Four Hands Are Better than Two: Mastering the Newest Advance in Minimally Invasive Skull Base Surgery

By Raj Sindwani, MD, and Pablo Recinos, MD

Minimally invasive skull base surgery is now a reality at Cleveland Clinic, with the recent establishment of the multidisciplinary Minimally Invasive Cranial Base and Pituitary Surgery Program. By accessing the brain and pituitary gland endoscopically through the nasal passages, our surgeons can effectively perform complex procedures with far less morbidity. Only a few centers in the world are performing these types of procedures at a high level.

It’s Dancing, Not a Tag Team

A distinctive aspect of our approach is that two surgeons — typically a neurosurgeon (Pablo Recinos, MD) and an otolaryngologist (Raj Sindwani, MD, or Troy Woodard, MD) — are both present throughout the entire procedure. This is a departure from the “tag team” approach used in traditional skull base surgery. Our “two
Dear Colleagues:

Cleveland Clinic’s Head & Neck Institute is dedicated to a team approach to patient care, one in which we erase traditional boundaries between specialties. With physicians, surgeons and other caregivers working together in patient-centered institutes throughout all of Cleveland Clinic, we strive to deliver collaborative care that produces a richer, more rational approach to complex cases. And that commitment to teamwork is illustrated in the lead articles in this issue.

In our cover story, Drs. Raj Sindwani and Pablo Recinos offer a “dancing lesson” as they describe how our neurosurgery and ENT units collaborate to perform minimally invasive skull base and pituitary surgery. Two surgeons work together throughout, with each taking the lead at various points. The advantages of this approach are multifold, and few U.S. centers are doing this at a high level.

Partnership was also the order of the day as we recently completed our first auditory brainstem implant (ABI) surgery. As explained on p. 4, our ABI team comprises practitioners in otology, neurology and audiology who collaborate to restore hearing in patients with auditory nerve damage who cannot be helped by cochlear implants.

For patients who can be helped with cochlear implants, we’d like to see more of them do so. In separate articles, Dr. Erika Woodson (p. 6) and Dr. Sarah Sydlowski (p. 7) detail how our Hearing Implant Program is taking the lead in providing patients with what they don’t have and making the most of what they do have.

While we take pride in our leading-edge technology, sometimes low-tech is the better option. Dr. Judith White explains how a humble six-decades-old procedure is far more effective than high-tech imaging for diagnosing vertigo, and she describes how we are ensuring it will not be overlooked (p. 8).

Other articles in this issue describe:

- How the emergence of human papillomavirus as a major etiologic factor is prompting us to overhaul the traditional treatment protocol for oropharyngeal cancer (p. 10).
- Another example of how multidisciplinary cooperation enhances care, this time for temporomandibular disorders (p. 12).
- The latest technique for facial reconstruction in patients with advanced maxillary cancers, which was developed right here in the Head & Neck Institute (p. 14).
- How tinnitus patients receive more information in less time with shared medical appointments (p. 16). Another article outlines the unprecedented approach we are taking to understand the mechanisms of tinnitus as well as hyperacusis (p. 24).
- Successful use of botulinum toxin, the “toxin turned treatment,” in pediatric otolaryngology (p. 18) and spasmodic dysphonia (p. 20).
- A convenient alternative to CPAP masks for patients with obstructive sleep apnea (p. 22).

I hope you enjoy this issue. We urge you to pass it on to your colleagues and to pass along to us any comments you may have.

Michael S. Benninger, MD
Chairman, Head & Neck Institute
benninm@ccf.org

Download our new Physician Referral App

With our new Physician Referral App, contacting us is easier than ever. Download it today at the App Store or Google Play.

24/7 Referrals
Referring Physician Hotline
855.REFER.123 (855.733.3712)
surgeons, four hands” approach allows us to tackle a wide array of complex skull base conditions. This partnership — which we like to call “the dance” — is a prime example of the multidisciplinary approach to healthcare that Cleveland Clinic aims to foster.

As with any dance, the trick is not to step on each other’s toes. The neurosurgeon and otolaryngologist must work in concert, with each taking the lead during different stages of the procedure. This requires not only physical coordination, but a shared philosophy and understanding of the surgical concept.

The Process at a Glance

The otolaryngologist takes the lead by first threading the endoscope through one nostril and the surgical instruments through the other. Since the inside of the nose and sinuses is largely composed of air, this “keyhole surgery” is minimally disruptive of normal structures, and no skin incision is required (Figure 1). When the instrumentation is sufficiently advanced, the otolaryngologist removes the thin layer of bone and the membranes at the base of the brain.

The neurosurgeon then takes the lead as the tumor is removed. Once the tumor is out and the surgical goals accomplished, the otolaryngologist initiates reconstruction of the skull base defect. The two surgeons then begin withdrawing the equipment, making repairs to any damaged tissue along the way until they exit the nasal corridor.

Neuronavigation identifies the precise site of the surgical target and guides the surgeons in navigating the best route to that site. Navigation can proceed by using MRI (Figure 2), CT or both as needed for improved surgical accuracy. In this manner, critical structures are more easily identified and avoided, which results in a safer surgery.

The Many Advantages

The primary advantage to using a natural passage to access the brain is that we no longer have to inflict so much damage to the skull with large external incisions and craniotomies. As a result, patients will experience less postoperative pain and no scarring. We also expect that they will enjoy a much easier recovery and a shorter hospital stay.

Another advantage is greater visibility. Because the light source is located at the tip of the endoscope, surgeons can visualize significantly larger areas of the surgical field. We are also able to look around corners to areas that were previously hidden from view.

Finally, this approach allows the team to achieve a more complete tumor removal, given that many of these benign tumors also involve the bone of the skull base.

The operating theater in which we perform these procedures is equipped with leading-edge technology and equipment. In addition to the neuronavigation system, our OR includes endoscopic ultrasound devices, specialty microdebriders and drills, and a large array of newly designed sinus and skull base instruments adapted for complex endoscopic cranial base and pituitary surgery.

Benefits All Around

Although not all skull base problems can or should be treated endoscopically, expertise in endoscopic approaches has become an essential part of our efforts to provide the highest level of comprehensive care. Our entry into minimally invasive skull base surgery promises to be productive both clinically and academically. Not only do our patients benefit, so does the training of our residents and fellows in otolaryngology and neurosurgery. The advantages to the healthcare system are also significant in that fewer resources are used and ICU stays (if any) are shorter.

Dr. Sindwani is Section Head of Rhinology, Sinus and Skull Base Surgery in the Head & Neck Institute and Co-Director of the Minimally Invasive Cranial Base and Pituitary Surgery Program. He can be reached at 216.445.2845 or sindwar@ccf.org.

Dr. Recinos is Section Head of Skull Base Surgery in the Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center in Cleveland Clinic’s Neurological Institute. He is also Co-Director of the Minimally Invasive Cranial Base and Pituitary Surgery Program. He can be reached at 216.445.2901 or recinop@ccf.org.

Figure 2. (Left and middle) T1-weighted MRIs showing a large anterior skull base meningioma that our minimally invasive skull base team resected completely via the endoscopic approach. Reconstruction of the large cranial base defect was performed with a pedicled nasoseptal flap. (Right) Postoperative MRI showing complete removal of the tumor and the presence of the nasoseptal flap (arrow).
Auditory Brainstem Implant Surgery Rescues Patients with Deafness Secondary to Nerve Damage

Only a Few U.S. Centers Offer the Procedure

By Thomas Haberkamp, MD

Auditory brainstem implant (ABI) surgery is now available in Cleveland Clinic’s Head & Neck Institute, thanks to a joint effort by the Section of Otology-Neurotology and the Section of Rhinology, Sinus and Skull Base Surgery. Our first such surgery here was performed in June 2014 (see sidebar). The addition of ABI surgery to our range of services will benefit patients in the Midwest, since only a handful of centers in the U.S. offer this procedure.

Bypassing the Damaged Nerve

The purpose of ABI surgery is to restore hearing in patients who have experienced damage to the auditory nerve. This procedure was developed in 1979 at the House Ear Institute in Los Angeles. The first implant was performed by placing two ball electrodes on the surface of the cochlear nucleus. Multichannel devices were introduced in 1992 and have been used ever since.

The ABI device was initially conceived for use in patients with neurofibromatosis type 2 (NF2). Most patients with NF2 develop neurofibromas on both auditory nerves. Affected patients experience profound bilateral deafness due to the disease itself or to tumor complications. Unfortunately, surgical removal of these tumors can lead to hearing loss as well, since surgery often compromises the auditory nerve.

Traditional cochlear implants may not help in these cases because of the damage to the nerve. In such cases, implantation of the ABI electrodes allows the surgeon to circumvent the damaged nerve so that acoustic signals are delivered from the ear canal directly to the brainstem.

In most cases, the ABI is placed during the same operation in which one of the acoustic neuromas is removed. Not all patients experience restoration of auditory perception following the first procedure, but another attempt can be made (1) when the surgery on the second side is performed or (2) as a separate surgery if both tumors have been removed already.

Almost All Patients Improve

Hearing outcomes in post-ABI patients with NF2 have been good, although not as good as those generally achieved with cochlear implantation (which, as mentioned, is not helpful in these cases). We believe ABI surgery is sometimes unsuccessful because the tumor causes a degeneration or alteration within the hearing centers of the brain.

Even so, about 85 percent of patients experience auditory sensations, and 93 percent experience better sentence understanding with lip reading and sound recognition three to six months postoperatively. Sound recognition and perception gradually improve for up to eight years following implantation. While open-set speech discrimination is usually not achieved, it is still possible, occurring in 10 to 20 percent of cases.

ABIs were approved by the FDA in October 2000 for use in patients with NF2 who are age 13 or older, are proficient in language and psychologically sound, and who have no medical contraindications to surgery.

It should be noted that there are no hearing criteria for ABI candidacy, since NF2 eventually causes profound bilateral hearing loss in everyone who has it.

Implantation of the ABI electrodes allows the surgeon to circumvent the damaged auditory nerve so that acoustic signals are delivered from the ear canal directly to the brainstem.

Looking Ahead

New uses for ABIs are on the horizon. In the U.S., a clinical trial has been approved for ABI use in children born without an inner ear; the first two patients received their implants last year. Also, European studies in similar patients without NF2 have shown that hearing results more closely approximate those of cochlear implant surgery, as approximately 62 percent of patients have achieved that level of performance.

Dr. Haberkamp is Section Head of Otology-Neurotology. He can be reached at 216.444.6696 or haberkt@ccf.org.
The ABI Team Makes Its Debut

The first ABI surgery at Cleveland Clinic was performed June 13, 2014. Because the patient’s tumor was so large, the procedure took approximately 16 hours. The device (bottom right image below) was placed without complication, and initial testing confirmed that it was stimulating the central hearing centers. It will take several months until the patient has fully recovered and the device can be activated.

The surgery was performed by Thomas Haberkamp, MD (top left image), and Erika Woodson, MD (top right), of the Head & Neck Institute and neurosurgeon Jorgé Gonzalez-Martinez, MD, PhD (at center of bottom left image), of the Neurological Institute. Sarah Sydlowski, AuD, PhD, performed the initial testing to confirm stimulation of the brain’s hearing centers.

The ABI program is directed by Dr. Haberkamp, who has performed ABI surgery since 2008, when he founded the ABI program at the University of Illinois, Chicago. A fourth member of the ABI surgery team is Pablo Recinos, MD, a skull base surgeon in the Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center.

Inquiries about the ABI program can be made by calling 216.444.0354.

Photos: © Russell Lee Photography

Photo of ABI device courtesy of Cochlear Americas.
When Hearing Is Good but Not Good Enough:
Expanding Criteria for Cochlear Implantation

By Erika Woodson, MD, FACS

The Hearing Implant Program at Cleveland Clinic, which has long been at the forefront of technology for the rehabilitation of advanced hearing loss, is pleased to announce that we will be participating in the latest FDA trial of cochlear implants (CIs) in adults.

The CI422 study will determine whether we can use newer, more challenging test methods to demonstrate that patients benefit from CIs under expanded eligibility criteria (Figure). This study is sponsored by Cochlear Americas, a manufacturer of hearing implant devices.

Why Do We Need New Criteria?

Traditional CI candidacy has been determined by measuring a patient’s sentence comprehension when listening binaurally with optimized hearing aids in both ears. Over time, candidacy tests have evolved from the easier hearing-in-noise tests (HINTs) to the more difficult AzBio test. However, the AzBio test still falls short of measuring hearing handicap in real-world conditions.

The aim of the CI422 study is to determine if additional, more challenging testing is necessary, and if patients who perform “too well” on HINT and AzBio testing may still obtain a greater benefit with a CI than with hearing aids alone. Our findings may ultimately pave the way for patients with significant but not profound hearing loss to qualify for cochlear implantation.

Restoring Hearing at the High Frequencies

The Hearing Implant Program has robust experience with patients whose hearing has traditionally been considered too good for a CI. Many of these patients have a sharply sloping sensorineural hearing loss, with good low-tone thresholds and profound high-frequency deafness. They can hear speech, but they must rely on contextual clues to differentiate words. A CI in these cases restores hearing at the high frequencies, which allows patients to hear much better in a variety of listening situations.

Moreover, we can often save low-frequency hearing in the implanted ear, which allows for better sound localization and music appreciation and even greater listening abilities in the presence of background noise.

Dr. Woodson is Medical Director of the Head & Neck Institute’s Hearing Implant Program. She can be reached at 216.444.6696 or woodsoe@ccf.org.

HOW YOU CAN HELP

If you have a patient who may qualify for the CI422 study or for a CI, please refer him or her to us for a CI evaluation. J.P. Podriznik, Hearing Implant Program assistant, can coordinate audiologic and surgeon appointments for patients who are traveling from a distance. He can be reached at 216.444.0354 or hipteam@ccf.org.

CI422 Clinical Trial Indications

*Indications not FDA-approved. CAUTION: Investigational device. Limited by U.S. law to investigational use.

Figure. Audiometric parameters of the CI422 study. Graph adapted, with permission, from Cochlear Americas.
Advancements in cochlear implant (CI) design and insertion techniques have allowed surgeons to preserve cochlear structures in patients with usable low-frequency hearing. Hearing preservation is affected by many factors, including the insertion technique (round window or cochleostomy), insertion depth (short or full-length array), type of electrode (straight, perimodiolar or mid-scala) and insertion force.

Combined Electric and Acoustic Hearing

Several standard-length (“cochlear coverage”) arrays already on the market have been successfully used during hearing preservation procedures. However, the recent FDA approval of the Cochlear Americas Hybrid™ CI device has further improved the opportunity to preserve and utilize residual hearing, and it has expanded the candidacy criteria such that patients with substantial residual hearing are now candidates for CI technology. With the approval of this new CI design, clinicians have the opportunity to utilize an acoustic component that can be placed in the implanted ear of patients with postoperative residual hearing.

Research has shown that this electric-acoustic configuration gives the recipient many hearing advantages, including improved music appreciation, improved perception of speech quality and better understanding of speech in noise. Because successful hearing preservation can influence CI programming and outcomes, it is critical that programming clinicians are aware of the patient’s level of acoustic hearing when completing CI programming.

A More Thorough Postop Evaluation

To accommodate our changing population of CI recipients, we have adapted our postoperative protocol to include audiometric evaluation (including air- and bone-conduction thresholds, speech recognition thresholds, word recognition scores and tympanometry).

Hearing preservation is routinely measured and reported in the literature as serial assessments of pure-tone air-conduction thresholds in the implanted ear. A limitation of this methodology is that the exclusion of bone-conduction thresholds can mask the introduction of an air-bone gap that develops as a result of hemotympanum. Evaluation is conducted before activation and then again at each postactivation programming appointment until the hemotympanum has resolved. Residual hearing is periodically re-evaluated for changes that may impact programming decisions.

Our early experience suggests that at least partial preservation of low-frequency (< 1500 Hz) acoustic hearing after cochlear implantation is possible for most patients (see example results in Figure), even with full insertion of a standard-length array.

Dr. Sydlowski is Audiology Director of the Head & Neck Institute’s Hearing Implant Program. She can be reached at 216.444.0354 or sydlows@ccf.org.

Air Conduction Thresholds

Figure. Pre- and postoperative serial audiograms in a recently implanted ear.
A New Approach to Dizziness and Vertigo
Our Latest Care Path Balances the Old and New

By Judith White, MD, PhD

Spring 2014 ushered in the completion of Cleveland Clinic’s Dizziness/Vertigo Care Path Guide after many months of development. Containing contributions from more than 50 providers, this 16-page guide is designed to provide direction to all Cleveland Clinic caregivers who become involved in the management of dizzy/vertiginous patients so that we may avoid inefficient and costly fragmentation of care. Our next step, now underway, is a pilot project to improve the scheduling of patients who call for an appointment with Cleveland Clinic’s Head & Neck Institute for symptoms of dizziness or vertigo.

The Lowdown on Care Paths
Not to be confused with practice guidelines, Cleveland Clinic care paths are comprehensive, evidence-based tools designed to show clinicians in multiple specialties how to coordinate the management of patients with a given disease through the acute, post-acute and outpatient phases of care. A care path guide is a brief manual that lays out the appropriate management steps on which a care path is based, including supportive rationales and evidence. While a care path guide may be similar to a set of practice guidelines, it is just the starting point for the care path itself, which is a broader organizing principle for managing a given condition. The distinction is important, because there is little evidence that practice guidelines improve care and outcomes.

Care paths are designed to operationalize practice guidelines through the embedding of order sets and elements of the care path guide into the electronic medical record (EMR) so that clinicians are encouraged to follow evidence-based management at every turn. Some Cleveland Clinic care path initiatives — which are underway for dozens of conditions — are also prompting refinements in the best mix of providers and support services for patients at different points along the care continuum.

Sometimes Low-Tech Care Is Better
The specific goals of the Dizziness/Vertigo Care Path are:

- To reduce the number of CT scans of the head in the absence of other neurologic complaints
- To increase use of the simple Dix-Hallpike maneuver and the history to diagnose benign paroxysmal positional vertigo (BPPV), which is the most common cause of dizziness
- To increase use of the canalith-repositioning maneuver as a simple treatment

Our effort to reduce utilization of costly and unnecessary CTs in favor of something as simple as the Dix-Hallpike maneuver is an example of the care path’s practical value. CTs of the head are of very limited value in the assessment of dizziness. A study published in 2010 showed that less than 1 percent of all head CT scans ordered for dizziness/vertigo yielded significant results, and those patients exhibited severe headache and neurologic deficits in addition to their dizziness. An expert review published last year concluded that emergency departments spend $360 million annually ordering head CTs to diagnose dizziness. The humble Dix-Hallpike maneuver is more effective, and it adds nothing to the cost of healthcare. CTs should be reserved for patients who exhibit focal neurologic signs and symptoms.

The Dizziness/Vertigo Care Path Guide features an easy-to-follow workflow algorithm to guide decision-making at every step in the patient’s journey from presentation to resolution (Figure).

Let the Rollout and Piloting Begin
The coming months will see gradual implementation of elements of the care path guide into Cleveland Clinic’s EMR system to maximize its reach and impact across our health system. These efforts will likely include a pilot test of an EMR alert to remind emergency
department providers who are about to order a head CT for dizziness that “head CTs are best reserved for patients with focal neurologic signs and symptoms in addition to vertigo.”

One of the first initiatives along these lines is a pilot project to change scheduling procedures so that patients who call with complaints of dizziness are offered a same-day or next-day appointment with a vestibular physical therapist. Patients who call specifically for an appointment with a vestibular and balance specialist will be scheduled, but they will be urged to consider an appointment with a vestibular physical therapist as well.

Lessons Learned

Care paths are unique to each institution. A team of multidisciplinary providers at any given institution can pool experiences and pearls that may improve that institution’s approach to implementing national practice recommendations. In creating our Dizziness/Vertigo Care Path, we included many different providers, specialties and points of view.

Our Ultimate Goals

For our dizziness/vertigo patients, we expect that the policies advocated in the Dizziness/Vertigo Care Path Guide will result in a measurable reduction in the incidence of falls and fractures, an improvement in patients' access to care and a high level of patient satisfaction. For Cleveland Clinic, we expect to see more efficient use of staff time, a reduction in the costs of care and ideally an elimination of unnecessary expenses.

References


Dr. White is Section Head of Vestibular and Balance Disorders and Director of the Dizziness, Balance and Fall Prevention Center. She can be reached at 216.839.3000 or whitej3@ccf.org.
Rethinking Traditional Therapies for Oropharyngeal Cancer: New Twists on an Old Disease

By Brian B. Burkey, MD, MEd, FACS

Despite the decreased incidence of tobacco use, the number of oropharyngeal cancers diagnosed in the U.S. has increased rapidly over the past decade. This rise is expected to continue for at least three more decades — not only here, but in most other developed countries as well.

This “epidemic” of oropharyngeal cancer is attributable to a corresponding rise in the prevalence of human papillomavirus (HPV)-related squamous cell carcinoma (SCC), which is now more common than HPV-related cervical cancer.

This emergence of this new twist on an old disease has fascinated head and neck surgeons across the country, and Cleveland Clinic’s head and neck cancer multidisciplinary team is very active in elucidating the facets of this disease. Much of our ongoing research was presented at the 2014 Multidisciplinary Head and Neck Cancer Symposium in Scottsdale, Arizona. Members of our team, some of whom are also staff in the Head & Neck Institute, made oral and poster presentations at the meeting highlighting the unique nature of this disease and how it is distinct from the tobacco-related cancers that were seen so often in the past. Summaries of some of those presentations follow.

The Disease, Not the Treatment, Can Determine Outcomes

Because of unexpectedly good outcomes, we were able to stop a phase 3 trial of two cisplatin-based regimens of concurrent chemoradiation therapy (CCR) for locally advanced SCC of the head and neck. Excellent results were observed in both arms, primarily because of the high incidence of HPV-related oropharyngeal cancer (71 percent) among study participants. With a locoregional control rate of 99 percent at two years of follow-up and recurrence-free and overall survival rates of 90 percent each, the treatment response in patients with HPV-positive SCC in our study was superior to that seen in studies of other head and neck cancers.

We are confident our findings will have an impact on future clinical trials. These findings should also make physicians wary of results of oropharyngeal cancer studies published in the past two decades that were not randomized by HPV status, since those outcomes may not depend on the type of treatment as much as on the type of disease treated.

This same trial also showed therapeutic and cost benefits in using cisplatin alone in CCR regimens for the treatment of advanced head and neck cancer rather than cisplatin and 5-fluorouracil (5-FU) combined. The simpler regimen achieved equal results with less morbidity and less expense.

Our findings should make physicians wary of studies that were not randomized by HPV status, since those outcomes may not depend on the type of treatment as much as on the type of disease treated.

A New Era in Treatment

HPV-positive SCC of the oropharynx also exhibits a quite distinct pattern and timing of recurrence. In a review of 285 patients treated for oropharyngeal cancer with chemoradiation therapy from 2002 to 2013, only 11 percent of those with HPV-positive tumors developed a distant metastasis, compared with 20 percent of those with HPV-negative tumors. The time from treatment cessation to development of those tumors was also longer in the HPV-positive group (21.6 months vs. 7.0 months). However, the HPV-positive tumors were much more likely to metastasize to multiple organ systems rather than to a single organ system, and these distant metastases arose in unusual locations (e.g., the pleura, bone and brain) (Figure).

Furthermore, patients who developed a distant metastasis often experienced a surprisingly long survival with treatment (median, 36 months). These data challenge us to reconsider the way we evaluate, treat and follow HPV-positive oropharyngeal cancers, and they make us rethink the old paradigms that were ingrained in us during the era dominated by tobacco-related, HPV-negative SCC.
Normal Diet Despite Aggressive Therapy

Finally, our work shows that patients with HPV-positive oropharyngeal cancer can enjoy excellent functional outcomes despite aggressive therapy, and this too should make us think differently about how we compare treatment options.

In a cohort of almost 200 patients rendered free of HPV-positive oropharyngeal SCC after CCR from 2002 to 2012, 91 percent returned to a normal diet while only 2.5 percent were left dependent on tube feedings.\(^5\) The rate of late toxicity was even lower in patients treated with intensity-modulated radiation therapy rather than with traditional radiation methods and was likewise lower in those who did not receive concomitant 5-FU.

Rare Chance to Study an Evolving Disease

Our research in this area continues, and more was presented at the American Head & Neck Society meeting in July 2014. This work focused on evaluating patients’ understanding of HPV and HPV-positive SCC as well as on opportunities for prevention through patient education and vaccination.

Moreover, surgeons and physicians at Cleveland Clinic recently received approval to participate in an NIH-sponsored phase 2 randomized trial that will compare four postoperative treatment regimens in advanced HPV-positive SCC of the oropharynx following transoral resections.

It is rare to have the opportunity to study a disease in evolution, and the clinicians and scientists in our head and neck cancer multidisciplinary team are excited to be taking a leading role in understanding and defining better treatment methods for this unique disease.

References


Dr. Burkey is Head of the Section of Head and Neck Surgery and Oncology as well as Vice Chairman of the Head & Neck Institute. He can be reached at 216.445.8837 or burkeyb1@ccf.org.

Figure. Distribution and number of distant metastases in a Cleveland Clinic study of nearly 300 patients with oropharyngeal squamous cell carcinoma, according to tumor HPV status.
Temporomandibular Disorders: A Compassionate, Conservative Interdisciplinary Approach

By Karyn Kahn, DDS; Michael Horan, MD, DDS, PhD; and Joseph Krajekian, DMD, MD

Pathology and dysfunction of the masticatory system are significant factors to consider in the diagnosis and management of patients with a temporomandibular disorder (TMD).

With this in mind, we thoroughly assess TMD patients who present to Cleveland Clinic’s Head & Neck Institute to identify all aggravating and perpetuating factors involved in compressive overload to the temporomandibular joints (TMJs), jaw muscles and dentition. We manage these factors through an interdisciplinary approach that involves clinicians trained in dentistry, oral and maxillofacial surgery, chronic pain management, physical therapy and psychology. Ideally, TMDs should be managed through an interdisciplinary approach; unfortunately, this approach is not always available in the community. We provide access to all disciplines under one roof.

Our aim is to treat patients with conservative measures when it is possible and with minimally invasive surgery when it is not — and with open procedures as a last resort.

How We Do It

Our comprehensive evaluation includes a thorough TMD-focused medical history and physical examination. During the exam, our goal is to identify all potential sources of pain and dysfunction and then determine whether their etiology stems from the TMJs, muscles, dentition or a combination of these structures.

We also examine TMJ function and dental occlusion in terms of the physical condition and position of the TMJs. When we find parafunctional wear patterns on the teeth, we discuss them with the patient so that he or she gains an understanding of the forces generated by bruxism. We might also recommend imaging of the TMJs with cone-beam CT, medical CT or MRI, depending on the initial diagnostic impression.

Many Layers of Treatment

Treatment of patients with TMDs is multifaceted (Figure). We provide self-help therapy so that patients can recognize and discontinue exacerbating daytime habits. We also offer diet recommendations and strategies for coping with short-term pain.

We can also prescribe dental appliance therapy as a conservative treatment to stabilize the patient’s occlusion and to reduce pressure in the joint. Physical therapy and exercise are important adjuncts for initiating myofascial trigger-point release, for joint mobilization and to strengthen posture.

We also screen for anxiety and depression. Referral for stress and pain management is available through Cleveland Clinic’s Chronic Pain Rehabilitation Program. This comprehensive three- to four-week outpatient program also involves a multidisciplinary approach to reduce patients’ pain and to help them master coping skills to improve their daily function.

Ideally, temporomandibular disorders should be managed through an interdisciplinary approach, but this approach is not always available in the community.

Pain Rehabilitation Program. This comprehensive three- to four-week outpatient program also involves a multidisciplinary approach to reduce patients’ pain and to help them master coping skills to improve their daily function.

The keys to conservative TMD management are patient education and long-term management of all factors involved in the disorder. We believe that conscientious patient education can empower patients to appreciate that they have control over their symptoms.

For More Difficult Cases

A certain subset of patients will not improve with conservative therapy, and they will require surgical intervention. When possible, we move on to minimally invasive approaches, such as arthroscopy and arthrocentesis. For more advanced cases, we can perform an open joint procedure such as disectomy or arthroplasty. Patients with end-stage disease or severe joint degeneration may require a total joint replacement.

Postoperatively, our surgical patients often achieve greater-than-average success as a result of continued conservative follow-up with our interdisciplinary team.
Our interdisciplinary approach in a setting of shared medical and dental findings, communication and referrals helps expedite total patient care. With our patient education programs, TMD patients can gain an understanding of their condition, as well as the professional guidance and therapeutic tools that are available to help them achieve manageable levels of acceptance and a better quality of life.

Dr. Kahn is a dentist in the Head & Neck Institute. She can be reached at 216.444.3265 or kahnk@ccf.org.

Dr. Horan is Section Head of Oral and Maxillofacial Surgery. He can be reached at 216.636.4329 or horanm@ccf.org.

Dr. Krajekian is an oral and maxillofacial surgeon in the Head & Neck Institute. He can be reached at 216.444.6398 or krajekj@ccf.org.

**THE MANY SYMPTOMS OF TMDs**

Muscle dysfunction of the jaw and cervical structures can refer to the cranium and facial structures, often presenting as seemingly unrelated symptoms. In a review of 102 patients who presented to the Section of Dentistry in the Head & Neck Institute for a comprehensive TMD evaluation, the incidence of reported symptoms was:

- Facial pain, 84 percent
- TMJ pain, 58 percent
- Tension headache, 52 percent
- Cervicalgia, 47 percent
- Ear pain, 46 percent
- Sinus pain, 21 percent
- Migraine, 18 percent
- Vertigo, 15 percent

Other symptoms can include ear fullness, tinnitus and odontalgia. Moreover, the review of 102 patients revealed that 58 percent reported daytime clenching of teeth and 62 percent reported nocturnal grinding/clenching.
The Layered Fibula Osteocutaneous Flap:
Setting a New Standard in Aesthetic and Functional Outcomes for Advanced Maxillary Cancers

By Michael A. Fritz, MD

Surgical defects created during total palatomaxillectomy for tumor resection present surgeons with one of their most daunting challenges in facial reconstruction. The maxillary bone provides height and width to the midface and contributes greatly to the overall aesthetic facial contour. From a functional aspect, the maxilla provides support to the orbital contents, serves as a bony framework for dentition and contributes to the oral phase of swallowing and speech articulation via palatal and alveolar arch integrity. Failure to account for each of these variables when composing an overall reconstructive strategy can result in significant quality-of-life issues.

Total palatomaxillary reconstruction poses difficult tasks in terms of re-establishing a complex three-dimensional form and providing vascular pedicle reach into the neck. The challenge of reconstruction increases with the amount of vertical and horizontal bone loss, and arguably it rises to a different order of magnitude when the orbital walls and/or floor are also absent.

Previous Techniques Have Come Up Short

Numerous techniques have been employed to reconstruct maxillary defects. Over the past decade, contouring of various soft-tissue and bony free flaps — including fibula, scapula, iliac crest, rectus abdominus, radial forearm, anterolateral thigh and latissimus dorsi flaps — has been endorsed for maxillary reconstruction. However, no technique has consistently addressed all aesthetic and functional deficits following total maxillectomy, particularly when a large component of the orbit is involved.

The fibula free flap has been advocated for reconstruction of lower palatal and alveolar defects with the advantage of allowing for osseointegrated dental implants. It has been cited, however, for having limited application for total maxillectomy defects, including those in the orbital floor, the alveolar arch and more than half of the palate.

A Novel Technique for Orbitomaxillary Reconstruction

Using a layered fibula free-flap design, we have developed a technique that addresses both form and function in total maxillary and orbital reconstruction. By modifying the fibula to address orbitozygomatic defects superiorly and palatal-alveolar absence inferiorly, we have adapted the fibula flap to (1) replace midface and orbital contour and (2) provide a platform for dental rehabilitation.

This method of reconstructing large additional defects of the orbital walls and floor allows us to preserve normal eye appearance and function. Further adaptation of our recently published technique has allowed us to reconstruct defects that have included up to three of the four orbital walls.

The layered fibula technique employs three to five bone segments with double-closing osteotomies to establish normal curvature of the orbital rim, zygoma and alveolar arch. The distal bone segment articulates with the remnant of the zygoma superolaterally, and the bony reconstruction sweeps medially to the nasomaxillary buttress and then falls inferomedially to connect to the medial remnant of the alveolar arch. The construct then sweeps inferolaterally toward the first segment and the inferior aspect of the zygoma. The bone segments are stabilized with titanium reconstruction plates (Figure 1).

Simultaneous orbital reconstruction is performed using titanium mesh anchored to native bone (i.e., the remaining orbit and skull base) and fibula and is utilized for orbital floor and wall reconstruction. The orbital mesh construct is secured in a nonanatomic fashion to restore periorbital volume loss from resection; this prevents postoperative enophthalmos. Importantly, the vascularized soft-tissue component of the fibula flap completely obliterates the maxillary sinus and surrounds the mesh to prevent movement or exposure over time. The cutaneous paddle replaces the palatal defect. Vascular anastomosis to the ipsilateral facial or angular vessels is performed.

Surgical Outcomes

We have used this reconstructive technique in 12 patients, with follow-up ranging from nine months to seven years (outcomes of the first seven cases are detailed and illustrated in our previous publication). Eight patients underwent postoperative radiation therapy. There were no partial or complete flap losses. Patients with no dentition began a soft diet within six weeks of reconstruction, while the rest returned to their regular diets. Aesthetic facial reconstruction with midface symmetry and unrestricted eye function was accomplished in all patients, as demonstrated by the photos in the case study sidebar and in Figure 2.
Dr. Fritz is a specialist in facial plastic and reconstructive surgery in the Head & Neck Institute. He can be reached at 216.444.2792 or fritzm1@ccf.org.

Reference

Case Study
A 55-year-old woman underwent resection of a right maxillary adenocarcinoma. Her defect included the entire medial orbital wall, rim and floor and the inferior aspect of the lateral wall. Orbital reconstruction was accomplished with titanium mesh anchored to the skull base and the remaining orbit; the mesh was articulated with the layered fibula at the rebuilt orbital rim. Follow-up one year after radiation therapy demonstrated good eye position and midface symmetry.
Head & Neck Institute

Shared medical appointments (SMAs) are gaining recognition in the healthcare arena as a cost- and time-efficient way to conduct office visits. SMAs allow clinicians to deliver the same information to multiple patients at the same time, thereby maximizing available resources in a busy clinical practice. From patients’ viewpoint, SMAs allow individuals to realize that others are coping with the same chronic condition and similar quality-of-life issues. Moreover, patients can learn management strategies from fellow patients as well as clinicians.

Small-Group Sessions
The Section of Audiology in Cleveland Clinic’s Head & Neck Institute has capitalized on the benefits of SMAs through our Tinnitus Management Clinic (TMC). The primary goal of the TMC is to equip patients with the knowledge and tools that will help them overcome tinnitus-related psychosocial problems (e.g., anxiety, depression, inability to participate in everyday work and recreation) and physical difficulties (e.g., sleep deprivation, muscular tension). Because this chronic, bothersome condition has multiple underlying causes, we take a multidisciplinary team approach that involves specialists in five areas.

Six patients participate in each monthly SMA, which we began offering in June 2007. Once patients receive medical clearance from an otolaryngologist and undergo examination by an audiologist, they are scheduled for a three-hour group appointment. Each SMA includes a 90-minute group education session (see photo, next page) followed by rotating individual 15-minute visits with two audiologists, a dentist, a neurologist, a physical therapist and a psychologist.

What Happens in the Group Education Session?
Each member of the clinical team participates in the group education session and uses a PowerPoint presentation to guide the flow of the session. The information presented is geared toward increasing patients’ understanding of tinnitus and their knowledge of the management strategies to be offered by each SMA team member. Specific objectives include:

• Clarifying misconceptions about tinnitus (e.g., Will I go deaf because of my tinnitus?)
• Demystifying tinnitus by providing simple explanations about its underlying mechanisms and the anatomy and physiology of the auditory system
• Describing common psychosocial reactions to tinnitus
• Offering practical suggestions and techniques that may provide patients with immediate relief
• Providing hope for future management options

At the beginning of the session, one of the audiologists explains the ground rules and the need for strict confidentiality outside the room. Then the patients are encouraged to share their experiences about their tinnitus. The clinicians take care to control this part of the session so that no single patient dominates.

What Happens in the Individual Sessions?
Each specialist conducts a short screening assessment to determine if a more thorough follow-up visit is necessary later:

• The audiologists review and demonstrate various sound therapy options for tinnitus relief.
• The dentist screens for specific dental problems, including temporomandibular disorders.
• The neurologist screens for potential neck/cervical disorders that may be related to somatic tinnitus.
• The physical therapist screens for problems associated with neck, spine, jaw or shoulder injuries, or strains caused by job requirements or poor posture.
• The psychologist screens for depression/anxiety disorders and introduces the importance of the mind-body connection.
What Happens After the Patients Leave?

After the patient sessions conclude, the clinical team gathers to discuss each patient’s case and provide recommendations. A summary of each specialist’s findings is mailed to each patient, along with a consensus treatment plan that includes specific recommendations for follow-up. Subsequent management may include one or more of the following options:

- Sound therapy incorporating use of hearing aids/sound generators/combination units
- Bite modification appliances
- Cognitive behavioral therapy/acceptance therapy
- Further medical management
- Physical therapy

Is There Evidence that the SMAs Work?

Following each SMA, questionnaires are mailed to the participating patients to ask them to assess the benefits they gained from their experience. The primary outcome measure is the Tinnitus Handicap Inventory (THI). The THI is used to evaluate how tinnitus limits patients’ daily activities.

We recently mailed questionnaires along with the THI to a sample of patients. Among the 63 patients who returned questionnaires, 69 percent experienced a clinically significant reduction in perceived disability/handicap by attending the TMC, as reflected in their THI scores. Of that group, 96 percent reported receiving some benefit from attending the SMA (Figure). Moreover, all those who knew someone with tinnitus said they would recommend the TMC to them.

Although the success of the SMA was not measured directly, we believe it helped establish trust and rapport between the patients and each clinician and thereby promoted adherence to recommendations beyond the TMC sessions.

Building on Success: SMAs for Cochlear Implant Recipients

Our experiences in the TMC have given us confidence that the SMA model can be applied to other areas of audiologic care in which self-management is critical to success.

We will soon expand the scope of our audiology SMAs to include a separate session for cochlear implant recipients. Just as we do for tinnitus patients, we will give implant recipients the chance to share experiences and benefit from the questions of others with a similar degree of hearing loss. We will also review the use, care and maintenance of the implants and discuss other therapy options. Patients will also receive written materials and video demonstrations. Finally, development of a cochlear implant SMA will lower costs by minimizing nonbillable activities and streamlining counseling.

Reference


Dr. Newman is Section Head of Audiology and Co-Director of the Audiology Research Laboratory. He can be reached at 216.445.8520 or newmanc@ccf.org.

Dr. Sandridge is Director of Clinical Audiology Services and Co-Director of the Audiology Research Laboratory. She can be reached at 216.445.8517 or sandridges@ccf.org.

Dr. Sydlowski is Audiology Director of the Hearing Implant Program. She can be reached at 216.445.8613 or sydlows@ccf.org.
Botulinum Toxin — the Cosmetic ‘Toxin Turned Treatment’ — Earns a Place in Pediatric Otolaryngology

By Brandon Hopkins, MD

Botulinum toxin (BTX) injections may have gained fame as a tool to slow the wheels of time, but their use has expanded to include the treatment of many head and neck disorders outside the cosmetic arena. We at Cleveland Clinic are pleased to offer this minimally invasive treatment to our pediatric head and neck patients.

Proliferating Clinical Applications in Pediatrics

The safety profile of this medication has opened doors for its use in pediatrics beyond strabismus, which was its first medical use. Spasmodic dysphonia (see p. 20) and essential voice tremor are well-known laryngeal indications, but in pediatric head and neck patients, BTX has been used to treat airway obstruction due to bilateral vocal cord paralysis and laryngeal dystonia.

Beyond laryngeal indications, there is strong evidence for BTX use in chronic daily headaches, cervical dystonia, masticatory myalgia, sialorrhea, temporomandibular joint disorders, bruxism, blepharospasm, hemifacial spasm and nasal rhinitis. Its use has also been reported for facial paresis, palatal and stapedial myoclonus, trigeminal neuralgia, first-bite syndrome and Frey syndrome. Four brands of BTX have been approved by the FDA: Botox®, Dysport®, Myobloc® and Xeomin®.

At Cleveland Clinic’s Head & Neck Institute, we have found BTX to be effective for three pediatric indications in particular: congenital muscular torticollis, sialorrhea and facial nerve dysfunction.

Torticollis: Avoiding a Surgery

Torticollis is a relatively common condition in newborns, with an incidence as high as 1:250. The most common type is congenital muscular torticollis (CMT). CMT is caused by a unilateral shortening of the sternocleidomastoid muscle (SCM), which leads to an ipsilateral head tilt and contralateral head rotation. This twisted position often leads to positional plagiocephaly. CMT can present as:

• A palpable SCM tumor
• Tightness or fibrosis of the SCM with no mass
• Torticollis without SCM tightness

At Cleveland Clinic, pediatric otolaryngologists work with our physical medicine and rehabilitation team, physical therapists, primary care teams and others to care for children with CMT. Our approach is to identify patients early, rule out other causes of torticollis and implement therapy early in life.

Standard treatment for CMT involves physiotherapy, stretching exercises, molding helmets and neck braces. These conservative treatments are most successful when started early in life. However, some children — especially those with an SCM tumor or fibrosis and those resistant to physical therapy and conservative interventions — are recommended for surgery. Since surgery can leave patients with functional and cosmetic limitations, families welcome the nonsurgical alternative offered by BTX injections. Studies have shown that BTX injections have a high rate of success when they are used early, often before 12 months of age.

With the child under light anesthesia, we turn the head to the contralateral side to isolate and grasp the SCM. Under sterile conditions, the syringe is placed and then pulled back to ensure that it is not being placed within a blood vessel. (Ultrasound guidance can be helpful but is not usually necessary.) The BTX is then injected under direct vision. It is common to find that trapezius tightness also limits head rotation; if so, this muscle can also be treated. Typically 25 to 50 units of BTX (10 units/0.1 mL) are injected into each muscle, depending on its size and bulk. We take care to avoid injection and diffusion into surrounding muscles to avoid the possibility of dysphagia.

BTX injections have a high rate of success when used early for congenital muscular torticollis, often before 12 months of age.
These outpatient injections are typically well tolerated by infants and children, which allows them to quickly return to physical therapy. Repeat injections are occasionally helpful.

**Excessive Drooling: Stemming the Flow**

Sialorrhea, which occurs in as many as one-third of children with cerebral palsy, is a common indication for BTX use at Cleveland Clinic. The clinical consequences of excessive drooling include skin breakdown and an increased risk of aspiration. Its quality-of-life implications can include constant bib changes, social isolation and compromised school performance.

As a form of chemical myectomy, BTX injections for facial paralysis give families a chance to “try before they buy” a procedure with lifelong cosmetic implications.

In addition to BTX, medical treatment options include optimizing body position to lessen salivary egress from the oral cavity, intraoral appliances and anticholinergic medications to decrease salivary flow. Traditional surgical options have included transtympanic neurectomy to decrease the neural input triggering salivation, submandibular gland excision, duct ligation, duct rerouting and other procedures.

BTX has been shown both subjectively and objectively to decrease salivation for up to four or five months. We inject bilateral parotid and submandibular glands with 70 to 100 units spread between the glands. Minimizing the volume of injection is important to prevent diffusion of BTX into the facial musculature, which can lead to facial weakness.

For selected compliant patients, the minimally invasive nature of these injections allows us to perform them with ultrasound guidance, minimal sedation and topical anesthesia in an outpatient setting. Other patients are treated in the operating room.

Our experience has been consistent with studies showing an improved quality of life with these injections, and families often wish to repeat the treatments. BTX injections can also serve as a trial to gauge improvement and help patients feel more comfortable proceeding to a more permanent surgical approach.

**Facial Paralysis: Restoring the Smile**

Marginal mandibular nerve paralysis is a relatively common condition that results in an asymmetric smile and even asymmetry at rest, which can be socially and emotionally distressing. Its causes include congenital anomalies, viral insults, trauma, iatrogenic surgery and many other etiologies.

Interventions can be directed to either the paralyzed side or the normal side. Procedures on the former include partial lip resection, hypoglossal nerve transfer, local muscle transfers and free tissue transfers. These approaches have their drawbacks, however, including scarring, the need for secondary incisions and often a lack of functional restoration. Procedures on the nonparalyzed side attempt to create facial symmetry, ideally at rest and with movement. Surgical options include severing the remaining marginal mandibular nerve and myectomy of the lower lip depressor muscles.

BTX injections are a form of chemical myectomy. Many children can be treated in the outpatient setting with topical anesthesia. The injection can be repeated as needed every four or five months, with dosage adjustments to achieve the desired effect. Again, BTX can be used as a trial before proceeding to a more permanent surgical approach, such as myectomy. This offers families the opportunity to “try before they buy” a procedure that has lifelong cosmetic implications.

**Further Exploration Ahead**

In a multidisciplinary effort, we work with our colleagues in the Head & Neck Institute to select appropriate pediatric candidates for treatment with BTX. We look forward to further exploring the varied uses of this “toxin turned treatment.”

A bibliography is available from the author at hopkinb@ccf.org.

Dr. Hopkins is a member of the Section of Pediatric Otolaryngology and the Department of Otology. He can be reached at 216.444.0322 or hopkinb@ccf.org.
An essential part of delivering quality care is helping patients make rational, informed choices about their treatment. Patients who present to the Voice Center in Cleveland Clinic’s Head & Neck Institute with a clinical diagnosis of spasmodic dysphonia are faced with a difficult care challenge because there is no cure.

The treatment options for spasmodic dysphonia include reassurance without active intervention, voice therapy, surgery and botulinum toxin (BTX) injections. The latter is considered the gold standard of care worldwide, although the voice benefit is only temporary.

Evidence-Based Counseling has Been a Challenge

In the absence of substantial evidence-based research on the effects of BTX injections for this indication, patients must rely heavily on the information provided by their treating clinicians. Unfortunately, counseling in this regard tends to be based loosely on anecdotal clinical experiences rather than on formal documented evidence. While taking the personal approach is a time-honored clinical tradition, it may not allow patients to make a “best” informed choice.

We saw a need for more accurate information about the BTX experience, so we undertook some research to obtain it and thereby improve clinician counseling and patient decision-making.

Explaining Side Effects and Benefits

As a start, we performed a preliminary study of results from our experience with BTX injections in a small cohort of our patients (80 total injections). This analysis revealed that our patients experienced less frequent and less lengthy side effects and accrued more benefits than what had been previously reported as generic, anecdotal trends.

95 percent of all BTX injections in our review resulted in a patient-reported benefit, well above the rate traditionally assumed.

These findings also underscored that counseling about possible side effects and benefits is key, in the following ways:

- **Side effects.** It is important to explain that side effects are possible rather than inevitable — and that when they do occur, they are always temporary, with almost all lasting from several days to no more than six weeks. Two possible side effects are disruptions of voice and swallowing. The manifestations of the former range from a soft, breathy voice to a voice no louder than a whisper. Swallowing issues can involve simple coughing when ingesting liquids or crumbly solids.

- **Benefits.** We explain that benefits are realized by approximately 80 percent of patients who have been correctly diagnosed with spasmodic dysphonia. The major benefit is a reduction in the characteristic tight, effortful, choppy voice delivery. This improved vocal proficiency, which can emerge as quickly as two days after the injection, creates communication ease, improved social confidence and more functional life interaction. In most cases, the duration of benefits ranges from two to eight months; thereafter, a pattern of decline continues until the benefits disappear.

Defining a Realistic Patient Experience

Encouraged by our preliminary research findings, we then conducted a 10-year retrospective review to investigate a much larger patient experience with this treatment. A larger database provided us with a more robust operational definition of the actual patient experience with BTX injections in terms of both side effects and benefits. In turn, a more representative experience should improve both clinician counseling and patient care decisions.
Our study focused on all injections administered to patients with adductor spasmodic dysphonia from 2005 to 2014. During this time, we administered 1,217 BTX injections. We found that only 59 percent of all injections were associated with any side effect, revealing that side effects were less prevalent than typically assumed (Figure).

Moreover, 95 percent of all injections resulted in a benefit (as reported by the patient), well above the 80 percent figure that is traditionally assumed. In 84 percent of those injections reported as yielding benefit, patients rated the benefit as “good to excellent” (Figure), which reflects a high degree of patient satisfaction and suggests a willingness to undergo repeat injections.

**Duration of Effects**

Among all injections associated with side effects, those effects lasted no more than six weeks in approximately 82 percent of cases — and lasted only two to four weeks in 69 percent of cases. These findings align with a general tendency of patients who experience side effects to report them as being tolerable, particularly in the context of satisfying benefits.

For 89 percent of our BTX injections, the duration of benefit ranged from two to eight months, which is consistent with previous anecdotal reports. Only 1 percent of injections conferred benefits that lasted either less than one month or beyond one year. These data support counseling patients that benefits should last approximately six months and that they can generally expect to need more than one injection per year to maintain beneficial effects.

**The Bottom Line**

Overall, our review revealed that patients who receive BTX injections enjoy a more tolerable side effect profile and a greater duration of benefit than what they once might have been told to expect. The satisfaction expressed by our patients is consistent with the standard-of-care status of BTX injections, which can be offered with confidence for consideration by patients with newly diagnosed spasmodic dysphonia.

Dr. Hicks is Section Head of Speech-Language Pathology and a member of the Voice Center in the Head & Neck Institute. He can be reached at 216.444.6691 or hicksd@ccf.org.

Dr. Abelson is a staff physician in the Department of Otolaryngology and the Voice Center. He can be reached at 216.839.3740 or abelson@ccf.org.
In both medical journals and the popular media, the comorbidities of obstructive sleep apnea (OSA) continue to gain attention. While continuous positive airway pressure (CPAP) remains the gold standard for treatment, several alternatives have been introduced that also provide effective therapy. Cleveland Clinic’s Head & Neck Institute is pleased to offer these alternatives.

For many patients, oral appliances are more comfortable and more convenient than CPAP masks. They are quiet, more portable and easy to maintain, and they are associated with higher rates of compliance. Within the past several years, the Centers for Medicare & Medicaid Services has approved payment for certain appliances when they are fabricated by a licensed dentist, provided that certain criteria are met.

Advances in Mandibular Advancement
Several types of oral appliances are available, but the largest body of literature pertains to the custom-fabricated mandibular advancement device (MAD), which patients wear during sleep to maintain an open, unobstructed airway. The MAD looks like a mouthguard. During the initial adjustment period, the device advances the mandible in small increments until a suitable degree of advancement is realized. Thereafter, the device keeps the airway from collapsing by moving the jaw to a forward position.

The MAD has been recognized by the American Academy of Sleep Medicine as an effective treatment for mild to moderate OSA.

Documenting Good Success Rates
Dentists in the Head & Neck Institute have been using the MAD for 15 years with good success. We recently studied its effectiveness in 49 patients over a two-year period. According to the results of repeat polysomnography (PSG), success was achieved in 40 of these patients (82 percent). Treatment success was indicated by either of two outcomes:

- A decrease of 50 percent or more in the total apnea-hypopnea index (AHI)
- A post-treatment AHI < 10

With MAD therapy, 23 patients (47 percent) achieved a normal AHI (< 5). Overall, the mean post-treatment AHI was 9, which was significantly lower than the pretreatment AHI of 23 (Figure 1). The following case study illustrates the positive impact that the MAD had on the quality of life of one of our patients.

Our recent review of outcomes in 49 patients treated with mandibular advancement devices over two years showed an 82 percent success rate.

![Figure 1. Our review of 49 cases revealed that use of the mandibular advancement device lowered the mean AHI score from 23 to 9.](image-url)
Case Study: Breathing Easier with a Mandibular Advancement Device

A 54-year-old woman presented to Cleveland Clinic’s Section of Dentistry in May 2013 after a neurologist had diagnosed her with OSA. Her medical history included fibromyalgia, asthma, osteoporosis, Sjögren syndrome and degenerative disk disease.

The patient had been receiving regular dental care from her family dentist, and she came to us to discuss the option of oral appliance therapy. For the previous 10 years, her snoring had been loud and disruptive, and she had experienced excessive daytime sleepiness for all that time.

PSG revealed the woman’s AHI to be 11.9. She had tried to comply with her CPAP therapy, wearing the mask for six or seven hours nightly. However, she complained of exacerbations of her asthma, headaches and mask leaks, all of which resulted in intolerance of the mask after about 10 weeks.

After we conducted an initial consultation with the patient, she was fitted for a SomnoDent® mandibular advancement device (Figure 2). Her mandible was initially advanced by 5 mm, which was half the distance of the total protrusive range of motion. We then adjusted the initial position and increased the advancement by an additional 2 mm over the course of four months. With the total protrusive distance at 7 mm, the patient began experiencing bilateral temporomandibular joint pain, so we shortened the advancement by 0.2 mm and her symptoms completely resolved.

After the patient had worn the appliance comfortably during sleep for several weeks, she underwent PSG at home, which revealed that her AHI had fallen to 0.7. She happily reported that she was no longer snoring, she experienced fewer awakenings at night and she had more energy throughout the day. She also reported that her asthma symptoms abated as a result of using the appliance.

One year later, our patient was still using the appliance. Volumetric analysis with cone-beam CT (Figure 3) showed that her airway diameter had increased by 2.32 mm³.

Dr. Coy is Section Head of Dentistry. He can be reached at 216.444.4802 or coyt@ccf.org.

Dr. Rifai is a staff member in the Section of Dentistry and Assistant Program Director of the Dental Residency. He can be reached at 216.444.6397 or rifaiah@ccf.org.
Cleveland Clinic’s Auditory Neurobiology Laboratory has been on the cutting edge of hearing research ever since it was established in 2008. We were among the first to investigate the role of the cholinergic system in the modulation of tinnitus, and we continue to be pioneers in pharmacologic approaches aimed at treating this condition.

For example, we have succeeded in abolishing tinnitus-related hyperactivity in the dorsal cochlear nucleus, a component of the central auditory pathway that is key to tinnitus generation. We accomplished this by using a variety of cholinergic agonists in our in vivo tinnitus animal model. We are now moving toward the use of more selective molecules that will allow us to translate our therapeutic findings to the clinic. Preliminary results have been promising.

An Unprecedented Approach to Understanding Tinnitus

To further understand the effects of drug application on tinnitus-related neural activity, we are using innovative microscopic techniques to explore the anatomy and ultrastructural properties of tinnitus-generating neurons — the fusiform cells. By combining scanning electron microscopy with powerful computer software, we are able to accurately reconstruct the different layers and cellular components of the dorsal cochlear nucleus, where these neurons are located. Then we identify and trace individual neuronal elements, which allows us to generate 3-D renditions of the desired structures (Figure).

This approach is unprecedented. It has allowed us to accurately map the fusiform cells, as well as the synapses on the different compartments of these neurons. Then we can examine the various features that provide measures of synaptic strengths (i.e., the sizes of synaptic terminals, the number of active zones within a synapse and the size of active zones).

The value of this information lies in its ability to define synaptic mechanisms that contribute to tinnitus and hyperacusis. It also provides us with a better understanding of the neuronal disequilibrium that occurs in the setting of tinnitus, as well as the mechanism of action of the drugs we use to abolish tinnitus-related hyperactivity.

Hyperacusis: In Search of Its Neural Signature

In addition to its long-standing history with tinnitus research, our lab has recently expanded its scope to cover yet another hearing condition: hyperacusis. Hyperacusis is a disorder of loudness perception in which sound intensities that are considered to be comfortable by most people are perceived as being unbearably loud, even painful, by affected patients.

We have recently established a first-of-its-kind animal model that exhibits chronic noise-induced hyperacusis and tinnitus simultaneously. Upcoming efforts are centered on establishing the first pure animal model of hyperacusis, which will allow us to accurately study the behavioral and neural correlates of hyperacusis.

We expect this effort to pave the way for future research aimed at uncovering the neural signature of hyperacusis, which is essential if we hope to ever effectively treat or cure this condition.

Dr. Kaltenbach is Director of Otolaryngology Research and Head of the Auditory Neurobiology Laboratory in the Head & Neck Institute. He is also a staff member in the Department of Neurosciences in the Lerner Research Institute. He can be reached at 216.444.5171 or kaltenj@ccf.org.

Figure. 3-D reconstruction of a fusiform cell neuron (blue: cell body; yellow: apical dendrites; red: basal dendrites; white: axon).
The Head & Neck Institute at a Glance

CLEVELAND CLINIC’S HEAD & NECK INSTITUTE POOLS THE EXPERTISE OF CLINICIANS IN MULTIPLE SPECIALTIES TO PROVIDE COMPREHENSIVE, COLLABORATIVE CARE FOR COMMON TO COMPLEX DISORDERS OF THE EAR, NOSE, THROAT AND MOUTH.

**WHO WE ARE**

<table>
<thead>
<tr>
<th>Count</th>
<th>profession</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>Professional staff</td>
</tr>
<tr>
<td>31</td>
<td>Otolaryngologists —</td>
</tr>
<tr>
<td>15</td>
<td>fellowship-trained</td>
</tr>
<tr>
<td>3</td>
<td>Pediatric otolaryngologists</td>
</tr>
<tr>
<td>20</td>
<td>Audiologists</td>
</tr>
<tr>
<td>8</td>
<td>Dentists</td>
</tr>
<tr>
<td>3</td>
<td>Oral and maxillofacial surgeons/prosthodontists</td>
</tr>
<tr>
<td>12</td>
<td>Speech-language pathologists</td>
</tr>
<tr>
<td>6</td>
<td>Advanced practice nurses</td>
</tr>
</tbody>
</table>

**OUR 2013 CLINICAL ACTIVITY**

- 66,800 Evaluation and management visits
- 19,044 Pediatric outpatient visits
- 5,661 Primary surgical cases
- 761 Admissions
- 1.78 APR-DRG severity rating

**QUALITY AND PATIENT EXPERIENCE**

- 4.26% 30-day morbidity rate for otolaryngology surgery, better than the expected rate of 6.61%
- 1.43% Surgical site infection rate for otolaryngology surgery, better than the expected rate of 2.62% (Source: American College of Surgeons National Surgical Quality Improvement Program, for July 2012-June 2013)
- 89% Proportion of Head & Neck Institute inpatients reporting they would definitely recommend the hospital (2012-2013) (Source: HCAHPS Overall Assessment, Centers for Medicare & Medicaid Services)
- 90th Percentile ranking in physician communication among all reporting hospitals (2012-2013) (Source: HCAHPS Domains of Care, Centers for Medicare & Medicaid Services)

More outcomes data are available in the Head & Neck Institute 2013 Outcomes Book at clevelandclinic.org/outcomes.
**New Staff**

The Head & Neck Institute welcomes the following new specialists:

**Brandon Hopkins, MD**, practices the full scope of pediatric otolaryngology/head and neck surgery. His specialty interests include the surgical care of patients with cleft lip, cleft palate, microtia and craniofacial abnormalities. He also focuses on complex pediatric multilevel airway obstruction and sleep apnea, including endoscopic and open airway reconstruction, upper airway surgery, and midface and mandibular distraction. Dr. Hopkins completed his fellowship at the University of California, Davis, following a residency at the University of Cincinnati College of Medicine and Cincinnati Children’s Hospital. (216.444.0322; hopkinb@ccf.org)

**Douglas Trask, MD, PhD**, a pediatric and adult otolaryngologist, joins the Head & Neck Institute with extensive experience in both academic and private practice. After completing his residency at the University of Michigan Medical Center, he served on the faculty of the University of Iowa College of Medicine for eight years and later worked in private practice in Grand Rapids, Michigan. Dr. Trask’s specialty interests include sleep apnea (he is board-certified in sleep medicine), nasal and sinus surgery, and the surgical treatment of thyroid disease and head and neck tumors. (216.442.5761; traskd@ccf.org)

**Advances in Otolaryngology & Dentistry**

**FALL 2014**

*Advances in Otolaryngology & Dentistry offers information from Cleveland Clinic otolaryngologists, speech pathologists, audiologists and dentists about new and emerging medical, surgical and rehabilitative techniques. It is written for physicians and should be relied on for medical education purposes only. It does not provide a complete overview of topics covered and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.*

© The Cleveland Clinic Foundation 2014

**New Appointments in the Head & Neck Institute**

**Raj Sindwani, MD**, has been named Co-Director of the Minimally Invasive Cranial Base and Pituitary Surgery Program.

**Staff Awards and Achievements**

**Michael S. Benninger, MD**, was re-elected to a new term as president of the International Association of Phonosurgery. He also was honored with the Cynthia S. Mabry Otolaryngic Allergy Lectureship at the 2013 Annual Congress and Nursing Symposium of the Society of Otorhinolaryngology and Head and Neck Nurses.

**Michael Horan, MD, DDS, PhD**, was named a Diplomate of the American Board of Oral and Maxillofacial Surgery.

**Paul Krakovitz, MD** served as Program Chair for the American Society of Pediatric Otolaryngology.

**Joseph Scharpf, MD**, received an Honor Award from the American Academy of Otolaryngology for exceptional service on its committees and in its scientific programs, exhibits, and continuing education and instructional courses.

**Erika Woodson, MD**, is the recipient of the inaugural *Otology-Neurotology* Impact Award, which is given to the paper in *Otology-Neurotology* with the most citations over two years following its publication among all the journal’s articles that were first-authored by a trainee. The award-winning paper is: Woodson EA, Dempewolf RD, Gubbels SP, et al. Long-term hearing preservation after microsurgical excision of vestibular schwannoma. *Otol Neurotol*. 2010;31(7):1144-1152.
CRITICAL CARE TRANSPORT WORLDWIDE
To arrange a critical care transfer, call 216.448.7000 or 866.547.1467. Learn more at clevelandclinic.org/criticalcaretransport.

OUTCOMES DATA
View Outcomes books at clevelandclinic.org/outcomes.

CONSULT QD BLOG FOR HEALTHCARE PROFESSIONALS
Discover the latest research insights, innovations, treatment trends and more at consultqd.org.

CME OPPORTUNITIES: LIVE AND ONLINE
Visit ccfcmce.org to learn about the Cleveland Clinic Center for Continuing Education’s convenient, complimentary learning opportunities.

EXECUTIVE EDUCATION
Learn about our Executive Visitors’ Program and two-week Samson Global Leadership Academy immersion program at clevelandclinic.org/executiveeducation.

PHYSICIAN REFERRAL APP: DOWNLOAD TODAY
Contacting us is easier than ever. With our free Physician Referral App, you can view all our specialists, transfer a patient and get in touch immediately with one click of your iPhone®, iPad®, or Android™ phone or tablet. Download today at the App Store or Google Play.

THE CLEVELAND CLINIC WAY
By Toby Cosgrove, MD
CEO and President, Cleveland Clinic
Great things happen when a medical center puts patients first. Visit clevelandclinic.org/ClevelandClinicWay for details or to order a copy.

ABOUT CLEVELAND CLINIC
Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,000 physicians and researchers represent 120 medical specialties and subspecialties. We are a non-profit academic medical center with a main campus, eight community hospitals, more than 75 northern Ohio outpatient locations (including 16 full-service family health centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2014, Cleveland Clinic was ranked one of America’s top 4 hospitals in U.S. News & World Report’s “Best Hospitals” survey. The survey ranks Cleveland Clinic among the nation’s top 10 hospitals in 13 specialty areas, and the top in heart care (for the 20th consecutive year) and urologic care.

The following Head & Neck Institute physicians have been recognized in Cleveland Magazine’s “Best Doctors 2014,” produced in partnership with national physician peer-rating organization Best Doctors Inc.®:

Tom Abelson, MD  Alan Kominsky, MD
Daniel Alam, MD  Robert Lorenz, MD
Michael S. Benninger, MD  Joseph Scharpf, MD
Brian Burkey, MD  Raj Sindwani, MD
Edward Fine, MD, PhD  Benjamin Wood, MD
Advances in Otolaryngology & Dentistry
A PHYSICIAN’S NEWSLETTER
FROM THE HEAD & NECK INSTITUTE
FALL 2014

CME from the Head & Neck Institute
Friday, Oct. 24, 2014
Contemporary Multidisciplinary Care of the Head and Neck Cancer Patient: Focus on Thyroid Cancer
7:30 a.m. to 5 p.m. (reception follows)
Cleveland Clinic Lerner Research Institute (NA5-08 Auditorium), Cleveland, Ohio
• Fifth annual offering of this popular daylong course, with a focus this year on thyroid cancer
• Expert faculty from Cleveland Clinic and other top U.S. and international centers
• Mix of focused lectures, case presentations and panel discussions
Register today at ccfcme.org/headneck14.
For registration questions, call 216.448.0777 or email cmeregistration@ccf.org.

Sign up for our Head & Neck Update e-newsletter
Get the latest clinical and research news and developments from the otolaryngologists, dentists and researchers in Cleveland Clinic’s Head & Neck Institute. Two to three issues a year delivered free to your email inbox.
To subscribe, visit clevelandclinic.org/headandneckupdate.