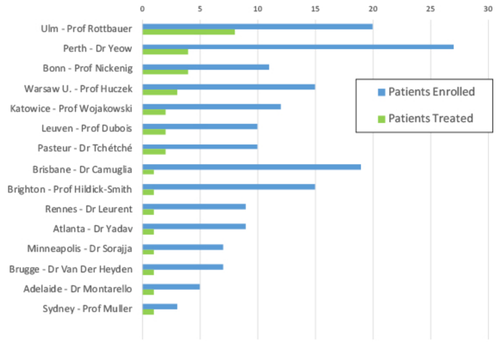
HighLife Trans-Septal Mitral Valve Replacement (TSMVR) system; Early and Long Term Clinical and Hemodynamic Outcomes of the First 30 Consecutive Cases; The HighLife Feasibility Studies in Europe/Australia and US.

W. Rottbauer, L. Schneider, G Nickenig, Z. Huczek, W. Wojakowski, D. Tchetche, C Dubois, M. Nasr, L. Verhees, M. Rothman, N. Piazza, J. Buithieu , WL.Yeow, S. Worthley

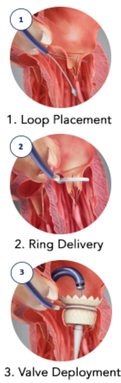
Objectives & Methods

The aim of the HighLife Eu/Au and US Early Feasibility Study is to evaluate feasibility, short and long-term safety and performance of the HighLife 28mm TSMVR and its delivery systems at 30 days. We report interim results of the first 30 consecutive cases with clinical and echocardiographic outcomes at 30 days.
From June 2019 till July 2021, 14 activated sites in 7 countries and 3 continents have enrolled 230 patients of which 31 were accepted by the screening committee and treated with the Highlife TSMVR system. We report on 30 patients having completed a minimum of 30 day follow-up. All except the first four patients have been implanted using remote teleproctoring.

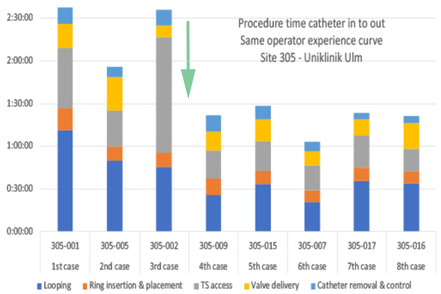
Top Implanters and Enrollers



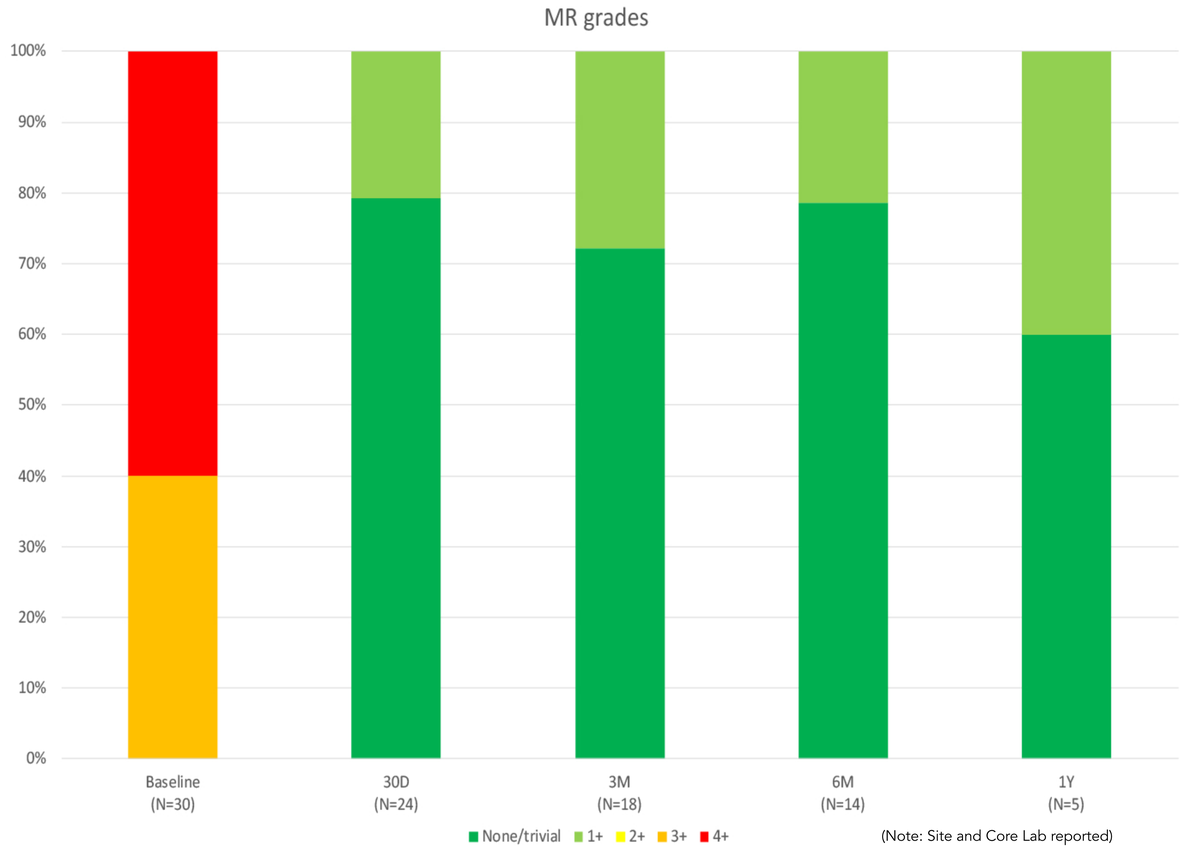
3-Step Procedure & Learning Curve



1. Loop Placement
2. Ring Delivery
3. Valve Deployment



Interim results show excellent valve performance:



(Note: Site and Core Lab reported)

All 30 procedures successfully performed to date have resulted in good technical success (90%) in a high surgical risk patient population with moderate/severe and severe MR, with a good primary safety endpoint and a high primary efficacy endpoint. Additionally, these cases demonstrate that HighLife's 3-step TSMVR procedure can be successfully implanted using teleproctoring support.

Demographics & Medical History

	N=30
Age (yrs)	75.6 (56 – 88)
Gender – female	27%
BMI	27.3 (19.8 – 37)
NYHA	II=15 / III=14 / IV=1
Secondary MR	89%
LVEF	41% (30 – 63)
STS-prom M-Replacement	5.2 (1.3 – 19.9)
History of Heart failure < 2wks	20%
Previous MI/PCI	50/70%
Diabetes	43%
Atrial Fibrillation/Flutter	70%
Ischemic Cardiomyopathy	30%

Safety

As Treated population (attempt to treat)	@ 30 Days (N=30)	> 30D up to 1 year (N=30)
All death	3	2
Major Stroke	1	0
MI – (non Q-wave)	0	1
Conversion to surgery	1	0
Re-intervention / operation	1*	0
Heart failure hospitalizations	1	3
Major Bleeding	4	0
AS closure	0	2
Pulse Generator implanted	1	1

Notes: partially monitored and events adjudicated / data includes all patients with follow-up to 1 yr
*Event related to AoR - TAVI implanted

Technical Success

Total subjects (N=30)	n/N	%
Technical success	**27/30**	**90**
- Leaving the Cathlab/OR alive	30/30	100
- Successful access, delivery, retrieval of delivery systems	28/30*	93%
- Freedom from emergent surgery or re-intervention	29/30**	97%

* 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

** The HighLife study valve was properly implanted but due to anatomical structures moved immediately into the Left Ventricle and patients was converted to surgery