AIM provides real-time feedback to the cochlear implant surgeon for optimal and atraumatic electrode insertions

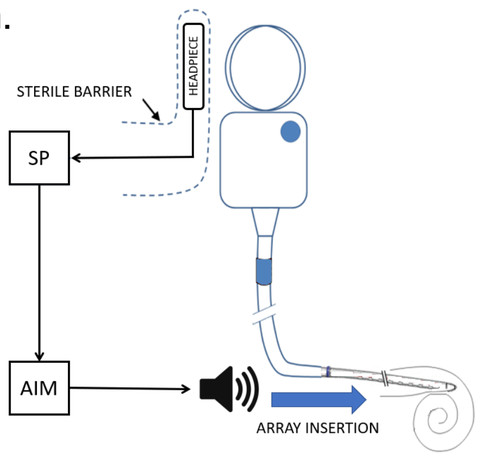
Unai Martinez de Estibariz[1], Martina Brendel[1], Laure Arnold[1], Patrick Boyle[1]

[1]Advanced Bionics GmbH, European Research Center, Hanover, Germany

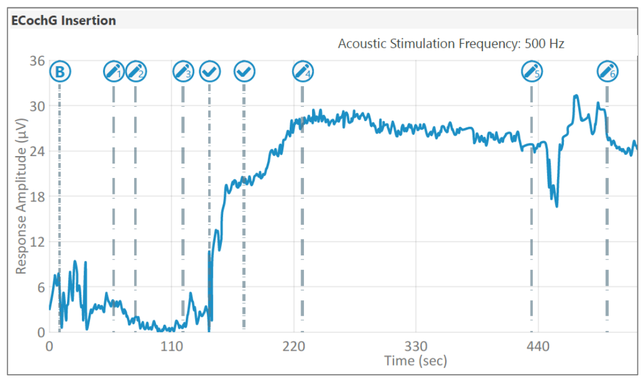
BACKGROUND & INTRODUCTION

ECochG is an acoustically evoked potential used for diagnostic purposes. In more recent years, focus has shifted to measuring ECochG intra-operatively during cochlear implant electrode insertions, by taking advantage of the most apical contact as the measuring electrode. The advantage of this setup is that signal is significantly larger than the extra-cochlear approach.

It is widely accepted that the presence and growth of the ECochG signal during surgery is a marker for cochlear integrity and for this reason, if the signal is maintained or left undisturbed during surgery, hearing and structural preservation of the cochlea is more likely.



AIM is a medical grade tablet that offers a suite of objective measures for Advanced Bionics devices. It is a standalone system that does not require of an external evoked potential system to record ECochG. It's a first-in-CI clinical platform that provides real-time monitoring of cochlear health function during electrode insertion.



The following studies being summarised, all carried out by independent investigators, have all used AIM with Advanced Bionics devices intra-operatively and have found positive and encouraging evidence on both hearing preservation and structure preservation.

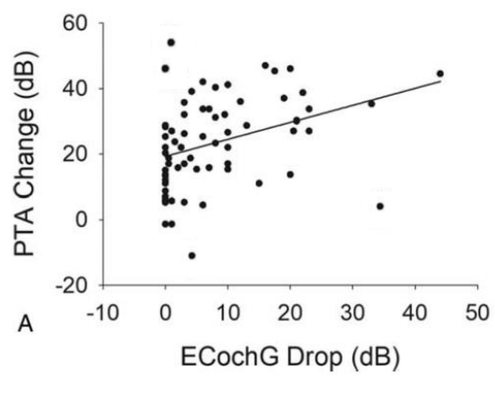
THE SIZE OF THE DROP MATTERS

Lenarz et al, 2022

This multi-center global study looked at the size of the ECochG drop during insertion measured via AIM and compared it to the change in PTA around 1 month post-operatively.

They showed that large ECochG drops are associated with lower rates of hearing preservation.

Using the peak amplitude as reference, for every drop of 10 dB in the ECochG signal, 7.4 dB were predicted to drop in PTA terms.

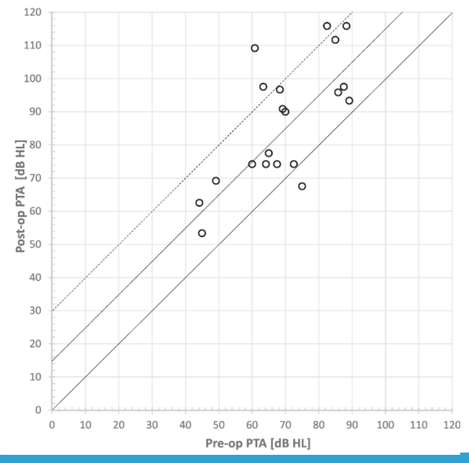


REAL-TIME FEEDBACK ON STRUCTURE

Lenarz et al, 2020

This study looked at preservation rates and scalar positioning of the straight SlimJ array with AIM monitoring. It found that in 85% of cases hearing was preserved within 30 dB of their pre-op audiogram 4 months post-operatively; and within 15 dB in 50% of cases.

Additionally, cone beam CT post-op analysis revealed that all electrode arrays were positioned within the scala tympani without trans-scalar dislocations, suggesting that monitoring provided guidance to ensure structural trauma was minimised, as a 2-7% translocation rate is often reported for straight arrays in the literature.



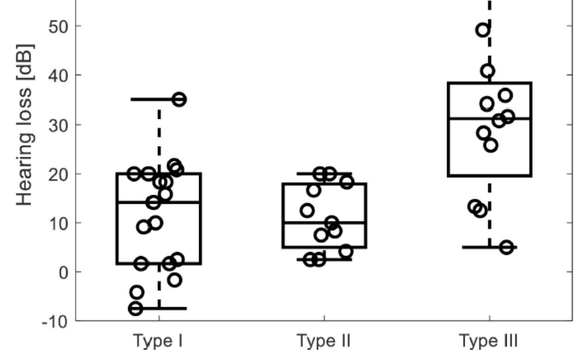
PHASE DIFFERENTIATES TRAUMA VS ADVANCE

Buechner et al, 2022

In this publication they looked at the amplitude as well as the phase shift of the ECochG signal. They were able to measure responses above the noise floor in 85% of cases, demonstrating that this measurement can be obtained in the majority of subjects.

They classified the responses in 3 groups based on the interaction of these two variables: Type I (no drop in amplitude), Type II (drop in amplitude with concurrent phase shift), and Type III (drop in amplitude without concurrent phase shift).

They found out that in cases where the amplitude drops but the phase does not, the change in residual hearing was significantly more pronounced. It was proposed that in cases where the amplitude drops and the phase does too, it is a sign of the recording electrode advancing past the generator site and thus not associated with cochlear trauma.



ASSISTS IN AVOIDING TRANSLOCATIONS

Harris et al, 2022

A global multi-center randomised controlled trial utilising data from 10 high-volume CI centers, evaluated the scalar positioning of electrode arrays via cone beam CT analysis and compared it to both the AIM monitored arm and the control unmonitored arm.

Their findings clearly showed a 7% rate of translocation overall, with no translocations in the AIM monitored group, while there was a 14% rate of translocation in the unmonitored group. This again highlights the assistive nature of the ECochG signal for avoiding scalar translocations and trauma in cochlear implant insertions.

	All Electrode Types		
	All	ECochG On	ECochG Off
Scala tympani	40	22	18
Scala vestibuli	3	0	3

SUMMARY

To summarise, we have seen how our partner investigators have used AIM to monitor ECochG recordings to improve both hearing and structure preservation.

AIM provides real-time objective metrics to aid the insertion process and maximise the chances of a more optimal and atraumatic outcome.

Advanced Bionics is committed and invested to finding answers to some of the posed questions as well as others that come up as we learn more about this area.

If you are interested in helping us drive this effort forward collaboratively, come speak to us and we can discuss ongoing activities or ideas you may have.

REFERENCES

- Buechner A, Bardt M, Haumann S, Geissler G, Salcher R, Lenarz T. Clinical experiences with intraoperative electrocochleography in cochlear implant recipients and its potential to reduce insertion trauma and improve postoperative hearing preservation. PLoS One. 2022 Apr 22;17(4):e0266077. doi: 10.1371/journal.pone.0266077. PMID: 35452461; PMCID: PMC9032378.
- Harris MS, Koka K, Riggs WJ, Saleh S, Holder JT, Dwyer RT, Prentiss S, Lefler S, Kozlowski K, Hiss MM, Ortmann AJ, Nelson-Bakkum E, Büchner A, Salcher R, Harvey SA, Hoffer ME, Bohorquez JE, Alzhrani F, Alshihri R, Fida A, Danner CJ, Friedland DR, Seidman MD, Lenarz T, Telischi FF, Labadie RF, Buchman CA, Adunka OF. Can Electrocochleography Help Preserve Hearing After Cochlear Implantation With Full Electrode Insertion? Otol Neurotol. 2022 Aug 1;43(7):789-796. doi: 10.1097/MAO.0000000000003588. Epub 2022 Jul 19. PMID: 35861647.
- Lenarz T, Buechner A, Gantz B, Hansen M, Tejani VD, Labadie R, O'Connell B, Buchman CA, Valenzuela CV, Adunka OF, Harris MS, Riggs WJ, Fitzpatrick D, Koka K. Relationship Between Intraoperative Electrocochleography and Hearing Preservation. Otol Neurotol. 2022 Jan 1;43(1):e72-e78. doi: 10.1097/MAO.0000000000003403. PMID: 34739427; PMCID: PMC8671360.
- Lenarz T, Buechner A, Lesinski-Schiedat A, Timm M, Salcher R. Hearing Preservation With a New Atraumatic Lateral Wall Electrode. Otol Neurotol. 2020 Sep;41(8):e993-e1003. doi: 10.1097/MAO.0000000000002714. PMID: 32569147.

Advanced Bionics GmbH • European Research Center
Feodor-Lynen-Str. 35 • 30625 Hanover • Germany