



24-25 May 2012
Crowne Plaza Lille



Clinical trial results of Treovance, the latest generation of AAA stentgraft

Roberto Chiesa

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San Raffaele Scientific Institute

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Vascular Surgery

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"Vita-Salute" University



Conflict of interest

- Dr Chiesa is the Co/PI for several thoracic and abdominal aortic stent graft trials (*Cook, Inc, Cordis® Corporation, Bolton Medical, and Trivascular, Inc.*)
- Dr Chiesa participated as a lecturer at symposia hosted by *Cook, Inc., Bolton, W.L. Gore and Associates, and Medtronic, Inc.*
- Dr Chiesa has received educational grants from *Cook, Inc.*



ADVANCE Investigational Study

- **Investigators:**

R. Chiesa (PI)



8 pts.

G. Coppi



7 pts.

S. Llagostera



3 pts.

V. Riambau



8 pts.

B. Zipfel



4 pts.

- **Sponsor:** Bolton Medical
- **CRO:** Harrison Clinical Research
- **Data management:** Quality Data Services, Inc.



Treovance (Bolton Medical)



Trimodular
abdominal
stent-graft

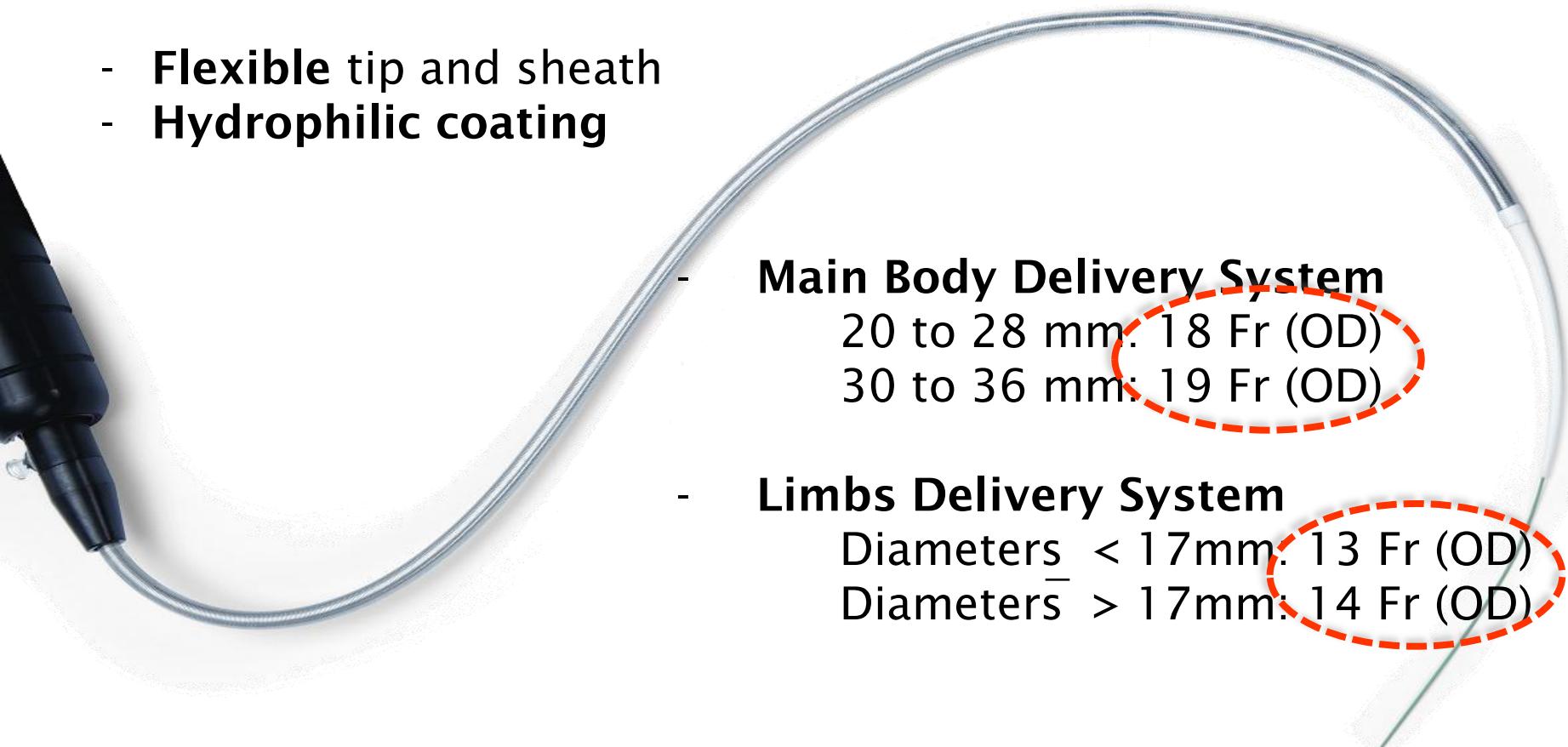
Nitinol +
tightly woven
polyester



Treovance: features (#1)

- Low profile introducer sheath

- **Flexible tip and sheath**
- **Hydrophilic coating**



- **Main Body Delivery System**

20 to 28 mm: 18 Fr (OD)

30 to 36 mm: 19 Fr (OD)

- **Limbs Delivery System**

Diameters < 17mm: 13 Fr (OD)

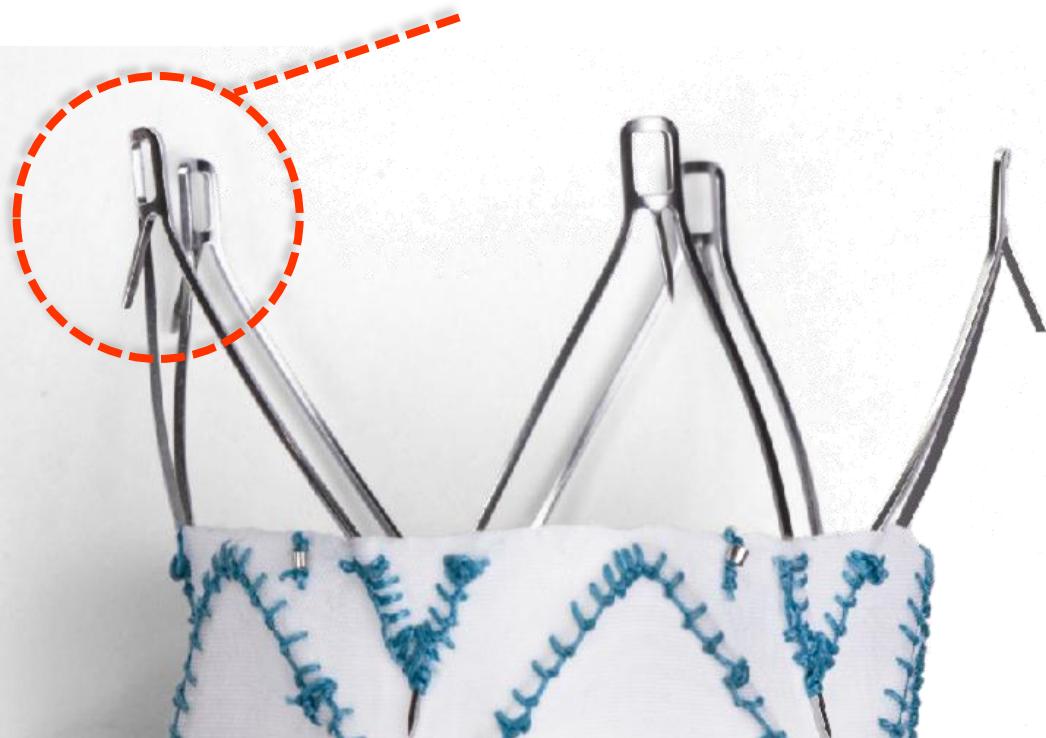
Diameters > 17mm: 14 Fr (OD)



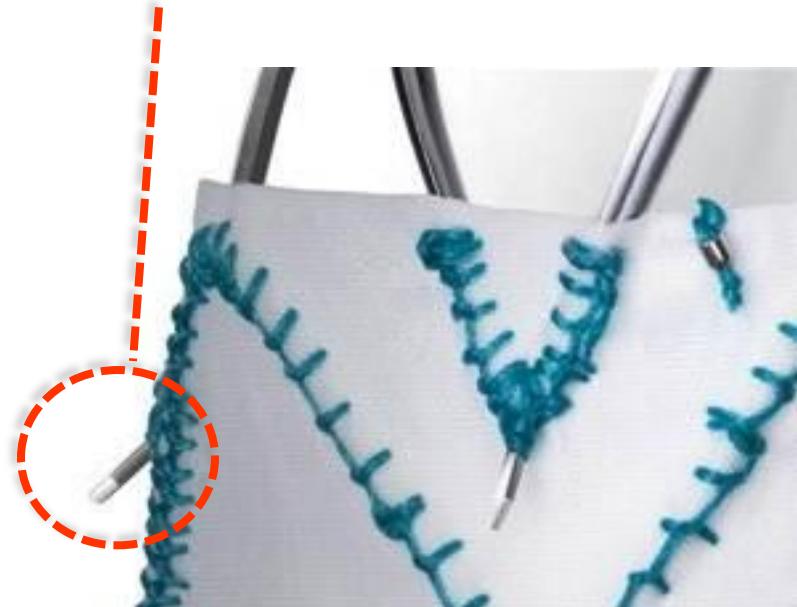
Treovance: features (#2)

- Multiple fixation points for migration resistance

Proximal bare stent
with **suprarenal barbs**



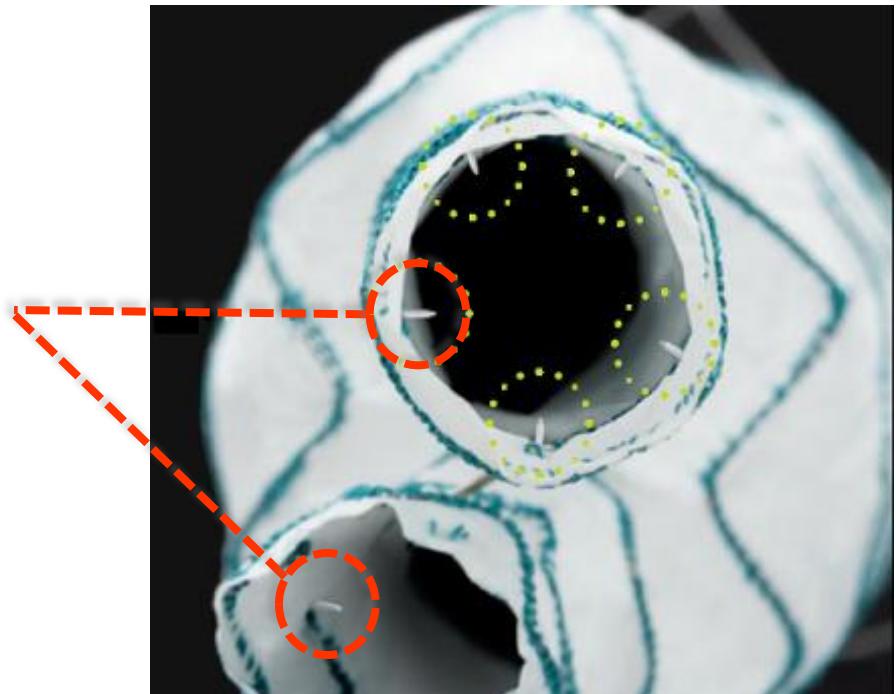
Infrarenal barbs
(supplemental fixation,
angulated anatomies)



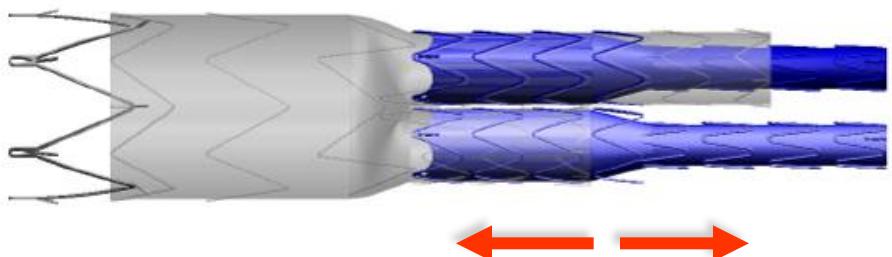
Treovance: features (#3)

- ENGAGEMENT System

5 dull barbs placed on each branch of the main body

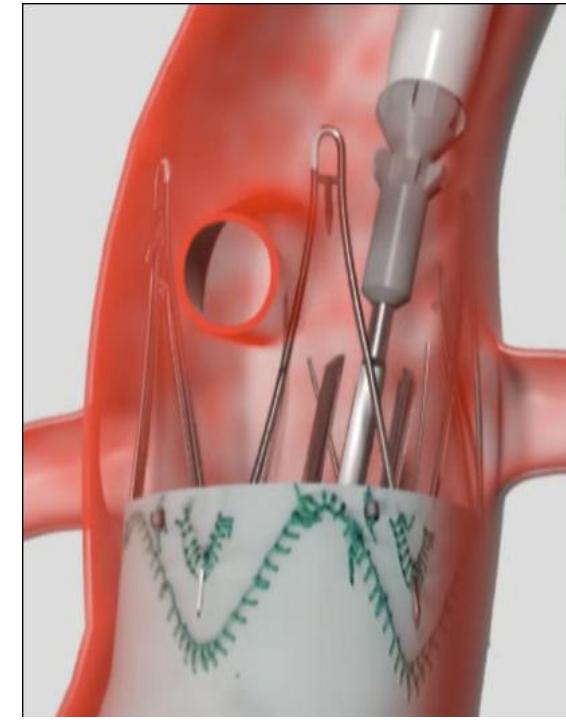
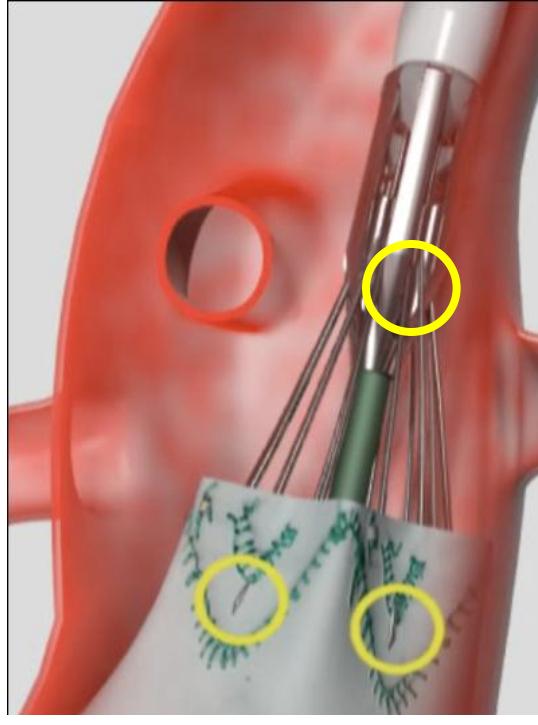
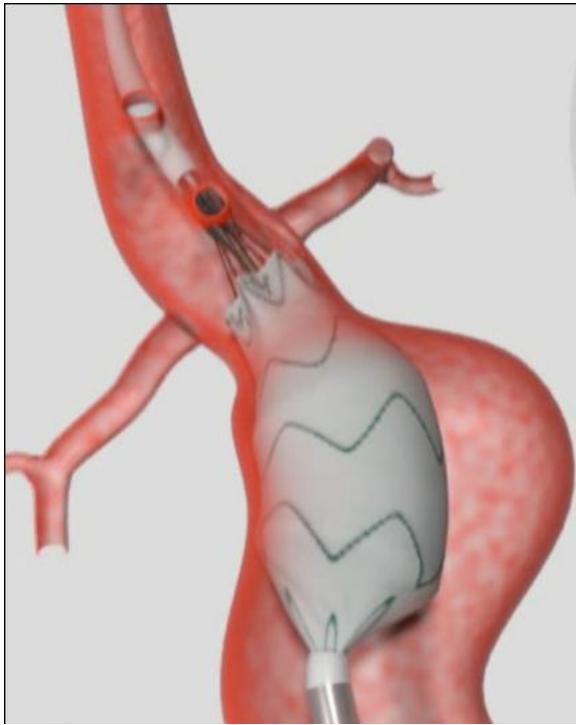


designed to prevent separation of the legs from the main body



Treovance: features (#4)

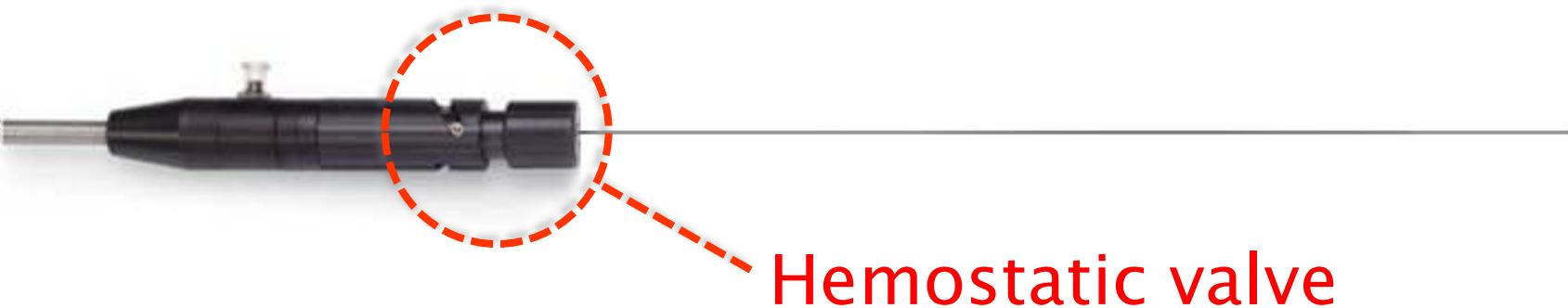
- Proximal clasping mechanism allows repositioning until first stent is released



Treovance: features (#5)

- Detachable sheaths

Sheath can be detached from main handle
for **introduction of leg extensions / balloons etc.**



Treovance “*first in human*” trials

ADVANCE Trial

- Prospective, multi-center, non-randomized study
- **5 European centers, 30 patients**



BENEFIT Trial

- Prospective, multi-center, non-randomized study
- **6 US centers, 30 patients**



ADVANCE trial: key points

- Electronic forms
- External review of all CT-scans (pre-op, 1-6-12 mo.)
- Monitoring by Clinical Research Organization

The screenshot shows a Windows Internet Explorer window displaying a web-based application for managing clinical trials. The title bar reads "Page Information - Windows Internet Explorer". The address bar shows the URL "https://qdr3.qdservices.com/". The main content area is titled "QDR" and displays "Treatment (Device Placement): Procedure Information >Page Information". The page includes a navigation menu with links like "Casebook Navigation", "Treatment (Device Placement)", "Procedure Information", "Audit Trail", and "E-Queries". A "Monitoring Queries" link is also present. The "Procedure Information" section contains various fields with data, such as:

Procedure Date	27-JUN-2011 DD-MMM-YYYY
Procedure Start Time	10:45 HH:MM
Procedure Stop Time	13:00 HH:MM
Anesthesia Type	Regional/Epidural
Were Pre- and Post-Implantation Angiograms Conducted?	Yes
Amount of Contrast used?	45 cc
Type of Contrast	Low Osmolar
Total Fluoroscopy Time	16 minutes
Estimated Blood Loss	100 cc
Anticoagulation, Antiplatelet, and/or Antibiotic treatment administered during procedure?	Yes
Contralateral Access	Left Femoral
Ipsilateral Access	Right Femoral
Internal Iliac Artery Covered?	No



ADVANCE study data

On behalf of all ADVANCE investigational study contributors



Study population

	N. pts. (tot = 30)	%
Gender (male)	29	97%
Age	72.1 yrs (50-81)	
CAD	13	43%
COPD	9	30%
Hypertension	19	63%
Hypercholesterolemia	16	53%
Smoking	27	90%
Antiplatelets / anticoagulants	19	63%



Intraoperative data

	N. pts. (tot = 30)	%
Primary technical success*	30	100%
Type I / III endoleak	0	0%
Type II endoleak	3	10%
Local / regional anesthesia	20	67%
Average Procedure Time		1h 42min
Estimated Blood Loss		225.4 mL (0 - 600)
LOS		3.2 days (2 - 8)

* Chaikof EL et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002



Case #1

- Aorto-iliac aneurysm
 - Aorta: \varnothing 68 mm
 - Right iliac: \varnothing 36 mm



Courtesy of Prof. Riambau

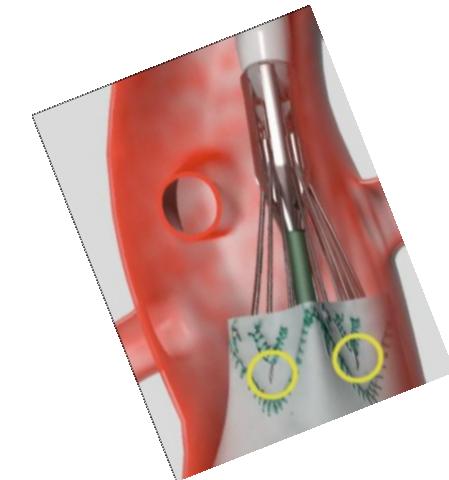
Case #1



Stent-graft
positioning

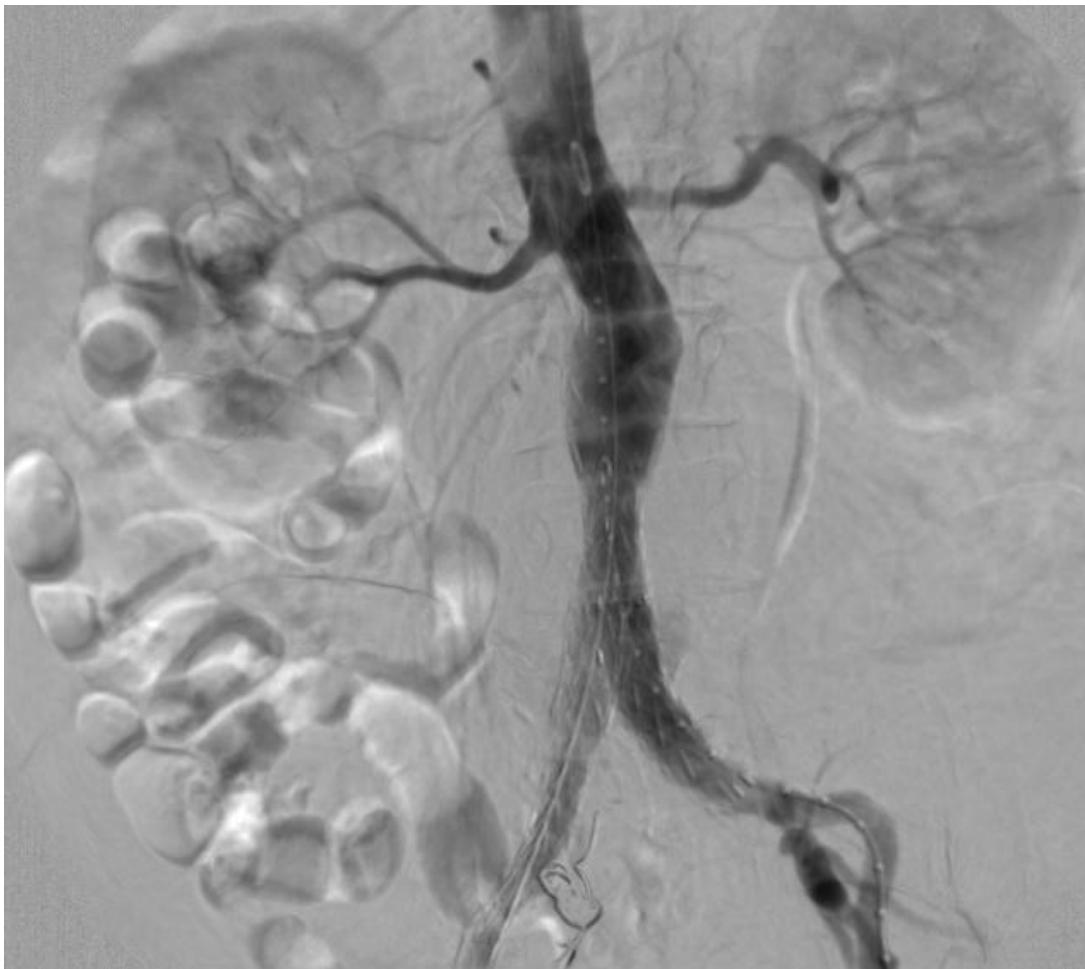


Partial deployment
(proximal stent clasped)



Case #1

Completion angiography

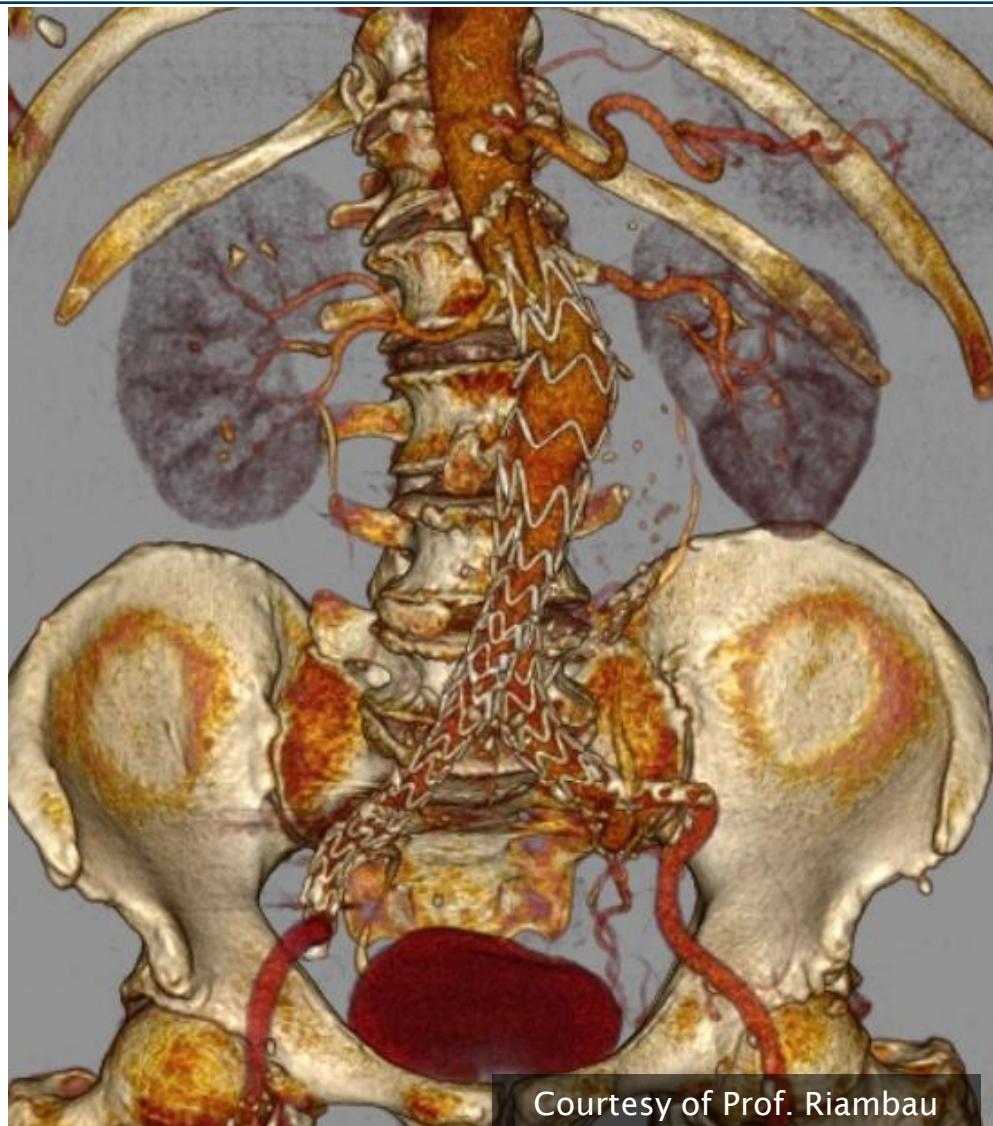


On behalf of all ADVANCE investigational study contributors



Case #1

6-month
Angio-CT
AAA complete
exclusion
No endoleak



Courtesy of Prof. Riambau



Case #2

- AAA Ø 58mm
- Left nephrectomy
for cancer



HSR

Case #2



1-month
Angio-CT

AAA complete
exclusion

No endoleak



HSR

ADVANCE: 30-day results

On behalf of all ADVANCE investigational study contributors



30-day results

	N. pts. (tot = 30)	%
Initial clinical success*	30	100%
Type I / III endoleak	0	0%
Type II endoleak	7	23%
Wire Fractures	0	0%
Infection / Thrombosis / Migration**	0	0%
Conversion to open surgery	0	0%
Aneurysm rupture	0	0%

* Chaikof EL et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002

** Migration is measured as > 10 mm compared with previous follow-up assessment

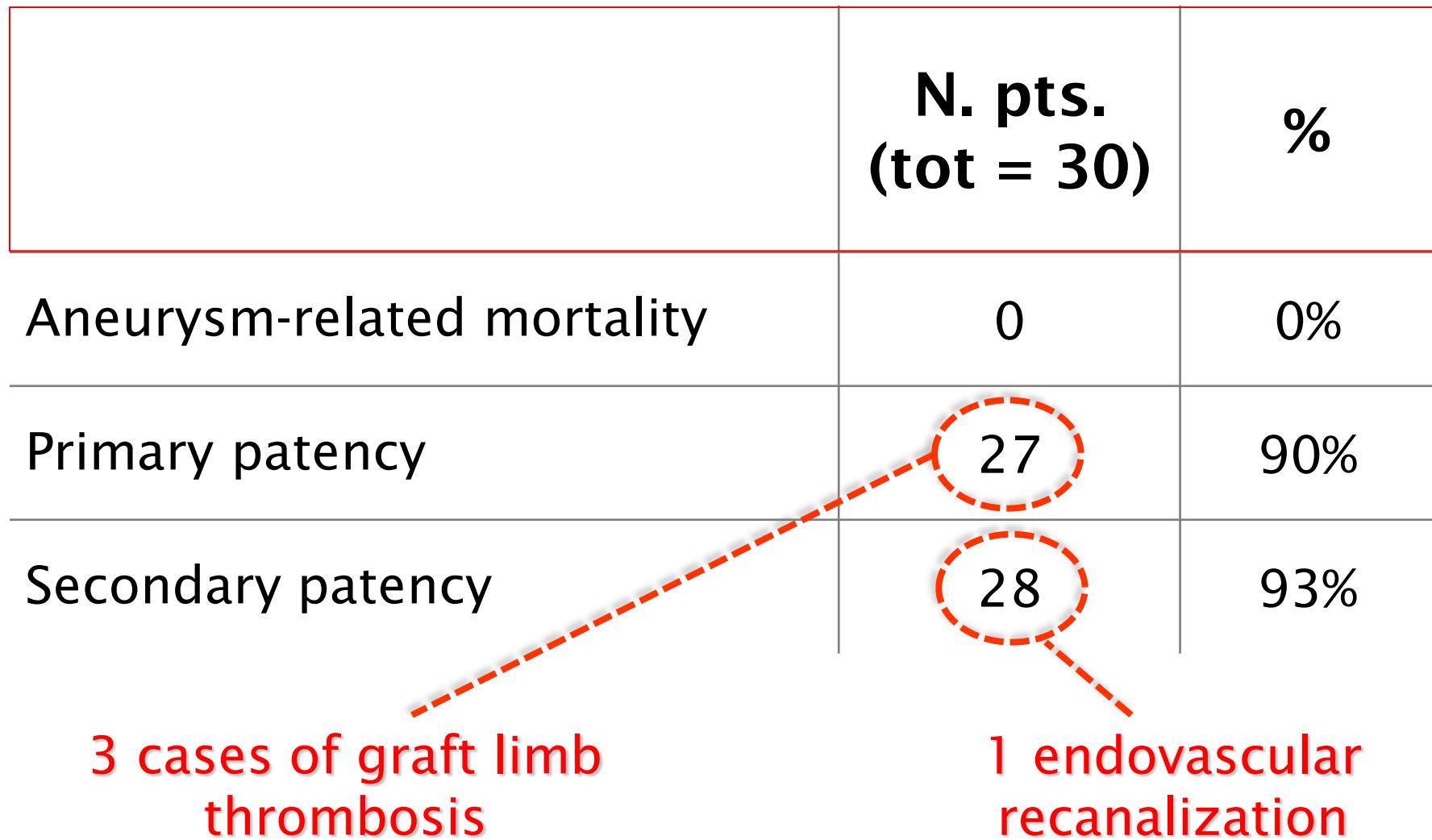


ADVANCE: actual follow-up

On behalf of all ADVANCE investigational study contributors



Mean follow-up = 7.8 months



Sac behaviour

Mean FU = 7.8 mths	N. pts. (tot = 30)	%
Decreased diameter (≥ 5 mm*)	6	20%
Unchanged	23	77%
Increased diameter (≥ 5 mm*)	1	3%

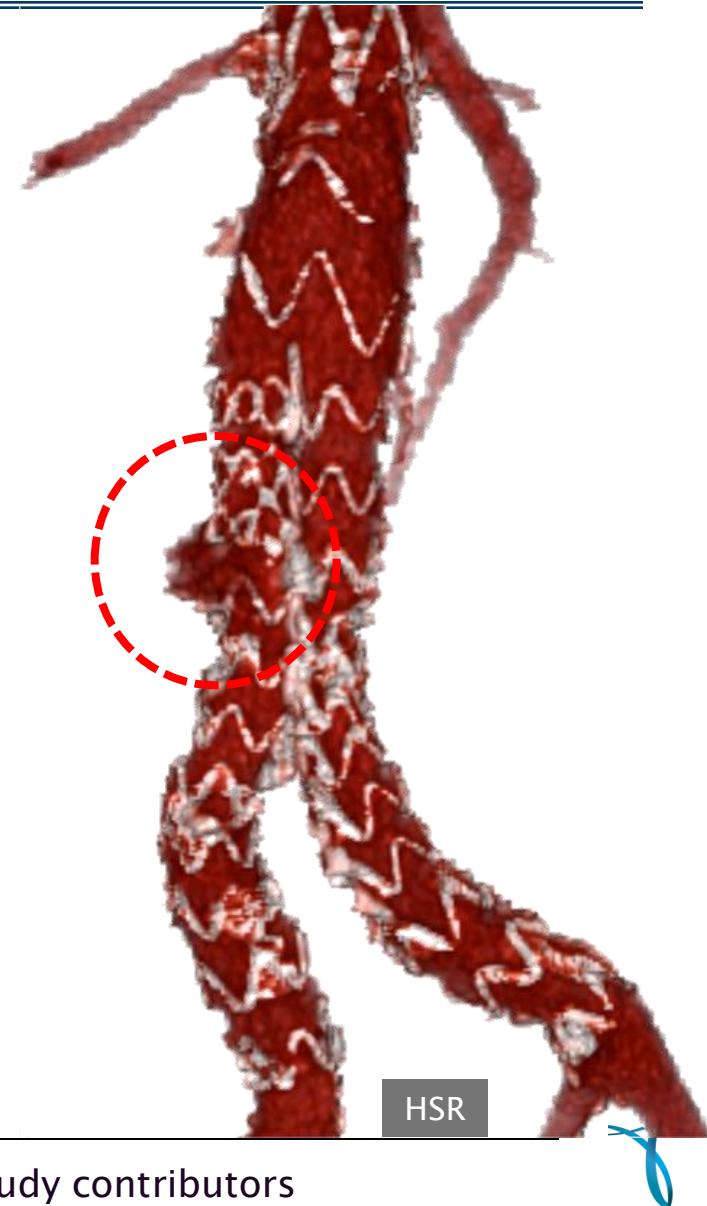
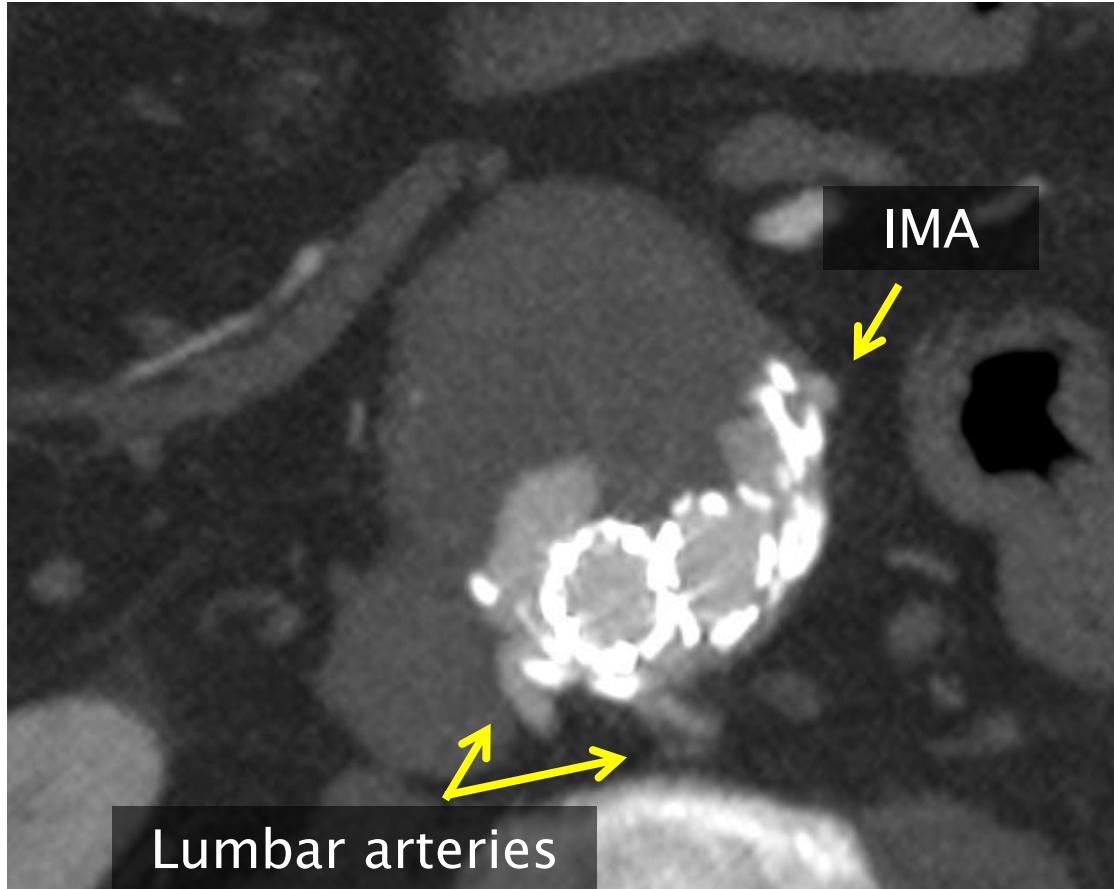
1

Pt. with type II endoleak
⇒ Treated with embolization

*Ahn SS et al. Reporting standards for infrarenal endovascular abdominal aortic aneurysm repair. J Vasc Surg. 1997

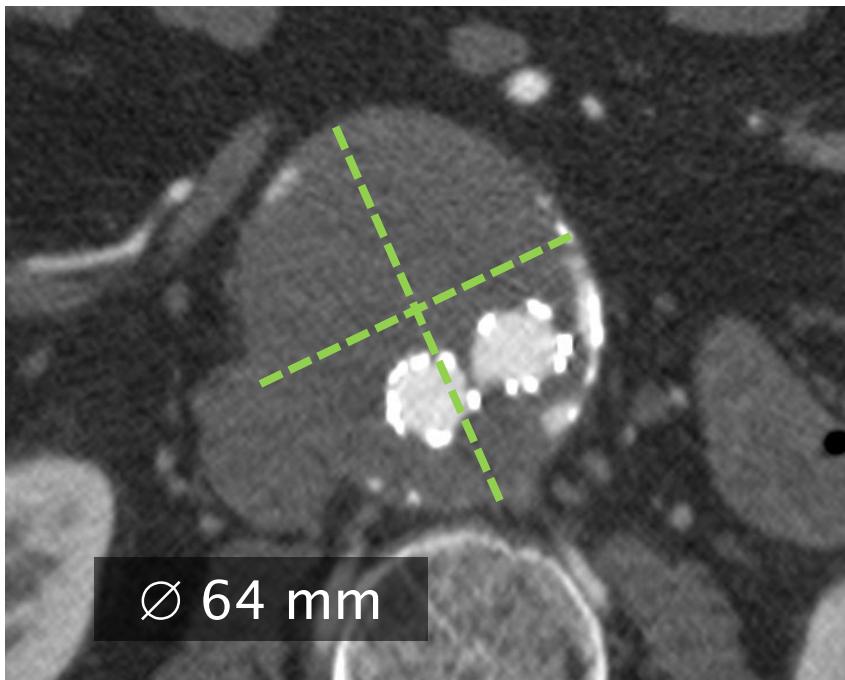


Type II endoleak

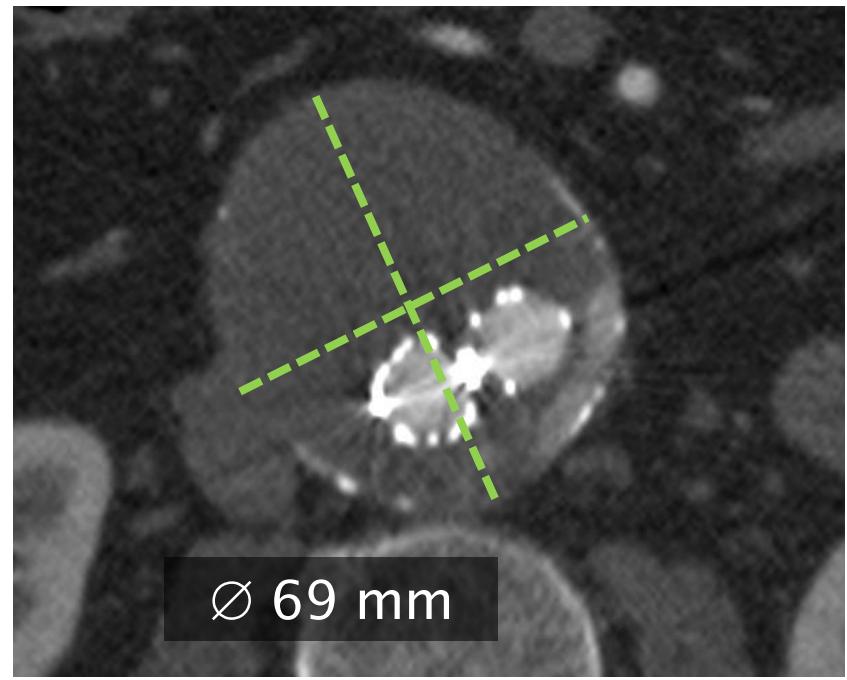


Type II endoleak

Sac enlargement



1 month



6 months



Percutaneous embolization



Right hypogastric / lumbar
artery catheterization



Endoleak direct visualization



Percutaneous embolization



Embolization with coils (0.025")
and glue (Glubran®)



Endoleak exclusion



Conclusions

1. Preliminary data: successful technical results, also in challenging anatomies

2. Treovance is expecting to receive CE mark during second half 2012

3. 1-year follow-up data will be available in December 2012

