

The Evolution of TAVR Explants

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Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Individual Stock(s)/Stock Options

Royalties/Patent Beneficiary

Executive Role/Ownership Interest

Other Financial Benefit

Ineligible Company

None

Medtronic Inc., Edwards
Lifesciences, Artivion, Terumo Aortic,
LeMaitre, LifeNet Health

None

None

None

None

Take Home Message

- Clinical relevance of TAVR explant is steeply rising
 - TAVR-first approach for younger patients is common
 - Redo TAVR is not feasible or suitable for everyone
 - Durability of redo TAVR is unknown
 - From rare procedure to common procedure
- TAVR explant is a valid post-TAVR reintervention option

TAVR Explant

What happened between 2011-2020?

TAVR Explant 2011-2020

JACC: CARDIOVASCULAR IMAGING
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PUBLISHED BY ELSEVIER

VOL. 10, NO. 1, 2017
ISSN 1936-878X/\$36.00
<http://dx.doi.org/10.1016/j.jcmg.2016.11.009>

Leaflet Thrombosis in Surgically Explanted or Post-Mortem TAVR Valves



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LEAFLET THROMBOSIS IS CURRENTLY ONE OF THE GREATEST CONCERNS RELATED TO TRANSCATHETER aortic valve replacement (TAVR). Symptomatic valve thrombosis is a rare occurrence, but reduced leaflet motion, diagnosed by computed tomography, seems to be a more common finding (1).

We screened our pathology registries for patients with a prior TAVR who underwent a post-mortem examination or who had a TAVR device surgically explanted in an attempt to understand better the causes of TAVR failure. Of 13 valves studied, we found 4 cases of leaflet thrombosis diagnosed only on pathological examination (Figures 1 to 4, Online Videos 1, 2, and 3). Two of the patients had a valve-in-valve TAVR (Figures 1 and 3), and in 3 cases, there was incomplete expansion or asymmetry of the valve (Figures 1, 2, and 4). None of the patients were on anticoagulation. There were also 2 cases of endocarditis, 1 coronary obstruction, and 2 cases of paravalvular leak. The other 4 patients had no substantial valve findings.

TAVR valve thrombosis is underdiagnosed, and the mechanisms for its development might be associated with underexpansion and asymmetry of the valve. Valve-in-valve TAVR may be associated with these features more often and might be a risk factor for leaflet thrombosis.

JOURNAL ARTICLE

Transapical explantation of an embolized transcatheter valve ^{FREE}

Parla Astarci , Quentin Desiron, David Glineur, Gebrine El Khoury

Interactive CardioVascular and Thoracic Surgery, Volume 13, Issue 1, July 2011, Pages 1–2,

<https://doi.org/10.1510/icvts.2011.267757>

Published: 01 July 2011 **Article history** ▼



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Heart, Lung and Circulation

Volume 27, Issue 4, April 2018, Pages 513–516



Original Article

Surgical Aortic Valve Replacement Following Early Sapien-XT Valve Failure: A First

Tanveer Ahmad MCh ^a , Prakash Ludhani MCh ^a, Ronen Gurvitch FRACP ^b,
John Goldblatt FRACS ^a, James Tatoulis FRACS ^a

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Case Reports or small series

- Post-mortem setting
- Procedural failure with surgical conversion
- PVL
- Very few SVD

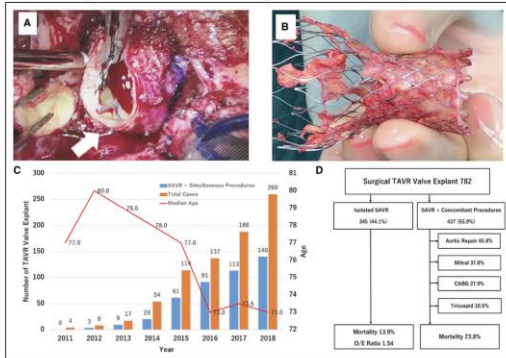
TAVR Explant 2011-2020

Surgical Explantation of Transcatheter Aortic Bioprostheses

An Analysis From the Society of Thoracic Surgeons Database

Shinichi Fukuhara, MD , Alexander A. Brescia, MD, MSc , and G. Michael Deeb, MD

Transcatheter aortic valve replacement (TAVR) is an established alternative to surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis.^{1,2} TAVR use has increased greatly, but the clinical impact and outcomes of surgical TAVR valve explantation and SAVR (TAVR explant) are not well understood.³ Despite the feasibility of a repeat TAVR procedure, there has been an increasing need for TAVR explant as the number of TAVR implants has increased. There are reports of TAVR valves causing neoendothelialization between the device and contacting native tissue (Figure, A and B), making device explantation a more morbid procedure than originally thought.³ The difficulty of SAVR after TAVR may be another consideration for the initial choice of TAVR versus SAVR in younger patients. This study was undertaken to review registry TAVR explant data to better understand the challenges and outcomes of surgical TAVR explant procedures.



Society of Thoracic Surgeons (STS) Database

- 782 TAVR explants
- 55% SAVR with concomitant surgery (most commonly aortic repair)
- High mortality & O/E ratio
 - 13.9% for isolated SAVR
 - 23.8% for SAVR with concomitant surgery

→ TAVR Explant is bad and feared

TAVR Explant

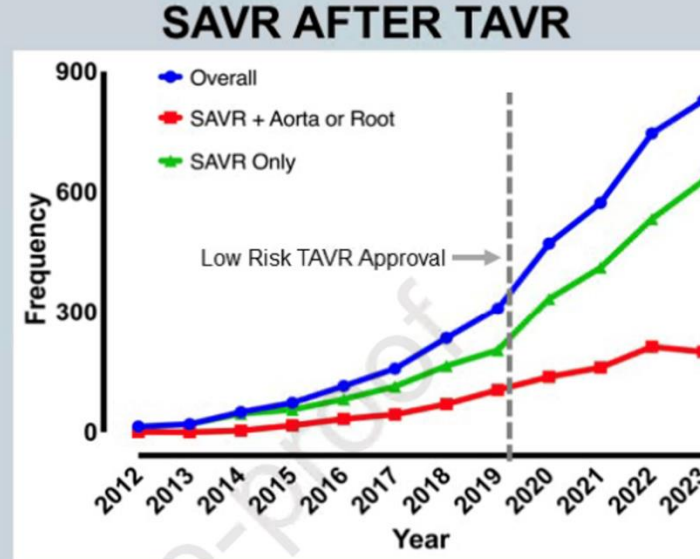
What happened between 2021-2024?

TAVR Explant 2021-2024

5,457 Operations after TAVR
2,972 (54.5%) SAVR
2,485 (45.5%) non-SAVR
*STS Adult Cardiac Surgery Database
2012 to 2023*

Stroke 4.5%
Mortality 15.5%

*Marked increase in TAVR
Explant and SAVR since Low
Risk TAVR Approval*



2012-2023: 2972 TAVR explants, 2485 non-aortic valve operations

- Mortality 15.5%
- Stroke 4.5%

TAVR Explant Pandemic??

TAVR Explant 2021-2024

Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study

Raj R Makkar, Samir Kapadia, Tarun Chakravarty, Robert J Cubeddu, Tsuyoshi Kaneko, Paul Mahoney, Dhairya Patel, Aakriti Gupta, Wen Cheng, Susheel Kodali, Deepak L Bhatt, Michael J Mack, Martin B Leon, Vinod H Thourani

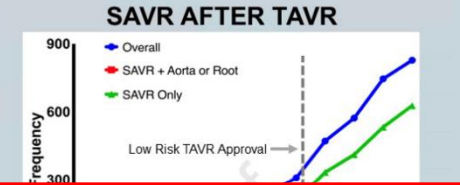
Lancet 2023; 402: 1529-40

STS/TVT Registry 2011-2022
1,320 balloon-expandable redo-TAVR

TAVR Explant 2021-2024

Outcomes of repeat transcatheter aortic valve replacement
with balloon-expandable valves: registry study

5,457 Operations after TAVR
2,972 (54.5%) SAVR
2,485 (45.5%) non-SAVR
STS Adult Cardiac Surgery Database
2012 to 2023
Stroke 4.5%



IS TAVR EXPLANT “ALREADY” MORE COMMON FORM OF POST-TAVR REINTERVENTION THAN REDO-TAVR?

TVT
Redo-TAVR
1320 (2011-2022)

32%

STS
TAVR Explant
2765 (2012-2022)

68%

Choosing TAVR for Patients < 65 yo?

Concerning

The proportion of TAVR and SAVR in patients <65 years old in the states of California, New York, and New Jersey between 2013 and 2021 from 2013-2021

SAVR TAVR



We cannot stop this trend.

We need to shift our mindset.

TAVR vs. SAVR	Before matching	After matching
8-year Mortality	HR: 4.75; CI: 4.05-5.58; p<0.001	HR: 2.27; CI: 1.82-2.83; p<0.001
30-day New permanent pacemakers	12% vs. 5.5%; p<0.001	10.7% vs. 6.2%; p<0.001

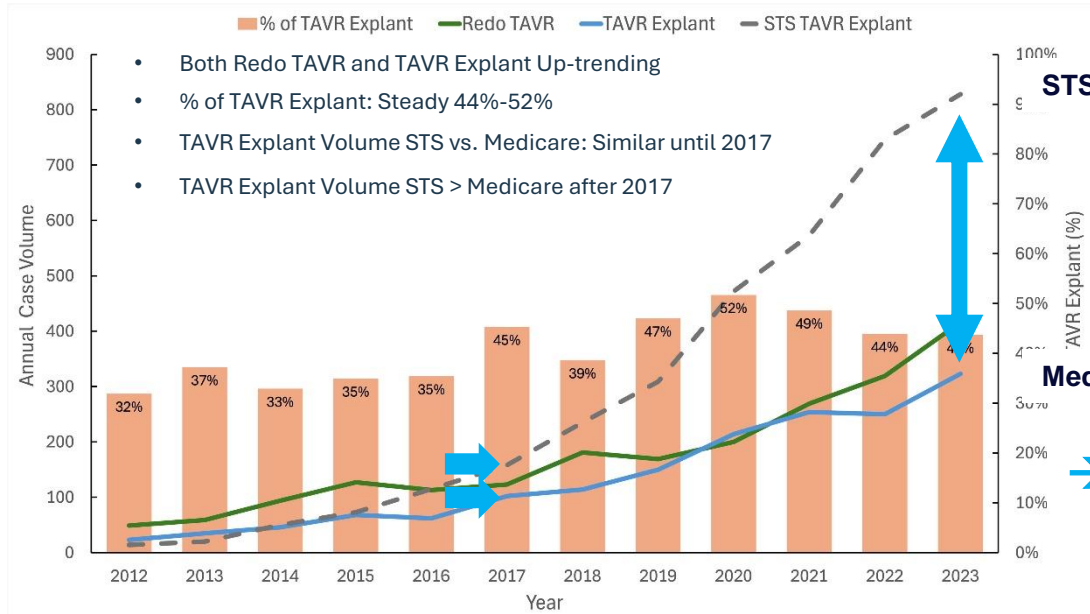
CI: Confidence Interval; RMET: Restricted Mean Event Time; sHR: Subdistribution Hazard Ratio.

We entered > 50% TAVR era in 2021 for patients < 65 yo

TAVR Explant

What is happening now?

Trend of Post-TAVR Reintervention Medicare Fee-For-Service Data



STS TAVR explant volume

Medicare TAVR explant volume

→ 20% of STS TAVR explant: < 65 yo

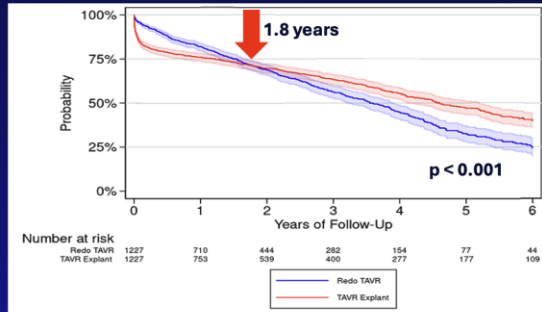
% of TAVR Explant = No. of TAVR Explant / No. of total reinterventions (Redo TAVR + TAVR Explant)

TAVR Explant: What's New

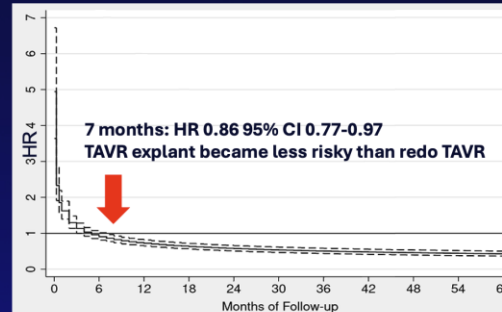
Adjusted Survival and Risk after Reintervention Redo TAVR vs TAVR Explant

*Doubly Robust Estimation
(Propensity Score Matching + Cox Non-proportional Regression)*

Adjusted Survival
Endocarditis Cases Excluded



Risk of TAVR Explant



Long-term survival: TAVR EXPLANT > Redo TAVR

TAVR Explant: What's New

University of Michigan

Overall 6.0% mortality
(10 out of 166 TAVR
explants)

2023-2025: 2.6%

2013-2017

2018-2021

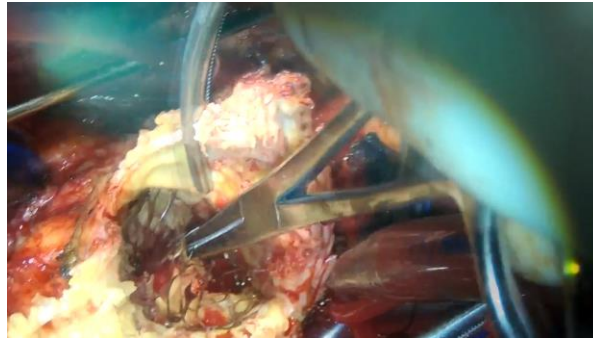
2022-2024

STS Database

New Data coming

→ Clinical outcomes improving

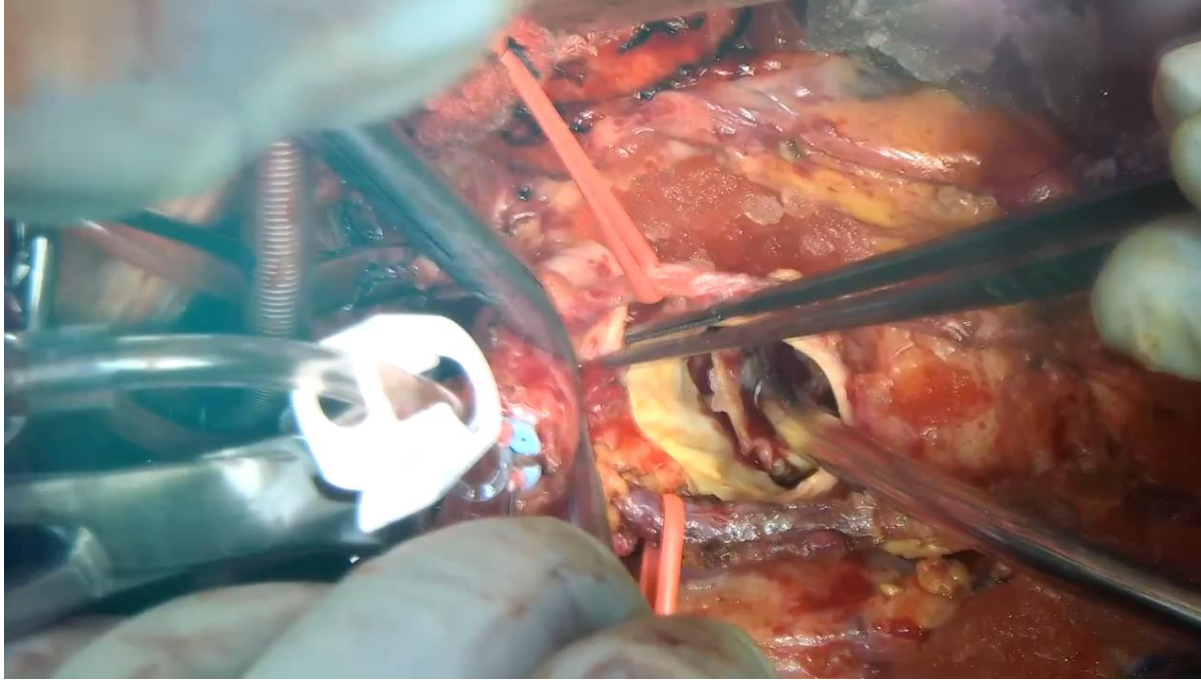
Explanting TAVR valve is straightforward in 85-90%
cases



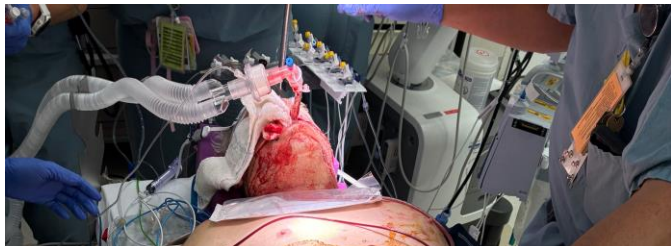
But

Real problem is often not the procedure itself

Importance of Understanding Redo TAVR Limitations



Importance of Understanding Redo TAVR Limitations



Massive pulmonary edema
+
Traumatic intubation with
hemorrhage



73 yo with failed 29 mm SEV TAVR
(67 yo at the time of TAVR)

Seeking 2nd & 3rd opinions at
different health systems

NYHA Class II → III symptoms

Started on Apixaban for possible HALT

P/w heart failure, placed on VA-
ECMO → continued pulmonary
edema → switched to LAVA-ECMO

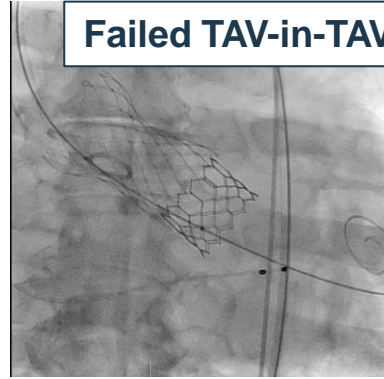
TAVR Explant: What's New

New Era of Extreme TAVR Explant

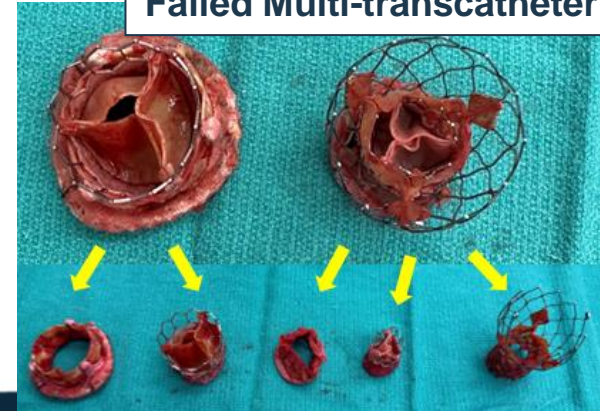
U of Michigan experience

- Failed TAV-in-TAV (n=7)
- TAVR explant with snorkel coronary stents (n=6)
- Transcatheter multivalve failure (n=19 Commando operations)

Failed TAV-in-TAV



Failed Multi-transcatheter valves



Surgical mitral

TMVR

SAVR

TAVR 2

TAVR 1

Summary: Evolution of TAVR Explants

- One of most common procedures within 10 years.
- Outcomes are improving.
- *From rare life-threatening procedure to common safe procedure with favorable long-term outcomes.*
- Tsunami of new normal anticipated: multiple failed transcatheter valves, snorkel coronary stents, failed TAV-in-TAVs.