Transcatheter Mitral Valve Replacement with the Edwards FORTIS Valve: Procedural and Midterm Results of the First-in-Man Compassionate Clinical Use Experience

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Potential conflicts of interest

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- ❑ **I have the following potential conflicts of interest to report: Research grants from Edwards Lifesciences**

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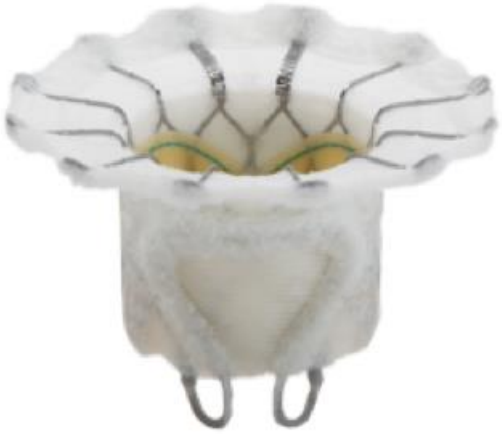
Background

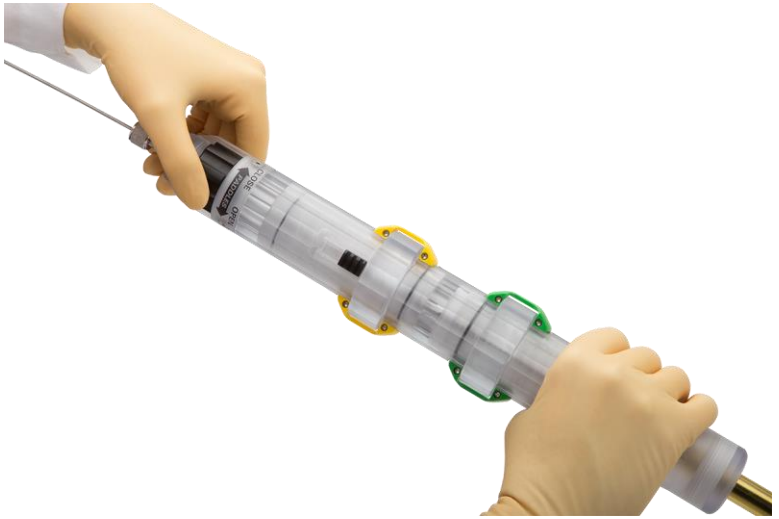
- Severe mitral regurgitation (MR) represents the second most prevalent valvular heart disease in western countries
- Up to one third to one half of patients requiring mitral valve repair/replacement are deemed to be at too high risk for surgery
- Percutaneous mitral edge-to-edge repair has emerged as a valid alternative to surgery but requires a favorable anatomy
- Transcatheter mitral valve replacement (TMVR) has recently emerged as a new therapeutic option for the treatment of mitral valve disease – however, current experience is very limited

Objective

- **To evaluate the procedural results and follow-up outcomes of the first-in-human experience of transcatheter mitral valve replacement (TMVR) with the Edwards FORTIS valve**

The Edwards FORTIS Valve

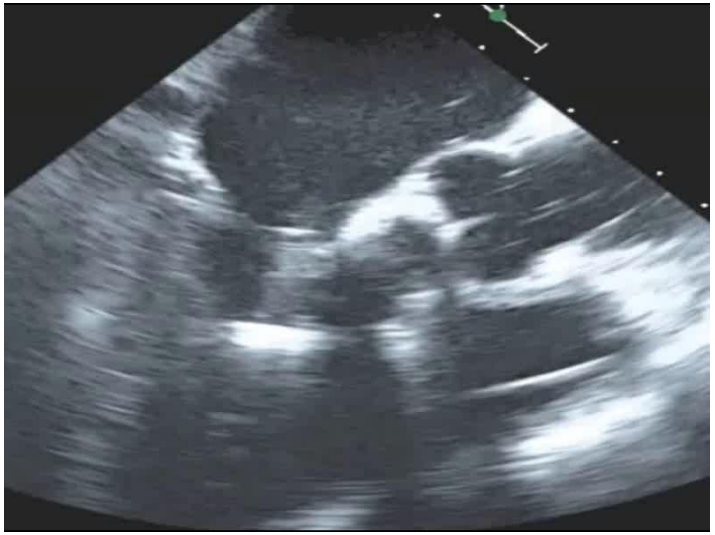


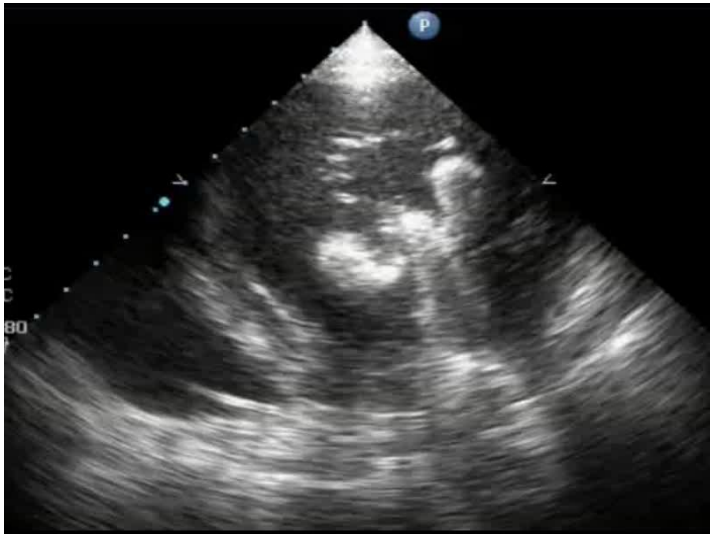


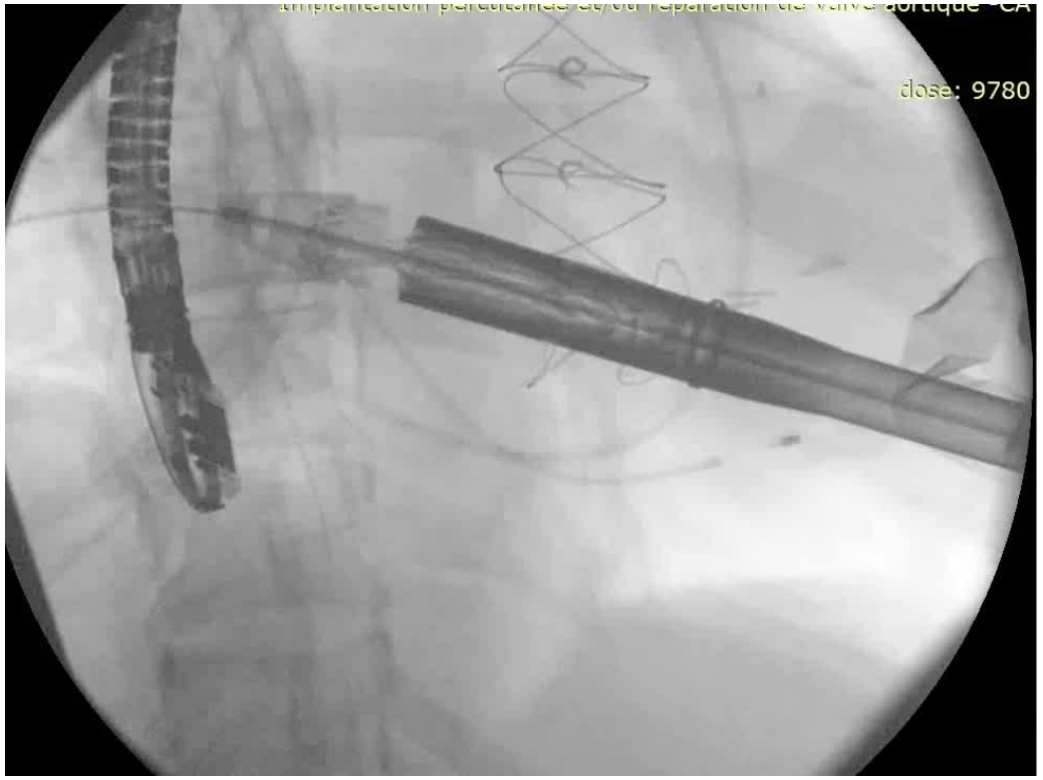
- Self-expanding Nitinol
- 29 mm
- Proven Edwards bovine pericardial tissue
- Anti-calcification

- Transapical approach
- 42 Fr
- Multiple levels of control
- Repositionable

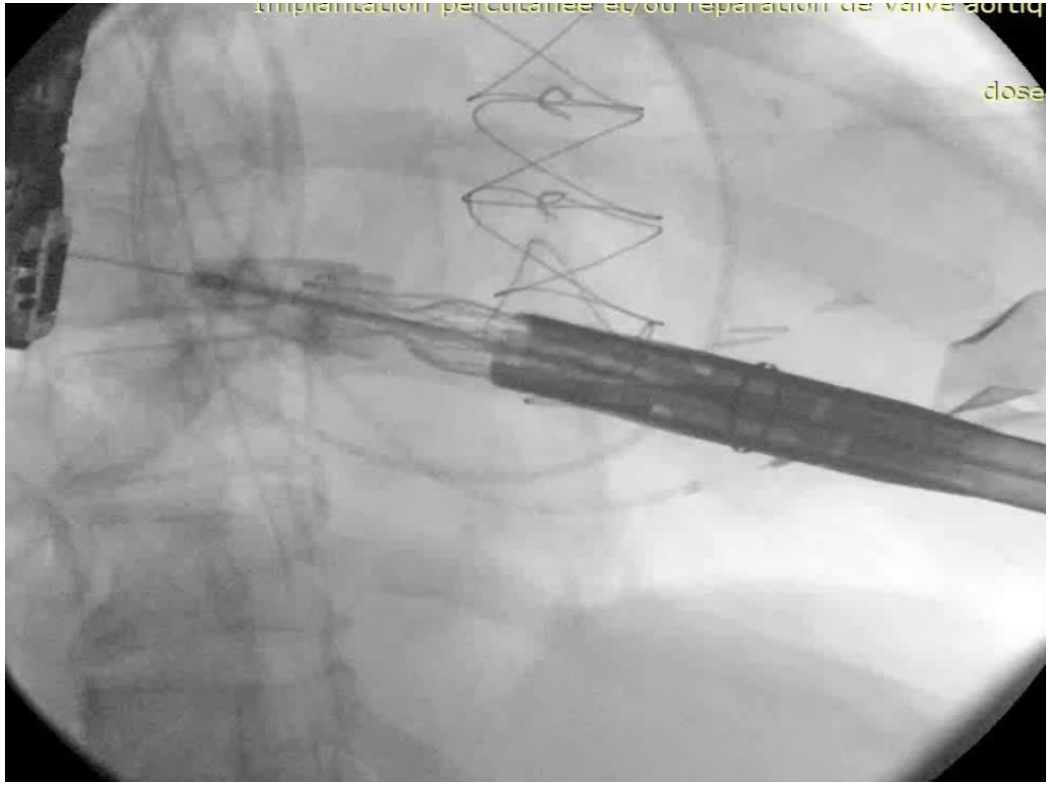
Procedure I – Leaflet Capture

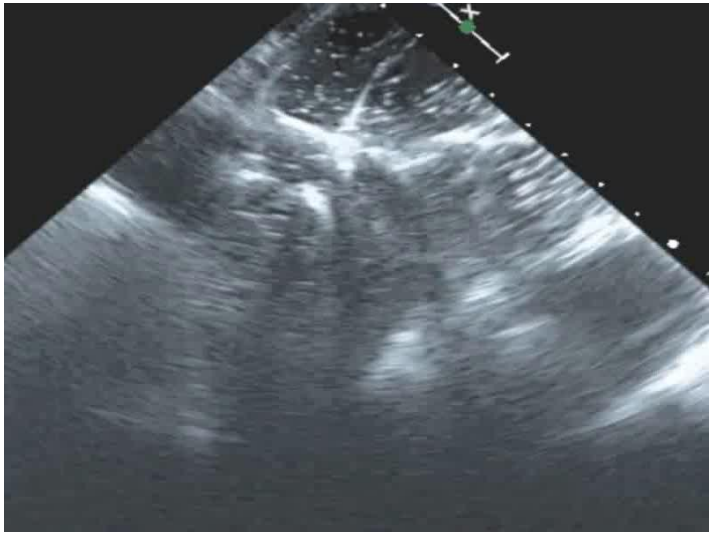




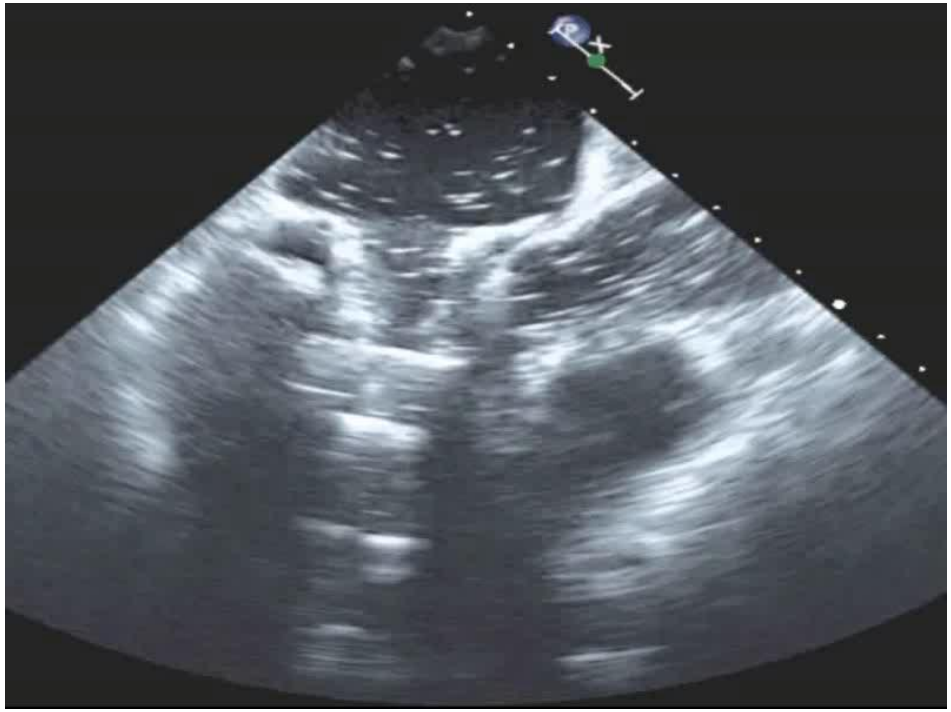


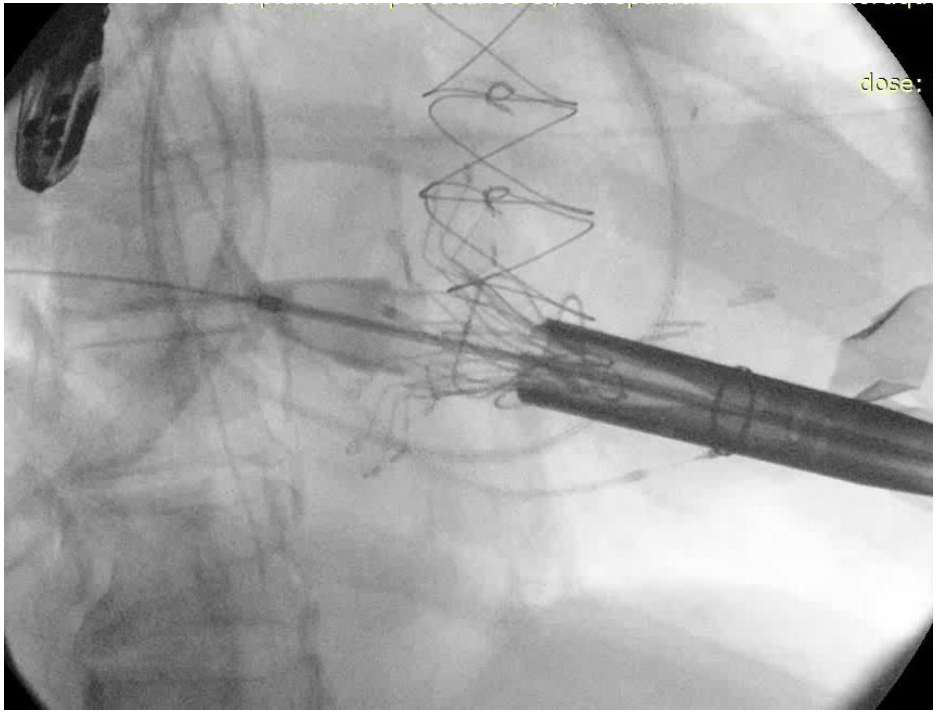
Procedure II – Flange Release



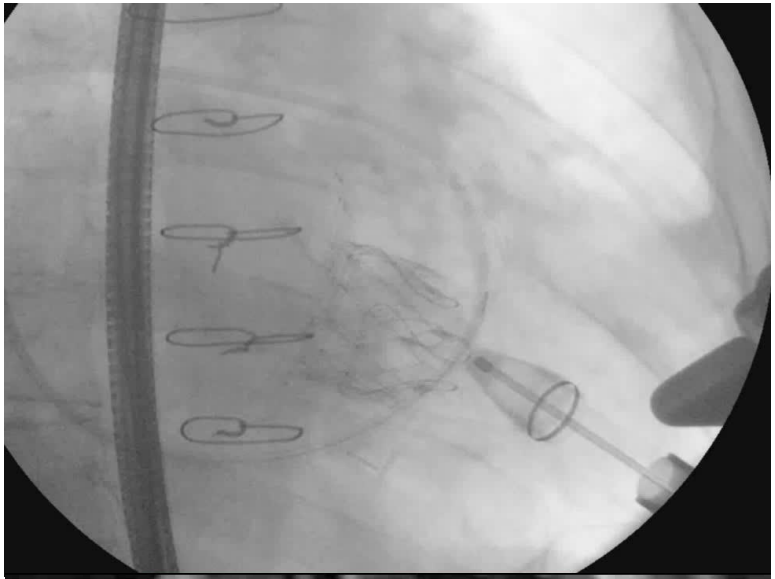


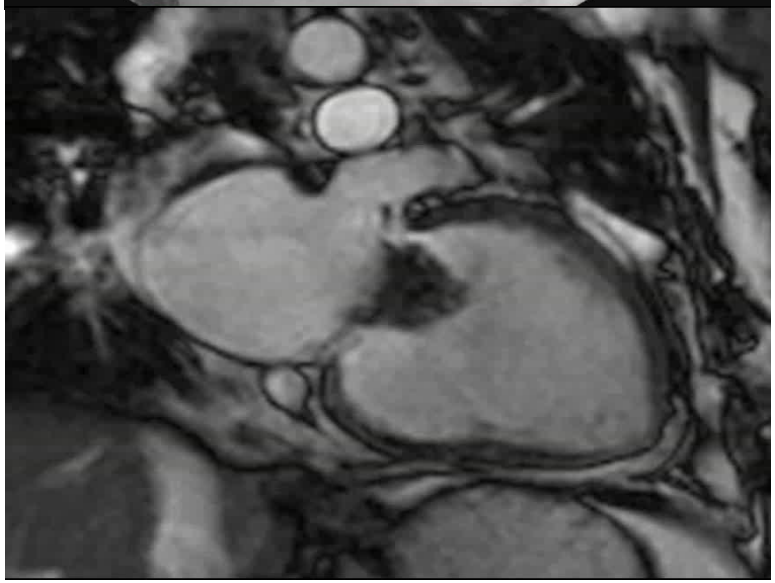
Procedure III – Valve Release

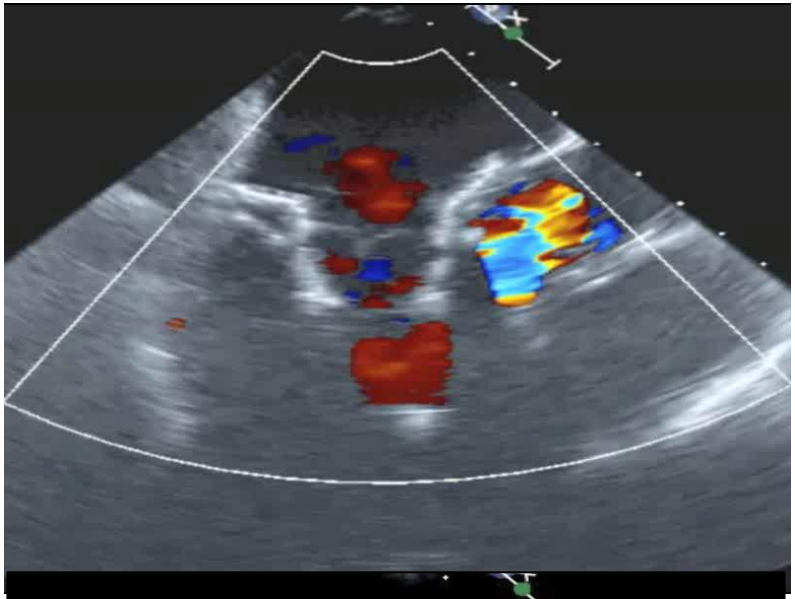


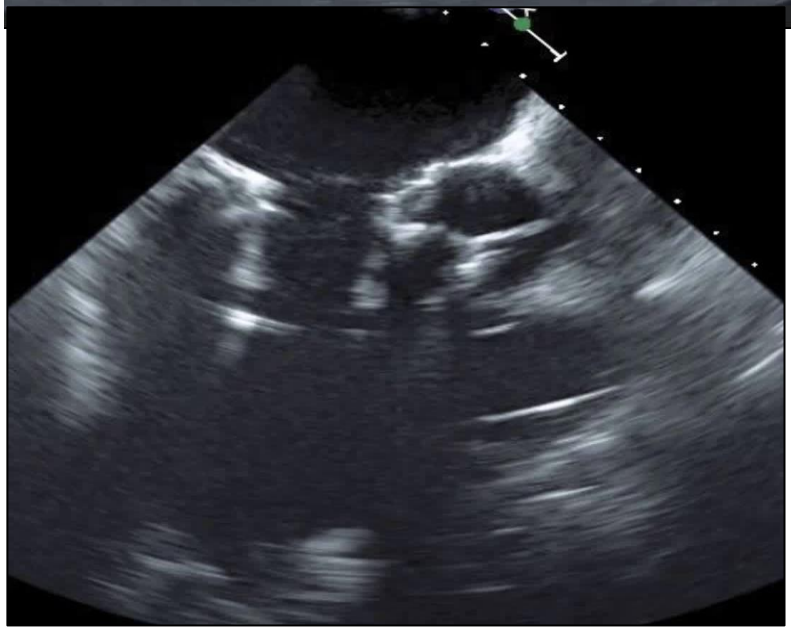


Procedural Result









Methods

- **13 patients treated with the FORTIS Valve (Europe and Canada) between February 2014 to March 2015**
- **Pre-procedural workup: clinical evaluation, TTE, TEE and CT scan**
- **Procedural and 30-day outcomes**
  - Procedural success: Absence of procedural mortality, correct positioning of the prosthetic valve into the proper anatomical location, and no more than mild MR
  - Peri-procedural complications: VARC-2 criteria
- **Follow-up: clinical and TTE (1- and 6-month follow-up)**
- **Imaging (CT scan and TEE) at 3-month follow-up (single center)**
- **Functional and QoL evaluation at baseline, 3- and at 6-month follow-up (single center)**
  - Functional: 6MWT, DASI
  - QoL: Kansas City Cardiomyopathy Questionnaire

Results: Baseline Characteristics

	N=13
Age (years)	71±8
Sex (male)	10 (76.9)
NYHA Class ≥ III	13 (100)
Coronary artery disease	10 (76.9)
Previous CABG	7 (53.8)
Atrial fibrillation/flutter	8 (61.5)
Previous Stroke/TIA	3 (23.1)
COPD	5 (38.5)
Clearance of creatinine (mL/min)	43±10
Heart failure hospitalizations (last year)	9 (75)
CRT	3 (23.1)
STS Score (%)	7.2±3.6
Log. EuroSCORE (%)	23.7±12.1
Baseline Echocardiogram	
LVEF (%)	34±9
MR etiology	
Functional	12 (92.3)
Mixed (functional + degenerative)	1 (7.7)
MR grade: Severe	13 (100)
PAPs (mmHg)	59±15

Values are expressed as n (%) or mean (±SD)

Results: Procedural and 30-days outcomes

	N=13
Procedural success	10 (76.9)
Conversion to open heart surgery	2 (15.4)
Procedure time (min)	48±19
Hospitalization length (days)	10±6
In-hospital mortality	4 (30.8)
Anti-thrombotic therapy at discharge (n=9)	
Warfarin alone	2 (22.2)
Warfarin+ASA	5 (55.6)
Warfain+ASA+clopidogrel	1 (11.1)
ASA alone	1 (11.1)
30-day Results	
Mortality	5 (38.5)
Stroke or TIA	0 (0)
Probable prosthesis thrombosis	1 (7.7)
Major bleeding	2 (15.4)
Echo at discharge (n=9)	
LVEF (%)	31±12
MR	
none-trace	8 (88.9)
mild	1 (11.1)
Transmitral gradient (mean, mmHg)	3±1

Values are expressed as n (%) or mean (±SD)

Results: Procedural and 30-days outcomes

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Mild	1 (11.1)
Transmitral gradient (mean, mmHg)	3 ± 1

Values are expressed as n (%) or mean (±SD)

Unsuccessful Procedures

- **Case #2.** Valve was not properly implanted due to partial posterior leaflet capture. Patient died on day #4 due to multi-organ failure. Autopsy confirmed that there was no posterior leaflet capture.
- **Case #8.** Valve was implanted with suboptimal short axis echo images, posterior leaflet was not fully captured. Patient was converted to surgery but died on day #7 due to septic shock.
- **Case #12.** Catheter balloon entanglement with subvalvular apparatus prior to delivery system insertion. Valve implantation was not attempted. Patient was converted to open surgery but died on day #3 due to intestinal ischemia.

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ASA alone	1 (11.1)
30-day Results	
Mortality	5 (38.5)
Stroke or TIA	0 (0)
Probable prosthesis thrombosis	1 (7.7)
Major bleeding	2 (15.4)
Echo at discharge (n=9)	
LVEF (%)	31±12
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Conversion to open heart surgery	2 (15.4)
Procedure time (min)	48 ± 19
Hospitalization length (days)	10 ± 6
LVEF (%)	31 ± 12
MR	
none-trace	8 (88.9)
mild	1 (11.1)
Transmitral gradient (mean, mmHg)	3 ± 1

Values are expressed as n (%) or mean (±SD)

30-day Death

- **Case #4.** Successful procedure. Patient was discharged under warfarin + ASA on day 8. Re-Hospitalization on day #13 (chest pain). Mass at the level of the valve, increased transmitral gradient. Patient died on day #15 due to suspected valve thrombosis.

- **Case #13.** Successful procedure. Patient died on day #26 due to respiratory failure (severe pre-op malnutrition and poor condition).

Results: Procedural and 30-days outcomes

	N=13
Procedural success	10 (76.9)
Conversion to open heart surgery	2 (15.4)
Procedure time (min)	48±19
Hospitalization length (days)	10±6
In-hospital mortality	4 (30,8)
Anti-thrombotic therapy at discharge (n=9)	
Warfarin alone	2 (22.2)
Warfarin+ASA	5 (55.6)
Warfain+ASA+clopidogrel	1 (11.1)
ASA alone	1 (11.1)
30-day Results	
Mortality	5 (38.5)
Stroke or TIA	0 (0)
Probable prosthesis thrombosis	1 (7.7)
Major bleeding	2 (15.4)
Echo at discharge (n=9)	
LVEF (%)	31±12
MR	
none-trace	8 (88.9)
mild	1 (11.1)
Transmitral gradient (mean, mmHg)	3±1

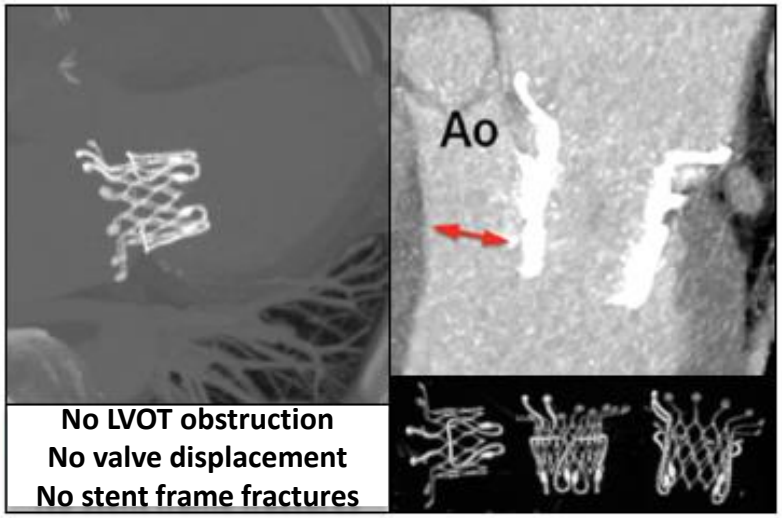
Values are expressed as n (%) or mean (±SD)

Follow up: Clinical and TTE

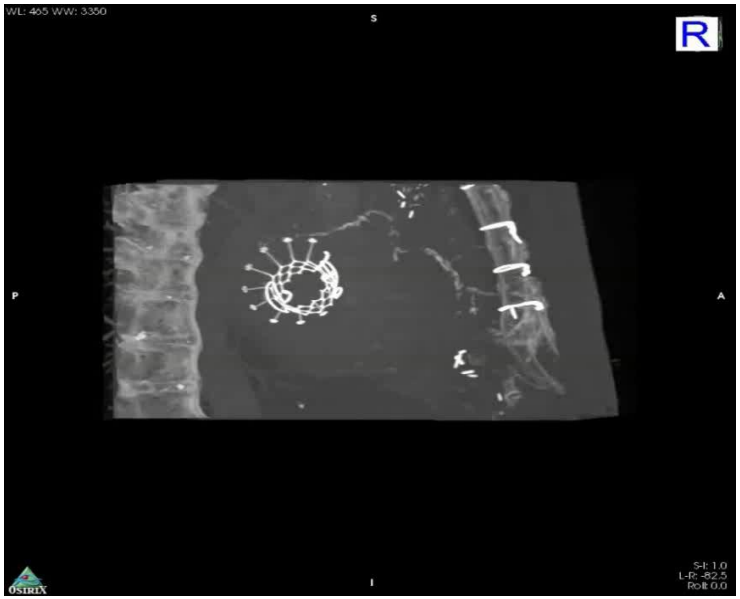
	N=8
Clinical follow-up time (months)	6 (1 – 15)
NYHA Functional Class I-II	6 (75.0)
Re-hospitalizations	2 (25.0)
Heart failure re-hospitalization	1 (12.5)
Stroke/TIA	0 (0.0)
Mortality, any cause	1 (12.5)
Echocardiography data (6-month FU)	
LVEF (%)	33±9
MR	
none-trace	4 (80)
mild	1 (20)
moderate or severe	0 (0)
Transmitral gradient (mean, mmHg)	4±1
PAPs (mmHg)	57±23

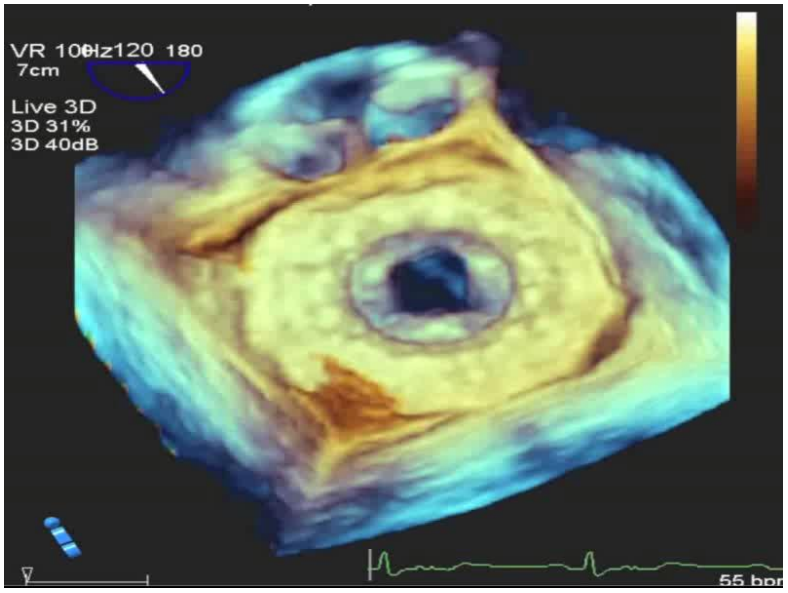
Values are expressed as n (%) or mean (±SD)

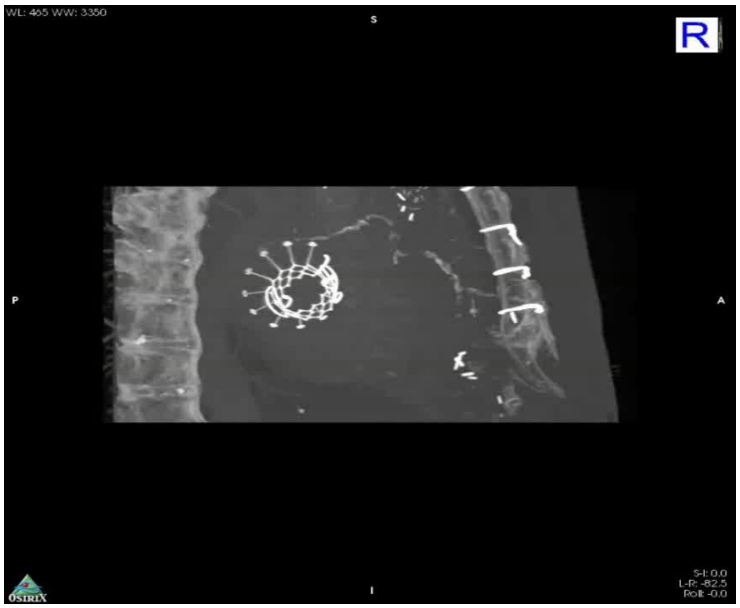
CT scan & TEE at 3 months (n=3; Quebec Heart & Lung Institute)



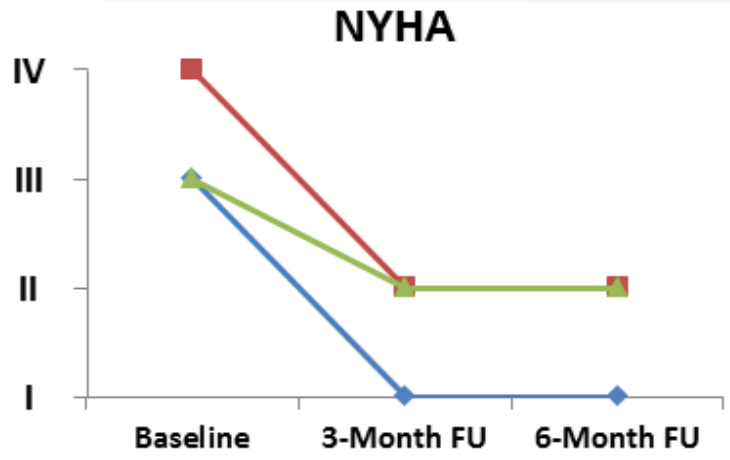
No LVOT obstruction
No valve displacement
No stent frame fractures

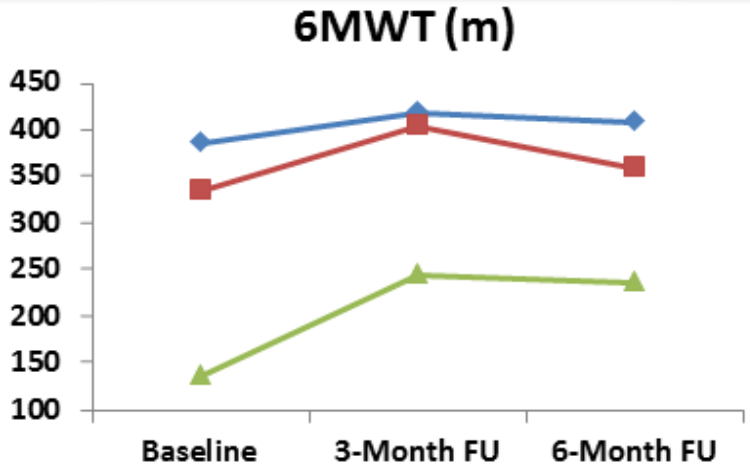


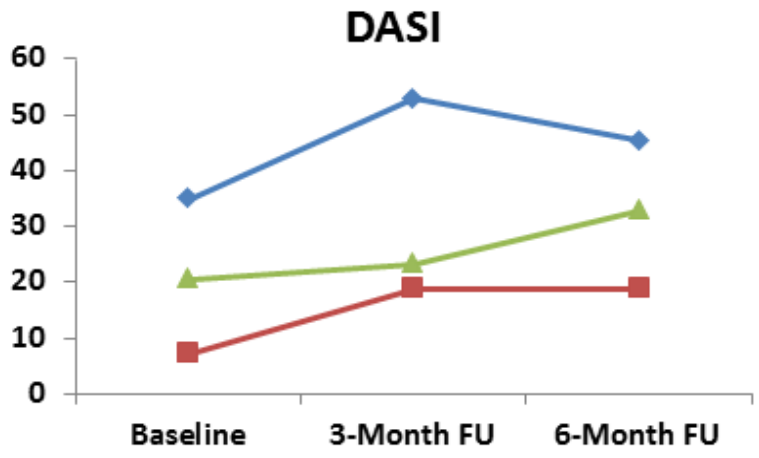


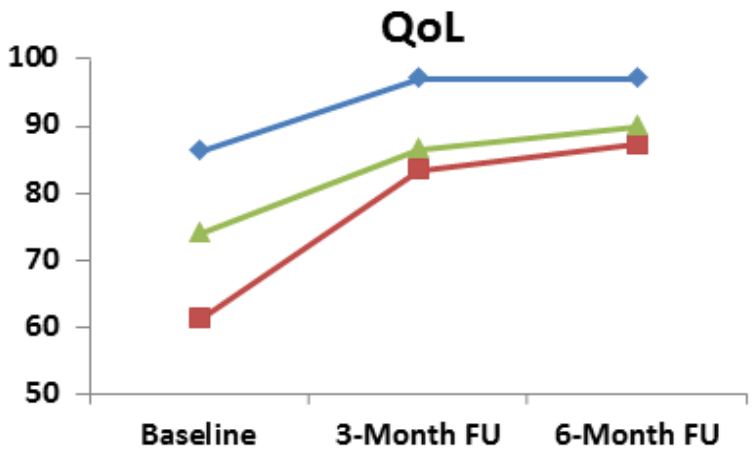


3- and 6-Month FU Functional and QoL Evaluation (n=3; Quebec Heart & Lung Institute)









DASI : Duke Activity Status Index
Quality of Life evaluated by Kansas City Questionnaire

Conclusions

- This first-in-man experience showed the feasibility of TMVR with the Edwards FORTIS valve
- Proper valve implant was associated with optimal valve performance in all cases
- Implantation and peri-procedural challenges may reflect the excessive risk of some of the selected patients, the complexity of the mitral valve system and the learning curve process
- Anticoagulation treatment is probably important for mitral transcatheter valves, and the optimal type and duration of antithrombotic treatment need to be further evaluated
- Valve performance was maintained at 6-month follow-up and was associated with improvements in functional status and QoL
- Larger studies with a longer follow-up are warranted