Comparison of Evolut FX with Latest-generation Evolut FX+ Transcatheter Aortic Valve Systems in Real-World Practice

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Disclosure of relevant financial relationships

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below:

Financial Relationship	Company
Institutional grants/research support	Dasi Simulations, Elixir, Boston Scientific, Medtronic
Consulting fees/honoraria	Dasi Simulations, Elixir, Boston Scientific, Medtronic
Shareholder/equity	
Editorial	

Medtronic supported this physician-initiated research and performed the statistical analysis. The views or opinions presented here do not represent those of the American College of Cardiology (ACC) Foundation, the Society of Thoracic Surgeons (STS), or the STS/ACC Transcatheter Valve Therapy (TVT) Registry. The industry data file upon which the analysis was performed is a subset of the full STS/ACC TVT Registry data submissions.

Background

- The evolution of Evolut transcatheter valves

CoreValve™
2014

First self-expanding TAVR valve

Evolut™ R
2015

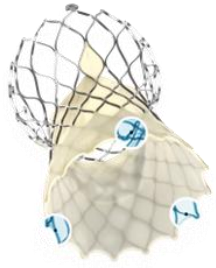
- Recapturability
- Lower delivery profile
- Consistent radial force

Evolut™ PRO
2017

Reduction in paravalvular leak

Evolut™ PRO+
2019

- Lower delivery profile
- Large valve PVL performance



Evolut™ FX
2022

- Greater precision and control
- Radiopaque markers deployment depth and commissure location
- Ease of use

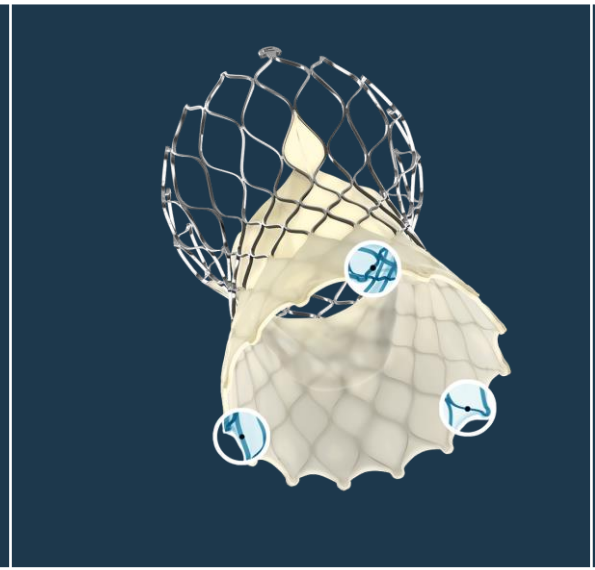
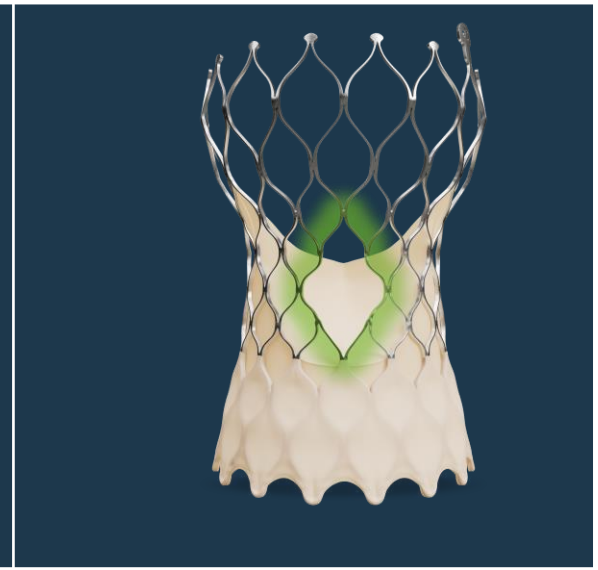
Evolut™ FX+
2024

- Larger window for enhanced coronary access
- Same valve performance as the CoreValve/Evolut platform

- Successful cannulation has been previously demonstrated for both FX and FX+.[1] Here, we aimed to confirm that FX+ and FX deliver similar early clinical outcomes in real-world practice using data from TVT Registry.

1. Feroze R, et al. Structural Heart 2025; 9(8):100483.

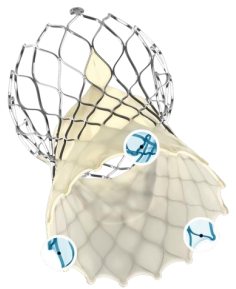
Valve Design

Valve Design Feature		
Self-expanding nitinol frame	✓	✓
Consistent radial force	✓	✓
Supra-annular, porcine pericardial valve	✓	✓
Pericardial wrap	✓	✓
Radiopaque markers for deployment depth and commissure location	✓	✓
Large apertures for coronary access		✓

Study Design

TVT Registry Analysis

9889 Tricuspid AS patients undergoing native TAVR with Evolut FX or FX+
from April 2024 to September 2024
at 613 centers



Evolut FX Implants
n = 7353

Evolut FX+ Implants
n = 2536

Procedural, in-hospital, and 30-day outcomes

Baseline Characteristics

Evolut FX and FX+ groups were well balanced

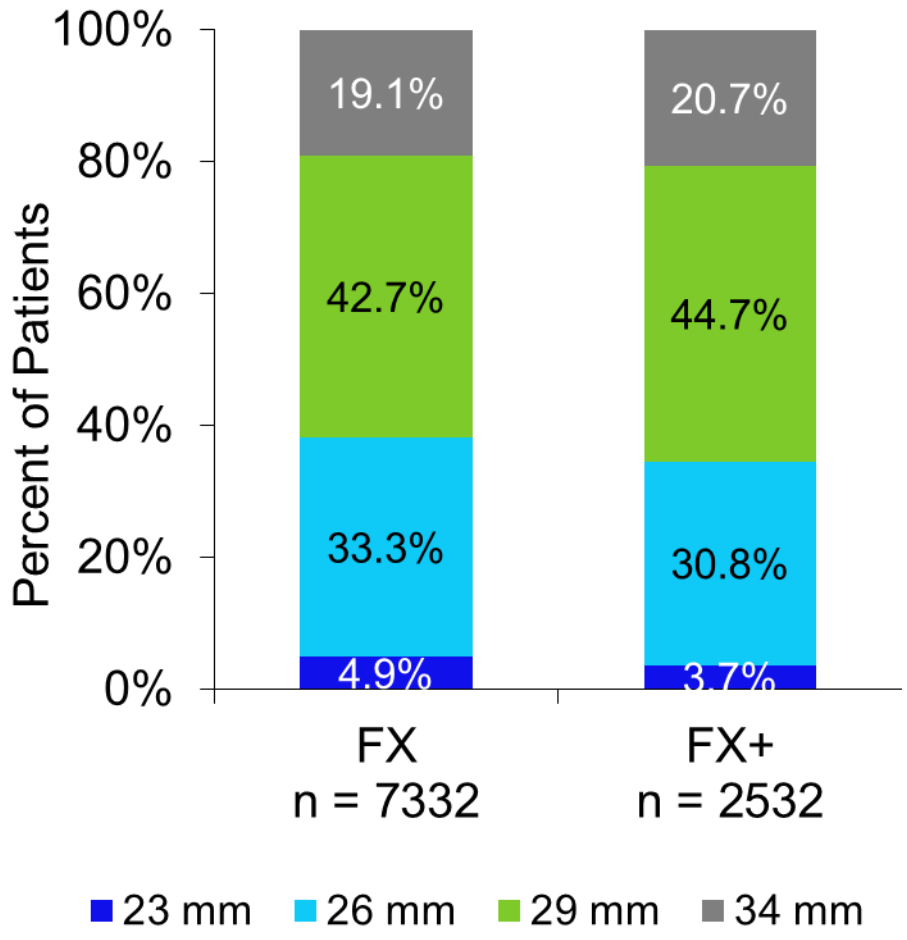
Characteristic	Evolut FX (n = 7353)	Evolut FX+ (n = 2536)	*P* Value	Absolute SMD
Age – years	**80.3 ± 7.4**	**79.9 ± 7.4**	**0.01**	**0.059**
Female sex	**54.5%**	**53.5%**	**0.41**	**0.019**
STS-PROM score – %	**5.7 ± 5.1**	**5.6 ± 5.2**	**0.48**	**0.016**
Body mass index < 21 kg/m^2	6.9%	7.4%	0.42	0.018
NYHA functional class III/IV	58.0%	52.5%	< 0.001	0.109
Diabetes mellitus	39.5%	38.8%	0.55	0.014
Creatinine > 2 mg/mL	5.9%	6.6%	0.21	0.029
Peripheral vascular disease	15.8%	14.7%	0.17	0.032
Previous PCI	26.3%	27.6%	0.18	0.031
Previous CABG	11.9%	10.5%	0.06	0.044
Conduction defect	31.5%	35.1%	0.001	0.076
Atrial fibrillation/flutter	33.6%	32.9%	0.51	0.015
Pre-existing pacemaker	12.0%	11.8%	0.76	0.007

Data presented as mean ± SD or %
SMD = standardized mean difference

Procedure Characteristics

Characteristic	FX n = 7353	FX+ n = 2536	*P* Value
Iliofemoral access	96.7%	96.4%	0.46
General anesthesia	33.4%	32.7%	0.56
Recapture/repositioning	17.7%	17.9%	0.80
More than 1 valve used	0.9%	1.1%	0.30
Implant success	99.8%	99.8%	0.56
Procedure time, min	60.0 (44.0, 81.0)	56.0 (41.0, 74.0)	< 0.001
Length of hospital stay post procedure, days	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	0.69

Implanted Valve Size



Data presented as % or median (Q1, Q3)

Major Safety Outcomes

	In Hospital			30 Days		
	FX (n = 7353)	FX+ (n = 2536)	*P* Value	FX (n = 7353)	FX+ (n = 2536)	*P* Value
All-cause mortality	1.0%	0.5%	0.03	1.8%	1.2%	0.05
Cardiovascular mortality	0.7%	0.2%	0.003	1.2%	0.4%	0.002
Stroke	2.1%	1.7%	0.14	3.1%	3.0%	0.74
Life-threatening or major bleed	3.8%	4.1%	0.51	4.4%	4.6%	0.72
Major vascular complication	1.5%	1.5%	0.92	1.7%	1.6%	0.85
Aortic-valve reintervention	0.1%	< 0.1%	0.69	0.1%	< 0.1%	0.26
New permanent pacemaker	10.6%	11.6%	0.19	13.7%	14.3%	0.38

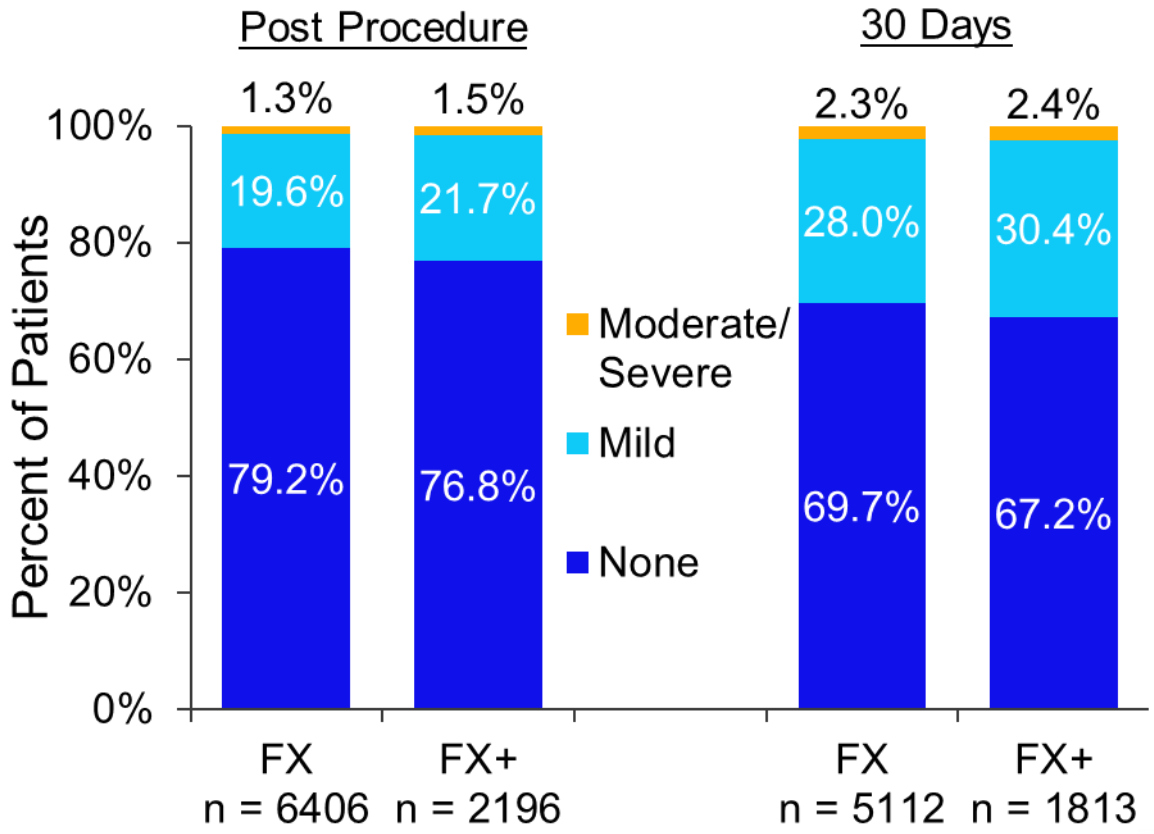
In-hospital rates reported as proportions; 30-day rates reported as Kaplan-Meier estimates.

Hemodynamics

	FX n = 7353	FX+ n = 2536	*P* Value
Post Procedure			
Effective orifice area – cm^2	2.1 ± 0.6 (4818)	2.2 ± 0.7 (1820)	< 0.001
Valve gradient – mm Hg	7.9 ± 4.6 (6792)	8.0 ± 4.2 (2260)	0.40
30 Days			
Effective orifice area – cm^2	2.0 ± 0.6 (3906)	2.0 ± 0.6 (1484)	0.86
Valve gradient – mm Hg	7.5 ± 3.9 (5529)	7.9 ± 4.3 (1910)	< 0.001

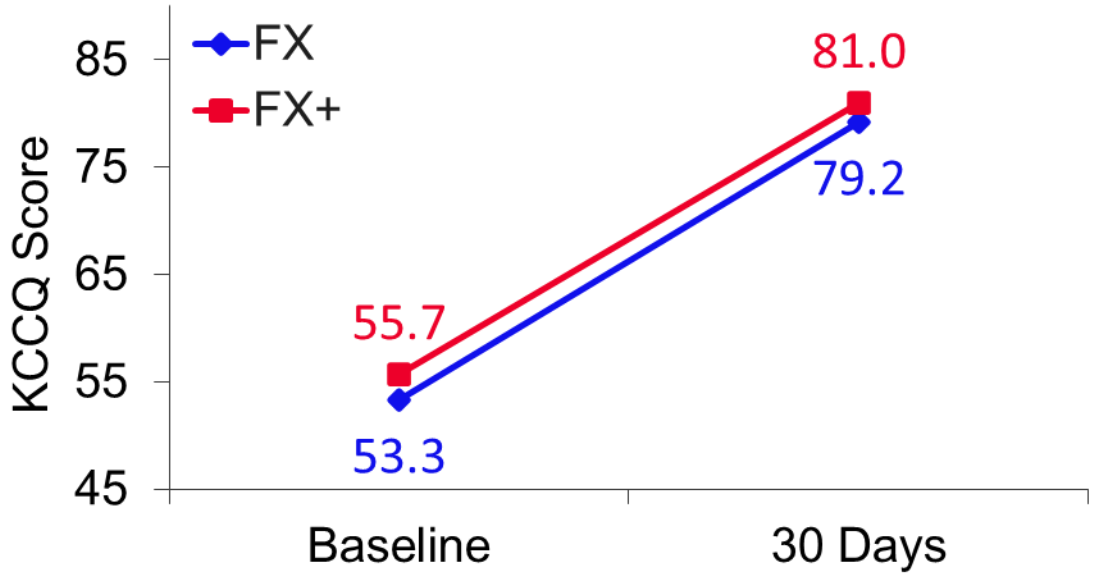
Data presented as mean ± SD (n).

Paravalvular Leak



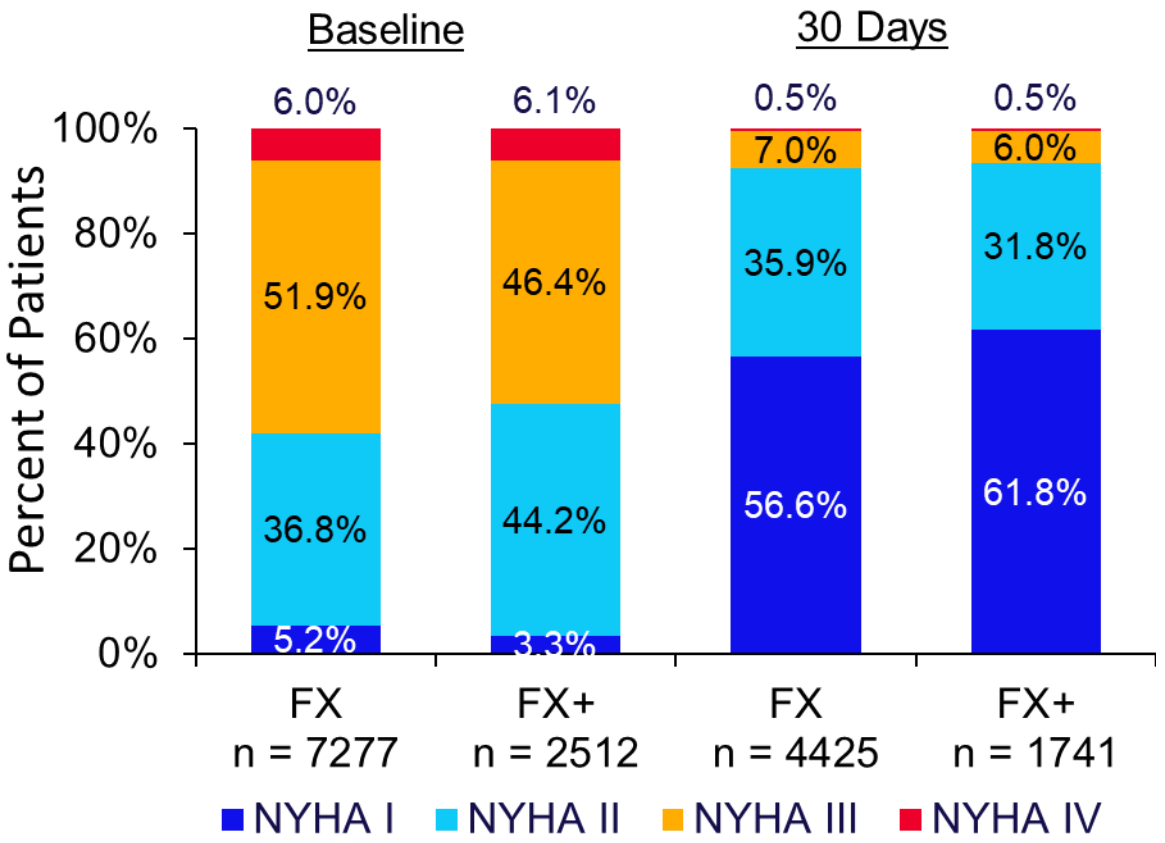
Quality of Life

KCCQ Overall Summary Score



FX	6893	5445
FX+	2445	1982
FX		25.2 ± 24.9 (5290)
FX+		24.7 ± 25.7 (1942)
P value		0.49

New York Heart Association



Conclusions

- **Evolut FX+ and Evolut FX valves showed similar early safety and echocardiographic outcomes in this real-world registry analysis of nearly 10,000 patients from >600 centers.**
- Evolut FX+ and FX valves had similarly high (99.8%) implant success rates, with shorter procedure times with FX+
- Evolut FX+ and FX valves had similar early safety profiles, with low rates of cardiovascular mortality and similar pacemaker implantation rates through 30 days
- Evolut FX+ and FX valves demonstrated excellent hemodynamics with low rates of moderate/severe PVR and similar improvements in quality of life at 30 days