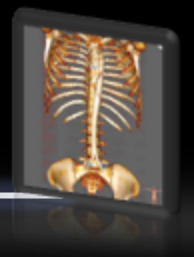
New Generation SMFM for Complex Aortic Disease

Victor S. Costache MD PhD
Associate Professor of Cardiovascular & Thoracic Surgery
University of Sibiu, Head of Cardiovascular Department
Director of Polisano European Hospital

Disclosure



- *NONE*

◆CLINICAL INVESTIGATION ◆

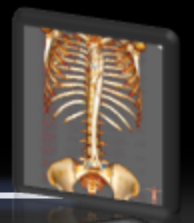
One-Year Outcomes Following Repair of Thoracoabdominal Aneurysms With the Multilayer Flow Modulator: Report From the STRATO Trial

Claude D. Vaislic, MD[1]; Jean Noël Fabiani, MD, PhD[2]; Sidney Chocron, MD, PhD[3]; Jacques Robin, MD[4]; Victor S. Costache, MD[5]; Jean-Pierre Villemot, MD, PhD[6]; Jean Marc Alsac, MD[2]; Pascal N. Leprince, MD, PhD[7]; Thierry Unterseeh, MD[8]; Eric Portocarrero, MD[6]; Yves Glock, MD, PhD[9]; and Hervé Rousseau, MD, PhD[10] on behalf of the STRATO Investigators Group

[1]Department of Cardiac, Vascular and Thoracic Surgery, Centre Hospitalier Privé Parly 2, Le Chesnay, France. [2]Department of Cardiovascular Surgery, Hôpital Europeen Georges-Pompidou, Paris, France. [3]Department of Thoracic and Cardiovascular Surgery, Hôpital Jean Minjoz, Besançon, France. [4]Department of Cardiovascular Surgery, Hôpital Louis Pradel, Lyon-Bron, France. [5]Department of Cardiac Surgery, Centre Hospitalier de la Région d'Annecy, Metz-Tessy, France. [6] Department of Cardiovascular Surgery and Transplantation, CHU-Nancy, Hôpital d'adultes de Brabois, Nancy, France. [7]Department of Thoracic and Cardiovascular Surgery, Hôpital Pitié-Salpétrière, Pierre and Marie Curie University, Paris, France. [8]Department of Interventional Cardiology, Institut Cardiovasculaire Paris Sud, Hôpital Privé Claude Galien, Quincy-sous-Sénart, France. [9]Department of Cardiovascular Surgery, CHU Toulouse, Hôpital Rangueil, Toulouse, France. [10]Department of Radiology, CHU Toulouse, Hôpital Rangueil, Toulouse, France.

Purpose: To evaluate endovascular repair of type II and III thoracoabdominal aortic aneurysms (TAAA) using the Multilayer Flow Modulator (MFM) in patients with contraindications for open surgery and fenestrated stent-grafts.

Global MFM Registry



ORIGINAL ARTICLES

Disruptive endovascular technology
flow modulator stents as a therapeu
management of thoracoabdominal a
Early results from the global independen

ITALIAN JOURNAL OF VASCULAR AND ENDOVASCULAR SURGERY

SICVE

CLINICAL INVESTIGATION

One-Year Results of the Multilayer Flow Modulato
the Management of Thoracoabdominal Aortic An
and Type B Dissections

Sherif Sultan, MD, FRCS, EBQS-VASC,[1,2] and Niamh Hynes, MRC

JOURNAL OF ENDOVASCULAR THERAPY

Archives Online

Early mid-term results of the first 103 cases
of multilayer flow modulator stent done under indication
for use in the management of thoracoabdominal aortic
pathology from the independent global MFM registry

S. SULTAN[1,2], M. SULTAN[2], N. HYNES[1]

VOLUME 55 NUMBER 1 FEBRUARY 2014

THE JOURNAL OF CARDIOVASCULAR SURGERY

MINERVA MEDICA


CLINICA
POLISANO
Polisano European Hospital
integrated structure of medical centers

THORACO-ABDOMINAL ANEURYSMS

Thoracoabdominal, 70 yrs

H

Clinica POLISANO
Abdomen^_Abdomen_Routine (Adult)
Abd_art 3.0 I30 MPR cor
10/9/2015 3:41:40 PM

APPLIED

THK: 3
HFS

9/16/1945
70 YEAR
M

R

L

RD: 459
Tilt: 0
mA: 268
KVp: 120
Acq no: 5

Z: 0.68
C: 40
W: 300
DFOV:87.5x67.6cm

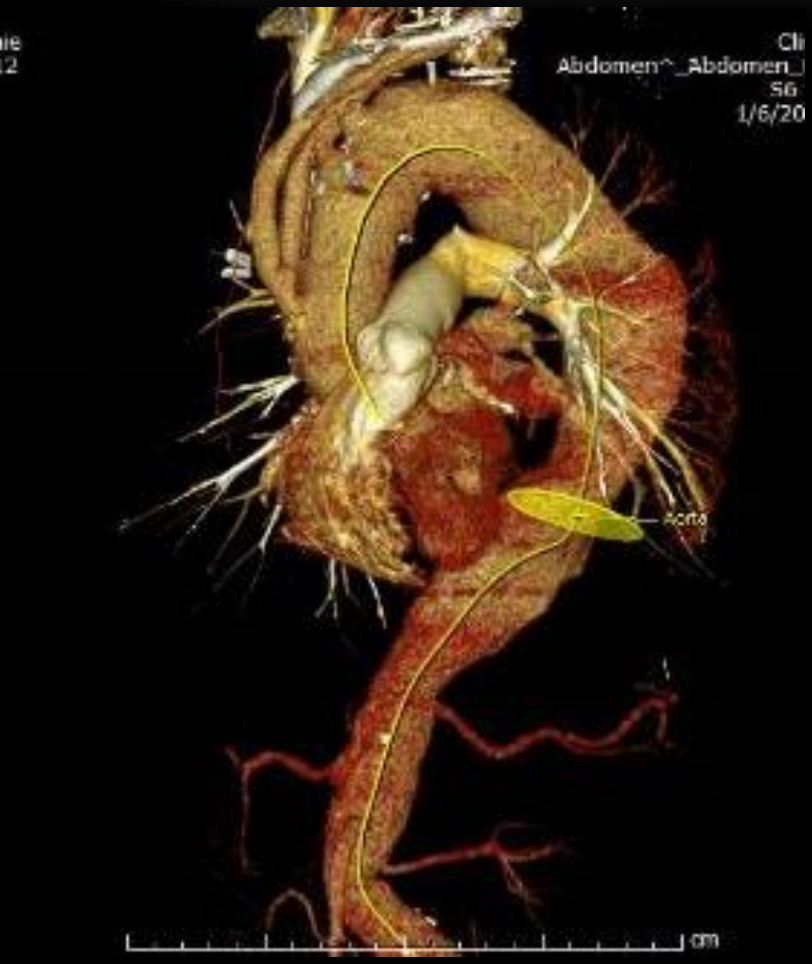
Page: 1 of 108

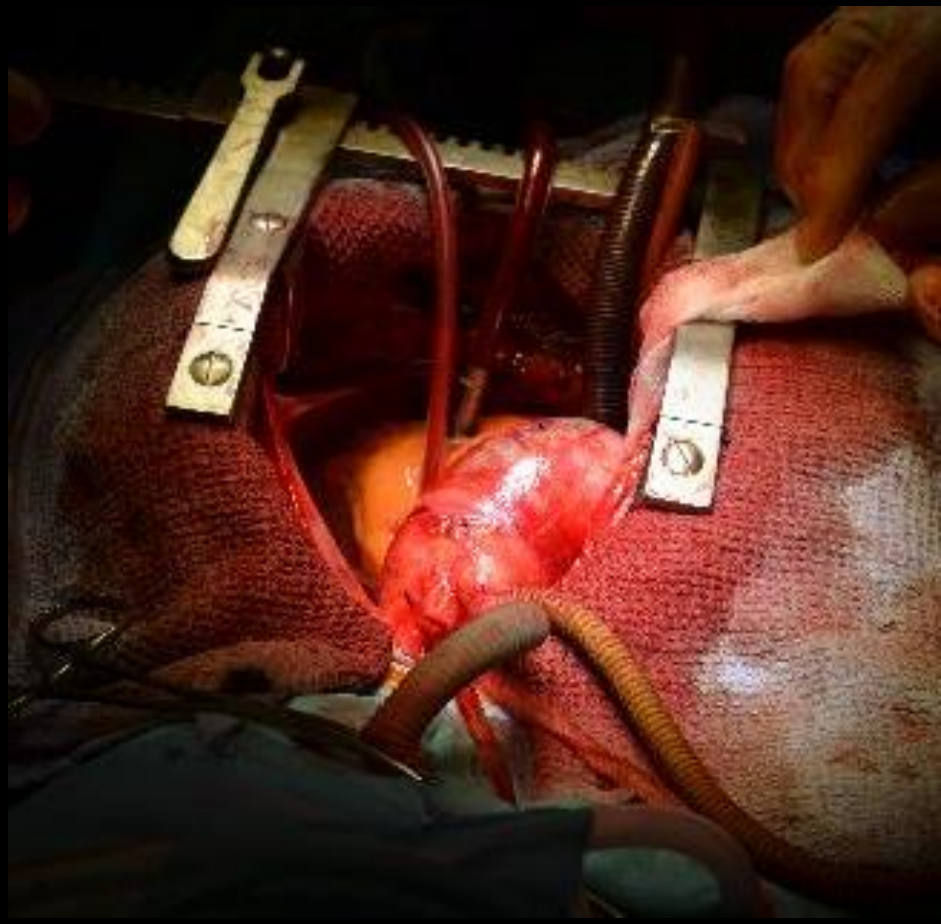
F

cm

IM: 2 SE: 10

Thoracoabdominal, 70 yrs



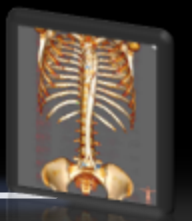


Thoracoabdominal, 70 yrs

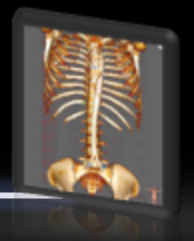
Thoracoabdominal, 70 yrs

Thoracoabdominal, 70 yrs

Pre-OP



Pre-OP

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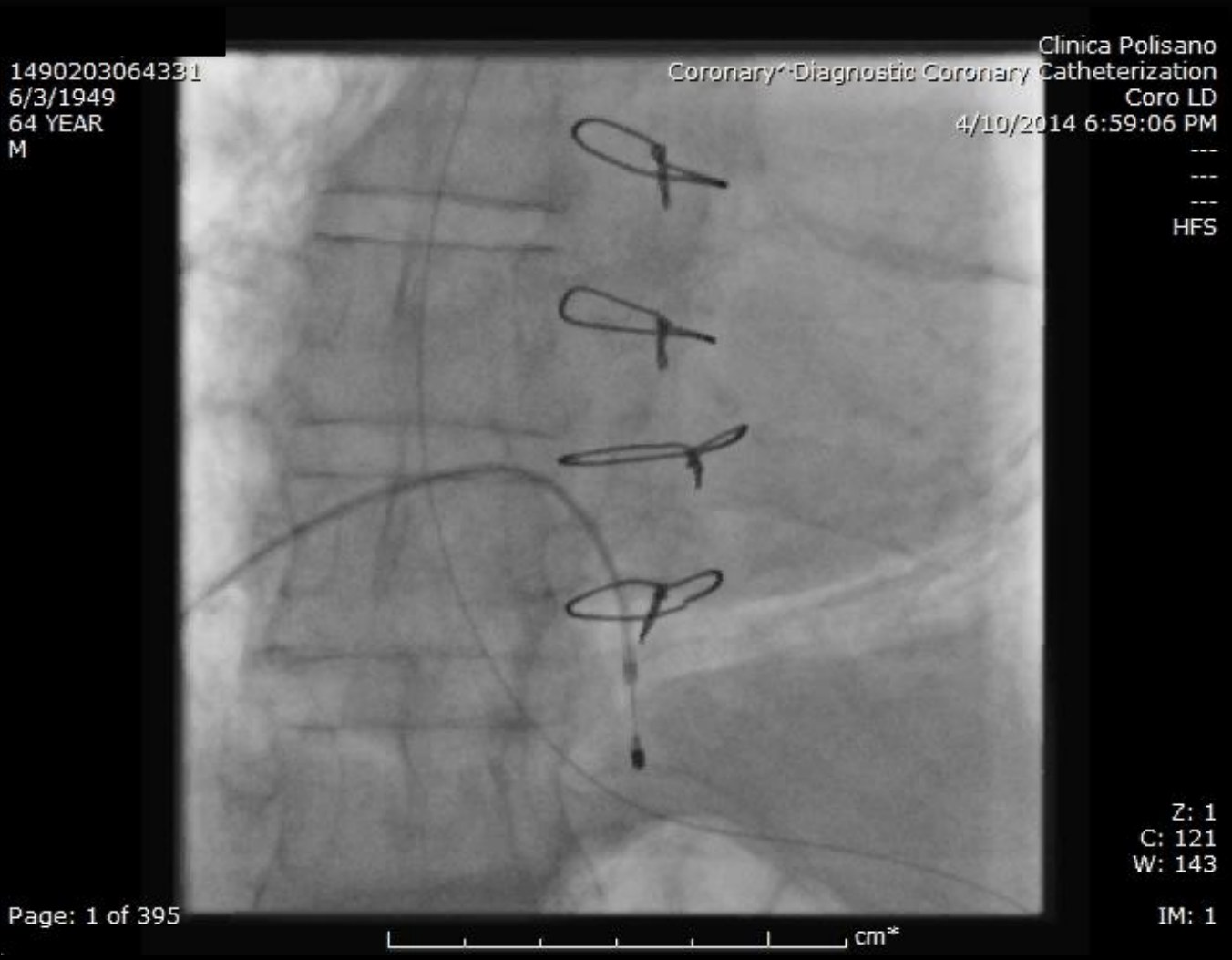
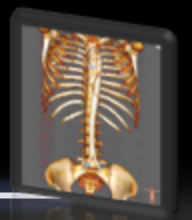
cm

The procedure



12 months follow-up

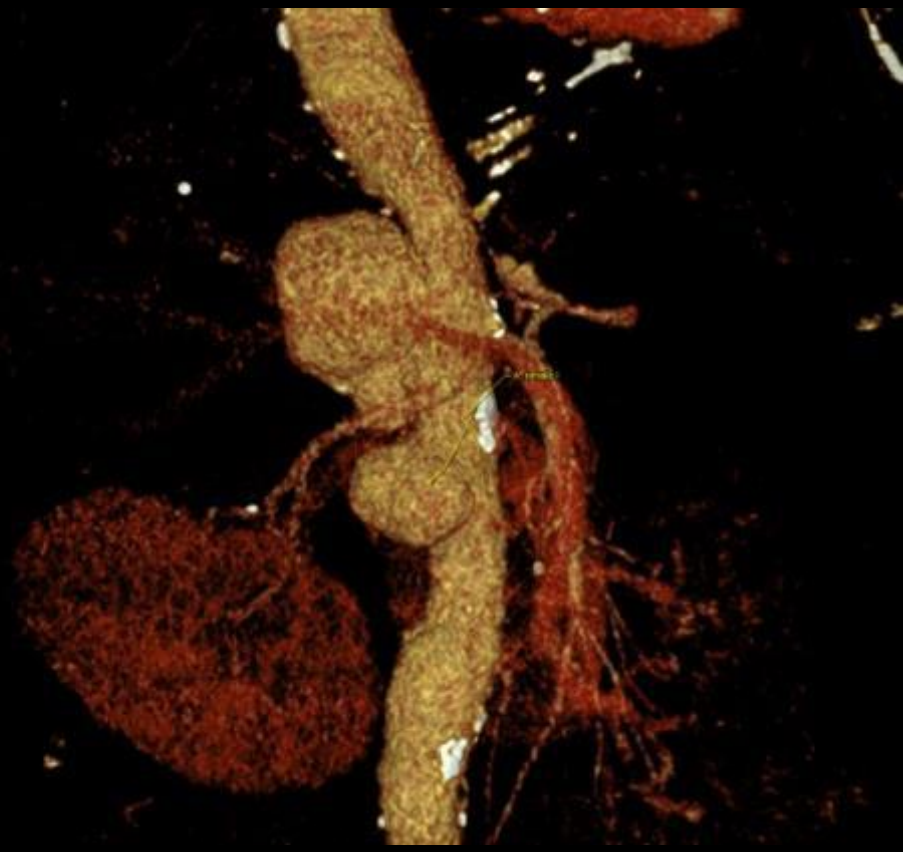


Streamliner Type II + AAA

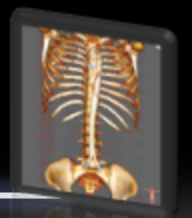
Streamliner Type II + AAA

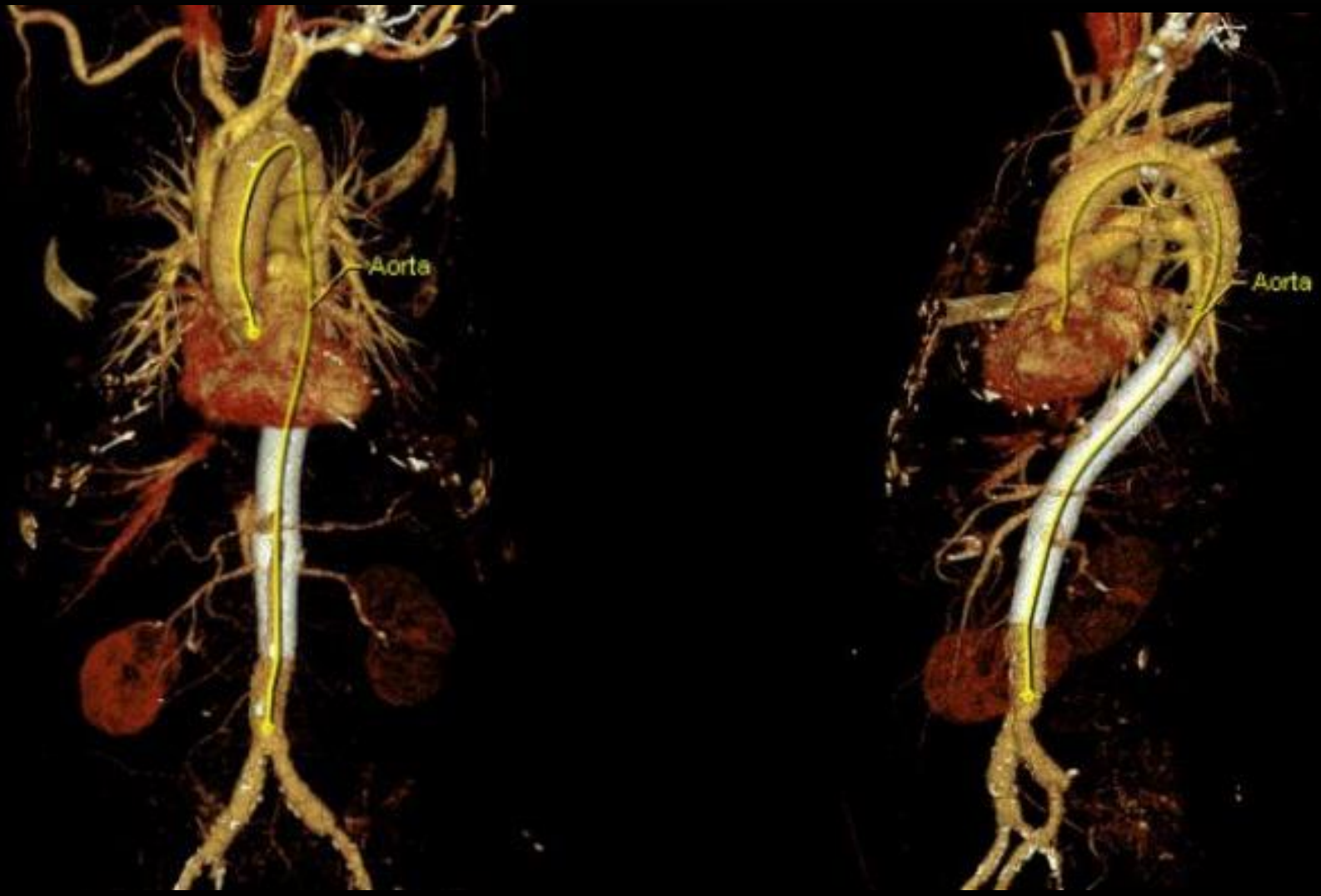
Last Follow-up

Saccular aneurysm

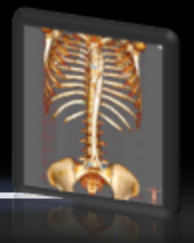


Saccular aneurysm





Why the Need for Streamliner?

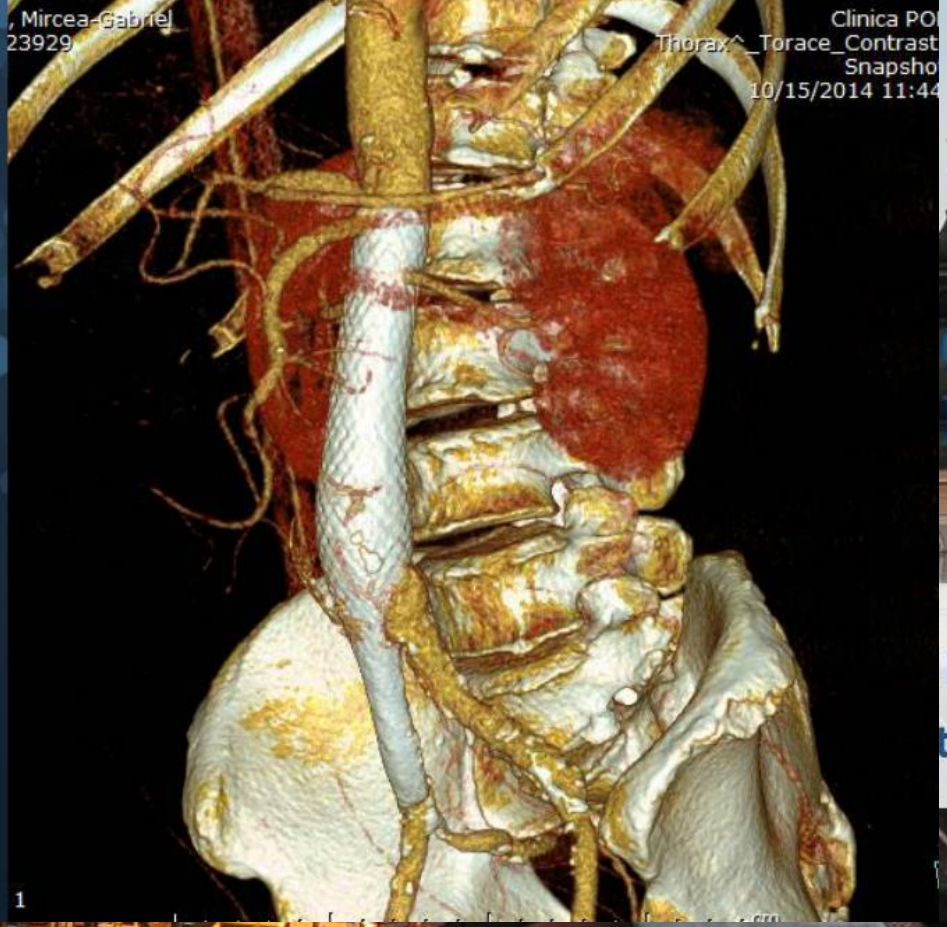


"4D" aortic Therapy

MONTHS IN RECOVERY

1

WESTERN VASCULAR INSTITUTE


, Mircea-Gabriel
23929
Clinica PO
Thorax^_Torace_Contrast
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1


CLINICA
POLISANO
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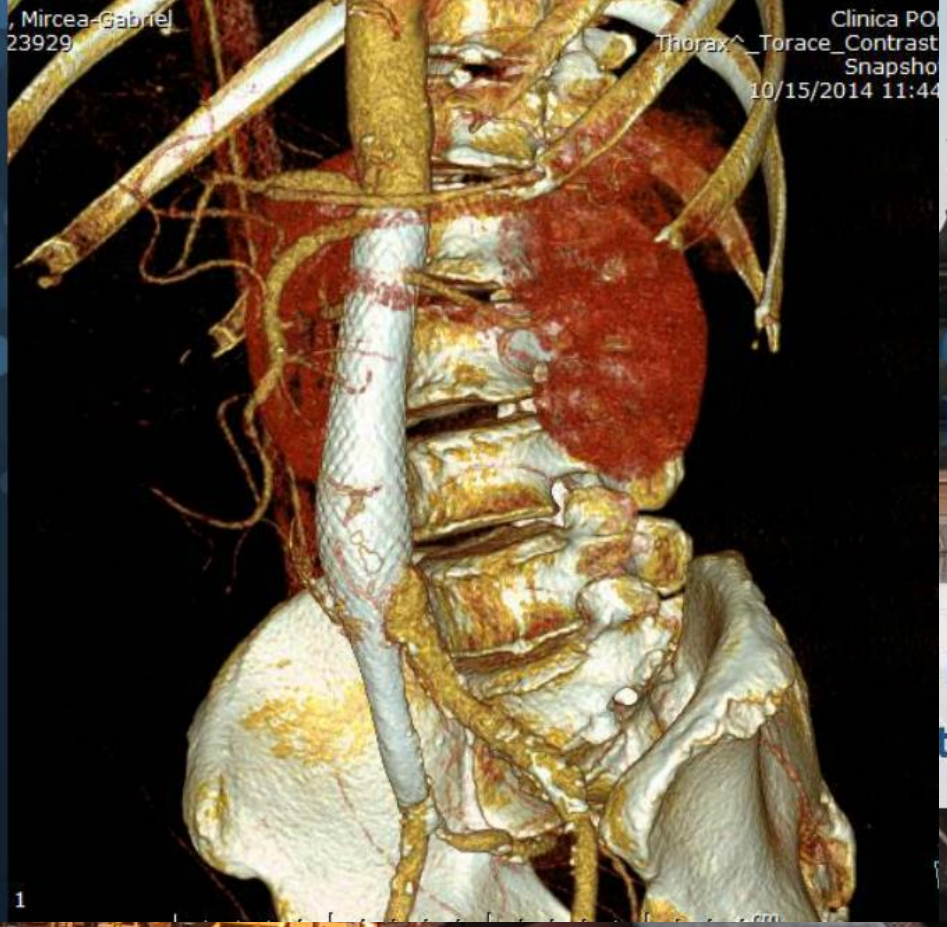
LINICA
OLISANO


, Mircea-Gabriel
23929
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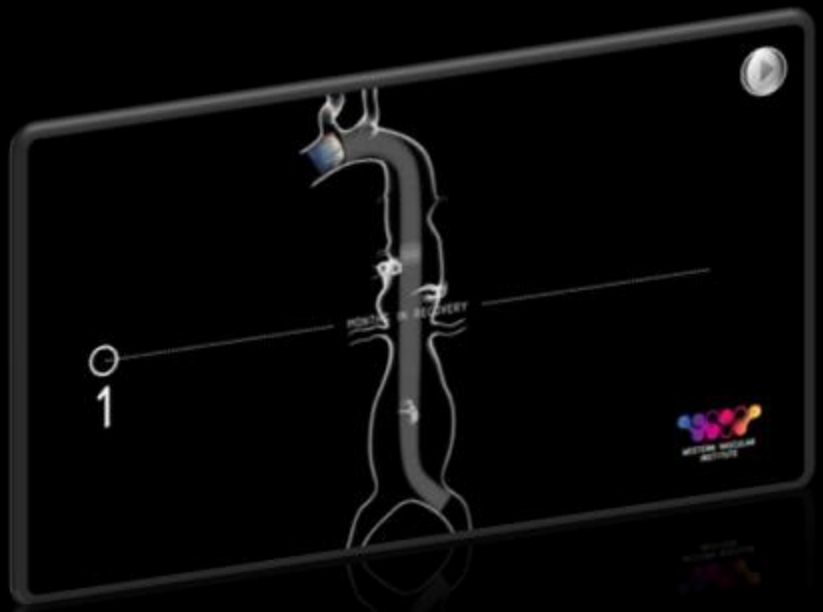
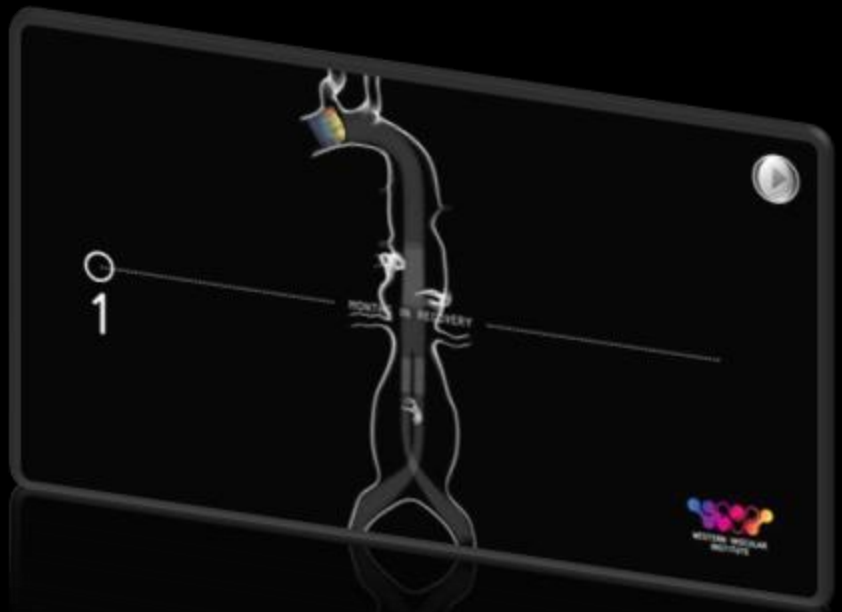
LINICA
OLISANO


5/13/1942
73 YEAR
M
54 Snapshot V
3/30/2016 10:03:55
Aorta
Page: 1 of 1
cm

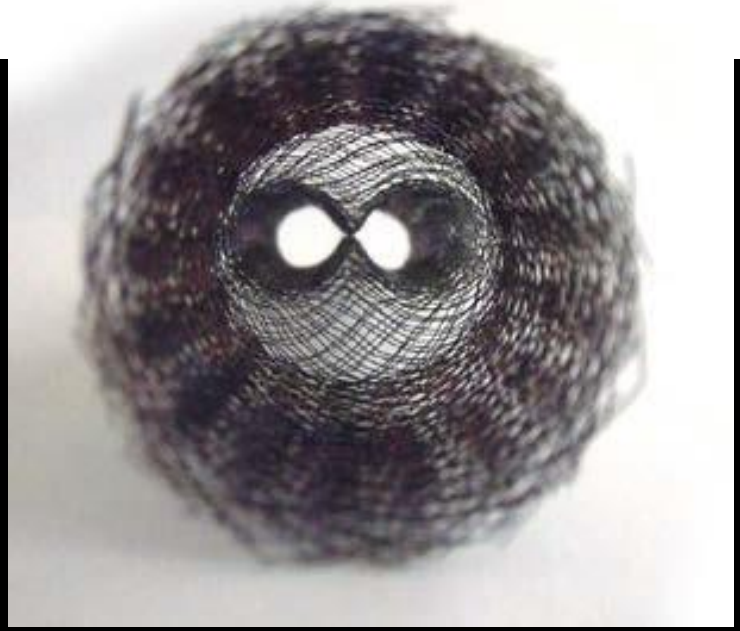
Why the Need for Streamliner?



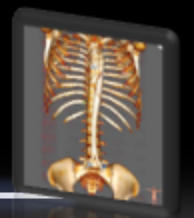


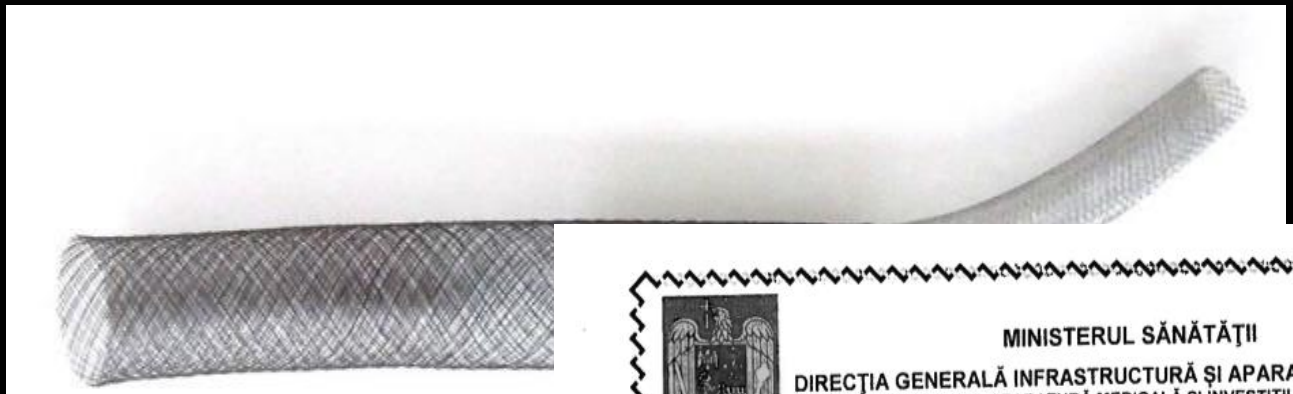
- *Streamliner treats terminal aorta and both Iliac arteries*
- *Straight MFM in AAA Increases Renal Outflows to 8%*
- *Streamliner Generates Double Renal Outflow Percentage Increase*
- *Difference in Spiral lamination Between Single & Ballerina MFM*

Streamliner 4 D Aortic Therapy



Streamliner 4 D Aortic Therapy





MINISTERUL SĂNĂTĂŢII

DIRECŢIA GENERALĂ INFRASTRUCTURĂ ŞI APARATURĂ MEDICALĂ
DIRECŢIA PATRIMONIU, APARATURĂ MEDICALĂ ŞI INVESTIŢII ÎN INFRASTRUCTURĂ
COMPARTIMENT APARATURĂ MEDICALĂ

AUTORIZATIE PENTRU INVESTIGAȚIA CLINICĂ A DISPOZITIVELOR MEDICALE

Nr. 31 din 04.04.2014

În conformitate cu prevederile Hotărârii Guvernului nr. 144/2010 privind organizarea şi funcţionarea Ministerului Sănătăţii, cu modificările şi completările ulterioare, ale Hotărârii Guvernului nr. 54/2009 privind condiţiile introducerii pe piaţă a dispozitivelor medicale şi în baza documentaţiei înaintate, Ministerul Sănătăţii autorizează desfăşurarea investigaţiei clinice pentru dispozitivul medical **Modulator de flux multistratificat bifurcat (BMFM),** în cadrul studiului cu titlul:

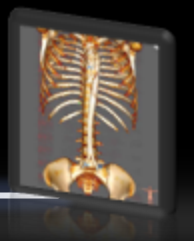
"Studiu STREAMLINER, evaluarea siguranței și eficacității Modulatorului **de flux multistratificat Bifurcat (BMFM)"**
Protocol nr.: 12 - 2013

Producător/Sponsor: CARDIATIS SA, cu sediul în Parc Scientifique Crealys, Rue Jules Poskin n.3,B -5032 ISNES Belgia.

AORTIC ANEURYSMS

Streamliner Patients

AAA preop

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Tor_contr 3.0 I31f 3
2/12/2016 12:48:07 PM

APPLIED
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HFS
R
L
RD: 462
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KVp: 100
Acq no: 10
Page: 1 of 224
Z: 1
C: 50
W: 350
DFOV:60x46.2cm
IM: 1 SE: 8
P
cm

AAA intraop


Clinica Polisano
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2/5/1943
73 YEAR
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Body 4
3/30/2016 9:32:38 AM

IODINE

HFS
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C: 1900
W: 2700
Page: 1 of 21
IM: 1
cm*


Clinica Polisano
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73 YEAR
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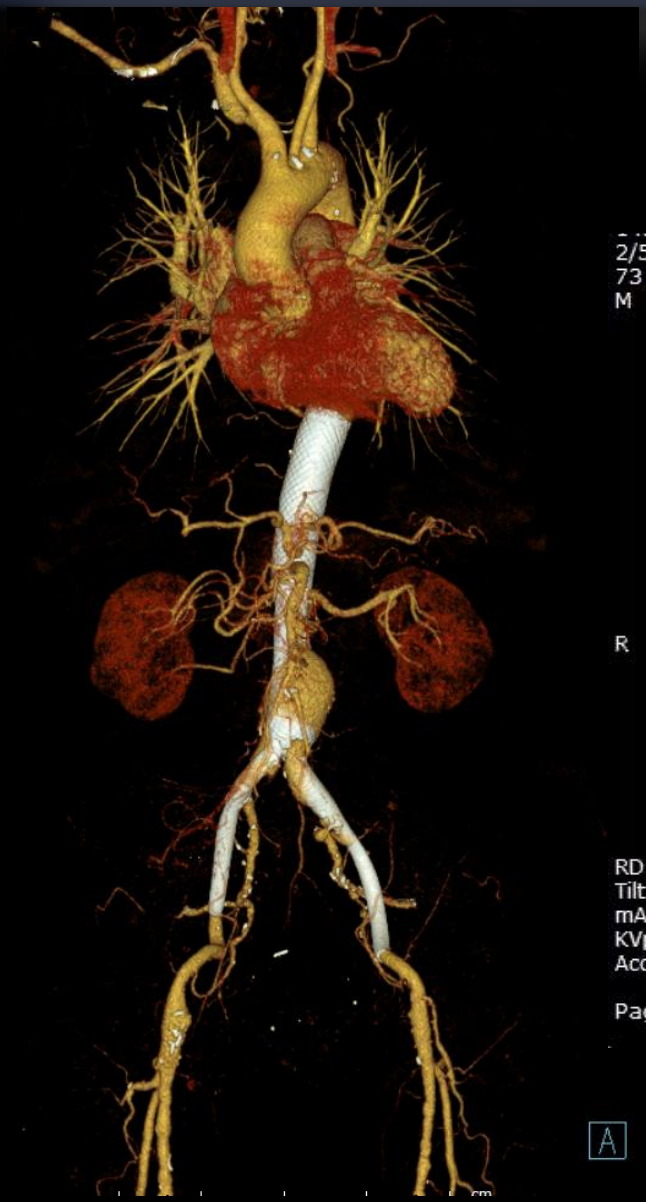
cm*

AAA postop

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2/5/1943
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Page: 1 of 247
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cm
IM: 1 SE: 3
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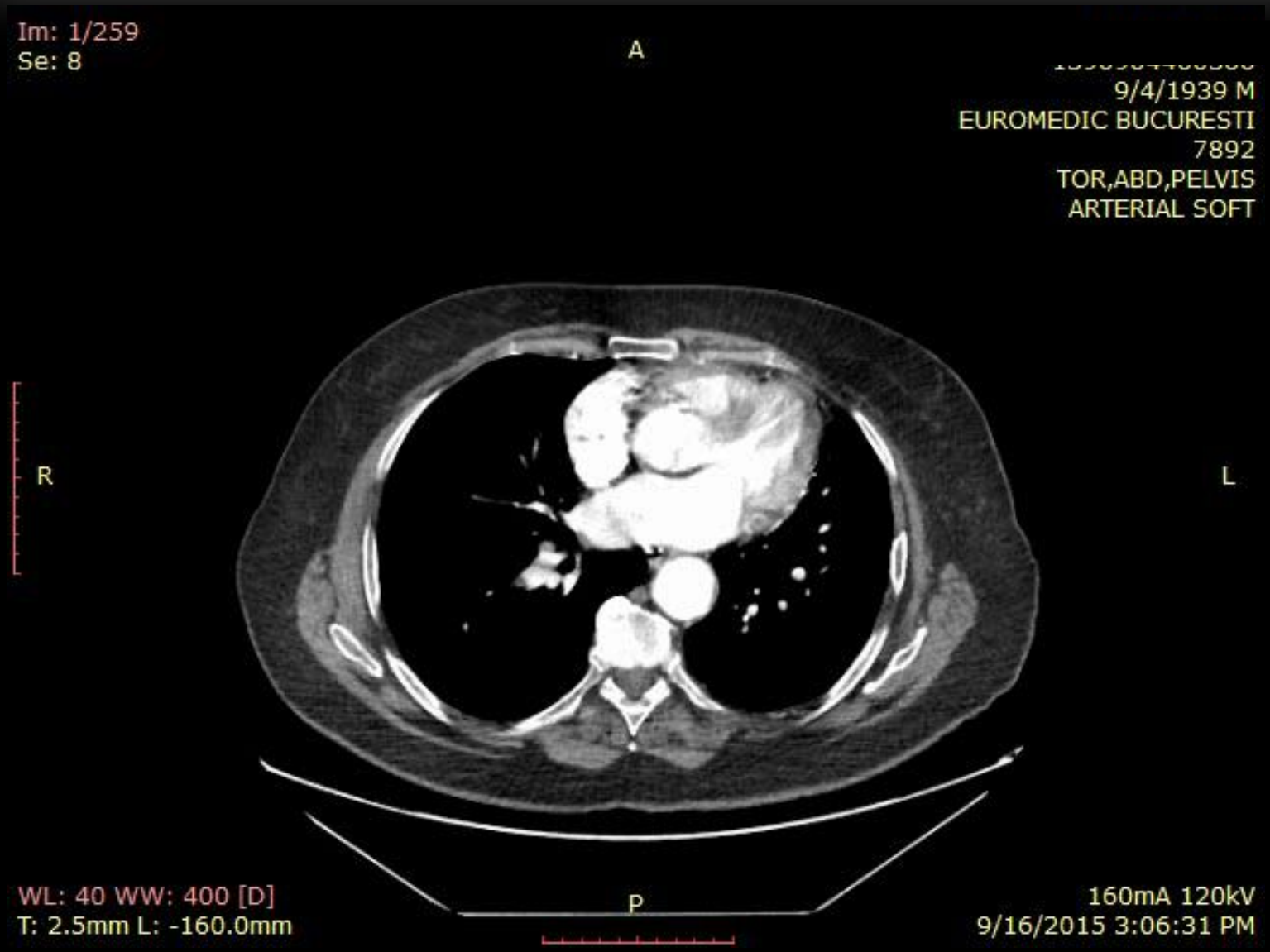
AAA+celiac pre-op

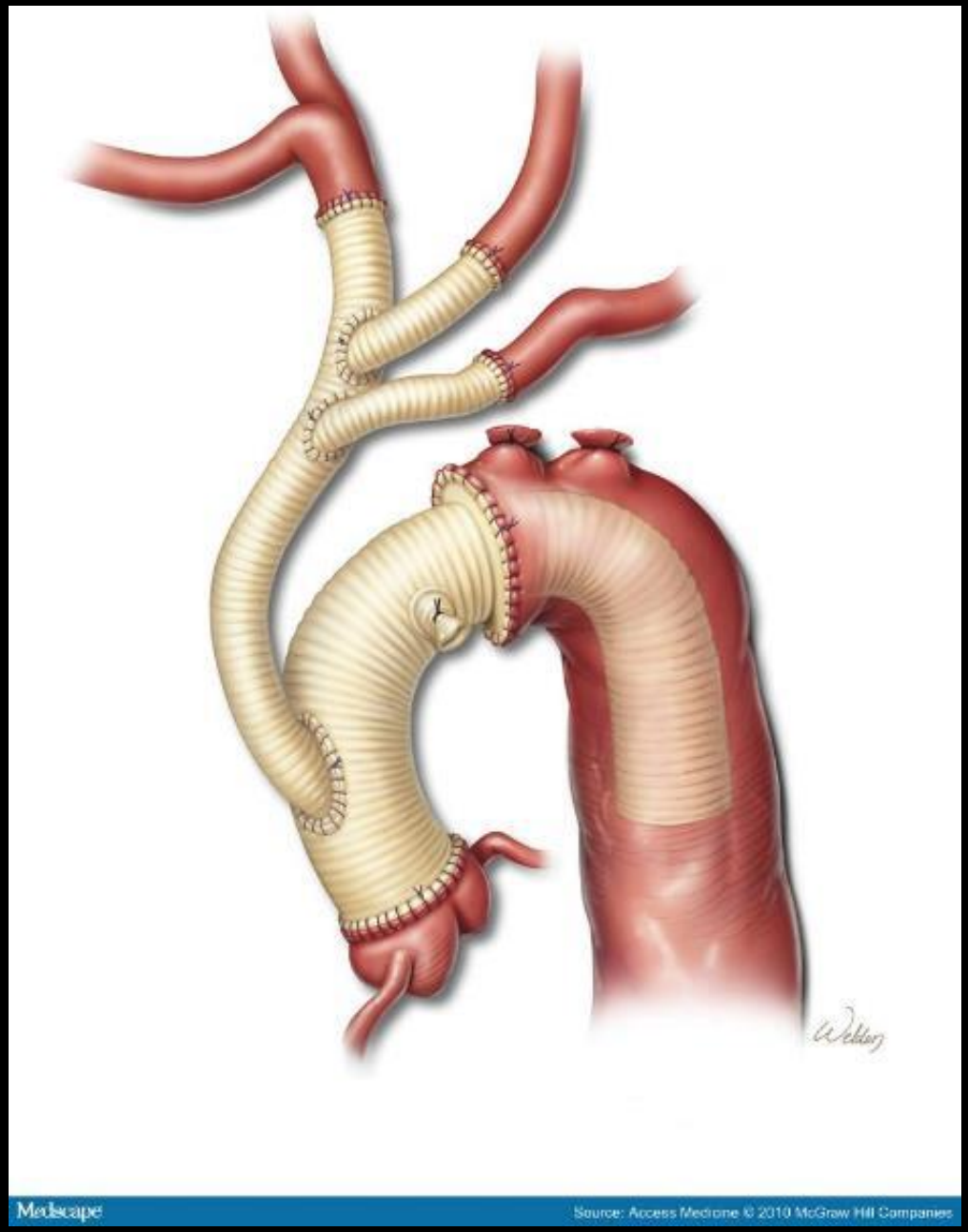


AAA+celiac intra-op

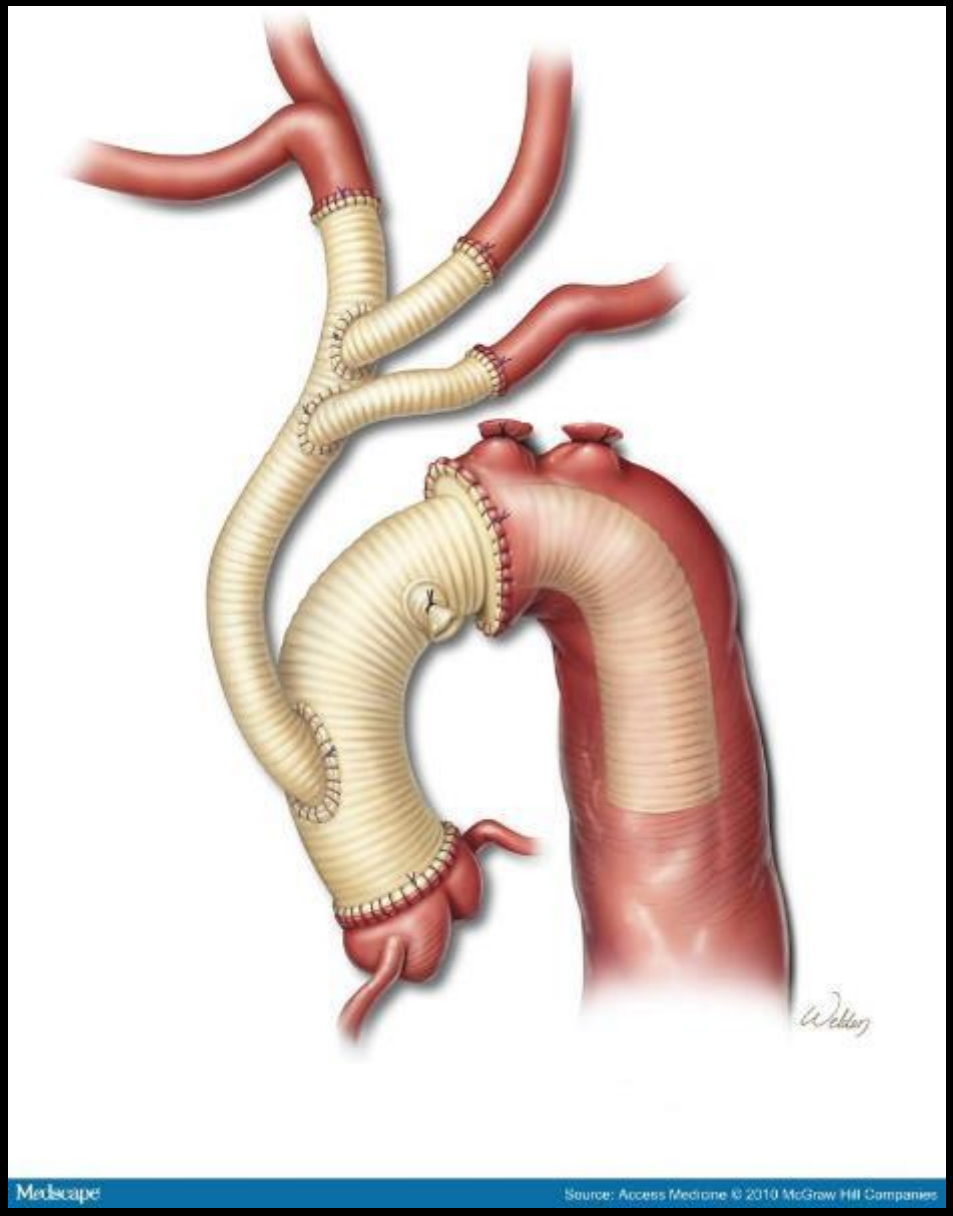
AAA+celiac post-op

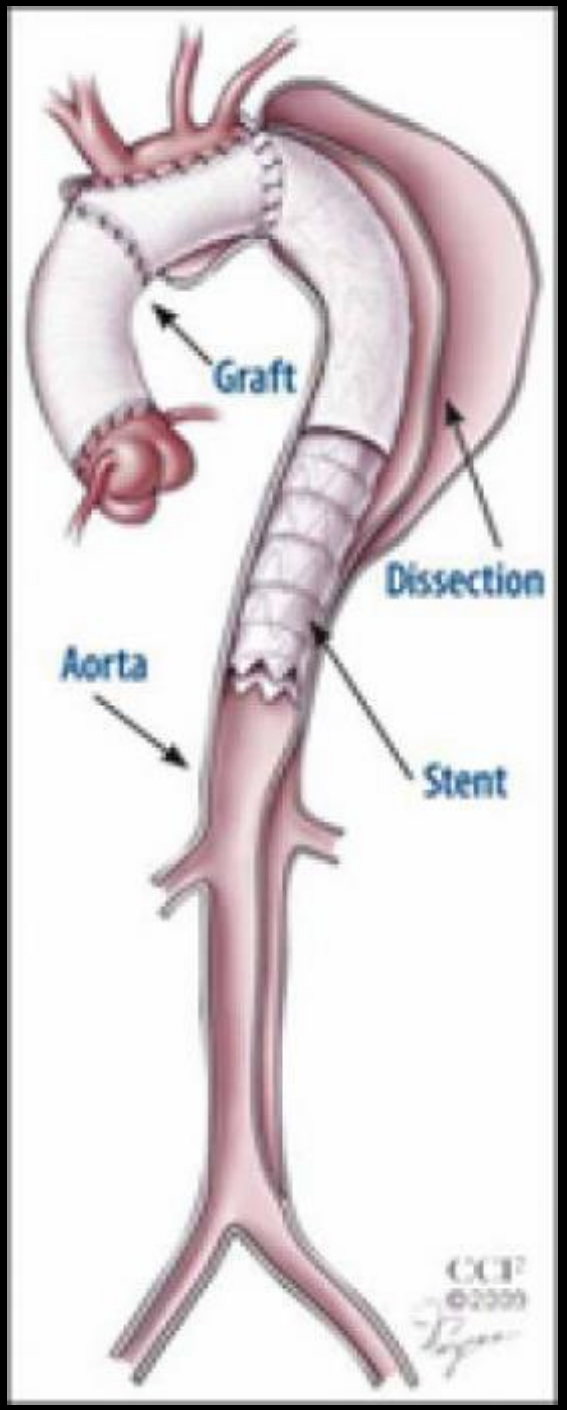
AORTIC DISSECTION

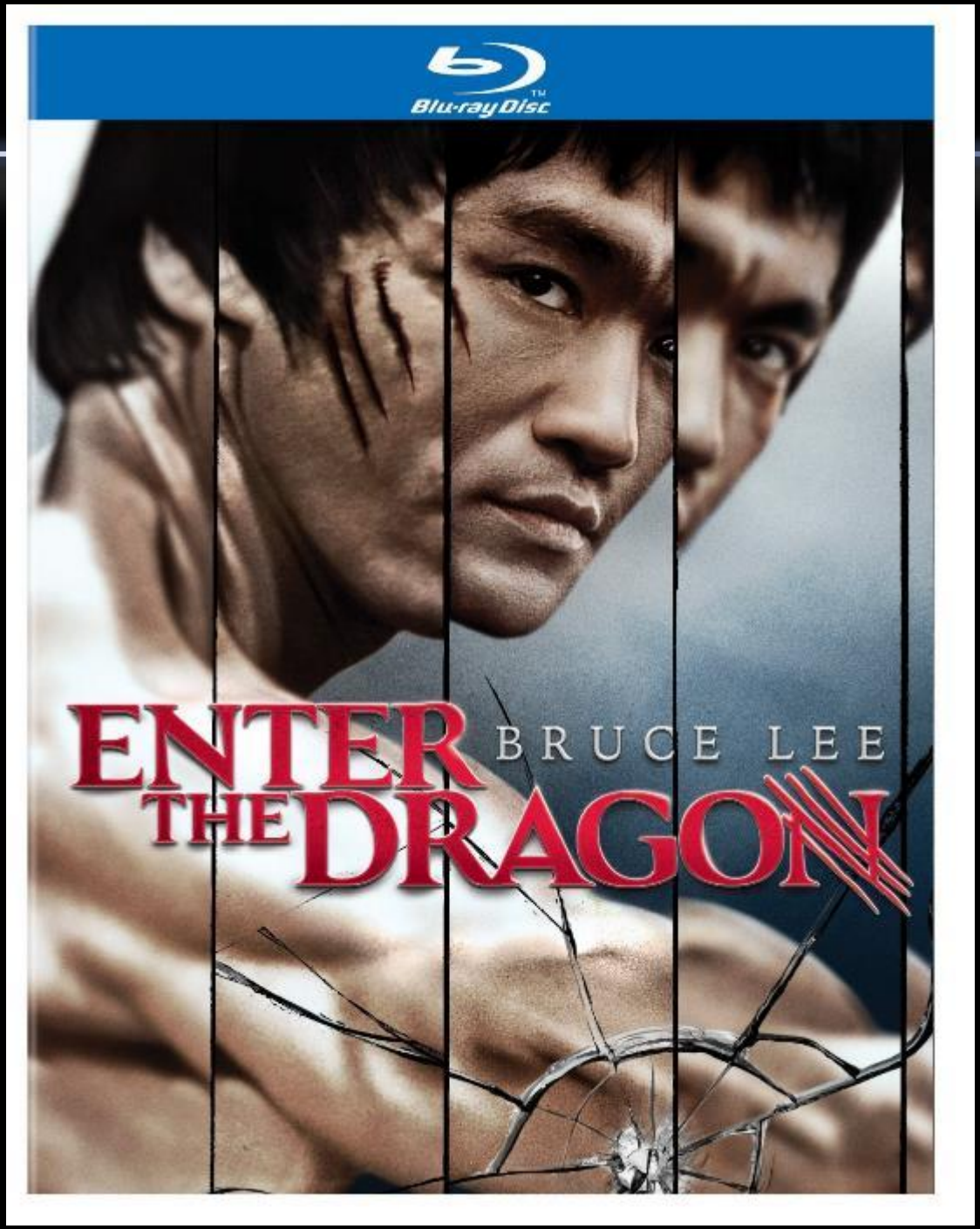
KYNETIC elephant trunk



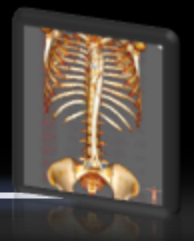
Medscape
Source: Access Medicine © 2010 McGraw-Hill Companies


Medscape
Source: Access Medicine © 2010 McGraw Hill Companies

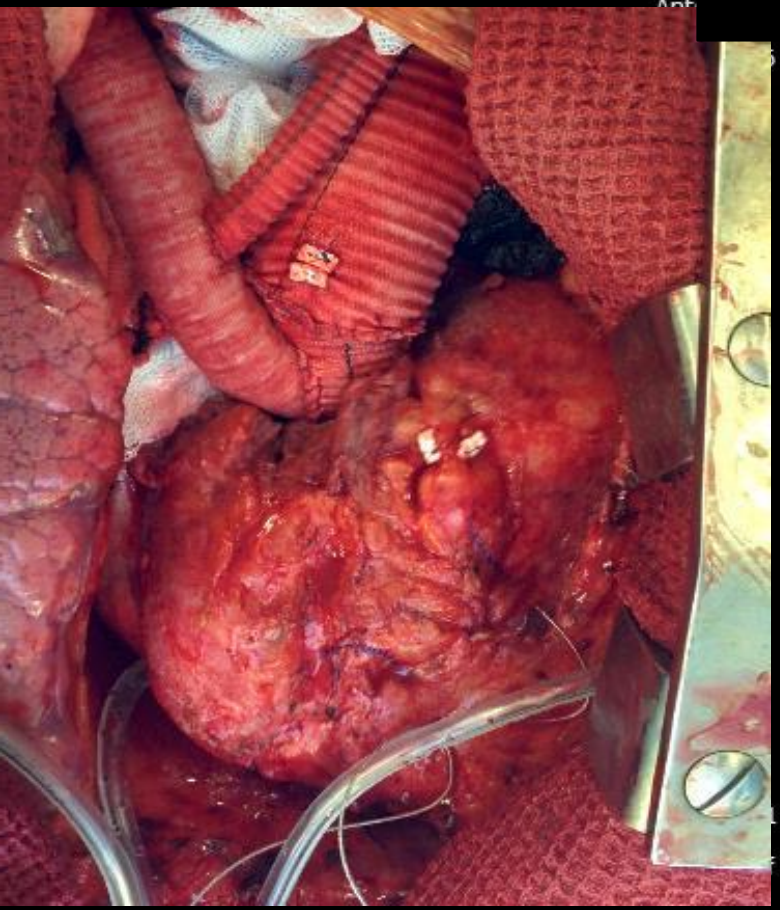

Graft
Dissection
Aorta
Stent


Blu-ray Disc
BRUCE LEE
ENTER THE DRAGON

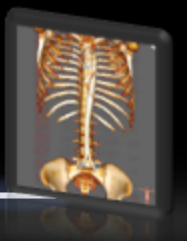
Aortic Dissection ET



Aortic Dissection

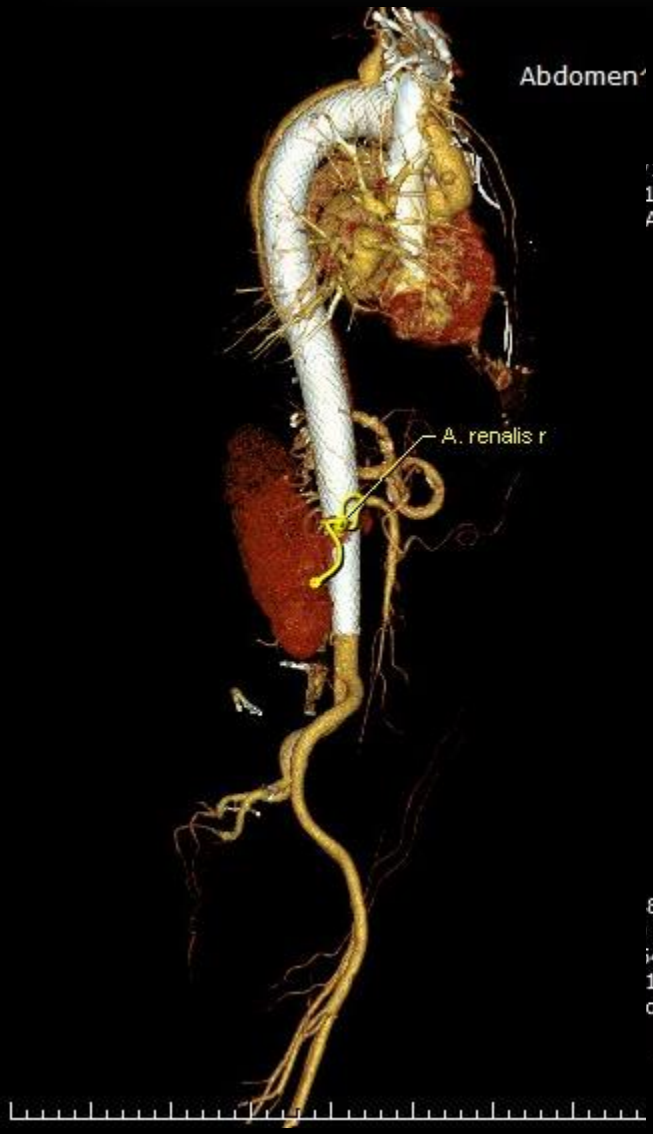


Aortic Dissection



Aortic Dissection

1 year Fw-up


Abdomen
A. renalis r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HFS
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1 of 233
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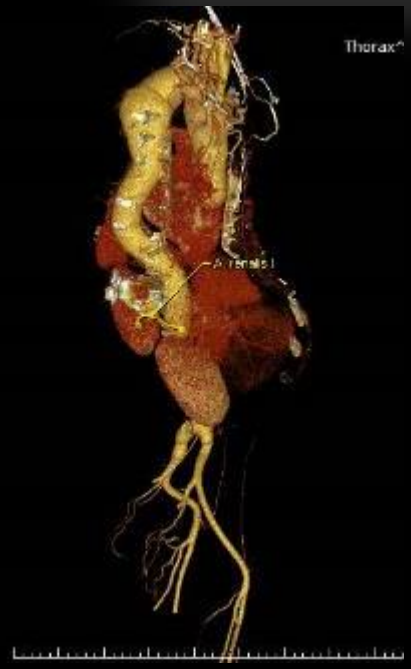
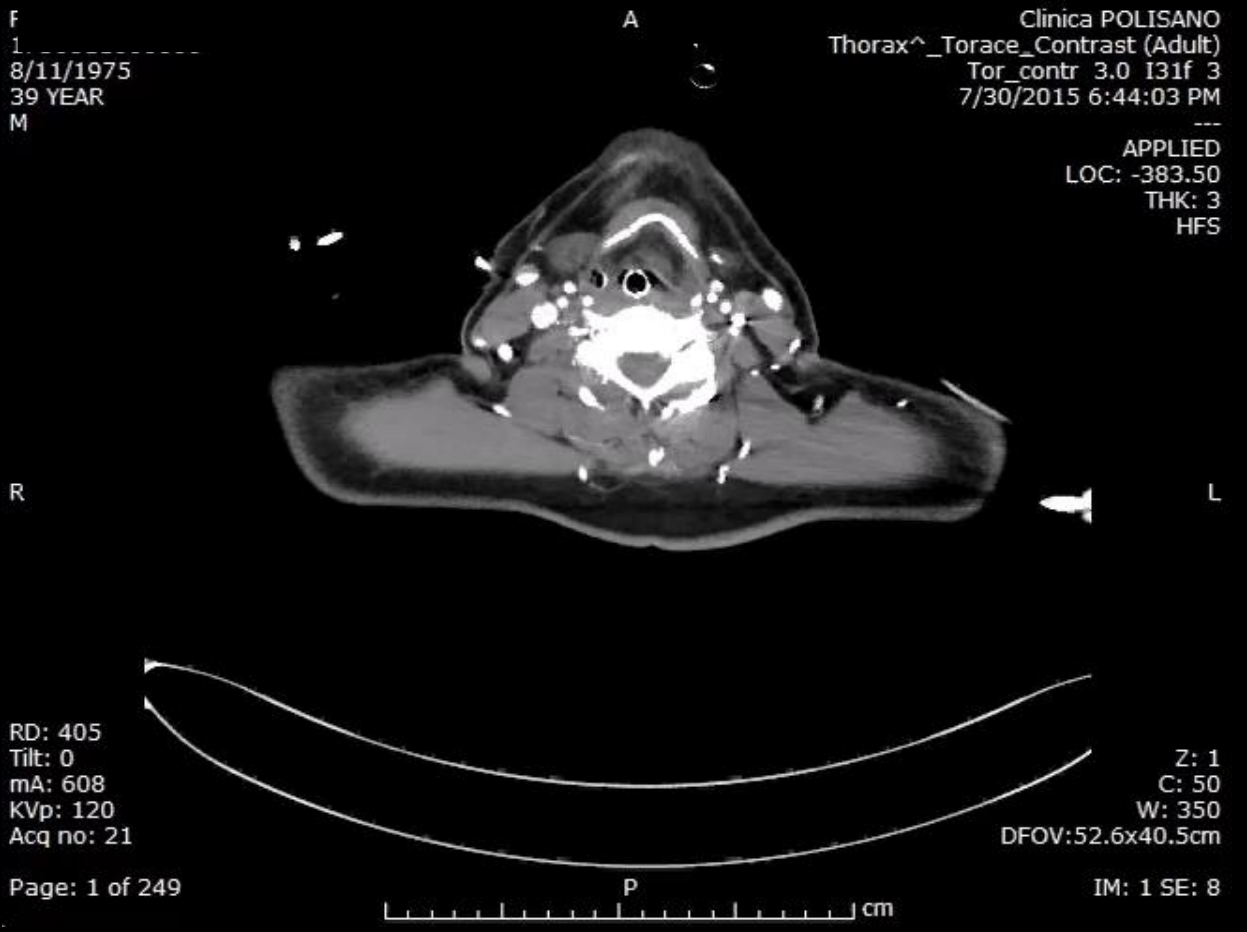
cm
IM: 1 SE: 9

Aortic Dissection ACUTE!

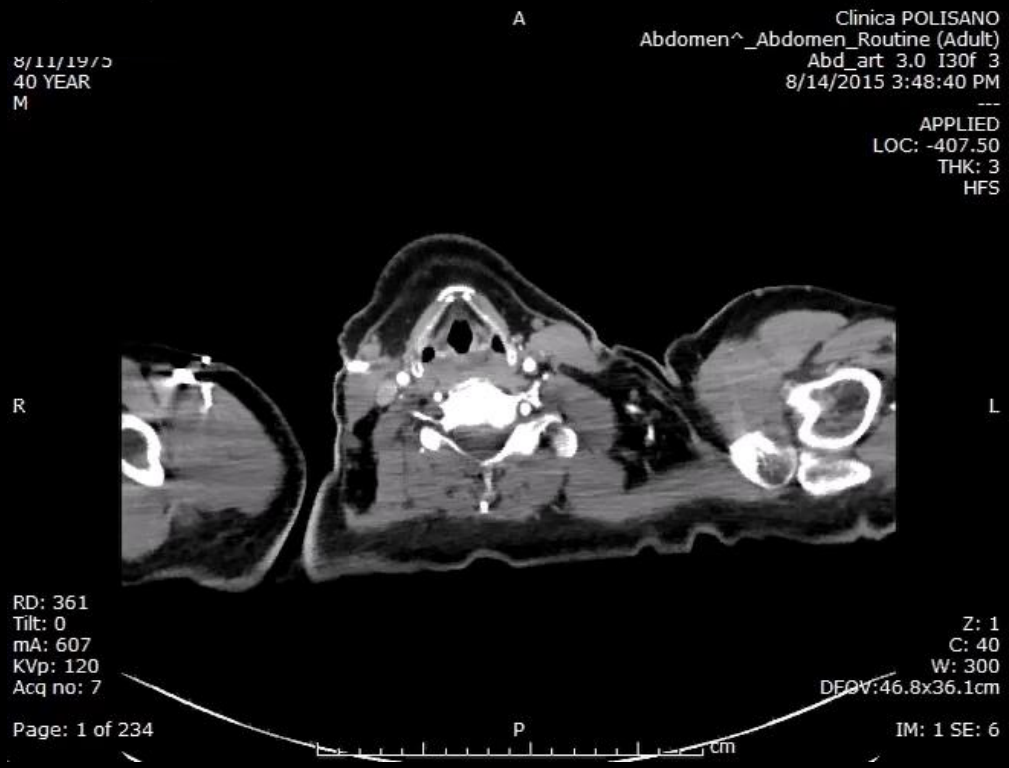


Aortic Dissection ACUTE!



Aortic Dissection ACUTE!

Aortic Dissection ACUTE!

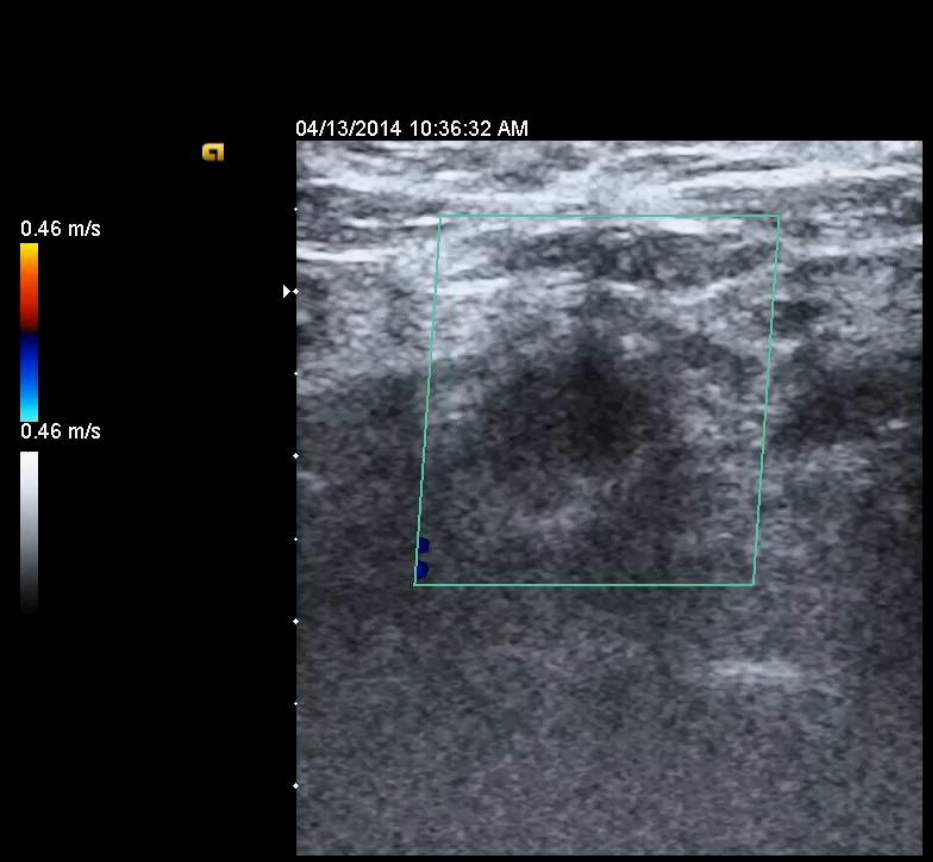


Aortic Dissection ACUTE!

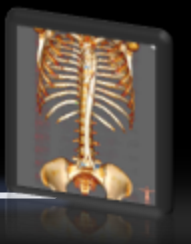
Aortic Dissection

Aortic Dissection

Aortic Dissection



Aortic Dissection



PRE

M06

M11

- 28 Years Id Female Patient with Type B Dissection
  - Normal prognosis: There is no solution


Marculescu, Oana Laura
2860209460083
2/9/1986
30 YEAR
F
A
Clinica POLISANO
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Abd_art 3.0 I30f 3
4/18/2016 11:11:01 AM

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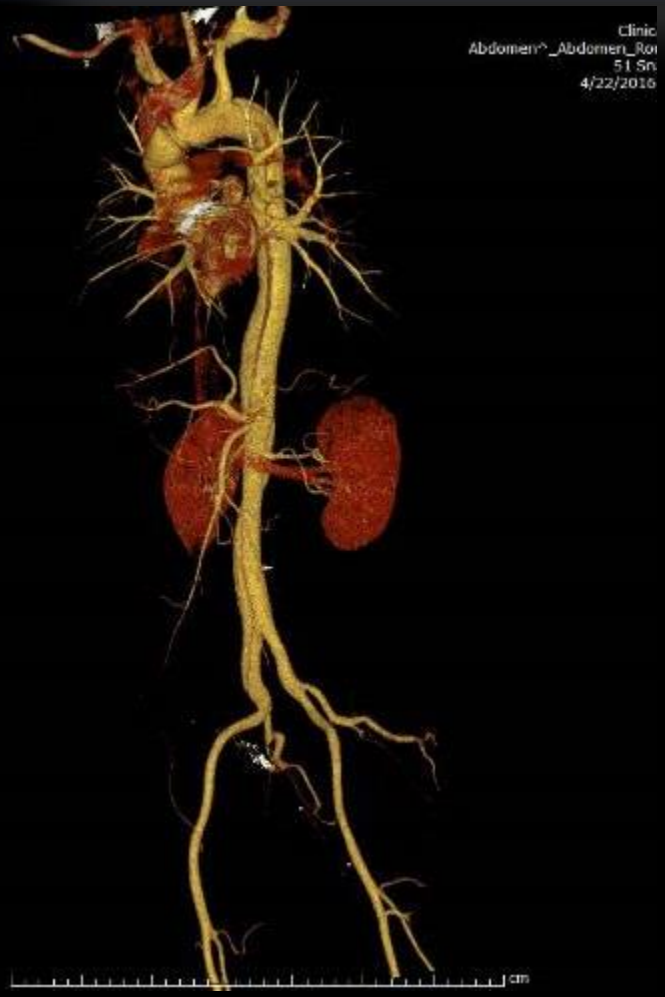
Page: 1 of 227
P
cm
IM: 1 SE: 8

Aortic Dissection



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7/12/1970
45 YEAR
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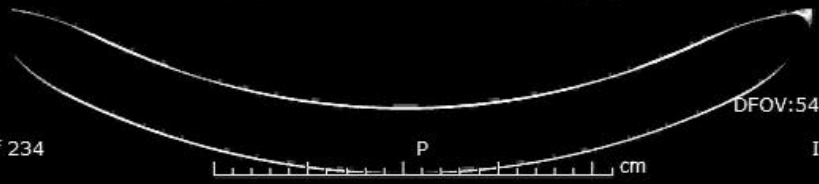
HFS

R

L

RD: 421
Tilt: 0
mA: 612
KVp: 100
Acq no: 7

Page: 1 of 234



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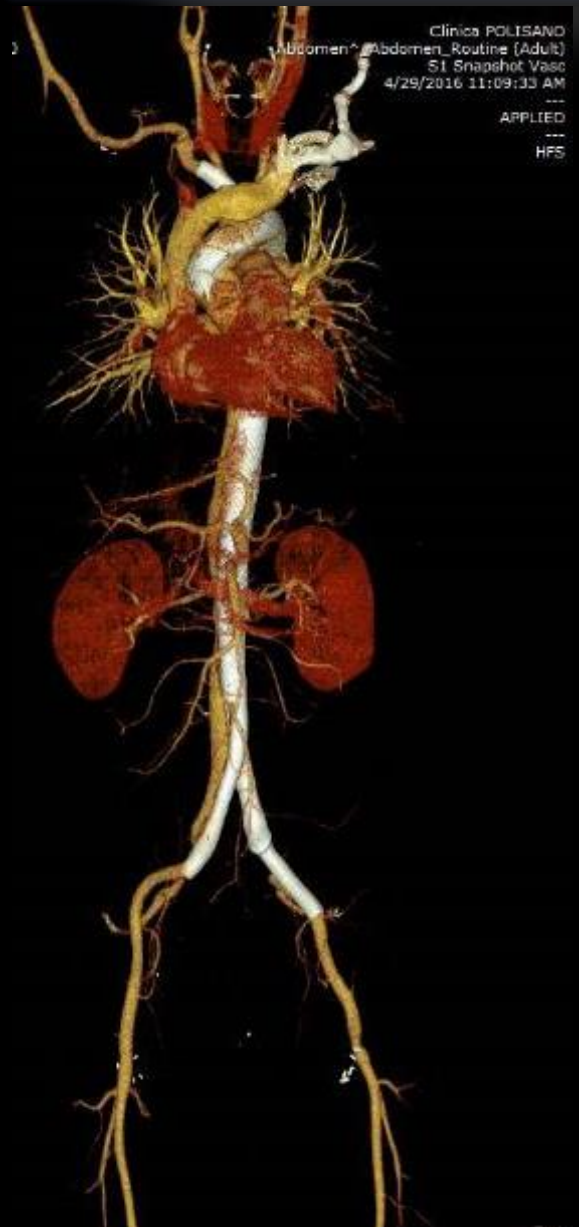
IM: 1 SE: 6

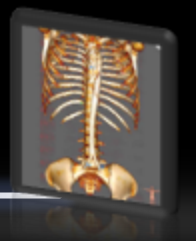
Aortic Dissection



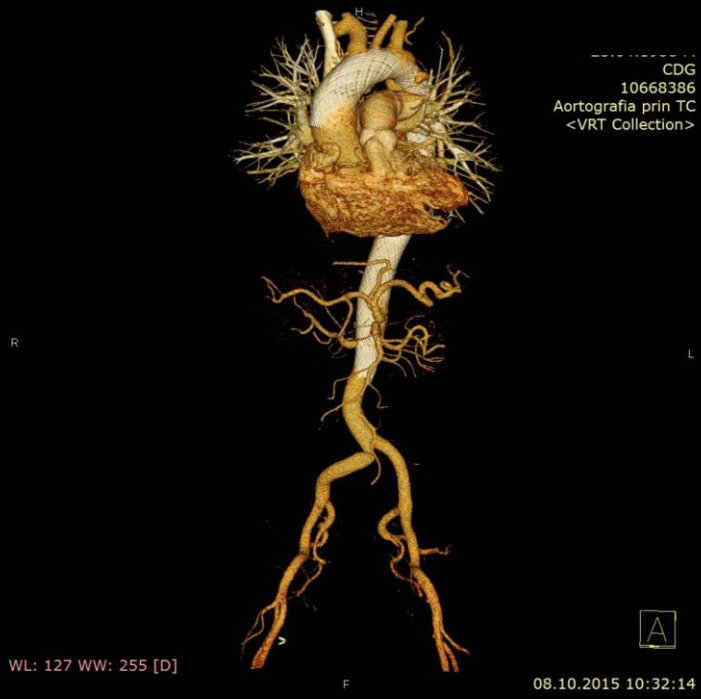
Aortic Dissection B

Aortic Dissection

Aortic Dissection

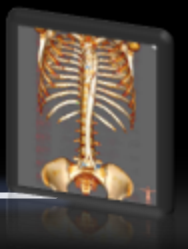


Aortic Dissection



S - MFM
Results

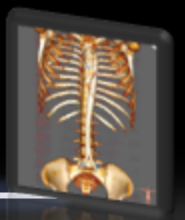
Types of Aneurysms Managed By Streamliner MFM



« World Premiere »

Crawford Type II+AAA	*3*
Crawford Type IV+AAA	*3*
Crawford Type I	*2*
Infrarenal /Juxtarenal AAA	*20*
Aortic dissection	*8*

Streamliner Results

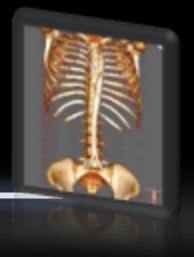


- *No Aneurysm-Related Death*
- *No Paraplegia Nor Stroke*
- *No Renal Impairment*
- *No Loss of Branch Patency*
- *No Rupture*
- *No Device Failure*

Multilayer Flow Modulator

GLOBAL REGISTRY

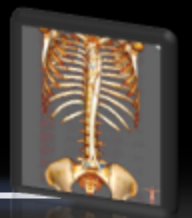
Discussion

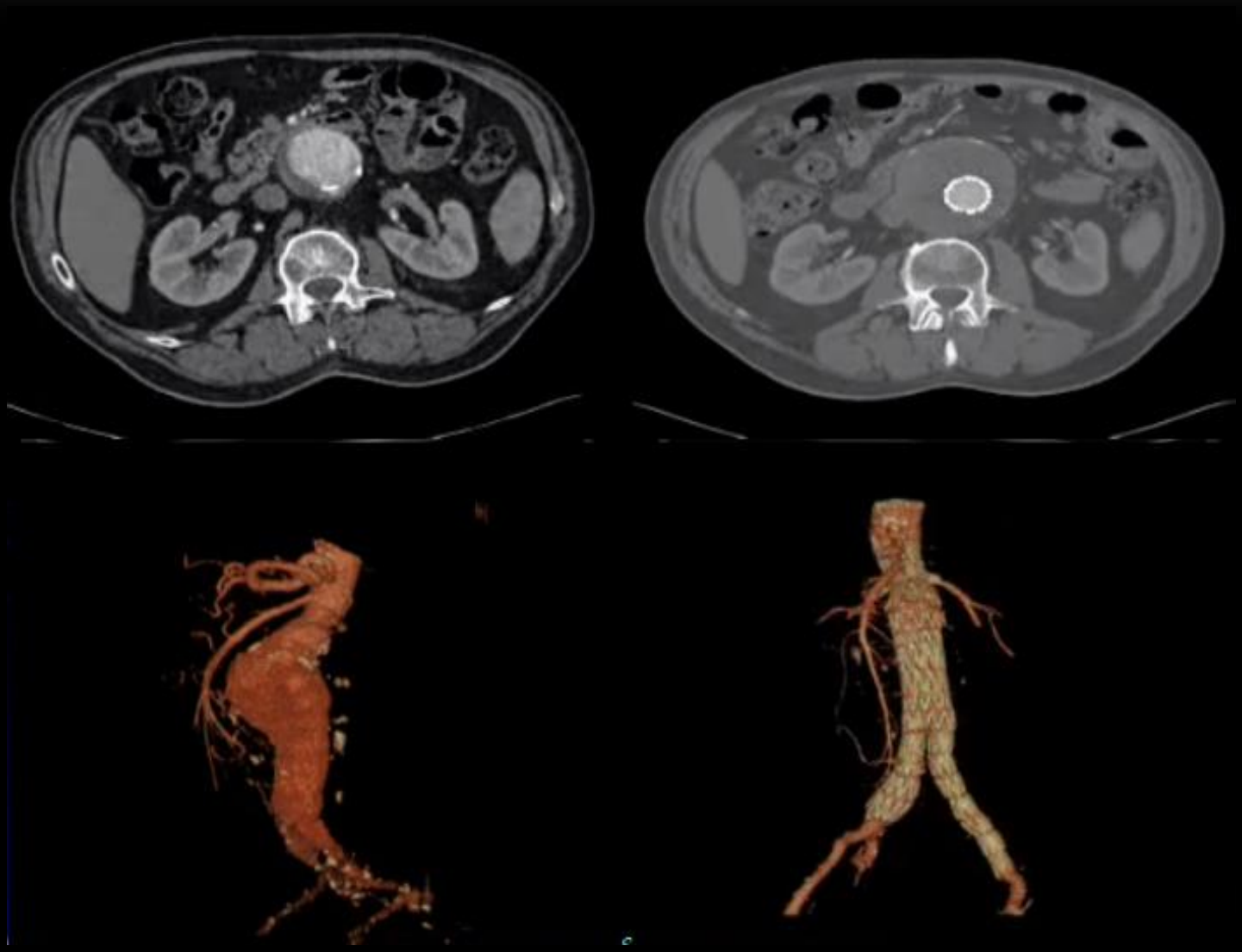


- *Surgery*
- *FEVAR*
- *MFM*

Open Surgical Society

Fenestrated Endovascular Grafts



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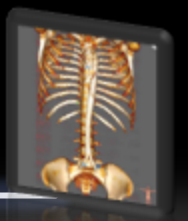
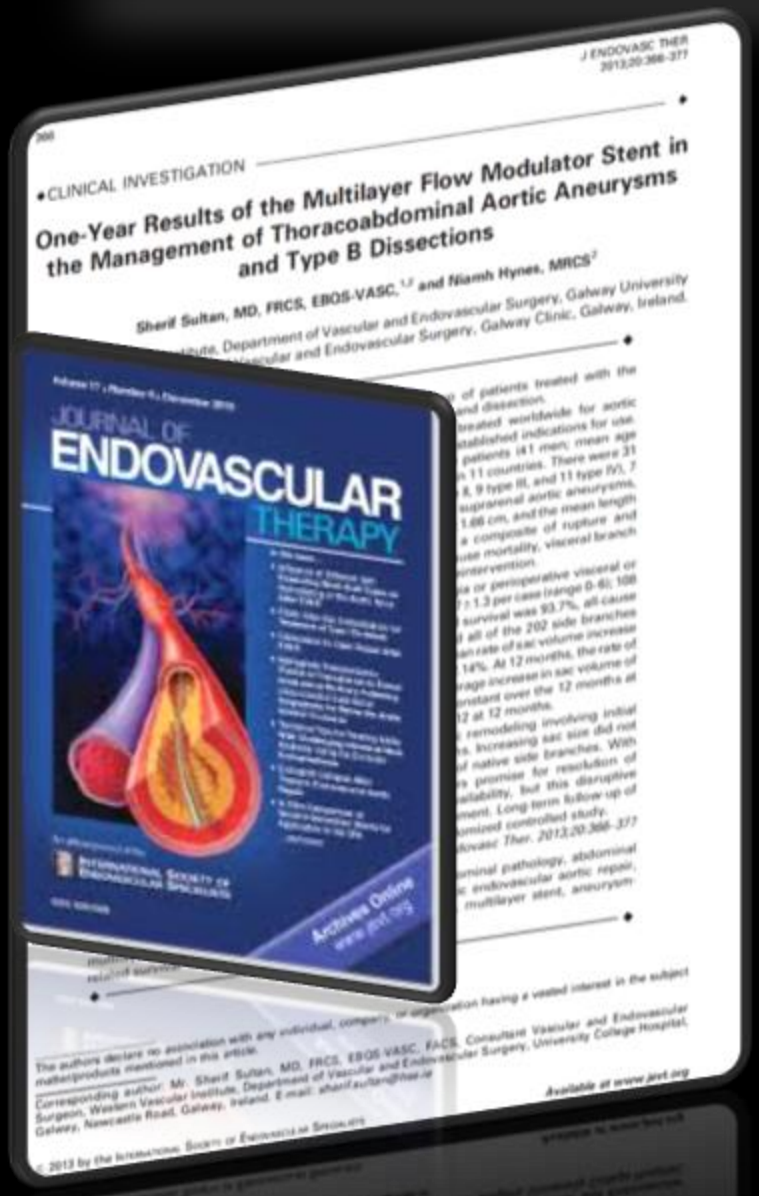
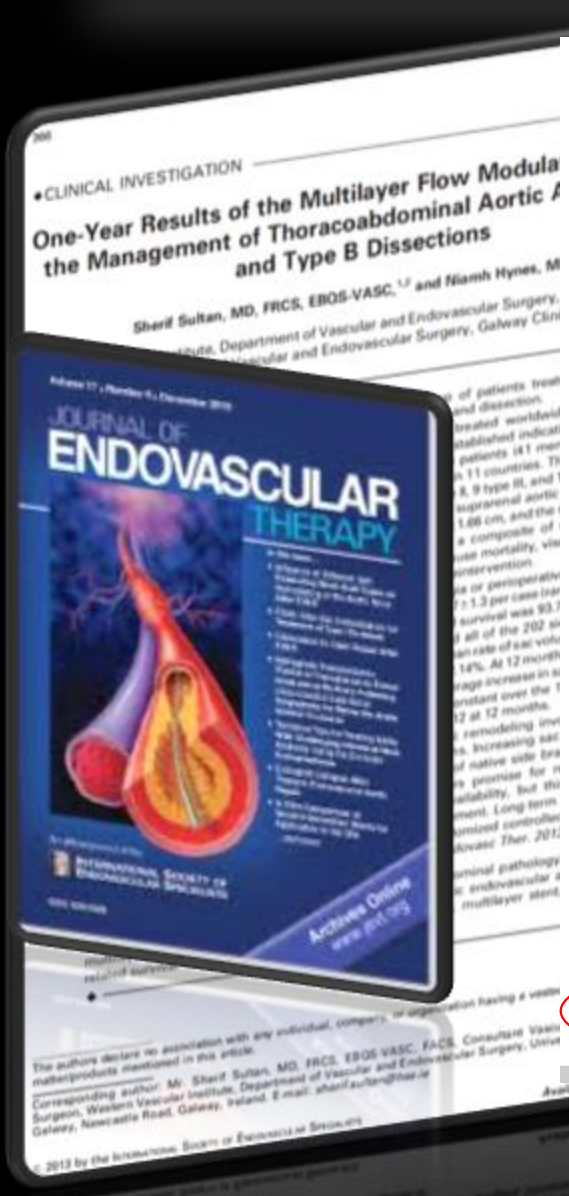
STRATO TRIAL





- *No device migration*
- *No loss of device integrity*
- *No spinal cord ischemia*
- *No aneurysm rupture*
- *MFM is safe and effective*

STRATO TRIAL



Review

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SAGE

Systematic Review and Patient-Level Meta-analysis of the Streamliner Multilayer Flow Modulator in the Management of Complex Thoracoabdominal Aortic Pathology

Niamh Hynes, MRCS, MMSc, MD[1,2*], Sherif Sultan, MCh, MD, FRCS, PhD[1,2*], Ala Elhelali, MSc[1,3], Edward B. Diethrich, MD[4], Edel P. Kavanagh, PhD[1], Mohamed Sultan, BSc[1], Florian Stefanov, PhD[1,3], Patrick Delassus, PhD[3], and Liam Morris, PhD[3]

Abstract

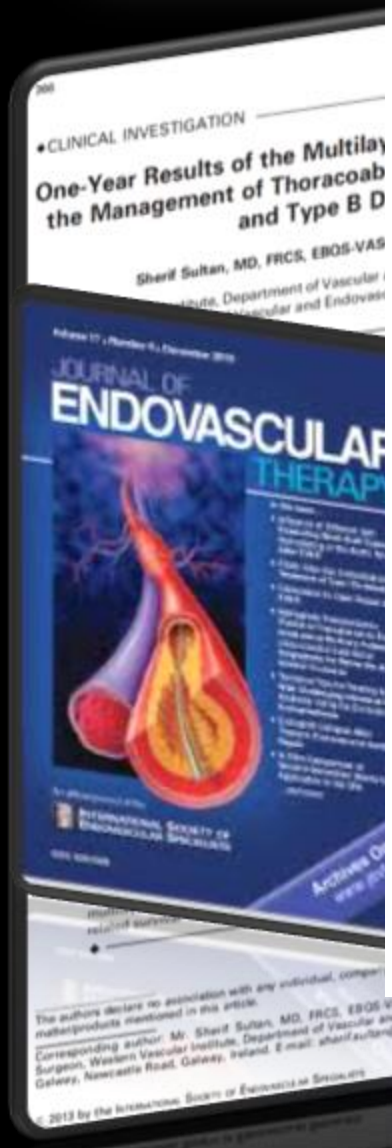
Purpose: To examine the safety and short-term efficacy of the Streamliner Multilayer Flow Modulator (SMFM) in the management of patients with complex thoracoabdominal aortic pathology who are unfit for alternative interventions.

Methods: Biomedical databases were systematically searched for articles published between 2008 and 2015 on the SMFM. A patient-level meta-analysis was used to evaluate aneurysm-related survival. Secondary outcomes were all-cause survival, stroke, spinal cord ischemia, renal impairment, and branch vessel patency. Other considerations were the impact of compliance with the instructions for use (IFU) on clinical outcome. Mean values and Kaplan-Meier estimates are presented with the 95% confidence interval (CI).

Results: Fifteen articles (3 multicenter cohort studies, 3 observational cohort studies, and 9 case reports) were included, presenting 171 patients (mean age 68.8±12.3 years; 139 men). The mean aneurysm diameter was 6.7±1.6 cm (95% CI 6.4 to 6.9 cm). Technical success reported in 15 studies was 77.2%. Aneurysm-related survival at 1 year was 78.7% (95% CI 71.7% to 84.4%). One-year all-cause survival was 53.7% (95% CI 46.0% to 61.3%). There were no reported cases of spinal cord ischemia, renal insult, or stroke.

Conclusion: The SMFM can be safely utilized in some patients with complex thoracoabdominal pathologies provided operators adhere to the IFU. The SMFM is a novel technology with no long-term published data on its sustained effectiveness and a lack of comparative studies. Randomized clinical trials, registries, and continued assessment are essential before this flow-modulating technology can be widely disseminated.

STRATO TRIAL



Clinical Investigation

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SAGE

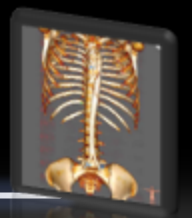
Three-Year Outcomes With the Multilayer Flow Modulator for Repair of Thoracoabdominal Aneurysms: A Follow-up Report From the STRATO Trial

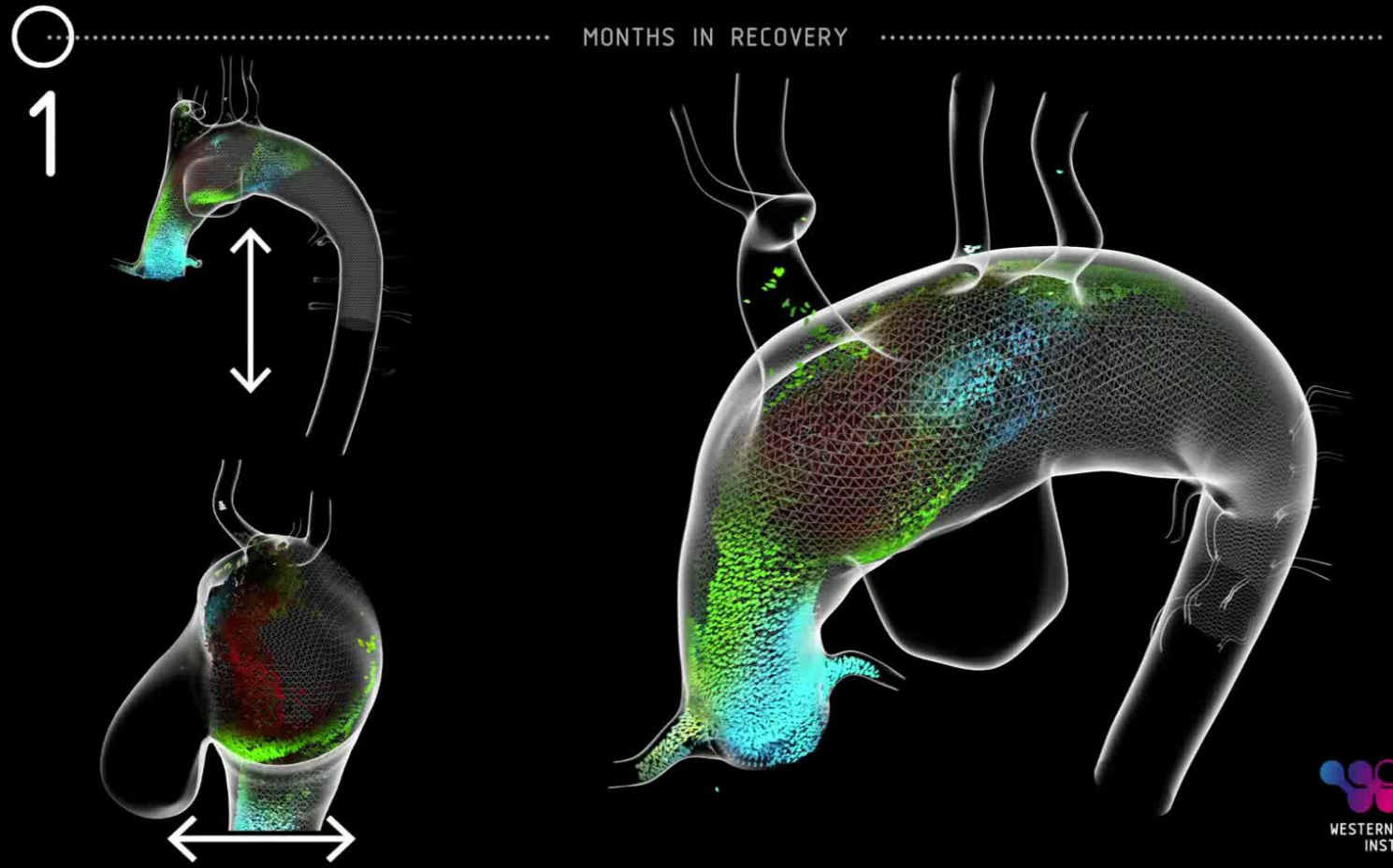
Claude D. Vaislic, MD[1], Jean Noël Fabiani, MD, PhD[2], Sidney Chocron, MD, PhD[3], Jacques Robin, MD[4], Victor S. Costache, MD, PhD[5], Jean-Pierre Villemot, MD, PhD[6], Jean Marc Alsac, MD[2], Pascal N. Leprince, MD, PhD[7], Thierry Unterseeh, MD[8], Eric Portocarrero, MD[6], Yves Glock, MD, PhD[9], and Hervé Rousseau, MD, PhD[10] for the STRATO Investigators Group

Abstract

Purpose: To evaluate midterm outcomes of endovascular repair of types II and III thoracoabdominal aortic aneurysms (TAAA) using the Multilayer Flow Modulator (MFM) in patients unsuitable for open surgery or fenestrated stent-grafts. **Methods:** In the prospective, multicenter, nonrandomized STRATO trial (EudraCT registration: 2009-013678-42; *ClinicalTrials.gov* identifier NCT01756911), 23 patients (mean age 75.8 years; 19 men) with Crawford type II and III TAAA (mean diameter 6.5 cm) were implanted between April 2010 and February 2011. Outcomes included all-cause mortality and stable aneurysm thrombosis with associated branch vessel patency. **Results:** Through 36 months, there were 7 deaths (none confirmed as aneurysm-related), and no cases of spinal cord injury, device migration or fracture, or respiratory, renal, or peripheral complications. Three patients were lost to follow-up and 2 devices were explanted. The device was patent in the 11 remaining patients at 3 years. Stable aneurysm thrombosis was achieved for 15 of 20 patients at 12 months, 12 of 13 at 24 months, and 10 of 11 at 36 months. The rate of branch patency was 96% at 12 months (primary patency), 100% at 24 months, and 97% at 36 months. Nine patients suffered from endoleaks (attachment site or device overlap); 9 patients underwent 11 reinterventions (3 surgical). Maximum aneurysm diameter was stable for 18 of 20 patients at 12 months, 11 of 13 at 24 months, and 9 of 11 at 36 months. For 10 patients with computed tomography at 36 months, the mean ratio of aneurysm flow volume to total volume had decreased by 83%; the mean ratio of thrombus volume to total volume increased by 159%. **Conclusion:** Through 3 years, endovascular repair with the MFM appears to be safe and effective while successfully maintaining branch vessel patency.

4 D – Aortic therapy



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J ENDOVASC THER
2011;18:146–153

◆ CLINICAL INVESTIGATION

Secondary Procedures After Aortic Aneurysm Repair With Fenestrated and Branched Endografts

Nicola Troisi, MD[1,2]; Konstantinos P. Donas, MD, PhD[1,2]; Martin Austermann, MD[1]; Jörg Tessarek, MD[3]; Thomas Umscheid, MD[4]; and Giovanni Torsello, MD[1,2]

from migration/type I endoleak, and freedom from any device-related secondary procedures were assessed with Kaplan-Meier analyses.

Results: The 30-day mortality rate was 1.9%. During follow-up (mean 25 months, range 1–94), 34 secondary procedures were performed in 28 (26.2%) patients for 6 (17.6%) limb graft stenoses/thromboses (5.6% of 107 cases), 8 (23.5%) migrations/type I endoleaks with/without visceral occlusions (7.5% of 107 cases), and 12 (35.3%) type III endoleaks (9.3% of 107 cases). The stent fractures (7.5% of 107 cases), 8 (23.5%) in-stent visceral vessel stenoses/ mean interval between the primary and secondary procedures was 12.9 months (range 1–68). In 26 (76.5%) of 34 cases, a secondary endovascular procedure was performed; in the remaining 8 (23.5%) cases, the complication was treated surgically. The secondary procedure was unsuccessful in 9 cases of visceral vessel compromise (failure to cannulation, stent fracture/migration, in-stent stenosis/occlusion). Estimated 3-year survival was 77%, while the 3-year rate for freedom from any device-related secondary procedure was 75.5%.

Conclusion: The incidence of early and late complications requiring a secondary procedure after treatment with fenestrated or branched devices was not negligible. Endoleak type III represented the most common cause for reintervention during follow-up. Secondary procedures performed for visceral vessel compromise had high rates of treatment failure. Accurate preoperative planning, the advent of new materials/techniques, and strict follow-up could be the key factors to improving the results of fenestrated or branched stent-graft interventions and to reduce the rate of secondary procedures.

J Endovasc Ther, 2011;18:146–153

Early & Late Complications Requiring Secondary Procedure After Fenestrated or Branched Devices is High

Secondary Procedures Performed for Visceral Vessel Compromise Had High Failure Rates

Endovascular treatment of thoracoabdominal aortic aneurysms

Matthieu Guillou, MD,[a] Aurelia Bianchini, MD,[a] Jonathan Sobocinski, MD,[a] Blandine Maurel, MD,[a] Piervito D'elia, MD,[a] Mark Tyrrell, MD,[b] Richard Azzaoui, MD,[a] and Stéphan Haulon, MD, PhD,[a] *Lille, France; and London, United Kingdom*

Background: Development in endograft design has extended endovascular treatment to include thoracoabdominal aortic aneurysms (TAAA). We report our experience using fenestrated and branched endografts in the management of TAAA.

Methods: We analyzed a cohort of consecutive patients treated electively for TAAA using endovascular techniques between 2006 and 2011. All data were collected prospectively. The relationships between preoperative risk factors and clinical outcome were examined using univariate and multivariate statistical techniques. We also compared the outcomes between 33 previously published early cases (EC) with the last 56 later cases (LC).

Results: Eighty-nine patients (83 men) were treated. Median age was 69 years. All patients were deemed unfit for open surgery. The 30-day and in-hospital mortality rates were 8.9% and 10%, respectively. Multivariate analysis showed in-hospital mortality was associated with preoperative chronic renal failure and advanced age. Higher postoperative mean arterial blood pressure was a protective factor. Technical success rate was 96.6% (94% and 98% in the EC and LC groups, respectively; $P = .14$). The spinal cord ischemia (SCI) rate was 7.8% (15% and 3% in the EC and LC groups, respectively; $P = .063$) and was associated with chronic obstructive pulmonary disease and procedure duration. Six patients (6.7%) required temporary filtration, but none required permanent renal support (associated with left ventricular ejection fraction < 40% and procedure duration). Median procedure duration decreased from 232 to 203 minutes ($P = .011$) in the EC and LC groups, respectively. Actuarial survival was 86.8% ± 3.7% at 1 year and 74.7% ± 6% at 2 years.

Conclusions: Although we have treated a cohort at high operative risk, our midterm results compare favorably with the published series of conventional surgery. Accurate hemodynamic control represented by high normal perioperative blood pressure seems to protect against severe postoperative complications. (J Vasc Surg 2012;56:65-73.)

Thoracoabdominal aortic aneurysm (TAAA) repair continues to represent a clinical and technical challenge. Conventional open repair still carries appreciable morbidity and mortality rates, even in high-volume, experienced centers.[1] Modern series report perioperative mortality rates ranging from 4% to 16% and in-hospital mortality approaching 20%.[2] Despite improvement in perioperative care and various surgical adjuncts, cardiopulmonary, renal, and neurologic complications, such as spinal cord ischemia (SCI), are still common problems after open repair.[3]

The endovascular treatment of infrarenal aortic aneurysms has gained widespread acceptance and has revolutionized the field of vascular surgery during the last decade. More recently, ingenious technical and material developments in endovascular technology have enabled the manufacture of custom-made endografts to treat even more challenging cases. These devices allow the treatment of aneurysmal segments of the TAAA, while preserving blood flow to visceral arteries through fenestrations, branches, or a combination of the two.

Although there is still a lot to be learned about these new techniques, encouraging results in feasibility and safety have been reported.[4-7] Nevertheless, patients undergoing these procedures, most of whom have been refused open surgery, remain vulnerable postoperatively and are particularly at risk of SCI and acute renal failure. In 2010, we published our initial experience of 33 patients.[8] Here we describe our single-institution experience with the endovascular treatment of 89 consecutive patients presenting with complex TAAA disease.

METHODS

Patients. Until 2006, 15 to 20 open TAAA repairs were performed each year at our institution. The number of yearly open repairs has now dropped to <10, but the overall number of TAAA repairs (open + endovascular) has increased because many high-risk patients are now referred to our center specifically for an endovascular repair. The indications for treatment have not changed: maximal aortic diameter >55 mm or rapid growth, defined as >5 mm in the last 6 months.

All data regarding the use of custom-made branched and fenestrated endografts for TAAA are collected prospectively. Between August 2006 and July 2011, we treated 89 consecutive patients at our institution. Written informed consent was obtained from all patients. All aneurysms but one were considered degenerative. The exception was a 38-year-old patient diagnosed with Behçet agammaglobu-

From Vascular Surgery, Hôpital Cardiologique, CHRU de Lille, Lille,[a] and King's Health Partners, London.[b]

Author conflict of interest: Dr Haulon is a consultant for Cook Medical Inc.

Reprint requests: Stéphan Haulon, MD, PhD, Chirurgie Vasculaire, CHRU de Lille, Institut National de la Santé et de la recherche Médicale U1008, Université Lille Nord de France, 59037 Lille Cedex, France (e-mail: stephan.haulon@chru-lille.fr).

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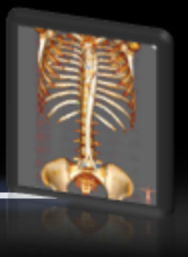
http://dx.doi.org/10.1016/j.jvs.2012.01.008

- *15.7% Peri-operative Mortality*
- *15.8% Spinal Cord Ischemia*
- *6% Multiple Organ Failure*
- *11% Chronic Renal Failure*

Causes of Death is Takotsubo Syndrome "Stress Cardiomyopathy"

Open TAAA VS FEVAR



- *A Propensity Score-Matched Comparison of Open Repair of Complex AAA with that of the French FEVAR Experience Did Not Bode Well for Proponents of FEVAR*

- *The Surgical Group had a Less than 5% Complication Rate while the FEVAR Patients had More than 45% Morbidity*

- *Malmö FEVAR Study Reported Greater than 60% Complication Rate*

- *This Has Raised Troubling Questions Regarding the Durability of FEVAR Technology*

Outcomes for supra-aortic branch vessel stenting in the treatment of thoracic aortic disease

Adrian O'Callaghan, MB, Tara M. Mastracci, MD, Roy K. Greenberg, MD, Matthew J. Eagleton, MD, James Bena, MS, and Yuki Kuramochi, RN, *Cleveland, Ohio*

Objective: Endovascular options for the treatment of proximal thoracic and arch disease have evolved over the years. In this manuscript, we review the midterm results of fenestrated compared with chimney configurations for proximal aortic aneurysm disease.

Methods: We performed an analysis of all patients with chimney grafts or custom fenestrated endografts used for treatment of proximal thoracic aneurysm disease (involving the supra-aortic trunk vessels) presenting to our institution between 2004 and 2013. Patients were identified by retrospective chart review and through the prospective database (National Institutes of Health study number NCT00583050). Details of devices placed, intraoperative details, and measurements from postoperative imaging were included in the analysis. The primary outcomes of interest were long-term freedom from branch stent complications and freedom from proximal endoleak, but we also included perioperative events, in-hospital mortality, and requirement for secondary interventions in our review. The log-rank test (Mantel-Cox) was used to compare survival data. Student *t*-test (two tailed) and Fisher exact test (two tailed) were used for continuous and categorical data, respectively.

Results: Of 767 patients who underwent thoracic endovascular repair from January 2004 to February 2013, 33 satisfied the inclusion criteria (4%): 18 of 33 noncustom and 15 of 33 custom graft designs. Overall, the rate of technical success was 97%. There were four branch stent-related problems in the follow-up period, one of 15 (7%) in the custom group and three of 18 (17%) in the noncustom group. There were three proximal sealing failures in the immediate postoperative and follow-up period, one of 15 (7%) in the custom group and two of 18 (11%) in the noncustom group. Overall, 10 patients underwent secondary procedures, four of 15 (27%) in the custom group and six of 18 (33%) in the noncustom group.

Conclusions: Although they are technically feasible, both custom fenestrated endografts and chimney repairs for proximal thoracic disease involving the supra-aortic trunk vessels suffer from failures in intermediate follow-up, with a trend toward better long-term outcomes for custom devices. More work is needed to develop durable devices for this anatomic territory in the future. (J Vasc Surg 2014;60:914-20.)

The endovascular treatment of thoracic aneurysm disease is superior to open repair with respect to mortality and time to recovery.[1] In some aneurysms and dissections, proximity of supra-aortic branch vessels to the intended sealing zone complicates stent graft use. Strategies for dealing with such anatomic configurations include an open or hybrid approach, use of chimney or snorkel stents, and incorporation of branches and fenestrations or scallops in the thoracic device to maintain branch vessel perfusion.[2] A pure endovascular solution remains the goal so that the invasiveness of open surgery may be minimized, without compromising the durability of repair.

From the Department of Vascular and Endovascular Surgery, Cleveland Clinic Foundation.

Author conflict of interest: T.M.M. has consultation and proctor agree-

Methods of endovascular incorporation of the supra-aortic branch vessels are variable and poorly studied, except for small case series proving feasibility.[3-13] Branched grafts for the arch have recently been developed, and although they are not commercially available in the United States, they are in the early stages of use and so no long-term data are available. Both custom fenestrated devices and snorkel or chimney configurations have been described for years, but the fate of the stented branches and the durability of either type of repair are unknown (Fig 1). Consequently, we have scant evidence with which to formulate management options. We sought to address this need by evaluating our experience to determine the intermediate outcomes with fenestrated/scallop and chimney configurations.

METHODS

Patients. All endovascular repairs involving the

Outcomes for supra-aortic branch vessel stenting in the treatment of thoracic aortic disease

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From the Department of Vascular and Endovascular Surgery, Cleveland Clinic Foundation.

Author conflict of interest: T.M.M. has consultation and proctor agree-

CONCLUSIONS

Our experience with endovascular treatment of aortic arch disease reveals technical feasibility, with perhaps better durability of branch stents in custom fenestrations compared with noncustom chimneys. Chimney grafts have provided an acceptable solution in emergency situations not amenable to hybrid or open repair. In both cases, however, the durability and late outcomes remain concerning, and an alternative option is needed.


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The Easy Way
The Hard Way
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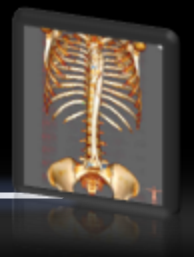
Conclusion

- *MFM 4D Aortic Therapy is a Promising Technology, Safe and Effective*
- *Protection from rupture in achieved immediately after implantation*
- *Off the shelf availability allowing treatment of most aortic aneurysms and type B aortic dissection*
- *The usual complications of FEVAR are non existent when Utilized Under Strict IFU*

Conclusion



- *Morphological analysis exhibited aortic wall remodelling, signifying a Total Different Mechnism in Modelating Laminar Flow*

- *The SMFM offers immense promise in the treatment of complex pan-aortic lesions*

THANK YOU !