

# High frequency immittance for neonates: a normative study

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## Abstract

*Conclusion.* High frequency immittance measurements demonstrate promise in clarifying middle ear status for neonates but age- and gender-specific norms should be consulted.

*Objective.* To describe high frequency immittance measurements using a 1000 Hz probe tone for a sample of 278 neonatal ears (0-4 weeks of age) in order to compile normative tympanometric and acoustic reflex criteria. *Subjects and methods.* Assessment of neonatal ears included 1000 Hz probe tone immittance measurements (tympanograms and ipsilateral acoustic reflexes), and distortion product oto-acoustic emission (DPOAE) screening. Results were compared and normative values were compiled for immittance measures in ears controlled for normal middle ear functioning ( $n=250$ ). *Results.*

Comparison of immittance results to OAE screening outcome provides estimates of sensitivity and specificity for middle ear fluid with tympanometry of 57% and 95%, and 57% and 90% for acoustic reflex presence, and 58% and 87% for combined tympanogram and acoustic reflex results, respectively. Normative data indicate that static peak admittance values differ significantly across gender and age with the 5th percentile cut-off value for the entire sample at 1.4 mmho. The 90% range of tympanic peak pressure normative values increases with increasing age from 140 daPa for neonates 1 week of age to 210 daPa for neonates 2-4 weeks of age. Acoustic reflexes were elicited at  $93\pm 9$  dB with a 90% normality range of 80-105 dB.

**Keywords:** acoustic reflex; high frequency probe tone; immittance; middle ear fluid; middle ear effusion; neonatal hearing screening; static peak admittance; tympanic peak pressure; tympanometry

## Introduction

As newborn and infant hearing screening programmes are being implemented as the standard of care in a number of world regions the need for an accurate measure to differentiate between true positive and false positive results due to middle ear fluid is becoming increasingly important. Newborns and infants with mild conductive hearing loss often refer hearing screenings resulting in higher false positive rates that lead to added expenses, decreased programme efficacy, and increased chances of anxiety for parents<sup>1,2</sup>. Even though significant efforts have been made to reduce the number of false positive results by comprehensive screening protocols, the question of compromised middle ear functioning due to otitis media with effusion, a transient middle ear effusion,

or middle ear cavities containing mesenchyme and not fully pneumatized at birth, has not yet been addressed sufficiently<sup>3</sup>. Middle ear fluid or middle ear effusion is a common diagnosis among newborns and infants, with infants in neonatal intensive care units (NICUs) especially prone to the condition<sup>4,5</sup>. A recent study has pointed out that otitis media with effusion may contribute up to 67% of the false positive newborn hearing screens<sup>5</sup>. The presence of middle ear fluid severely diminishes and even obliterates otoacoustic emissions (OAEs) and, while auditory brainstem response (ABR) screening is more robust with fewer failures due to mild middle ear conduction pathologies, it may still lead to a refer result in more serious cases<sup>6-10</sup>.

Unfortunately it is difficult to diagnose middle ear fluid in the newborn and young infant after referral on a screening test. The effect of sound transmission through the neonatal ear canal to the middle ear and cochlea has not been described sufficiently and is therefore not clearly understood<sup>3</sup>. Conventional immittance evaluations of middle ear functioning with a 226 Hz probe tone have been demonstrated to be unreliable for accurate assessment of middle ear status in infants younger than 7 months of age<sup>11-13</sup>. Reports have indicated that the use of low frequency probe tones to record tympanograms leads to a high false negative rate, which means a poor sensitivity rate for detecting middle ear pathology<sup>12,14</sup>. The sharp sensitivity contrast of 226 Hz tympanometry in young infants and adults has been attributed to the fact that the young infant's middle ear is mass-dominated compared with a stiffness-dominated system in adults. Low frequency probe tones are well suited to evaluate stiffness-dominated systems and not the mass-dominated middle ears of young infants<sup>11,15</sup>.

The use of high frequency probe tones has been suggested as a more reliable means of assessing a middle ear system which is mass-dominated as in the case of young infants. As a result a number of clinical programmes in several countries have included high frequency tympanometry as part of the screening protocol. Recent reports have demonstrated promising preliminary results using a 1000 Hz probe tone to detect middle ear dysfunction in neonates<sup>14,16-18</sup>. Some normative guidelines based on limited samples of neonates have been suggested by Margolis et al.<sup>17</sup> and Kei et al.<sup>16</sup>. Margolis et al.<sup>17</sup> suggested that a single cut-off value for static admittance of 0.6 mmho is useful for infants up to 4 weeks chronological age. The study by Kei et al.<sup>16</sup> classified 1000 Hz tympanogram shapes in a group of neonates who passed their OAE screening. Three distinct shapes were identified including a peaked, double peaked and flat sloping tympanogram, while 0.8% of the tympanograms did not fit any of these shapes. Flat sloping shaped tympanograms, measured in 5.7% of cases, demonstrated less robust OAE responses, which may indicate a degree of compromised middle ear functioning too low to lead to an OAE refer but enough to result in no tympanic peak<sup>16</sup>.

An alternative technique suggested for possible neonatal middle ear assessment has been the acoustical admittance and reflectance (YR) response<sup>3</sup>. Initial results have indicated promise that the YR response is sensitive to both forward and reverse sound transmission through the ear canal and middle ear<sup>3</sup>. Unfortunately the complex nature of the response, with over 30 variables in the response itself, and limited normative data and clinical

systems have prevented its use as a clinical tool for neonatal middle ear evaluation thus far.

A reliable test that is able to distinguish between sensorineural hearing loss and middle ear pathology for neonates and young infants will be an important way to identify screening failures caused by middle ear pathology to direct appropriate medical referral and diagnostic audiological evaluations<sup>17</sup>. The preliminary guidelines for interpreting 1000 Hz tympanometry hold significant promise for accountable application of the technique in neonatal screening programmes but require further normative studies on significant numbers of subject samples. This demand for more normative data is becoming increasingly important with the implementation of widespread UNHS programmes in developed and developing countries<sup>16-19</sup>. This study therefore investigated middle ear functioning in a sample of neonatal ears in order to describe normative data for high frequency immittance measurements using a 1000 Hz probe tone.

## **Subjects and methods**

The institutional review board at the University of Pretoria approved this project before any data were collected to ensure that the procedures followed were in accordance with the ethical standards as specified by the Helsinki Declaration of 1975, as revised in 1983.

### **Subjects**

Recordings were made from a total of 278 healthy neonatal ears (52% female) from 143 neonates attending two maternal and child health clinics in the Hammanskraal community in South Africa. All the neonates were full-term babies and their ages at time of testing varied between 1 and 28 days. Informed consent was obtained from all caregivers before any testing commenced. The testing protocol conducted on these ears included high frequency immittance measurements (tympanograms and acoustic reflexes) and a distortion product oto-acoustic emission (DPOAE) screening. The test procedures were conducted on both ears for all neonates as far as possible but in certain cases only one ear could be evaluated or only one test conducted for an ear due to the infant's restlessness or irritability.

### **Apparatus**

A GSI Tymptstar (version 2) Middle-Ear Analyzer was used to record immittance measures. A high frequency probe tone of 1000 Hz was utilized to measure Y-admittance tympanograms, with a positive to negative pressure sweep of 200 daPa at a pump speed of 200 daPa/s, as recommended for young infants<sup>11</sup>. The maximum point on a recorded tympanogram was marked to obtain the uncompensated peak admittance value with the corresponding pressure value at this point.

Ipsilateral reflexes at 1000 Hz using a 1000 Hz probe tone were also recorded with the GSI Tymptstar. Reflexes were determined at the lowest intensity eliciting a reflex

response with a deviation  $>0.02$ . This deviation was required to be repeatable and indicative of growth at higher intensities and decrease in amplitude at lower intensities.

The GSI AUDIOscreener was used for DPOAE screening. The test parameters used were according to the default screening protocol, setting 'DPOAE 2'. Five frequencies (2000, 3000, 4000, 5000 and 6000 Hz) were assessed for each ear and a pass criterion was based on passing at least four of the five frequencies evaluated. The recording of DPOAE was based on a F2 centre method and the frequencies were measured in a downward order starting with the highest and ending at the lowest using a linear averaging method of analysis. The minimum signal-to-noise difference was set at 6 dB for all frequencies.

## Procedure

Testing was conducted by three qualified audiologists. To avoid any order effects the immittance and OAE tests were conducted in a randomized manner on each neonate. This meant that some neonates were screened with OAE first followed by immittance testing and others were tested with immittance measures first followed by OAE screening. All testing was conducted in a quiet room dedicated to hearing screening. The neonate was placed in a comfortable position depending on state of wakefulness (in mother's arms or in a sleeping cot) before testing commenced.

To conduct immittance measures the infant's ear was investigated to select an appropriately sized probe tip. Once a good seal was attained 1000 Hz probe tone tympanograms were recorded. The peak of every tympanogram was marked with a cursor, thus providing the peak pressure (daPa) and peak compliance reading (mmho). If no peak was present it was recorded as such. The tympanograms were followed by the recording of acoustic reflexes with a 1000 Hz probe tone at a test frequency of 1000 Hz. Measurements were initiated at 70 dB HL and a reflex threshold seeking procedure of 10 dB up and 5 dB down increments was employed. A maximum intensity of 110 dB was tested. OAE screening was also conducted by investigating the ear canal for selection of an appropriate sized probe tip. Once a complete seal was attained the ear was screened. If the screen result referred the subject a second screening was conducted after readjusting and fitting the probe. If the second screen also yielded a refer result it was recorded as such and a follow-up appointment was scheduled.

The data recorded from these neonates were used to compile normative guidelines for high frequency immittance in neonates with normal middle ear functioning. To establish normative data for this group only the immittance data from neonatal ears with an OAE pass result and a discernible tympanogram peak were used ( $n=250$ ; 52% female). An OAE pass result was not used as the only criterion because previous reports have indicated that in a small number of cases with middle ear fluid a pass result may still be obtained with OAE<sup>16,20</sup>. To assure that reliable norms are specified, as far as the performed procedures accuracy allows, a second criterion requiring a discernible tympanogram peak for inclusion was set. A recent report indicated that an OAE pass result was obtained in 5.7% of ears with no discernible tympanometric peak, although reduced OAE amplitudes were observed in these ears<sup>16</sup>. Since such cases may indicate a

degree of compromised middle ear functioning and a discernible tympanometric peak is generally accepted as indicative of normal middle ear functioning with 1000 Hz tympanometry for neonates, this criterion was specified alongside an OAE pass result to ensure a high degree of confidence that only ears with normal middle ear functioning were included<sup>16,18</sup>.

## Results

Of the 278 neonatal ears evaluated by tympanometry and OAE screening, 8% (22/278) presented with no tympanometric peak and 5% (14/278) did not pass the initial OAE screening. Absent acoustic reflexes were observed in 12% (33/267) of the sample. No significant gender effect was found for any of these test procedures. Tympanograms with a double peaked configuration comprised 6% (16/264) of the peaked tympanogram sample and 93% (15/16) of these cases coincided with an OAE pass result. Even though this was a small subsample a significantly increased number of males (69%) presented a double peaked tympanogram configuration.

The incidence of OAE pass results, peaked high frequency tympanograms and present acoustic reflexes for the sample of neonatal ears was 95%, 92% and 88%, respectively. A comparison between the negative and positive predictive values of these test procedures as compared against each other is provided in Table I.

**Positive and negative predictive values for OAE, Table I. tympanogram (TYMPS) and acoustic reflex (AR) results for neonates.**

Predictive measure	TYMPS		AR	
	Peak (n=256)	No peak (n=22)	Present (n=236)	Absent (n=33)
OAE pass	95%	5%	90%	10%
OAE refer	43%	57%	43%	57%
Predictive measure	OAE		AR	
	Pass (n=264)	Refer (n=14)	Present (n=234)	Absent (n=33)
Tympanogram peak	98%	2%	93%	7%
Tympanogram no peak	64%	36%	32%	68%
	OAE		TYMPS	
	Pass (n=264)	Refer (n=14)	Peak (n=245)	No peak (n=22)
AR present	98%	3%	97%	3%
AR absent	76%	24%	55%	45%

Measured against the OAE result the sensitivity and specificity for middle ear pathology with high frequency tympanometry, i.e. no discernible tympanometric peak indicating

pathology, was 57% and 95%, respectively. OAE results compared to acoustic reflex presence indicate a sensitivity and specificity value of 57% and 90%, respectively, for high frequency probe tone acoustic reflex measurements in neonates.

## Normative data

To establish reliable norms for 1000 Hz immittance two criteria were set for including ears from the current sample: (1) an OAE pass result and (2) a discernible tympanometric peak. These criteria reduced the sample size to 250 neonatal ears that were used to compile a normative set of data. Table II indicates the descriptive peak admittance and tympanic peak pressure values for this normative sample.

**The 1000 Hz tympanometry norms for neonates. Table II.**

Parameter	<1 week of age ( <i>n</i> =73 ears)		1-4 weeks of age ( <i>n</i> =177 ears)		0-4 weeks of age ( <i>n</i> =250 ears)	
	Peak admittance	TPP (daPa)	Peak admittance	TPP (daPa)	Peak admittance	TPP (daPa)
Mean	2.2	-10	2.4	5	2.4	-1
SD	0.9	48	0.7	49	0.8	49
Max	7.7	185	5.1	115	7.7	185
Min	1	-130	1.2	-185	1	-185
5th percentile	1.2	-70	1.5	-80	1.4	-75
50th percentile	2.0	-10	2.3	5	2.2	-5
95th percentile	3.4	70	3.8	85	3.7	80

Statistical analysis indicates that there is a significant difference ( $p<0.01$ ; *t* test with pooled variance) between the peak admittance values for male and female ears. No statistically significant differences were obtained between the tympanic peak pressure values. Comparing different age groups within the sample of neonatal ears also indicated statistically significant differences for admittance values but not for tympanic peak pressure values. The admittance values for neonates younger than 1 week of age compared to those older than 1 week of age differed significantly on the 5% level of significance ( $p<0.05$ ; *t* test with pooled variance). When the admittance values for neonates younger than 1 week of age were compared to those of neonates who were 4 weeks of age a significant difference on the 1% level of significance was evident ( $p<0.01$ ; *t* test with pooled variance). The general trend indicates significantly increasing admittance values with increasing age in the neonatal period. These differences necessitate the consideration of age- and gender-specific normative data for the use of 1000 Hz probe tone tympanometry in neonates. Figures 1 and 2 provide a detailed presentation of admittance and tympanic peak pressure values for neonatal ears according to gender and age.

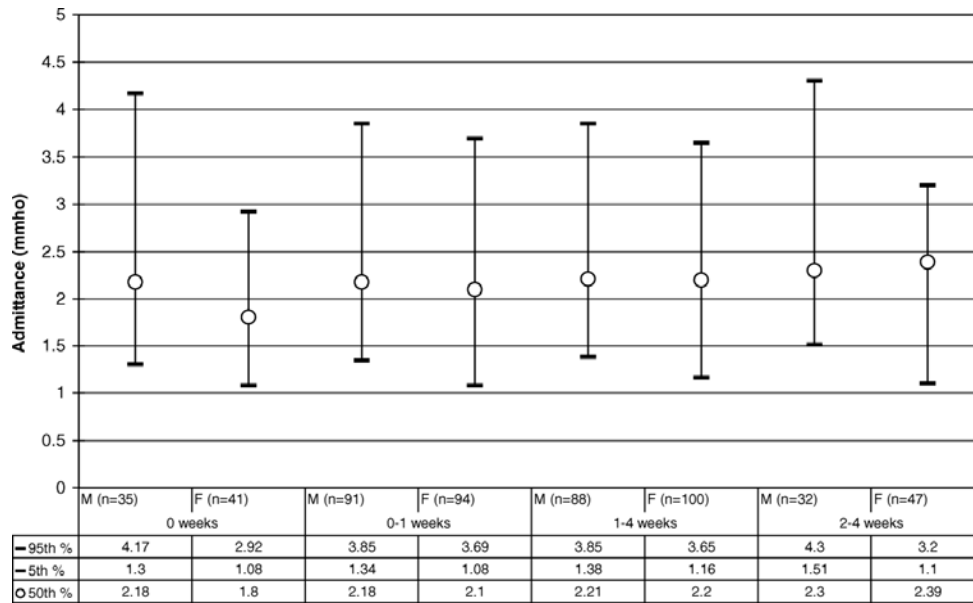


Figure 1. Age- and gender-specific admittance norms for neonates.

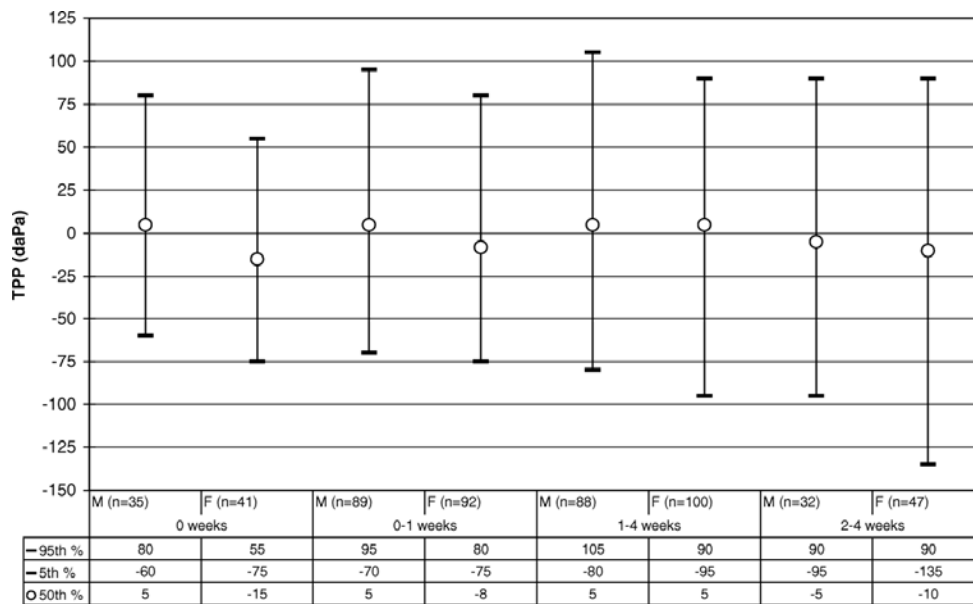


Figure 2. Age- and gender-specific tympanic peak pressure norms for neonates.

The range of admittance values across age groups for the lower limit (5th percentile) was between 1.30 and 1.51 mmho for male ears and between 1.08 and 1.16 mmho for female ears. The range of admittance values across age groups for the upper limit (95th percentile) was between 3.85 and 4.30 mmho for male ears and between 2.92 and 3.69 mmho for female ears. The median values for the male ears across all age groups varied between 2.18 and 2.30 mmho and for the female ears across all age groups between 1.80 and 2.39 mmho.

The range of tympanic peak pressure values for the lower limit (5th percentile) across age groups varied between -95 and -60 daPa for male ears and between -135 and -75 daPa for female ears. The range of tympanic peak pressure values for the upper limit (95th percentile) across age groups varied between 80 and 105 daPa for male ears and between 55 and 90 daPa for female ears. Median values varied between -15 and 5 daPa across gender and age groups.

In all age groups the female ears had lower or equivalent 5th and 95th percentile values. The values across age groups also indicated the smallest 90% tympanic peak pressure range (5th to 95th percentile) for male (140 daPa) and female ears (130 daPa) younger than 1 week of age. The highest 90% tympanic peak pressure value range was obtained in the oldest neonatal ears (185 daPa) for both male and female ears. The tympanic peak pressure 90th percentile range therefore increases with increasing age across gender.

### **Acoustic reflex thresholds for neonates**

Acoustic reflexes were present in 94% of ears with peaked tympanograms. No significant differences were obtained across gender or age for acoustic reflex thresholds in neonates. The mean threshold was 93 dB±9 dB with a maximum of 110 dB and a minimum of 60 dB. The 90% percentile range (5<sup>th</sup> to 95th percentile) was 25 dB (80-105 dB).

## **Discussion**

High frequency tympanometry is increasingly being implemented in neonatal and infant hearing screening programmes despite a general lack of normative guidelines across age and gender. Although no large-scale 1000 Hz probe tone tympanometry study of infants from birth to 1 year of age has been reported the incidence of peaked tympanograms for neonatal ears in this study is similar to that of a recent report for a group of 170 babies aged between 1 and 6 days<sup>16</sup>. Using 1000 Hz probe tone tympanometry, a peaked tympanogram incidence of 93.4% was reported in 228 ears compared to 95% for neonates (1-4 weeks of age) in the current study. The 1000 Hz tympanometric peak results for neonates in the current study and those reported by Kei et al.<sup>16</sup> are also similar to a 678 Hz probe tone study conducted on a group of 200 special care baby unit babies, which indicated a 91% incidence of discernible peak tympanograms<sup>21</sup>.

Double peaked tympanograms were also reported by Kei et al.<sup>16</sup> in 1.2% of the peaked tympanogram ears compared with 6% in the current study. The higher incidence of double peaked tympanograms may be due to the larger neonatal age range in the current study (1-4 weeks) compared with that of the neonatal ears in the study by Kei et al. (1-6 days). All double peaked tympanograms in the study by Kei et al.<sup>16</sup> were accompanied by OAE pass results, corresponding to the high percentage of ears (15/16) in the current study with OAE pass results. These results suggest that double peaked tympanograms are indicative of normal middle ear transmission and also correspond to previous reports suggesting that double peak tympanograms are not uncommon and are suggestive of normal middle ear transmission for 1000 Hz probe tone measurements<sup>2</sup>.



Although present OAEs are not a perfect gold standard for the absence of middle ear pathology, their measurement is very dependent on an intact uncompromised middle ear system<sup>16,21</sup>. This reliance on normal or near normal middle ear functioning make OAE a useful measure for comparison to immittance results for providing sensitivity and specificity estimates for high frequency immittance testing in the absence of air and bone conduction tone ABR measurements. This comparison revealed a high specificity rate for both 1000 Hz probe tone tympanometry (95%) and acoustic reflexes (90%) in correctly identifying normal neonatal middle ear functioning in the current study. A significant but poorer sensitivity rate of 57% was obtained for both tympanometry and acoustic reflexes for correctly identifying middle ear pathology. The decreased sensitivity may in part be attributed to the presence of middle ear effusion in a number of ears with present but decreased OAEs<sup>16,21</sup>. Such cases result in an overlap of true positive high frequency immittance results and false negative OAE results and lead to decreased immittance sensitivity. It is for this reason that normative high frequency immittance data in the current study were compiled from neonatal ears with both an OAE pass and a tympanometric peak result.

The significantly higher static acoustic peak admittance values ( $p < 0.01$ ;  $t$  test with pooled variance) for boys in the normative sample can primarily be attributed to the difference in middle ear and tympanic membrane sizes for female and male ears<sup>22</sup>. This difference highlights the consideration of gender in establishing normative high frequency tympanometry data. Statistically significant differences in peak admittance values ( $p < 0.05$ ;  $t$  test with pooled variance) for younger and older neonates indicate a general increase in admittance with increasing age. However, this trend is observed mostly for male ears. The close relationship between the 5th percentiles grouped for gender across age indicates the significance of this value as a more robust diagnostic criterion than the more variable 95th percentile, which is not usually an indication of pathology in neonates<sup>17</sup>. Using the 5th percentile as the primary diagnostic criterion requires differentiation for normative data between only gender for all age female neonates and male neonates younger than 2 weeks of age. Male neonates 2-4 weeks of age have a significant increase in 5th percentile peak admittance values that should be considered when assessing 1000 Hz probe tone tympanometry results.

The static peak admittance values of the current study correspond to the values reported by Margolis et al.<sup>17</sup> for 105 NICU and 46 full-term infant ears. The 5th percentile value for newborn neonates (0 weeks age) in the current study was 1.2 mmho compared to 1.3 mmho for the study by Margolis et al.<sup>17</sup> of NICU infants who were tested at a mean age of 37 weeks. Neonates in the current study aged between 1 and 4 weeks presented with a static peak admittance value of 1.5 mmho compared to 1.2 mmho for full-term infants in the study by Margolis et al. This difference may be accounted for by the small sample size used and the fact that the gender and race of subjects were not stated or controlled for in the latter study. The results from the present study clearly indicate that the admittance values measured with a 1000 Hz probe tone are significantly different between genders and the gender constitution of a sample may therefore have a significant effect on the average admittance value for a group of neonates.

Although the importance of peak pressure values for determining pathology in infant ears is not clearly understood and further studies have been recommended, previous reports have indicated a significant relationship between middle ear pressure, using a 1000 Hz probe tone, and OAE failure in neonatal ears<sup>2, 17, 23</sup>. Although there were no statistically significant gender or age effects for tympanic peak pressure values, the 5th and 95th percentile values were consistently lower for female ears across age. The 90% range of tympanic peak pressure values for newborn neonates (0 weeks of age) in the current study was 140 daPa compared to 146 daPa for the NICU infants (37 weeks gestational age) reported by Margolis et al.<sup>17</sup>. This range increased for older neonates in the current study (2-4 weeks of age) to 210 daPa compared to 243 daPa for the well-baby ears (2-4 weeks of age) reported by Margolis et al.<sup>17</sup>. Both studies demonstrate an increasing range of normative tympanic peak pressure values with increasing age. The slightly larger range for the older neonates reported by Margolis et al.<sup>17</sup> compared with the current study may be attributed to fact that gender was not reported or controlled for in the study by Margolis et al. and the sample size was limited.

The incidence (86%) of present acoustic reflexes in the current sample of neonates compares well with results from a normative study by Sprague et al.<sup>24</sup> in which a 660 Hz probe tone was used with a 1000 Hz stimulus to measure reflexes in a sample of normal neonates. Present reflexes were measured in 81% of the subjects tested. Another study by Sutton et al.<sup>21</sup> using a high frequency probe tone (678 Hz) to elicit reflexes in high-risk special care neonates, reported the presence of acoustic reflexes in only 42% of ears (71/168). This reduced incidence compared with the high incidence rate in the current study can be attributed to the risk status and young age of the neonates as well as to the use of a 678 Hz probe tone instead of a 1000 Hz probe tone. The high incidence of present reflexes recorded (86%) in the current study compared with the poor reliability of recording present reflexes using low frequency probe tones in infants can be attributed to the following facts: (1) a 1000 Hz probe tone was used, (2) an ipsilateral stimulus was used, and (3) a mid-frequency (1000 Hz) stimulus was used to activate the reflex<sup>18</sup>.

The mean acoustic reflex threshold (93 dB) using a 1000 Hz probe tone and 1000 Hz ipsilateral stimulus for neonates in the current study was 11 dB higher than the same mean threshold (82 dB) using a 220 Hz probe tone in adults<sup>25</sup>. A study on neonates using a 660 Hz probe tone to elicit ipsilateral 1000 Hz acoustic reflexes revealed the same 11 dB mean threshold difference when compared with the current study<sup>24</sup>. The 1000 Hz probe tone reflex thresholds for a 1000 Hz stimulus in normal neonates are therefore elevated by approximately 10 dB compared with conventional adult acoustic reflex thresholds using a 220 Hz probe tone.

## **Conclusion**

Clinical experience and initial reports demonstrate that high frequency immittance measurements using a 1000 Hz probe tone assist in clarifying false positive screening results due to middle ear pathology or transient middle ear effusion, which is a common occurrence in neonatal hearing screening programmes. The normative criteria for interpreting 1000 Hz probe tone immittance results in neonates (0-4 weeks of age)

demonstrate the important effect of age and gender on tympanograms and necessitate consideration of these variables when compiling norms. Correct identification of middle ear status in the neonatal period could direct timely and correct referrals to medical and audiological personnel that may lead to improved efficacy of neonatal hearing screening programmes.

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