

# HEAD & NECK INSTITUTE INNOVATIONS

A PUBLICATION FOR PHYSICIANS  
WINTER 2022/2023



THE UNIQUE PERSPECTIVE OF  
A HEAD AND NECK CANCER  
SURGEON-SCIENTIST

P. 8

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## Dear Colleagues,

It is an incredibly exciting time as we expand our scope both in the U.S. and abroad. As we enter this new period of growth, the question must be asked: How can we deliver unsurpassed care, no matter where in the world a patient presents to Cleveland Clinic? We believe the answer begins with expanding our vision globally. To this end, we have begun collaborating with our colleagues across Cleveland Clinic Florida, London and Abu Dhabi to strengthen our ability to deliver exceptional care to patients around the globe who present with conditions related to the head and neck.

The growth at Cleveland Clinic has provided new opportunities for some of the familiar faces in the Head & Neck Institute. Our own Brian Burkey, MD, has assumed leadership of the Surgical Subspecialties Institute of Cleveland Clinic Florida. Meanwhile, Mumtaz Khan, MD, also a head and neck surgeon, is Chief of Staff and Interim Chief Medical Officer of Cleveland Clinic Abu Dhabi. The elevation of these two head and neck specialists is incredibly exciting, and we are enthusiastic about the opportunities afforded to all our staff members — opportunities to engage in cutting-edge research, make an impact in our patients' lives and grow as physicians.

Cleveland Clinic is growing as well. Cleveland Clinic London opened last year and is delivering the same outstanding care associated with Cleveland Clinic to patients across the pond. The 184-bed, eight-story facility in Central London is located across the street from Buckingham Palace. The hospital houses head and neck specialists, and we are excited to develop relationships and work closely with our London-based counterparts. This hospital joins Cleveland Clinic Abu Dhabi as unparalleled extensions of Cleveland Clinic's model of care. These hospitals provide patients in both regions direct access to the world's best healthcare while reducing the need for travel.



Cleveland Clinic London

At home, we continue to expand our presence beyond Northeast Ohio. Cleveland Clinic Florida has been consistently ranked as a top hospital in that state, and a recent partnership with the Alice L. Walton Foundation will soon introduce Cleveland Clinic services to Northwest Arkansas. A recent study indicated that many residents of the area are traveling to other places outside Northwest Arkansas for specialty care. The organizations will assess specialty care needs in the region and develop recommendations for healthcare solutions to best meet those needs. We look forward to working with the Alice L. Walton Foundation to bring high-quality specialty care to the region.



Cleveland Clinic Abu Dhabi

The articles inside this issue of *Head & Neck Institute Innovations* are just a small representation of the wonderful things going on at Cleveland Clinic. They embody our group's commitment to innovation, growth, research, advancing care and, above all, providing and increasing access to unrivaled care in all corners of the globe.

Your votes have helped our program consistently rate as a top hospital in Ear, Nose and Throat by *U.S. News & World Report*, and I thank you for the continued support. As you cast your ballot for Ear, Nose and Throat on Doximity in this year's *U.S. News Best Hospitals* survey, I respectfully ask for your vote for Cleveland Clinic. Once again, I hope you find this issue informative, and please do not hesitate to contact me or my colleagues with any feedback.

**Patrick J. Byrne, MD, MBA**

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# WHY ARE PEDIATRIC THYROID CANCER CASES ON THE RISE?

*A pediatric oncologist and otolaryngologist share their insights*

Rates of thyroid cancer in adults and children have increased sharply over the past decade, making it the fastest-rising cancer in the U.S. However, the reasons for that rise remain a subject of debate.

“There has been a big push to minimize the number of scans done on kids because of radiation exposure, so it’s not like the adult population where we can confidently say, [the higher rates are] probably due to increased screening,” says Rachel Georgopoulos, MD, pediatric otolaryngologist and Director of the Thyroid Head and Neck Oncology and Pediatric Endocrine Center (Thyroid HOPE).

Stefanie Thomas, MD, pediatric medical oncologist at Cleveland Clinic Children’s, concurs, adding, “I don’t think this is a case of overdiagnosis; it’s likely we’re picking up more patients with known genetic predispositions to cancer, screening those patients better, and possibly identifying them earlier in their course, rather than presenting to us when they are young adults.”

## **A demonstrated increase**

A 2019 article in *JAMA Otolaryngology—Head & Neck Surgery* showed that after years of slow but steady increase (around 1% annually from 1973 to 2006), cases of pediatric thyroid cancer rose more than 9.5% between 2006 and 2013.

Cases in adults have also risen, but much of that increase is clearly attributable to increased screening and the detection of smaller and less dangerous tumors, asserts Dr. Georgopoulos.

One factor may be increased exposure to radiation, as can happen with childhood cancers, like Hodgkin’s lymphoma and leukemia, because patients begin receiving radiation treatment at a young age, and with some cardiac conditions requiring frequent imaging scans. Notes Dr. Thomas, “We are seeing a genuine increase in a few different cancers in adolescents and young adults in the U.S., and these could be related to environmental exposures or diet, but there isn’t a clear answer on what is driving this trend.”

## **The standard of care**

While cases may be increasing, the standard of care for pediatric thyroid cancer diagnosis and treatment remains the same.

The current method of diagnosis, including thyroid ultrasound and labs, utilizes a safe and effective approach that avoids additional radiation exposure. Biopsy of thyroid lesions is based not only on the size but also the characteristics of a lesion, including genetic information.

“For example, we had a patient with *p53* mutation and a thyroid lesion that was 0.8 cm, which we biopsied primarily because of this known genetic predisposition, as opposed to the size of the lesion,” she says. “We have a much lower threshold to biopsy or repeat ultrasounds in children.”

In most cases, a thyroidectomy will be curative, although higher-risk cases may go on to receive a full-body uptake scan to check for residual thyroid tissue and determine whether the patient will need additional treatment in the form of radioactive iodine.

“Pediatric thyroid cancer tends to have good outcomes and is managed mostly by our otolaryngology and endocrinology colleagues, but as medical oncologists, we partner to identify targeted therapies that may decrease morbidity associated with treatments, while also preserving good outcomes,” says Dr. Thomas.

A 2019 article in *JAMA Otolaryngology—Head & Neck Surgery* acknowledges this increasing incidence and includes additional data on risk for patients with multifocal disease. Findings suggest that patients age 10 or younger with T3 tumor stage and N1b nodal stage are at greater risk for multifocal disease.

Dr. Thomas is hopeful that this research may eventually lead to less-invasive treatment for some patients. “We may get to a point where we’ve determined certain patients are better candidates for lobectomies, as opposed to total thyroidectomies, decreasing the intensity of the surgical resection in this patient population and sparing those patients that morbidity.”

## **The Thyroid HOPE Center**

One sign of this increase in cases is the appearance of thyroid clinics at medical centers across the country, including Cleveland Clinic’s. “We’re seeing a number of centers pop up, and they’re all brand new programs,” Dr. Georgopoulos says. “That speaks to a genuine need.”



**Rachel Georgopoulos, MD,**  
*Director, Thyroid Head and Neck Oncology and Pediatric Endocrine Center*



**Stefanie Thomas, MD,**  
*Staff, Pediatric Hematology Oncology and Blood and Marrow Transplantation*

*continued on p. 16*

# CONSIDERING HNS AS AN ALTERNATIVE FOR PAP WHEN TREATING OSA

*New findings suggest that the therapy is associated with sustained improvements in insomnia, depression and quality of life*



**Alan Kominsky, MD**  
Section Head,  
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A new study indicates that hypoglossal nerve stimulation (HNS) can be considered as an alternative to positive airway pressure (PAP) for patients with obstructive sleep apnea (OSA). OSA, a highly prevalent sleep disorder, often coexists with other sleep and psychological disorders, such as insomnia and depression.

While PAP is the standard treatment for OSA, patient adherence to the treatment, both in terms of frequency and duration of use, remains an issue. The U.S. Food and Drug Administration has approved HNS for patients with moderate to severe OSA, and patient-reported outcomes (PROs) have been positive. The retrospective cohort study, which appeared in *JAMA Otolaryngology–Head & Neck Surgery*, compared the respective associations of HNS and PAP with improved PROs.<sup>1</sup> It also looked at whether using HNS can improve patient-reported sleepiness, insomnia and depression in the long term.

## Potential replacement for cumbersome therapy

“We believe this is the first study to compare PROs between HNS and PAP therapies for OSA,” says Alan Kominsky, MD, Section Head, Surgical Sleep and Snoring and one of the study’s authors. “PAP therapies are very effective at treating OSA, but patients often have trouble with them. We hear complaints about the facial interface discomfort, claustrophobia, inability to sleep through the night and pressure intolerance. So while the treatment itself is effective, we question how effective is it really if patients aren’t using it properly? This is where HNS comes in. We wanted to find out if HNS is better tolerated by patients and if the effectiveness of the therapy is on par with that of PAP.”

The authors collected data from patients who were treated for OSA at Cleveland Clinic. Participants received either HNS between November 2015 and September 2018 or PAP between January 2010 and December 2014. Patients were matched based on demographics at a 3-to-1 ratio for PAP versus HNS. Among the data collected were patient scores on the apnea-hypopnea index (AHI), and Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ), Insomnia Severity Index (ISI) and Patient Health Questionnaire-9 (PHQ-9; depression). For the ESS, ISI and PHQ-9, lower scores indicated no or minimal symptoms. A score of 18 is considered normal on

the FOSQ. A 2-point change on both the ESS and FOSQ indicates a clinically meaningful change. For the PHQ-9, 5 points is clinically significant, and 6 points is significant for the ISI.

## Results

Of the 85 participants in the HNS group, the majority consisted of older, overweight, white men with severe OSA. The 217 participants in the PAP group were of a similar makeup, but there was more racial diversity. Significant improvements were seen in PHQ-9 scores for HNS versus PAP, and the authors observed comparable improvements in ESS, FOSQ and ISI scores as well. The authors also observed clinically meaningful differences in ESS scores for 64.6% of HNS group patients vs 54.5% of PAP group patients, in FOSQ scores for 59.2% of HNS patients versus 30.9% of PAP patients, in PHQ-9 scores for 29.2% of HNS patients versus 24.4% of PAP patients and in ISI scores for 46.9% of HNS patients versus 36.4% of PAP patients.

After one month, all PROs improved significantly, and these improvements were maintained at the three-month post-HNS assessment. Furthermore, the authors did not observe any significant correlations between AHI change and any polysomnographic measure or PROs. Because the greatest changes in outcomes were observed during the first month, the authors believe there is not a significant confounding association between OSA severity and changes in PROs after HNS.

## Looking ahead

“HNS is a relatively new therapy, and much of the existing literature focuses on its effectiveness in treating OSA,” says Dr. Kominsky. “However, because of OSA’s relationship to insomnia, depression and other psychological disorders, we wanted to learn more about the association between HNS and clinically meaningful improvement in these areas. The participants in this study saw improvements in these symptoms, and we expect that patients treated with HNS will see improvements in OSA, insomnia and depression within a month and sustained improvements over time.”

Dr. Kominsky notes that the study did have a few limitations. HNS devices may need to be adjusted after the initial activation visit, and the study did not account



**Figure 1.** The hypoglossal nerve is approached via the neck just anterior to the submandibular gland.



**Figure 2.** The stimulation cuff is placed on selected branches of the hypoglossal nerve.



**Figure 3.** The stimulation and sensing leads are placed into the implantable pulse generator (IPG).



**Figure 4.** The IPG is placed in the anterior upper chest.



**Figure 5.** The stimulation and respiratory sensing functions are checked prior to closure.

for this. The study also did not account for prior diagnoses of comorbid conditions, concomitant medications or treatment adherence. In addition, results at two years post-activation weren't available for most of the participants, so the scope of interpretation is limited. Looking ahead, prospective studies are needed to confirm the results, and they should focus on longer follow-up times and a more diverse patient population. However, the findings from this study suggest that treatment of OSA with HNS is associated with sustained improvements in insomnia, depression and quality of life, and these improvements are comparable to the benefits associated with PAP therapy.

#### Reference

1. Pascoe M, Wang L, Aylor J, et al. Association of Hypoglossal Nerve Stimulation With Improvements in Long-term, Patient-Reported Outcomes and Comparison With Positive Airway Pressure for Patients With Obstructive Sleep Apnea. *JAMA Otolaryngol Head Neck Surg.* 2022;148(1):61-69.

# A NOVEL APPROACH TO TOTAL COLUMELLA RECONSTRUCTION

*By using free vascularized fascia lata flaps, surgeons can overcome some of the aesthetic and functional challenges historically associated with nasal reconstruction*



**Michael A. Fritz, MD, FACS**  
Section Head,  
Facial Plastic and  
Microvascular Surgery

The nasal columella is one of the aesthetic keystones of the central face, serving as a critical central divider of nasal subunits and providing coverage of critical tip support mechanisms including the lower lateral cartilages and the caudal septum. Reconstruction of defects in this region presents a significant challenge in part due to structural isolation between the lip, nasal tip and nasal airway. This issue is made vastly more complicated when underlying nasal cartilage and the septum are also absent. As a result, large defects of the columella have posed a perennial challenge for reconstructive surgeons; despite many described techniques, no ideal solution exists.

Recent innovations with minimal access microvascular techniques and free vascularized anterolateral thigh/fascia lata flaps have allowed complex reconstructions to be performed with near negligible morbidity and vastly abbreviated hospital stays. As a result, indications for these techniques have been extended to more minor reconstructive issues such as facial contour correction, palatal fistula repair, early intervention for osteoradionecrosis and new aspects of nasal reconstruction.

A recent article appearing in the *American Journal of Otolaryngology and Head and Neck Surgery* illustrates a new technique for reconstructing columellar and caudal septal defects using vascularized free fascia lata from the anterolateral thigh (ALT) with replacement of the tip support structure and concomitant skin grafting.<sup>1</sup> This technique has been employed for isolated columellar defect reconstruction or in combination with the repair of more extensive nasal or lip defects. “When it comes to lesions in the columella, the location and the potential for malignancies to spread to nearby parts of the nose make the prognosis poorer, so treatments are often more aggressive,” explains Michael A. Fritz, MD, FACS, Section Head, Facial Plastic and Microvascular Surgery in Cleveland Clinic’s Head & Neck Institute and the corresponding author of the study.

He continues, “Patients are often left with ablative defects involving significant cutaneous, nasal lining and structural loss. From a surgeon’s perspective, the nature of these resections has historically posed significant reconstructive challenges. This area of the nose has unique multilaminar

and three-dimensional functional architecture. In addition, the paucity of nearby skin, perichondrium, periosteum and mucosa, when septal resection is also performed, magnifies the difficulty of achieving a reasonable functional and aesthetic outcome.”

## **The procedure**

In the described technique, an ALT flap is harvested with dissection first begun to identify a dominant musculocutaneous or septocutaneous perforator entering fascia lata. A single perforator is typically employed due to the small flap size required. The size of the fascia lata harvested is based on the specific needs of the patient — if, for example, the defect is limited to the caudal septum and the columella, the flap will measure approximately 4 cm x 3 cm.

“Despite this being a fascial flap, we include an overlaying skin paddle in the harvest for two reasons,” says Dr. Fritz. “First, it allows for manipulation of the flap without having to worry about damaging the vascular plexus on the fascia lata. The second reason is that it offers substrate for the skin graft to be used as the outer layer of the columellar construct and thus saves the patient the morbidity of a skin graft harvest site.”

In cases where there is extensive loss of cartilage (lower lateral cartilage and caudal septum), harvest of donor cartilage is critical to reestablish nasal tip support and ensure appropriate stability and contour of the columella. This can include use of remaining septal cartilage along with costal and/or auricular cartilage.

A nasolabial fold incision is used to localize and isolate the preferred recipient vessels — the angular artery and vein. This provides a very aesthetically favorable approach to isolate vessels in proximity to the reconstruction. Consistent anatomic localization techniques and favorable outcomes with clinical use of these vessels have been previously demonstrated through studies performed at Cleveland Clinic. To accomplish revascularization, the flap is positioned in the central nose and the vascular pedicle is then passed from this location through a subcutaneous tunnel to the nasolabial fold with use of a 5/8-inch Penrose drain. “It’s critical that the flap be harvested as a pure perforator flap

to minimize any perivascular bulk and thus allow passage through the tunnel without compression or facial distortion,” says Dr. Fritz.

After the vascularized fascia lata has been inset into the defect from the nasal floor and along the posterior septal defect, it is trimmed to size. The structural cartilage that had been previously placed is wrapped with the fascia lata, and grafts are supplemented or modified to achieve a natural-looking nose. After circumferential inset, a split-thickness skin graft attained from the previously removed ALT skin paddle is overlaid. By taking the graft from the paddle, secondary harvest site morbidity may be avoided.

When performing nasal reconstruction, there are three critical elements to keep in mind according to Dr. Fritz: soft tissue coverage,

framework and internal lining. “So in order to achieve optimal columella reconstruction, you need to use something with appropriate skin color, subcutaneous thickness or bulk, width, transition with the tip and external nose, and continuity with the rostral septum and floor,” says Dr. Fritz. “Using free vascularized skin that came from a distant location usually results in a mismatched patch. A free vascularized fascia lata flap overcomes this challenge, as skin grafts on the fascia provide a vastly more favorable color match. Additional benefits of this technique include minimally visible scarring, low morbidity, a relatively predictable contour creation and airway maintenance and, most important for the patient, an acceptable aesthetic and functional outcome over time.”



**Figure 1.** Example of isolated columellar septal, nasal soft-tissue triangle and alar rim defect after Mohs micrographic surgery.

**Figure 2.** Free fascia lata inset wrapping around septum in nasal vestibule with skin graft placed over and wrapping around, secured with absorbable suture resection.

**Figures 3 and 4 are post-operative views at eight weeks.**

**Figure 3.** Posteroanterior view.

**Figure 4.** Worm's-eye view.

#### Reference

1. Aliota RE, Meleca J, Vidimos A, Fritz MA. Free vascularized fascia lata flap for total columella reconstruction. *Am J Otolaryngol.* 2022;43(1):103226.

## MORE WORK NECESSARY TO IMPROVE HEARING LITERACY AMONG PATIENTS

*A new study found that while patients are familiar with health metrics for other common conditions, knowledge about hearing loss and treatments lags well behind*



**Sarah A. Sydlowski,**  
**AuD, PhD, MBA**  
Audiology Director,  
Hearing Implant  
Program

Although most patients recognize the importance of eye exams, blood pressure tests and cancer screenings, awareness about hearing loss and hearing improvement lags behind that for many other health disorders. This is despite hearing loss ranking among the most prevalent and undertreated disorders worldwide. A recent study, which appeared in *Otology & Neurotology*, used a national cross-sectional survey to better characterize adult patients' awareness and perceptions of hearing loss and rehabilitation.<sup>1</sup>

### Study design

In the study, 1,250 patients between the ages of 50 and 80 years responded to the survey. Of these, 500 indicated at least moderate hearing loss (40% moderate, 48% moderately severe, 10% severe, 3% profound) and were currently using hearing aids, and 750 indicated that they had not been diagnosed with hearing loss and were not using hearing aids. The survey asked respondents about their knowledge of "normal" or average health metrics (i.e., vision, blood pressure, cholesterol and hearing) and their likelihood of prioritizing health conditions and life activities

in the next 12 months, and to rank the most important health conditions to manage. They were also asked about the timing of their last hearing test and their reasons for not having their hearing tested more frequently.

"Beyond just impaired communication and safety concerns, we know that untreated hearing loss is also linked to depression, social isolation, lower quality of life, heightened fall risk and premature mortality, among others," says Sarah Sydlowski, AuD, PhD, MBA, a co-author on the study and Audiology Director of the Hearing Implant Program at Cleveland Clinic. "But even though we know how prevalent hearing loss is and that these links exist, hearing loss remains greatly underdiagnosed and undertreated. This study quantifies patients' literacy surrounding hearing loss and hearing treatment and identifies any specific knowledge gaps."

### Findings

Based on survey answers, the authors found that the respondents had a disproportionately limited understanding of hearing loss compared to their understanding of other



Despite widely available technology, patients indicated hesitancy about taking corrective measures to improve hearing and only 40% of respondents would consider hearing aids.



## Percentage of patients who reported being likely to address common health conditions:

72%  
Annual  
physical exam

70%  
Cholesterol  
test

66%  
Eye exam

54%  
Bringing  
pet to the  
veterinarian

27%  
Hearing Test

common medical conditions. Only 9% of respondents were able to correctly identify the normal or average range of hearing, and the 500 respondents with hearing loss were only slightly more likely than their counterparts without hearing loss to select the correct answer (11% vs. 8%). However, the normal range of values for vision, blood pressure and total cholesterol were identified by 93%, 85% and 52% of respondents, respectively.

Both cohorts of respondents also ranked hearing loss as the third least important to address compared to 10 other common health conditions. For example, 72% said they were very likely to have an annual physical exam, very likely to have a cholesterol test (70%), very likely to have an eye exam (66%) and very likely bring their pet to the veterinarian (54%) — in contrast, only 27% reported they were very likely to have their hearing tested. When respondents were asked when their last hearing test was, the most frequent response (22%) was more than 10 years ago. Among respondents with hearing loss, the most frequent response was in the past six months (36%), but 64% of respondents with hearing loss had had their hearing checked within the past 12 months. The most common responses for why a respondent had not had a hearing test were “I do not think I am experiencing hearing loss” (47%) and “my healthcare provider has never mentioned getting my hearing tested” (30%).

“Because most patients mainly rely on their primary care physician for information regarding their medical conditions, a significant burden is placed on these front-line caregivers,” says Dr. Sydlowski. “However, we know that only a small percentage of primary care physicians regularly screen for hearing loss among their patients, and roughly half believe there is nothing to be done about hearing loss, which couldn’t be further from the truth.”

In regard to their knowledge about links between hearing loss and other health and social issues, less than a quarter of respondents indicated strong awareness. Although most respondents recognize the potential impacts of hearing loss on safety, quality of life and health, only 38%

believe that hearing loss is treatable, and only 17% believe that hearing loss is preventable. There was also much more hesitancy about taking measures to correct hearing loss versus addressing other conditions — 67% were open to corrective lenses for vision problems, but just 40% would consider using hearing aids. Respondents with hearing loss were more likely to consider hearing aids, but only a quarter of respondents were open to undergoing surgery for a cochlear implant (CI).

### Importance of improving hearing loss literacy

“Despite the wide availability of CIs to treat hearing loss, utilization among eligible patients in the United States is unbelievably low — about 2% of patients who could benefit from a CI have one,” says Dr. Sydlowski. “Improved technology and surgical techniques have expanded candidacy to include individuals with residual hearing, asymmetric hearing loss and single-sided deafness. But, as with the hearing aid population, even though the number of new CI users continues to rise, the number of CI candidates far outpaces the number of actual users.”

Dr. Sydlowski notes that one of the primary reasons for this trend is likely poor general knowledge about the long-term negative sequelae of hearing loss. “There is a significant onus placed on the front-line care providers because most patients don’t voluntarily bring up their hearing health during routine visits,” explains Dr. Sydlowski. “We don’t usually think of hearing loss as a vital part of our health — but it is.”

Dr. Sydlowski add, “With the recent ruling from the FDA that will make some hearing aids available without a prescription, patients can now take on some of the responsibility for managing their hearing loss. However, we must also take steps to help patients improve their hearing literacy.” She continues, “Hearing loss must first be recognized as important to health so patients prioritize managing it — then we can address the best devices to do that. Ideally, the results from this study will reduce the knowledge gap patients have in regard to their hearing health and will prompt primary care physicians and other front-line caregivers to prioritize hearing health by recommending a hearing test with an audiologist.”

### Reference

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# THE UNIQUE PERSPECTIVE OF A HEAD AND NECK CANCER SURGEON-SCIENTIST

*Cleveland Clinic's director of head and neck cancer research discusses one of her recent projects and the role physician-scientists have in driving medicine forward*



**Natalie Silver, MD, MS, FACS**  
*Director, Head and Neck Cancer Research*

When Patrick Byrne, MD, became the Chair of Cleveland Clinic's Head & Neck Institute, one of his major priorities was a recommitment to translational research. Bringing Natalie Silver, MD, MS, FACS, in as Director of Head and Neck Cancer Research was a major step toward achieving that goal. Dr. Silver, who has been in the position since August 2021, not only brings a strong research background to the department, but her role as a head and neck cancer surgeon-scientist gives her a distinct understanding of how to bridge the work of a scientist with that of a clinician.

"Cleveland Clinic has made a commitment to reach our full potential as a research institution," says Dr. Byrne. "This includes some very high-profile recruits and associated investments in oncology. Our Head & Neck Institute is therefore in the midst of a transformation, wherein we aim to leverage the strengths across our enterprise to push forward the boundaries of cancer care. Dr. Silver is one of our key recruits, and her work on cancer vaccines is perfect for us."

## Background

After finishing her fellowship at MD Anderson, Dr. Silver went to the University of Florida, where she was an assistant professor and, for six years, research leader of the Head and Neck Cancer Disease Site Group at the UF Health Cancer Center. In that role, she was responsible for the head and neck cancer clinical trials. While there, she started her translational research lab with her research partner and mentor, Elias Sayour, MD, PhD.

"Although we have different backgrounds — Dr. Sayour is a pediatric neuro-oncologist, and I'm in adult head and neck surgical oncology — our desire to cure cancer, to impact people, to lead clinical trials, to translate this research from the bench to the bedside is what we share."

Over a few years, their lab developed RNA nanovaccines that are personalized for head and neck cancer. "We have our own formulation that is patented, and it's similar, in a way, to the COVID-19 vaccine," explains Dr. Silver. "We use lipid nanoparticles to encapsulate messenger RNA. But our formulation is different in that this is not a preventive vaccine. This isn't something that you give to prevent COVID or cancer or an infectious disease. This vaccine is

a potent immunotherapeutic agent that has the ability to reprogram a patient's immune system against cancer."

The vaccine design is based on taking a small sample from a patient's tumor, which can be as little as a few hundred cancer cells. RNA is isolated from those cancer cells and a cDNA library is generated that is then amplified into mRNA for the vaccine. The mRNA, specific to the patient's cancer transcriptome, is taken and packaged with lipid nanoparticles before it is delivered intravenously.

## Current projects

As a head and neck cancer surgeon, Dr. Silver has a strong interest in oral cancer treatments, which is where she is focusing her next efforts with the vaccine. "I was fortunate enough to get an National Institutes of Health K08 Career Development Award, supporting my work in developing this vaccine for head and neck cancer," she explains. "The project is really focused on preclinical translational work. So I do a lot of mouse work to perfect our formulation and understand the biology of the vaccine, and make sure that it's safe for humans."

Dr. Silver also is co-principal investigator for a feline personalized RNA nanovaccine clinical trial ongoing at the University of Florida. She notes that these cats are not used for testing or being given cancer. Instead, these cats are pets that spontaneously get oral cancer. Dr. Silver's veterinary partner, Carlos Souza, DVM, MS, has treated four cats similarly to how a human would be treated, and they are seeing positive results.

"Our cats are doing really well," says Dr. Silver. "Generally, head and neck cancers in cats cause significant mortality; the overall life span is about one to four months, even with treatment. Our longest-term survivor is the first cat we ever treated, which was a year and a half ago. The cats haven't had any serious adverse reactions, and we have found a safe and tolerable dose."

The goal is to move into human clinical trials, and by the end of 2022 there will have been three patients with brain cancer treated in Florida. Once initial safety is established, the plan is to file an amendment with the FDA for head and neck cancer patient use. Then, the hope is to initiate a first-of-its-kind human clinical trial



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**Tim Chan, MD, PhD**  
*Chair, Lerner Research Institute Center for Immunotherapy and Precision Immuno-Oncology*

at Cleveland Clinic for patients with head and neck cancer who are resistant to current therapies.

“Dr. Silver’s work has tremendous potential to break new ground in the fight against head and neck cancer,” says Dr. Byrne. “We aim for the first human clinical trial within two years.”

Dr. Silver also recently published an article that explored the effect of *Fusobacterium* in oral cavity squamous cell carcinoma (SCC). The study included 37 patients with diagnosed tongue SCC who underwent surgery with curative intent between January 2010 and June 2015. Sixty-nine (33 tumor and 36 normal samples) were included in the final analysis. “One of the first steps we took was determining the taxonomic profile of the bacteria in both the normal and the tumor samples,” explains Dr. Silver. “We observed that *Fusobacterium* was significantly enriched in tongue cancer and that *Rothia* and *Streptococcus* were enriched in adjacent normal tissues. Our study demonstrates that *Fusobacterium* is associated with increased PD-L1 expression in oral cancer tumor samples and *Fusobacterium* can increase PD-L1 expression on oral cancer cells in vitro.”

#### Coming to Cleveland Clinic

Beyond the research opportunities, Dr. Silver highlights a few things that attracted her to Cleveland Clinic. The opportunity to help her clinical colleagues bridge the gap between what physicians do on a daily basis with what happens in the most advanced setting of science

in the Center for Immunotherapy and Precision Immuno-Oncology, and headed by Tim Chan, MD, PhD, was a big draw. Additionally, having Dr. Byrne as a mentor and leader was an important piece of Dr. Silver’s attraction to Cleveland Clinic.

“We are very excited to have recruited Dr. Silver to Cleveland Clinic,” says Dr. Chan. “She is already making a significant impact on our head and neck research programs. We are particularly excited about the new cancer vaccines she is working on, which have the potential to improve patient outcomes.”

With Dr. Silver’s background as an educator, and the opportunity to train the next generation of scientists, especially surgeon-scientists, was also alluring. “I know there are a lot of people who have an interest in science, but when they end up going down the surgical career pathway, it’s a different type of training,” says Dr. Silver. “I think a lot of people who originally wanted to do science, they maybe get discouraged because the surgical lifestyle is very challenging. So I think that by being who I am, doing both, I hopefully can help others see this path and learn more about it, and encourage other physician-scientists and surgeon-scientists to at least explore this type of career.”

Dr. Silver continues, “Not everyone can speak both the physician language and the intense basic science language, and I think that we, as physician-scientists, are an important piece of the puzzle for how to really change the future of medicine. You really need both of

these perspectives to communicate. I think the surgeon-scientist is really in a unique place to be able to help drive the questions and apply the latest science to the clinical side and can serve as a bridge for true bench-to-bedside translational research.”



# THE ROLE OF THE SLP IN GENDER-AFFIRMING VOICE MODIFICATION FOR TRANSGENDER WOMEN

*A Cleveland Clinic speech-language pathologist describes the techniques she uses with her patients and how new research reinforces that patients should be driving care decisions*



**Michelle Adessa, MS, BM, CCC-SLP**  
Staff, Speech-Language Pathology,  
Voice Center

For many transgender women assigned male at birth, voice can be a major source of gender dysphoria. Helping these women align the sound of their voice with their gender identity can be a big step toward gender affirmation. Although gender-affirming voice and communication training is multifaceted, treatment targets may include modifying resonance; increasing speaking fundamental frequency (f0); and working with articulation, prosodic variation/word stress, volume, speech rate and phrasing. It may also include nonverbal communication.

Treatment for gender-affirming voice modification (speech therapy) is provided by speech-language pathologists (SLPs) and in some cases may also involve surgical intervention or a combination of training/therapy and surgery. To better support this patient population, providers at Cleveland Clinic looked at the characteristics and outcomes of patients receiving gender-affirming care for voice feminization as well as which method may be more effective for feminizing a voice. Their research was published in *Transgender Health*.<sup>1</sup>

## Methods and outcomes

The retrospective cohort study focused on 16 transgender women treated over a 30-month period in the Head & Neck Institute's Voice Center. Patients were separated into groups depending on what treatment modality they had pursued (behavioral voice training vs. surgery vs. behavioral voice training + surgery).

"We picked two outcome measures," says Michelle Adessa, MS, BM, CCC-SLP, a speech-language pathologist in the Voice Center and one of the study's authors. "The first was a quality of life measure called the Trans Woman Voice Questionnaire (TWWQ). We also used speaking (f0) specifically to look at voice feminization, recognizing that these two measures don't necessarily encompass all of a patient's experience. We found that whether somebody had surgery or whether somebody had therapy, statistically speaking, outcomes were actually pretty comparable in terms of the quality of life measures and changes in speaking fundamental frequency."



Adessa uses a free app to help patients track their pitch so they can practice and receive feedback on their own time.

Adessa notes that from a statistical standpoint, there wasn't much difference in the patient groups. The researchers found that increased speaking f0 and decreased TWVQ scores (lower scores indicating more positive quality of life) were evident and statistically significant within the behavioral voice training cohort and the behavioral voice training plus surgery cohort. Both of the treatment groups appeared similar with respect to average changes, although pre- and post-data were not available for surgery-only patients, due to limited numbers.

However, the greatest change in speaking f0 was directly correlated with an increased number of voice training sessions. "I think what this study adds to the conversation is just a reminder that the patient should be driving these care decisions — there isn't much of a difference in the two outcome measures we looked at in terms of the results," says Adessa. "So for a patient who doesn't want to have surgery, they can achieve their goals therapeutically and — based on these outcome measures — the results are on par with patients who have surgery. I think this reinforces the importance of patient preference in terms of their care pathway since there's not one right way to get a feminine voice."

#### **Gender-affirming voice modification training (speech therapy)**

For patients interested in gender-affirming speech therapy at Cleveland Clinic, Adessa says she usually meets with them once every other week. This schedule allows her patients to practice some of the techniques they go over on their own. But for patients who express a desire to be seen more frequently because of more debilitating dysphoria with their voice, Adessa says she may see patients on a weekly basis. One of the trends that has made this easier is the increase in virtual visits.

"I see many of my patients virtually," says Adessa. "Usually I will meet people in person at first, and then we may switch to virtual if that is what the patient prefers. I have so many patients who have completed their courses of treatment virtually. That makes me happy because they can get care that integrates well with their everyday lives. They don't have to take time off of work if they have limited time off. If they're in school, they can meet via a virtual visit on their computer. So I think it really does increase access, which has been a huge barrier for this population."

#### **Reference**

1. Adessa M, Weston Z, Ruthberg J, Bryson PC. Gender-Affirming Voice Modification for Transgender Women: Characteristics and Outcomes. *Transgender Health*. 31 May 2022 (epub ahead of print): <http://doi.org/10.1089/trgh.2021.0071>



Many of the techniques that Adessa uses focus on the articulatory component of voice training. Some patients may be really focused on pitch, but there are several other characteristics of the voice that they work on with her. So even if her patients have had Wendler glottoplasty (endoscopic suturing of the vocal cords anteriorly to shorten their functional length) and their pitch is already elevated, the goal with Adessa would be to feminize every aspect of voice resonance and articulation, word choice, speech rate, and inflection. Many of the techniques that she works on with her patients are for forward resonance — shifting the sound from a throat-focused sound to a more orally focused sound.

"Sometimes we move through different sounds, and they may not know if they like something because they want me to tell them," says Adessa. "But they are really the ones driving the ship — I work for them. I don't get to put the stamp of femininity on them. We don't want to change the sounds of English, but we want to find a way to make them sound lighter. So I, along with our second speech pathologist, Emma Laurash, MS, CCC-SLP, who joined our practice in 2021, really work on how the lips and the tongue and the teeth touch the areas of the mouth and how that coordinates with the airflow," she says, adding, "It's been amazing to work with my transgender patients, and it's really just an honor to assist them on their journey. They're my most dedicated patient group, coming to every session, and really the dedication is very obvious — this work is so important to them."

# BEST PRACTICES IDENTIFIED FOR OBTAINING HUMAN INNER EAR TISSUE

*Pioneering surgical tissue recovery work could lead to new and more targeted approaches for treating many forms of hearing loss and vestibular disorders*



**Ksenia A. Aaron, MD**  
Staff, Otology;  
Director, Diversity,  
Equity and Inclusion

According to the World Health Organization, more than 1.5 billion people worldwide live with hearing loss, a number that could rise to over 2.5 billion by 2030 with the aging population. Current treatment for sensorineural hearing loss is limited to amplification devices or cochlear implants and, in rare cases, auditory brainstem implants. But as of now, there is no treatment for loss of inner ear hair cells, the most common underlying pathology associated with both auditory and vestibular disorders. Rehabilitation therapy is the only modality for addressing those.

More research on the inner ear tissue is needed to identify different therapeutic options, but until now, this has been mostly undertaken in animal models, human fetuses and occasionally adult humans with pathology, such as inner ear or lateral skull base tumors, with access to healthy adult inner ear tissue being scarce. But work from otologist/neurotologist Ksenia A. Aaron, MD, at Cleveland Clinic is changing the paradigm. She is one of only a few in the world procuring adult human inner ear tissue from deceased organ donors.

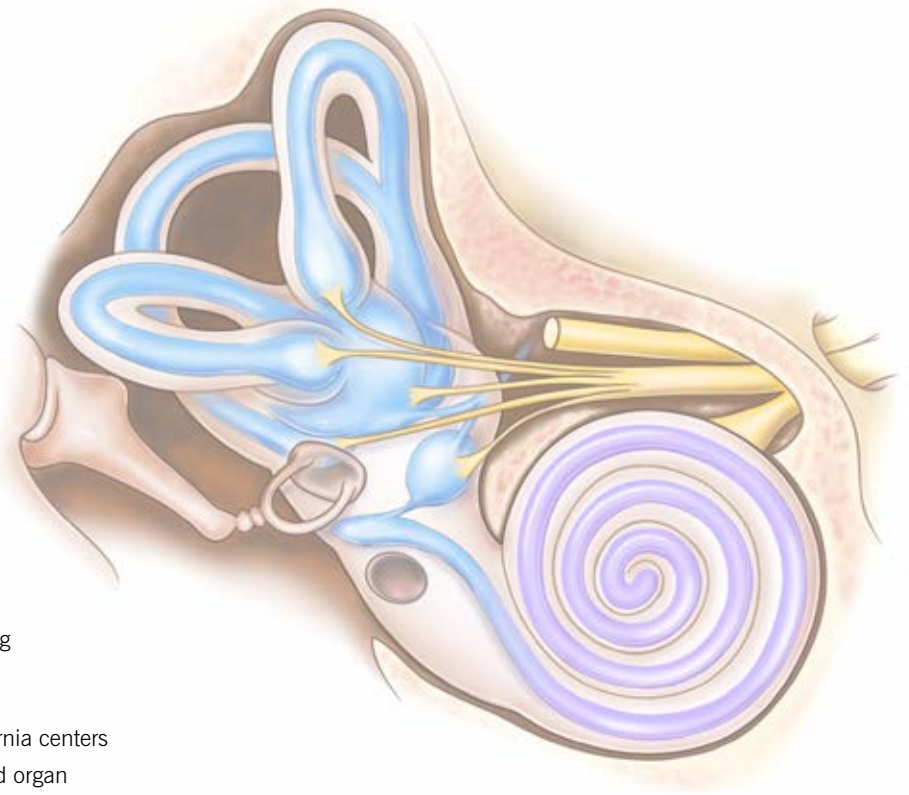
Dr. Aaron was an integral part of the team that developed the surgical technique while at Stanford University. She brought the skill to the Cleveland Clinic when she joined

in August 2021. Since then, she has worked with the nonprofit organ procurement agency LifeBanc Ohio to establish a process for procuring the tissue. When an organ donor becomes available, dedicated teams approach the family and obtain consent for the inner ear tissue donation along with donations of other tissues and organs for transplantation. For now, the inner ear tissue is only used for research.

“By looking at the human inner ear, we hope to answer a multitude of questions. One is the transcriptional profile of adult human inner ear tissue on a single-cell level: What are the single-cell transcriptomics that we can see as compared to other animal models like the mouse or nonhuman primates? To date, healthy human adult inner ear tissue, outside of a utricle, has not been processed on a single-cell level,” Dr. Aaron explains.

The translational clinical aim, she says, is “if we know the underlying landscape, then we can do targeted pharmacotherapy to treat those disease processes of hearing loss or vestibular insult instead of just giving these patients steroids in hopes that it might mitigate the hearing or balance deficit.”





**Best surgical practices described for obtaining donor inner ear tissue**

In two papers published in the April 2022 issue of *Otology & Neurotology*, Dr. Aaron and her colleagues at Stanford University highlight the surgical approach to obtaining inner ear tissue and the best practices for selecting appropriate deceased donors.

The first study, which was conducted across multiple California centers with the involvement of a regional nonprofit federally funded organ procurement organization, was aimed at developing a surgical approach for rapid and minimally traumatic recovery of fresh inner ear tissue.<sup>1</sup>

The paper details the steps designed to maximize speed and minimize damage, developed by modifying prior procedures: a retroauricular approach for a transcanal exposure, approach to the vestibule with extraction of the vestibular end organs, and approach to the cochlea with extraction of the cochlear duct. Optional modifications are also described for obtaining the petrous bone, including the eighth cranial nerve attached to the organs.

**Optimal donors have cardiac death, not brain death**

The second paper describes how the team used immunofluorescence to examine vestibular tissues from 33 ears recovered from 19 organ donors.<sup>2</sup> Five had cardiac death, and the rest had brain death. Their analysis showed that the subset of donors with cardiac death, rather than brain death, were optimal for obtaining intact sensory epithelia with hair cells and supporting cells. This was in part because they had shorter resuscitation time, less severe brain insults, and a shorter time between pronouncement of death and tissue procurement than did those with brain death.

We developed a protocol of [procuring the inner ear tissue] in a timely manner where we were able to procure one side of inner ear tissue in under 20 minutes and both sides in under 40 minutes.

“The two types of donors have different availability of viable tissue. With cardiac death, it’s more likely that there was enough oxygen and no tissue damage,” she explains.

**Efficiency is imperative**

“The initial challenge was whether we could procure the inner ear quickly. We developed a protocol of doing it in a timely manner where we were able to procure one side of inner ear tissue in under 20 minutes and both sides in under 40 minutes. How you handle the tissues is also very important, since mishandling can affect the quality and the ultimate results, based on the question being asked,” Dr. Aaron says.

But the need to work quickly means that logistics can be tricky. “I’ll get called at random hours of the day and am notified that there is an available organ donor, and the procurement will happen at this time. You have to be ready and available, and sometimes it is not possible as I have clinic or I’m in the operating room.”

But Dr. Aaron says she’ll be prepared to jump in as often as possible once the program is fully up and running at Cleveland Clinic. “I’ve applied for several grants. Now it’s just a matter of procuring the tissue and processing it in the lab once the funding is available.”

**References**

1. Vaisbuch Y, Hosseini DK, Wagner A, et al. Surgical Approach for Rapid and Minimally Traumatic Recovery of Human Inner Ear Tissues From Deceased Organ Donors. *Otol Neurotol*. 2022;43(4):e519-e525.
2. Aaron KA, Hosseini DK, Vaisbuch Y, et al. Selection Criteria Optimal for Recovery of Inner Ear Tissues From Deceased Organ Donors. *Otol Neurotol*. 2022;43(4):e507-e514.

# DOES EXTENDED USE OF PROPHYLACTIC ANTIBIOTICS IMPROVE NASAL HEALING AFTER ENDOSCOPIC TRANSSPHEOIDAL SURGERY?

*Randomized controlled trial finds no quality-of-life benefit after standard pituitary tumor surgery*



**Varun Kshetry, MD**  
Staff, Section of Skull  
Base Surgery

A week of prophylactic oral antibiotics taken after standard endoscopic transsphenoidal surgery for a pituitary tumor does not improve sinonasal quality of life compared with the standard 24 hours of postoperative oral antibiotics. So concludes a randomized controlled trial from researchers at Cleveland Clinic and two other U.S. centers that was recognized as the 2022 Top Paper of the Year by the Congress of Neurological Surgeons (CNS) at the 2022 CNS annual meeting this week. The study was published in the CNS journal *Neurosurgery*.<sup>1</sup>

“This clinical trial, conducted at three major U.S. pituitary centers, indicates no advantage for extended use of postoperative oral antibiotics after standard transsphenoidal surgery,” says skull base neurosurgeon and study co-author Varun Kshetry, MD, who served as site principal investigator at Cleveland Clinic. “Our findings provide support for improving antibiotic stewardship without harming outcomes.”

## Common practice lacks evidence

Surgeons commonly prescribe postoperative oral antibiotics beyond routine perioperative antibiotic use following transsphenoidal surgery for pituitary lesions, although there are no evidence-based guidelines recommending this practice. Postoperative oral antibiotics are believed to promote healing and help prevent the common adverse effects resulting from nasal mucosa disruption, e.g., bacterial sinusitis, foul smell, nasal obstruction, drainage, crusting, septal perforation and polyps. However, evidence is lacking that this is the case.

In an effort to promote responsible antibiotic stewardship, the study authors sought to determine whether extended prophylactic oral antibiotics improve outcomes for standard transsphenoidal surgery for pituitary tumors.

## A study of 113 patients at three centers

The study was designed as a prospective, randomized, double-blind, placebo-controlled investigation conducted at Cleveland Clinic in Cleveland, Barrow Neurological Institute in Phoenix, and Thomas Jefferson University in Philadelphia. All participants received a single intraoperative and a single postoperative dose of an intravenous antibiotic. They were then randomized to

receive either oral antibiotics or placebo for seven days after surgery. Antibiotics used were cefdinir or (for patients intolerant to cefdinir) trimethoprim-sulfamethoxazole. Patients were encouraged to use a saline nasal spray four times daily for the first postoperative week, then a sinus irrigation rinse twice daily through day 30.

Out of 461 patients screened between June 2016 and September 2019, 131 were randomized and 113 were analyzed (55 in placebo arm, 58 in antibiotic arm). All patients had a pituitary adenoma (i.e., nonfunctioning adenoma, acromegaly or prolactinoma) and planned binostriil endoscopic transsphenoidal surgery. Exclusion criteria included Cushing’s disease, chronic or active sinusitis, prior sinus surgery and a planned nasoseptal flap procedure.

The two arms had well-matched baseline demographic characteristics, length of hospital stay and readmission rates.

## Results: No significant between-group differences

Sinonasal quality of life was the study’s primary endpoint, in view of its importance to patients and clinicians. It was assessed using the following patient-reported tools:

- Anterior Skull Base Nasal Inventory-12 (ASK Nasal-12) score at two weeks
- Sinonasal Outcome Test-22 (SNOT-22) at intervals up to 12 weeks after surgery

Most patients in both arms had worse nasal scores at week 1, as expected shortly after surgery, but were back to preoperative baseline scores by week 8. The arms did not have clinically meaningful or statistically significant differences in scores using either assessment tool at any measured time point ( $P \geq 0.24$ ).

Other outcome measures were as follows:

- Postoperative nasal endoscopy findings of purulence, nasal crusting, polyps and synechiae (as assessed by the Lund-Kennedy endoscopic appearance system). Nasal cavity endoscopy scores were not significantly different between the groups at 1 to 2 weeks ( $P = 0.25$ ) or 3 to 4 weeks postoperatively ( $P = 0.08$ ).



**Raj Sindwani, MD**  
Vice Chair and Section  
Head of Rhinology





- Development of acute bacterial sinusitis, which was assessed according to patient report of symptoms and physical examination. Eleven patients were diagnosed with sinusitis — four in the antibiotic arm and seven in the placebo arm ( $P = 0.35$ ). Seven patients had sinus cultures, with the following causal organisms found: pan-susceptible *Staphylococcus aureus* ( $n = 5$ ), *Haemophilus influenzae* ( $n = 1$ ) and coagulase-negative *Staphylococcus epidermidis* ( $n = 1$ ). None of the isolates was multidrug-resistant.

No adverse effects associated with antibiotic use were noted.

#### **Conclusive findings, but don't apply too broadly**

Based on this trial, the authors conclude that postoperative oral antibiotic use beyond 24 hours following standard transsphenoidal pituitary surgery does not result in superior outcomes compared with no extended oral antibiotic use. They note that this finding is consistent with other clinical studies assessing antibiotic use for functional endoscopic sinus surgery for chronic rhinosinusitis.

“We have now changed our practice and no longer put patients on extended postoperative antibiotics,” notes co-author Raj Sindwani, MD,

Vice Chair and Section Head of Rhinology in Cleveland Clinic's Head & Neck Institute. “This protects patients against side effects frequently associated with the use of antibiotics, such as gastrointestinal symptoms, as well as reducing costs.”

The authors caution, however, that their findings are not necessarily applicable to patients with Cushing's disease, expanded endonasal skull base approaches or a planned nasoseptal flap procedure, as these groups were excluded from the trial because of greater likelihood of poorer healing. “Similarly designed investigations should be performed to evaluate the role of antibiotics in extensive endonasal surgery, such as expanded approaches and the use of a nasoseptal flap,” Dr. Sindwani says.

In addition to Drs. Kshetry and Sindwani, other Cleveland Clinic co-authors of the study were neurosurgeon Pablo Recinos, MD, Section Head of Skull Base Surgery, and Troy Woodard, MD, a rhinologist and skull base surgeon in the Head & Neck Institute.

#### **Reference**

1. Little AS, Kshetry VR, Rosen MR, et al. Postoperative Oral Antibiotics and Sinonasal Outcomes Following Endoscopic Transsphenoidal Surgery for Pituitary Tumors Study: A Multicenter, Prospective, Randomized, Double-Blinded, Placebo-Controlled Study. *J Neurosurg*. 2021 Oct 13;89(5):769-776.

# WHY ARE PEDIATRIC THYROID CANCER CASES ON THE RISE?

*continued from p. 1*

These clinical collaborations are formalized in Cleveland Clinic's Thyroid HOPE Center, which includes a team of pediatric otolaryngologists, endocrinologists and hematologist oncologists, who take a multidisciplinary approach to pediatric thyroid cancer cases. The team also works with adult head and neck surgeons on some cases.

"There aren't a lot of centers that have multidisciplinary clinics like the one we've established," she notes.

## Research is ongoing

Until more is known about the cause of the recent uptick in cases, there's not much information physicians can share with their patients about how to minimize risks for pediatric thyroid cancer, Dr. Georgopoulos says. However, current research aims to better understand the causes and risk factors of the disease.

"That's the million-dollar question," Dr. Georgopoulos says. "While there are a host of known genetic factors that predispose patients to developing thyroid cancer, there is little we can do to prevent it."

## Head & Neck Institute Innovations

### WINTER 2022/2023

Head & Neck Institute Innovations 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.

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