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UNIVERSITY OF SOUTHAMPTON

FACULTY OF ENGINEERING AND THE ENVIRONMENT

Institute of Sound and Vibration Research (ISVR)

Can the auditory late response indicate audibility of speech sounds from hearing aids with different digital processing strategies

By

Katie Helen Ireland

Thesis for the degree of Doctorate of Clinical Practice

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Abstract

Auditory late responses (ALR) have been proposed as a hearing aid (HA) evaluation tool but there is limited data exploring alterations to the waveform morphology from using digital HAs. The research had two phases: an adult normal hearing phase and an infant hearing impaired clinical feasibility phase. The adult normal hearing study investigated how different HA strategies and stimuli may influence the ALR. ALRs were recorded from 20 normally hearing young adults. Test sounds, /m/, /g/, /t/, processed in four HA conditions (unaided, linear, wide dynamic range compression (WDRC), non linear frequency compression (NLFC)) were presented at 65 dB nHL. Stimuli were 100 ms duration with a 3 second inter-stimulus interval. An $F_{\rm sp}$ measure of ALR quality was calculated and its significance determined using bootstrap analysis to objectively indicate response presence from background noise. Data from 16 subjects was included in the statistical analysis.

ALRs were present in 96% of conditions and there was good repeatability between unaided ALRs. Unaided amplitude was significantly larger than all aided amplitudes and unaided latencies were significantly earlier than aided latencies in most conditions. There was no significant effect of NLFC on the ALR waveforms. Stimulus type had a significant effect on amplitude but not latency.

The results showed that ALRs can be recorded reliably through a digital HA. There was an overall effect of aiding on the response likely due to the delay, compression characteristics and frequency shaping introduced by the HA. Type of HA strategy did not significantly alter the ALR waveform. The differences found in ALR amplitude due to stimulus type may be due to tonotopic organisation of the auditory cortex.

The infant hearing impaired study was conducted to explore the feasibility of using ALRs as a means of indicating audibility of sound from HA's in a clinical population.

ALRs were recorded from 5 infants aged between 5-6 months with bilateral sensori-neural hearing loss and wearing their customised HA's. The speech sounds /m/ and /t/ from the adult study were presented at an rms level of 65 dB SPL in 3 conditions: unaided; WDRC; NLFC. Bootstrap analysis of F_{sp} was again used to determine response presence and probe microphone measures were recorded in the aided conditions to confirm audibility of the test sounds.

ALRs were recordable in young infants wearing HAs. 85% of aided responses were present where only 10% of unaided were present. NLFC active improved aided response presence to the high frequency speech sound /t/ for 1 infant. There were no clear differences in the aided waveforms between the speech sounds.

The results showed that it is feasible to record ALRs in an infant clinical population. The response appeared more sensitive to improved audibility than frequency alterations.

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DECLARATION OF AUTHORSHIP

I, Katie Helen Ireland declare that this thesis entitled

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and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

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Signed:	 	
- 0		
Date:	 	

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List of acronyms

ABR = Auditory brainstem response

ACC = Acoustic change complex

AGC = Automatic gain control

ALR = Auditory late response

ASSR = Auditory steady state response

BSA = British Society of Audiology

CED = Cambridge electronic design

DSL = Desired Sensation Level

EEG = Electroencephalography

eHL = Estimated hearing level

ESL = Estimated sensation levels

FFT = Fast fourier transform

fMRI = Functional magnetic resonance imaging

HA = Hearing aid

HG = Heschyl's gyrus

ISI = Inter-stimulus interval

ITI = Inter-train interval

KEMAR = Knowles electronics mannequin for acoustic research

MEG = Magnetoencephalography

MMN = Mismatched negativity

MRC = Medical research council

MSC = Magnitude squared coherence

NAL = National acoustic laboratory

NLFC = Non linear frequency compression

PAM = Post auricular muscle

PEACH = Parent's evaluation of aural/oral performance of children

p-to-p = Peak-to-peak

PPE = Peak-to-peak equivalent

PT = Planum temporale

RMANOVA = Repeated measures analysis of variance

RMS = Root mean square

SDR = Signal-to-distortion ratio

SLM = Sound level meter

SNR = Signal-to-noise ratio

SPL = Sound pressure level

VCV = Vowel-consonant-vowel

WDRC = Wide dynamic range compression

Chapter 1. General introduction

1.1. Motivation for the research

The research was undertaken in the anticipation that the outcomes may direct clinical practice in the evaluation of hearing aid fitting in young infants and contribute to the development of national clinical guidelines. The ultimate hope is that this research will benefit infants detected early with deafness and their families with the aim to prevent delay in speech and language acquisition and maximise potential in social, emotional and intellectual development. In turn, this would be expected to reduce the need for costly intensive on-going support. The research is particularly pertinent where the adopted test technique is being promoted for the purpose of evaluating hearing aid fitting in commercial based systems.

1.2. Introduction and objectives

Two babies in every 1000 are born with permanent hearing loss requiring intervention (Davis et al 1997). Deafness is well known to impact on a child's social, emotional and intellectual development. Research has shown that children provided with early intervention and effective hearing aid provision before 8 months of age can develop speech and language skills in line with their normally hearing peers (Ching et al 2008), fundamental to these wider skills.

Newborn Hearing Screening for early detection of deafness was first introduced in England over 10 years ago. It has made a significant difference to the age of diagnosis with protocols in place to identify congenital hearing loss by 3 months of age (NHS Newborn Hearing Screening Programme 2008). Diagnosis and subsequent management of the hearing loss follows three main steps: assessment; prescription/verification of hearing aid fitting; evaluation of hearing aid benefit (Scollie and Seewald 2001).

Recommended guidelines are well established in order to accurately identify congenital hearing loss and optimally program hearing aids. This includes the use of the objective frequency specific tone-burst auditory brainstem response (ABR), and the fitting of hearing aids to validated prescription formulae verified using real ear measures (Stapells 2002a, Scollie and Seewald 2001). Fitting of hearing aids is offered within one month of diagnosis in line with National Deaf Children Society quality standards (2000) and infants as young as one month old have been fitted with hearing aids (Yoshinago-Itano 2004).

Evaluation of hearing aid fitting should provide evidence that the infant is able to access sounds across the speech spectrum and discriminate the difference between them. By 8-10 months of age, infants with normal hearing are already 'tuned in' to speech contrasts of their native language and have reduced the ability to discriminate non-native speech sounds (Werker and Tees 2002). It is therefore critical that evaluation to ensure optimal hearing aid benefit for hearing impaired infants takes place soon after fitting. However there remains no consensus to guide clinical practice of the method to use for hearing aid evaluation in this young age group.

The most widely used approaches for evaluating hearing aid benefit are using behavioural testing, parental observation and questionnaires. The reliability of behavioural testing is highly dependent on the infant's state and development (Golding et al 2007) and responses can be variable below the age of 6-8 months, by which time an important period for normal linguistic development has passed (Purdy et al 2005).

There are few questionnaires designed specifically to evaluate hearing aid benefit that have been validated and provide normative data for young infants (Ching 2006). One of the few available is the Parent's Evaluation of Aural/Oral performance of Children (PEACH), a parental observation based questionnaire, (Ching and Hill 2005). Golding et al (2007), in their study to assess the relationship between ALRs and functional measures in young infants, found wide variation in predicting age-corrected PEACH scores and suggested this was dependent on the amount of time each parent could spend observing their child's auditory behaviour, amongst the competing priorities they had in caring for the child and other siblings. This finding indicates that questionnaires cannot be regarded as a reliable outcome measure of benefit in all cases, suggesting the additional need for alternative more objective measures of benefit.

Because auditory evoked potentials provide an objective measure of the brain's response to sound, they are thought to be an ideal tool for investigating auditory function in young infants (Purdy et al 2005).

In the 1980's and early 1990's, the auditory brainstem response (ABR), an early evoked potential, gained considerable interest as a possible means to determine hearing aid benefit (Hecox 1983, Kiessling 1982, Kiessling 1983, Beauchaine et al 1986, Gorga et al 1987). The studies highlighted fundamental problems however of using the ABR for assessing amplification. Brief stimuli were used (clicks and tonebursts), as they are optimal for recording

the ABR, however they did not activate the hearing aid compression circuitry in the same way as longer-duration speech sounds (Brown et al 1999), and could be treated as 'noise' by hearing aids with speech detection algorithms. Clicks also have a much higher peak level than their root mean square (rms) level when compared to speech and would therefore be amplified differently.

More recent research demonstrated that an onset ABR and frequency following response (or envelope following response (Aiken and Picton 2006)) could be evoked using speech sounds in normal hearing subjects (Krishnan 2002, Russo et al 2004, Song et al 2006, Johnson et al 2005, Wible et al 2005). The auditory steady state response (ASSR) has also been used to obtain unaided and aided hearing levels to 70 Hz amplitude modulated tones in hearing impaired children (Picton et al 1998, Stroebel et al 2007) and to indicate speech discrimination capability in adults when compared to responses from independent amplitude and frequency modulated tones of the 40 Hz and 70 Hz ASSR (Dimitrijevic et al 2004). These stimuli can remove some of the problems highlighted with clicks and tone bursts but the ABR, 70 Hz ASSR and components of the 40 Hz ASSR are generated in the brainstem (Picton et al 2001) where the response remains short in latency and may therefore still be contaminated by stimulus artefact from electromagnetic pickup of the loudspeaker and hearing aid transduced signal by the recording electrodes (Purdy et al 2005).

Interest in the use of the auditory late response (ALR) as a means for evaluating hearing aid benefit in infants under 1 year has been re-invigorated in the last 10 years. Dillon (2005) describes certain characteristics of the ALR which suggests its suitability to this task above and beyond other electrophysiological measures. Firstly the stimulus is of longer duration allowing time for the hearing aid circuitry (e.g. compression) to react to the sound. The response amplitude is larger than that measured for the ABR or ASSR, since it originates in the auditory cortex, closer to the measuring scalp electrode. It therefore requires less repetition to obtain a response. The response can provide an indication that detection of the sound provided by hearing aids has transferred through all parts of the hearing system, to the level of the cortex, rather than the brainstem level only and the ALR can be measured to more real life sounds such as speech (Dillon 2005, Purdy et al 2005). This, along with different morphologies of the ALR waveform recorded to different suprathreshold speech stimuli (Agung et al 2006), (suggesting the potential for different neural representation) (Purdy et al 2005), led to the initial hypothesis that aided ALRs could indicate behavioural discrimination of sound and thus provide a measure of an infant's hearing aid benefit (Dillon 2005, Purdy et al 2005). This

theory, however, has since been moderated by additional research so that aided ALRs are currently thought to indicate physiological detection of a sound in the cortex where the absence or presence of a response demonstrates good correlation with inaudible and audible sounds (Billings et al 2012). Whilst this is an important precursor, it can only suggest that at least some portion of the sound is physiologically encoded and further understanding is still required before the aided ALR might be justified as a measure of sound discrimination and that a hearing aid has been fitted appropriately (Billings et al 2012, Billings 2013). However in addition, the morphology of the ALR, in particular the latency of the response compared to normal hearing listeners, is thought to be an indicator of maturation and remaining plasticity of the auditory system (Sharma et al 2002, Purdy et al 2013) which in turn may be a significant predictor of auditory outcomes for an individual. Certainly a lack of ALR response would prioritise the need for further clinical investigation and perhaps expedite referral for cochlear implantation.

The ALR is also sensitive to stimulus characteristics (Stapells 2002, Martin et al 2007) and Billings et al (2009, 2011, 2011a) warn of increased noise that may be introduced by the hearing aid, particularly relevant for users with mild or sloping high frequency hearing loss configurations, in addition to highlighting uncertainty in how the stimulus may be altered by hearing aid processing (Billings 2007, Dillon 2001).

Considering this information, the two main objectives of this thesis were as follows:

- To understand any effects that different digital hearing aid processing strategies and different stimuli have on the auditory late response in a normal hearing adult subject group.
- To investigate the feasibility of using the auditory late response as a tool for measuring hearing aid audibility in a group of hearing impaired young infants.

A secondary objective is:

 To evaluate how modifications of the test signal by hearing aid processing might explain differences, if any, between aided and unaided auditory late responses. 1.3. Thesis contribution

The principal contributions of this thesis are:

• Evidence from both adult and infant studies that short duration sounds may be used with

digital hearing aids to evoke the auditory late response (in contrast to recent literature).

Novel understanding of the effects of different digital hearing aid processing strategies on

the auditory late response, and in particular of non linear frequency compression, when

audibility of the stimulus is controlled.

Increased knowledge and clinical recommendation to introduce the use of the auditory

late response as a tool for indicating audibility of speech sounds in infants at around 5

months old and requiring hearing aids. There are currently no clear clinical guidelines for

this age group.

The following are publications based on research described in this thesis:

Journal papers

<u>Article in review:</u>

Ireland K.H., Bell S.L. and Farrell G. 'Effects of digital hearing aid processing on auditory late

responses'.

Conference abstracts

Ireland K.H. and Bell S.L. 'Cortical auditory evoked potentials in infants wearing hearing aids'.

Presented at: British Academy of Audiology conference, Manchester, UK, November 2013.

Ireland K.H. and Bell S.L. 'Can cortical auditory evoked potentials indicate access to speech

sounds when wearing hearing aids'.

Presented at: British Society of Audiology conference, Keele University, UK, September 2013.

Ireland K.H. and Bell S.L. 'Can cortical auditory evoked potentials indicate access to speech

sounds when wearing hearing aids with different processing strategies'.

Presented at: IERASG biennial symposium, New Orleans, USA, June 2013.

Ireland K.H. and Bell S.L. 'Cortical auditory evoked potentials and hearing aids'.

Presented at: British Academy of Audiology conference, Manchester, UK, November 2012.

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1.4. Thesis organisation

This thesis is organised in the following manner: In chapter 2, the auditory late response and its maturation and measurement is introduced. This is followed by a short review and critique of studies recording aided ALRs and alterations that hearing aid processing may contribute to. Test parameters to record the response are then considered. Chapter 3 describes an exploration on KEMAR of how hearing aid processing affects speech sounds and magnitude squared coherence and F_{sp} are used to estimate the level of noise and distortion in the stimuli. Chapter 4 pilots the equipment set-up and explores parameters for evoking the ALR. The findings from chapters 3 and 4 are used to develop the methodology for chapter 5 which describes a normative study investigating how different digital hearing aid strategies and different stimuli influence the ALR in a group of young adults. Four hearing aid conditions were examined for each of three speech sounds representing a range across low, mid and high frequencies. Differences between aided and unaided ALRs and those evoked from the different speech sounds were noted. Chapter 6 provides a discussion of the data obtained in chapter 5 with reference to hearing aid processing effects on the stimulus waveform and spectral content, as well as tonotopic organisation of the auditory cortex. Chapter 7 summarises a feasibility study of using the ALR as an evaluation tool in clinical practice for indicating hearing aid access in young infants identified early with hearing loss. Finally chapter 8 presents a concise summary of the findings from the thesis, and describes ideas for further work.

Chapter 2. Literature review

2.1. The Auditory Late Response

ALR's are divided in to two categories – the obligatory and discriminative (or cognitive) response (Kurtzberg 1989, Cone-Wesson and Wunderlich 2003, Stapells 2002, Martin et al 2007). The obligatory response is termed such as it is primarily determined by the physical properties of the stimulus. The discriminative response is highly correlated with behavioural discrimination of sound, from where its label is derived (Martin et al 2007, Stapells 2002, Picton et al 2000).

The obligatory ALR is suggested as an evaluation tool of hearing aid benefit in infants where (unlike the discriminative potentials) it does not require an active attention task to elicit a response (Purdy et al 2005).

The obligatory response is comprised of the slow P1-N1-P2 components (50-300 ms). It is not purely a sensory response since it is affected by attention (Martin et al 2007). So, whilst the obligatory response is primarily generated by the auditory cortex (primary and secondary), non auditory specific areas also appear to contribute (Stapells 2002, Martin et al 2007), perhaps explaining its interaction with attention.

The P1-N1-P2 complex can be evoked by the onset of a stimulus representing the change from silence to sound (Martin et al 2007). It can also be evoked in response to an acoustic change in an on-going sound resulting in overlapping P1-N1-P2 waveforms, known as the acoustic change complex (ACC) (Martin and Boothroyd 2000, Stapells 2002, Martin et al 2007). Martin and Boothroyd (2000) controlled for root mean square (rms) amplitude across the changing stimulus and found that the ACC could be evoked by changes in frequency spectrum, a capability requirement for speech discrimination. Other studies have also indicated reasonable agreement between presence of the ACC and behavioural measures of sound discrimination (Ostroff et al 1998) and more recently Martin et al (2007) demonstrated reliable recordings in individuals. However, the complex waveform pattern elicited by the ACC due to its overlapping nature can cause difficulty in identifying distinct components and it is possible some acoustic changes may not produce an observable ACC if the overlapping results in cancellation of the components (Martin et al 2008).

The discriminative response is comprised of late components between 150-1000 ms. The mismatched negativity (MMN) potential and the N2, P3 peaks are classified as discriminative evoked responses (Stapells 2002, Martin et al 2007). In contrast to the obligatory response, they require an attentional state whereby a change in the stimulus is 'noticed' indicating a higher level of cortical processing than that required for the obligatory response (Martin et al 2007, Stapells 2002, Picton et al 2000). These discrimination responses are, however, also affected by stimulus acoustics (Martin et al 2007).

The MMN and N2-P3 are evoked by an oddball paradigm in which deviant stimuli are embedded in a sequence of repetitive standard auditory stimuli (Martin et al 2007, Stapells 2002). The MMN requires a control for accurate interpretation (Martin et al 2007). The discriminative response is larger in magnitude when an active attention task is included such as counting or pressing a button to the deviant stimulus (Martin et al 2007). The MMN is thought to be generated from a combination of the auditory cortex and non auditory specific cortical areas (Stapells 2002). The latter area is more predominant when active attention is involved (Stapells 2002). Similarly, generators of the later waves (N2, P3) are not restricted to auditory specific cerebral regions (Stapells 2002).

The MMN is smaller in magnitude than other ALR responses (Martin et al 2007) and not always present in individuals with normal hearing sensitivity and normal auditory processing (Purdy et al 2005). This individual variability is also true of the later discriminative potentials (Sharma et al 2004). In addition, Oates et al (2002) found sensori-neural hearing loss had greater impact on the later evoked potentials than the earlier cortical potentials. For these reasons the discriminative evoked potentials in their current status do not appear to be a viable clinical tool for evaluating auditory access (Purdy et al 2005) and in particular in individuals with sensori-neural hearing loss requiring hearing aids. Furthermore, the requirement to incorporate an active attention task would suggest they are unsuitable for assessment in very young infants.

In considering the obligatory ALR as a hearing aid evaluation tool, there is limited research available with regards the ACC, however the onset P1-N1-P2 response has been recorded more extensively, including in infants, and documented in the literature (e.g. Wunderlich et al 2006, Golding et al 2007, Golding et al 2009, Chang et al 2012). Furthermore its use is promoted as a clinical tool with one commercial clinical system already available (Munro et al 2011, NAL 2012). The rest of the review will focus on the obligatory onset P1-N1-P2 ALR.

2.2. Maturation and measurement of the obligatory ALR

The P1-N1-P2 complex can be elicited by clicks, tone-bursts, tone-complexes and speech sounds. They have been reliably recorded in alert adults (Cone-Wesson and Wunderlich 2003, Tremblay et al 2003) and also observed to speech stimuli in awake infants and children (Kurtzberg 1989, Kraus et al 1993, Cone-Wesson and Wunderlich 2003, Golding et al 2007). The morphology of the response matures with age (Kraus et al 1993, Cone-Wesson and Wunderlich 2003) and distinct waveforms have been documented where spectral content between sounds is sufficiently different (Agung et al 2006). There is inconsistency across the literature between adopting a passive or odd-ball paradigm to record the response. This introduces variability since different designs alter the magnitude of the ALR making collective findings difficult to interpret (Billings et al 2011). The passive design is most commonly used in infant studies.

In an adult the ALR response is characterised by a small positive peak (P1) about 50 ms after stimulus onset, a large negative peak (N1) about 100 ms after stimulus onset, and a second large positive peak (P2) about 200 ms after stimulus onset (Stapells 2002, Martin et al 2007). The shape of the response is very different and more variable in infants (Dillon 2005). An infant's ALR waveform undergoes significant maturation in the first 6 years of life and is thought to reach maturity around 12 years of age as cognitive processing develops (Steinschneider 1992, Kraus et al 1993, Cone-Wesson and Wunderlich 2003). However there are differing descriptions of the infant ALR morphology in the literature. Dillon (2005) describes the response as comprising a single broad peak around 200 ms (a large late P1 response (Purdy et al 2005)) after stimulus onset whereas a number of other studies have shown that the infant ALR is dominated by the P1 peak occurring at about 100-300 ms after stimulus onset, followed by a late negativity at about 300-350 ms (Ponton et al 1996, Sharma et al 2002, King et al 2008, Purdy et al 2013). The response continues to change in shape as the auditory cortex matures (Kraus et al 1993, Dillon 2005). The shape of the potential can further differ as a function of the stimulus used (Kurtzberg 1989, Cone-Wesson and Wunderlich 2003).

Tremblay et al (2003) recorded the P1-N1-P2 response in a group of 7 young adults with normal hearing in response to four naturally produced speech tokens: /bi/; /pi/; /shi/; /si/. They found a high level of test retest repeatability with an intra class correlation coefficient of greater than 0.73 for all but one speech sound (/shi/) in one individual where it dropped to 0.6 (Tremblay et al 2003). Their results suggested that each speech token evoked a distinct neural

response pattern (Tremblay et al 2003). Agung et al (2006) support this finding where they recorded statistically significant differences in ALR amplitudes and latencies from speech sounds with greater spectral and temporal differences. The high frequency speech sounds /s/ and /sh/ were significantly smaller in amplitude compared to the lower frequency speech sounds /m/, /a/, /u/ and /i/.

Munro et al (2011) concur with the idea that auditory late response waveforms may only differ with larger differences in frequency content of the stimulus than perhaps initially thought. In a group of 24 normally hearing young adults with a simulated conductive hearing loss (from wearing ear plugs) results showed statistically significant differences between waveforms obtained from the speech sounds /m/ and /t/ and also /m/ and /g/ but not between /g/ and /t/. However the differentiation in waveforms between speech sounds noted at the group level was found to be less reliable at the individual level (Munro et al 2011).

Oates et al (2002) compared the auditory late response peak N1 (as well as the MMN, N2 and P3 peaks) between 20 young adults with normal hearing and 20 young adults with sensorineural hearing loss classified in to three groups: mild (25-49 dB HL); moderate (50-74 dB HL); severe/profound (75-120 dB HL). Auditory late responses were recorded to the speech sounds /ba/ and /da/ presented at 65 and 80 dB peak-to-peak equivalent (ppe) SPL in the sound field. As the degree of sensori-neural hearing loss increased, they found a significant decrease in the amplitude and an increase in the latency of the N1 response (as well as the other waveform components measured). Peak latency, however, appeared more sensitive than peak amplitude to the effects of sensori-neural hearing loss where latency increases started to occur from a mild hearing loss (Oates et al 2002). In contrast, amplitude of the ALR peaks remained more stable with increasing hearing loss until signal to noise ratio (SNR) diminished to between +12 dB (for the 65 dB ppe SPL input) and +15 dB (for the 80 dB ppe SPL input). ALR amplitude was considerably more variable than latency across individuals for both normal hearing and hearing impaired subjects. Unexpectedly, individuals in the moderate hearing loss group had significantly larger N1 amplitudes for their 80 dB ppe SPL responses compared with the normal hearing group but not for the lower stimulus intensity of 65 dB ppe SPL (Oates et al 2002). This might suggest that some recruitment is occurring in the hearing loss group or that the ALR amplitude has reached an upper limit at the higher stimulus intensity level in the normal hearing group, documented in the literature (Picton et al 1970, Adler and Adler 1989, Wunderlich and Cone-Wesson 2006).

Oates et al (2002) adopted an odd-ball paradigm to record the ALR, where deviant stimuli are embedded in a sequence of repetitive standard auditory stimuli (Martin et al 2007, Stapells 2002), which can alter the magnitude of the ALR peak response when compared to the passive design. Furthermore, all of the above studies adopted the dB SPL scale which does not control for sensation level of the sound across frequency (natural ear acoustics amplify frequencies differently). Tremblay et al (2003) also used sounds with different durations. Stimulus level and stimulus duration are known to change the ALR so this may cause interactions in responses recorded, making results difficult to interpret.

Collectively the results from these adult studies suggest ALR amplitude decreases and latency increases with increasing hearing level and responses to high frequency sounds are smaller in amplitude than low frequency sounds.

When testing children, Golding et al (2007) advise that infants can be kept awake during testing, sat on their parent's lap with another adult quietly distracting them. ALRs are known to be more variable and exhibit less reliable responses at threshold levels in infants than ABRs (Kurtzberg 1989, Stapells and Kurtzberg 1991, Carter et al 2010). In infants, maintaining optimum test conditions for the time it takes to obtain threshold is problematic (Cone-Wesson and Wunderlich 2003). This directed more recent research to test at suprathreshold levels in this subject group.

Sharma et al (2002) and Wunderlich et al (2006) documented normative data for maturation of ALRs in infants and young children. Sharma et al (2002) calculated the latency change of P1 from 51 normal hearing subjects ranging in age from 0.1 year to 20 years to a synthesised speech syllable /ba/ (although the majority of data appears to occur after 2yrs). Wunderlich et al (2006) expanded on this to measure normative data of latency and amplitude for ALR components P1, N1, P2 and N2 for a low frequency tone (400 Hz), high frequency tone (3000 Hz) and word token /baed/ (pronounced /bad/) at a level of 60 dB HL. Their participants included 10 newborns (<7 days), 19 toddlers (13-41 months), 20 children (4-6 years) and 9 adults (18-45 years). Unlike Sharma et al (2002), Wunderlich et al (2006) found that P1 peak latency did not vary significantly in infancy and early childhood (i.e. over the first 6 years of life).

Recording an auditory late response in young infants introduces greater variability than in adults where movement is more likely, increasing electrophysiological noise, and attention

state is harder to control, affecting magnitude of the response (Carter et al 2010). To improve the reliability of detecting a response, Dillon advocates the use of statistical analysis for waveform detection and adopts Hotelling's T^2 (Golding et al 2009, Carter et al 2010). Carter et al (2010) showed the ability to record ALRs in 14 of 17 infants with normal hearing aged 12 months \pm 3.4 months to the speech sounds /m/ and /t/. The three remaining subjects did not cooperate with ALR testing during the allocated test session (Carter et al 2010), which is a problem also found in other types of testing in this age group. They found that the Hotelling's T^2 was as accurate as detection based on the average of three expert examiners (Carter et al 2010). Since the general clinical group are more limited in experience of interpreting an infant ALR waveform in comparison to an expert, the addition of objective response analysis to subjective interpretation is considered important to ensure accuracy and may also improve speed of assessment (Carter et al 2010).

When recording the ALR in children it is important to recognise that the waveform morphology is different to that of adults, showing fewer peaks at increased latency. Incorporating objective response analysis with subjective interpretation can increase confidence in determining response presence.

2.3. Aided ALRs

Recording ALRs with hearing aids in adults, infants and children is not necessarily new, as its potential for evaluating amplification was first recognised by Rapin and Graziani (1967). The earliest studies reported findings from individual cases or small groups of subjects (Rapin and Graziani 1967, Kurtzberg 1989, Stapells and Kurtzberg 1991), limiting generalisation of the results. Research was also focussed at that time on evaluating the earlier auditory evoked response, the auditory brainstem response, when using hearing aids and interest quickly increased in this area (Kiessling 1982) over that of ALRs, perhaps where it was initially thought easier to record in infants.

More recently, research into the use of ALRs with hearing aids has been re-invigorated. Comparison across studies publishing findings from the aided auditory late response in general shows that the introduction of amplification results in shorter latencies, larger amplitudes and better waveform morphology. However there is evidence of conflict in findings across studies and at the individual level within studies where some unexpected results are found (Billings et al 2007, Billings et al 2009, Billings et al 2011a). In particular Billings et al (2007) unexpectedly

found no change in amplitude or latency in normal hearing participants between unaided and aided ALRs, even though 20 dB of hearing aid gain was added.

Korczak et al (2005) recorded the N1 response (as well as the MMN, N2b and P3b waves) in a group of 14 young adults with sensori-neural hearing loss which were divided into two categories: moderate (50-74 dB HL); severe/profound (75-120 dB HL). ALRs were obtained to unaided and aided speech sounds /ba/ and /da/ presented at 65 dB and 80 dB ppe SPL in the soundfield. The hearing aid output of the subject's personal amplification adjusted to their most comfortable listening levels was checked using real ear measures and documented to be close to the NAL-RP prescription target in around 83% of cases. Although not stated categorically by the authors, the lack of any further detail with regard hearing aid set up leads to the assumption the hearing aids were analogue and not necessarily the same model of hearing aid was used across subjects. Comparison of the N1 response across aided and unaided conditions showed that amplification generally resulted in shorter latencies, larger amplitudes, and better waveform morphologies but again, results were variable across individuals (Korczak et al 2005). This study adopted an odd-ball paradigm which can alter the magnitude of the ALR peak response when compared to the passive design (Billings et al 2011).

Billings and Tremblay's group confirmed this general aided effect on the auditory late response in a group of adults with normal hearing, which removes the unknown physiological effects of sensori-neural hearing loss on the response (Billings et al 2007). They increased stimulus level of a 1 kHz tone with a rise/fall time of 7.5 ms and duration of 757 ms in an unaided and aided condition (Billings et al 2007). The hearing aid was programmed to provide approximately 20 dB of gain with compression ratio of approximately 2:1, compression knee point of 65 dB and attack and release times of 5 and 30 ms respectively. The microphone was omnidirectional and all other features were deactivated. As would be expected, they found that P1, N1, P2 and N2 latencies decreased significantly and N1, P2 and N2 amplitudes increased significantly with increasing stimulus level within both the unaided and aided conditions (Billings et al 2007). They did not however find an effect on amplitude or latency between the unaided and the aided condition, even though the aided condition was verified to add approximately 20 dB of gain (Billings et al 2007). They hypothesised this was due to increased noise introduced by the hearing aid, altering the signal-to-noise ratio across conditions and individuals, and confirmed this when investigating two of their subjects (Billings et al 2007).

Purdy et al (2005) offers a review of aided ALRs in infants and practical suggestions for recording the response whilst Golding et al (2007) recorded ALRs to speech stimuli presented at conversational levels in infants aged between 8 weeks to 3 years 5 months (mean 8.8 months, SD 9.4 months) wearing hearing aids. Golding et al (2007) sought to validate the technique as a tool for evaluating hearing aids by analysing the relationship between the presence or absence of a response to the speech stimuli /ma/, /ga/ and /ta/ with outcomes from the PEACH questionnaire (Ching and Hill 2005). They found a statistically significant, albeit moderate, correlation of r=0.45 (p=0.03) when comparing the number of ALRs present to the infant's PEACH score and concluded that ALRs can be related to everyday auditory function in infants, providing an early objective indication of a child's aided ability to access speech (Golding et al 2007).

Sharma et al (2002) showed ALRs could also be recorded using cochlear implants when they compared the maturation of the P1 response latency to the speech sound /ba/ in congenitally deaf children fitted with cochlear implants compared to their collected normative data (Sharma et al 2002). Subjects were placed in three age of implantation groups: early (57 children implanted by 3.5 years, average age 2.5 years); middle (29 children implanted between ages 3.6-6.5 years, average age 5 years); late (18 children implanted after 7 years). Duration of implant use between subjects was not significantly different. Sharma et al (2002) found that the proportion of latencies falling within the 95% confidence limits of normal differed significantly between the early implanted group (55 children out of the 57) and the late implanted group (1 child out of 18). Similarly there was a significant difference between the early and middle implanted group in which 19 children of the 29 had latencies falling within the normal range (Sharma et al 2002). They concluded that following sound deprivation there is a sensitive period until the age of around 3.5 years during which the human central auditory system remains maximally plastic.

Chang et al (2012) recorded aided and unaided ALRs to the speech sounds /m/, /g/ and /t/ in a group of 18 infants with bilateral sensori-neural hearing loss ranging in age from 2.7 to 13 months after wearing hearing aids set to the NAL NL1 prescription for a mean of 4.6±3.4 months. Detection of responses was determined by Hotelling's T² statistical analysis only. Of the subjects tested, data from 14 (where aided and unaided testing had been completed during the same visit) was used to analyse the effects of amplification. The ALRs were compared to unaided and aided estimated sensation levels (ESL) calculated from the infants' subsequent behavioural thresholds obtained using visual reinforcement audiometry to narrow

band noise at an age of 13 ± 3 months. More ALR waveforms were detected in the aided condition than in the unaided condition. This was particularly the case for /g/ and /t/ but unexpectedly not for /m/, where fewer responses were detected in the aided condition. This correlated to the calculated ESL, which was always larger in the aided condition however more so for /g/ and /t/ than /m/, ranging from 3.2 to 21 dB. The mean ESL was 13 dB for stimuli with the response present and 4 dB for stimuli with the response absent, which was statistically significant (Chang et al 2012).

The study has a number of limitations. In particular the stimuli used to obtain behavioural thresholds (narrowband noise) and subsequently calculate the unaided and aided estimated sensation levels of the sounds used to evoke ALRs (speech segments) were different and cannot necessarily allow comparison of results. Secondly the hearing aid fitting does not appear to have been verified to prescription target in the research centre, only the output measured in a 2cc coupler. This does not evaluate appropriateness of the fit for providing optimal audibility and the frequency responses are not given for review. Although the age range of subjects is wide, which would likely alter the morphology of the ALR response across subjects, it is not necessarily important in this instance where the aim is to only compare detection of the ALR response between speech sounds. Whilst the outcome is useful in recognising that higher ESLs (from introducing amplification) lead to more statistically significant ALR responses and increased detection sensitivity, the ability to detect the response alone does not necessarily indicate that the hearing aids are providing effective amplification since a speech signal that is audible slightly above hearing threshold is clearly not sufficient for appropriate speech and language development (Chang et al 2012).

Similar to the unaided literature, much of the aided auditory late response research presents sounds in the dB SPL scale which again does not control for sensation level of the sound across frequency, which would subsequently alter the ALR response.

The auditory late response has been recorded in adults and children wearing hearing aids and cochlear implants. The effect of amplification is expected to increase amplitude and decrease latency of the peaks in the waveform. There is currently limited comparison between results of the aided auditory late response and behavioural measures of hearing aid benefit. Morphology of the waveform in hearing impaired children compared to normal hearing children is suggested to be an indicator of remaining plasticity in the auditory system.

2.4. Hearing aid processing

The P1-N1-P2 complex is sensitive to stimulus characteristics (Stapells 2002, Martin et al 2007). When sound is processed through a hearing aid, characteristics of the signal are modified (Billings 2007, Dillon 2001). Although the use of the dB SPL scale, which does not control for sensation level across frequency, is adopted in much of the aided auditory late response research, the interaction that the hearing aid has with the sound may explain the large range of variability within and across studies of aided ALR data (Billings et al 2009). It is therefore important to consider these hearing aid modifications and their effect on the evoked auditory late response. Recent research has focussed on better understanding such effects on the potential, in particular due to modifications of signal-to-noise ratio (SNR), rise time (time taken to reach plateau amplitude) and gain (Easwar et al 2012).

2.4.1. Signal-to-noise ratio

Signal-to-noise ratio over absolute signal level of the presenting sound has been documented as the primary determinant of the human obligatory ALR response where previously it was thought to be absolute signal level (Billings et al 2009, Billings et al 2011, Billings et al 2011a). In general, an increase in noise (resulting in reduced SNR) decreases amplitude and increases latency in normal hearing listeners (Billings et al 2009, Billings et al 2011).

Following from the research of Phillips (1990) and Phillips and Kelly (1992), who reported that in the cat the cortical neuron response adapted dependent on the level of background noise, Billings and Tremblay published a series of experiments investigating the effect of SNR on the ALR response (Billings et al 2009, Billings et al 2011, Billings et al 2011a). In 2009 they adopted a passive listening repeated stimulus paradigm to record the P1, N1, P2 and N2 response to a 1 kHz tone at different SNRs using two stimulus levels (Billings et al 2009). The results showed that as the noise level increased P1, N1, P2 and N2 latencies increased significantly and N1, P2 and N2 amplitudes decreased significantly. P1 amplitude was not significantly affected by SNR and Billings et al (2009) found no significant main effect of tone level on latency or amplitude for any of the ALR components.

Prior to this there were only two other studies that published data of human ALRs recorded from signals in noise whilst varying SNR (Whiting et al 1998, Kaplan-Neeman et al 2006). Both studies used speech segments as the test stimuli. Whiting et al (1998) reported findings that are in part consistent with those of Billings et al (2009), showing that, in general, amplitude of

the ALR components N1 (which is of most interest for the current study), N2 and P3 decreased and latency increased as SNR decreased. However they found that latency was the more sensitive measure showing the effects of introducing noise at SNR of +20 dB whereas amplitude did not significantly decrease until SNR degraded to 0 dB (Whiting et al 1998). Similarly Kaplan-Neeman et al (2006) found that N1 latency increased as SNR decreased (except for /da/ at 0 dB SNR) but there was a mixed effect on N1 amplitude across speech sounds. Both Whiting et al (1998) and Kaplan-Neeman et al (2006) adopted an oddball paradigm which by design improves elicitation of the discriminatory auditory late response namely peaks N2, P3 and beyond (Whiting et al 1998, Kaplan-Neeman et al 2006, Billings et al 2011). Although it is possible to record N1 using this paradigm Billings et al (2011) reported differences between responses evoked by the two different techniques and also for the two different stimuli types of tones and speech segments. By doing so they highlighted the difficulty of comparing ALRs evoked by different methodologies. They found significant increases in N1 amplitude for the oddball paradigm relative to the passive paradigm with the largest effects observed for tone-evoked responses rather than speech-evoked responses (Billings et al 2011) perhaps where speech sounds may already capture greater attention. Their results also showed the general trend that introducing noise to the signal (with -3 dB SNR) from the quiet condition decreased the amplitude of N1 and P2 and increased their latency for both tonal stimuli and speech stimuli (Billings et al 2011). Repeated measures analysis of variance completed on P1, N1 and P2 indicated main effects of signal type for all latency measures with speech evoked peaks generally occurring later for all components than toneevoked peaks. Although the difference in amplitude was slightly smaller for speech than tones when comparing the response in quiet to the response in continuous noise with -3 dB SNR, there was no significant main effect of signal type on amplitude (Billings et al 2011).

Billings et al (2011a) later replicated these findings using a hearing aid allowing better generalisation to the clinical setting. Using the same 1 kHz tone stimulus parameters as their previous studies they compared unaided and aided auditory late responses. By design, four of the aided in-the-canal output levels matched four of the unaided in-the-canal levels. The hearing aid was a digitally programmable analogue with omnidirectional microphone, with all other features deactivated and acting linearly in the tested conditions. In addition, they measured the in-the-canal SNR levels for each condition to determine its contribution to resulting ALR recordings. Within unaided and aided conditions the results remained consistent with previous outcomes in that increasing sound level resulted in increased amplitude and decreased latencies of the ALR waveform peaks (Billings et al 2011a). However ALR

morphology differed across the conditions. Aided ALR amplitudes were smaller and latencies more delayed than the unaided conditions. When SNR was instead verified, aided SNR was found to be considerably smaller than the equivalent unaided value (Billings et al 2011a). There is a similar effect of SNR seen at the subcortical level (Burkard and Hecox 1983, Russo et al 2004, Song et al 2011) and it may be that this is carried forward to the cortex (Billings et al 2009). The addition of noise interferes with the temporal precision of neural firing, in turn reducing neural synchrony resulting in decreased peak amplitudes and increased peak latencies (Kaplan-Neeman et al 2006, Russo et al 2004). The reduction in SNR in the aided condition is most likely due to the hearing aid's introduction of circuit noise (where the microphone is thought to be the dominant source of internal noise) and, to a lesser extent, amplification of ambient noise (Agnew 1997, Thompson et al 2002, Billings et al 2011a).

Billings et al (2011) noted that at least for amplitude, effect of amplification on SNR was greatest on the P2 wave and less on P1 and N1. This, along with no significant effect of the computer generated SNRs on P1 amplitude found in their earlier study (Billings et al 2009), implies that the P1 response, which is the predominant wave recorded in young infants (Purdy et al 2005, Wunderlich and Cone-Wesson 2006), may be unaffected by noise introduced to the stimulus due to amplification. However, P1 is known to be smaller and less reliable to record in adults (Stapells 2002, Martin et al 2007) and for this reason adult studies may not reveal the true impact of amplification on this feature of the infant auditory late response.

Although Billings et al (2007, 2011, 2011a) used a long stimulus with a rise/fall time of 7.5 ms and duration of 757 ms across their series of experiments to closely approximate speech syllables and words, it is atypical of stimuli used in the literature to record ALRs (Stapells 2002). Furthermore they used a low stimulus level of 40 dB SPL in the aided condition (Billings et al 2011a). At this level there is likely a greater interaction of the sound with the noise floor which could impact on the aided results more than the unaided. In addition, such a low level may not activate the hearing aid compression circuitry, which would again vary the noise floor, and is not representative of normal every day listening. The level is also atypical for evaluating amplification (the purpose for which the tool is being considered) where suprathreshold levels representing conversational levels of speech have been used (Golding et al 2007).

Hearing aids have been shown to introduce noise to the stimulus reducing the SNR which in turn has resulted in decreased amplitude and increased latency of the ALR waveform.

Although these studies importantly indicate the contribution of SNR on the auditory late

response, they may mask other effects of stimulus alterations caused by hearing aid processing (Easwar et al 2012). The effect of SNR has also only been investigated in normal hearing listeners and will likely vary with hearing impaired listeners as the effect of SNR is largely dependent on the relative level of hearing aid internal noise and hearing thresholds.

2.4.2. Rise time and gain

Previous literature has indicated that the first 30 ms of a stimulus determines the morphology of the ALR response (Onishi and Davis 1968, Marynewich et al 2010, Marynewich et al 2012, Jenstad et al 2012, Billings et al 2011). Onishi and Davis (1968) reported no significant change in ALR response amplitude when the combination of rise time and stimulus plateau duration was greater than approximately 30 ms. So understanding how hearing aid processing might affect this portion of the signal is important in interpreting the aided response (Easwar et al 2012, Billings et al 2011, Billings et al 2011a).

The few studies that have investigated this part of the signal, specifically in relation to rise time (the time taken to reach plateau amplitude) and the stimulus gain reached, are conflicting. Two studies conclude that the short duration sounds that are required to evoke ALRs do not allow enough time for hearing aid circuitry to react (Marynewich et al 2010, Jenstad et al 2012). These conclusions may be misleading however due to limitations identified in these studies.

Marynewich et al (2010, 2012) and Jenstad et al (2012) found differences in ALRs recorded from digital hearing aids compared to an analogue hearing aid and noted the digital hearing aids altered the onset envelope and the rise time (Marynewich et al 2010, Marynewich et al 2012, Jenstad et al 2012). Their analysis of a digital hearing aid processed 1 kHz tone showed that the aided stimulus amplitude reached its 'maximum' in a period after the first 30 ms from sound onset and that this 'maximum' remained lower for the short duration sound used to evoke the ALR than the gain programmed in the hearing aid (Marynewich et al 2010, Marynewich et al 2012, Jenstad et al 2012). They argued therefore that the short duration sounds required to evoke an ALR are not valid when using hearing aids. They did not however control for SNR. Furthermore, in contrast to the analysis of Marynewich et al (2010, 2012) and Jenstad et al (2012), hearing aid processing would be expected to reach maximum gain within the first 30 ms from sound onset, related to the hearing aids attack time (Dillon 2001). Most digital hearing aids have short attack times of less than 10 ms (Dillon 2001) and would

therefore reach maximum gain around that approximate time frame. It may be that the digital hearing aids used by Marynewich et al (2010, 2012) and Jenstad et al (2012) had atypical attack times, however these are not documented. In addition, a brief overshoot at the onset of the stimulus can occur when there are rapid changes in sound as the hearing aid stabilises to the required gain causing a slight increase in sound level (Dillon 2001) which in turn would be expected to increase the resulting aided ALR amplitude.

Easwar et al (2012) examined the exclusive effects of rise time changes caused by hearing aid processing on the ALR elicited by 1 kHz tone bursts by carefully controlling for the additional hearing aid effects of SNR, gain and delay between the aided and unaided conditions. They found no significant effect on the recorded ALR from rise time changes in the tone burst caused by hearing aid processing for a normal hearing adult group (Easwar et al 2012). Although the aided stimulus reached plateau gain earlier than the unaided stimulus and included an overshoot, the maximum difference in stimulus level between conditions was less than 2 dB in the first 30 ms period resulting in minimal difference between the evoked ALRs (Easwar et al 2012). This facilitates understanding of hearing aid processing effects on the auditory late response but the very controlled experiment does not mimic the clinical situation for using hearing aids where, for example, delay introduced by the hearing aid would not be removed.

The ALR has been found to be characterised by the first 30 ms of a sound from onset. There remains doubt in the literature as to whether digital hearing aid processing adversely alters a stimulus in this time period which could subsequently limit the use of the ALR with hearing aids.

2.4.3. Hearing aid processing strategy

Alongside stimulus modifications caused by hearing aid processing already discussed, digital hearing aids also apply frequency shaping and impose a delay on the signal which, in turn, might alter the resulting auditory late response (Dillon 2001, Kates 2005, Kates 2008, Schaub 2008). How the waveform might alter is less clearly understood and in particular there is limited knowledge of the effect non linear frequency compression (NLFC) processing may have on the ALR.

It is important to recognise distinctions between different types of hearing aid processing strategy since these will alter the stimulus differently. Compression is an example of this where amount of gain will vary based on the input stimulus level whereas for a linear circuit it will not (Dillon 2001). Whilst a wide dynamic range compression digital processing strategy is popularly prescribed in clinical practice both for adults and children (Dillon 2001, Jones and Launer 2010), developments in technology have now also introduced NLFC features in to practice (Scollie et al 2007). In the case of NLFC, the incoming hearing aid signal is split into two channels. The high frequency channel is compressed into a narrower bandwidth resulting in sound being lowered in frequency within that channel (Scollie et al 2007, Glista et al 2012). There is currently limited knowledge of whether aided ALRs might change in response to NLFC activation (Glista et al 2012).

Only one study published in the literature to date investigates whether ALRs elicited by high frequency tone burst stimuli (2 and 4 kHz) reflect the change in high frequency audibility due to use of NLFC hearing aid technology (Glista et al 2012). ALRs were recorded in a small group of teenagers with sloping high frequency hearing loss, wearing hearing aids. They were recorded in two conditions: NLFC on; NLFC off. In most cases, the NLFC active improved detection of ALR responses of the 4 kHz tone burst where audibility improved. This suggests the ALR may be sensitive to the effects of NLFC signal processing where it may improve audibility (Glista et al 2012). However stimulus audibility was not controlled in this study.

A stimulus may be modified by digital hearing aid processing strategies. Further research is therefore required to investigate any effects different strategies may have on the auditory late response when audibility is controlled and in particular when NLFC technology is activated using speech based stimuli. This is particularly important to understand in an infant group, where this tool is of interest to clinical practice.

2.5. Test parameters/conditions

It is well known that characteristics of the P1, N1 and P2 response are determined by stimulus variables (Stapells 2002, Martin et al 2007). Their amplitude, latency and scalp distribution can be manipulated by changes in stimulus intensity, SNR, rise time, duration, inter-stimulus interval (ISI), stimulus complexity and frequency (Stapells 2002, Martin et al 2007). The effects of these variables have been thoroughly investigated in the mature auditory system and

continue to be examined in the developing system (Wunderlich and Cone-Wesson 2006). These effects are outlined below.

2.5.1. Stimulus level and signal-to-noise ratio

Stimulus level and SNR are critical factors in the resulting ALR waveform morphology (Adler and Adler 1989, Picton et al 1977, Stapells 2002, Martin et al 2007). SNR however has been shown to be the primary determinant of the response over that of stimulus level (Billings et al 2009, Billings et al 2011).

When stimulus level is decreased, ALR amplitude decreases and latency increases (Adler and Adler 1989, Picton et al 1977, Wunderlich and Cone-Wesson 2006, Martin et al 2007).

Amplitude growth has been found to asymptote at moderate to high levels (above 50-60 dB HL) and at very high levels a decline in response amplitude has been noted suggesting saturation of the response (Wunderlich and Cone-Wesson 2006). However this phenomenon was observed for short ISIs in normal hearing listeners (Picton et al 1970, Adler and Adler 1989) and not by Billings et al (2007) when using longer ISIs of 1910 ms.

Where noise is introduced, if SNR is decreased, amplitude decreases and latency increases (as earlier discussed more fully in section 2.4.1) (Billings et al 2011, Billings et al 2011a, Billings et al 2009, Kaplan-Neeman et al 2006, Whiting et al 1998).

Amplitudes of ALRs have been found to be larger in infants than those recorded in adults (Purdy et al 2005, Wunderlich and Cone-Wesson 2006) however this was not the case for the newborn group (<7days) tested by Wunderlich et al (2006). Wunderlich et al (2006) did however find that larger amplitudes were evoked by words than from tones.

2.5.2. Stimulus duration

The interaction between stimulus duration and response magnitude is not wholly predictable. Very short stimulus durations (less than 100 ms) are regarded as optimal for tone-evoked ALRs (Stapells 2002) and overall the literature suggests that short duration stimuli of 100 ms or less are also optimal in evoking large amplitude, shorter latency ALRs for speech sounds (Stapells 2002).

In adults, Onishi and Davis (1968) reported that response amplitude did not change significantly once the stimulus plateau duration reached 30 ms. In contrast, Skinner and Jones (1968) found larger amplitudes for plateau durations as wide as 25-50 ms. Eddins and Peterson (1999) and Alain et al (1997) found that amplitude increased and latency decreased as duration increased between 0 and 128 ms. As overall stimulus duration decreased, Onishi and Davis (1968) and Skinner and Jones (1968) reported an increase in latency. Agung et al (2006) found for a set of speech sounds, that shorter stimulus durations (100 ms) evoked significantly larger amplitudes for N1 and P2 responses with no significant affect on P1 amplitude than longer stimulus durations (500 ms). P1, N1 and P2 latencies were all significantly earlier for 100 ms durations than 500 ms durations. Beukes et al (2009) using the same stimulus durations as Agung et al (2006) further confirm this effect for N1 amplitude for tones (500 Hz and 4 kHz) and speech sounds (/m/ and /sh/). Whilst the significant difference disappeared for the tones when ISI increased to 3 seconds, it persisted for the speech sounds. Only latency data for /sh/ was affected by duration, with later latencies for longer durations (500 ms). Overall this research suggests that short duration stimuli of 100 ms or less are optimal in evoking large amplitude ALRs for speech sounds. Such short stimuli are also recommended for tones (Stapells 2002).

In infants, Golding et al (2006) studied the influence of stimulus duration (less than 150 ms) on the amplitude and latency of ALR components evoked by speech sounds and found no significant effect on latency or amplitude with changes in duration.

2.5.3. Rise time

Stimulus rise time is often documented as a component of the stimulus duration time. Change in rise time can also affect peak amplitude and latency of the ALR response (Cody and Klass 1968, Onishi and Davis 1968, Skinner and Jones 1968, Prasher 1980). The general consensus among studies is that shorter rise times lead to larger amplitudes and shorter latencies. Longer rise time increases jitter in neuron firing which results in reduced neural synchrony and leads to broader peaks with lower amplitude (Onishi and Davis 1968). As rise time is increased beyond 30 ms, the effective intensity at the onset of the stimulus is reduced (Onishi and Davis 1968).

2.5.4. Inter-stimulus interval

Many studies in adults have reported that as ISI increases, N1 and P2 response amplitude increases but P1 amplitude and P1, N1 and P2 latencies do not differ significantly (Nelson and Lasserman 1968, Beukes et al 2009). This finding has been noted for both tone-burst and speech stimuli (Picton et al 1977, Picton 1990, Stapells 2002, Tremblay et al 2004).

Nelson and Lasserman (1968) reported dramatic increases in amplitude as ISI increased from 500 ms to 2 or 3 seconds, with more gradual increases between 3 and 10 seconds. Beukes et al (2009) also confirm larger amplitude responses for the longer ISI of 3 seconds compared to 1125 ms for both tones and complex speech stimuli and that preliminary findings of a further study with an ISI of 10 seconds show the same. This appears consistent with Picton (1990) who noted that the neural refractory period of the P1, N1, P2, N2 response is very slow and lasts more than 10 seconds.

The longer the ISI, however, the longer the test time. The findings documented above suggest that although an ISI of up to 10 seconds may produce the largest response amplitudes, an ISI of 3 seconds produce good amplitude responses (of the order of 10 μ V for N1 and P2 amplitude (Beukes et al 2009) and incorporate the time within which a dramatic increase in amplitude has been documented (Nelson and Lasserman 1968).

In their infant group Golding et al (2006) found that an increased number of response components evoked by speech sounds were reliably observed as the ISI was increased from 750 ms to 1500 ms. Furthermore they observed a significant amplitude increase in P1 of approximately 7 μ V when ISI was increased from 750 ms to 1500 ms for speech sound /t/ but not /m/ (Golding et al 2006).

2.5.5. Response repeats per average

The reviewed literature reports a wide range of number of repeats collected per ALR average, from 50 to 1200 (Ostroff et al 1998, Tremblay et al 2003, Agung et al 2006, Garanis and Cone-Wesson 2007, Sussman et al 2008, Billings et al 2009, Beukes et al 2009) however the majority of studies adopt 100 or more repeats per average and some of the studies split the total number of averages in to two blocks, for example 400 averages as two blocks of 200 averages (Billings et al 2009). The effect that habituation may have on the response (Prosser et al 1981, Schafer et al 1981), the interaction with response SNR determining quality of the waveform

and test time must be considered when deciding how many repeats to collect per average. A comparison of SNR with varying number of repeats is not documented in the literature.

Some authors have considered the effect of habituation on the ALR response (Prosser et al 1981, Rosburg et al 2004). Habituation is defined as a decline in the amplitude of the response to repeated stimuli delivered at constant intensity and repetition rate (Prosser et al 1981). Over a long period the decline has been shown to be exponential (Prosser et al 1981). Prosser et al (1981) and Rosburg et al (2004) analysed responses from trains of stimuli with shorter ISIs than the inter-train intervals (ITI). They both found that response amplitude decreased by 50% and 40% respectively between the first and second stimuli in the train with no further decrease in amplitude after the second stimulus (Prosser et al 1981, Rosburg et al 2004). However both studies employed short ISIs of 1000 ms and 500 ms with longer ITIs of 5000 ms and 8000 ms respectively. Since a larger response amplitude was evoked from the first stimulus of the train (following a longer gap of silence relevant to the ITI) compared to the second stimulus of the train (following a shorter gap of silence relevant to the ISI), this appears to show the effect not of habituation but of neural refraction with amplitudes known to be reduced by shorter ISIs (Nelson and Lasserman 1968, Prosser et al 1981, Rosburg et al 2004, Beukes et al 2009). One study however by Schafer et al (1981) which limited the effect of ISI by employing a long period of 10 seconds, found that response amplitudes for N1 and later peaks were attenuated by an average of 30% and latencies were significantly shorter when timing of stimuli was predictable. Lightfoot (2010) has therefore advocated 30% randomisation of the stimulus to minimise the effects of habituation but this has not been widely adopted in the literature.

2.5.6. Objective measures of ALR response detection

Incorporating an objective measure of determining ALR response presence is advocated to minimise variation of subjective tester interpretation. Relatively few studies have adopted a statistical measure. To date, only the studies published by researchers collaborating with the National Acoustics Laboratory routinely incorporate an objective measure of response presence, implementing Hotelling's T² (Golding et al 2009, Carter et al 2010, Munro et al 2011).

Hotelling's T² is suited to applications where there are multiple dependent variables that are likely to be correlated and is based on multivariate analysis of variance to test the hypothesis

that the mean of the data sets of interest (in this case each epoch of EEG) are identical to an independent specified value (Flury and Riedwyl 1988, Golding et al 2009). The statistic determines the probability that any linear combination of the data divided into bins, has a mean value significantly different from zero (Golding et al 2009). However the suitability of using this statistic for an objective measure of ALR response detection has been questioned in the wider scientific community since it assumes independence between EEG epochs (Don 2007). Instead Elberling and Don (1984) suggest the use of F_{sp} statistical analysis which uses an estimate of SNR of each EEG epoch and subsequently analyses the likelihood of response detection. Whilst this has not been used for the ALR response per se, it has successfully been used to analyse an alternate electrophysiological acoustical response, the ABR (Elberling and Don 1984, 1987, Don et al 1984).

2.5.7. Electrode configuration

The Cz to mastoid electrode configuration is often cited in the literature to record maximal ALR response (Tremblay et al 2003, Tremblay et al 2006, Agung et al 2006). Two channel recording is advocated to remove eye blink artefact (Stapells 2002).

When testing using a loudspeaker placed at 0° azimuth, maximal response for N1-P2 amplitude in adults was documented for midline central scalp locations such as Cz (Tremblay et al 2003, Tremblay et al 2006, Agung et al 2006). Similar results have been found when measured at Cz or for global field measures (Tremblay et al 2006, Billings et al 2007). Furthermore Cz receives less noise from muscle artefact than other electrode sites (Kerr et al 2008). Various options for the site of reference electrode have been cited with the use of the nose (Ostroff et al 1998, Tremblay et al 2003, Tremblay et al 2006, Billings et al 2007, Garanis and Cone-Wesson 2007, Billings et al 2009) and mastoid (Rosburg et al 2004, Golding et al 2006, Munro et al 2011) being most popular in adults.

In a child group, Wunderlich et al (2006) used an array of 4 recording electrodes positioned at Fz, Cz, C3 and C4 with reference to a mastoid electrode and ground on the opposite mastoid. They did not find any significant difference in amplitude or latency across electrode sites for the ALR waveform peaks in their newborn (<7 days) and up to 1 year old subjects. This finding was similar in their toddler group (aged from 13 months to 41 months) for ALRs evoked to words.

Two channel recording is recommended in order to monitor and remove artefacts due to eye blink since this can otherwise artificially enhance the response (Stapells 2002). Whilst this is relatively straightforward to carry out in an adult, it is not necessarily as easy to achieve for infants and children. Although Wunderlich et al (2006) used an electrode to record and correct for vertical eye movements in older infants and children, they did not use this set-up in infants under 2 years. This is similar to other studies in young infants (e.g. Golding et al 2007).

2.5.8. Artefact rejection

Artefact rejection ranges from $\pm 70~\mu V$ to $\pm 150~\mu V$ in the literature when recording ALRs in adults and is most often cited as 70-75 μV (Beukes et al 2009, Billings et al 2009, Garanis and Cone-Wesson 2007, Agung et al 2006, Golding et al 2006, Tremblay et al 2004, Ostroff et al 1998). This range is often increased for infants, where around $\pm 100~\mu V$ is generally used (Golding et al 2006, Golding et al 2007, Chang et al 2012).

2.6. Conclusions: literature review

- Since the introduction of newborn hearing screening, infants are identified early with deafness and fitted with hearing aids by around 3 months of age.
- There is currently no clinical consensus for evaluating the hearing aid fitting in this young age group.
- The potential use of objective electrophysiological measures have been recognised for the purpose of assessing aided detection levels, in particular the obligatory auditory late response.
- ALRs have been recorded in adults and infants, with and without hearing aids to tonal and speech sounds.
- The ALR waveform is altered by stimulus and recording parameters and these are therefore important to consider when drawing conclusions across studies.
- There is wide variation in ALR results within and across studies publishing aided data.
 Modifications to the stimulus introduced by hearing aid processing can affect the evoked auditory late response.
- There is currently limited knowledge of the effect that different digital hearing aid processing strategies, including non linear frequency compression, may have on the ALR. This technology is now being used routinely in clinical practice.

2.7. Research questions

The recording of auditory late responses from short duration sounds has been proposed as a means of assessing access to speech sounds of different frequencies in very young infants following hearing aid fitting. There remains uncertainty in the literature of the effects different digital hearing aid processing may have on the response and whether the short duration sounds required to evoke the ALR may be used with hearing aids. A number of questions therefore need to be explored before this approach can be routinely implemented in clinical practice:

- 1) How repeatable is the ALR response to short duration speech sounds (/m/, /g/, /t/)?
- 2) What is the effect of hearing aid processing on the stimulus waveform, spectral content and evoked response waveforms?
- 3) In particular, does the introduction of non linear frequency compression change the ALR response compared to it being inactive?

The following research explores the effect of different digital hearing aid processing on the short duration speech sounds; investigates how different digital hearing aid strategies and different speech stimuli influence the auditory late response in normal hearing adults; considers the feasibility of using the ALR as a clinical tool to evaluate hearing aid access in infants identified early with permanent hearing loss and wearing hearing aids. Controlling for stimulus effects such as signal-to-noise ratio, audibility and stimulus duration are important if any effects due to hearing aid processing are to be identified, since the ALR is sensitive to stimulus characteristics.

Chapter 3. Analysis of the effect of digital hearing aid processing on test stimuli using KEMAR

3.1. Aim: hearing aid processing analysis

Hearing aid processing can interact with a stimulus, altering its acoustics by generating components in the output signal that are not present in the input signal (Preves 1990, Dillon et al 2003, Kates 2008). Distortion, introduced through hearing aid processing, and internal hearing aid noise are two such additive components that can change the output signal from the input signal (Kates 1992, Kates 2008, Tan and Moore 2008, Lewis et al 2010). Where the ALR waveform is sensitive to stimulus characteristics (Stapells 2002, Martin et al 2007), in particular SNR (Billings et al 2009, Billings et al 2011a), it is important to consider the hearing aid modifications. The aim of this study therefore was to estimate the level of noise and distortion in the aided and unaided test signals in order to control for the variable of SNR in the adult normal hearing study and better understand the effects, if any, of non-linearities on the comparison between aided and unaided auditory late responses.

3.2. Test set-up: hearing aid processing analysis

Phonak Naida V SP digital hearing aids were programmed using manufacturer software in three conditions (to be used in the adult normal hearing study):

- 1). Linear setting with 20 dB of gain, all digital features turned off, omnidirectional microphone, volume control disabled. Denoted 'linear'.
- 2). Wide dynamic range compression setting (compression ratio 2:1; threshold kneepoint 30 dB SPL) with 20 dB of gain at 60 dB SPL, omnidirectional microphone, volume control disabled, digital feedback suppression disabled, frequency compression disabled. Denoted 'WDRC'.
- 3). WDRC setting (outlined in 2) with non-linear frequency compression activated (compression ratio 3:1; threshold kneepoint 3.8 kHz), omnidirectional microphone, volume control disabled, digital feedback suppression disabled. Denoted 'NLFC'.

The gain of the hearing aids was verified in a 2cc-coupler using Audioscan Verifit VF1 hearing instrument test box. A comparison aid (Siemens Prisma Pro – denoted 'siemens') was also programmed with 20 dB of linear gain with all other digital features switched off.

A recognised limitation of using three Naida V SP hearing aids to program each condition is the possibility that a level of distortion is created not linked directly to the experimental condition itself but due to any fault with the hearing aid. This limitation was minimised by using new hearing aids, carrying out clinical listening checks of the hearing aids and clinical test box measures of performance to manufacturer specifications. None of these checks showed any differences between the functioning of the hearing aids.

The test sounds /m/, /g/ and /t/ were cropped from the male spoken MRC Institute of Hearing Research vowel-consonant-vowel test (Faulkner 1998) using matlab programming (Appendix 4), with two stimulus durations of 30 ms (cropped at zero crossing) and 100 ms (with 20 ms rise/fall times). They were presented via a loudspeaker and 10 repeats recorded using KEMAR (Mueller 2006) in the unaided condition, three phonak aided conditions (to be used in the adult normal hearing study) and one siemens comparison aided condition. The same recordings were made for running speech and white noise stimuli. The equipment set-up used to make the KEMAR recordings is outlined in Figure 3.2.1.

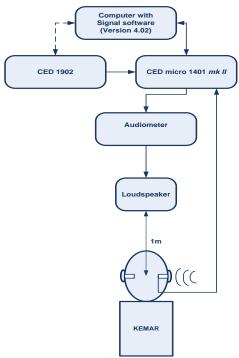


Figure 3.2.1: Equipment set-up for recording the test sounds using KEMAR in each hearing aid condition.

KEMAR was used as it incorporates a Zwislocki coupler which closely resembles the acoustic performance of the adult real ear (Muellar 2006, Lewis et al 2010). The recordings were collected on two occasions, one month apart, first at the stimulus levels designed for the adult

normal hearing study (65 dB nHL unaided – denoted 'quiet') and second at louder stimulus levels (85 dB nHL unaided – denoted 'loud') following biological calibration to find 0 dB nHL, described in Appendix section A5.4. In the aided conditions, the stimulus level was reduced by 20 dB accounting for the hearing aid gain, to maintain a consistent sound level to the unaided condition. Further details of the KEMAR recording set-up and stimulus levels are given in Appendix 1.

3.3. Analysis of distortion: magnitude squared coherence

A measure of distortion can be estimated based on coherence (Kates 1992, Kates 2000). Coherence compares the output of a system with the input of a system in the frequency domain to determine the system behaviour (Dyrlund 1989, Preves 1990, Kates 1992, Kates 2000). This allows calculation of a signal-to-distortion ratio (SDR) which, in the case of hearing aids, provides a collective estimate of noise and non-linear distortion (Kates 1992, Kates 2000).

Magnitude squared coherence (MSC) is calculated from cross-spectral density and estimated using fast fourier transforms (FFT) to provide a value of SDR. The data sequences x(n) (the input to a system) and y(n) (the output from the system) are divided into a number M of overlapping windowed data segments. The cross spectrum and autospectrum are calculated for each segment using the FFT and are then averaged across segments, and the MSC is computed from the averages (Kates 1992, Kates 2000). For M data segments, the estimated MSC is given by the equation:

$$|\hat{\gamma}(\omega)|^2 = \frac{|\sum_{m=0}^{M-1} X_m(\omega) Y_m^{\bullet}(\omega)|^2}{\sum_{m=0}^{M-1} |X_m(\omega)|^2 \sum_{m=0}^{M-1} |Y_m(\omega)|^2}$$

where the asterisk denotes the complex conjugate, and $X_m(\omega)$ and $Y_m(\omega)$ are the spectra of the mth windowed data segments of x(n) and y(n), respectively, computed using the FFT algorithm (Kates 1992, Kates 2000).

To reduce bias in the estimation, any delay between the input and output (which can occur in the case of hearing aids) must be removed by aligning the two sequences (Kates 1992, Kates 2000). Figure 3.3.1 shows a block diagram of the procedure to measure the MSC and estimate SDR.

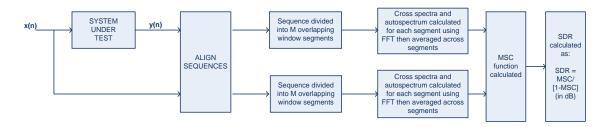


Figure 3.3.1: Block diagram of estimating SDR converted to dB using MSC.

Research has shown that estimating the SDR from magnitude squared coherence is a relatively good predictor of subjective quality perception scores in normal hearing people (Arehart et al 2007, Kates and Arehart 2010). It does not however model the physiological properties of the normal or impaired auditory system (Tan and Moore 2008).

Estimation of MSC requires the use of broadband stimuli for automatic gain control (AGC) hearing aids (like those used in this study) since the system gain changes with stimulus amplitude and frequency (Preves 1990, Kates 1992, Kates 2000, Tan and Moore 2008). The analysis was therefore performed with white noise and running speech stimuli. It was anticipated that the results from the running speech signal could be extrapolated for the short duration speech segment test signals since it includes the natural fluctuation of speech in the signal.

Matlab was used to perform MSC analysis and subsequently estimate the SDR (Appendix 2). The input signal was the unaided signal and the output signal it was compared to was the aided signal. Where 10 repeats of each stimuli were recorded via KEMAR, the MSC analysis was carried out using one repeat of the quiet stimulus KEMAR recordings, the loud stimulus recordings, and comparing the quiet stimulus unaided recordings with the loud stimulus aided recordings. One repeat of each stimulus was used to most accurately represent listening conditions through a hearing aid on a real subject and the results are given in Table 3.3.1. An MSC value of 1 indicates a perfect reproduction of the input signal and a value of 0 that of total degradation of the input signal (Preves 1990, Kates 1992, Kates 2000). A converted SDR value of 20 dB or greater is considered good.

HA condition	Stimulus	Quiet unaided-aided Loud unaided-aided		ded-aided	Quiet unaided-loud aided		
		stimulus recordings		stimulus recordings		stimulus recordings	
		Ave MSC	SDR	Ave MSC	SDR	Ave MSC	SDR
Phonak linear	Noise	0.5	0.1 dB	0.97	30.2 dB	0.96	29.0 dB
	Speech	0.51	0.2 dB	0.96	27.5 dB	0.96	27.8 dB
Phonak	Noise	0.58	2.9 dB	0.98	34.1 dB	0.97	32.3 dB
WDRC	Speech	0.68	6.5 dB	0.95	25.9 dB	0.94	25.5 dB
Phonak NLFC	Noise	0.44	-1.9 dB	0.71	7.6 dB	0.69	7.3 dB
	Speech	0.51	0.3 dB	0.7	7.4 dB	0.69	7.3 dB
Siemens	Noise	0.59	3.3 dB	0.79	11.4 dB	0.78	11.3 dB
linear	Speech	0.54	1.4 dB	0.77	10.7 dB	0.77	10.7 dB

Table 3.3.1: Estimation of magnitude squared coherence and signal-to-distortion ratio (in dB).

The results show poor MSC and SDR values in the quiet stimulus recordings indicating degradation of the aided output signal compared to the input signal. This was confirmed on subjective listening checks, where the aided recordings sounded very noisy. The increased level of noise compared to the stimulus level would be expected to impact ALR results from normal hearing adults by reducing the amplitude and increasing the latency of the response. The MSC and SDR values improved in the linear and WDRC hearing aid conditions for the loud stimulus recordings and when quiet stimulus levels for unaided input and loud stimulus levels for aided output were analysed. As might be expected, the introduction of nonlinear frequency compression which is designed to change the output frequency spectrum compared to the input caused deterioration in the values.

The results suggest that use of the quiet stimulus aided recordings should be ruled out from the adult normal hearing study due to degradation of the output signal compared to the input signal introduced by the hearing aid processing resulting in poor SDR values, which would subsequently be expected to impact on ALR recordings. The quiet aided stimuli were recorded at 45 dB nHL (equivalent to the unaided level of 65 dB nHL with 20 dB of hearing aid gain). At this level there is likely a greater interaction of the sound with the noise floor which may account for the poor SDR values.

3.4. Analysis of signal-to-noise ratio: F_{sp}

Variance is a measure of how spread out (or variable) a distribution is (Kates 2008, Lewis et al 2010) and is computed as the averaged squared standard deviation of each number from its mean (Kates 2008, Lewis et al 2010) using discrete fourier transforms to analyse the

waveforms (Lewis et al 2010). Variance in hearing aid output at discrete points within one repeat (an estimate of signal level) can be compared to variance at one point across multiple repeats (an estimate of noise), depicted in Figure 3.4.1, to provide an indication of SNR.

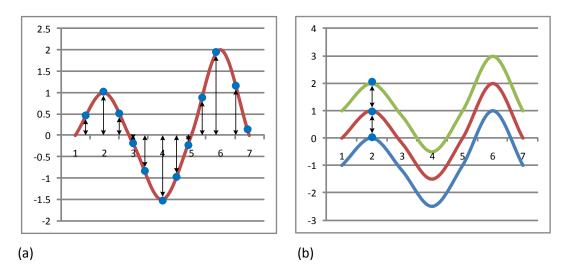


Figure 3.4.1: Diagram of estimating variance of (a) the signal and (b) the noise.

An F_{sp} measure of SNR (Elberling and Don 1984) provides a number of advantages. It can estimate the ratio when gain varies, for example from compression algorithms, and does not require alignment to the input signal since it is solely based on the output signal from the hearing aid (Lewis et al 2010). It can also in theory be applied to any signal including short duration sounds, such as the speech sounds used in this study. The method is however sensitive to phase variations and would over estimate the noise value if the hearing aid changes its response over time (Lewis et al 2010). It does not either provide an indication of non-linear distortion introduced by the hearing aid since this would not necessarily impact on the reproducibility of the output across repeated presentations of the same stimulus (Lewis et al 2010). Furthermore the method has not been investigated for its predictiveness to human perception of SNR (Lewis et al 2010).

Matlab was used to perform F_{sp} analysis and subsequently estimate SNR of the output signal (Appendix 3) using the KEMAR recordings across repeats within a sound for the quiet stimulus level recordings and the loud stimulus level recordings. The 10 repeats used for this study however is smaller than the 32 used in a study by Lewis et al (2010) measuring hearing aid internal noise as the variance of the output measures. It may therefore represent a less accurate measure of variance and be a limitation of the analysis.

Since SNR has been shown to be a primary determinant of waveform morphology of the ALR waveform (Billings et al 2009, Kaplan-Neeman et al 2006, Whiting et al 1998) it is important to maintain equivalent SNR as best as possible in the adult normal hearing study between the unaided condition compared to the aided conditions. For this reason the difference was calculated between unaided SNR and aided SNR for the different hearing aid conditions obtained from the quiet stimulus recordings, the loud stimulus recordings and across the quiet unaided recordings to the loud aided recordings. These values are given in Table 3.4.1 where a positive value indicates aided SNR is better than unaided SNR and values in black show differences within 10 dB, orange, differences within 20 dB and red, differences greater than 20 dB.

HA condition	Stimulus	Difference in SNR unaided to aided			
			Loud stimulus	Quiet unaided / loud	
		recordings	recordings	aided stimulus recordings	
Phonak linear	Noise	-34.13 dB	-24.81 dB	-13.82 dB	
	Speech	-32.70 dB	-15.78 dB	-11.8 dB	
	/m/30 ms	-16.93 dB	1.43 dB	5.98 dB	
	/g/30 ms	-9.47 dB	4.55 dB	6.33 dB	
	/t/30 ms	0.9 dB*	13.22 dB	17.44 dB*	
	/m/100 ms	-7.13 dB	-6.99 dB	10.69 dB	
	/g/100 ms	-7.39 dB*	4.87 dB	18.4 dB*	
	/t/100 ms	-2.86 dB	-2.7 dB	14.70 dB	
Phonak WDRC	Noise	-28.88 dB	-21.37 dB	-10.38 dB	
	Speech	-18.90 dB	-17.72 dB	-13.74 dB	
	/m/30 ms	-13.5 dB	2.46 dB	7.01 dB	
	/g/30 ms	-14.57 dB	11.03 dB	12.81 dB	
	/t/30 ms	-5.24 dB*	17.09 dB	21.31 dB*	
	/m/100 ms	0.41 dB	-5.2 dB	13.1 dB	
	/g/100 ms	-4.43 dB*	2.17 dB	15.70 dB*	
	/t/100 ms	-9.34 dB	-6.36 dB	11.04 dB	
Phonak NLFC	Noise	-27.28 dB	-39.02 dB	-28.03 dB	
	Speech	-23.53 dB	-19.02 dB	-15.04 dB	
	/m/30 ms	-13.86 dB	7.49 dB	12.04 dB	
	/g/30 ms	-7.9 dB	12.01 dB	13.79 dB	
	/t/30 ms	4.16 dB*	18.58 dB	22.8 dB*	
	/m/100 ms	-4.07 dB	17.98 dB	-0.3 dB	
	/g/100 ms	-1.58 dB*	6.31 dB	19.84 dB*	
	/t/100 ms	-8.3 dB	2.16 dB	19.56 dB	
Siemens linear	Noise	-26.64 dB	-27.44 dB	-16.45 dB	
	Speech	-24.01 dB	-3.8 dB	0.18 dB	
	/m/30 ms	NR	2.28 dB	6.83 dB	
	/g/30 ms	NR	4.92 dB	6.7 dB	
	/t/30 ms	NR	1.51 dB	5.73 dB*	
	/m/100 ms	NR	-1.18 dB	6.12 dB	
	/g/100 ms	NR	-18.81 dB	-5.28 dB	
	/t/100 ms	NR	-10.69 dB	6.71 dB	

Table 3.4.1: Difference in SNR from F_{sp} analysis between unaided and aided conditions. A positive value indicates aided SNR is better than unaided SNR. Black shows differences within 10 dB, orange differences within 20 dB and red differences greater than 20 dB.

The comparison showed that for both the quiet stimulus recordings and the loud stimulus recordings (after removing recordings with any artificial clicks) the difference in SNR between unaided and aided conditions remained within 10 dB for 95% of the 100 ms stimulus duration sounds compared to 50% for the 30 ms stimulus duration sounds. This suggests greater control

^{*}clicks in the recording have been removed; NR = not recorded

of SNR between unaided and aided conditions for the 100 ms stimulus duration important for investigating any differences in ALRs in normal hearing adults. Combining this with the MSC analysis, this would support the use of 100 ms stimulus durations using the loud level sound presentation for the adult normal hearing study design.

However on listening checks the unaided sounds recorded at the loud level sounded distorted which was most likely due to loudspeaker distortion, being at a higher audiometer dial setting (near to its limit). This ruled out the use of the loud stimulus unaided recordings from the adult normal hearing study. The loudspeaker distortion was not present in the equivalent aided conditions since the audiometer dial level was reduced by 20 dB to account for the hearing aid gain added. Where MSC analysis ruled out the use of the quiet aided recordings, the difference in SNR between the quiet unaided recordings and the loud aided recordings was checked. For the 100 ms duration sounds, the number of sounds in each hearing aid condition where the SNR between aided and unaided sounds matched to within 10 dB fell from 95% to 11% but remained within 20 dB for 100% of the 100ms duration sounds (where for the 30 ms duration sounds the value within 20 dB was 78%). Furthermore, SNR in each individual condition of the 100 ms duration sounds for the quiet unaided recordings and the loud aided recordings (Phonak hearing aid), given in Table 3.4.2, remained high, above 19 dB which is considered good. Importantly, SNR was in general higher in the aided conditions than the unaided conditions. Listening checks also indicated little perceptual difference in the noise levels between the unaided sounds (recorded using the quiet stimulus levels) and the aided sounds (recorded using the loud stimulus levels).

HA condition	Stimuli SNR			
	/m/ 100 ms	/g/ 100 ms	/t/ 100 ms	
unaided	22.12 dB	19.28 dB	26.38 dB	
(quiet stimulus recording)				
Phonak linear	32.81 dB	37.68 dB	41.08 dB	
(loud stimulus recording)				
Phonak WDRC	34.6 dB	34.98 dB	37.42 dB	
(loud stimulus recording)				
Phonak NLFC	21.82 dB	39.12 dB	45.94 dB	
(loud stimulus recording)				

Table 3.4.2: SNR from F_{sp} analysis in individual conditions of the 100 ms duration sounds.

An example of the original stimulus, a clean recording of the same stimulus (high SNR) and a noisy recording of the stimulus (poor SNR) is given in Figure 3.4.2 for the unaided speech sound /m/ with 100 ms duration.

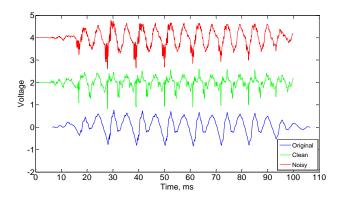


Figure 3.4.2: An example of an original stimulus and equivalent 'clean' recording and 'noisy' recording of the same stimulus.

It was recognised that presenting the loud stimulus levels directly via a hearing aid would be too loud for participants with normal hearing. Instead, it was decided to use ER2 insert earphones to present the processed KEMAR recorded sounds in order that the sound levels remained acceptable for participants with normal hearing. ER2 insert earphones minimise the additional frequency response of the occluded ear that would otherwise be introduced, as it has an almost flat frequency response when measured using a Zwislocki coupler (Killion 1984). The Zwislocki coupler is an occluded ear simulator that approximates the acoustics of an average human occluded ear (Killion 1984).

3.5. Conclusions: hearing aid processing analysis

From hearing aid processing analysis, the following conclusions were drawn to implement into the adult normal hearing study:

- The loud stimulus level KEMAR recordings should be used for the aided sounds and the quiet stimulus level KEMAR recordings for the unaided sounds.
- Presenting sounds at the loud stimulus levels will be too loud for participants with normal hearing when listening through a hearing aid.
- One repeat of the raw KEMAR recording was extracted and imported as the test stimulus for each of the speech sound and hearing aid conditions in order to maintain truer characteristics of listening through a hearing aid.

ER2 insert earphones will be used to present the KEMAR recorded sounds to minimise
the additional frequency response of the occluded ear and to allow sound levels to
remain comfortable for participants with normal hearing.

Chapter 4. Development of methods to study the effects of hearing aid processing on ALRs in adults

4.1. Aim: pilot study

A pilot study was undertaken with the primary aim to ensure ALRs could be recorded with the equipment set-up. Given the known interaction of stimulus parameters in defining the ALR peak characteristics (Stapells 2002, Martin et al 2007) and recognising that parameter variation is present in the published literature (Jacobson et al 1992, Tremblay et al 2003, Agung et al 2006, Billings et al 2007, Beukes et al 2009), the second aim of the pilot study was to refine certain test parameters in order to optimise recording of the waveform for the adult normal hearing study. The following questions were investigated:

- 1) Does a longer (100 ms) or shorter (30 ms) stimulus duration evoke a significantly larger amplitude waveform* distinguishable from background noise?
- 2) Do more or less repeats per average (100, 50, 25 or 10) evoke a significantly larger amplitude waveform* distinguishable from background noise?
- 3) Is there any evidence of habituation of the waveform*?

4.2. Methodology: pilot study

Auditory late responses were recorded using a repeated measures design from 5 young adults between 18-30 years (to ensure data collection was completed within a reasonable timeframe) with normal hearing thresholds in both ears (≤20 dB HL at frequencies from 0.25-8 kHz), type A tympanograms and no otological or family history of early onset hearing loss, following British Society of Audiology recommended procedures (BSA 1992, BSA 2004, BSA 2010). Signed consent for involvement in the study was obtained from each participant.

The naturally produced speech tokens /m/, /g/ and /t/, cropped from the male spoken MRC Institute of Hearing Research vowel-consonant-vowel test (Faulkner 1998) using matlab programming (Appendix 4) and whose spectral and temporal characteristics are given in Section 5.4.2, were presented at 65 dB nHL following biological calibration to find 0 dB nHL (Appendix 5). The sound level scale of dB nHL was chosen as this maintains equalisation of sound intensity across frequencies. Two different stimulus durations, 30 ms and 100 ms, were used with ISI of 3 seconds. The sounds were presented in the unaided condition from a Fostex 6301BX loudspeaker at 1 m distance, ear level height and 0° azimuth.

^{*}peak-to-peak amplitude/latency of N1 and P2

Subjects were asked to sit quietly in a sound proofed room, wearing an ear plug in their left ear. They were asked to minimise movement and read during data collection. ALRs were recorded from disposable surface electrodes positioned at Cz referenced to right mastoid with forehead as ground connected to a Cambridge Electronic Design (CED) 1902 (Appendix 5). Impedances were maintained at $\leq 5 \text{ k}\Omega$. Test order was randomised and a no sound trial included. Artefact rejection and data analysis were performed off line. F_{sp} measure of ALR response quality was calculated based on Elberling and Don (1984) and its statistical significance determined using bootstrap analysis (Lv et al 2007) to identify the presence of a response from the background noise (Appendix 6). Bootstrap analysis estimates the probability that the response obtained is due to random variation in the data rather than a physiological response. It is based on repeatedly drawing random samples, with replacement, from the original raw data to obtain a distribution of incoherent averages as would be expected if there were no stimulus response present (Lv et al 2007). Comparison of the coherent average obtained from the original data to the incoherent average distribution provides a probability value of response presence (Lv et al 2007). A low value, smaller than a chosen significance level (for example p≤0.01), rejects the null hypothesis of no response and accepts that a response is significantly present (Lv et al 2007).

A summary of the stimulus and recording parameters is given in Table 4.2.1.

Stimulus type:Electrode configuration:/m/, /g/, /t/ (cropped from VCV clusters)Channel 1: Cz − right mastoid (record0.4 kHz, 2 kHz, 4 kHz respectivelyALR)UnaidedGround: forehead Inter-electrode impedances: ≤5 kΩStimulus duration:Recording window:30 ms0 to 500 ms post stimulus100 msHigh pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter:100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain:3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection:0%All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10 3 averages	Stimulus parameters	Recording parameters
0.4 kHz, 2 kHz, 4 kHz respectivelyALR)UnaidedGround: forehead Inter-electrode impedances: ≤5 kΩStimulus duration:Recording window:30 ms0 to 500 ms post stimulus100 msHigh pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain: 3 seconds3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection: All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection: Left ear plugged	Stimulus type:	Electrode configuration:
UnaidedGround: forehead Inter-electrode impedances: ≤5 kΩStimulus duration:Recording window:30 ms0 to 500 ms post stimulus100 msHigh pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter:100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain:3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection:0%All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection:Loudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	/m/, /g/, /t/ (cropped from VCV clusters)	Channel 1: Cz – right mastoid (record
Stimulus duration:Recording window:30 ms0 to 500 ms post stimulus100 msHigh pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter:100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain:3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection:0%All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	0.4 kHz, 2 kHz, 4 kHz respectively	ALR)
Stimulus duration:Recording window:30 ms0 to 500 ms post stimulus100 msHigh pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter:100 Hz (24 dB/octave) online;15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain:3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection:0%All offline300 μV peak-to-peakStimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	Unaided	Ground: forehead
30 ms 100 ms Rise/fall times: Zero crossing for 30 ms stimuli 20 ms for 100 ms stimuli (60 ms plateau) Inter-stimulus interval: 3 seconds Amplifier gain: 3 seconds Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Low pass filter: 100 Hz (24 dB/octave) online and offline Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offline Amplifier gain: 3 seconds Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Loudspeaker; 1 m 0° azimuth Left ear plugged 100; 50; 25; 10		Inter-electrode impedances: ≤5 kΩ
Rise/fall times: Zero crossing for 30 ms stimuli 20 ms for 100 ms stimuli (60 ms plateau) Inter-stimulus interval: 3 seconds Stimulus randomisation: Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Repeats per average post artefact rejection: Light pass filter: 1 Hz (24 dB/octave) online and offline Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offline Amplifier gain: 1 000 CED gain; x3 electrode head box gain Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Repeats per average post artefact rejection: Left ear plugged 100; 50; 25; 10	Stimulus duration:	Recording window:
Rise/fall times:High pass filter:Zero crossing for 30 ms stimuli1 Hz (24 dB/octave) online and offline20 ms for 100 ms stimuli (60 ms plateau)Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain: 3 seconds3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection: All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection: Loudspeaker; 1 m 0° azimuthLeft ear plugged100; 50; 25; 10	30 ms	0 to 500 ms post stimulus
Zero crossing for 30 ms stimuli 20 ms for 100 ms stimuli (60 ms plateau) Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offline Inter-stimulus interval: 3 seconds Amplifier gain: 1 000 CED gain; x3 electrode head box gain Stimulus randomisation: Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Loudspeaker; 1 m 0° azimuth Left ear plugged 100; 50; 25; 10	100 ms	
20 ms for 100 ms stimuli (60 ms plateau)Low pass filter: 100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offlineInter-stimulus interval:Amplifier gain: 1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection: All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection: Loudspeaker; 1 m 0° azimuthLeft ear plugged100; 50; 25; 10	Rise/fall times:	High pass filter:
100 Hz (24 dB/octave) online; 15 Hz (24 dB/octave) offline Inter-stimulus interval: Amplifier gain: 1 000 CED gain; x3 electrode head box gain Stimulus randomisation: Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Loudspeaker; 1 m 0° azimuth Left ear plugged 100; 50; 25; 10	Zero crossing for 30 ms stimuli	1 Hz (24 dB/octave) online and offline
15 Hz (24 dB/octave) offline Inter-stimulus interval: 3 seconds 1 000 CED gain; x3 electrode head box gain Stimulus randomisation: Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Repeats per average post artefact Loudspeaker; 1 m 0° azimuth Left ear plugged 100; 50; 25; 10	20 ms for 100 ms stimuli (60 ms plateau)	Low pass filter:
Inter-stimulus interval:Amplifier gain:3 seconds1 000 CED gain; x3 electrode head box gainStimulus randomisation:Artefact rejection:0%All offline300 μV peak-to-peakStimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10		100 Hz (24 dB/octave) online;
3 seconds 1 000 CED gain; x3 electrode head box gain Stimulus randomisation: Artefact rejection: All offline 300 μV peak-to-peak Stimulus transducer: Repeats per average post artefact rejection: Left ear plugged 100; 50; 25; 10		15 Hz (24 dB/octave) offline
Stimulus randomisation:Artefact rejection:0%All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection:Loudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	Inter-stimulus interval:	Amplifier gain:
Stimulus randomisation:Artefact rejection:0%All offline300 μV peak-to-peakStimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	3 seconds	1 000 CED gain; x3 electrode head box
0%All offline 300 μV peak-to-peakStimulus transducer:Repeats per average post artefact rejection:Loudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10		gain
300 µV peak-to-peak Stimulus transducer: Repeats per average post artefact Loudspeaker; 1 m 0° azimuth rejection: Left ear plugged 100; 50; 25; 10	Stimulus randomisation:	Artefact rejection:
Stimulus transducer:Repeats per average post artefactLoudspeaker; 1 m 0° azimuthrejection:Left ear plugged100; 50; 25; 10	0%	All offline
Loudspeaker; 1 m 0° azimuth Left ear plugged rejection: 100; 50; 25; 10		300 μV peak-to-peak
Left ear plugged 100; 50; 25; 10	Stimulus transducer:	Repeats per average post artefact
	Loudspeaker; 1 m 0° azimuth	rejection:
3 averages	Left ear plugged	100; 50; 25; 10

Recording parameters

Table 4.2.1: Stimulus and recording parameters used in the pilot study.

4.3. Results: pilot study

4.3.1. ALR waveform

Stimulus parameters

The ALR peaks P1 (where visible), N1 and P2 were identified as the largest magnitude peaks on visual inspection and showed peak latencies following speech stimulus onset of P1 between 50-150 ms, N1 between 80-200 ms and P2 between 150-300 ms. These peak latency boundaries coincide with those defined by Garanis and Cone-Wesson (2007). As noted in the literature for speech sounds, the latency windows were longer than those traditionally defined for tone-bursts (Tremblay et al 2003). The N1-P2 peak-to-peak amplitudes recorded ranged from approximately 5 to 20 μ V. This is comparable to the average published by Agung et al (2006) of approximately 6 μ V with stimulus duration 100 ms and ISI of 1125 ms, and is about

half the size of the average published by Beukes et al (2009) of approximately 33 μ V using a 3 second ISI and 100 ms stimulus duration, the same as this study. Peak-to-peak amplitude was chosen over reporting separately N1 peak amplitude and P2 peak amplitude to minimise the effect of variation in DC offset. Bootstrap analysis indicated all responses to sound stimuli were significant at the level p<0.01 and no sound trial recordings showed no significant response with p>0.05, when number of repeats in the average was set at 100. Subject 4 required electrodes to be re-applied since they were noticed to be falling off after ALR recording had started. The N1 peak was found to be difficult to identify directly before electrode re-application indicating the importance of good electrode contact for the results.

Figure 4.3.1.1 (a) shows an example of the auditory late response for three averages from the speech sound /m/ with stimulus duration 100 ms and (b) a comparison of one average to the three different 100 ms speech stimuli /m/, /g/, /t/ in subject 5. It indicates reasonable reproducibility between averages for the same test sound and highlights some differences in waveform morphology between speech sounds within an individual.

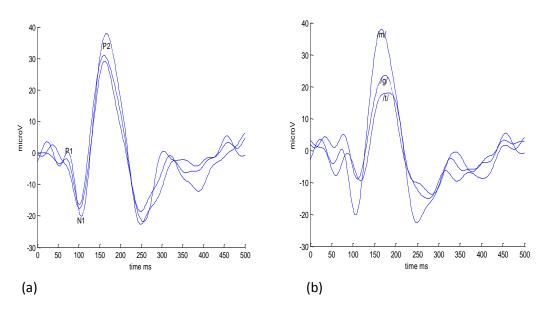


Figure 4.3.1.1: ALR waveforms from subject 5: a) 3 averages of 100 ms /m/; (b) 1 average of 100 ms /m/, /g/, /t/. F_{sp} values significant on bootstrap analysis p<0.01. The N1-P2 peak-to-peak amplitude scale is x3 that of the response due to the setting of gain on the electrode box.

4.3.2. Stimulus duration

Paired samples t-test of group data exploring 100 repeats and 50 repeats showed that only N1-P2 peak-to-peak amplitude of /g/ 30 ms was significantly larger than /g/ 100 ms with difference $5.4\pm2~\mu V$ (mean $\pm SD$). N1-P2 amplitude was significantly larger for /m/ 100 ms than /m/ 30 ms by $1.4\pm3~\mu V$ (mean $\pm SD$). Whilst the bigger difference is evident for /g/ 30 ms there is no strong indication across all the speech sounds that one stimulus duration evoked larger amplitude, shorter latency responses than the other, in this small pilot group. Furthermore, although the data was checked for normality, the sample size was small which could bias estimation of the distribution.

A 100 ms stimulus duration is more consistently adopted in the literature for adult studies (Stapells 2002). Whilst Golding et al (2006) advise of no clear advantage in using stimulus durations beyond 35 ms and ISI's beyond 1125 ms in infant assessments in order to minimise test time, they did record a larger amplitude response of approximately 2 μ V when using a medium (79 ms) stimulus duration compared to a shorter (32 ms) stimulus duration for the speech sound /t/ in a normal hearing infant group. They concluded that this was a minor outcome clinically however since the test parameter of ISI has been set at 3 seconds this will have the biggest impact on test time over smaller differences between 30 ms or 100 ms stimulus durations.

Another consideration of 100 ms stimulus duration is the theoretical destructive overlapping of the onset P2 and offset N1 responses documented by Lightfoot (2010). This however has not been reported further in the literature.

The 100 ms stimulus duration was chosen for the adult normal hearing study as 1) it more closely resembles the original speech sound, 2) it is the stimulus duration most widely adopted in the literature for adults and 3) it has shown larger, albeit minimally, response amplitudes in infants. It will not significantly add to the test time for either the adult or infant group since a 3 second ISI has been adopted.

4.3.3. Number of repeats

Use of the CED equipment to record the ALR requires that analysis to determine response presence is carried out off-line. The pilot data was therefore re-analysed with bootstrap analysis (Elberling and Don 1984, Lv et al 2007) varying the number of repeats per average, set

to 100, 50, 25 and 10, to determine the number required to evoke a significant response. Comparison between all four conditions showed that 100% of the data of 100 repeats had significant F_{sp} values with p<0.01. 93% of the data of 50 repeats had significant F_{sp} values with p<0.01 and 100% with p<0.05. Only 89% of the data of 25 repeats had significant F_{sp} values with p<0.05 and 14% of the data of 10 repeats had significant F_{sp} values with p<0.05. This indicated that data collected using 100 or 50 repeats per average appeared to be most robust and that less than 50 repeats should not be used for data collection due to the reduction in response quality below 50 repeats.

Paired samples t-test showed no significant difference between N1-P2 amplitude, N1 latency nor P2 latency for 100 repeats and 50 repeats per average. In addition one average of 100 repeats took approximately 5 minutes to run and one average of 50 repeats took approximately 2½ minutes to run so there is a trade off between data quality and test duration for subjects. Together this supported the use of 50 accepted repeats per average (post artefact rejection) for the adult normal hearing study data collection to ensure good quality data could be recorded in a reasonable test time. To achieve this 60 repeats were collected per average pre artefact rejection as a few epochs were likely to be discarded as artefacts.

4.3.4. Waveform habituation

Analysis of the ALR data showed a significant difference between N1-P2 amplitude when comparing 100 repeats and 10 repeats, and 50 repeats and 10 repeats where a larger amplitude of 2-3 μ V (p≤0.05) was recorded from 10 repeats. This may indicate a level of habituation of the ALR response which has been documented in the literature (Prosser et al 1981, Schafer et al 1981, Rosburg et al 2004) and for this reason the use of randomising stimulus presentation within the average has been suggested, in particular by Lightfoot (2010). This is not widely adopted in the literature however and was not explored in collection of the pilot data. Since robust ALRs were still recorded with 50 repeats and the effect of randomisation was not explicitly explored, it was not introduced in to the adult normal hearing study.

4.4. Conclusions: pilot study

From the data analysed in the pilot study, the following conclusions were drawn to implement in the adult normal hearing study:

- Use 100 ms stimulus durations.
- Collect 60 repeats per average pre artefact rejection.

In addition it was decided that the following should also be included in the adult study protocol:

- Collect 2 averages per condition.
- Use no randomisation of the stimulus presentation.

Chapter 5. Study of the effects of hearing aid processing on ALRs in adults

5.1. Aim: adult normal hearing study

The aim of the adult study was to investigate the repeatability of recording ALRs and to explore the effects that digital hearing aid signal processing may have on the test signal and evoked response in normally hearing listeners. The research was designed to answer the following questions:

- 1) How repeatable, on test retest measures, is the ALR recorded from three different unaided speech sounds /m/, /g/ and /t/?
- 2) Do different digital hearing aid strategies (linear, WDRC, NLFC) significantly change the ALR waveform* evoked by the three different speech stimuli compared to no amplification?
- 3) Is there any significant difference in the response waveform* recorded from the three speech sounds at a suprathreshold level?
- 4) Do the different digital hearing aid strategies alter the stimuli compared to the unaided test sound?

These generate the null hypotheses:

- 1) There is no significant difference between the ALR waveforms* from the three different unaided speech sounds when measured on two different occasions.
- 2) There is no significant effect of hearing aid condition on the ALR response* from the three different speech sounds.
- 3) There is no significant effect of stimulus type on the ALR waveform*.
- 4) There is no significant alteration to the test stimuli due to hearing aid processing.

5.2. Methodology: adult normal hearing study

5.2.1. Summary of hearing aid processing analysis and pilot study conclusions

The following summarises the conclusions drawn from the hearing aid processing analysis and pilot study that were used to develop the main adult study design:

• Use 100 ms stimulus durations.

^{*}peak-to-peak amplitude and/or latency of N1 and P2

- Collect 60 repeats per ALR average (pre artefact rejection) and 2 averages per condition.
- Use no randomisation of the stimulus presentation.
- Use one repeat of the raw KEMAR recorded sounds as the test signals, with the loud stimulus level recordings for the aided sounds and the quiet stimulus level recordings for the unaided sounds.
- Use ER2 insert earphones to present the KEMAR recorded test sounds.

5.2.2. Equipment

A Cambridge Electronic Design (CED) and Signal software v4.02 were used to record ALRs. The KEMAR recorded sounds were imported in to the CED Signal Software and the digital stimulus converted to an analogue stimulus using the CED 1401 mk II. Conversion rate was 20 kHz. The test sound was presented via ER2 insert earphone transducers routed through an audiometer. The electrical responses from the participant were routed into the CED 1902 through an external 1902-10 pre-amp. The 1902 controlled by the Signal software amplified and filtered the response detected by the electrodes. The CED 1401 mk II re-converted the analogue response signals into digital format for analysis. The equipment set-up and direction of flow of information is given in Figure 5.2.2.1.

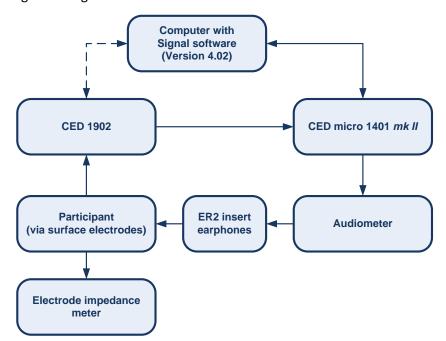


Figure 5.2.2.1: Equipment set-up and direction of flow of information (arrows) for ALR recordings.

5.2.3. Methodology

Approval for the adult normal hearing study was obtained from the University of Southampton Faculty of Engineering and the Environment Ethics committee.

Auditory late responses were recorded using a repeated measures design from 20 young adults (between 18-30 years). The sample size was calculated for an 80% power and significance level of 0.05 from data recorded in normal hearing adults published by Tremblay et al (2006), assuming a correlation of 0.5 between the unaided N1 mean amplitude of -2.20±0.61 and aided N1 mean amplitude of -2.88±1.07 to the test sound /shi/. Subjects for the current study were required to have normal hearing thresholds in both ears (≤20 dB HL at frequencies from 250 Hz-8 kHz), type A tympanograms and no otological or family history of early onset hearing loss, following British Society of Audiology recommended procedures (BSA 1992, BSA 2004, BSA 2010). Signed consent for involvement in the study was obtained from each participant.

KEMAR recordings of the naturally produced speech tokens /m/, /g/ and /t/ processed in four hearing aid conditions (unaided, linear, WDRC, NLFC) were presented to the right ear (to control for any ear effects and similar to other studies in the literature, for example Billings et al 2007) via ER2 insert earphones at 65 dB nHL (Appendix 7). The spectral and temporal characteristics of the stimuli are given in Section 5.4.2. Stimuli were 100 ms duration (including a 20 ms rise and fall time to avoid audible clicks) with a 3 second ISI. Signal-to-noise ratio between conditions was taken in to account.

Subjects were asked to sit quietly in a sound proofed room, wearing an ear plug in their left ear to limit audibility of any equipment noise. They were asked to minimise movement and read during data collection. Two ALR averages of 60 repeats were recorded for each condition. Test order was randomised and a no sound trial included. Data was collected over 2 sessions approximately 1 week apart and ALRs were recorded in the unaided condition during both sessions in order to assess test retest repeatability.

Evoked responses were recorded using a CED 1401 *mk II* laboratory interface and CED 1902 isolated amplifier, with Signal software v4.02. A two channel recording was used to monitor and allow removal of artefact due to eye blink using a fixed artefact rejection level to remove any epochs containing eye blink activity, since the response waveform from a non auditory eye

blink can appear similar to that of an auditory response. Disposable surface electrodes were positioned for channel 1 at Cz referenced to right mastoid with forehead as ground and channel 2, above and below the left eye linked to the forehead ground. Impedances were maintained at $\leq 5 \text{ k}\Omega$.

Data were amplified by 1000 and filtered offline from 1-15 Hz using a 700 ms analysis time window, including 100 ms pre-stimulus baseline. Artefact rejection for both channels was set at $\pm 70~\mu V$ and performed offline. The F_{sp} measure of quality in the ALR response was calculated based on Elberling and Don (1984). However the critical value of F_{sp} that indicates response presence can vary between subjects as the properties of subject noise varies. In order to determine whether responses were present, the statistical significance of F_{sp} values was determined using bootstrap analysis (Lv et al 2007) to objectively identify the presence of a response from the background noise (Appendix 8).

A summary of the stimulus and recording parameters is given in Table 5.2.3.1.

Stimulus parameters	Recording parameters
Stimulus type:	Electrode configuration:
/m/, /g/, /t/ (cropped from VCV clusters)	Channel 1: Cz – right mastoid (record
0.4 kHz, 2 kHz, 4 kHz respectively	ALR)
unaided, linear, WDRC, NLFC	Channel 2: above and below left eye
(cropped from KEMAR recordings)	(record eye blink)
	Ground: forehead
	Inter-electrode impedances: ≤5 kΩ
Stimulus duration:	Recording window:
100 ms	100 ms pre-stimulus to 600 ms post
	stimulus
Rise/fall times:	High pass filter:
20 ms with 60 ms plateau	1 Hz (24 dB/octave) online and offline
	Low pass filter:
	100 Hz (24 dB/octave) online;
	15 Hz (24 dB/octave) offline
Inter-stimulus interval:	Amplifier gain:
3 seconds	1 000 CED gain; x1 electrode head box
	gain
Stimulus randomisation:	Artefact rejection:
0%	All offline
	Limits set to $\pm 70~\mu V$ (140 μV peak-to-
	peak)
Stimulus transducer:	Number of repeats pre artefact rejection:
ER2 insert earphones	60 repeats
Left ear plugged	2 averages per condition

Table 5.2.3.1: Stimulus and recording parameters used in the adult normal hearing study.

5.3. Results from ALR recordings: adult normal hearing study

5.3.1. Data inclusion criteria

Data from 16 subjects (11 female, 5 male) was included in the final statistical analysis. One subject was excluded as tympanometry indicated presence of bilateral middle ear effusion. Three subjects were excluded since an ALR response was not present for at least one of the unaided conditions. This criterion had also been previously adopted by Marynewich et al (2010). All excluded subjects were male who in general appeared more restless than female subjects. Estimated noise levels were on average 8.64 nV and did not exceed 15.5 nV in any recordings.

Sixty repeats were recorded during data collection with the aim to have 50 accepted repeats per average, post off-line artefact rejection. Repeats were rejected if activity in either of the recording channels (channel 1 recording ALR activity and channel 2 recording eye blink activity) exceeded $\pm 70~\mu V$. Following artefact rejection it was found that less than 50 repeats were accepted into the average in many of the cases. It was decided that this did not exclude the data outright from statistical analysis since statistically significant waveforms, confirmed by visual observation, could be found in these instances.

ALR waveforms of the 16 subjects were included in the final statistical analysis if two of the following conditions were satisfied:

- F_{sp} value was ≥ 2 (this cut-off was based on an analysis of F_{sp} values for no sound trials for which values of up to 1.78 were found)
- p value from bootstrap analysis was ≤0.01 (given that p values of ≤0.05 were found for no sound trials)
- visual observation confirmed presence of a clear ALR waveform

A p value of \leq 0.01 was satisfied in all but one case of accepted data. For the data point where p>0.01, the F_{sp} value was 2.27 and visual observation confirmed a very clear ALR waveform by two independent reviewers. In this instance only 19 repeats had been accepted in to the average which is considerably below the target of 50 repeats.

ALRs were found to be present in 96% of test conditions.

5.3.2. Statistical distribution of the data

SPSS was used to perform statistical analysis on the ALR N1-P2 peak-to-peak amplitude and latency data. The Shapiro-Wilk test of normality showed that the data for the majority of the conditions was normally distributed and 5 of the 36 conditions were not. These 5 conditions were N1 latency of linear /m/, linear /g/ and WDRC /g/ and P2 latency of unaided /t/ and WDRC /g/, where p \leq 0.05. An outlier data point was present in 4 of these 5 conditions affecting the distribution of the data. In general, parametric statistics were deemed suitable and were adopted in the data analysis.

5.3.3. Investigating unaided test retest differences: Research question 1

Paired samples t-test was used to analyse test retest differences of the ALR N1-P2 amplitude, N1 latency and P2 latency in the unaided condition: between session 1 and session 2; within session 1 and within session 2. Two ALR averages per speech sound were recorded in each session. To analyse the differences between session 1 and session 2, the average of the two ALR waveforms within session 1 was used, and the average of the two ALR waveforms within session 2 was used. With Bonferroni correction, to take in to account multiple tests, no significant difference was found between the means of the two groups of test retest measures for N1-P2 amplitude, N1 latency and P2 latency either between sessions or within sessions where p>0.005. It is possible that smaller effects may become significant if a larger sample size was used, however as effect sizes are likely to be small they may have limited clinical significance. Analysis showed 95% of the test retest differences fell within the order of ±2 µV for N1-P2 amplitude and ±10 ms for N1 and P2 latency, indicating that differences between conditions larger than this are likely to be significant and smaller than this may not be distinguishable from measurement error. The mean differences, 95% confidence intervals of the differences and p value from paired samples t-test analysis are given in Table 5.3.3.1 for N1-P2 amplitude, Table 5.3.3.2 for N1 latency and Table 5.3.3.3 for P2 latency. N1-P2 amplitude of the unaided speech sound /t/ showed the least consistency in measurement between session 1 and session 2 (where p=0.007) as indicated by the asterisk in Table 5.3.3.1.

N1-P2 amplitude			Paired Differences	;	Sig. (2-tailed)
		Mean	95% confide the difference	nce interval of ces	With Bonferroni correction p is
			Lower	Upper	significant if <0.005
Between sessions	/m/	0.46	-0.89	1.80	0.48
	/g/	0.19	-1.02	1.40	0.75
	/t/	1.14	0.36	1.92	0.007*
Within session 1	/m/	0.21	-1.39	1.81	0.79
	/g/	-0.47	-1.77	0.83	0.45
	/t/	-0.63	-2.1	0.84	0.37
Within session 2	/m/	-0.68	-2.17	0.82	0.35
	/g/	-0.72	-1.68	0.25	0.13
	/t/	0.19	-1.61	1.99	0.83

Table 5.3.3.1: Paired samples t-test analysis of N1-P2 amplitude between test sessions, within session 1 and within session 2.

N1 latency			Paired Differences	S	Sig. (2-tailed)
		Mean	95% confide the differen	ence interval of ces	With Bonferroni correction p is
			Lower	Upper	significant if <0.005
Between sessions	/m/	0.89	-2.8	4.55	0.62
	/g/	0.5	-2.04	3.04	0.68
	/t/	0.19	-4.7	5.08	0.94
Within session 1	/m/	0.81	-5.45	7.08	0.79
	/g/	-1.81	-5.75	2.12	0.34
	/t/	0.06	-9.52	9.64	0.99
Within session 2	/m/	2.38	0.08	4.67	0.04
	/g/	-1.75	-5.29	1.79	0.31
	/t/	-2.81	-8.02	2.39	0.27

Table 5.3.3.2: Paired samples t-test analysis of N1 latency between test sessions, within session 1 and within session 2.

P2 latency			Paired Differences				
		Mean	95% confide the differen	ence interval of ces	With Bonferroni correction p is		
			Lower	Upper	significant if <0.005		
Between sessions	/m/	4.31	-0.27	8.89	0.06		
	/g/	3.56	-1.82	8.95	0.18		
	/t/	6.00	0.10	11.90	0.05		
Within session 1	/m/	3.00	-2.87	8.87	0.29		
	/g/	0.25	-5.38	5.88	0.93		
	/t/	1.69	-9.19	12.57	0.75		
Within session 2	/m/	-0.50	-6.79	5.79	0.87		
	/g/	1.56	-5.13	8.25	0.63		
	/t/	5.19	-3.34	13.71	0.21		

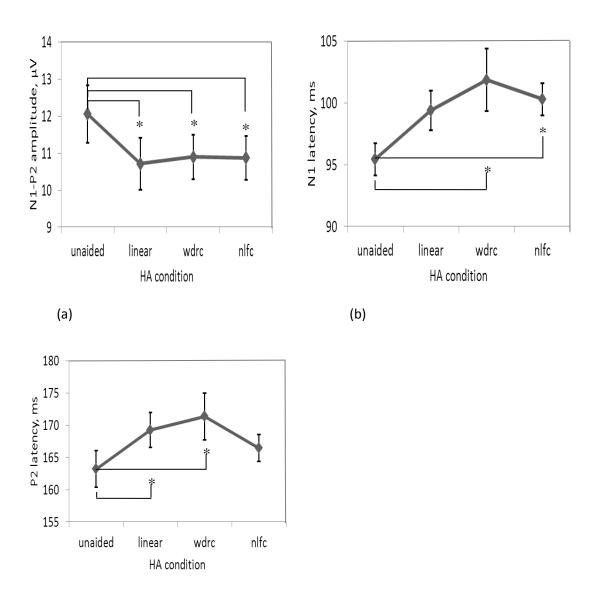
Table 5.3.3.3: Paired samples t-test analysis of P2 latency between test sessions, within session 1 and within session 2.

5.3.4. Investigating differences between ALR waveforms of the different HA conditions: Research question 2

Unaided N1-P2 amplitude was found to be significantly larger than any of the aided N1-P2 amplitudes and there was no significant difference when comparing between the aided conditions (Figure 5.3.4.1(a)). N1 latency was significantly earlier for unaided compared to WDRC and NLFC aided conditions (Figure 5.3.4.1(b)) and P2 latency was significantly earlier for unaided compared to linear and WDRC aided conditions (Figure 5.3.4.1(c)). A 2-way repeated measures analysis of variance (RMANOVA) with factors of HA condition and speech sound type was used to identify these significant differences in the ALR waveform evoked by the four HA conditions ([F=5.31, p<0.01] N1-P2 amplitude; [F=4.99, p<0.013] N1 latency; [F=3.90, p<0.015] P2 latency) and post hoc t-test comparisons with Bonferroni adjustment (Table 5.3.4.1). Significance level was taken as p≤0.01. The null hypothesis is rejected as there is a significant effect of hearing aid condition.

RMANOVA showed no significant interaction between HA condition and speech sound on N1-P2 amplitude [F=1.74, p<0.121], N1 latency [F=1.68, p<0.197] nor P2 latency [F=0.79, p<0.525].

The speech sound data was therefore amalgamated within each HA condition to illustrate the significant effects shown in Figure 5.3.4.1.



(c)
Figure 5.3.4.1. Differences between HA condition of estimated marginal means ± 1 standard error: (a) N1-P2 amplitude; (b) N1 latency; (c) P2 latency. Asterisks indicate significant differences at p≤0.01.

Pairs of averages			Sig. (2-tailed)			
		Mean	95% confidence differences	95% confidence interval of the differences		
			Lower	Upper	correction p is significant if <0.008	
N1-P2 amplitude	unaided-linear	1.35	0.65	2.05	0.000*	
	unaided-WDRC	1.16	0.51	1.82	0.001*	
	unaided-NLFC	1.19	0.56	1.82	0.000*	
	linear-WDRC	-0.18	-0.69	0.32	0.470	
	linear-NLFC	-0.16	-0.80	0.49	0.624	
	WDRC-NLFC	0.03	-0.56	0.61	0.932	
N1 latency	unaided-linear	-3.96	-7.04	-0.88	0.013	
	unaided-WDRC	-6.42	-10.12	-2.72	0.001*	
	unaided-NLFC	-4.85	-6.99	-2.72	0.000*	
	linear-WDRC	-2.46	-6.46	1.54	0.223	
	linear-NLFC	-0.90	-3.71	1.92	0.525	
	WDRC-NLFC	1.56	-2.73	5.86	0.468	
P2 latency	unaided-linear	-6.23	-10.60	-1.86	0.006*	
	unaided-WDRC	-8.33	-12.90	-3.77	0.001*	
	unaided-NLFC	-3.44	-6.79	-0.09	0.044	
	linear-WDRC	-2.10	-7.39	3.19	0.428	
	linear-NLFC	2.79	-1.90	7.48	0.237	
	WDRC-NLFC	4.90	0.18	9.61	0.042	

Table 5.3.4.1: Post hoc t-test analysis between HA conditions.

5.3.5. Investigating differences between ALR waveforms of the different speech sounds: Research question 3

All speech sounds showed a significant difference in ALR amplitude with the largest difference between /m/ and /g/, and /m/ and /t/ as presented in Figure 5.3.5.1(a). 2-way RMANOVA with factors of speech sound type and HA condition showed this significant effect on N1-P2 amplitude [F=37.72, p<0.01] but found no significant effect on N1 latency [F=3.79, p<0.052] nor P2 latency [F=3.29, p<0.075]. The post hoc t-test comparisons with Bonferroni adjustment (p≤0.01) are given in Table 5.3.5.1. The analysis rejects the null hypothesis of no effect of speech sound type on the ALR. Since RMANOVA showed no significant interaction between HA condition and speech sound on the ALR waveform (Section 5.3.4), the HA data was amalgamated within each speech sound to illustrate the significant effects shown in Figure 5.3.5.1.

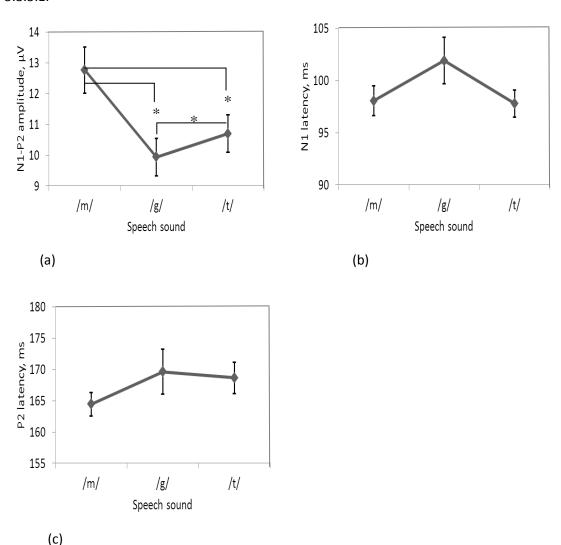


Figure 5.3.5.1. Differences between speech sound of estimated marginal means ± 1 standard error: (a) N1-P2 amplitude; (b) N1 latency; (c) P2 latency. Asterisks indicate significant differences at p≤0.01.

Pairs of averages			Paired Differences			
		Mean	95% confidence differences	With Bonferroni		
			Lower	Upper	correction p is significant if <0.017	
N1-P2 amplitude	/m/-/g/	2.83	2.30	3.36	0.000*	
	/m/-/t/	2.06	1.49	2.64	0.000*	
	/g/-/t/	-0.77	-1.22	-0.32	0.001*	
N1 latency	/m/-/g/	-3.84	-7.48	-0.21	0.038	
	/m/-/t/	0.25	-1.78	2.28	0.806	
	/g/-/t/	4.09	0.93	7.26	0.012*	
P2 latency	/m/-/g/	-5.19	-9.57	-0.80	0.021	
	/m/-/t/	-4.20	-7.07	-1.34	0.005*	
	/g/-/t/	0.98	-3.07	5.04	0.629	

Table 5.3.5.1: Post hoc t-test analysis between speech sounds.

5.4. Analysis of speech stimuli for the adult normal hearing study

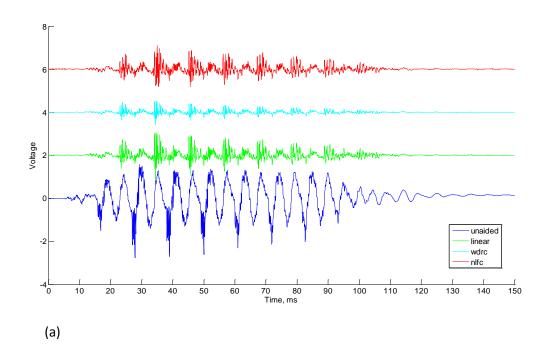
The waveform and spectral content of the speech stimuli used to evoke the ALR in the adult normal hearing study were analysed to explore whether any differences between conditions might explain the ALR results, since it is sensitive to stimulus characteristics (Stapells 2002, Martin et al 2007).

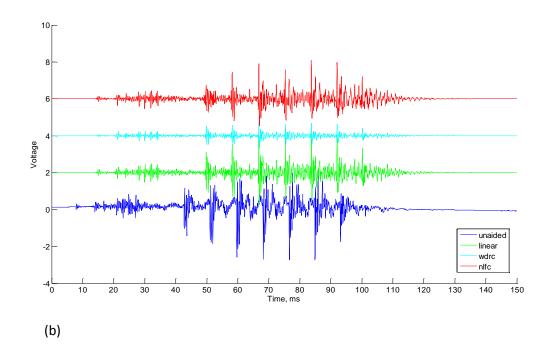
5.4.1. Analysis of the stimulus waveform envelope

Root mean square (rms) analysis was performed on the first 30 ms from the start of the waveform, since this portion of the sound has been shown to determine ALR morphology (Onishi and Davis 1968, Marynewich et al 2012, Jenstad et al 2012, Billings et al 2011), for each of the KEMAR recorded stimuli (shown in Figure 5.4.1.1) at the levels they were presented to subjects, described earlier, and for a 1 kHz tone (shown in Figure 5.4.1.2). A 1 kHz tone was included to compare findings to those of Marynewich et al (2010, 2012) who debated whether short duration sounds could be used to evoke the ALR with hearing aids. The analysis, summarised in Table 5.4.1.1 and detailed in Appendix 9 along with analysis from the 30-60 ms period and 60-90 ms period from waveform onset, consistently showed the unaided stimuli

were larger in magnitude than the aided stimuli but that the stimulus magnitude across the different HA conditions was similar. This pattern in rms amplitude was consistent with patterns in ALR amplitude seen in Figure 5.3.4.1(a). The rms value for the /g/ waveform was consistently smaller than /m/ and /t/ across HA conditions, consistent with the pattern of ALR results in Figure 5.3.5.1(a). However the magnitude of the /t/ waveform was always larger than /m/ which does not correlate with the low ALR amplitude for /t/ seen in Figure 5.3.5.1(a).

Figures 5.4.1.1 and 5.4.1.2 also show a delay of approximately 7 ms in the hearing aid processed sounds compared to the unaided sounds, comparable to the increase in N1 latency of the ALR response of up to 6 ms and an increase in P2 latency of up to 8 ms in the aided conditions compared to the unaided conditions.





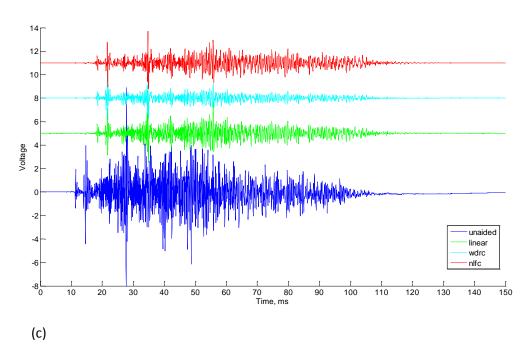


Figure 5.4.1.1: KEMAR recorded sounds by hearing aid condition presented to subjects: (a) /m/; (b) /g/; (c) /t/.

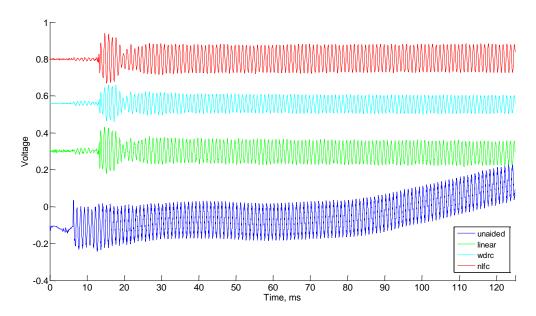


Figure 5.4.1.2: KEMAR recorded 1 kHz tone by hearing aid condition at 60 dB SPL aided equivalent.

HA condition	HA condition rms voltage			rms aided gain relative to unaided (dB)
	/m/	/g/	/t/	
unaided	0.67	0.15	1.32	-
linear	0.21	0.12	0.48	-2.91
WDRC	0.11	0.07	0.34	-4.88
NLFC	0.20	0.12	0.42	-1.74

Table 5.4.1.1: rms analysis of test sounds 0-30 ms from stimulus onset.

Figure 5.4.1.2 of the 1 kHz comparison tone indicates the hearing aid in each condition reaches its maximum gain before 30 ms but then decreases in amplitude as compression is activated. This is confirmed by the rms analysis when comparing the values across each 30 ms periods of the stimulus (Appendix 9). The analysis of the first 30 ms from waveform onset of the 1 kHz tone further showed the gain reached by the hearing aid to be only a little under the 20 dB that it was programmed with (by 2-3 dB) in the linear and NLFC processed sounds, however a greater reduction in gain (up to 5 dB), was present for the compressed WDRC sound (Table 5.4.1.1).

5.4.2. Analysis of the stimulus spectral content

Figures 5.4.2.1, 5.4.2.2 and 5.4.2.3 show the respective spectrograms for the speech sounds /m/, /g/ and /t/ processed by each of the HA conditions. The spectrograms were calculated using a Hamming window, 20 ms in length and 10 ms step size. Estimates of their spectral content are provided in Table 5.4.2.1 giving fundamental and formant frequencies. The spectrograms indicate differences from the unaided to aided conditions, in particular that all the aided conditions restrict the frequency output between approximately 4 and 5 kHz.

Overall the spectra across hearing aid processed conditions appear similar within each speech sound except for NLFC /g/ and NLFC /t/ where output frequencies show greater compression than their respective linear and WDRC aided conditions. Speech sound /t/ has a greater spread and higher frequency content that speech sound /m/.

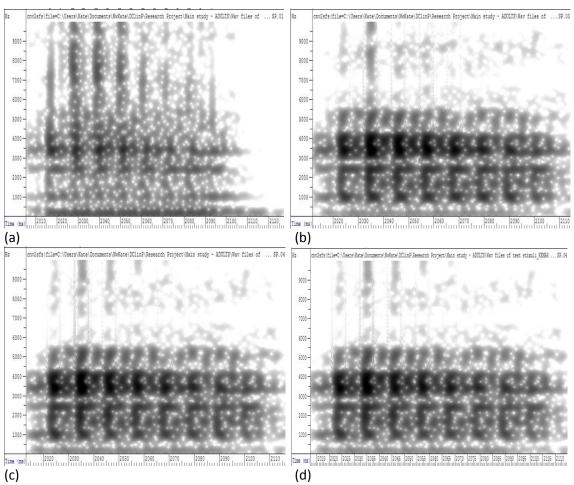


Figure 5.4.2.1: Spectrograms of speech sound /m/ processed by each hearing aid condition (a) unaided; (b) linear; (c) WDRC; (d) NLFC.

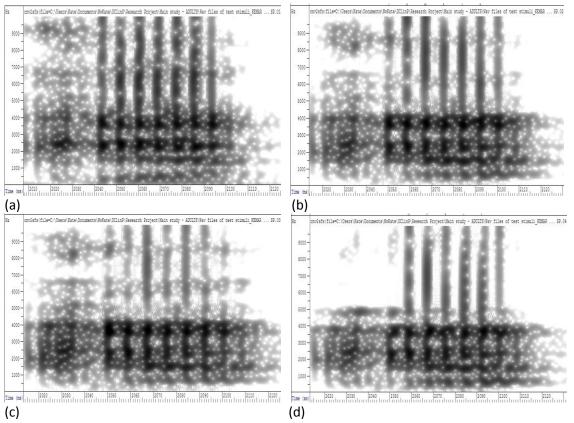


Figure 5.4.2.2: Spectrograms of speech sound /g/ processed by each hearing aid condition (a) unaided; (b) linear; (c) WDRC; (d) NLFC.

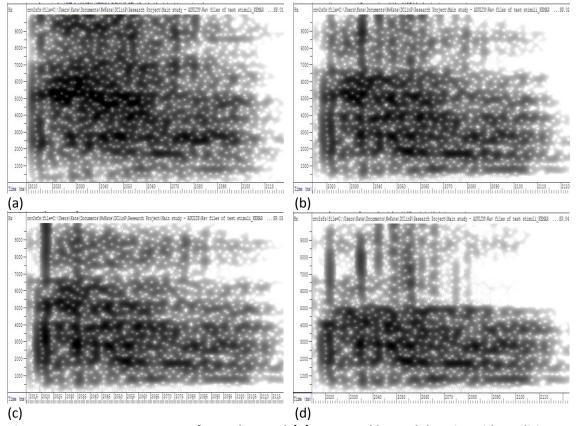


Figure 5.4.2.3: Spectrograms of speech sound /t/ processed by each hearing aid condition (a) unaided; (b) linear; (c) WDRC; (d) NLFC.

Stimulus		f0 (Hz)	f1 (Hz)	f2 (Hz)	f3 (Hz)	f4 (Hz)
unaided	/m/	90	1244	2454	3403	4044
	/g/	167	1755	2423	3716	4140
	/t/	-	1989	2732	3825	5224
linear	/m/	90	1054	3437	3994	5143
	/g/	142	1767	2434	3616	3989
	/t/	-	902	1884	2777	5071
WDRC	/m/	90	1106	3424	3984	5173
	/g/	142	1740	2477	3594	3916
	/t/	-	892	1861	2772	5066
NLFC	/m/	90	1022	2411	3394	3782
	/g/	119	1789	2428	3717	4871
	/t/	-	830	1854	2762	4792

Table 5.4.2.1: Spectral content of each speech sound /m/, /g/ and /t/ processed in each hearing aid condition.

5.5. Summary of findings: adult normal hearing study

The key findings concluded from the ALR results obtained in the adult normal hearing study and speech sound analysis are summarised as follows:

- ALRs were present in 96% of test conditions.
- There was no significant difference between unaided ALRs on test retest measures suggesting good repeatability.
- Unaided amplitude was significantly larger than aided amplitude in all conditions.
- Unaided latencies were significantly earlier than aided latencies in the majority of conditions. For N1, these were WDRC and NLFC HA conditions and for P2, linear and WDRC HA conditions.
- ALRs evoked with NLFC active were not significantly different to those without.
- Amplitude but not latency was significantly different between the speech sounds with the largest difference between /m/ and /g/, and /m/ and /t/.

- Rms analysis of the first 30 ms from the start of the stimulus waveform showed
 unaided stimuli were larger in magnitude than aided stimuli, consistent with the
 patterns in ALR amplitude. The magnitude of /g/ was consistently smaller than /m/
 and /t/ across condition, again consistent with the pattern of ALR results, but /t/ was
 always larger than /m/ which does not correlate with the ALR results.
- A delay to the start of the waveform is evident in the hearing aid processed conditions.
- The hearing aid reached maximum gain in the first 30 ms from the start of the waveform.
- Spectral analysis showed the hearing aid restricted frequency content below approximately 5 kHz compared to the unaided sounds. This effect was strongest when NLFC was active for the speech sounds /g/ and /t/.

Chapter 6. Discussion of the effects of hearing aid processing on ALRs in adults

6.1. Differences in the ALR waveform between unaided and aided test conditions

N1-P2 amplitude was found to be significantly larger for the unaided test condition compared to the aided test conditions and not significantly different between the aided conditions. This finding held across all the three speech sounds /m/, /g/ and /t/. N1 and P2 latency were also found to be significantly shorter in the unaided conditions compared to most of the aided conditions. This finding is consistent with previous suggestions by Billings et al (2007) when they found no effect of 20 dB of gain in amplification between unaided and aided conditions for a normal hearing adult group. However, their results showed no significant differences between unaided and aided amplitude and latency of the components in the ALR waveform (Billings et al 2007). This is different to the findings of the current study and may be due to their use of a digitally programmable analogue hearing aid (Billings et al 2007) different to the digital hearing aid used in the current study with advanced compression technology and altered time delay.

6.1.1. Effect of signal to noise ratio

Differences in SNRs of stimuli processed by hearing aids have been reported in the literature to alter the evoked ALR waveform (Billings et al 2009, Billings et al 2011a). SNR differences were estimated in the current study using F_{sp} analysis to be up to 20 dB better in the aided conditions than the unaided condition. Extrapolating from the data of Billings et al (2009) for a 1 kHz tone at 75 dB SPL, N1-P2 amplitude showed a mean reduction of the order of 2 μ V when SNR decreased by 20 dB, from +20 dB to 0 dB SNR. There was an increase in latency of the order of 20 ms for N1 latency and of the order of 10 ms for P2 latency with the same 20 dB reduction in SNR. Changes appeared exponential approaching 0 dB SNR (Billings et al 2009, Whiting et al 1998). There are difficulties directly extrapolating the data from Billings et al (2009) to the current study since different stimuli types were used in each study which was reported by Billings et al (2011) to evoke differences in the subsequent ALR response. However, since the SNR was estimated to be better in the aided conditions than the unaided condition in the current study, the findings of Billings et al (2009) would predict that the aided N1-P2 amplitudes should be larger than the unaided and the aided N1 and P2 latencies shorter than the unaided in the current study. This is the opposite to what was found, rejecting the

argument that SNR accounts for the differences in the ALR waveforms between the unaided and aided conditions in the current study.

6.1.2. Effect of hearing aid signal processing: speech sound waveform alterations

An alternative explanation is that the hearing aid processing acts on the stimulus in such a way that it impacts on the amplitude and latency of the aided responses compared to the unaided responses. Digital hearing aids are known to introduce a delay to the sound presentation (Dillon 2001). This is evident in the KEMAR recorded sounds depicted in Figures 5.4.1.1 and 5.4.1.2 of section 5.4.1 with the delay of approximately 7 ms in the HA processed tone compared to the unaided tone comparable to the increase in peak latencies of the ALR response in the aided conditions. It would suggest the hearing aid delay is the most likely explanation for the differences in ALR latencies.

Previous literature has suggested that the first 30 ms of a signal determines the morphology of the ALR response (Onishi and Davis 1968). Marynewich et al (2010, 2012) and Jenstad et al (2012) suggest that digital processing delays the rise time and reduces the maximum stimulus gain for a 1 kHz tone in this region such that amplitude of the aided ALR is reduced. In contrast to this conclusion, the results of the current study show that the hearing aid in each condition of the current study for the reference 1 kHz tone (Figure 5.4.1.2) reaches its maximum gain before 30 ms but then decreases in amplitude as compression is activated before stabilising within the time window. However it is not clear from Figure 5.4.1.2 how compression would be activated by speech sounds. Overall loudness of the stimuli in this experiment was controlled by the use of dB nHL, but the relative loudness of the first 30 ms of the stimulus may depend on the effect of compression. The effect of compression on the first 30 ms of the speech sounds, at the levels they were presented to subjects, is shown in the rms analysis of Table 5.4.1.1. The patterns in rms amplitude of the first 30 ms of stimuli, show that the unaided stimuli were larger in magnitude than the aided stimuli and that aided stimulus magnitudes were similar, which is consistent with the pattern of ALR results for N1-P2 amplitude seen in Figure 5.3.4.1(a) with an increase in unaided to aided conditions, but with no differences between aided conditions. This supports previous suggestions by Onishi and Davis (1968) that ALR amplitude depends on the waveform of the first 30 ms of the stimulus.

6.1.3. Effect of hearing aid signal processing: speech sound spectral alterations

In addition to processing delays and compression characteristics, digital hearing aids introduce a level of frequency shaping to sounds (Dillon 2001). Comparison of the spectrograms across hearing aid conditions in Figures 5.4.2.1, 5.4.2.2 and 5.4.2.3 of section 5.4.2, showed that the hearing aid restricted the frequency content of the speech sounds to up to around 4-5 kHz compared to the unaided speech sounds, which showed greater spread of frequencies. In addition, the speech spectra across hearing aid processed conditions overall appeared similar, although frequencies were more strongly compressed when NLFC was active for speech sound /g/ and /t/ than their respective linear or WDRC aided processing. The reduction in frequency content in the aided conditions compared to the unaided condition follows the pattern of reduced ALR amplitude in the aided responses compared to the unaided and may also indicate that frequency shaping introduced by digital hearing aid processing influences the ALR response.

6.2. Differences in the ALR waveform between the different speech sounds

A relationship between stimulus frequency and latency of the peaks in the ALR waveform has been suggested in the literature with latency increasing as frequency decreases (Martin et al 2007). Results of the current study however show no significant effect of speech sound on either the latency of N1 or P2. Agung et al (2006) similarly report no simple pattern of latency differences across speech stimuli.

The results of the current study showed a significant difference in N1-P2 amplitude between all of the speech sounds /m/, /g/ and /t/ independent of hearing aid effects (Figure 5.3.5.1). This significant difference cannot be explained by overall differences in intensity of the sound presentation level since this was controlled for by calibrating in the dB nHL scale. Possible causes for the difference may include differences in the first 30 ms of the stimuli due to hearing aid processing or the differing frequency content of the speech sounds. The largest difference was recorded between the pairs /m/ and /g/, and /m/ and /t/ with /m/ having a larger mean amplitude than /g/ or /t/ of the order of 2 μ V. The amplitude of /g/ was slightly smaller than /t/. This finding is similar to that of Munro et al (2011) who found a statistical difference between the waveforms obtained from /m/ and /t/ and /m/ and /g/ and identified differences in the mean waveforms between /t/ and /g/ that did not however reach statistical significance. It is also consistent with other reports in the literature noting that speech sounds

with dominant spectral energy in the lower frequencies (such as /m/) evoked significantly larger responses than speech sounds with higher frequency content (such as /g/ and /t/) (Agung et al 2006, Martin et al 2007).

6.2.1. Speech sound waveform differences

From the rms analysis of the first 30 ms of stimuli, shown in Table 5.4.1.1 of section 5.4.1 and Appendix 9, the stimulus /g/ was consistently smaller in magnitude than /m/ and /t/, matching the reduced ALR amplitude of /g/ compared to /m/ and /t/. However the rms values for /t/ were always larger than /m/, opposite to the results of ALR amplitude, where N1-P2 amplitude for /t/ was smaller than /m/. This suggests that differences in the stimulus waveform in the first 30 ms can only partially account for the ALR amplitude differences between speech sounds in this study.

6.2.2. Speech sound spectral differences

Comparing spectrograms of the speech sounds /m/ and /t/ (Figures 5.4.2.1 and 5.4.2.3, section 5.4.2), /t/ appears more dispersed across a greater spread of frequencies and with higher frequency content than /m/, independent of hearing aid condition. This might predict greater neural activity for speech sound /t/ suggestive of resulting larger ALR response amplitudes, however this is not consistent with the findings. In addition, spectral analysis identifies larger differences when NLFC is active, with an increased restriction of frequencies, compared to the linear and WDRC aided conditions in particular for speech sounds /g/ and /t/, however this was not evident in the ALR results. It would suggest the ALR is less sensitive to finer spectral frequency differences than changes in stimulus magnitude differences.

6.2.3. Tonotopic organisation of the auditory cortex

Differences in the ALR waveform evoked by different speech sounds have also been reported in the literature to reflect tonotopic organisation of the human auditory cortex (Agung et al 2006, Forminasso et al 2003, Talavage et al 2004, Woods and Alain 2009, Langers and van Dijk 2011) offering an alternative explanation for the current ALR results between speech sounds /m/ and /t/. Earlier studies into the organisation of the human auditory cortex evidenced two regions of activity stimulated by lower frequency sounds and higher frequency sounds (Romani et al 1982, Wood and Alain 2009, Langers and van Dijk 2011). Cortical areas that responded to

low frequency auditory information were located closer to the surface of the scalp than cortical regions that responded to high frequency information (Yetkin 2004). As such, energy would be dissipated for higher frequency sounds with greater distance travelling to the surface electrodes thereby reducing the magnitude of the recorded response. These studies adopted electroencephalographic (EEG) and magnetoencephalographic (MEG) methodologies to collect data (Romani et al 1982, Woods and Alain 2009, Langers and van Dijk 2011) based on the assumption that the active cortical region can be represented by a current dipole allowing for its location to be determined inside the brain (Romani et al 1982) and subsequently the construction of a map against stimulus frequency (Romani et al 1982, Langers and van Dijk 2011). These methodologies however were limited by coarse spatial resolution and the number of reconstructable dipoles restricting the detail of the map (Woods and Alain 2009, Langers and van Dijk 2011). Despite this, evidence emerged using these methodologies of a complex model showing multiple tonotopic progressions existing simultaneously (up to as many as 6) (Langers and van Dijk 2011, Forminasso et al 2003, Talavage et al 2004) and mirror imaged across adjacent subdivisions of the primary auditory cortex (Langers and van Dijk 2011, Forminasso et al 2003).

Later research using functional Magnetic Resonance Imaging (fMRI) to analyse location of activity to sound frequency in the human auditory cortex (Talavage et al 2000, Talavage et al 2004, Woods and Alain 2009, Langers and van Dijk 2011) provided the advantage of improved spatial and temporal resolution improving the accuracy of the map. Results have been inconsistent across studies however increasing the difficulty of definitively establishing the tonotopic organisation in the human auditory cortex (Langers and van Dijk 2011). Various factors complicate the interpretation of results. The functional structures of the auditory cortex are complex and cannot be designated to one specific anatomical landmark. At the same time, activity in the auditory cortex is influenced by additional parameters to frequency such as sound intensity and state of attention (Woods and Alain 2009, Langers and van Dijk 2011). Differences in experimental paradigm across studies therefore influence the resulting tonotopic organisation (Langers and van Dijk 2011). Often louder stimulus levels and the use of task relevant attention mechanisms were adopted resulting in spread of activation (Langers and van Dijk 2011) reducing accuracy of the map.

Langers and van Dijk (2011) attempted to overcome methodological difficulties by presenting task irrelevant unattended low level stimuli to avoid excessive spread of sound evoked activation. High resolution fMRI images were attained to detect responses to tone stimuli

spanning the octave bands from 0.25 kHz to 4 kHz. Two stimulus intensities were employed that were relatively low but that differed by 20 dB and were presented in the absence of acoustic scanner noise to control for signal to noise ratio. The sound levels were equalised across frequency within subjects by using the dB HL scale. A relatively large group of 20 subjects was included (Langers and van Dijk 2011). Their data showed that in general the louder stimuli always resulted in stronger activation than the softer stimuli and that the lower frequency stimuli also tended to result in stronger activation than higher frequency stimuli (although the 0.25 kHz stimuli was slightly less activating than the 0.5 and 1 kHz). Notable location differences were further observed between low and high frequency stimuli and three frequency progressions found. The lower frequency stimuli resulted in large activation clusters in one central location peaking in the lateral Heschl's Gyrus. In contrast, two separate end points were distinguished for the higher frequency stimuli, one on the posterior side of medial Heschl's Gyrus and one on the anterior side of medial Heschl's Gyrus. This is shown in the diagram from Langers and van Dijk (2011) given in Figure 6.2.3.1. In addition, their analysis revealed a posterior secondary low frequency end point, which was accompanied by another gradient reversal. This points towards the existence of an additional tonotopic gradient in the planum temporale (PT) (Langers and van Dijk 2011).

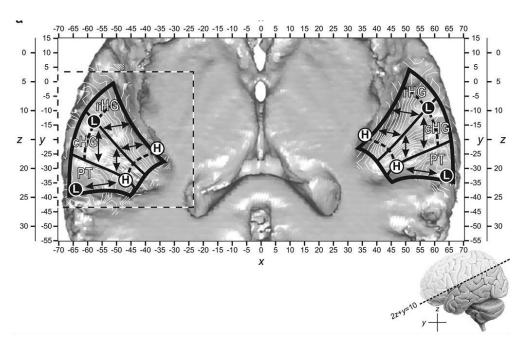


Figure 6.2.3.1. Tonotopic organisation of the primary auditory cortex identifying three tonotopic progressions on rHG (Heschyl's Gyrus), cHG (Heschyl's Gyrus) and PT (Planum Temporale). L indicates low frequency activation, H indicates high frequency activation. Reproduced with permission from Langers and van Dijk (2011).

Although Talavage et al (2000, 2004) published a pair of studies that identified 7 or 8 low and high frequency endpoints (2004 and 2000 respectively) connected by up to 6 tonotopic progressions (Talavage et al 2004) suggesting a contradictory model of tonotopic organisation to that of Langers and van Dijk (2011), other more recent studies using fMRI in humans appear to substantiate the findings of Langers and van Dijk (2011) with close resemblance between tonotopic maps (Humphries et al 2010, Woods and Alain 2009, Striem-Amit et al 2011). In addition 3 of the progressions documented by Talavage et al (2000, 2004) were reminiscent of the tonotopic progressions documented by Langers and van Dijk (2011). Woods and Alain (2009) further reported a relatively consistent tonotopic organisation emerging across studies once differences in experimental design were subjected to meta analysis and results projected on to average cortical surface anatomy.

These more recent reports confirm original understanding of a low-high tonotopic frequency gradient with increasing depth in the human auditory cortex, but they also imply that activity is also more disperse for higher frequency sounds. As such, energy would be dissipated for responses to higher frequency sounds due to greater distance to the surface electrodes and more dispersed activation regions, thereby reducing the magnitude of the recorded response. Such an effect might explain the reduced amplitude of the /t/ response compared to /m/ in the current study despite the fact that the /t/ stimulus has more energy that /m/ in the first 30 ms.

The literature is dominated by reporting tonotopic organisation of the primary auditory cortex however (Woods and Alain 2009, Langers and van Dijk 2011) the peaks in the obligatory auditory late response, in particular N1 and P2 which individually have multiple components, are known to be primarily generated by the primary and secondary auditory cortex and to a lesser extent by non auditory specific areas (Stapells 2002, Martin et al 2007). Less is known about the frequency interaction with the organisation of the secondary auditory cortex. However when the auditory late response is measured using an electrode on or near the vertex (Cz) and with a relatively short ISI of 3 seconds or less (as was the case in this study), it is thought to be the first component within N1 that is predominantly measured and this is generated in the primary auditory cortex (Stapells 2002, Martin et al 2007). In addition, although the generators of P2 are less understood, it is thought to have a centre of activity near Heschyl's gyrus of the primary auditory cortex (Stapells 2002, Martin et al 2007). This knowledge may imply that tonotopic organisation documented for the primary auditory cortex may be generalised to the N1-P2 results of this study.

6.3. Validity of the findings

A power calculation for the study showed that 20 adult subjects were required to detect any significant differences in the data with a power of 80%. Whilst 20 subjects were tested, only data from 16 could be included in the final statistical analysis. Data from 3 subjects was excluded due to poor quality in the ALR response. Although recording quality was good for the 16 subject majority, it suggests the ALR is not necessarily the test of choice in some individuals and for the most part this was due to subject restlessness. As the study did not quite reach a sample size of 20, the study is possibly underpowered which might have affected conclusions drawn for results that were found not significant (namely test-retest reliability, N1-P2 amplitude between the aided conditions, unaided-linear N1 latency, unaided-NLFC P2 latency and N1 and P2 latency between the speech sounds). However, as these effect sizes would likely be small, any differences that might become significant using a larger sample size may have limited clinical significance. Sample size may also have affected the significant conclusion that N1-P2 amplitude was different between speech sound /g/ and /t/, where a small difference was found. However, effect sizes calculated for all the findings shown to be significant were larger than 1, ranging from 1.26 to 4.14, which are considered to be large effect sizes, suggesting the study had sufficient power to detect key differences between conditions.

The conclusions from the current study suggest ALRs can be recorded using hearing aids but are drawn from a normal hearing adult population and may not be directly transferrable to a hearing impaired population. The findings do suggest that deactivation of digital features on a hearing aid may not necessarily alter the aided response however this conclusion can only be generalised to the hearing aid used within this study and perhaps to other hearing aids from the same manufacturer adopting similar technologies. The study would imply however that analysing how any hearing aid alters the spectral, temporal and waveform envelope of the stimulus is important to check prior to attempting ALR recording.

The results from this study were obtained using short duration test sounds. Although the short duration sounds were found to reach their maximum gain, show compression and then stabilise when processed by the hearing aid within the 30 ms time period that is thought to evoke the ALR, the presence of a response indicating audibility of such a sound cannot necessarily indicate that a longer duration sound (relevant to real life speech) also remains audible.

6.4. Conclusions: adult normal hearing study

- Auditory late responses can be reliably recorded through a digital hearing aid when different signal processing strategies are activated, including NLFC.
- Unaided responses were found to be larger in amplitude and shorter in latency than aided responses.
- The signal to noise ratio of the test sound recordings was higher for the hearing aid conditions than the unaided condition so the ALR results do not appear to be explained based on stimulus SNR.
- The hearing aid had an overall effect on the ALR responses likely due to the delay,
 compression characteristics and frequency shaping introduced by digital processing.
- The morphology of the ALR response was predominantly influenced by the first 30 ms
 of the stimulus waveform. Waveform alterations did not however account for the ALR
 results in the case of /m/ and /t/ where instead tonotopic organisation of the auditory
 cortex offers an alternative explanation to this finding.
- The type of strategy used in the hearing aids showed no significant effect on the ALR response suggesting that the ALR is less sensitive to the changes when frequency content is altered, for example by NLFC.
- The hearing aid in this study reached its maximum gain and stabilised in the first 30 ms
 from sound onset so it appears the short duration sounds that evoke ALRs are suitable
 for use with hearing aids but may not necessarily generalise to indicate audibility or
 not of longer duration sounds.

Chapter 7. A feasibility study recording ALRs in infants wearing hearing aids

7.1. Aim: infant hearing impaired study

The final part of the research was to undertake an infant feasibility study to explore the use of ALRs in clinical practice as a method of indicating audibility from hearing aid fitting in infants identified early with hearing loss. The main aims were to:

- Explore the feasibility of using ALRs to indicate audibility to speech sounds in infants wearing digital hearing aids.
- 2) Determine any effect on the response due to non linear frequency compression digital hearing aid technology.
- 3) Inform advancements in clinical practice of habilitation of babies detected early with hearing loss.

The study was designed to investigate the following research questions:

- 1) Is there any significant difference in the aided ALR response* compared to the unaided response when recorded from two different speech sounds, /m/ and /t/?
- 2) Is there any significant difference in the aided ALR response* recorded from the two different speech sounds when non linear frequency compression is active compared to not?
- 3) Is there any significant difference between ALRs* recorded from the two different speech sounds?

These generate the null hypotheses:

- 1) There is no significant difference between the aided ALR response* compared to the unaided response when recorded from two different speech sounds, /m/ and /t/.
- 2) There is no significant effect of non linear frequency compression on the ALR response* recorded from the two different speech sounds.
- 3) There is no significant effect of speech sound type on the ALR waveform*.

7.2. Methodology: infant hearing impaired study

Approval for the infant clinical study was obtained from the University of Southampton Faculty of Engineering and the Environment Ethics committee and NHS ethics committee.

^{*}peak-peak amplitude of P1-N1 and/or latency of P1

Subjects were recruited from patients of the Audiology department Royal Berkshire NHS Foundation Trust, where the researcher is employed. There are relatively small numbers of babies born with bilateral permanent hearing impairment and around 8-10 infants would be expected to be diagnosed in a year at the Royal Berkshire Hospital. Five infants were recruited within the 6 month timeframe available for completing data collection. The infants were between 5 and 6 months of age, were identified early with bilateral deafness (using frequency specific standard clinical tests) and fitted to real ear Desired Sensation Level (DSL) prescription targets with digital hearing aids and non-linear frequency compression available. Details of audiometric configuration and hearing aid settings are given in section 7.3. Subjects were included if their parent/guardian was able to provide informed consent. Subjects were excluded if tympanometry indicated middle ear effusion in both ears on the day of testing and/or if they were wearing their hearing aids for less than three hours each day.

The test stimuli used were the naturally produced speech sounds /m/ and /t/ from the normal hearing adult study with 100 ms duration (including rise/fall time of 20 ms to avoid audible clicks) and inter-stimulus interval of 3 seconds. These speech sounds were chosen since they showed a large difference in ALR responses in the adult study, provide a range in frequency across low and high frequencies and frequency compression interacts the most with the higher frequency speech sound /t/. They were presented at an rms level of 65 dB SPL (Appendix 10) from a Fostex 6301BX loudspeaker, 1 m distance, ear level height and 0° azimuth. Auditory late responses were recorded using a repeated measures design in three hearing aid conditions: without hearing aids; with hearing aids and non linear frequency compression inactive (WDRC); with hearing aids and non linear frequency compression active (NLFC). Testing was completed over 2 sessions of approximately 1½ hours each and at least one month post hearing aid fitting. Order of test condition was randomised. Testing was carried out in a sound treated room and participants were distracted by a second tester with quiet toys. Parents were aware that testing could stop if their child became very restless, sleepy or it was requested by the parent.

The evoked responses were recorded using a CED 1401 mk II laboratory interface and CED 1902 isolated amplifier, with Signal software v4.02, which also triggered sound generation. Disposable surface electrodes were placed on the head of each infant, positioned at high forehead referenced to the right mastoid with low forehead as ground. Impedances were maintained at \leq 5 k Ω . Each individual repeat of EEG activity was amplified by 1000 and filtered

offline from 1-15 Hz using a 700 ms analysis time window, including 100 ms pre-stimulus baseline. Artefact rejection was set at $\pm 80~\mu V$ and performed offline. 50 repeats were recorded per average (to ensure reasonable test time) and two averages recorded per condition. The ALR peak amplitude of P1-N1 and latency of P1 were the primary outcome measures and were identified as the largest positive-negative peak in the region 200-500 ms post stimulus onset for each subject. In addition, off line statistical analysis of the data was carried out to objectively determine the presence of a response from background noise using an F_{sp} measure of quality based on Elberling and Don (1984) and bootstrap analysis (Lv et al 2007) to determine statistical significance of the F_{sp} .

A summary of the stimulus and recording parameters is given in Table 7.2.1.

Stimulus parameters	Recording parameters
Stimulus type:	Electrode configuration:
/m/, /t/ (cropped from VCV clusters)	Channel 1: Fz – right mastoid (record
0.4 kHz, 4 kHz respectively	ALR)
unaided, WDRC, NLFC	Ground: forehead
	Inter-electrode impedances: ≤5 kΩ
Stimulus duration:	Recording window:
100 ms	100 ms pre-stimulus to 600 ms post
	stimulus
Rise/fall times:	High pass filter:
20 ms with 60 ms plateau	1 Hz (24 dB/octave) online and offline
	Low pass filter:
	100 Hz (24 dB/octave) online;
	15 Hz (24 dB/octave) offline
Inter-stimulus interval:	Amplifier gain:
3 seconds	1 000 CED gain; x1 electrode head box
	gain
Stimulus randomisation:	Artefact rejection:
0%	All offline
	Limits set to ±80 μV (160 μV peak-to-
	peak)
Stimulus transducer:	Number of repeats pre artefact rejection:
Fostex 6301BX loudspeaker	50 repeats
1m distance, 0° azimuth, ear level height	2 averages per condition

Table 7.2.1: Stimulus and recording parameters used in the infant hearing impaired study.

Real ear probe microphone measures were recorded for each infant using an Audioscan Verifit VF1 hearing instrument test box to measure sound pressure level at the ear drum. A probe microphone was placed in the infant's better hearing ear, measured at 11 mm from the entrance to the ear canal or no further than 4 mm beyond the end of the ear mould (Bagatto et al 2006), along with their ear mould coupled to their hearing aid. The test sounds were presented, maintaining the test position of the infant, and the sound pressure level at the ear drum recorded using the 'speech live' function within the on-ear mode of the Audioscan Verifit system for each of the aided conditions. This was displayed for comparison against the infant's hearing levels in dB SPL.

7.3. Audiometric and hearing aid data of the infant subjects

Of the five infants (4 male, 1 female) who participated in the study, the four male infants had mild-moderate symmetrical hearing loss in both ears. The one female infant had asymmetric hearing loss in the moderate range for her better hearing ear (right ear) and at least severe in her worse hearing ear (left ear). A summary of the audiometric data of all five subjects is given in Table 7.3.1 where better hearing ear thresholds in dB estimated HL (dB eHL) corrected from tone burst auditory brainstem response testing are displayed:

Participant	Age	Gender	Hearing thresholds (dB eHL) better hearing ear			
			500	1000	2000	4000
1	6m	М	45	-	55	60
2	5m	М	40	45	-	60
3	5m	F	75	55	75	60
4	5m	М	25	30	-	40
5	6m	М	30	40	35	40

Table 7.3.1: Summary of audiometric data of the better hearing ear in dB eHL for the infant subjects.

The five infants were fitted with bilateral Phonak digital hearing aids to DSL version 5, matching target to within 2-5 dB. NLFC was active. The four male infants had aided speech intelligibility index scores that ranged between 75 and 90 for a 65 dB SPL input level. The female infant with asymmetric hearing loss had an aided speech intelligibility index score of 60 for her better hearing ear with input level of 65 dB SPL. A summary of the hearing aid settings are given in Table 7.3.2:

Participant	Time wearing	HA model	WDR	С	NLFC		Attack time
	HAs		Kneepoint	Ratio	kneepoint	Ratio	
1	3 mth	Phonak Nios	<40 dB	2:1	3.2 kHz	2.4:1	10-20 ms
2	4 mth	Phonak Nios	<40 dB	2:1	3.2 kHz	2.4:1	10-20 ms
3	1 mth	Phonak Naida SP	<40 dB	2:1	3.2 kHz	2.4:1	10-20 ms
4	3 mth	Phonak Nios	<40 dB	1.5:1	3.2 kHz	2.4:1	10-20 ms
5	4 mth	Phonak Nios	<40 dB	1.5:1	3.2 kHz	2.4:1	10-20 ms

Table 7.3.2: Summary of hearing aid settings worn by the infant subjects.

7.4. Results from ALR recordings: infant hearing impaired study

Data from all five subjects met the criteria for inclusion in the data analysis. SPSS was used to perform statistical analysis on the ALR P1-N1 peak-to-peak amplitude and P1 latency data. The Shapiro-Wilk test of normality showed that the data was normally distributed and parametric statistics were therefore adopted in the data analysis. Since the sample size was small, however, which could bias estimation of the distribution, non parametric statistics were also performed and showed no difference in the findings.

Fifty repeats per average were recorded during data collection. Repeats were rejected offline post data collection if activity exceeded $\pm 80~\mu V$. Following artefact rejection it was found that less than 50 repeats were accepted in to the average in all cases. Data from two averages recorded per condition were therefore combined to increase the number of repeats and improve the quality of the ALR response, subsequently included in the analysis.

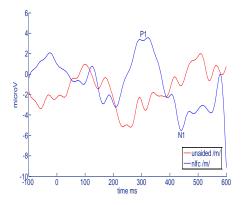
7.4.1. Investigating differences between ALRs from the different HA conditions: Research questions 1 and 2

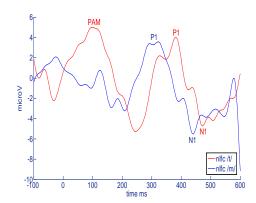
Of the 10 unaided ALR recordings (2 speech sounds from 5 subjects) only one (10%) was found to be statistically different from noise ($p \le 0.01$) for speech sound /m/ from subject 4. This coincides with his hearing level at 0.5 kHz reaching near normal (25 dB eHL) and might therefore be predicted. 90% of aided ALRs were present on statistical analysis (with $p \le 0.01$) when NLFC was active across the speech sounds and 80% of aided ALRs were present on statistical analysis (with $p \le 0.01$) when NLFC was inactive. This data is summarised in Table 7.4.1.1:

HA Condition	Number of significant responses (p≤0.01)	
	/m/	/t/
unaided	1/5	0/5
NLFC	4/5	5/5
WDRC	4/5	4/5

Table 7.4.1.1: Number of present ALR responses in each HA condition.

All the infant ALR waveforms are given in Appendix 11. Example ALR waveforms that represent the differences in unaided, WDRC aided and NLFC aided conditions are given in Figure 7.4.1.1. It can be seen that the P1-N1 peak in the region 200-500 ms post stimulus onset appears most prominent in this group of 5-6 month old infants. This is different to some areas of the literature which define a broad P1 peak around 200 ms after stimulus onset (Dillon 2005) but is more comparable to other studies documenting a dominant P1 peak at around 100-300 ms after stimulus onset followed by a late negativity at about 300-350 ms (Ponton et al 1996, Sharma et al 2002, King et al 2008, Purdy et al 2013). The post auricular muscle response (PAM response) is also apparent in the 100-200 ms region of the waveform for the speech sound /t/ in Figure 7.4.1.1 as documented elsewhere in the literature for high frequency sounds (Purdy et al 2005, Purdy et al 2013). The peaks of the PAM, P1 and N1 in most of the infant ALR waveforms of the current study shown in Figure 7.4.1.1 and Appendix 11 appear to show some delay in latency compared to that described in the literature that details the same three peaks, with an example given from Purdy et al (2013) in Figure 7.4.1.2 of group data from normal hearing infants.





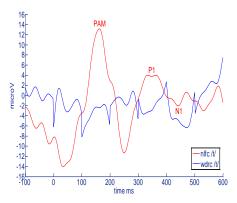


Figure 7.4.1.1: Example infant ALRs illustrating different hearing aid conditions. P1-N1 peaks are marked for waveforms with significant F_{sp} values p≤0.01.

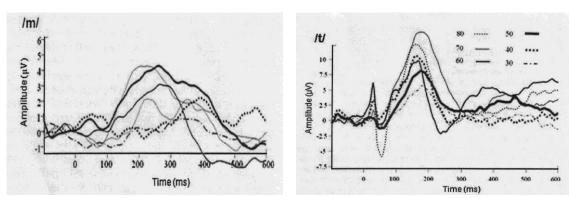


Figure 7.4.1.2: Grand average ALR waveforms for normal hearing infants (n = 6-8 infants per waveform, mean age 5.6 months \pm 2.6 months), showing P1 at \sim 150-200 ms and N1 at \sim 250-300 ms for speech sounds /m/ and /t/. The PAM response is evident at high intensity levels in the /t/ waveforms at \sim 20-50 ms. Reproduced with permission from Purdy et al (2013).

Real ear probe microphone measurements for each subject indicated that SPL recorded at the ear drum for the aided speech sounds in the WDRC condition (NLFC inactive) were louder than individual hearing levels in all subjects for speech sound /m/ and 4 out of 5 subjects for speech sound /t/, suggesting audibility of the sounds. When NLFC was activated, SPL at the ear drum for speech sound /t/ became louder than hearing levels for all subjects shown on probe microphone measures and /m/ continued to be audible for all subjects. An example real ear probe microphone measure indicating an improved sensation level around 4 kHz for the speech sound /t/ with NLFC active (pink curve) compared to inactive (green curve) against the infant's hearing levels (in red) is given in Figure 7.4.1.3. Probe microphone measurements for all subjects and speech sounds are given in Appendix 12.

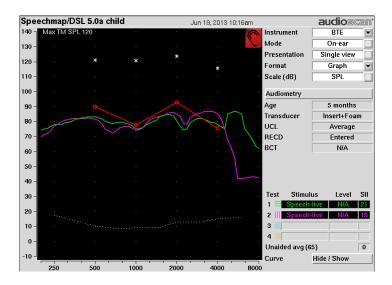
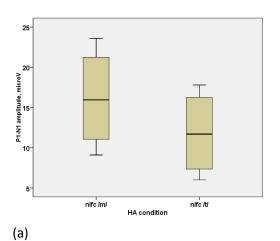
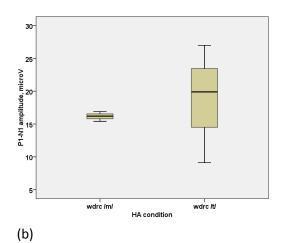


Figure 7.4.1.3: Real ear probe microphone measurement in dB SPL illustrating increased sensation level around 4 kHz of speech sound /t/ with NLFC active (pink curve) compared to inactive (WDRC condition green curve) against the infant's hearing levels (in red).

7.4.2. Investigating differences between ALRs from the different speech sounds: Research question 3

Paired samples t-tests were used to investigate any significant differences in the aided ALR waveforms evoked from the two different speech sounds. There were no significant differences found in this small infant group between the speech sounds, /m/ and /t/ for either P1-N1 amplitude, illustrated by the box plots in Figure 7.4.2.1, or P1 latency, in Figure 7.4.2.2, across any of the hearing aid conditions. The data is given in Table 7.4.2.1. The analysis therefore accepts the null hypothesis that there is no significant difference between the ALR responses recorded from the different speech sounds for this small subject group.





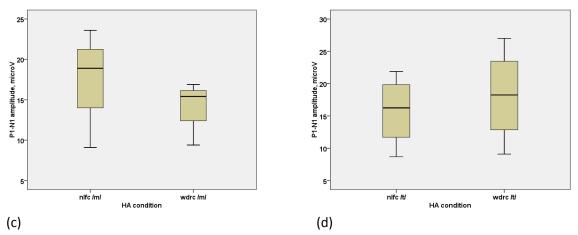


Figure 7.4.2.1: Aided P1-N1 amplitude median differences between speech sounds (*p≤0.05): (a) NLFC /m/-NLFC /t/; (b) WDRC /m/-WDRC /t/; (c) NLFC /m/-WDRC /m/; (d) NLFC /t/-WDRC /t/.

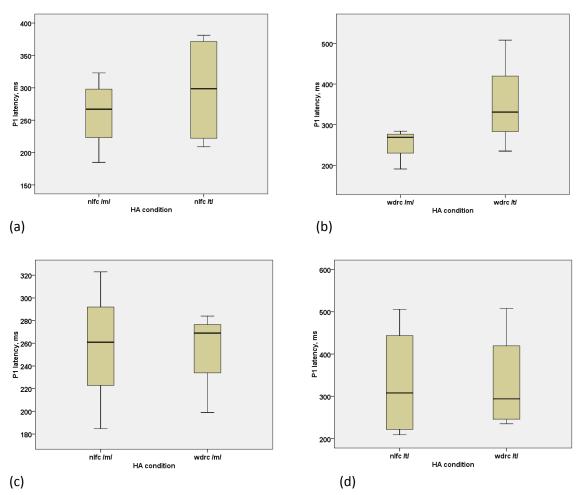


Figure 7.4.2.2: Aided P1 latency median differences between speech sounds (*p≤0.05): (a) NLFC/m/-NLFC/t/; (b) WDRC/m/-WDRC/t/; (c) NLFC/m/-WDRC/m/; (d) NLFC/t/-WDRC/t/.

Pair	s of averages		Paired Difference	es	Significance (2-tailed) (p<0.05 is significant)		
		Mean	95% confidence differences	e interval of the			
			Lower	Upper			
P1-N1 amplitude	NLFC /m/ - NLFC /t/	4.34	-9.83	18.53	0.401		
	WDRC /m/ - WDRC /t/	-2.50	-23.77	18.77	0.663		
	NLFC /m/ - WDRC /m/	3.30	-22.32	28.92	0.635		
	NLFC /t/ - WDRC /t/	-2.38	-5.51	0.76	0.095		
P1 latency	NLFC /m/ - NLFC /t/	-36.30	-206.36	133.76	0.546		
	WDRC /m/ - WDRC /t/	-110.00	-566.55	346.55	0.409		
	NLFC /m/ - WDRC /m/	5.60	-66.67	77.87	0.771		
	NLFC /t/ - WDRC /t/	0.00	-63.70	63.70	1.000		

Table 7.4.2.1: Paired samples t-test analysis of aided ALRs between speech sounds.

7.5. Summary of findings: infant hearing impaired study

The key findings concluded from the results obtained in the infant hearing impaired study are summarised as follows:

- ALRs are recordable in infants aged between 5-6 months in a clinical environment.
- There were clear differences between aided and unaided ALRs with the majority of aided responses present on statistical analysis and only 10% of unaided responses present.
- In general, there was no difference in ALR responses present between WDRC and NLFC conditions for speech sound /m/.
- Responses were present in all subjects for speech sound /t/ when NLFC was active but
 was only present in 4 of 5 subjects with NLFC inactive.
- A P1-N1 peak in the region of 200-500 ms post stimulus onset appeared most prominent in the ALR waveform for this group of 5-6 month old infants.
- Some delay in individual peak latency appeared evident in the current study compared to group data from normal hearing infants documented in the literature.
- There were no clear differences in the aided waveforms between the speech sounds in this small group.

7.6. Discussion: infant hearing impaired study

The results from this feasibility study demonstrate that ALRs are recordable in hearing impaired young infants whilst wearing hearing aids, consistent with the wider literature (Golding et al 2007, Chang et al 2012). Contrary to some areas of the literature, which details a broad late positive P1 peak around 200 ms after stimulus onset in young infants (Dillon 2005, Purdy et al 2005), a positive to negative peak, P1-N1, occurring between 200 ms and 500 ms instead appeared most prominent in the waveform in the current study. This appears more comparable to other studies documenting a dominant P1 peak at around 100-300 ms after stimulus onset followed by a late negativity at about 300-350 ms (Ponton et al 1996, Sharma et al 2002, King et al 2008, Purdy et al 2013). The PAM response documented to be present in an ALR recorded from high frequency sounds (Purdy et al 2005, 2013) was also present for the /t/ stimulus in the region 100-200 ms in the current study. However the peak latencies of most of the individual infant ALR waveforms of the current study appear to show some delay compared to that described by Purdy et al (2013) detailing group data from normal hearing infants (Purdy et al 2013). This may in part be due to 1) the delay introduced by digital hearing aid processing evident in the adult normal hearing study, described in section 5, (although this was relatively small at around 7 ms), 2) differences between study test parameters and individual sensation level of the sounds in the current study compared to the group data of Purdy et al (2013) which are known to influence the ALR response (Stapells 2002, Martin et al 2007, Billings et al 2011), 3) variability of individual waveforms compared to group waveforms (Stapells 2002) and 4) physiological effects of sensori-neural hearing loss on the ALR response (Sharma et al 2002).

There have been reports in the literature of substantial P1 latency reductions for children receiving early cochlear implantation (Dorman et al 2007) that exceed latency changes seen in normal hearing children when stimulus audibility improves and it has therefore been suggested that this change in P1 is reflecting more than just improved audibility in the cochlear implanted group (Purdy et al 2013). In addition, Sharma et al (2002) suggested that latency of P1 compared to normal hearing children could be an indicator of remaining plasticity in the auditory system, so any difference in ALR latency that might be attributable to the effects of sensori-neural hearing loss in the current study may be a significant indicator of auditory outcomes for an individual infant. It is difficult to fully understand this however since it is difficult to isolate any delay in latency due to physiological effects of the sensori-neural hearing loss from differences in study parameters. It suggests the importance of having access

to normative ALR latency data obtained from the same equipment set-up and infant age range by which to compare ALRs evoked from infants with hearing loss and wearing hearing aids.

Significant differences in ALR waveform presence between the hearing aid conditions appears most likely due to increased audibility. In the first instance, audibility is increased for aided compared to unaided hearing levels. In the second instance audibility of the high frequency speech sound /t/ was increased in one individual by the introduction of non linear frequency compression compared to the digital feature being deactivated, confirmed by real ear probe microphone measurements. Although this finding is apparent in only one subject and care must therefore be taken extrapolating conclusions to a wider population, this is consistent with one other study in the literature recording ALRs in teenagers whilst wearing hearing aids to high frequency tonal sounds with and without NLFC active (Glista et al 2012). It may therefore further support other claims in the literature that non linear frequency compression can improve access to high frequency sounds in some individuals (Simpson 2009). It also suggests the importance of verifying and evaluating the feature in individuals to determine the validity of introducing non linear frequency compression. Where NLFC was found to improve audibility of the high frequency /t/ speech sound in just 1 out of 5 of the infants, this may be due to the relatively flat and more mild-moderate hearing loss configuration of the subject group. NLFC is thought to be most beneficial where hearing loss is steeply sloping in the higher frequencies (Simpson 2009, Glista et al 2012). Furthermore, use of the stimulus /t/ may limit the effect of NLFC on the ALR waveform and a higher frequency speech sound such as /s/ may show greater effect.

In one individual (subject 5) there was no significant ALR response recorded from NLFC /m/ which was not expected, given the infants audiogram. Real ear probe microphone measures confirmed the sound was audible via the hearing aids when both NLFC was active and inactive (the WDRC condition). However the sensation level for WDRC /m/ was greater than NLFC /m/ compared to the infant's hearing levels (different to other subjects in the study where sensation levels were similar across NLFC or WDRC conditions) and this might therefore explain the lack of ALR response in the NLFC /m/ condition for this subject. This was not apparent for the speech sound /t/ in the same subject where sensation level was similar across hearing aid conditions and an ALR was present for both aided responses.

The comparison of ALR waveforms between speech sounds within the aided conditions showed no clear indication of differences for this subject group. Where this may be due to the

small sample size of the group, it may also be because hearing impaired listeners are known to have broader frequency tuning curves than do normal hearing listeners (Pickles 2008) and the ALR does not appear sensitive to show smaller differences in frequency content, as was indicated also in the adult study. Overall it appears that audibility over frequency is the more predominant indicator of the ALR response.

The results from this study were obtained from a moderate conversational rms sound level of 65 dB SPL and must be recognised as indicating audibility therefore at only these moderate levels. Further understanding of obtaining ALRs from quieter conversational levels, such as 55 dB rms SPL, is important for indicating an infant's functional access to sounds for speech and language development.

7.7. Clinical experience of recording ALRs in infant hearing impaired group

Undertaking this study with a group of hearing impaired infants showed that it was possible to record ALRs in young infants aged between 5-6 months in a clinical setting. Use of an experienced second tester to distract the infant and communicate awareness and state of the infant was paramount to successful results. All the infants remained in a good test state for the most part of the test session (1½ hours) with perhaps a short break. This was adequate time to gain useful clinical information regarding hearing aid audibility. Providing clear information to families of the requirements prior to the session optimised the testing, for example it was suggested to parents to bring along any favourite toys of the infant's, both quiet and perhaps noisy, to add to those available in the clinic. The noisy toys could be used as an alternative between recordings or for breaks and the quiet toys were used for distraction during the recordings. It was impossible to prevent some head movement and vocalisations for all the infants but where parents were well informed and the second tester experienced, it was possible to minimise them and it remained possible to record ALRs in these conditions.

Where all families were given the diagnosis of their child's hearing loss some 8-12 weeks earlier and no further hearing assessment was performed in between, all families were keen to participate in the testing, recognising the possibility of gaining beneficial information about their child's hearing to both corroborate, or not, the initial assessment results and find out their child's access to hearing with hearing aids. One mother commented 'it's really good the results are better with her hearing aids. It's what I thought from her responses' and another

commented 'it's helped keep me motivated to keep putting the hearing aids back in'. This same mother indicated 'wanting to know how it relates to a normal hearing child' highlighting the need for further work.

Current clinical guidelines suggest good practice is to have assessed and identified permanent hearing loss following newborn hearing screening by 3 months of age and to have fitted hearing aids within one month of diagnosis where appropriate and in conjunction with parental choice (NHS Newborn Hearing Screening Programme 2008). Frequent support should be provided in the early stages and regular ear moulds and real ear measures made. The first formal hearing aid review is then expected from around 5-7 months of age to start behavioural assessment in order to re-establish hearing levels and gain aided measures (NHS Newborn Hearing Screening Programme 2008). In the local region, infants born with hearing loss are often provided with their hearing aids between 2-3 months of age. Where literature and clinical experience shows it to be possible to gain a level of behavioural measurement from 5 months of age (Madell 2011) the response can take time to elicit and can be difficult to achieve in a routine clinical setting. Furthermore, parents have a high expectation of gaining reliable results that can corroborate, or not, the original results from electrophysiological assessment and this is not always achievable. Whilst guidelines suggest seeing families regularly until behavioural results are obtained, this is not necessarily feasible for the family. Instead, offering clinical assessment of aided-unaided outcomes using ALRs at around 5 months of age, as was the case with this study, seems an appropriate and family friendly alternative. At this stage, infants that are progressing along normal developmental milestones have established reasonable head control and can sit with support, facilitating good test conditions. Infants have also often established a reasonable sleeping pattern making it easier to decide optimal time for the appointment. Having gained indicators of aided-unaided measures of ALRs at this stage, seeing the family for the infant's next appointment within a 2-3 month time period allows the start of behavioural assessment to coincide with 7-8 months of age, increasing the chances of gaining reliable behavioural thresholds. The spacing of the appointments from fitting to outcome measures to behavioural assessment allows timely check of hearing aid fitting with real ear measures to account for the growing ear (where guidelines recommend real ear measures at least every 3 months for the first 2 years (NHS Newborn Hearing Screening Programme 2008)). Should results from the ALR session not be as expected, then it would indicate the need for a sooner appointment for further unaided hearing assessment. Discussion at this session with parents would help determine the most appropriate testing method for the individual infant taking in to consideration their young age

and development, whether to repeat electrophysiological testing (which would still be within a possible time period to perform relatively well) or attempt behavioural assessment.

7.8. Conclusions: infant hearing impaired study

- ALRs were recordable in an infant group whilst wearing hearing aids suggesting the
 procedure is feasible as an indicator of hearing aid audibility in this clinical population.
- ALR presence is a good indicator of improved audibility in different hearing aid conditions.
- The P1-N1 peak was the predominant waveform in this 5-6 month age group.
- Peak latency appeared delayed compared to group data from normal hearing infants and this may be significant to auditory outcomes when considering maturation and remaining plasticity of the auditory system.
- Non linear frequency compression appeared to increase audibility of the high frequency speech sound /t/ in one individual.
- There were no clear differences in the aided waveforms between the speech sounds in this small group. This may in part be due to widened frequency tuning curves in hearing impaired subjects and that the ALR is not sensitive to small differences in frequency.

Chapter 8. Conclusions and suggestions for further work

8.1. Conclusions

The research study was undertaken to develop understanding of using the auditory late response as a potential tool for evaluating hearing aid audibility and its feasibility for use with a population of hearing impaired young infants, where currently there is a gap in clinical guidelines. The morphology of the ALR is determined by stimulus variables. Since hearing aid processing modifies characteristics of a sound, it is important to understand how this might influence the ALR. The effect that digital hearing aid processing had on short duration speech sounds was explored and the test parameters to optimise the ALR were investigated before recording the potential in normal hearing adults whilst systematically altering the hearing aid strategy between unaided, linear gain, WDRC and NLFC. An objective measure to determine ALR response presence was incorporated to minimise variation of subjective tester interpretation. F_{sp} (based on Elberling and Don, 1984) was used which estimates the quality of the response and bootstrap analysis (Lv et al 2007) performed to determine statistical significance of the F_{sp} value from the background noise, where the properties of subject noise can vary. The test parameters and findings from the adult normal hearing study were adopted in developing the test strategy for the infant hearing impaired group. Real ear probe microphone measurements were further used in the infant study to determine the sound pressure level of the speech sounds at the ear drum when wearing hearing aids in relation to the infants hearing levels.

The objectives of the research, and a summary of how these have been addressed, are as follows:

 To understand the effects that different digital hearing aid processing strategies and different stimuli have on the auditory late response in a normal hearing adult subject group.

The results showed that unaided ALR responses were larger in amplitude and shorter in latency than aided responses when stimulus sensation level and signal to noise ratio were controlled. There was no significant difference in the responses between type of HA strategy including when NLFC was active or inactive.

Stimulus type showed a significant effect on amplitude but not latency of the response. For speech sound /m/ and /t/, the differences seen in amplitude may best be explained by the tonotopic organisation of the auditory cortex.

 To evaluate modifications in the test signal from hearing aid processing that might explain differences, if any, between aided and unaided auditory late responses.

Analysis of waveform differences of the first 30 ms of the stimulus and spectral differences between HA conditions suggest that digital HAs have an overall effect on the ALR response likely due to the delay, compression characteristics and frequency shaping introduced by digital processing. The ALR does not appear as sensitive to frequency alterations, for example when frequency content is altered by NLFC.

 To investigate the feasibility of using the auditory late response as an assessment tool for measuring hearing aid audibility in a group of hearing impaired young infants.

ALRs were recordable in young infants wearing digital hearing aids and were found to be a good indicator of improved audibility suggesting the tool is feasible as an assessment of hearing aid fitting in a young clinical group. NLFC active increased audibility of the high frequency speech sound /t/ in one infant (confirmed by probe microphone measurements) supporting other claims in the literature that non linear frequency compression may improve access to high frequency sounds in some individuals. In addition, the peak latency of the ALR in this hearing impaired group appeared delayed compared to group data from normal hearing infants and this may be significant to auditory outcomes when considering maturation and remaining plasticity of the auditory system (Sharma et al 2002, Purdy et al 2013).

8.2. Benefits of the study

The proposed benefits of the work described in this thesis are:

Confirmation that ALRs are recordable when wearing digital hearing aids and that the
hearing aid used reached its maximum gain and stabilised in the first 30 ms from sound
onset suggesting that the short duration sounds that evoke ALRs may be used with digital
hearing aids, contrary to recent literature (Marynewich et al 2012, Jenstad et al 2012).

- Understanding that analysing how any hearing aid alters the spectral, temporal and waveform envelope of the stimulus is necessary in predicting alterations to the resultant ALR waveform.
- Understanding that there is no difference in the ALR response recorded from different HA
 processing strategies used when audibility is controlled suggesting that it may not be
 necessary to deactivate digital features during testing.
- Evidence of the feasibility of using the ALR as a means of indicating audibility to sounds
 when compared to real ear probe microphone measures whilst wearing hearing aids for a
 clinical group of hearing impaired young infants thereby developing clinical practice and
 potential contribution to national clinical guidelines.
- Provision of valuable information to individual families of the access to sounds their child
 has whilst wearing their hearing aids, increasing motivation for use and supporting timely
 development of speech and language skills during a critical period.
- Development of bootstrap analysis of the F_{sp} with the ALR as an objective measure of statistical significance of the evoked response compared to background noise.

8.3. Limitations of the study

- The sample size of the adult normal hearing study is possibly underpowered with data from 16 subjects included in the statistical analysis below the number of 20 required to achieve 80% power. However, effect sizes calculated for all the findings shown to be significant were found to be large, suggesting the study had sufficient power to detect key differences between conditions.
- The infant hearing impaired study was a feasibility study and the sample size was small so that the conclusions may not, as they are, be generalised.
- The conclusions from the study can only predict outcomes to the general population and are not therefore externally valid. The conclusions are valid to the hearing aid used in the study and can perhaps transfer to other hearing aids from the same manufacturer where

the same technologies are adopted, but are not necessarily transferrable to other hearing aid manufacturers.

- The short duration sounds used in the study, whilst stabilising following hearing aid processing within the first 30 ms portion of the sound, may not necessarily suggest audibility of longer duration sounds that are more predictive of real life speech.
- The test sounds used in this study showed wide spectral content that overlapped between speech sounds and may therefore have limited realising differences due to frequency content in the ALR waveforms.

8.4. Suggestions for further work

Two main areas of further work highlighted by the findings from this research study which will be discussed in this section are: exploring the effects of hearing aid processing when recording the ALR to additional stimuli; developing the preliminary clinical information obtained to further support evidence based practice.

8.4.1. Additional stimuli

Whilst the speech sound /t/ used in this study is a speech sound with high frequency content, it may not explore the full extent of influence that NLFC might have on the ALR response. The use of NLFC was offered as a possible solution to improving access to high frequency sounds, such as /s/, /sh/ and /z/, where studies were found to show children with hearing loss fell behind their normal hearing peers in identifying and developing grammatical structures in speech, such as plurals (Stelmachowicz et al 2004). Furthermore, female voices are higher in frequency than male voices. Additional investigation that more appropriately encompasses the upper extent as well as the lower extent of important speech acoustic access that infants and children require to develop speech and language skills in line with their normal hearing peers should include, for example, the speech sound /s/ spoken by a female.

8.4.2. Developing clinical knowledge

The findings of the infant hearing impaired feasibility study provide an important foundation of information to support clinical practice. It is important however to further understand results compared to normal hearing infants. Comparing aided ALR peak latency to those of normal

hearing infants may provide a significant clinical indicator of auditory outcomes in an individual infant with hearing loss. Given than different equipment and test parameters alter the ALR response, normative ALR latency data is required for the same clinical equipment set-up and infant age range as would be used for infants with hearing loss. Correlating testing obtained from ALRs with that of a standard outcome measure for this age group would also improve understanding of the value of ALRs as an evidenced based tool for evaluating hearing aid benefit over hearing aid audibility alone. In other studies, this has been achieved by comparing ALR response presence to scores from the validated PEACH questionnaire whilst wearing hearing aids (Golding et al 2007). However Golding et al (2007) found wide variation in predicting PEACH scores and only a moderate correlation of r=0.45 (p=0.03) between outcomes of the two test methods suggesting that the use of questionnaires may not be the most reliable outcome measure of benefit for which to compare ALR results. Outcomes from speech discrimination testing is often thought of as the gold standard measure of benefit but relies on the child being old enough with an adequate language base to demonstrate speech discrimination skills. This may be possible from around 2 years of age but becomes more reliable from around 3 years of age. This is a wide age gap from obtaining ALRs at around 5 months of age where additional factors such as progression of hearing loss may impact results. An alternative option is to consider the use of the video analysis of pre-verbal communication developed by Tait and Lutman (1997) which can be undertaken around 1 year of age and evidence indicates it is a robust, reliable measure of early speech development that correlates highly to later measures of speech assessment and discrimination tasks (Tait and Lutman, 1997).

In addition to comparing the results to normal hearing infants and a standard method of measuring hearing aid benefit, testing at quieter conversational levels, such as an rms level of 55 dB SPL, would be important to assess audibility to sounds at levels expected for normal hearing children and would provide further indication of a hearing impaired infant's potential for developing speech and language skills at normal developmental milestones. Furthermore NLFC technology is anticipated to assist hearing losses where there is a greater high frequency slope than those subjects tested in this study. Testing a larger group of infants with different degrees of hearing loss would be important to ensure preliminary evidence is transferable to a wider clinical group, including those with sloping high frequency losses.

Appendix 1. KEMAR recordings

A1.1. KEMAR stimulus recording set-up

KEMAR (Muellar 2006) was used to record the test sounds in the different hearing aid conditions and the apparatus set up is given in Figure A1.1.1. The sound level meter used to measure dB SPL values was the Bruel and Kjaer Type 2231 with free field microphone type 4155 calibrated using the reference piston phone (94 dB SPL). It was situated 1 m from the loudspeaker at the ear height of KEMAR, maintaining the position of KEMAR during sound recordings. The sound level meter was set to 200 V polarisation voltage, linear weighting and fast time weighting. Background noise level in the test room was measured as approximately 26 dB A.

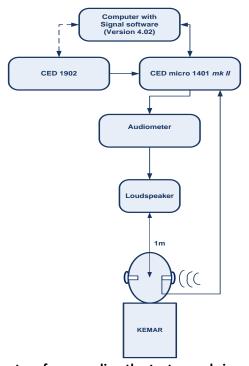


Figure A1.1.1: Equipment set up for recording the test sounds in each hearing aid condition.

A1.2. KEMAR stimulus levels

The stimulus levels at which the test sounds were presented to KEMAR are given in table A1.2.1. 0 dB nHL was calculated as outlined in section A5.4 along with the equivalent dB p-to-p SPL, recorded in table A5.4.2. For the quiet stimulus levels (65 dB nHL unaided) recorded in the first session, KEMAR gain was set at +40. For the loud stimulus levels (85 dB nHL unaided) recorded in the second session one month later, KEMAR gain was set at +20. The stimulus

level was reduced by 20 dB in the aided conditions, accounting for the hearing aid gain, to maintain a consistent sound level to the unaided condition.

Stimulus	S	Dial	dB	dB SPL	dB p-pSPL		Dial	dB	dB p-pSPL
Quiet le	vel		nHL					nHL	
m30	Unaided	95	65		101.4	aided	75	45	81.4
m100		90	65		97.3		70	45	77.3
g30		80	65		96.3		60	45	76.3
g100		75	65		91.3		55	45	71.3
t30		95	65		95.2		75	45	75.2
t100		95	65		94.4		75	45	74.4
Noise		40		60			20		
speech		60		58-63			40		
Loud lev	rel .						•		
m30	Unaided	115	85		121.4	aided	95	65	101.4
m100		110	85		117.3		90	65	97.3
g30		100	85		116.3		80	65	96.3
g100		95	85		111.3		75	65	91.3
t30		115	85		115.2		95	65	95.2
t100		115	85		114.4		95	65	94.4
noise		60					40		
speech		80					60		

Table A1.2.1: Stimulus levels used for KEMAR recorded sounds.

Appendix 2. Matlab file: magnitude squared coherence

Matlab program file 'speechlineup.m' used for magnitude squared coherence analysis of

hearing aid processing. Matlab uses 8 number of segments, 'm'.

```
clear; close all
load linearspeechraw.txt
linearspeechraw=linearspeechraw(1:210000);
[B,A]=butter(5,50/10000,'high'); % filter out below 100 Hz
output1=filtfilt(B,A,linearspeechraw);
figure; psd (output1, 4096, 20000); title ('freq response of aid')
scale=linspace(0,10000,length(output1));
figure; plot (scale, unwrap (angle (fft (output1)))); title ('phase response
of aid')
load unaidedspeechind.txt
unaidedspeechind=unaidedspeechind(1:210000);
[B,A]=butter(5,50/10000,'high'); % filter out below 100 Hz
output2=filtfilt(B,A,unaidedspeechind);
X=xcorr(output2,output1); % try and use Xcorr to align samples (phonak
and no aid)
figure;plot(X);title('autocorrelation function')
L=(length(X)/2)+0.5;
[Y,I] = max(X); % is it max of min to take?
[Y1,I1] = min(X);
if Y>-Y1
    delay=L-I
else
    delay=L-I1
    output1=-output1; % invert if -ve correlation
end
%delay=L-I
temp=output1(delay+1:end); %note inversion
output2=output2(1:length(temp));
figure; plot(output2, 'k'); hold on; plot(temp, 'c'); title('comparison of
speech through aid and direct to KEMAR')
errora=output2-temp; % compare size of error to size of original
signal
std(errora)/std(temp)
figure;plot(errora);title('difference between aligned signals
[noise]')
% hearing aid is introducing a delay about 150 samples
%% Compare noise estimate in gap of speech
%% segment from 63000:67000 samples seems to have a gap in it
mscohere(temp,output2,[],[],[],20000);title('mag squared coherence')
R=mscohere(temp,output2,[],[],[],20000);
for i=1:length(R)
    SDR(i) = R(i) / (1 - R(i));
end
scale=linspace(0,10000,length(SDR));
figure; plot(scale, 20*log10(SDR)); title('signal to distortion ratio')
averageR=mean(R(655:26210)) % average up 200 hz to 8k in samples
for i=1:length(averageR)
    SDR1(i) = averageR(i) / (1-averageR(1));
    SDR1dB(i) = 20*log10(SDR1)
end
```

Appendix 3. Matlab file: F_{sp}

Matlab program file 'speechanalysis.m' used for F_{sp} analysis of hearing aid processing.

```
clear;
load unaidedt100ind.txt
framelength=10000;
data=unaidedt100ind(1:(10*framelength)); % split to correct shape;
'10' means up to 10 frames in signal
[B,A]=butter(5,50/10000,'high'); % filter out above 100 Hz
data1=filtfilt(B,A,data); % remove below 20 Hz
A=reshape(data1, framelength, 10);
figure;plot(mean(A'))
hold on
plot(std(A'),'c')
av=(mean(A'));
noise=var(A(10000,:))
noise1=std(A(10000,:))
%% change fsp to only include window where the stimulus is present
fsp=var(av(1000:1500))*10/noise % use equivalent of fsp
fsp2=var(av(1000:1500))/noise % does not depend on number of averages
fsp3=std(av(1000:1500))/noise1 % compare amplitudes
fspdB=10*log10(fsp)%% ratio of power to power (fsp variance) not
amplitudes 20log10 is sound pressure level (amplitude of the sound)
fsp2dB=10*log10(fsp2)
fsp3dB=20*log10(fsp3)
figure; plot(A)
break
```

Appendix 4. Matlab file: speech sound generation

Matlab program file 'crop100msec.m' used to produce 100 ms speech sounds /m/, /g/, /t/ cropped from naturally produced VCV clusters (shown in Figure A4.1).

```
clear; close all
x=wavread('ata04.wav');
x=x';
fs=22050;
time=linspace(0,length(x)/fs,length(x));
figure;plot(x);title('sound in samples')
figure;plot(time,x);title('sound in s')
ramp=20; % in ms
plateau=60; % in ms
startpoint=8000 % samples to start of ramp for ata4 ='t'
% 6000 for ama1 -'m'
% 8000 for ata4 ='t' and 9200 aga1 - 'g'
startms=startpoint/fs
rampupend=ramp/1000*fs
for i=1:rampupend
    window(i)=i/rampupend;
end
rampup=window; % copy the ramp up
plateauend=(ramp+plateau)/1000*fs
for i=(rampupend+1):plateauend
    window(i)=1;
end
window=[window fliplr(rampup)];
temp=x(startpoint:(startpoint+length(window)-1));
figure; plot (temp);
output=temp.*window;
figure; plot (output)
for i=1:5
wavplay(output, 22050)
wavwrite(output, fs, 't.wav');
```

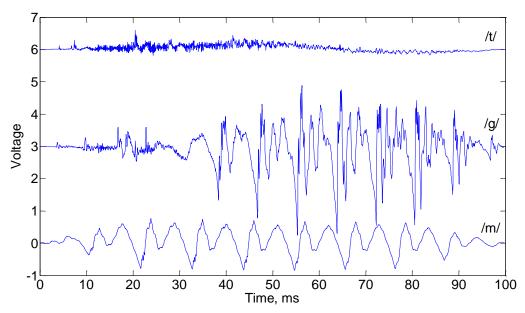


Figure A4.1: 100 ms speech sounds /m/, /g/, /t/ cropped from naturally produced VCV clusters used in the pilot study and adult normal hearing study.

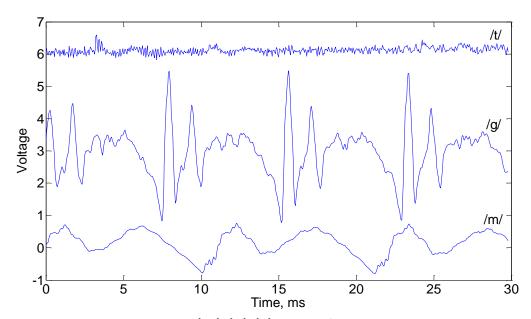


Figure A4.2: 30 ms speech sounds /m/, /g/, /t/ cropped from naturally produced VCV clusters used in the pilot study.

Appendix 5. Calibration: pilot study

A5.1. Equipment set-up

The equipment set-up and direction of flow of information for the process of recording ALRs in the pilot study is given in Figure A5.1.1.

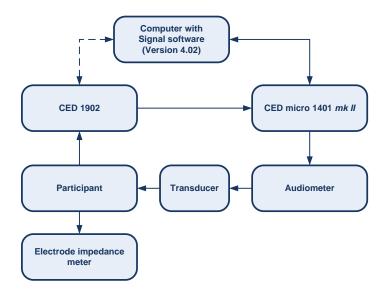


Figure A5.1.1. Equipment set-up and direction of flow of information (arrows) for ALR recordings.

A5.2. Stimulus calibration

The apparatus set-up for stimulus calibration through a loudspeaker for the pilot study is given in Figure A5.2.1. The sound level meter was set to 200 V polarisation voltage, linear weighting and fast time weighting. Full scale deflection was 106.9. Background noise level in the test room was measured as approximately 26 dB A.

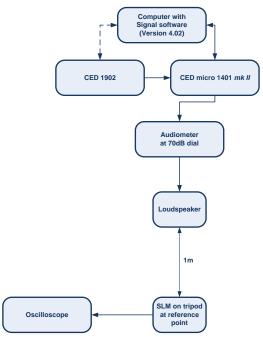


Figure A5.2.1: Calibration apparatus set-up for the pilot study.

The audiometric dial reading was maintained constantly at 70 dB throughout calibration. With the sound level meter routed to the oscilloscope and positioned at 0° azimuth, 1 m distance to the loudspeaker and at the average head height of a subject, the peak to peak voltage (p to p V) of each speech stimuli (/m/, /g/, /t/) with two stimulus durations (30 ms and 100 ms) was recorded and converted to dB p-to-p SPL with reference to the p-to-p voltage of the piston phone 4230 output. Table A5.2.1 below shows the p-to-p voltage of the reference tone and each of the stimuli presented from the loudspeaker. The conversion to dB p-to-p SPL is also given, calculated by the equation:

p-to-p SPL = $94 + 20 \times \log_{10}$ (p-to-p voltage of stimulus / p-to-p voltage of reference)

	Piston	/n	n/	/{	g/	/1	t/
	phone	30 ms	100 ms	30 ms	100 ms	30 ms	100 ms
p-to-p V	3.4 div x0.2	1.8 div	1 div	1.4 div	1.4 div	2.2 div	0.8 div
	V	x0.05 V	x0.1 V	x0.2 V	x0.2 V	x0.02 V	x0.05 V
		(0.09 V)		(0.28 V)	(0.28 V)	(0.044 V)	(0.04 V)
	(0.68 V)		(0.1 V)				
p-to-p SPL	94 dB SPL	76.4 dB	77.3 dB	86.3 dB	86.3 dB	70.2 dB	69.4 dB
(70 dB dial for		SPL	SPL	SPL	SPL	SPL	SPL
test sounds)							
p-to-p SPL		36.4 dB	32.3 dB	31.3 dB	26.3 dB	30.2 dB	29.4 dB
(0 dB nHL for		SPL	SPL	SPL	SPL	SPL	SPL
test sounds)							

Table A5.2.1: p-to-p Voltage and p-to-p SPL for test stimuli in the pilot study.

For an input of 0 dB nHL the p-to-p SPL was calculated based on biological calibration for 9 ears (see section A5.4) and is shown in table A5.2.1.

A check of linearity of the audiometer was performed using the /g/ 100 ms test sound with 50 dB dial level compared to the 70 dB dial level, given in table A5.2.2. The difference between the values is 20 dB SPL confirming the 20 dB difference in dial readings and linearity of the audiometer.

Dial reading	p-to-p V	p-to-p SPL		
70 dB		86.3 dB SPL (see table 5.1)		
50 dB	1.4 div x 0.02 V (0.028 V)	66.3 dB SPL		

Table A5.2.2: Linearity check of audiometer for the pilot study.

A5.3. Soundfield calibration

The sound field was tested to check if field uniformity met the recommendations proposed by ISO 8253-2 (2009) to carry out reliable sound field testing. The procedure checks variability in SPL within a sphere of defined radius (see figure A5.3.1).

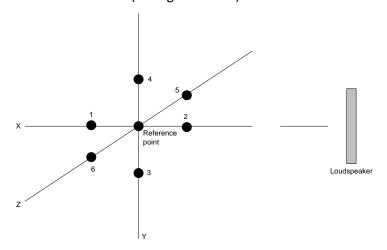


Figure A5.3.1: Soundfield calibration points.

The reference point was measured as 1 m from the speaker at the average ear level for a participant sitting on a chair. With the audiometer dial level set to 60 dB (a level chosen to be well above the noise floor to avoid any measurement variability due to noise), calibration measurements at the reference point and at the six points on the sphere with radius 0.15 m respective to the reference point, were made without the chair and participant in place. It is recommended to use the same stimuli that would be used in testing. Since the test stimuli used were short duration speech stimuli, reliable readings from the sound level meter could

not be obtained. Instead, 0.5 kHz, 1 kHz, 2 kHz and 4 kHz FM tones were substituted to measure the variation, since these span the frequency range of the test sounds, and a filter with the centre frequency of the FM tones was introduced with the SLM. The measurements recorded are given in table A5.3.1.

15 cm	0.5 kHz dB SPL	1 kHz dB SPL	2 kHz dB SPL	4 kHz dB SPL
Reference point	60.3	56.6	62.9	62.6
Up	60.9 (+0.6)	56.2 (-0.4)	64.2 (+1.3)	61.8 (-0.8)
Down	55.7 (-4.6)*	56.2 (-0.4)	63.9 (+1.0)	60.1 (-2.5)
Left	60.2 (-0.1)	55.9 (-0.7)	62.5 (-0.4)	62.0 (-0.6)
Right	61.9 (+1.6)	55.8 (-0.8)	64.0 (+1.1)	61.9 (-0.7)
Forwards	62.7 (+2.4)	54.3 (-2.3)	65.1 (+2.2)	62.6 (0)
Backwards	61.1 (+0.8)	52.7 (-3.9)*	64.3 (+1.4)	61.7 (-0.9)

Table A5.3.1: SPL values recorded for measurement of sound field variability using FM tones.

The numbers in brackets indicate the difference in the measurement to the reference point SPL. The values given in table A5.3.1 best match those conditions specified for a diffuse sound field as defined in ISO 8253-2 (2009) when FM test tones are measured. Tolerances of ±2.5 dB at positions 0.15 m from the reference point on the axes front-back, right-left, up-down and maximum tolerance of 3 dB difference between levels for the extreme right-left positions are allowable in a diffuse sound field. There were two FM tone measurements that fall outside this tolerance of variability. These were 0.5 kHz on the down axis and 1 kHz on the backward axis, marked with an asterisk.

A5.4. Determining dB nHL

Biological calibration was used to measure average hearing threshold of the test stimuli for the pilot study in dB nHL scale referenced to otologically normal adults (aged between 18-30 years). Pure tone audiometry and tympanometry were first measured to ensure each subject's hearing and middle ear showed otologically normal results. Each subject's left and right ears were used to assess threshold to the test stimuli from the loudspeaker with the contralateral ear plugged. The results obtained for 9 ears are given in table A5.4.1.

Thresholds from subject B4 for their right ear were excluded from results as otologically normal hearing was not found.

Subject	Test ear	/r	n/	/:	g/	/	t/
		30 ms	100 ms	30 ms	100 ms	30 ms	100 ms
B1	R	25	20	15	10	30	30
	L	30	25	20	10	30	30
B2	R	30	30	20	15	25	25
	L	30	25	15	10	25	25
В3	R	25	20	10	10	30	30
	L	25	20	10	10	30	30
B4	R*		Not valid: mir	nimal hearing	loss at 0.25 &	3 kHz on PTA	4
		+	middle ear c	ompliance ou	tside normal	range at 0.2 n	nl
	L	30	25	15	10	25	25
B5	R	25	20	15	10	30	30
	L	30	25	15	10	35	30
Mode		30 dB dial	25 dB dial	15 dB dial	10 dB dial	30 dB dial	30 dB dial
0 dB nHL							
SD		2.7 dB	3.5 dB	3.5 dB	1.7 dB	3.3 dB	2.5 dB

Table A5.4.1: Biological calibration thresholds in dB nHL calculated for the pilot study.

The mode threshold value was used to denote 0 dB nHL, defined in ISO 389-1 (2000) and a summary of the sound levels used in the pilot study are given in table A5.4.2.

Calibration	oration /m/			g/	/t/		
sound level	30 ms	100 ms	30 ms	100 ms	30 ms	100 ms	
0 dB nHL	30 dB dial 25 dB dial		15 dB dial	15 dB dial 10 dB dial		30 dB dial	
65 dB nHL	95 dB dial	90 dB dial	80 dB dial	75 dB dial	95 dB dial	95 dB dial	
dB p-p SPL	101.4	97.3	96.3	91.3	95.2	94.4	
at 65 dB nHL							

Table A5.4.2: Summary of sound levels used in the pilot study.

Appendix 6. Matlab file: bootstrap analysis pilot study

Matlab program file 'analyse_v2.m' used for bootstrap analysis of the ALR raw data. 1 channel recording. Low pass filtering applied to the raw data in Signal before exporting to matlab. ±150 µV peak-to-peak artefact rejection applied off line.

```
clear; % close all
load e3t100.txt
fs=500; epochlen=0.5;
data1=e3t100 (1:(50*fs*epochlen),1);
GAIN=1000; % gain of CED amp
data=data1; % NO FILTER
data=data*GAIN;
noiselevel=std(data) % noise size approx
epochs=length(data)/(fs*epochlen);
array=reshape(data,epochlen*fs,epochs); % IS THIS CORRECT? - SEEMS TO
reject=300 %% INCLUDE ARTERFACT REJECTION
count=1;
for i=1:epochs
temp=array(:,i);
    if max(temp)-min(temp)<reject</pre>
        array5(:,count)=temp;
        count=count+1;
    end
end
count=count-1
svr=mean(array5');
time=linspace(0,500,250); % time in ms for 250 samples
figure(1); hold on; plot(time, mean(array')); xlabel('time ms'); title('SVR
response')
figure; plot (data)
array1=array(:,1:17);
array2=array(:,18:34);
figure;plot(mean(array1'));hold on;plot(mean(array2'),'c');
A=(mean(array1')); B=(mean(array2'));
corrcoef(A(50:150),B(50:150))
noise=var(array5(75,:));
sig=var(svr(25:100)); % 50 to 200 ms NOT SIGNIFICANCE - SIGNAL
fsp=sig*count/noise % THE VALUE FOR THE COHERENT AVERAGE
for repeat=1:100 % bootstrap random segments of the same size as used
in FSP calculation;
    for i=1:34
        startpoint=fix(rand*149)+1; % start at a random point in each
epoch (not 0)
        arraynew(:,i) = array5((startpoint:startpoint+100),i);
    end
    svrtemp=mean(arraynew');
    noisetemp=var(arraynew(50,:));
```

```
sigtemp=var(svrtemp);
  fsptemp(repeat)=sigtemp*36/noisetemp;
end
figure; hist(fsptemp)

sort(fsptemp);
count1=0;
for i=1:length(fsptemp)
  if fsp>fsptemp(i)
      count1=count1+1;
  end
end
SIG=1-(count1/length(fsptemp))
```

Appendix 7. Calibration: adult normal hearing study

A7.1. Stimulus calibration

The apparatus set-up for stimulus calibration through ER2 insert earphones for the adult normal hearing study is given in Figure A7.1.1. The sound level meter was set to 200 V polarisation voltage, linear weighting and fast time weighting. Full scale deflection was 118.5.

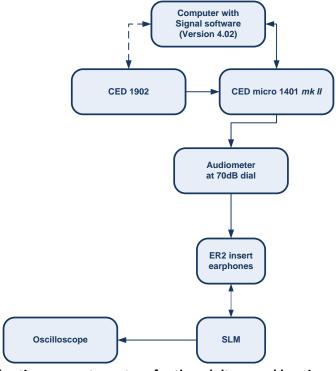


Figure A7.1.1: Calibration apparatus set-up for the adult normal hearing study.

The audiometric dial reading was maintained constantly at 70 dB throughout calibration. With the occluded ear simulator attached to the sound level meter and routed to the oscilloscope, the p-to-p voltage (p-to-p V) of each of the KEMAR recorded speech stimuli (/m/, /g/, /t/) with 100 ms stimulus durations in the 4 test conditions unaided (quiet sound level recordings), linear, WDRC and NLFC aided (loud sound level recordings) were measured and converted to dB p-to-p SPL with reference to the p-to-p voltage of the piston phone 4230 output. Table A7.1.1 below shows the p-to-p voltage of the reference tone and each of the KEMAR recorded stimuli presented from ER2 insert earphones. The conversion to dB p-to-p SPL is also given, calculated by the equation:

p-to-p SPL = $94 + 20 \times \log_{10}$ (p-to-p voltage of stimulus / p-to-p voltage of reference)

		p-to-p V	p-to-p SPL (70 dB dial	p-to-p SPL (0 dB nHL		
			for test sounds)	for test sounds)		
	Piston phone	4 div x 0.1 V (0.4 V)	94 dB SPL			
unaided	/m/	1 div x 0.1 V (0.1 V)	82.0 dB SPL	42.0 dB SPL		
	/g/	1 div x 0.1 V (0.1 V)	82.0 dB SPL	42.0 dB SPL		
	/t/	2 div x 0.1 V (0.2 V)	88.0 dB SPL	43.0 dB SPL		
linear	/m/	1.2 div x0.05 V (0.06 V)	77.5 dB SPL	37.5 dB SPL		
	/g/	1.8 div x0.05 V (0.09 V)	81.0 dB SPL	41.0 dB SPL		
	/t/	3 div x 0.05 V (0.15 V)	85.5 dB SPL	45.5 dB SPL		
WDRC	/m/	1.2 div x0.05 V (0.06 V)	77.5 dB SPL	42.5 dB SPL		
	/g/	1.4 div x0.05 V (0.07 V)	78.9 dB SPL	43.9 dB SPL		
	/t/	2.4 div x0.05 V (0.12 V)	83.5 dB SPL	43.5 dB SPL		
NLFC	/m/	0.8 div x0.05 V (0.04 V)	74 dB SPL	34.0 dB SPL		
	/g/	1.4 div x0.05 V (0.07 V)	78.9 dB SPL	38.9 dB SPL		
	/t/	2.4 div x0.05 V (0.12 V)	83.5 dB SPL	43.5 dB SPL		

Table A7.1.1: p-to-p Voltage and p-to-p SPL for test stimuli in the adult normal hearing study.

For an input of 0 dB nHL the p-to-p SPL was calculated based on biological calibration for 20 ears (see section A7.2).

A check of linearity of the audiometer was performed using the unaided KEMAR recorded stimulus /g/ and the p-to-p SPL at 10 dB dial level intervals is given in table A7.1.2. The difference between values is 10±1 dB SPL with every 10 dB change in dial reading confirming linearity of the audiometer.

Dial reading	p-to-p V	p-to-p SPL		
70 dB		82.0 dB SPL (Table A7.1.1)		
80 dB	1.8 div x 0.2 V (0.36 V)	93.1 dB SPL		
90 dB	1.2 div x 1 V (1.2 V)	103.5 dB SPL		

Table A7.1.2: Linearity check of audiometer in the adult normal hearing study.

A7.2. Determining dB nHL

Biological calibration was used to measure average hearing threshold of the adult study test stimuli in dB nHL scale referenced to otologically normal adults (aged between 18-30 years). Pure tone audiometry and tympanometry were first measured to ensure each subject's hearing and middle ear showed otologically normal results. Each subject's left and right ears

were used to assess threshold to the test stimuli from the ER2 insert earphones. The results obtained for 20 ears are given in table A7.2.1.

Subject	Test		Unaided			Linear			WDRC			NLFC	
	ear	/m/	/g/	/t/									
B1	R	30	30	25	30	30	30	30	30	25	35	30	30
	L	30	30	25	30	30	25	30	30	30	30	30	30
B2	R	25	25	25	30	30	25	30	30	30	30	30	25
	L	25	25	20	30	25	25	30	30	30	30	25	25
В3	R	30	30	30	35	30	30	35	35	35	35	35	30
	L	35	30	30	35	35	30	40	35	40	35	30	30
В6	R	30	30	25	35	30	30	35	35	30	30	30	25
	L	30	30	20	35	30	25	35	35	30	35	30	25
В8	R	30	30	20	30	30	30	35	35	30	35	30	30
	L	30	25	25	30	30	30	35	35	30	30	30	30
В9	R	30	25	25	30	30	25	30	30	25	30	30	25
	L	30	30	25	30	30	25	35	35	30	30	30	30
B10	R	30	35	25	40	30	30	35	35	35	35	30	30
	L	30	30	25	35	30	30	35	35	35	35	30	30
B11	R	35	30	25	35	30	30	40	35	30	35	30	25
	L	35	30	30	35	35	30	40	40	35	35	30	30
B12	R	30	25	25	30	30	25	35	30	30	30	30	25
	L	30	30	20	30	30	25	30	30	30	30	30	20
B13	R	20	25	20	30	25	25	30	30	30	30	30	25
	L	30	25	20	30	30	25	35	35	35	30	30	30
Mode 0 dB nHL		30 dB dial	30 dB dial	25 dB dial	30 dB dial	30 dB dial	30 dB dial	35 dB dial	35 dB dial	30 dB dial	30 dB dial	30 dB dial	30 dB dial
SD		3.4 dB	2.9 dB	3.4 dB	3.0dB	2.3dB	2.6dB	3.5dB	2.9dB	3.6dB	2.6dB	1.6 dB	3.0 dB

Table A7.2.1: Biological calibration thresholds in dB nHL calculated for the adult normal hearing study.

The mode threshold value is used to denote 0 dB nHL, defined in ISO 389-1 (2000) and a summary of the sound levels used in the adult normal hearing study are given in table A7.2.2.

Calibration	ı	Jnaided			Linear			WDRC	NLFC			
sound level	/m/	/g/	/t/	/m/	/g/	/t/	/m/	/g/	/t/	/m/	/g/	/t/
0 dB nHL	30	30	25	30	30	30	35	35	30	30	30	30
	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB
	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial
65 dB nHL	95	95	90	95	95	95	100	100	95	95	95	95
	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB	dB
	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial	dial
dB p-p SPL	107	107	108	103	106	111	108	109	109	99	104	109
at												
65 dB nHL												

Table A7.2.2: Summary of sound levels to be used for the adult normal hearing study.

Appendix 8. Matlab file: bootstrap analysis adult normal hearing study

Matlab program file 'analyse_v2_eyeblink_rejection.m' used for bootstrap analysis of the ALR raw data. 2 channel recording to remove eye blink recordings. Low pass filtering applied to the raw data in Signal before exporting to matlab. $\pm 70~\mu V$ peak-to-peak artefact rejection applied off line.

```
clear; % close all
load jpunaidedm1.txt
fs=500; epochlen=0.7;
data1=jpunaidedm1 (1:(60*fs*epochlen),1);
dataeye=jpunaidedm1 (1:(60*fs*epochlen),2);
GAIN=1000; % gain of CED amp
data=data1; % NO FILTER
data=data*GAIN;
dataeye=dataeye*GAIN;
noiselevel=std(data) % noise size approx
epochs=length(data)/(fs*epochlen);
array=reshape(data,epochlen*fs,epochs); % IS THIS CORRECT? - SEEMS TO
arrayeye=reshape(dataeye,epochlen*fs,epochs); % IS THIS CORRECT? -
SEEMS TO BE!
reject=140 %% INCLUDE ARTERFACT REJECTION 140=+/-70microV
count=1;
for i=1:epochs
temp1=arrayeye(:,i); % changed to work on the eye data
temp=array(:,i);
    if max(temp1)-min(temp1)<reject</pre>
       array5(:,count)=temp;
        count=count+1;
    end
end
count=count-1
counthalf=fix(count/2)
svr=mean(array5');
time=linspace(0,700,350); % time in ms for 250 samples
figure(1);hold on;plot((time-100),mean(array'));xlabel('time
ms');title('SVR response')
figure; subplot(2,1,1); plot(data); subplot(2,1,2); plot(dataeye,'c')
array1=array(:,1:counthalf);
array2=array(:,counthalf+1:count);
figure;plot(mean(array1'));hold on;plot(mean(array2'),'c');
A=(mean(array1')); B=(mean(array2'));
corrcoef(A(50:150),B(50:150))
noise=var(array5(75,:));
```

```
sig=var(svr(75:150)); % 150 to 300 ms NOT SIGNIFICANCE - SIGNAL - as
100ms prestimulus window
fsp=sig*count/noise % THE VALUE FOR THE COHERENT AVERAGE
for repeat=1:100 % bootstrap random segments of the same size as used
in FSP calculation;
    for i=1:count
        startpoint=fix(rand*149)+1; % start at a random point in each
epoch (not 0)
        arraynew(:,i) = array5((startpoint:startpoint+100),i);
    end
    svrtemp=mean(arraynew');
    noisetemp=var(arraynew(50,:));
    sigtemp=var(svrtemp);
    fsptemp(repeat) = sigtemp * 36/noisetemp;
end
figure; hist(fsptemp)
sort(fsptemp);
count1=0;
for i=1:length(fsptemp)
    if fsp>fsptemp(i)
        count1=count1+1;
    end
end
SIG=1-(count1/length(fsptemp))
```

Appendix 9. Root mean square analysis of test stimuli

Root mean square analysis of test sounds for the first 30 ms period, 30-60 ms period and 60-90 ms period from stimulus onset is given in table A9.1. The added gain from the hearing aid, difference in KEMAR gain setting across recordings and difference in audiometer dial level for stimulus presentation in dB nHL was accounted for in the analysis.

		rms Voltage			rms aided gain (dB)			Ratio	
Stimulus		0-30 ms	30-60 ms	60-90 ms	0-30 ms	30-60 ms	60-90 ms	0-30 ms cf 30-60 ms	0-30 ms cf 60-90 ms
unaided	m100	0.67	0.87	0.80				1:1.31	1:1.20
	g100	0.15	0.49	0.56				1:3.32	1:3.83
	t100	1.32	1.53	0.72				1:1.16	1:0.55
	1 kHz	0.07	0.07	0.071				1:0.96	1:0.99
linear	m100	0.21	0.24	0.15	-10.14	-11.36	-14.44	1:1.14	1:0.73
	g100	0.12	0.31	0.40	-1.72	-3.89	-3.00	1:2.59	1:3.30
	t100	0.48	0.57	0.34	-8.87	-8.50	-6.54	1:1.21	1:0.72
	1 kHz	0.05	0.05	0.05	-2.91	-3.59	-3.95	1:0.88	1:0.88
WDRC	m100	0.11	0.10	0.06	-15.94	-19.10	-21.99	1:0.91	1:0.60
	g100	0.07	0.12	0.12	-6.96	-12.19	-13.27	1:1.82	1:1.85
	t100	0.34	0.30	0.18	-11.67	-14.28	-12.23	1:0.86	1:0.51
	1 kHz	0.04	0.03	0.03	-4.88	-6.317	-6.81	1:0.81	1:0.79
NLFC	m100	0.20	0.23	0.16	-10.41	-11.46	-13.81	1:1.16	1:0.81
	g100	0.12	0.30	0.42	-1.97	-4.17	-2.57	1:2.58	1:3.57
	t100	0.42	0.55	0.37	-9.85	-8.81	-5.76	1:1.30	1:0.88
	1 kHz	0.06	0.05	0.05	-1.74	-2.11	-2.48	1:0.91	1:0.91

Table A9.1: rms analysis of test sounds from stimulus onset: 0-30 ms; 30-60 ms; 60-90 ms.

Appendix 10. Calibration: infant hearing impaired study

A10.1. Calibration: infant hearing impaired study part 1, ISVR

The equipment set-up for initial stimulus calibration for the infant study carried out at the Institute of Sound and Vibration Research (ISVR), University of Southampton is shown in Figure A10.1.1. The sound level meter was set to 200 V polarisation voltage, linear weighting and fast time weighting. Full scale deflection was 85.6 and K factor 5.6. Background noise in the test room was measured <35 dB A.

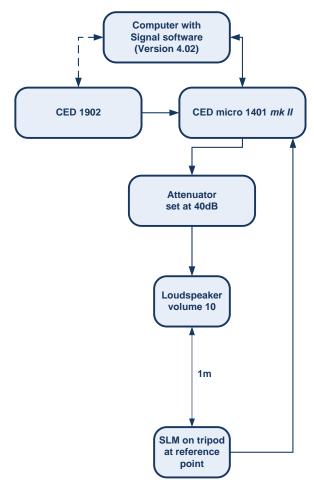


Figure A10.1.1: Calibration set-up: infant study.

The loudspeaker dial reading was maintained at volume 10 throughout calibration. With an attenuator of -40 dB the intensity of a 1 kHz reference tone presented from Signal/CED was measured as 76.2 dB SPL with the sound level meter (SLM). The output from the speaker was recorded by the CED micro 1401 mk II via the SLM for the 1 kHz tone and the speech sounds /m/ (100 ms duration) and /t/ (100 ms duration). A 100 Hz high pass filter was introduced in Signal to clean up the recorded output due to measurement and ambient noise on the

recording. Applying filters does not affect the measurement of peak to peak (p-to-p) value but may affect the root mean square (rms) measurement as some of the low frequency energy is filtered out. The impact would be greater when recording /m/ than /t/ as /m/ has greater low frequency energy.

<u>Calculating peak to peak SPL (p-to-p SPL)</u>: The p-to-p voltage of the 1 kHz tone and the speech sounds was measured from the Signal recordings. The voltage was converted to dB p-to-p SPL referenced to the 1 kHz tone calculated by the equation:

p-to-p SPL = 76.2 + 20 x log_{10} (p-to-p voltage of stimulus / reference voltage) The values are given in table A10.1.1.

<u>Calculating root mean square SPL (rms SPL):</u> The filtered recorded output in Signal of the speech sounds /m/ and /t/ were exported to matlab and the standard deviation of voltage across the 100 ms duration of the stimulus calculated to give the rms voltage. The rms voltage was converted to rms SPL referenced to the 1 kHz tone calculated by the equation:

rms SPL = $76.2 + 20 \times log_{10}$ (rms voltage of stimulus / reference voltage) The values are given in table A10.1.1.

	Vol	tage	SPL			
1 kHz reference	0.6	58 V	76.2 dB SPL			
	p-to-p	rms	p-to-p	Rms		
/m/	0.52 V	0.0945 V	73.87 dB SPL	59.06 dB SPL		
/t/	0.144 V	0.0168 V	62.72 dB SPL	44.06 dB SPL		

Table A10.1.1: p-to-p and rms values for test stimuli referenced to a 1 kHz tone with -40 dB attenuation and volume 10 (maximum) loudspeaker setting.

A10.1.1. Literature review: dB p-to-p SPL vs rms SPL

A comparison across 12 publications recording auditory late responses elicited by speech sounds showed variation in choice of stimulus calibration unit with dB p-to-p SPL, dB rms SPL, an impulse time constant SPL or no clarification of dB SPL documented. There was no clear consistent use of SPL unit. Subjective listening of the speech sounds by 2 adult listeners in dB p-to-p SPL indicated that at -40 dB attenuation of /m/ (approximating the loudest sound for the test protocol of 75 dB SPL) sounded quiet when considering that the lowest sound for the

test protocol (55 dB SPL) would require 20 dB more attenuation and this would likely be lost in the background noise floor. Subjective listening by the same listeners to the sounds in dB rms SPL sounded more appropriate to real life sound levels of loud speech, moderately loud speak and quiet speech. For this reason the calibration unit of the speech sounds for the infant study has been chosen as dB rms SPL referenced to a 1 kHz tone. It was noted that in dB rms SPL the /t/ stimulus sounded slightly louder subjectively than the /m/ stimulus at the equivalent 75 dB rms SPL, 65 dB rms SPL and 55 dB rms SPL. Where the stimulus is presented in the sound field, ear canal acoustics, with resonant frequency around 2 kHz for an adult ear, will give an advantage to frequencies of sound closer to 2 kHz than further away. Since /t/ is higher frequency than /m/ with spectral content nearer to 2 kHz this may account for the difference noted in loudness perception. For the infant study, the ear canal resonant frequency will be higher due to the smaller ear canals of the infant subject group and for recordings in the aided condition, an ear mould will be occluding the ear reducing the effect of ear canal advantage.

A10.1.2. Calibration in dB rms SPL

The attenuator values equating to sound levels of 55, 65 and 75 dB rms SPL were calculated with the loudspeaker volume set to 10 (maximum) and are given in table A10.1.2.1. The rms level of 65 dB SPL was used for the infant hearing impaired study. The output from the loudspeaker (at the calibration point) was measured using the SLM to ensure that an increase or decrease of 10 in attenuation was equivalent to 10 dB change in the SLM reading. These values are also given in table A10.1.2.1.

dB			/m/			/t/				
rms SPL		tor configu		R rmc SDI	SLM Attenuator configuration reading *-40 dB attenuation = 44.06 dB rms \$					SLM reading
3. 2	-40 dB	atteriuatioi	1 – 33.00 di	D IIIIS SI L	reading	-40 db dttelldation - 44.00 db Hiis SFL				reading
75		-20	-2	-2	73.5 dB SPL		-5	-2	-2	76.8 dB SPL
		-24	4 dB			-9 dB				
65	-20	-10	-2	-2	63.9 dB SPL	-10	-5	-2	-2	68.2 dB SPL
		-34	4 dB				-19 d	В		
55	-20	-20	-2	-2	53.7 dB SPL	-20	-5	-2	-2	59.2 dB SPL
		-44	4 dB			-29 dB				

Table A10.1.2.1: Attenuator configurations providing dB rms SPL referenced to p-to-p SPL 1 kHz tone required for the infant study.

The attenuator values were re-calculated (given in table A10.1.2.2) to reference to the 1 kHz tone in rms voltage, adjusted as follows:

rms voltage of 1 kHz reference at 900 to 1000 ms (calculating a 100 ms region the same as used for the test sounds) filtered or unfiltered rounds up to $0.21\,\mathrm{V}$

rms SPL = $76.2 + 20 \times \log_{10}$ (rms voltage of stimulus/rms reference voltage)

rms SPL /m/ = $76.2 + 20 \times \log_{10} (0.0945/0.21) = 69.26 \text{ dB rms SPL}$

rms SPL /t/ = $76.2 + 20 \times \log_{10} (0.0168/0.21) = 54.26 \text{ dB rms SPL}$

dB				/m/		/t/						
rms	Atten	uator cor	nfiguratio	n		SLM	Attenuator configuration				SLM	
SPL	*-40 c	IB attenu	ation = 69	9.26 dB rı	ms SPL	reading	*-40 dB attenuation = 54.26 dB rms SPL				reading	
75		-20	-10	-2	-2			-10	-5	-2	-2	
	-34.26 dB						-19.26 dB					
65		-20	-20	-2	-2			-20	-5	-2	-2	
			-44.26 d	В	1		-29.26 dB					
55	-20	-20	-10	-2	-2		-20	-10	-5	-2	-2	
	-54.26 dB						-39.26 dB					

Table A10.1.2.2: Re-calculated attenuator configurations providing dB rms SPL referenced to rms SPL of 1 kHz tone required for the infant study.

A10.2. Calibration: infant hearing impaired study part 2, Royal Berkshire Hospital

The second stage of calibration was carried out at the Royal Berkshire Hospital, Reading. The sound level meter was set to 0 V polarisation voltage, linear weighting and fast time weighting. Full scale deflection was 102.2 and K factor 2.2. Background noise in the test room was measured at 25 dB A. With the sound level meter positioned at 0° azimuth, 1 m distance and central to the speaker output, the 1 kHz Signal reference tone at maximum volume 10 on the loudspeaker required -32 dB attenuation to measure 76.2 dB SPL on the sound level meter to equate to the level as calibrated at ISVR. The attenuation levels of table A10.1.2.2 were

therefore re-calculated for the infant test tones to have equivalent sound levels in the test room of Royal Berkshire Hospital as that calibrated in the test room of ISVR. They are given in table A10.2.1. The rms level of 65 dB SPL was used for the infant hearing impaired study.

dB		/m/					/t/				
rms	Attenua	ator configi	uration		SLM	Attenuato	SLM				
SPL	*-40 dB = 69.26 dB rms SPL				reading	*-40 dB = 54.26 dB rms SPL			reading		
	*-32 dB	s used = 77.	26 dB rm	s SPL		*-32 dB used = 62.26 dB rms SPL					
75		-20	-5	-1	72 dB SPL / 62 dB A		-10	-1	75 dB SPL / 75 dB A		
		-26	dB		/ 62 UB A	-11 dB			/ /3 UB A		
65	-20	-10	-5	-1	52 dB A		-20	-1	65 dB A		
	-36 dB					-21 dB					
55	-20	-20	-5	-1	42 dB A	-20	-10	-1	56 dB A		
		-46 dB									

Table A10.2.1: Attenuator configurations providing dB rms SPL referenced to rms SPL of 1 kHz tone for infant test sounds with loudspeaker volume 10 and 1 m distance.

Appendix 11. ALR waveforms from infant hearing impaired subjects

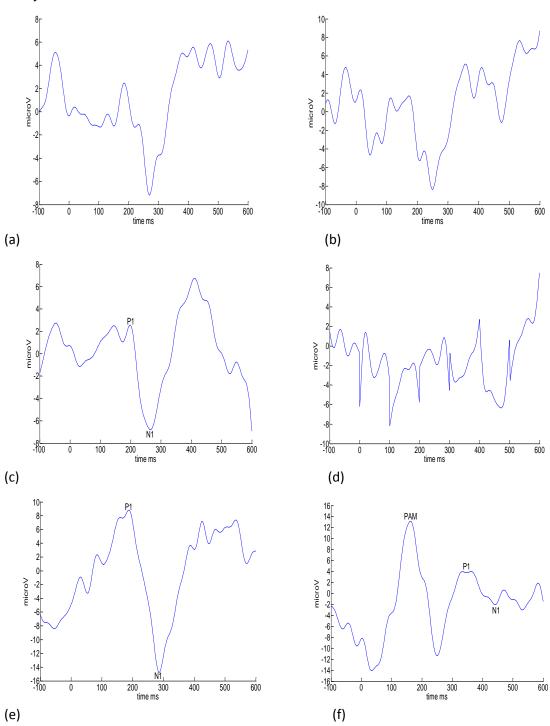


Figure A11.1. Combined ALR waveforms from 2 averages: (a) unaided /m/; (b) unaided /t/; (c) WDRC /m/; (d) WDRC /t/; (e) NLFC /m/; (f) NLFC /t/. P1-N1 peaks are marked for waveforms with significant F_{sp} values p \leq 0.01.

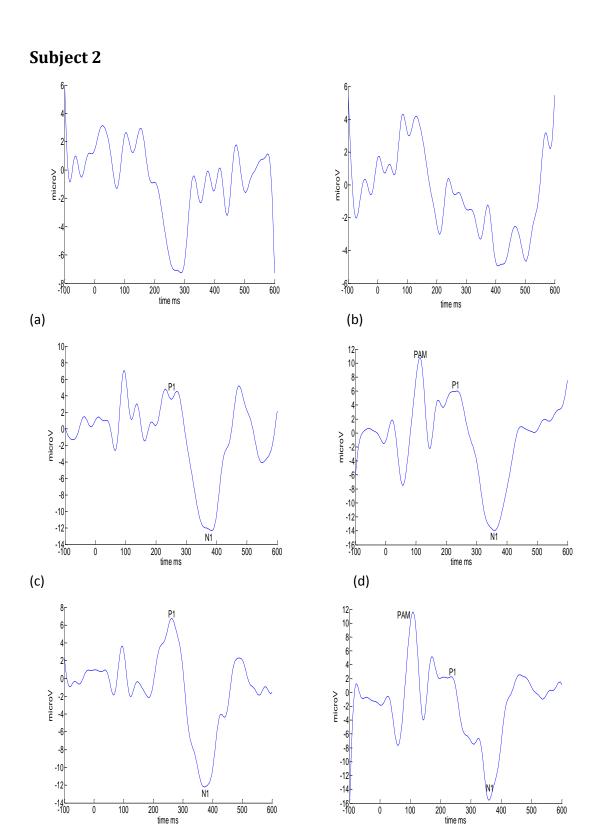


Figure A11.2. Combined ALR waveforms from 2 averages: (a) unaided /m/; (b) unaided /t/; (c) WDRC /m/; (d) WDRC /t/; (e) NLFC /m/; (f) NLFC /t/. P1-N1 peaks are marked for waveforms with significant F_{sp} values p \leq 0.01.

(f)

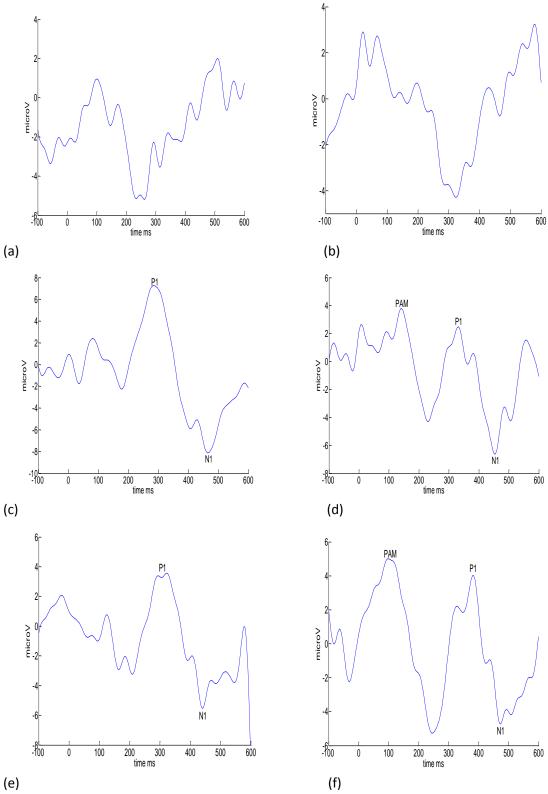


Figure A11.3. Combined ALR waveforms from 2 averages: (a) unaided /m/; (b) unaided /t/; (c) WDRC /m/; (d) WDRC /t/; (e) NLFC /m/; (f) NLFC /t/. P1-N1 peaks are marked for waveforms with significant F_{sp} values p \leq 0.01.



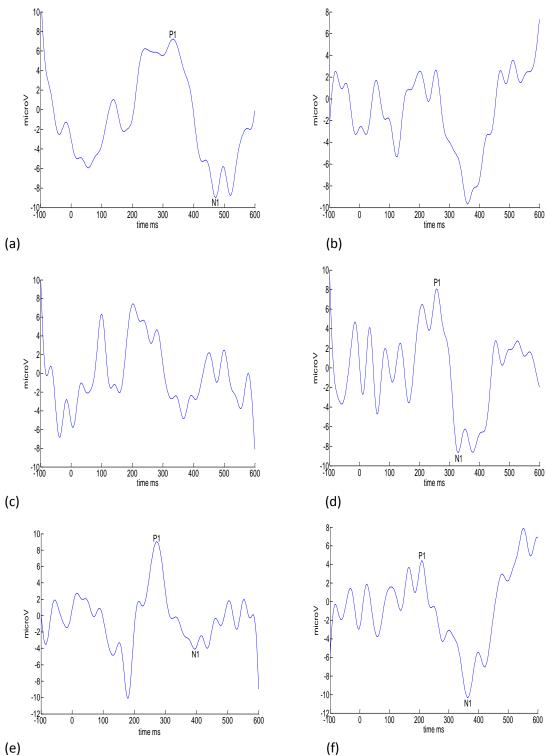


Figure A11.4. Combined ALR waveforms from 2 averages: (a) unaided /m/; (b) unaided /t/; (c) WDRC /m/; (d) WDRC /t/; (e) NLFC /m/; (f) NLFC /t/. P1-N1 peaks are marked for waveforms with significant F_{sp} values p≤0.01.

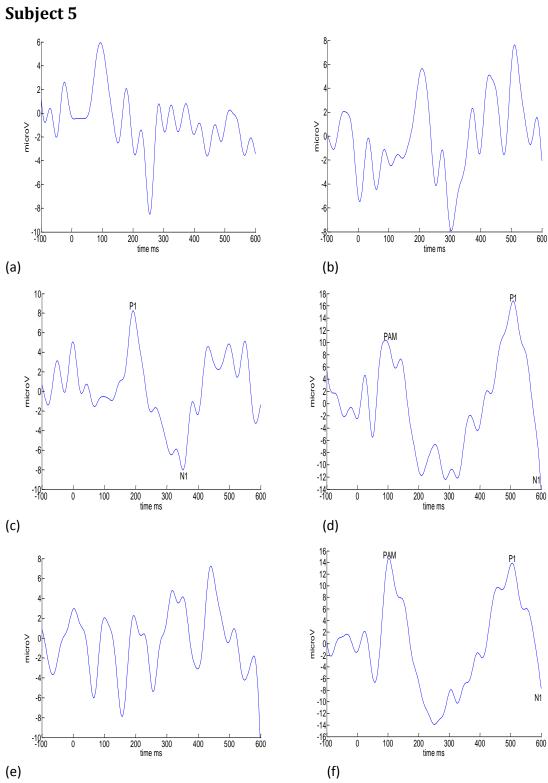


Figure A11.5. Combined ALR waveforms from 2 averages: (a) unaided /m/; (b) unaided /t/; (c) WDRC /m/; (d) WDRC /t/; (e) NLFC /m/; (f) NLFC /t/. P1-N1 peaks are marked for waveforms with significant F_{sp} values p \leq 0.01.

Appendix 12. Real ear probe microphone measures of aided speech sounds against hearing levels in dB SPL for each infant hearing impaired subject

Subject 1

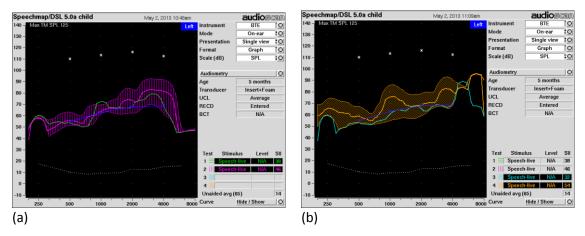


Figure A12.1: (a) NLFC condition - /t/ green, /m/ pink; (b) WDRC condition - /t/ blue, /m/ orange.

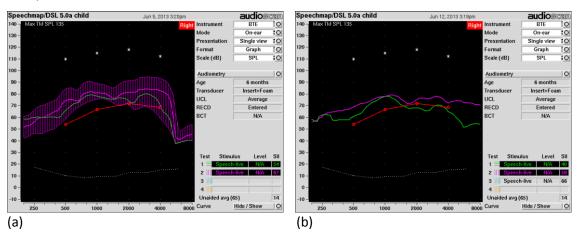


Figure A12.2: (a) NLFC condition - /t/ pink, /m/ green; (b) WDRC condition - /t/ pink, /m/ green.

Subject 3

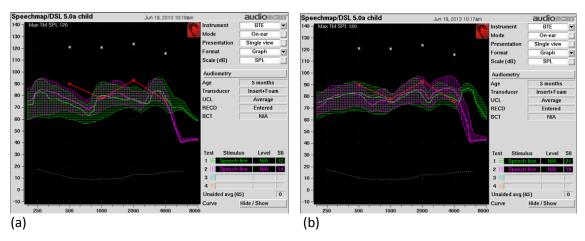


Figure A12.3: (a) NLFC /m/ pink, WDRC /m/ green; (b) NLFC /t/ pink, WDRC /t/ green.

Subject 4

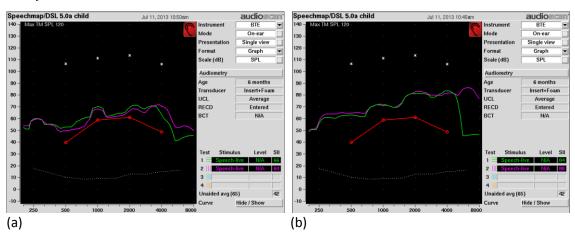


Figure A12.4: (a) NLFC /m/ green, WDRC /m/ pink; (b) NLFC /t/ green, WDRC /t/ pink.

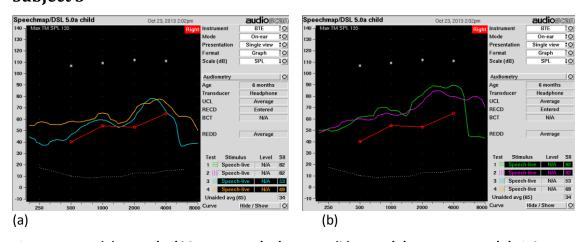


Figure A12.5: (a) NLFC /m/ blue, WDRC /m/ orange; (b) NLFC /t/ green, WDRC /t/ pink.

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