TCT-615

First Report of Three-Year Outcomes With the Repositionable and Fully Retrievable Lotus™ Aortic Valve Replacement System: Results From the REPRISE I Feasibility Study

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Introduction & Study Design

STUDY OBJECTIVE: Assess acute safety & performance of the Lotus Valve System (23mm valve) for TAVR

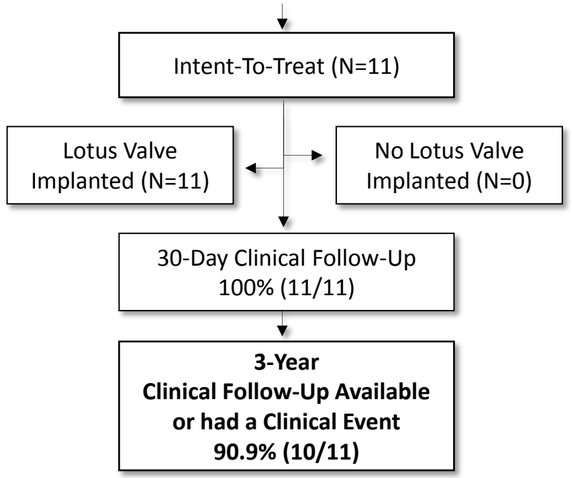
DESIGN: Prospective, single-arm feasibility study

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

ANALYSIS OBJECTIVE: to assess the long-term (3-year) outcomes with the Lotus Valve

Patients aged ≥70 years with:

- Aortic valve stenosis and NYHA Class ≥II
  - AVA <1.0cm² (or AVA index <0.6cm²/m²) plus either MPG >40mmHg or jet velocity >4m/s
- High risk for surgical AVR
- Aortic Annulus size 19-22mm (23mm valve used)

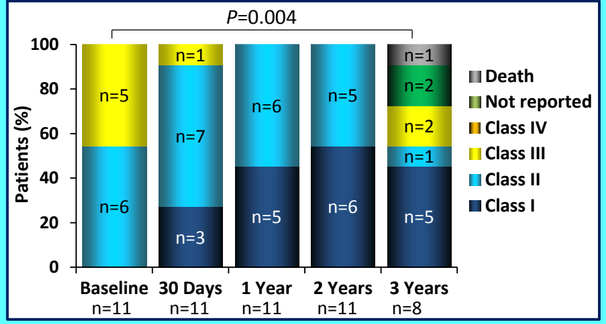


Information not intended for use in France. Lotus is an investigational device and not for sale or distribution in the US. CE Mark received 2013. Information for the Lotus Valve System is for use In countries with applicable product registrations. Indications, contraindications, warnings, and Instructions for use can be found in the product labeling supplied with each device.

Patients

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 3 Years



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: Grant support/Research contract: Boston Scientific (modest), Consultant Fees/Honoraria/Speaker's Bureau: Medtronic, Edwards Lifesciences (modest); DJA & KDD: Salary & Equity: Boston Scientific (significant); RW & JM: none
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Safety

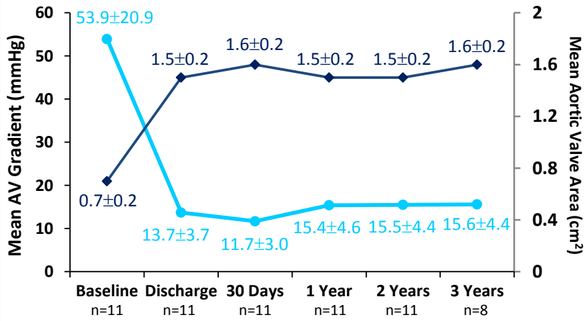
Safety Event Rates At 3 Years	n/11
MACCE	2
All cause mortality[a]	1
Peri-procedural MI (≤72 hours)	0
Major stroke	1
Urgent or emergent conversion to surgery or repeat procedure for valve-related dysfunction	0
Life-threatening/disabling bleeding[b]	2
Acute kidney injury – Stage 2 or Stage 3	0
Major vascular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

a: Death (non-cardiovascular; uncontrolled sepsis) at 843 days post procedure
b: Events at 14 days (pericardial effusion from pacemaker implant) and 20 days (GI bleed) post procedure
c: Left femoral artery dissection treated by cross-over contralateral balloon angioplasty
d: All unrelated to TAVR access

New Safety Events Between 2 Years and 3 Years

- Transient ischemic attack in 1 patient at Day 1037; resolved without residual effects
- Thromboembolic stroke (minor) in 1 patient at Day 818; resolved without residual effects
  - Patient had a history of atrial fibrillation and experienced non-cardiovascular death (uncontrolled sepsis) at Day 843

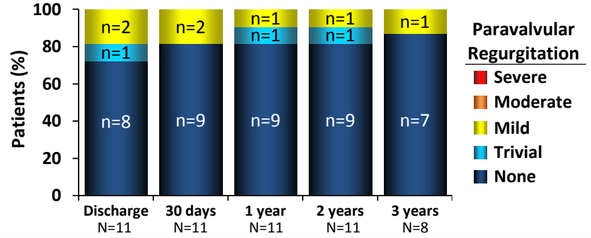
Valve Hemodynamics



Measurement	*P* value	
	Mean AV Gradient	Mean AVA
Baseline to Discharge	<0.001	<0.001
Baseline to 3 Years	<0.001	<0.001
Discharge to 3 Years	0.542	0.909

P values from repeated measures and random effects ANOVA model — Independent Core Lab adjudication

Aortic Valve Regurgitation



Conclusions

Three-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.

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