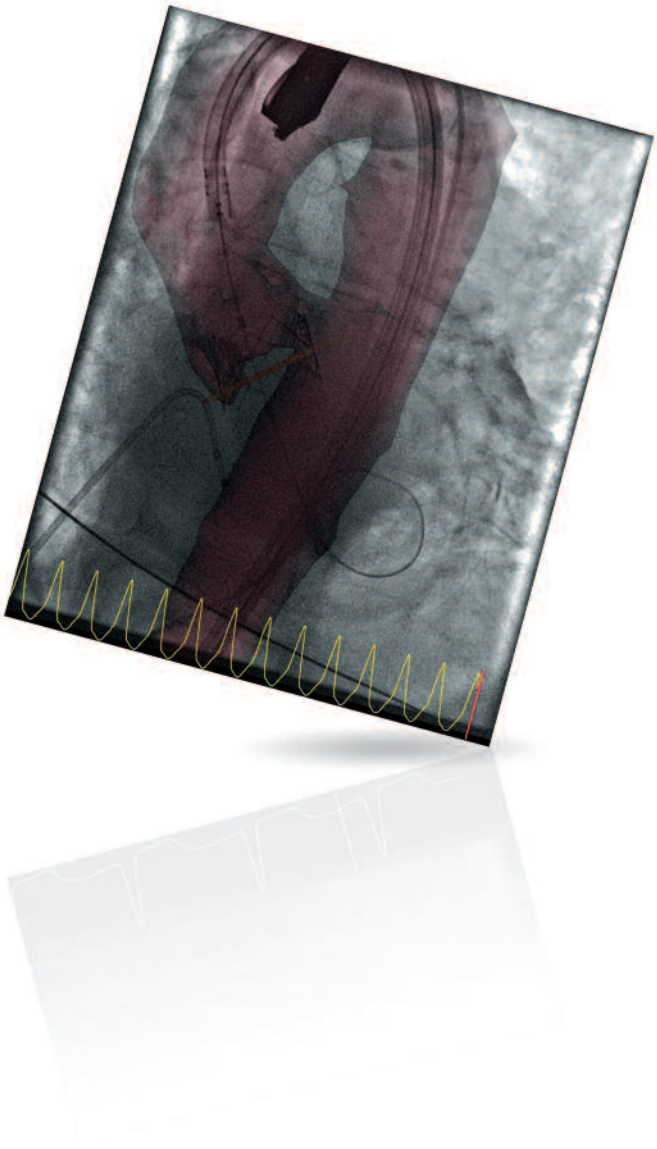
GE Healthcare

Guiding solution for TAVI procedures

Innova* Vision technology for TAVI
Clinical case study

A. Tirouvanziam
J.-C. Roussel
D. Crochet
Institut du Thorax
University Hospital of Nantes, France



Guiding solution for T

The hemodynamics and vascular interventional center, headed by Pr. Dominique Crochet, lies at the crossroads of clinical specialties. This specificity enables interdisciplinary work and has made it easier to integrate the « Institut du Thorax » with the university hospital of Nantes.

Earch year, the group performs 3,300 diagnostic and interventional cardiac catheterization exams (including 1,200 coronary angioplasties and 115 other interventional procedures for conditions such as congenital heart defects and valvular diseases).

The hemodynamics center is one of the 33 French units entitled by the national authorities to perform Transcatheter Aortic Valve Implantation (TAVI). The group has been applying these procedures since 2008.

An interdisciplinary group
Institut du Thorax,
University Hospital of Nantes

Clinical context

Aortic valve replacement (AVR) is the reference treatment for symptomatic aortic stenosis to alleviate symptoms and improve survival. At least 30% of the candidates do not undergo surgery because of advanced age or the presence of comorbidities. Percutaneous techniques, notably Transcatheter Aortic Valve Implantation **(TAVI)** offer a treatment alternative. More than 20,000 patients worldwide have been treated in this way since 2002.

The clinical case submitted by Dr. Ashok Tirouvanziam, Dr. Jean-Christian Roussel and Pr. Dominique Crochet from the Institut du Thorax in Nantes, France, illustrates ease of use and clinical potential interest of Innova Vision technology during a TAVI procedure.

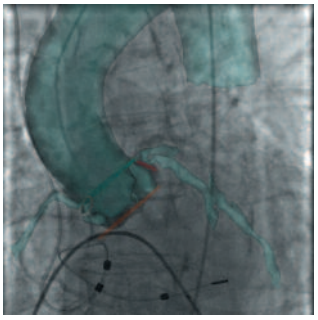
Innova Vision technology, *an advanced application that dynamically fuses 2D X-ray images and 3D models from multiple modalities to support localization and guidance of devices during interventional procedures, such as structural heart procedures.*

TAVI procedures

Plan

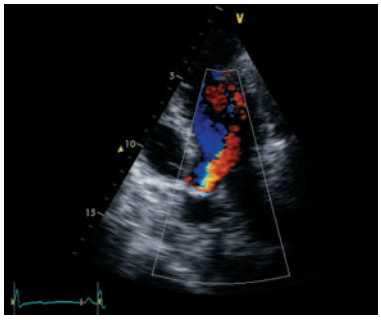
3D aortic imaging helps to detect bicuspid or tricuspid anatomy.
Peripheral artery and aorta anatomy influences patient selection and the implantation route.
The size of the aortic annulus is essential to select the prosthesis size, and identification of valve plane is necessary for correct prosthesis release.

Guide



Optimization of valve positioning inside the aortic annulus is critical, especially to avoid interference with the coronary ostia.
3D anatomy visualization and optimal working view are needed.

Assess



Device positioning is controlled, with a special focus on the presence of significant para-valvular leak and patency of the coronary arteries.

Pr. Dominique Crochet, Interventional Cardiologist and Radiologist

The development of TAVI procedures has brought about an increasing role for CT scanner. During the early stages following the introduction of the technique, patient selection, procedure guidance and control relied on echocardiography and angiography images. CT scan was then perceived as an optional feature.

After a few years of practice that witnessed an expanding number of procedures CT scan was further promoted as an essential tool. As for patient selection, CT scan enables to evaluate and select the implantation route. Combined with recently developed software, it improves the procedure course by detailing the valve structure, as well as annulus characteristics, positioning and relationship to the coronary ostia. Assessment of the result, which stems from the physical interaction between annulus, deployed valve and calcifications, also benefits from this modality, and there is an increasing potential for scanner mediated evaluation. »

Patient History

A 75-year-old male with a medical history of cerebrovascular disease and chronic renal failure requiring hemodialysis, was referred to the department for a critical aortic stenosis.

The mortality risk was 26% as predicted by Euroscore.
After multidisciplinary evaluation, he was denied a conventional valve replacement and instead underwent TAVI.

A balloon-expandable Edwards NovaFlex SAPIEN XT* 26 mm (Edwards Lifesciences, Irvine, California, US) was implanted via a percutaneous femoral access using a Prostar* XL preclosing device (Abbott Vascular, Inc., Abbott Park, III).

Procedure

The aorta, its diameter and its pathology, as well as vascular access, were assessed on initial CT images obtained before the procedure (Fig. 1). No additional exam was required for planning, sparing time, dose and use of contrast agent.

Using preprocedural CT images and the VesselIQ Express* protocol on the Advantage Workstation* (AW), the aorta was segmented out of the whole dataset. The aortic annulus diameter and contour were drawn to better visualize the valve plane (Fig. 1).

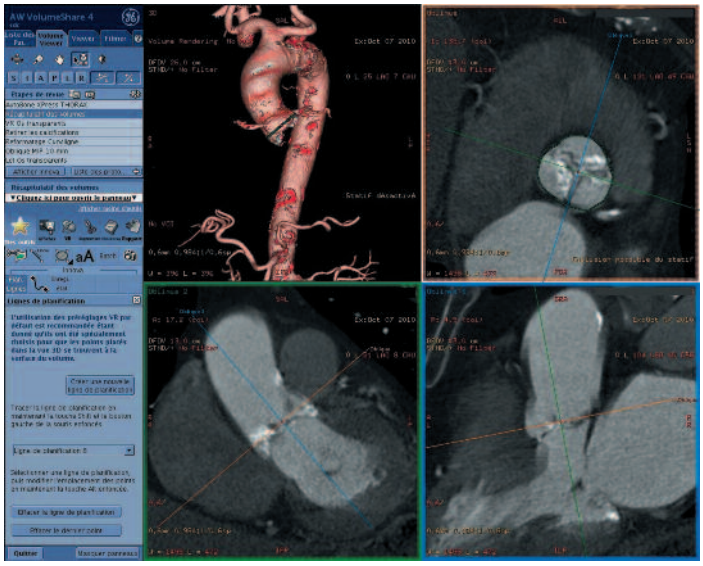


Fig. 1: AW screen capture displaying the aorta extraction, valve plane determination, and measurement of the annulus

3D landmarks are deposited on the 3D volume to locate coronary ostia (Fig. 2), determine the valve plane orientation, select the optimal views, and position the gantry at the working angles using Synchro3D (Fig. 3).

Fig. 2

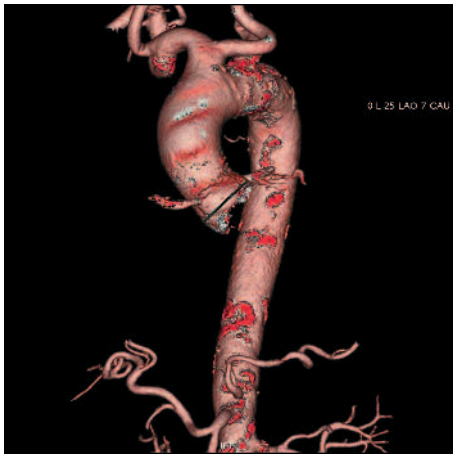


Fig. 3

The 3D anatomy from CT was displayed on one of the monitors on the suspension. The CT volume was registered, and the orientation of the anatomy could then be performed in real time with the gantry orientation and table position. This system helps identify the optimal perpendicular leaflets projection for valve deployment.

Using Innova Vision, the model was then overlayed on 2D fluoroscopic images (Fig. 4, 5, 6). Positioning could be refined using slight contrast injections. Images were displayed with ECG gating to compensate for heart-beat motion and could be automatically stabilized for further patient motion, including breathing.

Fluoroscopic images obtained with the Innova system helped support guidance during advancement of the valve through the aorta and positioning (Fig. 4), during balloon-expansion of the prosthesis under rapid right ventricular pacing (Fig. 5), and during deployment of the valve (Fig. 6).

Fig. 4

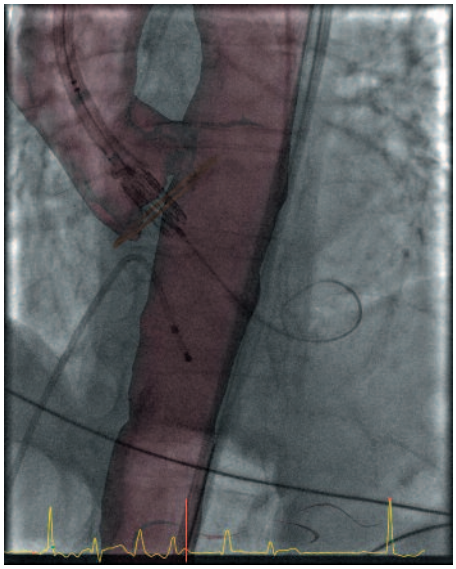


Fig. 5

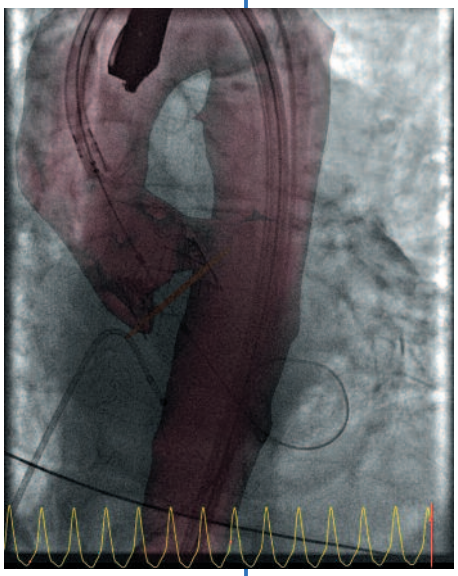


Fig. 6

Immediate post-implantation TEE (Fig. 7) and angiographic controls confirmed the proper position of the prosthesis, with only minor paravalvular regurgitation, no coronary ostial obstruction, and a mean residual transvalvular gradient of 6 mm Hg.

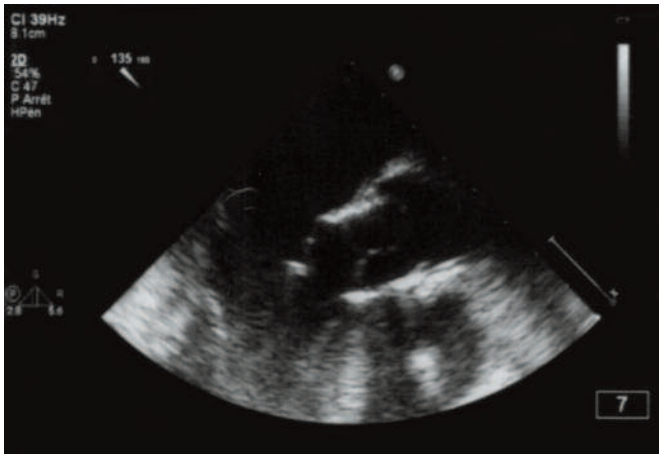


Fig. 7

Conclusion

Dr. Ashok Tirouvanziam,
Interventional Cardiologist

« Innova Vision technology provides precise diagnostic information before TAVI. During the procedure, the 3D model overlaid on the 2D fluoroscopic images shortens the procedure time by allowing optimal target site and angulation assessments. This provides more confidence and leads to quicker target deployment decision making, a reduction in X-ray dose, and a reduction of contrast media as well. This last parameter is particularly important in patients with chronic renal failure. »

Dr. Jean-Christian Roussel,
Cardiac Surgeon

« Locating the annulus plane and specifying the perpendicular working view is a strong concern during a transapical approach. Another valuable piece of information would be the 3D anatomy of the left ventricle apex to aid in tracking the insertion route of the catheter. »

Pr. Dominique Crochet,
Interventional Cardiologist and Radiologist

« With the emergence of TAVI procedures, we have entered a new therapeutic era. Even pioneers in the field still display caution regarding potential outcomes. During the learning curve, there is a strong need for dedicated tools that improve patient selection as well as procedure safety and control. »

The integration of 3D images to guide complex procedures like TAVI enhances confidence during the interventions.
It provides direct access to optimal angulations of the gantry.

The resulting images then help to improve the overall procedure workflow and potentially reduce the amount of injected contrast – a key consideration when treating patients suffering from renal insufficiency.

Innova Vision technology meets the challenge of moving anatomy, such as heart structures, by using dedicated algorithms to compensate not only for heartbeat motion but also for patient movement.

Commitment for excellence

Innova 2100

The Innova 2100[IQ] cardiovascular and vascular X-ray system incorporates GE's exclusive Revolution* solid-state digital detector to consistently provide excellent imaging performance though a full range of diagnostic, interventional and cardiovascular procedures.

AW workstation

Advantage Workstation* Premium (AW) for Interventional allows multimodality visualization, analysis and navigation.

- Physician can get access to 3D anatomy directly in the cath lab based on 3D datasets from CT, MR or rotational angiography.
- The 3D images are displayed in-room on the monitor boom and can be easily controlled at tableside using a dedicated user interface.

Volume Viewer* is the environment of choice for 3D processing of any CT, MR, 3D X-ray, PET and PET/CT dataset. It provides exceptional tools for analysis, segmentation, measurements, annotation, filming and exporting of clinically relevant images.

VesselIQ Express* CT facilitates vessel analysis by fast multibranch tracking and automated stenosis measurement. It also features an automated aorta and iliacs tracking and thrombus segmentation and analysis tool.

Innova Synchro3D* helps physicians select the optimal view for performing an intervention by synchronizing in real time a pre-acquired 3D model with the gantry angulations of the Innova 2100[IQ] positioner. Alternatively, the 3D model can be manipulated and the corresponding angles sent to the Innova 2100[IQ].

Innova Vision technology offers:

- Automatic image registration with patient position and image orientation
- Real-time adjustments for all modifications of gantry position, source- to-image distance
- Image stabilization features such as ECG-gated display or motion tracking in the image.
- To enhance workflow, all these functionalities can be controlled from the Innova Central* at tableside.

Data subject to change.
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France - Buc
Tel: +33 (0)1 30 70 40 40
Vélizy
Tel: +33 (0)1 34 49 50 00

Germany - Solingen
Tel: +49 (0)21 228 020

Italy - Milan
Tel: +39 02 260 01111

Spain - Madrid
Tel: +34 91 663 2500

Turkey - Istanbul
Tel: +90 212 36 62 900

UK - Slough
Tel: +44 1 75 387 4000

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Our “healthymagination” vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

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