Newcomers and Important Design Concepts: TAVR in the Future

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10 mins
# Disclosure Statement of Financial Interest

**TVT 2016, Chicago, IL; June 15-18, 2016**

**Martin B. Leon, MD**

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation / Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant / Research Support / SAB</td>
<td>Abbott, Boston Scientific, Edwards Lifescience, Medtronic</td>
</tr>
<tr>
<td>Consulting Fees / Honoraria</td>
<td>None</td>
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<tr>
<td>Shareholder / Equity</td>
<td>Claret, GDS, Mitralign, Valve Medical</td>
</tr>
</tbody>
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TAVR Systems

Global Inventory (#25)

- Shanghai Valve
- Trinity
- Colibri
- Inovare
- Thubrikar
- Valve Medical
- Syntheon Verso
- Triskele
- BioValve
- MyVal
- HLT
- NVT (Nautilus)
- J - Valve
- Xeltis
- Zurich TEHV

All of the Rest!
TAVR Systems
Global Inventory (#25)

International Device Parade

- China
- UK
- U.S.
- Brazil
- U.S.
- Israel
- U.S.
- UK
- Germany
- India
- U.S.
- Germany
- China
- Switzerland
- Switzerland
TAVR Systems

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Pre-clinical or Early clinical
Microport Shanghai TAVR

Valve & System Design

- Bovine pericardial leaflets with anti-calcification treatment
- Multi-level self-expanding nitinol frame (high radial force inflow and open cell outflow for CA access)
- 18F delivery system (motorized)
- Prolonged (beyond inflow) inner and outer layered double skirt PVL reduction

CardioFlow
Microport Shanghai TAVR

Valve & System Design

- Motorized controlled delivery (with manual backup)
- Stabilization layer
- 16/18 Fr housing capsule
- TF, TAo, Subclavian and Carotid delivery experiences
Trinity TAVR
Valve & System Design

- Controlled supra-annular positioning (TA access)
- Truly repositionable and fully retrievable
- Bovine pericardial valve
- Sealing of lower crown
- Detachable tip with pre-mounted valve
- No PVL and low new PM
Colibri TAVR

Valve & System Design

- Thin dry-leaflet technology; folded continuous surface design with few sutures; adjusts to out-of-round anatomies and large EOA (> 2cm

- Pre-packaged, pre-crimped, low profile, ready-for-use

- Balloon-expandable 14 Fr delivery system

- Valve sizes: 21mm, 24mm, and 27mm
Inovare TAVR

Valve & System Design

- Balloon-expandable CoCr frame design
- Single bovine pericardial cut-out
- Closed resting leaflet position; large EOAs
- Valve sizes 20, 22, 24, 26, 28, 30, and 32 mm diameters
- 16 Fr expandable sheath for all valve sizes
- Synthetic fibers (Proseal) added to outer frame aspect to interact with the annulus and prevent PVR

Proseal Synthetic Fibers
Optimum (Thubrikar) 
Valve & System Design

- Single bovine pericardial cut-out used for all three leaflets
- Commissure posts for proper opening and optimal coaptation surface
- Valve design minimizes sutures (no suture holes in moving leaflets) and provides large EOA
- 25mm OD self-expanding Nitinol frame
  - up to 23mm annulus
  - stronger radial force
  - 19-20 mm height
- 18 Fr sheathless delivery system
Optimum (Thubrikar)

Valve & System Design

18 Fr Delivery system

- 520 million cycles (insert right)
- All 5 valves >700 million cycles
- FDA standard: >200 million cycles
Valve Medical

Valve & System Design

- Ultra-low profile – 12 Fr delivery system for all valve sizes
- Modular design (frame and valve separate)
- Folded valve design (not crimped)
- 3-D (one-piece) valve leaflet construction (bovine pericardium)
- In-situ docking (valve to frame in ascending Ao)
- Two-component hydrogel coating on frame to reduce para-valvular regurgitation
- Temporary valve (in descending Ao) for safety
Syntheon Verso

Valve & System Design

- Actuator driven expansion
- Microprocessor controlled
- Maintains constant radial force
- Fully repositionable and retrievable
- Verification of valve position, dimensions, and seal quality
- Simple controls with continuous feedback of diameter and radial force
Syntheon Verso

Valve & System Design
BioValve (Biotronik)

Valve & System Design

- Porcine pericardial tri-leaflet valve
- Nitinol self-expanding frame with high radial force inlet and large cell outlet
- 18 Fr delivery system
- Pericardial skirt to reduce PVR
MyVal (MLS)

**Valve & System Design**

- Constructed from a single bovine pericardial patch (Origami design) to reduce “stress” (minimum sutures)
- Mounted on nickel cobalt alloy frame – balloon-expandable
- Valve sizes 20, 23, 26, and 29 mm diameters
- Pericardial tissue and PET skirt to reduce PVR

*Origami leaflet design*
NVT (Nautilus)

Valve & System Design

- Bovine pericardial tri-leaflet valve with flexible commissural fixation points
- Short nitinol frame; concave shape
- Valve sizes 23, 27, and 31mm diameters
- 18 Fr delivery system with integrated sheath and 2mm stepwise deployment
J - Valve

Valve & System Design

- Porcine pericardial tri-leaflet valve
- Nitinol short self-expanding frame for trans-apical delivery
- Nitinol claspers – independently operated 3D ring that aligns with native sinuses orienting the valve-stent to capture the native leaflets
- 27Fr sheathless delivery catheter with a flexible tip
Xeltis

**Endogenous Tissue Restoration (ERT)**

- Synthetic matrix made of novel bioborbable supramolecular polymers using electrospinning techniques
- Polymer leaflets mounted on nitinol self-expanding frame
- Regrowth of endogenous tissue coincident with bioabsorption of polymer implant
- Natural self-healing anti-inflammatory leaflets

*Valve after bioabsorption*
Xeltis

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*Animal implant*
Harvest of ~100mL bone marrow

Isolation of mononuclear cells + fabrication of TEHVs

Implantation via transapical technique

Zurich Tissue Engineered Heart Valve

Courtesy of Simon P. Hoerstrup, MD, PhD
New TAVR Systems

“I never think of the future – it comes soon enough!”

Albert Einstein
(1879 – 1955)