Hearing Preservation in Cochlear Implantation: Review of the Evidence

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May 18, 2020

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Disclosures

- Nothing to disclose

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Learning Objectives

- 1) To understand expanded candidacy criteria for electro-acoustic cochlear implantation.
- 2) To understand the role of electrode choice, surgical anatomy, intraoperative monitoring and perioperative medical management on hearing preservation.

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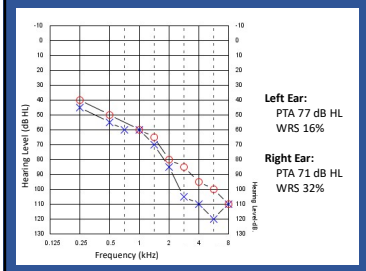
Case 1: 69 yo gentleman with progressive HL x 20 yrs with declining benefit from hearing aids



Left Ear:
PTA 77 dB HL
WRS 16%

Right Ear:
PTA 71 dB HL
WRS 32%

"Unable to hear grandkids"

PMH/PSH: OSA, heart valve dz, macular degeneration
Exam: normal otoscopic exam, tuning forks c/w audio o/w unremarkable

Cochlear implant candidate?

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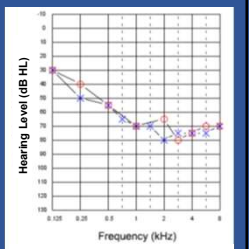
45 yo F presents with progressive SNHL since childhood with decreasing benefit from hearing aids

- Pertinent History
  - Possible ototoxicity (antibiotic treatment for cellulitis at 2 yo; twin sister w/o HL)
  - Appropriately aided since childhood with declining benefit in last 3 years
  - Increasing difficulty at work
  - PMHx & FHx significant for dense breast disease requiring yearly MRIs
- Relevant Exam
  - Normal Otologic Exam
  - Tuning forks c/w audiogram
- MRI shows no evidence of IAC/CPA lesions, no active middle ear disease, no facial nerve abnormalities

Candidate for cochlear implant?



AD: PTA 63 dB, WRS 56%
AS: PTA 70 dB, WRS 60%

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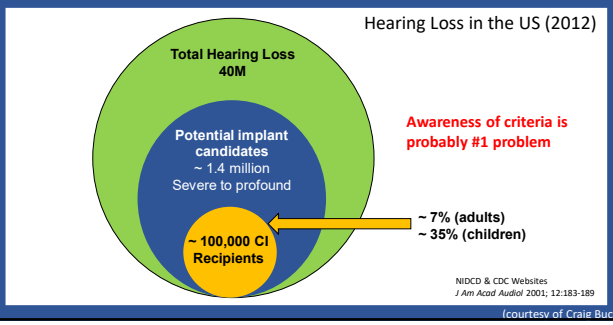
How many CI candidates are out there?



(courtesy of Craig Buchman)

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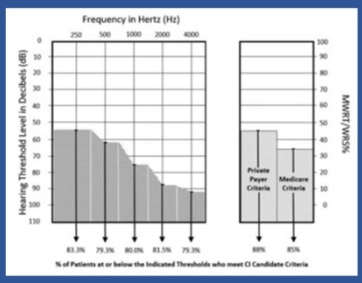
Office-based audiometry can predict CI candidacy



When to refer for testing?

- Greater than 80% chance of meeting Medicare Criteria for CI[1]
  - PTA (250, 500 & 1000 Hz) ≥ 75 dB OR
  - Monosyllabic word recognition test score ≤ 40%
    - Can be up to 60% for Hybrid hearing CI indications

- Decreasing benefit from HAs
  - Hybrid hearing / EAS CI Candidacy
  - May be candidates for implantable hearing aids
  - May qualify for recently FDA-approved CI indications (SSD, asymmetric SNHL)

(Gubbels et al, Laryngoscope, 2017)

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Section 1: Expanded Electric Acoustic Stimulation (EAS) CI Candidacy Criteria

Who is a candidate?

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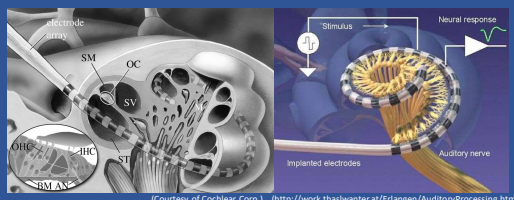
Cochlear implants bypass the cochlea and directly stimulate the auditory nerve



(Courtesy of Cochlear Corp.) (http://work.thaslwanter.at/Erlangen/AuditoryProcessing.htm)

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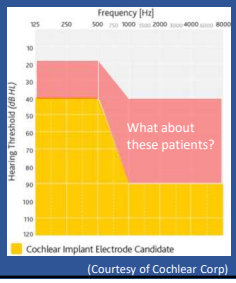
Electroacoustic stimulation (EAS) was designed to bridge the gap between good hearing aid candidates and traditional CI candidates



(Courtesy of Cochlear Corp)

How do we help patients who struggle with their hearing aids?

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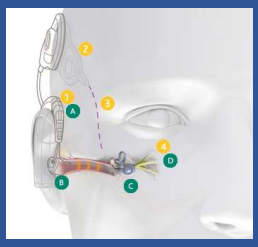
Modern cochlear implants have the potential to take advantage of both acoustic and electrical stimulation



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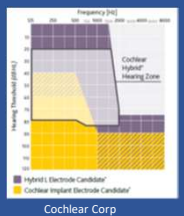
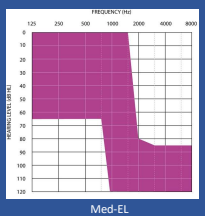
Evolving CI Candidacy Criteria



Cochlear Corp



Med-EL

- FDA-approved EAS devices (Cochlear, Med-EL)
- FDA Trial (Advanced Bionics, LLC)

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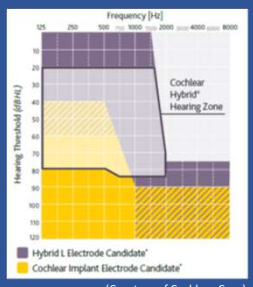
Hybrid CI Audiometric Criteria



(Courtesy of Cochlear Corp)

- Normal to moderate low frequency hearing in ear to be implanted
  - LF PTA (125, 250, 500 Hz) ≤ 60 dB HL
- Severe to profound mid to high frequency SNHL in ear to be implanted
  - PTA (2, 3, 4 kHz) ≥ 75 dB HL
- Limited benefit from appropriately fitted bilateral hearing aids
- Word Recognition Scores
  - Implanted ear → Aided CNC 10-60%
  - Contralateral Ear → Aided CNC ≤ 80%
- Contralateral Ear: PTA (2, 3, 4 kHz) ≥ 60 dB HL
- Unilateral use

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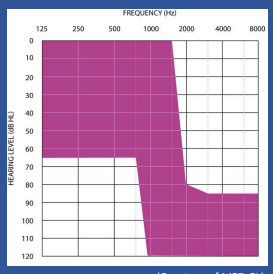
EAS CI Audiometric Criteria



(Courtesy of MED-EL)

- Monosyllable score (CNC) ≤60% at 60 dB SPL in the best aided condition
- No progressive hearing loss
- No autoimmune disease
- No hearing loss as a result of meningitis, otosclerosis or ossification
- No malformations or obstruction of the cochlea
- No air-bone gap >15 dB
- No external ear contraindications to using amplification devices

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EAS Candidacy Criteria: Summary

- Sloping sensorineural hearing loss
  - Normal to moderate SNHL (Low frequencies)
  - Severe to Profound SNHL (High frequencies)
- CNC ≤ 60% in ear to be implanted
- Limited or declining benefit from appropriately fit hearing aids

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What challenges do cochlear implant patients face?

Why should we care about hearing preservation in cochlear implant patients?

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Cochlear implant patients still have challenges

- Understanding speech in noise and complex listening conditions
- Music appreciation and tonal language perception
- Sound localization

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Low frequency hearing preservation augments the abilities of cochlear implant patients

- Improved speech understanding in noise (Welch et al, 2018; Gifford et al, 2013; Zhang et al, 2014; Dorman et al, 2015)
- Music appreciation (Parkinson et al, 2019; Prentiss et al, 2015; Turner et al, 2010)
- Localization (Welch et al, 2018; Turner et al, 2010; Gantz et al, 2019)
  - Temporal code & place code conflicts → temporal fine structure (LF hearing)

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What are the chances of preserving hearing?

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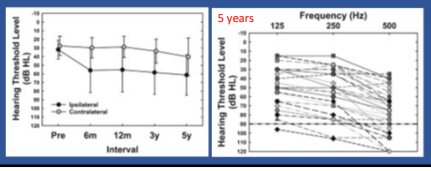
Hybrid L24 Hearing Preservation

- N = 32 patients from IDE trial followed for 5 years
  - Short electrode = Hybrid L24
  - Functional residual HP → LF PTA (125, 250, 500 Hz) ≤ 90 dB HL
  - 28 of 32 patients (87.5%) with functional residual HP at 5 years
  - 23 of 32 patients (72%) continued to use electric-acoustic hearing at 5 years
  - Stable at 5 years (minimal change after 6 months)



(Roland et al, 2018)

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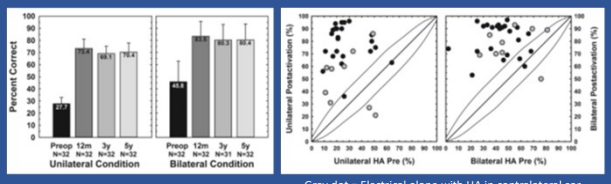
Hybrid L24 enables significant improvement in speech perception that largely exceeds that of hearing aids

- Outcome measure: CNC in quiet
- Improvements in CNC (Preop aided with HA vs. Postop with CI)
  - Unilateral: 87.5% improved (94% same or better)
  - Bilateral: 84.4% improved (97% same or better)



Grey dot = Electrical alone with HA in contralateral ear

(Roland et al, 2018)

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MED-EL EAS Hearing Preservation

- N = 67 of 73 patients completed all outcome measures
  - Electrode = MED-EL Flex^{24} ™
  - LF PTA (250, 500, 750, 1000 Hz) ≤ 80 dB HL
  - Primary outcome:
    - Speech perception: CUNY sentence test in noise, CNC in quiet

TABLE 2. *Summary of primary and secondary effectiveness endpoints*

	Acoustic Hearing Preop (Baseline) Mean ± SD	EAS 12 Mo Postactivation Mean ± SD		Electric Only 12 Mo Postactivation Mean ± SD	
	n = 67	n = 66*	Percentage point change from baseline†	n = 67	Percentage point change from baseline
CUNY sentences in noise	30.9 ± 27.2	73.4 ± 23.9	+42.2 ± 29.8	55.6 ± 29.6	+24.6 ± 31.5
CNC words	30.4 ± 13.4	66.9 ± 18.5	+36.5 ± 23.5	48.4 ± 19.0	+18.0 ± 23.0

*66 of 67 subjects were tested in an EAS condition.
†Percentage point change from baseline calculated using the baseline mean of subjects tested in the EAS condition.
CNC indicates consonant–nucleus–consonant; CUNY, City University of New York; EAS, electric-acoustic stimulation; SD, standard deviation.

(Pillsbury et al, 2018)

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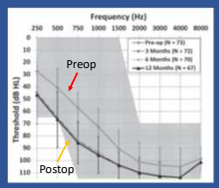
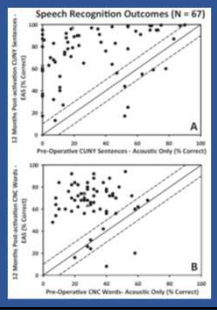
MED-EL EAS Flex24 Hearing Preservation



- 53/67 patients (79.1%) < 30 dB shift in LF PTA (250-1000 Hz)
- 97% using EAS at 12 mos



CUNY
85% improve
94% similar or better

CNC in Quiet
84% improve
97% similar or better

(Pillsbury et al, 2018)

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Despite these results, hearing preservation outcomes are still quite variable

- The methodology utilized to report hearing preservation varies considerably in the literature (Santa Maria et al, 2013)
  - Reported results may vary depending on how studies report complete versus partial hearing preservation and the definitions utilized to define these terms
- Mowry and colleagues reviewed hearing preservation surgery and estimated that patients can expect between 50 and 70% long term hearing preservation (Mowry et al, 2012)
  - Considerable range of reported hearing preservation rates: 18-100% (Wanna et al, 2017; Santa Maria et al, 2013; Mowry et al, 2012; Garcia-Ibanez et al, 2009; Arnoldner et al, 2010)
- Despite improvements in surgical technique and electrode design, causes for long term loss of residual hearing remain undefined

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Methods utilized to report hearing preservation vary

- LF PTA change
  - MEAN Method
- Percentile based
  - HEARRING Method (Skarzynski et al, 2013)
- Functional
  - LF PTA (125, 250, 500 Hz) ≤ 90 dB HL (Hybrid L24 Trial criteria)
  - LF PTA (250, 500, 750, 1000 Hz) ≤ 80 dB HL (MED-EL EAS Trial criteria)
- Minimum Reporting Standards (Adunka et al, 2018)
  - LF PTA (125, 250, 500 Hz) < 80 dB HL

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Minimum Reporting Standards for Adult Cochlear Implantation

Oliver F. Adunka, MD[1]*, Bruce J. Gantz, MD[2]*, Camille Dunn, PhD[2], Richard K. Gurgel, MD[3]*, and Craig A. Buchman, MD[4]*

- "Preservation of acoustic hearing should be determined preoperatively based on the presence of functionally relevant unaided low-frequency pure-tone thresholds. Functional hearing is defined with a pure tone average (PTA) < 80 dB HL at 125, 250, and 500 Hz."

(Adunka et al. 2018)

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Section 2: Factors related to hearing preservation

What have we learned?

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Successful hearing preservation may be partially dependent on a combination of medical management, surgical technique, and electrode selection

- Surgical
  - RW vs. ERW vs. Cochleostomy
  - RW orientation
  - Slow insertion
- Medical Management
  - Perioperative vs. Intraoperative Steroids
  - Periactivation Steroids
- Electrode Selection
  - Lateral Wall vs. Perimodiolar Electrodes
  - Insertion depth: Long vs. Short, Complete vs. Incomplete insertion

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Is hearing preservation more likely with a round window versus cochleostomy approach?

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Round window insertion (RWI) when possible is more optimal for hearing preservation

- RWI minimizes surgery-related trauma to cochlear structures (Gstoettner et al, 2004; Kiefer et al, 2004; Gantz et al, 2005; Roland et al, 2007; Eshraghi et al, 2017; Snels et al, 2018)
- Snels et al, 2018 (meta-analysis)
  - RW vs. Cochleostomy (C) → Hearing preservation rates in favor of RW
    - 1 month: RW (n = 253) vs. C (n = 137) → 13.1% in favor of RW (p = 0.066)
    - 6 month: RW (n = 172) vs. C (n = 124) → 18.6% in favor of RW (p = 0.001)*
    - 12+ month: RW (n = 441) vs. C (n = 102) → 1.7% in favor of RW (p = 0.858 = NS)
- RWI associated with closer proximity to osseous spiral lamina and modiolus and there achieve closer proximity to neural elements (Jiam et al, 2016)

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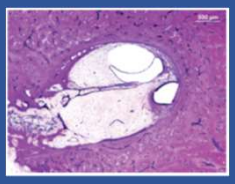
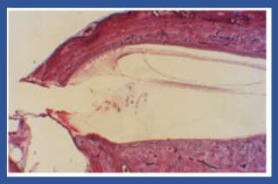
Human temporal bone histopathology suggests that cochlear fibrosis less likely with RWI



Cochleostomy
Fibrosis in SV ➔ 19 of 21 cases



Round Window
No fibrosis in SV (n = 8)

(Ishiyama et al, 2018)

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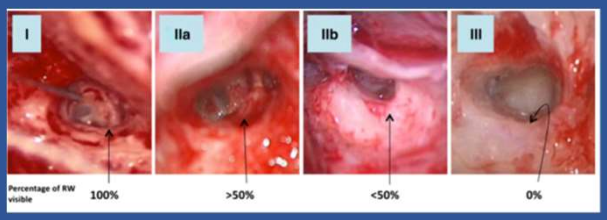
Round window membrane visibility affects ability to perform round window insertion



RW | RW ± ERW | ERW ± Coch | Coch

(Leong et al, 2013)

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Slow insertion may improve hearing preservation

- Rajan et al, 2013
  - Insertion speed: Standard (60 mm/min; n = 18) vs. Slow (15 mm/min; n = 22)
  - Slow insertions demonstrate:
    1. Improved rate of complete insertion
    2. Reduced average loss of hearing (Slow : Standard = 10 : 16 dB)
    3. Reduced postoperative imbalance (Slow : Standard = 0% : 22%)
- Eshraghi et al, 2017 ➔ Improved rates of complete and partial HP
- Effect of slow insertion may be due to intracochlear pressure gradients created by electrode insertion (Todt et al, 2014; Greene et al, 2016)
- Snels et al, 2018 ➔ Slow vs. Not Reported (not statistically significant)
  - Meta-analysis ➔ limited by lack of reporting and heterogeneity in studies

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Do steroids help preserve hearing? If so, how and when?

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Perioperative steroids improve hearing preservation

- Sweeney et al, 2015
  - 2 wk perioperative steroids
  - All patients = intraop IV & local steroids

TABLE 2. *Comparison of the two treatment groups*

Variable	Perioperative Steroid Taper	No Perioperative Steroid Taper
N (% of cases)	20 (74.1)	7 (25.9)
Mean age in years (median)	48.7	53.1
Percent of patients in whom some hearing was preserved*	90.0	28.6
Average percent of hearing preserved (median)*	45.5 (42.6)	6.6 (0)

*Statistical significance ($p < 0.05$) was achieved.

- Skarzynska et al, 2018
  - No local steroids intraop
  - IV steroids = intraop + 12 days of ~ 6 mg dexamethasone IV daily

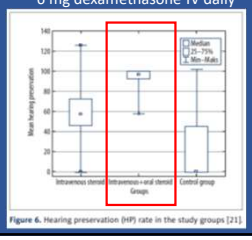

Figure 6. Hearing preservation (HP) rate in the study groups [21].

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Perioperative steroids improve hearing preservation

Hearing Preservation (%)				
	Complete	Partial	Minimal	None
Sweeney et al, 2015				
Peri-op Steroids (n = 20)	15	60	15	10
No Peri-op Steroids (n = 7)	0	14.3	14.3	71.4
	Complete	Partial	Minimal	
Skarzynska et al, 2018				
Peri-op Steroids (n = 5)	80.0	20.0	0	
No Peri-op Steroids (n = 9)	22.2	55.6	22.2	
No steroids (n = 22)	13.6	18.2	68.2	

- All patients underwent RW or ERW approaches
- Differences in categorization:
  - Sweeney (Minimal = 1-24% HP) vs. Skaryznska (Minimal = 0-24% HP)

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Hearing preservation tends to decline with age

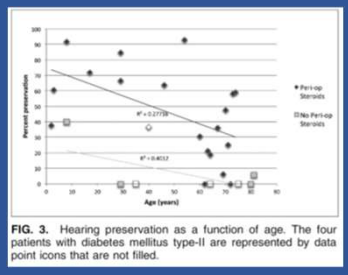

FIG. 3. Hearing preservation as a function of age. The four patients with diabetes mellitus type-II are represented by data point icons that are not filled.

- Personal bias:
  - Will not put a short electrode in older individuals
  - Lower expectations about maintaining hearing preservation over time

(Sweeney et al, 2015)

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Do locally applied steroids improve hearing preservation?

- In general, the evidence is weak
  - Sweeney et al, 2015 → Minimal effect with locally applied steroids (1 of 7 with partial HP)
  - Skarzynska et al, 2018 → Similar HP rates without use of locally applied steroids
- Rajan et al, 2011 → N = 22 patients (9 EAS, 13 with measurable hearing)
  - Patients: (all received 4 mg IV dexamethasone intraop)
    - EAS (N = 9) → 24 mm electrode → IT Steroids
    - Measurable hearing (N = 13) → 31 mm electrode → IT Steroids
    - Control (N = 12) → 31 mm electrode
  - Intervention (EAS patients, Measurable hearing patients)
    - IT dexamethasone (40 mg/mL) just before incision, fill middle ear with methylprednisolone
  - IT steroids → Less hearing loss in FlexSoft patients (11 dB vs. 19.5 dB, p < .05)

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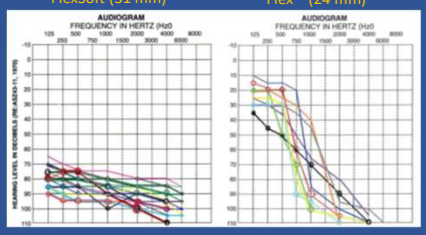
Local application of steroids *may* improve HP

FlexSoft (31 mm) | Flex^{24} (24 mm)



Measurable Hearing (FlexSoft vs. FlexSoft + IT) | EAS Flex^{24} + IT

(Rajan et al, 2011)

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Local application of steroids may improve HP

TABLE III.
Comparison of the Pre- and Postoperative Hearing Thresholds between the Control Group and the Interventional Flex Soft Patient Group.

	Flex Soft (n = 12, Control Group)	Flex Soft +IT (n = 13)	P Value
Sex	7 female, 5 male	7 female, 6 male	—
Age (mean,range)	63.5 years (48–81)	61.5 years (56–84)	Not significant
Preoperative low frequency PTA (±SD)	70.5 dB (±12.5 dB)	73.5 dB (±10.5 dB)	Not significant
Postoperative low frequency PTA(±SD)	90 dB (±11.5 dB)	84.5 dB (±10.5 dB)	P = .03
Average loss of hearing (±SD)	19.5 dB (±3.5 dB)	11 dB (±2.5 dB)	P < .05

Steroids > No steroids

TABLE IV.
Comparison of the Pre- and Postoperative Hearing Thresholds between the Two Flex EAS Groups.

	Flex EAS Adult Group (n = 4)	Flex EAS Pediatric Group (n = 5)	P Value
Sex	1 female, 3 male	4 girls, 1 boy	—
Age (mean, range)	54 years (21–62)	11 years (3–15)	P < .05
Preoperative low frequency PTA (±SD)	31.5 dB (±9.5 dB)	20.4 dB (±5.2 dB)	P < .05
Postoperative low frequency PTA (±SD)	38.5 dB (±7.5 dB)	23.5 dB (±5 dB)	P < .05
Average loss of hearing (±SD)	7 dB (±2.75 dB)	3 dB (±1.2 dB)	P < .05

Note the higher preoperative low frequency hearing thresholds in the pediatric patients.
EAS = electric and acoustic stimulation.

Children ~ Adults

(Rajan et al, 2011)

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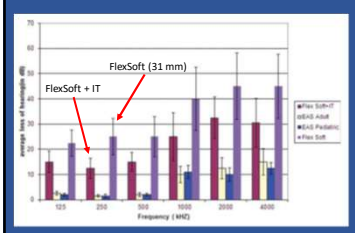
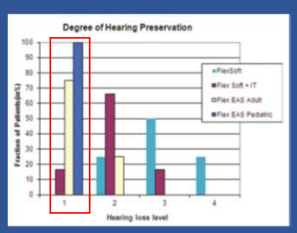
Local application of steroids may improve HP



More hearing loss with longer electrode (31 mm)



Better hearing preservation associated with shorter (24 mm) electrode

(Rajan et al, 2011)

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Use of steroids in clinical practice for hearing preservation

- Perioperative steroid course beginning 3 days before surgery
  - 10 to 14 day total course
  - Older patients may get shorter course
  - Diabetic patients may get perioperative steroids if PCP agrees & coordinates
- Intraoperative IV dexamethasone
- Intratympanic dexamethasone (10 mg/mL)
- Peri-activation steroid course beginning 3 days before activation
  - No effect of charge on retention of hearing preservation (Dillon et al, 2015)
  - However, unknown factors may contribute to loss of hearing over time

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ELECTRODE CHOICE

Which electrode type should we choose:
Lateral wall (LW) versus perimodiolar (PM) electrodes?
Long versus short electrodes?
Does this matter?

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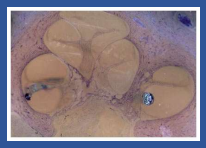
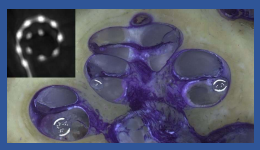
Types of Electrode Arrays



Perimodiolar / Curved



Lateral Wall / Straight

What electrode should you choose and why?

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Perimodiolar / Curved Electrodes

Cochlear CI612

Cochlear CI632

Advanced Bionics HiFocus Helix or Mid Scala

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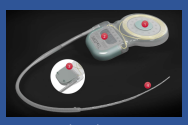
Lateral Wall / Straight Electrodes

Cochlear Slim Straight (CI622)



Med-EL Flex Series

Advanced Bionics HiRes Ultra 3D Slim J

Cochlear Hybrid (L24)

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Retrospective studies suggest that lateral wall electrodes are associated with better hearing preservation (HP)

- Retrospective
  - Mady et al, 2017 → Better short-term (1 month) but NOT long-term (1 yr) HP
  - Wanna et al, 2018 → Better short-term (1 month) & long-term (1 yr) HP
    1. RW/ERW approach and postop steroids only predictive of long-term HP
    2. Limitations: overall HP low (ST 38%, LT 18%), low power may bias the predictive ability of the multivariate analysis
- No significant difference in hearing preservation when controlling for baseline hearing and speech recognition ability (Fabie et al, 2018)
  - Reveals a general bias towards lateral wall electrodes
- Both recent MED-EL EAS and Cochlear Hybrid L24 and their generally good hearing preservation results support this contention

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Growing evidence that electrodes residing solely in the scala tympani are associated with better outcomes

- Electrodes residing completely with the ST correlate with better hearing outcomes (Wanna et al, 2014)
  - LW more likely than PM electrodes to reside in ST (89% vs. 58%)
  - Electrodes solely within the ST versus those outside the ST had better postop CNC (48.9% vs. 36.1%)
- PM and MS electrodes 22x and 55x more likely to reside outside of the ST (O'Connell et al, 2016)
  - Scala vestibuli insertion associated with a 12% decrease in CNC score
- Observed differences between short and long electrodes and complete and partial insertion may be related to a combination of trauma and ability to maintain the scalar position of the electrode in the ST.

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Intraoperative Electrocochleography (ECochG)

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Intraoperative Electrocochleography (ECochG)

- Components of the ECochG:
  - Cochlear microphonic (CM) → OHC stereocilia
  - Summation potential (SP) → Inner and outer hair cells
  - Compound action potential (CAP) → cochlear nerve activity
  - Auditory nerve neurophonic (ANN) → cochlear nerve activity
- Intraoperative use focuses on utilizing aspects of the CM to allow real-time detection of scalar translocation and cochlear trauma
- Investigational use → several CI manufacturers & research groups
  - Koka et al, 2018; Abbas et al, 2017; Tejani et al, 2018; Giardina et al, 2019

(Koka et al, 2018)

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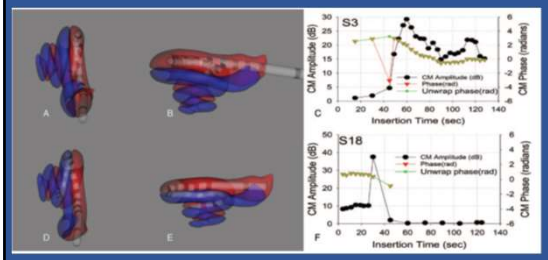
Intraoperative Electrocochleography (ECochG)



Stay in ST
ΔLFPTA = 17 dB
Insertion angle = 345°

Cross Scala
ΔLFPTA = 37 dB
Insertion angle = 416°

Methods to utilize intraoperative ECochG to detect and potentially reverse intracochlear trauma continue to be developed

(Koka et al, 2018)

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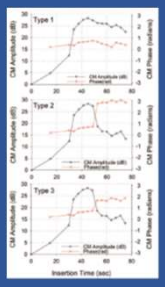
Intraoperative Electrocochleography (ECochG)



- ECochG algorithm:
  - Correctly estimated scalar electrode position in 82% of cases (26 of 32 subjects)
  - 18% (6 of 32 subjects) incorrectly identified as translocated
- Sensitivity = 100%, Specificity = 77%
- PPV = 54%, NPV = 100%
- Blinded study is currently being conducted

(Koka et al, 2018)

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Summary: Factors related to hearing preservation

- Cochlear structure preservation is critical to early hearing preservation outcomes
- Factors predictive of hearing preservation include:
  - Favoring round window insertion over cochleostomy
  - Use of peri-operative steroids ± locally applied intraoperative steroids
  - Complete scala tympani location of electrode
    - Lateral wall electrodes may have less propensity for scalar translocation
- Intraoperative electrocochleography may allow for real time detection of cochlear trauma and scalar translocation but the methods for such detection continue to evolve

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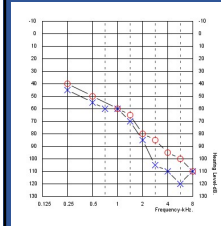
69 yo gentleman with progressive HL x 20 yrs with declining benefit from hearing aids



Left Ear Preop
LF PTA 45 dB HL (250, 500 Hz)
CNC in Quiet: 40%
AzBio (+10 dB SNR): 25%
Right Ear:
LF PTA 50 dB HL (250, 500 Hz)
CNC in Quiet: 56%
AzBio (+10 dB SNR): 24%

- Patient Priorities:
  - Full length electrode
  - Hearing preservation
  - Ability to pair with hearing aids
- Patient chose to proceed with Cochlear Corp device
- Cochlear CI522 electrode

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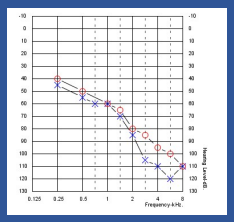
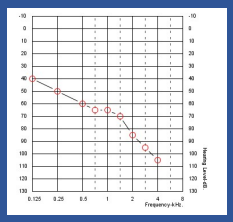
69 yo gentleman with progressive HL x 20 yrs with declining benefit from hearing aids



Left Ear Preop
LF PTA 45 dB HL (250, 500 Hz)
CNC in Quiet: 40%
AzBio (+10 dB SNR): 25%



Left Ear 1 year Postop
LF PTA 50 dB HL (< 80 dB HL)
CNC in Quiet: 78%
AzBio (+10 dB SNR): 50%

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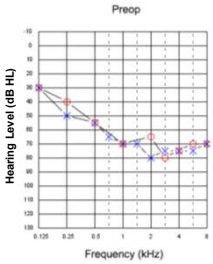
45 yo F presents with progressive SNHL with decreasing benefit from hearing aids



CI Testing
Right Ear:
PTA 63 dB, LF PTA 42 dB
CNC: 22%
AzBio (Quiet): 70%
AzBio (+5 dB SNR): 13%

Left Ear:
PTA 70 dB, LF PTA 45 dB
CNC: 50%
AzBio (+5 dB SNR): 45%

- Patient Priorities:
  - Full length electrode
  - MRI compatible
  - Hearing preservation
- MED-EL Flex 24

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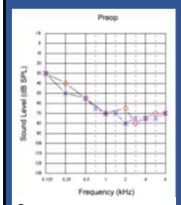
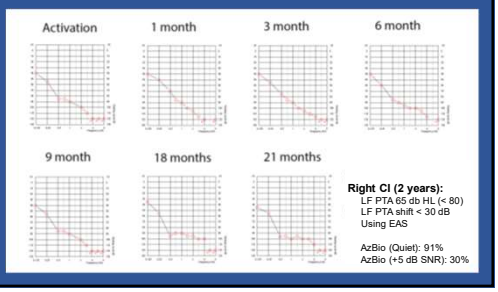
45 yo F presents with progressive SNHL with decreasing benefit from hearing aids



Preop
Right Ear:
LF PTA: 42 dB HL
CNC: 22%
AzBio (Quiet): 70%
AzBio (+5 dB SNR): 13%



Right CI (2 years):
LF PTA 65 db HL (< 80)
LF PTA shift < 30 dB
Using EAS

AzBio (Quiet): 91%
AzBio (+5 dB SNR): 30%

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Thank you for your attention
Questions?

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