



# Cardiology & Heart Surgery

2018 Year in Review



# NYU Langone Health's cardiovascular programs are among the top-ranked in the nation, and we always strive to reach the next level of excellence in clinical care, education, and research.

In 2018 our Heart Transplant Program achieved the fastest transplant rate in the region and we became the first in New York State to achieve the Adult Congenital Heart Association's highest level of accreditation. We pioneered new surgical and endovascular techniques for complex conditions, and led clinical trials for novel devices and medications. Our goal, as always, was to improve outcomes not only for our patients, but for patients everywhere.

The opening of the Kimmel Pavilion offers new surgical space in state-of-the-art operating rooms, and our brand-new Science Building includes nearly 110 benches of basic science lab space used by our cardiology research team to advance the science of heart disease treatment. We are proud to share the highlights of the past year's work.



### CAMPUS TRANSFORMATION

In 2018, NYU Langone Health opened a new, 830,000-square-foot inpatient facility, the **Helen L. and Martin S. Kimmel Pavilion**, featuring 374 exclusively single-bedded rooms, an outdoor terrace, and 30 operating rooms and image-guided labs.

(Photo credit: Jeff Goldberg)

### CARDIOLOGY & HEART SURGERY

# \$40M

IN NIH FUNDING

# 300+

SCIENTIFIC PUBLICATIONS

# 35

HEART TRANSPLANTS PERFORMED

# First and Only

IN NEW YORK STATE

to be accredited by the Adult Congenital Heart Association (ACHA) as an Adult Congenital Heart Disease Comprehensive Care Center

# 141

ACTIVE CLINICAL TRIALS

Statistics reflect 2018 figures



# Advancing Minimally Invasive Approaches to Valve Repair and Replacement

In 2018, NYU Langone spearheaded research efforts in transcatheter and robot-assisted procedures for valve disease that improved outcomes and enabled a greater number of structural heart patients to benefit from lifesaving interventions.



## 2018 Highlights

- NYU Langone is one of only a few cardiac centers in the world to use the state-of-the-art da Vinci Xi<sup>®</sup> robotic surgical system.
- The Robotic Mitral Valve Program—which includes specialized anesthesiologists, perfusionists, and nurses—has now treated more than 700 patients, making it the third-largest such program in the nation.
- NYU Langone's Heart Valve Center has been a pioneer of first implantations over the past two years with Medtronic's CoreValve Evolut<sup>™</sup> PRO TAVR System, the Meridian<sup>®</sup> Transcatheter Aortic Valve, and the Caisson TMVR investigational devices.

Cezar Staniloae, MD, Mathew Williams, MD, Homam Ibrahim, MD

## NEW MILESTONE IN TRANSCATHETER VALVE PROCEDURES

Transcatheter replacement of aortic and mitral valves took a significant step forward this year through the Heart Valve Center's participation in more than a dozen clinical trials.

Among the most notable recent research was the COAPT (Cardiovascular Outcomes Assessment of the MitraClip<sup>®</sup> Percutaneous Therapy for Heart Failure for Patients with Functional Mitral Regurgitation) study, in which 614 patients with severe heart failure in the United States and Canada were randomly assigned to receive either a MitraClip<sup>®</sup>—a tiny device, manufactured by Abbott Vascular, that clips together the mitral valve's two leaflets to reduce regurgitation—or standard care. Over a two-year period, 151 patients who received only medical treatment were hospitalized for heart failure and 61 died, compared with only 92 hospitalizations and 28 deaths among those who received the MitraClip<sup>®</sup>.

"This is a game-changer," says Mathew Williams, MD, associate professor of cardiothoracic surgery and medicine, chief of the Division of Adult Cardiac Surgery, and director of the Heart Valve Center. "Studies have estimated that up to 49 percent of patients with severe mitral regurgitation are denied surgery due to their high-risk features. We now know that a minimally invasive technique can keep many of these patients out of the hospital and significantly prolong their lives."

## HIGH-VOLUME TRANSCATHETER VALVE PROCEDURE CENTER

Led by Dr. Williams, who has performed more than 3,500 transcatheter valve procedures—more than any other surgeon in the nation—the Heart Valve Center is a national training site for TAVR (transcatheter aortic valve replacement) best practices, and home to the busiest TMVR (transcatheter mitral valve replacement) program on the East Coast. Cardiac valve device trials at NYU Langone often involve close collaboration between the Heart Valve Center and the Heart Failure Advanced Care Center. "We leverage the strength and expertise of multidisciplinary specialists as we select the appropriate treatment for each patient," notes Aubrey Galloway, MD, the Seymour Cohn Professor of Cardiothoracic Surgery and chair of the Department of Cardiothoracic Surgery.

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We leverage the strength and expertise of multidisciplinary specialists as we select the appropriate treatment for each patient.”

—Aubrey Galloway, MD

NYU Langone's research has helped provide evidence prompting regulators to approve TAVR devices for a growing number of patients—beginning with those at high risk for adverse effects from open surgery, then expanding to those at intermediate risk. The center currently serves as the third-largest enroller in the PARTNER 3 trial, studying the safety and effectiveness of the Edwards SAPIEN 3 device in low-risk patients with aortic stenosis. And as national principal investigator for the PRELUDE early feasibility study, Dr. Williams has now implanted 12 Caisson TMVR devices—almost half of the international total.

## ROBOTIC MITRAL VALVE SURGERY SAFELY STANDS UP TO COMPLEX CASES

Although the first robotic mitral valve repair was performed 20 years ago, many cardiac centers still use robotic approaches for only the simplest such procedures, relying on open-heart surgery for more complex cases. But a new study led by Didier F. Loulmet, MD, associate professor of cardiothoracic surgery, chief of cardiac surgery at Tisch Hospital, and director of robotic cardiac surgery, shows that robotic surgery can be performed safely and effectively on the great majority of mitral valve patients—including those with such challenging conditions as multi-scallop myxomatous degeneration, anterior leaflet involvement, and severe mitral annular calcification (MAC).



Advancing Minimally Invasive Approaches to Valve Repair and Replacement

Didier F. Loulmet, MD

“Robotic mitral valve repair is far less invasive than open surgery while allowing greater precision,” explains Dr. Loulmet, who was part of the French team that performed the first, groundbreaking robotic repair in 1998. “Patients have much less pain and bleeding, fewer infections, and go home sooner—typically in two days rather than a week. And we’ve now demonstrated that even the most complex patients consistently benefit from this approach.”



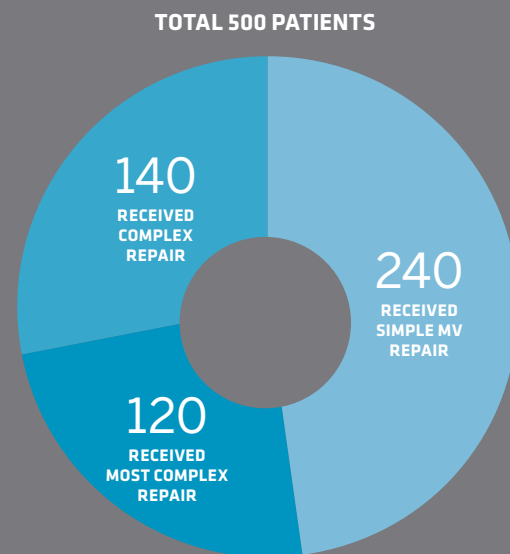
Totally Robotic Endoscopic Mitral Valve Repair (TERMVR) Outcomes

Dr. Loulmet’s study, presented at the European Association for Cardio-Thoracic Surgery (EACTS) meeting in October, followed 500 men and women who received totally robotic endoscopic mitral valve repair (TERMVR) at NYU Langone between May 2011 and August 2017.

Cases were divided into three levels of complexity:

- **Simple MV repair** (annuloplasty alone or with one leaflet segment repair), performed on 240 patients;
- **Complex repair** (involving more than one segment on the same leaflet) in 140 patients; and
- **Most complex repair** (bileaflet, or MAC excision with atrioventricular groove repair) in 120 patients.

These differences, the researchers found, did not significantly affect length of stay (median four days) or 30-day readmission rate (overall 3.6 percent). The overall repair rate was 99.4 percent, with just 0.6 percent early mortality and 1.2 percent stroke rate.



Disclosures: Aubrey Galloway, MD, receives royalties from Medtronic for valve repair products and royalties from Edwards Lifesciences for valve replacement. Didier F. Loulmet, MD, receives proctoring fees from Intuitive Surgical. Mathew Williams, MD, receives research funding from LivaNova, Edwards, Medtronic, Abbott and HLT, and consults for Medtronic.

Finding Better Therapies for Complex Arrhythmias

Larry A. Chinitz, MD, and Hank Gambino, PA

In 2018, NYU Langone’s Heart Rhythm Center, home to one of the busiest cardiac electrophysiology programs in the nation, continued to push boundaries in the treatment of complex arrhythmias and the investigation of novel devices and advanced techniques.

IMPROVING ATRIOVENTRICULAR PACING WITH A LEADLESS PACEMAKER

In recent years, a new generation of leadless pacemakers has offered a less-invasive option for bradycardic patients who can benefit from pacing therapy. But unlike conventional pacemakers, these tiny devices—delivered percutaneously to the right ventricle—have been unable to synchronize ventricular pacing with that of the atrium. A study led by Larry A. Chinitz, MD, the Alvin Benjamin and Kenneth Coyle, Sr. Family Professor of Medicine and Cardiac Electrophysiology, and clinical director of the Leon H. Charney Division of Cardiology, shows that this limitation can be overcome.

In the multisite, international study, 64 patients were implanted with a vitamin-sized Micra™ transcatheter pacing system. The device was then programmed with a downloadable algorithm aimed at enabling it to sense atrial contractions through its built-in accelerometer, and to synchronize ventricular pacing accordingly. Patients were monitored for a median of six months. The results, published in September in the journal *HeartRhythm*,

indicated that accelerometer-based atrial sensing can improve atrioventricular pacing—a function never before reported with a leadless, single-chamber pacemaker. “The next step is to develop a leadless atrial pacemaker, and test it in coordination with a ventricular implant,” Dr. Chinitz explains. “We think these devices represent the future of pacing.”

#### FORGING NEW FRONTIERS IN CARDIAC ABLATION

NYU Langone is at the forefront of developing improved ablation techniques—especially for complex arrhythmias such as atrial fibrillation (AFib), for which success rates lag those for simpler disorders. In 2018, researchers led by Anthony Aizer, MD, assistant professor of medicine, published a pair of studies in the *Journal of Interventional*

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Our Heart Rhythm Center has been at the forefront of innovation in cardiac rhythm management—developing new therapies to optimize the well-being of our patients.”

—Glenn Fishman, MD

*Cardiac Electrophysiology* and *JACC* showing that overdrive pacing during ablation enhances lesion quality. And last May, at the annual Heart Rhythm Society (HRS) meeting, Douglas S. Holmes, MD, assistant professor of medicine and pediatrics, presented the results of a two-year canine model study showing that high-power, short-duration lesions (50 watts at five seconds, rather than the traditional 25 to 30 watts for 30 to 40 seconds) can deliver precise, durable lesions with reduced risk of peripheral injury. Those results have been submitted for journal publication in the coming year.

#### ISCHEMIA Trial Completes Recruitment

In 2018 NYU Langone researchers completed recruitment for the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) and ISCHEMIA-CKD (chronic kidney disease) trials—a major milestone for the largest ever trials testing an invasive strategy in stable ischemic heart disease.

Since enrollment began in 2012, a total of 5,179 participants were randomized in the ISCHEMIA trial, and 777 in the ISCHEMIA-CKD trials, across 331 sites in 38 countries.

The National Heart, Lung, and Blood Institute (NHLBI)-funded ISCHEMIA trial compares the effectiveness of a conservative (optimal medical therapy alone with revascularization reserved for

failure of medical therapy) versus invasive (optimal medical therapy and upfront cardiac catheterization and revascularization) treatment strategy in patients with stable ischemic heart disease and at least moderate ischemia on a stress test. ISCHEMIA-CKD is a parallel NHLBI-funded study.

The initial follow-up period will end in June 2019, and researchers plan to report the results of the trials at the end of 2019.

“Clinical trials are a team effort,” says Judith S. Hochman, MD, the Harold Snyder Family Professor of Cardiology, associate director of the Leon H. Charney Division of Cardiology, senior associate dean for Clinical Sciences, and co-director of the Clinical and



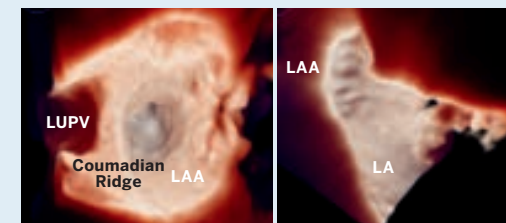
Judith S. Hochman, MD

Translational Science Institute, “the teams at NYU Langone, across the U.S., and around the globe, and the participants that contributed to advancing our knowledge of optimal care are responsible for the success of this international trial.”

#### Procedural Image Guidance with Transesophageal Echocardiography in Left Atrial Appendage Occlusion

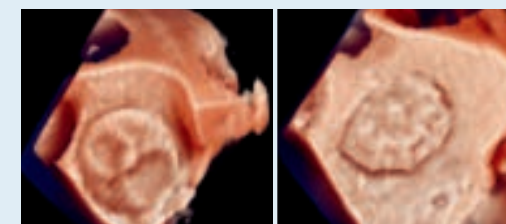
A team of NYU Langone researchers led by Muhamed Saric, MD, PhD, professor of medicine and clinical director of non-invasive cardiology, published an instructional paper in the *Journal of the American Society of Echocardiography* on procedural image guidance with transesophageal echocardiography (TEE) in left atrial appendage occlusion using the Watchman™, Amulet, and LARIAT® devices. Coauthors included Dr. Chinitz and Dr. Aizer as well as Alan F. Vainrib, MD, assistant professor of medicine,

Ricardo J. Benenstien, MD, assistant professor of medicine and associate director of the echocardiography lab at Tisch Hospital. “Successful implantation of these devices requires detailed knowledge of LAA anatomy as well as high-quality 2D and 3D TEE, used in conjunction with fluoroscopy,” Dr. Saric explains. “By sharing our team’s extensive experience, we hope to contribute to the establishment of best practices, and to help make these procedures more accessible to patients everywhere.”



1

Figure 1: 3D transesophageal echocardiography images of the left atrial appendage (LAA) prior to closure. The left panel shows the entrance (orifice) of the left atrial appendage as seen from the left atrium (LA) and adjacent to the left upper pulmonary vein (LUPV). The right panel demonstrates the detailed anatomy of the body of the left atrial appendage (LAA) including its pectinate muscles and the connection between the LAA and the left atrium (LA).



2

Figure 2: 3D transesophageal echocardiography images of the left atrial appendage (LAA) following percutaneous closure of its orifice in 2 different patients. In the left panel, the LAA was closed using the Watchman™ device while in the right panel it was closed using the Amulet device.

The Heart Rhythm Center’s leadership in treating arrhythmias was further highlighted at the HRS meeting when two complex procedures—an ablation for AFib using body surface mapping, and a pacemaker implantation using His bundle pacing (HBP) to avoid ventricular dyssynchrony—were broadcast live from NYU Langone to the conference hall.

#### BLAZING NEW TRAILS IN LEFT ATRIAL APPENDAGE OCCLUSION

New studies from the Heart Rhythm Center could help enhance the adoption of left atrial appendage (LAA) procedures as a stroke-prevention treatment for AFib—the most common heart rhythm abnormality, affecting more than 33 million people worldwide. Although oral anticoagulants can reduce stroke risk in AFib, these

medications are contraindicated or poorly tolerated in many patients. An alternative approach is to close off the LAA, the small pouch at the corner of the atrium where AFib-related clots typically originate. Several percutaneously delivered devices have been developed for this purpose in recent years.

NYU Langone researchers have led clinical trials for many of these technologies, including the plug-like Watchman™ implant (approved by the U.S. Food and Drug Administration in 2015) and the LARIAT®, which uses a Teflon-coated loop to ligate the LAA. The Heart Rhythm Center is currently participating in investigational device exemption (IDE) trials of three newer implants—the WaveCrest®, the Amulet, and the Pinnacle FLX—designed to treat a wider range of LAA anatomies or otherwise improve on existing devices.

Disclosure: Larry A. Chinitz, MD, was a Speaker Honoraria for Medtronic.



# Leadership in Treating— and Replacing—Failing Hearts

At NYU Langone’s Heart Failure Advanced Care Center, clinicians and researchers are leading innovative efforts to extend and improve patients’ lives—from novel medications and ventricular-assist devices to new techniques for surgical revascularization and transplants.



Deane Smith, MD, and Nader Moazami, MD

## HEART TRANSPLANT PROGRAM MEETS DEMAND WITH INNOVATION

Since its inauguration in January 2018, the Heart Transplant Program (part of the Transplant Institute) has generated strong outcomes that reflect the skill set and experience of NYU Langone’s multidisciplinary team, drawn from top programs across the country. “We organize the evaluation and testing process into a tight time frame, aggressively assess every single donor heart offer, and employ innovative strategies to enlarge our supply of donor organs,” explains Nader Moazami, MD, professor of cardiothoracic surgery and surgical director of heart transplantation and mechanical circulatory support.

One such innovation, undertaken as part of an ongoing prospective study, is to accept donor hearts that are positive for the hepatitis C virus (HCV). “A growing body of research shows that these hearts can be used safely because HCV typically has a 20-year incubation period and can be effectively controlled with anti-viral medications,” notes Alex Reyentovich, MD, associate professor of medicine, medical director of the Heart Transplant Program, and clinical director of the Heart Failure Program. “We’re exploring every possible pathway to help patients get the organs they need, as quickly as possible.”

As a result of this adaptive, forward-looking approach, the program—which was certified by the Centers for Medicare and Medicaid Services (CMS) in August—already has the fastest transplant rate and one of the shortest average wait times in the region. “Over the past decade, the wait list for transplant patients in New York State has increased by 40 percent,” notes Dr. Moazami. “By developing more efficient procedures and protocols, we hope to improve outcomes for patients everywhere.”

## PIONEERING IMPROVED TREATMENTS FOR COMPLEX HEART FAILURE

Patient volume growth of 46 percent at NYU Langone’s Heart Failure Advanced Care Center has been driven in part by the expansion of high-risk surgical revascularization—the complex treatment of coronary artery disease associated with abnormal heart muscle function. NYU Langone is among only a few institutions nationwide that perform such procedures, largely due to expertise in techniques to prevent or manage postcardiotomy cardiogenic shock.

“We use a variety of individualized strategies, enabling us to help many high-risk patients who would be turned away from other centers,” explains Deane Smith, MD, assistant professor of cardiothoracic surgery, associate director of Heart Transplant and Mechanical Circulatory Support, and co-director of the Thoracic Aortic Disease Program.

## Devices Under Investigation at the Heart Failure Advanced Care Center

- Medtronic HeartWare HVAD System—a small, centrifugal LVAD. Post-approval study. National co-principal investigator: Dr. Moazami.
- NuPulseCV iVAS—a balloon-pump device designed as a minimally invasive alternative to traditional LVADs. Feasibility study. Site principal investigator: Dr. Smith.

## Spotlight

35

HEART TRANSPLANTS performed in 2018

Fastest Transplant Rate

IN UNOS REGION 9, AT

280

TRANSPLANTS PER PATIENT YEAR on the wait list

Shortest Average Wait Times

IN THE REGION:

5X

MORE LIKELY

TO RECEIVE A HEART TRANSPLANT at NYU Langone than at other New York area programs, and

3X

MORE LIKELY

than the national average

97.1%

ONE-MONTH SURVIVAL RATE—six points higher than the national average

## A Cutting-Edge Approach to CTEPH

Chronic thromboembolic pulmonary hypertension (CTEPH) is a rare pathology that straddles the boundary between heart disease and lung disease. Although the recommended treatment, pulmonary thromboendarterectomy (PTE), is curative in more than 90 percent of cases, only a small number of surgeons nationwide are trained in the technically demanding procedure. One of the most experienced is Zachary Kon, MD, assistant professor of cardiothoracic surgery and surgical director of the Lung Transplant Program, who joined NYU Langone in January 2018.

Dr. Kon has developed a unique, minimally invasive approach to PTE, utilizing an upper hemi-sternotomy rather than a neck-to-abdomen incision, which is designed to reduce pain and promote faster recovery. NYU Langone's CTEPH Program also offers state-of-the-art percutaneous and pharmacological therapies for patients who are ineligible for open surgery. "With our multifaceted team" says Dr. Kon, "we are able to provide a full spectrum of care along this disease's entire continuum."



Surgical pulmonary endarterectomy specimen

These methods include a wide range of approved and investigational approaches—including extracorporeal membrane oxygenation (ECMO), and surgically or percutaneously implanted ventricular assist devices (VADs)—that can help patients tolerate revascularization procedures, and act as bridges to recovery, transplantation, or the implantation of VADs designed for longer-term use.

### EXPANDING OPTIONS FOR CARDIAC AMYLOIDOSIS

The Cardiac Amyloidosis Program at NYU Langone, led by Dr. Reyentovich, treats 100 patients for this complex cause of heart failure. One of just a handful of programs across the country focused exclusively on cardiac amyloidosis (CA), it brings together experts from a wide range of subspecialties.

Two types of CA account for the majority of cases: immunoglobulin light chain amyloidosis (AL-CA) and transthyretin amyloidosis (ATTR-CA). About 1,200 people are diagnosed with AL-CA each year, and while ATTR-CA was once thought to be similarly rare, a recent study found

that more than 25 percent of hospitalized heart failure patients 60 and older with preserved ejection fraction showed signs of the disease. "Fortunately, several new therapies have emerged that can improve survival and quality of life for these patients, including chemotherapeutic regimens for AL-CA and various new medications for ATTR-CA," says Dr. Reyentovich.

NYU Langone was a recruiting center for the landmark multisite, international Transthyretin Amyloidosis Cardiomyopathy Clinical Trial (ATTR-ACT), which tested an orally administered drug, tafamidis. According to a report published in September in the *New England Journal of Medicine*, the therapy significantly reduced overall mortality (to 29.5 percent, compared with 42.9 percent for placebo) and cardiovascular-related hospitalizations (to 0.48 per year, compared with 0.70 per year for placebo) in ATTR-CA patients. NYU Langone is one of the few national centers where patients have access to this lifesaving drug via the Tafamidis Early Access Program.

Disclosure: Alex Reyentovich, MD, sits on the advisory board for Pfizer.



Mark V. Sherrid, MD, and Daniel G. Swistel, MD  
(Photo credit: Karsten Moran)

## New Treatment Approaches for Hypertrophic Cardiomyopathy

Recent advancements in surgical techniques and intraoperative imaging methods at NYU Langone's Hypertrophic Cardiomyopathy Program can enhance outcomes for patients with the genetic heart condition.

### MODIFIED MYECTOMY ALLOWS MORE PATIENTS TO AVOID MITRAL VALVE REPLACEMENT

Surgical director Daniel G. Swistel, MD, associate professor of cardiothoracic surgery, originally pioneered a significant surgical modification to traditional myectomy, performed on patients with obstructive hypertrophic cardiomyopathy (HCM) for whom pharmacologic therapy is ineffective. The horizontal plication procedure improves blood flow by shortening the mitral valve, which often protrudes into the left ventricular chamber in HCM patients. As echocardiography has more precisely shown the abnormalities of the mitral valve, Dr. Swistel has altered his approach by excising the residual (extra) portion of the mitral valve, termed residual leaflet excision (ReLex). This can be especially useful in patients who preoperatively are shown to have only mild septal thickening.

"These patients used to require mitral valve replacement," explains Mark V. Sherrid, MD, professor of medicine, director of the HCM Program, and a nationally recognized cardiologist who was instrumental in establishing the utility of disopyramide therapy for obstructive HCM. "With these techniques, 95 percent of them can keep their own valve instead of receiving an artificial or bioprosthetic implant."



## Hypertrophic Cardiomyopathy Program Expands with New Recruit

In July, NYU Langone recruited cardiologist and clinical instructor of medicine, Daniele Massera, MD, to join the Hypertrophic Cardiomyopathy Program. A native of Austria, Dr. Massera earned his medical degree from the Medical University of Vienna in 2010 and completed his residency and a four-year fellowship at Montefiore Medical Center in New York City. During his postgraduate training, he published more than a dozen papers in peer-reviewed journals, launched a nascent HCM program, and was funded by two research grants (one from the National Institutes of Health and the other from the New York Academy of Medicine) during his final year. The addition of Dr. Massera is expected to enable the Hypertrophic Cardiomyopathy Program to double its patient volume, which currently comes from across the eastern United States.



Daniele Massera, MD

Affecting about 1 in 500 people, HCM is the most common inherited heart condition, and the leading cause of sudden death among people under 30 years of age. NYU Langone is one of just a handful of institutions to offer comprehensive management of this disorder. With more than 2,500 patients, the Hypertrophic Cardiomyopathy Program is among the largest such programs in the world, with a record of innovation spanning three decades.

Dr. Swistel and Dr. Sherrid have published two papers related to their work in this field. The first, “The Surgical Management of Obstructive Hypertrophic Cardiomyopathy: The RPR Procedure—Resection, Plication, Release,” appeared in the *Annals of Cardiothoracic Surgery* and was accompanied by a 23-minute online instructional video. The second, whose first author is Robert Nampiaparampil, MD, assistant professor of anesthesiology, perioperative care, and pain medicine, was “Intraoperative Two- and Three-Dimensional Transesophageal Echocardiography in Combined Myectomy-Mitral Operations for Hypertrophic Cardiomyopathy.” The article reviewed the innovative techniques used at NYU Langone for intraoperative two- and three-dimensional transesophageal echocardiography in combined myectomy-mitral operations for HCM and was published in the *Journal of the American Society of Echocardiography*. The two papers underscore NYU Langone’s eminence and leadership in this field.

### SURGICAL ADVANCES IN INTRAOPERATIVE IMAGING OF SEPTAL THICKNESS

One major challenge in the surgical treatment of HCM is that there is no way to monitor the depth of septal myectomy during the on-pump period, since transesophageal echocardiography is impossible when the heart is empty of blood. An experimental technique recently developed and named by NYU Langone’s HCM team, known as on-pump intraoperative echocardiography (OPIE), offers a solution. In this method, a tiny probe, originally designed for pituitary surgery, is inserted through the aortic valve while the right heart chamber is filled with fluid, creating an interface that the echocardiogram can differentiate.

An IRB-approved trial of OPIE involving 10 patients was completed last year, and an abstract has been submitted for presentation at the 2019 annual meeting of the American College of Cardiology. “Our initial findings suggest that this device can improve the efficacy and safety of myectomy procedures,” says Dr. Swistel, who led the study. “We think it will revolutionize the management of patients with only modest hypertrophy of the septum, for whom the line between ‘too little myectomy’ and ‘too much myectomy’ can be difficult to assess with current methods.”

## Enhancing Endovascular Aortic Aneurysm Repair, Vascular Access, and the Treatment of Venous Disease

NYU Langone Health is pioneering novel devices for treating peripheral vascular diseases, as well as a new, minimally invasive system for creating arteriovenous fistulas for kidney dialysis—while providing patients with world-class care.



Todd L. Berland, MD, and Thomas Maldonado, MD  
(Photo credit: Karsten Moran)

### LEADING THE WAY IN ENDOVASCULAR ANEURYSM REPAIR

In 2018, the Aortic Disease Center at NYU Langone piloted two new stent grafts designed to treat aneurysms that involve multiple branches of the thoracoabdominal region.

Studies involving these new devices, led by Neal S. Cayne, MD, professor of surgery and director of Endovascular Surgery, and Thomas Maldonado, MD, the Schwartz Buckley Professor of Surgery, build on the center’s innovation in endovascular aneurysm repair (EVAR) since it tested some of the first endografts 25 years ago. “Because each patient’s anatomy differs, a wide range of graft configurations is required to repair aneurysms without blocking essential arteries,” explains Dr. Maldonado, who is also medical director of the Venous Thromboembolic Center. “We’re partnering with industry to develop devices that bring the benefits of EVAR to more patients with complex aneurysms.”

One of those investigational products is a next-generation system from Cook Medical featuring a fenestrated or branched main graft that can be custom designed for each patient by attaching additional grafts to stent the mesenteric,



celiac, and renal arteries. “We’ve implanted these in six patients so far, and they’ve done exceptionally well despite severe comorbidities,” says Dr. Cayne. “With this minimally invasive approach, they’re out of the hospital in an average of two days.”

The center is also one of only five sites in the nation to pilot the Medtronic Valiant manifold stent graft—a unique off-the-shelf device featuring four arms that can be used to selectively stent vessels. Unlike custom devices, which take several weeks to manufacture, this branched graft requires little lead time before deployment, making it a potential lifesaver in emergent situations. It also allows the surgeon extraordinary flexibility in staging to best fit the patient’s tolerance. Five patients have received this device at NYU Langone to date, with encouraging results.

#### NEW APPROACHES TO DEEP VEIN OUTFLOW DISEASE

Deep venous obstruction affects an estimated 24 million people worldwide, increasing their risk of dangerous blood clots, and leading to symptoms ranging from varicose veins to debilitating pain, swelling, and ulceration of the legs. Although the therapy of choice is stenting of the iliac vein, no device designed specifically for that purpose has been approved by the Food and Drug Administration (FDA). Instead, the most common approach has been off-label use of the braided Elgiloy Wallstent Endoprosthesis, whose high degree of flexibility and compressibility can be problematic under some circumstances—resulting in foreshortening, narrowing, or inaccurate deployment.

NYU Langone is at the forefront of efforts to develop superior alternatives. “We’ve been involved in trials for all the dedicated vascular stents now coming to the market,” notes Todd L. Berland, MD, associate professor of surgery and director of Outpatient Vascular Interventions. “The goal is to find a device that will maintain the correct length, the correct width, and stay exactly where you put it.” Dr. Berland is currently a principal investigator of the Abre venous self-expanding stent system by Medtronic, a Nitinol-based device designed to achieve a better balance of strength, flexibility,

### Bringing Endovascular Intervention to the Outpatient Setting

NYU Langone is at the forefront of an endovascular revolution. Leveraging the decrease in size of vascular devices and state-of-the-art imaging technology, interventions are being transitioned into the outpatient arena. Accredited by the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), and operated in conjunction with colleagues from Interventional Radiology and Anesthesia, NYU Langone’s Outpatient Surgical Center allows surgeons to perform a wide array of endovascular procedures with outcomes equal to those performed in the main OR. In addition to the improved convenience of the experience, patients often realize reduced out-of-pocket expenses. Since its inception, more than 2,500 procedures have been safely performed in the outpatient setting.

and deployment accuracy. Patients began receiving these stents in October. In addition, Mikel Sadek, MD, assistant professor of surgery, has been a principal investigator for the Vici self-expanding system by Boston Scientific, also a Nitinol-based device designed to achieve similar benefits.

#### NEW AV FISTULA TECHNIQUE OFFERS GREATER EASE—AND EFFECTIVENESS

Nearly 500,000 people in the United States currently receive hemodialysis for end-stage renal disease. For more than 50 years, AV fistulas have been installed surgically in an operation that typically takes more than an hour, with failure rates of up to 60 percent. In 2018, Dr. Berland launched a national trial of the WavelinQ endoAVF System, which aims to reduce that time to a few minutes and produce far more consistent results.

“

We think this could revolutionize the way patients receive dialysis.”

—Todd L. Berland, MD

With the new technique, two flexible magnetic catheters are inserted into an artery and vein in the arm. A tiny pulse of radiofrequency energy is then used to connect the two vessels, creating the fistula. After the catheters are withdrawn, a brachial vein is coil-embolized, completing the procedure.

In 2016 Dr. Berland became the first surgeon in the world to create an AV fistula using the latest generation of this system, operating on a patient in Paraguay. In 2017 he co-presented the results of the single-arm, prospective, multicenter Novel Endovascular Access Trial (NEAT) at the Leipzig Interventional Course (LINC) in Germany. The study found that the procedure caused less pain and scarring than open surgery and that its re-intervention rate was four to five times lower.

Recently, in 2018, Dr. Berland completed a Paraguay-based study of a smaller version of the everlinQ device, with equally encouraging results, and he has submitted a manuscript for publication. “These methods have a success rate of approximately 90 percent and are easier on the patient,” Dr. Berland says. “We think this could revolutionize the way patients receive dialysis.”

### Spearheading the Latest Technology in Treatment of Aortic Dissections



Endovascular surgeons at NYU Langone will soon be able to treat aortic dissections with a new device. On January 1, 2019 Cook Medical received FDA approval for the first and only dissection stent graft specifically designed for aortic dissections.

The Zenith® Dissection bare stent was approved to help treat symptomatic Type B aortic dissections. Typically used in combination with a previously approved fabric covered thoracic stent graft, it allows for treatment of the dissection, which helps to re-expand the true lumen of the aorta and allows continued perfusion of important visceral and spinal arteries. It also helps the damaged aorta remodel back to its normal state. “Recent studies have shown data to suggest that Type B dissections, formerly treated with medical therapy alone, may be better treated early after diagnosis with stent grafts to prevent later complications and aneurysmal degeneration of the damaged aorta. The new availability of this device will allow us to now provide optimal treatment at NYU Langone Health for these critically ill patients with complex disease,” notes Glenn Jacobowitz, MD, Frank J. Veith Professor of Vascular and Endovascular Surgery and chief of the Division of Vascular and Endovascular Surgery.

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Disclosures: Neal S. Cayne is a consultant for Cook, Gore and BOLTON and participates in research with Cook and BOLTON. Todd L. Berland, MD, is a consultant for Becton Dickinson.

## Interventional Cardiology Announces New Director and Expands the Boundaries of Cardiovascular Intervention

Craig A. Thompson, MD, MMSc, an internationally recognized pioneer in the revascularization of chronic total occlusions (CTOs), joined NYU Langone in September 2018 as professor of medicine and director of the Interventional Cardiology Program. In his new position, he oversees the Cardiac Catheterization Laboratory at Tisch Hospital—among the busiest such facilities in the country—and satellite labs throughout the NYU Langone system.

NYU Langone's Cardiac Catheterization Laboratory was involved in more than 20 major clinical trials of pharmacological and device-based therapies in 2018. Anvar Babaev, MD, PhD, clinical professor of medicine and director of endovascular interventions, led several of these efforts, focusing on peripheral artery disorders. One notable example was the first-ever randomized,

controlled trial comparing two atherectomy devices—CSI's Diamondback 360 Peripheral Orbital Atherectomy System, and Medtronic's HawkOne Directional Atherectomy System—for plaque modification and luminal gain in patients with symptomatic obstructive femoropopliteal disease.

Researchers are also studying a variety of interventional therapies for coronary artery disease, with several trials led by Michael J. Attubato, MD, associate professor of medicine and associate director of the Interventional Cardiology Fellowship Program. "We are investigating new stent designs, in-stent restenosis, pharmacological regimens to prevent stent thrombosis, acute myocardial infarction, and other areas of unmet need," says Dr. Attubato, who is also a co-investigator in trials of peripheral-disease therapies.



Craig Thompson, MD, and Michael Attubato, MD

Disclosure: Anvar Babaev, MD, is a consultant for Boston Scientific, Medtronic, Cook, and Abbott.



Abigail Walsh, MSN, CPNP-AC, Frank Cecchin, MD, Dan G. Halpern, MD, and Rachel Smaldone, MSN, AGPCNP-BC

## Innovative Treatment for CHD at Every Stage of Life

The most common major birth defect, congenital heart disease (CHD), affects more than one percent of newborns in the United States.

NYU Langone is recognized for leadership in caring for CHD patients of all ages, and for research aimed at improving outcomes.

### SETTING NEW STANDARDS IN ADULT CONGENITAL HEART DISEASE CARE

NYU Langone's Adult Congenital Heart Disease Program was the first in New York State to be accredited by the Adult Congenital Heart Association (ACHA) as a Comprehensive Care Center—the ACHA's highest designation. Led by medical director Dan G. Halpern, assistant professor of medicine, the program includes three board-certified adult congenital heart disease specialists, more than any other in the state. And with more than 1,600 yearly clinic visits, volume has grown 30 percent since 2017.

The ACHA accreditation reflects NYU Langone's coordinated, multidisciplinary approach to treating adult patients with CHD, who face challenges ranging from a higher risk of complications from pregnancy or surgery, to a need for preventive care and monitoring for secondary conditions such as arrhythmias, heart failure, or liver failure. "We collaborate with a team representing every subspecialty that touches adult congenital heart disease, including congenital heart surgery, imaging, genetics, electrophysiology, pediatric cardiology, interventional cardiology, heart failure, anesthesia, and reproductive services," notes Dr. Halpern. "This core group meets weekly to discuss challenging cases and develop plans of care."



#### ADVANCING DIAGNOSIS AND TREATMENT OF PEDIATRIC CHD

In 2018, the Pediatric Congenital Heart Program introduced a software app that enables video consults between pediatric cardiologists and obstetricians who detect possible fetal heart defects during prenatal office visits. “The specialist can now see live ultrasound images from the obstetrician’s office over a smartphone or laptop, and analyze them instantly,” says Frank Cecchin, MD, the Andrall E. Pearson Professor of Pediatric Cardiology and director of pediatric cardiology. “Parents receive a cardiologist’s opinion at the moment heart disease is suspected, and we can start formulating a diagnosis and treatment plan at 12 to 14 weeks, rather than the 18- to 20-week period when abdominal fetal echocardiography typically occurs.”

“

Continuity is at the center of our approach to CHD treatment at every stage of life, with benefits that are measurable in our clinical outcomes.”

—Ralph S. Mosca, MD

#### Making Strides in CHD Research

Researchers in NYU Langone’s Congenital Heart Program are at the forefront of investigating new approaches for diagnosing and treating patients with CHD, through both basic research and clinical trials. In 2018, Achiau Ludomirsky, MD, professor of pediatrics, won the Echovation Challenge as lead developer of the Ultrasound Translator, which uses artificial intelligence and deep-learning algorithms to automatically assess and analyze cardiac images, whether prenatal, pediatric, or adult. The handheld device is designed to bridge the gap between the ultrasound expert and non-expert, improving workflow and patient care in both established echo labs and point-of-care settings.

Areas of investigation also include 3-D printing and airway virtual reality that precisely assesses preintervention anatomy, the impact of ischemic arrest on pulmonary valve implantation, the pathogenesis of diseases such as Barth and Marfan syndrome, and the effects of air pollution on the fetal heart.



Ralph S. Mosca, MD (Photo credit: Karsten Moran)

### NYU Langone’s Congenital Heart Program

specializes in complex neonatal heart surgeries, including:

- the Norwood operation for hypoplastic left heart syndrome,
- the arterial switch operation (ASO) for transposition of the great arteries, and
- the Starnes procedure for Ebstein’s anomaly

#### NEW FACILITIES AND ENHANCED CONTINUITY OF CARE

NYU Langone’s Congenital Cardiovascular Unit is the only unit in New York City dedicated to the care of neonates, infants, children, and young adults with CHD. These patients are now treated at the Hassenfeld Children’s Hospital, located in the new, 21-story Kimmel Pavilion. Open since June, the 160,000-square-foot facility is one of the most technologically advanced pediatric hospitals in the country, with 68 single-patient rooms, as well as imaging, surgical, catheterization, and electrophysiology facilities designed specifically for children. To optimize continuity of care, patients are assigned a single team of clinicians and trained nurses throughout their stay.

“Continuity is at the center of our approach to CHD treatment throughout every stage of life, with benefits that are measurable in our clinical outcomes,” says Ralph S. Mosca, MD, the George E. Reed Professor of Cardiac Surgery, professor of pediatrics, and chief of the Division of Pediatric and Adult Congenital Cardiac Surgery. After the initial intervention, pediatric patients can receive ongoing consults with members of their clinical team at locations close to home—including the Fink Ambulatory Care Center, NYU Langone Hospital—Brooklyn, and NYU Winthrop on Long Island (acquired this year). As they enter adolescence, they and their families begin a carefully planned transition to the care of specialists with expertise in the unique medical, psychological, and social issues involved with adult CHD.

### Pediatric Heart Surgery Procedures

200+

PEDIATRIC PROCEDURES PER YEAR

OVERALL  
PEDIATRIC HEART SURGERY  
SURVIVAL RATES THAT EXCEED  
NATIONAL AVERAGES:

94.9%

for neonates  
(versus 91.7 percent)

99.6%

for infants up to one year  
(versus 97.2 percent)

100%

for pediatric patients  
(versus 99 percent)

### Lower-than-average

LENGTH OF STAY IN

10

PROCEDURES

including ASO, tetralogy of Fallot,  
and Fontan

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5

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### Upcoming CME Courses in 2019

<b>APRIL 12</b>	<b>Invasive Cardiology Update for Practicing Healthcare Professionals</b>	Course Directors: Michael Attubato, MD Anvar Babaev, MD, PhD Craig Thompson, MD
<b>APRIL 27 – 28</b> (2 day course)	<b>Hypertrophic Cardiomyopathy: Comprehensive Management of a Complex Disease</b>	Course Directors: Mark Sherrid, MD Daniel Swistel, MD
<b>APRIL 26</b>	<b>Heart Failure in 2019 and Beyond</b>	Course Directors: Nader Moazami, MD Alex Reyentovich, MD
<b>MAY 17</b>	<b>Venous Thrombosis Update 2019</b>	Course Directors: Thomas Maldonado, MD Jonathan Newman, MD, MPH

To register and learn more about CME at NYU Langone, please visit: [med.nyu.edu/cme](http://med.nyu.edu/cme)

### ANNOUNCING

## Tuition-Free Initiative Addresses High Student Debt

NYU School of Medicine announced in August 2018 that it will begin offering full-tuition scholarships to all current and future students in its MD degree program regardless of need or merit—a bold effort to simultaneously address the rising costs of medical education and still attract the best and brightest students to careers in medicine. “This decision recognizes a moral imperative that must be addressed, as institutions place an increasing debt burden on young people who aspire to become physicians,” says Robert I. Grossman, MD, the Saul J. Farber Dean of NYU School of Medicine and CEO of NYU Langone Health.



(Photo Credit: Juliana Thomas Photography)



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