Mass General Brigham

Five-Year Results and Advantages of the TREO Endograft for Standard EVARs: Status in the US

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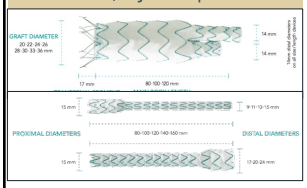
VEITH Symposium 2024
November 21, 2024

Disclosures

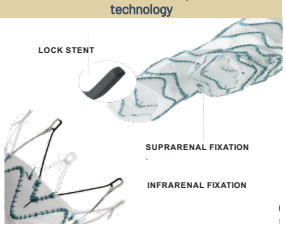
- PI on the TREO US Pivotal Trial

TREO® Abdominal Stent Graft System

Three-piece modular design with a wide variety of sizes, lengths and tapers[1]



TREO provides both, suprarenal and infrarenal active fixation as well as a unique Lock Stent technology



Pivotal Study to Evaluate the Safety & Effectiveness of the TREO Abdominal Stent Graft System

Multi-center, non-blinded, non-randomized study of treatment with TREO Stent-Graft in subjects with abdominal aortic aneurysms

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29 US Hospitals

↓

Patients: 150

Enrollment from November 2013 – November 2016

- IDE Number: G100200/S007
- ClinicalTrials.gov: NCT02009644

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Primary Analysis (published JVS, July 2021)

Primary safety endpoint was MAE rate at 30 days

- 0.7% (95% CI 0–3.7%)

Successful aneurysm treatment at 12 months

- 93.1% (95% CI 87.4, 96.8%)

Eagleton MJ, Stoner M, Henretta J, Chrzykl M, Panneton J, Tassiopoulos A, et al. Safety and effectiveness of the TREO stent graft for the endovascular treatment of abdominal aortic aneurysms. Journal of Vascular Surgery 2021;74(1):114–123.e5. Doi: 10.1016/j.jvs.2020.10.085.

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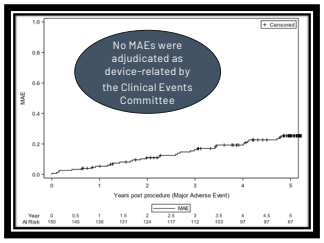
Compliance

77% of subjects had CT imaging performed at 5-Years

	Follow-up [b]			Assess Parameter [c]	
Analysis Window	Eligible for Visit [a]	Visit Perfor		Migration	Fracture
1 Month	150	150/150 (1		NA	148/150 (98.7%)
6 Months	149	139/149		149 (89.9%)	133/149 (89.3%)
1 Year	144	137/144 (		144 (88.9%)	131/144 (91.0%)
2 Years	131	119/131 (90		111/131 (84.7%)	111/131 (84.7%)
3 Years	119	108/119 (90.8%)		97/119 (81.5%)	94/119 (79.0%)
4 Years	111	96/111 (86.5%)	83/	71.2%)	79/111 (71.2%) 75/111 (67.6%)
5 Years	92	83/92 (90.2%)	70/92 (76.1%)	67/92 (72.8%)	68/92 (73.9%) 61/92 (66.3%)

NA – Not Applicable
[a] Eligible for Visit reflects those subjects eligible for follow-up calculated as: (previous eligible for follow-up) - (previous death + conversion + lost to follow-up + early withdrawal + not due for follow-up)
[b] Based on site-reported data
[c] Based on Core Laboratory analysis. Sac Diameter and Migration assessments use 1 month as baseline and are therefore not reported at 1 month. Eligible subjects require valid value at 1 month and at the specified time point.

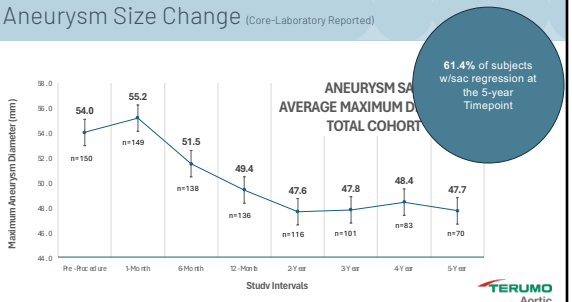
Kaplan Meier Curve MAEs



Major Adverse Events (MAE)	5-Year (n=105)	Total Subjects (N=150)
Patients with any MAE	10 (9.5%)	34 (22.7%)
Death (all-cause)	6 (5.7%)	25 (16.7%)
Stroke	1 (1.0%)	11 (7.3%)
Myocardial Infarction	2 (1.9%)	9 (6.0%)
Bowel Ischemia	1 (0.7%)	2 (1.3%)
Respiratory failure	0	2 (1.3%)
Procedural blood loss of 1000cc or more	0	1 (0.7%)
Paraplegia	0	0
Renal Failure	0	0

*Number of Subjects eligible for each timepoint reflects the number of subjects that were active in the study for a given timepoint, regardless of if a visit was completed during that interval.

Aneurysm Size Change (Core-Laboratory Reported)



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Summary of Effectiveness through 5-years

- No aneurysm-related mortality
- No aneurysm ruptures
- 1 migration (previously presented)

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Reasons for Secondary Interventions (Site reported)

Endoleaks (n=9)

- 7 subjects with Type Ia EL, 8 interventions, all resolved with extensions
- 2 subjects with Type II EL, 2 interventions, all resolved by embolization

Conversion to Open Surgery (n=0)

- No conversions to open surgery

Limb Occlusions (n=3)

- 3 subjects with occlusions, 3 interventions. 1 resolved with endarterectomy, arthroplasty and embolectomy, and resolved with angioplasty and embolectomy

Other Reasons for Secondary Interventions (n=4)

- Sac expansion, thrombosis, ischemia, AV fistula, most resolved with extensions

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Summary of Patency-Related Events (Core Lab reported)

	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years
Pivotal	100% (147/147)	100% (134/134)	100% (134/134)	100% (117/117)	100% (102/102)	100.0% (81/81)	100.0% (67/67)

*Core-Laboratory reported. These data may differ from the site reported data if an occlusion was treated more than one endpoint was present later, as the imaging submitted to the core Laboratory

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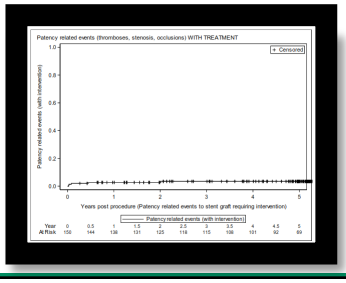
Kaplan Meier Curve for Patency-Related Events



No patency-related events reported by Core Lab

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Additional Review

- TA organized a review by an independent vascular surgeon, and internal parties, separate from the CoreLab review, to assess the differences between CoreLab and Site reported outcomes for endoleak and patency related observations, and potentially establish contributing factors associated
- Each subject with either a CoreLab or site-reported endoleak and patency-related event for the TREO IDE, CT images were reviewed, and all necessary clinical information was provided

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Additional Review

Endoleak Observations

- The table on the right provides the site and Core Lab reported Type I and Type III endoleaks that were reviewed.
- Of the 5 observations that had agreement between the Site and the Core Laboratory, the following were noted as potential contributing factors:
  - Type Ia observations (n=4 cases)
    - Reversed taper neck
    - Reversed taper neck / calcification
    - Neck degeneration (proximal) / under sizing
    - Reversed taper neck / angulation
  - Type Ib observations (n=1 case)
    - Landing zone / insufficient extension

SUBJECT ID	Procedure Date (site)	Endoleak	Core Lab	Core Lab Date	Lab	Core Lab POD	Site	Site Date	AE	Site AE POD	Reintervention	Reintervention Date	Reintervention POD
401-101	4/27/2015	Type Ib	x	11/6/2015		193	x	11/6/2015		193	x	12/14/2015	231
408-105	2/12/2014	Type Ia	x	3/28/2014		44	x	3/28/2014		44	x	4/18/2014	65
416-102*	12/18/2014	Type Ia	x	8/20/2015		245	x	8/31/2015		256	x	9/8/2015	264
429-107*	4/7/2015	Type Ia	x	4/9/2018		1098	x	4/9/2018		1098	x	7/2/2019	1547
430-101	10/20/2014	Type Ia	x	1/10/2017		813	x	1/10/2017		813	x	1/8/2017	870
420-103	2/25/2014	Type Ia					x	7/28/2014		153	x	8/13/2014	169
411-101	6/2/2014	Type Ib					x	6/27/2019		1851	x	8/6/2019	1891
423-108	9/3/2014	Type Ib					x	7/27/2020		2154			

*Subject had persistent endoleaks

Out of 8 observations, 5 had agreement between the site and Core-Lab

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Additional Review

Patency Observations

- The table on the right provides the site and Core Lab reported patency related observations that were reviewed.
- None of the patency observations had agreement between the Site and the Core Laboratory.
- All observations were reviewed by the internal and external parties.
- Of these eight observations, 7 observations had agreement between the internal and external reviewers. **Of the seven observations, the reviewers agreed that 4 observations did not have any patency-related findings.**
- For the other 3 observations, the following are potential contributing factors identified by the internal and external reviewers
  - Right Limb Occlusion Observations (n=2 case)
    - Oversizing / outflow
    - Oversizing / compression / thrombus
  - Left Limb Occlusion (n=1 case)
    - Limb compression (proximal)

SUBJECT ID	Procedure Date	Occlusion		Site	Site Date	AE	Site AE POD	Reintervention	CoreLab
401-103	7/20/2015	R. Limb Occlusion		x	7/31/2015		11	x	
423-116	1/14/2016	L. Limb occlusion		x	3/1/2016		49	x	
418-110	2/3/2016	R. Limb Occlusion		x	3/4/2016		30	x	
409-101	8/4/2014	Vascular graft occlusion		x	9/15/2014		42		
401-101	4/27/2015	Stent-graft patency	loss of	x	9/23/2020		1976		
402-102	6/12/2015	Stent-graft patency	loss of	x	8/1/2018		1146		
411-106	9/21/2015	Stent-graft patency	loss of	x	10/28/2020		1864		
429-111	5/11/2016	Stent-graft patency	loss of	x	9/15/2020		1588		

Out of 8 observations, reviewers agreed only 3 had patency-related findings

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Current Status of TREO in the US

US TREO PAS study (post-approval study) (NCT04697784)

- Enrollment of 338 subjects complete at up to 55 US centres (all subjects have completed 1-Year follow-up)
- The primary objective: real-world safety and effectiveness outcomes of TREO in an all-comers population

TREO Registry (now the abdominal module of the TIGER registry, NCT04246463)

- Enrollment is complete and follow-up continues

Fenestrated TREO

- FIH custom-made cases performed 2021 in Europe (enrolled in TIGER)
- 517 custom-made Fenestrated TREO devices have been implanted in Europe through EU Customs (June 2024)
- First US case October 2024 (PSIDE)
- Pivotal study in US planned 2025

Future Work

- Multiple additional analyses planned for long-term follow-up
- Planned publication in 2025

5-year follow-up continues to show positive long-term clinical outcomes supporting patient safety

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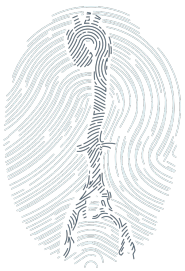
Thank you



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