SELECTED ABSTRACTS

ORAL PRESENTATIONS

IN ORDER OF PRESENTATION

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Cochlear Reimplantations following Device Dysfunction: A Retrospective Cohort Study

Mélyssa Fortin, MD; Richard Bussières, MD; Mathieu Côté, MD; Daniel Philippon, MD, DMD
Sandra Fortin, MPA; Mathieu Trudel, MD

Objective: Our cochlear implant (CI) program has over 40 years of experience in cochlear device implantation across pediatric and adult populations. As surgical indications have broadened, more patients are outliving their device's lifespan and encountering potential industry recalls. Our program's collaboration with all major CI manufacturers provides unique insights into contemporary surgical and technological challenges.

Study Design: Retrospective cohort study

Setting: Tertiary care center

Patients: All CI recipients within our program who underwent cochlear reimplantation between May 1st, 1984 - May 1st, 2024

Intervention: Therapeutic

Main Outcome Measures: The primary outcome was defined as reimplantation of a new cochlear device following the extraction of a previous CI, regardless of the reason for removal. Secondary outcomes included CI manufacturer, reasons for reimplantation, implantation-to-reimplantation interval, and associated complications.

Results: A total of 3,885 cochlear devices were implanted by our program (66% adults, 34% pediatric). Over the years, four industry recalls affected our patient population. We report 257 reimplantations, including 86 (33%) pediatric cases. The overall reimplantation rate was 6.6%, varying across manufacturers: 12.6% for Advanced Bionics, 3.4% for Cochlear, 8,9% for Oticon, and 1.8% for MED-EL. The majority of reimplantations (70.8%) were due to confirmed device failure, either from recalls (35.4%) or hard failures (35.4%). The average interval between implantation and reimplantation was 6.5 years, with 80% of reimplantations occurring within 10 years of the initial implantation.

Conclusions: Cochlear reimplantation imposes significant physical, emotional, developmental, ethical, and financial burdens on patients. The increasing need for reimplantations due to technological failures poses a modern challenge, with pediatric patients being particularly vulnerable. Surgical teams must closely monitor patients, especially those with devices from manufacturers with prior recall histories. Early identification of device issues and timely reimplantation are critical to preserving auditory function and reducing patient distress. These factors must be integrated into patient-centered care models and long-term healthcare planning.

Professional Practice Gap & Educational Need: This study underscores the complexities of cochlear reimplantation, encompassing both technological and human aspects. It offers valuable insights into the causes and outcomes of reimplantation within a large patient cohort. Understanding the drivers behind reimplantation, the variation in reimplantation timelines, and the unique challenges faced by pediatric patients will enable healthcare providers to better tailor their care strategies.

Learning Objectives:

- Describe the primary causes leading to cochlear reimplantation
- Examine the outcomes of patients who underwent cochlear reimplantation at our high-volume CI center
- Discuss the clinical, ethical, and social implications of reimplantation, particularly in the context of industry recalls

Desired Result: Optimize patient care pathways and policy planning to minimize the need for cochlear reimplantation

Level of Evidence - Level III

Indicate IRB or IACUC: Exempt

Does Early Tinnitus Improvement Influence Long-Term Quality of Life in Cochlear Implant Recipients?

Barak M. Spector, BS; Katelyn A. Berg AuD, PhD; David S. Haynes, MD
Terrin N. Tamati, PhD; Aaron C. Moberly, MD

Objective: 1) To evaluate tinnitus outcomes in adults after cochlear implantation, 2) to examine the impact of demographic factors on tinnitus outcomes, and 3) to determine the relationship between early tinnitus outcomes and long-term quality of life (QOL).

Study design: Retrospective Review of Prospectively Obtained Data

Setting: Tertiary Care Adult Cochlear Implant (CI) Center

Patients: Ninety-two adult CI recipients aged 20-84 years old (mean = 60.3 ± 15.3).

Interventions: QOL surveys

Main Outcome Measures: Tinnitus Handicap Inventory (THI); Speech, Spatial, and Qualities of Hearing Scale-12 (SSQ-12), and the Cochlear Implant Quality of Life-10 measure (CIQOL-10) assessed preoperatively and at one or more post-operative timepoints.

Results: 1) THI scores significantly improved from pre-CI to 1-month post-CI, with no additional gains within 12-months post-CI. Across timepoints, 71.7% of patients demonstrated a clinically significant improvement ($\Delta \leq 6$ points) in their tinnitus from pre-CI. 2) Comparisons of demographics between those with and without clinical improvements in their THI revealed only duration of deafness as significantly different, with shorter durations of deafness in those showing improvement. 3) Long-term (6-12 months) post-CI THI scores were negatively correlated with CIQOL-10 scores ($r = -.506$, $p = .002$) and overall SSQ-12 scores ($r = -.535$, $p < .001$). Early (1-3 months) post-CI THI scores were also negatively correlated with long-term overall SSQ-12 scores ($r = -.310$, $p = .029$).

Conclusions: Adult CI recipients reported tinnitus improvements at 1-month post-activation and maintained this improvement at 12 months. Patients with shorter durations of deafness reported greater tinnitus relief. Early tinnitus outcomes were associated with long-term quality of life. Clinicians should consider early evaluation of tinnitus outcomes to inform patient counseling regarding long-term CI outcomes.

Professional Practice Gap & Educational Need: This study aims to better understand how tinnitus changes shortly after cochlear implantation relate to patients' long-term quality of life. The findings could help clinicians provide more appropriate outcome expectations counseling.

Learning Objective: After this presentation, participants will be able to 1) describe the trajectory of tinnitus outcomes post-CI and 2) discuss the relationship between early tinnitus outcomes and a patient's long-term quality of life.

Desired Result: To improve patient counseling by providing a clearer understanding of how early tinnitus outcomes influence long-term quality of life in cochlear implant recipients.

Level of Evidence – Level IV: Historical cohort or case-controlled studies.

Indicate IRB: 240876

Optimizing Cochlear Implant Activation: A Prospective Patient-Preference Study

Arman Saeedi, MPH; Mihai A. Bentan, BS; Albina Islam, MD
Nauman F. Manzoor, MD; Daniel H. Coelho, MD

Objective: As many centers around the world are shifting towards earlier and earlier cochlear implant (CI) activation, there have been no studies of patient preference on such timing. The aim of this study was to determine patient timing preferences before and after standard 4-week activation, and to account for such changes.

Study Design: Prospective survey-based study.

Setting: A tertiary care academic CI center.

Patients: Adults 18 years and older receiving their first cochlear implant.

Interventions: Patients completed pre- and post-operative questionnaires (day of surgery, 1-week post-op, 1-week post-activation) assessing several patient-reported outcomes and their preferences regarding activation timelines. Data recorded were age, gender, BMI, preoperative CIQoL-10 Global, device brand, and processor style. Qualitative data regarding patient rationales were also recorded.

Main Outcome Measures: Percentage of patients who changed preferences between pre-op visit and 1-week post-activation visit. Several other outcomes measures were obtained.

Results: Thirty-nine patients (51.3% male) were included. Mean age and BMI were 64.6 ± 14.3 years old and 28.5 ± 5.8 kg/m^2, respectively. Preoperatively, the top three preferred activation times were immediately following surgery/same day (28.2%), 3 weeks postoperatively (23.1%), and 1 week postoperatively (20.5%). The most common cited reason was the desire to hear as soon as possible (38.6%). At follow-up, the top three preferred activation times were 3 weeks postoperatively (30.8%), 2 weeks postoperatively (20.5%), and 1 week postoperatively (17.9%), with only 10.3% preferring same day activation. The odds of preferring "standard" timing (2 weeks or later) post-implantation were approximately 2.88 times (95% CI: 1.14 - 7.23, $p = 0.025$) higher than pre-implantation.

Conclusions: While patients receiving a CI do want to hear as soon as possible, many change their minds about the exact timing once they have gone through the process, likely due to an underestimation of surgical recovery. This study highlights the dynamic nature of patient preferences for cochlear implant activation, with many shifting from same-day activation preoperatively to a preference for delayed activation postoperatively. Such findings suggest possible undercounseling of patients as to immediate post-operative expectations. In addition, it highlights the notion that patient input should be considered before uniformly changing activation protocols earlier.

Professional Practice Gap & Educational Need: Patient preferences are important considerations when deciding CI activation timing and should be considered to align clinical practice with patient expectations. This promotes patient-centered care and can lead to improved shared decision-making.

Learning Objective: To understand the variability in patient preferences for cochlear implant activation timing and factors influencing these preferences.

Desired Result: Clinicians will appreciate the importance of patient-centered outcomes and input prior to changing CI activation timing protocols. Doing so can improve patient satisfaction, engagement, and clinical outcomes.

Level of Evidence - III

Indicate IRB or IACUC: HM20020582.

High-resolution Flat-panel CT Analysis of Cochlear Implant Electrode Contact Orientation

Ana Marija Sola, MD; Nicole Jiam, MD; Melanie Gilbert, AuD
Luke Helpard, PhD; Charles J. Limb, MD

Objective: This study aims to describe a novel method for identifying cochlear implant (CI) electrode directionality from *in vivo* high-definition flat-panel computed tomographic imaging (FPCT) in post-surgical patients.

Study Design: Retrospective, observational

Setting: Tertiary care center

Patients: 6 participants with MED-EL FLEX 28 CI

Interventions: All patients underwent FPCT postoperatively with secondary reconstruction and transformation to a standard cochlear coordinate system.

Main Outcome Measures: FPCT images were aligned to a standard coordinate system where the X-Y plane corresponded to the basal turn plane and the Z-axis corresponded to the mid-modiolar axis, along which images were reformatted, and the electrode array insertion was measured. To estimate contact orientation, the two plates of the bipolar contacts and asymmetry of the monopolar contacts were identified in FPCT scans and 3D renderings. Using vectors perpendicular to the electrode contact faces, the post-operative orientations of the bipolar (0-179º) and monopolar (-179º-180º) contacts were estimated. A directionality of 0-degrees and 90-degrees corresponds to contacts oriented towards the modiolus and organ of Corti, respectively.

Results: Average angular insertion depth was 500.3º (444-630), in line with company-reported average of 500-550 degrees. Basal bipolar electrode contacts and the 5 most apical monopolar contacts in the MED-EL FLEX28 arrays were identified. 9/72 electrode contacts were excluded due to imaging artifact. The average contact orientation was 98º (standard deviation: 13.6) for the 7 basal electrodes and -25º (standard deviation: 13.1) for the 5 apical electrodes. In postoperative patients inserted with this flexible array, basal bipolar electrodes were reliably oriented toward the organ of Corti, while apical monopolar electrodes tended to be oriented towards the modiolus.

Conclusions: To our knowledge, this is the first study to use post-operative FPCT *in vivo* to identify electrode contact orientation. We have identified electrode orientation based on imaging characteristics using high-definition FPCT imaging and introduced a model for describing directionality of electrode contacts. In future studies, we will focus on correlating these rotational measurements to electrophysiologic and psychophysical outcomes, including electrode current spread, activation settings, and hearing performance.

Professional Practice Gap & Educational Need: Hearing outcomes with CI are influenced by electrode and patient-specific factors. Previous *in vivo* studies have examined electrode-specific factors such as location within the scala, insertion angle and depth of insertion, but not electrode orientation, which may have implications electrode performance and hearing outcomes.

Learning Objective: To describe electrode contact-level imaging characteristics and introduce a system for quantifying electrode contact rotation.

Desired Result: To provide information regarding postoperative electrode characteristics with increased resolution.

Level of Evidence – IV

Indicate IRB or IACUC: UCSF IRB:15-17575, Approval: 4/19/23

Pre-Curved Versus Straight Arrays for Hearing Preservation in Cochlear Implantation: A Systematic Review and Meta-Analyses

David Elisha, BS; Nicholas DiStefano, BS; Rahul Mittal, PhD; Andrea Monterrubio, BS
Jeenu Mittal MSc; Adrien Eshraghi, MD

Objective: To evaluate hearing preservation (HP) outcomes across various electrode array (EA) designs specifically straight/lateral wall compared to precurved/perimodiolar arrays.

Data Sources: A systematic review and meta-analysis were performed following PRISMA guidelines. Databases searched included PubMed, ScienceDirect, Web of Science, Scopus, and Embase, covering studies published in English from 2019 through 2024.

Study Selection: Studies were included if they reported HP rates for patients undergoing cochlear implantation with LW or PM EAs. Of 455 abstracts screened, 32 studies met the inclusion criteria, comprising 3,278 patients. Twelve studies directly compared EA types, and 20 assessed general HP outcomes without comparing EA designs.

Data Extraction:
Extracted data included HP rates, low-frequency pure tone averages (LFPTA), insertion depth, surgical approach, and electrode type. Study quality were assessed, including small sample sizes, variability in surgical techniques, device selection bias, and inconsistent steroid regimens.

Data Synthesis:
Statistical analysis used the Mantel-Haenszel method for dichotomous outcomes (e.g., HP rates), with odds ratios (OR) as the effect measure. Twelve-month HP rates favored LW electrodes with an OR of 0.47 [0.26, 0.85] ($Z = 2.48$, $p = 0.01$). SlimJ electrodes outperformed Mid-Scala electrodes (48.4% vs. 30.8% HP). Predictive factors for HP included preoperative LFPTA and age at implantation, accounting for 30.8% to 41% of variance in LFPTA shifts.

Conclusion:
Straight/LW arrays, paired with atraumatic techniques, provide superior HP outcomes. Tailoring EA selection to patient-specific factors during surgery are essential for optimizing HP and improving long-term outcomes.

Professional Practice Gap & Educational Need: There is a lack of consensus regarding the optimal electrode array (EA) type for achieving the best hearing preservation outcomes in cochlear implant recipients. Additionally, variability in surgical techniques, electrode design, and patient selection contributes to inconsistent preservation outcomes, highlighting the need for further research and clinical guidance.

Learning Objective: To evaluate and compare the impact of different EA designs on hearing preservation outcomes within 12 months of cochlear implantation and explore the role of surgical techniques and insertion strategies in optimizing hearing preservation.

Desired Result: Attendees will gain an understanding of how electrode array design and surgical techniques affect hearing preservation, enabling them to make informed decisions regarding electrode selection and surgical approaches to improve patient outcomes in cochlear implantation.

Level of Evidence: Level III

Indicate IRB or IACUC: Exempt

Outcomes of Tympanic Membrane Regeneration Therapy for Elderly Patients

Rie Kanai, MD; Shin-ichi Kanemaru, MD, PhD; Tomoya Yamaguchi, MD
Ryohei Yuki, MD; Razumu Shirai, MD; Toshiki Maetani, MD, PhD

Objective: To evaluate the outcome of tympanic membrane regenerative therapy (TMRT) for elderly patients age 65 years and older with tympanic membrane perforations (TMPs)

Study Design: Intervention study

Setting: Research institute hospital

Patients: One hundred twenty-three patients 134 ears under 65 years (mean age :37.4) as Group A, 80 patients 100 ears over 65 and under 75 years old (mean age :70.6) as Group B, 100 patients 106 ears over 75 years old (mean age :80.3) as Group C were evaluated in this study.

Interventions: All patients underwent TMRT: the freshening of the perforation edge, inserting a gelatin sponge with basic fibroblast growth factor, and applying fibrin glue. The treatment was repeated up to 4 times until TMP closure.

Main Outcome Measures: The closure rates of TMPs, hearing improvement, complications, and use of hearing aids (HAs) after the final treatment were compared between the three groups.

Results: The TMP closure rates were 97.8% (131/134) in Group A, 97.0% (97/100) in Group B and 97.2% (103/106) in Group C. The hearing level improved from 34.3± 12.8 dB before TMRT to 22.8 ± 11.1dB after TMP closure in Group A, from 51.7± 14.8 dB to 39.8± 13.4 dB in Group B, and from 64.3± 15.5dB to 52.8± 15.2 dB in Group C. The AB gaps improved from 16.0± 9.6 dB to 7.6± 5.3 dB in Group A, from 17.2± 9.6 dB to 8.8± 6.3 dB in Group B, and from 17.0± 9.8 dB to 9.3± 7.0 dB in Group C. No serious complications occurred in all groups. The percentage of HA user after TMRT were 0.7% (1/134) in Group A, 12.0% (12/100) in Group B, and 30.1% (32/106) in Group C.

Conclusions: Regardless of age, TMRT provided high TMP closure rates. After treatment, the AB gaps for all groups was within 10 dB, showing ideal hearing improvement. The results indicate that being elderly is not a disadvantage for the TM regeneration, and TMRT can be performed safely in elderly patients.

Professional Practice Gap & Educational Need: TMRT is a novel treatment covered by health insurance in Japan in 2019, and is currently undergoing Phase II clinical trials in the United States. TMRT is a minimally invasive treatment without cell transplantation and tissue harvesting, and it can regenerate a nearly normal-shaped TM and provide ideal hearing improvement with small AB gaps. Elderly patients often also develop presbycusis in addition to TMP. After TMP closure by TMRT, it is possible to use HAs more effectively, and this will motivate elderly patients to use HAs. In this presentation, we would like to present our treatment strategies of TMRT for elderly patients.

Learning Objective: Participants will be able to learn that TMRT is minimally invasive, safe, and highly successful, making it suitable for elderly patients who tend to have multiple comorbidities. They will also learn that for elderly patients, a treatment combining TMRT and HA can be provided.

Desired Result: We hope that TMRT or a treatment combining TMRT and HA will be widely applied to elderly patients with TMP, reducing the number of elderly people who become isolated from society due to hearing impairment. This may also lead to a reduction in the number of patients developing dementia in the future, as hearing impairment is one of the risk factors for dementia.

Level of Evidence - Level III

Indicate IRB or IACUC : IRB No.2106006, Medical Research Institute Kitano Hospital. Initial approval 14/06/2021 TMRT became covered by health insurance in Japan in November 2019.

Tympanoplasty Outcomes of Indigenous Populations

Catherine F. Roy, MD; Jeffrey C. Yeung, MD, MSc; Lamiae Himdi, MD
Tamara Mijovic, MD MSc

Objective: Chronic otitis media (COM) is highly prevalent in Indigenous populations, likely owing to risk factors (low socio-economic status, crowded housing, tobacco exposure) and limited access to specialized care. This study is one of the first contemporary accounts investigating the success rates of tympanoplasties a North American Indigenous population.

Study Design: Retrospective cohort study.

Setting: Community health center providing front-line and specialty services across seven Indigenous communities

Patients and Interventions: All patients having undergone a tympanoplasty from January 2015 to 2024.

Main Outcome Measures: The primary outcome was otoscopic confirmation of an intact tympanic membrane post-operatively, while secondary outcomes included audiometric parameters.

Results: A total of 194 patients (mean age 22.4 ± 14.7 years) and 224 tympanoplasties were included (195 primary, 29 revision). Successful closure of the perforation was achieved in 111/172 (64.5%) of patients with otoscopic follow-up, however varied widely according to the type of graft used. Cartilage tympanoplasties had a closure rate of 86% (37/43 patients), compared to 62% (51/82) for tympanoplasties using fascia or perichondrium, and 49% (23/47) for myringoplasties using fat or a hyaluronic acid scaffold ($P<0.001$). The average air bone gap in 87 patients with audiometric testing available significantly decreased from 27.3 (95%CI 25.4; 29.4) to 19.0 (95%C.I. 16.4;21.5) dB. The mean follow-up was 2.3 ± 1.9 years.

Conclusion: While tympanoplasty may improve audiometric parameters and recurrent otorrhea, outcomes in Indigenous patients are modest. This emphasized the superior closure rates associated with cartilage grafts, which may help improve outcomes in this population. Further efforts should focus on addressing broader healthcare disparities to ensure better access to specialized surgical care in Indigenous communities.

Professional Practice Gap & Educational Need: Surgical outcomes in Indigenous populations remain largely understudied and underreported, contributing further to observed health disparities.

Learning Objective: This study highlights suboptimal outcomes of tympanoplasty in Indigenous patients and provides an understanding of potentially modifiable surgical factors.

Desired Result: Clinicians and researchers will strengthen their knowledge of chronic otitis media in Indigenous populations and its surgical management, gaining insight into potential strategies to address observed health inequities.

Level of Evidence: Level 3 (retrospective cohort study)

IRB approval: This study was approved by the Director of Professional Services of the Inuulitsivik Health Center.

Comparing Pediatric and Adult Chronic Otitis Media with Cholesteatoma at the Single-cell Level

Daniel R. Romano, MD; Song-Zhe Li, MD, PhD; Richard A. Chole, MD, PhD
Michael Hoa, MD; Sidharth V. Puram, MD, PhD; Keiko Hirose, MD

Hypothesis: Pediatric and adult cholesteatoma tissue demonstrate significant differences in keratinocyte gene expression and immune cell-stromal cell signaling.

Background: Cholesteatoma is an otologic disease defined by keratinizing stratified squamous epithelium in the middle ear and/or mastoid. Although not a neoplasm, cholesteatomas demonstrate dysregulated differentiation, uncontrolled proliferation, and locally aggressive growth, with complications ranging from a conductive hearing loss to central nervous system infection. Surgery may be curative but published 5-year recurrence rates range from 21-38%. Cholesteatomas are especially aggressive in the pediatric population, with > 2-fold greater 5-year recurrence in children < 16 years. However, the molecular and cellular differences between pediatric and adult cholesteatomas are poorly characterized.

Methods: Surgical samples were collected from pediatric and adult patients undergoing planned surgery for cholesteatoma of the middle ear, and enzymatically and mechanically dissociated into a single-cell suspension. Magnetic-activated cell sorting was utilized to achieve a 1:1 ratio of CD45-positive to -negative cells, and the suspension was subjected to single-cell RNA-sequencing (scRNA-seq). Comparative analyses were performed between the adult and pediatric scRNA-seq datasets. Clinical information including audiometric results, previous ear surgeries, and STAMCO staging was obtained from the surgeon or medical records.

Results: scRNA-seq revealed a rich array of cell types in surgical cholesteatoma samples. Pediatric and adult scRNA-seq data are distinguished by differential gene expression, regulatory network utilization, and intercellular interactions. An interim analysis of 23,032 high quality cells has shown that adult and pediatric cholesteatoma keratinocyte clusters demonstrate differential expression of 587 genes.

Conclusions: These results may explain some of the observed clinical differences between pediatric and adult chronic otitis media with cholesteatoma. Future studies will investigate the relationship of the signaling pathways and regulatory networks identified to cholesteatoma pathogenesis.

Professional Practice Gap & Educational Need: Molecular mechanisms underlying formation of cholesteatoma remain controversial, and the increased aggressiveness of pediatric cholesteatomas is an incompletely understood phenomenon.

Learning Objective: Attendees will be able to describe the cellular and molecular complexity of cholesteatomas and recognize how transcriptional dysregulation may contribute to the clinical variability and pathogenesis of cholesteatoma.

Desired Result: We hope to improve our current understanding of the molecular mechanisms underlying the pathogenesis of cholesteatoma in the adult and pediatric populations, as well as how these may differ, which could allow for the successful identification of molecular targets for medical therapies.

Level of Evidence - III

Indicate IRB or IACUC: IRB #202302061, Washington University in St. Louis, originally approved on 02/15/23.

Does Mastoid and Epitympanic Obliteration with S53P4 Bioactive Glass Reduce Cholesteatoma Recidivism in Canal-Wall-Up Surgeries?
A Retrospective Clinical Study

Daniele Bernardeschi, MD, PhD; Hugo Delille, MD; Matteo Di Bari, MD; Olivier Sterkers, MD, PhD
Ghizlene Lahlou, MD, PhD; Lauranne Alciato, MD

Objective: The aim of this study was to compare two groups of patients who underwent canal-wall-up tympano-mastoidectomy with or without mastoid and epitympanic obliteration, to evaluate the rate of recidivism 5 years post-surgery

Study Design: Retrospective case-control study

Setting: Tertiary otologic referral center

Patients: The inclusion criteria were all patients who underwent a canal-wall-up tympano-mastoidectomy, either with or without obliteration using S53P4 bioactive glass between January 2003 and December 2019. Patients who underwent canal-wall-down tympano-mastoidectomy surgery, tympanoplasty without mastoidectomy, or those with incomplete data were excluded

Interventions: Cholesteatoma removal through canal-wall-up tympano-mastoydectomy

Main Outcome Measures: the rate of recidivism (recurrence and residual rates) 5 years post-surgery calculated using Kaplan-Maier analysis.
Results: A total of 174 procedures had been included: 73 in the non-obliteration group and 101 in the obliteration group. At five-years, the cholesteatoma recidivism rate was 19% in the non-obliteration group and 6% in the obliteration group ($p<0.01$). The overall cholesteatoma-free survival rate, calculated using the log-rank test for survival analysis (95% CI), was 83.0% (70.4% - 97.8%) in the obliteration group, compared to 54.4% (38.8% - 76.4%) in the non-obliteration group ($p<0.01$. The residual and recurrent cholesteatoma free survival rate (95% CI) was 98.7% (96.2% - 100%) and 84.1% (71.5% - 98.9%) in the obliteration group and 88.8% (78.7% - 100.0%) and 59.3% (42.9% - 82.0%) in the non-obliteration group. Difference on recurrence was significant.
Conclusions: Mastoid and epitympanic obliteration using S53P4 bioactive glass significantly reduces the recidivism of cholesteatoma in patients undergoing canal-wall-up tympano-mastoidectomy. Obliteration should be always considered when mastoidectomy is necessary for cholesteatoma removal.

Professional Practice Gap & Educational Need: Although mastoid and epitympanic obliteration has been proposed in cholesteatoma surgery for several years, its effect on reducing the risk of recurrent and residual cholesteatoma remains debated. This study aimed to clarify if obliteration is useful in canal-wall-up surgeries.

Learning Objective: Incorporating mastoid and epitympanic obliteration in the standard-of-care management of cholesteatoma

Desired Result: Reducing cholesteatoma recidivism in canal-wall-up surgeries

Level of Evidence - III

Indicate IRB or IACUC: Exempt

Meningitis and Temporal Bone Pathology – A Diagnostic Recommendation

Ava Karam, BS; Frank Rizzuto, BS; Isaac Erbele, MD; Julio Figueroa, MD
Rahul Mehta, MD; Moises A. Arriaga, MD, MBA

Objective: Evaluate the relationship between meningitis and radiologic temporal bone abnormalities by assessing the prevalence of concurrent mastoid abnormalities, tegmen defects, and lateral skull base encephaloceles in patients with meningitis.

Study Design: Cross-sectional study

Setting: Tertiary academic center

Patients: Patients with a history of meningitis who underwent radiographic imaging of the skull base between January 2015 and April 2024.

Interventions: Comprehensive review of radiologic imaging in patients with a history of meningitis.

Main Outcome Measures: Presence or absence mastoid abnormalities, tegmen defects, and lateral skull base encephaloceles on radiographic imaging.

Results: Among 2,570 patients with meningitis, 1,673 patients (68%) had cranial imaging to review. Middle ear and mastoid fluid or effusion were found in 291 individuals (17%). Additionally, tegmen dehiscence was identified in 35 patients (2%), 26 of whom also presented with concurrent mastoid abnormalities. Lastly, we identified 12 patients (1%) with lateral skull base encephaloceles.

Conclusions: At least 17% of patients with meningitis had imaging findings suggestive of otogenic meningitis. Based on our results, other results of high proportions of otologic causes, and recent descriptions of tegmen defects providing a pathway for otogenic meningitis, we recommend routine temporal bone CT in patients without an obvious cause for meningitis. This may identify occult mastoid pathology, tegmen defects, predisposing inner ear abnormalities, and encephaloceles. Otologic pathology is an important, common, treatable cause of meningitis which should be systemically considered.

Professional Practice Gap & Educational Need: There is a gap in recognizing otologic pathology as a cause of meningitis. Increasing clinician awareness and advocating for routine temporal bone CT scans in patients without obvious causes for meningitis may improve diagnostic accuracy and patient outcomes.

Learning Objective: Identify and recognize the significance of radiologic findings associated with otogenic meningitis and develop strategies for incorporating routine temporal bone imaging into clinical practice to improve diagnostic accuracy and patient outcomes.

Desired Result: To enhance clinician awareness of the association between otologic pathology and meningitis.

Level of Evidence – Level III

Indicate IRB or IACUC: LSUHSC 581

Retrospective Comparison of Hearing Preservation Outcomes following Robotic-Assisted and Manual Cochlear Implantation

Ilana Yellin, MD; Nathan Jacob, BS; Michael Seidman, MD; Ariel Brownlee, AuD

Objective: The purpose of this study is to compare low frequency hearing preservation (LFHP) in patients undergoing robotic assisted cochlear implantation (CI) to those undergoing manual CI.

Study Design: Retrospective review

Setting: Tertiary referral center

Patients: Adult CI patients with low frequency residual hearing defined as the low frequency pure tone average of 250Hz and 500Hz (LFPTA) ≤80dB.

Interventions: Patients underwent robotic-assisted or manual CI. All patients were implanted with lateral wall electrodes while the specific manufacturer was chosen by the patient in consultation with a qualified audiologist.

Main Outcome Measures: The main outcomes of interest were the change in low frequency pure tone average (ΔLFPTA) and the presence of LFHP, defined as ΔLFPTA ≤30, following robotic and manual CI.

Results: There were 76 robotic and 76 manual insertion CIs over a 28-month period. 19 robotic and 16 manual cases met the inclusion criteria for comparison of LFHP. The mean postoperative LFPTA was 86.97 dB and 86.09dB for robotic and manual insertion, respectively ($p = 0.4143$). The ΔLFPTA was not significantly different between the robotic and manual insertion groups (31.05dB robotic vs 27.19dB manual, $p=0.5137$). LFHP as defined by ΔLFPTA ≤30 was similar between groups (63.2% robotic vs 56.3% manual, $p=0.6777$).

Conclusions: There is no significant difference in LFHP between robotic and manual CI. Further studies are needed to fully evaluate the efficacy of each insertion method.

Professional Practice Gap & Educational Need: As the indications for CI have expanded to include patients with residual hearing, LFHP has become an area of increasing interest. LFHP outcomes with use of robotic-assisted insertion devices have not yet been well established.

Learning Objective: To understand the impact of robotic-assisted CI on hearing preservation outcomes as compared to manual CI.

Desired Result: Attendees will have a better understanding of the relationship between the use of robotic assistance during CI and post-operative hearing preservation outcomes.

Level of Evidence – Level III

Indicate IRB or IACUC: Exempt

A Within-Subject Comparison of Hearing Preservation Outcomes for Bilateral Cochlear Implant Recipients

Michael W. Canfarotta, MD; Ankita Patro, MD, MS; Aaron C. Moberly, MD; Marc L. Bennett, MD
Jourdan T. Holder, AuD, PhD; David S. Haynes, MD, MMHC; Elizabeth L. Perkins, MD

Objective: To compare hearing preservation outcomes between ears for bilateral cochlear implant (CI) recipients.

Study Design: Within-subject, retrospective cohort.

Setting: Tertiary referral center.

Patients: Adult CI recipients with preoperative residual acoustic hearing (low-frequency pure-tone average [LFPTA; 125, 250, and 500 Hz] ≤80 dB HL) in both ears.

Interventions: Bilateral cochlear implantation from 2012 to 2022.

Main Outcome Measures: Initial (1-month) and long-term (12-month) hearing preservation outcomes between ears were assessed by comparing the LFPTA shift of the first and second implanted ear.

Results: Among 68 bilateral CI recipients examined, the median age at first surgery and interval to second surgery was 64.0 and 1.2 years, respectively. At the 1-month postoperative interval, there was a positive correlation between LFPTA shift of the first and second implanted ear ($r = 0.28$, $p = 0.023$, $n = 68$), with 51 patients (75%) experiencing a similar LFPTA shift (≤20 dB) across ears. At the 12-month interval, there was no significant correlation between LFPTA shift of the first and second implanted ear ($r = -0.06$, $p = 0.688$, $n = 50$), with only 46% of patients experiencing a similar LFPTA shift across ears.

Conclusions: A majority of CI recipients experience similar initial hearing preservation between the first and second implanted ear. However, there is a greater degree of asymmetry in LFPTA shifts across ears by 12-months postoperatively, signifying that long-term hearing preservation in the first implanted ear is poorly predictive of long-term outcomes in the second ear. These findings could suggest distinct post-implantation inflammatory responses across ears within the same individual, likely in reaction to extrinsic factors such as surgical technique and electrode array position.

Professional Practice Gap & Educational Need: As indications for cochlear implantation continue to expand, CI candidates are more likely to present with residual low-frequency acoustic hearing in both ears. Despite this, there is limited data to counsel patients on the likelihood of initial and long-term loss of residual hearing when considering implantation in the second ear.

Learning Objective: (1) To understand variability in hearing preservation outcomes between the first and second implanted ear. (2) To describe possible mechanisms to explain the correlation between hearing preservation across ears acutely but not long-term.

Desired Result: At the conclusion of this presentation, providers should be able to better counsel patients on initial and long-term hearing preservation outcomes for the second implanted ear.

Level of Evidence – Level IV

Indicate IRB or IACUC: IRB #240876, Vanderbilt University

Speech Discrimination Outcomes in Patients with Perimodiolar vs Lateral Wall Cochlear Implant Arrays: A Systematic Review and Meta-Analysis

David Octeau, MD; Lacey Cantrell, MD; Molly Smeal, AuD; Mary Schleider, RN, MLIS
Samantha Anne, MD; Edward Doyle, MD; Mark Bassim, MD

Objective: Provide the first systematic review and meta-analysis of cochlear implant outcomes using either a perimodiolar or lateral wall electrode

Data Sources: Ovid Medline ALL®, Ovid Embase, and Wiley's Cochrane Central Register of Controlled Trials (searched 3/18/2024). A combination of indexing terms, keywords and brand names for cochlear implants were combined with electrode array concepts and speech or auditory outcomes. Truncation and adjacency operators were used to increase retrieval of all potentially relevant literature. No publication year or language filters were imposed on the search but letters, editorials, case reports, and conference abstract were removed.

Study selection: Inclusion criteria were adults >18 years of age, pre- and post- operative testing. Exclusion criteria included cochlear anatomic abnormalities, revision surgery, absence of pre- or post- operative testing, congenital malformation, prelingual never amplified individuals, meningitis, trauma and implantation with more than one array type

Data extraction: 2,219 studies were reviewed in accordance with the PRISMA workflow by two independent reviewers. Conflicts were resolved through discussion. Risk of bias was assessed using ROBINS-I. 18 studies were extracted for analysis. Pre- and post-operative CNC, AzBio and all other relevant testing outcomes were obtained. Standard mean differences (SMD) were calculated and meta-analysis was performed on CNC and AzBio scores to determine the weighted pooled standard mean difference using the random-effect model. Summary effect and heterogeneity were also reported.

Data synthesis: Nine studies of moderate to low risk of bias reported CNC results. Four studies reported statistically significant superiority of the perimodiolar array with the largest mean difference between groups of 14%. Meta-analysis revealed a pooled SMD of -0.23 [-0.45; -0.01] ($p = 0.04$), suggesting a statistically significant greater CNC scores in patients implanted with a perimodiolar array with a small effect size. No studies out of 6 available reported a statistically significant difference in AzBio scores. The pooled SMD -0.03[-0.36; 0.30] ($p = 0.81$) suggests no statistically significant difference in AzBio post-implantation scores between patients implanted with LW vs PM arrays.

Conclusions: Perimodiolar arrays seem to provide a slight advantage in word understanding but not in sentence recognition over LW arrays. The clinical significance of this advantage appears limited.

Professional Practice Gap & Educational Need: There is significant heterogeneity in the results of studies comparing the post-operative outcomes of patients implanted with a perimodiolar electrode to those implanted with a lateral wall array. This study aims to review the current literature and pool results to provide an up-to-date understanding of this topic

Learning Objective: Understanding the array features that result in improved speech recognition post-implantation

Desired Result: Improved, evidence-based electrode selection for cochlear implantation

Level of Evidence - III

Indicate IRB or IACUC: Exempt

Cochlear Implant Insertion Trauma is Associated with Spiral Ganglion Neuron "Dead Zones" in the Human

Christopher K. Giardina, MD, PhD; Anbuselvan Dharmarajan, MD, MPH
Julie G. Arenberg, PhD; Alicia M. Quesnel, MD

Hypothesis: Significant Cochlear Implant (CI) insertion trauma, as evidenced by fracture of the osseous spiral lamina (OSL), is associated with localized "dead zones" and focal spiral ganglion neuron (SGN) loss.

Background: Hearing and structure preservation approaches to CI insertion aim to minimize trauma and preserve residual SGNs. In cases of significant insertion trauma, peripheral axons running through the bony OSL inherently become damaged if the OSL is fractured. The current investigation sought to determine if the relative location of OSL fracture was associated with focal areas of SGN loss.

Methods: Six adult ears from the Mass Eye and Ear Otopathology Laboratory were identified with OSL fractures. Digitized e-Slides were used to create 3D cochlear reconstructions, and a coordinate system relative to the round window allowed for angular assignment of SGNs and OSL fracture locations. Abrupt changes in SGN density, defined as a drop >50% within a single 30 degree angular step, were used as criteria for a significant and focal SGN loss.

Results: SGN counts ranged from 10,440 to 26,660 SGNs. Abrupt and focal drops of >50% in SGN density occurred in 5 of 6 temporal bones with OSL fracture. In two cases the only areas of localized "dead zones" were immediately adjacent the OSL fracture site, whereas in other cases drops were seen in as many as three distinct locations along the cochlear length.

Conclusion: In temporal bones from CI patients, the angular location of OSL fracture explains some (but not all) of the SGN drops seen in traumatic CI insertions. Distinct regions of SGN density were observed across the length of these cochleae, indicating multiple processes likely contribute to SGN dead zones.

Professional Practice Gap & Educational Need: A longstanding assumption is that hearing preservation techniques and atraumatic CI electrode insertions afford superior hearing outcomes, though the specific histopathologic evidence to support specific causes of trauma, such as OSL fracture, are limited. A goal is to share and educate evidence of physiologic "dead zones" with relation to OSL fractures as well as other forms of insertion-related trauma.

Learning Objective: Reinforce the evidence that OSL fractures cause focal SGN loss and introduce the evidence of focal SGN loss from insertion trauma other than OSL fracture.

Desired Result: CI surgeons continue to learn the specific mechanisms of SGN loss with respect to various mechanisms of traumatic CI insertions.

Level of Evidence – Level III (Case-Control)

IRB – 2021P001593

Postoperative Outcomes with Bimodal Hearing and Bilateral Cochlear Implantation in the Elderly

William G. Cohen, MD; Ankita Patro, MD, MS; Michael W. Canfarotta, MD; Natalie Schauwecker, MD
Jourdan Holder, AuD, PhD; David S. Haynes, MD; Elizabeth L. Perkins, MD

Objective: To evaluate speech recognition and quality of life in elderly patients with bimodal hearing versus sequential bilateral cochlear implantation.

Study Design: Retrospective cohort.

Setting: Tertiary referral center.

Patients: 265 adults who were at least 65-years-old, had preoperative AzBio scores in quiet $\leq$60% bilaterally, and received a cochlear implant (CI) between 2012-2021.

Interventions: Bimodal hearing versus sequential bilateral cochlear implantation

Main Outcome Measures: CNC; AzBio sentences in quiet and noise (+5 SNR); Speech, Spatial, and Qualities (SSQ).

Results: Bimodal (n=227) and bilateral CI (n=38) recipients had similar durations of deafness, preoperative SSQ score, and preoperative CNC and AzBio in quiet and noise scores in both ears ($p>0.05$). Bimodal users were older (76.2 vs. 73.4 years, $p=0.009$) and had lower preoperative PTAs in their better hearing ear (80.0 vs. 85.7 dB HL, $p=0.014$). At 6 months, no differences existed in device usage or SSQ scores, but bimodal users had significantly lower CNC (40.5% vs. 51.2%, $p=0.008$) and AzBio in quiet (48.3% vs. 61.5%, $p=0.017$) scores in their CI ear, compared to the initially implanted ear in bilateral CI patients. After their second implantation, bilateral CI patients had significantly higher AzBio in quiet scores than bimodal users at 6 (77.5% vs. 62.3%, $p=0.010$) and 12 months (80.8% vs. 70.9%, $p=0.041$) in everyday listening conditions. There were no significant differences in speech recognition or SSQ scores at 6 and 12 months between implantations in the bilateral CI group ($p>0.05$).

Conclusions: Among elderly patients, bilateral CI users appear to have superior speech recognition outcomes compared to those with a bimodal hearing configuration. Elderly patients perform similarly with their second implant as their first, highlighting that bilateral CIs can be beneficial in this population.

Professional Practice Gap & Educational Need: The benefits of bimodal hearing and bilateral cochlear implantation have been extensively reported in the pediatric population. Aggregate clinical data on how our elderly patients perform is lacking. This study compares postoperative outcomes in bimodal versus bilateral CI patients who are at least 65-years-old in order to answer this question.

Learning Objective: To understand differences in outcomes with bimodal hearing versus bilateral CI in the elderly population.

Desired Result: Providers will have knowledge about the impact of receiving two CIs on speech perception and quality of life outcomes among the elderly. These findings can help counsel patients and guide them in their care pathway.

Level of Evidence: Level IV – Historical cohort or case-controlled studies.

Indicate IRB or IACUC: IRB Exempt (240876, Vanderbilt University, approved 8/23/24).

Working Behaviors and the Risk of Sensorineural Hearing Loss: A Large Cohort Study

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Objective: This study aimed to investigate the association between working behaviors and sensorineural hearing loss (SNHL).

Study design: Cross-sectional and prospective study.

Setting: Biobank Study.

Patients: 90286 participants.

Intervention: A cross-sectional analysis was conducted (2006–2010, n=90286) to assess the association between working behaviors (including shift work, night shift work and physical work) and the occurrence (yes/no), laterality (unilateral/bilateral), and severity (mild/severe) of SNHL. Additionally, a prospective analysis was conducted to explore the association between new-onset SNHL and working behaviors (n=8[illegible]41). Multivariable logistic regression and Cox regression models were performed. Subgroup analyses were further carried out, stratified by age, sex, and chronotype. Furthermore, a polygenic risk score (PRS) was calculated to assess the influence of genetic susceptibility on the relationship.

Results: Cross-sectional analysis indicated that shift work, night shift work and physical work were all associated with an increased risk of SNHL (all p<0.05). Higher frequencies of these working behaviors were also associated with increased severity of SNHL (all p<0.05) and a higher likelihood of bilateral SNHL (all p<0.05). In prospective studies, the trends were generally consistent with the aforementioned results. Furthermore, the relationship between night shift work and SNHL was particularly pronounced among individuals with a morning chronotype (P-interaction=0.003), or with ≤ 5 years noisy work environment (P-interaction=0.012). Importantly, regardless of the level of genetic risk of PRS, there remained a positive association between night shift work and physical work with SNHL.

Conclusions: Both cross-sectional and prospective analysis indicated that shift work, night shift work, and physical work were associated with increased risk of occurrence, laterality and severity of SNHL, regardless of PRS for SHNL.

Learning Objective: To investigate the association between working behaviors and sensorineural hearing loss (SNHL).

Desired Result: Enhance the understanding and educate medical professionals about the impact of shift work and physical work as potential risk factors contributing to SNHL.

Level of Evidence: LEVEL IV
Indicate IRB or IACUC: National Health Service National Research Ethics Service (ref. 21/NW/0157).

GLP1 Agonist Treatment in Metabolic Syndrome Improves Hearing Outcomes
A Multi-National Database Study

Emily Belding, BA, MMS; Zachary D. Urdang, MD, PhD; Peter Eckard, BS
Marlan Hansen, MD; Douglas Bennion, MD, PhD; Alexander Claussen, MD

Objective: Test the hypothesis that GLP1 agonist treatment for patients with a formal metabolic syndrome diagnosis associates with improved hearing outcomes.

Study Design: Retrospective cohort database study.

Setting: TriNetX is a live HIPPA-compliant federated cloud electronic health record research network representing pooled data from 125-million patients from 95 healthcare organizations in the United States, Taiwan, Japan, Brazil, and India.

Patients: Subjects with metabolic syndrome with or without GLP-1 agonist treatment after diagnosis. Patients were matched using propensity score matching for medical comorbidities and ototoxic risk factors.

Interventions: GLP-1 agonist treatment.

Main Outcome Measures: Odds-ratios with 95% confidence intervals (OR, 95%CI) for SNHL, tinnitus, and cochlear implantation.

Results: There were 12,051 patients with metabolic syndrome treated with a GLP-1 agonist that were 1:1 propensity score matched to patients without GLP-1 agonist exposure. The average age was 56 years old, with 65% female patients. The risk for SNHL was 3.64% compared to 6.78% in controls (OR: 0.52, 0.46-0.59). The risk for tinnitus was 1.71% versus 2.60% in controls (OR 0.65, 0.54-0.78). There were not enough patients receiving cochlear implants in either group for statistical analysis.

Conclusions: GLP-1 agonist treatment associates with decreased odds for poor hearing outcomes in a high-risk group of patients matched with clinically similar controls. These potential benefits could be an inadvertent benefit for this popular medication and could be related to weight loss.

Professional Practice Gap & Educational Need: GLP-1 agonists are a popular new weight loss medication that associates with a number of health benefits. We aim to investigate GLP-1 agonist effects on the auditory system if any.

Learning Objectives: Understand the protective association of GLP-1 agonist treatment against hearing loss and tinnitus in high risk patients with a formal metabolic syndrome diagnosis.

Desired Result: Motivate future clinical trials on the topic of GLP-1 agonist treatment and the auditory system.

Level of Evidence – Level III

Indicate IRB or IACUC: Exempt

Enhancing Early Detection: Evaluating Targeted Screening for Congenital Cytomegalovirus in Newborns

Peter Kfoury, MD; Megna D. Reddy, BS; Albert H. Park, MD

Objective: Update our expanded targeted screening program for congenital cytomegalovirus (cCMV) detection among newborns born in Utah.

Study Design: Retrospective Cohort Study identified prospectively.

Setting: Tertiary Referral Center.

Patients: Infants from Intermountain Health Care (IHC) facilities, born between September 1, 2022, and August 31, 2024, tested for CMV within 6 months of birth.

Interventions: Expanded targeted screening program for cCMV.

Main Outcome Measures: Prevalence of cCMV; Clinical Characteristics of cCMV-positive infants; Effectiveness of our expanded targeted screening program compared to other screening programs.

Results: Between September 1, 2022, and August 31, 2024, 5282 newborns (9.7%) underwent CMV testing within six months of age out of 54,283 births across 27 Intermountain Health Care (IHC) facilities. The overall positivity rate was 0.4%. Within two years, the expanded targeted screening program detected 22 confirmed cCMV cases, 18 (81.8%) were identified through urine PCR, 3 (13.6%) via dry blood spot (DBS) after 21 days, and 1 (4.5%) through saliva PCR confirmed by urine PCR. Of the infants diagnosed with cCMV, 50% were classified as small for gestational age (SGA), 45.5% exhibited hyperbilirubinemia, and 31.8% had thrombocytopenia. Six (27.2%) of the 22 cCMV-positive children failed their NBHS. If a hearing-targeted CMV testing approach was utilized, the estimated prevalence would have been 11 cases per 100,000 births. In contrast, the expanded targeted screening program estimated a prevalence of 39 symptomatic cCMV cases per 100,000 births and 41 total cCMV cases per 100,000. Of the 22 children with cCMV, 5 developed sensorineural hearing loss (SNHL). Among them, 3 had asymmetrical hearing loss, 1 experienced single-sided deafness, and 1 developed symmetrical hearing loss. The child with symmetrical hearing loss had profound bilateral hearing loss. In total, 4 out of 10 affected ears exhibited profound SNHL. To date, only one child has received bilateral cochlear implants, while three others use hearing aids.

Conclusions: This expanded targeted screening program identified a higher prevalence of symptomatic cCMV than universal screening estimates (30 per 100,000 births). While universal cCMV screening programs offer comprehensive detection, the cost may be prohibitive.

Professional Practice Gap & Educational Need: Despite advances in early cCMV testing, many institutions do not screen or test for cCMV. We present an approach for early cCMV testing that is feasible and effective in identifying those with more severe infection. These children are more likely to receive earlier access to sound and antiviral treatment to improve neurocognitive outcomes.

Learning Objective: Participants will be equipped to identify clinical indicators of cCMV infection that can be implemented into their clinical practice.

Desired Result: The desired result is to encourage healthcare providers' ability to test for cCMV infection.
Level of Evidence – IV

Indicate IRB or IACUC: Institutional Review Board approval from IHC was obtained (IRB# 107443).

Clinical Development of AK-OTOF Gene Therapy for *OTOF*-Mediated Hearing Loss

Marlan R. Hansen, MD; Chen-Chi Wu, MD; John A. Germiller, MD, PhD

Objective: Assess the safety, tolerability, and bioactivity of AK-OTOF in individuals with Profound hearing loss due to *OTOF* mutations

Study Design: Phase 1/2 clinical trial

Setting: Multi-institutional

Patients: Participants in the AK-OTOF-101 Clinical Trial have Profound hearing loss as assessed by auditory brainstem response (ABR) at baseline and confirmed mutations in the otoferlin gene (*OTOF).*

Interventions: Transcanal intracochlear administration of AK-OTOF (AAVAnc80-hOTOF), an investigational dual adeno-associated viral vector encoding full-length human otoferlin

Main Outcome Measures: The primary outcome measure is safety, and secondary outcomes include ABR and behavioral audiometry.

Results: The first participant, an 11-year-old with Profound congenital hearing loss, experienced restored hearing within 30 days of AK-OTOF administration, achieving behavioral thresholds of 65 to 20 dB HL. The second participant, an 8-year-old, also experienced restored hearing within 30 days of AK-OTOF administration. The surgical administration procedure and the product candidate were well tolerated, and no serious adverse events occurred as of the date of this report. Updated safety and efficacy data from these and additional participants from Dose Cohort 1 will be presented.

Conclusions: Interim data suggest that AK-OTOF may be safely administered to patients with onset of restoration of hearing as early as one month following administration.

Professional Practice Gap & Educational Need: Gene therapy is an emerging modality currently under investigation for otologic indications. Otologists need information regarding the status of clinical trials.

Learning Objective: - Understand the eligibility criteria for the AK-OTOF-101 Clinical Trial
Describe initial outcomes from the AK-OTOF-101 Clinical Trial

Desired Result: To understand the status of, and appropriate patient selection for referral to, gene therapy clinical trials for hearing loss.

Level of Evidence: Level II

Indicate IRB or IACUC: Children's Hospital of Philadelphia – IRB 22-019935. University of Iowa – IRB 1349813. National Taiwan University Hospital – 202208005MSD.

A Novel Transcanal Catheter for Delivery of Hypothermia to the Inner Ear

Maria F. Yepes, MD; Pavan S. Krishnan, MD; Aparna Govindan, MD; Curtis King, MS
Simon I. Angeli, MD; Suhrud M. Rajguru, PhD

Objective: Mild therapeutic hypothermia (MTH) has been shown to have neuroprotective effects in the cochlea, particularly against injuries such as electrode insertion trauma and noise-induced hearing loss by modulating pathways that reduce interleukin, oxygen-based free radicals, and inflammation. It has been postulated that MTH has neuroprotective effects in the vestibular system. Thus, our objective is to investigate the potential for inducing temperature decreases in the cochlea and vestibular endorgans through the application of a custom-designed cooling device placed in the ear canal.

Study Design: Cadaver study

Setting: Tertiary Laboratory

Patients: NA (Cadaver heads)

Interventions: We performed a mastoidectomy, facial recess approach, labyrinthectomy, and stapedotomy to access the auditory and vestibular endorgans. To record temperature, we placed thermistors through the round window into the cochlea, all three semicircular canals, near the otolith organs, and the scalp of each head. Cadaver heads were pre-warmed to 35.5-38°C to simulate human body conditions. Once stabilized, a cooling device with a saline-filled catheter and balloon tip, connected to a cooling machine, was positioned in the ear canal near the eardrum.

Main Outcome Measures: Temperature changes (recorded every 1 minute) in the inner ear organs, ear canal, and scalp

Results: Thermistors inserted through the round window demonstrated a mean temperature decrease of 2.5-3°C during a 30-minute cooling period when the cooling device was set to 3°C. Baseline cochlear temperatures were fully restored within 15 minutes after the device was removed. Thermistors in the semicircular canals demonstrated a mean temperature decrease of 1-1.5°C during a 45-minute cooling period when the cooling device was set to 3°C. Thermistors placed on the scalp recorded no temperature fluctuations throughout the experiments. Importantly, no morphological changes were observed in the ear canals or eardrums of any specimens during the trials.

Conclusions: Our results demonstrate that cochlear and vestibular hypothermia can be effectively achieved using an external cooling system positioned at the ear canal. These findings provide strong evidence for adopting a more accessible and simplified clinical approach to mitigate potential inner ear damage during invasive procedures.

Professional Practice Gap & Educational Need: It is hypothesized that hypothermia may have a similar neuroprotective effect as it does in the auditory system due to the vestibular system's proximity to the cochlea, shared embryological origin, and comparable molecular physiology. Our objective is to address the existing gap by developing a non-invasive, localized system capable of inducing MTH in both the cochlear and vestibular systems, without obstructing the surgeon's view, while ensuring stability, reproducibility, and rigorous application.

Learning Objective: Attendees will understand the current state of the literature regarding therapeutic hypothermia applied to the inner ear and learn about non-invasive methods for delivery of hypothermia to the audiovestibular organs.

Desired Result: Attendees will understand the potential of mild therapeutic hypothermia as a therapeutic neuroprotective approach as applied to the inner ear. Our studies lay the groundwork for future implementation of hypothermia intraoperatively, and potentially in cases of inner ear diseases affecting the cochleovestibular nerve.

Level of Evidence – Level V

Indicate IRB or IACUC: Exempt

Risk Factors Associated with Otosclerosis: A National Database Study

Prithwijit Roychowdhury, MD; Miriam Smetak, MD; Matthew Shew, MD; Jacques Herzog, MD
Craig Buchman, MD; Nedim Durakovic, MD

Objective: To characterize the demographics of patients with otosclerosis (OS) in the US, identify the prevalence of autoimmune & viral risk factors and understand the association of osteogenesis imperfecta (OI).

Study Design: Retrospective cohort study

Setting: National database (TriNetX) sourced from 67 HCOs in the USA

Patients: Adults diagnosed with OS (ICD-10H80).

Interventions: Evaluation of age, gender, race, presence of autoimmune markers (RF, ANCA, SS-A/B, ds-DNA), measles serology and clinical diagnosis of OI in patients with OS.

Main Outcome Measures: 1) Mean age, gender, race 2) Positive autoimmune markers or measles serology 3) OI diagnosis

Results: 31,184 subjects with OS were identified. The majority were female (62.5%, n = 19,533) and white (70.1%, n = 22,100). Age at diagnosis was similar between females and males [F:52.2 ± 15.6 vs M:53.1 ± 15.5 (mean ± SD), $p < 0.0001$]. Subjects with OS were 34x more likely to have OI (0.257% vs 0.008%, $p < 0.0001$) and were about 2x as likely to be positive for at least one autoimmune laboratory marker (0.683% vs 0.304%, $p < 0.0001$) when compared to age-matched controls (n = 78,331,542). There was no difference in positive measles serology between OS and controls (0.087% vs 0.081%, $p = 0.7077$).

Conclusions: Age at OS diagnosis was similar between females and males. Patients with OS demonstrated significant association with OI & slight association with positive autoimmune serology but no association with positive measles serology. Findings have implications for the understanding of the etiopathogenesis of OS.

Professional Practice Gap & Educational Need: Prior studies have implicated genetics, viral and autoimmune factors to the development of OS. Herein we leverage a large national database of healthcare outcomes to better characterize these associations.

Learning Objective: 1) Demonstrate the impact of age & gender on cases of otosclerosis in the US 2) Describe the association between otosclerosis and osteogenesis imperfecta, measles, and positive autoimmune serology.

Desired Result: Attendees will appreciate the associations between osteogenesis imperfecta as well as positive autoimmune serologies on the diagnosis of otosclerosis.

Level of Evidence - IV

Indicate IRB or IACUC: Exempt

Evaluating the Necessity of Preoperative CT Imaging for Stapedectomy

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Rance Fujiwara, MD, MBA; Joni K. Doherty, MD, PhD
Hitomi Sakano, MD, PhD

Objective: Investigate the utility of preoperative computed tomography (CT) in patients undergoing middle ear surgery for presumed otosclerosis. To date, there is no uniformity in ordering preoperative imaging.

Study Design: Retrospective chart review.

Setting: Two independent tertiary referral centers.

Patients: 606 adult patients (689 ears) with a preoperative diagnosis of otosclerosis who underwent surgical intervention from 2007 to 2024.

Interventions: All patients underwent operative intervention for presumed otosclerosis, with or without CT.

Main Outcome Measures: The number needed to treat (NNT) to have prevented unnecessary surgery (i.e. non-otosclerosis etiology) was calculated among patients who had not undergone preoperative CT.

Results: Data were gathered from 689 ears in 606 patients, 59.6% were female, and average age was 49.9 (± 11.9). 33.4% (230/689) had preoperative CT. Of 689, non-otosclerosis finding was discovered intraoperatively in 32 (4.6%): 16 (50.0%) lateral chain fixation, 7 (21.8%) normal ossicular chain, 6 (18.8%) ossicular chain discontinuity, 2 (6.3%) overhanging facial nerves (1 with stapes fixation), and 1 (3.1%) tympanosclerosis. 16/32 (50.0%) had a preoperative CT with findings that would not have prevented middle ear exploration. Among those without preoperative CT, the unexpected finding rate was 16/459 (3.5%), thus, the minimum NNT with preop CT is 28. Since 11 of these patients still benefited from surgery, the NNT to have prevented unnecessary middle ear surgery is 41. Based on average Medicare costs for stapes surgery ($6491) and CT ($163), there was no cost benefit of blanket preoperative CT to prevent unnecessary surgery.

Conclusions: Preoperative CTs in identifying the cause of hearing loss in presumed otosclerosis is insufficient to justify their routine use in all patients and should be reserved based on clinical judgement.

Professional Practice Gap & Educational Need: Variability exists in the use of preoperative CT imaging for otosclerosis, both domestically and internationally. The aim of this study was to examine the potential for improved diagnostic accuracy and cost savings with routine imaging.

Learning Objective: To evaluate the diagnostic utility of preoperative CT in preventing unnecessary surgeries in stapedotomy patients.

Desired Result: Improved diagnostic protocols and reduced unnecessary procedures in otologic practice.

Level of Evidence - Level IV

Indicate IRB or IACUC: UT Southwestern Medical Center STU-2023-1105; Keck Medicine of USC UP-23-01212

Endoscopic vs. Microscopic Stapedotomy for Otosclerosis: An Updated Meta-Analysis of Complications

Hamzah Jehanzeb; Dahir Ashfaq; Zayan Alidina; Hamdan A. Pasha, MBBS
Syed A. Abbas, MBBS

Objective: To evaluate and compare intraoperative and postoperative complications of endoscopic versus microscopic stapedotomy in patients with otosclerosis.

Data Sources: PubMed, Cochrane Library, CINAHL, and Scopus databases were searched for studies from inception to August 2024 using terms such as "endoscopic," "microscopic," "otosclerosis," and "stapes surgery," with no language restrictions.

Study Selection: Studies were included if they compared surgical visibility and postoperative complications between endoscopic and microscopic stapedotomy for otosclerosis. Excluded were studies involving cholesteatomas or ossicular chain reconstructions.

Data Extraction: Data extraction followed PRISMA guidelines. Key variables extracted included demographics, surgical visibility, postoperative complications, study design, and follow-up duration. Meta-analysis was performed using random-effects models to assess the differences.

Data Synthesis: In this analysis, 39 studies involving 2,309 patients (35.9% males, 64.1% females) were included. The meta-analysis revealed that endoscopic surgery significantly reduced operative time (SMD: -0.92; $p=0.009$) and the risk of bone removal (RR: 0.40; $p=0.03$), chorda tympani injury (RR: 0.55; $p=0.02$), chorda tympani manipulation (RR: 0.26; $p<0.00001$), dysgeusia (RR: 0.43; $p<0.00001$), and pain (RR: 0.46; $p<0.0001$). However, no significant differences were found in visibility (RR: 4.04; $p=0.17$), risk of vertigo (RR: 1.00; $p=0.95$), or tympanic membrane damage (RR: 0.66; $p=0.28$).

Conclusions: Endoscopic stapedotomy significantly improves operative time and reduces chorda tympani injuries, dysgeusia, pain, and bone removal compared to microscopic techniques, though surgical visibility and tympanic membrane damage remain similar.

Professional Practice Gap & Educational Need: Despite the advantages identified, there remains a knowledge gap among otolaryngology practitioners regarding the efficacy of endoscopic techniques in stapedotomy. This review provides critical insights that can guide preoperative counseling and decision-making for patients undergoing surgery for otosclerosis.

Learning Objective: To understand the comparative benefits and risks associated with endoscopic versus microscopic stapedotomy techniques for otosclerosis, focusing on intraoperative and postoperative outcomes.

Desired Result: Enhanced surgical decision-making and improved patient outcomes through increased awareness and adoption of endoscopic techniques in stapedotomy procedures for otosclerosis.

Level of Evidence - Level I (systematic review and meta-analysis including large RCTs with clear cut results)

Indicate IRB or IACUC: Exempt (systematic review and meta-analysis)

Temporal Bone 3D Reconstruction and Analysis of Endolymph Volume in Meniere's Disease

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John L. Go, MD; Stephen S. Cai, MD; Ivan A. Lopez, PhD
Gail P. Ishiyama, MD; Akira Ishiyama, MD

Hypothesis: Vestibular endolymph volume (VEV) differs between Meniere's disease (MD) and age-matched controls.

Background: Magnetic resonance imaging (MRI) is used to diagnose endolymphatic hydrops (EH) and MD. Archival human temporal bones (HTB) can be used to establish reference VEV values and the VEV to bony volume of the vestibule (VES) ratio for correlation with MRI.

Methods: 3D reconstruction and volume analysis were performed on HTBs from 10 patients (5 MD, 5 age-matched controls). VEV includes the volume of the utricle, saccule, and vestibular cecum of the cochlear duct (CD). VES is the volume of the bony vestibule.

Results: VEV was significantly higher in MD (22.28 ± 2.27 mm^3 vs 9.66 ± 2.29 mm^3, $p < 0.01$). The VEV:VES ratio indicative of EH was significantly higher in MD (0.62 ± 0.15 vs 0.25 ± 0.04, $p < 0.01$). There was no difference in VES (37.05 ± 5.78 mm^3 vs 38.47 ± 5.84 mm^3, $p = 0.84$). Saccular (5.35 ± 6.39 mm^3 vs 1.78 ± 0.60 mm^3 vs, $p = 1$) and utricular volumes (9.81 ± 3.87 mm^3 vs 7.81 ± 2.03 mm^3, $p = 0.5476$) were heterogenous and not different between groups. Three MD saccules were collapsed or compressed (0.06, 1.20, and 1.94 mm^3) and two hydropic (8.32 and 15.24 mm^3). One MD utricle was hydropic (15.22 mm^3). The CD was significantly larger in MD (27.68 ± 12.21 mm^3 vs 4.25 ± 0.87 mm^3, $p < 0.01$).

Conclusions: The VEV and VEV:VES is significantly higher in MD, indicative of EH, and provides the first histopathological reference values comparable to MRI. All MD saccules exhibited either hydrops or collapse. One utricle exhibited hydrops. The CD was dilated in all MD specimens.

Professional Practice Gap & Educational Need: Volume measurements of both MD and age-matched controls are necessary to better define EH and improve MRI reliability for diagnosis of MD.

Learning Objective: To understand differences in VEV and VEV:VES values in MD and age-matched controls.

Desired Result: To quantify VEV and VEV:VES differences in MD and age-matched control to contribute to more definitive diagnostic tools for MD.

Level of Evidence – N/A (basic science)

Indicate IRB or IACUC: UCLA IRB #22-001587

Cochlear Signal Intensity Changes in Vestibular Schwannoma: A Balanced Fast Field-Echo (bFFE) MRI Study

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Objective: To evaluate the signal intensity of the cochlea in patients with vestibular schwannoma (VS) using balanced fast field-echo (bFFE) magnetic resonance imaging (MRI) sequences.

Study Design: Retrospective cohort study.

Setting: Tertiary academic center from 2008 to 2019.

Patients: A total of 165 VS patients and 30 patients with unilateral sensorineural hearing loss (SNHL).

Interventions: Patients were followed up with MRI and audiometry.

Main Outcome Measures: The mean signal intensity of the cochlea was assessed using regions of interest (ROIs) on bFFE MRI. The signal intensity ratio (affected/normal) was calculated and analyzed for its correlation with tumor size and hearing level. Postoperative changes in signal intensity were also evaluated.

Results: VS patients had significantly lower cochlear signal intensity on the affected side compared to the normal side (75.3% vs. 100%, $p<0.0001$). No significant difference was found in SNHL patients. A significant correlation between cochlear signal intensity ratio and hearing level was observed only in Koos grade I tumors. In contrast, tumor size was negatively correlated with the cochlear signal intensity ratio in Koos grade II–IV tumors. Postoperative evaluations demonstrated a gradual normalization of cochlear signal intensity, with levels approaching normal within 1–2 years post-surgery, regardless of hearing preservation status.

Conclusions: bFFE MRI sequences can effectively assess cochlear signal intensity in patients with VS. The reduced signal intensity in the affected cochlea likely indicates changes in protein concentration due to VS secretions. This method has potential for tumor evaluation, surgical planning, and postoperative monitoring in VS patients.

Professional Practice Gap & Educational Need: There is a gap in understanding hearing loss mechanisms in vestibular schwannoma (VS) patients, along with an underutilization of advanced MRI techniques for diagnosis and monitoring. Additionally, there is insufficient knowledge about the clinical applications of balanced fast field-echo (bFFE) MRI sequences in this context.

Learning Objective: Attendees will be able to explain the utility of bFFE MRI in evaluating cochlear changes in VS patients, understand the relationship between cochlear signal intensity, tumor size, and hearing function, and interpret post-surgical changes in cochlear signal intensity and their clinical significance.

Desired Result: Improved understanding of VS-related hearing loss pathophysiology and stimulation of research into advanced MRI techniques for assessing inner ear changes.

Level of Evidence – IV

Indicate IRB or IACUC: Kobe University Graduate School of Medicine Institutional Review Board (B230044)