

Adapting the Frozen Elephant Trunk Stent-Graft Design to the Patient's Aortic Pathology and Anatomy Reduces Stent-Graft Related Complications: Concept and Outcomes of the COOK Frozen Elephant Trunk Graft

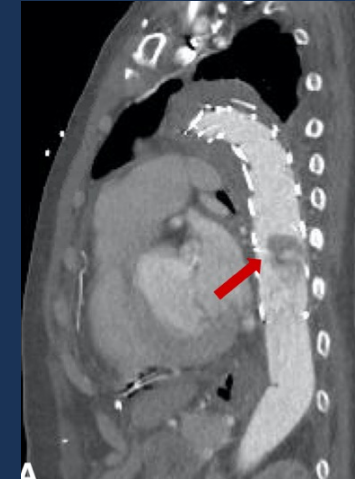
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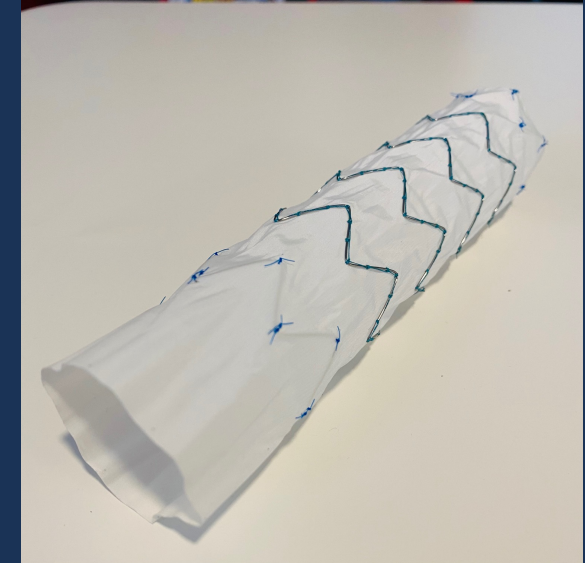
Background

- Outcomes after hybrid frozen elephant trunk (FET) stent-grafts are mainly focused on the perioperative results with minimal data on stent-graft related complications at follow-up
- Recently, concerns have been raised regarding the rates of thromboembolic events, ‘septal injury new entry’ tear (SINE) and type Ib endoleak after FET procedures
- Issues such as graft oversizing, graft foreshortening and distal radial stent pressure have been implicated in the pathogenesis of stent-graft related complications after FET
- The COOK FET graft may be customized to adapt to different aortic pathologies hence possibly decrease stent-graft related complications



Methods

- The COOK FET is based on the alpha graft platform with 3cm of unstented polyester graft proximally (allows for endovascular left subclavian revascularization and to ease arch anastomosis); stented length measured according to patient anatomy
- The graft is mounted on a clear sheath allowing for precise deployment in any arch zone and ensures graft conformability with no to minimal foreshortening
- Following the initial positive experience in 8 patients, grafts were customized according to the type and anatomy of the patient's aortic pathology mainly by:
 - graft tapering adapting to variation in the patient's aortic diameters (EX; chronic dissection with small true lumen)
 - Use of distal low-radial stents to minimize pressure on the septum in patients with acute and chronic aortic dissection
- We herein report stent-graft related complications at follow with the COOK FET graft within a single institution



Methods

- 56 consecutive patients operated with the COOK FET graft were reviewed
- Grafts were customized in terms of length and diameter according to patient anatomy and disease; in addition distal low radial stents were incorporated for dissection cases
- Mean follow-up: 32.9 ± 23.3 months
- 100% follow-up; data collected prospectively in a dedicated aortic clinic

Baseline Characteristics

	N=56
Etiology aortic disease	
Aneurysm	15 (26.8)
Dissection	20 (35.7)
Non A / Non B	2 (3.6)
Type I	11 (19.6)
Type II	2 (3.6)
Type B	5 (8.9)
Chronic dissection	11 (19.6)
Giant cell aortitis	2 (3.6)
Kommerell diverticulum	2 (3.6)
Other	6 (10.7)
Medical history	
Age	
Sex F	64.5±11.2
BMI	20 (35.7)
NYHA III-IV	26.8±5.6
Redo	7 (12.5)
Hypertension	19 (33.9)
Peripheral vascular disease	52 (92.9)
History CVA	14 (25.0)
Diabetes	4 (7.1)
Clearance MDRD <60 ml/mn/1.73m ²	3 (5.4)
COPD	10 (17.9)
Atrial fibrillation	6 (10.7)
Elective surgery	4 (7.1)
Urgent- Salvage surgery	35 (62.5)
	21 (37.5)

Intraoperative characteristics

	N=56
Root surgery	6 (10.7)
Aortic valve replacement	7 (12.5)
Arch reconstruction	
Tripod	46 (82.1)
4 branch	5 (8.9)
Other	5 (8.9)
Stent LSA	4 (7.1)
Distal anastomosis zone	
Zone 0	17 (30.4)
Zone 1	16 (28.6)
Zone 2	21 (37.5)
Zone 3	2 (3.6)
Length of stented graft portion	120±55
Associated surgery	
CABG	9 (16.1)
MVR/repair	2 (3.6)
Other	2 (3.6)
CPB time, min	135.9±36.7
Crossclamp time, min	70.0±33.3

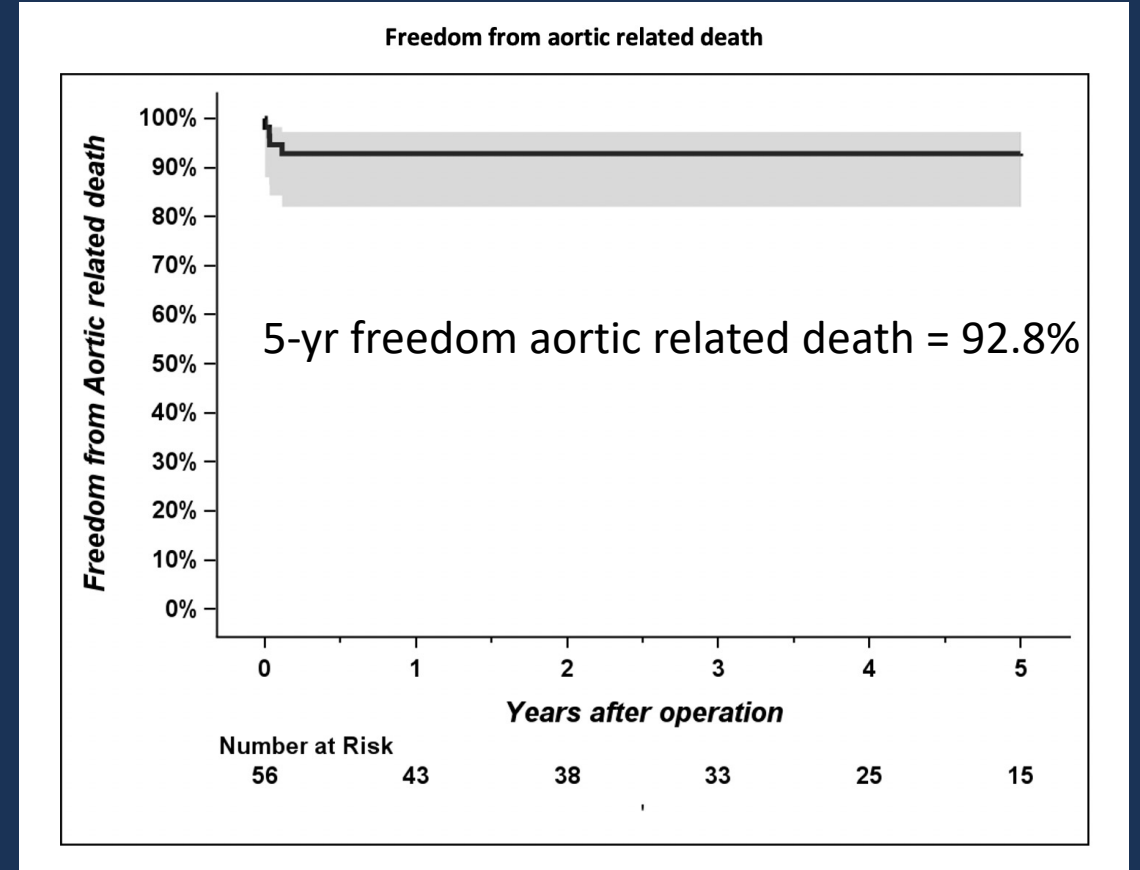
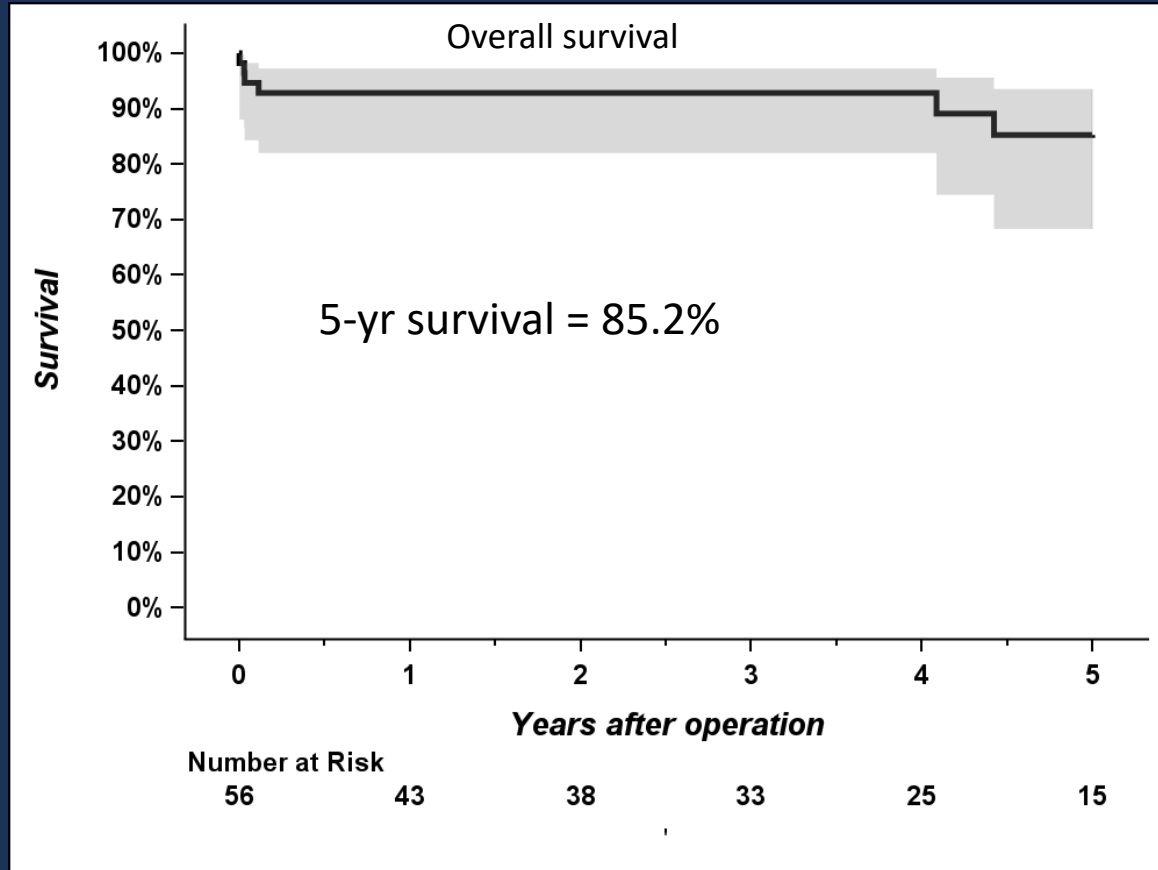
Values are mean ±STD or n(%).

CABG=coronary artery bypass grafting; CPB=cardiopulmonary Bypass;MVR=mitral valve replacement

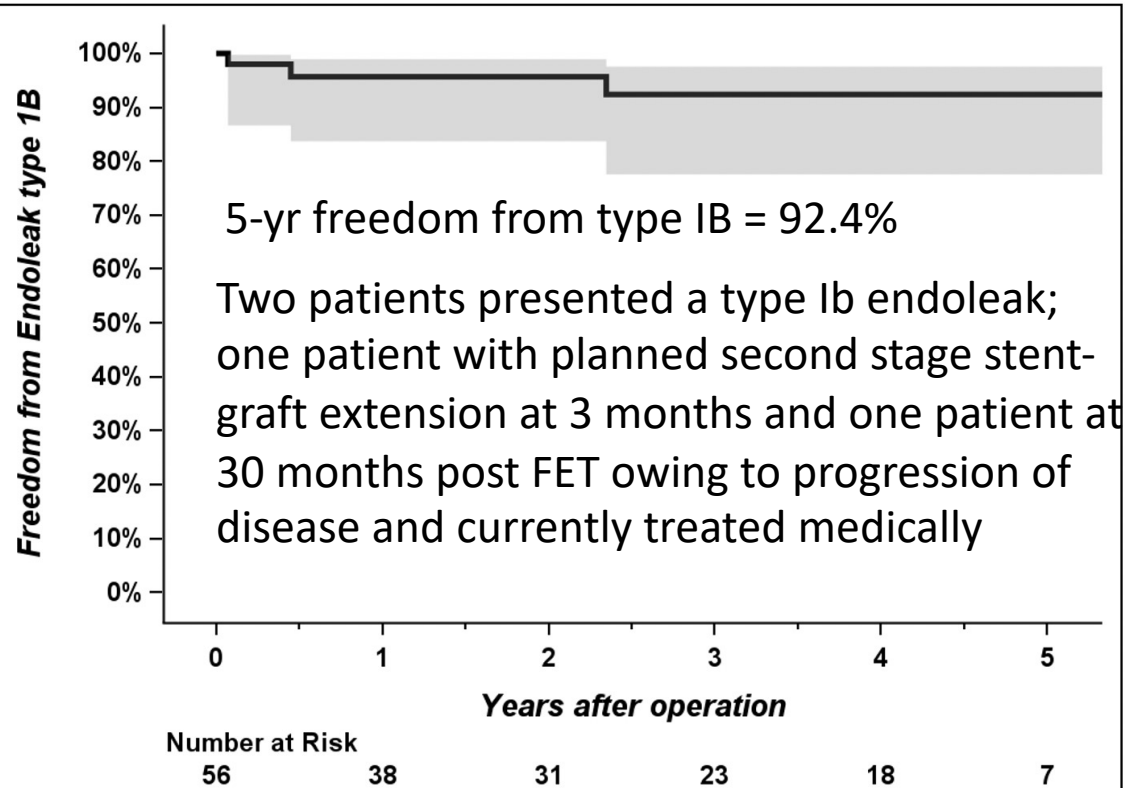
Postoperative adverse events

	N=56
Early postop	
Stroke/ TIA	6 (10.7)
Paraparesis	3 (5.4)
Dialysis	1 (1.8)
Intubation >48h	4 (7.1)
Reoperation for bleeding	9 (16.1)
LOS, days	10.8±7.6
In-Hospital mortality	3 (5.4)
Stroke	2/3
Maligna arrythmia	1/3
Follow-up	N=53
Length follow-up (months)*	32.9±23.3
Endoleak type 1b	2 (3.8)
Thrombo-embolic event	0
SINE	2 (3.8)
Aortic reintervention	2 (3.8)
Other stent graft complication	0

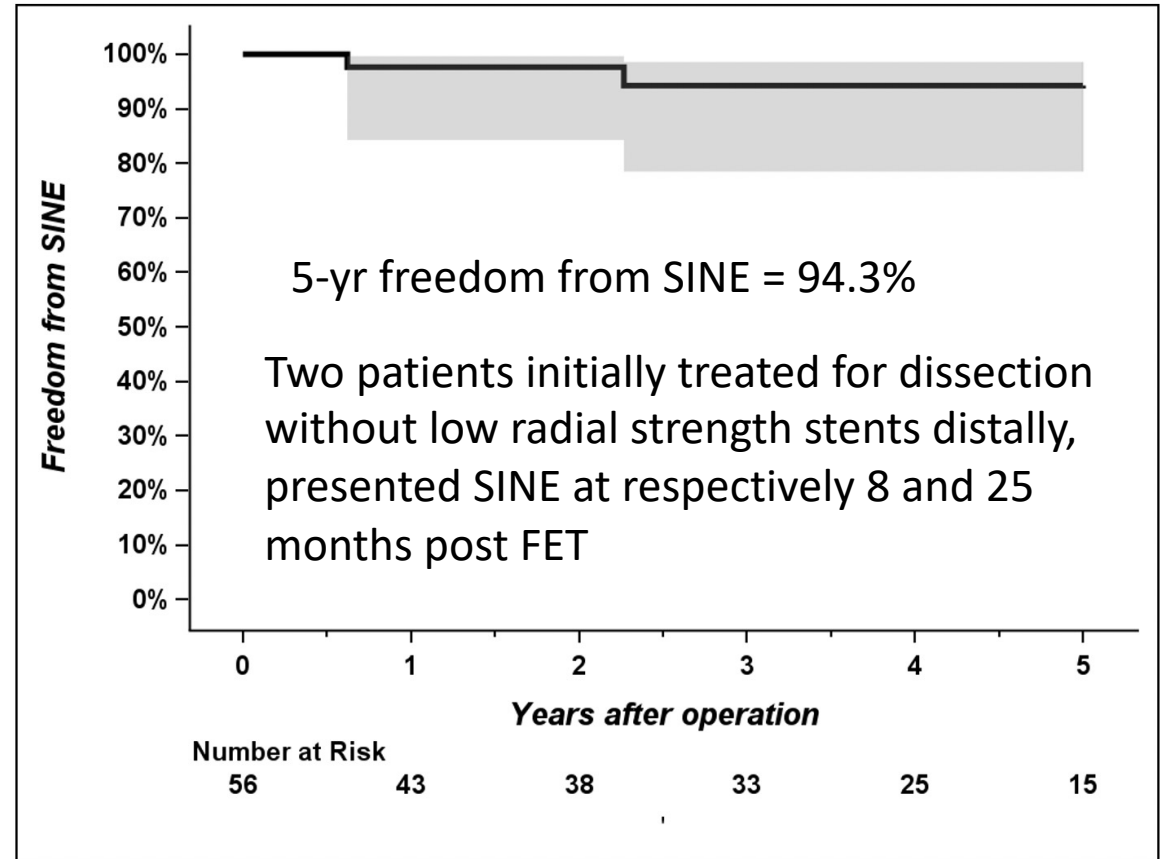
Survival



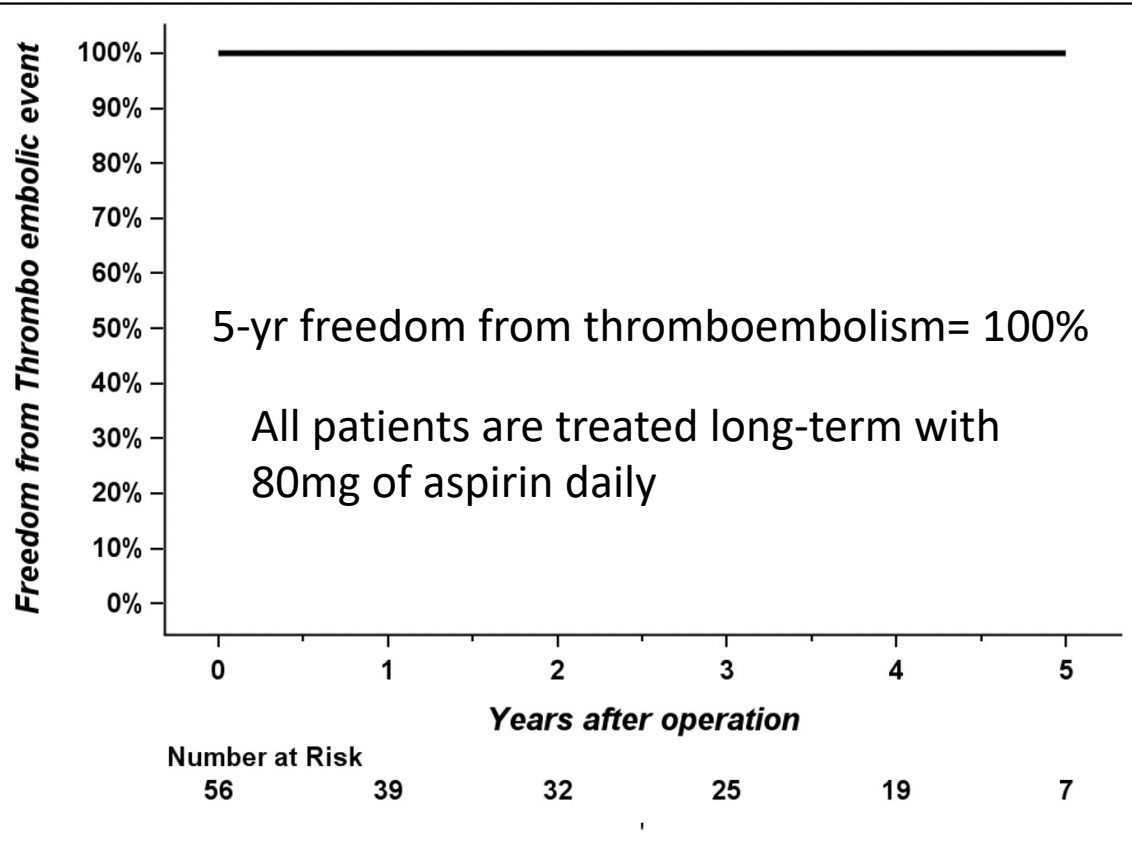
Freedom From Endoleak type 1B



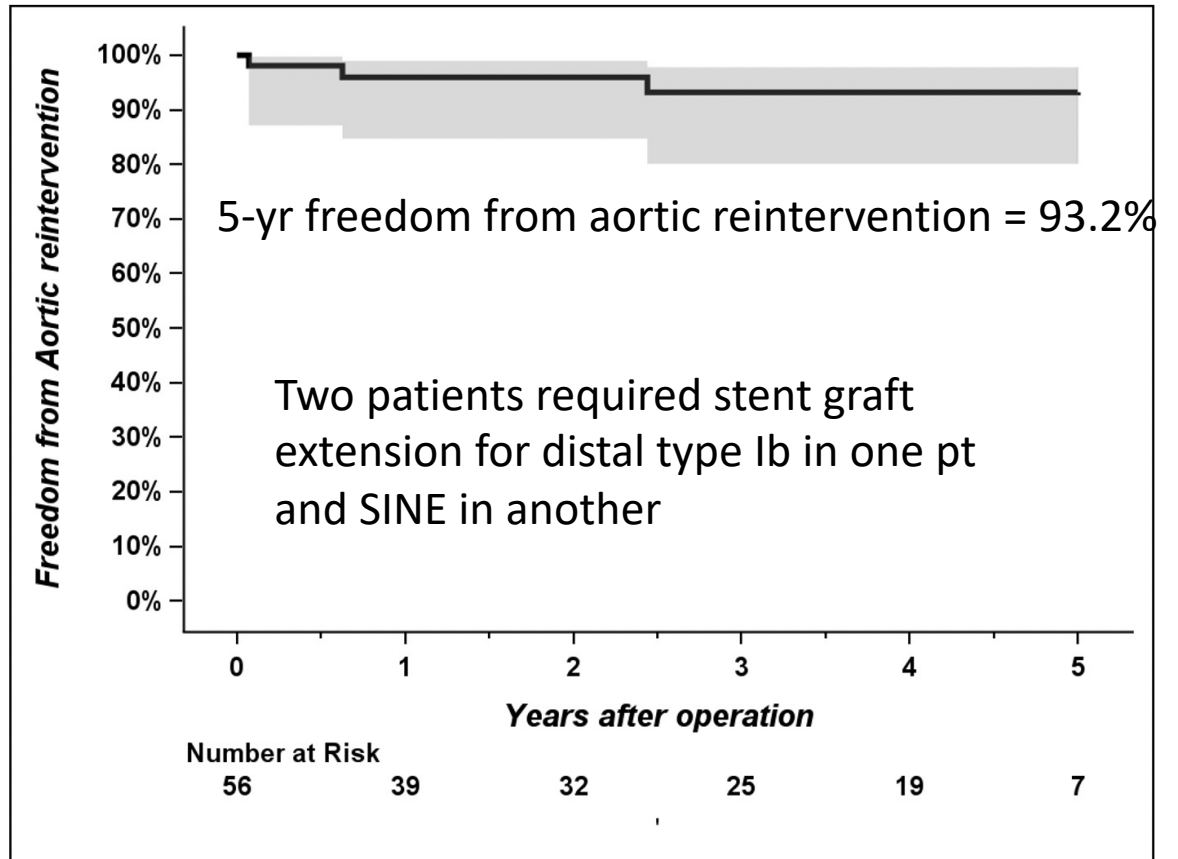
Freedom From SINE



Freedom From Thrombo Embolic Event



Freedom From Aortic Reintervention



Conclusion

- Stent-graft related complications following FET procedures are not uncommon and require serial imaging for early diagnosis and treatment and should to be better characterized in terms of incidence and device type
- The COOK FET graft may be customized to adapt to the patient's aortic pathology and anatomy and may contribute to lessen stent-graft related complications at follow-up
 - No thrombo-embolic event was encountered and may be related to the COOK graft conformability owing to the stent design and minimal graft foreshortening during deployment
 - Avoidance of graft foreshortening may further decrease rate of early/mid-term type IB endoleak
 - SINE may be lessened by decreasing radial force on the septum by specific graft tapering according to patient anatomy and use of low radial pressure distal stents
- Although adapting graft design to patient anatomy/pathology vs 'forcing patient anatomy' to adapt to the graft design is an interesting and logical concept further comparative studies are required