

***2010 ABSTRACTS SELECTED FOR AOS SPRING MEETING***

***May 1-2, 2010***

***Las Vegas, NV***

**Characterization of the Electrically-Evoked Compound Action Potential  
of the Vestibular Nerve**

Kaibao Nie, PhD, Steven M. Bierer, PhD  
Leo Ling, PhD, Trey Oxford, BA  
James O. Phillips, PhD, Jay T. Rubinstein, MD, PhD

**Abstract:**

**Hypothesis:** It is possible to record electrically-evoked compound action potentials (ECAPs) in Rhesus monkeys implanted with a vestibular implant and such measures will correlate with the generation of nystagmus induced by electrical stimulation of the implanted semicircular canal.

**Background:** A number of vestibular disorders could potentially be treated with a vestibular implant. Surgical placement of implant electrodes may potentially be guided by electrophysiological measures.

**Methods:** Four Rhesus monkeys were implanted with a vestibular implant modified from the Nucleus Freedom™. ECAP recordings were obtained during surgery or at various intervals post-surgery. Eye movements during electrical stimulation of individual canals were recorded with a scleral coil system in the same animals.

**Results:** Measurable vestibular ECAPs were observed intra-operatively or postoperatively in three implanted animals. ECAP waveforms were monitored during surgery for two animals. Robust ECAPs were collected in two monkeys at the test intervals of 0, 7 or >100 days post surgery. Electrical stimulation in monkeys with normal vestibular ECAPs also produced measurable eye movements in a direction consistent with the VOR from the implanted semicircular canal. Electrically-evoked eye movements could not be measured in two of four canals without distinct vestibular ECAPs.

**Conclusions:** Monkey vestibular ECAPs exhibit similar morphology and growth to cochlear ECAPs from human cochlear implant patients. The ECAP measure is well correlated with the functional activation of eye movements by electrical stimulation postoperatively. The intra-operative ECAP recording technique provides a reliable and efficient tool to guide the placement of electrode leads to the proximity of vestibular neurons.

Supported by NIDCD and the Wallace Coulter Foundation  
IRB Approval: N.A.

Define Professional Practice Gap:

Vestibular  
Educational Need:  
Knowledge

Learning Objective:

Desired Result:

## **Pharmacokinetic and Toxicity Profile of the Clinical Candidate OTO-104 : a Sustained Release Dexamethasone Hydrogel for Inner Ear Delivery**

Xiaobo Wang, MD, Rayne Fernandez, BSc, Anne Harrop, BSc, Luis Dellamary, BSc  
Qiang Ye, PhD, Elizabeth M. Keithley, PhD, Jeffrey P. Harris, MD, Jay Lichter, PhD  
Carl LeBel, PhD, Fabrice Piu, PhD

**Hypothesis / Background:** In recent years, intratympanic drug delivery has been investigated as a route of administration to treat various otic disorders. While constituting a significant improvement in safety and efficacy over traditional systemic approaches, several issues still remain to be addressed: large differences in dosing schedules / regimen, high variability in clinical outcomes and patient acceptance. These disparities are primarily the result of the nature of the current formulations, namely drug solutions with short residence time and rapid elimination from the middle and inner ear.

**Methods:** OTO-104, a poloxamer-based hydrogel containing micronized dexamethasone (DEX) was developed. Poloxamers are tri-block co-polymers with mucoadhesive and thermoreversible properties that behave as sustained release drug delivery vehicles. OTO-104 was administered to guinea pigs intratympanically and its pharmacokinetic and toxicity profile was examined.

**Results:** Following a single intratympanic injection, significant and prolonged exposure to dexamethasone in the inner ear was observed. Increasing the concentration of dexamethasone resulted in higher drug levels as well as a more prolonged duration of exposure. At the maximally deliverable drug concentration, therapeutic levels of dexamethasone could be sustained over 3-month. The toxicological evaluation included assessment of auditory function and histological analyses (cochlear paraffin sections, cytochromeograms). A small and transient shift in hearing threshold was observed, most probably of conductive nature. No significant histological changes in the middle or the inner ear tissues were noted.

**Conclusions:** OTO-104 appears to provide a well-tolerated and controllable delivery system to achieve prolonged sustained release of dexamethasone at multiple concentrations within the inner ear.

IRB Approval:  
N/A

Define Professional Practice Gap:  
Treatment of inner ear disease - Meniere's disease

Educational Need:  
develop new treatment approaches  
Knowledge  
Competence  
Performance

Learning Objective:  
Implement novel strategies to treat inner ear disorders  
Desired Result:  
medical knowledge

Medical Knowledge  
Practice-Based Learning

## **Connexin 26-Associated Deafness: Association of a Single Common Allele with Progressive Hearing Loss**

Dylan K. Chan, MD, PhD; Iris Schrijver, MD; and Kay W. Chang, MD

**Objective:** To evaluate genotype-phenotype correlation over time among children with connexin 26 (GJB2)-associated autosomal recessive hearing loss.

**Study design:** Retrospective case review series

**Setting:** Outpatient tertiary referral center

**Patients:** Children with SNHL and pathologic mutations in GJB2

**Intervention:** Gene sequencing for mutations in GJB2 and longitudinal audiologic and otolaryngologic evaluation

**Main outcome measure(s):** Correlation of GJB2 genotype with severity and progression of hearing loss.

**Results:** Among 52 individuals with GJB2-associated deafness, hearing loss was most severe in those with two truncating mutations and mildest in those with two non-truncating mutations. Progressive hearing loss was noted by serial audiometry in 24% of all subjects, and 50% of patients passed a newborn hearing screen at least unilaterally. Among the 39 subjects with CT scans, only one abnormality was noted- an enlarged vestibular aqueduct. Carriers of the V371 allele, either in homozygosity or compound heterozygosity with a truncating allele, demonstrated a statistically significantly higher incidence of progressive hearing loss (39%) compared to subjects with non-V371 GJB2-associated hearing impairment (7%;  $p < 0.05$ ). These children are primarily of Asian descent, have normal CT scans, and demonstrate mild, slowly progressive hearing loss.

**Conclusions:** Phenotype in GJB2-associated hearing loss is correlated with genotype. Progression of hearing loss is common, especially in association with the V371 allele, which has a carrier frequency of up to 10% of some East Asian populations. These results highlight the importance of thorough genotype analysis in GJB2-associated recessive hearing loss, and indicate that close audiometric follow-up is warranted for these patients.

IRB Approval: N/A

**Define Professional Practice Gap:** Genetics- Lack of or inconsistent knowledge of the genetic influence of inner ear disorders.

**Educational Need:** Apply the genetics of inner ear disorders to approaches and recommendations for assessment and treatment

Knowledge

Competence

Performance

**Learning Objective:** To inform clinicians of the diversity of phenotypes seen in hearing loss associated with Connexin 26, and most common form of genetic deafness. To emphasize the importance of genotype analysis and serial audiometry in the diagnosis and management of patients with Connexin 26-associated hearing impairment.

**Desired Result:** We hope that our study will influence the diagnostic paradigm and management of Connexin 26-associated hearing impairment in order to better serve and inform this patient population.

Patient Care

Medical Knowledge

Practice-Based Learning

Interpersonal and Commun

System-Based Practice

## **Gamma Knife Surgery of Vestibular Schwannomas: Volumetric Dosimetry Correlations to Hearing Loss Suggest Stria Vascularis Devascularization as the Mechanism of Early Hearing Loss**

P. Ashley Wackym, M.D., Christina L. Runge-Samuels, Ph.D., John J. Nash, M.D.  
Maureen Hannley, Ph.D.; David M. Poetker, M.D., Katherine Albano, M.S., Joseph Bovi, M.D.  
Michelle A. Michel, M.D., David R. Friedland, M.D., Ph.D., Yong-Ran Zhu, M.D.

**Objective:** Determine which variables are correlated with the early hearing changes following gamma knife surgery of vestibular schwannomas (VSs).

**Study Design:** Prospective clinical study of hearing outcomes, radiation dosimetry, conformity and tumor size of all sporadic unilateral VS patients treated between June 2000 and July 2009.

**Setting:** Tertiary Referral Center.

**Patients:** 59 VS patients with at least six-months follow-up data were studied.

**Interventions:** Audiometry and imaging were performed to determine auditory thresholds, speech discrimination, and tumor size. Radiation doses to five volumes were measured.

**Main Outcomes Measures:** Pre- and post-treatment comparisons were performed with regard to: change in tumor size; radiation dose to specific volumes including the internal auditory canal, cochlea, basal turn of the cochlea, and modiolus; and conformity of the treatment.

**Results:** The mean follow-up was 63.76 months ( $\pm$  29.02 months S.D., range 9 to 109 months). The median follow-up was 65.5 months. A statistically significant association between maximum radiation dose to the cochlea volume and three-frequency pure-tone average (PTA3) in patients starting with  $\geq$  80 dB PTA3 was demonstrated using linear regression analysis.

**Conclusions:** Longitudinal changes in hearing occur over time with the largest changes seen in the first 12 months after treatment. Based on our study outcomes, limiting the dose of radiation to the cochlea would likely reduce vascular injury to the stria vascularis and improve hearing outcomes. Shielding the cochlea during the treatment planning process would be one mechanism to accomplish this goal.

**IRB Approval:** Yes; HRRC# 186-04, FMLH# 04-092

**Define Professional Practice Gap:** Lack of knowledge of the current standards of care in the treatment of acoustic neuromas.

**Educational Need:** Define the role of radiation therapy in treating acoustic tumors and understand expected hearing outcomes.

**Knowledge**

**Patient Outcomes**

**Learning Objective:** Gamma knife surgery of acoustic neuromas has unpredictable hearing outcomes and the use of practice-based learning can be used to understand the variables associated with hearing loss after treatment.

**Desired Result:** Practice-based learning after assessment of treatment outcomes will help shape treatment protocols to optimize hearing outcomes.

**Patient Care**

**Medical Knowledge**

**Practice-Based Learning**

## Predictors of Vestibular Schwannoma Growth and Clinical Implications

Yuri Agrawal, MD; Charles J. Limb, MD; John K. Niparko, MD  
Howard W. Francis, MD

**Objective:** Vestibular schwannomas exhibit variable and unpredictable patterns of growth. We evaluated the extent to which tumor growth influences the management of these benign tumors, and we explored symptom markers present at diagnosis that may be predictive of tumor growth.

**Study design:** Retrospective case review.

**Setting:** Tertiary care hospital center.

**Patients:** 180 patients with unilateral vestibular schwannomas diagnosed between 1997-2007 who were initially managed conservatively by serial observation.

**Intervention(s):** Serial observation versus eventual micro- or radio-surgical treatment.

**Main outcome measure(s):** Tumor growth, defined as a 1mm/year or greater increase in tumor size.

**Results:** We observed that tumor growth was the most important predictor of a change in treatment strategy from serial observation to micro- or radio-surgical treatment. We further noted in multivariate analyses that larger tumor size at diagnosis was associated with a higher odds of tumor growth, such that each 1mm increment in tumor size at presentation increased the odds of growth by 20%. We also found that the symptom marker of tinnitus at diagnosis significantly increased the odds of tumor growth nearly three-fold.

**Conclusions:** Tumor growth plays a significant role in guiding the management of vestibular schwannomas. Assessment of tumor size at diagnosis and for the presence of tinnitus may allow for the risk stratification of patients with newly-diagnosed vestibular schwannomas, and for a more rational application of the conservative management approach.

**IRB Approval:** This study was approved by the Johns Hopkins University Institutional Review Board.

**Define Professional Practice Gap:** Lack of knowledge of the current standards of care in the treatment of acoustic tumors.

**Educational Need:** Define the role of surgery and radiation therapy in treating acoustic tumors.

Knowledge  
Patient Outcomes

**Learning Objective:** 1) To evaluate the extent to which tumor growth influences the management of vestibular schwannomas; and 2) to explore symptom markers present at diagnosis that may be predictive of tumor growth.

**Desired Result:** Allow for the risk stratification of patients with newly-diagnosed vestibular schwannomas, and for a more rational application of the conservative management approach.

Patient Care  
Medical Knowledge:

## **Hearing Preservation in Retrosigmoid Approach for Small Vestibular Schwannoma: Prognostic of Internal Auditory Canal Filling**

Stéphane Tringali, MD, Chantal Ferber-Viart, MD, PhD, Carine Fuchsmann, MD  
Sandra Zaouche, MD, Christian Dubreuil, MD

**Objectives:** To assess the contribution of preoperative radiologic appearance of the small vestibular schwannoma (VS) on the MRI in constructive interference in steady-state sequences (CISS) and demonstrated if the degree of the filling of the internal auditory canal (IAC) is correlated with hearing preservation.

**Study Design:** Between January 1993 to December 2007, 1000 patients with a unilateral, sporadic, VS were admitted in our department. The study involved 278 candidates for hearing preservation attempt with MRI in CISS sequences.

**Mean Outcome Measures:** We devised in 4 groups on the MRI depending on the percentage of IAC filling as Group IAC 1 (IAC empty or full less than 25% and with free fundus), Group IAC 2 (IAC full than 25 to 50% with free fundus), Group IAC 3 (IAC full than 50 to 75% with free fundus) and Group IAC 4 (IAC full but some CSL was visible on the fundus).

**Results:** A good correlation was observed between the IAC classification and the rate of hearing preservation. There was a significant difference between the group IAC1, 2, 3 and the group 4 for the each stage in term of hearing preservation.

**Conclusion:** We provide an additional criterion to predict the rate of preserved hearing after vestibular schwannoma surgery and confirm the predictive value of factors, such as the aspect of the VS in the IAC on CISS sequences. In this case, surgery is the treatment of choice for patients with serviceable hearing and the desire to retain it.

Retrospective study.

Acoustic tumors.

To provide an additional criterion to predict the rate of preserved hearing after vestibular schwannoma surgery.

Patient Outcomes

To assess the contribution of preoperative radiologic appearance of the small vestibular schwannoma (VS) on the MRI in constructive interference in steady-state sequences (CISS) and demonstrated if the degree of the filling of the internal auditory canal (IAC) is correlated with hearing preservation.  
To provide an additional criterion to predict the rate of preserved hearing after vestibular schwannoma surgery.

Patient Care

## **Management of Solitary Vestibular Schwannomas : Observation, Surgery or Irradiation?**

Olivier Sterkers MD, PhD, Michel Kalamarides MD, PhD, Alexis Bozorg Grayeli MD, PhD, Mustapha Smail MD, Daniele Bernardeschi MD, PhD  
Evelyne Ferrary MD, PhD

Objective : To evaluate the management of sporadic vestibular schwannomas (VS on a 4 year period in a tertiary referral center)

Study design: Retrospective chart review.

Setting: Tertiary referral center

Patients: Two hundred and four patients were included in this study, who were first seen in the department during the year 2005 for the management of VS: 70 were intracanal VS, 77 small VS (stage 2, < 15 mm CPA), 42 middle sized VS (stage 3, >15 <30 mm in CPA), 15 large VS (>30 mm in CPA). Three therapeutic options (observation surgery and stereotactic radiotherapy) were proposed as a function of VS volume, hearing loss, age, general status, and willing of the informed patients. The patients were followed-up for 4 years period (2008).

Results: Initial treatment was observation in 121 VS (59,5%), surgery in 75 VS (37%), irradiation in 3 cases (1,5%). Five patients refused initial treatment (2%). In 2008, 48 VS (23,5%) were still observed (47% of stage 1 and 19,5% of stage 2), 107 VS operated on (52,5%), 17 VS irradiated (8,3 %) and 32 VS lost for follow-up (15,7%: 24% of stage 1, 17% of stage 2, 5% of stage 3). Change of therapeutic management was induced by growing of VS in more than 90% of cases.

Conclusion: During the 4 years period of survey, 60% of VS were actively treated

Observation was recommended for the initial period for most of intracanal or small VS although follow up should be difficult in such non aggressive tumors.

IRB Approval:

### **ACOUSTIC TUMORS**

Practice Gaps— Lack of knowledge of the current standards of care in the treatment of acoustic tumors.

Better understanding of evolution of patients with vestibular schwannoma

Knowledge  
Competence

Learning Objective: To show and analyze changement of therapeutic management during 4 years period.

Desired Result: to choose the best therapeutic option in patient with vestibular schwannoma

Patient Care, Medical Knowledge, Practice-Based Learning

## **Predictive Factors of Hearing Preservation Following Surgical Resection of Small Vestibular Schwannoma**

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Edgar T. De Peralta M.D.; Philip E. Stieg M.D., Ph.D.  
Samuel H. Selesnick M.D.

**Objective:** To identify factors predictive of hearing preservation in patients undergoing resection of vestibular schwannoma.

**Study Design:** Retrospective chart review.

**Setting:** Tertiary-care medical center.

**Patients:** 41 patients with serviceable hearing pre-operatively who underwent a potentially hearing sparing procedure for resection of small vestibular schwannoma (extending 1 cm or less into the cerebellopontine angle).

**Intervention:** All patients underwent resection of vestibular schwannoma via the middle fossa (subtemporal) or retrosigmoid (suboccipital) approach.

**Main Outcome Measures:** Hearing was assessed pre- and post-operatively and classified according to the criteria of the American Academy of Otolaryngology-Head and Neck Surgery. Post-operatively, audiograms were unavailable for 8 patients without subjective hearing in the affected ear. These patients are included in the group without hearing preservation. Potential predictive factors of hearing preservation were tumor size, laterality, depth of penetration into the internal auditory canal (IAC), surgical approach, pre-operative hearing status, and intraoperative brainstem auditory evoked response (BAER) monitoring.

**Results:** Serviceable hearing was preserved in 23 patients (56%). Tumor size, laterality, depth of penetration into the IAC, surgical approach, pre-operative hearing status, wave V latency, and wave V amplitude were not predictive of hearing preservation. The presence of wave V on intraoperative BAER was the only significant predictor of hearing preservation ( $p=0.013$ ). Serviceable hearing was preserved in 77.7% of patients with wave V present. Of note, serviceable hearing was also preserved in 39.1% of patients without a measurable wave V.

**Conclusions:** Presence of wave V on intraoperative BAER is a significant predictor of hearing preservation. Additionally, absence of wave V does not preclude preservation of serviceable hearing.

IRB Approval: 0907010508

**Define Professional Practice Gap:** There currently exists a lack of awareness of the factors predictive of hearing preservation following surgical resection of small vestibular schwannoma. In addition, the reliability, or lack thereof, of key brainstem auditory evoked response (BAER) data is not well appreciated.

**Educational Need:** Predictive factors of hearing preservation are important tools for clinicians in the counseling and treatment of patients.

Knowledge  
Competence  
Performance  
Patient Outcomes

**Learning Objective:** 1. To describe the significant predictors of hearing preservation following surgical resection of small vestibular schwannomas. 2. To describe the reliability of intraoperative brainstem auditory evoked response

(BAER) monitoring as a predictor of hearing preservation.

Desired Result: The desired result is that based on a more complete understanding of the factors that predict hearing preservation following surgical resection of small vestibular schwannoma, clinicians will make more informed decisions when counseling patients on prognosis and recommended treatment modalities. Additionally, a more complete understanding of the utility of brainstem auditory evoked response (BAER) will allow clinicians to make more informed decisions intraoperatively to improve patient outcomes.

Patient Care  
Medical Knowledge

## **Long-Term Hearing Preservation Following Microsurgical Excision of Vestibular Schwannoma**

Erika A Woodson MD, Ryan D Dempewolf MD, Samuel P Gubbels MD  
Marlan R Hansen MD, Bruce J Gantz MD

**Objective:** To examine long-term hearing outcomes following microsurgical excision of vestibular schwannoma (VS).

**Study design:** Retrospective case review.

**Setting:** Tertiary referral center.

**Patients:** Forty-six subjects at a single institution who had undergone microsurgical excision of VS via middle fossa craniotomy between 1994 and 2007 with immediate post-operative hearing preservation and for whom long-term audiograms were available.

**Intervention(s):** Diagnostic.

**Main outcome measure(s):** Word Recognition Score (WRS) as defined by speech discrimination (SD via W-22 recorded word lists) scores of > 70 % (Grade I), 50-70 % (Grade II), < 50% (Grade III), and 0% (Grade IV).

**Results:** In subjects with greater than five years of follow-up (range 5-14 yrs), 23 (82%) maintained the same WRS as one month post-operative. Three subjects experienced a > 20% decline in WRS. One of these subjects lost significant hearing in the contralateral ear as well. For subjects with 2-5 years of follow-up, 15/18 (83%) maintained the same WRS as immediately post-operative. One subject experienced a one-grade decline in WRS. For this individual, his latest SD was 68% bilaterally and therefore likely represented a symmetric, progressive sensorineural hearing loss (SNHL).

**Conclusions:** Most subjects maintain their initial post-operative SD after microsurgical VS removal, and therefore initial post-operative WRS are predictive of long-term hearing in most patients. Post-surgical changes do not alter the natural rate or pattern of progressive bilateral SNHL in individual subjects.

IRB Approval: 200908784

Define Professional Practice Gap:

ACOUSTIC TUMORS

Practice Gaps— Lack of knowledge of the current standards of care in the treatment of acoustic tumors.

Educational Need:

6) Define the role of surgery in treating acoustic tumors.

Patient Outcomes

Learning Objective:

Evaluate long-term hearing outcomes after microsurgery for vestibular schwannoma removal.

Desired Result:

Retained hearing with no degradation over time.

Practice-Based Learning

## Evaluation of a Customized Acoustical Stimulus System in the Treatment of Chronic Tinnitus

Jack J Wazen MD, Julie A Daugherty NP-C

**Objective:** The purpose of this study is to evaluate the efficacy of a customized acoustical stimulus (Neuromonics) system in the treatment of chronic tinnitus.

**Study Design:** Multi-institutional prospective

**Setting:** Nine US Tertiary Otological referral centers; ambulatory

**Patients:** Fifty-one (51) adults suffering from chronic tinnitus for a minimum of 6 months, with poor or no response to previous treatments, and on no concomitant therapies were enrolled to participate in the study.

**Interventions(s):** Following diagnostic measures and signing the IRB approved informed consent, patients were enrolled in the study. Treatment was delivered in 2 phases: phase 1 consisted of stimulation with patient customized musical tracks and white noise masking of the tinnitus for 2 months, 2-4 hours a day. Phase 2 consisted of listening to the same tracks, with no tinnitus masking for 4 months. Both phases included education, cognitive therapy and periodic follow up.

**Main outcome measures:** The response to treatment was measured through validated psychometric testing: the Tinnitus Reaction Questionnaire (TRQ) and the Tinnitus Handicap Inventory (THI). Other measures included the Hospital Anxiety Depression Scale (HADS), tinnitus awareness and disturbance scores and Loudness Discomfort Levels (LDL).

**Results:** Patients responses were recorded at 2,4,6,12 and 24 months after initiation of treatment. The TRQ was significantly reduced in 80% of patients at 6 months. The THI was reduced in 61% of patients as opposed to 42% in tinnitus retraining therapy and 21% in masking alone as reported in other studies. Scores continued to improve over time. Results at 12 and 24 months will be presented on patients who completed those measures.

**Conclusion:** The customized acoustical stimulus system offers a safe and effective means of tinnitus management as shown in this study and previously published clinical trials.

**IRB Approval:** Western IRB

**Define Professional Practice Gap:**  
Lack of definitive treatment for tinnitus

**Educational Need:** Present a novel treatment for the control of chronic tinnitus

Knowledge  
Competence  
Performance  
Patient Outcomes

**Learning Objective:** Describe the theory and results of a novel treatment for chronic tinnitus

**Desired Result:** Apply new technology in the treatment of chronic tinnitus

Patient Care  
Medical Knowledge  
Practice-Based Learning  
Interpersonal and Commun  
Professionalism  
System-Based Practice

## **Melatonin: Can It Stop the Ringing?**

Agnes Oplatek MD; D. Bradley Welling MD, PhD  
Edward E. Dodson MD; Claudia Dome AuD  
Kelly Wolfe BA; Abraham A. Jacob MD

**Objective:** To report the effectiveness of melatonin on chronic tinnitus and to determine if there is a subset of tinnitus patients that will benefit from melatonin therapy.

**Study Design:** Prospective, randomized, double-blind, crossover clinical trial.

**Setting:** Ambulatory setting in a tertiary referral center.

**Patients:** Adults with chronic tinnitus greater than 6 months in duration.

**Intervention:** Study subjects were randomized to 3 mg melatonin or placebo pills nightly for 30 days followed by a 1-month washout period. Each group then crossed into the opposite treatment arm for 30 days. Tinnitus Matching (TM), Tinnitus Severity Index (TSI), Self Rated Tinnitus (SRT), Pittsburgh Sleep Quality Index (PSQI), and Beck Depression Inventory (BDI) were administered every 30 days to assess the effects of each intervention.

**Main outcome measures:** Subjective and objective impact of melatonin on chronic tinnitus severity. Establish whether patient specific factors correlate with melatonin response.

**Results:** A total of 53 patients were enrolled. Following treatment with melatonin there was a significant decrease in TM, TSI, SRT, and PSQI scores ( $p < 0.05$ ). Placebo was associated with a significant decrease in TSI scores. The change in TM and SRT were statistically different between melatonin and placebo. Male gender, bilateral tinnitus, and absence of depression or anxiety were predictors of a positive response to melatonin. Patients with TSI scores  $\geq 28$ , SRT  $\geq 6$ , and PSQI  $\geq 5$  were more likely to have improvement in both tinnitus and sleep with melatonin ( $p < 0.05$ ).

**Conclusions:** Melatonin is associated with a decrease in tinnitus intensity and improved sleep quality in patients with chronic tinnitus. Melatonin's greatest effect is seen in patients who are males, who have no history of depression or anxiety, have more severe bilateral tinnitus, and are poor sleepers.

**IRB Approval:** 2006H0263 Define Professional Practice Gap: Currently there are no definitive treatment options for tinnitus, a common problem effecting over 40 million people in the United States.

**Educational Need:** To report the effectiveness of one modality for the management of chronic tinnitus and to determine which patients may benefit from it.

Knowledge

Patient Outcomes

**Learning Objective:** 1. To understand the effectiveness of melatonin on chronic tinnitus. 2. To learn which subset of patients with chronic tinnitus may benefit from melatonin therapy.

**Desired Result:** Improve understanding of management options for chronic tinnitus.

Patient Care

## Complications of Bone-Anchored Hearing Aids: the Arkansas Experience

Christopher E. Lee MD; John L. Dornhoffer MD  
Gresham T. Richter MD; Lisa V. Christensen AuD

**Objective:** The aim of this study was to determine what factors increase the likelihood of complications, specifically osseointegration failure and implant extrusion, with the use of bone-anchored hearing aids in children.

**Study Design:** This was a retrospective case review of 60 patients (42 pediatric and 18 adult patients).

**Setting:** Tertiary referral center; procedure performed as hospital outpatient surgery.

**Patients:** All children  $\leq$  19 years of age and all adults 34–69 years of age who received an osseointegrated implant for a bone-anchored hearing aid at Arkansas Children's Hospital from October 2003 to May 2009 or at the University of Arkansas for Medical Sciences from November 2005 to May 2009, respectively.

**Intervention:** Bone-anchored hearing aid placement.

**Main Outcome Measures:** Age, postoperative complications (osseointegration failure and adverse skin reactions), single versus two-stage procedures, medical history, skull thickness, and size of implant used.

**Results:** Fifty-seven loaded fixtures were placed in the pediatric population, and 20 were placed in the adults. We had a 21% pediatric and 0% adult osseointegration failure rate and a 16.67% pediatric and 5% adult adverse skin reaction rate.

**Conclusions:** Young age, syndromic status, and failure to penetrate the inner table of the skull increased the risk of osseointegration failures in children. Bicortical placement of the implanted screw may decrease the extrusion rate. Fixtures that were 3 mm through and through skull had a decreased extrusion rate compared to 3-mm fixtures that were surrounded by bone. Fixtures measuring 3-mm and 4-mm had similar outcomes overall.

IRB Approval: yes  
110362

**Define Professional Practice Gap:**

**Practice Gap:** Lack of knowledge and inconsistent awareness of complications related to the use of bone-anchored hearing aids.

**Educational Need:**

Understanding of individual patient factors that contribute to complications seen with the use of bone-anchored hearing aids, specifically osseointegration failures in the pediatric population.

**Knowledge**

**Patient Outcomes**

**Learning Objective:**

To understand and identify individual patient factors that contribute to complications of bone-anchored hearing aids specifically osseointegration failures.

**Desired Result:**

(1) Improved knowledge about modifiable factors that contribute to osseointegration failures in bone-anchored hearing aids.

(2) To minimize postoperative complications with the use of bone-anchored hearing aids.

**Patient Care**

**Medical Knowledge**

**Practice-Based Learning**

## Inner Ear Anomalies in Congenital Aural Atresia

Jeffrey T Vrabec MD, Jerry W Lin MD

**Objectives:** To define the prevalence of inner ear anomalies in aural atresia patients. To recognize patterns of developmental anomalies in aural atresia patients.

**Setting:** Retrospective review in an academic medical center.

**Patients:** Pediatric patients with aural atresia.

**Main outcome measure:** Prevalence of inner ear anomalies and coexisting facial paralysis or sensorineural hearing loss.

**Results:** In this series of 119 patients with aural atresia, associated facial palsy was seen in 12% while inner ear anomalies were present in 21%, including all patients with facial palsy. Interestingly, the inner ear anomalies often did not display a significant sensorineural hearing loss. Bilateral inner ear anomalies were frequently encountered despite unilateral atresia. A novel anomaly, the dilated posterior semicircular canal, is described in this series.

**Conclusion:** Inner ear anomalies are common in the presence of aural atresia, especially when there is concurrent congenital facial palsy. The presence of inner ear anomalies should be recognized as a common feature of craniofacial microsomia.

**IRB Approval:** Yes

**Define Professional Practice Gap:** Inconsistent awareness of the prevalence of inner ear anomalies in patients with aural atresia.

**Educational Need:** Apply appropriate diagnostic strategies for identification of inner ear anomalies. Recognize the adverse effect of an inner ear anomaly on hearing outcomes in atresia surgery.

**Knowledge**

**Patient Outcomes**

**Learning Objective:** To define the prevalence of inner ear anomalies in aural atresia patients.

**Desired Result:** Awareness of the prevalence of inner ear anomalies in patients with aural atresia and their impact on surgical management.

**Patient Care**

**Medical Knowledge**

**Practice-Based Learning**

## Revision Aural Atresia Surgery: Indications and Outcomes

Eric R. Oliver, MD, David C. Shonka, MD, Brian B. Hughley, MD  
Bradley W. Kesser, MD

**OBJECTIVE:** To determine the most common indications for revision atresia surgery and the postoperative healing and hearing outcomes.

**STUDY DESIGN:** Retrospective case review.

**SETTING:** Tertiary care academic otologic practice

**PATIENTS:** Patients undergoing revision surgery for congenital aural atresia.

**INTERVENTION:** Revision surgery for congenital aural atresia.

**MAIN OUTCOME MEASURES:** Indications for revision surgery; postoperative ear canal patency, incidence of infection/drainage, and speech reception thresholds.

**RESULTS:** 74 patients underwent 106 revision operations for aural atresia as follows: 47% for stenosis/new bone growth, 22% for infection/drainage, and 31% for hearing loss alone. Fifty-four patients (73%) required a single revision. Twenty patients (27%) required two or more revisions, including bilateral patients. With follow-up greater than 3 months, 63% achieved a patent canal (7 patients required more than one revision), and 76% achieved a dry canal (6 required more than one revision). The average postoperative SRT of 25 dB HL was a significant improvement from the average preoperative SRT of 33 dB HL ( $p < 0.01$ , paired t-test).

**CONCLUSIONS:** Revision aural atresia surgery is most commonly indicated for stenosis of the external auditory canal. Despite the challenges of revision surgery, significant improvement in canal patency, epithelialization, and hearing outcomes can be achieved.

IRB Approval: University of Virginia IRB #13090

Define Professional Practice Gap:

Practice Gaps-- Inconsistent awareness or ability to implement strategies for improving conductive hearing loss in patients with congenital aural atresia.

Educational Need:

- 1) Proper use of standard and novel strategies for improving conductive hearing losses.
- 2) Understanding and refining techniques to improve overall outcomes for patients with congenital aural atresia

Knowledge

Patient Outcomes

Learning Objective:

Participants will be able to identify the most common indications for revision surgery for aural atresia and understand surgical outcomes with respect to canal patency and hearing improvement.

Desired Result:

Improvement in healing and hearing outcomes in patients with aural atresia.  
Patient Care

Practice-Based Learning

## **Clinical Experience in Diagnosis and Management of Superior Semicircular Canal Dehiscence in Children**

Gi Soo Lee, M.D., Guangwei Zhou, M.D., Sc.D., Dennis Poe, M.D.,  
Margaret Kenna, M.D., Manali Amin, M.D., Laurie Ohlms, M.D., Quinton Gopen, M.D.  
Quinton Gopen, M.D.

**Objective:** To identify clinical characteristics of pediatric superior semicircular canal dehiscence (SSCD) and explore suitable options for medical management.

**Study Design:** Retrospective case review.

**Setting:** Tertiary referral center.

**Patients:** Ten pediatric patients with definitive symptomatic SSCD.

**Interventions:** Pediatric patients with suspicious audiologic or vestibular complaints were evaluated using high-resolution temporal bone CT scan. Those suspected with SSCD underwent electrophysiological evaluation, i.e., vestibular evoked myogenic potential (VEMP) testing, for confirmation, in addition to routine audiologic tests.

**Results:** All ten patients had some degree of either auditory or vestibular impairment, or both. Auditory symptoms included autophony, tinnitus, and hearing loss. The hearing loss was either conductive or mixed. Bone conduction responses were occasionally seen better than 0dB HL. Vestibular dysfunction included attacks of vertigo and chronic dysequilibrium. One patient underwent surgical repair for disabling vestibular symptoms and had dramatic improvement in both her auditory and vestibular symptoms after the surgery.

**Conclusion:** Different from adult patients, children with SSCD usually present with auditory symptoms first, such as hearing loss and autophony, although they share some similarities with adults in clinical manifestations of SSCD. Our study has shown that SSCD syndrome (Minor's syndrome), a well accepted clinical entity, does exist in the pediatric population. Conservative approach is preferred in managing children with SSCD, with surgical plugging of the dehiscent superior semicircular canal reserved for patients with disabling vestibular or auditory symptoms. To date, this is the first clinical case series of symptomatic pediatric patients with SSCD.

**IRB Approval:** Yes

**Define Professional Practice Gap:**

Vestibular  
Diagnostics

**Educational Need:**

To report on a case series of symptomatic patients with superior canal dehiscence which has not yet been presented in the pediatric population (To date has only been presented within adult patients).

Knowledge  
Competence  
Performance  
Patient Outcomes

**Learning Objective:**

Education about pediatric superior canal dehiscence

**Desired Result:**

Better understanding of the condition

**Patient Care**

Medical Knowledge

## **IL-8 Production in Response to TNF-alpha by Cholesteatoma Keratinocytes in Cell Culture**

Christopher W. Hilton MD, Frank G. Ondrey MD, PhD  
Beverly R. Wuertz BA, Samuel C. Levine MD

### **Hypothesis:**

Keratinocytes harvested from acquired cholesteatoma and grown in cell culture will demonstrate increased IL-8 production in response to TNF-alpha compared to a control keratinocyte cell line.

### **Background:**

Immunohistochemical studies have identified IL-8 and TNF-alpha, mediators of bony destruction, in tissue samples of cholesteatoma. TNF-alpha stimulates IL-8 production in healthy epidermal keratinocyte cell lines. It is not known whether TNF-alpha stimulates IL-8 production in cultured cholesteatoma keratinocytes (CK).

**Methods:** Tissue samples of acquired cholesteatoma were dissociated into a single cell suspension and grown in keratinocyte serum-free media for eight weeks. CK and a control cell line of skin epidermal keratinocytes (SEK) were treated with 0 pg/ml, 2 pg/ml, and 20 pg/ml of TNF-alpha. Conditioned media was harvested after 24 hours. Production of IL-8 was measured by ELISA and cell counts were performed.

### **Results:**

At a zero concentration of TNF-alpha, mean production of IL-8 by CK was 39,809 pg/ml/24hr/1x10<sup>6</sup> cells versus 1907 pg/ml/24hr/1x10<sup>6</sup> cells from SEK cells, a statistically significant difference (p value <.05). The CK showed a 2.1-fold increase in response to 2 pg/ml of TNF and a 2.44-fold increase in response to 20 pg/ml of TNF alpha. The SEK cell line demonstrated a 1.07 and 1.13-fold increase to respective concentrations of TNF alpha.

### **Conclusions:**

CK appear to retain cell signaling characteristics in vitro that distinguish them from SEK. This may indicate that CK undergo a change in behavior in vivo that is preserved after the cells are removed from the inflammatory environment of the middle ear.

### **IRB Approval:**

University of Minnesota IRB#: 0810E51942, approval 11/08

Define Professional Practice Gap: Basic Science: Cholesteatoma pathogenesis

Educational Need: Pathogenesis of cholesteatoma  
Knowledge

Learning Objective: 1) Understand factors that influence the destructive behavior of cholesteatoma 2) Learn about behaviors of cholesteatoma keratinocytes in cell culture which distinguish them from a healthy epidermal keratinocyte cell line.

Desired Result: 1) Improved knowledge of cholesteatoma pathogenesis. 2) Improved understanding of the cholesteatoma keratinocyte as a unique phenotype.

Medical Knowledge

## **Immunocytochemistry of the Spiral Ganglia Obtained from Microdissected Human Temporal Bones**

Ashley E. Balaker, M.D., Mia M. Miller, M.D., Gail Ishiyama, M.D.  
Ivan A. Lopez, Ph.D., Akira Ishiyama, M.D.

### **Hypothesis:**

To describe the immunolocalization of specific neuronal markers in order to identify human spiral ganglia neurons and fibers in microdissected vestibular end organs.

### **Background:**

The use of microdissected specimens has several advantages over the traditional celloidin embedded archival human temporal bone specimens. First, each vestibular nerve can be properly oriented and thin cross sections of the microdissected vestibular nerve can be made. Secondly, immunohistochemistry can be successfully applied to the microdissected specimens.

### **Methods:**

Frozen sections were used from vestibular end organs microdissected from human temporal bones. Tissue sections were incubated with antibodies against pan-neurofilaments, peripherin and superoxide dismutase-2, synaptophysin, and myelin basic protein. This allowed us to visualize the axoplasm of nerve fibers using antibodies against neurofilaments.

### **Results:**

These antibodies specifically identified neuronal somata and nerve terminals. Type I and type II spiral ganglia neurons were also identified.

### **Conclusions:**

The present combination of microdissection and immunohistochemistry can be used to investigate the total number and size of nerve fibers in vestibular end organs in a range of clinical conditions, including aging, gentamicin ototoxicity, Meniere's disease or other auditory and vestibular disorders. These techniques, once only possible in animal models, have the potential to open up a new field for future human temporal bone research.

Supported by NIH/NIDCD grants DC005028; 5U24 DC008635; DC05187  
IRB Approval:

Practice Gaps- Under-utilization of recommended diagnostic strategies in cochlear and vestibular disease

4) Applying appropriate diagnostic strategies to inner ear (cochlear and vestibular) disease.

### **Knowledge**

To understand the immunolocalization of specific neuronal markers in order to identify human spiral ganglia neurons and fibers in microdissected vestibular end organs.

To use the combination of microdissection and immunohistochemistry to investigate the total number and size of nerve fibers in vestibular end organs in a range of clinical conditions, including aging, gentamicin ototoxicity, Meniere's disease or other auditory and vestibular disorders

Medical Knowledge

## **Characteristics of Osteoblasts Cultured from Stapes of Patients with Otosclerosis after Exposure to Alendronate**

Yvonne L Richardson MD; Kourosh Parham MD PhD  
Jonathan J Romak BA; Marc D Eisen MD  
Michael S Aronow MD; Gloria A Gronowicz PhD

Hypothesis: Bisphosphonates alter the characteristics of cultured otosclerotic osteoblasts.

Background: The mechanisms by which bisphosphonates help in treatment of otosclerosis are unknown. In this study we assessed how the characteristics of in vitro osteoblast cultures grown from stapes removed during stapedectomies are altered with exposure to alendronate.

Methods: Cell cultures from stapes of four patients with otosclerosis were compared to cell cultures from healthy human peripheral bone fragments harvested during four orthopedic procedures of patients matched for age and sex. Specimens were cultured in DMEM-F-12 with 15% FBS and antibiotics. Once cells reached confluence, 10,000 cells/cm<sup>2</sup> were replated, and adhesion and proliferation assays were performed.

Results: For adhesion studies, cells were treated with and without alendronate (10<sup>-10</sup> - 10<sup>-8</sup>M) for 1 week, then trypsinized and replated at the same density. Cells were assayed after 4 hours of culture. Significantly more stapes osteoblasts (SO) (mean±SEM 22616±2455) attached to the plates than normal human osteoblasts (NHO) (12651±90; p < 0.005). SO counts decreased in the presence of alendronate (e.g., at 10<sup>-8</sup> M 12630±1874). For proliferation studies cells were treated with and without alendronate (10<sup>-10</sup> - 10<sup>-8</sup> M) for 2 days. At 72 hours of culture, tritiated thymidine uptake for the SO was lower than NHOs (2884±391 vs. 3935±513 dpm; p < 0.05) but in the presence of alendronate, SO uptake increased (e.g., at 10<sup>-8</sup> M 4061±701).

Conclusions: Alendronate has a “normalizing” effect on otosclerotic osteoblasts. These present in vitro findings support a role for the bisphosphonates in the treatment of otosclerosis.

IRB Approval:  
Yes-Exempt

Define Professional Practice Gap: MIDDLE EAR  
Practice Gaps-- Inconsistent awareness or ability to implement strategies for improving conductive hearing loss.

Educational Need:  
Pathogenesis of otosclerosis and effects of bisphosphonates in otosclerotic osteoblasts.

Knowledge

Learning Objective:

1. Understand potential role of osteoblasts in pathogenesis of otosclerosis.
2. Understand potential role bisphosphonates in treatment of otosclerosis.

Desired Result:

1. Increased knowledge in otosclerosis and a potential future treatment.

Medical Knowledge

## **Partially Implantable Bone Conducting Hearing Aids without a Percutaneous Abutment. Technique and Preliminary Clinical Results**

Prof. Dr. Ralf Siegert

**Introduction:** We have developed new partially implantable BCHA (Bone Conduction Hearing Aids) without a percutaneous abutment and have been using them clinically for four years. The principle of these BCHA is a magnetic coupling and acoustic transmission between implanted and external magnets. The goal of this study was to evaluate clinical and audiological results.

**Methods:** Magnets are implanted into shallow bone beds in a one step procedure. The skin above the magnets is also reduced to a thickness of 4-5 mm, which reduces the attenuation to less than 10 dB compared to direct bone stimulation.

**Patients:** Eighty-four patients have been implanted in the last 4 years. Their average age was 22 yrs (6 – 63), sensorineural hearing deficit  $16 \pm 10$  dB (5 – 43 dB) and air-bone-gap  $54 \pm 12$  dB (18 – 75 dB).

**Results:** Except for temporary pressure marks in 4%, which healed after careful shimming of the external base-plate, there were no other complications. The magnetic force chosen by the patients was  $2.0 \pm 0.5$  N. The average hearing gain was  $38 \pm 8$  dB and the suprathreshold word-recognition tests “(Freiburger”) increased significantly from 2% without to 77% with the BCHA at 65 dB.

**Discussion:** The holding strength of the external components is equivalent to partially implantable hearing aids and Cochlea implants and the hearing improvement is similar to other bone conducting hearing aids. We have found the comfort and safety of this system is significantly improved compared to conventional or percutaneous bone conducting hearing aids.

IRB Approval:

MIDDLE EAR

Practice Gaps-- Inconsistent awareness or ability to implement strategies for improving conductive hearing loss.

Educational Objective

1) Proper use of standard and novel strategies for improving conductive hearing losses.

Educational Need:

Educational Objective

1) Proper use of standard and novel strategies for improving conductive hearing losses.

Knowledge

Competence

Performance

Patient Outcomes

Learning Objective:

Learn about the new technique

Desired Result:

Understand the technique and its indication

Patient Care

Medical Knowledge

Practice-Based Learning

## Applications of Cone Beam CT in the Temporal Bone

Richard T. Penninger, MD; John P. Carey, MD; Tanya S. Tavassolie

Objective: To determine if cone-beam CT can better estimate the size of superior canal dehiscences (SCD) than multislice CT.

Study design: Retrospective review of CT and surgical data; Comparisons of multislice and cone-beam CTs on cadaveric specimens

Setting: Academic medical center

Patients: Patients with SCDS, aged  $46.3 \pm 11.22$

Interventions: diagnostic CT scans

Main outcome measure, Result and Conclusion:

The gold standard for diagnosis of superior canal dehiscence (SCD) has been multi-slice CT. However, partial volume averaging and filtering may confound the ability to detect thin bone next to low-radiodensity brain and inner ear fluids. We correlated radiographic and surgical findings in SCD to determine if multi-slice CT overestimated the size of SCD and if a threshold radiodensity could be defined, below which actual dehiscence could be predicted.

Dehiscence length and width measured from multi-slice CT were compared to measurements made at microsurgery. Differences between radiographic and actual length and width were both  $>0$  ( $p < 0.001$ , one-sample t-test), indicating that CT tends to overestimate the size of SCD. Receiver operating characteristic analysis found that a threshold of -375 Hounsfield units predicted actual dehiscence.

Cone Beam Volumetric Tomography (CBVT) has a smaller radiation dose (e.g., 5mA and 120kV) than multislice CT (MSCT, 250mA and 135kV), which allows CBVT to be deployed directly to outpatient offices. There is potentially better spatial resolution compared to MSCT when inherent tissue contrast is high. Data from cadaveric temporal bones scanned with CBVT and MSCT are compared. Results demonstrate better spatial resolution of CBVT for some structures.

This study qualified for exemption from an IRB protocol based on DHHS Criteria 45 CFR 46.101(b) (15). The determination that the study was exempt from a protocol requirement was made by the Joint Committee on Clinical Investigation of the Johns Hopkins University School of Medicine.

Practice Gaps- Under-utilization of recommended diagnostic strategies in cochlear and vestibular disease

Applying appropriate diagnostic strategies to inner ear (cochlear and vestibular) disease. Specifically, understanding the role of novel cone-beam CT technology in diagnosing inner ear disease.

Knowledge  
Competence  
Performance  
Patient Outcomes

Comparison between Multi Slice CT and Cone Beam CT  
Getting a non biased overview of the new CT devices on the market

Patient Care  
Medical Knowledge  
Practice-Based Learning

Interpersonal and Commun  
Professionalism  
System-Based Practice

## **Robotic Mastoidectomy**

Andrei Danilchenko, BS, Jenna L Toennies, MS, Ramya Balachandran, PhD  
Stephan Baron, PhD, Benjamin Munske, BS, Robert J Webster III, PhD  
Robert F Labadie, MD, PhD

**Hypothesis:** Using image-guided surgical techniques, we propose that an industrial robot can be programmed to safely, effectively, and efficiently perform a mastoidectomy.

**Background:** While a mature field with surgical applications in urologic, cardiothoracic and head and neck oncologic surgery, robots have yet to be clinically utilized in otologic surgery despite significant advantages including reliability and precise-repeatability.

**Methods:** We designed a robotic system that incorporates custom software to an industrial robot Mitsubishi RV-3S (Mitsubishi Electric & Electronics USA, Inc., Cypress, CA) to allow complex path implementation. The software controls the movements of the robot based on real-time feedback from commercially-available Spectra optical tracking system (NDI, Waterloo, Ontario) via the reference markers. We custom-built an end effector to hold a surgical drill. The desired path of the drill was contoured on clinically-applicable temporal bone CT scan using planning software and then exported to the robotic system. Bone-implanted fiducial markers were used to provide registration between CT and physical space.

**Results:** On 3 phantoms, we drilled the mastoid cavity before moving on to implementation on cadaveric skulls. 5mm fluted ball bits were used for drilling. Drilling was subjectively accurate without violation of any major landmarks (i.e. tegemen, external auditory canal, sigmoid sinus). Video of the robotic drilling will be presented.

**Conclusions:** To the best of our knowledge, this is the first time that a robot has been used to perform a mastoidectomy. While significant hurdles remain to translate this to clinical use, we have shown that it is feasible.

**Acknowledgement:** Funded by NIH/NIBIB-R21EB006044-01A1

**IRB Approval:** N/A

**Define Professional Practice Gap:** Knowledge about robots

**Educational Need:** Knowledge about robots

**Knowledge**

**Learning Objective:** Feasibility of performing robotic mastoidectomy

**Desired Result:** Robot performing mastoidectomy

**Medical Knowledge**

# The Effect of Ultrasonic Bone Removal on the Guinea Pig Facial Nerve

Stella Lee MD; Alexander Vortmeyer MD, PhD  
Elias Michaelides MD

**Hypothesis:** Ultrasonic bone dissection over the facial nerve can provide a safe alternative than the otologic drill based on functional and histological parameters.

**Background:** High-speed drills in otologic surgery may injure nerve structures through direct contact and production of high temperatures. Ultrasonic dissection may be able to provide a safer means of bone removal around the facial nerve due its emulsification of bone eliminating torque, skipping, and bone dust.

**Methods:** Phase I comprised the feasibility study on a cadaveric temporal bone model in which a complete mastoidectomy and facial nerve decompression was performed on 6 temporal bones using either the ultrasonic device or the drill. Average time required to perform the procedure was measured and signs of damage to critical structures evaluated. Phase II comprised the in-vivo study in which facial nerve decompression was performed on 6 guinea pigs. Facial nerve function was examined post-operatively and histologic evaluation performed.

**Results:** Average time required to perform a mastoidectomy was higher with the ultrasonic method, however there were decreased signs of damage to the facial nerve in the ultrasonic group. In the in-vivo study no significant difference was noted for facial nerve function between the two groups. There was however a decreased number of inflammatory cells in the ultrasonic group in comparison to the drill group.

**Conclusions:** Contact with the ultrasonic device produced a lesser degree of inflammation of the facial nerve than contact with the drill. Use of the ultrasonic device appears to be a safe alternative in temporal bone surgery.

IACUC Approval Protocol#: 2008-11246

Lack of awareness/knowledge of alternative methods and technology in otologic surgery.

Discuss mechanisms of potential facial nerve injury in otologic surgery and introduce ultrasonic dissection as a potential safe alternative to the otologic drill.

## Knowledge

(1) Evaluate mechanisms of potential facial nerve injury in otologic surgery.  
(2) Discuss how ultrasonic bone removal in comparison to the otologic drill affects facial nerve function and histology in a guinea pig model.

(1) Improved knowledge/awareness of the mechanisms of facial nerve injury.  
(2) Discussion of ultrasonic technology in temporal bone surgery which may provide a safe alternative to the otologic drill.

## Medical Knowledge

## Thermal Properties of Operative Otoendoscopes: An Ovine Model

David D. Pothier MBChB MSc FRCS, Samuel A. Mac Keith MBChB MRCS

### Hypothesis

The temperature change in tissues of the middle and inner ear caused by oto-endoscopes during surgery can cause thermal injury

### Background

Endoscopes are being used more commonly in the middle ear space to improve surgical access. Heat is produced by these endoscopes and the safety of this heat needs to be measured.

### Methods

Thermocouples were inserted into the middle ear at the promontory, the inner ear within the cochlea, and on the tympanic membrane. Endoscopes of varying diameters and angulations (0°, 30°, 70°) were sequentially inserted into the ovine ear canal to a distance of 5mm from the tympanic membrane and illuminated by a xenon light source for 20 minutes. Changes in temperature were recorded.

### Results

The change in temperature caused by the endoscopes was considerable. Temperatures increased rapidly upon introduction of the endoscope, and then continued to rise for the duration of the test. Temperatures of up to 50.1°C were recorded at the tympanic membrane and temperatures within the cochlea rose by up to 7°C. The angulation of the oto-endoscope did not correlate negatively with the amount of heat produced, as previously thought.

### Conclusions

This study has demonstrated that the thermal effect of otoendoscopes can be considerable and may result in damage to middle and inner ear structures. Active cooling of oto-endoscopes must be undertaken to avoid this potentially hazardous effect.

IRB Approval: None required

Define Professional Practice Gap:

Lack of knowledge of heat production of endoscopes

Educational Need:

To learn about the potential damage caused by otoendoscopes and how to reduce the risk of this damage

Knowledge

Competence

Learning Objective:

Desired Result:

Patient Care

## **A Self-adjusting Ossicular Prosthesis Containing Polyurethane Sponge**

Richard L. Goode, M.D., Hiroyuki Yamada, M.D.

**Hypothesis:** Middle ear ossicular replacement prostheses whose length can adjust in vivo to changes in middle ear dimensions following insertion may have acoustic advantages.

**Background:** Optimal tension is an important factor in the acoustic performance of incus-stapes replacement prostheses. Length is the primary determinant of post-insertion tension with conventional prostheses.

Post-operative changes in prosthesis tension may occur leading to a worsening of post-operative hearing.

**Methods:** We studied a self-adjusting prosthesis containing a 2 mm diameter, 2 mm thick polyurethane sponge attached to the head of a titanium PORP; length 4.25mm. We compared this prosthesis to optimal length PORPs in five human cadaveric temporal bones at different tensions. Sound input was 0.1 - 10 kHz at 80 db SPL. Stapes footplate displacement was measured using a laser Doppler vibrometer before and after incus removal and prosthesis insertion between the malleus and stapes head. We then inserted 1-3 glass shims between the malleus and the conventional and adjustable prostheses to change prosthesis tension. Measurement of stapes displacement was repeated with increased prosthesis lengths of 0.15, 0.30 and 0.45mm.

**Results:** After shim insertion, there was a clear tendency in the conventional PORP's for a decrease in footplate displacement below 1.0 kHz proportional to the increasing length and less so below 0.6 kHz with the self-adjusting prosthesis. The self-adjusting prosthesis provided equivalent transmission at baseline and better transmission below 1 kHz at varying lengths.

**Conclusion:** A self-adjusting prosthesis appears to have acoustic advantages in a temporal bone model at lower frequencies.

IRB Approval: None

Define Professional Practice Gap:

Lack of knowledge of self-adjusting middle ear replacement prostheses.

Educational Need:

Provide information on design and potential advantages of self-adjusting middle ear replacement prostheses.

Knowledge

Learning Objective:

Understand reasons for certain inadequate hearing results after middle ear surgery and how improved prosthesis design may improve results.

Desired Result:

Improved knowledge of potential role of self-adjusting middle ear replacement prostheses.

Medical Knowledge

## Minimally Invasive BAHA Surgery

Peter C. Weber MD

Objective: To develop a surgical procedure to place a BAHA that lessens complications and is more cosmetic.

Study Design: Retrospective review of a minimally invasive surgical approach of all BAHA patients over the last 2 years

Setting: Academic Tertiary Medical Center

Patients: All adult patients who received a BAHA implant, for any reason, over last two years.

Interventions: BAHA surgery which eliminates almost all of the current soft tissue removal and the use of the 8.5mm abutment.

Main Outcomes: Complications and Hearing Results

Results: No patient had problems with soft tissue overhanging the abutment, wound breakdown, or non osseous integration. Hearing results were as expected for BAHA

Conclusion: Minimally invasive surgical approach for BAHA offers a technique that minimizes complications and is the best from an aesthetic point of view; all without compromising hearing.

IRB Approval:

Define Professional Practice Gap: Inconsistent methodology of surgically placing the BAHA and the associated complications

Educational Need: Method of placing the BAHA to eliminate significant risks and patient complaints.

Knowledge  
Competence

Patient Outcomes

Learning Objective: To avoid complications associated with BAHA surgery  
To understand how the procedure is completed

Desired Result: Be able to surgical place a BAHA in minimal time with minimal complications along with great hearing results.

Patient Care  
Medical Knowledge  
Practice-Based Learning

System-Based Practice

## **Patterns of Failure in Heat-Activated-Crimping Prosthesis in Stapedectomy**

Yu-Lan Mary Ying, MD, Todd A. Hillman, MD, Douglas A. Chen, MD

Study Design: Retrospective longitudinal stapedectomy case series with controls.

Methods: Retrospective chart review of all primary and subsequent revision stapedectomy surgeries performed by the senior authors with heat-activated-crimping pistons between June 2003 to September 2009. Patients who had history of previous stapedectomy done elsewhere were excluded.

Results: A total of 192 primary stapedectomies using heat-activated crimping pistons were performed between this period. There were 24 patients who had initial good hearing results that required revision or replacement with a different type of prosthesis. A common finding was lateral displacement of the prosthesis from the stapedotomy with detachment of the nitinol hook from the incus. This group of patients was compared to a control group that utilized manual-crimp prosthesis.

Conclusions: Heat-activated-crimping prosthesis has been reported to enhance stapedectomy hearing outcomes on short and long-term follow-up studies. Longitudinal analysis on its complication has not been reported. This case series demonstrated a 12% rate of possible eventual loosening of the heat-activated crimp with apparent reopening of the nitinol hook off the incus and/or displaced out of vestibule/stapedotomy. Failure rates were classified. The advantages and disadvantages of this popular prosthesis were reviewed.

IRB Approval: Pending

Define Professional Practice Gap: Lack of awareness regarding patterns of failure in heat-activated-crimping prosthesis in stapedectomy.

Educational Need: Describe the pattern and incidence of failure with heat-activated-crimping prosthesis in stapedectomy.

Knowledge  
Competence  
Performance  
Patient Outcomes

Learning Objective: To understand potential causes of failure in heat-activated-crimping prosthesis in stapedectomy and utilize potential remedy.

Desired Result: same as Learning Objective

Practice-Based Learning

## Nitinol Stapes Prosthesis Improves Low-Frequency Hearing Results in Otosclerosis Surgery

Charles A Mangham Jr. MD, MS

**Objective:** To determine if nitinol shape-memory stapes prostheses offer a hearing result advantage compared to platinum-Teflon pistons that must be manually crimped.

**Study Design:** Retrospective chart review.

**Patients:** 160 consecutive patients with either a platinum-Teflon or a nitinol-Teflon piston and primary stapes surgery between 2000 and 2008

**Setting:** Subspecialty private practice.

**Intervention:** One hundred and twenty ears received a platinum-Teflon 0.6 mm diameter piston and 40 ears received a nitinol-Teflon 0.6 mm diameter piston.

**Main outcome measures:** AAO-HNS guidelines including four-frequency pure-tone average (PTA) air-bone (AB) gap, and success (gap  $\leq$  10 dB) rate.

**Results:** Success at closing the AB gap was significantly better for the nitinol group (100% versus 84%,  $p=0.021$ ). The nitinol group had significantly smaller mean AB gaps in the lower frequencies (at 250 Hz, 9.8 dB versus 16.8 dB; and, at 500 Hz, 0.8 dB versus 6.0 dB,  $p's < 0.01$ ), but not at 1, 2, or 4 kHz. The highly malleable platinum loop was adaptable to various incus diameters and was easy to crimp. The 360 degree circumferential version of the nitinol prosthesis may adapt to various incus diameters better than the original version (minimum heat-crimped diameter 0.70 mm versus 0.76 mm). In some cases, both nitinol versions were difficult to crimp using only a laser and a manual crimp was also required.

**Conclusions:** The nitinol-Teflon stapes prostheses failed to live up to claims of consistent ease of crimping; however, the significantly better low-frequency hearing results justify an effort to make the devices more user friendly.

The author has no financial interest in the prostheses described above.

IRB Approval: Chairman of the Swedish Hospital Medical Center IRB approved this study.

**Define Professional Practice Gap:** Recent publications suggest that nitinol prostheses may help inexperienced surgeons who have difficulty crimping conventional devices, but offer no better hearing outcome for patients of experienced surgeons.

**Educational Need:** Nitinol prostheses are difficult to crimp in some cases, even for an experienced surgeon; however, ultimately a more secure crimp can be achieved in most cases which correlates with better hearing improvement at 250 and 500 Hz compared to a conventional crimpable prosthesis.

### Knowledge Competence Performance Patient Outcomes

**Learning Objective:** Inexperienced stapes surgeons will regard nitinol prostheses as a new technology that may help them with crimping in some cases, but is not a replacement for experience. Experienced stapes surgeons may consider nitinol prostheses to improve hearing results at frequencies below 1 kHz.

**Desired Result:** Inexperienced stapes surgeons will not take on cases that they would otherwise refer out just because nitinol is offered as a cure for crimping problems. Experienced surgeons will consider a trial of using nitinol devices in a temporal bone lab setting to see if they are comfortable with using a laser for crimping.

Patient Care  
Medical Knowledge  
Practice-Based Learning

Professionalism

## Reliability of CT-Scan in the Prognosis of Otosclerosis

Sebastien Lagleyre MD; Mathieu Marx MD; Young-Je Shin MD  
Bernard Escudé MD; Olivier Deguine MD; Bernard Fraysse MD

### Objective:

To evaluate on the operated ear the risk of sensorineural hearing loss according to CT-scan locations of otosclerotic focus.

To evaluate on the non-operated ear the audiometric evolution at 3 years after surgery according to CT-scan findings.

Study design: Prospective study

Setting: Tertiary reference center

Patients: 200 patients (209 ears) presenting progressive conductive hearing loss with normal tympanic membrane, abnormal stapedial reflex and scheduled for stapes surgery.

Intervention: All patients underwent CT-scan before surgery. Stapedotomy was performed in 99% of cases.

Main outcome measures: CT-scan results were categorized as positive, doubtful or negative. Concerning the 200 opposite ears, we defined 3 groups from pure tone audiogram: normal hearing, pure sensorineural hearing loss and conductive component.

Results: Of 209 CT-scans of operated ears, 84% were classified positive, 9% doubtful and 7% negative. The sensitivity of CT-scan to otosclerosis was 95.1%. In the operated ears, the mean preoperative and postoperative bone conduction thresholds were significantly lower in cases of otosclerotic focus involving the endosteum ( $p < 0.005$  and  $p < 0.0001$  respectively). Among the 200 non-operated ears, 69 ears presented a normal hearing (34.5%), 51 ears a pure sensorineural hearing loss (25.5%) and 80 ears a conductive component (40%). Normal opposite ear (absence of otosclerotic focus on CT-scan with normal hearing), pure opposite cochlear otosclerosis (endosteal involvement with pure sensorineural hearing loss) and infraradiologic opposite form (negative CT-scan with conductive component) were found in respectively 27 (13.5%), 16 (8%) and 9 (4.5%) of the 200 patients.

### Conclusion:

Foci involving otic capsule, internal auditory canal or round window led to a significantly higher risk of sensorineural hearing loss after stapes surgery. 3 years hearing survey of the non-operated ears will be presented at the congress.

IRB Approval:

**Define Professional Practice Gap:** Middle ear diseases: otosclerosis

**Educational Need:** Middle ear surgery

**Learning Objective:** Evaluate on the operated ear the risk of sensorineural hearing loss according to CT-scan locations of otosclerotic focus.

Evaluate on the non-operated ear the audiometric evolution at 3 years after surgery according to CT-scan findings.

**Desired Result:** Confirm that otosclerotic endosteal involvement increase the risk of sensorineural hearing loss after stapes surgery.

Find, 3 years after surgery, a difference of evolution of hearing between normal hearing opposite ear with and without otosclerotic focus on CT-scan.

Compare the progression of hearing loss between non-operated ears with pure sensorineural hearing loss and with conductive component

## **The Incus in Ossicular Chain Reconstruction: Take it or Leave it?**

Samuel D. Turner MD, David P. Mullin MD, Xianxi Ge MD  
Travis J Pfannenstiel MD, Ronald L Jackson PhD, Jianzhong Liu MD  
Ben J Balough MD

**Hypothesis:** The presence or absence of the incus body is an important determinant of middle ear sound transmission in ears reconstructed with partial or total ossicular replacement prostheses (PORP or TORP).

**Background:** The incus is necessarily removed in many ear surgeries, and its removal impacts the vibratory motion of the malleus by dissociating the incudomalleal joint. Whether the absence of the incus body is favorable or unfavorable to middle ear reconstruction is unknown.

**Methods:** Six cadaveric human temporal bones were prepared by performing a mastoidectomy and facial recess approach. Incudostapedial joint discontinuity was created using a KTP laser with the long process of the incus being removed. Ossicular chain reconstruction (PORP or TORP) was performed. Measurements of round window membrane (RWM) response were taken using a Laser Doppler Vibrometer at frequencies from 250 - 8000 Hz with the incus body both present and removed.

**Results:** Pooled RWM velocity measurements for reconstructed middle ears with and without the incus in place were compared. A difference in RWM velocity was observed from 1000 to 4000 Hz, showing higher velocities with the incus body removed. In this frequency range the RWM velocity was  $0.0032 \pm 0.0010$  (mean  $\pm$  SD) mm/sec with incus present and was  $0.0056 \pm 0.0018$  mm/sec with incus removed ( $p < 0.05$ ).

**Conclusions:** With regard to placement of PORP or TORP prostheses, the presence or absence of the incus body impacts the transfer of sound energy. A statistically significant increase in RWM velocity was seen from 1000 to 4000 Hz when the incus was removed.

IRB Approval: Not required

Define Professional Practice Gap:  
Basic Science: Middle Ear Mechanics

Educational Need: Effect of incus removal during ossicular chain reconstruction on middle ear sound transmission

Knowledge

Learning Objective: 1) To better understand the role of the incus in middle ear reconstruction. 2) To learn how removal of the incus during middle ear reconstruction affects middle ear sound transmission during middle ear reconstruction

Desired Result: 1) To determine whether removal of the incus or leaving it in place results in greater sound transmission after middle ear ossicular chain reconstruction

Medical Knowledge

## Active Middle Ear Implant Application in Case of Stapes Fixation: A Temporal Bone Study

Kanthaiah Koka PhD; Arnaud Devèze MD; Stéphane Tringali MD.  
Herman A Jenkins MD; Daniel J. Tollin PhD

Hypothesis: Driving the oval window (OW) with an active middle ear implant (AMEI) can produce high levels of input to the inner ear.

Background: Treatment of otosclerosis bypasses the stapes with a piston that penetrates the vestibule. Although this treats the conductive component of hearing loss it does not treat the sensorineural. AMEIs have been proposed to treat otosclerosis-related conductive and sensorineural hearing losses.

Methods: Seven temporal bones were prepared to expose the stapes and round window (RW). Stapes and RW velocities were measured while driving with an AMEI the stapes head with a bell shaped tip. The stapes footplate was then fixed with glue; fixation was confirmed via attenuated RW velocities. A cylinder tip (0.5 mm) was then used to drive the inner ear through a stapedotomy (KTP laser) with and without interposition of fascia material.

Results: Driving the stapes with an AMEI produced mean maximum equivalent ear canal sound pressure levels of 138 dB SPL (0.25-8 kHz, 1 Vrms). Stapes fixation caused ~25 dB attenuation. Driving with a cylinder tip through the stapedotomy produced 14 and 21 dB less performance with and without fascia, respectively, compared to the normal condition. Performance with fascia was significantly greater than without.

Conclusions: Driving the OW with an AMEI in a scenario of stapes fixation was demonstrated to be feasible with performance comparable to traditional AMEI coupling to the incus or stapes. These possibilities offer new perspectives to treat mixed hearing loss in otosclerosis.

Support: Otologics LLC Education Grant.  
Use of temporal bone tissue was in compliance with the University of Colorado Denver Institutional Biosafety Committee.

### Middle Ear Mechanics

Proper use of standard and novel strategies for improving conductive and mixed hearing losses.

### Knowledge

Active Middle ear implants are nowadays available to treat conductive and mixed hearing loss. The aim of this study was to assess the efficiency of an active middle ear implant in a scenario of stapes fixation.

Driving the oval window with an active middle ear implant in a scenario of stapes fixation in temporal bone study was demonstrated to be feasible with performance comparable to traditional coupling to the incus or stapes. These possibilities offer new perspectives to treat mixed hearing loss in otosclerosis.

### Medical Knowledge

## Magnetic Resonance Imaging after Cochlear Implantation Using 1.5 Tesla Magnet

Benjamin T. Crane, MD, PhD; John K. Niparko, MD

**Objective:** To assess the safety of 1.5 Tesla (T) magnetic resonance imaging (MRI) in patients with cochlear implants (CI) with the internal magnets.

**Study Design:** Retrospective review of 10 unilateral CI patients who underwent an MRI.

**Patients:** Patients averaging 42 years of age underwent a total of 12 clinically indicated MRI scans. Devices from 3 major CI manufactures were represented.

**Interventions:** Binding of CI with mold material and gauze was performed prior to most MRIs. Most patients were given oral sedation. Gadolinium contrast was used in all but one study.

**Main Outcome Measures:** Patients were assessed with regard to ability to complete the MRI, size of the artifact caused by the device, ability to make a diagnosis from the studies, post-MRI CI function, and magnet position.

**Results:** No CI malfunction, displacement, or magnet displacement was observed post-MRI. One patient did not tolerate the procedure due to device site pressure. One patient required intravenous sedation. The CI produced an artifact with a mean maximal anterior-posterior dimension of 6.7 cm and lateral dimension of 4.8 cm near the device. The contralateral internal auditory canal (IAC) was visualized in all patients and the ipsilateral IAC was at least partly visible in all but one patient.

**Conclusions:** Patients can safely undergo 1.5 T MRI after CI if the device is bound prior to scanning. Magnet displacement did not occur and we believe the risk to be minimal, when compared with the risk an inconvenient of removing the magnet prior to the study.

IRB approval - pending

### DIAGNOSTICS

Practice Gaps- Under-utilization of recommended diagnostic strategies in cochlear and vestibular disease

### COCHLEAR IMPLANTS

Practice Gaps- Lack of awareness/knowledge as to the expected results and limitations of cochlear implants.

4) Applying appropriate diagnostic strategies to inner ear (cochlear and vestibular) disease.

5) Outline the expected results and limitations of cochlear implants with respect to patient outcomes and quality of life.

This paper will specifically address how it is safe and effective to perform MRI on patients after cochlear implantation. Most clinicians are unwilling to perform an MRI in a patient with a cochlear implant due to concerns about potential harm to the patient or the device. This paper will address these concerns by demonstrating that MRI is safe and effective after cochlear implantation. Doing the MRI with the cochlear implant in place has several advantages over alternatives such as doing a CT scan, or removing the magnet prior to the MRI.

Knowledge

Competence

Performance

Patient Outcomes

This paper will specifically address how it is safe and effective to perform MRI on patients after cochlear implantation. Most clinicians are unwilling to

perform an MRI in a patient with a cochlear implant due to concerns about potential harm to the patient or the device. This paper will address these concerns by demonstrating that MRI is safe and effective after cochlear implantation when proper procedures are followed. Doing the MRI with the cochlear implant in place has several advantages over alternatives such as doing a CT scan, or removing the magnet prior to the MRI. Clinicians will understand that cochlear implantation is not a contraindication to MRI. MRI is a safe and diagnostic procedure in this patient population.

Patient Care

Medical Knowledge

Practice-Based Learning

System-Based Practice

## **Binaural Speech Recognition in Noise by Cochlear Implanted Patients**

Bernard Fraysse, Matthieu Marx, Olivier Deguine,  
Marie-Laurence Laborde, Chris James

Background: « Squelch » effects provide normal hearing listeners with a binaural advantage where speech and noise sources are separated. True “binaural release from masking” appears to be very limited or non-existent in many bilaterally implanted patients. Recent studies compare the within-subject performance of residual hearing patients implanted with “Hybrid” cochlear implants with similarly separated speech and noise. The aim of our study was to compare binaural release from masking between subjects for a range of cochlear implant and residual hearing configurations using the same test set-up.

Material and methods: Subjects were 15 unilaterally implanted patients with residual hearing (5 with bilateral, 10 with unilateral residual hearing) and 5 bilaterally implanted patients. A group of 10 unilaterally implanted “no residual hearing” subjects was used as a control to estimate the head-shadow and microphone effects. Sentence recognition in noise was tested for diotic S0°N0° and dichotic S-60°N+60° listening.

Conclusions: preliminary data suggests that Hybrid patients (CI + bilateral residual hearing) can show large squelch effects with a gain of 5 dB. Bimodal patients (CI + contralateral residual hearing) show little or no squelch although there appear to be several confounding factors such as the relative performance of each ear and the level of residual hearing.

Define Professional Practice Gap:

Educational Need:

Performance  
Patient Outcomes  
Learning Objective:

Desired Result:

Medical Knowledge

## **Residual Hearing Preservation during Cochlear Implantation in Gerbils with Noise Induced, High-Frequency Hearing Loss**

Thomas A. Suberman, BA, Adam P. Campbell, BA, Craig A. Buchman, MD  
Oliver F. Adunka, MD, Douglas C. Fitzpatrick, PhD

**Hypothesis:** Damage to high-frequency portions of the cochlea that are initially accessed during an insertion of cochlear implant will be identifiable in the residual responses to low frequency sounds.

**Background:** Thus far we have shown that cochlear microphonics (CM) and cochlear action potentials (CAP) can be used as markers to identify damage to intracochlear structures. Now that we have established reliable markers, we turn our focus to the clinically relevant scenario of high-frequency noise loss.

**Methods:** Gerbils are exposed to high-pass noise sufficient to produce high-frequency hearing loss, while preserving low frequency hearing. After two weeks of rest, an electrode is placed at the round window and the CAP and CM are measured in response to free field tone bursts. The electrode is then advanced and measurements are taken and compared with those of the round window. When a change in potentials is noted, the electrode is withdrawn to determine if the damage is reversible. Finally, the cochlea is fixed and histology is used to identify the extent of damage caused by both the noise and the electrode.

**Results:** In response to noise exposure, animals show equivalent bilateral hearing loss, as evidenced by increase in thresholds of CAP and CM in recordings taken at the round window. Furthermore, changes in the CAP and CM are detectable even when damage due to electrode impact is in the high-frequency region of the cochlea.

**Conclusion:** CM and CAP remain reliable markers of intracochlear damage in gerbils with noise induced, high-frequency hearing loss.

IRB Approval:  
UNC IACUC 08-135

**Define Professional Practice Gap:**

To preserve residual hearing during cochlear implantation, surgeons currently utilize "soft surgical practices," including careful opening of the cochlea, avoidance of intracochlear fluid disturbance, and careful handling of the electrode to facilitate proper cochlear electrode insertion. Though these may improve outcome, there is a lack of real-time physiological feedback that could help reduce intracochlear damage and subsequent loss of residual hearing. It is therefore important that real-time markers be established so that insertion techniques can be improved to optimize the preservation of electric and residual hearing.

**Educational Need:**

To establish the reliability of electrophysiological markers (compound action potential (CAP) and cochlear microphonics (CM)) in animals with noise induced hearing loss.

Knowledge  
Performance  
Patient Outcomes

**Learning Objective:**

To learn how best to approximate typical human hearing loss in an animal model, and to establish a near real-time monitoring system for improved cochlear implant insertion that can be translated to human cochlear implantation.

**Desired Result:**

To create an animal model that mimics human hearing loss such that established

markers could be used to create a near real-time monitoring system for improved cochlear implant insertion in humans

Patient Care  
Medical Knowledge  
Practice-Based Learning

System-Based Practice

## **Pediatric Cochlear Implantation in Children with Eighth Nerve Hypoplasia**

Nancy M. Young, MD; Francine Kim, MD; Beth Tournis

**Objective:** The purpose of this study is to characterize the range of auditory and speech perception skills achieved subsequent to cochlear implantation of children with eighth nerve hypoplasia.

**Study Design:** Retrospective review of the pediatric implant population at a tertiary care medical center. The study will examine nine children with significant eighth nerve hypoplasia identified pre-operatively in the ear to be implanted by magnetic resonance (MR) imaging. The main outcome measures are standard measures of auditory and speech perception in implanted children.

**Results:** Case studies will illustrate that MR imaging alone is not an accurate predictor of outcomes in children with eighth nerve hypoplasia.

**Conclusion:** Outcomes in children with eighth nerve hypoplasia as determined by MR are variable. Optimal management of children with eighth nerve hypoplasia requires further investigation and consideration.

**IRB Approval:** This retrospective study has been submitted for expedited review.

**Define Professional Practice Gap:**

Cochlear Implantation - Lack of awareness/knowledge as to the expected results and limitations of cochlear implants in pediatric population.

**Educational Need:** - benefits and limitations of cochlear implantation in children with eighth nerve hypoplasia is necessary to help determine implant candidacy and to better counsel families about range of outcomes.

**Knowledge**

**Patient Outcomes**

**Learning Objective:** A range of outcomes is possible in pediatric implant candidates with eighth nerve hypoplasia

**Desired Result:** 1.improved counseling of parents of children who are potential cochlear implant candidates. 2.consideration of implant candidacy in some children with nerve hypoplasia

**Patient Care**

**Medical Knowledge**

## **Apparent Cochlear Nerve Aplasia: To Implant or not to Implant?**

Frank M. Warren III, MD, Richard H. Wiggins III, MD  
H Ric Harnsberger MD, Clough Shelton, MD

**Objective:** To describe the imaging findings and clinical outcomes of children with apparent cochlear nerve aplasia undergoing cochlear implantation.

**Study Design:** Retrospective case review.

**Setting:** Tertiary care center.

**Patients:** Two patients with imaging findings consistent with absent cochlear nerve canal on diagnostic imaging and no reproducible audiometric responses on testing that underwent promontory stimulation and subsequent cochlear implantation.

**Intervention(s):** MRI and CT imaging, audiologic assessment and cochlear implantation.

**Main Outcome Measure(s):** Audiologic performance following cochlear impantation.

**Results:** Both patients were identified to have profound sensorineural hearing loss on newborn hearing screening and underwent ABR testing revealing absent brainstem responses. ASSR testing was inconclusive in each case as well. Imaging in both cases identified one ear with a small IAC with two nerves present, one of which appears to enter the vestibule in each case the other is assumed to be the functioning facial nerve. There was a bony plate present over the entrance to the cochlea in both patients. Over time, both families reported responses to auditory stimuli with amplification. Promontory stimulation testing showed reproducible responses to electrical stimuli in the ears in question. Following cochlear implantation, both patients have shown responses to auditory stimuli.

**Conclusion:** The absence of cochlear nerve canal in patients with apparent cochlear nerve aplasia does not preclude auditory innervation of the cochlea. Cochlear implantation in appropriately studied ears is a viable option for these patients.

IRB Approval: Utah IRB\_00030685

**Define Professional Practice Gap:**

Limitations of knowledge in the evaluation and mangement of congenital sensorineural hearing loss in the face of cochlear nerve aplasia/hypoplasia.

**Educational Need:**

Outline the role of diagnostic testing in the evaluation of congenital sensorineural hearing loss with associated cochlear nerve abnormalities, and describe the outcomes of cochlear implantation in these cases.

**Knowledge**

**Learning Objective:**

There are limitations to the current diagnosis and management of congenital sensorineural hearing loss with associated cochlear nerve abnormalities.

**Desired Result:**

Following this presentation, clinicians will better understand the limitations of clincal testing in the evaluation of children with cochlear nerve aplasia/hypoplasia, and the outcomes of cochlear implantation in this population.

**Medical Knowledge**