

United States Laser In-Situ Fenestrated Endograft (LIFE) Registry



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Disclosure

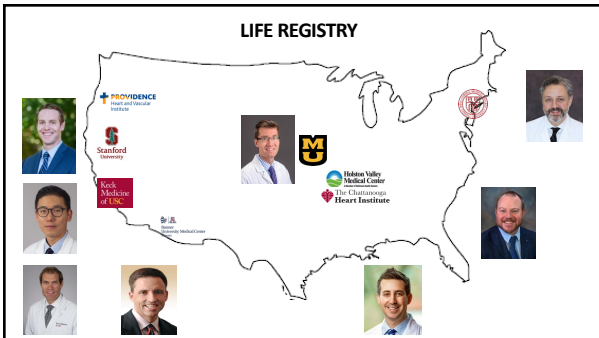
- Medtronic Advisory Board
- Venostent Advisory Board

- Investigational Device Exemption for laser fenestration G240064

- Discussion of off-label therapy

- This work was supported by Medtronic, Inc. (Santa Rosa, CA, USA)

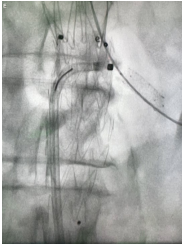
LIFE REGISTRY



Background


- Laser fenestration more commonly performed
- Role when unfit for open surgery
- Urgent/emergency cases
- Does not fit F/BEVAR criteria

- Largely untested!
- Off-label use



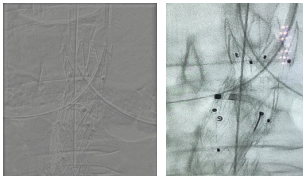
Methods

- Institutional experience 2017-2022
- In-situ laser fenestrated endografts
- Multicenter registry – 6 participating US sites
- Inclusion criteria:
 - Ineligible for open repair
 - Ineligible for commercially-available fenestrated/branched device



Demographics

- Thoracoabdominal endovascular repair:
 - 121 total enrollments
- Thoracic Aortic endovascular repair:
 - 82 total enrollments
- Total 203 patients at time of data analysis



Demographics of the overall cohort

N = 203	TAAA (N=121)	TEVAR (N=82)	Total	%
Age	71.3 (41-88)	62.4 (27-89)	67.8	
Sex				
Female	27	24	51	25
Male	97	57	154	76
Ethnicity				
Hispanic/Latino	16	9	25	12
Not Hispanic/Latino	95	69	164	81
Not reported	5	2	7	3
Race				
White	81	63	144	71
Black	5	5	10	5
Asian	7	4	11	5
Native Hawaiian	0	1	1	0.5
Other	12	7	19	9
Not reported	8	1	9	4

- Comorbidities:
 - CAD 61 patients (30%)
 - COPD in 39 patients (19%)
 - Renal Insufficiency 43 patients (21%)
 - Dialysis 7 patients (3%)
 - Prior stroke 31 patients (15%)
 - GTAD 3 patients (1.5%) – all TEVAR

Demographics of the overall cohort

N = 203	TAAA	TEVAR	Total	%
Prior Aortic Repair				
Open	16	39	55	27
Endo	50	13	63	31
Medications				
Antiplatelet agents	66	44	110	54
Oral anticoagulation	18	12	30	15
Statins	62	33	95	47
Laboratory values				
Preoperative creatinine	1.3	1.3	1.3	
oGFR	60.1	63	61.7	
Hemoglobin	11.6	12.3	11.9	

Thoracoabdominal laser fenestration

Operative characteristics TAAA

N = 121	N	%
TAAA repair indication*		
Egiform	85	70
Saccular	15	12
Pseudoaneurysm	3	2.5
PAU	4	3
IMH	4	3
Dissection	11	9
Type Ia Endoleak	22	18
Indication for ISLF*		
Urgent	64	53
Unsuitable for off-the-shelf	55	45
Ball out/Unintentional coverage	1	0.8
Surgeon preference	36	30

*multiple indications allowed

Asymptomatic 34%
Symptomatic/Ruptured 46%
Not reported 21%

Operative characteristics TAAA

162 arteries presented

1 vessel treated: 14%
2 vessel treated: 24.8%
3 vessel treated: 38.2%
4 vessel treated: 24%

Operative characteristics TAAA

N = 328 vessels	%
Immediate technical success	100
Aortic stent delivered	100
Laser fenestration successful	99
Bridging stent successfully delivered	94

Ischemia mitigation technique used in 29% of cases

Laser fenestration times: SMA – 31.8 mins, Right renal - 42.5 mins, Left renal - 55.6 mins, Celiac – 48.5 mins

Temporary gutter 2.4%, Snorkel sheath 25.8%, Left renal back table fenestration 0.8%

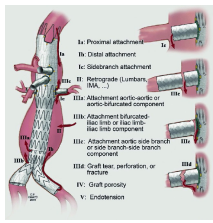
Outcomes TAAA

Post-op/Thirty-day follow-up			Mid-term follow-up		
N = 121	N	%	N = 121 (patients) 328 (vessels)	N	%
Selected complications					
Death	21	17	Mean follow-up (range)	9.3 (1-35 months)	
Average POD death	16		Selected complications		
Stroke	3	2	Death	5	4
-Complete recovery	2	2	-Related to aneurysm/repair	2	2
Spinal cord injury	6	5	Branched Stent reintervention	23	7
-Recovery from deficit	3	2	-Celiac artery	3	1
Postop CSF drain placed	13	11	-SMA	10	3
MI	3	2	-RRA	7	2
Respiratory failure	7	6	-LRA	3	1
Renal injury → dialysis	3	2	Mean reintervention interval	7.4 months	
Vascular access	3	2	Stents occluded	5	1
GI complications	8	7	Open conversion	0	0
ASA	93	75			
Clopidogrel	81	65			

Outcomes TAAA - Reintervention

Reintervention details		
N = 121 (patients) 328 (vessels)	N	%
Reason for reintervention		
-Endoleak	18	15
-Aneurysm expansion	5	4
-Graft infection	1	0.8
-Bridging stent issue	23	7
-Other	7	-
Endoleak		
-Type Ia	3	3
-Type Ib	6	5
-Type Ic*	4	1
-Type II	1	0.8
-Type IIIc* (junctional)	9	3
-Type IIIb (fabric leak)	1	0.8
-Undetermined	1	-

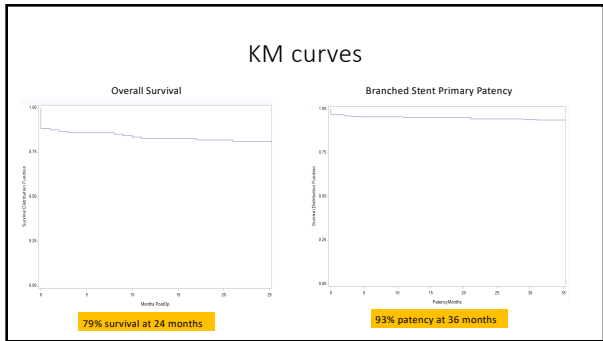
*n = of out 328 vessels



Outcomes TAAA - Reintervention

Reintervention details		
N = 121 patients, 328 vessels	N	%
Type of reintervention (n=43)		
-Aortic stent graft	13	10
-Bridging stent graft	23	7
-Balloon remodeling	1	0.8
-Embolization	2	2
-Other endovascular	2	2
-Other surgical	2	2

Bridging stent reintervention (n=23)



Aortic arch laser fenestration

Operative characteristics TEVAR

N = 82	N	%
TEVAR repair indication*		
Fusiform	15	18
Saccular	4	5
Pseudoaneurysm	5	6
PAU	9	11
IMH	6	7
Dissection	60	73
Type Ia Endoleak	4	5
Other	12	15
Indication for ISLF*		
Urgent	34	42
Unsuitable for off-the-shelf	12	15
Bail out/Unintentional coverage	0	0
Surgeon preference	51	62

*multiple indications allowed

