



ASSIST

MAGAZINE

Innovative Interventional Treatments



The power of CBCT in treating HCC and metastatic colorectal cancer

Driving growth of thrombectomy service delivery: The experience of St George's Hospital in London

Innovative tools to fight against pancreatic cancer

NOVEMBER 2017

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Chantal Le Chat
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Dear reader,

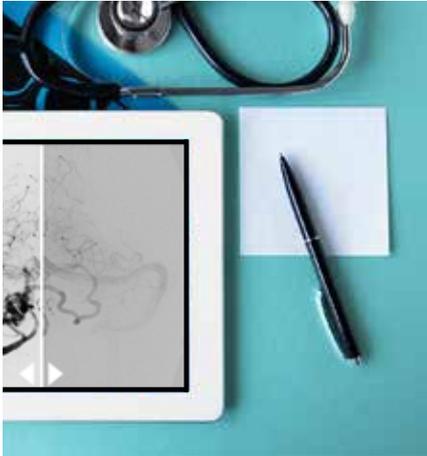
You have someone's life in your hands. It is our mission to give you the instruments that let your work shine and help you perform at your best in every procedure. Today, we are rethinking the era of interventional therapies to help you improve outcomes. In this new edition of the ASSIST Magazine, discover GE Healthcare's latest innovations in image quality, image-guided systems and advanced applications, and the impact they can have on customers and their procedures. These solutions are designed to provide the flexibility you need when facing challenging clinical situations everyday. We give you the tools ... you are in control!

In the second part of the magazine, leading clinicians in interventional oncology, neuroradiology, cardiology, and vascular minimally invasive procedures expand on clinical versatility, accuracy and improved outcomes by leveraging image-guided technologies and applications such as ASSIST.

We would like to thank our clinical partners for challenging us to always develop better solutions for them and ultimately for patients, and wish you a good reading!

Chantal Le Chat & Emmanuel Abate

ASSIST MAGAZINE



06_ Innovations

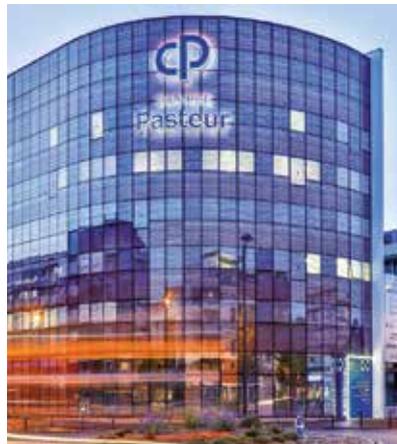
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Motion
Freeze

Clear it up ! With Motion Freeze

Meet the experts

More and more physicians are relying on Cone Beam CT (CBCT) images to conduct interventional liver procedures¹.

Today, we ask experts to share their point of view regarding Motion Freeze*, a pioneering solution commercialized by GE Healthcare to compensate for involuntary respiratory motion that degrades CBCT images.

¹ Tacher, V., Radaelli, A., Lin, M., and Geschwind, J.-F. (2015). How I Do It: Cone-Beam CT during Transarterial Chemoembolization for Liver Cancer. *Radiology* 274, 320–334.



Pr. Thierry De Baere

*Interventional Radiologist and Head of
Interventional Imaging Department,
Gustave Roussy Cancer Campus.*

The Gustave Roussy Cancer Campus (Villejuif, France), a leading European cancer center, brings together 2,500 men and women dedicated to treating patients suffering from cancer, conducting research to develop new therapies, and passing on knowledge to the medical and scientific communities in France and worldwide. The Interventional Radiology unit performs approximately 3,500 oncology procedures per year, including ablations, embolizations, biopsies, and others.



Dr. Lambros Tselikas

*Interventional Radiologist,
Gustave Roussy Cancer Campus.*

How often do you use CBCT for liver embolization?

Pr. De Baere: “For chemoembolization and radioembolization, I use it very often. CBCT is widely used for 3D anatomy and guidance, but it can also be an interesting tool for extrahepatic infusions.”

Dr. Tselikas: “We use CBCT in almost nine out of ten chemoembolization cases. At our institution, CBCT is very well adopted. The workflow has become a standard practice for doctors, interns and anesthesiologists. Everybody is familiar with the process.”

Could you quantify the occurrence of suboptimal CBCTs?

Pr. De Baere: “I would say that one-third of CBCT images are unusable. In 25% of cases, the cause is related to patients who have difficulty holding their breath, and in 5% the cause is something obstructing the field of view i.e, cables... A small percentage could be optimized further by the team at the moment of the acquisition. At our institution, most

of the vascular interventions are performed without general anesthesia, and therefore we are dependent on the goodwill or ability of the patients to hold their breath.”

Dr. Tselikas: “I would say that artifacts are present in 20% of cases. In those cases, we determine whether or not to retake the image. In one out of two cases of corrupted CBCT, a new acquisition is made.” ■

“The difference Motion Freeze provides is impressive – beautiful and clear. In the cases I examined, the Motion Freeze image has an incomparable quality and is usable, while the original acquisition was not.” Pr. De Baere

First case

Dr. Tselikas: “This case is a great example of what Motion Freeze can do. Motion Freeze was able to recover a highly degraded CBCT and turn it into an interpretable image. We were able to restore many branches. In the first image you cannot see the bifurcations, while in the second you can. On Figure 1A, we would have had to do the acquisition again.

On Figure 1B, we have the information we need in the original acquisition. Motion Freeze is also able to improve the visibility of soft tissue structures.”

Pr. De Baere: “By reducing the thickness of the cross-sections, the benefits of Motion Freeze are not as immediately apparent. However, the results are clinically very meaningful, particularly when looking for anatomical information such as the origin of arteries. In Figure 1A, for example, it’s very challenging if you’re looking at branch origins.”

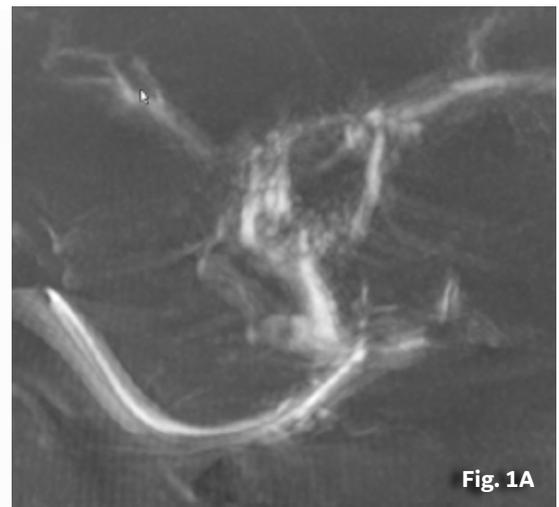


Fig. 1A



Fig. 1B

Fig.1 HCC case
A: CBCT before Motion Freeze.
B: CBCT after reconstruction with Motion Freeze.

Second case

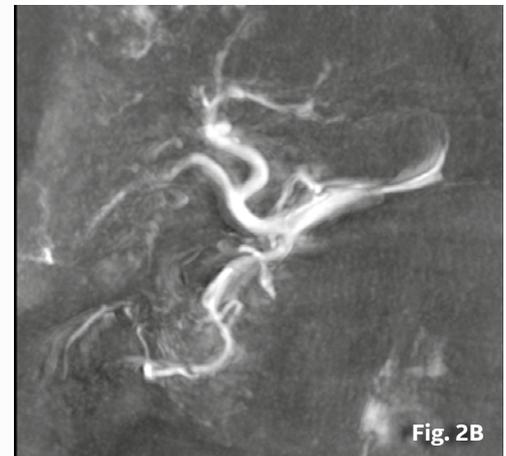
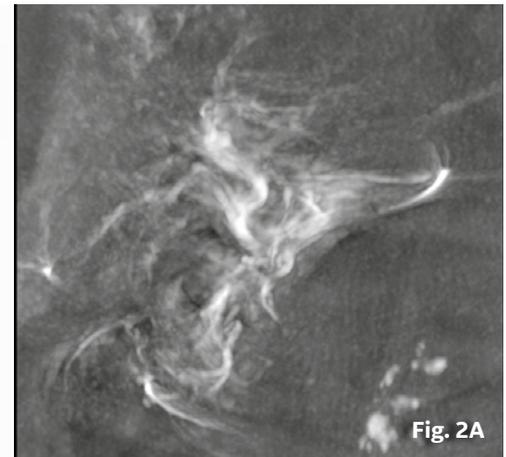
Dr. Tselikas: “The results on the vessels are undeniable. On Figure 2A, you can identify that there are plenty of arteries, but you cannot identify their starting point. However, on Figure 2B, you can determine the origin of small vessels. On Figure 2B, the image quality on distal vessels is incredible.”

Pr. De Baere: “The difference Motion Freeze provides is impressive – beautiful and clear. Figure 2B has incomparable quality and is usable, while Figure 2A is not. With Motion Freeze, we see the blush and we have the impression of seeing the feeder vessels, while in the original image we cannot.”

Fig.2 Hepatic artery case.

A: image affected by respiratory motion.

B: image with Motion Freeze.



Motion Freeze Benefits

After seeing these images, what is your general comment about Motion Freeze?

Pr. De Baere: “Based on my experience, approximately half of CBCT images are good quality, a third are unusable, and the remaining could be improved. So I would estimate that in over one third of the cases, CBCT could benefit from Motion Freeze. I think it’s an important tool as there is nothing more disappointing than making an acquisition and getting nothing out of

it. It is frustrating for the staff. In addition, when we expose a patient to radiation, we do everything in our power to ensure that the exposure and contrast media we have given leads to a usable image. Motion Freeze offers a perspective on both aspects.”

Dr. Tselikas: “Motion Freeze is essential. You have the potential to

increase the success rate of your CBCT. The first benefit is that we no longer have to wonder whether to retake the acquisition. We have an additional opportunity to get the information that allows us to move forward in the procedure. The second benefit is that it may help increase the consistency in CBCT image quality.” ■

“The first benefit of Motion Freeze is that we no longer have to wonder whether or not to retake the acquisition.” **Dr. Tselikas**

Motion Freeze is the first commercialized solution that compensates involuntary respiratory motion artifacts on interventional CBCT, based on competitive research, among major players in interventional imaging. *The improvement related to Motion Freeze depends on the acquisition conditions, table position, patient, type of motion, anatomical location and clinical practice. Motion Freeze is an optional feature of 3DXR (part of GE vascular systems IGS 5, IGS 6 and IGS 7 or IGS 7OR).

Pr. T. de Baere & Dr. Lambros Tselikas are paid consultants of GE Healthcare. During an interview, the physicians have based their opinions on de-identified images on which Motion Freeze has been applied. The Statements by GE’s customers described here are the opinions of these healthcare professionals.

Motion
Freeze

When breathing gets in your way...



Pr. Valérie Vilgrain

Radiologist and head of the Radiology and Imaging Department at Beaujon Hospital, Greater Paris University Hospitals - AP-HP.

Located at the gates of Paris, Beaujon Hospital, Greater Paris University Hospitals - AP-HP, combines excellence and community care. Its highly specialized activities make it in demand for patients nationwide. The hospital is a reference center for diseases of the digestive system and ranks first in France for treatment of cancers in the liver, colon, bowel and pancreas. Its Interventional Radiology Imagery Unit performs up to 1,600 interventional procedures per year with at least half of them in interventional oncology.



Dr. Maxime Ronot

Diagnostic and interventional radiologist at Beaujon Hospital, Greater Paris University Hospitals - AP-HP.



Dr. Carmen García Alba

Interventional radiologist at Beaujon Hospital, Greater Paris University Hospitals - AP-HP.



What problems do clinicians face when they use CBCT for chemoembolization?

Dr. Garcia Alba: “There’s the ergonomics of the room, the habits of the nursing staff, the technicians, and the position of the patient. Before, we used to position patients with arms up, but that was a bit of a strain because it lasted a little long. Now we place the arms down, and this slightly shortens the time for positioning of the patient who feels more comfort and therefore helps to decrease the occurrence of unexpected respiration. Then there are patients who sometimes can’t hold their breath,, so there is the risk of respiratory motion. These patients don’t understand how to do apnea. They are tired and anxious, and they breath unexpectedly, and as a result the CBCTs will not be usable. So, there are many reasons why respiratory motions occur, such as patient comfort, anxiety, impaired cognitive functions, obesity and elder patients...”

“Having a Motion Freeze solution that would reduce the number of involuntary respiratory artifacts would allow us to gain in performance and confidence and to have a higher success rate with CBCT.”

Pr. Valérie Vilgrain

Why do you perform CBCT for hypervascularized hepatic lesions treatments such as TACE or SIRT?

Pr. Vilgrain: “We do CBCT to obtain a certain amount of information that will allow us to be more efficient in our analysis and to better understand the problem and the disease. However, several obstacles can impact CBCTs. Motion artifacts, and specifically respiratory motion, are among the top reasons why a CBCT cannot be used.”

Dr. Ronot: “In my opinion, CBCT is useful throughout the procedure, in upstream planning, guidance and for the assessment of the treatment effectiveness. A number of studies show that using CBCT in treatment planning will significantly increase the number of lesions you find and the number of arteries you detect, spontaneously or with the help of dedicated software such as FlightPlan For Liver.

Guidance is fundamental, especially because we have to be increasingly selective in the way we approach treatment, either in chemoembolization or radioembolization.

When we can go as far as possible towards selectivity, we do it.”

So, CBCT helps you to make a more precise selection or at least a refinement to limit embolizations to the strictly needed ones?

Dr. Ronot: “Exactly! And, therefore, we use CBCT in almost 100% of intra-arterial treatments. In most cases, we won’t be satisfied with just one CBCT, but rather do two or more: At least one at the beginning of planning and one at the final evaluation for chemoembolization. For radioembolizations, we can perform several of them during a session but we will do it selectively, in different branches.”

So, respiratory motion is a main reason why a CBCT will not be usable?

Dr. Ronot: “Yes. Respiratory motion is a problem that all those who do CBCT have to face. As mentioned by Dr. Garcia Alba, patient positioning is important, but beyond this aspect, we need patients to cooperate in order to avoid respiratory motion. In some centers, chemoembolization is performed systematically under general anesthesia, and in that case, it’s simple – just turn off the ventilator for complete control of the apnea. In centers such as ours, where local anesthesia is given with premedication, we are totally dependent on the goodwill and cooperation of the patient. In this case a learning and repetition phase with the patient is necessary. This can be done while the nurses are installing the

patient on the table. Once the patient has tested and practiced apnea, our chances of success with CBCT are increased. Nevertheless, a significant percentage of refractory patients will breathe anyway. In our center, we estimate that about one in five patients will breathe, from a little bit to a lot.”

Is there a typical profile of patients who are unable to maintain apnea?

Dr. Ronot: “As Dr. Garcia Alba explained it, there are patients who simply do not understand how to do apnea, because they are tired and anxious. They are often elderly patients who do not clearly understand instructions because they have impaired cognitive functions. They may also find it physically difficult to do a sufficient apnea, especially since they are in a rather anxious situation. They can also be in a position that is uncomfortable for them. They may have back pain or osteoarthritis and will move a little bit because it relieves them.”

What about overweight or obese patients?

Dr. Ronot: “Overweight patients, and in particular those extremely obese, may cause problems during the set up as well as for apnea because they already have difficulty to breath. With obese patients, the contrast-to-noise ratio is not good, and we will be less tolerant to respiratory motion, because the image quality could be affected by the body mass.”

What do you do for patients who have had respiratory motion during CBCT today?

Dr. Garcia Alba: “In half of the cases, we make a new acquisition because we think the patient can do the apnea. In the other half, the CBCT is irreparable and we use only DSA images to perform the procedure. We understand that the patient cannot do the apnea, and we will work with obliques.”

Dr. Ronot: “It also depends on the level of CBCT degradation. Some CBCTs suffer from respiratory motion but remain sufficiently informative to extract the clinical data we need to perform the treatment. It also depends on the disease we are treating. There are patients with distributions and sizes of lesions for which even a tiny motion is problematic. There are others where the lesions are located in specific areas, or are larger, and we can see where we want to go, even if the image is less than ideal.”

In chemoembolization, what are the consequences of retaking an acquisition?

Dr. Ronot: “It’s a bit painful because we’re wasting time. The CBCT needs to be evaluated and a decision made whether to start again. If so, the patient needs to be prepared again and the acquisition re-launched, which can take 10 to 15 minutes. Added to this is the risk that the second CBCT will not be better than the first. And obviously, it’s never a good thing having to reinject a patient with contrast.”

“The results with Motion Freeze are quite impressive in terms of image quality improvement, making CBCTs with little motion almost perfect, and improving CBCTs with a lot of motion so that they became clinically usable in many situations.”

Dr. Maxime Ronot

What are your impressions of the Motion Freeze solution?* To what extent will it change your approach to CBCT?

Dr. Ronot: “The results are quite impressive in terms of image quality improvement, making CBCTs with little motion almost perfect, and improving CBCTs with a lot of motion so that they became clinically usable in many situations. If I extrapolate, I expect a very significant decrease in the number of CBCTs that can’t be used for reasons of movement.”

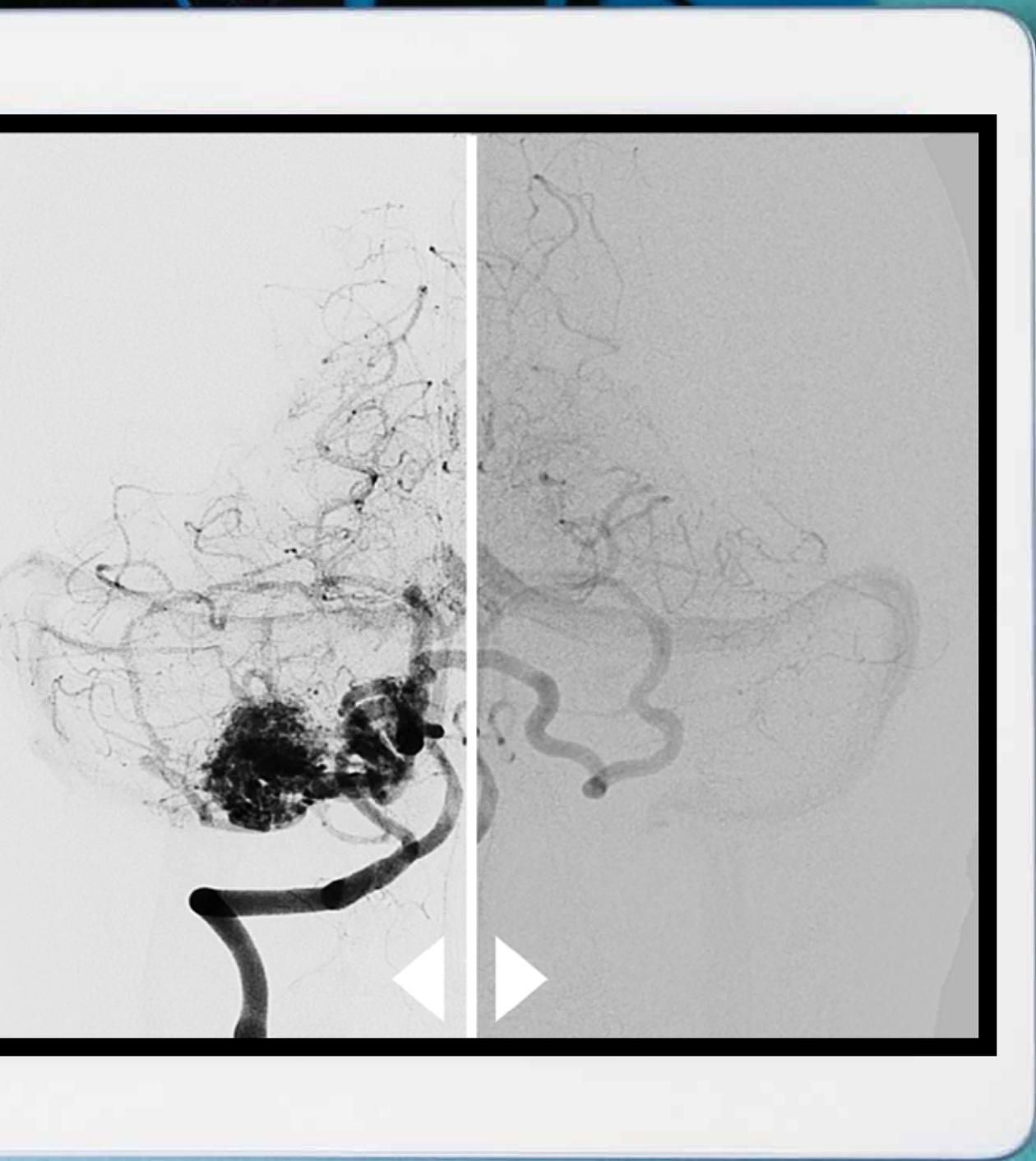
To conclude, what is your perspective with regards to Motion Freeze?

Pr. Vilgrain: “We do a CBCT because today it’s important and it enables us to treat patients more effectively. During this CBCT, we encounter difficulties such as respiratory artifacts. Having a Motion Freeze solution that potentially reduces the number of respiratory artifacts will allow us to gain in performance and confidence and to have a higher success rate on the CBCT. In our institution, respiratory motion affects about 20% of the exams. A solution that solves the problem in those cases, so that we can avoid reacquisition, is a very good solution.” ■

Motion Freeze is the first commercialized solution that compensates involuntary respiratory motion artifacts on interventional CBCT, based on competitive research, among major players in interventional imaging.

*The improvement related to Motion Freeze depends on the acquisition conditions, table position, patient, type of motion, anatomical location and clinical practice. Motion Freeze is an optional feature of 3DXR (part of GE vascular systems IGS 5, IGS 6 and IGS 7 or IGS 70R).

Pr. V. Vilgrain & Dr. Maxime Ronot are paid consultants of GE healthcare. During an interview, the physicians have based their opinions based on deidentified images on which Motion Freeze has been applied. The Statements by GE’s customers described here are the opinions of these healthcare professionals.



myIQ

You decide what's best for you!*

What is a good image? Over the past decades, each new generation of interventional systems claimed to bring “the best image quality”, and typically at lower dose levels. When tasked with the design of the next generation of Image Guided Systems (IGS), engineers at GE worked closely and iteratively with clinical teams to determine the qualitative and quantitative parameters that would lead to the best Image Quality (IQ) across multiple specialties: neuro, interventional radiology & oncology, as well as cardiovascular. The goal was initially to use the results of this exercise as input specifications for the development of a new image chain that could produce this best IQ.

Clinicians from all continents and specialties were involved and participated in the technical study. After some time, it became clear from these interviews that all physicians did not share the same definition of a good image in specific clinical contexts. This variability of feedback highlighted the subjective aspect of image quality assessment. Clinicians with different backgrounds can have very different preferences, as well as different needs based on the pathologies they treat and the techniques they use.

Therefore, the initially assigned goal had to be reviewed, acknowledging that IQ customization was a need, instead of converging towards a unique set of IQ settings to define one “GE look”. We chose to opt for flexibility as part of our system capabilities and offerings. This philosophy of image customization is myIQ!

You decide what's best for you!*

* System is delivered with default settings. Customization requires a GE representative.

* These image settings are only available on the GE vascular systems IGS 5, IGS 6, IGS 7 and IGS 7OR, and cannot be placed on the market or put into service until they have been made to comply with all required regulatory authorizations including the Medical Device Directive requirements for CE marking. myIQ cannot be marketed in countries where market authorization is required and not yet obtained. Refer to your sales representative.

Image Quality

Image chain hardware

Improving IQ and dose performance starts with high quality hardware components and their integration in a chain. The chain is only as good as its weakest link. This is why GE Healthcare designs and manufactures all components of the image chain, from the tube and generator, to the detectors and the image processing chain.

The GE square detectors provide a Detective Quantum Efficiency (DQE), the standard measure of detector imaging performance, that consistently ranks among the highest available, with the newest generation detector offering a DQE up to 84%¹.

Image parameters need to be balanced and adapted to different patient characteristics and clinical anatomy, ranging from patient size to visibility of fine anatomical and device details. For instance, for cerebral angiography where high spatial resolution is important to see fine anatomical and device details, the size of the focal spot goes down to 0.3mm.

Exposure parameters

The harmony of an imaging system is achieved when operator and machine work together. Operators choose the dose level they want, the machine optimizes the parameters for them. The IGS achieve this with a specific feature called “Dose Personalization”. Users can choose the IQ/dose level they want and need from preset and customized protocols and let the system automatically optimize the dose to achieve it. All of this can be done directly from table side, at any time during the procedure. This Dose Personalization feature is enabled by

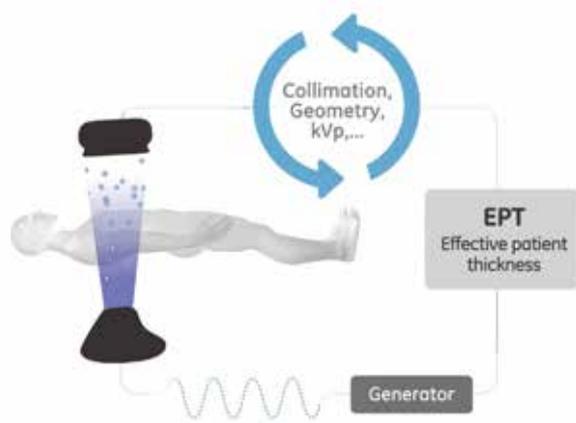
the AutoEx function of IGS systems. Every single image frame is automatically analyzed by AutoEx to select the best exposure parameters, including copper filtration, optimizing radiation, based on the estimated patient thickness at any time to deliver the IQ level requested by each user. AutoEx is able to continuously adapt exposure parameters based on gantry angulations, patient motion or panning.

Image chain processing

For interventional imaging, a good part of the IQ is directly linked to the technical specifications of the Xray system used to acquire the image (the “hardware”), as well as the radiation exposure parameters chosen. Still, with a given Xray system and a set dose level, images displayed can vary significantly depending on choices of image processing.

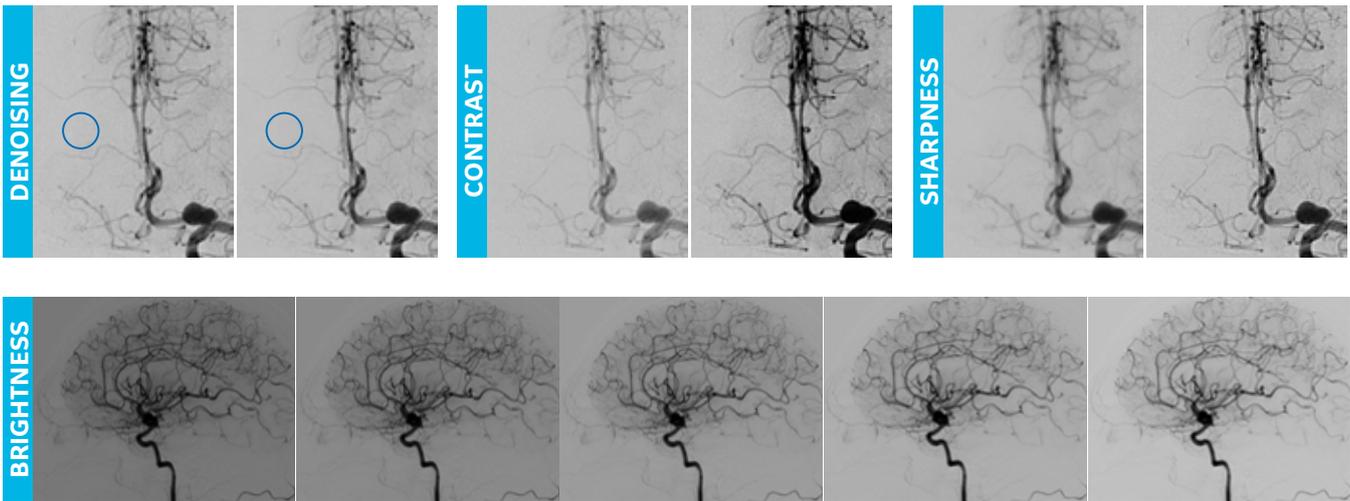
The GE Image Chain leverages advanced real-time processing including, but not limited to, the Dynamic Range Management (DRM), Denoising, Sharpness, Brightness, Contrast & Mask Pixel Shifting, all of which are adjustable to offer image presentation settings customizable to the needs and preferences of individual clinicians. With this approach, for each physician in his/her clinical practice, myIQ can help improve IQ at the same dose.

Image reviews with clinicians during the development stages allowed GE engineers to validate that up to 75% noise reduction is achieved, while



AutoEx for automatic exposure management and Dose Personalization

¹ For GE vascular system IGS 3, IGS 5, IGS 6, IGS 7 and IGS 7OR with 31x31cm or 41x41cm detector, DQE value at average record dose operating point, for DSA 175 nGy (20 uR).



Angiograms with different levels of processing showing the individual impacts of denoising, brightness, contrast and sharpness levels.

preserving the visibility of distal vessels and other small details on the image².

As there are numerous parameters to set, and as they all influence each other dynamically, it was key to develop and validate groups of optimal parameters that fit the needs and preferences of typical groups of users. Validation by clinicians has revealed

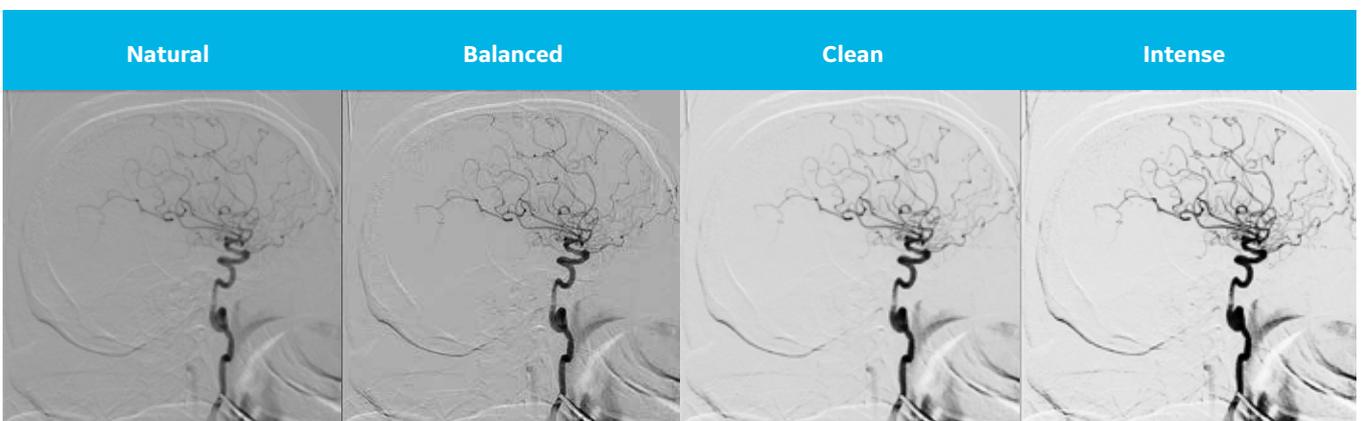
four preferred looks highlighted in the image below.

Clinical application support

Upon installation of the IGS and initial training, physicians view images at the preset dose levels in the proposed default look (balanced) and decide whether it fulfills their needs or

if a different look, with other background noise and brightness, vessel contrast and sharpness etc. parameters should be evaluated and implemented.

² Up to 75% DSA IQ improvements at the same dose compared to GE previous generations, based on noise variability on flat field measurements.



The 4 angiogram looks illustrating the customization capability introduced by myIQ.

Which image would you choose?

The example of AZ Groeninge illustrates the process of image customization through myIQ. The AZ Groeninge hospital in Kortrijk, Belgium, was part of the clinical team sharing real cases with the GE engineering team and giving feedback on the suggested improvements.

Two experienced neuroradiologists, Dr. Olivier François and Pr. Tommy Andersson, were asked to blindly review sets of images displayed in four standard “image looks” and rate their preferences. The physicians reviewed the images and commented on the looks to find the one that fits the most their clinical needs case by case.

The four image looks represented the different clinical preferences of the physicians involved and polled during the development phase of the new image chain: Natural, Balanced, Clean and Intense. These looks are the results of tradeoffs in terms of image processing parameters, such as noise to signal ratio, contrast, sharpness or brightness.

Image reviews were done on several cases covering various anatomies and multiple procedures:



Dr. Olivier François is an interventional radiologist who specialized in interventional neuroradiology in 2002 and worked in Antwerp and Aalst, before being hired to create the interventional radiology & neuroradiology department at AZG.



Pr. Tommy Andersson is an interventional neuroradiologist from Karolinska institute and he spends one week out of three at AZG to reinforce the team and work with Dr. François on neuro cases exclusively.

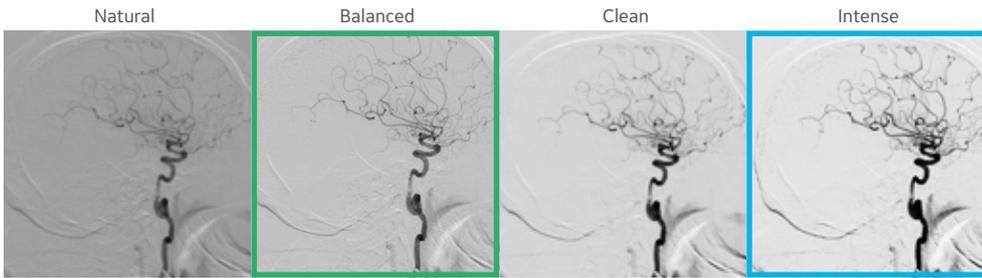
- Cerebral angiography for stroke patients
- Liver arteriography for transarterial chemoembolization
- Uterine artery embolization for primary post-partum hemorrhage
- Bladder arterio-venous malformation.

Results of the cases review

Dr. Olivier François chose the look “Balanced” in 81% of images, because according to him, it represented a good compromise between no loss of

information & the right amount of brightness and contrast.

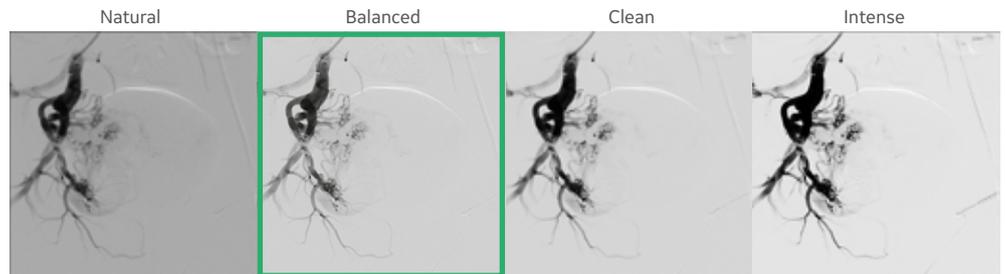
On the other hand, Pr. Tommy Andersson chose the look “Intense” in 78% of images, because he judged them to be sharper, less grainy and more contrasted.



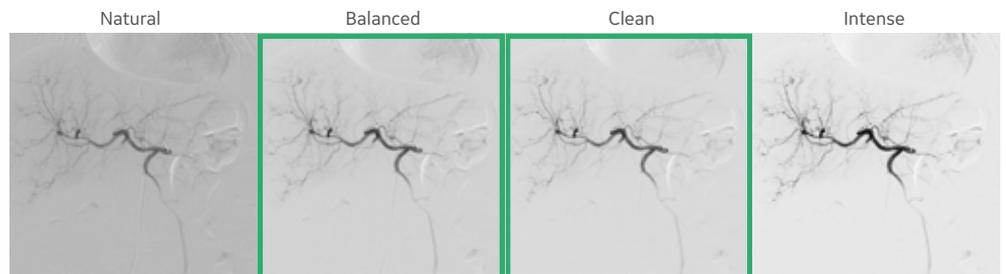
“I need to see the small collaterals in the arterial phase and distal emboli after thrombectomy. This image has the right level of detail and brightness to me, without too much contrast.”
Dr. Olivier François

“The natural look is too noisy for me. Intense seems best because it’s clear on small details and sharper. I’m used to working with a look like intense.” **Pr. Tommy Andersson**

“I would eliminate looks Natural & Intense right away. I think the large arteries are better seen on the Balanced look and the contrast is better between the background and small vessels.”
Dr. Olivier François



“Both Balanced and Clean looks are satisfactory to me, with the right amount of details, brightness and contrast.”
Dr. Olivier François



In conclusion, this example shows how GE engineers iterated on the development and clinical validation of myIQ, namely :

- Image quality is not one-size-fits all for physicians. On the contrary, preferred « looks » vary greatly from one clinician to another
- Preferences seem to be physician-dependent, rather than case-dependent, as a given physician chooses the same type of look in about four cases out of five when given the choice
- The reason for choosing one look over another seems to be linked to personal habit and visual comfort

The IGS don’t ask clinicians to choose. Where no two people are the same, why would your image system need to be?

Can we improve cerebral angiographies for controls of brain aneurysm treatment?

Background

Following up patients after cerebral aneurysm embolizations is part of the routine of neuroradiology and neurosurgery practices, from the immediate post-treatment control to the regular monitoring -monthly, yearly or longer. In all cases, from an imaging point of view, the challenges are first linked to image quality but also to the invasiveness of techniques. To assess the successful positioning of coils, stents or clips and their evolution in time, it's important to visualize the devices themselves in great detail, their interactions when several are jointly used and their relationship with the vascular structures (aneurysm, parent artery, branches). It's equally important to achieve these visualization goals while optimizing

the care pathway and reducing potential side effects.

CT scanners are commonly used for brain aneurysm controls. Great progress continues to improve the efficacy of this modality with better image quality, at reduced radiation levels and facilitated workflows. However, C-arm based interventional systems allowing rotational acquisition or Cone Beam Computed Tomography (CBCT) still offer meaningful advantages for technological intrinsic reasons. For instance, CBCT allows smaller details to be visualized thanks to the higher spatial resolution of their flat panel detectors.

Our solution: 3DCT HD with Metal Artifact Reduction (MAR)¹

To benefit from the advantages of interventional systems with flat panels for the post-treatment control of aneurysm cases, the focus was put on overcoming two specific challenges:

- Image Quality: spatial resolution being already high, efforts were made to reduce artifacts caused by the device themselves, as these “endogenous” artifacts can sometimes make the images unusable.
- Technique Invasiveness: traditionally CBCT acquisitions are performed with an intra-arterial (IA) injection of contrast media for optimal contrast

¹ MAR is an optional feature of 3DXR, which is included in 3DCT HD, a 3D application of the GE vascular system IGS 5, IGS 6, IGS 7 and IGS 70R, and removes metal artifacts generated by coils in the CBCT field of view.

of vessels. However, such access, compared to intra-venous (IV), is considered more invasive. Efforts were thus made to optimize IV-CBCT acquisitions and their image quality.

Based on the capabilities of the GE Image Guided Systems (IGS), more specifically the image chain, 3DCT HD, the latest generation of CBCT, brings a higher resolution needed to image both the small vascular structures and the small device details. To address the metal artifacts, MAR automatically detects coils and clips in the field of view of the CBCT and reduces the metal artifacts they generate in 3D reconstructed images. Lastly, to offer a less invasive solution suitable for routine follow ups, image setting parameters have been customized to optimize visualization of treated brain aneurysms following IV injections.

Evaluation of 3DCT HD with MAR and IV injection

A clinical collaboration with Dr. Jeremy Madigan and the interventional neuroradiology team at St George's Hospital in London, UK allowed the engineers to mature, test and fine tune these CBCT technologies as well as their clinical value for the follow up of patients with brain aneurysms. Reviewing sets of clinical images processed with and without MAR at various stages of the development process was key to validating the method and improving confidence. Doing so, it was possible to check that indeed MAR allowed improved clinical confidence when stents next to coil

masses, or surgical clips are imaged. Today 3DCT HD with MAR makes it possible to envision innovating from the standard Cerebral Angiography thanks to the use of IV CBCT to control treated brain aneurysms². ■

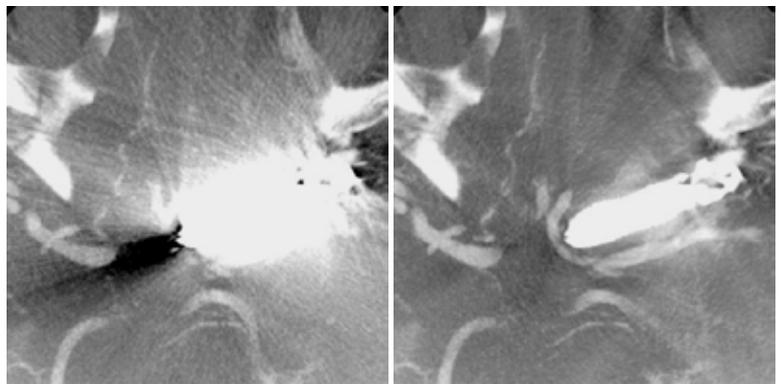


Fig.1 3DCT HD showing a cerebral angiogram for a follow up of an aneurysm surgical clipping case. Left without MAR; Right after applying MAR.

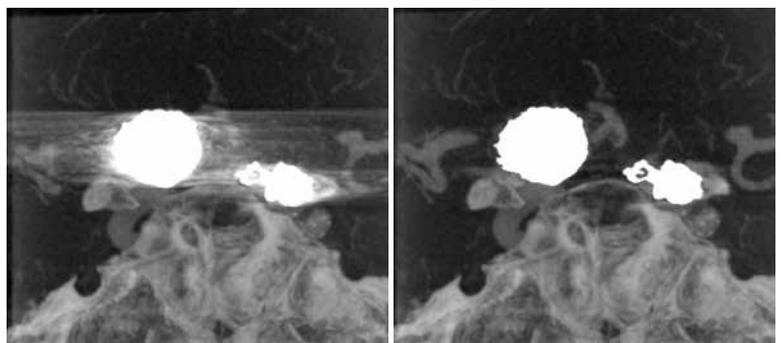


Fig.2 3DCT HD showing a cerebral angiogram for a follow up of an aneurysm endovascular coiling case. Left without MAR; Right after applying MAR

² Results may vary from one site to another. The statements by GE customers described here are based on results that were obtained in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g. hospital size, case med), there can be no guarantee that other customers will achieve the same results.



A journey on the Edge of Tomorrow: Behind the scenes of innovation

In the small town of Buc, some 20 km southeast of Paris, GE Healthcare hosts its European headquarters as well as the global Center of Excellence (CoE) for Interventional Imaging. Near the famous Château de Versailles, more than 1,500 employees dedicate their time to design, develop and manufacture image-guided solutions (IGS) for export around the world. Each year, hundreds of customers visit the Buc CoE to nurture thoughts on the future of equipment, exchange ideas with the Research and Development (R&D) team, receive training on their new interventional systems or attend user education clubs.



The visitor's journey

On the vast campus, visitors first discover the impressive Edison gallery, which bridges departments from Manufacturing to Marketing and Finance. One notable feature of the site is that the guest center is not isolated, but at the heart of the main building, stimulating interactions and fruitful meetings. It also includes a showroom with some of GE's best-selling equipment, surrounded by meeting rooms for more confidential discussions or product presentations.

"Our duty is to set up the best conditions to facilitate exchanges and enable our visitors to enjoy their experience, while catching up with the latest GE Healthcare innovations and enjoying French cuisine on site",





declares Solange Soullisse, Guest Visit Center Specialist.

The CoE is also the customer multimodality training center for advanced applications, where two classrooms, fully equipped with Advanced Workstations, host weekly sessions.

On the opposite corner of the campus, the Marie Curie building has an interesting history: designed by Gustave Eiffel, it was originally Louis Bleriot's aviation factory and is now home to the GE Global Design center which creates the look and feel of the medical equipment.

The building also houses several engineering cells where the newest and upcoming technologies are developed, tested and validated.

Image-guided systems such as the Discovery IGS 7 hybrid OR and the Innova IGS 630 biplane system are installed there in configurations similar to those found in the hospital, allowing easy hands-on sessions and procedure simulations using the most advanced features. This arrangement helps visitors understand how teams will interact with the equipment and its impacts and adaptability to their own clinical facilities.

The final highlight of the visit is in the Coolidge building, where the highest technology meets with the finest craftsmanship to produce the key components in all GE X-ray imaging modalities, such as X-ray tubes. Watching highly skilled technicians blow glass with fire to the tubes is always an exciting moment for visiting

customers. Finally, all imaging systems manufactured in Buc, including the Discovery IGS and the Pristina mammography system, are assembled in this factory before being tested and shipped to hospitals around the world.

If time allows, visitors can make a last stop at the GE service center for demonstrations of remote diagnostic capability of the IGS systems and the human and IT infrastructure that is in place to minimize unplanned downtime – a crucial attribute in the field of interventional imaging.

Live the present and shape the future

The GE campus has a long tradition of innovations. In the 1980s, for example, its R&D teams developed and



introduced the first 3D imaging on an angiography system. Initially developed for neuroradiology applications, this technology, called cone-beam CT, is now a standard of care for all interventional specialties. More recent technological breakthroughs that have changed patient care delivery include augmented fluoroscopy with image fusion, and the robotized and laser-guided Discovery IGS 7 hybrid OR. The purpose of GE engineering teams is to reshape the boundaries of clinical care through innovative and ergonomic platforms, intuitive image guidance, and effective advanced applications.

These innovations did not come from nowhere. They are linked to a deep culture of research and external

collaboration and, more important, they are constantly enriched with the inputs of users and customers. The voice of the customer is included in each and every step of the development process, from concept to final product, from installation to serviceability.

“Basically, those exchanges with clinicians are part of our DNA,” says Michel Grimaud, General Manager, Interventional Engineering. “They allow our teams to improve their clinical knowledge and to get a direct feedback loop from users. The spirit is to work in a startup mode to co-design applications or components with the end users. These exchanges are key to addressing clients’ needs as well as possible. For example, FlightPlan for

Liver was co-designed with the Gustave Roussy Cancer Campus team, and EVAR ASSIST with Professor Stéphane Haulon who is practicing now at Hopital Marie Lannelongue (le Plessis Robinson, France).

Validation of the clinical need is also at the heart of product development. Therefore, dedicated research teams work with senior scientists to actively generate pre-market and clinical studies with the most prestigious partners across the globe. The results are published in renowned peer-reviewed journals and contribute to product development and improvement.

A notable example of that culture is the Discovery IGS 7, designed to enable complex minimally invasive



endovascular and percutaneous procedures in an OR environment with advanced imaging capabilities. The system was developed in France as part of an industrial and academic partnership led by GE Healthcare and involving two subject matter experts (BA Systems and C&K) and several research laboratories (CEA - French Agency for Nuclear Energy, CNRS - French Scientific Research Agency, INRA- French National Institute for Agricultural Research, and AP-HP - Paris Area Public Hospital Group). The project, involving the collaboration of 150 researchers, was partially funded by the French government and led to 12 patents.

Feedback gathered throughout the development process guides the Interventional engineering team to focus on customers' most important challenges and concerns. In a very demanding environment, where minimally invasive surgery is growing and costs are being squeezed down, the simplification of routine and complex procedures is the ultimate goal. That is the philosophy of ASSIST, the GE portfolio of advanced interventional applications, all of which involve an integrated approach of pre-operative planning, peri-operative guidance and immediate post-operative assessment of the

procedure.

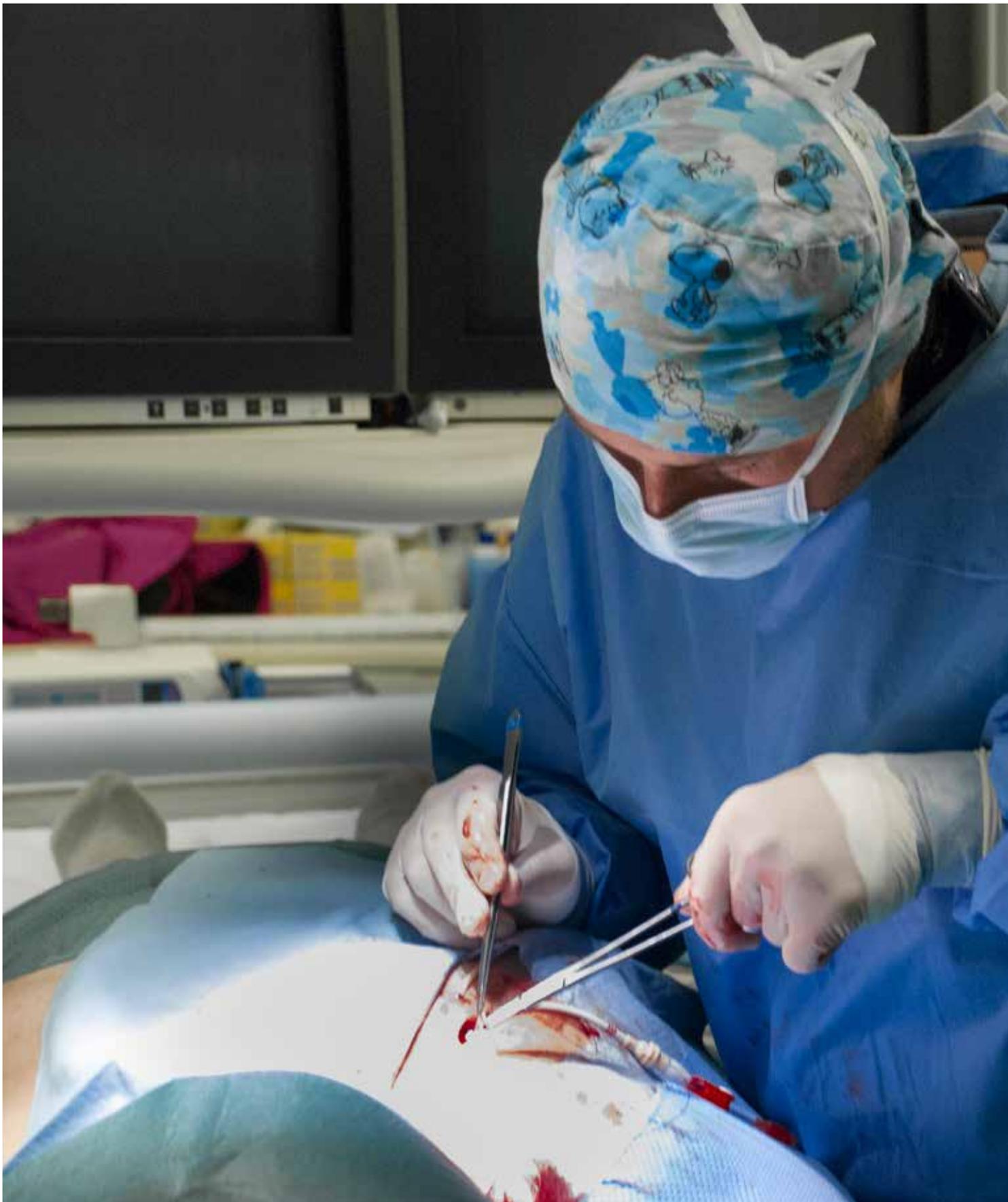
Above all, development initiatives strive to benefit patient care and operator safety. A core aspect of that is radioprotection, which has been a major area of investment since GE decided to design and manufacture the entire image chain, from X-ray tubes to detectors. This total control of the image chain means GE systems are designed from the ground up and

optimized to provide the highest image quality needed at the lowest possible dose.

In all these and other ways, the GE teams at Buc are working to shape the future of interventional care. To observe the state of the art and explore future directions, consider arranging a visit. ■

Global Design: Mission possible!

The design team that imagines the 'skin' and shape of GE devices is always involved at earliest stage in the product development process. *"We want to improve people's experience of the technology, both from the medical staff and the patients' perspective,"* says François Lenfant, Director of Global Design with GE Healthcare. His team also relies on market intelligence to identify both new technologies and emerging medical practices. *"It takes about three years to develop a new product,"* Lenfant adds. *"Our role is to anticipate what healthcare and clinical practices will be like in five to ten years so that we can stay one step ahead and innovate more effectively."*





The power of CBCT in treating HCC and metastatic colorectal cancer

Dr. Pierleone Lucatelli is an interventional radiologist in the IR unit of Siena University hospital directed by Carmelo Ricci. He is specializing in the endovascular treatment of liver cancer. Cone-beam CT (CBCT) plays a major role in his treatments for hepatocellular carcinoma (HCC). Thanks to CBCT, he developed a new way of assessing tumor response for starch microsphere treatments during the treatment phase. This early tumor response assessment helps avoid waiting for one month CT follow-up and enables him to redirect patients sooner to a more efficient therapy. He shared his experience with CBCT in an interview.



when there is indication for loco-regional treatment, like drug-eluting bead irinotecan (DEBIRI) or DSM-TACE.

In our service, we do about 30 percutaneous ablations a year for HCC and about the same amount for metastatic patients. Forty patients are undergoing TACE for HCC, and same amount for metastatic patients. Transcatheter procedures have the major drawback of requiring multiple sessions, so the number of procedures increases significantly. For instance, that is the case for our protocol for advanced Barcelona clinic liver cancer (BCLC) HCC. We perform a lobar approach, with degradable starch microsphere for each lobe. Starch microsphere is a sugar reabsorbable where liver penetration of the drug is maximized by the sugar. We really want to be sure that the lobar approach enables us to deliver the drug to the entire liver lobe.

In case of bilobar multifocal HCC, we perform the right lobe at T0, and then after 15 days, the contralateral lobe. This is followed one month after by the second treatment of the right lobe, and then again 15 days later the contralateral lobe. Each patient in that category undergoes four cycles of treatment.

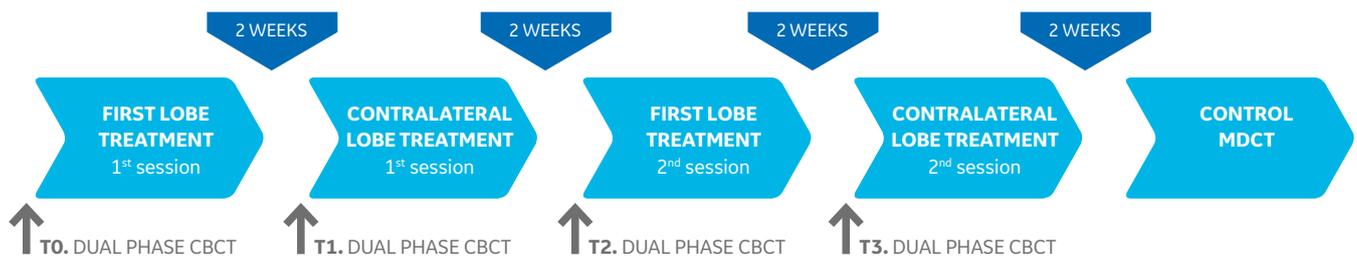
When you are doing transcatheter treatments, what are the main challenges you face with those patients?

What is the nature of your practice related to liver cancer treatment?

I am an interventional radiologist, mainly involved in the oncological field, in transcatheter liver procedures. Our main fields of application are HCC and colorectal cancer metastasis. Our unit is also involved in endovascular procedures such as EVAR. In my unit, I'm in charge of dealing with liver cancer patients for both percutaneous and endovascular procedures, and we publish many scientific papers about liver interventions.

Can you tell us about patient recruitment in Siena University Hospital? How do you deal with patients coming with liver disease?

We deal with two types of diseases: the primary liver cancer (HCC) and the metastasis of colorectal cancer (CRC met). HCC patients are screened by a multidisciplinary team, where the hepatologist plays a major role. This team refers the patient to either radiofrequency ablation (RFA) treatments, Transarterial Chemoembolization With Doxorubicin-Eluting Beads (DEB-TACE) procedures, or selective internal radiation therapy (SIRT) for patients with more advanced disease. The main clinicians involved in multidisciplinary teams for CRC met patients are oncologists; they recruit the patients for us. These patients are typically experiencing a progression of disease after first-line chemotherapy, and they are transferred to our service



There are several challenges, and it depends on which tumor we are facing. For hypervascular tumors such as HCC, especially advanced ones, we need to deploy the embolic agent in the right place to the entire lobe. Unfortunately, these patients undergo several sessions of treatment, and it makes our life more complicated. It sometimes leads to extra-hepatic recruitment of lesion feeders. Such tumors are not only fed by intra-hepatic vessels, but also by extra-hepatic ones (eg. mammary, gastric). Because of multi-session treatments, such as degradable microsphere treatments, something could change based on intraprocedural imaging.

That is why dual phase CBCT is an efficient imaging modality to help the operator perform the embolization. The arterial phase shows all the vessels

going to the tumor. Moreover, thanks to CBCT, we can adjust the dosage of drug administered during the embolization treatment, or adjust the catheter positioning if we have the feeling that there is incomplete tumor enhancement, or incomplete drug administration to the tumor.

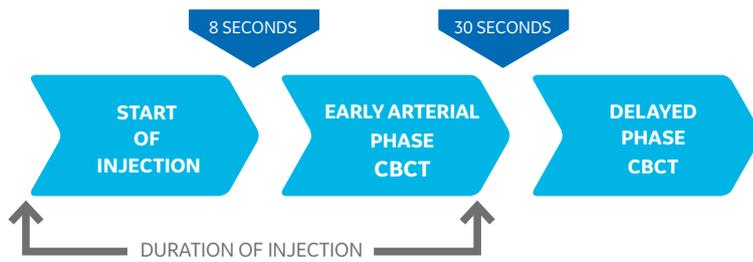
For hypovascular tumors (metastatic patients), it is much more difficult, as the enhancement pattern is not as clear as for hypervascular lesions. CBCT can allow us, even while doing super-selective catheterization, to target the treatment for a hypovascular tumor by just enhancing the segmental region where we want to deliver the drug. We never had any case where we missed a lesion that was visible on CT, but we experienced the opposite: we are seeing more lesions on CBCT than were visible

under CT. This is not only due to CBCT itself, but also to the way we administer contrast, which is more distal to the tumor. It gives us a stronger tumor enhancement compared to the healthy liver parenchyma. Thanks to the improved spatial resolution of CBCT, the tumor and feeder vessels are far more visible with this technique than with CT, where systemic administration of contrast is the conventional rule. For these metastatic patients, single-injection dual-phase CBCT is mandatory.

Please explain the technique of single-injection dual-phase CBCT.

In our practice, we perform single-injection dual-phase CBCT for all liver embolization procedures, which means that from a single injection, we are





able to get two CBCT datasets. The first one is the early arterial phase, and the second one is the delayed phase. We ask the patient to have a 6-second apnea during each acquisition. Once we have this collaboration with the patient, we set the right amount of contrast and the right delay before the acquisition. Usually, we perform the acquisition after 8 seconds of injection. After 30 seconds, we perform the second acquisition in order to have a delayed phase imaging. The acquisition should be performed as proximal as possible; the ideal point would be after the gastro-duodenal artery in order to have the complete liver enhancement.

What is the importance of having a dual-phase CBCT?

We do dual-phase, because we want not only to have the arterial bed enhancement, but also to have the parenchyma enhancement. Then we have both the route to the tumor and the enhancement. The early phase provides us with a roadmap that allows us to reduce the amount of DSA acquisitions we perform throughout the procedure. It is a benefit not only for the patient, but also for the operator, because we use less radiation and less contrast.

For hypervascular HCC, the delayed phase allows us to characterize the tumor; it gives us the washout information. It has already been

proven by our team that this allows us to depict an occult tumor¹ especially a hypervascular tumor that might not be visible on a pre-operative MDCT. This is particularly crucial when dealing with patients on an active waiting list for transplantation. This subset of patients should be prioritized for transplantation, as they have an aggressive pathology. For hypovascular lesions, both HCC and metastatic CRC, the delayed phase is the one that best depicts the tumor and is the one that should be used to perform treatment.

What about the ability of CBCT to predict the outcome of the embolization?

With advanced cancer patients, we could demonstrate a relationship

between the tumor answer seen on the CBCT done during the second lobar treatment and the one-month control MDCT. Indeed, we had an abstract accepted at CIRSE where we demonstrated that there is a correlation between the tumor density modification between the first and second session of STARCH treatment and the treatment outcome measured on the one-month MDCT for both HCC and bilobar metastatic cancer patients. This means that we would be able to predict the response to treatment for the second session, thus avoiding having patients go for the one-month follow-up for those whose results are positive, or performing a third-line treatment for the others.

In conclusion, we are seeing better results in terms of mRECIST criteria at one-month when we perform the procedure under CBCT dual-phase guidance. So, treatments are more effective and are easier for both patients and operators, with less contrast administrated and less radiation exposure for both operators and patients. ■

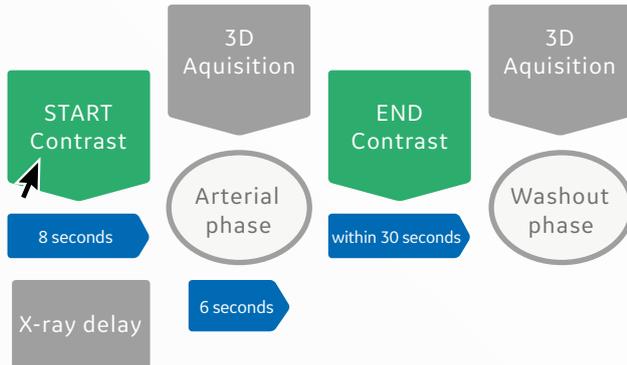


¹ Comparison of Image Quality and Diagnostic Performance of Cone Beam CT during DEB TACE and MDCT in the detection of HCC, Lucatelli et Al, JVIR, 2017.

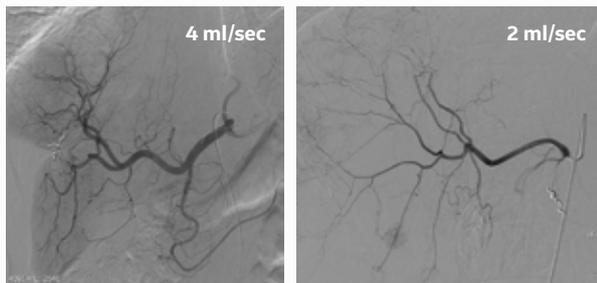
Purpose

To evaluate the role of dual-phase cone-beam-computed-tomography (DP-CBCT) in predicting 1-month mRECIST follow-up results of degradable starch microsphere TACE (DSM TACE) for both hypervascular HCC and hypovascular metastatic colorectal cancer (mCRC).

Material and Methods



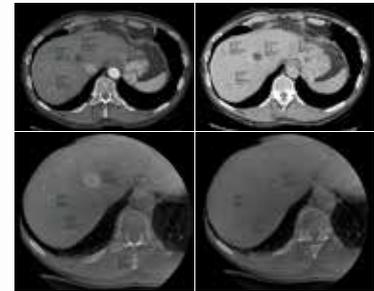
Optimal Power injector parameters were obtained on the basis of standard DSA adjusted according to different liver vasculature dimension



$$\text{LLCNR} = \frac{\text{ROI (tumor)} - \text{ROI (parenchyma)}}{\text{ROI (muscle) [image noise]}}$$

$$\text{LLSNR} = \frac{\text{ROI (tumor)}}{\text{ROI (muscle) [image noise]}}$$

Embolization protocol foresee a two step (1 month) lobar approach for each involved lobe. In case of bilobar pathology treatment sessions were interlaced within 14 days.



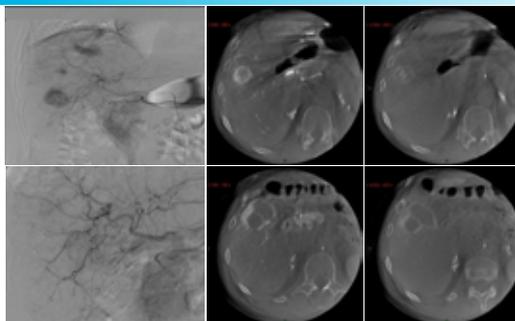
CT PRE ▷ 1°DP-CBCT ▷ 2°DP-CBCT ▷ CT POST

Results

Of the 33 patients, the 24 that experienced a significant reduction ($P < 0.05$) in the mean LLCNR and LLSNR values between the two sessions of DSM-TACE (measured at DP-CBCT) experienced an objective response (complete + partial response) to DSM-TACE treatment at the 1-month follow-up.

Clinical case

68 -year-old cirrhotic patient. Previous session of DEB-TACE, with segmental thrombosis and multifocal monolobar HCC

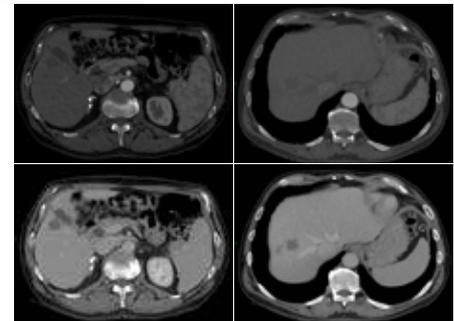


First and second right lobe DSM-TACE session

ROI 438 HU
LLCNR 1,8
LLSNR 2,9

$P < 0,005$

ROI 114 HU
LLCNR 0,4
LLSNR 1,4



mRECIST 1-month CT: Complete Response

Results

The remaining 9 patients, who demonstrated no significant reduction ($P > 0.05$) in the mean LLCNR and LLSNR values between the two sessions of DSM-TACE, experienced stable or progressive disease at the 1-month follow-up imaging.

Conclusion

Intraprocedural dual-phase cone-beam-computed-tomography (DP-CBCT) can predict the response of degradable starch microsphere TACE (DSM TACE) for both hypervascular HCC and hypovascular metastatic colorectal cancer (mCRC).

Driving growth of thrombectomy service delivery: The experience of St George's Hospital in London

Stroke is the second leading cause of death¹ and the leading cause of disability in Europe². The number of stroke cases is expected to grow by 34% by 2035³.

Thrombectomy offers up to 30% improvement in outcomes for selected patients suffering an ischemic stroke⁴. About 10% of the 90,000 UK stroke patients admitted each year to hospitals could benefit from thrombectomy.

Health services across Europe have now implemented new policies to sustain the development of

thrombectomy procedures. NHS England has made a commitment to expand availability of thrombectomy through specialised commissioning with a target of up to 8,000 procedures in the coming years.

St George's Hospital is at the helm of this expansion as the first fully staffed 24/7 thrombectomy service in the UK. It is also the site with the

largest number of thrombectomies across England with a procedure volume that has trebled within a year. The organization of regional stroke networks, patient care pathways, hospital stroke teams, as well as the use of imaging for both patient triage and endovascular guidance, were deeply transformed to enable this development.

KEY FACTS ABOUT STROKE ACTIVITY AT ST GEORGE'S HOSPITAL

- ▶ One of the 8 Hyper-Acute Stroke Units (HASU) and 22 Stroke Units (SU) of the London stroke network.
- ▶ Over 1200 stroke admissions per year
- ▶ About 180 thrombolysis and 87 thrombectomies per year
- ▶ First fully staffed 24/7 thrombectomy service since July 2016 covering a population of 3.5 million people
- ▶ About 60% of thrombectomy patients referred from local hospitals





Gillian Cluckie is Stroke Clinical Lead and Stroke Nurse Consultant at St George's Hospital. She has clinical and management responsibility for the stroke team and also drives clinical research projects. She gives us insights into the operational and financial implications of developing a 24/7 thrombectomy service.

Following the announcement of NHS England to expand thrombectomy services, what do you think are going to be the major changes in the next year?

The NHS Commissioning is currently exploring centralized solutions to make thrombectomy accessible across England and Wales. For this purpose, the NHS is likely to select several hospitals that can form a part of a robust national thrombectomy network. NHS Commissioning has requested statements of intent from suitable hospitals describing current capabilities and a trajectory of thrombectomy service development in the next 5 years. Ultimately this commitment in the NHS

will lead to significant improvement across the country in infrastructure and resources required to increase the number of patients receiving thrombectomy therapy.

What is the percentage of patients admitted directly to your hospital as opposed to those referred from a district hospital?

In July 2016, we became a 24/7 thrombectomy service and in the first few months 60-70% of patients were from South West London, the main catchment area of St George's. About 30% were from Surrey and parts of East Kent. This has transitioned over the last 6 months and we see a shift now to around 60% coming from outside of St

George's usual catchment areas. This is an expected development as our service is becoming better known, and we are the only hospital in the vicinity that is running 24/7; most of these referrals come outside of normal working hours when the local hospital services are not operating.

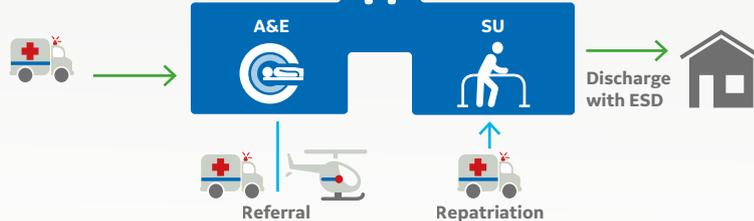
What critical elements of infrastructure have aided the development of your thrombectomy service?

We have a strong working relationship internally at St George's with neuroradiology, neuroanaesthesiology, and neuro critical care colleagues. These specialities are co-located within a single wing in the hospital and very

Stroke care network organization & care pathway of stroke patients admitted directly or referred to St George's Hospital

DISTRICT HOSPITALS

London area
Surrey
Part of Sussex & Kent



ST GEORGE'S

South West London



→ Referred patients
→ Direct admissions
A&E: Accident & Emergency
HASU: High Acuity Stroke Unit
SU: Stroke Unit
ESD: Early Supported Discharge Services

much embedded in the neurosciences department. It has been a key factor driving the development of our thrombectomy service.

Furthermore, we have good relationships with our external network including clinical colleagues across Surrey and East Kent. These initial relationships were important as we set out to build our thrombectomy referral process.

There is a need to ensure any developing services focusses on building and maintaining good relationships across the patient pathway and includes ambulance service colleagues.

What processes have you changed to support the delivery of thrombectomy services?

We transitioned our internal process to add a CT angiogram in the A&E department, in addition to a CT brain scan. This also involved ensuring that the radiographers and radiologists in emergency departments (St George's and district hospitals) were able and ready to perform CTA on people when they first present with a stroke. This was a change of practice that needed local clinical leadership, time, and education.

We changed the patient pathway within the hospital. Patients weren't just moving from emergency department to the hyper-acute stroke unit, but they were going directly to the neuroradiology department. This process required some pathway management to ensure patients had sufficient clinical care, particularly out of hours when the neuroradiology department would otherwise be closed.

How do you measure operational performance?

We developed a thrombectomy database so that data points are carefully recorded for every patient treated at our site.

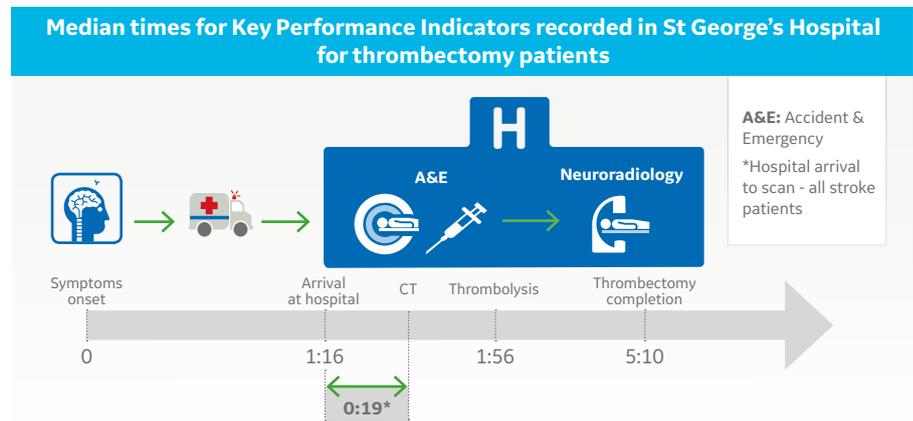
We review each thrombectomy case, every month, with the stroke clinicians, neuroradiologists, neuroradiology nurses, and stroke nurses. In each case, we are looking at patient selection, imaging, processes, timings, and eventually outcomes.

In addition to internal monthly operational performance reviews, a regional meeting is held every three

performance.

It is important to understand that it takes time to build referral processes, knowledge of your service, and external confidence in your service.

In the first 6 months, we were on target to delivering predicted patient flow. This year we will likely over deliver on our predicted income, creating a surplus for the organization.



Median times for Key Performance Indicators recorded in St George's Hospital for thrombectomy patients between April 2016 and March 2017 while the hospital was putting in place the 24/7 thrombectomy service in July 2016. During this ramp-up phase, the Onset to treatment times in St George's was still comparable to data from HERMES data⁵ (Onset to Thrombolysis time of 1h40 and Onset to reperfusion time of 4h45). Also, an excellent median arrival time to CT scan of 19 min was recorded at St George's hospital (national median is 58 min).

Source: Annual and Thrombectomy reports of Sentinel Stroke National Audit Programme (SSNAP) - April 2016 - March 2017.

months and includes stroke care providers in Surrey, East Kent, and air ambulance teams. At these meetings, we go through current performance data, deal with issues or challenges, and make sure that communication is open and transparent.

How do you measure financial performance?

At the beginning of a financial cycle, the team creates a business plan estimating the likely number of cases that will be performed each year and the income associated with these cases. On a monthly basis during the financial cycle, the predicted case-load is matched against the actual case-load and this is the key mechanism for measuring financial

What is the role of imaging in the stroke pathway?

In our stroke pathway, the role of imaging is critical. At the front door in the emergency department there is a CT scanner that can perform CT, CT Angiography, and CT Perfusion. In the neuroradiology department, there is 24/7 capacity to do CT, CT angiography, CT Perfusion, and MR. Critically for thrombectomy there are both a biplane and single plane angiography equipment should two cases be required simultaneously.

Each imaging technique and modality provides critical information about each patient's unique clinical condition. For us robust imaging capability is crucial to the performance of our stroke service. ■



Dr Jeremy Madigan is a Consultant Interventional Neuroradiologist based at the Atkinson Morley Neurosciences Centre at St George's Hospital. Along with the stroke team at St George's he is strongly committed to the local expansion of thrombectomy services.

What are the key challenges in stroke care delivery?

We operate a hub and spoke model: St George's (hub) accepts patients from its pre-defined catchment area. Probably one of the biggest challenges of accepting patients from a referring hospital within our catchment area is ensuring the prompt repatriation of these patients. This is impeded because of limited bed space in the same referring hospitals. This in turn creates pressures for us locally with our own bed status. We need to develop strong repatriation policies.

Access to the right sort of advanced imaging, particularly CT angiography, in the referral centres is still a challenge in some places. We are improving that with teaching sessions to raise awareness of the importance of CTA within our district hospitals.

Communication poses significant challenges. There are many steps and

people involved in the process of getting patients correctly diagnosed, referred, accepted, and transferred. The challenge is trying to make that as efficient as possible and make sure there aren't any delays in communication.

Finally, stroke is a complex pathway and making sure that we can respond as quickly as possible requires well defined protocols for each person at each step of the patient journey. This process of streamlining is not trivial but is necessary to deliver best outcomes for patients.

What are the best practices you have implemented while developing the thrombectomy activity?

We didn't go from just being a daytime service to delivering it 24/7. We slowly introduced the daytime working hours at the weekend and then extended to longer days (8 am to 8 pm). We went

from having 3 neurointerventionists to 5, and from 5 nurses to 10. We also increased the number of radiographers and neuroanaesthetists.

"Probably one of the biggest challenges of accepting patients from a referring hospital within our catchment area is ensuring the prompt repatriation of these patients"

We were also very keen that our pathway during the 9 to 5 schedule was reasonably slick before we decided to go 24/7. We ensured that we had ironed out most of the problems. We wanted to make sure that we had robust procedures of how to deal with problems that may arise during working hours so that out of hours we wouldn't run into difficulty.

We created a separate entrance to the hospital for ambulances that are

coming from the district hospital so that they don't have to go via the emergency department or the main entrance. They can arrive at a dedicated door, pick up the telephone and say that they've arrived.

There are two entrances to the hospital for stroke patients: one to the A&E for direct admissions and one to the neuroscience department including diagnostic and interventional neuroradiology for referred patients.

Within the hospital, we have regular monthly meetings between the interventional neuroradiologists, the stroke team, and our neuroanaesthetists looking at each individual case. We look at what we did well and what didn't go well, trying to identify any areas which can be improved and how.

We also have regular regional meetings where we invite the referring hospital teams along with the road and air ambulance services to identify any problems that have occurred in the preceding months and how we can address them. During these meetings

"If we are in the middle of a procedure and are concerned about a potential vessel rupture, we use high definition cone-beam CT. It is very good at showing sub-arachnoid haemorrhage of a decent volume and deep parenchymal haemorrhage as well."

we also highlight cases where we have excellent outcomes and we have

teaching session updates on the latest evidence so that we can see if we need to change anything within our service to align ourselves with best practice.

How important is CT Perfusion in your imaging protocol?

I was sceptical at first because I didn't think CT Perfusion would help much, but it gives a lot more confidence to the decision of moving forward with the thrombectomy.

We are now performing perfusion on all the patients whether they are presenting to us or coming from a remote hospital. Part of the reason for this is that a portion of the patients that we receive in good time and treat quickly with effective recanalization still experience outcomes consistent with a big stroke.



Multi-modality Advantage Workstation with CT Perfusion 4D and cone-beam CT post-processing capabilities displaying 3DCT HD imaging



GE Revolution HD with Gemstone Spectral Imaging (GSI)

“Instead of selecting a patient who fits into the 6-hour window from onset to treatment, we may even have patients in rare cases having treatment up to 24 hours after symptom onset.”

We assume that a stroke may be occurring between the time that they are referred from an outside hospital to the time we receive them. By performing the perfusion imaging on arrival we feel more confident that we are still doing the right thing by proceeding with the thrombectomy. We’ve had several cases recently where we received patients who developed a

large established infarct and we opted not to proceed with the thrombectomy.

What advanced imaging capability are you using in the interventional suite?

If we are in the middle of a procedure and are concerned about a potential vessel rupture, we use high definition cone-beam CT. It is very good at showing sub-arachnoid haemorrhage of a decent volume and deep parenchymal haemorrhage as well.

What are your thoughts on the current partnership with GE Healthcare?

We are very pleased with our collaboration with GE Healthcare. It

has allowed us to improve our image quality and we have benefited from having input from their engineering





Innova IGS 630 Biplane system with 3DCT HD cone-beam CT capability and 31 X 31 cm detector.

team but also more widely in terms of process mapping and helping us look at our own thrombectomy service to seek different avenues for improvement.

What trends do you see developing in stroke care?

Recently presented evidence from the DAWN trial may encourage the

increased use of advanced imaging techniques such as CT Perfusion in patient selection and that in turn will have an impact on reducing the dependence on rigid time criteria determining which patients may be eligible to receive treatment. Instead of selecting a patient who fits into the 6-hour window from onset to treatment, we may even have patients

in rare cases having treatment up to 24 hours after symptom onset. Patients with wake-up strokes who have unknown time of stroke onset may also benefit from this development. ■

1 Top 10 causes of death. Global Health Observatory. World Health Organization (WHO), 2017. - http://www.who.int/gho/mortality_burden_disease/causes_death/top_10/en/.

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5 Goyal M. et al Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *The Lancet*. Vol. 387 - pp. 1723-1731. 2016

Acute Ischemic Stroke treatment using Innova IGS 630

Courtesy of Dr. Jeremy Madigan, St George's Hospital (UK)



Fig.1 Angiogram showing ICA occlusion

Clinical Case Background

A 67-year-old woman was at home when she developed sudden onset right sided weakness and dysphasia at 15:00h. She was admitted at the nearest hospital at 16:47 where a plain CT head scan and CTA confirmed left middle cerebral artery (MCA)M1 occlusion without established infarction. The left ICA in the neck was also

occluded with thrombus near its origin. Intravenous thrombolysis was started at 17:55.

Triage and transfer from district hospital

She was referred to the Stroke Centre at St George's Hospital for consideration of thrombectomy and accepted for transfer after consultation with a neurologist.

Transfer from referring hospital to St George's took 1 hour by road ambulance. The referring hospital was outside of the official catchment area of St George's west of Surrey, highlighting the potential for expanded geographic coverage. At 19:30h the patient arrived at the hospital and was transferred immediately to the angio suite. Her NIHSS score was 20, indicating a severe neurological deficit.

Endovascular intervention

Initial angiography in the left common carotid artery confirmed proximal ICA occlusion by thrombus. This was aspirated using the guide catheter.

Further angiography in the distal left cervical ICA showed thrombus in the communicating segment (TICI 0). This was aspirated using a distal access catheter. The M1 segment of the left MCA was then cleared by further aspiration, restoring flow to most of the MCA territory (TICI 2b) at 20:16, 5 hours and 16 minutes after symptom onset.

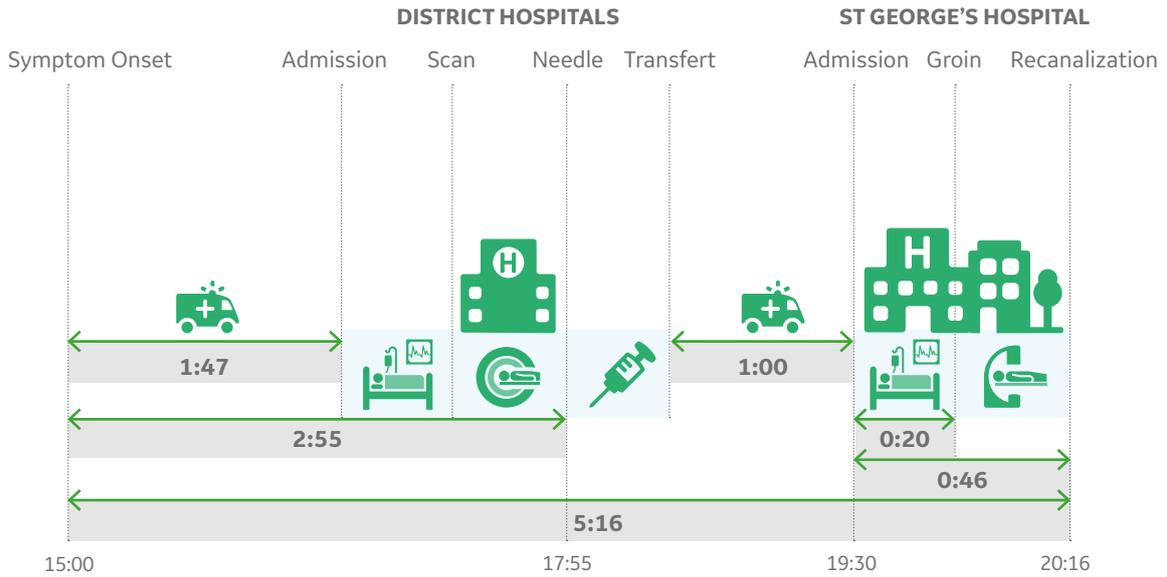


Fig.2 Pre-procedure angiogram showing clot located in M1 segment of the left MCA

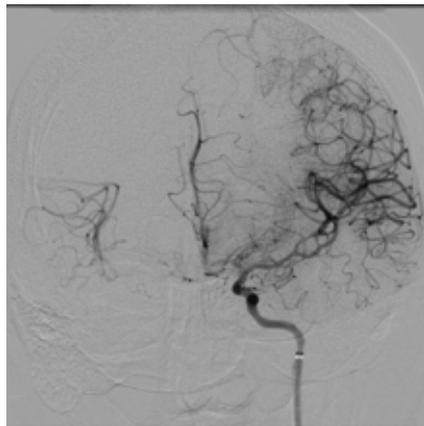


Fig.3 Post-procedure image showing blood flow after successful aspiration of clot

About

Dr Jeremy Madigan is a Consultant Interventional Neuroradiologist based at the Atkinson Morley Neurosciences Centre at St George's Hospital. Along with the stroke team at St George's he is strongly committed to the local expansion of thrombectomy services. St George's Hospital is one of the 8 hyper-acute stroke units of the London stroke network, and the first fully staffed 24/7 thrombectomy service in the UK. With over 1200 stroke admissions per year, it is also the site with the largest number of thrombectomies across England with a procedure volume that has trebled within a year.

Summary

The stroke care pathway within St George's hospital was quick, with a door-to-groin time of 20 minutes and a groin-to reperfusion time of 26 minutes. Overall reperfusion was achieved 5 hours and 16 minutes after symptom onset. A follow-up CT on the GE Revolution HD with GSI, 24 hours after thrombectomy showed a small left striatal infarct. The patient was discharged back to her local stroke unit and has made a good clinical recovery (mRS 1).

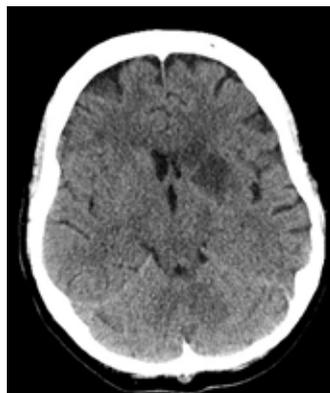


Fig.4 24 hour follow up CT after endovascular intervention. Axial 2.5mm slice showing low density area indicative of infarct

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Brain aneurysm treatment with flow diverter stent on Innova IGS 630 using Vessel ASSIST

Courtesy of Pr Istvan Szikora, National Institute of Clinical Neurosciences, Budapest, Hungary

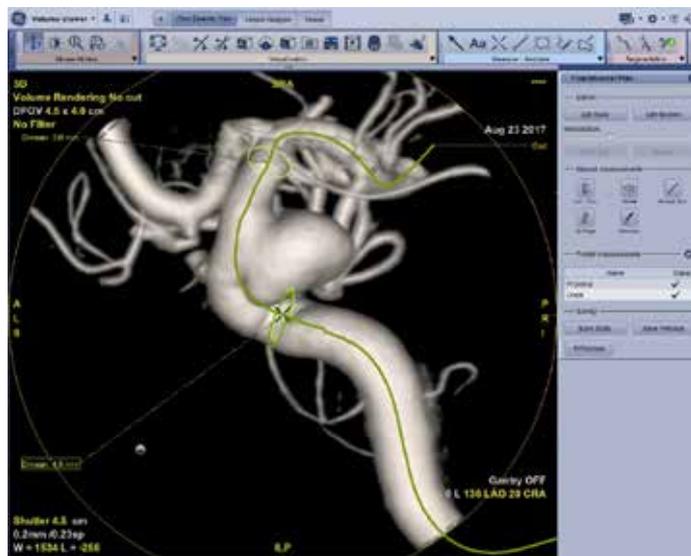


Fig.1 Planning on the AW with the CBCT 3D model



Fig.2 Planning on the AW with the CBCT cross sections and stretched view of the ICA

Clinical challenge

The endovascular treatment of wide neck aneurysms remains a challenging procedure. Such aneurysms can be treated with multiple coil placements and stents. More recently, flow-diverter stents were introduced and are now increasingly used to treat aneurysms larger than 6 mm with positive outcomes. Flow diverter procedures require very precise measurements of the aneurysm neck and parent vessel length and diameter for the selection of the stent. Careful deployment and assessment of the device placement at the end of the case are needed.

Clinical case

Patient History

This is a case of a female patient in her early sixties, who was discovered with an intracranial aneurysm, with no specific symptoms and no neurological deficit. An MRI demonstrated an aneurysm of the right internal carotid artery (ICA), which we decided to treat because of its size and the associated risk of haemorrhage. After analysis of the CT angiography, the decision was made to use a flow diverter for the treatment, due to a relatively broad neck.

Procedure

Planning

After a biplane DSA to visualize the aneurysm, we performed a compression test that

demonstrated good collateral flow in the arterial phase through the anterior communicating artery (ACA). However, there was a delay in the capillary phase, so we knew that carotid occlusion was not going to be an option for us. The DSA showed a distal circle ICA and an aortic arch which were both rather tortuous, which is why we decided to use a tri-axial access.

We performed a 3D rotational acquisition (3D CT HD, 5 seconds' spin) and used the 3D model to characterize the aneurysm neck and make precise 3D measurements using Vessel ASSIST*. Based on the measurement, we decided to use a flow diverter with sizes of 4.5mm diameter and 16mm length.

Guidance and deployment of the flow diverter stent

The proper angulations for deployment were selected on the 3D model and sent to the C arm. The chosen working view gave us a good overview of the proximal and distal landing zone, as well as the middle cerebral artery (MCA), into which the wire was going to move all the way through the procedure.

We were facing some difficulties pushing the distal access catheter through the tortuosity in the carotid artery, so we placed the distal catheter relatively proximal. Then, once the undeployed device was already in place, we used the flow diverted system as a strong guidewire to further advance the distal catheter. And then once in place, we pushed further the distal access catheter. We needed to replace the long sheath in the aortic arch to obtain enough support. During the deployment, we had some difficulties in opening the distal section of the flow diverter. This is, to some extent, due to the oversized diameter of 4.5mm compared to the distal carotid, which was only 3.7mm in diameter. So finally, we actually left the distal section partially opened and did some wire manipulation, which in fact managed to open the distal section. For security

reason, we did a balloon dilatation as well.

Assessment of the deployment

After the balloon dilatation, the wall apposition seemed perfect on the angiogram, but because of the difficulties we had earlier on, we decided to do a 3D rotational acquisition (3D CT HD) to assess if the wall apposition was complete and perfect all the way through.

The cone-beam CT demonstrated appropriate device position and perfect wall apposition in the critical section in the distal carotid artery. We were able to visualize this using the Virtual Dilution protocol on the AW, which allows us to use concentrated contrast with the injector, just like we would do in any other cases, and then virtually dilute the contrast in order to visualize both the vessel and the device placed inside of it.

Conclusion

Altogether, it was not an unusually complicated case. We did have some difficulties, particularly due to the tortuosity and the opening problem of the distal section of the flow diverter, but it went well, and the result is quite satisfactory.

About

Pr. Istvan Szikora is an interventional neuroradiologist, who has been working in the National Institute of Clinical Neurosciences in Budapest, Hungary since 1977. The National Institute of Neurosurgery was founded in the early 1950s as a major surgical neurocenter in Hungary. Its neuro-intervention department, led by Pr. Szikora is dealing primarily with aneurysm, ischemic stroke, AV malformation as well as spinal diseases with minimally invasive image-guided treatment.

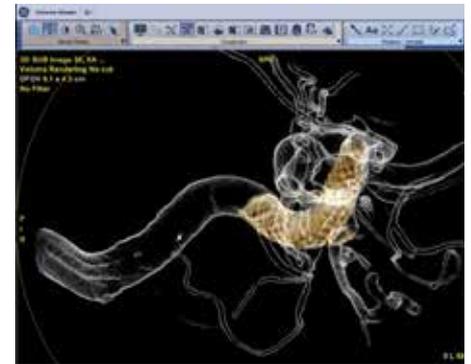


Fig.3 Control of the wall apposition of the flow diverter on the 3D cross sections and 3D model using the Virtual Dilution protocol on the AW.



Watch the case video !

Find more on GE Cares



Contact

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Innovative tools to fight against pancreatic cancer

A laser-guided mobile robotic angiography system helps an Italian gastroenterology unit deliver better diagnosis and treatment of pancreatic cancer and other diseases.





In the heart of one of Italy's most renowned regions for gastronomy, there is no lack of Parmigiano Reggiano, nor access to advanced technologies to fight cancer.

Despite the summer heat sometimes approaching 45°C, Dr. Romano Sassatelli, head of the gastroenterology unit at the Santa Maria Nuova oncology center, is fighting to put together all he can to treat patients with the most

aggressive tumors.

His goal is to push the limits of possible treatments by using new technologies. Among his current arsenal is a new hybrid operating room equipped with the Discovery™ IGS 740 mobile angiography system (GE Healthcare).

Modern facility

The recently built Center of Oncology and Hemodynamics of Reggio Emilia (CORE) is a highly specialized clinical care and research site devoted to cancer diagnosis and therapy. Its modern architectural layout provides high standards of privacy for personalized care, patient support and comfort.

Inaugurated in June 2016 by Matteo Renzi, then prime minister of Italy, the

CORE aims to deliver the future of healthcare. Dr. Sassatelli and his team recently moved to the CORE building, where a new environment of more than 1,500 square meters enables a significant improvement in patient care.

Dr. Sassatelli manages five endoscopy rooms, including wide rooms to prepare and hold patients before and after procedures. One of these rooms is equipped with the advanced Discovery IGS 740, a mobile robotic gantry system that brings both intuitive 3D fusion image guidance and complete workspace freedom to the hybrid operating room. Its unique mobile platform brings all the power of a fixed imaging system to the table, yet it can be moved aside so that multi-disciplinary teams can complete procedures comfortably with unobstructed access to patients.

An untethered, laser-guided gantry carries the imaging C-arm so that there are no obstacles on the floor or ceiling. It can be moved to the table to image any part of the anatomy, then moved back out of the way to precise pre-chosen positions. It offers high-end fluoroscopy image guidance, advanced applications, and 3D image fusion. The large 41x41cm detector panel from the IGS 740 lets Dr. Sassatelli see the whole abdominal anatomy in one view.

Complex challenges

The gastroenterology unit performs about 12000 procedures per year, including about 1,000 simple ultrasound studies, more than 600 endoscopic retrograde cholangiopancreatography (ERCP) cases, and complex treatments of the biliary tract, pancreas and bowel.

Most patients in the department

present with symptoms related to pancreatic or colorectal cancer. Dr. Sassatelli explains, “pancreatic cancer is a really dramatic disease, and we need to do all we can to obtain a good diagnosis, provide a good treatment when possible, and if not provide the best palliative care.”

Fighting a complex and aggressive disease means undertaking innovative treatment. Since the installation of the Discovery IGS 740 hybrid OR, Dr. Sassatelli has new hopes, especially for the care of pancreatic cancer patients. While most of his colleagues perform ERCP using mobile C-arms and endoscopy, he strongly believes that high-end radiological imaging can help significantly in treating complex pathologies. “In our world of digestive endoscopy, advanced X-ray image guidance can give us a better localization of the disease, allowing us to see what we cannot see using standard endoscopy,” he says.

Indeed, using the Discovery equipped with the Vessel ASSIST solution, Dr. Sassatelli can now superimpose reconstructions of various anatomic structures (such as organs, vessels and tumors) from pre-operative examinations on top of fluoroscopy. “If you have a structure you cannot fill with contrast media because of an occlusion or spasm, you would love to have a system on which you could fuse previously acquired imaging and see where you should go,” he says. “That’s exactly what I can do thanks to our Discovery system.”

Promising future

He even envisions new treatment options for his patients, such as electroporation, as the Discovery IGS system with image fusion provides accurate information on the location of the lesion on fluoroscopy.



Dr. Sassatelli says that choosing the Discovery IGS two years ago was quite straightforward: versatility, a small footprint and absence of constraints in the ceiling were the main reasons for his decision. *“There are no rails in the ceiling,”* he says. *“It’s a key point because as endoscopists, we already have a number of things in the ceiling. In our room, we have at least four systems hanging from the ceiling. The Discovery system is very versatile. It enables me to position the system around the patient, so that I can work in the most comfortable position possible, taking into account the procedure or the patient access I need.”*

With the new room, Dr. Sassatelli is making CORE the first hospital worldwide to use the Discovery IGS 740 in combination with endoscopy to treat gastrointestinal diseases. He believes the system can help increase the success rate of ERCP. *“In the literature, you don’t find much evidence that when you fail in diagnosing pancreatic cancer, it’s due to a low-quality radiological system,”* he says. *“But we all know it’s true. Moreover, with this new hybrid system, because we can have several modalities fused on a same fluoroscopy screen, we are introducing a new paradigm: See the lesion at the same time you treat.”*

On top of that, he’s proud to be totally autonomous in the use of the mobile angiography system. After one week of training provided by GE, he’s able, with the help of his technicians, to use the Discovery system to its utmost capabilities, without the help of a radiologist.

“The Discovery system is very intuitive,” he says. *“I’ve seen the technicians after training, and they appear very comfortable using the system. GE support was also key in the success of*

mastering the system and pushing it to its limits. I’ve seen in the past that you can have a great car with a lot of features, but you often use a small number of them. Thanks to our partnership with GE, we are able to use this machine to its highest potential.”

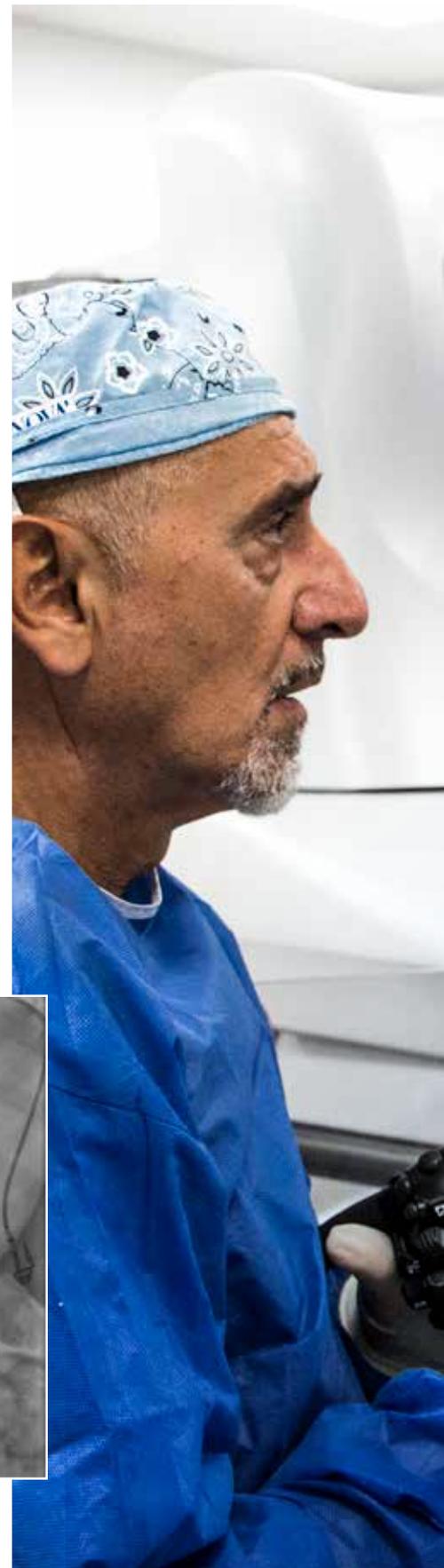
New possibilities

His next step is to run clinical studies in order to provide evidence showing the superiority of the hybrid room for diagnosing and treating gastrointestinal diseases.

Last but not least, he and his colleagues from other clinical fields see a potential to expand their activity through the use of the Discovery IGS 740: *“A few weeks ago, some thoracic surgeons told me they saw a great opportunity to use the Discovery system for lung biopsy, thus freeing up the CT for diagnostic purposes. I clearly see a great expansion of the use of the hybrid room in the hospital, and I fear it will become crowded much too quickly!”* ■



Fusion of biliary duct coming from pre-operative MRI on top of fluoroscopy. This fusion enables Dr. Sassatelli to see occluded vessels on the fluoroscopy, so that he can safely catheterize them.





A long-standing history of innovation for cardiovascular pathologies, Marie-Lannelongue hospital

With its colorful logo created by famous painter Joan Miro in 1972 as a tribute to the 1000th open heart surgery, the Marie Lannelongue hospital in Le Plessis Robinson, near Paris, thrives to continuously innovate in the field of cardiovascular pathologies, and decided therefore to invest in a Discovery hybrid operating room in 2017.



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The Marie-Lannelongue hospital

The Marie Lannelongue hospital (HML) was founded in 1909 by Professor Odilon Lannelongue, member of the academy of medicine and the academy of sciences, and his wife Marie. Odilon was famous for his work on congenital malformations and bone pathologies, in particular tuberculosis.

Since then, the HML has become a center of excellence for thoracic, vascular and heart surgery, dedicated

both to pediatric patients and adults. In addition, it is the reference center nationwide for complex congenital cardiopathies. Some of the most important innovations which have built its international reputation include the first pediatric open heart surgery in Europe in 1955 or the first European implantation of a mechanical valve in 1962. In 1986, HML performed successfully the first French heart-lung transplant. ■

SOME KEY NUMBERS ABOUT THE HML

201
beds



960
members of staff



8377
hospital stays,



split in 40% surgical, 35% interventional and 25% medical stays



6213

interventional procedures, among which 51% are coronary interventions, 26% vascular interventions, and 23% other types of interventions



3750

surgeries, including 776 on pediatric patients

The hybrid OR project

In 2017, the HML invested in a hybrid operating room (HOR), equipped with the Discovery IGS 740 system. The HOR opened part time this summer and full time in September, and patient recruitment is increasing since then. The room was co-financed by the hospital and by Medtronic, as part of a collaboration on implantable cardiac valves.



Pr. Elie Fadel, medical director of the HML, cardio-thoracic-vascular surgeon, tells us all about this project.

Where did the hybrid operating room project come from?

The project was born about 18 months ago and was pushed by an increase in our endovascular and TAVI (Transcatheter Aortic Valve Implantation) treatment activities. We also started to collaborate with Pr. Stéphane Haulon, head of the aortic center in the University hospital of Lille at that time, and he later decided to join us here when we invested in the Discovery IGS 740 hybrid OR. We aim to be constantly at the spearhead of surgical innovation, so we need to have the very latest high-end equipments to continue to lead in the percutaneous treatment of cardiac pathologies such

as mitral clip and valves, as well as thoraco-abdominal aneurysms. This is why a hybrid operating room was a must.

How is the hybrid OR currently used?

This room is used mainly for complex interventions that we would not be able to do without such an equipment, and is shared between all departments in the hospital. Currently, the room is dedicated to percutaneous cardiac interventions two days per week, aortic endovascular interventions another two days per week, and the last day is for pediatric cases. It is also used for open surgeries, as it truly works like a standard operating room when the



Therefore, I anticipate that image fusion technologies brought by the Discovery HOR will allow us to treat these cases more effectively and safely, by enabling to highlight and remove only the lesion itself.

How was the learning curve for the staff?

We were a bit worried initially about the learning curve, but were positively surprised as the staff adapted very quickly to the technical use of the system. This was even easier thanks to the involvement of Pr. Stéphan Haulon and Pr. Dominique Fabre from the vascular surgery department who were both familiar with the Discovery system. In the end, the main challenge was the re-organization of staff, in particular access to the room for all departments and anesthetists' rotations between rooms. We also had to redesign OR circulation, hygiene and sterility rules as the hybrid room is installed in the interventional radiology department and not in surgery. Now, after two months of use, we are over that learning curve and the room is fully occupied.

Why did you choose the Discovery hybrid OR from GE?

We felt the Discovery room was the most suited solution for our specialties, such as percutaneous valve repairs and endovascular interventions. In addition, we started a collaboration with Pr. Stéphan Haulon on aortic repairs, and he was very satisfied with his own Discovery room in Lille. Our hospital also has a strong collaboration with the GRCC (Gustave Roussy Cancer Campus), as we work like a virtual common entity by mutually taking care of each other's patients in our specialties, and Pr. Thierry de Baère, head of interventional radiology at GRCC, also promoted the choice of the Discovery HOR.

Finally, we have a close collaboration with GE on research as well, as we will soon have the same Discovery equipment in the animal lab to validate future applications and run basic research projects.

What are the main benefits of this Discovery HOR?

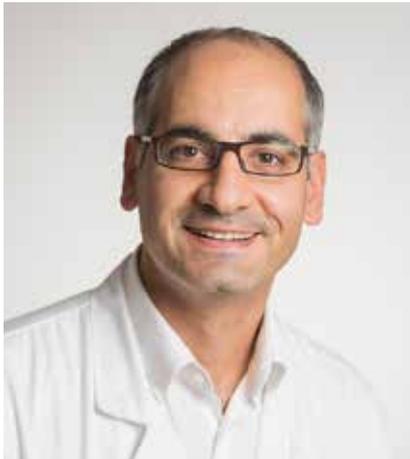
I would say that there are two main benefits. The first one is to be able to do what we did before in a simpler and safer way, with less radiation dose and contrast media. So, we are improving the security and results of procedures for patients, thanks to image fusion technology in particular. The second benefit is that we can now perform cases that we could not do before, we are enlarging our surgical indications and treating patients that were previously contra-indicated because they are too fragile. Now, thanks to the HOR and image fusion, we can offer an alternative to these patients.

In terms of economic benefits, it is too early to quantify them, but I am convinced that with better results we will be able to reduce the length of hospital stay thus decreasing costs. Between that and the overall increase in patients treated thanks to this room, we should see an increase in our revenues.

In conclusion, this technology is first and foremost for the patient, as we can offer safer surgeries, and propose minimally invasive surgical alternatives to more patients. It represents a true progress in our cardiothoracic and vascular specialties, both in terms of image quality and advanced applications, and it will continue to improve in the near future without any doubt. ■

Discovery is parked. We had for instance a case of open aortic repair last week with cardiopulmonary bypass.

We also anticipate to use it in the future for other applications, such as spinal tumors or lung tumor resections. Indeed, it is key to be able to locate precisely the extent of such tumors for the safety of the intervention and also to avoid removing healthy tissue that could be preserved. But in some cases, like for instance for ground-glass opacity pulmonary nodules, it can be hard to assess the tumor margins, so they are usually operated with video-assisted thoracoscopy, partly blindly with regards to tumor extension.



Dr. Saïd Ghostine,
Interventional
Cardiologist and Chief
of the Cardiology
department at Marie
Lannelongue Hospital.

Please introduce the scope of activity in your interventional cardiology department

"Our cardiac activity is above 1100 PCI, 200 TAVI, 20 Mitraclip a year so far. The department is also performing Left Atrial Appendage Closure procedures.

In our new hybrid environment, we are specifically performing TAVI, Mitraclip and LAAC procedures.

The indication criteria for these percutaneous procedures are decided within the heart team at the clinical staff. It includes our cardiac surgeon, anesthesiologist, and interventional cardiologist. If we take TAVI as an

example, we also define together the access route, the measurements of the annulus and finally the choice of the valve."

What is the benefit of such an hybrid OR environment ?

"The main benefit is the security for the patient, and also the sterile environment that conforms to the latest french regulation for TAVI.

Our TAVI procedures being performed together with a surgeon, he is ready to intervene in case of a procedure conversion to open surgery: thus the patient does not move and definitely benefits from this additional security.

The sterility is not compromised as the robot is made free from ceiling rails and enabling all different positioning we need.

95% of our TAVI are performed with a trans femoral access, and we are using the carotid access for the other procedures¹, enabled by the complete team set-up and the hybrid OR environment.¹

The quality of imaging is really good and helps us look at all the details we need. A better field of view enabled by the 40x40 flat panel enables us to do our TAVI with a single injection, lowering our contrast media use, which is very suitable for these patients suffering from moderate to severe renal failure.

We've also seen the radiation doses decrease, thanks to the use of collimation and the low-dose design of the system.

The structural heart field is expanding with important growth of TAVI procedures, as well as mitral annulus

repairs, and sooner or later mitral and tricuspid valves replacements.

TAVI is growing between 20-25% a year in France. Registries show a positive curve with 7000 TAVI in 2015, 9200 in 2016 and we expect around 12000 in 2017.

We will be able to grant TAVI access to more patients, as we expect to include patients with intermediate risk (Partner II and SURTAVI studies). If clinical evidences supports extending the indication to low risk patients, we forecast 20000 patients in total.

As a reference, 15000 aortic valve replacement surgeries are performed each year in our country.

Between 2016 and 2017 our activity has grown 26%, with high risk patients that have been discussed at the clinical staff."

What are the remaining challenges?

"TAVI is a well mastered procedure nowadays. The remaining challenge is mainly to simplify the whole procedure while keeping it safe.

Our patients are now under conscious sedation, as we moved away from general anesthesia.

We are now using hypnosis at Marie Lannelongue to enable a faster discharge of the patient, who is able as a consequence to recover faster than in the past.

We are using devices from the two main players, and they are still working on some improvements to decrease the size of the catheters, and valve technologies with skirt to reduce further the paravalvular leaks." ■

1 Reference: Eur J Cardiothorac Surg. 2014 Oct;46(4):693-8; discussion 698. doi: 10.1093/ejcts/ezt619. Epub 2014 Jan 14. Transcatheter aortic valve implantation through carotid artery access under local anaesthesia.



The benefits of 3D CTHD for immediate assessment of EVAR

Pr. Stéphan Haulon is a vascular surgeon and has specialized over the years in complex endovascular repairs of aortic aneurysms. He has recently moved to HML where he is the head of the aortic center. He explains to us the benefits of using a hybrid OR, in particular completion 3D angiography, for aortic endovascular repairs.

The Achilles heel of EVAR

The treatment of aortic aneurysms has switched in recent years from open repair to primarily endovascular repairs. Endovascular aortic aneurysm repair has lower early mortality and morbidity rates compared to open surgical repair, with equivalent technical success. For complex repairs, high technical success (over 95%) has

been reported by large tertiary centers, encouraging the development and adoption of the endovascular technique, with early mortality ranging from 1% to 5% for pararenal and 4% to 10% for thoraco-abdominal repairs^{1,2,3,4,5,6,7}.

However, with the increasing volume and complexity of aortic endovascular repairs, stent graft-related early

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4 Amiot S, Haulon S, Becquemin JP, et al. Fenestrated endovascular grafting: the French multicentre experience. *Eur J Vasc Endovasc Surg.* 2010;39:537-544.

5 Oderich G, Ribeiro M, Hofer J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones [published online December 13, 2016]. *J Vasc Surg.*

6 Oderich GS, Ribeiro M, Reis de Souza L, et al. Endovascular repair of thoracoabdominal aortic aneurysms using fenestrated and branched endografts [published online October 22, 2016]. *J Thorac Cardiovasc Surg.*

7 Eagleton MJ, Follansbee M, Wolski K, et al. Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms. *J Vasc Surg.* 2016;63:930-942.

complications due to technical issues during the initial procedure may occur, which potentially require re-intervention. The most common early complications include endoleak at the sealing zone and compression of side branches of the stent, putting the collateral arteries at risk or leading to potential aneurysm rupture in the case of an endoleak⁸. Therefore, these complications need to be monitored closely through follow-up post EVAR.

Value of CBCT post EVAR for early complications

Traditionally, follow-up includes a 2D angiogram immediately after stent deployment to verify the correct position of the endograft and patency of connecting arteries, as well as a post-op CTA (Computed Tomography Angiography) 48 hours to one month after EVAR. However, 2D angiography has limitations to correctly assess the potential presence of an endoleak or a kink in the stent. The sensitivity and specificity of completion angiography to detect endoleaks have been estimated respectively at 63% (range

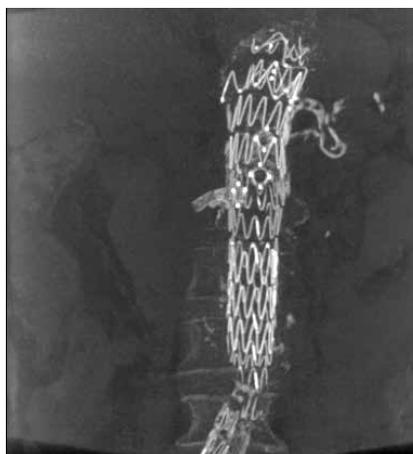
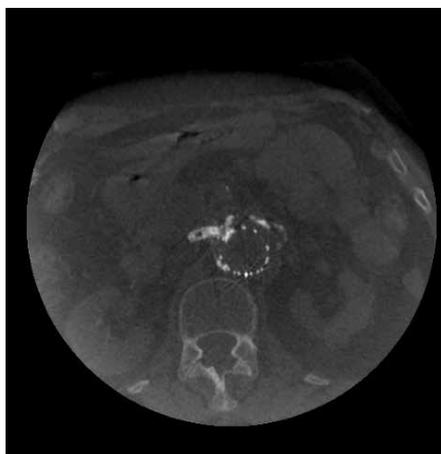
60-70%) and 77% (range 58-100%), while it is 92% (range 80-100%) and 90% (range 85-92%) for CTA⁹. If such complications are missed by completion 2D angiography, detection at the follow-up CTA might be too late to avoid a devastating complication, such as renal failure. Therefore, immediate assessment of the repair with intra-operative 3D imaging, namely cone-beam CT (CBCT), is more and more widely used and effective thanks to the recent advances in CBCT image quality. The benefits of immediate CBCT include the possibility to avoid secondary re-intervention if a complication is detected while the patient is still on the operating table. In the case of a compression or kink of a side-branch, endovascular maneuvers will re-open on the spot the connecting stents.

Post-operative surveillance protocol with CBCT and US

Another concern of endovascular repair compared to open repair is the long-term durability of endografts. Therefore, life-long surveillance is still

required with CTA or duplex ultrasound. At his institution, Pr. Stephan Haulon has changed the surveillance protocol for EVAR patients, moving from immediate DSA at the end of the deployment and post-operative CTA to immediate CBCT and post-operative Ultrasound (US). Not only has this strategy shown an improved detection of complications and decreased rate of re-intervention consequently⁸, but it has also been shown to be much more effective dose & contrast wise.

Indeed, repeated radiation exposure and contrast-induced nephrotoxicity are major concerns for EVAR patients given the lifelong surveillance that is needed. In his previously published study⁸, median exposure due to CBCT was 7.0 Gy cm², which represented important additional radiation exposure during bifurcated cases, but less than 10% of the total procedure in the most complex cases. According to this study, on the total hospital stay, the follow-up strategy of doing an immediate post-operative CBCT plus a contrast-enhanced ultrasound before patient discharge saved 50% radiation dose and 68% contrast media, compared to doing an immediate DSA followed by a post-op CTA.



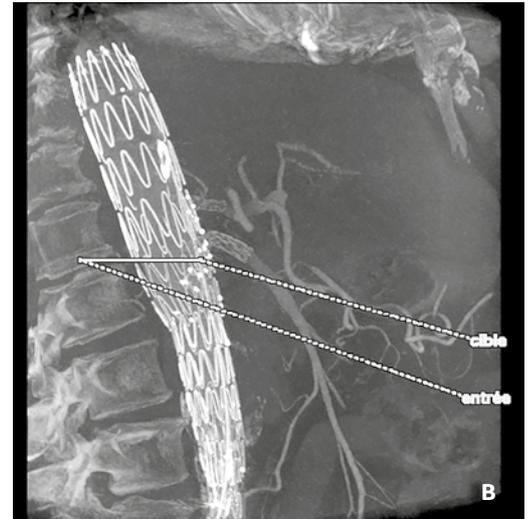
3DCT HD cross-sections with excellent spatial resolution to control endograft deployment.

New 3D CTHD for enhanced image quality at the same low dose

Recently, Pr. Stéphan Haulon noted an improvement in image quality of his CBCT acquisitions. Indeed, a new protocol called 3D CTHD, was introduced to improve the visualization of small devices and soft tissues.

8 Hertault A, Pontana F, Martin-Gonzalez T, Spear R, Sobocinski J, Sediri I, Gautier C, Azzaoui R, Rémy-Jardin M, Haulon S. Benefits of Completion 3D Angiography Associated with Contrast Enhanced Ultrasound to Assess Technical Success after EVAR. *Eur J Vasc Endovasc Surg* (2015) 49, 541e548

9 Armerding MD, Rubin GD, Beaulieu CF, Slonim SM, Olcott EW, Samuels SL, et al. Aortic aneurysmal disease: assessment of stent graft treatment-CT versus conventional angiography. *Radiology* 2000;215(1):138e46.



A: Translumbar approach to access the kinked renal stent

B: Trajectory planned on 3DCT HD with Needle ASSIST

Using high frame rate acquisition and an advanced scatter reduction algorithm, 3D CTHD reduces streak artifacts, brings uniform images for soft tissue visualization and higher spatial resolution for improved visualization of small devices, without increasing dose.

For 3D CTHD acquisitions, patient is under general anesthesia with arms along the side, and an easy spin acquisition over 200 degrees at 40 degrees per seconds is performed. A spin test is done just before to verify that there is no risk of collision between the patient and the C arm, and to check that the acquisition volume is well centered on the anatomy of interest. Patient centering is performed with the fusion mask only, saving unnecessary radiation dose due to fluoroscopy. Thanks to the wide bore C-arm of the Discovery, collision-free CBCT is easily performed and the spin test only takes a few seconds. In patients with impaired renal function, an antero-posterior (AP) fluoroscopy shot of diluted contrast media is performed to check for potential endoleaks, and then a non-injected CBCT is acquired to verify

in detail the endograft placement.

Compared to his previous CBCT protocol, Pr. Haulon noted an enhanced visualization of bridging stent struts and small endoleaks, and less artifacts in cross-sections.

Translumbar repair with 3D CTHD and Needle ASSIST

Another application of 3D CTHD which has been more recently utilized by Pr. Haulon is to repair a kinked renal stent or a type 2 endoleak through translumbar puncture using Needle ASSIST. Upon completion of a 3D CTHD acquisition, the kink or endoleak is localized and a needle trajectory is virtually created on the 3D model from the skin entry point to the target. This

trajectory is then superimposed on top of fluoroscopy to guide the needle until the target. Finally, two fluoroscopy views are used to precisely assess the real-time position of the needle tip and compare to the planned trajectory by reconstructing the automatically-detected needle into the initial CBCT. Once correct placement of the needle has been assessed, the translumbar embolization of the endoleak can be performed. In the case of a kinked renal stent, the translumbar approach may help to access the renal artery retrogradely if access from the aortic lumen has failed. ■

“Thanks to post-operative CBCT, we are able to immediately assess the technical success of the procedure and potentially avoid re-interventions, while reducing radiation dose and contrast. The new 3D CTHD protocol shows significant improvement for visualization of small details such as stent kinks and has the same low-dose features as our previous protocol.”

Stenting of the left pulmonary artery at the anastomosis with a left superior vena cava in a young boy with total cavo-pulmonary connection

Courtesy of Dr S. Hascouët, Hôpital Marie Lannelongue, France

Clinical challenge

One of the main challenges in complex congenital heart diseases is to understand the anatomical lesions before planning treatment either by surgery or interventional catheterization. Multimodal accurate preoperative imaging is thus essential.

Pulmonary valve atresia with intact ventricular septum and severe hypoplasia of the right ventricle leads to impaired arterial blood oxygen saturation and ventricle overload. Such cases require the same patient care strategy as single ventricle cases: the Fontan's intervention, a palliative pediatric cardiac surgery which allows deriving the systemic venous blood return by connecting the right atrium to the pulmonary artery. This technique has evolved to the total cavopulmonary bypass, connecting the vena cava directly to the pulmonary arteries, without interposition of the right atrium.

This cavopulmonary bypass allows to separate the pulmonary and systemic circulation and to restore a circulatory system "in series", leading to a non-pulsed blood flow to the pulmonary vascular system. In the present case, the patient has a pulmonary artery stenosis, compromising the flow through the pulmonary vascular tree.

A severe stenosis at the bifurcation between the left superior vena cava and the left pulmonary artery was also diagnosed. After medico-surgical evaluation and given a high surgical risk, it was decided to perform stenting of the left pulmonary artery stenosis.

Clinical case

Patient History

A young boy, with a pulmonary atresia with an intact septum and severe hypoplasia of the right ventricle, had multiple surgeries to achieve a total cavo-pulmonary assembly (connection of the inferior vena cava to the pulmonary artery with an extra cardiac tube and connection of right and left superior vena cava to the pulmonary arteries). The patient later developed a thrombosis of the right superior vena cava.

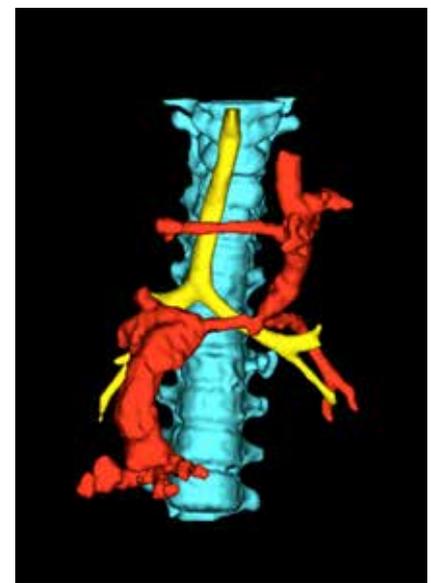


Fig. 1: 3D volumes extracted from pre-operative CT

Procedure

Planning

Before the procedure, an injected preoperative CT was studied and visualized to better understand the anatomy of the patient. Using EP Xpress, various anatomical structures were segmented to have a better representation in 3D and plan the procedure. The cavo pulmonary bifurcation and pulmonary artery were segmented to visualize precisely where to catheterize, as well as non-moving anatomical structures such as the bronchus and the spine, so as to use them during the registration phase. EP Xpress allowed to analyze multi-oblique views to opt for the best approach and to perform measurements to choose the right device. In this case, the stenosis was sub occlusive and the left pulmonary artery was nearly occluded. Measurements, landmarks and 3D volumes coming from the preoperative CT were recorded and fused with live fluoroscopy imaging during the procedure using Valve ASSIST 2.

Guidance

The procedure was performed in the Discovery IGS 740 hybrid room, with the patient under general anesthesia. As the two femoral veins of the patient were occluded, the procedure had to be performed with a trans-hepatic approach. The catheterization was performed using two vessels access. The right hepatic vein and the left internal jugular vein were punctured under ultrasound guidance. Angiography was performed to confirm the T-stenosis of the bifurcation between the superior vena cava and the left pulmonary artery. A 7x36 mm pre-mounted balloon expandable stent was chosen based on the measurements made. The fusion of 3D volumes from the preoperative CT on the live fluoroscopy with Valve ASSIST 2 helped the team to delineate the lesions and to minimize radiation dose.



Fig. 2: Procedure planning with EP Xpress

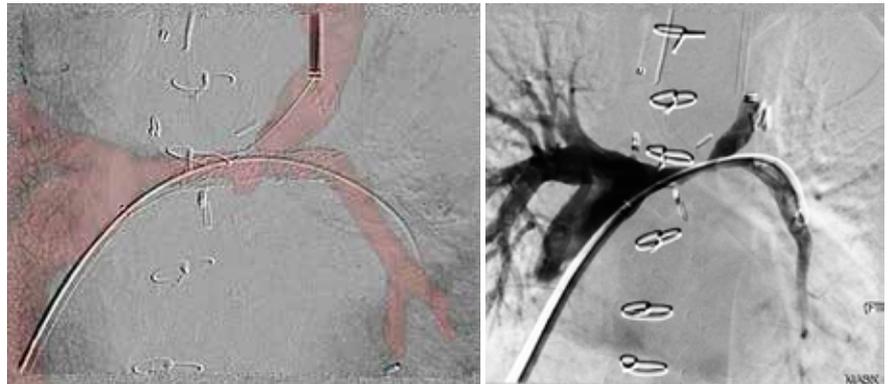


Fig. 3: Live guidance with Valve ASSIST 2 (left), injected DSA to visualize the stenosis of the pulmonary artery (right)

The stent was placed in the left pulmonary artery covering the cavo-pulmonary anastomosis. After the assessment of the right position of the stent with a DSA acquisition, balloon opening of the stent was performed towards the stenotic part of the left superior vena cava.

Conclusion

This case illustrated how multimodality imaging tools and image fusion can help perform complex congenital heart disease treatments.

Find more on GE Cares



Contact

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A leading Cardio Center designed around the patient journey at Clinique Pasteur, Toulouse

Clinique Pasteur in Toulouse France, has recently opened a new building called La Passerelle - The Bridge. Designed by and for caregivers, all necessary services have been built & organized under one roof. Equipped with an arsenal of high tech imaging modalities dedicated to complex cardiovascular treatments, it aims at optimizing the care of cardiology patients.





11,000 m² dedicated to Cardiology, designed by and for caregivers

From the beginning, the project was driven by the desire of physicians to maintain and enhance medical excellence in cardiology and cardiac surgery for the benefit of patients, with an ethical and innovative approach. Like major European cardiology centers, the project will provide a responsible and sustainable solution for local public health in a region with increasing aging population.

After the construction of the Atrium building dedicated to oncology and outpatient clinics, Clinique Pasteur, located in a dense urban landscape, carried out a major development project, connecting existing buildings dedicated to hospitalizations and consultations, even to the public transport network, thus earning the name of La Passerelle - The bridge.

The architecture firm Kardham

Cardete Huet Architecture managed major constraints around the building's construction including:

- Maintaining continuity of activity in the existing buildings throughout the construction process.
- Limiting inconvenience to the neighborhood and maintaining vital traffic flow
- Building the operating rooms at higher levels to optimize the treatment of air

Optimizing patient care

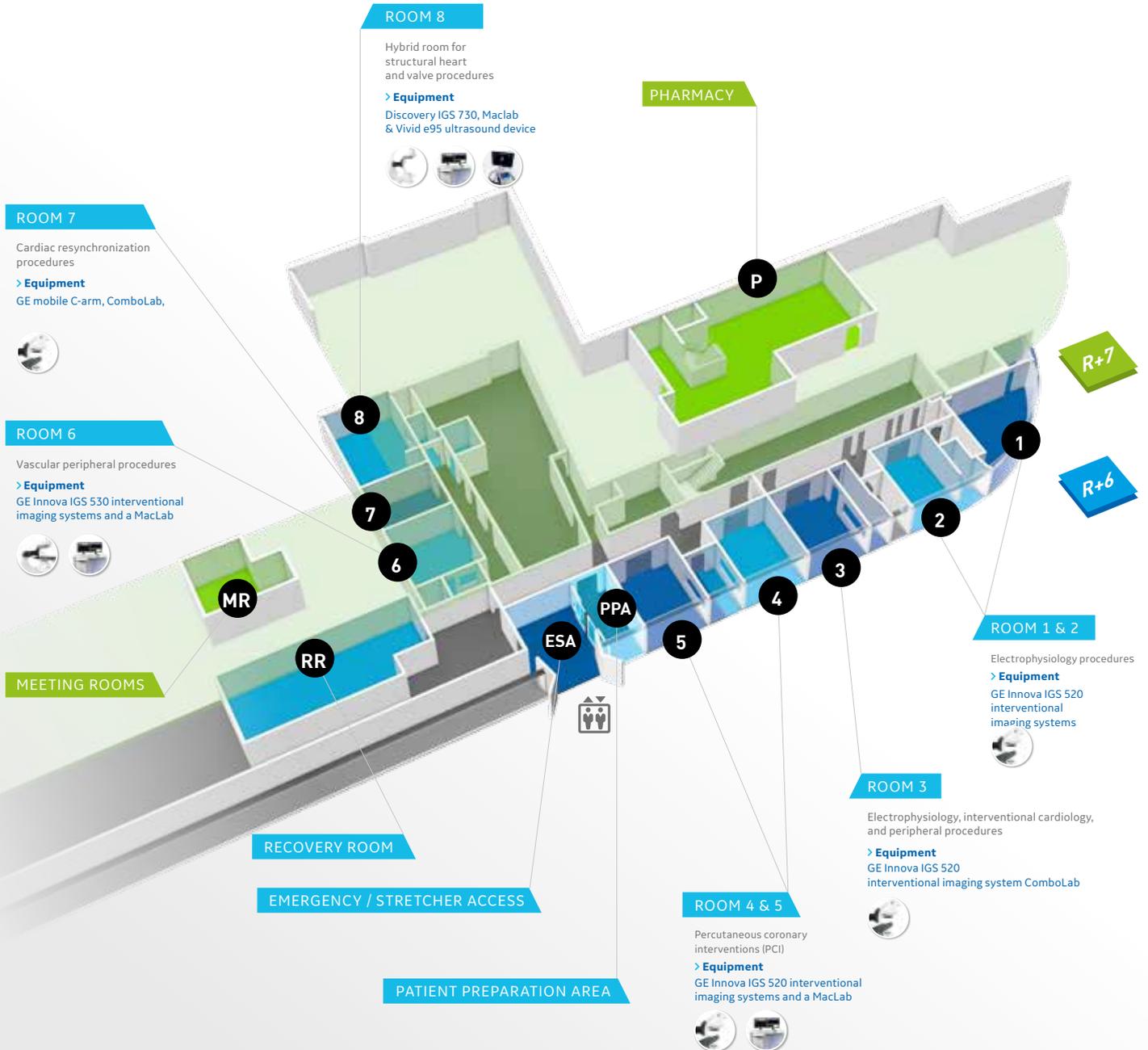
Conceived by doctors and other healthcare professionals, the building aims to optimize the care of cardiology patients, many in fragile health and in need of emergency care, by bringing together all necessary services under one roof. All patient services are concentrated within seven floors, including emergency reception for chest pain, intensive

care, hospitalization for short or medium stays, and a dedicated pharmacy.

Vertical circulation directly serves the surgical and interventional cardiology operating theaters and the medical imaging department. Patients are thus treated quickly with optimized travel times and proximity to all dedicated caregivers and technical platforms.

Upon completion of the Passerelle project, four cardiologists from Clinique Pasteur shared their perspectives on the new facility and what it means for patient care.

- Pharmacy - inside the cathlab department **R+7**
- Cathlabs **R+6**
- Short Stay Interventional Cardiology Unit & Patient rooms **R+5**
- Patient rooms **R+4**
- Chest pain Unit 24/24 and ICU **R+3**
- Medical Imaging Hospitalisation **R+2**
- Medical Imaging Consultations **R+1**
- Medical Imaging desk **0**
- MRI **R-1**



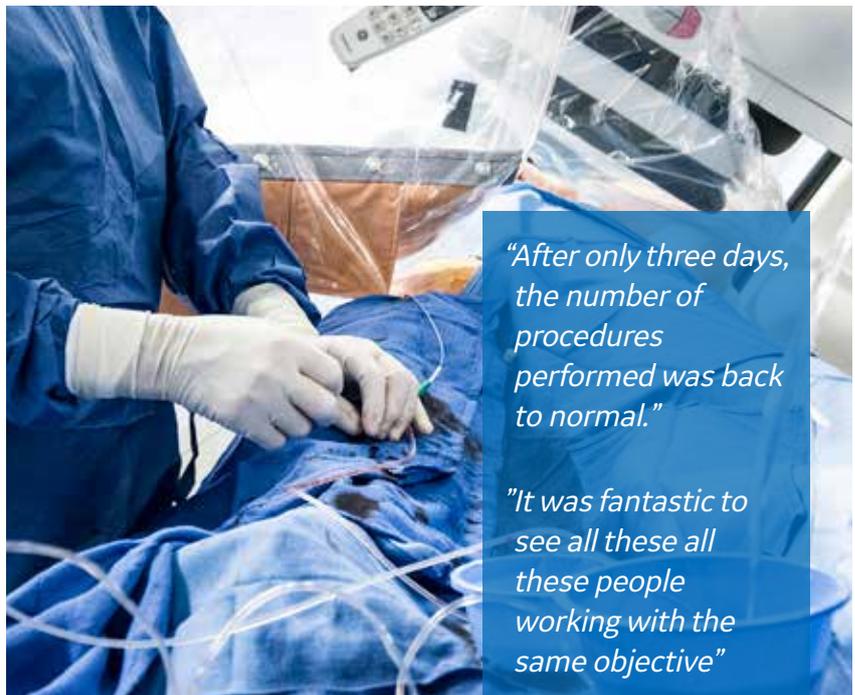
Four cardiologists share their perspectives



Dr. Jean FAJADET, Interventional Cardiologist, co-leader with Dr. Bruno FARAH of PCI program, Clinique Pasteur. EuroPCR Co-director, and past President of the European Association for Percutaneous Cardiovascular Intervention (EAPCI) executive committee.

“It is important to understand the role of interventional cardiology at Clinique Pasteur. In fact, interventional cardiology can be described as the heart of the cardiology department. All the diagnoses are done there, along with the treatments that include coronary interventions, structural heart, peripheral, endovascular procedures and electrophysiology.”

“We are celebrating the 40th anniversary of coronary angioplasty, which at the time we called PTCA. We have seen an evolution in indications of patients treated in this way. Nowadays we are treating patients with more complex lesions; with calcified, diffused disease; with multi-vessel disease; and with poor left ventricular function. We are treating more complex patients



“After only three days, the number of procedures performed was back to normal.”

“It was fantastic to see all these all these people working with the same objective”



“From the very beginning, I was impressed by the work taking place in the new rooms, by the GE equipment, and by the quality of the images.”

than in the past. And when we consider the efficiency and the safety of our procedures for the patients, the quality of imaging is certainly the most important point in the cardiology department. At the same time, as we move out of the coronary field and into endovascular, structural and valvular, vascular and electrophysiology procedures, we have followed the same trend with increasingly complex procedures.”

“We are really happy to open this new department, which is unique in the country. We now have eight rooms working every day. We initiated this project many years ago with the intent to place the patients at the

center of the system and to facilitate patient access to care. We aimed at facilitating the flow of patients from admission to discharge. We regarded imaging quality as the major criterion for achieving success with complex procedures, and that is why we selected GE to accompany us on this project.”

“The concept was to have total autonomy with respect to the rest of the hospital. One floor up to the cathlabs, we have our pharmacy for the management of devices, stents, catheters and balloons. We are working in total autonomy.”

“There was a question about our capability to adapt to a new system

when we had been working with systems from another vendor for the last 30 years. There was a question about the speed to adapt and to be comfortable. Yet we did the switch just over a long weekend, and right after this switch we came back to a normal procedure load.”

“This was very effective, thanks to GE, who accompanied all the physicians, the technicians, and the nurses. It was fantastic to see all these people working with the same objective. I think we were helped by the ergonomic design of the system, which is very intuitive and really easy to handle in daily practice. I was impressed by that.”

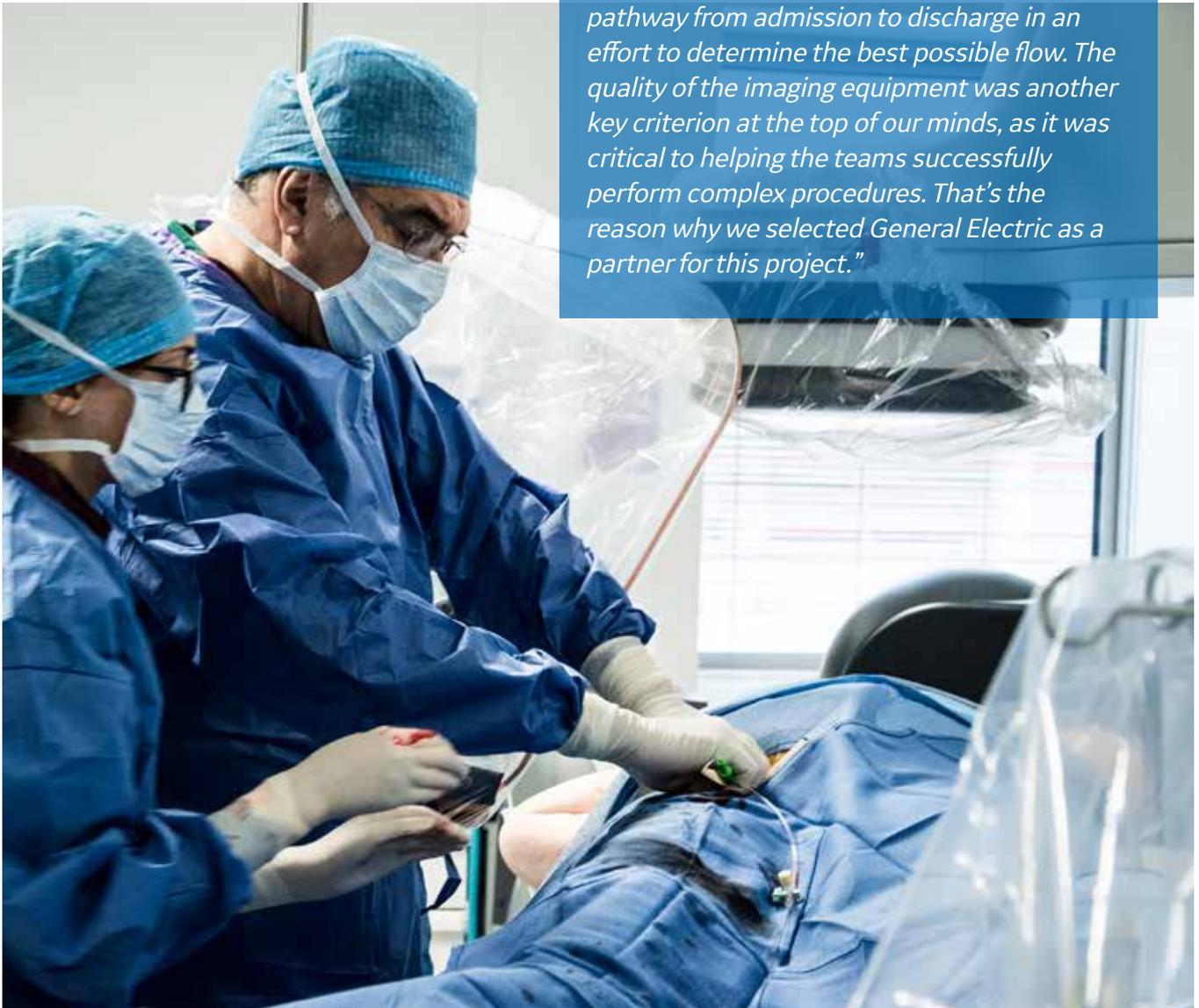
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"I have been personally impressed since the beginning by the image quality we achieve with these new rooms. That is very important, particularly for complex procedures. We have the ability to achieve different views than in the past, thanks

to the deep movements of the C arm to the right or to the left. In particular for LAD diagonal bifurcations, we see now extremely clearly the ostium of the diagonal and septal branches. The optimal visualization of the stents with Stentviz works very well. The

quality of the imaging helps with the duration of procedures, which are shorter, faster, with good results, and certainly safer for the patients." ■

"We tried to place the patient at the center of the system. This meant analysing the patient pathway from admission to discharge in an effort to determine the best possible flow. The quality of the imaging equipment was another key criterion at the top of our minds, as it was critical to helping the teams successfully perform complex procedures. That's the reason why we selected General Electric as a partner for this project."





Dr. Didier TCHETCHE, Interventional Cardiologist, co-leader with Dr. Nicolas DUMONTEIL of Structural Heart Disease Program, Clinique Pasteur.

“The structural heart program includes treatments for heart and valvular diseases, such as TAVI to treat aortic stenosis. Mitral regurgitation is treated here and is going to become a huge part of the valvular heart diseases we are addressing. We do Mitraclip, Cardioband and even transcatheter mitral valve replacement.”

“We also treat some kind of tricuspid disease. Apart from the valvular side, we also have pathologies such as septum defect, patent foramen ovale, and paravalvular leaks. So we are trying to treat all these kinds of structural heart diseases. The goal is to be able to treat them in traditional ways and also to be part of all the innovations. When a new device is available, we try to be one of the first teams to use it.”

“The new hybrid OR suite definitely has been a huge improvement for the collaboration between the cardiological team and the surgical team. We are able now to treat valvular disease percutaneously, but also from surgical access, and the same is true for mitral or tricuspid diseases. With this new

hybrid OR suite, image fusion is a clear improvement in the comprehension of valvular disease and the way we can treat it.”

“We are very proud and happy to have this type of equipment. It has been making everything easier for both the cardiology and surgical teams. We are very satisfied because at the same time we get very low doses of radiation to ourselves and the patients, while obtaining very good quality of imaging, both in fluoro and cine runs. We did not lose anything by reducing radiation dose.”

“The ability to combine echo images, and more importantly CT scanner imaging during procedures by fusion imaging, brings added value to the setup in the hybrid OR suite. The patients gain two key benefits from this new imaging set-up. First is the planning of the procedure based on the CT scan. We are now able to really plan what we are going to do. This enables shorter and more reproducible procedures, and at the end better outcomes for the patients. Second is the radiation dose reduction.”

“With the improved management of structural heart disease, we’ve learned to communicate effectively within specialties. We have to merge the skills of the echocardiographer, the anesthesiologist, the cardiologist and the surgeon. It is a new environment for us, a new philosophy. We really have to trust what the echocardiographers are telling us. They are guiding the procedures, particularly for mitral or tricuspid disease. We are more reliant on the echocardiographers’ advice than on our hands, and this is enabled by the new environment.” ■



Dr. Serge BOVEDA, Electrophysiologist, co-leader with Dr. Jean-Paul ALBENQUE of Cardiac Arrhythmias Management Department - Clinique Pasteur.

“We are a team that performs 1,500 ablations every year, along with implantation of devices such as ICDs, resynchronizations and pacemakers. About 900 devices are implanted every year at Clinique Pasteur.”

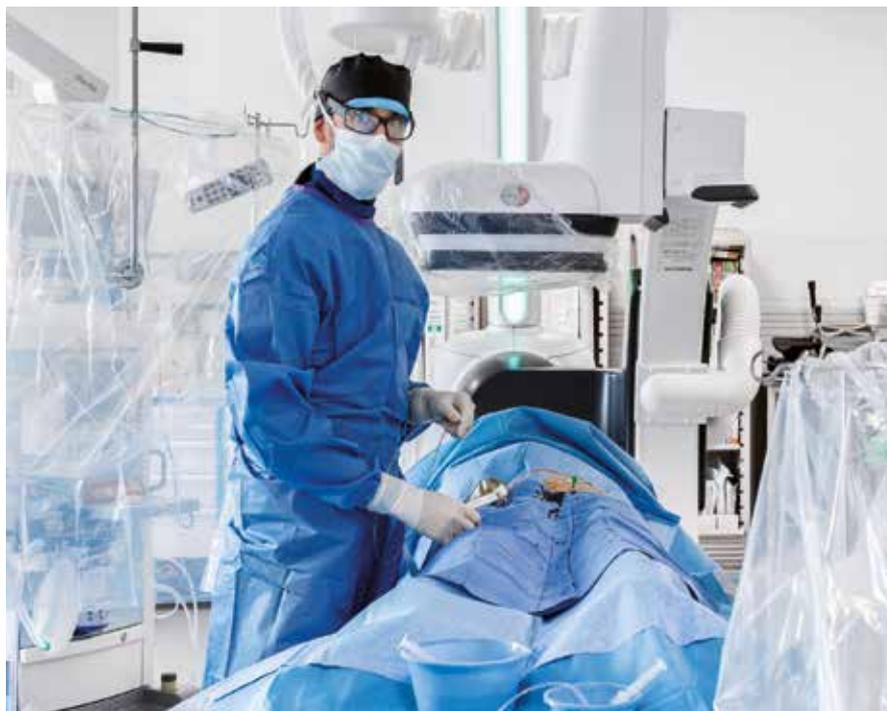
“Nowadays, the treatment of cardiac arrhythmias is more and more accurate and complex. We are treating every kind of arrhythmia, ventricular and atrial. We focus a lot on the treatment of atrial fibrillation, mainly by endovascular approaches but also surgical approaches, and hybrid approaches using both endovascular and surgical techniques. At the same time, we are treating more and more ventricular arrhythmias.”

“We went from the past to the future with a new platform that is very well equipped, with high quality imaging. The fluoro imaging is now of excellent quality, with low radiation dose, which is very important to the patient as well as the doctors and nurses. At the same time, we can integrate a lot of information with a large screen where we have access to all data needed during the intervention.”

“Surprisingly, the adaptation has been quite easy. The new system is easy to

use, so the team has been trained quite quickly. It has been easy for us to transition to this new generation of imaging systems. I think the new department is very valuable for the patients, because we can now provide high-quality treatment and high-quality procedures, thanks to the fusion of lot of different imaging in the same system. For example, we can

make a fusion between the pre-op CT scan and fluoro images, rotational angiography and 3D mapping systems, and we have all this information in a single screen. This is very important for guiding the operation and targeting the right spot at which to treat the patient.” ■





Dr. Antoine SAUGUET, Interventional Cardiologist,
co-leader with Dr. Benjamin HONTON of Vascular
Program, Clinique Pasteur.

“In the past I was more involved in coronary-angioplasty. I moved 10 years ago to peripheral angioplasties. We perform more than 1,000 peripheral angioplasties per year and more than 100 EVAR cases.”

“When we moved to the new cath labs, the purpose was to use vascular cath labs exclusively, and not only coronary/vascular cath labs with additional imaging tools like roadmap and digital subtraction angiography. We can now

also use pre operative CT scan and DSA in the room, and it is helping us to treat patients in the best way. Using fusion imaging, we significantly decrease X-ray dose for the patients and the staff.”

“When we plan to treat a patient with an abdominal infrarenal aneurysm, we have to plan the treatment strategy with the pre operative CT scan. That helps us when we use image fusion to precisely locate the renal arteries and

the superior mesenteric artery, and to place the prosthesis at the right location for the endograft deployment. We can reduce the dose thanks to the use of the pre operative CT scan, and it also allows us to decrease the amount of contrast media and decrease the X-ray exposure time versus in our previous cathlabs.” ■



Dr. Bernard ASSOUN,
Interventional Cardiologist and
CEO,
Clinique Pasteur

“Two of the essential values for this new establishment are clinical excellence and innovation. This project is the culmination of a remarkable

partnership with GE, which has been closely aligned with these essential values.” ■



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.

GE interventional imaging systems help you plan, guide and assess your wide range of interventional procedures precisely and efficiently. The new generation of ASSIST advanced applications allow you to extend your clinical capabilities and help simplify and streamline your procedural workflow.

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