

Department of Otolaryngology Head & Neck Surgery

An Update on Cochlear Implantation Research and Practice

Matthew L. Bush, M.D., Ph.D., MBA, FACS UK College of Medicine Endowed Chair in Rural Health Policy Professor and Chair

Disclosures

- No off-label treatment of patients related to this presentation or underlying research
- Consultant for Med El, Cochlear, and Advanced Bionics
- Research supported by NIH/NIDCD (R01DC017770, R01DC016957, R33DC019602, U01OD033247)







- Describe the history of CI and the burden of hearing loss
- Discuss the changes in cochlear implant candidacy and practice
- Evaluate the opportunities for cochlear implantation in non-traditional patients



The History of Cochlear Implantation



History of Cochlear Implantation

300 years of science 50 years of progress

• Standing on the shoulders of giants...



Http://health.howstuffworks.com/how-to-care-for-your-ears4.htm



• 1790: Alessandro Volta – ears & electricity





• 1790: Alessandro Volta – ears & electricity





• 1790: Alessandro Volta – ears & electricity





Kentucky

• 1790: Alessandro Volta – ears & electricity







• 1790: Alessandro Volta – ears & electricity





- 1790: Alessandro Volta ears & electricity
- 1950: Djourno and Eyries direct hearing nerve stimulation, performed 1st implant
- 1961: Bill House partnership with 3M
- 1970's: Work with multiple channels
- 1984: First FDA approved CI (over age 18)
- 1990: Approved for age 2
- 1998: Approved for 18 months
- 2000: Approved for 12 months



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Cochlear Implant Companies









Transmitter & external magnet

Microphone & sound processor



Receiverstimulator & internal magnet





The Burden of Hearing Loss and Challenges of Hearing Care



Sensorineural Hearing Loss

- 5 in 1000 children born with hearing loss
- 1 in 1000 children born with profound hearing loss
- 30% of adults (65-74), 40% of adults (75 or over)
- 38 million adults in US alone report hearing loss
- CI recipients: 200K US, 700K worldwide Kentucky

Utilization of CI in the US

~38 million with HL (NIDCD)

Potential implant candidates: 1.2 million severe to profound (iData Research)

> ~100k received CI (NIDCD)





- NIDCD, Quick Statistics About Hearing, <u>www.nidcd.nih.gov/health/statistics/quick-statistics-hearing</u>
- 2010 iData Research Report showed U.S. market for hearing aids and audiology devices in 2009
- 96K, (58k adults and 38k children) have received CIs in the U.S. as of December 2012 (NIDCD), <u>www.nidcd.nih.gov/health/cochlear-implants</u>)

Delays in Rural Pediatric Hearing Care (Bush et al, Laryngoscope, 2014)

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Assessment of Appalachian Region Pediatric Hearing Healthcare Disparities and Delays

Matthew L. Bush, MD; Mariel Osetinsky, BA; Jennifer B. Shinn, PhD; Thomas J. Gal, MD, MPH; Xiuhua Ding, MS; David W. Fardo, PhD; Nancy Schoenberg, PhD

Rural children with hearing loss take:

- 2x longer obtain HA's
- 2x longer obtain a CI



The Long and Winding Road



Would you get seek hearing healthcare?



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Nassiri AM, Marinelli JP, Sorkin DL, Carlson ML. Barriers to Adult Cochlear Implant Care in the United States: An Analysis of Health Care Delivery. Semin Hear. 2021 Dec 9;42(4):311-320.

Low HHC Utilization and High HL Prevalence

		Selected RHCs across eastern Kentuclay
Audiogram within last		Selected MITCS across castern Kentucky
1 year	13 (3.4)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
5 years	52 (13.4) 🔫	mon * * ?
Hearing loss		
Present	271 (69.9)	
Absent	117 (30.1)	(N=388, Average age 51.1)
		Kentucky

Linking Hearing, Education, and Mental Health

Variable	Odds ratio	95% CI	P value
Age	1.03	1.01 to 1.05	<0.01
Education[Some college or beyond]	0.47	0.26 to 0.86	<0.05
Ringing[Yes]	3.45	1.98 to 6.08	<0.001
Loud noise[Yes]	1.97	1.08 to 3.61	<0.05
Mental health[Fair or Poor]	3.48	1.74 to 7.18	<0.001

The Degree and Impact of Delayed Adult HHC

- Rural Adult HA Utilization
 - 26yrs (rural) vs 19yrs (urban)
 HL a barrier to education for rural adult HA users
- Rural Adult CI Utilization
 - 36yrs (rural) v 29yrs (urban)
 - Rural hearing related job loss (40% versus 12%, p=0.05)

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Rurality and Determinants of Hearing Healthcare in Adult Hearing Aid Recipients

> Stephen Chan, BS; Brian Hixon, MD; Margaret Adkins, AuD; Jennifer B. Shinn, PhD; Matthew L. Bush, MD

Timing and Impact of Hearing Healthcare in Adult Cochlear Implant Recipients: A Rural–Urban Comparison

*Brian Hixon, †Stephen Chan, *Margaret Adkins, *Jennifer B. Shinn, and *Matthew L. Bush

*Department of Otolaryngology-Head and Neck Surgery; and †College of Medicine, University of Kentucky, Lexington, Kentucky



Sociodemographic Factors

• Lower Likelihood of Pursing a CI

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Anthony M. Tolisano, MD¹, Natalie Schauwecker, BBA, BS², Bethany Baumgart, AuD¹, Johanna Whitson, AuD¹, Joe Walter Kutz Jr, MD, FACS¹, Brandon Isaacson, MD, FACS¹, and Jacob B. Hunter, MD¹

Factors Influencing Time to Cochlear Implantation

James R. Dornhoffer, Meredith A. Holcomb, Ted A. Meyer, Judy R. Dubno, and Theodore R. McRackan

Department of Otolaryngology—Head and Neck Surgery, Medical University of South Carolina, Charleston, South Carolina

- Non-white \rightarrow 52% lower odds

- <u>Older Age</u>
- <u>Single/Widowed</u>

Original Research Racial Disparities in Adult Cochlear Implantation

Geethanjeli N. Mahendran¹, Tyler Rosenbluth², Miriam Featherstone, AuD³, Esther X. Vivas, MD³, Douglas E. Mattox, MD³, and Candace E. Hobson, MD³ Colarpsglog-Head and Neck Surgery I-7 © American Academy of Oclarpsglog-Head and Neck Surgery Foundation 2021 Reprints and permissions: Reprints and permissions: Doi: 10.1177/0145998211027340 http://otojournal.org

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FOUNDATION

- Delayed Implantation: Non-white race
- Medicaid is a barrier to Adult CI (Sorkin 2019)



Sensorineural Hearing Loss

- Average length of severe-to-profound hearing loss prior to receiving a cochlear implant is <u>11-12 years</u>¹²
- Outcomes with cochlear implants exceed their performance with hearing aids¹²³
- Today, we are <u>treating <10% of people</u> who can benefit from implantable technology₄₅

 Parkinson, A.J., et al. (2002). The Nudeus 24 Contour cochlear implant system: Adult dinical trial results, *Ear and Hearing*, 23 (Suppl.), 41-48.
 Balkany, T., et al. (2007) Nudeus North American clinical trial, O-HNS, 136:757-762.
 Hol, M.K., et al. (2005) Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. Arch Oto-HNS. 131(4):321-3215.
 Blanchfield, B.B., et. Al. (2001). The severely to profoundly hearing-impaired opulation in the United States: Prevalence estimates and demographics. JAA. 12, 183-189 5. Cochlear internal estimate, recipients data 6. Cochlear recipient and candidate survey (April and Dec. 2008).



Epidemiology of SSD

• 1/1000 live birth and 6% of elementary children

Pediatric Single-Sided Deafness



Jacob B. Hunter, мD^{a,*}, Kristen L. Yancey, мD^a, Kenneth H. Lee, мD^b

• 0.14% of adults

Prevalence of Single-Sided Deafness in the United States

Emily Kay-Rivest, MD, MSc D; Alexandria L. Irace, BA; Justin S. Golub, MD, MS; Mario A. Svirsky, PhD



The Problem of SSD: Adults

- Pitch recognition (Kang et al, 2009; Wright 2012)
- Speech intonation recognition (Chatterjee et al, 2008)
- Chord, melody, timbre, and melodic contour recognition (Dorman et al, 2008; Gfeller et al, 2006; Kong et al, 2012; Prentiss et al, 2015)
- Speech recognition in quiet and noise (Dunn et al, 2005; Dorman et al, 2009; Gifford et al, 2014; van Hoesel et al, 2012)
- Poor spatial hearing (Rothpletz et al, 2012; Welsh et al, 2004)
- Reduced quality of life (Wie et al, 2010)
- Increased self-reported hearing handicap (Iwasaki et al, 2013)



The Problem of SSD: Children

- Poor spatial hearing
- Reduced quality of life
- Implications on speech-language development and cognition
- Increased risk for psychosocial/behavioral difficulties
- Poor functioning in educational settings

Rothpletz AM et al, *J Speech Lang Hear Res*, 2012 Wie OB et al, Ann Otol Rhinol Laryngol, 2010 Lieu JE. *B-ENT*, 2013 Anne S, et al. *Otolaryngol Head Neck Surg*, 2017



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The Problem of SSD Treatments

Limitations

Transcranial re-routing - CROS/BiCROS

 Bone implant hearing system Localization ability no better than chance (Bosman et al, 2003; Hol et al, 2010)
 Variable ability to use binaural cues for speech recognition in noise (Kunst et al, 2007)



Consider the Complexities that Create Hearing Health/Healthcare Disparities

Defining Disparities in Cochlear Implantation through the Social Determinants of Health

Marissa Schuh, M.P.H.¹ and Matthew L. Bush, M.D., Ph.D., M.B.A.¹

ABSTRACT

Hearing loss is a global public health problem with high prevalence and profound impacts on health. Cochlear implantation (CI) is a well-established evidence-based treatment for hearing loss; however, there are significant disparities in utilization, access, and clinical outcomes among different populations. While variations in CI outcomes are influenced by innate biological differences, a wide array of social, environmental, and economic factors significantly impact optimal outcomes. These differences in hearing health are rooted in inequities of health-related socioeconomic resources. To define disparities and advance equity in CI, there is a pressing need to understand and target these social factors that influence equitable outcomes, access, and utilization. These factors can be categorized according to the widely accepted framework of social determinants of health, which include the following domains: healthcare access/quality, education access/quality, social and community context, economic stability, and neighborhood and physical environment. This article defines these domains in the context of CI and examines the published research and the gaps in research of each of these domains. Further consideration is given to how these factors can influence equity in CI and how to incorporate this information in the evaluation and management of patients receiving cochlear implants.

Evaluating Equity Through the Social Determinants of Hearing Health

Marissa R. Schuh and Matthew L. Bush



(Schuh, Seminars in Hearing, 2021)

The Changes in CI Candidacy and Practice



Candidacy - The Audiogram

• No predictive value for post treatment benefit

(Walden and Walden, 2004)

• No predictive value for post treatment speech in noise performance

(Taylor, 2004, Nilsson, 2007, Snapp, 2010, 2012)

• No predictive value to speech outcomes in cochlear implant recipients

(McRackan et al., 2018)



Candidacy - The Audiogram \rightarrow 60/60 rule

Original Study

Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation

Teresa A. Zwolan, Kara C. Schvartz-Leyzac, and Terrence Pleasant

Department of Otolaryngology-Head and Neck Surgery, Michigan Medicine, Ann Arbor, Michigan

	Candidate	Non-candidate	Total	
Meets 60/60	212	67	279	PPV = 76%
Does not meet 60/60	8	128	136	NPV = 94%
Total	220	195	415	
	Sensitivity: 212/220 = 96.3%	Specificity: 67/195 = 65.6%		

Changes in CI Candidacy





FDA labelling for medical devices Insurance approval

(different for each product: Nucleus, Synchrony, HiRes Ultra 3D)
Criteria	1985	1990	1998	2000	2014	2019	2020
AGE of implantation	18 yrs +	2 yrs +	18 mos +	12 mos +	12 mos +	Adults & Children 5yrs+ (SSD, AHL) – Med EL	9mos+ - Cochlear
ONSET of hearing loss	Post- linguistic	Post- linguistic adults Pre- & post- linguistic children	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic	Pre- & Post- linguistic
DEGREE of hearing loss	Profound	Profound	Adults: Severe to profound SNHL Peds: Profound	Adults: Moderate to profound SNHL in both ears Peds: Sev to prof 2 yrs + Prof < 2 yrs	Adults - EAS & Hybrid: Normal to moderate SNHL in low to mid frequencies; severe to profound HL in high frequencies	SSD: Profound SNHL, one ear Normal or mild SNHL, other ear Asymmetrical HL: Profound SNHL, one ear Mild to mod severe SNHL, other ear 1 mo HA trial	Adults: Moderate to profound SNHL in both ears Peds: Sev to prof 2 yrs + Prof < 2 yrs
Speech SCORES	0%	0%	Adults: <u>≤</u> 40%	Adults: Sentence score ≤ 50% in ear to be implanted, ≤ 60% in best aided condition Peds: ≤30%	EAS/Hybrid: CNC word score > 10% but < 60% in ear to be implanted; < 80% CNC words in contralateral ear	≤5% correct on CNC word score	



Off-label \longleftrightarrow FDA labelling for medical devices approval

Adult Indications (Conventional)

MED-EL: severe to profound (≥70 dB HL) pre- or post-lingual hearing loss with ≤40% on sentence (HINT) testing

Cochlear Americas: moderate to profound (\geq 60 dB HL in LF) pre- or post-lingual hearing loss with \leq 50% on sentence testing in candidate ear and \leq 60% best aided (bilateral)

Advanced Bionics: severe to profound (≥70 dB HL) postlingual hearing loss with ≤50% on sentence (HINT) testing



Pediatric Indications (Conventional) MED-EL: <20% on sentence testing

Cochlear Americas: ≤30% word recognition

Advanced Bionics: ≤12% word recognition (PBK) or <30% sentence (HINT-C) scores



CNC word tests are harder than sentence tests and may give better approximation of who will do well (no ceiling effect)



FDA does not specify testing (noise) conditions



CMS: up to 60% sentence testing in the implanted ear





Traditional CI Candidacy

Medicare criteria:

- Bilateral moderate-toprofound SNHL
- ≤ 60% in best-aided listening condition on open set recorded test
- Intact auditory nerve and "acoustic areas of the CNS"
- Free from middle ear infection

<u>Pediatric</u>- variable

- Severe-profound SNHL bilaterally
- Limited benefit from proper amplification
- Family commitment and realistic expectations

No medical contraindication K Kentucky

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SSD CI Candidacy

- Profound SNHL in implanted ear and normal hearing in non-CI ear
- Four frequency pure-tone average (4PTA: 5, 1, 2, and 4 kHz) of
 >80 dB HL in the impaired ear and ≤30 dB HL in the contralateral ear
- ≥ 5 years of age (max 10 years duration of deafness)





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Medical Evaluation

- Newborn hearing screen OAE or ABR
- Audiogram
- Hearing history
- Family history
- Medical history
- Exam
 - Otitis media
 - Congenital anomalies
- Radiology
 - CT scan
 - MRI



Normal Cochlear Anatomy



University of Kentucky

Normal Cochlear Anatomy





Cochlear Agenesis – Michel Aplasia





Cochlear Agenesis – Michel Aplasia





Mondini Deformity





Cochlear Ossification Post-Meningitis



Candidacy - The Big Picture



Device and manufacturer selection involves mainly bells & whistles





MED[©]EL

Cochlear®





MED[©]EL

Low-frequency PTA (125, 250, 500 Hz) of <80 dB is thought to be worthwhile to preserve

Electrical power output affects voltage compliance, battery life, and inadvertent stim

Surgeon & Audiologist—electrode vs device

Scalar position and translocation

- Lateral wall vs peri-modiolar
- Electrode length & angular insertion depth

Intraoperative electrocochleography

Fully banded, compressed, & double arrays

Scalar translocation

Scala tympani insertions yield superior speech outcomes and residual hearing preservation

Lateral wall electrodes
Round window insertions

O'Connell et al 2016; PMID 28894813

Lateral wall vs peri-modiolar



Lateral wall vs peri-modiolar

Tip Fold-Over: Pre-curved Perimodiolar Electrode Array



Electrode length & angular insertion depth

VS

Minimizing cochlear trauma & preserving acoustic hearing Maximizing electrical transmission & speech outcomes

O'Connell et al 2017; PMID 28304096



Wide variability exists in Cl outcomes

Factors affecting cochlear implant outcomes

Neural substrate / 'Bottom-up' processing

Age at implantation Duration of deafness Residual acoustic hearing Better word & sentence scores

Surgical factors

Scalar position & translocation Angular insertion depth Acoustic insertion trauma Top-Down Processing

Neurocognitive function Linguistic ability Nonverbal reasoning

Processor wear time

Brain plasticity & adaptation

Advances in Care



Cochlear SmartNav

AB Remote Link





Med El Otoplan



Opportunities for Challenging and Non-Traditional Patients



Case Presentation

- 66-year-old attorney with a history of medically refractory Left Meniere's disease
- He underwent intratympanic steroid/gent injections, ELS surgery, and a left labyrinthectomy in 2015
- Vertigo is resolved but left with profound left hearing loss, persistent left tinnitus, difficulty hearing in noise, localization of sound
- Has consistently worn **BiCROS** hearing aid



Case Presentation



How can we counsel this patient and what options can we provide?



Outcomes of SSD CI


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Benefits of Cochlear Implantation in Childhood Unilateral Hearing Loss (CUHL Trial)

Kevin D. Brown, MD, PhD D; Margaret T. Dillon, AuD D; Lisa R. Park, AuD D

- 20 children with moderate to profound UHL
- Prospective clinical trial (ages 3-12)

Evaluated for speech perception in quiet, speech perception in noise, sound localization, and subjective benefits after implantation.

Improved Speech Outcomes

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Improved Localization

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Benefits of Cochlear Implantation in Childhood Unilateral Hearing Loss (CUHL Trial)

Kevin D. Brown, MD, PhD ^(D); Margaret T. Dillon, AuD ^(D); Lisa R. Park, AuD ^(D)





Cochlear Implants for Single-Sided Deafness: Quality of Life, Daily Usage, and Duration of Deafness

Nathan R. Lindquist, MD ^(D); Jourdan T. Holder, AuD, PhD; Ankita Patro, MD, MS ^(D); Nathan D. Cass, MD; Kareem O. Tawfik, MD; Matthew R. O'Malley, MD; Marc L. Bennett, MD; David S. Haynes, MD; René H. Gifford, PhD; Elizabeth L. Perkins, MD

- 66 adults with moderate to profound UHL
- Retrospective Case Series (ages 20-74)
- Evaluated for speech recognition, tinnitus (THI), subjective speech/spatial outcomes, QOL, device usage after implantation.



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Improved Speech Outcomes

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Noise



Tinnitus Reduction

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--- Minimal clinical important difference (MCID) for Δ THI = 7



Subjective Improvements

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Important SSD CI Guidelines



American Cochlear Implant Alliance Task Force Guidelines for Clinical Assessment and Management of Cochlear Implantation in Children With Single-Sided Deafness

Lisa R. Park,¹ Amanda M. Griffin,^{2,3} Douglas P. Sladen,⁴ Sara Neumann,⁵ and Nancy M. Young^{6,7,8}

- 1. Cochlear implantation to address SSD in an ear with cochlear nerve deficiency is contraindicated.
- 2. Cochlear implantation should be considered a priority for children at risk of hearing loss progression in the better hearing ear.
- 3. A CI evaluation is recommended for children with a unilateral three frequency pure tone average (3FPTA) of >60 dB HL
- 4. Trials with re-routing devices are not recommended for children seeking binaural hearing
- 5. Counseling and Testing battery summaries



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American Cochlear Implant Alliance Task Force Guidelines for Clinical Assessment and Management of Adult Cochlear Implantation for Single-Sided Deafness

Margaret T. Dillon,¹ Armine Kocharyan,² Ghazal S. Daher,² Matthew L. Carlson,² William H. Shapiro,³ Hillary A. Snapp,⁴ and Jill B. Firszt⁵

- 1. CI should not occur earlier than 3 to 6 months after the sudden hearing loss to allow ample time for potential recovery of hearing.
- 2. Preoperative imaging may include MRI w/ or w/o temporal CT.
- 3. Advanced cochlear ossification, severe labyrinthine dysplasia, and cochlear nerve aplasia are potential contraindications
- 4. Prolonged duration of deafness in an adult with post-lingual onset is not a contraindication to cochlear implantation.
- 5. Advanced age is not a contraindication for cochlear implantation.
- 6. Reduced tinnitus is frequently reported with CI use.



Case Presentation

- What about our 66-year-old attorney with Left Meniere's disease and SSD?
- He presented in 2021 inquiring about a CI for SSD
- On Medicare Insurance...





Head & Neck Surgery

Case Presentation

- CI Evaluation
 - Right HA only (+1 SNR) AzBio = <u>61%</u>
 - Right HA only (-2 SNR) Azbio = $15^{0/0}$
- Proceed with left CI under traditional candidacy (Medicare)





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MRI T2

MRI T2

CT

Patency of cochlea

Fibrosis in labyrinth remnant Patency of basal turn

Fibrosis in labyrinth remnant

Case Presentation

- Left Med El CI with Flex 28 Electrode
- Fibrosis of basal turn managed with 22G angiocath dilation



Case Presentation – 3 months Post-Op



Soundfield: AzBio 85% (L CI quiet, Right masked with speech noise insert)

- Preop -0%



Another Challenging Scenario...

- 74 year old with bilateral progressive SNHL
- Hx of Left vestibular schwannoma treated with Gamma Knife Radiotherapy 10 years ago. Left ear has been non-functional over the past 5 years with no benefit from a hearing aid. Consistent right hearing aid user but has lost benefit from the hearing aid at this point.
- No evidence of growth of left VS since treatment



Pre-op Audiogram



RIGHT EAR at 60 dB: CNC Words- 16% CNC Phonemes- 50% AzBio at +10 signal-to-noise ratio- 4%

LEFT EAR at 70 dB: CNC Words- 0% CNC Phonemes- 0% AzBio at +10 signal-to-noise ratio- 0%



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Post-op (3 months after Right CI)



CNC whole words = 48% CNC phonemes = 67% AzBio sentences at +10 dB SNR = 12%



Post-op (6 months after Right CI, Pre-op Left CI)



LEFT HEARING AID ONLY: CNC whole words in quiet = 0% CNC phonemes in quiet = 0% AzBio Sentences in QUIET = 0%

RIGHT COCHLEAR IMPLANT ONLY CNC whole words in quiet = 52% CNC phonemes in quiet = 75% AzBio Sentences at +10 dB SNR = 15%









Post-op (3 months after left CI)



LEFT cochlear implant ONLY: CNC whole words in quiet = 40%CNC phonemes in quiet = 61% AzBio sentences in quiet = 28%

Let (Due)

х

X,

П.



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Meet the UK CI Team

Audiology





Meg Adkins, AuD





Persis Ormond, AuD Abby Mattingly, AuD



Ricardo Vallejo, AuD Matt Bush, MD, PhD

Nate Cass, MD

Beth McNulty, MD

Raleigh Jones, MD



Chris Azbell, MD

Ken Iverson, MD



Caitlin Fiorillo, MD

Pediatric Otology



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Adult and Pediatric Otology



T

Thank You!