



Trans-Apical Mitral Valve of Sinomed

Patrick W. Serruys, MD, PhD

National Heart Lung Institute, Imperial College, London, The United Kingdom In collaboration with Francesco Maisano

Future Technology in Non-Coronary Interventional Cardiology Endovascular Theater, Level 1, 29 April 2016, 7:30AM-7:40AM

Potential Conflict of Interest

Speaker's name: Prof. P. W.Serruys

✓ I have the following potential conflicts of interest to report:

Consultant:

Abbott AstraZeneca Biotronik Cardialysis Europa Digital & Publishing Medtronic Sinomed Stentys Svelte Medical Systems Terumo Volcano



- Must adapt to complex anatomy to avoid residual MR
- Sealing (PV leaks/Hemolysis)
- Fixation
- Risk of damaging adjacent structures (LCX, Coronary Sinus, AV Node, Papillary Muscle)
- Risk of LVOT obstruction



- Residual MR Tubular leaflet design minimizes central leakage
- Sealing Sealing ring design minimizes PVL
- Fixation Self-expanding value body design for optimal native value "clipping" effect
- Damaging Low ventricular profile <14mm</p>
- LVOT Controlled deployment

Implant features and fixation

Device	CardiAQ	Neovasc	Edwards Fortis	Tendyne	Twelve	Sinomed
Access	TA (TV)	ТА	ТА	ТА	ТА	ТА
Nitinol frame	+	+	+	+	+	+
Bovine pericardial leaflets	+	+	+	-	+	+
Trileaflet valve	+	+	+	+	+	+
Symmetric leaflets	+	-	+	+	+	+
Asymmetric frame	-	+	+	+	-	-
Seal	pericardial	synthetic	synthetic	synthetic	synthetic	synthetic
Atrial flange	-	+	+	+	+	+
Apical tether	-	-	-	+	-	-
Barbs/Tines	+	-	-	-	+	-
Clips/Tabs/Paddles	+	+	+	-	-	+

Anatomic compatibility

Device	CardiAQ	Neovasc	Edwards Fortis	Tendyne	Twelve	Sinomed
Fixation required						
Posterior leaflet	-	-	+	-	-	+
Posterior ridge	-	+	-	-	-	+
Anterior leaflet	-	-	+	-	-	+
Suitable for						
FMR	+	+	+	+	-	+
DMR	+/-	+/-	-	+	+	+/-



Step 1 – Unsheathing the TMVR



Step 2 – LV Legs Advanced (note motion of test valve leaflets)



Step 3 – LA Legs Released and Clipping Complete





Deployment Completed



Unimpeded competent flow secured

Demonstration of No LVOT Obstruction





Echo-Ventriculogram/Echo-Doppler Clinically Insignificant Paravalvular/Transvalvular Regurgitation







Acute Performance Improvements (N=53)

More consistent positioning and clipping around the annulus







Nov. 20

Dec. 12

Dec. 30

Explant Assessment- Chordae spared without undue tethering





First Transapical Survival Study New Issues to Address





Baseline Dec. 30 <24 hrs. post-op Dec. 31

Explant Photos



Extensive chordae breakage w/ leaflets everted in the LA

Incomplete clipping and LV anchors in LA

Valve Design Changes

Curved the commissural tips in order to reduce the overall protrusion in LV and LA



Added covering on the LV commisural tips



Added "protective" suture layer on the LV anchors

 Stabilized the commissural tips in the LA with suture (transient fix) in order to reduce rocking motion of the commissural arms

Survival Study with Valve Design Changes

Feb. 6 Day 0

Rocking motion reduced



Lvgram for Implanted Valve at time 0



Results 18 Hour post Implant

2/7/16

Lvgram 18- hour Post Implant



Survival Study with Valve Design Changes



Feb. 6 Day 0 LA pressure tracing Baseline 34/-6 mean 10

LA pressure tracing Immediate postimplant 37/0 mean 12

> LA pressure tracing 18 hours post 31/-4 mean 10





 07-FEB-2016 10:09:46 25 MM/SEC delay=9 (ECG)HR:101 bpm CO2 RR:--- RPM SPO2: 98 %

 ART1 0 - 160 mmHg

 ART1 (- 160 mmHg

 ART1 (- 160 mmHg

 ART1 (- 160 mmHg

Aortic pressure tracing 18 hours post 99/66 mean 82

LV pressure tracing 18 hours post 105/-3 mean 54

Survival Study with Valve Design Changes

Feb. 7

Day 1



Three Month Chronic Echo Results



Three Month Chronic Explant

Tissue Integration





LV View

Summary of Studies w/ Conventional Leaflets

During our lab in Zurich in July of 2015, it was recommended that we abandon the reverse leaflet design in favor of a conventional tri-leaflet design. Since that time:

- A total of 40 implants have been performed,
- This includes a total of 14 chronic implants

Detail regarding the chronic studies to follow

Near-Term Focus

- Replicate impressive acute results in the sub-chronic setting
- Once achieved, perform series of chronic implants with short (2 week), intermediate (1 mos.) and 3-mos. endpoints
- Combine successful chronic results with bench-top testing (fluid dynamics and durability) as a basis of regulatory filing for FIM
- Use valve design as basis for TF approach



Volume 11 - Number 13 - April 2016 - ISSN: 1774-024X EuroIntervention

Asia Intervention

www.asiaintervention.org

Volume 2 - Number 1 - January 2016 - SSN: 2426-3958

CORONARY INTERVENTIONS

- 1457 COmplex coronary Bifurcation lesions: RAndomized comparison of a strategy using a dedicated self-expanding biolimus-eluting stent versus a culotte strategy using everolimus-eluting stents: primary results of the COBRA trial C. Dubois, T. Adriaenssens, et al
- 1468 Significance of prior percutaneous revascularisation in patients with acute coronary syndromes: insights from the prospective PROSPECT registry A. Iñiguez, G.W. Stone, et al
- 1475 Clinical outcomes following "off-label" versus "established" indications of bioresorbable scaffolds for the treatment of coronary artery disease in a real-world population T. Miyazaki, A. Colombo, et al
- 1479 A novel approach to treat in-stent restenosis: 6- and 12-month results using the everolimus-eluting bioresorbable vascular scaffold P Jamshidi F Cuculi et al
- 1487 Patient preference regarding assessment of clinical follow-up after percutaneous coronary intervention: the PAPAYA study M.M. Kok, M.J. Elzerman, et al.
- 1495 Does access to invasive examination and treatment influence socioeconomic differences in case fatality for patients admitted for the first time with non-ST-elevation myocardial infarction or unstable angina? S. Mårtensson, M. Osler, et al
- 1503 Virtual reality training in coronary angiography and its transfer effect to real-life catheterisation lab U.I. Jensen P. Tornvall et al.

1511 A disaster never comes alone: total ostial occlusion of the left main coronary artery with an anomalous origin P. Rodrigues, S. Torres, et al

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

- 1512 Left atrial appendage occlusion with the AMPLATZER Amulet device: an expert consensus step-by-step approach A Tzikas H Omran et al
- 1522 The prognostic value of acute and chronic troponin elevation after transcatheter aortic valve implantation J.M. Sinning, N. Werner, et al
- 1530 Emergency transcatheter aortic valve replacement in patients with cardiogenic shock due to acutely decompensated aortic stenosis C. Frerker, K.H. Kuck, et al
- 1537 First-in-man report of residual "intra-clip" regurgitation between two MitraClips treated by AMPLATZER Vascular Plug II M. Taramasso, F. Maisano, et al
- 1541 First transfermoral percutaneous edge-to-edge repair of the tricuspid valve using the MitraClip system T. Wengenmayer, S. Grundmann, et al
- 1545 First Lotus aortic valve-in-valve implantation to treat degenerated Mitroflow bioprostheses F. Castriota, A. Cremonesi, et al
- 1549 Direct Flow valve-in-valve implantation in a degenerated mitral bioprosthesis G Bruschi F De Marco et al

CORONARY INTERVENTIONS

- 19 Late angiographic and clinical outcomes of the novel BioMime[™] sirolimus-eluting coronary stent with ultra-thin cobalt-chromium platform and biodegradable polymer for the treatment of diseased coronary yessels: results from the prospective, multicentre meriT-2 clinical trial
- 28 Impact of chronic lung disease after percutaneous coronary intervention in Japanese patients with acute coronary syndrome
- 36 Distribution characteristics of coronary calcification and its substantial impact on stent expansion: an optical coherence tomography study
- 44 Smooth arterial healing after paclitaxel-coated balloon angioplasty for in-stent restenosis assessed by optical frequency domain imaging
- 48 Mediastinal haematoma complicating percutaneous coronary intervention via the radial artery

INTERVENTIONS FOR STRUCTURAL HEART DISEASE AND HEART FAILURE

- 49 Comparison of aortic annulus dimensions between Japanese and European patients undergoing transcatheter aortic valve implantation as determined by multi-detector computed tomography: results from the OCEAN-TAVI and a European single-centre cohort
- 57 Combined percutaneous transvenous mitral commissurotomy and left atrial appendage closure as an alternative to anticoagulation for rheumatic atrial fibrillation

EDITORIAL

- 7 Evolution and current status of interventional cardiology in India
- 10 Tailoring TAVI in Asia: insights from MSCT
- 13 Opening the shell for better stent results

ASIA-PACIFIC HOTLINES AT TCT 2015

- 16 Asia-Pacific Hotlines at TCT 2015: a prospective randomised trial of paclitaxel-eluting vs. everolimuseluting stents in diabetic patients with coronary artery disease (TUXEDO)
- 17 Asia-Pacific Hotlines at TCT 2015: bioresorbable vascular scaffolds versus metallic stents in patients with coronary artery disease (ABSORB China Trial)
- 18 Asia-Pacific Hotlines at TCT 2015: evaluation of initial surgical versus conservative strategies in patients with asymptomatic severe aortic stenosis (The CURRENT AS registry)

HOW SHOULD | TREAT?

- 58 How should | treat a patient with critical stenosis of a bifurcation of the left main coronary artery with an acute angulation between the left main artery and the left circumflex artery?
- 65 How should I treat a percutaneous posteromedial mitral periprosthetic paravalvular leak closure in a bioprosthesis with no radiopaque ring?

Official Journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

www.eurointervention.org

CHIEF EDITORS Runlin Gao, Upendra Kaul, Takeshi Kimura, Seung-Jung Park, Huay Cheem Tan

CONSULTING EDITORS Christoph Naber, Richard Ng SENIOR CONSULTING EDITOR Patrick W. Serruys