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Candidacy Expansion and Improved Outcomes in Cochlear Implant Surgery

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14 August, 2019

Grant supported by NIH R01 DC 010821

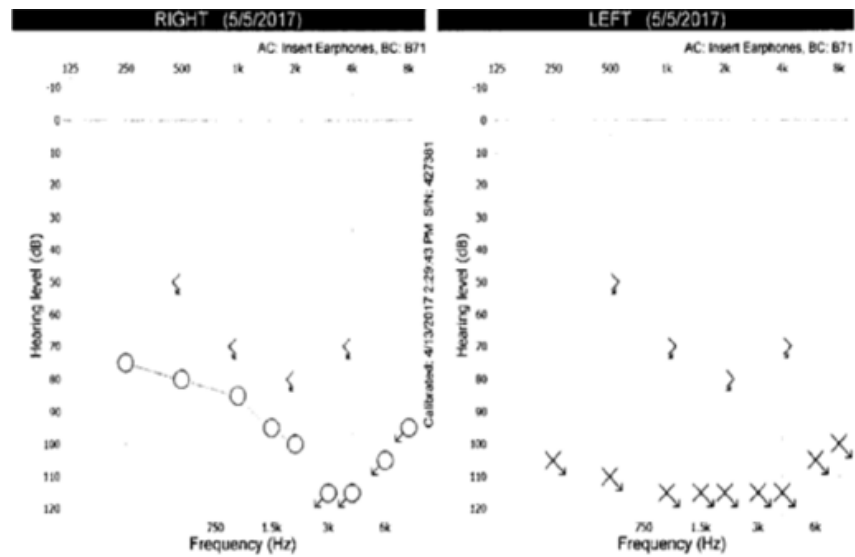
1

Learning Outcomes

1. Discuss the advances in surgical technique and electrode design that have contributed to improved outcomes following CI.
2. Discuss the use of cochlear implantation as a rehabilitative option for patients with single-sided deafness.
3. Review the use of objective tools to determine the subjective sound quality of a cochlear implant.

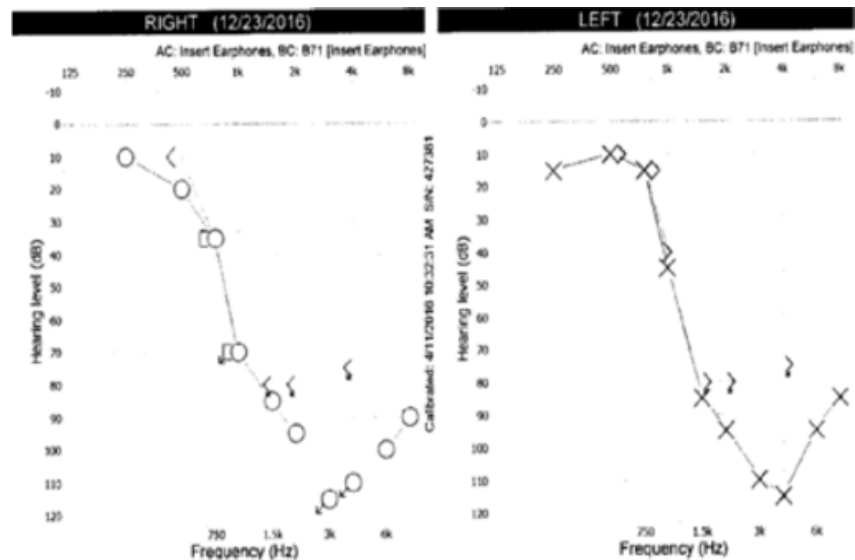
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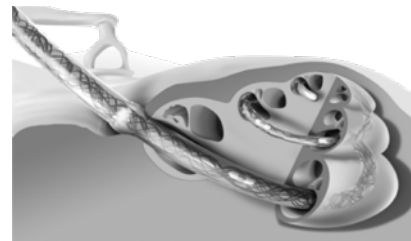
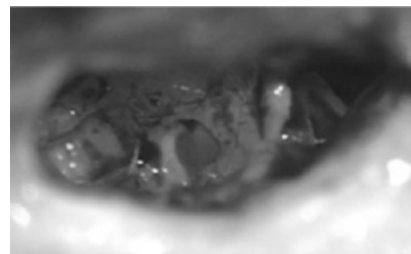
Why is LF HP important in CI patients?

- **Localization** (Dunn et al, 2010; Gifford et al, 2014)
- **Pitch recognition** (Kang et al, 2009; Wright 2012)
- **Melody recognition** (Dorman et al, 2009; Gfeller et al, 2006)
- **Hearing in noise** (Dunn et al, 2005; Dorman et al, 2009)
- **Speech recognition** (Carlson et al, 2011; O'Connell et al, 2016)

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Requirements for hearing preservation

1. Advances in surgical technique
2. Advances in electrode design



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continued



Advances in surgical technique

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continued

Soft surgical technique

- Ernst Lehnhardt, 1993 (Germany)
 - Minimizing drilling on the cochlea
 - Opening the cochlea as late as possible
 - Avoiding suctioning of perilymph
 - Use of lubricant during insertion (i.e. glycerol)

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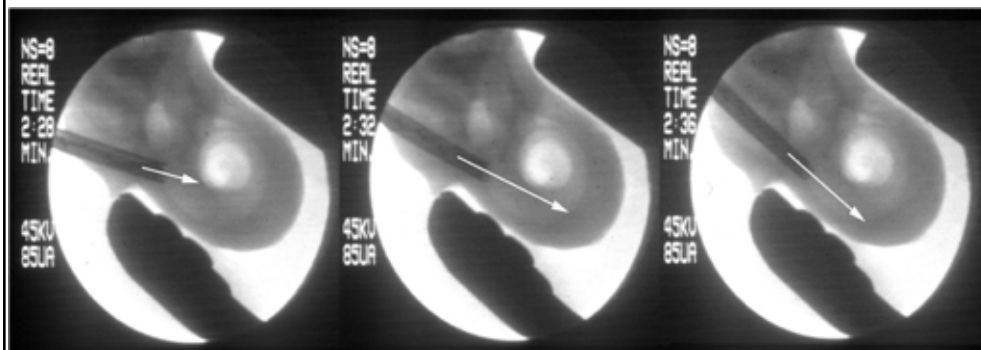
Surgical Technique

- Minimizing trauma should improve objective outcomes
 - Fracture of osseous spiral lamina
 - Injury to modiolus
 - Compression/tearing of microvasculature
 - Interscalar excursion from ST to SV

Roland & Wright, 2006

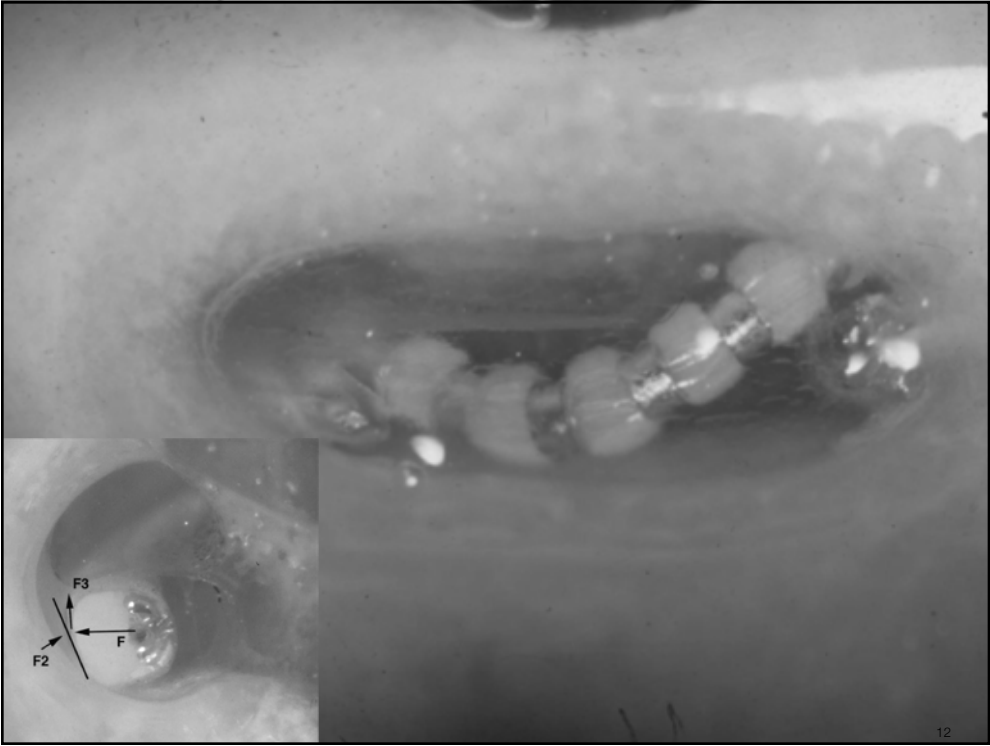
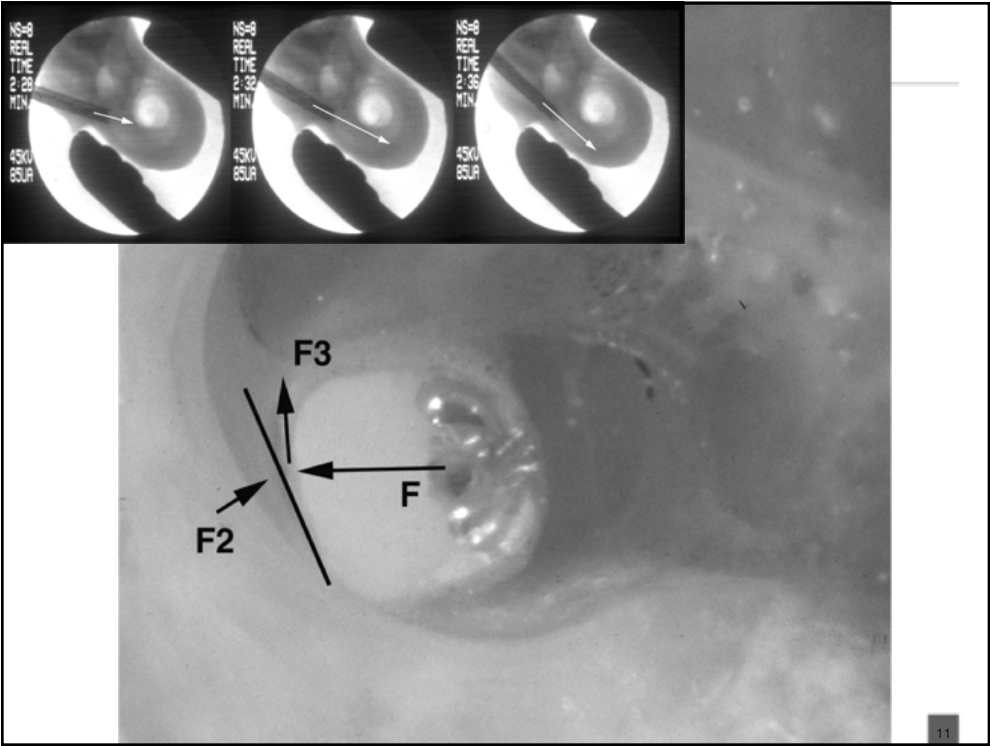
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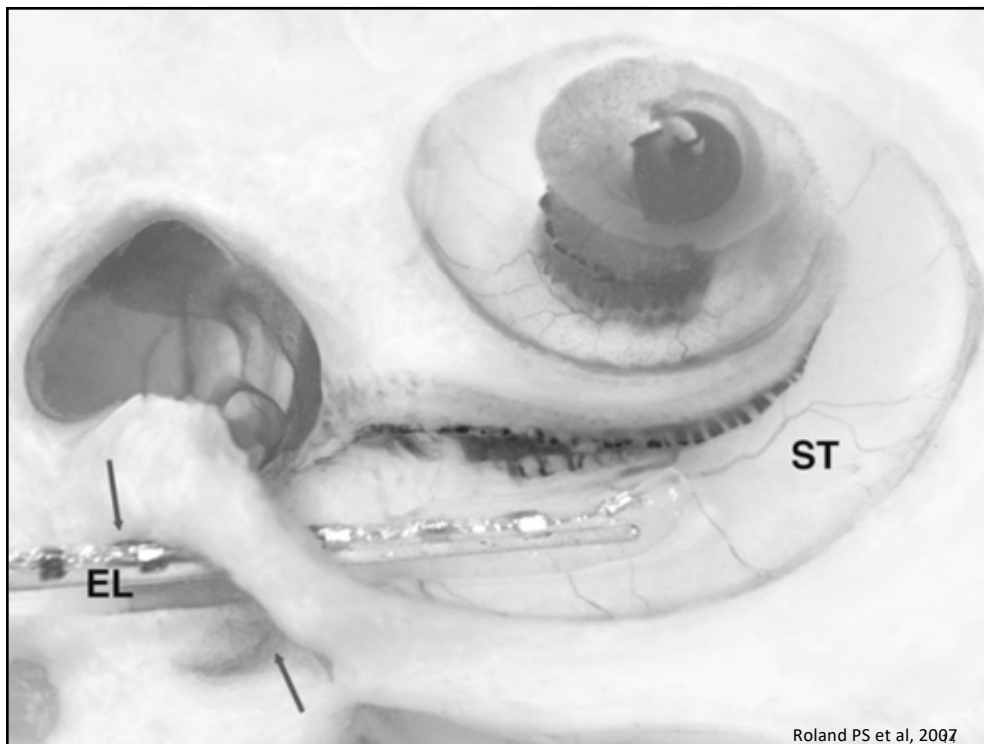


Cochleostomy for electrode insertion

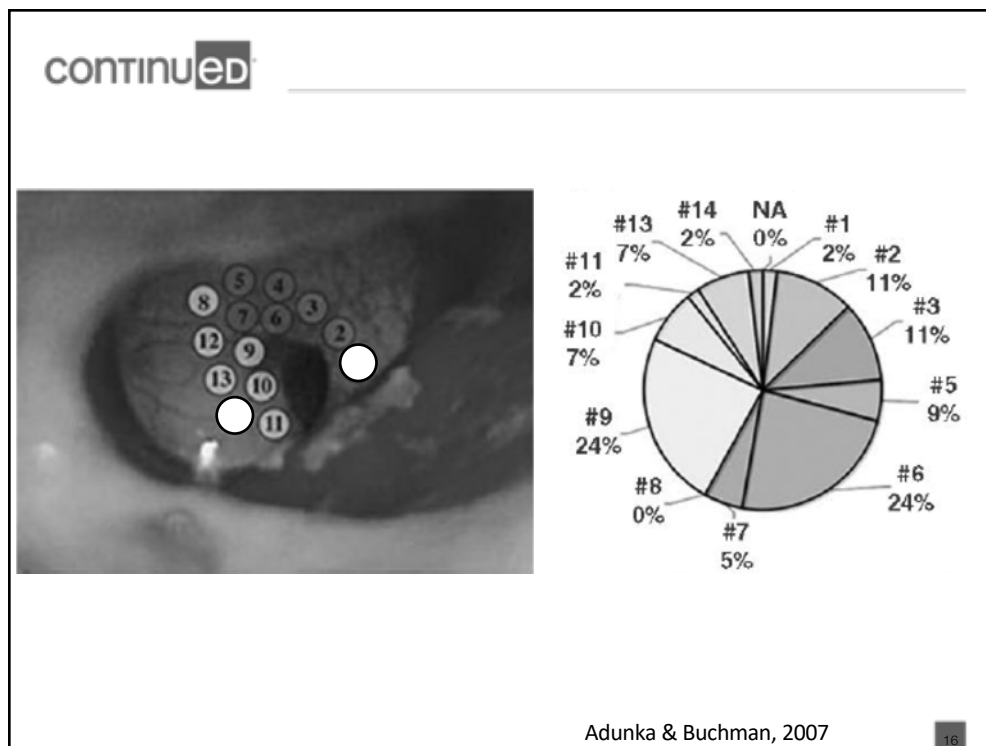
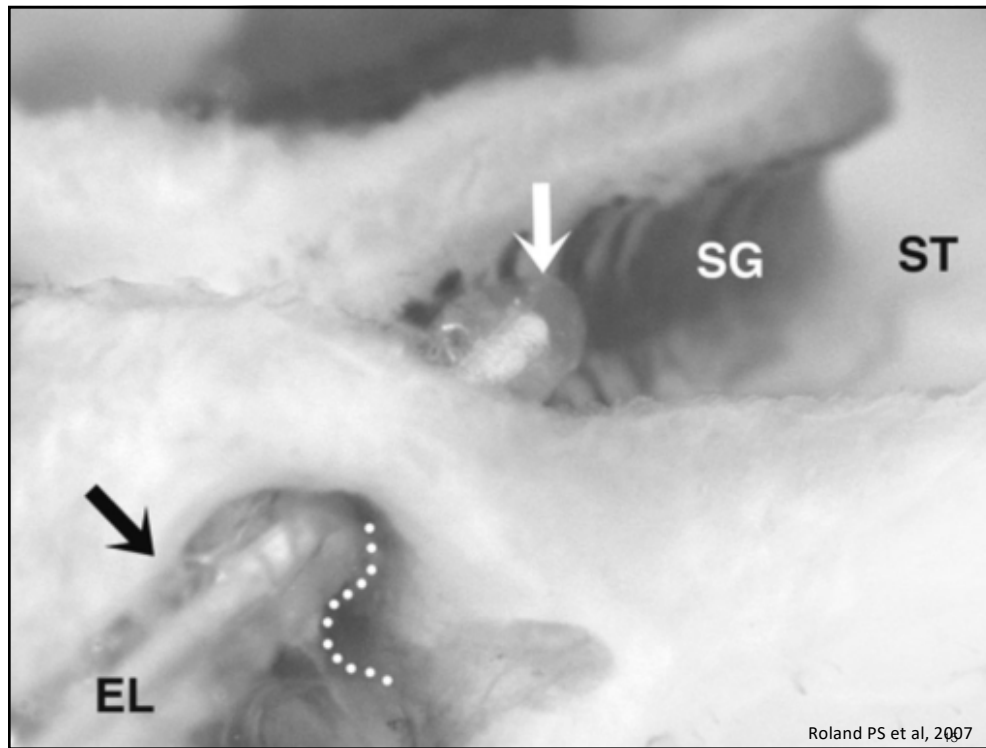
- Early years of CI surgery - cochleostomy was dogma
 - Improved visualization
 - Mid-scalar trajectory

Roland JT, 2005
Roland PS et al, 2007

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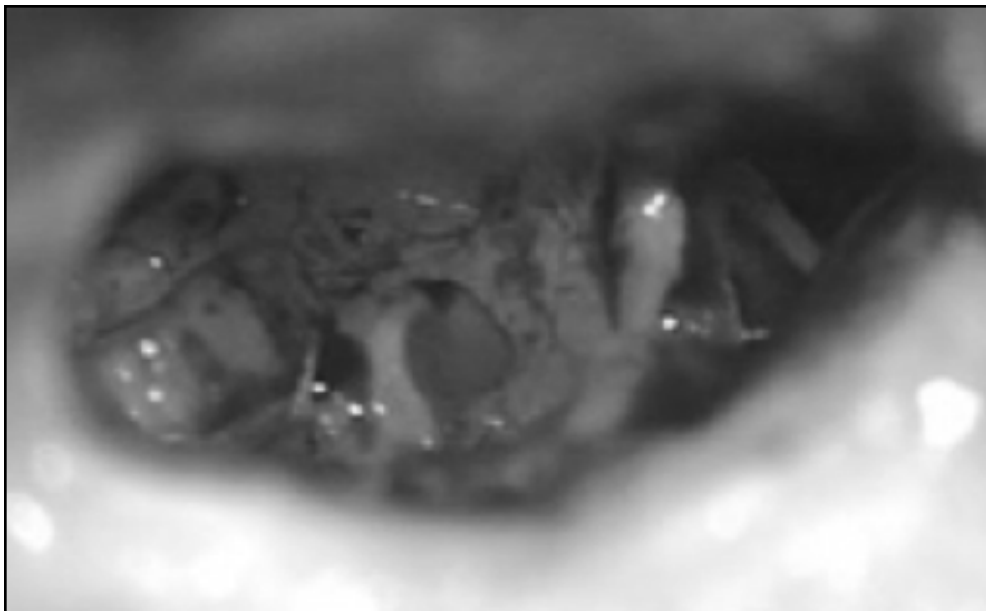
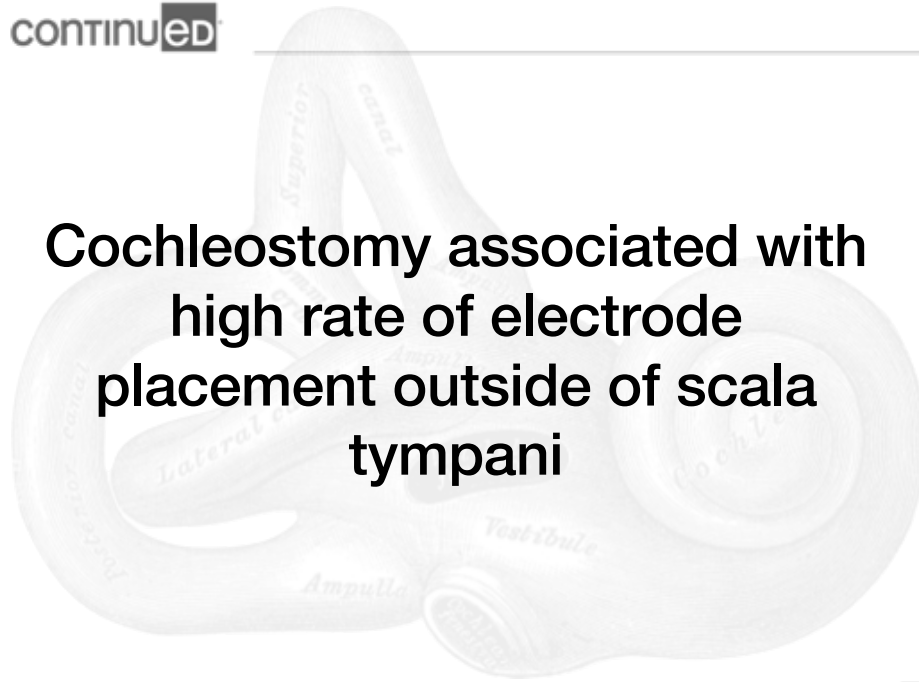


Roland PS et al, 2007



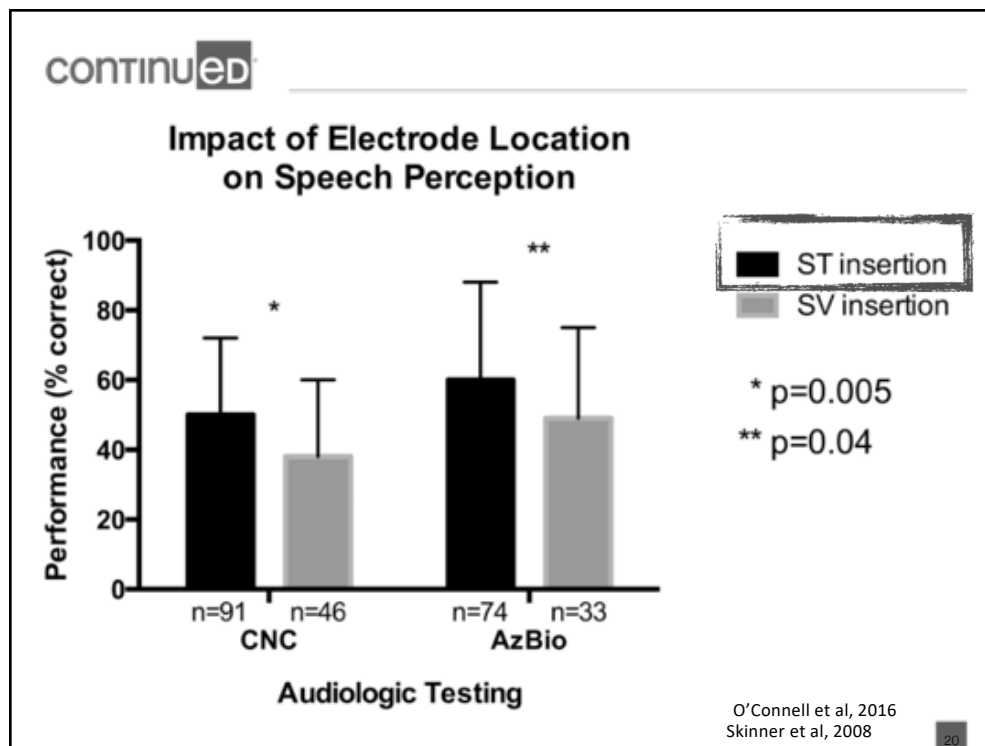
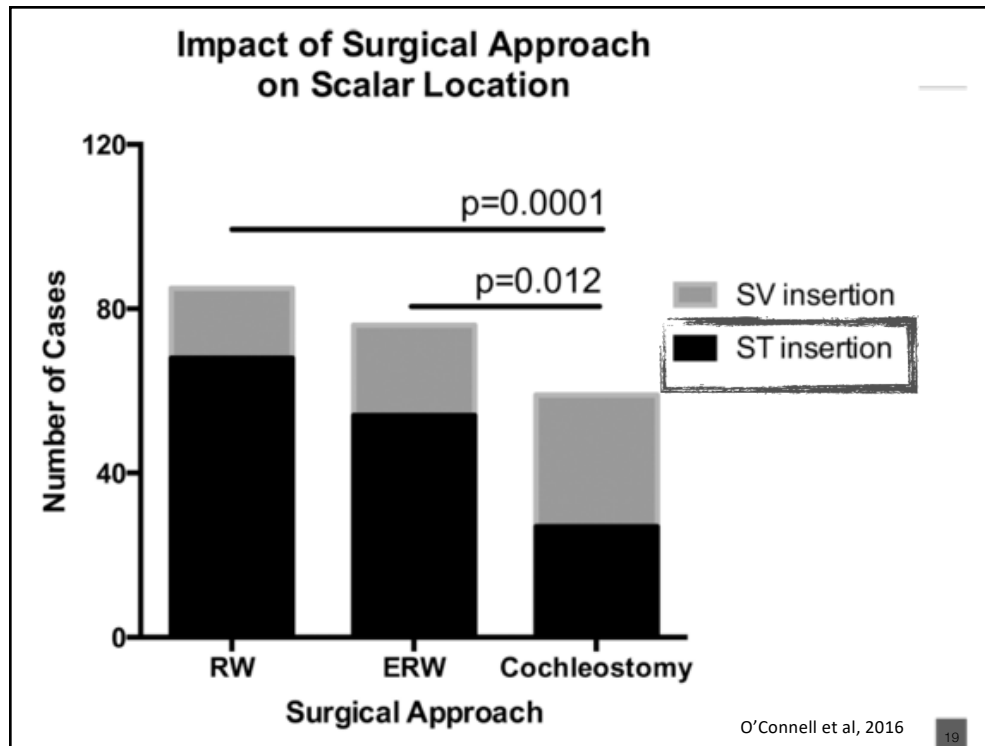
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Cochleostomy associated with high rate of electrode placement outside of scala tympani

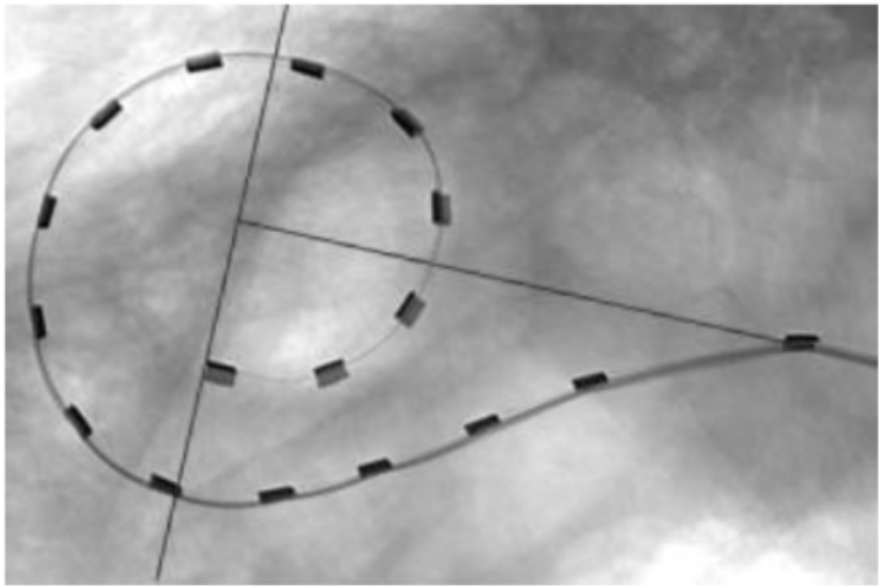


2000s - interest in RW insertion to reduce trauma and improve insertion accuracy

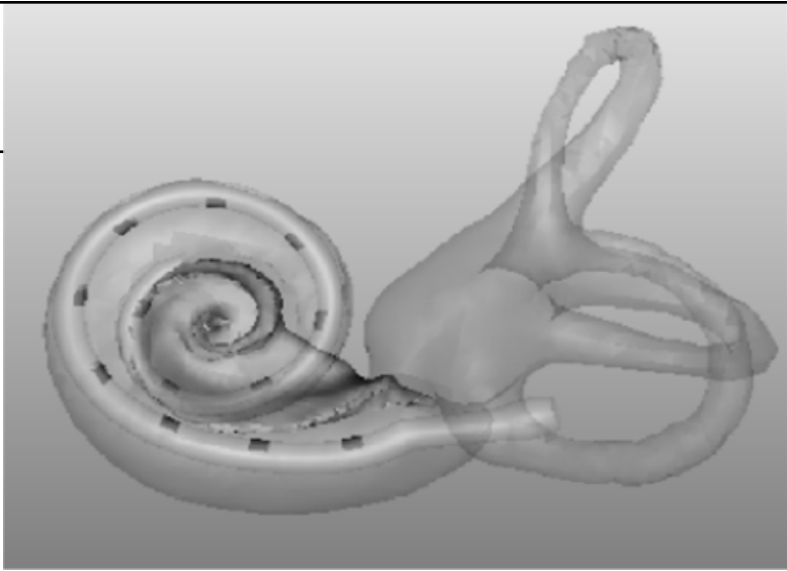
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Electrode	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Modiolar Distance (mm)	0.05	0.11	0.02	0.48	0.94	1.22	1.28	1.36	1.36	1.16	0.94	0.59	0.30	0.21	0.19	0.29
Angular Depth (degrees)	419	370	328	298	273	247	226	204	176	164	145	122	95	69	47	29
Spiral ganglion freq (kHz)	0.62	0.75	1.04	1.30	1.49	1.94	2.30	2.73	3.24	3.70	4.31	5.11	5.95	8.70	11.35	13.46
Scalar Location	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST
Active	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Inactive						X	X	X	X	X	X					

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continued

CONTINUED



Advances in electrode design

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CONTINUED

Wanna et al, 2017

Implant Type, Surgical Approach, and Electrode Location.

	<u>Total</u>	<u>Lateral Wall</u>	<u>Perimodiolar</u>	
	<u>(N = 116)</u>	<u>(n = 47)</u>	<u>(n = 69)</u>	
	N (%)	n (%)	n (%)	P Value
Surgical approach				
Cochleostomy	38 (32.8)	11 (23.4)	27 (39.1)	0.200
Extended round window	43 (37.1)	20 (42.6)	23 (33.3)	
Round window	35 (30.0)	16 (34.0)	19 (27.5)	
Completely within the scala tympani?				
Yes	82 (70.7)	42 (89.4)	40 (58.0)	<0.001
No	34 (29.3)	5 (10.6)	29 (42.0)	

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CONTINUED

TABLE III.
Multivariate Logistic Regression of Predictive Factors for
Short-term Hearing Preservation.

Hearing Preservation Activity	Odds Ratio	95% Confidence Interval	P Value
Preoperative AC threshold at 250 Hz	0.93	0.90-0.95	<.001
Diabetes	0.51	0.18-1.42	.20
Electrode type			
Perimodiolar	Reference		
Lateral wall	3.42	1.36-8.62	.009
Mid-scala	5.61	1.82-17.34	.003
Surgical approach			
Cochleostomy	Reference		
RW/ERW	0.63	0.22-1.84	.40
Postoperative oral steroids	1.24	0.64-2.40	.52

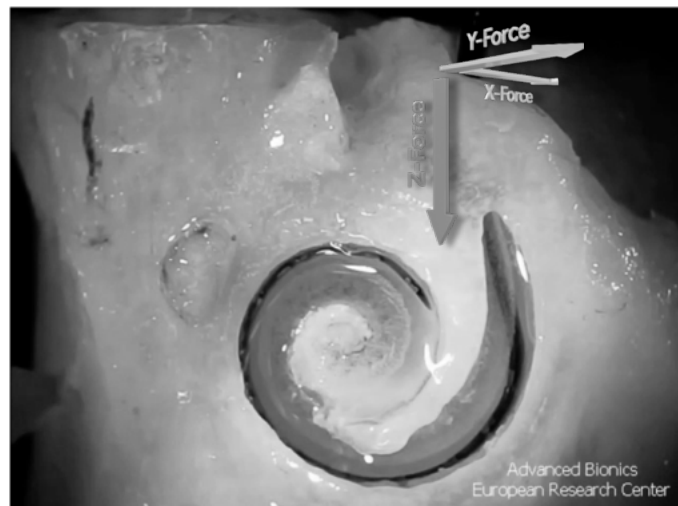
AC = air-conduction; ERW = extended round window; RW = round window.

Wanna et al, 2017

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continued

Low Insertion Forces



Video used with permission from Advanced Bionics Corporation

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continued

Considerations for design of future cochlear implant electrode arrays: Electrode array stiffness, size, and depth of insertion

Stephen J. Rebscher, MA; Alexander Hetherington, BS; * Ben Bonham, PhD; Peter Wardrop, FRCS; David
Whinney, FRCS; Patricia A. Leake, PhD
Department of Otolaryngology, University of California, San Francisco, CA

3 primary goals for future electrode design:

1. Reduced intracochlear trauma
2. Deeper insertion to access low frequency neurons
3. Greater operating efficiency (reduction in stimulus charge requirements)

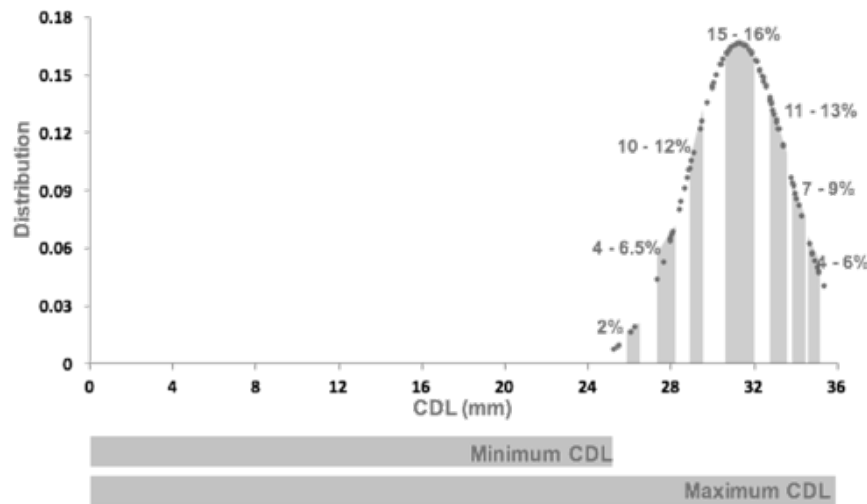
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Electrode location and audiological outcomes

- Positive correlation between CNC word score and:
 - ST electrode location (reduced trauma)
 - Insertion depth
 - Proximity to the modiolus

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Cochlear duct length



Lee J et al, 2010

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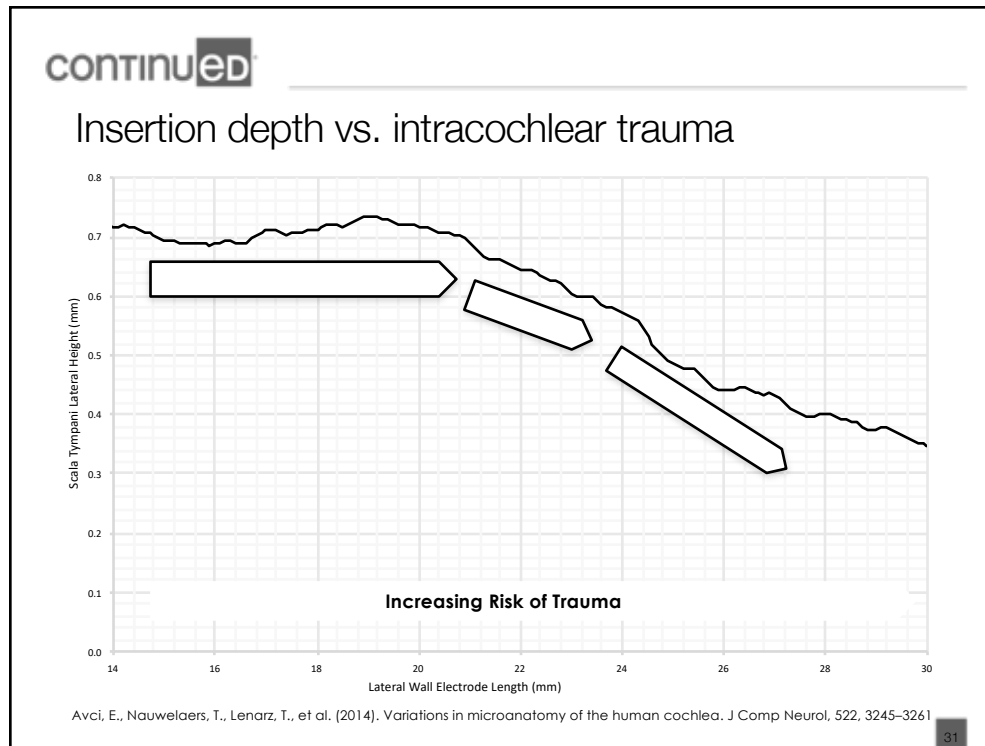
AID and speech perception outcomes

- Systematic review – 7 studies (2019)
 - 1/7 AID correlated with word scores (O'Connell, 2016)
- O'Connell, *Otol Neurotol* 2016**
 - 0.6% increase of CNC for every 10° AID regardless of HP
 - Correlation stronger in cases without HP
- 4/10 excluded for < 1 year with significant (+) correlation

Heutnik F. *Otol Neurotol*, 2019
 Chakravorti S. *Otol Neurotol*, 2019

** correlation only for lateral wall/straight arrays; shallower insertion predictive of success in PM arrays

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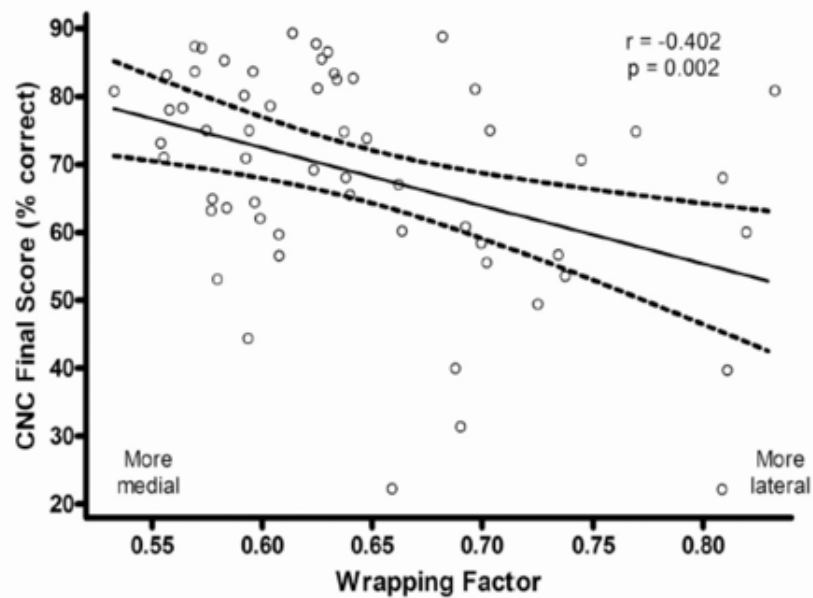


Electrode-modiolar distance

- Reducing EMD:
 - Decreases spread of excitation in cochlea
 - Lower stimulation currents
 - Lower psychophysical thresholds and comfortable levels
 - Improved speech recognition

Runge-Samuelson et al, 2009
Esquia et al, 2013

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Holden et al, 2013 34

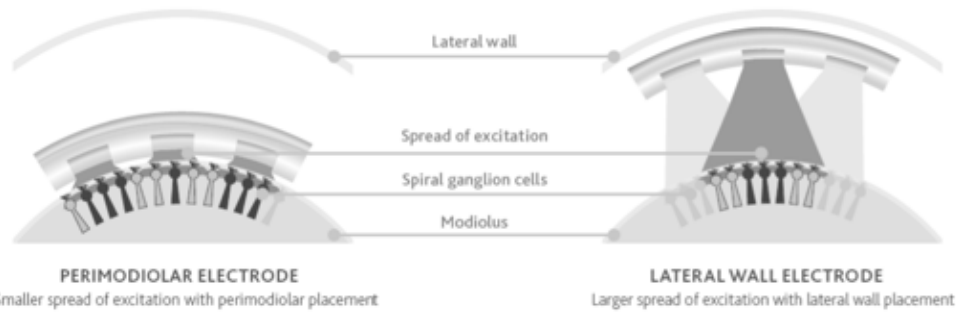
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Independent Measures (continued from Table 4) (All Participants)	Outcome Group	CNC Final	CNC Initial
Scalar Location for All Participants (N=114)			
% Elect in ST	.302 ***	.332 ***	ns
% Elect in Mid Pos	ns	ns	ns
% Elect in ST+Mid	.336 ***	.341 ***	ns
% Elect in SV	-.336 ***	-.341 ***	ns
Insertion Depth for All Participants (N=114)			
Array Trajectory Length	ns	-.204 **	-.214 *
Angular Pos Apical Elect	ns	ns	ns
Angular Pos Basal Elect	ns	-.200 *	ns
1 st PC Array Insertion Depth	ns	-.204 *	ns
Medio-lateral Position for Array Insertions with All Electrodes in ST (N=59)			
Wrapping Factor	na	-.378 **	ns

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continued

ELECTRODE POSITIONING



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continued



Advances in CI candidacy

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continued

Early
implantation
and cortical
neuroplasticity

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continued

Cortical neuroplasticity

- Juvenile brain has great capacity for plasticity
- “Sensitive periods” - stages with high neuronal plasticity
- “Endpoint” after which learning compromised
- Rapid proliferation for 3.5 years followed by “pruning” after 4 years
- Lack of auditory stimulation = lack of cortex development

Sale et al, 2009
Sharma et al, 2002
Huttenlocher et al, 1997

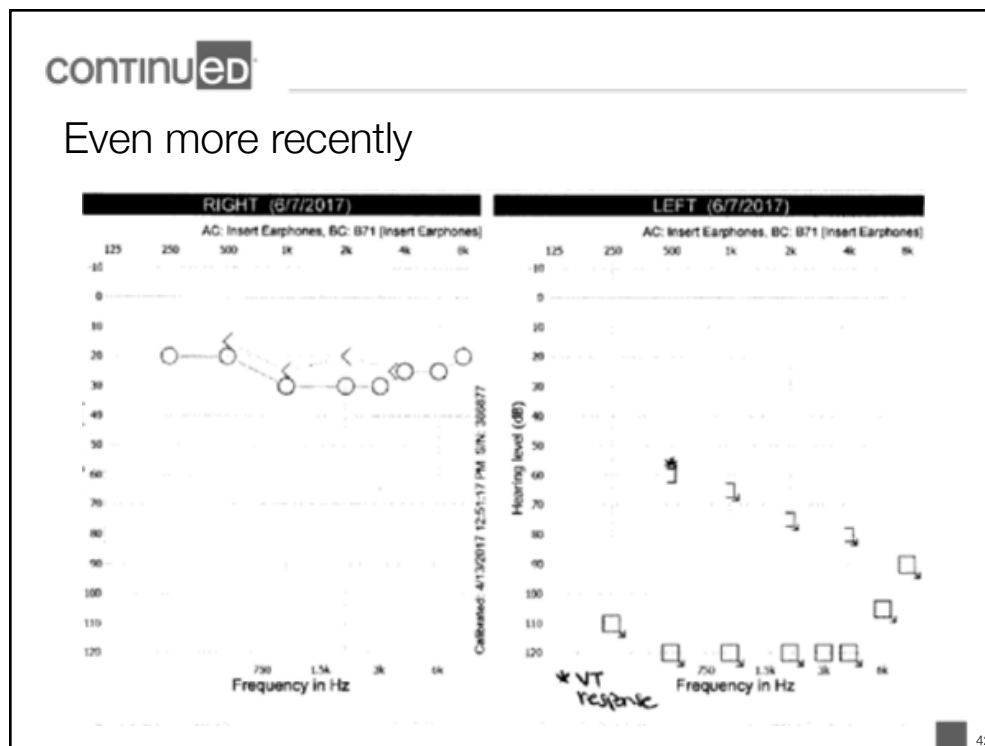
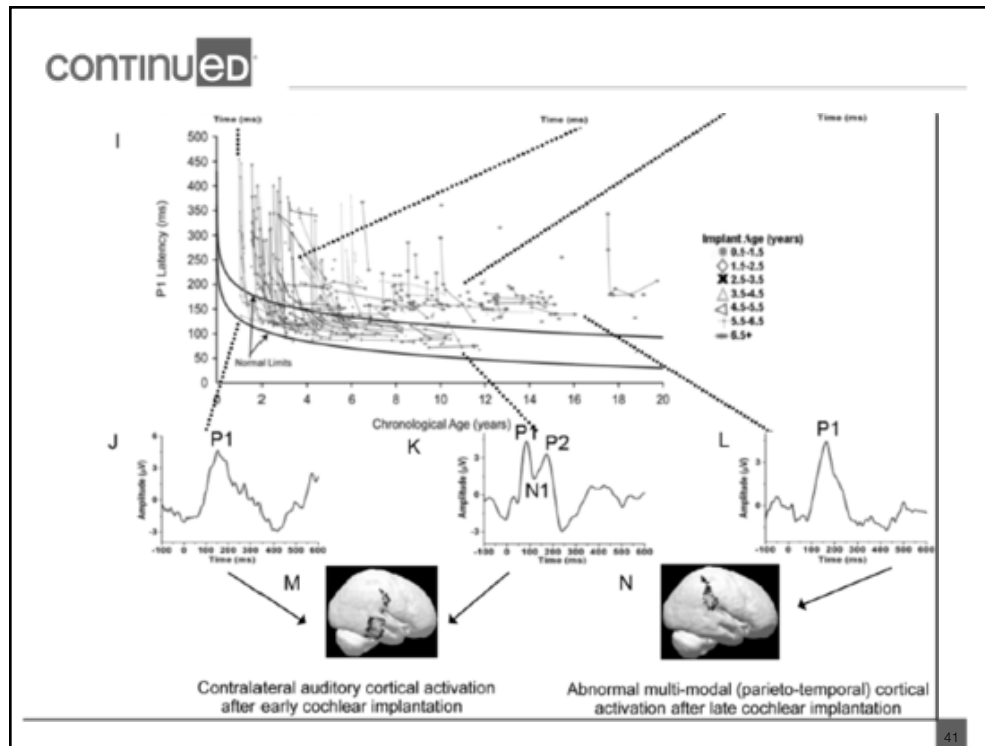
39

Benefits of early implantation

- Children implanted < 12 months show:
 - Improved comprehension & expressive communication
 - Improved word learning
 - Reduced language delay, equal to chronological age
 - Increased sentence complexity

Ching et al, 2009
Dettman et al, 2007
Cuda et al, 2014
Leigh et al, 2013

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continued

MED-EL

For Immediate Release

FDA Approves MED-EL USA's Cochlear
Implants for Single-Sided Deafness and
Asymmetric Hearing Loss

*MED-EL's are the First and Only Cochlear Implants
to Be Granted Indications for Traditionally
Underserved Population*



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continued

It's not only movement that creates new starting points...

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continued

continued

It's not only movement that creates new starting points...

Sometimes all it takes is a subtle shift in perspective or a new route to see new options and possibilities

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continued

Hypothesis 1: The Pessimist

- When excellent signal (NH) and poorer signal (CI) are present, the brain attends to the **better signal**
- Poorer signal suffers '**neglect**'
- Acquisition of speech recognition via CI is **slow**, asymptotic performance **low**, binaural function **poor**
- Subjective sound quality (judged against NH ear) **poor**

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continued

Hypothesis 2: The Optimist

- When excellent signal (NH) and poorer signal (CI) present, brain **always** has 'correct' signal
- Optimal condition for learning
- Acquisition of speech recognition via CI is **rapid**, asymptotic performance **better than average**, binaural function **good**
- NH ear 'teaches' poorer ear, Subjective sound quality **good**

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The Laryngoscope
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Rhinological and Otological Society, Inc.

Cochlear Implantation for Single-Sided Deafness: A Multicenter Study

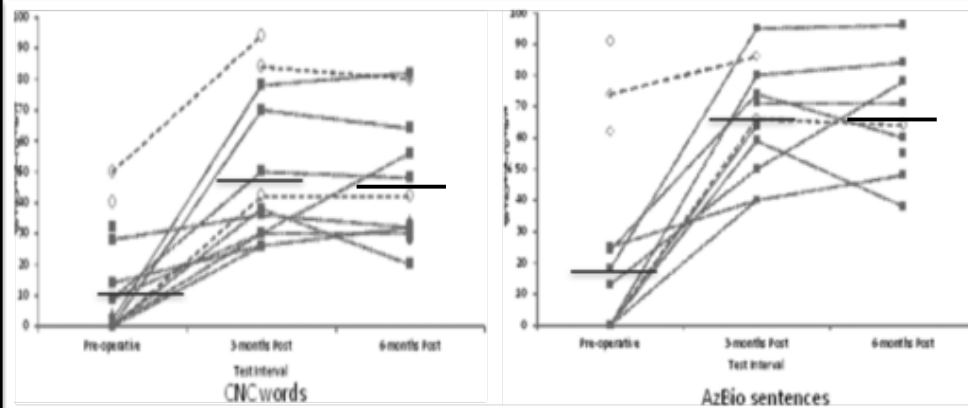
Douglas P. Sladen, PhD; Christopher D. Frisch, MD; Matthew L. Carlson, MD; Colin L.W. Driscoll, MD;
Jennifer H. Torres, MA, CCC-A2; Daniel M. Zeitler, MD

- 23 subjects (17 adults, 6 children)
- Duration of deafness 0.5-9.5 yr (mean = 4 yr)
- Etiology of deafness: ISSNHL=13 (Surgery=4; congenital=3; MD=1, Idiopathic=1; VS=1)

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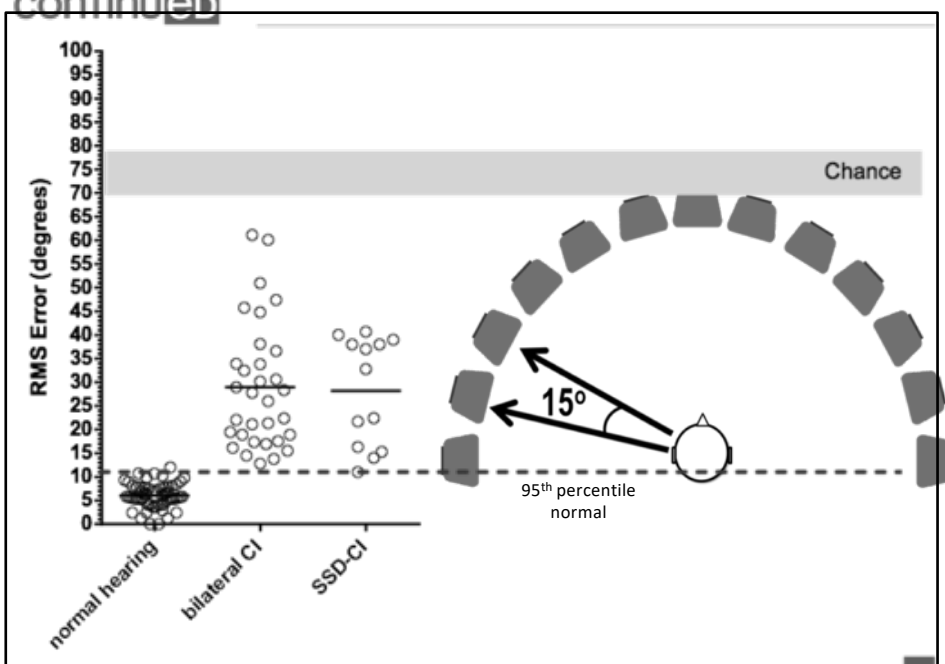
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Objective Outcomes



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continued



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continued

continued

CI for SSD in children & adolescents



continued

International Journal of Pediatric Otorhinolaryngology

Journal homepage: www.Elsevier.com/locate/ijporl

Cochlear implantation for single-sided deafness in children and adolescents

Daniel M. Zeitler^{a,*}, Douglas P. Sladen^b, Melissa D. DeJong^b, Jennifer H. Torres^c, Michael F. Dorman^d, Matthew L. Carlson^b

Zeitler, D. M., Sladen, D. P., DeJong, M. D., Torres, J. H., Dorman, M. F., & Carlson, M. L. (2019). Cochlear implantation for single-sided deafness in children and adolescents. *International journal of pediatric otorhinolaryngology*, 118, 128-133.

^aListen for Life Center, Department of Otolaryngology Head and Neck Surgery, Virginia Mason Medical Center, 1100 Ninth Avenue, Seattle, WA, 98101, USA

^bDepartment of Otolaryngology Head and Neck Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN, 55905, USA

^cDenver Ear Associates, 401 W. Hampden Place #240, Englewood, CO, 80110, USA

^dDepartment of Speech and Hearing Science, Arizona State University, PO Box 870102, Tempe, AZ, 85287, USA

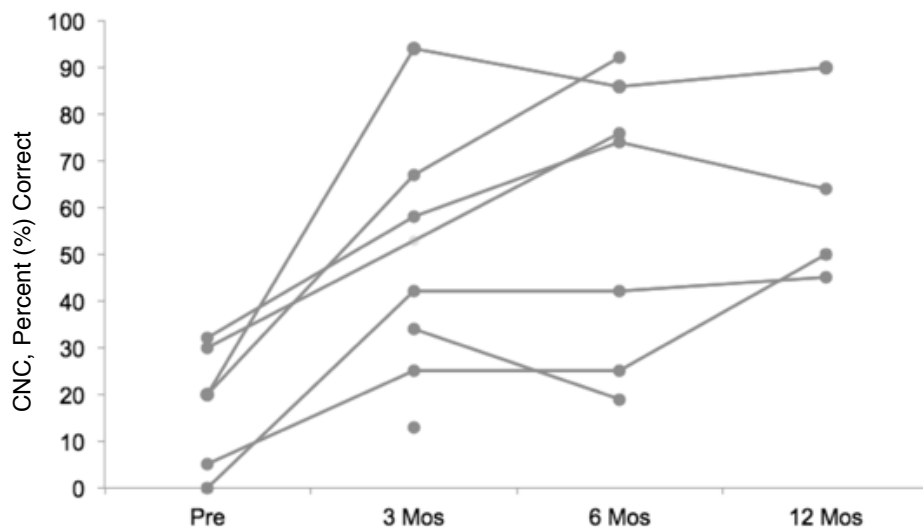
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Baseline demographics

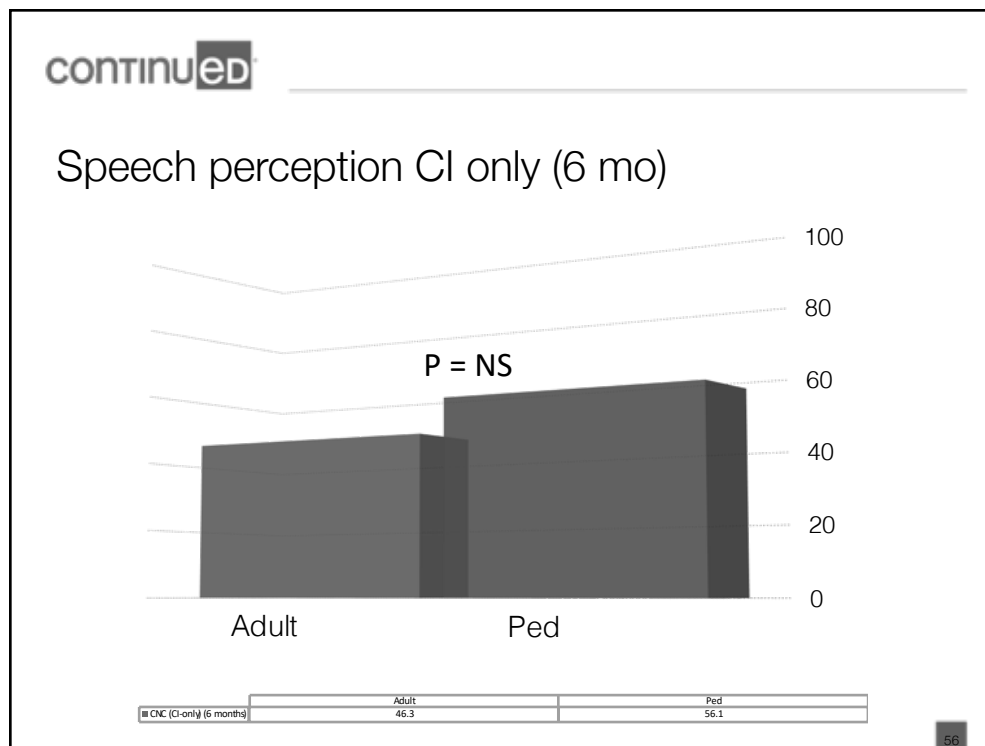
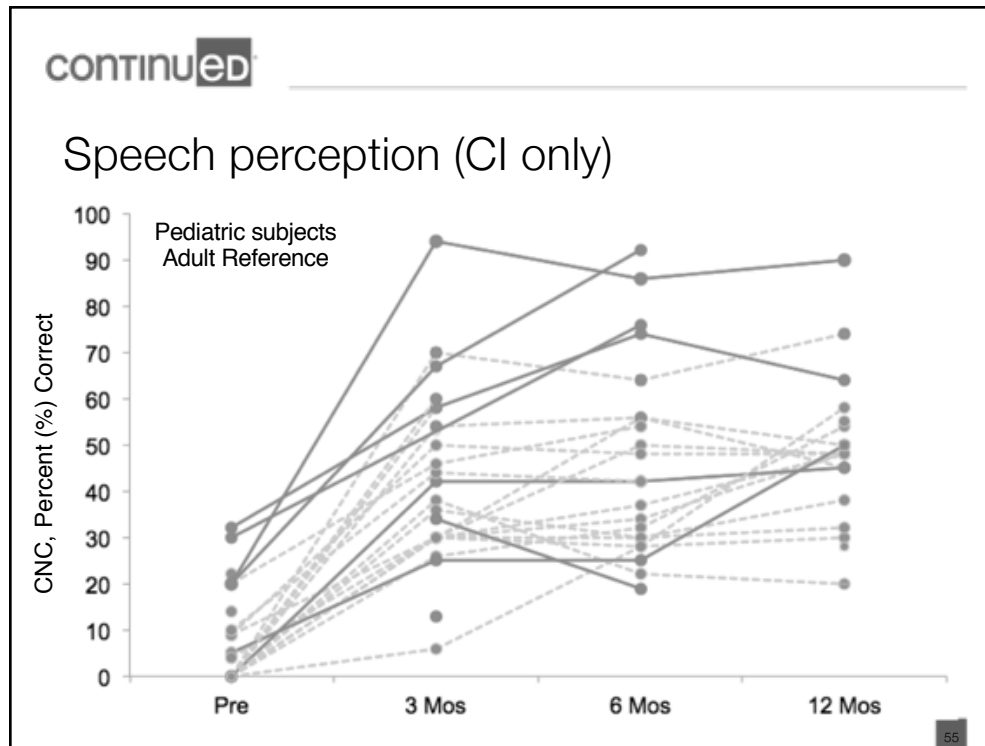
	Age (years)	Gender	Side	Etiology	LOD (years)	F/U (years)
	7.0	M	L	Idiopathic sudden	1.8	1.1
	11.0	M	R	Cholesteatoma	2.9	1.7
	15.0	F	R	Idiopathic sudden	1.6	2.1
	7.0	F	R	Idiopathic sudden	0.8	0.7
	1.5	F	L	Idiopathic congenital	1.5	0.1
	5.8	M	L	Idiopathic congenital	5.8	0.4
	8.9	M	L	Idiopathic congenital	8.9	0.3
	9.5	F	L	Idiopathic congenital	9.5	0.8
	10.0	F	R	Idiopathic progressive	4.0	2.3
Median	8.9	56% F	56% L		2.9	0.8
Mean	8.4				4.1	1.1

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Speech perception (CI only)



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continued

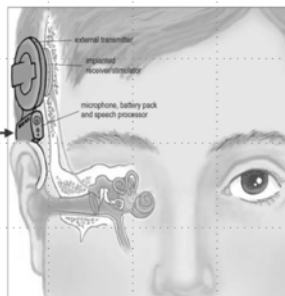
What does a CI sound like?



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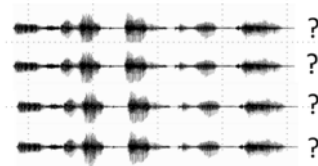
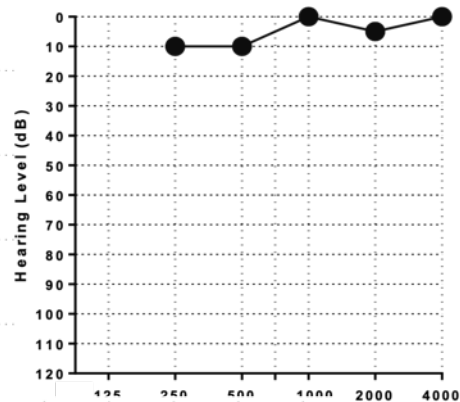
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Right Ear



clean signal direct input to CI

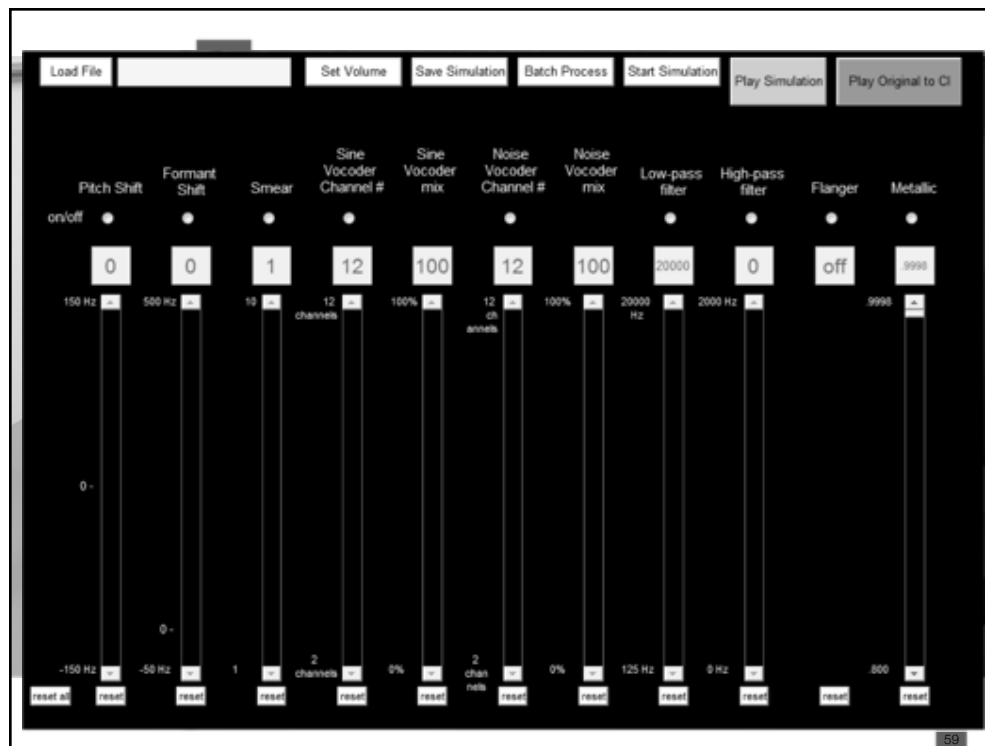
Left ear



via insert phone

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continued

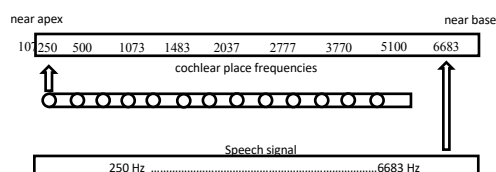


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What factors might influence sound quality of a CI?

PLACE-PITCH MATCH

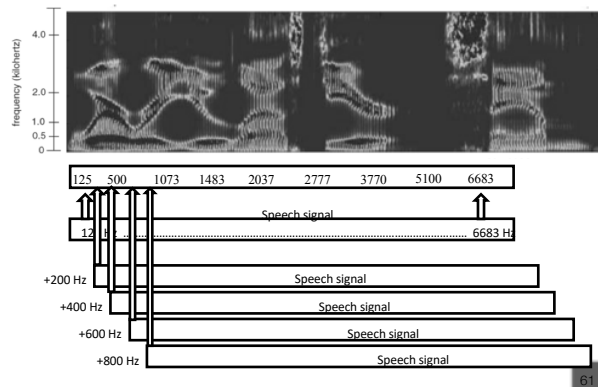
- Greenwood function predicts position of hair cells to frequency that stimulates auditory neuron in SG
- Creates **pitch map** of cochlea
- **Ideally**: energy at a given CI input frequency is delivered to a corresponding place frequency in SG



continued

PLACE-PITCH MATCH

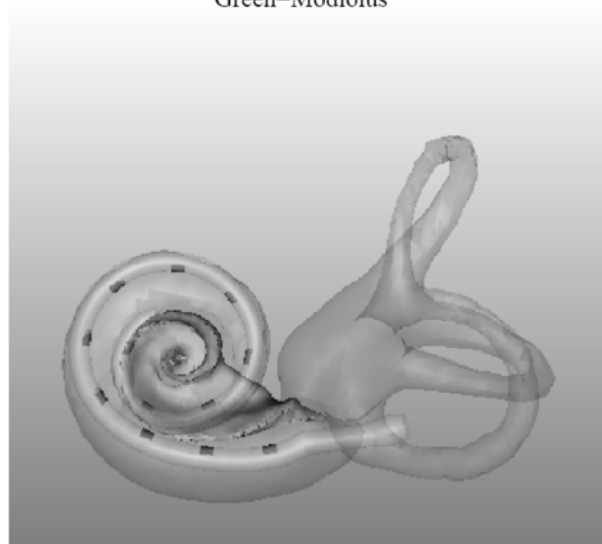
- Non-radial trajectories in apex cause failure of frequency alignment, worse further from base of cochlea
- **Realistically**: signals injected at **higher** frequencies



Dorman et al, 1997
Shannon et al, 1998
Stakhovskaya et al, 2007

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Anterior-to-Posterior
Green=Modiolus



Images courtesy of Jack Noble, PhD
Vanderbilt University

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Electrode	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Angular depth	419	370	328	298	273	247	226	204	176	164	145	122	95	69	47	29
Nearest tissue	620	750	1040	1300	1490	1940	2300	2730	3240	3700	4310	5110	5950	8700	11350	13460
Filter cf	333	455	540	642	762	906	1076	1278	1518	1803	2142	2544	3022	3590	4264	6665
Offset	+287	+295	+500	+658	+728	+1034	+1224	+1452	+1722	+1897	+2168	+2566	+2928	+5110	+7086	+6795

2.03x

Electrode	1	2	3	4	5	6	7	8	9	10	11	12
Angular depth (deg.)	525	434	382	337	281	244	210	161	119	81	42	18
Freq. at nearest tissue (Hz)	390	590	720	960	1430	1980	2630	3770	5210	7190	12010	14800
Filter center freq. (Hz)	120	235	384	579	836	1175	1624	2222	3014	4084	5507	7410
Offset (Hz)	+270	+355	+336	+381	+594	+805	+1006	+1548	+2196	+3106	+6503	+7390

1.95x

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Consequences of signal-place mismatch

1. Voice pitch (F0) and/or formant frequencies heard as higher than input pitch
2. Voices may have “munchkin” quality

continued

FUNDAMENTAL FREQUENCY (PITCH) UPSHIFT

original

+ 20 Hz

+ 40 Hz

+ 60 Hz

+ 80 Hz

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continued

WHOLE SPECTRUM (FORMANTS) UPSHIFT

original

+ 200 Hz

+ 400 Hz

+ 600 Hz

+ 800 Hz

66

continued

Electrode	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Angular depth	419	370	328	298	273	247	226	204	176	164	145	122	95	69	47	29
Nearest tissue	620	750	1040	1300	1490	1940	2300	2730	3240	3700	4310	5110	5950	8700	11350	13460
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Offset	+287	+295	+500	+658	+728	+1034	+1224	+1452	+1722	+1897	+2168	+2566	+2928	+5110	+7086	+6795

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Offset (Hz)	+270	+355	+336	+381	+594	+805	+1006	+1548	+2196	+3106	+6503	+7390

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continued

Place frequency of nearest tissue to most apical electrode and perceived upshift in frequencies

Matches **without** upward shift in pitch (F0) or formants


Place frequency = 270 Hz

Place frequency = 300 Hz

Place frequency = 300 Hz

Place frequency = 390 Hz

Place frequency = 440 Hz




Matches **with** upward shift in pitch (F0) and/or formants

Place frequency = 620 Hz

Place frequency = 650 Hz

Place frequency = 780 Hz



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continued

The diagram illustrates three scenarios of cochlear implant electrode placement relative to the cochlea's tonotopic map. Each scenario shows a horizontal row of 16 circles representing electrodes. An upward arrow indicates the location of the most apical electrode.

- Scenario 1:** The most apical electrode is at the 3rd position from the left. Text below: "Tissue nearest most apical electrode = 390 Hz". A speaker icon is shown. Text to the right: "No shift in formant frequencies to make match".
- Scenario 2:** The most apical electrode is at the 1st position from the left. Text below: "Tissue nearest most apical electrode = 590 Hz". A speaker icon is shown. Text to the right: "+250 Hz shift in formant frequencies to match".
- Scenario 3:** The most apical electrode is at the 2nd position from the left. Text below: "Tissue nearest most apical electrode = 720 Hz". A speaker icon is shown. Text to the right: "+400 Hz shift in formant frequencies to match".

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continued

Conclusions

- Surgical technique and electrode design advancements have led to improved outcomes following cochlear implant surgery
- Atraumatic insertion and scala tympani placement are paramount
- There appear to be significant advantages to implanting children with bilateral deafness younger than 12 months
- Place-pitch match does not have to be precise – system can normalize modest offsets...
- There appears to be a limit to normalization – at some offset there will be upshift in pitch and/or formant frequencies

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