Clinical validation of the Auditory Brainstem Response module in the HEARLab system

Presented by:
Sanna Hou

Teresa Ching[1,2], Sanna Hou[1,2], Teck Loi[1,2], Nicky Chong-White[1,2], Bram van Dun[1,2], Harvey Dillon[1,2], Jessica Sjahalam-King[1,2], Pragati Mandikal Vasuki[3], Mark Seeto[1,2]

[1] The HEARing Cooperative Research Centre
[2] National Acoustic Laboratories
[3] Macquarie University

NAL National Acoustic Laboratories

THE HEARing CRC

MACQUARIE University

Background

NAL National Acoustic Laboratories

THE HEARing CRC

MACQUARIE University

HEARLab Testing Suite

- The first module HEARLab ACA measures cortical auditory evoked potentials (CAEPs). It is commercially available and has been used in clinics around the world.

- This presentation is about the 2nd and a **new module that measures auditory brainstem response (ABR).**

  - **Using the HEARLab test suite, you can measure CAEP as well as ABR.**

National Acoustic Laboratories

Objective

This study aims to validate the clinical performance of the new Auditory Brainstem Response (ABR) module in the HEARLab test suite.

- To demonstrate the functionality and intended use of the new Auditory Brainstem Response (ABR) module; i.e., ***the HEARLab ABR system performs equally well with a commercially available ABR system.***

Study Design and Methods

NAL National Acoustic Laboratories

THE HEARing CRC

MACQUARIE University

Method

- Performed parallel recordings of ABR using the HEARLab system and the Interacoustics Eclipse EP 25 system.
- Expert judgment of waveforms recorded by the two systems in terms of
  - Wave V detection
  - Wave V latency

Interacoustics Eclipse EP25 was selected as the reference ABR device because:

1) well established clinically and commercially available;
2) PC software base test system;
3) equivalent in technology;
4) single use sensors can be connected to their electrodes
5) the ABR recordings can be exported for analysis

National Acoustic Laboratories

A parallel recording system

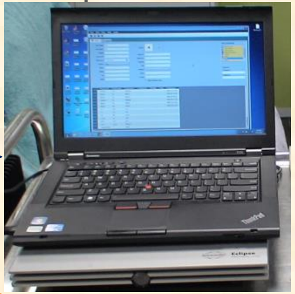
HEARLab ABR

Stimulus input

Trigger box

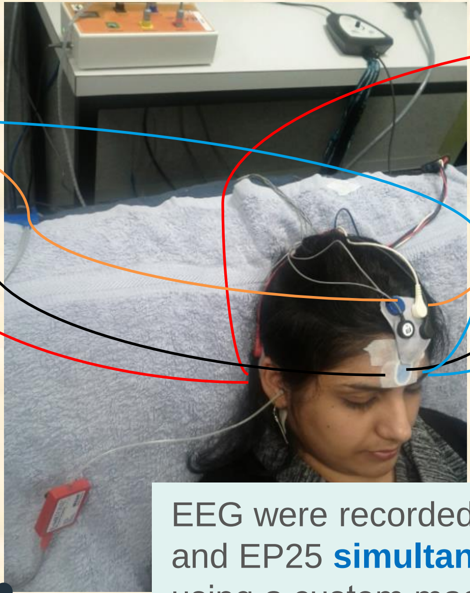
Trigger output

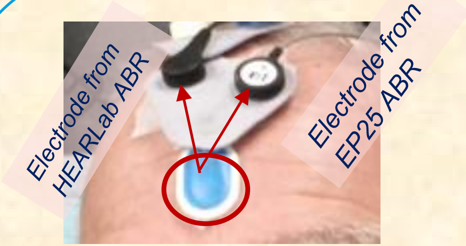
Eclipse EP25

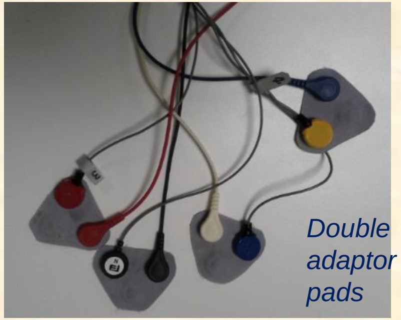


The HEARLab ABR system

- presented acoustic stimulus; &
- generated a pulse that was sent to EP25 device







EEG were recorded from HEARLab and EP25 **simultaneously**, by using a custom made "double adaptor" pad

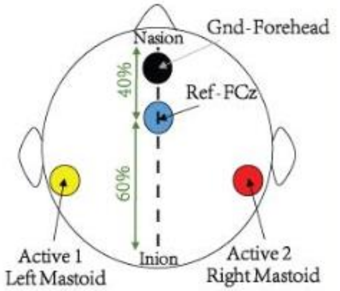
Methods

Participants:

- 17 adults with sensorineural hearing loss & 6 adults with normal hearing (M = 60yrs; SD:23)

Assessments:

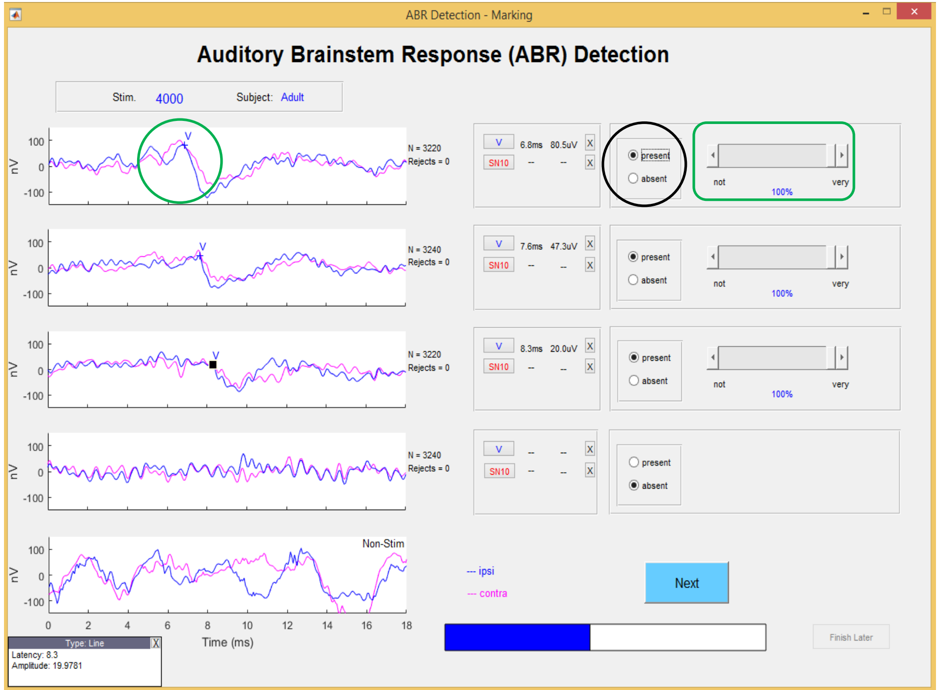
- Otoscopy and Tympanometry
- Audiometry
- ABR assessment (pre-test: included a loudness comfort check)
    - ABR stimuli:- tone bursts at 0.5, 1, 2 & 4 kHz and a click;
    - presented at 0, 10, 20, 30 or 40 dB sensation levels via insert earphones; also included non-stimulation; one repeated measurement
    - stimulus rate: 27.1 pps; high-pass filter - 100 Hz & low-pass filter - 3000 Hz
    - weighted averaging;
    - no of sweeps per replication: 3000
    - electrode locations: Reference: high forehead (Fz)
      Active 1: ipsilateral mastoid; Active 2: contralateral mastoid
      Ground: forehead (Fp)



NAL
National Acoustic Laboratories
THE HEARING CRC
MACQUARIE University

Expert Evaluation of waveforms and analyses:

Four experts in electrophysiological assessments were recruited to evaluate the recorded ABR responses.



The judges viewed a series of waveforms, presented in descending intensity for each frequency. For each trace,

- Indicated whether a wave V response was present or absent;
- Marked the wave V peak & rated how confidence (from 50% to 100%) about their decision if a response was present.

The assessment outcomes from the judges were collated for analysis on:

1) the number of ABR wave V identified as present
2) the differences in wave V latencies of each set of waveforms between the two systems
3) inter-judge agreement in wave V latency measurements.

NAL National Acoustic Laboratories

THE HEARING CRC

MACQUARIE University

Results

Presence or absence of ABR wave V responses

- A total 412 ABR recordings in each ABR system were presented to each expert for judgment.
- The mean percentage of the presence of wave V response for all 4 judges and stimuli:
  - **56.4%** for the HearLab ABR system;
  - **55.7%** for the EP25 ABR system

Table 1	**Mean percentage of response present** (number of responses present/total number of ABR recordings)	
Stimulus frequency	HEARLab	EP25
Click	50% (256/514)	48% (252/254)
4k Hz	70% (211/300)	66% (197/297)
2k Hz	61% (182/296)	62% (184/296)
1k Hz	52% (149/287)	57% (168/293)
500 Hz	52% (115/222)	48% (108/221)
Overall	**56%** (913/1619)	**56%** (909/1631)

NAL National Acoustic Laboratories

THE HEARING CRC

MACQUARIE University

Differences in wave V latency

Fig. 1

The difference in wave V latency (in *d* ms)
= the HEARLab wave V latency ***minus*** the EP25 wave V latency

Table 2	Proportion of absolute differences not exceeding ***d***	
d (ms)	Judge rating confidence ≥ 80%	Judge rating confidence ≥ 90%
0.1	0.563	0.564
0.2	0.756	0.767
0.3	0.850	0.863
0.4	0.892	0.901
0.5	**0.917**	**0.924**
0.6	0.917	0.924
0.7	0.937	0.945
0.8	0.948	0.956
0.9	0.957	0.965

I. Distribution of absolute wave V latency differences between the two systems.
(Absolute difference = all differences are positive)

II. Mean difference of all the wave V latencies of the two ABR systems.

Judge rating confidence	No. of ABR waveforms	Mean difference d (ms)	Standard deviation (ms)
≥ 90%	344	**0.05**	0.54
≥ 80%	446	**0.06**	0.52

Table 3. showed the mean difference & standard deviation

NAL
National Acoustic Laboratories

Inter-judge agreement and variability

The root mean square (RMS) difference across examiners:

- For the same presentation (same run) that had a latency difference value for at least one examiner, the RMS across examiners was calculated.
- There were 214 and 204 RMS difference values, respectively for judges' confidence rating of ≥ 80% and ≥ 90%.

Table 4: RMS average difference across examiners (ms)		
	Confidence ≥ 80%	Confidence ≥ 90%
RMS average	0.6	0.6
50th percentile	0.2	0.2
75th percentile	0.3	0.3
90th percentile	0.7	0.7
95th percentile	1.1	1
99th percentile	2.8	2.9

NAL National Acoustic Laboratories
THE HEARING CRC
MACQUARIE University

Conclusions & Discussion

NAL National Acoustic Laboratories

THE HEARing CRC

MACQUARIE University

Conclusion and Discussion

- This study compared ABR waveforms recorded in parallel by using the HEARLab ABR module and the Interacoustics EP25 system.
- The overall mean percentage of wave V detection was 56% for both systems.
- Over 92% of the wave V latency absolute differences between the two systems were within 0.5 ms.
- The mean difference in Wave V latencies between the two ABR devices was <0.06 ms.

➢ The new ABR module in the HEARLab system provided measurements that are equivalent to those obtained with a commercial system.

➢ The addition of an ABR module to the ACA module in the HEARLab allows efficient measurements of auditory brainstem responses and cortical auditory evoked potentials with the same clinical system.

Acknowledgements

Special thanks to

Expert judges:

Monica Wilkinson, Sydney Children’s Hospital
Andrew Geyl, Sydney Children’s Hospital
Florencia Montes, Sydney Children’s Hospital
Kirsty Gardner-Barry, Sydney Cochlear Implant Centre/NAL
Pragati Mandikal Vasuki, Macquarie University

Macquarie University Audiology Department:

Mridula Sharma

for loaning the Interacoustics Eclipse EP25 ABR equipment for use in this project.

NAL National Acoustic Laboratories

THE HEARING CRC

MACQUARIE University

Invitation to visit our poster

The new Auditory Brainstem Response module in the HEARLab testing suite

Poster number 25.
Session: Tuesday morning tea from 10am -11am

NAL website: www.nal.gov.au

Contact:

Teresa.Ching@nal.gov.au

Sanna.Hou@nal.gov.au

NAL National Acoustic Laboratories

THE HEARING CRC

MACQUARIE University