ENDOVASCULAR TAA REPAIR

STRATO STUDY

The French Prospective Multicenter Trial

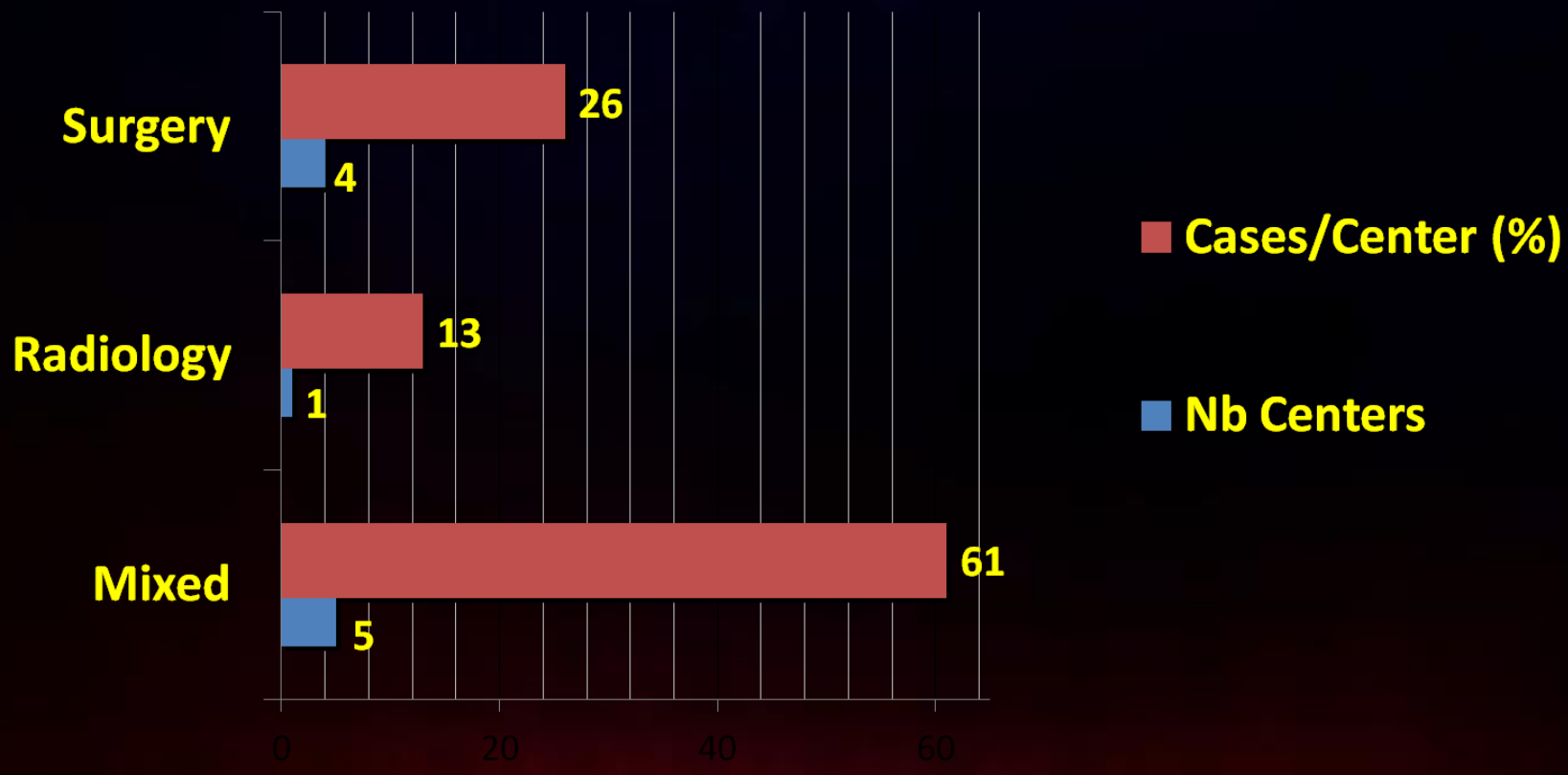
3 Year Follow Up

Disclosure Statement

No Disclosures

STRATO Study Enrollment

April 2010 - February 2011
10 Centers
23 pts (4 female, 19 male), Mean Age 77y



CT Imaging at 1-3-6-12-24-36 Months Corelab (CERC – France)

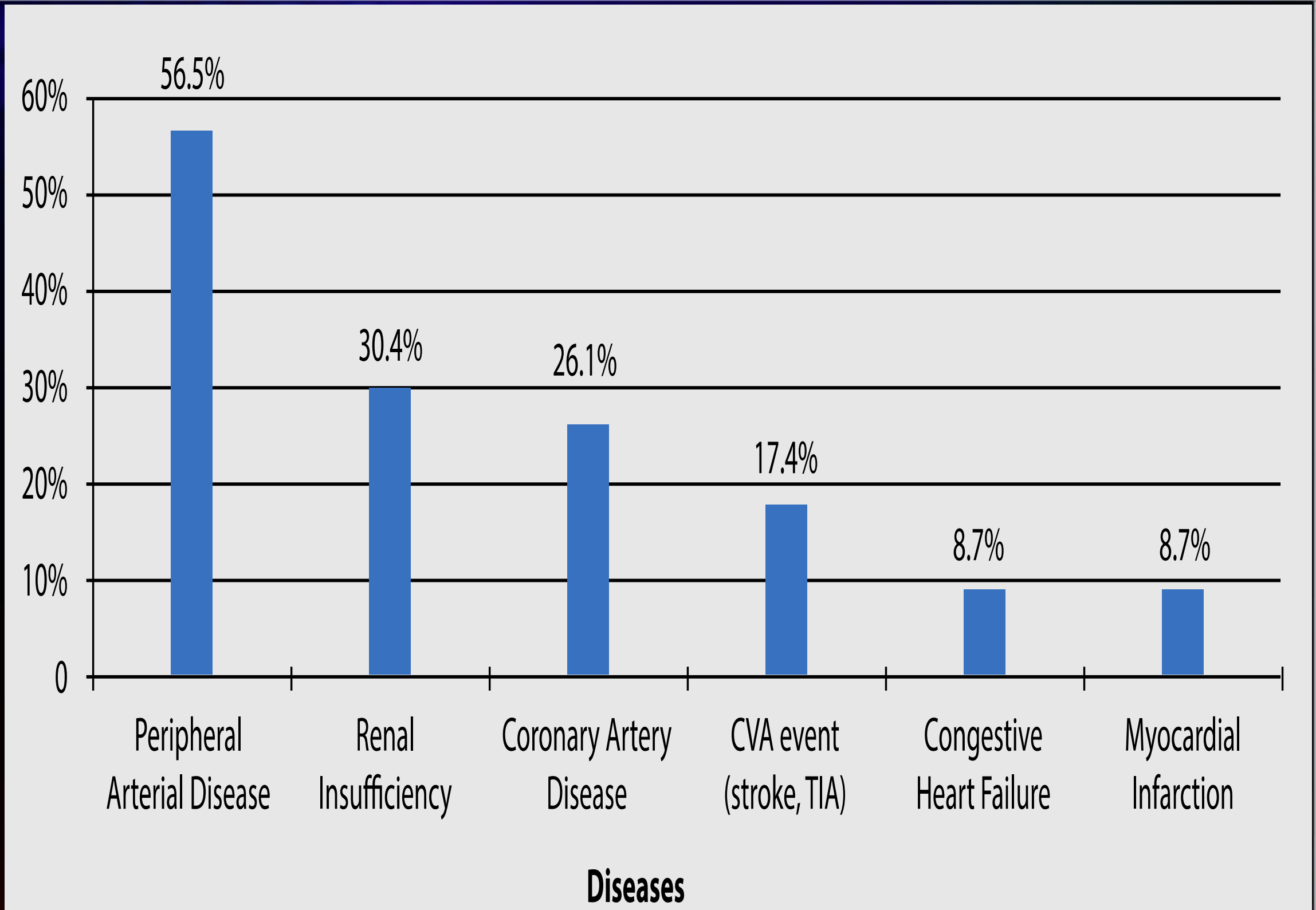
C Vaislic, JN Fabiani, S Chocron, JM Alsac, Y Glock, H Rousseau, P Leprince, J Robin, T Unterseeh, JP Villemot, V Costache, M Sapoval,

STRATO Endpoints

Primary efficacy endpoint : *Aneurysm exclusion from circulation*
Branch & Collateral patency

Primary safety endpoint : All cause *Mortality*

Secondary endpoints: *Type I or III endoleaks*
2nd open or endovascular procedure
Spinal cord ischemia
Stent migration or loss of stent integrity
Aneurysm rupture
Major adverse events
Change of size:
Maximum Diameter
Volume (thrombus and flow)

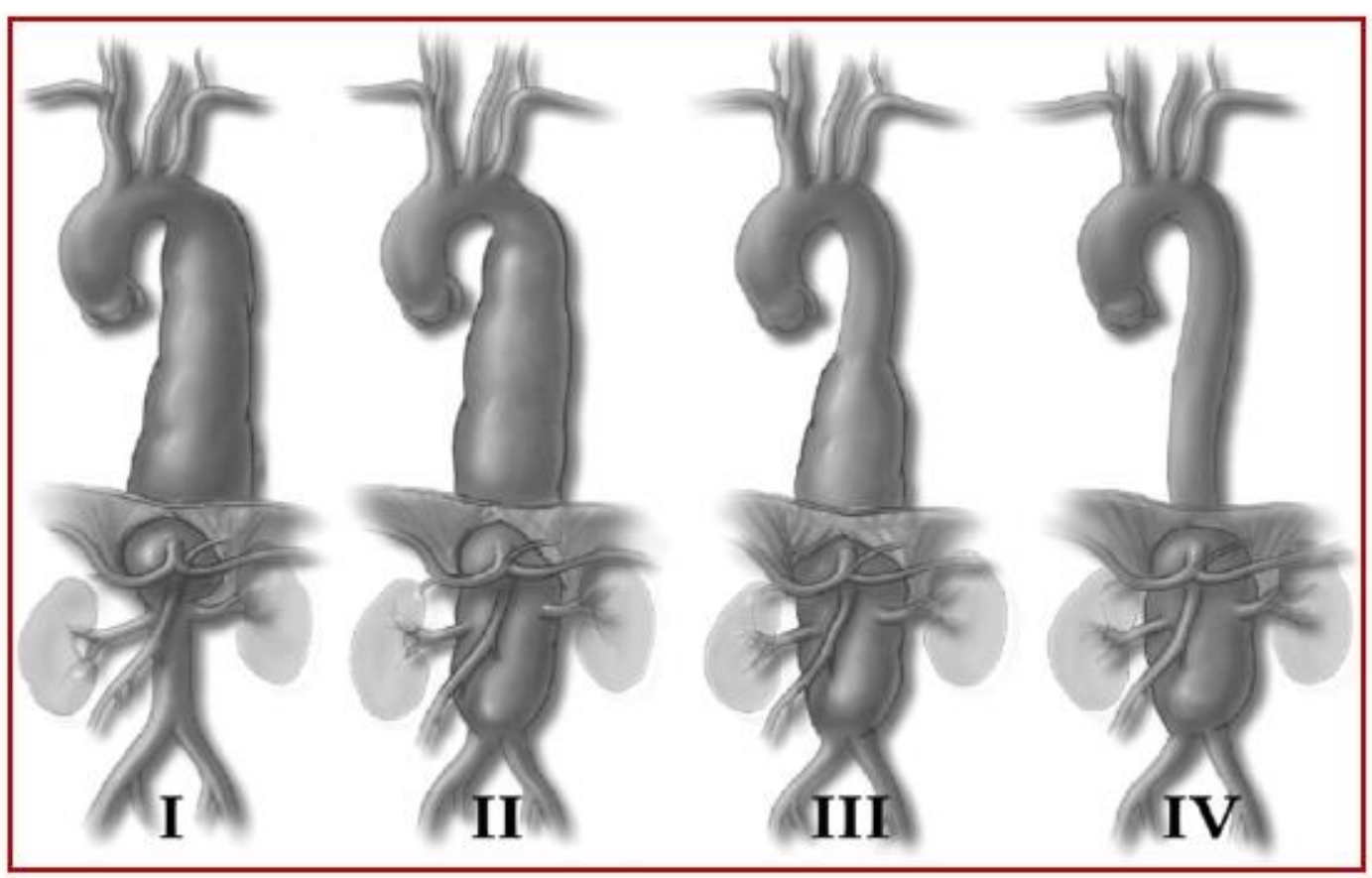

60%
50%
40%
30%
20%
10%
0
56.5%
30.4%
26.1%
17.4%
8.7%
8.7%
Peripheral Arterial Disease
Renal Insufficiency
Coronary Artery Disease
CVA event (stroke, TIA)
Congestive Heart Failure
Myocardial Infarction
Diseases

Previous Aortic Intervention

		Yes
Aortic Interventions (All types)		**15 (65.2%)**
	Endovascular	1
	Surgery	**14**

Aneurysm Description

- 10 Crawford Type II (43.5 %)
- 13 Crawford Type III (56.5 %)
- Mean Diameter: 65 mm (46 –85mm)
- Length: 162.5 mm (36-408mm)



Procedural Data

Acute Procedural Data	STRATO	HAS Report (Fenestrated endoprosthesis)
Average Deployment time (mean (range))	4.5 min (2-10min)	-
Duration of Procedure (min) (mean (range))	84 min (45-125min, n=19)	237 min (85-600, 6 studies)
Duration of Fluoroscopy (min) (mean (range))	19 min (5-120min, n=22)	60 min (5-117min, 7 studies)
Contrast Volume (cc) (mean (range))	129 cc (50-300ml, n=21)	199 cc (9-400ml, 9 studies)
Estimated blood loss (cc) (mean (range))	68 cc (0-250ml, n=21)	

All cause Mortalities

Mortality	30 days	6 months	12 months	24 months	36 months	Cumulative Mortality
All-cause	0	0	1/23	2/23	4/23	7/23

Mortality

Age	EuroScore	Cause of Death	Ø Aneurysm Discharge/ Last F-Up
88y	16	Cancer	Ø Discharge – 6,96cm Ø Last F-Up – M24 – 6,7cm
60y	14	Peritonitis	Ø Discharge – 7,82cm Ø Last F-Up – M15 – 8,32cm
60y	9	Endoleak Type I Post-explantation Infection	Ø Discharge – 7,07cm Ø Last F-Up – M36 – 9,01cm
86y	11	Endoleak Type I. Patient refused re-intervention	Ø Discharge – 7,35cm Ø Last F-Up – M12 – 8,65cm
78y	10	Endoleak Type III inadequate overlap.	Ø Discharge – 7,62cm Ø Last F-Up – M06 – 8,64cm
88y	12	Unknown reason	Ø Discharge – 6,95cm Ø Last F-Up – M24 – 8cm
82y	11	Unknown reason	Ø Discharge – 7,03cm Ø Last F-Up – M16 – 8,9cm

Study Exit

Age	Explantation	Ø Aneurysm Discharge/ Last F-Up
57y	at 21 months Pneumonectomy for ca days after MFM Chemotherapy months after	Ø Discharge – 5,9cm Ø Last F-Up – M12 – 6,79cm
62y	at 29 months Non corrected Type I Endoleak.	Ø Discharge – 7,07cm Ø Last F-Up – M24 – 7,85cm

Explanted Cases

Age	Lost to Follow-Up	Ø Aneurysm Discharge/ Last F-Up
80y	At 27 months	Ø Discharge – 5,26cm Ø Last F-Up – M24 – 4,78cm
85y	At 12 months	Ø Discharge – 6,01cm Ø Last F-Up – M03 – 6,18cm
91y	At 2 months	Ø Discharge – 7,9cm No Follow-Up available.

Lost to F-Up

Key Clinical Outcomes

- No Spinal Cord Ischemia
- No Aneurysm Rupture
- No Migration
- No Stent Fracture
- No Respiratory, Renal or Peripheral complications

Visceral Branch Patency

Branch Patency	12 months	24 months	36 Months
Number of patients	n=20	n=17 (13 follow-up)	n=11 (11 follow-up)
Celiac Trunk Patency	93% (13/14)	85% (11/13)	100% (11/11)
Secondary Patency	100% (14/14)		
Superior Mesenteric Artery Patency	94% (15/16)	100% (12/12)	100% (11/11)
Secondary Patency	100% (16/16)		
Left Renal artery Patency	100% (13/13)	100% (13/13)	91%* (10/11)
Right Renal Artery	100% (15/15)	100% (13/13)	100% (11/11)

At 36 months in 11 pts : 1 occluded branch. Patient diagnosed with Horton's Disease

Endoleaks

Endoleaks	Discharge	6 months	12 months	24 months	36 Months
All Endoleaks (any and persistent)	30,3% (7/23)	30% (6/20)	20% (4/20)	15% (2/13)	9% (1/11)
Type I (Proximal)	21,7% (5/23)	20% (4/20)	20% (4/20)	15% (2/13)	0% (0/11)
Type I (Distal)	4,3% (1/23)	5% (1/20)	0% (0/20)	0% (0/13)	0% (0/11)
Type III (Misoverlapping)	4,3% (1/23)	5% (1/20)	0% (0/20)	0% (0/13)	9% (1/11)*

Endoleak type 3 in 1 pt (9%)

Clinical Success

Clinical Success	6 months	12 months	24 months	36 Months
Aneurysm Exclusion	65% (13/20)	75% (15/20)	92% (12/13)	91% (10/11)
Aorta and MFM Patency	100% (20/20)	100% (20/20)	100% (13/13)	100% (11/11)

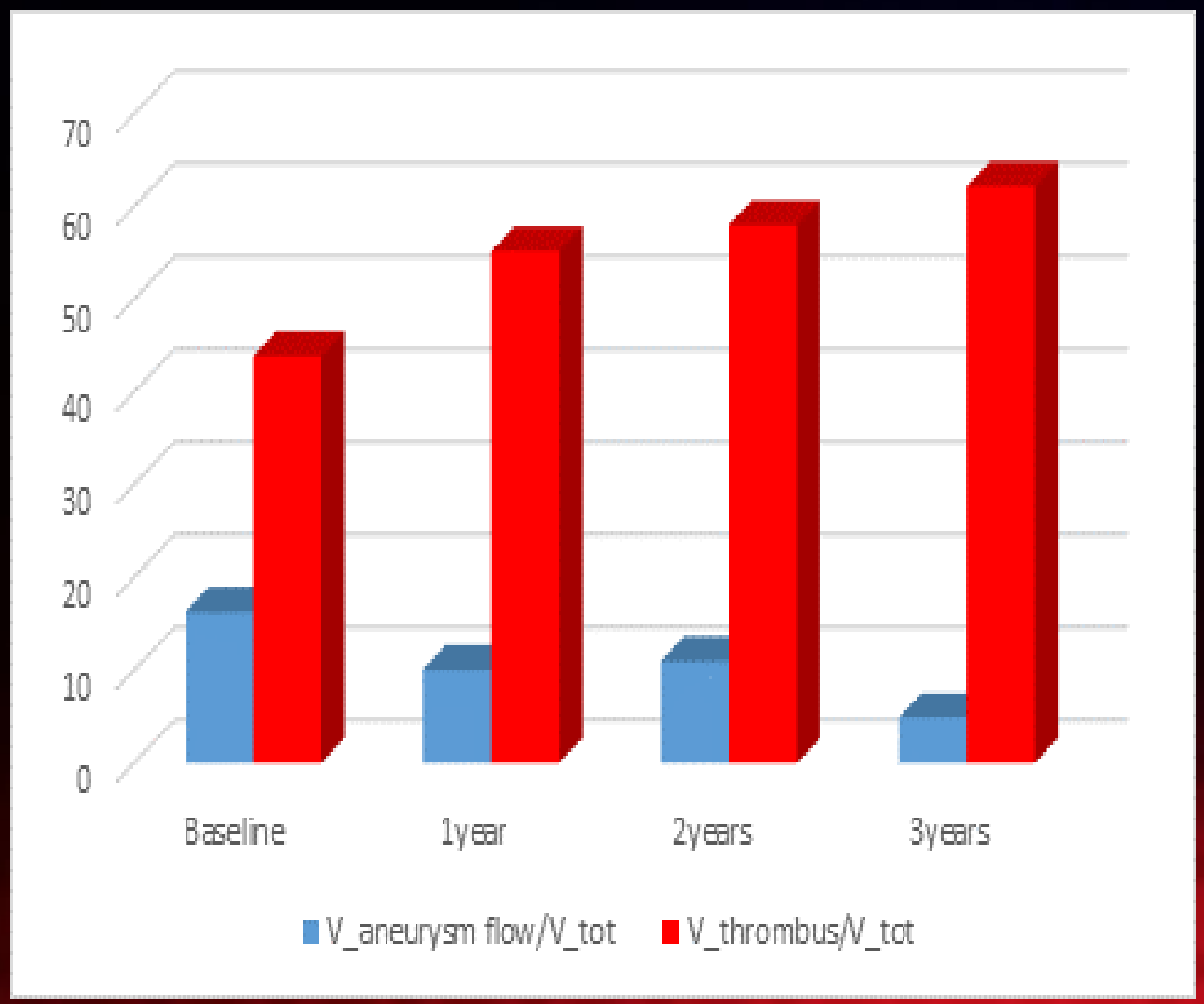
Change in Size

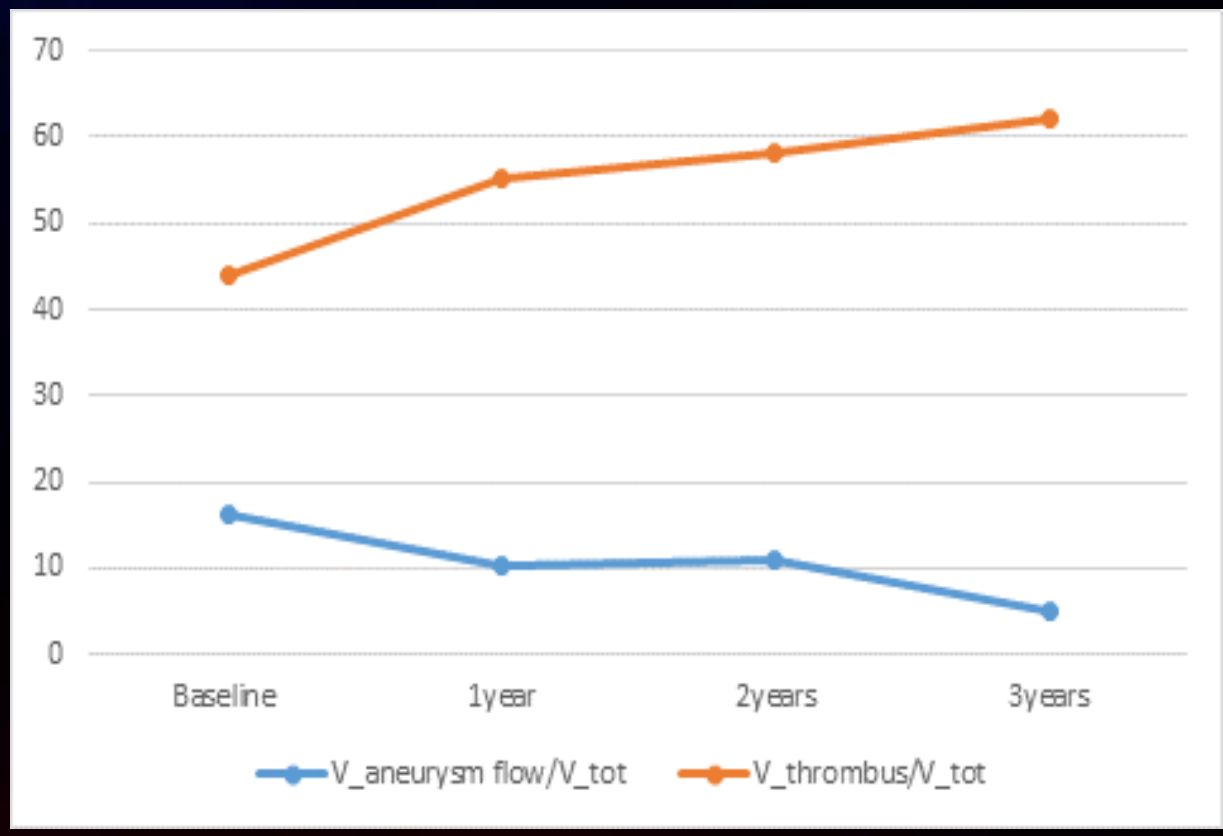
Change in Size	Baseline	12 months	24 months	36 Months
Maximal Diameter (mean (range) (nb patients))	**6,8mm** (5,3 – 8,1mm) (N=21)	**7,2mm** (5,4 – 9,0mm) (N=20)	7,0 mm (4,8 – 8,6mm) (N=13)	7,35 mm (5,7 – 9,0) (n=11)
Increase (>5mm/year)	-	45% (9/20)	0% (0/13)	27% (3/11)
Stable (<5mm/year)	-	55% (11/20)	92% (12/13)	64% (7/11)
Decrease (>5mm/year)	-	0% (0/20)	8% (1/13)	9% (1/11)
Aneurysmal Flow Volume / Total Volume (% / range (nb patients)	**16,3%** (2,2 - 42,9%) (N=19)	**10,1%** (0 - 31,7%) (N=17)	11% (0 - 45%) (N=12)	4,9% (0-25%) (n=10)
Thrombus Volume / Total Volume (% (range) (nb patients))	**43,9%** (17,1 - 80%) (N=19)	**55,2%** (37,9 - 79,4%) (N=17)	58% (10-86%) (N=12)	62,2% (34 – 86%) (n=10)

Thrombus change vs residual flow

(all patients [n=10])

All residual flows are less then 10% except in 1 patient with 25 % (Endoleak type III)

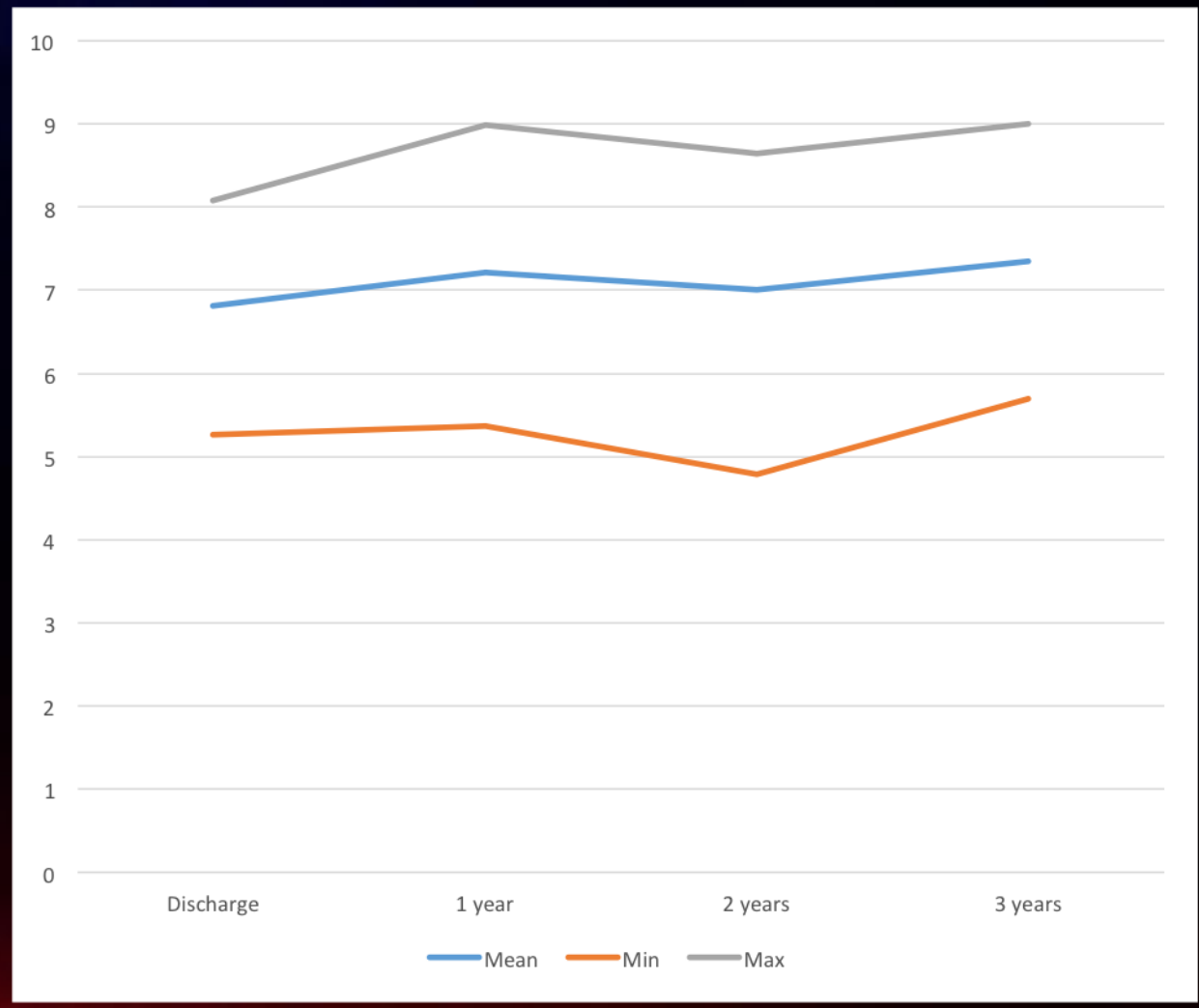




Evolution of the Max Diameter

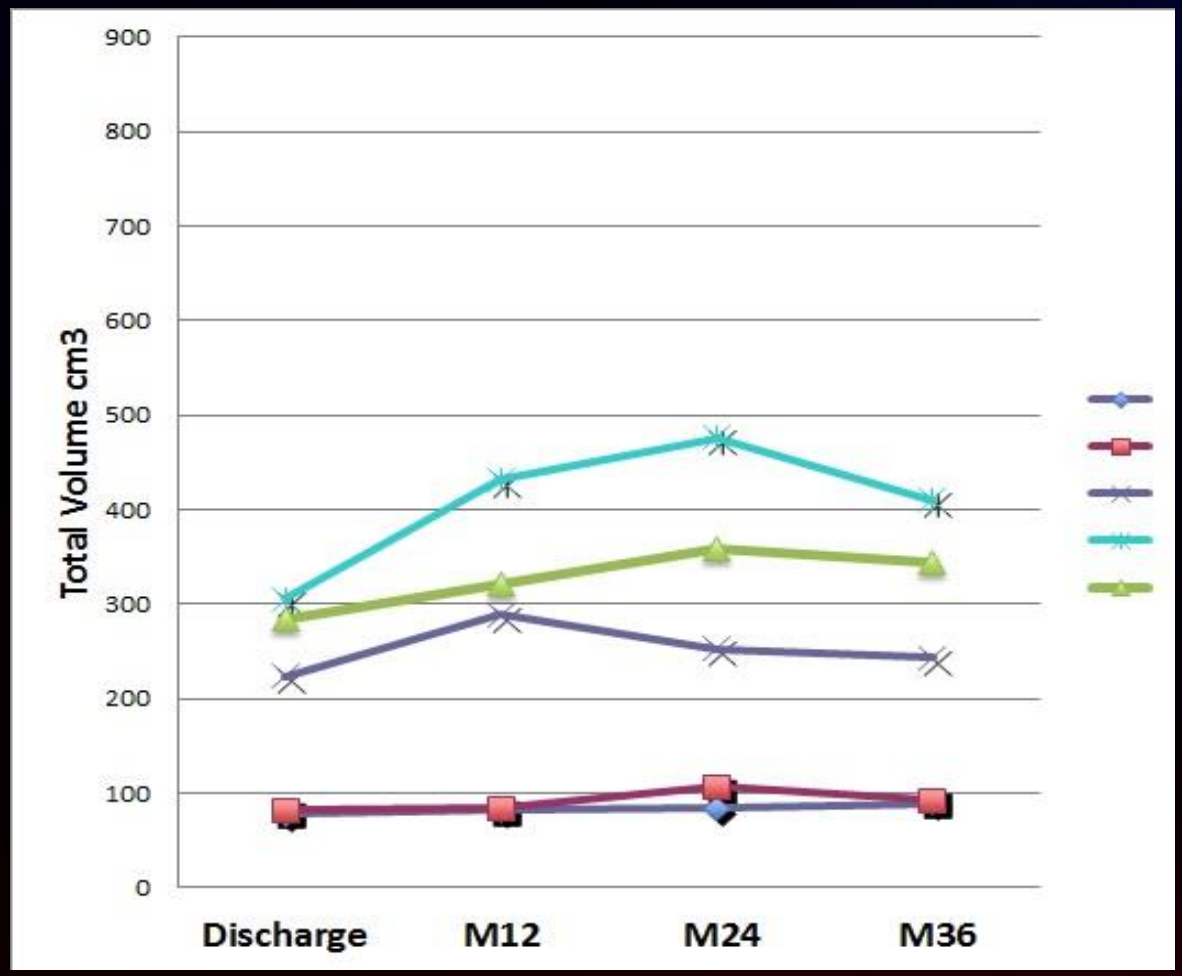
(all patients [n=11])

	Mean [cm]	Min [cm]	Max [cm]
Discharge	6,81	5,26	8,08
1 year	7,21	5,37	8,99
2 years	7,00	4,78	8,64
3 years	7,35	5,7	9*

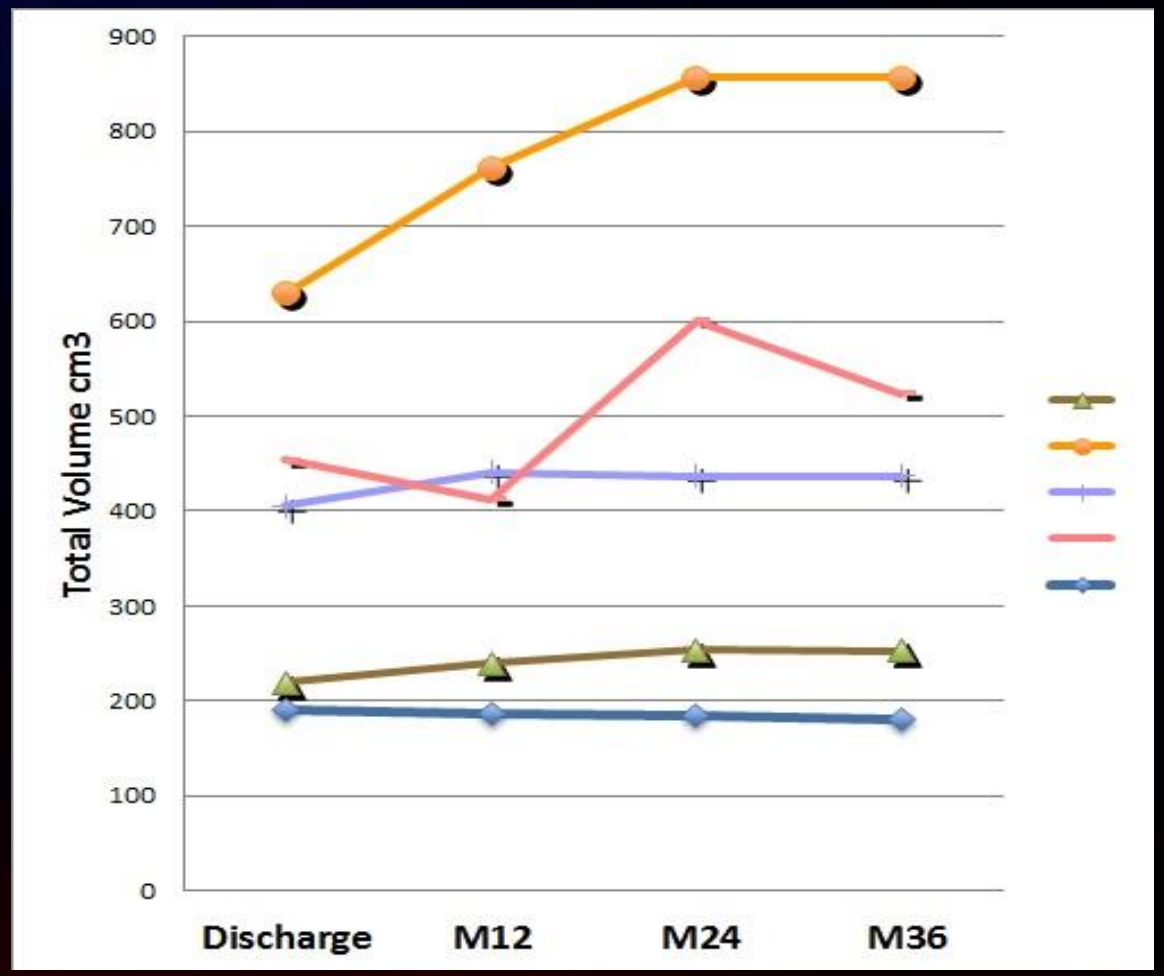


Aortic Diameter: Cut-off 70mm (+/- 2mm)

Patients **below** Cut-Off



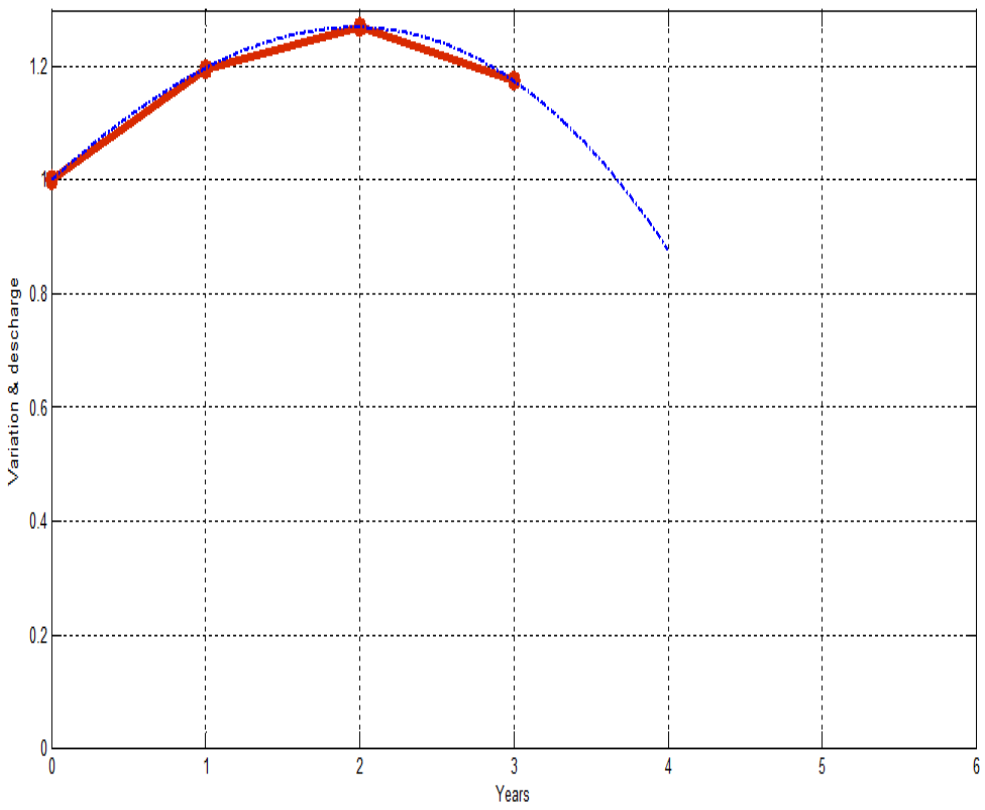
Patients **above** Cut-Off

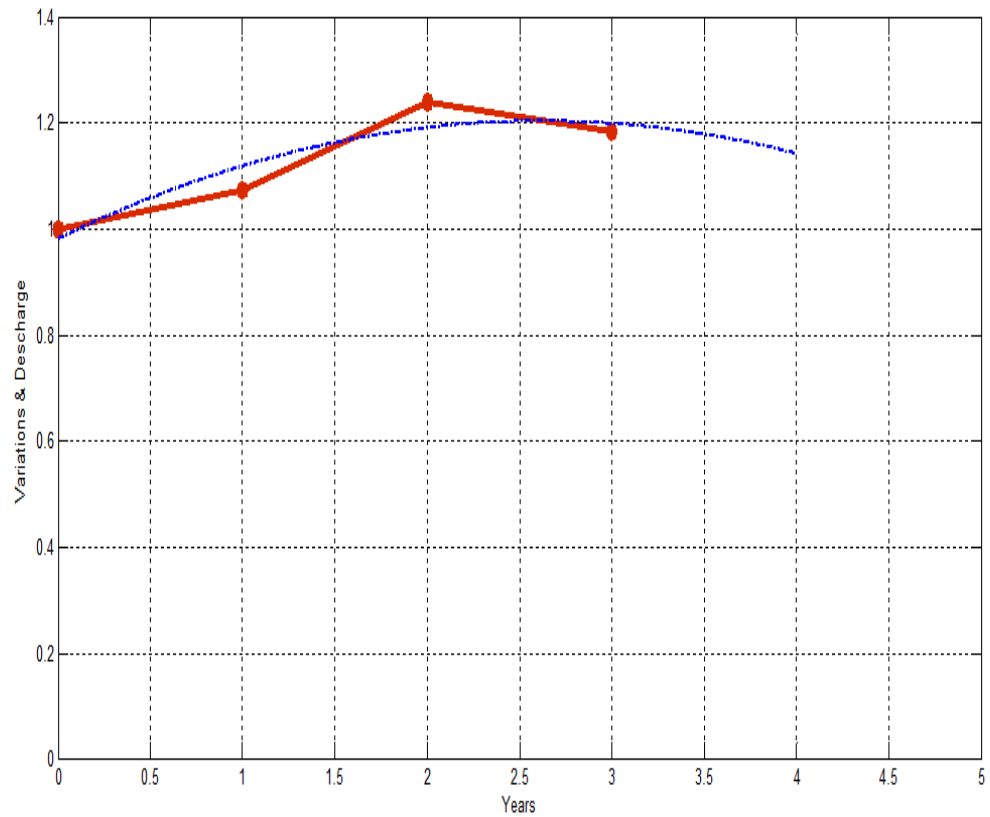


Aortic Diameter < 72mm

Aortic Diameter ≥ 72mm

Mean Total Volumes : Cut-off 70mm (+/- 2mm)





Aortic Diameter < 72mm

ELASTIC RECOIL

Aortic Diameter ≥ 72mm

NO ELASTIC RECOIL

Aortic Diameter: Cut-off 70mm (+/- 2mm)

When the Aorta exceeds the diameter threshold of 70mm (+/- 2mm), the standard configuration of elastin elements is lost.

< 70mm (+/- 2mm)

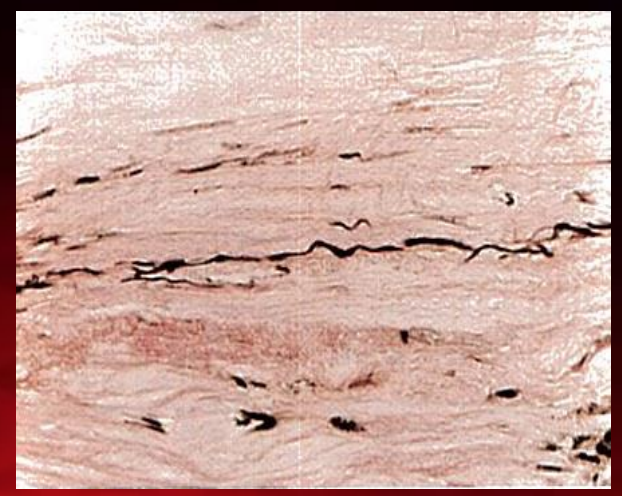
ELASTIC RECOIL

The patients with an initial Maximum Aortic Diameter < 70mm (+/- 2mm) present a Positive Evolution with diminution of the Total Volume.

≥70mm (+/- 2mm)

NO ELASTIC RECOIL

The patients with an initial Maximum Aortic Diameter ≥ 70mm (+/-2mm) present a Positive Evolution with stabilization of the Total Volume.

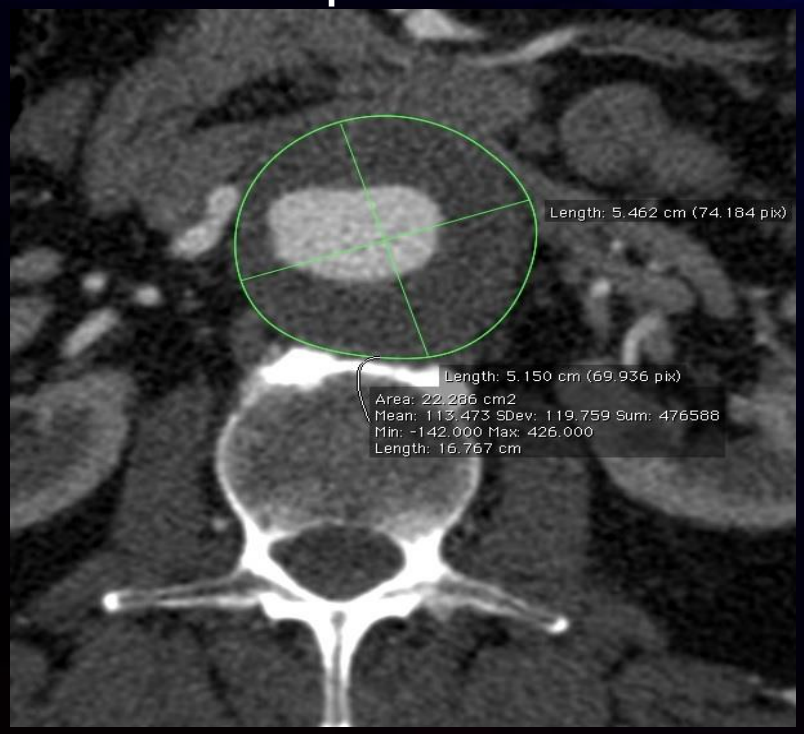


STRATO Study
3-years Results Summary

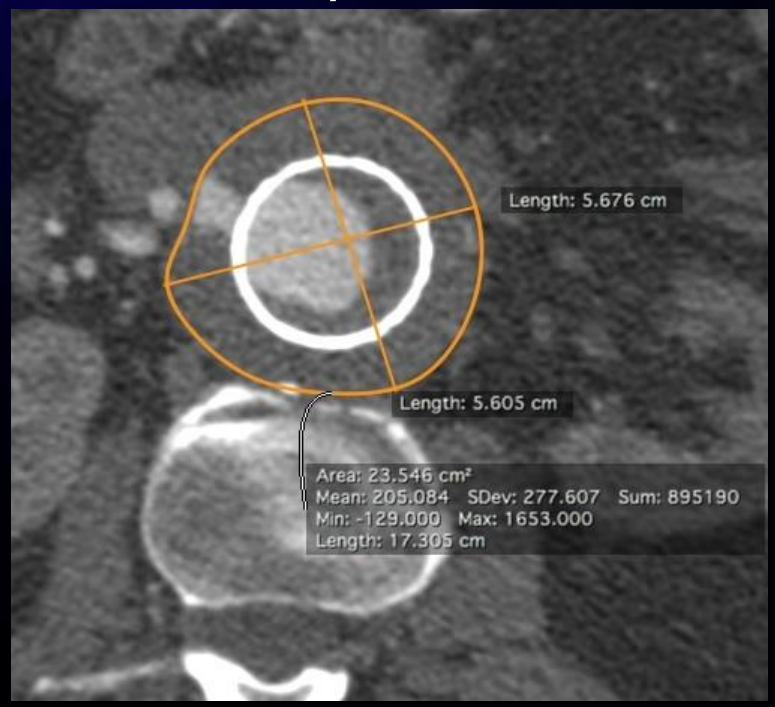
Criteria	STRATO
Aneurysm Exclusion	91% (10/11)
Aorta Patency	100% (11/11)
Primary Branch Patency	98% (51/52 covered visceral branches)
Migration	0%
Fracture	0%
Kinking	0%
Endoleaks	9% (1/11)
Re-interventions	35% (8/23: 6 endovascular (for endoleak) – 2 surgeries – 1 MFM extended)
Maximal Diameter	Baseline: 68mm (53-81mm) – 2 years: 72mm (48-90mm) - 3 years: 73mm (57-90mm)
Change (≠ 5 mm/year)	↘ 9% ; ➔ 64% ; ↗ 27% (Endoleak/ Surgery)
Residual Flow Volume Ratio	Baseline: 14.2% - 1 year: 10.1% - 2 years: 9% - **3 years: 4,9%**
Thrombus Volume Ratio	Baseline: 45.5% - 1 year: 55.2% - 2 years: 61% - 3 years: 62%
Paraplegia/Paraparesia	**0%**
Aneurysm Rupture	**0%**

Patient IC0308_FRA_69_01

PRE-Implantation



Follow-Up at 12 Months



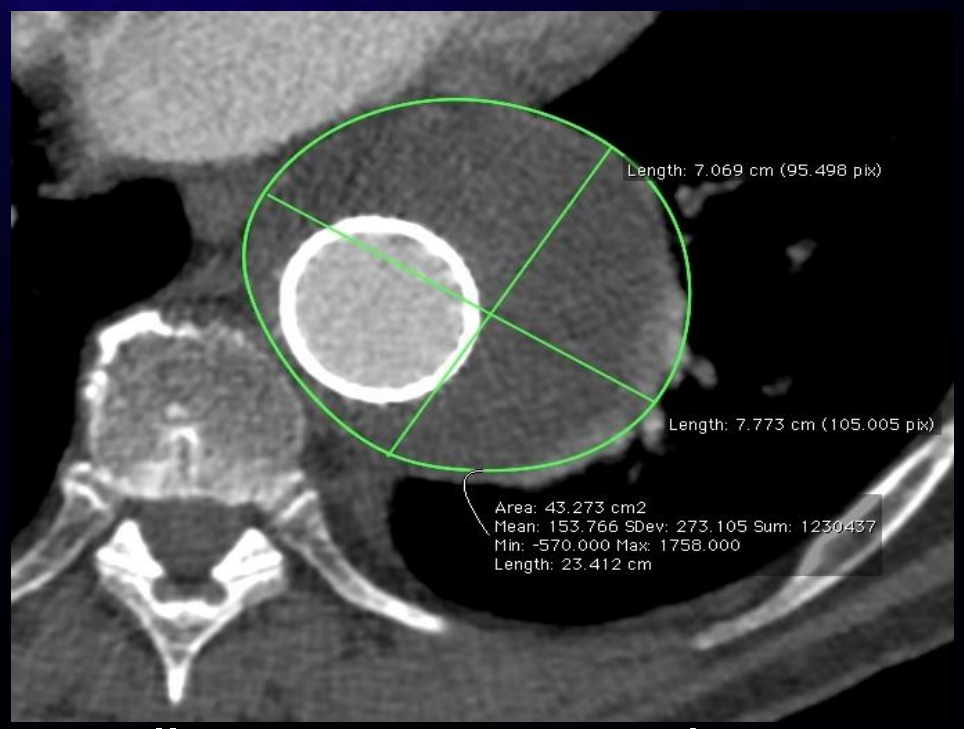
Follow-Up at 24 Months

Follow-Up at 36 Months

Patient IC0308_FRA_69_05

PRE-Implantation

Follow-Up at 12 Months



Follow-Up at 24 Months

Follow-Up at 36 Months

Conclusion

- All aneurysms thrombosed with a residual flow < 10% (except 1 with endoleak type III non-treated)

- At 3 years 7 out of 11 (64%) have stable aneurysm diameter

- An initial diameter < 70mm dictates a stabilization and reduction