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# Four-Year Clinical Outcomes Following TAVR with the Repositionable and Fully Retrievable Lotus Valve System: an Update from the REPRISE I Study

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## STUDY DESIGN

**STUDY DESIGN:** prospective, single-arm feasibility study

**STUDY OBJECTIVE:** assess the acute safety and performance of the transcatheter Lotus™ Aortic Valve (23 mm valve) in patients with severe aortic stenosis and at high risk for surgical intervention

**PRIMARY ENDPOINT:** Device success (VARC-1 definition) without in-hospital MACCE through discharge/7 days

**STUDY POPULATION:**

- Age ≥70 years
- Aortic valve stenosis and NYHA Class ≥II
  - AVA <1.0cm$^2$ (or AVA index <0.6cm$^2$/m$^2$) plus either MPG >40mmHg or jet velocity >4m/s
- High risk for surgical AVR
- Aortic annulus size 19-22mm

## STUDY FLOW

Intent-To-Treat
N=11

↓

Lotus Valve Implanted
(As-Treated)
N=11

↓

30-Day Clinical Follow-Up
100% (11/11)

↓

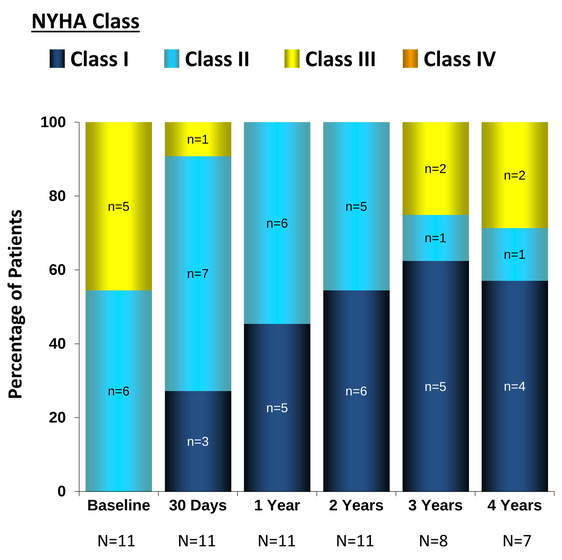
**4-Year Clinical Follow-Up Available or had a Clinical Event 90.9% (10/11)***

*In-person follow-up unavailable for one patient; vital status confirmed via telephone.

## PATIENT POPULATION

| Baseline Characteristics | N=11 |
|---|---|
| Age (years) | 83.0±3.6 |
| Gender (female) | 11/11 |
| STS Score (%) | 4.9±2.5 |
| Logistic euroSCORE (%) | 9.5±4.4 |
| NYHA Class III or IV | 5/11 |
| Diabetes, medically treated | 2/11 |
| Hypertension, medically treated | 10/11 |
| History of coronary artery disease | 5/11 |
| History of cerebrovascular accident | 2/11 |
| Atrial fibrillation | 5/11 |

## NYHA CLASS TO 4 YEARS



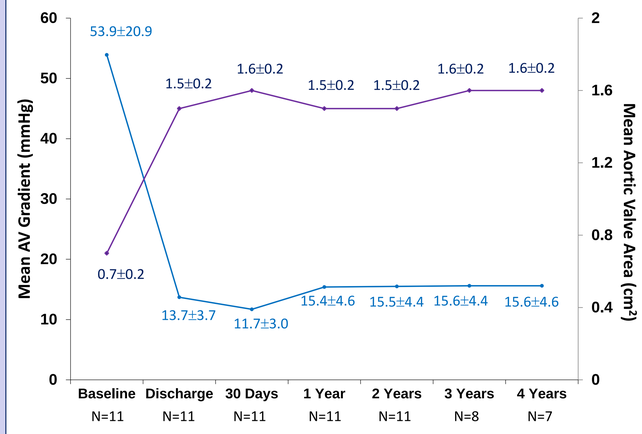

## SAFETY

| 4-Year Event Rate | n/11 |
|---|---|
| MACCE components | 4 |
| All cause mortality[a] | 3 |
| Peri-procedural MI (≤72 hours) | 0 |
| Major stroke | 1 |
| Urgent or emergent conversion to surgery or repeat procedure for valve-related dysfunction | 0 |
| Myocardial infarction | 0 |
| Minor stroke | 1 |
| Major vascular complication[b] | 1 |
| Bleeding | |
| Life-threatening/disabling bleeding[c] | 2 |
| Major bleeding[d] | 3 |
| Acute kidney injury – Stage 2 or 3 | 0 |
| Conduction disturbance requiring new pacemaker | 4 |

[a]Causes of death: uncontrolled sepsis (non-cardiovascular) at Day 843 in one patient; metastatic breast cancer at Day 1113 in one patient; congestive heart failure associated with acute kidney impairment at Day 1179 in one patient.
[b]Left femoral artery dissection treated by cross-over contralateral balloon angioplasty.
[c]Pericardial effusion from pacemaker implant at 14 Days in one patient; GI bleed at 20 Days in one patient.
[d]All unrelated to TAVR access.

## VALVE HEMODYNAMICS

*Core laboratory-adjudicated data*

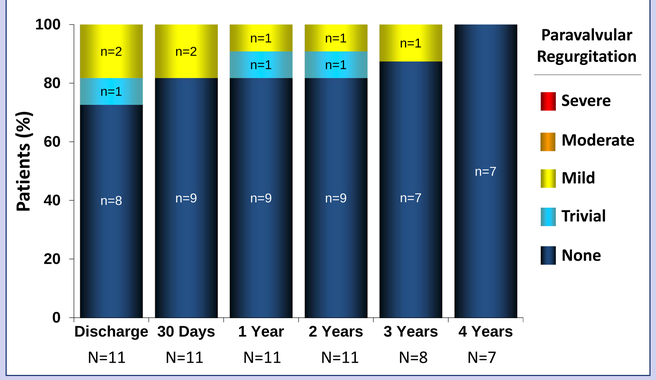



| Measurement | Mean AV Gradient | Mean AVA |
|---|---|---|
| Baseline to Discharge | *P*<0.001 | *P*<0.001 |
| Baseline to 4 Years | *P*<0.001 | *P*<0.001 |
| Discharge to 4 Years | *P*=0.469 | *P*=0.773 |

*P* values from repeated measures and random effects ANOVA model.

## AORTIC VALVE REGURGITATION

*Core laboratory-adjudicated data*




## CONCLUSIONS

- Four-year results from the REPRISE I study demonstrate excellent valve function with minimal paravalvular regurgitation and low clinical event rates.
- These data support the safety and performance of the Lotus Valve for the treatment of patients with severe aortic stenosis.

Disclosures: IM: Consultant Fees/Honoraria/Speaker's Bureau: Boston Scientific (significant); SW: Grant support/Research contract: Medtronic, St Jude Medical (significant), Consultant Fees/Honoraria/Speaker's Bureau: Medtronic (modest); AN: Consultant Fees/Honoraria/Speaker's Bureau: Edwards Lifesciences (modest); DJA & KDD: Salary & Equity: Boston Scientific (significant); RW & JM: none. The REPRISE I study is sponsored and funded by Boston Scientific.
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