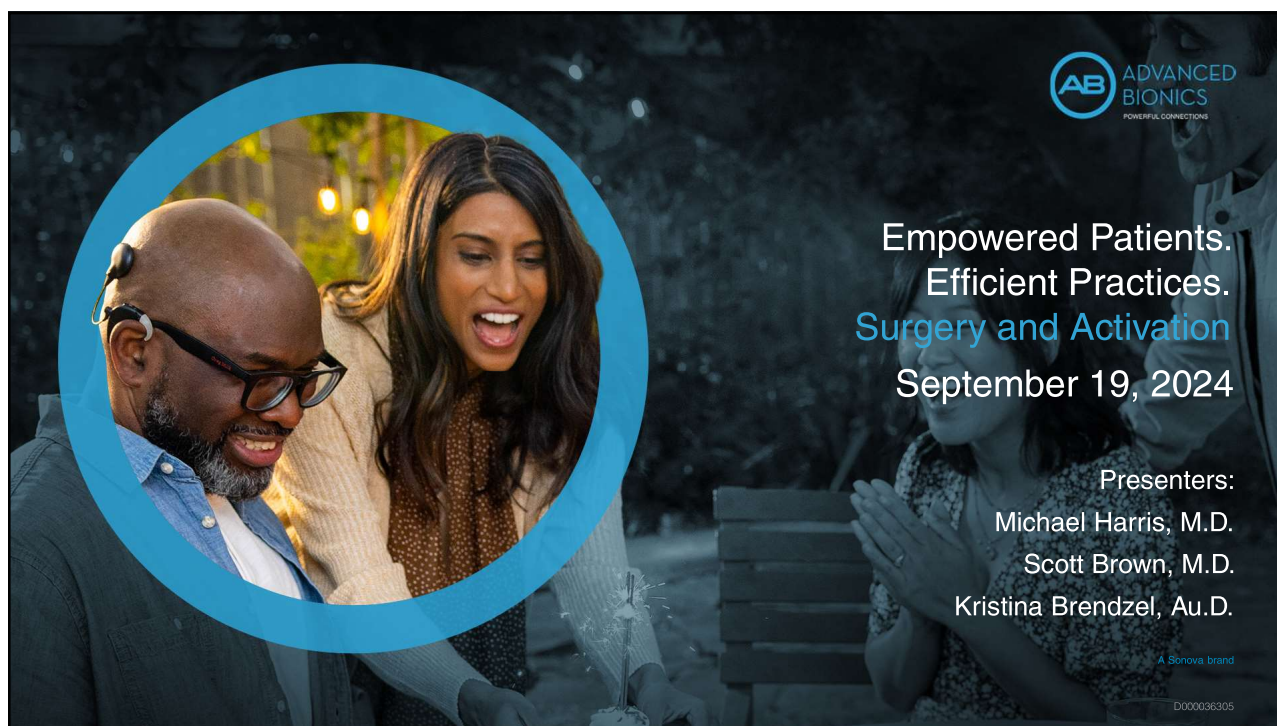




Empowered Patients. Efficient Practices.

Surgery and Activation



Course goals and objectives

After this course, participants will be able to:

- Identify one change that they could implement to improve clinical efficiency
- Explain the value of utilizing AIM
- Identify two ways in which AB staff can provide support to CI recipients at CI activation and beyond

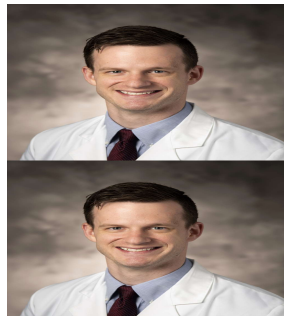
Empowered Patients. Efficient Practices.

Surgery and Activation



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Michael Harris, Scott Brown, and Kristin Brendzel are paid consultants for Advanced Bionics, LLC. The comments provided by them are their own opinions and do not reflect the opinion of Advanced Bionics.

AIM



The AIM system, developed by Advanced Bionics, provides us with an opportunity to take advantage of the unique recording capabilities of our implant.

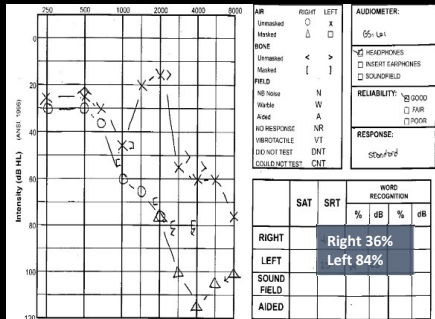
AIM provides **real time ECoChG measurement** during electrode insertion, combined with necessary **objective measures**, in one place:

- Electrocochleography (ECoChG)
- ECoChG Threshold Estimations
- Impedances
- Neural Response Imaging (NRI)
- Electrical Stapedial Reflex Thresholds (ESRT)



Central Premise

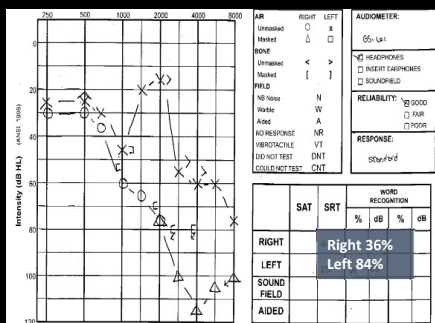
We Want More Control Over Our Outcomes



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Central Premise

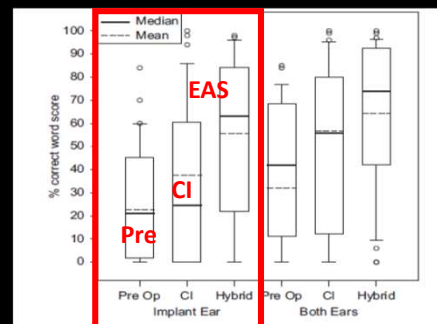
Structure Preservation/Hearing Preservation



Potential Benefits of Electro-Acoustic Hearing

- Speech understanding in complex listening environments
- Music appreciation
- Constant sound awareness potential
- CI-specific quality of life

AZBIO Noise + 10 SNR



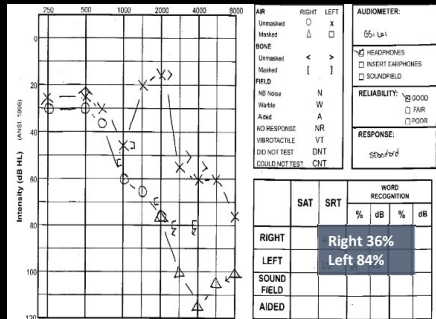
Lenarz et al. 2013. European multi-center study of the Nucleus hybrid L-24 cochlear implant



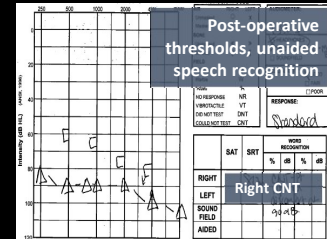
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Central Premise

Most crucial step of cochlear implant surgery is performed blind



Inference



Approximately 50% of time



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Electrocochleography (ECoChG)

- May reflect “health” of cochlear hair cells and the cochlear nerve
- Can detect insertion trauma, predict hearing outcomes, and reflect electrode position
- *Monitoring during electrode insertion*



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Knowledge Gap

Association between intraoperative ECoG amplitude parameters and structure and hearing preservation



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Randomized Prospective Clinical Trial

- **Hypotheses:**

- *Insertion track pattern and amount of signal drop would predict post-op residual hearing*
- *Decreased translocation rates with feedback "ON"*



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Sample

Conventional clinical CI criteria met
Pure-tone audiometry thresholds ≤ 80 dB HL at 500 Hz
No prior otologic surgery, chronic disease

Surgery

AB CI system w/ HiFocus SlimJ or MidScala
Round window (RW) or extended RW insertion

ECochG

Based ECochG response to single tone 500 Hz using AIM System
Randomized to audio feedback "ON" or "OFF"
ECochG always collected

Outcomes

Hearing Preservation: Post-CI CI ear only pure-tone audiometry
Scalar Location: Post-operative CT with image processing



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Insertion Parameters at Surgeons' Discretion

Randomized Clinical Trial

Speed--YES

Vector/angle--YES

Rotation/twist--YES

Slight retraction/insertion--YES

Partial Insertion--NO (full insertion was always attempted)



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Randomized Prospective Clinical Trial

Participants

- 9 clinical sites
- 25 surgeons
- N = 87
 - 44 feedback ON vs 43 feedback OFF
- AB HiRes Ultra (n = 15) or HiRes Ultra3D (n = 72)
 - HFMS (n = 14) or SlimJ (n = 73)
- ECoG monitored in both groups

United States

- ❖ Medical College of Wisconsin, Milwaukee, WI
- ❖ Washington University, St. Louis, MO
- ❖ The Ohio State University, Columbus, OH
- ❖ Vanderbilt University, Nashville, TN
- ❖ University of Miami, Miami, FL
- ❖ Tampa Bay General Hospital, FL
- ❖ Advent Health, Orlando, FL

Saudi Arabia

- ❖ King Abdullah Ear Specialist Center, Riyadh

Germany

- ❖ Medizinische Hochschule Hannover, Hannover



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Otology & Neurotology
In Press

Otology & Neurotology
Amplitude Parameters are Predictive of Hearing Preservation in a Randomized Controlled Trial of Intracochlear Electrocochleography During Cochlear Implant Surgery

Michael S. Harris, Karthi Koka, Adam Thompson-Harvey, Erin Harvey, William J. Riggs, Shaza Saleh, Jordan T. Holder, Robert T. Dwyer, Sandra M. Prentiss, Shannon M. Lefter, Kristin Kozlowski, Meghan M. Hiss, Amanda J. Ortmann, Erin R. Nelson-Bakkum, Andreas Buchner, Rolf Salcher, Steven A. Harvey, Michael E. Hoffer, Jorge E. Boborquez, Farid Alzhrani, Rana Alshihri, Alnuhawas Fida, Christopher J. Danner, David R. Friedland, Michael D. Seidman, Thomas Lenarz, Fred F. Telisch, Robert F. Labadie, Craig A. Buchman, Oliver F. Adunka

Medical College of Wisconsin, Department of Otolaryngology & Communication Sciences, Milwaukee, WI, USA; Advanced Bionics, LLC, Valencia, CA, USA; The Ohio State University, Wexner Medical Center, Department of Otolaryngology-Head & Neck Surgery, Columbus, OH, USA; King Saud University, College of Medicine, King Abdulaziz Ear Specialist Center (KAESC), Riyadh, Saudi Arabia; Vanderbilt University Medical Center, Vanderbilt Bill Wilkerson Center, Department of Hearing and Speech Sciences, Nashville, TN, USA; University of Miami, Miller School of Medicine, Department of Otolaryngology-Head & Neck Surgery, Miami, FL, USA; Washington University School of Medicine, Department of Otolaryngology-Head & Neck Surgery, St. Louis, MO, USA; Medizinische Hochschule Hannover, Hannover, Germany; University of Miami, Department of Biomedical Engineering, Miami, FL, USA; Tampa Bay General Hospital, Tampa Bay, FL, USA; AdventHealth, University of Central Florida, Orlando, FL, USA; Medical University of South Carolina, Department of Otolaryngology-Head & Neck Surgery, Charleston, SC, USA

Otology & Neurotology
43(7):p 789-796, August 2022

Original Study
Can Electrocochleography Help Preserve Hearing After Cochlear Implantation With Full Electrode Insertion?

Michael S. Harris, Karthi Koka, William J. Riggs, Shaza Saleh, Jordan T. Holder, Robert T. Dwyer, Sandra Prentiss, Shannon Lefter, Kristin Kozlowski, Megan M. Hiss, Amanda J. Ortmann, Erin Nelson-Bakkum, Andreas Buchner, Rolf Salcher, Steven A. Harvey, Michael E. Hoffer, Jorge E. Boborquez, Farid Alzhrani, Rana Alshihri, Alnuhawas Fida, Christopher J. Danner, David R. Friedland, Michael D. Seidman, Thomas Lenarz, Fred F. Telisch, Robert F. Labadie, Craig A. Buchman, Oliver F. Adunka

Department of Otolaryngology and Communication Sciences, Medical College of Wisconsin, Milwaukee, Wisconsin; Advanced Bionics, Valencia, California; Department of Otolaryngology-Head and Neck Surgery, Columbus, Wexner Medical Center, The Ohio State University, Ohio, U.S.A.; King Saud University, College of Medicine, King Abdulaziz Ear Specialist Center (KAESC), Riyadh, Saudi Arabia; Department of Otolaryngology-Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, Tennessee; Department of Otolaryngology-Head and Neck Surgery, Miller School of Medicine, University of Miami, Miami, Florida; Department of Otolaryngology-Head and Neck Surgery, Washington University School of Medicine, St. Louis, Missouri, U.S.A.; Medizinische Hochschule Hannover, Hannover, Germany; Department of Biomedical Engineering, University of Miami, Miami, FL; Tampa Bay General Hospital, Tampa Bay, and AdventHealth, University of Central Florida, Orlando, Florida, U.S.A.

Results



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Structural Preservation with ECochG Feedback

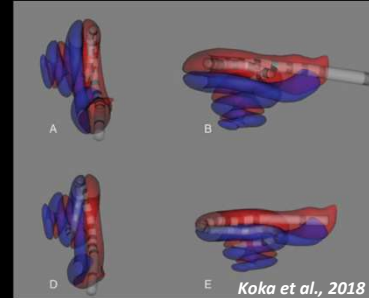
- 43 patients had post-operative CT scans (22 ON vs 21 OFF)
- Translocations analyzed blinded with Vanderbilt CT imaging analysis
- **3 translocations observed in ECochG feedback OFF**
- **No translocations observed in ECochG feedback ON**

TABLE 1 - Image-based electrode scalar location

	All	All Electrode Types	
		ECochG On	ECochG Off
Scala tympani	40	22	18
Scala vestibuli	3	0	2 HFMS 1 SlimJ 3

ECochG indicates electrocochleography; HFMS, Hifocus MidScala.

Harris et al., 2022



Koka et al., 2018

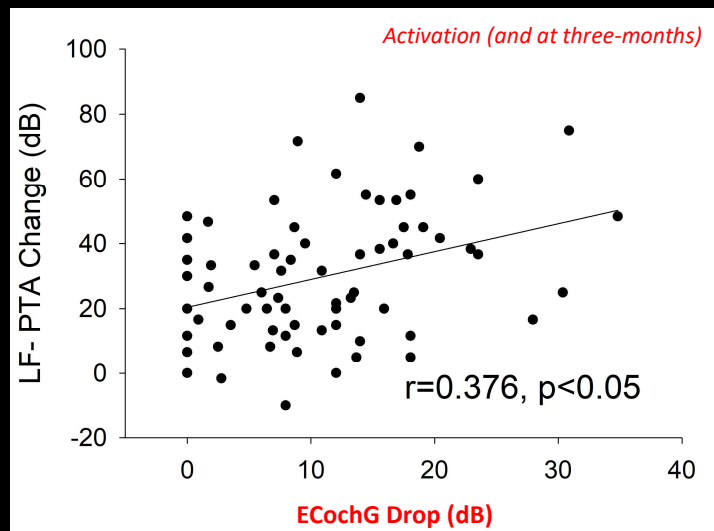
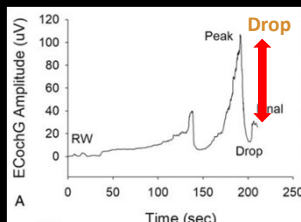


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Whole Sample

Amount of DROP
Predicts Hearing
Preservation

Larger the DROP...
Larger the hearing loss
No difference in electrode type

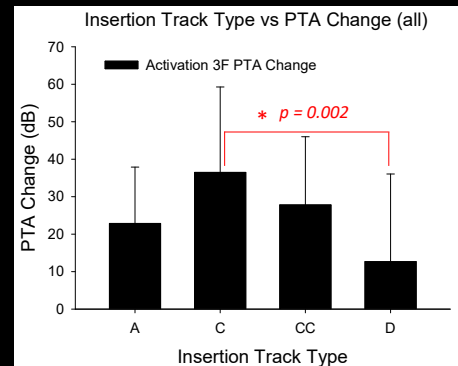
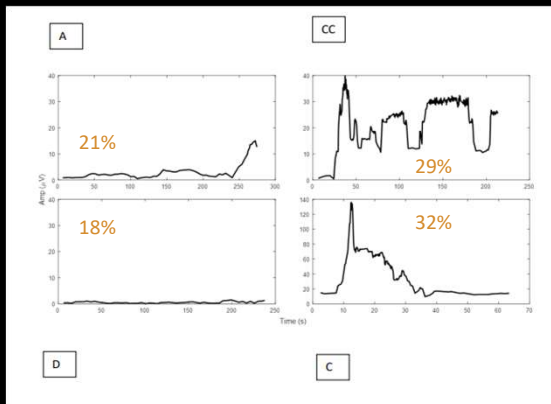


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Insertion Track Patterns

Four distinctive patterns observed

- Mean maximal signal drop significantly greater for Type C ($p = 0.15$)
- 'C' patterns have higher post-op hearing loss ($p = 0.002$)

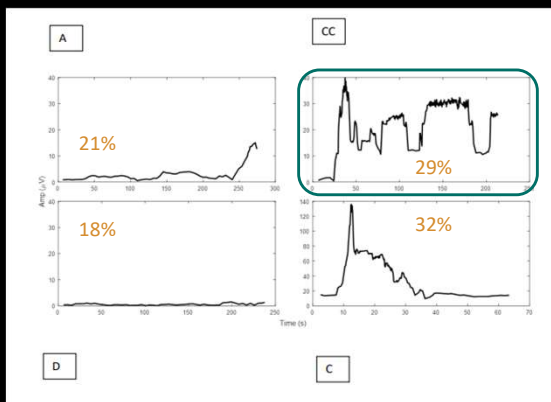


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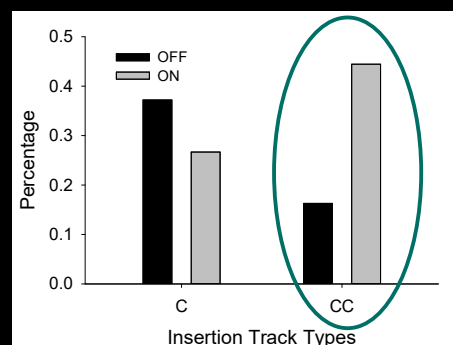
AIM ECoG feedback provides better chance to recover larger ECoG amplitude

More "recovered" (CC) cases with AIM feedback ON

- 76% with ON vs 24% with OFF

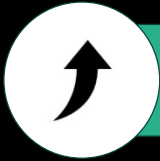


The Type CC insertion track pattern, representing corrected drops in ECoG 15 amplitude, was seen in 76% of cases with ECoG "on", compared to 24% of cases with 16 ECoG "off" ($p = 0.003$)



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Significance & Conclusions



AIM ECoChG feedback improved structural preservation with decreased translocations.



AIM ECoChG feedback provided better chance to preserve higher ECoChG responses (more type CC, fewer C).



Insertion pattern types and amount of drop correlated with post-op hearing loss.



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AIM Benefits



1

CI Candidates and Recipients

- Confidence in the team's approach to measure the responses and electrical behavior of the cochlea during surgery
- Objective Measures to confirm optimized programming

2

Surgeons

- Designed to measure the responses and electrical behavior of the cochlea in the OR with ECoChG and objective suite of measurements
- Longitudinal, objective measurements for testing and programming CI

3

Audiologists

- Efficient programming support with eSRT and ECoChG Audiogram
- Objective measures to optimize programming



ACIA Survey (2023)

- Semi-annual survey distributed to all ACIA members

Title: Cochlear Implant Activation Timeline

Brief Summary:

We would like to assess the typical timeframe of activation for cochlear implant centers across the country. In an examination of social media comments surrounding this topic, we have seen significant variability but also substantial patient-interest in others' timelines for this process. We are evaluating what factors, if any, go into the decision-making process for arranging this appointment.



Atlanta Institute for ENT

Activation

Q3: Does your program have a set timeframe for cochlear implant activation?

Answered: 27 Skipped: 0

ANSWER CHOICES	RESPONSES	
Yes	85.19%	23
No	14.81%	4
Unknown	0%	0
TOTAL		27

- Majority have set timeframe
- ~71% are ≥ 2 weeks

Q4: If you answered yes to question #3, what is the standard timeframe?

Answered: 22 Skipped: 5

ANSWER CHOICES	RESPONSES	
4 weeks post-op	18.18%	4
3 weeks post-op	13.64%	3
2 weeks post-op	40.91%	9
1 week post-op	13.64%	3
Other (please specify)	13.64%	3
TOTAL		22



Atlanta Institute for ENT

Why bother with early activation?

- Patient feedback
- Care coordination
 - Long-distance travel
- Improved outcomes?



Atlanta Institute for ENT

Patient Feedback

- Facebook group “Cochlear Implant Experiences”
 - >40,000 members worldwide
 - Frequently discussed topic/question

Top contributor
4 weeks?!! My surgeon only wants 1 week after surgery to activate

Top contributor
I almost went crazy

I went three weeks with no sound and it was emotionally overwhelming. I have a hearing family and thought I can lipread pretty well. Well.... I didn't do well lipreading without sound. I just really started praying for peace and dove into my Bible for strength during that time. Thankfully I was able to understand words on activation day. Those three weeks was tough but it proved that I had bigger things/success coming. I have been activated since June 2022 and I am soooo much better than I ever was.



Atlanta Institute for ENT

AI4ENT Protocol Pilot

- Reduce time between surgery and activation
- Based on “complete cochlear implant care” model¹
- Assess for any potential complications
 - Swelling/pain
 - Inability to activate
 - Worsened symptoms of dizziness/vertigo



Atlanta Institute for ENT

1. Vanderbilt University & Mayo Clinic

AI4ENT Activation

- 100 consecutive patients from August 2021 to January 2023
 - **Currently >225 patients**
- Average Activation Time: 7.3 days (range 1-13 days)
- Average Patient Age: 56 years (range 8 mo – 86 yr)



Atlanta Institute for ENT

AI4ENT Activation

- No complications related to surgical site or patient symptoms
- No patient unable to be activated
 - Stronger magnet used occasionally (reduced at 4 week follow-up)
- Unanimously positive feedback from patients & caregivers



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Implementation

- “Minimally invasive” subperiosteal pocket surgical technique
 - 4 cm (< 2 inch) incision
 - No “well” for implant
 - Updated implant profiles have reduce thickness
 - Implant secured by anatomical suture lines
 - **Reduces swelling and allows for early activation**
- Ensure activation is scheduled at the time of surgery scheduling
 - Can vary from 1-10 days postoperatively



Atlanta Institute for ENT

Benefits of Early Activation

- Early activation is feasible and safe for patients of all ages
- Patients prefer activation and auditory rehabilitation to start quickly
- Consolidation of appointments can improve clinic efficiency
- Early activation is associated with increased device usage and improved performance outcomes
 - ?Device usage
 - ?Spiral ganglion degeneration/preservation via stimulation



Atlanta Institute for ENT

Improved Outcomes?

Original Study

Improved Postoperative Speech Recognition and Processor Use With Early Cochlear Implant Activation

*Ankita Patro, MD, MS, †Nathan R. Lindquist, MD, ‡Jourdan T. Holder, AuD, PhD,
*Michael H. Freeman, MD, ‡René H. Gifford, PhD, *Kareem O. Tawfik, MD, *Matthew R. O'Malley, MD,
*Marc L. Bennett, MD, *David S. Haynes, MD, and *Elizabeth L. Perkins, MD

*Department of Otolaryngology—Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, Tennessee; †Department of Otolaryngology—Head and Neck Surgery, Baylor College of Medicine, Houston, Texas; and ‡Department of Hearing and Speech Sciences, Vanderbilt University Medical Center, Nashville, Tennessee

AbstractObjective: To report speech recognition outcomes and processor use based on timing of cochlear implant (CI) activation.
Study Design: Retrospective cohort.

Setting: Tertiary referral center.

Patients: A total of 604 adult CI recipients from October 2011 to March 2022, stratified by timing of CI activation (group 1: ≤ 10 d, $n = 47$; group 2: >10 d, $n = 557$).

Main Outcome Measures: Average daily processor use; Consonant-Nucleus-Consonant (CNC) and Arizona Biomedical (AzBio) in quiet at 1-, 3-, 6-, and 12-month visits; time to peak performance.

Results: The groups did not differ in sex ($p = 0.887$), age at CI ($p = 0.109$), preoperative CNC ($p = 0.070$), or preoperative AzBio in quiet ($p = 0.113$). Group 1 had higher median daily processor use than group 2 at the 1-month visit (12.3 versus 10.7 h/d, $p = 0.017$), with no significant differences at 3, 6, and 12 months. The early activation group had superior median CNC performance at 3 months

(56% versus 46%, $p = 0.007$) and 12 months (60% versus 52%, $p = 0.044$). Similarly, the early activation group had superior median AzBio in quiet performance at 3 months (72% versus 59%, $p = 0.008$) and 12 months (75% versus 68%, $p = 0.049$). Both groups were equivalent in time to peak performance for CNC and AzBio. Earlier CI activation was significantly correlated with higher average daily processor use at all follow-up intervals.

Conclusion: CI activation within 10 days of surgery is associated with increased early device usage and superior speech recognition at both early and late follow-up visits. Timing of activation and device usage are modifiable factors that can help optimize postoperative outcomes in the CI population.

Key Words: Cochlear implant—Datalogging—Early activation—Outcomes—Speech perception.

Otol Neurotol 45:386–391, 2024.



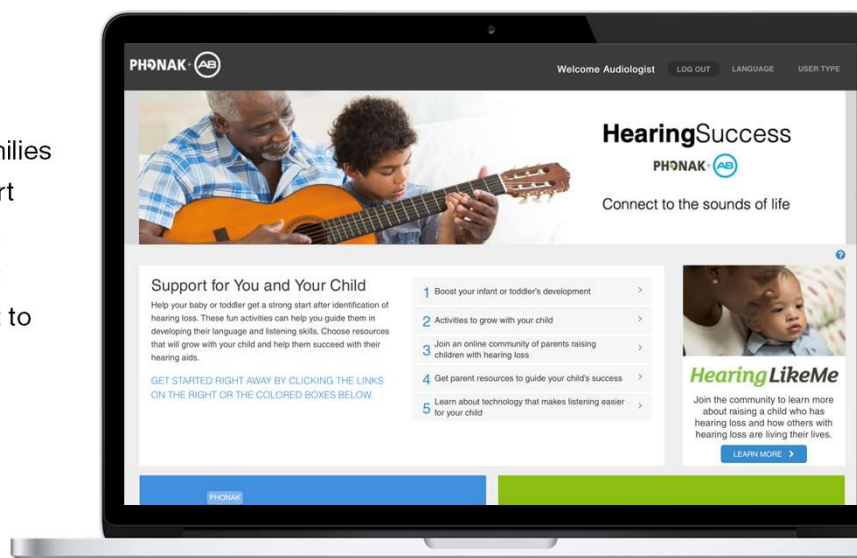
Atlanta Institute for ENT



RESOURCES



HearingSuccess provides families and adults with a place to start auditory skills training before, during and after they get their hearing technology at no cost to you or your client





Empowered Patients. Efficient Practices.



Digital Solutions for Personalized Patient Care

Thursday, September 26, 2024

9 AM – 10 AM Pacific



Jamie Jensen, Au.D.



Dawn Marsiglia, Au.D.



Carrie Spangler, Au.D.



Dina Vazouras, M.Aud.A.