HEARLab® technical paper

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1. Purpose of this document

This document informs the reader about the capabilities and limitations of the HEARLab® system, and more specifically the Aided Cortical Assessment (or ACA™) module. This document is intended for those who use HEARLab® ACA™, who come in contact with those who use HEARLab® ACA™, or those who are looking for a short introduction about what HEARLab® ACA™ can and cannot do.

2. What is HEARLab® ACA™?

The HEARLab® device records and analyses human electrophysiological data, in the form of the cortical auditory evoked potential (CAEP). CAEPs are responses from the auditory cortex to acoustic stimuli, and are recorded from an active electrode placed near the vertex with respect to a reference electrode placed near either mastoid, with a ground electrode placed on the forehead. In the ACA™ module, four speech stimuli with low (/m/), medium (/g/), high (/t/) and very high (/s/) frequency emphasis can be presented to the client at 55, 65 and 75 dB SPL in the free field through a loudspeaker. They have dominant power in the bands 200 to 500 Hz, 800 to 1600 Hz, 2000 to 4000, and 5500 to 8000 Hz respectively with durations of 30, 20, 30 and 50 ms respectively. These stimuli are considered to be sufficiently long to activate the compression circuits of a hearing aid, making it an effective tool for determining whether the amplification produced by the hearing aid provides a signal that is detectable at the cortical level of the patient.

HEARLab® ACA™ has been designed to make objective audiological assessment as easy and efficient as possible. It includes in-built statistical procedures to assist the clinician in determining whether a response is present or absent, allowing testing to be conducted by clinicians who are not expert electrophysiologists.

3. Who is HEARLab® ACA™ intended for?

HEARLab® Aided Cortical Assessment (ACA™) is intended for professionals with basic training in electrophysiology who wish to determine whether speech is audible to those fitted with hearing aids. The ACA™ module has application for populations of any age who are unable, or unwilling, to participate in standard age-appropriate behavioural hearing tests. The main application however is focused on infant populations, testing at an age where behavioural testing is unreliable (generally before the age of 6-8 months). Due to uncertainties in estimating hearing threshold from auditory brainstem responses (ABR) responses, different ear canal sizes of the child, and the fact that hearing aid fitting software is based on population averages, the fitting still needs to be confirmed for the individual child. As a result, there is a need to evaluate the hearing aid fitting in an objective way: either to confirm whether the fitting is adequate to allow detection of conversational-level speech, whether there still is some fine-tuning needed, or to assist in the process towards cochlear implantation in cases where the hearing loss is too severe.

The unaided response of the patient can also be measured, allowing the clinician to compare unaided with aided cortical responses to demonstrate to parents the importance of wearing hearing aids to achieve audibility of speech. Measurement of unaided speech detection in babies with auditory neuropathy spectrum disorder (ANSD) (for whom thresholds are usually not known) can also be used to help determine the need for amplification.

Before the introduction of CAEP testing in the clinic (through the ACA™ module), common practice was to fit hearing aids soon after a confirmed hearing loss, but to wait for hearing aid fitting verification when those aided were able to be tested behaviourally (at the age of 6-8 months, provided no other disabilities are involved). This opened the possibility of the infant being inadequately stimulated during a critical time in the infant's development.

4. What can HEARLab® ACA™ be used for?

4.1 Hearing aid fitting evaluation

The main purpose of the HEARLab® ACA™ module is hearing aid fitting evaluation in hearing-impaired infants after their first hearing aid fitting and prior to behavioural evaluation using visual reinforcement orientation audiometry (VROA). The whole premise of using CAEPs to assess the audibility of acoustic stimuli (speech sounds) is based on two observations (that are backed by evidence in the literature):

(1) Audibility of a sound is defined as the sound being presented above a person's hearing threshold and hence being audible to the person. Presence of CAEPs reflects audibility. An absence of CAEPs can predominantly be explained by an inaudibility of the sound. This relationship has been shown in both adult and infant populations, both with and without hearing aids[1–6].

(2) CAEP amplitudes increase with increasing hearing aid gain in hearing-impaired adults and children[7–10].

Therefore, absence of the CAEP most likely can be explained by inaudibility of the sound, and this CAEP absence can most likely be remedied by appropriate aiding or increasing hearing aid gain. Based on this approach, Australian Hearing has used HEARLab® ACA™ to evaluate all eligible hearing-impaired infants since 2011[11]. CAEP presence is a reassurance that sounds are audible to the client. However, CAEP absence can signify multiple things in young children, as discussed below.

Absent CAEPs in young children while stimuli are audible

Although CAEP sensitivities (CAEPs present while stimuli are audible) and specificities (not present while inaudible) in adults are very high (more than 95% in a most recent study at NAL, paper in preparation), it has been found that in young (8-30 months) hearing-impaired children up to 23% of CAEPs are not present if a speech sound is presented at audible levels (55, 65 or 75 dB SPL)[3]. Possible reasons for their absence are numerous, and have been described in detail[3], although not all of these reasons have been scientifically verified so far: high noise levels, varying levels of alertness, severe cases of auditory neuropathy spectrum disorder (ANSD), small CAEPs (due to skull morphology, skull thickness, orientation of the folds of the cortex), cortex maturation, or poor speech perception and discrimination. Currently NAL is conducting two studies to investigate the last hypothesis: a retrospective study with children seen by Australian Hearing who had CAEP testing conducted 5 years ago and now have reliable speech perception information, and a study focusing on speech

discrimination and the acoustic change complex (ACC), which is a CAEP in response to sound changes. Previous research has shown already that an absence of CAEPs in infants tends to negatively correlate with functional measures[12]. An absence of ACCs could potentially aid in a decision towards cochlear implantation in ANSD children by identifying poor performers when wearing properly fit amplification[13].

Practically, to allow cross-checking: avoid testing stimuli in isolation. Instead, test several sounds with different frequency ranges, and at different presentation levels. With the figure of 23% absent CAEPs in mind[3], the most likely explanation of CAEP absence is inaudibility or inadequate audibility. Nonetheless, if a child is shown to have no responses at all for 3 speech sounds (and maybe at multiple levels), while it is likely that hearing aids are set up adequately based on the child's hearing loss, the search should be prompted for other reasons than inaudibility.

4.2 An indication of hearing loss severity in ANSD children

Between 5 and 15% percent of children born with sensorineural hearing loss have auditory neuropathy spectrum disorder (ANSD)[14,15]. In this population, no initial hearing threshold information is available as brainstem responses cannot be recorded. Currently HEARLab® ACA™ is used at Australian Hearing to very approximately estimate hearing thresholds in ANSD children[11]. ANSD children are tested unaided prior to making a decision whether they need to be aided or not. Presence of unaided CAEPs at 55 dB SPL for example provides information that the child's hearing loss at least is not severe or profound, so that amplification is not critical to achieving at least some audibility of conversational speech. CAEPs present when aided, but not when unaided, indicates the importance of amplification in achieving audibility. Although the science in infants and young children is at a level that only a rough idea of their hearing thresholds can be obtained, in these specific cases this is more information than currently can be obtained with behavioural techniques.

4.3 Helping with the decision towards cochlear implantation

When repeated testing returns no evidence of CAEP presence, even when a child is provided with high-gain aids, CAEP absence can be a reason to refer these children early for cochlear implantation. Of course, CAEPs should *not* be used as the one and only measure, and the audiological principle of cross-checking needs to be adhered to at all times.

4.4 Cochlear implant fitting evaluation, at least to some extent

The information in this section is based on studies at NAL that still have to be published.

As research is still ongoing, it is not recommended to use HEARLab® ACA™ with populations wearing cochlear implants (CIs), unless the operator knows how to interpret the data visually (and not to rely on the built-in automatic detection statistic). The current main concern is that CI artefacts can impersonate the presence of CAEPs, leading to the incorrect conclusion that a CAEP is present.

To understand the extent of the problem, the following results have been obtained in a study with 34 CI adult users (13 Cochlear, 12 MED-EL, 9 Advanced Bionics). Three HEARLab® ACA™ speech sounds were presented in the free field at a suprathreshold level (either 65 dB SPL or 30 dB SL), and CAEPs were recorded. Two conditions were of interest. The first condition determined the proportion of CAEPs that could be recorded when all sounds were audible (hence 100% CAEPs were expected to be recorded). In AB devices, only 57% of CAEPs were present. In Cochlear devices, this proportion was 73%. For MED-EL, this was 91%. The second condition evaluated the proportion of large CI artefacts

present in the recordings. Large artefacts made it impossible to evaluate whether a CAEP was present or not (with 0% the preferred observed proportion, or at least a number close to the false positive rate). These values were 3, 34 and 4% for AB, Cochlear and MED-EL respectively.

These results seem to suggest that for now only clients with MED-EL devices can be tested reliably with HEARLab® ACA™, i.e. a large number of detectable CAEPs with a low number of large artefacts impeding CAEP interpretation. There is indeed clinical research available that suggests HEARLab® ACA™ can already be used for the clinical evaluation of CAEPs in MED-EL devices, more specifically in infants and young children. Julie Kosaner from MED-EL in Turkey has successfully recorded CAEPs in 45 MED-EL children with HEARLab® ACA™ and tracked their CAEPs over time in the clinic, without reporting any issues with CI artefacts[16] (manuscript in preparation). So far, there is no convincing clinical evidence that similar performance is possible with Cochlear or AB devices. This does not imply however that these CI devices are of lower quality or cannot be used in combination with CAEP testing. Further research is required, and a recent HEARLab® ACA™ pilot study at NAL in 9 Cochlear adult users has indicated that 100% of CAEPs can be recorded at 40 dB SL in the free field when longer stimuli (400 ms) are used instead of the current short stimuli. Moreover, in this pilot study CI artefacts could be sufficiently removed or reduced using a mathematical technique[17] to allow an informed decision about CAEP absence or presence.

5. Is there any clinical evidence that CAEP testing allows hearing aids to be optimally fitted earlier, infants to be referred to cochlear implantation sooner, or time/costs savings are significant?

According to the principal audiologist of paediatric services Alison King at Australian Hearing, the introduction of HEARLab® ACA™ to the paediatric clinics of Australian Hearing has allowed the provision of additional services during the same appointment. For example, more time is available to do additional evaluations of the child or to provide extra support for the families while the HEARLab system is collecting data. Principal audiologist King has also indicated that less appointments are necessary than before. This leads to earlier optimisation of hearing aids, which facilitates better outcomes for all children. In terms of cochlear implantation, facilitating earlier cochlear implantation by providing greater certainty that hearing aids will not provide adequate audibility, leads to better outcomes for children with implants. The observation of significantly earlier hearing fitting and cochlear implant referral seems to be confirmed by a research group in the United Kingdom who are currently in the process of publishing their work (more details will follow later).

Prior to HEARLab® ACA™, children were left with their initial hearing aid settings for much of the first 9 months of their life. Now, hearing aids can be adjusted with greater confidence about what children can hear. Pre-HEARLab® ACA™ audiologists spent considerable time trying to get conditioned responses using behavioural testing when the children were barely developmentally ready. This led to repeated testing with minimal benefit.

This does not take away the fact some additional research is needed to compare between a hearing-impaired group not receiving CAEP testing during the first 9 months of life, and a hearing-impaired group which does. Unfortunately, this type of study is not possible anymore in Australia (as all eligible hearing-impaired children, per clinical protocol, need to be CAEP tested).

6. Are there any other modules available for HEARLAB®?

Two modules are currently available: Aided Cortical Assessment (ACA™) and Cortical Threshold Evaluation (CTE™). Cortical Threshold Evaluation (CTE™) uses tone bursts to estimate the hearing threshold levels of hearing-impaired adults without requiring the active participation of the person being tested. This module will soon be superseded by a new module, the Cortical Automatic Thresholds Estimation (CATE™), which is a push-of-the-button, fully automatic, cortical module for threshold estimation in adults. An ABR module will be released soon as well. Research and development is currently underway of the Auditory CORtical Discrimination (ACORD™) module which aims to predict how well a hearing-impaired child will perform language-wise with a hearing aid at the age of 3, by recording its acoustic change complexes (ACCs) at the age of 3 months. The ACC is a cortical response to a change in stimuli, and reflects to some extent how well a child can discriminate between speech sounds. If sufficiently sensitive, this test could predict which children need to proceed to cochlear implantation (instead of keep of wearing hearing aids) at an early age (i.e., months), instead of waiting until the child has sufficient language capabilities (i.e., years) to evaluate the benefit of the hearing aid.

7. What can HEARLab® ACA™ *not* be used for?

HEARLab® ACA™ cannot be used for threshold estimation, as presentation levels are limited and stimuli are presented in the free field. We recommend the use of HEARLab® CTE™ (or soon CATE™) for reliable hearing threshold estimation using CAEPs, at least in adults. Research on threshold estimation in infants and children is ongoing.

HEARLab® ACA™ cannot be used to evaluate whether the auditory cortex can discriminate between two different speech sounds. This question will hopefully be addressed by the ACORD™ described in Section 6. Research is ongoing.

Any unguided use with populations wearing cochlear implants is not recommended. When testing CI users, always be wary of possible CI artefacts in recordings. Research in this field is still ongoing, as described in Section 4.4 of this document.

8. Where can I find more information?

The National Acoustic Laboratories have a dedicated section with a clinical protocol, videos and publications for HEARLab® which you can access here: hearlab.nal.gov.au

E-learning courses on HEARLab®. There are available two e-learning courses that cover the background and clinical uses of HEARLab® which you can access through HEARnet: www.hearnetlearning.net.au

UK-based site on CAEPs by Guy Lightfoot, PhD. Very useful: www.corticalera.com

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