GE HealthCare

Vivid™ Magazine

EDITION 3

Dagfinn Saetre,
General Manager
Cardiovascular Ultrasound

Dear Reader,

We are delighted to welcome you to the third edition of Vivid Magazine, dedicated to the forefront of echocardiography and the relentless pursuit of innovation in cardiovascular health. Within these pages, we present a curated selection of compelling articles that embody the spirit of collaboration, innovation, and dedication that defines our community.

Dr. Andrea Natale, a luminary at St. David's Medical Center, leads the way by exploring opportunities to simplify and streamline 4D ICE procedures. His in-depth examination of this cutting-edge technology sheds light on its potential to revolutionize echocardiography, reaffirming the transformative power of innovation in patient care.

We also have the privilege of featuring Dr. Jyothy Puthumana from Northwestern University, who presents a remarkable discourse focused on reshaping accessibility and safety with the mini 3D TEE probe. This article not only unravels the complexities of a unique medical scenario but also underscores the unwavering commitment of our clinicians to tackle even the most challenging cases. Such dedication propels us forward in advancing the boundaries of cardiovascular healthcare.

Dr. Justin Tretter, a pioneering figure at the Cleveland Clinic, contributes vital insights into interventional pediatric procedures using blood speckle imaging (BSI) with the innovative 9VT-D probe,[1] emphasizing the paramount significance of innovation in pediatric cardiology. Dr. Tretter's groundbreaking work vividly exemplifies our dedication to enhancing patient outcomes, especially in the intricate and highly specialized domain of cardiovascular care.

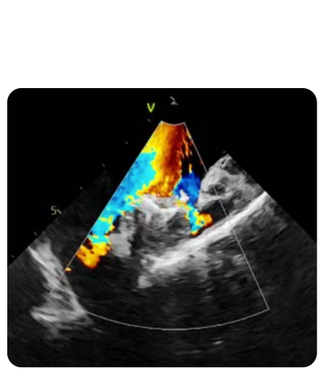
Through the exchange of experiences and insights like those mentioned above, we aspire to elevate patient care, inspire progress, and pave the way for a brighter future.

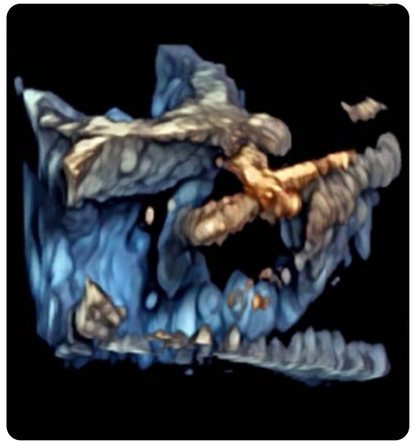
Thank you for being part of this journey, and I hope you enjoy the stories of this edition, a magazine from our GE HealthCare Vivid team dedicated to the entire cardiac ultrasound community.

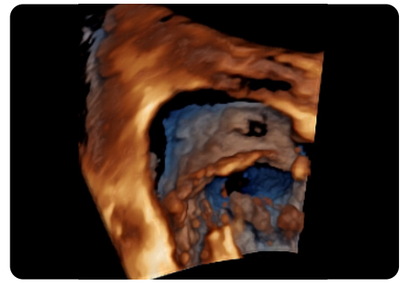
Dagfinn Saetre,

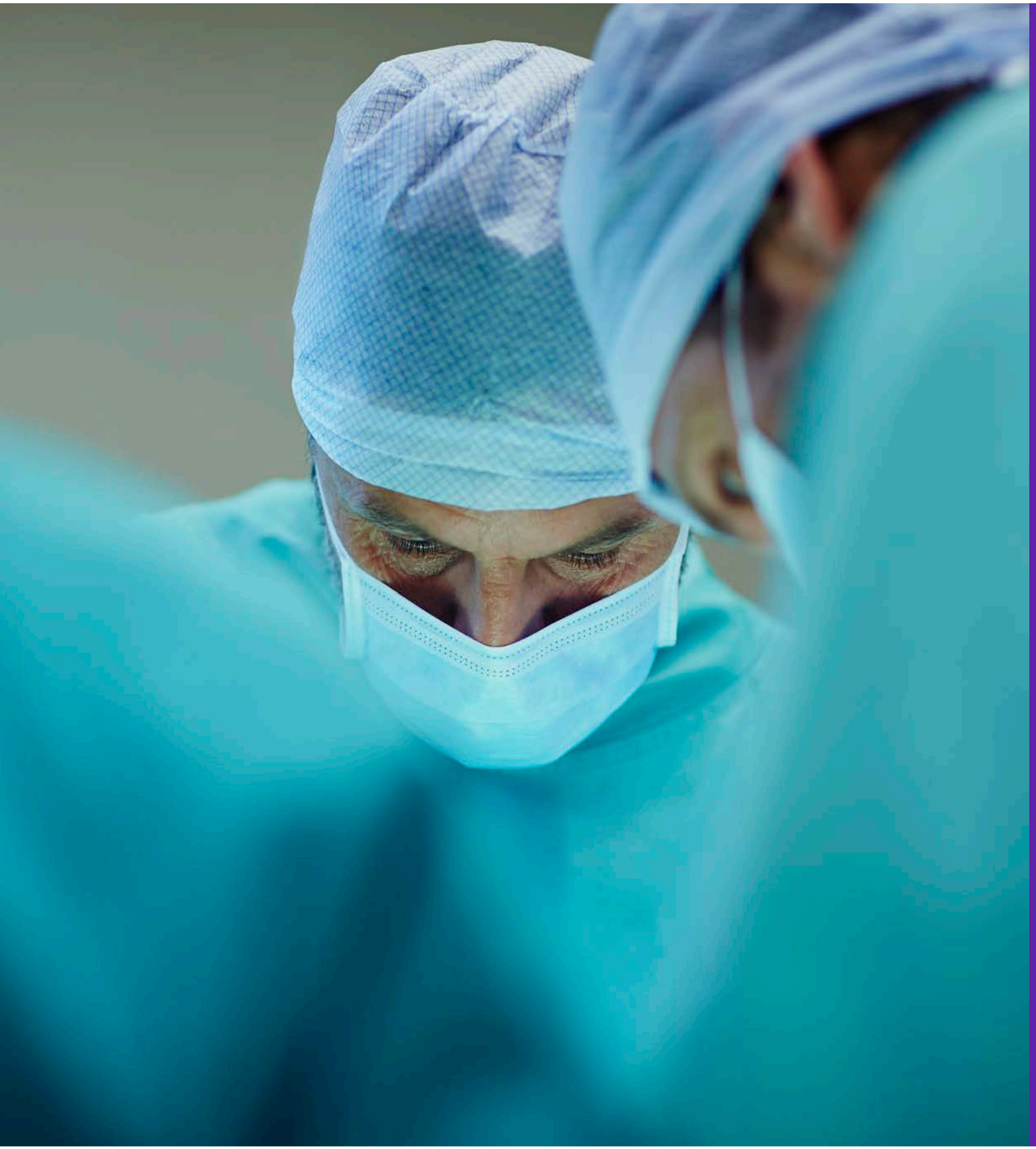
1. 9VT-D probe is exclusively available for Vivid E95 and Vivid E90 systems. Vivid Ultra Edition is released as of 25th August 2022. Ultra Edition is not a product name, it refers to the 2022 release of the Vivid portfolio.

Vivid Magazine









A new vision for LAAO

See more opportunities to simplify and streamline procedures with the 4D ICE NUVISION™ ultrasound catheter

Imaging advancements are driving significant progress in structural heart interventions. Through pioneering efforts and continuing research, the Texas Cardiac Arrhythmia Institute at St. David's Medical Center is helping set the pace. Executive Medical Director Andrea Natale, M.D., F.H.R.S., F.A.C.C., F.E.S.C., leads the team in exploring cutting-edge options that make it possible to treat more cardiac patients with less invasive techniques.

One of those emerging technologies is the 4D ICE NUVISION™ ultrasound catheter by Biosense Webster.[1] Physicians at St. David's Medical Center were among the first in the world to evaluate the intracardiac echocardiography catheter as an alternative to TEE, with early in-human trials in 2021. Now the 4D ICE NUVISION ultrasound catheter is the preferred tool in LAAO procedures, addressing the Institute's growing need for advanced imaging that goes beyond 3D capabilities.

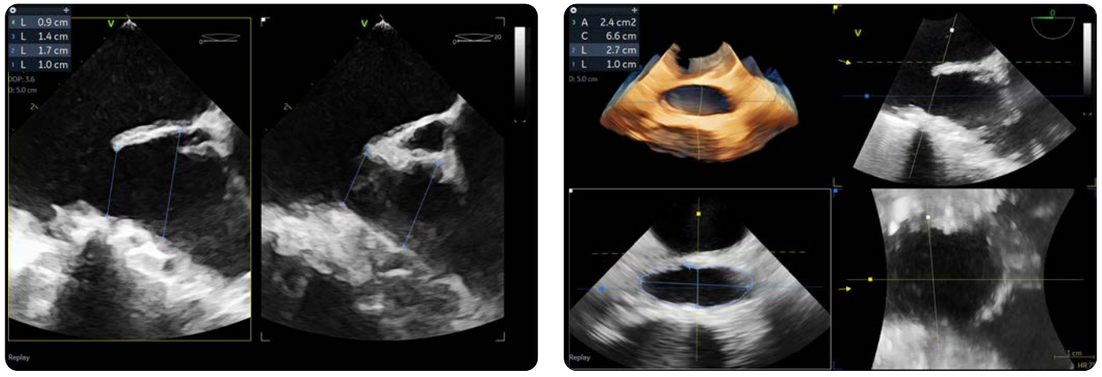
With real-time, volumetric imaging, a 90° x 90° field of view, 2D and 4D color Doppler flow ability and an independent rotating tip, the catheter was designed to allow multiplanar visualization of target cardiac structures with minimal manipulation.[1,2] The sophisticated imaging also enables physicians to perform procedures under conscious sedation, which can benefit patients and improve workflow efficiencies. It operates using GE HealthCare's Vivid™ ultrasound system.

We recently asked Dr. Natale to share his experiences with the 4D ICE NUVISION ultrasound catheter and the impact it has on structural heart interventions.

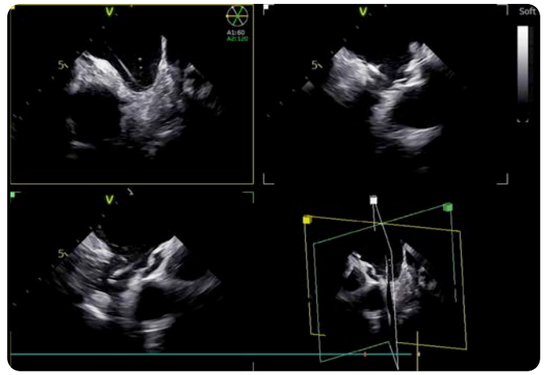
Can you tell us about the electrophysiology program at the Texas Cardiac Arrhythmia Institute and what types of procedures are performed at your facility?

Dr. Natale: *The EP program started in 1996 and expanded to the Texas Cardiac Arrhythmia Institute in 2008 with several expansions and remodeling projects over the years. We most recently opened a state-of-the-art Electrophysiology Center at St. David's Medical Center that has 6 dedicated EP labs that are all hybrid capable (with a seventh on the way), a 24 bed EP telemetry unit, training facility with integrated live broadcast capabilities, and a conference center. This recent expansion, which includes four VIP patient suites, will help accommodate the growing number of international patients traveling here to seek treatment. We perform complex ablations including atrial fibrillation (AF), ventricular tachycardia (ischemic and idiopathic), ventricular fibrillation, atrial tachycardia (AT), supraventricular tachycardia, and inappropriate sinus tachycardia (IST). We also perform implantation of biventricular devices, ICDs, pacemakers and loop recorders, laser lead extractions, and left atrial appendage occlusion devices. We currently perform well over 3,000 procedures a year.*

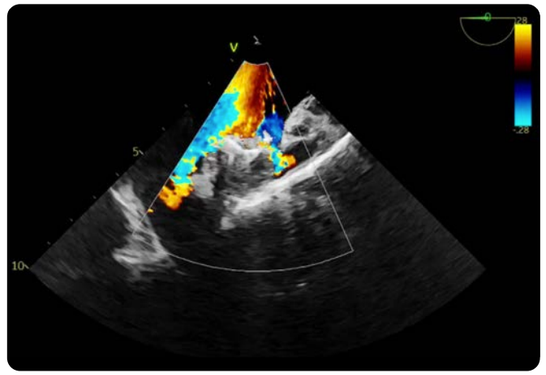
> *Now the 4D ICE NUVISION ultrasound catheter is the preferred tool in LAAO procedures, addressing the Institute's growing need for advanced imaging that goes beyond 3D capabilities.*



Using biplane and FlexiSlice 4D ICE allows better anatomy characterization helpful in complex anatomy.



4D ICE NUVISION ultrasound catheter with triplane imaging looking at 0, 60 and 120 degree view of left atrial appendage.



Using 4D Color Flow with the 4D ICE NUVISION ultrasound catheter is helpful while integrating intraprocedural leak detection and to guide leak closure procedure.

You were one of the first physicians to use the 4D ICE NUVISION ultrasound catheter. What intrigued you about 4D ICE and volume imaging that made you want to pioneer this technology?

Dr. Natale: *We have been using 2D ICE for procedures since early 2000s, mostly for ablation. But clearly when moving into more structural work, such as left atrial appendage closure and for some of our VT ablation, 3D imaging is certainly helpful.*

There wasn't an issue until recently when we did not have a good platform for 3D or 4D that interested us. So, when the 4D ICE NUVISION ultrasound catheter came along, we got involved in the early human testing in Europe. It was really the excitement we had when we were involved in that testing that raised our interest in the technology.

What were your initial thoughts using the real-time imaging tool in LAAO procedures?

Dr. Natale: *The quality of the picture was amazing, and we felt that we were getting adequate imaging to make sure the device was properly deployed without leaks. We also found the catheter was very nice in terms of 'ease of use.'*

How has the 4D ICE NUVISION ultrasound catheter's unique design been beneficial in these procedures?

Dr. Natale: *It's the rotating tip that makes the big difference. We can get the picture we want without spending too much time on manipulation. We can get multiple views of the same structure without too much manipulation, which really helps with left atrial appendage closure devices.*

How would you compare the 4D ICE NUVISION ultrasound catheter to 2D ICE in terms of imaging capabilities and functionality?

Dr. Natale: *It's really about the quality of the picture. With 2D ICE, you need more manipulation and it's sometimes difficult to get the view you want, so you always feel that you are relying more on geography.*

Whereas with the 4D ICE, I feel we get the picture that is equivalent to TEE in terms of the view we get, maybe better quality. We are right there. Usually, we advance the catheter in the left atrium, so I feel more comfortable with the 4D ICE NUVISION ultrasound catheter that we have a good deployment.

Why is using biplane or triplane imaging in left atrial appendage closure procedures so important?

Dr. Natale: *Those pictures are closer to what we are used to seeing with TEE, so we can make sure there is a good seal and no evidence of leaks. The 3D function is critical, and it's probably underutilized with the transesophageal echo. It's certainly valuable to maximize the fact that you've done a good job. The more information you get at the time of implant, the better it is for the future risk of leaks.*

> *"The workflow is better for us because we don't need anyone else in the room to help with the procedure. We can schedule whenever we want, rather than relying on others.*

What influences your decision to use transesophageal echo in left atrial appendage closure procedures versus 4D ICE?

Dr. Natale: *We've transitioned pretty much to ICE-guided procedures because it allows us to do the procedures without general anesthesia, so there's no intubation. It's less invasive and easier on the patient. In our hands, ICE has not caused any problem in terms of complications. Whereas with TEE, although the rate is low, there is more risk of esophageal perforation. With ICE, people don't complain the day after that they have a sore throat because of the intubation. I feel it's better for the patient.*

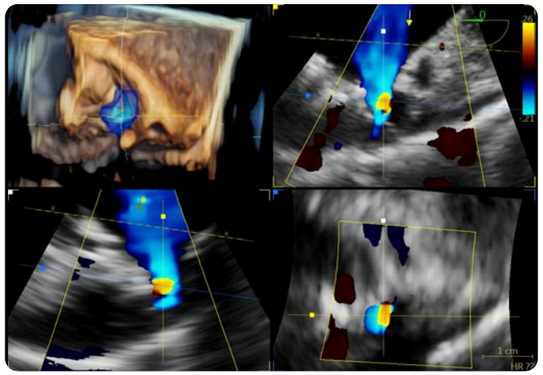
And most importantly, the workflow is better for us because we don't need anyone else in the room to help with the procedure. We can schedule whenever we want, rather than relying on others.

How is your team utilizing the 4D ICE NUVISION ultrasound catheter now and what is the potential for the future?

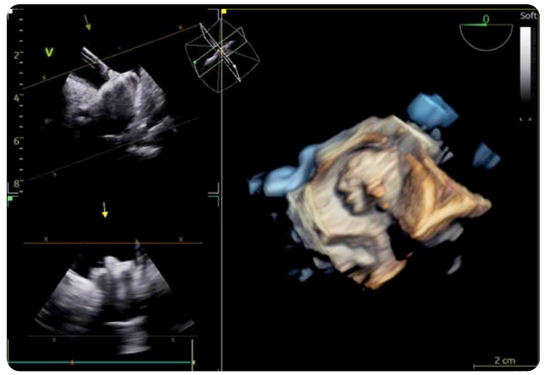
Dr. Natale: *For us, we are mostly using it for left atrial appendage closure, but the 4D is also very helpful for VT ablation procedures because it gives us a better-quality picture of the area we are trying to target. Our goal is to have all our LAAO procedures being done using the 4D NUVISION catheter for imaging.*

The price of the 4D ICE NUVISION ultrasound catheter is higher than 2D ICE. How have you addressed this concern in your facility?

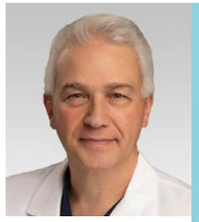
Dr. Natale: *I think the benefit of the catheter is significant. It really benefits our patients and our workflow. I think those benefits make it worth it.* ■



Using 4D Color Flow with FlexiSlice on the 4D ICE NUVISION ultrasound catheter is helpful to locate and visualize the leak in orthogonal planes.



4D Image using 4D ICE NUVISION ultrasound catheter of the closure device seated in the proper position.



Andrea Natale, M.D., F.A.C.C., F.H.R.S., F.E.S.C., is Executive Medical Director of the Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, Texas. Dr. Natale is an internationally renowned leader in the field of electrophysiology, who specializes in the use of percutaneous catheter ablation to treat complex atrial fibrillation. He pioneered a circumferential ultrasound vein-ablation system to correct AF, developed some of the current catheter-based cures for atrial fibrillation, and was the first electrophysiologist in the nation to perform percutaneous epicardial radiofrequency ablation. Dr. Natale has authored or co-authored hundreds of published articles and is editor-in-chief of the *Journal of Atrial Fibrillation*.

1 4D ICE NUVISION ultrasound catheter is only available in the US and distributed by Biosense Webster. The combination of Vivid™ E95 with 4D ICE NUVISION is not CE-marked.

2 Evaluating the role of transesophageal echocardiography (TEE) or intracardial echocardiography (ICE) in left atrial appendage occlusion: a meta-analysis – Akela et al. – 2020 – Journal of Interventional Cardiac Electrophysiology

Doctors are paid consultants for GEHC and were compensated for participation in this article. The statements described here are based on their own opinions and on results that were achieved in their unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

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9VT-D mini 3D TEE brings imaging option to patient getting a TAVR from transcarotid approach

Courtesy of Javier Gomez Valencia, M.D., Cook County Health, US

Patient history/ pathology

The patient is a 79-year-old gentleman with a history of end-stage renal disease on chronic hemodialysis, heart failure with preserved ejection fraction, hypertension, chronic obstructive pulmonary disease, and gastrointestinal angiodysplasia, who was evaluated for a transcatheter aortic valve replacement for severe aortic valve stenosis. Baseline transthoracic echocardiogram demonstrated a severely calcified aortic valve with severely restricted leaflet motion, peak velocity of 4.4 m/s, mean gradient of 50 mmHg and an estimated aortic valve area of 0.6 cm^2. CT angiography of the peripheral vasculature demonstrated severe peripheral vascular disease involving the common femoral artery bilaterally. After extensive review by a multidisciplinary team including cardiothoracic surgery, structural cardiology, and structural imaging experts, decision was to proceed with a transcarotid approach.

Challenges

Challenges in this case included a hostile transfemoral access secondary to peripheral vascular disease requiring the use of transcarotid access, limited space at the transcarotid access site to operate both for a surgical field, procedural equipment manipulation and the transesophageal echo probe, high risk of GI bleeding, the need to obtain high quality imaging for valve deployment including potential use of high-quality 3D images.

System, probe & device used

Due to severe peripheral vascular disease and the need to use a transcarotid approach, imaging with the 9VT-D mini 3D TEE probe was used to facilitate catheter and equipment manipulation while at the same time minimizing overlap and interference of imaging probe with the TAVR equipment at the access site. The ultrasound system used was Vivid™ E95 Ultra Edition from GE HealthCare.

Step-by-step procedure

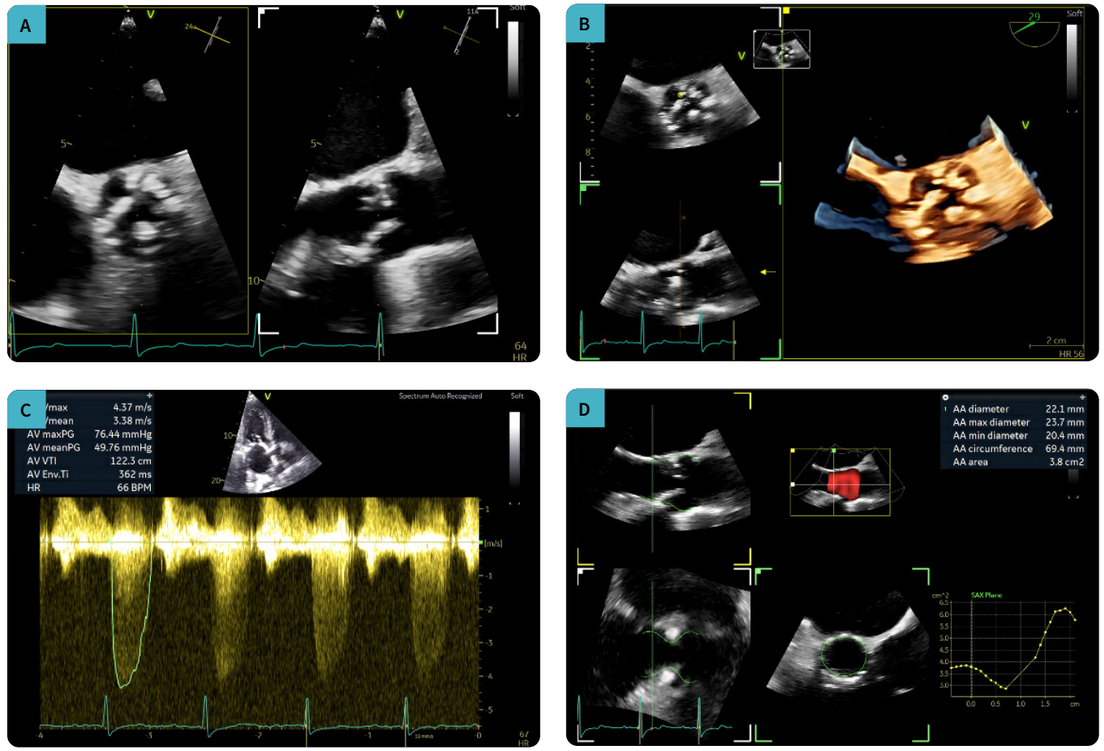
General anesthesia was achieved and a 9VT-D mini 3D TEE probe was advanced into the esophagus with ease. Transcarotid access was obtained by surgical cutdown by the cardiothoracic surgery team. Dedicated valve measurements including 3D aortic annulus size and gradients were obtained at baseline. A 26 mm Edwards Sapien™ 3 ultra TAVR valve was successfully deployed under direct echocardiographic guidance. Thorough evaluation of the valve immediately post deployment demonstrated normal function of the prosthetic valve, no pericardial effusion no significant paravalvular leak. All equipment was removed, and the procedure was completed.

Conclusion

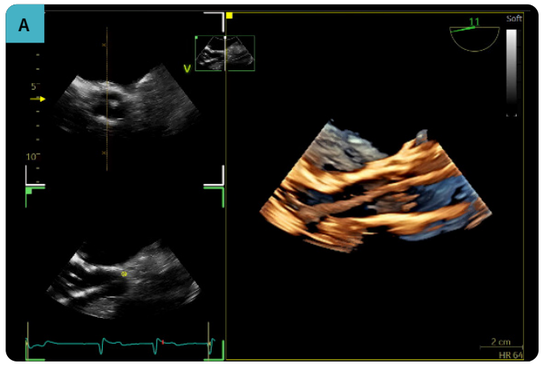
The complex transcatheter aortic valve replacement using a transcarotid approach was successful with a reduction in mean gradient from 50 mmHg to 6 mmHg and no residual paravalvular leak immediately post valve deployment. Imaging with the 9VT-D mini 3D TEE probe was instrumental to minimize interference of the TEE probe with the surgical field, facilitate surgical access, equipment manipulation and direct visualization of the valve deployment in real time.

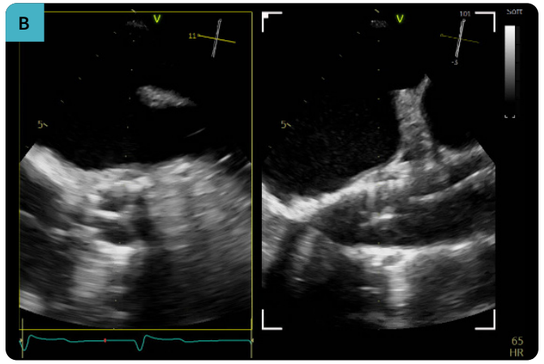
Echo lab follow-up

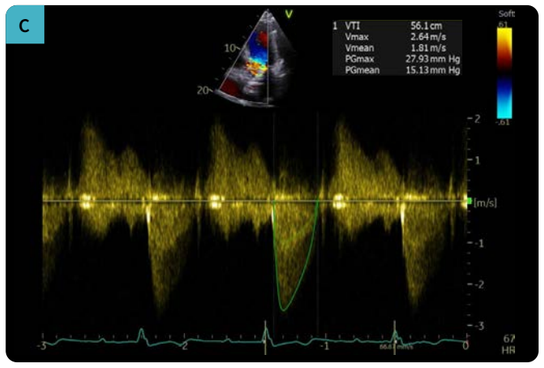
Follow up transthoracic echocardiogram prior to discharge and 2 months later demonstrated a well seated, normally functioning prosthetic valve in the aortic position, peak velocity decreased from 4.5 to 2.7 m/s, mean gradient from 50 to 15 mmHg, and there was no evidence of aortic regurgitation or paravalvular leak.



A) TEE images of aortic valve. 2D short and long axis views prior to device deployment.
B) TEE images of aortic valve. 3D short axis view prior to device deployment.
C) Aortic valve Doppler interrogation prior to valve deployment. Peak velocity 4.37 m/s, mean gradient 49.76 mmHg.
D) Intraprocedural aortic annulus measurements by 3D assessment using 9VT-D mini 3D TEE probe.







A) 3D valve assessment Immediately post deployment of 26 mm Edwards Sapien™ 3 Ultra TAVR valve.

B) TEE images of aortic valve. 2D evaluation post valve deployment.

C) Aortic valve Doppler interrogation after valve deployment. Peak velocity 2.64 m/s, mean gradient 15.13 mmHg.

Javier Gomez Valencia, M.D., is Director of Structural Cardiac Imaging and Cardio-Oncology services for Cook County Health. His clinical expertise includes multimodality cardiac imaging, cardiac CT, cardiac MRI, SPECT, PET and PYP imaging, 4D echocardiography and intraprocedural imaging. He has co-authored several publications and book chapters and his research focuses on applications different cardiac imaging modalities in clinical practice, risk stratification, prevention, and management of patients at risk or who have developed cancer therapy related cardiac dysfunction with a particular focus on the impact of healthcare disparities in clinical outcomes.

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Strain Imaging in Echocardiography

As pioneers in the field of strain imaging, our tools have been transformational in supporting healthcare professionals from research to clinical routine. Through the support of the American Society of Echocardiography, we have developed educational resources to empower professionals to enhance their skillset and techniques, boosting diagnostic confidence. This comprehensive curriculum features ten engaging episodes, covering foundational concepts, clinical use cases, and insights from renowned experts across the world.

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Episode 9	**Loading conditions can change strain values, how to utilize Myocardial work?** Presenter: Dr. Christos Mihos (USA) Guest speakers: Prof. Erwan Donal (France) and Prof. Otto Smiseth (Norway)
Episode 10	**How to report strain imaging?** Presenter: Juan Carlos Plana (USA)

Navigating unreachable hearts

Redefining accessibility and safety with the 9VT-D mini 3D TEE probe

There is growing evidence that the world's first mini 3D TEE probe is expanding possibilities in the structural heart space,[1,2] enabling more opportunities to reach complex and challenging patients. The latest example comes from Jyothy Puthumana, M.D., Director of Interventional Echocardiology at Northwestern Medicine's Bluhm Cardiovascular Institute.

Recognized among the top ten best cardiology, heart & vascular surgery programs in the United States, the Bluhm Institute is a leading destination for specialized heart care. Director of Interventional Echocardiology, Jyothy Puthumana, M.D., celebrates his 20th anniversary at the Institute next year. Over the years, he's welcomed innovation and change, exploring new ways to keep up with the increasing demand for structural heart interventions.

Dr. Puthumana and his team perform all the preprocedural TEEs for patients and trial participants who need structural heart interventions. Intraprocedurally, he works very closely with interventionalists, cardiac surgeons and electrophysiologists to assist in TEE, valve replacement on the mitral or tricuspid side, and other structural interventions, including ASD closures and left atrial appendage occlusion procedures. Northwestern Medicine performs more than 70 TEER procedures a year.

Dr. Puthumana recently experienced GE HealthCare's 9VT-D mini 3D TEE probe powered by the Vivid™ E95 Ultra Edition cardiovascular ultrasound system. With a 57% smaller tip volume than the 6VT-D conventional adult TEE probe,[3] the compact probe provided an imaging solution to evaluate and guide a TEER procedure in an elderly patient who could not tolerate an adult probe.

We asked Dr. Puthumana to share his initial impressions about the 9VT-D mini 3D TEE probe, along with some insights on the potential impact for the future.

Can you take us back and describe your evolving role in structural heart interventions during your time at the Bluhm Institute?

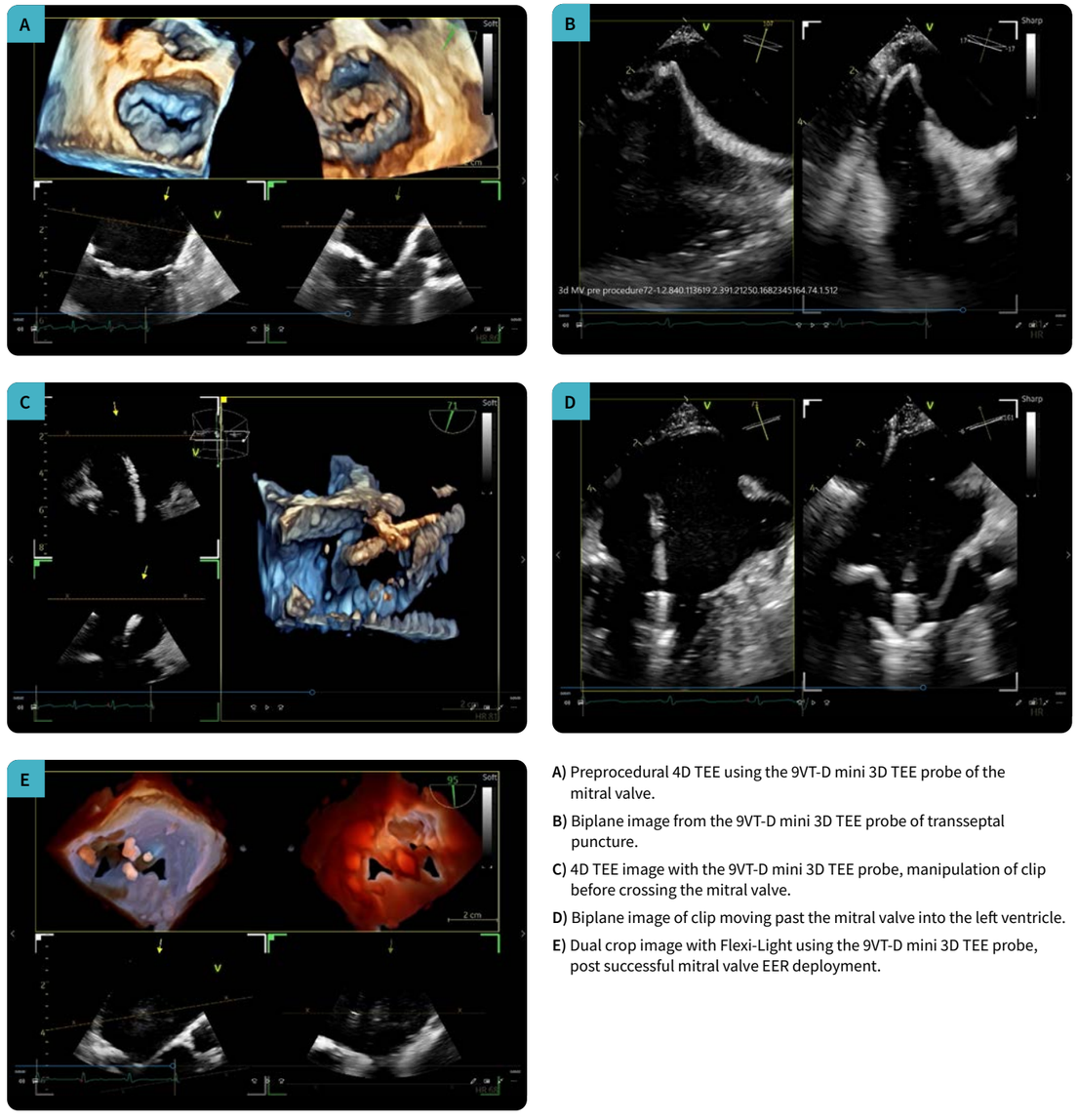
Dr. Puthumana: *During my first ten years, I got a lot of experience in the operating room because the echocardiologists would be there pre and post for every surgery case, mostly for valve repair, but also for valve replacements and later as TAVR started. As a result, we felt like we fit right in when nonsurgical valve repair/replacements came into foray.*

We used to perform the TEEs for TAVR assessment and intraprocedural guidance during the initial PARTNER trials. When TEER came into existence as the first of the nonsurgical mitral valve procedures as part of two trials, we were well-positioned because of our experience from the OR. Here was a procedure that was very attractive and interesting to us, and it felt like we were making a difference in both preprocedural assessment and intraprocedural guidance. We started off with the mitral valve transcatheter edge-to-edge repair and we were lucky to get involved in tricuspid trials early on, starting in 2015. We have been able to gain a lot of tricuspid experience because patients are being referred for these trials at Northwestern Medicine.

You've recently evaluated the new 9VT-D mini 3D TEE probe. Can you tell us more about the specific case, including the patient history and procedure?

Dr. Puthumana: *We had an elderly, frail patient, who had severe mitral regurgitation, in addition to a host of other medical issues. Her main problem was Scleroderma related esophageal stricture. So even for a diagnostic study, her esophageal size was too small to accommodate a regular TEE probe. She underwent two esophageal dilations, which could be safely and maximally dilated up to only 14 to 15 millimeters in diameter at the largest location. We were lucky we had access to the mini 3D TEE probe because she needed imaging to both evaluate and to guide a potential TEER procedure.*

> *"I see this as moving the field forward by having a device that will potentially cause less irritation, injury to the esophagus, but at the same time provide imaging that is comparable and adequate for a successful completion of the procedure. I think the size of the probe is going to be a big part of this entire discussion.*



A) Preprocedural 4D TEE using the 9VT-D mini 3D TEE probe of the mitral valve.

B) Biplane image from the 9VT-D mini 3D TEE probe of transseptal puncture.

C) 4D TEE image with the 9VT-D mini 3D TEE probe, manipulation of clip before crossing the mitral valve.

D) Biplane image of clip moving past the mitral valve into the left ventricle.

E) Dual crop image with Flexi-Light using the 9VT-D mini 3D TEE probe, post successful mitral valve EER deployment.

What were your initial impressions of the 9VT-D mini 3D TEE probe?

Dr. Puthumana: *This was the perfect probe that allowed us imaging from a biplane standpoint, imaging from a 3D standpoint and all the usual tools that we use in our routine mitral TEER procedures for transeptal puncture, navigating in the left atrium, navigating above the valve, orientation of the device arms, adequate leaflet grasp and capture, assessment of success of the procedure and finally safe removal of catheters and guide, post procedure.*

Without the mini 3D TEE probe, I don't think our patient would have been able to get this procedure. The only other potential option could have been ICE. While we have experience with ICE on the tricuspid side, we don't have a lot of experience with ICE on the mitral side. I think this was the perfect option that aligned our existing expertise with TEE imaging with 3D in the TEER space, but with a probe that was appropriate for her esophageal size.

Intraprocedural TEE plays an essential role in guiding TEER. How would you describe the imaging capabilities?

Dr. Puthumana: *We went into the case thinking that we would predominantly use the biplane feature to help us with positioning and capture. But once we were in the procedure, we used the three-dimensional multiplane cropping tool, FlexiSlice. We were able to get the 3D image of the mitral valve, device, and the clip, but also the commissure and the orthogonal view to help us both in terms of positioning and visualization of the entire device.*

We felt that the imaging that we obtained using this probe was comparable to what we've been able to achieve in our prior cases utilizing a conventional adult TEE probe with 3D and multiplanar imaging. Along with our interventionalists, we felt confident that leaflet capture and insertion was good and that we obtained our outcome with the lowest risk possible.

> *"Without the mini 3D TEE probe, I don't think our patient would have been able to get this procedure.*

What surprised you the most about the 9VT-D mini 3D TEE probe?

Dr. Puthumana: *Our patient was very frail and her esophagus had been dilated multiple times so we were apprehensive and conscious that we could potentially make her esophagus worse from probe manipulation. We were pleasantly surprised at how smooth the movement was within her esophagus and our ability to maneuver the probe without feeling any restriction or difficulty advancing or retracting.*

Do you think the 9VT-D mini 3D TEE probe can increase access of TEE-guided procedures to this subset of patients who have esophageal strictures?

Dr. Puthumana: *We definitely needed a probe that enables us to get comparable images, but does not risk injury to the esophagus, which would then compromise the benefit we get from taking care of the regurgitation.*

I see this as moving the field forward by having a device that will potentially cause less irritation, injury to the esophagus, but at the same time provide imaging that is comparable and adequate for a successful completion of the procedure. I think the size of the probe is going to be a big part of this entire discussion.

What other types of patients would benefit from having a much smaller 9VT-D mini 3D TEE probe?

Dr. Puthumana: *I suspect that from a mitral and tricuspid structural standpoint, the TEER space is going to be the first area where there is going to be a rapid expansion in the eligibility of the number of patients coming in. And most of the patients who are eligible for TEER at present are quite frail and tend to have multiple issues, including esophageal issues. You also have patients who are coming in with bleeding issues, liver issues. A lot of these patients have hepatic congestion, cirrhosis and so forth and are already at high risk for esophageal injury. I think this probe can be considered as an option for these high-risk and frail patients who are currently coming in for these procedures and for other tricuspid valve related procedures as more devices get approved for clinical use in the future.*

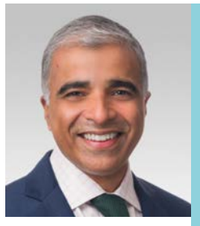
What are your thoughts about reducing esophageal injuries in longer TEE-guided procedures?

Dr. Puthumana: *As the number of structural procedures that need TEE guidance has increased, people are paying more attention to the risks associated with structural imaging. There have been several big studies looking into these risks of esophageal injury/irritation, and we have more knowledge in this arena than we did five years ago.*

I think all of us in the structural imaging arena were both stumped and concerned when one study reported that 86% of patients had a new injury noted on EGD post procedure, with complex lesions noted in close to 40% of patients. These were patients predominately undergoing mitral valve structural interventions, with a few appendage closures, and tricuspid devices.[4,5] I think we are now humbled by these studies that show structural imaging is not benign as we had presumed, and we are treating the sickest of sick patients. I think there's more awareness about how we can make imaging safer, make it shorter, and still get all the information we need for a successful result.

Do you think the 9VT-D mini 3D TEE probe may reduce the need for general anesthesia in the future? How could that benefit patients?

Dr. Puthumana: *It would be huge, as we've seen with the TAVR space and how it had a big impact on length of stay and other complications associated with general anesthesia. Obviously, the structural field is moving towards more and more procedures that can be done with as little general anesthesia as possible. I think it would be a huge advancement and would benefit our older, more frail patients. Hopefully that will be tested once the probe becomes more widely available and we perform a multicentric study with this approach starting off with procedures that have a very predictable time for procedure. (Example: straightforward mitral lesions at the A2-P2 location with no other procedural challenges expected.) It would be very exciting if we could push the field that way. I hope that's where things are headed, in the future of structural imaging.* ■



Jyothy Puthumana, M.D., is Director of Interventional Echocardiology at Northwestern Medicine's Bluhm Cardiovascular Institute. He is also Medical Director of the Martha and Richard Melman Family Bicuspid Aortic Valve Program at Northwestern Memorial Hospital. Dr. Puthumana's top areas of expertise include all valvular heart disease with a special expertise in bicuspid aortic valve disease and structural imaging. He has co-authored more than 40 peer-reviewed articles and is committed to research, participating in many clinical trials.

1 Hascoët S, Peyre M, Hadeed K, Alacoque X, Chausseray G, Fesseau R, Amadieu R, Léobon B, Berthomieu L, Dulac Y, Acar P. Safety and efficiency of the new micro-multiplane transoesophageal probe in paediatric cardiology. Arch Cardiovasc Dis. 2014 Jun-Jul;107(6-7):361-70. doi: 10.1016/j.acvd.2014.05.001. Epub 2014 Jul 1. PMID: 24996565

2 Sanchis L, Regueiro A, Cepas-Guillen P, Sitges M, Freixa X, First experience of left atrial appendage occlusion using a 3D mini transoesophageal echocardiographic probe with conscious sedation. EuroIntervention. 2023 Jan.; doi: 10.4244/EIJ-D-22-00921

3 Volume of the TEE probe tip compared to standard adult probe 6VT-D Vivid probe. DOC2636172

4 Freitas-Ferraz AB, Bernier M, Vaillancourt R, et al., J. Safety of Transesophageal Echocardiography to Guide Structural Cardiac Interventions. *J Am Coll Cardiol*. 2020 Jun 30;75(25):3164-3173. doi: 10.1016/j.jacc.2020.04.069. PMID: 32586591

5 Aragam JR, Almarzooq ZI. Transesophageal Echocardiography in Structural Heart Interventions: Is it Time to Rethink Our Approach? *J Am Coll Cardiol*. 2020 Jun 30;75(25):3174-3176. doi: 10.1016/j.jacc.2020.05.018. PMID: 32586592

9VT-D mini 3D TEE probe guiding personalized subaortic and aortic valve surgery

Courtesy of Justin Tretter, M.D., Cleveland Clinic Children's, US

Patient history/ pathology

9-year-old with recurrent subaortic membrane following initial resection at 3 years of age, with progression towards moderate-to-severe stenosis (peak gradient = 64 mmHg; mean gradient = 33 mmHg), supporting proceeding with repeat surgery. The trileaflet aortic valve had restricted motion and mild-to-moderate regurgitation.

Challenges

Surgeons often rely on visual inspection, limited by a narrow field of view and non-hemodynamic state, to understand the three-dimensional extent of the subaortic membrane and its relationship to the semilunar attachments of the aortic valvar leaflets. Standard two-dimensional echocardiographic imaging commonly misinterprets this relationship, with the imaging failing to appreciate the semilunar attachment lines of the leaflets.

System, probe & device used

Three-dimensional echocardiographic evaluation was possible in this small child using the 9VT-D mini 3D TEE probe during the preoperative study.

Step-by-step procedure

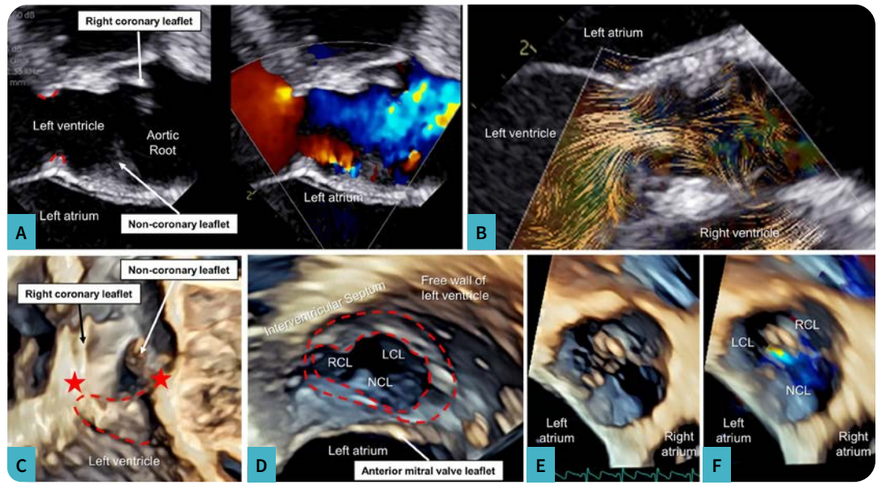
Preoperative 4D TEE delineated the circumferential subaortic membrane attaching to each leaflet nadir. Leaflet thickening suggested extension of fibrotic tissue along the undersurface of the leaflets, restricting leaflet motion. The membrane was resected circumferentially with meticulous resection of the membrane extension along the undersurface of the leaflets. Post-operatively there was no residual stenosis with trivial regurgitation, with improved leaflet motion and coaptation, and favorable hemodynamics suggested by Blood Speckle Imaging (BSI).

Conclusion

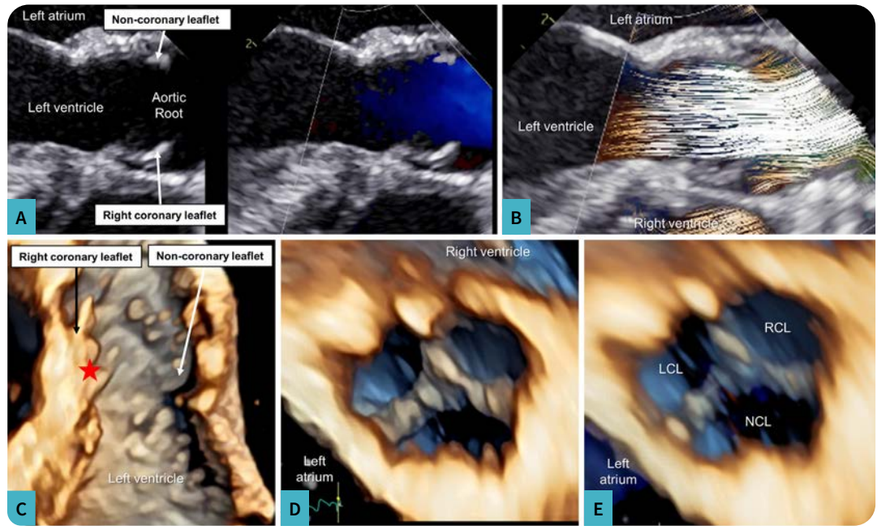
The 9VT-D mini 3D TEE probe provided improved understanding of the three-dimensional extent of the subaortic membrane, including its relationship to, and extension along the undersurface of the aortic valvar leaflets. In addition to standard Doppler assessment, BSI provided immediate understanding of improved, favorable hemodynamics following membrane resection with improved leaflet mobility.

Echo lab follow-up

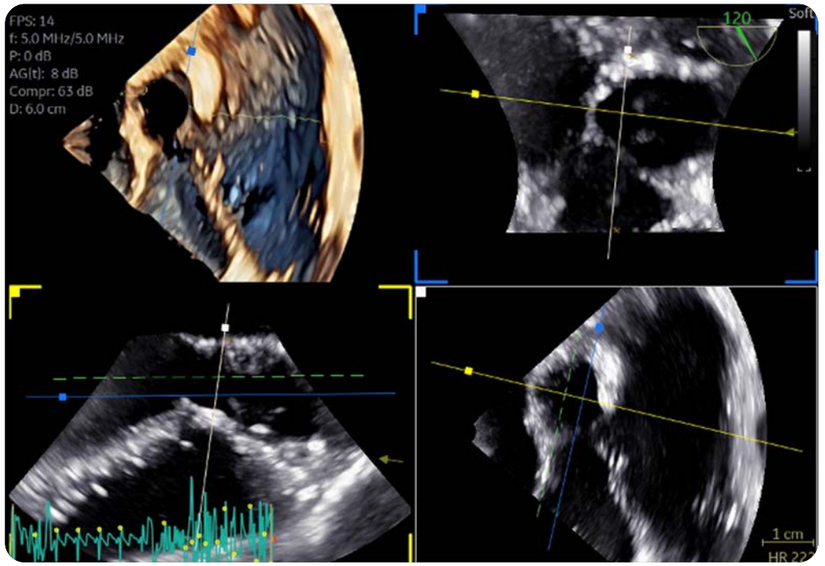
Two-month follow-up TTE demonstrate no residual subaortic or aortic valvar stenosis with trivial regurgitation.



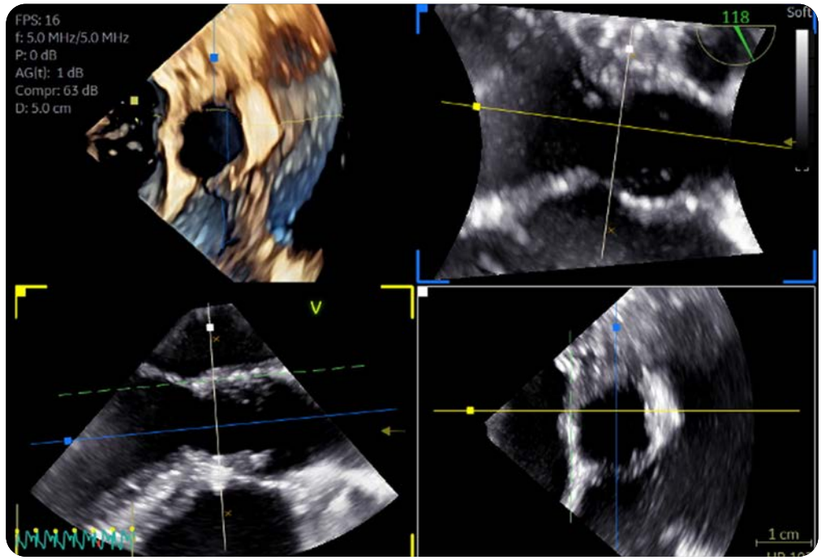
Preoperative transesophageal echocardiographic evaluation. **A)** Color Doppler comparison in systole demonstrates flow acceleration starting at the level of the subaortic membrane (red hashed lines outline the membrane in this and the other panels). **B)** BSI in systole demonstrates narrowing of the outflow jet at the level of the subaortic membrane with subsequent turbulence. **C)** 3D long axis imaging in systole shows the prominent subaortic membrane which has attachment to the nadir of the visualized leaflets (red stars) with mild thickening of the leaflets extending from leaflet hinge to tip. **D)** 3D short axis imaging in systole viewing left ventricular outflow tract and aortic valve from the ventricular apex demonstrates the circumferential membrane, which is most prominent under the coronary leaflets. **E)** 3D short axis of the aortic valve in diastole. **F)** 3D color Doppler demonstrates the trileaflet aortic valve with notable thickening of the right coronary leaflet (RCL) with mild to moderate central regurgitation. LCL, left coronary leaflet; NCL, non-coronary leaflet.



Post-operative transesophageal echocardiographic evaluation. **A)** Color Doppler comparison in systole demonstrates no significant residual subaortic membrane with laminar flow across the left ventricular outflow tract and aortic valve. **B)** BSI in systole depicts laminar flow. **C)** 3D long axis imaging in systole shows a very trivial residual subaortic membrane near the nadir of the right coronary leaflet (red star) with a noticeable thinner right and non-coronary leaflet. **D)** 3D short axis of the aortic valve in diastole. **E)** 3D color Doppler demonstrates notable thinning of the right coronary leaflet (RCL) tip with improve coaptation and no significant residual regurgitation. LCL, left coronary leaflet; NCL, non-coronary leaflet.



Preoperative transesophageal echocardiographic FlexiSlice evaluation of the aortic virtual basal ring. The short axis is reformatted in the bottom right-hand image, measuring 1.4 x 1.0 cm in systole. The subaortic membrane narrows this plane, most prominent along the ventricular septum to left ventricular free wall under the coronary leaflets.



Post-operative transesophageal echocardiographic FlexiSlice evaluation of the aortic virtual basal ring. The short axis is reformatted in the bottom right-hand image, now measuring 1.6 x 1.4 cm in systole following membrane resection.

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Breakthrough imaging for our most precious patients

Take a closer look at the world's first mini 3D TEE probe – 9VT-D. Designed for patients as small as 5 kg.

More than 1.5 million babies worldwide are born with a congenital heart defect each year.[1] The pressing health problem becomes even more daunting when you consider the smallest patients are often the most challenging.[1] Emerging technologies in echocardiography, including the 9VT-D mini 3D TEE probe, are providing clear advantages at Cleveland Clinic Children's. For their pediatric cardiologists and surgeons—like Justin Tretter, M.D.—everything is in the details.

Director of Advanced Imaging for the Pediatric and Adult Congenital Heart Center, Justin Tretter, M.D., has a unique background that includes training in advanced non-invasive imaging and cardiac morphology. He works alongside renowned surgeon, Hani Najm, M.D., and together they serve as Co-Directors of the Congenital Valve Procedural Planning Center. Their innovative techniques have helped Cleveland Clinic Children's earn its place as one of the top cardiology and heart surgery programs in the US.

Cleveland Clinic Children's features two leading-edge catheterization suites for both simple and complex interventional procedures, such as atrial septal defect closure or pulmonary valve implantation, avoiding the need for open-heart surgery. There is also a Hybrid Pediatric Catheterization Laboratory with advanced imaging technology that enables interventional cardiologists and surgeons to perform hybrid procedures without cardiopulmonary bypass.

Dr. Tretter and Dr. Najm rely on the latest 3D and 4D imaging techniques to get a detailed understanding of a patient's heart structure and function to personalize every interventional and surgical procedure. With advanced imaging, they can create a blueprint and plan before ever stepping into the operating room.

Their expanded toolbox now includes the world's first 3D TEE probe designed with children in mind.[2] The breakthrough innovation, powered by the Vivid™ E95 Ultra Edition, allows for real-time multiplane and 3D imaging in patients as small as 5 kg.[2]

We sat down with Dr. Tretter to find out more about how rapid advancements in imaging technology are impacting pediatric care at Cleveland Clinic Children's.

Can you tell us about your unique background and how it drives your daily practice?

Dr. Tretter: *I am trained as a pediatric cardiologist with additional training in advanced cardiac imaging, cardiac MRI, CT, and three-dimensional echo, but the foundation of my training is really as a cardiac anatomist. My passion is really understanding the basis of cardiac form, and how cardiac form dictates cardiac function and physiology—and ultimately patient outcomes. My approach starts with understanding very detailed cardiac development and cardiac anatomy, then figuring out what is clinically and surgically relevant, and then image that detail with standard 2D and more advanced 3D and 4D imaging to help personalize surgical and interventional procedures.*

> *"Now that good quality 4D echo imaging is easy and accessible, I think our patients deserve that detailed imaging evaluation before they go into the operating room or the cath lab.*

Why is 4D echo technology so important in pediatric cardiology and congenital heart disease?

Dr. Tretter: *The heart is a very complex structure with significant variability and when we deal with congenital heart disease that variability becomes even more significant. To try to understand that 3D complexity—and if we talk about the motion of the heart, 4D complexity—it becomes very challenging.*

Often, we can get by with 2D imaging when we're following patients, but now that good quality 4D echo imaging is easy and accessible, I think our patients deserve that detailed imaging evaluation before they go into the operating room or the cath lab. 3D and 4D imaging really help us to understand the specific patient and their specific lesion, whether they have congenital heart disease or acquired heart disease.

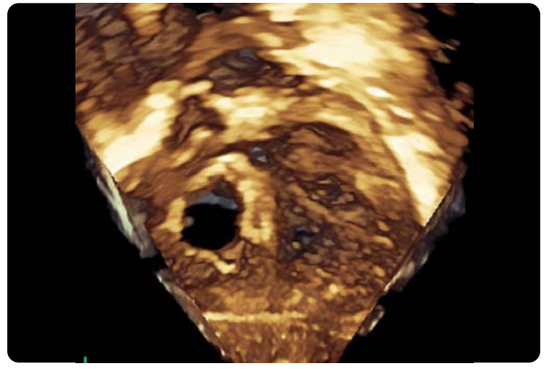


Image 1: 3D of newborn with DORV with subaortic VSD viewed in short axis of the ventricles with tricuspid valve seen in short axis, the VSD seen at the septal and anterior leaflet commissure, and the aortic valve seen near the VSD and above the tricuspid valve.

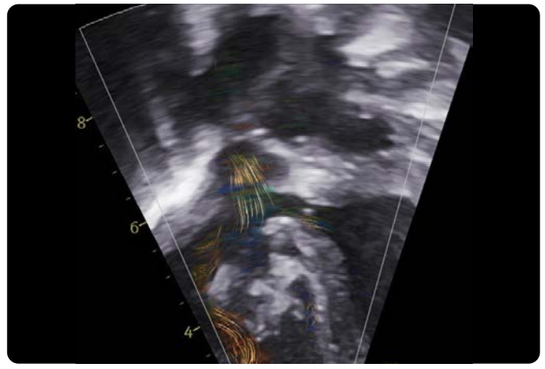


Image 2: Subcostal short axis view in a similar plane to Image 1, showing blood flow both from the LV to the aortic valve, and from the RV to aortic valve. Even though this patient had a subaortic VSD, and should have demonstrated normal oxygen saturations, the patient's anatomy resulted in streaming of blood with deoxygenated blood from the RV entering the aorta and causing lower oxygen saturations. This was not well appreciated with standard color Doppler imaging.

4D functionality is relatively new in the world of pediatric cardiology compared to adult echocardiography. How has the 9VT-D mini 3D TEE probe made a difference in your program?

Dr. Tretter: *The 4D technology has been around for a while with the 6Vc-D TTE probe, which has allowed us the ability to do 4D transthoracic echo in some of our pediatric patients and do it in the outpatient setting. But I think the honest truth is we're not as good as our adult acquired counterparts because many pediatric imagers are not trying to obtain 4D images on a daily basis.*

Now that we have the 9VT-D mini 3D TEE probe, I've seen a dramatic change. Our sonographers and cardiologists, who maybe weren't familiar or were intimidated to do 3D and 4D echo, are getting that daily exposure. They are getting comfortable and now a larger proportion of our providers can create these images. Surgeons and interventionists are seeing these imaging capabilities in our management conferences so now it's becoming, rightfully so, an expectation.

> *"The mini 3D TEE probe has enabled Dr. Najm to tailor his repair during surgery and it's also enhanced his ability to repair what was previously thought to be unrepairable. That includes many, many valves that would have gone for replacement.*

Has the 9VT-D mini 3D TEE probe changed the way surgeons and interventional cardiologists approach procedures?

Dr. Tretter: *Dr. Najm has told me it has exponentially increased the advanced imaging support of this program and that it really has made it an expectation for our patients. He says he's a better surgeon because it has improved his preoperative evaluation of looking at structures in their loaded condition. The mini 3D TEE probe has enabled Dr. Najm to tailor his repair during surgery and it's also enhanced his ability to repair what was previously thought to be unrepairable. That includes many, many valves that would have gone for replacement.*

Is there anything that surprised you about the 9VT-D mini 3D TEE probe?

Dr. Tretter: *Yes, the excellent image quality. You need good 2D image quality to create good 3D image quality. When we're using this probe, the 2D image quality is excellent, leading to good, useful, and additive 3D image quality. These programs I have trained and worked have all been multi-vendor programs, and having used different vendor systems I haven't seen this level of 2D imaging quality in a pediatric TEE probe. With 3D imaging, it's really garbage in, garbage out.*

Do you think the 9VT-D mini 3D TEE probe can possibly reduce some other testing that is ionizing or possibly reduce fluoroscopy time?

Dr. Tretter: *The short answer is yes, but as an expert in cardiac CT, I am a lover and promoter of the appropriate use of cardiac CT. I think there is a lot of benefit in certain scenarios and very often it may take a multi-modality imaging approach. But now, especially with increasing echo technology and with the new 9VT-D probe with our younger pediatric patients, often times echo is certainly enough.*

> *"Dr. Najm has told me the mini 3D TEE probe has exponentially increased the advanced imaging support of this program and that it really has made it an expectation for our patients.*

We hopefully have a paper coming out soon that will show how when using 3D echo and meticulously interrogating the surface area of the parts of the leaflets that coapt together, we can pick up very subtle abnormalities that are surgically and clinically significant that we aren't picking up by our detailed CT assessment and standard echo imaging. I think echo is certainly the mainstay of imaging and in many patients with the 4D echo, it can be the sole modality for imaging.

For example, in ASD device closures when there's potentially deficient rims. My experience has been that with the use of standard 2D echo imaging, there is often prolonged fluoroscopy time, failed attempts at putting in different size devices. That's where I think 4D echo could really reduce that fluoroscopy time.

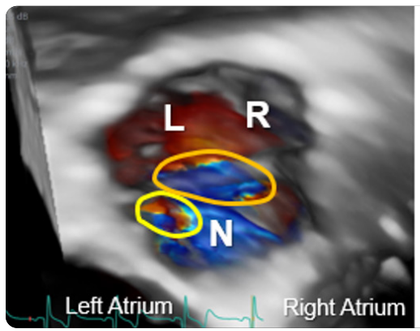


Image 1: Same patient showing these two jets (orange – central jet; yellow – jet near left/ non-coronary commissure).

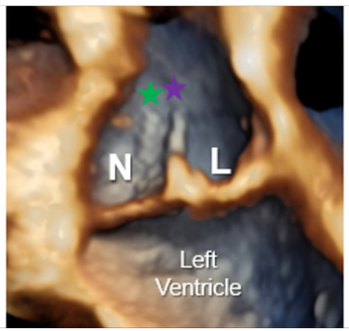


Image 2: Commissural long axis view in diastole demonstrating malalignment, or a separation between the left (purple star) and non-coronary leaflet (green star) at their commissure with coaptation deficiency.

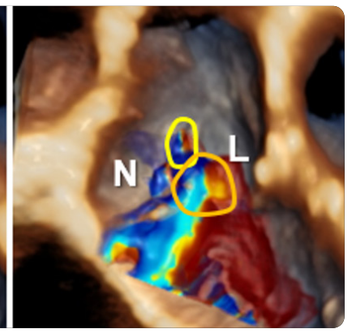


Image 3: Color comparison of the same colors as in Image 1.

What is the value of FlexiSlice, our multiplanar formatting tool, and how is it best utilized?

Dr. Tretter: *It's my favorite tool to use with 4D echo and I currently think it's underutilized. In my opinion, it should be the standard of care for any valve procedure, any procedure involving holes between chambers, such as Ventricular Septal Defect (VSDs), to obtain precise measurements in the short axis of the assessed structure utilizing FlexiSlice. Let's say in the setting of double outlet right ventricle where you're trying to baffle the left ventricle through interventricular communication to one or the other great arteries. Often, we will do very thorough preoperative planning, but that's where I think 4D echo and multiplanar formatting is necessary to quantitate the size of that communication and help to guide the surgeon creating the baffle.*

I've found that FlexiSlice is also helpful with any valve procedure. Besides the ability for accurate assessment of dimensions of the valve annulus, I teach our sonographers that FlexiSlice is the tool for very precise cropping. In addition to short axis views, it allows you to crop into orthogonal long axis planes so you can precisely get into the view you want.

Can you tell us a bit about blood speckle imaging. What information does BSI provide and how do you utilize it in your practice?

Dr. Tretter: *Many providers are familiar with 4D flow by MRI. In many ways, it's analogous. Blood speckle imaging shows you the vector flow lines of blood flow across a structure in two dimensions, whether you're looking across a VSD, ASD, or across a valve.*

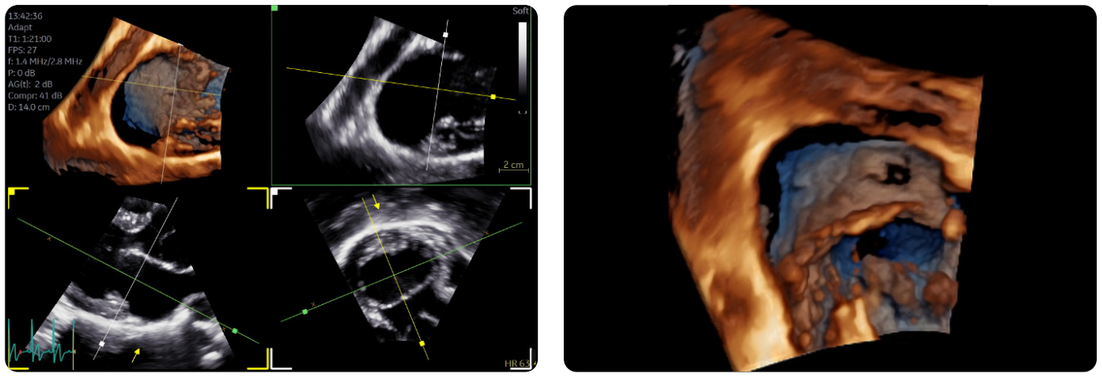
In our valve center, we have been creating computational models trying to understand how flow across a structure leads to stress and strain on adjacent structures, leaflets, walls and so on. In aortic valve cases, we try to use the patient's preoperative data to simulate surgeries to understand what options will lead to the most favorable hemodynamics. We are now working with blood speckle imaging, as it is more easily available than 4D flow MRI. The commercially available BSI is only a visualization tool currently, but we have had several scenarios where this is useful.

One example is valve surgery in the CV operating room. We can display BSI both pre-op showing very turbulent flow and post-op, we can understand immediately if we restored laminar flow, which will lead to more favorable hemodynamics long term. We may see a post operative result that we did not restore good laminar flow and that might lead us, depending on other findings on that postoperative study, to go back to modify that surgical repair.

> *"These programs I have trained and worked have all been multi-vendor programs, and having used different vendor systems I haven't seen this level of 2D imaging quality in a pediatric TEE probe. With 3D imaging, it's really garbage in, garbage out.*

Another example occurred in the cardiac ICU. We had a patient with double outlet right ventricle with a subaortic VSD. So the patient should have had normal oxygen saturation for a patient based on this general anatomy. However, the patient was desaturating, and we used BSI to better understand the hemodynamics within the right ventricle related to subtle variations in the anatomy, and the related outflows that lead to the desaturation.

No two patients are the same, even with the same congenital heart disease. The subtle variations can lead to significantly different hemodynamics and physiology. BSI is better than standard color flow, enabling quick and easy assessment of the patient's hemodynamics and physiology.



TTE FlexiSlice is used to view the anterior leaflet of the mitral valve in long axis 3D during systole with moderate prolapse, demonstrating mild leaflet thickening with mildly elongated chordae.

Are there any other tools or features that you find especially helpful?

Dr. Tretter: *The other thing that I love with the GE HealthCare platform is HD color. It makes the low velocity flows more translucent so we can focus on the high velocity flows. That really helps with color imaging of Ventricular Septal Defects, or the vena contracta of a regurgitant jet, and to really be able to visualize the anatomy along with the color flow of interest.*

I would also mention the 4D marker. As an anatomist, I spend my waking hours looking at nitty gritty anatomy, but I can still get disoriented when we crop into narrower fields of view with 4D echo. And as you rotate things, you can easily lose your orientation, especially if you're trying to narrow your field of view to improve resolution.

> *"I think echo is certainly the mainstay of imaging and in many patients with the 4D echo, it can be the sole modality for imaging.*

As your toolbox of innovations keeps expanding, what is the biggest impact on your program and your pediatric cardiology care?

Dr. Tretter: *I would go back to what I mentioned about my surgical colleague, Dr. Najm. He has a reputation as a phenomenal surgeon and his outcomes speak to that. As we've brought this imaging support to the next level, Dr. Najm has said over and over again that it's made him a better surgeon. To hear somebody who is already leading the pack, say he's become even better because of the imaging support, I think that speaks volumes towards the advantage.* ■

Justin Tretter, M.D., is Director of Advanced Cardiac Imaging and Co-Director of the Congenital Valve Procedural Planning Center at Cleveland Clinics Children's in Cleveland, Ohio. He is Professor of Pediatrics at Cleveland Clinics at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University. Dr. Tretter is a pediatric cardiologist with expertise in 3D echocardiography, cardiac magnetic resonance imaging, cardiac computed tomographic imaging, 3D and 4D reconstructions and other advanced imaging techniques used for personalization of interventional and surgical planning. Dr. Tretter also has unique additional training as a cardiac morphologist under the training of cardiac morphologist, Professor Robert Anderson. He has published over 140 peer reviewed articles with interests in translational (cardiac anatomical, developmental, computational modeling) and clinical (cardiac imaging and surgery) research. Dr. Tretter is also the founder and former editor-in-chief of Heart University, a popular educational platform for congenital heart disease, and editor-in-chief for the upcoming 5th edition of "Anderson's Pediatric Cardiology" textbook.

1 YUJIN HU et.al. | AIDAN: An Attention-Guided Dual-Path Network for Pediatric Echocardiography Segmentation | Source https://ieeexplore.ieee.org/abstract/document/8979379

2 The content herein refers to 2022 release of Vivid portfolio. 9VT-D probe is exclusively available for Vivid E95 and Vivid E90. Vivid Ultra Edition is released as of 25th August 2022

Doctors are paid consultants for GEHC and were compensated for participation in this article. The statements described here are based on their own opinions and on results that were achieved in their unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

JB26293XX

Profiles of progress

The people and experiences that make Vivid™ shine

They work for GE HealthCare, but these clinical experts are really here to work for you. To guide, collaborate, and help you deliver your most confident care. In this edition, meet the US Pediatric and Structural Heart Clinical team—your support system as you take on your toughest cases and treat your most delicate patients.

Daniel Amaguayo, RDCS, BS

Structural Heart Clinical Sales Specialist

Six years ago, Daniel Amaguayo decided to take his passion for cardiovascular ultrasound on the road. He went from managing a Cardiovascular Department at a Philadelphia hospital to sharing insights about GE HealthCare technologies with physicians and sonographers in the Northeastern US. For Amaguayo, trust and dependability are a point of pride as he helps to solve some of their biggest challenges. *"I enjoy being part of the most advanced cardiac procedures where ultrasound is essential. In the structural heart environment where seconds matter, my commitment is to be ready to support physicians with imaging techniques that simplify and make it efficient to obtain critical information."*

James O'Byrne, ACS, RDCS (AE, PE), RVT

Structural Heart Clinical Sales Specialist

From the first time he watched a bedside echo, Jason O'Byrne was hooked on cardiovascular imaging. He was a US Navy Hospital Corpsman at the time, but it spurred him to apply for Cardiovascular Technology School and pursue a career in the field. The Advanced Clinical Leader joined GE HealthCare a little more than a year ago and serves hospitals in the Midwest and South-Central US. He loves being on the ground floor of innovations in structural heart and sharing bold breakthroughs with customers. *"We can collaborate on bringing the future of technology to your hospital's doorstep by incorporating 4D ICE, the very first mini 4D TEE probe, CT Fusion, and virtual reality using our proprietary RAW data. The sky is the limit, and we want to be there to help you along the way."*

Ed Vinson, RDCS

Structural Heart Clinical Sales Specialist

Ed Vinson says the best part of his day is going to work because he loves his job. It's easy to believe when you consider Vinson has been involved with echo for 35 years—trained in invasive/non-invasive cardiology, respiratory therapy and pulmonary. Based in South Carolina, Vinson has worked with GE HealthCare for six years. He says he still gets excited teaching new features and demonstrating how they can make a meaningful impact. "*My job involves working shoulder to shoulder with world-class physicians and it is such a great environment with bi-directional learning. It's really awesome to then cross pollinate all that I learn clinically and technically to physicians across my territory and beyond."*

Steve Richards, RCS

Structural Heart Clinical Sales Specialist

Steve Richards fell in love with the heart as a Cardiopulmonary Specialist while serving in the Air Force in 1996. A decade later, Richards became part of the GE HealthCare team and continues his mission to ensure imagers and interventionalists are confident and comfortable with the technology. He appreciates the opportunity to provide SH teams in the North Central US with transformative solutions and deliver plenty of 'wow' moments. *"I remember a case in Chicago. There were three implanters on the other side of the table, and we were behind the boom. They loved the 2D and biplane imaging, but when we went to 4D, there was a combined 'Ooooooooooh!' from the other side of the table. I wish I had been recording."*

Charles Polosky, RDCS, MBA

Structural Heart Clinical Sales Specialist

Charles Polosky is humbled that many of his cardiovascular ultrasound customers make him feel like part of their team. He's spent the last 18 years building close relationships with physicians and sonographers at hospitals around the country and working on product development with GE HealthCare global engineering. Polosky is now serving the West Coast as a Structural Heart Clinical Expert. *"My customers need to know that they have an accessible, reliable, experienced echo-focused resource in their corner. I'm here to help guide them in 4D imaging and provide training on the correct applications to answer their clinical questions quickly and easily. My relationships are the key to my job fulfillment."*

Zachary Gruetzner, RDCS (AE, PE)

Pediatric Clinical Leader

Zachary Gruetzner has always been drawn to 'service' careers. First joining the Marine Corps, then becoming a police officer, and now as a clinical leader supporting pediatric heart centers across the country. He's been part of GE HealthCare for five years and is happiest when he can see the impact of the technology firsthand. *"My passion is being able to help tell a patient's story when they may not have the ability to speak for themselves. I might never know the potential of the patient I am serving. I could be helping a future farmer that helps feed the world, a future Nobel laureate, or another healthcare worker that will impact other patients' lives. The possibilities are endless, but I get to help in that journey."*

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About GE HealthCare

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from prevention and screening, to diagnosis, treatment, therapy, and monitoring. We are an $18 billion business with 51,000 employees working to create a world where healthcare has no limits.

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