



**SOUTH FLORIDA
DENT ASSOCIATES**

Fall 2019 edition



A high-angle photograph of a middle-aged couple lying in bed, embracing. The woman is on the left, wearing a light-colored tank top, and the man is on the right, wearing a grey t-shirt. They are both looking towards each other with a gentle expression. The bed is made with white linens and pillows. A bedside table with a lamp and a phone is visible on the right side of the bed.

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The doctors in our group take care of patients with hearing disorders, nasal and sinus problems, head and neck diseases, and allergies. We have general ENT physicians and subspecialists who treat both pediatric and adult patients.

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Sincerely,

Frank G. Kronberg, M.D., F.A.C.S.

President, South Florida ENT Associates

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Greater Than the Sum of Their Parts: Exploring Unilateral Hearing Loss and Modern Therapeutic Modalities



BY ARIEL B. GROBMAN, M.D.

Background

The prevalence of unilateral hearing impairment approximates 9% of the population (1). It is estimated that 9,000 new cases of unilateral

profound sensorineural hearing loss (UPSNHL) present per year, with an overall impact to 1% of the population (2). The etiology of UPSNHL is widespread including such pathologies as temporal bone trauma, Meniere's disease, vestibular schwannoma, vascular ischemia, autoimmune disorders, and viral infection; however, hearing loss is commonly idiopathic in nature. Often this loss can be sudden in onset, leaving the victim extremely debilitated (3). Despite this, the historical misconception that having one normal hearing ear is sufficient for daily communication persists. Unlike other paired systems such as vision where the impact of unilateral impairment is readily acknowledged, hearing is subject to an invisibility factor where the disability itself is less overt and subsequently underappreciated.

“...hearing is subject to an invisibility factor where the disability itself is less overt and subsequently underappreciated.”

The disability associated with UPSNHL is not a novel concept; the deleterious effects of UPSNHL have been well demonstrated in the pediatric population. Children with UPSNHL demonstrate poor language comprehension compared to their peers(4-6), up to 1/3 of children with unilateral hearing loss will fail a grade in school, and as many as 41% will require additional educational support (5,6). Those who manage to keep up with their academic peers are more likely to suffer from other behavioral and social issues such as fatigue, irritability, and social isolation (5). Adults with UPSNHL, however, continue to be overlooked in both the workplace and the healthcare arena. Most public and private insurers provide no medical coverage for unilateral hearing

loss despite a large body of evidence which supports that one ear is in fact not enough to restore auditory function.

The deficit experienced by monaural listening is far more than what is represented on the pure tone audiogram. Unilateral PSNHL results in a loss of binaural cues, which are critical to processing complex acoustic signals. Our central nervous system uses binaural inputs to “summate” or boost sound, and we have a mechanism to “squellch” or dampen noisy input coming into one ear in favor of a purer signal from the other ear. Binaural listeners rely on precise auditory timing and intensity differences between sounds arriving at each ear to determine their quality and localize properly. The head acts as a natural sound barrier to the ear furthest from the sound, the so called “head-shadow” effect, which helps us spatially separate speech and noise. UPSNHL strips the person of these benefits and requires excess attention to distinguish signal from noise, leading to fatigue and frustration.

A tailored approach to diagnosis is important in patients with monaural hearing loss, namely speech in noise (SIN) testing, rather than simply pure tone audiometry alone. This is most important as the head shadow effect attenuates (i.e., dampens) high frequency sounds, which directly contributes to decreased clarity of speech.

The primary treatment strategy for MLs is to route the acoustic signal from the poorer ear to the normal ear. This is accomplished using contralateral routing of signal (CROS) hearing aids where the listener wears a transmitter with a microphone on the poorer ear to collect the sound which is then sent wirelessly via a frequency modulated signal to a receiver worn in the normal hearing ear. The microphone stimulates the implant using vibratory force output, which transmits the acoustic signal across the cranium to the normal cochlea via bone conduction. Again, these treatment options lift the head-shadow effect, and rely on monaural processing of bilateral inputs by routing the signal from the poorer side to the better hearing ear, they do not restore binaural hearing.

Bone conduction soft-bands are typically used in children with atresia/microtia and adults who wish to simulate the effects of bone anchored conduction devices. They

have the benefit of being easily placed and removed but are very conspicuous.

Bone anchored implants (BAIs) rely on the concept of osseointegration and are typically implanted in a percutaneous fashion with a skin incision as well as an implant drilled into the calvarium. The BAHA (Cochlear Corp.) and Ponto (Oticon Medical) systems are the two most commonly employed devices for BAIs. They require a quick outpatient surgery, which is typically covered by insurance, then the patient waits four weeks for the implant to integrate into the skull before being attached to a small processor. BAIs are well tolerated in the large majority of cases, but can be associated with skin complications typically requiring some minor office treatment.

The new Bonebridge system (Med-El Corp.) uses a BAI coupled in a trans-cutaneous fashion (no implant crossing the skin) to a thin processor via magnet. This system avoids potential implant & skin complications from traditional percutaneous BAIs such as BAHA and Ponto, however, it requires a longer surgery than a typical BAI, and no long-term data exists regarding its efficacy. (Figure 1)

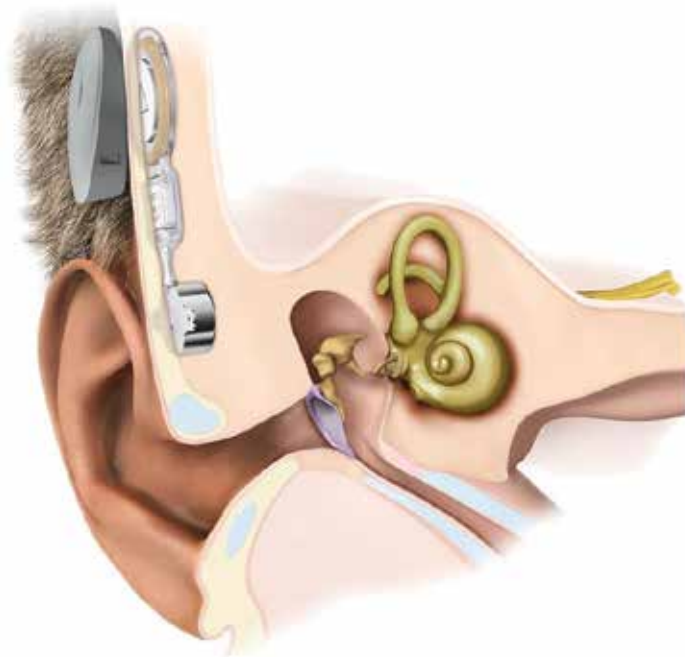


Figure 1

Patients who are averse to wearing hearing aids and not keen on BAIs may be candidates for the new ADHEAR system by Med-El. ADHEAR (FDA approved May 2018) consists of a skin colored adhesive placed behind the ear which connects to an adapter that functions as a bone conduction hearing aid. Early data has shown similar audiological performance to BAIs (7)



Figure 2

albeit without the need for a surgical procedure. (Figure 2)

Neither BAIs nor CROS devices are successful in improving auditory processing abilities that require binaural inputs. Early studies of localization ability in BAI and CROS users indicated no benefit in the ML population(8). This is not surprising given that binaural processing cannot be restored with a treatment strategy that relies only on a monaural system.

The only potential treatment to restore binaural input in patients with UPSNHL is cochlear implantation (CI). CI would provide stimulation to both auditory pathways in cases of UPSNHL. In doing so, CI benefit this population by improving speech understanding in the poorer hearing ear and offering binaural cues for improved localization and speech understanding in noise. (9)

Currently, UPSNHL is not an approved FDA indication for CI, however, there is an abundance of literature supporting CI as a beneficial treatment over current options. Many centers worldwide are now performing CI for UPSNHL, and many insurance carriers are approving patients on a case-by-case basis, especially patients with debilitating tinnitus in the ear with the hearing loss.

Regardless of the etiology, we now understand that unilateral hearing loss can be devastating and significantly affect patient quality of life. Close collaboration between physicians and audiologists well versed in diagnosis and treatment of UPSNHL is vital to provide patients with the appropriate treatment option. The road for patients and families never ends at device activation. Every patient must receive individualized auditory rehabilitation, this is achieved using well established methods and integrating new technology and auditory learning programs.

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Voice Health: What Should You Know?



BY RICHARD J. VIVERO, M.D., F.A.C.S.

Hoarseness is a common problem affecting a broad range of people, from young to old, and professional and non-professional voice users alike. The lifetime incidence is approximately 30%, which means there is a 1 in 3 chance that a person will be hoarse during some point of his life. Voice changes can range from mild to severe and have a significant impact on quality of life. The degree of hoarseness can make it difficult to engage others socially and professionally. When we lose our ability to communicate, feelings of isolation can set in, which can spiral into feelings of depression and anxiety. Identifying and managing voice issues is therefore important.

It is best to start with simple changes that can improve your voice. Voice hygiene is the foundation. First and foremost, it is important to minimize vocally abusive or traumatic behaviors, such as yelling or throat clearing. Conversations should be ideally had within arms length and with a normal volume. If you have to strain to be heard, you are likely too far away from the person with whom you are communicating.

Second, adequate hydration and lubrication is important to the proper function of the vocal folds. As we live in South Florida, we are exposed to nearly year round warm temperatures, which prompt sweating and loss of water from the body. It is critical to stay hydrated by drinking 13 cups a day of water for men and about 9 cups of water daily for women. A good rule of thumb is to watch the color of your urine. Barring underlying medical problems, your urine will tend to be clearer when you are adequately hydrated.

Irritant avoidance can also play a tremendous role. There are two major areas to consider – reflux and allergies. Reflux,

or laryngopharyngeal reflux (LPR), is acidic or nonacidic contents from the stomach that pass via the esophagus back into throat and irritate the vocal folds. You may feel a lump in the throat, increased phlegm, sour taste, or cough among other symptoms. Management can be either via medicines, such as antacids or reflux reducers, or behavioral changes. Reflux is often diagnosed and often aggressively treated with medicine. However, attention to behavioral changes is often times as important, if not more, than medical management. It is recommended that patients avoid reflux inducing foods such as spicy, foods high in fat, alcohol, caffeine, etc. It is also important to regulate the amount consumed and not “over eat,” especially prior to bedtime or before lying down for an extended period of time. Allergies complement reflux and



can cause vocal fold irritation due to postnasal drip and increased secretions. Allergen avoidance and use of allergy medicines, including antihistamines or nasal steroid sprays, can play a major role in managing the effects of allergy on the voice.

If the voice does not improve with conservative management, evaluation by an ENT or otolaryngologist is very important to ensure there are no underlying problems with the vocal folds, such as nodules, polyps, or possibly

a cancerous lesion. Evaluation is initially done in the clinic with flexible or rigid cameras to look at the vocal folds and assess their function. Management may be a combination of medicine, surgery, or therapy, including speech therapy. Speech therapy is akin to physical therapy but for the vocal folds. If you have a voice issue that lasts greater than 2 or 3 weeks, seek an evaluation with your local provider to get back on the road of good health and good voicing.

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Hearing Loss: The Importance of Early Intervention



BY MONICA BLANCO TAGGART, AU.D., FAAA

“It’s not that I can’t hear—I just have trouble understanding.”

“I hear fine—it’s my spouse who thinks I have a problem.”

“I don’t have any problem hearing—it’s my kids who mumble.”

As audiologists, these are comments we hear from patients daily. If this sounds like you, you could be one of the 28.8 million U.S. adults who could benefit from amplification.



Image Source: Oticon

Learning you have hearing loss can be difficult, but it is the first step in improving your overall quality of life. The average wait time is seven years between the time someone is first affected by hearing loss and when they are fit with hearing aids. That is seven years of asking, “What?” one too many times, seven years of smiling and saying, “Yes,” to questions you did not hear clearly, and seven years of your brain missing out on important information it should be receiving.

Despite popular belief, hearing is not done with the ears--it is done with the brain. Our ears help us hear sounds while our brain helps us understand them. We must treat our brain like

a muscle—stimulating it to keep it functioning at its best. This is especially important when it comes to our hearing.

In a person with untreated hearing loss, the area responsible for hearing in the brain becomes weaker over time as it is missing out on many sounds it should be hearing. This causes the brain to draw cognitive resources from other areas of the brain that are not attuned to hearing to assist in piecing together what is being heard. The result is a reorganization of the brain’s functions that is not ideal for optimal cognitive function and leaves you with significant difficulty in understanding what you are hearing. This is why untreated hearing loss has been linked to increased memory loss, early onset dementia, and early onset cognitive decline.

Although this reorganization of the brain cannot be reversed, it can be paused or slowed down. Early intervention is a crucial component in making this happen. Be proactive and don’t wait for your cognitive function to be affected by your hearing loss before pursuing amplification. Research shows that even a mild hearing loss can begin the process of reorganization in the brain.

The thought of needing hearing aids can be a daunting realization; however, over 84% of patients with hearing aids reported satisfaction with their devices. Besides the stimulation you are providing your brain by treating your hearing loss, hearing aid patients have also reported less mental and physical exhaustion at the end of the day, less social isolation, and 9 out

of 10 patients said their hearing aids provided significant help in the workplace.

At the first sign of hearing difficulty, contact our team of licensed audiologists and board certified Ear, Nose & Throat physicians to get a head start on your journey to better hearing.

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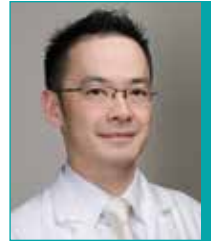
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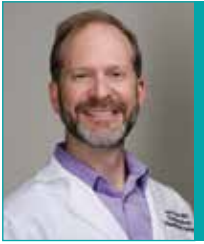
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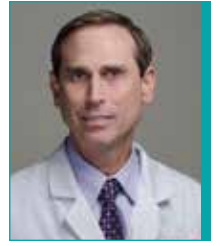
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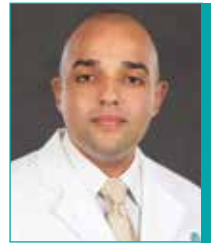
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Physicians



Dissolvable Stents Vanquishing the Sinus Fight



BY SINA JOORABCHI, D.O., F.A.A.O.A.

Over 30 million people suffer from sinusitis, comprising one out of every eight people in the United States. Sinusitis is defined as an inflammation of the cavities inside and around the nasal passages. This inflammatory response can block sinus drainage and can cause mucus retention. The typical symptoms include facial pressure, nasal congestion, headaches, loss of smell, fatigue or discolored nasal discharge. The majority of cases are an acute form lasting less than 4 weeks. However, some suffer from symptoms for three months or longer, a condition defined as chronic sinusitis.

In cases of chronic sinusitis, the primary treatment is often times Functional Endoscopic Sinus Surgery (FESS) which essentially aims to surgically re-establish the drainage pathways of the sinuses. Unfortunately, there is a recognizable recurrence risk of sinus disease after undergoing FESS. However, recent clinical advances have increased the success rates of FESS by utilizing a dissolvable sinus stent, The Propel, that delivers Mometasone Furoate (a topical steroid) directly to the sinus drainage pathway. The Propel sinus stent has become a crucial complement to FESS by reducing the need for post operative intervention, incidence of occlusion or restenosis of

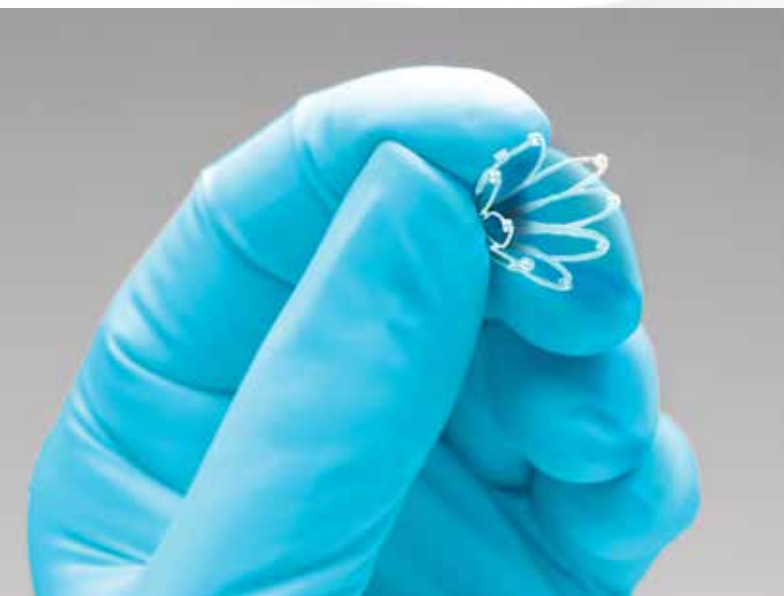
the sinus, need for oral steroid or surgical interventions. The implant is designed to dissolve over 45 days with the majority of the steroid deposition occurring in the first 2 weeks. The propel is lightweight and usually not felt once placed inside the nose. Furthermore, the Propel is backed by clinical evidence and has been used in over 150,000 cases to date.

More recently, a novel implant was developed named the Sinuva, a non surgical treatment for nasal polyposis used for patients with previous sinus surgery. The Sinuva has shown promise in clinical trials by successfully shrinking polyps and sinus symptoms, thereby reducing the likelihood of revision sinus surgery.



If you or a loved one suffer from sinusitis, know that there are now great options to successfully treat and prevent sinusitis from reoccurring. There are a multitude of surgical and non surgical options in which are exponentially more successful when utilized earlier in the disease course. Therefore, consider a sinus evaluation by an Otolaryngologist if you have persistent headaches or nasal congestion in which nasal sprays or decongestants have failed to help.

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Board Certified in Otolaryngology & Facial Plastic Surgery
Pembroke Pines, Florida
954-438-7171



Precision and Accuracy of the Hospital Now in Our Centers



BY ADAM WEISSTUCH, M.D.

Millions of Americans suffer from sinusitis, a disease that causes inflammation of the sinuses and nasal passages. Common symptoms include congestion, facial pain or pressure, fevers, colored nasal discharge, headaches, and fatigue. These symptoms can interfere with

daily life and cause people to limit their activities and even miss work. At South Florida ENT we have been able to help a countless number of patients who struggle with sinusitis and specialize in working with them to get them back to a state where they are disease-free.

Most sinus disease can be treated with medications like antibiotics, decongestants and nasal sprays. However, when these options fail, nasal procedures have been shown to improve symptoms and restore quality of life.

Our doctors are able to offer patients multiple treatment options for their sinus disease that range from targeted medical therapies, in-office procedures as well as surgical interventions, when deemed necessary. When a procedure is recommended, depending on the severity of the symptoms, we can provide patients options to have these procedures performed in the hospital, surgery center or an office-based setting.

Through our partnership with Medtronic, we are able provide state-of-the-art surgical navigation for these procedures both in the office and operating room. In the continuously evolving age of minimally-invasive procedures, surgical navigation provides image-guided technology which can help make the process more accurate. The GPS is helpful for guiding around difficult anatomy, use in revision surgeries and for sinus procedure like balloon sinuplasty which require precise placement of instruments within the sinus cavities of a patient. Through the years, our partnership with Medtronic has allowed us to provide our patients the best care possible with cutting-edge technology and we will continue to offer those advancements to our patients for years to come.

For more information about Medtronic's technology and how we use this within our practice, please visit <http://www.sinusitisurgery.com>.

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Weston, Florida
954-389-1414



Medtronic

Expanded Indications for Cochlear Implants Benefit People with Deafness in One Ear

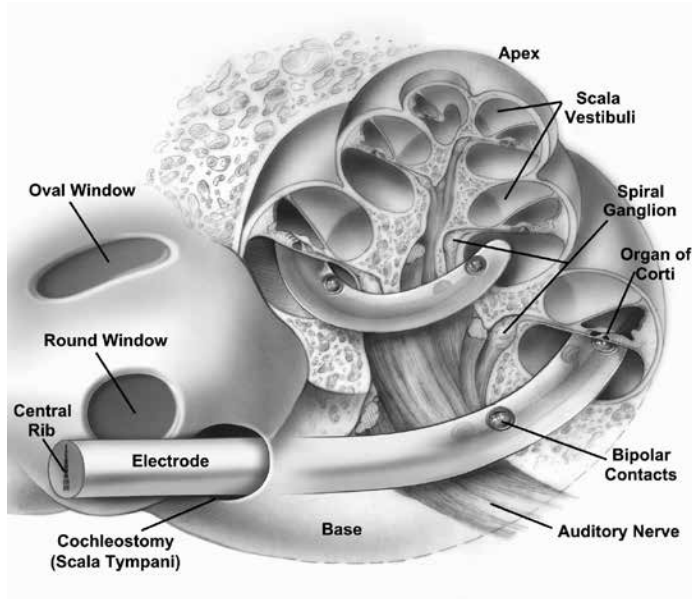


BY PETER G. VOLSKY, M.D.

Cochlear implant (CI) technology is a proven cost-effective and clinically successful treatment to restore hearing in ears with advanced hearing loss. These are ears that do not benefit from hearing aids. CI surgery has an

excellent record of safety and reliability, in both the very young (less than 1 year of age) and elderly (more than 80 years of age). More than 600,000 people worldwide have cochlear implants; most have hearing loss in both ears and benefit dramatically from one or two devices. Children who cannot hear at birth or lose their hearing shortly after birth are able to learn spoken languages because of CI.

Some adults and children have advanced hearing loss in one ear only, a condition termed single-sided deafness. Their opposite ear has normal hearing. For them, the benefit of CI is less dramatic, but still important. In other cases, the opposite ear is not normal but has some hearing that can still benefit from a hearing aid; this is termed asymmetric hearing loss. Otolologists (ear surgeons) agree that a CI for single-sided deafness and asymmetric hearing loss improves speech awareness, reduces tinnitus, and mounting high-quality research shows significant benefits in objective and subjective measures of hearing.



On July 22, one of the leading three cochlear implant manufacturers (Med-El USA, Durham, NC) announced that its newest cochlear implant is labeled for use in patients age 5 and older with single-sided deafness and asymmetric hearing loss. This announcement, long-awaited by otologists and patients, has been a standard in Europe and other continents for years. Until now, patients with one deaf and one normal or “aidable” ear have been officially excluded from



CI candidacy in the United States, and even now, there are regulations still in place (especially Medicare and insurance providers) that do not allow these people to receive CI. The reasons for this are complex.

An ear that cannot be helped with a hearing aid is likely to benefit from a CI. However, regulations in the U.S. limit access to CI: the hearing status of each ear individually is not the criterion for CI candidacy. Rather, it is the better-hearing ear that dictates whether someone is a candidate. Consequently, single-sided deafness and asymmetric hearing loss are considered off-label indications—that is, cases where there may be a proven medical benefit, but CI is not approved by regulatory agencies. In day-to-day practice, decisions about CI candidacy are complicated, because an otologist seeks to meet his or her patients’ hearing needs with several sets of rules that dictate CI candidacy. In the U.S., all implantable devices are approved for certain “labeled” indications by the U.S. Food and Drug Administration (FDA), which is primarily concerned with safety. In addition, reimbursement for CI is subject to policies of the payer. Medicare payments are governed by the Centers for Medicare and Medicaid Services (CMS), which has a more stringent CI policy than the FDA, and many commercial insurance providers have proprietary criteria for CI coverage benefits based upon (but not necessarily identical) to what is set by the CMS and FDA. Altogether, CMS, and insurance companies’ policies may (and do) differ



from one another, and FDA labeling is different for every device and manufacturer.

The significance of the announcement by Med-El USA is that until now, all regulations in the U.S. officially excluded people with single-sided deafness and asymmetric hearing loss from accessing CI. (The exceptions are those who can afford to pay out of pocket or, more recently, enroll in a clinical trial.) With the new FDA-label, there is hope that this “crack in the ice” will begin a stream of expanded criteria for CI candidacy and coverage benefits across regulatory agencies and payers for both adults and children.

CI is arguably a miraculous technology and for many people it is life-changing. The freedom to access this technology, in a manner commensurate with scientific advances in otology and neurotology, enable individuals and parents of children to make informed decisions about how their hearing can be helped. Refinements in cochlear implantation and its role in the hearing care continuum have evolved a great deal since their introduction in the 1980s. At first, CI was used only for people with total

“The advancing design of implants and surgical techniques continue to evolve to enhance the benefits of CI to all who receive one.”

deafness of both ears. Today, CI is available to people whose ears have various levels of hearing loss. The advancing design of implants and surgical techniques continue to evolve to enhance the benefits of CI to all who receive one. If regulatory change continues, the chance to hear better will extend to young children and adults who are learning and struggling to communicate with just one ear.

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Chronic Tinnitus: You Don't Have to “Learn to Live With It”



BY JACLYN KOWALONEK, AU.D., CCC-A

Introduction

Tinnitus refers to the perception of sound in the ear(s) or head, commonly described as “hissing, ringing, or roaring”. Primary tinnitus, the most common type, does not have any clear cause and is often thought to be related to changes within the auditory system. Secondary tinnitus is associated with an underlying condition, such as Meniere’s disease, vascular anomalies, or intracranial hypertension. Approximately 50 million people in the U.S. report experiencing tinnitus, however only 2 million people report that it impacts their daily lives. While tinnitus can be considered a symptom, it has the potential to develop into a chronic disorder when it begins to interfere with a person’s sleep, concentration, relaxation, and overall quality of life. Additionally, a high percentage of people experiencing tinnitus also have some degree of hearing loss.

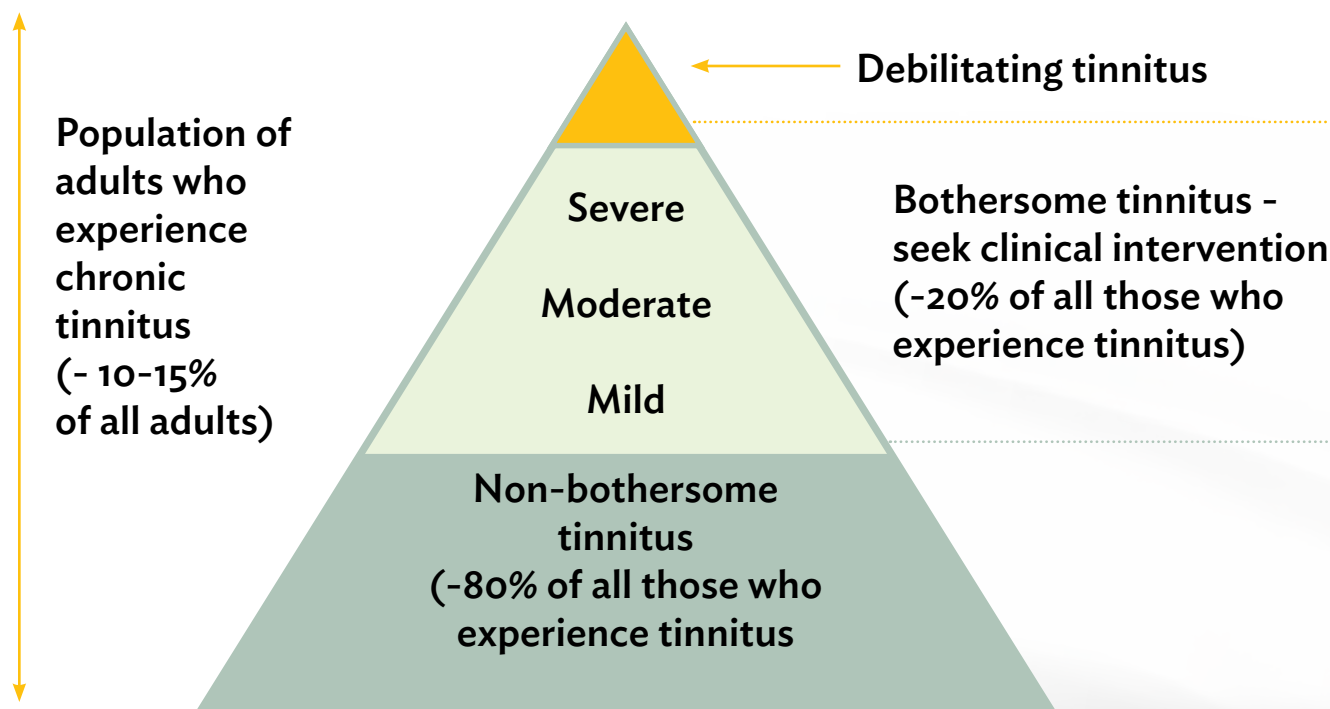
Evaluation

An ENT consultation can aid in ruling out any underlying conditions that may be causing the tinnitus. Additionally, those with persistent, bothersome tinnitus should undergo a comprehensive audiological evaluation and tinnitus assessment. A qualified hearing healthcare professional is equipped to evaluate the characteristics of tinnitus and impact on quality of life and provide patients with a “toolbox” of management strategies. Information gathered during the assessment will help shape the provider’s recommendations for each patient.

Management

Given the wide variety of perceived impact amongst people experiencing tinnitus, management can range from basic counseling and lifestyle modifications to a multidisciplinary approach.

Prevalence of Tinnitus in the United States



Henry et al., 2015



Otoharmonics' Levo System

amplification and a tinnitus sound generator (i.e., white noise) have been a successful form of sound therapy in patients with and without hearing loss for many years. A benefit of today's hearing aid technology is Bluetooth streaming which allows patients to have ear level sound therapy of their choice directly from their smart phone.

More recently, alternative sound therapy strategies have shown promise. Otoharmonics' Levo System is a nightly therapy that retrains the brain during

sleep resulting in a reduction of tinnitus perception over time.

Conclusion

Although there is no “cure” for tinnitus, there are many ways to manage tinnitus and reduce the negative effects it can have on daily life. You do not have to “just live with it”, as many patients have been told! Everybody perceives their tinnitus differently and the impact on quality of life will differ from person to person. This is why there is not a “perfect” management strategy for every patient and typically why patients use a combination of techniques to manage their tinnitus.

If you or a loved one has been experiencing bothersome tinnitus, contact our office today to schedule an ENT consultation and audiological evaluation.

Jaclyn Kowalonek, Au.D., CCC-A
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954-389-1414

A crucial part of any tinnitus assessment is patient education. Knowledge is power; the more a patient is able to understand about the mechanisms behind tinnitus and the interaction between different systems within the brain, the easier it is to understand and employ the management strategies.

Simple adjustments to daily life including engaging in pleasant activities, listening to enjoyable music or nature sounds, sleeping with a white noise generator, and/or meditation can help patients gain control of their tinnitus and in turn reduce the perception and impact on quality of life. Keeping stress levels low is a key aspect of tinnitus management. There are several free smart phone applications that are available to supplement this process. Additionally, cognitive behavioral therapy has been shown to be an effective supplement to any tinnitus management strategy.

Sound therapy is often used in combination with the aforementioned strategies as a way to increase auditory stimulation and divert the brain's attention away from the tinnitus. Over time, this facilitates the process of habituation, or “getting used to” the tinnitus. Hearing aids with

“Simple adjustments to daily life including engaging in pleasant activities, listening to enjoyable music or nature sounds, sleeping with a white noise generator, and/or meditation can help patients gain control of their tinnitus and in turn reduce the perception and impact on quality of life.”

Vivaer - Minimally Invasive Option to Improve Nasal Obstruction



BY JAY YOUNG, M.D.

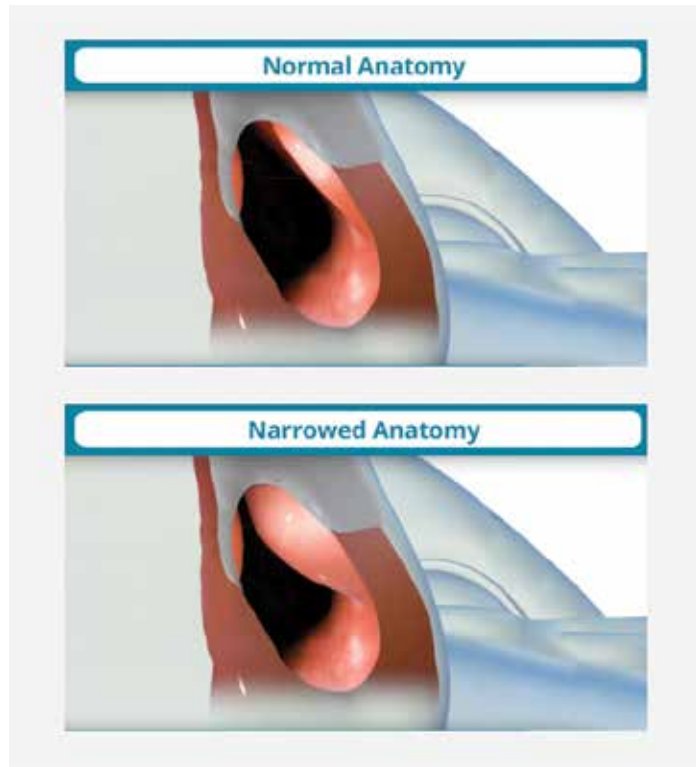
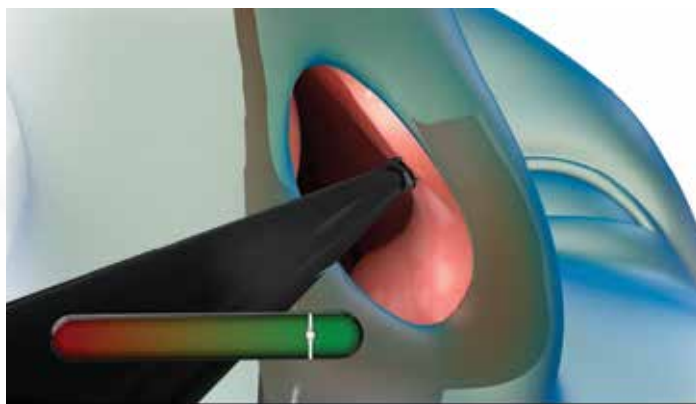
Millions of people suffer from nasal airway obstruction, which makes it difficult to breathe through the nose. Symptoms may include congestion, stuffiness, snoring, and sleep disturbances. Some may even have

physical activity restrictions with trouble breathing through the nose during exercise or exertion.



Home remedies, including external breathing strips, internal nasal dilators, and sprays have been tried but home remedies typically do not completely alleviate the problem. Furthermore, they usually do not offer lasting relief from symptoms. For patients

seeking a long-term solution, options have included surgery such as septoplasty/rhinoplasty in a hospital or outpatient setting. Some patients have even had variations of the above procedures but still have obstructive breathing. Now there is a one-time treatment, performed in a physician's office, that can open the nasal passages and restore free breathing.



Vivaer is an innovative device utilizing radiofrequency energy to improve the nasal airway by gently reshaping nasal tissues so that patients can breathe better.

For congestion and snoring, patients do not have to rely solely on nasal sprays, breathing strips, and surgery. Rather, they can consider Vivaer as a viable in-office treatment with little discomfort and downtime. Amongst the first in South Florida to provide this minimally invasive procedure, Dr. Young is pleased to offer consults to see if Vivaer may be an option for you.

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R5P0616MFSN	RELIEVA® SPINPLUS NAV Balloon Sinuplasty System, 6mm x16mm, 5 pack
EN501RP01	Registration Probe**
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*Fully ENT adapters are purchased separately. Acclarent does not distribute (or provide) TruDi adapters.
**Registration probe is for limited reuse.
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Acclarent US-2009-00 (04A), TruDi™ Navigation System Instructions for Use, March 2008.
Important Safety Information: Acclarent Navigation Technology is intended for use by or under the direction of a physician. Devices guided by the Acclarent Navigation Technology have several risks including the potential for contamination by the orbits, or CEF as a consequence of inaccurate navigation. Prior to use, it is important to read the Instructions for Use and understand the surgical approach, and the contraindications, warnings, and precautions described for the system.
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