

# AATS DAILY NEWS

Official newspaper of the AATS 102nd Annual Meeting

**Issue 2** Monday May 16, 2022

#### In this issue

4 Lung cancer screening in 2022



- Monday's Congenital Summit
- 5 Pearls and pitfalls of neochordal reconstruction
- 6 'Consensus on mechanical circulatory support is needed'
- 8 The AATS Foundation
- 10 FAME 3 closes the gap for CABG vs.

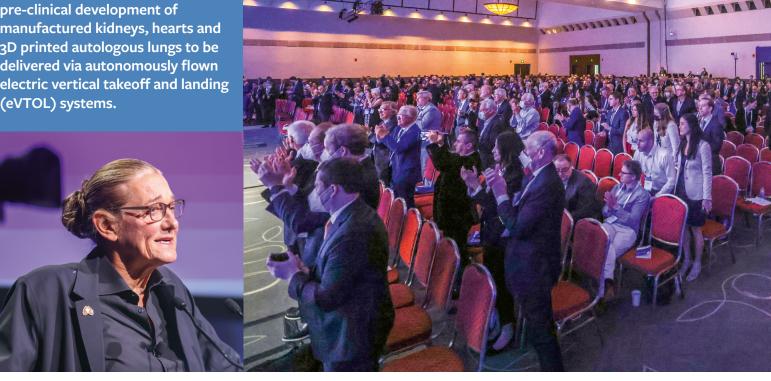


- 11 Regionalization a must for better
- 12 Noted abstracts
- 14 Dissecting ATAAD



16 Awards abound at the Annual Meeting

**Martine Rothblatt delivered** her featured lecture Doing the impossible: time and time again on Sunday at the Annual Meeting to captivated audience. Dr. Rothblatt, who is Chairperson and CEO of United Therapeutics Corporation (UT), is responsible for several innovations in aviation and architecture. UT is also in pre-clinical development of manufactured kidneys, hearts and 3D printed autologous lungs to be delivered via autonomously flown electric vertical takeoff and landing (eVTOL) systems.



Perioperative Care Summit Room 206 Sunday 7:30 AM

# 'More questions than answers' around federal management of pandemic supplies

erious questions need answering around the supply of ventilators during the COVID-19 crisis, with some states making false cries for help, others being over-supplied, raising doubts according to Mr. Hargan. about the reliability of decision-making over vital supplies during the pandemic. This was the message of former United States Deputy Secretary of Health and Human Services, Eric Hargan, in his keynote address on Sunday morning.

"When we did [supply ventilators in response to demand] we saw deaths start rising," he told the audience. New Orleans turned to more 'creative' measures and proning when ventilators were in short supply, yet preliminary findings suggest it came off better than New York that had more than it needed,

Mr. Hargan was involved in swiftly developing the necessary regulatory and policy protections under immense time pressure to mitigate the impact of the pandemic, tackling supply chain issues, workforce shortages, economic losses and resource constraints. As the largest department in the federal government, Health and Human Services and has an annual budget in excess of \$1.3 trillion and "It is incumbent upon us to learn from these events, and whether our decisions were useful or not in preparation for the next one."

Eric Hargan

over 80,000 employees.

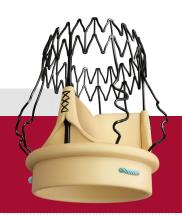
Mr. Hargan served on the Board of Operation Warp Speed, started in March 2020 as the federal effort to catalyze the development of COVID-19 vaccines. He coordinated the first major Warp Speed project, starting in Spring of 2020. Here at the Annual Meeting, he recalled events around provision of care for patients and clinicians, at a time of high demand and low supply, in particular personal protective equipment (PPE) and provision of ventilators for ICU patients.

"A lot of the dilemmas were Continued on page 2

INTRODUCING **PERCEVAL PLUS** 

DESIGNED FOR THE FUTURE

Uniquely suited for Valve-in-Valve





corcym .com Page 2 102nd Annual Meeting AATS Issue 2 May 14–17, 2022

Continued from page 1

unanticipated, and it is incumbent upon us to learn from these events, and whether our decisions were useful or not in preparation for the next one," said Mr. Hargan, stressing that lessons need to come from the clinical and medical side but also the legal and administrative too. "There will be a next time, and there will be another rise in infectious diseases – it's inevitable at some point."

The Office of the Assistant Secretary of Preparedness Response (ASPR) leads the nation's medical and public health preparedness in response to, and recovery from disasters, for example hurricanes, wildfire, nuclear events, and public health emergencies (infectious disease outbreaks).

One role of the ASPR is to maintain a national stockpile of medical equipment, said Mr. Hargan. "It has to decide what to respond to. Sometimes it's successful, as it was with the mRNA vaccine response. Warp Speed took this technology that was on the edge and supercharged it to bring it to a successful conclusion."

At other times, its response was less successful, take for example the supply of masks and gowns for PPE. "There were not enough, and there was a planetary inability to respond," explained Mr. Hargan, adding that clinicians changed their view on mask-wearing from not wearing to wearing them. "In the former scenario, we were focusing on supplying gowns, hats and caps, but then masks were needed, and we started running out of gowns.

"We were told our sewing machines only have so much capacity. You can have masks or gowns, but not both."

#### Ventilators - help or harm?

The federal government has a stockpile which often sits unused but at other times is insufficient. Decisions around how much to supply, and to where, was a question dependent on having the correct information. Such reliable information, said Mr. Hargan, was often in short supply in the surge scenario.

"We had a few thousand ICU beds in the stockpile, but we needed more. ICU beds are expensive, so we don't buy endless amounts and have them sit there empty," he said.

Ventilator use over the pandemic is a particular case in point. Research is needed to look at to what extent, and when, the supply of ventilators was suddenly made available, said Mr. Hargan. In a crisis setting, in addition to the non-crisis scenario, there is a big question around which interventions are helpful, and which ones are harmful. "If we have an endless number of ICU beds and everyone is hooked up to ventilators, is this a good thing or a bad thing from a public health point of view, will it help or harm patients?"

Mr. Hargan highlighted that these were hard decisions to make, but the pandemic required that they moved quickly. "Essentially, were there enough clinical people making the decision to determine whether such interventions should be supplied? This needs to be considered from a legal and administrative standpoint."

He went on to highlight when a government

# lack of childhood varcinations over the pandemic. Reality Check - political

"Federal government has to rely on state government officials to give us a reality check on what is needed."

#### Eric Hargan

official erroneously told a reporter how many ventilators the government had, and in response the governor of New York City asked for more ventilators than they had allocated for national supply. "New York didn't end up using the ventilator supply it had, and it didn't use the 2,000 ICU beds that they had. In fact, New York had a greater supply than the United Kingdom overall," he recalled.

Regarding ventilators, New Orleans did not have many because it is a relatively poor state, so they developed a lot of techniques for managing patients, for example proning, and other creative responses. In contrast, New York had a lot of ventilators and they used the ventilators, "But when I left office in 2021, early results suggested that New Orleans by and large fared better than New York. These are the numbers that speak for themselves," he said.

"Was this because New Orleans responded with non-ventilator interventions or not? Was it a characteristic of the population? We need to break down these results to find out if ventilators were a negative intervention for these patients, particularly for the less severe.

"In light of the fact that we were dealing with an unknown virus and unknown disease, a decision has to be made in the heat of the moment. But the question is are we going to learn from what happened in the middle of all this for the next time?"

# Prioritizing COVID-19 or other surgeries – 'lockdown never again'!

Another question that emerges now that the pandemic has started to subside, is how much non-emergency care was canceled. The question to ask is how do we prioritize these patients if there is another crisis?

The next time a pandemic hits, governors and mayors may not take the same actions again, Mr. Hargan pointed out. There were damaging effects of the lockdown, for example developmental issues with children, mental health, behavioral health, and rising drug use, as well as around the

lack of childhood vaccinations over the pandemic. "This all raises questions about how we deal with a surge capacity for infectious disease. In the future, they might decide not to do lockdown but continue with the same level of cancer care, heart disease, screening and all the other areas of medicine," he said.

"I spoke to a lot of people after I left office, and they said 'never lockdown, never again. We will never support this.' This is a widespread view from hospital side of things."

Next time, the response will need to be much more "complicated", he notes. Lockdowns were widespread and lasted for a significant time, adding that, "the effects are now appearing such that they will avoid this response next time, in many cases."

There are going to be a lot of questions for the medical and research community, for which

"When it comes down to resource allocations, and we are stretched, then we are making decisions based on reality. This isn't an area for overreacting."

#### Eric Hargan

answers will be needed before the next time, and before decisions are made.

During yesterday's session, the moderator asked whether the federal government might take a more effective look at the social determinants of health in preparation for the next pandemic, given that some of these policies were already "behind" before the pandemic started, and were in need of correction.

Mr. Hargan replied: "We all know that social determinants have an effect. The question for federal government is how to restart, and fund, the various projects around social determinants, because these clearly had huge effects. If you look at the characteristics of the population that was worst affected, whether obesity, or general health, these had a huge effect on what happened with COVID-19.

"With COVID-19, the mortality curve went straight up toward the overweight, toward those who had comorbidities, immunosuppressed, while the young experience very little."

#### Reality check - political statement or real need?

Rakesh C. Arora (Winnipeg, Canada), asked Mr. Hargan about supply of equipment, in particular ECMO. "There was a lot of resource, but it was not distributed in a way that people could access it. There was a lack of coordination over equipment both in the US and Canada during this pandemic. How will that be different next time?"

Mr. Hargan responded, saying that it was important to understand the signals coming in for demand, and to separate those from the noise. "This is a big problem. Federal government has to rely on state government officials to give us a reality check on what is needed."

The problem, he said, was that people had to react to reports that came out of nowhere, for example a large city called them in the middle of the night and said they needed 500 ventilators "before 8:00 AM tomorrow due to a surge." At 2:00 AM, calls were received to say the former information was false. "At this point we were already getting pallets together to move ventilators to the city. By the time this information arrived lots of people and resources had already been committed," said Mr. Hargan.

He explained that they saw signals like this coming in all the time. New York was an example, of "wanting everything now." But often, he stressed, upon checking need with various health governors, they received a reality check of what was needed

"Sometimes, we had to make a decision about supplies based on a story or a call that came in. This is the dilemma going forward: how do we separate out the signals from the noise, the truth from the false information? There were lots of signals going on – for example images of nurses in trash bags that were false. There were political statements being made.

"At other times, a hospital administrator would say they're going to run out of an item in two weeks, while other places were running out in three days. We had to prioritize. We have to ask where is this information from, who's giving it to us, is it real, is it claims data or clinical data?"

Indeed, there were a lot of emotional reactions, not based on data. "Panic kills," said Mr. Hargan. "Emotion is a good thing and a bad thing, but in many cases it was taking us away from the truth. And, when it comes down to resource allocations, and we are stretched, then we are making decisions based on reality. This isn't an area for over-reacting."

"We need data dashboards, and we need to ask how they're made up and where the sources are. And ask if they get down to reality, and show what is actually taking place."

#### AATS DAILY NEWS

Publishing and Production Captivate Media Limited contact@captivatemedia.co.uk www.captivatemedia.co.uk

**AATS President** Shaf Keshavjee

Marketing Manager Alexis Merry

Editors

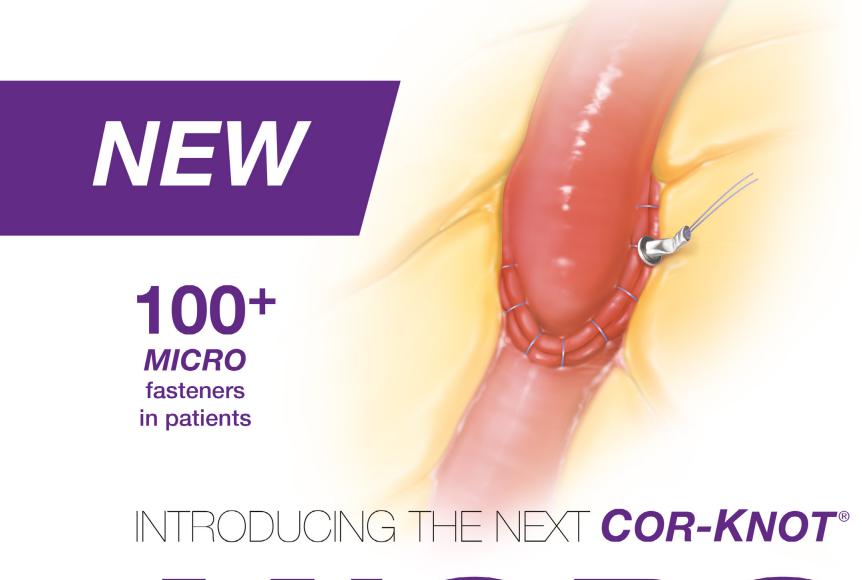
Tatum Anderson Caroline Chambers Becky McCall Marc Allen Michelle Roberts

Design

Peter Williams

Copyright © 2022: AATS. All rights reserved.

No part of this publication may be reproduced, stored in a retrieval system, transmitted in any form or by any other means, electronic, mechanical, photocopying, recording or otherwise without prior permission in writing from the AATS or its associated parties. The content of AATS Daily News does not necessarily reflect the opinion of the AATS 102nd Annual Meeting, its Chairs, Scientific Advisors or Collaborators.



# MICRO



**SOLUTIONS®** 

Page 4 102nd Annual Meeting AATS **Issue 2** May 14–17, 2022

Screening, Staging, Treating Early Stage Lung Cancer Room 312 Saturday 4:15 PM

# Lung cancer screening in 2022

Betty Tong from Duke University Medical Center, Durham, NC, USA, tackled the topic of lung cancer screening on Saturday afternoon, walking the audience through the current screening landscape, unmet needs, and strategies to improve adherence. AATS Daily News spoke to Dr. Tong to gather her brief perspectives on the status of lung cancer screening in 2022.

**National Lung Screening** Trial (NLST) and NELSON have proven that lung screening can have a dramatic effect on saving lives, don't screening rates still have a long way to go? Yes, that's true. The latest studies imaging facilities for show that national screening rates are hovering around 5% - that is, only 5% of screeneligible patients are actually getting a low-dose computed tomography (LDCT) scan of the chest. The newest United States Preventive Services Taskforce (USPSTF) guidelines have a lower age and smoking history requirement. With this, an even larger number of individuals are eligible for LDCT screening, and it remains to be seen if there is a proportional change in the

While studies such as the

#### What are your thoughts on improper follow-up (according to guidelines), especially in selfpaying individuals?

number of people who actually

do get their CT scan.

Nationally, adherence to annual screening for people with normal or benign baseline CT scans ranges from 12 to 91%, with the mean around 55%. In some patient populations it's even lower. Unfortunately, when adherence drops that low, some modeling studies have suggested that we lose the beneficial effects of screening.

Adherence to screening guidelines and follow-up is suboptimal right now. One way to improve this would be to provide screening through a centralized program. This, in and of itself, has been shown to be strongly predictive of patient adherence.

#### What about a lack of proper screening?

Our group's prior research has shown that geographic access to CT scanners varies widely throughout the country. There are some patients who live more than 200 miles from a CT facility that is accredited by the American additive process where one College of Radiology. With inflation and gas prices today, it's not likely at all that these patients are going to take the time, or pay Shared decision-making is the money, to get to that scanner a core component of lung for a screening study.

Are there particular demographics failing to receive sufficient screening experience, there is wide for lung cancer? What's the fallout?

Uninsured and underinsured

"Adherence to screening guidelines and follow-up is suboptimal right now. One way to improve this would be to provide screening through a centralized program. This, in and of itself, has been shown to be strongly predictive of patient adherence."

**Betty Tong** 

"It's a really exciting time for lung cancer screening. There are studies underway evaluating the role of serum biomarkers, or 'liquid biopsy,' as well as artificial intelligence and radiomics, as possible adjuncts to low-dose CT scans."

#### **Betty Tong**

patients are likely not being screened at rates that insured patients are being screened. Currently, coverage for LDCT screening is not mandatory for patients with Medicaid. Unfortunately, these patients have smoking rates that are more than twice those of patients with private insurance and Medicare. So, it's an problem may be compounded by another.

cancer screening, but are their challenges, especially in terms of consistency?

Absolutely. In our institutional variability in documentation of shared decision-making, much less how it's delivered.

#### Are there misconceptions about lung screening at both patient- and provider level that should be better explored?

Yes there are. Several studies have shown that there is a lack of buy-in from providers. As an example, the USPSTF and Centers for Medicare & Medicaid Services have endorsed and approved LDCT screening since 2013 and 2015, respectively, based on Level 1 evidence in the NLST showing a reduction in lung cancer mortality with LDCT screening. But despite this, the American Academy of Family Physicians, did not recognize or endorse LDCT screening until the last year or so.

Some of my colleagues have also demonstrated that there are patient-related barriers to both initial screening, as well as compliance with annual follow-up.

#### Many would assume that COVID-19 will have had a rather detrimental impact on lung cancer screening. What's the realworld evidence?

Right now there are few studies on this topic. Probably the best one was published in CHEST recently. It might surprise you to know that screening rates were reasonably stable, albeit low, in 2020 compared to 2019. Our colleagues in Italy showed that screening can be done safely

"Geographic access to CT scanners varies widely throughout the country. There are some patients who live more than 200 miles from a CT facility."

#### **Betty Tong**

in the setting of the COVID pandemic with specific safety and cleaning protocols.

#### What's important going forward?

While some really important work There are studies underway has been done to demonstrate the efficacy of LDCT screening for biomarkers, or 'liquid biopsy,' as lung cancer, we must continue in our efforts to increase screening uptake in appropriate individuals,

and help them remain adherent to guidelines for follow-up. Education of patients, as well as our colleagues, is paramount.

In fact, it's a really exciting time for lung cancer screening. evaluating the role of serum well as artificial intelligence and radiomics, as possible adjuncts to LDCT scans.

#### Congenital Summit

Monday, 1:45 PM, Room 210

**MODERATORS Christopher Caldarone** Texas Children's Hospital

Glen Van Arsdell UCLA Ronald Reagan Medical Center

he Monday afternoon Congenital Summit is a highlight session featuring a keynote lecture, top ranked abstracts, and an AATS consensus presentation on tetralogy of Fallot. The agenda is packed with important and hot topics. It is easy see why it is featured as a Summit session!

Frank Hanley opens the event with a Keynote Lecture entitled William's Syndrome: Supravalvar, Arch, Coronaries, and Pulmonary Arteries: Is Comprehensive Repair Advisable and Achievable? Dr. Hanley has once



**Christopher Caldarone** 

again made a major contribution in changing the way we think about a congenital condition involving the pulmonary arteries. He will highlight innovation and educate on the extent of correction that can be achieved including his unique approach to



Glen Van Arsdell

peripheral pulmonary artery stenosis. A European multicenter study looking at en bloc double root

translocation for various forms of transposition and double outlet right ventricle is the first abstract to be presented. Dr. Victor Morell will

discuss the manuscript to help define the nuances of this study.

The Boston group follows with a presentation on staged septation of double-inlet left ventricle. Septation for complexity has been a reoccurring theme this decade. Have we made progress in this endeavor, or are the pitfalls of the previous attempts still present? As the invited discussant, Dr. Jonathan Chen will provide insight and questions.

Aortic arch growth in repaired coarctation continues to be a vexing issue that is approached differently by different institutions. The Helsinki group looks specifically at reintervention and arch growth for those having a small arch dichotomized above or below a z value of -3. The invited discussant, Dr. Kristine Guleserian, will lead the discussion regarding the surgical decision-making and implications.

The AATS is undertaking a series of consensus documents for important topics. Sitaram Emani and Pirooz Eghtasady have led the herculean task of creating a consensus document for newborn tetralogy management. Dr. Emani will present the teams findings of an extensive literature review and expert panel strategy. The presentation will help surgeons understand what the data supports, current trends, and where there are gaps in knowledge.

The afternoon then rounds out with an abstract culled from a large administrative dataset demonstrating that 20% of newborn hypoplastic left heart syndrome do not undergo surgical treatment. The Cincinnati team's paper will be discussed by Dr. Adil Husain who will help to define the highlights of the findings.

The presenters will then join for a panel discussion and questions from the audience.

events.aats.org/102nd-annual-meeting 102nd Annual Meeting AATS Page 5

Minimally Invasive Mitral Masterclass Room 302 Sunday 7:30 AM

# Neochordal reconstruction: pearls and pitfalls

minimally invasive mitral masterclass was featured on Sunday morning, where a number of invited experts gathered to present their perspectives on this important branch of valvular care. In his talk, Volkmar Falk (German Heart Center Berlin, Germany) offered some 'pearls and pitfalls' of neochordal reconstruction.

Chordal replacement, or the so-called 'respect approach', harnesses artificial neochordae to resuspend prolapsed segments of the affected leaflet. Conversely, the 'resect approach' involves resection of the diseased leaflet segment, after which the remaining segments are sutured together.'

"Resection techniques are less forgiving. An imperfect result is difficult to correct as the amount of remaining tissue is already reduced."

#### Volkmar Falk

Giving a brief snapshot of his talk to AATS Daily News, Professor Falk relayed the modern consensus that the 'perfect' mitral valve repair includes a line of coaptation below the annulus, at least 2:1 anterior/posterior leaflet ratio (better 3:1), coaptation length at least 6–8 mm, and no causal inflow gradient.

While both resection and artificial chordae are methods to achieve such a repair, resection has been associated with a number of challenges, including restoration of normal coaptation length, mis-sizing of the valve orifice, and the limiting of re-repair options later on. "Resection techniques such as triangular or quadrangular resection of the posterior leaflet can effectively reduce leaflet height, and correct prolapse," said Professor Falk. "However, after such a correction, often the posterior leaflet is largely immobile, and the coaptation depth is limited.

"In addition, the lack of abundant tissue typically leads to the implantation of smaller annuloplasty rings. Also, resection techniques are less forgiving. An imperfect result is difficult to correct as the amount of remaining tissue is already reduced."



In contrast, leaflet-preserving techniques using neochordae provide a large coaptation area that reduces the stress on the leaflets, while maintaining leaflet mobility, noted Professor Falk. "Some studies found lower inflow gradients with these so-called 'respect' techniques," he said.

"A recent meta-analysis that compared resect versus respect techniques found lower mean gradients and larger annuloplasty rings with the respect technique." While this meta-analysis has its methodological limitations, it seems that the respect techniques also offer an advantage with regard to the long-term need for reoperation for recurrence of mitral regurgitation. Freehand

neochordae techniques may lead to unintended shortening during knot tying, and result in leaflet restriction. The use of preformed loops can largely avoid this problem."

There are situations where combined approaches are warranted, noted Professor Falk: "In patients with multi-segment prolapse, such as in Barlow's disease, a combination of techniques may be useful. Large posterior prolapse can also lead to systolic anterior motion, if the neochordal length is not appropriately chosen."

Touching on what might be next for this arena, Professor Falk highlighted transapical neochordae, which have been successfully applied in a number of cases. "At this time, patient selection is key:

"It seems that the respect techniques also offer an advantage with regard to the long-term need for reoperation for recurrence of mitral regurgitation."

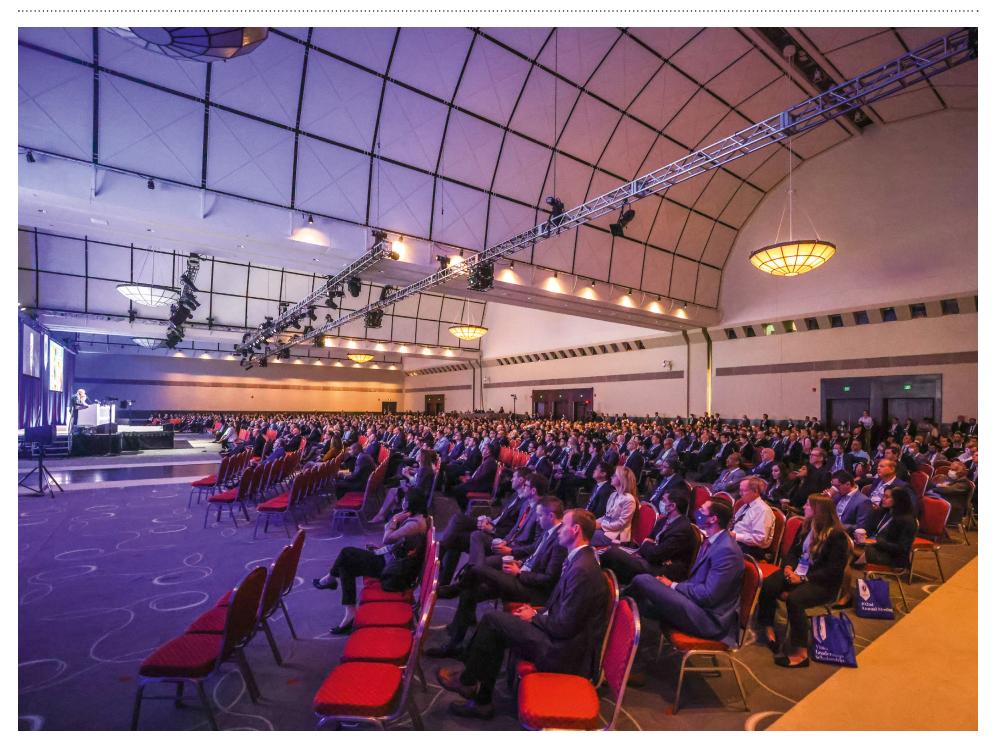
#### **Volkmar Falk**

indications are limited to simple pathologies (such as P2 prolapse) and normal annular geometry, as no ring annuloplasty is supporting the repair. But early results are encouraging."

Concluding with his overarching message for the AATS Daily News readers, Professor Falk commented: "The use of preformed loops facilitates mitral repair and allows for reconstruction of most pathologies ranging from simple P2 prolapse to multi-segmental disease. It is important to respect the midline principle, and use appropriate length selection to preserve leaflet mobility. Over correction – should it occur – can be easily addressed by changing the fixation depth at the leaflet level. Finally, all loops should be connected, as unconnected loops can cause arrhythmia."

#### References

 Sá MP, Cavalcanti LRP, Van den Eynde J, et al. Respect versus resect approaches for mitral valve repair: A study-level meta-analysis [published online ahead of print, 2022 Jan 18]. Trends Cardiovasc Med. 2022;S1050-1738[22]00007-X.



Page 6 102nd Annual Meeting AATS Issue 2 May 14–17, 2022

Extracorporeal Lung Support and Transplant Room 312 Monday 1:45 PM

#### 'Consensus on mechanical circulatory support is needed'

roposals for a new AATS consensus document on the use of mechanical circulatory support (MCS) for lung transplantation will be introduced this afternoon by Matthew G. Hartwig, Associate Professor of Surgery, Division of Thoracic Surgery at the Duke University Health System (NC, USA). Dr. Hartwig is a general thoracic surgeon with a particular interest in end-stage lung disease and lung transplantation. "In order to provide the best care possible for our patients with lung failure or requiring lung transplantation, thoracic surgeons require knowledge and expertise in mechanical devices that can support the failing lung," he told AATS Daily News.

According to Dr. Hartwig, MCS for lung or heart failure has changed considerably over the years. "With improvements in pump technologies, requisite cannulas and tubing, and miniaturization of circuits (for example), the use of these devices is changing rapidly," he said. Those improvements, and the way in which they are used, mean there are relative merits of different devices. "There is a suggestion that gaps in practice for the nuances of using MCS exist, and that the transplant community lacks clear, comparative evidence to demonstrate superiority of one technique over another."

Dr. Hartwig is one of the co-chairs of the AATS expert committee working alongside surgeons such as Victor van Berkel from the University of



"Establishing an expert consensus document would be the most appropriate way to meet our needs."

Matthew G. Hartwig

Louisville (MO, USA). He will explain the thinking, therefore, behind the consensus document. "The AATS believes it's important to provide the latest guidance on how to best use modern MCS to benefit our patients before, during, and after lung transplantation," he said. "Establishing an expert consensus document would be the most appropriate way to meet our needs."

The fact is there can be considerable variation in how different lung

transplant programs and different surgeons utilize MCS technologies. "Understanding those differences and how they impact outcomes would go a long way toward helping surgeons continue to make the right choices, and optimize outcomes," said Dr. Hartwig. To help with that understanding, the AATS has supported an international, multicenter registry detailing the use of extracorporeal life support (ECLS) before, during and after lung transplantation.

"The AATS believes it's important to provide the latest guidance on how to best use modern mechanical circulatory support to benefit our patients before, during, and after lung transplantation."

Matthew G. Hartwig

Dr. Hartwig is on the steering committee of this so-called ECLS in lung transplantation (LTx) registry, that is led by Gabriel Loor of Baylor College of Medicine (TX, USA). The ECLS registry currently collects data from seven US and two European centers. "It is exciting that hundreds of patients have already been enrolled in the ECLS LTx registry, and from this work we hope to learn how best to use these technologies," he said.

Dr. Hartwig said one of the biggest challenges in this field is the lack of high-level evidence to support current practices. "This remains a relatively low-volume, niche field where individual centers lack sufficient volumes to perform well-controlled studies," he explained. "That, combined with the multiple variations in how MCS can be performed, remains the Achilles' heel to better reach consensus."

Collecting data within such a document is an important first step in the quest for consensus, and should help to form the basis for future research efforts in this space, said Dr. Hartwig. "Like the ECLS LTx registry, the community would benefit greatly from a multicenter clinical trials organization and infrastructure through which we could perform prospective and randomized clinical trials that provide the level of evidence to clearly guide practice and build consensus," he added.

For example, one persistent and unresolved concern with MCS in lung transplantation remains

what optimal form of MCS, if any, should be utilized during the actual explant and implantation of the donor lungs. "There continues to be strong disagreement among those who believe that their chosen technique – be it cardiopulmonary bypass, extracorporeal membrane oxygenation, or non-mechanical support - is the optimal choice," said Dr. Hartwig. A high-quality, prospective, randomized clinical trial would go a long way toward defining the optimal mechanical support, if any exists, for lung transplantation, he said. "This type of study could also go a long way toward helping understand the mechanism of primary graft dysfunction following lung transplantation, and whether the use of mechanical circulatory support would be propagative or protective," he said.

Of course, reaching consensus might see some pushback, conceded Dr. Hartwig. "Any time a guidelines or consensus document tackles a topic with so much heterogeneity and such a low level of evidence in the literature, there will always be some degree of consternation and disagreement among the readership," he concluded. "Consensus does not mean unanimity, and therefore real-world practice and opinions will necessarily vary somewhat with that published in the guidelines."

#### References

 Loor G, Huddleston S, Hartwig M, et al. Effect of mode of intraoperative support on primary graft dysfunction after lung transplant [published online ahead of print, 2022 Feb 4]. J Thorac Cardiovasc Surg. 2022;S0022-5223[22]00119-2.





Save the Date

May 4-5, 2023 New York Hilton Midtown New York, NY, USA

For more information, visit aats.org/mitral

**Program Directors** 

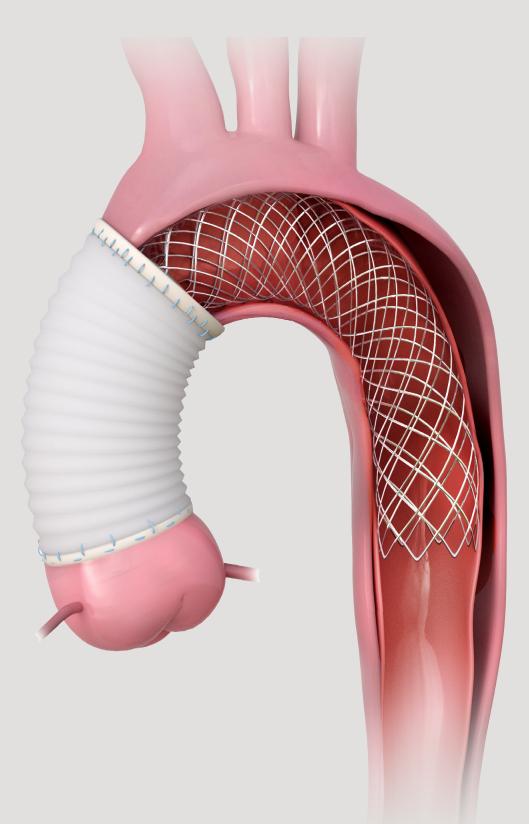
David H. Adams Anelechi C. Anyanwu

# FDA Accepts IDE Application

# PERSEVERE

# **Pivotal IDE Study**

A **P**rosp**E**ctive, Single A**R**m, Multi-Center Clinical Inve**S**tigation to **EV**aluat**E** the Safety and Effectiveness of AMDS in the T**RE**atment of Acute DeBakey Type I Dissection



#### **Intended Use**

AMDS is intended for aortic repair, aortic remodeling, and re-expansion of the intimal flap within the ascending aorta, aortic arch, and into the descending aorta for patients with acute DeBakey type I aortic dissection undergoing open surgical repair within 0 to 14 days after diagnosis.

Visit **Booth #1623** to learn more about this Clinical Trial.

Except as otherwise noted, all trademarks are owned by Artivion, Inc. or its subsidiaries. The AMDS is approved as an Investigational Device only and is not approved for commercial use in the US. Not all products and indications are available or approved in all markets. © 2022 Artivion, Inc. All rights reserved.

MLENG1548.000 (2022-05)



Page 8 102nd Annual Meeting AATS Issue 2 May 14–17, 2022



## The AATS Foundation

.....

he AATS Foundation honored awardees, mentors, donors, and partners at the AATS Foundation Reception on Sunday. Each year, the Foundation honors incoming awardees and welcomes back a number of former recipients whose careers have been positively impacted by the funding they received. Thanks to the support of Foundation constituents, educational and research initiatives continue to thrive. Donors and partners are making a significant impact on the careers of future leaders.

Dr. David Adams, President of the AATS Foundation, shared details about the *Get Together*, *Give Together* campaign, a special initiative in recognition of the AATS 102nd Annual Meeting. Reiterating the importance of giving back, Dr. Adams thanked those wearing donor pins this year – a true testament to the generosity of the community. The engagement and support of donors and partners is critical to the Foundation's ongoing success.

AATS Foundation leadership proudly shared information on the unique program offerings including the Cardiac Surgical Robotics Program, Valerie Rusch Mentored Career Development Award, and the newly established Honoring

Our Mentors Program recognizing Professor Alain Carpentier.

AATS President-Elect, Dr. Yolonda Colson reflected on the overwhelming support of the Rusch program, highlighting the enormous respect for Dr. Rusch and the impact of her contributions to thoracic surgery and the importance of supporting women in the field globally.

Dr. Rusch stated, "It is my firm belief that we have the obligation to give back to others around the world who may not have had that privilege. I look forward not only this year, but in future years, to seeing this award work to that end to promote transfer of knowledge in career development for younger surgeons in somewhat less fortunate environments, and to help us build the specialty around the world."

The reception was an opportune time to recognize awardees, who are the future of the cardiothoracic field, along with donors, whose generous contributions ensure that the mission of the Foundation is fulfilled.

Please visit aatsfoundation.org to make a gift, learn more about our programs, and view award opportunities currently accepting applications.



.....



Member for a Day Session
Saturday, 4:00-6:00 PM

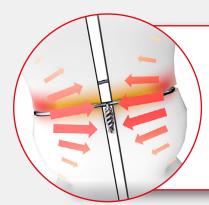
On Saturday, May 14, Member for a Day awardees and trainees joined us for a two-hour session with a panel of AATS members, AATS leadership, and senior fellows. Faculty offered guidance to trainees concerning pathways in cardiothoracic surgery, why they love being cardiothoracic surgeons, as well as what is means to be a part of the American Association for Thoracic Surgery. The session was followed by a reception offering light appetizers and beverages for socializing and networking with AATS members, mentors, and trainees.

# **Better Outcomes**

don't always come at high costs

LSS

**Longitudinal Sternal Stabilization** 



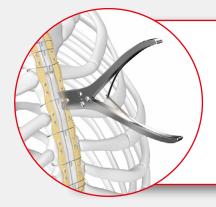
5.6x fewer patients with DSWIs<sup>1</sup>



3-Day reduction in length of stay<sup>1</sup>



2.1x more patients healed at 90 days post-op<sup>1</sup>



Zero Cost re-entry

1. Madjarov JM, Katz MG, Fazal S, Kumar A, Madzharov S, Handa A, Madjarova SJ, Robicsek F. Use of Longitudinal Rigid Sternal Fixation in Prevention and Treatment of Wound Complications Among High-Risk Patients After Cardiac Surgery.

J Card Surg. 2021 May 30. doi: 10.1111/jocs.15687

To learn more about LSS and other thoracic products, please visit: https://www.klsmartin.com/en-na/products/implants-thd\_acic/implants-sternal-closure/

KLSmartin

1

1

1

1

GROUP
klsmartinnorthamerica.com

Page 10 102nd Annual Meeting AATS Issue 2 May 14–17, 2022

Cardiothoracic Surgical Trials Room 304–306 Monday 7:30 AM

# FAME 3 closes the gap for CABG vs. PCI

n important trial evaluating fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) compared with coronary artery bypass graft (CABG) surgery will be under discussion this morning by William F. Fearon, a professor of medicine and the director of interventional cardiology at Stanford University School of Medicine, and the Chief of the Cardiology Section at the Palo Alto VA Health Care System (CA, USA).

Professor Fearon told AATS Daily News about his role as principal investigator for the Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) 3 trial. During the session, Professor Fearon will discuss the design of and rationale behind the trial, noting that, until recently, patients with three-vessel coronary artery disease had been found to have better outcomes with CABG than with PCI. Large, randomized trials have showed improved outcomes in patients with three vessel coronary artery disease when coronary revascularization was performed with CABG compared to PCI. They include the 1900-strong Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM)1 and Bypass Surgery Versus Everolimus-Eluting Stent Implantation for Multivessel Coronary Artery Disease (BEST)2 trials.

Second-generation drug-eluting

stents have improved early- and late outcomes, leading to lower rates of associated stent thrombosis, spontaneous myocardial infarction, restenosis, and death than first-generation drug-eluting stents.

"But studies in which PCI is guided by measurement of FFR have been lacking," said Professor Fearon.

The thinking is that FFR is an index, measured with a coronary pressure wire, that provides a more accurate assessment of the hemodynamic significance of a coronary stenosis than an angiogram alone. Professor Fearon's FAME 3, therefore, is a multicenter, international, non-inferiority trial, with a total of 1,500 patients undergoing randomization at 48 centers. Patients with three-vessel coronary artery disease were randomly assigned to undergo CABG or FFR-guided PCI with current generation zotarolimus-eluting stents. The primary end point was the occurrence of a major adverse cardiac or cerebrovascular event at one year, defined as death from any cause, myocardial infarction, stroke, or repeat revascularization.

Professor Fearon will discuss the main results from the trial<sup>3,4</sup> during his talk. Giving a snapshot ahead of time, he noted that one-year incidence of the composite primary end point was 10.6% among patients randomly assigned to undergo FFR-guided PCI, and 6.9% among those assigned to undergo CABG – findings that were not consistent with non-inferiority of



"Surgeons will likely feel that CABG is better in all cases, while interventional cardiologists will likely feel that there is a role for PCI in patients with multivessel disease."

#### William F. Fearon

FFR-guided PCI. The incidence of death, myocardial infarction, or stroke was 7.3% in the FFR-guided PCI group, and 5.2% in the CABG group. The incidences of major bleeding, arrhythmia, and acute kidney injury were higher in the CABG group than in the FFR-guided PCI group.

Professor Fearon added that FFR-guided PCI with current generation drug-eluting stents did not meet the criterion for non-inferiority when compared with CABG. "We discovered that outcomes after PCI have improved significantly using FFR and newer

stents when compared to historical control. Outcomes after CABG have also improved," said Dr. Fearon. "Finally, the difference in outcome between the two strategies has decreased."

Both patients and physicians now have more contemporary data in order to make informed and shared decisions, reasoned Professor Fearon. "Surgeons will likely feel that CABG is better in all cases, while interventional cardiologists will likely feel that there is a role for PCI in patients with multivessel disease," he explained.

Professor Fearon said he'd like to see further studies into CABG. "Hybrid procedures comparing minimally invasive CABG plus PCI to traditional CABG would be interesting to study."

Offering his take-home message for the FAME 3 trial: "We now have updated data regarding clinical outcomes and quality of life after PCI and CABG in patients with multivessel coronary artery disease, which can help guide decisions regarding the optimal strategy for a particular patient."

#### References

- Farkouh ME, Domanski M, Sleeper LA, et al. Strategies for multivessel revascularization in patients with diabetes. N Engl J Med. 2012;367(25):2375-2384.
- Park SJ, Ahn JM, Kim YH, et al. Trial of everolimus-eluting stents or bypass surgery for coronary disease. N Engl J Med. 2015;372[13]:1204–1212.
- Fearon WF, Zimmermann FM, De Bruyne B, et al. Fractional Flow Reserve-Guided PCI as Compared with Coronary Bypass Surgery. N Engl J Med. 2022;386(2):128-137.
- Fearon WF, Zimmermann FM, Ding VY, et al. Quality of Life After Fractional Flow Reserve-Guided PCI Compared with Coronary Bypass Surgery [published online ahead of print, 2022 Apr 2]. Circulation. 2022;10:1161/CIRCULATIONA-HA122.060049.



Vision. Leadership. Scholarship.

# Surgical Treatment for Arrhythmias and Rhythm Disorders



Save the Date

December 9–10, 2022 The Westin Boston Seaport District Boston, MA, USA

For more information visit **aats.org/stars** 

**Program Directors** 

Ralph J. Damiano, Jr. A. Marc Gillinov

Cardiothoracic Careers College Room 311 Saturday 10:00 AM

# Regionalization a must for better outcomes

ealing with bullies, bias, and burnout was the order of business on Saturday during the Cardiothoracic Careers College, with Jennifer Romano, a congenital heart surgeon at the University of Michigan (MI, USA) and the Second Vice President to the Society of Thoracic Surgeons, stepping up to the podium to share her insights. Her practice encompasses all elements of pediatric cardiac surgery, with a focus on neonatal surgery and hybrid interventions. "I am also one of the very few women in my specialty, and will serve as the first female president," she told AATS Daily News.

"By virtue of the hurdles that I have overcome to get to my current position, I have faced all of the challenges discussed in this session." She added that there are so many talented individuals interested in joining and succeeding in this profession. "I wanted to contribute whatever wisdom I may have to make their path easier. I am certainly not an expert – rather a lifelong learner and a survivor!"

"It's important to determine when you can make a difference, and when you will be banging your head against the wall."

**Jennifer Romano** 

In the session on Saturday, Dr. Romano spoke about the importance of self-awareness, personal reflection, friends and feedback, and an ongoing commitment to self-improvement. "Some of this is about picking your battles," she advised. "It's important to determine when you can make a difference, and when you will be banging your head against the wall. My biggest pearl of wisdom is the importance of self-preservation, and how easily that can be threatened."

Dr. Romano did not present a great deal of data – instead she focused on framing the concepts and management strategies based on various coaching materials and self-experience. The thinking behind such strategies, she said, was that bullying could and should be seen in context with ongoing initiatives. "The entire field of medicine, and surgery in particular, is placing increasing focus, and appropriately so, on concepts of wellness and safe work



environments," she said. "Minimizing bias and removing bullies are cornerstones of these initiatives, along with addressing the epidemic of burnout among physicians."

Dr. Romano added that she did not think it is controversial to talk about such topics. "Certainly, components are opinion," she added. "There any many strategies individuals can use."

The greatest challenge is helping people make these concepts a priority, said Dr. Romano. "We are so busy with academic efforts, patient care, and advancement that these 'softer skills' have historically not received the attention they are due," she said.

Just raising awareness is enough, therefore. "It's important to know that it's ok to speak up about these issues, and ask for help," she added.

Burnout among physicians is on the rise, and the recent pandemic has only added to the stressors. Even before the

pandemic, national data suggested that 44% of US physicians experience symptoms of burnout, characterized by emotional exhaustion and/or de-personalization, at least weekly.¹ Medical errors are then a risk. "We cannot truly be the best to our families and patients if we are struggling in a difficult work environment, or overcome with commitments and expectations," said Dr. Romano.

By way of a challenge to fellow delegates, Dr. Romano mentioned an encounter with an executive coach. "It is a bit depressing, but she asked me to write my obituary as if it was tomorrow," she said. "She asked me if it would say what I wanted my legacy to truly be. It was a sobering exercise that helped to rebalance my priorities."

#### References

 Shanafelt TD, West CP, Sinsky C, et al. Changes in Burnout and Satisfaction With Work-Life Integration in Physicians and the General US Working Population Between 2011 and 2017. Mayo Clin Proc. 2010;6(1):1829-1869.

# MITRIS RESILIA™ Mitral Valve

A mitral-specific tissue valve designed with the lowest profile



Important Safety Information: MITRIS RESILIA Mitral Valve

Indications: For use in replacement of native or prosthetic mitral heart valves. Contraindications: There are no known contraindications with the use of the MITRIS RESILIA mitral valve. Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information.

© 2022 Edwards Lifesciences Corporation. All rights reserved. PP--US-7084 v1.0



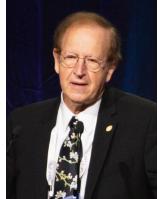
Page 12 102nd Annual Meeting AATS **Issue 2** May 14–17, 2022

# Noted abstracts at the **AATS 102nd Annual Meeting**

Presidential Plenary Session Ballroom ABC Monday 9:45 AM

165. Extending Cold Static Preservation at 10°C to Avoid Overnight Lung Transplantation: A Prospective Multi-Center **Proof-of-Concept Clinical Trial** 





Abstract presenter Marcelo Cypel Toronto General Hospital, Toronto, ON, Canada Invited discussant Joel Cooper Hospital of The University of Pennsylvania, PA, USA

#### **Abstract**

**Objective:** In preclinical studies, we have demonstrated that cold static preservation (CSP) at 10°C is an effective and reliable strategy for prolonged (>24h) preservation of pulmonary grafts, with underlying protective mechanisms related to the maintenance of mitochondrial health (Science Trans Med, 2021). Here, we report on a prospective multi-center clinical trial designed to investigate the feasibility of intentionally prolonging CSP at 10°C to avoid overnight (10pm - 6am) lung transplants.

**Methods:** To date, 40 consented patients have been enrolled in this prospective, non-randomized, single armed, multi-center study (n=63 target, NCTo4616365). Donors with cross clamp times between 6pm and 4am were allowed to be enrolled in the study with the earliest allowed transplant starting time of 6am. Donor exclusion criteria included the need for ex vivo lung perfusion, while recipient exclusion criteria included retransplantation and multi-organ transplantation. Lungs meeting study criteria were retrieved and transported in the usual fashion using a cooler with ice. Immediately upon arrival to the transplant hospital, lungs were transferred to a 10°C temperature-controlled refrigerator until implantation. The primary outcome of this study was incidence of ISHLT Primary Graft Dysfunction (PGD) Grade 3 at 72h, with secondary endpoints including: recipient time on the ventilator, ICU Length of Stay (LOS), hospital LOS, 30-day survival and lung function at 1-year. Outcomes were compared to a contemporaneous cohort of recipients at each center selected using propensity score matching for medical diagnosis, BMI, recipient status, and donor type at a 1:2 ratio.

Results: Currently, 37 patients have achieved at least 30 day follow up and were included in the analysis. The median recipient age was 65 years (55 - 74 years). Most patients (97%) received bilateral lung transplantation. Donor and recipient characteristics, and recipient outcomes are shown in Table 1. Mean CSP was significantly longer in the study group vs. matched controls for both the first (11h  $\pm$  2.6h vs. 6.1h  $\pm$  1.9h; p<0.001) and second implanted lung (13h  $\pm$  2.8h vs. 8.1h  $\pm$  2.1h, p<0.001). PGD 3 at 72h was 3% in the study group vs. 11% in matched controls (p=0.27). No differences were seen in the need for post-op ECMO (5 vs.

9%; p=0.72), patients extubated by 72h (76 vs. 70%; p=0.66), median ICU LOS (5 vs 5 days; p=0.53), and median hospital LOS (24 vs. 23 days; p=0.33). In a median follow up of 248 days, 2 study patients have died at days 136 and 370 from sepsis and lymphoma, respectively.

**Conclusions:** Intentional prolongation of donor lung CSP using 10°C storage appears to be clinically safe and feasible, with promising results. Avoidance of overnight transplants using this simple approach has the potential to improve transplantation logistics and performance, potentially significantly altering practice in clinical lung transplantation.

Cardiothoracic Surgical Trials Room 304–306 Monday 7:30 AM

#### LB4. 3-Year Outcomes of the Dissected Aorta Repair Through **Stent Implantation Trial**





Abstract presenter Sabin Bozso University of Alberta Hospital, Edmonton, AB, Canada Invited discussant Eric Roselli Cleveland Clinic, Cleveland, OH, USA

**Objective:** To evaluate clinical and radiographic outcomes of the Ascyrus Medical Dissection Stent (AMDS) in a prospective, non-randomized, international study (DARTS) of patients with acute DeBakey type I aortic dissection (ATAD I). The AMDS is a hybrid prosthesis that seals and depressurizes the false lumen (FL) at the distal anastomosis, while expanding and pressurizing the true lumen (TL) to treat and prevent malperfusion and induce positive remodeling.

**Methods:** Patients were enrolled in the DARTS trial between March 2017 and January 2019; the median age was 62.5 and 67.4% (31/46) were male. The AMDS was used in combination with the standard surgical management of ATAD I to treat patients with 56.5% (26/46) and without 43.5% (20/46) pre-operative clinical and radiographic malperfusion. All patients had a primary entry tear in the ascending aorta and 97.8% (45/46) were treated with a hemiarch repair.

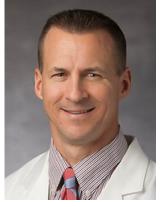
**Results:** All 47 patients underwent emergent surgical repair with successful AMDS implantation. One patient was excluded from analysis due to use in iatrogenic dissection. Overall mortality at 30-days, 1-year, and 3-years was 13.0% (6/46), 19.6% (9/46), and 21.7% (10/46) with no strokes recorded after 1-year. No devices were explanted at any time during 3-year median follow-up. Within 3-months, 6.5% (3/46) of patients required malperfusionrelated secondary procedures and 2.2% (1/46) of patients required aortic-growth related secondary procedure. No devicerelated reinterventions occurred at any time during 3-year median follow-up. Independent analysis evaluated computed tomography angiography (CTA) of the AMDS up to 4-years post-procedure.

The total aortic diameter in the aortic arch remained stable or decreased in size in 82.6% of patients. Supra-aortic vessel patency at last follow-up was 100%.

Conclusions: The AMDS is a safe, time efficient, and reproducible addition to the current standard-of-care surgical therapy in ATAD I. The use of the AMDS in the treatment of ATAD I holds promise as a simple technology that enables repair of the aortic arch and proximal descending aorta, while promoting positive aortic remodeling. The rates of secondary procedures following treatment with AMDS compare favorably with published literature. Ongoing follow-up of the DARTS trial will provide longterm, prospective, clinical outcomes and radiographic data on positive remodeling of the aortic arch.

Cardiothoracic Surgical Trials Room 304–306 Monday 7:30 AM

LB<sub>5</sub>. CoGnitive effects Of body Temperature during hypothermIC circulatory arrEst (GOT ICE trial): A Multi-Center **Prospective RCT Comparing Neurocognitive Outcomes** Following Aortic Arch Surgery





Abstract presenter G. Chad Hughes Duke University Medical Center, Durham, NC, USA Invited discussant Lars Svensson Cleveland Clinic, Cleveland, OH, USA

#### Abstract

**Objective:** Deep hypothermia has long been the standard for hypothermic circulatory arrest (HCA) during aortic arch surgery. Over the past decade, however, many centers worldwide have shifted towards lesser degrees of hypothermia in conjunction with the use of selective antegrade cerebral perfusion (sACP). This practice change has occurred mainly based upon retrospective observational clinical data, and there has yet to be a prospective study comparing deep versus moderate hypothermia during HCA that includes brain imaging/connectivity and neurological/neurocognitive outcomes. Given this lack of prospective comparative-effectiveness data, the optimal temperature for HCA remains unclear. As such, the purpose of this first-ever multi-center prospective single-blind randomized controlled trial (RCT) was to comprehensively evaluate the neurocognitive effects of deep versus low-moderate versus highmoderate HCA with sACP during aortic arch surgery.

Methods: In this National Institutes of Health (NIH) funded trial (NIH 1 Ro1 HL130443: Cognitive Effects of Body Temperature During Hypothermic Circulatory Arrest; Clinicaltrials.gov:

#### Congratulations to our Case Report and Poster Competition winners!

Case Report Winner **Brittany Potz** 

Perioperative Poster Competition Kari DiVito Boston Children's Hospital West Virginia University School

COVID+ ECMO Patients

Complete Endocardial Cannulate, Extubate, Ambulate Fibroelastosis Resection Effect of Mobility-Focused Program on Outcomes of

Perioperative Runner up Alison Davidson Mount Sinai

Reducing 30-Day Readmissions after Coronary Artery Bypass Grafting for High-Risk Populations: A Focus on Medicaid Insurance

**Poster Competition Derrick Tam** Sunnybrook Health Sciences Centre

Real World Examination of Percutaneous Coronary Intervention Versus Coronary Artery Bypass Grafting for Left Main Coronary Disease in Ontario, Canada

Poster Competition Adnan Al-Ayoubi University of Iowa

An atrial switch procedure for heart transplantation in an infant with heterotaxydextrocardia

Poster Competition Manish Karamchandani Tufts Medical Center

Outcomes following Tracheostomy for patients requiring ECMO secondary to COVID-19 Pneumonia

NCTo2834065), n=282 patients undergoing elective aortic arch surgery with HCA and sACP were enrolled from August 2016 to December 2022 at 4 enrolling sites (Baylor Scott and White, The Heart Hospital, Dallas, TX; Duke University, Durham, NC; Emory University, Atlanta, GA; University of Pennsylvania-Penn Presbyterian Medical Center, Philadelphia, PA). Patients were randomly assigned (stratified by age and sex) to 1 of 3 treatment groups: Group 1: Deep (<=20°C) hypothermia; Group 2: Lowmoderate (20.1-24.0°C) hypothermia; Group 3: High-moderate (24.1-28.0°C) hypothermia. Study aims included: 1. Determine impact of degree of hypothermia on neurocognitive function and quality of life (QOL); 2. Determine impact of degree of hypothermia on brain volume and functional connectivity in regions critical to global cognition. Table 1 details the assessments used for each study aim.

**Results:** Trial enrollment is complete with 251/282 patients having completed their 1-month follow up assessments. Magnetic resonance imaging was performed only on patients enrolled at Duke University and results are available in 119 subjects. Data analysis is ongoing, with the 1-month results available for presentation at the AATS late-breaking clinical trial session.

**Conclusions:** Data analysis from this first-ever multi-center prospective single-blind randomized controlled trial comparing neurocognitive outcomes following aortic arch surgery with varying levels of hypothermia will provide much needed objective data to help guide creation of evidence-based guidelines for optimal perfusion strategies in aortic arch surgery. In addition, the trial outcomes will be unique in their inclusion of baseline and serial postoperative detailed imaging and functional neurocognitive assessments.

Mechanical Circulatory Support: Essentials Room 302 Monday 7:30 AM

LB6. Randomized Trial of Surgical Treatment of Tricuspid Valve Regurgitation in Patients Undergoing LVAD Implantation: Interim Analysis of the TVVAD Trial





Abstract presenter Yuting Chiang
New York Presbyterian/Columbia University Irving Medical Center,
New York, NY, USA

Invited discussant Scott Silvestry AdventHealth

#### **Abstract**

**Objective:** To evaluate whether concurrent surgical correction of moderate or greater tricuspid valve regurgitation (TR) in patients undergoing LVAD implantation prevents post-operative right heart failure (RHF) compared to LVAD implantation alone.

**Methods:** Patients with moderate or severe TR on preoperative echocardiography were randomized to either LVAD implantation alone (No TVR) or LVAD implantation with concomitant tricuspid valve surgery (TVR). Randomization was stratified by pre-operative right ventricular (RV) dysfunction (none/mild vs moderate vs severe). TVR consisted of either

annuloplasty or replacement and was determined at the time of surgery at the surgeon's discretion. Patients were followed for 6 months after surgery. The primary outcome was the frequency of moderate or severe RHF, determined by an adjudication committee, using INTERMACS definitions.

**Results:** 60 patients were randomized (28 No TVR and 32 TVR). Mean age for No TVR was 58.4 versus 59.3 years old for TVR. Gender distribution was 82.1% male and 17.9% female for No TVR versus 78.1% male and 21.9% female for TVR. At 6 months, 46.43% of patients in the TVR group and 43.75% of patients in the No TVR group had experienced moderate or severe RHF. There was no significant difference in the primary outcome between the two arms (p=0.84). The frequency of moderate or RHF before discharge from the index admission was 46.4% in No TVR versus 43.8% in TVR. The frequency of severity of RHF was 38.5% moderate, 30.8% severe, and 30.8% severe acute in the No TVR group; the frequency was 42.9% moderate, 35.7% severe, 21.4% severe acute in the TVR group. The average hospital length of stay was shorter for LVAD versus TVR but did not reach statistical significance (24.9 vs 36.5 days, p=0.35). The average ICU length of stay was longer for No TVR versus TVR but also did not reach statistical significance (11 vs 8.4 days, p=1.00). Among severe adverse events, there was no statistically significant difference in all-cause mortality (p=0.82), atrioventricular block (p=0.97), major bleeding (p=1.00), prolonged mechanical ventilation (p=1.00), unplanned RVAD (p=1.00), or stroke (p=1.00). Additionally, there was no statistically significant difference in 6-minute walk test performance at 3 or 6 months between No TVR and TVR (3mo: 892.8 vs 837.7 feet, p=1.00; 6mo: 888.9 vs 915.0 feet, p=1.00).

**Conclusion:** The presence of moderate or severe TR prior to LVAD is associated with a high incidence of RHF during the first 6 months after the procedure. For these patients, TV annuloplasty or replacement at the time of LVAD implantation does not appear to lower the incidence of RHF.

**Mitral Valve Repair: Essentials** Room 302 *Monday* 1:45 PM

LB8. Pacemaker Implantation Associated with Tricuspid Repair in the Setting of Mitral Valve Surgery: Insights from a Cardiothoracic Surgical Trials Network Randomized Trial





Abstract presenter Gorav Ailawadi
University of Michigan, Ann Arbor, MI, USA
Invited discussant David Adams
Mount Sinai Health System, New York, NY, USA

#### Abstract

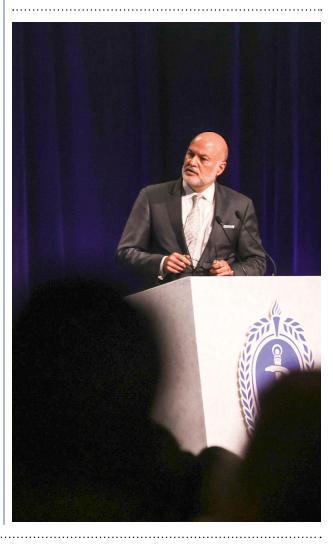
**Objectives:** In a recent CTSN trial, the addition of tricuspid annuloplasty (TA) at the time of mitral valve surgery (MVS) in patients with degenerative MR and moderate or less TR reduced the composite rate of death, re-operation for tricuspid regurgitation (TR), or TR progression at 2 years. However, this outcome was counterbalanced by an increased incidence of permanent pacemaker (PPM) implantation. We analyze here

the timing, indications, and risk factors for PPM implantation in patients enrolled in this trial.

**Methods:** We randomly assigned 401 patients undergoing MVS for degenerative MR to receive MVS with (n=198) or without TA (n=203). Two patients with PPMs at baseline were excluded. The association between potential risk factors and PPM implantation was assessed using multivariable time to event models with death and implantation for indications other than conduction abnormalities as competing risks. Potential risk factors (baseline characteristics, echocardiographic parameters, and operative details) were compared between patients with and without PPM.

**Results:** A PPM was implanted in 36 patients (9.0%) within 2 years of randomization, with 30/198 (15.2%) in those randomized to MVS+TA and 6/201 (3.0%) in the MVS alone group (RR 5.08; 95% CI 2.16-11.94; p<0.001). The indication for PPM was AV block in 50.0% (3/6) of MVS alone patients and 73.3% (22/30) of MVS+TA patients. The majority (29/36, 80.6%) of implants occurred within 30 days of surgery (Figure 1). Univariate analysis identified age, history of AF, TA procedure, and concomitant MAZE as potential risk factors for PPM within 30 days. However, in the multivariable model, TA was the only independent risk factor (HR 4.24; 95% CI 1.73-10.41; p=0.002). In the subset of patients who received concomitant TA (n=197), those who required PPM, compared with those who did not require PPM, were older (mean age: 70.9±10.2 vs. 66.0±10.7; p=0.02) and had slightly larger baseline TV annulus dimensions (43.7±4.6 vs. 41.7±4.5; p=0.03), but had similar preoperative atrial fibrillation, need for MV replacement, surgical approaches to the TV, and TV implant size. Univariate analysis identified the following potential risk factors for PPM within 30 days (23/197): age, history of AF, MV procedure type, concomitant MAZE, and TV annulus dimension. The final model included age (5 years; HR 1.23; 95% CI 0.96-1.57; p=0.096), MV replacement (HR 2.20; 95% CI 0.92-5.28; p=0.078), and TV annulus dimension (5mm; HR 1.46; 95% CI 0.95-2.26; p=0.087), but none was statistically significant. PPM implantation did not prolong index LOS and was not associated with an increase in 2-year mortality risk.

**Conclusions:** Our study identified concomitant TA as the only independent risk factor for PPM implantation in patients undergoing MV surgery for degenerative MR. Larger studies with longer follow-up are needed to identify additional risk factors and fully assess the impact of PPM implantation on clinical outcomes in these patients.



## Know Earlier. Intervene Sooner. Improve Outcomes.







Page 14 102nd Annual Meeting AATS Issue 2 May 14–17, 2022

**Aortic Dissection Masterclass Room 304–306** Tuesday 8:00 AM

# 'Live to fight another day'

## Maximizing survival after Type A dissection

Opening Tuesday's Aortic Dissection Masterclass will be Leonard Girardi (Weill Cornell Medicine, New York, NY, USA) who will present his views on how to 'live to fight another day' after acute Type A aortic dissection (ATAAD). Dr. Girardi was one of the authors of the 2021 AATS Expert Consensus Document on the surgical treatment of ATAAD, the aim of which was to provide surgeons with a wide range of experience a summary of best practices in dissection diagnosis, operative treatment and follow-up after surgery.

s Dr. Girardi described, the writing group for this document was a well-rounded cohort of very experienced surgeons from centers with a high volume of aortic surgery cases who also have access to the latest innovations and technology to improve the outcomes for these desperately ill patients.

AATS Daily News caught up with Dr. Girardi to catch a glimpse of the main messages he will be presenting during his talk.

# Perhaps we can start by framing the incidence and devastation of ATAAD? While relatively uncommon, don't mortality rates escalate quickly with time unless treated, and even then, remain relatively high?

While rare relative to more common cardiovascular conditions such as coronary artery disease, ATAAD is being recognized with greater frequency, as cardiologists caring for patients with aneurysms – as well as emergency department physicians – recognize the signs and symptoms of an acute dissection more readily.

Despite the initiation of front-line antiimpulse therapy, mortality is still estimated at approximately 1% per hour from the time symptoms begin, until an operation is undertaken. Should malperfusion, shock, contained rupture, and other dissection-related complications arise, the mortality for even a promptly performed operation will escalate dramatically.

"Resolution of malperfusion is always a focus of ATAAD treatment. Sometimes it may be appropriate to attempt endovascular resolution of a malperfusion syndrome before open repair. However, those situations mandate significant endovascular experience."

**Leonard Girardi** 

Is prompt surgical intervention applicable for the majority of patients? What about those with neurological deficits? And is transfer to a dedicated aortic center reasonable if surgery is not immediately available?

Prompt surgical intervention is the treatment of choice for an overwhelming majority of patients presenting with ATAAD, including those with neurologic deficits. Patients with advanced neurologic injury and other significant comorbidity may be considered for palliative care under certain circumstances, but a gratifying percentage of patients presenting with focal deficits will recover neurologic function after ATAAD repair. Transfer to a dedicated center is reasonable if surgery at the center of diagnosis is not available, or if complexity suggests a better opportunity for success in more experienced hands.

Open surgery is the gold standard, and thoracic endovascular aneurysm repair is still in the experimental phase. For patients with prohibitive risk for surgery, an endovascular repair may be appropriate.

What are the essentials when treating ATAAD?

Pesclution of

Resolution of malperfusion is

significant endovascular experience.

Temperature management is still a topic of discussion, even amongst high-volume aortic surgeons at high-volume aortic centers.

Depending on the strategy employed for cerebral protection, deep hypothermia and moderate hypothermia are acceptable strategies. There

While central aortic and axillary artery cannulation are the most commonly applied arterial cannulation strategies, femoral artery cannulation may at times be appropriate and life-saving.

may be cases in which mild hypothermia

always a focus of ATAAD treatment. Sometimes

it may be appropriate to attempt endovascular

resolution of a malperfusion syndrome before

open repair. However, those situations mandate

Getting patients to the operating room as quickly as possible is the appropriate strategy in an overwhelming majority of cases. Rapid diagnosis, initiation of anti-impulse therapy and a safe and simple operation will be life-saving for a majority of the patients requiring surgery

Attention to detail in the postoperative period is critical to a successful outcome. Prompt treatment of shock, and resolution

of malperfusion syndrome, will further reduce the mortality associated with

ATAAD repair.

What can be done to lower the chance of

late reoperation?
Technology and innovations in
ATAAD surgery are focused on
the reduction of late downstream
reoperations. Frozen elephant trunk
procedures and other antegrade
stent-graft deployment
strategies have clearly
improved downstream

aortic remodeling, but have yet to show a definitive benefit for "The key to long-term survival is short-term survival, and the application of advanced techniques in the wrong patient by an inexperienced team may not be in the patient's best interest."

**Leonard Girardi** 

preventing late reoperations, or improving longterm survival. Lifelong anti-impulse therapy and serial imaging can help avoid catastrophic late events such as aortic rupture.

## What about genetic testing and screening for families to mitigate potential risk?

Genetic testing is improving, and in patients with family histories of aortic dissections and/or aneurysms, should be strongly encouraged.

#### What should take center stage in future studies of ATAAD?

The mortality and neurologic injury rates for ATAAD surgery continues to improve, but has a long way to go. Prompt diagnosis and treatment is still the key to improving survival, and the elective repair of aneurysms when approaching guideline-directed diameters for intervention may also prevent ATAAD from occurring.

Technology may be the key to reducing the longer-term need for reinterventions and additional operations.

#### How would you sum up your key messages here?

I'd refer back to the title of my talk: 'Live to fight another day'. While the Expert Consensus Document and numerous manuscripts published by the writing group members touch on a myriad of advanced surgical techniques and innovations that are meant to reduce the late morbidity for those surviving the operation, the goal is still a safe and expeditious index operation that saves the patient's life. The key to long-term survival is short-term survival, and the application of advanced techniques in the wrong patient by an inexperienced team may not be in the patient's best interest.

# Don't miss!

## High Performance Cardiothoracic Surgery in the Digital Age\*

Tuesday, 10:00 AM, Room 309

Program:

#### Introduction

**Speaker Marc Moon** *Baylor College of Medicine / Texas Heart Institute* 

LB14. Heart Rate Variability Correlates with Emotional Exhaustion in Thoracic Surgery Trainees

Invited Discussants Mara Antonoff, MD Anderson Cancer Center; Andrew Goldstone, NYP-Columbia

**Abstract Presenter Lauren Barron** Barnes
Jewish Hospital

Building High-Performing Hybrid Teams: What CT Surgery can learn from F35 Fighter Pilots, Formula 1 Racing, and Navy SEALs About Robots, Distributed Work and Cognitive Overload

Keynote Brian Ferguson Arena Labs

#### Clinical

Speaker Y. Joseph Woo Stanford Hospital

#### Research

**Speaker David Jones** *Memorial Sloan Kettering* 

#### Education

**Speaker Yolonda Colson** *Massachusetts General Hospital* 

Maximizing performance in cardiothoracic surgery: Where do we go from here?

Speaker Douglas Johnston Cleveland Clinic

Fireside Chat: How did WFH Change, Worsen, Improve, Accelerate Technologic Adoption?

Panelists David Jones, Memorial Sloan Kettering; Yolonda Colson, Massachusetts General Hospital; Douglas Johnston, Cleveland Clinic; Brian Ferguson, Arena Labs \*(non-CME) events.aats.org/102nd-annual-meeting 102nd Annual Meeting **AATS** Page **15** 



## Innovative, quality surgical products. Lowest possible cost.

#### Michler® Heart Vent Catheter

Designed by Dr. Robert Michler, Montefiore-Einstein Healthsystem



The Michler® Heart Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery. Uniquely, the device is securely positioned and maintained in the LV by inflating a soft positioning balloon against the mitral annulus/valve.

- Prevent LV distention and unintended LV perforation
- Prevent air ejection from left heart
- Aspiration of air, blood and debris
- Malleable and flexible
- Optimize LV positioning
- Aspiration from both LA and LV
- Diminishes RBC shearing resulting in higher hemoglobin and hematocrit
- Lattice formation diminishes turbulent flow resulting in decreased emboli formation

#### The Original Cosgrove® Mitral Valve Retractor System

- Universal Self-retaining Heart Retractor
- Mitral Valve Repair or Replacement Surgery
- Exceptional Exposure for Right & Left Atrium

Kapp is the EXCLUSIVE Manufacturer of the ORIGINAL Cosgrove Design



#### **Gillinov Self-Retaining Maze Retractor**

The Gillinov Self-Retaining Maze Retractor/attachment is designed to provide exposure of the pulmonary veins and atrial appendage during the Maze procedure or operations for atrial fibrillation that include pulmonary vein ablation. The visualization of these structures is greatly enhanced with this retractor.



#### **McCarthy Mini-Sternotomy Retractor**

The McCarthy Mini-Sternotomy Retractor is designed to provide excellent exposure for a variety of valve operations, Maze procedure or other intra-cardiac procedures. It is also used for mini sternotomy procedures or coronary artery bypass operations, based upon the patient's size. The removable lift attachment allows optimal exposure for valve procedures.

- Mounted on a 5 inch modified chest spreader.
- Small, durable, with unique smaller blades for ease of access and retracting for either proximal or distal ministernotomy procedures.
- Provides optimal surgical exposure.
  Optional CO2 tubing clip can be attached at any point along the rear bar.





Worldwide Sales, Service and Manufacturing 4919 Warrensville Center Rd., Cleveland, Ohio 44128, USA Phone 216-587-4400 / Fax 216-587-0411 / 800-282-5277 www.kappsurgical.com / info@kappsurgical.com

EN ISO 13485: 2016

Visit Kapp Surgical at The AATS Annual Meeting – Booth 1732 www.KappSurgical.com

Page 16 102nd Annual Meeting AATS Issue 2 May 14–17, 2022

# Celebrating excellence at the Annual Meeting

unday's Plenary Session was a chance to highlight two esteemed members of the cardiothoracic community for their excellence and commitment to the field. The AATS Lifetime Achievement Award was bestowed upon Michael Mack (Baylor Scott & White The Heart Hospital - Plano, TX, USA), while Joel Cooper (Hospital of The University of Pennsylvania, PA, USA) was given the Scientific Achievement Award.

Congratulations go to Dr. Mack and Dr. Cooper in receiving these honors.



Joel Cooper receives his Scientific Achievement Award

"This year's awardee Dr. Michael Mack has had a truly profound impact on the direction of our speciality. He's a visionary in the transcatheter valve space, and very, very importantly, has collaborated effectively with our cardiology colleagues and counterparts to firmly establish the place of surgeons in this space, and advance the concept of the heart team as a standard of care."

#### Thoralf M. Sundt, III

"I'd like to thank the nominating committee and the Association for this prestigious award. In looking back over the nine previous recipients, I'm truly humbled to be considered in their ranks. This truly is the capstone of my career."

#### **Michael Mack**

"This award serves to honour individuals who have achieved scientific contributions in the field of thoracic surgery, worthy of the highest recognition the Association can bestow. The nominating Committee and Board of Directors unanimously supported the nomination of Dr. Joel Cooper for this incredibly deserving award."

#### Thoralf M. Sundt, III

"Thank you to Thoralf and the Association. I was notified recently that I was to receive this very distinguished award, and I started to think how could I express my gratitude, and my thoughts immediately were flooded with just so many wonderful memories of the last 50 years, and of all the people who contributed to this ... I want to thank all of those who participated, and of course the Association for this very distinguished award."

**Joel Cooper** 



Michael Mack with AATS President Shaf Keshavjee and Nominating Committee Chair Thoralf M. Sundt, III



## Vision. Leadership. Scholarship.

# Clinical Trials Methods Course



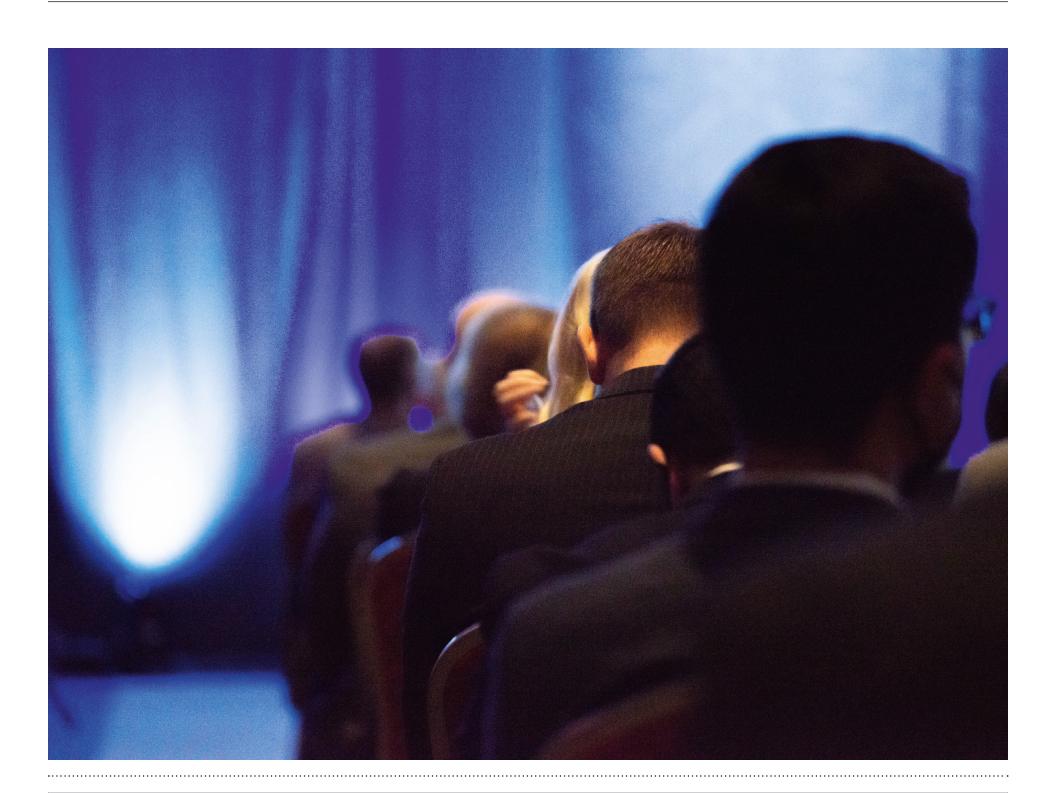
#### Save the Date

November 17–19, 2022 JB Duke Hotel Durham, NC, USA

For more information visit aats.org/clinicaltrials

**Program Directors** 

David H. Harpole, Jr. Marco A. Zenati



#### **MEDISTIM**

# G t th full pi tu e



Visit us at booth #807 and see what's missing in your CABG surgeries

www.medistim.com

Page 18 102nd Annual Meeting AATS Issue 2 May 14–17, 2022





Alphonso Queensland Children's Hospital Nelson Arnaoutakis Shands Teaching Hospital George David Barron Hospital for Sick Children William Brinkman The Heart Hospital Baylor Scott and White, Plano Errol Johns Hopkins Hospital Pedro Catarino Cedars Sinai Medical Center Subhasis Chatterjee Baylor St. Lukes Medical Center Robert Cusimano Toronto General Hospital Robert UAB Medical Center/Children's of Alabama Primary Children's Hospital Aaron Eckhauser **Fsmailian** Fardad Cedars-Sinai Medical Center Christian Heart Center Leipzig Alberto Forteza Hospital Universitario Puerta de Hierro Fukushima Satsuki National Cerebral and Cardiovascular Center Jeffrey Duke Hospital Kendra **Emory University Hospital Midtown** Huiming Guo Guangdong Provincial People's Hospital Benjamin Haithcock University of North Carolina Mark Hazekamp Leiden University Medical Center Hiesinger William Stanford Medical Center Michiaki Imamura Texas Children's Hospital James Isbell Memorial Sloan Kettering Cancer Center Akinobu Washington University School of Medicine Central University Hospital Marek Jasinski Sanghoon Jheon Seoul National University Bundang Hospital Mingqiang Kang Fujian Medical University Union Hospital Jacob Klapper **Duke University** 

UCSF

Peter

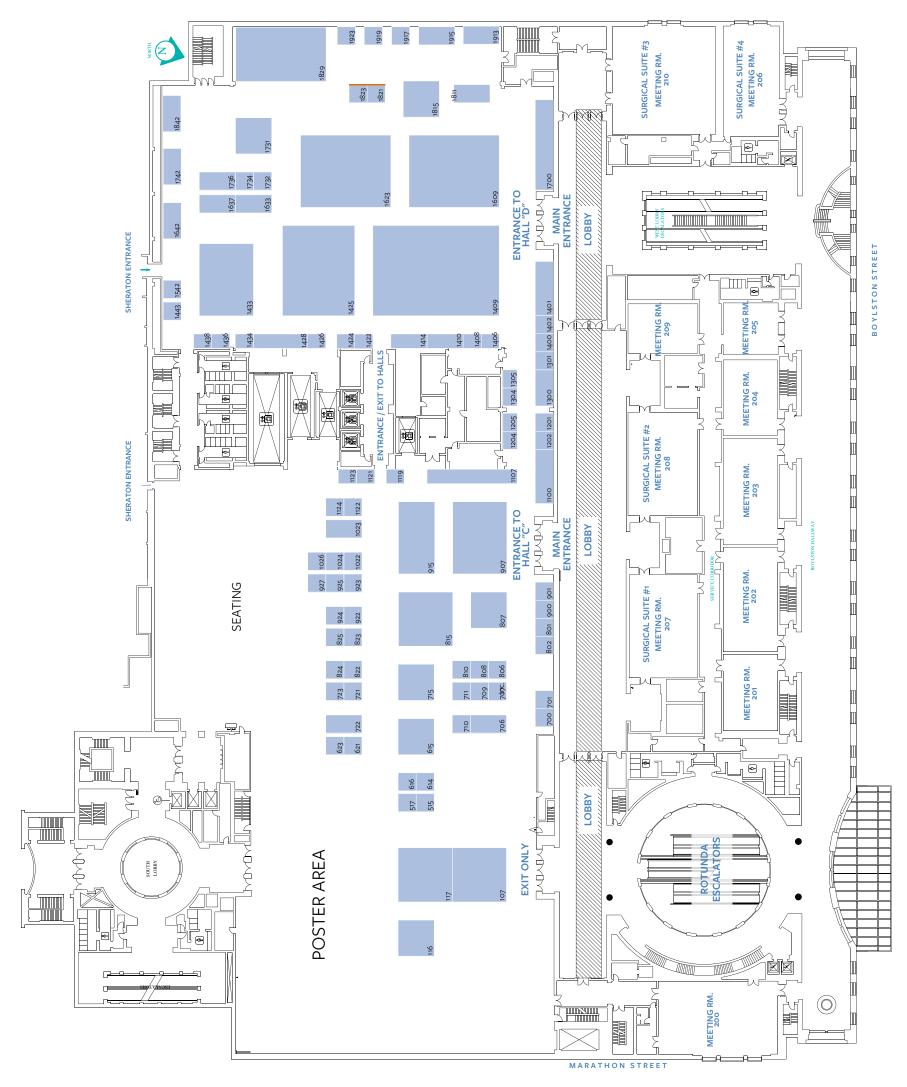
Kouretas

Anthony Bradley Zhigang Stella Philip Nabil Dave John James Sunil David In Kyu Park Julie Allan Keshava Nathalie Rana Francis Carla Michael Tong Shuiyun Richard Dominik Lanjun Zhang

Rutgers Robert Wood Johnson Hospital Lemaire Leshnower **Emory University Hospital** Shanghai Chest hospital UF Health Martinez Clinica Reina Sofía Walter Reed Mullenix Munfakh Christian Northeast Hospital London Health Sciences Centre Nagpal Rady Children's Hospital Nigro O'Brien Children's Mercy Hospital University Hospital Southampton Overman Children's Minnesota Seoul National University Hospital Phillippi University of Pittsburgh Medical Center Emory University Hospital, Midtown Rajagopal **HCA Houston Medical Center** Arkansas Children's Hospital Reemtsen Boston Children's Hospital Sayeed John Radcliffe Hospital Universitas Hospital Instituto do Coração Tanamati Cleveland Clinic Fuwai Hospital Wang Whitlock Hamilton Health Sceinces Wiedemann General Hospital Vienna Sun Yat-sen University Cancer Center

Susheel Kumar Hassenfeld Children's Hospital

# AATS 2022 Floor plan



Abbott	1425
Abiomed	1023
Able Medical Devices	823
Abyrx, Inc.	1304
ActiCare Health	621
Acumed, LLC	706
Arthrex, Inc	1734
Artivion, Inc	1623
AtriCure	715
Auburn University Physician's MBA Porgram	s Executive <b>721</b>
Auris Health	900
Baxter Healthcare Corporation	808
Baylis Medical	1122
BD	1026
Berlin Heart Inc.	1100
bioMérieux, Inc.	806
BioStable Science & Engineering / HAART	1821

Bristol Myers Squibb (BMS)	1201
Centese	1406
Congenital Heart Surgeons Soci	ety <b>517</b>
Corcym Inc.	1731
CTSNet	1434
CytoSorbents, Inc.	1121
DePuy Synthes	515
Designs for Vision, Inc.	707
(EACTS) European Association for Cardio-Thoracic Surgery	1436
Edwards Lifesciences	1609
egnite	1736
Elsevier	1426
Essential Pharmaceuticals	901
ESTS	1205
Ethicon	801
EziSurg Medical	1202
Fehling Surgical Instruments, Inc.	1637

Foldax	1408
FUJIFILM Healthcare Americas Corporation	1422
Genentech	825
Genesee BioMedical Inc.	1642
Gore & Associates	1633
Heart Valve Society (HVS)	1542
HemoSonics, LLC	616
Intuitive	915
rrisept	810
SMICS	1443
JACE Medical	1305
JEIL Medical Corporation	923
Japanese Organization for Medical Device Development (JOMDD)	711
Device Development (JOIVIDD)	
Kapp Surgical Instrument, Inc.	1732
	1732 925
Kapp Surgical Instrument, Inc. Key Surgical –	

LeMaitre	709
LifeLike BioTissue	1024
LifeNet Health	1414
LSI Solutions	1811
Mauna Kea Technologies, Inc.	924
MED Alliance Solutions, LLC	1815
Medela LLC	1410
Medistim	807
Medtronic	1409
Neos Surgery SL	1424
Northside Hospital	1402
Novocure Inc.	802
Olympus America Inc.	1022
On Target Laboratories	1301
Optellum	1027
Osso VR	824
Peters Surgical USA	1401
Pinnacle Biologics	1119
ProCell Surgical US, Inc.	614

Xenosys USA	922
Rultract/Pemco Inc.	1742
Scanlan International, Inc.	1700
STS / National Database	1428
Sontec Instruments, Inc	722
Southeast Health	7 <del>2</del> 3
SurgiTel	822
Terumo Aortic & Terumo Cardiovascular	815
Thoracic Surgery Oncology Group (TSOG)	1204
Tisgenx, Inc.	1400
Transonic Systems, Inc.	1123
USB Medical	927
Wexler Surgical & TeDan Surgical Innovations	1107
Women in Thoracic Surgery	1438
Xodus Medical	710
Zimmer Biomet	1300

P&D Surgical LISA Inc./



# 103rd Annual Meeting

Save the Date

May 6-9, 2023 Los Angeles Convention Center Los Angeles, CA, USA **President**Yolonda L. Colson