

MEET 2015



Ovation™ Prime Stent Graft System can be used for challenging anatomy in EVAR cases

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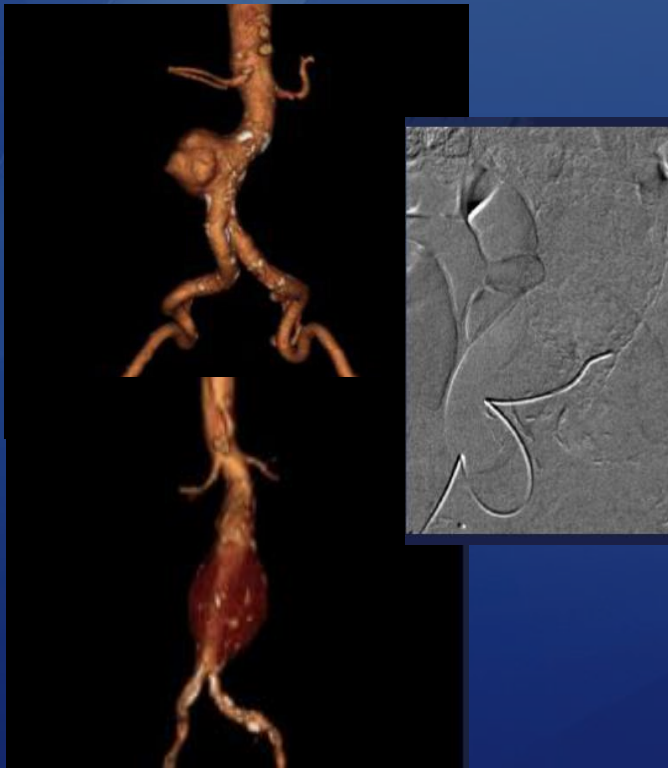
Disclosure slide

Speaker name: **Koen Keirse, MD**

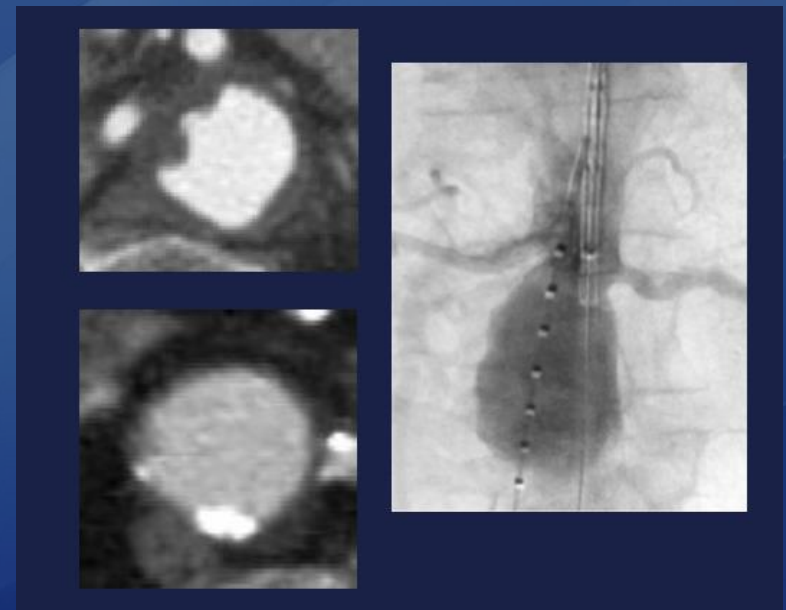
- I have the following potential conflicts of interest to report:
 - Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest

Problems with Commonly Used Stent Grafts for AAA

Narrow and tortuous iliac arteries preclude access to treatment area



Hostile necks, thrombus and calcium prevent an effective seal



OvationTM Prime Stent Graft System

- Appears to be a compelling therapy option for EVAR

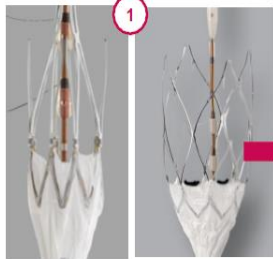
The ultra low profile (14F OD) and novel sealing technology expands the treatable pool of patients on label

The pre-market clinical data (CE and FDA) are very encouraging

- But can excellent Clinical Trial Results be mirrored in our Clinical Practice

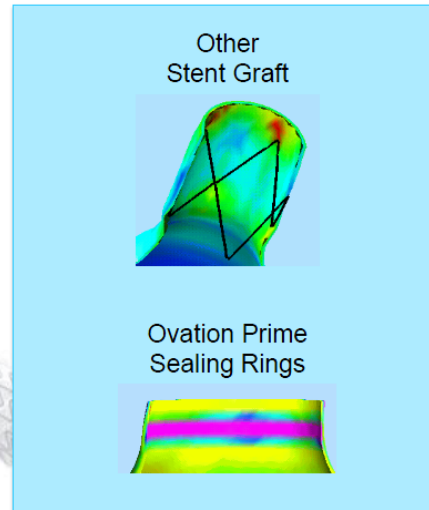
Novel Design Paradigm

Robust and Conformable Seal



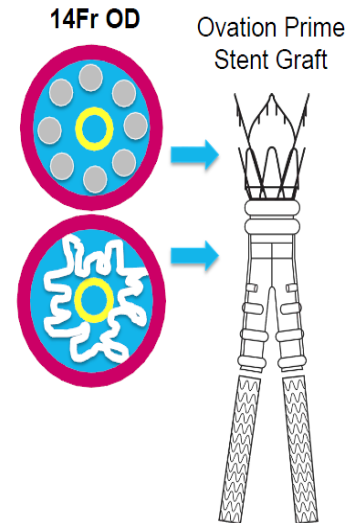
The Ovation Prime components deliver

1. Suprarenal secure the seal
2. Biocompatible for a robust seal



Other stent grafts use wire and fabric to create *points* of apposition

Ovation Prime's sealing ring provides *continuous* apposition, even in irregular and / or tapered anatomy



Significantly eliminates stent / material
Significant reduction in profile
Improving durability

Comparison of a stent graft

Note: FEA simulations indicate elevated stress points in pink and red coloring

EU Postmarket Ovation™ REGISTRY

INCLUSION criteria

- Subject > 18 years
- Intention to electively implant the Ovation SG
- Treatment of AAA in accordance with IFU of Ovation SG
- Subject signs Informed Consent Form
- Subject has the willingness to comply with follow-up exams

Two challenging

cases in the center

Re

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	Becquemin	6
	Bosiers	1
	Bresadola	6
	Castelli/Carrafiello	5
	Chiesa	7
	Chong	1
	Delle	3
	Fanelli	4
	Giudice	8
	Krankenber	22
	Labarbera	2
	Lammer	5
	Lermusiaux	19
	Liapis	1
	Maene	15
	Maleux	18
	Nano/Malacrida	12
	None	49
	Peeters	8
	Ruckert	8
	Scheinert	18
	Serracino Inglott	6
	Sievert	4
	Storck	17
	Taurino	6
	Tenholt	25
	Thompson	4
	Vermassen	4
	Volpe	8

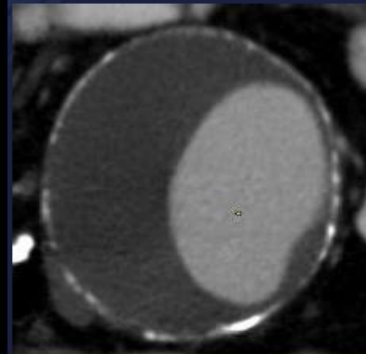
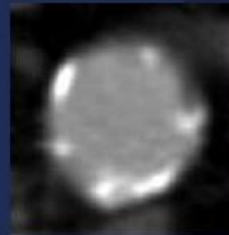
30 patients at 30 sites



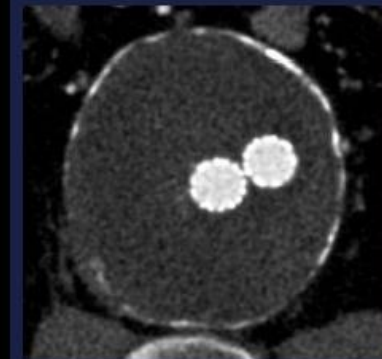
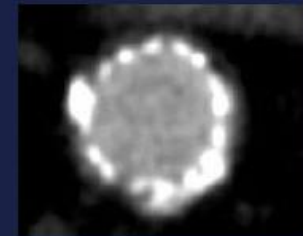
More than 2/3 of the operators were new to the Ovation technology when enrolling first patient in registry

Case 1 (#006 Registry)

Preoperative

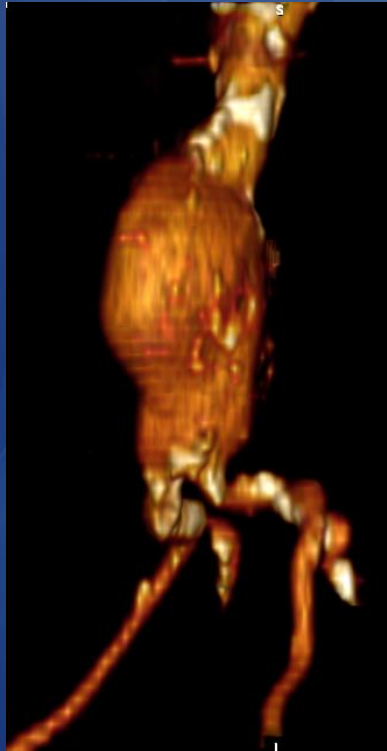


Post Operative

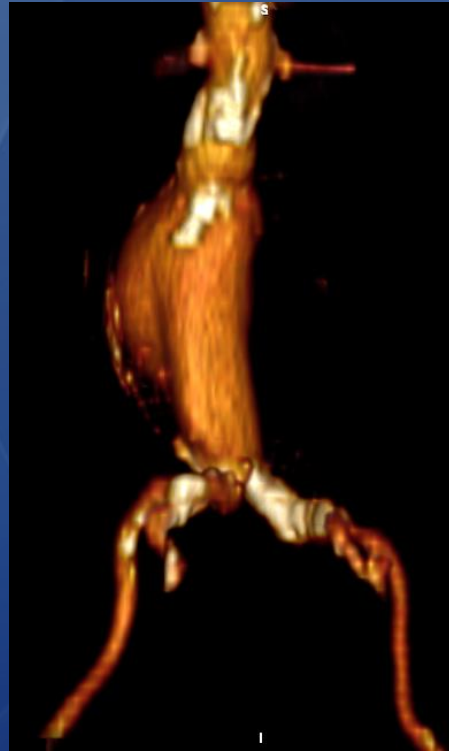


AAA diameter at baseline: 90 mm

Preop aortic views



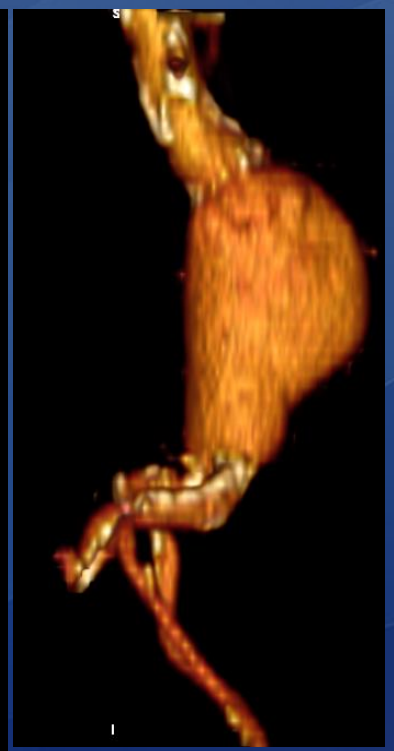
RPO



PA

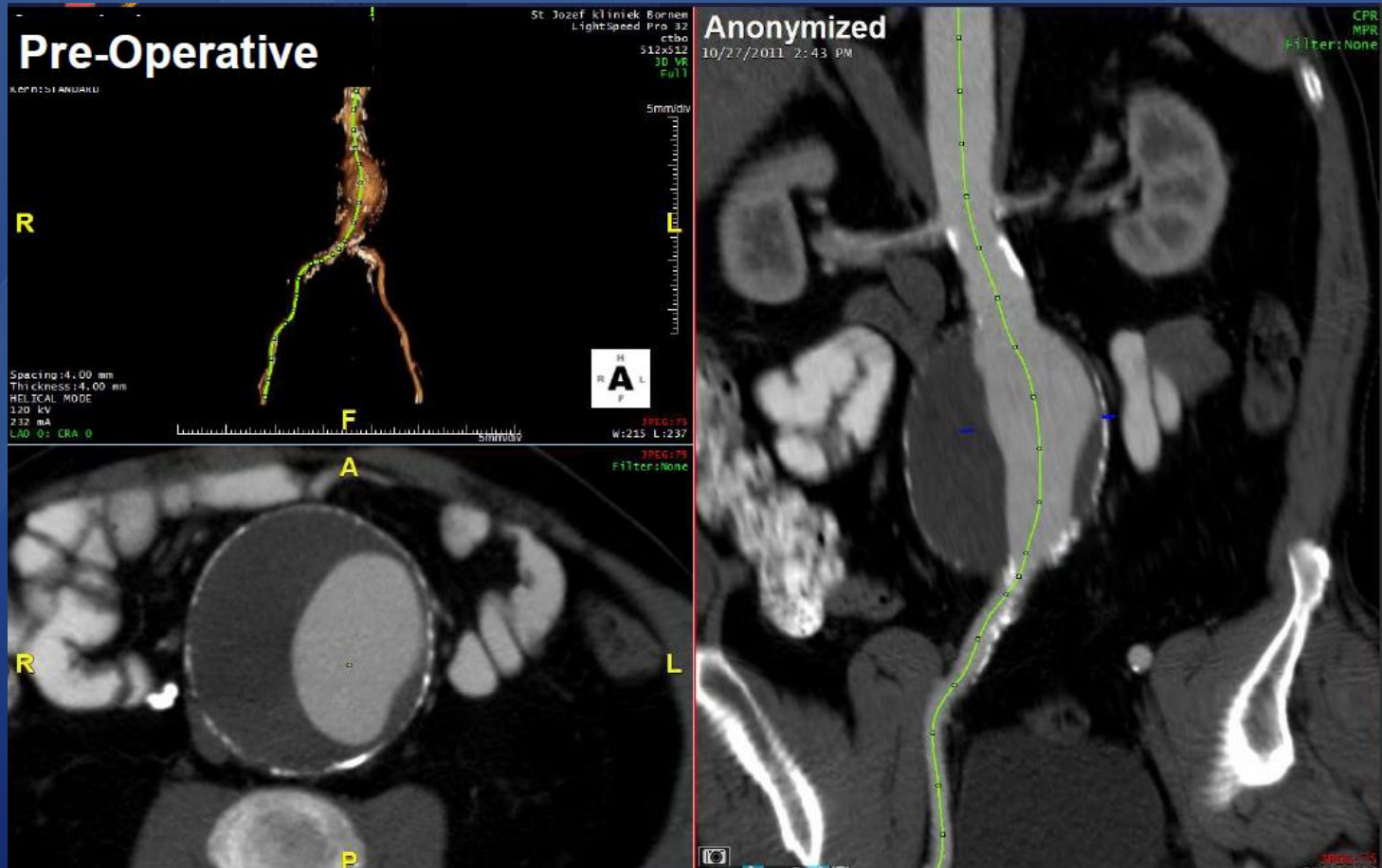


LPO



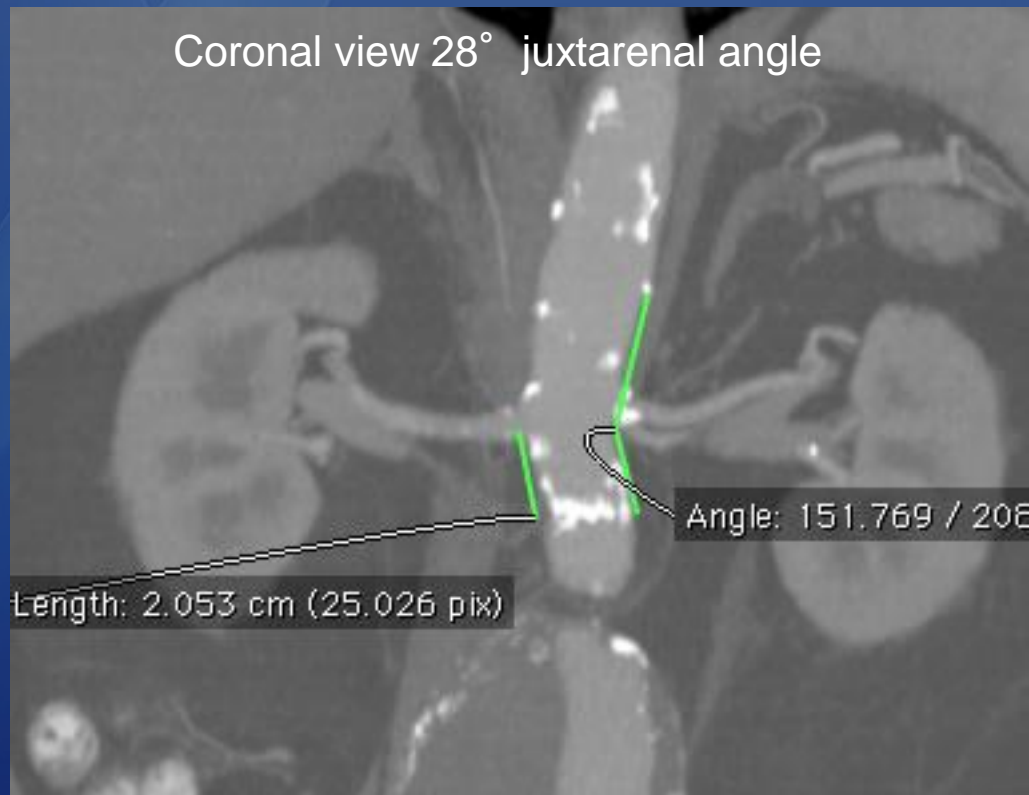
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Preop angio-CT

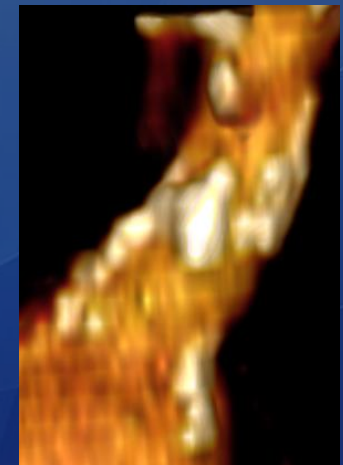


Proximal Neck

Calcium present in perirenal neck.
At 15 minutes post mix time perform angio to evaluate proximal seal. Treat if necessary with compliant balloon.



Right Lateral View
of calcium in neck

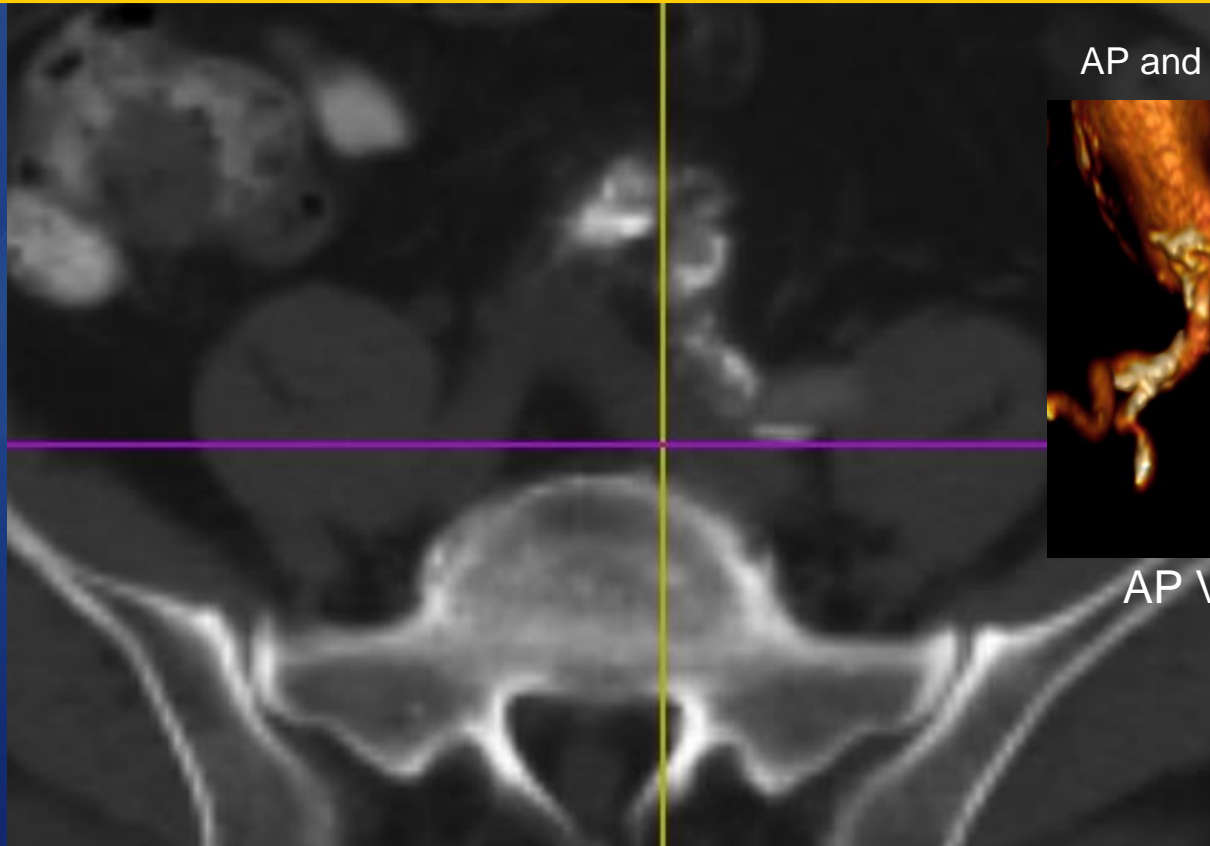


Also note calcium @ IR20 and 2 left renal arteries with common origin.

Landing Zone

Highly calcified bilateral common iliac arteries. Advancing a 14Fr dilator through commons to sac might help. Dilatation with PTA balloon may be necessary to allow delivery catheter to advance.

Prepare kissing post deployment 12x40 PTA from flow divider, through native bifurcation to end of grafts.



AP and PA View of Aortic Bifurcation



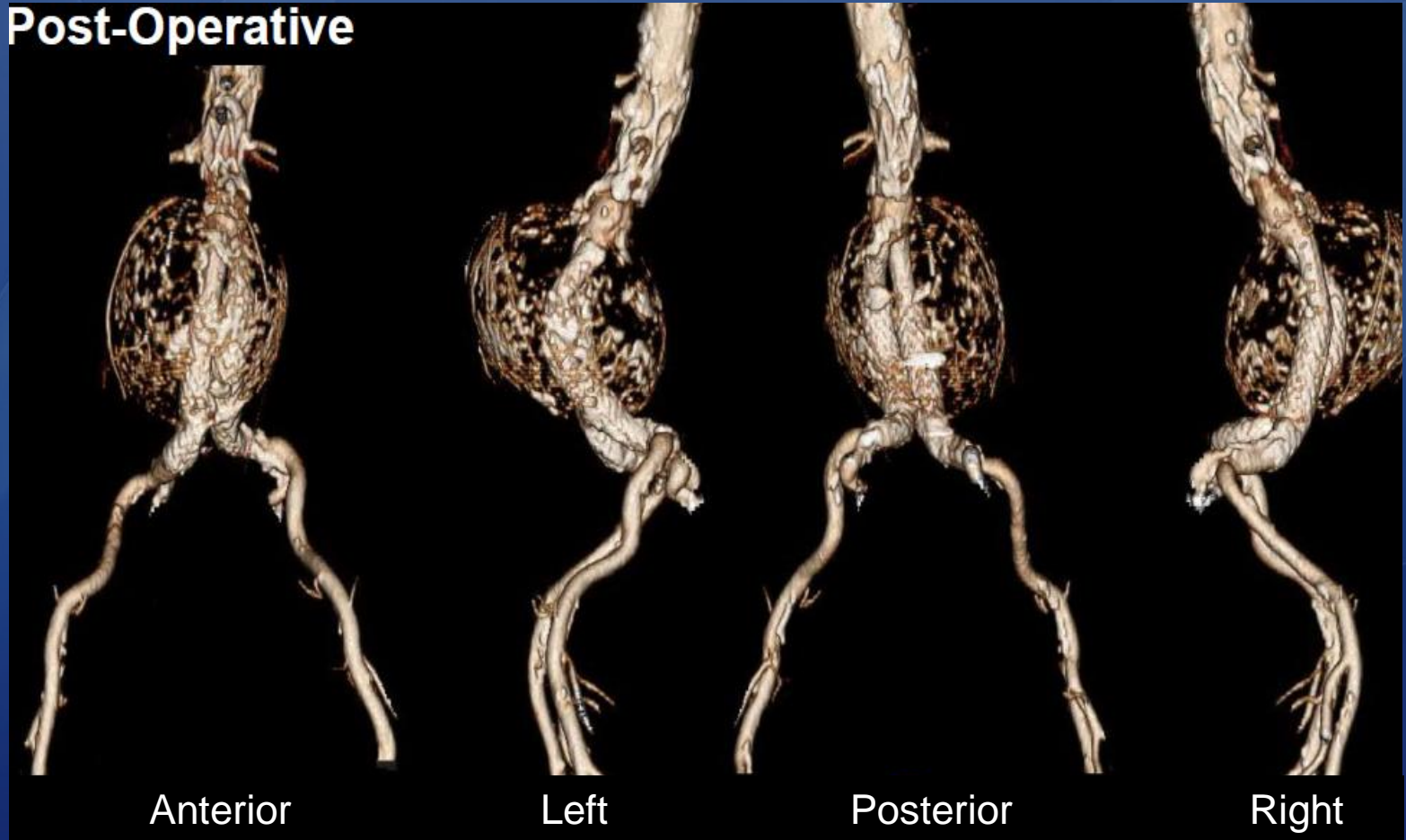
AP View



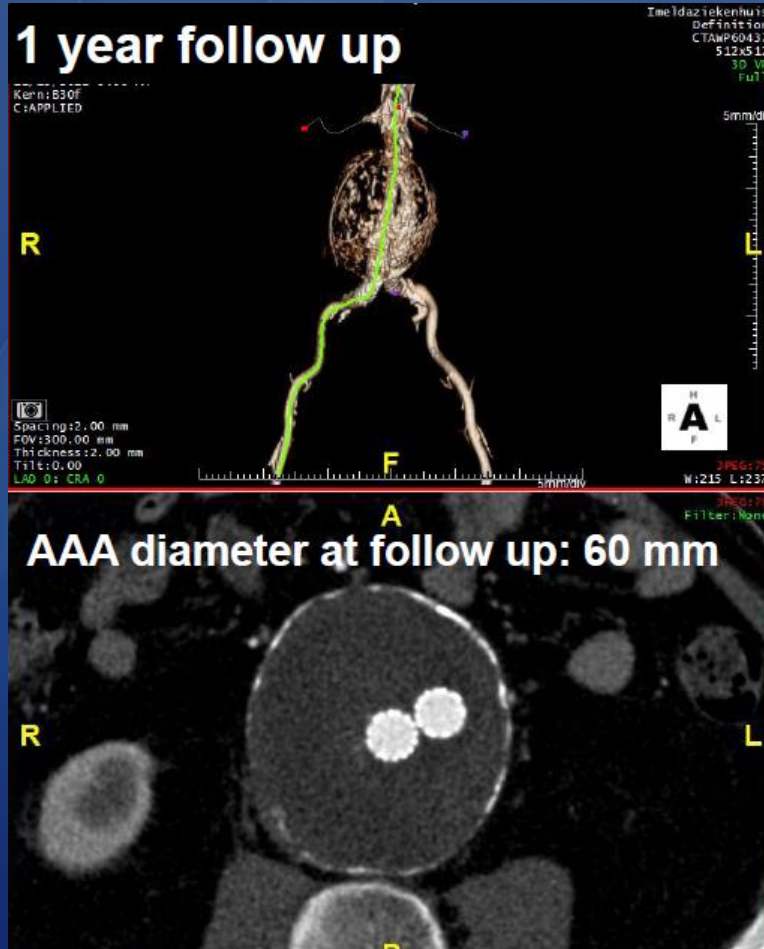
PA View

RESULT

Post-Operative



RESULT



Case 2 (#320 Registry)



Anterior

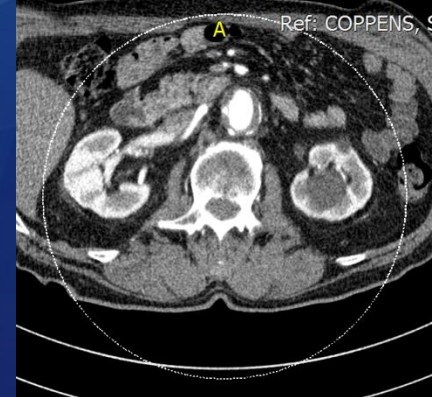
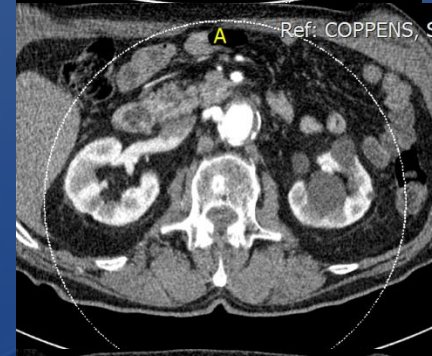
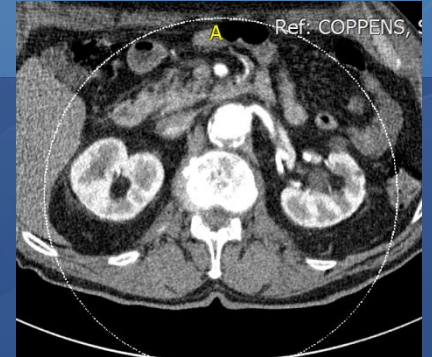
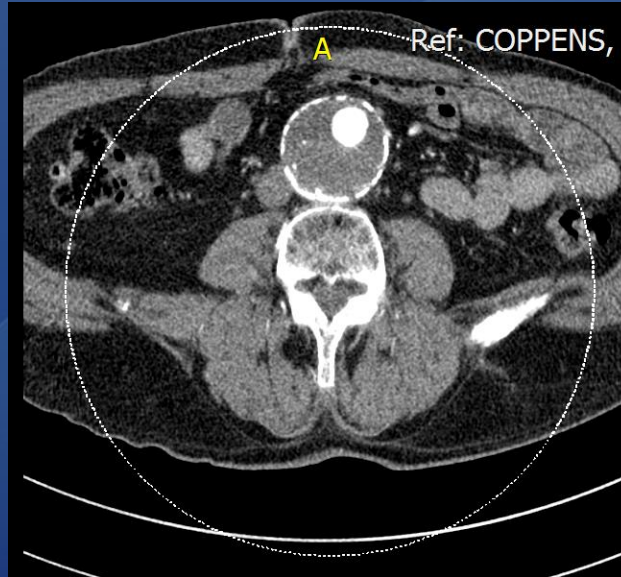
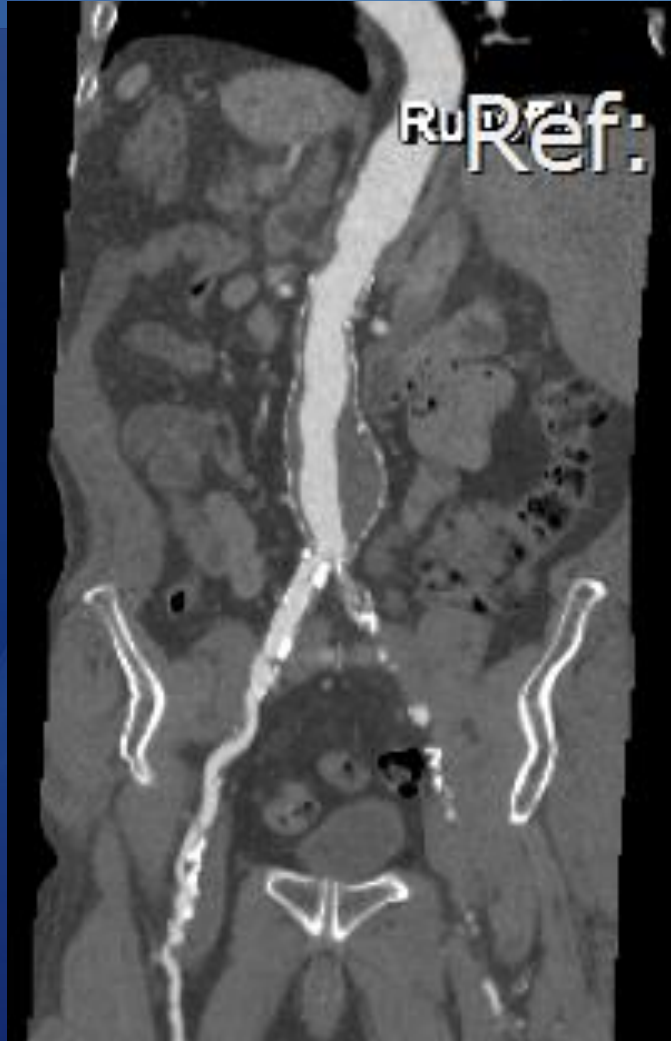


Left

Posterior

Right

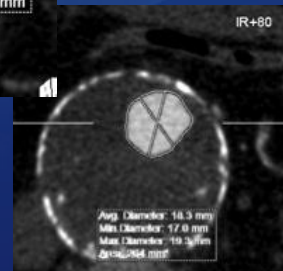
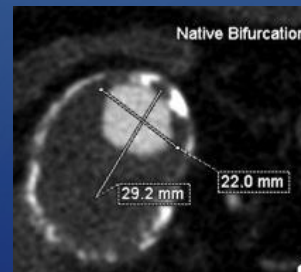
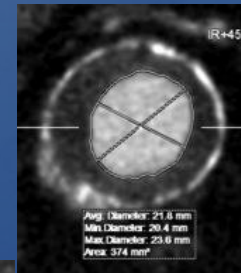
Preop



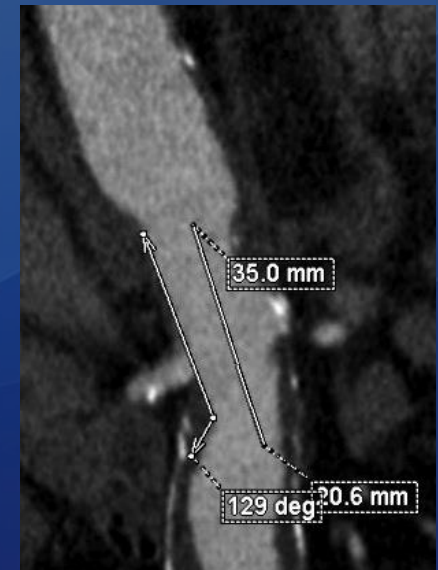
Proximal Neck

Thrombus present in perirenal neck.
Pull stiff guidewire back during polymer fill. Ease tension on delivery catheter if present. Suggest angio at 15 minute mix time to assess seal. Treat with compliant balloon if needed.

- Heavy thrombus and circumferential calcium in the aortic neck down to the native bifurcation.
- Narrow flow lumen at IR+80 (~18.6mm in diameter).



- Juxtarenal angulation of 51 degrees (apex @ ~IR+16).



Iliac Landing Zone

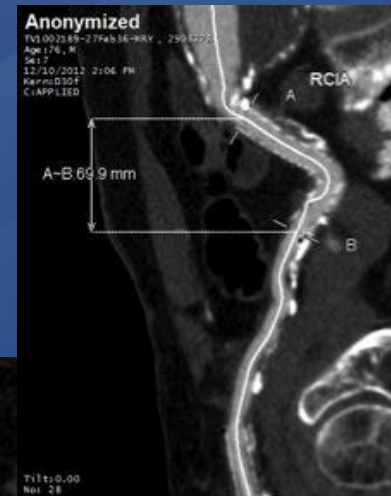
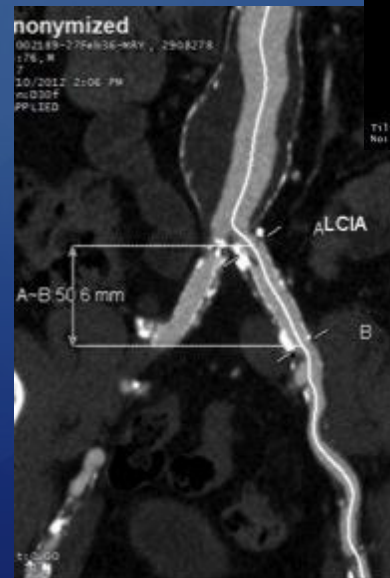
Suggest kissing balloons post deployment 12x40 PTA from Aortic Body overlap through native bifurcation .

- Bilateral stents in common iliacs as well as a stent in the right external iliac.

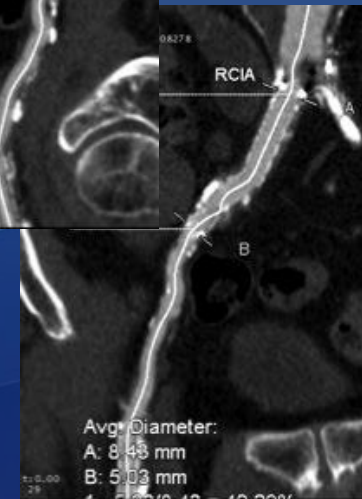
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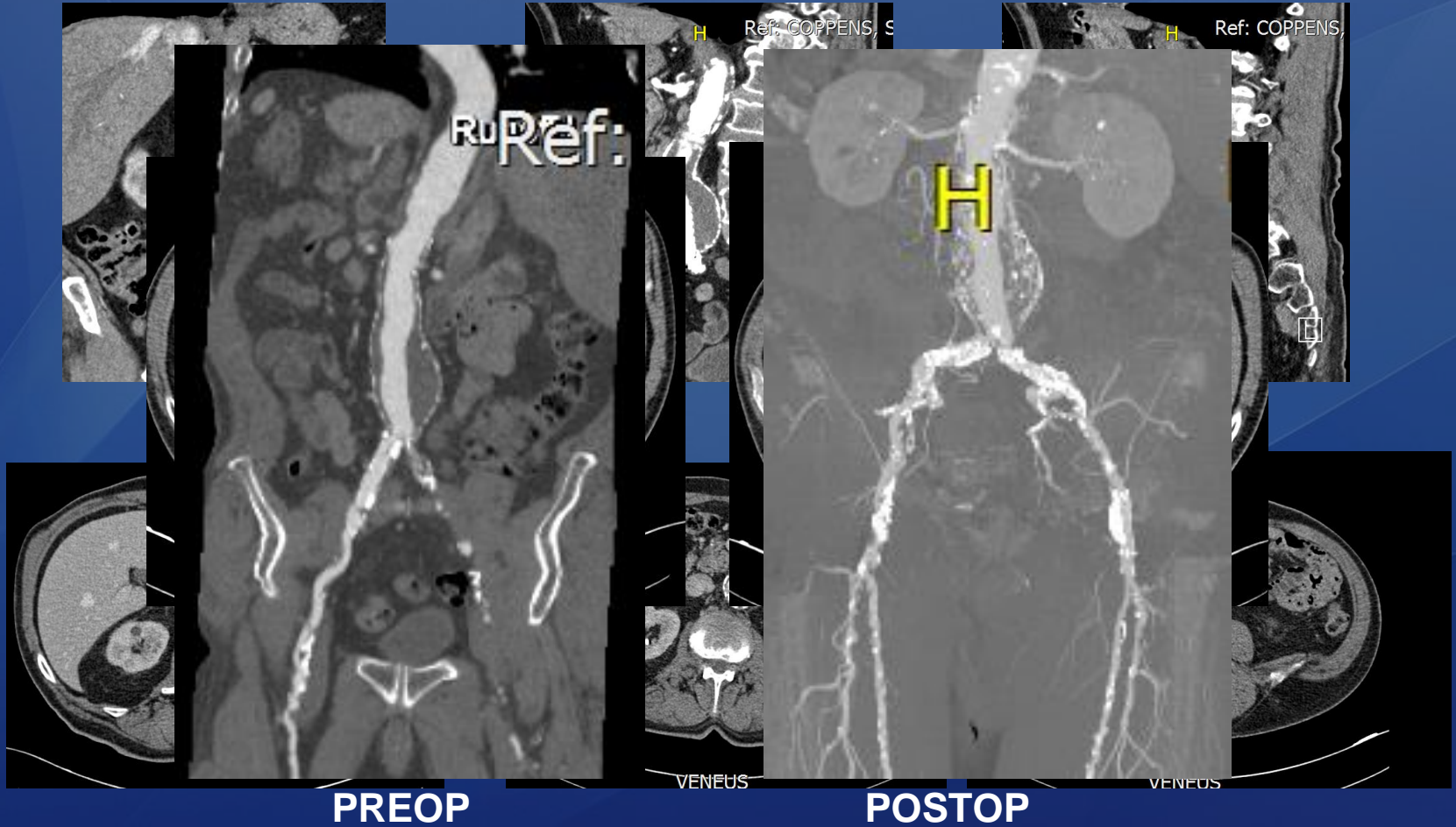
LCIA



RCIA



RESULT



EU Post Market Registry

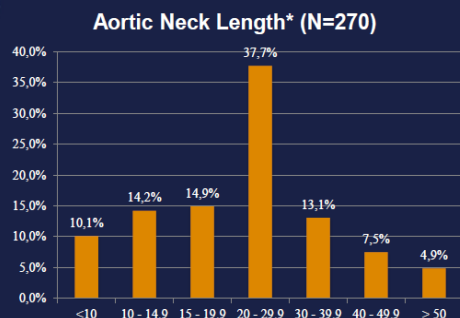
Ovation Stent Graft continues to show excellent results in the treatment of AAA. The unmatched low profile delivery system offers reliable options also in patients with challenging anatomies.

Data courtesy of D. Scheinert PI Registry

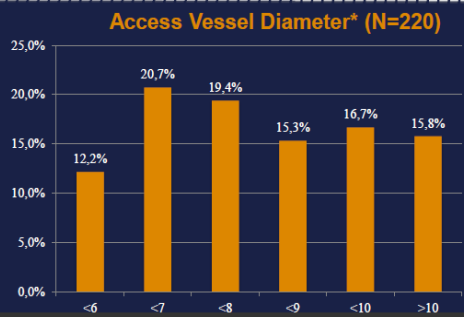
Aortoiliac Characteristics

1/4 of treated aortic necks were shorter than 15 mm

- 53% had moderate/severe calcification
- 63% had moderate/severe thrombus



1/3 of treated patients had access vessels < 7 mm



Challenging anatomy mirrors prospective clinical study

Data courtesy of D. Scheinert PI Registry

Clinical Outcomes

Based on Investigator Reported Data

PERFORMANCE	30 Day (N=250)	6 months (N=150)	1 Year (N=50)
Technical Success	100%	N/A	N/A
Freedom from Type I and III Endoleaks	98.6%	99.3%	100%
Freedom from Migration	100%	100%	100%
Freedom from Rupture	100%	100%	100%
Freedom from Conversion to Open Repair	100%	100%	100%
Freedom from Occlusion	99.6%	100%	100%
ANEURYSM ASSESSMENT	30 Day	6 months	1 Year
Enlargement >5mm	Baseline	2.7% (3/112)	5.3% (2/38)
No change	Baseline	80.3% (90/112)	68.4% (26/38)
Reduction >5mm	Baseline	17% (19/112)	26.3% (10/38)

SUMMARY

- 14F OD has enabled or simplified treatment of patients with narrow and calcified vessel
- The polymer filled sealing rings increased confidence in patients with calcified or thrombus filled necks
- Expanded our ability to treat more challenging anatomies on-label (IFU)
- Encouraging results from the tightly controlled clinical study appear to be confirmed in broader use in the context of a post market registry
- Additional follow-up will be evaluated to confirm these early results