Trans-Septal - Mitral Valve Replacement (TSMVR)

HighLife feasibility study (HL-2018-01)

52 **consecutive** patients

Prof. Stephen Worthley, Macquarie University, Sydney

On behalf of the HighLife study Investigators

Potential conflicts of interest

Speaker's name : Prof Stephen Worthley, Sydney, Australia

I have the following potential conflict of interest to declare:

Consultancy/Honoraria

Edwards Lifesciences, Abbott, HighLife Medical.

Shareholder

Three Peaks Medical.

HighLife TSMVR Feasibility study

- Single-arm, prospective, multicentre, non-randomized, open-labelled study
- Evaluation of feasibility, safety and performance of the HighLife TSMVR system in symptomatic patients with MR grade ≥III at high risk for surgical treatment
- **Primary objectives:** Feasibility, safety and performance at 30 days
- **Secondary objectives:** Long-term safety and performance (5-year follow-up)

NCT04029363

	HighLife HL-2018-01
Countries approved	6
Sites active	32/40
Patients to be implanted	50
Pts treated/implanted	52/50
Device	

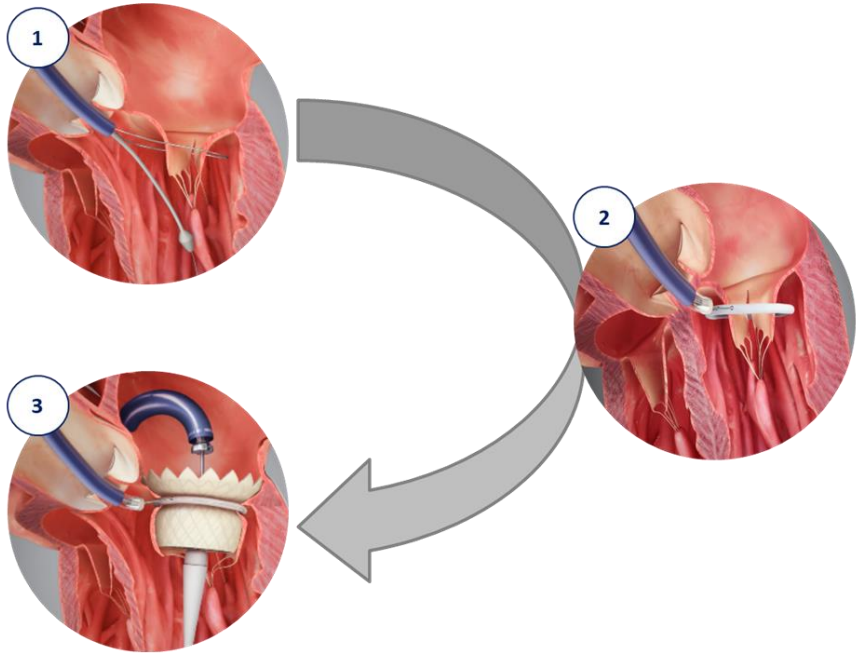
HighLife implantable devices and 3-step procedure

Transcatheter Mitral Valve (TMV)

- Nininol self expandable frame
- Bovine Pericardial Tissue Leaflets
- PET (Dacron) Outer Sealing

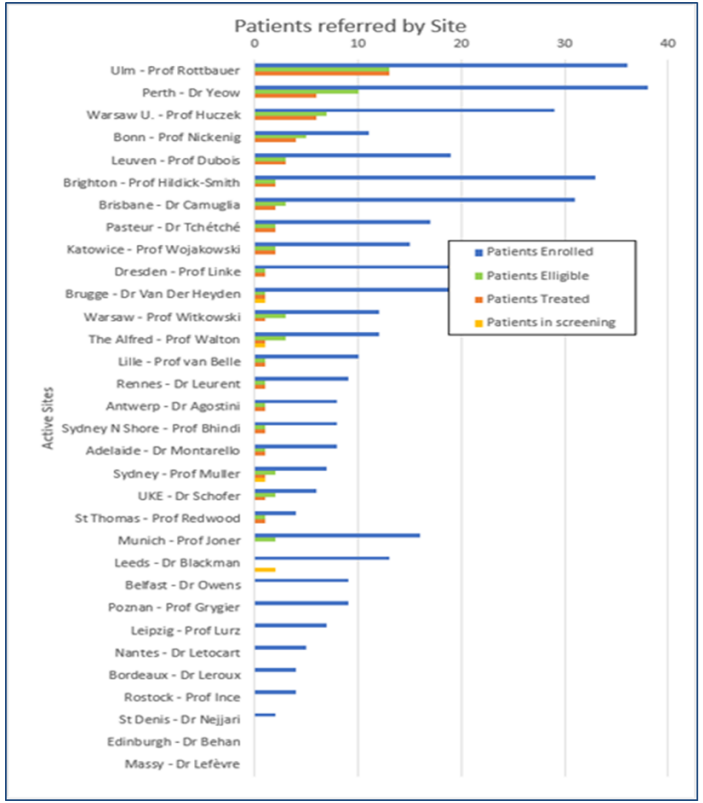
Sub-Annular Implant (SAI/Ring)

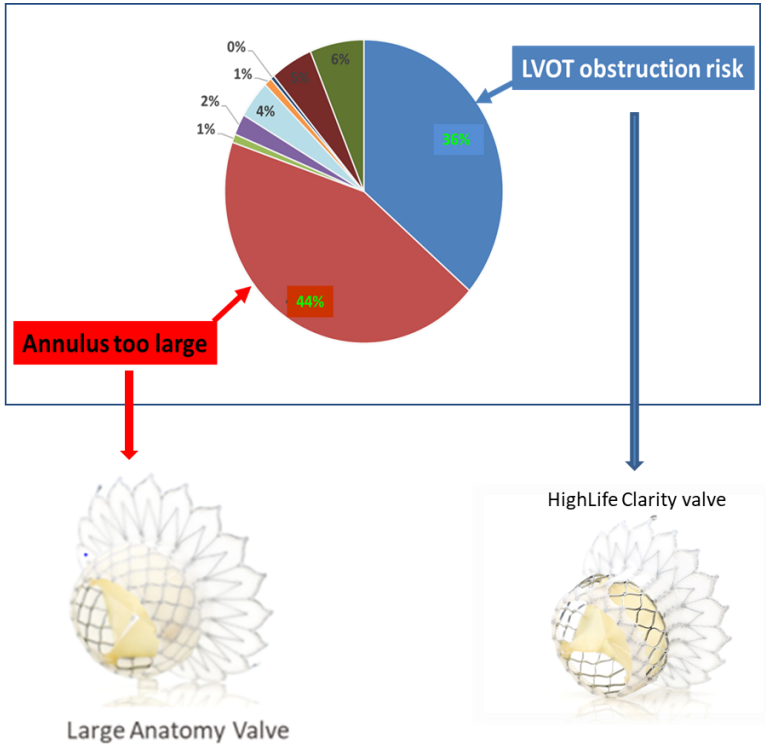
Provides flexibility and high durability to conform to native annulus and support valve



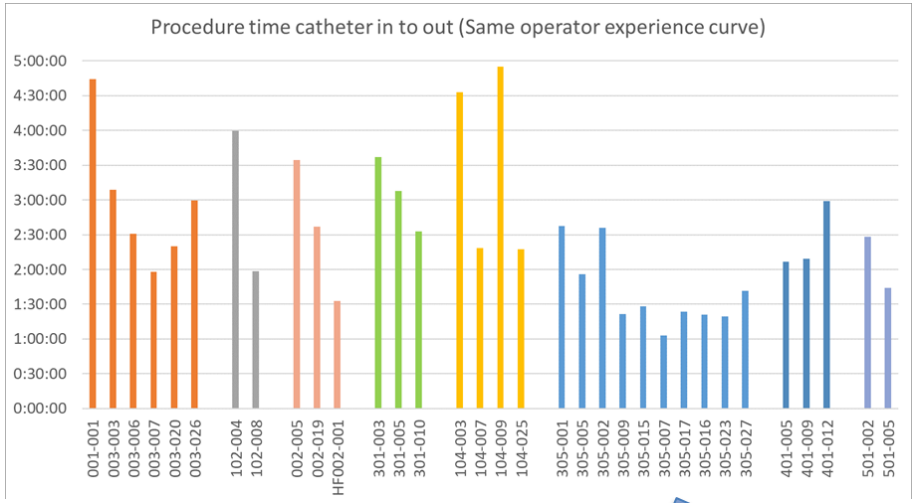
28mm HighLife mitral valve
18 F ring delivery system, 30F venous valve delivery catheter (with 18F shaft)

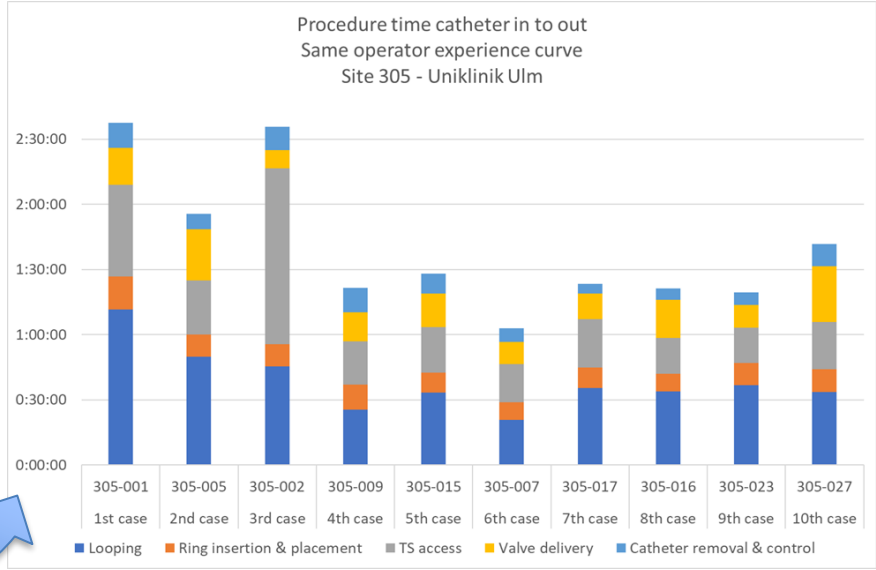
Patients screened and treated





Procedural times (learning curve)





Patient Demographics & Medical History (HL-2018-01) - 1

As Treated Population	N=52
Age	75.2 (50 – 88)
Female Gender	20 (38.5%)
BMI	27.1 (17.4 – 37)
NYHA	II=52% / III=46% / IV=2%
STS-prom M-Replacement	5.6 (0.7 – 19.9)
LVEF	45.7% (30.7 – 60.2)
Mitral Regurgitation ≥ 3+	100%
Primary MR (DMR)/Mixed	11/2%
Secondary MR (FMR)	87%

Patient Demographics & Medical History (HL-2018-01) - 2

As Treated Population	N=52 (%)
History of Heart failure < 2wks	19
Previous MI	37
Previous Stroke/TIA	10
Hypertension	67
Diabetes	35
Atrial Fibrillation/Flutter	77
Ischemic Cardiomyopathy	21
Dialysis	2
COPD	21
Prior PCI	46
Prior CABG	23
Prior Pulse Generator (PM/ICD/CRT)	42

Patient Demographics & Medical History (HL-2018-01)

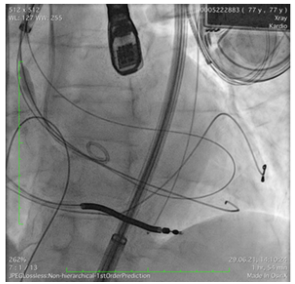
As Treated Population	N=52
Age	75.2 (50 – 88)
Female Gender	20 (38.5%)
BMI	27.1 (17.4 – 37)
NYHA	II=52% / III=46% / IV=2%
STS-prom M-Replacement	5.6 (0.7 – 19.9)
LVEF	45.7% (30.7 – 60.2)
Mitral Regurgitation ≥ 3+	100%
Primary MR (DMR)/Mixed	11/2%
Secondary MR (FMR)	87%

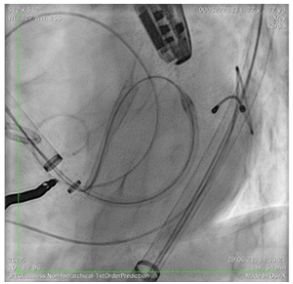
As Treated Population	N=52 (%)
History of Heart failure < 2wks	19
Previous MI	37
Previous Stroke/TIA	10
Hypertension	67
Diabetes	35
Atrial Fibrillation/Flutter	77
Ischemic Cardiomyopathy	21
Dialysis	2
COPD	21
Prior PCI	46
Prior CABG	23
Prior Pulse Generator (PM/ICD/CRT)	42

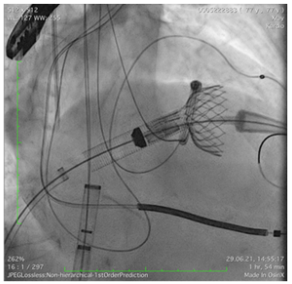
Technical success (Primary feasibility)

Total subjects (N=52)	n/N	%
Leaving the Cathlab/OR alive	52/52	100
Successful access, delivery, retrieval of delivery systems	49/52*	94
Freedom from emergent surgery or re-intervention	48/52**	92
Technical success	46/52	88

* In two patients, guidewire looping could not be completed due to anatomical or patient condition, and thus mitral ring and valve could not be implanted. One patient with low valve delivery and emergent cardiac surgery.
** The HighLife study valve was properly implanted (N=2) but due to anatomical structures moved immediately into the left ventricle and patients were converted to surgery, one patient treated with balloon inflation due to perceived high gradient and one patient with low implant, subsequent valve migration and emergent cardiac surgery.



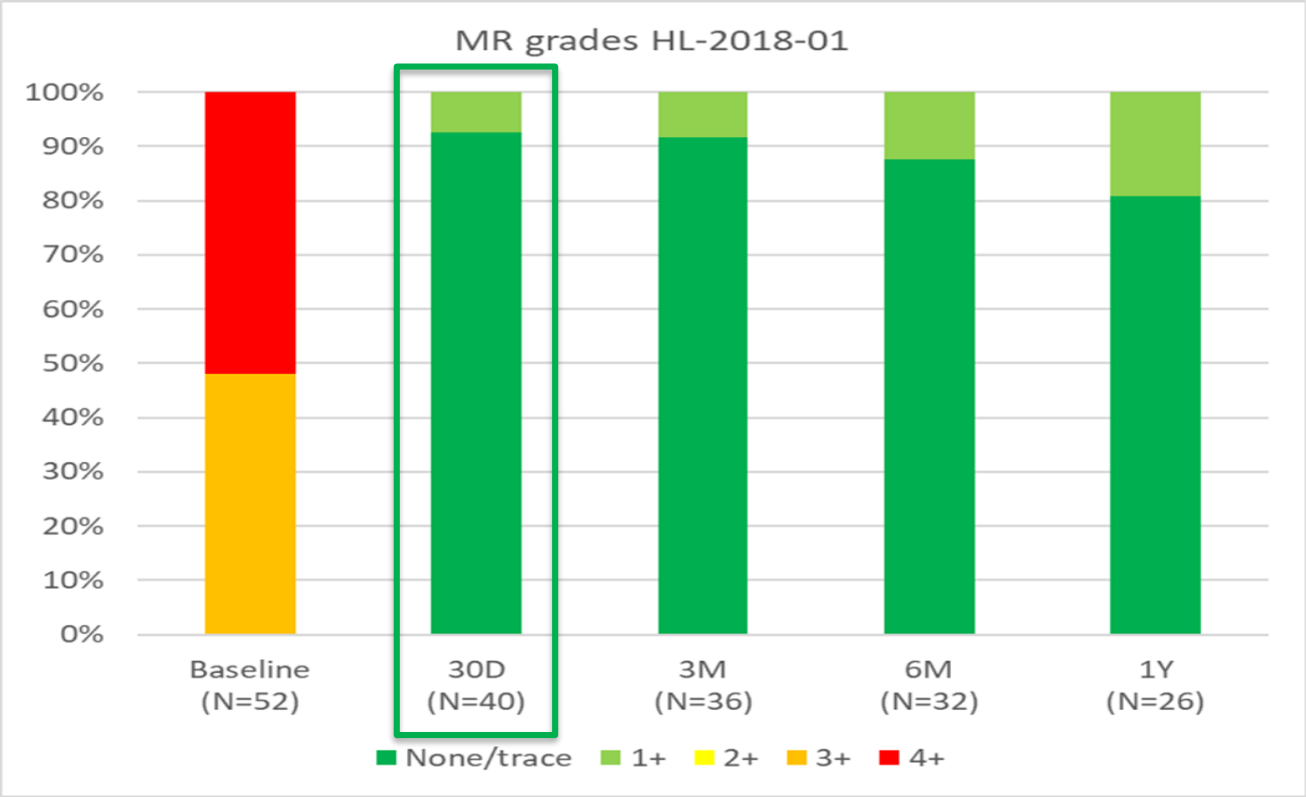




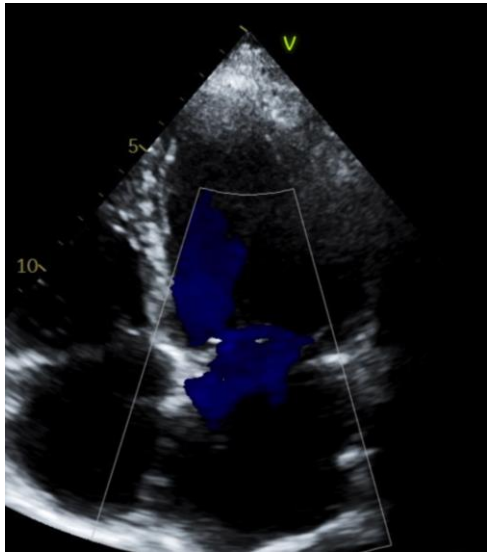
Clinical Outcomes (Primary Safety) HL-2018-01

As Treated Population at 30 Days (N=52)	Non-Hierarchical		Hierarchical (composite EP)	
	N	%	N	%
All-cause mortality	7	13.5	7	13.5
MI – (non Q-wave) – PCI or CABG	1	1.9	0	
Major/Disabling Stroke	2	3.8	1	
Life Threatening Bleeding (CEC)	7	13.5	1	
Major access and vascular complication	3	5.8	1	
Stage 2-3 acute kidney injury	6	11.5	1	
Conversion to Surgery/intervention (ViV)	4	7.7	2	
Re-intervention / Operation	2	3.8	0	
Severe hypotension, HF, Resp Failure, IV Vasopresors	8	15.4	2	
Per Protocol Prim Safety Endpoint			15	28.8
TAVI for AoR treatment	2	3.8		
AS Closure	2	3.8		
Pulse Generator Implanted	1	1.9		

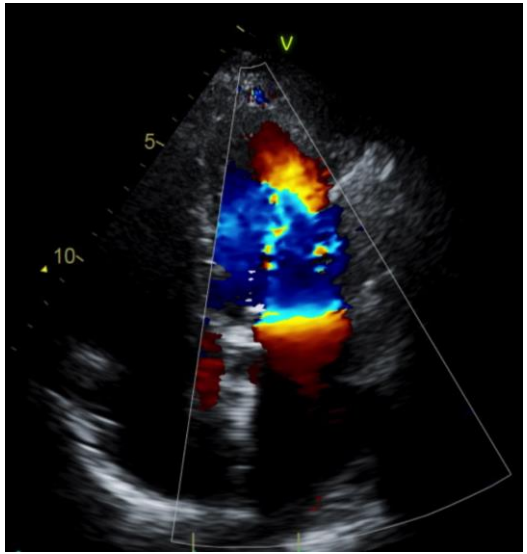
Echocardiographic outcomes (Primary performance)



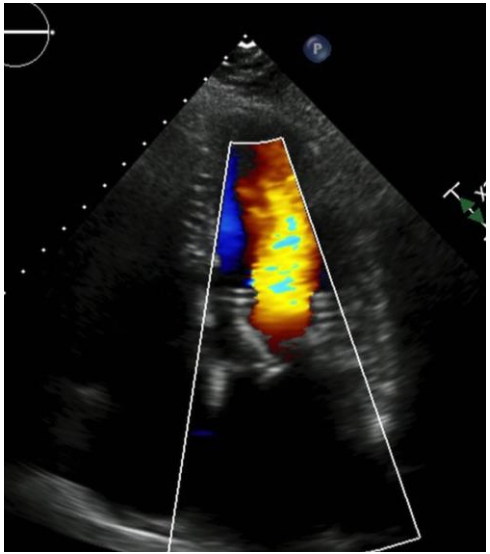
Echo example; Pre-procedure at 24hrs and 30days FU (TTE)



Pre-procedural



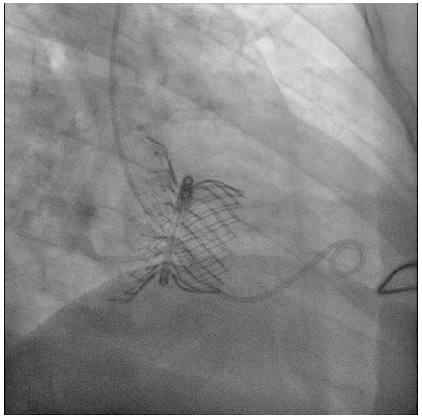
24 Hours



1 Month

Conclusion

- HighLife TSMVR is feasible and could be achieved with a high technical success rate in patients with no suitable alternative therapy as defined by the local Heart Teams.
- HighLife TSMVR resulted in acceptable primary safety and excellent echocardiographic outcomes
- HighLife continues further development of TSMVR and patient recruitment in the ‘’Expanded’’ HighLife study



PCRonline.com