



ASSIST

MAGAZINE

Innovative Interventional Treatment

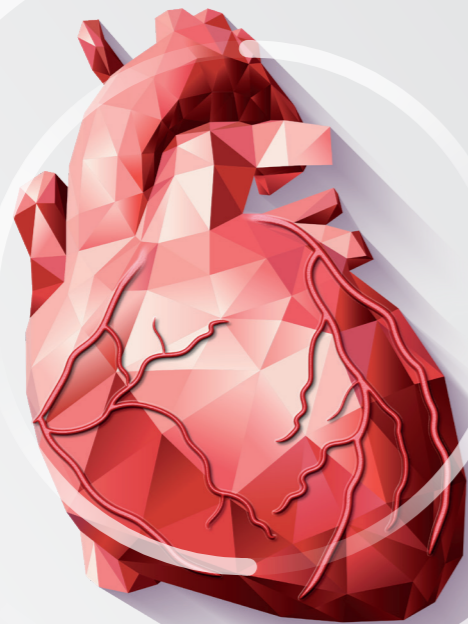


Image based FFR
with **QFR[®]**



Heart Care

Dedicated to Interventional Cardiology



A comprehensive set of solutions for the cardiac care pathway. From diagnostic to PCI to structural heart interventions, GE's portfolio provides a comprehensive set of solutions to the Heart Teams, enabling them to make the appropriate decisions for the optimal patient care pathway, in an accurate and timely manner, at very low dose.



Chantal Le Chat
General Manager Global,
Image Guided Systems



Erika Saillant
Product Marketing
Manager Europe
Interventional Cardiology
& Electrophysiology

Dear reader,

We would like this special ASSIST edition to focus on QFR® from Medis, a novel technology that derives a FFR value from angiograms only. We have developed an exclusive integration between our Image Guided Systems and QFR®, providing you with an easier workflow.

Challenges to PCI procedures and the explicit benefits of QFR® are followed by testimonials and a clinical case report on the implementation in LAD stenting.

Hoping you find this reading enjoyable.

Chantal Le Chat and Erika Saillant

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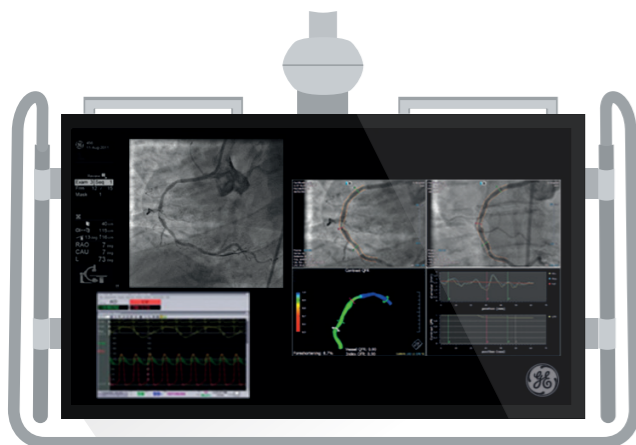
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QFR® | INNOVATIVE NON-INVASIVE PHYSIOLOGICAL ASSESSMENT

QFR®
Quantitative
Flow Ratio



QFR® IS A NOVEL, non-invasive, image-based tool that can accurately and rapidly compute FFR (fluid dynamic equations, emulated hyperaemic flow velocity), without the need for a pressure wire, nor hyperemic drug¹. Exclusive integration of GE IGS imaging systems to optimize speed of workflow.



< 5min²
av. in-procedure
time

It **ELIMINATES** some risks
and **INCREASES POSSIBILITIES**

- No wire to manipulate **Patient safety**
- No adenosine to inject **Patient comfort**
- No threat of signal drift (i.e., impaired accuracy) **Measurement accuracy**
- No limitation with tortuous vessels **Adaptation**
- Automatic QFR® pullback curve **Speed**

UNIQUE GE INTEGRATION TO ENHANCE QFR® WORKFLOW

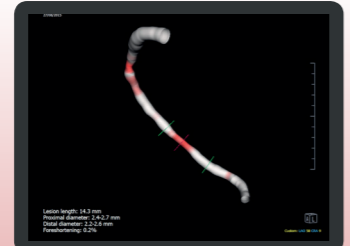
1 Guided acquisition workflow



2 projections
> 25°
apart

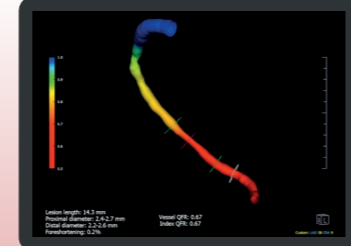
- GE Gantry synchronized with Medis QFR® software to ease second projection
- ECG synchronized to choose optimal frames

2 3D reconstruction and QCA calculation



- GE Gantry synchronized with Medis QFR® software: fast access to optimal angulations to reduce foreshortening, enabling precise lesion measurement and optimal viewing during treatment

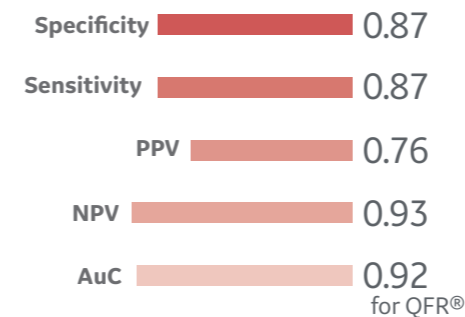
3 QFR® display



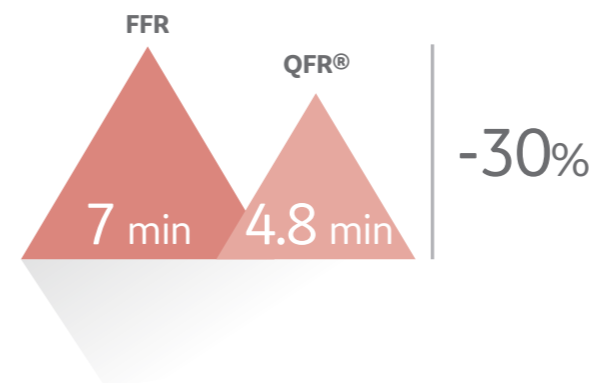
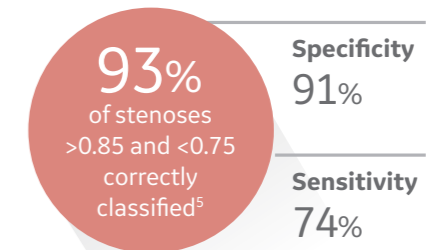
- QFR® computation and result on the large display monitor
- Dicom report created at the end of the exam

CLINICAL EVIDENCES

FAVOR II Europe-Japan³
>Results:
Mean difference ± sd QFR®-FFR is 0.00 ± 0.06 (r = 0.81)



FAVOR pilot study 2016⁴
(2016, Leiden, The Netherlands)
>Results:
QFR® improves the diagnostic accuracy of 3D-QCA.



FAVOR II Europe-Japan³

>Results:
QFR® is superior to 2D-QCA.
In-procedure QFR® is faster than FFR (30%)
Non-inferiority randomized trials are required for QFR® vs FFR.
AuC=0.92

* Available on InnovalGS 520, InnovalGS 530 and InnovalGS 540, InnovalGS 620, InnovalGS 630, Discovery IGS 730, Discovery IGS 740.

1. FAVOR II China study (2017, Bo Xu, Beijing, China)
2. Yazaki K, Otsuka M, Kataoka S, Kahata M, Kungai A, Inoue K, Koganei H, Enta K, Ishii Y - Applicability of 3-dimensional Quantitative Coronary Angiography Derived Computed Fractional Flow Reserve for intermediate coronary stenosis. Circulation Journal 2017; doi.org/10.1253/circ-CJ-16-1261.
3. FAVOR II Europe-Japan Study: Jelmer Westra, BSc; Birgitte Krogsgaard Andersen, BSc; Gianluca Campo, MD; Hitoshi Matsuo, MD, PhD; Lukasz Koltowski, MD; Ashkan Eftekhari, MD, PhD; Tommy Liu, MD; Luigi Di Serafino, MD, PhD; Domenico Di Girolamo, MD; Javier Escaned, MD, PhD; Holger Nef, MD, PhD; Christoph Naber, MD, PhD; Marco Barbierato, MD; Shengxian Tu, PhD; Omeed Neghabat, BSc; Morten Madsen, MSc; Matteo Tebaldi, MD; Toru Tanigaki, MD; Janusz Kochman, MD; Samer Somi, MD, PhD; Giovanni Esposito, MD, PhD; Giuseppe Mercone, MD; Hernan Mejia-Renteria, MD; Federico Ronco, MD; Hans Erik Botker, MD, PhD; William Wijns, MD, PhD; Evald Høj Christiansen, MD, PhD; Niels Ramsing Holm, MD - J Am Heart Assoc. 2018;7:e009603. DOI: 10.1161/JAHA.118.009603.
4. FAVOR Pilot Study: S Tu, J Westra, J Yang, C von Birgelen, A Ferrara, M Pellicano, H Nef, M Tebaldi, Y Murasato, A Lansky, E Barbato, L van der Heijden, HC Reiber, NR Holm, W Wijns. On behalf of the FAVOR study group. JACC: Cardiovascular Interventions, 9(19), 2024-2035, 2016
5. Yazaki K. et al. Applicability of 3-Dimensional Quantitative Coronary Angiography-Derived Computed Fractional Flow Reserve for Intermediate Coronary Stenosis. Circ J. 2017; 81(7), 988-992. DOI: 10.1253/circ.CJ-16-1261.
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Perspective on QFR®, a novel physiological assessment based on imaging

Dr. Jean Fajadet,
Clinique Pasteur, Toulouse (France)



How do you see the evolution and place of physiology in routine practice?

"I think that during the first 20 years of interventional cardiology, we have focused only on the angiographical aspect of the vessels and the lesions. We totally ignored the physiological aspect.

Then came FFR with clinical studies: a major change was on the way to interpret the results of a diagnostic catheterization:

When a patient presents with an acute coronary syndrome, or deep dynamic changes on the ST segment, the patient must undoubtedly be treated immediately.

On the other hand, when we have a patient with mild atheroma, the lesion

angiographically obstructing less than 30% of the vessel lumen, the lesion is thus not significant, and we do not perform PCI.

What should we do if the patient is presenting with chest pain, showing an ECG with normal ST waves, and the coronary angiography is showing an intermediate lesion? Especially when we do not have a scintigraphy nor stress echocardiography.

The physiology information we get from FFR and now with QFR®, helps us to better triage the patients who require an interventional procedure and the patients who only require oral medication."

What do you think of the QFR® concept?

"Here at Clinique Pasteur, we now have the possibility to quantify the

physiological consequences of a narrowed vessel on myocardial perfusion, using the QFR®.

The main advantage is that we can do that during diagnostic angiography, without placing a wire in a distal vessel.

When a wire is positioned distally within a vessel, there is always a risk induced to dissect a mild atheroma plaque. Since no wire is required to compute QFR®, the risk of endothelium trauma disappears.

This is certainly a major change in the physiological evaluation of the coronary stenosis."

What do think of the robustness of the tool?

"We have some data reporting equivalence between QFR® and FFR



"When a wire is positioned distally within a vessel, there is always a risk induced to dissect a mild atheroma plaque. Since no wire is required to compute QFR®, the risk of endothelium trauma disappears."

Dr. Fajadet

results. Today, we need a larger study, a randomized control trial.

When we look at our experience, I think that the results are really reproducible.

We computed QFR® on some patients, both during diagnostic angiography, and a few days later at the beginning of the PCI procedure. Interestingly, we got exactly the same result."

What do you think about the interfacing between the QFR® and GE IGS imaging system?

"I think that the interaction between the MEDIS QFR® and the GE system works well.

Of course, our experience helps us to find the correct projections required to compute QFR®. For example, when we have an intermediate lesion on a RAO cranial view, we would find the correct second projection by switching to a view that is nearly orthogonal.

It is true that with this integration*, it is easier to identify the precise views that we need to calculate the QFR®. This is critical to make the best

possible calculation and to get an accurate value for the QFR®."

What will be the place of physiological assessment in the coming years ?

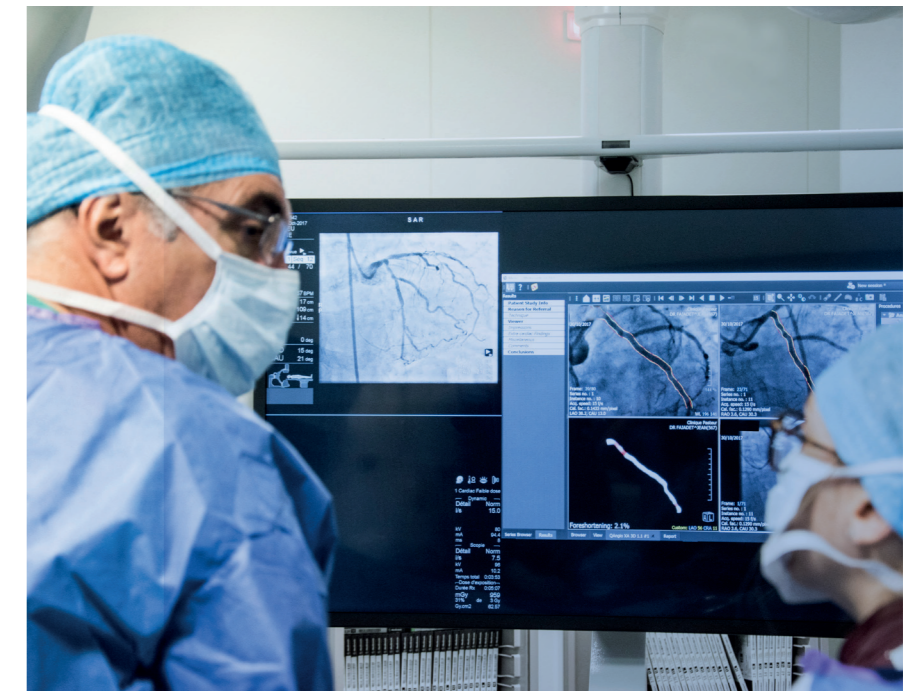
"The difficulty is that, as interventional cardiologists, we've been taught, and we are also used to the fact that everything is based on angiography. We had to change the

way we were assessing the lesions because of new evidences presented.

The objective is not to replace angiography with physiology, but to base our patient selection for revascularization or medical treatment, on both criteria.

The right place of physiological assessment should be during catheterization.

In other words, what we can expect in the future, is that all patients who will undergo diagnostic catheterization in the cathlab will leave the cathlab with a precise and accurate diagnostic and treatment plan." □



*Between QFR® and IGS.

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

JBS7300FRa

Perspective of the radiographer

Philippe Vareille,
Clinique Pasteur, Toulouse (France)



Can you please introduce yourself and your role at clinique Pasteur ?

"My name is Philippe Vareille, I have been a radiographer for 23 years at Clinique Pasteur. My role is to provide technical support on imaging systems. I am also running the QCA calculations and creating the patient reports on all PCI's in the cathlabs. During the day, I also help installing the patients and during the night shifts, I am called upon to replace the nurses when they get scrubbed."

How have you been involved in QFR®?

"We've been contacted to participate in a training session on QFR® in Buc (GE Healthcare, European GE Healthcare and global Image Guided Systems Headquarter located close to Versailles, France). I was curious to see which

noninvasive technique, alternative to FFR, was possible. I see an obvious interest as we obtain the same result and we find this really interesting for the patient, the doctor and all the stakeholders.

We were trained for two days by Medis and GE. The content of the training was very clear and precise. We learnt how the application is working and how the IGS imaging system is interfaced to the Medis QFR® software, because we had access to a real system."

What was your first impression?

"We're used to introducing a guide inside the artery and making measurements; this is concrete. Understanding the QFR® concept and algorithm was not obvious at the early stage. I did not understand that a pressure ratio can be derived only from

imaging! The software is easy to use, and upon training completion and user certification, the process is much more fluent. By doing more cases, we can work much faster; this is a question of training and experience."

Would you mind describing the team work during QFR®?

"This is a team work with the cardiologist, since he/she is the one who makes the imaging projections. He/she chooses a first angulation where the stenosis is well visible, showing no superimposition with other arteries. Using the graphical information on the large display monitor, he/she moves the gantry without emitting x-rays to find the optimal second angulation. The second angulation can then be done, and I can start the QFR® calculation. The

cardiologist can either follow my computation on the large display monitor, or treat another artery in case of a multi-vessel disease.

We regularly do QFR® computation on diagnostic angiography. We do our usual diagnostic, and during the exam, if the doctor wishes we can also run a QFR® on the right coronary or the left main for intermediate or limit lesions.

Since we're called to cover other tasks, it happens we are asked to also run a QFR® once the exam is completed. As the cardiologist has done six or seven angulations on the left coronary, we always find two of them which will suit the computation."

What are critical elements to compute a precise QFR® value?

"We're looking to get well injected angulations along the coronary artery. Then, we make sure the same artery is selected on both views to ensure a precise 3D reconstruction of the vessel. The contouring of the vessels is automatically defined by the software, and we fine-tune them to get as close as possible to the actual anatomy, according to what we see. This is of importance as we are attentive on the contours at the proximal and distal sides, as well as at the stenosis; this is similar to QCA. The last step is to select the start and end of the injected contrast so that the software receives flow velocity information."

Does it replace QCA?

"At Pasteur, from what I remember, we've always done QCAs. We do a QCA before and after each dilation. This might replace QCA in the sense that it provides the required information, but the procedure takes longer than when using only one angulation to compute QCA; therefore, I would keep QCA in the first line when looking only at the stenosis length and diameter.

In my opinion, what is interesting is to get this information along with the QFR® computation. Once the two angulations have been selected, and the contouring defined on the two views, we can see the 3D model. The 3D model follows the IGS Imaging system, which makes it easier to find the optimal view of the vessel without pushing the x-ray pedal.

I can tell that QFR® is a good solution since it is noninvasive and thus helps avoid coronary complications. When we do a FFR calculation on a stenosis which is about 20 or 30% of the lumen, we use a guidewire, which can touch the plaque and potentially cause a plaque rupture. We then need to dilate while it can be avoided when doing QFR® measurement."



"Since we have been working in the new cathlabs, we have been doing many interesting and different technical things, such as QFR® or image fusion. This is really of great interest."

P. Vareille

What is your confidence level with the tool?

"The reconstruction itself has been very easy thanks to our QCA knowledge and practice. We can also do post-PCI analyses which can also be very interesting. I am very comfortable with the software, and - if needed - I provide feedback to Medis and GE team and get the appropriate support in return."

Would you recommend that your peers get trained and practice QFR®?

"I do think the QFR® solution can be very useful to reconstruct a vessel in three dimensions. This is above all beneficial to the patient since it is a non invasive technique. We do nothing more than an angiography!"

What is your experience being involved with technology ?

"We always enjoy using new technologies such as QFR®. This is very interesting, our role is evolving. Since we have been working in the new cathlabs, we have been doing many interesting and different technical things, such as QFR® or image fusion. This is really of great interest." □

The statements by GE's customers reported here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results. JB57301FRa

LAD stenting using QFR® (Medis)

Courtesy of Dr. Jean Fajadet, Clinique Pasteur, Toulouse (France)

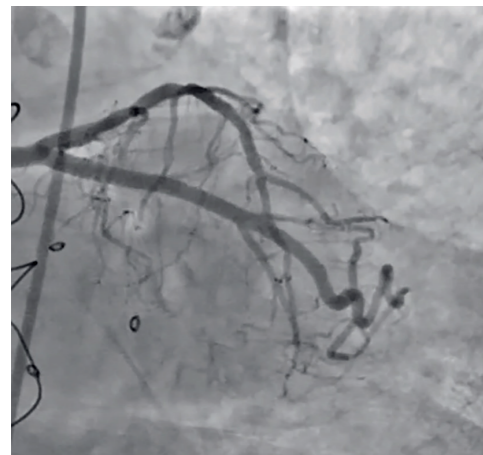


Fig.1 Left Main CA

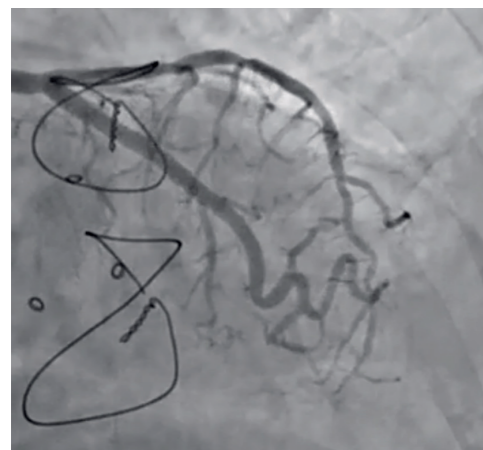


Fig.2 Lesion in the LAD

Patient History

A 75 years old female with chest pain had been referred for a coronary angiography. The patient had a previous cardiac surgery with mitral valve replacement in 2010, but normal coronary arteries. In the last 48 hours, the patient has suffered from chest pain with irradiation in the two shoulders. The ECG of the patient showed normal sinus rhythm, negative T waves to V1 to V5 and elevation of Troponine : 6.5ng/mL.

Procedure

Arterial access was made through the right femoral artery since the radial access was not suitable (right radial artery pulse was very weak).

Diagnostic Angiography

First view of the LM shows no significant lesion of the left main trunk (Fig.1). Injection in the left coronary showed a long atheroma plaque on the proximal segment of the LAD, followed by a tight lesion at the mid segment (Fig. 3). The distality was

correct with a long diagonal branch (Fig. 3, 4). The right coronary didn't show any significant lesion (Fig. 5).

Treatment planning

Atheroma is present in the proximal segment of the LAD but without any significant stenosis. More critical stenosis at the origin of the second septal branch (Fig.3). The evaluation of the LAD lesion will then be done using QFR® to assess the severity of the lesion.

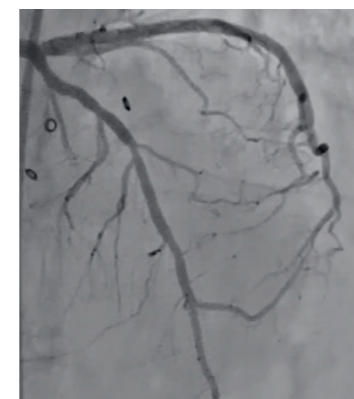


Fig.3 AP/Cranial 30. LAD with the long atheroma plaque on the proximal segment and tight lesion at the mid segment

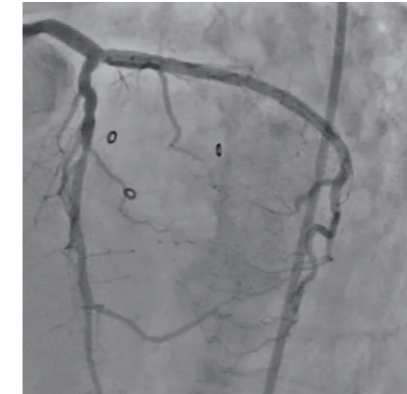


Fig.4 LAO 36°/CRA 25°: Eccentric lesion on the mid LAD

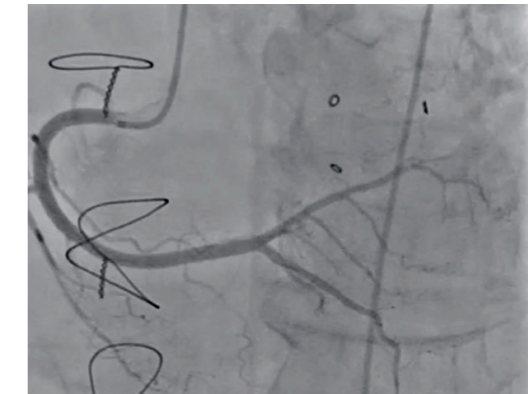


Fig.5 RAO 41°/CRA 6° Right coronary artery.

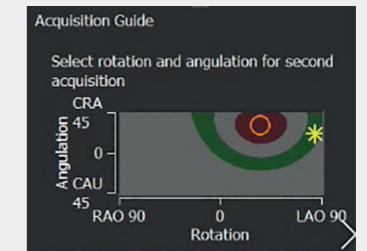
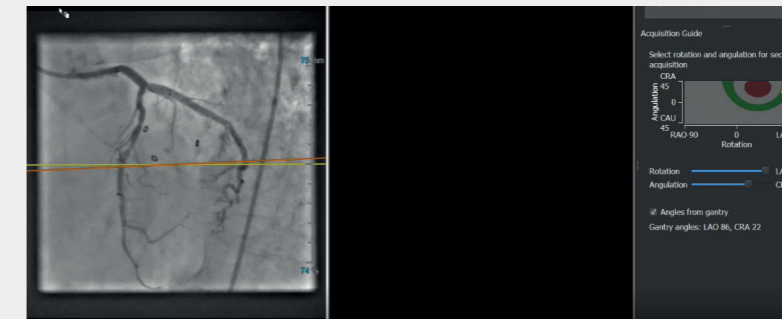
QFR® Assessment of the lesion

Step 1
Acquiring projections of the LAD



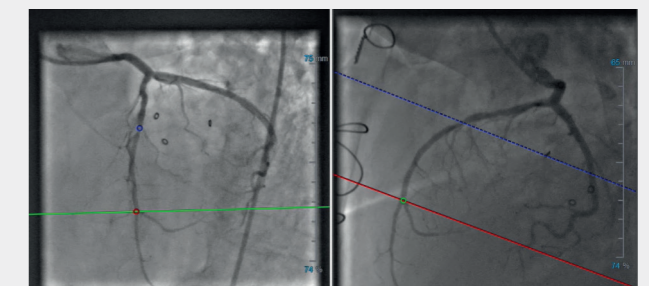
2 projections are required in order to reconstruct the LAD in 3D. An acquisition guide, directed interfaced to the GE Image Guided System, helps the physician to get the best angle for the second projection.

A first projection of the LAD is acquired at 35 LAO CRA 30.



Ideal angulation for the second angulation is represented by the yellow star, and the current gantry position is represented by the red circle.

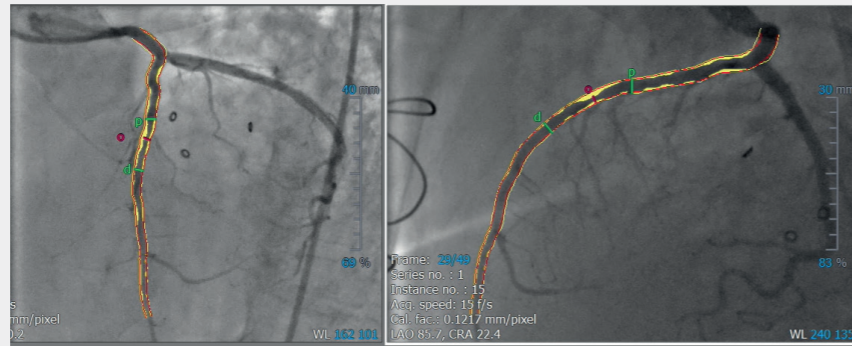
Once both images are acquired following the acquisition guide, a 2 points registration is performed to align the images.



Corresponding epipolar lines/points are represented on each image to check registration and ensure accuracy during the reconstruction

Step 2
Segmentation of the lesion

A 2D QCA is performed on both images, and a 3D QCA is automatically computed by the software, thus providing the degree of stenosis at the level of the lesion.



Step 3
3D reconstruction and QFR® computation

The software is then indicating a degree of stenosis of 54%. After giving information of the contrast arrival time in the LAD, the resulting cQFR is : 0.71. The physician thus decided to treat the lesion.

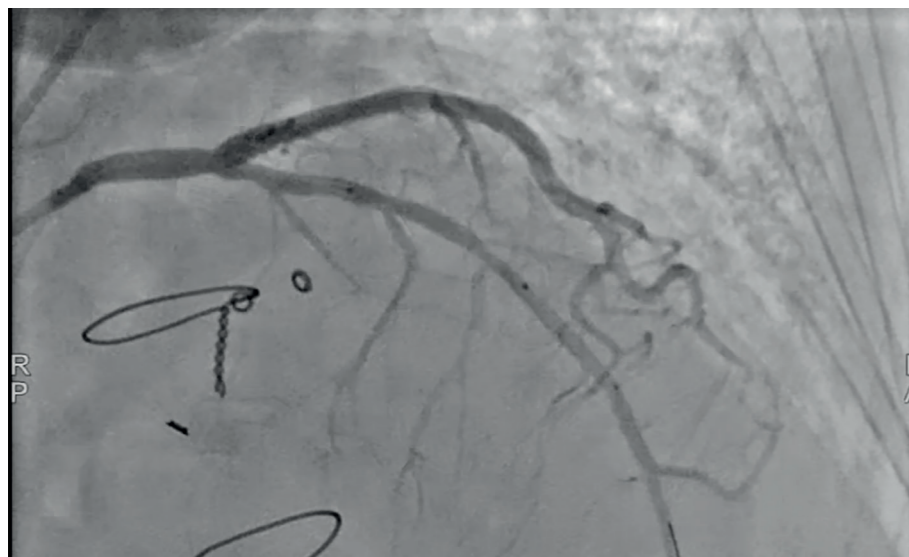
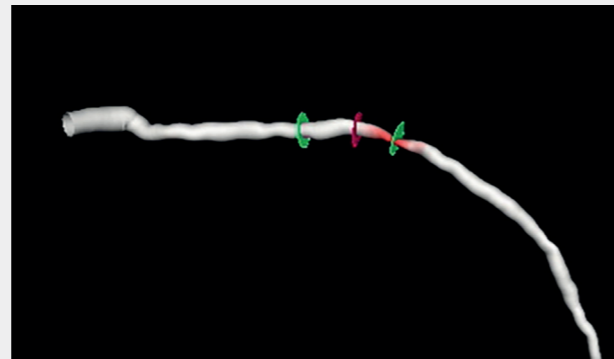


Fig.6 Stent is brought at the level of the lesion

Guide

The goal of the PCI will be to treat the lesion, but also the plaque proximal to the lesion (origin of the first septal branch). A 28mm stent (2.75 / 28mm) will therefore be used to treat this lesion. (Fig. 6)

The stent is brought at the level of the lesion, confirming that both proximal and distal lesion are covered. The balloon is then inflated.

PCI ASSIST (StentVesselViz feature) is used at this time of the procedure in order to see if the stent is correctly opened (Fig.7)

A proximal post dilatation might be needed as well as for the proximal plaque.

A 3.0mm balloon is then brought at the level of the distal lesion, and PCI ASSIST (StentViz feature) acquisition is done to check that the balloon is positioned within the stent, at the distal part of the lesion in order to avoid any risk of a distal dissection (Fig. 8).

The same acquisition is performed on the proximal lesion, to ensure a 3.5 mm balloon is inside the stent (Fig. 9). In this case, the interpretation of PCI ASSIST (StentViz feature) suggested that the balloon could be inflated more proximally (Fig. 10).

Assessment

The stent looks well apposed on the final control angiography (Fig. 11), no dissection on proximal nor distal edge of the stent and normal TIMI III flow. A post-stent QFR® is done to confirm perfect revascularization of the LAD ; QFR®=1 (Fig. 12).

Clinical challenge

Thanks to PCI ASSIST and QFR®, the clinical challenges that were overcome are:

- assessing the severity of the lesion
- determining the right position of the stent to cover the whole lesion
- achieving proper stent apposition to the vessel wall.

About

Dr Fajadet is an interventional cardiologist and co-leader with Dr. Bruno Farah of PCI program at Clinique Pasteur. He is also EuroPCR Co-director, and past President of the European Association for Percutaneous Cardiovascular Intervention (EAPCI) executive committee.

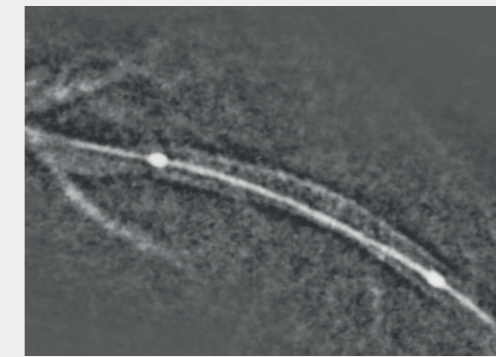


Fig. 7 PCI ASSIST (StentVesselViz feature) acquisition showing a post dilation is needed, and a larger balloon should be inflated at the proximal part of the lesion.

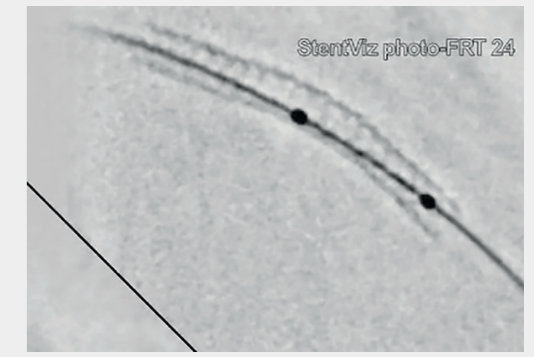


Fig. 8 PCI ASSIST (StentViz feature) acquisition confirming the position of the balloon with respect to the distal lesion



Fig. 9 PCI ASSIST (StentViz feature) acquisition done to check balloon position with respect to the stent

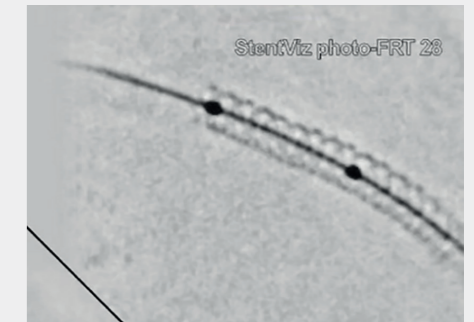


Fig. 10 PCI ASSIST (StentViz feature) acquisition confirming good position of the balloon prior to inflation



Fig. 11 Control angiography

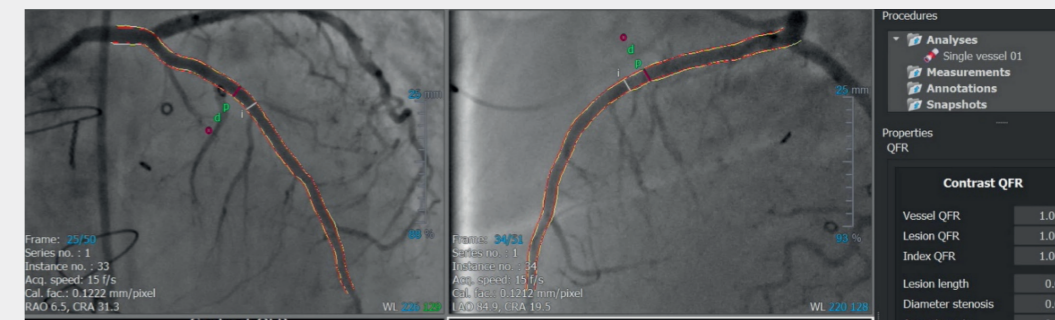


Fig. 12 QFR® done at the end of the case showing perfect revascularization of the LAD.



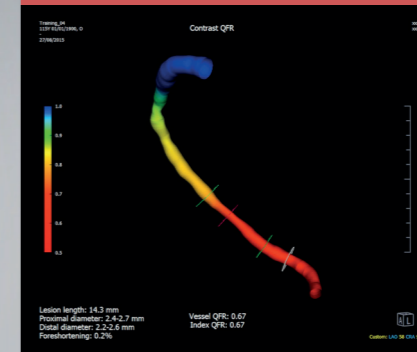
A complete solution for PCI procedures



PLAN. GUIDE. ASSESS.

QFR[®] is a novel, non-invasive, image-based tool that can accurately and rapidly compute FFR (fluid dynamic equations, emulated hyperaemic flow velocity), without the need for a pressure wire, nor hyperemic drug. Exclusive integration of GE IGS imaging systems can optimize the speed of workflow.

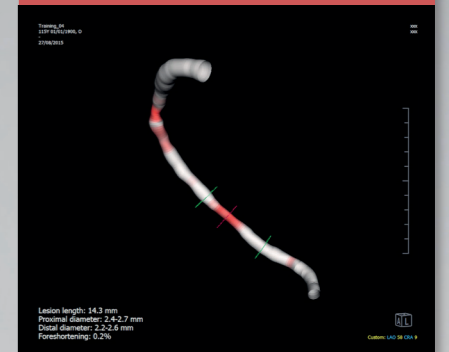
QFR[®]



1. SHOULD I USE A STENT?

Assess the functional severity of a lesion with accuracy, and without a pressure wire or hyperemic drug. Workflow eased by exclusive integration with GE IGS imaging system.

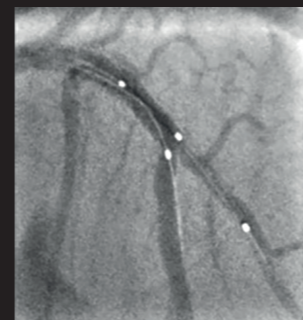
3D QCA



2. WHAT SIZE SHOULD THE STENT BE?

GE IGS imaging system connected to 3D model. 3D QCA helps reduce foreshortening to measure the lesion with precision and select the most appropriate stent.

PCI ASSIST*

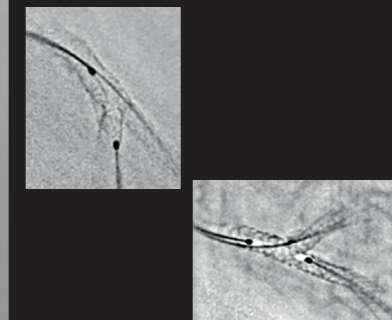


3. WHERE TO POSITION THE STENT VERSUS THE BIFURCATION?

Clear visualization of the stent position relative to the vessel to help assess the position of the stent versus the bifurcation.

* StentVesselViz feature

PCI ASSIST*

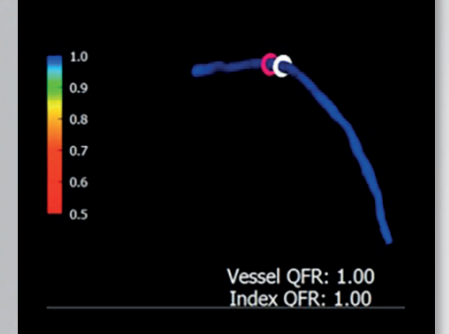


4. IS THE STENT WELL DEPLOYED?

Enhance the visibility of the stent structure to help assess the stent deployment and architecture.

* StentViz feature

QFR[®]



5. HAS THE PHYSIOLOGY BEEN IMPROVED?

Assess the functional severity of a lesion with accuracy, and without a pressure wire or hyperemic drug. Workflow simplified with GE IGS imaging system.

PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6 and Discovery IGS 7. PCI ASSIST refers to features of Interventional X-ray system: StentViz, StentVesselViz.

QFR[®] and 3D QCA above mentioned are part of Medis QAngio XA 3D.

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GE Healthcare

GE Healthcare provides medical technologies and services to help solve the challenges facing healthcare providers around the world. From medical imaging, software, patient monitoring and diagnostics, to biopharmaceutical manufacturing technologies, GE Healthcare solutions are designed to help healthcare professionals deliver better, more efficient and more effective outcomes for more patients.

GE Healthcare is betting big on digital; not just connecting hospital departments and physicians more effectively, but utilizing the masses of data from its equipment and the collaboration between hardware and software – “digital industrial” – to help clinicians make better care decisions. Sensors, software and smart data analytics are converging to enhance GE Healthcare’s offerings not just in diagnostics, but also pathology, gene sequencing and even hospital asset tracking.

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

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