UNIVERSITÄTS KLINIKUM HEIDELBERG

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LINC Around the world

3 years of experience in more than 100 patients using TAG conformable with active control - what did we learn ?

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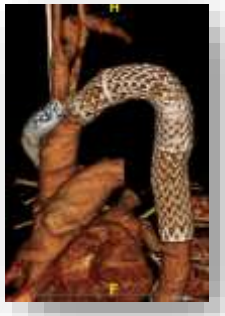

Disclosures

- Consultant
  - Cook, Endologix, Gore, Medtronic
- Research Grant
  - Cook, Gore, Maquet, Medtronic, Siemens
- Advisory Board
  - Endologix, Gore, Maquet, Medtronic, Siemens
- Speaker Honoraria
  - Cook, Endologix, Gore, Maquet, Medtronic, Siemens
- Major Stokeholder
  - none

23 Years of Stent Graft Evolution

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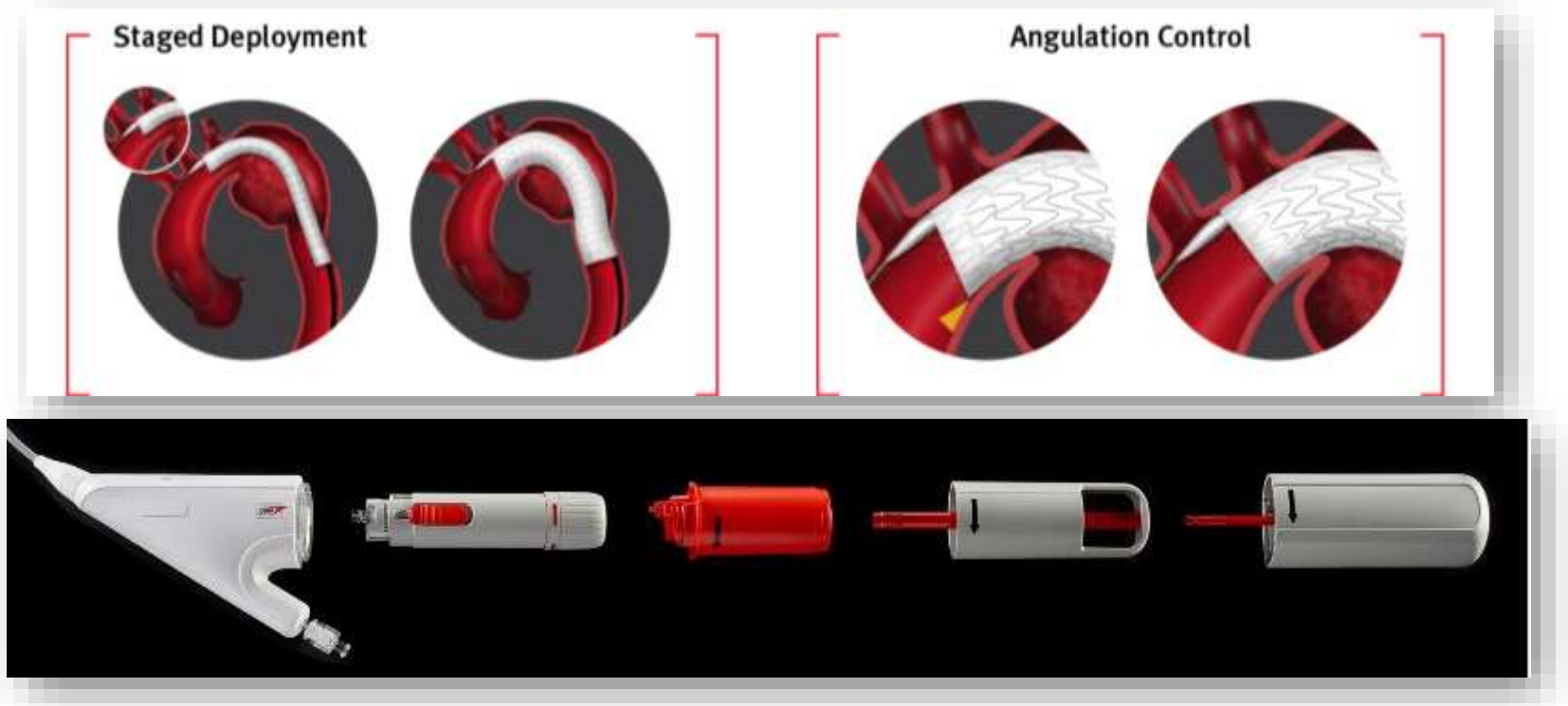
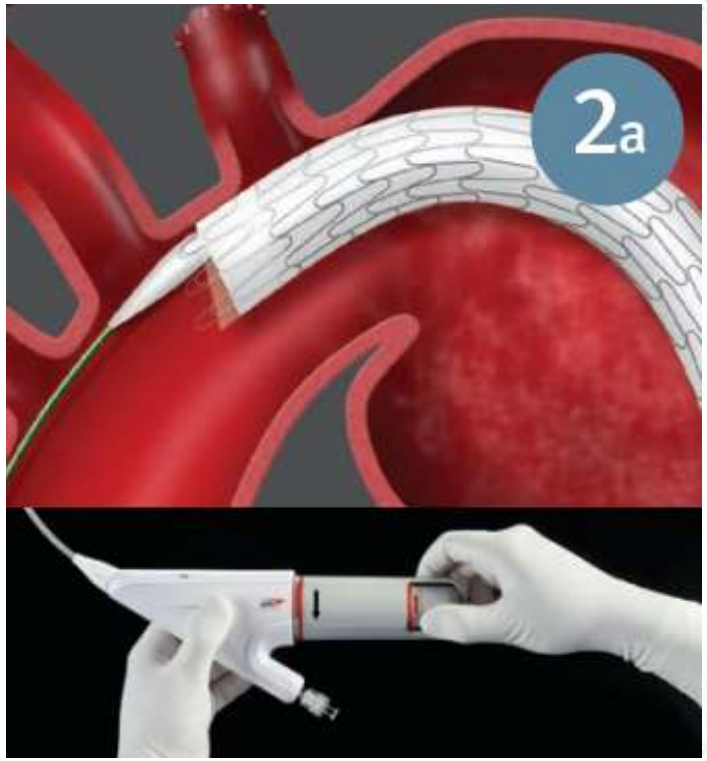
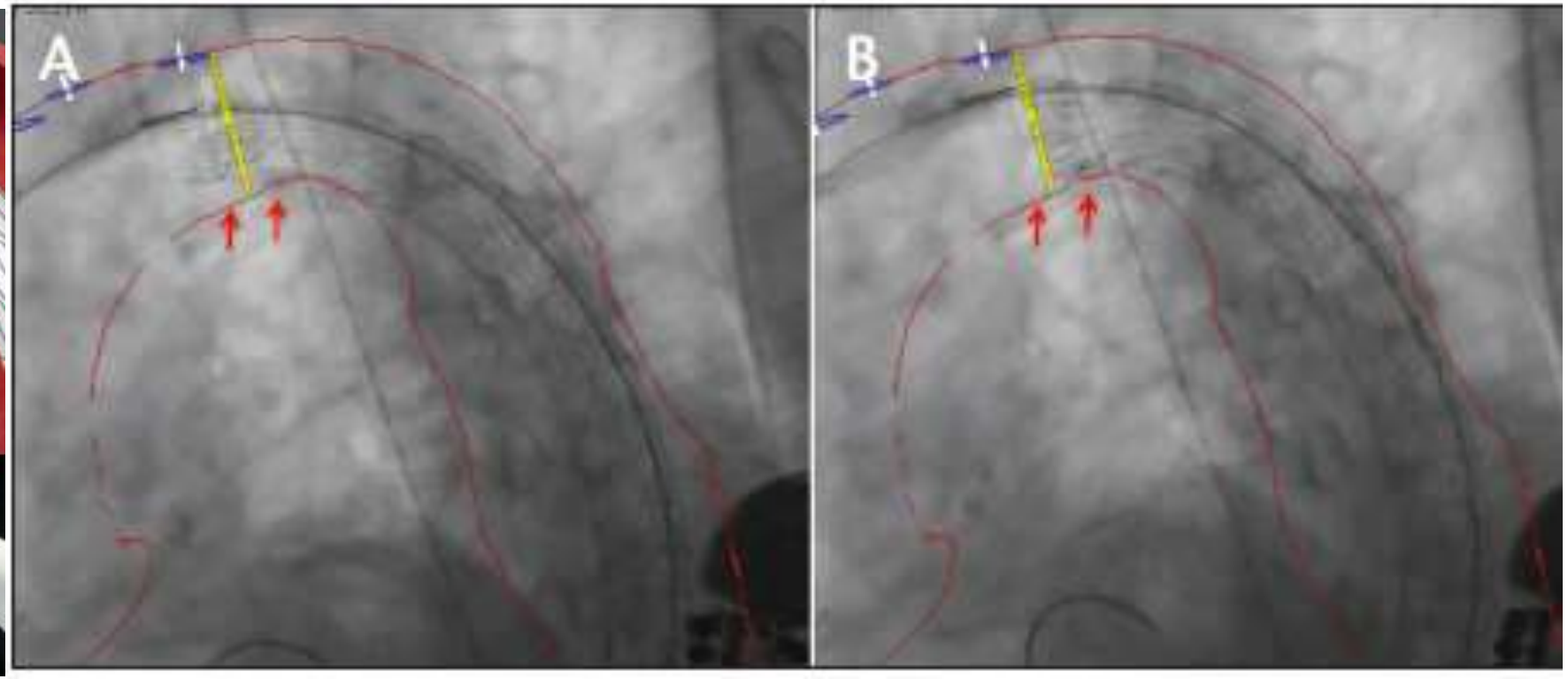
CTAG with ACTIVE CONTROL System (ACS)



- Staged deployment > continous blood flow ensures heodynamic stability
  > enabling adjustment of device placement
- Deployment sequence changed – intermediated (50%) and full deployment
- Lockwires attach stentgraft to the catheter system
- Active proximal angulation > enabling apposition in the arch

Angulation Control is Optional





at physician discretion – at intermediate and after full deployment – but can not be reversed or undone

Overall TEVAR Experience Heidelberg (n=684)

March 1997 – January 2021

	Total	Elective	Emergency (47.5%)
Thoracic aortic aneurysm (TAA)	122	86	36
Ruptured TAA	44	-	44
Thoracoabdominal aneurysm	93	63	30
Penetrating aortic ulcer (PAU)	103	57	46
Traumatic aortic rupture	35	-	35
Chronic Typ B dissection	80	62	18
Acute/subacute Typ B dissection	104	42	62
Intramural haematoma (IMH)	47	28	19
Typ A Dissection	13	4	9
Aortobronchial/-esophageal fistula	20	-	20
Patch Rupture	3	1	2
Post CoA Aneurysm	10	7	3
Anastomotic aneurysm	10	9	1

CTAG with ACS - Experience Heidelberg

July 2017 – Januar 2021 – 3.5 years

684 TEVAR procedures

361 patients with 556 CTAG

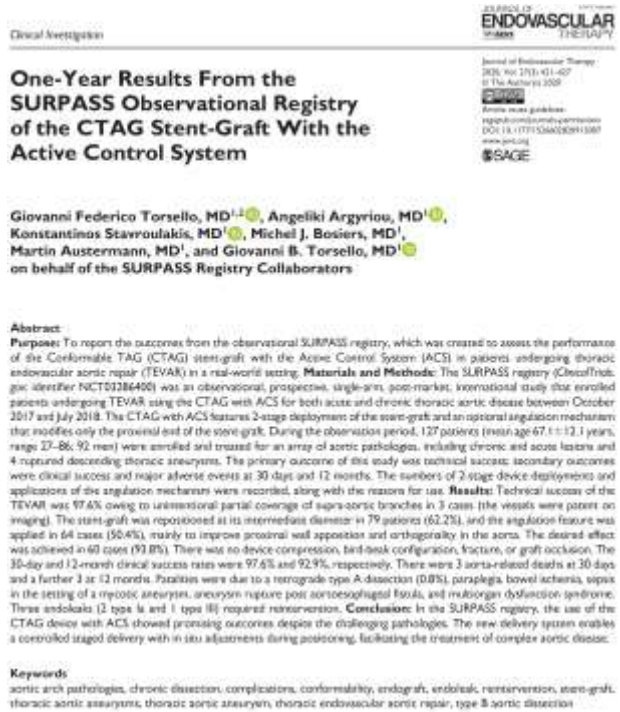
145 patients with 217 devices CTAG with Active Control System

1st pat. in July 2017 – post-coarctatio aneuyrsm

Objective & Methods

- To evaluate 3 yrs. technical and clinical outcomes of CTAG with ACS
- Retrospective single center study - prospectively mantained data base

submitted



Clinical Investigation

ENDOVASCULAR THERAPY

One-Year Results From the SURPASS Observational Registry of the CTAG Stent-Graft With the Active Control System

SAGE

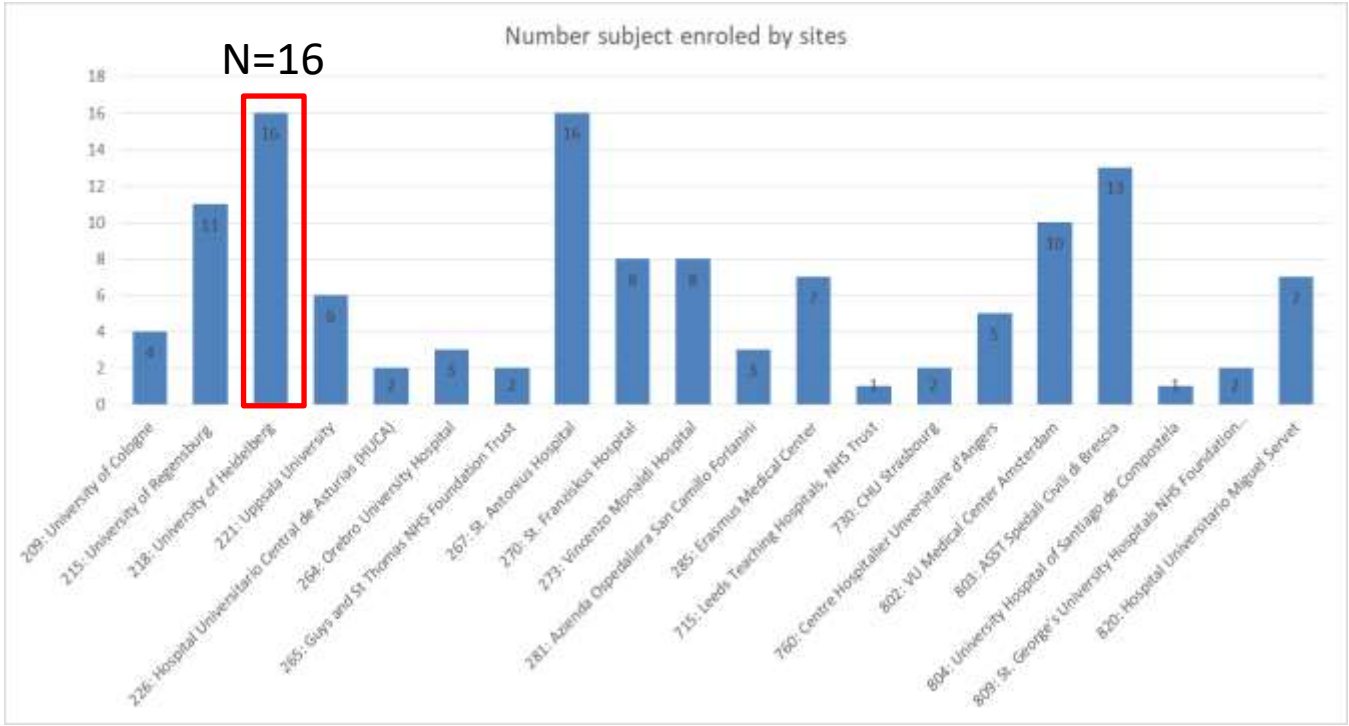
Giovanni Federico Torsello, MD[1,2], Angeliki Argyriou, MD[1], Konstantinos Stavroulakis, MD[1], Michel J. Bosiers, MD[1], Martin Austermann, MD[1], and Giovanni B. Torsello, MD[1] on behalf of the SURPASS Registry Collaborators

Abstract

Purpose: To report the outcomes from the observational SURPASS registry, which was created to assess the performance of the Conformable TAG (CTAG) stent-graft with the Active Control System (ACS) in patients undergoing thoracic endovascular aortic repair (TEVAR) in a real-world setting. **Materials and Methods:** The SURPASS registry (ClinicalTrials.gov identifier NCT01286400) was an observational, prospective, single-arm, post-market, international study that enrolled patients undergoing TEVAR using the CTAG with ACS for both acute and chronic thoracic aortic disease between October 2017 and July 2018. The CTAG with ACS features 2-stage deployment of the stent-graft and an optional angulation mechanism that modifies only the proximal end of the stent-graft. During the observation period, 127 patients (mean age 67.1 ± 12.1 years, range 27–86; 92 men) were enrolled and treated for an array of aortic pathologies, including chronic and acute lesions and 4 ruptured descending thoracic aneurysms. The primary outcome of this study was technical success; secondary outcomes were clinical success and major adverse events at 30 days and 12 months. The numbers of 2-stage device deployments and applications of the angulation mechanism were recorded, along with the reasons for use. **Results:** Technical success of the TEVAR was 97.6% owing to unintentional partial coverage of supra-aortic branches in 3 cases (the vessels were patent on imaging). The stent-graft was repositioned at its intermediate diameter in 79 patients (62.2%), and the angulation feature was applied in 64 cases (50.4%), mainly to improve proximal wall apposition and orthogonality in the aorta. The desired effect was achieved in 60 cases (93.8%). There was no device compression, bird-beak configuration, fracture, or graft occlusion. The 30-day and 12-month clinical success rates were 97.6% and 92.9%, respectively. There were 3 aorta-related deaths at 30 days and a further 3 at 12 months. Fatalities were due to a retrograde type A dissection (0.8%), paraplegia, bowel ischemia, sepsis in the setting of a mycotic aneurysm, aneurysm rupture post aortoesophageal fistula, and multiorgan dysfunction syndrome. Three endoleaks (2 type Ia and 1 type III) required reintervention. **Conclusion:** In the SURPASS registry, the use of the CTAG device with ACS showed promising outcomes despite the challenging pathologies. The new delivery system enables a controlled staged delivery with in situ adjustments during positioning, facilitating the treatment of complex aortic disease.

Keywords

aortic arch pathologies, chronic dissection, complications, conformability, endograft, endoleak, reintervention, stent-graft, thoracic aortic aneurysms, thoracic aortic aneurysm, thoracic endovascular aortic repair, type B aortic dissection



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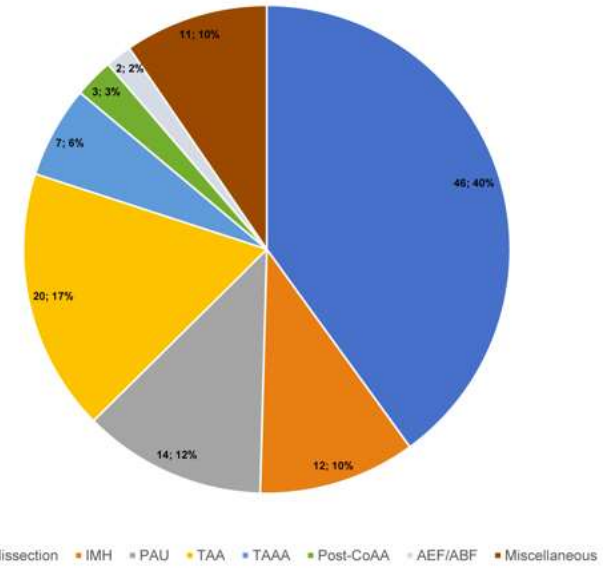
Patient Characteristcs (n=115)

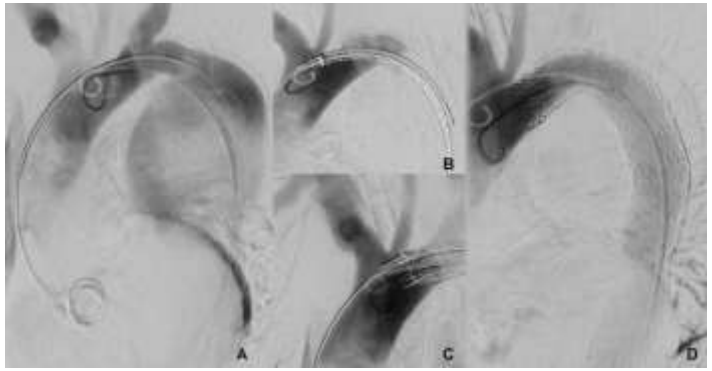
	Total (N = 115)
Age, years (median/IQR)	63 (53-74)
Gender (male/female)	82/33
ASA-classification (median/IQR)	3 (2-4)
Heart failure	10 (8.7%)
Ischemic heart disease	28 (24,3%)
History of stroke	11 (9.5%)
COPD	13 (11.3%)
Diabetes mellitus	14 (12.2%)
Peripheral vascular disease	4 (3.5%)
Renal Insufficiency (Crea > 1.2 mg/dl)	27 (23.5%)
Arch types	
Type I	30 (26.1%)
Type II	55 (47.8 %)
Type III	30 (26.1%)

Data are expressed using median/interquartile range; ASA: American Society of Anesthesiologists; COPD: chronic obstructive pulmonary disease; Crea: creatinine

Indications (n=115)

Underlying pathology	Numbers (%)
Aortic Dissection	46
IMH	5
PAU	9
TAA	5
TAAA	1
AEF /ABF	5
Miscellanous	9





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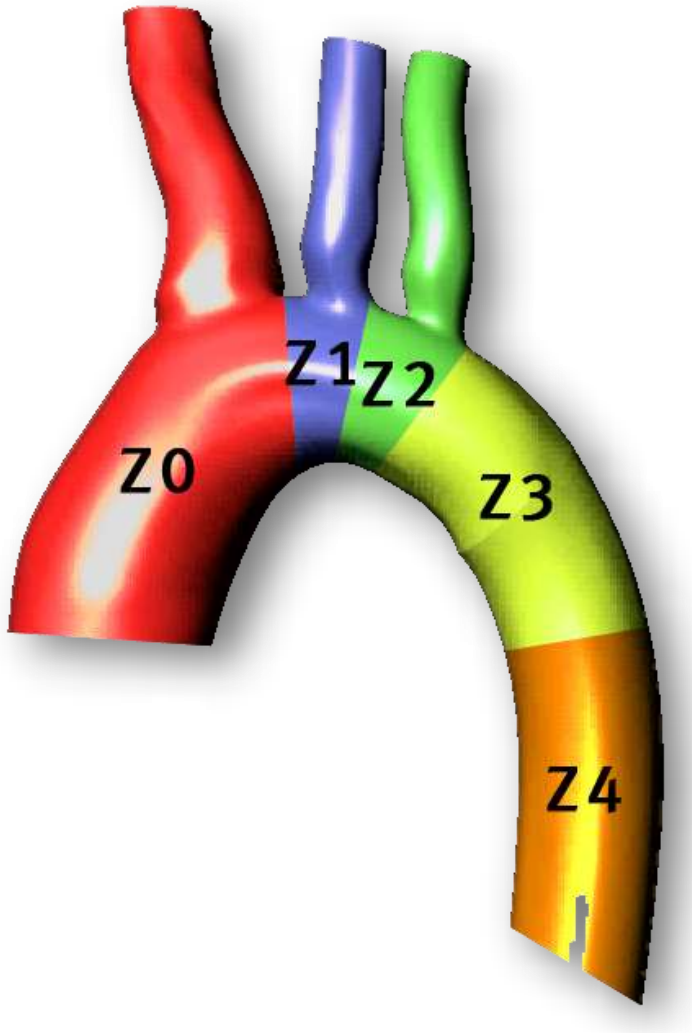
Procedural Data

- 173 devices in 115 consecutive patients
- Percutaneous access 58.2%
- Duration 190 min (70-142)
- Fluoroscopy time 9 min (7-14)
- Contrast volume 94 cc (70-145)
- LSA coverage 44.3% (n=51)

Landing Zones – Aortic Arch Involvement (n=115)



Proximal Landing Zone	Numbers
Zone 0	1 (0.9%)
Zone 1	15 (13%)
Zone 2	38 (33%)
Zone 3	31 (26.9%)
Zone 4	30 (26.1%)

Technical Results (n=115)

Median Follow up : 6 mths. (1.2- 13.8)

		% (n)
Technical Success		95.7 % (110)
Accuracy*	Landing Zone	87.8 % (101)
Inner Wall Apposition *	Bird beaking	93 % (107)

* Different patients : 4 in total

Definitions:

- Technical Results : according to the reporting standards [1]
- Accurate placement was deployment within the intended LZ [2]
- Non-conformability: gap of more than 2 mm between the proximal gold band and the inner aortic wall [2]

[1] Fillinger MF, et al. Society for vascular surgery Ad Hoc committee on TEVAR reporting standards reporting standards for thoracic endovascular aortic repair (TEVAR). J Vasc Surg 2010;52(4):1022-33.

[2] Böckler D et al. Thoracic Endovascular Aortic Repair of Aortic Arch Pathologies with the Conformable Thoracic Aortic Graft: Early and 2 year Results from a European Multicentre Registry, Eur J Vasc Endovasc Surg (2016) 51, 791- 800

Clinical Results (n=115)

Mean Follow up : 6.2 mths. (1.2- 18)

SAE	Specification	% (N)
Endoleak	Overall	11.3 % (13)
	Type Ia	0.8 (1)
	Type Ib	1.7 % (2)
	Type II	% (9)
	Type III	0.8 %(1)
Stroke	Overall	3.5 % (4)
	Ischemia	2
	Bleeding	2
Spinal Cord Ischemia	Grading 3 b [1]	3.5 % (4)

[1] Fillinger MF, et al. Society for vascular surgery Ad Hoc committee on TEVAR reporting standards reporting standards for thoracic endovascular aortic repair (TEVAR). J Vasc Surg 2010;52(4):1022-33.

Reintervention Rates

Mean Follow up : 6.2 mths. (1.2- 18)

- Overall reintervention 20.9 %
- Inhospital reintervention 15.7 %
- Reintervention during FU 3.8 %

Procedure-related reintervention	Total	RI in hospital	RI during FU
Conversion	1	0	1
Distal endograft extension	2	1	1
Endolining	3	2	1
Proximal extension ± rerouting	2	1	1
LSA revascularization	2	2	
LSA occlusion	6	6	
False lumen occlusion/candy plug	1	1	
Balloon dilatation/type III EL	1	1	
LCCA revascularization	1	1	
LCCA ligation + balloon dilatation/type Ia EL	1	1	
Visceral bypass	2	1	
Thrombendarterectomy CFA	2	2	
Access wound complication	3	3	
Stent graft iliac artery	1	1	
Craniotomy for intracranial bleeding	1	1	
Total	**29 in 24 patients (24/115; 20.9%)**	**24 in 18 patients (18/115; 15.7%)**	**4 in 4 patients (4/103; 3.8%)**

Mortality

Mean Follow up : 7 mths. (0,1- 20)

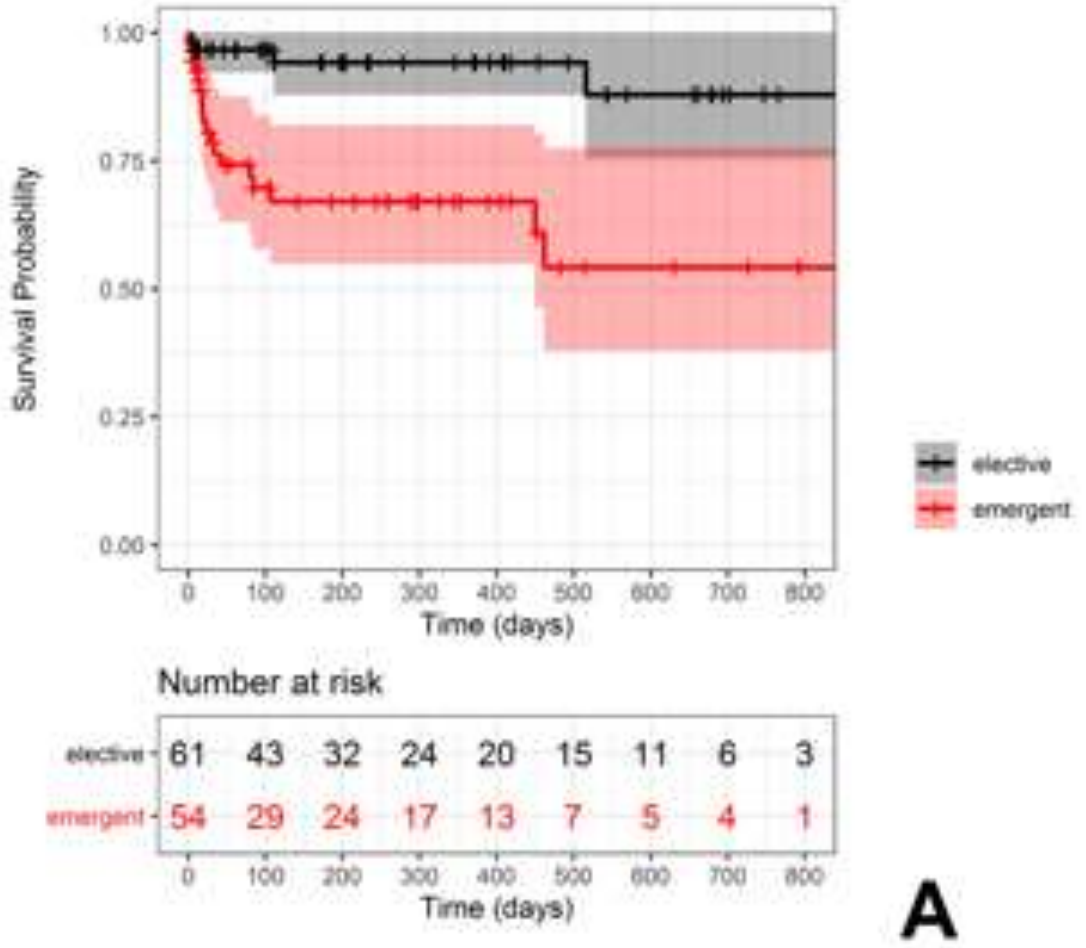
- All cause mortality 19 % (22/115)
- Procedure related mortality 12 % (14/115)

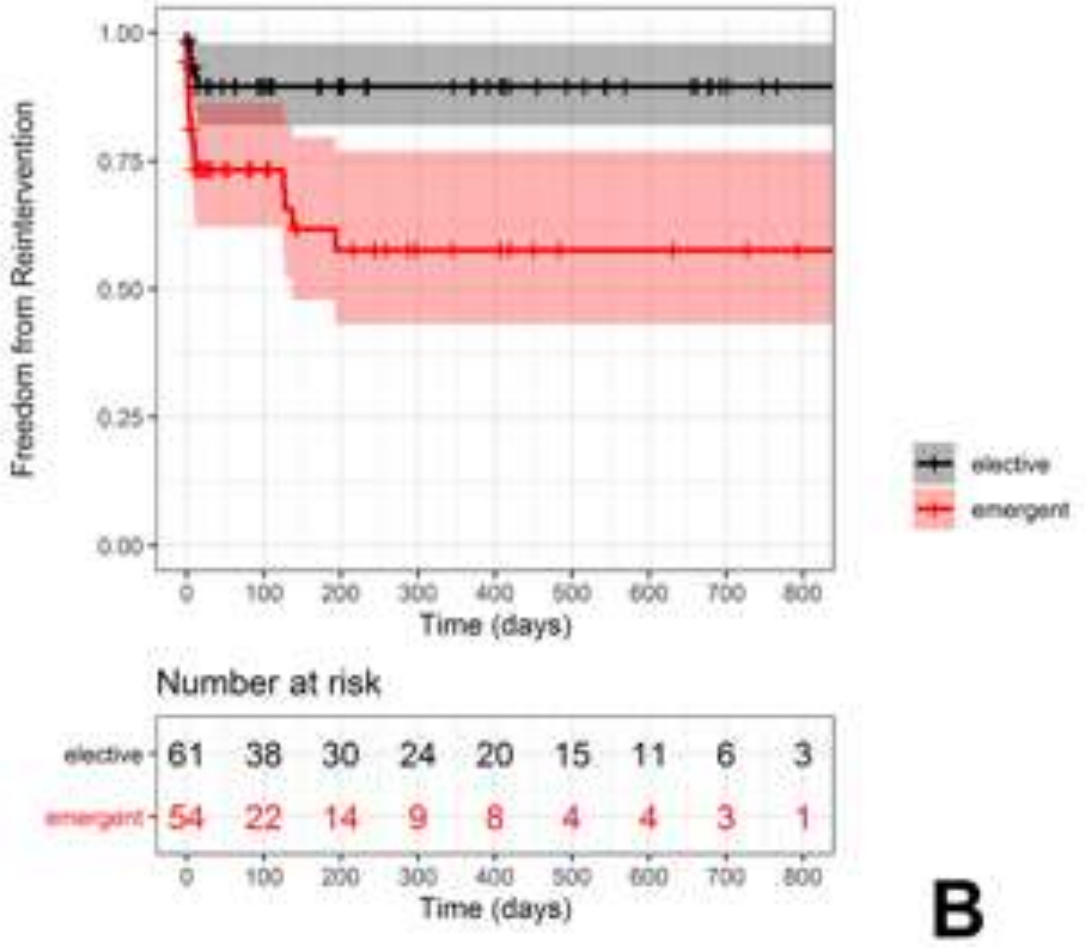
	All-cause-mortality	Procedure-related mortality
Multi-organ failure	10	8
Cardiac failure	2	2
Respiratory failure	1	1
Stroke	1	0
Cancer	1	1
Aorto-esophageal fistula	1	0
Upper gastrointestinal bleeding	2	1
Rupture/death during surgery	1	1
Undetermined	3	0
Total	**22/115 (19.1%)**	**14/115 (12.2%)**

Data are presented as absolute/relative numbers

Survival & Reinterventions electiv versus emergency (n=115)

Mean Follow up : 6 mths. (1.2- 18)





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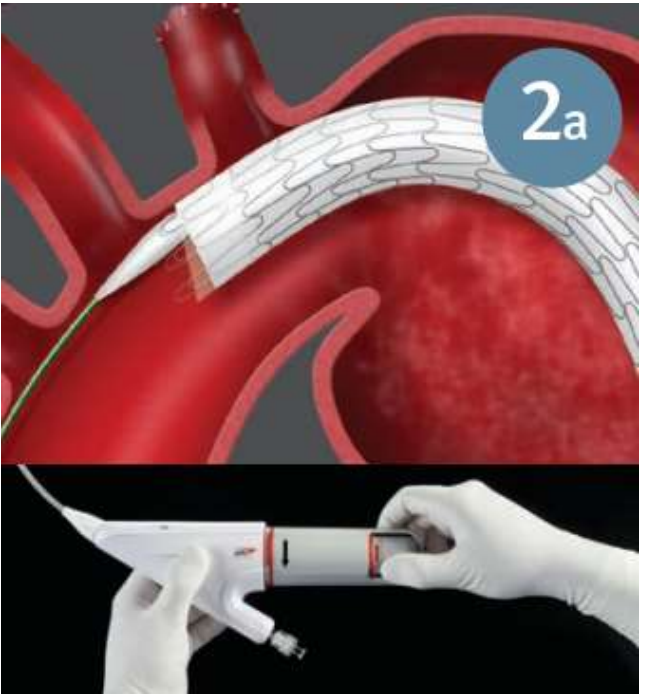
Use of Active Control (n = 115)



	When / Where	% (n)
Optional angulation used		22 % (25)
	intermediate deployment alone	78 % (18)
	intermediate and full deployment	22 % (5)
	after full deployment alone	0
Depending on Arch Type	Type I	8 % (2)
	Type II	52% (12)
	Type III	39 % (9)
Underlying Pathology	Degenerative disease (TAA & PAU)	35 % (8)
	Dissection (AoD & IMH)	48 % 11)
	Others	17 % (4)

When did I use or not use angulation
some learnings

- optional , at your discretion, but irreversible!
- expecially in gothic arches and aneurysms
- if in dissections, IMH or trauma, only at the intermediate deployment
- no angulation in short PLZ and pathology at inner curvature
- don‘t angulate in straight descending aorta > crimping of the device

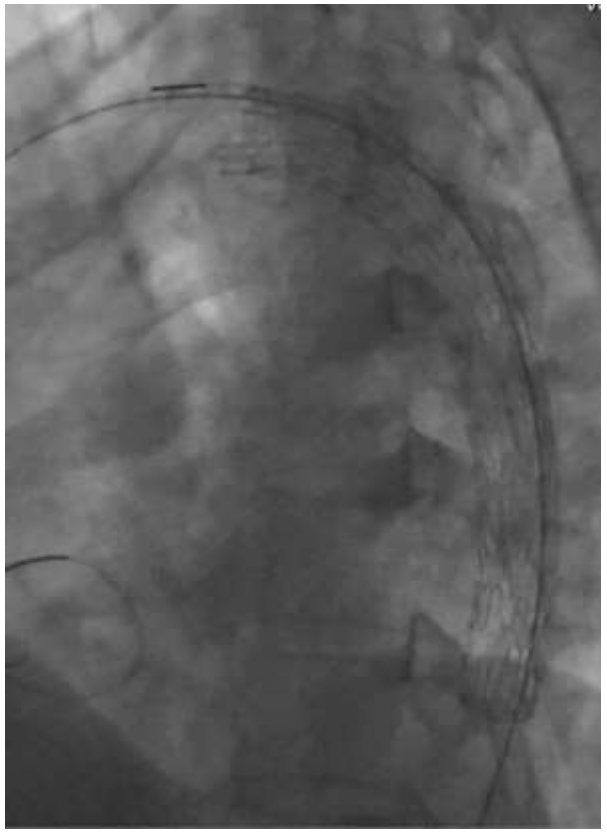
Benefits of CTAG with Active Control System

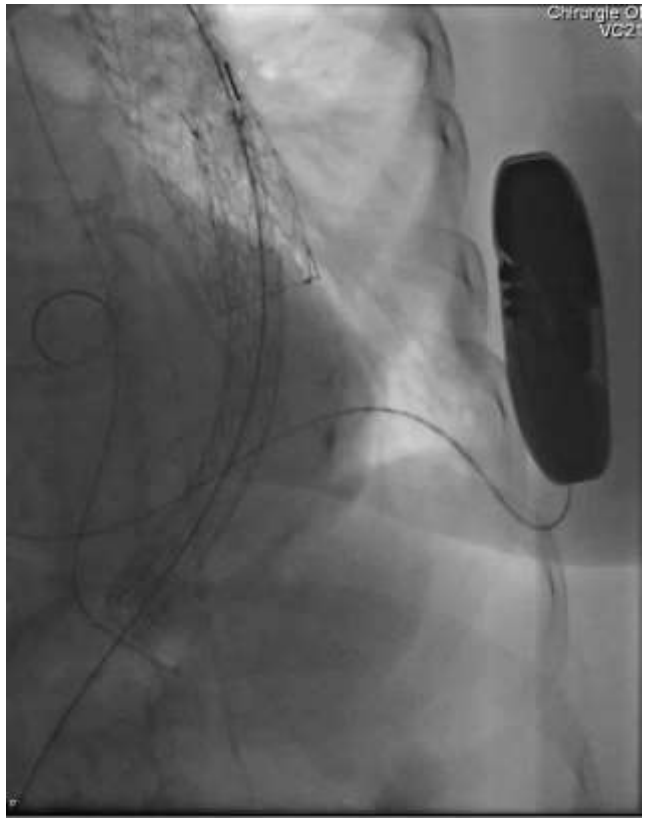
BENEFITS OF THE GORE® TAG® CONFORMABLE THORACIC STENT GRAFT WITH ACTIVE CONTROL SYSTEM

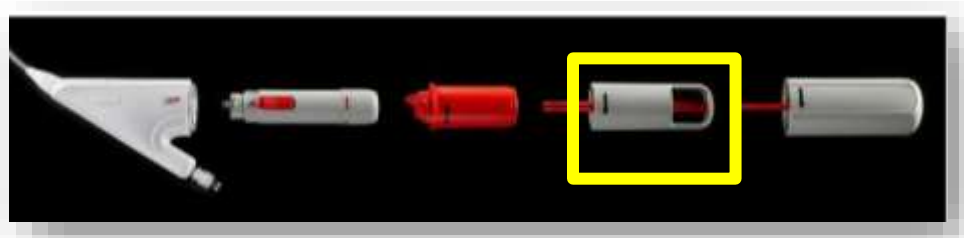
1. Approved for aneurysms, isolated lesions, and type B aortic dissections
2. Radial force adapted to underlying disease
3. Highly conformable and therefore ideal for aortic arch pathologies
4. No significant bare stent lengths, which mitigates risk of retrograde dissections
5. Short precurved olive
6. Unsheathed device allows the use of multiple devices with one access
7. Staged deployment for parallax correction, with no rapid pacing necessary
8. Stent graft attached onto the catheter for total placement control
9. Deployment from trailing to leading ends allows for accurate landing at the celiac trunk level
10. There is time to optimize accuracy, angulation, and apposition
11. A good device for teaching new operators

Stentgraft is fixed to the delivery system with lockwires

Full control during deployment > enhancing precise placement

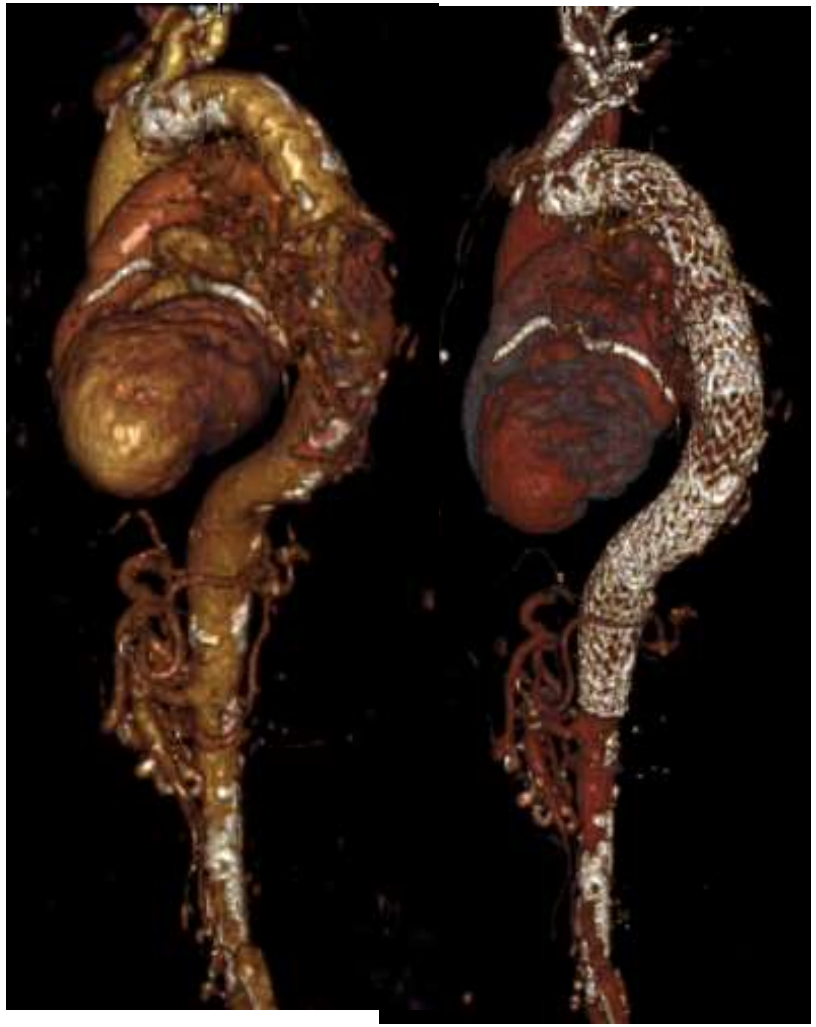


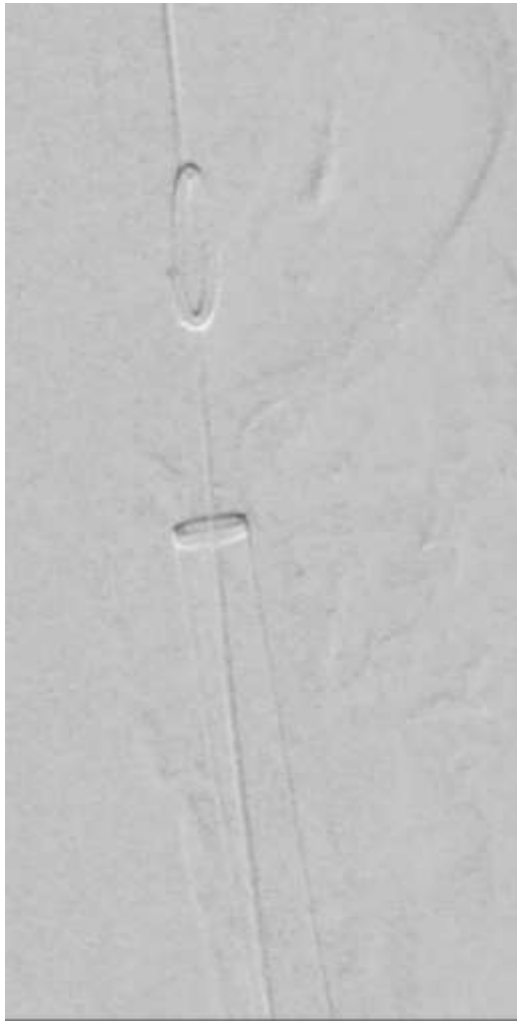


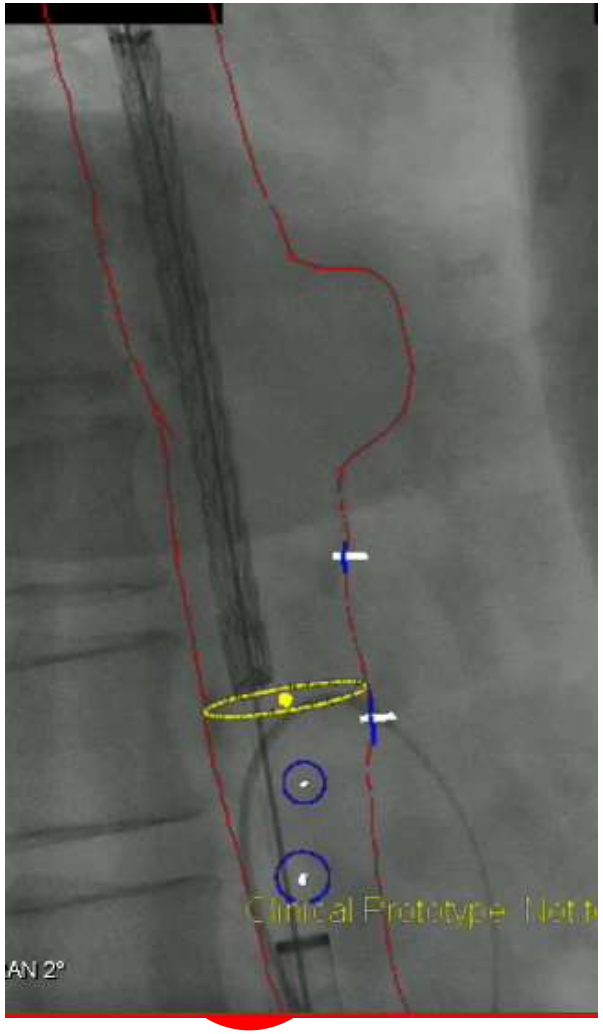


New Deployment Sequence

Precise deployment at distal landing zonesclose to celiac trunk



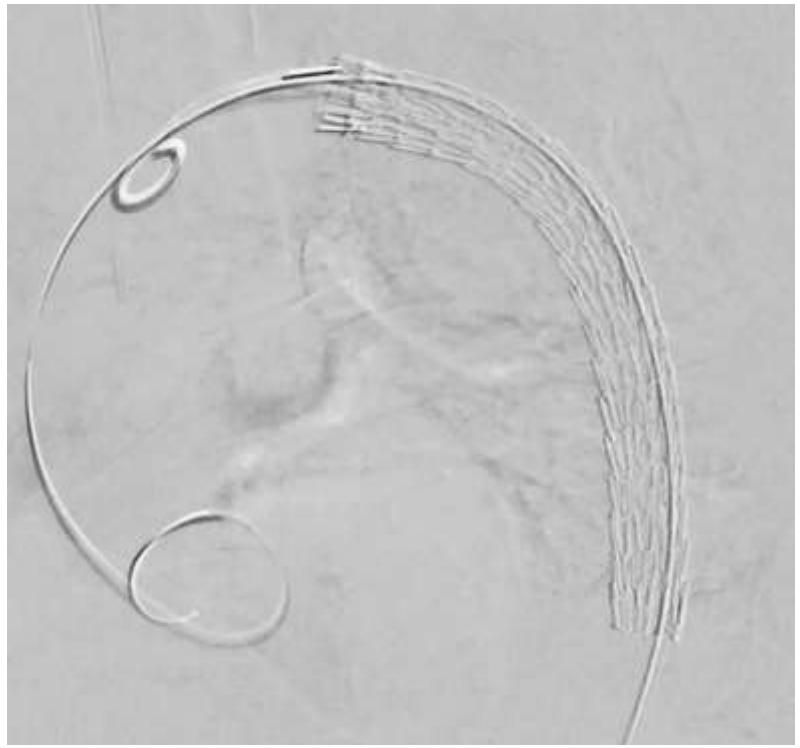




Staged Deployment

No rapid pacing > less invasive

more cases in local anesthesia > time saving

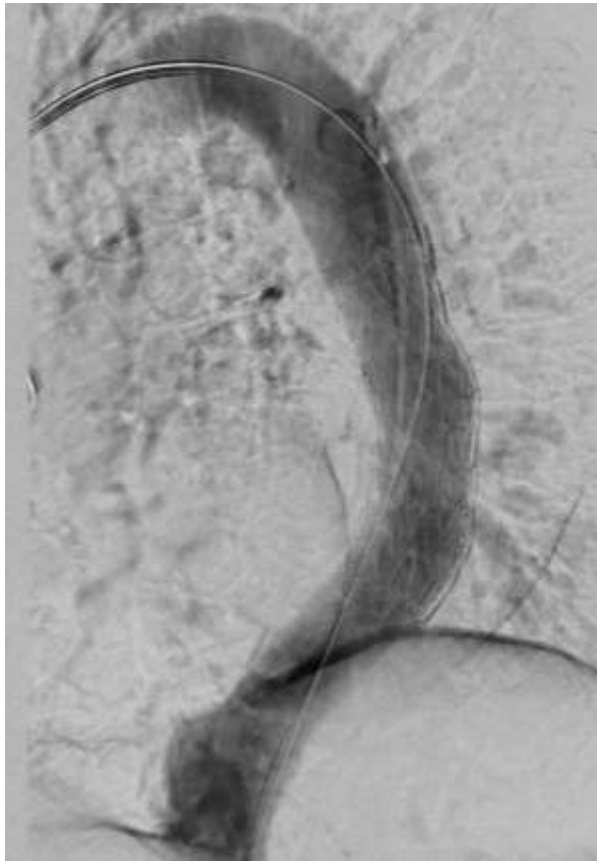


Staged Deployment > Time for optimization

Ideal decive for teaching

Reduced profile (minus 2 French)

To reduce & avoid access problems, to facilitate percutaneous approach



- First low profile CTAG Active Control Implant worldwide on 21st January 2019
- percutaneous procedure in local anesthesia

Summary & Conclusion

- This single center study shows encoring performance of the CTAG
- 3.5 year experience in 115 patients is absolutely convincing
- New CTAG has additional features:
  - Staged deployment > more accuracy
  - New deployment sequence > precise proximal and distal placement
  - Optional angulation (22%) > better apposition > no Type Ia EL

> Longterm results to be awaited