5. CONCLUSIONS AND RECOMMENDATIONS

Chapter 5 presents conclusions drawn from the current research results and recommendations for clinical practice and for future research. A critical evaluation of the study is included,

5.1 INTRODUCTION

Objective measurement of middle-ear function continues to be refined and in recent years high frequency tympanometry has enjoyed added awareness and is increasingly being implemented in neonatal and infant hearing assessment protocols. In accordance with a dearth in current research, this study explored and validated the use of high frequency acoustic immittance measures in a large group of infants and described age- and gender related normative values.

To date, no large scale studies have been reported on high frequency tympanometry and acoustic reflex testing in the neonatal and infant population and limitations in subject size and the shortfall of age appropriate normative data in previous studies have been identified. Although the use of high frequency tympanometry has generally been proven and accepted as superior over conventional 226 Hz tympanometry in infants below 7 months of age (Lilly, 2005:24; Kei *et al.,* 2003:27; Margolis *et al.,* 2003:391; Purdy & Williams, 2000:10; Meyer *et al.,* 1997:194:); the need exists for classification systems and norms for interpreting these results to ensure effective diagnosis of middle ear pathology in infants (Sutton *et al.,* 1996:15).

Conclusions from the research findings in the current study will be presented in the following section to ascertain the significance of the obtained results and to determine implications for clinical practise.

5.2 CONCLUSIONS

This study has investigated and highlighted the use of high frequency probe tone (1000 Hz) tympanometry as a method of middle ear assessment in infants. Conclusions are discussed in Table 5.1 against the framework of the main and sub-aims formulated for the study.

TABLE 5.1 Conclusions according to sub-aims

- ***Sub aim 1 – Admittance (Y_a) tympanogram shape and characteristics within subgroups***

  ~ The total case sample of 936 ears was divided into two groups, depending on outcome of OAE testing. 869 ears (93%) that passed OAE-screening were considered to have normal middle ear functioning and were assigned to Group A. 67 ears (7%) failed OAE screening, were postulated to have possible middle ear pathology and were assigned to Group B.

  ~ 88% (n = 823 ears) of ears in the total case sample displayed *peaked* admittance tympanograms and in conjunction with an OAE pass, this was considered confirmation of normal middle ear functioning. *Flat* tympanograms, considered indicative of middle ear pathology, were recorded in 12% (n = 112) of the test ears.

  ~ Significantly high associations were observed between tympanogram shape and OAE outcome: 93% of ears with OAE-pass results (n = 869) displayed *peaked* 1000 Hz admittance tympanograms. In 7% of ears (60/869) in which flat tympanograms were recorded, OAE's were however still found to be present. 79% of ears failing OAE testing displayed *flat* (abnormal) tympanograms. Results of this study showed greater agreement between OAE failure and abnormal 1000 Hz tympanomgrams compared to results by Sutton *et al.,* (1996:12) who reported only about half of OAE fails (16/33) to correspond with abnormal 1000 Hz tympanograms.

  ~ This study has confirmed that abnormal 1000 Hz tympanometry is strongly associated with OAE failure, and that normal, peaked 1000 Hz tympanometry is strongly associated with OAE pass results.

- 88% of Y_a tympanograms displayed discernable peaks. Double peaked tympanograms were recorded in 4.5% of the total sample and comprised 5% of ears (41) with peaked tympanograms (n = 823). A considerable *gender* effect was observed within the group displaying double peaked tympanograms, and 64% were male. The incidence of double peaked tympanograms were much higher in the present study compared with results by Kei *et al.,* (2003:24) who reported recording of double peaked tympanograms for only 3 out of 224 ears (1%). Differences in sample size and age of subjects could account for discrepancy in results.
- Statistically significant differences (p = 0.00) were observed in Y_a tympanograms between the group passing OAE testing (mean admittance 2.5 mmho) and the group failing OAE testing (mean admittance 1.78 mmho)
- For ears displaying a peaked Y_a tympanogram in conjunction with an OAE pass result, the mean value for uncompensated acoustic admittance (Y_a) tympanograms was recorded at 2.85 mmho, with a standard deviation of 1.13 mmho. Maximum admittance values corresponding to an OAE *pass* result were recorded at 9.64 mmho and minimum admittance relating to OAE *pass* result was 0.86 mmho.
- The mean pressure value in admittance tympanograms for ears *passing* OAE testing and displaying a peaked Y_a tympanogram, was 0.13 daPa with a standard deviation of 60.93 daPa. The highest extreme pressure value related to an OAE pass resulted was 185 daPa, and the lowest extreme was measured at -275 daPa. 87% of ears passing OAEs displayed peak pressure values bigger than -100 daPa and smaller and equal to 100daPa.

- **Sub aim 2 – Characteristics of susceptance (B_a) and conductance (G_a) tympanograms**
  - Notching was mainly evident in the susceptance (B_a) tympanograms and this pattern was in agreement with Holte *et al.,* (1991:9) who found that reactance shifts towards mass with high probe frequencies and towards asymmetrical resistance, with the interactions resulting in notched susceptance (B_a) tympanograms.
  - A great range of variation of B/G tympanogram shapes occurred across all age groups with the most frequent shape being the 3B1G and 1B1G Vanhuyse type.

- Complex configuration and notching patterns were observed in susceptance and conductance tympanograms, making interpretation of B/G tympanograms more difficult (Holte *et al.,* 1991:22).

- Mass and stiffness related elements can be assessed by 1000 Hz B/G tympanograms, but prior to more definite results and large scale investigations on the interpretation of B/G tympanograms, the use of **Y-admittance** tympanograms appear superior as a screening tool for middle ear functioning in infants to ease interpretation and classification. Highly significant associations between OAE pass results and single peaked admittance tympanograms (93%) and between OAE fail results and flat admittance tympanograms (79%) obtained in the current study suggest that admittance tympanograms have good sensitivity and specificity for assessment of middle ear status in infants. Kei *et al.,* (2003:27) reported single-peaked tympanograms, indicative of normal middle ear functioning, in 92.2 % of neonate ears.

- **Sub aim 3 – 1000 Hz probe tone acoustic reflexes**

  - Ipsilateral acoustic reflexes at 1000 Hz were evaluated with a high frequency (1000 Hz) probe tone. Reflex thresholds were found to be present in 86% (n=760) of the ears tested.

  - A mean threshold of 93 dB with a standard deviation of 9 dB and a 90% range of 80 – 105 dB was obtained.

  - The higher percentage of present acoustic reflexes obtained in the current study compared to previous studies in infants was attributed to the fact that a 1000 Hz probe tone and an ipsilateral mid-frequency (1000 Hz) stimulus was used to activate the reflexes (Wetherby & Bennet 1980:107).

  - Good agreement was observed between acoustic reflex presence or absence and normal and abnormal OAE and tympanometry results. This validated the use of OAE pass results and peaked admittance tympanograms as a control variable for normal middle ear functioning with identification of the subgroup of subjects used for the description of normative tympanometric values.

  - Acoustic reflexes appear a good adjunct to 1000 Hz tympanometry for the confirmation of middle ear functioning in infants below seven months of age.

- **Sub aim 4 – High frequency immittance norms**

  ~ Age and gender specific normative values for 1000 Hz acoustic admittance, susceptance and conductance tympanograms were compiled for ears displaying peaked tympanograms in conjunction with OAE pass results.

  ~ An increase in mean admittance and standard deviation values were observed across age groups. Mean admittance for infants aged 0 – 4 weeks was 2.4 mmho, with a standard deviation of 0.8, compared to 2.9 mmho with standard deviation 1.0 and 3.8 mmho with standard of deviation of 1.5 for infants aged 5 – 28 and 29 – 52 weeks respectively.

  ~ In agreement to Palmu *et al.,* (2001:181) age specific normative values are needed for the interpretation of tympanometry obtained from infants and young children. Results obtained from this study may serve as a preliminary normative data for the interpretation of age specific tympanograms.

5.3 IMPLICATIONS OF FINDINGS

This study has provided normative values and results for 1000 Hz tympanometry and this may serve as a guide to further research and as preliminary norms for the identification of normal and abnormal high frequency tympanograms. However, as this study did not include results of abnormal tympanometry, more research on data of abnormal ears is needed to fully understand the effect of abnormal middle ear functioning on tympanograms recorded with a high frequency probe tone.

The prospect of employing high frequency tympanometry for timely identification and treatment of middle ear effusion in infants may serve as an important adjunct to tests currently used for audiological diagnosis in the infant population, to differentiate between middle ear pathology and sensori-neural hearing loss. This may also serve as a means to reduce high false positive test outcomes during neonatal hearing screening program relating to transient middle ear effusion. Thus high frequency tympanometry demonstrates promise for inclusion in neonatal audiological assessment procedures and hearing screening programs.

Previous studies investigating developmental changes and characteristics of high frequency tympanometry in infants have utilized susceptance and conductance tympanograms (Holte *et al.,* 1991:3, Meyer *et al.,* 1997:191) while others have utilized admittance tympanograms (Kei *et al.,* 2003:23, Margolis *et al.,* 2003:385, Meyer *et al,* 1997:191, Sutton *et al,* 1996:11, Thornton *et al.,* 1993:320) in analysis and description of results. Purdy and Williams (2000:19) reported that the majority of studies investigating high frequency tympanometry measured admittance (Y_a) or susceptance (B_a) tympanograms and that conductance (G_a) tympanograms had a limited diagnostic role in infants. Their recommended test protocol consequently suggested the use of susceptance or admittance tympanograms (Purdy *et al.,* 2000:22) for measurement of high frequency tympanograms in infants.

Conductance (G_a) tympanograms recorded in the present study showed notable similarities with admittance (Y_a) tympanograms when a simple visual analysis was applied (see Figure 4.12 for examples). Analysis of B/G tympanograms in terms of number of extrema can determine contribution of mass and stiffness related systems in the middle ear. The most frequent shapes observed in the current study were classified as 3B1G and 1B1G. The diagnostic value of the assessment of the mass- and stiffness related elements in the infant middle ear still remains to be determined (Purdy & Williams, 2000:22).

Owing to high associations observed between results of admittance tympanograms and OAE outcome, with a significant association of 93% between OAE pass results and peaked admittance tympanograms and of 79% between OAE fail results and flat admittance tympanograms, total admittance (Y_a) appears a valid method of categorisation of 1000 Hz tympanograms in infants. Due to greater variation in notching patterns that occur in susceptance and conductance tympanograms and complicates interpretation, an additional benefit of the use of admittance tympanograms is that it facilitates and simplifies interpretation as less variability in notching patterns occur.

5.4 CRITICAL EVALUATION OF RESEARCH PROJECT

A critical evaluation in the form of strengths and limitations of the current study is provided in Table 5.2.

TABLE 5.2 Strengths and limitations of the current study

STRENGTHS
• The study encompassed a large sample of subjects on which high frequency immittance measurements were performed, which allows for increased sensitivity of normative values that were compiled.
• 1000 Hz probe tone tympanometry and acoustic reflexes were analyzed and age and gender specific norms were reported.
• The use of an OAE pass result as a control variable for normal middle ear functioning proved successful and useful for identification of normal middle functioning and correlated well to peaked tympanogram results and present acoustic reflexes.
LIMITATIONS
• Poor infant co-operation prevented the whole test procedure to be performed on all infants. Breast or bottle feeding to pacify distressed infants in addition to visual distraction proved successful in enhancing infant co-operation, though 100% success rate could not be obtained.
• Due to failure of subjects to return for follow-up OAE screening it had not been possible to confirm or reject sensori-neural hearing loss in cases with a combination of a peaked tympanogram and absent OAEs. A further limitation was due to the fact that ABR screening results were not considered in the analysis of the results for subjects that underwent AABR testing,
• Uncompensated acoustic admittance and tympanometric peak pressure were the only variables analysed in this study. For more detailed analysis and for comparison between studies tympanometric width, compensated static admittance and tympanometric gradient could be included as measurement variables in subsequent investigations.

5.5 CLINICAL GUIDELINES FOR INTERPRETATION OF HIGH FREQUENCY IMMITTANCE MEASURES

~ High frequency tympanometry in combination with acoustic reflexes proves a useful and sensitive measure of middle ear functioning in infants. *Peaked tympanograms and present acoustic reflexes strongly indicate normal middle ear functioning*.

~ High frequency admittance (Y_a) tympanograms are easier to interpret and proves a suitable measure if the assessment of mass and stiffness-related elements are not the primary objective.

~ In agreement with previous reports, double peaked tympanograms indicate good agreement with OAE pass results, and can therefore be interpreted as normal.

~ OAE pass results were highly associated with tympanic peak pressures values *greater than -100 daPa and smaller than 100 daPa*, with 87% of ears in the OAE pass group falling within this region. Positive middle ear pressure >150 daPa may be an important indicator of the presence of middle ear effusion in infants.

~ Age related normative data described in this study offer guidelines for the interpretation of high frequency tympanometry and reflexes in infants.

5.6 RECOMMENDATIONS FOR FUTURE RESEARCH

o Further research is needed on larger subgroups with abnormal middle ear functioning for comparisons to be made between results of normal and abnormal measures of high frequency tympanometry.

o More research on the validation of admittance tympanograms in relation to OAE outcome and other tests of middle ear assessment is necessary to further validate the use high frequency (1000 Hz) Y_a tympanograms as a single indicator of middle ear functioning in infants.

- Classification systems based on single component admittance tympanograms should be explored and developed to ease classification and interpretation of 1000 Hz tympanograms. This could provide a more scientific base for interpretation of high frequency tympanometry opposed to the current practise employing a simple pass criteria based on the presence of any peaked tympanometric pattern.

5.7 FINAL COMMENTS

The prospect of employing high frequency tympanometry to assess middle ear functioning in infants, addresses one of the major challenges of early identification and differentiation between middle ear pathology and sensori-neural hearing loss in infants. High frequency admittance tympanograms prove useful as part of a paediatric audiologic test battery for infants less than twelve months of age, though it is important to remember that concerns about hearing sensitivity after referral from newborn hearing screen cannot be dismissed on the basis of a flat tympanogram (Holte & Margolis, 2002:390). 1000 Hz admittance tympanometry proves a valid and useful method for identification middle ear pathology in infants. Normative values, as described in this study, offer guidelines for further research into universal normative values and a classification system for high frequency acoustic immittance measures in infants.

5.8 SUMMARY

Chapter 5 provided conclusions and recommendations based on the results obtained in this study. Significant findings were highlighted and recommendations for clinical practise provided. High frequency tympanometry shows great promise for timely diagnosis of middle ear dysfunction in infants and for differentiation between true and false positive results from hearing screening.

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APPENDIX A: Data recording sheet

DATA SHEET

ID NO.												

Respondent no					V1					1-4

SECTION A ~ IDENTIFYING INFORMATION

a) Gender

Male	1	Female	2

V2 [ ] 5

b) Child's Age

Weeks		

V3 [ ] [ ] 6-7

c) Mother's Age

Years		

V4 [ ] [ ] 8-9

d) Home Language

Tswana	1
Sepedi	2
Shangaan	3
Zulu	4
English	5
Afrikaans	6
Other	7

V5 [ ] 10

e) Race

Black	1
Coloured	2
Indian	3
White	4

V6 [ ] 11

f) Primary Caregiver

Mother	1
Father	2
Both	3
Grandparents	4
Extended family	5
Foster parents	6

V7 [ ] 12

g) Educational Qualifications

i. Biological Mother

< St. 6	1
St. 6-8	2
St. 8-10	3
Diploma/Degree	4
Postgraduate	5

V8 [ ] 13

ii. Biological Father

< St. 6	1
St. 6-8	2
St. 8-10	3
Diploma/Degree	4
Postgraduate	5

V9 [ ] 14

h) Average Household Income (p/m)

<R500	1
R501 – R1000	2
R1001 – R2000	3
R2001 – R 5000	4
R5000+	5

V10 [ ] 15

i) No. of children (Biological mother)

Born		
Still living		

V11 [ ] [ ] 16-17
V12 [ ] [ ] 18-19

j) Marital status of Biological parents

Married	1
Never married	2
Divorced	3
Widow	4

V13 [ ] 20

k) Housing

Own house/flat	1
Informal housing	2
Renting	3
With others	4

V14 [ ] 21

SECTION B ~ RISK INDICATORS

a) Family History of childhood Hearing loss

Yes	1	No	2	Info unavailable	3

V15 [ ] 22

b) Hyperbillirubinemia

Levels requiring blood transfusion/exchange

Yes	1	No	2	Info unavailable	3	V16		23

If levels are known, are they in excess of the following amounts,

Birth weight (grams)	Bili level
≤ 1000	10.0
1001 – 1250	10.0
1251 – 1500	13.0
1501 – 2000	15.0
2001 – 2500	17.0
2500 +	18.0

Yes	1	No	2	Info unavailable	3	V17		24

c) Congenital infections

Yes	1	No	2	V18		25

If 'Yes', specify:

	YES	NO			
Toxoplasmosis	1	2	V19		26
Cytomegalovirus	1	2	V20		27
Syphillis	1	2	V21		28
Herpes	1	2	V22		29
Rubella	1	2	V23		30
Measles	1	2	V24		31
HIV	1	2	V25		32
Malaria	1	2	V26		33

d) Craniofacial defects (Head and neck)

Yes	1	No	2	V27		34

e) Birth weight < 1500g

Yes	1	No	2	Info unavailable	3	V28		35

f) Bacterial meningitis

Yes	1	No	2	Info unavailable	3	V29		36

g) Asphyxia

Apgar 0-4 at 1min and/or 0-6 at 5min

Yes	1	No	2	Info unavailable	3	V30		37

If 'Yes' specify at:

1 min			V31			38-39
5 min			V32			40-41

h) Ototoxic medications

Used for more than 5 days (e.g. gentamycin, tobramycin, kanamycin, streptomycin, aminoglycosides and loop diuretics combined with amino's)

Yes	1	No	2	Info unavailable	3	V33		42

i) Persistent pulmonary hypertension / persistant fetal circulation. Prolonged mechanical ventilation ≥ 5 days

Yes	1	No	2	Info unavailable	3

V34 [ ] 43

j) Syndrome present

Yes	1	No	2

V35 [ ] 44

If 'yes', specify syndrome:

_____

V36 [ ][ ] 45 - 46

k) Admitted to the NICU

Yes	1	No	2

V37 [ ] 47

If 'Yes', for how long?

No of days			

V38 [ ][ ][ ] 48-50

SECTION C ~ IMMITTANCE

a) 1000 Hz Tympanogram

i. Y – Admittance

	RIGHT		LEFT	
i.i Performed	Yes	No	Yes	No
i.ii Discernable peak	Yes	No	Yes	No
i.iii Admittance (mmho)	[ ][ ], [ ][ ]		[ ][ ], [ ][ ]	
i.iv Pressure (daPa)	[ ][ ][ ][ ]		[ ][ ][ ][ ]	
i.v Double peak	Yes	No	Yes	No
i.vi Time taken (min)	[ ][ ]		[ ][ ]	

V39R [ ] 51
V39L [ ] 52
V40R [ ] 53
V40L [ ] 54
V41R [ ][ ], [ ][ ] 55-58
V41L [ ][ ], [ ][ ] 59-62
V42R [ ][ ][ ][ ] 63-66
V42L [ ][ ][ ][ ] 67-70
V43R [ ] 71
V43L [ ] 72
V44R [ ][ ] 73-74
V44L [ ][ ] 75-76

ii. B – Susceptance

	RIGHT		LEFT	
ii.i Performed	Yes	No	Yes	No
ii.ii Admittance (mmho)	[ ][ ], [ ][ ]		[ ][ ], [ ][ ]	
ii.iii Pressure (daPa)	[ ][ ][ ][ ]		[ ][ ][ ][ ]	

V45R [ ] 77
V45L [ ] 78
V46R [ ][ ], [ ][ ] 79-82
V46L [ ][ ], [ ][ ] 83-86
V47R [ ][ ][ ][ ] 87-90
V47L [ ][ ][ ][ ] 91-94

iii. G– Conductance

	RIGHT		LEFT	
iii.i Performed	Yes	No	Yes	No
iii.ii Admittance (mmho)		,		,
iii.iii Pressure (daPa)				

V48R			95		
V48L			96		
V49R		,			97-100
V49L		,			101-104
V50R					105-108
V50L					109-112

b) 1000 Hz Probe Tone Reflex

	RIGHT		LEFT	
i. Performed	Yes	No	Yes	No
ii. Threshold present	Yes	No	Yes	No
iii. Threshold value (dB)				

V51R		113		
V51L		114		
V52R		115		
V52L		116		
V53R				117-119
V53L				120-122

SECTION D ~ HEARING SCREENING

a) First Screen

	RIGHT		LEFT	
i. OAE	Pass	Refer	Pass	Refer
ii. AABR	Pass	Refer	Pass	Refer

V54R		123
V54L		124
V55R		125
V55L		126

iii. Time taken:

iii.i OAE

		min

V56			127-128

iii.ii AABR

		min

V57			129-130

b) Follow-up Screen

i. Returned?

Yes	1	No	2	V58	131

	RIGHT		LEFT			
ii. OAE	Pass	Refer	Pass	Refer	V59R	132
					V59L	133
iii. AABR	Pass	Refer	Pass	Refer	V60R	134
					V60L	135

SECTION E ~ DIAGNOSTIC ASSESSMENT

a) Returned?

Yes	1	No	2	V61	136

b) Hearing loss?

None	1	Bilateral	2	Unilateral	3	V62	137

c) Type of hearing loss?

S/N	1	V63	138
Conductive	2		
Mixed	3		
AN	4		

d) Ear

Left	1	Right	2	Both	3	V64	139

e) Degree of hearing loss?

i. Right ear

Mild (15-30 dB)	1	V65	140
Moderate (31-50dB)	2		
Severe (51-70dB)	3		
Profound (71dB+)	4		

ii. Left ear

Mild (15-30 dB)	1	V66	141
Moderate (31-50dB)	2		
Severe (51-70dB)	3		
Profound (71dB+)	4		

COMMENTS

APPENDIX B: Ethical Clearance

University of Pretoria
Pretoria 0002 Republic of South Africa Tel 012-420-2357
/ 012-420-2816 Fax 012-420-3517 http://www.up.ac.za
Department of Communication Pathology
Speech, Voice and Hearing Clinic

18 November 2003

To: Chair Research Proposal and Ethics Committee, Faculty of Humanities, University of Pretoria

Re: M. Communication Pathology research project: Ms. S Werner (9807345)

The student participated in a larger research project initiated by Mr. DCD Swanepoel for which ethical clearance was obtained at the end of 2002 (See attached clearance letter). Ms Werner collected a sub-set of data for her research project that was included in the research proposal and ethical applications form submitted by Mr Swanepoel. The project entailed data collection at maternal child health clinics in the Hammanskraal district and ethical clearance was therefore also obtained from the North West Province Department of Health for the Moretele District (See attached clearance letter). The title registration for Ms Werner is attached for registration purposes.

Thank you,

Mr. DCD Swanepoel
DEPARTMENT COMMUNICATION PATHOLOGY