The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study

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Background: The St Jude Medical Inc (St Paul, Minn) Trifecta valve is a novel aortic biological prosthesis that incorporates several design features, including a true supra-annular sewing cuff, a stent design that maximizes valve hemodynamics while minimizing leaflet stresses, and an ethanol-based anticalcification technology. This study establishes the safety and early clinical and hemodynamic performance of the Trifecta valve.

Methods: The Trifecta bioprosthesis was implanted in 1014 eligible patients between 2007 and 2009 at 31 centers. The mean age of the population was 72.5 ± 9.0 years, of whom 650 (64.1%) were male and 364 (35.9%) were female. Eighty-two subjects (8.1%) had undergone previous open surgery. Indications for aortic valve replacement surgery included stenosis in 556 patients (54.8%), regurgitation in 61 patients (6.0%), and mixed pathology in 397 patients (39.2%).

Results: The overall follow-up included 844.3 late patient-years. Early (≤ 30 day) mortality occurred in 18 patients (1.8%), and there were 23 late (≥ 31 days) deaths yielding a linearized mortality rate of 2.72% per late patient-year. There were 27 early thromboembolic events, including 8 (0.8%) strokes, 17 (1.7%) reversible neurologic events, and 2 (0.2%) systemic embolic events. There were no instances of early valve thrombosis, endocarditis, or clinically significant hemolysis. There were 16 late thromboembolic events (linearized rate of 1.90% per year of follow-up), including 4 strokes and 12 reversible neurologic events. In total, there were 5 late valve explants, including 1 structural deterioration and 4 prosthetic valve endocarditis cases. Overall, freedom from valve explant was 99.4% at 2 years. At the time of discharge, average mean gradients ranged from 9.3 to 4.1 mm Hg and effective orifice area ranged from 1.58 to 2.50 cm² for valve sizes 19 to 29 mm, respectively.

Conclusions: The St Jude Medical Trifecta valve is a unique pericardial bioprosthesis with design elements that provide excellent hemodynamic performance while providing ease of implantation. Long-term follow-up continues to confirm the promising results of this innovative bioprosthesis. (*J Thorac Cardiovasc Surg* 2014;147:590-7)

Bioprosthetic valves are implanted in approximately 80% of patients requiring aortic valve replacement in North America.¹ During the past 4 decades, there has been a consistent, iterative improvement in bioprosthetic valve longevity and hemodynamic performance based on valve design and tissue processing.²⁻⁵ The St Jude Medical Inc (St Paul, Minn) Trifecta valve is a novel biological prosthesis that incorporates several design features, including a true supra-annular sewing cuff, a stent design

that maximizes valve hemodynamics while minimizing leaflet stresses, and an ethanol-based anticalcification technology.

The Trifecta pericardial aortic valve was evaluated in a rigorous multicenter US Food and Drug Administration Investigational Device Exemption study conducted between 2007 and 2011. Data from 31 centers in the United States, Canada, Germany, France, Italy, The Netherlands, and Switzerland involving 1022 patients were collected to obtain regulatory approvals. This study establishes the safety and early clinical and hemodynamic performance of the Trifecta valve in one of the largest prospective evaluations ever performed on any surgical aortic valve prosthesis.

MATERIALS AND METHODS

Patients

The Trifecta bioprosthesis was implanted in 1022 patients between 2007 and 2009. Eight subjects were excluded from the analysis who did not meet the prespecified study eligibility criteria, resulting in an analysis dataset of 1014 patients. A list of participating institutions and Principal Investigators is in [Appendix Table I](#). Inclusion criteria necessitated a patient of legal age requiring aortic valve replacement who could sign for informed consent and complete the follow-up requirements of the study. Exclusion criteria included being pregnant or nursing; requiring other concomitant valve

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Abbreviations and Acronyms

EOA	= effective orifice area
EOAI	= effective orifice area index
NYHA	= New York Heart Association
PPM	= patient–prosthesis mismatch
TAVR	= transcatheter aortic valve replacement

replacement surgery; active endocarditis; presence of other significant cardiovascular abnormality, such as aortic dissection; acute preoperative (within 30 days before implant) neurologic event; renal dialysis; a history of substance abuse in the past year; inability to perform follow-up requirements or predicted life expectancy less than 2 years; or participating in another Investigational Device Exemption or Investigational New Drug study. Institutional review board approval was obtained at every participating site.

The mean age of the population was 72.5 ± 9.0 years. Among the 1014 study patients, 95 (9.4%) were aged less than 60 years at the time of implant and 210 (20.7%) were aged 80 years or more at the time of implant (Figure 1). There were 650 men (64.1%) and 364 women (35.9%). Eighty-two subjects (8.1%) had undergone previous open surgery. Preoperatively, the majority of patients had New York Heart Association (NYHA) class II or III symptoms. NYHA class IV symptoms occurred preoperatively in 55 patients (5.4%). Indications for aortic valve replacement surgery included stenosis in 556 patients (54.8%), regurgitation in 61 patients (6.0%), and mixed pathology in 397 patients (39.2%). Sixteen patients (1.6%) had a previous prosthetic aortic valve or aortic homograft explanted, whereas the remainder of procedures were performed on the patient's native aortic valve. Calcific stenosis of a trileaflet valve was observed in 696 patients (68.6%), bicuspid pathology was observed in 295 patients (29.1%), and 23 patients (2.3%) had rheumatic disease. Other aortic valve disease and causes were observed in 53 patients (5.2%). Preoperative demographic information is presented in Table 1.

Aortic Valve Implantation Operative Details

Valve description. The Trifecta valve is a 3-leaflet stented pericardial valve designed for supra-annular placement in the aortic position. The valve is fabricated using a polyester-covered titanium stent. The stent, excluding the sewing cuff, is covered with porcine pericardial tissue. This covering is designed to provide protection from mechanical wear by allowing only tissue-to-tissue contact during valve opening and closing. A silicone insert in the polyester sewing cuff is contoured to conform to the shape of the native annulus while providing access to the coronary artery ostia. The valve leaflets are fabricated from bovine pericardium. The porcine and bovine pericardium are preserved and crosslinked in glutaraldehyde. Glutaraldehyde, formaldehyde, and ethanol are used in the valve-sterilization process. The Trifecta valve is processed with ethanol-based Linx anticalcification technology.⁶ Valve sizes are available in 2-mm increments from 19 to 29 mm. The nominal valve size is based on the outer diameter of the stent. Implanted sizes are outlined in Figure 2. The valve is designed to be implanted in the true supra-annular position, typically with noneverting pledgeted mattress sutures placed on the ventricular side of the aortic annulus.

Among 1014 implanted valves, 56 were placed with simple interrupted sutures, 34 were placed with nonpledgeted mattress sutures, 57 were placed using a continuous running technique, 56 were placed using an intra-annular technique with everting pledgeted mattress sutures placed on the aortic side, and 811 were placed using the recommended supra-annular technique. Concomitant procedures included coronary artery bypass grafting in 372 patients (36.7%), mitral valve repair in 38 patients (3.7%), tricuspid valve repair in 23 patients (2.3%), Maze or other cardiac ablation

FIGURE 1. Distribution of enrolled patients by age range, N = 1014.

procedures in 66 patients (6.5%), and atrial septal defect repairs in 38 patients (3.7%). Aortic root enlargement was performed in 17 patients (1.7%). An intra-aortic balloon pump was placed at the time of surgery in 17 patients (1.7%). The mean aortic crossclamp time for isolated aortic valve replacement with the Trifecta valve was 64.3 ± 25.5 minutes. Operative information is presented in Table 2.

End point definitions. Adverse events were classified according to the standardized definitions from the Society of Thoracic Surgeons/American Association for Thoracic Surgery “Guidelines for Reporting Morbidity and Mortality and Cardiac Valvular Operations” and the requirements of the US Food and Drug Administration.⁷ Events were classified as occurring early (within 30 days of implant) or late (≥ 31 days after implant).

Data Analysis

Statistical analyses were performed using SAS software (v 9; SAS institute Inc, Cary, NC). Descriptive data are presented as mean values with standard deviation for continuous variables and as counts with percentages for categorical variables. Statistical significance was determined using a 2-sample *t* test or Fisher exact test as appropriate. Late adverse event rates (ie, those occurring ≥ 31 days postimplant) were determined using both linearized rates and Kaplan–Meier analyses.

Patient Follow-up

The overall late follow-up included 844.3 patient-years with a median follow-up interval of 0.90 years (standard deviation, 0.45 years; interquartile range, 0.50–0.99 years). The completeness of follow-up at 1 and 2 years was 97.7% and 98.0% of patients, respectively. Echocardiographic evaluation was completed at discharge, 6 months, and 1 year in 98.4%, 96.9%, and 94.5% of patients, respectively. The follow-up was performed at the local investigating sites by clinic evaluation at 6 months, 1 year, and annually thereafter. Study visits included clinical determination of NYHA functional classification, study echocardiograms, blood assessment including plasma free hemoglobin, medication review including anticoagulants, and documentation of any adverse events. Study echocardiograms and blood laboratory assessments were evaluated at central core laboratories.

TABLE 1. Patient demographics

Variable	All implants (N = 1014)
Age at implant (y)	72.5 ± 9.0 (32-95)
Subject gender (male)	64.1% (650)
Medical history	
Hypertension	81.9% (830)
Low ejection fraction (<50%)	12.4% (126)
Hyperlipidemia	71.2% (722)
Coronary artery disease	58.2% (590)
Smoking history (previous or current)	55.7% (565)
Diabetes	24.8% (251)
Carotid artery disease	21.3% (216)
Pulmonary hypertension	17.3% (175)
Myocardial infarction	12.9% (131)
Peripheral vascular disease	10.9% (111)
Kidney disease	7.0% (71)
Stroke, cerebrovascular accident, reversible ischemic neurologic deficit	6.0% (61)
Transient ischemic attack	7.3% (74)
Preoperative NYHA	
Class I	6.6% (67)
Class II	44.1% (447)
Class III	43.9% (445)
Class IV	5.4% (55)
Predominant preoperative cardiac rhythm	
Sinus	88.3% (895)
Atrial fibrillation/flutter	8.8% (89)
Paced	2.7% (27)
Other	0.3% (3)
Previous cardiovascular surgery/procedure	
None	72.4% (734)
Aortic valve repair	0.3% (3)
Aortic valve replacement	1.5% (15)
Mitral valve repair	0.1% (1)
Mitral valve replacement	0.0% (0)
CABG	6.5% (66)
Percutaneous coronary intervention	14.3% (145)
Balloon valvuloplasty	1.1% (11)

NYHA, New York Heart Association; CABG, coronary artery bypass grafting.

RESULTS

Clinical Events

Early (≤ 30 days postimplant) mortality occurred in 18 patients (1.8%). There were 27 early thromboembolic events, including 8 (0.8%) strokes, 17 (1.7%) reversible neurologic events, and 2 (0.2%) systemic embolic events. Of the 27 early thromboembolic events, 8 were known to be in atrial fibrillation. There were 81 (8.0%) instances of major bleeding, of which 61 (6.0%) were procedure-related. There was 1 early valve explant due to suture injury to a congenitally malpositioned intramural coronary artery. The bioprosthetic valve was functioning normally at the time of explant. The coronary artery was not obstructed by the prosthesis. There were no instances of early structural deterioration, valve thrombosis, endocarditis, or clinically significant hemolysis. Early clinical events are presented in Table 3.

FIGURE 2. Distribution of valves sizes implanted, N = 1014.

Late Clinical Events

Late clinical events are those events that occurred 31 days or more postimplant. There were 23 deaths, yielding a linearized mortality rate of 2.72% per late patient-year. Of these, 3 (0.36% per late patient-year) were valve related and 4 (0.47% per late patient-year) were cardiac related. Overall Kaplan–Meier survival was 95.8% at 1 year and 94.5% at 2 years. Freedom from valve-related mortality was 99.4% at 2 years.

There were 16 thromboembolic events (linearized rate of 1.90% per late patient-year of follow-up), including 4 strokes and 12 reversible neurologic events. Of these patients, 1 was known to be in atrial fibrillation. Overall freedom from thromboembolic events was 92.9% at 2 years. There were 22 instances of major bleeding (linearized rate of 2.61% per late patient-year). Freedom from major bleeding events was 86.0% at 2 years. There was 1

TABLE 2. Operative details

Variable	No. of patients (N = 1014)	Mean ± SD (min)
Aortic crossclamp time		
All subjects	1014	83.2 ± 37.3
With concomitant procedure	586	96.9 ± 38.5
Without concomitant procedure	428	64.3 ± 25.5
Cardiopulmonary bypass time		
All subjects	1014	111.5 ± 51.0
With concomitant procedure	586	129.7 ± 52.8
Without concomitant procedure	428	86.6 ± 35.8
	No. of patients (N = 1014)	%
Concomitant procedures		
CABG	372	36.7
Mitral valve repair	38	3.7
Tricuspid valve repair	23	2.3
Maze	42	4.1
Cardiac ablation	29	2.9
Maze or cardiac ablation	66	6.5
ASD	38	3.7
Root enlargement	17	1.7

SD, Standard deviation; CABG, coronary artery bypass grafting; ASD, atrial septal defect.

TABLE 3. Early adverse event rates

Safety measures for the early postoperative period	No. of early events* N = 1014	Early rate† % (95% upper CL)
Thromboembolism	27	2.7 (3.7)
Neurologic	25	2.5 (3.4)
Transient ischemic attack	3	0.3 (0.8)
Reversible ischemic neurologic deficit	14	1.4 (2.2)
Stroke	8	0.8 (1.4)
Systemic	2	0.2 (0.6)
Valve thrombosis	0	0.0 (0.3)
Major bleed	81	8.0 (9.5)
Procedure related	61	6.0 (7.4)
Anticoagulant or antiplatelet related	14	1.4 (2.2)
Anticoagulant with or without antiplatelet	9	0.9 (1.5)
Other bleed	6	0.6 (1.2)
Nonstructural dysfunction	3	0.3 (0.8)
Paravalvular leak	1	0.1 (0.5)
Minor paravalvular leak	1	0.1 (0.5)
Major paravalvular leak	0	0.0 (0.3)
Endocarditis	0	0.0 (0.3)
Clinically significant hemolysis	0	0.0 (0.3)
Structural deterioration	0	0.0 (0.3)
Reoperation	1	0.1 (0.5)
Repair	0	0.0 (0.3)
Explant	1	0.1 (0.5)
Mortality	18	1.8 (2.6)
Valve-related	2	0.2 (0.6)

CL, Confidence limit. *Early events are those occurring on or before 30 days post-implant. †Early rate is calculated as number of early events*100/number of subjects.

instance of nonstructural dysfunction that did not require explantation. Endocarditis occurred in 9 patients (linearized rate of 1.07% per late patient-year). Freedom from prosthetic valve endocarditis was 98.6% at 2 years. There was 1 instance of structural valve deterioration requiring explantation. There was no overt calcification of the valve cusps. In total, there were 5 valve explants, including 1 case of structural deterioration and 4 cases of prosthetic valve endocarditis. Overall, freedom from valve explant was 99.4% at 2 years. There were no instances of valve thrombosis or clinically significant hemolysis. Late clinical event rates are summarized in Table 4 and Figures 3 to 6.

New York Heart Association Results

At 2 years of clinical follow-up, 83.5% of patients had NYHA class I functional status. A further 14.4% of patients had NYHA class II status, and 2.1% of patients had NYHA class III status. There were no instances of NYHA functional class IV status in follow-up. At 2 years, freedom from NYHA class III or IV symptoms was 96.1%.

Hemodynamic Results

Hemodynamic results at discharge and 1 year for each valve size are presented in Figures 7 to 10. At the time of

TABLE 4. Late adverse event rates

Safety measures for the latepostoperative period (≥31 d postimplant)	No. of late events	Late rate* (late patient-y = 844.3) %/late patient-y (95% upper CL)
Thromboembolism	16	1.90 (2.88)
Neurologic	16	1.90 (2.88)
Transient ischemic attack	11	1.30 (2.16)
Reversible ischemic neurologic deficit	1	0.12 (0.56)
Stroke	4	0.47 (1.08)
Systemic	0	0.00 (0.35)
Valve thrombosis	0	0.00 (0.35)
Major bleed	22	2.61 (3.72)
Anticoagulant or antiplatelet related	16	1.90 (2.88)
Anticoagulant with or without antiplatelet	7	0.83 (1.56)
Other bleed	6	0.71 (1.40)
Nonstructural dysfunction	1	0.12 (0.56)
Paravalvular leak	0	0.00 (0.35)
Minor paravalvular leak	0	0.00 (0.35)
Major paravalvular leak	0	0.00 (0.35)
Endocarditis	9	1.07 (1.86)
Clinically significant hemolysis	0	0.00 (0.35)
Structural deterioration	1	0.12 (0.56)
Reoperation	5	0.59 (1.25)
Repair	0	0.00 (0.35)
Explant	5	0.59 (1.25)
Mortality	23	2.72 (3.86)
Valve-related	3	0.36 (0.92)

CL, Confidence limit. *More than 31-day adverse event rate (%) is calculated as the number of events divided by the total patient-years times 100.

discharge, average mean gradients ranged from 9.3 to 4.1 mm Hg and average peak gradients ranged from 17.8 to 7.8 mm Hg for valve sizes 19 to 29 mm, respectively. At 1 year of follow-up, average mean gradients ranged from 10.7 to 4.7 mm Hg and average peak gradients ranged from 19.9 to 9.2 mm Hg for valve sizes 19 to 29 mm, respectively. Average effective orifice area (EOA) ranged from

FIGURE 3. All-cause mortality.

FIGURE 4. Valve-related mortality.

1.58 to 2.50 cm² at the time of discharge and from 1.41 to 2.35 cm² at 1 year for valve sizes 19 to 29 mm, respectively.

At the time of discharge, 12 patients (1.2%) had mild aortic insufficiency, and 4 patients (0.4%) had moderate aortic insufficiency. There were no early cases of severe insufficiency. At 1 year, 11 patients (1.8%) had mild aortic insufficiency, 6 patients (1.0%) had moderate aortic insufficiency, and 3 patients (0.5%) had severe aortic insufficiency (Figure 11). At 1 year, moderate or greater aortic insufficiency was observed in 9 patients (1.5%). Paravalvular leaks were exceedingly uncommon with only 1 (0.1%) minor paravalvular leak observed in the early period (Figure 12).

Mild to moderate patient–prosthesis mismatch (PPM) as defined by an effective orifice area index (EOAI) of 0.65 to 0.85 cm²/m² occurred in 209 patients (22.8%) at the time of discharge. Severe PPM, defined as an EOA less than 0.65 cm²/m², was found in 18 patients (2.0%) at the time of discharge and 32 patients (5.5%) at 1 year. Overall freedom from severe PPM at 1 year was 94.8%. Mean indexed left ventricular mass for subjects who had values at all 3 postoperative time points decreased from 115.4 g/m² at the time of discharge to 107.0 g/m² at 6 months, 105.1 g/m² at 1 year,

FIGURE 5. Freedom from Trifecta (St Jude Medical Inc, St Paul, Minn) valve explant.

FIGURE 6. Freedom from NYHA III or greater. NYHA, New York Heart Association.

and 100.2 g/m² at 2 years ($P < .001$ for all time points vs left ventricular mass at discharge) (Figure 13).

DISCUSSION

Characteristics of the ideal aortic prosthesis include ease of implant, lack of intrinsic thrombogenicity that does not require therapeutic anticoagulation, no residual transvalvular pressure gradient, a physiologic orifice area that can adapt to exercise conditions, and long-term durability.^{6,8,9} The Trifecta valve prosthesis was designed to specifically address some of the fundamental limitations of previous aortic valve bioprostheses. Specifically, it was designed with a concave, slightly scalloped sewing ring to conform to the aortic annulus and provide adequate clearance for the native coronary arteries. Attachment of the bioengineered single sheet of bovine pericardium around the external aspects of the titanium stent allows for maximal cylindrical opening during systole. In addition, the titanium stent has intrinsic distensibility, potentially allowing for further expansion of the prosthesis in high-load conditions such as exercise.

The purpose of the current investigation was to establish the safety and hemodynamic profile of the Trifecta aortic valve prosthesis. One important trend observed in the current study and other recent multicenter evaluations of

FIGURE 7. Average mean valve gradients over time.

FIGURE 8. Average peak valve gradients over time.

biologic valve prostheses is that the average age of the patients was fairly high at 72.5 years.^{6,10,11} Despite the advanced age and higher risk profile, the clinical results of the patients in this study were exemplary. Perioperative mortality was 1.8%, and overall survival was 94.5% at 2 years. This compares favorably to contemporary multicenter valve performance studies in similar patient populations by Conte and colleagues¹⁰ evaluating the Sorin Mitroflow (Sorin Group, Milan, Italy) pericardial aortic prosthesis, Fradet and colleagues¹¹ evaluating the Medtronic Mosaic (Medtronic Inc, Minneapolis, Minn) porcine aortic prosthesis, and Jamieson and colleagues⁶ evaluating the St Jude Epic (St Jude Medical Inc) porcine prosthesis.

On the basis of the results of the current study, the Trifecta valve represents significant progress in the development of a stented bioprosthesis with near physiologic hemodynamics. The nearly cylindric opening of the prosthesis on systole provides gradients and EOAs that surpass any other available stented aortic prosthesis and approach those of stentless prostheses.^{6,10-12,14,15}

Although study-to-study comparisons of different aortic prostheses are confounded by many factors, among multicenter studies with rigorous centralized core laboratory analysis echocardiographic follow-up, the Trifecta valve showed favorable hemodynamics to other pericardial prostheses.^{10,12} At 1 year, EOAs for the Trifecta valve, Sorin Mitroflow,¹⁰ Medtronic Mosaic,¹¹ and Edwards Magna Ease¹² (Edwards Lifesciences, Irvine, Calif) were 1.4, 1.1, 1.2, and 1.3 cm² for the 19-mm prosthesis; 1.6, 1.2, 1.3, and 1.5 cm² for the

FIGURE 9. Average EOA. EOA, Effective orifice area.

FIGURE 10. Average EOA. EOA, Effective orifice area index.

21-mm prosthesis; and 1.8, 1.4, 1.5, and 1.8 cm² for the 23-mm prosthesis, respectively. In a nominal size-by-size comparison, the 6-month EOAs for the Trifecta valve versus the St Jude Medical Toronto stentless porcine valve (full root implants only) were 1.7 and 1.2 cm² for the 21-mm prostheses, 1.9 and 1.5 cm² for the 23-mm prostheses, 2.1 and 1.9 cm² for the 25-mm prostheses, 2.2 and 2.3 cm² for the 27-mm prostheses, and 2.5 and 2.6 cm² for the 29-mm prostheses, respectively.¹³ The presence of a titanium stent that may be able to expand during high loading conditions, such as exercise, may provide additional clinical benefit and minimize leaflet stresses as seen in stentless porcine valves. In addition, optimal leaflet shaping and coaptation are achieved through a proprietary leaflet fixation method.

The favorable hemodynamics led to an incidence of severe PPM that was uniquely low for the Trifecta valve. Among patients receiving 19-, 21-, and 23-mm prostheses, at 1 year, the mean EOA was 0.85, 0.90, and 0.91 cm²/m², respectively. Severe mismatch with an EOA less than 0.65 cm²/m² was found in only 2.0% of patients at the time of discharge. The presence of severe PPM has been shown in several studies to lead to significantly poorer long-term survival in a variety of patient groups. In series with older-generation prostheses and varying definitions of mismatch, its incidence has been reported up to 51%.^{15,16}

The discussion of near physiologic hemodynamics seen in the Trifecta valve is particularly important with the

FIGURE 11. Total aortic insufficiency over time.

FIGURE 12. Paravalvular leak over time.

proliferation of transcatheter aortic valve replacement (TAVR) technologies.¹⁷⁻¹⁹ TAVR valves have been purported in several nonrandomized studies to have hemodynamics superior to open surgical valves, with low residual gradients due to the nonobstructive nature of the metallic stent and lack of sewing ring.¹⁹ In the only large multicenter randomized controlled trial comparing TAVR with open aortic valve replacement in high-risk patients, the difference in postoperative gradients was in the low single digits and not likely to be clinically significant.²⁰ Although TAVR valves tend to be hemodynamically efficient in systole, paravalvular leaks, and to a lesser extent intravalvular leaks, seen frequently in the first-generation devices represent true sources of energy loss that may limit the full clinical benefit of the relief of severe aortic stenosis. A recent bench study by Azadani and colleagues²¹ revealed that energy loss in the setting of even mild aortic regurgitation from a paravalvular leak may be as hemodynamically important as a modest residual gradient. Aortic regurgitation, predominantly from paravalvular sources, is present in more than 51% of TAVR valves, and moderate or worse regurgitation is generally described in up to 13% of TAVR valves.^{17,18,22,23} In the current study, the Trifecta valve had a low rate of paravalvular leak (Figure 12) despite having a highly efficient low-profile sewing ring, indicative of ease of implantability. There was also minimal valvular

FIGURE 13. Left ventricular mass regression.

regurgitation even in larger sizes, a problem more common in previous-generation surgical pericardial valves.²⁴

CONCLUSIONS

The St Jude Medical Inc Trifecta valve is a unique pericardial bioprosthesis with design elements that incorporate significant improvements in hemodynamic performance over previous-generation valves while providing ease of implantation. Long-term follow-up continues to confirm the promising results of this innovative bioprosthesis.

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APPENDIX TABLE 1. Principal Investigator list

Principal Investigator	Investigational sites
Joseph Bavaria, MD	Hospital of the University of Pennsylvania
Michael Petracek, MD	Vanderbilt Medical Center
Hartzell Schaff, MD	Mayo Clinic
Mark Groh, MD	Mission Health and Hospitals
Scott Goldman, MD	Lankenau Hospital
Kent Jones, MD	Intermountain Medical Center
Vibhu Kshetry, MD	Abbott Northwestern Hospital
A. Marc Gillinov, MD	Cleveland Clinic Foundation
Marc Sakwa, MD	William Beaumont Hospital
Mamdouh Bakhos, MD	Loyola University Medical Center
David Kress, MD	St Luke's Medical Center
Vaughn Starnes, MD	University of Southern California
Joseph Coselli, MD	St Luke's Episcopal Hospital
Donald Glower, MD	Duke University Medical Center
Stephen Dewan, MD	Cardiothoracic and Vascular Surgeons
Thomas Kelly, MD	Sarasota Medical Center
Charles Schwartz, MD	New York University Medical Center
Allen Stewart, MD	Columbia University Medical Center
Anson Cheung, MD	St Paul's Hospital
Eric Charbonneau, MD	Hôpital Laval
Vivek Rao, MD	Toronto General Hospital
Jeremy Wood, MD	Queen Elizabeth II Health Science Centre
Guy Fradet, MD	Vancouver General Hospital
Michel Pellerin, MD	Institut de Cardiologie de Montréal
Roderick MacArthur, MD	University of Alberta
Frederick W. Mohr, MD, PhD	Herzzentrum Leipzig GmbH
Frederik N. Hofman, MD	Onze Lieve Vrouw Gasthuis, Netherlands
Alain Leguerrier, MD	CHRU Rennes
Rüdiger S. Lange, MD, PhD	German Heart Center München
Thierry Carrel, MD, PhD	Inselspital Bern
Gino Gerosa, MD, PhD	Azienda Ospedaliera Di Padova