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VALVULAR HEART DISEASE

CASE REPORT: CLINICAL CASE

Transcatheter Aortic Valve Implantation Using the Evolut FX+ Platform With Optimal Diamond-Coronary Alignment

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ABSTRACT

We present one of the inaugural transcatheter aortic valve implantation procedures using the latest Medtronic platform, Evolut FX+. Successful coronary angiography was achieved within 28 seconds and 1 minute 49 seconds for the left and right coronary arteries, respectively. Postoperative cardiac computed tomography scan demonstrated optimal commissural and diamond-coronary alignment. (JACC Case Rep. 2024;29:102506) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

HISTORY OF PRESENTATION

A 76-year-old man with coronary artery disease (CAD) and severe aortic stenosis (AS) presented to our clinic experiencing shortness of breath (NYHA functional class III), fatigue, and exertional dizziness.

TAKE-HOME MESSAGES

- This case highlights the importance of preprocedural planning in TAVI, focusing on evaluating coronary access and ensuring proper commissural alignment.
- Understanding the procedural steps and hemodynamics when using the Evolut FX+ platform is crucial for optimizing coronary access and minimizing associated complications.
- The benefits of Evolut FX+ extend beyond its technological advancements to improve procedural outcomes and patient care.

PAST MEDICAL HISTORY

The patient had hypertension; end-stage renal disease requiring hemodialysis; diabetes mellitus; CAD with prior stent placements in the left anterior descending, left circumflex, and right coronary arteries; pulmonary hypertension; severe AS; and frailty.

DIFFERENTIAL DIAGNOSIS

The differential diagnosis included symptomatic AS, worsening CAD, and/or heart failure exacerbation.

INVESTIGATIONS

Transthoracic echocardiogram findings revealed an ejection fraction of 40% to 45% and severe calcific AS (mean gradient of 40 mm Hg, aortic valve (AV) area of 0.6 mm^2, and pulmonary artery systolic pressure of 90 mm Hg). Selective coronary angiogram (CA)

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ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

AV = aortic valve

CA = coronary angiogram

CAD = coronary artery disease

CT = computed tomography

LAO = left anterior oblique

TAVI = transcatheter aortic valve implantation

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

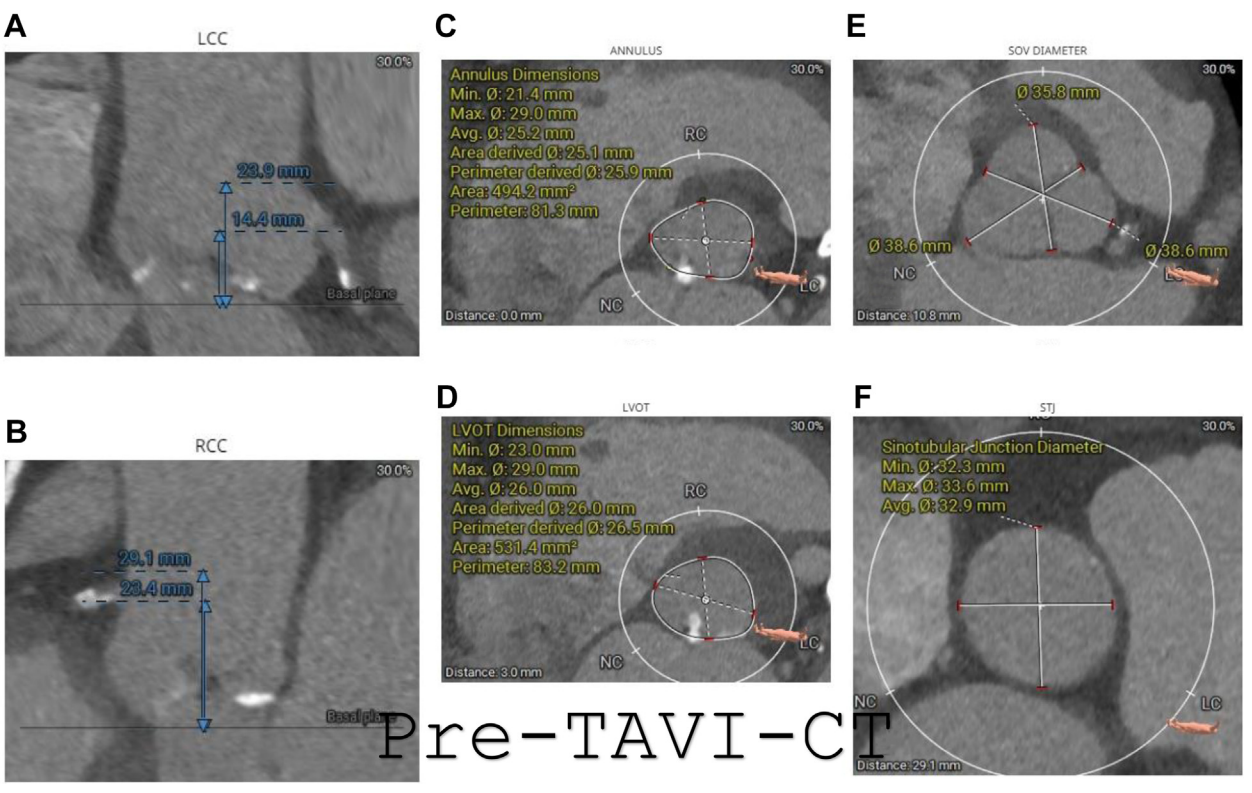
confirmed patent stents. Transcatheter AV implantation (TAVI) computed tomography (CT) indicated an annulus perimeter of 81 mm; an area of 494 mm^2; sinus of Valsalva diameters of 38.6, 35.8, and 38.6 mm; a sinus of Valsalva height of 23.9 mm; and a left ventricular outflow tract size of 83 mm and 531 mm^2, suitable for TAVI via a transfemoral approach (Figure 1).

MANAGEMENT

Following a multidisciplinary team review, TAVI was determined appropriate, considering the patient's age, frailty, multiple comorbidities, and intermediate surgical risk (STS mortality: 5.8%). Given his extensive CAD history, future coronary interventions may be necessary. This emphasizes the importance of appropriate transcatheter heart valve (THV) selection. The balloon-expandable Sapien S3 Ultra/Resilia valve (Edwards Lifesciences), the self-expanding intra-annular Navitor valve (Abbott), and the supra-annular Evolut FX valve (Medtronic) are suitable options for this patient. The Evolut FX+ is a novel Medtronic platform launched on May 13, 2024, designed to facilitate coronary access. Amidst these choices, our multidisciplinary team opted to use a 34-mm Evolut FX+ platform. Additionally, given the large dimensions of the sinus of Valsalva, the possibility of future redo transcatheter AV replacement (TAVR) seems highly feasible.

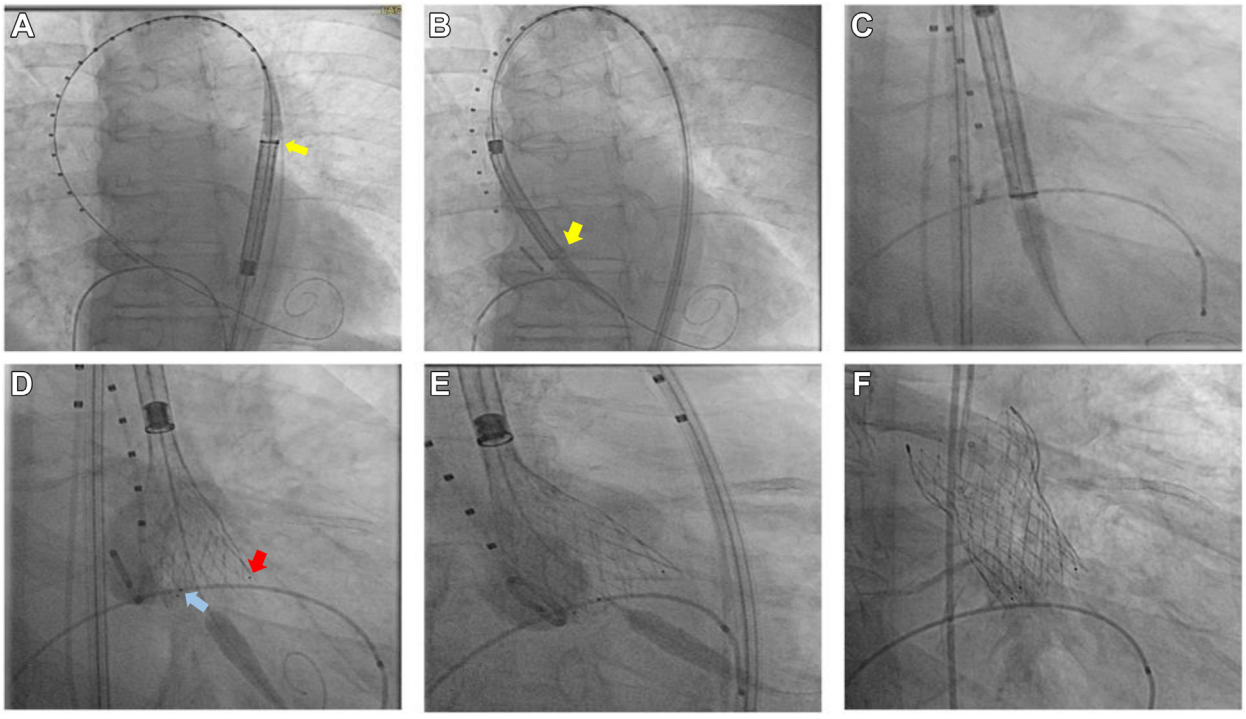
TAVI was performed with monitored anesthesia care. Transthoracic echocardiogram was used perioperatively. A pigtail catheter was advanced into the noncoronary cusp. After crossing the valve, the following hemodynamics were obtained: AV mean gradient of 40 mm Hg, peak gradient of 45 mm Hg, left ventricular systolic pressure of 195 mm Hg, end-diastolic pressure of 30 mm Hg, and aortic pressure

FIGURE 1 Pre-TAVI CT to Assess Suitability for TAVI



(A, B) Left and right coronary height. (C, D) Annulus and left ventricular outflow tract dimensions. (E) Sinus of Valsalva dimensions. (F) Sinotubular junction dimensions. Avg. = average; CT = computed tomography; LVOT = left ventricular outflow tract; Max. = maximum; Min. = minimum; SOV = sinus of Valsalva; TAVI = transcatheter aortic valve implantation.

FIGURE 2 **Cusp Overlap Technique to Ensure Commissural Alignment and Subsequent Diamond-Coronary Alignment**



Hat marker at the outer curve of (A) the descending aorta (LAO view), (B) the ascending aorta (LAO view), and (C) the center front of the ascending aorta (cusp overlap view). Parallax removed from the delivery system ring. (D) Cusp overlap view: 2 dots are toward the noncoronary cusp (blue), and 1 is toward the overlapped cusps (red). Depth: 3 mm. (E) Depth on the left coronary cusp side (LAO view). (F) The THV postdeployment. LAO = left anterior oblique; THV = transcatheter heart valve.

of 150/67 mm Hg. An extra small Safari wire was placed in the left ventricle. The AV was predilated using a 20-mm True balloon (Bard), and then the valve was deployed using the cusp overlap technique (**Figure 2**). Predilation was performed in the setting of high valve calcium burden and the 34-mm-size device. This technique entails isolating the noncoronary cusp and overlapping the left and right coronary cusps to achieve optimal positioning of the valve during deployment, ensuring a consistent depth of 3 mm on the noncoronary cusp side. The depth was confirmed by the dot position relative to the noncoronary cusp.

During advancement of the delivery system, the flush port was maintained at the 3 o'clock position. The hat marker was aligned with the outer curve of the descending aorta in the left anterior oblique (LAO) projection and remained at the outer curve of the ascending aorta while the system was advanced to the aortic annulus.

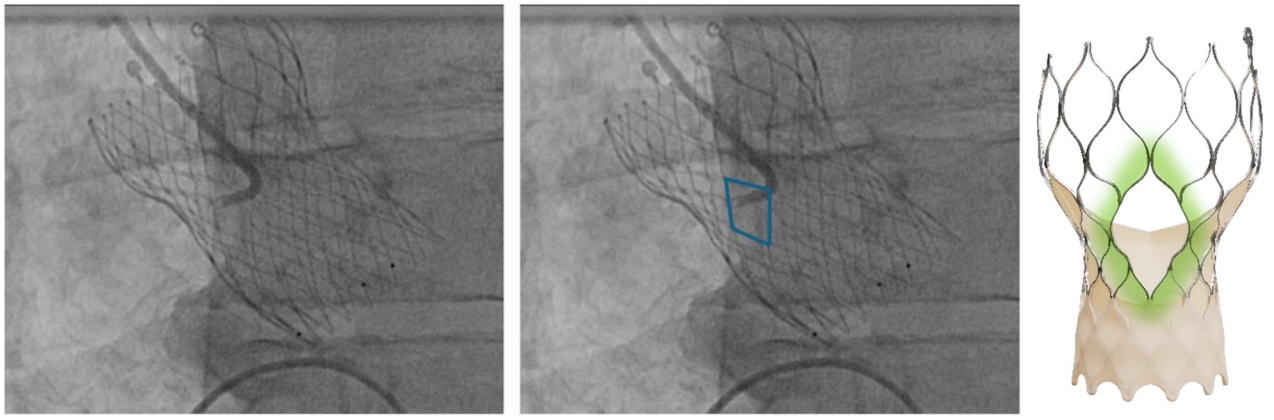
The cusp overlap angle[1,2] (right anterior oblique: 20; CAU: 36) confirmed that the hat marker was in the center front position, serving as a reliable predictor of commissural alignment before valve deployment.

Partial deployment of the valve was performed under pacing at 140 beats/min. Commissural alignment was confirmed by observing 2 dots at the side of the noncoronary cusp and 1 at the side of the overlapped cusps. After confirming the depth of the valve in the cusp overlap and LAO views, the Evolut FX+ was released.

Postdeployment, hemodynamic measurements were obtained: AV mean gradient of 5 mm Hg, peak gradient of 5 mm Hg, left ventricular outflow tract of 181 mm Hg, left ventricular end-diastolic pressure of 35 mm Hg, and aortic pressure of 181/64 mm Hg.

Selective coronary angiography was timed from catheter insertion with the J-wire to obtaining the CA. The left CA was completed in 28 seconds (Videos 1 and 2) using a Judkins left 3.5 catheter, and the right CA was performed in 1 minute and 49 seconds using a Judkins right 4 catheter (**Figure 3**, Video 3). Post-TAVI CT showed optimal commissural and diamond-coronary alignment (**Figures 4 and 5**, Video 4).

FIGURE 3 Diamond-Shaped Coronary Window Allowing Coronary Access to the Right Coronary Artery



OUTCOME AND FOLLOW-UP

The patient was discharged on postoperative day 1 without complications.

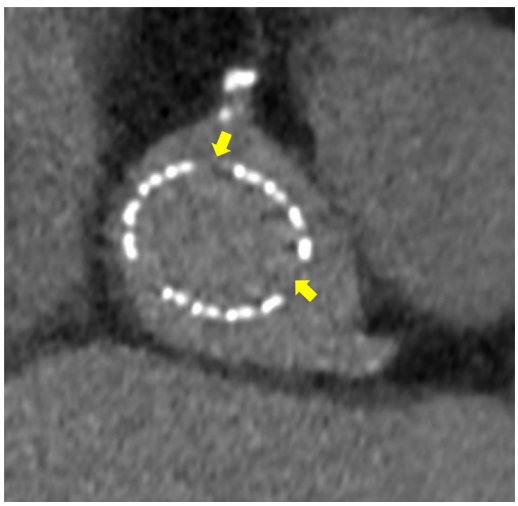
DISCUSSION

This case is the first, to our knowledge, to document the use of the latest Medtronic platform, Evolut FX+. With the growing number of TAVR procedures and the ongoing expansion of TAVR indications, including patients with long life expectancy, coronary artery access post-TAVR is becoming more common. Despite the rare occurrence of unplanned percutaneous coronary intervention post-TAVR, CAD and AS share the same pathogenesis and frequently coexist.[3] According to Reardon et al[4] and Leon et al,[5] 40% to 75% of TAVR candidates have CAD and might require future coronary access for selective CAs and/or percutaneous coronary intervention.

TAVI using tall-frame THVs has long faced criticism related to coronary access. ALIGN-ACCESS reported that commissural alignment of supra-annular THV with the native AV improves the coronary access success rate.[6] According to RE-ACCESS 2, 5.5% of the coronary cannulations post-TAVR were unsuccessful, mostly because of commissural misalignment.[7] Zaid et al[8] reported that more than 95% commissure alignment was established using the Evolut FX TAVR system, with fewer device recaptures and more symmetrical implantation.[8] In addition to concerns regarding commissural alignment, the small supra-annular THV cells pose an additional challenge for coronary access.

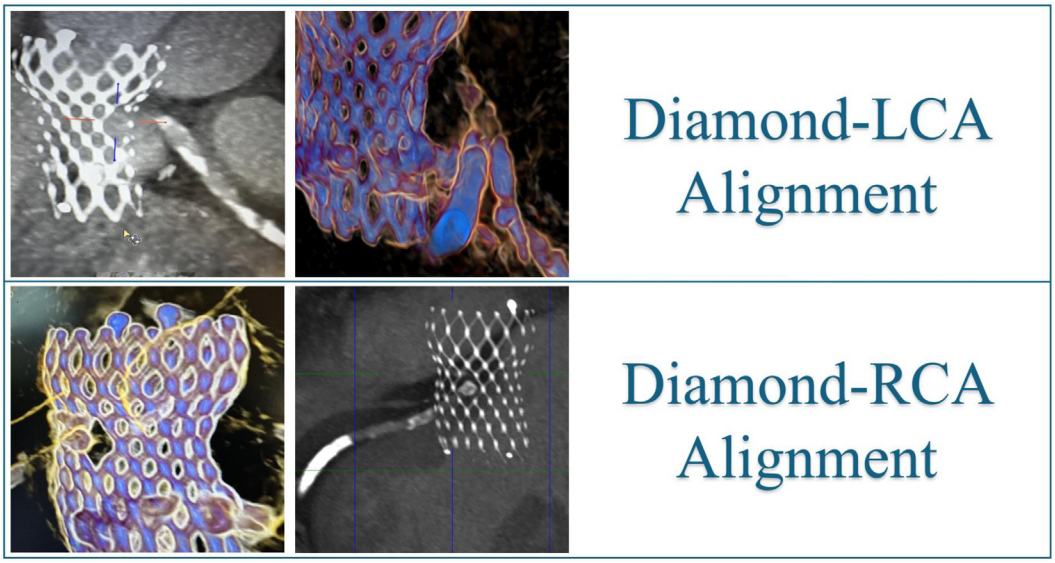
Optimizing future coronary access with this platform relies on an implantation technique to optimize commissural alignment and on widening the cells to facilitate access with FX+ in commissural misalignment. Addressing this concern, Evolut FX+ introduces a revolutionary design enhancement, with larger coronary access windows at 120° apart, improving access without affecting radial strength or valve performance. In this case, we have demonstrated that adhering to implantation steps for achieving commissural alignment can also enhance diamond-to-coronary alignment, facilitating rapid coronary access, as evidenced by the brief duration required for coronary angiography. Evolut FX+, with its innovative coronary windows, represents a

FIGURE 4 Post-TAVI CT Showing Optimal Diamond-Coronary Artery Alignment



Abbreviations as in Figure 1.

FIGURE 5 A 3-Dimensional Volume-Rendering CT Demonstrating Optimal Diamond-Coronary Artery Alignment



The cross-hair is at the diamond-shaped coronary window, giving access to the left coronary cusp. CT = computed tomography.

significant advancement in this supra-annular platform, promising enhanced future coronary access.

CONCLUSIONS

The Evolut FX+ platform demonstrates promising advancements in facilitating coronary access and achieving optimal commissural alignment after TAVI procedures.

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Dr Reardon has served as a consultant for Medtronic, Boston Scientific, Abbott, and W. L. Gore & Associates. Dr Kleiman has served as a local principal investigator in trials sponsored by Boston Scientific, Medtronic, Abbott, and Edwards Lifesciences. Dr Goel has served as a consultant for Medtronic, W. L. Gore & Associates, and J. C. Medical and on the Speakers Bureau for Abbott Structural Heart. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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KEY WORDS aortic stenosis, commissural alignment, coronary access, Evolut FX+, transcatheter aortic valve implantation

APPENDIX For supplemental videos, please see the online version of this paper.