Normative Reflectance Measurements on Healthy Newborn and One-Month Old Infants

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INTRODUCTION

LONG-TERM GOAL

The long-term goal of this research project is to determine if energy reflectance measurements can be used as an objective measure to detect middle-ear fluid in newborn babies, both at the time of newborn hearing screening and when middle-ear fluid is suspected. Energy reflectance measures provide a possible alternative to tympanometry, which appears to be an unreliable measure of middle-ear status for ages less than six months (Holte et al. 1991)

SPECIFIC GOAL OF THIS WORK

The specific goal of the work presented here is to characterize the energy reflectance of normal-hearing, healthy newborn babies. Keefe et al. (1993) demonstrated that the energy reflectance changes systematically with age, from one month past the age of two years. Other work focuses on energy reflectance in NICU babies (e.g. Shahnaz et al. 2008; Keefe et al. 2000), babies one month and older (Sanford and Feeney 2008; Keefe and Levi 1996; Keefe et al. 1993), or groups that include a range of newborn to more than one month (Hunter et al. 2008). Here, we present measurements of energy reflectance on normal-hearing, healthy newborn and one-month old babies.

RATIONAL FOR TEST OF MIDDLE EAR FUNCTION IN NEWBORNS

One to three percent of newborns fail newborn hearing screening and are referred for further audiological assessment; of these referrals, 90% are false-positives that can occur as a result of transient fluid or debris within the external or middle ear (Thompson et al. 2000; Doyle et al. 2000). The differentiation between transient loss associated with middle-ear fluid or debris and permanent conductive or sensorineural hearing loss is made via follow-up testing. In order to provide more complete audiological information starting at birth, a recent study funded jointly by the Centers for Disease Control and Prevention and the Association of Teachers of Preventative Medicine recommends the development of a screening tool for middle ear function at the time of newborn screening (Gravel et al. 2005).

Reflectance measurements may also help diagnose and manage young infants with otitis media, which affects 91% of children by age two (Paradise and Rockette 1997); medical management of children who suffer from recurrent otitis media includes substantial efforts to evaluate their middle-ear air space for fluid, as this fluid leads to conductive hearing loss and increased risk for developmental delays (Gravel and Ellis 1992). It is difficult to diagnose middle-ear fluid in children under six months of age, a population for which tympanometry is not reliable (Holte et al. 1991). However, medical management of infants with middle-ear fluid is essential in order to ensure they develop language appropriately and don't suffer from long-term effects of chronic otitis media. Thus, reflectance measurements could be useful in following middle-ear fluid in babies under the age of six months.

DESCRIPTION OF ENERGY REFLECTANCE

Reflectance is the ratio between the reflected pressure wave and the incident pressure wave, and its magnitude is between 0 (all energy absorbed) and 1 (all energy reflected). Energy reflectance is the square of the reflectance magnitude. The reflectance can be calculated from the impedance, which can be calculated from a pressure measurement in the ear canal combined with the Thevenin equivalent of the sound delivery system (Allen 1985).

EXPERIMENTAL METHODS

OVERVIEW: Reflectance was measured on newborn and one-month old babies using the FDA approved HearID system from Mimosa Acoustics (version 4.0) with an Etymotic ER-10c sound delivery system. To minimize acoustic leaks, foam tips (size 14B, Etymotic Research) were used (VanderWerff and Prieve 2007), and these tips were thinned out with scissors to allow them to fit into newborn ear canals (personal communication, Navid Shahnaz). The measurements were approved by the Smith College Institutional Review Board.

SUBJECTS: Eight newborn (ages 3 to 9 days) and eleven one-month old (age 28 to 34 days) babies were recruited by their pediatrician at a local pediatric office during their routine well-baby visit. One baby was recruited into both groups. Subjects were full-term, healthy babies who passed their newborn hearing screening. During their well-baby visit, each subject underwent an otoscopic examination to ensure a clear ear canal. All parents consented for their baby via an IRB approved consent form. Reflectance measurements were made as a part of the well-baby visit.

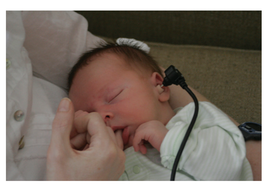

Figure 1: Reflectance measurement being made on an infant ear using an Etymotic ER-10c probe with 14B foam tip. (Photo used with permission from Navid Shahnaz.)

TESTING PROCEDURE: Measurements were taken on both ears from 7 of 8 newborns and on 8 of 11 one-month olds. In other cases, one ear was not measured due to excessive wax, and three were not measured due to a noisy baby. Parents held their babies, and if the baby cried, he or she was encouraged to suck on a pacifier or nurse. The cord of the probe tip was held by the experimenter in order to maximize its stability.

DATA ANALYSIS: Measurements were made every 25 Hz and were smoothed using a 7-point moving average filter. The reported p-values were computed with a numerical, bootstrap permutation test [i.e. "resampling" described by Efron and Tibshirani (1993)]. For all analyses, all subject data was used, regardless of whether or not both ears were tested, with the exception of comparisons between the left and right ear, in which case only subjects with data collected on both ears was analyzed.

RESULTS

1 Individual Measurements:

Energy reflectance measured on eight newborn and eleven one-month old babies.

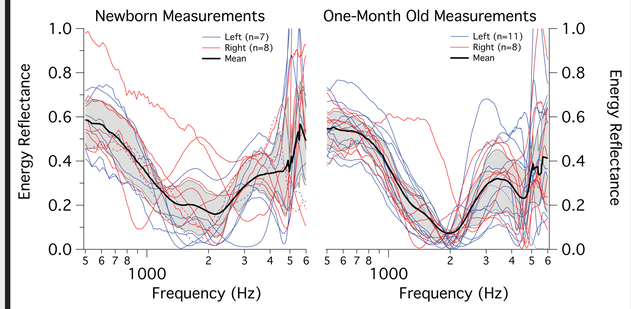

Figure 2. Individual energy reflectance measurements for left (blue) and right (red) ears, means (black), and 25 to 75 percent ranges (gray shaded region) measured on 8 newborn and 11 one-month old healthy babies, with one subject (represented as a dotted line) tested in both groups. Measurements on both ears were obtained for 7 of the 8 newborns and for 8 of the 11 one-month olds.

2 Left vs. Right Ears:

The mean energy reflectance from the left and the right ear is not significantly different for newborns or one-month olds.

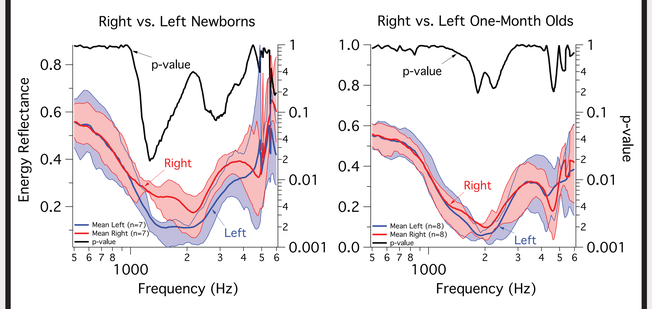

Figure 3. Comparisons of the mean energy reflectance from left (blue) and right (red) ears for both the newborns (left) and the one-month olds (right). The shaded ranges indicate the 25 to 75 percent ranges of data. Only data where both right and left ears were measured were used here. At each frequency, we tested the null hypothesis that there is no difference in the energy reflectance between the groups of left and right ears. The corresponding unadjusted p-values are plotted, and there does not appear to be any significant differences between the left and right ears.

3 Male vs. Female:

The mean energy reflectance from males and females is not significantly different for newborns or one-month olds.

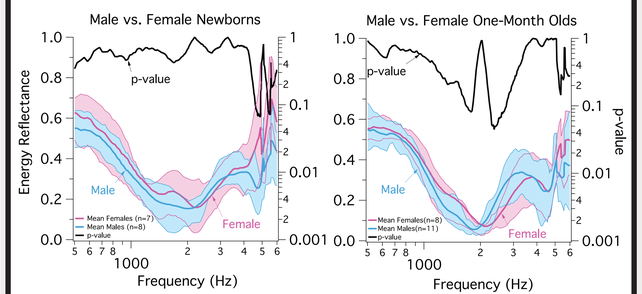

Figure 4. Comparisons of the mean energy reflectance from male (blue) and female (pink) ears for both the newborns (left) and the one-month olds (right). Here, all tested ears (left and right) were included. The shaded ranges indicate the 25 to 75 percent ranges of data. In the newborn population, 4 males and 4 females were tested, and in the one-month old population, 7 males and 4 females were tested. At each frequency, we tested the null hypothesis that there is no difference in the energy reflectance between the groups of male and female ears. The corresponding unadjusted p-values are plotted, and there does not appear to be any significant differences between the male and female ears.

4 Newborns vs. One-Month Olds:

The energy reflectance from newborns and one-month olds is generally not significantly different. However, near 2000 Hz it appears there could be differences.

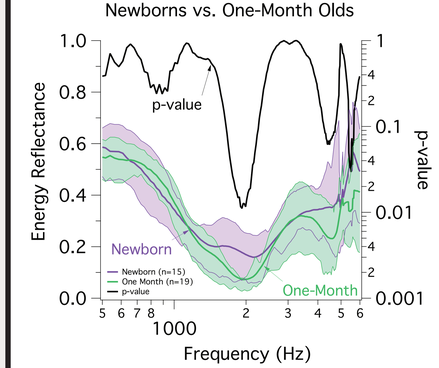

Figure 5. Comparisons of the mean energy reflectance from newborn ears (purple) and one-month old ears (green). Here, all tested ears (left and right) were included. Measurements from one subject are included in both groups. At each frequency, we tested the null hypothesis that there is no difference in the energy reflectance between the newborn and one-month old ears. The corresponding unadjusted p-values are plotted. While there does appear to be a significant minimum in the p-values near 2000 Hz, the calculated p-values do not account for multiple comparisons. The dip does suggest that there may be some systematic differences between newborns and one-month olds near 2000 Hz. More measurements are needed to determine the significance of the difference.

COMPARISON TO OTHER DATA

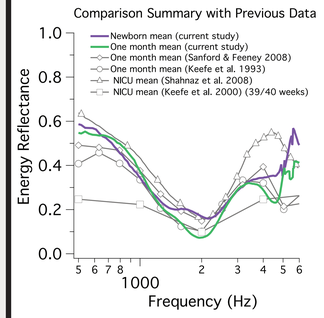

Figure 6: The mean energy reflectances measured on newborns (purple) and one-month old (green) babies are plotted in comparison with previous mean data reported by Keefe et al. 1993 (healthy one-month olds), Sanford and Feeney 2008 (healthy one-month olds), Keefe et al. 2000 (median from NICU, healthy, and at-risk for hearing loss babies at 39 to 40 weeks conceptional age), and Shahnaz 2008 (newborn and young babies in a NICU). These other measurements show similar patterns to the current study, with the most variation at frequencies below 1000 Hz and above 4000 Hz.

- Keefe et al. (2000) reported energy reflectance (ER) measurements from a population that included NICU babies, healthy newborns, and newborns at risk for hearing loss. Within this population, they found significant differences in ER between left and right ears in the 1000-1400 range. They also showed that below 2000 Hz, the male ER was larger than the female ER. Our current study, which has both fewer ears and ears from only healthy babies, does not show any of these differences. These Keefe et al. (2000) measurements appear to have lower ER values than other reported measurements, except near 2000 Hz.

- Keefe et al. (1993) reported measurements of energy reflectance (ER) from age groups ranging from one-month to adult; they found the largest changes in ER occurred from one month to six months of age, with an increase in ER with age at frequencies below 1000 Hz. Hunter et al. (2008) report ER measurements that are similar to Keefe et al. (1993) from 1000 to 6000 Hz, but Hunter et al.'s ER measurements are larger in the 250 to 750 Hz range.

CONCLUSIONS

1. Energy reflectance measurements were made on 8 newborn (8 left and 7 right ears) and 11 one-month old (11 right and 8 left ears) healthy babies.

2. Mean energy reflectance measurements comparing the left and right ears from both newborn and one-month old babies show no significant differences.

3. Mean energy reflectance measurements comparing male and female ears from both newborns and one-month old babies show no significant differences.

4. Mean energy reflectance measurements comparing newborn and one-month old ears show no significant differences at most frequencies. There is some evidence of differences near 2000 Hz, and more measurements are needed to determine the significance of this difference.

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