Glimpse into the Future of Structural Heart Interventions

Francesco Maisano MD, FESC
University Heart Center
University Hospital of Zurich
Conflict of interest statement

Francesco Maisano is

- Consultant for Abbott, Mitraltech, Medtronic, Edwards Lifesciences, St Jude
- Grants from Abbott, Mitraltech, Medtronic, Edwards Lifesciences, St Jude, Boston Scientific, Biotronik
- Founder of 4Tech, Transseptal Solutions, AFFix,
- Receives royalties from Edwards Lifesciences
### The Evidence

<table>
<thead>
<tr>
<th>Published Year</th>
<th>AS with no symptoms</th>
<th>Low</th>
<th>Intermediate</th>
<th>High</th>
<th>Extreme</th>
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<td>2017</td>
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<td><strong>Upcoming</strong></td>
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<td>2021</td>
<td></td>
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</tbody>
</table>

#### Symptomatic AS: SAVR Risk

- Low
- Intermediate
- High
- Extreme

- **PARTNER 1A**
- Corevalve US HR
- Corevalve US ER
- CHOICE
- **PARTNER 2B**
- **PARTNER 2A**
- **PARTNER 2 S3**
- SURTAVI
- **UK TAVI**
- REBOOT
- REPRISE 3
- SALUS (stopped)
- PORTICO IDE
- SOLVE-TAV
- SCOPE 1
- TAVR UNLOAD
- SCOPE 2

### Pipeline of TAVR Trials across the spectrum of aortic stenosis

#### Investigational devices

- Edwards Sapien/Sapien XT/S3
- Medtronic CoreValve/Evolut R
- Boston Lotus
- Direct Flow Medical Direct Flow
- Abbott Vascular Portico
- Symetis Acurate Neo
- Any available TAVR system

#### 24 TAVR RCTs
Current role of TAVI in the ESC guidelines 2017

Management of severe AS

No

Yes

LVEF < 50%

No

Yes

Absence of comorbidity or general condition that make benefit unlikely

Physically active

No

Yes

Medical therapy

Low risk and no other characteristics that favour TAVI

Careful individual evaluation of technical suitability and risk-benefit ratio of intervention modes by the Heart Team

Presence of risk factors and low individual surgical risk

No

Yes

Symptoms or fall in blood pressure below baseline

Re-evaluate in 6 months or when symptoms occur

SAVR

SAVR or TAVI

Symptoms

Management of severe AS

No

Yes

SAVR

SAVR or TAVI

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SAVR or TAVI

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SAAV
The expanding portfolio of transcatheter mitral repair and replacement

- MitraClip
- Pascal
- Neochord
- Harpoon
- Cardioband
- Mitralign
- Carillon
- Millipede
- Tendyne
- Neovasc
- CardiaQ
- Intrepid
MitraClip is not a palliative therapy… when performed properly,

Proper performance implies:

- Correct patient selection
- Periprocedural imaging
- Procedural performance
- Assessment of intraprocedural outcomes
75 year old man, severe idiopathic FMR, EF 35%
depth indentation between P1 and P2
Two converging clips technique

First

Second
Mitral valve replacement / implantation

- valve in valve
- valve in ring
- valve in MAC
- TMVI
<table>
<thead>
<tr>
<th>Device Name</th>
<th>MitraClip</th>
<th>Trialign</th>
<th>TriCinch</th>
<th>Cardioband</th>
<th>Millipede</th>
<th>FORMA Repair System</th>
<th>Caval valve implantation</th>
<th>TRAIPTA</th>
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<tbody>
<tr>
<td>Device Image</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
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<td><img src="image7.png" alt="Image" /></td>
<td><img src="image8.png" alt="Image" /></td>
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<tr>
<td>Description</td>
<td>Bicuspidisation of the TV by plicating</td>
<td>Bicuspidisation of the TV by plicating</td>
<td>Bicuspidisation of the TV by cinching</td>
<td>Direct annuloplasty device</td>
<td>Complete semi rigid ring</td>
<td>Spacer to occupy the regurgitant orifice area</td>
<td>Caval valve implantation in vena cava</td>
<td>Pericardial circumferential device</td>
</tr>
<tr>
<td>Access</td>
<td>Transfemoral</td>
<td>Transjugular</td>
<td>Transfemoral</td>
<td>Transfemoral</td>
<td>Transfemoral</td>
<td>Transsubclavian</td>
<td>Transjugular/transfemoral</td>
<td>Transjugular/transfemoral</td>
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<tr>
<td>Status*</td>
<td>• About 60 patients</td>
<td>• About 15 patients</td>
<td>• About 25 patients</td>
<td>• About 10 patients</td>
<td>• About 2 patients</td>
<td>• About 20 patients</td>
<td>• About 40 patients</td>
<td>• Only pre-clinical data</td>
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* At the moment of reporting from recently international meeting
Combined structural procedures

- TAVI + LAAC
- TAVI + MC
- MC + LAAC
- TAVI + MC + LAAC
- ...
The track of MV therapies
Palliation vs cure: Timing makes the difference

Table 15-1. Parachute reliability data for varying altitudes.

<table>
<thead>
<tr>
<th>Exit altitude in feet AGL</th>
<th>T-10-Series PARACHUTE</th>
<th>MC1-Series PARACHUTE</th>
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<tr>
<td></td>
<td>Percentage of canopies that would be open</td>
<td>Percentage of canopies that would have 100 feet or more to prepare to land</td>
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<tr>
<td>200</td>
<td>76.11</td>
<td>4.00</td>
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<td>300</td>
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<tr>
<td>800</td>
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OPTIMIZING TIMING: Synergistic care of patients with HF

OMT  CRT  TMVR

Clinical Course

Onset  Death  Transplantations

Quality of Life

Intensity of Care

Palliative Care Including symptom management

Time

Allen et al, Circulation 2012
Which are the unexplored fields?

**Expand the limits of feasibility**
- Imaging
- training
- Combination therapies

**Improve durability**
- learning curve
- technology (tissue management, regenerative medicine, engineering…etc)
- Combination therapies

**Improve prognosis**
- Early indications
- Combination therapies
- Biocompatibility

**Improve efficiency**
- Heart Team 2.0
- role of surgeons and non-interventional cardiologists
- Medical education
## Cardiovascular Areas of Focus

<table>
<thead>
<tr>
<th>Area</th>
<th>Abbott</th>
<th>St. Jude Medical</th>
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<tbody>
<tr>
<td>Structural heart</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Coronary intervention</td>
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<td>✔</td>
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<tr>
<td>Vascular imaging</td>
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<tr>
<td>Heart failure</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Peripheral BMS stents</td>
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<td>✔</td>
</tr>
<tr>
<td>Cardiac rhythm management</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Electrophysiology</td>
<td>✔</td>
<td>✔</td>
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</table>
A comprehensive structural heart portfolio

**Structural Heart Occluders**
- Patent Ductus Arteriosus
- Atrial Septal Defects and Patent Foramen Ovale
- Left Atrial Appendage
- Ventricular Septal Defects

**Valvular Solutions**
- **Mitral Valve**
  - Surgical Repair/Replacement Transcatheter Repair
  - Transcatheter Replacement*
- **Aortic Valve**
  - Surgical Replacement
  - Transcatheter Replacement
- **Tricuspid Valve**
  - Transcatheter Repair*

*Product currently in development at Abbott. Not available for sale.*

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Abbott (St Jude Medical) Cardiac surgery therapies

OVER 40 YEARS OF LEADERSHIP IN VALVE TECHNOLOGIES

TISSUE VALVES

MECHANICAL VALVES

ANNULOPLASTY RINGS

TRIFECTA™ GT/
TRIFECTA™
EPIC™/BIOCOR™

REGENT™
MASTERS HP™
MASTERS
VAVGJ AND CAVGJ
(AORTIC VALVED GRAFTS)

TAILOR™
ATTUNE™
RIGID SADDLE RING
SÉGUIN

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Transcatheter heart valve therapies

ADVANCING NEXT GENERATION VALVE PLATFORMS

MITRAL VALVE REPAIR

MITRAL VALVE REPLACEMENT

AORTIC VALVE REPLACEMENT

TRICUSPID VALVE REPAIR

MITRACLIP®

TENDYNE™*

PORTICO™

TRICUSPID CLIP*

*Product currently in development at Abbott. Not available for sale.

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Proven surgical and innovative transcatheter options

INDIVIDUALIZED PATIENT CARE WITH A FULL ARMAMENTARIUM

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Growing the clinical body of evidence to bring innovation to patients worldwide

**MITRACLIP® INDICATION EXPANSION**
- COAPT
- Intermediate Risk DMR*

**MITRACLIP® MARKET EXPANSION**
- MitraClip® Japan
- MitraClip® China*

**TRANSCATHETER MITRAL VALVE REPLACEMENT**
- Tendyne CE

**TRANSCATHETER AORTIC VALVE REPLACEMENT**
- Portico I Trial
- Portico US IDE Trial
- Portico Japan Trial
- Portico Alternative Access EU Pre-CE Mark Trial
- Portico Intermediate Risk European Trial
- Portico Valve-in-Valve Trial

**TRANSCATHETER TRICUSPID VALVE REPAIR**
- Tricuspid CE*
- Tricuspid US Pivotal*

**SURGICAL VALVES**
- Trifecta LTFU(U.S.)
- Trifecta Durability (W. Europe)
- Trifecta GT PMCF (W. Europe/Canada)
- HALO US IDE

**CONGENITAL**
- VPA-Muscular VSD US/CA PAS
- ADO II Additional Sizes US IDE
- PIVSD US PAS
- PFO US Post Approval Study

**REAL WORLD MARKET DEVELOPMENT**
- TVT/MitraClip® US PAS
- COAPT Continued Access*
- XT/Bolt European Registry*

*Study in development

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A vision for the 2025: a toolbox for a tailored approach
The valley of death of knowledge gaps
Structure of the course

**Who should attend:** Physicians who want to become the new leaders the field

**Focus:** clinical competence (60%), innovation (20%), leadership (20%)

**Interdisciplinarity:** teamwork based education

**Networking:** crossmentoring, networking with leaders, Alumni, Exposure, participation in the School

**Interactivity:** hands on, case observations and workshop (50% of the program)
Certificate of Advanced Sciences in Aortic Structural Interventions

The world of structural interventions is changing. Physicians are called to work in teams rather than to perform as stand alone champions.

Participate to a new educational standard for the future: a mix of clinical and scientific training, with strong emphasis on management, leadership and innovation.

Join an innovative international network

Become the Leader of your Heart-Team!

www.structuralinterventions.org
• We will diagnose SHD earlier
• Early treatment will impact prognosis
• We will be able to perform surgical-like interventions through catheters
• Surgical procedures will use devices inspired by transcatheter therapies
• We will have enough scientific evidence to support indications, timing and choice of treatment