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OBJECTIVE COMPARATIVE ANALYSIS OF SELF-FIT PERSONAL SOUND AMPLIFICATION PRODUCTS (PSAPs) USING THREE TYPES OF FITTING PROTOCOLS: OUT-OF-THE-BOX SELF-FIT, ADVANCED-USER SELF-FIT, AND AUDIOLOGIST FIT

By:

Antoinette Oliver

A Thesis

Presented to the faculty of

Towson University

in partial fulfillment

of the requirements for the degree

Doctor of Audiology

Department of Audiology, Speech-Language Pathology, and Deaf Studies

Towson University
Towson, Maryland 21252

May 2017

TOWSON UNIVERSITY
OFFICE OF GRADUATE STUDIES

THESIS APPROVAL PAGE

This is to certify that the thesis prepared by Antoinette Oliver, B.S. entitled "Objective Comparative Analysis of Self-Fit Personal Sound Amplification Products (PSAPs) Using Three Types of Fitting Protocols: Out-of-the-Box Self-Fit, Advanced-User Self-Fit, and Audiologist Fit" has been approved by the thesis committee as satisfactorily completing the thesis requirement for the degree of Doctor of Audiology.

Peggy Korczak — 4/28/17

Peggy Korczak, Ph.D.
Chairperson, Thesis Committee — Date

Nirmal Srinivasan — 04/28/2017

Nirmal Srinivasan, Ph.D.
Committee Member — Date

4/28/17

Frank Lin, M.D., Ph.D.
Committee Member — Date

Janet V DeLany — May 12, 2017

Janet DeLany
Dean of Graduate Studies — Date

ACKNOWLEDGMENTS

I would like to thank everyone who supported and guided me during the preparation of this thesis. First, I would like to thank the chair of my thesis committee, Dr. Peggy Korczak, for her patience and encouragement throughout this process. I could not have completed this thesis without her guidance or her exceptional ability to keep me on schedule. I would also like to thank my committee members, Dr. Nirmal Srinivasan and Dr. Frank Lin, for their advice and support during this process. I consider myself fortunate to have worked with you both and have truly benefitted from your knowledge and expertise in this area of research. I would also like to thank Dr. Nicholas Reed for his expertise, assistance, and recommendations, which were instrumental in planning and completing this study. Finally, I would like to thank my family for their support and encouragement during this process. I could not have done this without you all.

ABSTRACT

OBJECTIVE COMPARATIVE ANALYSIS OF SELF-FIT PERSONAL SOUND AMPLIFICATION PRODUCTS (PSAPs) USING THREE TYPES OF FITTING PROTOCOLS: OUT-OF-THE-BOX SELF-FIT, ADVANCED-USER SELF-FIT, AND AUDIOLOGIST FIT

Antoinette Oliver, B.S.

The purpose of this pilot study was to compare the objective benefit of two self-fit advanced PSAPs (Soundhawk and CS 50+) versus an audiologist fitting of these devices. Nine participants with slight to moderate sensorineural hearing loss were evaluated with both devices in each fitting condition. Electroacoustic analysis was performed for each PSAP device prior to each test session. Each participant was evaluated in the unaided and aided condition using the AzBio speech-in-noise test. Real-ear measurements were obtained and compared to NAL-NL2 targets using descriptive statistics and a 3-frequency root mean square (3-RMS) value for the NAL-NL2 targets met in each condition. Lastly, the relationship, if any, between the 3-RMS values and aided AzBio score improvement was explored.

The electroacoustic measures for both PSAP devices were in relatively good agreement with the manufacturers' specifications. The mean aided AzBio scores showed an improvement over the mean unaided scores in all test conditions for both PSAP devices. The greatest mean aided AzBio improvement occurred in the gold-standard fitting condition for both devices: Soundhawk (18%) and CS 50+ (15%).

During real-ear measurements, the highest total percentages of NAL targets were met in the gold-standard fitting condition for both devices: Soundhawk (64%) and CS

50+ (69%). The lowest mean 3-RMS values also occurred in the gold-standard fitting condition, reflecting the greatest accuracy in meeting NAL targets. In addition, the highest positive correlation between a low RMS value (i.e., good fit) and greater aided improvement in AzBio scores occurred in the gold-standard fitting protocol. However, this relationship did not reach statistical significance for either device.

Collectively, the results of the current pilot study are in good agreement with recent preliminary studies and suggest that advanced PSAPs have the ability to meet NAL prescribed targets and may offer improvement in speech-in-noise performance for individuals with slight to moderate sensorineural hearing impairments. This pilot study also suggests that the audiologists' fine-tuning of advanced PSAPs results in the greatest accuracy in meeting NAL prescribed targets and the greatest improvement in speech-in-noise performance.

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KEY TO ABBREVIATIONS

3MS: Modified Mini-Mental State

AGC: Automatic gain control

ANSI: American National Standards Institute

ASHA: American Speech, Language, and Hearing Association

BHMS: Blue Mountain Hearing Study

BKB-SIN: Bamford-Kowal-Bench Speech-in-Noise

BLSA: Baltimore Longitudinal Study of Aging

BTE: Behind-the-ear

CIC: Completely-in-the-canal

dB HL: Hearing loss in decibels

DSL v5: Desired Sensation Level version 5

DSP: Digital Signal Processing

DSS: Digit Symbol Substitution

EIN: Equivalent Input Noise

FDA: United States Food and Drug Administration

fMRI: Function Magnetic Resonance Imaging

FTC: Federal Trade Commission

HFA: High-frequency average

ITC: In-the-canal

ITE: In-the-ear

LTASS: Long-Term Average Speech Spectrum

MLD: Masking-level difference

NAL: National Acoustics Laboratory

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

NHANES: National Health and Nutritional Examination Survey

NIH: National Institute of Health

NU-6: Northwestern University Auditory Test number 6

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

POGO: Prescription of Gain and Output

PSAPs: Personal Sound Amplification Products

PTA: Pure tone average

QuickSIN: Quick Speech-in-noise

REMs: Real-ear measurements

REUR: Real-ear unaided response

RMS: Root Mean Square

SNR: Signal-to-noise ratio

SPL: Sound pressure level

THD: Total harmonic distortion

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

VBM: Voxel-Based Morphometry

WHO: World Health Organization

WIN: Words In Noise

CHAPTER 1

INTRODUCTION

Age-related hearing loss ranks fourth as the most common chronic health condition reported by individuals aged 65 years and older (Lin & Bhattacharyya, 2011). Hearing loss can affect many aspects of daily life including social relationships, socioeconomic status, and personal safety. For example, an individual with age-related hearing loss may become withdrawn as they encounter difficult communication situations. As a result of this state of isolation, an individual with hearing loss may suffer emotionally, cognitively, and physically (Lin et al., 2011c; Nachtegaal et al., 2009). Treatment, such as amplification with hearing aids, can help keep an individual with hearing loss involved in supportive social networks, which also helps preserve their cognitive functioning (Crooks et al., 2008).

Even a mild hearing loss can impact an individual's ability to communicate by filtering out important speech sounds (Krueger & Ferguson, 2002). These communication difficulties are worsened as the level of background noise increases (Nachtegaal et al., 2009). Despite the impact on their quality of life, many individuals with hearing loss do not wear hearing aids (Lin, 2012). Several factors may influence this disparity including lack of awareness regarding the impact of age-related hearing loss, inaccessibility to hearing health professionals, the cost of hearing aids and necessary follow-up appointments after fitting, and the stigma attached to wearing hearing aids (Chien & Lin, 2012; NIH, 2013).

Recently, the President's Council of Advisors on Science and Technology (PCAST) initiated an effort to address the increasing importance of hearing health as the population ages. The council stressed the need for more accessible and affordable treatment options, such as personal sound amplification products (PSAPs) (PCAST, 2015). Currently, PSAPs are intended for those individuals without hearing impairment who wish to amplify environmental sounds for recreational purposes and these devices are not currently approved for hearing loss treatment by the U.S. Food and Drug Administration (FDA) (Blum, 2016; FDA, 2013). However, PSAPs may be a more affordable treatment option for hearing loss since adults with hearing loss can purchase them on-line or over-the-counter from retail chains. These individuals can then self-fit the PSAPs by following the manufacturers' instructions, thereby eliminating several of the costly steps involved in purchasing a traditional hearing aid. Unfortunately, at present there is little empirical data regarding the use and benefit of PSAPs in hearing healthcare.

In the proposed study, we will compare the impaired subjects' performance with self-fitting of two advanced PSAPS versus an audiologist fitting of these devices. These devices will be fit using three different protocols: 1) the "out-of-the-box" self-fitting protocol, 2) the "advanced-user" self-fitting protocol, and 3) the "gold-standard" audiologist fitting protocol. Their performance will be measured using functional outcome measures consisting of real-ear measurements (REMs) and speech-in-noise testing via the AzBio Sentence test. We will also investigate whether an audiologist fine-tuning of the self-fitting protocols will result in improvement in these functional outcome measures.

In order to understand the substantial impact hearing loss may have on the aging population, this literature review will discuss a number of topics that are relevant to this issue. These topics include the classifications of hearing loss, the prevalence of hearing loss, factors affecting the prevalence of hearing aid usage, the consequences of untreated age-related hearing loss, types of amplification devices available for individuals with hearing loss, and methods of assessing the functional outcomes of wearing these devices.

CHAPTER 2

LITERATURE REVIEW

Classifications of Hearing Loss

Hearing loss is classified by several factors that influence the level of impact that hearing impairment has on an individual's ability to understand speech and communicate. One factor is the type of hearing loss, which governs whether the hearing loss is permanent or curable through medical or surgical treatment. Another factor is the degree, or severity, of the hearing impairment.

Type of hearing loss. Hearing loss is primarily categorized into three types: conductive, sensorineural, or mixed. Differentiation between these three types of hearing loss is based on the location of dysfunction within the auditory system. A conductive hearing loss occurs when there is dysfunction in the outer ear canal, eardrum, or middle ear space. It is often possible to resolve this type of hearing loss medically, since it is typically caused by treatable conditions, such as ear infections, fluid in the middle ear space, or earwax (ASHA, 2015). Sensorineural hearing loss, in contrast, occurs when there is dysfunction of the inner ear, or cochlea, or when there is damage to the auditory nerve pathways from the cochlea to the brain. It is caused by conditions such as aging, genetic or hereditary factors, noise exposure, trauma, or ototoxic medications (ASHA, 2015). Sensorineural hearing loss is most often a permanent condition with treatment options that include amplification with hearing aids or a cochlear implant. A mixed hearing loss occurs when there is both a conductive and a sensorineural hearing loss (ASHA, 2015). Overall, any one of these types of hearing loss can occur suddenly, can fluctuate, or can have a progressive nature.

Degree of hearing loss. The degree of hearing loss is based on the severity of hearing impairment (Clark, 1981). The most commonly used classification system describes hearing loss in decibels, or dB HL. Normal hearing is 15 dB HL or below; while a slight hearing loss is 16 to 25 dB HL, a mild hearing loss is 26 to 40 dB HL, a moderate hearing loss is 41 to 55 dB HL, and moderately-severe and severe hearing losses are 56 to 70 dB HL and 71 to 90 dB HL, respectively. Hearing loss that is 91 dB HL or greater is considered to be profound (ASHA, 2015; Clark, 1981). The degree of hearing loss can be the same or different in both ears.

Prevalence of Hearing Loss

It has been reported that hearing loss is ranked as either the third or fourth largest non-fatal disabling health condition worldwide. In the U.S., hearing loss ranks fourth in prevalence among chronic conditions affecting individuals aged 65 years and older (Fagan & Jacobs, 2009; Lin & Bhattacharyya, 2011).

Prevalence of hearing loss internationally. According to the World Health Organization (WHO) (2016), disabling hearing loss, or hearing loss greater than 40 dB HL in the better ear, affects 360 million people throughout the world. This WHO (2016) estimate includes 32 million children throughout the world. The international prevalence of hearing loss increases with age, rising from approximately 7 percent of individuals aged 15 years or less to an estimated 33 percent of adults aged 65 years and older (WHO, 2012). The greatest prevalence of individuals with hearing loss is found in South Asia, East Asia, Asia Pacific, and Sub-Saharan Africa, affecting approximately 100 million, 75 million, 37.4 million, and 36.8 million people with disabling hearing loss, respectively (WHO, 2012). In contrast, Turton and Smith (2013) state that an estimated 10 million people in the United Kingdom have hearing loss, including 800,000 who have severe or profound hearing loss.

In 2007, Chia and colleagues examined the incidence of unilateral and bilateral hearing loss in approximately 2,500 Australian individuals aged 50 years and older, the results of which became known as the Blue Mountain Hearing Study (BHMS) (Chia et al., 2007). Chia and colleagues found that the incidence of hearing loss increases with age and there is a greater number of individuals with bilateral versus unilateral hearing loss (Chia et al., 2007). As seen in Figure 1 below, these researchers reported that the incidence of unilateral hearing loss ranged from 9 percent of those participants aged 50 to 59 years of age to 16 percent of those participants aged 70 to 79 years of age. In contrast, the incidence of bilateral hearing loss was more prevalent, ranging from 7 percent of those participants aged 50 to 59 years to 49 percent of those participants who were aged 70 to 79 years (Chia et al., 2007).

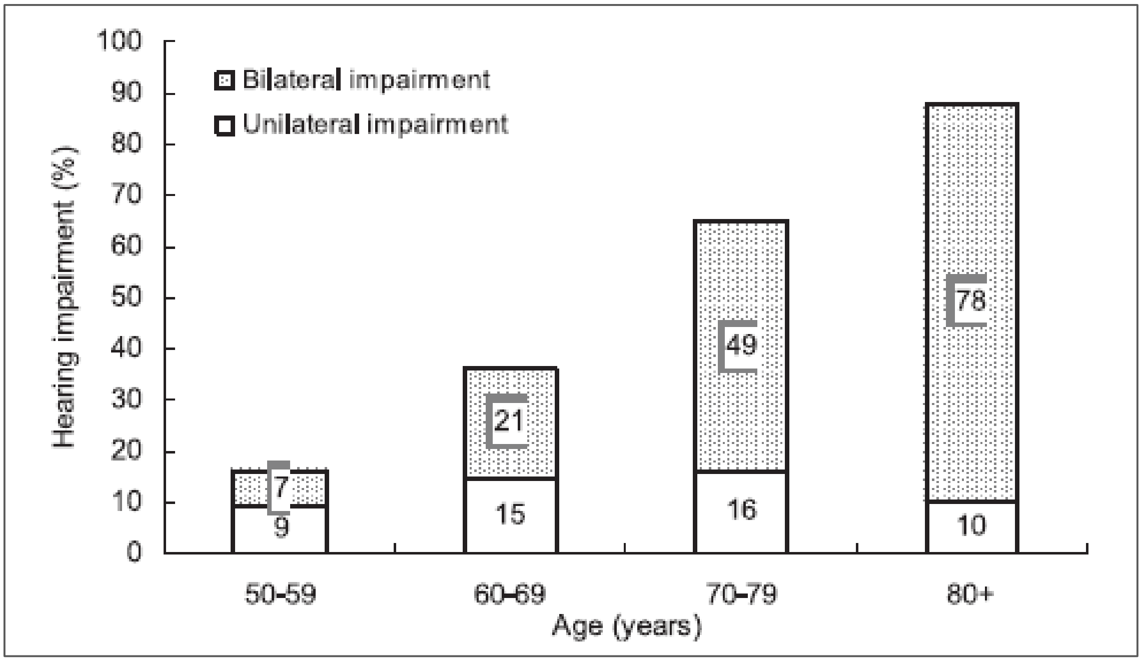


Figure 1. Prevalence of unilateral and bilateral hearing loss by age. Adapted from "Hearing Impairment and Health-Related Quality of Life: The Blue Mountains Hearing Study." By E. Chia, J. Wang, E. Rochtchina, R. Cumming, P. Newall, and P. Mitchell, 2007, *Ear and Hearing, 28*(2), 187-195.

Prevalence of hearing loss among adults in the United States. Hearing loss has impacted approximately 30 to 48 million individuals aged 12 years and older in the United States (Lin, Niparko, & Ferrucci, 2011a; WHO, 2016). The increased occurrence of hearing loss with age makes it one of the most prevalent health conditions in the United States, with an estimated 30 million Americans affected with bilateral hearing loss (Lin et al., 2011a; Lin et al., 2011c). As seen in Figure 2 below, these researchers estimate that the prevalence of hearing loss in the United States increases almost two fold for each decade between 50 to 80 years of age. Among adults in the United States, approximately 63% of individuals aged 70 years and older have hearing loss of 25 dB HL or worse (Lin et al., 2011c). This trend is quite concerning because the number of Americans over the age of 65 years is expected to rise from 35 million to 71 million people by the year 2030 (Lin & Bhattacharyya, 2011). Therefore, one can anticipate that the number of individuals with hearing loss will increase as the population ages.

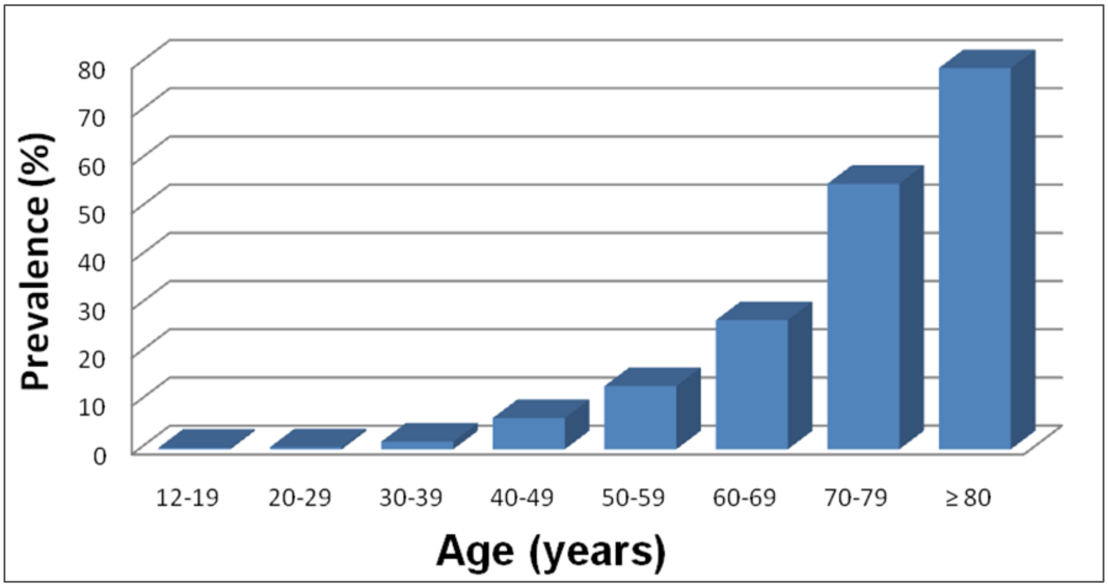


Figure 2. Prevalence of hearing loss in the United States, National Health and Nutritional Examination Survey (NHANES) 2001-2008. Adapted from "Hearing Loss in Older Adults: A Public Health Perspective." by F. Lin, 2016. Data from Lin et al., 2011a.

In summary, the collective results of these studies indicate that hearing loss is a substantial global health problem. In addition, the prevalence of bilateral hearing loss increases with age, with older adults representing the majority of individuals with a permanent sensorineural hearing loss. The primary intervention for many individuals with permanent hearing loss is amplification of sound through the use of hearing aids.

Prevalence of Hearing Aid Usage

Despite the growing number of adults with hearing loss, a disproportionately low number of those individuals use hearing aids (Bainbridge & Ramachandran, 2014). In a study by Chien and Lin (2012) of participants in the National Health and Nutritional Examination Survey (NHANES) of 1999-2006, only 14.2 percent of the American adults with hearing loss who were aged 50 years and older used hearing aids. As seen in Figure 3 below, although the prevalence of hearing loss increases dramatically between the 5^{th}

and 8th decade of life, the number of hearing aid users remained fairly low and ranged from only 4.3 percent of those aged 50 to 59 years to only 22.1 percent of those aged 80 years and older (Chien & Lin, 2012).

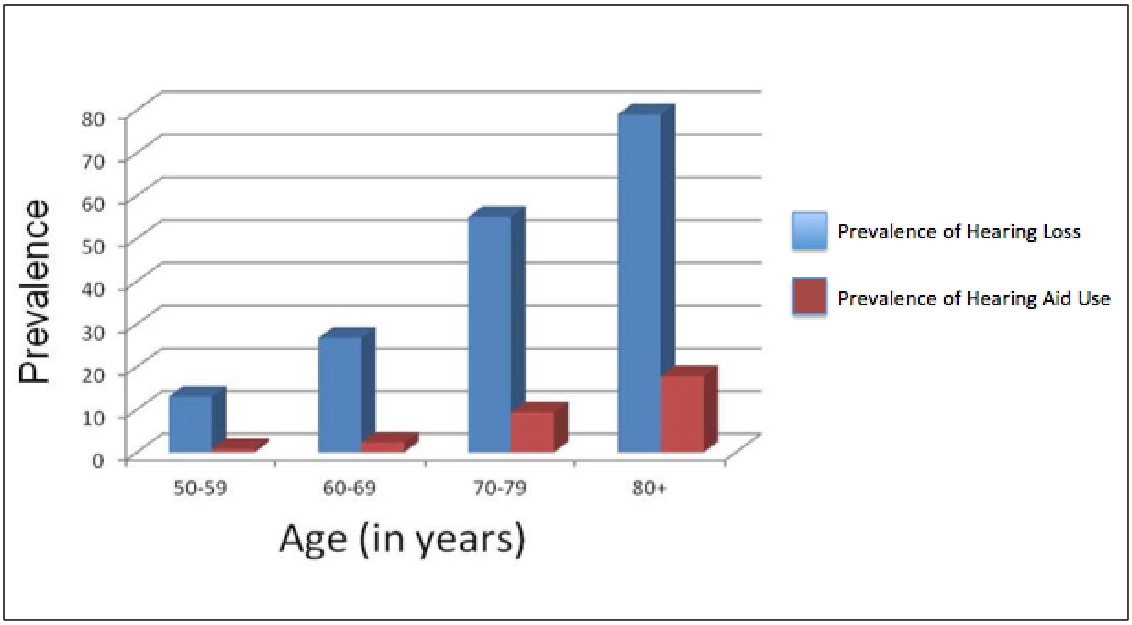


Figure 3. Prevalence of hearing loss and hearing aid use in the United States according to age. Adapted from "Hearing Loss in Older Adults: A Public Health Perspective." by F. Lin, 2016. Data from Chien and Lin, 2012.

Researchers have also found that hearing aid usage varies based on the degree of hearing loss. Lin et al. (2011c) studied the data of 717 participants from the 2005-2006 NHANES, with a focus on those individuals who were aged 70 years and older with mild, moderate, or severe degrees of hearing loss. These researchers examined the influence of the degree of hearing loss on hearing aid usage. For those participants with mild hearing loss, only 3.4 percent of them used hearing aids. This percentage increased to 40 percent for individuals with moderate hearing loss and 76.6 percent for those with severe hearing loss. The researchers estimate that within the general population approximately 1 in 5, or 20 percent, of hearing impaired adults aged 70 years or older use hearing aids (Lin et al, 2011c).

International rates of hearing aid usage are also low, even in countries with socialized medicine. Taylor and Paisley (2000) studied the treatment options available to individuals with hearing loss in England and Wales, both of which practice socialized medicine. The researchers estimated that of the 8.1 million individuals with a sensorineural hearing loss greater than or equal to 25 dB HL, only 1.4 million, or 17 percent, wore hearing aids. Similarly, Dawes et al. (2014) reviewed the data of 164,770 hearing-impaired adult participants included in the United Kingdom Biobank resource and reported that only 9.4 percent of the individuals were regular hearing aid users. Lastly, there are also low rates of hearing aid usage reported among Australian hearing-impaired adults. In 2007, Chia and colleagues examined data from 707 individuals aged 49 years and above with bilateral hearing loss who participated in the Blue Mountains Hearing Study. These investigators reported that only 33 percent of the participants owned hearing aids and only 25 percent of these participants wore their hearing aids regularly (Chia et al., 2007). It has been speculated that many factors may be directly influencing this low rate of global hearing aid usage, which will be discussed below.

Factors That Affect Hearing Aid Usage

Several researchers assert that a combination of factors may influence the prevalence of hearing aid use including cost and maintenance of the hearing aid; accessibility to hearing health professionals, and the perceptual stigma attached to wearing hearing aids (Chien & Lin, 2012; NIH, 2013). Each of these factors will be discussed in further detail below.

Cost of hearing aids and audiological follow-up. In the U.S., the cost of hearing aids can vary and is correlated with the level of technology within the device. Hearing aid technology can range from a basic analog circuit to more advanced digital circuitry and complex algorithms (Taylor & Mueller, 2011). According to NIH (2013), the cost of hearing aids can average from $1,500 for one basic device up to $5,000 for a pair of hearing aids with more advanced technology. It is often recommended that an individual with hearing loss obtain two hearing aids because there are advantages in speech understanding and sound localization when listening with both ears, thereby doubling the cost (Gopinath et al., 2011; Taylor & Mueller, 2011).

There are also costs associated with the maintenance of the devices. For example, even though hearing aid batteries are fairly inexpensive, they require changing approximately once a week (Campbell, 2015). In addition, it is estimated that the average hearing aid will last approximately 4 to 7 years, with the likelihood of repairs increasing with the age of the hearing aid (Donahue, Dubno, & Beck, 2010; Hearing Health, 2014; Johns Hopkins Medicine, 2007). Hearing aids typically come with a 2 to 3 year warranty that covers repairs, damage, and loss. However, after the expiration of the warranty, the patient must incur the cost of a replacement hearing aid or any repairs that the audiologist is unable to make within the office. In the United States, the costs of batteries and maintenance are not covered by Medicare or most health insurance plans. This means that an individual with hearing loss is usually responsible for the substantial out-of-pocket cost of multiple hearing aid purchases over a lifetime, batteries, and maintenance of the device (Donahue et al., 2010; Kochkin, 2009; Swanepoel et al., 2010).

In addition to the obvious costs associated with the devices, there are hidden costs in terms of the time spent with the various professionals involved in the fitting process and their costs per hour. As seen in Figure 4 below, the costs associated with the "gold-standard" model of fitting hearing aids can total approximately $3,050 to $5,050 and extend up to approximately 6 months (Lin, 2016).

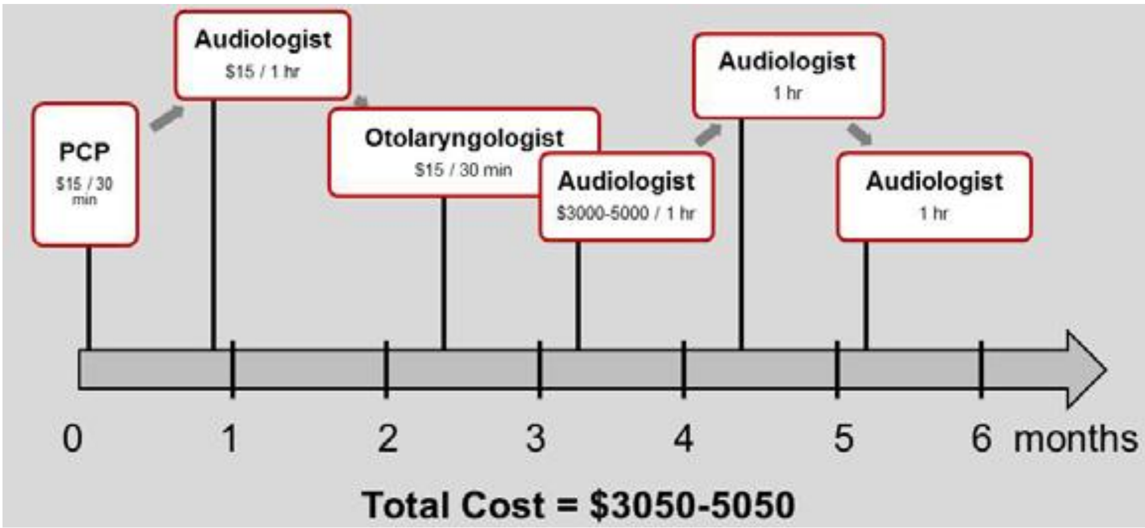


Figure 4. Timeline of costs associated with the "gold-standard model of hearing health care". Adapted from "Hearing Loss in Older Adults: A Public Health Perspective." by F. Lin, 2016, *Towson University*.

The cost of hearing aids has been speculated to be a considerable factor that influences the prevalence of hearing aid usage, especially in the United States. However, studies conducted internationally have also shown that hearing aid usage rates are surprisingly low even in countries where socialized medicine is practiced. As noted above, individuals with bilateral hearing loss who live in the United Kingdom can obtain hearing aids at no cost through the National Health Service, yet only 10 to 33 percent of these individuals use hearing aids (Davis et al., 2007; Lin et al., 2011c; WHO, 2016). This implies that the cost of hearing aids may only be one of several factors influencing the prevalence of hearing aid usage nationally and internationally.

Accessibility to hearing health professionals. According to the Bureau of Labor Statistics, in 2014 there were approximately 13,000 audiologists and an estimated 3,000 hearing aid dispensers, compared to the estimated 30 million Americans with bilateral hearing loss (Bureau of Labor Statistics, 2016; Lin et al., 2011a; Margolis & Morgan, 2008). Therefore, there is an obvious shortage of hearing professionals. This causes an accessibility issue particularly for those individuals with hearing loss who live in more rural areas of the country.

In some developing countries where hearing loss is considered the third largest non-fatal disabling health condition there are as few as one to six audiologists per 100,000 people (Fagan & Jacobs, 2009). Accessibility to the few available audiologists may be further limited by distance and harsh weather patterns of the local climate (Swanepoel et al., 2010). In addition, other health issues in these areas may place a greater demand on limited financial and technical resources, thereby decreasing the focus on hearing loss intervention (Goulios & Patuzzi, 2008).

Stigma of hearing aids. The perceptual stigma of wearing hearing aids may also influence an individual's decision to use hearing aids (Wallhagen, 2010). In 2007, Kochkin conducted a Marketrak VII online survey of 3,000 individuals over the age of 22 years with mild to profound hearing loss who had not adopted hearing aids. He reported that approximately 50 percent of the participants referenced the stigma associated with hearing aid use as their reason for not wearing hearing aids. For the majority of them, wearing hearing aids was a public sign of aging and hearing disability (Kochkin, 2007).

Several years later, Wallhagen (2010) performed a longitudinal study of approximately 85 individuals with hearing loss who were not wearing hearing aids. The participants were aged 60 years and older and were interviewed, along with their communication partners, three times during the course of one year. In describing their reluctance to wear hearing aids, the participants and their communication partners discussed concerns that the participant would feel old, disabled, or unintelligent while wearing the hearing aid. Wallhagen (2010) also reported that the participants had concerns regarding ageism and a loss of authority among younger individuals in the workplace (Wallhagen, 2010).

Collectively, the results of these studies indicate that the stigma of wearing hearing aids may contribute, at least in part, to the low rates of hearing aid usage. It is important to note that in recent years several manufacturers have developed more aesthetically pleasing amplification devices that utilize Bluetooth technology. These devices may help to decrease the perceptual stigma of wearing hearing aids (Blustein & Weinstein, 2016). There is also a need in the general population for an increased awareness that hearing loss can impact all age groups and can have negative consequences on other aspects of their cognitive, physical, and emotional health.

Consequences of Age-Related Hearing Loss

Recent evidence has shown that hearing loss negatively impacts an individual's ability to communicate and is linked to other major health conditions, including cognitive decline, brain changes, dementia, social isolation, depression, and an increased risk of falls (Kamil et al., 2015; Lin et al., 2014; Lin et al., 2013; Lin et al., 2011b; Nachtegaal et al., 2009; Pichora-Fuller, Mick, & Reed, 2015; Sung et al., 2015). These consequences of age-related hearing loss will be further discussed below.

Impact of hearing loss on communication. Hearing loss acts as an "acoustic filter" that weakens or eliminates sounds within words and hinders an individual's ability to communicate, particularly in noisy listening situations (Levey et al., 2012; Madell & Flexer, 2014). Age-related hearing loss, or presbycusis, is common in older individuals and typically begins with a decrease in hearing abilities within the higher frequency, or higher pitch sounds (Arvin, Prepageran, & Raman, 2013). Higher pitch speech sounds include consonants, such as the /s/ in the word "son", which may be mistaken for a similar high pitch consonant, like the /f/ in "fun". Individuals with hearing loss may have problems discriminating between these higher pitch sounds, which can make it difficult to respond appropriately during a conversation (Helfer, 2015).

Cognitive decline. The aging process may result in a decline in cognitive functioning, which can lead to problems thinking and difficulty remembering names or the flow of a conversation (Podea & Palici, 2015). Over time, cognitive decline can lead to a cognitive impairment that compromises communication with others, thereby decreasing the quality of life, particularly for an individual with hearing loss (Pichora-Fuller et al., 2015).

During the last two decades, Lin and colleagues have conducted a series of studies examining the link, if any, between hearing loss and cognitive decline. In 2011, Lin and colleagues studied 605 participants from the 1999-2000 NHANES cross-sectional data who were aged 60 to 69 years. The participants included 172 individuals with hearing loss equal to or greater than 25 dB HL and 433 individuals with normal hearing. The researchers administered the Digit Symbol Substitution (DSS) test, which assesses executive function and psychomotor processing, to each group of participants. Lin and colleagues reported that the individuals with hearing loss had significantly lower DSS scores of cognition when compared to the individuals with normal hearing. Secondly, the DSS scores decreased with the increased severity of hearing loss (Lin et al., 2011d). As seen in Table 1 below, the researchers estimated that the presence of hearing loss (- 3.86) equated to approximately 7 years of additional aging effects (- 0.55 per year) on the DSS (Lin, 2011d). For example, a 60-year-old hearing-impaired participant had a DSS score that was equivalent to a 67-year-old normal-hearing adult.

Table 1

Age Equivalent Scores on the Digit Symbol Substitution (DSS) Test in 605 Adults Aged 60-69 Years Administered per the National Health and Nutritional Examination Survey (NHANES) 2005 Protocol

	Age (per year) β^a (95% CI)	P	Hearing loss (per 25 dB) β^b (95% CI)	P	Δ Age (years) equivalent to 25 dB of hearing loss
Digit Symbol Substitution Test	-0.55 (-0.92 – -0.18)	<.01	-3.86 (-7.15 – -0.56)	.02	7.0

Note. This table is adapted from "Hearing Loss in Older Adults: A Public Health Perspective." by F. Lin, 2016, *Towson University*.

In 2013, Lin and colleagues further examined the link between hearing loss and cognitive decline by studying the longitudinal data of 1,966 participants in the Health ABC Study. During the course of six years, cognitive testing was performed four times. The participants were aged 70 to 79 years and had a hearing loss of 25 dB HL or greater and no prevalent cognitive impairment (Lin et al., 2013). The researchers compared performance on the DSS and the Modified Mini-Mental State (3MS) examination between the individuals with hearing loss and an age-matched normal control group. The 3MS is a cognitive examination of orientation, concentration, language, praxis, and memory. The researchers found that cognition measured on the DSS declined in individuals with hearing loss at a rate that was 32 percent greater when compared to individuals with normal hearing. In addition, the rate of cognitive decline for individuals with hearing loss was 41 percent greater on the 3MS examination when compared to individuals with normal hearing (Lin et al., 2013).

Lin and colleagues have speculated that cognitive decline and decreased working memory associated with hearing loss places a very high demand on cognitive resources (Lin et al., 2011b). An older individual with hearing loss is at a further disadvantage since greater demand is placed on his or her cognitive resources for decoding auditory information. This additional strain on cognitive resources requires this individual to put forth a greater listening effort in all listening environments (Degeest, Keppler, & Corthals, 2015; Lin et al., 2011b; Seeman & Sims, 2015).

Results of neuro-imaging studies. Several neuro-imaging studies have investigated the effects of aging and hearing loss on the processing that occurs in the brain during complex listening and working memory tasks. In a study by Holtzer et al. (2009), the researchers compared the functional magnetic resonance imaging (fMRI) scans of 25 young adults (aged 19 to 34 years) to 25 older adults (aged 65 to 84 years). During fMRI scanning, the researchers administered the delayed item recognition (DIR) test of working memory. This test consists of three stages including a set presentation stage, a retention delay period, and a probe presentation stage. During the set presentation stage, participants were presented with one to three random shapes. After a retention delay, the participants were then presented with an individual shape, or probe item, and asked to identify whether it was included in the initial set presentation. The researchers found that the older individuals were slower, less accurate, and showed a decrease in activity in areas of the brain related to the memory retrieval process when compared to the younger individuals (Holtzer et al., 2009).

A few years later, Peelle, Troiani, Grossman, and Wingfield (2011) used fMRI and voxel-based morphometry (VBM) to examine neural activity (n=16) and cortical brain volume (n=25) in adults ranging from 60 to 77 years of age. The participants had pure tone average (PTA) hearing thresholds ranging from 10 dB HL to 38 dB HL. Specifically, Peelle and colleagues were interested in examining the neural effects of hearing loss on the structures of the brain and on speech comprehension. Each participant was administered a series of 240 sentences that were either subject-relative or more complex object-relative. Each participant was asked to identify the person performing the action as either male or female. During normal language-related processing, an increase in language-driven neural activity on fMRI would be expected for the more complex object-relative sentences when compared to the subject-relative sentences. As seen in Figure 5 below, Peelle and colleagues reported that the individuals with the poorer hearing showed less language-driven neural activity on fMRI in both superior temporal gyri when listening to complex object-relative sentences, compared to those participants with normal hearing (Peelle et al., 2011).

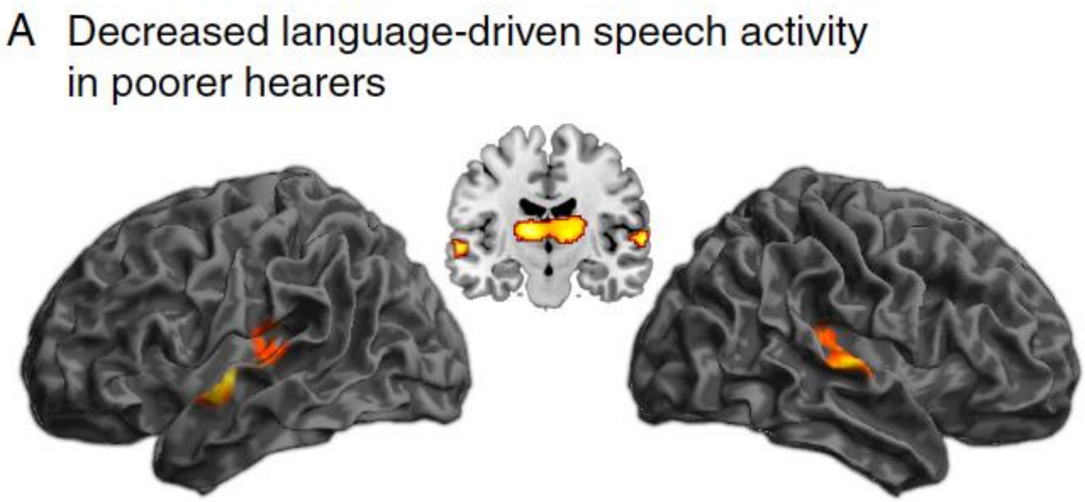


Figure 5. Highlighted regions of decreased language-driven neural activity on fMRI in both superior temporal gyri for individuals with poorer hearing when listening to sentences with varying linguistic demands. Adapted from “Hearing Loss in Older Adults Affects Neural Systems Supporting Speech Comprehension,” by J.E. Peelle V. Troiani, M. Grossman, and A. Wingfield, 2011, *The Journal of Neuroscience*, *31*(35), 12638-12643.

Peelle and colleagues also reported that the individuals with poorer hearing had less grey matter volume in their primary auditory cortex on VBM when compared to those participants with normal hearing. As seen in Figure 6 below, the results of VBM show that the volume of grey matter decreases with an increase in severity of hearing loss (Peelle et al., 2011).

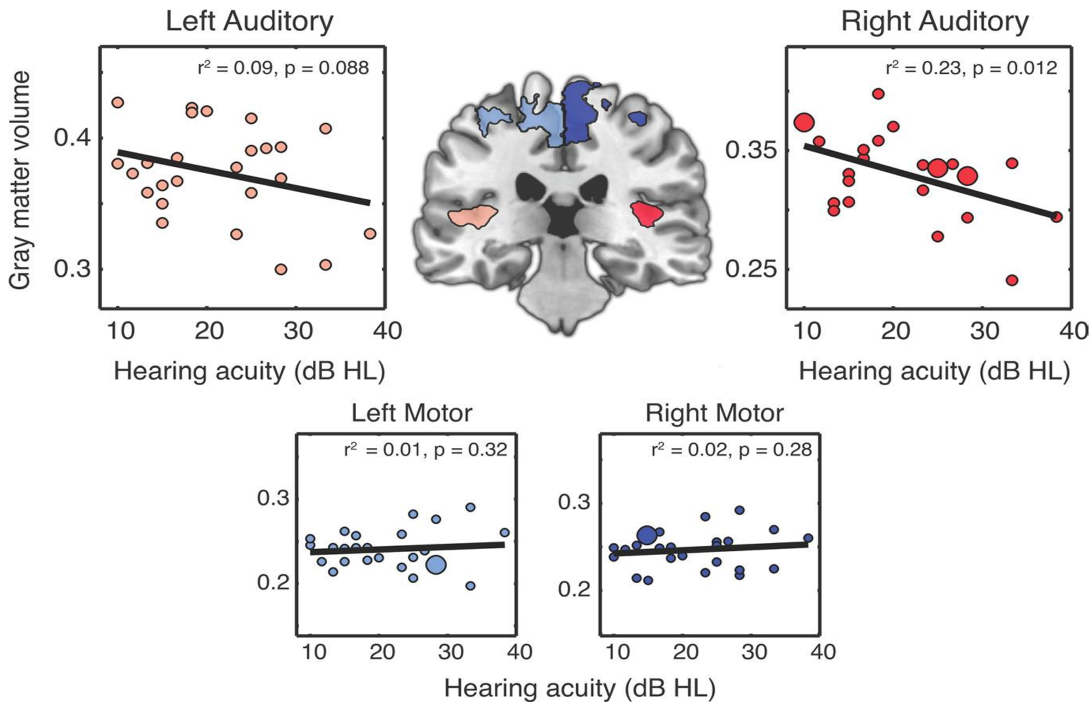


Figure 6. Relationship between grey matter volume and severity of hearing loss. Adapted from "Hearing Loss in Older Adults Affects Neural Systems Supporting Speech Comprehension," by J.E. Peelle V. Troiani, M. Grossman, and A. Wingfield, 2011, *The Journal of Neuroscience, 31*(35), 12638-12643.

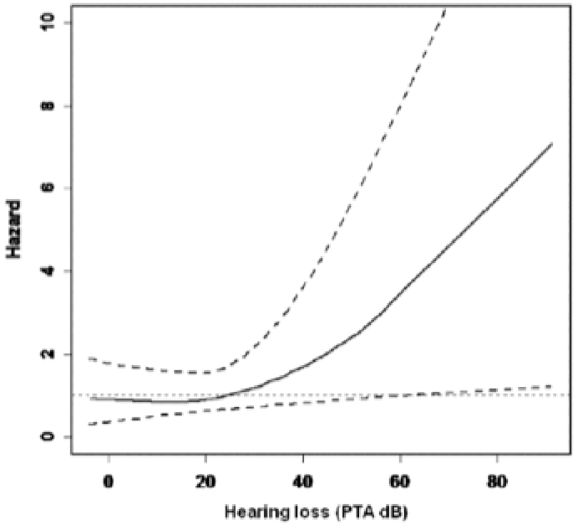
Recently, Lin et al. (2014) studied 126 individuals aged 56 to 86 years with hearing status ranging from normal hearing to moderately-severe hearing loss who were participants in a neuro-imaging study as part of the Baltimore Longitudinal Study of Aging (BLSA). The researchers studied the participants for 6.4 years and found that the individuals with hearing loss had an increased rate of brain volume decline in the right temporal lobe when compared to individuals with normal hearing. These researchers speculated that this occurred because there is greater spoken language processing occurring in the left temporal lobe, which may help to preserve the brain volume in this region (Lin et al., 2014).

Collectively, the results of these neuro-imaging studies provide strong evidence of a significant correlation between hearing loss and cognitive dysfunction (Lin et al., 2013;

Uhlmann et al., 1989). Cognitive dysfunction within the aging population is a growing concern, due to the risk of dementia within this population.

Dementia. Dementia is a decrease in cognition that impairs daily living, affecting approximately 5 to 7 percent of individuals aged 60 years and older worldwide (Prince et al., 2013). According to Prince et al. (2013), the prevalence of dementia is expected to double every 20 years. Therefore, the medical community has taken a preventative approach to addressing this major health problem, which includes research into the association of hearing loss with dementia (Lin et al., 2011b).

Lin et al. (2011b) studied 639 participants in the BLAS who were aged 36 to 90 years with hearing ranging from normal hearing to severe hearing loss. The participants were followed for 11.9 years and administered testing that included screening using the Blessed Information Memory Concentration test and a standard battery of neurological and neuropsychological tests. Diagnosis of dementia and Alzheimer's disease were made based on the Diagnostic and Statistical Manual of Mental Disorders and the National Institute of Neurological and Communicative Disorders and Stroke – Alzheimer's Disease and Related Disorders Association criteria (Lin et al., 2011b). Lin and colleagues reported that an increase in the severity of hearing loss is associated with an increased risk of dementia. This relationship was described as a hazard ratio (HR), which is seen in Figure 7 below. These researchers found that individuals with mild, moderate, and severe hearing loss had approximately two, three, and five times greater risk of developing dementia respectively when compared to individuals with normal hearing (Lin et al., 2011b).



	HR	95% CI	p
Mild	1.89	1.00 – 3.58	0.05
Moderate	3.00	1.43 – 6.30	.004
Severe	4.94	1.09 – 22.4	.04

Figure 7. Risk of incident all-cause dementia by baseline hearing loss after adjustment for age, sex, race, education, diabetes, smoking, and hypertension. Adapted from "Hearing Loss and Incident Dementia." by F. Lin, E. Metter, R. O'Brien, S. Resnick, A. Zonderman, and L. Ferrucci, 2011b, *Archives of Neurology*, *68*(2), 214-220 and "Hearing Loss in Older Adults: A Public Health Perspective." by F. Lin, 2016.

Out of the 639 participants, there were 58 diagnoses of dementia and 37 diagnoses of Alzheimer's disease (Lin et al., 2011b). The researchers assert that given the public health concern regarding dementia an increased focus on hearing loss as a modifiable later-in-life risk factor for incident dementia is warranted (Lin et al., 2011b).

Social isolation and depression. Several researchers have examined the association of hearing impairment and psychosocial deficits, including poorer mood, social isolation, and depression (Chia et al., 2007). These psychosocial deficits can result when an individual with hearing loss finds it difficult to communicate with others and withdraws from daily activities that may have once enhanced their quality of life (Weinstein, 2015).

In a cross-sectional study of 1,511 individuals aged 18 to 70 years, Nachtegaal et al. (2009) examined the influence that hearing loss has on psychosocial health. The participants were enrolled in the National Longitudinal Study on Hearing conducted in the Netherlands and their hearing status was determined using the National Hearing on-line speech-in-noise screening test. These researchers studied six areas of psychosocial health including distress, depression, anxiety, and loneliness by using the Four-Dimensional Symptom Questionnaire, the Loneliness Scale, and the 12-item General Self-Efficacy Scale (Nachegaal et al., 2009). They found that, for participants with poorer hearing, there was an increase in depressive thoughts, anxiety, and longing for relationships, or loneliness, when compared to participants with normal hearing (Nachegaal et al., 2009).

A more recent study by Sung et al. (2015) investigated the psychosocial status of 145 individuals who were receiving hearing aids or cochlear implants for the first time and were recruited for the Studying Multiple Outcomes After Aural Rehabilitative Treatment (SMART) study. The participants were aged 50 to 94 years with hearing ranging from normal hearing (PTA less than 25 dB HL) to profound hearing loss. The researchers administered several questionnaires. Specifically, they assessed social functioning via the Social Network Index, communicative functioning via the Revised Quantified Denver Scale of Communication, physical functioning via the 36-Item Medical Outcomes Study Short-Form Health Survey (SF-36), and mental functioning via the 15-question Geriatric Depression Scale and the UCLA Loneliness Scale. The researchers found that for individuals with hearing loss, there was an association between hearing loss and loneliness. The level of loneliness increased by 1.26 points with every 10 dB increase in PTA. The researchers also found that the severity of hearing loss correlated with an increase in depressive symptoms and increased difficulties communicating (Sung et al., 2015).

Risk of falls. Falls are the leading cause of injury, hospitalization, and death among older individuals (Hosseini & Hosseini, 2008). Hearing loss has also been associated with an increased risk for falls as a result of poorer physical functioning. Poor physical functioning includes limitations in an individual's ability to walk that restricts their mobility and participation in activities of daily living (Gispen, Chen, Genther, & Lin, 2014). In a study by Gispen et al. (2014), 706 participants in the NHANES of 2005-2006 aged 70 years and older with hearing loss ranging from normal to severe were assessed for physical activity levels using self-report questionnaires and accelerometry. The self-report measures consisted of several questions regarding the frequency and duration of vigorous leisure activities. The participants were required to wear an accelerometer for 7 days, which measured their physical activity. These researchers reported that sensorineural hearing loss of moderate or greater degree was independently associated with lower levels of physical activity when compared to individuals with normal hearing. Approximately 60 percent of these hearing impaired individuals reported a low level of physical activity and this was confirmed by their accelerometry results (Gispen et al., 2014).

Kamil et al. (2015) reported that a decrease in physical activity in older adults may lead to several changes such as increased frailty and an increased risk of falls. Kamil and colleagues studied the frailty and number of falls that occurred in 2,000 participants in the Health ABC study from 1997 to 2007. These participants were 70 to 79 years of age and their hearing ranged from normal to severe hearing loss. The participants were initially recruited based on their ability to walk a quarter mile, climb 10 steps without resting, and independently perform activities of daily living. Frailty, or a gait speed less than 0.60 meters per second, was measured by timing the participants' completion of a 20-meter walk and assessing their ability to stand from sitting in a chair with their arms folded. These researchers reported that participants with a moderate or greater hearing loss had a 63 percent increased risk of frailty when compared to individuals with normal hearing. Kamil and colleagues also investigated the risk of falls over the period of a year. The risk of falls was determined by asking questions regarding the number of falls that occurred during the prior year. As seen in Figure 8 below, the odds of falling increased twice as fast for individuals with moderate or greater levels of hearing loss when compared to individuals with normal hearing. Specifically, the average risk of falling increased 4.4 percent for those participants with normal hearing, 6.3 percent for those with mild hearing loss, and 9.7 for those with moderate or greater hearing loss.

Table 3. Association of HI With Annual Percent Increase in Odds of Falls Over Time.

	Annual percent increase in odds of falls over time					
	Normal hearing		Mild HI		Moderate-or-greater HI	
Model	% increase in odds (95% CI)	*p*	% increase in odds (95% CI)	*p*	% increase in odds (95% CI)	*p*
All (n = 2,000)	4.4 [2.6, 6.2]	<.001	6.3 [4.4, 8.2]	<.001	9.7 [7.0, 12.4]	<.001

Normal hearing vs. Mild HI: *p* = .17

Normal hearing vs. Moderate-or-greater HI: *p* = .001

Figure 8. Average increase in risk of falling during the 10-year period (1997-2007). Adapted from "Association of Hearing Impairment with Incident Frailty and Falls in Older Adults." by R. Kamil and colleagues, 2015, *Journal of Aging and Health*, Advance online publication.

Overall, these studies show that age-related hearing loss that is not addressed can negatively impact numerous aspects of an individual's physical, cognitive, and emotional health and well-being. It is important to address hearing loss with treatment options, such as amplification of sounds, in order to help reduce this impact.

Treatment Options for Age-Related Hearing Loss

There are several devices available to amplify sound for individuals with hearing loss. These devices are categorized into either traditional hearing aids or over-the-counter personal sound amplification products (PSAPs). There are similarities and differences between hearing aids and PSAPs that can impact their use as treatment options for hearing loss. In addition, both hearing aids and PSAPs can be designed with basic, mid-, or advanced levels of technology with corresponding levels of cost. The following section of this literature review will define these devices and discuss their similarities and differences. These similarities and differences include FDA regulations on the devices, basic components and design, acoustic features, utility for various degrees of hearing loss, and cost.

Hearing aids. Hearing aids are electronic devices used to amplify sounds that are too soft for an individual with a hearing loss to hear (Hampson, 2012; Taylor & Mueller, 2011). The FDA regulates the use of hearing aids, defining them as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing" (FDA, 2013). According to the FDA, hearing aids are primarily classified into two categories: class I and class II medical devices. Air-conduction hearing aids are classified as class I medical devices and are most often used to treat age-related hearing loss. Some hearing aids are designed to conduct sound through the mastoid bone behind the ear via bone conduction and these devices are classified as class II medical devices (FDA, 2013). Bone-anchored hearing aids (BAHAs) are used when traditional air-conduction hearing aids are not an option due to outer or middle ear issues (Mraz, 2015). Hearing aids are generally more customizable based on the type and degree of hearing loss when compared to PSAPs (Blum, 2016). For the purposes of this literature review, further discussion of hearing aids will refer primarily to air-conduction hearing aids.

Hearing aid manufacturers must comply with FDA regulations regarding labeling, which require the placement of the device model, serial number, and date of manufacture on each hearing aid. A brochure containing user instructions and safety specifications for the hearing aid must also be provided to the wearer. FDA regulations also specify that, prior to being fit with hearing aids, an individual must have received a hearing evaluation within the preceding 6 months. The individual must also receive medical clearance from a licensed physician within 6 months of the hearing aid fitting, which must be retained in the patient's medical record for at least 3 years. This helps to ensure that individuals with treatable causes of hearing loss receive the appropriate medical intervention. Individuals who are aged 18 years and older are eligible to sign a document waiving the medical clearance requirement, while younger individuals are not allowed this option (FDA, 2013).

PSAPs. PSAPs are over-the-counter electronic products that also amplify sounds. Unlike hearing aids, the FDA defines PSAPS as products that are "intended to amplify environmental sound for non-hearing impaired consumers" (FDA, 2013). For example, a PSAP may be used when listening to soft sounds, such as birds or distant speakers, which an individual with normal hearing may experience difficulty hearing. Since the FDA does not classify PSAPs as medical devices, manufacturers of PSAPs are not required to register them with the FDA, which holds true as long as the manufacturer does not label or promote a PSAP as intended for individuals with hearing impairment. However, manufacturers of PSAPs are required to comply with the Radiation Control for Health and Safety Act of 1968, by which the FDA regulates products that emit sonic vibrations. Manufacturers of PSAPs are also required to report defects or “adverse” events, in addition to complying with the FDA re-purchase, repair, and replacement requirements (FDA, 2013).

Basic components and design. There are several basic components found in both hearing aids and PSAPs including a microphone, an amplifier, a receiver, and an earpiece. Microphones are designed to convert acoustical sound into an electric signal. The electric signal is then increased, or made louder, by an amplifier and sent to a receiver, which converts the electric signal back into an acoustical sound. An earpiece is coupled to the receiver, either by direct wiring or plastic tubing, to deliver the acoustical sound to the ear canal. An additional component of some hearing aids and PSAPs is a telecoil. A telecoil converts the electromagnetic energy from a telephone or the induction loop system of a large room into an electric signal that can be amplified and converted to acoustical sound (Taylor & Mueller, 2011).

Hearing aids are designed for placement in the ear (ITE), behind the ear (BTE), or on the body. ITE hearing aids are custom designed from an impression of an individual’s ear and sized to fill the entire concha (full-shell), fill half the concha (half-shell), fill the opening to the ear canal (ITC), or sit completely in the ear canal (CIC) (Taylor & Mueller, 2011). In contrast, PSAPs that are designed for placement in the ear are usually not customized and offered in one standard size. BTE hearing aids and PSAPs are designed to sit behind the ear, with either a tube or wire coupled to an earpiece. Body worn hearing aids are typically coupled to custom earpieces and may be easier to use for individuals with physical limitations, since they are larger than on-the-ear hearing aids and contain easy to use volume and tone controls (Dillon, 2012; Taylor & Mueller, 2011).

There are several types of earpieces that couple to BTE hearing aids, including pre-formed domes and custom-fit earmolds. These earpieces are designed in a variety of sizes and shapes in order to fine-tune the sound entering the ear canal (Taylor & Mueller, 2011). Dome earpieces leave most of the ear-canal open, which provides a more natural sound for individuals who have a lesser degree of hearing loss, particularly in the lower pitches. However, custom earmolds typically occlude most of the ear canal to maximize the sound entering the ear canal for greater degrees of hearing loss. Custom earmolds help retain the hearing aid in the ear canal and can be modified with venting or various materials (e.g., acrylic, vinyl, silicone) to increase listening comfort and acoustic performance (Dillon, 2012; West, 2012). In contrast to the customizable earpiece options offered with hearing aids, PSAPs are typically coupled to a standard sized dome, with some PSAPs offering venting and the option of changing to either a smaller or a larger dome (Soundworld Solutions, 2016; Tweak, 2016).

Sound processing and acoustic features. Both hearing aids and PSAPs amplify sounds using either analog or digital sound processing (Bean, 2016; Dillon, 2012; Soundworld Solutions, 2016). In analog devices, an acoustic sound wave is converted into an electrical waveform and the amplifier increases the gain of the waveform by a specified amount. This occurs without changes to the spectral shape of the original electrical waveform and is applied similarly to both speech and background noise (Hampson, 2012; Taylor & Mueller, 2011). In contrast, digital devices utilize a computer chip and digital signal processing (DSP) to convert the original electrical waveform into a digital signal, or string of bits. This results in less internal noise and distortion from the device and allows precise manipulation of the frequencies that the device is designed to amplify, also known as the frequency response of the device. The digital signal is then converted back into an analog electrical waveform for processing through the receiver (Hampson, 2012; Taylor & Mueller, 2011). While some analog hearing aids allow the use of a digital programmer for global adjustments of the analog electrical waveform, digital hearing aids use detailed algorithms to make fine adjustments to digitized sound (Taylor & Mueller, 2011).

There are also several acoustic features that are similar among hearing aids and PSAPs. For example, both hearing aids and PSAPs may be designed with a volume control that allows the user to increase or decrease the gain of the device. However, in contrast to most PSAPs, most digital hearing aids utilize advanced technology such as compression to control the amount of gain applied to the incoming sound, noise reduction and directional microphones to improve listening comfort in the presence of background noise, and feedback suppression to decrease "ringing" which was a common problem with hearing aids in the past (Caccamo, Voloshchenko, & Dankyi, 2014; Taylor & Mueller, 2011). Hearing aids, in addition to some PSAPs, may also be designed with multiple programming channels that allow manipulation of the digital signal, based on an individual's degree of hearing loss within specific frequency regions. Manufacturers of hearing aids and PSAPs may also offer Bluetooth compatibility, cellphone applications, and remote microphones to improve communication on the telephone or in noisy environments (Blum, 2016; Dillon, 2012; Taylor & Mueller, 2011). These acoustic features become more prevalent as the level of technology within the device progresses from basic to advanced. In addition, most hearing aids allow manipulation of these advanced features via customized software, while most PSAPs are pre-set and these features cannot be tailored to needs of the wearer (Blum, 2016).

Use based on degree of hearing loss. The degree of hearing loss often determines which amplification device and acoustic features will be most beneficial to an individual with hearing loss. BTE hearing aids are beneficial to individuals with all degrees of hearing loss. However, they are often recommended for individuals with greater degrees of hearing loss because they typically have greater power, more features, and a longer battery life. In contrast, ITE hearing aids are generally designed for individuals with mild to severe degrees of hearing loss because they do not provide as much amplification as a BTE (Taylor & Mueller, 2011). Lastly, for individuals with mild to moderate degrees of hearing loss, ITC or CIC hearing aids can typically provide an adequate amount of amplification (Hampson, 2012; Taylor & Mueller, 2011).

In contrast, PSAPs are more appropriate for individuals with milder degrees of hearing loss, particularly those individuals who have more situational difficulties and may not be ready or willing to pursue hearing aids (Clark, 1981; Kochkin, 2010; Shaw, 2014). However, there are PSAPs with the capability of accommodating up to a moderately-severe degree of hearing loss, such as the Soundhawk device that has a maximum output of 104 dB SPL or the CS 50 device that has a maximum output of 112 dB SPL (Soundhawk, 2016; Soundworld Solutions, 2016).

Cost of hearing aids and PSAPs. Within each category of amplification device, there are basic, middle, and advanced levels of technology and features of the device that correspond to the cost. Basic hearing aids typically feature simple technology and audiologists have limited control over their ability to program the devices. These basic hearing aids generally cost approximately $1500 per hearing aid. The cost of the device increases to approximately $3,000 for a hearing aid with more advanced technology, multiple programming channels, and greater acoustic performance (Caccamo et al., 2014; Mamo et al., 2016). Some manufacturers offer hearing aids that are designed to use rechargeable batteries in order to reduce costs for the wearer (Martin, 2012).

Similarly, basic PSAPs utilize lower levels of technology with less acoustic features and limited benefit for individuals with a greater degree of hearing loss (Cheng & McPherson, 2000; Mamo et al., 2016). Basic PSAPs can range in cost from $10 to $80 each and are often "one-size-fits-all" devices, offering only a volume control with high gain levels that may lead to over-amplification (Callaway & Punch, 2008; Cheng & McPherson, 2000). However, as seen in Table 2 below, some advanced PSAPs offer multiple programming channels and acoustic features, such as directional microphones, noise reduction, Bluetooth compatibility, and compression to maintain safe sound limits. The cost of advanced PSAPs is considerably lower than traditional hearing aids and they range in price from $100 to $500 per device (Blum, 2016; Callaway & Punch, 2008; Mamo et al., 2016). Some PSAPs are also designed to use rechargeable batteries, which further reduces the costs associated with wearing these devices (Blum, 2016; Soundhawk, 2016).

In summary, hearing aids and PSAPs have similarities, as well as differences, in their regulation, components, acoustic features, use in treating various degrees of hearing loss, and cost which are summarized in Table 2 below. The functioning and benefit of hearing aids and PSAPs can be evaluated with outcome measures that will be discussed in the next portion of this literature review.

Table 2

Acoustic Features of 5 PSAP Devices (Bean T-Coil, CS 50+, Soundhawk, Tweak) and Their Approximate Cost

PSAP Device	Sound Processing	Volume Control	Frequency Range	NAL-NL2 Targets Met (%)	Internal Noise Level	Maximum Output	Advanced Features	Cost
Soundhawk (Advanced)	Digital	Yes	200 Hz – 7000 Hz	67.31%	EIN: 20 dB SPL	101 dB SPL @ 4000 Hz	4 Eartips Wireless Microphone Smartphone Programming DM, NR, RB, BT	$399 each
CS 50+ (Advanced)	Digital	Yes Range: -12 to +12 dB SPL	200 Hz – 7300 Hz	63.46%	EIN: 28 dB SPL	120 dB SPL	3 Eartips 16 Channels 3 Programs Voice Prompts Smartphone Programming DM, NR, FC, RB, BT	$349 each
Bean T-Coil (Advanced)	Analog	2 Options: Low/High	200 Hz – 8000 Hz	53.85%	EIN: 34 dB SPL	101 dB SPL	7 Eartips T-Coil, C	$349 each
Tweak (Mid-Level)	Digital	Yes. 4 Settings	200 Hz – 7000 Hz	69.23%	EIN: 28 dB SPL	111 dB SPL	4 Eartips 4 Channels 2 Programs DM, NR, FC, C	$224.99 each
MSA 30x (Basic)	Analog	Yes	350 Hz – 4000 Hz	21.15%	EIN: 50 dB SPL	129 dB SPL	10 Eartips RB	$29.95 pair

Note: Acoustic Features of 5 PSAP Devices. Meeting targets defined as percentage within ± 5 dB to ±10 dB of prescribed NAL-NL2 targets at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz. DM = Directional Microphones; NR = Noise Reduction; FC = Feedback Cancellation; C = Compression; RB = Rechargeable Battery; BT = Bluetooth. Adapted from "Personal Sound Amplifiers for Adults with Hearing Loss" by S. Mamo and colleagues, 2016, *The American Journal of Medicine*, 129, 245-250; "Objective Analyses and Comparisons of Personal Sound Amplification Products" by Reed and colleagues, 2015, Poster session presented at the ASHA Convention, Denver, CO; and "Objective and Subjective Comparative Analysis of Personal Sound Amplification Products (PSAPs) and a Hearing Aid" by Polyak, 2016, (Unpublished doctoral thesis) Towson University, Maryland.

Measures of Hearing Aid or PSAP Benefit

Functional outcome measures can be used to ensure that hearing aids and PSAPs are operating properly, providing an appropriate amount of amplification, and benefiting the wearer in quiet and noisy environments. These functional outcome measures include electroacoustic analysis, real ear measurements, and speech-in-noise testing.

Electroacoustic analysis. Electroacoustic analysis is a quality control measure of hearing aid performance. During electroacoustic analysis, the hearing aid is attached to a standardized 2 cubic centimeter coupler that simulates the volume of the average adult ear canal. Several measures are obtained during electroacoustic analysis including the OSPL90, frequency range, automatic gain control, total harmonic distortion, equivalent input noise, and battery drain. Each measure is compared to the manufacturers' specifications to ensure that the hearing aid is operating properly before being fit to a patient (Dillon, 2012; Taylor & Mueller, 2011).

As seen in Figure 9 below, the OSPL90 curve (1) is a measure of the maximum output that a hearing aid is capable of delivering at all frequencies when there is a 90 dB SPL input, minimal compression, and the highest volume control setting (Dillon, 2012). The frequency range (2) is also obtained, which is the range between the highest and lowest frequencies with gain values 20 dB below the high-frequency average (HFA) gain. The HFA (3) is the average of the gain values at 1000 Hz, 1600 Hz, and 2500 Hz with a 60 dB SPL input signal (Audioscan, 2015).

Another measure obtained during electroacoustic analysis is automatic gain control (AGC) which evaluates the responsiveness of the compression feature of a hearing aid. The AGC (4) measures the time it takes for the hearing aid to attack, or apply compression to a loud input sound and release, or remove compression when the loud sound decreases. In addition, battery drain (not shown) is measured to assess the amount of current being drawn during operation of the hearing aid (Taylor & Mueller, 2011).

Lastly, the quality of the output sound from the hearing aid is measured via equivalent input noise (EIN) and total harmonic distortion (THD). The EIN (5) quantifies the internal noise generated by the hearing aid's microphone and receiver, while THD (6) is the percentage of distortion that is contained in the output of the hearing aid with an input of 70 dB at three frequencies: 500 Hz, 800 Hz, and 1600 Hz (Audioscan, 2015; Dillon, 2012; Taylor & Mueller, 2011).

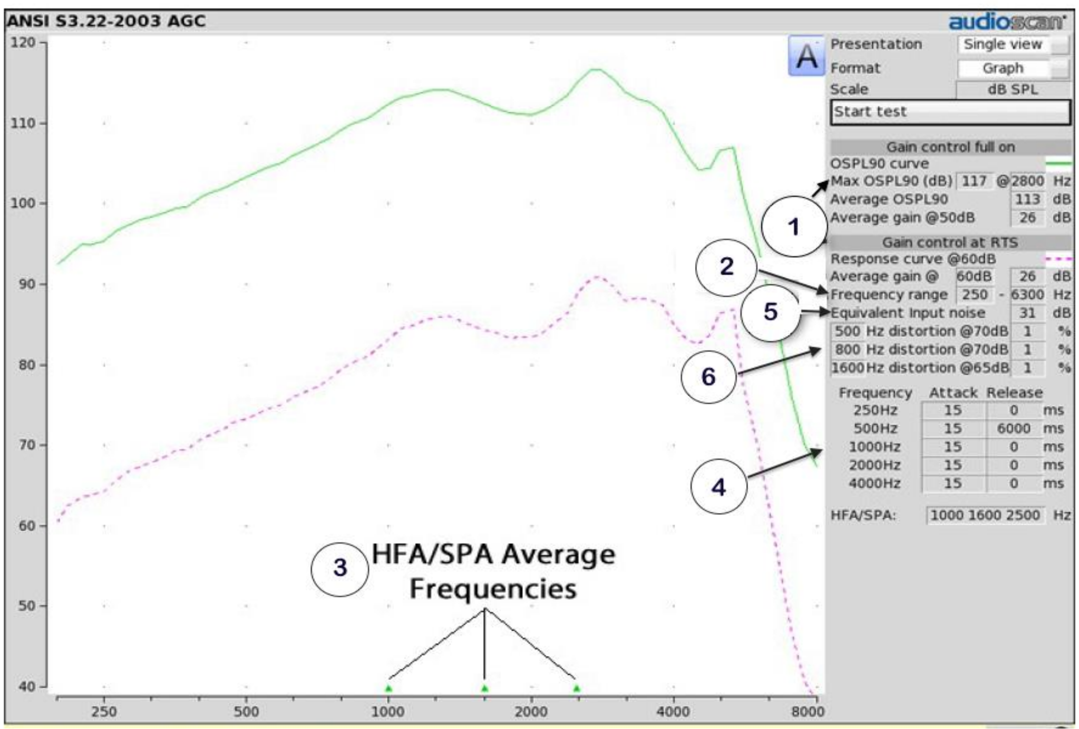


Figure 9. Example of electroacoustic analysis. Adapted from "Test box measures – setup." by Audioscan, 2015, *Verifit User's Guide Version 4.4*.

Real-ear measurements. Real-ear measurements are obtained to ensure that a hearing aid or PSAP is providing an appropriate amount of amplification in the patient's ear. This measure varies based on the size of the patient's ear canal, the design of the device, and the fit of the earpiece (Dillon, 2012). The process of obtaining real-ear measurements begins with placement of a small probe tube into the individual's ear canal without the hearing aid in place. This measures the individual's unique ear canal resonance, also known as the real-ear unaided response (REUR). A validated prescriptive method is then used to pre-program the device based on the individual's degree of hearing loss at each frequency (seen as yellow line in Figure 10). Two of the most common prescriptive methods are the National Acoustic Laboratories Non-Linear version 2 (NAL-NL2) and the Desired Sensation Level version 5 (DSL 5). These fitting formulas are used to prescribe target gain levels for soft, average, and loud input sounds (Taylor & Mueller, 2011). Once the fitting targets have been prescribed (seen as green hash marks in Figure 10), the hearing aid or PSAP is placed on the individual's ear and speech sounds are presented. These speech sounds are presented at soft, average, and loud levels and are plotted on a graph that displays the output of the device at each sound level.

The hearing aid output is plotted according to the Long-Term Average Speech Spectrum (LTASS) (seen as the green shaded region in Figure 10), which is an average of the spectral energy of the speech signal over time (Mendoza, Valencia, Munoz, & Trujillo, 1996). In addition, a series of brief loud tones are presented to ensure that the maximum output of the device does not exceed the uncomfortable loudness levels (UCLs) for the wearer (seen as red stars in Figure 10). This process is followed by adjustments to the amount of gain until the amplified LTASS, or the output of the device, closely matches the prescribed target gain in each frequency region (seen as the blue line in Figure 10) (Dillon 2012; Taylor & Mueller, 2011). Figure 10 displays an example of a real-ear measurement of hearing aid output that matches NAL prescriptive target gain for an average input sound of 65 dB SPL (Mueller, 2014).

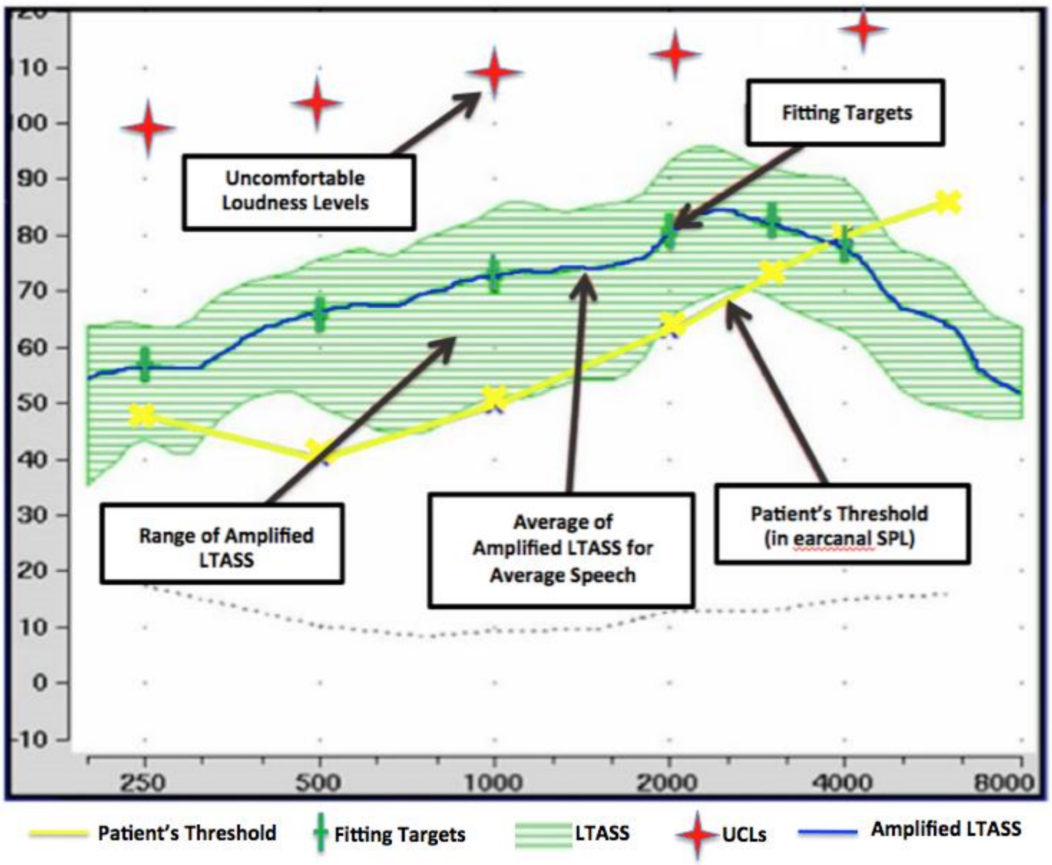


Figure 10. Examples of real-ear measurement of hearing aid output using a 65 dB SPL speech input with NAL prescriptive targets. Adapted from "20Q: Real-ear probe-microphone measures – 30 years of progress?" by H.G. Mueller, 2014, *Audiology Online*.

Speech-in-noise measures. One of the most common problems encountered by individuals with hearing loss is a decrease in the ability to understand speech in the presence of background noise (Wilson & McArdle, 2007). Speech-in-noise measures are used to validate the improvement in speech understanding in noise that occurs when individuals wear amplification devices. There are several speech-in-noise measures available for clinical use. Two of the most valid measures are the AzBio and the WIN (Spahr et al., 2012; Wilson & McArdle, 2007). These speech-in-noise measures will be described below.

AzBio. Spahr and Dorman developed the AzBio in 2004 at the Arizona Biomedical Institute at Arizona State University (Spahr et al., 2012). This speech-in-noise test originally consisted of 1000 sentences recorded with two female and two male voices. In 2012, Spahr and colleagues presented the AzBio sentences to 15 individuals with normal hearing using a cochlear implant simulation. The 1000 sentences were assessed for speech intelligibility and subsequently condensed into 33 lists of 20 sentences with an equivalent level of difficulty. List equivalency was then validated by randomly presenting all 33 lists to 15 individuals with cochlear implants. These researchers found that there was no significant difference in scores for 29 out of the 33 lists. This led to the development of the current AzBio Sentence Test that consists of 15 lists of 20 sentences. This test can provide a speech recognition score in percent correct in both a quiet setting and in the presence of background noise (Schafer, Pogue, & Milrany, 2012; Spahr et al., 2012).

The AzBio can be used to evaluate the speech recognition abilities of individuals with hearing loss before and after cochlear implantation. Individuals with cochlear implants often have difficulties understanding speech in the presence of background noise and may frequently undergo speech-in-noise testing. The AzBio can be useful in these cases because it is newer, less familiar, and one of the more difficult speech-in-noise tests (Spahr et al., 2014; Spahr et al., 2012). For example, Wilson and Dorman (2007) used the AzBio test to assess the speech recognition abilities of an individual with profound hearing loss who was fit with a cochlear implant. The AzBio sentences were presented at a signal-to-noise ratio (SNR) of +10 dB and +5 dB. The AzBio score of the cochlear implant recipient was compared to those of 6 individuals with normal hearing.

These researchers found that the AzBio score of the cochlear implant recipient was approximately 10 percent below the scores of the individuals with normal hearing demonstrating functional benefit from the cochlear implant (Wilson & Dorman, 2007).

The AzBio can also be useful in assessing the speech recognition abilities of individuals who use bimodal amplification, which is the use of a cochlear implant in one ear and a hearing aid in the opposite ear. For example, Dillon and colleagues used the AzBio to investigate the difference in speech recognition occurring when the hearing aid is programmed according to the cochlear implant manufacturer's recommendations versus when the NAL-NL1 prescriptive formula and real-ear measures are used. The AzBio was presented at a +10 dB SNR to 9 individuals with bimodal amplification. These researchers found that AzBio scores increased from an average of approximately 68 percent when using the manufacturer's recommended hearing aid settings to an average of approximately 80 percent when using the NAL-NL1 prescriptive formula and real-ear measures to program the hearing aid (Dillon et al., 2014).

Words in Noise (WIN). The Words in Noise (WIN) is another speech-in-noise test that can be used to evaluate the speech understanding of individuals who are fit with hearing aids or PSAPs. In 2003, Richard Wilson developed the WIN from words in the Northwestern University Auditory Test number 6 (NU-6). The WIN consists of 5 monosyllabic words presented at seven signal-to-noise ratios decreasing from 24 dB to 0 dB with a fixed level of multi-talker babble. The WIN test provides an SNR-50 which is the SNR at which an individual is able to understand 50 percent of the words presented. An SNR-50 that is less than or equal to 6 dB is considered normal speech understanding in noise (Wilson, Abrams, & Pillion, 2003; Wilson & Watts, 2012).

The WIN has been used in several studies that have examined the speech recognition abilities of individuals with hearing loss in the presence of background noise. For example, Wilson and Weakley (2005) examined the speech recognition abilities of 25 individuals aged approximately 23 years with normal hearing and 125 individuals aged 40 to 89 years with sensorineural hearing loss ranging from mild to severe. The participants were administered a 500 Hz masking-level difference (MLD) test of temporal resolution and the WIN test. These researchers found that the average WIN SNR-50 for the younger group with normal hearing was 3.5 dB and ranged from 9.4 to 14.6 dB for the older individuals with hearing loss. In addition, an increase in the WIN SNR-50 related more to the degree of hearing loss than to the age of the individual (Wilson & McArdle, 2007; Wilson & Weakley, 2005).

Reliability and stability of AzBio and WIN. Several studies have found the AzBio and WIN tests to be reliable tests of speech recognition in noise. In 2012, Schafer and colleagues examined the reliability and validity of the AzBio test by administering 15 lists of the AzBio to 14 adults aged 21 to 26 years with normal hearing and 12 individuals aged 14 to 76 years with cochlear implants. The individuals with cochlear implants were screened with the Bamford-Kowal-Bench Speech-in-Noise (BKB-SIN) test to confirm their speech recognition abilities in noise. Two SNRs of 0 and -3 were used when testing the individuals with normal hearing and an SNR of +10 dB was used when testing those with cochlear implants. These researchers calculated the within-subject difference scores between the test lists and found that the standard deviation for the individuals with normal hearing was 5.4 percent for the 0 dB SNR and 5.9 percent for the -3 dB SNR. For individuals with cochlear implants, the standard deviation of the within-subject difference scores was 2.7 percent. In addition, there was a significant correlation between the AzBio and BKB-SIN results for the patients with cochlear implants. Based on the results of their findings, Schafer and colleagues determined that the AzBio is a reliable and valid measure of speech recognition in noise for individuals with hearing loss (Schafer et al., 2012).

Wilson and McArdle (2007) also evaluated the intra- and inter- session retest reliability and the retest stability of the WIN test in a study of veterans from four VA Medical Centers. In the evaluation of the intra- and inter- session retest reliability of the WIN, two groups of 48 veterans aged approximately 52 to 87 years were administered the WIN in two sessions separated by 1 to 3 months. The first group had mild to severe sensorineural hearing loss and the second group had moderate to severe sensorineural hearing loss. These researchers found that the average SNR-50 scores for the first group were 13.0 and 13.4 dB for each session and for the second group they were 15.3 and 15.8 dB indicating that the WIN is reliable (Wilson & McArdle, 2007). In the evaluation of the retest stability of the WIN, one group of 315 veterans aged approximately 70 years with mild to severe sensorineural hearing loss were administered the WIN in two sessions separated by 1 year. These researchers found that the average SNR-50 score changed from 12.5 dB to 12.8 dB over the course of the two sessions indicating that the WIN is also stable (Wilson & McArdle, 2007).

Collectively, these studies demonstrate how the AzBio and the WIN can be used to assess improvements in speech understanding in noise for individuals who are fit with cochlear implants or hearing aids. Similarly, these two speech-in-noise tests have been used to evaluate the improvements in speech understanding in noise that occur when individuals are fit with either traditional hearing aids or PSAPs. Currently, there are only a limited number of studies that have examined the acoustic performance and benefits of PSAPs using electroacoustic analysis, real-ear measurements, and speech-in-noise testing. These studies will be discussed in further detail below.

Prior Research Examining the Acoustic Properties and Benefits of PSAPs.

The need for more affordable treatment options for hearing loss has led to a growing number of studies examining the acoustic properties and benefits of PSAPs. Several early PSAP studies have looked at both the electroacoustic and real-ear performance of several basic and mid-level devices (Cheng & McPherson, 2000; Callaway & Punch, 2008). More recent studies have used these functional outcome measures along with speech-in-noise testing to evaluate the performance and benefit of basic, mid-level, and advanced PSAP devices in comparison to traditional hearing aids (Polyak, 2016; Reed et al., 2015).

An early study by Cheng and McPherson (2000) examined the acoustic properties of 10 basic PSAP devices (six body-worn and four BTEs) that could be purchased for $80 U.S. dollars or less. The participants in this study were 10 adults with normal hearing. These researchers used electroacoustic analysis to assess the acoustic properties of each device including OSPL90, frequency range, total harmonic distortion, and equivalent input noise. They also obtained real-ear measurements to determine how well these devices met targets for the four different prescriptive fitting formulas: NAL-R, Prescription of Gain and Output (POGO), Berger, and Lilly. These researchers found that these basic PSAPs generally provided low amounts of gain and were not able to successfully meet the prescribed target gain levels in the mid- to high frequencies. They also reported that the total harmonic distortion levels were within the ANSI S3.22-1987 acceptable limits for most of these devices. However, 50 percent of the devices had high levels of equivalent input noise. Lastly, these basic PSAPs contained volume controls with a limited range which could result in under- or over-amplification (Cheng & McPherson, 2000).

Several years later, Callaway and Punch (2008) examined the acoustic properties of eight basic (< $100) and three mid-level ($100-$500) PSAP devices. These researchers were interested in assessing whether these 11 PSAPs would be appropriate amplification options for individuals with high-frequency hearing loss ranging from mild to moderately-severe. Electroacoustic and real-ear measurements were conducted on each of these PSAP devices. Callaway and Punch reported that the majority of the basic PSAPs had a limited frequency range and met only 12 to 33 percent of the prescribed NAL-R target gain levels. In contrast, the mid-level PSAPs offered a broader frequency range and met 55 to 89 percent of the prescribed target gain levels. These researchers also found that most of these PSAP devices had total harmonic distortion levels that were within the ANSI S3.22-1987 acceptable limits. However, the equivalent input noise was unacceptably high and the overall gain of these devices was emphasized mainly in the lower frequencies. Overall, these findings are in good agreement with the results reported by Cheng and McPherson (2000). Based on the results of their findings, Callaway and Punch determined that mid-level PSAPs may be more appropriate amplification options for individuals with hearing loss (Callaway & Punch, 2008).

In a recent study, Reed et al. (2015) compared the acoustic properties and benefit of 10 PSAPs (one basic PSAP and nine advanced PSAPs) to a traditional hearing aid.

These researchers used several functional outcome measures to evaluate patient outcomes with these devices. These outcome measures included electroacoustic analysis, simulated real-ear measurements, and speech-in-noise testing. Electroacoustic analysis revealed that the basic PSAP ($30) had high levels of both total harmonic distortion and equivalent input noise, as well as a limited frequency range. In contrast, approximately 44 percent of the advanced PSAPs ($150-$400) had broad frequency ranges and acceptable levels of total harmonic distortion and equivalent input noise. In addition, the results of simulated real-ear testing using a 2-cc HA1 coupler revealed that this select group (44%) of the advanced PSAPs met NAL-NL2 prescribed target gain levels (±10 dB) for the majority of the test frequencies (6/9 or 67%) (Reed et al., 2015).

In this same study, Reed and colleagues compared the benefit of 2 advanced PSAPs (the CS-50 and the Bean) to a traditional hearing aid. Both of these devices were fit by the audiologist. The participants were 5 individuals aged approximately 67 years with mild to moderate sensorineural hearing loss. These participants were presented the QuickSIN and WIN speech-in-noise tests at a SNR of +5 dB in both the unaided and aided conditions. Reed and colleagues found that the amount of improvement in aided speech-in-noise scores was similar across these three devices (Reed et al., 2015). Collectively, the results of electroacoustic analysis, real-ear measurements, and speech-in-noise testing suggest that advanced PSAPs may offer more benefit to individuals with mild to moderate sensorineural hearing loss when compared to basic and mid-level PSAPs. Also, these preliminary findings suggest that these two advanced PSAPs offer similar objective results when compared to a traditional hearing aid. Given these promising results, Reed and colleagues recommend that the potential clinical utility of advanced PSAPs warrants further research (Reed et al., 2015).

Another recent study by Polyak (2016) expanded upon our current knowledge in this area by directly comparing electroacoustic analysis, real-ear measurements, and speech-in-noise performance in 13 hearing impaired patients fit with 5 PSAPs versus one traditional hearing aid. Similar to the Reed et al. (2015) study, all of these devices were fit by an audiologist. The two primary aims of this study were to 1) examine the difference in functional outcome measures for a traditional hearing aid versus a PSAP device and 2) examine the difference in functional outcome measures for advanced versus basic PSAPs. The 5 PSAPs included one basic, one mid-level, and three advanced devices. The participants ranged in age from 61 to 80 years and had mild to moderately-severe sensorineural hearing losses. Electroacoustic analysis revealed that the mid-level and advanced PSAPs (CS-50 and the Bean) had similar frequency ranges, equivalent input noise, and total harmonic distortion when compared to the traditional hearing aid. In contrast, the basic device had a narrow frequency range and high levels of equivalent input noise and total harmonic distortion when compared to the traditional hearing aid. Real-ear measurements revealed that the traditional hearing aid performed best and met the NAL-NL2 prescribed target gain levels (±5 dB) from 500 to 4000 Hz approximately 94 percent of the time. The mid-level and advanced PSAPs, in contrast, met target gain levels approximately 55 to 70 percent of the time and the basic device only met the NAL-NL2 prescribed target gain levels approximately 20 percent of the time (Polyak, 2016). In addition, the participants' speech-in-noise performance on the AzBio was similar for the traditional hearing aid and the three advanced PSAPs. However, for the basic PSAP, the participants did consistently poorer in the aided condition versus the unaided condition for the speech-in-noise testing (Polyak, 2016).

Collectively, the preliminary results across these studies suggest that a select group of advanced PSAPs perform similarly to traditional hearing aids on electroacoustic analysis, real-ear measurements, and speech-in-noise testing. In contrast, basic PSAPs typically have high levels of equivalent input noise, emphasize low frequency gain, and fail to meet the majority of prescriptive target gain levels.

It is important to remember that in all of these preliminary studies the PSAP devices were fit by an audiologist. Since one of the advantages of PSAPs is that they are widely available for purchase on-line or over-the-counter, it is likely that many prospective users of these devices will be following the manufacturers' instructions to self-fit these devices. For the purposes of this literature review, we will refer to this as an "out-of-the-box" self-fitting. To date there has been no published research investigating differences, if any, in subjects' performance on functional outcome measures with an audiologist fit PSAP versus an "out-of-the-box" self-fitting. This issue will be discussed further in the following section of this literature review.

How PSAPs are Accessed and Approaches to Fitting.

In October 2015, the President's Council of Advisors on Science and Technology (PCAST) initiated an effort to address the hearing health of the aging population. One of their recommendations was the need for more accessible and affordable treatment options for hearing loss, such as PSAPs. Specifically, the council emphasized the need to "enhance the pace of innovation, decrease cost, and improve the capability, convenience, and use of assistive hearing devices for individuals whose hearing has diminished in a mild to moderate way with age" (PCAST, 2015). Specifically, their recommendations included 1) "Federal Trade Commission (FTC) enabling of a hearing aid prescription process similar to what is available for eyeglasses and contact lenses", 2) FDA creation of "a new category for "basic" hearing aids and associated hearing tests that are meant for sale "over-the-counter" allowing "innovators to enter the market" with "creative solutions to improve mild-to-moderate age-related hearing loss with devices that can be sold widely, allowing consumers to buy a basic hearing aid at the local pharmacy, online, or at a retail store for significantly less", and 3) FDA rescinding "it's previous draft guidance about (PSAPs) and allowing these devices to make truthful claims about capabilities like improving hearing or understanding in situations where environmental noise or crowded rooms might interfere with speech intelligibility" (PCAST, 2015).

As previously mentioned, currently PSAPs are not regulated by the FDA and can be purchased on-line or at a local drug store or retail chain (Mamo et al., 2016). Given this fact, adults with hearing loss may purchase these devices and follow the manufacturers' instructions to personally fit these devices. For the purposes of this literature review we are referring to this approach as an "out-of-the-box" self-fitting protocol.

Some of these hearing-impaired adults may be more technically savvy than others and may use the cell phone application that is offered with several of the advanced PSAPs, such as the CS 50+ or the Soundhawk, to fine-tune this fit. Both the CS 50+ and Soundhawk cell phone applications allow the user to fine-tune the acoustic features of the device including the volume, treble, and bass levels. The CS 50+ cell phone application also allows "personalization" of the acoustic settings of the device via a hearing screening that uses an algorithm to modify the gain for the device. For the purposes of this literature review this approach will be referred to as the “advanced-user” self-fitting protocol.

In contrast, if a hearing-impaired adult is pursuing a traditional hearing aid, they are required by the FDA to be fit with amplification by an audiologist or hearing aid dispenser. These hearing healthcare professionals may perform standard hearing testing as well as functional outcome measures to verify the appropriateness of the hearing aid fitting. This approach is considered the “gold-standard” fitting protocol and it serves as the benchmark for comparison of the performance of PSAPs to traditional hearing aids.

In the proposed study we are interested in comparing the hearing-impaired adult subjects’ performance with the CS 50+ and the Soundhawk PSAP devices that have been fit using three different fitting protocols. These three protocols are the “out-of-the-box” self-fitting, the “advanced-user” self-fitting, and the “gold-standard” fitting. For each protocol, the participants’ performance will be evaluated using two functional outcome measures: real-ear measurements (REMs) and speech-in-noise testing via the AzBio. The specific aims are to determine the following:

1. Are there any significant differences in the hearing impaired subjects’ performance on the AzBio speech-in-noise test in the aided versus unaided conditions while wearing the CS 50+ and Soundhawk PSAP devices?
2. Does the intervention of an audiologist via the “gold-standard” fitting protocol improve the subjects’ functional outcome measures

obtained via either the "out-of-the-box" or the "advanced-user" self-fitting protocols?

CHAPTER 3

METHODS

Participants

Nine subjects aged 51 to 82 years were recruited from the Towson University Institute for Well-Being Audiology Clinic, the Johns Hopkins Audiology Clinic, and the local community via flyers and word-of-mouth. The criteria for participation in this pilot study was 1) bilateral symmetrical slight to moderate sensorineural hearing loss defined as pure tone averages (3-PTAs: 500 Hz, 1000 Hz, 2000 Hz) of ≥20 dB and ≤55 dB, 2) air-bone gaps <10 dB, 3) normal immittance, 4) no evidence of noise-induced hearing loss, 5) no evidence of hearing loss secondary to a diagnosed medical condition, 6) no significant cognitive decline as evidenced by a score of ≥25 on the Department of Veterans Affairs St. Louis University Mental Status (VA-SLUMS) examination, and 7) no history of hearing aid usage > 1 month. Participants received reimbursement for their time in the form of a gift card.

Procedures

The participants were evaluated during one 2-3 hour test session at the Towson University Audiology Clinic. Audiologic testing was conducted in a double-walled sound-proof test booth using a calibrated audiometer. Each participant was administered the VA-SLUMS to ensure normal cognitive functioning and underwent an otoscopic examination, immittance testing to ensure normal middle ear functioning, pure tone air conduction testing at frequencies from 250 to 8000 Hz, bone conduction testing at frequencies from 500 to 4000 Hz, and un-aided speech-in-noise testing via the AzBio sentence test. The order of presentation of the AzBio sentence test lists was randomized across subjects.

Electroacoustic analysis via an Audioscan Verifit hearing aid analyzer was performed on the two advanced PSAPs (CS 50+ and Soundhawk) prior to the test session for each participant to ensure proper functioning of the devices. The measurements obtained during electroacoustic analysis included: average OSPL90, frequency range, equivalent input noise, and total harmonic distortion. These electroacoustic analysis measures were compared across the devices.

As previously mentioned, three separate fitting protocols were employed in this study. These fitting protocols were the "out-of-the-box" self-fitting protocol, the "advanced-user" self-fitting protocol, and the "gold-standard" fitting protocol. All subjects were tested with the "out-of-the-box" self-fitting protocol and the "gold-standard" fitting protocols with both the CS 50+ and the Soundhawk PSAP devices. Those hearing-impaired individuals who demonstrated a certain minimal level of technological skill and were able to utilize the manufacturer's cell phone application were also tested using the "advanced-user" self-fitting protocol for each of the two PSAP devices. Each of the three fitting protocols will be discussed further below.

Out-of–the-box self-fitting protocol. Each of the participants were asked to follow the manufacturer's instructions for an "out-of-the-box" self-fitting of each PSAP device. The "out-of-the-box" self-fitting protocol consisted of the following five steps:

1. The audiologist initially obtained the subject's real-ear unaided response (REUR) via placement of a probe-tube in the individual's ear canal.

2. Each participant was asked to follow the PSAP manufacturer's instructions to select a pre-programmed acoustic setting.
3. Each participant was asked to adjust the volume control button on the PSAP while listening to an AzBio list. This AzBio list was presented in the soundfield at a SNR of +5 dB using a sensation level approach regarding the participant's 3-frequency PTA (500 Hz, 1000 Hz, 2000 Hz). The subject's score on this specific list was not included in the report of their speech-in-noise scores.
4. Aided real-ear measurements were then be obtained via the Audioscan Verifit hearing aid analyzer with the probe-tube and PSAP device in the individual's ear to measure the output of the PSAP device. Real-ear measurements were obtained at an average speech (65 dB SPL). This real-ear data was compared to NAL-NL2 prescribed target gain levels.
5. Aided speech-in-noise testing was then administered via the AzBio Sentence test with an SNR of +5 dB using the same sensation level approach discussed above.

Advanced-user self-fitting protocol. Those participants who were able to perform an "advanced-user" self-fitting of each PSAP device via the manufacturer's cell phone application were allowed to do so. The audiologist had the two cell phone applications for these two PSAP devices installed on her phone. She was available for any questions the participant had during this process. The "advanced-user" self-fitting protocol consisted of the following six steps for each of the two PSAP devices:

***CS 50+ device*:**

1. Individual was asked to open the CS 50+ cell phone application and complete the hearing screening seen in Figure 11 below.
2. The CS 50+ cell phone application then modified the gain at low, mid-, and high frequencies based on the participant's degree of hearing loss.
3. Each participant was asked to select the "everyday" environmental setting seen in Figure 12 below.
4. The participant was asked to utilize the "equalize" feature on the CS 50+ cell phone application while listening to an AzBio list presented in the soundfield at SNR of +5 dB using a sensation level approach regarding the participant's 3-frequency PTA. As seen in Figure 12 below, this feature allows separate adjustments for the volume, treble, mid-, and bass gain levels. The subject's score on this specific list was not included in the report of their speech-in-noise scores. Once the participant completed their adjustment of these acoustic features, the real-ear measurement and speech-in-noise testing were completed at these settings.
5. Aided real-ear measurements were then obtained via the Audioscan Verifit hearing aid analyzer with the probe-tube and CS 50+ PSAP device in the individual's ear to measure the output of the PSAP device. Real-ear measurements were obtained at an average speech (65 dB SPL). This real-ear data was compared to NAL-NL2 prescribed target gain levels.

6. Aided speech-in-noise testing was then administered via the AzBio Sentence test with an SNR of +5 dB using the same sensation level approach discussed above.

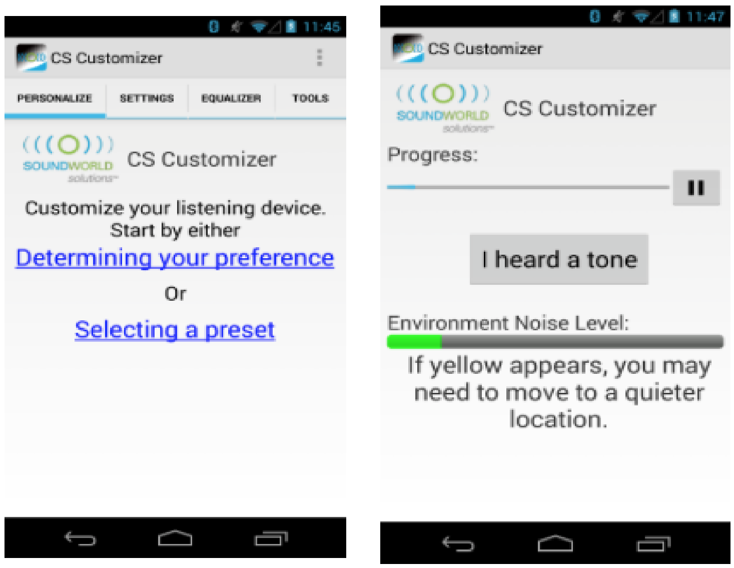


Figure 11. Examples of the hearing screening from the CS 50+ cell phone app. Adapted from "Soundworld solutions – CS50+ customizer app." by Soundworld Solutions, 2016.

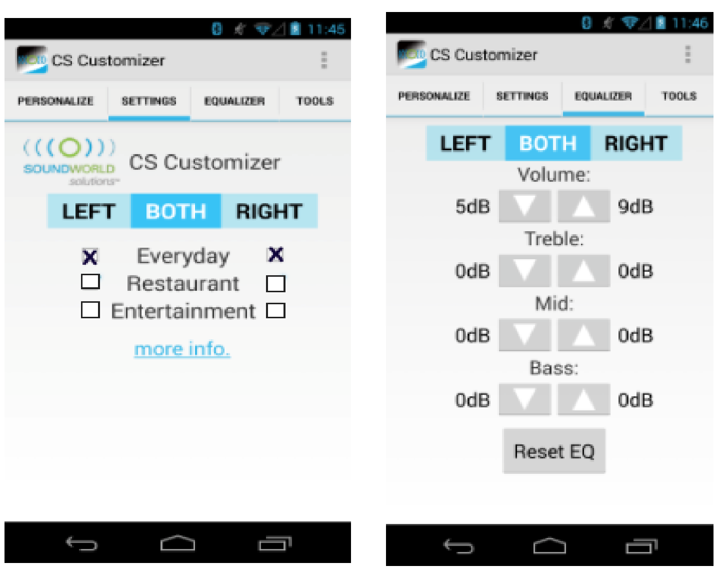


Figure 12. Examples of environmental and equalizer settings from the CS 50+ cell phone app. Adapted from "Soundworld solutions – CS 50+ customizer app." by Soundworld Solutions, 2016.

***Soundhawk device*.**

1. Each participant was asked to open the Soundhawk cell phone application and select the "indoors" listening environment as seen in Figure 13 below.
2. The participant was asked to utilize the "sound scene" feature on the Soundhawk cell phone application while listening to an AzBio list presented in the soundfield at SNR of +5 dB using a sensation level approach regarding the participant's 3-frequency PTA. As seen in Figure 13 below, this feature allows separate adjustments for the volume, low-, mid-, and high-frequency emphasis. The subject's score on this specific list was not included in the report of their speech-in-noise scores. Similarly, once the participant completed these adjustments, real-ear testing and speech-in-noise testing were conducted at this setting.
3. Aided real-ear measurements were then obtained via the Audioscan Verifit hearing aid analyzer with the probe-tube and Soundhawk PSAP device in the individual's ear to measure the output of the PSAP device. Real-ear measurements were obtained at an average speech (65 dB SPL). This real-ear data was compared to NAL-NL2 prescribed target gain levels.
4. Aided speech-in-noise testing was then administered via the AzBio Sentence test with an SNR of +5 dB using the same sensation level approach discussed above.

Figure 13. Examples of listening environment and sound scene settings from the Soundhawk cell phone app. Adapted from "Soundhawk smart listening system." by Soundhawk, 2016.

Gold-standard fitting protocol. During the "gold-standard" fitting protocol, the audiologist made adjustments to the acoustic settings of each of the two PSAP devices to meet NAL-NL2 prescribed target gain levels. Meeting targets is defined as within ± 5 dB of prescribed NAL-NL2 targets at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz. The "gold-standard" fitting protocol consisted of the following 3 steps:

1. The audiologist made adjustments to the acoustic settings of the PSAP device using the manufacturer's cell phone application and the volume control buttons.
2. Aided real-ear measurements were then obtained via the Audioscan Verifit hearing aid analyzer with the probe-tube and PSAP device in the individual's ear to measure the output of the PSAP device. Real-ear measurements were obtained at an average speech (65 dB SPL). This real-ear data was compared to NAL-NL2 prescribed target gain levels.

3. Aided speech-in-noise testing was then administered via the AzBio Sentence test with an SNR of +5 dB using the same sensation level approach discussed above.

In order to account for the effects of learning and fatigue, the order of devices and speech-in-noise sentence lists were randomized. In order to simulate a real world “out-of-the-box” and “advanced-user” self-fitting procedure, the participants were not informed of the results of their audiologic testing until the end of the test session. The results of electroacoustic analysis, real-ear measurements, and speech-in-noise testing were compared between each device and fitting protocol.

Statistical analysis. This is a pilot study and the ability to perform inferential statistics is limited by the small data set. All data analysis was primarily driven by descriptive statistics. The descriptive analysis of the AzBio speech-in-noise test data for each participant was performed using Microsoft Excel 2011 to include the range, mean, and standard deviation of scores. Real-ear measurement data was also analyzed using Microsoft Excel 2011 to include the percentage and root mean square (RMS) value of NAL-NL2 prescribed targets met within ± 5 dB. Excel and the Statistical Package for the Social Sciences (SPSS) were used to create figures and graphs for display of the collected data.

CHAPTER 4

RESULTS

The first two sections of the results will cover the demographics of the participants in this study and the results of the electroacoustic analyses performed for each of the two PSAP devices (Soundhawk and CS 50+). This will be followed by a discussion of the aided versus unaided AzBio speech-in-noise test results and the results of real-ear measurement for these two PSAP devices in the three fitting conditions (i.e., out-of-the-box, advanced-user, and gold-standard). Lastly, the relationship between AzBio score improvement in the aided versus unaided fitting condition and the accuracy of the real-ear measurements, revealed by the root mean square (RMS) values, will be explored.

Participants

The participants in this study consisted of 9 hearing impaired individuals (6 males and 3 females) with a mean age of 62.67 years. All participants had slight to mild sensorineural hearing losses. Their 3-frequency PTAs (500 Hz, 1000 Hz, and 2000 Hz) ranged from 18.33 to 36.67 dB HL. Table 3 below displays demographic information for each participant, including his or her age, gender, behavioral thresholds for each frequency, and 3-frequency pure tone average.

Table 3

Demographic Characteristics of Participants

Participant	Gender	Age	500 Hz	1000 Hz	2000 Hz	4000 Hz	3-PTA
001	Male	82	15	15	40	65	23.33
002	Male	51	20	20	30	25	23.33
003	Female	54	25	35	25	10	28.33
004	Female	59	20	25	20	25	21.67
005	Male	61	10	20	25	55	18.33
006	Male	51	15	25	25	35	21.67
007	Male	58	40	40	30	30	36.67
008	Male	78	20	30	35	75	28.33
009	Female	70	25	30	30	30	28.33
Mean		**62.67**	**21.11**	**26.67**	**28.89**	**38.89**	**25.55**
SD		11.45	8.58	7.91	6.01	21.33	5.47

Note. 3-PTA = pure tone average in dB HL for 500 Hz, 1000 Hz, and 2000 Hz.
SD = standard deviation.

Electroacoustic Analysis Results

The mean and standard deviation for all electroacoustic measurements taken in the current study, as well as the manufacturers' specifications for these parameters are presented in Table 4 below. As seen in this table, the electroacoustic results obtained for both PSAP devices are in relatively good agreement with the manufacturers' specifications for these four parameters. This is especially true for frequency range, total harmonic distortion, and average OSPL90 measures. The complete manufacturers' specifications for the two PSAPs can be found in Appendix A.

Table 4

Mean and Standard Deviation for Electroacoustic Analysis Measurements Taken for the Two PSAPS in Current Study and the Manufacturers' Specification for These Parameters

Device		Average OSPL90	Frequency Range	Equivalent Input Noise	Total Harmonic Distortion
Soundhawk	*Mean*	93.71 dB SPL	<200-6871 Hz	41.57 dB SPL	1.00%
	SD	2.06		1.40	.58
Manufacturer's Specifications		96 dB SPL	<200-6720 Hz	<34 dB SPL	<2%
CS 50+	*Mean*	102.43 dB SPL	<200-7807 Hz	36.29 dB SPL	1.29%
	SD	5.32		5.59	.49
Manufacturer's Specifications		Not Available	200-8000 Hz	26 dB SPL	≤1%

Note: Mean values for all electroacoustic analysis measurements taken for both PSAP devices (Soundhawk and CS 50+). SD = standard deviation.

Aided versus Unaided AzBio Results

Table 5 (below) contains the mean unaided and aided AzBio scores for all three fitting protocols. The results for the Soundhawk device are found on the left side of the table, while the results for the CS 50+ are found on the right side of the table. The individual subject data for these three fitting conditions is also displayed. This same organization will be followed in Table 6.

The mean aided AzBio scores showed an improvement over the unaided scores in all test conditions, as seen in Table 5 below. The variability in AzBio scores, reflected in the standard deviation values, were similar across the aided and unaided test conditions.

The majority of the individual subjects, 5 out of 9 (56%), also showed improvement in their aided versus unaided AzBio test scores for both PSAP devices. Participant 8 showed the most improvement from an unaided score of 28% to aided scores ranging from 48% to 68% across all test conditions. There were two additional patterns seen in the individual subject results. For example, one participant (participant 7) showed the opposite pattern when compared to the group data. Specifically, he had an unaided performance of 72% which decreased to aided scores ranging from 44% to 70% across test conditions. The only exception to this was his aided score of 78% with CS 50+ device in the gold-standard fitting protocol. Lastly, three participants (1, 2, and 6) showed little, if any, change in aided versus unaided performance in either their out-of-the-box or advanced-user self-fitting protocols. For example, participant 2 had an unaided performance of 55% which decreased to an aided score of 54% in the out-of-the-box self-fitting protocol with both PSAP devices.

Table 5

Descriptive Statistics for Unaided and Aided Performance on the AzBio Test for Two PSAPs: Soundhawk (Left) and CS 50+ (Right)

		PSAPs					
		SOUNDHAWK			CS 50+		
Participant	**Unaided**	**Out-of-the-Box**	**Advanced User**	**Gold Standard**	**Out-of-the-Box**	**Advanced User**	**Gold Standard**
001	63	75	87	77	62	82	85
002	55	54	75	84	54	61	59
003	62	80	81	84	74	86	82
004	64	72	69	80	72	69	74
005	55	70	77	68	60	71	75
006	64	67	51	64	67	63	67
007	72	62	60	70	44	66	78
008	28	58	56	68	48	51	52
009	52	90	87	81	66	77	77
Mean	**57.16**	**69.80**	**71.60**	**75.09**	**60.61**	**69.38**	**71.97**
SD	12.58	11.12	13.51	7.66	10.42	10.73	10.83

Note: Descriptive statistics (mean and standard deviation) for unaided and aided performance on the AzBio speech-in-noise sentence test for two PSAPs: Soundhawk (on left) and CS 50+ (on right) for each subject using three different fitting protocols: out-of-the-box, advanced user, and gold-standard. SD = standard deviation.

Aided versus unaided difference scores for AzBio results for each fitting protocol. Difference scores were calculated for each fitting protocol for both PSAP devices. These difference scores were calculated by subtracting the participant's unaided AzBio score from their aided AzBio score for each test condition. A positive AzBio difference score indicates an improvement in the participant's aided performance over their unaided performance.

Figure 14 (below) displays a graph of the mean difference scores on the AzBio test as a function of the three fitting protocols (out-of-the-box, advanced-user, and gold-standard). These results are plotted separately for the two PSAP devices: Soundhawk (blue) and CS 50+ (green). These mean difference scores ranged from 3.45% to 17.93%, showing aided improvement occurred for all fitting conditions. The greatest improvement in the mean aided versus unaided AzBio scores occurred in the gold-standard fitting condition for both the Soundhawk and the CS 50+ devices, which were approximately 18% and 15%, respectively. This was followed by the advanced-user self-fitting condition in which the mean difference scores ranged from approximately 12% to 14%. As expected, the least improvement in the mean difference scores occurred in the out-of-the-box self-fitting condition. This was true for both PSAP devices with the mean difference scores ranging from 3.45% to 12.64%.

When comparing the two PSAP devices, the greatest improvement in the mean difference scores occurred with the Soundhawk device across all three test conditions. The mean difference score was 12.64% for the out-of-the-box self-fitting protocol and improved to 17.93% for the gold-standard fitting protocol. In contrast, for the CS 50+ device, the mean difference score was 3.45% for the out-of-the-box self-fitting protocol and improved to 14.81% in the gold-standard fitting protocol. Overall, the variability in these mean difference scores, reflected in the standard deviation values, was similar across test conditions.

In general, the difference scores for each individual participant showed a positive improvement in their AzBio scores for all three test protocols, as shown in Table 6. The extent of that aided improvement, however, was quite variable across subjects and test conditions: ranging from 3% to 40%. There were a few instances, in contrast, where the participant performed poorer in the aided condition versus the unaided condition creating a negative difference score. This occurred more frequently in the out-of-the-box and the advanced-user self-fitting protocols versus the gold-standard fitting protocol.

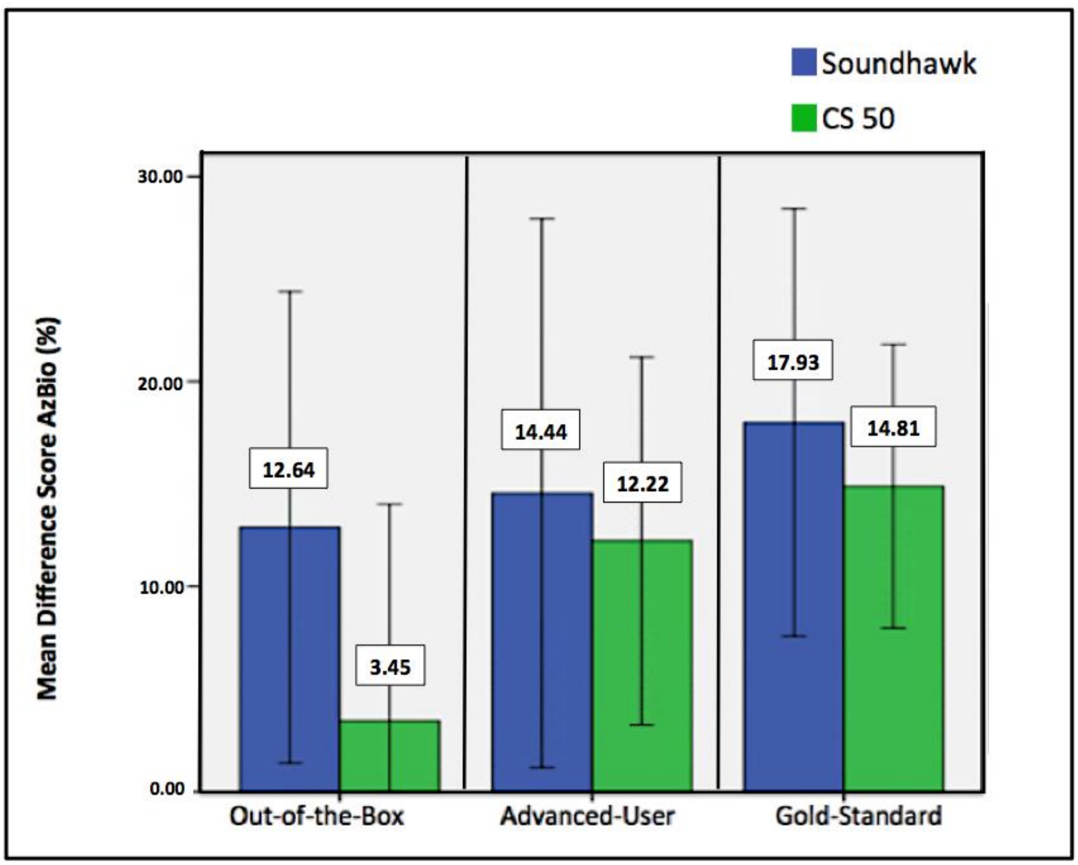


Figure 14. Mean difference scores in percentage (%) between unaided and aided performance on the AzBio speech-in-noise test for each PSAP device in each fitting condition. Error bars represent 95% confidence interval.

Table 6

Descriptive Statistics for Difference Scores between Unaided and Aided Performance on the AzBio Speech-in-noise Test

	PSAPs					
	SOUNDHAWK			**CS 50+**		
Participant	**Out-of-the-Box**	**Advanced User**	**Gold Standard**	**Out-of-the-Box**	**Advanced User**	**Gold Standard**
001	12	25	14	-1	19	22
002	-1	20	29	-2	6	4
003	18	19	22	12	23	20
004	8	5	16	7	4	10
005	16	23	13	6	16	20
006	3	-13	0	3	-1	3
007	-9	-12	-1	-28	-6	6
008	31	28	40	20	24	24
009	38	36	29	14	25	25
Mean	**12.64**	**14.44**	**17.93**	**3.45**	**12.22**	**14.81**
SD	14.99	17.28	13.52	13.68	11.62	9.12

Note: Descriptive statistics (mean and standard deviation) for difference scores between unaided and aided performance (aided – unaided = difference score) on the AzBio speech-in-noise sentence test for two PSAPs: Soundhawk (on left) and CS 50+ (on right) for each subject using three different fitting protocols: out-of-the-box, advanced user, and gold-standard. SD = standard deviation.

Real-Ear Measurement Results

Real-ear measurements were obtained for each PSAP device as a function of fitting protocol. Initially, the subject's hearing thresholds were entered into the Verifit system. A probe was then inserted into the subject's ear canal and the PSAP device was placed onto the subject's ear. Real-ear aided measurements were then obtained at an average speech level (65 dB SPL) and compared to NAL-NL2 prescribed target gain levels. Meeting targets is defined as falling within ± 5 dB of prescribed NAL-NL2 targets at each test frequency (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz).

Table 7 (below) contains the mean NAL targets met for each PSAP device for all three fitting protocols. The results for the Soundhawk device are found in the upper panel of the table, while the results for the CS 50+ are found in the lower panel. As seen in Table 7, the percentage of NAL total targets met by the two PSAP devices ranged from approximately 53% to 69%. The targets were met best at 500 Hz with a total of 45/54 (83%) targets met versus only 15/54 (28%) targets met at 4000 Hz. These values for the total number of targets met are collapsed across the devices and fitting protocols.

The accuracy in meeting NAL targets did not differ substantially across the three fitting protocols. Specifically, the highest total percentages of NAL targets were met in the gold-standard fitting condition for both PSAP devices. The CS 50+ met approximately 69% of the total targets in the gold-standard fitting condition, followed by the Soundhawk which met approximately 64% of the total targets. In contrast, the out-of-the-box self-fitting protocol yielded the lowest percentage of total NAL targets being met for the CS 50+ (approximately 53%); whereas the advanced-user self-fitting protocol yielded the lowest percentage of total NAL targets met for the Soundhawk (approximately 58%).

Table 7

NAL-NL2 Targets Met for Each PSAP Device in Each Fitting Condition

Device		500 Hz	1000 Hz	2000 Hz	4000 Hz	Total Targets Met (%)
Soundhawk	Out-of-the-Box	6/9	5/9	7/9	4/9	22/36 (61.11%)
	Advanced User	9/9	6/9	5/9	1/9	21/36 (58.33%)
	Gold Standard	7/9	5/9	7/9	4/9	23/36 (63.89%)
CS 50+	Out-of-the-Box	7/9	6/9	4/9	2/9	19/36 (52.78%)
	Advanced User	8/9	7/9	4/9	1/9	20/36 (55.56%)
	Gold Standard	8/9	8/9	6/9	3/9	25/36 (69.44%)
	Total Targets	45/54 (83%)	37/54 (69%)	33/54 (61%)	15/54 (28%)	131/216 (60.64%)

Note: The percentage of NAL-NL2 target met within ± 5 dB for the frequencies 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz was calculated for each PSAP device (Soundhawk and CS 50+) in each fitting condition (out-of-the-box, advanced-user, gold-standard).

There were several instances where the PSAP devices did not meet the NAL targets within ± 5 dB. For these instances, the amount of over-shoot or under-shoot was calculated and these results are displayed below in Table 8. The amount of over-shoot or under-shoot was quite variable across subjects and test conditions, however the PSAP devices tended to over-shoot or under-shoot most often at 4000 Hz.

Table 8

Amount of Overshoot and Undershoot for NAL-NL2 Targets Not Met for Each Device in Each Fitting Condition

Device	Fitting Condition	500 Hz	1000 Hz	2000 Hz	4000 Hz
Soundhawk	Out-of-the-Box	2 - ↑10dB 1 - ↓10dB	1 - ↑15dB 1 - ↓15dB 2 - ↑10dB	1 - ↑15dB 1 - ↑10dB	1 - ↑20dB 1 - ↑15dB 1 - ↓15dB 1 - ↑10dB 1 - ↓10dB
	Advanced User		1 - ↑15dB 1 - ↑10dB 1 - ↓10dB	1 - ↑20dB 1 - ↑15dB 2 - ↑10dB	1 - ↓20dB 3 - ↑15dB 2 - ↓15dB 2 - ↓10dB
	Gold Standard	1 - ↑10dB 1 - ↓10dB	1 - ↓15dB 1 - ↑10dB 2 - ↓10dB	1 - ↑10dB 1 - ↓10dB	2 - ↓15dB 3 - ↓10dB
CS 50+	Out-of-the-Box	1 - ↑15dB 1 - ↓10dB	1 - ↑10dB 2 - ↓10dB	1 - ↑15dB 3 - ↑10dB 1 - ↓10dB	1 - ↑20dB 1 - ↓20dB 2 - ↑15dB 2 - ↓15dB 1 - ↓10dB
	Advanced User	1 - ↓10dB	2 - ↓10dB	1 - ↑20dB 3 - ↑15dB 1 - ↓10dB	1 - ↑25dB 1 - ↓20dB 1 - ↑15dB 2 - ↓15dB 2 - ↑10dB 1 - ↓10dB
	Gold Standard	1 - ↓10dB	1 - ↓15dB	2 - ↑10dB 1 - ↓10dB	1 - ↑20dB 1 - ↓20dB 1 - ↓15dB 2 - ↑10dB 1 - ↓10dB

Note: This table only displays data for NAL-NL2 targets not met. The amount of overshoot and undershoot for NAL-NL2 targets not met within ± 5 dB for each device (Soundhawk and CS 50+) for each of the three fitting conditions (out-of-the-box, advanced-user, gold-standard) is displayed. The number of conditions for which targets were not met at each frequency is followed by either an up arrow (↑) indicating that the output from the device was above target or a down arrow (↓) indicating that the output from the device was below target. The number following the arrow indicates whether the output was within 10 dB, 15 dB, or 20 dB of the NAL-NL2 target. A shaded space indicates that all targets were met at that frequency and test condition for all participants.

For the purposes of this study, root mean square (RMS) values were calculated to determine how far off the outputs of the two PSAP devices (Soundhawk and CS 50+), assessed via the real-ear measurements, were from the prescribed NAL targets. A low RMS value indicates greater accuracy in meeting the prescribed NAL targets. The RMS is calculated by 1) squaring all values, 2) calculating the arithmetic mean of all squares, and 3) taking the square root of the mean of all squares (Freedman, Pisani, & Purves, 2007).

For each subject, we took the prescribed NAL target and compared it to the actual output of the PSAP device at each test frequency (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz). For example, if the prescribed NAL target at 500 Hz was 54 dB and the output of the device was 50 dB, the difference between these two values was entered into the RMS formula. The 3-frequency (500 Hz, 1000 Hz, and 2000 Hz) and 4-frequency (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) average RMS values were calculated for each subject for each PSAP device. Table 9 (below) contains the 3-frequency and 4-frequency RMS values represented as 3-RMS and 4-RMS, respectively, for each of the three fitting protocols. The values for the Soundhawk device are displayed in the top table and the values for the CS 50+ device are displayed in the bottom table. The difference scores (%IMP) for the aided versus unaided AzBio results are also contained in Table 9 for each subject and fitting protocol.

Overall, the mean 3-RMS values were lower than the mean 4-RMS values for both PSAP devices across all fitting conditions, suggesting that the 3-RMS value more accurately represents how well the PSAP devices met NAL targets. As shown in Table 9, the greatest accuracy in meeting the NAL prescribed targets, reflected in the lowest mean

3-RMS and 4-RMS values, occurred in the gold-standard fitting condition for both the Soundhawk (3-RMS: 6.66) and the CS 50+ (3-RMS: 7.15) devices. In contrast, the least accuracy in meeting the NAL targets, reflected in the highest 3-RMS values, occurred in the advanced-user fitting condition for the CS 50+ device (mean 3-RMS: 10.70) and in the out-of-the-box self-fitting protocol for the Soundhawk device (mean 3-RMS: 9.43).

When comparing the mean RMS values of two PSAP devices, the Soundhawk device showed an overall greater accuracy in meeting NAL prescribed targets in comparison to the CS 50+ device. This was true for both the 3-frequency and 4-frequency RMS values across the majority of the fitting conditions. Overall, the variability in the difference scores, reflected in the standard deviation values, was similar across test conditions.

Table 9

Descriptive Statistics for Difference Scores between Unaided and Aided Performance on AzBio Speech-in-Noise Test and RMS Values for NAL-NL2 Targets Met for Each PSAP Device

SOUNDHAWK									
Participant	**Out-of-the-Box**			**Advanced User**			**Gold Standard**		
	%IMP	3-RMS	4-RMS	%IMP	3-RMS	4-RMS	%IMP	3-RMS	4-RMS
001	12	3.74	3.74	25	8.54	15.56	14	6.00	12.53
002	-1	8.31	13.00	20	17.15	22.14	29	3.61	7.00
003	18	15.26	22.85	19	23.37	27.77	22	1.41	7.14
004	7	5.41	10.07	5	2.29	9.77	16	2.06	10.70
005	16	9.41	9.87	23	8.22	8.46	13	4.85	5.70
006	3	10.17	10.22	-13	6.20	16.23	0	13.51	13.51
007	-9	14.05	14.92	-12	7.71	18.67	-1	14.37	14.68
008	30	14.12	18.53	28	4.74	7.65	40	7.58	12.55
009	38	4.39	12.31	36	5.77	11.98	29	6.58	6.60
Mean	**12.64**	**9.43**	**12.84**	**14.44**	**9.33**	**15.36**	**17.93**	**6.66**	**10.05**
SD	14.99	4.38	5.51	17.28	6.67	6.72	13.52	4.60	3.44

CS 50+									
Participant	**Out-of-the-Box**			**Advanced User**			**Gold Standard**		
	%IMP	3-RMS	4-RMS	%IMP	3-RMS	4-RMS	%IMP	3-RMS	4-RMS
001	-1	14.49	20.15	19	17.46	17.72	22	10.72	14.66
002	-2	7.48	13.30	6	15.03	19.24	4	6.16	9.33
003	12	10.10	22.41	23	15.59	29.46	20	5.66	19.82
004	7	3.64	13.98	4	3.20	8.15	10	5.22	6.28
005	5	6.28	10.17	16	5.43	8.86	20	4.30	9.97
006	3	5.87	6.20	-1	15.12	17.59	3	7.45	7.45
007	28	11.81	18.32	-6	10.37	15.86	6	13.87	14.20
008	20	9.46	18.59	24	12.06	20.04	24	7.45	21.34
009	14	12.70	12.94	25	2.06	12.67	25	3.50	11.07
Mean	**3.45**	**9.09**	**15.12**	**12.22**	**10.70**	**16.62**	**14.81**	**7.15**	**12.68**
SD	13.68	3.56	5.17	11.62	5.79	6.46	9.12	3.29	5.26

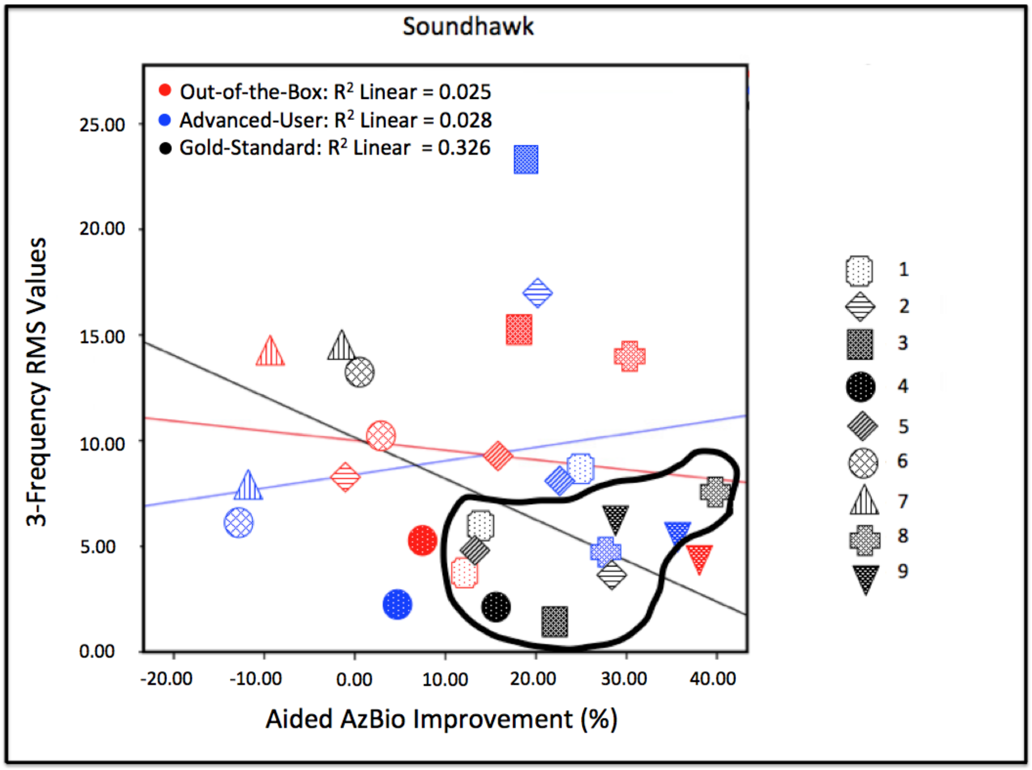
Note: Descriptive statistics (mean and standard deviation) for difference scores between unaided and aided performance (aided – unaided = difference score) on the AzBio speech-in-noise sentence test and 3- and 4-frequency RMS values for NAL-NL2 targets met for two PSAPs: Soundhawk (top table) and CS 50+ (bottom table) for each subject using three different fitting protocols: out-of-the-box, advanced user, and gold-standard. %IMP = percent aided AzBio score improvement; 3-RMS = 3-frequency RMS (500 Hz, 1000 Hz, and 2000 Hz); 4-RMS = 4-frequency RMS (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz); *SD* = standard deviation.

Aided Improvements in AzBio Scores As It Relates To RMS Values

We examined whether there was a relationship between aided improvements in AzBio scores, reflected in participants' difference scores, and their 3-RMS values. The relationship was investigated separately for each of the PSAP devices. As previously mentioned, a low 3-RMS score indicates that the PSAP met NAL targets well. A high difference score on the AzBio test suggests better aided benefit from the PSAP device.

Figure 15 (below) presents each of the nine participants' 3-RMS values as a function of their aided AzBio improvement in percentage. Linear regression lines were fit to the data for each fitting protocol. The results obtained with the Soundhawk are displayed on the top panel and the CS 50+ results are on the lower panel. As seen in Figure 15, it appears that there is a cluster of responses for the gold-standard fitting protocol, as indicated in the circled region, for both PSAP devices. The responses within this region show low 3-RMS values, as well as relatively high aided AzBio improvement with difference scores ranging from approximately 10% to 40%. These clustered regions suggest that the PSAPs fit using the gold-standard fitting protocol were more accurate in meeting NAL targets, which in turn yielded higher aided improvement on the AzBio test.

It was observed that the highest positive correlation between a low RMS value (i.e., good fit) and greater aided improvement in AzBio scores was seen in the gold-standard fitting protocol. However, this relationship did not reach statistical significance for either PSAP device, as shown by the low correlation values of R^2 equaling 0.326 for the Soundhawk device and 0.094 for the CS 50+ device. In contrast, the results for the two self-fitting protocols (out-of-the-box and advanced-user) appeared to yield a much more random pattern with lower positive correlations. Specifically, the advanced-user correlation values of R^2 were 0.028 for the Soundhawk and 0.004 for the CS 50+, while the out-of-the-box correlation values of R^2 were 0.025 for the Soundhawk and 0.034 for the CS 50+. These preliminary results are encouraging; however, they should be interpreted with caution due to the small data set (*n*= 9).



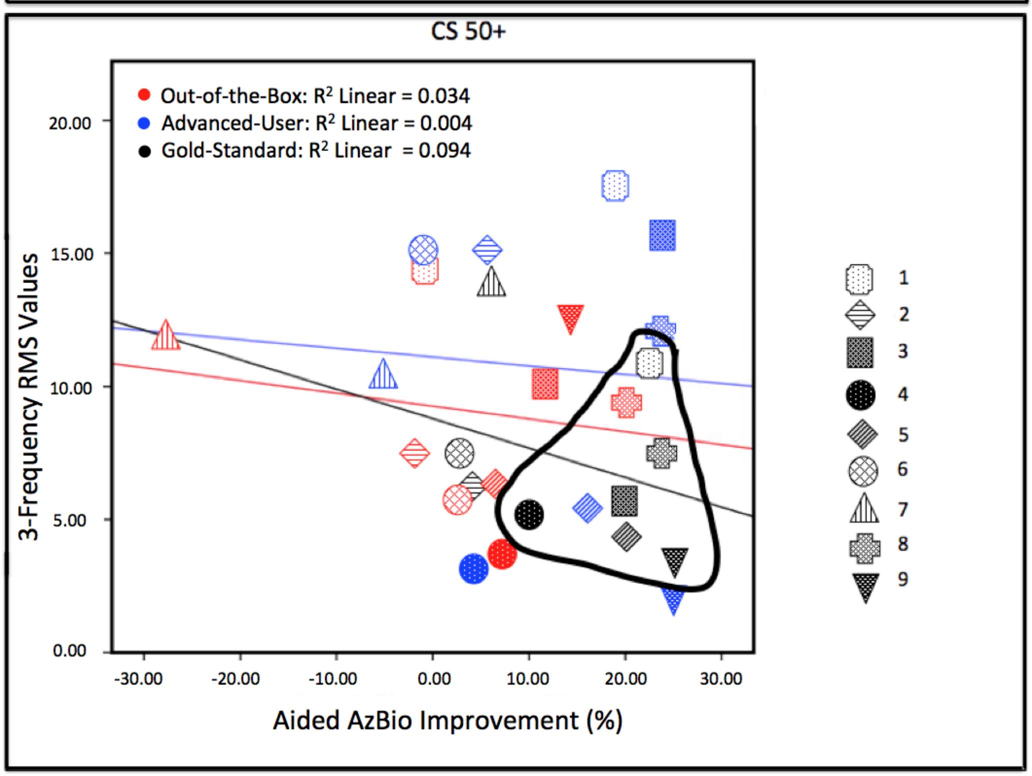


Figure 15. The 3-frequency (500 Hz, 1000 Hz, 2000 Hz) root-mean-square (RMS) values were calculated for each participant, PSAP device: Soundhawk (top panel) and CS 50+ (lower panel), and fitting condition: out-of-the-box (in red), advanced-user (in blue), gold-standard (in black). Separate linear regression lines were fit to the data for each fitting protocol.

CHAPTER 5

DISCUSSION

The aims of this pilot study were to examine 1) differences in the subjects' performance on the AzBio speech-in-noise test in the aided versus unaided conditions while wearing the Soundhawk and CS 50+ PSAP devices and 2) the influence of fitting approach for these two PSAP devices on the subjects' functional outcome measures (i.e., AzBio scores and real-ear measurements). This section will include a discussion of the data obtained from electroacoustic analyses, aided and unaided AzBio testing, and real-ear measurements. We will also explore the relationship of the AzBio scores to the RMS values. This will be followed by a discussion of the limitations, future directions, and possible clinical implications of the findings from this current study.

Electroacoustic Analysis

Electroacoustic analysis was performed on both PSAP devices (Soundhawk and CS 50+) prior to each test session. Several acoustic measures were examined which included average OSPL90, frequency response, equivalent input noise, and total harmonic distortion. Overall, both PSAP devices had broad frequency ranges and acceptable mean average OSPL90 and total harmonic distortion levels based on ANSI standards for hearing aids. However, the mean equivalent input noise levels were high for both devices, ranging from 36.29 dB SPL (CS 50+) to 41.57 dB SPL (Soundhawk).

To date, there are few published studies that have examined the electroacoustic properties of advanced PSAP devices. Prior studies, such as those by Callaway and Punch (2008) and Cheng and McPherson (2000) have examined the acoustic properties of basic PSAP devices and consistently found that they have narrow frequency ranges, high total harmonic distortion, and poor equivalent input noise levels. In contrast, this study focuses on advanced PSAPs; therefore a direct comparison to the results of those studies cannot be made. However, a few preliminary studies have examined the electroacoustic properties of advanced PSAP devices.

For example, a recent study by Reed et al. (2015) examined the electroacoustic properties of ten PSAP devices: one basic PSAP device and nine advanced PSAP devices that included the Soundhawk and CS 50. These researchers looked at the same electroacoustic measures investigated in the current study. Reed and colleagues reported that a select group of advanced PSAP devices, which included the Soundhawk and CS 50 had broad frequency ranges and acceptable levels of total harmonic distortion and equivalent input noise as specified by ANSI standards for hearing aids.

In addition, a follow-up study by Polyak (2016) also examined the electroacoustic properties of 5 PSAPs that included one basic, one mid-level, and three advanced devices (Soundhawk, CS 50, Bean). Again, the same electroacoustic parameters, as previously discussed, were assessed. Polyak (2016) reported that these advanced PSAPs had frequency ranges and total harmonic distortion levels that were similar to a traditional hearing aid. However, the researcher found that the equivalent input noise levels were high for all of the PSAP devices.

Collectively, the results of these recent studies are in good agreement with the findings of this current study. These studies suggest that advanced PSAPs generally have similar electroacoustic properties to traditional hearing aids.

Aided versus Unaided AzBio

Each of the nine participants were administered the AzBio speech-in-noise test in the aided versus unaided condition while wearing each of the two PSAP devices. This test protocol was conducted in each of the three fitting protocols: out-of-the-box, advanced-user, and gold-standard. Specifically, we were looking for the following: 1) any differences in the hearing impaired subjects' performance on the AzBio test in the aided versus unaided conditions while wearing the PSAP devices, and 2) any differences in performance between the three fitting protocols.

We found that the mean aided AzBio scores showed substantial improvements over the unaided scores across all test conditions for both PSAP devices. These results are similar to the findings of several recent preliminary studies in this area. For example, Reed and colleagues (2015) examined the aided benefit of two advanced PSAP devices (CS 50 and the Bean) versus a traditional hearing aid. Each of the participants were administered the QuickSIN and WIN speech-in-noise tests. These researchers found that the participants' aided performance was substantially higher than their unaided performance for all test conditions. In addition, the participants' aided performance with the CS 50 was similar to their aided performance with the traditional hearing aid. Specifically, the mean difference score on the QuickSIN test was 30.8 for the traditional hearing aid and 31.2 for the CS 50, while the mean difference score on the WIN test was 25 for the traditional hearing aid and 23 for the CS 50 (Reed et al., 2015).

In another recent study, Polyak (2016) directly compared the aided versus unaided performance on the AzBio speech-in-noise test of thirteen hearing impaired individuals who were fit with five PSAPs (one basic, one mid-level, and three advanced: CS 50, Soundhawk, the Bean) and one traditional hearing aid. The participants were administered the AzBio test for all test conditions. This researcher found that the participants' speech-in-noise performance on the AzBio improved in the aided versus unaided condition, which is similar to the findings of the current study. In addition, the level of improvement was similar for the each of the three advanced PSAPs and the traditional hearing aid. Specifically, the mean difference score on the AzBio test was 9.58 for the traditional hearing aid and 8.92, 9.69, and 10 for the CS 50, Soundhawk, and the Bean, respectively (Polyak, 2016).

A follow-up study by Reed et al. (2017) examined the aided versus unaided performance of 42 hearing impaired individuals who were fit with five different PSAPs (including 3 advanced devices: CS 50+, Soundhawk, and the Bean) and one traditional hearing aid. Similar to the current study, the participants were administered the AzBio speech-in-noise test while wearing each of the devices. These researchers found that the participants' performance improved in the aided versus unaided condition with each of the advanced PSAP devices and the traditional hearing aid. They also found that the level of aided improvement was similar (within 5 percentage points) to the traditional hearing aid. The mean difference scores were as follows: 11.9 (traditional hearing aid), 11 (CS 50+), 10.2 (Soundhawk), and 7.7 (the Bean) (Reed et al., 2017).

In this current study, we were also investigating any differences in participants' performance on the AzBio test between the three fitting protocols. We found the most improvement in the mean aided versus unaided AzBio scores with the gold-standard fitting condition for both the Soundhawk and the CS 50+ PSAP devices. Overall, the mean difference scores decreased in the advanced-user self-fitting condition and, as expected, they showed the least improvement in the out-of-the-box self-fitting condition. This was true for both of the PSAP devices. To date, there are no other studies that have looked at the influence of fitting protocol on speech-in-noise results. Therefore, a direct comparison of the current results cannot be made to the literature.

Collectively, the results of these preliminary studies are in good agreement with the results of the current pilot study and suggest that advanced PSAPs may offer improvement in speech-in-noise performance for individuals with slight to moderate sensorineural hearing impairments. The current study also suggests that the audiologists' fine-tuning of self-fit advanced PSAPs results in the greatest improvement in speech-in-noise performance. This warrants further research examining the potential clinical utility of these advanced PSAP devices.

Real-ear Measurements

In this portion of the study, two specific questions were asked: 1) How well did each of the PSAP devices meet the NAL targets as a function of fitting protocol? and 2) If they did not meet targets, were the errors a result of over-shooting or under-shooting the targets? We found that the highest total percentage of NAL targets was met in the gold-standard fitting condition for both PSAP devices: CS 50+ (69%) and Soundhawk (64%). As expected, the lowest percentage of total NAL targets were met in the self-fitting protocols, with the lowest percentages of total NAL targets met in the out-of-the-box self-fitting protocol for the CS 50+ (53%) and in the advanced-user self-fitting protocol for the Soundhawk (58%). This suggests that the audiologists' fine-tuning of the self-fit advanced PSAPs yields a greater accuracy in meeting NAL targets and is agreement with several recent preliminary studies in this area.

For example, these results are similar to the findings of Reed et al. (2015) who examined how accurately 10 PSAPs (one basic PSAP and nine advanced PSAPs) and one traditional hearing aid met NAL targets when the devices are fit by an audiologist. These researchers performed simulated real-ear measurements on each of the devices using a 2-cc HA1 coupler. They found that almost half, 44%, of the advanced PSAPs met NAL targets within ±10 dB for most of the test frequencies (6/9 or 67%) (Reed et al., 2015).

In addition, a recent study by Polyak (2016) examined how accurately 5 PSAPs met NAL targets when compared to a traditional hearing aid. The 5 PSAPs included one basic device, one mid-level device, and three advanced devices (including the Soundhawk and CS 50). This researcher found that the traditional hearing aid met the greatest percentage of NAL targets (45/48 or 94%) within ±5 dB when compared to the 5 PSAP devices. However, the advanced PSAP devices, specifically the Soundhawk and CS 50 devices, met 35/52 (67%) and 33/52 (64%) of NAL targets, respectively. These findings are similar to the results of this current study.

When examining accuracy of the two PSAP devices in meeting NAL targets at each frequency (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz), we found that the highest total percentage of NAL targets, 83%, was met at 500 Hz versus only 28% of NAL targets met at 4000 Hz. In addition, the PSAP devices tended to over-shoot or under-shoot the NAL targets most often at 4000 Hz when compared to the other test frequencies. These results are similar to the findings of Polyak (2016) who also found that the majority of the PSAP devices met the highest percentage of NAL targets at 500 Hz and had a tendency to meet a lower percentage of NAL targets at 4000 Hz. This researcher also looked at the amount of over-shoot and under-shoot for 5 PSAP devices and found that the Soundhawk and CS

50 tended to undershoot the NAL targets by approximately 10 to 20 dB across most of the test frequencies (Polyak, 2016).

In this study, we performed an additional analysis of the real-ear measurements. Root-mean-square (RMS) values were calculated to see how well the devices met the NAL targets. A low RMS value indicated greater accuracy in meeting NAL targets. Due to the decreased accuracy of the devices in meeting targets at 4000 Hz, the 3-frequency (500, 1000, and 2000 Hz) RMS values (3-RMS) were examined. We found that the lowest 3-RMS values, reflecting greater accuracy, occurred in the gold-standard fitting condition for both PSAP devices: Soundhawk (6.66) and CS 50+ (7.15), across all fitting conditions. In contrast, the highest 3-RMS values occurred in the two self-fitting protocols. Specifically, the Soundhawk had the highest 3-RMS in the out-of-the-box self-fitting condition (9.43) and the CS 50+ had the highest 3-RMS in the advanced-user self-fitting condition (10.70). When comparing the two advanced PSAP devices, the Soundhawk showed an overall greater accuracy in meeting NAL prescribed targets in comparison to the CS 50+ device. To date, there is no published data examining the RMS values of real-ear measurements obtained with PSAP devices. Therefore, this is an area that warrants further research.

Overall, the results of real-ear measurements found in the current study are similar to the results of several recent studies. These findings suggest that advanced PSAPs have the ability to meet NAL prescribed targets, with the greatest accuracy occurring when an audiologist fine-tunes the acoustic settings of these devices in the gold-standard fitting condition.

Relationship Between Aided AzBio Improvement and RMS Values

We investigated if there was a relationship between the participants' aided improvement in the AzBio score, reflected in the difference score, and their 3-RMS values. We were interested in determining if there was a correlation between greater aided improvement on the AzBio test and lower 3-RMS values in any of the three fitting conditions. Preliminary results seem to suggest that the PSAPs fit using the gold-standard fitting protocol resulted in greater improvement in AzBio speech-in-noise scores when compared to the out-of-the-box and advanced-user self-fitting protocols. This was reflected in a cluster of responses for the gold-standard fitting protocol that showed low 3-RMS values and relatively high aided AzBio improvement (see Figure 15). In contrast, a much more random pattern of findings occurred for the two self-fitting protocols. However, this relationship between AzBio test scores and 3-RMS values did not reach statistical significance for any of the fitting conditions, as evidenced by the low correlation values of R^2 ranging from 0.004 to 0.326. Therefore, even though these preliminary results for the gold-standard fitting protocol are encouraging, they should be interpreted with caution due to the small data set (n= 9).

Limitations

There are several limitations in this current study. One limitation was the use of the AzBio speech-in-noise test for the sample population in this study. It is possible that the AzBio test was not the most appropriate test, since it was developed as a tool for evaluating the speech recognition abilities of individuals with hearing loss before and after cochlear implantation. Individuals who receive cochlear implants often have severe to profound sensorineural hearing loss across all test frequencies, resulting in poor frequency resolution. However, the participants in the current study had only slight to moderate sensorineural hearing loss with normal or near-normal hearing sensitivity in the lower frequencies up to 500 Hz. Therefore, the participants in this study would be expected to have relatively good frequency resolution.

Secondly, the current study utilized a small data set (*n*= 9) which limits the interpretation of these findings. A study with a larger data set would be needed in order to further examine the best use and potential benefits of advanced PSAP devices in individuals with mild to moderate sensorineural hearing loss.

Lastly, the current study was conducted in a quiet listening environment. However, it is likely that a real-world listening environment would contain competing speech or background noise. Therefore, the findings of this study are not transferrable to the real world.

Future Research

Based on the limitations of this current study, we can make several suggestions for future research. First, as previously mentioned, the current pilot study used a small data set; therefore, future studies should examine a larger number of participants to see if similar trends are shown in aided speech-in-noise scores and real-ear measurements when wearing advanced PSAP devices. In addition, the series of preliminary studies that have been performed in this area have been conducted in a quiet test environment. Future studies should examine how these PSAP devices perform in more adverse listening conditions, such as in environments with reverberation or in the presence of speech masking.

Finally, since the gold-standard fitting protocol resulted in the highest aided improvement in AzBio scores and the greatest accuracy in meeting NAL targets, future studies should investigate the performance outcomes for an individual who purchases an over-the-counter amplification device and then presents it to an audiologist for the gold-standard fitting. Considering the potential benefits of the gold-standard fitting and the possibility of changes in the FDA regulation of PSAPs, it may behoove audiologists to un-bundle hearing aid and fitting charges. Audiologists could either carry advanced PSAPs in their practice as a low cost option for their patients, or offer fitting of these devices after hearing impaired individuals have purchased them over-the-counter or online.

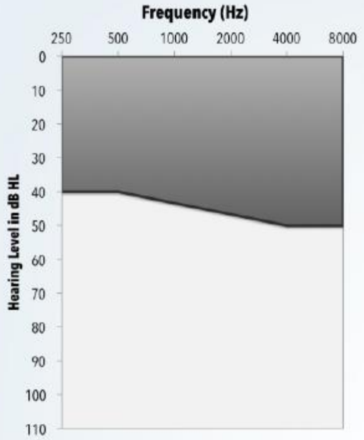
APPENDIX A

Manufacturers' Specifications for Soundhawk

soundhawk®
Smart Listening System

Professional Selection Guide

Fitting Guide



Test Box Data

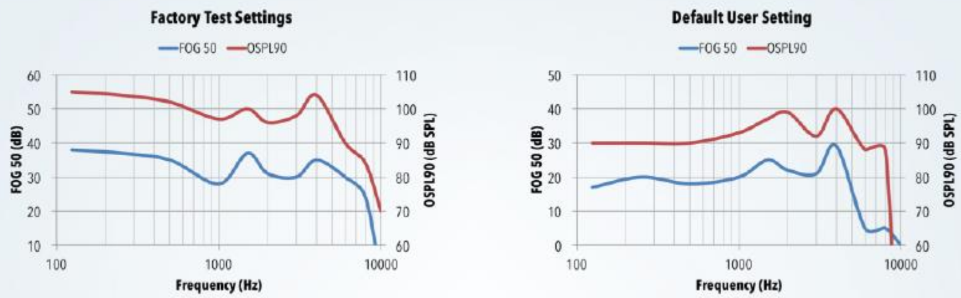
Measurement	ANSI/IEC 2cc Coupler
(Default User Setting)	
Peak OSPL90 (dB SPL)	104@4KHz
HFA OSPL90 (dB SPL)	96
Peak Gain (dB)	29
HFA Full-on Gain (dB)	20
Frequency Range (Hz)	<200 - 6720
HFA Frequencies (KHz)	1.0,1.6,2.5
Reference Test Gain (dB)	11
Equivalent Input Noise (dB)	<34
Harmonic Distortion	
500 Hz (%)	<2
800 Hz (%)	<2
1600 Hz (%)	<2

Color Guide

Test Setup

1. Putty Scoop directly to HA-1 2CC coupler.
2. Orient Scoop to face the test box speaker.
3. Select 'Dining' sound scene.
4. Select center of tuning screen & maximum volume control setting.
5. Run desired test per test equipment manufacturer's directions.

2CC Coupler Full on Gain and OSPL90 Response Curves



Manufacturers' Specifications for CS 50+

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CS50+ SPECIFICATIONS

Input	Omnidirectional & Directional (Hypercardioid)
Gain	25 dB SPL, depending on preset selection
Volume Range	-12 dB SPL to +12 dB SPL
Equalizer (3 Bands)	-12 dB SPL to +12 dB SPL
Max Output	112 dB SPL
Signal Processing	Digital 16 channel dynamic compression, noise reduction, output compression, feedback cancellation
Frequency Response (Amplifier Mode)	200Hz - 8000Hz
Total Harmonic Distortion (THD)	≤ 1%
Equivalent Input Noise	26 dB SPL
Battery Type	Rechargeable Lithium Ion
Battery Life	Up to 18 hours

Purchase your own CS50+ personal sound amplifier today to Get Back into the Conversation

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Park Ridge, IL 60068
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APPENDIX B

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 a 3-hour test session 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 two different PSAPs as we obtain real-ear measures and perform speech-in-noise testing. 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.

Participation in this study is voluntary. 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, Antoinette Oliver, at agreen50@students.towson.edu or 804-476-4327; Dr. Korczak (faculty sponsor) at pkorczak@towson.edu or 410-704-5903; 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. IRB Approval # 1608004152

Appendix C

IRB Approval

TOWSON UNIVERSITY

APPROVAL NUMBER 1608004152

Office of Sponsored
Programs and Research

Towson University
8000 York Road
Towson, MD 21252-0001

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

MEMORANDUM

TO:	Antoinette Oliver
FROM:	Institutional Review Board for the Protection of Human Participants, Elizabeth Katz, Chair
DATE:	October 7th, 2016
RE:	Approval of Research Involving the Use of Human Participants, Approval Number 1608004152

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 Self-Fit Personal Sound Amplification Products (PSAPs) Using 3 Types of Fitting Protocols: Out-of-the-Box Self-Fit, Advanced-User Self-Fit, and Audiologist Fit

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.

TOWSON UNIVERSITY

Date: October 7th, 2016

Office of Sponsored
Programs and Research

Towson University
8000 York Road
Towson, MD 21252-0001

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

NOTICE OF APPROVAL

TO: Antoinette Oliver **DEPT:** Aud Speech Deaf Study

PROJECT TITLE: *Objective Comparative Analysis of Self-Fit Personal Sound Amplification Products (PSAPs) Using 3 Types of Fitting Protocols: Out-of-the-Box Self-Fit, Advanced-User Self-Fit, and Audiologist Fit*

SPONSORING AGENCY: None

APPROVAL NUMBER: 1608004152

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 10/7/2016.
This research will be reviewed every year from the date of first approval.

Lissa Rapin (for)

Elizabeth Katz, Chair
Towson University Institutional Review Board, IRB

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CURRICULUM VITA

Antoinette Oliver, B.S.
[redacted]

Education:

Doctor of Audiology, Towson University	May 2018
Bachelor of Science, Towson University Major: Speech Language Pathology/Audiology	May 2014
Associate, Applied Science, University of the District of Columbia Major: Radiologic Technology	June 1991

Clinical Experience:

National Institute of Health (NIH)	Spring 2017
Maryland School for the Deaf (MSD)	Fall 2016
Walter Reed National Military Medical Center (WRNMMC)	Summer 2016
Chesapeake Ear, Nose, and Throat	Spring 2016
Towson University Hearing and Balance Center	Spring 2015 – Fall 2015

Professional Affiliations:

Member, Student Academy of Audiology	2014-Present
Member, National Student Speech Language Hearing Association	2012-Present
Member, American Registry of Radiologic Technologists	1991-Present