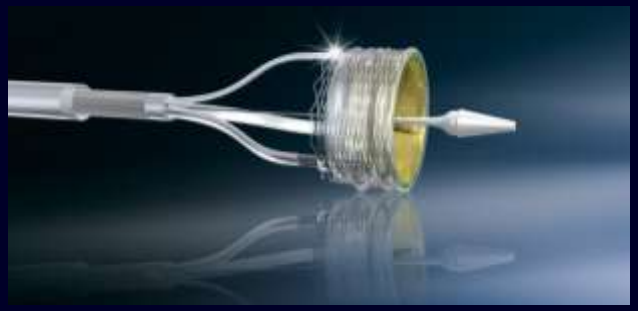
REPRISE II

A Prospective Registry Study of Transcatheter Aortic Valve Replacement with a Repositionable Transcatheter Heart Valve in Patients with Severe Aortic Stenosis.



Ian T. Meredith AM,

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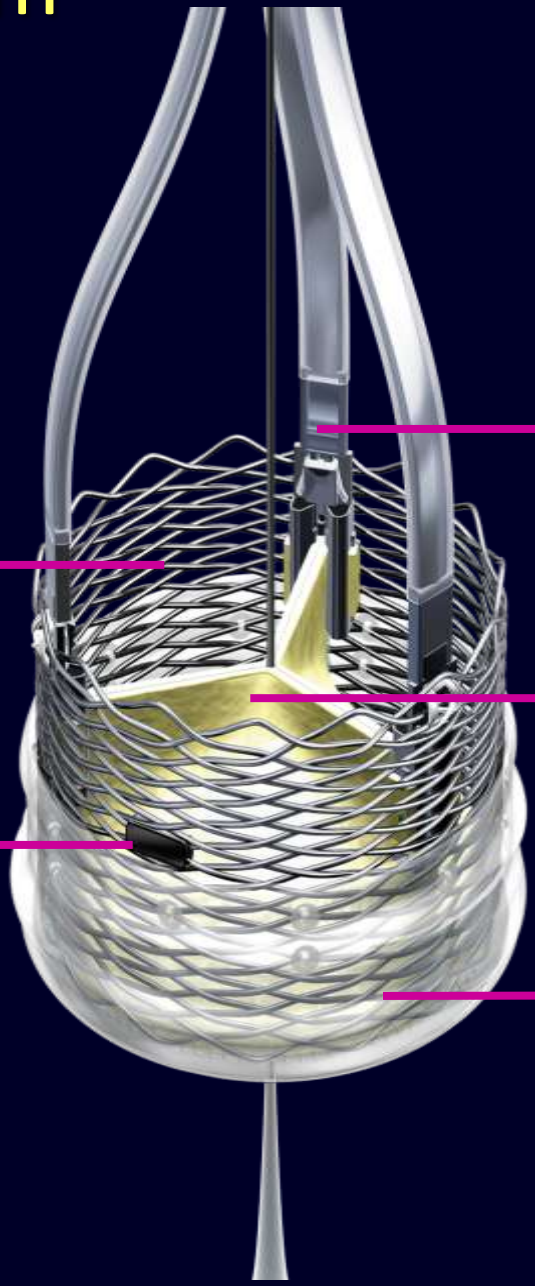
Professor and Director of MonashHEART,
Monash Health, Monash Medical Centre
and Monash University Clayton, Victoria, Australia

Lotus Valve System



Locking Mechanism

Braided Nitinol Frame

Bovine Pericardium

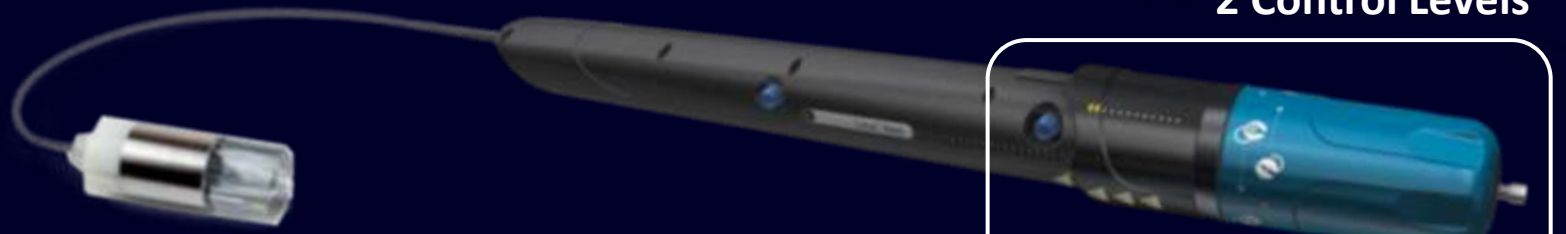
Central Radiopaque Positioning Marker

Adaptive Seal

Lotus Valve System Design Goals

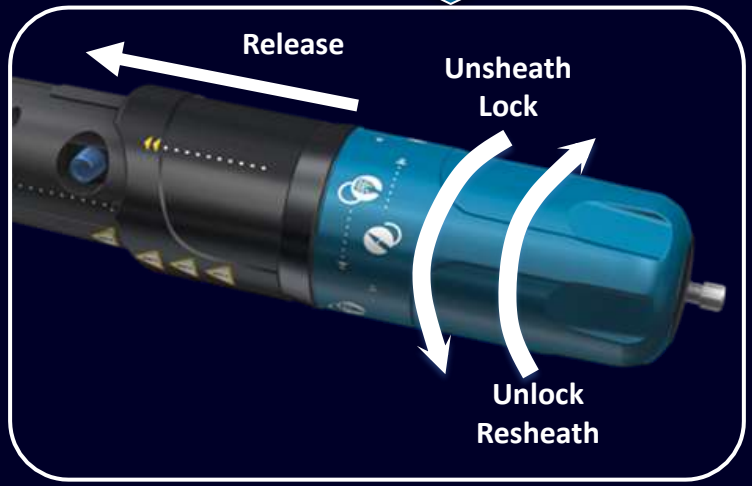
Pre-mounted valve and simple handle design

Designed for Ease of Use



Pre-Attached System

2 Control Levels

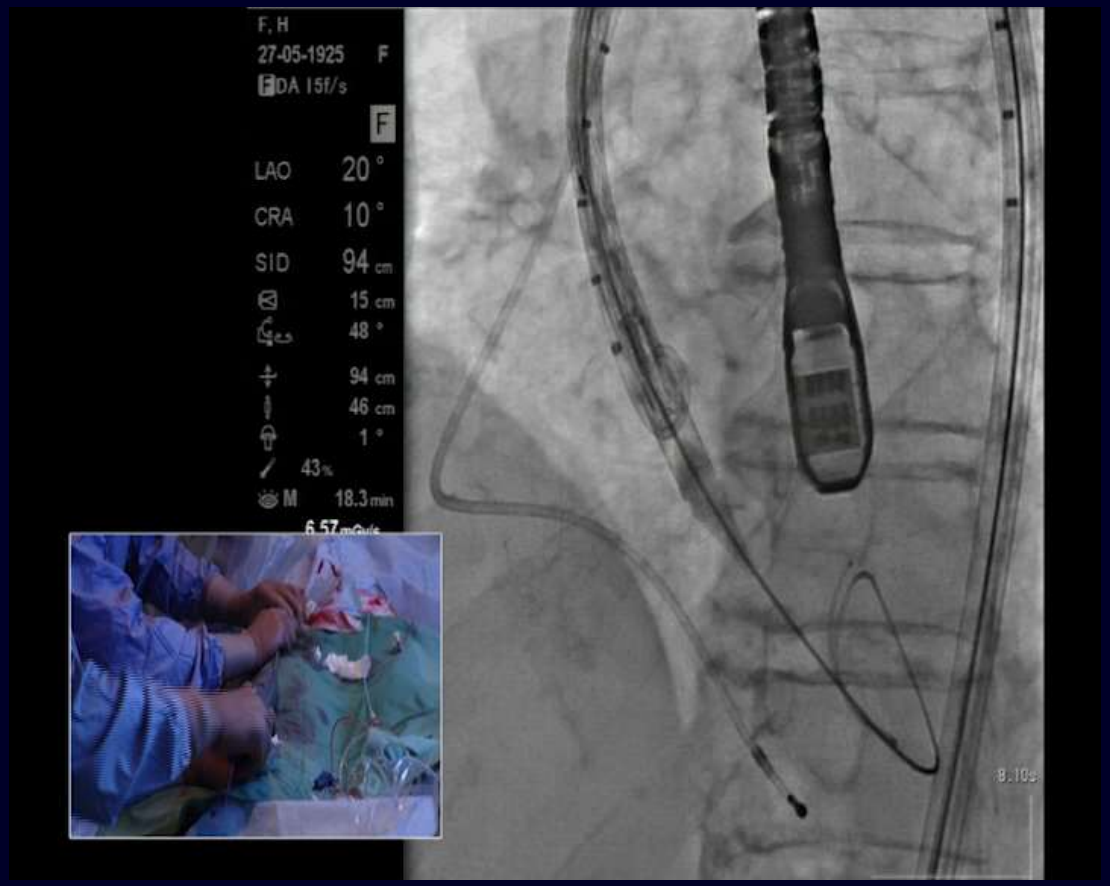


Easy to Prepare

Lotus Valve System Design Goals

Controlled Mechanical Expansion

- Valve deployed via controlled mechanical expansion.
  - ➡ Neither balloon expandable nor self-expanding.
- No rapid pacing during deployment
- Valve functions early
- No valve movement on release



Lotus Valve System Design Goals

Controlled, Accurate, and Predictable Positioning

- Central radiopaque positioning marker to guide placement
- Valve is repositionable throughout entire deployment process

Partial Re-sheathing to Reposition
(Focus on the marker)

REPRISE II Case Example

Minor Repositioning to reduce AR and influence AV conduction

23mm Lotus Valve

Reprise II Lotus Case Ian Meredith AM

REPRISE II Case Example

23mm Lotus Valve Retrieval and Exchange for 27mm Valve

23 mm valve deployed.
Too small; significant PVL

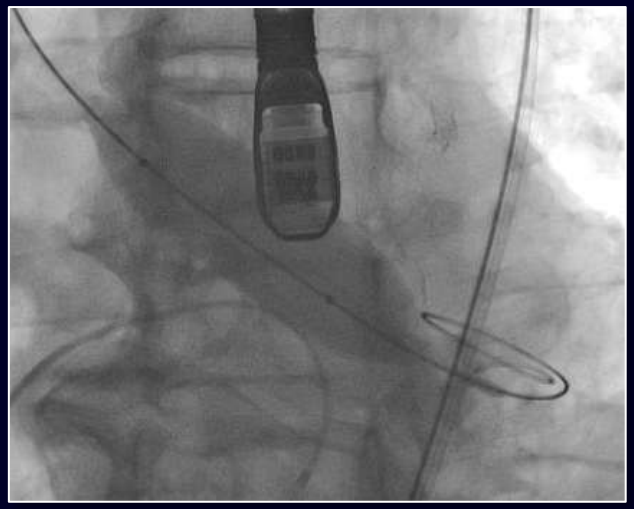
Atraumatic resheathing to retrieve and remove

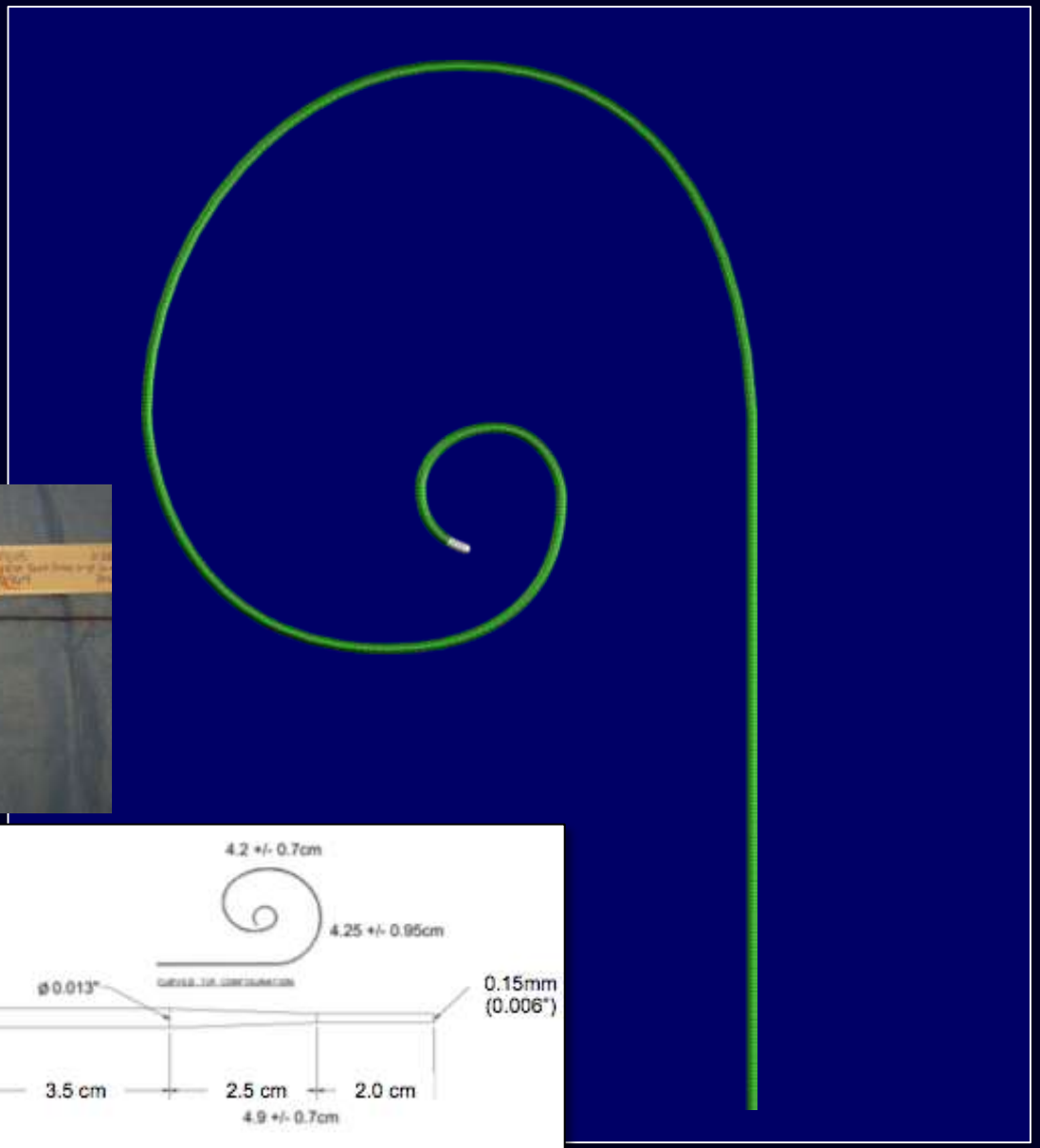
Replaced with 27mm valve
No PVL

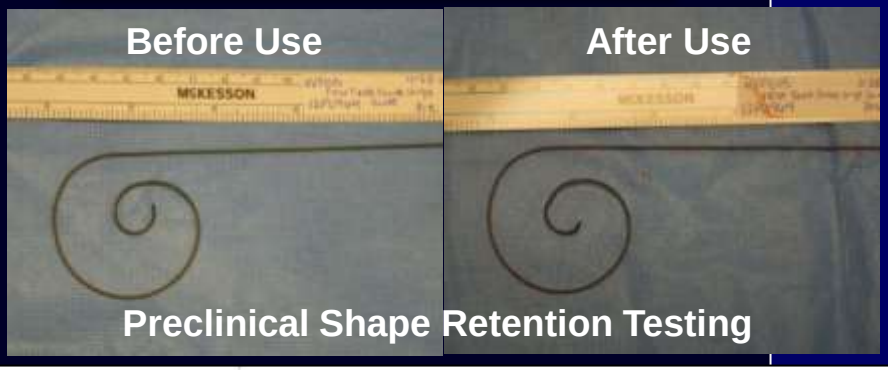
Reprise II Lotus Case Ian Meredith AM

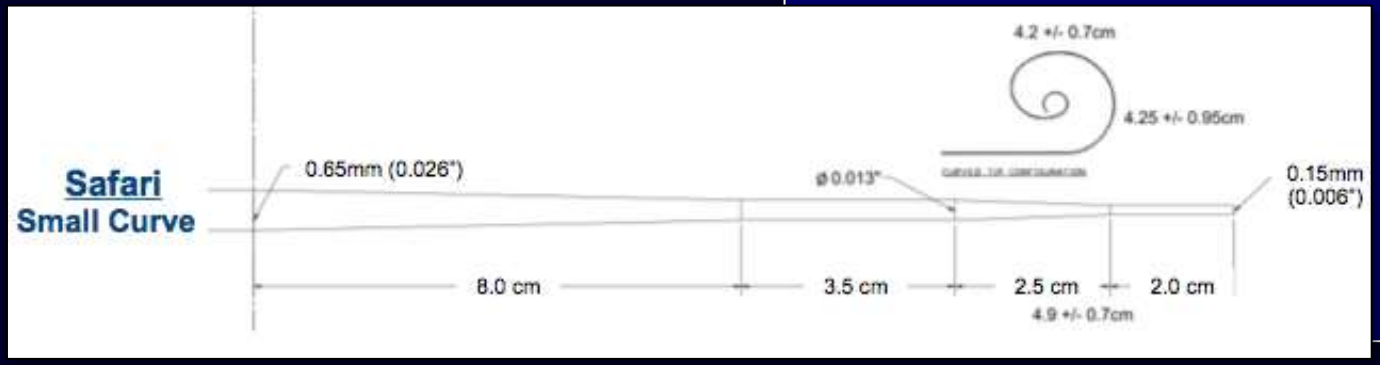
Case study not necessarily representative of all cases. Results in other cases may vary.
Lotus is an investigational device and not for sale in the US. CE mark received 2013. Information for the Lotus Valve System is for use in countries with applicable product registrations

Safari Guidewire









The Safari™ guidewire is manufactured by Lake Region Medical and distributed by Boston Scientific Corporation

Lotus Clinical Program

REPRISE I

Feasibility Study; Acute Safety & Performance (Extreme/High Risk)
N=11; single arm; 23mm valve size
Primary Endpoint: Device success (VARC-1) without MACCE
12-month follow-up reported
Meredith et al, *EuroIntervention 2013;* In Press

REPRISE II

CE Mark Study; Safety & Performance (Extreme/High Risk)
N=120; single arm; 23 & 27mm valve sizes
Primary Device Performance Endpoint: Mean pressure gradient at 30d
30-day follow-up reported
Meredith et al, *JACC;* In Review

REPRISE II Extension

Safety & Performance Study (Extreme/High Risk)
N=130; single arm; 23 & 27mm valve sizes
Primary Safety Endpoint: All-cause mortality at 30d
Enrolling

RESPOND

Post Market Safety & Performance Study (Real World)
N=1000; single arm; 23, 25 & 27mm valve sizes
Primary Endpoint: All-cause mortality at 30d & 1y
Anticipated start: 2Q 2014

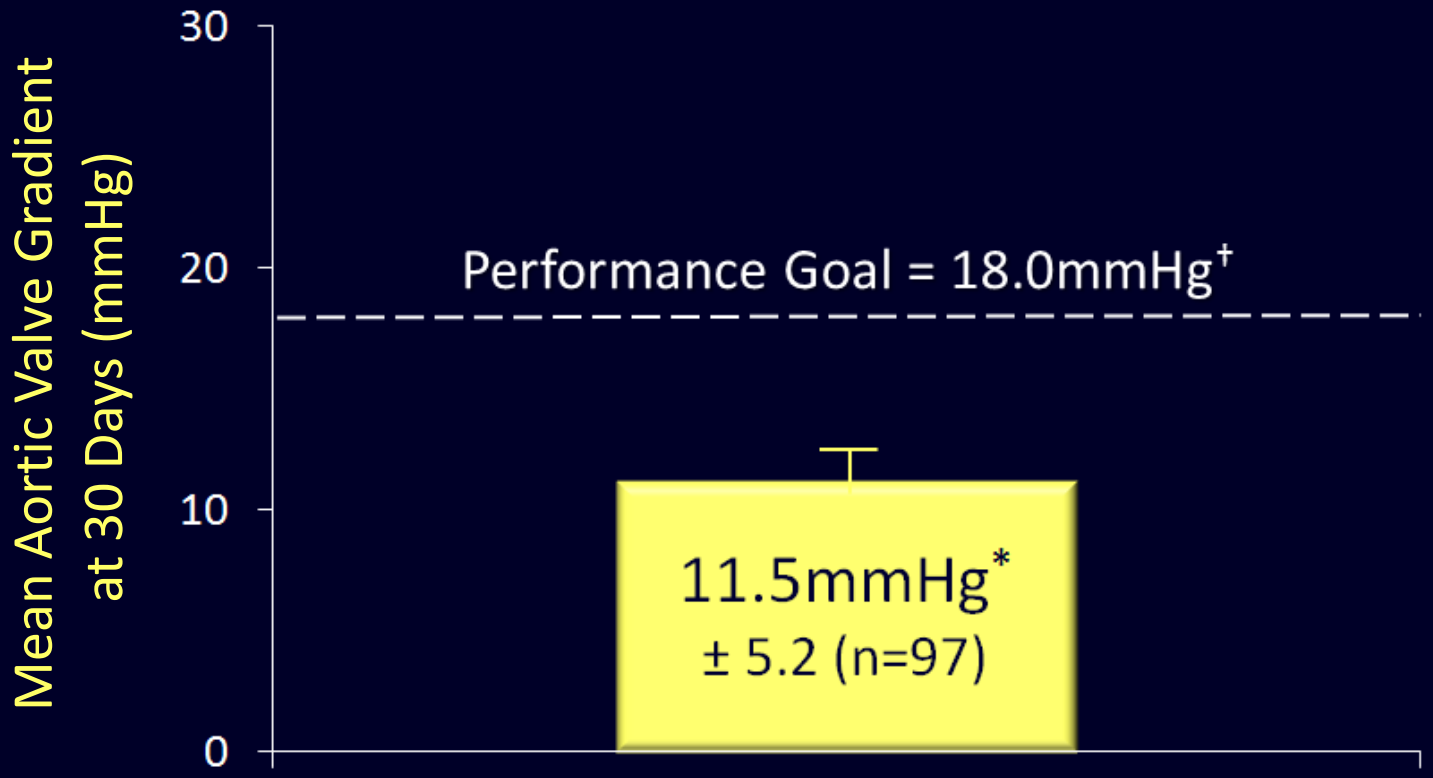
REPRISE III

FDA Approval Study; Safety & Efficacy (Extreme/High Risk)
N~1000; Global RCT vs. EDW; 23, 25 & 27mm valve sizes
Primary Endpoint: All-cause mortality & disabling stroke at 12m
Anticipated start: 2H 2014

Lotus Valve currently not available in 25 mm size

REPRISE II Trial

Primary Device Performance Endpoint



** Value of 11.5mmHg with a 98.7%‡ UCB of 12.6mmHg is significantly less than the performance goal (P <0.001)*

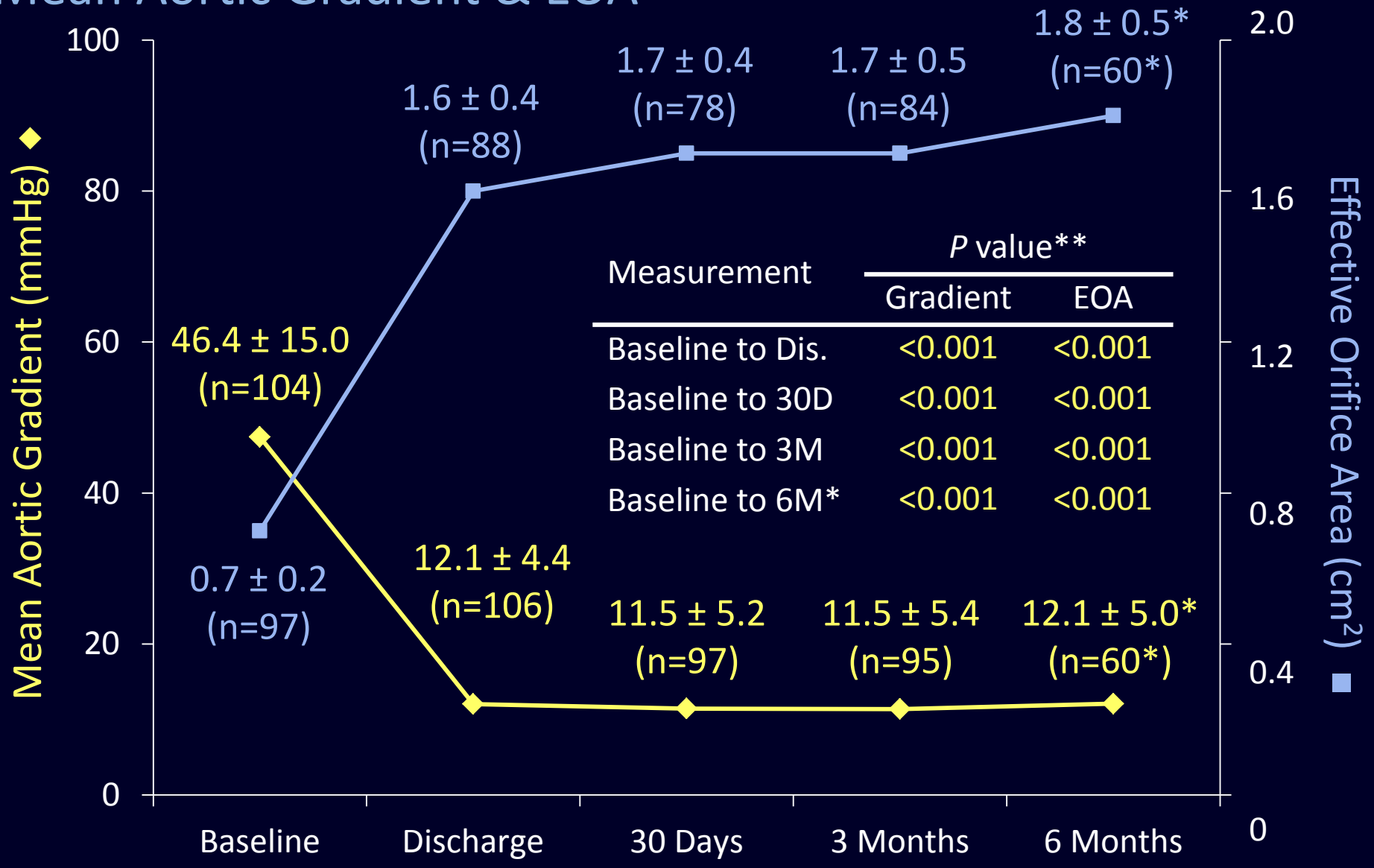
Presented by Ian Meredith AM, MBBS, PhD at TCT 2013

‡ Alpha-level adjustment for multiple analyses (final analysis)

† Based on an expected mean of ≤15 mmHg (literature review) plus a test margin of 3mmHg

REPRISE II Trial

Mean Aortic Gradient & EOA



Measurement	*P* value**	
	Gradient	EOA
Baseline to Dis.	<0.001	<0.001
Baseline to 30D	<0.001	<0.001
Baseline to 3M	<0.001	<0.001
Baseline to 6M*	<0.001	<0.001

*6M data available only from first 60 patient cohort to date. **Repeated measures and random effects ANOVA

REPRISE II Trial

Valve Malpositioning / Other Complications

	Patients (N=120)
Correct positioning; 1 valve in proper location	100.0% (0)
Aortic valve malpositioning	0.0% (0)
Valve migration	0.0% (0)
Valve embolization	0.0% (0)
Ectopic valve deployment	0.0% (0)
TAV-in-TAV deployment	0.0% (0)
Aortic valve endocarditis	0.0% (0)
Aortic valve thrombosis	0.0% (0)

REPRISE II Trial

3-Month Safety Results

	Patients (N=119*)
All-cause mortality (Primary Safety Endpoint at 30 days)	5.0% (6/119)
Disabling stroke†	2.5% (3/119)
Myocardial infarction	3.4% (4/119)
Life-threatening or disabling bleeding	5.0% (6/119)
Major vascular complication	2.5% (3/119)
New permanent pacemaker	28.6% (34/119)
LVOT overstretch ≥10%	55.9% (19/34)
Annulus overstretch ≥10%	41.2% (14/34)

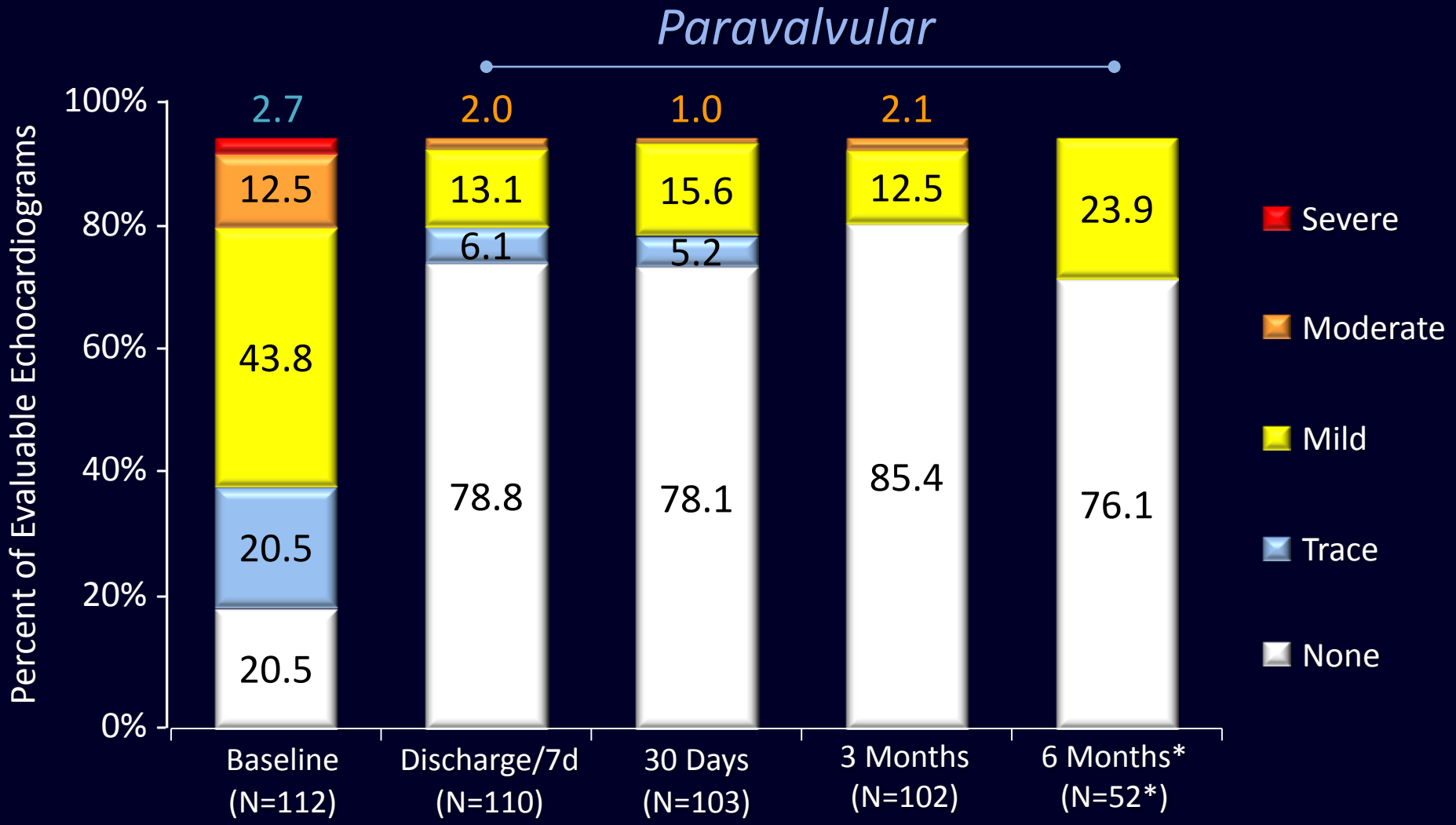
Presented by Ian Meredith AM, MBBS, PhD at ACC 2014

* One patient withdrew consent

† Neurologic assessment was performed on all patients pre- and post-procedure.

REPRISE II Aortic Regurgitation

Paravalvular Aortic Regurgitation Over Time



No severe paravalvular aortic regurgitation post-implantation

Presented by Ian Meredith AM, MBBS, PhD at ACC 2014

*6M data available only from first 60 patient cohort to date.

Summary

Lotus Valve Design Goals

- Adaptive seal to mitigate PVL
- Controlled mechanical expansion
- Precise and accurate positioning
- Repositionable & retrievable any time before release
- Size matrix expansion to reduce pacemaker implants

- Second generation TAVR technologies show promise in reducing PVL and improving clinical outcomes