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# The current state of redo transcatheter aortic valve replacement (TAVR) and limitations: why TAVR explant is important as the valve reintervention strategy

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The rise of transcatheter aortic valve replacement (TAVR) over the past two decades has substantially changed the lifetime management of patients with aortic valve disease. As the indications for TAVR expand to include younger and lower-risk patients, the proportion of patients who subsequently require reintervention for failed transcatheter heart valves (THVs) will increase. The two primary options for reintervention are redo TAVR and TAVR explant followed by surgical aortic valve replacement (SAVR). The indications for redo TAVR in the short term include emergency “bailout” procedures due to malpositioning, embolization, or long-term device failure due to paravalvular leak (PVL) or valvular degeneration. However, redo TAVR is not suitable for all patients. Those with prohibitive coronary anatomy, multivalvular involvement, severe patient-prosthetic mismatch, or endocarditis should be referred for TAVR explant, which is a comparatively higher-risk procedure. Redo TAVR has generally been associated with low mortality and complication rates, with key procedural considerations being valve selection [e.g., sizing, balloon-expandable valve (BEV) *vs.* self-expandable valve (SEV)], access, and coronary protection. TAVR explant poses numerous technical challenges, including concomitant ascending aorta or aortic root replacement, mitral valve involvement, or adhesions to the coronary ostia. Compared to redo TAVR, TAVR explant is associated with higher rates of short-term mortality and periprocedural complications. The 30-day mortality rates of TAVR explant approach 20%, and 1-year mortality rates range from 20% to 30%, with significantly greater risk associated with concomitant procedures. The data on both redo TAVR and TAVR explant are limited to observational cohorts without long-term follow-up. Given that patient populations and indications for redo TAVR and TAVR explant are vastly different, direct comparisons of outcomes between these two groups should be avoided. Nonetheless, multidisciplinary Heart Team collaboration remains imperative to advancing our knowledge of redo TAVR or TAVR explant procedures and the careful lifetime management of patients with aortic valve disease.

**Keywords:** Redo transcatheter aortic valve replacement (redo TAVR); TAVR explant; TAVR; aortic valve replacement; transcatheter

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## Introduction: the rising prevalence of transcatheter aortic valve replacement (TAVR) and TAVR reintervention

### The rising prevalence of TAVR

The favorable results of randomized trials involving TAVR and surgical aortic valve replacement (SAVR) in high-, intermediate-, and low-risk patients have resulted in an exponential increase in the number of TAVR over the past 20 years (1-3). The American College of Cardiology (ACC)/American Heart Association (AHA) 2020 Guidelines now recommend either SAVR or TAVR for patients aged 65–80 years with severe aortic stenosis (AS) after shared decision-making within the Heart Team (Class 1A) (4). Similarly, the European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS) Guidelines state that TAVR is recommended for patients aged above 75 years and patients with high surgical risk (Class 1A) (5). These guidelines are in concordance with the increasing numbers of TAVR conducted in the United States. The Society of Thoracic Surgery (STS)-ACC Transcatheter Valve Therapy (TVT) Registry showed that the total number of TAVR rose from 14,000 in 2011 to 72,991 in 2019, exceeding the number of SAVR that year [57,626] for the first time (6).

### TAVR in young patients and special populations

In the early pivotal TAVR trials in high- and prohibitive-surgical-risk patients, there was less concern around reintervention for failing TAVR prostheses due to the competing risk of death in a much older and more comorbid population. While TAVR is now indicated across the entire spectrum of risk, consensus guidelines still recommend TAVR in low-risk patients older than 65 years. In the PARTNER and Evolut Low-Risk trials, patients less than 65 years comprised less than 10% of the study cohort, which is reflected by the 2020 ACC/AHA guidelines recommending SAVR in this cohort. However, a recent 2024 study of the California State administrative database found that TAVR was conducted in 47% of patients less than 65 years, which has sparked debate about the divergence of practice from guidelines (7). Given the increased use of TAVR in younger patient populations, the incidence of TAVR failure and the need for reintervention will likely increase over time.

Similarly, there is ongoing uncertainty as to whether patients with bicuspid aortic valve (BAV) should be deemed

suitable for TAVR due to both operative challenges associated with complex anatomy (e.g., calcified raphe and leaflets, irregular annulus, aortopathy) and their tendency to present at an earlier age (8). The available observational evidence suggests that the potential need for post-TAVR reintervention is high after 6 months, even in the absence of procedural complications (9-11). The NOTION 2 trials also showed an almost two-fold higher rate of all-cause mortality, stroke, or rehospitalization in patients with BAVs who received TAVR compared to patients with tricuspid aortic valves (12). Despite this lack of evidence, there has been an increasing number of observational studies and registries examining TAVR in BAV patients, along with a randomized controlled trial (RCT) that has been approved to examine this topic.

Other patient groups for which the benefit of TAVR is unclear include those with concomitant coronary artery disease (CAD), multivalvular involvement, and asymptomatic AS (13). Even barring operative complications in these groups, the trajectory and longevity of TAVR remain unclear. The durability of highly studied transcatheter heart valves (THVs) in RCTs is only known up to 10 years, as per the most recent NOTION trial results (14). Furthermore, we continue to scrutinize the durability of new THVs, as demonstrated by the US Food and Drug Administration's 2023 warning of early structural valve deterioration (SVD) in Abbott Trifecta valves (15). With the increasing adoption of TAVR as the initial intervention strategy, questions emerge surrounding its longevity and the need to anticipate for reintervention in patients with a higher life expectancy.

### When TAVR fails: redo vs. explant

The Valve Academic Research Consortium 3 (VARC-3) describes four potential mechanisms for failure of bioprosthetic aortic valves: SVD, non-SVD, thrombosis, and endocarditis (16). This criterion has been applied to THVs as the rise of TAVR has given rise to patients with THV degeneration. As it stands, the two options for reintervention in patients with THV failure are redo TAVR and TAVR explant with SAVR.

“Redo TAVR”—distinct from “valve-in-valve TAVR”, which usually refers to TAVR in an existing surgical bioprosthesis—refers to a second TAVR in an index (failed) THV. The earliest studies of redo TAVR focused on “bailout” procedures performed within the context of index TAVR (17-19). One of the first cohorts that studied

this identified 19 patients who required delayed redo TAVR out of 2,301 index TAVR procedures (0.8%) from 2011 to 2015 across two German centers (*Table 1*) (20-25). This was followed by a multicenter cohort study that recorded 50 redo TAVR procedures over 13,876 patients (0.4%) from 2014 to 2016 (21). The Redo-TAVR Registry reported a redo TAVR rate of 434/63,867 (0.68%) from 2019 to 2020 alone across 47 centers (*Table 1*) (22).

The alternative to redo TAVR is TAVR explant with SAVR. Currently, TAVR explant is the fastest growing cardiac surgical procedure in the United States, a trend that is only expected to continue alongside the growing number of patients who receive TAVR. Fukuhara and colleagues examined the STS Database between 2011 and 2018, finding that the number of TAVR explants rose dramatically from four in 2011 to 260 in 2018 (26). Similarly, a more recent STS Database study found that the annual number of patients undergoing SAVR following TAVR explant increased from 14 in 2012 to 828 in 2023—a nearly 1.5-fold growth rate per year (27).

The rise in both redo TAVR and TAVR explants is likely attributed to an increased number of index TAVR procedures in lower risk populations. TAVR was initially approved for high-risk populations only; hence, many patients did not live long enough to require a redo TAVR or TAVR explant. Correspondingly, Bowdish and colleagues noted in their STS Database study an exponential uptick in TAVR explant volume specifically following publication of the ACC/AHA low-risk guidelines in 2019 (27,28). This suggests that the increasing numbers of redo TAVR and TAVR explants are attributed to a rise in TAVR, as opposed to increasing THV failure rates (29).

### **Indications for reintervention: when to redo and when to explant?**

#### **Indications for redo TAVR**

Despite the gradual refinement of THVs, they are subject to both long- and short-term failure, which may necessitate reintervention either in the form of redo TAVR or TAVR explant and SAVR. Some of the first case series and small observational cohorts on redo TAVR described bailout procedures within the same procedure or hospital admission (19). Clerfond and colleagues published the FRANCE2 Registry outcomes of 72 patients who required a redo TAVR within the same index procedure, for which the main indications were device malpositioning (too high,

too low, in the left ventricle) and device embolization (to the ascending aorta, aortic arch, abdominal aorta, or iliac artery) (30). Other indications for acute reintervention included intraprosthetic leakage due to valvular dysfunction and annular rupture. Early studies of TAVR in high-risk populations, such as by Toggweiler and colleagues, reported no significant difference in 30-day and 1-year mortality between bailout TAVR compared to conventional TAVR (18). However, a 2023 study by Makkar and colleagues of the PARTNER trials found that in contemporary low-risk TAVR populations, bailout redo TAVR was associated a higher rate of 1-year cardiovascular mortality [hazard ratio (HR), 1.86; 95% confidence interval (CI): 1.03–3.38] (25).

Nevertheless, bailout TAVR within the same admission is considered separate from studies of “true” redo TAVR. The Redo-TAVR Registry in 2020 excluded bailout TAVR and classified redo TAVR as “procedural failure” if they occurred within 1 year, and “device failure” if they occurred after 1 year of the index TAVR. Landes and colleagues found that pure aortic regurgitation (AR) was the most common indication amongst patients in the “procedural failure” group compared to pure AS, which was more common amongst patients in the “device failure” group (22). PVL was recorded as the most common cause of AR by several cohort studies and can be caused by low index THV implantation, incomplete dilatation, or undersizing (20,21). THV failure can be intrinsic to the valve or attributed to initial handling and implantation. This may occur due to leaflet trauma during preparation, balloon dilatation, and compression or asymmetrical expansion within the aortic annulus (21).

#### **Contraindications to redo TAVR**

While redo TAVR is considered less invasive, several anatomic and clinical characteristics become indirect indications for TAVR explant. Anatomic considerations may include obstructed or low coronary ostia, small annulus, previous redo TAVR, or anticipated mitral valve impingement (31). The need for concomitant cardiac surgery is a significant exclusion criterion for redo TAVR (29,31). From a hemodynamic standpoint, PVL and patient-prosthesis mismatch (PPM) are difficult to resolve with redo TAVR and thus may require SAVR (32,33). Finally, treatment of endocarditis requires excision of the infected prosthesis and serves as an unequivocal contraindication for redo TAVR in 5–10% of cases (29,34). Interestingly, Hirji

**Table 1** Studies examining redo TAVR to date

Study	Database/registry	TAVR redo population	Follow-up time	Time to redo	Indications for TAVR redo	Perioperative outcomes	Short- and mid-term outcomes
Schmidt <i>et al.</i> , 2016 (20)	Two centers in Germany [2011–2015]	N=19. Age: 77.8±6.6 years	404±304 days	644 [191–1,831] days	AR in 16 (84%); AS in 3 patients (16%). For AR: 12 PVD, 3 mixed paravalvular and valvular AR, 1 valvular AR	Periprocedural mortality: 0. Valve embolization: 1 (5.2%)	30-day mortality: 2 (11%). 30-day stroke: 1 (5%). 30-day permanent pacemaker implantation: 2 (11%). 1-year mortality: 6 (33%)
Barbanti <i>et al.</i> , 2016 (21)	Multicenter [2014–2016]	N=50. Age: 78 [71–89] years	586 [8–2,460] days	812±750 days	Moderate-severe PVL (50%), SVD (50%); AS (18%); intravalvular AR (26%); combined AS/AR (6%)	In-hospital mortality: 0. Stroke: 1 (2%). Coronary obstruction: 1 (2%). Bleeding requiring exploration: 1 (2%). Permanent pacemaker implantation: 3 (8.6%). Hospital LOS: median 13 (IQR, 9–12) days	Survival at latest follow-up (approximately 3 years): 85.1%
Landes <i>et al.</i> , 2020 (22)	Redo-TAVR Registry [2019–2020]	N=212. Age: 79±8.2 years	447 [95–1,091] days	IQR, 2 days–11.6 years	Probable procedural failure (34.9%); probable valve failure (65.1%). Pure AS: 12 (16.2%) <1 year vs. 51 (37.0%) >1 year. Pure AR: 54 (73.0%) <1 year vs. 41 (29.7%) >1 year	Periprocedural mortality: 0. Stroke: 3 (1.4%). Coronary obstruction: 2 (0.9%). Valve malpositioning: 7 (3.3%) Permanent pacemaker implantation: 20 (9.6%). Annular rupture: 1 (0.4%). Conversion to open surgery: 1 (0.4%). Hospital LOS: 5 [4–9] days	30-day survival for early valve dysfunction: 94.6%. 30-day survival for late valve dysfunction: 98.5%. 1-year survival for early valve dysfunction: 83.6%. 1-year survival for late valve dysfunction: 88.3%
Percy <i>et al.</i> , 2021 (23)	Medicare [2012–2017]	N=617. Age: 76.9±8.2 years	28 [15–43] months	154 [58–537] days	Not reported	ICU LOS: 1.0 [0–3] days. Hospital LOS: 6 [3–10] days. Major bleeding: 142 (23%). Blood product transfusion: 130 (21.1%). AKI: 77 (12.5%)	30-day mortality: 6%. 30-day permanent pacemaker implantation: 4.2%. 30-day stroke: 1.2%. 1-year mortality: 22%
Testa <i>et al.</i> , 2021 (24)	TRANSIT [2020–2024]	N=172. Age: 79.9±7.9 years	6 years maximum follow-up	Moderate PPM: 597.5±132.2 days. Severe PPM: 702±946.1 days. No PPM: 980.6±906.7 days	AR: 97 (56.4%). AS: 57 (33.1%). Mixed AR/AS: 18 (10.5%)	In-hospital mortality: 7 (4.1%). Permanent pacemaker implantation: 7 (4.1%). Annular rupture: 1 (0.6%). Valve embolization: 0. Conversion to open surgery: 1 (0.6%). Coronary obstruction: 0	30-day mortality: 12 (7%). 30-day MI: 2 (1.2%). 30-day stroke: 6 (3.5%). 1-year mortality: 17 (10%). 1-year MI: 2 (1.2%). 1-year stroke: 6 (3.5%)
Makkar <i>et al.</i> , 2023 (25)	STS/ACC TVT Registry [2011–2022]	N=1,320. Age: 78±9 years	Not reported	Not reported	Not reported	Coronary obstruction: 4 (0.3%). Intraoperative mortality: 8 (0.6%). Conversion to open surgery: 6 (0.5%)	30-day mortality: 4.7%. 30-day stroke: 2.0%. 1-year mortality: 2.0%. 1-year stroke: 3.2%

Data are presented as mean ± SD, median [IQR], or n (%), unless otherwise stated. We excluded studies that examined redo TAVR within the same index procedure (“bailout” procedures). TAVR, transcatheter aortic valve replacement; AR, aortic regurgitation; AS, aortic stenosis; PVD, paravalvular disease; PVL, paravalvular leak; SVD, structural valve deterioration; LOS, length of stay; ICU, intensive care unit; AKI, acute kidney injury; PPM, patient-prosthesis mismatch; MI, myocardial infarction; STS, Society of Thoracic Surgeons; ACC, American College of Cardiology; TVT, transcatheter valve therapy; SD, standard deviation; IQR, interquartile range.

**Table 2** Studies examining TAVR explant and SAVR

Study	Database/registry	TAVR explant population	Follow-up time	Time to explant	Indications for TAVR explant	Perioperative outcomes	Short- and mid-term outcomes
Fukuhara <i>et al.</i> , 2020 (26)	STS Database [2011–2018]	N=782. Age: 74.0 [67–81] years	Not reported	Not reported	Failed repair/positioning/sizing (27%); aortic insufficiency/PVL (21.5%); aortic stenosis (20.2%); endocarditis (17.7%); SVD (6.5%)	SAVR vs. SAVR + concomitant procedure: hospital readmission: 18.3% vs. 11.1% (P=0.011); mechanical ventilation: 43.3% vs. 29.9% (P<0.001); postoperative sepsis: 6.6% vs. 2.6% (P=0.009)	30-day mortality: 19.4%. 30-day mortality STS-PROM O/E ratio: 1.54. SAVR vs. SAVR + concomitant procedure: 30-day mortality: 14.8% vs. 23.8% (P=0.002)
Hirji <i>et al.</i> , 2020 (35)	Medicare [2012–2017]	N=227. Age: 73.7±8.9 years	22 [14–144] months	212 [69–398] days	Endocarditis (20.7%); bioprosthetic valve failure (4.4%)	Bleeding complications: 55.9%. AKI: 5.7%. Stroke: 29.1%. ICU LOS: 5 [1–10] days. Hospital LOS: 11 [8–16] days	30-day mortality: 13.2%. 1-year mortality: 22.9%. TAVR explant: HR, 4.03 (95% CI: 1.81–8.98). KM estimated survival 6 months: 91.2% (95% CI: 87.5–92.9%) TAVR explant vs. 92.4% (95% CI: 92.3–94.6%) no-explant. KM estimated survival 1 year: 84.1% (95% CI: 79.4–85.9%) TAVR explant vs. 86.8% (95% CI: 86.6–88.4%) no-explant (P<0.001)
Jawitz <i>et al.</i> , 2020 (36)	STS Database [2011–2015]	N=123. Age: 77 [67–84] years	Not reported	2.5 [7–13] months	PVL (15%), SVD (11%); failed repair (11%); sizing or position issues (11%); prosthetic valve endocarditis (10%)	Permanent pacemaker implantation: 18 (15%). Reoperation within same hospital admission: 17 (14%). >24 hours mechanical ventilation: 50 (41%). Renal failure: 12 (10%)	30-day mortality: 21 (17%). 30-day stroke: 4 (3%). STS-PROM low-risk O/E: 5.48 (95% CI: 1.17–13.93). STS-PROM medium-risk O/E: 1.66 (95% CI: 0.35–4.40). STS-PROM high-risk O/E: 1.16 (95% CI: 0.68–1.79)
Malvindi <i>et al.</i> , 2021 (45)	8 European centers	N=13	2 years	12 [5–76] months	Endocarditis (46.2%); SVD (30.8%); valve thrombosis (23.1%)	In-hospital mortality: 2 (15%). Hospital LOS: 14 [5–42] days. ICU LOS: 4 [2–18] days. Dialysis: 3 (23.1%). Permanent pacemaker implantation: 1 (8%). Deep sternal wound infection: 1 (8%). Stroke: 0. Postoperative bleeding requiring exploration: 0	2-year mortality: 29%
Fukuhara <i>et al.</i> , 2021 (34)	Single-Institution [2011–2020]	N=17. Age: 73±9.3 years	Not reported	195 [69–486] days	Symptomatic PVL (41.2%); SVD (23.5%), intraoperative conversion (23.5%); endocarditis (5.9%); bridge-to-surgical intervention (5.9%)	In-hospital mortality: 2 (11.8%). Stroke: 0. Bleeding requiring exploration: 0. Renal failure: 8 (53.4%). Permanent pacemaker implantation: 3 (27.2%). Hospital LOS: 13 [9–12] days	Estimated 3-year survival: 68.0%±12.2%
Brescia <i>et al.</i> , 2021 (29)	STS Database + TVT Registry [2012–2020]	N=46. Age: 73±8 years	1.8 [0.7–6.5] months	139 [3–611] days	Procedure-related failure (34.8%); PVL (28.3%); other cardiac surgery (26.1%); endocarditis (13%); valvular insufficiency (10.9%); SVD (10.9%); aortic stenosis (4.3%); aortic dissection (2.2%)	Hospital LOS: 11 [9–17] days. ICU LOS: 113 [47–209] days. Stroke: 2 (4%). Reoperation for bleeding: 5 (11%). Renal failure: 9 (23%). Atrial fibrillation: 17 (37%). Permanent pacemaker implantation: 2 (6%)	All-cause mortality: 15 (33%). 30-day readmission: 10 (27%). Estimated survival 3 months: 73%±14%. Estimated survival 6 months: 68%±15%. Estimated survival 12 months: 56%±20%
Bapat <i>et al.</i> , 2021 (31)	EXPLANT-TAVR [2009–2020]	N=269. Age: 72.7±10.4 years	29.8 [13.2–49.3] months	11.5 [4.0–32.4] months	Endocarditis (43.1%), SVD (20.1%), PVL (18.2%), severe PPM (10.8%), and delayed valve migration (3.7%)	Operative mortality: 2 (0.7%). ICU LOS: 74 [36–168] hours. Hospital LOS: 12 [7–20] days. Major bleeding: 44 (16.4%). In-hospital stroke: 16 (5.9%). Atrial fibrillation: 22 (9.0%). Permanent pacemaker implantation: 39 (18.4%). Renal failure: 20 (8.2%)	30-day mortality: 34 (13.1%). 30-day stroke: 18 (8.6%). 30-day readmission: 28 (13.7%). 1-year mortality: 53 (28.5%). 1-year stroke: 23 (18.7%)
Fukuhara <i>et al.</i> , 2022 (46)	STS Database [2016–2019]	N=483. Age: mean 72.8 years	Not reported	Not reported	Procedure-related failure (30%); endocarditis (21%), stenosis (18%); aortic insufficiency or PVL (16%)	Total cohort: permanent pacemaker implantation: 16%. Balloon expandable vs. self-expandable: stroke: 5% vs. 7%; renal failure: 12% vs. 16%; permanent pacemaker implantation: 16% vs. 17%; ICU LOS: 93 [47–175] vs. 114 [60–204] days; hospital LOS: 13 [7–20] vs. 14 [8–19] days	Total cohort: 30-day mortality: 18%; STS-PROM O/E mortality: 2.2; STS-PROM low-risk O/E: 3.1; STS-PROM medium-risk O/E: 1.6; STS-PROM high-risk O/E: 1.4. Balloon expandable vs. self-expandable: 30-day mortality: 18% vs. 20%; O/E ratio: 2.0 vs. 2.3
Tang <i>et al.</i> , 2023 (32)	EXPLANTTORREDO-TAVR Registry [2009–2022]	N=181. Age: 72.1±9 years	11.3 [1.6–27.1] months	17.6 [5–40.7] months	SVD (51.9%); PVL (28.7%); PPM (17.1%); delayed valve migration (3.3%)	Operative mortality: 2 (0.5%). In-hospital mortality: 27 (6.8%). In-hospital stroke: 10 (2.7%). In-hospital major bleeding: 18 (10.1%). ICU LOS: 25.5 [4.3–86.5] hours. Hospital LOS: 7 [4–13] days. Permanent pacemaker implantation: 42 (14.1%)	30-day mortality: 30 (8%). 30-day stroke: 12 (3.4%). 30-day readmission: 41 (13.8%). 1-year mortality: 61 (22.3%). 1-year stroke: 13 (5.3%)

Table 2 (continued)

**Table 2** (continued)

Study	Database/registry	TAVR explant population	Follow-up time	Time to explant	Indications for TAVR explant	Perioperative outcomes	Short- and mid-term outcomes
Hawkins <i>et al.</i> , 2023 (28)	STS Database [2011–2021]	TAVR-SAVR: N=1,126; SAVR-TAVR-SAVR: N=674	Not reported	Not reported	Not reported	Risk-adjusted operative mortality of TAVR-SAVR compared with SAVR-SAVR: OR, 1.53 (95% CI: 1.14–2.06; P=0.004). TAVR-SAVR: operative mortality: 195 (17%); stroke: 58 (5%); acute renal failure: 138 (12%); reoperation: 103 (9%); ICU LOS: 95 [48–169] hours; hospital LOS: 9 [7–15] days; readmission: 141 (17%). SAVR-TAVR-SAVR: operative mortality: 81 (12%); stroke: 18 (3%); acute renal failure: 75 (11%); reoperation: 58 (9%); ICU LOS: 77 [45–159] hours; hospital LOS: 9 [6–14] days; readmission: 76 (15%)	Not reported
Fukuhara <i>et al.</i> , 2024 (44)	Single-Institution [2011–2020]	N=66. Age: 72.0 [63.5–77.0] years	Minimum 2-year follow-up	1.8 [0.3–4.1] years	Not reported	Operative mortality: 6 (9.1%). Hospital LOS: 12.5 [7.8–19.3] days. Stroke: 3 (4.5%). Renal failure: 22 (38.6%). Reoperation for bleeding: 3 (4.5%). Permanent pacemaker implantation: 5 (11.4%). Readmission: 22 (26.7%)	Not reported
Zaid <i>et al.</i> , 2023 (33)	EXPLANT-TAVR Registry [2009–2020], excluding patients with same-admission procedures	N=199. Age: 73.1±9.8 years	28.3 [12.9–46.6] months	8.7 [4.0–28.4] months	Endocarditis (45.2%); PVL (20.3%); SVD (19.6%); PPM (9.0%)	Isolated SAVR: operative mortality: 1 (10%); in-hospital mortality: 8 (7.6%); ICU LOS: 72 [25–144] hours; hospital LOS: 13 [8–19.5] days; stroke: 6 (5.7%); permanent pacemaker implantation: 13 (12.4%). SAVR + concomitant procedure: operative mortality: 0; in-hospital mortality: 15 (16%); ICU LOS: 89 [46–184] hours; hospital LOS: 11 [7–17] days; stroke: 4 (4.3%); permanent pacemaker implantation: 16 (17%)	SAVR + concomitant procedure vs. SAVR: 30-day mortality: 16.7% vs. 9.9% (P>0.05); 1-year mortality: 36.1% vs. 22.1% (P>0.05); 3-year estimated survival: 56.8% vs. 81.1% (P=0.02)
Bowdish <i>et al.</i> , 2024 (27)	STS Database [2012–2023]	N=2,972. Age: 72.0 [66–78] years	Not reported	Not reported	Endocarditis (36.0%); SVD (64.0%)	Operative mortality: 419 (14.1%). Stroke: 137 (4.6%). Renal failure: 328 (11.0%). Atrial fibrillation: 888 (29.9%). Permanent pacemaker implantation: 435 (14.6%). Hospital LOS: 9.0 [7–15] days	Not reported

Data are presented as mean ± SD, median [IQR], or n (%), unless otherwise stated. We excluded studies that examined TAVR explant within the same index procedure (“bailout” procedures). TAVR, transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; PVL, paravalvular leak; SVD, structural valve deterioration; STS-PROM, STS Predicted Risk of Mortality; O/E, observed/expected; AKI, acute kidney injury; ICU, intensive care unit; LOS, length of stay; HR, hazard ratio; CI, confidence interval; KM, Kaplan-Meier; TVT, transcatheter valve therapy; PPM, patient-prosthesis mismatch; OR, odds ratio; SD, standard deviation; IQR, interquartile range.

and colleagues opted to exclude patients who were eligible for TAVR explant based solely on anatomical characteristics, as they believed these represented inherently high-risk individuals (35). In their EXPLANT-TAVR study, Bapat and colleagues recorded more than one contraindication for redo TAVR in 24% of patients (31). This is consistent with most cohorts and suggests that the decision to undergo TAVR explant, a comparatively more invasive procedure than redo TAVR, requires a higher indication threshold.

### Indications for TAVR explant

In a state-specific STS Database analysis of TAVR explants performed in Michigan from 2012 to 2020, Brescia and colleagues found that short-term (<12 months) indications for TAVR explant included procedure-related failures (50.0%), PVL (25.0%), concomitant cardiac surgery (17.9%), endocarditis (14.3%), valvular insufficiency (7.1%), SVD (3.6%), and aortic dissection (3.6%) (29). Procedure-related failures or operative complications are those that occur in a high-acuity period and may require direct intraoperative conversion from TAVR to surgical explant. In Jawitz and colleagues' 2020 STS Database study, "sizing and positioning issues" comprised 13 out of 123 patients (10.6%) undergoing TAVR explant (36). Similarly, Fukuhara and colleagues reported that of 17 patients who received TAVR explant within their institution from 2011 to 2019, four patients were converted intraoperatively due to either severe device migration (n=2) or coronary obstruction resulting in hemodynamic instability (n=2) (34). Although these patients initially present at varying baseline statuses, they may become high-risk candidates due to the acuity of their TAVR explant and possible hemodynamic instability.

Late TAVR explant is primarily attributed to valvular degeneration and endocarditis. A meta-analysis by Yokoyama and colleagues found that most explants occurred due to endocarditis (37.6%), SVD (27.7%), and PVL or valvular AR (14.2%); however, this could be skewed by some studies that only examined explant due to endocarditis (37). Brescia and colleagues reported the main indicators of explant after 1 year to be concomitant cardiac surgery (43.8%), PVL (31.3%), SVD (25.0%), and valvular AR (18.8%) (29). The 2023 EXPLANTORREDO-TAVR registry by Tang and colleagues had a median follow-up of 17 months. After excluding endocarditis and explants occurring in the same index admission, SVD (51.9%) was found to be the most significant indicator, followed by PVL (28.7%) and PPM (17.1%), with delayed valve migration

(3.3%) being relatively uncommon. Compared to short-term reintervention, the aetiologies for late THV failure and explant are driven primarily by valve durability and endocarditis. These are two important factors to consider as TAVR expands to younger patients and those with BAVs, and when considering TAVR explant and redo TAVR as alternatives for reintervention.

### Technical considerations of redo TAVR

For patients who are deemed eligible for redo TAVR, detailed preoperative planning with multidetector computed tomography (MDCT) and echocardiography is a key determinant of success. Some of the most important considerations for redo TAVR include access, device selection, and coronary protection.

#### Access

Only a handful of studies have reported routes of access for redo TAVR. In general, transfemoral access continues to be the preferred mode of access. In the Redo-TAVR Registry, Landes and colleagues reported that transfemoral access was most used (89%), with transapical access comprising 6.9% of redo TAVR (22). Testa and colleagues similarly reported a transfemoral approach in 91.9% of patients (24). Barbanti and colleagues recorded that 86% of patients in their cohort underwent redo TAVR via the same route as the index TAVR, but 82.5% of transfemoral TAVR were inserted into the contralateral artery (21).

#### Device selection

In terms of valve sizing, Landes and colleagues reported that in 60% of redo TAVRs, THV size and model remained similar, compared to 25% undersized and 15% oversized in redo TAVR (22). More importantly, the choice of balloon-expandable valve (BEV) *vs.* self-expandable valve (SEV) should be driven by the mechanism of failure of the index THV. Some early studies of redo TAVR showed a greater propensity towards using BEV in SEV (11 out of 19 patients) by comparison (20). When the THV failure is due to PVL, BEV in SEV may offer greater stability and the ability to obliterate PVL during the balloon dilatation process. An index BEV may be suited for redo SEV that is placed supra-annularly to reduce the risk of PPM (38). Conversely, the Redo TAVR Registry recorded the same THVs (SEV in SEV in 34.9%, BEV in BEV in 24%) reimplemented in



59% of patients, while BEV in SEV were reimplemented in 26.4% of patients and SEV in BEV were reimplemented in 14.6% of patients (22). In BEV in BEV scenarios, the same size valve is generally selected, whereas redo SEV inside index SEV can be the same or smaller size (21).

### Coronary protection

One of the most important considerations of redo TAVR is avoiding coronary obstruction. This devastating complication is associated with a mortality rate of 22% after successful percutaneous coronary intervention (PCI) and 50% when emergent coronary artery bypass grafting (CABG) is initiated. Emergent PCI has been reported to be unsuccessful in 18% of cases and, when this occurs, associated with 100% mortality (38). The importance of careful MDCT assessment has brought forth new terminology such as “neoskirt”, “neoskirt plane”, and “functional neoskirt”, which describe the height of the index THV leaflets that will be pinned in the open position when a redo THV is expanded within (39). Operators should consider the height of the sinotubular junction (STJ) compared to the height of the redo TAVR stent frame, with a higher risk associated with supra-annular valves (e.g., Evolut, Accurate Neo) (38,40). For valves where the stent frame exceeds the height of coronary ostia, the open cells of the THV frame can be arranged to allow future PCI via a coronary catheter. This is more achievable in SEVs where commissural alignment is possible, and the valve struts are wide. Rogers and colleagues conducted a detailed MDCT simulation study which found that coronary obstruction was highest risk in patients where the neoskirt or new stent frame lies above the STJ height and the valve-to-STJ distance is less than 2 mm (the size of a 6 Fr catheter) (41).

Two techniques have been developed to avoid coronary obstruction in high-risk patients. First, “snorkel” stenting involves passing a coronary stent or balloon in the threatened artery, followed by deployment after THV reimplantation. The second technique developed to mitigate the risk of neoskirt obstruction is the BASILICA procedure, where leaflets that may occlude the coronary ostia are lacerated down the midline to splay outwards with electrocautery. The BASILICA feasibility trial was initially conducted in 30 patients with inoperable anatomy and showed promising outcomes at 30 days (3.3% all-cause mortality, 3.3% myocardial infarction) and 1 year (40). However, it remains unclear whether the BASILICA procedure can be applied easily to redo TAVR, where the

previous THV leaflets may not be sufficiently splayed to prevent obstruction, and commissural alignment of the index THV would have to be necessary. (40,42). Several authors have also raised concerns regarding the risks associated with the BASILICA procedure (40). As such, the optimal means of preventing coronary obstruction may be to improve commissural alignment in novel THVs.

### The limits of redo TAVR: technical considerations for TAVR explant

Patients for whom redo TAVR is not feasible due to mechanistic indications (i.e., infectious endocarditis) or unfavorable anatomy (i.e., high risk for coronary obstruction) may be considered for TAVR explant and SAVR. An in-depth review of surgical techniques in TAVR explant has been explored elsewhere (43). Nevertheless, an overview of the technical challenges and high-risk components of TAVR explant is necessary to understand the outcomes to date and identify future areas for growth.

#### Cannulation, arrest, and aortotomy

First, different THVs introduce different challenges for the explant procedure. As such, experts emphasize the importance of understanding the design of TAVR valves. Many TAVR devices have become widely available (e.g., Sapien, CoreValve, Portico, Lotus, Jenavalve, Engager), all of which involve unique materials, geometries, and mechanisms for deployment. Several studies have compared TAVR explant between BEVs and SEVs and found no significant difference in operative outcomes. That said, BEVs, such as the Sapien 3<sup>TM</sup>, typically have a lower stent frame and lower risk of ascending aortic injury but a higher risk of annular involvement, conduction disturbances, and involvement of the mitral valve leaflets. SEVs require a higher aortotomy, and explant may injure the ascending aorta, necessitating replacement. Depending on the extent of aortic injury, replacement of the ascending aorta may require deep hypothermic circulatory arrest. Aortic root replacement is reported to be necessary in 15–25% of cohorts, with most studies citing no difference in the likelihood of requiring root replacement between BEVs and SEVs (26,35).

#### Excision

MDCT is crucial to evaluating valve anatomy for the

excision. Studies have described the “double Kocher” and “roll” techniques for short stent frame valves *vs.* the “tourniquet” or “handlebar and mustache” techniques for tall stent frame valves to excise the valve without injury to the surrounding structures. Neo-endothelialization further complicates excision in delayed TAVR explants and requires meticulous dissection, especially for newer valves which are designed to increase tissue incorporation to prevent PVL. As such, a thorough understanding of valve anatomy is crucial to avoid permanent pacemaker insertion (31). Conversely, valve-in-valve TAVR are relatively simpler to excise due to their clear separation from the endothelium by the original valve frame. A 2023 study by Fukuhara and colleagues comparing native TAVR explant *vs.* valve-in-valve TAVR explant found that valve-in-valve TAVR explant was associated with a higher likelihood of reoperation but lower operative risk and mortality (44).

### Concomitant procedures

Significant neo-endothelialization, endocarditis, or small annular size with PPM may require concomitant aortic root replacement or enlargement. Adequate myocardial protection should be considered throughout the operation with direct antegrade followed by retrograde cardioplegia if necessary, and direct ostial cardioplegia upon excision of the THV. Coronary preservation is of paramount importance and may be complicated by severe adhesions between the stent and the TAVR frame if the patient has previously undergone PCI. Finally, preservation of the mitral valve may not be possible if the previous TAVR involved the aorto-mitral curtain or in patients with severe endocarditis. This may necessitate mitral valve repair or a Commando reconstruction (40).

### Current data on TAVR reintervention

We performed a literature search of major studies documenting the outcomes of redo TAVR and TAVR explant to date and have summarized their results in *Tables 1,2* (26-29,31-36,44-46) respectively. We excluded studies that solely examined TAVR reintervention within the same index procedure (“bailout”) and case studies.

### Outcomes of redo TAVR

Despite the rising prevalence of redo TAVR, the data on

this topic remain limited to small observational cohort studies. We found only six studies spanning from 2016 to 2023 that described redo TAVR, all of which were either registry-based or conducted in multiple centers. The sample sizes were generally small, with the largest being 1,320 patients in the STS/ACC TVT Registry study by Makkar and colleagues (25). Only one study by Barbanti and colleagues collected follow-up data beyond 1 year (21).

### Mortality and perioperative complications

Redo TAVR has generally been associated with favorable clinical outcomes (*Table 1*). Periprocedural mortality ranged from 0% in three studies to 4.1% in the TRANSIT study. Thirty-day mortality ranged from 4.7% to 11%, with the highest mortality rates attributed to early studies of redo TAVR (20-22). Schmidt and colleagues recorded the highest rate of 1-year mortality at 33% in 2016, whereas the 2023 STS/ACC TVT Registry study recorded a 1-year mortality rate of only 2.0% (20). The decline in mortality over time may be attributed to several factors. First, early TAVR was limited to high-risk populations only; therefore, those requiring explant would likely be at higher procedural risk. Second, Percy and colleagues have raised the possibility of a learning curve associated with redo TAVR, where patients with similar comorbidity fared better in the “late” era compared to the “early” era (23).

Procedural complications associated with redo TAVR, such as valve embolization, annular rupture, and conversion to open surgery, were rare, as reported by Schmidt *et al.*, Landes *et al.*, and Testa *et al.* (20,22,24). The incidence of permanent pacemaker implantation was less than 10% in all studies (*Table 1*). Most importantly, the incidences of coronary obstruction were low: 2% as reported by Barbanti *et al.*, 1% as reported by Landes *et al.*, 0.5% as reported by Makkar *et al.*, and 0% as reported by Testa *et al.* (21,22,24,25). Of note, these cohorts represent selected populations where patients with high-risk coronary anatomy may have been excluded from redo TAVR.

### Transvalvular gradients

Significant reductions in transvalvular gradients were also reported across most studies and used as an indicator for successful TAVR reintervention. Barbanti *et al.*, Makkar *et al.*, and Testa *et al.* reported immediate postprocedural mean pressure gradients to average 10–11 mmHg at

discharge (21,24,25). Interestingly, Barbanti and colleagues reported higher transvalvular pressure gradients on average following redo TAVR for PVL compared to SVD (21).

### Outcomes of TAVR explant

All studies examining TAVR explant had an observational design and were published following the low-risk guidelines in 2019 (Table 2). Four of the 13 studies were published by the same senior author (Fukuhara), and 10 out of 13 studies collected information from major databases such as the STS Database, Medicare, and the EXPLANT-TAVR registry (Table 2). The TAVR explant sample sizes ranged from 13 (47) to 2,972 (27). Almost all studies recorded the major indications for TAVR explant or contraindications for redo TAVR, as well as major in-hospital outcomes. Few studies recorded outcomes beyond 1 year, with the longest median follow-up being 29.8 months by Bapat and colleagues (31).

### Mortality and perioperative complications

Across all studies, TAVR explant is associated with high operative and perioperative mortality, especially in comparison to outcomes following redo TAVR. Our review found that 30-day mortality ranged from 11% to 19.4%, which echoes a recent meta-analysis by Yokoyama and colleagues that found a pooled 30-day mortality rate of 16.7% (95% CI: 12.2–21.2%) (37). This is significantly higher than the 30-day mortality rate of 4.6% in redo SAVR and higher than the 30-day mortality in redo TAVR (13.6% vs. 3.4%,  $P < 0.001$ ). Similarly, the mid-term outcomes of TAVR explant are comparatively poor, with one study reporting a 1-year mortality rate of 23% (43).

The reasons for such high mortality rates have been attributed to both patient risk and operative complexity. Those presenting for TAVR explant may be acutely ill (e.g., endocarditis) or have long-term valvular disease and decreased physiological reserve. In the acute phase, the EXPLANT-TAVR registry noted a higher operative risk score for patients undergoing TAVR explant, likely due to indications such as PPM, PVL, and valve migration that required immediate intervention due to hemodynamic compromise (32). For those undergoing delayed TAVR explant, this procedure may be seen as a “last resort” for patients initially deemed unsuitable for SAVR, subsequently turned down for redo TAVR, and thus present late in their disease course with advanced New York Heart Association (NYHA) status. Interestingly, although TAVR explant had

a higher 30-day and 1-year mortality than redo TAVR, the EXPLANT-TORREDO-TAVR registry found no difference in all-cause mortality in their 4-year landmark analysis (32).

Similarly, Brescia and colleagues’ 2021 STS-TVT registry study described 76% of patients having at least one postoperative in-hospital complication, including 37% with new atrial fibrillation, 23% with new renal failure, and 4% with permanent stroke. The authors recorded a 30-day readmission rate of 27%, and 77% of patients required cardiac rehabilitation on discharge (29).

### Elevated risk with concomitant procedures

The STS-PROM was consistently found to be a poor predictor of perioperative mortality in TAVR explant. Several studies determined the observed/expected (O/E) mortality rates to be significantly higher in all risk categories, but particularly in the low-risk group, with an O/E ratio of 3.1, as recorded by Fukuhara and colleagues (34), and 5.48, as recorded by Jawitz and colleagues (36). This was attributed to the increased operative risk associated with concomitant procedures involving the coronaries, aortic root and ascending aorta, or mitral valves.

Concomitant procedures were found across the board to be one of the most significant predictors of perioperative mortality and morbidity, as well as short-term survival. The 2023 EXPLANT-TAVR registry reported a 1.5-fold increase in 30-day (16.7% vs. 9.9%), 1-year (36.1% vs. 22.1%), and estimated 3-year mortality (56.8% vs. 81.1%) in patients who received SAVR and a concomitant procedure compared to SAVR alone, respectively (33). Whether a similar effect is observed for perioperative outcomes remains unclear. Fukuhara and colleagues reported higher rates of hospital readmission, extended mechanical ventilation, and postoperative sepsis associated with concomitant procedures, but the EXPLANT-TAVR analysis found no differences in the rates of intraoperative mortality, strokes, pacemaker insertions, or hospital and intensive care unit (ICU) lengths of stays (33,34).

Patients with multiple cardiac pathologies have lower physiological reserve, may be frailer, and are more likely to be decompensated prior to the surgery. There is the added operative complexity of multiple reconstructions, thus increasing risk of damage to native structures (i.e., conduction pathways resulting in pacemaker implantation) and extending cardiopulmonary bypass and clamp times. Mitral valve reconstruction and mitral regurgitation were

discussed as particularly significant predictors of mortality, likely because they combine increased operative complexity with increased patient risk due to poor physiologic reserve.

### Limitations of the evidence and the way forward

As described above, the past decade has seen increasing attention and a growing body of literature on TAVR reintervention. Exploring the existing data on redo TAVR and its alternative, TAVR explant, sheds light on current limitations in our understanding and the path forward.

### Long-term follow-up through TAVR-specific registries

The current understanding of both redo TAVR and TAVR explant is limited to observational studies with short follow-up periods. The data on redo TAVR are particularly sparse, as only six cohort studies have been published since the first PARTNER trials in 2012. Most of these studies had limited sample sizes, although patient recruitment may become more feasible as the numbers of THVs requiring reintervention increases. That said, only one study has examined outcomes beyond 1-year (21). Similarly, observational cohorts on TAVR explant thus far have only examined short- or mid-term outcomes. PCI *vs.* CABG studies and SAVR *vs.* TAVR studies have historically found that surgical intervention carries higher up-front risk with the potential for greater long-term benefits compared to transcatheter techniques. This is especially relevant as THVs are implanted into younger patients for which the long-term benefits of subsequent interventions must be considered.

There is a need for studies with extended follow-up periods, such as 3- to 5-year outcomes, to better understand the trajectory of patients who undergo TAVR explant compared to those who undergo redo TAVR. There is also a need for detailed echocardiographic and computed tomography (CT) follow-up of patients who undergo TAVR reintervention to determine how valvular durability and hemodynamics are affected in the long-term following TAVR-in-TAVR *vs.* SAVR following TAVR explant (48).

### Lifetime management of patients with aortic valve disease

The continued innovation of transcatheter techniques and improved long-term survival of patients with THVs has introduced greater complexity than ever before into the management of aortic valve disease. There is not only a need

to consider the first valve replacement (SAVR *vs.* TAVR) but also reintervention upon bioprosthetic surgical valve failure (valve-in-valve TAVR) and now, THV failure. Good lifetime management of patients with aortic valve disease requires providers to carefully consider the lifespan of a patient, their likelihood of requiring reintervention of their initial valve, and their anatomical and clinical presentation when such reinterventions are needed. This begins with choosing an appropriate index valve: patients who are young and have low surgical risk or anatomical variants (e.g., BAV) may be better suited for initial SAVR with future SAVR explant or valve-in-valve TAVR, which, at the time of this manuscript, both report better outcomes than TAVR explant and redo TAVR. Patients undergoing TAVR as their index procedure should have suitable anatomy (e.g., good arterial access, suitable coronaries) for reintervention. Concomitantly, the initial THV should be chosen and positioned carefully to facilitate future reintervention. This may include ensuring adequate valve-to-STJ distance or commissural alignment to ensure struts face away from coronary ostia to permit future redo TAVR, or choosing a lower-profile valve to avoid extensive aortic endothelialization for TAVR explant. Annual CT and echocardiographic follow-up are also of utmost importance to diagnose THV failure early and ensure timely reintervention. This is especially relevant for patients referred for TAVR explant, as delays in treatment only further increase their surgical risk.

Heart Team collaboration is central to providing good lifetime management for patients with aortic valve disease. The number of redo TAVR procedures remains low, and expertise in TAVR explant is currently localized to a small proportion of surgeons within centers of excellence with little standardization in operative technique. There is a pressing need to form multidisciplinary working groups with the goal of (I) standardizing the indications for redo TAVR *vs.* TAVR explant, and (II) refining the operative techniques to ensure safe TAVR reintervention. Efforts to do this for TAVR explant have come in the form of the Heart Valve Collaboratory, but to our knowledge, there is no such working group for redo TAVR (43). Finally, pooled clinical data in the form of global registries with long-term echocardiographic and CT data will pave the way for more accurate risk profiling and simulations to aid lifetime management in future patients.

### Conclusions

The expanding prevalence of TAVR for younger and low-

risk populations has substantially changed the lifetime management of patients with aortic valve disease. Many patients with TAVR as their initial intervention will outlive their THV and require reintervention in the form of redo TAVR or TAVR explant. Early studies appear to indicate favorable clinical outcomes with redo TAVR, although the data remain limited to small observational cohort studies with short follow-up. Nevertheless, TAVR explant may be necessary in patients with endocarditis, prohibitive coronary anatomy, PPM, or multivalvular disease. The current data on TAVR explant allude to higher short-term risk, but potentially similar long-term survival, and may be biased by inherently higher risk patients with late-stage valvular dysfunction. In the face of such emerging complexities, the role of the Heart Team becomes more important than ever in optimizing the lifetime management of patients with aortic valve disease. One thing remains certain: the number of transcatheter procedures will only increase. It is our responsibility to ensure that patients receiving TAVR do so at the right time, under the right indications, and with a viable plan for potential future redo TAVR or TAVR explant.

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