts the level or intensity difference between the nearer ear and father ear.

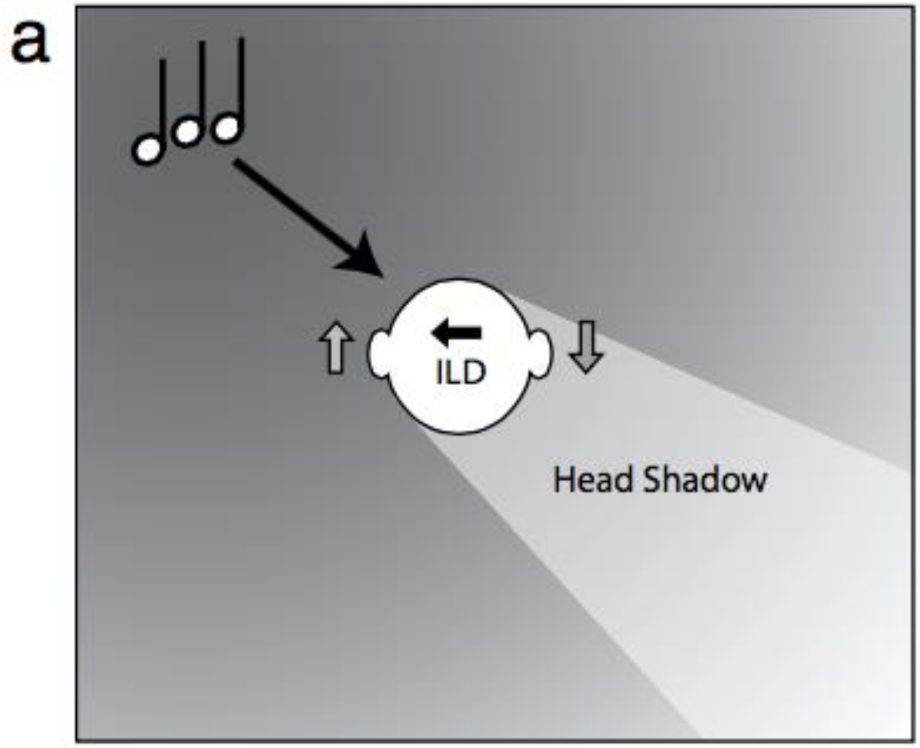

Figure 5. A depiction of ILD with decreased sound level due to the head shadow effect. Adapted from “Translational perspectives in auditory neuroscience: Normal aspects of hearing”. By Stecker & Gallun, 2012.

Listeners are also sensitive to differences in the timing of sound. ITDs are based on the speed of sound, the geometry of the head and ears of the listener (Stecker & Gallun, 2012). A sound source originating from 0° is equidistant from both the right and left ears, lateral sound sources may arrive to the ears with a timing difference up to 600 μsec in humans. ITDs depend of a combination of sound frequency and direction. Sound may also be transmitted around the head depending on frequency and wavelength. ITDs are more effective at lower frequencies <1500 Hz (Wightman & Kistler, 1997.) ITD delays may be detected as a delay of fine structure for sounds < 1600 Hz or as a fluctuation in the amplitude of sound at each ear due to amplitude modulation (Stecker &

Gallun, 2012). Figure 6 depicts an ITD resulting from the delay in arrival time at the farther ear from the sound source.

b

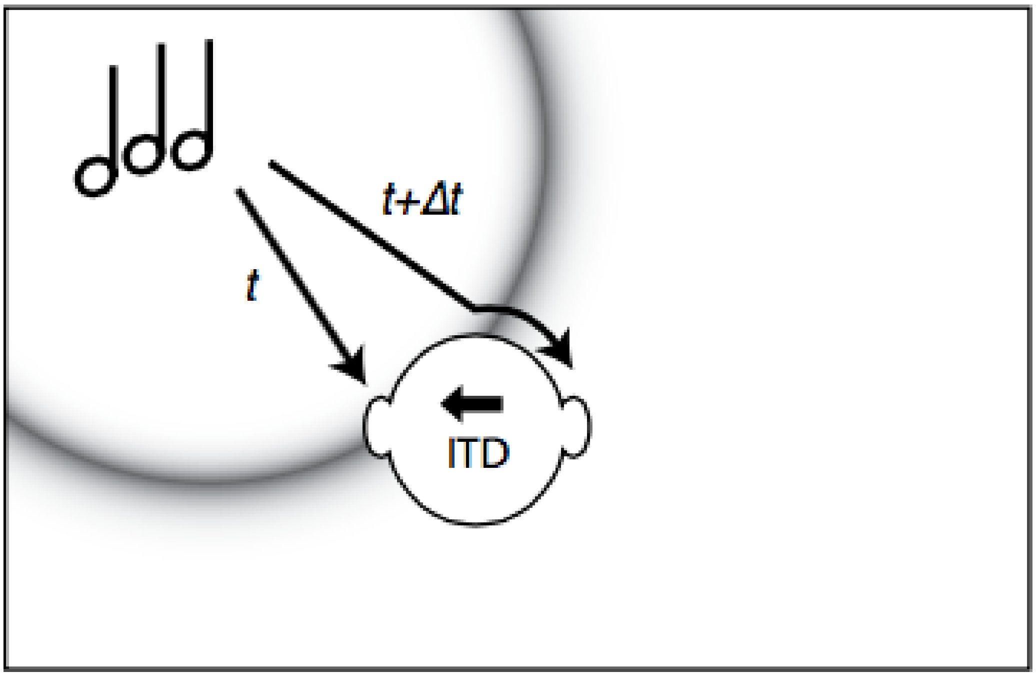

Figure 6. ITD due to sound source from a lateral azimuth. Adapted from "Translational perspectives in auditory neuroscience: Normal aspects of hearing". By Stecker & Gallun, 2012.

Energetic and Informational Masking

Brungart (2001) examined the intelligibility of a target phrase masked by a competing masker that is measured in Speech to Noise Ratio (SNR). Maskers can be applied in both an energetic and informational condition. Energetic masking occurs when both the target and masker contain energy in the same critical bands at the same time and portions of one or both speech signals are rendered inaudible (Brungart, 2001). Informational masking occurs when the signal and masker are both audible, but the listener is unable to separate the elements of the target from the similar sounding distracter (Brungart, 2001). Listener performance is most influenced by informational masking rather than energetic masking (Brungart, Simpson, Ericson, & Scott, 2001). Brungart (2001) found that when target signals were masked with an informational signal performance decreased with decreasing SNR, and plateaus at a chance level of 50%.

Spatial Release from Masking

Many studies demonstrated that speech recognition in noise improves when the original source of the speech is horizontally separated from the background noise (Freyman Helfer, McCall, & Clifton, 1999; Freyman, Balakrishnan, & Helfer, 2001). When listening in a complex auditory environment the listener can benefit from the use of spatial cues to determine the location of the intended sound source (Gallun, Diedesch, Kampel, & Jakien, 2013). The smaller amount of separation between the target signal and noise along the horizontal plane lowers the threshold for detecting signals in background noise (Freyman et al., 1999). When completing a spatial release from masking test the head shadow effect is removed by presenting simultaneous maskers on both sides of the head, ensuring that the SNR delivered is equivalent to both ears.

Feyman et al. (1999) investigated how individuals perceived spatial separation of target and masker by eliminating the direction advantages that spatial separation provides. Freyman and colleagues created spatial separation without directional advantages by using the precedence effect (Freyman et al., 1999). Non-meaningful sentences were presented from a loudspeaker directly in front of the listener while a continuous speech-spectrum noise was presented from loudspeaker in different locations. Speech recognition did not improve with spatially separated speakers as compared to co-located sentences, indicating that the perception of speech and noise is not important when listening to speech in stationary background noise (Freyman et al., 1999).

Results differed when the masker was a recording of a different female voice relative to the target. Listeners performed much better when the target sentence was presented from the center speaker and masker presented from perceptually far to the right, suggesting that spatial separation was important when the masker consisted of a speech signal (Freyman et al., 1999). Performance improved when a speech masker was used rather than steady noise because the speech signal contained informational masking in addition to energetic masking, thus giving the listener an additional cue to separate the target sentence from the masker (Freyman et al., 2001).

Freyman and colleagues (2001) completed three experiments to determine the extent to which interference improves speech recognition in the free field. The speech corpus contained 320 grammatically correct but non-meaningful sentences presented using a female voice. The experiment presented a sentence directly in front of the listener and a masker coming from the same degree of azimuth (0 degrees) and a second test condition where the target sentence was presented from directly in front of the listener and the masker from a right loudspeaker (60 degrees) with the right speaker leading by 4 ms. An improvement was seen when the masker was presented from 60 degrees to the right and a 4ms separation due to the precedence effect (Freyman et al., 2001). The second experiment revealed no advantage to a spatially separated loudspeaker when the masker was a single- or multi-channel envelope of the two-talker masker (Freyman et al., 2001). The third experiment in Freyman and colleagues research indicated that perceived separation aids in extracting the target sentence is not only limited to understandable interfering speech (Freyman et al., 2001).

Age and spatial release from masking

Srinivasan, Jakien, and Gallun (2016) examined SRM at eight different azimuth angles (0^0, 2^0, 4^0, 6^0, 8^0, 10^0, 15^0, or 30^0) in order to find the minimum degrees of separation between target and masker that young normal hearing, old normal hearing, and old hearing impaired listeners could identify. In all three subject test groups, greater spatial separation was associated with a decreased threshold to masker ratio (TMR) for 0^0-10^0 degrees of spatial separation. However, there was a steep decrease in TMR when spatial separation was greater than 15^0 degrees. Figure 7 depicts the relationship between TMR and the degrees of separation for all three test groups. Hearing loss and aging were found to influence the predicted SRM (Srinivasan et al., 2016).

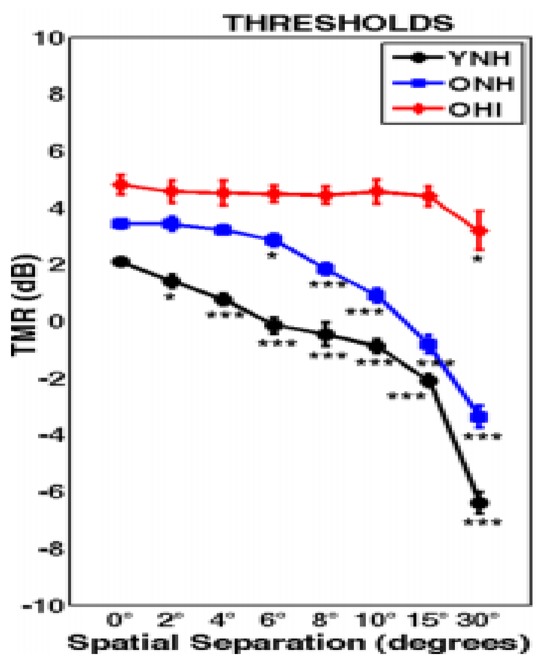

Figure 7. Target-to-masker ratio plotted as a function of spatial separation between target and masker for the three groups. Adapted from "Release from masking for small spatial separations: Effects of age and hearing loss". By Srinivasan, Jakien, & Gallun (2016).

Aging and hearing loss can both independently affect an individual's performance in background noise and combine to create a difficult listening environment for the older hearing impaired listener. It is well documented that hearing loss affects an individual's ability in a spatial release from masking task. Gallun et al. (2013) continues to look deeper at the effects of sample size and attempts to separate the effects of age from the effects of hearing loss. Researchers hypothesized that aging, independent from hearing status, can reduce performance during a spatial release from masking environment (Gallun et al., 2013). In this study, Gallun and colleagues (2013) used the CRM to assess the listener's ability to understand speech. The results indicated that age and hearing loss are independently responsible for a decline in spatial release from masking. This research suggests that the combination of increased age and hearing loss will result in poorer performance in a spatial release from masking task, suggesting poorer performance in a real world difficult listening environment.

Real world listening

Two main factors that can independently impact the auditory system are age and hearing loss. This study examined the effect that age and hearing loss have on spatial release from masking and sound localization when provided with amplification. Once an individual is fit with amplification they enter real world environments, where background noise is a common occurrence. All previous PSAP testing has been completed in a sound booth or an ideal listening environment, not providing us with any information suggesting how an individual might perform in the real world. The current study aimed to simulate a real world difficult listening environment for older hearing impaired individuals by employing speech on speech masking trials and their impact on speech localization. Functional outcome measures including electroacoustic analysis, real-ear measurements, speech assessments, and CRM are useful for investigating the benefit of different forms of amplification including a simulated real world listening environment. These assessments can be useful for validating the function and benefit of PSAPs.

Aims of the study

This study is the third segment of PSAP research at Towson University. Two research studies have been completed to (1) evaluate the performance of high end and low end PSAPs compared to a traditional hearing aid; and (2) to evaluate the influence of fitting strategies of two high end PSAPs.

In Polyak's (2016) research, electroacoustic analysis, real ear measurements, and AzBio were used to evaluate five different PSAPs (CS-50, Soundhawk, Bean, Tweak, MSA 30X) against one FDA approved hearing aid, the Oticon Nera RITE. All participants were aged from 61 to 80 years old, had three-frequency pure tone average, defined as ≥20 and ≤55 dB in at least one ear, no air bone gaps, hearing loss not due to a medical condition, no significant cognitive decline, and had not worn hearing aids for more than one month (Polyak, 2016). Electroacoustic analysis was performed on all devices prior to the start of testing to ensure the devices were functioning properly. The EAA analyses included: OSPL 90, average OSPL 90, frequency range, equivalent input noise, and total harmonic distortion. The traditional hearing aid was found to have the highest average OSPL 90. The frequency range examined between the hearing aid and the PSAPs was broad (<200 – 7-8000 Hz) except for the MSA 30 X which was recorded as much narrower. The Oticon hearing aid was programed based on NAL-NL 2 prescriptive targets and PSAPs were programed based on the manufacturer instructions and matched to NAL-NL2 targets by an audiologist. Real ear measurements were performed for each individual and each device. The Oticon hearing aid and the three high end PSAPS matched the NAL-NL2 targets better at each frequency than any of the low end PSAPs, suggesting a difference in real ear performance especially between low end and high end PSAPs. The AzBio speech-in-noise test was performed monaurally with the listener’s better ear wearing the hearing aid and all five PSAPs. AzBio scores obtained from the 3 high-end PSAPs (Soundhawk, CS-50, and Bean) and the hearing aid were relatively similar. Polyak (2016) concluded that the high end PSAPs performed similarly to the FDA approved Oticon hearing aid.

The second installment of the PSAP research conducted at Towson University examined three approaches to fitting PSAPs and their effect on patient performance. Oliver (2017) examined three functional outcome measures (electroacoustic analysis, real-ear measures, and the AzBio speech-in-noise sentence test) with two advanced PSAPs (i.e., CS-50 and the Soundhawk). The participants were 51-82 years old who presented with bilateral symmetrical slight to moderate sensorineural hearing loss, no history of hearing aid use, hearing loss unrelated to a medical condition or noise exposure, and no evidence of cognitive decline. The three fitting approaches included (1) the out-of-the-box self-fit, using only the manufacturer’s user guide; (2) the advanced user self-fit for tech savvy users; and (3) the audiologist “gold-standard” fit (Oliver, 2017).

When examining the results from the real-ear measures the highest number of total NAL-NL2 targets and highest percentage met were measured using the gold-standard fit. A greater percentage of targets were met at 500 Hz than 4000 Hz. The mean aided scores showed improvement over unaided scores across all test conditions for both PSAPs. All listeners had the greatest improvement with the gold-standard audiologist fit. This study indicated that older listeners with a mild to moderate hearing loss performed the best when the PSAP was fit by an audiologist in the gold standard fitting protocol (Oliver, 2017).

The current study investigated the performance of one high end PSAP and one traditional hearing aid in a simulated real world speech localization scenario, by using different noise scenarios. Both the hearing aid and the PSAP were tested in a binaural fit condition. Performance was tested in an audiologist fit condition only. Previous studies evaluating PSAPs have been completed in a soundproof booth or test box. This current study aims to determine the effectiveness of a PSAP in a simulated real world difficult listening environment.

CHAPTER 3

METHODS

Participants

Fifteen adults aged 40-80 years were recruited from the Towson University Speech, Language, and Hearing Center, from Towson University through flyers, and word of mouth. To be included in the study the participants must have had a bilateral symmetrical slight to moderate sensorineural hearing loss, defined as a three-frequency pure tone average (PTA) of ≥20 dB and ≤55 dB at 500 Hz, 1000 Hz, and 2000 Hz with no air bone gaps present in either ear. Each participant must have had normal immittance results, which is defined in adults as static admittance values (0.2-1.5 ml), tympanometric peak pressure (-103.50-4.2 daPa), and ear canal volume (0.9-2.0 ml) (Roup, Wiley, Safady, & Stoppenbach, 1998; Wiley et al., 1996). They must also have had no evidence of hearing loss caused by extraneous factors, such as extremely loud noise or secondary to a diagnosed medical condition. To be included in the study participants also must have had no cognitive decline, defined as a score of $\geq$25 on the Department of Veterans Affairs St. Louis University Mental Status (VA-SLUMS) examination (U.S.VA., Kansagara, Freeman, 2010; Stewart, O'Riley, Edelstein, & Gould, 2016; Tariq, Tumosa, Chibnall, Perry, & Morely, 2006). Participants reported on any previous hearing aid use. They must not have had previously worn a hearing aid for more than a month to participate in the current study. Participants received a reimbursement of a $30.00 gift card per session for their time and effort.

Procedures

Thirteen participants ages 40-80 were evaluated to participate in this pilot study. Ten of the participant's hearing thresholds disqualified their participation in the study. The 3 participants that had hearing thresholds to qualify them for this pilot study were tested during two 2-hour sessions at the Towson University Audiology Clinic. Each participant completed the VA-SLUMS to ensure normal cognitive functioning prior to testing. All testing was completed in a double-walled sound-proof test booth. The first test session was comprised of audiometric testing, EAA, REM, speech intelligibility testing using the AzBio sentence list, and speech-in-noise ability assessed using the CRM. During the second test session, localization ability of the participant was assessed. Audiometric testing was completed on a GSI-61 audiometer calibrated to ANSI standards. The audiologic exam included an otoscopic examination, immittance testing, pure tone air conduction from 250-8000 Hz, bone conduction from 500-4000 Hz and an un-aided speech-in-noise test using the AzBio sentence lists. Presentation of the AzBio sentence tests was randomized to remove any order effects.

One of the top performing PSAPs from Polyak (2016) was the high-end CS 50+. The Sidekick, an advanced PSAP from the same developer (Soundworld Solutions) was used in this study. Both the Oticon Nera miniRITE and the Sidekick were programmed in an audiologist fit condition, the top performing condition in Oliver (2017). Electroacoustic analysis was performed on the hearing aid and the PSAP to ensure proper functioning of the devices prior to testing. Average OSPL90, frequency range, equivalent input noise, and total harmonic distortion were obtained during the electroacoustic analysis. The EAA measurements were compared to manufacturer specifications and between devices. Both the Sidekick and the Oticon Nera miniRITE were fit by the audiologist to best meet NAL-NL2 targets for average speech (65 dB HL). Speech-in-noise testing was completed using the AzBio sentence test at a 20 dB SL presentation level above the participant's 3-frequency PTA with a +5 dB SNR. In this study, we used 6 lists comprised of 20 sentences each presented in the sound field. The sentence lists were presented in the sound field in three different hearing conditions 1) unaided, 2) aided with the Sidekick PSAP, and 3) aided with the Oticon Nera hearing aid. In all three test conditions, noise was coming from a speaker 180° azimuth to the patient in a sound-treated booth. Unaided performance was assessed first and the PSAP and hearing aid test conditions were randomized to control for any order effects. The AzBio sentence test was scored by counting the number of words correctly identified in the target sentence. The total score was calculated by the following formula: $Total\ score = \frac{\#\ of\ words\ correct}{total\ \#\ of\ words\ present\ in\ the\ sentence} x100.$

A second speech-in-noise test evaluating speech identification was used during test session two. The CRM has become one of the most popular tools for English speech materials with a corpus containing 256 unique sentence combinations that follow the same syntactic structure (Humes et al., 2017). Each sentence follows the structure: “Ready <call sign> go to <color> <number> now.” Each of the sentences was spoken by three male voices and four female voices. The CRM uses a lexical call sign as a signal for the target sentence the participant should pay attention to. The participant chose the correct color and number combination paired with the lexical call sign. An example CRM test screen is depicted in figure 8.

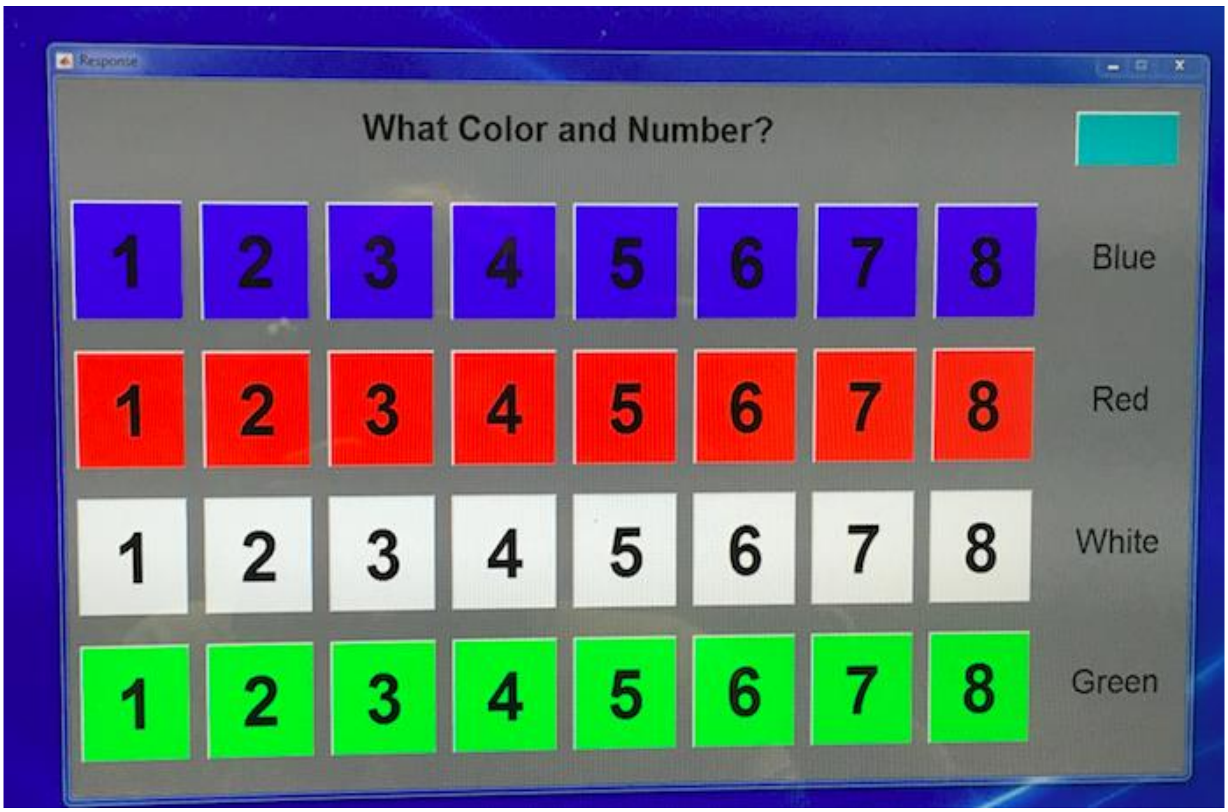

Figure 8. An example CRM test screen as seen by a participant Numbers 1-8 in the four test colors (blue, red, white, and green).

CRM threshold was obtained by presenting the target speech signal at 20 dB SL above the participant’s 3-frequency pure tone threshold. CRM thresholds were obtained in 3 listening conditions in the sound field 1) unaided, 2) aided with PSAP, and 3) aided with the hearing aid. The unaided threshold was obtained first, followed by the PSAP and hearing aid conditions. The order of PSAP and hearing aid testing was randomized to reduce order effects. The CRM testing was completed in the sound field with a 16-speaker array oriented in a 360° orientation. All test conditions were presented at two spatial separations: co-located (target and maskers presented from 0° azimuth) and spatially separated (target at 0, symmetrical maskers at ± 45°). The spatially separated condition was presented before the co-located listening condition for all the three device conditions: 1) unaided, 2) aided with PSAP, and 3) aided with the hearing aid. Table 2 depicts the six CRM test conditions that were used in this study. A depiction of the speaker set up used for CRM testing is depicted in figure 9.

Table 2
Six CRM test conditions used in this study

Unaided		PSAP		Hearing aid	
SS	Co-located	SS	Co-located	SS	Co-located

Note. SS = spatially separated

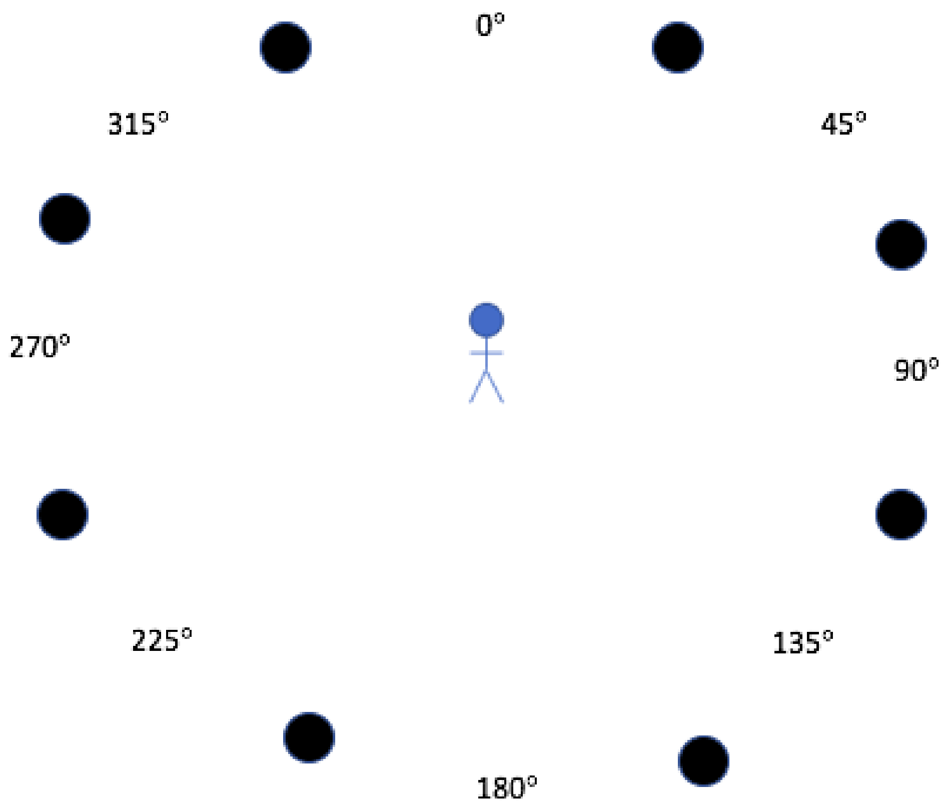

Figure 9. An overview of the 16-speaker array used for CRM testing. Black circles indicate additional speakers.

CRM threshold measurement always started with threshold measurement for the spatially separated condition, which is defined as the level required to obtain 50% correct point on the psychometric function (Levitt, 1971). Thresholds were obtained using a one-up, one-down adaptive procedure, based on whether or not the color and number of the target sentence was reported correctly. The speech level was initially set 20 dB above the PTA (pure-tone average of audiometric thresholds for 0.5, 1, 2, and 4 kHz). The masker level was varied adaptively in order to estimate the SRT (in dB SNR) associated with 50% correct identification performance. The initial target-to-masker ratio was set at +10 dB. The level of the masker sentences was reduced by 5 dB after every correct trial and increased by 5 dB after every incorrect trial until three reversals of direction occurred, at which point step size was reduced to 1 dB from the fourth reversal onwards. Each track had 9 reversals and the threshold was estimated based on the average of the last six reversals. Figure 10 depicts an example of the adaptive tracking method and ten reversals.

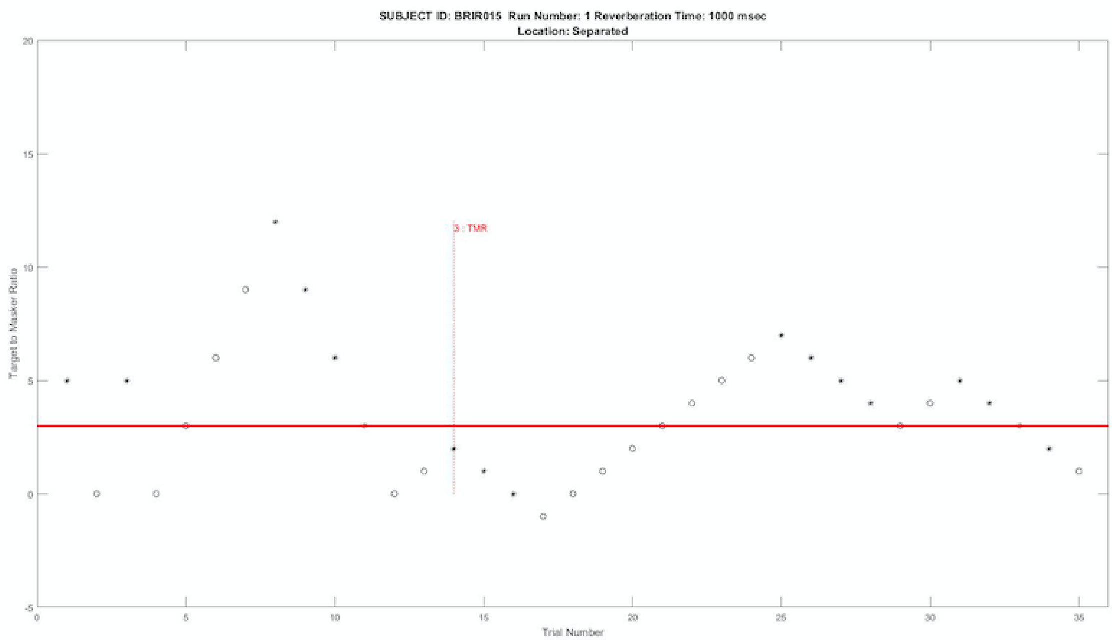

Figure 10. An example image of a participant’s responses using the adaptive tracking method.

Set up

The second session consisted of localization tasks performed in the sound field in three conditions 1) unaided, 2) aided with the PSAP, and 3) aided with the hearing aid. All testing was completed in a sound-treated booth. Participants were seated inside an array of 13 speakers. The speakers were located in the frontal horizontal plane at angles -90° to +90° relative to the participant. The speakers were set up 15° apart and placed 4 feet from the participant. These speakers were labeled 1 to 13.

Stimuli

A participant localizes high and low frequency sounds with different binaural processing strategies. Interaural timing differences are primarily used to localize low frequency sounds, while an interaural level difference is primarily used to locate high frequency sounds (>1500 Hz) (Van den Bogaert, Klasen, Moonen, Van Deun, & Wouters, 2005). 1/3 octave band wide white noise centered around 500 Hz and 3150 Hz were used in this experiment. The noise stimuli used was 200 ms in duration with 10 ms on and off ramps.

Test Protocol

All participants were instructed to keep their head fixed and pointed to 0° during stimulus presentation. The participants were instructed to identify the speaker where the target sound was heard. Both the 500 Hz and 3150 Hz stimulus were presented 10 times per speaker, resulting in 130 presentations per condition. Three tests were performed in the sound field 1) unaided, 2) aided with the PSAP, 3) aided with the hearing aid. The unaided localization results were obtained prior to amplified responses. PSAP and hearing aid test conditions were randomized to eliminate order effect. Participants were given a break between the three conditions. All stimuli presentation and data collection were done using MATLAB and data analysis was performed using Excel. The speaker set up is depicted in figure 11.

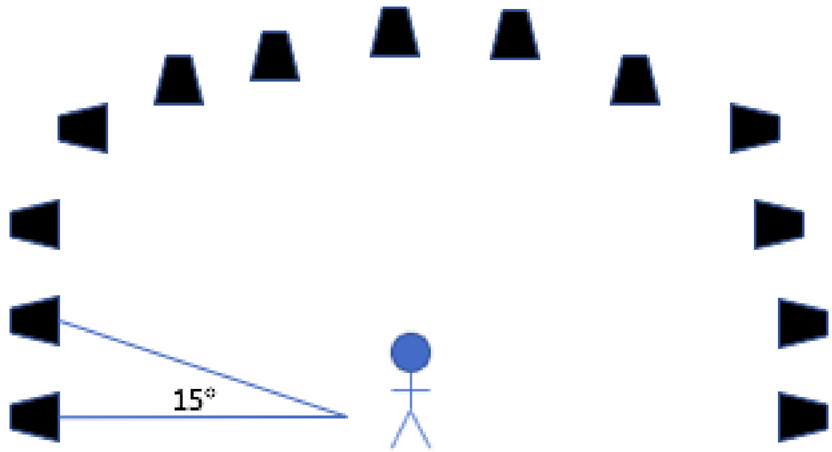

Figure 11. An overview of the speaker set up for localization tasks. Adapted from "Horizontal localization with bilateral hearing aids: Without is better than with." by Van den Bogaert, Klasen, Moonen, Van Deun, & Wouters, 2005.

Statistical Analysis

Statistical analysis was completed on the data obtained in this study. Electroacoustic analysis was completed to ensure proper functioning of each device. Values of the electroacoustic analysis measurements (average OSPL90, frequency range, equivalent input noise, and total harmonic distortion) were compared to manufacturer specifications.

When analyzing real-ear measurements the individual gain at frequency specific values were compared to evaluate how well the devices met the prescribed NAL-NL2 targets. The amount of overshoot and undershoot at each frequency was compared to target values between devices.

The descriptive statistics of the AzBio speech-in-noise test and CRM data was compared across test conditions. Localization performance was evaluated by comparing the average root-mean-square (RMS) error, the formula is depicted in figure 12.

$$rms(°) = \sqrt{\frac{\sum_{i=1}^{n}(stimulus - response)^2}{n}}$$

Figure 12. Formula to calculate root-mean-square error. Adapted from "Horizontal localization with bilateral hearing aids: Without is better than with. "by Van den Bogaert, Klasen, Moonen, Van Deun, & Wouters, 2005.

CHAPTER 4

RESULTS

The results section will cover the demographics of the individual participants in this study as well as their individual results for the electroacoustic analysis and real ear measurements for both the PSAP (Sidekick) and traditional hearing aid (Oticon Nera miniRITE). This will be followed by a discussion of AzBio speech-in-noise sentence test results and coordinate response measure (CRM) thresholds for co-located and spatially separated conditions for each of the three hearing test conditions (unaided, PSAP, traditional hearing aid (HA)) for each participant. Localization performance for a 1/3 octave narrow band noise centered around 500 Hz and 3150 Hz for each test condition (unaided, PSAP, traditional hearing aid) will be evaluated using the root mean square localization error. Lastly, the average performance for AzBio and CRM thresholds for each test condition will be discussed. Performance will be discussed as individual cases due to the limited sample size (*n*=3) and results should be interpreted with caution.

Participant 105

The first participant (participant 105) was a 62-year-old male reporting some difficulty hearing his children. He reported bilateral tinnitus and a family history of hearing loss. He has no history of amplification. Otoscopy revealed moderate cerumen with tympanic membranes able to be visualized bilaterally. Tympanometry revealed type

A tympanograms, indicating adequate middle ear function bilaterally. An audiometric evaluation revealed a mild sloping to a severe sensorineural hearing loss in the right ear and hearing within normal limits (250-500 Hz) sloping to a severe sensorineural hearing loss in the left ear. No air bone gaps were noted. The 3-frequencny PTAs (500, 1000, 2000 Hz) were 21.67 dB HL for the right ear and 20 dB HL for the left ear. Frequency specific thresholds are displayed in Figure 13.

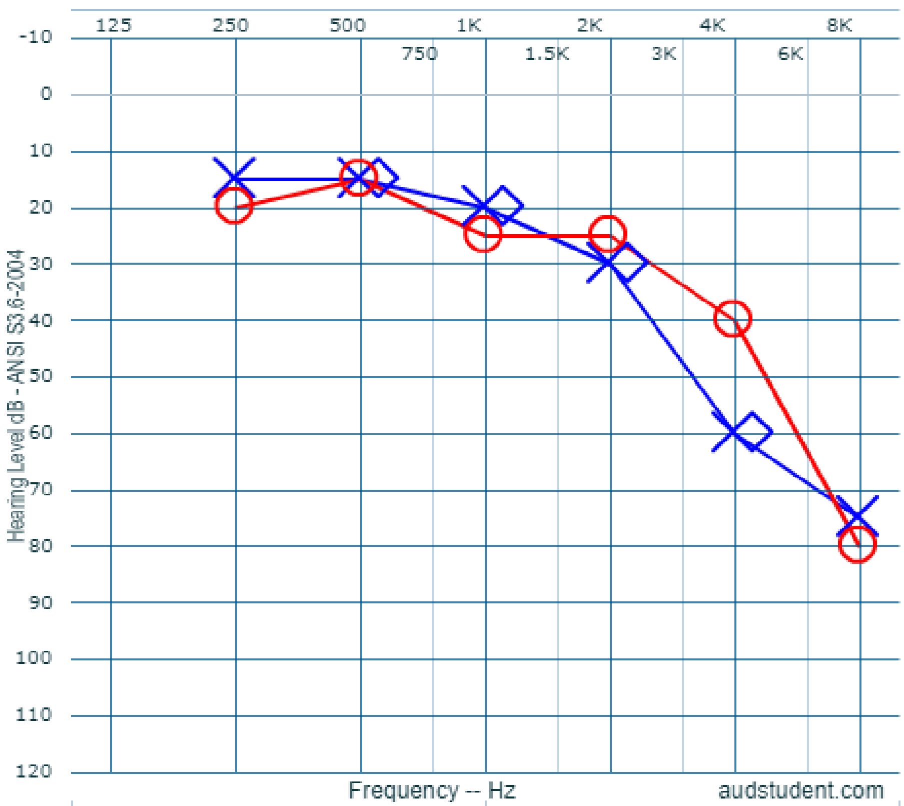

Figure 13. Air conduction and bone conduction thresholds obtained for participant 105.

Electroacoustic Analysis Results

Electroacoustic analysis measurements were taken in the current study prior to each test session. Measurements for average OSPL90, frequency range, equivalent input noise, and total harmonic distortion were compared to the manufacturers' specifications. The measurements obtained prior to testing and manufacturer's parameters are presented in Table 3. It is evident from Table 3 that the measurements from both the PSAP and the traditional hearing aid were generally in good agreement with the manufacturer's specifications. The frequency ranges and THD were particularly in good agreement with manufacturer's specifications. The average OSPL 90 measurements recorded were slightly below the specifications provided by the manufacturer and the EIN was slightly higher than the manufacturer specifications.

Table 3

Electroacoustic Analysis Measurements and Manufacturers' Specifications for the PSAP and Hearing Aid

Device		Average OSPL90	Frequency Range	Equivalent Input Noise	Average Total Harmonic Distortion
PSAP	Right	94 dB SPL	<2000-8000 Hz	31 dB SPL	0.33%
	Left	92 dB SPL	<2000-8000 Hz	33 dB SPL	0.67%
Manufacturer's Specifications		124 dB SPL	100-7500 Hz	26 dB SPL	1.43%
Traditional hearing aid	Right	91 dB SPL	300-5600 Hz	34 dB SPL	1%
	Left	93 dB SPL	670-6300 Hz	32 dB SPL	2%
Manufacturer's Specifications		119 dB SPL	100-7500 Hz	25 dB SPL	<2%

Note. Average total harmonic distortion = average percent distortion at 500, 800, and 1600 Hz.

Real-Ear Measurement Results

Real-ear measurements were obtained for both the PSAP and the traditional hearing aid as a functioning of the fitting protocol. The participant's hearing thresholds obtained in the first test session were entered into the Verifit system. A probe was inserted into the participant's ear canal and the device (PSAP or traditional hearing aid) was placed onto the subject's ear. Real-ear aided measurements were obtained at an average speech volume (65 dB SPL). Gain was adjusted by the audiologist to meet NAL-NL2 prescribed targets. A target was considered “met” if it fell within ± 5 dB of prescribed NAL-NL2 targets at each test frequency (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz). Frequency specific results recorded from real-ear aided measurements are depicted in table 4. An answer of “yes” indicates that the target was met within ± 5 dB. An answer of “no” indicates that the target was not met ± 5 dB.

The PSAP met 3 out of 4 targets for the right ear and 2 out of 4 targets for the left ear. The targets that the PSAP were not able to meet were 1000 Hz in the left ear which was an over-shoot of the prescribed target and 4000 Hz in both the right and left ears which was an under-shoot of the prescribed target bilaterally. The traditional hearing aid met 3 out of 4 targets in both the right and left ear. The traditional hearing aid had an under-shoot at 4000 Hz in both the right and left ears. The accuracy in meeting NAL-NL2 targets did not differ substantially for either device.

Table 4

NAL-NL2 Targets Met for Each Device After Audiologist Programming for Participant 105

Device		500 Hz	1000 Hz	2000 Hz	4000 Hz	Total Targets Met (%)
PSAP	Right Ear	yes	yes	yes	no	3/4 (75%)
	Left Ear	yes	no	yes	no	2/4 (50%)
Traditional Hearing Aid	Right Ear	yes	yes	yes	no	3/4 (75%)
	Left Ear	yes	Yes	Yes	no	3/4 (75%)

Note. NAL-NL2 targets were said to be met if the gain fell within ± 5 dB of the target for frequencies 500, 1000, 2000, and 4000 Hz. Yes = met within ± 5 dB and No = not within ± 5 dB

AzBio Speech-In-Noise Test Results

The AzBio sentence test was performed in all three test conditions (unaided, PSAP, hearing aid). In each test condition the participant was presented with 20 sentences in the presence of background noise. Participant performance was evaluated by calculating the number of words correctly repeated divided by the total number of words in the sentences, then multiplying by 100 to determine a percent correct score for each test condition. Results of the AzBio sentence testing are depicted in table 5. The participant performed similarly on all three test conditions demonstrating essentially no difference in performance between the three conditions.

Table 5

Participant 105's AzBio Sentence Test Scores for the Three Hearing Conditions

	Unaided	PSAP	Traditional Hearing Aid
Percent Correct	95.5%	94.9%	92.0%

Speech Identification Results

Speech identification thresholds determined using coordinate response measure testing were obtained in all three hearing test conditions (unaided, PSAP, and HA). The participant was asked to identify the color-number combination for the target call sign in the presence of masker phrases. The maskers were either co-located with the target at 0° azimuth or the targets were symmetrically separated by 30 degrees. The difference between the identification thresholds for the co-located and spatially separated conditions was spatial release from masking for each hearing condition. Table 6 depicts the CRM threshold and SRM for each hearing condition. The traditional hearing aid condition yielded the lowest thresholds in both the co-located and the spatially separated test conditions. Participant performance improved in all three of the spatially separated conditions compared to the co-located conditions. The SRM was the highest in the unaided condition.

Table 6

Identification Thresholds (measured in dB) and Spatial Release from Masking (dB) for All 3 Hearing Conditions for Participant 105

	Unaided	PSAP	Traditional Hearing Aid
Spatially Separated	-5	-3	-6.4
Co-Located	7.7	7.6	1.8
SRM	12.7	10.6	8.2

Note. SRM = spatial release from masking

Localization Results

In the localization task participants were asked to identify which speaker a stimulus was being presented from. The two stimulus conditions were a 1/3 octave wide noise burst centered around one low frequency (500 Hz) and one high frequency (3150 Hz). Speakers were arranged 15° apart with speaker number 1 at -90° and speaker number 13 at +90°. Figure 13 depicts the localization responses for each speaker when presented with a 500 Hz stimulus in an unaided condition. For example, a 500 Hz stimulus was presented from speaker 1 (-90°) 10 times and the participant indicated that they heard the sound from speaker 1 at -90° seven times but responded that they thought the stimulus was coming from speaker 2 (-75°) three times. The bubble would be larger where the grid for -90° on the x-axis and -90° on the y-axis meet. A small bubble would also appear at -90° on the x-axis and -75° on the y-axis. The more responses for a certain speaker is depicted as a larger bubble. Figure 14 indicates that there was more variability in responses when the low frequency stimulus was presented to the right of the participant in the unaided hearing test condition. When a high frequency stimulus (3150

Hz) was presented from the speakers in an unaided condition, participant performance was much more varied in the speakers to the left of the participant. The performance at 90° to the right was much poorer than the rest of the speakers in the high frequency unaided condition. Specific results from each speaker are depicted in Figure 15.

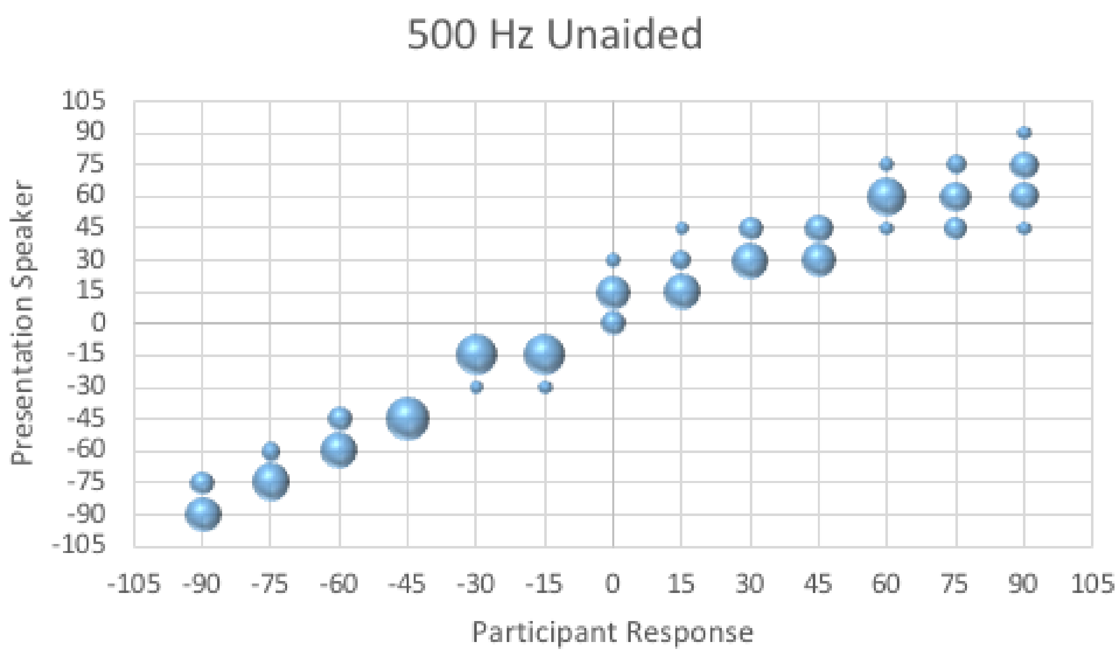

Figure 14. Participant 105's localization responses for a 500 Hz stimulus at each speaker in an unaided condition.

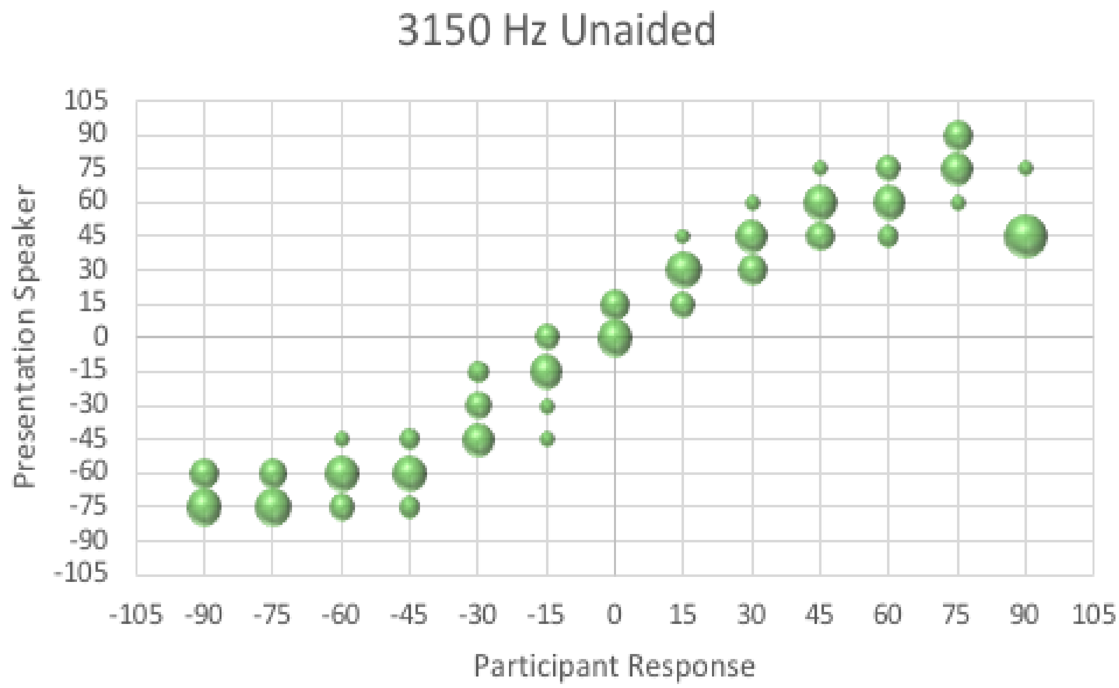

Figure 15. Participant 105's localization responses for a 3150 Hz stimulus at each speaker in an unaided condition.

Figure 16 depicts participant performance for a 500 Hz stimulus in an aided PSAP condition. The figure demonstrates that the responses for this test condition were more variable on the right side of the speaker set up and generally the participant chose the speaker to the right of the presentation speaker. In a high frequency condition participant performance was better for speakers closer to 0° azimuth and more variable for the speakers farther from 0°. Participant performance in a PSAP condition for a high frequency stimulus is depicted in Figure 17.

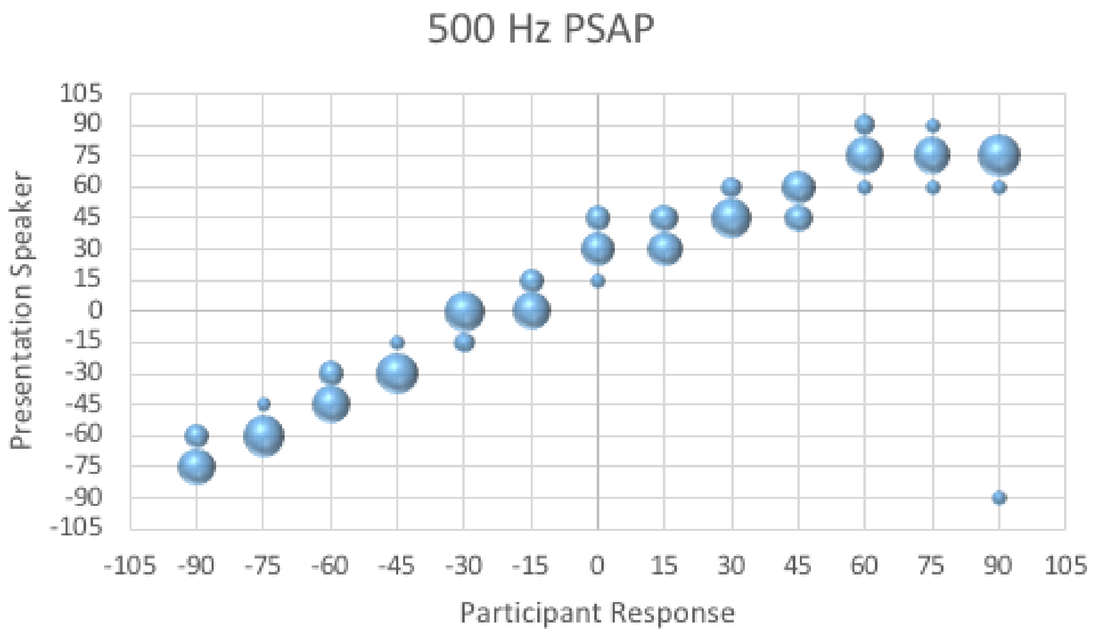

Figure 16. Participant 105's localization responses for a 500 Hz stimulus at each speaker in a PSAP condition.

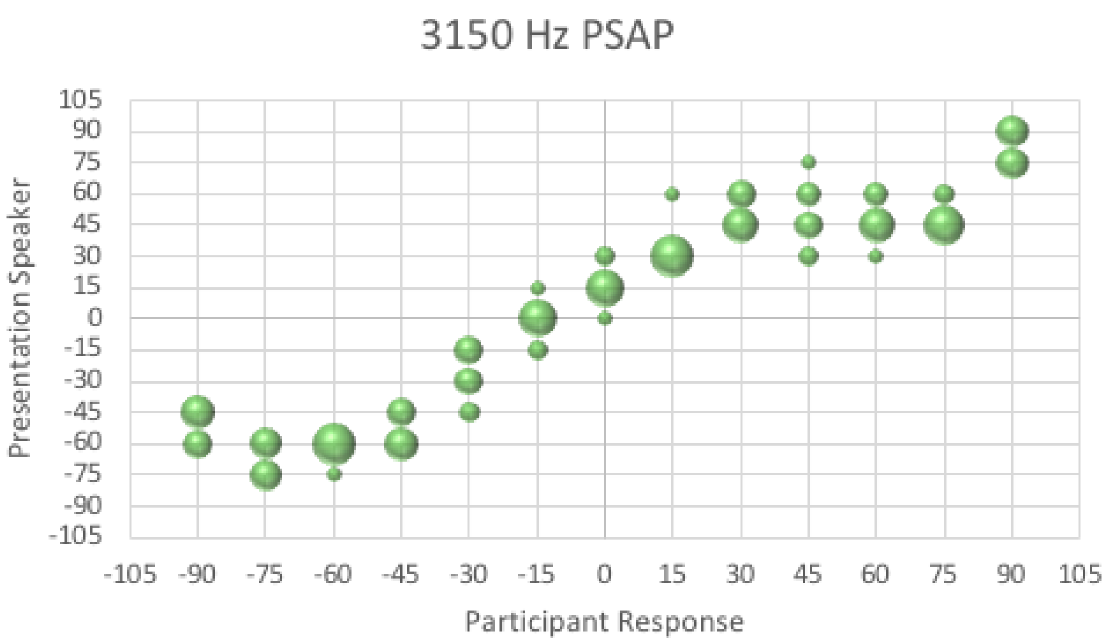

Figure 17. Participant 105's localization responses for a 3150 Hz stimulus at each speaker in a PSAP condition.

In the hearing aid test condition participant 105 performed relatively similarly for all speakers, but localization performance was more variable for speakers 75° and 90°, the furthest to the right of the participant. Figure 18 depicts the response at each speaker for a 500 Hz stimulus in the traditional hearing aid condition. When tested with a high frequency stimulus localization performance was variable for all speaker, but more variable for the speakers to the right of the participant. Figure 19 depicts the speaker specific results for the high frequency stimulus in an aided hearing aid condition.

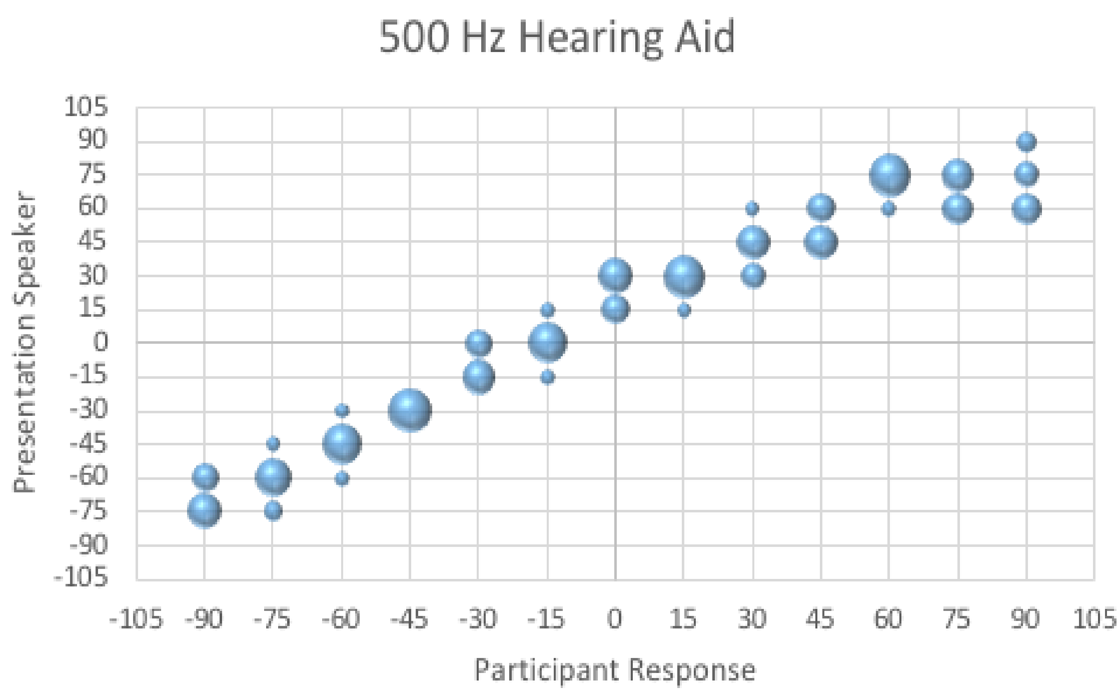

Figure 18. Participant 105's localization responses for a 500 Hz stimulus at each speaker in a traditional hearing aid condition.

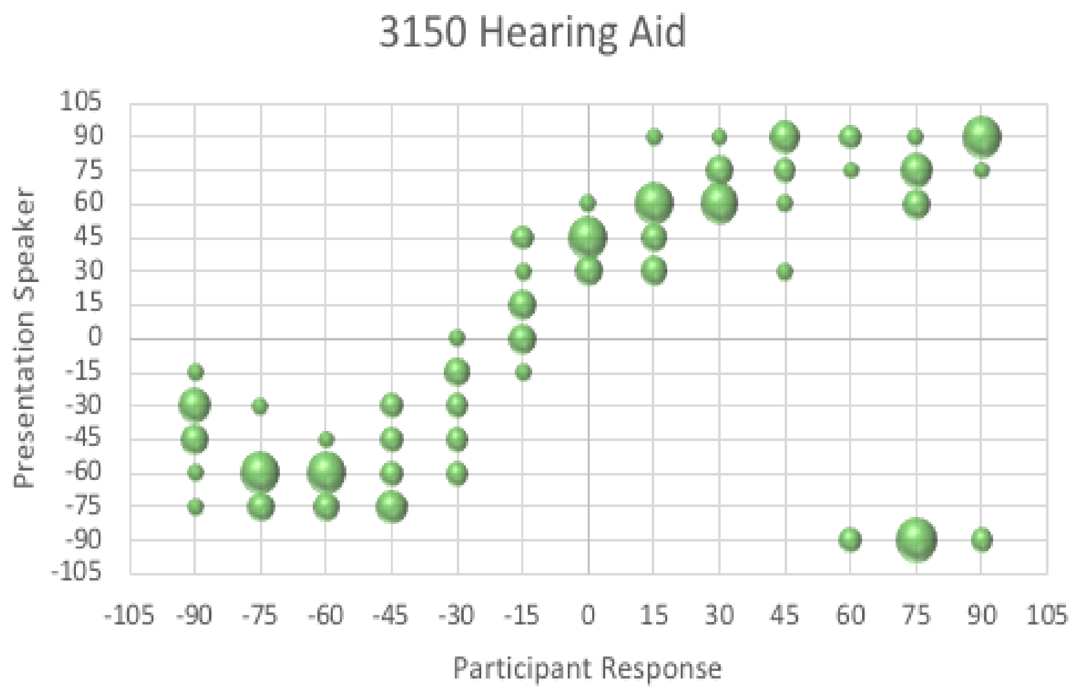

Figure 19. Participant 105's localization responses for a 3150 Hz stimulus at each speaker in a traditional hearing aid condition.

Participant performance was determined by calculating the root mean square error for each speaker at each stimulus frequency. Root mean square error was calculated by 1) squaring the errors, 2) calculating the mean of all squared values, and 3) taking the square root of the mean of all squares (Freedman, Pisani, & Purves, 2007). Results from the localization task for both frequencies are depicted in table 7 below. RMS error is displayed in degrees (°). Lower RMS error indicates better localization performance. The participant had better localization capabilities for the low frequency noise burst as opposed to the high frequency burst. Localization performance was relatively similar across hearing conditions (unaided, PSAP, and traditional hearing aid) for 500 Hz and was also similar across hearing conditions for the high frequency stimulus (3150 Hz). Localization accuracy was examined by calculating the number of correct responses divided by the 130 total trials multiplied by 100 to find the percent of correct responses for each condition. The highest percent of correct responses were seen for the low frequency stimulus compared to the high frequency stimulus. More correct responses were recorded in the hearing aid condition for the 500 Hz stimulus (59.23%) and for the unaided condition when tested with the 3150 Hz stimulus (33.08%). Localization accuracy represented in percent correct scores for each condition are displayed in table 8.

Table 7

Participant 105's RMS error for a low and high frequency stimulus in three listening conditions.

	Unaided	PSAP	Traditional Hearing Aid
500 Hz	12.55°	13.61°	14.23°
3150 Hz	22.90°	20.59°	26.15°

Table 8

Participant 105's localization accuracy in three listening conditions

	Unaided	PSAP	HA
500 Hz	56.92%	53.85%	59.23%
3150 Hz	33.08%	31.54%	19.23%

Participant 107

The second participant (participant 107) was a 61-year-old male with bilateral hearing concerns. He reported a family history of hearing loss, reporting his brother has a unilateral profound hearing loss. Additionally, he reported some occasional exposure to loud noise including music and lawn mowers. He has no history of amplification. He reported no other significant otologic symptoms. Otoscopy revealed clear canals with tympanic membranes able to be visualized bilaterally. Tympanometry revealed type A tympanograms, indicating adequate middle ear function bilaterally. An audiometric evaluation revealed a mild sloping to a moderate sensorineural hearing loss bilaterally. No air bone gaps were noted. The 3-frequency PTAs (500, 1000, 2000 Hz) were 26.6 dB HL in the right ear and 31.6 dB in the left ear. Frequency specific thresholds are displayed in Figure 20 below.

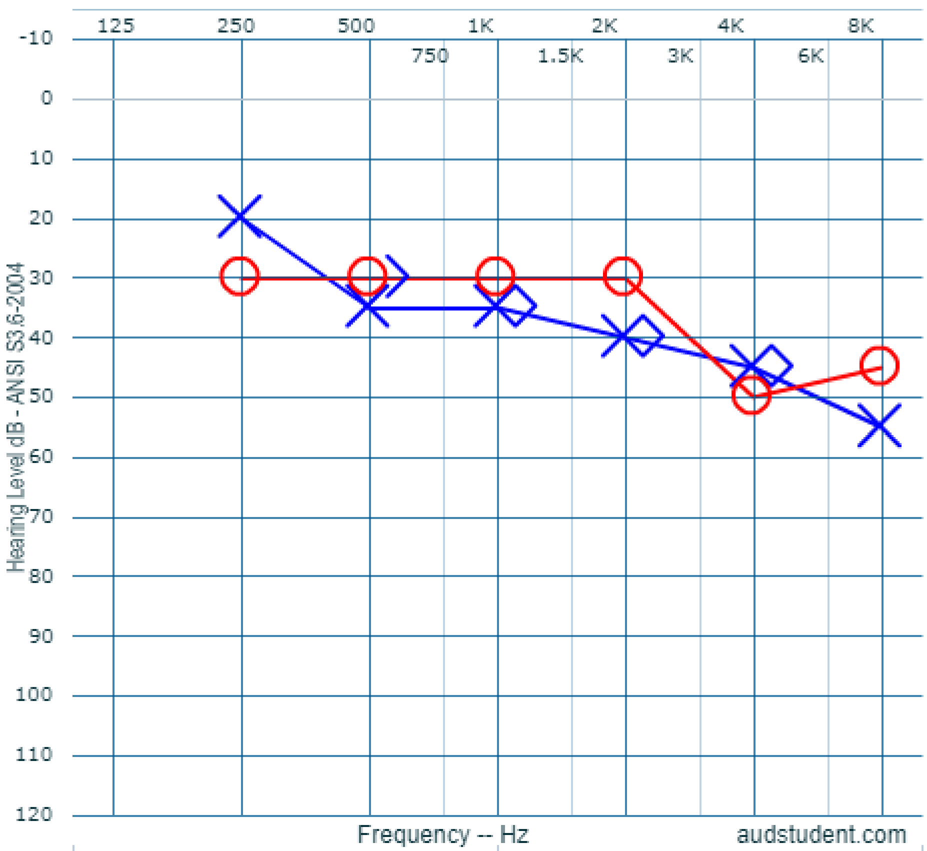

Figure 20. Air Conduction and Bone Conductions Thresholds Obtained for Participant 107

Electroacoustic Analysis Results

Measurements for average OSPL90, frequency range, equivalent input noise, and total harmonic distortion were compared to the manufacturers' specifications for the parameters and are presented in Table 9. For a more detailed explanation of the electroacoustic analysis refer back to participant 105. Results displayed in the table below demonstrate that the PSAP was in relatively good agreement with some of the manufacturers' specifications for these four parameters (Average OSPL90, frequency range, EIN, and THD). Frequency range and THD are in good agreement with the manufacturer's specifications while average OPSL90 is slightly below the specifications and the EIN is slightly higher than the manufacturers' specifications. The measurements recorded from the traditional hearing aid were also in good agreement with the manufacturer's specifications, especially the frequency range and EIN. The average OSPL90 recorded was slightly below the manufacturer's specifications while the equivalent input noise recorded was slightly higher than the specifications.

Table 9

Electroacoustic Analysis Measurements and Manufacturers' Specifications for the PSAP and Hearing Aid

Device		Average OSPL90	Frequency Range	Equivalent Input Noise	Total Harmonic Distortion
PSAP	Right	83 dB SPL	<2000-8000 Hz	34 dB SPL	0.67%
	Left	87 dB SPL	<2000-8000 Hz	32 dB SPL	0.67%
Manufacturer's Specifications		124 dB SPL	100-7500 Hz	26 dB SPL	1.43%
Traditional Hearing Aid	Right	92 dB SPL	560-7100 Hz	33 dB SPL	0.67%
	Left	93 dB SPL	500-6275 Hz	32 dB SPL	1.3%
Manufacturer's Specifications		119 dB SPL	100-7500 Hz	25 dB SPL	<2%

Note. Average total harmonic distortion = average percent distortion at 500, 800, and 1600 Hz.

Real Ear Measurement Results

Real-ear aided measurements were obtained to an average speech volume (65 dB SPL). Table 10 depicted below indicates how well each device (PSAP and traditional hearing aid) was able to meet NAL-NL2 targets at 500, 1000, 2000, and 4000 Hz ±5 dB.

The PSAP was able to meet 2 out of the 4 targets for both the right and left devices. The real-ear measurement indicates an overshoot at 2000 Hz and an undershoot at 4000 Hz for both the right and left devices. The traditional hearing aid was able to meet the targets slightly better than the PSAP in this test session. The measurement was able to meet all 4 targets in the right hearing aid and 2 out of 4 targets in the left ear. The real ear measurement at 1000 and 4000 Hz in the left ear undershot the NAL-NL2 target.

Table 10

NAL-NL2 Targets Met for Each Device After Audiologist Programming for Participant 107

Device		500 Hz	1000 Hz	2000 Hz	4000 Hz	Total Targets Met (%)
PSAP	Right Ear	yes	yes	no	no	2/4 (50%)
	Left Ear	yes	yes	no	no	2/4 (50%)
Traditional Hearing Aid	Right Ear	yes	yes	yes	yes	4/4 (100%)
	Left Ear	yes	no	yes	no	4/4 (100%)

Note. NAL-NL2 targets were said to be met if the gain fell within ± 5 dB of the target for frequencies 500, 1000, 2000, and 4000 Hz. Yes = within ± 5 dB and No = not within ± 5 dB

AzBio Speech-In-Noise Test Results

Results of the AzBio sentence testing for participant 107 are depicted in table 11. This participant performed similarly on all three test conditions indicating essentially no difference in performance between the three test conditions.

Table 11

Participant's 107 AzBio Sentence Test Scores for the Three Device Conditions

	Unaided	PSAP	Traditional Hearing Aid
Percent Correct	97.0%	99.3%	100%

Speech Identification Results

Table 12 depicts the CRM thresholds and SRM for each condition. Participant performance improved in the spatially separated conditions compared to the co-located conditions. Performance in the co-located conditions was similar for the unaided and PSAP test conditions. The traditional hearing aid yielded the lowest thresholds for both the spatially separated and co-located conditions.

Table 12

Identification Thresholds (dB) and SRM (dB) for All 3 Hearing Conditions for Participant 107

	Unaided	PSAP	Traditional Hearing Aid
Spatially Separated	4.6	2.2	-3.4
Co-Located	5.5	6.3	3.6
SRM	0.9	4.1	7.0

Note. SRM = spatial release from masking

Localization Results

The localization task consisted of identifying a low frequency (500 Hz) and a high frequency (3150 Hz) white noise from 13 speakers. For a more detailed explanation of the localization task refer back to participant 105. Localization ability for 500 Hz was relatively similar for all speakers in the unaided condition but were generally incorrectly identified as the speaker 15° to the right. Results can be seen in Figure 21. When the participant was tested with a high frequency stimulus (3150 Hz) results were also relatively similar across speakers except for speakers at -90° and 90°, the furthest from 0° azimuth to the left and right of the participant. Speaker specific results can be seen in Figure 22.

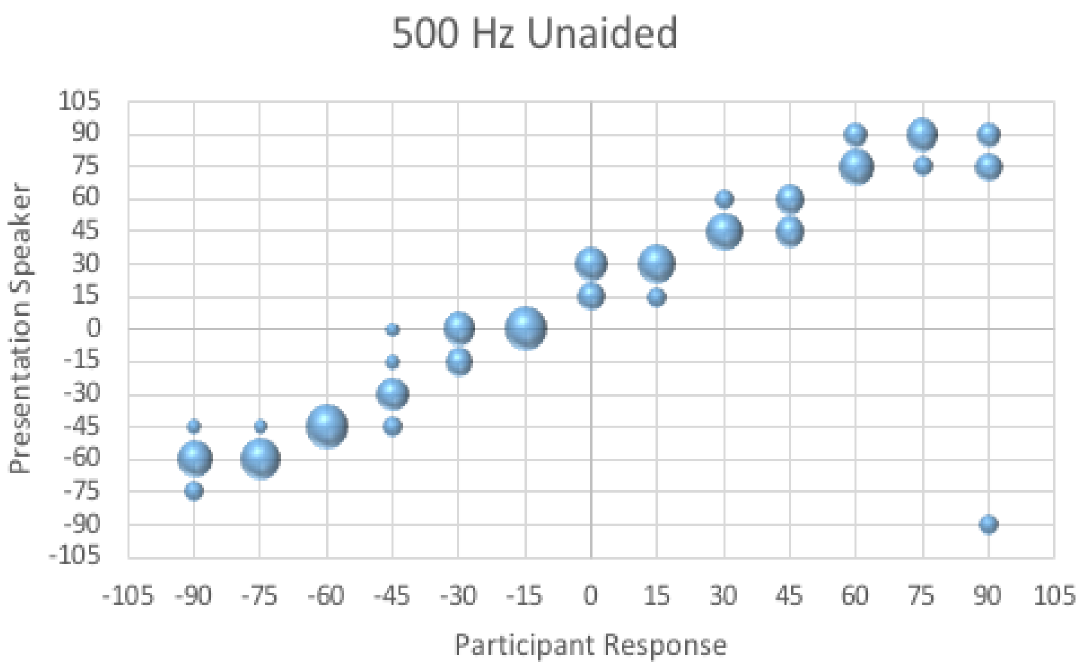

Figure 21. Participant 107's localization responses for a 500 Hz stimulus at each speaker in an unaided condition.

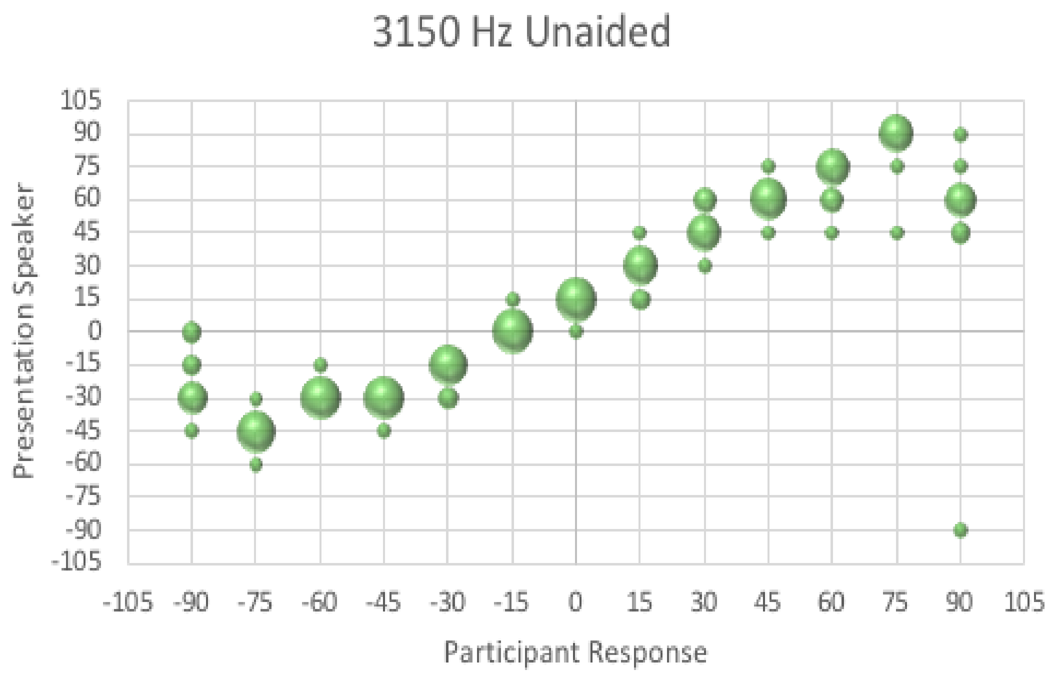

Figure 22. Participant 107's localization responses for a 3150 Hz stimulus at each speaker in an unaided condition.

Participant performance for a 500 Hz stimulus in a PSAP hearing condition can be seen in Figure 23 below. Performance across speakers was relatively similar. When tested with a high frequency stimulus (3150 Hz) localization performance was more variable father away from 0°, toward -90° and 90°. Speaker specific results are depicted in Figure 24 below.

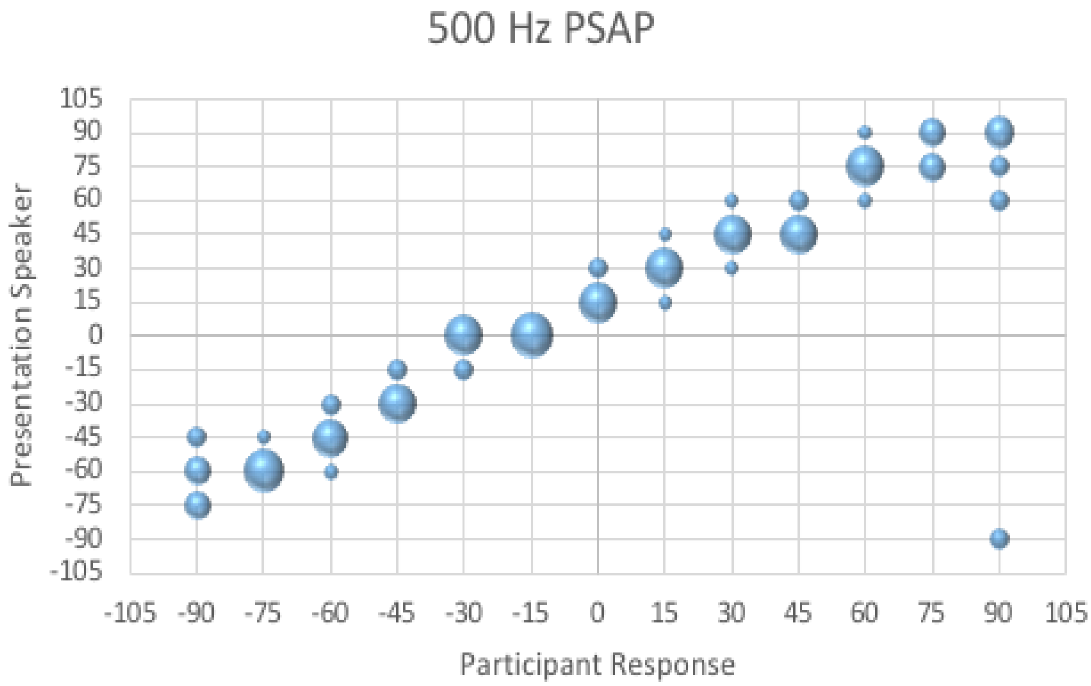

Figure 23. Participant 107's localization responses for a 500 Hz stimulus at each speaker in a PSAP condition.

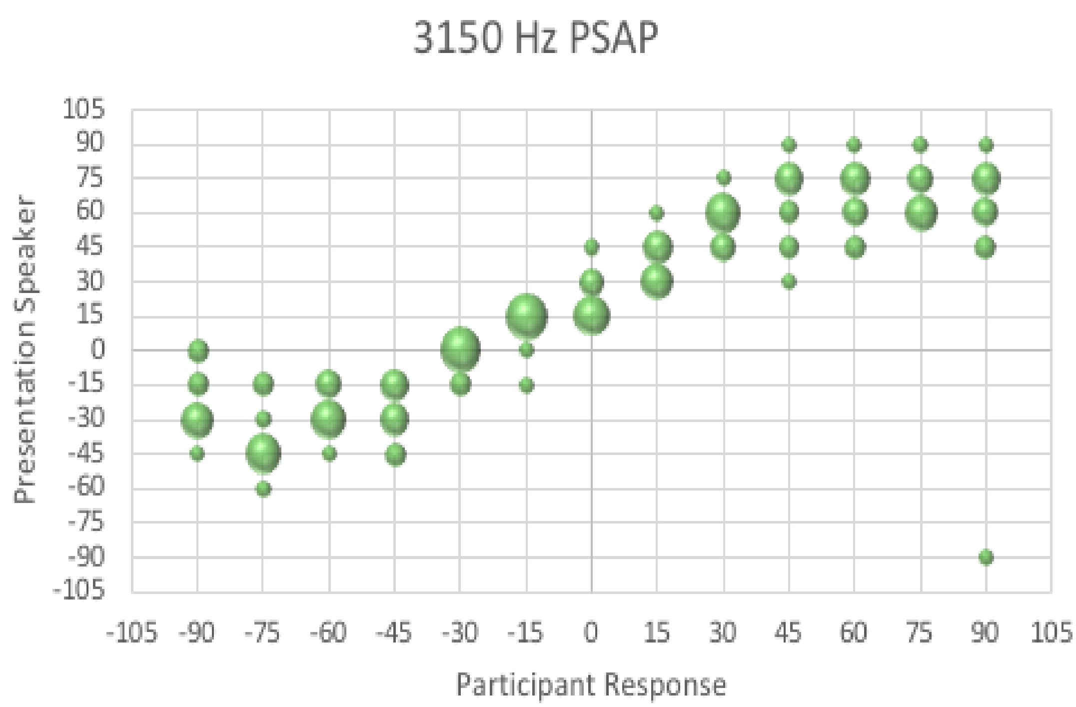

Figure 24. Participant 107's localization responses for a 3150 Hz stimulus at each speaker in a PSAP condition.

When tested with hearing aids in in the 500 Hz localization task, participant performance the responses were more variable for speakers oriented on the right side of the participant. Speaker specific results are depicted in Figure 25. When the localization task was performed with 3150 Hz, responses were variable for all speakers and can be seen in Figure 26 below.

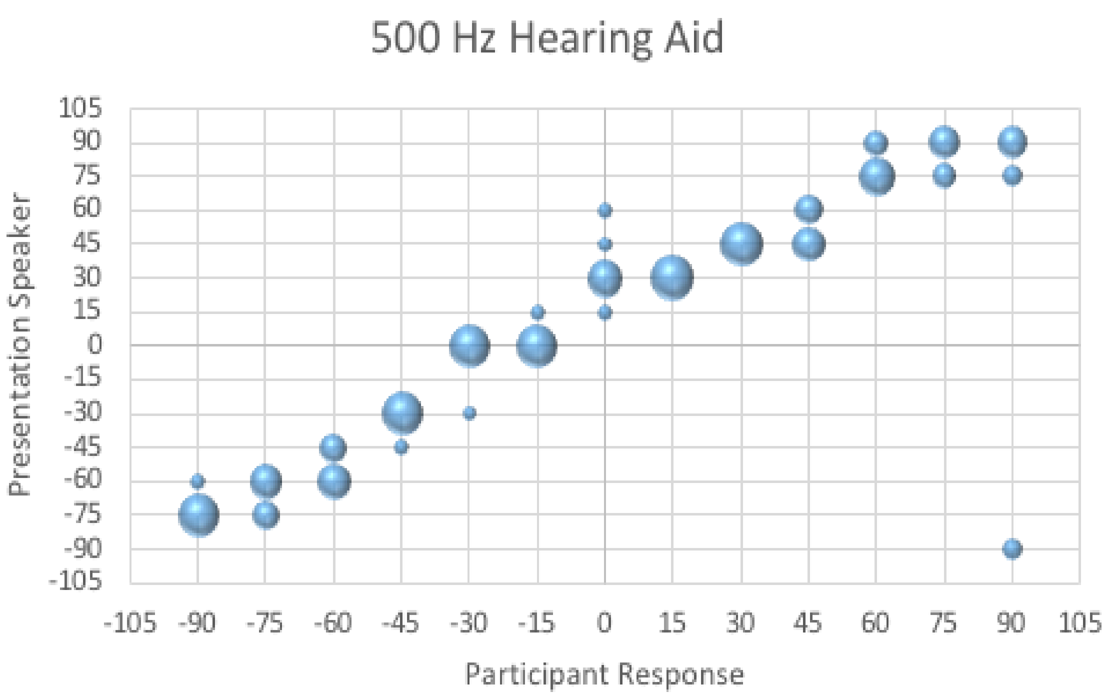

Figure 25. Participant 107's localization responses for a 500 Hz stimulus at each speaker in a traditional hearing aid condition.

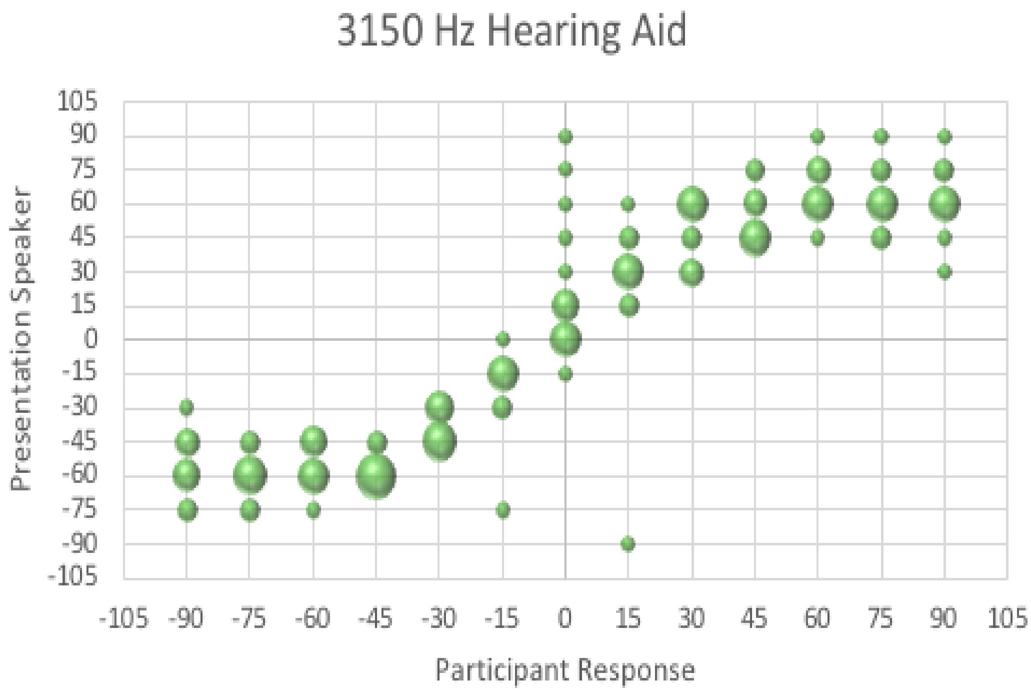

Figure 26. Participant 107's localization responses for a 3150 Hz stimulus at each speaker in a traditional hearing aid condition.

RMS errors from the localization task for both frequencies are depicted in table 13. Participant performance in localization tasks was better for the low frequency test condition across all hearing conditions compared to the high frequency stimulus. Localization performance for the high frequency stimulus was best in the unaided hearing condition compared to both the PSAP and the traditional hearing aid. Participant performance was similar across hearing conditions for the low frequency stimulus. Localization ability was also assessed by the percent of correct responses divided by the total 130 responses for each condition. The participant had a higher percentage of correct speaker identifications for 500 Hz compared to 3150 Hz. Localization accuracy was also better in the unaided condition compared to both aided conditions for both the high and low frequency stimulus conditions. Localization accuracy displayed in percent of correct responses for all test conditions is depicted in Table 14.

Table 13

Participant 107's RMS error for a low and high frequency stimulus in three listening conditions.

	Unaided	PSAP	Traditional Hearing Aid
500 Hz	10.69°	11.62°	11.01°
3150 Hz	17.45°	24.65°	23.39°

Table 14

Participant 107's localization accuracy in three listening conditions

	Unaided	PSAP	HA
500 Hz	63.08%	60.77%	59.23%
3150 Hz	54.62%	23.08%	23.85%

Participant 110

The third participant (participant 110) was a 67-year-old female with no reported hearing concerns. She reported that she feels that co-workers speak at a low volume. She reported occasional tinnitus that is more noticeable in the morning. She reported a family history of hearing loss and no previous history of amplification. She reported no other significant otologic history. Otoscopy revealed clear canals with tympanic membranes able to be visualized bilaterally. Tympanometry revealed type A tympanograms, indicating adequate middle ear function bilaterally. An audiometric evaluation revealed a moderate rising to mild sensorineural hearing loss in the right ear and a moderately-severe rising to a slight sensorineural hearing loss in the left ear. No air bone gaps were noted. The 3-frequency PTAs (500, 1000, 2000 Hz) were 45.0 dB HL in the right ear and 42.0 dB HL in the left ear. Frequency specific thresholds are displayed in Figure 27 below.

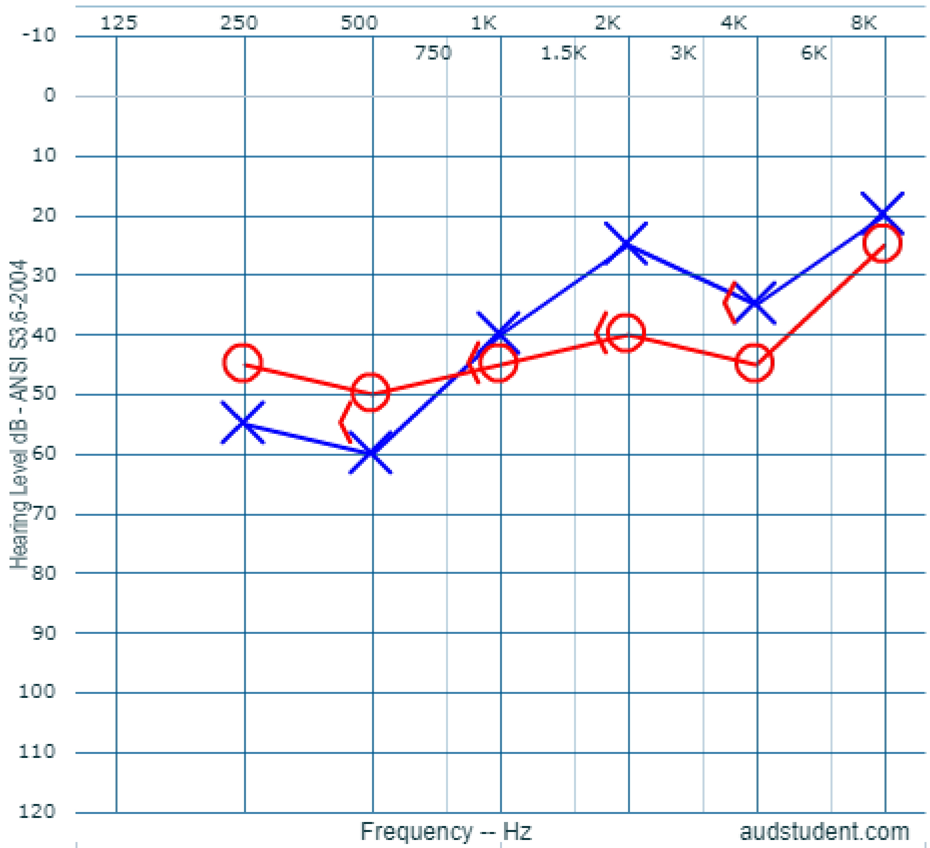

Figure 27. Air Conduction and Bone Conductions Thresholds Obtained for Participant 110

Electroacoustic Analysis Results

Measurements for average OSPL90, frequency range, equivalent input noise, and total harmonic distortion were compared to the manufacturers' specifications. The measurements obtained prior to testing and manufacturer's parameters are presented in Table 15. For a more detailed explanation of the electroacoustic analysis refer back to participant 105. Results from electroacoustic analysis indicate that the measurements from both the PSAP and traditional hearing aid were in relatively good agreement with the manufacturer's specifications for the four measurements (average OSPL90, frequency range, EIN, and THD). The measurements were in especially good agreement for the frequency range and THD for both devices. The measurements from the traditional hearing aid were found to be in good agreement with the manufacturer's EIN specifications, while the PSAP's EIN measurement was slightly higher than the specifications. Average OSPL 90 measurements obtained before the test session for participant 110 were slightly lower than the manufacturer's specifications for both devices.

Table 15

Electroacoustic Analysis Measurements and Manufacturers' Specifications for the PSAP and Hearing Aid

Device		Average OSPL90	Frequency Range	Equivalent Input Noise	Total Harmonic Distortion
PSAP	Right	90 dB SPL	<2000-8000 Hz	35 dB SPL	0.67%
	Left	89 dB SPL	<2000-8000 Hz	36 dB SPL	0.33%
Manufacturer's Specifications		124 dB SPL	100-7500 Hz	26 dB SPL	1.43%
HA	Right	97 dB SPL	420-5600 Hz	27 dB SPL	1%
	Left	93 dB SPL	300-5600 Hz	31 dB SPL	1.3%
Manufacturer's Specifications		119 dB SPL	100-7500 Hz	25 dB SPL	<2%

Note. Average total harmonic distortion = average percent distortion at 500, 800, and 1600 Hz.

Real-Ear Measurement Results

Real-ear aided measures obtained to an average speech signal (65 dB SPL) were recorded after the audiologist adjusted the amplification to meet the NAL-NL2 targets. Table 16, indicates how well each device (PSAP and traditional hearing aid) was able to meet NAL-NL2 targets at 500, 1000, 2000, and 4000 Hz ±5 dB.

The device fitting for participant 110 did not meet as many of the NAL-NL2 prescriptive targets compared to the fittings for the other participants. The amplification was adjusted to the general average of the long-term average speech spectrum while maximizing audibility and maintaining comfort for the participant simultaneously, as she reported the volume of the devices was uncomfortably loud when attempting to meet NAL targets. The PSAP was only able to meet the prescriptive target at 2000 Hz while undershooting the prescribed amplification at 500, 1000, and 4000 Hz for both the right and left devices. The traditional hearing aid was only able to meet the target for 2000 Hz in the right ear while undershooting the prescribed amplification at 500, 1000, and 4000 Hz. The left hearing aid was able to meet the target at 1000 and 2000 Hz while undershooting prescribed amplification at 500 and 4000 Hz.

Table 16

NAL-NL2 Targets Met for Each Device After Audiologist Programming for Participant 110

Device		500 Hz	1000 Hz	2000 Hz	4000 Hz	Total Targets Met (%)
PSAP	Right Ear	no	no	yes	no	1/4 (25%)
	Left Ear	no	no	yes	no	1/4 (25%)
Traditional Hearing Aid	Right Ear	no	no	yes	no	1/4 (25%)
	Left Ear	no	yes	yes	no	2/4 (50%)

Note. NAL-NL2 targets were said to be met if the gain fell within ± 5 dB of the target for frequencies 500, 1000, 2000, and 4000 Hz. Yes = met within ± 5 dB and No = not within ± 5 dB

AzBio Speech-In-Noise Test Results

Results of the AzBio sentence testing for participant 110 are depicted in table 17 below. Participant 110 performed similarly on all three test conditions indicating essentially no difference in performance between the three test conditions.

Table 17

Participant 110's AzBio Sentence Test Scores for the Three Device Conditions

	Unaided	PSAP	Traditional Hearing Aid
Percent Correct	96.9%	94.9%	96.1%

Speech Identification Results

Table 18 depicts the CRM thresholds and SRM for each condition. Participant performance was improved in all spatially separated conditions compared to the co-located conditions. Participant 110 had the lowest thresholds in the unaided condition rather than an amplified condition, however the PSAP condition had the highest SRM.

Table 18

Identification Thresholds(dB) and SRM (dB) for All 3 Hearing Conditions for Participant 110

	Unaided	PSAP	Traditional Hearing Aid
Spatially Separated	0.7	1.0	4.4
Co-Located	2.3	6.3	5.3
SRM	1	5.3	-0.74

Note: SRM = spatial release from masking

Localization Results

In an unaided condition localization results for a low frequency stimulus can be seen in Figure 28 below. When localization ability was assessed with a low frequency stimulus performance was more variable in the speakers to the right of the participant. High frequency localization testing with a 3150 Hz stimulus revealed similar localization performance across speakers in an unaided condition. Participant performance was more variable in the two conditions further to the right at 75° and 90°. High frequency localization results in an unaided condition are depicted in Figure 29 below.

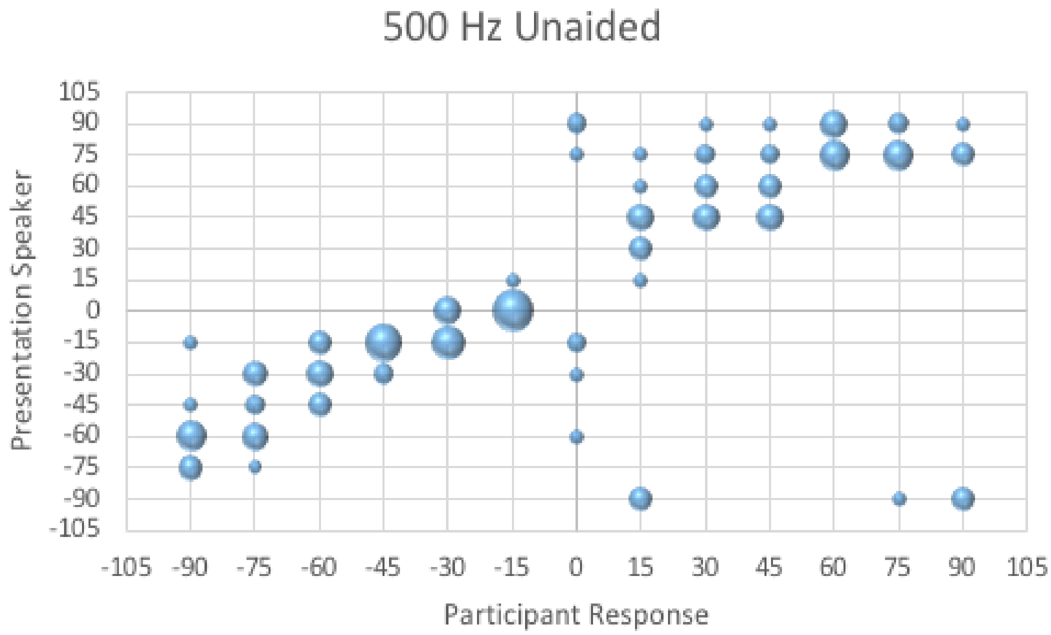

Figure 28. Participant 110's localization responses for a 500 Hz stimulus at each speaker in an unaided condition.

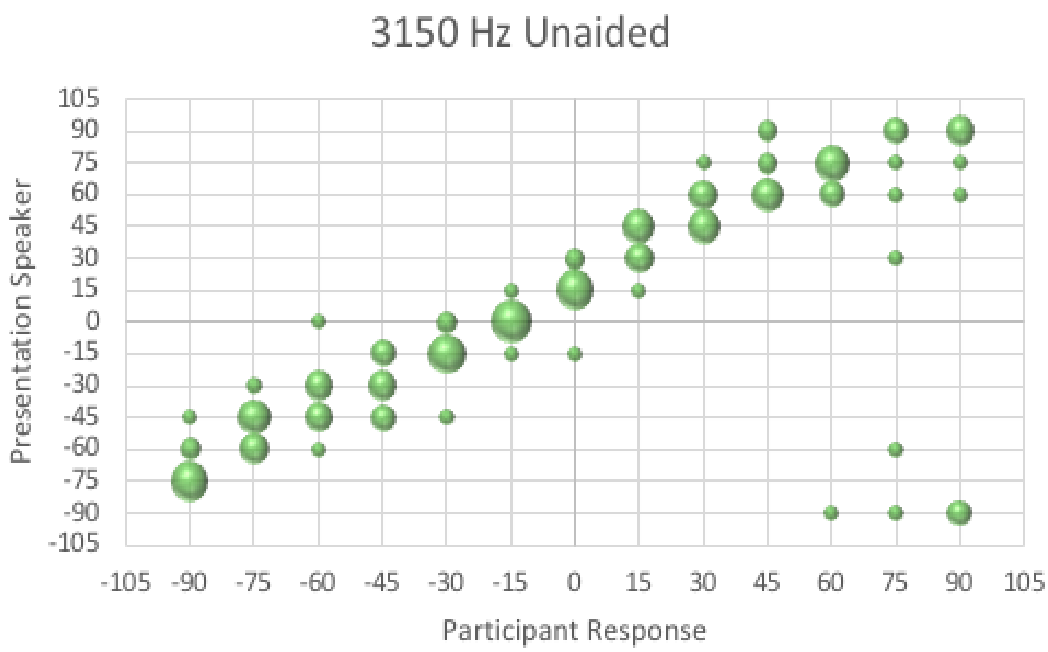

Figure 29. Participant 110's localization responses for a 3150 Hz stimulus at each speaker in an unaided condition.

Participant performance in a low frequency PSAP condition was more variable closer to speaker -90° and speaker 90° responses closer to 0° azimuth were more consistent. Results of speaker specific data can be seen in Figure 30. Localization results with a high frequency stimulus while wearing a PSAP was variable across all speakers and can be seen in Figure 31 below.

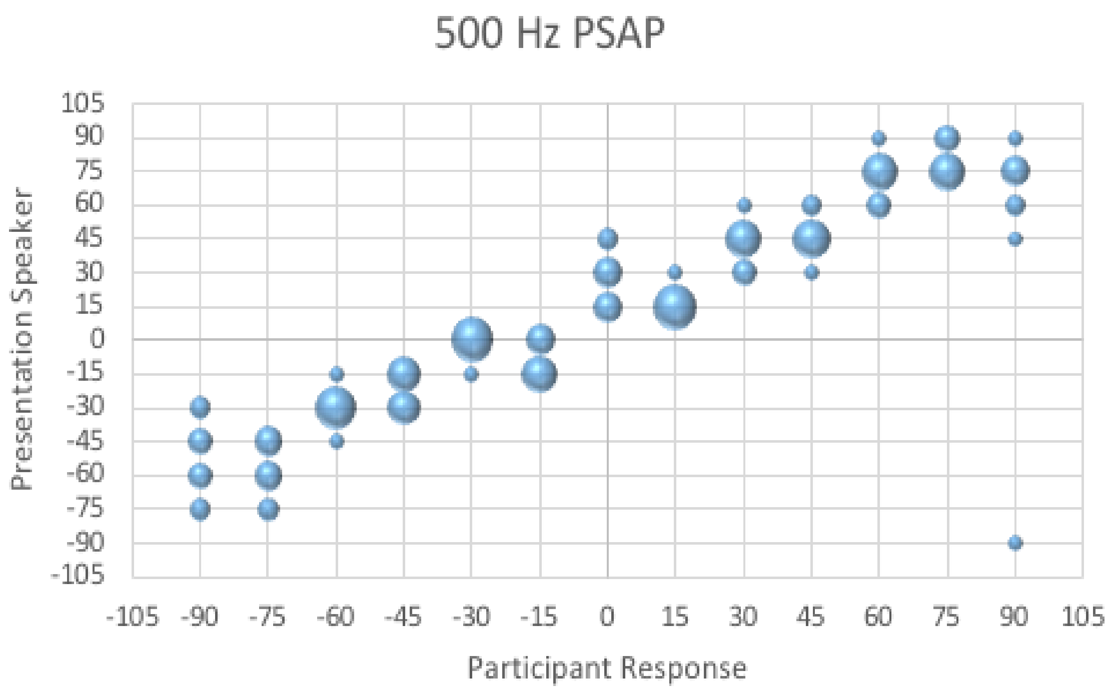

Figure 30. Participant 110's localization responses for a 500 Hz stimulus at each speaker in a PSAP condition.

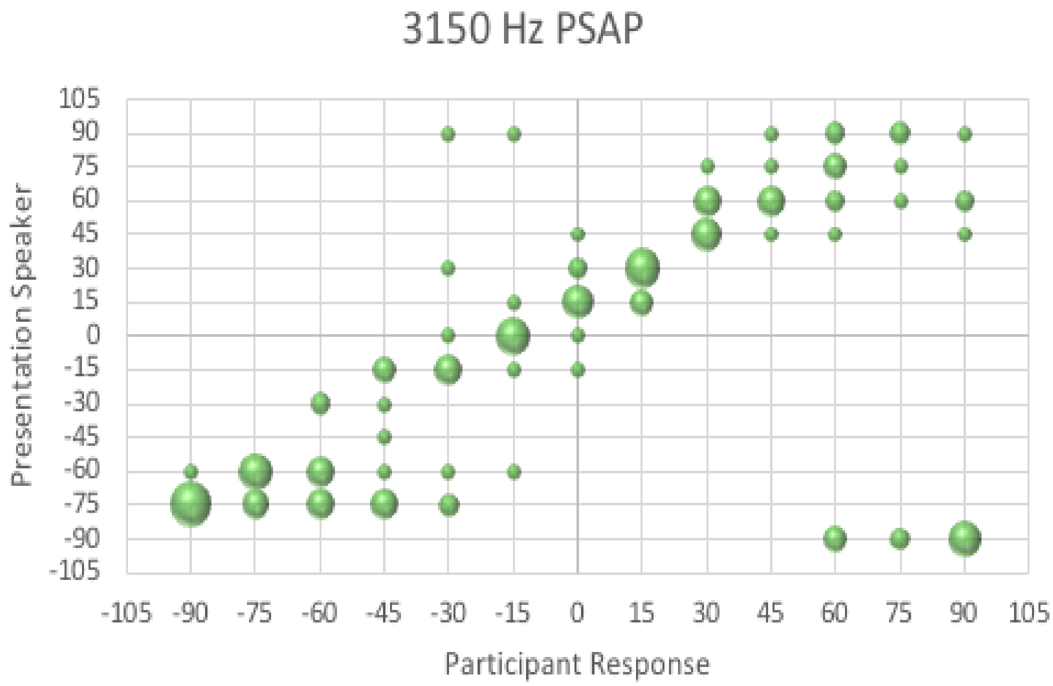

Figure 31. Participant 110's localization responses for a 3150 Hz stimulus at each speaker in a PSAP condition.

In the third condition using hearing aids, the participant's performance was more variable for speakers oriented to the right of the participant when tested with a low frequency stimulus, speaker specific results can be seen in Figure 32 below. Localization ability for high frequency stimulus revealed significantly variable results for speakers oriented toward the right side of the participant when wearing a pair of hearing aids. Results from a high frequency localization testing utilizing a pair of traditional hearing aids can be seen in Figure 33 below.

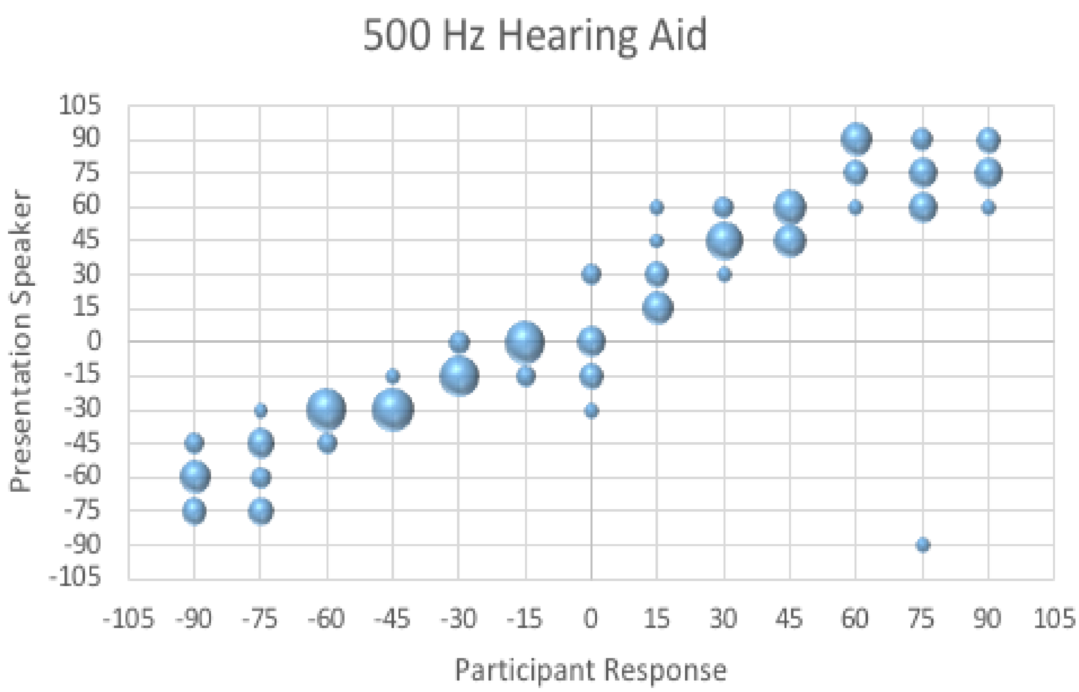

Figure 32. Participant 110's localization responses for a 500 Hz stimulus at each speaker in a traditional hearing aid condition.

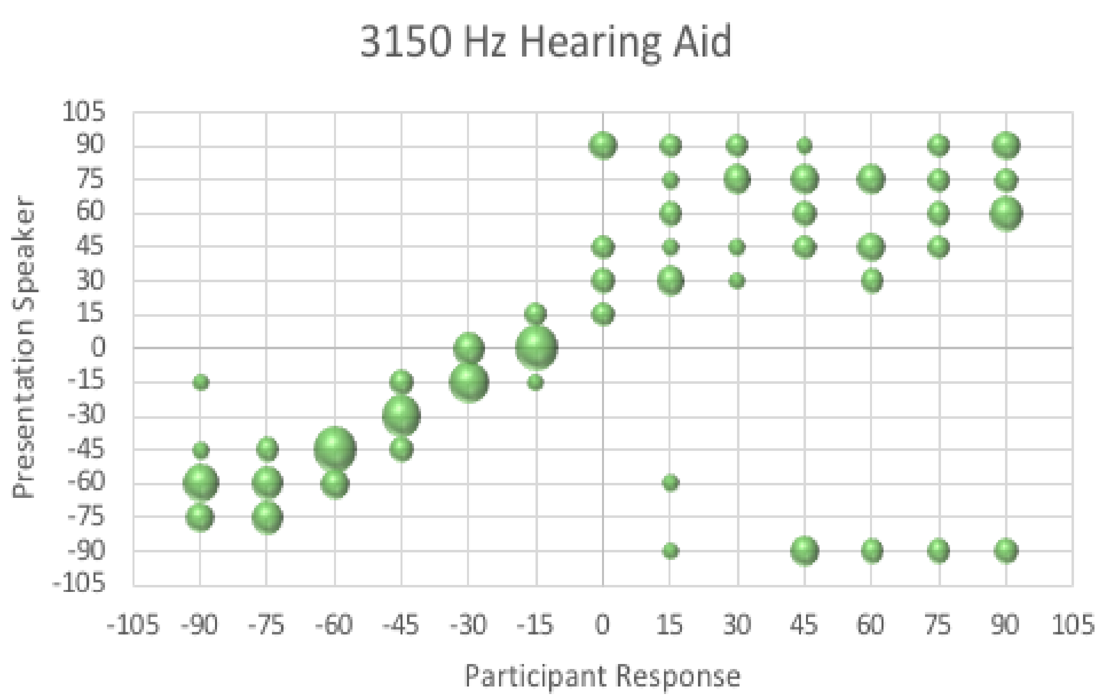

Figure 33. Participant 110's localization responses for a 3150 Hz stimulus at each speaker in a traditional hearing aid condition.

RMS errors for the localization task for both frequencies are displayed in table 19. Participant performance for the low frequency stimulus was best when participant 110 was utilizing the PSAPs compared to the unaided and traditional hearing aid conditions. Performance for the high frequency stimulus was similar in the unaided and traditional hearing aid hearing conditions. RMS error increased in the PSAP condition for the high frequency stimulus. Localization accuracy was found to be better in the high frequency stimulus condition compared to the low frequency stimulus. The participant identified the correct speaker more accurately in in the hearing aid condition for the 500 Hz stimulus. In the 3150 Hz stimulus the participant identified the correct speaker more accurately in the unaided condition. Localization accuracy depicted in a percent correct score is displayed in table 20.

Table 19

Participant 110's RMS error for a low and high frequency stimulus in three listening conditions

	Unaided	PSAP	Traditional Hearing Aid
500 Hz	25.03°	17.01°	25.31°
3150 Hz	19.95°	31.22°	19.34°

Table 20

Participant 110's localization accuracy in three listening conditions

	Unaided	PSAP	HA
500 Hz	38.46%	31.54%	41.54%
3150 Hz	52.31%	44.62%	36.15%

Average AzBio Speech-In-Noise Test Results by Device

AzBio sentence test scores with all three hearing conditions have been discussed for individual participants. For a detailed explanation of AzBio sentence testing refer back to the description of the sentence testing depicted for participant 105. Table 21 depicts the average percent correct scores for each hearing condition. Performance across hearing conditions was relatively similar indicating that there was no difference between the unaided and aided conditions regardless of device worn during testing. The unaided percent correct score was so high that ceiling effects may have prevented a difference between hearing condition.

Table 21

Average AzBio sentence test scores by device condition

	Unaided	PSAP	Traditional Hearing Aid
Percent Correct	96.5% (0.83)	94.9% (4.4)	96.1% (4.0)

Note. Parenthesis indicate standard deviation

Speech Identification Results by Device

Identification thresholds as well as spatial release from masking results from all three hearing conditions have been discussed for individual participants. On average participants performed better in the hearing aid condition. Table 22 depicts the average speech identification thresholds and SRM for each hearing condition across the three participants.

Table 22

Average speech identification thresholds and SRM by device

	Unaided	PSAP	Traditional HA
Spatially Separated	0.1 (4.83)	0.07 (2.72)	-1.8 (5.55)
Co-Located	5.2 (2.70)	5.9 (1.91)	5.9 (3.08)
SRM	5.1	5.83	7.7

Note. Parenthesis indicate standard deviation

Average Localization Results by Device

Localization performance in all three hearing conditions have been discussed for individual participants. On average the participants had higher RMS error in the traditional hearing aid and unaided conditions for the 500 Hz stimulus and higher RMS error in the PSAP condition for the 3150 Hz stimulus. Table 23 depicts the average RMS error by hearing condition. Average localization accuracy by device is depicted in table 24. On average the participants were able to identify the correct speaker more accurately in the unaided condition for both the 500 Hz and 3150 Hz stimulus.

Table 23

Average RMS error by device

		Unaided	PSAP	Traditional Hearing Aid
Participant 105	500 Hz	12.55°	13.61°	14.23°
	3150 Hz	22.90°	20.59°	16.23°
Participant 107	500 Hz	10.69°	11.62°	11.01°
	3150 Hz	17.45°	24.65°	23.39°
Participant 110	500 Hz	25.03°	17.01°	25.31°
	3150 Hz	19.95°	31.22°	19.34°
Mean	**500 Hz**	**16.09**° (7.80)	**14.08**° (14.08)	**16.85**° (16.85)
	3150 Hz	**20.01**° (2.73)	**25.49**° (5.36)	**22.96**° (3.59)

Note. Parenthesis indicate standard deviation

Table 24

Average localization accuracy by device

	Unaided	PSAP	HA
500 Hz	52.82%	49.05%	53.33%
3150 Hz	46.67%	33.41%	26.41%

CHAPTER 5

DISCUSSION

The first aim of this pilot study was to examine the differences between the participant's performance in a localization task in an unaided versus an aided PSAP (Sidekick) and traditional hearing aid (Oticon Nera miniRITE) condition. The second aim of this study was to examine the differences between participant performance in a speech-in-noise task and a speech identification task in an unaided, PSAP, and traditional hearing aid condition. This section will include a discussion of the data obtained from electroacoustic analyses, AzBio sentence testing in an unaided as well as two aided conditions (PSAP and traditional hearing aid), and real-ear measurements. We will also examine spatial release from masking ability and localization ability in an unaided condition and two aided conditions (PSAP and traditional hearing aid). This section will conclude with a discussion of the limitations, future directions, and possible clinical implications resulting from the findings of this current study.

Electroacoustic analysis

Electroacoustic analysis was performed on both the PSAP and the traditional hearing aid prior to each test session. Four main acoustic measures were examined including average OSPL90, frequency response, equivalent input noise, and total harmonic distortion. Both the PSAP and the traditional hearing aid had frequency responses and total harmonic distortion similar to the manufacturer's specifications. However, overall the average OSPL90 values were slightly below specifications and equivalent input noise levels were slightly above the manufacturer specifications for both the PSAP and traditional hearing aid. The PSAP device had average OPSL90 values ranging from 83-94 dB SPL compared to the manufacturer's specifications of 124 dB SPL. The traditional hearing aid had OSPL values ranging from 91-97 dB SPL compared to the manufacturer's specifications of 119 dB SPL. Overall, EIN values for both the PSAP and traditional hearing aid were 4-10 dB SPL above the acceptable EIN values determined by manufacturer's specifications.

Currently there are few published studies that have studied the electroacoustic analysis results of PSAP devices. Studies have found that PSAP devices have had narrow frequency ranges, high total harmonic distortion, and high equivalent input noise levels (Callaway & Punch, 2008; Cheng & McPherson, 2000). This study uses an advanced PSAP, the sidekick, as determined in preliminary studies by Polyak (2016) and Oliver (2017) therefore a direct comparison to previous published studies cannot be made.

Polyak (2016) examined the same electroacoustic measurements discussed in this study. The advanced PSAP devices examined in this study (Soundhawk, CS50, and Bean) had frequency ranges and total harmonic distortion levels that were comparable to the traditional hearing aid included in the study; however, she found that all PSAP devices had high EIN in comparison to the traditional hearing aid. In addition, a follow-up study to Polyak (2016) was conducted by Oliver (2017) found electroacoustic analysis results obtained from the two PSAPs used in the study (Soundhawk and CS50+) were compared to manufacturer's specifications in three fitting conditions. This study found that the two PSAP devices met manufacturer specifications relatively well, although with high EIN values for both devices. Overall, the results of these recent studies are in good agreement with the findings of this study, suggesting that PSAPs have similar electroacoustic analysis measurements when compared to a traditional hearing aid or manufacturer specifications.

Real-Ear Measurement

This study examined how well the PSAP was able to meet NAL-NL2 targets in a gold-standard fitting protocol condition in comparison to targets met by a traditional hearing aid using the same protocol. The PSAP and traditional hearing aid were examined by how well the devices were able to meet prescribed targets at 500, 1000, 2000, and 4000 Hz within ±5 dB. The PSAP and traditional hearing aid were found to meet the NAL-NL2 targets relatively well prior to each test session, typically meeting 3 out of 4 of the targets. The most common missed targets were an overshoot of a low frequency target for the PSAP or an undershoot at a high frequency target for both devices. This suggests that in an audiologist gold-standard fitting protocol the PSAP and traditional hearing aid were able to match prescriptive targets with similar accuracy.

Polyak (2016) found that the traditional hearing aid was able to meet the greatest number of prescriptive targets within ±5 dB when compared to the PSAP devices. The advanced PSAP devices Soundhawk and CS 50 met 67% and 64% of NAL targets respectively. In addition, Oliver (2017) found that a gold standard fitting protocol was found to be the most accurate method to meet NAL targets in two advanced PSAPs within ±5 dB resulting in 64-69%% of NAL targets met. Polyak (2016) and Oliver (2017) found that PSAP devices were most likely to meet the targets at low frequencies and either undershoot or overshoot the target at higher frequencies. These results found in Polyak (2016) and Oliver (2017) are similar to the results of this current study indicating that an advanced PSAP is capable of meeting prescribed NAL-NL2 targets similar to a hearing aid when fit in a gold standard fitting protocol.

Overall, the results of real-ear measurements obtained in this study are similar to the results of previous research. This suggests that advanced PSAP devices have the ability to meet NAL prescriptive targets similar to a traditional hearing aid when an audiologist programs the devices in the gold-standard fitting condition.

AzBio Speech-In-Noise Test

The AzBio sentence test was administered to all participants in an unaided condition as well as an aided PSAP and aided traditional hearing aid condition after the devices were fit using the gold standard fitting protocol from Oliver (2017). The results were examined to 1) determine if the subject's performance differed in the unaided condition compared to the two device conditions and 2) determine if there were any differences in subject performance between device conditions.

In this study there were essentially no differences between the unaided and either device condition. In previous studies we have seen improved participant performance when in an aided condition for both PSAP and traditional hearing aid devices. The unaided scores in this study were so high that improvement was not able to be shown in either aided condition as compared to the unaided AzBio speech-in-noise test.

Polyak (2016) compared the aided and unaided performance on the AzBio sentence test for five PSAPs and one traditional hearing aid. AzBio performance improved in the aided versus unaided condition. The performance with the advanced

PSAP devices included in the study were similar to the participant's performance with the traditional hearing aid.

A follow-up study by Reed et al. (2017) examined participant performance of hearing impaired individuals fit with five different PSAPs including the 3 advanced devices from Polyak's (2016) study (Soundhawk, CS 50+, and the Bean) and one traditional hearing aid. Participant performance improved in the aided versus unaided condition with each of the advanced PSAPs and the traditional hearing aid.

Oliver (2017) examined AzBio test performance and found the most improvement in performance in the gold standard fitting protocol. The results from Oliver (2017) suggest that the audiologist's fine tuning of PSAPs results in improved speech-in noise performance. The sentence and noise were separated by 45° in Oliver's (2017) study and by 180° in the current pilot study. The location difference for the sentence and noise may have been a factor in participant performance between the current study and previous studies (Oliver, 2017; Polyak, 2016).

Coordinate Response Measure

The coordinate response measure test was administered to all three participants in an unaided condition as well as an aided PSAP and aided traditional hearing aid condition after the devices were fit using the gold standard fitting protocol from Oliver (2017). The results were examined to 1) determine if subject performance differed in the spatially separated compared to the co-located condition, 2) determine if the subject's performance differed in the unaided condition compared to the two device conditions, and 3) determine if there were any differences in subject performance between device conditions.

In this study participants generally performed better in the spatially separated conditions compared to the co-located conditions for all hearing conditions. This is consistent with previous spatial release from masking research (Srinivasan et al., 2016). Participant 105 had the highest SRM in the unaided condition; however, SRM scores in all hearing conditions were comparable to SRM scores of a young adult. Participant 107 demonstrated the best SRM in the traditional hearing aid condition. Participant 110 performed the best in the aided PSAP condition. While on average spatially separated conditions yielded better SRM scores compared to the co-located conditions, the hearing aid condition had a greater release from masking in dB compared to the unaided condition. As the data for this study was obtained from a small sample no conclusions were able to be drawn.

Localization

Localization ability was assessed in an unaided condition as well as an aided PSAP and aided traditional hearing aid condition after the devices were fit using the gold standard fitting protocol from Oliver (2017). The low frequency noise burst was used to evaluate the ability to use ITD cues and the high frequency noise burst was used to evaluate the ability to use ILD cues.

Two out of the three participants had a smaller root mean square error for the low frequency stimulus, consistent with findings from Van den Bogaert et al. (2006). Both of these participants had a sloping hearing loss with greater hearing loss in the higher frequencies. The third participant had similar root mean square errors for both frequencies. This result may be due to greater hearing loss in the low frequencies than the higher frequencies for this participant.

In this study localization accuracy was generally best in the unaided hearing condition compared to the two aided conditions. This result is consistent with finding from Van de Bogaert et al. (2006) who found that localization ability was better without hearing aids indicating that binaural localization cues were not preserved with hearing aids. All three participants were able to identify the correct speaker in an unaided condition more accurately for the 3150 Hz noise burst stimulus. Participants 105 and 110 were able to localize the 500 Hz noise burst more accurately in the hearing aid condition. Participant 107 localized the 500 Hz noise burst more accurately in the unaided hearing condition. On average participants were able to localize more accurately in the hearing aid condition for the 500 Hz noise burst and in the unaided condition for the 3150 Hz noise burst.

Van den Bogaert et al. (2006) found that hearing impaired subjects can still use binaural cues but current state of the art hearing aids and noise reduction algorithms can degrade localization performance in a hearing-impaired subject. In this study there were no large differences between the hearing conditions indicating that amplification of either the PSAP or traditional hearing aid did not improve or hinder localization performance. However, the sample size in this study was small and may have had an impact on the conclusions that can be drawn.

Limitations

There are several limitations in this current study. One limitation of this study is the small data set (*n*=3) which limits the conclusions that can be drawn from the data collected. The three participants' data was examined individually, only minimal descriptive statistics were able to be calculated. A larger data set would be needed to further examine the performance of PSAPs in simulated difficult listening environments and localization ability in individuals with mild to moderate sensorineural hearing loss.

Another limitation in this study was the use of the AzBio sentence test for the sample population in this study, as it may not be the most appropriate speech test for the population. AzBio was originally developed to evaluate speech recognition abilities pre and post cochlear implantation. Candidacy for a cochlear implant often includes severe to profound sensorineural hearing loss at all frequencies resulting in poor frequency resolution and poor word recognition ability. The participants in this study only had mild to moderate sensorineural hearing loss and therefore expected to have relatively good frequency resolution and word recognition ability. Participants in this study obtained such high AzBio percent correct scores that we were not able to demonstrate an improvement in either aided condition due to the ceiling effect. A more difficult speech task may be more appropriate to use in a future study.

Future Research

Based on the limitations of the current study future recommendations can be suggested. The current pilot study used a small data set making it difficult to see trends or draw conclusions based on the results obtained in the study. Future studies should examine a larger number of participants to see trends in aided speech-in-noise results, spatial release from masking testing, and localization tasks when wearing advanced PSAP devices compared to performance with a traditional hearing aid.

The small data set used in this study made inter-subject performance comparison difficult. A larger set would include more study participants but would also include more varied degrees of hearing loss. With a larger data set and more varied configurations of hearing loss we would be able to examine more subtle differences in test performance.

APPENDIX A

Informed Consent Form

The Towson University Audiology Department is conducting a research study to examine the potential benefits of personal sound amplification products (PSAPs) that can be purchased online or over-the-counter by individuals with hearing loss. PSAPs are less expensive than traditional hearing aids and may be beneficial for individuals with mild to moderate hearing loss. However, currently there is little empirical research regarding the actual benefit of these devices for adults with hearing impairment.

Upon participation in the study, you will attend two 2-hour test sessions at the Towson University Department of Audiology in Van Bokkelen Hall that will begin with questions regarding your hearing and a hearing test. During the remainder of the test session, we will ask you to wear a high end PSAP and a traditional hearing aid as we obtain real-ear measures, perform speech-in-noise testing, and localization tasks. Real-ear measurement is a standard audiologic procedure in which a small flexible probe tube is placed in your ear to measure sound. During the speech-in-noise test you will be asked to repeat sentences that are played from an audio recording with background noise. During the localization tasks the participant will be asked to identify which speaker a noise signal is coming from.

Participation in this study is voluntary. Participants will be compensated $30.00 for each test session in the form of a gift card. Any questions that you may have may be asked freely at any time and will be answered to the best of my ability. If you wish to withdraw at any time prior to or during the study, you may do so without consequence. All data collected in the study will be kept confidential. If any data collected in this study is presented at a future conference or is published, your identity will remain confidential.

If you have any questions at any time feel free to contact myself, Tiffany Connatser, at tconna1@students.towson.edu or 703-608-6006; Dr. Srinivasan (faculty sponsor) at nsrinivasan@towson.edu or 410-704-3920; or Dr. Elizabeth Katz, Chairperson of the Institutional Review Board for the Protection of Human Participants at Towson University at irb@towson.edu or 410-704-2236.

I, ________________________________, affirm that I have read and

understood the above statement and have had all of my questions answered.

Signature: ________________________________Date: ____________________

Witness: ________________________________ Date: ____________________

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW

BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY. **If investigator is not the person who will witness participant's signature, then the person administering the informed consent should write his/her name and title on the "witness" line.

APPENDIX B

IRB Approval

TOWSON UNIVERSITY

Office of Sponsored
Programs and Research

Towson University
8000 York Road
Towson, MD 21252-0001

t. 410 704-2236
f. 410 704-4494

APPROVAL NUMBER 1712026830

MEMORANDUM

TO: Tiffany Connatser

FROM: Institutional Review Board for the Protection of Human Participants, Elizabeth Katz, Chair

DATE: December 14th, 2017

RE: Approval of Research Involving the Use of Human Participants

Thank you for submitting an Application for Approval of Research Involving the Use of Human Participants to the Institutional Review Board for the Protection of Human Participants (IRB) at Towson University. The IRB hereby approves your proposal titled:

Objective comparative analysis of localization performance using a personal sound amplification product (PSAP) and a traditional hearing aid

Please note that this approval is granted on the condition that you provide the IRB with the following information and/or documentation:

N/A

If you should encounter any new risks, reactions, or injuries while conducting your research, please notify the IRB. Should your research extend beyond one year in duration, or should there be substantive changes in your research protocol, you will need to submit another application for approval at that time.

We wish you every success in your research project. If you have any questions, please call me at (410) 704-2236.

cc: Nirmal Srinivasan

Date: December 14th, 2017

Office of Sponsored
Programs and Research

Towson University
8000 York Road
Towson, MD 21252-0001

t. 410 704-2236
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NOTICE OF APPROVAL

TO: Tiffany Connatser ***DEPT:*** Audiology

PROJECT TITLE: ***Objective comparative analysis of localization performance using a personal sound amplification product (PSAP) and a traditional hearing aid***

SPONSORING AGENCY: Graduate Student Association

APPROVAL NUMBER: 1712026830

The Institutional Review Board for the Protection of Human Participants has approved the project described above. Approval was based on the descriptive material and procedures you submitted for review. Should any changes be made in your procedures, or if you should encounter any new risks, reactions, injuries, or deaths of persons as participants, you should notify the Board.

A consent form ☑ is required of each participant
☐ is not

Assent ☐ is required of each participant
☑ is not

This protocol was first approved on 12/14/2017.
This research will be reviewed ***every year*** from the date of first approval.

Elizabeth Katz, Chair
Towson University Institutional Review Board, IRB

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CURRICULUM VITA

Tiffany Connatser, B.A.
[redacted]

Education:

Doctor of Audiology, Towson University	May 2019
Towson, MD	
Bachelor of Arts, Temple University	
Major: Communication Sciences and Disorders	May 2015
Minor: Psychology	
Philadelphia, PA	

Clinical Experience:

Chesapeake Hearing Center	Spring 2018
Nemours/ Alfred I. DuPont Hospital for Children	Fall 2017
Chesapeake Ear Nose and Throat	Summer 2017
ENTAA Care	Spring 2017
Towson University Hearing and Balance Center	Spring 2016 – Fall 2016

Related Experience:

Starkey University Workshop	July 2016
Hearing Conservation Program	Spring 2016
Special Olympics	Spring 2017

Professional Affiliations:

National Student Academy of Audiology	2015 – Present
Local Chapter of Student Academy of Audiology	
Member	2015 - Present
Executive Board Member	2016 – 2017
Vice President of Fundraising and Philanthropy	