Endovascular treatment of aortic arch using Relay branched stent grafts

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Disclosure of Interest

Speaker name: SAINT-LEBES

- I do not have any potential conflict of interest

Introduction

- Endovascular treatment of aortic arch aneurysms using branched stent graft provide attractive alternativ for elderly patients
- Feasibility study
- Prospective, multicentre study
  - Assessment of morbidity and effectiveness
    - 1st step: mono branched, after double branched

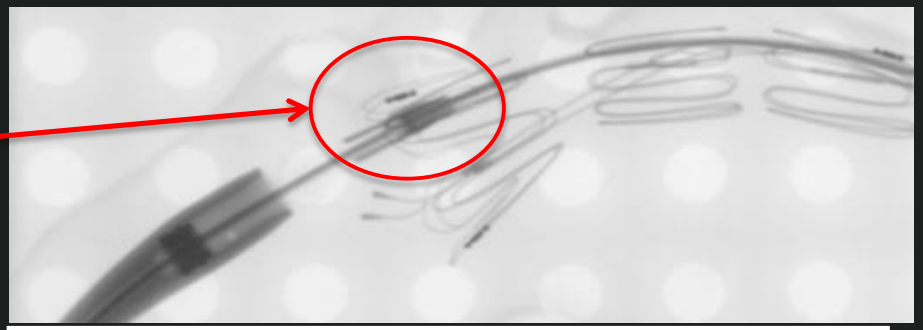
Relay branched stent graft

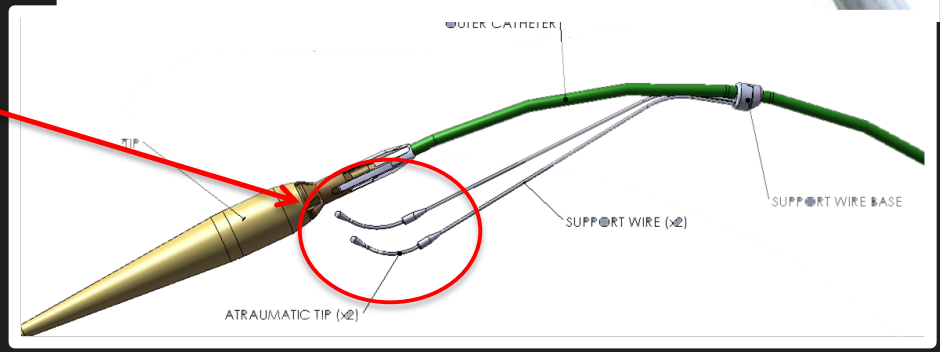
- 25-26Fr
- Custom-made version
  - Based on Relay NBS (Non-Bare Stent) platform
- Nosecone shorter: 40 mm (LV Trauma)
- Window with one or two internal tunnels, 14 mm Ø for the extension to the supra-aortic trunks
- Introduced by a trans femoral approach
- Implementation of branches by cervical approach

Device overview

Delivery system is based on relay NBS Plus Thoracic Stent-Graft

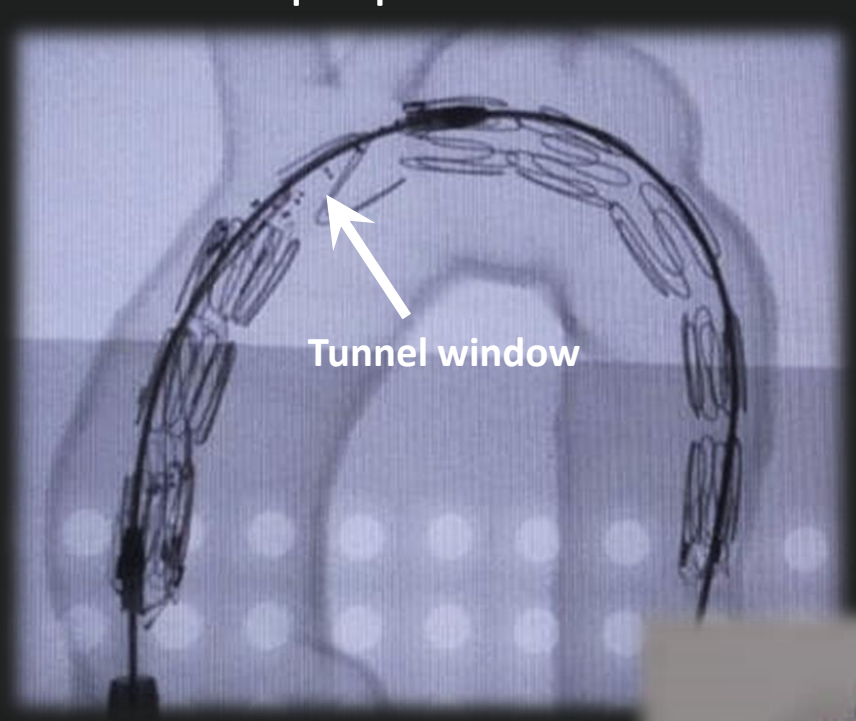
- **Proximal Clasping** mechanism to allow stent-graft **repositioning** and **pre-curved guidewire lumen** to allow **self-orientation**
- **V-Patch inner sheath** to allow expansion and **optimal alignment** of the inferior portion of the graft to the inner aortic curve
- Atraumatic **Support Wires** to **control the expansion** of the inferior portion of the graft and **prevent retroflex**

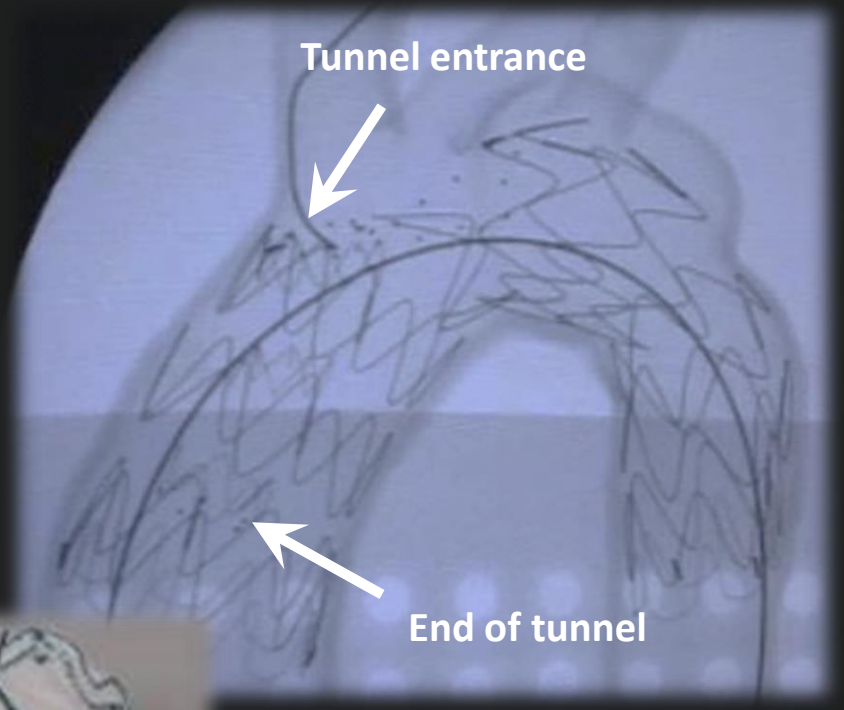




Device overview

Radiopaque markers

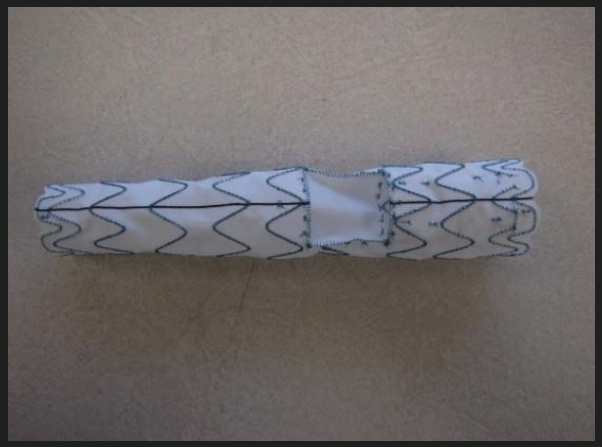
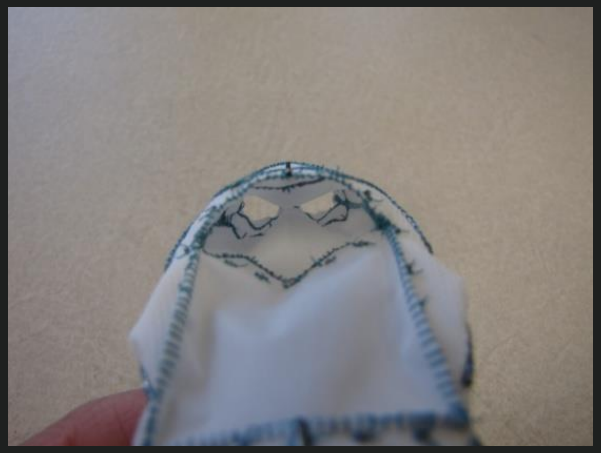
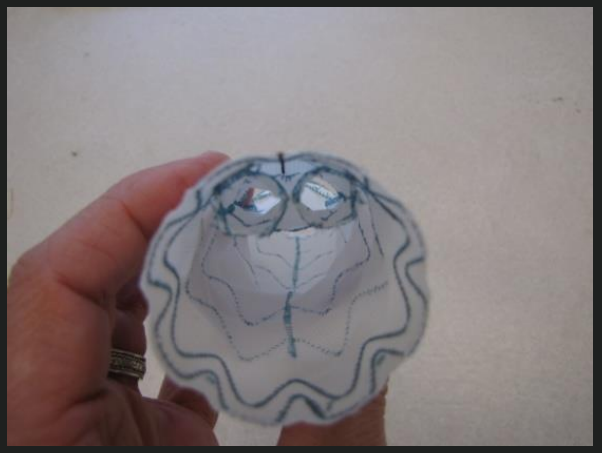
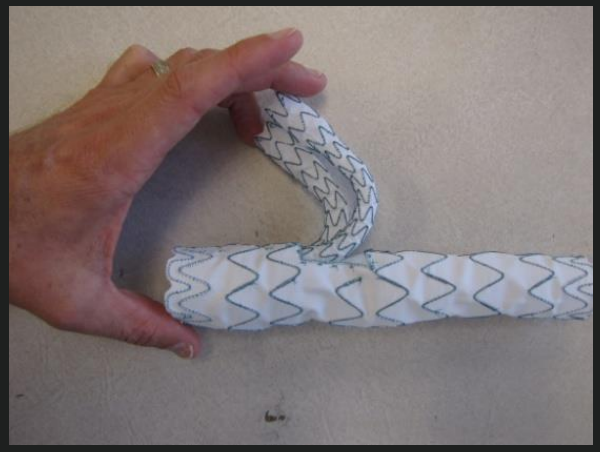




Mono-branched

- Internal branch proximally oriented and window-targeted to be deployed under ostium of target vessel(s)
- Single internal branch (innominate)
- Intended for zone 0 deployment combined with extra-anatomic arch branch bypass(es): carotid-carotid (-LSA)

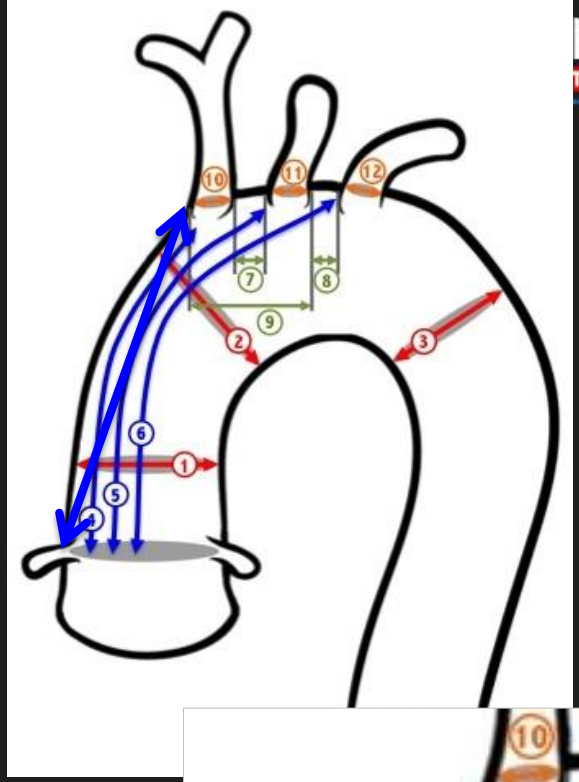
Double-branched

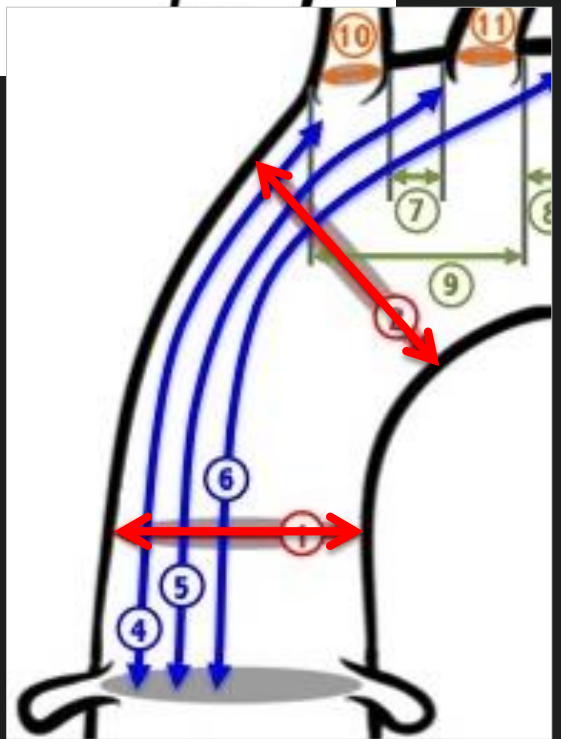





Sizing: case assessment

Anatomical Limitations

- Subject must have a **proximal landing neck** with:
  - ✓ Diameter of 42 mm or less and a healthy proximal neck length of 40mm (measurement 1 and 2)
  - ✓ Minimum required distance between the sinotubular junction and the innominate artery of 60mm (measurement 4)
- Distance between proximal end of ostium of BCT and distal end of ostium of LCCA of 45mm or less (measurement 9)
- **Access Vessels:** Compatible with sheath caliber (24 FR to 26FR outer diameter)

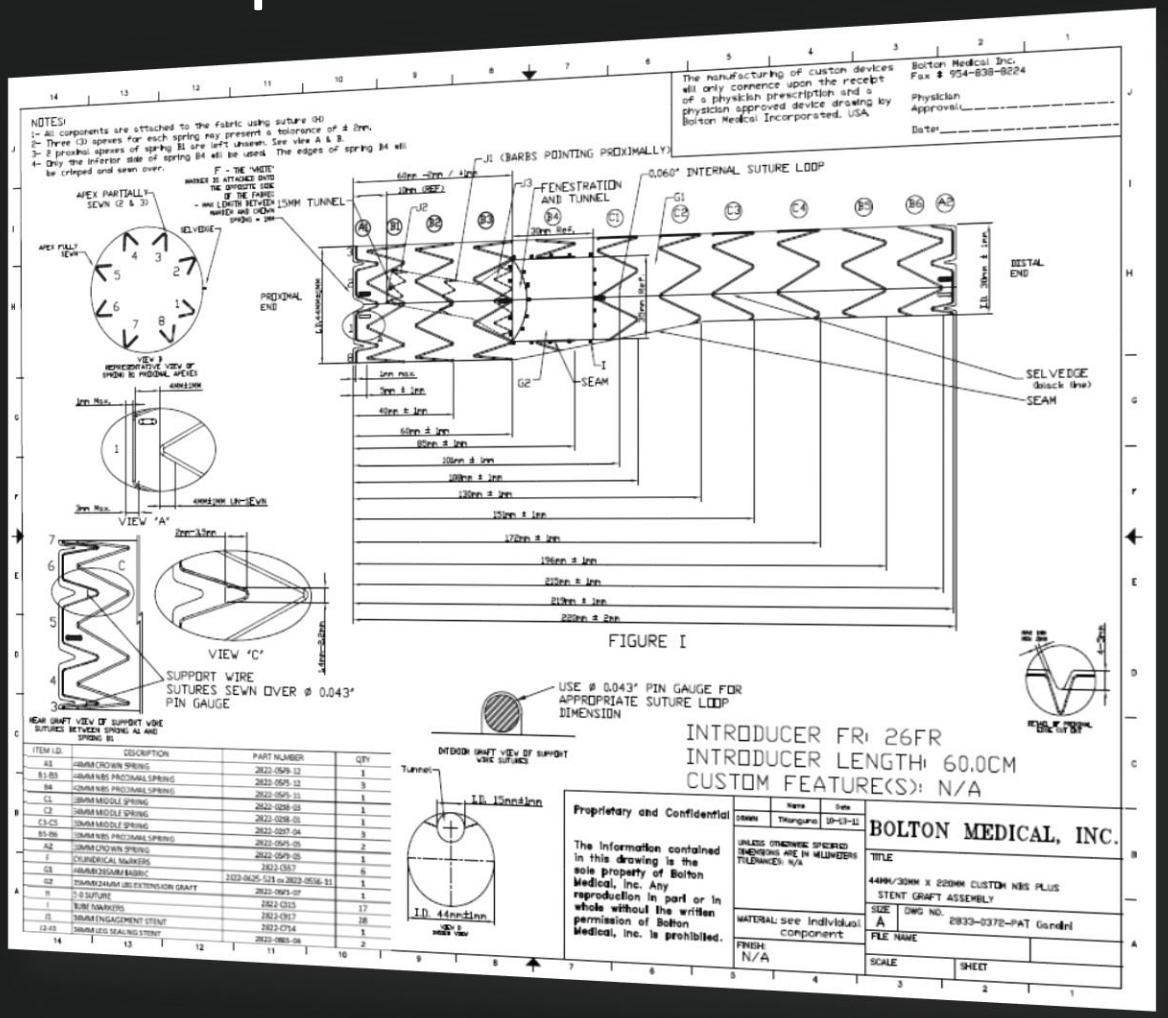




Computer Assisted Design

Design attributes of previous request

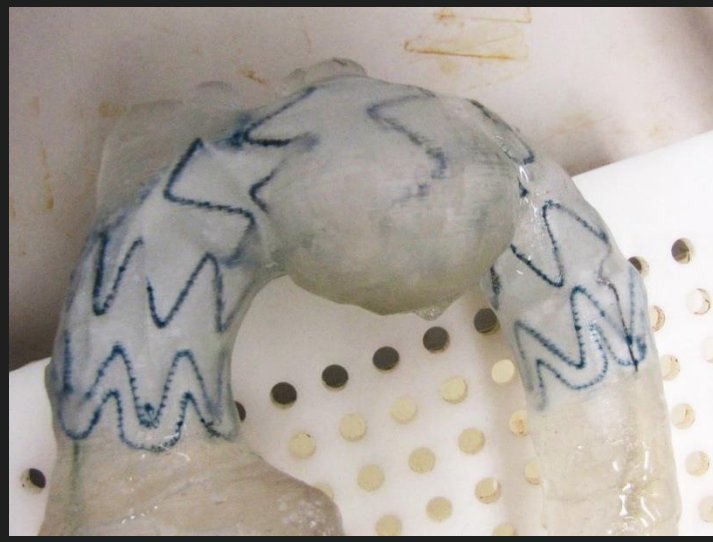
- Graft Diameters
- Window Dimensions
- Tunnel Dimensions
- Marker Locations
- Zone 0 length

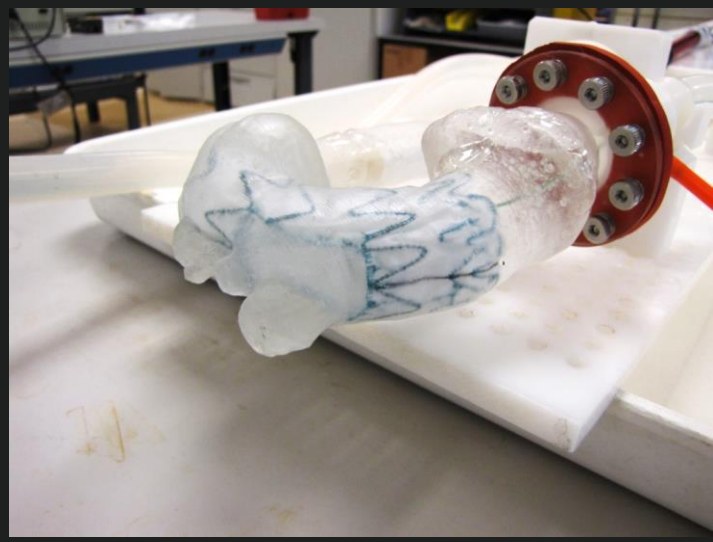


In-vitro analysis

After approval…

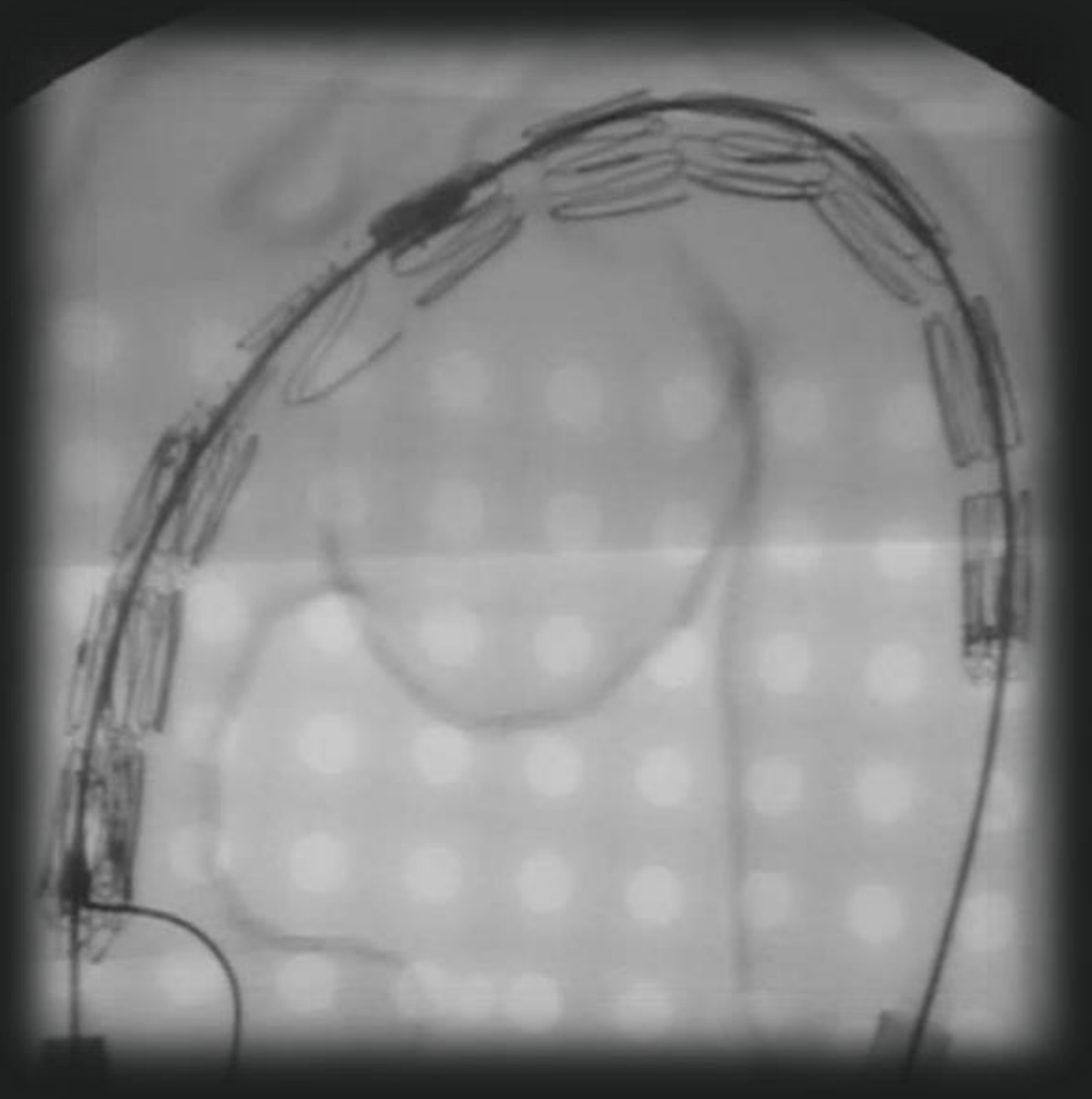
- Construction of anatomical model based on converted CT data
- Manufacturing of prototype graft and delivery system
- In-vitro deployment testing under fluoroscopy
- Submit proposed procedural steps and deployment images to treating physician
- Deployment in anatomical model under fluoroscopy with treating physician the day before
- Perform implant





Device Deployment Technique

STEP 1 – Advance graft with tunnel (Tunnel Graft) to deployment site in Ascending Aorta

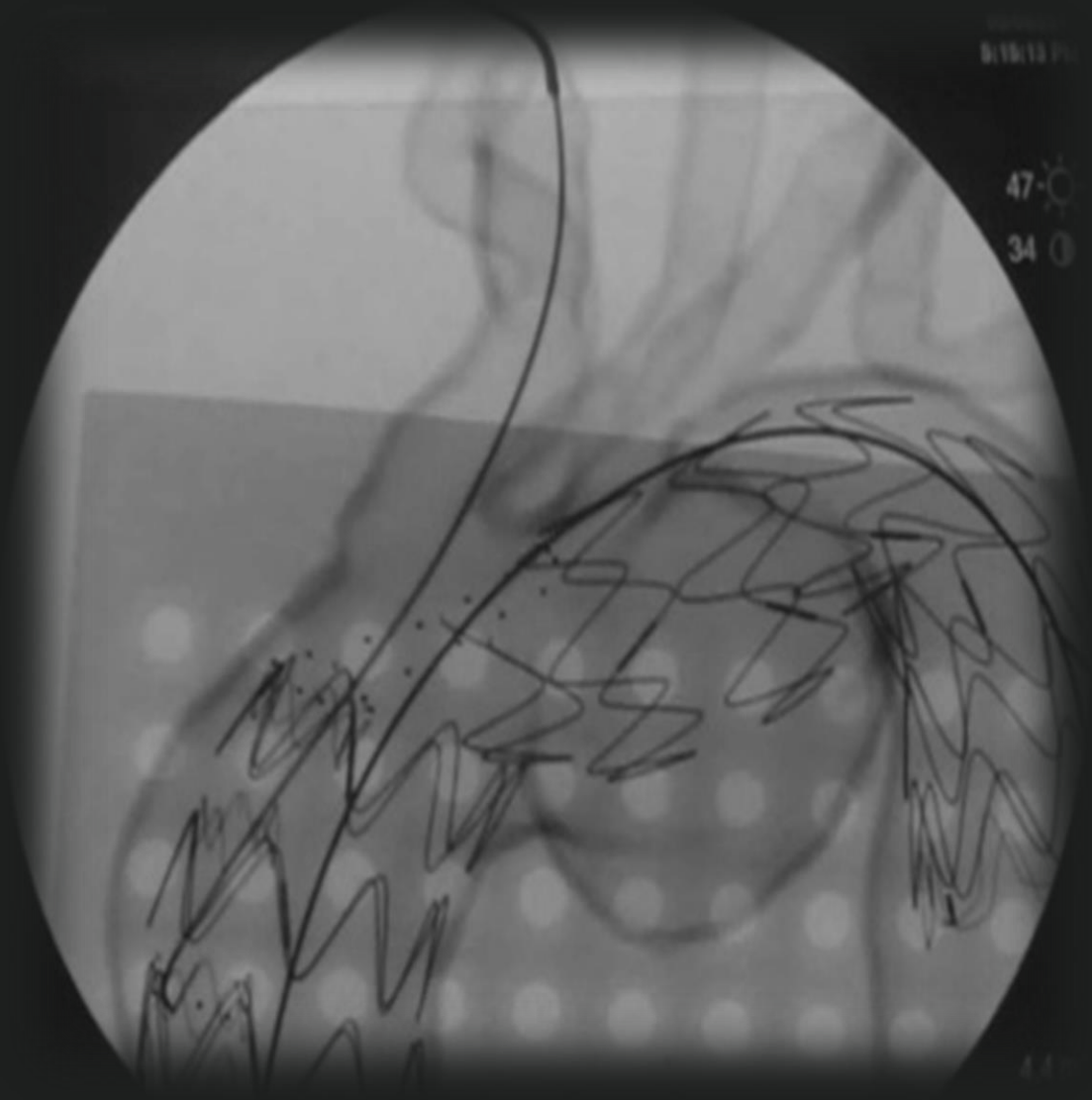


Device Deployment Technique

STEP 2 – Full deploy tunnel graft with PACING

Device Deployment Technique

STEP 3 – Cannulate tunnel prior to deployment of branch graft (bridging graft)



Device Deployment Technique

STEP 4 – Deploy branch graft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Taille de la vue : 2338 x 1316
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GE MEDICAL SYSTEMS
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Single-branched
Clinical experience

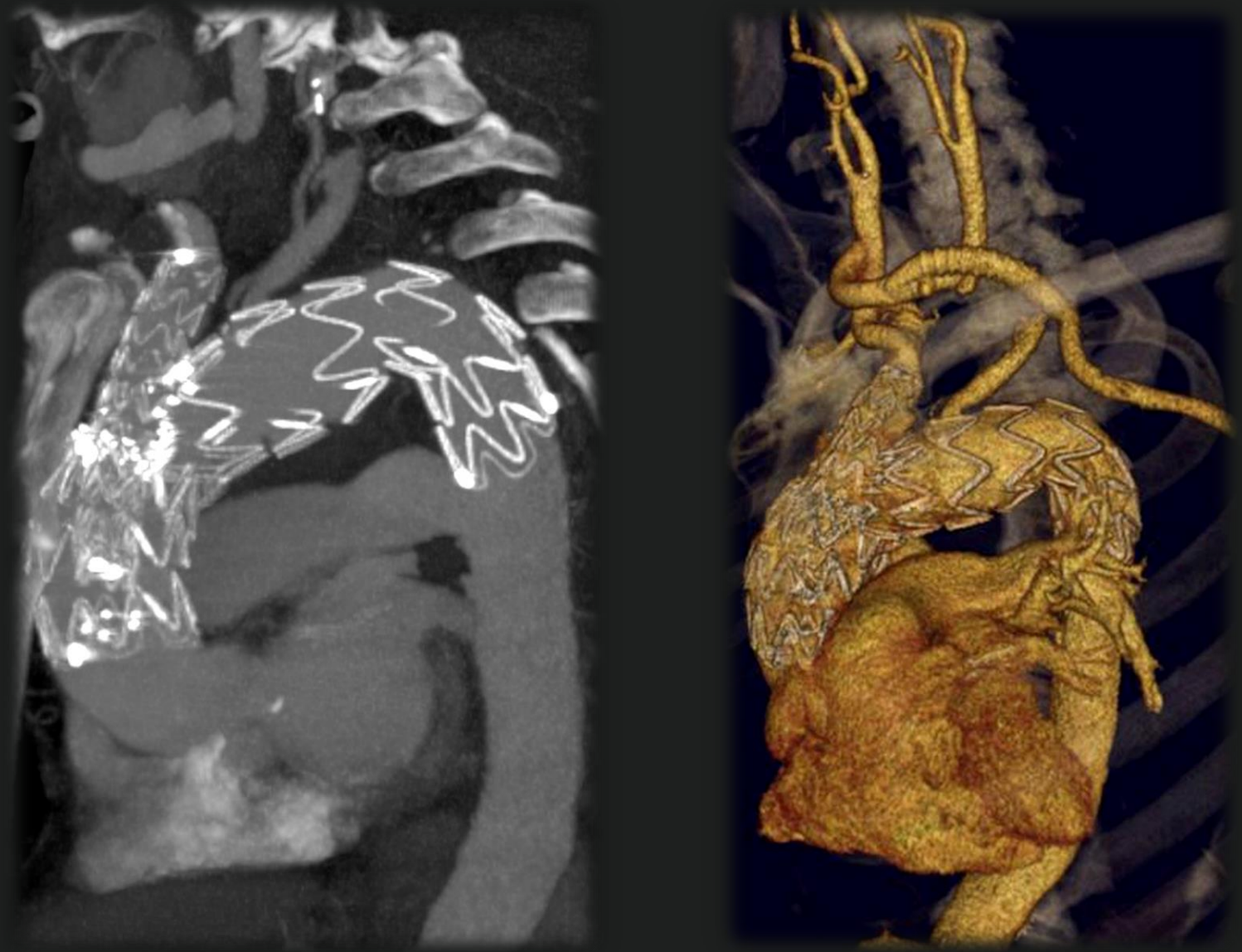
Implanting centers

Center	Investigator	City	Country
Ospedale Niguarda Ca Granda	Dr. Rampoldi – dr. Martinelli	Milano	Italy
Ospedale G. Brotzu	Dr. Camparini	Roma	Italy
Ospedale di Circolo	Prof. Castelli – dr. Piffaretti	Varese	Italy
Ospedale San Camillo Forlanini	Prof. Cao	Roma	Italy
Policlinico di Bari	Prof. A. S. Bortone	Bari	Italy
Osaka University Hospital	Dr. Kuratani	Osaka	Japan
Linköping University Hospital	dr. C. Forssell	Linköping	Sweden
Utrecht University Hospital	prof. F. Moll, dr. J. Van Herwaarden	Utrecht	Netherlands

Mono-branched Results

	Total	Male	Female
N	**8**	**75% (6/8)**	**25% (2/8)**
Age	74	76	69
TAA	3 (37,5%)	2	1
PAU	4 (50%)	3	1
Type B Dissection	1 (12,5%)	1	0
General anesthesia	100%		
Target vessel bridged	100%	100%	100%
Procedures completed	100%	100%	100%
Freedom from endoleak	87,5% (7/8)	83,3% (5/6)	100% (2/2)
Perioperative death	25% (2/8)	33,3% (2/6)	0% (0/2)

3D CT reconstruction



Double-branched Clinical experiences

Implanting centers

#	Center	Country	Investigators
1	Ospedale G. Brotzu - Cagliari	Italy	Dr. S. Camparini
2	Osaka University Hospital	Japan	Dr. T. Kuratani
3	Hopital Rangueil - Toulouse	France	Pr. H. Rousseau Dr. Saint-Lèbes
4	Ospedale San Camillo - Roma	Italy	Pr. P.G. Cao
5	Hôpital George Pompidou - Paris	France	Dr. J. M. Alsac
6	St. Mary's Hospital - London	United Kingdom	Dr. M. Hamady
7	Linköping University Hospital - Linköping	Sweden	Dr. C. Forssell
8	Hospital UCA de Oviedo	Spain	Dr. M. Alonso
9	Utrecht University Hospital - Utrecht	Netherlands	Dr. F. Moll, Dr. J. Van Herwaarden
10	Mainz Hospital	Germany	Dr. M. Youssef
11	Hospital de La Coruña	Spain	Dr. V. Mosquera
12	Heart Center Freiburg University	Germany	Dr. M. Czerny
13	Universitätsklinikum Standort Gießen	Germany	Dr. A. Koshty

Double-branched Results

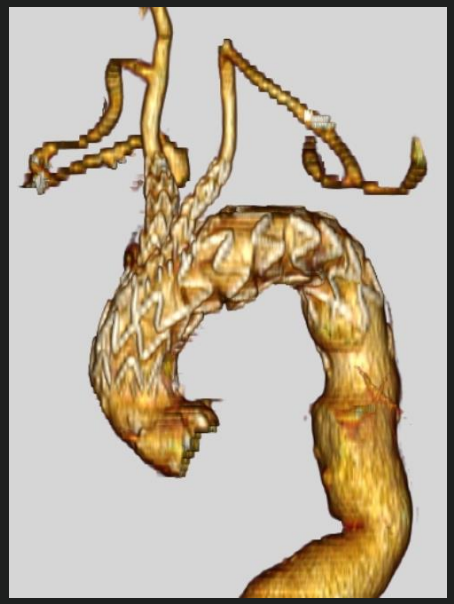
	Total	Male	Female
N	**26**	**69,2% (18/26)**	**30,8% (8/26)**
Age	72	75	64
TAA	21 (80,8%)	14	7
PAU	1 (3,8%)	1	0
Type B Dissection	4 (15,4%)	3	1
General anesthesia	100%		
Target vessels bridged	100%	100%	100%
Procedures completed	100%	100%	100%
Freedom from endoleak	92,3%	88,9%	100%
Perioperative death	11,5% (3/26)	11,1% (2/18)	12,5% (1/8)
late death	11,5% (3/26)	11,5%	0

Arch graft Clinical experience
Branch usage

Manufacturer	N
Cook-Zenith AAA	7
Medtronic-Endurant AAA	6
Atrium (combination with Viabhan)	1*
Innomed – Bently	2
Trivascular-Ovation	5
Gore-Excluder AAA	38
Gore-Viabahn	3*
Jotec covered stent (combination with Viabhan)	1*

Double branched
Clinical experience

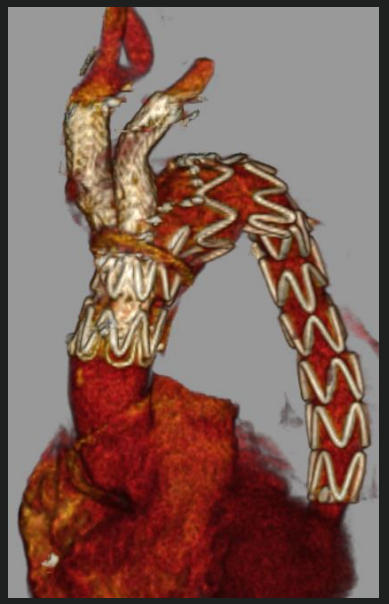
Case 1: First in Human
Courtesy of Dr. Camparini,
Az. Osp. “Brotzu”, Cagliari (IT)



Pre-op CT scan

1 month F. up

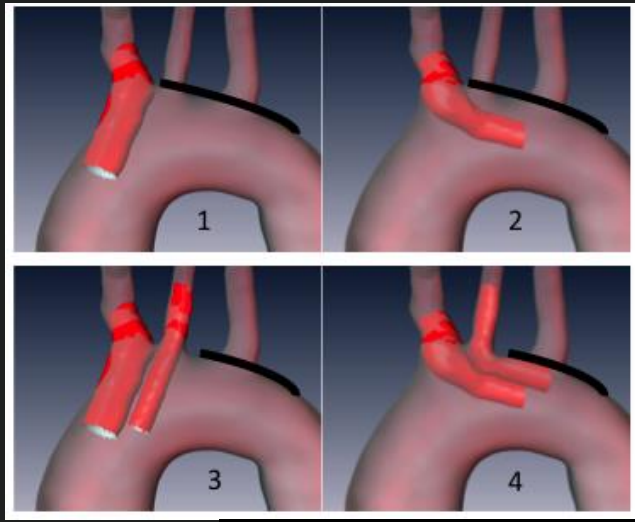
Case
Courtesy of Dr. Kuratani,
Osaka University Hospital, Osaka (JP)

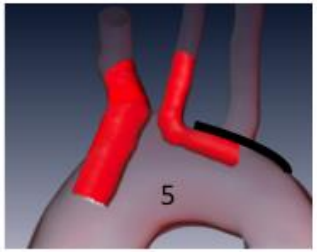


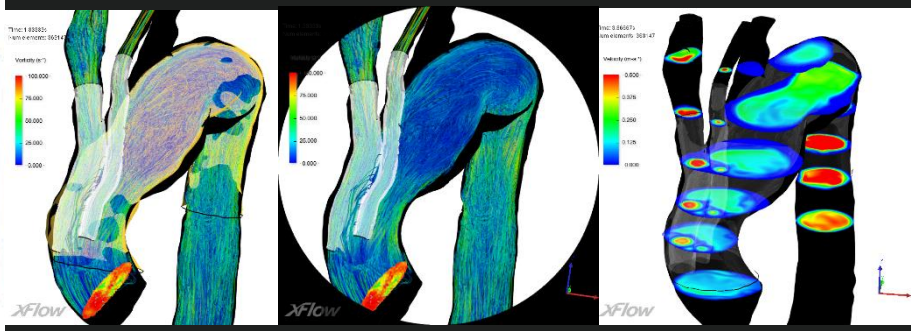
Pre-op CT scan

1 month F. up

Computational Fluid Dynamic



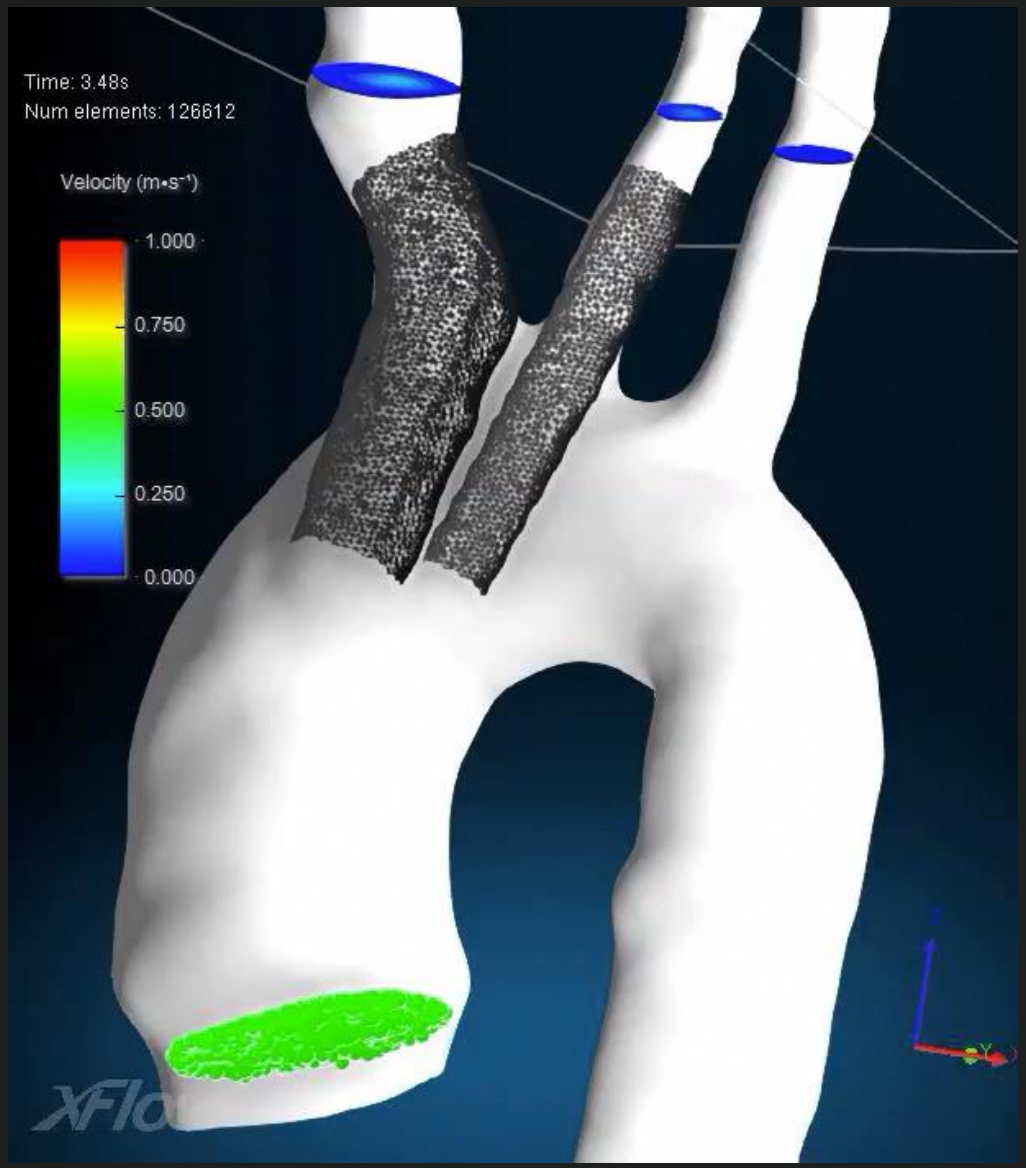




Configuration	1	2	3	4	5
sens du flux *TABC*	*Physiologique*	*contre-courant*	*Physiologique*	*contre-courant*	*Physiologique*
sens du flux CPG	*fermé*	*fermé*	*Physiologique*	*contre-courant*	*contre-courant*

flux in/out					
Inlet	100,0%	100,0%	100,0%	100,0%	100,00%
TABC	**13,5%**	5,2%	**12,8%**	4,7%	**13,04%**
CPG	0,0%	0,0%	**5,4%**	**5,7%**	**4,67%**
SCG	0,0%	0,0%	0,0%	0,0%	0,00%
Aorte abdominale	86,2%	94,3%	**81,6%**	89,3%	**81,99%**
reste	0,3%	0,5%	0,3%	0,3%	0,3%

Computational Fluid Dynamic



Conclusion

- We have demonstrated the technical feasibility of a new modular trans femoral branched stent graft for treatment of aortic arch aneurysms
- The method is relatively safe, based on initial experience and we currently recommend it to high-risk patients and suitable anatomy
- Safety and efficacy will be better defined with longer follow-up and increased worlwide experience