TRANSACTIONS

AMERICAN OTOLOGICAL SOCIETY, INC.

VOLUME 93

One Hundred Thirty-Eighth Annual Meeting



May 14-15, 2005

BOCA RATON RESORT & CLUB BOCA RATON, FL

OFFICERS

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PRESIDENT-ELECT JOHN K. NIPARKO, M.D. THE JOHNS HOPKINS HOSPITAL BALTIMORE, MD

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CLOUGH SHELTON, M.D. UNIVERSITY OF UTAH SCHOOL OF MEDICINE SALT LAKE CITY, UT 84132

EDITOR-LIBRARIAN C. PHILLIP DASPIT, M.D. PHOENIX, AZ 85013

COUNCIL

The above officers and Horst R. Conrad, M.D. Jeffrey P. Harris, M.D., Ph.D. Antonio De La Cruz, M.D. Joseph B. Nadol, Jr, M.D.

M I N U T E S
THE AMERICAN OTOLOGICAL SOCIETY, INC.
ANNUAL MEETING
MAY 14-15, 2004
BOCA RATON RESORT & CLUB
BOCA RATON, FLORIDA

MINUTES OF THE BUSINESS MEETING - SATURDAY, MAY 14, 2005

- I. CALL TO ORDER: The President, Dr. Sam E. Kinney, called the Business Meeting to order at 7:00 a.m.
- II. APPROVAL OF MINUTES: The minutes of the May 1-2, 2004, Annual Meeting of the American Otological Society, Inc., held at J. W. Marriott Desert Ridge Resort & Spa, Phoenix, Arizona, were approved.
- III. INTRODUCTION OF NEW MEMBERS: The following new members were introduced to the Society by their respective proposers:

FIVE ACTIVE MEMBERS

Craig A. Buchman, MD - Proposed by: Harold C. Pillsbury, MD; Seconded by: Thomas J. Balkany, MD Roberto A. Cueva, MD - Proposed by: Karen Jo Doyle, MD, PhD; Seconded by: Michael E. Glasscock, III, MD

Richard D. Kopke, MD - Proposed by: J. V. D. Hough, MD; Seconded by: Joseph G. Feghali, MD Blake C. Papsin, MD - Proposed by: Julian M. Nedzelski, MD; Seconded by: Glenn D. Johnson, MD J. Thomas Roland, Jr., MD - Proposed by: Anil K. Lalwani, MD; Seconded by: Noel L. Cohen, MD, PhD

THREE CORRESPONDING MEMBERS

Marcus D. Atlas, MBBS, FRACS - Proposed by: Bruce J. Gantz, MD; Seconded by: Derald E. Brackmann, MD

Gabor Répássy, MD - Proposed by: Eugene N. Myers, MD; Seconded by: Steven M. Parnes, MD Haruo Takahashi, MD - Proposed by: Eugene N. Myers, MD; Seconded by: Charles D. Bluestone, MD

IV. NOMINEES FOR NOMINATING COMMITTEE: A Nominating Committee composed of Dr. A. Julianna Gulya, Chairman, Drs. Charles Luetje, John R. E. Emmett, John W. House and Lloyd B. Minor was elected to prepare the slate of nominees for AOS officers for 2005 - 2006.

- V. REPORT OF THE SECRETARY-TREASURER: Dr. Clough Shelton presented the following items of information:
 - A. The present membership totals 312 and includes the induction of new members on May 14, 2005, as follows:

140 Active, 82 Senior, 47 Associates, 10 Emeritus, 22 Corresponding, and 11 Honorary.

Membership applications are available on the AOS website at www.americanotologicalsociety.org or through the AOS Administrative Office.

B. Members deceased since the 2004 Annual Meeting:

Eugene L. Derlacki, MD (Senior) Alexander Schleuning, MD (Active) Harold G. Tabb, MD (Senior) Dudley J. Weider, MD (Senior)

C. Members transferred to senior status:

Charles D. Bluestone, MD Robert A. Dobie, MD George A. Gates, MD Dennis Pappas, MD

D. Members transferred to emeritus status:

Horst R. Konrad, MD

E. Income and Expense Statements:

The following Income and Expense Statements were presented to the membership.

AMERICAN OTOLOGICAL SOCIETY INC. FINANCIAL STATEMENT July 1, 2004 – April 30, 2005

OPENING BALANCE ON HAND (07/01/2004)	96,065.48
DEPOSITS	131,957.06
OPENING BALANCE + TOTAL INCOME	228,022.54
TOTAL DISBURSEMENTS	140,747.63
Balance on Hand 4/30/2005	87,274.91
SUMMARY of INCOME (July 1, 2004-April 30, 2005)	
Membership Dues & Initiation	58,950.00
AOS Ties	500.00
Interest & Dividends	1,802.89
Research Fund to AOS for Common Expenses	15,696.67
AJO 2003 Profit Share	40,000.00
COSM 2004	15,007.50
Total Income	131,957.06
DISBURSEMENTS (July 1, 2004-April 30, 2005	
Annual Meeting	4,756.81
Midwinter Council Mtg.	13,119.77
Office Expenses (Postage, Supplies, AOL, Ph, Mileag	
Space)	5,473.17
Accounting Fees/Professional Fees	10,924.26

AOS Secretarial Stipend	15,820.00
ACCME Dues & Reaccreditation	2,057.66
AOS Basic Science Lectureship	44,200.00
O&N 2003-2005 Subscriptions	38,790.00
Insurance	1,262,00
Miscellaneous	4,343.96
Total Disbursements	140,747.63

The AOS Basic Science Lectureship has been established by the President, Dr. Sam Kinney, to support a basic science lecturer at the AOS Annual Meeting. The profit share of the journal is being used to fund this lectureship, and the goal is to have the interest share from the fund pay the travel expenses for the lecturer.

AOS Research Fund Report: Dr. Clough Shelton presented the AOS Research Fund Report. The market value of the research fund as of April 30, 2005, was \$7,625,674. The value of the research fund on April 30, 2004, was \$7,438,271. The intent of the Council is for the research fund to continue to grow as well as provide funding of the grants that are approved by the Research Advisory Board.

The expenses to the research fund were \$190,687.66. This includes the grants funded in the fourth quarter, the RAB Annual Meeting, journal advertising and administrative support. The balance in the checking account as of 4/30/2005 was \$100,686.08.

The membership approved the Secretary-Treasurer's report.

VI. EDITOR-LIBRARIAN REPORT:

Dr. C. Phillip Daspit reported the Transactions for the 2004 meeting are now on the AOS website and available for download.

VII. PROGRAM ADVISORY COMMITTEE - Dr. Kinney thanked the following individuals for serving on the 2005 Program Advisory Committee: Drs. H. Alexander Arts, Karen Jo Doyle, Barry E. Hirsch, John W. House, Samuel C. Levine, Michael J. McKenna, Lloyd B. Minor, Peter S. Roland, Seth Rosenberg, John J. Rosowski, and D. Bradley Welling. All of the abstracts are now submitted electronically. Forty-one abstracts were submitted and twenty-six abstracts were selected for the program. The panels were selected from the requests from the previous year's CME evaluations.

VIII. PRESIDENT'S REMARKS, INTRODUCTION OF GUEST OF HONOR, PRESIDENTIAL CITATION, SPECIAL PRESIDENTIAL AWARDS, May 14, 2005: The Business Meeting was adjourned and the first Scientific Session started at 7:30 a.m. with brief remarks from the President, Dr. Sam E. Kinney. The Presidential Citation was presented to Jack L. Pulec, MD and accepted by Marlene Pulec. The President introduced the Guest of Honor, George A. Gates, MD.

MINUTES OF BUSINESS MEETING - SUNDAY, MAY 15, 2005

The President, Dr. Sam E. Kinney, called the Business meeting to order at 12:30 pm.

IX. REPORTS OF COMMITTEES:

AOS Research Advisory Board Report: Dr. Lloyd B. Minor presented the AOS Research Advisory Board Report.

The AOS Research Advisory Board (RAB) held their annual meeting in New York on April 9, 2005. Drs. Joseph B. Nadol. Alan Ryan and Alec Salt have completed their term of service on the RAB. Dr. Michael McKenna was elected as a new trustee. Drs. Yehoash Raphael and Dr. Brad Schulte were elected to serve as basic scientists consultants.

The RAB reviewed 14 grant applications, 9 research grants and 1 application for a clinical trial and 4 applications for a fellowship. Three research grants and two research fellowships were approved for funding in the amount of \$238,000 for 2006.

American Board of Otolaryngology Report: Dr. Richard Chole reported the qualifying and oral examinations were held Chicago, IL on April 15, 2005. The exam was administered to 289 candidates. There were 109 guest examiners, senior examiners and board members giving the oral examination. Exam results will be available on June 17. The Otolaryngology Training Exam was conducted on March 5, 2005. More than 1100 residents and practitioners participated in the examination. The results have been released.

This year's officers are Dr. Harold C. Pillsbury, President; Dr. Jesus E. Medina, President Elect; Dr. Paul A. Levine, Treasurer. Dr. Robert Miller is the full time executive director of the board. Dr. H. Bryan Neel, III has retired after a long service on the Board. Dr. Gerald S. Berke was elected as a member of the Board of Directors.

Most of the activity of the Board has been with Maintenance of Certification (MOC). The 2002 diplomates have a time-limited certificate of 10 years. There are four components to the MOC which ultimately all will be required to take including 1) Documentation of Professional Standing, 2) Documentation of Lifelong Learning and Self-assessment, 3) Evidence of Cognitive Expertise, and 4) Evaluation of Performance in Practice.

The Neurotology Examination was held April 18, 2004. Twenty-five examiners and 42 candidates participated and the exam results will be released by June 17, 2005.

The ABOto has become a sponsoring board of the American Board of Sleep Medicine. The application is supported by all three member boards of the conjoint program and should be approved at the September 2005 ABMS Assembly meeting.

As further refining the examination process, the quality and reliability of the examination, anyone who fails the examination, may take action against the Board and this puts the Board in the position of having to defend the examination process, and the Board spends a lot of time with this.

Award of Merit: Dr. Horst R. Konrad, Chairman, reported he and his committee members, Drs. Sam E. Kinney, Jeffrey P. Harris, Douglas E. Mattox and Herman A. Jenkins recommended Dr. David J. Lim for the 2005 Award of Merit. Dr. Lim received the award at the banquet held on Saturday evening, May 14, 2005.

Audit Committee: Dr. Karen Jo Doyle Chairman, and committee members, Drs. David Barrs and Herman Jenkins reviewed the records of the Society and found no errors, deletions, or other abnormalities in the records. The deposits and withdrawals correctly balanced. There have been stable administrative expenses. The committee recommended the membership accept the report as an indication that the financial status of the American Otological Society, Inc., is excellent and is being maintained appropriately. The members accepted the audit report as presented.

American College of Surgeons: Dr. Richard Wiet reported currently the College has 62,000 members with assets totaling 245 million dollars. Just fewer than 4000 members of the College are Otolaryngologists. The College use part of their assets to carry out the directness of the Board of Regents. There are four areas of interest of the American College of Surgeons:

Education: The College will be collecting data for the office of evidence-based medicine. A program known as the National Search for Quality Improvement Program (NSQIP) will collect quality and outcomes data both by institution and by individual surgeons. The College will ask its members and hospitals to be supportive of the study to educate physicians on quality improvement.

Research and Optimal Patient Care: The College committees have produced information on bioterriorism, chemical weapons, radiation and nuclear energy. This is called a new era of disaster planning. Pertinent to many physicians in this segment is the committee on ethics statement and a review of the previous policy of the ACS to limit physician involvement in ambulatory care centers. This is undergoing a new statement

evaluation that will be more appropriate for our time. For example, fellows may be free to enter into lawful, contractual arrangements as long as they disclose that to their patients and financial disclosures are assured. The final action from the committee on ethics is not known at this time.

Advocacy: The College has been most responsive due to a recommendation of the Board of Governors. A 501C6 PAC has been formed. Dr. Wiet encouraged the members to invest money in this because it is a powerful force in Washington.

Member Services: Dr. Wiet referred to the ACS Website to review all the services available.

In summary, the future of surgeons is in surgeons' hands and dialogue to frame issues regarding these things should not be imposed on surgeons and Dr. Wiet encouraged the members to take an active stance.

The College has taken an active position to encourage residents to join at a resident level at a reduced membership fee, and the College understands the need to have young physicians involved.

American Academy of Otolaryngology: Dr. David R. Nielsen, Executive Vice-President of AAO-HNSF presented the AAO-HNSF report summarizing the state of the Academy/Foundation and its initiatives. Dr. Nielsen reported the Academy is making good progress with the evidence-based medicine initiative. The Academy has reviewed all of their health policy statements as well as the compendium of clinical indicators and has developed a process whereby the Academy will prioritize those that have a low level of evidence and work to increase that level of evidence. The Academy has a new learning content management system that the Academy will be investing two million dollars in over the next five years, which will provide a platform that will allow the Academy to meta-tag all of the content and intellectual capital in a way to conversion it for multiple uses. The Academy will encourage other societies, who feel they would like to share in this platform to work with the Academy. The Academy would like to make this available to other societies that wish to use it.

The Socioeconomic agenda is focusing on the sustainable growth rate formula fix. The Academy foresees an evidence-based, relevant valid, patient-centered pay for performance system to be in place. The ABMS and CMSS has engaged in a joint planning committee and this committee has been looking at how the specialty societies and boards can cooperate more fully to avoid wasted resources and non-synergistic parallel processes.

The AAA sent a letter to the Office of the Inspector General and to the CMS stating that physicians are not skilled or capable of doing hearing tests or interpreting the validity of hearing tests. The Academy will pursue legal action against the AAA, as they have not responded to the Academy's demand letter to cease and desist; they have not retracted their statements, and have not written back to OIG or CMS. The Academy has been assured that the otological leadership will work with the Academy, as the Academy tries to work with the leadership of AAA and ASHA to ensure the establishment of an equitable process for handling these disputes in the future.

The Joint Committee on Infant Hearing is engaging in its five-year paper production and in the year 2000 produced their first paper basically focused on identification. The Joint Committee is planning to produce a second paper that will deal primarily with referral and management.

Dr. Nielsen thanked the otological society for their cooperation in working with the Academy.

Membership Development: Dr. Samuel H. Selesnick presented the membership development report. The committee has been contacting potential qualified members from ANS and the Triological Society. The composition of the society revealed a net increase of three new active members this year and three corresponding members. In May 2003 the mentor system was reinstituted. There are six regional mentors. The goal of the mentorship program is to improve the ability to regionally identify potential applicants. The first official convening of this meeting was a conference call on June 3, 2004, discussing potential membership issues.

Dr. Kinney thanked Dr. Selesnick for his four years of work on this committee.

Report of the Nominating Committee: Dr. A. Julianna Gulya presented the following nominations for the slate of officers of the AOS for the 2005-2006 year: Drs. John K. Niparko, President; Antonio De La Cruz, President-Elect; C. Phillip Daspit, Editor-Librarian; Clough Shelton, Secretary-Treasurer; Council Members: Drs. Jeffrey P. Harris, Sam E. Kinney, Joseph B. Nadol, Jr., and Bruce Gantz. There were no nominations from the floor. The nominated slate was elected by the membership.

Drs. Robert A. Jahrsdoerfer and Thomas McDonald were elected to serve on the 2006 Award of Merit Committee.

X. OLD BUSINESS - Dr. Kinney reported the results of the AOS Bylaws amendment that had to do with modifying some of the requirements for Corresponding Membership to make this category more consistent with the Active Member category. Secondly, the costs involved in maintaining both Associate Members and Corresponding Members, and due to these costs, the Council decided to add a dues structure to these two categories. There were 217 ballots mailed to the active and senior members and 91 ballots were returned – 88 for and 3 against. The AOS Bylaws change has been approved.

Adjournment: The Business Meeting was adjourned at 12:55 pm and the Scientific Program continued until 5:30 p.m.

Respectfully submitted,	
Clough Shelton, MD	

Banquet Notes:

Award of Merit recipient – David J. Lim, MD

Dr. Horst R. Konrad presented the Award of Merit.

Dr. Kinney – the American Otological Society has a long history of 138 years and I certainly believe this particular award of which I was so excited about for Dr.

David Lim represents the kind of recognition that this society gives to outstanding scientists and contributors to otology – so David our hats off to you, Congratulations!

Transactions Continued

SCIENTIFIC PROGRAM

Introduction of the Guest of Honor, George A. Gates, M.D.

SCIENCE IN OTOLOGY: Past, Present, & Future

George A. Gates, M.D.

The theme of this talk is that good otologic practice is based on good science and that science is an integral part of otology.

Science is science, whether conducted in the basic science lab, the dog lab, the clinic, or in the operating room. Science is both a body of knowledge as well as the process of deriving knowledge. Science is everybody's business, because everyone benefits. Scientific medicine bases diagnosis and therapy on evidence or, lacking evidence, best judgment derived from current concepts of the pathophysiology. Scientific medicine also means clarifying areas of uncertainty through research. Science cannot solve all our problems because science does not have all the answers. Science is a work in progress.

The Past

Otology has a distinguished history of science interwoven with clinical practice going back to the early European leaders in the field. Otolaryngology has led the way in supporting fundamental science in clinical departments.

The Present

Clinical research has gained respectability as it has gained in scientific stature. High quality, evidence-based papers are increasing. The practice of scientific medicine is more than evidence; how one uses the evidence is just as important as how one evaluates it.

The Future

We are poised to move otologic science to the next level, collaborative science, and this new paradigm will enable us to reach the goal of finding ways and means to cure deafness through regenerative medicine and inner ear surgery. Cochlear regenerative therapy will be the new era in otology.

Presentation of Presidential Citation--Jack Pulec, M.D.—award given to Marlene Pulec

Scientific Program May 14, 2005

Session: Inner Ear, Hearing Aids, Cancer of the Ear

Cogan Syndrome: 60 patients Over One Half-Century

Michael Gluth, MD, Colin L.W.Driscoll, MD Keith H. Baratz, MD, Eric L. Matteson, MD

Objective: To evaluate the spectrum of disease presentation and clinical course manifested in patients with Cogan syndrome at a single institution over an extended period of time.

Study Design: Retrospective chart review

Methods: Medical records of all patients ever diagnosed with Cogan syndrome at our institution were comprehensively reviewed including otolaryngologic, ophthalmologic, and systemic manifestations. Analysis included patient demographics presenting and delayed manifestations, laboratory testing, physical exam findings, vision/hearing outcomes, therapeutic interventions, and disease course.

Results: Records from a total of 60 patients with Cogan syndrome were identified from within the experience at a single institution over one half-century. Most patients presented initially with vestibuloauditory symptoms, sudden hearing loss being the most common initial manifestation. The most common inflammatory ophthalmologic condition noted was bilateral interstitial keratitis. Headache, fever, and arthralgia were the most frequently noted systemic manifestation. Deafness was eventually noted in 41% of patients. Cochlear implant outcomes were uniformly good. Permanent loss of any degree of vision was uncommon. Death directly attributed to an acute flare-up of systemic disease activity was confirmed in 3 patients.

Conclusions: Cogan syndrome is a disease condition of presumed autoimmune etiology usually consisting of relapsing inflammatory vestibuloauditory and ophthalmologic manifestations. In general, patients now diagnosed with this condition have an increasingly better prognosis that may be attributed to earlier disease recognition and less delay in the administration of corticosteroid therapy.

Newer chemotherapeutic medical treatment regimens are evolving. Cochlear implant technology has been of major benefit in modern hearing rehabilitation efforts within this patient population.

Michael B. Gluth, MD Mayo W-5-Otolaryngology 200 1st St. SW Rochester, MN 55902

Long Term Hearing Preservation Following the Partial Labyrinthectomy— Petrous Apicectomy Approach to the Skull Base

Philip E. Azpanta, MD, David A. Schessel, MD, PhD

Objective: The partial labyrinthectomy petrous apicectomy (PLPA) has been refined and utilized at our institution to enable improved access for more definitive treatment to the petroclival region while avoiding the inherent hearing loss associated with related transpetrosal approaches. Despite the removal of portions of the membranous labyrinth, hearing can be preserved. In this study we review the long-term audiologic outcomes of our patients and quantitate the hearing loss risk associated with the PLPA.

Study Design: An IRB approved retrospective chart review.

Setting: George Washington University Medical Center, a tertiary academic hospital.

Patients: All individuals undergoing treatment of petroclival pathology via the PLPA.

Interventions: Diagnostic and therapeutic.

Main Outcome Measures: Pre-operative and post-operative audiograms: pure tone averages and speech discrimination scores.

Results: From 1991 to 2004 150 PLPAs were performed and 92 patients had post-operative audiometric data available. The mean follow-up was 20 months (range 3 days to 8 years). Following an initial mixed hearing loss, hearing stabilized and typically returned to near baseline values. 95% retained serviceable hearing (PTA</=50 dB and SD >/=60dB) and 5% had ipsilateral deafness. The mean pre-operative and post-operative PTA were 12 dB (median 7 dB) and 22 Db (median 19dB) respectively. The mean pre-operative and post-operative SD were 89% (median 96%) and 79% (median 92%) respectively.

Conclusions: This study demonstrated the long-term stability of auditory function associated with the PLPA approach. The risk of severe loss of hearing is approximately 5%.

Philip E. Zapanta, MD 1631 Kenwood Ave. Alexandria, VA 22302

Incidence and Interval of Contralateral Ear Involvement after Diagnosis of Meniere's disease or Endolymphatic Hydrops

Joni K. Doherty, MD, PhD, Laurel M. Fisher, PhD Zarina Iqbal, MRH, John W. House, MD

Objective: Determine the percentage and time interval for conversion from unilateral to bilateral involvement with Meniere's disease (MD) and endolymphatic hydrops.

Study Design: Retrospective **Setting:** Tertiary referral center

Patients: 374 patients (748 ears) with a diagnosis of MD or hydrops diagnosis

between 1959 and 2004

Intervention: Patients, who consented, filled out a survey detailing symptom onset, frequency, disability index, and treatments. Medical charts were reviewed.

Main Outcome Measures: (1) Incidence of hydrops relative to MD (2) Progression from unilateral to bilateral involvement; (3) Interval between unilateral onset of symptoms and bilateral involvement.

Results: Diagnosis was hydrops in 26% and MD in 74%. MD involvement was unilateral in 88%, bilateral in 1% at presentation, and 10% became bilateral. For hydrops, 92% were unilateral, 5% were bilateral at presentation, and 3% became bilateral. Conversion from endolymphatic hydrops to Meniere's occurred in 0.7%. The time interval for conversion from unilateral to bilateral was 5.4 years, ranging from 1-11 years. Treatment was medical in 70% and surgical in 30% cases across both diagnoses.

Conclusions: Contralateral ear involvement after diagnosis of both endolymphatic hydrops and Meniere's disease is significant, requires long-term follow-up for detection, and may necessitate further treatment.

Joni K. Doherty, MD, PhD University of California San Diego 408 N. Cleveland Drive, Oceanside, CA 92054

Experience with CROS/BiCROS Digital Hearing Aids

Herbert Silverstein MD, Samuel Hill III, MD Avron Marcus MD, Nancy Gilman, MS, CCC-A

Objective: To assess patient satisfaction and acceptance rate with digital CROS/BiCROS hearing aids.

Study Design: Retrospective case review. **Setting:** Neurotology clinic/referral center.

Patients: 87 patients with severe to profound asymmetric hearing loss and poor speech discrimination (below 40% in the worst ear) due to Meniere's disease, acoustic neuroma, autoimmune inner ear disease, temporal bone fracture, or noise exposure.

Interventions: Patients underwent hearing evaluation (audiometry, OAEs, ECoG, and BAER). Patients wee fit with digital BiCROS (N=74) or CROS (N=13) aids in various configurations (BTE/ITE, corded/uncorded). A one-week follow-up for adjustments and sound field testing was performed. A one-month follow-up was

initiated to evaluate hearing aid performance and patient satisfaction.

Questionnaires were completed to assess patient satisfaction.

Main outcome measures: Acceptance rate and patient satisfaction.

Results: A 68% overall acceptance rate was found after the 30-day trial period. A 71% acceptance rate was demonstrated after exclusion of suboptimal candidates. A 69% and 62% acceptance rate was noted for the BiCROS and CROS aids respectively. A 79% and 33% acceptance rate was noted for the corded and cordless aids respectively. Reasons for returning the aids included: dissatisfaction with device aesthetics, no perceived improvement over previous aid, complexity of aid, cost and suboptimal candidacy selection.

Conclusion: Historically, CROS/BiCROS systems have shown poor patient satisfaction and approximately 20% acceptance rates. This study demonstrates high patient satisfaction and a 71% acceptance rate with newer, digital CROS/BiCROS aids in appropriate candidates. In addition, corded aids showed a substantially higher acceptance rate as compared with the cordless device.

Herbert Silverstein, MD Silberstein Institute 1901 Floyd St. Sarasota, FL 34239

Complications of the Bone Anchored Cochlear Stimulator

Sam Marzo, MD, John P. Leonetti, MD

Objective: To discuss complications of the bone-anchored cochlear stimulator

(BAHA) and their management. **Study Design:** Prospective **Setting:** Tertiary referral center

Intervention: Implantation of BAHA

Main Outcome Measure: Postoperative complications.

Results: Between September 2003 and October 2004, 34 patients underwent implantation of a BAHA for unilateral conductive, mixed, or sensorineural hearing losses. There were 16 female patients and 19 male patients, with an average age of 47 years (range 11-77 years). Complications occurred in 26% of patients, and most were early in the series. The most common complication was partial or complete loss of the skin graft, occurring in 5 patients. These were managed successfully with local wound care. Three patients had skin growth over the abutment. Two of these cases were managed with office debridement, while one patient required revision under general anesthesia. There were 2 implant extrusions, and both of these patients later underwent successful reimplantation. All patients underwent implant activation three months after surgery. There were no perioperative or postoperative deaths.

Conclusion: The bone anchored cochlear stimulator has an acceptable complication rate. The extrusion rate is low. Most complications are minor and related to partial or complete loss of the skin graft.

Sam Marzo, MD

2160 South First Ave Bldg. 105, Room 1870 Maywood, IL 60153

Squamous Cell Carcinoma of the External Auditory Canal and Middle Ear: Proposal of Modification of Pittsburg TNM Staging System

Takashi Nakagawa, MD, PhD, Yoshihiro Natori, MD, PhD Yoshihiko Kumamoto, MD, Kideki Shiratsuchi, MD, PhD Shizuo Komune, MD PhD

Objective: We evaluated therapeutic strategy and survival status for squamous cell carcinoma of temporal bone regarding stage, treatment, and certain prognostic factors.

Study Design: A retrospective case review.

Setting: University hospital and outpatient clinic.

Patients: 28 patients with primary squamous cell carcinoma of the external auditory canal and middle ear.

Intervention: Lateral temporal bone resection was done for T2 lesions. Subtotal temporal bone resection was performed with pre-operative radiation (60 Gy) to T3 and T4 lesions unless there was no invasion to pyramidal apex, carotid canal, dura, and metastasis. Other T4 lesions were conservatively treated by combination of radiation and chemotherapy.

Main Outcome Measures: The survival rates for T2, T3 and T4 lesions. **Results:** The 3-year survival rate for T2 lesions (n=5) was 100%. The 5-year survival rates for T3 (n=6) and T4 (n=17) were 80% and 40%, respectively. The 5-year survival rate improved up to 75% for T4 tumors with operation (n=5), whereas 20% for the 3-year survival rate for T4 tumors without operation (n=12). Lymph node metastasis and concomitant otitis media were significant factors for poor prognosis.

Conclusions: Radical surgery with pre-operative radiation was remarkable effective to T3 tumors. When T4 lesions did not involve pyramidal apex, carotid canal, dura and any lymph nodes, the survival rate was as good as T3 lesions. According to the outcome, the lateral extension of T4 tumors could be classified into T3.

Takashi Nakagawa, MD, PhD Kyushu University 3-1-1 Maidashi Higashi-ku Fukuoka 812-8582, Japan

Approach Design and Closure Techniques to Minimize CSF Leak Following Cerebellopontine Angle Tumor Surgery

Roberto A. Cueva, MD, Bill Mastrodimos, MD

Objective: To identify specific aspects of surgical approach design and closure technique aimed at reducing the incidence of cerebral spinal fluid (CSF) leak following cerebellopontine angle (CPA) tumor surgery.

Study Design: Retrospective case review.

Setting: Tertiary referral center

Patients: All patients undergoing CPA tumor surgery at the study institution form January 1996 through September 2004

Main Outcome Measure: The presence or absence of SCF leak following various surgical approaches for a wide variety of CPA tumors.

Results: 343 patients underwent surgery for CPA tumors at the study institution during the study period. Tumor types in descending order of frequency were: acoustic neuroma-244, CPA meningiomas-33, petroclival meningiomas 32, foramen magnum meningiomas-10, **epidermoid** tumors-9, facial nerve tumors-6, hemangiopericytoma-3, schwannomas of glossopharyngeal/spinal accessory nerves-3, unusual internal auditory canal tumors-3.

Surgical approaches employed for tumor resection included: translabyrinthine, retrosigmoid, combined trans-petrosal approaches, far lateral/transcondylar, middle cranial fossa, and extended middle cranial fossa.

During the nearly 8 year study period four postoperative CSF leaks were encountered resulting in a leak rate of 1.2%. Two of these patients required surgical repair of their leaks, the other two stopped spontaneously. The authors describe specific aspects of approach design and closure which appear to have a positive impact on postoperative CSF leak rates.

Conclusions: Attention to specific aspects of surgical approach design and wound closure results in a reduced incidence of SCF leak following surgery for CPS tumors.

Roberto Cueva, MD Southern California Permanente Medical Group 4647 Zion Ave. San Diego, CA 92120

Discussion of Papers:

Gordon Hughes, Cleveland, OH

A question for Dr. Gluth. In a national study of primary autoimmune inner ear disease chaired by Jeff Harris, we found no apparent benefit to methotrexate but in your report retrospectively of Cogan syndrome you said the methotrexate helped reduce the maintenance dose of steroids necessary to prevent difficulties. I was wondering if you had studied this by controlled study or if it was your impression. Taking into the fact that Cogan syndrome is more of a secondary systemic immune mediated problem, I'm not surprised there could be some apparent benefit to methotrexate. Was a placebo controlled randomized trial done to see if this were true?

Michael B. Gluth, Rochester, MN

This was a small study population. Certainly there was no randomized placebo controlled trial and this was just an impression. The intent of this study was not to actually study the treatment outcomes with methotrexate or any other chemotherapeutic agents. It was mentioned just because that is something we routinely do attempt in certain patients but it is not something in particular we have studied.

Moises Arriaga, Pittsburgh, PA

I wanted to congratulate Dr. Nakagawa on his paper on his modification of the staging system for Squamous Cell Carcinoma of the temporal bone. Could you comment on the use of MRI since early on we relied only on CT scanning for staging? Does it help give additional definition of those structures particularly in the infratemporal fossa where soft tissue involvement is probably not as well defined by CT.? My second question or comment is that I am really impressed by the results with those lateral T4's. Does this represent an advancement of treatment in the role of combined modality with newer chemotherapeutic agents? I certainly agree that the staging system can be enhanced.

Sam Kinney, Moreland Hills, OH

Dr. Nakagawa, I noticed that you did preoperative radiotherapy and chemotherapy. Is there any difference between pre and post operative therapy? In the work that we did we found that we had a little better response if we did radiation therapy and chemotherapy in the postoperative period.

Takashi Nakagawa, Fukuoka, Japan

Thank you for the questions. The MRI scan is a very good method to distinguish soft tissue extension into the infratemporal fossa. Another aid is to distinguish the tumor from the effusion in the middle ear cleft. Giving the chemoradiation preoperatively did decrease the extent of the tumor. Dr. Kinney, I have read your papers and I note your use of postoperative chemoradiation. I still think there is controversy regarding this topic. In our study, giving the chemoradiation preoperatively reduced the size of the disease allowing us to ressect the whole tumor enbloc.

Sam Kinney, Moreland Hills, OH

Thank you for your answer. Your results are outstanding and this is certainly something to be looked at.

John May, Winston Salem, NC

Regarding the paper on the BAHA, I was interested in two of Dr. Leonetti's solutions—the sleeper implant and the longer abutment. In North Carolina we

have a very difficult time getting approval because of cost issues. Multiple surgeries also drive the cost up. Is this cost borne by the hospital, the patient or are the third parties covering the costs.

Sam Marzo, Maywood, IL

I will answer for Dr. Leonetti who is not here. In Illinois we try to obtain insurance approval on all and it is a very tedious process. The key is never use the word hearing aid as this is an automatic denial. We use the term cochlear stimulator. The surgery is performed in the outpatient surgery center and we try to limit the operating time to thirty minutes to keep the costs down. This surgery is very helpful to our patients and we will write letters to the insurance company justifying the surgery. It is rare that you would need a larger implant—the standard one usually suffices. Re: the sleeper implant, each case is unique and it may take multiple letters to obtain authorization. However, there are many patients that we have not done because we don't have preauthorization.

Derald Brackmann, Los Angeles, CA

Roberto, those are fantastic results in terms of CSF leaks. I would offer a different approach if you do have a leak. The common pathway is the eustachian tube and what we have done recently is to transect the external auditory canal, do a blind sac closure, remove the skin of the canal and then directly pack the eustachian tube, first with surgical and then bone wax and then fill the remaining defect with muscle. These leaks are often in the hypotympanic air cells. This prevents one from going back through a fresh wound and avoids the facial nerve and allows a direct approach to the eustachian tube and I find it very fast and efficient in closing these leaks.

Jack Wazen, Sarasota, FL

Re: the BAHA complication paper, the authors stated that most problems are related to soft tissue issues. The surgeon must focus on the flap. With proper thinning and surgical technique and respect of soft tissues we could avoid a lot of these problems. Hemostasis is very important. I have never had to use a longer abutment because I thin down the skin in the area to get down to the periosteum and always preserve the periosteum.

Sam Marzo, Maywood, IL

I agree with those comments. Our use of a longer implant was due to what we called meat head. No matter what we tried the skin grew back over the abutment. The bigger implant solved the problem and we did obtain insurance coverage.

Thomas Linder, Meggen, Switzerland

Dr. Nakagowa, some of your T4 patients have not been operated and their outcome was poor. What are your contraindications for surgery? I realize that Dr. Natori and works with you and is a neurosurgeon. Is dural invasion a definite contraindication?

Takashi Nakagawa, Fukuoka, Japan

Invasion of the carotid artery canal and metastasis as well as dural involvement can be relative contraindications.

Dennis Poe, Boston, MA

I enjoyed Dr. Doherty's paper. I am intrigued by your comments that you do not see contralateral development in patients who have had a labyrinthectomy. Mendell Robinson suggested for years doing a labyrinthectomy for just that reason. What were your numbers and do you think we should be looking at some king of autoimmune sympathetic dystrophy?

Joni Doherty, Oceanside, CA

This is a very good question and interesting topic that you bring up. I think there maybe some correlation to sympathetic ophthalmia with the autoimmune response. None of our patients who progressed to bilateral disease had a labyrinthectomy. In our group that did not progress to bilateral disease, only three had had a labyrinthectomy. We just did not have enough patients to note a significant difference. It would be interesting to look at this with a larger group of patients who have had surgery versus no surgery.

Session: Cochlear Implants, BAHA

Histopathology of the Peripheral Vestibular System Following Cochlear Implantation in Human

Ophir Handzel, MD, LLB, Barbara Burgess, Joseph B.

Nadol, MD

Objectives: To describe the histology of the peripheral vestibular system in temporal bones from patients who in life had undergone cochlear implantation and to correlate the findings with previous reports of vestibular dysfunction after cochlear implantation. This is the first quantitative report of the impact of implantation on the vestibular neuronal end organ.

Materials and Methods: There were 19 temporal bones available for histological study. Of these, 17 were suitable for the description of the morphology of the membranous labyrinth, 8 for counting Scarpa's ganglion cells and 6 for measuring the densities of vestibular hair cells. The bones were fixed, cut and stained according to previously published methods. Preferably, the

implanted electrode was left in-situ. Vestibular hair cells were counted with Nomarski's optics.

Results: Differences in Scarpa's ganglion cell counts and hair cell densities between the implanted and non-implanted sides were not statistically significant. In 59% of the implanted bones the cochlea was hydropic and in the majority of these bones the saccule was collapsed.

Conclusion: Cochlear implantation does not cause deafferentation of the peripheral vestibular system. Cochlear hydrops accompanied by saccular collapse is common and may cause attacks of vertigo of delayed onset, similar to Meniere's syndrome as previously reported in several clinical series. Hydrops could be caused by obstruction of endolymphatic flow in the ductus reuniens or in the hook portion of the cochlear or by damage to the lateral cochlear wall caused by implantation.

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Minimally Invasive Approaches in Pediatric Cochlear Implantation

Daniel J. Lee, MD, Elizabeth J Mahoney, MD

Objective: Efforts to make pediatric cochlear implantation less invasive and more efficient are essential to improve patient safety, facilitate recovery as well as enhance cost-effectiveness. We review our experience with a minimally invasive technique which combines a small skin incision and titanium screw fixation. Unlike a "keyhole" incision, this approach provides adequate exposure for resident and fellow teaching, while still minimizing the surgical incision. Additionally, carefully-designed flaps allow for the use of screw fixation, decreasing the risk of migration. The purpose is to describe our experiences with this minimal access technique.

Study Design: Retrospective review of the records of pediatric patients (<18 years) undergoing cochlear implantation.

Patients: Pediatric patients undergoing cochlear implantation via a minimally invasive approach at our institution.

Intervention(s): Cochlear Implantation

Main Outcome Measures: Surgical time, skin flap viability, device migration, and adequacy of exposure for resident teaching.

Results: Surgical time averages less than two hours. No perioperative complications were encountered. Residents participating in these cases uniformly felt that this approach provided exposure appropriate for teaching.

Conclusions: Our modification of current pediatric cochlear implantation techniques combines a small skin incision and screw fixation. We propose that this technique, unlike its "keyhole" counterpoint, preserves adequate exposure for both stable fixation as well as resident teaching while still ensuring a small surgical scar and short operative time. The continued evolution of minimally

invasive surgical approaches is crucial to improving the safety and costeffectiveness of pediatric cochlear implantation.

> Daniel J. Lee, MD 55 Lake Avenue North Worcester;, MA 01655

Choosing Sides in Cochlear Implantation: Is the Worse Ear Better:

D.A. Miller, BS, Todd Hillman, MD, Clough Shelton, MD

Objective: To examine the effect that choice of ear has on hearing results in adult cochlear implantation.

Study Design: Retrospective chart review.

Setting: University teaching hospital

Patients: Adults with profound sensorineural hearing loss (n=53) with a better

hearing ear prior to implantation.

Intervention(s): Cochlear implantation.

Main Outcome measurement(s): Postoperative Hearing in Noise Test (HINT) sentences, consonant-nucleus-consonant (CNC) monosyllabic word scores and pure tone threshold averages (PTA) (500, 1K, 2K, 3K) within 1 year of implantation.

Results: We identified 39 patients who underwent cochlear implantation in their better ear. The decision to implant the worse hearing ear was made to preserve the benefit many of these patients continued to receive from conventional amplification. Subjects implanted in the worst ear had mean scores of 64.3% on HINT, 33.4% CNC and a 31.4 dB PTA. The mean scores for subjects receiving implants in the better ear were 69% HINT, 36% CNC and a 34.2 dB PTA. There was no statistically significant difference between these groups. The results indicate that selecting to the worse hearing ear does not compromise overall speech recognition results.

Conclusions: Patients receiving cochlear implants in their worse hearing ear showed similar outcomes in performance as those receiving better ear implants. Worst ear implantation gives the advantage of using a hearing aid in the non-implanted ear. By current implant indications some patients with significant residual hearing are being implanted, many who enjoy wearing a hearing aid in the non-implanted ear.

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Residual Hearing Conservation and Electro-Acoustic Stimulation with the Nucleus 24 Contour Advance

Objective: We describe a multi-centre prospective study of conservation of residual hearing in recipients of the Nucleus 24 Contour Advance electrode array and the benefits of combined electrical and acoustic stimulation.

Patients: Subjects were adult candidates for cochlear implantation.

Methods: A "soft" surgery protocol was defined: 1-1.2 mm cochleostomy anterior and inferior to the round-window, Nucleus Contour Advance perimodiolar electrode array inserted using the "advance-off-stylet" technique. The insertion depth limited to about 400 degrees or 17 mm linear depth.

Main Outcome Measures: Pure tone thresholds were measured pre-operatively and post-operatively at intervals. To assess the benefits of combined electrical and acoustic (El-Ac) stimulation patients who still retained thresholds less than 90dBHL up to 500 Hz were fitted with an ITE hearing aid. Speech recognition was tested for cochlear implant alone for all patients and additionally with an ipsilateral hearing aid for El-AC patients.

Results: Preliminary results showed that hearing threshold levels wee conserved to between 10 to 20dB of pre-operative levels for 7 of 12 subjects implanted. Half of these patients retained hearing threshold levels less than or equal to 90dBHL up to 500Hz. For three subjects with at least 3 months experience El-AC stimulation improved words scores by 10-3- percentage points, and in noise the signal-to-noise ratio for the speech reception threshold could be improved by 0.5-3.0 dB compared to that observed for the implant alone condition.

By the time of presentation hearing conservation data will be available for a further 1w patients (N=24) and speech perception data for the 14 patients total.

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Bilateral Cochlear Implants with 8-Channels/813 pps or 16 Channels with Rates of Either 2900 and 5100 pps

Camille C. Dunn, PhD, Richard Tyler, PhD, Shelley Witt, MA Beth Macpherson, MA, Bruce Gantz, MD, Diana Kain, MA

Objectives: Three different Advanced Bionics processing strategies were evaluated:

1)8-Channels /813 pps (CIS), 2) 16-Channels/2900 pps (HiResolution Sequential), and 3) 16-channels/5100 peps (HiResolution Paired). Increasing the rate might provide a better temporal representation and improved binaural cues. **Study Design and outcome Measures:** Sentence recognition in multi-talker babble from the front and an eight-speaker everyday sounds localization the test was administered to subjects using an eight-channel, 813 peps, Continuous Interleaved Sampling (CIS) processing strategy for at least 18 months. Subjects were then programmed with a 16-channel HiResolution Sequential strategy and

16 channel HiResolution Paired strategy. Sentence recognition and localization was again collected. AN ABAB design was then implemented for one month whereby subjects alternated their HiResolution strategies every other day. For the next two months, subjects were given the choice to where the strategy they preferred. Sentence Recognition and localization abilities were repeated at one-month and again at three-months.

Subjects: Seven adult bilateral Clarion CII cochlear implant recipients participated in the study.

Results: Comparisons between the 8-channel CIS and the 16-channel HiResolution programs showed immediate 10-20% improvements on 5 subjects for the HiResolution programs (2 subjects did not have complete test results at this stage in the study). After one month of alternation between the HiResolution Paired and Sequential programs, there were no differences between the two rates. However, remarkably two subjects showed improvements of 60%; two subjects showed improvements of 40%; and two subjects showed improvements of 30% over the 8-channel/813 peps CIS strategies they had previously worn for at least 18 months. Small or no differences ere observed on the localization tasks. Results after three months of use were consistent with those obtained after one month.

Conclusions: The 16-channel, 2900 and 5100 peps Advanced Bionics HiResolution Sequential and Paired strategies resulted in dramatic improvements in speech perception in noise in subjects who had been using binaural 8 channel/813 peps CIS strategies. Further work is needed to determine the independent affects of rate and number of channels.

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Extended Assessment of Bone-Anchored Hearing in the Rehabilitation of Unilateral Deafness

Li-Mei Lin, BA, Stephen Bowditch, MS, Bradford May, PhD Kenneth Cox, MA, CCC-A, John Niparko, MD

Objective: Vibromechanical stimulation with a semi-implantable bone-conductor (Entific BAHA device) overcomes some of the head-shadow effects in unilateral deafness. What specific rehabilitative benefits are observed when the functional ear exhibits normal hearing v. moderate SNHL?

Design: Prospective trial of subjects with unilateral deafness in a tertiary care center.

Patients: Adults with unilateral deafness (PTA>90dB; SDS<20%) and either normal monaural hearing (n=18) or moderate SNHL (PTA=25-50 dB; SDS>75%) in the contralateral functional ear (N=5).

Intervention: Subjects fit with CROS devices for one month and tested before (mastoid) implantation, fitting, and testing with BAHA.

Outcome Measures: 10 Subjective benefit; 2) source localization tests (SAINT); 3) speech discrimination in quiet and in noise assessed with HINT protocols.

Results: Consistent satisfaction with BAHA amplification; poor acceptance of CROS amplification. General directional hearing above chance for unaided and in BAHA conditions, but not for CROS. Relative to baseline and CROS, BAHA produced significantly better speech recognition in noise.

Conclusions: BAHA amplification on the side of a deaf ear yields greater benefit in subjects with monaural hearing than does CROS amplification. Advantages likely relate to averting the interference of speech signals delivered to the better ear, as occurs with conventional CROS amplification, while alleviating the negative head-shadow effects of unilateral deafness. The advantages of head-shadow reduction in enhancing speech recognition with noise in the hearing ear outweigh disadvantages inherent in head-shadow reduction that can occur by introducing noise from the deaf side. The level of hearing impairment correlates with incremental benefit provided by the BAHA: Patients with moderate SNHL in the functioning ear perceived greater increments in benefit, especially in background noise, and demonstrated greater improvements in speech understanding with BAHA amplification.

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The Usefulness of Head-Shaking Nystagmus as a Screening Test for Vestibulopathy

Jennifer Smullen, MD, Simon Angeli, MD

Objective: To determine if the head-shaking nystagmus (HSN) test performed during clinical office examination is a useful tool in the diagnosis of vestibular dysfunction.

Study Design: Retrospective chart review.

Setting: Academic, outpatient, tertiary referral center.

Patients: 43 consecutive adult patients with complaints of vertigo or disequilibrium met the inclusion criteria of documented HSN and electronystagomography (ENG) testing.

Interventions: Clinical evaluation including the HSN test gave an initial clinical diagnosis followed by computerized ENG with bithermal caloric stimulation to achieve a final diagnosis.

Main Outcome Measures: The positive predictive value as well as the sensitivity and specificity of the HSN test in making a clinical diagnosis of vestibular dysfunction was compared to the final diagnosis made with gold standard ENG.

Results: The positive predictive value of the HSN test was 97%, and the specificity in detecting a vestibular lesion was 96%. However, the sensitivity of

the HSN test in identifying vestibular disease is quite low (53%). When the HSN test is positive, the clinical diagnosis before and after ENG rarely changes. When the HSN is negative, however, the diagnosis after ENG and balance testing is frequently different from the initial clinical impression.

Conclusions: A positive test of head-shaking nystagmus predicts the presence of a vesitbulopathy in patients with symptoms of vertigo or disequilibrium and can be useful in establishing the diagnosis of vestibular dysfunction. However, a negative HSN is less clinically valuable and further vestibular testing is required. Furthermore, the direction of HSN was not predictive of the side of lesion in this series.

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Discussion:

Sam Kinney, Moreland Hills, OH

I first want to compliment this morning's entire group of presenters on the quality of the power point presentations and honoring the time assigned. Congratulations to you all of you. These past seven papers are now open for discussion.

Steve Telian Ann Arbor, MI

I direct the cochlear implant at Ann Arbor. We have long advocated the use of the poorer hearing ear for cochlear implantation and generally have found the same sort of results the Utah group reports. However, you can have too much of a good thing. Often we are faced with patients who benefit from a hearing aid significantly in one ear and the other ear has been long deafened with no residual hearing, have not used a hearing aid for many years and have poor promontory stimulation results in that ear. In this setting we do recommend implanting the better hearing ear if the patient meets candidacy. We are seeing an increasing number of referral of patients who have been implanted in ears like that because the patient was reluctant to give up their hearing aid use. The patient may have very poor performance with their implant and then one wonders if it would have been better to have implanted the better ear and now he/she is faced with a second operation. I would like to hear the comments from the Utah group on this issue.

Todd Hillman Salt Lake City, UT

Thank you for your comments. Agreed, typically our patients who are implanted in the worst hearing ear there is asymmetry to the hearing loss. It is not a large difference.

John Oghalai Houston

At out pediatric hospital we follow exactly the same protocol with regards implanting the poorer hearing ear unless there are any medical contraindications. With our prelingually deafened children we may find that they still favor the hearing aid in their other ear and it may be difficult to get them to work with the implant so we have adopted a strategy of asking the parents not to use the hearing aid in that other ear for a few months after we have implanted and activated the device. This is usually very hard for the parents to accept. Any suggestions? Steve? Bruce?

Todd Hillman Salt Lake City, UT

What is your rational for not having them use the aid in the other ear—just so they can learn to use the CI?

John Oghalai Houston, TX

Early on, when we started this, some of them actually wouldn't use their CI. They favored the hearing aid in the other ear. They must have gotten some very small benefit from that. In the long term everybody really loves the CI and still uses the hearing aid in the other ear just as you have found.

Todd Hillman Salt Lake City, UT

My experience has been primarily adults and I will defer to Clough for the children. I do not limit my adults' use of hearing aids. In fact, I encourage it because of the benefit that they seem to derive and it does not seem to inhibit their learning ability of how to use the CI.

Clough Shelton Salt Lake City, UT

Just to add, John, we do the same thing with the kids—we have them not use their hearing aids for a few months to get use to the CI sound and then add the hearing aid later on.

Bruce Gantz Iowa City, IO

Bernard and Chris I enjoyed your paper. We have also had some experience with the advanced off-stylet technique. In our experience we have been able to save pure tones but we were not able to save acoustic speech perception in the postoperative period. They could still use their hearing aid but they did not understand much speech after the CI. Were you able to preserve acoustic speech perception with the seventeen mm electrode?

Bernard Fraysee Toulouse, FR

Thank you Bruce. One of the main goals of this presentation was to state that using this protocol in trying to save some residual hearing is better than doing nothing. We hope that by doing "soft" surgery we may improve our residual hearing performance. I guess that the difference between 17 mm and 10 mm

electrode that you use probably is one KH preoperatively. In our group of patients where we have used this protocol, nine of them were able to use acoustic stimulation and acoustic reception on the side of implantation. I can not state exactly what the discrimination scores with the hearing aid was-I will have to review this data. It is clear that in nine of these patients we were able to use the hearing aid on this side because we were able to keep enough residual hearing. The main difference was in using a bimodal stimulation—both electrical and acoustical. It definitely improved the pitch and discrimination.

Adrian Eshraghi Miami, FL

Dr. Fraysee, very nice presentation. Did you look at the pattern of loss for the patients that did not preserve their hearing: In some the hearing was lost right after surgery and in others gradually? What was the time period after surgery?

Bernard Fraysee Toulouse, FR

Most of these occurred immediately postoperatively. There was only one that gradually lost the hearing.

Jack Wazen Sarasota, FL

Re: the BAHA paper, there are two groups of happy patients that my audiologists see in my office. These are the stapes patients and the BAHA patients. There is such a great satisfaction with the return of auditory function whether it is conductive or single sided deafness (SSD). When we tested these patients initially during the FDA trial for the SSD paper, all had been tested with a CROS device before implantation and none wanted to go back to the CROS after implantation with the BAHA. With all due respect to Dr. Silverstein's paper, I think the CROS corded device still has some negative acceptance in our patient population.

Sam Kinney Moreland Hills, OH

Is there a response to that comment?

John Niparko Baltimore, MD

Jack, thank you for your comments. In fact we were able to see that the primary cost associated with cross amplification is placing the receiver in the better hearing ear and, in fact, that has a negative impact and a cost associated with it. There is also seemingly a psychological impact of putting a device in the better hearing ear and thus the resistance that we have seen to cross amplification.

Sam Kinney Moreland Hills, OH

Dr. Silverstein, did you want to respond to that question?

Herbert Silverstein Sarasota, FL

Well, I guess I will have to respond to my first son Jack Wazen (my first fellow) because he has done all of the work on the BAHA. We have had a hard time with the BAHA, first getting it authorized by writing letters frequently to the insurance companies. We seem to have a tough time getting approval for payment. The cost differential is significant--\$10,000.00 for a BAHA and \$3000.00 for a BiCROS system. Regarding using the implant in the better hearing ear, many of the patients has a loss in their better ear so you have to amplify the better ear for them to hear better. Even if you use a BAHA, patients do much better when you have a hearing aid in their good ear if they have a loss. The cost benefit is not comparable.

John Niparko Baltimore, OH

Herb, thank you for your comment. In fact, as Dr. Linn showed for our six patients who had a moderate SNHL in their functional ear (SRT between 25-50 dB and SDS 80% or better) they showed measurable benefit that was actually a greater increment relative to those individuals who had normal hearing in their functional ear. With regards reimbursement, we have all experienced some difficulties of late because of the CMS decision to withdraw funding for the BAHA device in association with requests from semi-implantable hearing aid systems that they be covered as well which is now under consideration. The latest feedback we have from CMS is that they see BAHA technology as distinctly different form semi-implantable hearing aids.

Eric Sargent Farmington Hills, MI

Did you test your patients using a single word test like a CHC? We have been studying our patients comparing CROS to BAHA patients and the BAHA patients are very happy with their device. However, our results are trending towards some improvement especially in single word function with the CROS aid. I can not explain the difference. I presume that it is from central processing issues or something like that. Comments?

John Niparko Baltimore, MD

To best test hearing in noise we use the Hinch protocols which are sentence tests with and without noise.

Eric Sargent Farmington Hills, MI

Yes, we have been doing both.

Charles Luetje Kansas City, MO

With regards to the development of endolymphatic hydrops in the implanted ear, can the presenter give me an explanation as to why the hearing may fluctuate with the CI in these patients?

Ophir Handzel Tel-Aviv, Israel

We were thinking about that since first we don't know exactly what neuronal elements are stimulated by the electrode in those implanted patients. We are not certain why that happens although changes in the ionic contents of the inner ear fluids might influence the electrical activity of these fluids and might cause a threshold shift. For example, this may be caused by extreme hydrops seen in many of these cases.

Unknown Speaker

Just to follow up we don't know what we are stimulating with the implant. We presume it is the nerve leading to the brain. Does it make sense that there could be pressure changes in the fluids that would alter the hearing with the CI?

Ophrir Handzel Tel-Aviv, Israel

An assumption which we don't have proof of is the presumed ad mixture of the contents of the inner ear due to a tear in the membranes due to increased pressure. What is the ionic makeup of these fluids? This could cause a change in the ionic contents and lead to a threshold shift.

Loren Bartels Tampa, FL

In response to Dr. Luetje and the paper on hydrops, Dr. Richard Gasek has some very interesting findings on viral neuritis in Meniere's disease patients that may actually explain your question. If he is here, maybe he could address this issue.

Sam Kinney Moreland Hills, OH

Dr. Gasek, do you want to respond?

OK, thank you very much for your questions, we very much appreciate it. We have a very exciting panel presentation coming up on Non-Syndromic Genetic Hearing Loss. Dr. Kenna will chair and Drs. Grundfast and Friedman are going to be panel members.

Genetic Counseling for Hearing Loss: How and Why to do it

Margaret Kenna, MD

Genetic Diagnosis of Hearing Loss: What to Test for and Why

Kenneth Grundfast, MD

Finding and Cloning New Hearing Loss Gene: The Future is Now

Rick Friedman, MD

Session: External Ear, Middle Ear

The Evaluation and Management of Salivary Fistula in Aural Atresia

Robert Miller, MD, Robert Jahrsdoerfer, MD, George Hashisaki, MD, Bradley Kesser, MD

Objective: Salivary fistula is an uncommon and unreported yet significant complication associated with the repair of congenital aural atresia. The capsule of the parotid gland may be violated during two steps of the operation: the initial dissection around the glenoid fossa or while aligning he auricle with the bony canal at the end of the case. We present the first described series of patients with salivary fistula after repair of atresia.

Study Design: Retrospective case review from 1985-2004

Setting: Tertiary referral center.

Patients: We included all patients who were diagnosed with a salivary fistula after atresia surgery.

Main Outcome Measure: The diagnosis of salivary fistula or salivary tissue in the external auditory canal after atresia repair was based on one of the following criteria: 1) identification of a fistula tract or salivary tissue in the EAC, 2) otorrhea positive for amylase, or 3) intermittent otorrhea associated with eating. Results: Of over 1500 patients operated for atresia, we identified 6 patients with salivary fistula after atresia repair. Fistulas were diagnosed from 10 days to 12 years postoperatively, and the duration ranged from 6 months to 14 years. Treatment included observation, medical management, and surgical intervention. Conclusion: Salivary fistulas may present with granulation tissue, persistent crusting, or persistent otorrhea, and therefore it is necessary to have a high degree of suspicion when managing postoperative atresia patients. Salivary fistula secondary to repair of atresia may be managed conservatively or surgically.

Robert Sean Miller, MD 3046 Chimney Ridge Charlottesville, VA 22911

Patulous Eustachian Tube Reconstruction (PETR)

Dennis Poe, MD

Objective: The patulous eustachian tube (ET) appears to be due to a longitudinal concave defect in the mucosal valve at the superior aspect of its antero-lateral wall and causes troublesome autophony. It was hypothesized that submucosal graft implantation to fill in the concavity within the patulous tubal valve by PETR may produce lasting relief of symptoms.

Study Design: Retrospective review

Setting: Tertiary referral center, ambulatory surgery

Patients: 11 eustachian tubes in 8 adults with two or more years of confirmed continuous patulous ET symptoms refractory to medical care.

Intervention: Endoluminal PETR was performed in 11 separate cases using a combined endoscopic trans-nasal and trans-oral approach under general anesthesia. A submucosal flap was raised along the antero-lateral wall of the tubal

lumen up to the valve and mobilized superiorly off of the basi-sphenoid. The pocket was filled with Alloderm implant restoring the normal convexity and competence to the mucosal lumen valve.

Main Outcome Measure: Autophony symptoms were scored as 1) complete relief, 2) significant improvement, 3) unchanged, 4) worse

Results: All cases reported immediate complete relief of autophony. Results with follow-up ranging from 2 to 18 months (ave 9.2 months), 6 (55%) cases had complete relief of symptoms, 5 (45%) significant improvement. There were no complications. Correlation between patulous ET and other conditions was strongest with laryngopharyngeal reflux and rheumatological conditions. **Conclusions:** Patulous ET appears to be caused by a concave defect in the tubal valve's antero-lateral wall. Submucosal graft implantation to restore the normal convexity to the valve wall appears capable of giving lasting relief of symptoms. Long term study is needed.

Dennis Poe, MD Zero Emerson Place Boston, MA 02114

Comparison of the SMART Stapedotomy Prosthesis with Conventional Piston Prostheses

Jeffery Harris, MD, PhD, Shusheng Gong, MD, PhD

One of the well-recognized causes for stapedotomy failure is incus erosion or necrosis secondary to a loose crimp of a prosthesis. Recently, a new piston prosthesis was introduced that permits facile, tight self-crimping when heat is applied to the wire. In order to substantiate the favorable initial observations with the Gyrus SMART piston, this study was undertaken to compare these results (N=26) with those obtained with a stainless steel or platinum ribbon prosthesis (N=28 according to the guidelines established by the AAO/HNS Committee on Hearing and Equilibrium. Consecutive cases performed by the same surgeon were analyzed. The stainless steel piston and platinum ribbon piston showed a PTA of 22.58 dB hearing improvement and a residual PTA air-bone gap of 6.38 dB. The SMART prosthesis showed a PTA of 25.33 dB hearing improvement and a residual PTA air-bone gap of 7.07 dB. These differences were not shown to be statistically significant (p>0.05). Results demonstrate that experienced surgeons may achieve comparable results with both prostheses. However, the ease of selfcrimping and the tightness of the crimp may provide advantages that have longterm benefits. The issue of a potential nickel allergy to the SMART piston prosthesis will be discussed

> Jeffery Harris, MD, PhD University of California, San Diego 200 West Arbor Drive, 8895 San Diego, CA 92103

Enhanced Hearing in Heat-Activated Crimping Prosthesis Stapedectomy

Moises Arriaga, MD, Douglas Chen, MD, Rebecca Arriaga

Objective: Compare short-term hearing outcomes with a heat-activated crimping

versus mechanical crimping stapedectomy prosthesis.

Study Design: Retrospective chart review. **Setting:** Tertiary care neurotology referral center

Patients: 100

Intervention: Laser stapedectomy **Main Outcome Measures:** Audiometric

Methods: Retrospective study comparing one-month post op hearing in 50 consecutive mechanical crimp prostheses stapedectomies versus 50 consecutive heat-activated crimp prostheses stapedectomies.

Results: While the preoperative hearing characteristics were not statistically different, postoperative hearing was significantly improved for postoperative means air-bone gap (3.8 dB) and percent of patients with <10 dB gap and <15dB gap.

Conclusion: Heat activated crimping prostheses may enhance stapedectomy hearing outcomes versus mechanical crimping prostheses. The effects of case selection and long term incus necrosis require prospective longitudinal analysis.

Moises Arriaga, MD 420 East North Ave. Pittsburgh, PA 15212

Cholesteatoma in the Normal hearing Ear

Eric Smouha, MD, Javanshir Javidfar, BS

Objective: Surgical treatment of cholesteatoma in ears with normal or near-normal hearing represents a challenge, in that complete removal of disease may require sacrifice of the ossicular chain. Our aim was to identify the predictive factors and surgical strategies that favor hearing preservation in these patients.

Study design: Retrospective case review.

Setting: Tertiary otologic referral center

Patients: 54 patients were identified who had cholesteatoma and a preoperative speech reception threshold (SRT) of <25 dB. Complete audiometric date were available in 51.

Intervention(s): All patients had complete surgical removal of cholesteatoma. When indicated, ossicular reconstruction was performed at the time of the initial surgical procedure.

Main Outcome Measure(s): Early and late postoperative hearing thresholds, recidivistic disease, need for additional surgery.

Results: The pure-tone average was preserved to within 5 dB of pre-operative level in 71% of patients, but this declined to 57% long term. An intact ossicular chain was found in 70 of the cases, and could usually be preserved at surgery.

However, maintaining an intact ossicular chain resulted in hearing preservation to within 7 dB in only 77% of cases. Similar hearing outcomes resulted after ossicular reconstruction, and in open vs. closed mastoidectomies. The recidivism rate was 19% and was not influenced by preservation of the ossicular chain. **Conclusions:** Preservation of hearing is often possible in cholesteatoma presenting with normal or near-normal hearing levels. Preservation of the ossicular chain does not routinely lead to hearing preservation, however, and should not be allowed to compromise the complete removal of disease.

Eric Smouha, MD State University of New York HSC T -19 Stony Brook, NY 11794

Revision Tympanoplasty Using Subcutaneous Scar Tissue Graft

Hamid Djalilian, MD

Objective: To evaluate the success rate of subcutaneous post-surgical scar tissue as graft material for revision tympanoplasty operations.

Study Design: Retrospective case review.

Setting: Tertiary referral center.

Patients: 35 patients who underwent revision tympanoplasty with or without mastoidectomy procedures and 36 patients undergoing primary surgeries who had all the data necessary for the study and a minimum follow up of 6 months. The mean follow-up period was 12 months (range, 6 to 18 months). Mean age, perforation size, cholesteatoma presence, time required for harvesting, and adjunctive mastoidectomies were similar between the two groups.

Intervention(s): The patients undergoing revision tympanoplasty had graft material harvested from the subcutaneous scar tissue. In the control group temporalis fascia graft was used as graft tissue.

Main Outcome Measure(s): The rate of perforation closure and post-operative hearing change was measured.

Results: In the scare tissue tympanoplasty, 32 (91%) of 35 patients had successful closure of the TM perforation, whereas in the control group, the success rate was 92% (p>0.05). Mean post-operative pure tone average improvement was 21dB in the scar tissue tympanoplasty group and 18 dB in the control group (p>0.05).

Conclusions: Subcutaneous scar tissue is as successful in perforation closure and hearing improvement as temporalis fascia. The use of subcutaneous scar tissue graft is advantageous to other graft materials used in revision tympanoplasty operations in that it can be harvested through the same incision does not add to the operative time, and does not carry the cost or risk of acellular dermis.

Hamid Djalilian, MD Charles Drew University 12021 S. Wilmington Ave. Los Angeles, CA 90059 Role of Prophylactic Antibiotics in Reducing Postoperative Infection Rates in Mastoid and Middle Ear Surgery: Implications of the JCAHO Requirement for Postoperative Infection Rate Reporting

Natasha Pollak, MD, William Kinney, MD, MPH, Taylor Tidmore, MD

Objective: The use of prophylactic preoperative antibiotics in mastoid and middle ear surgery has been controversial. In light of equivocal prospective studies and new JCAHO requirements for reporting of postoperative infection rates, we expect an increase in use of perioperative antibiotics in otologic surgery. Study goals are: first, to report postoperative infection rates as a function of surgery duration, ASA rating, and preoperative infection status; second, by stratifying patients in the above categories preoperatively to identify patient populations at high risk of postoperative infection.

Study Design: Retrospective chart review

Setting: Tertiary referral hospital

Patients: The most recent 144 patients who underwent middle ear and mastoid at our institution were included in the chart review. Patients with incomplete records, or those without follow-up appointments, were excluded.

Interventions: Patients who undergo otologic surgery at our institution do not routinely receive preoperative prophylactic antibiotics. Postoperatively, most patients receive prophylactic oral cephalosporins and antibiotic eardrops.

Main Outcome Measures: The postoperative infection rates are reported as a function of the following variables: presence or absence of preoperative infection, duration of operation, type of operation, and ASA rating.

Results: Results indicate a low overall incidence of postoperative infection despite the decision to routinely forego preoperative antibiotics.

Conclusion: This is the first study to report otologic postoperative infection rates as a function of duration of surgery and ASA rating, a reporting formant now required by JCAHO. Postoperative infection rates were low in most categories. Number of patients in some categories was insufficient to draw valid conclusions. Further study is needed.

Natasha Pollak, MD University of Missouri Healthcare, Columbia, MO 75212

Discussion of preceding papers:

Sam Kinney Moreland Falls, OH

These papers are now open for discussion. Could we please have the lights up? Dr. Shelton will lead this discussion.

John McElveen Raleigh, NC

To Dr. Poe first of all I want to commend him on a superb presentation. He is scientifically accurate and has great videos. Dennis, three questions. Do you inject the area around the eustachian tube? Does that distort the contour that you are going to be trying to change? Secondly, this really smacks closely very closely of thyroplasty and I am wondering if you have talked with some companies about potentially doing the same thing for the ET that they are doing to the larynx and lastly are you aware of a barb or quill suture being used. This may facilitate suturing in this difficult area.

Dennis Poe Boston, MA

Thanks, John. Yes, the injection does distort things and that is why it is very important to make some judgments preoperatively. I use slow motion video for that to judge how big a graft I will need and exactly where does it need to be placed. Also, lying supine distorts the preoperative image because the valve is now much more full when they are supine. Re: Thyroplasty, that is where I get most of my ideas. I think it is very applicable so we have to maintain vigilance of what is going on in the whole specialty. Absolutely, I am interested in that quill suture. I look forward to speaking with you about this.

Robert Gravis San Diego, CA

For Dr. Pollock, while you did not use preoperative antibiotics I note that they are commonly used postoperatively. Why do you do that?

Natasha Pollock Columbia, MO

Thank you for the question but I do not have an answer for you. We did not have any studies to guide us to help us choose our postoperative antibiotic regimen so this study focused on the preop part rather than the postop.

Herbert Silverstein Sarasota, FL

I would like to discuss three papers and make three comments. Dennis, wonderful work. I was wondering if you had considered using Dr. John Shea's technique of putting a tube into the ET through the middle ear in those cases that did not work out. To Jeff Harris, tell us how you can compare results from different sized diameter pistons. As you know, a .4 piston gives a conductive hearing loss in the lower frequencies which makes it difficult to compare unless you are comparing the exact diameter in both of these series. And to Dr. Smooha, wonderful paper. Please let us know how to take out a cholesteatoma via a tympanotomy.

In tympanotomy we elevate the flap but don't need to repair the drum because the TM is intact.

Dennis Poe

Boston, MA

Thank you, Herb. I have considered using the Teflon catheters that Drs. Shea and Emmett are using in the ET. It will cause some bulk and perhaps it can work. I have been contacted by a couple of patients who have failed that technique so nothing is perfect. We will keep looking at other solutions. It is hard to keep things in place in the ET and that is my concern about using aspirating catheters.

Jeffery Harris

San Diego, CA

Herb, thank you for that question. There was only one patient with a .4mm piston so I don't think the data would be different.

Glen Knox

Jacksonville, FL

This is for Drs. Harris and Arriaga. Both are excellent presentations. I would question the concern of nickel allergy with the Nitinol prosthesis. Nitinol has had extensive use in biomedical application for more than twenty years without evidence of allergic reactions and this includes orthodontic arch wires and endovascular stents. The combination of nickel and titanium may change its antigenicity, also, the SMART prosthesis is coated with pure titanium. Also, consider how toxic mercury is and probably more than half the people in this room have silver mercury amalgam dental work. Thank you.

Jeffery Harris

San Diego, CA

I don't know if nickel allergy will play an important role but I raise this question I had two patients that had a reaction and because nickel allergy is very prevalent in the population. So we ask our patients and test them if they think they have an allergy. I have tested three patients who turned up to have an allergy to nickel.

Moises Arriaga

Pittsburgh, PA

I echo what Dr. Harris said. The one concern is the one delayed SNHL and even though there is a coating on the prosthesis at least on the ribbon part and we can have delayed losses with any technique. We have to be vigilant and identify any potential issues and not dismiss concerns because we are coating the devices and because they have been used in other areas.

Richard Wiet

Chicago, IL

Jeff, you mentioned longer term studies may point out problems with incus necrosis and I have seen that with the SMART piston. Has others in the room seen this and what precautions do you take—turning down the laser?

Jeffery Harris

San Diego, CA

Well, let's see a show of hands. How many have seen incus necrosis. Two! I did speak with Rick Friedman earlier and he told me that one of the reps told him that the laser may cause shortening of the prosthesis. You very well might want to consider using a slightly longer piston to prevent dislodgement. I have not seen this but keep it in mind. I have noted that when lasering the shepherd's crook I can see heat activation on either side of where I am crimping. I use .5 to .7 watts with .1 millisecond duration. Sometime I have to go to 1 watt with .2 ms duration.

Moises Arriaga

Pittsburgh, PA

We have been very cautious about the lasing issue and I use .5 watt, single pulse at .1 millisecond. This would be an interesting area to study histologically in animal preparations. We did try to lase lower on the shaft—you really have to be on top of the device.

Robert Muckle

Denver, CO

I have been convinced that the prosthesis does get a little shorter so I use one size longer and I have not had any patients have balance issues. I wonder about the crimp always being tight enough. Have either of you, Jeff or Moises, had that problem and what did you do about it.

Moises Arriaga

Pittsburgh, PA

It is not amenable to crimping manually and some of the animal data suggests that you may be injuring the mucous membrane on the incus trying to combine laser crimping with manual crimping. I, too, have noted a slight shortening especially after everything is in place and you push on the piston at the fenestra and it tends to move and then you change it out for a longer one. It is fairly easy to remove and replace.

Herbert Silverstein

Sarasota, FL

One other point is that the prosthesis is measured at an exact dimension and we all know that there are variations in the diameter of incus long processes. So when you crimp it down it may not close all the way if the incus is flatter. On a narrow incus or a smaller incus it will tighten more.

Sam Kinney

Moreland Falls, OH

Thank you all for your questions. Our next presentation is something I have been looking forward to. I have asked Dr. John Carey to select some colleagues to help

bring to us some information on what is happening in research in the area of vestibular physiology particularly Meniere's disease and so our next panel with be Dr. John Carey, Dr. Zolten Vass, and Dr. Alec Salt to bring us up to date.

Presentations:

How Endolymphatic Volume is Regulated and How it is Relevant to Endolymphatic Hydrops. Dr. Sault

Alec N. Salt, Ph.D.

Mechanisms of endolymph homeostasis in the inner ear.

Endolymph is unique both in terms of its composition and in the processes underlying its regulation. In contrast to other extra cellular fluids, endolymph has higher potassium and lower sodium content, although the precise composition varies substantially between different parts of the inner ear. Endolymph is also not secreted in volume and in the normal state does not flow from one region to another, as other fluids do. Instead, its ion composition is maintained by local ion transport processes that recycle ions between endolymph and perilymph with no associated water flux yet demonstrated. Under abnormal conditions, when endolymph volume is disturbed, volume flow can play a part in the recovery process. Endolymph volume movements occur passively, depending on the mechanical properties of the membranous walls bounding the endolymphatic space. The saccular membranes appear to be the most compliant, so flow is directed there in a manner similar to that of air moving towards a "weak spot" of a balloon. Dilation of the endolymphatic sinus, a membranous structure between the saccule and the endolymphatic duct, seems to play a part in volume regulation. It is thought that when the sinus is dilated, pressures in the labyrinth will drive a greater volume of endolymph into the endolymphatic sac before the endolymphatic duct is closed by the sinus membrane. The sinus may thus act to regulate endolymph entry into the sac in manner that will correct endolymph volume changes. Endolymphatic hydrops could result from dysfunction at the levels of the endolymphatic sac, endolymphatic duct or endolymphatic sinus.

Trigeminal Vascular Efferent Innovation of the Inner Ear. Dr. Vass

The Effects of Intratympanic Gentamycin. Dr. Carey

Physiological and structural changes in the labyrinth after intratympanic gentamycin treatment

Human and animal studies are beginning to elucidate the sites and degree of damage necessary for intratympanic (IT) gentamycin to control vertigo in Meniere's disease. Tests of the human angular VOR with head thrusts before and after IT gentamycin suggest that those who have greater loss of semicircular canal function are more likely to have vertigo control. Even a single dose is often enough to sufficiently reduce vestibular function, but the loss is usually less

severe than that seen after labyrinthectomy or vestibular nerve section. In chinchillas, a single IT gentamycin treatment severely reduces ipsilateral vestibular afferent modulation in response to vestibular stimulation. However, afferents continue to fire spontaneously and have normal galvanic sensitivities, implying that the spike initiation zones are not damaged. Histological and ultrastructural examinations of the vestibular end organs show that IT gentamycin treatment severely reduces vestibular type I hair cell density. Type II density is not significantly reduced, but their stereocilia are often lost, which likely explains the loss of afferent responses to head acceleration. Synaptic specializations on remaining hair cell bodies are preserved, and this likely explains the preservation of spontaneous vestibular afferent activity. The emerging picture is that IT gentamycin treatment works by creating a selective type I hair cell and stereociliary lesion. Preservation of type II hair cell bodies and synaptic activity may maintain vestibular afferent activity, making this lesion distinctly different from surgical labyrinthine ablation. The central compensatory mechanisms may benefit from the preservation of baseline firing.

Sam Kinney Moreland Falls, OH

It is quite clear we could have used a whole day on this subject but I think this has been a fabulous update. We are obviously going to have to think some different thoughts about how the mechanisms of the inner ear fluids are taking place. I am going to let Dr. Carey take questions from you if you have any.

Michael Ruckenstein Philadelphia, PA

John, Drs. Chen and Harrison from Toronto showed a number of years ago in the chinchilla model a differential cochlear toxicity versus vestibular toxicity ratio that differed considerably from that we see in the human. And that the relatively minimal cochlear toxicity was quite maximal in the gentamycin treated chinchillas and the vestibular toxicity was not quite as dramatic at the onset. Did you consider the dose treatment for the animals? Do you think you got enough gentamycin delivered to exert a full vestibular effect?

John Carey

That is a good question. The round window membrane in thinner in the chinchilla and you might predict that more gentamycin gets in. There are huge concentration gradients that get set up and much more of the cochlear really never

sees that drug. Alex is really the expert on the distribution of the drug once it gets into the endolymph and I would like to hear his comments.

Alex Salt

The human has a much longer cochlea which is almost twice as long as the chinchilla. This means that the amount of drug reaching the high regions in the human cochlea is far less that what is seen in the animal model. Comparing toxicity amounts is really very difficult because of the difference in the length of the cochlea.

John Carey

There are admittedly a lot of problems trying to come up with any animal model because of the species differences but I would submit that we are seeing at least the comparable finding of a partial lesion in both cases and I think that there is something to work with.

Herbert Silverstein Sarasota, FL

In patients we can get a 100% ice water caloric reduction after gentamycin and yet some of these patients will have vertigo attacks afterwards even though we have no response. If you do a labyrinthectomy or a nerve section on those patients you make them better. Obviously, even thought we think we have completely destroyed the entire labyrinth with the gentamycin it is a partial lesion is some cases. Alex, in 1963 I found out that the level of potassium was very low in the endolymphatic sac which is just the opposite in the endolymph. There is also high protein content and a lot of enzymatic activity showing dead cells in the sac. Do you have an explanation of why there is so much difference in the biochemistry of the sac versus the endolymph in the vestibule?

Alec Salt

If you look at the histology of the sac and the different conditions we see remarkable histologic changes. You can see the homogenous substance that partly fills the sac in the normal ear. This disappears once you inject drugs into the inner ear and one notes a lot of macrophages. Helga Rascanan thinks these cells are responsible for digesting the substance in the sac and if you reduce endolymph volume then this substance gets very dense and there are really quite dramatic cellular changes as well. So I think the sac is still a very dynamic ion transport structure and in the normal state it is sort of balanced between these two possible extreme states which makes this a very interesting abstract.

John Carey

Following up on Dr. Silverstein's comments, we found that there was a poor correlation between our head thrust VOR findings and caloric testing. I think they are different test. Remember that the caloric test really produces a very low frequency endolymph movement as opposed to this very high frequency and I

would argue that more physiologic tests are needed. We are testing different things so I'm not certain we get a complete handle with one test or the other. I think it is good to have both. We also do not have a great test of high frequency otolithic function that we can apply in the clinic. We do know that gentamycin is more toxic to the crista in the macula and that is maybe where the residual vertigo is coming from.

George Gates Seattle, WA

Could Dr. Vass comment on the recent findings that migraine headaches is associated with atrial septal defects of the heart and white lesions of the cerebellum and many people are now getting the defects closed endovascularly with cessation of the migraine. How does this relate to your concept of migraine and in particular basilar migraine?

Zolten Vass

Good question and I don't know the answer.

John Carey

There is also a very strong central component of migraine. One of the fundamental problems is electrical disturbance not only in the cortex but in the brainstem. A recent paper from the London group showed brainstem electrical activation after nitroglycerin induced migraine in susceptible subjects. The PET CT on the left side in this slide you see that the dorsal portions on the floor of the fourth ventricle light up. This is the area where the vestibular and auditory nuclei are located so it is clear that the brainstem has abnormal electrical activity in the course of migraine and I think there could very well be a central component to migraine. The whole issue of patent foramen ovale and the issue of small emboli being related to migraine is very controversial and I know the neurologist do no as yet have a consensus on whether or not that is a good procedure to perform for migraine. There is probably a huge placebo effect in migraine but there is definitely a role for central component in migraine and I think this is why we see a lot of patients with vestibular or auditory symptoms who do not have a peripheral deficit and we throw our hands up and we call it recurrent vesitbulopathy. Maybe we call it vestibular Meniere's disease or we call it vestibular migraine but we really don't have a handle yet on what is going on. I hope that functional imaging in these patients will help us sort this out.

Richard Kopke Oklahoma City, OK

John, if you follow these animals for a longer period of time do the type 1 hair cells return and do the type 2 hair cells repopulate their stereocilia bundles. Do your patients that you treat with gentamycin and follow over time have a recovery of their head shake function, especially when they might become symptomatic again?

John Carey

We have seen recovery of the VOR reflex gain in some groups of patients. We don't have a good handle on whether that correlates with recurrent symptoms. We did afferent measurements on animals at 6 and 12 months and we did not see recovery of the modulated responses and we have not seen recovery of type 1 hair cells. There is good evidence from others that hair cells do repair themselves and there is a lot of ongoing work about regeneration. There is certainly good evidence for repair of sterocilia and I think there is probably some peripheral recovery.

Sam Kinney Moreland Hills, OH

I want to thank the panel profusely for this very stimulating presentation and particularly those that have come a long distance to be with us. I am certain you will have a chance to talk with them here the rest of the day. We now have a twenty minute break with the exhibitors. Please return on time. Thank you.

Session: Inner Ear Medical Treatment, Research

Distribution of Low Frequency Cochlear Nerve Fibers in the Auditory Nerve: Temporal bone Findings and Clinical Implications

Jose Fayad, MD, Fred Linthicum Jr., MD, Manuel Don, PhD

Hypothesis: Low frequency cochlear nerve fibers travel on the outer surface of the auditory nerve adjacent to vestibular nerve fibers in the distal part of the IAC. **Background:** There is a misconception that low frequency cochlear nerve fibers travel within the core of the cochlear nerve surrounded by high frequency nerve fibers.

Methods: Analyzed temporal bones with total loss of upper spiral ganglion cells due to different etiologies (n=6) and traced the corresponding fibers into the distal IAC. Counted spiral ganglion cells for each segment of the cochlear (I-IV) according to Ott et al. and measured the amount of degenerated nerve.

Results: There was near total degeneration of the upper spiral ganglion cells in these bones. Corresponding low frequency cochlear nerve fibers traveled on the outer surface of the cochlear nerve adjacent to vestibular nerve fibers in the distal part of the IAC.

Conclusion: These findings explain low frequency SNHL in 10% of patients with acoustic neuroma and have clinical relevance in the diagnosis of these retrocochlear lesions by Stacked auditory brainstem responses.

Jose N. Fayad, MD 2100 W. Third St. First Floor Los Angeles, CA 90057

Selective Gene Expression Profiling in Supporting Cells from the Inner Ear of the Rat

Ricardo Cristobal, MD, PhD, P. Ashley Wackym, MD, Joseph

Cioffi

Christy Erbe, Joseph Roche, Paul Popper

Hypothesis: The role of supporting cells and hair cell precursors can be evaluated selectively using laser capture micro dissection and global gene expression profiling techniques.

Background: Multiple studies demonstrated hair cell regeneration in the vertebrate vestibular sensory epithelia. However, little is known about the gene expression patterns of supporting cells and hair cell precursors. We recently reported a method for selective acquisition of RNS from individual cell populations from the inner ear sensory epithelia using laser capture microdissection.

Methods: We have performed expression profiling of RNA microcaptured from the supporting cell and hair cell populations using a rat microarray chip containing 29,842 probes with unique UniGene identities.

Results: There were 11,008 individual genes present with good quality flags. The analysis demonstrated 1556 genes expressed in supporting cells and 3615 in hair cells only. With the supporting cell only genes 167 are well annotated. Among these we identified genes involved in cell cycle regulation and proliferation, consistent with the presence of hair cell precursors or stem cells within the supporting cell population. Other genes of interest identified are involved in development and neurogenesis, calcium homeostasis and metabolism, signal transduction, cell surface receptors and cytoskeletal proteins.

Conclusion: We present the first selective analysis of the supporting cell transcriptome. This study identified genes involved in cell proliferation, and provides a deeper understanding of the role of supporting cells. Furthermore, some of the identified genes may be used as supporting cell markers.

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Hyperbaric Oxygen Therapy for Sudden Sensorineural Hearing Loss: A prospective Trial of Patients Failing Steroid and Antiviral Treatment

Corinne Horn, MD, MS, Harvey Himel, MD, MPH, Samuel Selesnick, MD

Objective: To investigate the safety and efficacy of Hyperbaric Oxygen Therapy (HBOY) in adult patients with sudden sensorineural hearing loss (SSNHL) who fail standard of care steroid and antiviral therapy.

Study Design: A prospective cohort study.

Setting: An urban tertiary care referral center.

Patients: 9 adult patients presenting with SSNHL from December 2002 through February 2004. Patients with acute onset of SSNHL of >30dB in 3 contiguous frequencies who failed to show audiometric improvement after 2 weeks of systemic steroids and antivirals ere enrolled.

Interventions: Study patients received HBOT at 2.0 atmospheres for 90 minutes while breathing 100% oxygen under a clear plastic hood in the chamber. Treatments were administered daily for 10 days over a 2 week period.

Main Outcome Measures: Pre- and post-HBOT mean hearing gains measured in dB for pure tone audiometry at 0.5,1,2,3 4KHz for bone and additional 8KHZ for air; pure tone averages for air and bone; speech reception thresholds; and speech discrimination levels. Patient reported subjective recovery rates (complete, substantial, partial, and not improved) were recorded.

Results: One patient had substantial improvement, 1 patient had partial improvement, and 7 patients had no improvement in their bone line thresholds. 2 patients had complication of serous otitis media requiring myringotomy and pressure equalizing tube placement. No other complications were observed. **Conclusions:** Secondary HBOT after failure of systemic steroid and antiviral

Conclusions: Secondary HBOT after failure of systemic steroid and antiviral therapy is not associated with hearing gains in patients with SSNHL

Corinne Horn, MD, MS Weill Cornell Medical College 520 E. 70th St. #541 New York, NY 10021

Etanercept Treatment for AIED: Results of a Randomized, Double-Blind, Placebo-Controlled Study

Jeffery Harris, MD, PhD, Stanley Cohen, MD, Michael Weisman, MD, Angela Shoup, PhD

Purpose: Recent animal data supports the role of TNF-Alpha in inner ear inflammation and a recent open label trail of etanercept (ETA) suggested potential treatment benefit in AIED. Therefore, we conducted a pilot placebo controlled trail of etanercept in AIED patients.

Methods: 20 AIED patients were enrolled in a 12 week blinded placebo (PLA) controlled randomized clinical trial of ETA 25 mg sc twice weekly. History of AIED and a previous documented response to high dose corticosteroids was required for enrollment. Pts. received treatment for 8 weeks with a 4 week follow-up off treatment. Serial audiograms were obtained along with evaluation of auditory acuity, tinnitus and vertigo severity by VAS(0-100), and hearing disability as measured by a validated questionnaire (PIPHL). The primary study endpoint was an improvement in pure tone threshold (PTA) of 10dB in two consecutive frequencies and/or improvement in speech discrimination of >12% at week 8.

Results: 17 subjects (8 ETA, 9PLA) completed the trial. 1ETA and 2 PLA subjects achieved the primary endpoint (P>0.999). 1 ETA and 1 PTA pt demonstrated improvement in auditory acuity, vertigo severity by VAS and

hearing disability. These 2 pts also met the primary endpoint. No safety issues were observed.

Conclusions: The results of this pilot trial demonstrate that ETA 25 mg twice weekly for 8 weeks was no better than placebo for treatment of AIED in this patient population.

Jeffery P. Harris, MD, PhD University of California, San Diego 200 West Arbor Drive, 8895 San Diego, CA 92103

Corticosteroids are Otoprotective for Hair Cells and Stimulate Neuritogenesis by Auditory Neurons While Inhibiting Fibroblastic Outgrowth in Vitro

Thomas R. Van De Water, PhD, Thomas J. Balkany, MD

et al.

Hypothesis: Corticosteroids protect hair cells from oxidative stress-induced loss and promote neuritogenesis while inhibiting the outgrowth of fibroblasts in vitro. **Background:** Both systemic and round window membrane applied corticosteroids have been successfully used to treat some patients with sudden idiopathic sensorineural hearing loss. Dexamethasone has also been shown to be protective against sound trauma in an animal model. Triamcinolone acetonide has been applied into the scala tympani of cochlear implant patients as part of a soft surgery approach for patients with residual hearing.

Methods: Organotypic cultures of P-4 organ of Corti and spiral ganglion explants were the in vitro test systems. A naturally occurring ototoxin produced by oxidative stress (i.e. 4-hydroxy-2, 3-nonrenal: HNE) was the ototoxic challenge for hair cells. Hair cell counts were done on phalloidin stained explants and spiral ganglion neuritic outgrowth was detected by anti-neurofilament staining. Neuritic and fibroblast outgrowth was measured by image analysis. The corticosteroids tested on ganglion explants were: triamcinolone acetonide: dexamethasone; and methylprednisolone.

Results: Triamcinolone acetonide protected auditory hair cells in the organ of Corti explants from damage and loss caused by exposure to toxic levels of HNE. Both triamcinolone acetonide and dexamethasone stimulated neuritic outgrowth and prohibited fibroblastic outgrowth from the spiral ganglion mini-explants. **Conclusion:** Triamcinolone acetonide and dexamethasone stimulate a neuritogenesis response from auditory neurons and inhibit outgrowth of fibroblasts. The results of this in vitro study support the use corticosteroids during cochlear implantation.

Thomas R. Van De Water, PhD University of Miami Ear Institute 1600 NW 10th Ave, RMSB 3160 Miami, FL 33136

Sam Kinney Moreland Falls, OH

The last five papers are now open for discussion. Please state your name and location.

Tom Balkany Miami, FL

Jeff, that was a great paper and I enjoyed your presentation. However, as a clinical otologist would you think that Embrel was useful if it only maintained an improvement that occurred after steroid use rather than improved on the improvement that occurred?

Jeff Harris La Jolla, CA

That is a difficult question to answer because obviously the patients would like not to lose further hearing so in some way maintenance of hearing could be a good end point.

Tom Balkany

I know that is not what your study....

Jeff Harris

Exactly, but if one were on Embrel and had maintenance of hearing we would suggest that they continue but if their hearing fell then obviously it is not doing what it is supposed to do because it is trying to be a steroid sparing drug and that is why it is used to treat arthritis.

Tom Balkany

Right, in this case one of the criteria for entry was an improvement on steroids.

Jeff Harris

Yes

Tom Balkany

If you were to look back at the data now do you think that the embrel did maintain that improvement that was the entry criteria?

Jeff Harris

When we looked at the ones that did improve, the ones that were in the ETA group and improved, they fell away after time. We had one patient that did

improve and after 15 months he failed and nothing could bring back the hearing. So it is a wonderful question and it is something we are struggling with. I know Dennis Poe (if in the audience) may want to say what his finding are as well but maintenance of hearing is important but that is not exactly what we were testing.

Mansfield Smith Davis, CA

From 1996-2000, I saw seven physicians who had a sudden hearing loss. Our current medical system causes delays in seeing patients—in some cases it may take 1-2 months to see an Otolaryngologist or Otologist. At any rate, physicians would call in the middle of the night or early in the morning and I would bring then down and treat them exactly like a stroke or heart attack. They would be anticoagulated and given steroids. Three of four of these doctors came back but they were treated within 12 hours, 2 within 6 hours which is what the requirement is for stroke or cardiac disease. There maybe some similarities between the vasculature of the inner ear and the heart. Three of four doctors came back, two of them to surprisingly normal levels, almost the same as the other ear. This is an observation and not a controlled series. The problem is the delay is seeing these patients. We need to design a study where we can see these patients early and treat them exactly as if they had had a stroke or a heart problem. I would be interested in your comments.

Sam Kinney

Doctor Horn or Dr. Selesnick do you want to respond.

Sam Selesnick New York City, NY

Thank you for your insights. We certainly saw in the literature that there is a big break at about less than two weeks in between two and six weeks in terms of recovery from HBO. These patients where treated from a primary standpoint and a good number of those will resolve spontaneously so it is really tough to differentiate exactly what the cause was.

John House Los Angeles, CA

Either Dr. Horn or Dr. Selesnick, patient seven did not have much of an improvement, very minimal hearing loss to start with if I read the data correctly. What is the cost of the HBO treatments?

Corinne Horn New York, NY

That patient did have a significant improvement in speech discrimination and still had, I think, moderate speech reception thresholds. We are happy with relative improvements but the patients care about is whether they are hearing well or not. So if they go from a SDS of 20% to 60% how much are we really offering to them? There was no cost for the HBO treatments to the patients so I don't know actual costs.

Dennis Poe Boston, MA

Thank you Dr. Harris for that really excellent paper. I really don't have much more to add other than from Dr. Balkany's comments. I was going to make the same observations. We all appreciate your putting together this type of controlled randomized trial to definitively answer certain question like this. I also share your idea that the other disease modifying rheumatologic drugs do need to be looked into. Perhaps they do have some promise down the line. There are new ones coming out all the time so other trials looking at both end points of hearing improvement or at least stabilization would be of interest. Thanks.

Joe Farmer Durham, NC

I want to second what Mansfield said. I have for years been dealing with altered atmospheric pressures and the effects on the organs of hearing and balance. The question of HBO for sudden deafness has frequently come up. There is a lot more to this story that we don't have time for now. HBO is not expensive. The problem with oxygen in micro-circulation to the inner ear is that higher tensions of oxygen induces a vasospasm so with oxygen you've got a vaso-spastic circulatory condition which may add to what was already there, it may not but you then are dependant on passive diffusion of oxygen and it won't passively diffuse much more that maybe 4 mm no matter what the pressure differential to drive it in is. We should continue to study this treatment modality but it should not be part of routine treatment now. You had two patients with barotrauma and that is about the frequency you see when treating patients for other things. Thank you.

Tom McDonald Rochester, MN

Jeff, those are great papers and you continue to be a giant in this country in otology and I admire your material particularly your attempts to address patients with immune mediated otologic diseases. Eric Mattison whom you know well worked with me in Rheumatology at Mayo. We have a small cohort of about 90 patients with this devastating disease. We conducted a trial much like yours with embrel, same results, dismal as we continue to try to treat them. We see marginal results with methotrexate. The only break through is that they make good CI candidates. We have not found the heat shock proteins to be a very helpful marker. There is information from Ann Arbor that supports this. Can you comment on this?

Jeff Harris

That is a very difficult question for me to answer in two minutes. A study from Boston which was controlled that looked at prednisone responsiveness and whether or not that particular test or marker is useful in predicting steroid responsiveness in active bilateral disease, the incidence was 89%. It our studies it was around 58%. That doesn't mean you can't treat people with steroids and not get a benefit; it just means that this is a marker for demonstrating steroid

responsiveness. I can not answer it anymore than that. I have tried to continue to be objective and use it myself. If you find it not helpful then don't use it. I find it useful because if the patients are positive and the treatment is not working, I will increase the dose of steroids. If it is negative and it does work I just say that is it one of those patients that may have a subset of this disorder. A viral infection of the inner ear is not going to be an autoimmune problem but they may respond to steroids. They should be negative in testing for steroid responses. We really don't understand this disease and until we do, we should to search both for a better treatment and for a better way of diagnosing it. Thanks for the questions and compliments.

Sam Kinney

Thanks to all of the discussants. The final presentation of our meeting should be quite interesting. I asked Phil Daspit to chair a panel on an update on stereotactic radiosurgery. I will let him introduce his outstanding speakers.

Phil Daspit Phoenix, AZ

Sam, thank you very much for asking me to put this panel together. I have certainly enjoyed doing this. I have been involved in radiosurgery for four years now using the Gammaknife and one year using the Cyberknife. In Phoenix, I treat patients in conjunction with a neurosurgeon and a radiation oncologist. I feel quite strongly that we as a subspecialty need to be very involved in treating patients with this modality. There is absolutely no question in my mind that radiosurgery will play an increasingly larger role in the definitive treatment of lesions in and around the temporal bone. There is now much information for patient review on the internet. Most patients now come having reviewed a significant amount of information regarding the particular problem. In some cases, the patient may know more that you. Why do we need to be involved?? The complications of current treatment strategies lie in our area of expertise. Dizziness, hearing loss and facial nerve problems. There has been a gradual reduction in the doses of radiation used so that, now, it is very rare to see neurosurgical problems after treatment—i.e. hydrocephalus, radiation necrosis or trigeminal nerve injury. I encourage all of you to develop an interest in this area and to arrange a working relationship with your neurosurgical and radiation oncologist colleagues and to go out and get trained. We must get our heads out of the sand!

Each speaker will introduce themselves in order to save time.

My first speaker is John Kresl, MD who is the radiation oncologist I work with and he will start things off by discussing radiobiology.

John Kresl MD

Several advances in technology have combined to move stereotactic radiation therapy techniques into a new era, which allows for the exploitation of fractionation of treatment. The basics of the radiobiology of the interaction of ionizing radiation with tissue will be presented. This introduction to radiobiology will be the basis of a panel discussion session to explore the potential

clinical significance of single versus multiple fraction stereotactic radiation therapy treatment schemes for vestibular schwannomas.

P. Ashley Wackym, MD

Gamma Knife radiosurgery: Neurotologic participation and technique improvement via outcomes assessment

Objective: To outline the role of a neurotologist in both treatment and technique improvement for Gamma knife radiosurgery of acoustic neuromas and other skull base tumors.

Background: Gamma knife radiosurgery is one of the available methods to treat acoustic neuromas, in addition to microsurgical resection. Neurotologists have long been associated with microsurgical resection of these tumors; however, the application of Gamma knife radiosurgery to the treatment of these tumors by neurotologists began five years ago.

Setting: Acoustic Neuroma and Skull Base Surgery Program / Tertiary Referral Center.

Study Design/Patients/Intervention: Retrospective case reviews, including quantitative assessment of treatment planning, of all patients treated by the senior author and our Gamma knife team since June 2000.

Main Outcome Measures: Gamma knife treatment plans containing MR images were reviewed at each axial, sagittal, and coronal slice. The length of the greatest displacement of the treatment plan was measured and the volume of the treatment plan that fell outside of the internal auditory canal (IAC) calculated. Preoperative MRI, audiometry, vestibular testing and facial nerve electromyography was completed. At six-month intervals postoperatively, audiometry, caloric testing and MRI were performed to determine thresholds and speech discrimination ability, vestibular function, and the size of the tumor.

Results: Tumor control was achieved in all patients. Various patterns of changes in auditory function, both in threshold and speech discrimination were observed in either positive or negative directions. We also demonstrated a small, but potentially significant shift in the treatment plan of Gamma knife radiosurgery when based on MR images.

Conclusions: Preliminary experience with Gamma knife radiosurgery indicates that this treatment method represents another option for neurotologists to use in managing patients with skull base tumors. Continued assessment of outcomes by neurotologists will contribute to the development of improved practices in Gamma knife radiosurgery treatment.

Dheerendra Prasad, MD Gamma Knife from a neurosurgical perspective

John Adler, MD CyberKnife-development and use-Is fractionation better?

Rick Friedman, MD What happens when radiosurgery fails?

Robert Jackler, MD Evidence based results.

Sam Kinney

Thanks for staying a little bit late. I now have the honor and pleasure of introducing our next President, John Niparko.

John Niparko

Thank you and thank you Sam. We have been blessed with a wonderful leader of our Society over the past year. Sam, your steady leadership has grown our collaboration with the academy and with federal payers including the CMS. You have exercised stewardship of our research and training programs, our financial matters, no small feat in this day and age of accountability. You have also put together a marvelous 138th program the last couple of days and it has been very educational for all of us. The banquet last night will foster stories for years. Your passion for otology is very evident from the Kinney family history. Your stories held all of us in complete attention. Your knowledge of otologic history and actually living some of these stories is wonderful. We have all benefited from your passion that you have for otology. Sam, thank you very much.

Safe travels and we will see you next year in Chicago.