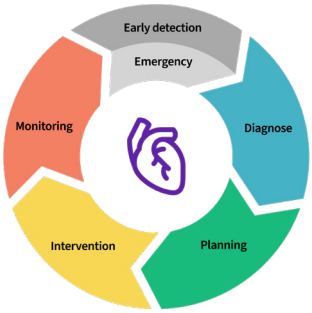
GE HealthCare



Allia™ Magazine

2024
EDITION 1

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GE HealthCare

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Dear Reader,

We continue to see development and new practice evolve across coronary intervention, structural heart and electrophysiology procedures. The development in both image guidance and device technology has led to greater precision, speedier procedures and an increased cohort of patients being suitable for treatment in the Cath Lab.

At GE HealthCare we are dedicated to creating a world where healthcare knows no limits. We also recognize the pressures that come with a service in high demand. To that end, combined with our focus on delivering Imaging systems which enable clinicians to deliver the best clinical outcomes, we innovate to create an integrated workflow which gives the all of those who interact with our systems confidence, intuitive control and customized platforms.

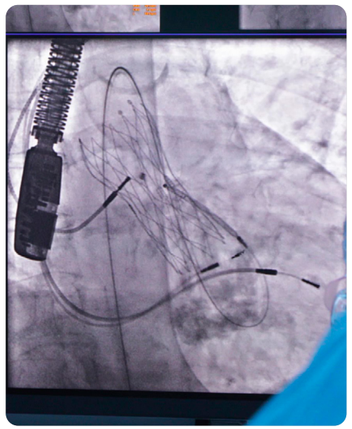
We are delighted to be able to share with you the first Allia Magazine. In creating the Allia Magazine, we have partnered with leading Cardiologists, Cath Lab team members and our Internal GE HealthCare innovation team to bring you a variety of clinical case studies from around the Globe.

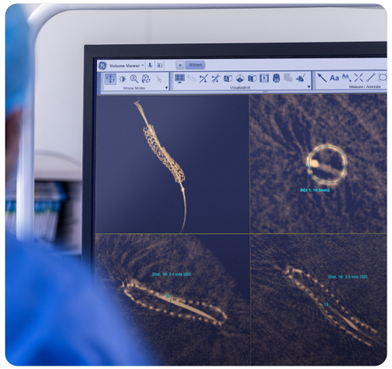
The articles in this magazine extends beyond clinical case studies and interviews, they also highlight how our technology can support Clinicians, Cath Lab staff and hospitals to deliver a higher standard of patient care with superior clinical outcomes. At GE HealthCare we have a true vision in minimally invasive cardiology and we hope that the articles in this magazine gives you a feel for our commitment, our capabilities and partnerships in this evolving area.

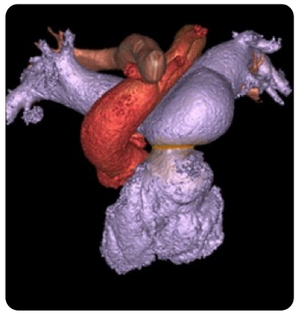
It's been a real pleasure putting this magazine together and I'm delighted to be able to share this first edition with you. We hope you enjoy.

Philippe de Larambergue and
Florian Guillemin

Allia™ Magazine







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Improving the patient care pathway and the physician experience

Prof. Martine Gilard and Dr. Romain Didier

Augment Imaging with Allia IGS 5

Allia IGS 5 offers a leading hemodynamic center personalization, integration and ergonomic improvement. CHRU of Brest, France.

Located in the Brittany region of France, CHRU Brest is a university hospital and a leading public healthcare institution which covers a population of 1.2 million people. CHRU Brest has more than 6,500 employees over nine sites including 500 doctors. The hospital is performing 800 angioplasties and about 300 TAVI annually in addition to other valve replacements.

Recently, the Cardiology Department at Brest University Hospital had a new Allia IGS 5 installed in the cathlab which has helped the team there simplify and streamline workflows while also improving image integration and quality and optimizing dose management.

The GE Healthcare team worked with interventional cardiology leaders at Brest University Hospital and other institutions to ensure that, as they were developing Allia IGS 5, they were building in functionality that met the needs of the clinicians.

"*At the starting point, we asked ourselves how to improve the user experience. What was the possible optimization to most easily access patients,*" said Jean Michel Marteau, design architect at GE Healthcare. "*We had to improve the access to the main functions and make the physician more autonomous; improve the way they interact with the table controllers to better meet their needs.*"

The collaboration resulted in a system purpose built to serve the needs of interventional cardiology departments and their patients – the Allia IGS 5.

Interventional cardiology leaders at Brest University spoke about how the new system is improving the patient care pathway in their cathlab.

"*Allia offers the capability to integrate all the imaging sources that are mandatory for the good patient care pathway in a very simple way,*" explained Prof. Martine Gilard, MD, PhD, FESC, director of interventional cardiology at Brest University Hospital. "We have a direct access to the QFR that we can control directly from the side of the table in autonomy."

Dr. Romain DIDIER, MD, PhD, an interventional cardiologist at the hospital added, "*It is about time saving. With Allia's personalization and ergonomic improvement, we have quick and direct access to all functionalities. One example is the StentViz application that allows us to check the stent deployment in the coronary that is now instantaneously displayed.*"

Intuitive and customizable interfaces

Getting the interfaces just right was a key component in the design of the system.

"*The biggest challenge with Allia was developing a system that is both customizable and versatile,*" said Laure Laporte, usability, and validation leader at GE Healthcare. "*We wanted to make sure that the users had interfaces that looked like what they prefer from their day-to-day experiences with devices they use and enjoy, like their smartphones.*"

The goal was to use personalization to make the physician feel that each room they enter is their own room. Customized profiles in the system interface ensure that the physician sees the display monitor, dose, protocol, and interface as he or she set it up.

"*For me, the main change is the personalization from the touch panel. We have direct access to all the parameters, StentViz, image gallery or sequences review in a very simple way,*" said Dr. Romain DIDIER, MD, PhD. "*You can personalize your interface depending on the operator with our own frame rate, dose setup or preferred angles for example.*"

Prof. Martine GILARD concurs that the personalized interfaces are a benefit. "What I like the most with Allia are the new interfaces. We have a very quick and intuitive access to the parameter for the fluoro, the graphy etc."

Dose optimization

"*The image quality team designed the features of Allia to not only optimize image quality but also help give more information to the cardiologist on the dose he or she delivers,*" said Bastien Guery, image quality engineer at GE Healthcare. "*We met with several cardiologists in their hospitals and their input was critical. Now, with Allia,*

Prof. Martine GILARD MD, PhD, FESC, is the Director of Interventional Cardiology department at Brest University Hospital. Involved in more than 400 publications, she is specialized in Hemodynamic and Structural Heart Interventions. She is the past president of the French Society of Cardiology in 2020 and has been involved in the EAPCI association since 2009.

Dr. Romain DIDIER, MD, PhD, is a permanent member of the CHRU of Brest institution as Interventional Cardiologist. Leading operator for innovative treatment in PCI and structural heart.

the physician can very easily control the dose. It is very simple, and it is done via the touch panel."

Related to dose management, Prof. Martine GILARD said, "*One improvement I've experienced is Allia's InnovaSense feature. This is an intelligent system that ensures we always get the optimal distance between the detector and the patient regardless of the angulation. We know that this is a critical point to get a good image and a dose reduction for the patient and the staff. With all the dose / IQ improvement done during the years, we are now working at 3.75 frame per second in fluoro that is very low.*"

Dr. Romain DIDIER, MD, PhD added, "*The most important innovation is the Dose Cockpit. This application enables the live and instantaneous display of the dose we are delivering to the patient. it means that during the procedure we can see if we are in an angulation that delivers a too much dose and make little moves to decrease the dose delivered. It comes in addition to the Dose Map that allows us to monitor the skin dose received by the patient in the different areas where X-ray shots have been performed.*"

Allia IGS 5 features AutoRight, an AI-powered tool that enables clinicians to reach the level of image quality that they define, at the lowest possible dose, regardless of the patient anatomy or angulation. With AutoRight, the machine assists the clinician in optimizing the technical parameters allowing him or her to focus their attention and expertise on the patient.

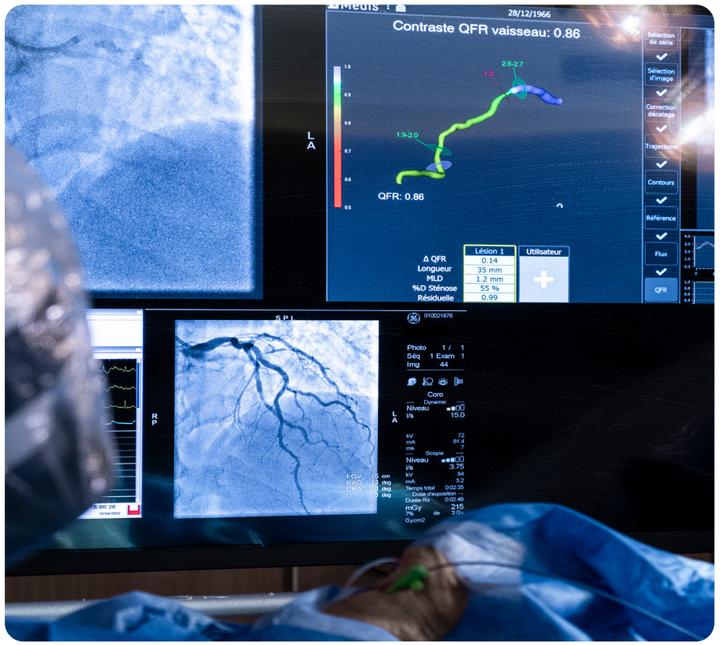
Multi-modality integration

cathlabs like the one at Brest University Hospital work with a wide range of image sources and need a solution that can integrate them all.

"*With Allia, the multi-modality integration is a step further," explained Dr. Romain DIDIER, MD, PhD. "From functional evaluation (OCT) to robotic integration this new platform is very open and 'all in one' in terms of plugging but also for by its interface. Switching between advanced applications is like using a smartphone, intuitive and playful.*"

Allia ISG 5's integration capabilities enable clinicians to easily integrate and connect with other imaging sources such as OCT, IVUS, FFR, QFR, and Echo.

"*In our center we are using many third-party imaging tools to complete the 2D images from the coronary arteries with, for example, endocoronary ultrasound that is directly displayed on Allia's large monitor display,*" said Prof. Martine GILARD. "I*t really helps us to confirm our coronarography with these tools. It is very easy to use and to plug and play.*"



Prof. Martine GILARD called Allia's imaging integration tools a "revolution" and highlighted the benefits of being able to integrate all essential images while being able to work at a very low dose. "*This gives us the best possibility of treatment and the best possibility of diagnosis with the lowest irradiation possible.*"

A legacy and a vision for interventional cardiology

the Allia IGS 5 is GE Healthcare's latest offering in interventional cardiology, and it builds on a legacy of innovation and meeting the needs of clinicians.

"*GE Healthcare was the first 20 years ago to introduce a digital detector system in cardiology. Today, with Allia IGS 5, GE Healthcare takes a further step to be prepared for the challenges of interventional cardiology with improvements in ergonomics, customization of the environment and the ability to connect to third party equipment," said Christophe LePage, program manager, GE Healthcare. "Nothing excites us more than seeing doctors find ways that the Allia IGS 5 can optimize their work and improve patient care.*"

The statements by GE HealthCare customers described here are based on their own opinions and on results that were achieved in the customer's 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.

Allia may not be available in all countries. Refer to your sales representative for more information. JB05637XE

Meet the first European Allia IGS 7 dedicated to Cardiovascular procedures

Hospital Clínic de Barcelona, Spain

Hospital Clínic de Barcelona has been a leading public healthcare provider in the city of Barcelona, (Catalonia, Spain) for over 100 years. It is a university hospital, developed together with the Faculty of Medicine of the University of Barcelona.

Healthcare, research, and teaching are their three main areas of actions which, together with the deep commitment to excellence that characterizes all the people who work there, make Hospital Clínic a well-known center of excellence not only in the country but also all over the world.

Prof. Marta Sitges, MD, PhD; is a senior consultant non-invasive cardiologist at the Cardiovascular Institute in Hospital Clinic at the University of Barcelona. Her main clinical practice is related to clinical and interventional echocardiography, sports cardiology at heart valve disease. She has published more than 280 peer reviewed papers, presented more than 300 lectures in National and International meetings,received 60 grants, and directed 12 completed PhD theses. She is the coordinator of the Sports Cardiology Group at Hospital Clinic and responsable of the program of Sports Cardiology at FC Barcelona since 2009. She has formerly been Head of Cardiac Imaging from 2013 to 2015 and Director of the Cardiovascular Institute since October 2015.

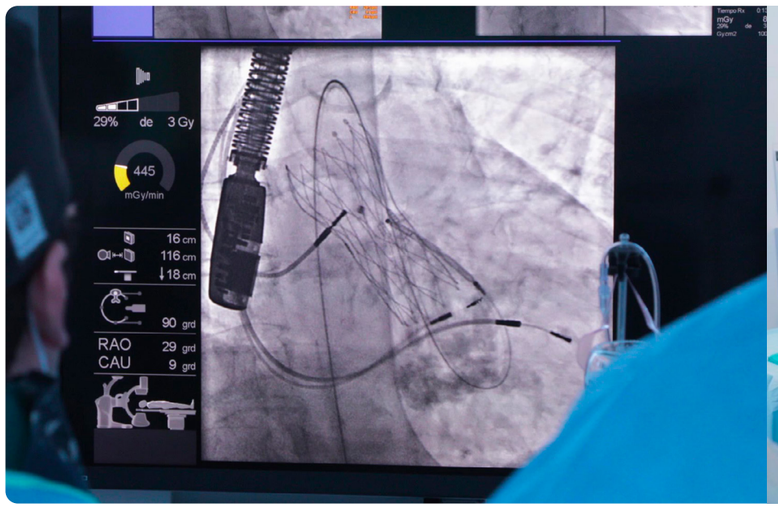
Dr. Manel Sabaté, MD, PhD; is Chief of the Interventional Cardiology Department at the Clínic University Hospital in Barcelona and Associate Professor of the Central University of Barcelona. He is author of more than 500 papers (H index 60), >20 book chapters and is the editor of 5 books. He is member of the editorial Board of several journals in the specialty and has been the recipient (as a Principal Investigator or Collaborator) in several competitive grants. His experience includes diagnosis and treatment of ischemic heart disease and other cardiac disorders, and he is specifically trained at cardiac catheterization and percutaneous coronary intervention and treatment of congenital and acquired structural heart disease including transcatheter aortic valve implantation and Mitraclip implantation.

Dr. Xavier Freixa, MD, PhD; is an Interventional cardiologist at the Hospital Clínic of Barcelona, University of Barcelona. Dr. Freixa has been trained in interventional cardiology at the Hospital Clínic, University of Barcelona, the Toronto General Hospital, University Health Network and the Montreal Heart Institute, University of Montreal. He has a major interest in complex percutaneous coronary interventions, structural heart and adult congenital diseases. Among the main areas of interest highlight some advanced percutaneous techniques like mitral and tricuspid transcatheter repair, left atrial appendage occlusion, ASD/VSD occlusion, TAVR and other advanced transcatheter interventions.

The Cardiovascular Institute of Hospital Clínic de Barcelona (ICCV) is the healthcare area dedicated to treating cardiovascular diseases.

All professionals who work at Cardiovascular Institute offer top quality healthcare assistance to people that come to their institute. As the entire hospital, it is located in the town center of Barcelona, representing a perfect combination between tradition and innovation. Localized in the beating heart of the city, the hospital was built close to the historical building of the University Faculty of Medicine. Here, ICCV professionals teach several subjects in bachelor's degree courses in Medicine, Nursing and Biomedical Engineering. The institute therefore has a story that starts more than one century ago, representing a great example of tradition of a European university hospital. From that day, clinical activities have been carried out with an increasing attention to cardiovascular research and technological innovation, that now makes ICCV one of the most advanced and state-of-the-art hospitals in the world.

From 2021, the Cardiovascular Institute of Hospital Clínic began to renew its operatory area. All the spaces were completely redesigned to modernize all technologies, including the two existing angiography suites. In addition to them, a new hybrid room has been designed, intended to support mostly an ever-growing number of structural heart procedures. The two angiography rooms were completely transformed and equipped by two Innova IGS520 with Autoright, the AI-based image chain that automatically works in real time to optimize IQ & dose. For the hybrid room, ICCV has chosen the latest system of the GE Family, Allia IGS7 with Autoright, becoming the first European site installing this innovative robotic system in a cardiovascular hybrid room.



From 2015, Prof. Marta Sitges is the director of the Cardiovascular Institute at Hospital Clínic. We asked her to introduce us to their Institute and to tell us about the activities they routinely carry on there.

Prof. Marta Sitges: *Our institute is dedicated to cardiovascular patient care based on three specialties: vascular surgery, cardiovascular surgery and cardiology. There are more than 60 medical professionals working here, along with more than 300 nursing and administrative support professionals. Every year we handle 3000 interventions, in addition to countless cardiovascular consultations.*

We can count on a wide variety of multi-modalty imaging capabilities that allow us to carry out a wide range of cardiovascular diagnoses and interventions, which goes from percutaneous to surgical treatments.

Why did you make the decision to incorporate a hybrid room?

Prof. Marta Sitges: *In recent years, cardiovascular medicine has evolved in such a way that the same disease can be treated with different approaches: in a minimally invasive manner, percutaneously, with open surgery, with medical treatments and so on. The need to work with multidisciplinary teams is evident in the field of cardiovascular diseases, especially for example on heart valve interventions or on some arrhythmias' treatments. In these cases, to offer the patient the best care, we combine different techniques with different accesses. For this, it is essential to have a hybrid interventional room in which open surgery procedures can be simultaneously combined with percutaneous interventional procedures, keeping always in mind patient's safety.*

Why did you choose Allia system for your new hybrid operating theatre?

Prof. Marta Sitges: *We have been working with General Electric for many years in the field of echocardiography, cardiac resonance, and electrocardiographic monitoring. We have always noticed and felt that this is a company that takes care of its customers and provides support after a system has been purchased. In addition to that, with Allia General Electric offered us an extremely high-tech system, with technical characteristics that more than met our requirements.*

What type of procedures are currently carried out in the hybrid room and what procedures are intended to be incorporated in the future?

Prof. Marta Sitges: *At the moment we are using the hybrid operating theatre to carry out structural interventional procedures, transcatheter valve implantation procedures, percutaneous repairs to heart valves, atrial appendage closures and septal defects closures.*

We are also aiming to incorporate vascular surgery procedures, which also require a hybrid approach combining open surgery with endovascular techniques.

In the future, we think we will be able to use this hybrid operating theatre to carry out procedures that are currently being developed, such as endocardial and epicardial hybrid ablation for atrial fibrillation. Maybe even some kinds of ventricular tachycardia could also be optimal interventions that we could perform in our center with our new Allia hybrid room.

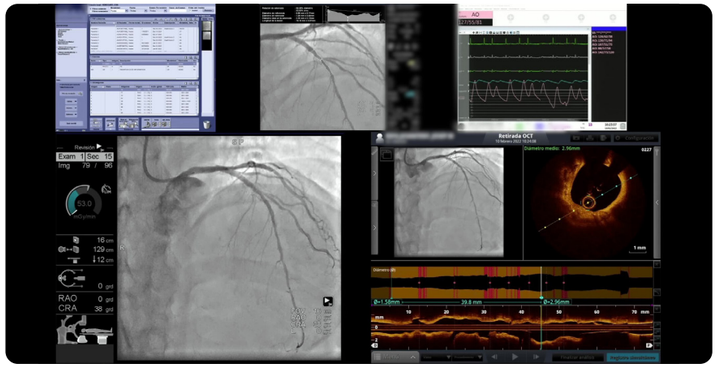
In the Cardiovascular Institute at hospital Clínic also work Dr. Manel Sabaté and Dr. Xavier Freixa. Dr. Sabaté is head of the hemodynamics and interventional cardiology department, and he is mostly dedicated to the treatment of coronary heart disease and the most frequent valve diseases at aortic and mitral level. Dr. Freixa is an interventional cardiologist specialized in structural and adult congenital heart disease.

What do you value the most in a angiography system for your procedures?

Dr. Manel Sabaté: *I think there are several points to keep in mind when treating patients, especially in the cardiac district. The first one is certainly radiological protection, both for the personnel treating the patient and the patient itself. Then, for sure a system needs to provide a proper and optimized image quality, which could be adapted to any procedural step.*

How has your daily practice improved since you got the Allia system?

Dr. Xavier Freixa: *I really think Allia has been a significant improvement for our Institute for three reasons. The first is that Allia provides great images, so we improved in image quality enormously compared to what we were used to. Thanks to Autoright feature, the system can adjust both the dose and IQ for you,*



and adapts to whatever you need in different procedural steps. The second is that being able to move the system around means we can configure the room considering the various equipment needed. Since Allia is not fixed either to the ceiling or to the floor, we are always able to find the perfect positioning so that we -as well as echocardiologists, surgeons and anesthetists- have all got exactly the right amount of room to work in. This feature is always important, but it is key when you speak about structural procedures. Finally, Allia allows you to incorporate advanced software, and let you control it from right inside the theatre.

Speaking of image quality and dosimetry, which Allia innovations do you use to optimize this image quality/dose ratio?

Dr. Manel Sabaté: *The Allia system really does have the ability to combine the two key things that I think are the most important during a procedure, which is maintaining good image quality and protecting both the patient and the staff from radiation.*

During the procedure, with Allia you always know the dose you are giving the patient thanks to dose quantity speedometer systems. This feature has also the possibility to activate a dose limiter, that really helps us to control the dose you give the patient in real time. This way you can even customize the image quality you produce at different angulations during the procedure.

Finally, with Innovasense the detector adapts to the patient's contour in safety conditions, which means that the amount of received and scattered radiation is much less.

Allia presents the possibility to move both the table and the C-arm from the buttons of the detector. What do you think about this new feature?

Dr. Xavier Freixa: *It is great having the possibility to control all system movements, including table motions, even from the detector side. Being able to move things around in various areas means that different team members can work and move around the table without the need to go to each part of the theatre. This has given much more autonomy to us during the procedure.*

Speaking about the Advanced Application portfolio, what benefits you find fundamental using image fusion?

Dr. Xavier Freixa: *The truth is that the benefits of fusion imaging are obvious, in particular in all kinds of procedures where the morphology of the structures is important such as Transcatheter Aortic Valve Implantation, paravalvular leak closures, left atrial appendage closures and so on. Actually, fusion imaging with ASSIST packages is a huge help both with pre-op preparation and during the procedure. This way we are able to reduce the dose of contrast and radiation significatively.*

In coronary procedures, more and more different imaging systems such as OCT, IVUS, etc. are regularly used. What do you think about the integration of these systems with Allia?

Dr. Manel Sabaté: *Nowadays, when we are treating a coronary patient we need to be able to combine various imaging and coronary physiology systems. For instance, we can use Allia to capture the image we get at the same time using techniques such as OCT. We can even use Online QCA, and very easily carry out a really high-quality coronary quantitative analysis directly from the touch panel of the system. Coronary physiology images are very well integrated within this system.*

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Para-valvular leak closure in aortic mechanical valve

Courtesy of Dr. Freixa, Hospital Clínic de Barcelona

Patient History

70 years old female.
Cardiovascular Risk Factors: Hypertension and Hyperlipidemia.
Mitral and aortic mechanical valve replacement in 1995 (27 Carbomedics Mitral and 21 Carbomedics Aortic). LVEF 30%. Severe aortic paravalvular leak (PVL) at the left coronary sinus.
Symptoms: Poor functional class (NYHA 3) with severe hemolytic anemia requiring blood transfusions every 1-2 weeks.

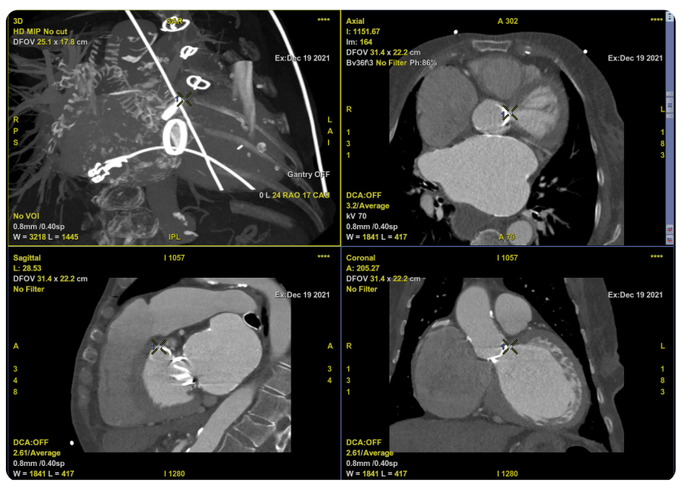
PVL Diagnosis

Transthoracic echo (TTE) and Angio-CT showing a 7x3 mm aortic PVL at the left coronary cusp.

Preparation

Step 1
Pre-op CT

Find leak in pre-op CT and place landmark. From CT, select an angulation where the PVL is visible.



Step 2
Model generation

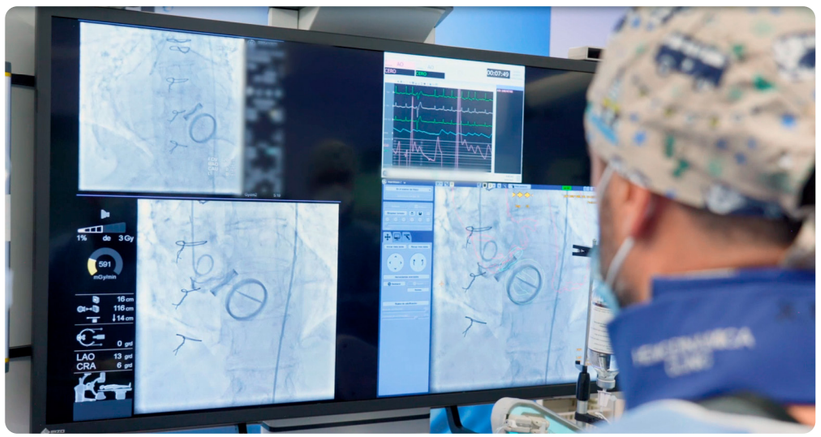
Using Valve ASSIST, the aorta was automatically segmented, and 3D models of the mechanical valves were created. The target POI at the level of the PVL is also converted into a visible landmark when the model is exported to Vision.

Theatre Setup

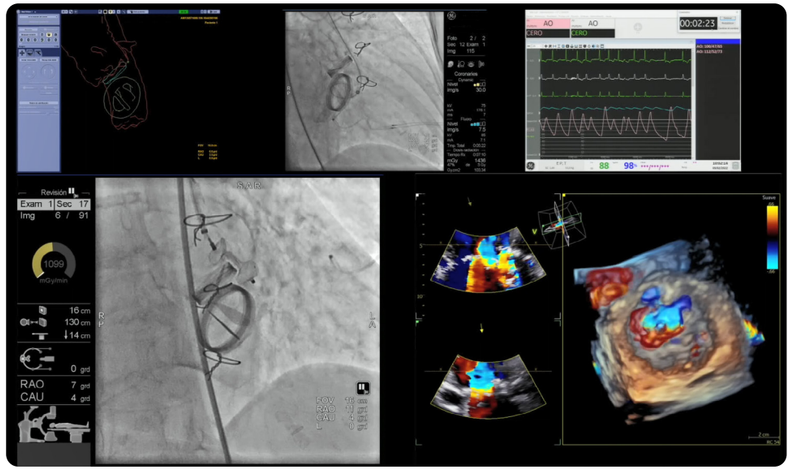
The patient was placed headfirst with Allia at 0 degrees. Another option would have been to place it at 90 degrees, as either way allows easy access to the patient's head for anesthetist and echocardiographer.

PVL Intervention

Procedure done with general anesthesia and guided by TEE and CT-Fluoro Fusion.
Acquisition parameters: Dynamic @15fps Level 2; Fluoro @7.5fps Level 3 with Dose Limiter on.
A Large Display Monitor configuration with a big AW screen was used at the beginning of the procedure to perform the bi-view registration, which was easily performed at tableside with the touch panel using LAO/RAO fluoro images and the mechanical valves as anatomical landmarks.

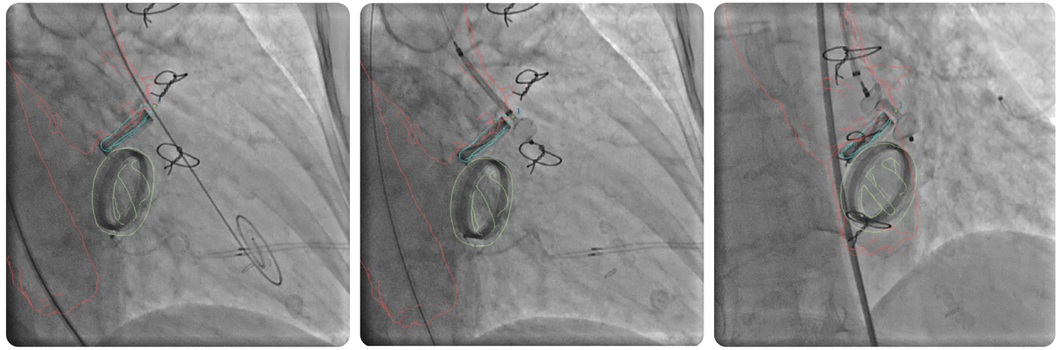


Afterwards, the LDM layout was changed to show the U/S guidance.



Access through the right femoral artery (6Fr). AL-1 (5Fr) and hydrophilic wire to cross the PVL and wire exchange with a high-supportive Safari.

Then, an AVP-3 14x5 mm through a 6Fr 110cm Flexor Catheter was successfully implanted at 24 RAO 17 CAU angulation.



Good result with minimal residual leak. No interference with the mechanical valve or the left coronary artery.

"CT-Fluoro fusion was crucial to minimize radiation and contrast dose."

Dr. Freixa

"The positioning of a marker at the level of the PVL allowed a very easy and straight forward leak crossing and identification of the best projection, that provided a better visualization of the plug implantation."

Dr. Freixa

Clinical Evolution

Clinical follow-up in 1 month showing a relevant clinical improvement with no more transfusions and good functional class (NYHA 1-2)

The statements by GE HeakthCare customers described here are based on their own opinions and on results that were achieved in the customer's 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.

Allia™ IGS Pulse

Cardiac imaging excellence. Visible impact.

BMI 25kg/m²

Case 1 : Diagnostic

A patient with a BMI of 25 was admitted to the clinic for a pacemaker intervention. The day before her intervention, she had a coronary angiography on the Allia IGS Pulse system.
The four angiographies showed that the arteries of this patient were free of lesion.
The radiation dose area product (DAP) was 0.85 Gy.cm² and the total air Kerma (CAK) was 11mGy.

"Since the installation of the new system, I managed to reduce x-ray exposure by decreasing the image rate of the cine acquisition mode to 7.5 frame per second, for all my coronarography and angioplasty procedures, with no loss in image quality."

Dr Philippart, Pasteur Clinic, France

BMI 53kg/m²

Case 2 : Diagnostic/Guidance/Treatment/Control

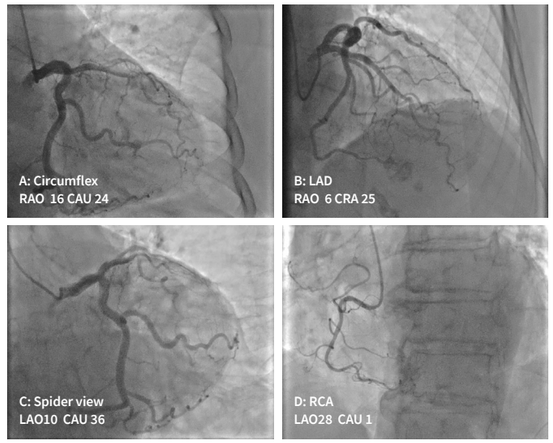
After 6 days of hospitalization due to a cardiac decompensation, a patient (BMI 53) was diagnosed with a CTO of the mid-LAD (E,F) and with a tight stenosis at the mid and distal segment of the right coronary (G). The left main and the circumflex didn't show any lesion (E, F).
Two stents were used to treat the patient: the first one at the distal segment of the right coronary (H) and the second one at the mid segment of the right coronary (I).
The total air kerma was 1.4Gy.
Imaging, guidance for stents' placement and final control were performed with the Allia IGS Pulse system without the need of extra tools (J).

"For this patient, we have an optimal image quality for a precise treatment"

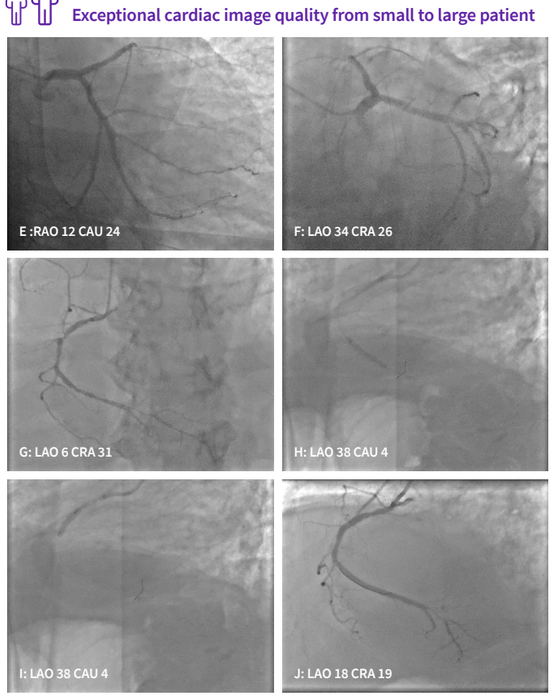
Dr Sauguet, Pasteur Clinic, France

**Allia IGS Pulse.
Exceptional imaging at the right dose for
a visible impact in cardiology interventions.**

Optimize image quality and dose for you



Exceptional cardiac image quality from small to large patient



Allia™ IGS Pulse is the commercial name of the latest generation of Allia IGS 3, Allia IGS 5, Allia IGS 7, Allia IGS 7 OR products in their 20cm or 30cm detector configurations. Allia™ IGS Pulse is not yet CE marked. Cannot be marketed or placed into service until it has been made to comply with CE marking and any other regulatory authorizations as applicable. Product may not be available in all countries. Refer to your sales representatives for more information.
Dr Philippart and Dr Sauguet are paid consultants for GE HealthCare. The statements described here are based on their own opinion and on results that were achieved in their unique setting. Results may vary.

3DStent: A New Era in Stent Enhancement

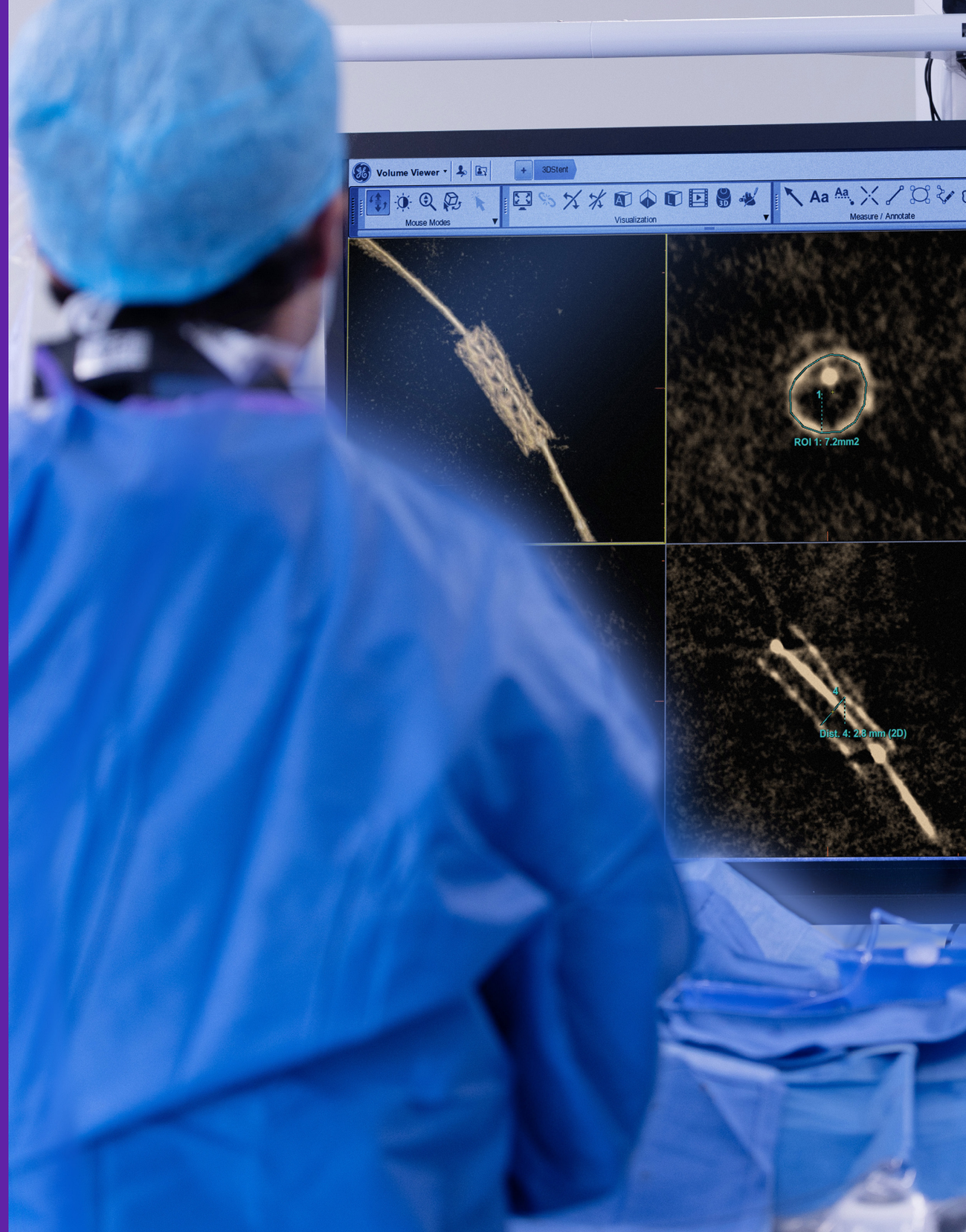
There are around 620 million people across the world living with heart disease and that number is on the rise.

Given this prevalence and the increased incidence, it's critical that the way in which we diagnose and treat heart disease continues to evolve.

Interventional cardiology specifically, and the tools that these physicians use, have evolved and are continuing to do so. This is especially true of stents and procedures such as Percutaneous Coronary Intervention (PCI) that are performed countless times per year around the globe.

Now, clinicians will have a new tool to use in the cath lab to help provide clarity and important information during procedures. 3DStent from GE HealthCare will, for the first time, allow clinicians to visualize the stent in 3D using only rotational angiography, without any additional device.

We had the opportunity to talk with three leading interventional cardiologists about the challenges they face, advances in technology and the future of PCI.



Dr. Benamer
Interventional Cardiologist
ICPS Massy

Dr. Carlos Collet
Interventional Cardiologist.
Physician-Scientist.
Co-director Cardiovascular Center OLV-Aalst

Dr. Giulio Guagliumi
Head of Innovation in Interventional Cardiology and Clinical Research Area of the Hospital Cardiology Unit of the IRCCS Galeazzi Hospital - Sant'Ambrogio

We started by asking each physician to tell us a bit about their practice.

Dr. Benamer: *I am an interventional cardiologist working in different centers around the Paris area, performing Percutaneous Coronary Interventions as well as structural heart procedures such as TAVI, Patent Foramen Oval closure and a few left atrial appendage closures. We see all types of patients both chronic and unstable, and I am performing more than 500 angioplasties per year.*

Dr. Collet: *I'm an interventional cardiologist at the Cardiovascular Center Aalst in Belgium. Every day, my job consists of doing diagnostic and therapeutic interventions in coronary arteries. We are a cath lab treating approximately 1,000 coronary patients a year and we treat all types of coronary artery disease including the challenging calficic disease. In the cath lab today we receive a mix of about 50% of the patients with stable coronary artery disease and the other 50% of the patients come to us with an acute coronary syndrome.*

Dr. Guagliumi: *Galeazzi Sant'Ambrogio is a new hospital that recently opened its doors in the innovation district in Milan. It is a fusion of the experience of many years accumulated by the doctors at the Sant'Ambrogio with a passion for innovation. It spans the entire spectrum of interventional cardiology including coronary artery disease, especially highly complex disease. We do a lot of imaging and handle about 1,000 coronary artery interventions per year.*

What are the challenges you are facing during PCI procedures, especially when stenting lesions?

Dr. Benamer: *The different issues we face with coronary angioplasty are twofold. The first challenge is the setup of the stent for which we can use different tools to help approach calcified lesions and prepare the vessel. Then, once the stent is placed, we must ensure that it is correctly expanded since that has an important impact on the patient's long-term prognosis.*

Dr. Collet: *Calcium is an important element in predicting stent underexpansion. If you are unaware of the plaque that you are treating and you implant the stent in a heavy calcific lesion, the minimal stent area will remain low, and we have seen how Important that is in terms of outcomes.*

Dr. Guagliumi: *The challenges we are facing with coronary interventions are more or less spreading across the entire world and it's driven by the increasing complexity of the patients due to factors like age and comorbidities such as diabetes and renal failure which means more calcium. So, it's a more difficult procedure and more demanding in terms of achieving optimal results.*

Can you explain the risk of stent underexpansion and the reasons behind it?

Dr. Benamer: *We know today that underexpansion of the stent impacts long term outcomes for the patient and can increase mortality by leading to complications such as thrombosis. Additionally, incorrect deployment of the stent, including stent underexpansion, can elevate the risk of restenosis of the targeted vessel.*

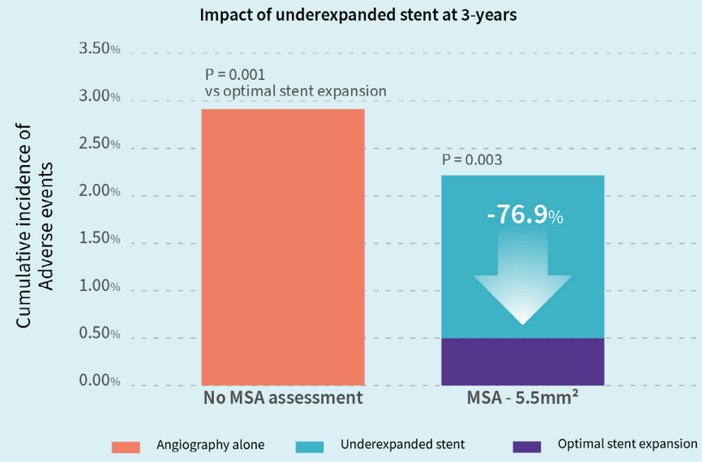
Dr. Collet: *When we implant the stent, it is very important that the stent is well expanded. Why? Because underexpansion - and that can be expansion rate under 80% or simply a small stent area - is associated with something that we call target vessel failure. What is target vessel failure? A combination of death, myocardial infarction and stent restenosis. So, patients that have stent underexpansion have a higher risk of stent restenosis and stent thrombosis.*

Dr. Guagliumi: *One of the biggest challenges in these highly complex cases is in to get a full expansion of the stent and doing it carefully and getting the measurements and the visualization of what we are doing. When you are expanding the stent, many times you stay underexpanded and the main reason behind that is calcium. Calcium is the most important enemy of stent expansion.*

How are clinicians currently assessing stent expansion?

Dr. Benamer: *I am a strong believer and a strong user of StentViz but when we only have an image in 2D we can lose some information about the stent's expansion. When needed, we have the capability to use intravascular*

Studies have shown that an underexpanded stent is a strong predictor of adverse outcomes including cardiac death, target lesion related myocardial infarction or stent thrombosis. Conversely, optimal stent expansion, defined as a Minimal Stent Area (MSA) greater than 5.5mm2 was associated with significantly improved long-term clinical outcomes.



How to read : performing MSA assessment decreases the risks linked to stent underexpansion up to 76.9%

imaging tools to confirm the correct expansion of the stent and assess peripheral underexpansion of the stent.

Dr. Collet: *Over the past few years, the field of intracoronary imaging has really provided us with novel insights and is allowing us to improve the work that we're doing by understanding how we implant the stent and importantly how the stent was expanded after the procedure.*

Additionally, there are ways to assess stent expansion that leverage the techniques coming from angiography that actually enhance the stent image after implantation. Today, these are widely available from several of the vendors. For example, you have the technology like StentViz from GE HealthCare and there are others from different OEMs.

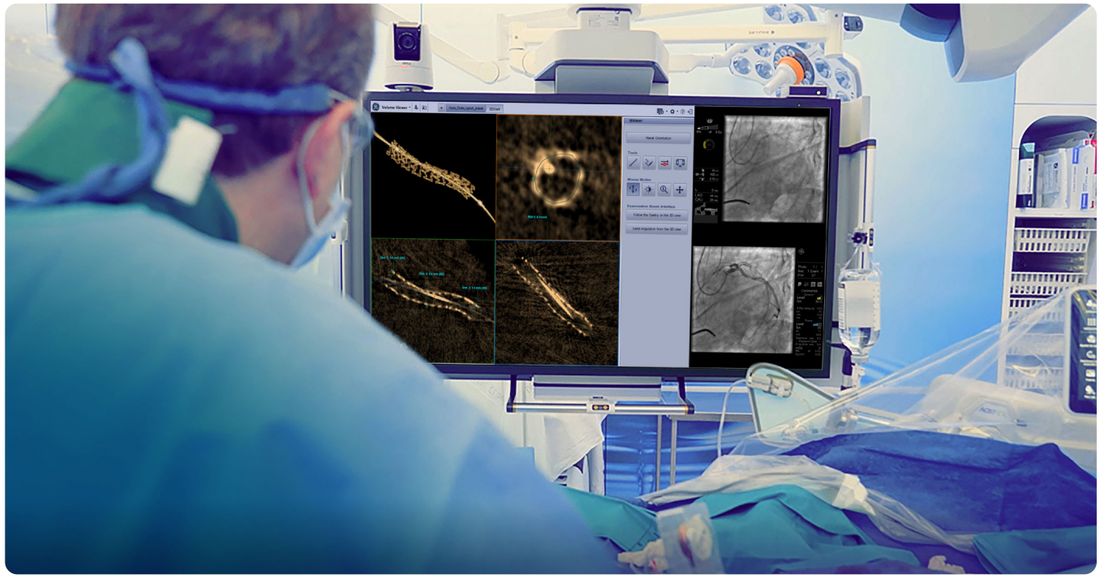
Dr. Guagliumi: *Assessing stent expansion is becoming more and more important. How are we doing? Well, for the vast majority of the interventional cardiologist, angiography remains the referral point. But we know that angiography has a clear limit in getting the details of the stents. This was the reason behind the increase in enhanced technology in angio to try to detect the border of the stents.*

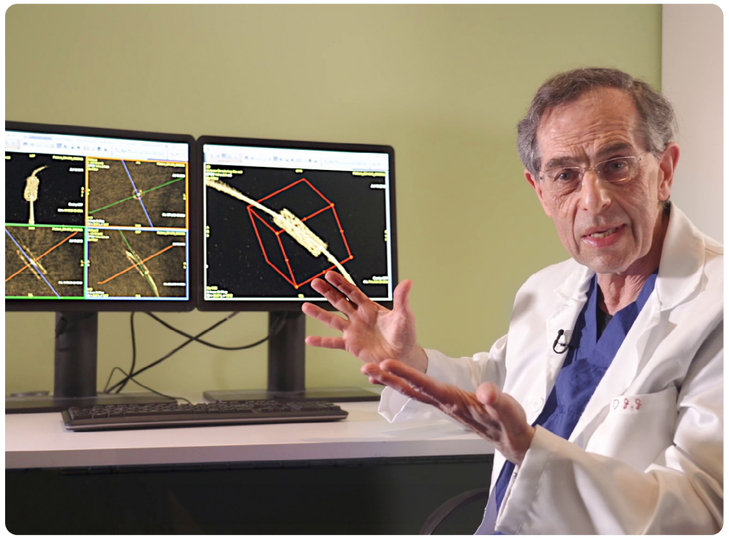
Why would you need intravascular imaging during PCI procedures?

Dr. Benamer: *There is a general agreement around the value of intravascular imaging to get the most possible information about the stent and its expansion – especially if there is any doubt. Unfortunately, the proportion of cases using intravascular imaging is still low - less than 10% France - but for risky angioplasty the clinician must leave no doubt as to the result. (from the Sympo)*

Dr. Collet: *There are a number of trials in the field of intravascular imaging that will likely demonstrate that assessing the extent of stent expansion with intravascular imaging results in better outcomes compared to angiography alone.*

Dr. Guagliumi: *There is a growing attention toward intravascular imaging as it is able to navigate inside and make precise measurements. Of course, these are additional technologies with additional costs. And you need additional training, though artificial intelligence is helping make intravascular ultrasound and OCT easier.*





On a global scale, intravascular imaging is strongly underused, and many say that it's too complex. There are regions like Japan where intravascular imaging is used in more than 90% of the cases with the great results. There is a longer tradition there. In the US it goes down into 15% and in Europe it goes down to 5-8%. That is too few to guarantee a high level of precision in what we are doing with the stents.

GE HealthCare's new 3DStent uses C-arm Motion Compensated CT (CMCT) to provide three-dimensional images of the stent during the procedure.

Can you tell us what potential you see in this innovation?

3DSTENT

3DStent creates a 3D reconstruction of the stent using C-arm Motion Compensated Computed Tomography (CMCT) resulting in an intraprocedural 3D visualization.

The cardiologist can then manipulate and rotate the image on the screen to see all views in the 3D space to assess the expansion of the stent.

Dr. Benamer: *This will allow a good visualization of the stent over the three dimensions. We can assess stent underexpansion but also the root cause of an underexpansion over the different slices displayed on the large display monitor.*

The acquisition is easy and doesn't require any additional device or contrast injection making it a complement to our current tools of visualization.

Dr. Collet: *This new technology lets us assess stent expansion using angiography and is actually using existing concepts like stent enhancement and mixing that with rotational angiography. The result is a three-dimensional depiction of the stent done inside the cath lab during the PCI.*

This is the first time we can quantify MSA only with angiography and, for me, this is one of the biggest steps forward.

Dr. Guagliumi: *We know it's important to have a simple tool and we know how much the community is tied to coronary angiography. We have some two-dimensional enhancements, but today this new tool is bringing 3D visualization and showing the stent from a different perspective. It's making the expansion of the stent longitudinally available but also has the capability to go cross section by cross section and take accurate measurements.*

How much clinical information can you get from 3DStent reconstruction?

Dr. Benamer: *I am a big user of 2D stent expansion visualization tools (StentViz) and that is very useful, but*

I always felt limited by the information provided. So, I always dreamed about a 3D angiography tool, and GE did it.

Dr. Collet: *For the first time, we have a detailed description of the stent during the procedure without the use of intracoronary imaging which will facilitate the assessment of the expansion.*
We're quantifying the information we receive from 3DStent and are starting to understand that this technology is also able to provide us, using angiography alone, measures of Minimal Stent Area.

Dr. Guagliumi: *With 3DStent, you can see the longitudinal view and then we can see inside the stent. So, you can see not only the longitudinal arrangement and expansion of the stent but also the cross-sectional area from the inside.*

What advantages do you see with this new technology and what potential does it have?

Dr. Benamer: *We clearly see from 3DStent additional information about the prosthetic and its correct deployment. For example, in the case below (), rotating the volume and playing with the slices will bring additional information compared with the initial view.*

We see that the rotation () shows the expansion of the stent but also one possible explanation with what we think to be calcium impeding the correct stent expansion.

Dr. Collet: *I see 3DStent actually bridging the gap resulting from the lack of use of intravascular imaging in a systematic way in most of our cath labs. It will provide the physician with the information they need to actually perform an optimal procedure.*
It's intuitive to analyze and it literally takes 10 seconds to understand what we're seeing during the live procedure. It's a game changer.
This technology has the potential to help us understand where the stent has been actually placed and if it has resulted in underexpansion, we can fix it with additional maneuvers such as post-dilatation.

Dr. Guagliumi: *By providing more information in a simple way, 3DStent has the potential to improve daily practice of interventional cardiologists.*

See more. Know more.

With millions of stents implanted around the globe every year, each advancement in technology has the opportunity to impact the lives of patients and their families.

GE HealthCare's 3DStent is the latest leap forward in a long history of advancements in cardiac care from the first angioplasty in the 1970s and the first stent in the 1980s to advanced visualization tools including intravascular imaging more recently.

Like those tools transformed the way we treat patients, so will 3DStent.

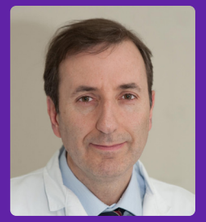
As Dr. Benamer noted at the 2023 EuroPCR symposium, "I'm completely sure this will change our practice."

3DStent solution includes Allia™ system, 3DXR and Volume Viewer Innova and requires AW workstation with Volume Viewer. These applications are sold separately. Available on Allia™ IGS 5 with 20cm or 30cm detector and Allia™ IGS 7 with 30cm detector. Commercial availability of GE HealthCare medical systems is subject to meeting local requirements in a given country or region. Contact a GE HealthCare Representative for more information. Intended for healthcare professionals only. The statements described here are based on their own opinion and on results that were achieved in their unique setting. Results may vary. JB26610XX

3DStent: Addressing major stent imaging barriers

Hospital Clínic de Barcelona, Spain

The Hospital Clínic's Cardiovascular Institute (ICCV) is devoted to treating cardiovascular diseases, with specialties that include vascular surgery, cardiovascular surgery and cardiology. Its interventional cardiology section has recently deployed GE HealthCare's new 3DStent which is designed to address major stent imaging barriers.



Dr. Manel Sabaté, MD, PhD, is the Head of the Interventional Cardiology Department at Hospital Clínic in Barcelona and Associate Professor at the University of Barcelona. He has authored more than 500 papers (H index 60), more than 20 book chapters and is the editor of five books. Dr. Sabaté is a member of the editorial board of several journals in the specialty and has been the recipient (as a Principal Investigator or Collaborator) of several competitive grants. His experience includes diagnosis and treatment of ischemic heart disease and other cardiac disorders, and he is specifically trained on cardiac catheterization and percutaneous coronary intervention and treatment of congenital and acquired structural heart disease including transcatheter aortic valve and Mitraclip implantation.

Dr. Salvatore Brugaletta, MD, PhD, is a Consultant Interventional Cardiologist with extensive experience in coronary and structural heart disease (intracoronary imaging and physiology, complex heart disease, left main, bifurcation, STEMI, cardiogenic shock, TAVI, etc). Highly skilled in clinical research, medical education and medical devices Dr. Brugaletta's expertise is well regarded within medical communities. He has authored more than 400 manuscripts, 11 textbook chapters, and he has delivered about 200 invited lectures at international meetings. He is member of PCR board and he serves as Editor-In-Chief of PCROnline and Editorial Consultant for JACC Cardiovascular Interventions. He practices as an Interventional Cardiologist at Hospital Clínic in Barcelona.

The Interventional Cardiology department at Hospital Clínic de Barcelona fully renovated their cathlabs and OR area in 2021. It is now equipped with two Innova IGS 520 with AutoRight and a hybrid room with the latest GE HealthCare platform, Allia IGS 730 with AutoRight. This hybrid operating theatre is mainly used to carry out structural heart procedures such as TAVI, LAAC, Mitral and Tricuspid valve interventions and percutaneous coronary interventions, among others.

In 2023, GE HealthCare launched 3DStent, an innovative tool which allows the intraprocedural visualization of a coronary stent in 3D and multi-slice images. The image is acquired through an automated rotation of the C-arm and thanks to the new CMCT (C-arm Motion compensated Computed Tomography) technology, 3DStent allows the clinician to see the stent from all angles without inserting an additional device or contrast.

It became CE marked in July 2023 and Hospital Clínic de Barcelona was the first site worldwide to use it in clinical practice.

Dr Sabaté: *In the coronary field we are facing more and more complex cases in our daily practice, what we call CHIP (Complex and High-Risk Interventional Procedures) cases, meaning that we have to deal with calcified plaques, bifurcations, coronary total occlusions, etc. In this scenario, it is critical to be able to assess the outcome of the procedure during the case. In these complex procedures, it is of the upmost importance that we're using good imaging techniques and good equipment to ensure that we have a high-quality image of what we are doing.*

As the first 3DStent users worldwide, Dr. Sabaté and Dr. Brugaletta tell us about their experience with this innovative intraprocedural 3D stent reconstruction technology in their clinical practice.

What is the impact of stent underexpansion?

Dr Sabaté: *Stent expansion is really important for the outcome of the patient. We cannot leave a stent underexpanded because it is a trigger for both restenosis and thrombosis. We have to make sure that the stents we have implanted are in the right position and well expanded inside the vessel wall, otherwise you will end up with problems for the patient down the road.*

Dr Brugaletta: *Stent expansion is one of the most important factors we consider during stent implantation. The expansion that we're able to achieve when we implant a stent is directly related to the outcome of the procedure. We cannot leave a stent that's not at least 80-90% expanded.*

How are you dealing with stent expansion at Hospital Clínic?

Dr Sabaté: *To make sure that the stent is well-apposed, well-expanded, we have several techniques. Of course, angiography is first, but with angiography alone we cannot be sure that the stent is optimally expanded. Another option we typically use is StentViz and we also use imaging techniques like intravascular ultrasound (IVUS) and optical coherence tomography (OCT). These are the typical techniques we use to assess expansion in our cathlab.*

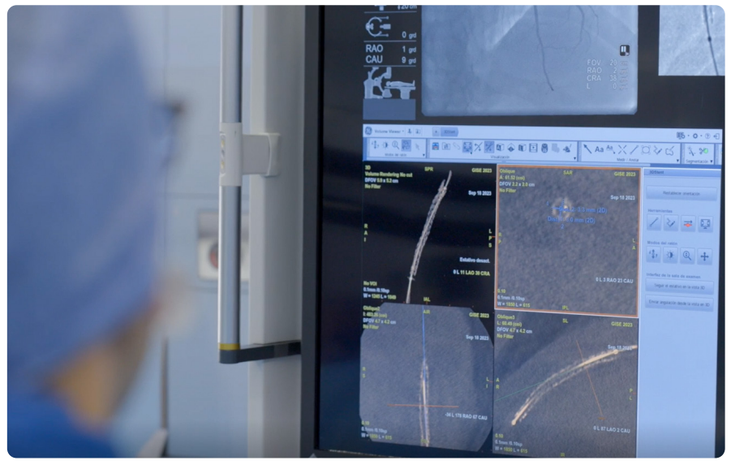
Dr Brugaletta: *Usually when we do not see any calcium, we can see with StentViz or just with angiography if the stent is well expanded or not. But in cases where we have some calcification, tortuosity, or for example, a left main or a bifurcation, all these different angiographic features are strictly associated with bad outcomes. It's especially important for these patients that we confirm a good stent expansion. We usually use intracoronary imaging, like IVUS or OCT, in order to ensure the correct expansion of the stent, not only in terms of percentage, but also in terms of square millimeter of area.*

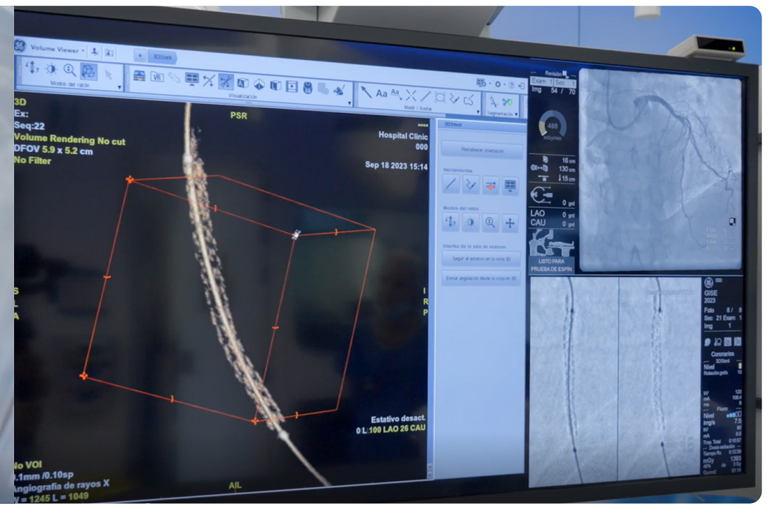
As the first 3DStent user worldwide, can you tell us what important information you can see during the procedure in the 3DStent images?

> *"We can see if there are areas of underexpansion that may require postdilation and we can also see calcified plaques behind the stent."*
> **Dr. Sabaté**

Dr Sabaté: *First, we're looking at the expansion of the stent. That's what we want to see with the 3D reconstruction. We can see the expansion of the entire stented area and, importantly, we can see if there are areas of underexpansion that may require postdilation with a non-compliant balloon, or other technique.*

We can also see calcified plaques behind the stent, which is important because these typically correspond to areas of underexpansion. This is what we want to see with a 3D reconstruction of the stent using a non-invasive tool.





Dr Brugaletta: *When I saw the images for the first time, I was quite surprised by the fact that we can see 3D also on the angio. We get lots of important information. The novelty is that we measure directly on the angiogram the minimum stent area of our stent, and this is something totally new. We usually use IVUS or OCT, but with 3DStent we save the cost of these catheters and assess what we need quite easily.*

> *"We measure directly on the angiogram the minimum stent area of our stent, and this is totally new."*
> **Dr. Brugaletta**

The second bit of important information is the presence of calcification. Sometimes the vessel is calcified, and we can see where the calcifications surround the stent. We can understand if we are talking about a 360° calcification, or if it is just located in one quadrant. This information is very important because it tells us if there is plaque located behind the stent preventing it from being well expanded.

What do you like about 3DStent?

Dr Sabaté: *You can measure the lumen of the stent, the length of the stent, the expansion of the stent, and you do not need to use an OCT catheter, so you can save some devices. We normally use OCT catheters, but not in every case and we can do 3DStent in every single case. I think this is the difference and may be the key factor of this new technology — you can use it in every single case in your daily practice.*

Dr Brugaletta: *What I like the most about 3DStent is actually how easy it is. All we need to do is to make sure that everything is set around the patient so we do not have any obstructions and that the x-ray can move freely around the patient. Then, it just takes 30 seconds to make the acquisition and 30 seconds of analysis. I find it very simple and intuitive to use.*

How do you plan to integrate 3DStent in your clinical practice?

Dr Sabaté: *What is important is to do a proper job for the patient and if you have a tool which only within 1-2 minutes can assess the entire expansion of the stent and the result of the PCI, I think you have to use it. When you are used to it, you will use it in every single case. I do not see any exceptions for not using it.*

> *"It can easily be done in 100% of PCI."*
> **Dr. Brugaletta**

Dr Brugaletta: *In all your procedures 3DStent makes it very easy to check stent expansion. Every time that you have a complex procedure, and want to guide that procedure by angio, you can do the 3D reconstruction. It may also save the cost of an imaging catheter if you don't want to open it or if you have some OCT fatigue. Especially after the procedure, if you have used the catheter several times, you can use the 3D reconstruction just to check that the stent is well expanded and that you have done a good job instead of opening a new OCT catheter.*

How do you think 3DStent will impact the interventional cardiology segment?

Dr Sabaté: *We are an early user of this technology, but if we can compare it with invasive or catheter-based technologies like IVUS or OCT and it is comparable, we may save some catheters. So, at some point it may replace some catheters, may save some money we can use it in almost every single case.*

Dr Brugaletta: *In my opinion, it will have a positive impact. Of course, when we have something new in the lab, in our profession, we have to learn all of the utilities and software but once we do, it's important that the new technology is easier to use compared to what it's replacing and also less expensive than what we already have. 3DStent addresses both because it is quite easy to use and it's also less expensive. This will impact our practice because it can easily be done in 100% of PCI.*

Can you tell us about your partnership with GE HealthCare?

Dr Sabaté: *I am really happy to be part of the launch of this new technology coming from GE HealthCare, to partner with them, and help improve this technology. I am pretty sure this is just a version 1.0 and in the future we will have new versions that will make our lives and the lives of our patients easier.*

3DStent solution includes Allia™ system, 3DXR and Volume Viewer Innova and requires AW workstation with Volume Viewer. These applications are sold separately.
Available on Allia™ IGS 5 with 20cm or 30cm detector and Allia™ IGS 7 with 30cm detector. Commercial availability of GE HealthCare medical systems is subject to meeting local requirements in a given country or region. Contact a GE HealthCare Representative for more information. Intended for healthcare professionals only. The statements described here are based on their own opinion and on results that were achieved in their unique setting. Results may vary. JB07563XE

Introducing the world’s first mini 4D TEE probe: Early experiences in structural heart interventions

Research and innovation that advance patient care are driving forces behind the century-old Hospital Clinic de Barcelona in Spain. Recognized as a center of excellence around the world, the public university hospital continues to push for progress. Most recently, its state-of-the-art Cardiovascular Institute was one of the test sites for the new 9VT-D mini 4D TEE probe.
Prof. Marta Sitges, MD, Ph.D., who is the director of the Cardiovascular Institute, and Dr. Laura Sanchis, MD, Ph.D. shared their initial experiences with the novel probe.

The Cardiovascular Institute is a referral center for all of Spain for heart transplantation, mitral valve repair, pulmonary hypertension, inherited heart disease and adult congenital heart disease. With specialists in cardiology, cardiac surgery and vascular surgery, the Cardiovascular Institute at the Hospital Clinic reported an estimated twenty-two thousand patient visits, fourteen thousand echocardiograms, and nine hundred cardiac surgeries during 2022. The staff includes more than 60 medical professionals, along with three hundred nursing and administrative support professionals.

The Institute's structural heart interventions program began in 2009 with TAVI and expanded to include edge-to-edge procedures in 2011, followed by tricuspid interventions in 2018. In 2021, the operatory area was completely redesigned to modernize all technologies, including the two existing angiography suites. A new hybrid interventional room was also created to support an ever-growing number of structural heart procedures. Today, the Cardiovascular Institute remains focused on exploring new ways to keep up with the growing demand for diagnosis and treatment.

"*The number of patients is rising. We need to know how to do more patients in less time with less beds,*" says Dr. Laura Sanchis .

Easing workload challenges by improving efficiencies continues to be a driver for the entire healthcare community. Institutions are moving towards advanced technology that provides wider access to minimally invasive therapies that increase the number of patients treated per day and enable same day discharge. Procedures that negate the need for general anesthesia allow for faster interventions, fewer staff, and can reduce overall hospital costs (inpatient vs. outpatient).

"*An important challenge is the need for anesthesia, and that's a universal problem everywhere. It may increase the risk and the complexity of the intervention, so we are going towards less invasive procedures with the same safety. Without general anesthesia and without the need of a conventional probe, it makes everything go faster and quicker,*" says Dr. Marta Sitges.

A Small Solution

A recent innovation in probe technology, first released for pediatrics, could address these challenges, and provide opportunities to treat more patients. For certain indications, the 9VD-T mini 4D TEE could be a potential option for older and clinically fragile patients not suited for general anesthesia or those who can't tolerate 4D TEE adult probes.

Some of the latest research on the mini 4D TEE comes from the structural heart team at the Cardiovascular Institute at Hospital Clinic. Dr. Laura Sanchis and Dr. Marta Sitges explored the capabilities and potential benefits of the mini 4D TEE performing percutaneous left atrial appendage occlusion (LAAO) procedures on adult patients. Their paper, 'First Experience of left atrial appendage occlusion using 3D mini transesophageal echocardiographic probe with conscious sedation[1],was published in *EuroIntervention* in January 2023.

> *"An important challenge is the need for anesthesia. It may increase the risk and the complexity of the intervention, so we are going towards less invasive procedures with the same safety. Without general anesthesia and without the need of a conventional probe, it makes everything go faster and quicker."*
>
> **Prof. Marta Sitges**

Background

Percutaneous left atrial appendage occlusion procedures rely heavily on transesophageal echocardiography (TEE) or computed tomography (CT). 4D TEE is typically used for intraprocedural guidance and requires general anesthesia in most centers[1].

The Cardiovascular Institute utilizes the standard 4D TEE adult probe (6VT-D) with the Vivid E95 ultrasound system for most complex LAAO cases. For simpler procedures, the team trusts the 2D micro TEE probe (10T-D) in conjunction with the Vivid S70N ultrasound system.

For their research, Dr. Sanchis and Professor Sitges utilized the new mini 4D TEE with conscious sedation to help guide LAAO procedures on four patients treated consecutively on the same day. According to their paper, 'The initial experience showed good tolerance (despite minimal sedation and the supine position of the patient) with excellent image quality of the LAA that allowed an effective and safe LAAO guidance[1].

The experts shared more about their experience with the world's first mini 4D TEE probe, along with some insights about the potential for future interventions.

The Cardiovascular Institute was one of the test sites for the new mini 4D TEE probe. In your experience, what are some of the advantages of the mini 4D probe?

Prof. Sitges: *Compared to the micro TEE, I think we should highlight the 3D and good quality images. Probably for LAAO procedures, the image quality is as good as the conventional 3D TEE probe.*

Dr. Sanchis: *The 3D is very nice for me and is the same that we can get with the standard probe. When we were doing the left atrial appendage occlusion—closing it with the mini TEE was super easy and you are super relaxed because you have all the control.*

Prof. Sitges: *Laura and our team have extensive experience in this type of interventions, but for less experienced echocardiographers and interventionalists in the learning part or the initial experience, I think the 3D is really useful because you have this smaller probe with the same capabilities as the conventional one.*

Dr. Sanchis: *To do it without 3D is risky if you are not very skilled in left atrial appendage occlusion. It's always better to do it with biplane than monoplane because you have more control. So, it's another point for the mini 4D TEE probe.*

I also want to bring up that many people are not using the micro TEE because it's difficult to manipulate and you need to be very skilled. I think it's easier with the mini because it's a little thicker and it's easier to use.

How did the mini 4D TEE probe impact your workflow?

Prof. Sitges: *The advantage of the mini is that we can optimize the process by making it quicker. The mini TEE probe has 3D so the planning can be performed during the procedure. With the micro, it's only 2D so we need to do another 3D screening echo before the procedure day to do all the measurements for planification.*

Dr. Sanchis: *For me, the main benefit is for the left atrial appendage occlusion because with the mini TEE we may simplify the patient pathway because we can do all the measurements in the cath lab.*

Does the mini 4D TEE probe enable other opportunities to increase efficiencies when performing LAAO procedures?

Prof. Sitges: *With the mini TEE, you can avoid general anesthesia and you are reducing or avoiding hospital stays. So that's a big impact.*

Dr. Sanchis: *We tested the mini TEE and you can also make many patients in one morning and the tolerance was nice.*

Along with simple LAAO cases, do you think the mini 4D TEE probe could be beneficial in other structural heart interventions?

Dr. Sanchis: *The thing is that when we have a new technology, we start exploring how it can be used and try to apply it to different procedures.*

Prof. Sitges: *We have limited experience with the probe, but I am sure we will discover new indications. We didn't have time to test it, but maybe in some very simple, straightforward cases of functional MR, for example. These cases are usually very easy to treat with an edge-to-edge repair and it typically gets us less than an hour.*

Dr. Sanchis: *If we have this probe, we will of course use it for the left atrial appendage occlusion. I think that is the main value of this probe. PFO is simple and you can do it without 3D, but some cases are difficult, and I think it's great if you can use 3D and biplane. We could use it also for percutaneous valvuloplasty of the mitral valve. As Marta said, I think that for functional mitral regurgitation in patients where we think it will be easy, it could be also an option.*

Prof. Sitges: *Choosing the 4D mini probe will not depend on the tolerance of the probe. It will depend on the quality of the image that you need to do the procedure. If it's an easy procedure, we can do it. If it's a very complex and long procedure, probably not. Taking that into account, ASD and PFO are indeed a possibility in the experienced hands as Dr. Sanchis and our interventional team.*

In addition to the mini 4D probe, what other ultrasound features or applications are useful in your structural heart procedures?

Dr. Sanchis: *If they are complex intervention, I really like Vivid's FlexiSlice, the Live MPR feature. I really like that, for example, for MitraClip, as you can guide it all will 3D and MPR at the same time.*

With the new Ultra Edition release, the quality of 3D and MPR is much better, so it is very nice.

Prof. Sitges: *Dr. Sanchis explained very nicely the advantages of MPR, which I completely agree with. Then there is the CT-Echo fusion that is getting better and better, but still need to work on it to add it to more procedures.*

Looking ahead, what advances would you like to see in technology, and how do you envision the cath lab of the future?

Prof. Sitges: *For the cath lab of the future, we should have a robot that would allow remote manipulation of catheters, but also of the mini TEE probe with all the 3D capabilities. We would have tools that would help get rid of anesthesia, of course.*

Dr. Sanchis: *We will make more things than now. I think it's increasing exponentially.*

Prof. Marta Sitges, MD, PhD. is a senior consultant non-invasive cardiologist at the Cardiovascular Institute in Hospital Clinic at the University of Barcelona. Her main clinical practice is related to clinical and interventional echocardiography, sports cardiology, and heart valve disease. She has published more than 280 peer reviewed papers and presented more than three hundred lectures in national and international meetings. Professor Sitges has been Director of the Cardiovascular Department since 2015.

Dr. Laura Sanchis, MD, PhD. specializes in noninvasive cardiac imaging at the Cardiovascular Institute. She is part of the Valve Team and performs echocardiography and advanced echocardiography techniques, as well as echo-guidance of structural interventions in the catheterization lab. Her main research currently focuses on the application of cardiac imaging to understand the pathophysiology of heart valve disease, its clinical management, and the structural heart interventions planification. Dr. Sanchis is credited with more than one hundred research publications.

1 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

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.

Doctors are paid consultants for GE HealthCare 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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Left Atrial Appendage Closure with 9VT-D, mini 4D TEE probe

Courtesy of Prof. Marta Sitges and Dr. Laura Sanchis, Hospital Clinic Barcelona, Spain

Patient History/ Pathology

68-year-old man was admitted due to heart failure after new-onset rapid atrial fibrillation (AF). Despite having a previous episode of paroxysmal AF, oral anticoagulation had been suspended after recurrent hematuria (chronic cystitis resulting from a previous radiotherapy treatment for prostate carcinoma). A transesophageal echocardiography (TEE) was performed to rule out thrombus before electric cardioversion. The patient was discharged with low-dose subcutaneous heparin and, after another episode of hematuria, percutaneous left atrial appendage (LAA) occlusion (LAAO) was proposed.

Challenges

Percutaneous LAAO needs planning with a 3D imaging technique (CT or TEE). Our patient had a previous TEE but without 3D measurements of the LAA and dedicated evaluation. Performing a new imaging test would have implied a delay in treatment as well as additional cost and risk (radiation, esophageal intubation). Alternatively, LAAO with general anesthesia and 3D TEE guiding had to be performed to evaluate the LAA and guide the procedure.

System, probe & device used

As we had available the 9VT-D mini TEE probe with 3D capabilities with the Vivid E95 (206 release) echocardiographic system, we decided to perform LAAO under conscious sedation and on an ambulatory basis with same day hospital discharge. The patient was admitted in the morning, LAAO was performed under conscious sedation and after 6 hours monitoring and a transthoracic echocardiography to rule out pericardial effusion and device embolization, the patient was discharged from the hospital.

Step-by-step procedure

The tolerance of the probe was excellent with only pharyngeal topic lidocaine and conscious sedation (fentanyl 0.05 mg and midazolam 2 mg). 3D measurements of the LAA (ostium 14x23 mm and landing zone 16x21 mm) were performed during LAAO with live MPR and an Amplatzer Amulet 25-mm device was chosen for closure. Transseptal puncture and device implantation were guided with biplane 3D imaging with a successful implantation.

Conclusion

The use of a mini TEE probe with 3D capabilities (9VT-D) allowed us to directly perform a safe and effective LAAO with conscious sedation and same day hospital discharge. Without this probe it would have been necessary to do a previous 3D imaging technique (TEE or CT) or to perform LAAO with general anesthesia and 3D TEE guiding with the standard probe.

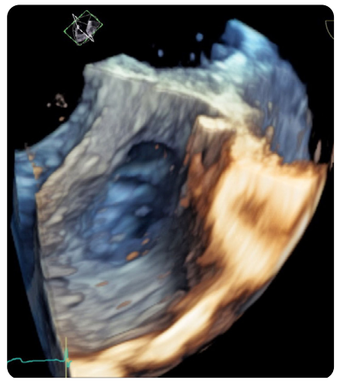

Figure 1. 3D visualization of the LAA ostium.

3D measurement of LAA

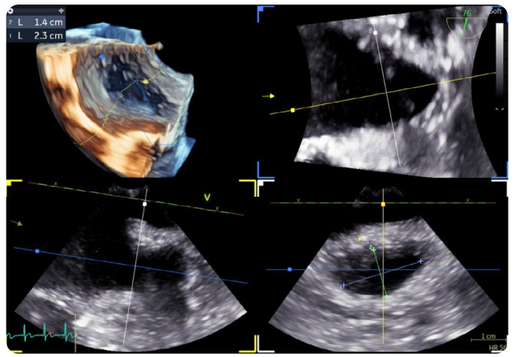

Figure 2. Ostium.

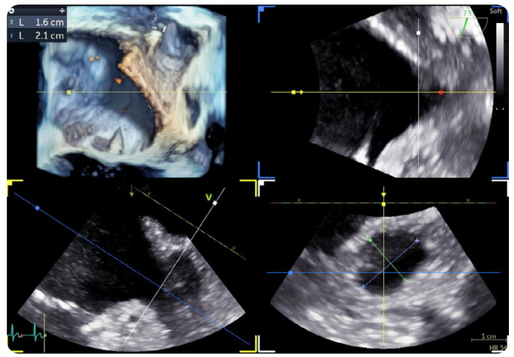

Figure 3. Landing zone.

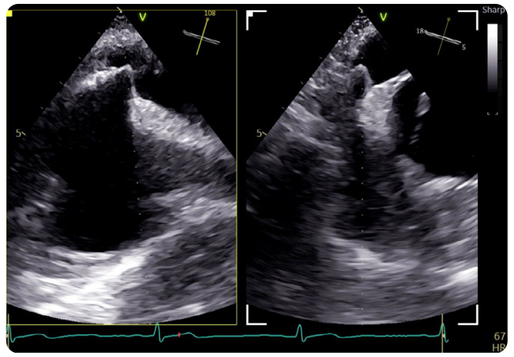

Figure 4. Transseptal puncture.

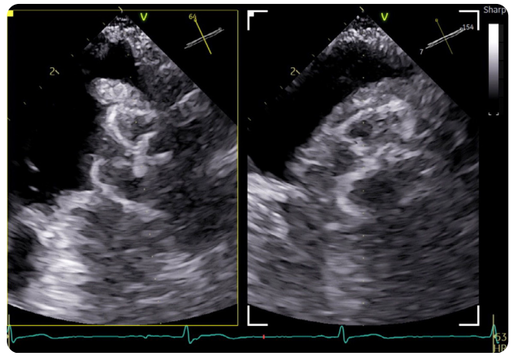

Figure 5. Lobe opening.

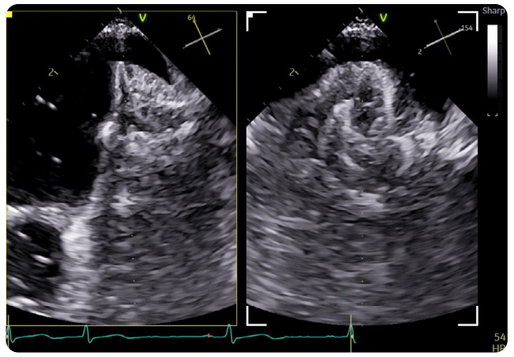

Figure 6. Disc opening.

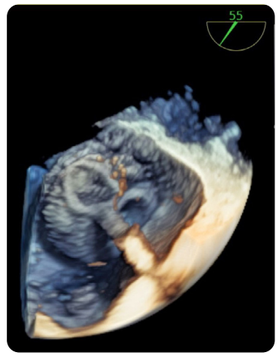

Figure 7. 3D evaluation of leaks before release.

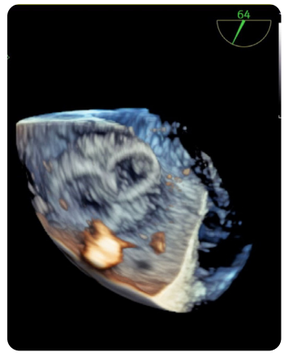

Figure 8. Final result.

Pediatric Pulmonary Valve Replacement using Vision and Innova IGS 6

Courtesy of Dr. Gregory Fleming, Duke University Hospital, Durham, USA

Patient history

A 15-year-old female with severe pulmonary insufficiency and severe right ventricular enlargement was referred for transcatheter pulmonary valve replacement. She had a history of Noonan's syndrome and congenital pulmonary valve stenosis and underwent surgical valvotomy as an infant.

Non-invasive imaging with MRI and Echocardiogram demonstrated severe pulmonary regurgitation with regurgitant fraction of 51%, no significant pulmonary stenosis, dilated main and branch pulmonary arteries, and severe right ventricular enlargement with RVEDVi of 165 ml/m2.

Valve

Transcatheter pulmonary valve replacement (TPVR) has become a viable treatment option over the past two decades and has demonstrated comparable safety and short-term outcomes to open-heart surgical pulmonary valve replacement. [1]

These valves are designed to delay, or potentially completely avoid, patients' need for open-heart surgery by restoring pulmonary valve function with a minimally invasive procedure.

Dr Fleming is site principal investigator at Duke for the multi-center COMPASSION S3 and COMPASSION S3 PAS sponsored by Edwards Lifesciences and for the Harmony valve post-approval study sponsored by Medtronic.

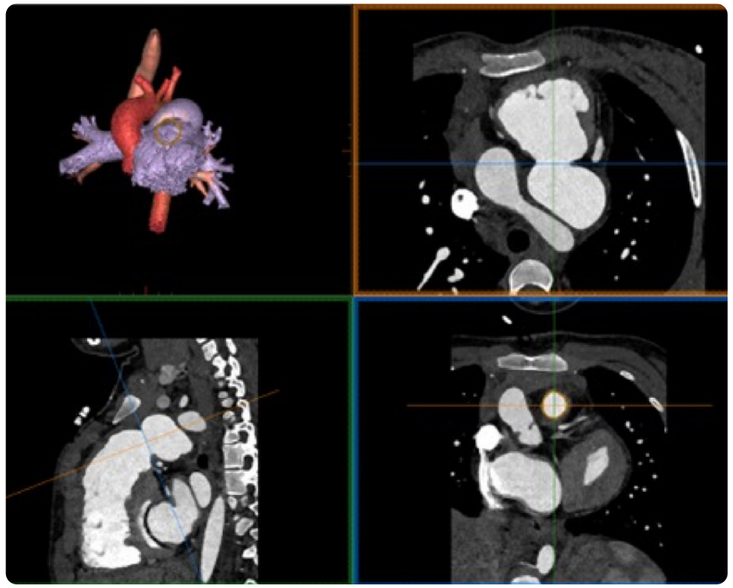

Fig 1. CTA image showing the narrowest area of the stenosis in the pulmonary artery.

CTA analysis

Current options for transcatheter pulmonary valve replacement in the US include the Medtronic Melody and Harmony valves and the Edwards SAPIEN S3 valve.

An ECG gated CTA was performed per protocol in order to show systolic and diastolic dimensions. Based on evaluation of the CTA, the RVOT was severely dilated with a narrowed "choke point" at the level of the valve annulus. Based on this anatomy, the self-expanding Medtronic Harmony valve was chosen as the best option.

The computed tomography angiography (CTA) of 557 slices done in Naeotom Alpha (Siemens Healthnineers) (Fig 1) was analyzed remotely via the GEHC thin client server technology Advance Workstation Server(AW Server). Using the segmentation tool General Vessel Analysis, allowing for reconstruction and automatic segmentation of vessels in 3D, as well as a detailed analysis of vessels exact dimensions and calcium burden. The 3D model can be used to mark any stenosis, bifurcation of left and right pulmonary arteries, landing zones or any other relevant ROI using the planning lines tool or oblique reformats generated from centerlines done with General Vessel Analysis. Additionally, other structures of interest may be segmented semi-automatically.

This analysis and the resulting segmented images (Fig 2), in this case: the aorta, the pulmonary artery (PA) and the bronchial tree; are needed to precisely plan the intervention including, morphologic analysis, ideal device landing zone and to determine the optimal device size.

Duke's practice uses the bronchial tree segmentation or previous surgical landmarks/clips close to the area of interest to facilitate the registration process and adds planning lines around the PA stenosis to facilitate the valve landing zone. In this case the clinical team decided to use a self-expanded Harmony TPV 25.

Innova VISION (Fusion)

These 3D Rendered volumes are transferred to the procedure room using Innova Vision (Fusion) option where these volumes can be dynamically superimposed/fused, in real time on to the fluoroscopic images, allowing the operator to ensure a correct valve deployment while having a simultaneous view of both the fluoroscopy, the 3D PV and landing marks.

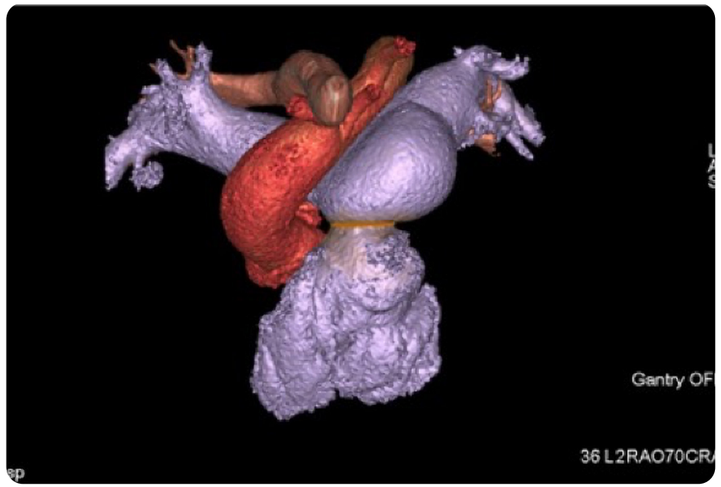

Fig 2. Segmented main 3D volumes to support localization and catheter guidance during the TPVR procedure. Pulmonary artery(purple), Aorta (red) and bronchial tree (brown). Special landing marker placed over the stenotic area of the PV to facilitate valve deployment.

Vision adjusts in real time for all modifications of the frontal C-arm angulations, source-to-image distance, field of view and table height or lateral/longitudinal position automatically.

The registration process using the frontal view was quickly and efficiently undertaken in the control room AW using Bi-view registration LAO/RAO fluoro images and matching the 3D airways volume without the need for any contrast. To enhance workflow, all these functionalities, as well as Innova Vision sequence storage, can be controlled from the Innova Central at tableside by the operator. For the lateral view, an extra manual correction is needed.

Once the registration was complete, the PA model was used with specific points of interest highlighted by planning lines. The aorta and its coronary tree outline model can be used to avoid any compression over the coronaries due to the new valve deployment.

Thanks to Vision, during the procedure, live fluoro images can be digitally zoomed to minimize radiation dose to both patient and operator.

Angiographic study

The exam was done using an Innova IGS 620 Biplane installed in 2018. A low reduced dose protocol with 7.5 fps and 15 fps for fluoro and cine is used.

The procedure was done under general anesthesia from the femoral vein.

A 26 Fr x 65cm Gore Dry Seal sheath was advanced into the RVOT and the Harmony delivery system was advanced through the sheath and into the left pulmonary artery (Fig 3).

The relationship of the aortic root and coronary arteries to the RVOT had been assessed using the 3D modeling of the CTA and felt not to be a concern.

From the preoperative CTA, 3D modeling was performed on the AW system. The 3D model is used to optimize gantry angulation allowing placement of the anatomy of interest in the optimal view/ orientation prior to exposure or contrast injection. Planning lines were developed from the 3-D modeling and placed as an overlay on the live fluoroscopy with Vision images in order to help navigate and position the valve, thus reducing the need of contrast and fluoro dose (Fig 4).

Valve deployment was successfully achieved using a retractable sheath and the landing marker visible in vision.

Following deployment, hemodynamics and PA angiography were repeated (Fig 5) and showed no significant pressure gradient across the valve and no residual insufficiency or paravalvular leak.

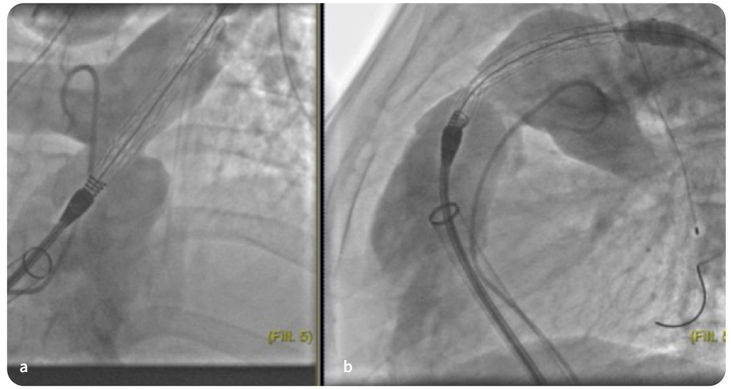

Fig 3. (a) Pulmonary artery outflow tract angiogram in a left anterior oblique (LAO) and cranial projection. The stenosis and bifurcation of the pulmonary arteries are nicely demonstrated. (b) Lateral or 90° left anterior oblique (LAO) projection of the same angiogram

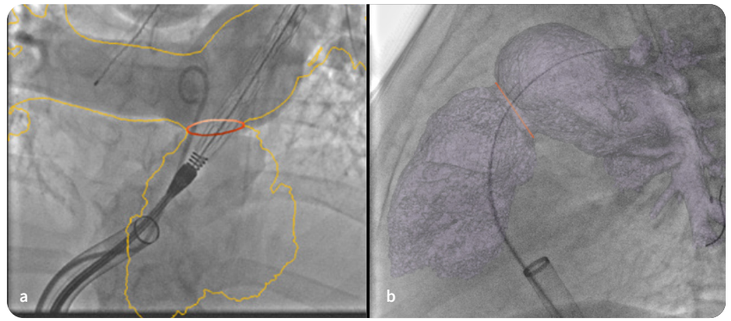

Fig 4. (a)LAO-CRA angiogram contrast injected displayed in Innova Vision with the PA outline (yellow) and the landing plane (orange) over the stenosis. (b) Lateral or 90° left anterior oblique (LAO) projection of the same angiogram with the PA virtual volume (violet) fused in live with the fluoroscopy. Contrast injection shows matching of the PA 3D volume and the PA shape in the angiogram.

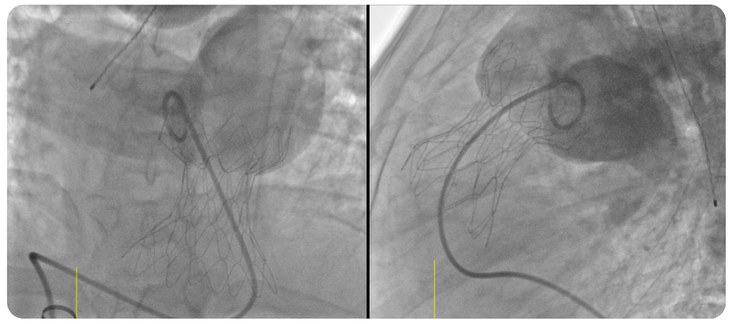

Fig 5. Final biplane angiograms (Frontal and Lateral) following valve deployment demonstrate a competent valve in stable position without pulmonary valve regurgitation.

Patient outcomes

The patient had no post-procedural complications and was discharged the following day. The patient remains clinically well at 6 months follow up with no valve insufficiency and no significant valve gradient.

Conclusion

This case demonstrates how 3D modeling with the AW system is extremely helpful with pre-operative planning for transcatheter pulmonary valve replacement procedures. Furthermore, the use of 3D planning lines overlayed on live fluoroscopy with Vision is extremely helpful for this procedure. We feel that these tools help reduce fluoroscopic dose and contrast load and improve the safety of these procedures.

3D fusion helps guide each step with confidence, by fusing the CT image utilized for pre-procedural planning as well as the markers added, from the navigation to the device deployment.

Significantly reducing procedure time, while decreasing contrast media & dose.

Dose analysis	Fluoroscopy time 33.26 min; with 1.23 min of dynamic
Air Kerma	498 mGy (183 mGy Fluoro || 315 mGy Dynamic)
DAP	43.41 Gy.cm2 (16.13 Gy.cm2 Fluoro || 27.28 Gy.cm2 Dynamic)
Contrast media volume	165 ml

1 Marchini F, Meossi S, Passarini G, Campo G, Pavasini R. Pulmonary Valve Stenosis: From Diagnosis to Current Management Techniques and Future Prospects. Vasc Health Risk Manag. 2023 Jun 30;19:379-390. doi: 10.2147/VHRM.S380240. PMID: 37416511; PMCID: PMC10320808.

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