

SELECTED ABSTRACTS

***ORAL
PRESENTATIONS***

IN ORDER OF PRESENTATION



***155th Annual Meeting
AMERICAN OTOLOGICAL SOCIETY***

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Hyatt Regency
Dallas, TX***

Microneedles Facilitate Intracochlear Delivery without Anatomic or Physiologic Injury

*Stephen Leong, BA; Aykut Aksit, MS; Elizabeth S. Olson, PhD
Jeffrey W. Kysar, PhD; Anil K. Lalwani, MD*

Hypothesis: Microneedle-mediated intracochlear injection through the round window membrane (RWM) will facilitate intracochlear delivery, not affect hearing, and allow for full reconstitution of the RWM within 48 hours.

Background: Previously, hollow microneedles developed in our laboratory were shown to be capable of perforating the RWM and aspirating perilymph for diagnostic proteomic analysis without cochlear damage. There is similar need for tools to facilitate atraumatic intracochlear delivery to implement inner ear therapies. In this study, we assess the feasibility and consequences of direct intracochlear injection of material via hollow microneedles.

Methods: Two-photon polymerization lithography was used to 3D-print 100µm-diameter hollow microneedles. Tympanic bullae of guinea pigs were extracted, RWMs were perforated *ex vivo*, and 1µL of 10mM rhodamine was injected into the cochlea over 1 minute. Similarly, 1µL of artificial perilymph was injected over 1 minute *in vivo* in guinea pigs. Distortion product otoacoustic emissions (DPOAE) and compound action potential (CAP) were recorded prior to *in vivo* perforation and 48 hours following injection. After euthanasia, the RWM was harvested for confocal microscopy.

Results: *Ex vivo* assessment of the cochlea under light microscopy revealed distribution of rhodamine throughout the basal turn of the cochlea immediately following injection, followed by slow diffusion through the middle and apical turns. Following *in vivo* injection, there were no significant changes in DPOAE and CAP. Confocal microscopy demonstrated full reconstitution of the RWM without inflammation or residual perforation.

Conclusions: Hollow microneedles are safe and effective for intracochlear injection of agents, thus making inner ear therapy possible without concomitant damage or hearing loss.

***Professional Practice Gap & Educational Need:** Currently, no clinical technology exists for diagnostic aspiration of perilymph and direct intracochlear injection of therapeutics. Our 3D-printed hollow microneedles have the potential to fill this practice gap. By demonstrating the safety and efficacy of direct intracochlear injection via hollow microneedles, we create new avenues for inner ear intervention, including inner ear gene therapy.

***Learning Objective:** To understand the current landscape of direct intracochlear delivery. To understand the contribution that our technology makes to the field.

***Desired Result:** Increased interest and investment in 3D-printed hollow microneedles for intracochlear delivery of therapeutics.

***Level of Evidence:** n/a

***Indicate IRB or IACUC:** Columbia University Irving Medical Center – IACUC No. AABA5450 (approved 3/8/2021)

Risks of Noise-Induced Hearing Loss during Cochlear Implant Insertion Errors

*Carolyn A Chabuz, MD; Joseph Gonzalez, MD; Kenny Rodriguez, MD; John Peacock, PhD
Renee M. Banakis Hartl, MD; Stephen P. Cass, MD; Nathaniel T. Greene, PhD*

Hypothesis: We have previously shown that during cochlear implantation (CI), the electrode contacts cochlear structures and generates high pressure transients that may cause injury; we hypothesize that pressure transients may coincide with and be used to identify insertion errors.

Background: CIs have been an effective treatment for severe to profound hearing impairment, and are increasingly offered to patients with residual acoustic hearing; however, a large subset of patients lose this residual hearing after CI implantation. Several mechanisms have been investigated as sources of this hearing loss, and we have identified generation of high amplitude pressure transients in the cochlea during CI insertion that may be sufficiently loud to cause noise induced hearing loss. Insertion errors may represent an additional cause of residual hearing loss, but are often difficult to identify during surgery

Methods: To determine whether intracochlear pressures predict errors, cadaveric human heads were surgically prepared with a mastoidectomy and extended facial recess. Fiber-optic pressure sensors were inserted into the scala vestibuli and scala tympani near the oval and round windows to measure intracochlear pressures. CI electrodes were inserted via a round window approach under fluoroscopy.

Results: CI electrode mis-insertions produced pressure transients in the cochlea up to 160-170 dB SPL equivalent. The electrode position within the cochlea, design-related electrode dynamics, and poor surgical technique were associated with increased rates of insertion errors and pressure transients.

Conclusions: These results provide insertion pressure profiles for CI mis-insertions and suggest that appropriate 'soft' surgical techniques can minimize acoustic exposure during CI surgery.

Professional Practice Gap & Educational Need: There are a variety of speeds/depths for electrode insertion along with different techniques and surgical skill levels that can affect residual hearing outcomes. We hope to create insertion pressure profiles for the major CIs on the market along with profiles for purposeful mis-insertions to better understand the generation of these intracochlear pressure transients and how to further preserve residual hearing.

Learning Objective: Understand the dynamics of CI insertion, including the extant and patterns of cochlear damage associated with surgical approaches, electrode types, and speed and depth of insertion. Determine whether similar pressure transients are generated with CI mis-insertions and if intracochlear pressure monitoring may be used to identify such deleterious outcomes.

Desired Result: Create insertion pressure profiles for specific CI electrodes along with profiles for mis-insertions.

Level of Evidence - Level III

Indicate IRB or IACUC : Exempt.

Predictive Value of Trans-Impedance Matrix Measurements to Detect Electrode Tip Foldovers

*Emily Kay-Rivest MD, MSc; Sean O. McMenomey MD; Daniel Jethanamest MD, MSc
William H. Shapiro AuD; David R. Friedmann MD, MSc
Susan B. Waltzman PhD; J. Thomas Roland Jr., MD*

Objective: To evaluate the ability of the trans-impedance matrix (TIM) measurement to detect cochlear implant electrode tip foldover by comparing results to a gold standard, the intraoperative plain film radiograph.

Study design: Retrospective case series.

Setting: Tertiary referral hospital.

Patients: 103 patients who underwent cochlear implantation between June 2020 and August 2021.

Interventions: Intraoperative electrophysiologic monitoring (electrode impedances, Neural Response Telemetry, and TIM measurement) and modified Stenver's view plain film radiographs.

Main outcome measures: Identification of tip foldover on both TIM and plain films.

Results: In total, 103 patients (117 ears) had both a TIM measurement and intraoperative -ray available for review, including 68 adults and 35 children. 100 (85%) received the *Cochlear Slim Modiolar* electrode. Tip foldovers were noted in three of 117 implants (2.5%). In all cases, TIM was able to detect the foldover, and the electrode arrays were reinserted with repeat X-ray demonstrating a normal configuration. Two other abnormal TIM patterns were identified. One was in a patient with an obstructed cochlea in whom only 10 electrodes could be inserted, the other was in a patient with a common cavity abnormality. One additional patient required electrode revision intraoperatively, due to overinsertion. In this patient, the TIM appeared to be within normal limits but the overinsertion was apparent only on X-ray. Overall, the sensitivity of TIM measurements in detecting tip foldover was 100%.

Conclusions: TIM measurements were able to accurately identify tip foldovers but were not sensitive to overinsertion of the array. More research is needed to define the adjunctive role of TIM as an intraoperative measure.

***Professional Practice Gap & Educational Need:** In certain cochlear implant centres, routine intraoperative X-ray may not always be readily available. We explore the TIM and its ability to detect tip foldovers, which may represent a feasible alternative for position placement check in the context of normal cochleovestibular anatomy.

***Learning Objective:** TIM measurements were able to detect tip foldovers in all cases.

***Desired Result:** To provide the attendee with the knowledge of an additional tool for intraoperative monitoring and explore other possible benefits of the transimpedance matrix.

***Level of Evidence - Level III**

***Indicate IRB or IACUC:** NYU School of Medicine Institutional Review Board i21-01186.

Dynamic Behavior and Insertional Forces of a Pre-Curved Electrode Using the Pull-Back Technique in a Fresh Micro-Dissected Cochlea

*Miriam R. Smetak, MD, MS; Katherine E. Riojas, PhD
Jack H. Noble, PhD; Robert F. Labadie, MD, PhD*

Hypothesis: This study evaluated the utility of the pull-back technique in improving perimodiolar positioning of a pre-curved cochlear implant electrode with simultaneous insertion force profile measurement and direct observation of dynamic electrode behavior in a cadaveric cochlea through an intact, semi-transparent basilar membrane.

Background: Pre-curved electrodes with closer proximity to the modiolus have improved outcomes compared to straight electrodes. The effectiveness of the pull-back technique in further improving perimodiolar positioning and the insertion force profile have not been adequately studied.

Methods: The bone overlying the scala vestibuli was removed in 15 fresh cadaveric temporal bones, leaving the scala tympani unviolated. Each specimen was then mounted to a force sensor and robotic insertions of Cochlear 532/632 electrodes were performed. Force profiles were obtained during standard insertion, over-insertion, and pull-back with simultaneous video recording of the electrode through the semi-transparent basilar membrane.

Results: Standard insertion resulted in a mean peak force of 0.14 N (95% CI 0.10-0.18) and occurred at either sheath insertion (n=11, 73.3%) or complete electrode insertion (n=4, 26.7%). Over-insertion was associated with a peak force of 0.18 N (95% CI 0.14-0.21) which was not significantly higher than standard insertion ($P = 0.18$). Pull-back had a mean peak force of 0.10 N (95% CI 0.06-0.14), which was significantly lower than standard insertion ($P = 0.02$). Six temporal bones (40%) demonstrated visibly improved perimodiolar positioning.

Conclusions: Pull-back technique was not associated with significantly higher insertional forces compared to standard insertion. This study demonstrated improved perimodiolar positioning compared to standard insertion in 40% of temporal bones studied.

***Professional Practice Gap & Educational Need:** Various electrode insertion techniques have been proposed in order to position the electrode closer to the modiolus, thereby improving postoperative hearing outcomes. Here, we investigate the utility of the pull-back technique in a micro-dissected cadaveric cochlea with simultaneous measurement of force profile and video recording of electrode behavior, allowing for direct observation of the effects of the technique on electrode positioning.

***Learning Objective:** For the pre-curved electrode, the pull-back technique may improve perimodiolar positioning. Gentle over-insertion followed by electrode pull-back does not lead to significantly increased forces compared to standard insertion.

***Desired Result:** Cochlear implant surgeons should consider using the pull-back technique when inserting pre-curved electrodes. The technique involves a gentle over-insertion followed by pulling the electrode back to the standard insertion depth to achieve close contact of the electrode with the modiolus.

***Level of Evidence – Level I**

***Indicate IRB or IACUC : N/A**

RESIDENT RESEARCH TRAVEL AWARD

Comparative Analysis of Robotics-Assisted and Manual Insertions of Cochlear Implant Electrode Arrays

*Alexander D. Claussen, MD; Seiji B. Shibata, MD, PhD; Christopher R. Kaufmann, MD
Allan Henslee, PhD; Marlan R. Hansen, MD*

Hypothesis: Robotics-assisted cochlear implant (CI) electrode array insertions will result in improved trauma scoring when compared to manual.

Background: Although techniques to reduce intracochlear trauma and translocations are well established, significant variability in CI outcomes remains. To address this issue, we have developed a robotics-assisted insertion system designed to aid the surgeon in inserting electrode arrays with consistent speeds and reduced variability. This study evaluated the effect of robotics-assisted insertions on the intracochlear trauma as compared to manual insertions in cadaveric cochleae in a simulated operative environment.

Methods: Using a round window approach, 12 neurotologists performed bilateral electrode insertions into cochlea of full cadaveric heads using both the robotics-assisted system and manual insertion by hand. Lateral wall electrodes from 3 different manufacturers (n=24) were utilized and randomized between surgeons. Insertion angle of the electrode and trauma scoring were evaluated using high resolution 3D X-ray microscopy and compared between robotics-assisted and manual insertions.

Results: 3D X-ray microscopy provided sufficient resolution to characterize the *in situ* trauma and insertion angle. Robotics-assisted insertions significantly decreased the trauma score compared to manual insertions (average 1.3 vs 2.2, device vs manual respectively, $p < 0.05$ Wilcoxon signed-rank test). There was no significant difference between insertion angles observed for both manual and robotics-assisted techniques ($328 \pm 87^\circ$ vs $335 \pm 109^\circ$, device vs manual respectively).

Conclusions: Robotics-assisted insertion systems provide a means to standardize electrode insertions across individual surgeons and experience levels. Insertion techniques which reduce insertional variability and the likelihood of intracochlear trauma have the potential to improve CI outcomes.

***Professional Practice Gap & Educational Need:** The need for atraumatic techniques during CI electrode insertion is well established, but the effects of insertion speed and variability on intracochlear trauma-related events are not well defined or characterized.

***Learning Objective:** To evaluate the difference in electrode translocation incidence during robotics-assisted CI electrode insertions vs. manual (by-hand) insertions in cadaveric cochleae.

***Desired Result:** Understand quantified difference in intracochlear trauma score of electrodes inserted with robotics-assisted device vs. manual insertions; and be aware of human related limitations of manual electrode insertions.

***Level of Evidence:** N/A

***Indicate IRB or IACUC:** Exempt

Prevalence of Subclinical Hearing Loss in the United States

*Jacqueline M. Dragon, BA; Alexandria L. Irace, BA
Maehar R. Grewal, BS; Justin S. Golub, MD, MS*

Objective: Worse hearing has recently been associated with worse cognition and depressive symptoms. This holds true even among adults considered to have normal hearing (4-frequency pure tone average [PTA4] \leq 25 dB), thus supporting the term subclinical hearing loss (SCHL). A detailed study of the prevalence of SCHL in the U.S. has not been performed.

Study Design: Analysis of biennial cross-sectional epidemiological survey (NHANES; 1999-2012, 2015-2016).

Setting: Community

Subjects: Non-institutionalized U.S. citizens age \geq 12 years

Main Outcome Measures: 4-frequency (500, 1000, 2000, 4000 Hz) PTA (PTA4) and high frequency (6000, 8000 Hz) PTA (PTAhf).

Results: 81% percent (95% CI=80.1-82.1%) of participants (~227.3 million Americans) had SCHL defined by $1 \leq \text{PTA4} \leq 25$ dB. 65% (63.1-66.1%) had SCHL defined by $1 \leq \text{PTAhf} \leq 25$ dB (~181 million Americans). The average age of hearing loss (HL) onset at PTA4 thresholds of 25, 20, and 15 dB was 75.4, 67.4, and 58.4 years, respectively. The average age of HL onset at PTAhf thresholds of 25, 20, and 15 dB was 52.4, 46.9, and 40.6 years, respectively. Across the lifespan, the PTA4 showed constant acceleration of 0.0044 dB/year² (95% CI=0.00429-0.00443). PTAhf showed constant acceleration of 0.0091 dB/year² (95% CI=0.00900-0.00924).

Conclusions: This study informs national discussions on the definition of HL onset. Recent data has suggested that the threshold to define adult HL may be too high, particularly because even so-called subclinical levels of HL may be associated with deleterious conditions of aging. We present the prevalence of SCHL as well as of HL defined by various stricter cutpoints.

***Professional Practice Gap & Educational Need:** Recent evidence has suggested that the association between HL and neurocognitive conditions of aging may begin at earlier levels of HL than previously expected. A granular characterization of the prevalence of so-called SCHL has not been reported.

***Learning Objective:** Determine the prevalence of SCHL in Americans. Understand the prevalence of HL based on stricter cutpoints.

***Desired Result:** Providers will understand that the current definition of HL has been challenged as well as the prevalence of HL based on stricter definitions.

***Level of Evidence - III**

***Indicate IRB or IACUC :** Exempt

Diabetes Mellitus and Sensorineural Hearing Loss: A TriNetX Network Study

*Saima Wase, BS; Divya Balachander, BS
Claudia Cabrera, MD, MS; Sarah Mowry, MD*

Objective: The literature reports a high prevalence of sensorineural hearing loss ranging from 54-67.5% among patients with diabetes mellitus. The inconsistency in literature reveals the need for further study. Our objective is to evaluate the relationship between diabetes and hearing loss.

Study Design: We utilize the TriNetX global health research network, a database with real-time access to millions of electronic medical records.

Setting: Database

Patients: Adult patients from 2015 to 2020 in the United States, aged ≥ 18 presenting with and without diabetes

Interventions: N/A

Main Outcome Measures: Likelihood of hearing loss

Results: 939,238 were included in the analysis. After matching sensorineural hearing loss was found in 1,438 diabetic patients (.307%) and 657 in our control group (.14%). The odds of having hearing loss were found to be 2.2 [95% CI (1.99, 2.40)] times higher in patients with diabetes compared to their non-diabetic counterparts. DM patients had significantly higher proportion of minorities, including Asians (3.789% vs 2.563%, $P < .001$), American Indians (0.545% vs 0.347%, $P < .001$), Native Hawaiians (0.225% vs 0.11%, $P < .001$), Hispanics (10.582% vs 5.847%, $P < .001$), and non-Hispanics (64.27% vs 58.80%, $P < .001$).

Conclusions: Our study of the TriNetX database in the last five years suggests a relationship between diabetes and sensorineural hearing loss. We believe this study is among the first to corroborate this finding in a large sample size. Further research is needed to investigate the mechanism of these complications and the vulnerability of population groups.

***Professional Practice Gap & Educational Need:** Understand the risk factors of hearing loss.

***Learning Objective:** Understand the association between diabetes and hearing loss.

***Desired Result:** Heightened awareness of the association between diabetes and hearing loss.

***Level of Evidence – N/A**

***Indicate IRB or IACUC:** Exempt

Video Analysis of Otologic Instrument Movement during Resident Mastoidectomies

*Royal M. Pipaliya, BS; Mallory J. Raymond, MD
M. Andrew Rowley Jr., BS; Polly Jasper, BS; Ted A. Meyer, MD, PhD*

Objective: To measure surgical instrument movement during resident mastoidectomies and identify metrics that correlate with experience.

Study Design: Retrospective case series

Setting: Tertiary care center

Subjects: Ten PGY2, six PGY3, seven PGY4, and nineteen PGY5 otolaryngology residents

Interventions: One-minute intraoperative recordings of mastoidectomies performed during cochlear implantation were collected. Drill and suction-irrigator motion were analyzed with sports motion tracking software.

Main Outcome Measures: Instrument speed, acceleration, distance travelled, angle, and angular velocity were calculated. Mann-Whitney U tests were used to compare mean instrument metrics between PGY levels. Change in drill distance, speed, and acceleration over time for seven residents were individually analyzed.

Results: The mean drill distance, speed and acceleration increased from 11.0 cm, 1.8 cm/s, and 13.8 cm/s² for PGY2s to 18.4 cm, 2.9 cm/s and 29.1 cm/s² for PGY5s ($p = 0.0007$, $p = 0.001$, $p = 0.0008$, respectively). The mean suction-irrigator distance travelled increased from 5.8 cm for PGY2s to 9.0 cm for PGY4s ($p = 0.04$), but decreased to 7.9 cm for PGY5s ($p=0.2$). Mean suction-irrigator speed increased from 1.0 cm/s for PGY2s to 1.5 cm/s for PGY4s ($p = 0.04$), then decreased to 1.2 cm/s for PGY5s ($p=0.2$). Of the seven residents individually analyzed, drill distance, speed, and acceleration increased for five, six and seven residents, respectively. Group mean drill distance, speed, and acceleration improved by 3.3 cm, 0.2 cm/s, and 5.7 cm/s² yearly.

Conclusions: Drill movement metrics increase with resident experience level and can differentiate novices from more experienced surgeons. These and other objective metrics could be used to evaluate and monitor surgical skills progress.

***Professional Practice Gap & Educational Need:** Objective measures of surgical performance are lacking. Resident education continues to rely on subjective forms of feedback to monitor progress and influence promotion and certification.

***Learning Objective:** To understand the application of objective video analysis for measuring surgical instrument movement; to compare objective measures of resident surgical instrument movement across experience levels; to understand the variation in progress of surgical instrument movement amongst resident experience level.

***Desired Result:** Attendees should appreciate the application of objective video analysis for measuring surgical instrument movement, be able to compare objective measures of resident surgical instrument movement across experience levels, and understand the variation in progress of surgical instrument movement amongst resident experience level.

***Level of Evidence - Level V**

***Indicate IRB or IACUC:** Approved - IRB Pro00068069 on 10/02/2017 at the Medical University of South Carolina.

**Immediate Improvement in Subjective Visual Vertical (SVV) and Disequilibrium
Predicts Resolution of Benign Paroxysmal Positional Vertigo
following Single Canalith Repositioning Maneuver**

*Christine C. Little, BA; Zachary G. Schwam, MD; April Barresi, PT
Conrad Nytko, PT; James Gurley, PT, DPT; Jennifer Kelly, PT, DPT
Maura K. Cosetti, MD; Jennifer Kelly, PT, DPT*

Objective: To evaluate whether immediate post-canalith repositioning maneuver (CRM) balance changes are predictive of Benign Paroxysmal Positional Vertigo (BPPV) resolution.

Study Design: Retrospective cohort study

Setting: Tertiary referral center.

Patients: Adults (n=33, average age 59, range 56-64) with confirmed unilateral BPPV.

Interventions: single CRM with frenzel goggles

Main Outcome Measures: Visual Analog Scale (VAS) for disequilibrium, the Subjective Visual Vertical (SVV), the Subjective Visual Horizontal (SVH), and the Modified Clinical Test of Sensory Interaction on Balance (mCTSIB) were administered pre- and immediately following single CRM. Dix-Hallpike was performed 2-3 weeks after CRM to assess for BPPV resolution. Pre- and post-treatment balance assessments were compared between groups to determine if post CRM balance changes could predict BPPV resolution.

Results: Change in VAS and SVV score following CRM treatment was statistically different between BPPV patients who responded to CRM therapy (n=18) and those who did not (n=15), ($p = .02$ and $p = .02$ respectively). Change in SVH and mCTSIB score did not predict improvement. Patients who responded to CRM treatment were statistically younger ($p = .03$) and more likely to present with idiopathic BPPV compared to secondary causes ($p = .02$).

Conclusions: Immediate improvement in VAS and SVV following CRM can be used to predict which patients are likely to experience resolution of BPPV and may assist in directing timing and need for future interventions. BPPV etiology and younger age may have a favorable predictive value for improvement following single CRM .

***Professional Practice Gap & Educational Need:** Although canalith repositioning maneuvers (CRMs) are highly effective in treating BPPV, an estimated 8-50% of patients treated with a single session of CRM will experience persistent BPPV. BPPV can lead to significant medical costs when managed incorrectly, with >65% of the BPPV population undergoing unnecessary imaging, diagnostic testing, or therapeutic interventions. The burdensome financial cost to individuals, difficulty in complying with follow-up care and impact on quality of life warrant better predictive outcomes of BPPV resolution. Outcome measures that could predict the efficacy of CRM treatment can help reduce these costs, promote efficient care and improve allocation of healthcare resources.

***Learning Objective:** demonstrate the utility of VAS and SVV balance changes as a predictive tool for evaluating which patients are likely to experience persist BPPV following CRM treatment.

***Desired Result:** empower clinicians to make informed decision regarding which patients may benefit from closer follow up care for signs of persistent BPPV.

***Level of Evidence:** III

***Indicate IRB or IACUC:** IRB 15.07, Mercy College

Cochlear Implants: When Hardware Fails, Using Impedance as an Initial Indicator of Decline

Walleed H. Almutairi, MD; Justyn F.D. Pisa, AuD; Jordan B. Hochman, MD

Objective: In February of 2020, a cochlear implant manufacturer initiated a field action notice to remove an electrode array from circulation. In this study, we quantify device failure and specifically examine the relationship of impedance change as a precursor to declining speech perception.

Study Design: Retrospective/Cohort Study.

Setting: Tertiary Referral Center

Patients: 48 patients (51 devices) were implanted between October 2017 to December 2019. Post-operative speech perception (AzBio) scores at 12 months were used as a reference, with further testing at 3-6 month intervals. Degree of change in impedances from 1-month post-activation were analysed at similar intervals. Exclusion Criteria included: <18 years of age, medical/surgical/soft failures and English as an additional language.

Interventions: Diagnostic.

Main Outcome Measures: Device failures were confirmed by the following: impedance levels $\leq 3.0\mu\Omega$ and/or declines of 50% from their original (baseline) value, and speech perception decline >15% on the AzBio test.

Results: To date, 11 (22%) electrodes have failed. The number of devices currently being monitored for suspected failure is 12 (24%). There are statistically significant differences ($p<0.001$), in speech perception scores and impedance levels between normative and suspect/failed devices. The entire electrode array (Channels 1-16) may be impacted. There was no relationship between degree of impedance change and speech scores. The average length of time for a change to become apparent was 22 months (+/- 5) post implantation.

Conclusions: Impedance values can be used as a reliable indicator of future decline facilitating patient counselling and possible early intervention. No relationship was identified that correlated changes in impedance with speech perception.

Define Professional Practice Gap & Educational Need: Cochlear implant recalls are rare unfortunate events. It is imperative that a patient have access to recalled device performance and be provided the requisite information for best possible counselling. Impedance values can be used to inform patient decision making.

Learning Objective: The use of impedance values to monitor implant function and possible decline. Changes in impedance of >50% or a drop of 3.0 uO provide a strong suggestion of future change in device function.

Desired Result: If impedance decline can be used as a predictor for a decline in speech performance.

Level of Evidence - III

Indicate IRB or IACUC: HS18623 (H2015:209)

Electrode Positioning after Cochlear Reimplantation with Same Device

*Miriam R. Smetak, MD, MS; Shanik J. Fernando, MD; Robert T. Dwyer, AuD; Benoit M. Dawant, PhD
Jack H. Noble, PhD; Robert F. Labadie, MD, PhD*

Objective: To investigate whether revision surgery with the same device results in a change in three key indicators of electrode positioning: scalar location, mean perimodiolar distance (\bar{M}), and angular insertion depth (AID).

Study Design: Retrospective analysis of a cochlear implant database from 2017 to 2021.

Setting: University-based tertiary medical center.

Patients: Sixteen patients underwent revision cochlear implantation with same device.

Interventions: Intra-operative CT scans were obtained after initial and revision implantation. Electrode position was calculated using auto-segmentation techniques.

Main Outcome Measures: Initial and revision scalar location, \bar{M} , and AID were compared. Changes in electrode positioning were calculated for all combinations of initial and revision electrodes.

Results: Mean change in \bar{M} for all ears was -0.07 (95% CI [-0.18, 0.03]) (P = 0.16). The mean change in AID for all ears was -5° (95% CI [-35°, 25°]) (P = 0.72). Overall, there was no significant difference in \bar{M} or AID for any of the initial and revision electrode combinations studied. Three initial implantations with pre-curved electrodes resulted in a translocation from Scala Tympani (ST) to Scala Vestibuli (SV). Two remained translocated after revision, while one was corrected when revised with a straight electrode. An additional 5 translocations occurred only after revision.

Conclusions: In this study examining revision cochlear implantation with a single device, we demonstrated no significant change in key indicators of cochlear positioning, even when revising with a different style of electrode. However, the revision electrode is not necessarily confined by the initial trajectory and additional translocations can occur.

***Professional Practice Gap & Educational Need:** With increasing prevalence and longer duration of device use, rates of revision cochlear implantation can only be expected to continue to rise. In this study we sought to understand the effect of revision surgery on electrode positioning.

***Learning Objective:** We demonstrate that there is no significant difference in key indicators of electrode positioning after revision cochlear implantation, even when revising with a different type of electrode. There may be an increased risk of translocation during revision cochlear implantation, although this requires further study.

***Desired Result:** To demonstrate that overall revision cochlear implantation does not result in significant change in electrode positioning but that the revision electrode is not necessarily confined to the tract of the initially implanted electrode.

***Level of Evidence – LEVEL V – Case series, studies with no controls**

***Indicate IRB or IACUC:** Vanderbilt University Medical Center, IRB #101743, #090155, #202094

**Differential Speech Perception in Quiet and Noise for Adults and Children
Before and After Cochlear implantation
for Unilateral Sensory Hearing Loss**

*Kevin D. Brown MD, PhD, Lisa R. Park AUD, Anne M. Selleck MD
Matthew M. Dedmon, MD, PhD; Harold C. Pillsbury MD
Margaret T. Dillon AUD*

Objective: Determine the patterns of speech perception growth in quiet and noise with cochlear implant (CI) use for adults and children with unilateral hearing loss (UHL).

Study Design: Repeated measures of speech perception in quiet for the affected ear and speech perception in noise with both ears.

Setting: Tertiary academic healthcare center

Patients: Two FDA-approved prospective clinical trials evaluated the benefits of cochlear implantation for adults and children with UHL. Criteria for inclusion were moderate to profound UHL and poor CNC word recognition in the affected ear (adults: <60%, children: <30%).

Interventions: Cochlear implantation

Main Outcome Measures: Speech perception was assessed preoperatively and 6, 12, and 24 months post-activation by 40 adults and children with UHL. Performance was quantified for CNC words in quiet with the CI alone and sentence recognition in noise (BKB-SIN) with the CI plus normal-hearing ear in three target-to-masker configurations to assess summation, squelch, and head shadow effects.

Results: Both adults and children experienced a significant improvement in CNC scores post-activation (24-month: $59 \pm 13\%$ and $59 \pm 15\%$, respectively), with adults reaching asymptote earlier. Children had poorer performance in noise than adults without the CI. With the CI, children had significant improvements for the summation, squelch, and head shadow conditions; adults showed benefits in the head shadow condition only.

Conclusions: Children with UHL perform more poorly than adults in noise without a CI, yet experience significant improvement in binaural hearing (summation, squelch and shadow) with a CI. Adults show benefits primarily in head shadow.

***Professional Practice Gap & Educational Need:** There is incomplete knowledge of the differences in benefits experienced by adults and children for speech perception in noise following cochlear implantation for UHL.

***Learning Objective:** The learner will understand that children with UHL require a higher signal to noise ratio to understand speech in noise. They also gain benefits in all noise configurations, including summation, squelch and head shadow, while only adults experience benefits in head shadow.

***Desired Result:** The learner will be able to inform patients of the benefits of cochlear implantation for UHL in adults and children.

***Level of Evidence – Level 3**

***Indicate IRB or IACUC:** IRB 14-1544 and 15-3350, University of North Carolina, Chapel Hill

Speech Recognition Performance Differences Between Precurved and Straight Electrode Arrays

*Rahul K. Sharma, MD; Miriam R. Smetak, MD; Ankita Patro, MD
Nathan R. Lindquist, MD; Elizabeth L. Perkins, MD
Jourdan T. Holder, AuD, PhD; Kareem O. Tawfik, MD*

Objective: Precurved cochlear implant (CI) electrode arrays have shown superior audiometric outcomes compared to straight electrodes. Previously reported results are confounded by other influential variables such as pre-operative hearing and age. This study compares hearing outcomes for precurved and straight electrodes while controlling for other factors.

Study Design: Retrospective Cohort Study

Setting: Tertiary Academic Medical Center

Patients: 171 adult CI recipients between 2015-2020 with Cochlear brand 522/622 (straight) or 532/632 (precurved) electrode arrays.

Interventions: None

Main Outcome Measures: Speech recognition testing (CNC and AzBio) was collected at 6 and 12 months post-activation. Analyses included Fisher's exact test, chi-square test of independence, and multivariable linear regression models.

Results: 171 patients (189 ears) with either 6-month and/or 12-month CNC or AzBio testing were included. 112 (59%) and 77 (41%) ears were implanted with straight and precurved electrode arrays respectively. Average age at implantation was 69 years (IQR 58-77). CNC scores were significantly different ($p=0.008$) between straight (52% Correct, IQR 36-68) and precurved arrays (66% Correct, IQR 48-74). AzBio scores were not significantly different ($p=0.130$) between straight (74% Corrected, IQR 56-86) and precurved arrays (82% correct, IQR 58-90). Controlling for age, race, sex, pre-operative hearing, and follow-up time, precurved electrodes performed significantly better on CNC ($b=9.42$, 95% CI 2.75-16.1, $p=0.006$) but not AzBio ($b=6.48$, 95% CI -1.21-14.2, $p=0.10$) testing.

Conclusions: Precurved electrodes exhibit superior speech recognition scores at 6 and 12 months postoperatively. Strong consideration should be given to implanting precurved electrode arrays due to benefits associated with perimodiolar positioning.

***Professional Practice Gap & Educational Need:** Understanding the difference in audiometric outcomes between precurved and straight electrodes will help to guide electrode selection.

***Learning Objective:** To understand differences in speech recognition scores post-operatively by electrode type (precurved vs. straight)

***Desired Result:** To demonstrate a difference in hearing performance post-operatively by electrode type.

***Level of Evidence - III**

***Indicate IRB or IACUC :** Approved by the Vanderbilt University IRB (# 090155)

Are Cochlear Implant Recipient Speech Performance Scores Consistent Across Different Tests?

*Nicholas S. Andresen, MD; Varun Vohra, BA; Stephen P. Bowditch, AuD
Nae-Yuh Wang, PhD MS; Charles C. Della Santina, MD PhD; Daniel Q. Sun, MD*

Objective: Cochlear implant (CI) candidacy and post-operative outcomes are assessed through multiple different speech discrimination tests, limiting comparisons across time periods or institutions. The objective of this study was to investigate the extent of agreement among commonly used speech understanding scores in assessment of CI candidacy or performance in individual patients.

Study Design: Pre- and post-operative AzBio Sentence Test, Consonant-nucleus-consonant Word (CNCw), and Hearing in Noise Test (HINT) scores in quiet, collected during the same testing session, for individuals who received a CI between 1985-2018 were analyzed to derive transformation functions between test instruments. Simple linear regression with logit-transformation was used to determine mean scores and variances. Bland-Altman plots were used to assess agreement between testing methods.

Setting: Single academic medical center.

Patients: 1,710 individuals with a mean age of 57.9 years (range 18-95 years) and 46% (784/1,710) male.

Interventions: N.A.

Main Outcome Measures: Mean, variance, correlation coefficients, and agreement as a function of test score.

Results: Same-session AzBio/CNCw (n=2,052), AzBio/HINT (n=525), and CNCw/HINT (n=7,187) scores were available in 1710 unique patients. Pair-wise test comparisons demonstrated score correlation between different speech tests, but also revealed large variance and limited agreement between different tests performed in the same session.

Conclusions: Transformation functions between test batteries were predictive of mean but not variance in scores, or extent of agreement between test batteries. Point-wise comparisons of scores across CI test batteries should be used with caution in clinical and research settings.

***Professional Practice Gap & Educational Need:** There is a need to understand how different speech performance scores can be compared.

***Learning Objective:** Understand the variability of different speech performance scores (AzBio, CNCw, HINT) recorded during the same testing session in a large cohort of cochlear implant recipients at a large academic medical center.

***Desired Result:** Individuals will be able to describe the large amount of variability between different speech performance scores and that speech performance scores cannot be reliably converted.

***Level of Evidence - Level IV.**

***Indicate IRB or IACUC :** IRB00188251.

Initial Experience with Two Active Transcutaneous Bone Anchored Implants

*Zachary G. Schwam MD; Samuel Oh BA; Kevin Wong MD; Caleb Fan MD
Enrique Perez, MD, MBA; Maura K. Cosetti MD; George B. Wanna MD*

Objective: Evaluate our initial experience with two active transcutaneous bone anchored implant (BAI) systems.

Study Design: Retrospective cohort study.

Setting: Tertiary otology-neurotology practice.

Patients: Those with conductive hearing loss meeting criteria to undergo BAI.

Interventions: Implantation with Med El Bonebridge BCI602 and Cochlear™ OSIA® among other indicated procedures.

Main Outcome Measures: ease of procedure, procedure time, patient satisfaction.

Results: Five Bonebridges and ten OSIA® were implanted 2020-2021. Average patient age was 34.8 years, BCPTA 18.0dB, ABG 47.3dB. Etiology of hearing loss was microtia/atresia (n=6), radical mastoidectomy (n=4), tympanosclerosis, ossicular discontinuity, and inability to wear conventional hearing aids in the remainder. Operative times were similar between the implants (Bonebridge mean 78.0 mins, OSIA® 80.8 mins). Difficult implantation was encountered in one case with Bonebridge compared to 5/10 OSIA® due to circumferential clearance and skull shape. One Bonebridge patient had a prominent device profile postoperatively, while 5/10 OSIA® patients had significant edema, inflammation, and issues with the magnet. While all patients were pleased with the audio quality and derived benefit with a mean follow-up of 2.4 months, two OSIA® patients reported static noise with usage. Two OSIA® were explanted due to infection; one was performed one year prior and referred by an outside provider; the other occurred 4 months later with wound breakdown. There were no statistically significant differences in any of the outcomes measured.

Conclusions: Active transcutaneous implants are effective in indicated cases with similar operative times. Additional data are needed to compare postoperative infections and device prominence.

***Professional Practice Gap & Educational Need:** Educate otolaryngologists and otologists/neurotologists on newer bone anchored implants.

***Learning Objective:** To describe the various important factors that go into decision making when choosing between these two implants, describe the learning curve associated, and to use the above information to inform one's own practice.

***Desired Result:** Attendees will be able to report on the differences between the two manufacturers for ease of implant placement and soft tissue effects in each group.

***Level of Evidence – V.**

***Indicate IRB or IACUC:** Exempt.

RESIDENT RESEARCH TRAVEL AWARD

Dynamic Molecular Markers of Otosclerosis in the Human Cochlea

*Sarah Hodge, MD; Ivan A Lopez, PhD; Hirooki Matsui, MD
Gail Ishiyama MD; Alex Cronkite MD; Akira Ishiyama, MD*

Objective: To investigate the role of key proteins in the complex pathogenesis of otosclerosis in human temporal bones

Background: Molecular biological proteomic studies have suggested key proteins involved in bony remodeling in otosclerosis. The present study investigates the expression of some of these key proteins: transforming growth factor beta-1 (TGF beta-1), ubiquitin, nidogen-1, collagen-X, and bone sialoprotein (BSP) using immunohistochemistry techniques on celloidin embedded sections of the inner ear from patients with otosclerosis.

Methods: Archival celloidin formalin-fixed 20-micron thick sections from 7 patients diagnosed with otosclerosis were studied. Sections in the mid-modiolar region were immunoreacted with rabbit polyclonal antibodies against nidogen-1, collagen X, BSP, and monoclonal antibodies against TGF beta-1 and ubiquitin. Digital images were acquired using a high-resolution light and laser confocal microscope.

Results: TGF beta-1, ubiquitin, nidogen-1, and collagen-X were expressed in the otospongiotic region, and to lesser extent, in the otosclerotic region, the latter previously believed to be inactive. BSP, meanwhile, was present in the extracellular bone matrix. TGF beta-1 was specifically localized to the perivascular bone within the otospongiotic region. Ubiquitin distribution localized to both the otosclerotic and otospongiotic foci, and within the membranous labyrinth. There was a basal level of expression of these markers in the normal hearing specimens with increasingly more expression as hearing loss progressed.

Conclusions: These proteins identified and described using immunohistochemistry may play an important role in the pathogenesis of otosclerosis. Results support an active bone remodeling process, particularly in the otospongiotic foci suggesting these proteins may be targets for future therapeutic interventions.

Professional Practice Gap & Educational Need: The definitive biochemical changes involved in otosclerosis are widely unknown. Identifying and characterizing molecular markers is a crucial component to better understanding this disease process.

Learning Objective: To describe the role of key biochemical markers in the complex pathogenesis of otosclerosis

Desired Result: Identifying the presence and distribution of key proteins can help elucidate molecular processes and identify possible targets for future therapeutics.

Level of Evidence – Level IV

Indicate IRB or IACUC : #10-001449, UCLA

Impact of Modern Surgical Techniques on Rates of Sensorineural Hearing Loss and Revision Surgery after Stapedotomy

*Nabil F. Darwich, MD, PhD; Alexandra E. Quimby, MD, MPH
Tiffany P. Hwa, MD; Stephen J. Eliades, MD, PhD; Jason A. Brant, MD
Douglas C. Bigelow MD; Michael J. Ruckenstein, MD MSc*

Objective: Historically, stapedectomy complication rates are quoted at 1% for profound postoperative sensorineural hearing loss (SNHL), 5-6% for non-profound SNHL, and 5% for revision surgery. We sought to reassess the rates of these and other common post-operative complications in our experience using modern surgical technique.

Study Design: Retrospective case series.

Setting: Single academic tertiary referral center.

Patients: Adults (≥ 18 years) who have undergone stapedotomy from 2013-2020.

Interventions: Stapedotomy.

Main Outcome Measures: Rates of post-operative profound SNHL, dizziness, tinnitus, and dysgeusia; successful air-bone-gap closure; and revision rates.

Results: 468 stapedotomies performed in 402 patients by 4 surgeons were reviewed. Mean age was 49.85 years. The average preoperative air-bone gap was 31.60 dB. In 366 operations (78.20%), the patient experienced closure of the air-bone gap within 10 dB, and in a further 74 (15.81%) there was closure to between 10-20 dB. Air pure tone audiometry scores improved by an average of 25.63 dB after surgery. Rates of postoperative dizziness, tinnitus, and dysgeusia were 6.20%, 3.63%, and 7.26%, respectively. There were 2 cases (0.43%) of postoperative profound SHNL and no non-profound SNHL. There were 54 (11.72%) revision stapedotomies; however, in 20 of these (37.03%), the original stapedotomy was performed over 20 years ago. The revision rate for stapedotomies performed at our institution within the past 20 years was 3.63% (17 revision surgeries), completed within an average of 14.35 months from initial surgery.

Conclusions: Rates of post-operative SNHL and revision surgery following stapedotomy performed using modern technique are substantially lower than those commonly cited to patients based on classic techniques and historical data.

***Professional Practice Gap & Educational Need:** Complication and success rates of stapedotomy cited to patients in pre-operative counselling are in many instances based on historical data that does not take into account modern surgical technique.

***Learning Objective:** Gain an updated understanding of the risks of stapedotomy in the modern era in order to better inform discussions with patients surrounding surgery.

***Desired Result:** At the conclusion of this presentation, the participants should be able to recognize the rates of hearing loss and revision surgery after stapedotomy using modern surgical techniques compared to historical techniques. Participants will also be able to discuss surgical outcomes of modern stapedotomy.

***Level of Evidence – V**

***Indicate IRB or IACUC :** University of Pennsylvania, IRB exempt.

National and International Rates of Stapedectomy Performed at Academic and Non-Academic Centers across the Department of Defense

*Jason K. Adams, MD; John P. Marinelli, MD; Ronit E. Malka, MD
Carlos R. Esquivel, MD; Travis R. Newberry, MD
Samuel A. Spear, MD; Isaac D. Erbele, MD*

Objective: Stapedectomy remains a key indicator case reportable to the ACGME despite the decline in the incidence of otosclerosis over the last half-century. This study compared the rates of stapedectomy performed by otolaryngologists at academic and non-academic centers.

Study Design: Retrospective review.

Setting: Tertiary referral academic centers, non-academic centers, civilian purchased care across the Department of Defense between 2015 and 2020.

Patients: Tricare beneficiaries with otosclerosis near a military treatment facility with an otolaryngologist.

Interventions: Stapedectomy (CPT codes 69660, 69661, and 69662).

Main Outcome Measures: Number of stapedectomies performed by setting.

Results: From 2015 to 2020, 426 stapedectomies were performed at or near a military treatment facility with an otolaryngologist (274 directly by military otolaryngologists, 152 by community providers). At tertiary care centers (n=7), 214 were performed by military otolaryngologists and 14 were performed in the surrounding area (direct care rate = 94%). At non-academic centers (n=65), 60 stapedectomies were performed by military otolaryngologists and 138 were performed in the community (direct care rate = 30%). Among the 60 stapedectomies performed at non-academic centers, 43 were performed by fellowship trained neurotologists and 17 were performed by general otolaryngologists (4% of stapedectomies). The difference in the rate of direct care was statistically significant between stapedectomies performed at academic and non-academic centers ($p<0.0001$).

Conclusions: Low surgical volume by general otolaryngologists reinforces recent epidemiologic trends and suggests that stapes surgery should most appropriately be considered a key indicator case for fellows pursuing otology subspecialty training, rather than a key indicator for otolaryngology residents.

Professional Practice Gap & Educational Need: Recent population-based data suggest the incidence of otosclerosis is likely too low to support the development of meaningful proficiency in stapes surgery at most otolaryngology training programs. Despite the strongly suggestive epidemiologic trends, limited data characterizes the surgical implications of modern incidence rates and the resultant stapes surgery rates after graduation from residency.

Learning Objective: Describe the differences in rates of stapedectomy performed at comprehensive general otolaryngology centers and academic specialty otolaryngology centers within a single healthcare system.

Desired Result: Given the declining incidence of otosclerosis, in combination with the infrequency of stapes surgery performed by general comprehensive otolaryngologists, stapedectomy should be removed as a key indicator case for otolaryngology trainees and instead emphasized as a fellowship-level case.

Level of Evidence – Level III

Indicate IRB or IACUC : Approved IRB number C.2022.002n.

Cochlear and Vestibular Dysfunction in the COVID-19 Era: A Population Based Study

*Claudia I. Cabrera, MD, MS; Benjamin Johnson, MD (presenter); Maroun Semaan, MD
Alejandro Rivas, MD; Sarah Mowry, MD; Nauman Manzoor, MD*

Objective: During the recent pandemic sudden hearing loss, vertigo and tinnitus have been reported as clinical manifestations of COVID-19 infection or a side effect of the COVID-19 vaccination. The aim of our study was to investigate the likelihood of the aforementioned otological symptoms between COVID-19 + unvaccinated, and COVID-19 negative (–) vaccinated patients, within the first 8 weeks after diagnosis of COVID-19 or after the vaccine.

Study Design: Retrospective Longitudinal study using 1:1 greedy nearest-neighbor propensity score matching based on age, gender, race, and ethnicity.

Setting: TriNetX Research Network.

Patients: January 1, 2020 through September 2, 2021 (date of data access).

Interventions: N/A

Main Outcome Measures: Sudden hearing loss, acute vestibular disorders and tinnitus.

Results: A total of 1,078,487 patients met our criteria for the COVID-19 (–) vaccinated cohort, and 383,907 for the COVID-19 + unvaccinated one. After matching we found a higher likelihood of vertigo OR 3.8 ($p < 0.001$), tinnitus OR 1.2 ($p < 0.01$) among those COVID-19 + unvaccinated patients when compared to those COVID-19 (–) vaccinated. There was no difference in the likelihood of sudden hearing loss between groups.

Conclusions: Our study suggests there is a higher likelihood of developing vertigo and tinnitus related to a COVID-19 infection when compared to being vaccinated against the disease. This study is the first to study this by utilizing data from approximately 50 large healthcare organizations using a large sample size and a matched design. Further research is needed to investigate the mechanism and long-term effects in the quality of life of patients who develop these conditions.

***Professional Practice Gap & Educational Need:** Understand the likelihood of a patient experiencing sudden hearing loss, vertigo and tinnitus after diagnosis of COVID-19 or after being vaccinated.

***Learning Objective:** Understand the association of those symptoms and COVID-19.

***Desired Result:** Increase awareness of otological symptoms and COVID-19 and future practices.

***Level of Evidence – N/A**

***Indicate IRB or IACUC :** Exempt.

Standardization of Outcome Measures for Intratympanic Steroid Treatment for Idiopathic Sudden Sensorineural Hearing Loss

*Neil K. Osafo, BS; David R. Friedland, MD, PhD; Michael S. Harris, MD
Jazzmyne Adams, MPH; Chasity Davis; Ling Tong, MA; Jake Luo, PhD*

Objective: To compare patient response to intratympanic steroid (IT) treatment using the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNSF) guideline vs other reported criteria.

Study Design: Retrospective chart review

Setting: Academic otology practice

Patients: 74 patients with a diagnosis of idiopathic sudden sensorineural hearing loss (ISSNHL) between April 2003 and December 2020 were included. All patients had at least 1 treatment with IT steroids and both pretreatment and follow-up audiograms.

Interventions: IT steroid injection

Main Outcome Measures: 1) Determination of the efficacy of IT steroids for ISSNHL using the AAO-HNSF guideline vs other reported criteria; 2) Correlation of clinical and treatment variables with response to IT steroid

Results: PTA-4 using AAO-HNSF reporting criteria demonstrated full recovery in 24.32% of patients. Applying the 8 other reported outcomes criteria to our patients showed full recovery ranging from 14.87% to 40.54% of patients. Similarly, AAO-HNSF criteria showed no recovery in 51.35% of patients, while applying the other reported criteria showed no recovery in 51.45% to 82.43% of patients. Low frequencies exhibited full recovery in 33.78% of patients while high frequencies recovered in 27.03%. Younger age ($p=0.003$, effect size 0.924) and IT injection within a week of onset ($p<0.001$, effect size 1.099) positively correlated with full recovery. There was no impact of prior or concurrent oral steroids nor number of steroid injections on outcome.

Conclusions: Great variability exists in the literature for assessment of IT steroid outcomes in ISSNHL. AAO-HNSF standardization of outcome measures is necessary to accurately characterize IT steroid efficacy.

***Professional Practice Gap & Educational Need:** Lack of accurate information regarding the efficacy of IT steroid treatment for ISSNHL

***Learning Objective:** 1) To promote standardization of reporting outcomes for ISSNHL; 2) To recognize variables associated with recovery from ISSNHL

***Desired Result:** Utilization of AAO-HNSF guideline as standard for reporting outcomes

***Level of Evidence - IV**

***Indicate IRB or IACUC :** IRB#: 1538127

Changes and Trends in the Cochlear Implant Literature over a 40-year period: A Comprehensive Historical Literature Review

Jacob Kahane, MD; Anne Maxwell, MD; Moises Arriaga, MD, MBA

Objective: The objective of this study is to historically evaluate changes and trends within the cochlear implant literature over time.

Study Design: Comprehensive Literature Review

Setting: Tertiary care academic medical center

Patients: A historical review of the cochlear implant literature was conducted in 10-year intervals from 1980 to 2020. The 5 journals with the highest volume of cochlear implant literature in 1980 and still in publication today were queried using PubMed.

Interventions: Address the trends and changes within the cochlear implant literature from 1980 to 2020.

Main Outcome Measures: The main outcome of this literature review is the change in the quality and quantity of cochlear implant studies over time. .

Results: 182 articles met inclusion criteria. A statistically significant increase in publications occurred every decade from 1980 to 2020. The mean level of evidence of all articles significantly improved every decade after 1990. The mean level of evidence for articles primarily concerning pediatric populations (3.8) was not significantly different than from those investigating adult patients (3.7). Articles from the United States (3.8) had a significantly lower level of evidence than those from other regions (3.0) across all time frames. The percentage of prospective studies increased every decade until 2020. The percentage of articles from non-university practices decreased significantly from 1990 to 2000. The percentage of articles mentioning the single channel electrode in a historical context significantly decreased from 1980 to 2000. The percentage of articles citing either William House or Graeme Clark as the inventor of the cochlear implant decreased from 1980 to 1990. Across all time frames, William House is mentioned significantly more often than Graeme Clark as the inventor of the cochlear implant.

Conclusions: The evaluation of the historical trends within the cochlear implant literature sheds light on significant developments and events within the field over time. Overall, the quality of evidence has become stronger within the last 20 years, with a trend toward more prospective studies. This review shows how developments in the field of neurotology and world events, such as the development of the ACGME accredited fellowship program in the mid to late 1990s and the COVID pandemic of 2020, have influenced the cochlear implant literature.

Define Professional Practice Gap & Educational Need: This study addresses a knowledge gap in the historical cochlear implant literature. We have found no other studies that use historical literature to evaluate the trends and changes in quality of cochlear implant research over time.

Learning Objective: Review cochlear implant literature over the past 40 years in order to critically evaluate future directions of study and gain historical perspective.

Desired Result: Improve future directions of study within the field of cochlear implantation by evaluating the historical literature

Level of Evidence - I

Indicate IRB or IACUC: Exempt

Association of Baseline Frailty Status and Age with Postoperative Complications Following Cochlear Implantation: A National Inpatient Sample Study

*Kyril L. Cole, MPH; Alis J. Dicpinigaitis, BA; Eric Babajanian, MD
Steven A. Gordon, MD, MPH; Neil S. Patel, MD
Christian A. Bowers, MD; Richard K. Gurgel, MD, MSCI*

Objective: To determine the independent associations of chronological age and frailty, as measured by a validated, 5-factor modified frailty index (mFI-5 respectively), on postoperative outcomes of patients undergoing cochlear implantation (CI).

Study Design: Cross-sectional national database study

Setting: National Inpatient Sample Database

Patients: Adult patients undergoing CI surgery from 2001-2018.

Interventions: Cochlear implantation. In addition to demographics and postoperative complications, the mFI-5 (comprising a pre-operative history of chronic obstructive pulmonary disease, congestive heart failure, hypertension, diabetes mellitus, and partial or total-dependent functional status) was calculated for all patients included in the analysis.

Main Outcome Measures: Any postoperative complications, including major complications (pneumonia, sepsis, etc.), minor complications (urinary tract infections, blood transfusions, etc.), and implant-specific complications (otitis media, implant failure, etc.). Predictors of complications were examined using multivariate logistic regression with an odds ratio (OR) and a 95% confidence interval (95% CI) reported.

Results: There were 5,130 patients included with a median age of 60 (interquartile range 44-73) and a female predominance (53.5%). There were 2,979 (58.1%) robust patients (non-frail, mFI-5=0), 1,710 (33.3%) pre-frail (mFI-5=1), 362 (7.1%) frail (mFI-5=2), and 78 (1.5%) severely-frail (mFI-5≥3). There were 328 (6.5%) patients who experienced postoperative complications. Multivariate analysis showed no statistically significant correlation between patient age and complications, however, increasing frailty did show an independent correlation with non-home discharge (severely frail, OR 16.99, 95% CI 10.36-27.90, $p < 0.001$).

Conclusions: Increasing frailty and age do not predispose to postoperative complications in this patient cohort. However, frail patients are at increased risk for non-home discharge.

***Professional Practice Gap & Educational Need:** Patients and clinicians may believe that older patients should not be considered for CI due to risks of surgery. Many studies have been devoted to the safety of CI in older adults, though few report on an accurate metric to account for medical comorbidities, i.e., frailty, and how frailty may impact the postoperative course of CI patients. This study suggests that CI is low risk at the ages studied, but patients with increasing frailty may require more intensive postoperative monitoring for discharge to home.

***Learning Objective:** Understanding frailty's predictive ability on postoperative complications following CI.

***Desired Result:** To provide a metric that can risk stratify adult CI patients for postoperative complications or non-home discharge.

Level of Evidence - Level III

Indicate IRB or IACUC: University of Utah IRB_00147585

Influence of Fractalkine Receptor CX3CR1 Deletion on Cochlear Hair Cell Survival and Macrophage Expression in Chronic Suppurative Otitis Media

*Viktoria Schiel, MD, PhD; Anping Xia, MD, PhD; Jing Chen, MPH, DABT
Brian Bacacao, BS; Laurent A. Bekale, MD, PhD; Peter L. Santa Maria, MD, PhD*

Background: Chronic Suppurative Otitis Media (CSOM) is a neglected disease that afflicts 330 million people worldwide and is the most common cause of permanent hearing loss among children in the developing world.

Hypothesis: We have demonstrated that CSOM causes macrophage associated sensory hearing loss. In this report, we examined the influence of fractalkine receptor (CX3CR1) deletion (CX3CR1^{GFP/GFP}) in CSOM.

Methods: We investigated in our novel pseudomonas aeruginosa PA CSOM animal model, previously validated to mimic the human disease.

Results: We observed partial outer hair cell (OHC) loss in the cochlear basal turn, no OHC loss in the middle and apical turns in both CX3CR1^{GFP/GFP} and wild type (WT) mice at 14 days after bacterial inoculation. The number of OHCs in the base remained as 26.6/100 μ m of the basilar membrane in CX3CR1^{GFP/GFP} mouse and 27.0/100 μ m of the basilar membrane in WT mouse. There was no significant difference ($p = 0.95$). In contrast to OHC loss, no IHC loss was found in all cochlear turns. We also counted F4/80 macrophages in hair cells area and outer sulcus region with Z-stack images in whole mount samples. Macrophages have 6.0/100 μ m of the basilar membrane in CX3CR1^{GFP/GFP} mice and 5.6/100 μ m of the basilar membrane in WT mouse. There was also no significant difference ($p = 0.68$).

Conclusions: Together, the data did not support the correlation in HC loss and macrophage numbers between fractalkine receptor deletion and WT CSOM. We will further investigate the immune responses in the whole cochlea in CX3CR1^{GFP/GFP} comparing with WT mouse.

***Professional Practice Gap & Educational Need:** We propose to investigate how sensory hearing loss (SHL) is caused by chronic suppurative otitis media (CSOM): severe chronic middle ear infections. CSOM is a neglected disease that afflicts 330 million people worldwide and is the most common cause of permanent hearing loss among children in the developing world. It is characterized by a chronically discharging infected middle ear, and there is currently no effective cure.

***Learning Objective:** To investigate the interaction between the CX3CR1 receptor function on macrophages and hair cells loss in chronic suppurative otitis media.

***Desired Result:** To show a correlation between the CX3CR1 receptor function on macrophages and hair cells loss in CSOM to further investigate the immune response in sensory hearing loss.

***Level of Evidence - Level III**

***Indicate IRB or IACUC :** APLAC (Administrative Panel on Laboratory Animal Care, Stanford University) protocol number 32855

Evaluation of Safety and Efficacy of Povidone-Iodine Solution as an Otological Treatment in a Murine Model of Chronic Suppurative Otitis Media

Adam C. Kaufman, MD, PhD; Brian Bacacao, BS
Laurent Bekale, PhD; Peter L. Santa Maria, MD, PhD

Hypothesis: Povidone-Iodine solution can eliminate biofilms and persister cells rapidly in *in vivo* achievable concentrations without inducing ototoxicity.

Background: Chronic suppurative otitis media (CSOM) is a substantial global problem. Current treatment options often induce a temporary remission without leading to a permanent cessation of symptoms secondary to the inability treatments inability to eliminate biofilm and persister cells. Povidone-Iodine has been shown to be able to clear biofilm and planktonic cells in *in vitro* assays, but there are reports of ototoxic effects limiting its utility.

Methods: Bacterial and biofilm growth with quantification by spectrophotometer, murine auditory brainstem response (ABR) and distortion product otoacoustic emissions (DPOAE), immunohistochemistry, *in vivo* povidone-iodine treatment of murine CSOM, persister cell assay

Results: Commercially available 10% povidone-iodine solution is able to completely eradicate multiple clinical strains of *pseudomonas aeruginosa* (PA) and *staphylococcus aureas* (SA) is as little as 5 minutes of exposure. 1% povidone-iodine solutions are able to reduce bioburden of PA and SA to levels that are not clinically relevant (10^4 CFU/mL). Mice that have received a transtympanic injection of 1% povidone-iodine solution did not have significantly different ABR or DPOAE results compared to mice that received a saline injection. The DPOAE of mice that received a povidone-iodine scrub worsened by almost 30 decibels which is a significant change ($p < 0.05$). Immunohistochemistry was performed to confirm loss of outer hair cells. A murine model of CSOM was inoculated with PA and a persister cell assay was completed to determine clearance of infection.

Conclusions: Povidone-iodine solution is effective at eliminating biofilm and persister cells at *in vivo* achievable concentrations. The diluted solution does not have ototoxic potential while the scrub variant, which contains detergents, significantly worsened hearing thresholds after a single treatment.

***Define Professional Practice Gap & Educational Need:** CSOM is a recalcitrant disease requiring frequent courses of otological treatments often eventually needing surgical intervention. There is a desperate need for more effective medical options. Povidone-iodine is often overlooked as treatment option due to prior reports of ototoxicity. Diluted solutions of povidone-iodine without detergent do not appear to raise the hearing thresholds in mice. Povidone-iodine solutions are able to clear biofilm and persister cells of PA and SA.

***Learning Objective:** Povidone-iodine is able to rapidly sterilize PA and SA in all bacterial states
Povidone-iodine scrub is ototoxic while the solution variant does not appear to impact ABR and DPOAE in murine models

***Desired Result:** Diluted povidone-iodine solutions should be considered earlier in the treatment algorithm for CSOM.

Level of Evidence – Laboratory Science

Indicate IRB or IACUC : IACUC Protocol 33535 Stanford University

Improvement of Eosinophilic Otitis Media with Targeted Biologic Therapy

C. Yoonhee Ryder, BS; Mark A. Zacharek, MD; Christopher M. Welch, MD, PhD

Objective: To compare the responses of eosinophilic otitis media to treatment with or without a targeted biologic therapy against IL-4, IL-5, or IL-13 signaling

Study Design: Retrospective review

Setting: Tertiary referral center

Patients: Subjects with Type 2 chronic rhinosinusitis with nasal polyposis (CRSwNP) and eosinophilic otitis media who underwent treatment between 2005 and 2021

Intervention: Treatment with targeted biologic therapy

Main Outcome Measures: Pre- and post-treatment nasal endoscopy, ear examination, and audiologic evaluation

Results: Four hundred seventy-seven subjects were identified with Type 2 CRSwNP treated between 2005 and 2021. Sixty-two had symptomatic otitis media with pre- and post-treatment evaluation. Retrospective chart review assessed pre- and post-treatment exam findings, nasal endoscopy findings, and audiologic measures (hearing loss, tympanometry). During treatment nineteen subjects received a targeted biologic therapy, while forty-three did not. Exam, endoscopy, and audiometric findings were graded on a 3-point scale and compared pre- and post-treatment to generate a differential score (a larger value indicates improvement). Nasal endoscopy scores improved with biologic therapy relative to the control group, though not statistically significant (control 1.04, biologic 1.36, p 0.22). Subjective ear exam and audiometric findings were significantly improved with biologic therapy (control 0.05, biologic 0.84, p 9.3×10^{-5} ; control -0.1, biologic 0.62, p 0.0002).

Conclusions: Biological therapies targeting IL-4, IL-5, and IL-13 signaling have changed treatment strategies for eosinophilic conditions such as Type 2 CRSwNP. This is the largest study to date demonstrating improvement in ear symptoms in subjects with eosinophilic otitis media in response to targeted biologic therapy, and immune modulation represents a novel treatment strategy for this challenging condition.

Professional Practice Gap & Educational Need: Current treatment strategies for otologic symptoms in eosinophilic disease are not tremendously effective or durable, resulting in a need for improved treatment options

Learning Objective: To determine if targeted biologic therapy, often used for eosinophilic asthma and Type 2 chronic rhinosinusitis with nasal polyposis, improves coexistent eosinophilic otitis media

Desired Result: Treatment of eosinophilic otitis media with targeted biologic therapy will result in improvement of otologic symptoms with a durable response compared to current treatment options

Level of Evidence – Level IV

Indicate IRB or IACUC: Exempt.