Innovating imaging for structural heart interventions
Session evaluation and key learnings

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WHAT HAVE WE LEARNED?

IMAGING

DEVICE INNOVATIONS

IMPROVED PERFORMANCE AND OUTCOMES OF STRUCTURAL HEART INTERVENTIONS
TAVI in Bicuspid Aortic Valve (BAV)

Technical Challenges

- **Elliptical and large annulus**
  - Impaired valve positioning and sealing

- **Asymmetrical and heavy leaflets**
  - Calcification
  - Inadequate valve expansion and impaired valve hemodynamics

- **Concomitant aortopathy (~50%)**
  - Increased risk of complications
### Intervention

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Valve Ann Min Diam</td>
<td>18.7 mm</td>
</tr>
<tr>
<td>Aortic Valve Ann Max Diam</td>
<td>23.2 mm</td>
</tr>
<tr>
<td>Aortic Valve Ann Diam (Area Deriv...)</td>
<td>20.9 mm</td>
</tr>
<tr>
<td>Aortic Valve Ann Perimeter</td>
<td>66.6 mm</td>
</tr>
<tr>
<td>Aortic Valve Ann Area</td>
<td>344.1 mm²</td>
</tr>
<tr>
<td>Root STJ Min Diam</td>
<td>23.8 mm</td>
</tr>
<tr>
<td>Root STJ Max Diam</td>
<td>25.3 mm</td>
</tr>
<tr>
<td>Root SoV Min Diam</td>
<td>25.3 mm</td>
</tr>
<tr>
<td>Root SoV Max Diam</td>
<td>28.3 mm</td>
</tr>
<tr>
<td>L Ostium Height</td>
<td>17.8 mm</td>
</tr>
<tr>
<td>R Ostium Height</td>
<td>13.7 mm</td>
</tr>
</tbody>
</table>
NEW-GENERATION DEVICES

301 consecutively enrolled patients since 2013
199 pts (71.1%) early generation device Sapien XT, CoreValve
102 pts (29.9%) new generation device Sapien 3, Lotus

Propensity-score matching analysis of 561 BAV and 4,546 TAV patients undergoing TAVI with early- (Sapien XT/CoreValve) or new- (Sapien 3/Lotus/Evolut R) generation devices
Lotus Ongoing and Upcoming Core Trials and ISRs for the Lotus Valve

BSC Core Trials:
- REPRISE I
- REPRISE II
- REPRISE II EXT
- REPRISE III
- REPRISE JAPAN
- RESPOND
- REPRISE CAS
- REPRISE IV & V
- REPRISE China
- REPRISE Bicuspid
- REPRISE V-in-V

Real World:
- Ulm Registry**
- LEAR** (LOTUS Edge)

Combined Procedures:
- LAAC & TAVR Pilot

Int./Low Risk:
- NOTION II

Lotus vs Other TAVR*:
- Hemodynamic Eval.
- LV Mechanics
- Monash Exp.
- MRI Study
- Ulm Registry**
- SELECT!**

TAVR vs SAVR:
- MRI Study,
- 4D MRI Assessment

*TAVR includes: CoreValve, Evolut-R, S3, and SAPIEN XT. **Includes LOTUS Edge

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Lotus Investigator-Sponsored Research (1 of 2)

- **Monash Lotus vs CoreValve**
  - Head to head core lab adjudicated comparison VARC2 outcomes
  - Follow-up: Discharge, 30d
  - Complete

- **MRI Study SAVR vs TAVR**
  - MRI substudy in 4 UK study centers; Cranial and cardiac MRI data assessment
  - Complete

- **Comparison of LV Mechanics**
  - Lotus (n=50) vs CoreValve (n=50) Echo Study
    - Follow-up: Baseline, Pre-discharge, 6 months, and 1 year assessments
    - Measuring effects of TAVR on LV mechanics by myocardial deformation parameters by 2D strain and conventional 2D parameters
  - Complete

- **4D MRI Assessment**
  - Comparison of 10 SAVR Patients with 20 Lotus Patients
    - 4D contrast MRI assessment measuring turbulent flow
    - Baseline and 90d CMR
  - Enrolling

- **LEAR Registry**
  - LOTUS Edge All-Comers Registry
    - Prospective, non-randomized, single arm, multicenter, N=1000
    - 30-d safety and efficacy (VARC 2) with LOTUS Edge
  - Enrolling Q2/Q3 2017

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Real World Registry
CoreValve, Sapien XT, Sapien 3, Lotus, and LOTUS Edge
N= 500 total (100/value); Safety and efficacy, PVL; Follow-up: 12 months

Procedural Technique to Minimize Conduction Disturbances
Safety and Efficacy, PVL and PPM; Follow up: 12 months

Feasibility of TAVR LAAC in AF Patients with Severe AS
Prospective, multicenter, non-randomized observational study in 50pts

Hemodynamic Evaluation of Next Generation Valves
Prospective Cohort (n=45), Sapien 3 (n=45), Evolut R (n=30), DirectFlow Medical (n=30) compared to retrospective cohort
Assessing hemodynamic parameters (AR Index) before and after TAVR as surrogate marker for PVL and outcome

TAVR vs SAVR in Low Risk Patients with Severe AS
Prospective, randomized 1:1, multicenter, N=780
Post-procedural, 3m, 12m and then yearly follow-up for 5 years
Composite all-mortality, MI, and stroke within 1 year (VARC-2)

LOTUS Edge vs EVOLUT R All-Comers Study
Prospective, multi-center, randomized (1:1), non-inferiority study
Comparison of event-free TAVI procedures at 30d (VARC-2)
**LAA Closure: Role of Imaging**

**Assessment of LAA morphology**

**Procedure Planning**

- Cardiac CT
- 2D and 3D imaging for device selection sizing, procedure planning

**Measurements for optimal sizing of LAA device**

1. LAA ostium
2. Landing zone
3. Maximum length of anchoring lobe in the axis of the device
LAA Closure: Role of Imaging

Device Placement

- Angiography
- 2D and 3D real-time true volume TEE
- DynaCT 3D imaging
- 2D/3D Overlay

Validation

- Angiography
- 2D and 3D real-time true volume TEE
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**WATCHMAN™ Investigator Sponsored Research**

**LAAC + DES**
- LAAC after DES to reduce triple therapy
- Stroke and bleeding risk reduction by LAAC instead of OAC.
- 50 patients, single center RCT pilot, 1y FU.

**LAAC and 3D RA**
- LAAC with 3D rot. Angiography instead of TEE
- Safety/feasibility and efficacy.
- 20 patients, single center trial, 6w FU.

**LAAC and hybrid ablation**
- Combined approach LAAC, ext. and internal PVI
- Safety/feasibility and efficacy.
- 10 patients, single center trial, 3m FU.