

TWIST-EFS – TLFs for ROP

2025-08-07

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Table 2 Patient Disposition & Follow-up Visit Compliance by Interval

Enrolled Population (N=42)

Patient Status at Follow-Up	30 Days	6 Months	1 Year	2 Years
Eligible for Visit ¹	41/42 (97.6%)	30/42 (71.4%)	25/42 (59.5%)	13/42 (31%)
Visit Completed Within Window	32/42 (76.2%)	27/42 (64.3%)	21/42 (50%)	11/42 (26.2%)
Visit Completed Outside Window	9/42 (21.4%)	3/42 (7.1%)	3/42 (7.1%)	0/42 (0%)
Visit Not Performed	0/42 (0%)	0/42 (0%)	1/42 (2.4%)	2/42 (4.8%)
Ineligible for Visit	1/42 (2.4%)	12/42 (28.6%)	17/42 (40.5%)	29/42 (69%)
Visit Not Due	0/42 (0%)	8/42 (19%)	9/42 (21.4%)	19/42 (45.2%)
Died Before Window	1/42 (2.4%)	4/42 (9.5%)	8/42 (19%)	10/42 (23.8%)
<p>[1] Patients are eligible if they complete the visit or their visit window is open and prior to FU visit window , they (a) are alive , (b) are not explanted, (c) did not withdraw from study, (d) are not lost to FU.</p> <p>Visit Windows: 30 Days FU window (23-37 days), 6 FU window (166-194 days), 1 year FU window (335-390 days), 2 year FU window (680-765 days)</p> <p>Categorical measures: n/Total N (%)</p> <p>Source: t2_patientdisposition.R Extract Date: 2025JUL28 Run Date (Time): 07Aug2025 (22:34)</p>				

Table 3 Demographics and Baseline Characteristics

Enrolled Population (N=42)

Baseline Characteristic	Total
Age (Years)	73.2 ± 10.3 (42) 76 (44, 90)
BMI (kg/m ²)	27.5 ± 6 (42) 27.1 (18.6, 52.7)
Sex at Birth Female Male	16 / 42 (38.1%) 26 / 42 (61.9%)
NYHA Class Class II Class III	11 / 42 (26.2%) 31 / 42 (73.8%)
LVEF (TTE) 21 - 25 26 - 30 31 - 35 36 - 40 41 - 45 46 - 50 51 - 55 56 - 60 61 - 65	2 / 40 (5%) 4 / 40 (10%) 2 / 40 (5%) 5 / 40 (12.5%) 9 / 40 (22.5%) 2 / 40 (5%) 5 / 40 (12.5%) 5 / 40 (12.5%) 6 / 40 (15%)
Stroke	6 / 42 (14.3%)
Atrial Fibrillation	28 / 42 (66.7%)

Baseline Characteristic	Total
PCI	13 / 42 (31%)
CABG	12 / 42 (28.6%)
Continuous variables: Mean \pm SD (n); Median (min, max)	
Categorical measures: n/Total N (%)	
Source: t3_baselinedem.R Extract Date: 07AUG2025 Run Date (Time): 07Aug2025 (22:34)	

Table 4 Device Success at Exit from Or/Cath Lab (Per Device Analysis)

Enrolled Population (N=42)

Device Outcome	Total
Device success ¹	41/42 (97.6%)
Device deployed as intended	41/42 (97.6%)
Device system successfully retrieved as intended	41/42 (97.6%)
<p>[1] Device Success: Device is deployed as intended and the delivery system is successfully retrieved as intended at the time of the patient's exit from the cardiac catheterization laboratory.</p> <p>Categorical measures: n/Total N (%)</p> <p>Source: t4_devicesuccess.R Extract Date: 08AUG2025 Run Date (Time): 07Aug2025 (22:34)</p>	

Table 8: CEC Adjudicated Endpoints for Events up to 1 Year

Enrolled Population (N=42)

Event	Early Events (≤ 30 Days)		Late Events (> 30 days to 1 Year)		Total
	No. Events	Patients	No. Events	Patients	No. Events
Composite MAE	9	6/42 (14.3%)	26	12/41 (29.3%)	35
Death	1	1/42 (2.4%)	6	6/41 (14.6%)	7
Stroke	0	0/42 (0.0%)	2	2/41 (4.9%)	2
Bleeding ¹	4	4/42 (9.5%)	7	7/41 (17.1%)	11
Major Vascular Complications Requiring Surgery to Repair	1	1/42 (2.4%)	0	0/41 (0.0%)	1
Major Cardiac Structural Complications Requiring Surgery to Repair	1	1/42 (2.4%)	0	0/41 (0.0%)	1
Stage 2 or 3 Acute Kidney Injury (Including New Dialysis)	0	0/42 (0.0%)	5	3/41 (7.3%)	5
Myocardial Infarction or Coronary Ischemia Requiring PCI or CABG	0	0/42 (0.0%)	0	0/41 (0.0%)	0
Unexpected Cardiogenic Shock	0	0/42 (0.0%)	3	3/41 (7.3%)	3
Any Valve-Related Dysfunction, Migration, Thrombosis, or Other Complications Requiring Surgery or Repeat Interventions	2	2/42 (4.8%)	3	3/41 (7.3%)	5
[1] Includes fatal, life-threatening, extensive or major bleeding as defined by MVARC Categorical measures: n/Total N (%) Source: t8_CEC_MAEs.R Extract Date: 2025AUG06 Run Date (Time): 07Aug2025 (22:34)					

Table 11 CEC Adjudicated Heart Failure Hospitalizations and Non-elective Mitral Valve Reinterventions

Enrolled Population (N=42)

Category	Early Events (≤ 30 Days)		Late Events (> 30 Days to 1 Year)		Total Events	
	No. Events	Patients	No. Events	Patients	No. Events	Patients
Heart Failure Hospitalization	2	2/42 (4.8%)	13	9/41 (22.0%)	15	10/42 (23.8%)
Non-elective mitral valve re-intervention, percutaneous or surgical	2	2/42 (4.8%)	3	3/41 (7.3%)	5	5/42 (11.9%)
Categorical measures: n/Total N (%)						
Source: t11_CEC_HFH_MVR.R Extract Date: 2025AUG06 Run Date (Time): 07Aug2025 (22:34)						

Table 13 NYHA Class: Unpaired Analysis

Implanted Population (N=41)

NYHA Class	Baseline (N=41)	30 Days (N=41)	6 Months (N=30)	1 Year (N=24)
Class I	-	9/41 (22.0%)	10/30 (33.3%)	11/24 (45.8%)
Class II	11/41 (26.8%)	23/41 (56.1%)	14/30 (46.7%)	8/24 (33.3%)
Class III	30/41 (73.2%)	8/41 (19.5%)	4/30 (13.3%)	3/24 (12.5%)
Class IV	-	1/41 (2.4%)	2/30 (6.7%)	-
Categorical measures: n/Total N (%)				
Source: t13_NYHA.R Extract Date: 2025AUG06 Run Date (Time): 07Aug2025 (22:34)				

Table 14 MR Grade by Core Lab TTE: Unpaired Analysis

Implanted Population (N=41)

MR Grade	Baseline (N=41)	Discharge (N=41)	30 Days (N=41)	6 Months (N=30)	1 Year (N=24)
None/Trace	0/36 (0%)	26/37 (70.3%)	15/36 (41.7%)	13/30 (43.3%)	9/19 (47.4%)
Mild	0/36 (0%)	10/37 (27%)	18/36 (50%)	15/30 (50%)	9/19 (47.4%)
Mild-Moderate	3/36 (8.3%)	1/37 (2.7%)	3/36 (8.3%)	2/30 (6.7%)	1/19 (5.3%)
Moderate-Severe	22/36 (61.1%)	0/37 (0%)	0/36 (0%)	0/30 (0%)	0/19 (0%)
Severe	11/36 (30.6%)	0/37 (0%)	0/36 (0%)	0/30 (0%)	0/19 (0%)
Baseline column reports cumulative MR grade, while all other columns report transvalvular MR grade					
Categorical measures: n/Total N (%)					
Source: t14_MRgrade.R Extract Date: 2025AUG06 Run Date (Time): 07Aug2025 (22:34)					