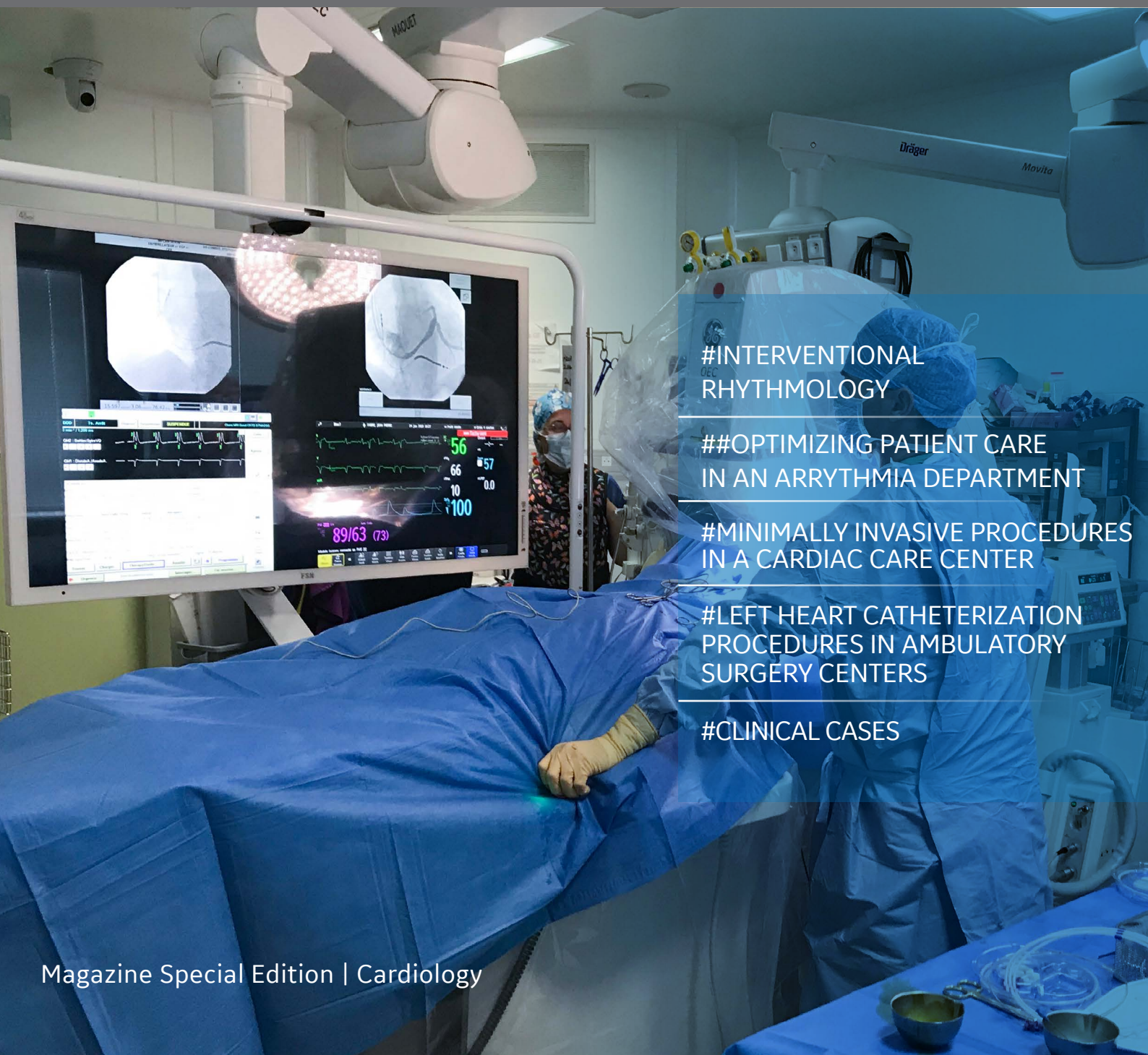
OEC MAGAZINE

Innovation in Surgical Imaging for Cardiology with OEC C-arms



#INTERVENTIONAL RHYTHMOLOGY

##OPTIMIZING PATIENT CARE IN AN ARRYTHMIA DEPARTMENT

#MINIMALLY INVASIVE PROCEDURES IN A CARDIAC CARE CENTER

#LEFT HEART CATHETERIZATION PROCEDURES IN AMBULATORY SURGERY CENTERS

#CLINICAL CASES

Magazine Special Edition | Cardiology

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Dear reader,

In these times when our societies are focused on solutions to stop the pandemic, many healthcare professionals continue to fight to enable treatment for patients with chronic diseases.

Among those diseases, heart diseases remain a leading cause of mortality in the world. According to the World Health Organization about half of the deaths due to cardiovascular disease (heart attacks and strokes) are related to coronary artery disease. Another cause of sudden cardiac death is arrhythmia.
They represent a major global public health problem and are the subject of various screening programs.

Overmore pandemic diseases can disrupt screening programs, patient care and clinical studies and can cause chronic damage to the cardiovascular system.

As a result, many cardiac centers have reconsidered their patient care pathway to allow more access to cardiac care for diagnosis and treatment of chest pain diseases with efficient cathlab setups. In this magazine dedicated to cardiac imaging, we have selected four articles which illustrate such cardiology centers proceeding to left heart catheterization and arrhythmia procedures. In these type of procedures, high quality intraoperative fluoroscopic imaging is required.

Interventional cardiologists and interventional rhythmologists explain in their interviews how OEC Elite CFD premium mobile C-arms, in their different configurations, meet their clinical expectations.

We hope you will find this magazine informative and want to thank our clinical partners again for sharing their experiences to treat their patients.

Good reading,

Cécila Felix
Image Guided Therapy
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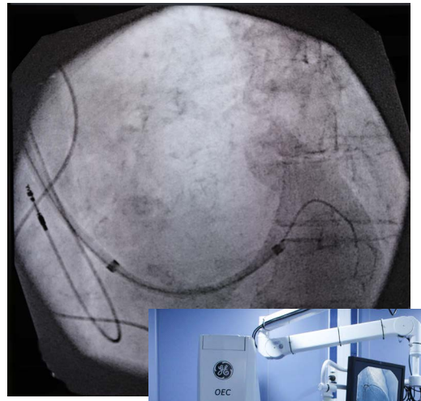
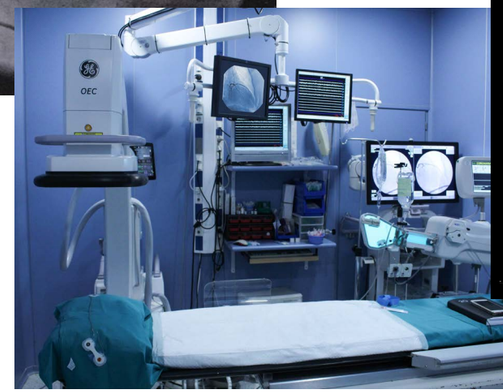
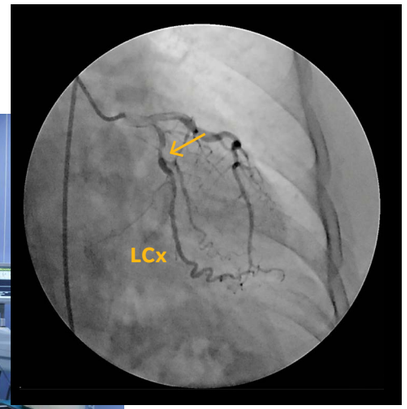






Interventional Rhythmology with OEC Elite CFD

Dr. Stéphane Combes, Cardiologist and Interventional arrhythmia specialist, Clinique Pasteur, Toulouse (France)

The Clinique Pasteur is the leading cardiology and cardiac surgery institution in France in terms of number of procedures. The recently completed building called La Passerelle - The Bridge, has been designed by and for caregivers, such that all necessary services have been built and organized under one roof. Equipped with high-tech imaging modalities dedicated to complex treatments, it is aimed at optimizing the patient's care pathway.

Among the eight cathlabs dedicated to Interventional Cardiology, Electrophysiology and Rhythmology, one room has been equipped with an OEC Elite CFD motorized Cardiac C-arm, dedicated to pacemaker placement and CRT device implantation.

Dr. Stéphane Combes, Interventional rhythmology Cardiologist, explains the needs in image quality and patient access with OEC Elite CFD for these procedures.

Can you explain the organization of the activity of the Interventional Rhythmology department?

There are about 30 cardiologists at Clinique Pasteur. Everyone has a different specialty to cover across the different cardiology domains. Our rhythmology group specializes in placing cardiac stimulators to provide arrhythmia treatments. As a national reference center of excellence, we participate in national and international research studies in rhythmology for cardiac stimulation and the management of ventricular and atrial disorders.

The Pasteur Clinic's department of rhythmology performs more than 1500 ablations per year, as well as the implantation of about 900 pacemaker and multisite cardiac stimulators, and 150 to 200 defibrillators.

What type of procedures are performed in the mobile C-arm room?

The procedures performed in this room are essentially stimulation, including multisite stimulation and defibrillation procedures. We sometimes perform simple ablation procedures in this room, i.e. endocavitary electrophysiological exploration and ablation of the cavo-tricuspid isthmus or of the HIS junction.

We reserve fixed angiography rooms for complex procedures that are of three types: procedures that require a transseptal puncture in order to realize an ablation into the left atrium, the ablation of ventricular tachycardia, and complex ablation procedures. Complex ablation procedures might involve a higher operating risk for the patient, such as procedures where the positioning of the catheter needs to be very precise like for the ablation of the slow path of the HIS intra-nodal junction. About 50% of these complex procedures are performed under general anesthesia of the patient, and the size of our fixed rooms has been designed to include a large space for the anesthesiologist set-up in case of the need to switch to intensive patient care, that is not the case in our mobile C-arm room. For these procedures, we are using Cartography systems that take up quite a lot of floor space in the operating room and require a dedicated engineer assisting us during the procedure. As our room with OEC Elite CFD is small, we cannot work comfortably with these systems, and cases of acute patient care management require extra space.

What are the challenges in terms of image quality and detector size?

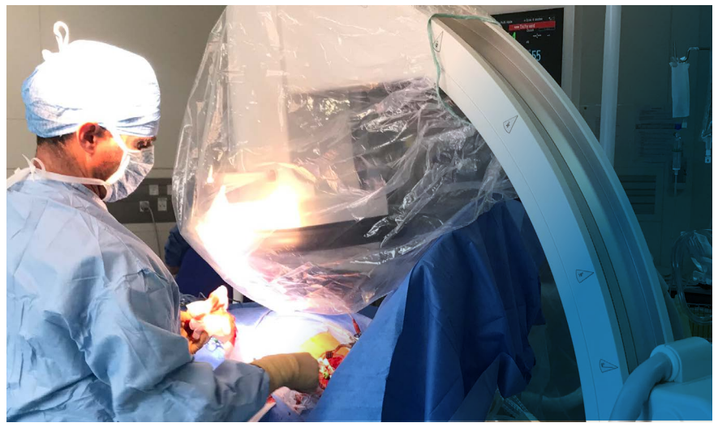
The most complex imaging procedures are multisite stimulation, requiring the precise visualization of very small guidewires (about 0.014 inches or 0.35 mm of diameter) while navigating in the venous vasculature of the back of the heart.

It is also critical to see clearly the heart's venous tree and then the stimulating probes that are a little larger. We need fluoroscopic coverage large enough in order to get a full cardiac shadow in the image. The patients we treat are in cardiac insufficiency with cardiomegaly. There is always a tradeoff between the size of the flat panel, the coverage of the anatomy in the image and the obstruction of the detector in the working space. We work very close to the detector, unlike vascular surgeons who can work away from the anatomy explored. The 21 by 21 cm flat panel detector size is a good compromise. Indeed, if we took a larger detector field of view, would take up too much space and the ratio between the obstruction of the working space to image benefit would not be advantageous.

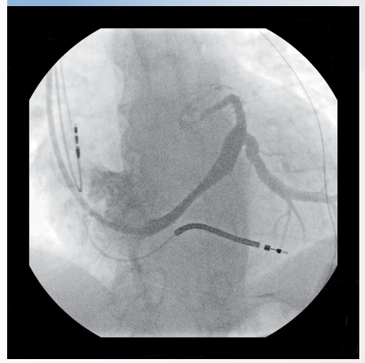
What fluoroscopy modes do you use during your procedures?

In our department, we want to optimize the amount of radiation dose during the procedure, so we are working with low-dose modes: decreasing the image rate using the pulsed mode (8 pulses per second – pps) and decreasing the level of radiation dose using the low-dose mode. Of course, we modify these parameters during the procedure to manage the image quality depending on the complexity of the step of the procedure. It is very easy to improve the image quality by increasing the pulse mode rate from 8 to 15 pps, removing the low-dose mode or setting up the collimation from the Remote User Interface during the procedure.

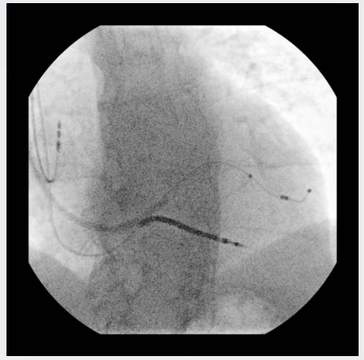
When performing multisite stimulations, we inject contrast media into the cardiac venous tree, and record the sequence using the dynamic recording mode. We inject the coronary sinus vein to position the probe at the level of the left ventricle in such a way as to safely anchor the probe at the level of a bifurcation. The dynamic recording allows us to visualize the full venous tree in the image in order to select the optimum site to anchor the lead.



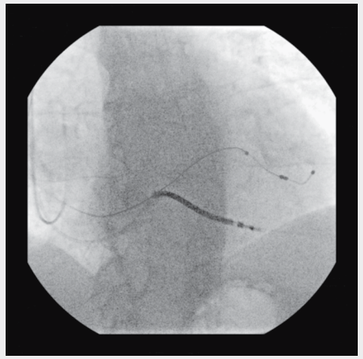
CASE 1 | Defibrillator implantation



Coronary sinus venogram - Digital Cine Pulse 15 pps - AP view – Cardiac profile



Defibrillator lead placement control - standard fluoroscopy low dose 8 pps - AP view – Cardiac profile



Final control - standard fluoroscopy Low dose 8 pps - AP view – Cardiac profile

CASE 2 | Multisite pacemaker implantation

Final control standard fluoroscopy 8 pps - AP view – Cardiac profile

How did you set up the C-arm in the room with space constraints?

As the C-arm is very deep, we placed it along the axis of the patient table, at the patient head. This position allows us to perform both right and left sub-clavicular accesses very easily. During our procedures, we often angulate the C-arm in order to get right or left oblique views. With this set up it is very easy to modify the angulation of the C-arm without interfering with our working space.

We optimize the space in our operating room. We selected the OEC Elite CFD C-arm in order to avoid the congestion of this operating room.

The remote user interface is very easy to install and remove from the table-side rails. Its ergonomics are quite simple and robust. The interface possesses the essential functionalities, we do not need more than this. The buttons are easy to activate. We also use it to modify the position of the C-arm from the sterile field. This interface allows the integration of staff into the procedure workflow such that they actively participate in the procedure.

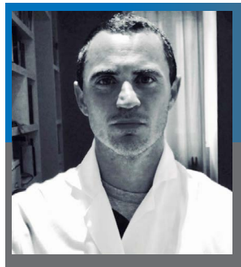
Also the laser aimer is a very interesting tool that can assist in positioning the detector and may limit the number of images taken.

How do you think fluoroscopic imaging is going to evolve as rhythmology techniques progress?

In rhythmology, we have two main domains of activity: Electrophysiology/ ablation and cardiac stimulation. In Electrophysiology, we are moving towards developing integrated systems without fluoroscopic imaging. We are using cartography systems. They were developed for complex procedures, but now we are using them for simpler procedures. These systems are still expensive, but as they contribute to reduce radiation exposure, we are driving our activity to extend their use.

In cardiac stimulation, we are very far away from working without fluoroscopic imaging. We need fluoroscopic guidance. The evolution of the C-arm needs to go in the direction of miniaturizing the footprint and reducing X-ray dose.

Today, the cost of cardiac stimulation procedures has been reduced making them accessible to more centers. The OEC Elite CFD mobile C-arm is well suited to cardiac stimulation procedures. Nothing prevents using the C-arm with a cartography system, only the size of the room determines if we can add an additional system and personnel for the procedure. n



Dr. Stéphane Combes is an Interventional Cardiologist specialized in Interventional Rhythmology, after a fellowship in cardiology. He has worked at Clinique Pasteur for the last 11 years, in Toulouse.
He is a member of the French cardiology society and of the European Heart Rhythm Association.
Dr. Combes is involved in the RETAC (European network for the Treatment of Arrhythmias in Cardiology), which promotes sharing experiences to improve the management of cardiac arrhythmias, particularly in the field of radiofrequency catheter ablation[1]. With the rhythm group of Clinique Pasteur, he participates in national and international multicentric studies in the field of arrhythmia and stimulation/ defibrillation.

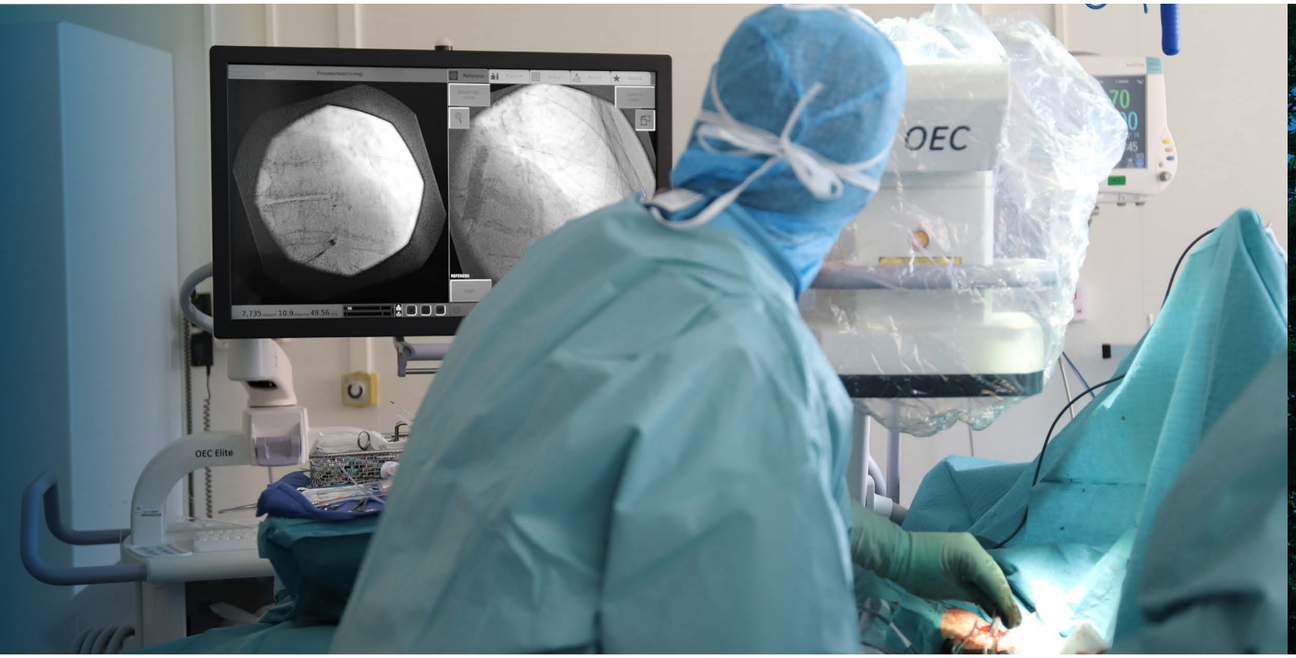
1 http://www.retacgroup.com/about-us/

The statements by GE's 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.

Optimizing patient care in an arrythmia department

Dr. David Mörtsell, Director of device surgery and arrhythmology unit , Skane University Hospital, Lund (Sweden)

The arrhythmia department of Skane University Lund, with its remote electronic heart-monitoring system, performs up to 1700 procedures a year. About 60% of those more standard procedures are performed on the OEC Elite CFD Ergo C-arm. Dr. Mortsell sat down with us to discuss his practice.



What are the economic challenges that your department is facing to optimize patient care?

Last year, we had a block-budget for 800 devices and 700 ablation procedures and we ended up doing about 1700 treatments. The additional cost was supported by our hospital administration because we demonstrated that it was necessary for the patients, and the patient outcome was positive. Compared to some other European countries where procedures are reimbursed on a fee-for-service basis, like lead extraction for example, we have a lower procedure volume. For additional procedures over budget, we discuss patient benefit with the administration before proceeding. What is more important: performing device implantations or lead extractions?

Sweden is divided into 21 counties; each county has a different budget. In Skane county, we are evolving slowly towards performing more and more complex procedures in centralized departments. We have grants for lead extraction, and ablation to treat patients primarily from Skane county, but patients come from anywhere in Sweden. In addition, my department is specialized in children's heart diseases and Grown-Up Congenital Heart disease (GUCH), for which we receive specific subventions. These subventions also cover lead extraction, which is relatively expensive. We are growing as a center of excellence for children's heart care therapy and GUCH. We are one of the largest centers in Sweden for these four patient groups. This allows us to apply for increased budgets to improve patient care.

What type of imaging lab do you use in Lund arrhythmia department and how do you triage the procedures among these rooms?

In the arrythmia clinic we have two cathlabs where we primarily do ablation procedures. The complex heart rhythm treatments are performed in one of the cathlabs with two physicians, where we can use the Niobe (Stereotaxis, Saint Louis, MO USA) magnetically-driven robotic system. The department is a reference center for Stereotaxis. The other cathlab is equipped with a fixed angiography room setup for manual ablation and both labs are equipped with 3D mapping system CARTO® (Biosense Webster). In addition to the two fixed angio rooms, we built an additional room dedicated to device surgery with the OEC Elite CFD Ergo C-arm (GE Healthcare) and an imagiQ2™ surgery table (Stille). We have one shared hybrid room in the surgery department that I can use for some procedures twice a week. We also have access to the children's surgery department on demand (approximatively once a week), that is also equipped with a C-arm. We are one of the two reference centers for children's heart surgery and arrhythmia treatment in Sweden, together with Sahlgrenska University hospital.

What are the most demanding procedures in terms of fluoroscopy?

I think that lead extraction is the most demanding procedure for fluoroscopy. We need to see the lead extraction tool, i.e., a special sheath, and position it in a controlled manner over the lead to break the fibrous tissue that makes the lead adhere to the vessels and heart muscle. Fluoroscopy imaging is used to make sure that the sheath is aligned with the lead. If the sheath deviates from the lead, we can damage it, or even break it. This procedure can be long.

...

We perform standard extractions on the OEC Elite CFD C-arm when the lead has been in place for only a few years and calcified fibrous tissue has not had time to develop over the lead and where the lead design is standard and not fractured. The most complex extractions are performed in the fixed hybrid room. We routinely perform this procedure under general anesthesia in the hybrid operating room in case we need to do an emergency sternotomy, as we are unable to do this down here in the EP Lab.

Balloon cryoablation is a standard procedure performed at Skane university Hospital - Lund as a primary intervention to treat atrial fibrillation. This procedure is performed using fluoroscopy alone to guide the catheter containing the balloon, to inflate the balloon, and check that we have a good occlusion of the pulmonary veins by the balloon before introducing the refrigerant liquid into the balloon and proceeding with the creation of scars in the heart tissue. For this procedure, there is no need for image fusion. The CT scanner is used to confirm the anatomy of the patient, checking that there are 4 separate pulmonary veins. We can then merge the CT images in the CARTO® mapping system, to create a 3D model of the heart chambers.

Some centers perform cryoablation using a very simple set up, with a C-arm and the ablation system. To be able to perform ablation, you need a high-quality left anterior oblique projection to do the trans-septal puncture. However, once you are in the left atrium, you can simply navigate with an AP projection and the electrical signal from a mapping catheter. In routine ablation cases, it is possible to perform ablation without fluoroscopy, as we know where we are in the heart just by looking at the ElectroCardioGram (ECG) signals.

Typically, if you have a standard case, you need just a few seconds of fluoroscopy to verify that the catheters are in the heart, and in the position where you need to have them, and maybe you will need to perform fluoroscopy for an another few seconds to check where your ablation catheter is. Thus, many procedures only have between 20 to 60 seconds of fluoroscopy time, and we can rely on 3D electroanatomical mapping systems and minimize fluoro, even if the procedure itself may be 2 hours or more. But, if our 3D mapping fails, we need to rely on fluoroscopy. For pacemaker implants, we use fluoroscopy to guide and position the leads. This is the main activity in this mobile room in the device surgery lab.

Why did you choose the OEC Elite CFD Ergo C-arm for your activity?

I am the referent for the choice of the C-arm in the clinic, but as it is a major investment, the decision is taken by the team within the heart-lung center.

The main criteria we examine when choosing a C-arm are: ease of use, well-designed and intuitive interface, and image quality/dose. It is important for me to try to limit my X-ray dose without compromising image quality, especially as some procedures take more fluoroscopy time. We are always screening in low-dose fluoroscopy mode, just increasing the dose with a Cine loop for the final check. Because the OEC C-arm is easy to move, I can easily change the projection during the procedure, and optimize my exposure time thus minimizing the overall dose.

The image quality of the OEC Elite CFD C-arm is really good. I can clearly see the border of the heart as well as my leads and guidewires, and I have good visualization of the motion of the tip of the leads. The OEC Elite CFD C-arm performs well on low dose and IQ, and is easy to use, which are the two most important criteria. n

Dr. David Mörtsell
Director of device surgery and arrhythmology unit, Skane University Hospital, Lund, (Sweden)

Dr Mörtsell - how did you train to become an arrythmia specialist?

I started as a general medicine and emergency room physician and specialized in cardiology in 2006. As I had a preference for arrhythmology within cardiology, I completed my training during a fellowship at the EP lab at Royal Brompton Hospital (London, UK). On my return to Sweden I decided to specialize in invasive arrhythmology. So I moved from interventional cardiology to invasive arrhythmology. Since then I perform only electrophysiology procedures and device surgery with a split in my activity of about 50% EP ablation and 50% device surgery.

How do you manage the quality of care within your arrythmia department?

As director of arrythmia devices, I define what procedures we are going to do, how we are going to do them, and we report the number of procedures with their associated cost. I define the routines, how we do the procedures, and I define the training courses for the staff and other physicians. We work in collaboration with device companies for training courses and I am responsible for the relations with them. In addition to managing the patient workflow, I am also responsible for ensuring that we work within our quality charter requirements, optimizing for example X-ray exposure time and fluoroscopy protocols. But I also work 100% as a clinician as well. On a national level, we contribute with research projects, such as the multicentric evaluation of new cryoballoon ablation techniques[1].

How do you foresee the evolution of device and arrhythmology procedures in the future?

The trend for arrythmia procedures is to move towards leadless devices through percutaneous access.
If you are asking me where we will be in 5 years, I would say that subcutaneous ICDs will be the largest portion of ICD procedures. This type of device implantation does not require fluoroscopic imaging guidance. We just need to perform a quick final control image to check the positioning of the device, that is located under the muscle, and the position of the defibrillator lead connected to the device, that is placed under the skin, over the ribs, and over the sternum, creating a defibrillation field.
The implantation of leadless pacemakers will also become widespread. This device, which is no larger than a big vitamin pill, is brought directly into the right ventricle via the inferior cava vein using a delivery system through femoral vein access. The device is anchored directly to the heart tissue. The implantation procedure duration is shortened as there are no leads to be placed inside the heart. For this procedure, fluoroscopy is used to guide and position the device.
Today, radiation exposure is a concern for young doctors. They are training with mapping systems, navigation systems, 3D models, and when something happens and they do not have these tools available, but just fluoroscopy imaging, they are lost, they don't know how to read the image. Teaching them how they can perform simple procedures using fluoroscopy alone, and only one catheter, relying on ECG signals is an important part of training. It is important to be able to manage our procedure with minimalistic equipment and effective fluoroscopic imaging while at the same time, learning how to use more sophisticated mapping tools. n

1 "Cryoballoon vs. radiofrequency ablation for atrial fibrillation: a study of outcome and safety based on the ESC-EHRA atrial fibrillation ablation long-term registry and the Swedish catheter ablation registry". Mörtsell D et all. Europace. 2019 Apr 1;21(4):581-589.

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Jakob Aronson (Nurse), Kerstin Sjögren (Operations Nurse), Maria Eltén (Assistant nurse) and Dr. David Mörtsell

The arrhythmology unit is a sub-division of the hospital's heart-lung center.

The center comprises the cardiology department, itself divided into 3 subsections: ischemia (including Percutaneous Coronary Interventions), structural heart interventions and heart failure, and the arrythmia clinic.

The EP activity of Skane University Hospital is split between two departments, one located in Malmö and one located in Lund. In Malmö regular pacemakers are implanted in up to 600 patients per year.

Lund's EP department has been developing its activity in more advanced procedures, training the staff to perform the programming of the devices itself. The department is equipped with a remote electronic heart-monitoring system where the data saved on the device is transmitted to the clinic through a transmitter in the patient's home. Regular reports are sent to the clinic so the medical staff can check the diagnostic data, modify the programming of the device if needed, and feed the database. This electronic system allows us to increase patient safety while saving costs and time to concentrate the medical staff on patients with the greatest needs[1]. The volume of procedures is about 700 ablations, 400 Implantable Cardioverter Defibrillators (ICDs), 300 CRTs, 500 pacemakers, 100 lead extractions, and a number of congenital treatments per year. For ICD and pacemaker activities, patients are mainly recruited in the county of Skane. For pediatric care, complex CRT, lead extraction, and ablation in GUCH, patients come to the ward from the entire country.

1 http://skanecare.com/care-projects/

Complete Atrioventricular (AV) block treatment with Cardiac Resynchronization Therapy (CRT) device implant using the OEC Elite CFD Ergo C-arm

Courtesy of Dr. David Mörtsell, Director of device surgery and arrhythmia clinic, Skane University Hospital, Lund (Sweden)

OEC Elite CFD Ergo C 21 cm, VAS MTS

Clinical Challenge

CRT device implantation (or biventricular pacing) is a common treatment for cardiac arrhythmia. The procedure involves implanting a pacemaker under the skin below the collarbone, connecting the pacemaker to three leads: one inside the right atrium, one inside the right ventricle, and the third one inside the coronary sinus vein at the level of the left ventricle of the heart.

The leads are brought to the heart through venous access, from the subclavian vein to the superior vena cava. Fluoroscopy is used to guide the different leads to their final anchorage location.

While the guidance of the leads in the right atrium and right ventricle is quite straight-forward, the cannulation of the coronary sinus can be more complex. In addition, the third lead needs to be guided to the great cardiac vein, and placed into one of its bifurcations using a 0.014" guidewire.

As the procedure can be long and is performed under fluoroscopy guidance, with demanding image quality, radiation exposure must be managed during the procedure, optimizing each step.

Solution

The procedure was performed with assistance of X-ray imaging from OEC Elite CFD Ergo C. To control the exposure, the fluoroscopic guidance of the leads was set to standard pulse mode at 15 pps. Coronary sinus venogram was performed in Digital Cine 15 pps mode. The anatomic profile was set to General HD to navigate 0.014" guidewires.

Clinical example

An 80-year-old female patient with a history of chronic heart failure presented with a left bundle branch block. She was treated 6 months earlier for pulmonary edema and received optimal pharmacological treatment but remained highly symptomatic and left ventricular function stayed poor. The patient was thus eligible for a CRT device implantation.

This procedure was performed under local anesthesia, under ambulatory conditions.

Venous access was obtained by axillary vein puncture. Catheterization and subsequent venogram of the coronary sinus was performed injecting about 20 cc of iodine at 50% dilution.

The final verification of the lead was performed and compared to a post-op X-ray control image. The same information was found in both the fluoroscopy control and X-ray images.

The total exposure time was 1 minute and 20 seconds, and the total DAP was 11.7 Gy cm².

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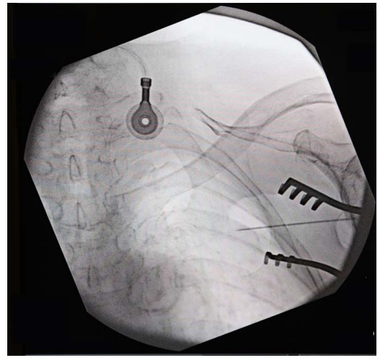
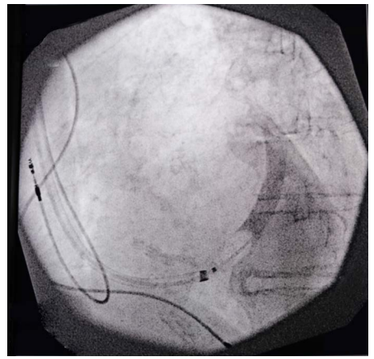
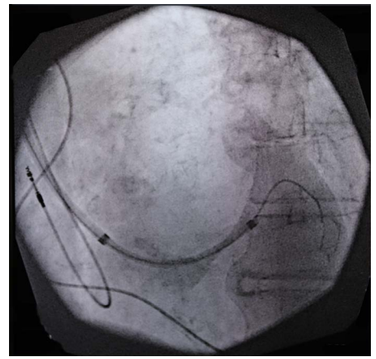


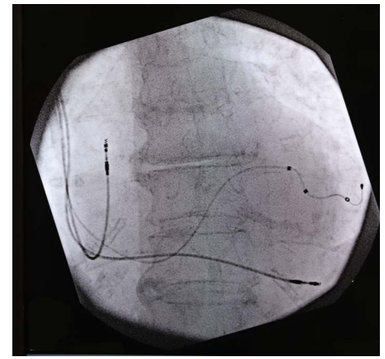
Puncture of axillary vein – Antero Posterior (AP) View.



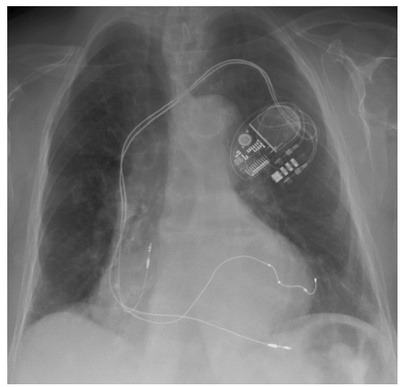
Coronary sinus injected with contrast media 30° Left Anterior Oblique (LAO).



Catheterization of coronary sinus – 30° LAO.



Final perioperative control of CRT leads in coronary sinus – AP view.



X-ray control post procedure AP view.

Pacing treatment with leadless device implant using the OEC Elite CFD Ergo C-arm

Courtesy of Dr. David Mörtsell, Director of device surgery and arrhythmia clinic, Skane University Hospital, Lund (Sweden)

OEC Elite CFD Ergo C 21 cm, VAS MTS.

Clinical Challenge

Pacing devices are evolving towards systems without leads. The advantage of such devices is that they require no lead guidance and no surgical pocket under the skin. Potential complications associated with venous access (such as pneumothorax), lead dysfunction and local symptoms from the surgical pocket (such as hematoma or infection) are less likely. The device (Micra™ Transcather Pacing System – TPS Medtronic), which is no larger than a large vitamin pill, is brought directly into the right ventricle via the inferior vena cava using a delivery system through femoral vein access. The device is anchored directly to the heart tissue without external leads.

Solution

The procedure was performed with assistance of X-ray imaging from OEC Elite CFD Ergo C. The guidance of the delivery sheath was achieved using continuous fluoroscopy. The verification of the anchorage of the device on the heart tissue was performed in Digital Cine 15 pps mode. The anatomic profile was set to General HD. In order to visualize the small anchor tines located at the extremity of the device and ensure that there is no dislodgment, the magnification mode was used during live fluoro control.

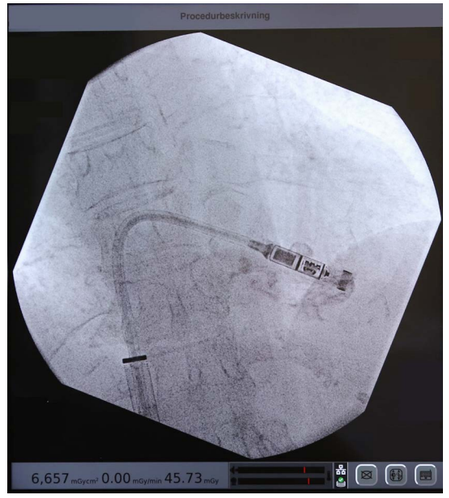
Clinical example

An 85-year-old female patient with a history of chronic atrial fibrillation and bradycardia was offered this treatment instead of a conventional pacemaker in ambulatory conditions. This device implant placement requires only femoral vein access, and no other incisions during the procedure, potentially reducing post-op complications.

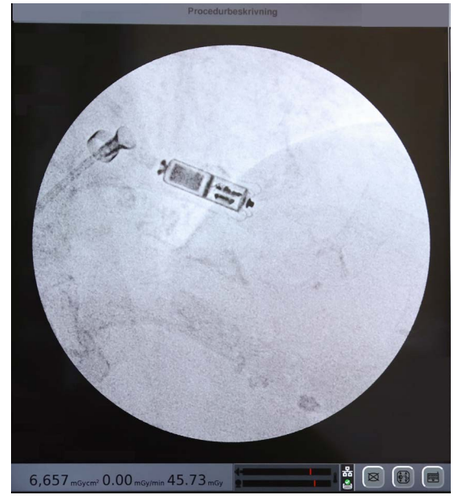
Femoral vein access was performed under local anesthesia.

The total exposure time was 1 minute and 53 seconds, and the total DAP was 6.6 Gy cm².

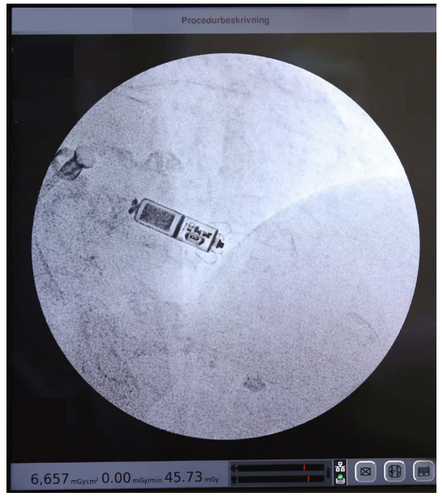
Preparation of the device delivery sheath.



Placement of the device next to heart tissues – AP view.



Release of the device from delivery system – AP view, Magnification 1.



Final verification of device implantation – 30° Right Anterior Oblique (RAO) view, Magnification 1.

The statements by GE's 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.

Minimally invasive procedures in a cardiac care center

with OEC Elite CFD

Interview with Dr. Jesus Oneto Otero, head of Cardiology department at the Hospital San Rafael in Cadiz, Spain.

Considering the growing volume of heart diseases linked to lifestyle changes, Cardiology is one of the medical specialties with an increasing demand for both diagnostic and therapeutic medical means. Since cardiovascular diseases affects individuals in their midlife years, prevention strategies are a central focus of development for clinical cardiac care.

The Hospital San Rafael is a private hospital that has been expanding its cardiology department over the past 20 years. It has the capacity to diagnose and treat heart disease in patients from the metropolitan area of Cádiz and the autonomous cities of Ceuta and Melilla.

With the creation of a new cathlab to host the Hemodynamics and Interventional activities of Dr. Oneto, the Hospital San Rafael is reinforcing its cardiology capacity, providing a complete patient care pathway from the initial diagnosis of chest discomfort, to treatment and post operating follow up of the patient.

The Hemodynamics and Interventional Cardiology Unit of the Department of Cardiology lead by Dr. Oneto constitutes a reference center in treatments related to heart diseases.

Facing an increasing number of procedures, the department of Cardiology has equipped a new operating room with the OEC Elite CFD motorized Cardiac C-arm.

Dr. Oneto shares with us his motivation for this choice.

Can you describe the activity of the Hemodynamics and Interventional Cardiology unit?

The Hemodynamics and Interventional Cardiology unit has developed the capacity to diagnose and treat cardiac arrhythmias from electrophysiological studies to ablation procedures. In coordination with the chest pain unit, after in-depth diagnosis and where appropriate, patients can go through coronary angiography in the early stages of coronary disease.

The unit has been implementing minimally invasive approaches for most interventions to allow the patient to go down the ambulatory pathway. In addition, the unit has the capacity to hospitalize patients needing longer monitoring and beds in the Intensive Care area unit for patients going through more complex cardiology procedures.

About 95% of the procedures are done through radial access and cover a wide range of treatments for different pathologies. These include simple arrhythmia to more complex cases such as emergencies, complex pacemaker device implantations, atrial septal defect closure, valve repair and coronary interventions.

All these procedures require fluoroscopic imaging guidance and control.

What motivated the hospital to choose a mobile cathlab with OEC Elite CFD?

As we have an increasing volume of patients, we decided to open a new Operating Room. The hospital budget required us to use the current infrastructure and reallocate some equipment.

Therefore, to optimize our working space that already contains an assortment of all necessary patient care hemodynamic equipment, we decided to install a mobile cathlab with the newest generation of flat panel detectors.

This new installation includes a cardiovascular table with a floating tabletop, an injector coupled with OEC Elite CFD, a workstation for procedure planning (GE Cardio Vascular Review Workstation), a multichannel hemodynamic recording system, and two ceiling suspended medical video monitors to display fluoroscopic images.

After an evaluation of different C-arms, we selected the OEC Elite CFD motorized Cardiac C-arm, mainly due to its high performance in image quality for our longer procedures.

Can you tell us how OEC Elite CFD is fulfilling your needs in fluoroscopic imaging?

The procedures that have the most stringent needs in fluoroscopy are those performed on coronary arteries. The anatomy is very small, which means we work inside vessels of less than 2mm in diameter. Image resolution must allow us to clearly see the different types of guides, expandable material, balloons, stents and other devices we bring inside the coronary artery. We need a maximum of image clarification and detail.

> *"The excellent image quality with OEC Elite CFD allows us to carry out all the different types of cardiac procedures we perform. The user interface improves our procedure workflow.*
>
> **Dr. Jesus Oneto Otero**

"The Cardiac profile of OEC Elite CFD provide us with the clarity we need during the procedure. We always activate the eNR function which reduces the noise artefacts during guidewires or catheter movement. We see the tip of our guidewires clearly while pushing them."

To manage radiation doses for the patient, we manage image quality needs at all steps of the procedure using all the tools available in the C-arm (Live zoom, collimation and fluoroscopy modes, for example).

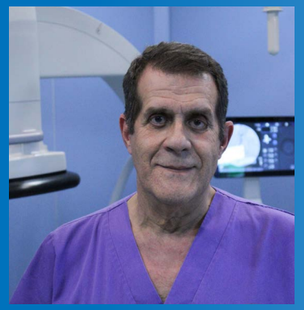
Like all cardiology units we also treat over-weight patients. Our experience with OEC Elite CFD has been very positive, with high quality imaging for these patients allowing us to complete even long procedures.

Image Quality has leapt forward with CMOS detector technology compared to our previous equipment. We now see more clearly during coronary procedures regardless of the projection angle or the patient profile.

We chose the motorized version of OEC Elite CFD, as we often switch from Anterior Posterior, Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) views during the procedures. The C-arm can be moved to a precise angle from the remote user interface on the table side by the cardiologist which improves the procedure workflow. The interface is simple and provides quick access to functions. We can also store the most common angulations and retrieve them by simply pushing a button, without staff help.

Other functions that I appreciate being able to manage by myself are selection of the low dose mode, setup of the collimation and access to the image directory to retrieve images and use them as reference images. For example, I like to set up the OEC Elite CFD C-arm in low dose mode at the beginning of the procedure, and when I need to see the stent mesh, I remove the low dose mode and use the digital cine pulse for three or four seconds.

One projection that is specific to coronary artery surgery is about 45°



Dr. Jesus Oneto Otero is an Interventional Cardiologist, specialized in Hemodynamics, a member of the Spanish and European Societies of Cardiology and a practitioner of interventional Cardiology for 37 years. In this context, Dr. Oneto has contributed to the evolution and the development of hemodynamics and participation in the early stages of coronary angioplasty in Spain.
Dr. Oneto is Head of the Cardiology department at the University Hospital of Jerez and Head of the Cardiology and Hemodynamic department at the Hospital San Rafael in Cadiz.

Left Anterior Oblique (LAO) with 25° Caudal (CAU). This view permits to visualize the left anterior descending coronary artery. It is difficult to position the C-arm for this view and in this position the X-ray beam goes through thicker amounts of tissues. The deep shape of the OEC Elite CFD C-arm allows us to get this angulation.

What are the features of the OEC Elite CFD C-arm that you like and use regularly?

"I always try to get the most out of my C- arm, so I spend a lot of time learning about the different functions, and I use them all.

But if I must choose, I will highlight two features that I think are very successful in the type of interventions we perform.

The first one is the fluoroscopy mode called 'Digital Cine Pulse' (DCP). I can activate this mode directly from the three-pedal footswitch on the far-right X-ray switch. In fact, I use this mode when I need maximal image quality to visualize the coronary arteries at the most critical moments of the procedure. It is a high intensity pulsed mode that automatically records the images in a cine record on the workstation. To manage patient radiation exposure, I run DCP sequences for three or four seconds. Once saved, the sequences are automatically replayed. In this mode I can see dynamic images clearly even with the continuous heartbeat motion, without kinetic artifacts.

The second feature I use a lot is the digital Live Zoom. This function is used to zoom in or zoom out on the anatomy under live fluoroscopy. It gives the possibility to magnify the anatomy displayed without increasing the amount of radiation. This is useful for very long procedures."

Dr. Miguel Alba - Cardiologist, Dr. Jesus Oneto Otero - Interventional Cardiologist , Mrs. Lara Shorbaji Puertas - Operating room Nurse, Mrs. Juana V. Perez Carrasco – Nurse, Mr. Francisco Medina Camacho - Operating room Nurse

How do you think your activity will evolve in a near future?

"Interventional cardiology is constantly evolving and developing. It is hard to predict exactly where this is taking us because there are many branches that are following their own evolution. If we look at the progress in rhythmology and interventional cardiology since I started up until present, great technology improvements occurred in a short period of time, while others have been completely dropped. This is the case, for example, of resorbable stents that we thought would be the solution for many treatments, and which turned out not to be the case.

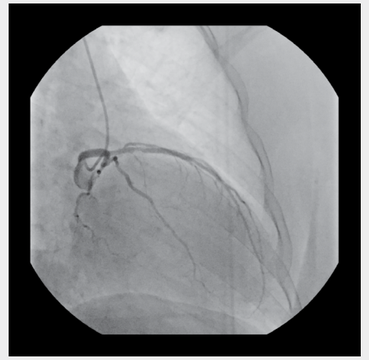
What I believe is that everything is leading us to increasingly treat patients with less invasive procedures. Some time ago, we could not imagine repairing an aortic valve. Today not only is it a quite common procedure, but we are starting to repair mitral or tricuspids valves using a peripheral approach.

And since the idea is to perform complex procedures in a less invasive way, fluoroscopic image guidance becomes essential in the evolution of our specialty. I believe that imaging technology and cardiology are somewhat linked to each other".

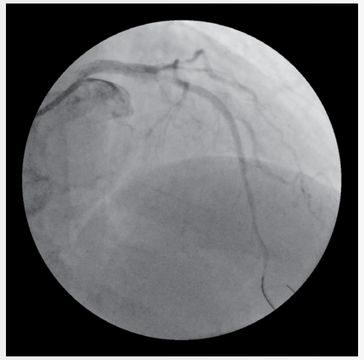
The statements by GE's customers described here are based on their own opinions and on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc.. there can be no guarantee that other customers will achieve the same results.

ANGIOPLASTY CASE

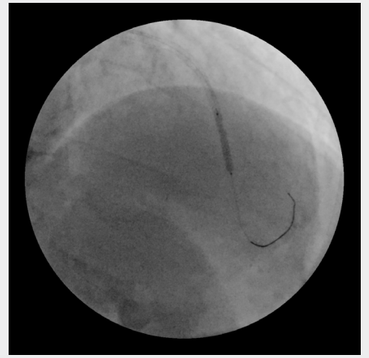
Courtesy of Dr. Oneto, Interventional Cardiologist, Hospital San Rafael in Cadiz, Spain.



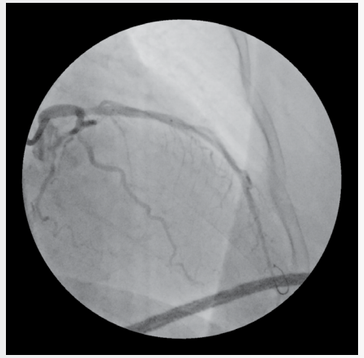
Initial arteriography: Left and right coronary arteries
Fov 21 cm
29° Right Anterior Oblique (RAO)
2° Cranial (CRA)



Arteriography of Left descending artery
FoV 19cm (MAG1)
0° RAO
31° CRA



Angioplasty
FoV 19 cm (MAG1)
0° RAO
31° CRA



Arteriography of left and right arteries
FoV 19 cm (MAG1)
36° RAO
4° CRA

A total of 73 series of images were taken with a total exposure time of 14.5 min, and total DAP was 37 Gy.cm².

Left Heart Catheterization procedures in Ambulatory Surgery Centers

with OEC Elite CFD

Interview with Dr. Andre Bouhasin, M.D., Interventional Cardiologist, Medical Director. St. Louis Specialty Surgical Center

St. Louis Specialty Surgical Center is located in the metropolitan area of St. Louis, Missouri, United States. Composed of eight cardiologists, the Surgical Center recently expanded its capabilities to capture the increasing demand to perform Left Heart Catheterization procedures in Ambulatory Surgery Centers (ASC).

Left heart catheterization procedures address coronary artery disease, valve disease, blood flow issues, and left ventricle dysfunctions for diagnostic or therapeutic purpose. These techniques are commonly used for the measurement of cardiac hemodynamics, diagnosis, and treatment at early stage, to avoid heart damage or risk of further events.

OEC Elite CFD configured with 31 cm detector, cardiac software, and motorized control

The OEC Elite CFD introduces innovative software features, like Enhanced Noise Reduction (eNR) and Cardiac profile, to enable a superb image quality experience and optimal workflow during cardiac and vascular procedures.

eNR is an advanced software algorithm that automatically reduces noise by more than 30 % during Vascular and Cardiac imaging, presenting an equivalent image to twice the effective power, without increasing radiation dose. Visualizing medical devices, such as guidewires, stents, or implants, can be challenging during Vascular and Cardiac imaging, due to motion of anatomy and/or devices.
The OEC Elite CFD eNR feature automatically adjusts images for visualization of catheter tips and/or edges in Vascular and Cardiac configuration with equivalent image appearance of 30kW power and no change in dose.

The Cardiac profile available in the OEC Elite CFD, automatically reduces blooming artifacts and enhances visibility of moving features, such as 0.014" guidewires in thoracic region, which needs to be guided precisely to the surgical location in the heart.

The team of cardiologists of St. Louis Specialty Surgical Center decided to broaden their capabilities to service an increasing patient need, and after testing different equipment, decided that the OEC Elite CFD Mobile C-arm was the best mobile C-arm solution to meet their needs and address the increasing volume in patients. Dr. Andre Bouhasin explains why.

Why did you choose a mobile C-arm for the center and what are the type of procedures that you are performing with it?

Once the ASC started to develop the need for Percutaneous Coronary Interventions (PCI) and once Medicare included reimbursement, we realized we needed a capable C-arm.

An imaging system is a large investment, when we were talking about adding another fixed unit, trying to retrofit an existing space is a big challenge. There are power and shielding requirements for a fixed unit and our center wasn't designed for that, we didn't anticipate PCIs being performed. So, finding a C-arm that could fit into the existing space was a big factor for us, at an affordable cost.

In terms of procedures, we started slow, being conservative doing diagnostic cases, then we added some easy PCIs on thin patients, without advanced lung disease. As we performed more cases, we started to get more and more comfortable with the OEC Elite CFD, pushing the limits of what it is capable of doing. Now we have done some challenging cases that we would never expect that we could do with the C-arm.

Procedures such as ostial LAD (Left Anterior Descending) and heavier patients, and we've had fantastic results with OEC Elite CFD.

Why the OEC Elite CFD ?

We tried multiple different C-arms and the OEC Elite CFD really made a big difference in clarity on what can be done from a cardiac standpoint. The difference between this C-arm and most of the others is the image quality.

> *" We have done some challenging cases... such as ostial Left Anterior Descending, and heavier patients, and we've had fantastic results with OEC Elite CFD."*
>
> **Dr. Andre P. Bouhasin**

The workstation monitor is big enough to get amazing images, and at the same time compact to get the flexibility needed to bring the display over the patient and get close enough to review and manage the images.

In addition, having a motorized C-arm with tableside controls, is key in terms of independent control and workflow, instead of having someone moving the C-arm during cardiac procedures and adjusting the settings.

The OEC Elite CFD Motorized C-arm is fast and it moves quickly. The detector is large enough to get a nice Field of View for cardiac imaging.

You've mentioned the articulating monitor. Can you share what's the value you found in that design?

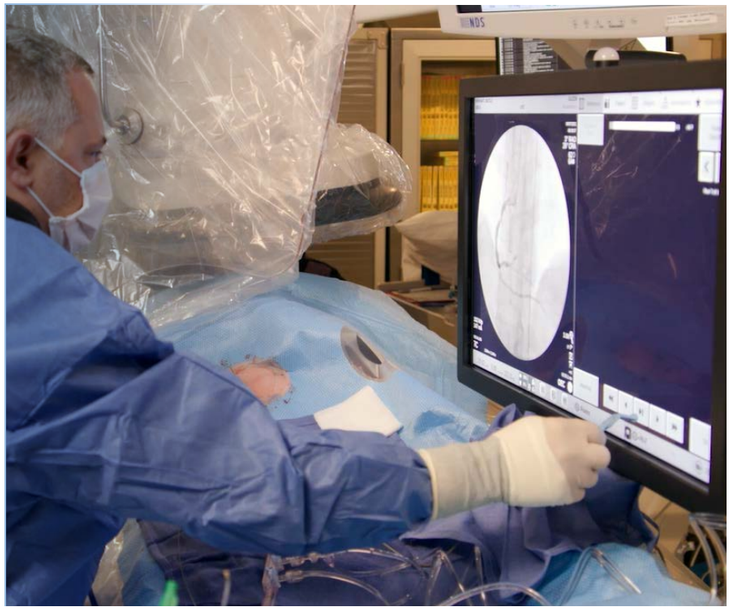
A fixed unit cathlab requires an articulating monitor system which can take a lot of space. It can be suspended from the ceiling, from the walls or it can be floor-mounted, usually taking a lot of space from the room. A surgical C-arm, it's portable, it has its own workstation, and the articulating monitor of the OEC Elite CFD is wonderful and very versatile.

The display has a touchscreen interface, making it easy to use a sterile object to playback Cine, review frame by frame, and it provides full system control.

The flexibility of the articulating arm really makes a difference. Bringing the monitor right up over the patient's legs to get close and see everything.

"The difference between this C-arm and most of the others is the image quality."

Dr. Andre P. Bouhasin



In terms of flexibility, what advice would you give to other surgeons that are considering a mobile C-arm for their practice?

With a mobile solution, it is possible to perform 90% of the procedures that can be done with a fixed unit once the surgeon gets used to it. In addition to have the portability to remove the C-arm in case there is the need to perform procedures that won't require fluoroscopy.

The cost differential is large, a mobile C-arm is more of an affordable solution than a fixed unit, it requires minimal site preparation and lower operating costs, allowing us to take the risk of proceeding and minimize long term investment.

Overall, how satisfied are you with the OEC Elite CFD for your Ambulatory Surgery Center?

We've been using it now for approximately eight months, and I've tackled some things I never thought I would have ever tackled, outpatient nonetheless on a C-arm. We've had fantastic results with it.

Overall, I'm very satisfied with it. It was a good financial decision for the center. It allows us to deliver quality care for the patients, procedures are done in a more economical and faster pace. It's a huge win for everybody and patient satisfaction has been amazing. n

" The articulating monitor of the OEC Elite CFD is wonderful."

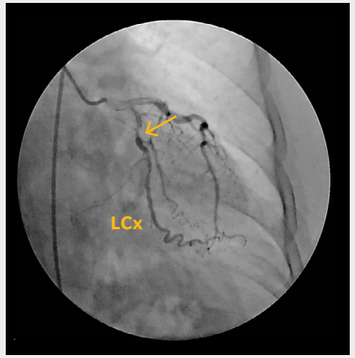
Dr. Andre P. Bouhasin

CORONARY ARTERIES ANGIOGRAMS

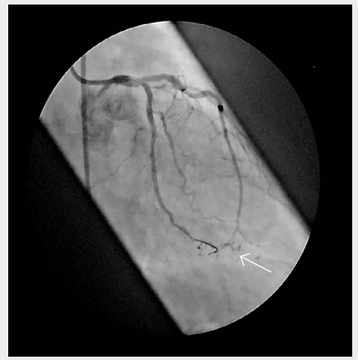
Courtesy of Dr. Bouhasin

The images below are extracted from series of images performed in Digital Cine Pulse 30 pps, with the Cardiac imaging profile and MAG1 mode (21cm) Field of View.

LEFT CORONAL ARTERY (LCA)

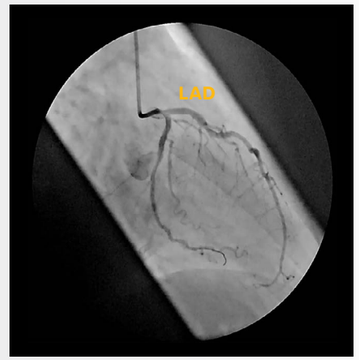


Diagnosis angiogram showing a lesion in the Left Circumflex (LCx) artery.



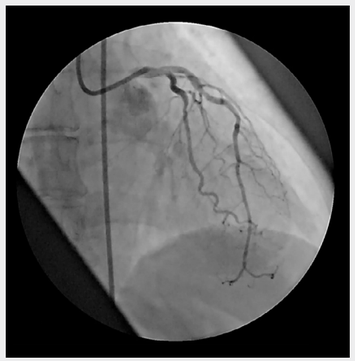
LCx lesion dilated Images. 0.008 inches guidewire in distal LCx. Acquired with collimator leaves in to reduced exposed anatomy.

LEFT ANTERIOR DESCENDING (LAD) ARTERY ANGIOGRAM

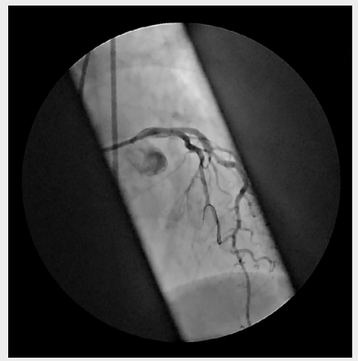


Yellow marks on images are for reference only. These are not part of product annotations feature.

LEFT CORONAL ARTERY (LCA)



LCx and LAD Angiogram.



LCx and LAD Angiogram.

RIGHT CORONARY ARTERY (RCA)

Diagnosis image of distal bifurcation.

CORONARY ARTERIES ANGIOGRAMS AND VENTRICULOGRAM ON A PATIENT WITH CARDIAC IMPLANT

Courtesy of Dr. Bouhasin

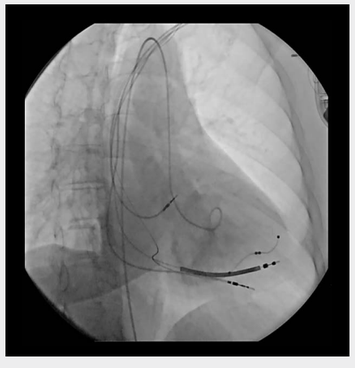
The images below are extracted from series of images performed in Digital Cine Pulse 30 pps, with the Cardiac imaging profile and MAG1 mode (21 cm Field of View, except fpr the left ventriculogram acquired without MAG mode (31 cm Field of View).

LEFT CORONAL ARTERY (LCA)

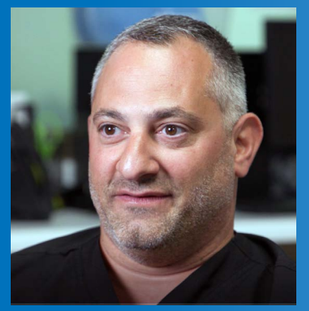
LAD and LCx (Left Circumflex Artery) angiograms in different oblique and craniocaudal views to avoid overlap with the 4 leads implant..

RIGHT CORONARY ARTERY (RCA)

LEFT VENTRICULOGRAM



Diagnosis mid segment.



Dr. Andre P. Bouhasin M.D. is an Interventional Cardiologist from St. Louis, MO. and is graduate of St. Louis University School of Medicine in 2001 who completed his fellowship in 2009 at the University of Nebraska Medical Center.

"Cardiology has always fascinated me. My father was a physician, he used to take me when I was a kid after church on Sundays to rounds at the hospital.

The outpatient world of cardiology is very exciting. As you start to learn the business side of medicine and about outpatient labs, it's exciting trying to figure out that you can be a good physician clinically, and then from a business standpoint, learn how to capitalize and perform more procedures out of the hospital, where they can be done faster and more efficiently, which is good for the patients, for the institution and for the payers. It's a win-win"

Dr. Bouhasin is a paid consultant for GEHC and was compensated for participation in this testimonial, video, article, etc.. The statements described here are based on Dr. Bouhasin own opinions and on results that were achieved in his 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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EXTREMITIES SURGERY

OEC MiniView **NEW!**

GENERAL SURGERY

OEC One CFD **NEW!**

OEC Brivo

ADVANCED SURGERY

OEC Elite CFD

OEC One

OEC 3D **NEW!**

OEC Elite

** CMOS flat panel detector*
*** Image Intensifier*

INNOVATION. PERFORMANCE. INTUITIVENESS. RELIABILITY.

The OEC family of mobile C-arms has been used by surgeons for more than 40 years enabling clinical and operational excellence.

More than 35,000 systems installed worldwide remain hard at work close to 15 years after their first procedure.

GE Healthcare

GE Healthcare provides medical technologies and services to help solve the challenges facing healthcare providers around the world. From medical imaging, software, patient monitoring and diagnostics, to biopharmaceutical manufacturing technologies, GE Healthcare solutions are designed to help healthcare professionals deliver better, more efficient and more effective outcomes for more patients.
GE Healthcare is betting big on digital; not just connecting hospital departments and physicians more effectively, but utilizing the masses of data from its equipment and the collaboration between hardware and software –"digital industrial" – to help clinicians make better care decisions. Sensors, software and smart data analytics are converging to enhance GE Healthcare's offerings not just in diagnostics, but also pathology, gene sequencing and even hospital asset tracking.

Make your Surgical Imaging easy GE Healthcare Surgery is dedicated to improving lives during the moments that matter most by providing the imaging guidance platform for diagnostic, interventional and surgical procedures.
Innovation, leveraging one of the latest imaging technologies such as CMOS flat detectors, advanced features and software enabling stunning image quality while following the ALARA dose principles for patient and staff.
Performance, providing C-arms with simplified workflows, great anatomical coverage and ergonomic design enabling accurate and smooth positioning.
Intuitiveness, simplifying user experience while optimizing surgery time.
Reliability, being a trusted and long-term collaborator building a strong and sustainable relationship.

Building a world that works.

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The statements by GE's customers reported here are based 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. JB05859XE