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# Normative wideband reflectance measures in healthy neonates

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ABSTRACT

*Objective:* Presently, normative wideband reflectance data are available for neonates who have passed a distortion product otoacoustic emission test. However, passing the distortion product otoacoustic emission test alone does not ensure normal middle ear function. The objective of this study was to establish normative wideband reflectance data in healthy neonates with normal middle ear function, as justified by passing a battery of tests.
*Method:* Wideband reflectance was measured in 66 infants (mean age = 46.0 h, SD = 21.0, range = 13.3–116.5 h) who passed a test battery that included high frequency (1000 Hz) tympanometry, acoustic stapedial reflex, transient evoked otoacoustic emissions and distortion product otoacoustic emissions.
*Results:* The analysis of variance (ANOVA) results showed significant variations of reflectance across the frequencies. There was no significant difference between ears and genders. The median reflectance reached a minimum of 0.21–0.24 at 1–2 kHz, but increased to 0.45–0.59 below 1 kHz and 0.24–0.52 above 2 kHz.
*Conclusions:* The normative reflectance data established in the present study were in agreement with, but marginally smaller than, those of previous normative studies, except for the Keefe et al. (2000) study. While the use of a test battery approach to ensure normal middle ear function in neonates has resulted in slightly reduced reflectance across most frequencies when compared to studies that have used only otoacoustic emissions, further research is needed to accurately determine the middle ear status of neonates using test performance measures.



## 1. Introduction

Determination of middle ear function is an important aspect of diagnostic assessment in infants and young children. The standard tools used to determine the middle ear status in older children are neither efficient nor accurate in evaluating neonates. Myringotomy, which is the gold standard to determine middle ear fluid, is neither ethical nor justified with neonates in a screening context. Both otoscopy and pneumatic otoscopy are not effective in neonates due to difficulties in visualising the tympanic membrane [1–4]. Conventional 226 Hz tympanometry has been found to be inaccurate in assessing infants younger than six months of age due to differences in acoustical and anatomical properties between adults and young infants [5–11]. Several studies have recommended high frequency (1000 Hz) tympanometry (HFT) for the assessment of middle ear function in infants less than six months of age [6,10–12]. Nonetheless, recent studies [13,14] that have compared the test performance of HFT and wideband reflectance (WBR) with distortion product otoacoustic emissions (DPOAE) in newborns found that the WBR test predicted DPOAE outcomes more accurately than the HFT.

The WBR test measures the power reflectance at ambient pressure using a wideband stimulus such as a click or chirp which covers a frequency range from 0.2 to 8 kHz. Power reflectance is defined as the ratio of reflected energy to incident energy [15] and ranges from 1 (representing total reflectance of sound by the tympanic membrane) to 0 (representing complete transfer of sound into the middle ear). Several studies have shown that, at all ages, power reflectance is the highest at frequencies below 1 kHz and above 4 kHz and lowest in the frequency region between 1 and 4 kHz, which corresponds to the most effective frequency region of the middle ear transfer function [13,16–18].

The WBR test has been shown to be useful in the assessment of middle ear function in neonates [13,14,19–23] and is, therefore, recommended as an adjunct tool with newborn hearing screening programs. For instance, Keefe et al. [20] demonstrated that inclusion of the WBR test in newborn hearing screening programs decreased the false positive rates from 5% to 1%, thus, suggesting that information on middle ear status improves the ability to predict hearing status. Sanford et al. [13] measured WBR in 455

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healthy, full-term newborn infant ears that passed their DPOAE screening within 24 h of birth and compared the findings with 80 ears that were referred. They found that the referred ears had higher energy reflectance between 0.4 and 2.5 kHz when compared with those that passed the DPOAE test. In a study of 127 infants in screening and diagnostic test conditions, Vander Werff et al. [22] also found that infants who failed DPOAE screening had higher reflectance in the range from 0.63 to 2 kHz than infants who passed the screening.

Despite its potential regarding the assessment of middle ear function in infants, there are limited normative WBR data for this population. Keefe et al. [24] reported the first set of normative WBR data in 2081 neonates. However, this study did not include any measure to determine the middle ear status of the neonates. It is only in recent years that studies have reported WBR results in healthy neonates with normal middle ear function as determined by a pass result in either DPOAE [13,14,21,22] or transient evoked otoacoustic emissions (TEOAE) testing [25]. In a study of 324 newborns, Hunter et al. [14] described normative WBR regions for predicting DPOAE status in newborns. Hunter et al. [14] also proposed the use of a reflective area index (RAI), wherein the reflectance values are averaged over a specified frequency range (e.g., 1–2 kHz, 1–4 kHz, 2–6 kHz). They found that RAIs at 2 kHz or involving 2 kHz, successfully differentiated between ears that passed or referred on the DPOAE test, with areas under the ROC curve of 0.93 and 0.90, respectively. Merchant et al. [21] described normative reflectance and transmittance measurements on 12 ears from seven newborns that passed DPOAE screening. They found that the mean power reflectance was maximum (0.6) at 0.5 kHz and deceased with frequency until 2 kHz where it reached a minimum of 0.18 and then increased with frequency above 2 kHz.

As can be seen from the above studies, the DPOAE test is often used as the reference standard to determine normal middle ear function in infants. However, the DPOAE alone may not accurately identify minor or sub-clinical middle ear pathologies [26] and, hence, may not serve as an ideal reference standard [13,14]. Similarly, other tests such as HFT, acoustic stapedial reflex (ASR) or TEOAE in isolation are not effective measures of middle ear function in neonates. For example, there are unresolved issues for interpreting HFT results. To date, there are no universally agreed methods for interpreting HFT results, nor is there agreement regarding the test parameter or combination of parameters that are most sensitive to middle ear dysfunction in neonates [27]. Although normative ASR data is now available for neonates [28,29], the ASR test alone cannot determine middle ear status as the presence or absence of ASR is dependent on several factors such as hearing sensitivity and auditory function up to the brainstem region. Finally, TEOAEs alone are not perfect as a reference standard because TEOAEs can be recorded in some ears with middle ear dysfunction [30,31].

In the absence of a single gold standard test for identifying middle ear dysfunction in neonates, Mazlan and Kei [32] suggested that the use of a battery of tests including TEOAE, HFT and ASR tests may be an accurate measure for detecting middle ear dysfunction in young infants. Whilst a single measure such as HFT or DPOAE may not be sensitive to subtle middle ear dysfunction, a battery of tests may provide a robust measure of middle ear function for the evaluation of WBR in neonates. Such a battery may also provide the best reference standard available for newborns without resorting to invasive procedures such as myringotomy. To date, there are no WBR studies that have used a combination of tests as a reference standard to determine middle ear status in healthy neonates. The objective of this study was to describe normative WBR measures in healthy neonates who passed all tests in a reference standard battery that included HFT, ASR, TEOAE and DPOAE tests.

## 2. Method

### 2.1. Participants

A total of 195 (107 males, 88 females) healthy neonates were enrolled in the study. Only 66 neonates (35 males, 31 females) who passed all tests in the test battery in one or both ears were selected for the study. A total of 23 neonates passed the test battery in the right ear only, 21 passed in the left ear only and 22 neonates passed in both ears. When a neonate passed the test battery in both ears, either the right or left ear was chosen randomly for inclusion in the data analysis. Altogether, 66 ears (32 right and 34 left ears) that passed all the tests in the test protocol were included in the study.

Mean gestational age of the neonates was 38.7 weeks (SD = 5.01, range = 36–42 weeks). Thirty-four neonates (51.5%) were born via spontaneous vaginal delivery, six (9.1%) via assisted vaginal delivery, 24 (36.4%) via caesarean delivery and information was not available for two neonates (3%). Mean birth weight was 3534.9 g (SD = 468.7, range = 2290–4640 g). Fifty-five neonates (83.3%) were breast-fed, five (7.6%) were bottle-fed and information was not available for six (9.1%) neonates. Mean age of the neonates at the time of testing was 46.0 h (SD = 20.9, range = 13.3–116.5 h). Fifty-five neonates (83.3%) were asleep during testing, while four (6.1%) were awake but quiet, three (4.5%) were awake and restless, one (1.5%) was being fed and information was not available for three (4.5%) neonates.

### 2.2. Test battery

*Tympanometry* was performed using a GN Otometrics Otoflex acoustic immittance device with a 1000 Hz probe tone. During the test, the admittance ($Y$) was measured as the pressure was changed from +200 to −400 da Pa at a rate of 400 da Pa/s. A visual classification system was used to classify the tympanometric results. The pass criterion was a single positively peaked tympanogram with middle ear pressure between 50 and −150 da Pa [33–35].

*ASR* was measured using the same Otoflex instrument. ASR responses were recorded at the tympanometric peak pressure for a 2 kHz tone presented ipsilaterally in the presence of a 1000 Hz probe tone. The stimulus tone was presented for 1 s at an intensity level starting at 70 dB HL using a manual threshold search mode. A change in admittance exceeding 0.04 mmho was considered as an ASR response [29]. A pass was awarded if an ASR was present up to 90 dB HL [28].

*TEOAE* was performed using a Biologic Navigator Plus. The signal consisted of wide band clicks of 80 μs duration, at a target amplitude of 80 dBpkSPL. The pass criteria included reproducibility of at least 70% and a difference between the amplitude of the emissions and the associated noise floor of at least 3 dB at 2, 3 and 4 kHz [22,34].

*DPOAE* was performed using the same biologic device. DPOAEs were measured in response to pairs of primary tones with F2 set at 1.5, 2, 3, 4, 6 and 8 kHz. The F2/F1 ratio was 1.2 for each primary pair. The level of F1 was 65 dBSPL and F2 was 55 dBSPL. Pass criteria included if the noise level was less than 0 dBSPL and the difference between the amplitude of the emission and associated noise floor was at least 6 dB in at least three out of four frequencies from 2 to 6 kHz [13,14].

*WBR* was performed using a prototype research system developed by Interacoustics. The Reflwin computerised system consisted of a Windows-based computer, a 24 bit resolution sound card, a pressure pump and controller system contained in an acoustic immittance instrument (AT235), and custom software for stimulus generation and data acquisition. Calibration was performed every day [36] to determine the source reflectance and