



**May 20 & 21**

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20<sup>TH</sup> INTERNATIONAL EXPERTS SYMPOSIUM

**CRITICAL ISSUES**

**in aortic endografting 2016**

[www.critical-issues-congress.com](http://www.critical-issues-congress.com)

# Arch branch endografting: current results

Piergiorgio Cao, MD, FRCS

## **Disclosure**

Speaker name:

**Piergiorgio Cao**

I do not have any potential conflict of interest

# Aortic arch debranching and thoracic endovascular repair

JVS 2014

Paola De Rango, MD, PhD,<sup>b</sup> Piergiorgio Cao, MD, FRCS,<sup>a</sup> Ciro Ferrer, MD,<sup>a</sup> Gioele Simonte, MD,<sup>b</sup> Carlo Coscarella, MD,<sup>a</sup> Enrico Cieri, MD, PhD,<sup>b</sup> Gabriele Pogany, MD,<sup>a</sup> and Fabio Verzini, MD, PhD,<sup>b</sup>  
*Rome and Perugia, Italy*

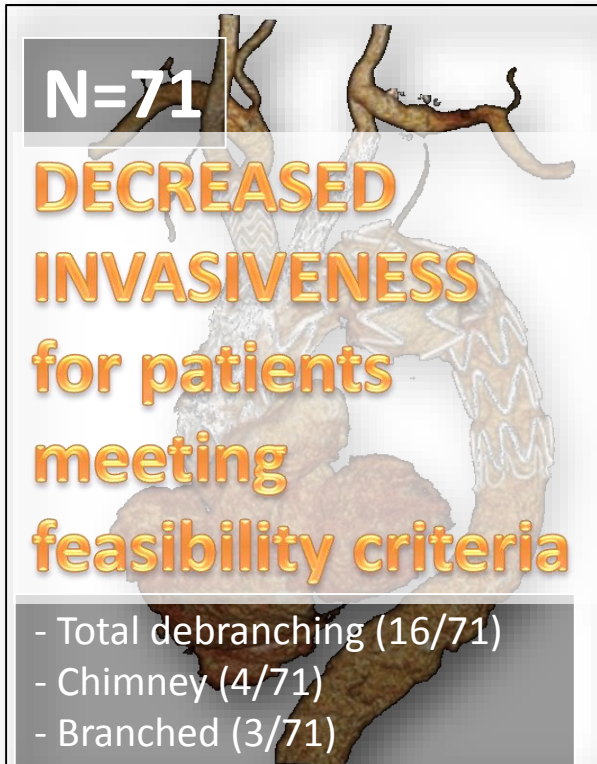
30-day outcomes (104 patients)	(%)
Mortality	5.8
Stroke	3.8
Spinal cord ischemia	2.9



Morphological feasibility  
**Prox landing  $\geq$  2cm in length and  
 $\leq$  4.2cm in diameter**

# Contemporary comparison of aortic arch repair by endovascular and open surgical reconstructions

Paola De Rango, MD, PhD,<sup>a</sup> Ciro Ferrer, MD,<sup>b</sup> Carlo Coscarella, MD,<sup>b</sup> Francesco Musumeci, MD,<sup>c</sup> Fabio Verzini, MD, PhD, FEBVS,<sup>a</sup> Gabriele Pogany, MD,<sup>b</sup> Andrea Montalto, MD,<sup>c</sup> and Piergiorgio Cao, MD, FRCS,<sup>b</sup> *Perugia and Rome, Italy*

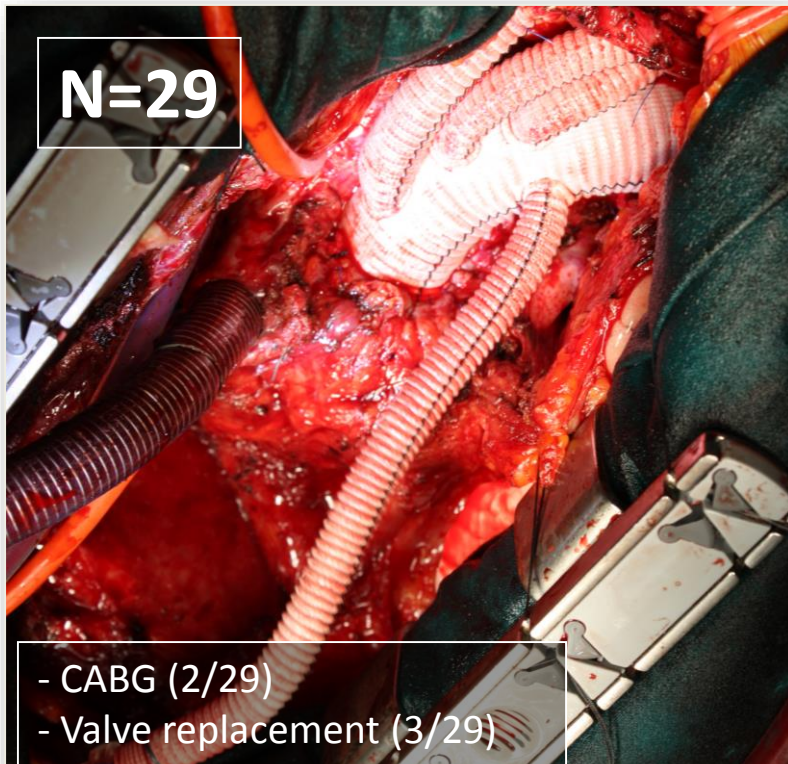


**N=71**

**DECREASED  
INVASIVENESS  
for patients  
meeting  
feasibility criteria**

- Total debranching (16/71)
- Chimney (4/71)
- Branched (3/71)

Zone 0 – 1 Endovascular procedures



**N=29**

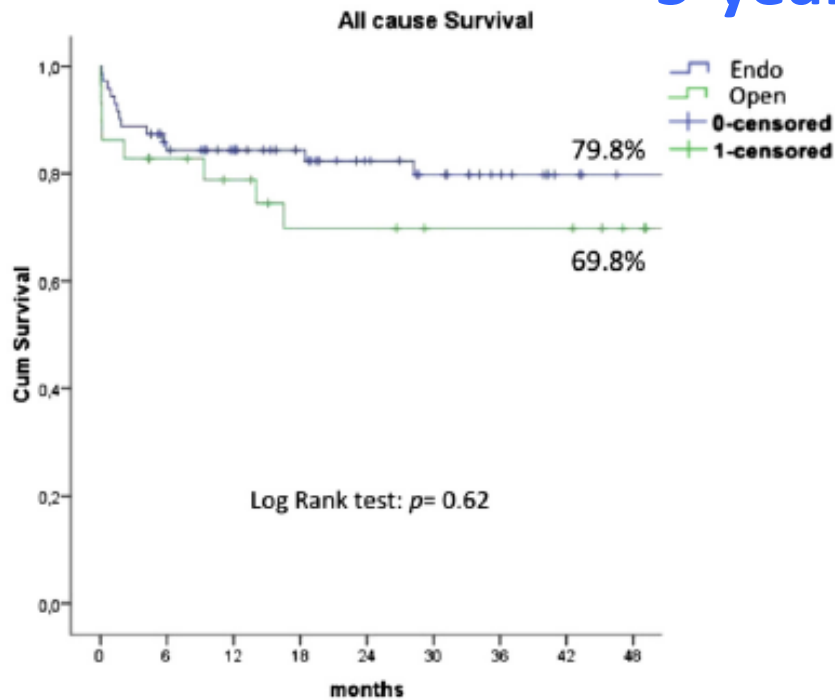
- CABG (2/29)
- Valve replacement (3/29)

Ascending aorta + total arch replacement

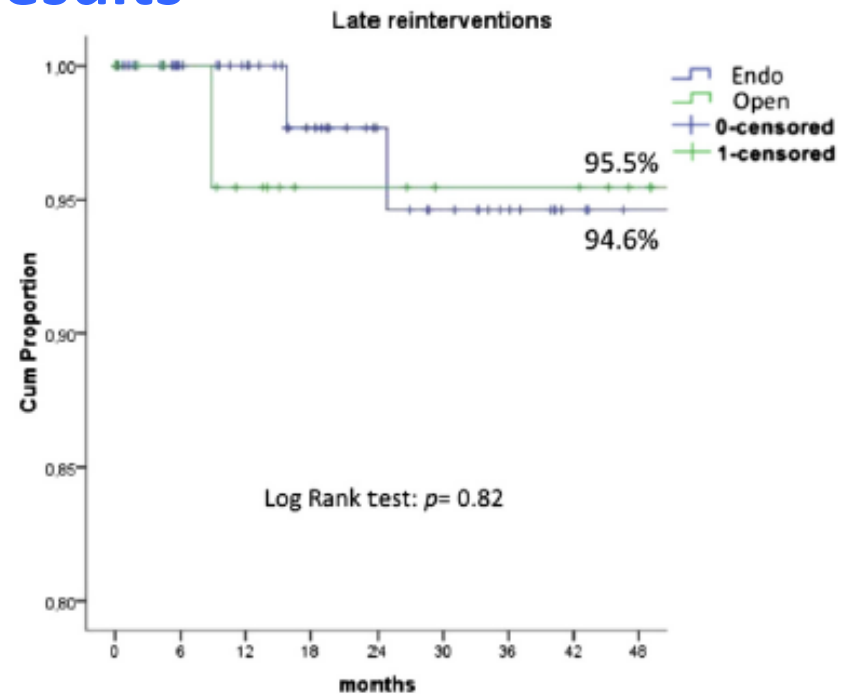
# Perioperative results

	Endo	Open	P
Death	8.5%	13.8%	0.47
Stroke	5.6%	3.4%	1
Spinal cord ischemia	2.8%	0%	0.50

## 5-year results



	months	0	12	24	36	48
ENDO	<i>n</i> <sup>*</sup> at risk	71	49	34	22	14
	st. error	0	0.04	0.05	0.05	0.05
OPEN	<i>n</i> <sup>*</sup> at risk	29	19	14	13	10
	st. error	0	0.08	0.09	0.09	0.09



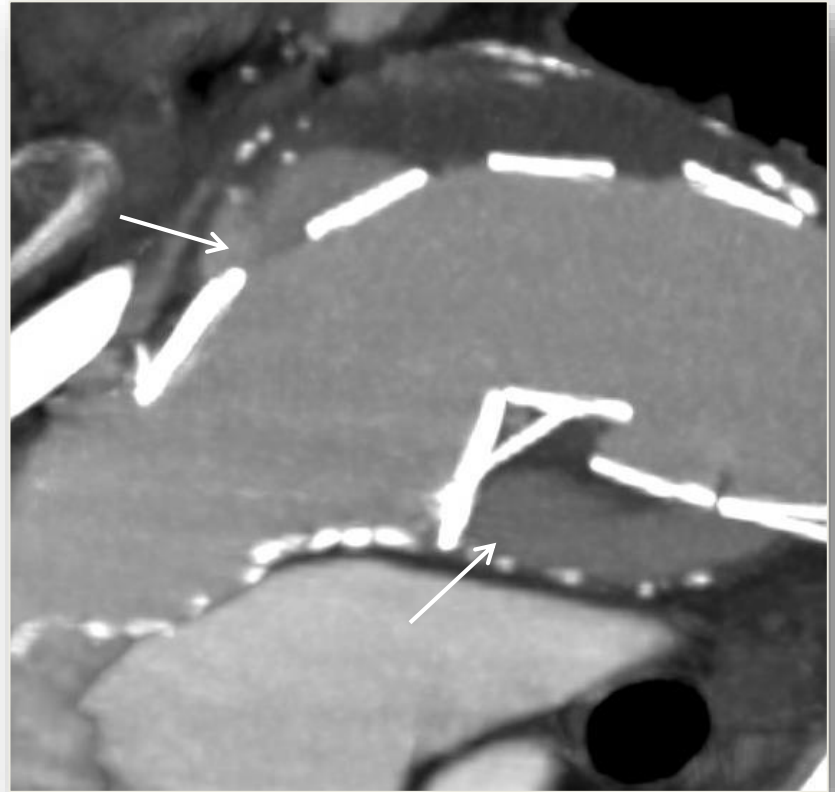
	months	0	12	24	36	48
ENDO	<i>n</i> <sup>*</sup> at risk	71	47	32	22	14
	st. error	0	0	0.02	0.04	0.04
OPEN	<i>n</i> <sup>*</sup> at risk	29	19	14	12	10
	st. error	0	0.04	0.04	0.04	0.04

# Conformability

Deployment related issues



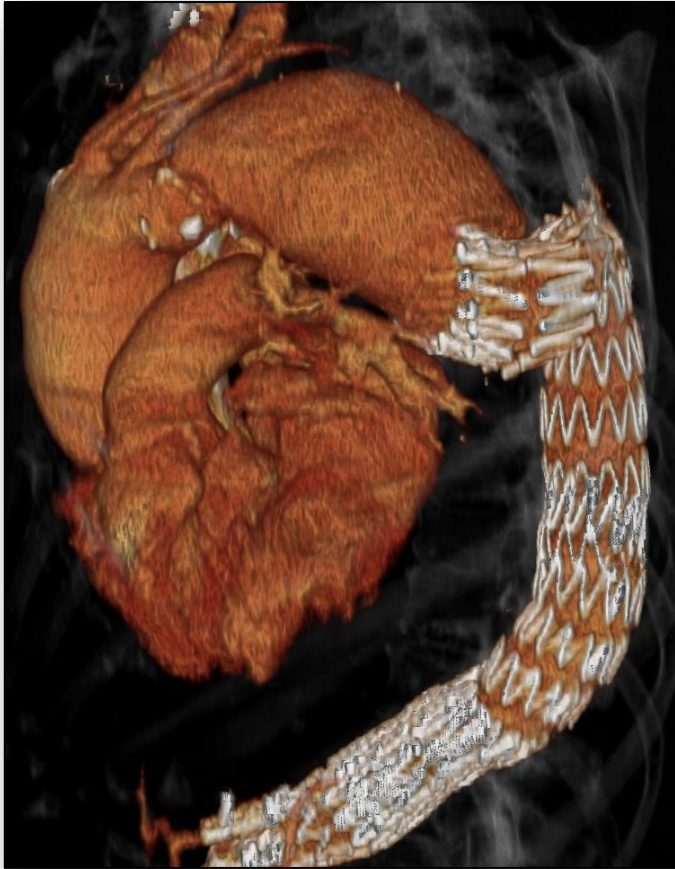
**BIRD-BEAK**  
effect



**WIND-SOCK**  
effect

# Conformability

Migration and type I endoleak



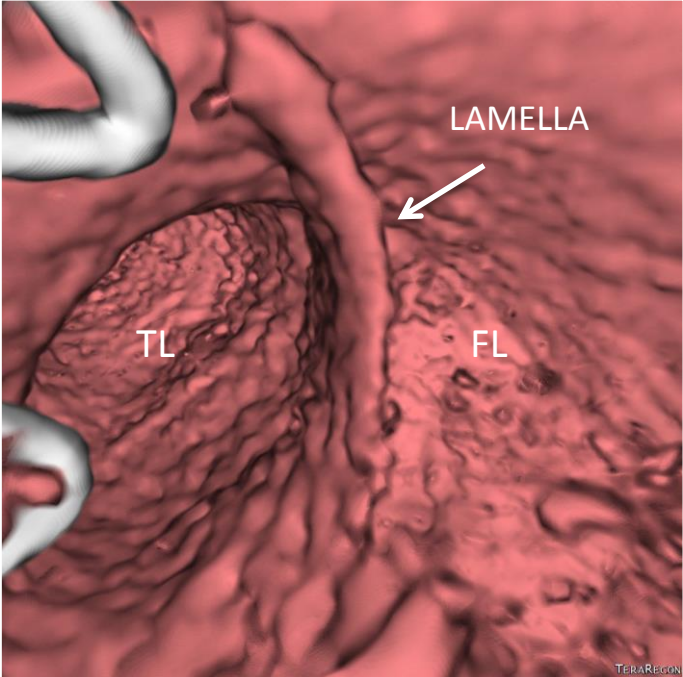
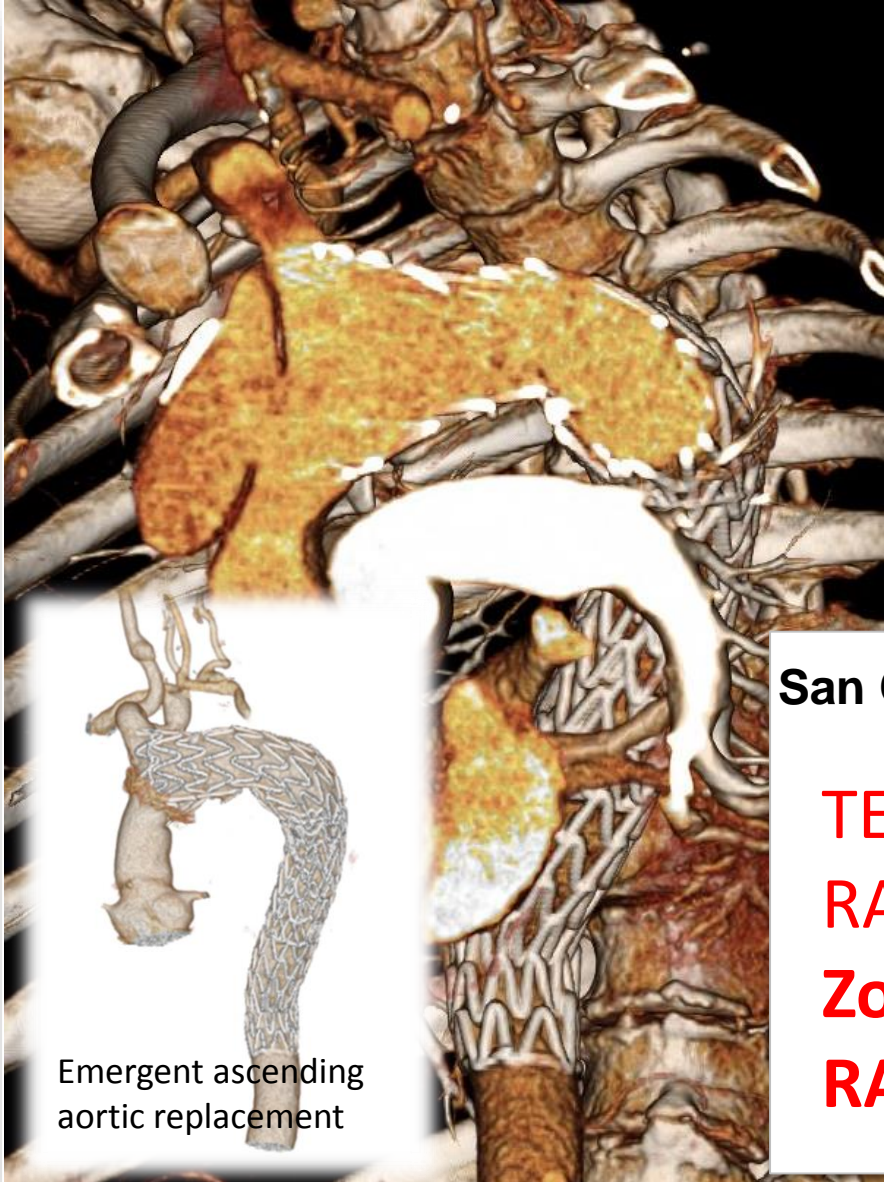
**MIGRATION**



**GUTTER  
endoleak**

# Retrograde dissection

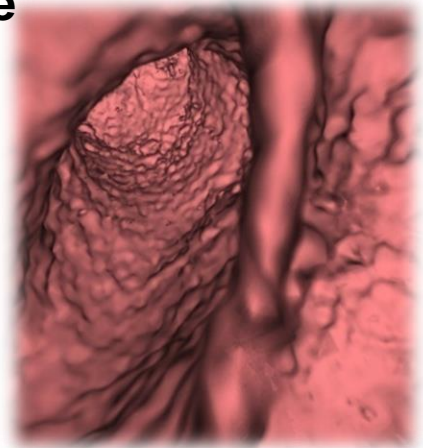
## Zone 1 repair



### San Camillo Experience

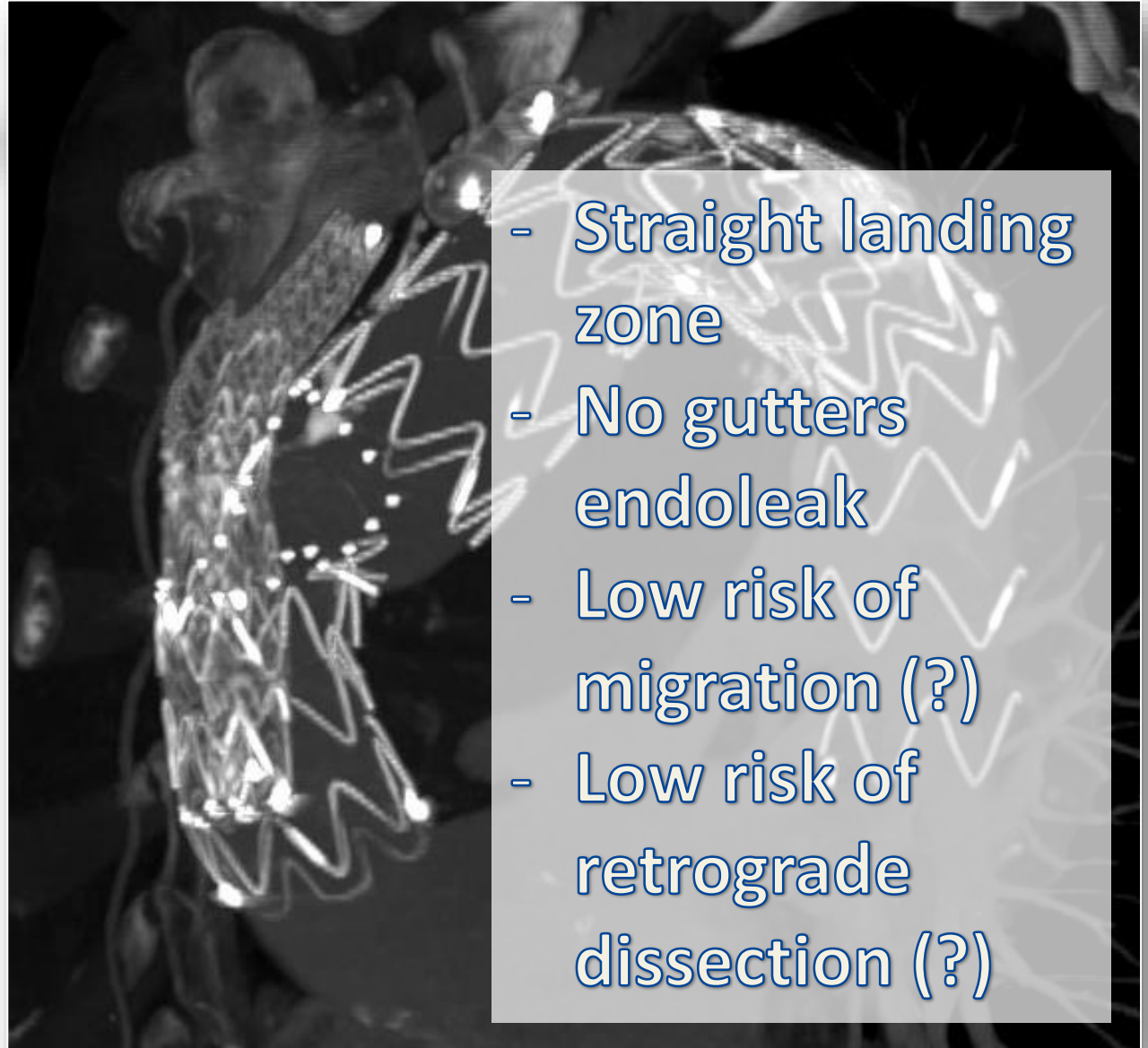
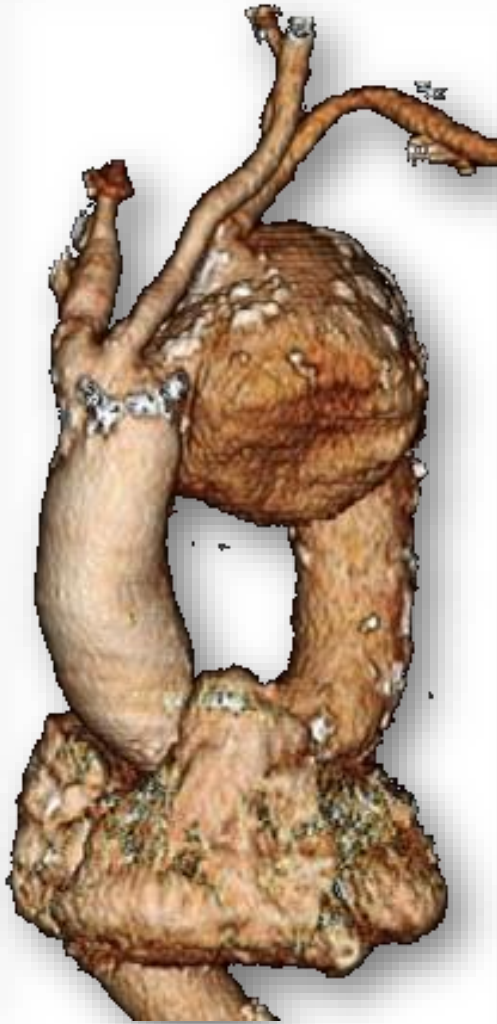
2009 - 2015

**TEVAR: 483**  
**RAD: 7 (1.4%)**  
**Zone 0-1: 109**  
**RAD: 5 (4.7%)**





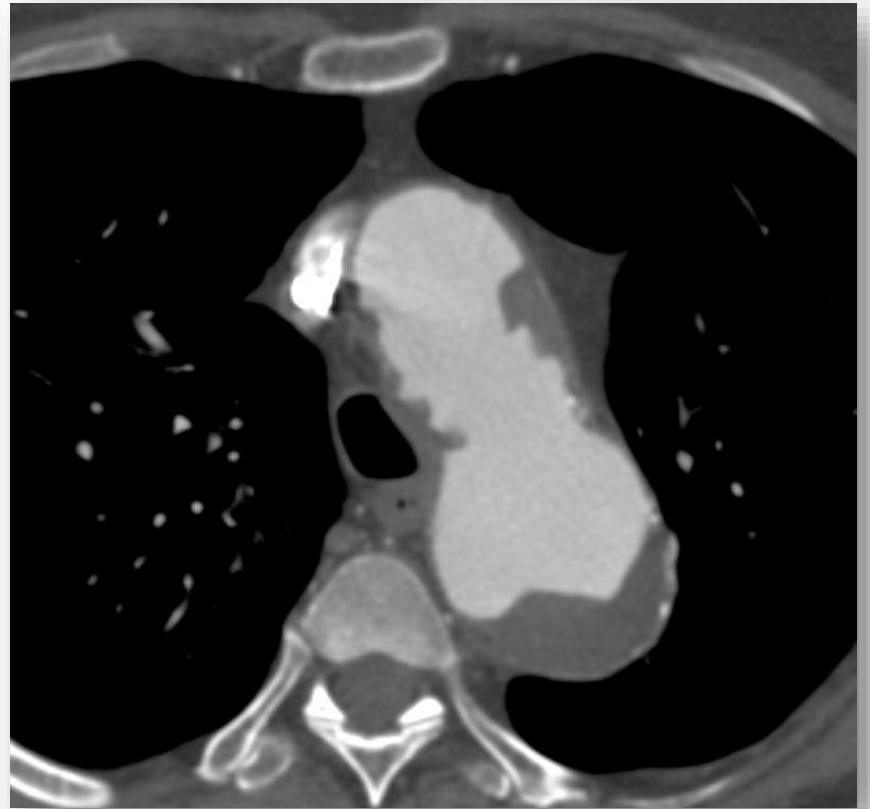
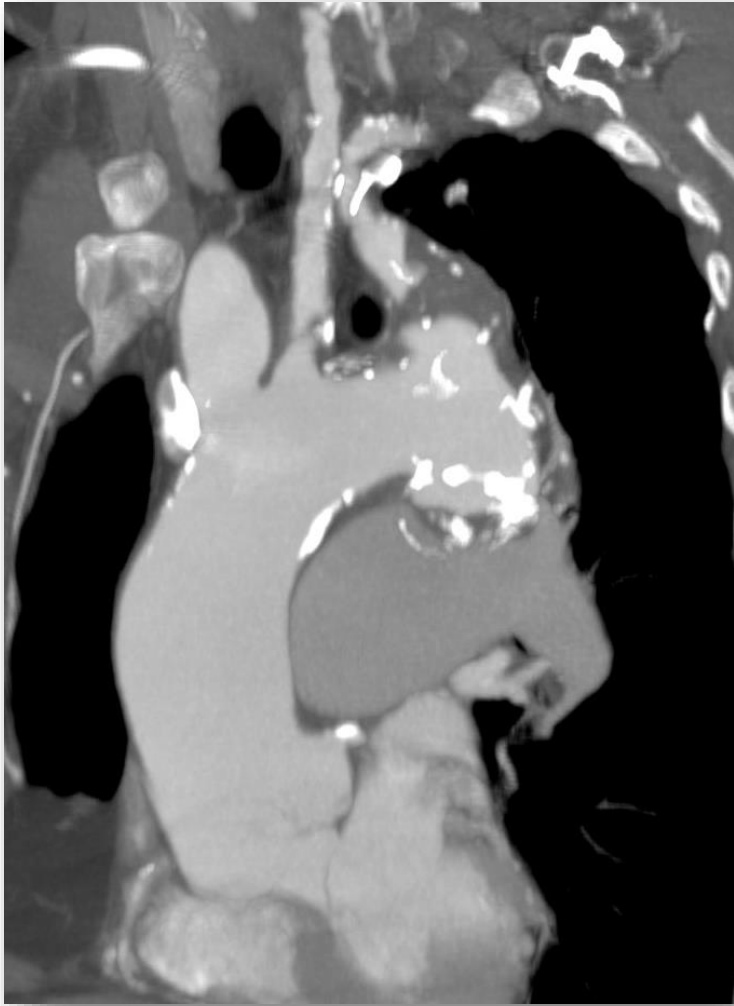
# Potential advantages of Arch Branched stentgrafts



- Straight landing zone
- No gutters endoleak
- Low risk of migration (?)
- Low risk of retrograde dissection (?)

# Patients' selection

“Shaggy” aorta

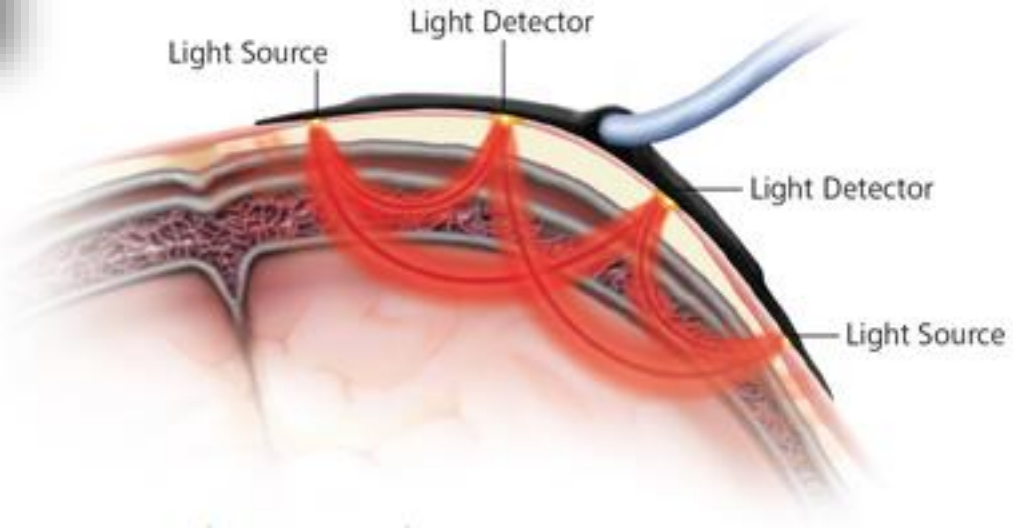


# Intraoperative monitoring

rSO<sub>2</sub>



TCD



Cerebral oximetry sensor

# Prevention of air embolism

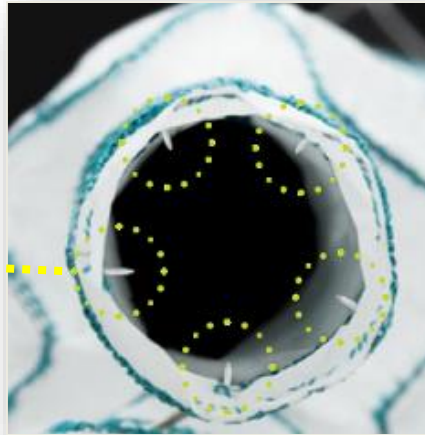
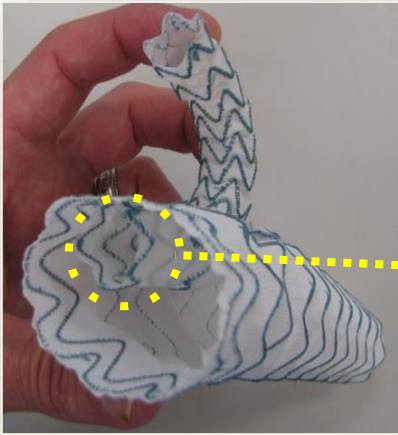
## Stentgraft flushing with CO<sub>2</sub> (before flushing with saline)



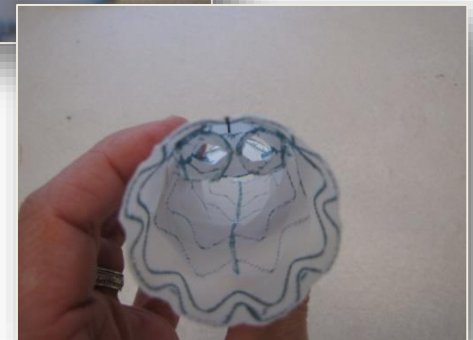
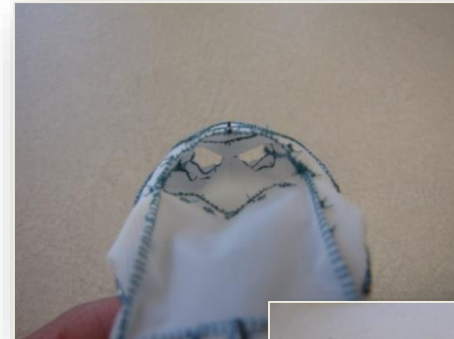
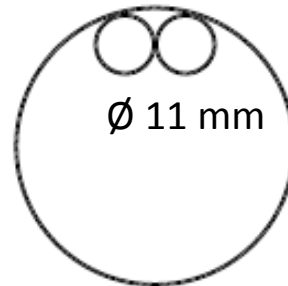
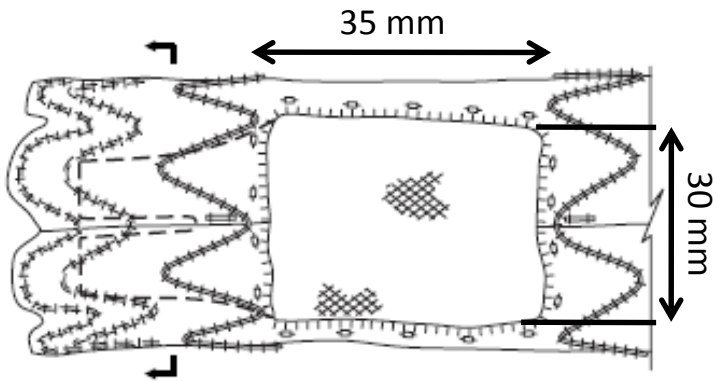
- More effective de-airing (higher diffusion of CO<sub>2</sub>)
- Lower risk of air embolism (higher solubility of CO<sub>2</sub> in the blood)

# Bolton Arch Branched Device

- Based on Relay NBS (Non-Bare Stent) Plus platform



- Single or double inner branch



# Bolton Arch Branched Device

Worldwide experience with double branch

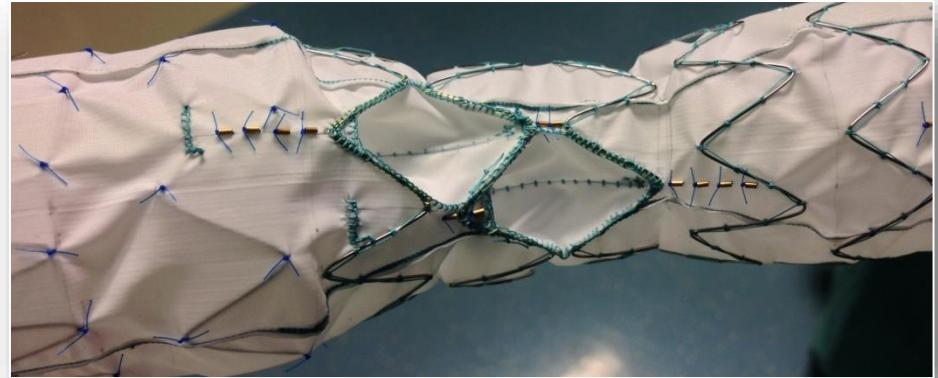
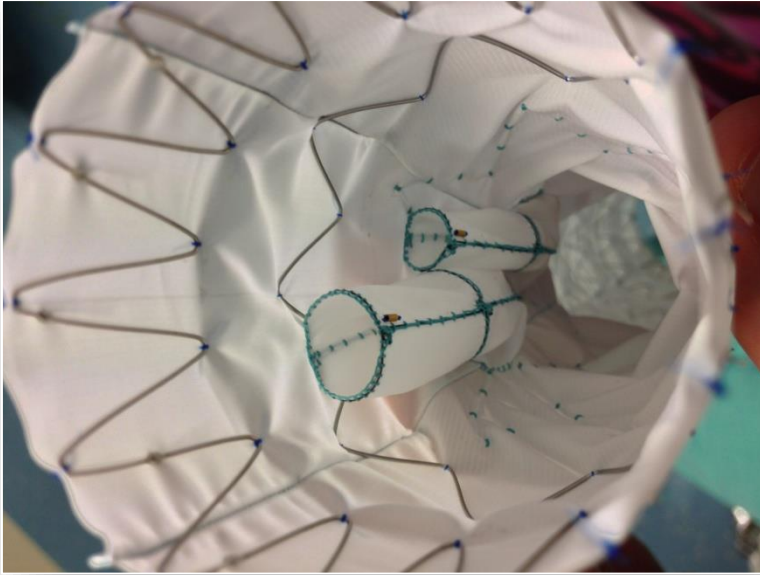
Center	Investigator	City	Country
Ospedale San Camillo Forlanini	Prof. Cao	Roma	Italy
Ospedale G. Brotzu	Dr. Campanini	Cagliari	Italy
Hopital Rangueil	Prof. H. Rousseau	Toulouse	France
Osaka University Hospital	Dr. Kuratani	Osaka	Japan
UMC Utrecht	Prof. F. Moll – dr. Van Herwaarden	Utrecht	Netherlands
Hopital George Pompidou	Dr. J. M. Alsac	Paris	France
Hospital UCA de Oviedo	Dr. M. Alonso	Oviedo	Spain
St. Mary's Hospital - London	Dr. M. Hamady	London	United Kingdom
Linköping University Hospital	dr. C. Forssell	Linköping	Sweden

	Total
<b>N</b>	<b>26</b>
Male	69,2%
Mean Age	72y
TAA	80,8%
PAU	3,8%
Type B Dissection	15,4%
Procedure completed	100%
Freedom from endoleak	92,3%
Perioperative overall death	11,5%
Perioperative procedure related death	3.8%

# Cook Arch Branched Device

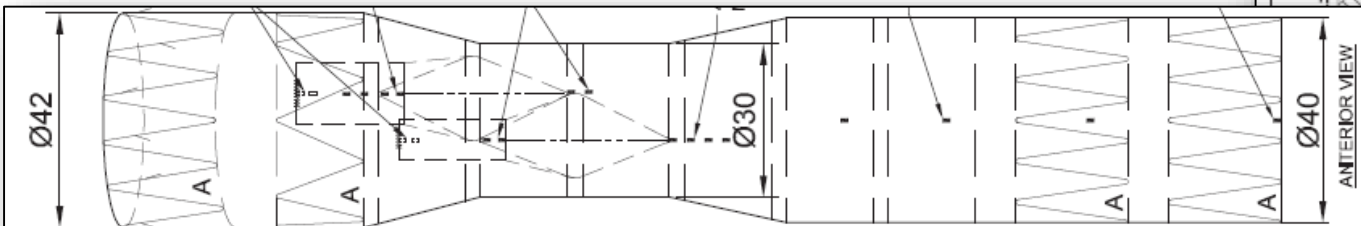
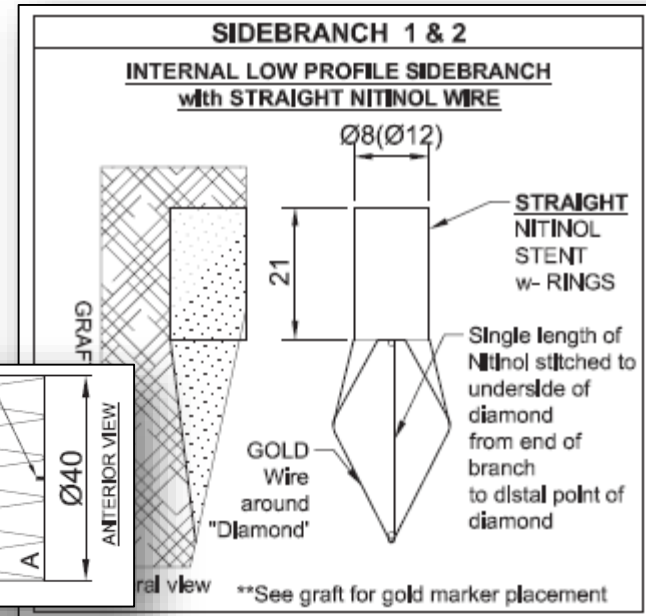
First worldwide reported cases from Stephan Haulon

- Based on TX2 platform



- Double inner branch

INNOMINATE LCCA LENGTH  
12 or 8 mm x 21 mm



# Editor's Choice — Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts, ☆

R. Spear <sup>a</sup>, S. Haulon <sup>a,\*</sup>, T. Ohki <sup>b</sup>, N. Tsilimparis <sup>c</sup>, Y. Kanaoka <sup>b</sup>, C.P.E. Milne <sup>a</sup>, S. Debus <sup>c</sup>, R. Takizawa <sup>b</sup>, T. Kölbel <sup>c</sup>

Eur J Vasc Endovasc Surg 2016

	Group 1 (n = 38)	Group 2 (n = 27)	p
Procedure			
Length (min)	250 (210–330)	295 (232–360)	.35
X-ray time (min)	46 (32–84)	39.3 (34–61)	.07
Volume of contrast (mL)	150 (95–207)	183 (120–290)	.03
Early post-operative			
Endoleaks	11 (28.9%)	3 (11.1%)	.08
Secondary procedures	4 (10.5%)	4 (14.8%)	.61
Cerebrovascular events	6 (15.8%)	3 (11.1%)	.60
Systemic complications	17 (44.7%)	13 (43.3%)	.79
Mortality	5 (13.2%)	0 (0%)	.05
Follow up (n = 33)			
Endoleaks	3 (9.1%)	2 (7.4%)	.82
Secondary procedures	3 (9.1%)	2 (7.4%)	.82
Mortality	4 (12.1%)	1 (3.7%)	.24
Overall mortality	9 (23.6%)	1 (3.7%)	.02

Aortic center	Patients included in current study	Total experience (November 2014)
Hamburg, Germany	12	15
Tokyo, Japan	9	9
Lille, France	6	16

Three-center experience demonstrated an improvement in patient outcome when compared with the early global experience of the technique published in 2014

Group 1: early experience study. \*  
Group 2: current study.

\* Haulon S, Greenberg RK, Spear R, Eagleton M, Abraham C, Lioupis C, et al. Global experience with an inner branched arch endograft. J Thorac Cardiovasc Surg 2014





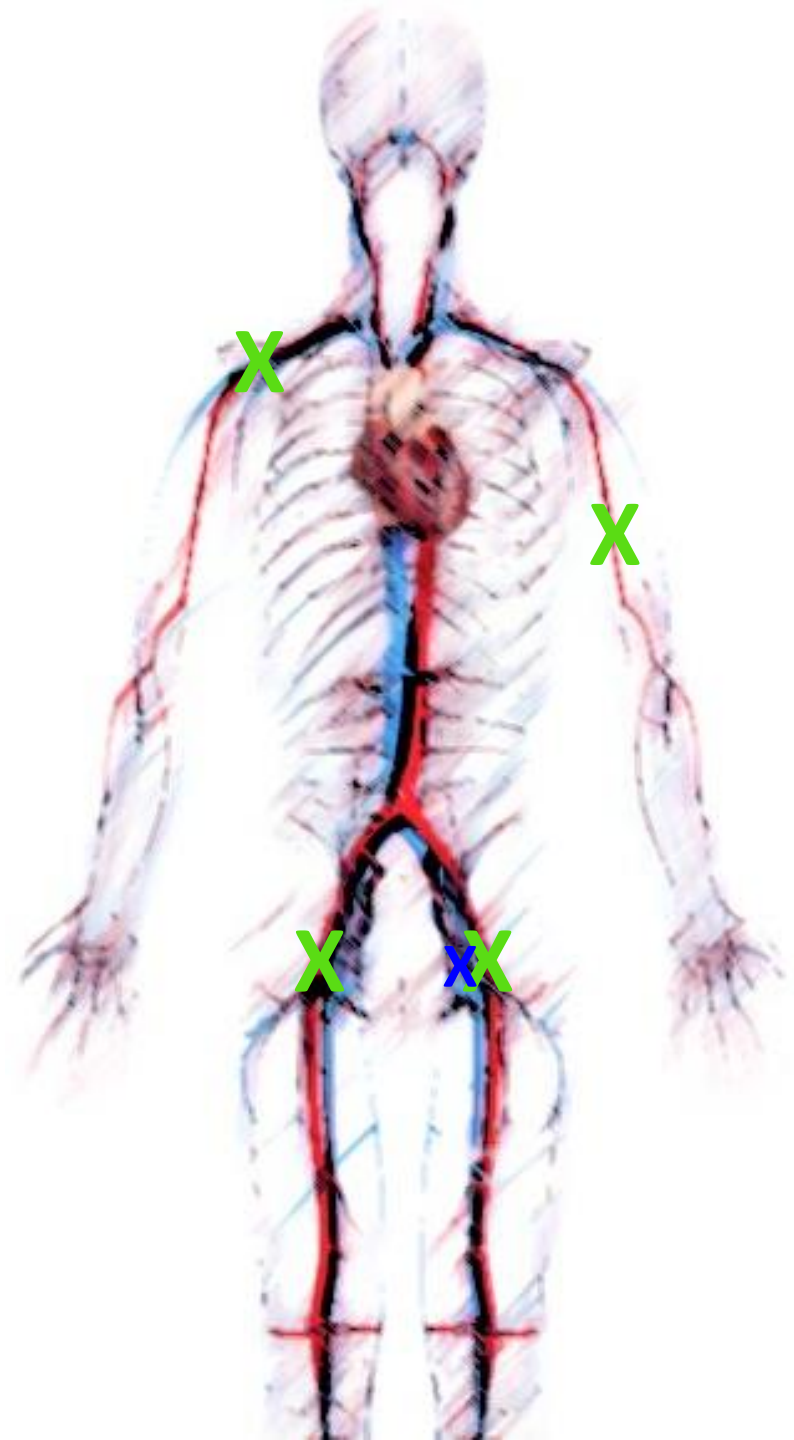
# Anatomic criteria for total endovascular arch repair

- Arch aneurysms and chronic dissections, no previous mechanical aortic valve replacement
- Ascending aortic length  $\geq 50$  mm (measured from sinotubular junction to origin of innominate artery)
- Sealing zone in the ascending aorta  $\geq 40$  mm in length and  $\leq 38$  mm diameter ( $\leq 42$  mm for Bolton device)
- Sealing zone in the innominate artery  $\geq 20$  mm in length and  $\leq 20$  mm in diameter
- Access able to accommodate 22- or 24-F sheaths

# Arch branched stentgraft OPERATIVE DETAILS

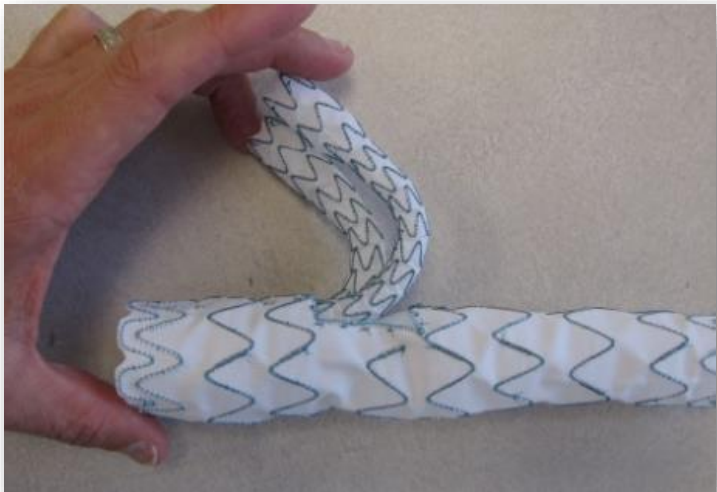
## VASCULAR ACCESSES:

- R femoral a (aortic main body)
- L femoral a (angiography)
- L femoral v (pacing)
- R axillary (innominate branch)
- L brachial (L carotid branch)



# Limits of Arch Branched stentgrafts

- **Time for customization**
- **Morphological criteria:**
  - Asc Ao diameter
  - Asc Ao length
  - Prosthetic valve



# Total Endovascular Treatment of an Aortic Arch Aneurysm in a Patient with a Mechanical Aortic Valve

R. Spear <sup>a</sup>, R. Azzaoui <sup>a</sup>, B. Maurel <sup>a</sup>, J. Sobocinski <sup>a</sup>, B. Roeder <sup>b</sup>, S. Haulon <sup>a,\*</sup>

<sup>a</sup> Aortic Centre, CHRU de Lille, INSERM U1008, Université Lille Nord de France, 59037 Lille Cedex, France

<sup>b</sup> Cook Medical, Bloomington, IN, USA

Eur J Vasc Endovasc Surg 2014

Modified short  
*bullet nose tip*  
positioned **against**  
**the mechanical**  
**valve**



# Ospedale San Camillo 2012 – 2016

## Arch branched procedure: 13



Bolton (n=8)



Cook (n=5)

Single branch:	2/13
Double branch:	11/13
Technical success:	13/13
30-day mortality:	3/13
30-day major stroke:	2/13

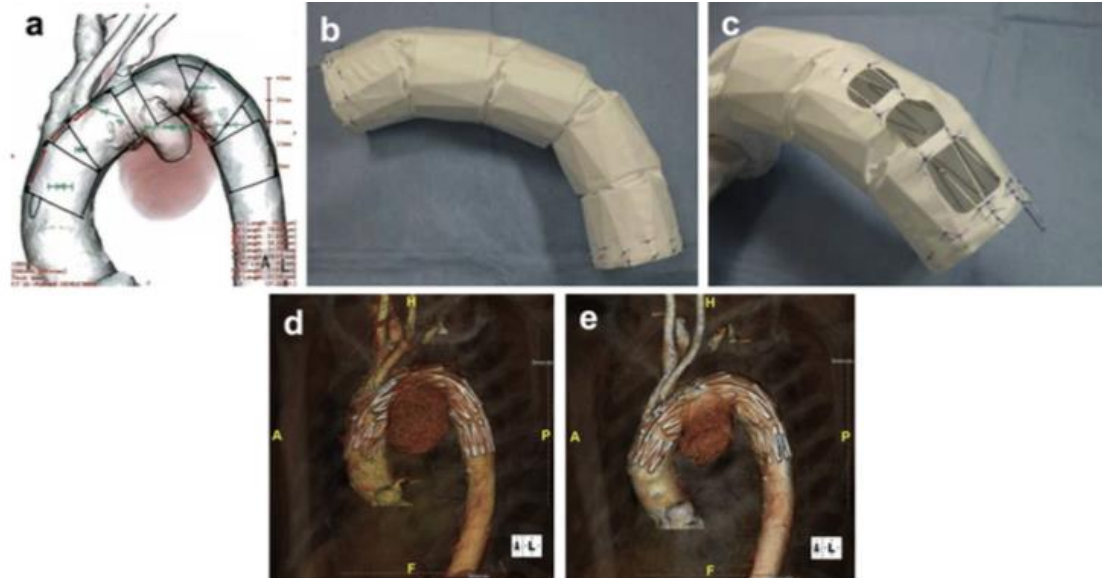
# NAJUTA

## Clinical outcomes of thoracic endovascular aneurysm repair using commercially available fenestrated stent graft (Najuta endograft)

Shinichi Iwakoshi, MD,<sup>a</sup> Shigeo Ichihashi, MD,<sup>a</sup> Hirofumi Itoh, MD,<sup>a</sup> Nobuoki Tabayashi, MD,<sup>b</sup> Shoji Sakaguchi, MD,<sup>c</sup> Takeshi Yoshida, MD,<sup>d</sup> Yoshihisa Nakao, MD,<sup>c</sup> and Kimihiko Kichikawa, MD,<sup>a</sup>  
*Nara, Matsubara, and Yao, Japan*

32 patients

Perioperative death	0/32
Technical success	91%
Type I endoleak	3/32
Stanford A dissections	2/32
Stroke	1/32
SCI	1/32



# ENDOSPAN NEXUS

**ClinicalTrials.gov**

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

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## NEXUS™ Aortic Arch Stent Graft System First In Man Study

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

*Verified February 2015 by Endospan Ltd.*

### Sponsor:

Endospan Ltd.

### Information provided by (Responsible Party):

Endospan Ltd.

### Investigators

Principal Investigator: **Mario Lachat, Prof. MD** Zurich University Hospital

### ClinicalTrials.gov Identifier:

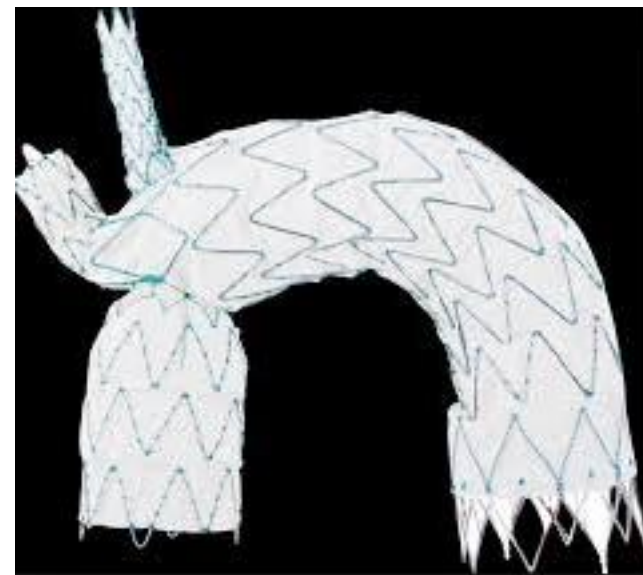
NCT02365454

First received: February 11, 2015

Last updated: February 18, 2015

Last verified: February 2015

[History of Changes](#)



## Conclusion

- ✓ Literature data are still **scarce** and reported from highly selected centers using a single model of endograft
- ✓ Major limitation in branched endograft for Aortic Arch is the **morphological feasibility for a suitable proximal landing zone**
- ✓ **Techniques and technology still in evolution** ( Type of approach and monitoring system, endograft visibility, dedicated branches etc..) although modality of deployment seems relatively simple .
- ✓ **Stroke the major concern** (as in OS)