Chapter 5

CONCLUSIONS AND IMPLICATIONS

This chapter aims to draw general conclusions and implications from the research, critically evaluate findings, and make recommendations for future research

5.1 INTRODUCTION

Within a relatively short period of time, there has been remarkable and revolutionary changes in the field of pediatric audiology that demand professionals to rethink diagnostic and intervention paradigms (Kurtzer-White & Luterman, 2001: introduction). 'Evidence Based Practice' (EBP) is therefore an approach to clinical service delivery that has become increasingly advocated (Gravel, 2005:17). EBP refers to '*conscientious, explicit, and judicious use of current best evidence in making decisions about the care of patients*' (Oxford-Centre for Evidence Based Medicine, 2004: online). The primary element of EBP is the major role of *scientific* evidence in *clinical* decision-making (Gravel, 2005:17). This sentiment has been the underlying driving force behind the research endeavor of this study.

There has always been a need for objective tests that assess auditory function in infants, young children, and/or any patient whose developmental level precluded the use of behavioral audiometric techniques (Gorga & Neely, 2002:49). The ASSR have therefore gained

considerable attention and is seen as a promising addition to the AEP 'family'. This study proposed to gather evidence with regards to the clinical value of the ASSR in infants. It is thus logical to evaluate 'best evidence' through *critical appraisal* of this research endeavor (Hill & Spittlehouse, 2005:1). *Critical appraisal* is an essential part of evidence-based clinical practice that includes the process of systematically finding, appraising and acting on evidence of effectiveness. *Critical appraisal* is a systematic process, examining research evidence to assess its validity, results and relevance. This process allows making sense of research evidence and thus begins to close the gap between research and practice (Hill & Spittlehouse, 2005:1).

The purpose of this chapter is therefore to draw relevant conclusions from the results reported and discussed in chapter 4. A critical evaluation of the study is subsequently provided to identify the inherent and methodological limitations of this study, followed by recommendations for future research. Finally a conclusion and summary of the chapter is provided.

5.2 CONCLUSIONS

The need for research to provide evidence to justify clinical practices is acknowledged by most clinicians (Jenkins, Price & Straker, 2003:4). This exploratory study was conducted according to two sub-aims, which resulted in the summarized conclusions that follow below.

5.2.1 Sub-aim 1: To investigate the potential clinical value of the ASSR in early diagnosis of hearing loss in a group of infants by determining and comparing unaided ASSR, ABR and behavioral thresholds

- This study concluded that both the ABR and ASSR could both be used to estimate hearing thresholds – as positive correlations were found between these two measurements. However the ASSR proved to be more beneficial in the severe to profound hearing loss population to quantify their hearing losses.
- This study indicated that the ASSR procedure can accurately identify and quantify hearing loss in infants as a strong relationship was noted between the ASSR thresholds obtained during infancy and their subsequently obtained behavioral audiograms.
- Although the tone burst ABR and click evoked ABR indicated to provide reasonably accurate estimates of the 500 Hz, 2000 Hz and 4000 Hz behavioral audiogram, it was evident that the severe to profound sensory neural hearing losses will not be identified and evaluated through the use of the ABR.

The ASSR has the potential to provide accurate predictions of the behavioral audiogram and be used successfully with populations with severe to profound losses.

5.2.2 Sub-aim 2: To investigate the clinical value of the ASSR for relevant early fitting of hearing aids in infants by determining and comparing aided ASSR and aided behavioral thresholds

- All subjects showed recognizable aided ASSR responses above their unaided ASSR thresholds. There was an inability to determine aided ASSR's at 500 Hz in four subjects.
- In the group of six subjects, the aided ASSR *measured* thresholds were on average between 9.2 dB and 16 dB higher than the aided behavioral thresholds. The aided ASSR *predicted* were on average between 4 dB and 9.2 dB lower than the aided behavioral thresholds – indicating to the aided *measured* thresholds to underestimate behavioral thresholds and the aided *predicted* thresholds to overestimate the aided behavioral thresholds.

The ASSR has the potential to determine aided ASSR thresholds. This procedure can therefore be used to determine functional gain and thus play a role in the ongoing process of validating hearing aid fittings in infants.

The ASSR, despite some limitations identified, demonstrated great promise for early diagnosis and amplification of infants with hearing loss. The discussions according to the specified sub-aims, revealed valuable theoretical and clinical implications and made recommendations for protocols to serve as a guide for future use of the ASSR in the clinical setting.

5.3 THEORETICAL AND CLINICAL IMPLICATIONS

A major justification for electrophysiologic audiometry is that reasonable measures of hearing thresholds in a frequency specific manner can be obtained in order to construct an audiogram (Goldstein & Aldrich (1999:3). Neonates provide the prime example. At present the tone-evoked ABR is the only technique that can provide both the air- and bone- conduction results required for early intervention for children with conductive or sensorineural hearing loss. The tone-evoked ABR has sufficient research, clinical database, and clinical history to recommend it as the **primary technique** for threshold estimation in infants (Stapells, 2005:55).

This present study has proved however that both the ASSR and ABR demonstrated efficacy for estimating the pure-tone audiogram in infants with hearing loss. No significant difference in threshold determination was found between these two techniques. The ASSR did however have the advantage over the ABR in determining residual hearing in the severe to profound group.

It is therefore evident that both techniques have its own advantages and its disadvantages. As indicated by the review of the current literature, the evidence is lacking and not yet sufficient to recommend the ASSR as the **primary** electrophysiologic measure of hearing in infants (Stapells, 2005:56). These two techniques should probably be used in conjunction with each other (Hall, 2005: conference presentation). Jerger & Hayes (1976) in Diefendorf (2002:473) promoted the concept of a test battery approach so that no single test will be interpreted in isolation, but various tests act as a cross-check on the final outcome. Inappropriate or

incomplete diagnostic conclusions will lead to inappropriate management and the consequences thereof will be with the child forever (Seewald, 2001:70). By using these techniques in combination, a more solid foundation for intervention will be provided.

When considering two of the most important 'truths' in EBP (Oxford-Centre for Evidence Based Medicine: online), namely:

- *Practice must always be considered in view of the needs, culture and preferences of the individual;*
- *There is the real probability that some of the evidence-base supporting current practice will change or, indeed, be entirely refuted by evidence that will emerge in the future,*

there is a need to continually re-examine the current approach to evaluate hearing abilities in infants.

The ASSR and ABR present with unique qualities that can be combined to provide complementary results, which will serve to verify results obtained with each procedure (Swanepoel, 2001:114). Time is limited when working with infants. It is therefore essential to use a test protocol that is fast, efficient, and one that provides the greatest amount of clinical information with each successive step taken (Stapells, 2002a:14) for each individual infant (Oxford-Centre for Evidence Based Medicine: online).

Although Stapells (2004: conference) has called for the click ABR to be abolished, the click ABR has proven itself over the last three decades as a reliable predictor of auditory sensitivity in the high frequency region despite its lack of frequency-specificity (Swanepoel, 2001:115). It has

remained the most commonly used electrophysiologic measure because of the clear response, the high reproducibility and stability of the response (Arnold, 2000:455). The click ABR is also the only technique at present to assess the presence of auditory neuropathy (AN) – also known as auditory dys-synchrony (Tharpe & Haynes, 2005:271). Both procedures approximated the behavioral thresholds well in this study – however the ASSR approximated behavioral thresholds closer than the ABR (group results). This aspect was influenced by the fact that fewer ears could be tested with the ABR than with the ASSR. Although additional research on ASSR testing in infants with hearing loss is needed (Stapells, 2005:55), by using the ASSR in addition to the ABR, useful information may already be provided to help distinguish between infants with severe and profound losses (Roush, 2005:105).

These results suggest a test-battery approach to objective audiometry. These two techniques are independent measures of auditory sensitivity that are able to provide different, though complementary information. The *needs* and *preference* of each infant will be accommodated by using this test-battery approach. Not only will a cross-check principle be advantageous to each individual infant, but the specific advantages of each procedure will give the most comprehensive assessment necessary to ensure that a true reflection of each infant's auditory status is available from which rehabilitative decisions can be made (Roush, 2005:105).

After hearing loss is diagnosed, fitting of hearing instruments can occur when infants are as young as five weeks old (Yoshinago-Itano, 2004:451). Objective measures such as AEP's offer the possibility of evaluating the effectiveness of hearing instruments in infants. This present study did not evaluate the ABR's ability to determine hearing instrument effectiveness

as the literature has shown that the brief stimuli that are optimal for ABR recordings may be contaminated by stimulus artifacts. This specific procedure was also seen as complicated and attempts to use the ABR to evaluate hearing instruments have largely been abandoned (Purdy, 2005:116). This study indicated to the ASSR being a reliable method to determine aided thresholds to ensure audibility of speech sounds. The results from the aided ASSR may suggest the need to consider alternative management – such as in the case of two subjects in this study who both had profound sensory neural hearing losses and were fitted with high-powered hearing aids. The decision to proceed with cochlear implantation was expedited. The idea that the ASSR can be used to validate hearing instrument fittings is reasonable, but is yet to be validated as a procedure.

5.4 CRITICAL EVALUATION OF THE CURRENT STUDY

Critical appraisal of an empirical research endeavor is essential to determine the value of the results obtained and is an essential part of evidence-based clinical practice. Reliability and validity of the results as well as the influence of identified limitations, inherent to the study, is required to ensure the appropriate interpretation thereof. Several aspects deserving critical appraisal will be discussed in the following paragraphs.

The first aspect to be considered is the sampling size of the current study. The basic rule is, *the larger the sample, the better* (Leedy & Ormrod, 2005:207). The sampling size necessary for a study depends on the type of study and is required to provide a representative population from which inferences can be drawn regarding a specific phenomenon in a specific population. Although the sample in the current study was representative

of both sexes and covered a range of ages in infants, the sample size was not significantly representative of hearing impaired infants. This was however an exploratory study – only the second reporting on aided ASSR's and the first of its nature on infants.

The second aspect that needs to be taken into consideration is the test environment. All behavioral thresholds (aided and unaided) were obtained in a double walled, sound-attenuated booth, while the electrophysiological assessments were completed in a quiet room without any sound attenuation. The acoustical ambient background noise levels were not measured and therefore did not allow for comparison between acoustic noise levels between the double-walled, sound-attenuated booth and the quiet room. The possible difference was not considered when interpreting the results. This noise factor might have played a role – especially in obtaining aided ASSR results. Higher levels of ambient acoustic noise in the quiet room might have caused elevated thresholds and the absence of the reported aided 500 Hz ASSR thresholds. Thus the threshold differences could be inflated on account of the variability in the test environments (Perez-Abalo et al., 2001:210; Swanepoel, 2001:120; Lins et al., 1996:95).

A third aspect identified in the critical appraisal of the current study is the lack of test-retest reliability measures. According to Stapells (2000a:13), one of the limitations with the ABR is the inappropriate interpretation of waveforms. A way to improve reliability of a test is to have two administrators correlating the results of the same procedure. This may be of value in both the interpretation of ABR and behavioral threshold assessment. The responses measured during this study, was interpreted by the researcher alone.

A fourth aspect that needs to be taken into consideration, is the fact that a click-evoked ABR and only a 500 Hz tone burst were used to compare with the ASSR. Narrow frequency regions (ASSR) were therefore compared with those from broad and uncertain frequency regions (click ABR). Ideally a comparison should be made between the infants' ASSR thresholds to their tone-evoked ABR – the current 'gold standard' infant threshold measure (Hyde, 2005:287; Stapells, 2002:14).

The critical evaluation of the literature, current study and consideration of significance of the results obtained has revealed future research implications that are discussed in the following paragraph.

5.5 RECOMMENDATION FOR FUTURE RESEARCH

Clearly, there is an important role for the ASSR in estimating hearing thresholds and validating hearing aid fittings of infants. However, a research question answered raises new questions to be answered. The results obtained in and conclusions drawn from this present research endeavor, revealed aspects that require further investigation. These are presented to provide suggestions for future research endeavors.

In order to validate the ASSR procedure in the infant population, it will be of value to compare the ASSR obtained at all frequencies, with tone burst ABR – using different frequency tone bursts. This data will not only provide comparative data to the accuracy of threshold determination, but also reliability and time-efficiency of each procedure.

In order to further validate the ASSR procedure in the infant population, it will be of value to determine bone conduction ASSR. By determining the

BC ASSR, possible middle ear involvement will be ruled out during the assessment and a true picture of the hearing loss will emerge.

Although the vast majority of research has focused on threshold determination and optimal detection strategies, this present study and a study from Picton (1998) explored the use of ASSR and hearing aid performance. The results from this study are very promising, but the procedures need to be validated on a larger group of infants as well as on children of other ages – as this procedure will probably be of use to the difficult-to-test population, including older children with developmental delays. Different prediction formulae might also be necessary to be developed for the application of the ASSR for this purpose.

An aided threshold supplies certain information about audibility of sounds, but no information about perception of sounds is given. Studies by Dimitrijevic et al. (2004:68) used the ASSR to predict suprathreshold auditory abilities such as word discrimination. Multiple carriers of independently modulated frequency and amplitude ('IAFM') stimuli have been modeled to have similar acoustic spectra to speech. Using these speech-modeled stimuli, significant correlations between word discrimination and detection of IAFM were found in normal-hearing and hearing-impaired subjects (Dimitrijevic et al., 2004:84). Although ASSR's represent a relatively low level of auditory processing, IAFM may be used to determine whether or not the auditory system has sufficiently processed the necessary input required for speech perception at a later and higher level of processing (Stapells, 2005:56).

5.6 CONCLUSION

AEP's are an ideal tool for investigating auditory function in young infants, as they provide an objective measure of the brain's response to sound (Purdy et al., 2005:115). Recent technological and research advancements have aided the development of this field, ensuring the continuation of endeavors generating techniques that approximate the accuracy, reliability, frequency-specificity and time efficiency of behavioral pure tone audiometry (Swanepoel, 2001:121) – both unaided and aided.

This investigation of the clinical value of the ASSR in infants has demonstrated the ASSR's ability to estimate behavioral pure tone thresholds reasonably well. It has also shown that the ASSR has the potential to play a role in the ongoing process of hearing instrument fitting in infants as aided ASSR thresholds compared reasonably well with aided behavioral thresholds. However, while additional research on ASSR testing in infants with hearing loss is needed, it is important to critically consider currently available procedures alongside the new. In his closing address of *A Sound Foundation through Early Amplification* conference in 1998 Bess challenged the clinicians to become more evidence based with the following words: '*Effective clinicians produce improved techniques and constantly question and evaluate evidence, methods, and procedures, discarding the unproductive, and developing and testing the new' (*Bess, 2000:250).

This becomes essential in order to implement techniques in accordance to the advantages and disadvantages of each procedure. Evidence from the current study indicated that the ASSR presented with unique

characteristics that should be incorporated in a test-battery approach and therefore has clinical value for early diagnosis and amplification of infants with hearing loss.

'if we truly desire to afford the best possible services to children and their families, we must be willing to continually modify our clinical protocols as new evidence emerges' (Bess, 2000:250)