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Medtronic Structural Heart Analyst and Investor Briefing

Discussion of the SMART Trial Data

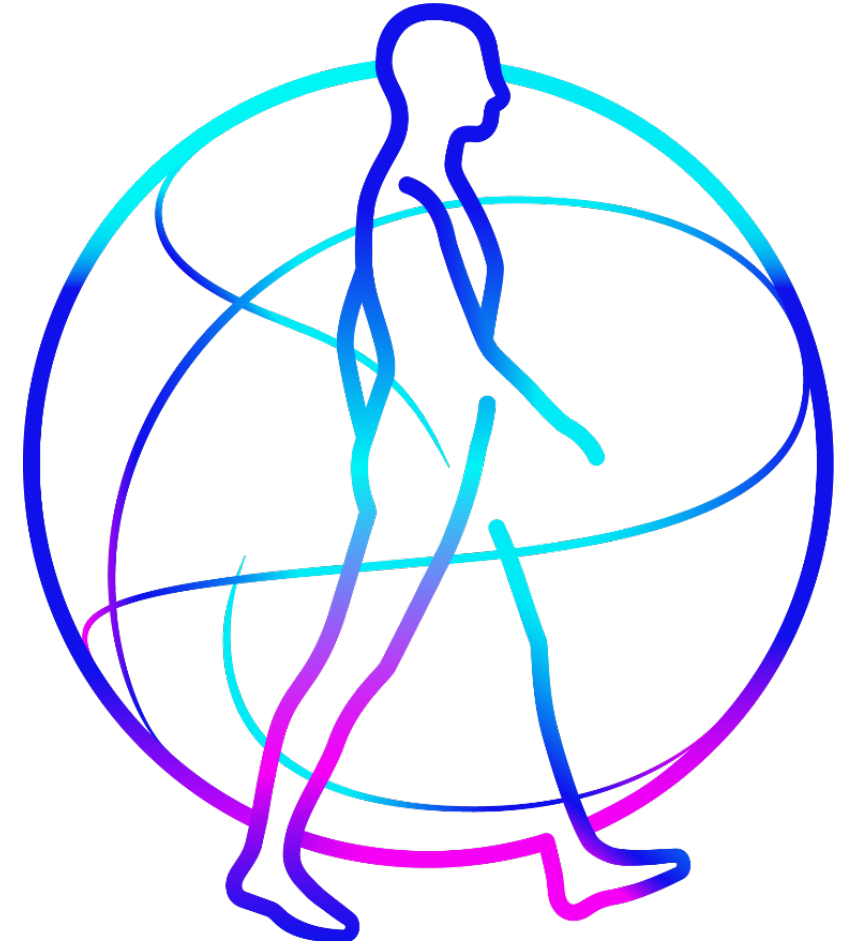
ACC.2024 | Atlanta, GA | April 7, 2024



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Today's agenda

01 Opening Remarks

Ryan Weispfenning
Geoff Martha

02 SMART Trial Introduction

Nina Goodheart

03 1-Year SMART Trial Results

Dr. Jeffrey Popma

04 Closing

Sean Salmon

05 Panel Q&A

All

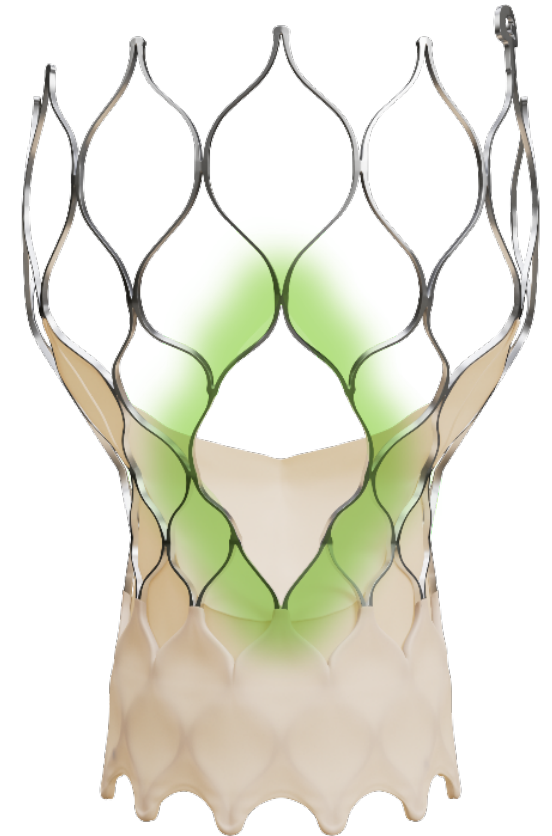
Establishing track record of consistency and driving durable growth

Data-driven momentum is building for Structural Heart franchise

Leading positions across large secular growth markets
amplified by new product cycles

Innovation and evidence generation positions
Medtronic to take share in high growth TAVR market

Executing on commitments and focused on delivering
strong shareholder returns



SMART Trial | A clear win for Medtronic

Structural Heart poised to deliver strong growth with product launches and superior clinical data



All primary and prespecified secondary endpoints met

- **Superiority** in coprimary valve performance endpoint
- **Superiority** in all powered secondary endpoints
- **Numerically better, non-inferior** in coprimary clinical endpoint



Simultaneous publication in **The New England Journal of Medicine**



First head-to-head TAVR RCT with **intentional focus on women** that answers valve selection question for small annulus patients and **solidifies valve performance leadership**



1-yr data is critically meaningful because **early valve performance (BVD) is associated with a 50% increase in mortality and rehospitalization¹**

Small annulus TAVR market

40% of total WW TAVR market

35% of EW's US TAVR valves



Additional opportunities across multiple TAVR populations (women, Asian-descent, valve-in-valve)

Strong cadence of MDT product launches and clinical data are growth catalysts in \$6B WW TAVR market growing high-single to low-double digits

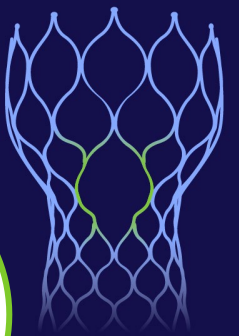
Evolut FX+ full US market release anticipated Summer 2024

Continued Evolut™ FX launch in Japan and Western Europe

Evolut Low Risk Trial 4-year data demonstrated TAVR outperformed surgery with sustained valve performance² and proved cost-effectiveness of Evolut TAVR versus SAVR³

Decade of durability data from NOTION Trial, showing continued benefit of CoreValve platform vs. gold-standard surgical arm⁴

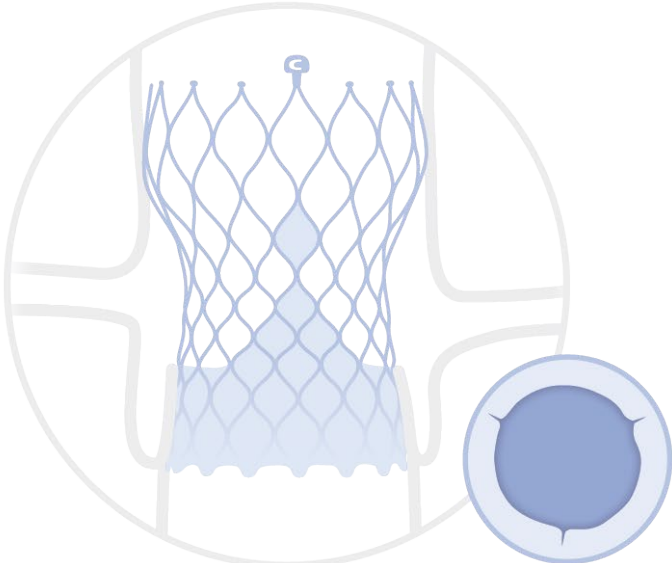
Evolut™ FX+ TAVR System now FDA approved



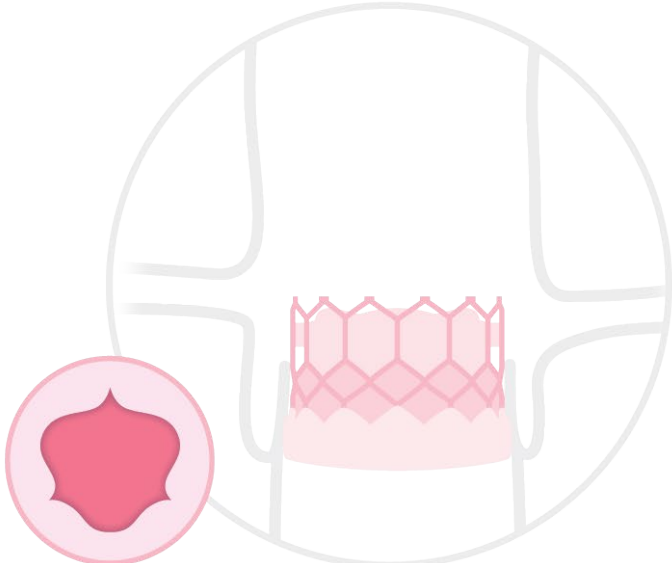
Valve Design | Importance of valve design proven in head-to-head SMART Trial

Highly anticipated trial proves not all TAVR platforms are built the same

Implanters have asked for a direct comparison of two most used TAVR valves



Evolut™ TAVR System
Supra-annular | Self-expanding



SAPIEN™* TAVR System
Intra-annular | Balloon-expandable

Trial Details

Small annulus as defined by $\leq 430 \text{ mm}^2$ by MDCT

- Prospective, multi-center, international, randomized controlled trial
- **83 sites** in Canada, EMEA, and United States
- **716 patients** 1:1 Randomization stratified by sex
- 30-day and annual follow-ups for patients out to **5-Yrs**

The **SM**all **Ann**uli **R**andomized **T**o **E**volut or **S**APIEN Trial, or **SMART Trial**, studies how fundamental valve design differences affect treatment of symptomatic, severe aortic stenosis in patients with small aortic annuli.⁵

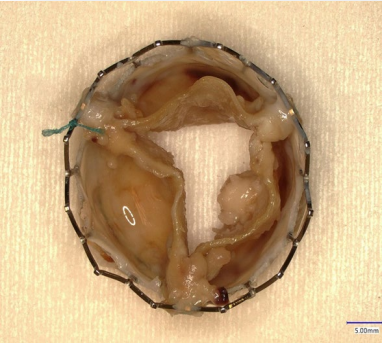
Bioprosthetic Valve Dysfunction (BVD) portends death and rehospitalization

Aortic Valve Replacement (AVR) patients want great valve performance for their lifetime

Four categories of "Bioprosthetic Valve Dysfunction"

Structural Valve Deterioration

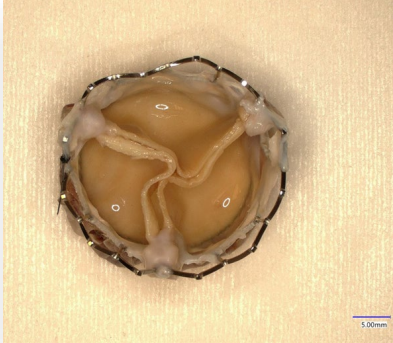
Occurs Years After AVR



Valve becomes **calcified, damaged,** or otherwise **not functioning correctly**

Non-Structural Valve Dysfunction

Occurs Immediately After AVR



Valve is not damaged, but the **orifice is not large enough** to permit sufficient blood flow for the patient or is leaking around the edge

Thrombosis

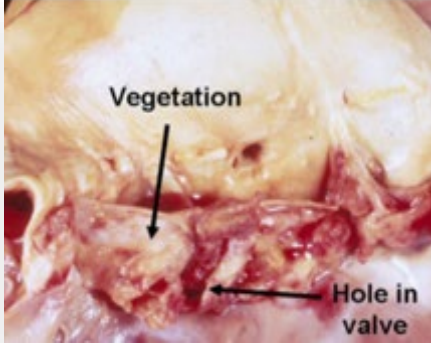
Occurs Unpredictably Anytime After AVR



Blood clots form on the leaflets that restrict movement and blood flow

Endocarditis

Occurs Unpredictably Anytime After AVR



Bacterial infection of the bioprosthetic valve leaflets

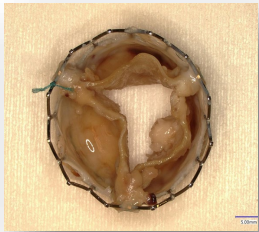
Bioprosthetic Valve Dysfunction (BVD) leads to death and rehospitalization

Each component of BVD portends an adverse outcome

Four categories of "Bioprosthetic Valve Dysfunction"

Structural Valve Deterioration

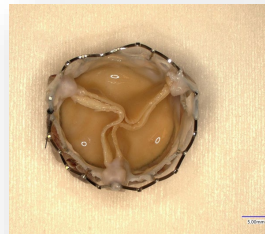
Occurs Years After AVR



18

Non-Structural Valve Dysfunction

Occurs Immediately After AVR



19

Thrombosis

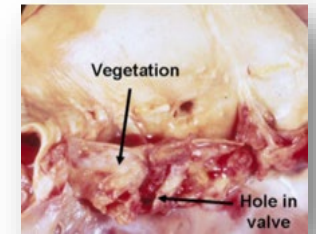
Occurs Unpredictably Anytime After AVR



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Endocarditis

Occurs Unpredictably Anytime After AVR



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ECHOCARDIOGRAPHY IN VALVULAR HEART DISEASES

Poor Survival with Impaired Valvular Hemodynamics After Aortic Valve Replacement: The National Echo Database Australia Study

Check for updates

David Playford, MBBS, PhD, FCSANZ, FESC, FACC, Simon Stewart, FESC, FAHA, FHFA, PhD, David Celemajer, MBBS, PhD, FCSANZ, FAHA, David Prior, MBBS, PhD, FCSANZ, FESC, FACC, Gregory M. Scalia, MBBS (Hons), FCSANZ, FACC, MMedS, Thomas Marwick, MBBS, PhD, MPH, Marcus Ilton, MBBS, FCSANZ, FRACP, Jim Codde, PhD, and Geoff Strange, FCSANZ, PhD, on behalf of the NEDA Contributing Sites, Fremantle, Adelaide, Sydney, Melbourne, Brisbane, and Casuarina, Australia

frontiers | Frontiers in Cardiovascular Medicine

TYPE Original Research
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Check for updates

Self-expanding vs. balloon-expandable transcatheter heart valves in small aortic annuli

Anastasiya Kornyeva^{1*}, Melchior Burri¹, Rüdiger Lange^{1,2,3} and Hendrik Ruge^{1,2}

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EDITED BY
Luca Testa,
IRCCS San Donato Polyclinic, Italy

REVIEWED BY
Guido Carlomagno,
Clnica Mediterranea, Italy
Andreas Schaefer,
University Medical Center Hamburg-Eppendorf,
Germany

*CORRESPONDENCE

¹Department of Cardiovascular Surgery, German Heart Centre Munich at the Technical University Munich, Munich, Germany, ²Institute for Translational Cardiac Surgery, Department of Cardiovascular Surgery, German Heart Centre Munich at the Technical University of Munich, Munich, Germany, ³DZHK German Center for Cardiovascular Research-Partner Site Munich Heart Alliance, Munich, Germany

ORIGINAL ARTICLE

Clinical Impact of Hypoattenuating Leaflet Thickening After Transcatheter Aortic Valve Replacement

Santiago Garcia¹, MD; Miho Fukui², MD, PhD; Marshall W. Dworak³, BS; Brynn K. Okeson⁴, MS; Ross Garberich⁵, MS, MBA; Go Hashimoto⁶, MD; Hiroto Sato, MD, PhD; João L. Cavalcante, MD; Vinayak N. Bapat, MD; John Lesser, MD; Victor Cheng, MD; Marc C. Newell, MD; Mario Goessi, MD, PhD; Sammy Elmariah⁷, MD, MPH; Steven M. Bradley⁸, MD, MPH; Paul Sorajja, MD

BACKGROUND: Hypoattenuated leaflet thickening (HALT), identified on functional cardiac computed tomography (CTA), can affect valve function and clinical outcomes. The objective of this study was to assess the impact of HALT on clinical outcomes in patients treated with transcatheter aortic valve replacement (TAVR).

Journal of the American Heart Association

ORIGINAL RESEARCH

Prosthetic Valve Endocarditis After Aortic Valve Replacement With Bovine Versus Porcine Bioprostheses

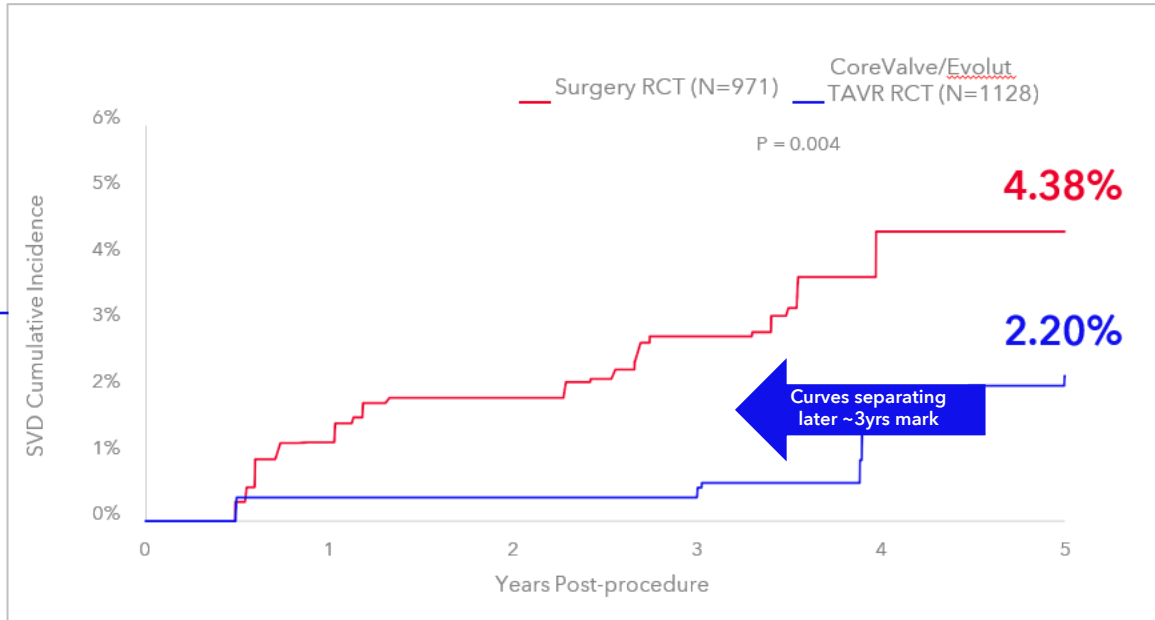
Natalie Glaser¹, MD, PhD; Ulrik Sartipy², MD, PhD; Michael Dismorr³, MD, PhD

BACKGROUND: Whether a bovine or porcine aortic valve bioprosthesis carries a higher risk of endocarditis after aortic valve replacement is unknown. The aim of this study was to compare the risk of prosthetic endocarditis in patients undergoing aortic valve replacement with a bovine versus porcine bioprosthesis.

Poor valve performance causes an increase in 5-year hard clinical endpoints

Structural Valve Deterioration (SVD) occurs later

SVD Cumulative Incidence



SVD Predicts 5-Year Mortality

Worsened Clinical Outcomes in Patients Who Develop SVD

	HR (95% CI)	P value
Pooled Surgery RCT and All CoreValve/Evolut* (N=4762)		
All-cause mortality	2.03 (1.46, 2.82)	<0.001
Cardiovascular mortality	1.86 (1.20, 2.90)	0.006
Aortic valve-related hospitalization	2.17 (1.23, 3.84)	0.008
Composite †	2.02 (1.42, 2.88)	<0.001
Surgery RCT (N=971)		
All-cause mortality	2.45 (1.40, 4.30)	0.002
Cardiovascular mortality	2.37 (1.10, 5.08)	0.03
Aortic valve-related hospitalization	2.20 (0.81, 5.98)	0.12
Composite †	2.73 (1.53, 4.88)	<0.001
All CoreValve/Evolut TAVR* (N=3791)		
All-cause mortality	2.34 (1.55, 3.53)	<0.001
Cardiovascular mortality	2.17 (1.26, 3.76)	0.006
Aortic valve-related hospitalization	2.45 (1.22, 4.93)	0.01
Composite †	2.03 (1.29, 3.19)	0.002

*RCT and Non-RCT cohorts
CoreValve 97%, Evolut R 3%
† All-cause mortality or aortic valve-related hospitalization

0.10 1.00 10.00
Lower risk with SVD ← → Higher risk with SVD

When SVD occurs, it is associated with⁶



100%
5-YR rate of

DEATH

CV DEATH

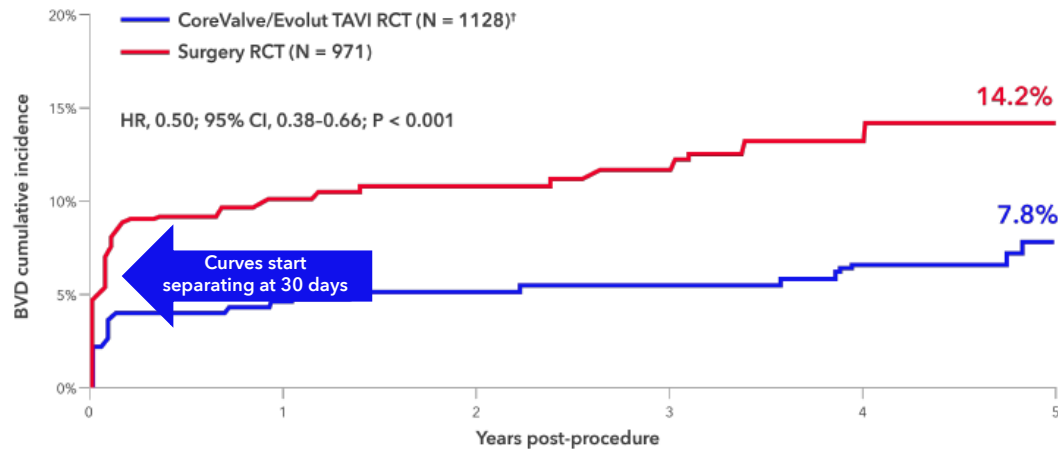
REHOSPITALIZATION

COMPOSITE

Poor valve performance causes an increase in 5-year hard clinical endpoints

BVD occurs **earlier** with curves separating starting at 30 days

BVD Cumulative Incidence



BVD Predicts 5-Year Mortality

	HR (95% CI)	P value
Pooled surgery of RCT and All CoreValve/Evolut TAVI (N = 4762)		
All cause mortality	1.49 (1.31, 1.71)	< 0.001
Cardiovascular mortality	1.68 (1.43, 1.99)	< 0.001
Hospitalization for valve disease/worsening HF	1.34 (1.10, 1.63)	0.003
Composite	1.40 (1.23, 1.60)	< 0.001
Surgery RCT (N = 971)		
All cause mortality	1.58 (1.15, 2.19)	0.005
Cardiovascular mortality	2.14 (1.44, 3.18)	< 0.001
Hospitalization for valve disease/worsening HF	1.67 (1.11, 2.51)	0.01
Composite	1.51 (1.12, 2.02)	0.007
All CoreValve/Evolut TAVI (N = 3791)		
All cause mortality	1.55 (1.34, 1.80)	< 0.001
Cardiovascular mortality	1.70 (1.41, 2.04)	< 0.001
Hospitalization for valve disease/worsening HF	1.31 (1.05, 1.64)	0.02
Composite	1.44 (1.25, 1.67)	< 0.001

Lower risk to patients with BVD (0.10) | Higher risk to patients with BVD (10.00)

The presence of BVD is associated with¹



50%
5-YR rate of

DEATH

CV DEATH

REHOSPITALIZATION

COMPOSITE

SMART | Clear win for Evolut™ and better outcomes for patients vs. SAPIEN™

Both co-primary and all secondary powered endpoints met⁵

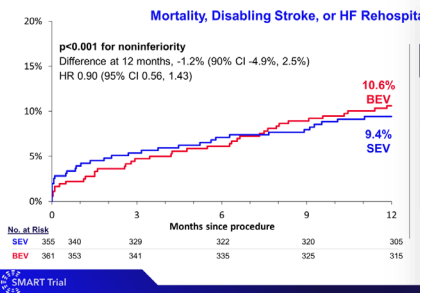
Co-primary Endpoints [through 12 months]:

- ✓ **Numerically better, non-inferior clinical outcomes:** Mortality, disabling stroke, or heart failure rehospitalization
- ✓ **Superiority on valve function:** Bioprosthetic valve dysfunction; composite of:
 - Hemodynamic Structural Valve Dysfunction (HSVD)^{†,‡}
 - Non-Structural Valve Dysfunction (NSVD)^{†,‡}
 - Thrombosis
 - Endocarditis
 - Aortic valve re-intervention

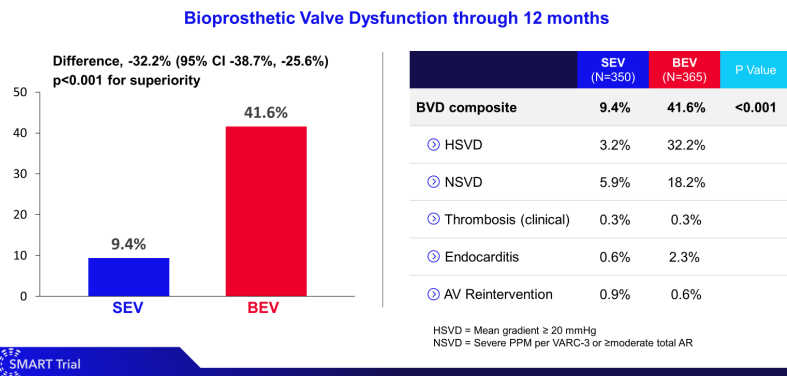
Secondary Endpoints [through 12 months]:

- ✓ **Superiority on all five endpoints:**
 - ✓ Bioprosthetic valve dysfunction in female subjects
 - ✓ Hemodynamic structural valve dysfunction in all subjects
 - ✓ Hemodynamic mean gradient (continuous variable)
 - ✓ Effective orifice area (EOA) as continuous variable
 - ✓ Moderate or severe PPM at 30 days

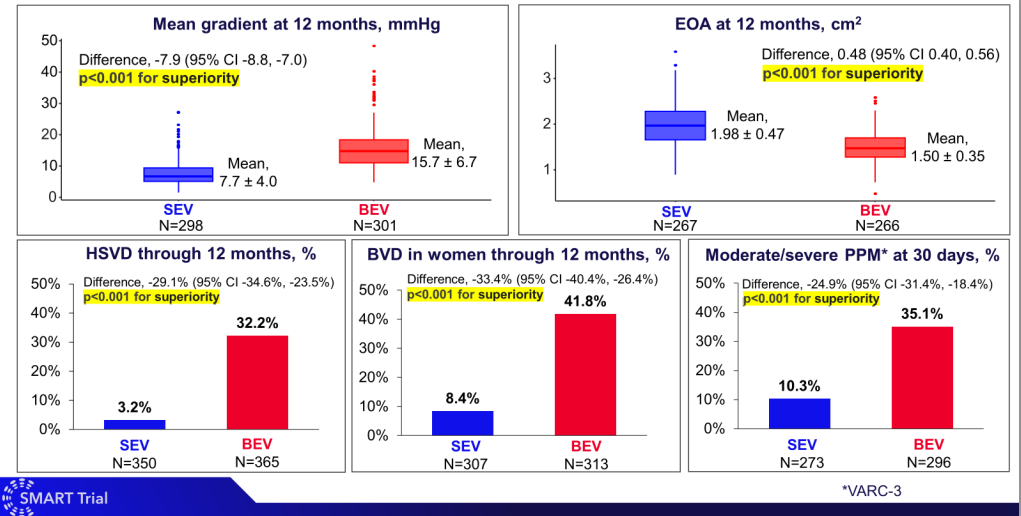
Co-primary endpoint 1: Clinical outcome composite through 12 months



Co-primary endpoint 2: BVD through 12 months powered for superiority



Hypothesis-tested secondary endpoints



[†] HSVD and NSVD are based on Echo core lab data, and events thrombosis, endocarditis, and aortic valve reintervention are from CEC adjudications.
[‡] HSVD: mean gradient ≥ 20 mmHg; Non-structural valve dysfunction: severe Patient Prosthesis Mismatch (PPM), ≥ moderate total Aortic Regurgitation

Evolut™ demonstrated superior valve performance in small annulus patients

4.4x fewer Evolut™ patients developed BVD at 1year⁵



Number Needed To Treat (NNT):

For every 10 patients treated with SAPIEN™ TAV, 4 developed BVD. Of those, 3 could have been avoided if they had been treated with an Evolut™ TAV.

Valve function superiority

Bioprosthetic valve dysfunction through 1 year, $p < 0.001$

9.4%

Evolut™ platform

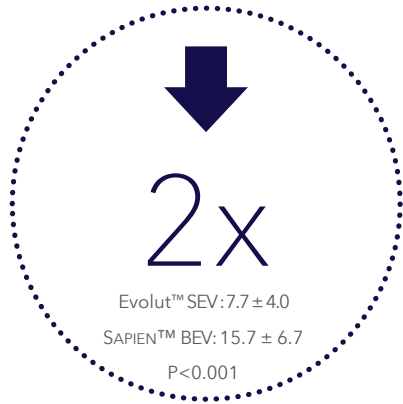
41.6%

SAPIEN™ platform

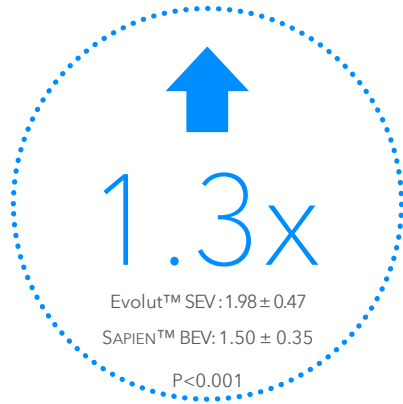


Evolut™ TAVR demonstrated vastly superior valve performance in small annulus patients vs. SAPIEN™ TAVR at 1 year⁵

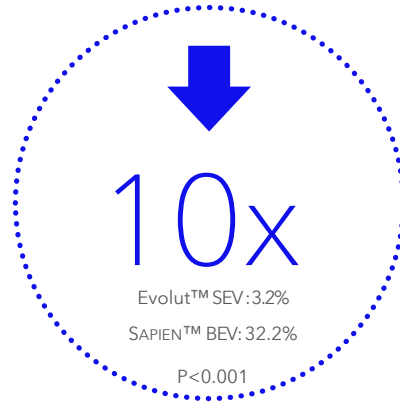
All five powered secondary endpoints met superiority



lower mean gradient



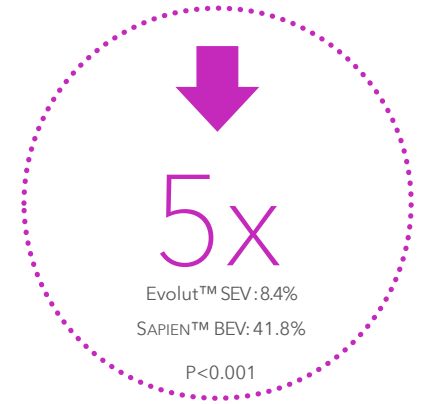
greater effective orifice area



less frequent residual gradients (≥ 20 mmHg)



less ≥ moderate prosthesis-patient mismatch (PPM) at 30 days

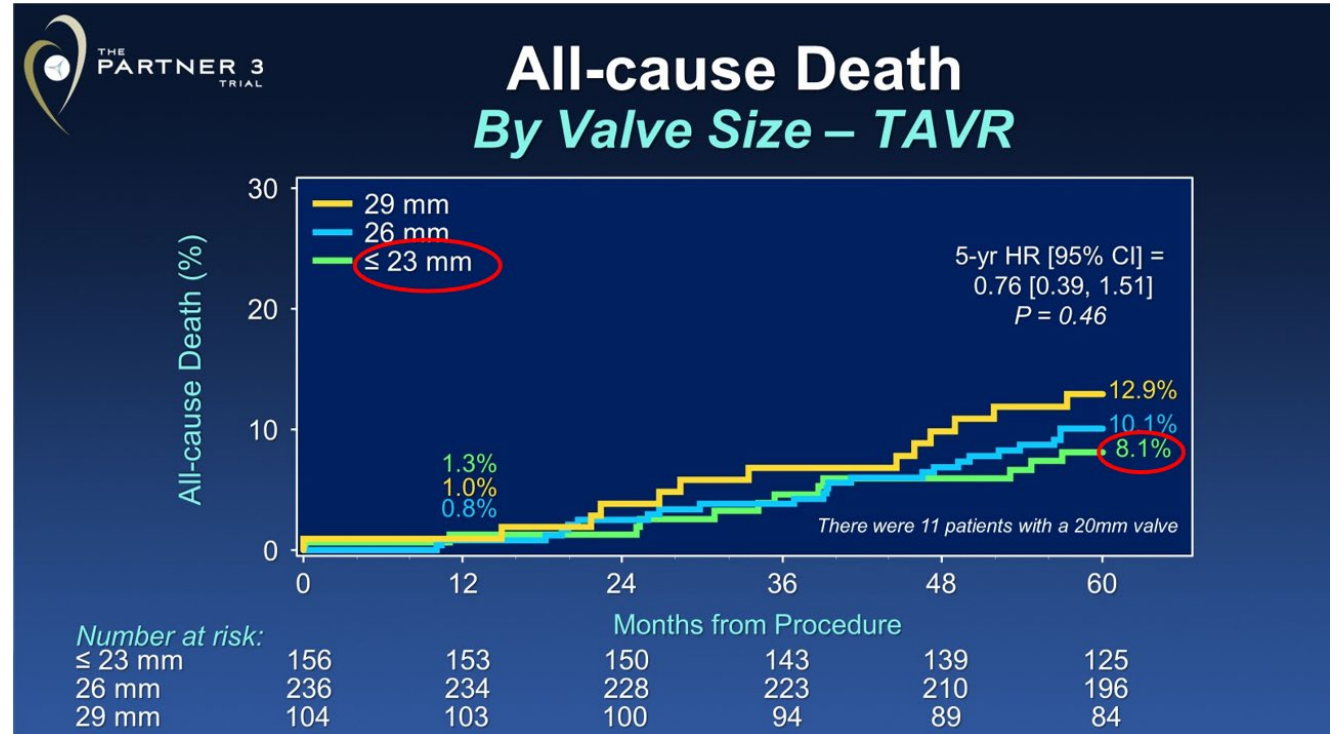
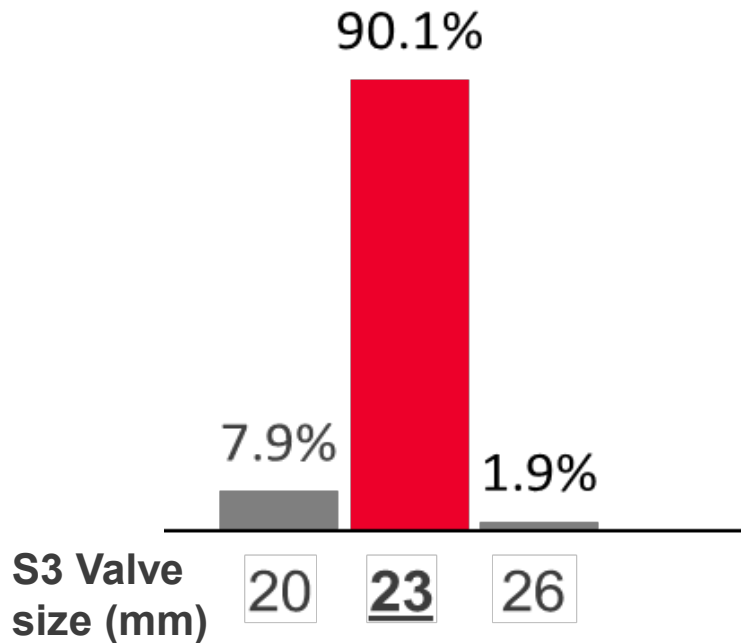


less BVD in women



SMART evaluated patients treated with the best performing SAPIEN™ valve size in PARTNER 3 Trial

SAPIEN™ valve size mix in SMART (N=365)



Note: 23mm S3 = 93% of ≤23mm size grouping in P3 5YR

The SMART trial is the largest, most rigorous trial to date, to randomize patients to the 2 most widely used TAVR devices, and the largest TAVR trial to enroll mostly women.

The SMART trial met both primary and all 5 prespecified secondary endpoints.

Compared with SAPIEN™, the supra-annular Evolut™ demonstrated:

- Noninferior clinical outcomes at 1 year
 - Superior valve performance at 1 year:
 - 32.2% lower incidence of BVD
 - 8 mmHg lower mean gradient
 - 0.5 cm² greater effective orifice area
 - 0.19 larger Doppler velocity index
 - 6.8% lower incidence of severe PPM
- Improvements in other secondary outcomes at 1 year:
 - Less total AR and better QOL per the KCCQ ordinal outcome

Based on the large differences observed in valve performance,
Dr. Herrmann expects that Evolut will demonstrate improved valve durability and outcomes during longer follow-up

Global small annulus market estimate is ~40%^{8,10-13}

SMART creates opportunities for share capture across multiple patient populations

Women

In the US and Europe, small annular anatomy is predominately found in women



90%

Women constitute up to 90% of the small annulus population^{8,10,11}

SMART is largest TAVR RCT⁵ to primarily enroll women, addressing a research gap for this underrepresented group

Patients of Asian descent

Regardless of gender, patients of Asian descent are much more likely to have a smaller aortic annulus (<430mm²)



84%

In recent data out of Japan^{12,13}, ~84% of implants are small annulus valve sizes (<430mm²)

Valve-in-valve patients

Most valve-in-valve (non-native) patients will present with an artificially small (<430mm²) annular area



85%

85% of TAV-in-SAV patients and >40% of redo-TAV patients would qualify as small annulus^{8,10,11,14}

First head-to-head TAVR RCT provides answers to valve selection questions

Findings from SMART nullifies common EW narrative and solidifies clear valve performance leadership

	Competitive Narrative		Fact
Resilia	"SMART didn't use S3 Ultra Resilia (S3UR), so the findings are no longer relevant"	→	We did a post-hoc analysis factoring in their claimed gradient improvement - Evolut™ is still superior in small annulus valve performance at one year ¹⁵
Valve performance (gradients & hemodynamics)	"BVD does not translate to worse mortality"	→	Recent studies, such as the Playford ¹⁸ study and the Van Mieghem presentation at EuroPCR 2023 ¹ , highlight a 30-50% increased late mortality risk associated both with elevated gradients exceeding 20mmHg and BVD
Ease of use and pacemaker rate	"Evolut™ has a high permanent pacemaker (PPI) rate, plus it's too difficult to use"	→	PPI rates were low and broadly comparable between treatment arms, and Evolut™ implant times were only 4 minutes longer on average than SAPIEN™ ⁵
Stroke and Aortic Regurgitation (AR)	"Evolut™ has worse stroke and AR"	→	There was no difference in stroke between treatment arms and Evolut™ had statistically better ≥mild AR than SAPIEN™ ⁵
Mortality	The SAPIEN™ 3 platform has lower all-cause death and death or disabling stroke in recent LR studies	→	Indirect comparisons between two trials is not an effective comparative analysis. We chose to directly compare to S3 in SMART . Evolut already has a numerically lower rate of mortality than SAPIEN™ at 1 year in SMART . ⁵
Valve performance definition	"SMART didn't use the "gold standard" VARC-3 definitions or invasive cath gradients"	→	Regardless of the BVD composite used, ESC ¹⁶ , VARC-3 ¹⁷ , or SMART ⁵ (primary endpoint w/ mo echo only) - Evolut™ superiority was unchanged

Strong cadence of MDT product launches and clinical data

Numerous growth catalysts in \$6B WW TAVR market growing high-single to low-double digits

Lower rates of BVD = less death and rehospitalizations



Low Risk 4-yr²

50% less SVD/BVD than SAVR at 5 years

Pooled IR/HR Analyses¹

50% less SVD than SAVR at 10 years

NOTION 10-year⁴

Evolut™ had Superior valve performance versus S3 in small annulus patients



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

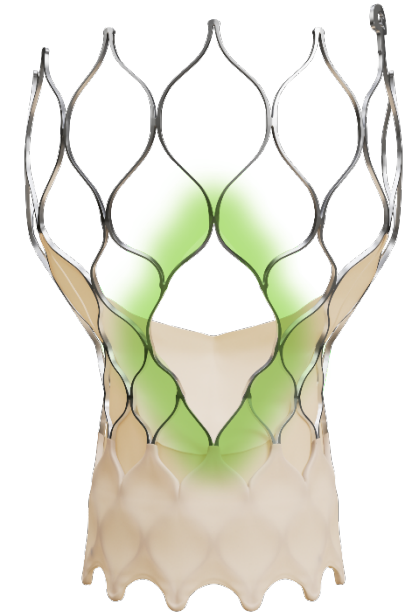
Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus

H.C. Herrmann, R. Mehran, D.J. Blackman, S. Bailey, H. Möllmann, M. Abdel-Wahab, W. Ben Ali, P.D. Mahoney, H. Ruge, D.A. Wood, S. Bleiziffer, B. Ramlawi, H. Gada, A.S. Petronio, C.D. Resor, W. Merhi, B. Garcia del Blanco, G.F. Attizzani, W.B. Batchelor, L.D. Gillam, M. Guerrero, T. Rogers, J.D. Rovin, M. Szerlip, B. Whisenant, G.M. Deeb, K.J. Grubb, R. Padang, M.T. Fan, A.D. Althouse, and D. Tchétché, for the SMART Trial Investigators*



SMART Trial

Evolut™ FX+ offers TAVR without compromise

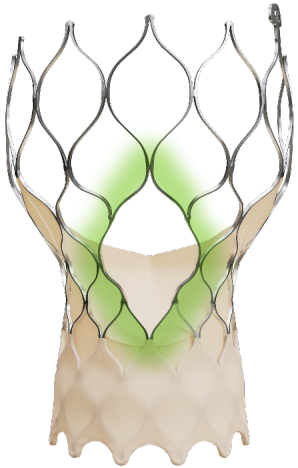


Evolut™ FX+ TAVR System
 US first cases Spring, FMR Summer 2024

Extending category leadership across Cardiovascular Portfolio

New product innovation across markets driving high growth opportunities

Structural Heart



Evolut™ FX+
TAVR system

Cardiac Ablation Solutions



Affera Sphere-9™ and PulseSelect™
Pulse Field Ablation (PFA) catheters

Hypertension



Symplicity Spyral™
blood pressure procedure

Cardiac Rhythm Management



Micra™ AV2 and VR2 transcatheter
pacing system & Aurora EV-ICD™
MRI SureScan™ system

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