

Could human stem cells be used to build up a trachea graft for transplantation? Turn to page 1 for more.

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Welcome New Researchers



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Isidore Friesner Research Scholar
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Message from the Chair

“Unless you try to do something beyond what you have already mastered, you will never grow.”

- Ralph Waldo Emerson

Challenging traditional treatment modalities, and ourselves, to boldly take the next step defined 2022 for the Department of Otolaryngology–Head and Neck Surgery at the Icahn School of Medicine at Mount Sinai. This commitment manifested in various forms: hiring pioneers in otolaryngology research, reenergizing a decades-old rhinoplasty technique, elevating clinical trials to the next level, employing virtual reality for vestibular balance, and devising programs to equip aspiring researchers with personalized paths to success. Last year also marked two inaugural events—the Airway Research Symposium and the Skull Base Surgery Course at Mount Sinai, a comprehensive review of open and endoscopic approaches, which drew nearly 500 trainees from multiple disciplines around the world.

On the heels of completing the first donor tracheal transplant worldwide in 2021, Mount Sinai recognized the urgent needs of individuals suffering from tracheal injuries and patients with airway disorders post COVID-19 infection. This inspired the launch of the Institute for Airway Sciences in 2021 and the hiring of Ya-Wen Chen, PhD, who pioneered lung organoid research using human stem cells to better understand molecular mechanisms of lung and trachea regeneration. Within one year, she was appointed to Isidore Friesner Research Scholar. We also recruited Alison May, PhD, Assistant Professor of Cell, Developmental and Regenerative Biology, and Otolaryngology, to continue her work with stem cell-mediated regeneration of multiple epithelial tissues in an effort to define causative mechanisms of upper airway disease, including chronic rhinosinusitis.

The Division of Laryngology received a grant to map the vocal folds and trachea, which Benjamin Laitman, MD, is spearheading. Additionally, the Sinai Robotic Surgery clinical trial advanced to a new phase, continuing the studies of deescalated radiotherapy post-transoral robotic surgery for oropharyngeal cancers, particularly those associated with HPV.

The Division of Rhinology, which has exponentially expanded clinical trials over the past few years, onboarded a study with Waypoint with the goal of shrinking nasal polyps using tezepelumab. The Skull Base Surgery Center team made significant strides with the 7-Tesla MRI for improved visualization of the relationship between acoustic neuromas and the cochlear and seventh cranial nerves in the internal auditory canal, in an effort to improve surgical outcomes.

Our Facial Plastic and Reconstructive Surgery team breathed new life into dorsal preservation rhinoplasty, a more than 100-year-old technique with enhanced nasal framework and structural integrity, and the Hearing and Balance Center at the New York Eye and Ear Infirmary of Mount Sinai did remarkable work utilizing virtual reality for vertigo diagnosis and treatment. All of this extraordinary work—in addition to our Research Scholars Program for four specialized trainees—is highlighted in this edition of the Otolaryngology Specialty Report.

Thank you for perusing the otolaryngologic developments at Icahn Mount Sinai in this year's report.

Wishing you a productive and invigorating 2023.



Eric M. Genden, MD, FACS
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Researchers Advance Lung and Tracheal Transplantation Using Human Pluripotent Stem Cells

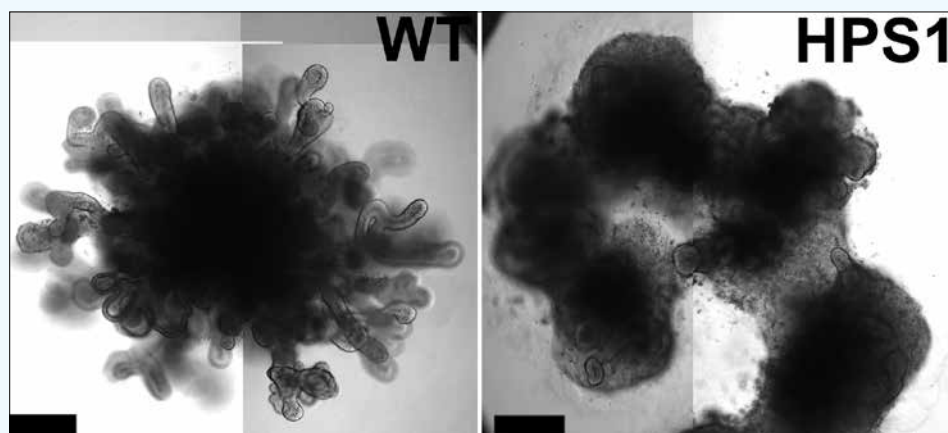
Ya-Wen Chen, PhD, is investigating the potential for using cells from a patient's own body to develop tissue for lung and trachea transplantations.

Transplantations involving the trachea or the lungs are challenging in terms of suitability and patient outcomes. However, research conducted by Ya-Wen Chen, PhD, could one day eliminate such complications.

“Our idea is that if we can take cells from a patient, reprogram them back to stem cells, and then use those cells to grow airway stem cells or lung stem cells to transplant them back to the patient, that might reduce the immune rejection or lower the requirement for immune suppression,” says Dr. Chen, Assistant Professor of Otolaryngology, and Cell, Developmental, and Regenerative Biology, at the Icahn School of Medicine at Mount Sinai. “There is also the potential that we could use these cells to repair the trachea or the lungs, eliminating the need for transplantation altogether.”

Dr. Chen could achieve those aims, and a better understanding of the molecular drivers of respiratory diseases, through her work with human pluripotent stem

cells (hPSCs). These cells, which include embryonic stem cells and induced pluripotent stem cells (cells from an adult that have been reprogrammed back to stem cells), have the potential to develop into any cell or tissue in the body. Using directed differentiation, a bioengineering methodology in which



1. Bright-field images showing day 50 lung organoids without (WT) and with (HPS1), a mutation that would cause fibrosis.

hPSCs are given specific developmental instructions through growth factors or small molecules, Dr. Chen is harnessing that potential by attempting to mimic the necessary in vivo signaling to grow everything from basal cells to lung organoids.

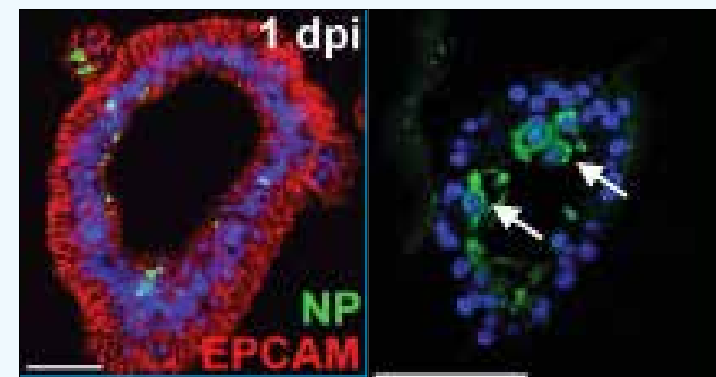
“We developed the first lung organoid model using hPSCs, which we can grow in a dish and transplant into a mouse, that

has part of the lung structure performing part of the lung function,” says Dr. Chen. “We are using the organoid model to do modeling of diseases such as COVID-19, influenza, and fibrosis, so that we can understand how these diseases were initiated, and conduct drug screening to help us identify preventive or therapeutic

agents. We are also using the model to explore lung development, mechanisms of lung injury repair, and regenerative medicine approaches.”

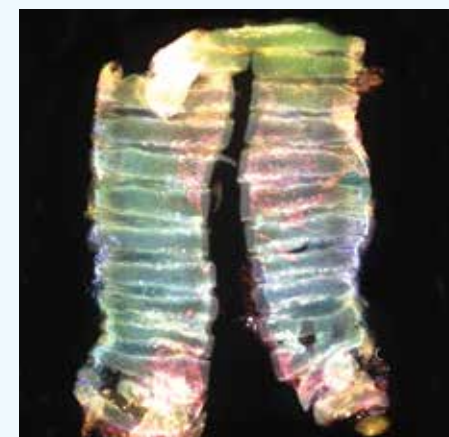
Could Stem Cells Eliminate the Need for Transplantations Entirely?

The potential of Dr. Chen's work is exemplified by a partnership with the Institute of Airway Sciences at Mount



2. Confocal images of lung organoids infected with SARS-CoV-2 (NP) or RSV (arrows: infected cells in the lumen).

Sinai that is assessing the efficacy of using hPSCs to generate and expand basal cells to reconstruct the trachea's epithelial cells, and thus the trachea. This method could result in patients receiving a trachea transplant with epithelial cells that have been bioengineered from their own cells rather than relying on a transplant from a donor. This could mitigate the risk of immune rejection, or lower the requirement for administration of immunosuppressants. But it is also



Immunostaining of human-specific markers (red) showing transplanted hPSC-basal cells engrafted and expanded on the luminal surface of a de-epithelial mouse trachea.

possible that direct delivery of these stem cells to the airway could eliminate the requirement for transplantation among certain patients.

“We will be exploring this first in an

animal model,” Dr. Chen says. “We will remove the epithelial cells in the trachea, apply the cells to the site, and then monitor them to see whether they attach, survive, proliferate, and,

most important, differentiate into the right cell types at the right location to perform the correct functions. We know that they differentiate when we culture them in the lab environment, but we do not know how they will behave in animals or in humans.”

Gaining Better Insight into SARS-CoV-2

Dr. Chen's research is also advancing our understanding of the mechanisms by which SARS-CoV-2 enters the lungs. Using her lung organoid model, she is assessing the potential of using antibodies to block the virus from using transmembrane serine protease 2 (TMPRSS2), a protease used by the virus to enter cells. She will first test whether TMPRSS2 antibodies are toxic to the lung cells she has grown and, once she has established a safe dosage, assess their ability to block the virus. She will then investigate whether that blockage occurs through reduction of TMPRSS2 on the surface of the lung cell or by blocking the function of TMPRSS2. The outcomes of these inquiries will be validated with lung organoids and animal models.

“Our findings could impact the lives of millions of people who have been

affected by COVID-19 and other respiratory viruses, such as influenza A, that use TMPRSS2 to enter cells,” says Dr. Chen. “Furthermore, given that most of the coronavirus family relies on TMPRSS2 to infect lungs, our findings could also provide a means of defense against the next coronavirus outbreak.”

The Potential to Generate a Human Lung Using hPSCs

These undertakings would be impactful, but Dr. Chen has ambitions that go beyond what is currently achievable in the realm of hPSCs. She hopes to recapitulate a human lung ex vivo using a patient's hPSCs for possible transplantation, which would help resolve the suitability, shortage, and quality issues related to organ donation. But she also envisions regenerating the lung in vivo, which could eliminate the need for transplantation.

“Again, we know we can generate lung organoids in the lab, transplant those into a mouse, mimic human lung development, and then generate mini lungs,” Dr. Chen says. “To do that in a human patient, we need to increase our stem cell population and scale up our techniques. Even so, we do not know if signals from the injured site will stimulate the stem cells to regrow the lung, but my goal is to see if that is possible.”



Ya-Wen Chen, PhD

Assistant Professor of Otolaryngology, and Cell, Developmental, and Regenerative Biology

Mapping the Human Vocal Folds in High Resolution

A new high-resolution imaging technology, combined with access to fresh healthy tissue, is giving Benjamin Laitman, MD, PhD, an effective way to analyze the vocal folds.

Investigating the mechanisms that drive phenomena such as scarring and wound regeneration in the vocal folds is of interest to Benjamin Laitman, MD, PhD. But accessing healthy tissue for analysis can often be difficult.

“It is a very delicate structure, so you don’t want to biopsy it and risk damage,” says Dr. Laitman, an otolaryngology resident at The Mount Sinai Hospital. “You typically do not remove any of it unless it is already diseased.”

Obtaining healthy vocal folds from cadavers, he adds, is also challenging because there are often delays in harvesting, and healthy tissue typically is not taken at autopsy. However, a new technology, combined with access to fresh healthy tissue, is helping Dr. Laitman gain insight into the vocal folds without having to rely on traditional methods.

“We are using tissue that would otherwise go to waste to conduct high-level genetic sequencing to understand which cells are present in the vocal folds,” he says.

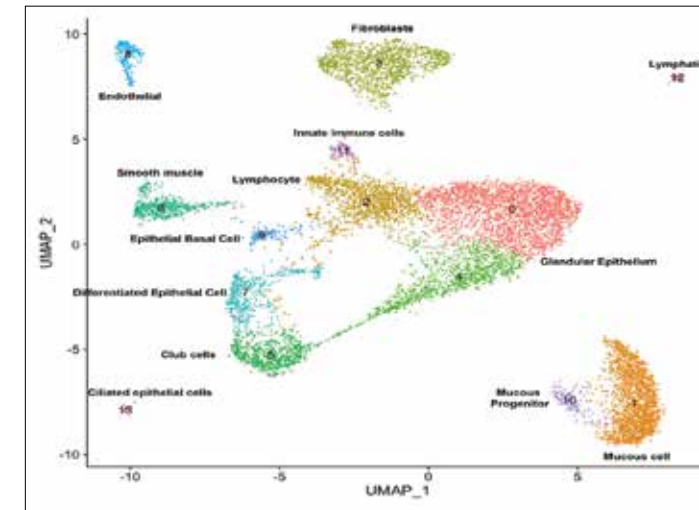
Using Cell-by-Cell Sequencing Technology to Map the Vocal Folds in High Resolution

Using tissue resected from patients who have undergone pitch elevation surgery—tissue that would otherwise be discarded—Dr. Laitman is collaborating with the Genomics Core Facility at the Icahn School of Medicine at Mount Sinai to create a high-resolution map of the human vocal folds. He is achieving this goal with 10x Genomics’ single-cell RNA-seq (scRNA-seq) technology, which enables researchers to analyze transcriptomes—the full range of messenger RNA molecules expressed by an organism—on a cell-by-cell basis using microfluidic partitioning to capture individual cells.

“This technology gives us a much higher-resolution look at what is going on genetically as opposed to a bulk RNA sequencing approach,” he says. “Through cell-by-cell sequencing, we are developing a baseline map of the vocal folds that we can use as

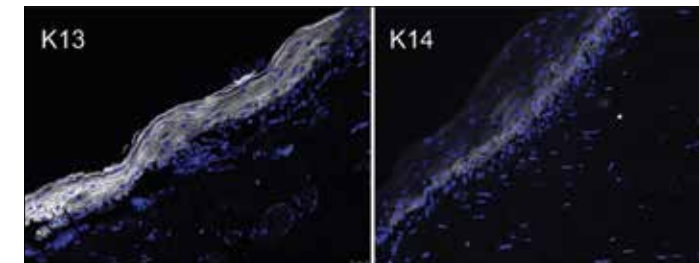
a basis for comparison when looking at diseased tissue, be that benign disease, cancer, or scarring.”

The effort, which began earlier this year with a grant from the American Laryngological Association, is one of the first-ever attempts to map the vocal folds using this technology. It is an undertaking that has gained urgency in the wake of the pandemic, which resulted in many patients being intubated for management of COVID-19-related acute respiratory failure, putting them at risk for developing life-altering complications.



Laryngeal epithelial microarchitecture. Immunofluorescent image of human laryngeal epithelium Keratin 13 (K13) is expressed in more differentiated layers, while K14 is expressed in basal layers.

“Intubation can impact everything from how the patient’s voice sounds to their ability to breathe and swallow,” Dr. Laitman says. “Even before the pandemic, there was a big push to understand the dynamics of wound healing and scar formation in the airways to address those risks. Although we have some



Single-cell RNA sequencing of human vocal folds. Uniform manifold approximation and projection (UMAP) plot of human vocal fold clusters.

understanding of the cells regulating that process, we need a more comprehensive picture.”

Advances in technology, such as single-cell sequencing, are delivering those insights, enabling Dr. Laitman to explore the types of cells that are present in the vocal folds to a degree

that was not previously possible. More importantly, it creates opportunities for potentially co-opting those cells in ways that benefit the patient.

“For example, if we identify certain types of fibroblasts that are usually involved in scarring, we could possibly block those while potentially stimulating others that promote wound generation,” he says.

Mapping Disease-State Samples

But there is considerable work to do before such benefits can be realized. Dr. Laitman and the team have sequenced a set of five samples, effectively mapping out one region of the vocal folds. Any findings as to the drivers of wound regeneration or scarring in this region may not be applicable to the other regions of the vocal folds. Thus, the goal is to complete the atlas of the vocal folds so that Dr. Laitman can begin what he characterizes as the most interesting and important step in his research: mapping disease-state samples.

“The sequencing technology has advanced to the point where we can use previously banked, paraffin-embedded samples and not only achieve high-resolution single-cell data, but also spatial sequencing data where we can put the genes in context to map them out,” Dr. Laitman says. “We can then compare the healthy- and disease-state maps, zero in on the cells at play in the disease state, and see both the differences in the cells and the genetic pathways that are activated. That would facilitate the identification and development of therapeutic agents to address these differences.”

For now, Dr. Laitman has the foundation for what he believes will be a hypothesis-generating resource that will be invaluable for Mount Sinai and other academic medical centers. “I am really excited about what could emerge from the work we are doing,” he says.



Benjamin Laitman, MD, PhD

Otolaryngology Resident,
Icahn School of Medicine
at Mount Sinai

Plastic Surgeon Revives 100-Year-Old Rhinoplasty Technique With Cutting-edge Results



Facial plastic surgeons at Mount Sinai are embracing dorsal preservation rhinoplasty, which is resulting in improved outcomes for patients.

Traditionally, facial plastic surgeons at Mount Sinai have followed the standard approach to rhinoplasty—shave down the dorsum, fracture the nasal bones from below, and reset them. It is a procedure that worked well for more than 50 years despite its associated risks and complications. But in 2021, a different technique caught the attention of the Facial Plastic and Reconstructive Surgery team at the Mount Sinai Health System—one that was first described more than 100 years ago and is now being regarded as a cutting-edge alternative to the standard approach: dorsal preservation rhinoplasty.

“In the Baltics and in Turkey, it has been popular for quite a while, but for whatever reason, dorsal preservation rhinoplasty fell out of favor with most surgeons,” says Joshua Rosenberg, MD, Chief of the Division of Facial Plastic and Reconstructive Surgery at the Icahn

Mount of Medicine at Sinai. “However, it has made a comeback over the past several years because it represents a potential improvement over the standard way of doing rhinoplasty.”

Why the Technique Is Beneficial

From Dr. Rosenberg’s perspective, there are several factors that account for the potential improvements. For one, the technique limits disruption of key nasal valve regions, ostensibly reducing the risk of post-procedure breathing issues associated with traditional rhinoplasty. The technique also preserves patients’ natural dorsal aesthetic lines while still allowing

surgeons to precisely contour the nasal bridge. There is also a significant difference in the postoperative structural stability after dorsal preservation rhinoplasty compared with traditional

hump reduction techniques.

“The bones are in a solid position when patients leave the operating room,”

Dr. Rosenberg says. “The likelihood that they will disrupt the work we have done by accidentally sleeping on their face or wearing glasses in the first few weeks after

surgery appears significantly smaller.”



How Dorsal Preservation Rhinoplasty Is Performed

Although there are several different methods for performing dorsal preservation rhinoplasty, Dr. Rosenberg prefers the subdorsal strip technique.



A nose marked for dorsal preservation rhinoplasty.

After exposing the framework of the nose back to the bony septum, Dr. Rosenberg makes an incision approximately three to five millimeters below the dorsum followed by several lateral and transverse osteotomies around the nasal bones. This enables the entire framework of the nose to drop down and the height of the dorsum to be reset. Once that is done, Dr. Rosenberg addresses any irregularities in the cartilage or bone through rasping and then completes the procedure by refining the nasal tip.

Typically, Dr. Rosenberg favors a closed approach for the procedure, creating the osteotomies inside the nose. However, in cases involving a broken nose, a significantly deviated septum, or significant asymmetries in the nasal tip, Dr. Rosenberg adopts an open approach, starting with a small incision at the base of the nose before exposing the framework and creating the osteotomies.

“The learning curve for this procedure is not particularly significant, which is advantageous,” Dr. Rosenberg says.

“Once you are comfortable with it, it can be done relatively quickly—usually within two to two-and-a-half hours—because it eliminates the time and effort needed to refine irregularities in the bridge of the nose. It also is effective in straightening crooked noses, which is notoriously hard to do, because we are able to shift the bone in place by making a few asymmetric bone cuts.”

Reducing Challenges and Risks

Despite those advantages, Dr. Rosenberg says the technique does pose challenges. For example, it can be difficult to achieve the desired height reduction among patients who present with a large dorsum. But a more pressing concern is the potential risk of fracturing the skull base during the procedure, given its proximity to the bony septum, which could lead to life-altering complications for the patient, such as loss of smell.

“That is the one aspect that scares surgeons away from trying this approach,” Dr. Rosenberg says. “At Mount Sinai, we employ a number of techniques to avoid skull base damage, including the use of piezoelectric instrumentation.”

Having completed approximately 100 dorsal preservation rhinoplasties with a high rate of patient satisfaction, Dr. Rosenberg is interested in refining the technique further. His overarching goal is to create a highly reproducible rhinoplasty technique that delivers desired results with a high degree of certainty. Optimally, he envisions an approach that reduces the worldwide revision rhinoplasty rate to less than 5 percent, perhaps even less than 1 percent.

“Is it possible to simplify the procedure to the point where that goal is achievable? It is hard to say,” Dr. Rosenberg says. “However, we will continue perfecting dorsal preservation rhinoplasty to lower the risk profile and the overall revision rate for surgery to the fullest extent possible.”



Joshua Rosenberg, MD
Chief of the Division of Facial Plastic and Reconstructive Surgery at Icahn School of Medicine at Mount Sinai

Unveiling the Causes of Chronic Rhinosinusitis in the Upper Airways

Alison May, PhD, is using her expertise in developmental biology to investigate the drivers of the condition.



Inflammation and overproduction of a thick mucus in the nose and sinuses—the hallmarks of chronic rhinosinusitis (CRS)—are familiar to many physicians. However, the causes of these symptoms remain elusive.

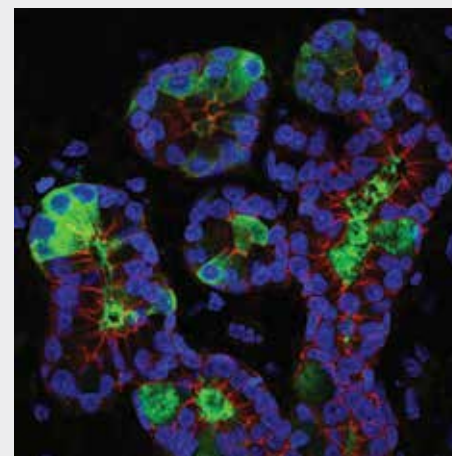
“We have a greater understanding of the mechanisms implicated in the distal lung that occur in airway diseases than we do of those associated with the upper airway, including the nose and sinus,” says Alison May, PhD, Assistant Professor of Cell, Developmental, and Regenerative Biology, and Otolaryngology, at the Icahn School of Medicine at Mount Sinai. “I have made the drivers of CRS the main focus of my lab so my team can help patients not just in the general population, but also among the cystic fibrosis population, where we see an extremely high prevalence of CRS.”

Drawing on her expertise in developmental biology, Dr. May is working to elucidate the causative mechanisms of diseases, specifically those involving changes in the structure and function of the epithelial organs. The changes that are of particular interest to her are those that occur in the submucosal airway glands, resulting in abnormal mucus production, and thus infection and chronic inflammation.

“By studying the development of these tissues, we can understand the mechanisms that give rise to different cell types, as well as their locations and functions,” she explains.

“That will provide us with insights not just into drivers of congenital upper airway alterations, but also into changes that may occur in adult sinonasal disease.”

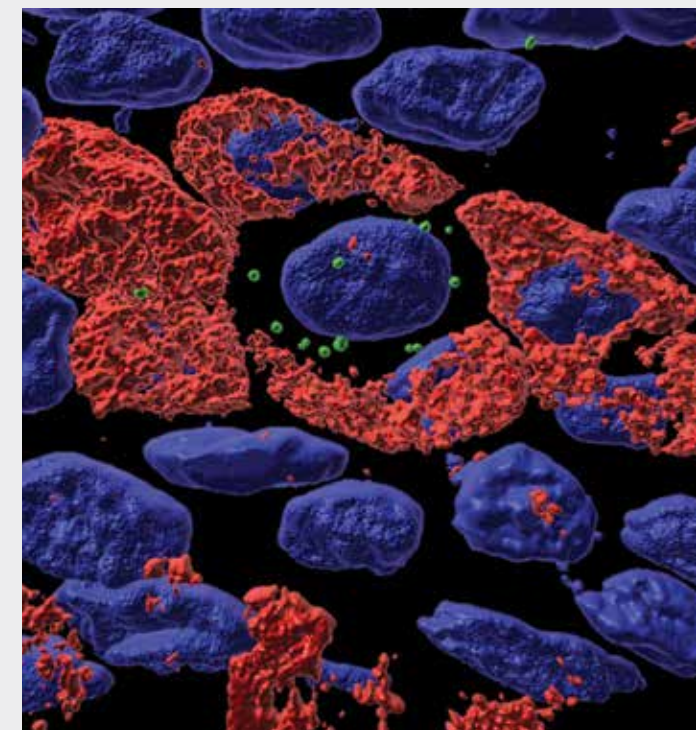
Another approach involves image analysis of biopsies and nasal brushings from adult patients who have undergone surgery to investigate if any epithelial morphological changes have occurred, along with RNA-sequencing techniques to determine if changes in cell populations and gene expression are occurring in different disease conditions.



Immunofluorescent image of cells of an airway submucosal gland of the nasal septum. Epithelial cells are outlined in red, mucus secretion shown in green, and cell nuclei shown in blue.

Examining the Results

In one study, Dr. May analyzed biopsies from adults with CRS and non-CRS controls to characterize the morphology and secretory cell identities of the nasal septum submucosal glands. She observed a significant decrease in gland density in the posterior septum of patients who presented with CRS, both with (23 percent \pm 3.09 percent) and without nasal polyps (28 percent \pm 6.15 percent) compared to control participants (53 percent \pm 1.59 percent, $p < 0.0001$). Furthermore, she observed a decrease in mucin 5B+ gland mucus among the CRS cohort as well as dilated and cystic ductal structures filled with inspissated mucus. The results of this study were published March 22, 2021, in the International Forum of Allergy & Rhinology.



3D image rendering of cells of the airway epithelium. Target RNA highlighted in green, cellular mucus production shown in red, and cell nuclei shown in blue.

“Traditionally, it was thought that too many glands were associated with CRS,” Dr. May explains. “But now we know that, at least in this region of the nose, a loss in glandular volume and a notable change in specific glandular cell types occur compared to healthy nasal tissue. This indicates that it might not be a hypersecretory result in that region so much as a hyposecretory one, and we plan to explore these findings further to see if there is a cell type we can target to address this phenomenon.”

Uncovering the Development of the Nasal Epithelial Cells

Dr. May is also exploring the potential of organ explant cultures—cells grown in vitro using patient tissue samples—to glean further insights on the development of the nasal epithelial cells and how they respond to the introduction of different factors. If successful, her research could accelerate the drug development process or enable precision medicine approaches to treatment. Moreover, it could open the door for bioengineered therapeutic approaches.

“If we can define the factors that are required for creating and directing the different cell populations of the glands, we can then use this knowledge in the application of stem cell-based therapies for organ regeneration and repair,” Dr. May says.

Although techniques have been established for growing epithelial cells, Dr. May says there is still considerable work to be done to fully understand the biology behind the development of the submucosal glands and changes that occur in their cell types. Gradually, she is advancing that knowledge through further studies. She is collaborating with the Department of Otolaryngology–Head and Neck Surgery to garner more insights on different types of CRS among the general and cystic fibrosis populations through biopsies, computational biology, and both organ and air-liquid interface cultures. She is also interested in studying the factors that account for the significant prevalence—approximately 40 percent—of CRS among World Trade Center first responders. Dr. May believes these efforts will help establish new, more effective therapeutic modalities for patients with CRS.

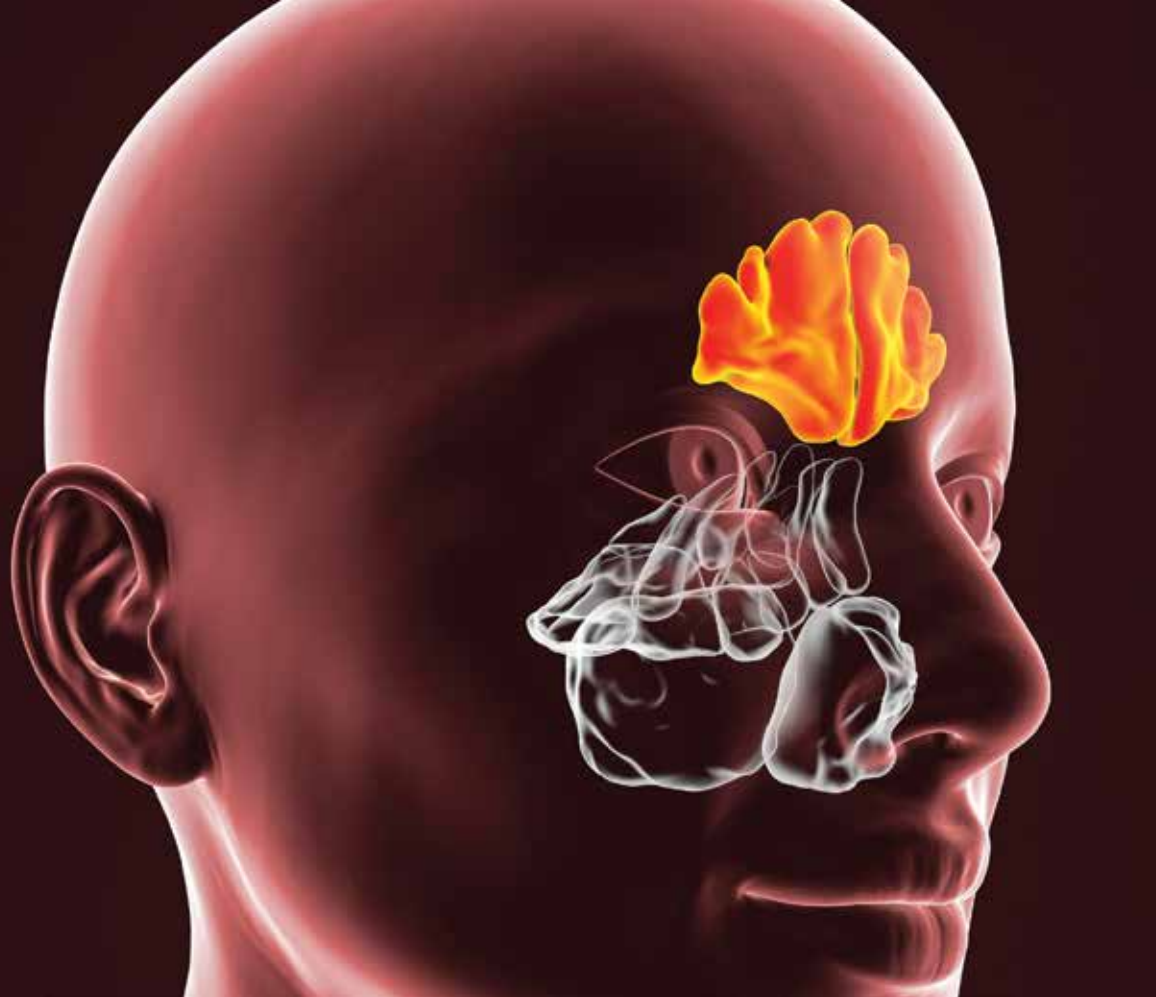
“It is very important we make great efforts to explore these questions,” Dr. May says. “Not only to advance our understanding of airway biology, but to make critical steps in improving treatment and therapeutics for people living with CRS.”



Alison May, PhD

Assistant Professor of Cell, Developmental, and Regenerative Biology, and Otolaryngology
Icahn School of Medicine at Mount Sinai

New Therapy Could Help Patients with Chronic Rhinosinusitis With Nasal Polyps



Anthony Del Signore, MD, is investigating the use of tezepelumab — typically used to treat severe asthma and allergies — to shrink polyps caused by chronic rhinosinusitis.

Could injection therapy involving a biologic therapeutic agent reduce or eliminate the need for surgery or steroids among patients who present with chronic rhinosinusitis with nasal polyps (CRSwNPs)? That is a question that Anthony Del Signore, MD, hopes to answer.

Dr. Del Signore is a sub-principal investigator at Mount Sinai Beth Israel for a multicenter, randomized, double-blind, placebo-controlled, parallel-group phase 3 study that is evaluating the efficacy and safety of administering tezepelumab among adults with severe CRSwNPs. The therapeutic agent, which

is indicated for add-on maintenance for severe asthma, acts on thymic stromal lymphopoietin (TSLP), a protein belonging to the cytokine family that plays a key role in allergic inflammation. Although CRSwNPs are associated with eosinophilic T helper type 2 inflammation, and there are biologics that block this pathway, Dr. Del Signore explains that TSLP is another chemical messenger that is found in elevated levels in patients with nasal polyps. Therefore, it acts as an alternative pathway that can be blocked and lead to polyp reduction.

“Tezepelumab is thought to disrupt some of the fibrosis that often occurs in nasal polyps,” says Dr. Del Signore, Assistant Professor of Otolaryngology at the Icahn School of Medicine at Mount Sinai, and Director of Rhinology and Endoscopic Skull Base Surgery at Mount Sinai Beth Israel. “It delivers an antibody

that binds to the TSLP receptor, which then prevents some of the downstream signaling that drives a lot of the polyp formation.”

If tezepelumab blocks the signal, he explains, it could potentially reduce the size of the polyps, which could provide an effective treatment among patients with polyps and reduce the need for surgery. “It could also be beneficial for patients who have undergone multiple courses of surgery due to recurring polyps,” says Dr. Del Signore.

What Will the Study Entail?

Approximately 400 subjects will be enrolled in the study globally and randomized into two cohorts of 200 participants. The treatment cohort will be administered tezepelumab every four weeks via subcutaneous injection using pre-filled syringe over a 52-week

treatment period. The control cohort will be administered a placebo. Eligibility criteria include a diagnosis of CRSwNPs for at least 12 months prior to first visit, with a severity consistent with need for surgery as defined by total Nasal Polyp Score ≥ 5 (≥ 2 for each nostril at screening), nasal congestion score ≥ 2 at first visit, and ongoing documented NP symptoms over more than eight weeks prior to screening such as rhinorrhea and/or loss of smell. Other criteria include a ≥ 30 score in the Sino-nasal Outcome Test (SNOT-22), which consists of 22 questions that gauge the severity of the patients’ CRSwNPs symptoms.

How Will Outcomes Be Measured?

The primary outcome measures are nasal polyp scores, based on a sum of the right and left nostril scores as evaluated by nasal endoscopy, and participant-reported changes in nasal congestion. The secondary outcomes include loss of smell, SNOT-22 scores, time to surgery among both cohorts, sinus opacification, and changes in lung function. The study also includes a post-treatment follow-up of 12 to 24 weeks for participants who complete the 52-week treatment period.

“In addition to their injections, we will be conducting ongoing overall assessments of adverse events related to medication and quality of life,” Dr. Del Signore says. “We will also look at their sense of smell and their lung function, and we will perform blood tests to assess factors, such as changes in immunoglobulin levels. In some patients who consent

to it, we will conduct a nasal swab to determine what strains of bacteria are present and potentially obtain a small biopsy of tissues to investigate the effects of the therapeutic agent on polyps.”

If the study is successful, tezepelumab could be approved as a treatment for nasal polyps by the U.S. Food and Drug Administration.

“By isolating and elucidating this treatment, we have the potential to offer patients a safe-and-effective alternative to the traditional standards of repeated doses of oral steroids and extensive sinus surgery and the risks associated with them,” Dr. Del Signore says. “I believe that would have significant advantages for our patients and truly disrupt our current treatment paradigm for nasal polyps.”



Anthony Del Signore, MD

Assistant Professor
Otolaryngology,
and Director of
Rhinology and
Endoscopic Skull
Base Surgery at
Mount Sinai
Beth Israel

Reducing the Need for Adjuvant Chemoradiotherapy Among Patients With HPVOPSCC



Raymond Chai, MD, FACS, is leading an innovative trial into how a test measuring circulating HPV tumor DNA in the blood can be used to de-intensify toxic therapies while maintaining high cure rates.

Human papillomavirus-associated oropharyngeal squamous cell carcinoma (HPVOPSCC) accounts for approximately 85 percent of all oropharyngeal cancers nationwide. As the incidence continues to rise, Mount Sinai researcher Raymond Chai, MD, FACS, is concerned about the impacts of the standard of care among patients who present with this disease.

“We are applying the same therapeutic modality as we do for environmentally related oropharyngeal squamous cell carcinoma from smoking and alcohol consumption, which is lots of chemotherapy and lots of radiation,” says Dr. Chai, Associate Professor, Otolaryngology (Head and Neck Surgical Oncology), Institute for Thyroid, Head, and Neck Cancer at the Icahn School of Medicine at Mount Sinai.

Despite excellent cure rates, these therapies often result in negative side effects, including dry mouth, hearing loss, neuropathy, muscle fibrosis, and difficulty in swallowing. Rarer but potentially life-altering late complications can include cranial nerve deficits and necrosis of the jaw. Many of these patients, who are young and healthy, must live with the lifelong side effects of this toxic treatment. It is a problem Dr. Chai aims to solve through an innovative study: the Sinai Robotic Surgery Trial in HPV-Positive Oropharyngeal Squamous Cell Carcinoma (SIRS 2.0). The study is assessing the potential of achieving cancer control and survival rates that are comparable to the standard of care through transoral robotic surgery (TORS) alone or in combination with greatly reduced doses of radiation and chemotherapy among patients with HPVOPSCC.

“We are investigating how we can greatly de-intensify therapy to improve our patients’ long-term quality of life without impacting the outcomes we are seeing,” Dr. Chai says.

Testing for Circulating HPV Tumor DNA in the Blood

The trial builds on the findings of the earlier SIRS 1.0 study, a non-randomized phase 2 study in which patients with early stage HPVOPSCC who underwent TORS followed by reduced-dose radiation demonstrated highly favorable survival rates with excellent function. What makes this trial unique is that Dr. Chai is using NavDx®, a test that measures circulating HPV tumor DNA in the blood. The test offers a biomarker to predict treatment response and likelihood of cancer recurrence among patients with HPVOPSCC, and thus potentially enable either complete avoidance or significant de-escalation of adjuvant chemoradiotherapy. Data from existing studies suggest that HPV circulating tumor DNA (ctDNA) during the surveillance period following treatment is a highly accurate test for the detection of microscopic residual disease.



Raymond Chai, MD, FACS, performing TORS.

“Traditionally, the decision as to whether to administer radiation or chemotherapy following surgery was based on predicted risk level for recurrence from the pathology results, but there is no strong data informing that decision,” Dr. Chai says. “However, many of these patients receiving these treatments likely would do equally well if they did not undergo radiation or chemo. We just do not know who they are. This is one of the first studies in the world to use HPV ctDNA, which detects microscopic levels of residual disease in the blood, to identify those patients. Based on the results we see, this test has the potential to be an effective new paradigm for treatment.”

How the Trial Will Be Performed

The trial will recruit 200 individuals who have been diagnosed with HPVOPSCC, have a positive preoperative HPV ctDNA test, and who have not received any prior chemotherapy, radiation therapy, or surgery for their cancer. All participants must demonstrate overexpression of p16 (a known surrogate for HPV-mediated disease) and positive HPV DNA expression

on a polymerase chain reaction test. Patients with a history of more than 20 years of smoking, or who are active smokers, are excluded from the trial.

Mount Sinai researchers will be looking at recurrence rates within the first two years of surgery among two groups of patients with early stage HPVOPSCC and undetectable HPV ctDNA: those with early stage disease who are treated with surgery alone (low-risk group) and those who are treated with surgery and a significantly de-intensified adjuvant chemoradiotherapy protocol of 46 Gy, with Gy being the unit of measurement for

the radiation dose that patients receive (high-risk group). The research team will also collect blood and tumor samples from participants to gain more insights into the biological factors that influence the growth and response of HPVOPSCC to treatment. Furthermore, patients will participate in quality-of-life surveys to gain additional insights on outcomes.

Although this trial is exploratory and further studies are warranted, Dr. Chai believes the results could be a game-changer for patients with HPVOPSCC.

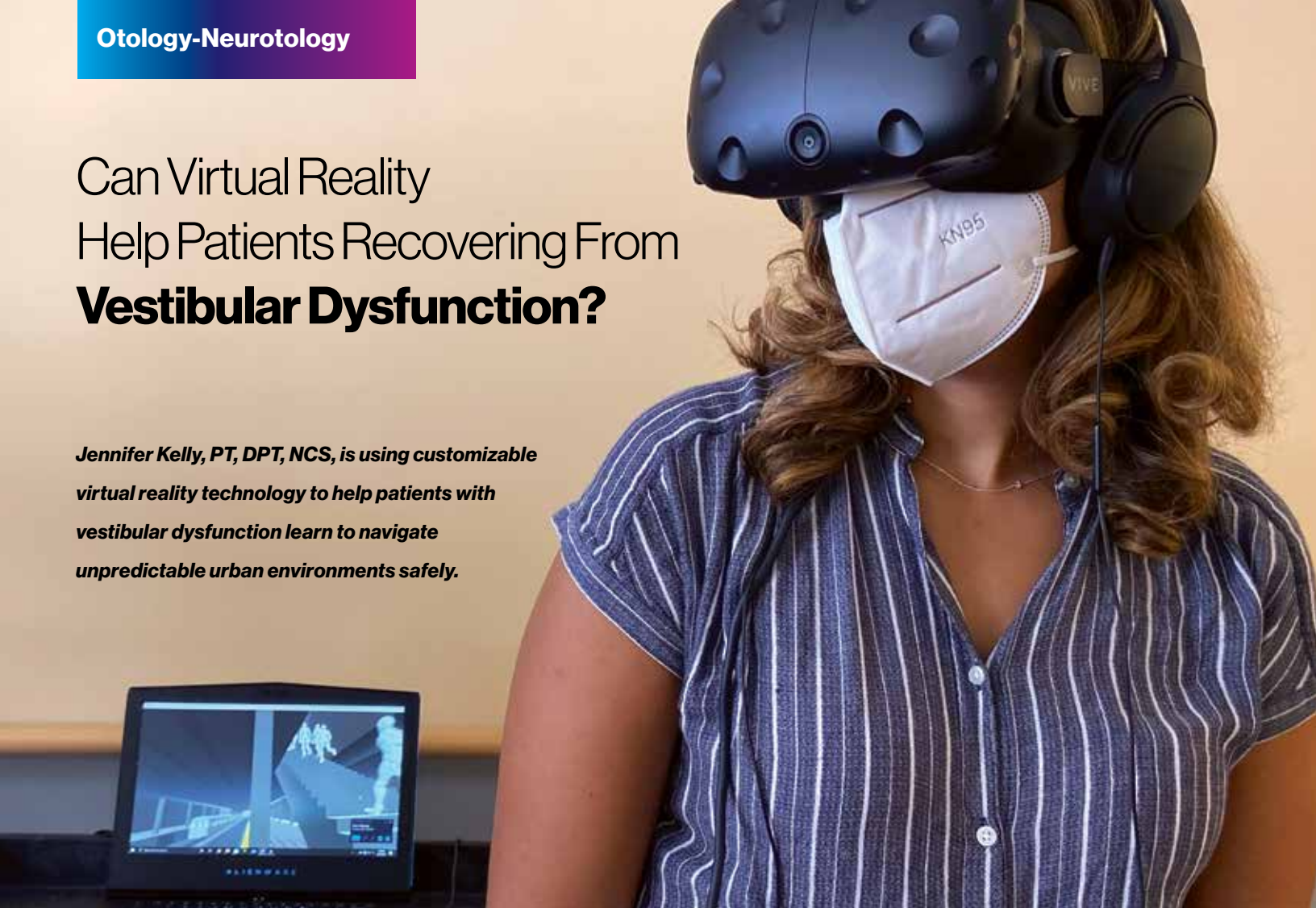
“We believe this therapeutic approach has the potential not just to decrease the toxicity necessary to maintain the outstanding cure rates we are able to achieve, but also to streamline the logistical requirements of treatment—the time off work, the constant travel—that have significant impacts on patients’ lives,” he says.



Raymond Chai, MD, FACS
Associate Professor, Otolaryngology
- Head and Neck Surgery
Director, Head and Neck Robotic Surgery
Mount Sinai Beth Israel

Can Virtual Reality Help Patients Recovering From Vestibular Dysfunction?

Jennifer Kelly, PT, DPT, NCS, is using customizable virtual reality technology to help patients with vestibular dysfunction learn to navigate unpredictable urban environments safely.



In the safe clinical environment of New York Eye and Ear Infirmary of Mount Sinai, patients undergoing standard-of-care therapy for vestibular dysfunction typically demonstrate progress in their gait and balance. But those gains are hard to maintain when navigating the streets of New York City.

“Uneven sidewalks, ramps, traffic noise, and crowds pose considerable balance and stimuli challenges for our patients,” says Jennifer Kelly, PT, DPT, NCS, Supervisor of Rehabilitation Services at the Ear Institute and Assistant Professor of Otolaryngology at the Icahn School of Medicine at Mount Sinai. “We found that they were still experiencing symptoms during these high-level activities that are hard to replicate in

the clinic. Based on that feedback, we started thinking about how we could create a bridge for patients to confidently navigate those real environments.”

Virtual Reality Can Help Patients Learn at Their Own Pace

The Vestibular Rehabilitation team at Icahn Mount Sinai, led by Dr. Kelly, partnered with the physical therapy, music science, and computer science departments at the New York University (NYU) Steinhardt School of Culture, Education, and Human Development to develop a prototype virtual reality (VR) system for therapeutic interventions among patients with vestibular dysfunctions. Using HTC VIVE VR headsets, patients are trained to navigate either an abstract or a busy environment

that has been customized to address their specific vestibular dysfunction challenges. Dr. Kelly believes that this context-based training approach to VR therapy distinguishes this prototype from other systems, which have adopted a game-based approach.

“For example, for the busy environment, they have a choice of a city street, subway, airport, or park scenario,” Dr. Kelly explains. “We consult with the patient about these options and where they would like to start. It is a graded experience, so we can adjust elements such as their direction, their speed, the number of people around them, and stimuli such as signage and sound to approximate a real-life experience.”

There are some limitations to the realism that the system delivers. For one, the VR experience is delivered in a space that has a walking span of four feet. Furthermore, the scenarios are not hyperrealistic. But these limits are believed to be beneficial for patients, resulting in a controlled environment that mitigates the stress associated with navigating real-life situations.

“Visual movement is a significant trigger for our patients’ symptoms,” Dr. Kelly says. “We do not want to overwhelm them. For that reason, the people who approach them in the simulation do not look like real people, which helps to reduce their stress levels, as does the ability to offer a graded experience so we are not starting them off with something that approximates rush-hour chaos. Essentially, we are creating an opportunity for them to engage in an environment they might normally avoid and do so without the anxiety that would make it difficult to learn from and adapt to these scenarios. That has the potential to keep them moving and socializing and thus avoid a downward physical and mental spiral.”

Advancing the Prototype With a Pilot Study

Based on these factors, Dr. Kelly and the team believe this prototype system would result in improved outcome measures versus traditional vestibular rehab—a hypothesis she explored through a pilot study. The goal was to recruit 28 patients and randomize them on a one-to-one basis into VR and standard treatment cohorts, both of which would also engage in-home exercise programs. However, the COVID-19 pandemic limited



A patient (right) is fitted with a VR headset.

recruitment to 18 participants—10 who underwent VR treatment and eight who underwent standard treatment.

Using traditional outcome measures, such as functional gait, dizziness, confidence scale, and the visual vertigo analog scale, Dr. Kelly found that both cohorts achieved similar results. “That was surprising,” she says. “Does that mean home exercise was the most important element, or is movement the most important factor regardless of approach? Those are questions we need to explore further. The main takeaway is that everyone demonstrated improvements in fall risk and subjective scores across the board.”

Regardless, some patients in the VR treatment cohort indicated that this approach was more tailored to their functional challenges than traditional forms of therapy—another reason it merits further study. Dr. Kelly and the research team at Mount Sinai and NYU are interested in conducting multisite studies to gain more insights on the efficacy of the prototype. She is also interested in assessing the impact of

VR therapy among patients who have experienced a concussion. But she has a more ambitious plan in mind for this technology.

“Although we are fortunate to be in an urban environment where people have access to vestibular dysfunction programs and experts, those resources are not as accessible for patients across the country or around the world,” Dr. Kelly says. “For that reason, we are interested in seeing whether it is possible to bring this therapeutic modality safely into patients’ homes. Our collaborators in computer science at NYU are working to realize that goal.”



Jennifer Kelly, PT, DPT, NCS

Supervisor of Rehabilitation Services at the Ear Institute and Assistant Professor of Otolaryngology



New Study Investigates 7-Tesla MRI's Ability to Visualize Acoustic Neuromas

Anatomic visualization of cranial nerves from 7-Tesla MRI in the operating room.

Mount Sinai researchers are investigating the potential of the most powerful imaging technology available to create better surgical outcomes for patients with acoustic neuromas.

A new Mount Sinai study is investigating the pathophysiological, prognostic, and surgical potential of 7-Tesla magnetic resonance imaging (MRI)—the most powerful imaging technology available—among patients who present with acoustic neuromas.

“The ability to visualize the relationship of the tumor to the cochlear nerve and to the seventh cranial nerve in the internal auditory canal is very important for us,” says George Wanna, MD, Chair of Otolaryngology at New York Eye and Ear Infirmary of Mount Sinai and Mount Sinai Beth Israel, and Executive Vice Chair of Otolaryngology at the Mount Sinai Health System. The study is recruiting 20 participants with acoustic neuromas who have not previously undergone surgery, and who do not have a metal cranial implant. The research team will assess the technology’s ability to visualize factors such as anatomy, vascularity, location of the cranial nerves, the secondary audio pathway, and the tumor itself.

“It will enable us to preserve hearing and achieve better facial outcomes among patients who present with these tumors in collaboration with neurosurgery,” explains Dr. Wanna, who is also Professor of Otolaryngology, and Neurosurgery, at the

Icahn School of Medicine at Mount Sinai. “It will also give us a better understanding of the relationship between the tumor and the structure of the ear, which will enable us to tailor the surgery to achieve the best possible outcome for the patient.”

The first time Raj Shrivastava, MD, used the 7-Tesla MRI for anatomic visualization of cranial nerves among patients with pituitary adenomas, he was impressed. In fact, the degree of detail he observed exceeded his expectations. “It was remarkable,” says Dr. Shrivastava, Professor of Neurosurgery, and Otolaryngology, at Icahn Mount Sinai, and Vice Chair for Clinical Affairs for the Department of Neurosurgery at the Mount Sinai Health System.

“We were able to see the nerves running through the tumor, the blood vessels, even distal projection connectivity with such clarity that we can anatomically map those connections in a way that was not possible before. We also observed anatomic changes to the cortex resulting from the tumor, which was unexpected but fascinating.”



7-Tesla MRI.

How the 7-Tesla MRI Could Lead to Better Patient Outcomes

If successful, the study could establish the 7-Tesla MRI as a more effective tool than facial nerve stimulators in minimizing the risk of treatment-related complications, such as facial nerve paralysis, loss of hearing, and tumor bleeding among patients who present with acoustic neuromas. But Dr. Wanna is already thinking about other otolaryngological applications of the technology, such as investigating potential anatomical factors associated with hearing loss or Meniere’s disease, that would be beneficial for patients.

“Right now, we are only able to definitively diagnose Meniere’s disease postmortem,” Dr. Wanna says. “If the higher resolution of this technology is able to deliver new insights on the disease etiology, we could potentially diagnose it immediately or even identify new therapeutic targets.”

The study also holds the potential to advance understanding of the downstream impacts of acoustic neuromas on the cochlear nerve, and thus help set patient expectations for both the length and degree of postoperative recovery. In a study of the technology involving lesions of the skull base, a research team led by Priti Balchandani, PhD, investigated imaging metrics that displayed or indicated damage to cranial structures due to the presence of the lesion—something that had not been thoroughly explored previously.

“In addition to providing a better visualization of the main anatomy often involved in surgical decision-making, the 7-Tesla MRI technology also enhanced our understanding of the pathophysiology of the disease and its effects on both the brain and brain function, and that enabled us to link those effects to prognosis,” says Dr. Balchandani, Professor of Diagnostic, Molecular, and Interventional Radiology, Neuroscience, and Psychiatry; Director of the Advanced Neuroimaging Research Program; and Associate Director of the BioMedical Engineering and Imaging Institute, all at Icahn Mount Sinai.

The study has resulted in several publications, including a November 21, 2019 paper, published in the *Journal of Neurological Surgery Part B: Skull Base*, reporting the overall utility of the 7-Tesla MRI for surgical resection of pituitary adenomas. “Based on those findings, we believe the acoustic

neuromas study will demonstrate that 7-Tesla MRI is invaluable in both the treatment and prognosis of these lesions,” Dr. Balchandani says.

Looking Beyond Acoustic Neuromas

Although the acoustic neuromas study is in its early stages, Mount Sinai researchers are preparing a one-year National Institutes of Health-funded research project to explore the potential of 7-Tesla MRI to determine disease etiology among patients who present with trigeminal neuralgia. There are also plans for a pilot study of the technology’s efficacy in guiding radiation therapy dosage decisions among patients who have malignant lesions of the skull base. The imaging collected through these and other initiatives will form the basis for a database that could support the development of a predictive algorithm for various otolaryngological conditions.

“We have to ask the right questions to build the algorithm, but we need more data from the 7-Tesla MRI to make that possible,” Dr. Wanna says. “I expect that in the next five years, we may be able to build something really meaningful.”



George Wanna, MD
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Raj Shrivastava, MD
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Priti Balchandani, PhD
Professor of Diagnostic, Molecular, and Interventional Radiology, Neuroscience, and Psychiatry; Director of the Advanced Neuroimaging Research Program; and Associate Director of the BioMedical Engineering and Imaging Institute



Endowed Research Fellowships for Students Interested in Otolaryngology

Dr. Kirke (center) with research fellows.

The Department of Otolaryngology–Head and Neck Surgery at the Icahn School of Medicine at Mount Sinai offers four fellowships for third- and fourth-year medical students.

As the competition to secure otolaryngology residencies becomes increasingly fierce, Diana Kirke, MD, is noticing more interest among medical students in the research fellowships offered by the Department of Otolaryngology–Head and Neck Surgery at the Icahn School of Medicine at Mount Sinai.

“Students really need to have a strong resume that sets them apart from their peers,” says Dr. Kirke, Assistant Professor of Otolaryngology at Icahn Mount Sinai and Director of the Research Fellowship program. “What sets our offering apart is that we have four endowed research fellowships, the largest residency program nationwide, and many attendings. Our fellows gain a strong, broad overview in both the clinical and research side of the field

and an opportunity to conduct their own research projects.”

What Fellowships Are Available?

The Department’s research fellowships offer third- and fourth-year medical students options for engaging in a yearlong research project with a faculty mentor that they can tailor to suit their interests. The four fellowships are:

- *The Eugen Grabscheid, MD, Research Fellowship*, which encourages medical students to consider a career in otolaryngology and/or head and neck surgery
- *The Ronald Hoffman, MD, Research Fellowship*, which encourages young scholars to pursue a career as a physician-scientist
- *The William Lawson, MD, DDS, Research Fellowship*, which encourages young scholars to pursue a career as a physician-scientist
- *The Steven Sacks, MD, and Carole Sacks Research Fellowship* in

Otolaryngology–Head and Neck Surgery, which has been instrumental in furthering the careers of medical students interested in otolaryngology

Students can also shadow clinical activities and are expected to participate in all departmental educational activities, such as head-and-neck-cancer tumor board and grand rounds.

“We average between 20 and 25 applications each year for these four fellowships,” Dr. Kirke says. “That reflects the interest among students in working alongside our academic surgeon-scientists, learning their techniques, and ultimately matching into residency in otolaryngology.”

What to Expect

Students accepted into the fellowships begin their academic year with a research boot camp, in which they participate in introductory statistics and population health courses and meet with department faculty to learn about the full

scope of research being conducted at Mount Sinai.

“The intent is not just to give them an idea as to what they will be working on, but also to inspire them to think about the research they want to conduct and how it will complement our efforts,” Dr. Kirke says. “We want them to be able to develop an idea, formulate a hypothesis, investigate that, and reach an outcome—all of which provides them with a strong foundation to pursue a career as an academic surgeon-scientist.”

Over the course of each fellowship, students will work on an average of 15 to 20 projects, including database creation, poster presentations, and publications. Although Dr. Kirke meets with the fellows periodically to assess progress and make necessary adjustments in their objectives, much of their work is self-directed to ensure they develop the confidence and competence to excel academically and professionally. At the end of the year, each fellow conducts a grand round of their fellowship experience and delivers a seven-minute presentation during the Otolaryngology Resident Research Day.

“The fellowships are very comprehensive, with more research opportunities than fellows can cover in a year,” says Dr. Kirke. “We see that as a positive in that they can continue to explore those ideas as a resident or junior attending or hand them off to the incoming cohort.”

When the Fellowship Is Complete
After offering the fellowships informally for several years, the Department formalized them in 2021. All students



who completed informal fellowships were subsequently matched into otolaryngology programs. Moreover, the two cohorts who have participated in the formalized fellowships have demonstrated impressive productivity in their research, and a third cohort has been enrolled. Based on that success, Dr. Kirke is exploring ways to evolve the fellowships, such as incorporating a master’s degree, and is looking at accepting international candidates. For now, however, the priority is to ensure that candidates are chosen not only based on academic excellence, but also on considerations such as diversity and inclusion.

“We had a very nice balance in terms of gender and race in our second cohort,” Dr. Kirke says. “We want to continue that because we believe that diversity contributes to outstanding research that has benefits for everyone.”



Diana Kirke, MD
Assistant Professor
Otolaryngology
and Director of
the Research
Fellowship
Program

Alumni Credit Mount Sinai's Otolaryngology Residency Program as Fundamental to Their Success

Karen B. Zur, MD, and Ian N. Jacobs, MD, MLA, learned valuable skills during their residencies that enabled them to become experts in their field.

When Karen B. Zur, MD, recalls her interview with the Otolaryngology Residency Program at the Icahn School of Medicine at Mount Sinai in 1998, two things come to mind: her nervousness while waiting to be interviewed, and the hot chocolate that Steven H. Sacks, MD, Assistant Clinical Professor of Otolaryngology, brought to help calm her.

"I thought, 'They are really nice here,'" says Dr. Zur, who is now Division Chief of Otolaryngology, Director of the Pediatric Voice Program, and Associate Director of the Center for Pediatric Airway Disorders at Children's Hospital of Philadelphia (CHOP).

"Mount Sinai had been my No. 1 choice because of the expertise in head and neck, and that kindness validated my decision to train there," adds Dr. Zur, who completed her residency in 2003. "I met so many great doctors and mentors who had a huge impact on me and my career." They include Mark Urken, MD, Professor of Otolaryngology; the late Peter Som, MD, Professor of Radiology, and Otolaryngology; and Peak Woo, MD, and Michael Rothschild, MD, both Clinical Professors of Otolaryngology.

Collaborating With Leading Experts

Her positive experiences echo those of her colleague Ian N. Jacobs, MD, MLA, the Medical Director of the Center for Pediatric Airway Disorders in the Division of Otolaryngology at CHOP, who completed his residency in 1991. More than the



breadth and depth of cases he worked on, it was the dedication and teaching of Mount Sinai attendings such as Dr. Urken; the late Hugh Biller, MD, Chair of Otolaryngology–Head and Neck Surgery at The Mount Sinai Hospital; and William Lawson, MD, Professor of Otolaryngology, that both inspired and equipped him with the necessary skills to advance his medical career. "I was fortunate to be able to collaborate with Ira Sanders, MD, who was pretty much 100 percent research-focused," Dr. Jacobs recalls of the former Associate Professor of Otolaryngology and Research Director of what is now the Grabscheid Voice and Swallowing Center of Mount Sinai. "It was very intricate and detailed work, which helped me build some credibility in the field. Having opportunities to be published and deliver a presentation at the American Laryngological Association were beneficial for me."

Dr. Sanders also helped shape Dr. Zur's residency experience through lingual nerve anatomy research. That experience was complemented by translational work with Dr. Urken involving sensory outcomes from free flaps of the tongue, and pediatric

research with Dr. Rothschild involving the formation of biofilm in the endotracheal tubes of newborns. "At the time, it was an emerging concept," Dr. Zur says. "I believe our paper was one of the first to look at that phenomenon."

Gaining Valuable Team and Leadership Skills

Training at Icahn Mount Sinai proved invaluable for Drs. Zur and Jacobs in progressing to leadership positions. Dr. Jacobs credits the opportunity to serve as Chief Resident of Mount Sinai's Otolaryngology Residency Program as fundamental for instilling him with the necessary confidence and knowledge. "It was the complexity of the role that was particularly invaluable," he notes. "You are responsible for running a very large system and for knowing everything about every patient. Overall, it was inspiring and many of the practices I apply to this day are based on experiences I had during residency."

For Dr. Zur, it was Mount Sinai's model of multidisciplinary care that shaped her career and her approach to medicine. She values the fact that experts such as Dr. Som and Margaret S. Brandwein-Weber, MD, Professor of Pathology, Molecular and Cell-Based Medicine, and Chair of Pathology at Mount Sinai West and Mount Sinai Beth Israel, contributed their perspectives to patient cases.

"We learned not just about the surgical aspects of each case but also the essentials for interpreting imaging and examining slides, which was really helpful for our boards," Dr. Zur says. "Not everyone has that kind of experience and exposure in terms of integrating expertise, but we really learned the benefit of working as a team."

Advice for Future Trainees

These experiences continue to inspire Drs. Zur and Jacobs in their efforts to advance the field of otolaryngology in their current roles: Dr. Zur introduced recurrent laryngeal nerve reinnervation as a treatment modality for dysphonia and aspiration among children with iatrogenic unilateral vocal fold paralysis. Dr. Jacobs and his team contributed to updated National Capital Poison Center guidelines that recommend administering honey to children who have swallowed a button battery to potentially reduce the risk of injury.

Having benefited from the Icahn Mount Sinai residency experience, Drs. Zur and Jacobs have advice for the trainees following in their footsteps. Dr. Jacobs recommends exploring unresolved research issues or questions, which could provide focus for their careers, while Dr. Zur encourages them to seize every opportunity to gain experience and to keep an open mind about their area of specialization.

"There will come a point in training when you need to think about what your next steps will be," she says. "I had no interest in pediatric otolaryngology, but that changed based on my experiences with Dr. Rothschild. Listen to your heart and your gut based on the mentorship you receive, and that will help you make the right decision for your career."



Karen B. Zur, MD
Division Chief of Otolaryngology, Director of the Pediatric Voice Program, and Associate Director of the Center for Pediatric Airway Disorders, Children's Hospital of Philadelphia



Ian N. Jacobs, MD, MLA
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- 10 Mount Sinai West**
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- 11 New York Eye and Ear Infirmary of Mount Sinai**
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How to Reach Us

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