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# TRANSACTIONS AMERICAN OTOLOGICAL SOCIETY, INC. 2001



# VOLUME 89 ONE HUNDRED THIRTY FOURTH ANNUAL MEETING MARRIOTT'S DESERT SPRINGS RESORT PALM DESERT, CA MAY 12–13, 2001



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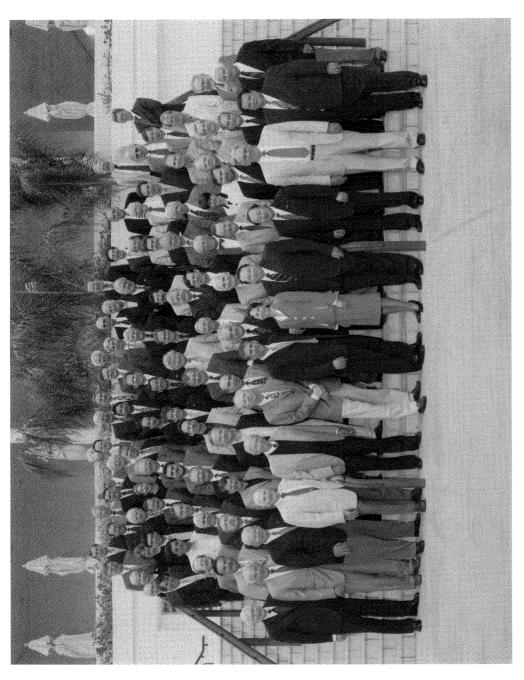
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#### INTRODUCTION OF AWARD OF MERIT WINNER

Gregory J. Matz, M.D.

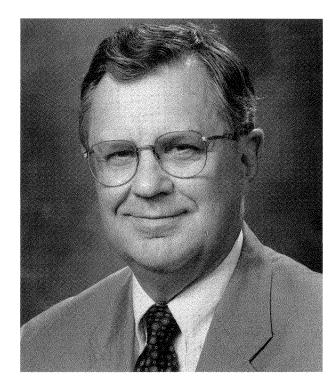
As you know, each year it's the tradition of the American Otological Society to present an Award of Merit to a person in our profession who has distinguished his or herself during their lifetime. This year it's my privilege to present this award. Our 2001 awardee was born in February of 1937 in a small town in Illinois, central Illinois, in the middle of nowhere. The town's name was Buckley. Buckley was a community of about 200 people. It was predominantly German speaking and Lutheran. Since it's located in central Illinois, it's surrounded by farms, which mostly produced corn and soybeans.

Here we see our awardee with his father who was a barber in Buckley. He was the youngest child of four. It is reported that he cried incessantly his first year of life. I think this was because he couldn't talk and our awardee went through his whole life time thinking he was a stand up comedian, which is hard to do if you can't talk. He is renowned to many for his story telling abilities.

By age two, he was blue eyed and had this innocent, angelic appearance. From grades one through eight he attended a Lutheran parochial school. He knew early in his life that he wanted to become a physician, however, his mother always hoped that he would become a preacher.

His mother ran a boarding house in hopes that this extra income would provide a better education for her sons. Later the family moved to Champaign-Urbana, Illinois that is the home of the University of Illinois. She did this so her sons could attend an academic high school. Later our awardee matriculated at the University of Illinois. He graduated from high school in 1955 and attended the University of Illinois as a pre-medical student from 1955 to 1958. This was followed by a move to Chicago so he could attend the University of Illinois Medical School there and of course he graduated with honors and was an AOA recipient.

Somewhere in our awardee's life testosterone appears. He met this lovely young lady who unfortunately was dating his best friend. Here they are pictured on one of their first dates. I've heard it from reliable sources that theirs was definitely love at first sight, at least that's one side of the equation.



Gregory J. Matz, M.D.

He marries this lovely young lady. She became a schoolteacher in LaGrange Park, Illinois, which is a suburb of Chicago and they recently celebrated their 42<sup>nd</sup> wedding anniversary.

Later he completed his internship at the University of Illinois and took his first training in OB-GYN. Along comes good old Uncle Sam. He had a tour of duty in Vietnam as a flight surgeon. In 1964 he trained flight surgeons at Brooks Air Force base in San Antonio and later he was stationed at George Air Force base in Victorsville, California. He was sent to Thailand and the Arctic Circle and indeed he became a world traveler as pictured here.

Since there was this connection to California, water, fishing and the west coast, our awardee then takes a residency at the University of Southern California followed by a two year fellowship at the House Ear Institute, a legendary group with whom he continues to practice and has made great contributions throughout the years.

He is not only a master surgeon but also a loving husband, a father of four sons and a grandfather of two. He is an avid hunter. He enjoys hunting quail, pheasant, boar, mountain goats and deer. This is a quail and this is our awardee. I didn't want you to get confused. In addition he's an avid tennis player. He is an expert fly fisherman and here he is shown with one of his best friends Bill Williams.

His fishing accomplishments are legendary. He has a boat, which is frequently sited in the waters of southern California near the Baja Peninsula. Fishing with his four boys has become an annual and worldwide event. Besides all of these many hobbies, he includes among his interests, bridge playing and being an outstanding standup comic.

With all of these accomplishments and hobbies, most importantly our awardee is a true family man. Here pictured with his beautiful lovely wife, Charlotte, four sons David, Doug, Mark and Steve and daughters in law Marla and Jill and last but not least his two very special grandchildren, Laura and Nick

He has received many honors throughout his professional life. I happen to know that the one that he is most proud of is the one he received as an outstanding alumni achievement award from the University of Illinois. This award is given to few people. Nobel Prize winners are among its recipients. I know of no one who is more deserving of this award than he.

It is with great pleasure that I present to you our 2000 American Otologic Society Award of Merit recipient to Derald E. Brackmann. Derald, in recognition of your personal integrity, leadership and outstanding contributions to Otology and Neurotology, congratulations.

#### RESPONSE OF THE AWARD OF MERIT RECIPIENT

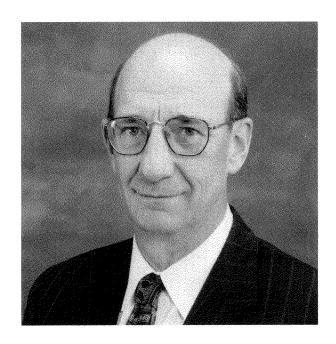
Derald E. Brackmann, M.D.

I'm overwhelmed. I'm not old enough. I certainly have a lack of hair befitting the honor. I'm glad you showed the picture that proved that I once did have hair, lots of it. It has been a wonderful career.

I have so many people to thank and first and foremost, Charlotte. She literally did everything that made all of this possible. She truly put me through school. As Greg said my dad was the town barber in this little town in central Illinois. I still have the distinction of being the only doctor that has ever came from that town and when I go home, which I still enjoy doing, we joke because you don't say how are you doing in my hometown or you get what we call an organ recital. You go through every system and organ and they'll tell you how it's doing.

Believe it or not I was shy and retiring. I really didn't talk a whole lot back in those days and when I met Charlotte, this beautiful young lady, it changed my whole life. She made me somehow feel that I was worthy of something and could accomplish something and she gave me confidence.

We were married when we were 22 and have traveled the world together. We had the opportunity to spend three months in Africa when I was between our junior and senior year in medical school and then traveled a month in Europe for \$1000. We were living in hostels, traveling and stealing food off of airplanes and so on and so forth.



But it's been wonderful honey and I'd do it tomorrow twice. Thank you so much for all you've done for me and for our family.

Howard is here and Bill was here. I was fortunate to graduate from medical school with my family and Charlotte's help. Someone defined serendipity at the Otology dinner last night and I guess that's what you would call it, just a sequence of events.

I went into OB and hated it. I was in the Berry plan and when I quit that I had to go into the service. I became a flight surgeon, which got me interested in vertigo and ENT. They sent me to California. The obstetrician that I worked with was a good friend of Jim Crabtree and had trained at LA County. He introduced me to LA County and to the Otologic Medical Group. I applied to the residency at USC and from that point on the opportunities that have come to me have been unbelievable.

Howard has provided for generations of us opportunities beyond belief. Howard I'm eternally grateful to you for all of the opportunities that you have given me and to many of my friends and colleagues, two generations of otologists.

Without Bill I couldn't be doing what I'm doing now, nor could many of us, and I'm eternally grateful to Bill as well.

The way things have happened, it's been so remarkable, that regardless of what your religion, you have to believe that some source greater than us directs things.

I thank all of you who have supported me. It's a great honor. Honey, maybe I do deserve it, I guess you allowed me to, I'm not sure I do but I surely do appreciate it. Thank you so much.

#### AWARD OF MERIT RECIPIENTS 1949-2001

1949 George M. Coates, MD 1951 Barry J. Anson, Ph.D. Theodore H. Bast, Ph.D.

1952 Edmund P. Fowler, Sr., MD

1953 Julius Lempert, MD 1954 Stacy Guild, Ph.D.

1957 Georg von Bekesy, Ph.D.

1959 Ernest Glen Wever, Ph.D.

1960 Hallowell Davis, MD

1961 John R. Lindsay, MD

1962 William J. McNally, MD

1965 Anderson C. Hilding, MD

1966 Gordon D. Hoople, MD

1967 Merle Lawrence, Ph.D.

1968 Lawrence R. Boles, MD

1969 Sir Terence Cawthorne

1970 Senator Joseph A. Sullivan, M.B.

1971 Samuel Rosen, MD

1972 Howard P. House, MD

1973 Moses H. Lurie, MD

1974 George E. Shambaugh, Jr., M.D.

1975 Catherine A. Smith, Ph.D.

1976 Harry Rosenwasser, MD

1977 Frank Lathrop, MD

1978 Juergen Tonndorf, MD

1979 John Bordley, MD

1980 Ben H. Senturia, MD

1981 J. Brown Farrior, MD

1982 William F. House, MD

1983 Victor Goodhill, MD

1984 Harold F. Schuknecht, MD

1985 Wesley H. Bradley, MD

1986 John J. Shea, Jr., MD

1987 Jack V. Hough, M.D.

1988 George D. Nager, MD

1989 Brian F. McCabe, MD

1990 Eugene L. Derlacki, MD

1991 Richard R. Gacek, MD

1992 James L. Sheehy, MD

1993 James A. Donaldson, MD

1994 Fred H. Linthicum, Jr., MD

1995 D. Thane Cody, MD 1996 F. Blair Simmons, MD

1997 Michael E. Glasscock, III, MD

1998 Michael M. Paparella, MD

1999 Mansfield F. W. Smith

2000 Robert A. Jahrsdoerfer, MD

2001 Derald E. Brackmann, MD

#### GUESTS OF HONOR 1949-2001

1974 Harry Rosenwasser, MD

1975 John E. Bordley, MD

1976 Ben H. Senturia, MD

1977 Henry B. Perlman, MD

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1999 Barbara A. Bohne, Ph.D.

2000 Derald E. Brackmann, MD

2001 James B. Snow, Jr., MD

#### SCIENTIFIC SESSIONS 2001 PRESIDENTIAL ADDRESS

## ETHICAL AND REGULATORY CONSIDERATIONS IN HUMAN SUBJECTS RESEARCH

A. Julianna Gulya, M.D.

#### **INTRODUCTION**

It is imperative that clinician-researchers have a clear understanding of the ethics and regulations applicable to the conduct of human subjects research (HSR). As evidenced by the highly publicized irregularities in HSR over the past year or so (see below) not all clinician researchers are fully informed regarding such matters. In addition, some (or many) may not be aware of the actions taken by the Department of Health and Human Services (DHHS) in response to the recent irregularities, or how they may affect current and contemplated research.

So, I hope in the next few minutes to give an overview of human subjects protections, including their history, recent changes, and possible future developments.

#### **HISTORY**

The 1947 Nuremberg Code (NC) is generally thought of as the initial articulation of principles to be followed in using humans as research subjects. Immediately after WWII, 20 Nazi physicians were tried for "atrocities committed in the name of medical science". In their deliberations, the US judges enumerated "certain basic principles". (Table I) for the conduct of medical experiments involving human beings. First and foremost amongst these 10 principles, which have come to be known as the Nuremberg Code, was the dictum that the "voluntary consent of the human subject is absolutely essential".<sup>2</sup>

In 1964, the World Medical Association first issued its Declaration of Helsinki<sup>3</sup> (DOH). This document, the 5th revision of which was ratified in October 2000, represents an attempt to "bring the stan-



dards enumerated in the Nuremberg Code into line with the realities of medical research"<sup>4</sup>, as well as the first self-regulatory effort of the medical community in the HSR arena<sup>5</sup>.

Despite the issuance of the NC and the DOH, a number of highly publicized irregularities in HSR in the 1960s and 1970s indicated that additional steps were necessary to protect human research subjects. These irregularities, many of which were chronicled by Beecher<sup>6</sup>, include the "Jewish Chronic Disease Hospital Case" <sup>7</sup>(in which live can-

#### TABLE I THE NUREMBERG CODE<sup>2</sup>

- 1. The voluntary consent of the human subject is absolutely essential.
- 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
- 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
- 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
- 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
- 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
- 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

cer cells were injected into 22 chronically ill and debilitated patients without telling them what was being injected, nor that the purpose was to "measure the patient's ability to reject foreign cells"<sup>7</sup>), and the Tuskeegee Syphilis Study<sup>8</sup>.

It was in the wake of such revelations that the 1974 National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "National Commission"). The purpose of the National Commission was "to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with these principles"9. It was also in 1974 that DHEW (the Department of Health, Education, and Welfare—now DHHS) promulgated regulations – 45 Code of Federal Regulations (CFR) 46, Subpart A<sup>10</sup> – for the protection of human research subjects, including a requirement establishing, and prescribing procedures for, IRB (Institutional Review Board) review of all DHHS-funded HSR.

In its 1979 report, known as the Belmont Report<sup>9</sup>, the National Commission articulated three principles governing HSR:

- 1. Respect for persons persons should be treated as autonomous agents, and persons with diminished autonomy are entitled to additional protections;
- 2. Beneficence efforts should be made to secure the well-being of research subjects as well as to protect them from harm; and,
- 3. Justice—the benefits and burdens of research should be distributed equitably.

Applying these 3 principles to HSR mandates (1) informed consent, (2) risk/benefit assessment, and (3) fairness in the selection of research subjects.

In 1981, in response to the Belmont Report, DHEW revised 45 CFR 46, further defining a number of parameters, including; human subjects; human subjects research; human subjects research subject to 45 CFR 46; exemptions; IRB structure and function, including expedited review; and additional protections for fetuses, pregnant women, human in vitro fertilizations, prisoners, and children.

One decade later, in 1991, 17 federal departments and agencies formally adopted the core (Subpart A) of the DHHS regulations; known as the "Common Rule" this core remains the skeleton of current regulations.

It is important for clinician-researchers to understand the broad applicability of the Common Rule. In brief, any systematic investigation designed to contribute to generalizable knowledge that involves obtaining data or identifiable information from living individuals and which is conducted by, funded by, or is otherwise subject to regulation by any Federal Department or Agency, is potentially subject to IRB review as described in the Common Rule. It is also important to note that: (1) many institutions voluntarily have expanded the Common Rule requirements to all HSR, regardless of funding source; and, (2) depending on location, there may be state and/or local laws that expand

upon the protections provided for in the Common Rule.

There are 6 established exemptions from the Common Rule<sup>11</sup> (Table II), and the Common Rule allows an IRB to use expedited review procedures to review either or both of the following:

- "1. some or all of the research appearing on the list" 10 (issued by the Secretary, DHHS) "and found by the reviewer(s) to involve no more than minimal risk.
- 2. minor changes in previously approved research during the period (of one year or less) for which the approval is authorized."<sup>10</sup>

Although the Food and Drug Administration (FDA) has its own regulations with respect to HSR (21 CFR 56) the general requirements for IRBs and informed consent are in keeping with the Common Rule<sup>5</sup>.

### TABLE II EXEMPTIONS FROM THE COMMON RULE<sup>11</sup>

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly, or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### **RECENT CHANGES**

In the late 1980s and early 1990s, partly owing to AIDS research activism, public perspective on HSR changed, focusing not so much on the risks/burdens involved, but rather on the benefits of participating in research.

Then came the September 1999 death of 18-year-old Jesse Gelsinger as a consequence of his participation in a U of Penn gene transfer trial. His death "raised new questions about the safety of patients in clinical research" as well as about apparent "substantial financial conflict of interest" on the part of the principle investigator.

In response to the Jesse case DHHS Secretary Shalala<sup>12</sup>:

- 1. directed NIH/FDA to improve education and training of investigators and relevant personnel (resulting in "Required Education in the Protection of Human Research Participants" 13).
- 2. mandated NIH and FDA to issue specific guidelines on informed consent;
- 3. directed NIH to require investigators conducting phase I/II trials to submit monitoring plans with submission of grant applications (resulting in "Further Guidance on a [sic] Data and Safety Monitoring for Phase I and II Trials"<sup>14</sup>), and FDA to issue new guidelines for DSMBs;
- 4. required NIH to issue documents "to clarify regulations relating to conflict of interest"<sup>12</sup> (resulting in "Financial Conflicts of Interest and Research Objectivity"<sup>15</sup>) and to hold public forums to develop new guidelines;
- 5. announced the intent of DHHS to pursue legislation enabling the FDA to levy civil monetary penalties (>/= \$250k/investigator and \$5 million/research institution) for violation of informed consent and other important research protections; and,
- 6. transferred the administrative function for protecting human research subjects from the NIH-based Office of Protection from Research Risks (OPRR) to the Office for Human Research Protections (OHRP) in the Office of the Secretary of DHHS.

#### **FUTURE DEVELOPMENTS**

In the previous session of Congress, legislation (HR 4605–"The Human Research Subjects Act of 2000") was introduced by Representative De-Gette<sup>16</sup>. The intent of HR 4605 was to extend the Common Rule to all HSR independent of setting and funding source. This bill died in committee with the end of the 106<sup>th</sup> Congress. Whether the

107<sup>th</sup> Congress will consider this issue remains unknown.

In accordance with the recommendations from an August 2000, DHHS-sponsored conference on human subjects protections and financial conflict of interest, DHHS has issued a draft interim guidance—"Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection"<sup>17</sup>. Look for finalization of this guidance.

The NBAC (National Bioethics Advisory Committee) draft report "Ethical and Policy Issues in Research Involving Human Participants" calls for the establishment of a "single, independent office with jurisdiction over all" federally and privately funded—HSR. In addition, in this report NBAC proposes "developing a single, uniform set of rules to govern such research" devising means for compensating individuals harmed in the course of HSR; improving the education of investigators and IRBs on HS protections; altering the membership of IRBs to include more non-expert and community members; and "improving the scrutiny of research protocols" 19.

The NBAC, in another draft report "Ethical and Policy Issues in International Research" presents its "recommendations for researchers conducting biomedical studies" overseas, especially in developing countries<sup>21</sup>.

Both these reports are likely to be finalized by summer 2001 with action on the recommendations to be the prerogative of the DHHS Office for Human Research Protections and the National Human Research Protections Advisory Committee.

"The National Committee for Quality Assurance (NCQA) has issued draft standards for accrediting human . . . " subjects " . . . research protection programs at ... Veteran's Affairs (VA) Medical Centers"22. The VA directed NCQA to coordinate its "standards setting effort"22 with that of the Institute of Medicine's (IOM's) Committee on Assessing the System for Protecting Human Research Subjects (CASPHRS), which was created in response to a request from the Secretary, DHHS "to examine how to improve the structure and function of human research review programs"<sup>23</sup>. In its phase I report<sup>23</sup>, CASPHRS favored the NCQA standards over those developed by Public Responsibility in Medicine and Research "for not only pilot testing in VA facilities, but also, with modification, for the accreditation of other research institutions"23. Look for additional recommendations from CASPHRS upon completion of the second phase of its study next

year, with implementation by DHHS likely to follow soon thereafter.

In late April 2001, the FDA issued two announcements regarding human subjects protections. The topic of one announcement was the imminent publication in the Federal Register of FDA's interim rule providing "additional safeguards for children enrolled in clinical trials of medical products the agency regulates"24. Subsequent to a 90-day comment period, look for finalization of this interim rule. The other announcement concerned the appointment of a Director of the FDA's newly created Office for Human Research Trials (OHRT)<sup>25</sup>. OHRT is expected to have a key role in FDA policy regarding HSR protections, coordinate FDA's bioresearch monitoring program for clinical trials, and to work with other government agencies and external stakeholders in the arena of HSR protections. Look for enhanced educational outreach and monitoring activities emanating from this office.

#### **SUMMARY**

Historically, codification of protections has been prompted by irregularities in the conduct of HSR. Disruption, by the Gelsinger case (and others), of the apparent "steady-state equilibrium" that had dominated since the 1970s has unleashed a torrent of HSR reforms, the intended and unintended consequences of which will become manifest in the coming years.

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### INTRODUCTION OF GUEST OF HONOR: JAMES B. SNOW, JR., M.D.

A. Julianna Gulya, M.D.

I am delighted to present to you Dr. James B. Snow, Jr., the American Otological Society's Guest of Honor for 2001.

Jim was born in Oklahoma City, Oklahoma, and, having earned the BS degree from the University of Oklahoma, journeyed east to attend Harvard Medical School, from which he received the MD degree, cum laude. Completing his surgical residency at the Johns Hopkins Hospital, he finished his formal training with an otolaryngology residency at the Massachusetts Eye & Ear Infirmary.

Jim fulfilled his military obligation as a consultant in otolaryngology (with the rank of Captain) both in Korea and at Fort Leonard Wood in Missouri.

Returning home to Oklahoma, Jim embarked on his academic career, quickly rising to Professor and Head of the Department of Otorhinolaryngology at the University of Oklahoma Medical Center. His publications during this era reflect his broad interest in otolaryngology complemented by a research focus in cochlear physiology, especially cochlear blood flow.

After a decade at the University of Oklahoma, he headed east again, on this occasion to assume the Chair of the Department of Otorhinolaryngology and Human Communication at the University of Pennsylvania—a position he held for some 18 years. He excelled there as an academic triple threat—demonstrating excellence in clinical care, teaching, and research, in the latter arena maintaining an impressive consistency in NIH funding.

His leadership roles over the years have been numerous, including the Presidencies of many of the AOS' sister societies, such as the ALA, ABEA, SUO, and AADO. He also has served on the Council of the AOS and as a member of the BOD of the ABOto. Similarly, he has been honored by numerous organizations, such as the DRF, the Triological Society, the AAO-HNS, as well as the AOS.

Over his career he has contributed over 150 papers, 4 books, and 40 chapters to the literature, in



addition to numerous abstracts, editorials, and book forwards.

However, it is likely that most in attendance here today remember Jim best for his service as the first Director of the NIDCD. His administrative skills guided the fledgling institute through its formative years and his scientific vision enabled him early on to recognize the importance of molecular biologic and molecular genetic approaches to the understanding of normal and disordered communication.

Currently, far from resting on his laurels, Jim remains busy with the Tinnitus Consortium and with the CORLAS. On a personal note, he has had the

good fortune to have married, while a medical student, his delightful wife Sallie, and to have been blessed with 2 sons and one daughter.

It gives me great pleasure to present this certificate to Dr. Snow which reads, "The American

Otological Society presents the Award of Guest of Honor to James B. Snow, Jr., MD, in 2001, for his contributions to the scientific foundations of otology, on the occasion of its 134<sup>th</sup> Annual Meeting."

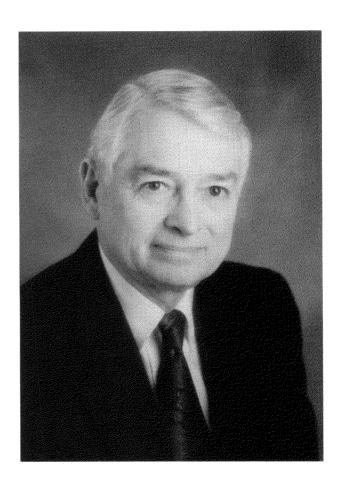
# REMARKS OF GUEST OF HONOR: PROGRESS IN THE PREVENTION OF OTITIS MEDIA THROUGH IMMUNIZATION

James B. Snow, Jr., M.D.

The role of respiratory viruses in the pathogenesis of otitis media is well recognized. It would appear that the respiratory syncytial virus, parainfluenza viruses, influenza viruses, enteroviruses and adenoviruses are the viruses most frequently associated with the development of acute otitis media. Indeed, the respiratory syncytial virus is most commonly recovered from the middle ear and is especially capable of causing inflammation in the middle ear. Some propose that an effective vaccine against the respiratory syncytial virus would greatly reduce the incidence of otitis media in children.

The principal bacteria that cause acute otitis media in this country and abroad are the Streptococcus pneumoniae, nontypeable Haemophilus influenzae (NTHi), and Moraxella catarrhalis. It is to these microorganisms that most of the effort to develop vaccines has been directed. The common feature of these microorganisms is that they present to the host a polysaccharide capsule that has low immunogenicity in infants and young children. The problem of the immunogenicity in infants and young children was solved with the development of the Haemophilus influenzae Type b (Hib) vaccine against meningitis in the 1980s. The capsular polysaccharide of the H. influenzae Type b was conjugated with a protein, and the conjugate had abundant immunogenicity in infants. The near universal immunization of infants with this vaccine in the United States and elsewhere has virtually eliminated H. influenzae meningitis and supraglottitis.

The same strategy has been followed over the last 15 years in the development of a vaccine for infants and young children against S. pneumoniae. The vaccine is a heptavalent pneumococcal conjugate known as Prevnar. Prevnar became commercially available in the United States in April of 2000 and



has been recommended by the American Academy of Pediatrics for universal use in children 23 months old and younger to prevent pneumococcal infections. It is given concurrently with other recommended childhood vaccines at 2, 4, 6, and 12 or 15 months of age. In the first reported clinical trial addressing the effect of the vaccine on otitis media, the efficacy in reducing the incidence of otitis media from all causes was 7%. For culture positive pneumococcal otitis media, the point estimate of efficacy

for fully vaccinated children was 66.7%. We now have from the Finnish Otitis Media Study Group additional evidence of the efficacy of Prevnar against otitis media. The vaccine reduced the number of episodes of acute otitis media from any cause by 6%, culture confirmed pneumococcal episodes by 34% and the number of episodes due to sero-types contained in the vaccine by 57%.

The work on the development of a vaccine against NTHi has been limited by difficulty in choosing a worthy surface antigen. In the early 1990s shortly after the creation of the National Institute on Deafness and Other Communication Disorders, an intramural program for the development of a conjugated vaccine against NTHi otitis media was initiated. Dr. Xin-Xing Gu was selected to lead the effort. With the good advice of Dr. John B. Robbins of the National Institute of Child Health and Development and Dr. C. M. Tsai of the Food and Drug Administration, she fortuitously chose to work on the lipooligosaccharide, a major surface antigen and virulence factor that elicits bactericidal antibodies. Her first step was to detoxify the lipooligosaccharide, and then she conjugated it to proteins. The conjugates have high immunogenicity for mice and rabbits and induce complement mediated bactericidal activity against NTHi in rabbits. Furthermore, they are protective against NTHi otitis media in chinchillas. The Phase I clinical trial has demonstrated the safety of this vaccine, and subsequent trials are being planned.

Gu and associates are following the same strat-

egy in the development of a detoxified lipooligosaccharide vaccine against M. catarrhalis that she used in the development of the NTHi vaccine. Gu and associates conjugated the M. catarrhalis detoxified lipooligosaccharide to proteins, and the conjugates elicit strong immune responses in mice and rabbits. The antisera induced have complement mediated bactericidal activity against homologous and heterologous strains of M. catarrhalis in rabbits. Since there is no satisfactory animal model of M. catarrhalis otitis media, protection induced by the conjugates has been demonstrated in pulmonary clearance of homologous and heterologous M. catarrhalis in an aerosol challenge mouse model. These results indicate that a detoxified lipooligosaccharide protein conjugate is a promising vaccine candidate against M. catarrhalis. Throughout this extraordinary work, Dr. Gu has had the support and encouragement first of Dr. David J. Lim as Scientific Director and subsequently of Dr. James F. Battey, Jr. as Scientific Director and then as Director of the Institute as well as their intellectual participation in the research effort.

It now appears likely that the prevention of otitis media will require multivalent pneumococcal, NTHi and M. catarrhalis vaccines, and it is reasonable to expect this great breakthrough within a decade to the enormous benefit of unborn millions of children who would have suffered from this worldwide scourge.

Thank you for your kind attention; and, Julie, thank you for this wonderful honor.

# PRESENTATION OF PRESIDENTIAL CITATION: ROBERT J. RUBEN, M.D.

A. Julianna Gulya, M.D.

It gives me great pleasure to present to you Dr. Robert J. Ruben, the American Otological Society's Presidential Citation recipient for 2001.

Bob is a native New Yorker. He left NYC to obtain his AB at Princeton and both his MD and surgery/otolaryngology residency training at the Johns Hopkins University. Once he completed a research fellowship at the NINDB, he returned to NYC for good!

Bob's research career is truly remarkable. While still a medical student, and continuing through residency, he was co-PI on an NIH grant. As an intern, he first-authored the paper "Cochlear Microphonics in Man" (the first report of successfully obtaining CMs in humans of the amplitude seen in animal models), thus opening the door to a new era of investigation. As an otolaryngology resident, he also served as the Director of the Neurophysiology Laboratory at the Johns Hopkins Hospital.

Bob has served the Montefiore Hospital & Medical Center and the Albert Einstein College of Medicine of Yeshiva University as Professor and Chairman for over 30 years—he now is Distinguished University Professor and Chairman Emeritus. His consistent NIH funding and collaborative relationships—notably with AOS member Dr. Tom Van De Water—enabled him to contribute nearly 200 papers, 50 book chapters, and 5 books to the otolaryngology literature.

Bob's leadership abilities have benefited a number of the AOS' sister societies, in particular the ARO, SENTAC, and ASPO, which he served as President.

However, Bob is recognized on this occasion for his achievements in two distinct endeavors. Firstly, the AOS, in particular its Research Fund, is indebted to Bob. He, during his service as Trustee, Secretary-Treasurer, and Chairman of the Board of Trustees, was instrumental in restructuring the financial management of the RF assets, setting the RF on a growth course. Secondly, otology, as well as otolaryngology, is indebted to Bob for his tireless advocacy for funding research in otology and otolaryngology. In addition to testifying as a witness before the House and Senate Appropriations Committees on numerous occasions, he has been similarly active behind the scenes in championing the cause of funding for research in communication disorders.

On a personal note, Bob is the quintessential New Yorker, living with his wife Yvonne, off Central Park. Bob is a confirmed bibliophile.

It is a privilege to present this certificate to Dr. Ruben, which reads, "The American Otological Society presents this Presidential Citation to Robert J. Ruben, MD, for his advocacy for research in otology and for his service to the American Otological Society."

#### AUDIOLOGICAL CHARACTERISTICS OF INITIAL PRESENTATION OF NF2 PATIENTS: PRELIMINARY RESULTS

Ann Masuda, M.S., William H. Slattery III, M.D., Laurel M. Fisher, Ph.D., and Mark L. Oppenheimer, M.S.

#### **ABSTRACT**

The "Natural History of Vestibular Schwannomas in NF2" is a multi-center international study conducted by House Ear Institute. The study, funded by the Department of Defense, aims to investigate the relationship between the growth of vestibular schwannomas and changes in audiological functioning over time. Five domestic sites and 4 foreign sites participate in the study. The results of a preliminary analysis of the audiological history of the 107 patients will be reviewed.

Date of documentation of the NF2 diagnosis was considered to be the date of the first MRI showing the presence of bilateral vestibular schwannomas. For each patient, all audiological examination results from the diagnosis date to enrollment in the study were requested. Pure-tone threshold testing was the most common measure captured across the myriad of audiological testing sites prior to the patient's evaluation at the site of enrollment.

At the time of documented diagnosis of NF2, a preliminary data analysis indicated that 57% had normal hearing, 34.4% had mild to moderate loss, 2% had severe loss, and 6.5% had profound loss. Change from the onset of hearing difficulties to date of enrollment in the study will be discussed and the relationship between the change in hearing difficulties and the size of the vestibular schwannoma will be reviewed. The results will be discussed in terms of a classification of rates of changes in hearing, enabling clinicians to better inform patients about the long-term course of their condition.

Reprint requests: Ann Masuda, M.S., House Ear Institute, 2100 West Third St. 5th Floor, Los Angeles, CA 90057

#### VESTIBULO-OCULAR REFLEXES (VOR) AFTER RESECTION OF INTERNAL AUDITORY CANAL TUMORS: RETROSPECTIVE ANALYSIS OF POST SURGICAL VOR TRENDS IN MILITARY AVIATORS

Paul C. Johnson IV, M.D., David G. Schall, M.D., Jeffrey J. Kuhn, M.D., and Kennith W. Stevens, B.S.

#### **ABSTRACT**

**Objective:** Determine the aeromedical significance of permanent phase lead and decreased gain on vestibulo-ocular reflex (VOR) tests conducted on USAF aviators following internal auditory canal (IAC) tumor resection.

Study Design: Retrospective

Setting: U.S. military multi-specialty service.

**Patients:** Fifteen USAF aviators evaluated following IAC tumor removal from January 1982 to present. 150 pilot candidates represented the normal aviator population.

**Interventions:** Annual post-operative VOR testing conducted as a part of aeromedical re-evaluations required for maintaining continued flight qualification.

**Main Outcome:** Eight aviators have resumed active flying with the USAF after IAC tumor resection with four flying high performance aircraft.

**Results:** Short-term mean gain for all postoperative aviators was below two standard deviations of the normal aviator population. Long-term gain showed normalization in the mid-frequencies and elevation in the upper frequencies. Mean phase was well above ("phase lead") the normal population at the four lowest frequencies (0.01Hz–0.08Hz). The long-term results showed no differences in gain and phase between grounded and HP aviators.

Conclusion: In 1989, the USAF began evaluating aviators following IAC tumor resections with rotary VOR testing to determine the aeromedical significance of post-surgical vestibular dysfunction. These tests demonstrate abnormal patterns but the interpretation of these differences has been limited. The threshold of necessary vestibular function is not clearly defined. Currently eight USAF aviators have successfully returned to military flying after resection of an IAC tumor. Permanent phase lead and decreased gain measured by VOR testing do not represent impairment for high performance aviators surgically treated for IAC tumors.

Reprint requests: Paul C. Johnson IV, M.D., Otolaryngology-HNS, Naval Medical Center (Code 0609) Charette Health Care Center, 27 Effingham St. Portsmouth, VA 23708-2197; ph 757-953-2788; fax 757-953-0848.

## NEW INDICATIONS FOR ABI: HEARING RESTORATION IN THREE CHILDREN WITH COCHLEAR APLASIA

Vittorio Colletti, M.D., Francesco Fiorino, M.D., Luca Sacchetto, M.D., Marco Carner, M.D.

#### **ABSTRACT**

**Objective:** Patients with aplasia and hypoplasia of the cochlear nerve have no chance of hearing restoration by stimulating the periphery of the auditory system using the traditional cochlear implant. A possible approach to auditory rehabilitation may be electrical stimulation of the cochlear nuclei with auditory brainstem implant (ABI).

Study Design: Clinical study.

Setting: ENT Department University of Verona.

**Patients:** Three children 4, 3 and 3 years old with bilateral severe cochlear malformations and cochlear nerve aplasia received an ABI.

Intervention: The classic retrosigmoid approach was used.

Main Outcome Measure: The correct position of the electrodes was estimated with the aid of EABRs and neural response telemetry (NTR). High-resolution CT scan with a bone algorithm reconstruction technique were taken postoperatively to evaluate electrode placement before discharge.

**Results:** No postoperative complications were observed. The ABI was activated 30 days after implantation in all patients. Up to now total of 21 electrodes 18 and 8 electrodes are respectively activated in the three children. Three months after activation the first patient reached a good environmental sound awareness, a good speech detection and some speech discrimination. The second child one month after reached a good environmental sound awareness, and moderate speech detection. The third child reached a good environmental sound awareness.

**Conclusion:** To the best of our knowledge this is the first patients with hypoplasia of the cochlea and aplasia of the cochlear nerve, aged below 5 years old treated with an ABI.

Reprint requests: Vittorio Colletti, M.D., ENT Department, University of Verona, L.go Lodovico Scuro 10, 37134 Verona, Italy.

#### A NEW THEORY TO EXPLAIN THE GENESIS OF PETROUS APEX CHOLESTEROL GRANULOMA

Michael Cho, B.A. and Robert K. Jackler, M.D.

#### **ABSTRACT**

**Objective:** To propose a new hypothesis which seeks to explain the pathogenesis of petrous apex cholesterol granuloma (PA CG).

Classical Hypothesis: PA CGs form when mucosal swelling blocks the circuitous pneumatic pathways to the apical air cells. Trapped gas resorption results in a vacuum that triggers bleeding. CG forms through anaerobic break down of blood products.

**Problems with the Classical Hypothesis:** Exclusion of pneumatic tracts is very common in the middle ear, mastoid, paranasal sinuses, and lung but CG is rare. The extraordinary levels of temporal bone pneumatization typically observed in PA CG cases is indicative of excellent ventilation and freedom from inflammatory mucosal disease. If under pressure due to gas absorption alone is sufficient to trigger hemorrhage, why is this seldom seen in otitis media with effusion.

**Patients:** The opposite PA of 18 Patients with PA CG compared with 33 highly pneumatic PAs (in 21 patients) in patients imaged for non-otologic reasons.

Main Outcome Measure: The nature of the bony partition, as seen on CT scan, between the PA air cell system and adjacent marrow compartment.

**Results:** 4 of 13 PA with CG on the opposite side showed deficient septation between air cells and marrow while this was not observed in any of the 33 extensively pneumatized normals.

New Hypothesis: As cellular tracts penetrate the apex during young adult-hood, budding mucosa invades and replaces hematopoietic marrow. The bony interface becomes deficient with coaptation of richly vascular marrow and the mucosal air cell lining. Hemorrhage from the exposed marrow coagulates within the mucosal cells and occludes outflow pathways. Recurrent hemorrhage from exposed marrow elements provides the engine responsible for the progressive cyst expansion. As the cyst expands, bone erosion increases the surface area of exposed marrow along the cyst wall. This theory explains the unique proclivity of the healthy and well pneumatized PA to form CG.

Reprint requests: Robert K. Jackler, M.D., University of California San Francisco, Dept. of Otolaryngology, 400 Parnassus Ave, A-730, San Francisco, CA 94143-0342; ph 415-353-2757; fax 415-353-2603.

# COMPUTERIZED VIDEOMIMICOGRAPHY: A NEW OBJECTIVE TEST OF FACIAL MOTOR FUNCTION

Pavel Dulguerov, M.D., Ph.D., Desheng Wang, M.D., Thomas V. Perneger, M.D., Ph.D., and Willy Lehmann, M.D.

#### **ABSTRACT**

**Objectives:** 1) determine the best measures for five basic facial movements in normal patients; 2) correlate these measurements with the House-Brackmann grades in patients with facial paralysis.

**Methods:** Eleven facial landmarks were placed on the face and five movements (forehead lift, eye closure, nose wrinkling, lip puckering, and smiling) with maximal contraction force were requested. No head immobilization was used. The video frames with maximal movement digitized and measurements performed with the Osiris image analysis software. For each measure the change from rest was computed. Inter- and intrasubject variability were determined through a multivariate ANOVA analysis and correlation with HB was assessed with the Pearson correlation coefficient.

**Results:** In all movements, surfaces changes were higher than distance changes. For forehead lifting and eye closure the best measure was the "eye surface" changes (area F-Na-lo) with 12(9% and –31(8% respectively. For nasal wrinkling, lip puckering, and smiling the best measures were the paranasal area (area Na-lo-A, change: –28(14%), upper lip area (area A-Ls-M, change –23(8%), and mouth area (area Ls-Li-M, change 63(21%), respectively. Distance changes were all below 10%. Same day repeatability was below 15% and day-to-day repeatability was below 7%. In normal subjects >80% of the total variation was accounted for by the intersubject variability. An excellent correlation with HB was found (0.5–0.8; p<0.001).

**Conclusion:** Videomimicography is a simple and objective linear measurement system based on facial surface changes. The measures exhibit good reliability and correlation with HB grades.

Reprint requests: Paul Dulguerov, M.D., Ph.D., Dept. of Otolaryngology-HNS, Geneva University Hospital, 24 rue Micheli-du-Crest, Geneva, CH-1205, Switzerland.

#### Discussion Period I: CP Angle/Skull Base/VIIth Nerve Papers 1–5

**Dr. Rick Chole** (St. Louis, MO): For Mr. Cho and Rob Jackler: Its an interesting theory, I was just wondering if the marrow is bleeding into the petrous apex and if the petrous apex is pneumatized, why doesn't the blood just appear in the middle ear at least sometimes early on in the course?

Michael Cho (San Francisco, CA): I think the key component in the production of this cholesterol granuloma is that it has to be trapped and so one would presume that once the bleeding has started to ooze that it would clot and cause an obstruction and therefore have a trapped cavity of hemorrhage. That would probably be the best explanation.

**Dr. Gerald Chee** (Toronto, Ontario, Canada): I'd like to ask a question of Ms. Musuda. You presented your results using the PCA. As we know neurofibromatosis is a retrocochlear disease. Have you looked at your results with speech discrimination scores and how that varies over time in the short term?

Ann Masuda, M.S. (Los Angeles, CA): A lot of the data that we presented is rather limited because we don't have all of the data to present. What I gave you here is rather limited at this point. If you give us a few more years to collect some more data we will probably have that speech discrimination information for you.

**Dr. Robert Ruben** (New York, NY): Very interesting paper and really interesting progress. One has to ask a question. In these very severe malformations of the otic capsule, many times they are associated with central nervous system malformation, one induces the other, and it goes back to the oto cyst. My question is have you reviewed your MRI's for abnormalities within central nervous system and have you been able to identify on the MRI the various way stations to the auditory pathways?

**Dr. Vittorio Colletti** (Verona, Italy): Thank you for the question. This is a fundamental question and actually before trying the surgery a fundamental question was, how is the central auditory system? The only way that we could have information was through the imaging. I was in one way disappointed and in one way lucky to hear that in those particular patients there were no abnormalities as

reviewed by MRI. I am sure that when MRI is more precise, we will find abnormalities also in the central nervous system. Right now I think that the MRI that we used is not so specific.

The question that I posed to the neuroradiologist was how am I going to identify the cochlear nucleus area. This is the foramen of Luschka, this is the bulging of the area that has to be the cochlear nucleus and the foramen of Luschka is very well located.

**Dr. Robert Ruben** (New York, NY): Can I add one more thing, Julie? Perhaps the central nervous system is extremely plastic, especially for languages. I would suggest that if you do have a facility, it might be very nice to follow these children using MRI as they develop. You may find other parts of the central nervous system are accommodating your stimulus and allowing for the lovely product that you see.

**Dr. Vittorio Colletti** (Verona, Italy): Yes, but now comes the problem with the ABI. I don't know if they will accept to have the magnet removed. But I will ask, in Italy we can do many things.

**Dr. A. Julianna Gulya** (Washington, DC): I thought that statement was going to go unchallenged. Dr. Gobel, I think that's you in the background.

**Dr. Joel Gobel** (St. Louis, MO): A question to Dr. Johnson about the pilots that returned to flying. That's a major issue for commercial airline pilots as well. I didn't see enough correlation in the VOR testing to confidently say that you can use that alone as a measure to send somebody back to the cockpit.

I wanted to know about using a flight simulator. Many of these people have a terrible problem with visual vestibular mismatch and I wasn't convinced enough to use the VOR testing alone to feel I could put a pilot back in the cockpit.

**Dr. Paul C. Johnson IV** (Portsmouth, VA): A very good question and something that I know the Air Force perseverated over for a very long period of time. Actually the VOR test is not the standard, which is used solely to make the decision to recommend for returning to flying. It's interesting that the VOR data is available. The Air Force actively exam-

#### **DISCUSSION**

ines aviators from a number of measures but for the most part it is a standards issue. You're not allowed to take a population or an individual who comes down with a particular disease and create a new standard. The decision process is convoluted. The VOR data is available so we look at the VOR data because it's available and hopefully it can teach us something about how the aviator performs. The actual permission to return is much more complicated than what I presented. Thank you.

**Dr. Thomas Linder** (Zurich, Switzerland): I'd like to make a comment to Mr. Cho's paper. It's a

very interesting paper and we have looked at over a hundred CT scans of patients who underwent subtotal petrosectomy. This is a procedure where you close the eustachian tube and external ear canal. Many of these patients do have pneumatized cells in the temporal apex. These cells have no drainage and no ventilation but these patients do not develop a cholesterol granuloma.

I think we should abandon the previous theory that you have noted. I am very interested to follow your new developmental theory. I thank you for this very interesting paper.

#### TREATMENT OF UNILATERAL SUDDEN SENSORINEURAL HEARING LOSS WITH SYSTEMIC STEROIDS AND VALACYCLOVIR

Debara L. Tucci, M.D., Joseph C. Farmer, Jr., M.D., and David L. Witsell, M.D.

#### **ABSTRACT**

**Objective:** To determine if the addition of an antiviral medication to systemic steroids for treatment of idiopathic sudden sensorineural hearing loss significantly improves recovery.

**Study Design:** Randomized, double-blind, placebo-controlled prospective multicenter clinical trial.

**Setting:** Administrated from tertiary care center and clinical research institute; patients enrolled by otolaryngologists in academic and private practice outpatient settings.

**Patients:** Major inclusion criteria: (1) loss of at least 30 dB in three contiguous frequencies over <3 days in patients with previous audiometry, (2) subjective marked loss of hearing in patients with subjectively normal hearing and no previous audiometry, with contralateral hearing taken as baseline, and (3) patients seen within 10 days of onset of hearing loss. Pre-treatment evaluation included audiometry and CBC, chemistries, FTA-ABS. ABR or MRI was recommended.

**Intervention:** Patients received prednisone (80 mg/day, tapered over 12 days) with placebo or prednisone with valacyclovir hydrochloride (1 gm TID, 10 days).

**Main Outcome Measure:** 1) Audiometric assessment at presentation, weeks 2 and 6, 2) Hearing Screening Inventory questionnaire twice weekly/ six weeks, 3) Acute SF-12 questionnaire at presentation and week 2.

**Results:** Goal is enrollment of 135 patients by close-of-study October 31, 2000. Data will be analyzed using a variety of measures to determine whether there are statistically significant differences between groups in maximal hearing recovery and time to maximal hearing recovery.

**Conclusion:** Data to be presented are expected to show whether the addition of an antiviral to conventional treatment with steroids alone is beneficial in the treatment of SSNHL.

IRB approval number: 1452–99-BR2

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### THE EFFECT OF DIABETES ON SENSORINEURAL HEARING LOSS

Vasu Kakarlapudi, M.D., Robert Sawyer, M.D., and Hinrich Staecker, M.D., Ph.D.

#### **ABSTRACT**

**Objective:** Determine the incidence of SNHL in a diabetic vs. control population and assess the impact of blood sugar control on SNHL.

Study Design: Retrospective chart review.

Setting: Tertiary referral center.

**Patients:** Age matched populations of diabetic (8062) and nondiabetic (66,036) patients with complete medical records.

Main Outcome Measures: Hemoglobin A1c, serum creatinine, hearing (pure tone threshold, speech discrimination), LDL, cholesterol, serum triglycerides.

**Results:** 8062 patients with diabetes were compared to an age matched control population of 66,036. The incidence of SNHL in the diabetic population was 23.4% and was significantly lower in the control population. There was a higher incidence of elevated serum creatinine in the patients with diabetes and hearing loss compared to diabetes alone and compared to controls with SNHL. There were no statistically significant differences in cholesterol, LDL or triglycerides in diabetics or diabetics with SNHL, indicating that vascular disease due to hyperlipidemia was not a cause of SNHL. Analysis of audiometric measurements showed a correlation between extent of hearing loss and elevation of creatinine. Hemoglobin A1c elevation did not correlate with worse hearing.

**Conclusions:** Diabetes and progression of microvascular disease increases the incidence and severity of hearing loss.

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#### INFLAMMATORY CYTOKINES IN THE SPIRAL LIGAMENT

Joe C. Adams, Ph.D.

#### **ABSTRACT**

**Hypothesis:** The spiral ligament plays a central role in cochlear homeostasis and pathophysiology.

**Background:** The spiral ligament is usually considered be ligament-like. However, it is now known that K+ ions which carry hair cell receptor currents reach the stria vascularis via gap junctions within the ligament. Deafness caused by mutations of the gene encoding the gap junction protein connexin 26, which is richly expressed in the ligament, emphasize the importance of gap junctions there. Further, spiral ligament cells show extreme reactions in experimental endolymphatic hydrops.

**Methods and Results:** Inflammatory cytokines, their transcription factors, and associated proteins were identified in the cochlea using RTPCR and localized in the spiral ligament using immunocytochemistry. Type 1 fibrocytes immunostain for NF kappaB forms P65, P50, P52, and C Rel, and for I kappaB, IL-1, IL-6, and TNF-alpha.

Conclusions: There is no evidence that these cytokines and associated proteins play an immunodefensive role in the cochlea. Rather, the demonstrated roles of these compounds in various other stresses appear to explain their presence within the ligament. However, their presence, along with that of their receptors, make the ligament vulnerable to disruption by local or systemic inflammatory signals because cytokine activation has been shown to control gap junctions and several ion controlling proteins found within the ligament. Disruption of cytokines in the ligament may be involved in a number of poorly understood otologic disorders, including deafness following infections, immune mediated hearing loss, sudden hearing loss, and sensorineural hearing loss associated with otosclerosis.

Reprint requests: Joe C. Adams, Ph.D., ENT Department, Massachusetts Eye and Ear Infirmary, 243 Charles St. Boston, MA 02114.

## IN VIVO IMAGING OF THE GUINEA PIG COCHLEA USING OPTICAL COHERENCE TOMOGRAPHY

Brian J.F. Wong, M.D., Mark. K. Yamaguchi, B.S., Yonghua Zhao, Ph.D., B. Hyle Park, M.S., Nader Nassif; Zhongping Chen, Ph.D., and Johannes F. de Boer, Ph.D.

#### **ABSTRACT**

**Hypothesis:** The objective of this study was to use Optical coherence tomography (OCT) to obtain in vivo cross sectional images of the internal structure of the cochlea in guinea pigs

**Background:** OCT is an evolving imaging modality based on coherence gating which produces cross-sectional images of embedded anatomic structures with axial and lateral spatial resolution on the order of 10–20 microns. Whereas computed tomography, magnetic resonance imaging, and ultrasound reflect differences in electron and proton density, or elastic modulus, respectively, OCT is based on differences in tissue optical properties. This imaging modality is similar to ultrasound except that light, rather than sound, is used to probe the tissue, and reconstructed images depict changes in tissue optical properties rather than elastic modulus.

**Methods:** A 1310 nm semiconductor optical amplifier (bandwidth 65 nm) was used as a low-coherence source and allowed imaging to a depth of approximately 1.5 mm. Cross-sectional images ( $1.87 \times 2.00$  mm,  $10 \times 10$  microns/pixel) were acquired at a frame rate of 1 Hz. The promontory was surgically exposed by removing skin, soft tissue, and the mandibular ramus. The mastoid bulla was removed allowing access to the middle ear space.

**Results:** The scala vestibuli, scala media, scala tympani, modiolus, stria vascularis, and all four and a half turns of the guinea cochlea were identified. Cross-sectional tomographic images were obtained across the length of the cochlea from the medial to lateral direction with a slice thickness of 50–100 microns.

**Conclusions:** These images demonstrate the efficacy of OCT in imaging the internal structures of the cochlea with micron scale resolution and at near-real time frame rates. The fundamentals of OCT are discussed along with future applications of this technology in research and clinical practice with respect to imaging the cochlea.

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#### DISCUSSION PERIOD II: SENSORINEURAL HEARING LOSS Papers 6–9

**Dr. Bruce Gantz** (Iowa City, IA): Dr. Tucci, what a wonderful presentation and a difficult piece of work to do in any type of clinical trial. I hope the membership appreciates the effort that you put into this. I would hope that as we look at new methodologies of putting things in the inner ear that we use your standard of double blind clinical trials. Thank you.

**Dr. Jack Pulec** (Los Angeles, CA): Also to Dr. Tucci. I enjoyed the work and I followed the project but had a couple of questions. Did you make an effort to separate out patients who have allergic hydrops, in my opinion a large number of what we call sudden deafness? They generally have a better result. The other is a question of treatment with an antiviral. If we treat a type A influenza, the first three days, when the virus is still in the replication stage, we are able to stop it or kill it with antivirals. Here we are treating up to ten days. Would you address those two questions?

**Dr. Debara Tucci** (Durham, NC): I think those are both very important questions. The first question related to the hydrops, we did not question allergy. We had to rely on our enrolling physicians to make the decision about whether they thought that the patient had sudden sensorineural hearing loss. It was truly idiopathic. In some ways we made recommendations. We recommended the FTABS and the MRI to rule out an acoustic neuroma but we really felt that it would be very difficult to stipulate an excessive number of requirements so we did not directly address allergy.

The second question relates to the antiviral treatment over ten days. We used that as a criteria because its been used in the past. I think that it's an important point to make. My personal feeling is that the virus probably does its damage within the first day or so and that could very well be the reason why we didn't see an affect. I think that it was impractical in our study to say that all patients had to be treated within a really very short period of time so I think we did the best that we could. We did break out the data to look at those who were enrolled sooner than later.

We wished see if the antiviral had an effect just in a sub-group of those patients. We didn't see that there was although we didn't have tremendous numbers of patients to work with.

**Dr. Michael Seidman** (Detroit, MI): I have one question for Dr. Tucci and a comment on the diabetes paper. The question for Dr. Tucci: you mentioned that forty percent of the patients had vertigo. If they had vertigo and sudden sensorineural hearing loss I would argue that those are not sudden sensorineural hearing losses but perhaps labyrinthitis. What happens if you separate them out?

A comment for Dr. Kakarlapudi. It seems clear that there's diabetes and mitochondrial disorders so there's definitely a molecular basis. The 32–43 point mutation that he spoke about in Milan and a 10.4 kilo based deletion is associated only with diabetes in sensorineural hearing loss. There's a definite association.

**Dr. Debara Tucci** (Durham, NC): As far as the question about the vertigo, I think we again looked at a large number of patients who had sudden hearing loss and certainly vertigo has been lumped into this. Patients with vertigo have been examined in large studies. In every large study of treatment of sudden sensorineural hearing loss there was certainly a better result in those subjects that did not have vertigo. In terms of just the treatment with Valacyclovir, it really didn't matter whether they had vertigo or not.

**Dr. Lawrence Grobman** (Miami Beach, FL): Also for Dr. Tucci, did you do any serological testing for the presence of viral infection in these patients?

**Dr. Debara Tucci** (Durham, NC): No we did not. **Dr. Hinrich Staecker** (Baltimore, MD): This is a question for Dr. Adams. I enjoyed your presentation. Are you planning on looking at the effect of cytokines on inducible nitric oxide synthesis and its potential role in the cochlea?

**Dr. Joe Adams** (Boston, MA): The answer is we are planning on looking at everything we can. We have looked at the area of your question but the results are too preliminary yet to talk about in public. I will be happy to discuss it with you.

**Dr. George Gates** (Seattle, WA): Two comments. First I thank Joe Adams for this wonderful contribution. He's an original thinker in this area and this work has helped us understand how Conexin 26

#### **DISCUSSION**

affects hearing and the fact that not all deafness comes from hair cell disease. So keep the spiral ligament in your thought processes because you will hear more about this in the future.

I have a question to Dr. Kakarlapudi regarding the diabetes project. I have been looking at this for a number of years. Surely there must be a relationship between diabetes and hearing loss but it's very tenuous. When you get thousands of people, you can find that small differences become significant. It looks to me from this initial run that it's only the sick diabetics who have a little bit more hearing loss. We have shown that people with cardiovascular disease also have more hearing loss and diabetes is a precursor of that so it's a complex situation. We have looked at people with retinal disease on retinal photography for diabetes and related that to hearing loss. The presence or absence of retinal dis-

ease doesn't correlate with hearing loss. It is a very complex picture and I think it may be through the degree of systemic disease in the diabetics rather than the presence of the diabetes itself. Would you comment on that?

**Dr. Joe Adams** (Boston, MA): Certainly there have been conflicting reports in literature and usually when different people are telling you a whole bunch of different things, it's probably because no one really knows the truth.

I might also comment on the most recent article in Otology and Neurotology from I think Lusowska from Poland. They actually found that those patients with retinopathy did not have significant hearing loss so perhaps they are two separate mechanisms and like you commented perhaps the very sick patients do eventually get hearing loss but attributing that to diabetes alone can be difficult.

### THREE DIMENSIONAL MODELING OF MIDDLE EAR BIOMECHANICS AND ITS APPLICATIONS

Rong Z. Gan, M.S., Ph.D., Qinli Sun, M.S., Robert K. Dyer, M.D., and Kenneth J. Dormer, Ph.D.

#### **ABSTRACT**

**Hypothesis:** Combined technologies of finite element analysis and 3-D reconstruction of human temporal bones can be used to construct a computational model, useful in describing normal and pathological middle ear transmission.

**Background:** Finite element models (FEA) for biological systems have been used in ear biomechanics. 3-D reconstructions have been performed previously but not in combination with FEA and laser interferometry. Due to size, variability and complexity of the middle ear, accurate morphometric data and boundary conditions are necessary for accurate modeling.

**Methods:** We initiated a model based on digitized 3-D images of temporal bone morphometry. Using histological sections of normal middle ears, a CAD model (Adobe Photoshop and Solid Works Inc.) was constructed with ligaments, muscles or tendons as boundary conditions. CAD data were imported into an FEA mechanical model (Hypermesh and ANSYS). Finally, the model was validated by comparing it with displacements obtained by laser Doppler interferometry on 17 fresh human temporal bones.

**Results:** Fresh temporal bones were decalcified, sectioned and stained, scanned, digitized and reconstructed. An FEA model was generated whose dynamic analysis was very close to the actual mechanical performance of human temporal bones with 90 dB SPL at the tympanic membrane across auditory frequencies.

**Conclusions:** Accurate FEA modeling can predict normal mechanical performance of the ossicular chain. Potential applications of the model include perforations, otosclerosis and mass loading in the middle ear, as with implantable hearing devices.

Whitaker Foundation: GR 98-035.

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#### STIMULATOR IMPLANTABLE HEARING AID

John M. Fredrickson, M.D., Ph.D., Thomas Lenarz, M.D., Ph.D., J. Gail Neely, M.D., John K. Niparko, M.D., and William Slattery, M.D.

#### **ABSTRACT**

**Objective:** The goal of the FDA Phase I Clinical Trial was to determine the safety of a new middle ear implantable hearing aid for individuals with moderately severe to severe sensorineural hearing loss. Safety results for the first nine US patients implanted with the Otologics device are reported.

**Study Design and Setting:** Nine patients (6 male and 3 female, age range 27–68) participated in the prospective tertiary multi-center trial.

**Intervention:** Implanting the device consisted of the creation of an atticotomy that exposed the body of the incus. The device is coupled to the incus and directly stimulates the ossicles.

**Results:** No patient exhibited clinically significant change in air conductive ( $\Delta PTA^4 = 4.31dB$ ) or sensorineural ( $\Delta PTA^4 = 2.24 dB$ ) hearing loss. Post implant tympanograms showed a slight but clinically insignificant stiffening of the ossicular chain. Despite limited device output, patients performed slightly better with the implant than with their previously worn hearing aids. Feedback was not a problem and quality of sound was superior. No perioperative complications were noted with the exception of one delayed wound infection. Delayed device malfunction limited long term results.

**Conclusion:** Clinical results from this Phase I trial demonstrated device safety. Although the device had limited output it compared favorably to the patients' own hearing aids. The output of the device has been increased for the Phase II clinical trials and is expected to show improved benefit over the Phase I device. Phase II data will be presented.

Reprint requests: John M. Fredrickson, M.D., Ph.D., Dept. of Otolaryngology, 517 South Euclid Ave, St. Louis, MO 63110; ph 314-362-7344; fax 314-362-7522.

# RESULTS OF THE PHASE II SOUNDTEC DDHS CLINICAL TRIAL

J.V.D. Hough, M.D., Pamela Matthews, M.S. C.C.C.-A., Mark W. Wood, M.D., and R. Kent Dyer, Jr., M.D.

## **ABSTRACT**

**Objective:** To assess the safety and efficacy of the SOUNDTEC DDHS, a partially-implantable electromagnetic middle ear hearing device.

**Study Design:** Randomized Food and Drug Administration (FDA) Phase II Clinical Trial of 100 subjects at 10 sites across the United States.

**Setting:** Tertiary Referral Medical Centers.

**Patients:** Individuals with bilateral moderate to moderately-severe sensorineural hearing impairment who had worn optimally-fitted hearing aids for at least 45 days.

**Interventions:** Therapeutic intervention included implantation of a 27 mg neodymium iron boron magnet encased in a laser-welded titanium canister onto the incudostapedial joint followed, after a 10-week healing period, by fitting with a deep Earmold/Coil Assembly and activation of the sound processor.

Main Outcome Measures: Functional gain, speech recognition in quiet and noise, articulation index scores, aided benefit, sound quality judgments, satisfaction, and occurrence of feedback and occlusion as compared to the subjects' optimally-fitted hearing aids.

**Results:** The results of this multi center clinical trial are pending FDA review in March 2001 and will be presented.

**Conclusions:** Based on initial clinical results from the first 10 subjects implanted, the results of this Phase II clinical trial substantiate positive outcomes regarding safety and efficacy of the SOUNDTEC DDHS in the management of moderate to moderately-severe hearing impairment.

Reprint requests: J. V. D. Hough, M.D., Hough Ear Institute, 3400 N. W. 56th St., Oklahoma City, OK 73112; ph 405-946-5563; fax 405-947-6226.

# BONE ANCHORED VS CONVENTIONAL HEARING AIDS: COMPARATIVE BENEFITS FOR AUDITORY INFORMATION PROCESSING

S. M. Abel, Ph.D., Manohar Bance, M.B., B.Sc. F.R.C.S.C., B. C. Papsin, M.D., M.Sc., F.R.C.S.C., P. Wade M.D., F.R.C.S.C., and J. Vendramini, B.Sc.

## **ABSTRACT**

**Hypotheses:** Bone-anchored (BAHA), conventional bone conduction aids (BCHA), and air conduction hearing aids (ACHA) will improve patients' psychoacoustic performance relative to unaided listening. BAHAs will not affect detection of the temporal characteristics of the acoustic stimulus compared to ACHAs.

**Background:** BAHAs transduce sound by vibrating the skull directly through an osseointegrated screw. BAHA is used in cases of congenital atresia or severe drainage. Although patients report different sound quality with BAHAs compared with BCHAs and ACHAs, objective psychoacoustic measurements are almost non-existent. In particular, it is unknown if temporal cues are processed similarly by air and bone conduction hearing aid users, No systematic comparison of BAHA and ACHA has been performed.

**Methods:** In 22 BAHA users, measurements were made of soundfield hearing thresholds, temporal auditory acuity, and consonant discrimination in quiet and noise, unaided and with patient's own BAHA and ACHA, or BCHA if previously worn. Questionnaires relating to hearing and general health were also completed with each. Results were compared to those of 15 normal subjects.

**Results and Conclusions:** Of the 22 impaired listeners, 17 had previously worn ACHA, and 5 BCHA. Preliminary analysis indicated that BAHAs and CHAs were equally beneficial for sound detection. If the stimuli were audible unaided, there was no additional improvement with either type of aid for speech understanding. Gap discrimination was better with BAHA. Thus, BAHAs were not detrimental in temporal processing, and in some tasks objective benefit for BAHA was shown.

Reprint Requests: S. M. Abel, PhD,EN7-221, The Toronto General Hospital, 200 Elizabeth St, Toronto, Ontario Canada, M5G 24C.

# DISCUSSION PERIOD III: IMPLANTABLE HEARING AIDS Papers 10-13

**Dr. Richard Wiet** (Chicago, IL): Dr. Fredrickson, that was a brilliant paper. I really appreciated all the effort that went into it. I didn't quite catch, what is the mechanism of sound transfer? You mentioned a direct drive system. Is that a floating mass transducer and can you project the costs. The same question directed to Dr. Hough.

**Dr. John Fredrickson** (St. Louis, MO): The mechanism of sound transfer is an electromechanical motor. It produces a vibratory signal and the probe tip, which is aluminum oxide and which is coupled to the body of the incus transfers that vibration to the ossicular chain.

As far as cost is concerned, we are still in a FDA study and frankly we haven't made any decision about cost whatsoever but as Dr. Hough mentioned his device is implanted under local anesthesia and ours is implanted under general anesthesia. Now when we finally get to a fully implantable device if Dr. Hough wants to get involved in that I guess he's going to have to go to general anesthesia. Dr. Hough by his own admission is addressing a different group of hearing impaired patients. The functional gain with Dr. Hough's device does not come close to the functional gain with our device, which is up in the 50-55 dB range. We are targeting those patients who are the most needy, those patients who have the most difficulty, those patients with moderately severe to severe sensorineural hearing loss.

Dr. Jack Hough (Oklahoma City, OK): Yes I think that cost is going to be the deciding factor in a lot of the things we do. There's a place for the Cadillac and also the Chevrolet but most people are not going to be able to afford the very expensive devices that require general anesthetic and are expensive to apply. As far as functional gain is concerned Dr. Fredrickson I disagree with you on that because we are getting an enormous amount of functional gain. I think we get more than the patient can handle just as with a hearing aid. So I think we can reach that and we are already reaching those that have not profound sensorineural hearing loss but severe sensorineural hearing impairment. But I would say the cost should stay pretty close to

a very high level hearing aid as far as price is concerned.

**Dr. Monahar Bance** (Halifax, Nova Scotia, Canada): This question is for Dr. Hough as well. In the study that Dr. Abel reported which we did with BAHA, we found that the biggest impairment for the hearing aid users was in noise. I was wondering from Dr. Hough's data if he had done any tests with speech in noise or hint or any background noise. I presume those results you reported were in quiet.

**Dr. Jack Hough** (Oklahoma City, OK): Is my coauthor here, Pamela Matthews? Well anyway I was going to ask her to elaborate on the audiometric data. Yes we did test in noise but in fact I gave you some statistics there on improvement in background noise and reverberant noise etc. so that is important.

I think the same electronic material that can be used in an ordinary hearing aid including some of the newer digital processes can be used in this without difficulty. As far as the process of direct drive and so forth is concerned, ours is a direct drive system.

As you know a copper wound coil when you send electricity through it produces an electromagnetic field. That field can encompass the small magnet on the incudostapedial joint so the magnet will vibrate in perfect synchrony then with the impulse it's given. It is a direct drive straight to the cochlea and that is the reason we can eliminate a lot of the defects in the ordinary hearing aid.

**Dr. John Niparko** (Baltimore, MD): I have a question for Dr. Abel. One difference between the designs of the devices with the conventional aid versus the BAHA obviously is the microphone design. Conventional amplification often provides some degree of focality whereas the BAHA has an omni directional microphone. Can you comment what you perceive those differences do manifest in your data?

**Dr. S. M. Abel** (Toronto, Ontario, Canada): In fact it would be interesting to do sound localization testing to really address the issue that your commenting on. I have done some sound localization work with cochlear implant users and even though

### **DISCUSSION**

they sometimes think they have an impression of directionality, in fact when you test them objectively and when you speak with them in room conditions, you find that that's not the case.

I would venture to guess that the same would be true for BAHA and air conduction aids, particularly with unilateral fittings. Does that answer your question? **Dr. John Niparko** (Baltimore, MD): In fact most of the conventional hearing aids that you examined had a directional microphone, is that correct?

**Dr. S. M. Abel** (Toronto, Ontario, Canada): You don't really get directionality of sort of precise sound localization that I am referring to. That's really not responsible for our outcomes.

# PHASE I RESULTS OF THE OTOLOGICS MET<sup>TM</sup> OSSICULAR MIDDLE EAR ELECTROMAGNETIC SEMI-IMPLANTABLE HEARING DEVICE: IMMUNOLOGIC AND SEROLOGIC TESTING IN MÉNIÈRE'S DISEASE

Michael J. Ruckenstein, M.D., Anna Prasthoffer; Douglas C. Bigelow, M.D., Joan M. von Feldt, M.D., and Sharon L. Kolasinki, M.D.

### **ABSTRACT**

**Objective:** To establish the value of immunologic and serologic testing in patients with Ménière's disease.

Study Design: Prospective cohort.

Setting: University-based Balance Center.

**Interventions:** Patients with active unilateral or bilateral Ménière's disease underwent testing including antinuclear antibodies, anti-DNA, rheumatoid factor, complement levels, anti-SSA/B, ESR, antiphospholipid antibody assay, western blot for anticochlear antibody (anti-HSP-70), c-ANCA, FTA-ABS, and Lyme titers.

Outcome Measures: Results of laboratory tests.

**Results:** In patients with unilateral Ménière's disease (n = 40), 27% demonstrated elevated antiphospholipid antibody titers (population norm 6–9%). The vast majority of these patients manifested negative assays on the other tests listed above. In patients with bilateral Ménière's disease (n = 20), elevations in ANA titers (38%) were the most notable finding. As part of a broader study of patients with progressive hearing loss, 4 patients with positive syphilis titers were identified, however, none of these patients complained of vertigo.

**Conclusions:** In general, the results of this study to do not support the hypothesis that immune or infectious pathologies are involved in the pathogenesis of Ménière's disease. In particular, Lyme disease does not appear to cause labyrinthine pathology. However, the potential role of the thrombogenic antiphospholipid antibodies must be further investigated. Patients with bilateral Ménière's disease may be more likely to suffer from a systemic autoimmune process.

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# TRANSTYMPANIC ELECTROCOCHLEOGRAPHY: A TEN-YEAR EXPERIENCE

Xianxi Ge, M.D. and John J. Shea, Jr., M.D.

## **ABSTRACT**

**Objective:** To report our experience with transtympanic electrocochleography (ECoG) during the last ten years.

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

**Patients:** Transtympanic ECoG was performed on 2421 ears of 2140 patients from May 1990 to April 2000.

**Intervention:** Clicks and tonebursts were used in ECoG testing. Summating potential/action potential ratio (SP:AP) was calculated. AP latency shift by rarefaction and condensation clicks was measured. Cochlear microphonics (CM) were recorded.

Main Outcome Measure: An enlarged SP:AP ratio (>0.40), broadened AP waveform (>3 msec) and/or prolonged AP latency shift (>0.2 msec) were considered to be indicative of endolymphatic hydrops. Presence of CM indicates hair cells survival.

**Results:** An enlarged SP:AP ratio was found in 78.4%, and a prolonged AP latency shift was found in 62.2% of ears with Ménière's disease. Combined use of SP:AP ratio and latency shift indicated the presence of Ménière's disease in 81.3%. SP:AP ratio > .40 was found 35% in Stage 1 of Ménière's disease, 80% in Stage 2, 85% in Stage 3, and 90% in Stage 4. SP:AP ratio > .40 was associated with the duration of the disease, 43% in <1-year group and 100% in >30 years group. CM was present in 69% of ears in Stages 3 and 4 of Ménière's disease.

**Conclusion:** Transtympanic ECoG is a reliable test to detect the presence of endolymphatic hydrops in Ménière's disease. The CM measurement may be helpful in identifying patients whose hearing may be recoverable.

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# EFFICACY OF INCREASED GENTAMICIN CONCENTRATION FOR INTRATYMPANIC INJECTION THERAPY IN MÉNIÈRE'S DISEASE

Ashraf Saad Abou-Halawa, M.D. and Dennis S. Poe, M.D.

#### **ABSTRACT**

**Objectives:** 1) Update of our case series of intratympanic gentamicin (ITG) in intractable Ménière's disease. 2) Comparison of the treatment results of two gentamicin concentrations: 30 mg/ml and 40 mg/ml.

**Study Design:** Retrospective case-matched study of an ongoing protocol.

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

**Patients:** Eighty-seven patients are included in this study using the 1995 reporting guidelines of the American Academy of Otolaryngology-Head and Neck Surgery.

**Intervention:** Intratympanic injection of a buffered gentamicin solution (30 mg/ml) was used in 44 patients (Group I) in years 1992-1995. Stock gentamicin solution (40 mg/ml) was used in 43 patients (Group II) in years 1996-1999. The end point of treatment is the clinical evidence of complete cessation of vertigo spells.

Main Outcome Measures: Hearing results, vertigo control scores, and ice water. Thirty-two patients from each group were selected for case-matched statistical analysis.

**Results:** In group I, vertigo control was achieved in 84% while the hearing remained the same or improved in 72% of patients. In group II, vertigo control was achieved in 70% while the hearing remained the same or improved in 80% of patients. Treatment was aborted in 7 patients of group II for early hearing loss with 21/25 (84%) patients who completed the protocol having lasting vertigo control.

**Conclusion:** Increasing gentamicin concentration to 40 mg/ml does not increase the risk of hearing loss if treatment is stopped at the first indication of injury. Earlier cessation in group II caused an overall drop in vertigo control and a trend for improved hearing results and vertigo control was comparable among patients who tolerated gentamicin treatment.

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# PATIENTS SUBJECTIVE EVALUATION OF QUALITY OF LIFE RELATED TO DISEASE SPECIFIC SYMPTOMS, SENSE OF COHERENCE AND TREATMENT IN MÉNIÈRE'S DISEASE

Anne-Charlotte Hessén Söderman, M.D., Dan Bagger-Sjöbäck, M.D., Ph.D., Johan Bergenius, M.D., Ph.D., Carsten Tjell, M.D., Ph.D., and Ann Langius, R.N., Ph.D.

### **ABSTRACT**

**Objective:** To evaluate self-rated disease specific quality of life in Ménière's patients, and to identify potential relationships between these findings, treatment regimens and sense of coherence.

Study design: Cross sectional.

**Setting:** Two tertiary referral centers.

**Patients:** 112 patients with Ménière's disease as defined by the AAO/HNS criteria.

**Interventions:** Three groups of patients were included-untreated, endolymphatic sac surgery, gentamicin intratympanically.

Main Outcome Measure: Questionnaires concerning quality of life aspects and symptom-specific instruments, the AAO/HNS criteria and the Sense of Coherence Scale.

**Results:** In all treatment groups a majority of the patients reported their quality of life in general as very good or good. There was no difference in general quality of life, present hearing loss or tinnitus between the three treatment groups, but the gentamicin treated patients had less vertigo than the other groups. Sense of coherence showed a strong correlation to reported quality of life in all measurements.

**Conclusions:** Even though the gentamicin treated patients had less vertigo no difference in over-all quality of life was found between the surgically treated and untreated patients. The sense of coherence seems to be an important factor in the patient's experience of quality of life. Quality of life instruments might give complementary information to the AAO/HNS classification when evaluating treatment of patients with Ménière's disease.

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# MEDICAL PROFILE OF A GROUP OF ELDERLY FALLERS

Marian Girardi, M.A., Manali Amin, M.D., Horst R. Konrad, M.D., and Larry F. Hughes, Ph.D.

## **ABSTRACT**

**Objective:** To examine co-morbidity and other health factors in order to better predict falls risks for elderly patients.

Study Design: Retrospective.

Setting: Balance Disorders/Falls Prevention Clinic; Tertiary referral center.

**Patients:** 36 patients over age 65 who had fallen once or more in the year prior to their visit to the clinic. Average age was 78.4 years and mean number of falls was 3.4.

**Interventions:** Rehabilitative (mainly balance and gait retraining with physical therapists).

Main Outcome Measures: Frequency of co-morbidity factors, results on posturography, ENG, Tinetti Balance and Gait Tests, Berg Balance Test, other past medical history information.

Conclusions: The mean number of medications taken by these patients was 5.8 for prescription and 1.6 for over-the-counter drugs. Computer Dynamic Posturography was the most sensitive of the items examined with 83.3% of the elderly fallers demonstrating abnormal results. The Tinetti and Berg assessments ranked next with 63.9% patients having sub-threshold scores for both tests. ENG results were significantly abnormal for 55.6% of the patients. Other medical factors, ranked in decreasing order were: musculoskeletal complaints 69.4%; cardiovascular problems 61.1%; hypertension 58.3%; hearing loss, anxiety, and depression, each 44.4%; vision difficulty 36.1%; tinnitus 30.6%; cancer and closed head trauma, each 16.7%; panic attacks 13.9%; diabetes and stroke, each 11.1%; and knee replacement surgery 8.3%. Identifying older individuals at risk of falling is of paramount importance in order for these persons to participate in intervention programs offering preventative therapeutic and rehabilitative measures, thereby reducing their risks of falls related injury or death.

Reprint requests: Marian Girardi, M.A., SIU School of Medicine, P.O. Box 19662, Springfield, IL 62794-9662.

# MOLECULAR PATTERNING OF THE ENDOLYMPHATIC DUCT AND SAC

Krystyn Z. Bourne, M.S., Manual Lopez, M.D., Colm Madden, M.D., and Daniel Choo, M.D.

## **ABSTRACT**

**Hypothesis:** To test the hypothesis that the Jagged/Notch signaling system plays a role in the molecular patterning of the developing endolymphatic duct and sac (ELDS), we examined the temporal/spatial expression patterns of this ligand and receptor in embryonic mouse inner ears.

**Background:** The ELDS are critical inner ear organs involved in endolymph homeostasis. Only recently have gene expression studies suggested a molecular heterogeneity to cells of the ELDS. Different cells within the ELDS likely perform different functions related to maintenance of homeostasis. This study was performed to examine a potential role of Jagged/Notch signaling in differentiation of these important inner ear cellular systems.

**Methods:** A systematic immunohistochemical study of mouse inner ears ranging from embryonic day (E)10-17.5 was performed using polyclonal antibodies (Santa Cruz Biotechnology, Inc.) and a Diaminobenzidine (DAB) technique. Analysis of alternating cryosections allowed comparison of Jagged and Notch expression domains.

**Results:** Jagged is first detectable in the ELDS at embryonic day 12 (E12) and continues in a diffuse expression pattern until E15. At E15, Jagged signal then becomes restricted to a distinct subset of cells within the ELDS. In contrast, Notch is expressed at low levels from E11 to E13. Expression of Notch continues stronger and homogeneous throughout the ELDS from E13-17.5.

**Conclusion:** Expression data suggest that Jagged/Notch signaling is involved in ELDS development and patterning. Such data indicate that a heterogeneous population of cells can be identified in the developing ELDS and warrant further investigations to determine their characteristics and potential importance to endolymph homeostasis.

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# DISCUSSION PERIOD IV: MÉNIÈRE'S DISEASE, DIZZINESS, AND IMBALANCE Papers 14–19

**Dr. Robert Ruben** (New York, NY): Question for Dr. Poe. In those patients who have dead ears after Gentamicin, have you screened them for mitochondrial susceptibility to Aminoglycoside?

**Dr. Dennis Poe** (Boston, MA): That is an excellent question. I have not done that. There is no reason why we can't go and look at that in the future, now that this sort of testing is available.

**Dr. Robert Ruben** (New York, NY): Yes, I think it may prove interesting because they may have other abnormalities. You always have to ask the question why do a few ears loose function. You certainly have the capability to do the tests in Boston.

**Dr. Denis Poe** (Boston, MA): That is correct. Thank you for that suggestion.

**Dr. Ilmari Pyykko** (Stockholm, Sweden): I also have a short question for Dr. Poe because that was a very important treatment. I wonder, did you take care of the availability and concentration of the buffered Gentamicin because it is destroyed very quickly. You have to use a fresh solution or otherwise your results may not be as good as forty milligrams, which is not destroyed by time? Did you take care of that?

**Dr. Dennis Poe** (Boston, MA): Yes. In fact this is one of the reasons why I proceeded to this study. The 30- milligram solution is thought to be unstable after even as much as 12-24 hours and that creates a stocking and preparation issue. One of the purposes of this study is to see if that was necessary. All of the thirty-milligram patients did have a fresh solution prepared that day.

**Dr. Judith Maw** (San Jose, CA): Question for Dr. Ruckenstein. Congratulations on an interesting paper but what is the cost effectiveness of performing the additional test or the expense of those tests for the anti-phospholipid antibody and how does it impact how you manage a patient? Do these patients go on to develop the anti-phospholipid antibody syndrome, is counseling important, etc.?

**Dr. Michael Ruckenstein** (Philadelphia, PA): That is an important question, which we are trying

to answer. We were caught a little bit by surprise by the incidence of anti-phospholipid antibodies in this group. We have not yet affected any management change in these patients. The only treatment that is effective is systemic anti-coagulation. To commit a young to middle age person to a life long anti-coagulation based on a single manifestation of hearing loss is not yet acceptable. We need basic science data to confirm that these antibodies can mediate the hearing loss. Until such data is available, I can't tell the rheumatologist that this is definitely a manifestation of APL and therefore warrants treatment. In order to determine cost effectiveness we have to determine causality as opposed to association and we are looking into that as we speak.

**Dr. Mohamed Hamid** (Cleveland, OH): Comment to Dr. Poe. I'm glad you showed that there is no difference between buffered solution and non-buffered solution because those of us who use it, it is kind of messy to get the solution to be buffered.

A question to Dr. Manali Amin. A question about LOS (limits of stability), is it really the amplitude of the limits itself or what happens at the limits of stability that makes these patients prone to falling?

**Dr. Manali Amin** (Springfield, IL): I believe it is the amplitude. The limits of stability also addresses one other concern. It takes into account fear. Patients are essentially asked to voluntarily use ankle strategy so it is the amplitude of swaying four directions, anterior, posterior and both sides laterally as well as taking into account fear.

**Dr. Mohamed Hamid** (Cleveland, OH): So you instruct them to use ankle strategy at the end of the limits of stability? You don't let them choose basically between hip sway and ankle sway.

**Dr. Manali Amin** (Springfield, IL): No you instruct them on ankle strategy and then ask them to perform the test as the computer reads the shift in their center of gravity.

**Dr. Mohamed Hamid** (Cleveland, OH): That is a subconscious choice and if we try to make it a con-

scious choice the results would be different. Thank you.

**Dr. Paul Kileny** (Ann Arbor, MI): Dr. Amin, I just want to ask another question. You mention that one of the possible factors in the frequency of falls may be cognitive function or central dysfunction. Have you thought about it, have you looked at any cognitive measures in these patients and if not, is it something that may be reasonable to include in your model?

**Dr. Manali Amin** (Springfield, IL): We have not. One of the commonly used cognitive measures is the mini mental status exam and that probably was something we should have done. I appreciate the input.

**Dr. Ilmari Pyykko** (Stockholm, Sweden): While Ms. Girardi is there I would like to address one more question about the fallers because I think it's a great challenge for otolaryngology. It seems that if an elderly patient at the age of 85 is falling down and cannot stand up, the risk of dying is about fifty percent within one year so it's a severe problem.

The problem you are telling us is that you are just looking for posturography and certain functional movements. There are known risk factors, such as Parkinson's and dementia, which you actually cannot help effectively.

I wonder if you did reconstruction of your fallers because in about thirty percent the reason seems to be sick sinus syndrome in the elderly. There may be many different factors, which you actually cannot explain by posturography, or performance test.

**Dr. Manali Amin** (Springfield, IL): I'm sorry I didn't catch the last part of that.

**Dr. Ilmari Pyykko** (Stockholm, Sweden): My question is did you reconstruct the falling happenings?

**Dr. Manali Amin** (Springfield, IL): No. If you are looking at the biomechanics or reconstruction of the fall itself, we did not. There have been studies that have been done by Tonetti et al. who have gone into the home and examined environmental conditions to reconstruct it in that way. We didn't look at those environmental aspects.

# THE FENESTRATION OPERATION OF LEMPERT: HISTORICAL PERSPECTIVE

Jack L. Pulec, M.D.

## **ABSTRACT**

The one stage fenestration operation was a monumental development in otology. Although the first formal presentation of the Lempert operation was made to the American Otological society, the manuscript appears nowhere in print. What started out as a routine review of the literature by me in the preparation of a paper on surgery for otosclerosis to be given to The Surgical Society of the Mayo Clinic lead to the fascinating events surrounding the introduction of the fenestration operation. The search turned up a story of intrigue which involves the expulsion of The President-Elect of The American Otological Society, the expunging of all minutes and notes of The American Otological Society concerning the events and the failure to publish the original paper of The Fenestration Operation. The earliest published accounts appeared in Time. Newsweek and the publication of the New York Academy of Science. In 1973 Dr. Gordon Hoople, who at that time was the last living member of the council involved in the event told me what had actually occurred in The American Ontological Society and his official investigation of the affair. He requested that the knowledge not be made public until all of those principally involved had died. Dr. Hoople died two weeks after our talk. This paper will give Dr. Hoople's account of the events along with a review of the printed evidence surrounding the introduction of the fenestration operation of Lempert.

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# LASER STAPEDOTOMY MINUS PROSTHESIS (LASER STAMP): ABSENCE OF REFIXATION

Herbert Silverstein, M.D., W. Sean Conlon, M.D., Seth I. Rosenberg, M.D., Lance E. Jackson, M.D., Jack H. Thompson, Jr., M.D.

## **ABSTRACT**

**Objective:** To determine what percentage of patients with otosclerosis could successfully undergo a Laser Stapedotomy Minus Prosthesis (Laser STAMP) over a five-year period (from 4/17/95 to 5/23/00), and to determine what percentage of patients develop refixation in this period of time.

**Study Design:** Retrospective case review of 135 patients who underwent primary surgery for otosclerosis.

**Setting:** An otology/neurotology tertiary referral center.

**Patients:** Patients were chosen if they had clinical evidence of otosclerosis without a history of prior surgery.

**Interventions:** A hand-held probe and argon laser were used to vaporize the anterior crus and perform a linear stapedotomy across the anterior one third of the footplate. If otosclerosis was confined to the fissula antefenestrum, the stapes became completely mobile. Adipose tissue graft sealed the stapedotomy.

**Main Outcome Measures:** Pure-tone audiometry and auditory discrimination testing were performed before surgery, 6 weeks postoperatively, and yearly.

**Results:** Of the 135 patients in the study, 44 (33%) underwent Laser STAMP procedure. Sixty-five percent of the patients could not undergo the procedure due to extensive otosclerosis, or anatomic or technical difficulties. Six weeks postoperatively the air-bone gap was closed to a mean of 6dB (SD  $\pm$  6dB). Thirty of the patients had additional testing at an average of 20 months (SD  $\pm$  15 months). The air-bone gap was 7dB (SD  $\pm$  6dB) and did not significantly change compared to the original 6 week postoperative value.

**Conclusions:** Laser Stapedotomy Minus Prosthesis (Laser STAMP) is a minimally invasive procedure, which, over the follow-up period, has a very low incidence of refixation as evidenced by lack of progressive conductive hearing loss.

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# CAUSES FOR CONDUCTIVE HEARING LOSS FOLLOWING STAPEDECTOMY OR STAPEDOTOMY: A PROSPECTIVE STUDY OF 279 CONSECUTIVE SURGICAL REVISIONS

S. George Lesinski, M.D., Stephanie Grace, Ph.D., and Paula Day, M.A., C.C.C.-A.

### **ABSTRACT**

**Objective:** To analyze the causes for residual or recurrent conductive hearing loss following stapedectomy or stapedotomy and then propose surgical techniques to avoid these complications.

**Study Design:** Prospective study of 279 consecutive stapedectomy (otomy) revisions performed by the author.

**Setting:** Tertiary referral center Otology/Neurotology

**Patients:** 260 patients presented with a 20dB or greater average air bone gap in the speech frequencies 1 month to 35 years following stapedectomy or stapedotomy. (19 patients were explored for possible oval window perilymph fistula)

Interventions: Stapedectomy (otomy) surgical revision.

Main Outcome Measures: Microscopic inspection and palpation assessed the mobility and continuity of the malleus, incus, and prosthesis. Infrared laser vaporization thinned the oval window neomembrane to identify the precise depth and margins of the oval window, the presence of residual stapes footplate, and finally, the relationship of the prosthesis to the fenestra into the vestibule.

**Results:** 81% (211/260) demonstrated prosthesis displacement out of the oval window fenestration with fixation of the prosthesis against the residual stapes footplate or otic capsule margin. 31% of these patients had complete incus erosion and an additional 60% demonstrated partial incus erosion usually on the undersurface of the incus. Residual fixed stapes footplate was found in 14%. Malleus fixation 4%. Incus dislocation 4%. Incus fixation 2%.

**Conclusions:** Prosthesis migration and subsequent fixation caused the majority of stapedectomy failures. Collagen contracture of the oval window neomembrane lifts the prosthesis out of the oval window fenestration. Prosthesis displacement then results from adhesions pulling the prosthesis or mechanical forces further tilting the prosthesis. Incus erosion results from vibration against the fixed prosthesis. Six specific stapedotomy recommendations are made to minimize postoperative prosthesis migration.

# THE EFFECTS OF VARYING LEVELS OF UNILATERAL CONDUCTIVE HEARING LOSS ON SOUND FIELD SPIN SCORES: IMPLICATIONS FOR THE SURGICAL CORRECTION

Jon Nia, B.Sc. and Manohar L. Bance, M.B., M.Sc., F.R.C.S.C.

#### **ABSTRACT**

**Hypothesis:** Unilateral conductive hearing loss causes measurable disability in realistic hearing environments, and the benefits of improving this loss depend on both the final hearing level and the final asymmetry.

**Background:** Surgical success is often measured by change in either the air-bone gap or in air thresholds. The Glasgow Benefit Plot and the Belfast Rule of Thumb suggest that a given hearing gain will give greater benefit if the thresholds in the worse ear end up less than 30dB HL, or within 15 dB of the contralateral ear. Despite the important surgical implications, little audiometric validation for this assertion currently exists.

**Methods:** Speech-in-Noise (SPIN) soundfield scores were measured in 16 normal volunteers at three intensity levels at two different Signal/Noise (S/N) ratios. Two different levels of unilateral conductive hearing loss were simulated with ear plugs, and the effect on SPIN scores based on degree on conductive loss calculated and analyzed.

**Results:** Unilateral hearing loss is a disadvantage at lower sound intensities and low S/N ratios, but can be compensated for by increasing the volume or S/N ratio. The benefits of improving unilateral conductive loss are more marked if the final asymmetry is less than 25dB and the final hearing threshold is <25dB.

**Conclusions:** Unilateral conductive hearing loss is a significant disadvantage at low S/N ratios or presentation volumes. The benefits of surgery to improve hearing loss depend not only on the degree of hearing improvement but the final hearing threshold in both ears.

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# DISCUSSION PERIOD V: CONDUCTIVE HEARING LOSS Papers 20–23

**Dr. Dennis Poe** (Boston, MA): I want to congratulate Herb Silverstein on very nice work. I would like to echo that I have had very similar results using your technique. I really appreciate the work that you've done. The question is: you showed a thirty three percent incidence that you are able to do this when you open up a stapes case. Would you say that this number is getting better over time as you get better with the procedure?

**Dr. Herbert Silverstein** (Sarasota, FL): I'm not sure. I think it is but I think its how the cases come. Sometimes we seem to do two or three in a row and then we don't see one for awhile so I think its probably going to be about 35–40% over a long time.

**Dr. Herbert Silverstein** (Sarasota, FL): I have a comment to make about Dr. George Lesinski's paper, which was a very nice paper. George, I noticed I didn't see any Teflon pistons that had eroded the incus.

I have stopped using wire because I've seen so many platinum wires and stainless steel wires erode the incus over a period of time. I think that we are all going to be seeing tremendous numbers of revisions due to the wire eroding the incus. I think we will see more and more of this over a period of time and I don't think that we are seeing it as much with the Teflon piston cup over the incus.

**Dr. George Lesinski** (Cincinnati, OH): We have not seen any Teflon erosion of the incus but the mechanism for partial erosion gives us a clue. As the prosthesis migrates and becomes fixed, this living biologic bone continues to vibrate against a fixed metal and gradually the bone will remodel. I was very meticulous describing even 10% erosion. In almost all of the cases we see, there's some type of erosion and it starts on the undersurface. As far as using a softer material, I think that would help. I think there would be more give.

I think ultimately over-crimping is not the answer because we have seen erosion with Lippy Robinson bucket handle prosthesis as well.

I don't mean to imply that any prosthesis is better than another. The incidence of use is so widely varied in this patient population that I revised that we can't draw any conclusions about the pros-

Dr. Eugene Derlaki (Chicago, IL): You know you sit here and listen and it takes you way back. I would say to Dr. Silverstein that I think his technique is going to be a successful one because in 1960, when Dr. Schuknecht had a marvelous symposium at Henry Ford Hospital, I presented our technique. We were very conservative. We were going slowly from what we called the graduated stapes technique. We used a technique by hand without the laser that was exactly the same as you described here with the STAMP. I have many of those cases in whom I have done a second ear thirty years later with the first year holding up just beautifully with that technique so it has a good chance for survival. So I'm happy to see that come back.

**Dr. Rodney Perkins** (Palo Alto, CA): I'd like to thank all three of the presenters for their contribution. I think they are all very good observations and work. I have a comment on two of the papers one is Dr. Silverstein's. I like that technique. I think the importance of observation of the details of the footplate in this situation is very important. Not always doing a routine procedure and conserving tissues as much as you can and decreasing trauma.

The second thing, I think the high frequencies looked a little better at first and then you disclaimed that it wasn't statistically significant. I would think that over a long run that if you compared that with conventional stapedectomy or even stapedotomy, they might be better because there's probably less iatrogenic trauma in that case.

The third thing, I think the conservation of the tendon there is attractive, particularly in view of the fact that the portion of the normal footplate is still intact. There's been some work done I think by Pang and Peak on the function of the stapedial tendon. The best evidence on that I could read in preparing for a paper at this meeting last year was that the stapes tendon helps perceive higher frequencies in noise. Perhaps those patients will have a little better high frequency perception.

### **DISCUSSION**

One comment on Dr. Lesinski's paper that I find that very interesting. I think we are all troubled with incus erosion. I think in a stapedectomy with the collagen membrane, that probably the lateral force as he put forth is why most of those erode, when they erode the incus that's probably it.

I think that is the same thing that causes lateralization of grafts in tympanoplasty. If you put the

fascia membrane lateral to the bony wall or placed on the bony wall as a cone it will contract and become a plane and the same thing happens with any collagenase membrane in the oval window. As that contracts it tries to become a plane at its attachment point and therefore would forcing the wire into the incus. So I would like to thank both of them for their contribution.

# MANAGEMENT OF ANTERIOR EPITYMPANIC CHOLESTEATOMA: EXPECTATIONS AFTER EPITYMPANIC APPROACH AND CANAL WALL RECONSTRUCTION

Larry G. Duckert, M.D., Kathleen H. Makielski, M.D., and Jan Helms, M.D.

#### **ABSTRACT**

**Introduction:** The epitympanic approach to cholesteatoma provides excellent access to the anterior epitympanic space (AES). When combined with reconstruction of the scutum, it is tempting to propose that the approach may offer the patient the advantage of both canal up (CWU) and canal wall down (CWD) techniques and the disadvantages of neither. In theory, then, the incidence of residual/recurrent cholesteatoma should be no greater than canal wall down surgery, and the need for a second look often associated with the canal up procedure should be less compelling. However, validation of this theory is lacking.

**Objective:** To test this theory we sought:

- 1. To establish incidence of recidivism in a population undergoing cholesteatoma removal via the epitympanic approach followed by canal wall reconstruction.
- 2. To identify anatomical factors predisposing to persistent disease.
- 3. To identify technical features or problems associated with recurrent cholesteatoma.

Study Design: A retrospective case series.

**Setting:** A tertiary referral center.

**Patients:** Fifty-four adults and eleven children with extensive cholesteatoma involving but not limited to the anterior epitympanic space.

**Intervention:** All patients underwent removal of cholesteatoma via the epitympanic approach with canal wall reconstruction followed by re-exploration at one year.

**Results:** Recurrent/residual disease was observed in six adults (11%) and five of eleven children (45%). The anterior epitympanic space harbored cholesteatoma in 100% of adult patients and 80% of pediatric patients with recurrent disease.

#### **Conclusions:**

- 1. The epitympanic approach does not eliminate the need for reexploration in cases of extensive cholesteatoma.
- 2. The anterior epitympanic space is highly likely to harbor recurrence.
- 3. Features of the canal wall reconstruction can be identified with predisposed recurrence.
- 4. A long-term follow-up and close surveillance is mandatory especially in the pediatric population.

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# DEMINERALIZED BONE MATRIX AS AN ALTERNATIVE FOR MASTOID OBLITERATION AND POSTERIOR CANAL WALL RECONSTRUCTION: RESULTS IN AN ANIMAL MODEL

Bryan D. Leatherman, M.D., John L. Dornhoffer, M.D., Chun-Yang Fan, M.D., and Perkins Mukunyadzi, M.D.

## **ABSTRACT**

**Hypothesis:** This study was conducted to evaluate the use of Grafton® human demineralized bone matrix (Osteotech, Inc., Eatontown, NJ) as a graft material for mastoid cavity obliteration and canal wall reconstruction in an animal model.

**Background:** Canal wall down procedures in treatment of cholesteatoma may result in a problematic mastoid cavity. Elimination of the mastoid cavity by obliteration or canal wall reconstruction can prevent or correct this problem. Many techniques and implant materials have been utilized for this application, yet no single material has proven to be ideal.

**Methods:** Athymic rats received tympanic bulla obliteration and lateral bulla wall reconstruction utilizing the Grafton Putty® and Flex® formulations, respectively. Wound healing was monitored twice a week. Brainstem auditory-evoked responses were obtained 8 weeks post-implant. Nine weeks post-implant, the animals were sacrificed, and histologic sections were prepared. A histologic bone formation score (range 0–4) was determined for each implant.

**Results:** Wound healing occurred without complication. ABR thresholds (average 23.5) fell within normal range for all ears tested. The average histologic bone formation score for all implants was 3.7. The average scores for obliteration implants and wall reconstruction implants were 3.5 and 3.9, respectively. All wall reconstruction implants underwent partial or total collapse into the bulla.

**Conclusions:** The high level of bone formation obtained using Grafton implants in this study makes this material a promising resource for use in mastoid obliteration. The use of the material for canal wall reconstruction will likely require a sturdier preparation to prevent collapse into the mastoid cavity.

Reprint requests: Bryan D. Leatherman, M.D., 4301 West Markham, Slot 543, Little Rock, AR 72205-7199; ph 501-686-5141; fax 501-686-8029.

# BONE CEMENTS AS ADJUVANT TECHNIQUES FOR OSSICULAR CHAIN RECONSTRUCTION

Karen K. Hoffmann, M.D., Jeffrey J. Kuhn, M.D., Barry Strasnick, M.D., F.A.C.S.

#### **ABSTRACT**

**Hypothesis:** The osseointegrative capacity of medical grade bone cement can be used to prevent displacement of an ossicular prosthesis in a guinea pig model.

**Background:** Successful ossiculoplasty requires a firm connection between the vibrating tympanic membrane and the inner ear. In patients requiring revision surgery, half of failures are due to prosthesis displacement. Bone cements have been used as prosthetic material in craniofacial surgery, but their adhesive and integrative properties make them ideal for use in ossiculoplastic surgery.

**Methods:** Twenty-four adult male guinea pigs underwent a postauricular surgical approach for access to the middle ear. Hydroxyapatite and Dahllite cements were used in an alternating fashion to fix ossicular bone. Four animals were sacrificed immediately to demonstrate mechanical bonding of the ossicles at the time of application. Nineteen animals were sacrificed at eight weeks to assess bonding capacity and histologic inflammation.

**Results:** Both cements mechanically bonded the ossicles at the time of application, but Dahllite cement set faster in the moist environment of the middle ear space. Histopathologic examination showed bonding of the ossicles with both cements, with little evidence of inflammation or foreign body reaction.

**Conclusions:** Hydroxyapatite and Dahllite bone cements showed evidence of osseointegration with ossicular bone in the guinea pig model. Further studies are underway to determine the osseointegrative capacity of Dahllite cement between the guinea pig malleus and a partial prosthesis, and any ototoxic effects with use in the middle ear.

This study was supported by unrestricted grants from Stryker-Leibinger Corporation and AO North America.

Reprint requests: Karen K. Hoffmann, M.D., 825 Fairfax Ave, Ste 510, Norfolk, VA 23507.

# PROGRESSIVE ATELECTASIS IN THE GERBIL

Matthew R. O'Malley, B.S., David A. Lehman, M.D., Angela R. Prevatt, B.S., Gregory S. Schultz, Ph.D., Patrick J. Antonelli, M.D.

## **ABSTRACT**

**Hypothesis:** Gene transfection may be used to treat or prevent tympanic membrane (TM) pathology.

**Background:** Progressive TM pathology (eg, atelectasis) may be amenable to intervention with topically applied agents. Genetic therapy of TM pathology may be possible using existing vectors. These vectors have shown promise in the treatment of other clinical conditions.

**Methods:** Progressive TM atelectasis was induced in Mongolian gerbils by Eustachian tube cauterization. Vectors were topically applied to atelectatic and control TMs (n = 194) in one treatment. TMs were harvested at intervals from 2 to 28 days and analyzed for reporter gene expression (using ELISA and microscopy of stained sections). Vector-reporter gene combinations included adeno-associated virus (AAV) with E. coli  $\beta$ -galactosidase ( $\beta$ -gal), AAV with E. coli chloramphenicol acetyltransferase (CAT), PMP-6 plasmid with CAT (with or without lipid solution).

**Results:** Transfection with AAV yielded β-Gal expression in both normal (3/3 of samples) and pathological (2/3) tympanic membranes at 14d. Epithelial β-gal expression continued through 21days. AAV-CAT treatment failed to provide significant CAT expression. TMs treated with PMP-6 plasmid demonstrated CAT expression in 8 of 105 (7.6%) samples. CAT expression in 4 of these 8 specimens was minimal (0.290–2.65 pg/ml).

**Conclusions:** PMP-6 plasmid does not produce reliable gene expression in the gerbil TM. AAV vector may result in gene product expression in the TM and may allow for topical gene therapy directed at progressive TM pathology.

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# DISCUSSION PERIOD VI: CHRONIC EAR SURGERY Papers 24–27

**Dr. Jennifer Maw** (San Jose, CA): I just have a comment of caution for Dr. Leatherman. It's hard to discuss our complications but I've worked a lot with Neurion and bone source by Livelinger. I was comfortable with them for retrosigmoid reconstructions and other skull base reconstructions and felt that the results were very positive.

I moved forward to using them for mastoid obliteration and early on the patients had dry ears and seem to be doing very well but after several months there was granulation tissue formation and breakdown. Several of these patients had to be brought back to the operating room for removal of the substances. Just a caution that I look forward to long term results with that product.

**Dr. Arun Gadre** (San Antonio, TX): Also a comment for Dr. Leatherman. I wanted to let you know that there is one patient that Dr. Hamerschlog, my teacher had in New York. This article is about to be published in the Laryngoscope. This particular patient had the same problem that you mentioned, the DMB bone matrix gel placed in the mastoid bowl along with a Grote hydroxyapatite prosthesis. The material got infected. This is an N of 1 but this patient went on to develop a fistula of the lateral semicircular canal with severe vertigo every time the patient chewed. So once again I will underscore what Dr. Maw mentioned, be very careful about using this in the presence of an infected cavity.

**Dr. Hillary Brodie** (Sacramento, CA): I want to compliment Dr. Hoffman on her study. I have one question regarding the hydroxyapatite solutions. As they are bonding when they are in contact with fluid in the middle ear and mastoid, is there any suspension or dissolving of the material, which may coat the ossicular chain, the stapes and be resulting in osteogenesis?

**Dr. Karen Hoffmann** (Norfolk, VA): That was certainly one thing we were concerned about. What we did was to place gel-foam in the middle ear and around the stapes footplate. I think that is what you would have to do to make sure

there was no bone cement that would become adherent to that area. We did find that with hydroxyapatite cement it had a bit of a delusional affect and it was probably a little less easy to use. It had a bit more firm consistency and would probably make better cement for the middle ear. It is a valid concern.

**Dr. Arun Gadre** (San Antonio, TX): One question I had for Mr. O'Malley was the model you are using. Are you using the model cauterizing the eustachian tube and if so when are you seeing fluid in the middle ear? When are you seeing cholesteatoma and what are you calling atelectasis?

Mr. Mathew O'Malley (Gainesville, FL): Thank you for that question. The model we use in that experiment I believe was proposed by Dr. Chole in 1986. We define atelectasis and we stage it based on the papers presented by Kim and Chole in the mid 90's. Additionally we assess the gerbils at 30 days following cauterization for the presence of fluid, atelectasis, effusion and cholesteatoma. Those are seen in some specimens and not others. The specimens in which atelectasis was not seen were discarded from the final analysis of the data. Additionally the specimens are analyzed or observed again before they are harvested which can be anywhere from five to eight weeks following the initial cauterization. They are staged again at that point.

**Dr. Anil Lilwani** (San Francisco, CA): A question for Mr. O'Malley. Your expression following exposure to the recombinant DNA looked extremely low and in fact at the sensitivity range possibly below what Eliza can detect. In the absence of expression in your histological specimen, it makes me concerned: one, about simply noise of your assay and second, could this be pseudo-transduction, that is simply the protein that is present as part of your assay that you use?

Mr. Mathew O'Malley (Gainesville, FL): Those are valid concerns, however, the acid we use does report a sensitivity of greater than 30 picograms per

#### **DISCUSSION**

ml and included in that data are data points with expression of greater than 30 picograms per ml. Your second question is perhaps a reasonable concern. Another additional concern perhaps is that tissues surrounding, if indeed the tympanic membrane is not transected and tissues around it are, perhaps there's contamination from other tissues. Those are all considerations that can be revealed

with further experimentation but I believe that our data at this point shows very minimal expression as you mentioned in the tympanic membrane but expression that is encouraging in the glandular elements. Additionally, other studies have shown that even very low levels of expression following transduction can have a very profound effect on a clinical picture. Thank you.

# CHANGES IN QUALITY OF LIFE AND THE COST-UTILITY ASSOCIATED WITH COCHLEAR IMPLANTATION IN LARGE VESTIBULAR AQUEDUCT SYNDROME

Bradford G. Bichey, M.D., Jon M. Hoversland, B.S., Michael K. Wynne, Ph.D., and Richard T. Miyamoto, M.D.

## **ABSTRACT**

**Objective:** The major objective of this study was to explore the improvements in quality of life associated with cochlear implantation in patients with LVAS, as well as the cost-utility of cochlear implantation in this group.

Study Design: A prospective case-control study.

Study Setting: A large academic medical center in the Midwest.

**Patients:** Twenty patients with Large Vestibular Aqueduct Syndrome (LVAS) were selected from 70 patients who had a vestibular aqueduct measuring greater than 1.5 mm in anteroposterior diameter noted on thin-section temporal bone CT studies at this medical center. Participants were selected who were post-lingually deafened and who currently had severe, progressive or fluctuating hearing loss. Two groups were formed, comprising either cochlear implant patients with LVAS or patients with LVAS currently using hearing aids. Ten of the 16 cochlear implant patients and 10 of the remaining 54 LVAS patients met selection criteria.

**Intervention:** Mark III health utility indexes were distributed to patients in each group and scored. Health utility indexes that were not completed by the patients were scored by proxy using the audiologist at this center most familiar with the patient.

Main Outcome Measures: Health utility index results of the two groups were compared. Cost-utility measures were made using discounted costs per QALY's (5%), and a sensitivity analysis was performed which evaluated changes in scoring done by proxy.

**Results:** Results from the base case indicate a 0.20 gain in health utility from cochlear implantation (HA=0.62, Cl=0.82, p=0.037) resulting in a discounted cost per QALY of \$12,774. Sensitivity analysis of the proxy scoring indicated that decreasing the hearing score one level on the health utility index resulted in a gain in health utility with cochlear implantation of 0.15 resulting in a discounted cost per QALY of \$17,832. A decrease of the hearing score by two levels on the health utility survey resulted in no significant gain in quality of life with cochlear implantation.

**Conclusions:** This study found an improvement in quality of life associated with cochlear implantation in postlingually deafened LVAS patients. This gain in quality of life was similar to prior published studies for cochlear implantation in other types of patients. Cost-utility results from this study also compare favorably to published figures for other disease states and indicate that cochlear

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implantation can be offered as a beneficial, life-improving therapy in post-lingually deafened LVAS patients with severe hearing loss.

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# PREDICTION OF COCHLEAR IMPLANT PERFORMANCE WITH PROMONTORY STIMULATION ADAPTATION

Kristen Baker, B.A., Franklin M. Rizer, M.D., John Burkey, M.A., Kathie Griffith, M.A., and Barbara Foster, M.A.

### **ABSTRACT**

**Objective:** Studies examining the value of the promontory stimulation test as a predictor of cochlear implant performance have been contradictory. This study was to examine whether promontory stimulation testing can be used as a predictor of postoperative cochlear implant performance.

**Setting:** Private otology practice.

Study Design: Retrospective.

**Method:** Seventy-four adult patients were evaluated using promontory stimulation testing prior to cochlear implantation. Patient performance was assessed using Central Institute for the Deaf (CID) sentence testing before and after implantation.

**Outcome Measures:** Postoperative CID sentence test results.

**Results:** The amount of adaptation measured during promontory stimulation was found to be negatively correlated with performance on CID sentence tests. The mean postoperative CID score was 61% for patients with no adaptation, 40% for patients with mild adaptation and 6% when there was severe adaptation. Promontory stimulation thresholds, maximum acceptable loudness levels and gap detection ability were not found to be correlated with cochlear implant performance.

**Conclusion:** The adaptation subtest performed during promontory stimulation was found to be predictive of postoperative performance with a cochlear implant.

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# ADULT COCHLEAR IMPLANT FUNCTION INDEX (CIFI) IN RFAI - WORLD SETTING

Paul E. Hammerschlag, M.D., F.A.C.S., Pat Rothschild, M.A., C.C.C.-S.P., Yael Bat-Chava, Ph.D., and Darius Kohan, M.D.

# **ABSTRACT**

**Objective:** The Cochlear Implant Function Index (CIFI) is created to assess adult cochlear implant (CI) auditory effectiveness in real world situations. Our objective is to evaluate the CIFI that rates 1) reliance on visual assistance, 2) telephone use, 3) communication at work, 4) "hearing" in noise, 5) in groups, and 6) in large room settings.

**Study Design:** Based upon Guttman scaling properties, the CIFI elicits implanted respondent's functional level with auditory independence lowest level 1, still requiring signing to level 4 consistent without any help beyond CI. A blinded, retrospective questionnaire is anonymously answered.

**Setting:** CI centers of tertiary care medical centers, CI support group and interactive web page of a hearing and speech center in a large metropolitan region.

**Subjects:** 75 respondents from a varied adult CI population implanted longer than one year.

**Intervention:** Achieve user-friendly assessment tool for CI function for benchmark and comparative analysis.

**Main Outcome Measure:** A coefficient of reproducibility (CR) for the Guttman scale format that is equal or greater than .90 indicating good scalability.

**Results:** Demonstrate CR in the CIFI above .90 consistent with effective scalability and mean scores from 2.7 to 3.4 for the six areas examined (1.00-4.00).

**Conclusion:** A quick and easy CIFI is available to quantitative CI efficacy in six areas of real world activity. The CR psychometric properties of this user friendly CIFI are consistent with good or better scalability for the Guttman scale format.

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# PERFORMANCE OF OLDER ADULTS WITH COCHLEAR IMPLANTS

Mary Joe Osberger, Ph.D. and Dawn B. Koch, Ph.D.

#### **ABSTRACT**

**Objective:** This study examined cochlear implant performance in adults who received a cochlear implant at an older age (> 65 years) (n=24) compared to the performance of adults implanted at a younger age ( $\leq$ 65 years) (n=32).

**Study Design:** A repeated-measures design was used to assess pre- and post-implant speech perception data from a recent clinical trial. Performance was assessed preoperatively with hearing aids, and after 1, 3, and 6 months of implant use. Mean scores of the older adults were compared to those of the younger adults.

**Setting:** The study was carried out in cochlear implant programs primarily affiliated with tertiary medical centers.

**Patients:** Patients consisted of 56 adults with postlingual onset of severe-to-profound hearing loss (age at onset 6). Age at implantation ranged from 26 to 88 years.

**Main Outcome Measures:** Speech perception tests routinely used in cochlear implant studies (CNC monosyllabic words, CID Sentences, HINT sentences in quiet and noise).

**Results:** Statistical analyses revealed that both younger and older adults showed significant improvement between the pre-and postoperative intervals. After one month of implant use, there was no significant difference between the performance of the younger and older adults. However, with more implant experience, the mean scores of the younger adults were significantly higher than those of the older adults on most measures.

**Conclusions:** Even though the scores of the younger adults were higher than those of the older adults, patients implanted after age 65, nevertheless, derived substantial benefit from their implants. Thus, older adults are appropriate candidates for cochlear implants.

Reprint requests: Mary Joe Osberger, Ph.D., Advanced Bionics Corporation, 12740 San Fernando Road, Sylmar, CA 91342.

# DISCUSSION PERIOD VII: COCHLEAR IMPLANTS I Papers 28-31

**Dr. Bruce Gantz** (Iowa City, IA): Dr. Osberger I enjoyed that paper. Have you been able to look beyond six months in any of these patients? Do you have any data to follow them over years? Because we have a number of patients that have now reached their mid-80's that were implanted in their mid-60 and we are still seeing an improvement in their performance.

**Dr. Mary Jo Osberger:** No I think that's very important. Our data is relatively short term because we have the data submitted to us as long

as we have an ongoing clinical trial. Fortunately the clinical trials are ending soon and so our data is relatively short term but I think the improvement that we see from 3-6 months in the data that I presented here confirms what you are saying. In fact, the highest performer in our study was an 88-year-old woman who had substantial residual hearing before she was implanted and I think her three-month C & C score was close to 80%. I think they're a very interesting group to follow.

# MECHANISMS OF COCHLEAR IMPLANT ELECTRODE TRAUMA

Andrew J. Fishman, M.D., J. Thomas Roland, M.D., Michael Tykocinski, M.D., and Noel L. Cohen, M.D.

### **ABSTRACT**

**Hypothesis:** Cochlear implant electrodes cause intra-cochlear trauma that are related to insertion techniques and electrode design.

**Background:** The theoretical advantages of achieving electrode to modiolar proximity have spawned an effort to design a variety of peri-modiolar electrode arrays. The three major design concepts include straight electrode with lateral tension band; precurved electrode with straightening stylet; and space occupying positioning systems. The histologic characteristics of insertion trauma have been well documented for traditional straight electrodes in both human and animal studies. The deleterious effects on spiral ganglion cells of trauma to the basilar membrane and osseous spiral lamina have been described in animal models as well.

**Methods:** Our two centers have collaborated in studying insertion trauma, in a human cadaver model, resulting from the implantation of peri-modiolar electrode arrays. These insertions were performed under videofluoroscopic guidance with a variety of array prototypes, both peri-modiolar and straight. Histologic sections were obtained in either traditional cross sectional analysis or as radially oriented surface preparations. Over 30 insertions were performed. Traumatic injuries generally occur to selected regions of the basilar membrane, spiral ligament and osseous spiral lamina depending on the electrode design and insertion technique utilized.

**Results:** Trauma may occur as localized penetration, regional displacement, gross disruption or fracture. Traumatic forces may also be hydraulic in nature. A model for the study of hydraulic injury is described.

**Conclusions:** A classification scheme of inner ear trauma is detailed so that the nature of trauma specific to each electrode design and insertion technique may be characterized.

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# BILATERAL COCHLEAR IMPLANTATION IN POSTLINGUALLY DEAFENED ADULTS

Bruce J. Gantz, M.D., Richard S. Tyler, Ph.D., Jay T. Rubinstein, M.D., Ph.D., Mary Lowder, M.S., and Abigail Wolaver, M.S.

## **ABSTRACT**

Potential advantages of binaural hearing include sound localization and improved speech perception in noise. Patients with one cochlear implant have difficulty localizing sound and speech perception ability deteriorates in a noisy environment. Ten postlingually deafened adults were prospectively selected to undergo bilateral implantation during a single surgical procedure at a tertiary referral center. Patients have used binaural implants for one year. The purpose of this study was to evaluate the ability of subjects to localize sound and determine performance in noise when binaural implants are employed.

Speech stimuli were presented from the front of the subject in quiet and in noise. In the latter conditions, speech was from the front and noise was either from the right or the left. Localization was tested with noise bursts presented at 45 degrees azimuth from the right or left. All testing was performed with patients using their right, left or both cochlear implants.

Bilateral implantation during the same operation did not cause any postoperative problems such as severe vertigo or ataxia. The age range of this group was 37-76 years. Both ears were fitted with speech processors at the same sitting. The average monosyllabic word understanding at 3 months for the ten subjects was 58%. Speech perception tests in noise showed that six patients performed better with both devices than with either device alone. Localization ability improved with both devices for all patients. Binaural cochlear implants can provide binaural advantages. The ability of binaural stimuli to complement each other may depend on the similarity of performance between the two ears.

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#### **ACKNOWLEDGMENT**

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tion Disorders, National Institutes of Health; grant RR00059 from the General Clinical Research Centers Program, NCRR, National Institutes of Health; and the Iowa Lions Sight and Hearing Foundation.

Reprint requests: Bruce J. Gantz, M.D., Dept. of Otolaryngology-HNS, University of Iowa Hospitals, Iowa.

# COCHLEAR IMPLANTATION IN AUDITORY NEUROPATHY

Colm Madden, F.R.C.S.I., Michael J. Rutter, F.R.A.C.S., Lisa Hilbert, M.A., C.C.C.-A., and Daniel Choo, M.D.

# **ABSTRACT**

**Objective:** Auditory Neuropathy (AN) is a newly described condition characterized by varying sensorineural hearing loss, an absent A.B.R but normal O.A.E. or cochlear microphonics on testing. The site of the lesion has been suspected to be at the level of the Inner Hair cells or the Vestibulo-Cochlear nerve. Cochlear implantation would appear to offer little benefit to these patients. To examine this question, we reviewed our population of children with AN, and those having undergone cochlear implantation.

**Study Design:** A retrospective case review of those patients diagnosed with AN from 1993-present.

**Patients:** 17 patients were diagnosed with AN, female:male ratio 10:7, with 3 sets of siblings including 1 set of identical twins. Three patients were implanted over the past 5 years.

**Results:** Eleven out of the 17 patients had classical risk factors for AN (prematurity, hyperbilirubinemia or a positive family history). Degree of hearing loss varied in our patients with a predominance of severe to profound deficits. All patients undergoing implantation first underwent hearing aid and FM system trials. All implanted children showed improvement in auditory and verbal development but this improvement was variable. As an example, one patient demonstrates 88% speech recognition in closed set testing 52 months after implantation, while her younger sibling has improved from a pre-implant IT-MAIS score of 0 to 27 post-implant.

**Conclusion:** The success of our cochlear implants in these patients suggests that some children have a more proximal lesion – perhaps in the Inner Hair Cells – that can be managed with cochlear implantation.

Reprint requests: Daniel Choo, M.D., Dept. of Pediatric Otolaryngology, Children's Hospital Medical Center,3333 Burnet Avenue, Cincinnati, OH 45229.

# COCHLEAR IMPLANT PERFORMANCE IN CHILDREN WITH AUDITORY NEUROPATHY

Robert Labadie, M.D., Ph.D., Carolyn Brown, M.S.; Emily Buss, Ph.D., Aimee Gross, B.S., John Grosse, Ph.D., Harold Pillsbury, M.D.

### **ABSTRACT**

**Objective:** To study cochlear implant performance in patients with auditory neuropathy.

Study Design: Retrospective case review.

**Setting:** Tertiary referral center.

**Patients:** Pediatric cochlear implant patients with auditory neuropathy as defined by hearing loss with absent or severely abnormal auditory brainstem responses (ABR's) in the presence of normal cochlear outer hair cell function as assessed by otoacoustic emissions. Four patients (average age = 4.9 years) from our implant population met these criteria.

**Intervention:** The patients underwent cochlear implantation with Clarion devices at an average age of 3.75 years.

Main Outcome Measure: Pre and post-operative audiologic testing.

**Results:** Auditory function, as documented from soundfield thresholds (SFT's), improved from pre-operative severe to profound loss (> 70 decibels) to post-operative mild to moderate loss (averaged SFT's at 250, 500, 1000, 2000, 4000, and 6000 Hz at 3 months after implantation = 37.7 decibels; standard deviation = 6.4 decibels). Initial results from post-operative, electrically-evoked ABR's using the cochlear implant electrodes as stimulus show positive ABR's on apical, middle, and basal stimulation for the first of the four patients tested. Furthermore, electrically-evoked acoustic reflexes were observed in the ear contralateral to the implant.

**Conclusions:** Patients with auditory neuropathy benefit from cochlear implantation. Our data supports that electrical stimulation from the implant is capable of overcoming the poor neural synchrony thought to account for auditory neuropathy.

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# DISCUSSION PERIOD VIII: COCHLEAR IMPLANTS II Papers 32–35

**Dr. Paul Kileny** (Ann Arbor, MI): I'd like to ask Drs. Madden and Labidie a common question regarding patients with auditory neuropathy. When this entity was identified, it has been around for quite a while, the initial approach to this was somewhat alarmist and it resulted in holding treatment from these patients.

Parents have access to various popular web sites. They began to question the diagnosis in the audiology and otology clinics. It's really nice to see that we are progressing in patients who are being implanted and are doing well.

However, there may be some contraindications to implanting patients who are diagnosed with auditory neuropathy and what might those contraindications be? Are there any patients who really would not benefit from cochlear implantation who have been diagnosed with auditory neuropathy?

**Dr. Colm Madden** (Cincinnati, OH): I think it is important if you are thinking of implanting a child with suspected auditory neuropathy to look at the age of diagnosis. As I have shown in our study, of our 18 children, 9 of them – 50% showed a spontaneous improvement.

We have delayed implanting our children until at least a year and a half (18 months). By that stage the child would have had eighteen months without any sign of improvement. I think that one of the most important things is the delay and follow-up of the child with serial testing to ensure that there is not evidence of a spontaneous improvement or resolution in the child's audiogram.

**Dr. Robert Labadie** (Chapel Hill, NC): I agree with Dr. Madden's comments. I think we are going to find that auditory neuropathies really have a lot of different things going on and as our testing becomes better, we are going to break it down into where the lesions are.

Certainly genetic testing is going to help out with that. I was very interested to find that Dr. Madden found these patients were Conexin 26 negative as were ours. I think as our genetic screens become better we are going to break this down into many different ideologies and not just one label of auditory neuropathy.

Dr. Kenneth Dormer (Oklahoma City, OK): For

Dr. Gantz, the bilateral implantation is an ideal application of active beam formation, a processing scheme that seems to have been abandoned. It was used for a while in the single channel cochlear implants with the two microphone availabilities. Will your results have any stimulation on active beam formation for noise elimination and directionality?

**Dr. Bruce Gantz** (Iowa City, IA): I'm sure we are going to find there are many applications or opportunities to use applications that we haven't used at this point. Anything that improves localization is going to improve signal noise ratio especially in a noisy environment. I'm sure that as we explore that it will be something that needs to be used. These patients also didn't have symmetry and we might find that using a more sophisticated processor that can deliver the signals independently to each ear but programming them similar might have some advantage.

**Dr. Arun Gadre** (San Antonio, TX): I wanted to compliment Dr. Roland and Dr. Fishman on a wonderful presentation. I have one question. Do we not know what kind of pressures are involved in the disruption of the membranous labyrinth utricle or saccule? Particularly with conforming electrodes with positioners because there's a dip in the graft at the end. Did that represent a disruption? If that's the case then it brings up the second issue with these new electrodes and doing bilateral cochlear implantation, are we risking Dandy's oscillopsia?

Dr. Thomas Roland (New York, NY): The graph was really the end of the flush so it was just my fingers letting off the pressure. It wasn't as though something broke loose and the footplate popped out or something like that. We think we have a model that is reliable and it's almost real life in a sense because there's going to be fluid aggression around the electrode. We are trying to apply it to new electrode designs. I don't know that anyone knows what pressures are needed to start bumping off neuro-epithelium but it would be interesting to study. Maybe an animal mode with implanting them with pressure measurements somehow would be useful.

**Dr. Bradford Welling** (Columbus, OH): Two questions for Dr. Gantz. There was one patient, pa-

tient number eight who it looked like on the C & C sentences actually did worse with binaural implantation but I think you said at the end that all of the patients did better binaurally. I know that was one that you had quite a disparity in length of deafness but does that patient continue to use both implants?

**Dr. Bruce Gantz** (Iowa City, IA): Yes, its interesting at three months that patient was significantly better and subsequently we have tested that patient again and they are much better than they were at a year. So if you do a lot of implant patients and you follow them over time, people have variations on different days. Why we don't know, it may have been a bad test day but there was no patient that did significantly worse. There were some patients that did better with one implant than binaurally but it wasn't a significant difference.

**Dr. Thomas Roland** (New York, NY): A question for Dr. Rizer. On your adaptation, will you not implant a patient who has poor adaptation scores or do you just use that as a predictor to counsel them preoperatively?

**Dr. Franklin Rizer** (Warren, OH): We use it as a predictor to help with counseling our patients so that they know what they can expect. It helps us evaluate patients who take longer to perform.

**Dr. Ilmari Pyykko** (Stockholm, Sweden): I would like to address the first paper on surgical trauma. We have been working several years on animal models and looking for outcome of animal implants. We can show that by using anti oxidants or preferable neurotrophans the electrical auditory brainstem responses and also the spiral ganglion cell survival rate is much better. These results very much support the data that when inserting the implant we are really inducing trauma in the cochlea.

We have a large program where we try to use these preventional drugs in human implantation. I want to ask if you have some kind of program going on for neurotrophans and cochlear implants? When I was looking at your data you were demonstrating that you could with a certain technique avoid the trauma but how about using drugs, which will improve the survival of this paraganglion source, which are of vital importance for success rate?

**Dr. Thomas Roland** (New York, NY): That is a good point. We are actually in the early stage initiating a study in animals with two things. One slow release micro particles imbedded in the electrode that will release A) steroids possible to prevent that initial fibrotic reaction that might occur from the trauma and B) growth factors to encourage or enhance spiral ganglion cell survival. Thank you.

**Dr. Patrick D'Hease:** I have two questions for Dr. Gantz. The first question is that a mutual benefit by means of localization in ten patients out of ten and then you mentioned the fifteen-degree angle. Is it that all patients having localization abilities up to fifteen degrees angles or what is the angle for the localization to be significant?

**Dr. Bruce Gantz** (Iowa City, IA): I can't tell you at this point because we haven't done all the patients with that test. In an an-echoic chamber these patients – a small group of patients were able to localize down to fifteen degrees.

**Dr. Patrick D'Hease:** Second question was if you test patients binaurally in comparison to one implant, do you take any measures to take into account the loudness summation affect or were patients tested with normal setting in both speech processors switched on? Do you know that?

**Dr. Bruce Gantz** (Iowa City, IA): If they were tested with their comfortable loudness individually and then together, not changed.

Dr. Patrick D'Hease: You didn't change?

**Dr. Bruce Gantz** (Iowa City, IA): No.

Dr. Patrick D'Hease: Thank you.

# INTRODUCTION OF THE NEW PRESIDENT

A. Julianna Gulya, M.D.

I would like to thank the Membership of The American Otological Society for entrusting me with the Presidency. It's been the experience of a lifetime and within the year it's been a lifetime's worth of experience. This had its challenges but it has also had its considerable rewards so I would like to

thank you very much for giving me that opportunity. I would like now to turn over the gavel to Dr. Richard Chole who will be the President of The American Otological Society for the year 2001-2002 and I'm sure in Rick's capable hands the AOS will continue to flourish.

# REMARKS OF NEW PRESIDENT

Dr. Richard Chole

Thank you Julie, its really an honor to assume the Presidency of this great Society and especially having the gavel turned over from Julie who has done such a fine job with the program. It's a special honor to take the gavel from the first female President of this 134 year old Society. In honor of you we have a plaque honoring your Presidency which is in

the form of a certificate reading "The American Otological Society Inc. presented to A. Julianna Gulya, MD, President in appreciation and recognition of her service to this Society 2001." We have a special lapel pin for a present. Thank you all very much and the 134<sup>th</sup> Annual Meeting of The Otological Society is now over.

# **EXECUTIVE SESSIONS**

# MINUTES THE AMERICAN OTOLOGICAL SOCIETY, INC. ANNUAL MEETING MAY 12–13, 2001 MARRIOTT'S DESERT SPRINGS RESORT PALM DESERT, CA

MINUTES OF THE BUSINESS MEETING—SATURDAY, MAY 12, 2001

I. CALL TO ORDER: The President, Dr. A. Julianna Gulya, called the Business Meeting to order at 7:00 a.m. II. APPROVAL OF MINUTES: The minutes of the May 13–14, 2000, Annual Meeting of the American Otological Society, Inc., held at the Olando World Center Marriott, Orlando, Florida, were approved.

III. INTRODUCTION OF NEW MEMBERS: The following new members were introduced to the society by their respective proposers:

# Fourteen Active Members

Patrick Antonelli, M.D., Proposed By: George T. Singleton, M.D., Seconded By: Jack M. Kartush, M.D., H. Alexander Arts, M.D., Proposed By: Steven A. Telian, M.D., Seconded By: Paul R. Lambert, M.D., Hilary A. Brodie, M.D., Ph.D., Proposed By: Robert K. Jackler, M.D., Seconded By: Thomas Balkany, M.D., Margaretha L. Casselbrant, M.D., Ph.D., Proposed By: Charles Bluestone, M.D., Seconded By: Eugene N. Myers, M.D., John M. Epley, M.D., Proposed By: F. Owen Black, M.D., Seconded By: Mansfield F. W. Smith, M.D., Rick A. Friedman, M.D., Ph.D., Proposed By: John W. House, M.D., Seconded By: Derald E. Brackmann, M.D., Paul E. Hammerschlag, M.D., Proposed By: Noel L. Cohen, M.D., Seconded By: Richard R. Gacek, M.D., Karl L. Horn, M.D., Proposed By: J. V. D. Hough, M.D., Seconded By: John W. House, M.D., Glenn D. Johnson, M.D., Proposed By: Dudley J. Weider, M.D., Seconded By: Michael E. Glasscock, M.D., Barry P. Kimberley, M.D., Proposed By: Michael M. Paparella, M.D., Seconded By: Jack L. Pulec, M.D., Lloyd B. Minor, M.D., Proposed By: Michael E. Glasscock, M.D., Seconded By: John K. Niparko, M.D., Seth I. Rosenberg, M.D., Proposed By: Herbert Silverstein, M.D., Seconded By: Jack M. Kartush, M.D., Michael D. Seidman, M.D., Proposed By: Herbert Silverstein, M.D., Seconded By: Jack M. Kartush, M.D., Stephen J. Wetmore, M.D., Proposed By: Brian F. McCabe, M.D., Seconded By: James J. Pappas, M.D.

## Two Associate Members

Joe C. Adams, Ph.D., Proposed By: Joseph B. Nadol, Jr., M.D., Seconded By: Saumil N. Merchant, M.D., James F. Battey, M.D., Ph.D., Proposed By: Philip A. Wackym, M.D., Seconded By: Bruce J. Gantz, M.D.

# One Corresponding Member

Thomas E. Linder, M.D., Proposed By: Mansfield F. W. Smith, M.D., Seconded By: John W. House, M.D.

# Nominees For Nominating Committee

A Nominating Committee composed of Dr. Joseph Farmer, Chairman, Drs. Paul Lambert, Debara Tucci, Jack Hough, Frank Rizer and alternate, Harold C. Pillsbury, was elected to prepare the slate of nominees for AOS officers for 2001–2002.

# REPORT OF THE SECRETARY-TREASURER

Dr. Horst R. Konrad presented the following items of information:

A. The present Membership totals 286 and includes the induction of new members on April 24, 1999, as follows:

> 133 Active 8 Emeritus 10 Honorary \* 44 Associate 74 Senior 17 Corresponding

Dr. Konrad again encouraged the membership to seek out new qualified candidates who would be worthy of proposal for membership in the society. The society is particularly interested in proposing candidates for AC-TIVE membership.

B. Members deceased since the last Annual Meeting: Dr. Lavonne Bergstrom (Senior), Dr. Raymond Jordan (Senior), Dr. Ben T. Withers (Senior)

C. Members requesting transfer to Senior status: Vijay S. Dayal, M.D., Malcolm D. Graham, M.D., Cecil W. J. Hart, M.D., Robert A. Jahrsdoerfer, M.D.

Request for transfer to Emeritus Status: Warren Adkins, M.D., Roger C. Lindeman, M.D.

# D. INCOME AND EXPENSE STATEMENTS:

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

# AMERICAN OTOLOGICAL SOCIETY, INC.

# **INCOME STATEMENT**

# July 1, 2000 to April 30, 2001

Membership Dues
COSM
Research Fnd. Income
Transactions
Interest & Dividends
AJO (O&N)
IRS Refund
Certificate of Deposits
TOTAL INCOME

# AMERICAN OTOLOGICAL SOCIETY, INC. **EXPENSE STATEMENT**

# July 1, 2000 to April 30, 2001

7	1, 2000 to 11p111 50, 2001
	Certificate of Deposit125000.00
	Professional Fees
	MidWinter Council Meeting15144.11
	Annual Meeting
	AOS Administrative Stipend 5250.00
	Office Expenses
	ACCME Dues & Accreditation
	IRS
	Insurance (Directors & Officers) 4603.00
	Other: Subscriptions, Transactions, Office
	Rent, AOS Memberships, Misc 25640.87
	TOTAL EXPENSES

# AMERICAN OTOLOGICAL SOCIETY, INC.

# FINANCIAL STATEMENT T

ul	y	1,	2000	to	April	30,	2001	
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Balance On Hand 7/1/00	90854.70
Deposits: Income	171317.59
Total	262172 29

Disbursements	209326.04
Balance in Checking 4/30/01	.52846.25
Certificate of Deposit	.50000.00
Balance on Hand 4/30/01	102846.25

EDITOR-LIBRARIAN REPORT: Dr. Sam E. Kinney reported the 1999 Transactions have been shipped to the membership. The 2000 Transactions has been submitted to Lippincott Williams and Wilkins, 250 copies will be printed at a price of \$50.15, a \$7.50 increase over previous year. At the February Council meeting of the AOS it was determined to move the Transactions into a desktop publishing format, which will be attempted for the 2001 Transactions. The goal is to have the Transactions mailed to the membership before the subsequent meeting of the following year.

Members were reminded to pick up their numbers for the annual photograph, which was taken immediately following the morning session.

PROGRAM ADVISORY COMMITTEE: Dr. Gulya thanked the following individuals for serving on the 2001 Program Advisory Committee: Bruce J. Gantz, MD, Joel A. Goebel, MD, Herman A. Jenkins, MD, Paul R. Kileny, PhD, John P. Leonetti, MD, Brenda Lonsbury-Martin, PhD, Saumil N. Merchant, MD, John K. Niparko, MD, Dennis S. Poe, MD, Clough Shelton, MD, and Thomas Van De Water, MD.

PRESIDENT'S REMARKS, INTRODUCTION OF GUEST OF HONOR, PRESIDENTIAL CITATION, SPECIAL PRESIDENTIAL AWARDS, May 12, 2001: The Business Meeting was adjourned and the first Scientific Session started at 7:30 a.m. with brief remarks from the President, Dr. A. Julianna Gulya. The President introduced the Guest of Honor, James B. Snow, Jr., M.D. The Presidential Citation was presented to Dr. Robert J. Ruben.

#### REPORTS OF COMMITTEES

Board of Trustees of AOS Research Fund: Dr. Jeffrey Harris presented the Board of Trustees Research Fund Report. The Research Fund has had a very positive uphill growth in the value of the fund, which in 1980 was valued at 1.9 million and currently as of March 30, 2001, is valued at \$8,211,835.00. The Board of Trustees of the Research Fund met in New York on March 10, 2001, to review the 10 grants received. Three grants and one fellowship were funded for 2001-2002 in the amount of \$155,000. One application was received for the AOS Clinician-Scientist Award and it was reviewed by CORE, the Academy's research review procedure, and was not recommended for funding.

American Board of Otolaryngology: Dr. Bruce Gantz reported a qualifying/certifying examination was given in October 2000 and 319 candidates sat for the exam and 303 became candidates for the oral examination. In April 2001 120 examiners conducted the oral exam. Three hundred and twenty-four candidates were examined and 303

# TRANSACTIONS 2001 / AMERICAN OTOLOGICAL SOCIETY

passed the exam and became certified. The Otolaryngology Training Exam (OTE) was given in March 2001. Twelve hundred residents and practitioners participated in the exam. The election of officers in 2000 remains unchanged. Dr. Michael E. Johns serves as President. Dr. David E. Schuller serves as President-Elect and Dr. Gerald Healy serves as Executive Vice-President. Dr. H. Bryan Neel, III was elected to a second 3-year term as Treasurer. Dr. Charles W. Cummings, elevated to senior counselor, has completed 18 years of service on the Board. No new Directors were added to the Board. The 2001 written examination will be conducted on September 24 in four cities: Chicago, Boston, Houston, and San Francisco and the oral examination will be April 27-28, 2002 in Chicago. The OTE (Resident Examination) will be March 2, 2002.

American Academy of Otolaryngology: Dr. A. Julianna Gulya presented the AAO-HNSF report on behalf of Dr. G. Richard Holt, Executive Vice-President of the AAO-HNSF Board of Directors. Dr. Gulya reported on the Hearing Healthcare Team Initiative. Particularly relevant to the AOS membership is the effort of the Hearing and Balance Coalition, a multifaceted effort in which to deal with the audiologists' attempts at becoming autonomous healthcare deliverers. Dr. Gulya discussed the Internet endeavor of the Academy with respect to the ENTLink, setting up an Internet portal for use by the Academy membership. The Academy continues to be active in their ability to improve the political socioeconomic environment and the quality of patient care which the Academy feels will be improved by the Hearing Healthcare Team Initiative.

# REPORT OF THE AMERICAN COLLEGE OF SURGEONS

Dr. Richard J. Wiet, ACS Governor representing the AOS updated the membership on the activities of the College of Surgeons. Dr. Wiet reported he attended the American College of Surgeons meeting in Chicago as well as the Advisory Council for Otorhinolaryngology Meeting. The Board of Governors by unanimous vote have decided to go from a 501C3 organization to a 501C6 Political Action Committee (PAC) and begin taking a forceful role with politicians in Washington. The Board would confront issues related to insurance and promote political action from the American College of Surgeons toward improvement in healthcare. At the Governors meeting, Dr. David Narwald, who represents the American Board of Medical Specialties Task Force, stated that

public dissatisfaction with health care profession is driving a trend to review competency among physicians. Errors in medicine cost 17–29 billion dollars per year in the division of healthcare services. The ABMS approved six general competencies for the physician education/practice; patient care, clinical knowledge, interpersonal skill and communication, professionalism, practice based learning, and improvement in systems based practice of medicine. These general competencies will formally be used in accreditation of rendering programs after July 2002. Every year an awardee is selected for the Jacobson Award, which is given for innovations in medicines, specifically in surgery, and AOS member, Dr. William House's name has been submitted for that award this year.

# REPORT OF THE AWARD OF MERIT

Dr. Gregory Matz, Chairman, reported that he had conferred with his committee members: Drs. C. Gary Jackson, A. Julianna Gulya, Richard T. Miyamoto, and George Facer

for the selection of the 2001 recipient of the Award of Merit. Dr. Derald E. Brackmann was the recipient of the award at the banquet held on Saturday evening, May 12, 2001.

# REPORT OF THE AUDIT COMMITTEE

Dr. John R. E. Dickins, Chairman, reported he and his committee members, Drs. John Emmett and Gordon Hughes, reviewed the transactions of the Society and found all of the transactions to be appropriate and the cash flow activity statement of the American Otological

Society appeared to be in order. The committee recommended that the council and the membership accept this report as an indication that the financial status of the American Otological Society, Inc., is excellent and being maintained appropriately.

# REPORT OF THE NOMINATING COMMITTEE

Dr. Joseph C. Farmer presented the following nominations for the slate of officers of the AOS for the 2001–2002 year: Drs. Richard A. Chole, President, Horst R. Konrad, President–Elect/Secretary–Treasurer, Sam E. Kinney Editor–Librarian and Clough Shelton Secretary–Treasurer–Elect; and Council Members, Drs. C. Gary Jackson, A.

Julianna Gulya, Jeffrey P. Harris, John K. Niparko and Antonio De la Cruz. There were no nominations from the floor. The nominated slate was elected by the membership.

Drs. Debara Tucci and Michael Glasscock were elected to serve on the Award of Merit Committee for 2002.

# **NEW BUSINESS**

AOS Bylaws—Dr. Gregory Matz reported that in order to change the bylaws of the AOS, it is necessary to give a year's notice (Article 13 of the AOS bylaws). Dr. Matz stated he is here today to give notice of a change in the bylaws that will allow future bylaw changes to go from a one-year notice to a 30-day notice. The change will be voted on next year and will read, "The Council or any 10 voting members may propose amendments to these bylaws. Written notice of the proposed amendments shall be sent by the Secretary—Treasurer to each Active and Senior member of the Society at least 30 days before the Annual Meeting at which time action thereon will be taken." A three–quarters vote will be needed to change an amendment.

There will be bylaw changes anticipated next year to do with how the Internal Revenue Service is looking at the Society and the strategy to restructure the Society.

The members present voted in favor of the proposed change in the bylaws. The above change in the by-laws will be presented to the remainder of the active and senior members and formally voted on at next year's annual business meeting.

**ADJOURNMENT:** The Business Meeting was adjourned at 1:00 p.m. and the Scientific Program continued until 5:00 p.m.

Respectfully submitted, Horst R. Konrad, M.D., Secretary–Treasurer

# IN MEMORIAM LaVonne B. Bergstrom, M.D.

LaVonne B. Bergstrom, M.D. passed away January 10, 2001 in Los Angeles, California at the age of 72. She was born on October 17, 1928 in Erskine, Minnesota. She graduated from the Wadena, Minnesota High School in 1946 as class valedictorian. She graduated from the University of Minnesota School of Journalism in 1950 and the University of Minnesota Medical School in 1953.

After serving an internship at Minneapolis General Hospital Dr. Bergstrom was commissioned by the Presbyterian Church USA to work as a physician at the Embudo Presbyterian Hospital in New Mexico. She became the Medical Director of the Sangre de Cristo Medical Unit at San Luis, Colorado. She was the only physician in a 1215 square mile county.

Dr. Bergstrom completed her Residency in Otolaryngology at the University of Colorado. In 1969 she joined the faculty of the University of Colorado where she began her work with children's hearing problems. She was a pioneer in the study of the genetics of hearing loss.

Dr. Paul Ward at UCLA recruited Dr. Bergstrom in 1975 where she advanced to the rank of Professor in the Department of Surgery, Head and Neck Division. She retired from UCLA in 1989.

Dr. Bergstrom was active in many societies and

The information for this memorial was kindly supplied by Dr, Bergstrom's nephew, Tim Johnson, Curator of Special Collections and Rare Books, University of Minnesota.



served as President of the American Auditory Society in 1987. She was a member of the American Academy of Otolaryngology-Head and Neck Surgery, the American Academy of Pediatrics and the American Neurotology Society.

Dr. LaVonne Bergstrom became an Active member of the American Otological Society in 1977 and an Emeritus member in 1992.

# IN MEMORIAM Raymond E. Jordan, M.D., Professor Emeritus of Otolaryngology, University of Pittsburgh School of Medicine, 1908–1998

Raymond E. Jordan, M.D. died in December 1998 after a long illness. Many of our younger colleagues in otolaryngology will not have remembered Dr. Jordan because he had retired from active participation in otolaryngology in 1972. Nonetheless, Dr. Jordan was a very important leader in the development of the field of otology during the important decades of the 1950s and 1960s. Dr. Jordan completed his undergraduate studies at the University of Pittsburgh and graduated from its medical school in 1934. He did postgraduate work in otolaryngology at Washington University in St. Louis and was certified by the American Board of Otolaryngology in 1946. Dr. Jordan was assigned to the Army Medical Corps and served his country from 1941 through 1945. He was discharged with the rank of Lt. Colonel. When Dr. Jordan returned from active duty in 1946, he became a member of the active staff of the Department of Otolaryngology at the Eve and Ear Hospital of Pittsburgh where he remained until his retirement in 1972. Dr. Jordan served as Chairman of the Department of Otolarvngology at the University of Pittsburgh School of Medicine from 1961 to 1972. He served as President of the Eye and Ear Hospital of Pittsburgh medical staff from 1959 to 1961. Dr. Jordan spent most of his active medical career as an otologist. He studied with Dr. Julius Lempert in New York learning the fenestration operation in the late 1930s. When he came back from the service, he practiced with Dr. Kenneth Day Sr. and Dr. Kenneth Day Jr. in Pittsburgh who also specialized in surgery for deafness. In the middle 1950s when Dr. Samuel Rosen developed the stapes mobilization operation, Dr. Jordan was influenced by Dr. Rosen and began to practice this form of middle ear surgery for the relief of deafness from otosclerosis. Not long after, Dr. John Shea of Memphis introduced the idea of stapedectomy using a vein graft procedure. This technique



was the gold standard of middle ear surgery for deafness from otosclerosis for many years though there were many variations on this theme and Dr. Jordan was one of the pioneer otologists who performed and taught this procedure.

Dr. Jordan was very highly recognized for his dedication to teaching and produced many residents from the Eye and Ear Hospital of Pittsburgh who went on to be well recognized practitioners of otolaryngology.

Dr. Jordan held memberships in many societies including the American Medical Association, American Academy of Ophthalmology and Otolaryngology, Pittsburgh Otologic Society, American Otological Society, the American College of Sur-

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#### IN MEMORIAM

geons, and the Triological Society, of which he was Treasurer from 1963 to 1972. He was also the recipient of many honors and was presented with a Certificate of Award for Distinguished Service in Educational Programs by the American Academy of Ophthalmology and Otolaryngology and was guest of honor of the Triological Society in 1974 and of the Eastern Section of the Triological Society in 1978. When Dr. Jordan retired from his position as Chairman of the Department of Otolaryngology at the University of Pittsburgh School of Medicine in 1972, he moved to Washington, DC in the role of Executive Director of the American Council of Otolaryngology which eventually merged with the

American Academy of Otolaryngology-Head and Neck Surgery. Due to ill health, he retired from this position in 1974.

Dr. Jordan enjoyed a very rich family life and was married for many years to his wife, Thelma. They were the parents of two sons and had two grandsons. Upon the death of his wife, Thelma, Dr. Jordan was married for many years to the late Jean Dickinson who had been the wife of John Dickinson, M.D., a lifelong professional colleague of Dr. Jordan's in Pittsburgh. Dr. Jordan was an excellent surgeon, teacher and leader in otolaryngology. Dr. Jordon became an Active member of the American Otological Society in 1953 and a Senior member in 1975.

# IN MEMORIAM Bennie Terrel Withers, M.D.

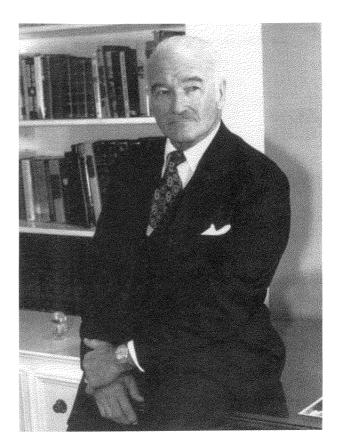
Ben Withers, M.D. passed away August 10, 2000 at the age of 85. He was born in Jasper, Texas in 1915. He graduated from San Angelo High School, the University of Texas, Austin and the University of Texas Medical School, Galveston, Class of 1940.

After internship at Jefferson Davis Hospital, Houston, he entered the military. He served in England and France in the office of the Surgeon General of the U.S. Army Air Corp (Medical Corps), where he was awarded a Bronze Star.

After military service he pursued graduate training at Jefferson Davis Hospital, Houston, Washington University School of Medicine, St. Louis, Temple University, Philadelphia, PA: and the Lempert Institute of Endaural Surgery, New York.

Dr. Withers practiced Otolaryngology for 43 years in Houston. He was a Clinical Professor at Baylor University College of Medicine and was Associate Chief of E.N.T. at Hermann Hospital in Houston. He authored more than 30 scientific articles. He was a member of numerous local, state and national societies including the American Academy of Otolaryngology – Head and Neck Surgery and the Triological Society.

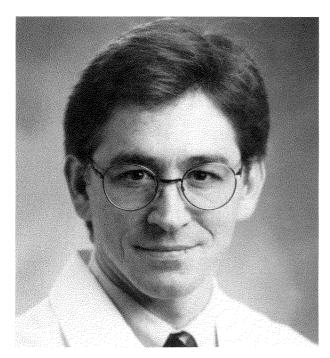
Ben Withers, M.D. became an Active member of



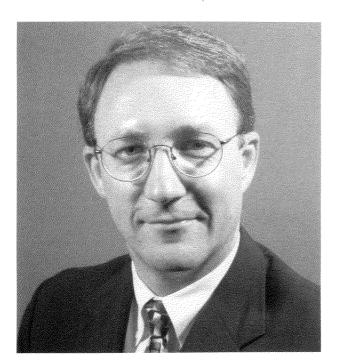
the American Otological Society in 1964 and a Senior member in 1986.

The information in this memorial was kindly supplied by Dr. Withers wife, Mrs. Denise A. Withers of Houston, Texas.

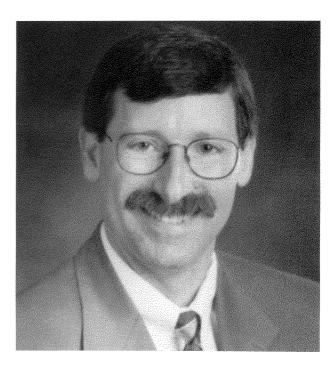
# Active Members



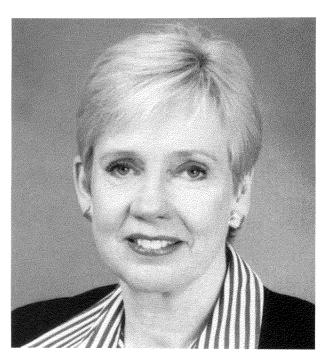
Patrick Antonelli, MD



H. Alexander Arts, MD



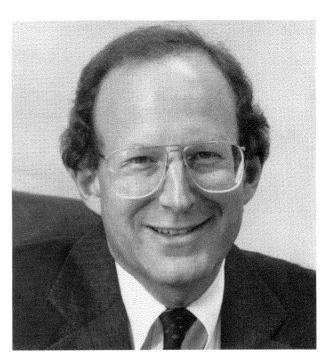
Hilary A. Brodie, MD



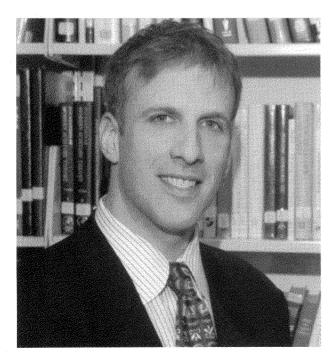
Margaretha A. Casselbrant, MD, PhD



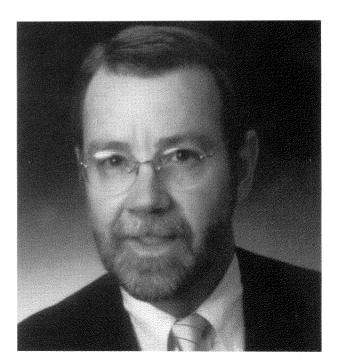
John M. Epley, MD



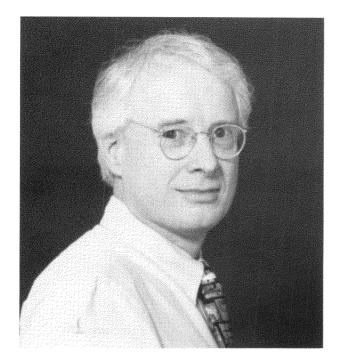
Paul E. Hammerschlag, MD



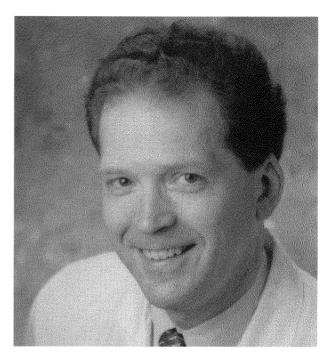
Rick A. Friedman, MD



Karl L. Horn, MD



Glenn D. Johnson, MD



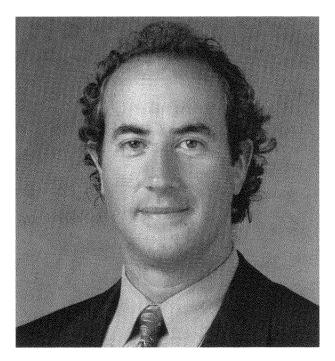
Lloyd B. Minor, MD



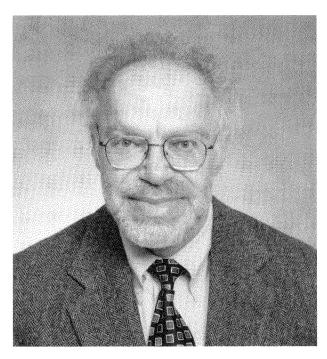
Barry P. Kimberly, MD



Seth I. Rosenberg, MD

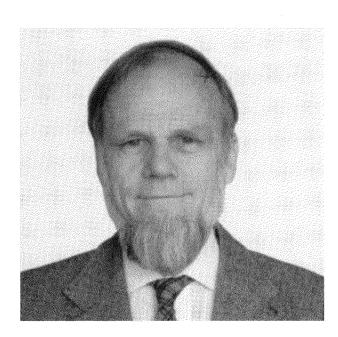


Micheal D. Seidman, MD

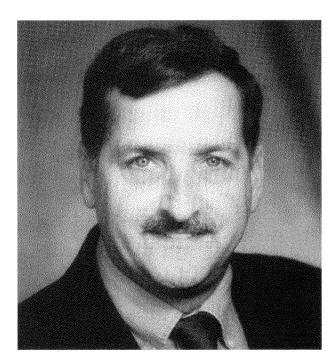


Stephen J. Wetmore, MD

# Associate Members

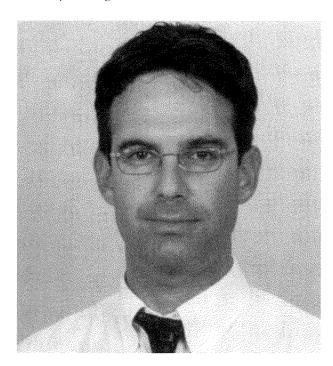


Joe C. Adams, PhD



James F. Battey, MD, PhD

# Corresponding Member



Thomas E. Linder, MD

# 2000–2001 MEMBERSHIP LIST AMERICAN OTOLOGICAL SOCIETY, INC.

#### Active Members

- 1987 Adkins, Warren Y., 1187 Farm Quarter Rd. Mt. Pleasant, SC 29464
- 1982 Alberti, P.W., 107 Clemanti Road, Kent Vale, Block F, #13-03, Singapore 129790
- 1987 Althaus, Sean R., 5201 Norris Canyon Rd. #230, San Ramon, CA 94583-5405
- 1995 Amedee, Ronald G., 1430 Tulane Ave., New Orleans, LA 70112
- 1985 Applebaum, Edward, 1855 W. Taylor St., Chicago, IL 60612
- 1993 Babin, Richard W., 1830 Hwy, 51 So., Covington, TN 38019
- 1991 Balkany, Thomas J., PO Box 016960-D48, Miami, FL 33101
- 1997 Barrs, David M., 3404 Wake Forest Rd., Ste. 303, Raleigh, NC 27609
- 1992 Bartels, Loren J., 4 Columbia Dr., Ste. 610, Tampa, FL 33606
- 1995 Beatty, Charles W., 200 First St. SW Rochester, MN 55905
- 1983 Black, F. Owen, 1225 NE 2nd Ave (97232), PO Box 1950, Portland, OR 97208-3950
- 1996 Blakley, Brian, Rm GB 421-820 Sherbrook St., Winnipeg, Manitoba, Canada R3A 1R9
- 1977 Bluestone, Charles D., 3705 Fifth Ave., Pittsburgh, PA 15213
- 1979 Brackmann, Derald E., 2100 W. Third St., 1st Floor, Los Angeles, CA 90057
- 1988 Brookhouser, Patrick, 555 N. 30th St., Omaha, NE 68131
- 1991 Canalis, Rinaldo, 457-15th St., Santa Monica, CA 90402
- 2000 Cass, Stephen P., 4200 E. 9th Ave. B 205; Denver, CO 80262
- 1984 Chole, Richard A., 660 S. Euclid, Box 8115, St. Louis, MO 63110
- 1976 Clemis, Jack D., 734 LaVergne Ave., Wilmette, IL 60091
- 1985 Cohen, Noel L., 530 First Ave., New York, NY 10016
- 1991 Coker, Newton J., 6550 Fannin St., Ste. 1727, Houston, TX 77030
- 1995 Daspit, C. Phillip, 222 W. Thomas Rd., Ste. 114, Phoenix, AZ 85013
- 1975 Dayal, Vijay S., 5841 S. Maryland Ave., Chicago, IL 60637
- 1991 De la Cruz, Antonio, 2100 W. Third St. 1st Fl, Los Angeles, CA 90057
- 1991 Dickins, John R. E., 10201 Kanis Rd., Little Rock, AR 72205

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