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schn8407@bears.unco.edu

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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

MEASURING SPATIAL HEARING ABILITIES IN LISTENERS
WITH SIMULATED UNILATERAL HEARING LOSS

A Scholarly Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Audiology

Elizabeth Dawn Benson

College of Natural and Health Sciences
Department of Audiology & Speech-Language Sciences

May 2022

This Scholarly Project by: Elizabeth Dawn Benson

Entitled: *Measuring Spatial Hearing Abilities in Listeners with Simulated Unilateral Hearing Loss*

has been approved as meeting the requirement for the Degree of Doctor of Audiology in the College of Natural and Health Sciences in the Department of Audiology & Speech-Language Sciences.

Accepted by the Doctoral Committee

Kathryn Bright, Ph.D., Co-Research Advisor

Tina Stody, Ph.D., Co-Research Advisor

Lori Leibold, Ph.D., Committee Member

Ryan Darling, Ph.D., Faculty Representative

Accepted by the Graduate School

Jeri-Anne Lyons, Ph.D.
Dean of the Graduate School
Associate Vice President of Research

ABSTRACT

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Spatial hearing is the ability to use auditory cues to determine the location, direction, and distance of sound in space. Listeners with unilateral hearing loss (UHL) typically have difficulty understanding speech in the presence of competing sound; this is likely due to the lack of access to spatial cues. The assessment of spatial hearing abilities in individuals with UHL is of growing clinical interest, particularly for everyday listening environments.

Current approaches used to measure spatial hearing abilities include Spatial Release from Masking (SRM), Binaural Intelligibility Level Difference (BILD), and Listening in Spatialized Noise-Sentences (LiSN-S) test. Spatial Release from Masking is the improvement in speech recognition thresholds (SRT) when the target and masker are co-located as opposed to when they are spatially separated, utilizing a sound-field setup. The LiSN-S test also measures improvement in SRTs when the target and masker are spatially separated. Although similar, the LiSN-S utilizes a more clinically assessable procedure by simulating a three-dimensional auditory environment under headphones. Akin to the LiSN-S, the BILD also utilizes headphones but instead elicits improved SRTs by presenting target speech 180° out-of-phase to one ear instead of in-phase to two ears.

The purposes of this study were (a) to determine if patterns of individual variability were similar across the three measures for 30 adults with normal hearing and 28 adults with simulated

UHL and (b) to evaluate the effects of simulated UHL on performance. Results of this study confirmed the three tests were all sensitive measures of binaural hearing deficits in participants with UHL. Although all measures were correlated with each other, only the measures conducted under headphones (BILD and LiSN-S) were influenced by magnitude of asymmetry. These findings suggested that although the measures were producing similar results, they might be reflecting different aspects of binaural processing.

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LIST OF ABBREVIATIONS

Abbreviation	Explanation
ITD	Interaural timing difference
ILD	Interaural level difference
SNR	Signal to noise ratio
BILD	Binaural intelligibility level difference
SRT	Speech recognition threshold
LiSN-S	Listening in spatializes noise - sentences test
N_0S_π	Target speech 180° out-of-phase in one ear
N_0S_0	Target speech in-phase in both ears
UHL	Unilateral hearing loss
PTA	Pure tone average
dB HL	Decibels hearing level
SOC	Superior olivary complex
IC	Inferior colliculus
NLL	Nuclei of the lateral lemniscus
MSO	Medial superior olive
MLD	Masking level difference
APD	Auditory processing disorder
BTNRH	Boys Town National Research Hospital
BKB	Bamford-Kowal-Bench
HRTFs	Head related transfer functions

CHAPTER I

STATEMENT OF THE PROBLEM

Introduction

Spatial hearing is the human body's innate ability to take advantage of auditory cues to determine the location, direction, and distance of sound in three-dimensional environments, and to differentiate sounds that originate from discrete locations in space (Culling & Akeroyd, 2010). Spatial hearing requires input delivered to two ears, what is referred to as binaural hearing. The differences in input between the two ears produces cues our brain uses to separate the target sound from background noise. These cues also allow us to perceive where the sound source is located in relation to our own bodies. Three primary cues underlie spatial hearing: monaural spectral, timing differences, and level differences (Macpherson & Sabin, 2007).

The ability to integrate input from two ears has a major influence on functioning in everyday life. Listening to speech in the presence of background noise is a common listening environment, and the ability to follow a target talker in the presence of competing noise is important for proper social functioning (Avan et al., 2015). The ability to localize sound is also an important part of simple environmental safety. Interacting with an environment safely requires correct identification of where sounds are coming from in space (Clarkson, 2008).

When listening in complex environments, three binaural effects are traditionally thought to be associated with the benefit experienced when listening with two ears rather than one: the head shadow effect, binaural squelch, and binaural summation. The head shadow effect is the high-frequency acoustic shadow the head casts when the target and masker are spatially

separated. The spatial separation of target and masker allows the masker to arrive to the listener's ears at different times and intensities. The brain uses these differences as cues; they are known as interaural timing difference (ITD) and interaural level difference (ILD). Binaural squelch occurs when the differences in the signal-to-noise ratio (SNR) between the ears allows the brain to “squelch” out the background noise. Binaural summation is the benefit of simply listening with two ears rather than one (Bronkhorst & Plomp, 1988).

Historically, many people have attempted to understand spatial hearing abilities of binaural and monaural listeners. The study of spatial hearing is thought to have started in the late 1700s with the first study describing the ability to understand where sounds were spatially located in relation to our bodies—what we know today as localization (Venturi, 1796). The study of spatial hearing continued into the late 1800s and early 1900s with the emergence of theories describing interaural timing and intensity differences (Helmholtz, 1885/1954; Myers & Wilson, 1908; Rayleigh, 1907). It was not until the 1930s that these theories were confirmed with clinical research (Stevens & Newman, 1936). A binaural release from masking was first described when the improvement in signal detection was observed when an interaural phase difference was present (Licklider, 1948). This finding was similar to the interaural timing differences that had been previously explored (Licklider, 1948). These historical findings continued to shape the way we understand spatial hearing today and laid the foundation for the principals of spatial hearing research.

Current approaches to investigating how well children and adults use binaural cues in the laboratory setting are the spatial release from masking (SRM) and the binaural intelligibility level difference (BILD). The SRM is the improvement in masked speech recognition thresholds (SRT) when the target and masker are co-located as opposed to when the target and masker are

spatially separated on a horizontal plane (Misurelli & Litovsky, 2012). Traditional SRM in a laboratory is measured in a sound-field setup requiring several speakers and a sound-treated room. A more clinically accessible option for measuring SRM is the Listening in Spatialized Noise-Sentences (LiSN-S) test (Cameron & Dillon, 2008). The LiSN-S test is a simulated three-dimensional auditory environment under circumaural headphones presented using a personal computer that measures a listener's ability to understand speech in the presence of a two-talker masker (Cameron & Dillon, 2008). The second measure of spatial hearing used in the laboratory setting is the BILD. The BILD occurs when masked SRTs in a diotic masker are better for adults when target speech is presented 180° out-of-phase to one ear (N_0S_π) than when it is presented in-phase across the two ears (N_0S_0). In the N_0S_π condition, the N_0 denotes the noise that is presented 0° out-of-phase (in-phase), while S_π denotes the target speech that is presented 180° out-of-phase, the point that is equal to pi radians. In the N_0S_0 condition, the N_0 also denotes the noise that is presented in-phase, while the S_0 denotes the target speech that is now also presented in phase. (Goverts & Houtgast, 2010).

There is major interest in developing a clinical measure of spatial hearing to assess the real-life challenges of people with unilateral hearing loss (UHL). Unilateral hearing loss is defined as having an audiometric threshold pure tone average (PTA) of less than or equal to 25 decibels hearing level (dB HL) in one ear and a hearing loss of greater than 25 dB HL (mild hearing loss) in the other ear (Golub et al., 2018). Listeners with unilateral hearing loss typically have difficulty understanding speech in the presence of competing speech or noise; this is likely due to the lack of access to binaural cues (Firszt et al., 2017). It is known that people with unilateral hearing loss have poorer spatial hearing abilities than people with normal hearing (Bronkhorst & Plomp, 1988).

The BILD and SRM tests have been used to assess binaural hearing abilities in school-aged children and adults with unilateral hearing loss (Corbin et al., 2017; De Sousa et al., 2019; Wilson et al., 1985). A positive SRM for listeners with simulated unilateral hearing loss has been observed when the masker was presented on the same side as the simulated hearing loss. Similar to the SRM, the BILD has been sensitive to unilateral hearing loss. When comparing speech recognition thresholds for the in-phase (N_0S_0) condition and the out-of-phase condition ($N_0S\pi$), people with unilateral hearing loss were unable to utilize the phase cue (De Sousa et al., 2019; Wilson et al., 1985). While the LiSN-S test has been used to measure binaural hearing abilities in normal hearing listeners and listeners with bilateral hearing loss, it has yet to be used to evaluate binaural hearing abilities in listeners with unilateral hearing loss.

There is growing interest in the clinical assessment of spatial hearing abilities in children and adults with unilateral hearing loss, particularly in the types of complex listening environments they encounter in everyday life. The BILD, SRM, and LiSN-S are promising measures of binaural hearing abilities and might be sensitive to binaural deficits in individuals with unilateral hearing loss. The BILD, SRM, and LiSN-S might be sensitive to deficits in listeners with unilateral hearing loss, especially in those with mild to moderate degrees of loss. A unilateral hearing loss can be simulated by plugging one of the ears with a hearing protection device such as earplugs and/or earmuffs (Marrone et al., 2008). This method could potentially be useful to estimate binaural hearing deficits in individuals with unilateral hearing loss.

Research Questions and Hypotheses

Data collected in this study were used to answer the following research questions:

- Q1 Will there be similar patterns of individual variability across subjects who are evaluated using the Binaural Intelligibility Level Difference (BILD), Spatial Release from Masking (SRM), and Listening in Spatial Noise-Sentences (LiSN-S) tests?

- H01 Different ways of measuring binaural hearing should result in similar outcomes. Consistent patterns of individual differences for BILD, SRM, and LISN-S tests will be observed.
- Q2 How does the simulated unilateral hearing loss impact performance on the BILD, SRM, and LISN-S tests?
- H02 Asymmetric hearing loss will reduce binaural hearing abilities. As threshold asymmetry increases, the BILD, SRM, and the spatial advantage on the LISN-S test will decrease.

Summary

The human body is designed to utilize auditory cues to gather information about sound in three-dimensional environments (Culling & Akeroyd, 2010). Spatial hearing requires binaural input to best differentiate characteristics of sound; these differences between the two ears produce cues the brain uses to locate sound in space and to separate the target sound from background noise. The ability to utilize binaural cues not only impacts how the listener functions in everyday listening environments, but also how they safely navigate the world around them (Avan et al., 2015; Clarkson, 2008). The head shadow effect, binaural squelch, and binaural summation are the three binaural effects traditionally thought to be associated with the benefit experienced when listening with two ears rather than one. Understanding how our brain utilizes this information has been the subject of research since the late 1700s and continues to be of interest in the present day (Venturi, 1796). Current approaches to investigating how well children and adults use binaural cues in the laboratory setting are the SRM and the BILD. A more clinically accessible option is the LiSN-S test (Cameron & Dillon, 2008; Goverts & Houtgast, 2010; Misurelli & Litovsky, 2012). It is of clinical interest to develop a measure that assesses the spatial hearing abilities of people with UHL. It is known that people with unilateral hearing loss have poorer spatial hearing abilities and have more difficulty understanding speech in the presence of competing noise (Bronkhorst & Plomp, 1988; Firszt et al., 2017). While the BILD

and SRM tests have been used to assess binaural hearing abilities in people with unilateral hearing loss, the LiSN-S test has only been used to measure binaural hearing abilities in normal hearing listeners and listeners with bilateral hearing loss (Corbin et al., 2017; De Sousa et al., 2019; Wilson et al., 1985). The BILD, SRM, and LiSN-S are promising measures of binaural hearing abilities that might be sensitive to binaural deficits in individuals with unilateral hearing loss. Simulating a unilateral hearing loss by plugging one of the ears with a hearing protection device is a method that could potentially be used to evaluate binaural hearing deficits in individuals with unilateral hearing loss (Marrone et al., 2008).

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

There is growing interest in the clinical assessment of spatial hearing abilities in children and adults with unilateral hearing loss, particularly in the types of complex listening environments they encounter in everyday life. Spatial hearing refers to the ability to take advantage of auditory cues to determine the location, direction, and distance of sound in three-dimensional space, and to disentangle sounds that originate from different locations in space (Culling & Akeroyd, 2010). Spatial hearing abilities appear to be present at birth but develop in childhood for children with normal hearing in both ears (Johnstone et al., 2010).

Spatial Hearing Cues

Three primary cues underlie spatial hearing: monaural spectral, timing difference, and level difference. Timing and level differences allow the listener to perceptually differentiate the target and masker. Interaural timing difference (ITD) and interaural level difference (ILD) result from the way the sound interacts with the pinnae, head, and shoulders. The relationship between where the sound source is located in space and how it arrives at each ear differently can be explained by the ITD and ILD. Interaural timing difference is the difference in time of arrival of the sound wave to each ear, resulting from the difference in distance that sound has to travel to reach both ears. Interaural timing difference typically yields a timing delay of about 660 μ sec (Gelfand, 1998). Interaural level difference is the difference in intensity between the two ears. This difference occurs because one sound wave might need to travel farther from the source to

reach one of the ears, resulting in the attenuation of the intensity of the sound wave to the ear farther away from the source (Johnson & Hautus, 2010). Typical ILDs can range from 0 dB in the low frequencies to as much as 20 dB in higher frequencies (Gelfand, 1998). Similar to the ITD and ILD, monaural spectral cues are altered by the pinnae, head, and shoulders. The monaural spectral cues work together with the ITD and ILD to determine location on the horizontal plane. The spectral cues are referred to as monaural spectral cues because a single ear can be utilized to locate a sound source (Macpherson & Sabin, 2007).

Historical Perspective

The study of binaural hearing is thought to have started in the late 1700s with Giovanni Battista Venturi who suggested the ability to understand where sounds are spatially located in relation to our bodies required input from both ears; his work was the cornerstone for what we know today as localization (Venturi, 1796). In the late 1800s, German physicist and physiologist Hermann von Helmholtz (1885/1954) described his findings as suggesting humans experience “phase deafness” and are not sensitive to timing cues. Helmholtz’s idea changed the trajectory of research toward a focus on intensity cues rather than timing cues. However, in 1907, Lord Rayleigh proposed a theory that provided an explanation for the listener’s ability to localize sound by utilizing ITDs. Myers and Wilson (1908) suggested it was not one or the other but instead a combination of both intensity and timing differences that allowed humans to localize sound. In 1936, Stevens and Newman at Harvard University published the first studies putting these theories to the test. Their findings were consistent with the hypothesis that the localization of low tones was made on the basis of phase-differences at the two ears and the localization of high tones was made on the basis of intensity differences (Stevens & Newman, 1936). Licklider (1948) was the first person to use these principals to describe a binaural release from masking.

Licklider observed the improvement in signal detection when there was an interaural phase difference, similar to the interaural time differences that had been previously explored. He theorized that because the underlying cues varied with sound direction, binaural unmasking might play a role in the cocktail party effect. These historical findings continue to shape the way we understand binaural hearing today.

Physiology of Spatial Hearing

Structures that allow the auditory system to encode and use information from two ears are located in the brainstem. The brainstem pathway primarily lies within three principal structures: the superior olivary complex (SOC), the inferior colliculus (IC), and the nuclei of the lateral lemniscus (NLL; Moore, 1991). This portion of the auditory pathway starts in the SOC—the location in the central auditory pathway where binaural information is first integrated. Binaural convergence is observed at the medial superior olive (MSO) where there are connections on both sides to the adjacent cochlear nuclei. Interaural timing and intensity differences are a result of the neurons in the SOC coding binaural information through an interaction of excitatory and inhibitory inputs. Similar to the SOC, binaural information is also available at the inferior colliculus. The interaural intensity and timing differences produce excitatory and inhibitory inputs to the IC neurons; these neurons depend on the interaction of these inputs to fire. Although the majority of binaural interaction takes place at the SOC and IC, responses to interaural time and intensity differences have been observed in the NLL. The interaction of excitatory and inhibitory inputs contributes to the processing of binaural information at all levels where binaural inputs are represented including the primary and secondary auditory areas of the cortex (Gelfand, 1998).

Spatial Hearing in Daily Functioning

The human body's design to integrate input from two ears has evolutionary advantages as our primitive ancestors needed to protect themselves from predators. It was once important for humans to be able to hear slight changes in the environment around them in the presence of other background noise in order to survive. This ability is so deeply ingrained into our physiologic blueprints that our brains have developed and maintained an impressively refined auditory system. Today, primitive survival might not be at stake for humans but understanding speech in complex listening environments is important for functioning in everyday life. Being unable to follow a target talker in the presence of competing noise is a common complaint for people with unilateral hearing loss, resulting in a considerable social and often professional disability (Avan et al., 2015). Unilateral hearing loss has also shown a negative effect on the functioning of children. Children with unilateral hearing loss often experience educational and social delays (Bess et al., 1986; Lieu et al., 2013). Teachers have also reported that children with unilateral hearing loss often have reduced access to support services such as intervention or therapy, and their educational staff are often unaware of the negative effects unilateral hearing loss might have on their class performance (Most, 2004). Beyond social, professional, and educational issues, the ability to localize sound is also an important part of simple environmental safety. Interacting with an environment safely requires correct identification of where sounds are coming from in space (Clarkson, 2008).

Spatial Hearing in Multi-Source Environments

When listening in multi-source environments, three binaural effects are traditionally thought to be associated with the benefit experienced when listening with two ears rather than one. The head shadow effect, binaural squelch, and binaural summation account for the benefit

of utilizing binaural cues (Bronkhorst & Plomp, 1988). The head shadow effect is the high-frequency acoustic shadow the head casts when the target and masker are spatially separated. The spatial separation of target and masker allows the masker to arrive to the listener's ears at different times and intensities; the brain uses these differences as cues (ITD and ILD) to improve the signal-to-noise ratio (SNR) in the ear farthest from the masker. This benefit allows listeners to experience 3 to 8 dB of improved SRT performance (Bronkhorst & Plomp, 1988). Timing and level differences allow the listener to perceptually differentiate the target and masker. The differences in SNR between the ears also allows the brain to have the ability to attend to the ear with the more favorable SNR. This effect, known as binaural squelch, gives normal hearing listeners 3 to 7 dB of benefit (Bronkhorst & Plomp, 1988; Hawley et al., 2004). There is also a benefit of simply having access to acoustic information from two ears so even when the target and masker originate from the same source location, there are no timing or intensity differences. This phenomenon, known as binaural summation, is the benefit of listening with two ears. The listeners should experience 1 to 3 dB of benefit from having access to two neural copies of the target and masker (Bronkhorst & Plomp, 1988; Davis et al., 1990; Hirsh, 1948).

Measuring Spatial Hearing Abilities in the Laboratory

Current approaches to investigating how well children and adults use binaural cues in the laboratory setting are measurements of the SRM and the BILD. The SRM is the improvement in masked SRT when the target and masker are co-located as opposed to when the target and masker are spatially separated on the horizontal plane (Misurelli & Litovsky, 2012). The spatial separation of the target and masker elicits a release from masking in normal hearing listeners (Freyman et al., 1999). In the "cocktail party" environment, many different sounds are coming from different locations in space, interacting with the pinna, head, and shoulders of the listener

(Cherry, 1953). The binaural hearing system utilizes spatial cues to produce an SRM. These cues include ITD and ILD, resulting from the way the sound interacts with the pinnae and shoulders. In complex listening conditions such as a two-talker masker, the SRM benefit is thought to be heavily influenced by auditory stream segregation where ITD and ILD are used as cues when differentiating the target from the masker (Bregman, 1990; Bronkhorst & Plomp, 1988; Freyman et al., 1999; Licklider, 1948; Zurek, 1993). In everyday listening environments, the listener often faces the sound source of interest at 0° azimuth. In this condition, the target sound and masker arrive at the ears at a virtually identical time and intensity. When the target and masker are spatially separated on the horizontal plane, the sound arrives at the listener's ears at different times and intensities. The brain uses these differences in time and intensity as cues to better understand speech in background noise (Bronkhorst & Plomp, 1988).

The SRM can be as large as 12-15 dB in normal hearing listeners, and the benefit is typically most robust in conditions where the target and masker are largely separated (Misurelli & Litovsky, 2012). An SRM is typically measured in separate conditions where the target and masker are either co-located at 0° azimuth or the target and masker are spatially separated by either $+90^\circ$ or -90° azimuth (Corbin et al., 2017; Misurelli & Litovsky, 2012).

The second measure of spatial hearing used in the laboratory setting is the BILD. Masked SRTs in a diotic masker are better for adults when target speech is presented 180° out-of-phase to one ear (N_0S_π) than when it is presented in-phase across the two ears (N_0S_0 ; Goverts & Houtgast, 2010). This effect, called the BILD, was first described by Licklider (1948). The BILD is a manifestation of binaural release from masking, similar to the masking level difference (MLD). Both the MLD and BILD are phenomena for which the binaural auditory system uses phase cues to improve thresholds in the presence of background noise. The MLD is a detection

task that uses either tonal or speech stimuli in the presence of a narrowband noise masker. On the other hand, the evaluation of SRT in the presence of a speech masker allows one to observe a BILD (Gerber, 1988). Assessing speech perception in the presence of competing speech, as opposed to relatively steady noise maskers, is important because it could provide insight into the listener's performance in real-world environments (Hillock-Dunn et al., 2015).

Normal hearing adults should experience a BILD of about 5 dB when taking the difference between the N_0S_0 and N_0S_π conditions (Blauert, 1997; Johansson & Arlinger, 2002; Wilson et al., 1982). The BILD has been used to measure the impact of experience on listeners' ability to use binaural phase cues. Summerfield et al. (1994) measured the BILD in 113 normal hearing subjects between the ages of 3 and 30 years. Between the ages of three and adulthood, thresholds improved by 5 dB in the N_0S_0 condition, 11 dB in the N_0S_π condition, and 13 dB in quiet. The average BILD also improved from 2.5 to 8.5 dB (Summerfield et al., 1994).

The BILD has also been used to assess supra-threshold coding deficits in hearing-impaired listeners. Goverts and Houtgast (2010) calculated the BILD in 25 listeners with mild to moderate sensorineural hearing loss when compared to reference data from normal hearing listeners. A normal hearing listener is sensitive to changes of phase, time, and intensity information. In the eight individuals who showed a reduced BILD, deficits in the phase and time domains were observed, suggesting the BILD was sensitive to coding deficits of phase and timing.

Measuring Spatial Hearing Abilities in the Clinic

Traditional SRM in a laboratory, as described above, is measured in a sound-field setup, requiring several speakers and a sound treated room. A more easily accessible option to measure SRM in the clinical setting is to utilize the LiSN-S test (Cameron & Dillon, 2008). The LiSN-S

test is a simulated three-dimensional auditory environment under circumaural headphones, presented using a personal computer. Created by Sharon Cameron and Harvey Dillon (2008), the LISN-S test is designed to assess a child's ability to understand speech in the presence of a two-talker masker. In four separate conditions, the LiSN-S test accesses SRT for sentences in the presence of a competing speech masker. Each condition's masker is manipulated to reflect a different location (0° or $\pm 90^\circ$ azimuth). Additionally, the vocal quality of the masker might be changed (same as or different than the speaker of the target sentences). Performance is measured as difference scores, representing the benefit in dB that listeners experience as an effect of their ability to utilize the spatial or vocal cues provided (Cameron & Dillon, 2007).

Although the purpose of this test was originally designed to assess children with a suspected auditory processing disorder (APD), the LiSN-S test was based upon the hypothesis that APD is majorly impacted by deficits that result in the inability to utilize cues such as ITD, ILD, and the head shadow effect, which are considered binaural cues (Cameron & Dillon, 2007). The LiSN-S test has been shown to be a measure sensitive to binaural hearing deficits. Graydon et al. (2017) used the LiSN-S test to investigate the effects of early conductive hearing loss on binaural processing. School-aged children with a history of otitis media ($n = 82$) and normal hearing controls with no history of otitis media or conductive hearing loss ($n = 36$) completed the LiSN-S test. The authors found that children with a history of otitis media performed poorer on the conditions of the LiSN-S that relied on the use of binaural cues, indicating a relationship between early conductive hearing loss and binaural listening deficits that remained even after hearing had returned to normal (Graydon et al., 2017).

Another emerging way to measure spatial hearing abilities in the clinic is a rapid, automated test of spatial release from masking called SR2 (Jakien & Gallun, 2018). This

program runs on an iPad under headphones and can be completed in five to seven minutes. The automated test presents one target and two masker speech sentences simultaneously in one of two spatial configurations. The two configurations include co-located (with the target sentence and masking sentences at 0°) and spatially separated (with the target at 0° and the maskers at ±45°) presentations. The SR2 is defined as the difference between the co-located and spatially separated conditions (Jakien & Gallun, 2018).

Unilateral Hearing Loss

There is a major interest in developing a clinical measure of spatial hearing to assess the real-life challenges of children and adults with unilateral hearing loss (UHL). It is estimated that UHL impacts 7.2% of adults in the United States. Unilateral hearing loss is defined as having an audiometric threshold pure tone average (PTA) of less than or equal to 25 decibels hearing level (dB HL) in one ear and a hearing loss of greater than 25 dB HL (mild hearing loss) in the other ear (Golub et al., 2018). Although relying on normal hearing in one ear could suffice in some listening situations, there are several acoustic cues only listeners utilizing both ears could benefit from. Listeners with ULH typically have difficulty understanding speech in the presence of competing speech or noise. This is likely due to the lack of access to binaural cues (Firszt et al., 2017). Having absent or reduced access to these binaural cues might help explain why individuals with UHL experience increased difficulty in complex listening environments.

It is known that people with UHL have poorer spatial hearing abilities than those with normal hearing. The lack of access to binaural cues is one of the reasons children with unilateral hearing loss often experience difficulty understanding speech in complex listening environments (Bronkhorst & Plomp, 1988). The BILD and SRM tests have been used to assess binaural hearing abilities in school-aged children and adults with a simulated UHL (Corbin et al., 2017;

De Sousa et al., 2019; Wilson et al., 1985). Corbin et al. (2017) tested listeners in conditions with and without a foam earplug and earmuff in the presence of a speech-shaped noise and two-talker masker in separate conditions. All listeners showed a benefit from the spatial separation of the target and masker without the plug and muff. When the unilateral hearing loss was simulated, a positive SRM was only observed when the masker was presented on the same side as the simulated hearing loss. When using the speech-shaped noise masker, SRM in the no-plug condition was similar to when the masker was presented to the same side as the simulated hearing loss. In the two-talker masker, SRM in the no-plug condition was much larger than when the masker was on the same side of the simulated hearing loss. There was a negative SRM when either masker was presented to the opposite side to the simulated hearing loss. Based on these results Corbin et al. concluded that children and adults with normal hearing experienced a larger SRM in a two-talker masker than in speech-shaped noise, suggesting that using a more realistic masker could reflect a more accurate prediction of SRM. The researchers found the results were the same for both children and adults, although children performed poorer across all conditions (Corbin et al., 2017).

Similar to the SRM described previously, the BILD was sensitive to UHL. Wilson et al. (1985) investigated the BILD in people with unilateral sensorineural hearing loss. In the in-phase condition (N_0S_0), only slight SNR variations were observed across a range of interaural level differences. However, in the out-of-phase condition ($N_0S\pi$), SNRs became worse with increasing interaural level differences (Wilson et al., 1985). De Sousa et al. (2019) also observed much higher sensitivity to UHL in the out-of-phase condition when compared to the in-phase condition. These results were suspected to be due to the listener's inability to use the timing cue

induced by the difference between the signals produced in-phase to one ear and out-of-phase to the other ear (De Sousa et al., 2019; Wilson et al., 1985).

While the LiSN-S test has been used to measure binaural hearing abilities in normal hearing listeners and listeners with bilateral hearing loss, it has yet to be used to evaluate binaural hearing abilities in listeners with UHL.

Simulated Hearing Loss

Unilateral hearing loss has been simulated in normal hearing subjects by plugging one ear with various hearing protectors including earplugs and/or earmuffs. The goal of simulated UHL is to create absent or reduced access to binaural acoustic information by attenuating the sound going to one ear. Normal hearing listeners with a simulated UHL demonstrated worse SRT in spatialized noise than in co-located conditions (Corbin et al., 2017; Firszt et al., 2017; Persson et al., 2001).

Corbin et al. (2017) simulated UHL in order to measure SRM. The hearing loss was simulated by using both a foam earplug and a supra-aural earmuff, each with a noise reduction rating of 30 dB. The plug was deeply inserted into the listener's ear canal and the earmuff was placed over the pinna by the examiner. The muffs were modified by removing the cup on the opposite side of the simulated hearing loss. These methods produced on average a moderate flat conductive hearing loss (Corbin et al., 2017). Firszt et al. (2017) also simulated UHL by using a combination of a plug and muff, resulting in an average attenuation of 48 dB across frequencies. Persson et al. (2001) achieved a simulated UHL by occluding one ear with hearing protectors. The authors of this study used different kinds of hearing protectors on different subjects to achieve at least 25 dB of attenuation across low, middle, and high frequencies (Persson et al., 2001).

Conclusion

In conclusion, there is growing interest in clinical tools to evaluate binaural hearing abilities in individuals with UHL. The BILD, SRM, and LiSN-S are promising measures of binaural hearing abilities and might be sensitive to binaural deficits in individuals with UHL. The BILD, SRM, and LiSN-S might be sensitive to deficits in listeners with UHL, especially in those with mild to moderate degrees. A UHL could be simulated by plugging one of the ears with a hearing protection device such as earplugs or earmuffs (Marrone et al., 2008). This method could potentially be useful to estimate binaural hearing deficits in individuals with UHL.

CHAPTER III

METHODS

The purposes of this study were (a) to determine if patterns of individual variability were similar across three different measures of spatial hearing abilities for participants with simulated UHL and (b) to evaluate the effects of simulated UHL on performance. Prior to data collection, Institutional Review Board approvals were obtained (see Appendix A)and a data use agreement was established between Boys Town National Research Hospital (BTNRH) and the University of Northern Colorado (see Appendix B). The participants included in this study were adults with normal hearing. All interested participants were provided written consent (see Appendix C). Testing was conducted in the Human Auditory Development Laboratory at BTNRH in Omaha, Nebraska.

Participants

A total of 58 adults with normal hearing participated in this experiment. Participants ranged in age from 19 to 40 years. All participants were recruited using the human subjects core data base at BTNRH, were native speakers of English, and passed a hearing screening prior to testing (i.e., thresholds less than or equal to 20 dB HL for octave frequencies between 250 and 8000 Hz; American National Standards Institute, 2010). Prior to testing, otoscopic examinations were performed on all participants to ensure their ear canals were clear of occluding cerumen or foreign bodies. The participants were divided into two groups: (a) normal hearing ($n = 30$) and (b) simulated UHL ($n = 28$). Unilateral hearing loss was simulated by having the examiner place a foam earplug (Howard Leight Max® Small or Maxx Lite®) in the participant's left ear. To

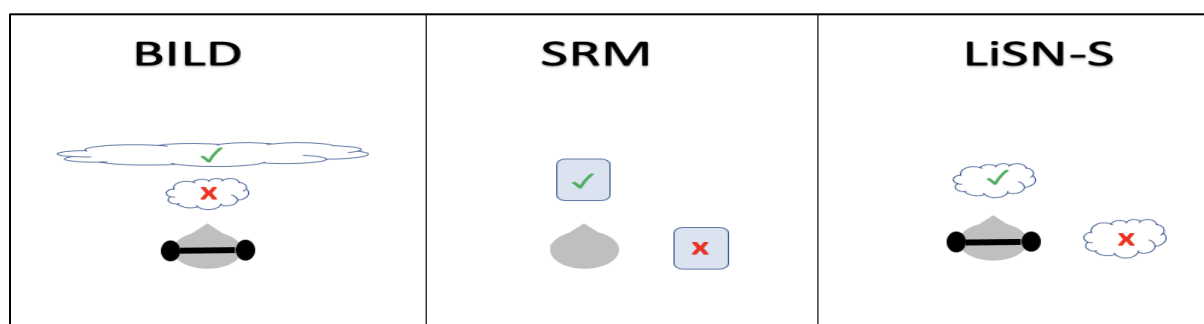
simulate varying degrees of hearing loss, the examiner varied the insertion depth of the earplug across participants. At times, to achieve even milder levels of hearing loss, the plug was trimmed down or a small hole was created in the middle of the plug. Most participants were plugged with a Howard Leight Max plug but for larger ear canals, a larger plug (Howard Leight Maxx Lite) was used. Once inserted, the earplug remained in place throughout testing and participants were instructed to not touch the ear plug. Pure-tone audiometric thresholds were measured at octave frequencies from 250 to 8000 Hz in the plugged ear prior to speech recognition testing and again after speech recognition testing was completed.

Procedures

Each participant was tested in three speech-in-speech recognition assessments: (a) BILD, (b) SRM, and (c) LiSN-S. Testing order for the three measures was randomized across participants. Figure 1 illustrates each measure's testing procedure.

Figure 1

Cartoon Illustration of Each Testing Procedure



Note. The grey character represents the location of the listener's head. The listener in the BILD and LiSN-S procedures is shown wearing headphones. In the BILD task, the wider bubble represents the diffuse perception of where the target speech is in space, due to the primary spatial cue elicited by the phase differences of the target stimulus between the two ears. In contrast, the in-phase noise has a central perception; this is represented by the smaller bubble. The LiSN-S task's primary spatial cue is elicited using HRTFs to simulate co-located and spatially separated conditions in a simulated three-dimensional auditory environment. The simulated conditions are represented by the spatially separated bubbles. The SRM task's primary spatial cue is elicited by the physical separation of the target and masker using two different loudspeakers located 90 degrees apart; this is illustrated by the two boxes that are spatially separated.

Binaural Intelligibility Level Difference

Target stimuli were revised Bamford-Kowal-Bench sentences (BKB; Bench et al., 1979). The revised BKB corpus contains 21 lists of 16 sentences, each with three or four key words, for a total of 50 keywords per list. An example sentence with three keywords was “The ice cream was pink” with each keyword underlined. The sentences were spoken by an adult female talker with a standard American English dialect using a conversational speaking style.

The masker was composed of two streams of speech produced by the same female talker. The talker, who was not the same female who recorded target sentences, was recorded while reading passages from the children’s book, *Jack and the Beanstalk*. Two separate streams were created from this recording. Each stream was edited to reduce silent pauses of 300 milliseconds or greater to approximately 100 milliseconds. The two streams were root mean square-normalized and then summed. The resulting two-talker masker was 2 minutes, 48 seconds long. The two-talker masker sample was repeated without discontinuity during testing.

A custom MATLAB script was used to select the test conditions and present the stimuli. Target and masker stimuli were processed using a real-time processor (Tucker Davis Technologies, RZ6), sent to an amplifier (Applied Research Technology; SLA-4), and presented via headphones (Sennheiser, HD 25-1 II).

Speech recognition thresholds were measured in the context of an adaptive, open-set sentence recognition procedure. Participants wore headphones and were seated in a 7 feet by 7 feet, single-walled sound booth facing a window. A microphone (Grason-Stradler, GSI-61 talkback microphone) mounted above the booth window routed the participant’s verbal responses to an audiometer (Grason-Stradler, GSI-61). An examiner sat inside the booth, next to the participant throughout testing, and scored the participant’s verbal responses in real-time.

Participants were instructed to ignore the people talking in the background and to repeat aloud the sentences they heard using their regular speaking voice. They were informed their responses were scored on a word-by-word basis and they should repeat as many words as they heard. If they were unsure, they were encouraged to guess. The examiner scored each keyword as correct or incorrect. Keywords were scored “correct” if the entire word was correctly repeated. If the participant did not respond, the examiner marked all keywords as incorrect. Feedback was not provided to the participant.

An adaptive tracking procedure was used to capture individual psychometric functions. The level of the masker was fixed at 60 dB SPL. The level of target sentences was adaptively varied using a pair of interleaved tracks following a 1-down 1-up stepping rule. One track used a strict criterion; the participant had to get three or more keywords correct for the SNR to decrease. The other track used a lax criterion; the participant had to get one keyword correct for the SNR to decrease. For each track, an initial step size of 8 dB was used, which was reduced to 4 dB after the first reversal and then 2 dB after the second reversal. Each run stopped after 64 sentences were presented (four lists each with 16 sentences). The data for all trials were saved to disk. The SRT was estimated by fitting a psychometric function to all the data and computing the SNR at which 50% of the keywords were correctly identified.

Participants were tested in each of two conditions: (1a) N_0S_0 in which the target and masker speech were both presented diotically and (b) N_0S_π in which the target speech was presented 180° out of phase between the two ears while the masker speech was presented diotically. Participants in the normal hearing group completed two runs per condition. The two SRTs for each condition were averaged and that average SRT was used for subsequent analysis. Participants in the simulated unilateral group completed one run per condition. The first target

sentence for each participant was randomly selected from the set of BKB sentences and sentences thereafter were presented in random order to ensure that sentences were not repeated. Test order was randomized across participants. The BILD testing took less than 30 minutes to complete.

Spatial Release from Masking

Described in detail by Corbin et al. (2017), target stimuli were BKB sentences (Bench et al., 1979) spoken by an adult female talker. The female talker used for the SRM task differed from the female talker stimuli used to measure the BILD. The target sentences were digitized at a resolution of 32 bits and a sampling rate of 44.1 kHz, normalized with respect to root-mean-square level, and then down sampled to 24.4 kHz before presentation.

The masker for the SRM task was the same two-talker masker described above for the BILD procedure except for the two streams of speech produced by two different female talkers. The masker was presented continuously over the course of the threshold estimation procedure. A custom MATLAB script was used to select the test conditions and present the stimuli. Target and masker stimuli were processed using a real-time processor (Tucker Davis Technologies, RZ6), sent to an amplifier (Applied Research Technology; SLA-4), and presented via one or two loudspeakers (Elipson, Planet M). Target sentences were always presented from a loudspeaker directly in front of the participants at 0° azimuth. The two-talker masker was presented either at 0° azimuth or from a loudspeaker positioned at 90° azimuth and contralateral to the plugged ear.

An adaptive, open-set sentence recognition procedure was used to obtain SRTs. A 1-up 1-down tracking procedure (Levitt, 1971) was used to estimate speech recognition thresholds corresponding to the average SNR required for 50% sentence recognition. The overall level of the target plus masker was fixed at 60 dB SPL throughout testing; SNR was adaptively varied. If

a word was missed, signal level increased and masker level decreased; whereas if all keywords are correctly identified, signal level decreased and masker level increased. The starting SNR for each run was 15 dB SNR for children and 10 dB SNR for adults. The initial step size was 4 dB, which reduced to 2 dB after the first two reversals. Once eight reversals were obtained, the run was completed and SRT was estimated by averaging the SNRs for the final six reversals.

Participants were tested in two conditions: co-located and spatially separated. For both conditions, participants were instructed to always face the speaker directly in front of them and repeat the sentences they heard while ignoring the background speech. The tester sat inside the booth with the participant and had a clear view of the participant throughout testing. Participants were instructed to repeat sentences clearly so the tester could record responses accurately. Seeing the participants' faces allowed for the tester to take advantage of visual cues when noise from the speakers became loud enough to possibly interfere with perceiving participants' responses. The first target sentence for each participant was randomly selected from the set of BKB sentences and sentences thereafter were presented in order to ensure the sentences were not repeated. Each participant in the normal hearing group completed two runs in each condition (four total runs). The mean of the two runs was calculated and used for subsequent analyses. Each participant in the simulated UHL group completed one run per condition (two total runs).

Listening in Spatialized Noise-Sentences

Described in detail by Cameron and Dillon (2007), target sentences were original to the LiSN-S and were developed using the same criteria used in the development of the original BKB sentences (Bench et al., 1979). Up to 30 sentences were used in each condition and selected from a pool of 120 target sentences. Two of the same target sentences were not used twice. An example sentence was "The boys are watching the game" with each word in the test sentences

scored individually including articles such as “the” or “an.” The target sentences of the LiSN-S test were initially presented at 62 dB SPL, with a competing masker of two looped children’s stories presented simultaneously to both ears at 55 dB SPL. The LiSN-S software was downloaded onto a laptop, following the instructions provided in the test manual. In separate conditions, the masker was presented either from 0° or from both + and – 90° azimuth. For both conditions, the target sentences and competing masker were spoken by two different female talkers. The target sentences were pre-synthesized using average head related transfer functions (HRTFs) and presented via circumaural headphones. At this level, the masker at 0° had a long-term root mean square level of 55 dB SPL. The masker at + or -90° was 1 dB higher than when the maskers were at 0°. This discrepancy was due to the HRTFs and was intentionally not corrected for.

Speech recognition thresholds for each condition were estimated using an adaptive 1-up 1-down tracking procedure, corresponding to the average SNR required for 50% correct sentence recognition performance. In this procedure, the SNR decreased by 2 dB if the participant repeated more than 50% of the words in the test sentence correctly and the SNR increased by 2 dB if the participant repeated less than 50% of the words in the test sentence correctly. Signal to noise ratio was not adjusted if exactly 50% of the words in the test sentence were repeated back correctly. A minimum of five practice sentences were presented prior to the test sentences. Each condition used up to 30 sentences and testing was automatically concluded when the participant had either completed 30 test sentences in one condition or completed five practice sentences and an additional 17 test sentences with a standard error of less than 1 dB. All participants completed one run in which the masker was located at 0° and one run in which the masker was located at ±90° in the auditory space. Participants were instructed to repeat sentences and a tester, who sat

directly in front of the participant throughout testing, scored the verbal responses in real time. The difference between the two conditions—different voice $\pm 90^\circ$ and different voice $\pm 0^\circ$ —were calculated to determine spatial advantage, which was defined as the improvement in threshold due to spatial separation between the target and masker.

Data Analysis

The independent variables in this experiment included the BILD, SRM, and LiSN-S tests. The dependent variables were the difference values obtained from SRT scores in each condition for each test. A statistical comparison was used to identify possible trends between these difference scores for each independent variable in both the normal hearing and simulated UHL groups.

CHAPTER IV

RESULTS

Study Participants

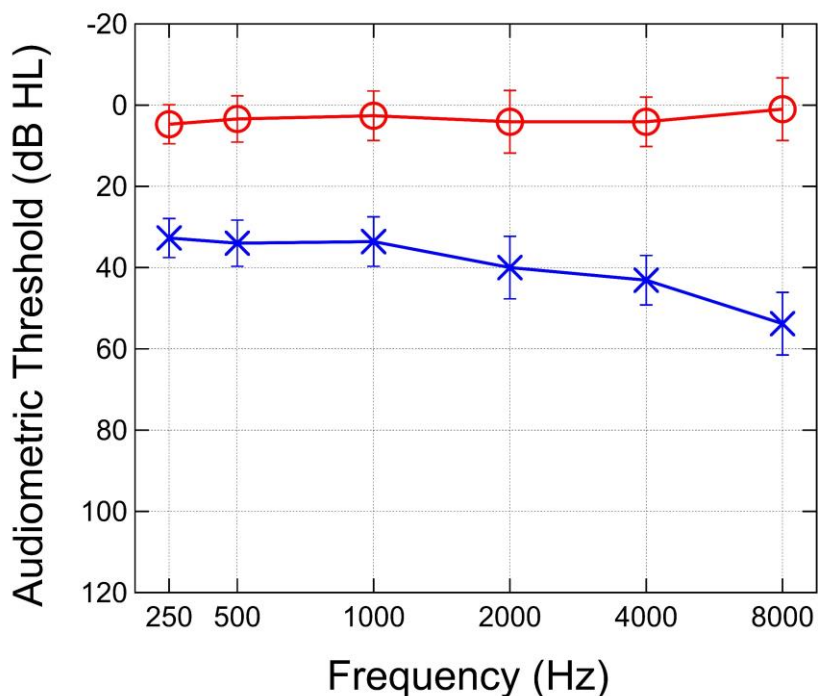
Sixty adults between the ages of 19 and 40 years participated in the study with a mean age of 27.5 years (19 to 38.17 years). Of the 60 adults, 31 were assigned to the normal hearing group and 29 were assigned to the simulated UHL group. No participants were excluded from the study and all participants met inclusion criteria as described in Chapter III.

Attenuation for Participants with Simulated Unilateral Hearing Loss

Figure 2 shows the mean pure-tone thresholds for participants with simulated UHL displayed on an audiogram. Thresholds are represented with red circles for the right ear (no earplug) and with blue Xs for the left ear (ear plug inserted). Thresholds were measured at octave frequencies between 250 and 8000 Hz. On average, insertion of the earplug resulted in a mild sloping to moderate conductive UHL in the left ear. The magnitude of pure tone average threshold (PTA; average threshold at 500, 1000, and 2000 Hz) asymmetry between ears ranged from 16.7 to 48.3 dB across subjects. Thresholds in the plugged (left) ear measured before and after completing the speech perception measures remained unchanged at all frequencies for 19 of 29 participants. For the remaining 10 participants, a change in the amount of attenuation greater than 5 dB was only observed at a single frequency.

Figure 2

Mean Pure-Tone Thresholds for Participants with Simulated Unilateral Hearing Loss



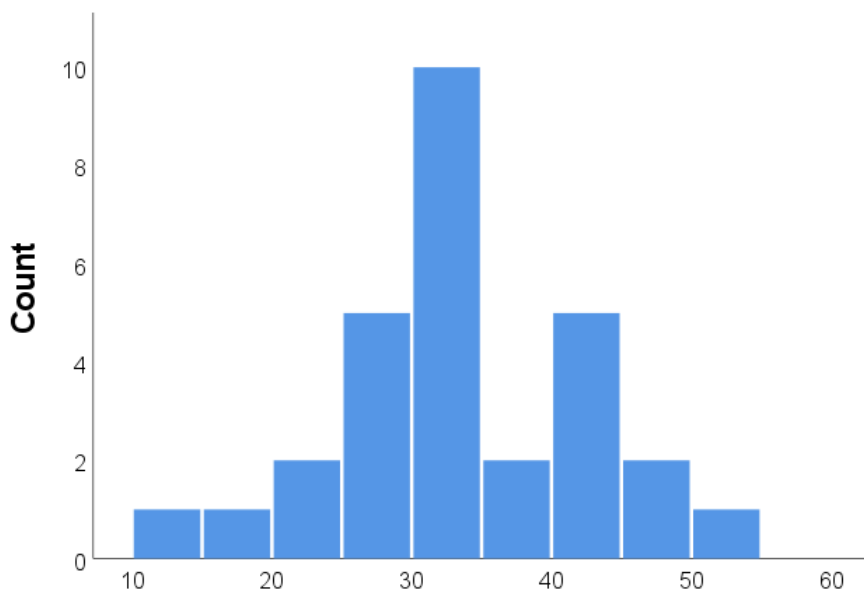
Note. Thresholds are represented with red circles for the right ear (no earplug) and with blue Xs for the left ear (ear plug inserted). Lower thresholds indicate better hearing acuity. Normal hearing is considered 20 dB HL or lower. On average, insertion of the earplug resulted in a mild sloping to moderate conductive UHL in the left ear.

The approach of varying insertion depth of the earplug placement resulted in a range of threshold attenuation values across participants. Figure 3 shows the frequency distribution of the amount of attenuation observed with the earplug across participants. The magnitude of attenuation was calculated as the difference in the pure tone average (PTA) observed with and without the earplug. The average PTA attenuation ranged from 11.7 to 50 dB across participants ($M = 32.9$ dB HL; $SD = 8.7$). Amount of attenuation increased with audiometric frequency. The average amount of attenuation provided to the left ear by the earplug at 250 Hz, 500 Hz, 1000

Hz, 2000 Hz, 4000 Hz, 8000 Hz was 29 ($SD = 10.23$), 30.69 ($SD = 10.17$), 32.07 ($SD = 10.67$), 36.04 ($SD = 7.68$), 37.31 ($SD = 14.27$), and 50.35 ($SD = 12.5$) dB, respectively.

Figure 3

Frequency Distribution of Attenuation



Note. The frequency distribution of the amount of attenuation observed across participants in the UHL group is shown. The blue bars indicate the number of participants that fall into the corresponding category of attenuation. Greater 3-frequency attenuation indicates a greater degree of simulated UHL.

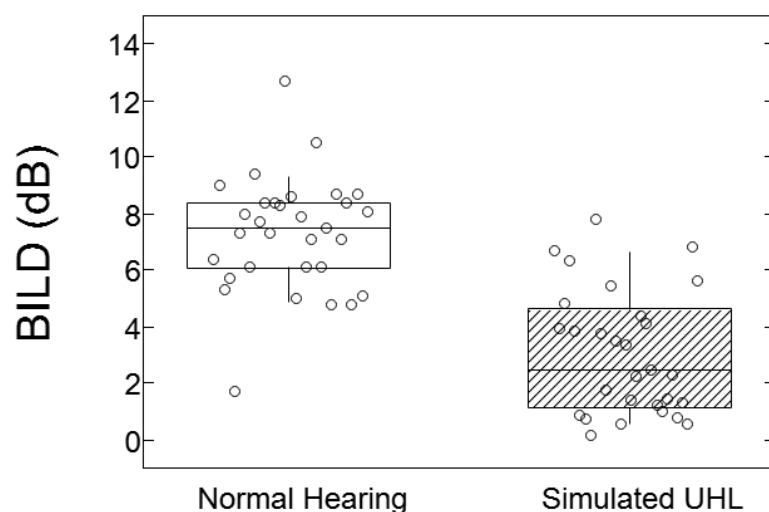
Binaural Intelligibility Level Difference Results

Figure 4 provides box plots that indicated the range of BILD scores for both normal hearing and simulated UHL groups. The box depicts the interquartile range crosscut by the median score. The tails represent the 10th to 90th percentiles and outliers are represented by circles beyond the tails. Recall that the BILD is the difference in threshold between the N_0S_0 and N_0S_{π} conditions. The average BILD was 4.22 dB higher for participants with normal hearing ($M = 7.3$ dB; $SD = 2.04$) relative to participants with simulated UHL (3.08 dB; $SD = 2.2$). As

expected, the participants in the normal hearing group performed better on the BILD measure than the participants in the simulated UHL group.

Figure 4

Binaural Intelligibility Level Difference Speech Recognition Thresholds for Normal Hearing and Simulated Unilateral Hearing Loss Participants



Note. Difference scores using the BILD method are shown for participants in the normal hearing and UHL groups. Higher difference score values indicate better performance. White and shaded boxes show the range of performance spanning the 25th to the 75th percentile for participants in the normal hearing group and UHL group, respectively. Median scores are shown by the horizontal lines inside each box. The 10th and 90th percentiles are shown by the vertical lines.

A one-way between-subjects analysis of variance (ANOVA) was conducted to compare the effect of group (normal hearing, simulated UHL) on the BILD. The results indicated a significant effect of group [$F(1,58) = 59.29; p < .001$], indicating a reduced BILD for participants with simulated UHL relative to participants with normal hearing.

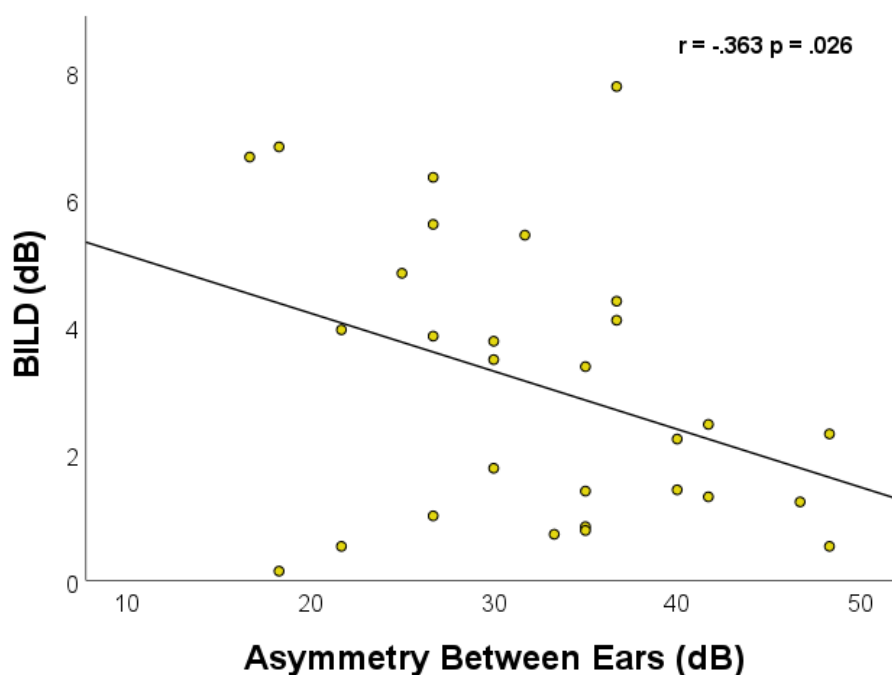
For both the normal and simulated UHL groups, large individual differences were observed. Across the two groups, the BILD scores ranged from 0.15 to 12.7 dB. Scores ranging from 1.7 to 12.7 dB and 0.15 to 7.8 dB were recorded for the normal hearing and UHL groups,

respectively. Although the group effect was significant, some overlap was noted in the distribution of the BILD estimates between the two groups.

Figure 5 shows estimates of the BILD as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry) for participants with simulated UHL. A significant negative linear relationship was observed [$r = -.363$, $p = .026$; one-tailed], indicating participants with a larger asymmetry in thresholds between the two ears tended to have a smaller BILD.

Figure 5

Binaural Intelligibility Level Difference as a Function of Asymmetry



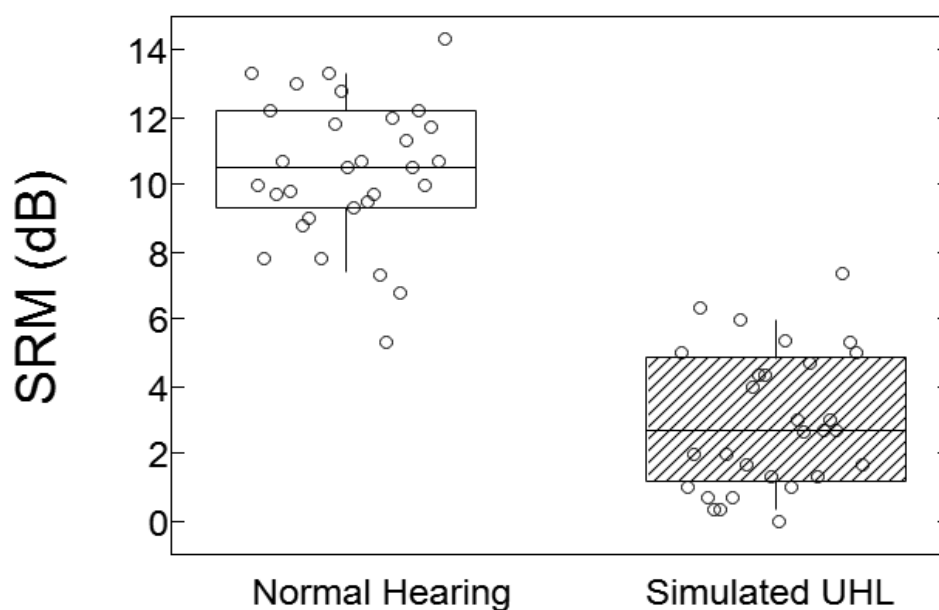
Note. Binaural intelligibility level difference estimates as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry) for participants with simulated UHL are shown. The line indicates the significant negative linear relationship observed.

Spatial Release from Masking Results

Using the format described for Figure 4, Figure 6 shows the distribution of SRM scores for participants in the normal hearing and simulated UHL groups. Recall that SRM is the difference in threshold between the co-located and spatially separated conditions in the sound field. The average SRM was 7.6 dB higher for participants with normal hearing ($M = 10.6$ dB; $SD = 2.25$) relative to participants with simulated UHL ($M = 3$ dB; $SD = 2.06$). As expected, the participants in the normal hearing group showed considerably more SRM than the participants in the simulated UHL group.

Figure 6

Spatial Release from Masking Speech Recognition Thresholds for Normal Hearing and Simulated Unilateral Hearing Loss Participants



Note. Difference scores using the SRM method are shown for participants in the normal hearing and UHL groups. Higher difference score values indicate better performance. White and shaded boxes show the range of performance spanning the 25th to the 75th percentile for participants in the normal hearing group and UHL group, respectively. Median scores are shown by the horizontal lines inside each box. The 10th and 90th percentiles are shown by the vertical lines.

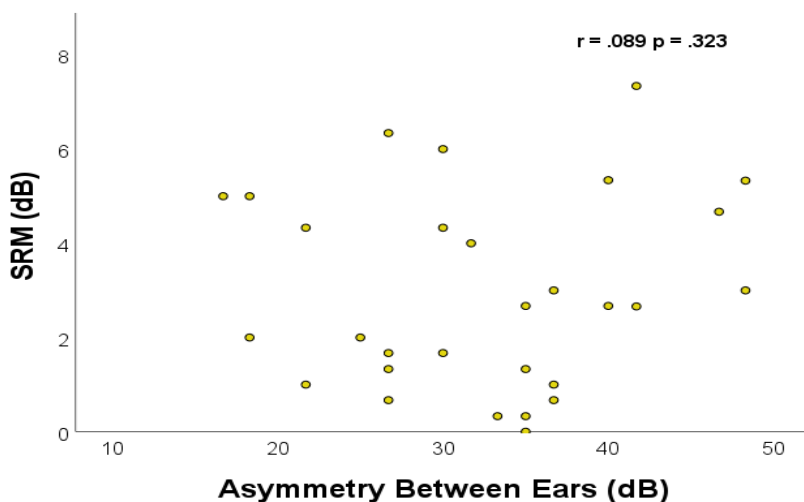
A one-way between-subjects ANOVA was conducted to compare the effect of group (normal hearing, simulated UHL) on SRM. The results indicated a significant effect of group [$F(1,58) = 185.21; p < .001$] consistent with the trend observed in Figure 4 showing smaller SRM for participants with unilateral UHL relative to participants with normal hearing.

Similar to the BILD, individual differences in SRM scores were also observed in both the normal and simulated UHL groups. The SRM scores ranged from 0 to 15.3 dB across the two groups. Group specific SRM scores ranged from 5.3 to 15.3 dB and 0 to 7.3 dB for the normal hearing and UHL groups, respectively.

Figure 7 shows estimates of the SRM for participants with simulated UHL as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry). No significant linear relationship was observed between magnitude of asymmetry and SRM [$r = .089, p = .323$; one-tailed].

Figure 7

Spatial Release from Masking as a Function of Asymmetry



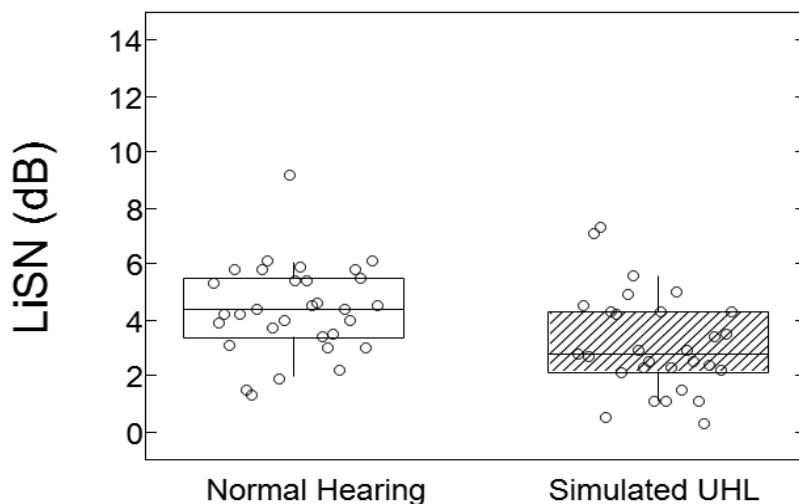
Note. Spatial release from masking estimates as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry) for participants with simulated UHL are shown. The absence of a line indicates no significant linear relationship was observed.

Listening in Spatialized Noise-Sentences Results

Using the format described for Figure 4, Figure 8 shows the distribution of LiSN-S scores for participants normal hearing and with simulated UHL. Recall that the LiSN-S score is the difference in threshold between the co-located and spatially separated conditions, under headphones. The average LiSN-S score was 1.2 dB higher for participants with normal hearing ($M = 4.4$ dB; $SD = 1.62$) relative to participants with simulated UHL (3.2 dB; $SD = 1.8$). A one-way between-subjects ANOVA was conducted to compare the effect of group (normal hearing, simulated UHL) on the LiSN-S benefit. The results indicated a significant effect of group [$F(1,58) = 7.70$; $p = .01$]. As shown in Figure 4, there was considerable overlap in the LiSN-S benefit across the two groups of participants.

Figure 8

Listening in Spatialized Noise-Sentences Speech Recognition Thresholds for Normal Hearing and Simulated Unilateral Hearing Loss Participants



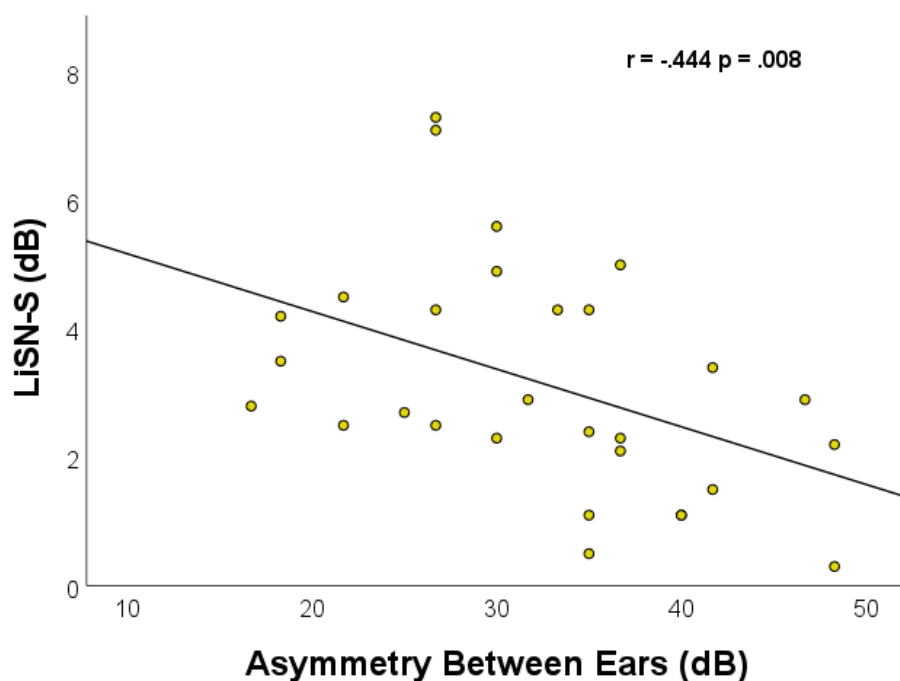
Note. Difference scores using the LiSN-S method are shown for participants in the normal hearing and UHL groups. Higher difference score values indicate better performance. White and shaded boxes show the range of performance spanning the 25th to the 75th percentile for participants in the normal hearing group and UHL group, respectively. Median scores are shown by the horizontal lines inside each box. The 10th and 90th percentiles are shown by the vertical lines.

Consistent with the measures already listed, individual differences in LiSN-S scores were also observed in both the normal and simulated UHL groups. The LiSN-S scores ranged from 0.3 to 9.2 dB across the two groups. Group specific LiSN-S scores ranged from 1.3 to 9.2 dB and 0.3 to 7.3 dB for the normal hearing and UHL groups, respectively.

Figure 9 shows estimates of the LiSN-S scores as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry) for participants with simulated UHL [$r = -.444$, $p = .008$; one-tailed]. A significant negative linear relationship was observed; as asymmetry increased, LiSN-S scores decreased.

Figure 9

Listening in Spatialized Noise-Sentences as a Function of Asymmetry



Note. Listening in Spatialized Noise-Sentences estimates as a function of the difference in PTA between the plugged and unplugged ear (i.e., asymmetry) for participants with simulated UHL are shown. The line indicates the significant negative linear relationship observed.

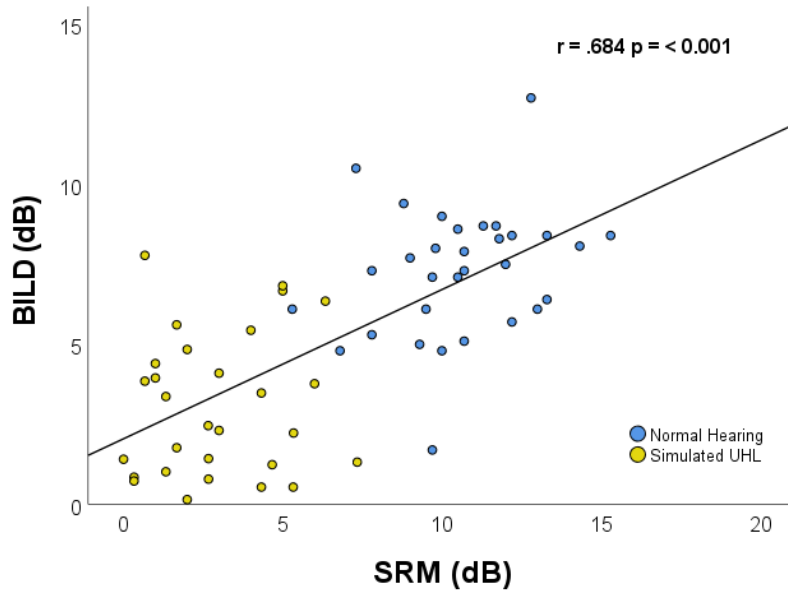
Relationships Between Binaural Intelligibility Level Difference, Spatial Release from Masking, and Listening in Spatialized Noise-Sentences Scores

The purpose of this study was to evaluate the association between the three binaural measures—the BILD, SRM, and LiSN-S tests—for individuals with normal hearing and simulated UHL. This was accomplished by computing a Pearson product-moment correlation between the BILD and SRM estimates (see Figure 10), BILD and LiSN-S benefit estimates (see Figure 11), and SRM and LiSN-S benefit estimates (see Figure 12). In the following figures, scores from normal hearing participants are represented by blue circles and scores from participants with simulated UHL are represented by yellow circles. The diagonal lines represent the line of best fit, which illustrates the linear relationship between the two measures that are being compared.

Figures 10, 11, and 12 are scatter plots depicting the relationships between the BILD and SRM estimates [$r = .684, p = < .001$], SRM and LiSN-S benefit estimates [$r = .315, p = .007$], and BILD and LiSN-S benefit estimates [$r = .353, p = .003$] across participants with normal hearing and simulated UHL, respectively. A significant positive linear relationship was observed for all measures; as BILD, SRM, or LiSN-S scores increased, the score of the test it was being compared to also increased.

Figure 10

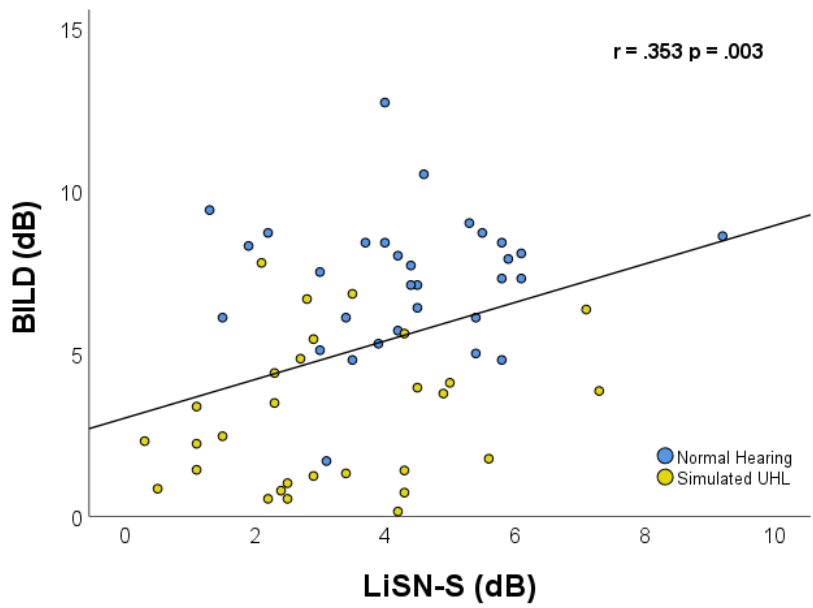
Binaural Intelligibility Level Difference as a Function of the Spatial Release from Masking



Note. Binaural Intelligibility Level Difference estimates as a function of the SRM estimates across participants with normal hearing and simulated UHL, respectively. Blue circles represent the scores from the participants in the normal hearing group and the yellow circles represent the scores from participants in the simulated UHL group. The line represents the significant positive linear relationship that was observed.

Figure 11

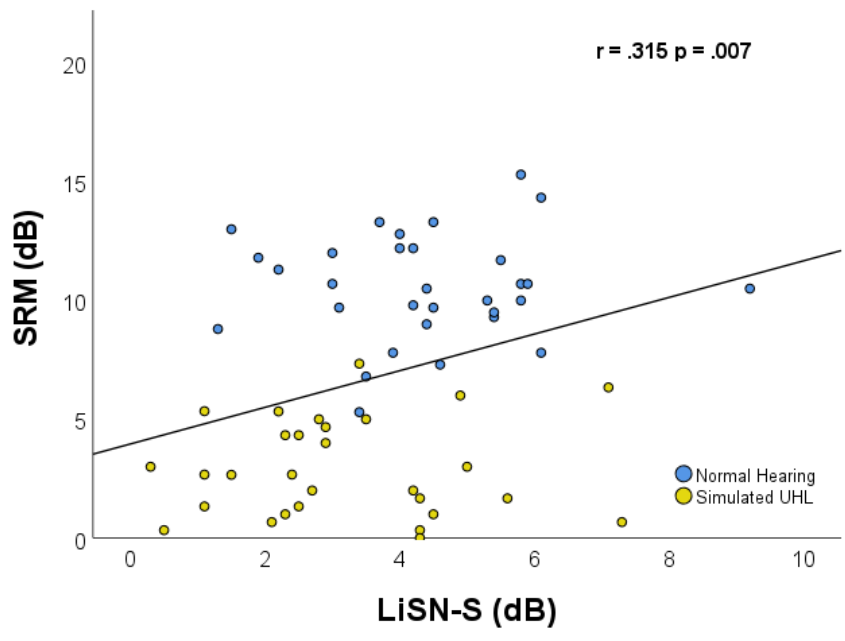
Binaural Intelligibility Level Difference as a Function of the Listening in Spatialized Noise-Sentences



Note. Binaural Intelligibility Level Difference estimates as a function of the LISN-S estimates across participants with normal hearing and simulated UHL, respectively. Blue circles represent the scores from the participants in the normal hearing group and the yellow circles represent the scores from participants in the simulated UHL group. The line represents the significant positive linear relationship that was observed.

Figure 12

Spatial Release from Masking as a Function of the Listening in Spatialized Noise-Sentences



Note. Spatial Release from Masking estimates as a function of the LiSN-S estimates across participants with normal hearing and simulated UHL, respectively. Blue circles represent the scores from the participants in the normal hearing group and the yellow circles represent the scores from participants in the simulated UHL group. The line represents the significant positive linear relationship that was observed.

CHAPTER V

DISCUSSION

The goals of this study were to (a) determine if patterns of individual variability were similar across the three binaural hearing measures (BILD, SRM, and LiSN-S) for adults with normal hearing or for adults with simulated unilateral hearing loss (UHL), and (b) evaluate the effects of simulated unilateral hearing loss on performance for each of the three measures. There were three main findings. First, significant effects of group were observed across all measures, indicating reduced BILD, SRM, and LiSN-S scores for participants with simulated UHL relative to participants with normal hearing. Second, patterns of individual variability were similar for estimates of the BILD, SRM, and LiSN-S; significant correlations were observed for each pairwise comparison for each group. Third, participants with simulated UHL who had greater asymmetry in thresholds between the two ears tended to have poorer scores on the BILD and LiSN-S measures relative to participants with simulated UHL who had smaller asymmetry. Degree of asymmetry was not associated with the magnitude of SRM observed.

Impact of Unilateral Hearing Loss on Binaural Intelligibility Level Difference, Spatial Release from Masking, and Listening in Spatialized Noise-Sentences Estimates

Overall, the UHL group performed worse than the normal hearing group on all three measures. Significant group effects on all measures indicated reduced BILD, SRM, and LiSN-S scores for participants with simulated UHL relative to participants with normal hearing. These results were consistent with previous research indicating participants with UHL performed

poorer on measures of binaural hearing than participants with normal hearing (Corbin et al., 2017; De Sousa et al., 2019; Wilson et al., 1985).

In the present study, the average BILD score was 4.2 dB higher for participants with normal hearing relative to participants with simulated UHL. Similarly, De Sousa et al. (2019) found the average BILD estimate was 5.6 dB greater for participants with normal hearing relative to participants with moderate unilateral sensorineural hearing loss and 5.4 dB greater relative to participants with severe to profound unilateral sensorineural hearing loss. In both studies, reduced access to phase cues created a disadvantage to listeners, especially when listening in background noise.

Like the BILD, estimates of SRM for adults with normal hearing and adults with simulated UHL in the present study followed the same trends as observed in previous studies. Corbin et al. (2017) found that participants with simulated UHL had a mean SRM that was 12.2 dB poorer than that observed in participants with normal hearing. Similarly, the average SRM in the present study was 7.6 dB poorer for participants in the UHL group compared with the normal hearing group. The presence of simulated UHL appeared to result in an inability to properly utilize the ITD and ILD cues that underlie the binaural benefit.

The LiSN-S test was originally developed to evaluate children with APD and has not been used to evaluate binaural hearing abilities in listeners with simulated UHL. Nonetheless, prior studies have examined the effect of chronic unilateral or bilateral conductive hearing loss on LiSN-S performance. Graydon et al. (2017) found that children with a history of conductive hearing loss performed significantly poorer on the LiSN-S relative to children with no history of conductive hearing loss. The authors found the average LiSN-S score was 1.3 dB higher for participants with normal hearing relative to participants with a history of conductive hearing loss.

Similarly, the present study found the average LiSN-S score was 1.2 dB higher for participants with normal hearing relative to participants with simulated UHL.

In the present study, asymmetry in the pure tone average of audiometric thresholds between ears ranged from 16.7 to 48.3 dB across participants with simulated UHL. The results of simple correlational analyses revealed that, while magnitude of asymmetry for participants with UHL was negatively associated with both the BILD and LiSN-S estimates, there was no relationship between magnitude of asymmetry and SRM. This unique finding was likely due to the differences in methodology between the three measures and, specifically, the SRM task's reliance on the head shadow effect as the primary binaural cue elicited. Similarly, Reeder et al. (2015) and Noble et al. (1994) also suggested the degree of hearing loss did not impact SRM as they found that even a mild degree of UHL could disrupt the listener's ability to utilize binaural cues, potentially resulting in functional communication difficulties.

Relationships Between Measures

The BILD, SRM, and LiSN-S tests all assessed binaural hearing abilities; yet it was not clear whether the different tests captured the same aspects of binaural processing (Graydon et al., 2017). As described in earlier chapters, the BILD referred to the improvement in masked SRTs observed in a diotic masker when target speech was presented 180° out-of-phase to one ear relative to when target speech was presented in-phase across the two ears. The interaural phase difference provided a binaural phase cue that improved speech recognition in noise (Goverts & Houtgast, 2010). Although the BILD manipulated the phase of the signal under headphones, it was suggested that the BILD is a manifestation of binaural release from masking, which is the result of the central auditory system's ability to utilize spatial cues from the brain's analysis of ITD and ILD when the target and masker are spatially separated (Bronkhorst & Plomp, 1988;

Gerber, 1988; Licklider, 1948). Recall the brain utilizes the ITD timing cue when it compares time of arrival between the ears. Presumably, these differences in timing arose because the sound waves arrived to each ear at different points of progression in the wave cycle or different phases (Licklider, 1948; Stevens & Newman, 1936).

The SRM measure, on the other hand, elicited a binaural cue by physically separating the target and masker in a sound field. The SRM is the improvement in masked SRTs when the target and masker are spatially separated as opposed to when the target and masker are co-located (Misurelli & Litovsky, 2012). The SRM measure was the closest of the three measures to recreating a “real world” environment as the target and masker sound waves were not manipulated and were traveling through the air like they would in a natural listening environment. Like the BILD, the SRM was also a display of binaural release from masking as it was measuring how the central auditory system used differences in timing and intensity to better understand speech in background noise. While the BILD measure mimiced ITD by manipulating the phase, the SRM measure changed the physical location of the masker, allowing the masker to arrive to the listener’s ears at different times and intensities. The brain then used the head shadow effect and timing (ITD) and intensity (ILD) cues to create a more favorable SNR in the ear farthest from the masker (Bronkhorst & Plomp, 1988). Arguably the most prominent binaural cue elicited using this approach to measure SRM was the head shadow effect. The head shadow effect is the high-frequency acoustic shadow the head casts when the target and masker are spatially separated. The signal arrives attenuated to the ear opposite of the target as its path of travel is obstructed by the head. The signal arriving to the ear adjacent to the target arrives with greater intensity as its path of travel is unobstructed. The head shadow effect observed while measuring SRM in the sound field is sometimes referred to as the “better ear effect” as the head

shadow results in an increased SNR to the ear adjacent to the target. This difference in SNR between the two ears created the binaural intensity cue, the interaural level difference (Bronkhorst & Plomp, 1988; Litovsky, 2012).

The LiSN-S test recreated a simulated three-dimensional auditory environment under headphones, which allowed for an assessment of the listener's ability to understand speech in the presence of a two-talker masker in different conditions that were manipulated to reflect a different location in space (0° or $\pm 90^\circ$ azimuth). The LiSN-S stimuli were created using head related transfer functions (HRTFs) to simulate what the sound wave should sound like after it has traveled from a specific location in space, through the sound field, and to each ear. The HRTFs characterized how the ear received sound from a location in space, in this case, 0° or $\pm 90^\circ$ azimuth. In the sound field, the size and shape of the head, pinnae, and shoulders transformed sound and impacted how it was perceived. These factors resulted in amplification of sound at some frequencies and attenuation at others (Algazi et al., 2001). By using HRTFs to manipulate the signal, the LiSN-S stimuli recreated the way the sound waves would arrive at the ears when the signals were co-located or spatially separated. The difference between the scores in the co-located and spatially separated conditions were calculated to determine spatial advantage or the improvement in threshold due to spatial separation between the target and masker (Cameron & Dillon, 2008). Like the SRM and the BILD measures, the LiSN-S test was based upon the hypothesis that the test was sensitive to auditory processing deficits resulting from the inability to utilize cues such as ITD, ILD, and the head shadow effect (Cameron & Dillon, 2007). The results of the present study also indicated the three measures were significantly correlated, suggesting the three measures reflected, at least in part, contributions from similar binaural processes.

It was of interest to understand why participants with greater magnitudes of asymmetry tended to have poorer scores on the BILD and LiSN-S measures while no relationship was found between magnitude of asymmetry and SRM scores. In the literature, there did appear to be a relationship between the magnitude of unilateral low frequency hearing loss and SRM scores. Both Corbin et al. (2017) and Reeder et al. (2015) found significant correlations between SRM and the magnitude of simulated UHL attenuation at 500 Hz only. No correlations between SRM and magnitude of attenuation at 1000 and 2000 Hz were significant. These results might suggest that like the relationships observed between the BILD and LiSN-S measures and magnitude of asymmetry, SRM was also impacted by degree of asymmetry but only for simulated UHL at low frequencies. Note that a similar trend was not observed in the present study; no association between amount of attention at 500 Hz and SRM was observed for participants with simulated UHL.

Although the relationship between the BILD and LiSN-S has not been extensively studied, both Cameron and Dillon (2008) and Graydon et al. (2017) studied the LiSN-S test alongside the MLD measure. The authors of both studies found no correlation between the two measures. It was suspected the level of language possessing required to complete the tasks was related to the lack of relationship between the measures. While it is known that both the MLD and LiSN-S are measures of binaural interaction, MLD is a detection task that uses either tonal or speech stimuli in the presence of a narrowband noise masker and the LiSN-S is a speech recognition task using speech stimuli in the presence of a two-talker masker, which is a more complex task (Cameron & Dillon, 2008; Gerber, 1988). In the present study, the BILD was studied alongside the LiSN-S instead of the MLD. While the MLD and BILD are both similar tasks that utilize phase cues to improve thresholds in the presence of background noise, the BILD

offered a more complex procedure as it is a speech recognition task in the presence of a speech masker (Gerber, 1988). In this study, the BILD and LiSN-S had a significant positive linear relationship. This relationship was likely due to the more complex nature of the BILD task when compared to the MLD task. As the BILD and LiSN-S measures both employed speech recognition procedures in the presence of a two-talker masker, it was more equitable to compare the LiSN-S to the BILD than it was to compare the LiSN-S to the MLD. Another factor that might have influenced the discrepancies between findings could have been the age of the participants in the studies. The current study evaluated binaural hearing only in adult listeners, while the other authors were both evaluating children. The maturation of the auditory system seemed to impact the magnitude of the listener's ability to utilize binaural phase cues and these skills appeared to develop with experience (Summerfield et al., 1994).

Clinical Implications

It is of interest to develop an efficient and accessible tool to evaluate spatial hearing abilities in a clinical setting. Measures that utilize headphones rather than a sound field set-up are appealing as they require less equipment and setup time, and might be easier to calibrate in a busy audiology clinic. Although SRM in the sound field utilizes the most realistic methods to evaluate spatial hearing abilities by physically manipulating the target and masker, testing under headphones could be a promising component of the test battery as all measures appeared to produce similar outcomes.

Limitations

One limitation in the current study's methodology was the normal hearing and UHL groups contained different participants. Due to time restraints and the difficulty of scheduling, the same participants could not be used to complete both the normal hearing and simulated UHL

tasks. It might have been beneficial to have the same participants complete both tasks for the most direct comparisons. This study's methodology was also limited to conductive hearing loss with an acute onset; chronic conductive, sensorineural, or mixed hearing losses were not explored. Therefore, the results might not translate to a population with longstanding hearing loss. The current study's results did not reflect compensatory skills individuals with chronic hearing loss might possess.

Conclusion

Results in this study confirmed that the BILD, SRM, and LiSN-S tests were all sensitive measures of binaural hearing deficits in participants with UHL. Similar patterns of individual variability were observed for the three measures; different ways of measuring binaural hearing resulted in similar outcomes. Although all three measures studied were correlated with each other, only two measures conducted under headphones (BILD and LiSN-S) were influenced by magnitude of asymmetry. This contrasted with the original hypothesis that as threshold asymmetry increased, scores would decrease for all measures. These findings suggested that although the three measures were producing similar results, the tests might be reflecting different aspects of binaural processing. Assessing spatial hearing abilities under headphones is a promising clinical tool that could be an efficient and effective way of evaluating the impact of unilateral hearing loss on functional communication but further investigation needs to be done to ensure that measuring binaural hearing abilities under headphones accurately reflects the skills needed to perform in the real world.

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APPENDIX A
INSTITUTIONAL REVIEW BOARD APPROVALS



UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

Date: 11/13/2020

Principal Investigator: Elizabeth Benson

Committee Action: **IRB EXEMPT DETERMINATION – New Protocol**

Action Date: 11/13/2020

Protocol Number: [2010013043](#)

Protocol Title: Measuring Spatial Hearing Abilities in Listeners with Simulated Unilateral Hearing Loss

Expiration Date:

The University of Northern Colorado Institutional Review Board has reviewed your protocol and determined your project to be exempt under 45 CFR 46.104(d)(704) for research involving

Category 4 (2018): SECONDARY RESEARCH USING IDENTIFIABLE DATA OR SPECIMENS. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.



You may begin conducting your research as outlined in your protocol. Your study does not require further review from the IRB, unless changes need to be made to your approved protocol.

As the Principal Investigator (PI), you are still responsible for contacting the UNC IRB office if and when:

- You wish to deviate from the described protocol and would like to formally submit a modification request. Prior IRB approval must be obtained before any changes can be implemented (except to eliminate an immediate hazard to research participants).
- You make changes to the research personnel working on this study (add or drop research staff on this protocol).
- At the end of the study or before you leave The University of Northern Colorado and are no longer a student or employee, to request your protocol be closed. *You cannot continue to reference UNC on any documents (including the informed consent form) or conduct the study under the auspices of UNC if you are no longer a student/employee of this university.
- You have received or have been made aware of any complaints, problems, or adverse events that are related or possibly related to participation in the research.

If you have any questions, please contact the Research Compliance Manager, Nicole Morse, at 970-351-1910 or via e-mail at nicole.morse@unco.edu. Additional information concerning the requirements for the protection of human subjects may be found at the Office of Human Research Protection website - <http://hhs.gov/ohrp/> and <https://www.unco.edu/research/research-integrity-and-compliance/institutional-review-board/>.

Sincerely,

A handwritten signature in black ink that reads "Nicole Morse".

Nicole Morse
Research Compliance Manager

University of Northern Colorado: FWA00000784



INSTITUTIONAL REVIEW BOARD

DATE: 5 April 2019

TO: Lori Leibold, PhD

IRB PROTOCOL: **15-04-XP**, Susceptibility to and release from masking in infancy and childhood

SUBJECT: **Re-approval for 12 months with no change to level of risk.**
 Since last continuing review, the Chair approved the following changes:

1. Removed former employees (approved 4/20/18)
2. Add Intake form (approved 4/27/18)
3. Added new employee Raj Persaud as programmer, CITI completed (approved 10/24/18)
4. Addition of recruiting materials, marketing approved (approved 12/7/18)
5. Add individuals with Down syndrome as a subject category, add Spanish-language intake and consenting forms, add ad and video for Facebook, marketing approved (approved 2/5/19)

At time of re-approval, the Chair approved the following requested changes:

1. Increase target enrollment size from 500 to 600 subjects to allow continued recruiting over the next 24 months

FUNDING SOURCE: NIH R01 DC011038

INITIAL APPROVAL 5 June 2015

VALID THROUGH: 4 April 2020

The Chair of the Institutional Review Board has reviewed the above referenced protocol. It is his opinion that your protocol provides adequate safeguards for the rights and welfare of the subjects involved in this study and complies with DHHS Regulations for the Protection of Human Subjects (45 CFR 46.404, no greater than minimal risk to children, 45 CFR 46.111, low risk for adults).

This letter constitutes official notification of re-approval of your study by the IRB for 12 months.

Please destroy all unused copies of the Permission, Assent and HIPAA forms. The IRB Office will email the PI approved forms for your use. Please save the email with the attachments as backup in case you accidentally delete the forms in the future.

BTNRH Federal Wide Assurance (FWA 00004176, exp. 7/3/2023) to DHHS for the protection of human subjects holds the principal investigator directly responsible for the following:

1. Promptly report to the IRB any unanticipated problems involving risks to subjects or others.

Chair: Patrick H. Connell, 531-355-6392

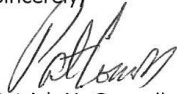
Office: Rebecca Cash, 531-355-6700

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2. Submit any proposed changes to the protocol, consent forms or recruitment materials to the IRB for review and approval prior to implementation.
3. Obtain approval from the BTNRH Marketing department for your recruitment materials (including those provided by a sponsor) before you submit them to the IRB.
4. If you complete this protocol during the approval period, submit Form 3 (Continuing Review and Report to Close) to the IRB Office within 30 days from date of completion or before the expiration date, whichever is earlier.
5. Submit continuing review materials to the IRB office 30 days prior to the expiration date listed above.

Please contact me with any questions.

Sincerely



Patrick H. Connell, RN, MBA, FACHE, CBHE, CHC
IRB Chair



4/2b

**PROTOCOL CONTINUING REVIEW or
REPORT TO CLOSE
INSTITUTIONAL REVIEW BOARD (IRB)**

MAR 2019
BTNRH
IRB

Chair: Patrick Connell, 531-355-6392
IRB Office: Becky Cash, 531-355-6700

Date of report: 2/15/2019

STUDY INFORMATION

Principal Investigator: Lori Leibold	Phone: 531-355-6322
IRB # 15-04-XP	
Project Title: Susceptibility to and release from masking in infancy and childhood	
Date of most recent IRB continuing renewal (or initial approval) for this study: April 20, 2018	

FUNDING

Sponsor/Grant: National Institutes of Health
Grant Number: NIH R01 DC011038
<ul style="list-style-type: none"> If this protocol is grant-related, a copy of the latest progress report MUST either accompany this submission or be available in the grant folder on the network drive.

STAFF

Boys Town Employees: Lori Leibold, Margaret Miller, Jenna Browning, Mary Flaherty, Manuel Vicente, Ryan McCreery, Meredith Spratford, Judy Kopun, Sarah Al-Salim, Kayla Samuelson, Barb Peterson, Mary Thomas, Elizabeth Schneider, Heather Porter, Raj Persaud
Non-Boys Town Staff: Emily Buss (UNC), Nicole Corbin (UNC), Lauren Calandrucchio (CWRU)
<ul style="list-style-type: none"> All PIs and Key staff must include an updated Statement of Significant Financial Interest (form 19) All staff members must have current CITI Bio-medical and HIPs certification (within last 3 years) on file in the IRB office for continuing review

PROJECT STATUS (check ALL that apply)

<input checked="" type="checkbox"/> Continuing review requested, AND:
<input type="checkbox"/> No changes were made to study design, risks or subject categories since last continuing review
<input type="checkbox"/> No changes were made to staffing or sponsor since last continuing review
<input checked="" type="checkbox"/> Changes were made since last continuing review
List: (1) Added the Assurance of Confidentiality section for Adult, Parent Permission, and Youth Assent forms; (2) Added an Adult Demographic Intake form; (3) Added Demographic Intake form for parents of children enrolled in studies; (4) Added flyer, email, and phone script for community recruitment of infants and preschoolers; (5) Added Waiver of Authorization to recruit infants and preschoolers with hearing loss; (6) Added advertisement and video for Facebook to expand efforts in recruitment of infants; (7) Added individuals with Down syndrome as a subject category; (8) Added wide-band reflectance to English-language consenting forms; (9) Added Spanish-language intake and consenting forms for new subject category to align with national

demographics for Down syndrome (10) Added Waiver of Authorization to recruit children with Down syndrome

- Changes were made to staffing or sponsor since last continuing review

List: (1) Added Raj Persaud who has completed CITI training; (2) Removed the following BTNRH employees: Paula Garcia, Hannah Hodson, Steve Lockhart, Mary Pat Moeller, Heidi Lang, Sara Robinson, and Jessica Tran.

- Request review of the following proposed changes to study design, risks or subject categories

List:

- Request review of the following proposed changes to personnel or sponsor

List:

- No subjects have been enrolled since last continuing review

Explain:

- Study never initiated.** Please sign the last page of this form and return it to the IRB Office.

Explain:

- Study closure requested.** No further contact with human subjects is planned. Complete this form, sign it, and return it to the IRB Office.

Date project terminated:

Does this study involve collection of biologic material for genetic study? Yes No

SUBJECT POPULATION (check all that apply)

- | | |
|--|---|
| <input checked="" type="checkbox"/> Youth (11 through 18 years of age) | <input type="checkbox"/> Patient records or archival documents |
| <input checked="" type="checkbox"/> Child (7 through 10 years of age) | <input checked="" type="checkbox"/> Adult volunteers (19 yrs or older) |
| <input checked="" type="checkbox"/> Child (under 7 years of age) | <input type="checkbox"/> Pregnant women (intended inclusion) |
| <input checked="" type="checkbox"/> Children with Guardians | <input checked="" type="checkbox"/> Pregnant women (incidental inclusion) |
| <input type="checkbox"/> State wards | <input checked="" type="checkbox"/> Employees/Families |

Human Subjects Record Keeping

To protect human subjects who participate in research and to meet reporting and audit requirements, the IRB needs accurate counts of how many subjects have signed consent forms and participated in research, along with demographic information to judge equity of recruitment.

The demographic information requested follows current NIH grant reporting requirements. Note that these IRB counts are based on the protocol approved by the IRB under which the subjects were recruited. A protocol may include multiple sub-studies (e.g., experiments), and perhaps subjects may participate in more than one sub-study over the duration of the protocol.

For the summary below enter the number of unique subjects enrolled in the protocol (to date and since the last continuing review). Subjects that have signed a consent form and are "screened" but later may not meet all sub-study criteria are still to be counted as enrolled.

TARGET ENROLLMENT

What is the target sample size (the most recently IRB-approved enrollment target number): 500

If you wish to change this number, please explain and justify the new target enrollment plan: We wish to increase the target sample size to 600. We just reached our enrollment target number of 500 participants and would like to continue recruitment over the next 24 months.

ACTUAL ENROLLMENT

Total number of unique subjects enrolled since initial approval of the protocol:	497
Number of unique subjects enrolled since the last continuing IRB review, using the following date range:	103
Number of repeat subjects enrolled since the last continuing IRB review using the date range above (i.e., subjects already enrolled in this protocol who participated in one or more sub-studies. This would be each time any subject was re-consented):	54
Is enrollment of subjects ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If yes, estimate of number of subjects to be enrolled:	<u>100</u>
Number of months needed to complete enrollment:	<u>18</u>
Number of months needed to complete data collection:	<u>18</u>
If no subjects have been enrolled or if enrollment is much lower than anticipated since the last IRB review, please explain why (e.g., lack of funding, use of repeated subjects across sub-studies, etc.):	

RECRUITMENT SOURCES (check all that apply)

<input checked="" type="checkbox"/> Boys Town National Research Hospital Medical Records
<input checked="" type="checkbox"/> Human Subject Core
<input checked="" type="checkbox"/> Boys Town Clinics
<input type="checkbox"/> Non-BTNRH institutions - List collaborating institution name, contact and phone number for each:
<input checked="" type="checkbox"/> Other (self-referral, public places, advertisements, etc.) Please describe: word of mouth; clinical measurement core; flyers

NOTE: If there are any plans to recruit subjects from outside of the United States, please contact the IRB Chair.

DEMOGRAPHICS

Total number of unique subjects enrolled to date, by gender and age:			
Males, age 0 through age 18	<u>163</u>	Males, age 19 or older	<u>54</u>
Females, age 0 through age 18	<u>176</u>	Females, age 19 or older	<u>104</u>
Total number of unique subjects enrolled to date by ethnicity (two NIH categories):			
Hispanic or Latino	<u>45</u>	Not Reported	<u>11</u>
Not Hispanic or Latino	<u>441</u>		
Total Number of Unique Subjects Enrolled to Date by Race (five NIH categories):			
Asian	<u>10</u>	White	<u>441</u>
Black or African American	<u>12</u>	More than one	<u>19</u>
Native American/Alaska Native	<u>1</u>	Not Reported	<u>14</u>

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Native Hawaiian/Other Pacific Islander 0

Do the subject enrollment demographics comply with the requirement for equitable selection? Yes No

If there is the appearance of inequitable recruitment of subjects based on the demographics of the available subject population, please explain: **Our subject enrollment demographics are not in-line with demographics for the catchment area. We believe this recruitment trend reflects an emphasis on testing of infants and 2- to 4-year-old children. These children are typically tested during regular work hours (9am – 5pm) and it is our observation that most of these children had a parent that stayed at home to provide childcare. This likely influenced the sample of children that have been tested, leading to an unbalanced demographic selection.**

To address this important issue, we are taking the following steps:

1. We have begun to recruit from specific zip codes associated with greater socioeconomic, racial and ethnic diversity. We have also started to post flyers in the clinics at Boys Town and around Omaha to allow individuals who aren't enrolled in the database to participate.
2. We also offer families the option to come in for testing after work hours or on the weekends. This has already led to improvements in our ability to recruit a more diverse and representative sample.

Did any subject complain in person or ask to record a complaint about the research? Yes No

If yes, what resolution was made by the research staff as the result of the complaint(s)?:

Was the IRB notified of the complaint? Yes No

SUBJECTS WITHDRAWN

Have any subjects withdrawn from the study since the project began? Yes No

Number of subjects who withdrew of their own choice: 2

Number of subjects withdrawn by investigator: 8

Have any subjects withdrawn since the date of the last IRB review? Yes No

Number of subjects withdrawn for research related: 4

Explain: **1 child subject used their right to withdraw. They were not interested in participating.**

Number of subjects withdrawn by investigator: 3

Number of subjects that did not meet inclusion criteria: 3

Number of subjects withdrawn for other reasons: 0

Explain:

ADVERSE EVENTS

Have there been any unanticipated adverse events related to this protocol since it was first approved? Yes No

If yes, specify the date the incident was reported to the IRB:

If not reported, explain why the IRB was not notified:

Have there been any unanticipated adverse events related to this protocol since the last IRB review? Yes No

If yes, specify the date the incident was reported to the IRB:

If not reported, explain why the IRB was not notified:

Since the protocol began, has the frequency of serious adverse events been greater than predicted? Yes No

If yes, please explain:

ADVERSE EVENTS WHICH OCCURRED AT NON-BOYS TOWN SITES (multi-site studies only)

Since the protocol began, have there been any external adverse event reports where the adverse event was related or possibly related to the drug / intervention and was both serious and unexpected? Yes No

If yes, briefly summarize the adverse events:

RISK

Briefly summarize your current assessment of the risk/benefit ratio based on protocol results. Reference any literature that disclosed unanticipated risk or adverse events from similar or related studies:

Participation in this study is considered to be low risk. Subjects' privacy will be protected by conducting the consent process and all experimental and clinical testing in a private laboratory or suite. Only the required and described data collection will be performed. Subjects will be informed that they have the right to refuse further participation at any time during the study. Sounds are presented at safe and comfortable levels that are below the damage risk criteria.

INFORMED CONSENT

Describe the informed consent process (when, how and by whom the consent is administered):

Informed consent will be obtained prior to the beginning of the study for all participants. We will ensure that participants and their parents (if applicable) recognize they have the alternative of not participating in the study. If they choose to participate in the study, a member of the research team will ensure that they understand the procedures and the time involved. Standard procedures for consenting the subjects and their families will be used. A consent form will be signed, witnessed and kept on file. Lori Leibold and IRB-approved lab personnel will administer consent.

PROGRESS REPORT

In lay terms, briefly summarize the findings of the research thus far, even if you have only preliminary data to report:

The findings of this research indicate large age-related changes in the ability to hear and understand sounds like speech in the presence of competing background sounds. Infants show the great vulnerability whereas adults show the least. These difficulties are larger, and take longer to mature, when the competing background sounds are similar to the target sound. For example, the ability to recognize speech when other people are talking appears to remain immature into adolescence.

Attachment instructions:

Continuing Review: • If there are any changes to the consent/assent forms, email the IRB Office the modified forms. Please use "Track Changes" or otherwise mark the changes.

- If there are previously - approved recruitment materials, survey instruments and/or informational materials (brochures, etc.) that are to be used during the coming renewal period, provide a list to the IRB Office or email copies.

ATTACHMENTS (select all that are included)

Currently used consent/assent/permission forms:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Adult (19 years and older) Consent Form | <input checked="" type="checkbox"/> Parental Permission Form |
| <input checked="" type="checkbox"/> Youth (11 through 18 years of age) Assent Form | <input checked="" type="checkbox"/> HIPAA Addendum (Adult) |
| <input checked="" type="checkbox"/> Child (7 through 10 years of age) Assent Form | <input checked="" type="checkbox"/> HIPAA Addendum (Youth) |

Modified consent/assent/permission forms (include Track Change copies):

- | | |
|---|---|
| <input type="checkbox"/> Adult (19 years and older) Consent Form | <input type="checkbox"/> Parental Permission Form |
| <input type="checkbox"/> Youth (11 through 18 years of age) Assent Form | <input type="checkbox"/> HIPAA Addendum (Adult) |
| <input type="checkbox"/> Child (7 through 10 years of age) Assent Form | <input type="checkbox"/> HIPAA Addendum (Youth) |

Miscellaneous:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Recruitment materials | <input checked="" type="checkbox"/> Informational materials |
| <input checked="" type="checkbox"/> Survey instrument(s) | <input type="checkbox"/> PI's Financial Interest Form |
| <input type="checkbox"/> Individual Investigator's Agreement(s) | |
| <input type="checkbox"/> Other (describe): | |

CONTINUING REVIEW ONLY (select all that apply):

 If there have been IRB approved changes to study design since the last renewal, or changes planned for the coming renewal, you must enclose a revised protocol application.

<input checked="" type="checkbox"/> Revised protocol attached
<input type="checkbox"/> There were no changes to design

 If the change was or is in *personnel* only, a revised protocol is not required.

<input type="checkbox"/> Personnel changes only

 If this is a grant-supported study, the PI must attach a copy of the most recent annual report or make available in the grant folder on the network.

<input checked="" type="checkbox"/> Attached/Emailed or on network
<input type="checkbox"/> Not Applicable

 If applicable, attach or email current IRB approval from collaborating institution(s) to the IRB Office.

<input checked="" type="checkbox"/> Attached/Emailed
<input type="checkbox"/> Not Applicable

Principal Investigator's Assurance

I certify that the approved protocol and approved method for obtaining informed consent have been followed during the period covered by this progress report. I certify that all signed consent forms are on file (unless requirements were waived). I also certify that the information provided for continuing review or closing of protocol is complete and accurate to the best of my knowledge. I understand that failure to use a consent form that has been properly stamped by the IRB and within the approved time period may result in disciplinary action and may be reportable to the funding agency as well as the OHRP.



 Signature of Principal Investigator

2/22/2019

 Date

Continuing Review or Report to Close – Form 3

Version 2018.02

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APPENDIX B
DATA USE AGREEMENT



INSTITUTIONAL REVIEW BOARD

DATA USE AGREEMENT

For a Limited or De-identified Data Set

The PI is to complete all sections, sign where indicated and submit to the IRB Office.

***DATA CANNOT CONTAIN ANY OF THE FOLLOWING PHI ELEMENTS:**

Name, Address, Phone number, Email, Fax number, Social Security Number,
 Medical record number, Health plan beneficiary number, Account number,
 Device ID or Serial number, certificate or license number,
 Biometric ID, including finger and voiceprints, Full-face photos or comparable images,
 Vehicle ID, serial or license plate number, Web or IP address,
 Any other unique ID, characteristic or code

DATA CAN CONTAIN THE FOLLOWING:

Dates (admission, discharge, service)
 Age or date of birth
 City, state, ZIP code (not street address)
 Any other unique code or ID that is not listed as a direct identifier

***Contact the IRB Chair or IRB Office if additional PHI must be included.**

Effective Date	April 1, 2020
Covered Entity	Boys Town (BT)
Primary Investigator Name	Lori Leibold
Protocol Number(s) and Title(s)	15-04-XP, Susceptibility to and release from masking in infancy and childhood
Individual Recipient Name	Elizabeth Schneider Bensen
Institution	University of Northern Colorado
Phone or Email	Elizabeth.Schnedier@unco.edu
List additional individuals with access to data:	
IRB Chair Name	Dr. Silvia Correa-Torres & Dr. Michael Aldridge
IRB Chair Phone or Email	Silvia.Correa-Torres@unco.edu ; Michael.Aldridge@unco.edu IRB administrator is Nicole Morse: Nicole.Morse@unco.edu
Describe the purpose for use	Elizabeth Schneider is a former employee of the Human Auditory Development Laboratory at BTNRH. She is now a graduate student at the University of Northern Colorado. The

	purpose of use is to access and report de-identified data in a graduate research project.
Describe or list data	The data include age and speech-in-noise threshold data collected during a laboratory visit from 58 adult participants. No PHI will be shared.
PHI Elements	<input type="checkbox"/> Service Date <input type="checkbox"/> Admission or Discharge Date <input type="checkbox"/> Date of Birth <input type="checkbox"/> Age <input type="checkbox"/> City <input type="checkbox"/> State <input type="checkbox"/> Zip
Method of transferring data	osf.io using BTNRH approved protocols
Use for future research	<input type="checkbox"/> Within Subject Area Only <input checked="" type="checkbox"/> Not Allowed
Upon completion of activities	<input type="checkbox"/> Return Data <input checked="" type="checkbox"/> Destroy data
Ending Date	<input checked="" type="checkbox"/> Upon completion of activities <input type="checkbox"/> Three years from Effective Date <input type="checkbox"/> Other:
Publication Rights	<input type="checkbox"/> Not allowed or Not Applicable <input checked="" type="checkbox"/> Yes, describe: Anticipated that Ms. Schneider will work with Dr. Leibold and her team to prepare a manuscript for publication following completion of the graduate project.

The Data Set Recipient agrees to the following:

- To not use or disclose the data set other than as permitted by the data use agreement or as otherwise required by law
- To use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement
- To ensure that any other agents or subcontractors to whom it provides the data set agrees to not use or disclose the data set for any other purpose(s)
- To not identify the information nor contact the individuals
- To destroy all data or return to BT if destruction of data infeasible
- To ensure that upon completion of the permitted activities, no residual data or images will exist on any type of electronic storage device, nor hardcopies be retained if data destruction required
- To report to BT any use or disclosure of the data not provided for by the data use agreement of which the recipient becomes aware
- To acknowledge BT for its participation in any publication or presentation about the data

- BT reserves the right to revoke this agreement should it find out that the Data Set Recipient is in breach of this agreement, and/or the Recipient is to provide evidence of returning or destroying the data.

Form submitted by (PI): Lori Leibold Lori Leibold March 18, 2020
 Signature Print Name Date

Data Set Recipient Signatory Official

[Signature] Chris Saxton 9/25/2020
 Signature Print Name Date
 Director, Office of Research & Sponsored Programs

Title

BT Signatory Official

[Signature] Edward M Kolb, MS, MBA Edward M Kolb, MS, MBA 3-27-2020
 Signature Print Name Date
 EUP Boytann, healthcare ; Director BTNRH

Title

Approved by:

[Signature] Patrick Connell, RN, MBA, FACHE, CBHE 3/20/20
 Signature Print Name Date
 BT IRB Chair

[Signature] Theresa Crum 3/18/2020
 Signature Print Name Date
 BT Privacy Officer

APPENDIX C

CONSENT TO PARTICIPATE IN HUMAN RESEARCH



ADULT INFORMED CONSENT

(19 years of age and older)

To participate in a research project entitled
**Susceptibility to and Release from Masking in
 Infancy and Childhood**

This form shows that

Subject's First Name	Middle Name	Last Name	Date of Birth
----------------------	-------------	-----------	---------------

agrees to participate in a research study at the Boys Town National Research Hospital in Omaha, Nebraska.

Please ask if you want something explained to you. Some of this may be unfamiliar to you.

PROCEDURES: The purpose of this study is to learn how children hear in noisy backgrounds.

- An audiologic exam (hearing tests) may be done.
- You may be asked to answer questions about your hearing history and your family background.
- An audiologist will perform all clinical tests.
- An audiologist or research staff member may perform other tests.

Audiologic Exam (hearing tests):

These tests tell how well you hear and what part of your hearing system is damaged if you do have a hearing loss. Your hearing system is made up of the outer ear, the middle ear, the inner ear, and the pathways for hearing to your brain. The following procedures may be completed:

Otoscopy - An otoscope is the size of a small flashlight. It is used to look into your ear canal.

- It will not cause you any discomfort.
- This exam typically takes less than a minute.
- There are no known risks from this exam.

Acoustic Immittance or Tympanometry - This tests how well your middle ear works.

- A small earplug will be placed into each ear. You may notice slight discomfort from the earplug.
- You will hear a low-pitched sound and feel pressure in your ear.
- Testing takes 3 - 5 minutes.

BTNRH IRB - Protocol # 15-04-XP
Adult Consent Form
 Form 5 - v2016.1
 Page 1 of 4

IRB approved for ONE year
 Valid through: 25 May 2018



DN: cn=Rebecca J Cash, o=Boys
 Town National Research Hospital,
 ou=Research Compliance,
 email=rebecca.cash@boystown.o
 rg, c=US

- There are no known risks from taking this test.

Probe Microphone Testing - This test measures how loud your hearing aid(s) are.

- A small and flexible tube with a microphone is placed into your ear canal. Some find the tube to be uncomfortable. Then your ear mold is inserted.
- You will hear a series of sounds. The sounds will not be loud enough to damage your hearing.
- All you have to do is sit quietly during the test, which should take 5 - 15 minutes.
- There are no known risks from taking this test.

Pure-tone Audiometry (Standard Hearing Test) - This test measures how well you hear.

- You will hear sounds presented over earphones and indicate when you hear a sound.
- You may be asked to play a game to tell the tester when you hear the sounds.
- This test will take about 30 minutes.
- There are no known risks from taking this test.

Speech Recognition - This test measures how well you can understand speech.

- You will hear speech sounds over earphones and will respond by either repeating the word or pointing to a picture of the word.
- The test will take 5 - 15 minutes.
- There are no known risks from taking this test.

Sound perception testing: This test measures how well you hear speech and other sounds.

- You listen to sounds presented over a loudspeaker or earphones.
- The sounds are played in quiet, with noise in the background, or with speech in the background.
- You let us know what you heard by raising your hand, by touching a picture on a touch-screen computer monitor or by repeating back words or sentences.
- We may record you repeating back words or sentences using a microphone.

Each visit lasts from 1 to 2 hours. This study requires 1-3 visit(s) that last 1-3 hour(s) each. You will get breaks during testing. You can stop at any time.

You will be paid \$15 for the first hour of testing and \$5/20 minutes after the first hour.

POTENTIAL RISKS, DISCOMFORTS, OR OTHER PROBLEMS:

- No sounds will be loud enough to cause discomfort or damage hearing.
- A risk or discomfort may occur to you that we cannot predict.

BENEFITS:

- Your participation will help researchers understand how children and adults hear in noisy environments.
- It will also provide us with information about how children with hearing loss understand speech when there are background sounds.
- As part of this study, you may receive a hearing test for free.
- We will tell you if we find out any important information about your health.

AVAILABILITY OF MEDICAL TREATMENT:

- We use safe procedures.
- The chance of injury is small.
- If you are injured:
 - We will provide emergency treatment for free.
 - We will not pay you or your family any other money.

RIGHT TO WITHDRAW:

- You do not have to take part in this project.
- You can withdraw at any time without a penalty.
- Simply tell the researcher.
- Boys Town will not change the way they treat you if you do quit the study.

RESEARCH SUBJECT AGREEMENT: Taking part in this study will not make you an employee of Boys Town National Research Hospital.

ASSURANCE OF CONFIDENTIALITY:

- We keep all of our records in secured filing cabinets or in a password-protected computer file.
- We will not reveal your identity unless it is required by a law.
- We won't use your real name if we publish or present the results from this study.
- With your written permission, we can share results of hearing and/or speech and language tests with your audiologist, doctor or other agency.

RESEARCHER'S ASSURANCE: Lori Leibold, Ph.D. is responsible for this research. She will:

- Make sure that all of your questions are answered.
- Tell you of any changes to the procedures, risks or benefits.
- Make sure that all information stays confidential.

Lori Leibold, Ph.D.
 Director of the Center for Hearing Research
 Director, Human Auditory Development Laboratory
 Boys Town National Research Hospital, 555 N. 30th Street, Omaha, NE 68131
 Email: lori.leibold@boystown.org | Phone: (402)498-6322

Someone from Boys Town may contact you so that we can hear about your experience.

Please contact the Chairperson of the Institutional Review Board if any of the following occur:

- The researchers do something that is different from what they told you.
- They ignore requests for information.
- You have questions that they did not answer.
- You are injured during this research project.

Institutional Review Board
 Boys Town National Research Hospital
 555 North 30th Street, Omaha, NE 68131
 402-498-6700 (TDD/TTY 1-800-883-0920)

STATEMENT OF CONSENT:

- I have the legal authority to sign this form.
- I have discussed the above information with the researchers.
- All of my questions have been answered.
- I agree to take part in the study.
- I have been offered a copy of this consent form.

Signature of research subject

Date

Signature of witness

Date

I have discussed with this subject the procedure(s) described above and the risk involved. I believe she/he understands the content of the consent form and is competent to give legally effective and informed consent.

Signature of researcher administering this consent

Date