ASSIST MAGAZINE

Innovative Interventional Treatments

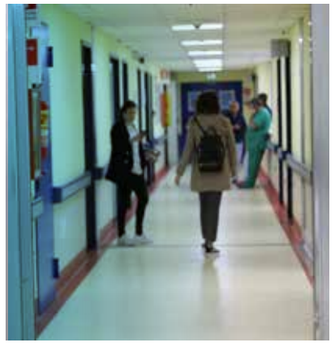
Single point of care for patients

EXPANDING SERVICE LINES IN INTERVENTIONAL RADIOLOGY

COMBINED PROCEDURES FOR MORE EFFICIENCY

Magazine#8

ASSIST MAGAZINE



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Hybrid OR

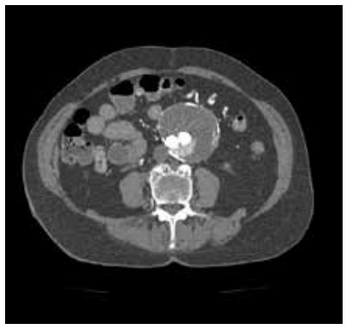
Leveraging the ASSIST softwares to maximize the outcome of a novel transgraft approach for Type II endoleak repair

Advocate Aurora Health operates 27 hospitals, more than 500 sites of care, and employs more than 3,300 physicians and 70,000 caregivers; it is the largest health system in the Midwest and of the top 10 largest health systems in the US. The vision and strategy of the institution is strongly focused on minimally invasive therapies and on using artificial intelligence to improve outcomes.

Dr. Mewissen is a vascular and interventional radiologist recognized by his peers as a world-renowned specialist in the endovascular treatment of patients who suffer from lower limb ischemia and as an expert in the use of stents in the femoral-popliteal arterial segment. He is also one of the pioneers in the endovascular treatment of complex abdominal aortic aneurysms. Dr. Mewissen has demonstrated exceptional dedication to clinical research and is currently the primary investigator for over 10 trials at Aurora St. Luke's. He recently received the 2013 Aurora Health Care Clinical Trial Research award.

What is a Type II Endoleak and what is the risk for the patient?

Endoleaks occur in 20–25% of patients after EVAR. Type II endokeaks, the most common, are the result of retrograde flow from arterial aortic side branches refilling the aneurysm sac. They are complex vascular structures that contain an endoleak cavity, or nidus, with several feeding and draining vessels, similar to an arteriovenous malformation. Most are transient and either resolve spontaneously within a few months or remain benign. However, persistent type II endoleaks can be associated with sac expansion and therefore require secondary interventions to avoid rupture. Most clinicians consider reintervention for patients with type II endoleaks who have aneurysm sac growth of > 5 mm or persistent endoleaks (> 6 months).



Example of type II Endoleak on CTA

What are the different conventional approaches to repair a Type II endoleak and what are their limitations?

Successful type II endoleak embolization requires complete obliteration of the aneurysm sac as though it was the nidus of a vascular malformation. Most commonly used endovascular techniques include transarterial embolization (TAE) and translumbar embolization (TLE). TAE requires catheter and guide wire manipulations through small and tortuous arteries, which can be technically challenging if not impossible in many instances. TLE is not always feasible due to the location of the endoleak relative to the inferior vena cava, bowel loops, kidney, or its location in the pelvis where safe needle access is impossible owing to surrounding bony structures. Despite satisfactory results reported with TAE and TLE, some anatomic and technical limitations remain, the most important of which relate to incomplete or partial elimination of the endoleak nidus. Incomplete embolization invariably leads to continued aneurysm sac growth.

Can you describe the unique transgraft approach? How did this idea originate and what benefit does it provide?

Transgraft embolization (TGE) was designed to access the aneurysmal sac from within one of the limbs of the endovascular graft (1). The technique uses laser energy to micropuncture the endograft via a transfemoral arterial approach. The laser atherectomy catheter is tracked through a 6 french C-shaped steerable guide advanced into one of the limbs of the endograft and aimed at the anatomic location of the endoleak (based on thorough 3D analysis of the CT angiogram). A quick burst of laser energy allows for micropuncture of the endograft and advancement of the laser catheter into the sac. A 0.014-inch steerable guide wire then serves as a track for the microcatheter (Echelon 10; Medtronic), which can be predictably advanced into the nidus of the endoleak to be treated. TGE is an attractive method compared to TAE and TLE because catheter access into the endoleak is predictable and precise, regardless of its anatomic location. The risk of partial or incomplete treatment of the nidus is minimized or even eliminated, compared to the other described techniques.

What is it about GE's software that allows you to complete the TGE procedure so successfully?

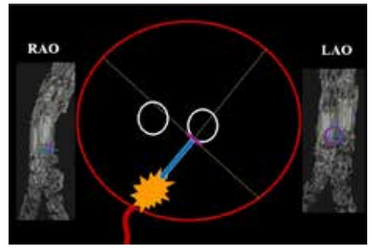
The ability to create a vessel model from the CT Angiogram and overlay it during our case is of great benefit to the success of the embolization procedure. In creating a model with planning lines, we can visualize the patient's endoleak anatomy under live fluoroscopy and use that anatomic representation to precisely identify the optimal location to laser puncture the endograft and navigate a microcatheter to the center (nidus) of the endoleak. This allows us to ascertain, with confidence, that the embolic material (Onyx) is delivered accurately and effectively and minimizes the risk of recurrence.

Can you elaborate on the value of GE's Advanced Fusion options that help you maximize the outcome of these specific procedures?

GE's advanced fusion techniques greatly simplify this procedure and aid in its success. From the AW, we can grow out a vessel model from the CT angiogram and use it to plan our procedure. From this model, we identify the target point from the graft to the center of the nidus to embolize and draw a planning ring around it. We also create a line perpendicular to the exit point through the graft so that we know the angle at which we would like to transect it. During the procedure, Bi-View Registration is used to align the patient's anatomy properly with our model and maintain accuracy. We are able to switch between the bullseye view and the perpendicular line view using saved table and gantry positions to track our progress and ensure an accurate navigation to the target.

How many patients have you been able to perform this procedure on and what successes have you seen?

We've treated about 50 patients using the TGE method and have seen a decreased or stable aneurysm sac size in 85% of patients based on their follow-up CT Angiography.



Mock up of planning stages; ring (purple) placed on endograft limb (white) at puncture site. Catheter (arrow) directed to endoleak nidus (orange) for accurate and complete embolization

Type II Endoleak treatment using transgraft approach guided with image fusion

Clinical Case

Introduction

This patient's CT Angiogram post-endovascular abdominal aortic aneurysm repair showed a Type II Endoleak originating from a lumbar artery. Dr. Mewissen performed a complete embolization of the endoleak nidus using the TGE technique outlined above.

Plan

Prior to starting the procedure, the CT Angiogram was used to create a Volume Rendered (VR) model of the endoleak nidus to be used as an overlay during the procedure (Fig. 1). On the same model, a planning ring and line were drawn to identify the entry point into the nidus through the graft.

Guide

During the procedure, a Digitally Rendered Radiograph (DRR) of the stent model was overlaid using Bi-View Registration and used to confirm the registration of the 3D VR with the patient's anatomy throughout the case. The gantry was shifted between two positions to visualize the purple planning ring and the blue planning line in the plane of the detector in order to measure progress (Fig. 2).

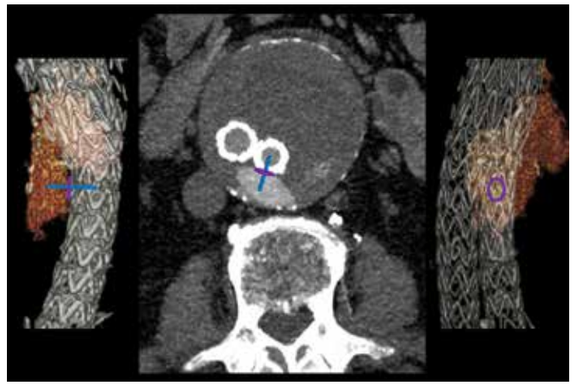


Fig. 1 Endoleak Nidus/Planning lines from CTA with 3D model

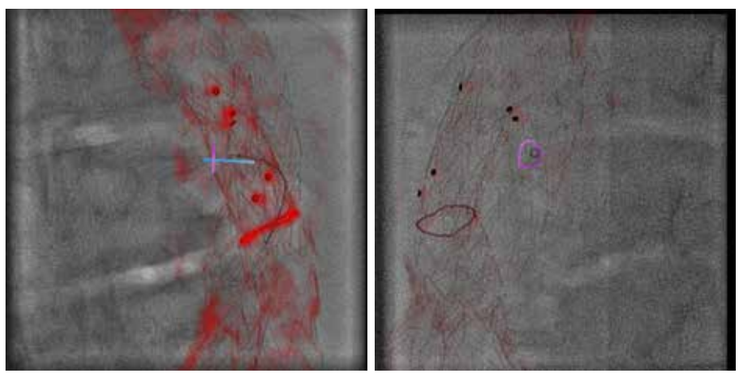


Fig. 2 Progress Views Normal to Planning Line (left) and Planning Ring (right)

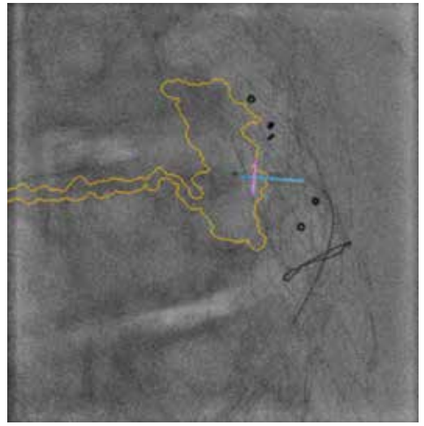


Fig. 3 . Outline View of Nidus/puncture with Planning Lines

The planning lines were used in conjunction with the outline view of the nidus model in order to confirm position of the catheters and wires during the procedure. Using these views, Dr. Mewissen was able to perform his trans-graft puncture to embolize the endoleak with Onyx (Fig. 3).

Assess

While embolizing with Onyx, Dr. Mewissen was able to use the DRR stent model to simultaneously confirm the precise location of the microcatheter into the nidus model as well as the flow of Onyx into the nidus outlined by the VR model (Fig. 4).

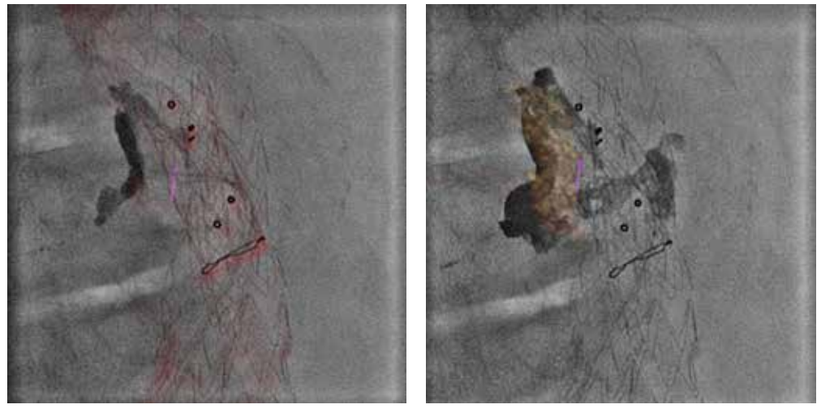


Fig. 4 Confirmation of the Model Registration and Nidus Embolization

Conclusion

The advanced fusion techniques available on the GE Innova system allowed Dr. Mewissen's team to complete a TGE resulting in complete obliteration of the nidus. The ability to adjust the model registration under live fluoro and view it in multiple angles contributed to the speed and success of the case.

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Interventional Radiology

Increasing diagnostic confidence and reducing radiation dose in PAE using Cone Beam CT based planning and guidance solutions

By Francisco Cesar Carnevale, MD, PhD*

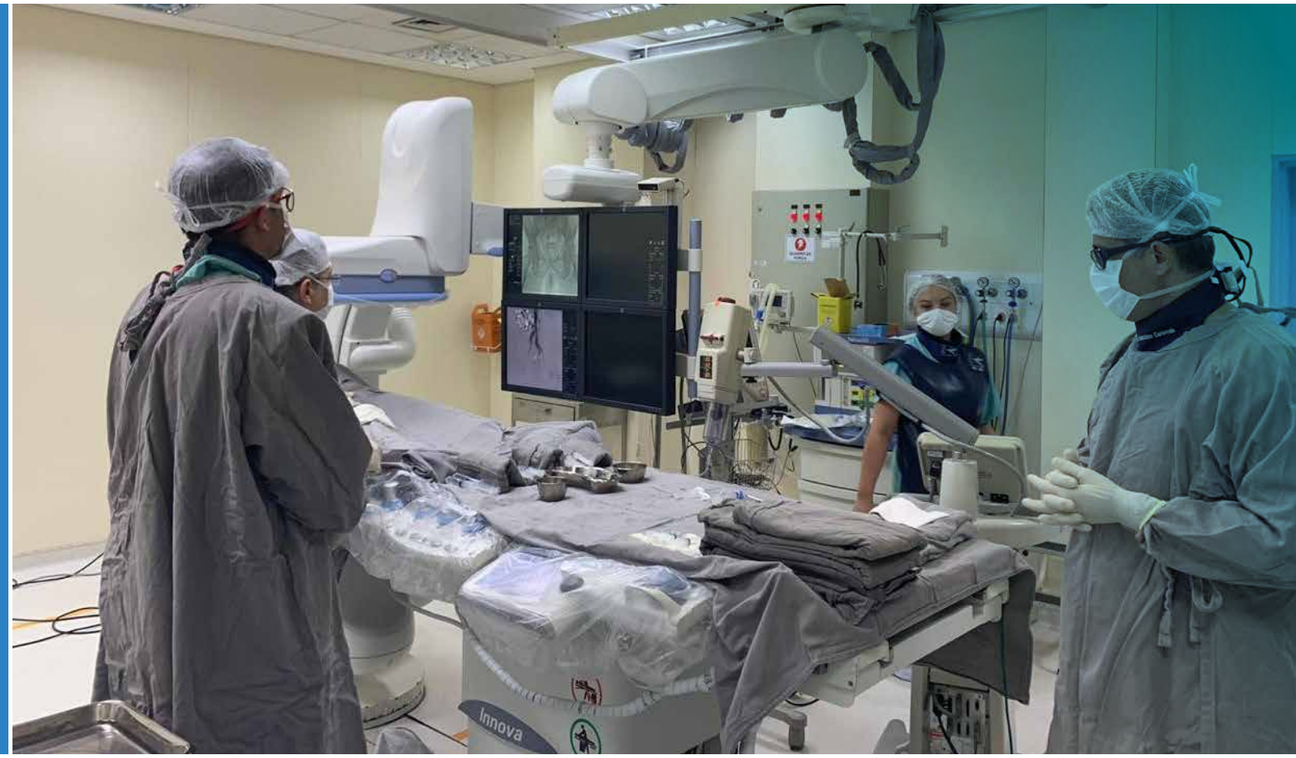
"One of the main challenges in PAE is the identification of the prostatic arteries, including its origins and connections to surrounding organs. With Cone beam CT (CBCT) acquisition and segmentation techniques we are now able to correctly assess the prostatic vascularization, increasing diagnostic confidence. This also helps avoiding repeated DSA imaging, reducing use of contrast media and radiation exposure to patients and interventional team."

Interventional Radiology

Francisco Cesar Carnevale is Professor at the Hospital das Clinicas da Faculdade de Medicina at University of Sao Paulo Medical School, Chief of the Section for Interventional Vascular Radiology, former President of Brazilian Society of Interventional Radiology and the pioneer of the PAE procedure.

About the Institution: Hospital das Clinicas Complex has a total area of 600 thousand square meters with about 2,400 beds between its eight specialized institutes and 2 Hospitals. “Pride in Doing Best for People, with People” is the commitment and the reason why every member of the Institution devotes their efforts day after day.

Collaborators: Arthur Rocha, MSc, Rodrigo Souza, Adv. Application Specialist, Thomas Martin Doring, PhD, Clinical Product Manager GE Healthcare LATAM.



Benign Prostatic Hyperplasia (BPH) is one of the most common diseases in men over 50 years of age. Prostate Artery Embolisation (PAE) is a minimally invasive procedure that has emerged as an alternative treatment for surgery to treat BPH. It is a non-surgical X-ray guided procedure aiming at blocking off the arteries supplying the prostate and making it shrink. We asked Pr Francisco Cesar Carnevale, an interventional radiology expert who heads the section for interventional vascular radiology at the Hospital das Clinicas da Faculdade de Medicina at University of Sao Paulo Medical School, to share his thoughts regarding PAE technique and the evolution of this procedure.

How does PAE technique emerge?

Pr Francisco Cesar Carnevale: *“PAE was introduced into clinical practice as an alternative of treatment for lower urinary tract symptoms (LUTS) due to BPH in June 2008 after a successful experimental study in dogs in 2007. A pilot study[1] including two patients suffering from urinary retention with high risk for traditional surgery (transurethral resection of the prostate - TURP) due to several comorbidities were treated. Patients had the Foley catheter removed, symptoms relief and improved quality of life after PAE.”*

How many PAE procedures have you performed so far?

Pr Francisco Cesar Carnevale: “We have performed about 500 procedures since we performed the world first PAE in a patient with BPH in June 2008.”

What are the main challenges of this procedure?

Pr Francisco Cesar Carnevale: *“The biggest challenge is the identification of the prostatic arteries including their origin and potential connections with other anatomical structures like the rectum, penis and bladder. Another big challenge is the superselective catheterization of the prostatic arteries and the placement of the microcatheter in the most appropriate position. It is crucial to fully understand the anatomical region being fed by the catheterized artery to avoid non target embolizations. In many patients, we identified, and had to catheterize several prostatic arteries and shunts, making the procedure even more challenging.”*

What would be the ideal imaging solution?

Pr Francisco Cesar Carnevale: *“The ideal imaging solution would help to identify these arteries, with a minimal amount of angiographic acquisitions, help guide the microcatheter to the right position, and confirm the prostate territory that would be embolized from this position, in order to limit risks of non-targeted embolization and achieve better technical and clinical results.”*

Why is a training program crucial to become efficient in this practice?

Pr Francisco Cesar Carnevale: *“It is key to practice and share our experience with the community. Training programs aid physicians to achieve good clinical success while minimizing risks of complications. Our institution’s training program includes theoretical and practical sessions through the use of simulators and live cases performed under proctor supervision. After theoretical and edited cases and playing with PAE cases in simulators, physicians are able to scrub and actively participate during the live cases. They can use microwires and microcatheters experiencing our recognized PErFecTED[2] (Proximal Embolization First, Then Embolize Distal) technique. It’s an amazing experience for everyone.”*

Can you describe the importance of the PErFecTED technique?

Pr Francisco Cesar Carnevale: *"The PErFecTED embolization technique has been developed in our institution. Medium and long-term follow-up in different centers worldwide using this technique have demonstrated better clinical and imaging results, both in terms of symptoms and quality of life, as well as higher incidence of prostate infarcts with volume reduction and lower rate of symptoms recurrence at long-term follow-up."*

How do you envision the evolution of PAE?

Pr Francisco Cesar Carnevale: *"After celebrating the 10th anniversary, PAE is now recognized as an alternative treatment for patients suffering from LUTS originating from BPH. It has been demonstrated to be safe and efficient[3] to treat different BPH-related symptoms. However, there are different areas of research with the aim to identify the best candidate for PAE as well improve its technical aspects. There's a huge opportunity for physicians and companies explore the field of PAE trying to understand the patient's expectation. We have an international collaboration team working hard in this field of innovation and new tools will help physicians to bring alternatives for patients."*

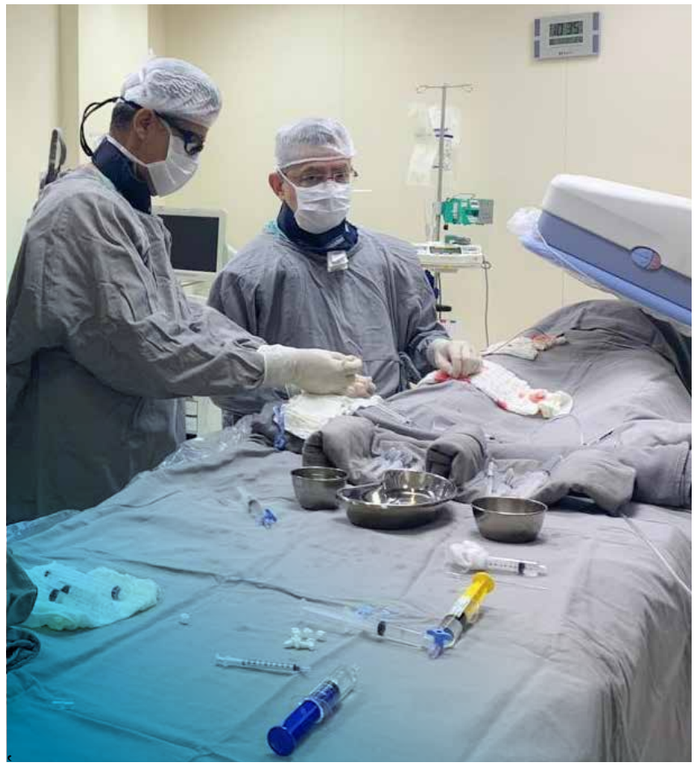
What equipment are you using for your PAE cases at Hospital Das Clinicas of the University of Sao Paulo Medical School?

Pr Francisco Cesar Carnevale: *"In our institution, we work on a GE Innova 4100-IQ system which has been upgraded early 2019 with Vessel ASSIST[4]. This solution allows pelvic and prostatic vascular anatomy segmentation from CBCT and 3D augmented fluoroscopy."*

Can you share your experience with the Vessel ASSIST solution for your PAE practice?

Pr Francisco Cesar Carnevale: *" In the past, several Digital Subtraction Angiographies (DSA) had to be repeated to correctly identify and characterize the internal iliac and prostatic arteries. It was cumbersome and time-consuming. Now we can switch from DSAs to cone-beam computed tomography (CBCT) to image the overall pelvic vascular anatomy. With the Vessel ASSIST solution, we can fuse the segmented 3D arteries over real-time fluoroscopy to assist the interventionalist during the catheter navigation. This has changed the way we perform PAE. With this new solution, we have reduced procedure time and radiation levels. We feel more confident in planning the procedure during the treatment. It's a new exciting era for PAE."*

Below two cases on patients presenting with BPH, enlarged prostate, suffering from disturbed urinary function, with recurrent daily and nightly urinary incontinence, abdominal pain and weakness.



Case 1

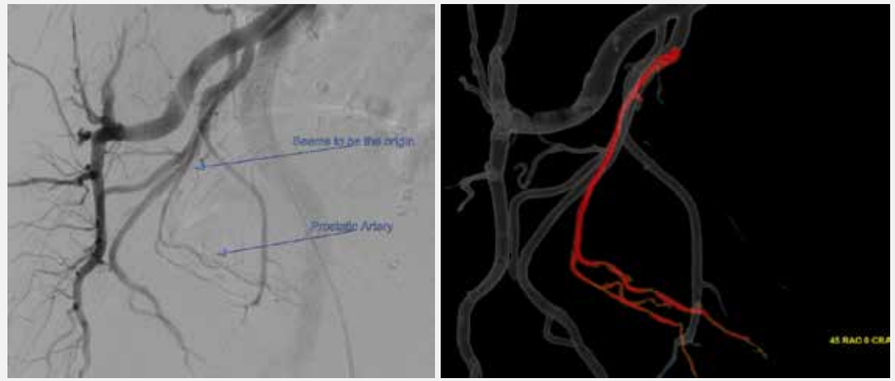


Figure 1. *57 years old male patient.* ***Left:*** *45° ipsilateral DSA showing vessels overlap hiding the prostatic artery's origin.*
Right: *CBCT imaging depicting the ostia of the prostatic artery (classified in this case as Type 1 anatomical variant[6,7]).*

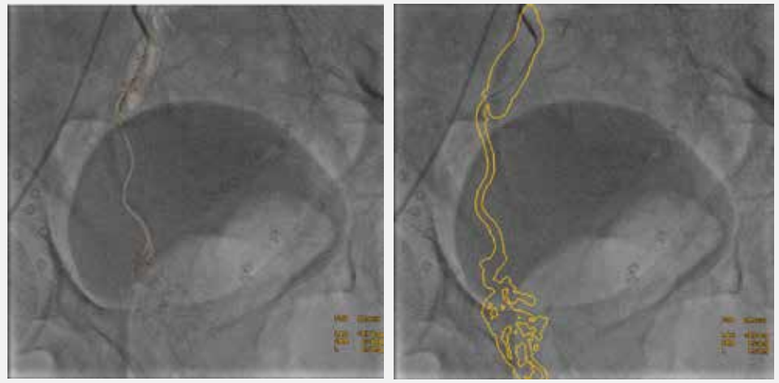


Figure 2. *Vessel ASSIST.* ***Left:*** *overlay of the segmented prostatic artery and the ostium from the right internal iliac to help navigate to the desired injection point (which will be further confirmed with distal CBCT acquisition).*
Right: *outline rendering can be helpful to enhance catheter visualization.*

Figure 1 illustrates why 2D DSA alone is limited to accurately identify the origin of the prostatic artery. In our experience, it is often necessary to acquire a second or even a third DSA. A CBCT 3D image provides a comprehensive understanding of the vascular pelvic anatomy with a higher accuracy. This can lead to a reduction in radiation dose when compared to multiple DSAs.
As an example, in this case, the left side DSA Air Kerma was 31.5 mGy while the CBCT Air Kerma was 52.8 mGy.
Without the CBCT, one or two additional DSAs would have been needed resulting in a total of 63 mGy or 95 mGy. In this scenario, CBCT allowed a dose reduction of 16% to 44%[5].

Case 2

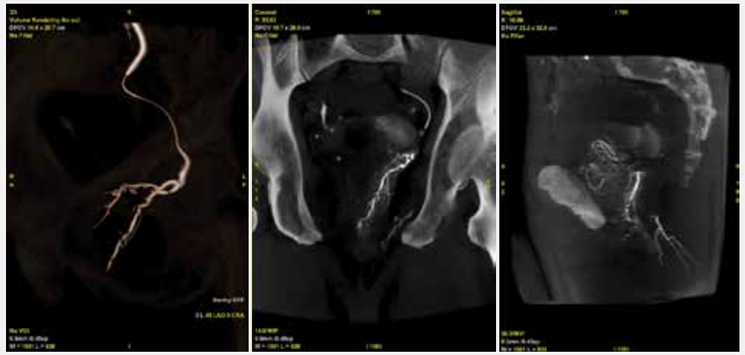


Figure 3. *Left Prostatic Artery: Selective CBCT helped depict a rectal branch. To avoid risks of non-target embolization, a coil was deployed to protect the rectum.* ***Left:*** *Volume Rendering,* ***Middle:*** *Coronal view,* ***Right:*** *Sagittal view.*

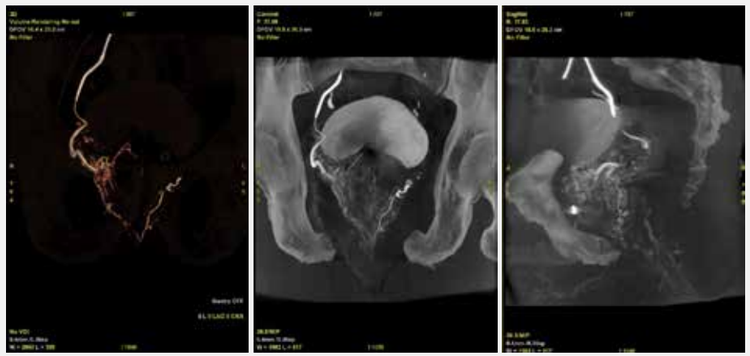


Figure 4. *Right Prostatic Artery. A vessel going to the rectum was detected and a protection coil was placed similarly to the left side.* ***Left:*** *Volume Rendering,* ***Middle:*** *Coronal view,* ***Right:*** *Sagittal view.*

Conclusions:

"When dealing with complex vascular anatomies such as the pelvic vasculature, multiple DSAs are usually necessary to identify small arteries origin and connections. This contributes to an increased radiation dose, contrast media injection and procedure time. Based on our experience, CBCT is sufficient and the best tool to characterize the vasculature and identify the prostatic arteries, and can be used instead of multiple DSAs. In our experience, this practice is associated with a dose reduction of approximately 30%."

Pr Carnevale's main takeaways:

- *Based on our experience, CBCT acquisition overcomes the limitation of the projective nature of 2D DSAs.*
- *Vessel ASSIST provides 3D visualization and segmentation of vessels. In our practice, it is key for efficient identification of prostatic arteries, their origins and connections to other organs.*
- *Vessel ASSIST provides real time fusion of 3D prostatic arteries with fluoroscopy to augment live imaging during the catheterization.*
- *We experience a significant dose reduction when using CBCT and Vessel ASSIST, in substitution of multiple DSAs.*

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* The statements described here are Dr. Carnevale's professional opinion.

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4. Vessel ASSIST solution includes Vision 2, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.
5. The Statements described here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist i.e. hospital size, case mix, there can be no guarantee that other customers or patients will achieve the same results.
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Interventional Radiology

Pushing the Boundaries of Palliative Care

St. Luke's Presbyterian Hospital, Denver CO

How two clinicians with completely different specialties are coming together in one operating room to improve the outcomes of patients with bone cancer

Dr. Daniel Lerman
Orthopedic Oncologist at OrthoONE
at St. Luke's Presbyterian Hospital

Dr. Lerman is a board-certified orthopedic oncologist who specializes in the care of adult and pediatric patients with benign and malignant tumors of the bone and soft tissue. His clinical expertise includes the treatment of sarcomas, bone and soft tissue tumors, metastatic bone disease, avascular necrosis, osteoarthritis, and complex total joint reconstructions. Dr. Lerman completed an orthopedic surgery residency at NYU Hospital for Joint Diseases followed by a musculoskeletal oncology fellowship at the Huntsman Cancer Institute at the University of Utah.

Dr. Tony Brown
Interventional Radiologist
at RIA Radiology Imaging Associates

Dr. Brown is a board certified, fellowship trained Interventional Radiologist who performs minimally invasive image-guided procedures in the metro Denver area. He trained as a resident in Diagnostic Radiology at The University of Colorado, Denver, where he was Chief Resident. He then completed his fellowship training at the Medical College of Wisconsin in Milwaukee. Prior to joining RIA, Dr. Brown practiced Interventional Radiology and was teaching faculty at Aurora Saint Luke's hospital in Milwaukee, Wisconsin.
After completing his board certification with the American Board of Radiology in 2016 he received a Certificate of Added Qualification in Interventional Radiology in 2017. Dr. Brown has broad experience in all interventional techniques with a special interest in treatment of cancer and cancer related pain. He uses a variety of cutting edge treatments including ablation, embolization and cement stabilization to treat painful soft tissue and bone that have not responded to conventional therapies. He is a published author and member of several professional organizations.

During the advanced stages of cancer, tumors can spread throughout the body and metastasize in the spine, pelvis and femur, causing excruciating pain and impairment for patients. In Denver, two doctors from different specialties are coming together in one Hybrid OR and combining their areas of expertise to treat this advanced cancer and provide patients hope for palliative care.

Dr. Anthony Brown and Dr. Daniel Lerman first met in 2017 after Dr. Brown transferred his practice to Denver. Both clinicians had experience treating patients with complex osteolytic metastatic cancer, but in different capacities. As an Orthopedic Oncologist and Surgeon, Dr. Lerman performed limb-sparing surgeries and complex limb reconstruction. As an Interventional Radiologist, Dr. Brown had worked on musculoskeletal cases during and after his fellowship, ablating tumors and stabilizing cancerous, fractured bones using minimally invasive techniques.

Dr. Lerman and Dr. Brown both understood the growing demand for palliative care for patients with metastatic carcinoma; this is the second fastest growing population in oncology. But they also recognized the challenges ; most of these patients were unable to undergo major surgery. Optimal treatments would minimize recovery time while improving patient's pain and dysfunction.

Dedicated to tackling these complex cases head on, Dr. Lerman and Dr. Brown struck up a partnership at St. Luke's Presbyterian Hospital in Denver. They would perform surgery together in the Hybrid OR, combining their respective expertise to provide more efficient palliative treatment-decreasing patient's pain and improving their function.

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A new surgical setting:

St. Luke's Presbyterian Hospital is uniquely positioned to support surgical collaborations, because it is equipped with some of the latest imaging technology, including GE Healthcare's Discovery IGS 7. A Hybrid OR is an advanced surgical room where medical staff perform some of the most complex, high-risk surgeries using minimally invasive techniques.

"To achieve an optimal patient outcome, we knew we needed to take a collaborative approach and the Hybrid OR provides a comfortable atmosphere for both Dr. Lerman and I to do this." Dr. Brown said.

Unlike a traditional surgical room, a Hybrid OR is equipped with the imaging technology, tools and space for Dr. Brown to perform interventions as well as a controlled, completely sterile environment that enables Dr. Lerman perform open surgery and implantation, if necessary.

"The sterility issue cannot be overstated; patients with an advanced metastatic cancer are typically immune-suppressed," Dr. Lerman says. "Additionally, this is a huge advantage for me as a surgeon because it allows me to quickly address any problem that may occur during the procedure and turn to open surgery if need be."

Behind the curtain - working in the Hybrid OR:

Recently, Dr. Brown and Dr. Lerman worked together to treat a patient with an advanced left pelvic metastatic bone cancer. This was a highly complex case; the patient's pelvis was completely obliterated, and he was incapable of walking as a result. Additionally, the patient was unable to receive blood products during the procedure.

Aware of these constraints, Dr. Brown and Dr. Lerman developed a plan for the procedure. It was decided that a combined approach would be necessary to percutaneously insert screws into the patient's pelvis, inject cement to strengthen the construct and bridge the healthy parts of the bone to create a framework, which would provide a foundation for Dr. Lerman to install a replacement hip socket.

To begin the procedure, Dr. Brown used the Discovery IGS 7 to take cone-beam CT images of the patient's affected pelvis, and enabling real-time visualization using fluoroscopy. Dr. Brown then embolized the patient's left internal iliac artery with gelfoam to prevent excessive bleeding.

After the embolization was complete, Dr. Brown and Dr. Lerman had to address a major roadblock: the patient's femoral head had migrated superiorly so much that it was interfering with the screw trajectories.

"This case would not be doable by an interventional radiologist alone. Period." Dr. Brown explained. "The screws would have bounced off the femoral head."

Dr. Lerman then opened the patient's hip joint in order to remove the femoral head as well as the bony tumor region of the left pelvis. This cleared the entire pelvis, enabling the team to work more efficiently to stabilize the bone structure.

"Without the Hybrid OR, we would not have been able to handle a procedure so complex." Dr. Lerman said. *"When you are opening up the patient or working with hardware like screws, sterility is of the utmost importance."*

Once the femoral head was removed, the surgical team used the cone-beam CT images and Needle ASSIST [1] to help plan their surgical needle trajectories and map out how to effectively frame and stabilize the decimated acetabulum, or pelvic head, using surgical screws and cement.

"Needle ASSIST[1] is the best needle guidance I've seen, it is very user friendly when you're outside of the room planning the trajectory,"

Interventional Radiology

Dr. Brown says. "During the procedure, it shows very easily onto the monitor and it becomes like a video game where you put the needle along a path. It is very intuitive."

Needle ASSIST[1] on Discovery IGS 7 is designed to allow the surgical team to manually adjust the 3D anatomy overlay from tableside, which is particularly helpful in orthopedic procedures where the patient's position often changes during augmentation.

"Manually adjusting the 3D overlay to accommodate a patient's change in position is crucial in orthopedic procedures." Dr. Brown said. *"When performing these surgeries, you're moving the patient to insert screws, for example. If the patient moves and you can't adjust the overlay, then you need to stop what you're doing to capture another cone-beam CT, because you don't know where you are. To be able to manually adjust the overlay in real time has saved us countless minutes, perhaps hours, during these procedures.[2]"*

After the trajectories are mapped and the needles advanced following the corresponding path, Dr. Brown wanted to ensure the screws would be placed accurately.

"We were trying to bridge the defect in the pelvis by going from normal bone to normal bone and stabilizing it on either end." Dr. Brown says. *"But that's a difficult task because the landing zone is incredibly small – we were trying to insert an 18 centimeter screw in a 1.5 centimeter landing zone. Precision is key."*

Typically, clinicians need to acquire additional cone-beam CTs to verify the needles are in the right place, a process that takes time and increases dose exposure to the patient and clinicians. However, the Discovery IGS 7 is equipped with Stereo3D, a tool that allows clinicians to visualize their reconstructed needle placement in 3D with just two orthogonal fluoro shots.

"Had we not used Stereo3D, this complex procedure would have required nine additional cone beam CTs." Dr. Brown said. *"That would have been a massive increase in dose and added an additional hour to an already lengthy procedure. This procedure would have been non-viable.[2]"*

Once Dr. Brown was confident the needle positions were correct, he used Needle ASSIST[1] to guide the screws into their place, verifying their location with Stereo3D, connecting the healthy parts of the pelvis and injected cement for added stability.

Finally, the framework was in place for Dr. Lerman to complete the total hip replacement and insert a socket. He did so successfully and concluded the procedure.

Within two days, the patient was released from the hospital, able to move around to stimulate bone growth and healing. Two weeks after the procedure, he was walking completely unassisted.

"This surgical approach is incredibly beneficial for a patient like this." Dr. Lerman explained. *"Had we provided a conventional orthopedic surgery option, this patient would have undergone a massive operation. His quick recovery was facilitated by the fact that we were able to minimize the surgical work on his pelvis and provide a descent screw fixation through a percutaneous approach."*

Reflecting on the procedure, Dr. Brown and Dr. Lerman agree that the sterile, collaborative, high-tech Hybrid Operating Room is enabling better care for their patients.

"We're on the forefront of how these procedures should be done, and the technology is helping us do this." Dr. Brown said. *"Collaboration is irreplaceable, in my opinion."*

1 Needle ASSIST solution includes TrackVision 2, stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.

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

Embolization, Cemetoplasty Pelvic Reconstruction and Total Hip Arthroplasty (THA)

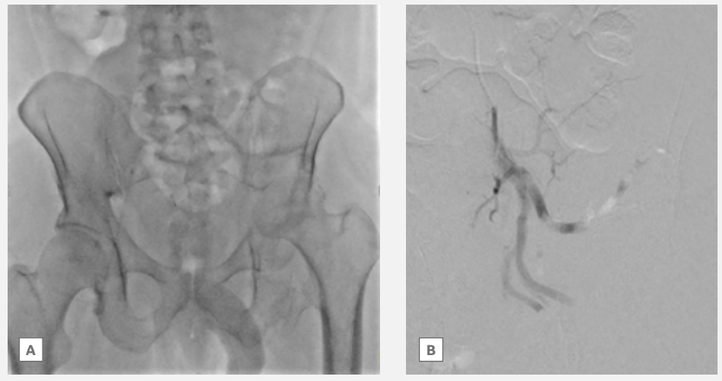
Dr. Brown and Dr. Lerman used GE Healthcare's Discovery IGS 7 and Needle ASSIST[1] with Stereo3D to help create a greater quality of life for this patient, and greatly improved his chances of walking again

Patient history

40-year-old non-ambulatory male with a history of left pelvic metastatic bone cancer with related fractures. Due to religious reasons, this patient would be unable to receive blood products during the procedure.

Step 1

Embolize the left internal Iliac artery to reduce bleeding from the pelvic/acetabular region

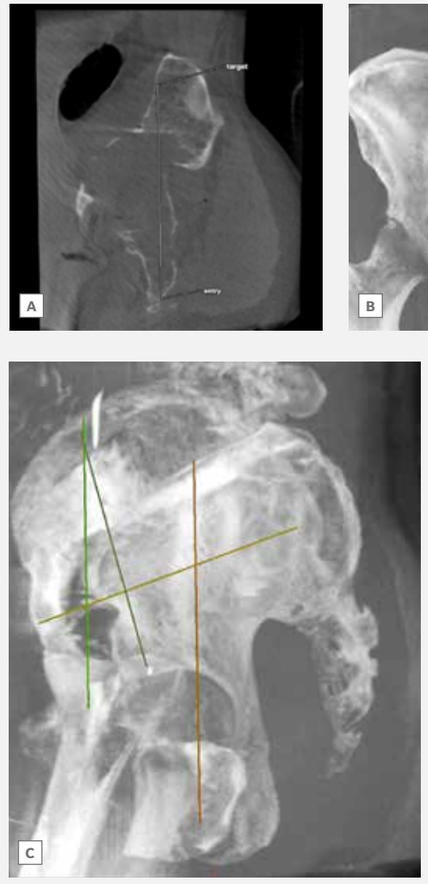


1. Antero-posterior view of the pelvis showing a left femoral head displacement (A). The left internal Iliac artery was embolized with gel foam to staunch any excessive bleeding from the pelvic/acetabular region during the upcoming surgery (B)

Step 2

Surgically remove of femoral head and bony tumor region. Planned screw trajectories

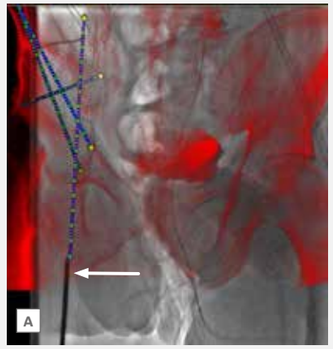
Dr. Lerman surgically removed both the femoral head and bony tumor region of the left pelvis. After that surgical intervention, the team captured Cone Beam CT for treatment planning).

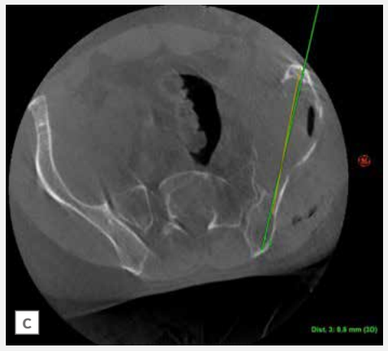


2. Using Needle ASSIST[1], the entry point to the pelvic bone and final landing position were determined for each needle on the CBCT images (A). Dr. Brown, Dr. Lerman, and the Clinical Consultant planned 4 separate needle trajectories from the CBCT to effectively "frame" the decimated left acetabulum (B, C)

Step 3

Implant fixation screws (Fig. 3) and check with Stereo 3D + inject cementoplasty for added stability

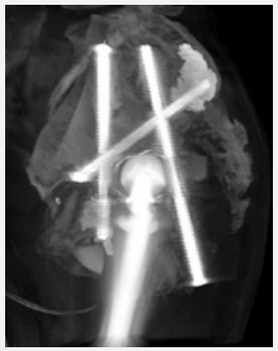




3. The first needle is introduced following the corresponding overlaid trajectory (A, white arrow), using bone rendering to check for misregistration. Upon request, the position of a needle was checked in 3 dimensions using Stereo 3D. With only 2 fluoroscopic views the system automatically detects the needle to be checked (B, dashed arrow) and shows the reconstructed needle in the initial CBCT reformatted views, along with the originally planned trajectory (C, green virtual needle). This drastically reduced both the procedure time and dose by not having to acquire additional CBCTs for each hardware component.

Step 4

Perform Total Hip Arthroplasty (THA) and CBCT for final assessment



4. Final CBCT showing the positioning of the screws and cement in relationship to the prosthesis

X-ray time	40.4 min
Cumulative	429mGy, 166.37Gy.cm¬¬2

Dr. Lerman: *"This case wouldn't have been feasible without Needle ASSIST[1,2] and, to a higher degree, Stereo 3D. Although all of the individual interventions for this patient are performed in a majority of facilities on a daily basis, this "single-point of care" approach yielded fantastic results"*

Dr. Brown: *"The procedure was a success and the patient was up and walking the next morning."*

How did you leverage the Hybrid OR setting to expand treatment options?

DR. BROWN: *This case demonstrates the importance of taking a collaborative approach and working in a Hybrid Operating Room setting. I could not have performed this as an interventional procedure, as the femoral head was in the way. Had the Hybrid Operating Room or Dr. Lerman's expertise not been available, this exceedingly complex case would have been hopeless from a surgical and interventional perspective[2].*

DR. LERMAN: *This patient had surgical opinions at other sites and I talked to him about conventional orthopedic solutions to his problem. If we performed that kind of orthopedic operation, and ignored Dr. Brown's resource, it would have been a massive operation.*

How did the Hybrid OR helped you to perform this procedure more efficiently?

DR. BROWN: *This kind of procedure is not common and only a few specialized centers around the United States are using a similar approach that Dr. Lerman and I are using. As far as I know, we are the only team using a Hybrid Operating Room. Other teams perform these surgeries in a CT room or angio suite. That said, there are incredible significant limitations in these rooms, particularly the issue of sterility.*

The features on the Hybrid OR also enable efficiency. With the gantry's large bore, Needle ASSIST with overlay adjustment capabilities and Stereo 3D, these procedures become very doable even on patients with the worst pelvic disease. As we continued to refine this technique, procedural time have already gone down and this wouldn't be possible without the advanced applications of the room.

What is the future of this kind of procedure and collaborative approach?

DR. LERMAN: *This kind of procedure is going to be focused in the palliative domain. That said, it can still provide benefits for years and years. We have many patients who walk around with metastatic cancer to their bony skeleton, and that is just their chronic medical problem. Metastatic Carcinoma is really evolving into a chronic disease, like diabetes.*

DR. BROWN: *In certain cases, patients with oligometastatic disease – a single site or limited sites of metastatic disease to the bone – can achieve disease control and survive for a long time. This procedure is still palliative in the sense that you haven't gotten rid of the cancer entirely. That said, it stabilizes the pelvis so patients can enjoy a better quality of life. This treatment presents a huge benefit because patients could have years with improved mobility.*

What unique GE Applications or design features helped improve your procedural outcomes?

DR. BROWN: *There are Interventional Radiologists who have a similar skillset as I do, who understand how to use bone corridors to stabilize the pelvis. However, most have not moved to the Hybrid Operating Room and their approach is not collaborative. Instead of working with orthopedic colleagues and taking a joint approach in a sterile environment – which I think is best for patients, especially in cases of joint destruction where an arthroplasty is needed – they do it in their own CT or angio settings.*

"The way we're doing these cases is optimal, sterile, collaborative and it is high tech. I really do believe we are at the forefront of the way these procedures should be done."

1 Needle ASSIST solution includes TrackVision 2, stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.

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

Interventional Oncology

Review of an Automatic Ultrasound & 3D Pre-operative Images Fusion Solution

A user experience in the context of Liver Ablation

Located in Cleveland, Ohio, USA, Cleveland Clinic is a non-profit multispecialty academic medical center that integrates clinical and hospital care with research and education. Ranked No. 2 in the nation by U.S. News & World Report “2017-18 Best Hospitals.”, it has 1,400 hospital beds, 101 operating rooms and 7 hybrid surgical suites. Its campus of 44 buildings includes the 377,700-square-foot Taussig Cancer Center.

Gordon McLennan, MD, is Professor of Radiology & Biomedical Engineering at the Lerner College of Medicine at Case Western Reserve University, Ohio, USA. He is also a member of the Department of Interventional Radiology at the Cleveland Clinic Main Campus. His practice includes all liver cancer treatments, covering both hepatic arterial embolization and ablation.

Percutaneous tumor ablation are commonly guided using 3 techniques:[1]

- Computed tomography (CT),
- Ultrasound (U/S) only or in combination with CT guidance,
- Cone Beam CT (CBCT) and live fluoroscopy.

None of these options is optimal, each having its own benefits and challenges.

Today, we ask Dr. McLennan to share his point of view regarding an advanced solution allowing live Ultrasound automatic fusion with CBCT, as well as with pre-operative CT, MR and PET volumes for effective needle ablation procedures in the Interventional Suite : INTERACT Active Tracker[2].

How many ablations do you perform each year?

Dr. McLennan: *"We perform 50 to 75 a year, about half in CT and half in the angio room."*

What are the imaging requirements to guide & perform successful percutaneous tumor ablations?

Dr. McLennan: *"We need to see the entire lesion, the needle path and confirm that our ablation zone entirely encapsulates the lesion and a normal zone of tissue around it."*

What modalities can you use to guide percutaneous tumor ablation?

Dr. McLennan: *"We could use CT, CBCT with fluoroscopic needle guidance software, ultrasound, ultrasound and CT, or ultrasound fusion to other imaging modalities. Certain types of ablation units can now even be used in an MRI scanner. At our institution we perform about half of our ablations in the angiography room, where we can fuse live ultrasound with all the pre-operative imaging the patient has."*

What are the advantages and challenges of ablation with ultrasound guidance only?

Dr. McLennan: *"It is easy to place the needle under ultrasound. But ultrasound alone may or may not show the lesion. Now that we have contrast, it might be possible to do it. It was not possible before ultrasound contrast. That's something we are interested in, because if you can do a procedure entirely with ultrasound and have good contrast, you save a lot of time."*

Do you use ultrasound in combination with CT?

Dr. McLennan: *"Occasionally. It is easier to place the needle under ultrasound and then use CT to check the needle location and confirm the effect of the ablation."*

What are the benefits of using ultrasound in combination with angiography?

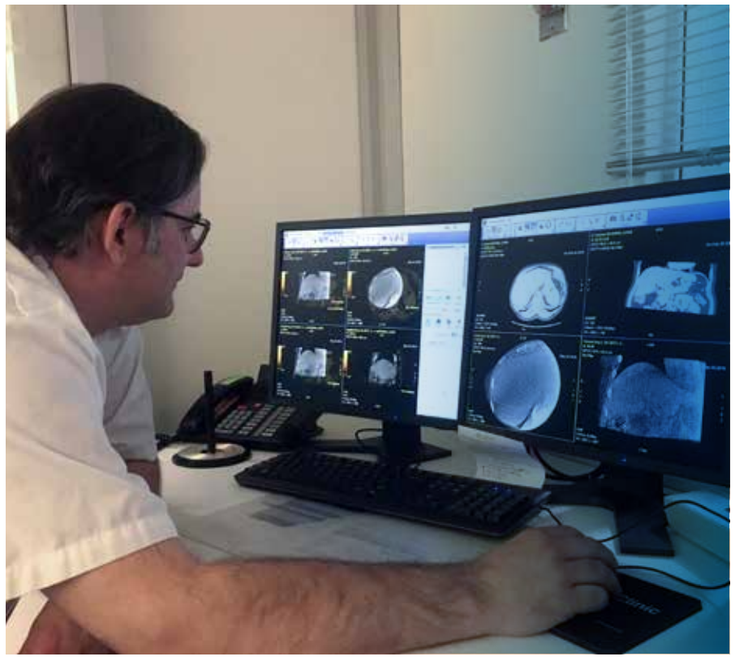
Dr. McLennan: *"In many IR departments it's very hard to get access to the CT room. INTERACT Active Tracker that allows me to easily fuse the patients pre-operative CT or MR or PET with the live ultrasound is allowing me to work within my assigned environment, which is the angiography suite, independently from which modality optimally shows the lesion. So, it eases our workflow. The combination of ultrasound and angiography also eases some complex procedures that would be difficult without toggling between the two modalities. And post-ablation CBCT can be a substitute to a confirmatory CT that we would otherwise do on the CT scanner."*

Why do you use fusion of pre-operative images with ultrasound for ablations?

Dr. McLennan: *"The fusion allows you to identify where your target is on the real-time ultrasound, even when the target is not visible under ultrasound. Then you place your needle under live ultrasound. You can then visualize with the planning software that is built in the Ultrasound, where the ablation zone will be, even before you activate the ablation device. That gives confidence that you will cover the tumor and the normal tissue margin around it. The fusion also helps you assess the actual coverage of your lesion post-ablation, even if you can not see your lesion under ultrasound anymore."*

In what percentage of your cases do you see value in fusing CT/MR/PET-CT to live ultrasound?

Dr. McLennan: *"I see value in almost all cases, assuming that the fusion process is easy to do and accurate."*



What about fusing live ultrasound with an injected CBCT acquired during the case?

Dr. McLennan: *"that is very doable, and I commonly do it when it is appropriate. Occasionally the target tumors are best seen on a very early arterial enhancement. The contrast resolution between the enhancing mass and the background liver is much more distinct on an injected CBCT than it is on the pre-procedure CT. Or sometimes I want to check that there are no new tumors. In this case, I place the electromagnetic tracker on the patient during the injected CBCT so the fusion between ultrasound and CBCT is fully automatic. When I do not need a new injected CBCT because the patient has recent images showing me what I need to see, then I usually save the contrast dose upfront."*

There are several techniques to fuse 3D volumes (CT/MR/PET/CBCT) to live ultrasound: manual registration, image-based registration, and automatic electromagnetic registration. What are the challenges and benefits of each technique?

Dr. McLennan: *"Automatic fusion is time-efficient. Manual registration and image-based fusion are essentially equivalent manual techniques. They provide a fair amount of accuracy to where your images correlate, but you have to know what you are looking at, so it takes a lot of time. Typically, I start with automatic registration, and if I am not happy with it, I would go for manual registration."*

Automatic electromagnetic registration can be used to fuse the live ultrasound to any DICOM volume showing the target, if the volume is acquired with tracker on the patient. In what percentage of your cases was the diagnostic pre-operative CT, MR or PET image acquired with the tracker on?

Dr. McLennan: *"If I do not request it specifically, the tracker is never placed on the patient for pre-operative images. For about half of my patients this last year, I requested a new CT/MR/PET to be acquired with the tracker on. It allowed me to have a more recent image and to get automatic fusion.*

When I do this, I plan the procedure on the day after the imaging study, to be able to mark the tracker location on the skin during the imaging study and put the tracker back on the exact same location for the procedure on the following day. But it's not always possible, reimbursement is not always approved, and sometimes you prefer to save radiation & contrast. "

GE Healthcare recently developed an automatic multi-modality fusion solution that allows to automatically fuse live ultrasound to any CT/MR/PET images previously acquired with no tracker on the patient, by using a non-injected CBCT acquired at the beginning of the case, acting as a bridge between live ultrasound and the other modalities. What are the benefits of this solution?

Dr. McLennan: *"it is fast. It makes the process of getting the fusion very efficient. It allows me to easily use any modality or image I already have, to guide my ablations in the angio suite."*

This new automatic multi-modality fusion solution allows the CBCT/live ultrasound automatic fusion, even if the tracker is not in the CBCT reconstruction. Before this solution, both the lesion and the tracker had to be included in the CBCT for the fusion to be automatic.

Was this often a challenge?

Dr. McLennan: *"Yes. That is a big deal, especially when centering CBCTs with large patients, meaning time delays or simply not being able to use automatic fusion."*

How long does a standard CBCT centering usually take, when no tracker is involved?

Dr. McLennan: *"Under three minutes."*

How long does a CBCT centering take on average when both the lesions and the tracker have to be included?

*Dr. McLennan: "That can take a little longer. It depends upon the size of the patient. For some patients we were just not able to do it, even with a 40*40 cm detector and the wide bore C-arm. But with the new INTERACT Active Tracker solution this should not be an issue anymore, it will help us save time and facilitate the automatic fusion workflow."*

What would you say are the main benefits of such an automatic multi-modality fusion enabler?

Dr. McLennan: *"The main benefits are:*

1. The fusion is accurate so I can confidently use preoperative CT, MR, PET or CBCT fused to live ultrasound to guide ablation probe placement, which may significantly reduce radiation dose to the patient & to the operators. I do not have to see the lesion with ultrasound, I can easily get the pre-operative imaging automatically fused to live ultrasound and use the fusion to guide me the way simultaneous CT, MR or PET imaging would.

2. With the ablation profiles stored in the ultrasound, I can confidently confirm whether my ablation zone will encompass the target.

3. Using ultrasound with an automatic multi-modality fusion solution allows me to perform ablations in the angio suite where I can approach the lesions with more complex angulations than I can in a CT or MR room."

In which cases would you recommend using such an automatic ultrasound multi-modality fusion solution?

Dr. McLennan: *"I have used it for kidneys and livers. I would use it in any case that you would consider doing in CT, especially if your access to the CT scanner is limited "*

•••

Is it possible to combine ultrasound multi-modality fusion with advanced fluoroscopic needle guidance solution?

Dr. McLennan: *"I do it commonly. Being able to efficiently toggle between these two guidances without losing any fusion allows me to adapt & optimize my guidance to any clinical situation, it is very reproducible."*

What practices or physicians do you believe would find value in such an automatic ultrasound multi-modality fusion solution?

Dr. McLennan: *"It could have impact in a variety of situations. One is small hospitals with limited resources, where tying up a CT scanner for an intervention is a problem financially. Doing ablations in an ultrasound-angiography integrated room, can be much more financially feasible while achieving the expected clinical results.*

During a recent American College of Radiology meetingin 2017, we have presented the conclusion of an analysis[3] we did to evaluate the financial impact of transitioning the interventional procedures we have been doing in our CT rooms to our Interventional suite. Our analysis showed that the procedures we performed in CT, that could have been performed in IR with no suspected clinical impact, represented ~1600 hours of room occupation per year, and that transferring them from CT to IR would increase any hospital net annual income by 1.5 million dollars on average, maintaining clinical workflow while increasing accessibility to diagnostic CT.

Some of these procedures could even be facilitated by the advanced guidance tools available in our Discovery™ IGS 7[4] angiography suite, and that includes automatic ultrasound multi-modality fusion for liver and renal ablations.

Having this complete set of advanced solutions available in a practice is also very helpful because it keeps the radiation dose down, especially for complex procedures."

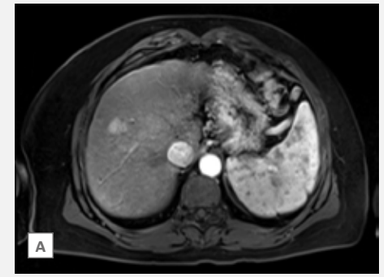
A. Pre-operative MR

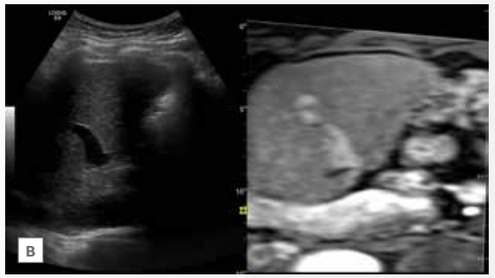
B. Fusion pre-operative MR with live ultrasound using non-injected 5 sec CBCT as a bridge between modalities (INTERACT Active Tracker, GE Healthcare)

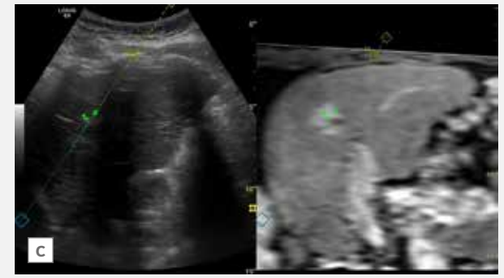
C. Needle trajectory planning and guidance

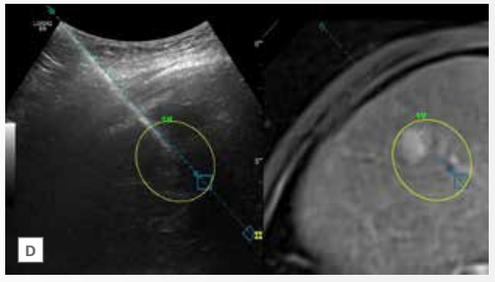
D. Microwave ablation parameters planning to optimize lesion coverage

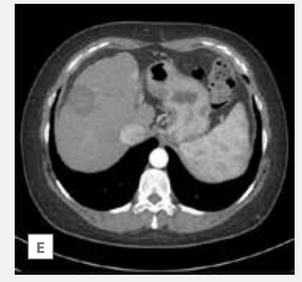
E. Post-operative confirmation of ablation zone











1. Abdel-Rehim M., Ronot M., Sibert A., Vilgrain V. Assessment of liver ablation using cone beam computed tomography. World J Gastroenterol. 2015 January 14; 21(2): 517–524. doi: 10.3748/wjg. v21.i2.517

2. INTERACT Active Tracker may not be available in all markets. INTERACT Active Tracker is an optional feature of 3DXR (part of GE vascular systems Innova IGS 5, Innova IGS 6 and Discovery IGS 7 or Discovery IGS 7OR). This feature supports only one 'Active Tracker' type: OmniTRAX™ Active Patient Tracker (sold separately). 3DXR may not be available in all markets. Refer to your sales representative. The OmniTRAX™ Active Patient Tracker contains 4 metal beads that are visible either directly in the Cone Beam CT volume or visible in some projections of the Cone Beam CT acquisition. INTERACT Active Tracker requires a LOGIQ E9 XDclear 2.0 or LOGIQ S8 XDclear 2.0 or LOGIQ E10 (where available) (sold separately) into the GE angio suite.

3 . https://www.acr.org/-/media/ACR/NOINDEX/Abstracts/2017/17012_Martin.pdf?la=en

4. IGS 740 configuration

Interventional Oncology

The One-Stop-Shop

The implications of the Discovery as a One-Stop-Shop for physicians are vast. Patients' care can be customized for efficiency, and a single case with multiple procedures is becoming a regularity in the One Stop Shop – the GE Discovery system is changing the status quo.

Wake Forest Baptist Medical Center is an academic medical center located in Winston-Salem, North Carolina. It is a preeminent, internationally recognized center of the highest quality with balanced excellence in patient care, research, and education.

Dr. Trevor Downing received his medical degree at the University of South Carolina and proceeded to complete his residency in Winston-Salem, NC at Wake Forest Baptist University. After residency, he attended the University of Michigan in Ann Arbor for an IR Fellowship in 2015. From there, he returned to Wake Forest Baptist University where he has been an Assistant Professor for the past three years.

Dr. Downing, why is the Discovery system a differentiator for "basic" IR procedures?

"Basic" IR procedures such as line placements, biopsies, and drains take up a substantial amount of our time and equipment in IR, so streamlined efficiency is a big deal here. What we are trying to accomplish is using fewer rooms and personnel to do more cases. So what would ordinarily require two rooms, two schedulings, inconvenience for patients, and inconvenience for providers can now all be done in the GE room. For example, we can combine central line placements with abscess drains or biopsies and make our workflow in IR more efficient that way.

Can you talk a bit about the typical clinical indications in a case combining an abscess drain with a central line placement?

The clinical indication we normally have for that specific request – the power line placement plus an abscess drain – is someone who comes in with a bacterial infection and an abscess within the abdomen of the body. We place a drain in that patient, and in addition, those patients are discharged from the hospital with long-term IV antibiotics. Since patients can't have an IV at home, they get a PICC line or a Powerline® so they can receive systemic antibiotics. Previously, that would have required two separate rooms so that we could do the abscess drain first in a CT-guided room. Historically that was impossible in our fluoro suites because you can't visualize around the bowel and other structures. Instead we would take that patient to do a CT-guided abscess drain and then either that same day, occupying more room and tech time, we would then move them over to a fluoro room and place a power line, or even worse, we would reschedule them for the next day in a different room, which delayed their discharge from the hospital. But now we can place the drain and the power line in the GE room; we can place the abscess drain under fluoroscopic guidance using the cone beam technology, and it not only gives us the ability to place the drain but also to see real time under fluoroscopy where that drain is going, whereas previously it was blind in the CT room. Then at the same time we can place the power line using fluoroscopy guidance so that the patient has one anesthesia encounter, and the whole time of patient being treated here in IR is reduced. The Discovery system has allowed us to have streamlined efficiency in treating patients using a single room.

Could you elaborate on the combination of a port placement and a biopsy?

In those particular scenarios, we place a lot of ports for oncology patients. Surgeons used to place them, but they are now 80% or more placed by IR because they are done so safely in the angio suite. We are also one of the highest referrals for biopsies, to establish a diagnosis or to reestablish a diagnosis. For example: a patient had lung cancer and now has a new mass somewhere in the body, and they want us to biopsy it. At the same time, the oncologist suspects it is going to be recurrent cancer, so they want a port placed. Traditionally we would do the biopsy, and we would wait for the results. We couldn't schedule the port at the same time because you can't do a port in a CT-guided room, so we'd delay the port placement, which would then delay the use of chemotherapy for that patient. The result is that you're delaying their care for about a month by the time you are able to schedule everything, which is a lot for a patient who's concerned about their cancer diagnosis. Now what we can do instead is streamline our workflow by doing both procedures in the GE room. Now by the time the biopsy results are back, the port is healed – ready to be used – and it's a one-stop-shop for the oncologist. They don't have to keep sending the patient back to IR for various visits.

What are the main advantages of the one-stop-shop to the hospital, the patient, and yourself?

For hospitals, doing combined procedures in the same encounter provides a streamlined efficiency – we can schedule and treat patients more quickly. From the patient perspective, if it was you: would you want to come in to get a port placed under anesthesia, go home, get a ride, and then take another day off work to come back for your biopsy? A single session of care where patients come to the hospital once and then go home is the efficiency for them. As a provider, when I do procedures in a CT room I have to stand in the room with the patient and am getting a CT dose when I do that. Since we do these procedures every day, I get a CT to my own dose every day, which as a provider is very unattractive. When we do these procedures in the GE room, we are out of the room for the cone-beam CT spins – I don't get any of that dose. Essentially all I get is the fluoro dose, which is minimal. Also from a scheduling perspective, it's difficult to find separate rooms for these cases on different days with different providers. The procedures themselves are not the bottleneck – it is the time to get the patient into the room, sedate them, and prep them that takes longest. So

...

to be able to combine two procedures only marginally adds time to a single procedure, and it effectively adds more time to our schedule. There are a lot of benefits to the GE room, and it is just nice to get it all done at once for a provider.

What is it about the GE cone-beam CT that enables you to have that one-stop-shop?

Let's just talk about ports and power lines to start. When you do those placements, the patients' arms are down because you have to be working on the chest and the clavicle. Raising those patients' arms up in the middle of a procedure is not ideal since it is a freshly-placed wound and line. The larger bore allows me to spin with a patient's arms down, and the large detector and offset c-arm allow me to image the anatomy of the pelvis, which is often hard to reach, without much manipulation of the patient. The primary enabler of the one-stop-shop is the fact that the patient does not have to move to do a spin. In the GE room, it is not a long process – the patient is in the same position from the start of the procedure to the end regardless of the fact that I'm doing procedures on two different anatomies.

How does the capability for live fluoro play into traditionally CT-guided procedures?

The live fluoro aspect is a big deal. When I teach residents, I tell them during CT procedures that it is 50% feeling – you have to get used to the feeling of pushing a dilator in a patient. When I am training someone, that is an uncomfortable feeling for me because these procedures are learned through practice. With the GE Discovery I tell residents to fluoro, and we are able to see the dilator on the wire. So they won't kink the wire, they know how deep they are dilating, and they can push the drain in to their desired point. Within CT-guided rooms, that is impossible to do. The live fluoro makes a difference – you can do your procedure under live fluoro and confirm your placement.

What would you say about the comparison between cone-beam CT and traditional CT imaging?

While the contrast resolution of a traditional CT is slightly better, we can account for that while performing our spin by spinning at the slower speeds. I would trade the contrast resolution for the ability to perform a procedure under live fluoroscopy. By using the Trajectory Planning technology, I have learned to trust it so that I can be confident that my needle will land where I want it to land during a case.

Could you talk about the software that enables you to use the Discovery as a one-stop-shop?

The Trajectory Planning is nice because you place the needle and you do not have to push a little bit, scan, push a little bit, scan, and so on. The software allows you to watch the needle the whole time so that the procedure becomes much quicker. And again, the radiation dose to me as a provider is far less in the GE room than in a CT room because I can step out to do a cone beam CT.

Regarding any complications, how does the Discovery system give you confidence?

As an example: when we do a lung biopsy, if the patient gets a pneumothorax we have to place a chest tube. It works similarly to putting in an abscess drain in that when you place a chest tube, you ideally want it to reach the apex of the lung so that when the patient sits up, the air will rise to that point and leave through the tube. In a CT room, you generally stay in the axial plane since a CT provides axial images. With the Discovery system, on the other hand, you can see steep trajectories in any obliquity. So to place a chest tube, I can use Trajectory Planning to make sure that the drain will end up perfectly at the apex of the lung, and I can watch the drain reach its target.

Do you feel like you have time to use the software during those cases?

I didn't think when we first got the machine that it would be feasible to do things quickly like that, but we can do spins on some of these patients in five seconds. It's that quick. I consider doing a spin on some of my trauma patients, which I never would have done before.

How do other teams, for example: oncologists, benefit from the one stop shop?

One of the biggest attractive features to oncologists is to offer a port, biopsy, and ablation of a lesion because for them that's the one-stop-shop. If you do the biopsy, ablation, and port placement all at once, you've done what used to take two months in one day, in two hours.

How does the one-stop-shop change your operating workflow in IR?

When we do biopsies combined with port placements, those patients tend to be predominantly outpatients; most of the abscesses with power lines are inpatients. Many of those inpatients are add-on cases, which are hard to organize into an already full schedule. So it helps a lot with scheduling to be able to say "I'll bring them in today for both of those procedures" rather than "today we will do the line and tomorrow we will do the abscess drain," which we used to do very regularly because we just couldn't facilitate it and avoid disrupting our existing workflow for the day. The one-stop-shop is a very simple concept: improve your workflow by combining procedures you can do in one place. And the more we have used the system, the more comfortable we have become with the software, the more likely we are to use it again – the opportunities open up the more you use it.

How do you envision combined procedures will change with the adoption of the Discovery as a one-stop-shop?

We've already started using the system to combine complex procedures such as a Y90 or TACE and an ablation for HCC cases. But what this system really provides is flexibility, so I could imagine using the one stop shop for combinations like a lung biopsy and a chest tube placement, or for something like a G-tube placement along with a uterine fibroid embolization. We look for the opportunities to streamline our workflow.

A One-Stop-Shop Approach to Combining a Pelvic Biopsy with a PermCath™ placement and a Powerline®

Clinical Indication

This patient required a PermCath™ for dialysis in addition to a Powerline® for vascular access. The patient also had a lesion in the pelvis, which required a biopsy. The lesion was located deep inside the pelvis, so that it was unreachable using ultrasound imaging.

Execution

PERMCATH™ AND POWERLINE® PLACEMENTS

The patient was placed on the table in a supine position with the Discovery IGS 740 in AP position over the patient's chest. Both lines were placed using only fluoroscopy and a final documentation image was captured (Fig 1).

Fig. 1. Placed Permacath and Powerline®.

PELVIC BIOPSY

Prior to starting the biopsy, a non-contrasted cone beam CT was acquired at 40˚/s and was utilized with the Trajectory Planning software to develop a pathway for the needle biopsy (Fig 2).

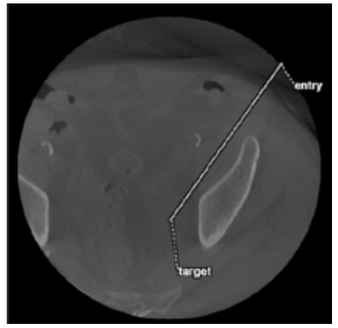


Fig. 2. Planned entry and target positions from the cone beam CT.

After identifying the target needle entry and biopsy location, the needle was inserted into the pelvis to collect the sample. Live fluoro was used to confirm needle position during the procedure, and another non-contrasted cone beam CT was acquired at 40˚/s to confirm the placement of the biopsy needle in both the axial and coronal planes (Fig 3).

Conclusion

The capabilities of the Discovery IGS 740 made it possible for the team to complete the pelvic biopsy and line placements in a single setting. The patient was able to go home on the same day after receiving all three procedures in one visit to IR in a true demonstration of the One-Stop-Shop.

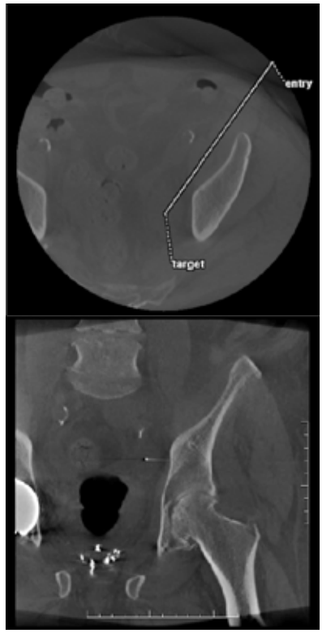


Fig. 3. Planned entry and target positions from the cone beam CT.

Case Report
using Vessel ASSIST

A One-Stop-Shop Approach to Combining a Lung Biopsy with a Port Placement

Clinical Indication

The patient had a lesion near the left lung apex, which required a biopsy. He also needed a port placed in order to start chemotherapy.

ExecutionStage

ONE: PORT PLACEMENT

The patient was placed on the table in a supine position with the Discovery IGS 740 in AP position over the patient's chest. The port was placed using fluoroscopy and a final documentation image was captured (Fig 1).

Fig. 1. Placed port.

STAGE TWO: LUNG BIOPSY

Plan

The patient was put under conscious sedation during the procedure and was placed in a supine position on the table. A non-contrasted cone beam CT was acquired at 40˚/s and used with the Trajectory Planning software to plan the path of the biopsy needle (Fig 2). A planning ring was then drawn around the lesion in the 3D volume so that it could be visualized under live fluoroscopy during the case.

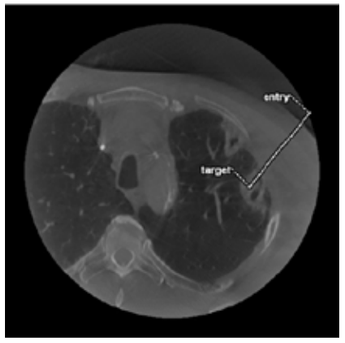


Fig. 2. Trajectory Planning for the lung biopsy.

Guide

The planned trajectory was exported into TrackVision for use in the Bullseye and Progress views (Fig 3-4) during the procedure.

Assess

After the needle was inserted, another non-contrasted cone beam CT was acquired at 40˚/s to confirm the placement of the needle in the target (Fig 5).

Conclusion

Thanks to the Trajectory Planning software, the lung biopsy on a conscious patient went smoothly, and the patient was able to receive both a biopsy and a port placement in a single case.

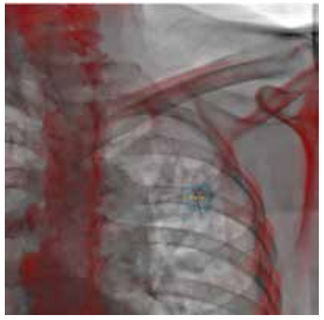


Fig. 3. Bullseye view of the trajectory.

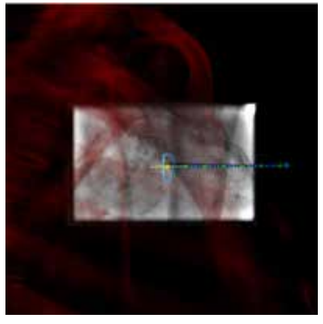


Fig. 4. Collimated progress view of the trajectory.

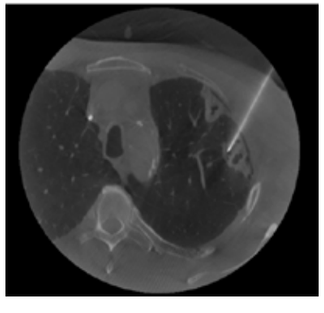


Fig. 5. Biopsy needle in target lesion.

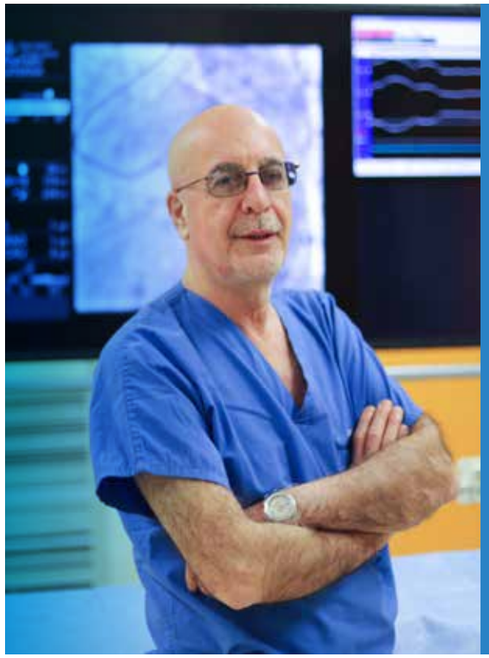
Intervention Cardiology

Innovative & high standard cardiac department in south of Italy

@ Magna Graecia University, Catanzaro (Italy)

Focused on routine clinical efficiency, as well as being capable of innovation and research, the Cardiology Department at the Magna Graecia University in Catanzaro offers a comprehensive service to the region of Calabria in the south of Italy.
We met with Pr. Indolfi and his team and could feel an incredible energy and pride in their achievements.
The main achievement was to build this department from scratch in 2000 since there was no cardiology department nor even this hospital.
In the south of Italy, few industries are supporting local economic environment, and there was a real need to build this center to support the local population.

Intervention Cardiology



Legacy of a cardiology department created in 2000

Pr. Ciro Indolfi
Head of cardiac department

Legacy of a cardiology department created in 2000

Originally from Naples, Pr. Ciro Indolfi came by chance working in the region of Calabria : Indeed there was an open position of associate professor, which he took right after his studies at the University of California San Diego in the United States.

"I had 2 big mentors: John Ross Junior and Massimo Chiariello and they pushed me to accept this position, I was ready to make a lot of sacrifices."

Pr. Indolfi met at this time the hospital director Pr. Venuta and convinced him to purchase GE solutions, which he considered to be the best equipment. *"We have a long-standing cooperation with GE, our local representative Vincenzo is near to us and is always supporting, being the interface with our department and GE organization."*

The cathlabs activity was then getting started in 2000, knowing what it means in terms of organization to set up such an activity. One of the main lessons learnt from his years in the US is that the patient should always be at the center, and this was the driver for the organization in this department.

Later on, 3 additional cathlabs were opened, the CCU, and the EPlab.

Project leaders in the different specialties have been assigned and Pr. Indolfi continued the coordination of the team developing this activity further, including the training of physicians.

In 2008 the Cardiology Department was a pioneer in this region in the development of transcatheter aortic valve implantation (TAVI), a minimally invasive option for patients too diseased to undergo open heart surgery. "*For me, the main milestone in the last 15 years is TAVI. I was skeptical that this would be feasible, at the time I was myself implanting the first coronary stents.*"

Pr. Alain Cribier came to Catanzaro to assist the first cases, and since then they have worked as a Heart Team, before the term officially existed. Pr. Indolfi strongly believes that TAVI will be the future gold standard technique, since it is a very established and successful therapeutically strategy for aortic stenosis.

"Interventional cardiology is such an exciting field, there can be surprises beyond imagination. This is what we've seen in the past! I would have never thought that TAVI would be feasible as it is today."

The team is now implanting MitraClip® (Abbott) devices and performing PFO and ASD closures. PTCA on STEMI, NSTEMI and CAD patients are routinely addressed.

Pr. Indolfi has indeed been lucky enough to witness of all these evolutions, starting with the femoral approach while now the center has moved to 100% radial approach for PCI.

High standard of care

The Cardiology Department at the Magna Graecia University offers comprehensive services provided by a highly skilled medical team. *"Our Cardiology Department's reputation is impeccable. High standards of care is the cornerstone of our success"* comments Pr. Indolfi.

The Cardiology Department is a 40-bed facility. Of those, 12 beds are dedicated to the coronary care unit (CCU) on the first floor. The CCU was built to meet the increasingly complex needs of patients from all over the region of Calabria.

General Cardiology, Cardiac Diagnostic Investigations, Cath Lab, Arrhythmia Management, Pacemaker Clinic, Paediatric Echolab, and CCU are all part of the cardiology department activities, and the main

Intervention Cardiology

axis of development of this hospital in cardiology is certainly the Cath Lab.

"My physicians have a record of nationally ranked excellence. They are known for their research and innovation that advances heart care, ensuring that the latest treatment options are available for our patients. Our physicians specialize in treating a wide range of heart and coronary conditions, and they have extensive experience diagnosing and treating advanced and complex cases."

In recent years, the percentage of patients with multivessel disease and multiple complex stenosis have significantly increased. Mostly, the complexity of these patients is characterized not only by their comorbidities but also by multivessel disease, bifurcation disease, left main disease, or stenoses of calcified or tortuous vessels, degenerated saphenous vein graft lesions, and thrombotic lesions. These specific lesion types are typically associated with lower rates of procedural success and higher rates of recurrence or major adverse cardiac events.

Equipped with the latest generation of IGS system

Pr. Indolfi believes that one of the more significant advancements for interventional X-ray in the past few years has been an increased focus on core and supporting technologies to provide high-quality, high-resolution images without a corresponding increase in radiation dose.

"I really wanted to keep the ergonomic design of the IGS, which I find helpful as it is very intuitive and really easy to handle in daily practice."

The team routinely exploits the imaging capabilities with PCI ASSIST[1]

StentViz is providing helpful information in many use cases, helping to assess stent deployment, position stents more precisely with respect to existing stents, accurately evaluate stent overlap in cases, long lesions or bifurcation stenting, and finally increasing clinical confidence with immediate and routine control of stent deployment.

"This is saving time and money by choosing the right stenting strategy to avoid additional procedures and patient re-treatment. My level of confidence about StentViz is high and it is clearly easy, cheap, and fast; it is helping me to clearly visualize stent borders and details from images in which the stent is barely visible and is providing critical clinical information" adds Pr. Indolfi. As a complement, the team uses coronary intracardiac imaging for diagnostic purposes to assess plaque characteristics, and after stent deployment also when required.

Pr. De Rosa, working closely with Pr. Indolfi, believes that the intra procedural tools should always be very simple and provide useful information such as PCI ASSIST (including StentViz and Stentvesselviz). *"In case of stent restenosis, we want to differentiate if the stent is hypo expanded or understand what is behind the restenosis. When there is a restenosis, there is a complex interplay between the flow and the angiogram and the resistance from the stent itself, and usually it magnifies"* says Pr. De Rosa. They also routinely use PCI ASSIST[1] during stent release and optimization.

A center oriented towards Research and development

Pr. Salvatore De Rosa
Head of the research activity

Research is an important side of the activity here, divided in 3 main areas: Clinical research, basic research in laboratory dedicated to cardiovascular science, and research and development applied to cardiology applications. Below three examples among the rich scope of projects the team is leading:

Radial complication prevention

The main access route used in the cathlabs in the Cardiology Department at the Magna Graecia University in Catanzaro is the radial artery. *"An issue that we're not enough aware of is post-procedural radial artery occlusion, which can range from to 6 % to 20% of patients depending on the studies"*, explains Pr. De Rosa.

Since it is mostly asymptomatic, the patient is not aware that the complication arises. When it happens, only one artery remains. The direct consequence if the remaining artery becomes occluded, the patient can lose his arm. Furthermore, if another PCI needs to be performed, the radial artery can't be reused. And for fragile patients, in case of kidney injury, no fistula can be performed.

It can simply be checked using bidimensional and doppler echo, which nevertheless requires an operator ; which in the reality is not done systematically.

"In our preliminary reference[2], we were able to identify 8% of totally asymptomatic radial artery occlusions when we check 24 to 74 hours after the PCI has been performed. This can occur despite the occlusive bandage which is applied after the procedure, and the event can indeed happen later", comments Pr. De Rosa.

One of the requirements of the study was to avoid patients having to return to the hospital, and this is the reason why we perform this on the patient's discharge.

We have about 2500 patients a year and we will involve other centers since we wish to include the pre-care of the patient, before he comes here and also the rehabilitation of the patient. This will be a regional approach.

Coronary robotization and beyond

A very specific initiative is to move toward robotization in the cathlab: the Catanzaro team has designed a robotic system to perform transcatheter angioplasty, in partnership with the university of Calabria in Cozensa, and Pr. Dianele, professor in mechatronics.

It is based on a very simple system, including both a measuring unit, called Master, used by the physician to lead the operations, and an actuation device, called Slave, located near the patient, that actively reproduces the movements commanded by the operator at the passive Master unit. Both systems require a small additional element that makes direct contact with guides and catheters and needs therefore to be sterile on the Slave unit. The system has been designed with the possibility of adding an alternative Master station equipped with two joysticks and a series of knobs and can drive up to three different Slaves, one dedicated to the guiding catheter, the second and third to balloon catheters and relative guide wires, that may be used also in coupled mode. Two patents applications have already been submitted on this topic.

"My experience with the first case was extremely positive, since it allowed the separation of the physician from the patient, ensuring the physician could keep the patient under continuous radiographic control, without being affected by ionizing radiation, while operating in the way in which he has been already trained." Comments Pr. Indolfi.

The team is not far from their final experimentation and starting pre-clinical trials. *"We believe that this system will indeed be suitable not only for angioplasty, but for a number of other procedures thanks to the ability to drive the initial catheter in situations that can be much more complex than simply reaching the coronaries."* says Pr. Indolfi. The system is potentially not very expensive, even the investment for its development was substantial.

Applications in patient workflow

Patient workflow is definitely a field that the team of Catanzaro University hospital is looking at streamlining for the benefit of the patient's comfort.

A patient tracking system based on a bracelet tagged to each patient has been developed. The patient journey can then be analyzed, since the patient is automatically scanned by panels located in the different parts of the department including at the entrance of the waiting area and in the cathlabs. "We use this to analyze the efficiency of our patient pathway and propose improvements", comments Pr. De Rosa.

"Our next project relates to heart failure patients to understand the detailed picture of this patient's management. We will use process mining which is a novel way of analyzing retrospectively data connected to patients and the process itself", concludes Pr. De Rosa.

Linking clinical routine and research in electrophysiology

Pr. Antonio Curcio
Head of cardiac electrophysiology activity

The main fields of clinical activity in the EPlab of Catanzaro university are AF ablation using cryoballoon, EP studies, RF ablation of supra ventricular and ventricular tachyarrhythmias, and cardiac rhythm management through device implantation, beyond simply intravascular devices and subcutaneous cardiac defibrillators.

The daily activity of the outpatient clinic is split into inherited congenital disease followed with noninvasive assessment in an ambulatory setting in the next building, and the activity of the EP lab described previously.

At the same time, critical patients in CCU sometimes with cardiogenic shock due to arrhythmia or persistent tachyarrhythmia, are stabilized to further be treated in the EP lab.

Looking specifically at the outpatient activity, the site is the first department in the country for the evaluation of sub-clinical AF for patients implanted with devices for cardiac rhythm.

Pr. Curcio comments two ongoing clinical studies, one from the US (ARTISIA[3]) and one from Europe (NOAC[4]):
"Both studies randomize patients with sub-clinical AF and sometimes AF but the patient is not aware that he has this arrythmia. The main question is whether or not to treat these patients."
The center belongs to the five European centers involved in the NOAC trial that are randomizing patients between placebo and anticoagulants, which is currently the recommended guideline.

Cryo and Radiofrequency ablation

Both techniques are used here. Cryoablation is used as a first approach. If an ablation has to be redone, the team prefers then carto-mapping ablation to visualize the scared tissues within the left atrium and pulmonary veins.

Pr. Curcio comments the recent Fire and Ice Clinical Trial[5], published in 2016 on The New England Journal of Medicine, comparing radiofrequency current and cryoballoon catheter ablation for the treatment of patients with drug/refractory symptomatic paroxysmal atrial fibrillation: *"It showed that the two procedures are basically similar, but the patients treated with cryoenergy required less antiarrhythmic drug therapy as compared to radiofrequency ablation patients. This study demonstrated that, as long as the cardiac electrophysiologist can see clearly the anatomy under radiation exposure, there are several clinical benefits for the patients undergoing cryo-ablation."*

In both ablation technics, electrophysioly signals remains key: *"The signal is now of very good quality. This allows us to reach the right position and place the electrode exactly where you want to study or ablate"*, comments Pr. Curcio.

On his current EP lab setting, Pr. Curcio develops: CardioLab/Mac-Lab and Carto®3* Biosense Webster[6] are integrated in this cathlab. *"When the 3D mapping engineers support us, this really enhances the communication with the physician, we then see and speak about the same thing, certainly we are more efficient. It makes us more comfortable"*. And finally, CARTOUNIVU™ Module* is available in our practice too, we use it mainly in AF ablation to reduce X-rays."

Advice to next gen

Pr. Indolfi was lucky enough to find great mentors at an early stage. He greatly recommends research fellows to choose a good mentor. *"Research fellows are not sufficiently aware that this represents a real opportunity, or do not dare ask. This is critical to get some perspective, and in this sense mentorship is of paramount importance"*.

Pr. Indolfi enjoys mentoring colleagues, supporting trainees and research fellows to initiate careers in interventional cardiology by encouraging them to perform practical training and clinical research. He also organizes weekly meetings and web-seminars.

He sees an evolution in physicians' profiles: *"I see them taking less risks and aiming to strike a balance between their private and professional lives. They want things to move faster. That's a significant change"*.

1. PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 and Discovery IGS 7 OR. PCI ASSIST refers to features of Interventional X-ray system: StentViz and StentVesselViz.
2. Indolfi C, Passafaro F, Mongiardo A, Spaccarotella C, Torella D, Sorrentino S, Polimeni A, Emanuele V, Curcio A, De Rosa S. HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed/25761194" Delayed sudden radial artery rupture after left transradial coronary catheterization: a case report. Medicine (Baltimore). 2015 Mar;94(10):e634. doi: 10.1097/MD.0000000000000634.
   De Rosa S, Passafaro F, Polimeni A, Sorrentino S, Indolfi C. A novel quick and easy test for Radial Artery Occlusion with the Laser Doppler Scan. JACC Cardiovasc Interv. 2014;7(8):e89-90. doi: 10.1016/j.jcin.2013.11.028.
   De Rosa S, Torella D, Caiazzo G, Giampa S, Indolfi C. Left radial access for percutaneous coronary procedures: from neglected to performer? A meta-analysis of 14 studies including 7603 procedures. Int J Cardiol. 2014 Jan 15;171(1):66-72.
3. Indolfi C, Passafaro F, Sorrentino S, Spaccarotella C, Mongiardo A, Torella D, Polimeni A, Sabatino J, Curcio A, De Rosa S. HYPERLINK "https://www.ncbi.nlm.nih.gov/pubmed/30279350" Hand Laser Perfusion Imaging to Assess Radial Artery Patency: A Pilot Study. J Clin Med. 2018 Oct 2;7(10). pii: E319. doi: 10.3390/jcm7100319.
4. New Oral Anticoagulants (NOAC) in Stroke Patients (NOACISP), NCT03826927.
5. Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation, N Engl J Med 2016; 374:2235-2245
6. CARTO is a trademark of Biosense Webster, Inc.

*Product availability may differ in each country. Please contact Biosense Webster to find out further information.

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

Reduction of patient radiation dose with Innova IGS 520 and PCI ASSIST during a Cardiac CTO procedure

Courtesy of Dr. V. Decalf, Pontoise Hospital Center (France)

Clinical Challenge

CTO procedures involve two parameters that must be taken into account: radiation exposure and volume of contrast media used.
The complexity of traversing the lesion, the use of dual-approach techniques increase the X-Ray exposure and contrast media volume.

Solution

The procedure was performed using the Innova IGS 520 system and the PCI ASSIST[1] Solution. PCI ASSIST helps improve visibility in larger patients without increasing the radiation dose. StentViz helps enhance stent visibility and visualization to assess stent deployment. Several features helped during this procedure: Firstly, InnovaSense[2], which automatically reduces the patient/detector distance to optimize overall procedure dose. Secondly, DoseMap[3], which enables to visualise the estimated local cumulative dose during the
exam dose with a map. Finally, a low-dose protocol, collimation and a frame rate of 7.5 fps were used throughout this procedure despite the patient's high BMI.

Clinical case

A 58-year-old man with a BMI of 31.8 (180 cm - 103 kg) suffered from stable angina with myocardial ischemia authenticated by scintigraphy. The coronary angiogram shows a multivessel complex coronary artery disease with double CTO (circumflex and RCA), LAD and obtuse marginal significant stenosis. The SYNTAX score (Syntax Score Working Group)[4] was 28.5.

After discussion in medico-surgical staff, a complete percutaneous revascularization strategy was planned. Firstly, the patient had a successful RCA CTO PCI. Then, this circumflex CTO PCI procedure. An additional LAD and obtuse marginal PCI will be scheduled after the circumflex CTO PCI.

Procedure

ANGIO

Dynamic images (Fig. 1) showed a long (over 20 mm in length) mid circumflex CTO including the origin of the marginal branch (bifurcation lesion). The proximal cap is clear but the entry shape is blunt. There is no calcification. The bending isn't superior to 45°. It's a first attempt. We calculated that the JTO Score was 2 points that means a difficult CTO.
There is only homolateral epicardial collaterals from the LAD (Rentrop classification, grade 2), none from RCA. The quality of the distal vessel is good with a 3 mm diameter at this level.
So we planned an antegrade approach with wire escalation.

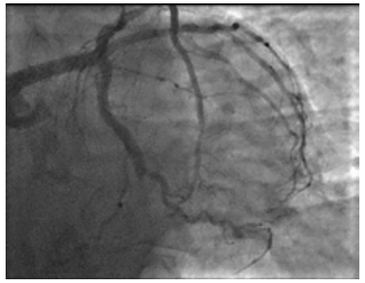


Fig. 1 Mid Circumflex CTO, Dynamic Acquisition

PROCEDURE

The procedure was performed under local anesthesia with a right radial approach and 6 french sheet. The angulation used during the procedure was LAO11°, CAU38° (Fig. 2).

- A guiding catheter was positioned in the left main coronary artery.
- Then, a coronary micro-guide catheter was used to support the guidewire during crossing attempts, to enhance the penetrating capacity of the guidewire, and to allow for easy guidewire reshaping and exchanges.
- After two attempts with two different guidewires (a polymer-jacketed guidewire and a stiff guidewire), increasing stiffness, a last one crossed the lesion and was positioned into the distal true lumen of the circumflex (Fig. 3)
- Then the microcatheter was advanced over the crossing guidewire which was exchanged for a floppy guidewire. Another guidewire was positioned distal to the marginal branch (Fig. 4).
- A predilatation of the circumflex lesion was achieved with two balloons (1.5 x 10 mm and 2.5 x 20 mm).
- A 2.75 x 33 mm DES was implanted in the mid circumflex (Fig. 5).
- A POT (Proximal Optimization Technique) is performed to optimize the deployment of the proximal part of the DES with a 3.50 x 12 mm balloon catheter.
- A StentViz acquisition was performed to assess the right position of the balloon (Fig. 6).
- After the guidewires exchange, a "kissing balloon" was realized with an 2.75 x 12 mm balloon catheter positioned at the marginal branch ostium and a 3.50 x 12 mm balloon catheter positioned in the mid circumflex (Fig. 7).

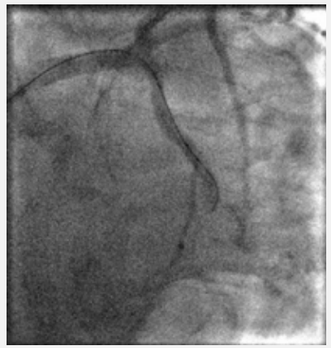


Fig. 2 Mid Circumflex CTO, Fluoroscopy - LAO 11°CAU38°

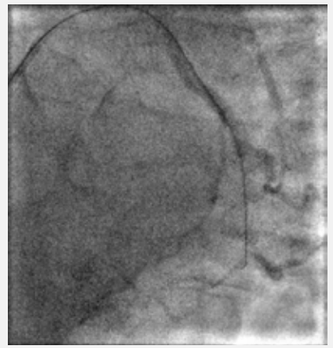


Fig. 3 CTO guidewire crossed the lesion and positioned into the distal true lumen of the circumflex

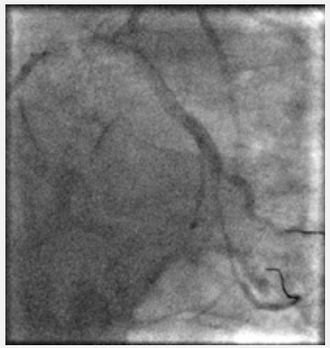


Fig. 4 Guidewires positioned distal to the circumflex and the marginal branch

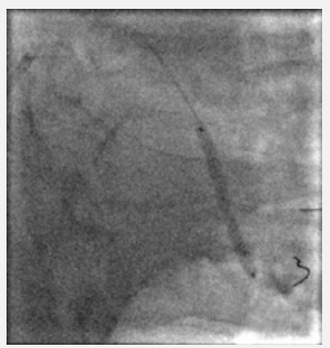


Fig. 5 DES deployment

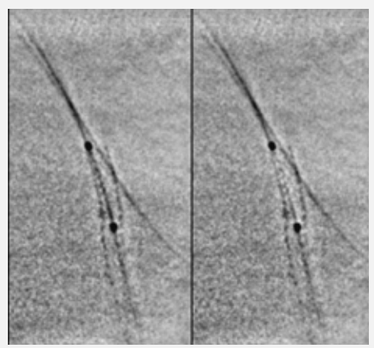


Fig. 6 StentViz

DoseMap

Result

The circumflex has been successfully recanalized (Fig.8). The circumflex/marginal bifurcation was treated with the provisional T stenting technique, one long DES in the main circumflex branch and a final “kissing-balloon” procedure to open the strut for the side marginal branch.

Conclusion

« InnovaSense allows patient contouring at the optimal distance. We use it routinely, it reduces the irradiation of the patient. Now we don’t need to think of moving the detector at optimal distance of the patient, it is done automatically. There is a clear dose reduction in routine activity and a preserved or even optimized image quality compared with previous generation systems. The image quality allows us to visualize anatomical details, unlike other imaging brands, that are too smooth and less contrasted. »

Total DAP (Gy.cm²)	40.03
Total AK (mGy)	1233
Fluoro Time (min)	17:66
Contrast media (ml)	154
DSA runs	28

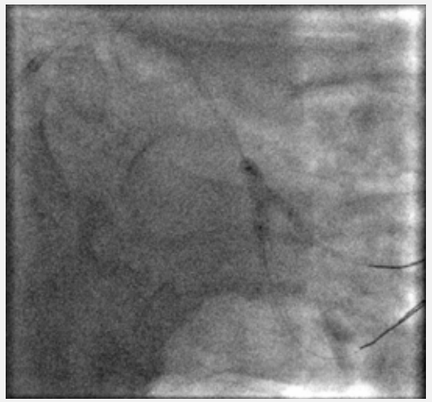


Fig. 7 Kissing balloon, Fluoroscopy

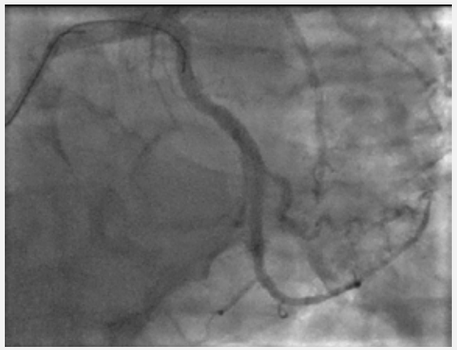


Fig. 8 Final result.

1. PCI ASSIST refers to PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 an1. PCI ASSIST refers to PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 and Discovery IGS 7 OR.
   PCI ASSIST refers to features of Interventional X-ray system: StentViz and StentVesselViz.
2. Applicable to Innova IGS 5 (IGS 520 and IGS 530 configurations), Innova IGS 6 and Discovery IGS 7 (IGS 730 configuration).
3. Applicable to Innova IGS 5, Innova IGS 6 and Discovery IGS 7.

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

4. The SYNTAX Score is a tool developed in connection with the SYNTAX Trial, a trial comparing PCI and Cardiac Surgery in complex, high-risk LM and/or 3VD patients. It is important to note that the safety and effectiveness of drug-eluting stents have not been established in these high risk patients, and physicians are strongly encouraged to review the indications, contraindications, warnings and instructions included in the products’ Directions for Use.

The SYNTAX Score and related materials are not intended to provide medical advice or guidance as to appropriate treatment strategies for individual patients. Risks and benefits should be carefully considered for each patient taking into account all available data and treatment options and physicians and other healthcare providers should always exercise their own clinical judgment for any given situation. In cases where SYNTAX Score and related materials are relevant to the diagnosis, prevention or treatment of medical conditions which can also be diagnosed, prevented or treated by any products, physicians and other healthcare providers must take care to always follow individual product instructions for use in order to ensure safe use and that the products intended performance(s) is/are achieved. Physicians and other healthcare providers are therefore cautioned that such tools are not intended to supersede individual product instructions for use in any way.

The Syntax Score and related materials were developed under the direction of the SYNTAX Steering Committee, and was made possible by support from Boston Scientific Corporation and Cardialysis BV.

GE Healthcare

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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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