

The logo for i-MEET, featuring the letters 'i-MEET' in a stylized, bold, white font on a black background. The 'i' is lowercase and the 'MEET' is uppercase.

NEXT GENERATION

* The Interactively MEETing

Multidisciplinary European Endovascular Therapy

MAY 30 - JUNE 1, 2018 - NICE, FRANCE

What is the best Treatment of Arch aneurysms?

Sonia Ronchey MD, PhD

San Filippo Neri Roma

CONFLICT OF INTEREST

- FIRST IN MAN NEXUS DEVICE

I AM THE LORD THY GOD
THOU SHALT HAVE NO
OTHER GODS BEFORE ME
THOU SHALT NOT MAKE UNTO
THEE ANY GRAVEN IMAGE
THOU SHALT NOT TAKE THE
NAME OF THE LORD THY
GOD IN VAIN
REMEMBER THE SABBATH
DAY TO KEEP IT HOLY

HONOUR THY FATHER AND
THY MOTHER
THOU SHALT NOT KILL
THOU SHALT NOT COMMIT
ADULTERY
THOU SHALT NOT STEAL
THOU SHALT NOT BEAR
FALSE WITNESS
THOU SHALT NOT COVET

Current and future perspectives in the repair of aneurysms involving the aortic arch

B. MAUREL¹, J. SOBOCINSKI¹, R. SPEAR¹, R. AZZAQUI¹, M. KOUSSA¹, A. PRAT¹, M. R. TYRRELL², A. HERTAULT¹, S. HAULON¹

¹Vascular and Cardiac Surgery, Aortic Centre
Hôpital Cardiologique, CHRU de Lille, France
²King's Health Partners, London, UK

The repair of aneurysms involving the aortic arch is technically and physiologically demanding. Historically, these aneurysms have been treated using open surgical techniques that require cardiopulmonary bypass and deep hypothermic circulatory arrest. Many patients have been deemed "untreatable" and among those selected for surgery there are reported risks of death in 2% to 16.5% and stroke rates ranging from 2% to 18%. "Hybrid arch repair" combines one of a number of open surgical procedures (to secure a proximal landing zone for an endograft) with subsequent or immediate placement of an endograft in the arch and descending aorta. Although this concept is described as "minimally invasive" because it avoids aortic cross-clamping and hypothermic circulatory arrest, the morbidity and mortality rates remain considerable (mortality 0% to 15%, stroke 0% to 11%). Ongoing development of endograft technology has enabled total endovascular repair of complex aortic aneurysms involving the visceral segment, using fenestrated and branched endografts. Encouraging early results in his anatomy have inspired extension of the concept to include the aortic arch and great vessels. These strategies can be considered in patients generally at high-risk for the conventional procedures. However, the endeavour is of its development and the arch poses

remains a formidable undertaking. The "minimally invasive" options involving great vessel debranching and subsequent placement of aortic endografts have not materially reduced the operative risks. Total endovascular arch repair, using branched or fenestrated arch endografts, is technically challenging and represents the limit of current material science. Nevertheless, this approach may lower the morbidity associated with arch aneurysm repair hitherto. Currently, this approach is unproven and is offered to selected patients deemed to be at "high risk" for the conventional options.

The aim of this article was to review all of the current technical options available for the treatment of patients with aortic arch aneurysms.

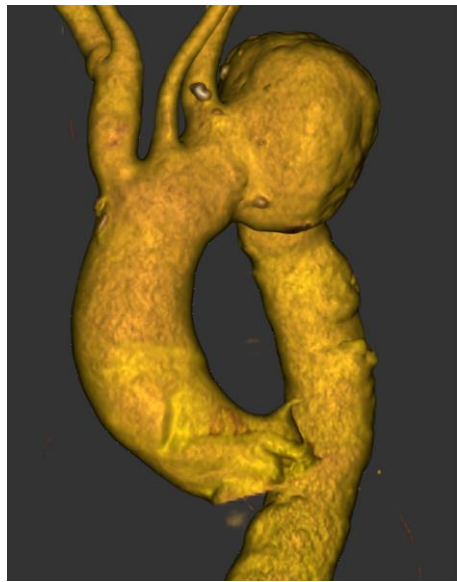
include the aortic arch and great vessels. These strategies can be considered in patients generally at high-risk for the conventional procedures. However, the endeavour is at an early stage of its development and the arch poses unique challenges including the potential for stroke, angulation of the arch and the great vessel ostia to the arch, extremely high volume flow, three-dimensional pulsation and rotation with the cardiac cycle and the proximity of the aortic valve and coronary arteries.

- Proximity
- Aortic valve

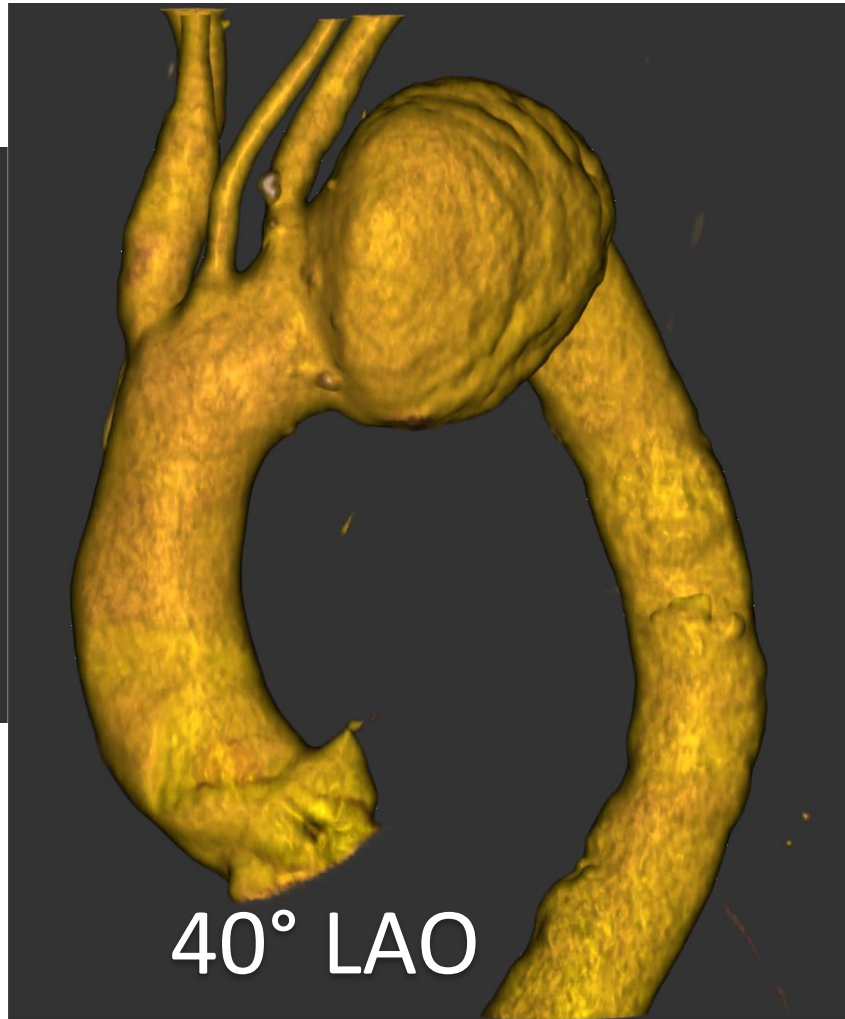
- Cerebral
- vessels

- Arch
- Anatomy

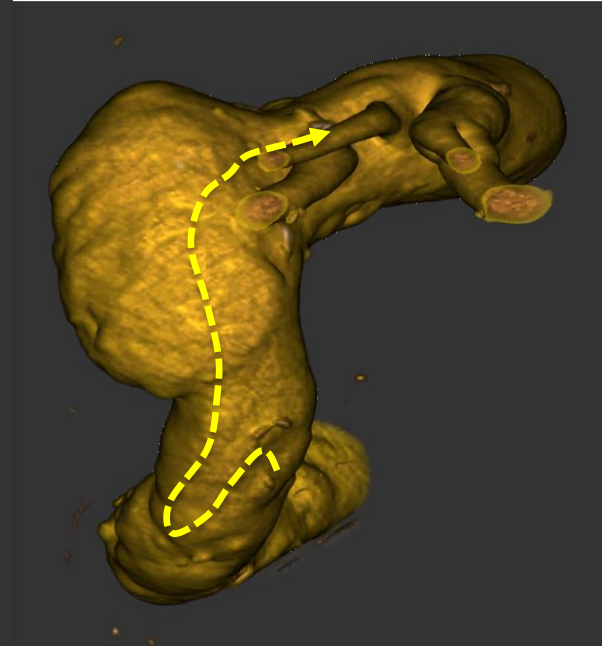
3 PLANES TORTUOSITY



A



40° LAO



S

Arch Repair - Adjuncts

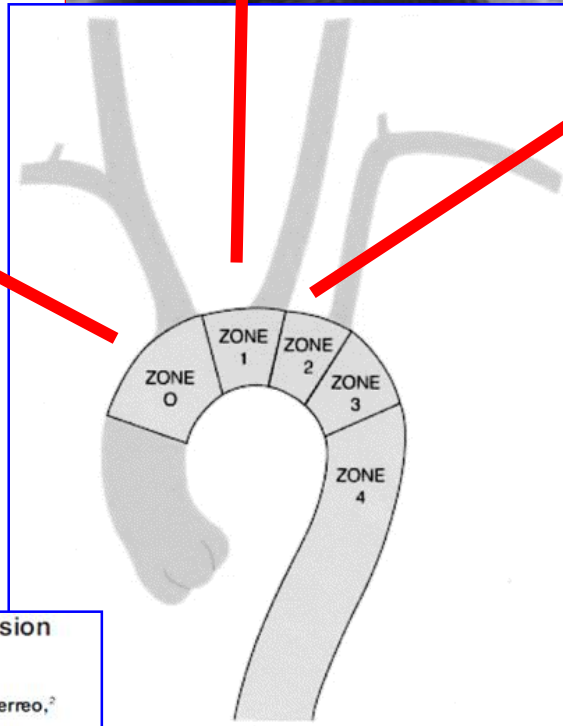
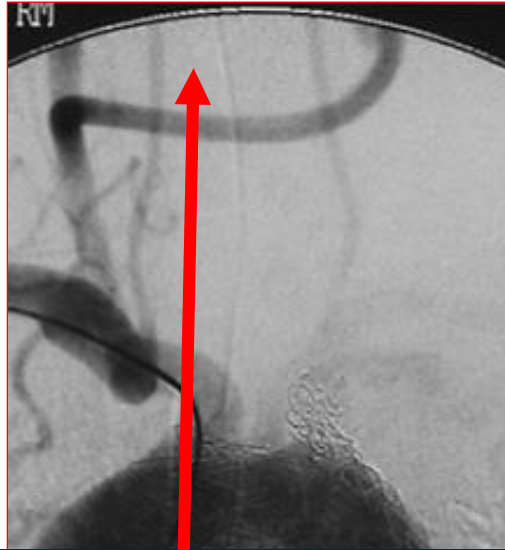
- Trackability (Trough & Trough, double stiff wire, wire fixed in the ascending)
- Controlled Hypotension (Cardiac Pacing, Adenosine, IVC ballooning)
- Hybrid room (hopefully!!!!!!)

ENDOVASCULAR OPTIONS



- HYBRID TREATMENT
 - SURGICAL DEBRANCHING + TEVAR
- ENDOVASCULAR TREATMENT
 - CHIMNEY
 - BRANCH/FENESTRATED

DEBRANCHING



Great Vessel Management for Endovascular Exclusion of Aortic Arch Aneurysms and Dissections

P. Bergeron,^{1*} N. Mangialardi,² P. Costa,² P. Coulon,¹ V. Douillez,¹ E. Serreo,² I. Tuccimei,² C. Cavazzini,² F. Mariotti,² Y. Sun¹ and J. Gay¹

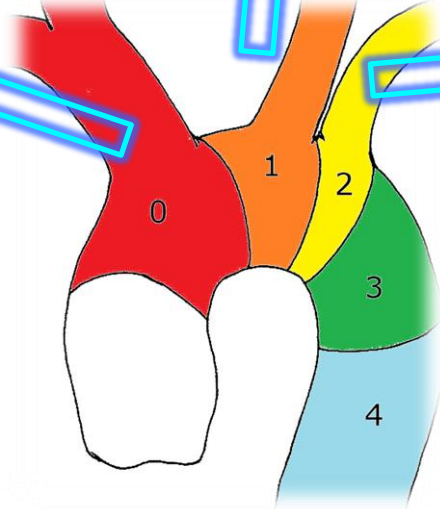
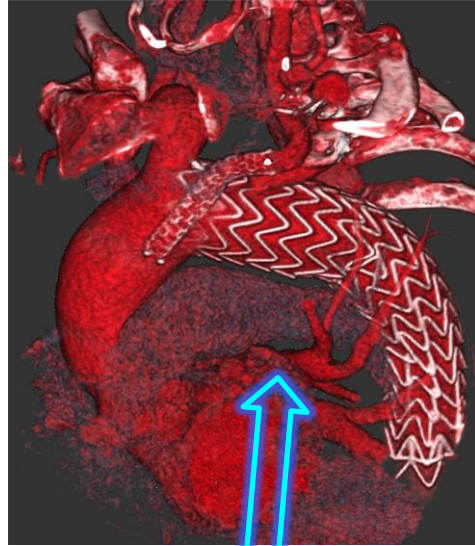
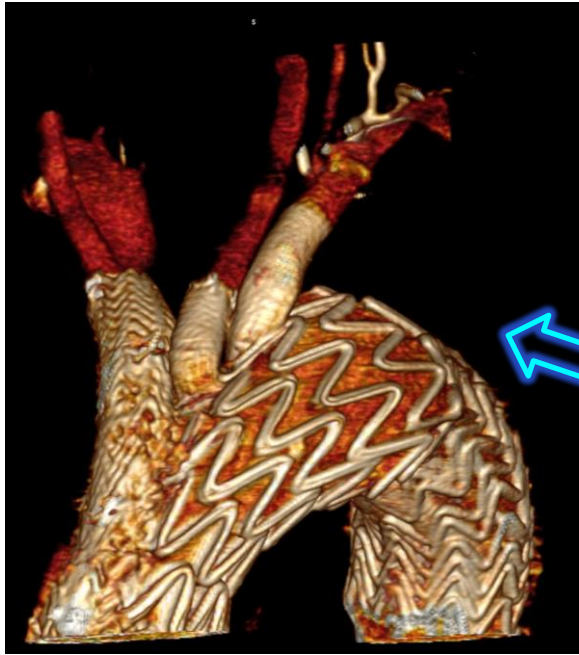
Eur J Vasc Endovasc Surg 32, 38–45 (2006)

INTRAOPERATIVE COMPLICATIONS

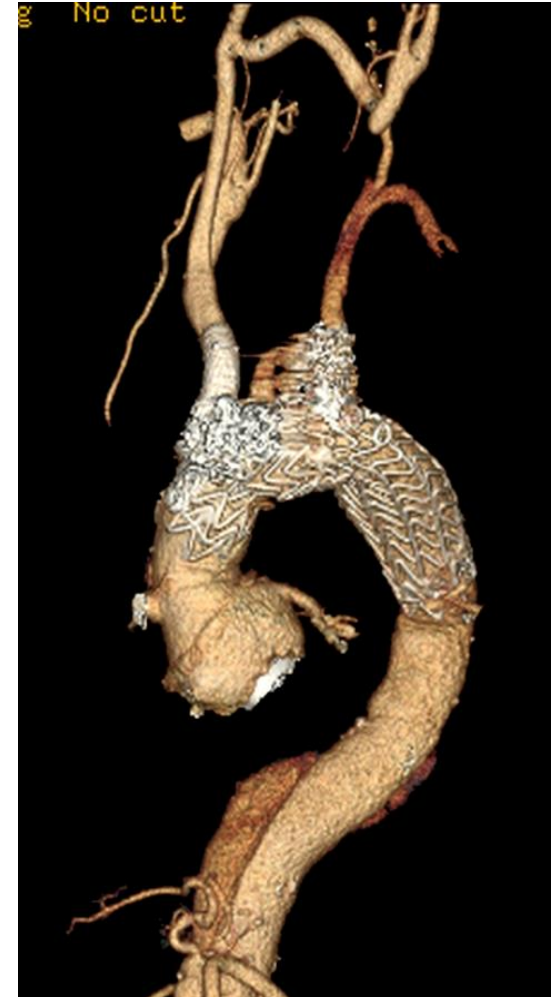
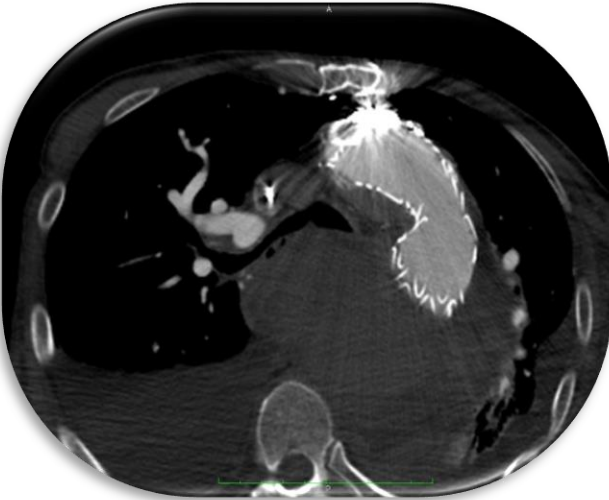
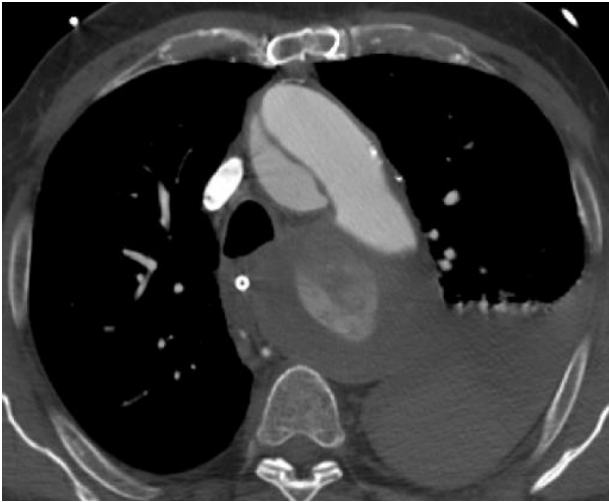
TEVAR RELATED

- Mortality 0-25%
- Malapposition 0.7-2.0%
- Misplacement/Migration 0/30%
- Type I e-leak 5-20%
- Retrograde dissection 0.5-6.8%
- Infolding 0.15%
- Stroke 0-18,6%

CHIMNEY



Debranching + Chimney For a ruptured Aneurysm on a chronic dissection



DO THEY WORK?

Chimney Technique for Aortic Arch Pathologies: An 11-Year Single-Center Experience

Nicola Mangialardi, MD; Eugenia Serrao, MD; Holta Kasemi, MD; Vittorio Alberti, MD;
Stefano Fazzini, MD; and Sonia Ronchey, MD, PhD

Department of Vascular Surgery, San Filippo Neri Hospital, Rome, Italy.

- TECHNICAL SUCCESS 39/39 100%
- MORTALITY 4 10.2%
- PROCEDURE REL COMPLICATIONS 4 10.2%
- MINOR STROKE (2 RUPT-1 ELECT) 3
- PARAPARESIS 1
- EARLY TYPE I EL 0

OS & T1EL Gutters

Ann Vasc Surg. 2018 Jan;46:285-298. doi: 10.1016/j.avsg.2017.07.018. Epub 2017 Jul 21.

"Over-SIRIX": A New Method for Sizing Aortic Endografts in Combination with the Chimney Grafts: Early Experience with Aortic Arch Disease.

Fazzini S¹, Ronchey S², Orrico M², Martinelli O³, Alberti V², Praquin B², Mangialardi N².

⊕ Author information

Abstract

BACKGROUND: Large gutters after chimney procedures are one of the main causes of type I endoleak (EL-I). This study aims to evaluate a new tailored planning named "Over-SIRIX," based on Osirix Imaging Software, to choose the correct main graft oversizing in order to minimize EL-I incidence.

METHODS: From 2008 to 2015, 34 patients were treated with parallel grafts for aortic arch diseases at our institution. The study included 22 patients with single stent and antegrade flow configuration; they were divided into 2 groups (PRE- and POST-"Over-SIRIX"). "Over-SIRIX" was carried out in the retrospective group (PRE-"Over-SIRIX"), and it was used to plan the endovascular procedure in the prospective group (POST-"Over-SIRIX"). Through the multiplanar reconstruction (MPR) of the preoperative computed tomography angiography (CTA), the proximal neck of the chimney grafts was studied. Stent and endograft configurations were drawn in order to minimize the "gutters." To obtain the ideal main graft sizing (I-Size), a formula was used by adding the custom sizing (C-Size) to the disease oversizing (D-Over). The same MPR imaging was evaluated on postoperative CTA to study gutters area and presence of EL-I.

RESULTS: The mean I-Size was 41.67 mm that was equivalent to an ideal oversizing of 19.3% (range 10-28%). The gutters area decreased from 7.3 to 1.7 mm² (PRE/POST) and EL-I rate from 28.5% to 0% (PRE/POST). Gutters area bigger than 7.5 mm² and planning made without "Over-SIRIX" were significantly associated (P < 0.05) to EL-I.

CONCLUSIONS: "Over-SIRIX" appears to be a feasible method to customize planning during chimney technique, reducing the risk of EL-I which is significantly related to the presence and size of the gutters.

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from 7.3 to 1.7 mm² (PRE/POST) and EL-I rate from 28.5% to 0% (PRE/POST). Gutters area bigger than 7.5 mm² and planning made

European Multicenter Registry for the Performance of the Chimney/Snorkel Technique in the Treatment of Aortic Arch Pathologic Conditions

Michel J. Bosiers, MD,* Konstantinos P. Donas, MD,* Nicola Mangialardi, MD, Giovanni Torsello, MD, Vincent Riambau, MD, Frank J. Criado, MD, Frank J. Veith, MD, Sonia Ronchey, MD, PhD, Stefano Fazzini, MD, and Mario Lachat, MD

95 PTS → 48 EMERGENCY

- TECHNICAL SUCCESS 89.5%
- 30 DAYS MORTALITY 9.5%
(NONE AORTA RELATED)
- TYPE I EL 10.5%
(SOLVED SPONTANEOUSLY 50%)
- PRIMARY PATENCY 98%
- INTERVENTION RATE 5.8%

TIME IS RUNNING...

FENESTRATED / BRANCH DEVICE

- EARLY/MID STAGE
- NO LARGE COHORT STUDY
- NO LONG TERM DATA AVAILABLE
- CENTER AVAILABILITY

FENESTRATED / BRANCH DEVICE

- ARCH SHAPE (orientation)
- TARGET VESSELS ANGULATION
- TARGET VESSELS HEALTHY SZ (20 MM)
- HIGH VEL/BLOOD VOL/SHEAR STRESS
- THREE DIMENSIONAL MOVEMENTS
- PROXIMITY TO CORONARY & A-VALVE

Global experience with an inner branched arch endograft

COOK[®]

MEDICAL

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



Conclusions: Our preliminary study confirms the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options. Clinical trial registration information: Thoracic IDE NCT00583817, FDA IDE# 000101. (J Thorac Cardiovasc Surg 2014;148:1709-16)

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

ASA III/IV	38 PTS 89.5%
ASSOC STERNOTOMY (1)	2.6%
30 DAY MORTALITY (5)	13.2%
SYSTEMIC COMPLIC (17)	44.7%
CEREBR COMPLIC (6)	15.8%
STROKE 1	
EARLY SEC PROC (4)	10.5%

Conclusions: Our preliminary study confirms the feasibility and safety of the endovascular repair of arch aneurysms in selected patients who may not have other conventional options. Clinical trial registration information: Thoracic IDE NCT00583817, FDA IDE# 000101. (J Thorac Cardiovasc Surg 2014;148:1709-16)

Global experience with an inner branched arch endograft



LEARNING CURVE

TABLE 6. Comparative analyses between first 10 patients (early experience group) and next 28 patients (late experience group)

	Early experience (n = 10)	Late experience (n = 28)	P value
Early mortality	3 (30.0; 0.0-60.0)	2 (7.1; 0-16.9)	.066
Overall mortality	3 (30.0; 0.0-60.0)	6 (21.4; 5.9-36.9)	.67
Technical failure	3 (30.0; 0.0-60.0)	3 (10.7; 0.0-22.5)	.15
Type 1 endoleak	3 (30.0; 0.0-60.0)	2 (7.1; 0-16.9)	.066
Intraoperative complications	4 (40; 8.0-72.0)	3 (10.7; 0.0-22.5)	.04
All secondary procedures	4 (40; 8.0-72.0)	3 (10.7; 0.0-22.5)	.04
Early secondary procedures for endoleak	2 (20; 0.0-46.1)	0 (0)	.015
All secondary procedures for endoleak	3 (30.0; 0.0-60.0)	0 (0)	.014
Transient ischemic attack and strokes	3 (30.0; 0.0-60.0)	3 (10.7; 0.0-22.5)	.15
Transient ischemic attack	3 (30.0; 0.0-60.0)	1 (3.6; 0.0-10.6)	.019
Stroke	0 (0)	2 (7.1; 0-16.9)	.38
Operative time, min	320 (271.5-360)	248.3 (199.0-270.0)	.03
Radiograph duration, min	120 (52.8-264.5)	39 (30.0-59.4)	.007
Volume of contrast media injected, cc	150 (136.0-220.0)	150 (86.0-206.25)	.34
Ascending aorta diameter >38 mm	4 (40; 8.0-72.0)	7 (25; 8.7-41.3)	.37

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

R. Spear ^a, S. Haulon ^{a,*}, T. Ohki ^b, N. Tsilimparis ^c, Y. Kanaoka ^b, C.P.E. Milne ^a, S. Debus ^c, R. Takizawa ^b, T. Kölbel ^c

Table 3. Comparative analysis (median [Q1–Q3] or n [%]).

Procedure	Group 1 (n = 38)	Group 2 (n = 27)	p
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

Group 1: early experience study.⁴

Group 2: current study.

CONCLUSION

The results of inner branched endograft repair of the aortic arch in this contemporary series, from three centers experienced in performing the procedure, demonstrates an improvement in patient outcome when compared with the early global experience of the technique published in 2014. The results from this series confirm that inner branched endograft repair of the aortic arch is a feasible option and compares favorably with open surgery and hybrid repairs for patients with significant comorbidities who are considered unfit for open surgery. No early mortality was observed and technical success was always achieved in this latest experience with strict adherence to the inclusion and exclusion criteria.

MORTALITY

0%

MORBIDITY

43.3%

Complex endovascular repair of postdissection arch and thoracoabdominal aneurysms.

Spear R¹, Hertault A¹, Van Calster K¹, Settembre N², Delloye M¹, Azzaoui R¹, Sobocinski J¹, Fabre D³, Tyrrell M⁴, Haulon S⁵.

Author information

Abstract

OBJECTIVE: We report our experience of the treatment of postdissection arch aneurysms and thoracoabdominal aortic aneurysms (TAAAs) by endovascular repair using fenestrated and branched endografts.

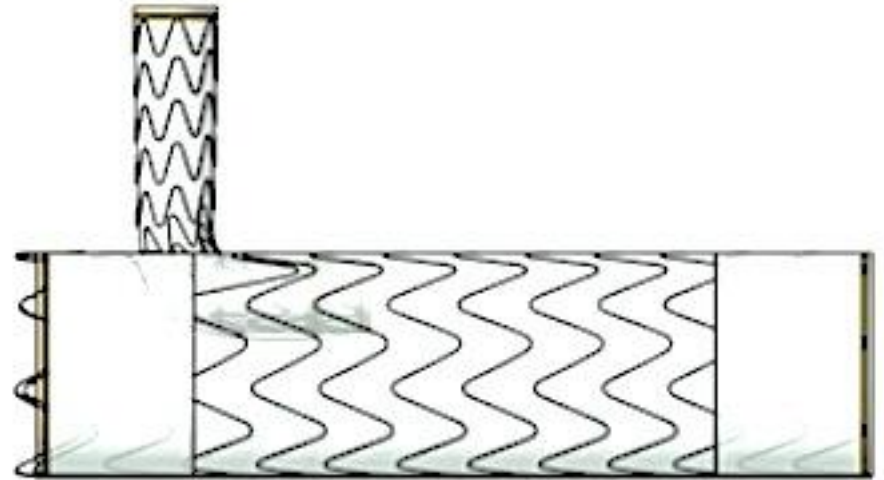
METHODS: This study includes all patients presenting with chronic postdissection aneurysms >55 mm in diameter deemed unfit for open surgery and treated by complex endovascular repair strategies including left subclavian artery revascularization. Primary end points were technical success, endoleaks, target vessel patency, aneurysm diameter, and mortality.

RESULTS: We treated 40 patients with 19 arch repairs using fenestrated endografts (or branched endografts) and 21 TAAA repairs using both arch and TAAA repair. Median follow-up was 25.5 months (3.0-10.0 years). Stroke, spinal cord ischemia, and in-hospital mortality rates were 4.7% (2/43), 7% (2/43), and 4.7% (2/43), respectively. The spinal cord ischemia rate was 7% and occurred only after TAAA repair. One stroke with partial recovery and one transient ischemic attack were observed (4.7%) after arch repair. Six early reinterventions (14%) were performed: three for access complications, two to treat acute hemorrhage, and one to treat a type II endoleak. Median follow-up was 25.5 months (11-42.25 months). The 1- and 5-year survival rates were 90% and 76.4%, respectively. Late reinterventions were required in eight patients, two in the arch group (to treat endoleaks at 3 and 33 months) and six in the TAAA group (2 iliac and 1 bifurcated endograft extensions, 2 additional renal stents, 1 inferior mesenteric artery embolization). Aneurysm diameter was stable (72%) or shrank (23%) during follow-up. Enlargement was shown in two patients with endoleaks.

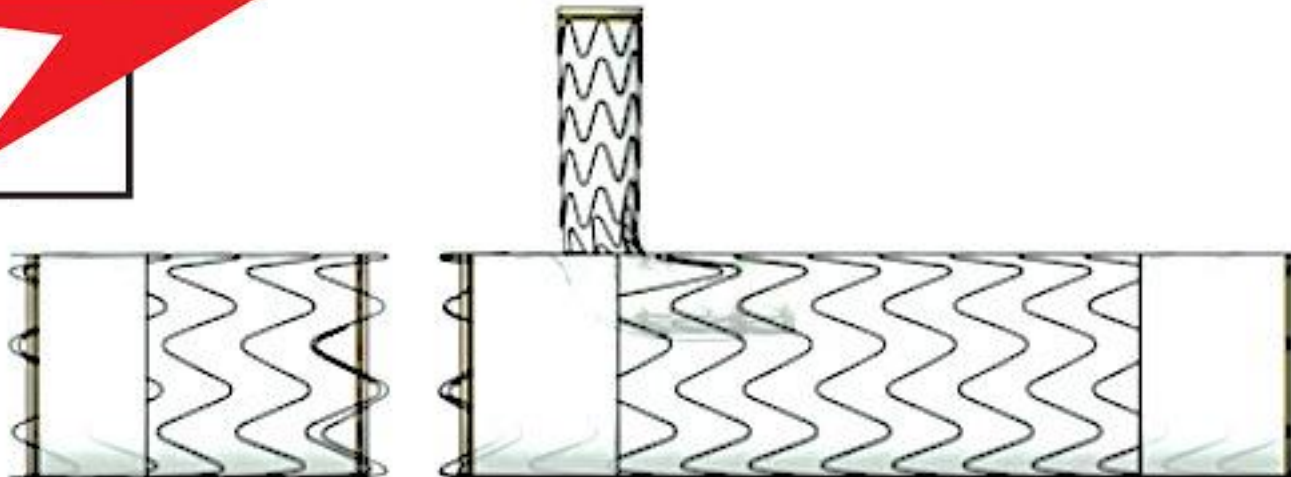
CONCLUSIONS: Complex endovascular repair of postdissection aneurysms is a safe procedure in patients deemed unfit for open surgery. Our experience suggests that close follow-up is mandatory as secondary procedures are frequently required to completely exclude the false lumen.

19 Post Dissection Arch

TECHNICAL SUCCESS	93%
IN HOSPITAL MORTALITY	4.7%
STROKE	4.7%



WIRE PRELOADED IN THE FENESTRATION



TBE Device Clinical Trials Overview

Enrollment Complete – PI Michael Dake

Zone 2 Feasibility Study

- 31 patients enrolled
- Primary endpoints
 - Successful access and deployment of TBE
 - Primary patency of side branch assessed by angiography at conclusion of procedure
- Secondary endpoints
 - One month Core lab analysis
 - Side branch primary patency assessed
 - Device-related endoleaks

Zone 0/1 Early Feasibility Study

- 9 patients enrolled
- Patients must be high risk for open repair
- Primary endpoints
 - Successful access and deployment of TBE
 - Primary patency of side branch assessed by angiography at conclusion of procedure
- Secondary endpoints
 - One month Core lab analysis
 - Side branch primary patency assessed
 - Device-related endoleaks

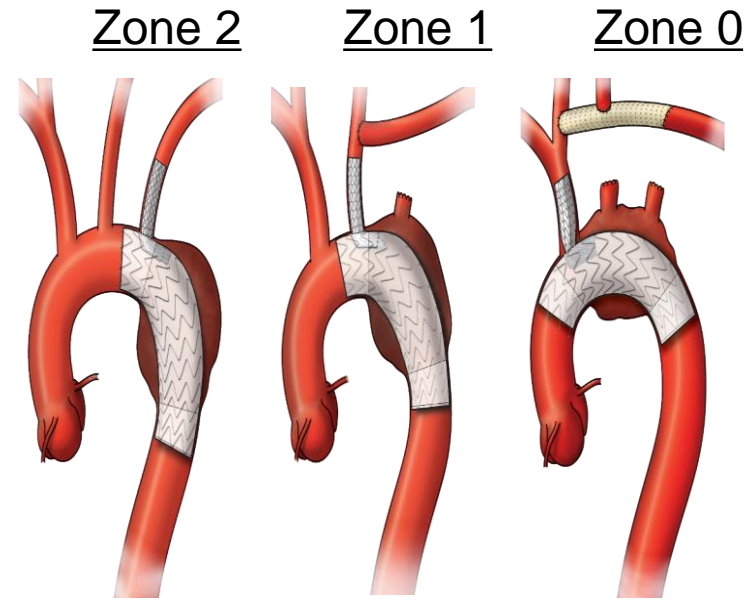
Endpoints		
	Zone 2	Zone 0/1
Number of Enrolled Subjects	31	9
Primary Endpoints (procedural)		
Successful Access	100%	100%
Successful Deployment	100%	100%
Side Branch Primary Patency	100%	100%
Side Branch Primary Patency*	100%	100%
No Device-Related Endoleaks	96.6%	100%

*Will not meet primary patency if either the Core Lab assesses as not patent or if there is a reintervention to maintain patency/flow in the Side Branch reported anytime during the 1 month window.

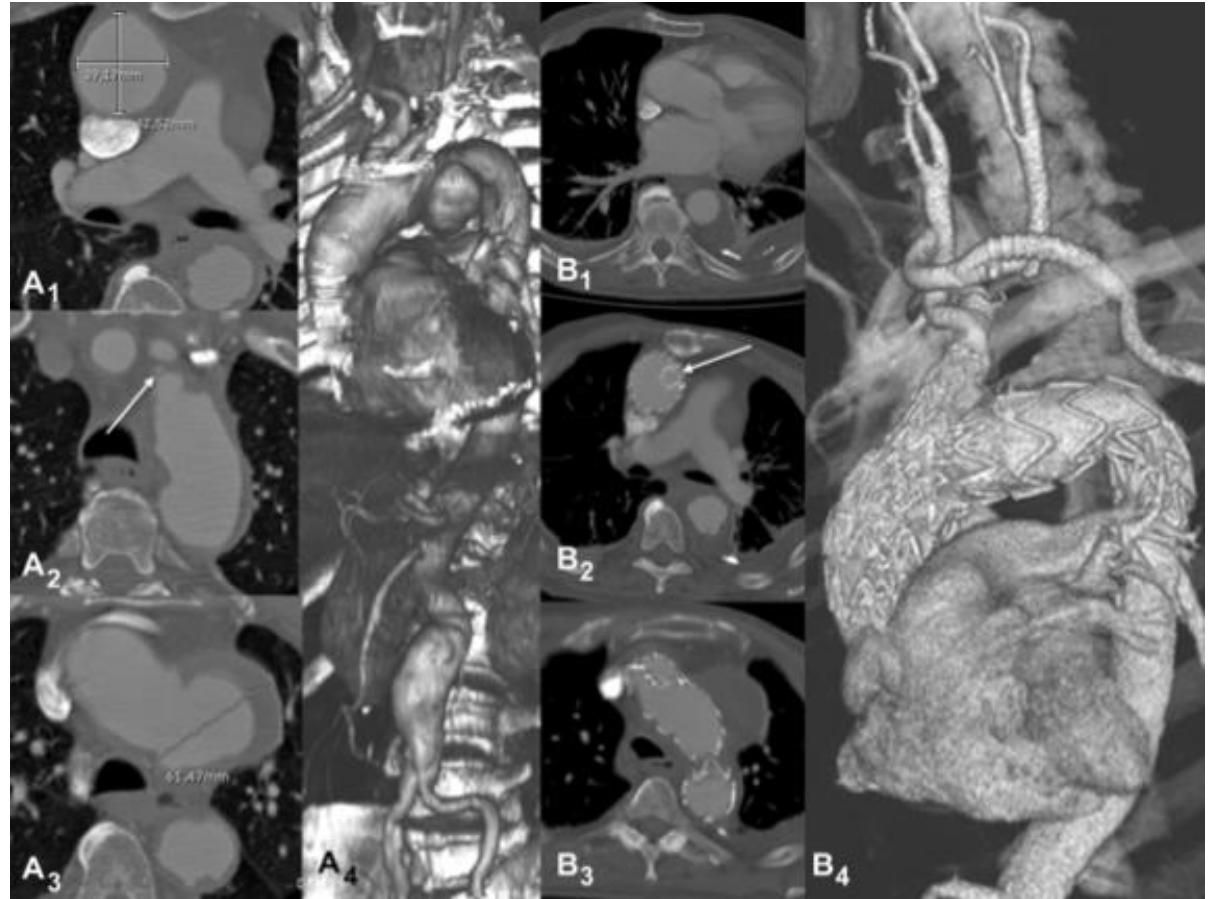
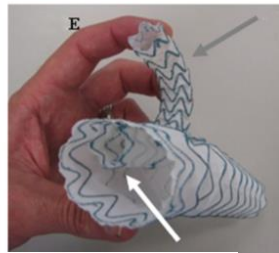
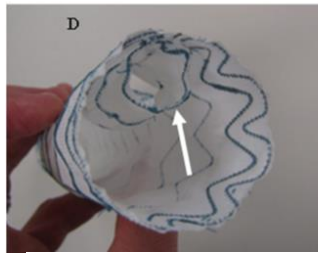
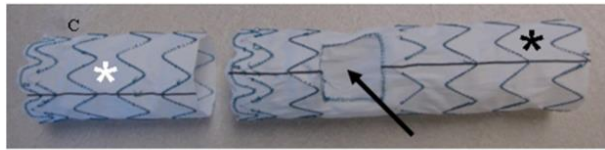
The one device related endoleak was a type III endoleak identified between the side branch and aortic components at 1 month.

Summary of Preliminary Results

- 100% Technical success for Zones 0-2
- 100% Survival at 1 month for Zones 0-2
- Peri-Procedural Stroke
 - 3.3% (1/31) Zone 2
 - 22.2% (2/9) Zone 0/1
- Side Branch Patency
 - 3.3% (1/31) Zone 2 loss of patency
 - No loss of patency in Zone 0



BOLTON DOUBLE BRANCHED



Application of the Bolton Relay Device for Thoracic Endografting In or Near the Aortic Arch

Vincent Riambau, MD, PhD*

#	Age/Sex	Pathology	Endoleak	Intraoperative Complication
1	69/M	TAA	N	R SCA coverage ¹
2	73/F	TAA	N	L CCA dissection ¹
3	78/F	TAA	N	LV perforation ¹
4	79/F	TAA	N	N
5	66/M	Dissection	N	N
6	77/M	TAA	N	N
7	71/M	TAA	N	N
8	66/M	TAA	N	N
9	70/M	TAA	lc ²	N
10	82/M	TAA	N	N
11	78/F	TAA	N	N
12	83/M	TAA	N	N
13	70/F	TAA	N	N
14	74/M	TAA	la ¹	N
15	81/M	TAA	N	N
16	82/M	TAA	N	N
17	84/M	TAA	N	N
18	64/F	Dissection	N	N
19	83/M	TAA	N	N
20	79/M	Dissection	N	N
21	59/M	Dissection	N	N
22	68/M	PAU	N	N
23	82/M	TAA	N	Y ²
24	65/F	TAA	N	N
25	74/F	TAA	N	N
26	72/M	TAA	N	N

24 PTS

R-LSA COVERAGE

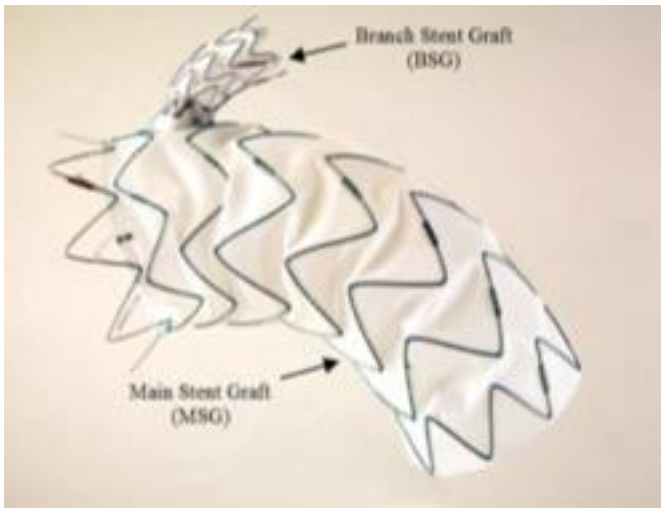
L-CCA COVERAGE

L-V PERFORATION

MEDTRONIC MONA LSA



- Flexible cuff “volcano” on main body
- 2 wire system
 - Main system wire
 - LSA branch thru & thru wire
- Precannulated LSA cuff
- Tip capture
- Diameters: 30 → 46
- Length 15 cm



MEDTRONIC MONA LSA

- 9 patients at 3 sites

-

TECHNICAL SUCCESS 100%

PATENCY 100%

TIPE I/III EL 0%

Eric E. Roselli, MD

Cleveland Clinic

Cleveland, OH, USA

Frank R. Arko III, MD

Carolina's Medical Center

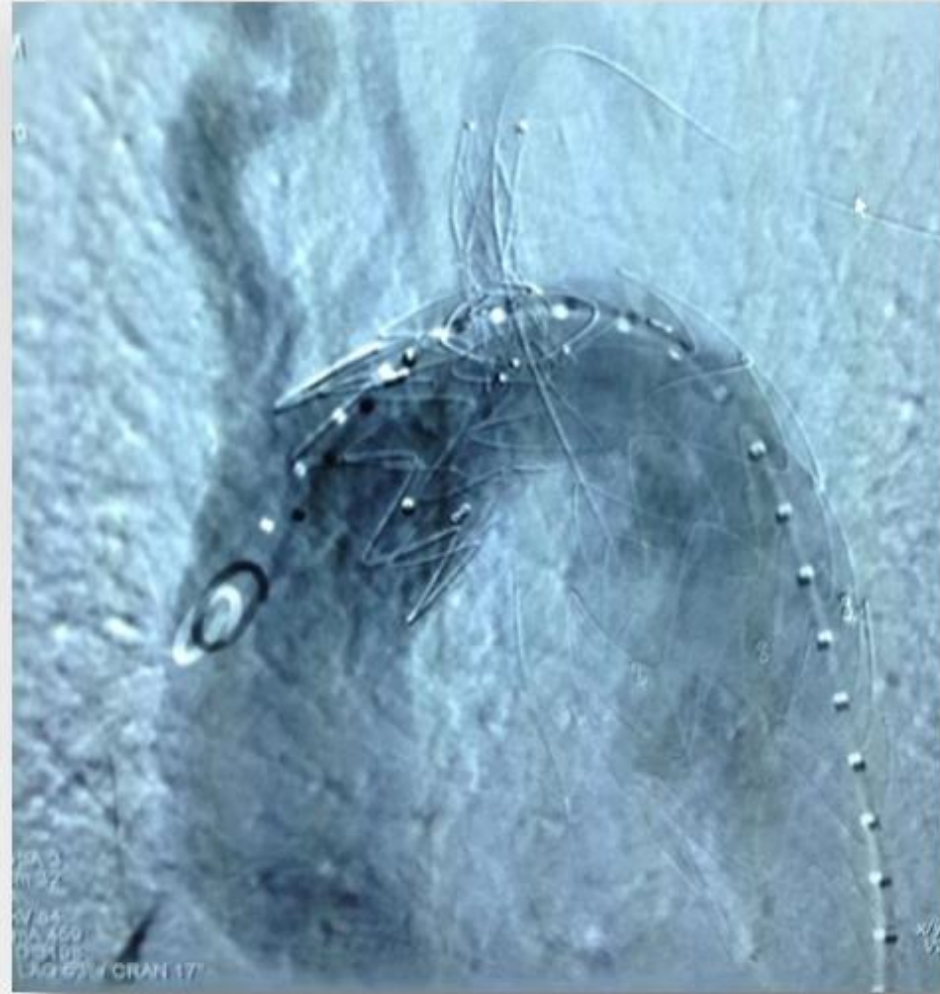
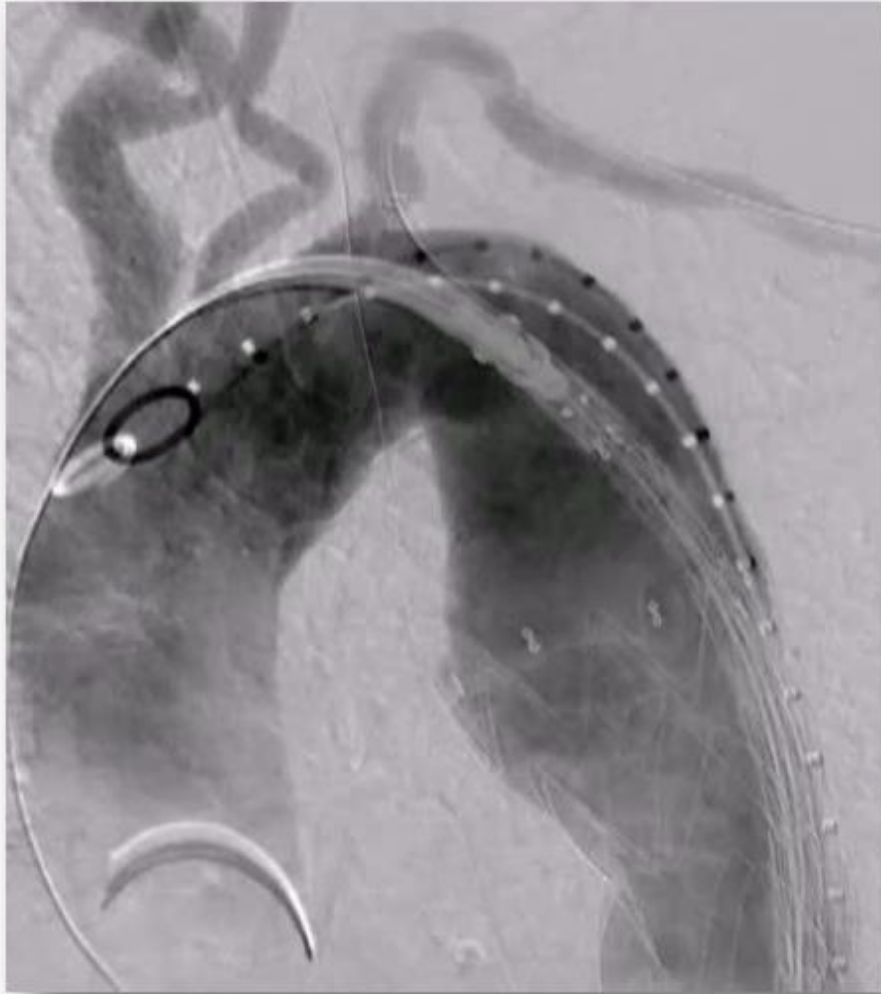
Charlotte, NC, USA

Matt Thompson, MD

St. George's

London, UK

MEDTRONIC MONA LSA



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)

As a less-invasive treatment, thoracic endovascular aortic repair (TEVAR) has emerged over the last decade. TEVAR for the descending thoracic aorta has been shown to reduce short-term morbidity and mortality compared with open aortic arch disease, however, some challenges must remain to be addressed. Its complex morphologic features and the involvement of supra-aortic branches still remain. In 2008, the first 3-dimensional (3D) precurved fenestrated endograft Najuta (Yokoi Surgical Lines, Inc, Tokyo, Japan) was developed to achieve good conformability and to extend the proximal landing zone. The multicenter clinical trial for approval by the Japanese Ministry of Health, Labor, and Welfare was conducted, with feasible results, in 2008 and 2009. In 2010, the multicenter clinical study commenced in 35 Japanese hospitals with the latest version of the Najuta graft, which is evolving continuously. The aim of this study was to evaluate the results of our previous study on endovascular treatment with a precurved

fenestrated endograft for aortic arch disease and to explain the advantages and limitations of this device.

MAJOR RESULTS AND METHODS

Patients

From January 2010 to December 2011, a total of 383 patients at 35 Japanese centers who required stent-graft landing in the aortic arch underwent endovascular repair with a fenestrated endograft (clinical use of this device was approved by the individual institutional review board of each hospital). There were 329 men and 54 women (mean age, 75.69 ± 9.82 years; range, 23-93 years). All the patients were considered to have serious risk factors for open surgical repair and also to be ineligible for endovascular repair with commercially available devices because of an inadequate proximal landing zone. Of the patients, 332 had a degenerative aneurysm, 44 had an aortic dissection, 5 had a traumatic transection of the aortic isthmus, and 2 had a patent ductus arteriosus with congestive heart failure.

Anatomic Indications

All the patients underwent preoperative contrast-enhanced multilayered coronal tomographic (CT) scans to assess the feasibility of endovascular repair, sizing of the endograft, and implantation strategy. The aortic arch configuration, including angulation and the location of branches and the proximal sealing zone of the endograft, was evaluated by 3-dimensional (3D) reconstruction with volume rendering of the CT data.

The anatomic exclusion criteria for endovascular aortic arch repair with precurved fenestrated endograft were (1) proximal or distal landing zone diameter greater than 42 mm; (2) all supra-aortic branches involved in the aneurysmal wall; and (3) prohibitive occlusive disease, tortuosity, or calcification of intended access vessels and angulation of the aorta that would preclude advancement of the introduction system. In addition, an adequate proximal sealing zone was required between the supra-aortic

NAJUTA FENESTRATED SG



383 PTS

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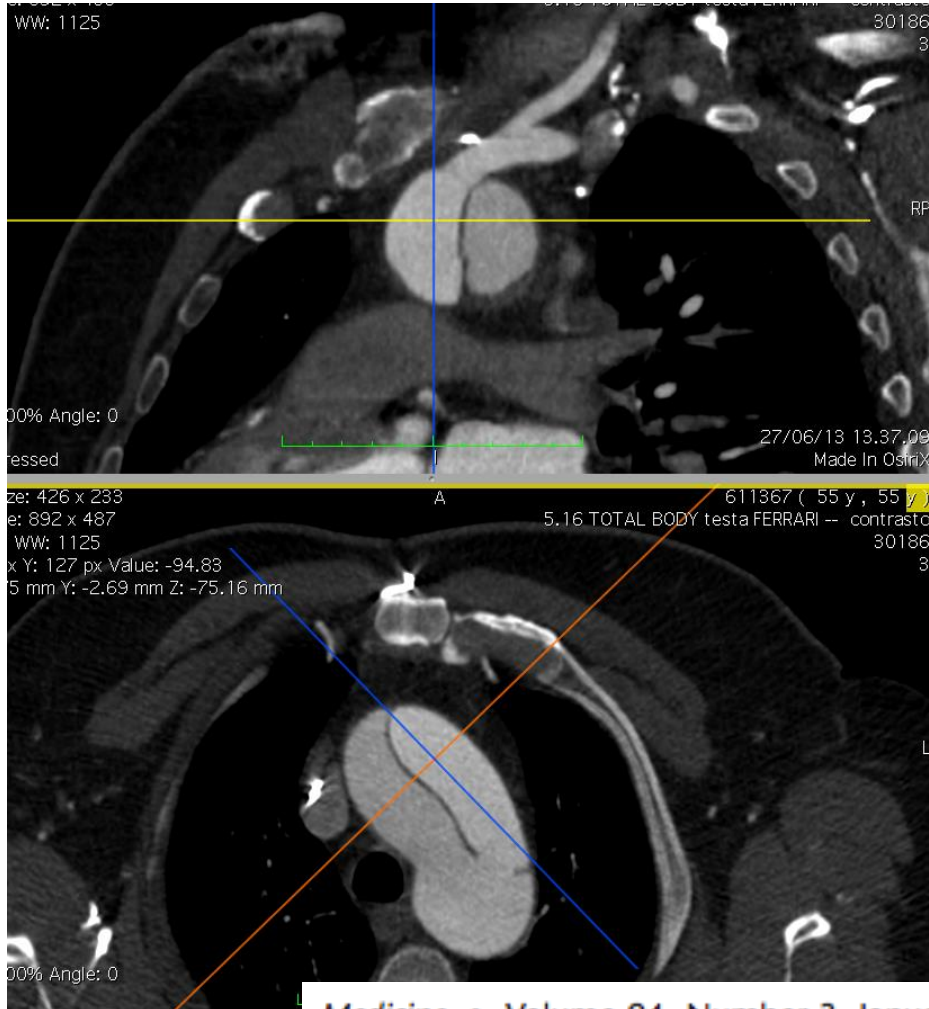
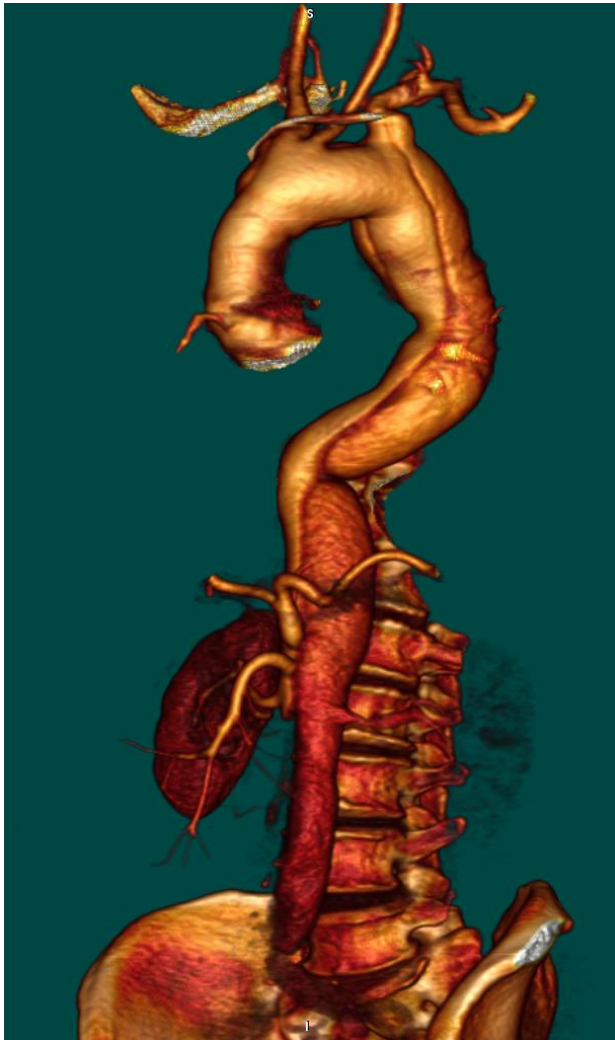
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Case Report of an Endovascular Repair of a Residual Type A Dissection Using a Not CE Not FDA-Approved Najuta Thoracic Stent Graft System

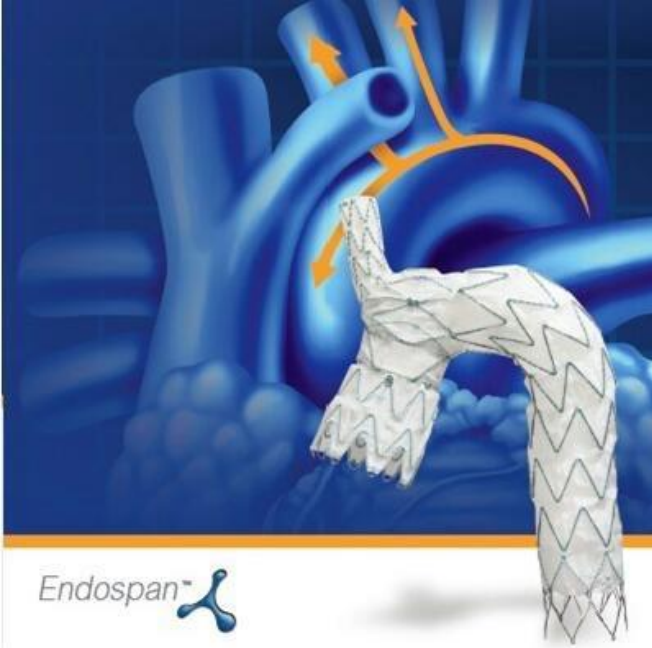
N. Mangialardi, MD, S. Ronchey, MD, A. Malaj, MD, M. Lachat, MD, E. Serrao, MD, V. Alberti, MD, and S. Fazzini, MD



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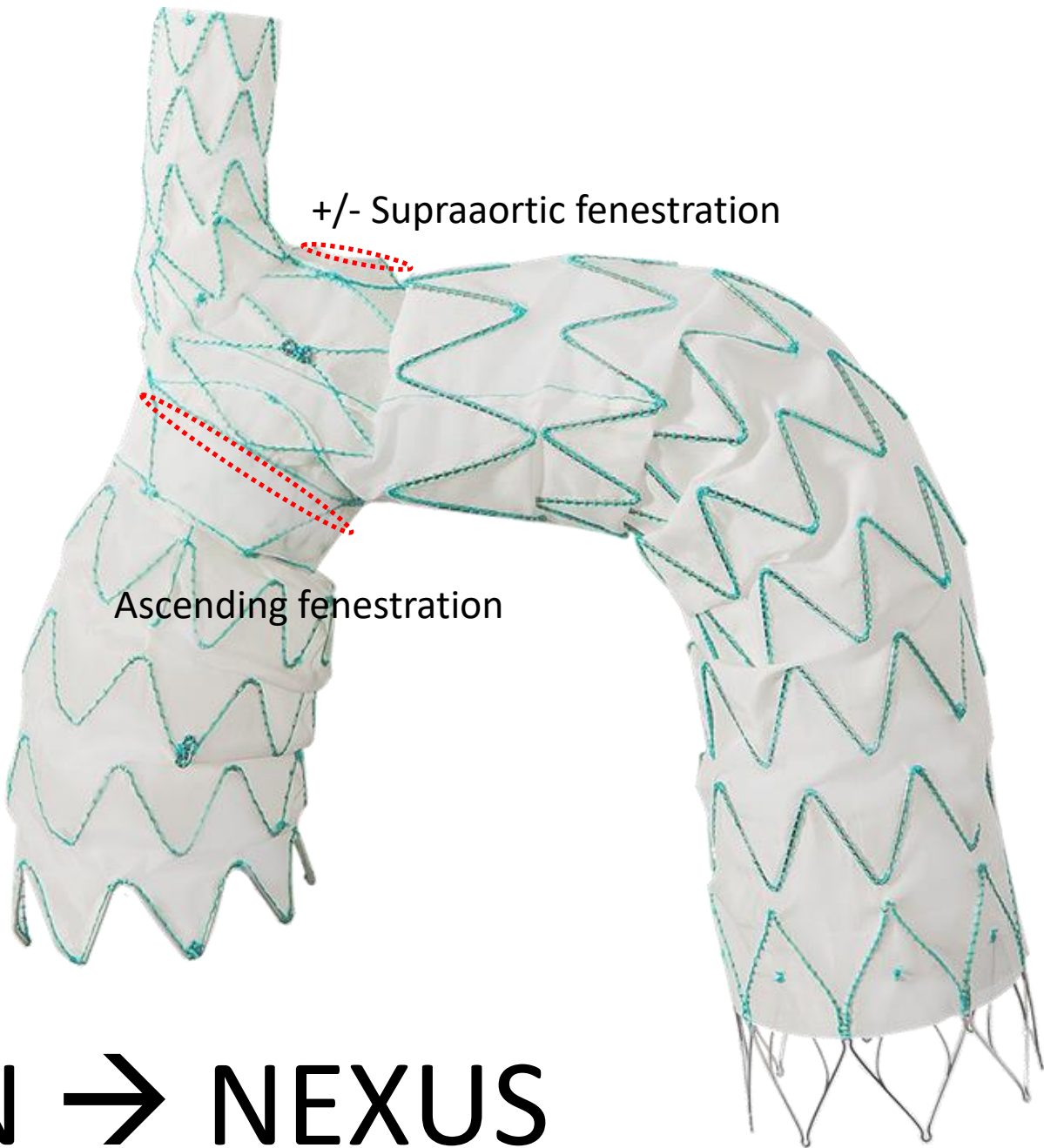




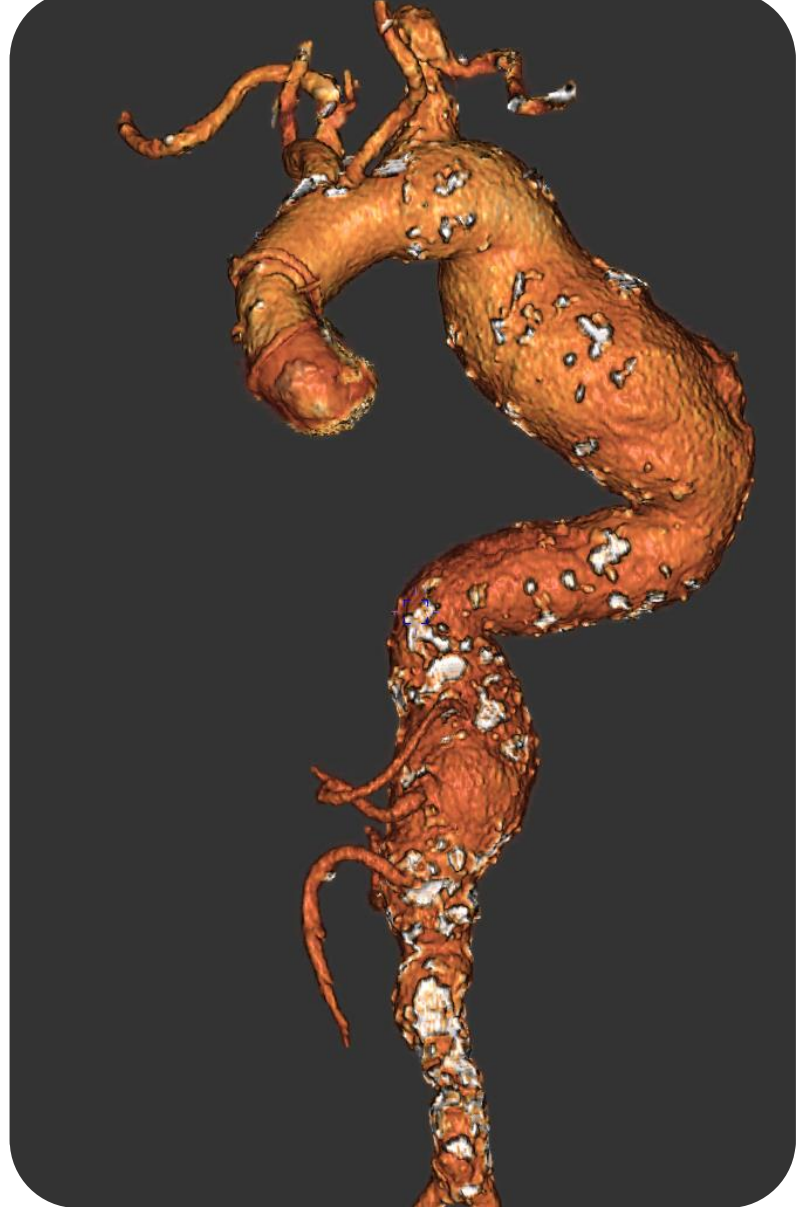
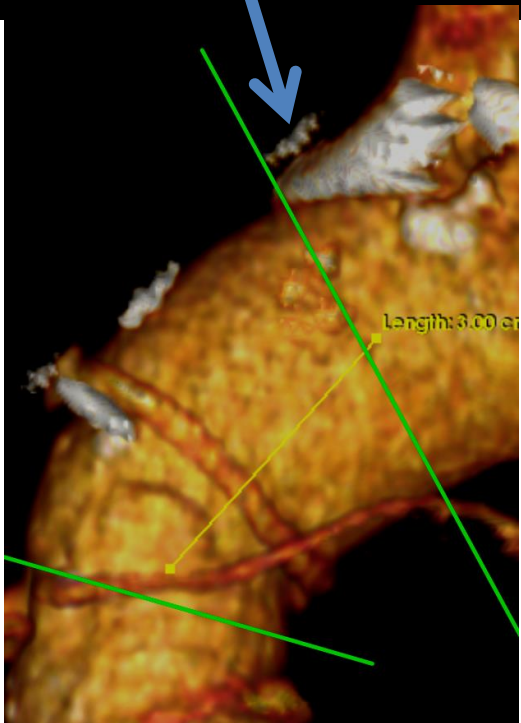
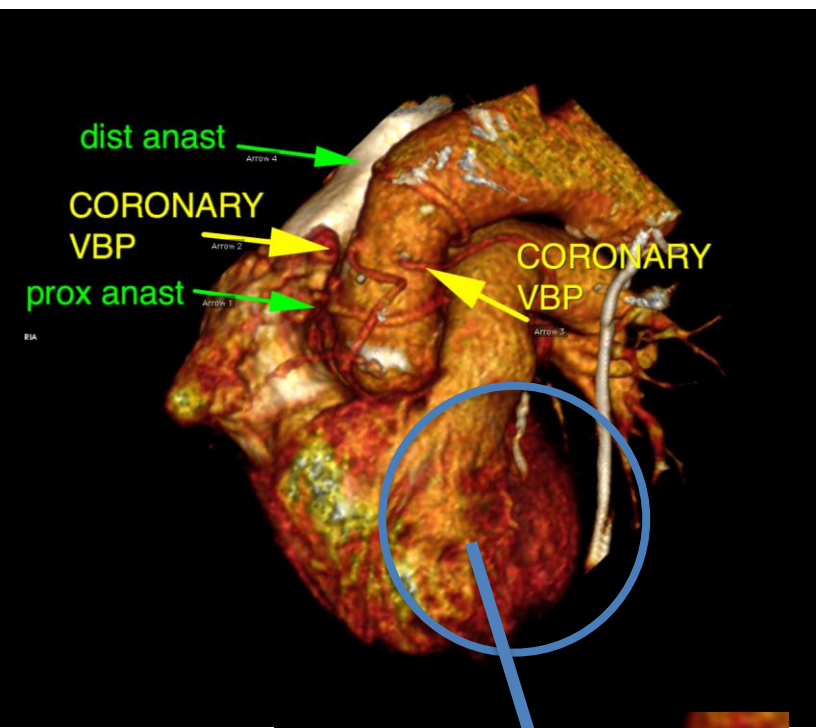
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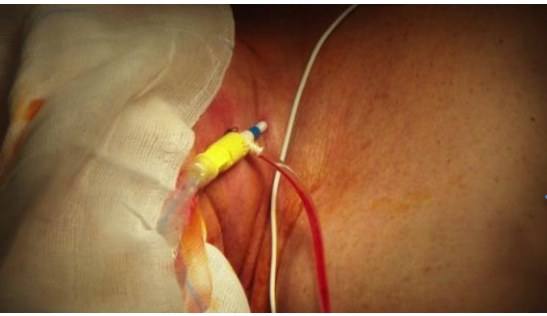
+/- Supraaortic fenestration

Ascending fenestration

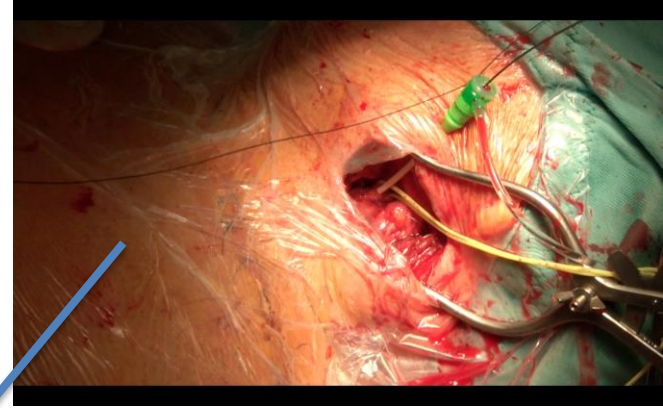


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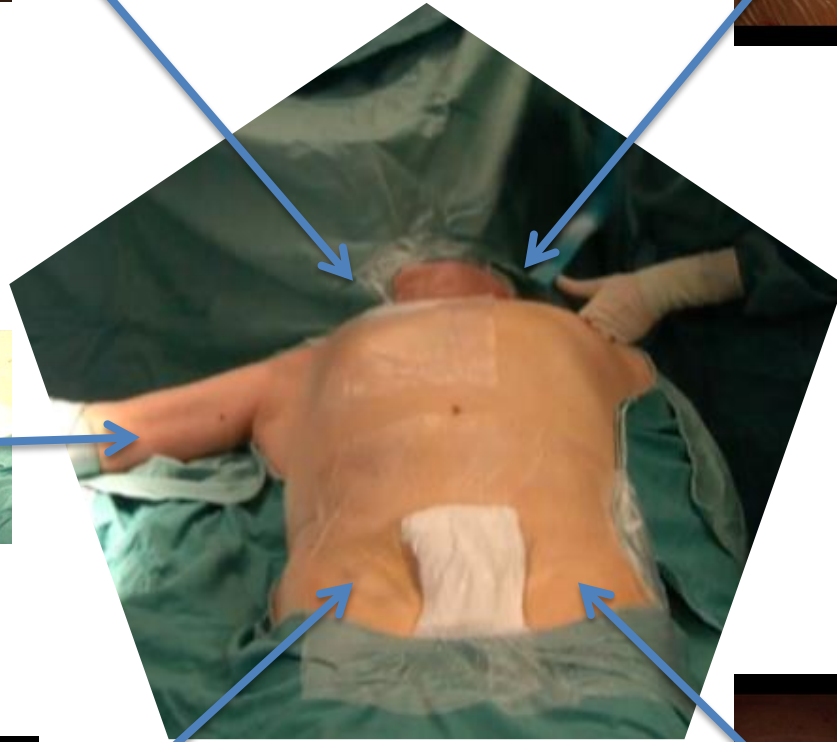




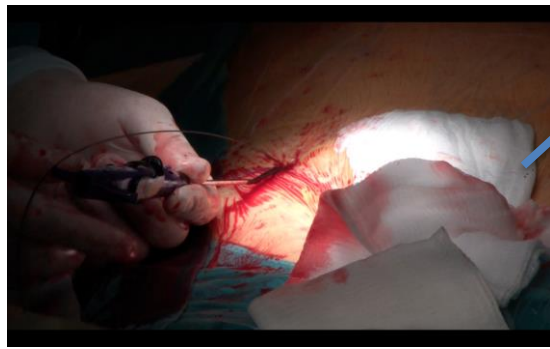
RJV 7F INTRODUCER
FIAB CATH PACING



RCA 6F INTRODUCER
FEN CATH



RBA 8F INTRODUCER
THROUGH/THROUGH



R/DOUBLE PROGLIDE
L/ SINGLE PROGLIDE





Smart-Guide

Single Like City
Hauptgebäude Smart-Guide 220 640 400 am Berg
HETAG, Single Like "Smart-Guide" 220 1 400 000
Prozessleiste Metallurgie, Produktionslinie: 0307488 000
Für Geräte in HETAG, Pflanzentherapie, 0307488 000

REF: 21635480	REF: 91301709
Revisionsnummer: 0300	Lot: "A" 030 000
Hersteller: HETAG	Hydrophilic Spitze
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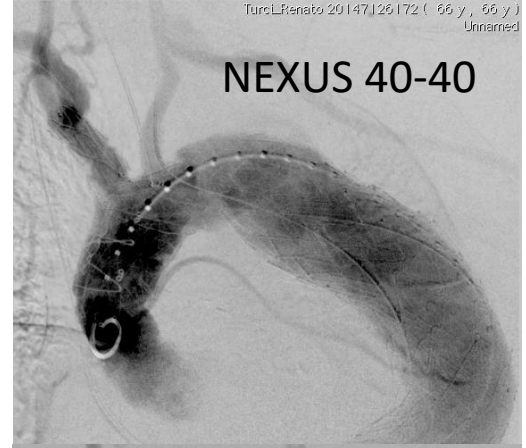
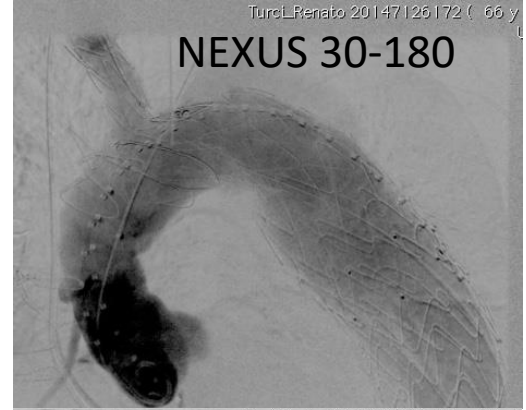
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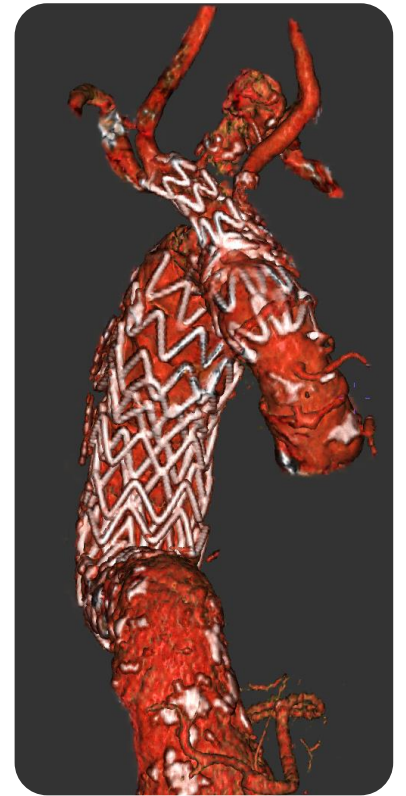
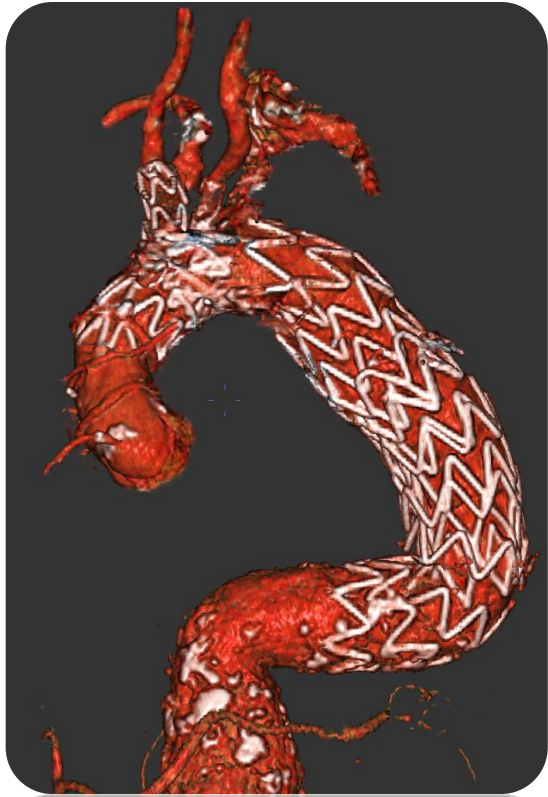
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OUR EXPERIENCE

6 CASES

- TECHNICAL SUCCESS 100%
- MORTALITY 0%
- MINOR STROKE 1%

WHAT IS BEST...FOR ARCH LESIONS

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES → CHIMNEY

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES → CHIMNEY
- FOR ANATOMICALLY SUITABLE CASES

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES → CHIMNEY
- FOR ANATOMICALLY SUITABLE CASES →
CUSTOM DEVICES ?
DEBRANCHING + TEVAR?

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES → CHIMNEY
- FOR ANATOMICALLY SUITABLE CASES →
CUSTOM DEVICES ?
DEBRANCHING + TEVAR?
- OTHERS

WHAT IS BEST...FOR ARCH LESIONS

- FOR ACUTE CASES → CHIMNEY
- FOR ANATOMICALLY SUITABLE CASES →
CUSTOM DEVICES ?
DEBRANCHING + TEVAR?
- OTHERS → SURGICAL DEBRANCHING + TEVAR