

TURIN,
October
25th-27th
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GIORNATE CARDIOLOGICHE TORINESI



Aortic arch aneurysm: is endovascular choice ready to become gold standard?

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*Radiologia 3 - Radiologia Vascolare
Città della Salute e della Scienza Torino*



WORK
IN PROGRESS

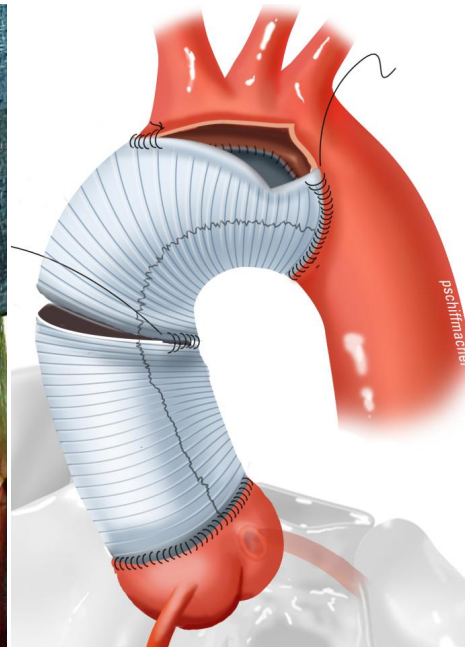
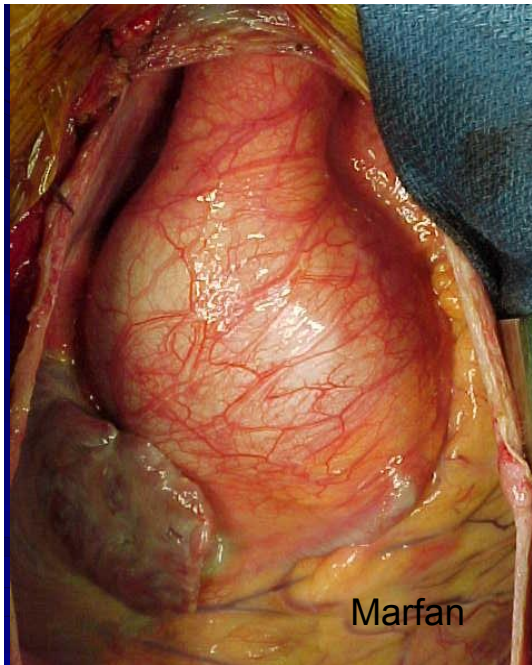
*La riparazione chirurgica open è il gold standard per il trattamento delle patologie dell'arco aortico . A causa della natura invasiva della procedura, che comporta sternotomia o toracotomia, arresto circolatorio ipotermico e bypass cardiopolmonare, molti pazienti sono ritenuti non idonei per la chirurgia . Le riparazioni ibride dell'arco aortico, come la tecnica del »frozen elephant trunk«, riducono i tempi di ischemia cardiaca, ma sono ancora procedure invasive associate a tassi di *ictus* post-operatorio sino al 13% e tassi di mortalità a 30 giorni sino al 12%.*

La riparazione endovascolare dell'aorta toracica (TEVAR) potrebbe essere una valida alternativa minimamente invasiva per i pazienti ritenuti inadatti alla riparazione chirurgica aperta o ibrida. Tuttavia, l'origine delle arterie sopra-aortiche e l'angolazione dell'arco aortico pongono sfide anatomiche per il posizionamento degli endografts .

Pazienti che non devono essere trattati con **TEVAR**:

SINDROMI CONGENITE AORTICHE

PATOLOGIE COINVOLGENTI SOLO L'AORTA TORACICA ASCENDENTE



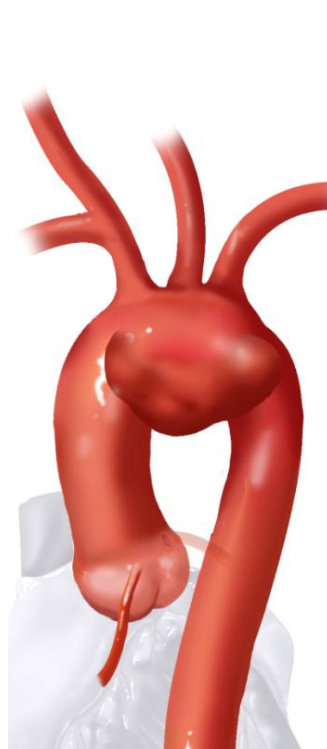
**<2% Mortality/Stroke
for straight forward
Ascending/Hemiarch
+/- Root in
experienced centers**

PAZIENTI CHE POSSONO ESSERE TRATTATI CON **ENDOPROTESI BRANCHED** PER PATOLOGIE DELL'ARCO AORTICO:



**Distal Arch
Aneurysm**

Zone 2 Landing



**Saccular Arch
Aneurysm**



**Mega aorta – intact
ascending LZ**



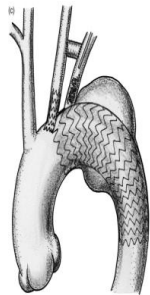
**Residual
Dissection after
Type A repair**

Zone 0/1

OUTCOME DEI TRATTAMENTI ATTUALMENTE USATI PER PATOLOGIE COMPLESSE DELL'ARCO AORTICO



- Open surgical repair
 - Longer hospital stays
 - Younger, healthier patients



- Endovascular Repair (parallel, branched, and fenestrated)
 - High risk for open repair



- Hybrid Repair
 - High risk for open repair

- Perioperative mortality
 - Open = 8.6% (Leshnower, 2011)
 - Parallel device = 4.8% (Moulakakis, 2013)
 - Hybrid = 10.8% (Cao, 2012)
- Stroke/neurological events
 - Open = 8.2% (Hiraoka, 2014)
 - Parallel devices = 4% (Moulakakis, 2013)
 - Hybrid = 6.8% (Cao, 2012)
- Reinterventions
 - Open = 9% (Sundt III, 2008)
 - Parallel = 30.8% (Mangialardi, 2014)

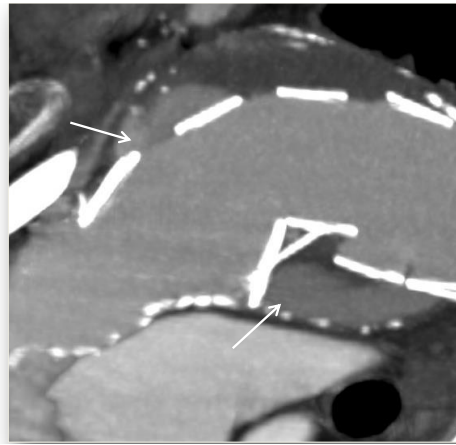
PROBLEMI PER IL TRATTAMENTO ENDOVASCOLARE DELL'ARCO AORTICO

Aumento della pressione e delle forze di migrazione

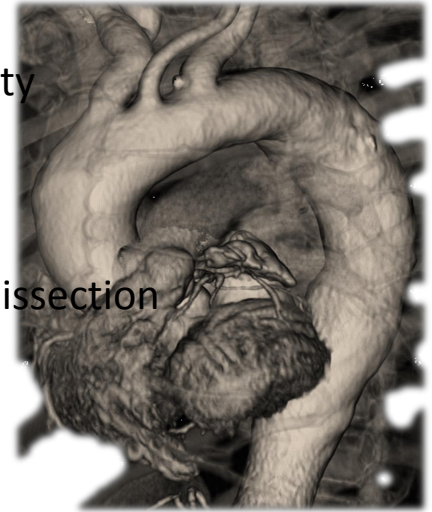
Imaging difficoltoso

Problemi del delivery system

Arterie coronariche e valvola aortica



- ✓ Conformability
- ✓ Endoleak
- ✓ Retrograde dissection
- ✓ Stroke



Piergiorgio Cao, MD, FRCS

Per salvaguardare la pervietà dei vasi epiaortici si possono usare protesi branched o fenestrate (standard o custom)

Table 1 Technical characteristics of investigational branched endografts

First author, year	Manufacturer*	Stent material	Graft material	Landing zone	No. of branches	Inner branch	Separate branch component	Total no. components	Aortic graft diameter (mm)	Branch graft diameter (mm)	Sheath main device (F)	Sheath branch device (F)
Inoue, 1999; Tazaki 2017	PTMC	Nickel titanium	Dacron	0–2	1–3	No	No	1	18–46	8–20	20–24	5–7
Piffaretti, 2013	Bolton	Nitinol	Polyester	0	1	1 antegrade	Yes	2	46	20	26	NA
Haulon, 2014; Spear, 2016	Cook	Nitinol	Polyester	0	2	2 antegrade	Yes	3	38–46	N/A	22–24	14–16
Lim, 2015	S&G	Nitinol	Polyester	0	2	No	Yes	3	44	18, 10	21, 18	N/A
Lu, 2015	MicroPort	Nitinol	Polyester	0	1	No	No	1	28–40	7.5–14	22	4–8
Roselli 2015	Medtronic	Nitinol	Polyester	2	1	No	Yes	2	30–46	10–14	24–25	15
Zhang, 2016; Huang, 2017	MicroPort	Nitinol	Polyester	2	1	No	No	1	30–34	10–16	18–24	8
Patel, 2016	W.L. Gore	Nitinol	PTFE	2	1	1 retrograde	Yes	2	21–53	N/A	N/A	N/A
Spear, 2017	Cook	Nitinol	Polyester	0	3	2 antegrade, 1 retrograde	Yes	4	N/A	N/A	22–24	N/A
D’Onofrio, 2017	Endospan	Nitinol	PTFE	0	1	No	No	2	36–43	14–20	20	N/A
Czerny, 2018	Bolton	Nitinol	Polyester	0	2	2 antegrade	Yes	3	N/A	N/A	25	14

*, device manufacturers: Bolton Medical (Sunrise, FL, USA); Cook Medical (Bloomington, IN, USA); Endospan (Herzlia, Israel); Medtronic Vascular (Santa Rosa, CA, USA); MicroPort Medical Co., Ltd. (Shanghai, China); PTMC Institute (Kyoto, Japan); S&G Biotech Inc. (Seongnam, Korea); W.L. Gore (Flagstaff, AZ, USA). PTFE, polytetrafluoroethylene; N/A, not available.

Theodorus M. van Bakel^{1,2,3#}, Hector W. de Beaufort^{1,2#}, Santi Trimarchi^{2,4}, Massimiliano M. Marrocco-Trischitta², Jean Bismuth⁵, Frans L. Moll¹, Himanshu J. Patel⁶, Joost A. van Herwaarden¹

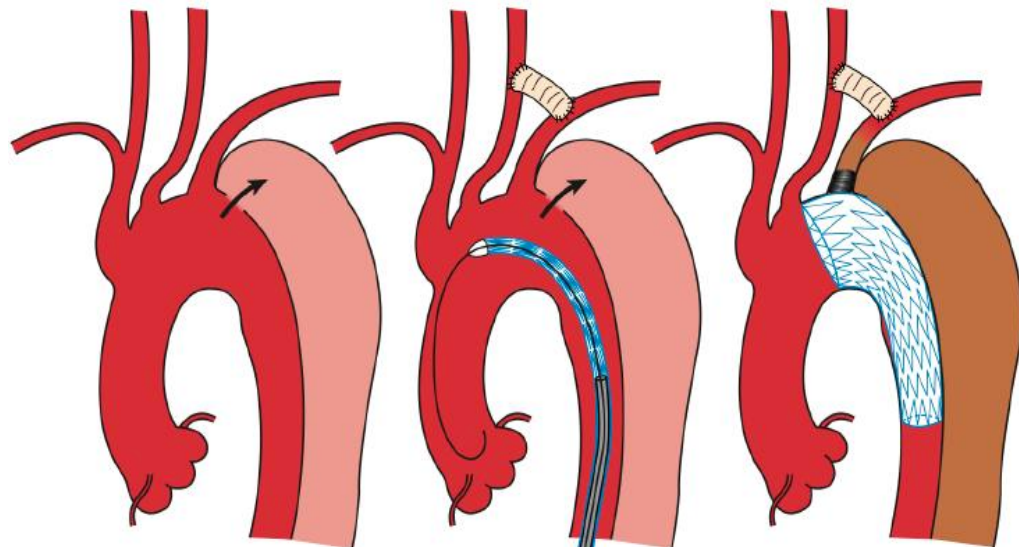
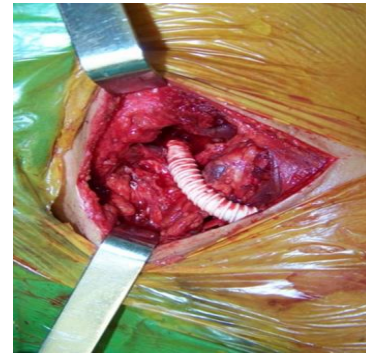
TEVAR ESTESA ALLA ZONA 2: COPERTURA DELL'ARTERIA SUCCLAVIA SINISTRA

Estensione della zona di atterraggio prossimale:

- Estensione prossimale dell'aneurisma
- Angolazione dell'arco
- Rottura traumatica
- Dissezione tipo B

Aspetti negativi del by-pass C-S:

- 1 - 4% STROKE
- Drenaggio della ferita
 - Ematoma
 - Cicatrice
- Difficoltà di legatura della succlavia



Thoracic endovascular aortic repair with branched Inoue Stent Graft for arch aortic aneurysms

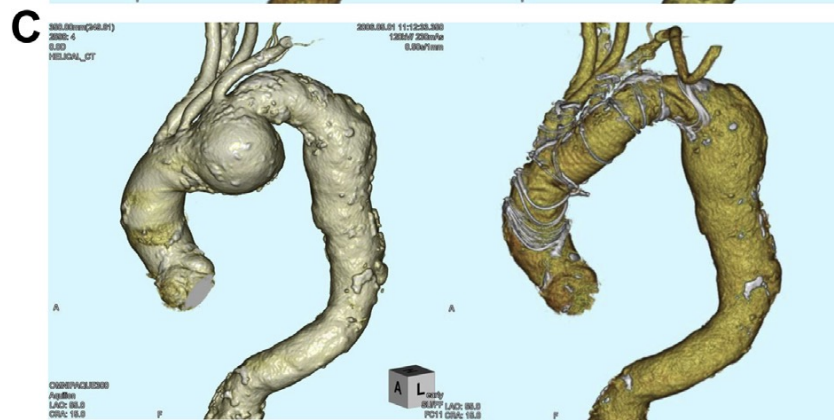
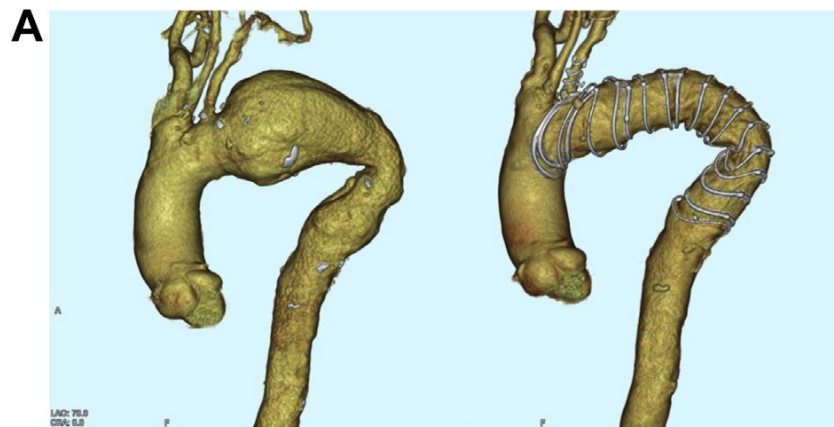
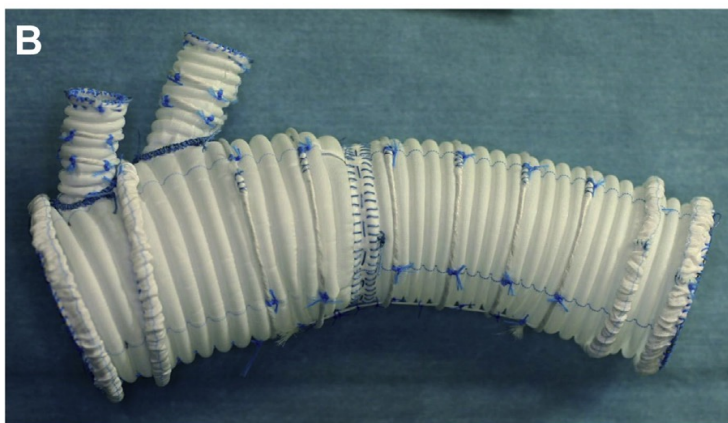
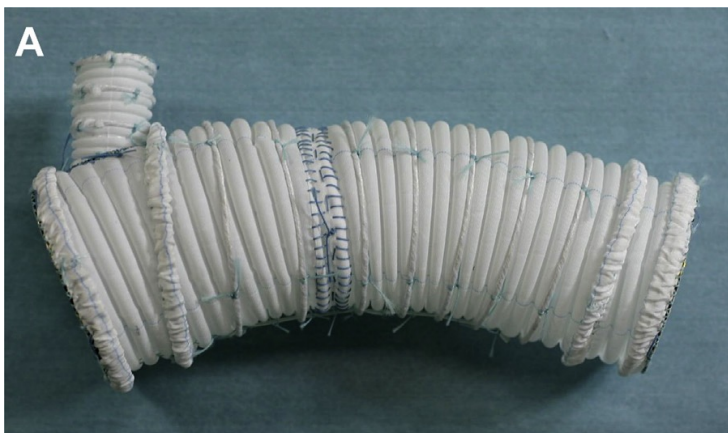
Junichi Tazaki, MD,^a Kanji Inoue, MD,^b Hirooki Higami, MD,^c Nobuya Higashitani, MD,^c Masanao Toma, MD,^d Naritatsu Saito, MD,^a Masahide Kawatou, MD,^e and Takeshi Kimura, MD,^a Kyoto, Otsu, and Amagasaki, Japan

Type of Research: Retrospective analysis of prospectively collected registry data

Take Home Message: Thoracic endovascular aortic repair was performed in 89 consecutive patients for aortic arch aneurysm with branched Inoue Stent Graft with 100% technical success, a mortality of 4.5%, and a periprocedural stroke rate of 7.8% with single-branched device and higher with multiple branches. Freedom from aneurysm-related death at 5 years was 93%.

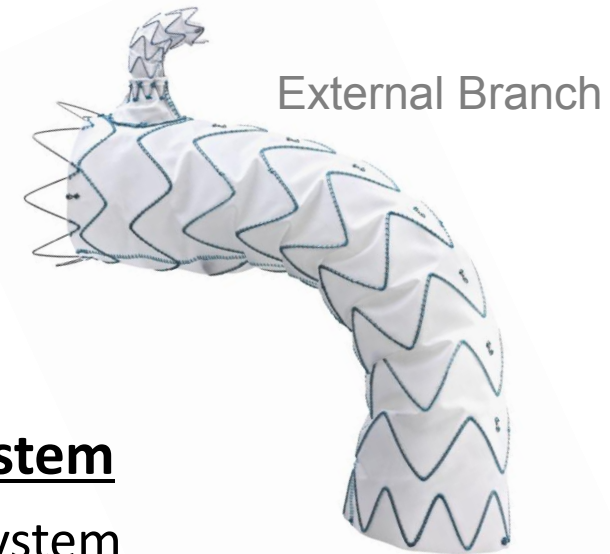
Recommendation: The single-branched Inoue Stent Graft is safe and durable, with acceptable periprocedural complications. ***Caution using multiple branches is warranted.***

- N=89
- Single-64
- Double-18
- Triple-7
- Mortality (30d): 4.5%
- Stroke: 16%
- Branch Occlusion: LSCA-I
- ACM @ 1 and 5 yrs: 85%/59%



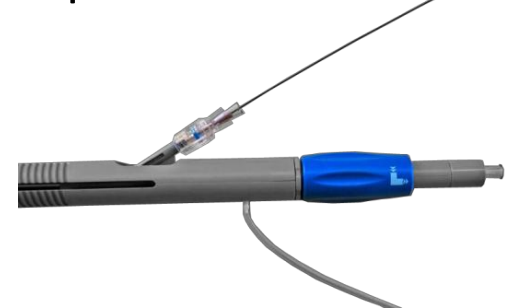
Medtronic Valiant Mona LSA

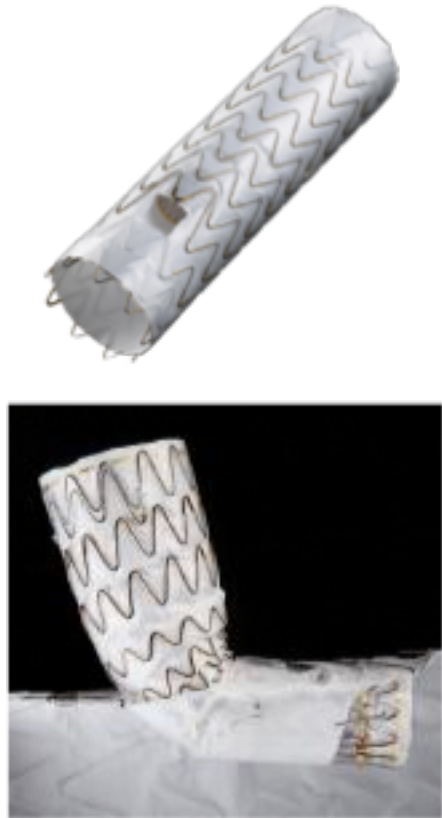
Early Feasibility



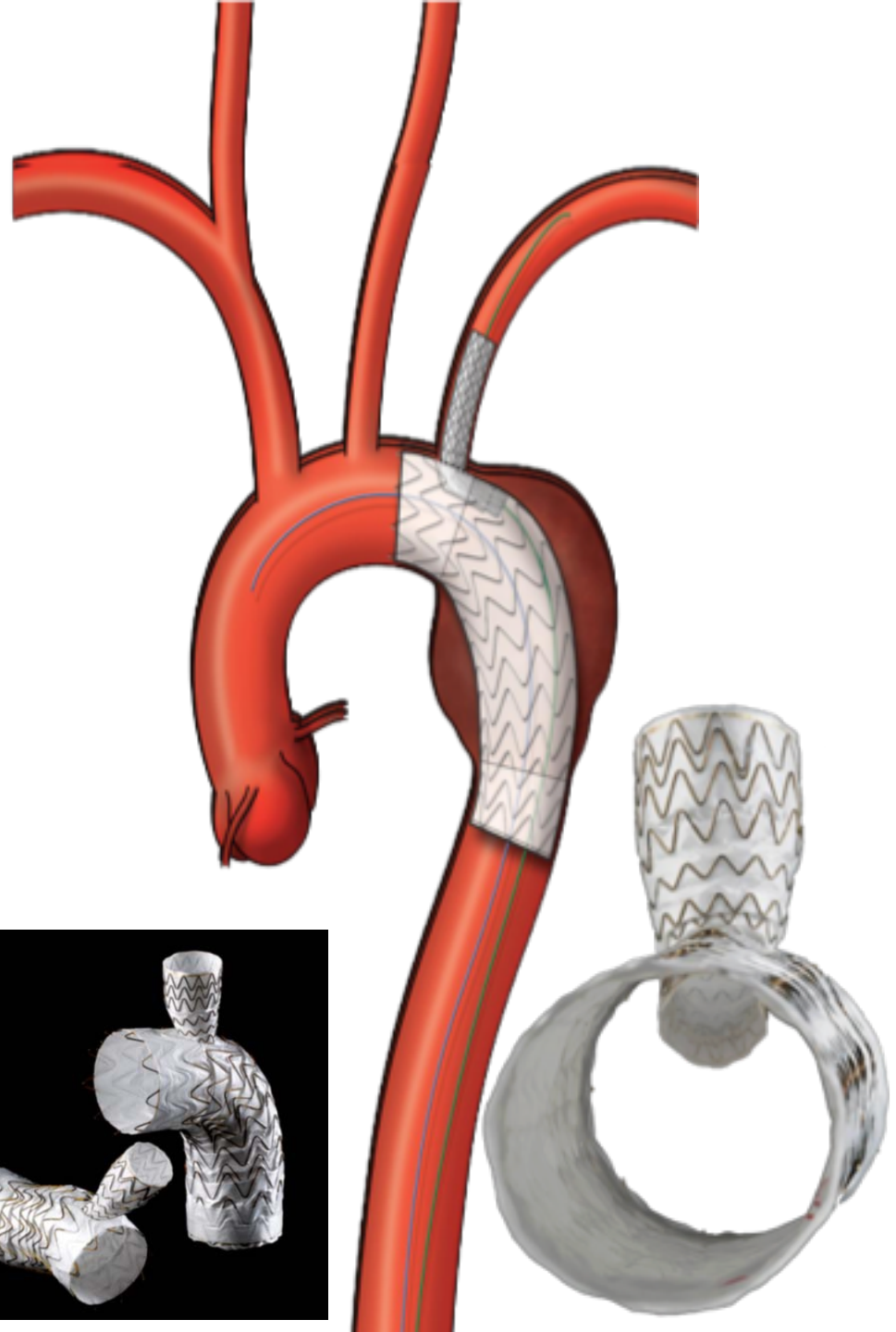
Delivery System

- Two wire system
 - Main/primary aortic tracking wire
 - LSA cannulation wire
- Pre-cannulated LSA cuff
- Tip capture for precise MSG delivery

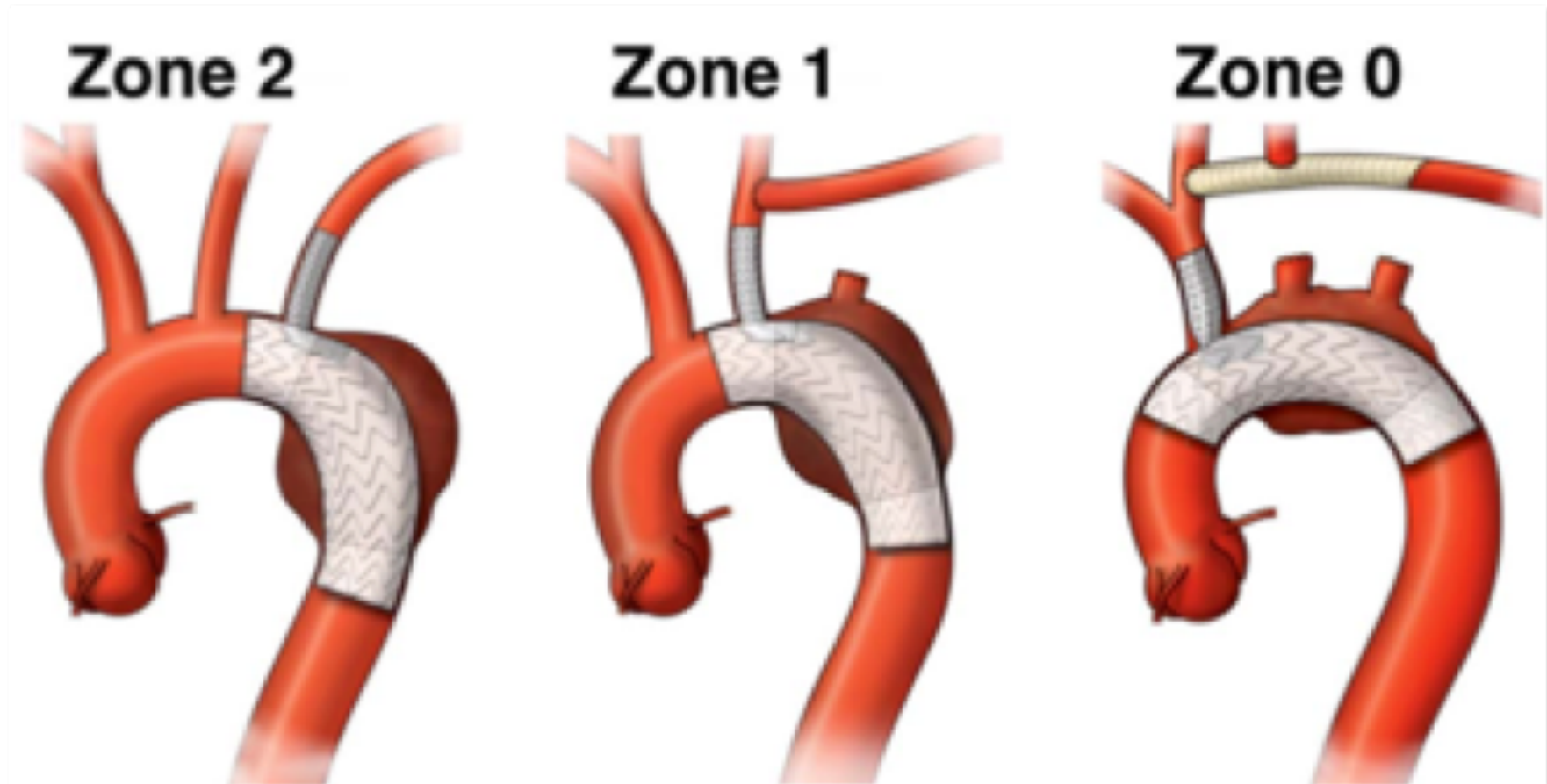




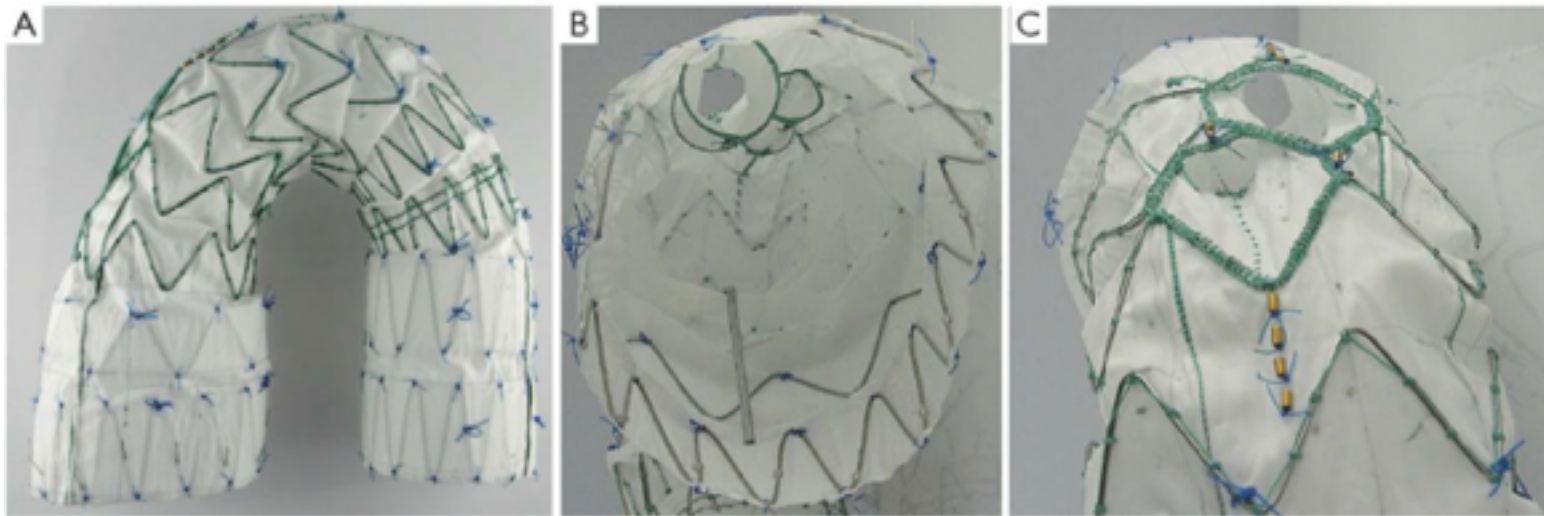
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*Thoracic Branch
Endoprosthesis*



GORE® TAG® *Thoracic Branch Endoprosthesis*



COOK MUTIBRANCH GRAFT AORTICO



Global experience with an inner branched arch endograft

Stéphan Haulon, MD, PhD,^a Roy K. Greenberg, MD,^b Rafaëlle Spear, MD,^a Matt Eagleton, MD,^b Cherrie Abraham, MD,^c Christos Lioupis, MD,^c Eric Verhoeven, MD, PhD,^d Krassi Ivancev, MD,^e Tilo Kölbel, MD, PhD,^f Brendan Stanley, MD,^g Timothy Resch, MD,^h Pascal Desgranges, MD, PhD,ⁱ Blandine Maurel, MD,^a Blayne Roeder, PhD,^j Timothy Chuter, MD,^k and Tara Mastracci, MD^b

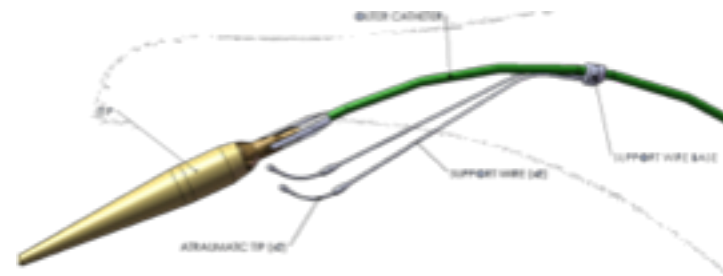
- Pts: 38 with a mean age of 71
- Technical Success: 84.1%
- Mortality: 13.2%
- Cerebrovascular Complications: 15.8%



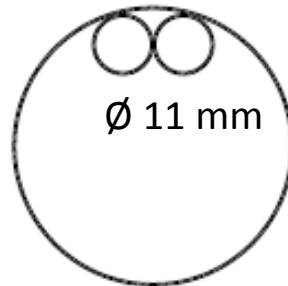
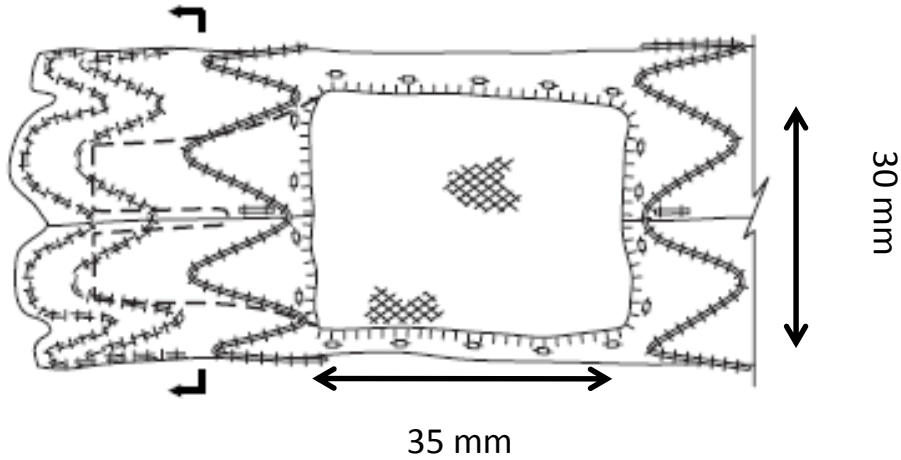
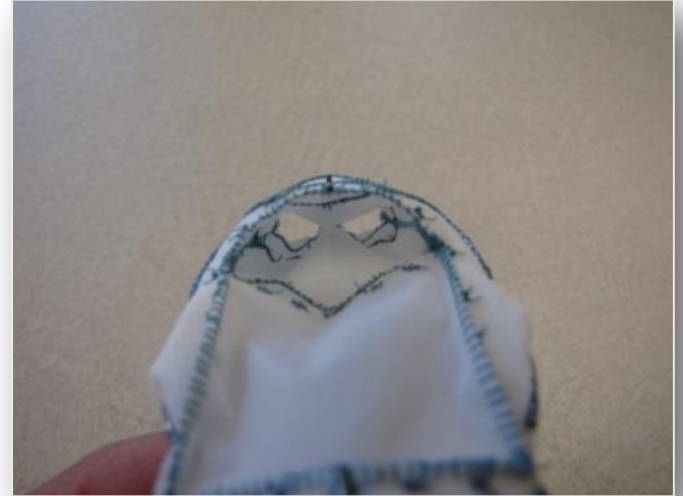
bypass carotido-succlavio pre intervento



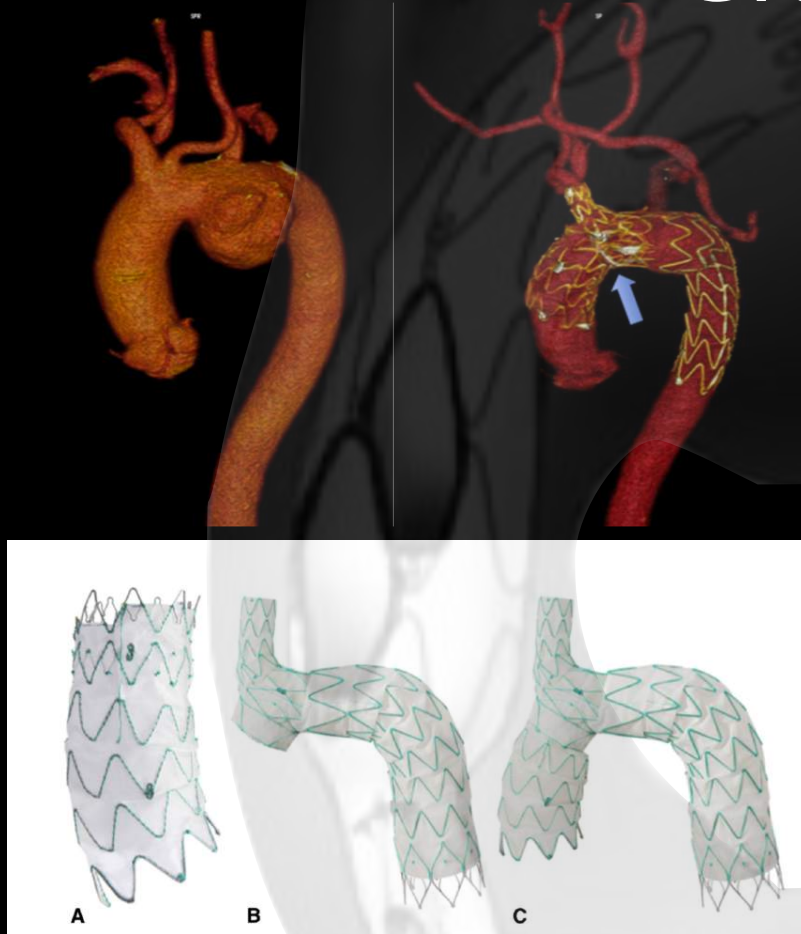
Bolton Relay Dual Branch



Bolton Arch Branched Device



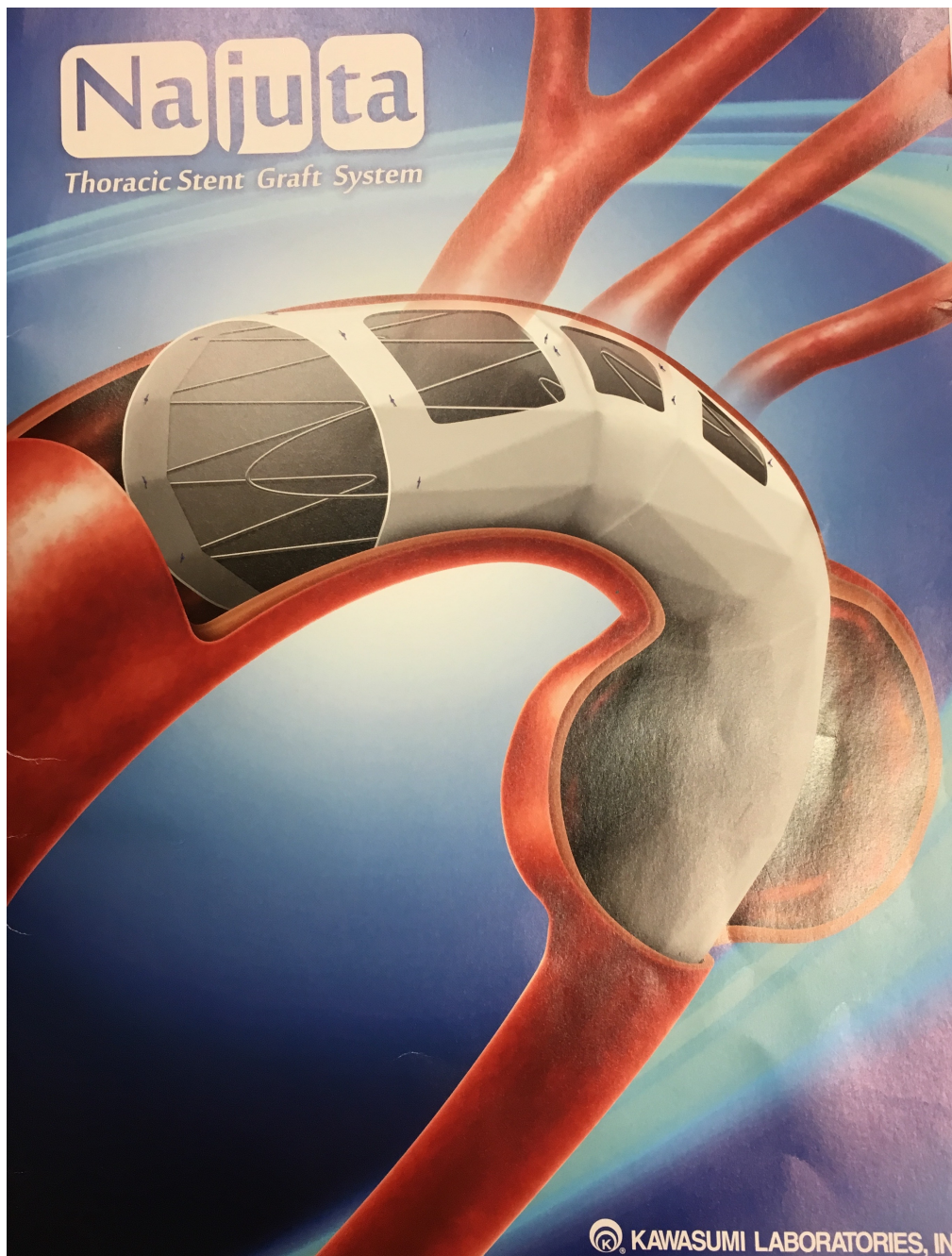
Nexus Endospan Aortic Branched Graft Graft



- Comprised of a curved aortic component
- Ascending Component



D'Onofrio, A, et al. (2017). Endovascular treatment of aortic arch aneurysm with a single-branched double-stage stent graft. *JTCVS*. 2017.06.030



Report of implant simulation

Case control number: E0007

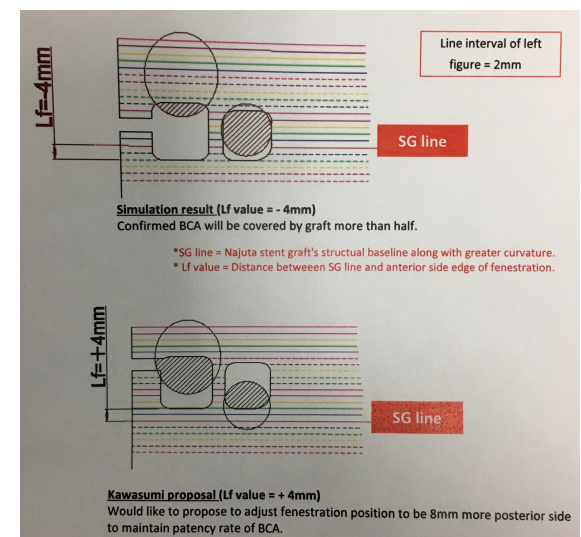
Surgeon: Maria Antonella Ruffino Patient's ID: 9001046164

Proximal stentgraft recommended specifications			Distal stentgraft recommended specifications		
Skeleton	Graft	Sheath	Skeleton	Graft	Sheath
AR4L	V42CL2	3U73			

Result of implant simulation using vessel model

confirmation of fenestration position using industrial endoscope

	innominate artery posterior	left common carotid artery posterior	subclavian artery posterior
ascending			
anterior			
	BCA is half or less-covered with graft.	LCA is preserved by fenestration.	LSCA is full-covered with graft.



Advantage of a precurved fenestrated endograft for aortic arch disease: Simplified arch aneurysm treatment in Japan 2010 and 2011

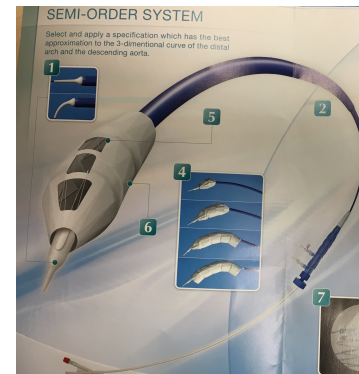
Yoshihiko Yokoi, MD, Takashi Azuma, MD, and Kenji Yamazaki, MD, PhD

Objective: We evaluated the results of our previous study investigating a precurved fenestrated endograft treatment for thoracic aortic aneurysms and aortic dissection extended to the aortic arch.

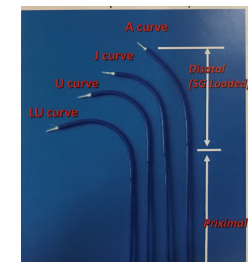
Methods: From February 2010 to December 2011 at 35 Japanese centers, 383 patients (mean age, 75.7 ± 9.4 years) who required stent-graft landing in the aortic arch were treated with a precurved fenestrated endograft. The device has 19 3-dimensional curved stent skeleton types similar to aortic arch configurations and 8 graft fenestration types and is 24 to 44 mm in diameter and 16 to 20 cm long. The endografts were fabricated according to preoperative 3-dimensional computed tomographic images.

Results: Technical and initial successes were achieved in 380 and 364 cases, respectively. Device proximal end was at zones 0 to 2 in 363, 15, and 2 patients, respectively. Lesions' proximal end ranged from zone 0 to 3 in 16, 125, 195, and 44 patients, respectively. The mean operative and fluoroscopic times were 161 ± 76 and 26 ± 13 min, respectively. The complications included stroke (7 patients), permanent paralysis (3), and perioperative death (6). No branch occlusion or proximal migration of the device occurred during follow-up.

Conclusions: A precurved fenestrated endograft for endovascular repair in aortic arch disease rendered catheter manipulation simple and minimized operative complication risks. Although most patients had inadequate proximal landing zone and severely angled complex configuration, low mortality and morbidity and satisfactory clinical success were early outcomes, suggesting that this simplified treatment may be effective for aortic arch disease. (J Thorac Cardiovasc Surg 2013;145:S103-9)



Customized fenestrated device
19 types precurved stent body
8 types fenestrations for arch vessels
383 patients @ 35 sites in Japan 1.6% Mortality
1.8% Stroke



Sheath Distal Diameter (SG loading section)			
O.D	21Fr	22Fr	23Fr
I.D	18Fr	19Fr	20Fr
Compatible stent diameter	24 - 30 mm	32 - 34 mm	36 - 42 mm
Sheath Proximal Diameter			
18Fr			
Sheath length			
950mm, 730mm, 580mm			

Major Adverse Event

N (%)

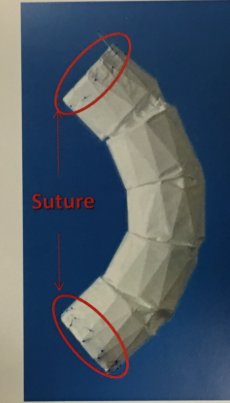
	≤30 days N=393	1 year N=393	2 year N=204	3 year N=59
Stroke	24 (6.1)	1 (0.3)	0 (0)	1 (1.7)
Hemorrhage	0 (0)	2 (0.5)	0 (0)	0 (0)
SCI	4 (1.0)	0 (0)	0 (0)	0 (0)
Aneurysm rupture	1 (0.3)	2 (0.5)	0 (0)	0 (0)
Type A dissection	2 (0.5)	1 (0.3)	0 (0)	0 (0)
Vascular injury	11 (2.8)	0 (0.0)	0 (0.0)	0 (0)

◆ "Najuta" Stent Graft System Outline

- Semi-order system with a combination of graft and metallic stent



◆ **Graft**
Material : PTFE
(Polytetrafluoroethylene)



◆ **Suture**
Material : PVdF
(Polyvinylidene Fluoride)



◆ **Metallic Stent**
Material : Stainless-Steel
(ISO 5832-1)

◆ SEMI-ORDER SYSTEM STENTGRAFT

- Stent shape matching 3-dementional curve of vessel and proper select of fenestration make its application wider. →1590specs



For Arch
(Fenestrated)

For Arch
(non-Fenestrated)

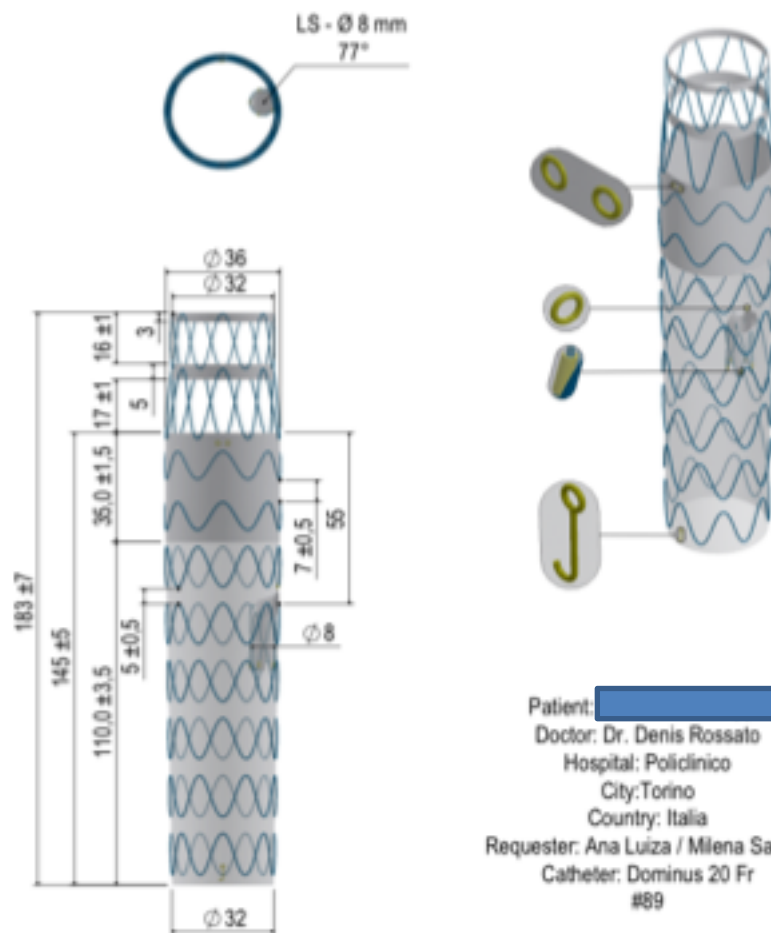
For
Descending aorta

For
Thoraco-abdominal

Endoleak (True Aneurysm)

N (%)

		Discharge N=342	1year N=288	2year N=158	3year N=46
Type	I	29 (8.5)	13 (4.5)	11 (7.0)	3 (6.5)
	II	37 (10.8)	17 (5.9)	2 (1.3)	2 (4.3)
	III	4 (1.2)	1 (0.3)	2 (1.3)	1 (2.2)
	IV	0 (0)	0 (0)	1 (0.6)	0 (0)
	Unknown	6 (1.8)	6 (2.1)	4(2.5)	0 (0)
	Not evaluated	15 (4.4)	110 (38.2)	78 (49.4)	27 (58.7)



Patient: [REDACTED]
 Doctor: Dr. Denis Rossato
 Hospital: Policlínico
 City: Torino
 Country: Italia
 Requester: Ana Luiza / Milena Santos
 Catheter: Dominus 20 Fr
 #89



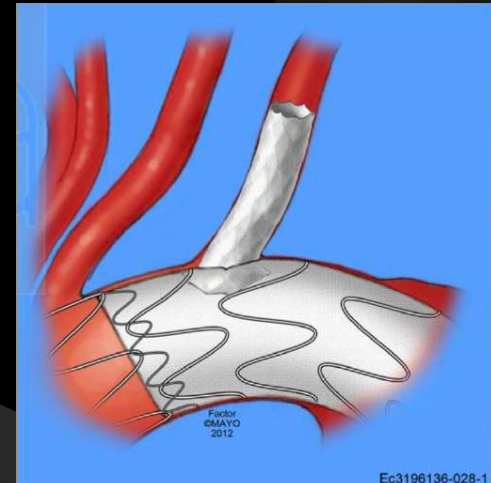
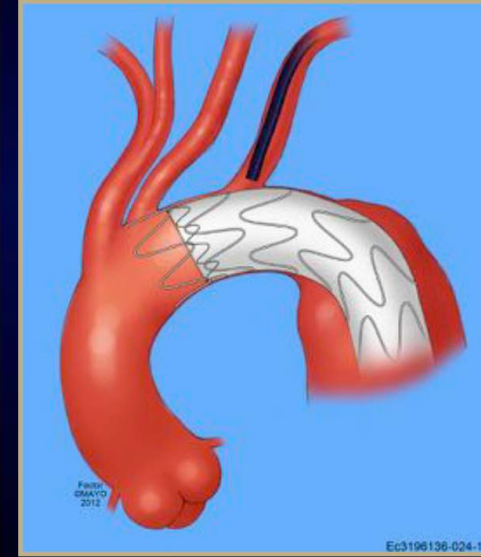
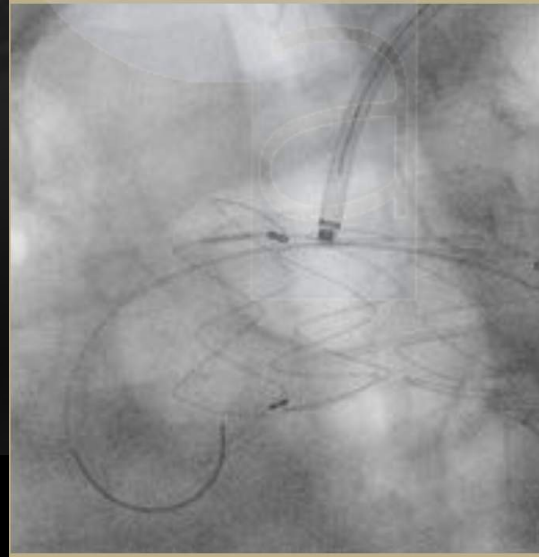
3			1	Sub End. 3.0. Branch 20 x 32 - 150 FFS0 (Pac. Monocore Uniaxial)	SEE TABLE	---	---
2			2	NAME	MATERIAL AND DIMENSIONS	CONSUMPTION	
1	06/04/2018	added proximal patch, increased intermediate patch, inserted the second distal catheter	DATE	SIGNATURE	 BRAILE[®] BIOMÉDICA Orgulhosamente brasileira São José do Rio Preto - SP / www.braille.com.br		
1	Ana Luiza		06/04/2018	Wellington F.			
Units in mm except where indicated.			 CUSTOMIZED ENDOPROTHESIS		ERA-50-218 A4		
Tolerances not indicated: 0 a 30 ± 0.1 mm >30 a 120 ± 0.15 mm >120 a 0.2 mm			CODE 612355		RECIPES DOCC		

In-Situ Laser Fenestration

Mark A. Farber

Professor of Surgery and Radiology
Director, UNC Aortic Network
University of North Carolina
Chapel Hill, NC

- N=41 (39 LSCA, 2 LCCA)
- Operative Mortality: 7.3%
- Neurologic Complications:
 - Stroke: 2 (4.9%)
 - SCI: 3 (7.3%, 2 permanent, 1 transient)
- No Type III endoleaks
- Type Ic: 3 7.3%
- All stents patent
- 2 asymptomatic stenosis



Conclusioni

Numerosi produttori di dispositivi medici stanno sviluppando endografts branched e fenestrati per il trattamento delle patologie dell'arco aortico con ridotta manipolazione dell'arco e salvataggio dei vasi epiaortici senza necessità di by-pass, fornendo una soluzione minimamente invasiva per i pazienti ritenuti inadatti alla riparazione open dell'arco. L'approccio endovascolare è una valida alternativa alla chirurgia per tutti i pazienti quando morfologicamente fattibile. L'identificazione di una valida zona di atterraggio prossimale resta la preoccupazione maggiore; se non esiste meglio usare protesi fenestate.

I risultati di F e B-TEVAR sono promettenti, eppure l'ictus rimane la complicanza maggiore periprocedurale predominante.

Per ora, queste procedure dovrebbero essere limitate a Centri selezionati in cui la progettazione e la procedura possono essere ulteriormente sviluppati per un migliore outcome del paziente.



**WORK
IN PROGRESS**