ESC European Society of Cardiology

European Heart Journal - Case Reports (2024) **8**, ytae582
https://doi.org/10.1093/ehjcr/ytae582

CASE REPORT
Structural intervention

Transcatheter tricuspid valve implantation with LuX-Valve utilizing a novel patient-specific virtual and physical simulator: a case report

Enzo Delamarre[1]*, Mohammed Nejjari [2], Julien Dreyfus [2], Frédéric Lesage[1,3], and Walid Ben Ali [1]

[1]Research Center Department, Montreal Heart Institute, 5000 Rue Bélanger, Montréal, QC H1T 1C8, Canada; [2]Cardiology Department, Centre Cardiologique du Nord, 32-36 rue des moulins gémeaux, Saint-Denis 93200, France; and [3]Department of Electrical Engineering, Polytechnique Montréal, 2500 Chem. de Polytechnique, Montréal, QC H3T 1J4, Canada

Received 10 July 2024; revised 4 September 2024; accepted 21 October 2024; online publish-ahead-of-print 11 November 2024

Background The rise of transcatheter tricuspid valve implantation (TTVI) therapies represents a major advancement for high-risk patients with severe tricuspid valve regurgitation, offering a safer, minimally invasive alternative to open-heart surgery. However, the low volume of procedures and training highlights an urgent need for skills development and pre-procedural preparation, which simulation can address by enhancing learning and expanding treatment availability.

Case summary An 87-year-old woman with permanent atrial fibrillation and symptomatic severe functional tricuspid regurgitation underwent a transcatheter tricuspid valve replacement with the LuX-Valve system. We developed a novel patient-specific virtual reality simulator, combining virtual and physical simulations, to enhance training and education for TTVI. This system utilizes high-resolution computed tomography images, machine learning algorithms, and a video game engine to recreate realistic procedural environments. We performed a safe intervention following the simulation session, achieving successful clinical outcomes in the patient.

Discussion The developed platform is the first to propose a patient-specific hybrid simulation for TTVI engaging both interventional and imaging cardiologists. The simulator's potential to improve clinical and safety outcomes warrants further evaluation through specifically designed comparative studies.

Keywords Case report • Learning • Patient-specific • Simulator • Tricuspid regurgitation

ESC curriculum 4.5 Tricuspid regurgitation • 6.1 Symptoms and signs of heart failure • 4.10 Prosthetic valves

Learning points

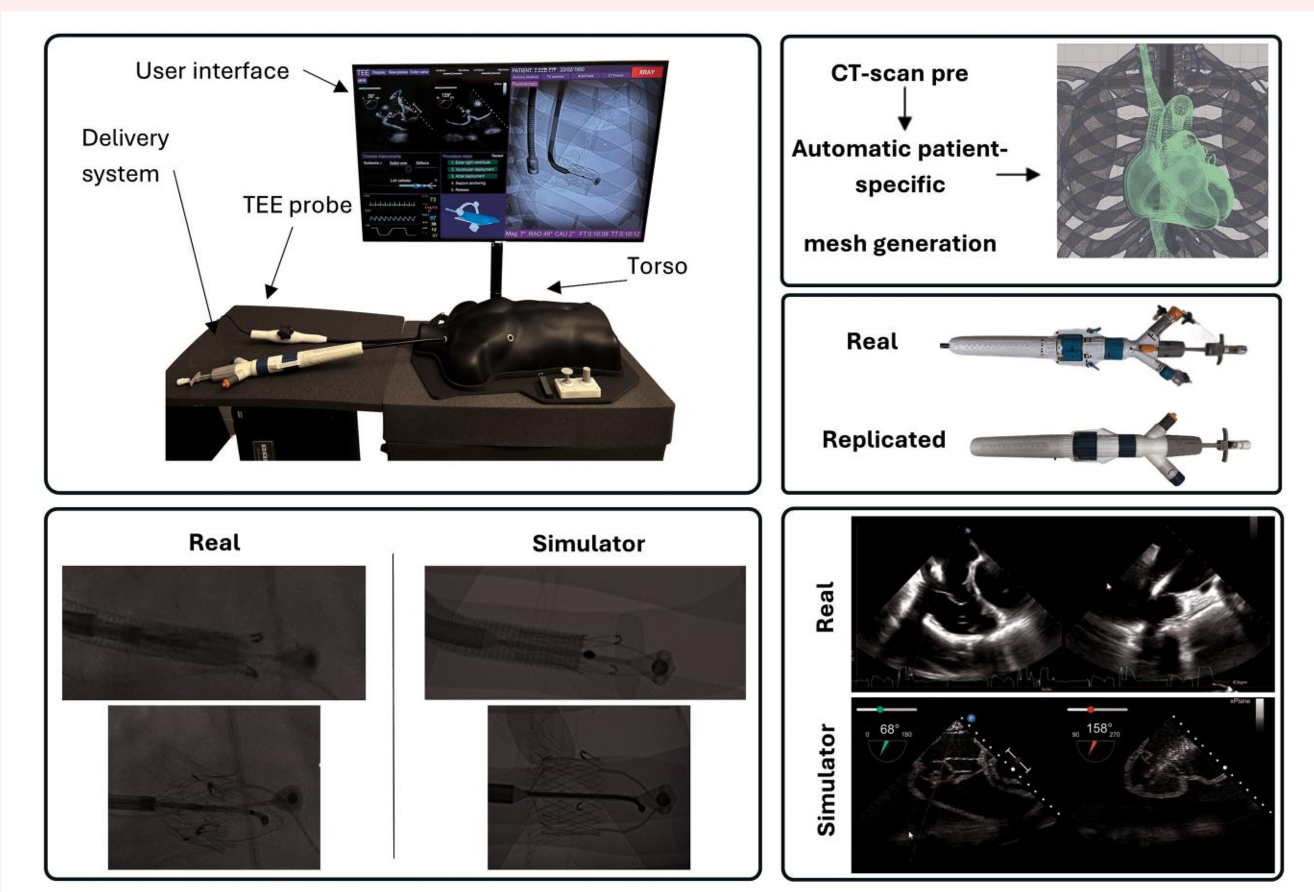
- The rise of transcatheter tricuspid valve implantation (TTVI) offers a minimally invasive alternative for high-risk patients with severe tricuspid valve regurgitation, reducing the need for open-heart surgery.
- The low volume of TTVI procedures highlights the urgent need for enhanced training and pre-procedural preparation. Simulation can play a critical role in addressing this need by improving learning and expanding treatment availability.
- The development of a novel patient-specific virtual reality simulator, combining virtual and physical simulations, shows promise in enhancing training for TTVI procedures. This system, which uses high-resolution imaging, machine learning, and a video game engine, has demonstrated potential for improving clinical outcomes and warrants further comparative studies.

* Corresponding author. Tel: +5149717525, Email: delamarreenzo8@gmail.com
Handling Editor: Josip Andelo Borovac
Peer-reviewers: Marco Angelillis; Sebastian Ekkehard Beyer
Compliance Editor: Sheetal Vasundara Mathai

Introduction

The recent rise of transcatheter tricuspid valve implantation (TTVI) therapies marks a significant advancement in cardiology, particularly for patients with severe tricuspid valve regurgitation (TR) who are at high risk for conventional surgery. The TR, often secondary to tricuspid annulus dilatation and right ventricular remodelling, is a common and serious valvular heart disease with a 5-year survival rate below 50%.[1] Minimally invasive procedures offer a safer alternative, leveraging catheter-based techniques to implant a new valve without the need for open-heart surgery. The adoption of TTVI is driven by technological innovations, promising clinical trial outcomes,[2] and growing recognition of the importance of treating tricuspid valve disease to improve patients' quality of life and survival rates. However, TTVI development faces a significant challenge due to the low volume of procedures performed and taught. There is a clear unmet need for training and pre-procedural technical expertise.[3,4] Simulation is proposed to be an effective solution to this problem by accelerating the learning process, facilitating mastery of the new delivery systems, and improving clinical and safety outcomes.[5] However, current simulators do not adequately meet the needs in terms of patient-specific features, instrument training, and training for transcatheter tricuspid valve treatments that require multiple teams of physicians.[6] Therefore, we aim to enhance the training and education of these procedures by using a patient-specific virtual reality and physical simulator. Here, we report a case of a patient who underwent a TTVI with the LuX-Valve Plus system (Jenscare Biotechnology Co. Ltd, Ningbo, China), with prior training with the new virtual reality simulator.

Summary figure



Case presentation

A TTVI procedure with the LuX-Valve was performed in an 87-year-old White woman (weight = 98 kg, body mass index = 42 kg/m^2), preceded by physical and virtual simulation for procedural training the same day. She had permanent atrial fibrillation and severe functional TR, exhibiting symptoms such as anasarca for 2 years and signs of biventricular heart failure (New York Heart Association function Class III) despite 125 mg of furosemide per day. Physical examination at first hospitalization, 1 year before the procedure, was consistent with right-sided heart failure displaying bilateral lower limb oedema without hepatojugular reflux. She was at high surgical risk (TRI-SCORE = 7/12 points[7]) and not eligible for transcatheter TV repair (large coaptation gap). Two months before the procedure, she was declared eligible to receive a LuX-Valve prosthesis and underwent a computed tomography (CT) scan, which was studied for planning and simulation of the intervention. At admission, 2 days before the procedure, she had a 119/71 mmHg blood pressure, saturation 97% in ambient air, and her electrocardiogram showed chronic atrial fibrillation with an average rate of 70 b.p.m. and pulmonary auscultation was normal. The blood investigations showed a haemoglobin level of 10.4 g/dL (normal 12–16 g/dL), a creatinine level of 113 µmol/L (normal 40–90 µmol/L), a N-terminal prohormone of brain natriuretic peptide level of 1354 pg/mL (normal <450 pg/mL), and a bilirubin level of 2.9 mg/L. The LuX-Valve Plus system is a radial force-independent valve composed of a tri-leaflet prosthetic valve, a self-expanding nitinol valve stent, an interventricular septal anchoring component, and two polytetrafluoroethylene-covered graspers.[8,9] Procedures are performed under general anaesthesia with transoesophageal echocardiographic (TEE) and fluoroscopic guidance.

A small incision is made in the right side of the neck to expose the right jugular vein, which is punctured to insert a short introducer sheath. The delivery system is advanced and positioned centrally and perpendicularly to the tricuspid annulus. The valve is then released, with anterior leaflet graspers expanded to capture the leaflet, followed by deployment of the atrial disc to initiate valve function. A septal tongue is then deployed and anchored onto the ventricular septum. The valve is completely released, and the delivery catheter is removed. This device allows for repositioning and retrieval before the atrial disc is fully released.

To develop the simulator, a personalized virtual animated patient was generated based on cardiac CT images of the patient. High-resolution meshes of the cardiac anatomy were created using automatic segmentation with machine learning algorithms, following a method adapted from generating meshes for transcatheter aortic valve implantation.[10] The model was then imported into Blender, where it was animated to recreate the motion of a beating heart (*Figure 1*). Guidewire, delivery system, and bioprosthetic valve were 3D modelled and coded using a discretization model in the video game engine Unity 3D (Unity Technologies, San Francisco, CA, USA) to simulate functions such as flexing, torquing, and valve deployment. The physics of collisions between virtual instruments, veins, and heart walls was simulated using a physics engine (Nvidia PhysX) and mesh-based colliders (*Figure 1*).

An intuitive interface incorporating fluoroscopic and TEE views was developed (*Figure 2A*). These views were recreated in real time using a shader-based approach on the anatomical meshes. The TEE probe and the delivery device were physically recreated using Fusion 360 (Autodesk, San Francisco, CA, USA) and 3D printing and equipped with sensors. Bluetooth Low Energy technology was added to the delivery systems to transmit information about knobs to the virtual delivery system in real time (*Figure 2B*). All the functions of the real delivery system were recreated, such as flexing the tip, unsheathing, rotating, and septal anchoring.

A physical platform featuring a plastic human torso and joysticks to control the fluoroscopic view was designed, with holes at the insertion points (oesophagus for TEE, transatrial, and transjugular). Tubes connected to the holes contained optical tracking units to monitor the replicated instruments and transmit position and torque data to the virtual instruments in real time (*Figure 2A*). The system was designed to be lightweight and portable, allowing device manufacturers to use this teaching tool in multi-centre clinical studies.

Both interventional and imaging cardiologists trained on the simulator simultaneously, one using the delivery system and the other using the TEE probe. They implanted on the simulator a 50 mm LuX-Valve via transjugular venous access on the simulator, utilizing the individual patient's anatomy. The anatomical challenges related to the patient, such as the restricted septal leaflet, were discussed and assessed, thanks to the fluoroscopic and TEE simulated views, manipulated in real time (*Figure 3*). A procedural success was then achieved the same day, and the patient was discharged at Day 4 without complication. Transoesophageal echocardiography performed at discharged showed mild septal peri-prosthetic leak (*Figure 4*; Supplementary material online, *Videos S1* and *S2*).

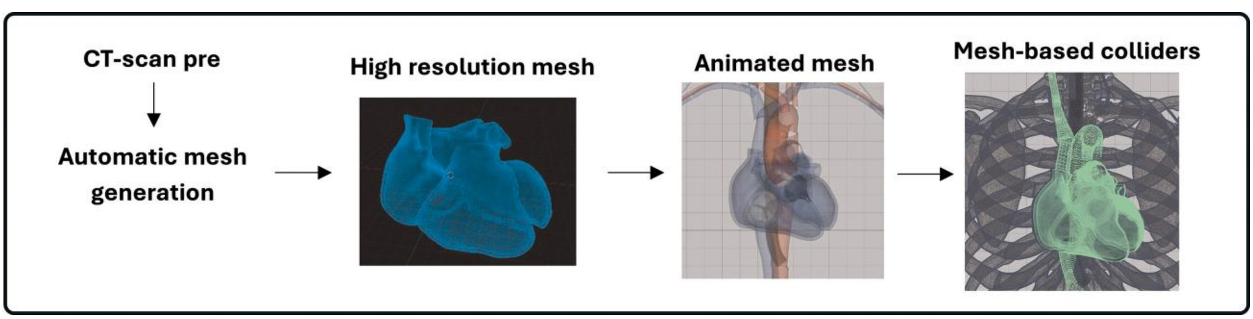


Figure 1 Patient-specific mesh generation workflow. CT, computed tomography.

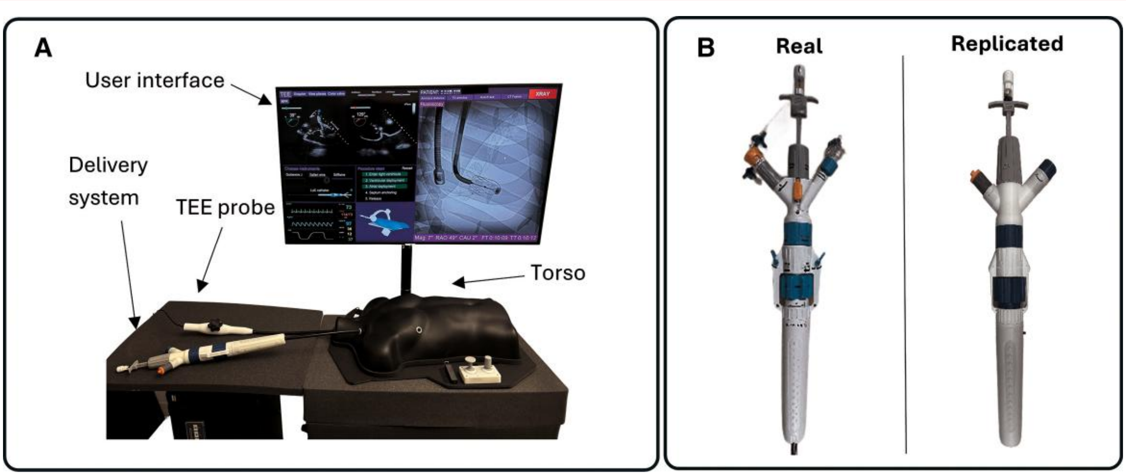


Figure 2 Patient-specific virtual reality simulator. (*A*) Patient specific simulator. (*B*) Real and replicated delivery system for the LuX-Valve. TEE, transoesophageal echocardiography.

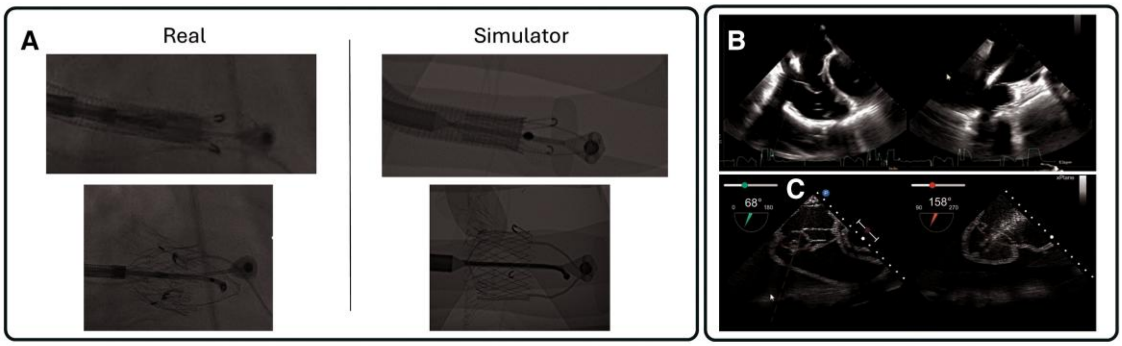


Figure 3 Comparisons with real images. (*A*) Real and simulated fluoroscopic images of the deployment of the LuX-Valve. (*B*) Real transoesophageal echocardiography bi-plan view of the deployment of the LuX-Valve. (*C*) Simulated transoesophageal echocardiography bi-plan view of the deployment of the LuX-Valve.

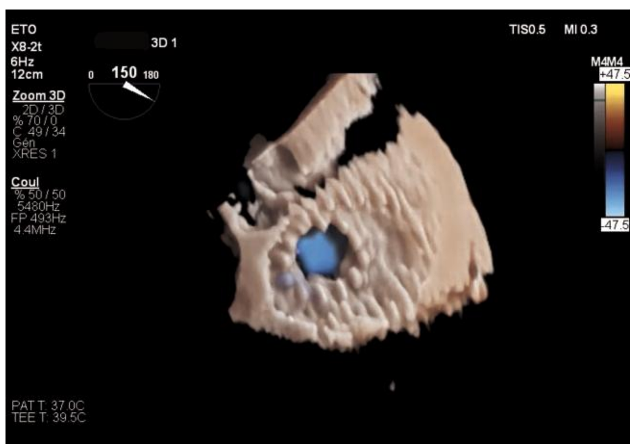


Figure 4 3D transoesophageal echocardiography view of the implant with colour.

Discussion

The landscape of simulators, not only for structural heart interventions, is divided between virtual simulations and physical simulations. Virtual simulators provide highly flexible training environments, while physical simulators offer a more realistic experience.[11] Efforts have been made to combine these two types for structural heart interventions, although previous attempts have not included TEE and imaging views.[12] Our approach intentionally excludes the impractical 3D-printed heart model, focusing solely on the components that cardiologists manipulate, which is the delivery system. Replicating the instruments exactly allows for the realism of physical simulators to be combined with the flexibility of virtual reality simulators. The platform shows significant educational potential for training or refining skills for the LuX-Valve procedure. This simulator is also the first transcatheter valve implantation simulator developed using Unity. Additionally, a two-in-one simulator that combines digital and physical simulations of the delivery system and TEE allows simultaneous training for all members of the team involved in performing the intervention. This simulator can also be adapted for other procedures, such as transcatheter edge-to-edge repair, annuloplasty, or valve-in-valve, including for other valves (aortic, mitral, and pulmonary). This new type of simulator, combining virtual and physical patient-specific simulation, may play a significant role in the training and planning of TTVI. As this is the first case reported, further studies are warranted to evaluate its impact.

Lead author biography

Enzo Delamarre is a conceptor of simulators with a biomedical engineering background and is focusing on virtual reality patient-specific simulation for structural heart intervention.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports* online.

Acknowledgements

The authors would like to thank Dr Thomas Modine for his full support and advice during the conception of the simulator and Denis Corbin for his help on producing 3D heart meshes. The authors thank the team of the catheterization laboratory in Centre Cardiologique du Nord, Paris, France.

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with the COPE guidance.

Conflict of interest: None declared.

Funding: None declared.

Data availability

The data underlying this article are available in the article and its online supplementary material.

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