Mount Sinai Health System

Department of Otolaryngology–Head and Neck Surgery

Outcomes and Performance 2013

Mount Sinai

Mission

The mission of the Mount Sinai Health System is to provide compassionate patient care with seamless coordination and to advance medicine through unrivaled education, research, and outreach in the many diverse communities we serve.

Vision

The Mount Sinai Health System's vision is to continue to grow and challenge convention through our pioneering spirit, scientific advancements, forward-thinking leadership, and collaborative approach to providing exceptional patient care.

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This material and more information on The Department of Otolaryngology–Head and Neck Surgery can be found at www.mountsinai.org/ent

A Message from the Dean

In 2013, the Department of Otolaryngology-Head and Neck Surgery was ranked among the top 10 by *U.S. News & World Report*. Growth in clinical programs, translational science programs, and a focus on service excellence have been instrumental in the consistent success of the department. The Department continues to make progress in academic and clinical areas. Basic science funding through the National Institutes of Health continues to be strong in the areas of oncology and laryngology. The addition of the Ear Institute at New York Eye and Ear Infirmary of Mount Sinai and Mount Sinai Beth Israel will strengthen the clinical program and unquestionably provide a great advantage for our patients.

It is my pleasure to share with you the accomplishments of this outstanding Department, one that exemplifies Mount Sinai's mission to advance biomedical research, drive clinical improvements, and accelerate medical innovation.

Dennis

Dennis S. Charney, MD
Anne and Joel Ehrenkranz Dean
Icahn School of Medicine at Mount Sinai
President for Academic Affairs
The Mount Sinai Health System

A Message from the Chair

This year, The Mount Sinai Medical Center merged with New York Eye and Ear Infirmary, Beth Israel Medical Center, and St. Luke's-Roosevelt Medical Centers to form the Mount Sinai Health System. Expansion of Department of Otolaryngology-Head and Neck Surgery to 72 full-time faculty and 341 voluntary faculty brings with it the challenge of maintaining the high standard of patient care across the Mount Sinai Health System. The Division of Clinical Outcomes and Performance Excellence (COPE) was formed to standardize outcomes reporting and identify areas of excellence and areas of deficiency. This initiative has been instrumental in establishing new programs like the Integrated Quality Improvement Program, designed to integrate quality programs across the Health System.

We are pleased to report our 2013 performance outcomes and highlight areas of excellence and new programs dedicated to improving patient care. The formation of the Mount Sinai Health System represents an opportunity to improve patient care. I hope that you will find this report informative.

Eric M. Genden, MD, MHCM, FACS
Professor and Health System Chairman
Department of Otolaryngology -
Head and Neck Surgery
The Mount Sinai Health System

Outcomes and Performance

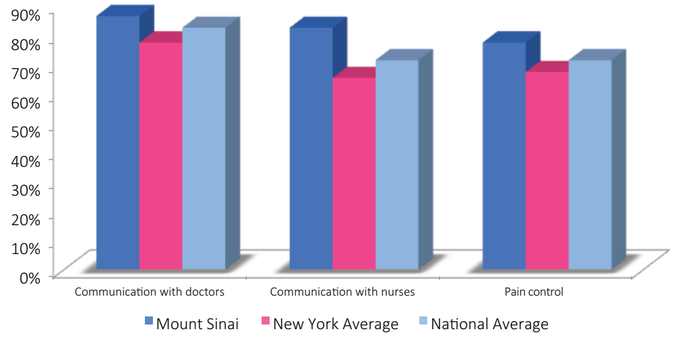
What Have We Accomplished?

Measuring our performance and patient outcomes is critical to improving patient care. The initiation of our Patient First Program, a program designed to identify patients at high risk for extended hospital stay, has been an overwhelming success. Identifying high risk patients allows our preoperative medical team to intervene and optimize the patient's medical status preoperatively. This has resulted in lower complication rates, decreased hospital length of stay, and improved patient experience. This year we have set a goal to focus on safety and outcomes in our ambulatory surgical patient population. Members of the division of outcomes and performance excellence will focus on optimizing outcomes in those patients undergoing ambulatory surgery. We look forward to reporting our progress in next year's Outcomes Report.

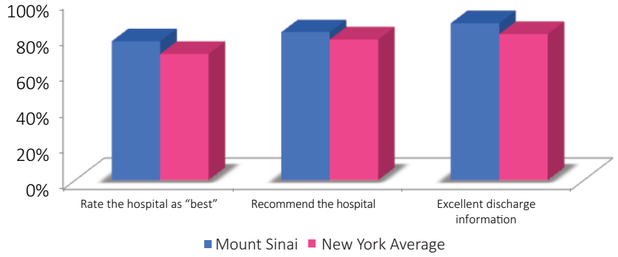
The Patient Hospital Experience

As required by The Centers for Medicare and Medicaid Services, our patients participate in the Hospital Consumer Assessment of Healthcare Provider and Systems (HCAHPS) survey. This survey is important in tracking a variety of outcomes measures, including pain management, and nurse communication with both the doctor and the patient. Mount Sinai has made great strides in achieving excellent HCAHPS scores and continues to improve on these important outcome measures.

Dr. Edward Shin, Chairman, New York Eye and Ear Infirmary of Mount Sinai.



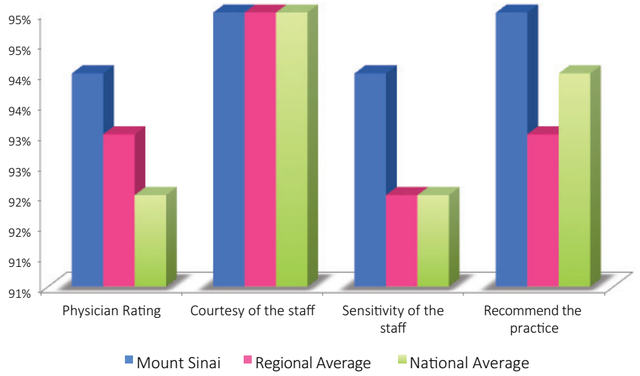
At Mount Sinai, the patient experience is central to our mission. Using Press Ganey, a national hospital survey vendor, we administer patient surveys to carefully track more than 60 patient-experience data points. Feedback from our patients helps us to determine our strengths and identify our shortcomings so we can improve programs and procedures. We find that excellent care and patient satisfaction go hand in hand.



Source: The Centers for Medicare and Medicaid Services and Hospital Consumer Assessment of Healthcare Provider and Systems Survey. Medicare.gov Hospital Compare, http://www.medicare.gov/HospitalCompare/profile

The Patient Practice Experience

Dr. Fred Lin, Director of the Sleep Surgery Center at Mount Sinai.

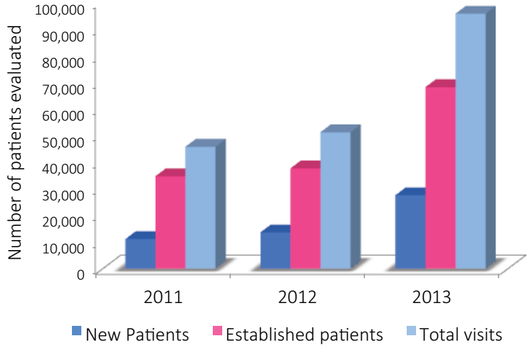


Source: Press Ganey Patient Experience Survey

Department Volume and Growth

Patient Encounters

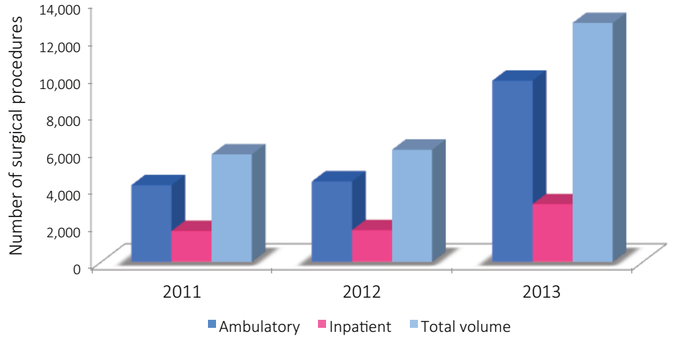
With the addition of the New York Eye and Ear Infirmary, Beth Israel Medical Center (Manhattan and Brooklyn) and St. Luke's-Roosevelt Medical Centers, patient encounters increased significantly compared to prior years. The Department of Otolaryngology currently evaluates nearly 100,000 patients a year. The volume provides an extraordinary data set to focus on the patient experience and surgical and medical outcomes.



Department Volume and Growth

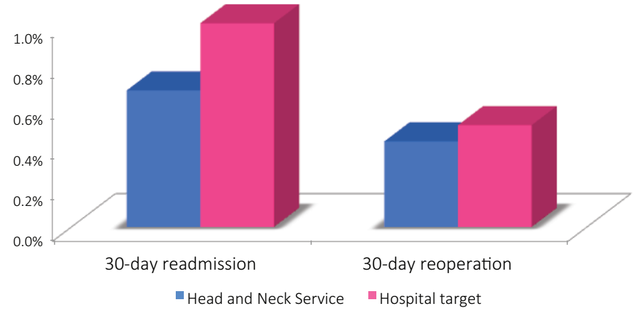
Surgical Volume

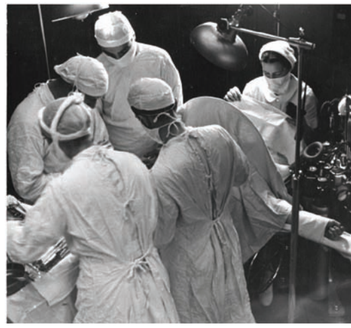
In 2013, Department staff provided care for 9696 ambulatory surgical patients and 3087 day of admission surgical patients. Surgical volume grew by 113 percent in 2013.



Rate of Readmission and Reoperation

Readmission rate is a measure of unplanned readmissions to the hospital after a previous hospital stay. It is commonly used as a measure of quality of hospital care. Unplanned readmissions may result from a variety of causes including wound infections or surgical complications. Readmissions are defined as any admission to the same hospital occurring within seven, 15, or 30 days after discharge from the initial visit. The Mount Sinai Head and Neck surgical service has maintained readmission rates below the national average.





In 1904, the new 456-bed, 10-pavilion Mount Sinai Hospital was dedicated on Fifth Avenue at 100th Street. The President of the Hospital, Isaac Wallach, described Mount Sinai as "this House of noble deeds" with a three-fold mission of "Benevolence, Science, Education." Over the years the Hospital has expanded rapidly both physically and in terms of service.

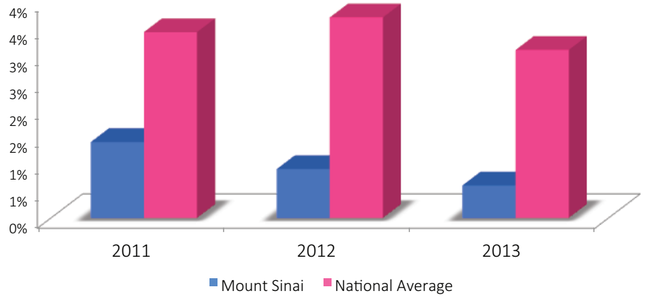
Source: University Health System Consortium

Departmental Volume and Growth

Dr. Joseph Bernstein, Director of Pediatric Otolaryngology at the Mount Sinai Health System.

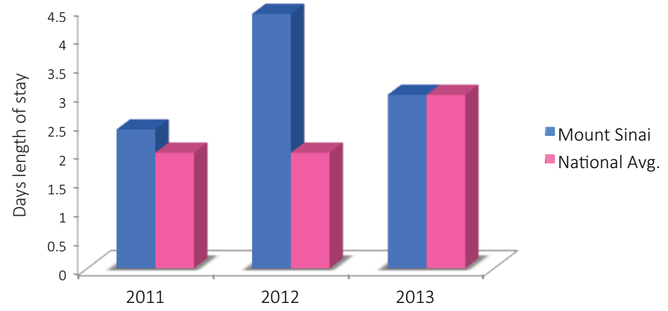
Infection Rate

Wound infections are a major source of hospital morbidity and cost. Wound infections can result in delayed healing, scarring, and an increased length of stay. At Mount Sinai, we have focused on wound infection prevention. The rate of wound infections, which is determined by the number of infections that delay healing or discharge from the hospital, are below the national average and have been decreasing as a result of programs designed to optimize patient wound care.



Length of Stay

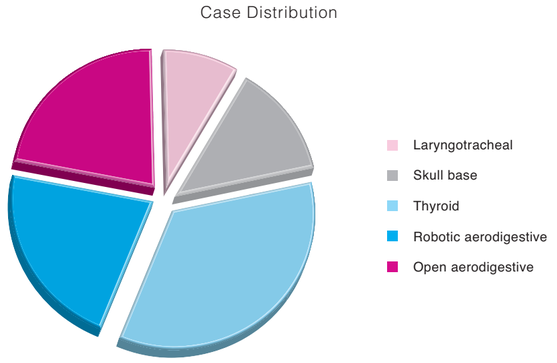
Length of stay rate is calculated as a ratio of the observed and the expected length of stay. The Head and Neck surgical service has maintained a length of stay below the national average by reducing perioperative complications and proactively managing patients with extensive comorbidities. The Patient First program has targeted high risk patients and as a result we have seen length of stay below the national average. By identifying patients with significant risk factors such as diabetes, malnutrition or cardiac disease, we can intervene early to optimize their care and reduce the rate of complications and as a result reduce the length of stay.



Source: University Health System Consortium

The Multidisciplinary Head, Neck, and Thyroid Center- A Center of Excellence

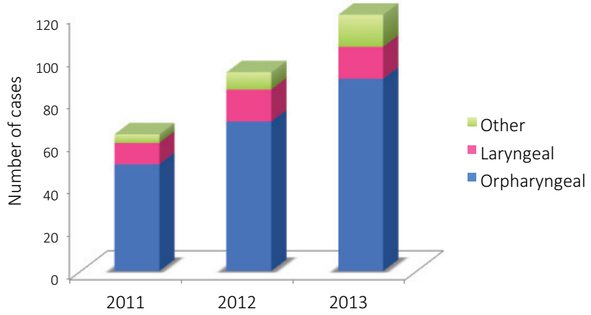
Head and Neck Oncology



The Department attracts experts from all otolaryngology disciplines to lecture at its various conferences. Here, Dr. Megwalu, Director of Otolaryngology at Mount Sinai Queens, listens intently to one of the speakers.

Robotic Surgery Case Distribution

In 2013, the case distribution demonstrated an increase in the number and proportion of robotic cases. The annual worldwide increase in Human Papillomavirus-associated oropharyngeal cancers has translated into an increase in robotic surgery. In 2013, Mount Sinai opened a unique clinical trial focused on treating high risk patients with HPV-associated disease with low dose radiotherapy in an effort to decrease the short and long term toxicity associated with external beam therapy.

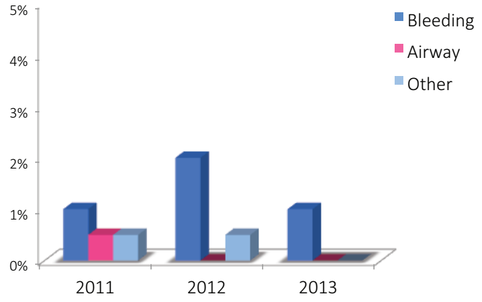


The Multidisciplinary Head, Neck, and Thyroid Center- A Center of Excellence

Dr. Stimson Schantz, Head and Neck Surgeon, New York Eye and Ear Infirmary of Mount Sinai.

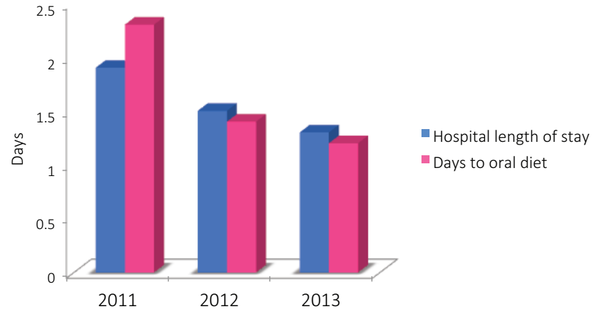
Complications Related to Robotic Surgery

As robotic surgery has become more common, the overall rate of complications has decreased. Rates of bleeding remain a concern and a potential catastrophic complication. In our experience, we find that ligation of the superior thyroid, lingual, and ascending pharyngeal arteries reduces the rate of hemorrhage. This approach has been effective and has resulted in a bleeding rates of less than 2%.



Functional Outcomes- Robotic Surgery

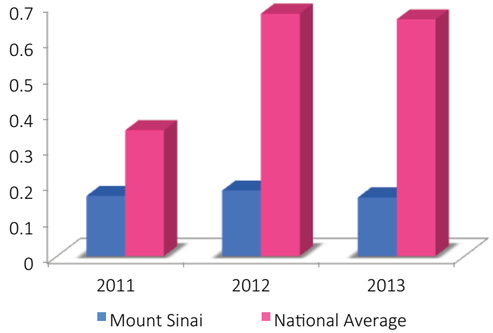
Robotic surgical approaches decrease the length of stay by allowing patients to recover more quickly. Most patients begin an oral diet between one and two days postoperatively. This allows a discharge home more quickly than traditional open surgical approaches. In our study of over 500 patients, less than 1% required gastrostomy tube nutrition.



The Multidisciplinary Head, Neck, and Thyroid Center- A Center of Excellence

Head and Neck Oncology- Mortality Rate

Mortality rate is the measure of patients that expire during hospitalization. The rates are calculated as a ratio of the number of deaths among hospital patients with the specific medical condition or procedure by the total number of patients admitted for that same medical condition or procedure. The risk adjustment method is used to account for the impact of individual risk factors such as age, severity of illness and other medical problems that can put some patients at greater risk of death than others.

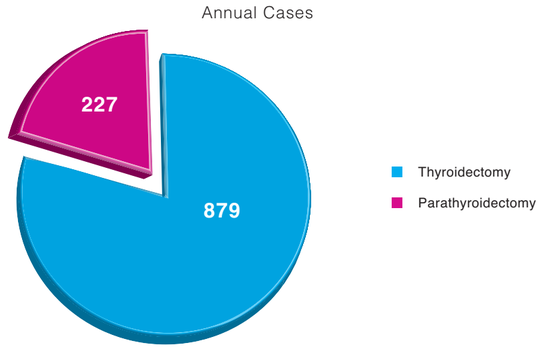


Dr. Daniel Buchbinder, Health System Chief of Oral and Maxillofacial Surgery, Mount Sinai Beth Israel.

Dr. Gregory Randolph, Associate Professor at Harvard University and Director, General and Thyroid Surgical Services at Massachusetts Eye and Ear Infirmary. The Mount Sinai Health System attracts high-profile speakers from across the country to speak at their monthly Grand Rounds. These speakers provide updates and new information in the field of Otolaryngology."

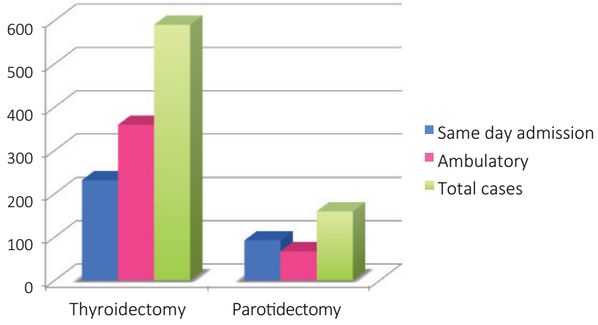
The Multidisciplinary Head, Neck, and Thyroid Center- A Center of Excellence

Head and Neck Oncology- Endocrine Surgery



Head and Neck Oncology

Midway through 2013, our service transitioned thyroidectomy and parotidectomy from day of admission (DAS) to ambulatory procedures. An early experience suggests that ambulatory thyroidectomy and parotidectomy are well tolerated. There has not been an increase in complications and patient experience scores remain high.



The Multidisciplinary Head, Neck, and Thyroid Center- A Center of Excellence

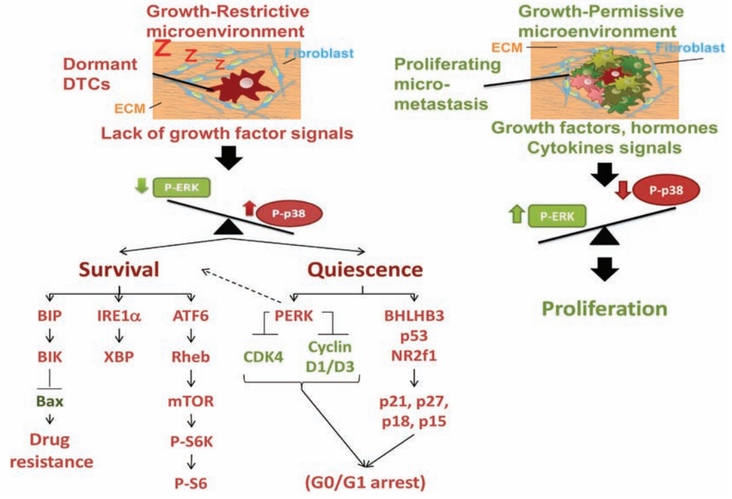
New Research

Why do cancer cells that have been dormant for years suddenly become activated leading to metastasis after years of quiescence? Dr. Julio A. Aguirre-Ghiso, PhD and his team explain.

The development of metastasis is the major cause of death in cancer patients. In certain instances, this occurs shortly after primary tumor detection and treatment, indicating these lesions were already expanding at the moment of diagnosis or initiated exponential growth shortly after. However, in many types of cancer, patients succumb to metastatic disease years — and sometimes decades — after being treated for a primary tumor.

Dr. Aquirre-Ghiso explains how therapy may cause the onset of dormancy in the surviving fraction of cells after treatment and how autophagy may be a mechanism that maintains the residual cells that are viable for prolonged periods.

Aguirre-Ghisso et al., *Adv Exp Med Biol.* 2013 ; 734: 73–89



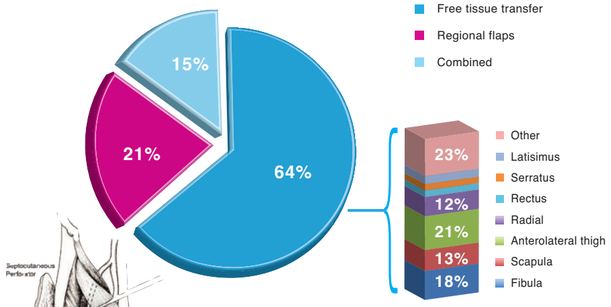
Dr. Aguirre-Ghiso explains that upon arrival at secondary sites, the crosstalk between the disseminated tumor cells and the new microenvironment will determine the fate of the tumor cells. In a permissive microenvironment (right), such as the lungs, interactions with the extracellular matrix and stromal cells of the favorable microenvironment will allow tumor cells to adapt and integrate growth-promoting signals thereby promoting tumor cell proliferation and the formation of micrometastasis. However, in restrictive microenvironments (left) such as bone marrow or liver for some cancers, either the loss of surface receptors or the interaction with non-growth-permissive ligands will result in activation of stress signaling that will induce both quiescence and survival signals, which will in turn lead to a prolonged phase of dormancy.

The Division of Facial Plastic and Reconstructive Surgery

Dr. Anthony Sclafani, Director of Facial Plastic and Reconstructive Surgery at the Mount Sinai Health System

Outcomes

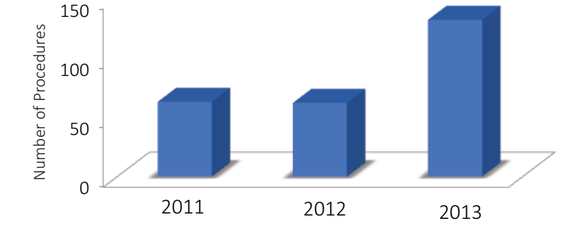
Mount Sinai performed over 300 major reconstructive procedures utilizing a variety of donor sites. The diversity of procedures provides an excellent training experience and ensures the optimal donor site for complex head and neck reconstruction.



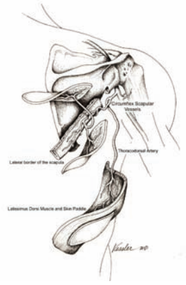
The Division of Facial Plastic and Reconstructive Surgery

Management of Facial Nerve Paralysis

The Facial Plastic and Reconstructive Surgery Program for Facial Paralysis is a multidisciplinary team of neurologists, surgeons, and neurophysiologists dedicated to improving the function and form of patients with facial paralysis. The program's growth has been instrumental in evaluating the impact of care on quality of life and function.



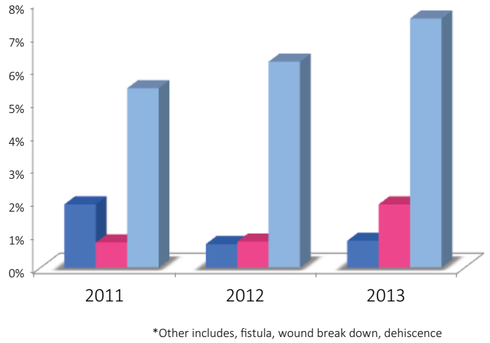
Head and Neck Reconstruction



The Division of Facial Plastic and Reconstructive Surgery

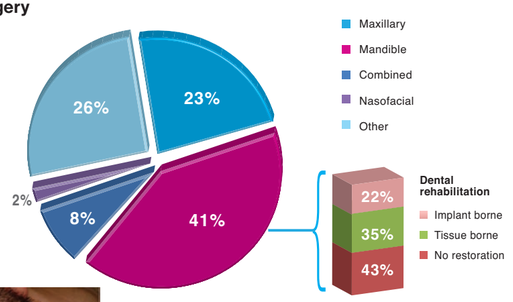
Functional Outcomes

The Mount Sinai experience with mandibular and maxillary reconstruction has revealed that osseointegrated implant-borne dentures improve functional outcomes. While cost remains prohibitive, nearly one- quarter of our patients undergo implants.



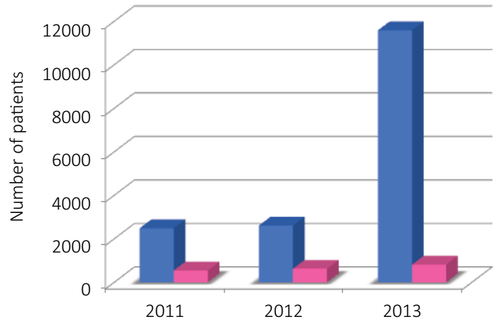
*Other includes, fistula, wound break down, dehiscence

Facial Plastic Surgery



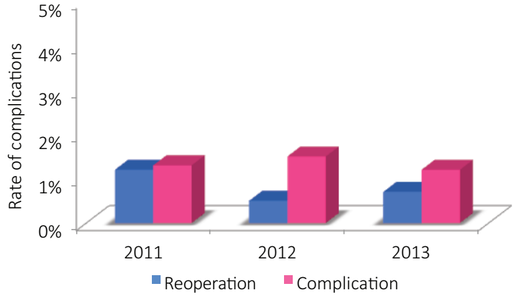
The Division of Laryngology

Patient Volume



Tracheal Reconstruction

Complication Rate (*n*= 23)



Kristina Simonyan, MD, PhD, Associate Professor of Neurology and Otolaryngology, studies spasmodic dysphonia combining her knowledge of neuroanatomy and voice disorders to establish a unique program.

Basic Science Research

Primary dystonia is a movement disorder of unknown etiology and pathophysiology, which is characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive, movements. Dr. Kristina Simoyan's laboratory studies spasmodic dysphonia with the long-term goal to identify the neural mechanisms underlying the pathophysiology of this disorder and develop new strategies for its enhanced clinical management.

As a research tool for elucidation of brain organization in dystonia, she uses a variety of neuroimaging methodologies: Functional MRI (fMRI) for mapping brain functional activity and networks; pharmacological fMRI (ph-fMRI) for assessment of the drug effects on brain function; high-resolution structural MRI and diffusion weighted imaging (DWI) with tractography for evaluation of brain structural organization; and, positron emission tomography (PET) with radiolabeled ligands for neuroreceptor mapping.

Figure 1.

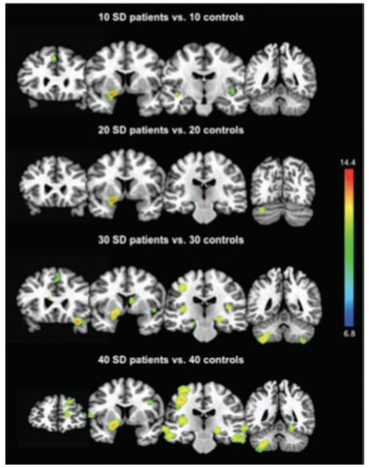


Figure 1: Increase differences of GMV in patients with SD compared to healthy controls are dependent on sample size. The color bar represents F values and reflects the significance of changes in patients compared to controls.

Dr. Simoyan has demonstrated that structural brain imaging studies have shown that not only the basal ganglia but also the sensorimotor cortical regions and cerebellum may be instrumental in the pathophysiology of this disorder.

Primary Dystonia: Conceptualizing the Disorder Through a Structural Brain Imaging Lens
Ritesh A. Ramdhani and Kristina Simonyan.
Tremor and Other Hyperkinetic Movements, 2013.

Basic Science Research

Optimal management of vocal fold paralysis would entail recurrent laryngeal nerve reinnervation resulting in normal vocal fold motion. Unfortunately, reinnervation currently results in a nonfunctional vocal fold due to synkinetic reinnervation. Therapeutic interventions that guide regenerating axons back to the appropriate muscle would prevent synkinesis and restore vocal fold and glottal function.

Dr. Michael Pitman believes that the initial step toward developing these therapies is the elucidation of the embryologic innervation of the larynx. Dr. Pitman and his research group studied the age of occurrence, timing, and pattern of embryologic innervation of the rat larynx, hypothesizing that differences in these parameters exist between distinct laryngeal muscles.

Figure 1.

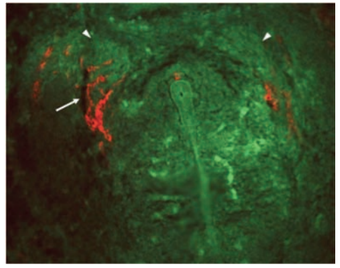


Figure 1 . Embryologic day 15 rat glottis. Axons are labeled red with neuronal class III b-tubulin polyclonal antibody. Axonal branching is noted and most significant dorsally (arrow). A collection of mesodermal cells are seen lateral and dorsal to the epithelial lamina and are identifiable as the progenitors of the posterior cricoarytenoid muscle (arrow heads).

Figure 2.

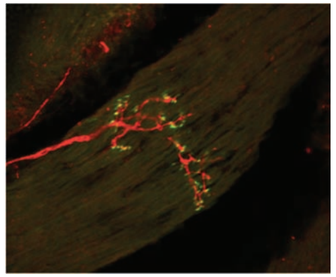


Figure 2. A 603 confocal image reveals formed neuro- muscular junctions with a single axon innervating multiple MEPs arranged in a central band within the posterior cricoarytenoid muscle.

Dr. Michael Pitman, Director of Laryngology and The Voice and Swallowing Institute at New York Eye and Ear Infirmary of Mount Sinai.

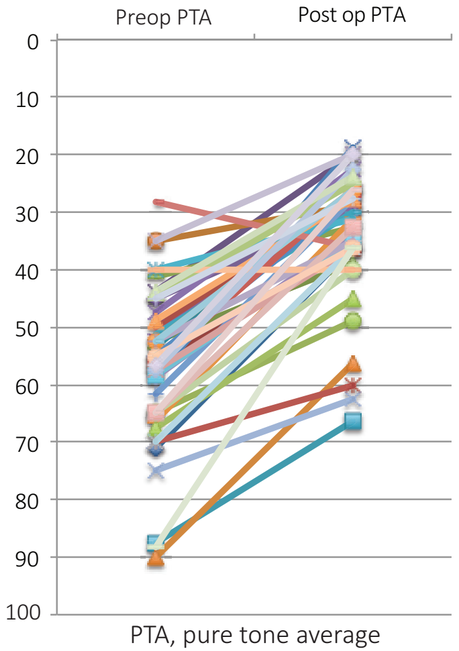
Pitman et al.: Embryologic Innervation of the Rat Larynx. *Laryngoscope 123*: December 2013.

Dr. Eric Smouha, Director of Neuro-Otology and the Center for Hearing and Balance at The Mount Sinai Hospital.

Treatment of Otosclerosis
The Ear Institute provides a wide spectrum of care for patients with otologic, neurotologic, and balance disorders.

People who have otosclerosis have an abnormal sponge-like bone growing in the middle ear. This growth prevents the ear bones from vibrating in response to sound waves. Such vibrations are needed in order for you to hear.

A stapedectomy involves removing the immobilized stapes bone and replacing it with a prosthetic device. The prosthetic device allows the bones of the middle ear to resume movement, which stimulates fluid in the inner ear and improves or restores hearing. The figure shows the improvement in 51 patients treated in 2013. The average improvement was 21 decibels.



The Ear Institute provides patients with a full range of services including communicative sciences, adult and pediatric hearing and balance programs, and adult and pediatric cochlear implant programs. Additionally, the Institute provides vestibular evaluation as well as rehabilitation and a craniofacial anomaly center.

17 full-time audiologists administered over 10,000 audiograms and dispensed over 500 hearing aids.

Balance Disorders

The Hearing and Balance Center administered more than 900 videonystagmographies (VNG's), 160 rotational chair analyses, and over 100 electrocochleographies (ECG's). This multidisciplinary center provides diagnostic and therapeutic services.

Pediatric Hearing Center
The Pediatric Hearing Center is comprised of five full-time pediatric audiologists, a social worker, an educator, and an early intervention team.

The team saw 4000 pediatric patients and administered 231 auditory brain response tests. The Center provided over 100 pediatric hearing aids and the early intervention team provided 150 new audiology evaluations.

The Division of Otology and Neurotology

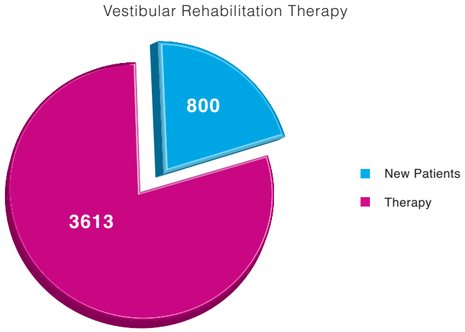
Dr. Ronald Hoffman, Otologist, The Ear Institute of New York Eye and Ear Infirmary of Mount Sinai.

The Cochlear Implant Center
The adult and pediatric cochlear implant program is comprised of three full-time and three part-time cochlear implant audiologists.

Over 180 surgical procedures were performed with more than 1,900 cochlear implant mappings.

The Vestibular Rehabilitation Therapy Program
The vestibular rehabilitation therapy program is comprised of four full-time therapists.
The therapists evaluated over 800 new patients and provided therapy for 3,613 patients.

Dr. Christopher Linstrom, Otologist, The Ear Institute of New York Eye and Ear Infirmary of Mount Sinai.



The Division of Allergy and Rhinology

New Research
Sinonasal sarcoidosis is a disease of unknown etiology. Dr. William Lawson and his research group proposed a new classification system for the disease based on Dr. Lawson's more than 30 years of experience treating it:

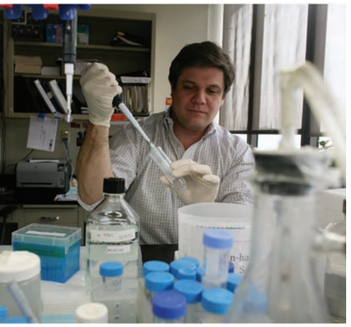
I. Mucosal hypertrophic
II. Atrophic
III. Destructive
IV. Nasal enlargement

The classification system serves to characterize the various forms of the disorder and guides clinicians on treatment approach. Each subgroup responds differently to treatment and has its own differential diagnosis. Surgery is only indicated for a select group of patients and the vast majority of patients benefit from medical management alone.

Sinonasal sarcoidosis: case series and a proposal for a new classification system. *American Journal of Allergy and Rhinology*. Lawson W., Jiang N., Cheng J., 2013.

Dr. Satish Govindaraj, Vice Chairman for Clinical Affairs, The Mount Sinai Hospital and Director of Rhinology at The Mount Sinai Hospital.

Dr. William Lawson, Vice Chairman and Endowed Grabscheid Professor of Rhinology and Facial Plastic Surgeryy.



Julio Aguirre- Ghiso, PhD, Professor of Medicine and Otolaryngology/Head and Neck Surgery and Director, Head and Neck Cancer Basic Research. Dr. Ghisso's research emphasizes to her microenvironments and tumor dormancy.

Dr. Yao, Head and Neck Surgeon at The Mount Sinai Hospital.

New Research

(Advaxis) Window of Opportunity Trial of Neoadjuvant ADXS11-001 Vaccination prior to Robot-Assisted Resection of HPV-Positive Oropharyngeal Squamous Cell Carcinoma.

This is an investigator-initiated prospective pilot clinical trial of patients with squamous cell carcinoma of the oropharynx (OPSCC) who are to undergo ablative transoral robotic surgery (TORS). We propose to test the hypothesis that the listeria-based HPV vaccine ADX11-001 induces circulating and tumor-infiltrating antigen- specific T cells in HPV16+ oropharyngeal cancer patients undergoing TORS resection. The primary aim of this study is to determine the immunogenicity of ADX11-001 vaccination in patients with HPV+ SCC of the oropharynx and to evaluate the tolerability, safety, of ADX11-001.

Phase I Study of Cabazitaxel-PF Induction Chemotherapy in Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck.

The primary objective of this study is to assess the safety, the maximum tolerated dose (MTD) and the dose limiting toxicity of cabazitaxel when combined with cisplatin and 5-FU induction chemotherapy in patients with locally advanced SCCHN. Furthermore, the trial aims to establish the phase II recommended dose of cabazitaxel when combined with cisplatin and 5-FU induction in patients with locally advanced SCCHN.

The Quarterback Trial: A Randomized Phase III Clinical Trial Comparing Reduced and Standard Radiation Therapy Doses After Induction Chemotherapy for Locally Advanced HPV 16 Positive Oropharynx Cancer.

This is a randomized Phase III study comparing two doses of definitive radiation therapy (5600 cGy and 7000 cGy) given with TPF induction chemotherapy and concurrent chemotherapy in HPV-positive oropharynx, nasopharynx or unknown primary cancer. The primary objective of this study is to determine the comparative rate of progression free survival (PFS) and of local-regional control (LRC) at 3 years in patients treated with reduced or standard dose chemoradiotherapy.

New Research

A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors.

High risk resected salivary gland malignancies represent a clinical scenario with potential for improving outcomes through multimodality therapy. The obvious limitations to prospective scientific inquiry in this group of malignancies are the infrequency of the disease and the retrospective quality of historical data. The cooperative group is the ideal mechanism for study of these tumors. This randomized phase II study is an unprecedented effort that primarily focuses on 2 objectives: determining the feasibility of a multi-institutional prospective study in this group of malignancies and obtaining preliminary efficacy data on outcomes after postoperative chemoradiation therapy using weekly cisplatin compared to radiation therapy alone.

The SIRS Trial: The Sinai Robotic Surgery Trial in HPV Positive Oropharyngeal SCCA

This is a non-randomized Phase II de-escalation clinical trial to establish recurrence rates, site of recurrence, survival and quality of life outcomes for early T-stage HPV positive oropharyngeal SCCA treated with upfront surgery. The primary objective of this study is to determine the rate of local regional control (LRC), progression free survival (PFS), and overall survival (OS) at 5 years in patients with early and intermediate stage HPV-related oropharynx cancer treated with surgery alone and at 3 years in patients with HPV related oropharynx cancer treated with a de-intensified adjuvant protocol.

Palliative Therapy Clinical Trials

Phase II multicenter, randomized, double blind, placebo-controlled study assessing the efficacy of buparlisib (BKM120) plus paclitaxel vs. placebo plus paclitaxel in patients with platinum pre-treated recurrent or metastatic head and neck squamous cell carcinoma.

This is a multicenter, randomized, double blind study to assess the efficacy and safety of daily buparlisib in combination with weekly paclitaxel vs. buparlisib-matching placebo plus weekly paclitaxel on median progression free survival (PFS) in patients with recurrent or metastatic HNSCC that has progressed after prior platinum-based regimen. The study will also explore the role of PI3K pathway activation as a potential predictive factor for response to buparlisib in this patient population.

A Randomized Phase II, Multicenter, Open-label Study of BYL719 in Combination with Cetuximab in Patients with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC).

This is a multicenter, randomized, open-label Phase II study with the primary endpoint of progression-free survival (PFS). The phase II study will assess the anti-tumor activity of BYL719 (PI3 kinase inhibitor) in combination with cetuximab versus cetuximab alone in cetuximab-naïve patients. BYL719 will be assessed in combination with cetuximab for efficacy, safety and tolerability, and PK profile, in both cetuximab-naïve and cetuximab-resistant settings.

A Randomized, Double-Blind, Placebo-Controlled Study of Chemotherapy Plus Cetuximab in Combination with VTX-2337 in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck.

This is a randomized, double-blind, VTX-2337 in combination with cisplatin or carboplatin, 5-FU and cetuximab in prolonging the progression-free survival in subjects with recurrent or metastatic (R/M) SCCHN. This is a first line therapy for patients with locoregionally recurrent or metastatic disease. The primary objective is to compare the progression-free survival of subjects treated with cisplatin or carboplatin + fluorouracil (5-FU) + cetuximab combined with VTX-2337 to those treated with cisplatin or carboplatin + 5-FU + cetuximab alone (standard-of-care; SOC).

Thyroid Clinical Trials

A Randomized, Double Blind Study to Compare the Complete Remission Rate Following a 5-Week Course of Selumetinib or Placebo and Single Dose Adjuvant Radioactive Iodine Therapy in Patients with Differentiated Thyroid Cancer.

This is a Phase II study to compare the efficacy of selumetinib with radioactive iodine therapy (RAI), versus placebo with RAI, by assessment of complete remission rate at 18 months post RAI treatment in the overall study population.

Dr. Marshal Posner, Professor of Medicine and Otolaryngology and Director of Head and Neck Medical Oncology. Under the direction of Dr. Posner, Mount Sinai offers patients a broad spectrum of clinical trials.

Oncology Grants

Tumor microenvironments determining migration, dissemination and dormancy. U54CA163131 , 09/01/2011 - 08/31/2016, Tumor Microenvironment Network (TMEN). Agency: NIH/NCI , 1.8 Cal months. Goal - The major research focus of our proposed TMEN Center is the study of the microenvironments in primary tumors that drive tumor cell dissemination and survival, and dormancy and growth at secondary organs.

Functional determinants of metastatic dormancy. R01CA109182, 07/01/2004 - 12/31/2015 Agency: NCI/NIH. 4.2 cal months; Goal - Study the role of p53, BHLHB3 and ATF6 signaling pathways in the induction of dormancy and survival of dormant disseminated tumor cells in the bone marrow. Isolate and functionally characterize bone marrow disseminated tumor cells in different target organs

Regulation of disseminated tumor cell fate by RARb and NR2F1 signaling. COLLABORATIVE GRANT. 06/2009 – 07/2014, Samuel Waxman Cancer Research Foundation. 1.0 Cal months; Goal - Study the role of RARb and NR2F1 to the dormancy of disseminated tumor cells to the bone marrow and lung in HNSCC and breast cancer models.

Development of novel anti-dormancy therapies, Collaborative Grant, 09/01/2012 - 08/31/2015, Agency: ImClone Systems – Eli Lilly. Goals - To identify, validate and pharmacologically target novel surface proteins as well as surface or intracellular kinases that might affect dormant tumor cell survival, quiescence or outgrowth after dormancy.

Tumor microenvironments driving disseminated tumor cell dormancy. German Research Council, 2/01/2014-01/31/2016. Goal – Study the role of stress microenvironments present in the primary tumor as determinants of proliferation or dormancy of DTC fate.

Grants *(continued)*

The state-of-the-art Leon and Norma Hess Center for Science and Medicine increases Mount Sinai's research capacity by a half a million square feet, and serves as the focal point for basic and translational research. Opened in Fall 2012, it features six full floors of laboratory space, two floors of outpatient clinical space, and houses the country's most advanced imaging facilities.

Imaging genetics of spasmodic dysphonia. 04/01/2012-03/31/2017 - NIDCD/NIH R01 DC011805: PI: Kristina Simonyan

Voice tremor in spasmodic dysphonia: central mechanisms and treatment response. 07/01/2012-06/30/2017- NIDCD/NIH R01 DC012545: PI: Kristina Simonyan

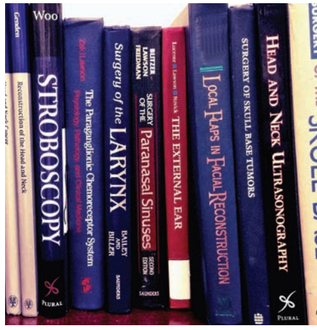
Cortical-subcortical interactions in Parkinson¹s disease and normal speech. 04/01/2012-03/31/2017 - NIDCD/NIH R01 DC007658: PI: Sidtis, Subcontract PI: Kristina Simonyan

Neuropathological basis of spasmodic dysphonia and related voice disorders. 09/2009-05/2019 - Intramural NINDS/NIH (05-N-0189): No direct costs - research expenses are covered from the NINDS Clinical Director¹s budget. PI: Hallett, Adjunct PI: Kristina Simonyan

Differences in brain activation via the utilization of functional magnetic resonance imaging in patients with spasmodic dysphonia and voice tremor. 02/2015-01/2016 Royal Australasian College of Surgeons, Foundation for Surgery Reg Worcester Research Fellowship:PI: Diana Kirke, MBBS, FARC; Sponsor: Kristina Simonyan

Publications – 2013

Head and Neck Oncology



Amit M, Binenbaum Y, Sharma K, Naomi R, Ilana R, Abib A, Miles B, Yang X, Lei D, Kristine B, Christian G, Thomas M, Klaus-Dietrich W, Fliss D, Eckardt AM, Chiara C, Sesenna E, Frank P, Patel S, Gil Z. Adenoid cystic carcinoma of the nasal cavity and paranasal sinuses: a meta-analysis. *J Neurol Surg B Skull Base.* 2013;74(3):118-25.

Strojan P, Corry J, Eisbruch A, Vermorken JB, Mendenhall WM, Lee AW, Haigentz M Jr, Beitler JJ, de Bree R, Takes RP, Paleri V, Kelly CG, Genden EM, Bradford CR, Harrison LB, Rinaldo A, Ferlito A. Recurrent and second primary squamous cell carcinoma of the head and neck: when and how to reirradiate [published online ahead of print November 7, 2013]. *J Otol Head Neck Surg.* doi: 10.1002/hed.23542.

Paleri V, Drinnan M, van den Brekel MW, Hinni ML, Bradley PJ, Wolf GT, de Bree R, Fagan JJ, Hamoir M, Strojan P, Rodrigo JP, Olsen KD, Pellitteri PK, Shaha AR, Genden EM, Silver CE, Suárez C, Takes RP, Rinaldo A, Ferlito A. Vascularized tissue to reduce fistula following salvage total laryngectomy: a systematic review. *Laryngoscope.* 2014;124(8):1848-53.

Kann BH, Buckstein M, Carpenter TJ, Bakst R, Misiukiewicz K, Genden E, Posner M, Kostakoglu L, Som P, Gupta V. Radiographic extracapsular extension and treatment outcomes in locally advanced oropharyngeal carcinoma. *Head Neck.* 2014;36(12):1689-94.

Kostakoglu L, Fardanesh R, Posner M, Som P, Rao S, Park E, Doucette J, Stein EG, Gupta V, Misiukiewicz K, Genden E. Early detection of recurrent disease by FDG-PET/CT leads to management changes in patients with squamous cell cancer of the head and neck. *Oncologist*. 2013;18(10):1108-17.

Prisman E, Miles BA, Genden EM. Prevention and management of treatment-induced pharyngo-oesophageal stricture. *Lancet Oncol.* 2013;14(9):3380-e386.

Madorin CA, Owen R, Coakley B, Lowe H, Nam KH, Weber K, Kushnir L, Rios J, Genden E, Pawha PS, Inabnet WB. Comparison of radiation exposure and cost between dynamic computed tomography and sestamibi scintigraphy for preoperative localization of parathyroid lesions. *JAMA Surg.* 2013;148(6):500-503.

Genden EM. Use of vascularized muscle flaps in the healing of compromised wounds. *JAMA Otolaryngol Head Neck Surg.* 2013;139(11):1162.

Jang DW, Teng MS, Ojo B, Genden EM. Palliative surgery for head and neck cancer with extensive skin involvement. *Laryngoscope*. 2013;123(5):1173-1177.

Rangaswamy B, Fardanesh MR, Genden EM, Park EE, Fatterpekar G, Patel Z, Kim J, Som PM, Kostakoglu L. Improvement in the detection of locoregional recurrence in head and neck malignancies: F-18 fluorodeoxyglucose-positron emission tomography/computed tomography compared to high-resolution contrast-enhanced computed tomography and endoscopic examination. *Laryngoscope.* 2013;123(11):2664-2669.

Publications – 2013

Facial Plastics and Reconstructive Surgery

Lorenc ZP, Kenkel JM, Fagien S, Hirmand H, Nestor MS, Sclafani AP, Sykes JM, Waldorf HA. Consensus panel's assessment and recommendations on the use of 3 botulinum toxin type A products in facial aesthetics. *Aesth Surg J.* 2013; 33(1S):35S- 40S.

Patel ZM, Setzen M, Sclafani AP, Del Gaudio JM. Concurrent functional endoscopic sinus surgery and septorhinoplasty: using evidence to make clinical decisions. *Int Forum Allergy Rhinol.* 2013; 3: 488- 492.

Sclafani AP, Sclafani JA, Sclafani AM. Successes, revisions and post-operative complications in 446 Mohs defect repairs. *Facial Plastic Surg.* 2012; 28: 358-365.

Oral Maxillofacial Surgery

Okay, DJ, Buchbinder D, Urken M, Jacobson A, Lazarus A, Persky M. Computer-assisted implant rehabilitation of maxillomandibular defects reconstructed with vascularized bone free flaps. *JAMA Otolaryngol Head Neck Surg.* 2013;139(4):371-381.

Laryngology

Kuet ML, Pitman MJ: Photoangiolytic laser treatment of recurrent respiratory papillomatosis: a scaled assessment. *J Voice.* 2013;27(1):124-128.

Pitman MJ, Berzofsky C, Alli O, Sharma S: Embryologic innervation of the rat laryngeal musculature-a model for investigation of recurrent laryngeal nerve reinnervation. *Laryngoscope.* 2013;123(12):3117-3126.

Simonyan K, Frucht SJ. Long-term effect of sodium oxybate (Xyrem®) in spasmodic dysphonia with vocal tremor. *Tremor and Other Hyperkinetic Movements.* December 2013:3. PMID: 24386608.

Berman BD, Hallett M, Herscovitch P, Simonyan K. Striatal dopaminergic dysfunction at rest and during task performance in writer's cramp. *Brain.* 2013;136(1):3645-58.

Simonyan K, Berman BD, Herscovitch P, Hallett M. Abnormal striatal dopaminergic neurotransmission during rest and task production in spasmodic dysphonia. *J Neuroscience.* 2013;33(37):14705-14.

Ramdhani RA, Simonyan K. Primary Dystonia: Conceptualizing the disorder through a structural brain imaging lens. *Tremor and Other Hyperkinetic Movements.* (2013) April 2013:152-3638-4.

Simonyan K. Herscovitch P, Horwitz B. Speech-induced striatal dopamine release is left lateralized and coupled to functional striatal circuits in healthy humans: A combined PET, fMRI and DTI study. *NeuroImage.* 2013;70:21-32.

Publications – 2013

Otology and Neurotology

Kang B, Kim AH. Comparison of cochlear implant performance after round window electrode insertion compared to traditional cochleostomy. *Otol Head and Neck Surg.* 2013;48(5):822-826.

Dean C, Felder G, Kim AH. Analysis of speech perception outcomes among patients receiving cochlear implants with auditory neuropathy spectrum disorder. *Otol Neurotol.* 2013;34(9):1610-1614.

Kim AH, Nahm EA, Sollas A, et al. Connexin 43 (Cx43) and hearing:possible implications for retrocochlear auditory processing. *Laryngoscope.* 2013;123(12):3185-3193.

Sleep Disorders

Menachem MW, Lin FY, Jang DW, Malkin BD. Adult sleep apnea and related procedures, In: Levine AI, Govindaraj S, DeMaria S, eds. *Anesthesiology and Otolaryngology. 1st ed.* Springer Publishing, New York, NY, pp 133-147, 2013.

Olarte L, Lin FY. Obstructive sleep apnea, In: Lin FY, Patel ZM, eds. *ENT Board Prep. 1st ed.* New York, NY: Springer Publishing; 2013.

Prince A, Louisias M, Lin FY. Fluid, hemostasis, nutrition, and pulmonary physiology, In: Lin FY, Patel ZM, eds. *ENT Board Prep. 1st ed. New York, NY: Springer Publishing; 2013.*

Del Signore A, Lin FY. Therapeutics. In: Lin FY, Patel ZM, eds. *ENT Board Prep. 1st ed.* SNew York, NY: Springer Publishing; 2013

Olarte L, Magliocca KM, Lin FY. Pathology. In: Lin FY, Patel ZM, eds. *ENT Board Prep. 1st ed.* New York, NY: Springer Publishing; 2013.

Lin FY. Salivary gland disorders, In: Lin FY, Patel ZM, eds. *ENT Board Prep. 1st ed.* New York, NY: Springer Publishing; 2013.

In 1877 the hospital divided the House Staff into Medical and Surgical Divisions, each with a Senior and a Junior Resident. Surgical volume continued to increase, and in 1899 the caseload exceeded 2,000 operations. By 1904, when the hospital moved to its current site, four House Surgeons completed their training every year.

Faculty List

The Mount Sinai Hospital sent medical units to both World Wars. Of the 24 physicians and 65 nurses serving in World War I with Base Hospital No. 3 of the U.S. Army Medical Corps in France, the majority of doctors and nurses were from Mount Sinai. The group finished the conversion of a 15th century monastery in Vauclaire, Dordogne into a 500-bed hospital that at one point housed 2,800 patients.

Allergy
Anne Maitland, MD
Sujan Patel, MD

Facial Plastics
Grigoriy Mashkevich, MD
Alexander Ovchinsky, MD
Joshua Rosenberg, MD
Joseph Rousso, MD
Anthony Sclafani, MD
Marc Zimbler, MD

General Otolaryngology
Bart Castellano, MD
Claude Douge, MD
Benjamin Malkin, MD
Uchechukwu Megwalu, MD
Sabina Omerhodzic, MD
Anthony Reino, MD

Head and Neck Surgery
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David Philip Culang, MD
Eric Genden, MD
Neil Gildener-Leapman, MD
Brett Miles, MD, DDS
Stimson Schantz, MD
Edward Shin, MD
Marita Teng, MD
Mark Urken, MD
Mike Yao, MD
Helen Yoo-Bowne, MD

Laryngology
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Babak Sadoughi, MD
Peak Woo, MD

Oral and Maxillofacial
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Vincent Carrao, DDS, MD
Devin Okay, DDS
Alan Schwimmer, DDS
Michael Turner, MD, DDS
Joshua Verona, DDS

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Ronald Hoffman, MD
Ana Kim, MD
Christopher Linstrom, MD
Eric Smouha, MD

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Alyssa Hackett, MD
Michael Rothschild, MD

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Cathy Lazarus, PhD
Uchechukwu Megwalu, MD
Kristina Simonyan, MD

Rhinology and Skull Base Surgery
Satish Govindaraj, MD
Alfred Iloreta, MD
William Lawson, MD, DDS
Madeleine Schaberg, MD
Abtin Tabaee, MD

Sleep Disorders
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Fred Lin, MD
Gennady Ukrainsky, MD

Clinical Specialists

Audiologists
Meghan Brady, AuD, CCC-A
Sandra Delapena, MA, CCC-A
Michele DiStefano, MS, CCC-A
Brittany Fishbane, AuD, CCC-A
Karla Fernandez , AuD, CCC-A
Jessica Gallatioto , AuD, CCC-A
Lisa Goldin, MPhil, CCC-A
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Sabrina Vitulano, AuD, CCC-A
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Amy Cooper, MS, CCC-SLP
Denise Cruz, MS, CCC-SLP
Lisa Erlichster, CCC-SLP
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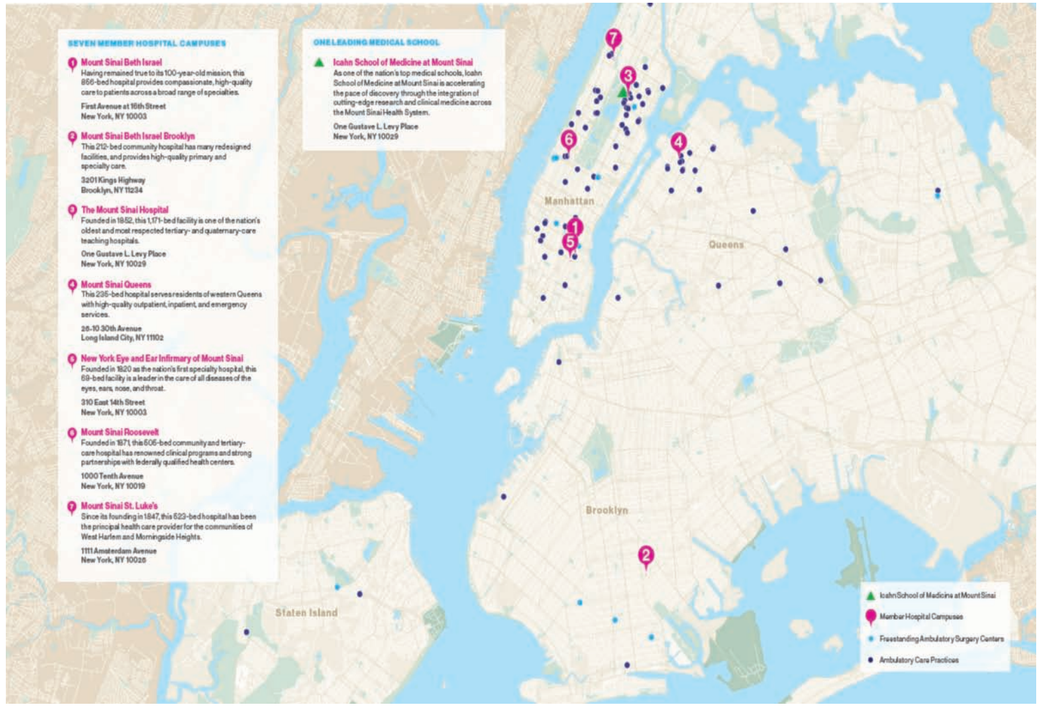
Sheryleen Elisca, RPA-C
Stephanie Mendez, RPA-C
Lyudmila Milman, RPA-C
Alizza Retter, RPA-C
Tanya Sharrieff, RPA-C
Mei Xei, RPA-C

Mount Sinai Health System at a Glance



Practice Locations

THE MOUNT SINAI HOSPITAL

Mount Sinai Otolaryngology—Manhattan Campus
Faculty Practice Associates
5 East 98th Street, 8th floor
New York, NY 10029
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Center for Science and Medicine—Cancer Center
10 East 102nd Street, 3rd floor
New York, NY 10029
Telephone: 212-241-9410

Mount Sinai Otolaryngology—Staten Island
2052 Richmond Road, Suite 1C
Staten Island, NY 10306
Telephone: 718-420-1279

Mount Sinai North Shore Medical Group
325 Park Avenue
Huntington, NY 11743
Telephone: 212-241-9410

Elmhurst Hospital Center Otolaryngology
79-01 Broadway – H2-69
Elmhurst, NY 11373
Telephone: 718-334-3392

James J. Peters Veterans Medical Center Otolaryngology
130 West Kingsbridge Road
Bronx, NY 10468
Telephone: 718-584-9000 x5992

The Queens Hospital Center Otolaryngology
82-68 164th Street
Jamaica, NY 11432
Telephone: 718-334-3392

St. Barnabas Hospital
4422 3rd Avenue
New York, NY 10457
Telephone: 718-960-9000

MOUNT SINAI BETH ISRAEL

Mount Sinai Beth Israel Phillips Ambulatory Care Center (PACC)
10 Union Square East
New York, NY 10003
Telephone: 212-844-8450

Mount Sinai Beth Israel–Westchester Head, Neck and Thyroid Institute
244 Westchester Avenue
Suite 405
White Plains, NY
212-844-8775

Practice Locations

NEW YORK EYE AND EAR OF MOUNT SINAI

New York Eye and Ear Infirmary of Mount Sinai
310 E. 14th Street
New York, NY 10003
Main Number: 212-979-4000
Physician Referral Line:
212-979-4472

Columbus Circle
200 W 57th Street, Suite 1410
New York, NY 10019
212-957-6933

Ear Institute
380 2nd Avenue, 9th Floor
New York, NY 10010
212-614-8379

Financial District
65 Broadway, #901
New York, NY 10006
212- 514-6933

Madison Avenue
161 Madison Avenue
New York, NY 10016
212-213-3339

Tribeca
77 Worth Street
New York, NY 10013
212-966-3901

Upper East Side
1430 2nd Avenue
New York, NY 10021
212-535-2298

Upper East Side
Office Relocation & Expansion
62 East 88th Street
New York, NY 10128
Opening Summer 2015

Bay Ridge
9020 5th Avenue, 3rd Floor
Bay Ridge NY 11209
718-333-5120

Midwood
1630 E 15th Street, #203
Brooklyn, NY 11229
718-375-6933

Sheepshead Bay
2560 Ocean Avenue, 2nd Floor
Brooklyn, NY 11229
718-646-1234

Williamsburg
101 Broadway, #201
Brooklyn, NY 11249
718-384-6933

Bayside
45-64 Francis Lewis Blvd., 2nd Fl.
Bayside, NY
Opening Winter 2014 - 2015

Forest Hills
108-12 72nd Avenue
Forest Hills, NY 11375
718- 544-9300

Bronx ASC
3170 Webster Avenue
Bronx, NY 10467
Opening Fall 2013 –Winter 2014

Chappaqua
59 S Greeley Ave
Chappaqua, NY 10514
914-238-5500

White Plains
244 Westchester Avenue, #215
White Plains, NY 10604
914-997-9100

WEBSITE SHORTCUTS

The Department of Otolaryngology – Head and Neck Surgery
www.mountsinai.org/ent
www.nyee.edu/ent

Center for Head and Neck Cancer
www.mountsinai.org/oralcancer
www.headneckandthyroid.com

Center for Hearing and Balance
www.mountsinai.org/hearing

Center for Minimally Invasive Robotic Surgery
www.headandneckrobotics.com

Center for Thyroid and Parathyroid Diseases
www.mountsinai.org/thyroid

Eugen Grabscheid MD Voice Center
www.mountsinai.org/voicecenter

Facial Plastics and Reconstructive Surgery
www.mountsinai.org/facialplastics

Skull Base Surgery Center
www.mountsinai.org/skullbase

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