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Development of 90th Percentile Norms for Ipsilateral Acoustic Reflex Thresholds: A Feasibility Study

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DEVELOPMENT OF 90[TH] PERCENTILE NORMS FOR IPSILATERAL ACOUSTIC REFLEX THRESHOLDS: A FEASIBILITY STUDY

By:

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This manuscript has been read and accepted for the Graduate Faculty in Audiology in satisfaction of the dissertation requirement for the degree of Doctor of Audiology.

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The acoustic reflex threshold has been well established in the literature as an involuntary bilateral contraction of the stapedius muscle in response to loud transient sounds. Additionally, the clinical utility of the acoustic reflex threshold has been established as it allows for the differential diagnosis of many different conductive, cochlear and retrocochlear pathologies. Gelfand, Schwander and Silman (1990) have established and validated 90th percentile normative data for use with the contralateral acoustic reflex threshold. Much of the literature on the acoustic reflex threshold has focused on the contralateral acoustic reflex threshold; however, surveys have found that many clinicians are performing the ipsilateral acoustic reflex threshold in lieu of either the contralateral reflex or both together. The purpose of this study was to determine the feasibility of establishing 90th percentile normative data for use with the ipsilateral acoustic reflex threshold in view of the lower maximum outputs. Results indicated that ipsilateral acoustic reflex thresholds were likely to be present for hearing losses through at least moderate levels and were likely to be absent at levels of 70 dB HL and above. Results of the current feasibility study indicate the need for a larger-scale exploration of the ipsilateral acoustic reflex threshold as a function of hearing loss with particular emphasis on the moderately severe range.

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TABLE OF CONTENTS

LIST OF TABLES

INTRODUCTION

The acoustic reflex, also known at the stapedius muscle reflex, occurs via the contraction of the stapedius muscle and is elicited by a loud and transient stimulus which can be a single frequency pure tone or broadband noise. Moller (1962) and his early work on this topic found that once the stapedius muscle contracts, the ossicular chain stiffens and there is a decrease in admittance. The reflex is a bilaterally obligatory contraction, meaning that when elicited, even if only on on side, both the right and left stapedius muscles contract. Thus, the acoustic reflex can be elicited in one ear and measured in the contralateral ear, or elicited and measured ipsilaterally.

Both ipsilateral and contralateral reflexes require designated anatomical way stations to complete the contraction. After the activator stimuli is introduced, the pathway for the ipsilateral acoustic reflex is as follows: outer and middle ear, cochlea and the VIIIth cranial nerve, ventral cochlear nucleus and superior olivary complex to the facial motor nucleus and motor branch of cranial nerve seven, terminating in the contraction of the stapedius muscle on the side of the activator sound. The contralateral pathway includes all the main components of the ipsilateral pathway, but crosses the midline between the ventral cochlear nucleus and the superior olivary complex.

The acoustic reflex is postulated to serve several functions. First, it helps decrease the intensity of low frequency sounds allowing the contractions to serve as a protective mechanism. This concept was first introduced in the 1600’s by Fabricius ab Aquapendente who suggested that the muscles protected the ear drum from rupturing when the ear was exposed to loud sounds. This was titled the “intensity control theory” by Kato in the early 1900’s who experimented with cats and rabbits to investigate the contraction of the stapedius and tensor tympani muscles (Borg, Counter & Rosler, 1984). Second, the reflex allows for a “gain control mechanism” which allows certain frequency sounds to be transmitted more efficiently. In an experiment using cats, this attenuation was found to be greater in the ipsilateral ear than the contralateral ear (Guinan & McCue, 1987). Third, internal physiological sounds have been found to be attenuated for the comfort of the individual by the acoustic reflex (Hunter & Shahnaz, 2014).

Three methods of monitoring have been outlined by Green and Margolis (1984); electromyography, manometry and use of acoustic impedance. Electromyography utilizes a recording electrode that is placed on the stapedial tendon. When the contraction occurs to the stimulus, the measurement is made and recorded. Manometry monitors changes in air pressure in the ear canal. When the stapedius muscle contracts the tympanic membrane will either move inward or outward, changing the air pressure in the ear canal by changing the volume of the sealed off ear canal. Both electromyography and manometry are seldom used as they are difficult to measure and cumbersome to set up. Changes in acoustic impedance is the more widely used measure of the acoustic reflex.

Using the acoustic impedance method, the reflex is elicited and then measured by presenting two sounds, one to elicit the stapedial contraction and the second measures the changes in impedance (Green & Margolis, 1984). Clinically, a probe tone of either 226 Hz or 1000 is placed in a sealed ear canal and used to measure the reflex (Schairer, Feeney & Sanford, 2013). An eliciting stimulus is delivered to the ear (either contralaterally or ipsilaterally depending on desired measurement). The reflex is typically elicited using pure tones at frequencies from 500-4kHz. The frequency of 1kHz has been used as the most common activator frequency for screening methods and also has been shown to be the most reliable frequency (Hunter & Shahnaz, 2014; Ferekidou et al., 2008*).* When the stapedius muscle contracts, the impedance of the middle ear increases due to the mass reactance to the low frequency probe. The increase in impedance is detected as the sound pressure level of the probe tone in the ear canal increases (Green & Margolis, 1984). The criterion used to show a change in impedance and a present acoustic reflex is typically 0.02 to 0.03 mmhos (Schairer et al., 2013). The acoustic reflex threshold is considered to be the lowest level at which an impedance change is viewed, but below which no deflection is observed (Hunter & Shahnaz, 2014; Wallin, Mendez-Kurtz & Silman, 1986).

Many studies looking at the utility of the reflex have investigated differences between ipsilateral and contralateral reflex thresholds. In 1962, Moller studied the sensitivity of the reflex to ipsilateral and contralateral stimulation. He found that the sensitivity of the ipsilateral stimulation was greater than that of the contralateral stimulation, specifically an average of 3 dB greater. He noted that some subjects had ipsilateral reflexes up to 12 dB better than contralateral. In 1975, Fria and colleagues replicated Moller's study utilizing newer and more advanced immittance instrumentation, while only looking at 1kHz and 2kHz reflex thresholds like Moller (1962). They compared the ipsilateral and contralateral reflex threshold in normal hearing individuals and individuals with sensorineural hearing loss. Fria et al. (1975) found, that in individuals with normal hearing, ipsilateral reflex thresholds were 7 dB lower than contralateral thresholds at 1kHz and 3 dB lower at 2kHz. In individuals with sensorineural hearing loss the ipsilateral acoustic reflex threshold was 6 dB more sensitive at 1kHz and approximately 3dB more sensitive at 2kHz. The difference at 1kHz in the participants with sensorineural hearing loss and normal hearing was statistically significant whereas the difference at 2kHz was not found to be statistically significant. Laukli and Mair (1980), however, did not find any significant differences between ipsilateral and contralateral thresholds in 20 individuals. They attributed the discrepancy between their study and the literature identifying significant differences between ipsilateral and contralateral thresholds to differences in methods (using 5 dB steps versus 2 dB steps), calibration of instrumentation and uncertainty in regard to actual versus “artifactual responses” (Laukli & Mair, 1980). In summary, aside from Laukli and Mair’s (1980) study, classical literature discussing differences in ipsilateral and contralateral reflex thresholds have found the ipsilateral reflex threshold to be measured at lower levels than the contralateral reflex threshold.

In addition to studying the differences in sensitivity between ipsilateral and contralateral reflexes, researchers have analyzed the level at which ipsilateral and contralateral acoustic reflex thresholds are present. Margolis (1993) found typical reflex thresholds to be about 90-95 dB SL for pure tones. Additionally, according to Margolis (1993), individuals with sensorineural hearing loss up to 40 dB HL tend to have have reflex thresholds to tonal stimuli at a constant level. Once hearing loss increases past 40 dB HL, reflex thresholds begin to increase along with the magnitude of hearing loss. Alternatively, Gelfand, Piper and Silman (1983) found that acoustic reflex thresholds remain constant up until approximately 50 dB HL in individuals with sensorineural hearing loss. The reflex threshold will increase with further increases in hearing loss up until 70 dB HL. The acoustic reflex will often times not even be measurable in individuals with hearing losses greater than 70 dB HL (Margolis, 1993).

The acoustic reflex has been used by the diagnostician to determine the integrity of the ascending auditory pathway (Flamme et al., 2016); additionally, it allows for the differential diagnosis of multiple sclerosis, facial nerve pathology, intra-axial brainstem lesions, auditory neuropathy spectrum disorder and superior canal dehiscence (Emanuel, Henson and Knapp, 2012; Hunter et al., 1999). In comparison to an MRI, which is also utilized in the diagnosis of the aforementioned pathologies, the acoustic reflex threshold in conjunction with acoustic reflex decay allows for shorter test time, increased availability to studies, lower cost and no radiation (Hunter at al., 1999). The acoustic reflex is useful as it requires no behavioral response and is measured quickly, especially in comparison to auditory brainstem response tests, and measurement does not require ideal signal to noise ratios like in otoacoustic emissions, and can be used to obtain audiometric information in challenging to test patients. Both contralateral and ipsilateral acoustic reflexes can assist in the differential diagnosis of retrocochlear lesions (Ferekidou et al., 2008). Each pathway has its benefits and pitfalls when measured in the clinical setting. Stach (1987) suggested that the ipsilateral reflex and contralateral reflex when measured in isolation of each other served little diagnostic utility. However, when measured together, the reflex thresholds provided useful diagnostic information. It should be noted that both contralateral and ipsilateral reflex measurements are used by some clinicians and not all.

The utility of the acoustic reflex was enhanced by the 90^{th} percentile study by Gelfand, Schwander and Silman (1990) which is predicated on the concept that there is a range of reflex thresholds associated with normal and cochlear hearing loss, and a range that indicates the presence of a retrocochlear pathology. Silman and Gelfand (1981) followed by Gelfand et al. (1990) identified the relationship between acoustic reflex thresholds and magnitude of hearing loss utilizing large samples. Silman and Gelfand (1981) retrospectively analyzed 544 ears with normal hearing and hearing loss of cochlear/sensorineural origin. Mean reflex thresholds as a function of hearing loss in addition to 90^{th} percentiles for 10 dB increments of hearing loss were calculated for 500Hz, 1kHz and 2kHz. The 90th percentile values for contralateral acoustic reflex thresholds were proposed to be used as cut off values whereby if a patient's threshold fell beyond the 90^{th} percentile it would imply retrocochlear involvement. Gelfand et al. (1990) repeated an analysis similar to their 1981 article using 2,748 ears. They altered the study by grouping means and 90th percentile values into hearing loss increments of 5 dB HL, changing the study from a retrospective study and made changes to better assess no response results at each of the given frequencies. The tables/figures they developed are used clinically to assist in differentiating between cochlear and retrocochlear pathology in ears found to be sensorineural.

The ability of the acoustic reflex threshold to accurately identify retrocochlear pathology has been researched and validated. In 129 ears with retrocochlear impairment and in 100 ears with cochlear impairment, Sanders (1984) found that the sensitivity the 90th percentile in accurately identifying the retrocochlear pathology. When paired with the reflex decay the sensitivity was 85%. The false positive rate was only 11% in this study (Sanders, 1984). Bauch, Olsen and Harner (1983) found similar results in 30 ears with cerebellopontine angle (CPA) tumors and 30 ears without tumors. The acoustic reflex threshold data was found to be abnormal in 25 of the participants, 83%, with CPA tumors and 2 participants, 7%, without tumors. Abnormality of the acoustic reflex threshold in the Bauch et al. (1983) study was determined by an absent reflex when hearing sensitivity was less than 70 dB HL or when reflex decay was abnormal. These results indicate the success in using the contralateral reflex threshold in positively and accurately identifying retrocochlear pathologies such as acoustic neuromas.

Historically, there have been more studies on the contralateral acoustic reflex threshold; the use of the contralateral reflex may have been preferred, at least in part, because of the potential artifact that resulted from eliciting and measuring the ipsilateral reflex. Due to the set up of the ipsilateral acoustic reflex measurement, the stimulation and measurement occur in one ear and additive artifact can occur (Margolis et al., 1983). Modern instrumentation, including the Welch Allen GSI tympstar, which was used for the data collection in this study, utilize a multiplex circuit eliminating the additive artifact possible in the older immittance instrumentation. A multiplex system alternates the presentation of the probe tone and stimulus alternatively to eliminate any distortion or artifact that would arise from them being presented simultaneously (Silman & Emmer, 2011). Therefore, when the elicitation signal is off, the probe microphone is on to record accurate changes in immittance (Sells et al., 1997). Whereas normative data in the form of tables or figures have been developed for use with contralateral reflex testing, similar ones for use with ipsilateral testing are not currently available. One benefit of the ipsilateral reflex test is that the procedure is inherently less prone to artifact due to the fact that only one probe needs to be inserted into the ear canal accurately and properly. The contralateral probe is not used during this procedure, so any artifact as a result from the adversely positioned contralateral probe is irrelevant (Green & Margolis, 1983).

Another advantage to the use of ipsilateral reflexes is related to the concern expressed by some patients and clinicians regarding the intensity levels used to elicit the reflex (Emanuel et al., 2012). Due to the high presentation level needed to elicit the reflex, there have been concerns regarding acoustic trauma or noise induced hearing loss. There have been case studies presented by Hunter et al. (1999) demonstrating permanent threshold shifts after the presentation of the stimuli for the acoustic reflex threshold test. As noted earlier, the ipsilateral reflex threshold has been found to be 2-16 dB HL lower than the contralateral threshold (Hunter & Shahnaz, 2014). Therefore, testing for ipsilateral reflex would likely require a lower intensity stimulus than the contralateral reflex test; thus, concerns regarding presentation level can be reduced.

The above advantages and convenience of ipsilateral reflex testing may be responsible for the decision of some clinicians to test only in this manner. According to a recent study which surveyed practicing audiologists, Emanual et al. (2012) discovered that although a majority (60%) of respondents reported administering both ipsilateral and contralateral reflex testing, over a third (34%) used only ipsilateral reflex testing. Whereas the data on the 90th percentile has been established only for contralateral reflex testing, this useful tool is not available for ipsilateral reflexes. Even for clinicians who test contralaterally, the opportunity to use the 90th percentiles may be confounded by conductive pathology on the other side. Thus, the establishment of norms for ipsilateral reflexes would add an important tool to the clinician's armamentarium. A potential complication, however, is the output limitations for stimulus intensity required to avoid intermodulation distortion by the two signals during ipsilateral testing. Whereas in the case of contralateral reflexes, one could potentially test as high as 120 dB HL at 500, 1k and 2k Hz ipsilateral testing is limited to 110 dB HL at 500 and 1kHz and 105 at 2kHz. It is not clear at which hearing level one would be likely to reach output limits, resulting no response.

Reason for the Study

The purpose of the current research was to conduct a feasibility study to investigate the potential value in establishing the 90th percentile during ipsilateral reflex testing. Results of the current investigation would provide valuable information regarding the importance of pursuing a full-fledged investigation establishing norms.

The following research questions were addressed:

1. What are the hearing levels which are limited by maximum output of the eliciting stimulus, resulting in the absence of a response during ipsilateral reflex threshold testing?
2. What are the 90th percentiles values as a function of hearing loss and frequency? What is the relationship between the ipsilateral and contralateral 90th percentile values?

METHODS

Participants

The sample included 28 ears of 14 participants ranging in age from 24 to 78 with a mean age of 38, and included 4 males and 10 females. Inclusion criteria for all participants were the following: hearing thresholds ranging from within normal limits to 80 dB HL at the test frequencies of 500, 1000 and 2000 Hz, normal middle ear function as determined by otoscopy and tympanometry (static admittance results from .30-1.30 mmhos, equivalent ear canal volume of .3-2.0 mmhos, tympanometric peak pressure point >-100 daPa) and air-bone gaps less than 15 dB HL and sensorineural hearing loss consistent consistent with cochlear pathology based on contralateral acoustic reflex thresholds which did not exceed Gelfand et al. (1990) 90th percentiles at 500Hz, 1000 Hz and 2000 Hz. One participant was excluded from participation based on a contralateral reflex threshold exceeding Gelfand et al. (1990) 90th percentile.

Participants were recruited via email sent to patients from the audiology clinic at both the City University of New York Graduate Center and Brooklyn College, and by word of mouth (Appendix A). Participation in this study was voluntary and participants were able to refuse participation at any point with no penalty. Approval for this research was granted by the City University of New York Integrated Institutional Review Board on February 9, 2016 (Appendix B).

Instrumentation

All tests were completed in sound treated suites and testing was done using a Grason Stadler Instruments (GSI)-61 audiometer. Insert earphones and a bone oscillator with mastoid placement were used. Immittance testing, and acoustic reflex thresholds (both contralateral and ipsilateral) were measured using a Welch Allyn GSI tympstar. All equipment was calibrated according to the ANSI standards for audiometric instrumentation.

Procedures

Testing was performed at the Hearing Science Laboratory at the City University of New York Graduate Center (GC) by the primary investigator. Participants were asked to complete the informed consent before participating in the study (Appendix C). Otoscopy was performed to ensure clear canals, and clear and visualized tympanic membranes. Air and bone conduction thresholds were obtained for frequencies 500 Hz, 1000 Hz, and 2000 Hz using a Hughson-Westlake method for the ascending-descending procedure in a sound treated suite (Carhart & Jerger, 1959). Tympanometry and contralateral acoustic reflex threshold were assessed at this point. Activating signals for contralateral acoustic reflex thresholds were 500 Hz, 1000 Hz, and 2000 Hz pure tones presented in 5 dB increments with a maximum level at instrumentation limits. The criterion for a reflex response was an observed meter deflection time locked to the presentation of the activator and differentiable from background activity (Silman & Gelfand, 1981). Reflex thresholds were recorded as the lowest activator level at which these criteria were met. Ipsilateral acoustic reflex thresholds were determined at the end of the session utilizing the same criterion used for the determination of the contralateral acoustic reflex thresholds.

RESULTS

Ipsilateral and contralateral acoustic reflex threshold results for all participants as a function of pure tone thresholds and activator frequency appear in Table 1. Pure tone thresholds obtained from the participants included in the study were found to range from 10-70 dB HL at 500Hz, 5-75 dB HL at 1000 Hz and 0-80 dB HL at 2000 Hz**.** Perusal of Table 1 reveals a preponderance of the data from participants with hearing levels of 55 dB HL and below. Whereas data were collected from a convenience sample of individuals who responded to a recruitment email, five participants were found to have hearing within normal limits at all three activator frequencies, with the others having sensorineural hearing loss, mostly with sloping configurations. The data from both ears of one participant with sensorineural hearing loss were excluded from data analysis due to contralateral reflexes exceeding 90th percentiles (Gelfand et al. 1990). This was based on the selection criteria chosen to reduce the risk of including a participant with potential retrocochlear pathology.

An important question posed in this feasibility study was whether the lower output limitations when performing ipsilateral reflex testing, compared to contralateral testing, would interfere significantly with the success in obtaining a reflex threshold. The results from Table 1 revealed that in the case of all pure tone hearing thresholds levels from 0-60 dB HL, ipsilateral reflex thresholds were obtained. It should be noted, however, that there were only two data points for hearing levels of 60 dB HL and none at 65 dB HL. These results suggest that at least for mild to moderate degrees of hearing loss, it is reasonable to expect present acoustic reflex thresholds. For hearing levels of 70 dB HL or greater, there was evidence of absent reflexes at the maximum outputs for both ipsilateral and contralateral acoustic reflex thresholds. Only five data points were obtained at these hearing levels, however. Acoustic reflexes were absent in four of the five cases during ipsilateral testing, but only in one case during contralateral testing. With a higher maximum output, it is likely that more responses would have been obtained in the ipsilateral condition.

Table 1
Ipsilateral and contralateral acoustic reflex threshold results for all participants as a function of pure tone thresholds and activator frequency

IPSILATERAL REFLEX THRESHOLDS				CONTRALATERAL REFLEX THRESHOLDS			
HL	**500 Hz**	**1000 Hz**	**2000 Hz**	**HL**	**500 Hz**	**1000Hz**	**2000Hz**
0	***No Data***	***No Data***	85, 90	***0***	***No Data***	***No Data***	85, 90
5	***No Data***	90, 85, 95, 95	95, 80	***5***	***No Data***	100, 100, 100, 100	100, 90
10	95, 80, 80, 80	80	95, 85, 90	***10***	95, 95, 95, 90	95	95, 90, 85
15	90, 90, 95, 80, 80, 95	90, 85, 95, 90, 85	95, 90	***15***	85, 85, 90, 95, 95, 95	95, 95, 90, 95, 100	95, 95
20	95, 85, 90, 85, 85, 90	90, 85, 85, 85, 80	100	***20***	95, 95, 95, 90, 95, 95	90, 100, 95, 85, 85	95
25	***No Data***	***No Data***	85, 80	***25***	***No Data***	***No Data***	85, 90
30	***No Data***	90, 85, 90	100	***30***	***No Data***	95, 85, 95	100
35	75, 75, 95, 100, 85, 80	95	95, 90	***35***	80, 90, 95, 100, 85, 85	100	105, 90
40	90	90	***No Data***	***40***	95	95	***No Data***
45	***No Data***	90, 100, 95	100, 85	***45***	***No Data***	95, 95, 105	100, 90
50	90, 90, 90	75, 75	100, 95, 95, 105	***50***	105, 90, 95	85, 95	95, 95, 105, 95
55	105	90	85, 80, 95	***55***	105	100	95, 85, 100
60	***No Data***	***No Data***	100, 95	***60***	***No Data***	***No Data***	105, 105
65	***No Data***	***No Data***	***No Data***	***65***	***No Data***	***No Data***	***No Data***
70	110	NR@110	***No Data***	***70***	115	110	***No Data***
75	***No Data***	NR@110	NR@105	***75***	***No Data***	115	NR@120
80	***No Data***	***No Data***	NR@105	***80***	***No Data***	***No Data***	120

Note: NR@X indicates no response at specified pure tone level, which was the output level of the immittance instrumentation at the given frequency

Table 2 shows the data points used for the calculation of the means and the 90th percentiles, which excludes data points for thresholds greater than 55 dB HL. Due to the very limited number of data points obtained at pure tone thresholds of 60 dB HL and above, only those data from hearing thresholds up to 55 dB HL were included for establishing mean and 90th percentile values as a function of hearing level. The elimination of data points from pure tone thresholds greater than 55 dB HL also avoided the problem of calculating means from no-response data as acoustic reflex thresholds were obtained in all cases at these pure tone thresholds; it, however, prevented these data from providing information for hearing levels above that range.

Table 2
Ipsilateral and contralateral acoustic reflex threshold results function of pure tone thresholds and activator frequency, used in the calculation of mean and 90th percentile values

IPSILATERAL REFLEX THRESHOLDS				CONTRALATERAL REFLEX THRESHOLDS			
HL	**500 Hz**	**1000 Hz**	**2000 Hz**	**HL**	**500 Hz**	**1000Hz**	**2000Hz**
0	***No Data***	***No Data***	85, 90	***0***	***No Data***	***No Data***	85, 90
5	***No Data***	90, 85, 95, 95	95, 80	***5***	***No Data***	100, 100, 100, 100	100, 90
10	95, 80, 80, 80	80	95, 85, 90	***10***	95, 95, 95, 90	95	95, 90, 85
15	90, 90, 95, 80, [illegible]	90, 85, 95, 90, [illegible]	95, 90	***15***	85, 85, 90, 95, [illegible]	95, 95, 90, 95, 100	95, 95
20	95, 85, 90, 85, [illegible]	90, 85, 85, 85, [illegible]	100	***20***	95, 95, 95, 90, [illegible]	90, 100, 95, 85, 85	95
25	***No Data***	***No Data***	85, 80	***25***	***No Data***	***No Data***	85, 90
30	***No Data***	90, 85, 90	100	***30***	***No Data***	95, 85, 95	100
35	75, 75, 95, 100, [illegible]	95	95, 90	***35***	80, 90, 95, 100, [illegible]	100	105, 90
40	90	90	***No Data***	***40***	95	95	***No Data***
45	***No Data***	90, 100, 95	100, 85	***45***	***No Data***	95, 95, 105	100, 90
50	90, 90, 90	75, 75	100, 95, 95, 105	***50***	105, 90, 95	85, 95	95, 95, 105, 95
55	105	90	85, 80, 95	***55***	105	100	95, 85, 100

Mean acoustic reflex threshold data as a function of hearing level, obtained for ipsilateral and contralateral acoustic reflex testing appear in Tables 3, 4, and 5 for 500, 1000 and 2000 Hz respectively. In the case of the ipsilateral reflexes, mean results fell within the 90 dB HL range for the most part, with no clear pattern, except perhaps for a small increasing trend at 2000 Hz. With regard to the contralateral reflexes, there also was no consistent increase of the mean with increase in hearing threshold. Comparing ipsilateral versus contralateral means revealed that the ipsilateral means were consistently more sensitive, better by about 4-5 dB at 500 Hz, 3-13 dB at 1000 Hz and 2-4 dB at 2000 Hz.

Table 3

Mean comparisons between ipsilateral and contralateral acoustic reflex thresholds for 500 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	No Data	No Data	85.4/85.9
10 15	86.5	92	86/86.7
20-25	89.375	94.375	86.7/85.8
30-35	85	89.16667	85.7/85
40-45	90	95	87.2/88.3
50-55	93.75	98.75	89.9/94.4

Note: x/y indicates the mean for the x-y range. Included for comparison are mean contralateral reflex thresholds from Gelfand et al (1990)

Table 4

Mean comparisons between ipsilateral and contralateral acoustic reflex thresholds for 1000 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	91.25	100	86.1/87.3
10 15	87.5	95	87.4/88.6
20-25	85	91	87.6/87.9
30-35	90	93.75	88.5/90.2
40-45	93.75	97.5	88.2/89.1
50-55	80	93.3333	91.1/90.7

Note: x/y indicates the mean for the x-y range. Included for comparison are mean contralateral reflex thresholds from Gelfand et al (1990)

Table 5

Mean comparisons between ipsilateral and contralateral acoustic reflex thresholds for 2000 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	87.5	91.25	87.6/88.1
10 15	91	92	88.6/89.2
20-25	88.33333	90	89.8/89.6
30-35	95	98.33333	91.6/91.3
40-45	92.5	95	93/93.4
50-55	93.57143	95.714	93.9/95.1

Note: x/y indicates the mean for the x-y range. Included for comparison are mean contralateral reflex thresholds from Gelfand et al (1990)

To establish an upper limit associated with an etiology of cochlear pathology, the 90th percentiles were also calculated for both ipsilateral and contralateral acoustic reflex thresholds, and these results appear in tables 6, 7 and 8 for 500, 1000 and 2000 Hz, respectively. It should be noted that the reason there are two values for the Gelfand et al. (1990) 90th percentile for 2kHz from 50-55 dB HL is due to the fact that when the tables from the literature were condensed 50 dB HL had a different 90th percentile than 55 dB HL, 95 for 50 dB HL and 100 for 55 dB HL. For all other hearing level ranges, the values were the same. Here again, it should be kept in mind that even with eliminating higher level hearing losses, as a result of the small sample size used in this pilot study, some of the calculations were based on only a small number of data points or even only one. Thus, these results, especially in the case of the 90th percentiles, must be treated with caution. Results revealed, as seen with the mean data, that the 90th percentile values varied little as a function of hearing loss through levels of 55 dB HL. In addition, these values, almost without exception, were either more sensitive ipsilaterally or the same as the contralateral reflex thresholds.

Table 6

90th percentile comparisons between ipsilateral and contralateral acoustic reflex thresholds for 500 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	No Data	No Data	95
10 15	95	95	95
20-25	95	95	95
30-35	97.5	97.5	95
40-45	90	95	95
50-55	100.5	105	100

Note: Included for comparison are 90th percentile contralateral reflex thresholds from Gelfand et al (1990)

Table 7

90th percentile comparisons between ipsilateral and contralateral acoustic reflex thresholds for 1000 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	95	100	95
10 15	92.5	97.5	95
20-25	88	98	95
30-35	93.5	98.5	95
40-45	98.5	102	95
50-55	87	99	95/100

Note: Included for comparison are 90th percentile contralateral reflex thresholds from Gelfand et al (1990).

Table 8

90th percentile comparisons between ipsilateral and contralateral acoustic reflex thresholds for 2000 Hz activator frequency as a function of hearing level

HL	Ipsilateral	Contralateral	Gelfand et al (1990)
0-5	93.5	97	95
10 15	95	95	95
20-25	97	94	95
30-35	99	104	100
40-45	98.5	99	100
50-55	102	102	105

Note: Included for comparison are 90th percentile contralateral reflex thresholds from Gelfand et al (1990)

DISCUSSION

The current study was designed, with a sample of 28 ears with normal or sensorineural hearing loss, to gather data on the relationship between hearing level and acoustic reflex thresholds during ipsilateral acoustic reflex testing. These preliminary data were collected to begin a systematic replication of the study by Gelfand et al., (1990) by focusing on the ipsilateral reflex threshold. Once data were collected, mean reflex thresholds and 90^{th} percentiles were calculated for each 10 decibel hearing threshold range. The goal was to determine the potential of obtaining sufficient useful data, despite the more stringent output limitations associated with ipsilateral reflex testing; positive findings would support an investigation with a larger sample size.

Contralateral Means

There have been few published studies or calculation of normative data regarding the ipsilateral acoustic reflex threshold, due perhaps in part to concerns of instrumentation artifact, prior to multiplex systems. There are numerous studies documenting average contralateral acoustic reflex thresholds at 500Hz, 1000 Hz and 2000 Hz to pure tone stimuli in individuals with normal hearing, as evidenced by the review of Gelfand (1984), as well as studies that calculated means for the contralateral acoustic reflex in individuals with hearing loss of sensorineural origin (Gelfand et al., 1990; Green & Margolis, 1984; Gelfand, et al., 1983). Included in Tables 3, 4, and 5, along with the results of the present study, are the mean data for contralateral reflexes provided by Gelfand et al. (1990) for comparison.

Results from the present study were consistent with those of Gelfand et al. (1990) who found no consistent increase in contralateral acoustic reflex means with increase in hearing thresholds up to 50-55 dB HL. Gelfand et al. (1983) identified the same consistency up until 50 dB HL as did Margolis (1993) who found a constant level at least through to 40 dB HL. It should be noted, however, that all of the mean results collected for the contralateral acoustic reflex threshold for the current project were found to be greater than the mean data from Gelfand et al. (1990) at all hearing levels by amounts ranging from 0.2 to 13.9 dB.

Differences in means can be the result of many possible factors. Differences are most likely due to the relatively small sample size used for this project; had there been more data points, it is possible means would have been lower. Gelfand et al. (1990) assessed the contralateral acoustic reflex in 2,748 ears whereas for the present project, mean data were based on only 28 ears. Additionally, for this project, visual detection of the acoustic reflex threshold was the method for identifying the presence of an acoustic reflex. If the data collector employed a more conservative criterion for visual monitoring it is possible that higher acoustic reflex thresholds were identified. Due to progression in instrumentation, a more modern Tympstar was used for this project, while a Grason Stadler Model 1723 was used for the collection of Gelfand at al. (1990) data. Calibration was likely not the cause for this discrepancy as appropriate calibration was performed prior to data collection. For this project, reflexes were not collected unless a hermetic seal was obtained in the ear canal. It is possible to obtain an acoustic reflex threshold without a hermetic seal. Diagnosticians and researchers should be especially discerning when assessing present or normal acoustic reflex thresholds when obtained without hermetic seals (Gelfand, 1984). It is possible that what they are visually identifying as a reflex is just artifactual deflections as a result of the lack of seal.

Ipsilateral means vs. contralateral means

Results from the current study were consistent with the literature, as shown in Tables 3, 4 and 5, in that impedance change was greater in the ear where the eliciting stimulus is presented.

In other words, the threshold in the ipsilateral ear was lower compared to the threshold in the contralateral ear (Moller, 1984). Moller (1962) found ipsilateral thresholds to be lower than contralateral thresholds. Our findings were very similar to those of Fria et al. (1975) who found that ipsilateral acoustic reflex thresholds were 7 dB lower than contralateral acoustic reflex thresholds at 1kHz and 3 dB lower at 2kHz. Laukli and Mair (1980) calculated the contralateral and ipsilateral reflex threshold means in 20 normal hearing individuals. They found the differences between contralateral reflex means and ipsilateral means to be 5.1, 2.7, 2.5 dB HL for 500, 1k and 2kHz respectively. These results are similar to the results calculated by Wiley, Oviatt and Block (1987) performed a similar data collection and analyses of 253 ears and calculated means for ipsilateral and contralateral acoustic reflex thresholds. Their results yielded differences of 4.7, 3.9 and -1.8 dB HL for 500, 1k, and 2k Hz respectively between contralateral and ipsilateral reflexes.

Ipsilateral reflex testing and absent reflexes

An important research question posed in the current study was whether the lower output limitations would interfere significantly with the ability to obtain a reflex threshold during ipsilateral testing. The fact that reflexes were found to be present through at least 55dBHL is not surprising for two reasons: 1) data obtained using contralateral reflex testing has shown that, up through moderate degrees of hearing loss, the acoustic reflex threshold does not change significantly (Gelfand, 1984) and 2) ipsilateral reflex thresholds tend to be lower than contralateral reflex thresholds as noted above. It is unfortunate that more data could not be collected in the hearing loss range of 60-65 dB HL, although the two data points at 60 dB HL both revealed present acoustic reflexes. Thus, these preliminary results suggest that the output limitations of ipsilateral testing do not appear to negatively impact acoustic reflex results at least through 55dB HL and possibly 60 dB HL. For hearing levels of 70 dB HL and above, more absent reflexes were obtained during ipsilateral as opposed to contralateral testing, potentially revealing a disadvantage for ipsilateral testing for that hearing level. During contralateral reflex testing, the likelihood of absent reflexes has been shown to be minimal up until a hearing threshold of 70 dB HL (Gelfand et al., 1990). Thus, there is evidence that at hearing levels above 70 dB HL, the ability to elicit acoustic reflex responses is negatively impacted for both ipsilateral and contralateral testing. More research is needed to investigate ipsilateral acoustic reflex thresholds at hearing levels particularly in the 60-70 dB HL range.

90th Percentiles

Gelfand et al. (1990) has pointed out that acoustic reflex threshold means have little predictive value in relation to hearing loss levels due to the wide variability. This led the researchers to establish 90th percentile cut-off values for diagnostic utility in assessing present, elevated or absent contralateral acoustic reflex thresholds. Therefore, 90th percentiles were calculated for the ipsilateral as well as the contralateral reflex thresholds in this investigation. To gain more insight into the ipsilateral 90th percentiles, comparisons were first made between the contralateral 90th percentiles obtained in the present study and those of Gelfand et al. (1990). With regard to the contralateral reflex thresholds, the 90th percentiles were quite similar. All were the same or within 5 dB HL, except for one hearing level at 1000 Hz where it was within 10 dB HL.

Ipsilateral 90th percentiles

Given the similarity between the contralateral 90th percentiles, it is interesting to compare the ipsilateral 90th percentiles from the current study with the contralateral results from Gelfand et al (1990). Ipsilateral 90th percentile values were on average similar to Gelfand et al. (1990)

contralateral 90th percentile values at all hearing levels for all frequencies. This is not expected based on the mean ipsilateral results. The small sample size could be expected to affect the 90th percentile data more than the mean data since it is difficult to arrive specifically at a 90th percentile value with so few data points. In addition, according to Gelfand (1984), 90th percentile normative data cannot be evaluated in isolation from the hearing losses at frequencies adjacent to the activating frequency. Should hearing loss be more severe at other frequencies, acoustic reflex threshold might be affected by that hearing loss. It is important to note that the ipsilateral 90th percentile were all within 5 dB HL of the contralateral 90th percentiles. Had they been greater, it would be seemingly possible to conclude that there is no diagnostic utility to the ipsilateral reflex threshold. Further research is necessary to make conclusions regarding the diagnostic utility of the present or elevated ipsilateral threshold.

Clinical implications

In Emanuel et al. (2012) survey, one third of audiologists reported that they perform only ipsilateral testing. Anecdotal observation suggest it is currently even greater. Therefore, it is important to have norms based on ipsilateral reflexes. Thus, the following conclusions can be drawn based on the current study:

1. Ipsilateral acoustic reflex thresholds were found to occur at a lower mean intensity as compared with contralateral thresholds.
2. Contralateral and ipsilateral acoustic reflex thresholds remain essentially constant with changes in hearing level up to 50-55 dB HL.
3. The difference in maximum output limitations between ipsilateral and contralateral reflex testing (with greater maxima in contralateral reflex testing) do not appear to negatively impact recording of acoustic reflex thresholds at least through 55 dB HL

and possibly through 60 dB HL. There is preliminary evidence that at hearing levels of 70 dB HL and above, the ability to elicit acoustic reflex responses is negatively impacted.

4. Although 90^{th} percentile measures were calculated in this study, it is not possible to make any definitive statements regarding the ipsilateral 90^{th} percentiles at this time understandably due to the sample size. A larger-scale exploration of ipsilateral reflexes as a function of hearing level is warranted with establishment of norms for the 90^{th} percentile to aid in the diagnosis of cochlear versus retrocochlear pathology.
5. The current project was designed as a feasibility study, until a larger scale study is implemented, it is recommended that if ipsilateral reflexes are found to fall at or above above the 90th percentile, contralateral reflex testing should be performed and certainty be compared to the Gelfand et al. (1990) norms.

Recommendations for future research

In addition to implementing a larger investigation of the topic, a new survey would glean interesting information addressing some of the following issues: questioning audiologists' rationale for performing ipsilateral acoustic reflex in isolation and what audiologists are looking for when performing the test (absence, presence, actual level, etc.); how acoustic reflex thresholds are being reported (whether numerically or present/absent) and identifying what recommendations are being made in the absence of ipsilateral reflex thresholds in the presence of hearing within normal limits. Is the audiologist retesting to rule out instrumentation or artifactual errors, and is further testing being recommended?

APPENDIX A: RECRUITMENT EMAIL SENT TO POTENTIAL PARTICIPANTS

Hello,

My name is Iris Wertheimer and I am an Audiology Doctoral Student at the CUNY Graduate Center. I am conducting a study to describe the relationship between the ipsilateral acoustic reflex threshold and hearing thresholds to further increase its diagnostic value. This is a procedure that is part of the standard battery of tests done during a hearing test.

I am interested in knowing if you would be interested in participating in the study. What is required from you would be (a) to sign a consent form (stating that there is no risk) and (b) to participate in a brief hearing test. Once we finish the testing, I would be happy to elaborate on the process, tell you your results and answer any additional questions you may have. The entire procedure will take about 30 minutes and I will be happy to share and explain the results of the tests, should you request. All results and identifying information will remain confidential.

I hope you consider assisting in this study. Should you have any questions or wish to express interest, please do not hesitate to contact me.

Email address: iwertheimer@gradcenter.cuny.edu

Should you have any additional concerns please feel free to contact Dr. Dorothy Ditoro at dditoro@brooklyn.cuny.edu.

I look forward to hearing from you,

Iris Wertheimer

Doctoral Student of Audiology '17

CUNY Graduate Center

APPENDIX B: IRB APPROVAL LETTER

CUNY The City University of New York

University Integrated Institutional Review Board
205 East 42nd Street
New York, NY 10017
http://www.cuny.edu/research/compliance.html

Approval Notice
Initial Application

02/09/2016

Iris Wertheimer,
The Graduate School & University Center

RE: IRB File #2015-1363
The Relationship Between Magnitude of Hearing Loss and Ipsilateral Acoustic Reflex Threshold Levels

Dear Iris Wertheimer,

Your Initial Application was reviewed and approved on 02/09/2016. You may begin this research.

Please note the following information about your approved research protocol:

Protocol Approval Period:	02/09/2016 - 02/08/2017
Protocol Risk Determination:	Minimal
Expedited Categor(ies):	, (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual., (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey,

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interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Documents / Materials:

Type	**Description**	**Version #**	**Date**
Recruitment Script		1	10/04/2015
Recruitment Script	IRB-script.docx	2	10/20/2015
Recruitment Script	IRB-script.docx	1	10/22/2015
Scientific/Sponsor Protocol	IRB-protocol.docx	1	10/22/2015
Informed Consent Document	Consent form revisions.docx	1	02/08/2016

Please remember to:

- Use **the IRB file number** 2015-1363 on all documents or correspondence with the IRB concerning your research protocol.

- Review and comply with CUNY Human Research Protection Program policies and procedures.

The IRB has the authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

If you have any questions, please contact:
Natalie Wright
718-951-5000 ext3829/5519
nwright@brooklyn.cuny.edu

APPENDIX C: INFORMED CONSET

CITY UNIVERSITY OF NEW YORK

Graduate Center

Department of Audiology

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Project Title: The Relationship Between Magnitude of Hearing Loss and Ipsilateral Acoustic Reflex Threshold Levels

Principal Investigator: Iris Wertheimer
Graduate Student
CUNY Graduate Center
365 5th Avenue
New York, NY 10016

Faculty Advisor: Dr. Adrienne Rubinstein Ph.D
Professor
Brooklyn College Campus
Dept. of Speech Communication Arts and Sciences
2900 Bedford Avenue
Brooklyn, NY 11210
718 951-5186

Site where study is to be conducted: Graduate Center, CUNY 365 Fifth Avenue – Lab Room #7306, New York, NY 10016 **or** Brooklyn College Speech Language Hearing Center 2900 Bedford Avenue – Room 4400 Boylan Hall, Brooklyn, NY 11210

Introduction/Purpose: You are invited to participate in a research study. The study is conducted under the direction of Iris Wertheimer, Graduate Student, CUNY Graduate Center. The purpose of this study is to describe the relationship between a) the intensity level at which an ipsilateral acoustic reflex in the middle ear occurs and b) hearing ability in ears with hearing loss due to damage in the inner ear. The results of this study may contribute to the body of literature in use of these reflexes in the diagnosis of ear disease.

Procedures:
Approximately 20 individuals are expected to participate in this study. You will be participating in a hearing test where your ability to hear certain sounds at various volumes will be determined. Additionally, various involuntary responses will be measured. You will be in a sound treated suite with headphones and will be hearing certain tones and asked to respond. Additionally, an ear plug will be placed into your ear at which point you will be hearing additional tones; however, at this point you will not need to respond. This hearing evaluation will enable us to record various measurements in the hopes of adding to the body of literature on the ipsilateral acoustic reflex threshold.
The time commitment of each participant is expected to be about 30 minutes. Each session will take place either at the CUNY Graduate Center, 365 5th Avenue, New York, NY 10016 or Brooklyn College Hearing and Speech Science Center, 2900 Bedford Avenue, Brooklyn, NY 11210.

Possible Discomforts and Risks: Your participation in this study may involve breach of confidentiality, if proper precautions are not taken. To minimize this risk, all identifying information will be coded to protect the identification of each participant. No other risks should be encountered by the subject. If you are troubled or upset as a result of this study, please refer to the following website. -- http://www.cuny.edu/research/compliance/feedback.html

<u>Benefits</u>: There are no direct benefits. However, participating in this study may increase general knowledge of audiology and provide the participant with information about their hearing sensitivity.

<u>Alternatives:</u> *N/A*

<u>Voluntary Participation</u>: Your participation in this study is voluntary, and you may decide not to participate without prejudice, penalty, or loss of benefits to which you are otherwise entitled. If you decide to leave the study, please contact the principal investigator Iris Wertheimer to inform her of your decision.

<u>Financial Considerations</u>: Participation in this study will involve no cost to the subject.

<u>Confidentiality:</u> The data obtained from you will be collected via written documentation. The collected data will be accessible to Iris Wertheimer, the principle investigator and the faculty advisor, Dr. Adrienne Rubinstein. Additionally, IRB members and staff will have access to the collected data. The researcher will protect your confidentiality by coding the data. The collected data will be stored on a computer and in a locked file cabinet with no identifying information.

<u>Contact Questions/Persons</u>: If you have any questions about the research now or in the future, you should contact the Principal Investigator, Iris Wertheimer, (301) 523-5079, iwerthieimer@gradcenter.cuny.edu. If you have any questions concerning your rights as a participant in this study, you may contact Michael Brown, Research Compliance Administrator, (646)664-8906, Michael.brown@cuny.edu.

<u>Statement of Consent:</u>

"I have read the above description of this research and I understand it. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions that I may have will also be answered by the principal investigator of the research study. I voluntary agree to participate in this study.

By signing this form I have not waived any of my legal rights to which I would otherwise be entitled.

I will be given a copy of this statement."

________________________ Printed Name of Subject	________________________________ Signature of Subject	_____________ Date Signed
______________________ Printed Name of Person Explaining Consent Form	________________________________ Signature of Person Explaining Consent Form	_____________ Date Signed
______________________ Printed Name of Signed Investigator	________________________________ Signature of Investigator	_____________ Date Signed

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