

EVAR-Evolving Techniques and Devices

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Disclosure Statement of Relationships with Industry

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Consulting Fees/Honoraria

Company

- Cook, Cordis, Medtronic, Trivascular, WL Gore

US Marketed EVAR Devices



Aorfix



Endologix



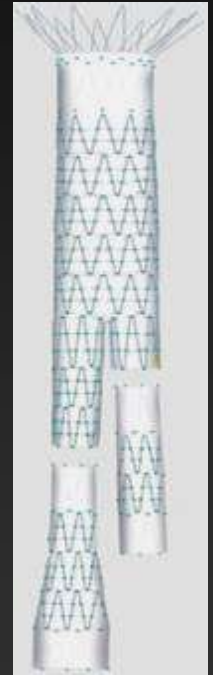
Excluder



Endurant



Ovation



Zenith

Aortic Endografts Current Limitations



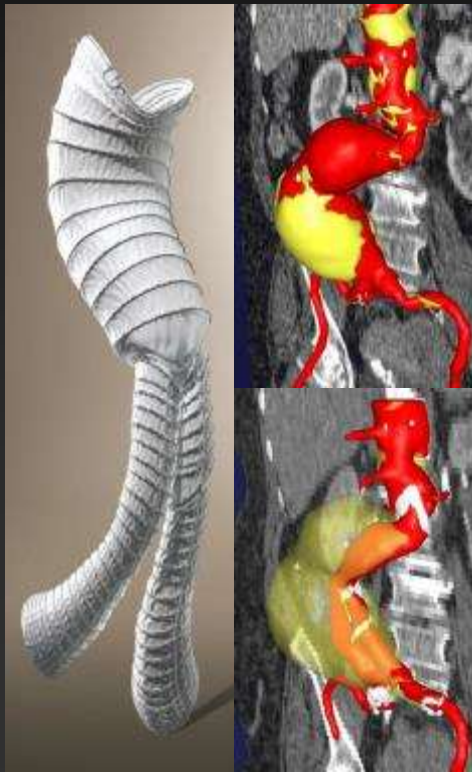
Anatomic Predictors of Type I Endoleak (N=238)

Table VII. Univariate and multivariate logistic regression analyses

<i>Regression analyses</i>	<i>Early type I endoleak</i>		
	<i>OR</i>	<i>95% CI</i>	<i>P</i>
<i>Univariate</i>			
Neck angle	1.91	0.89-4.1	.0984
Neck length	4.59	1.76-11.93	.0018 ^a
Diameter	0.93	0.26-3.34	.909
Calcified neck	5.5	1.93-15.65	.0014 ^a
Circumferential thrombus	1.07	0.54-2.12	.8376
Reverse taper	5.97	2.87-12.42	<.0001 ^a

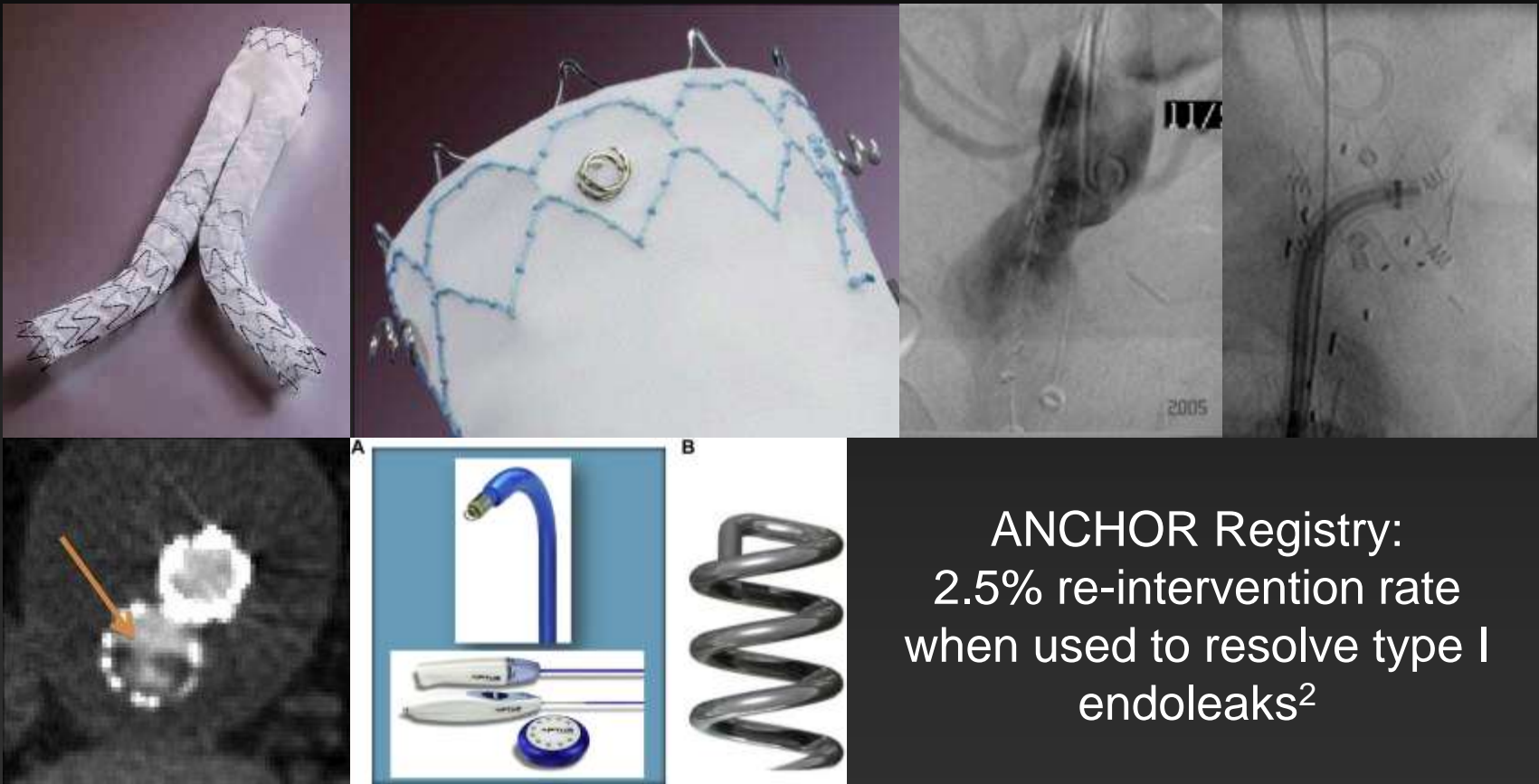
Aorfix Endograft

The PYTHAGORAS Trial (N=205) Highly Angulated Neck (60-90°) 12-month Results



- Procedural Success 96% (197/205)
 - 8 access failures (4 of 8 not attempted)
- 30-day mortality 2.0% for the entire cohort (4/205) vs. 2.6% for open controls (9/323, p=ns)
- Type I/III endoleak rate 1.6% (2.4% in >60° necks)
- Sac shrinkage >5 mm 43.9% (45.3% in >60° necks)
- Sac enlargement >5 mm 1.4% (2.1% in >60° necks)

Aptus Endostapling AAA Device



ANCHOR Registry:
2.5% re-intervention rate
when used to resolve type I
endoleaks²

FIH 7-30-05 Venezuela

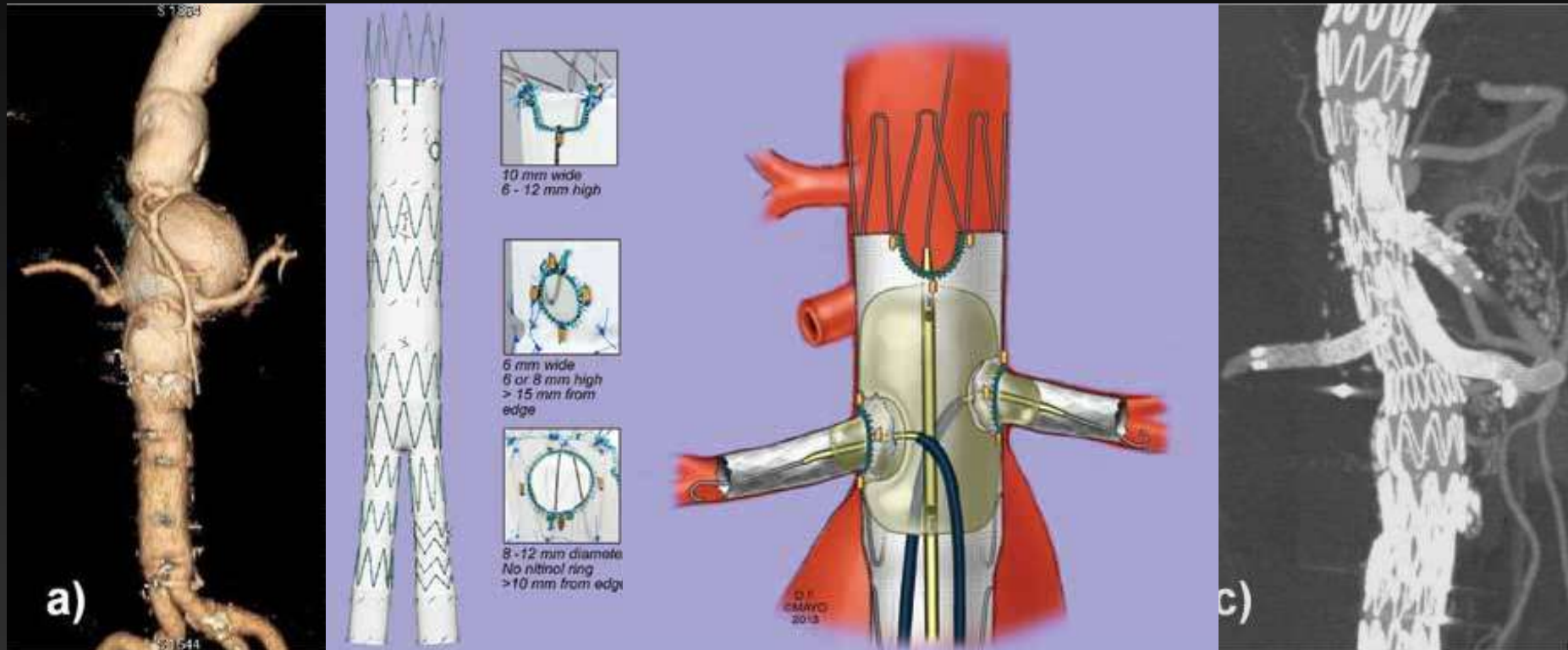
STAPLE-2 US IDE Pivotal Trial (155 patients) completed enrollment 2-10-2009

Only 2 type I/III leaks (1.2%) but thrombus-related events (TRE) occurred in 34.8%¹

¹Mehta M et al *J Vasc Surg* 2014; 60: 275-285

²Jordan Jr WD et al *J Vasc Surg* 2014; 60: 885-892

Fenestrated Endografts F-EVAR



No type I endoleaks pre- or post-market release (N= 113, 56/57)
Patency rates of visceral artery stents with F-EVAR were 95.7% at 1 year and 88.6% at 4 years (N=138)

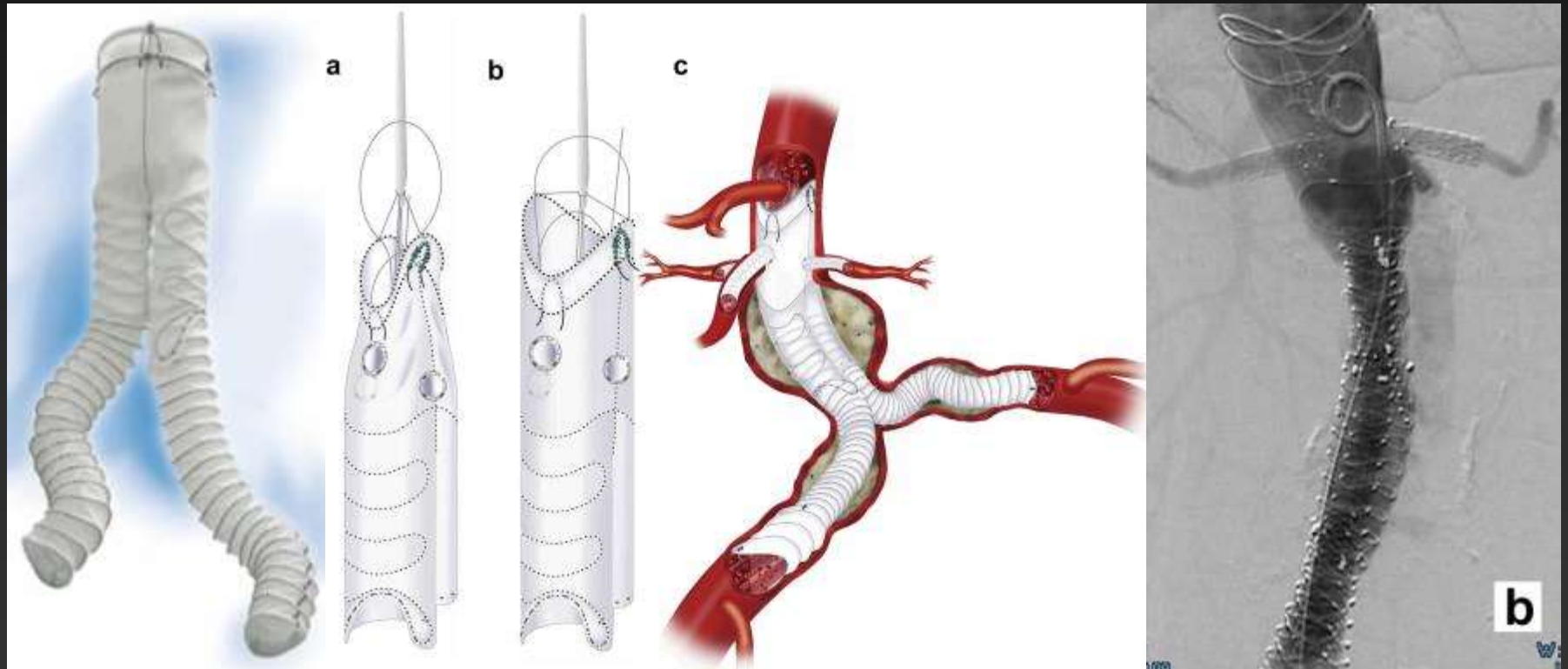
Grimme FAB et al *J Vasc Surg* 2014; 59: 298-306

Vemuri C et al *J Vasc Surg* 2014; 60: 295-300

Zenith® Fenestrated AAA Endovascular Graft (P020018/S040) Annual Clinical Update 2013

Anaconda Endograft

Flexible Design for Highly Angulated Necks and Fenestrated Aortic Cuff for Short Necks



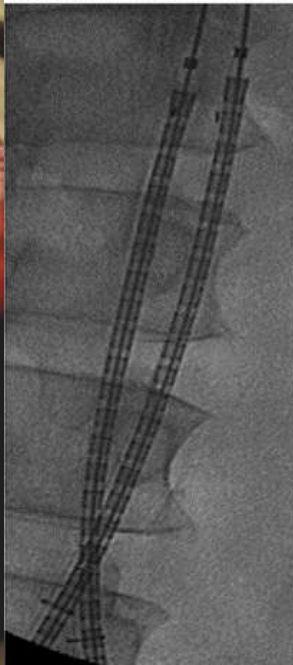
Renal Chimneys for Thoracoabdominal Aneurysms



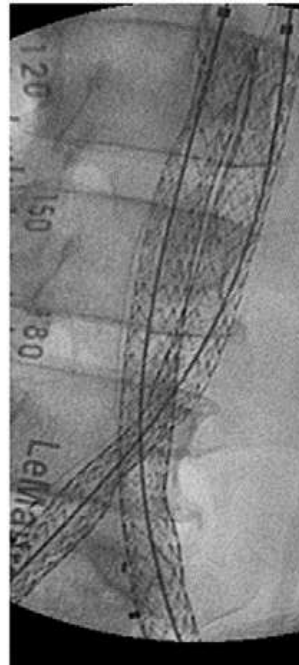
Nellix AAA Therapy: A No Neck Solution?



Introduce
Devices



Deploy
Endoframes



Fill Polymer



Final Angiogram



New Low Profile EVAR Devices

Common Design Characteristics

- Three-piece modular
- Suprarenal stent with hook fixation
- Lower-profile delivery: 14-18F OD



Cook
Zenith LP
18F



Tri-Vascular
Ovation 14F



Cordis
INCRAFT 14F

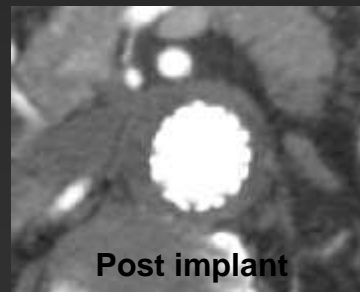
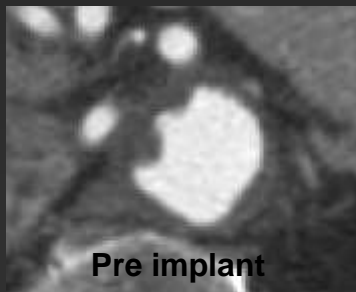
Ovation Abdominal Stent Graft System



- Tri-modular design
- Suprarenal stent with anchors for fixation
- Inflatable rings for optimal seal
- Low viscosity, radiopaque polymer fill
- Hydrophilic catheter coating
- 14F OD Aortic Body
- 13F OD Iliac Limbs
- CE Mark approved - August 2010

Trivascular Ovation Global Pivotal Trial

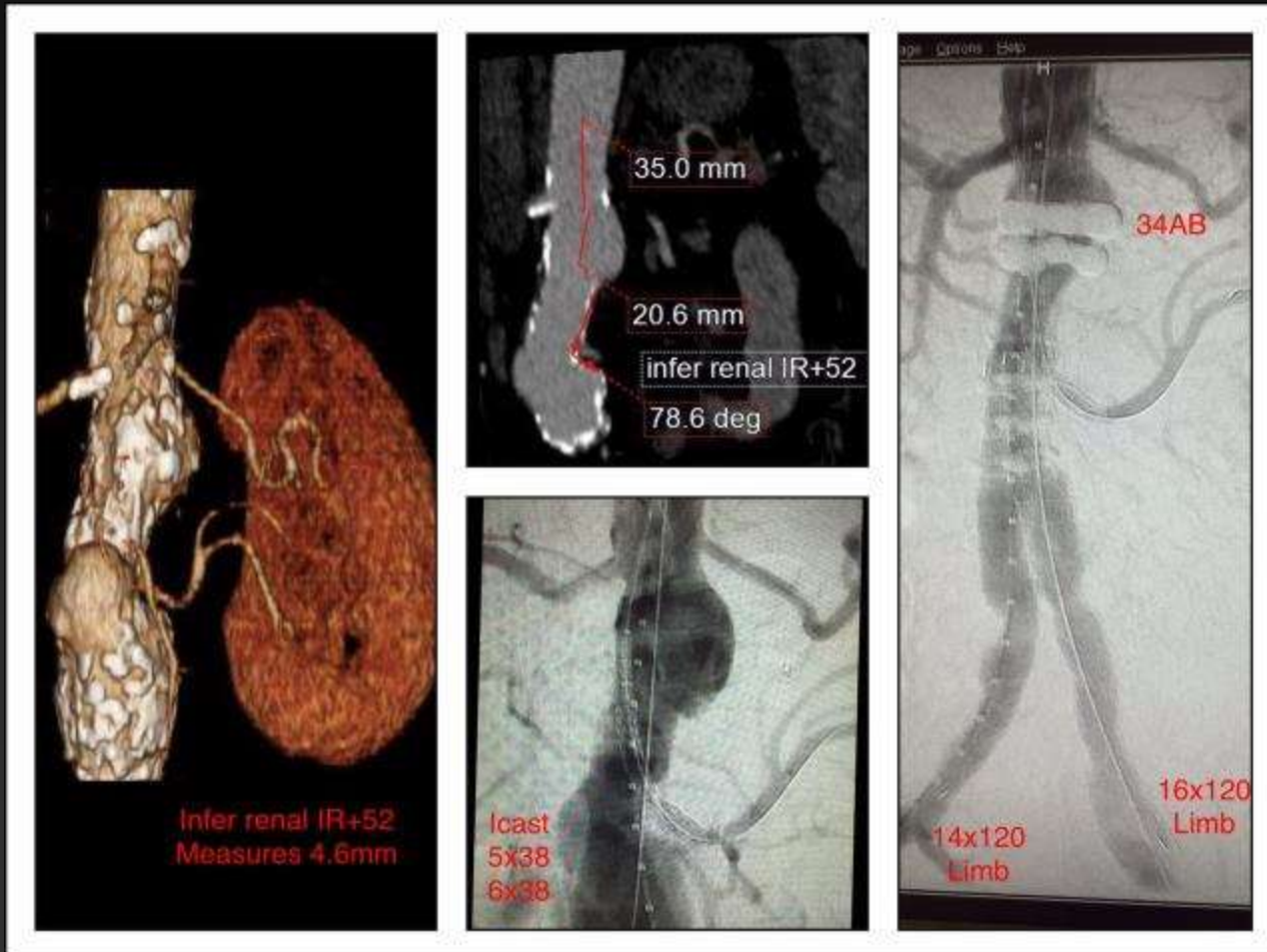
No Type I Leaks in Patients with Adverse Neck Anatomy



35% of enrolled patients had 1 or more hostile neck features (56/161)

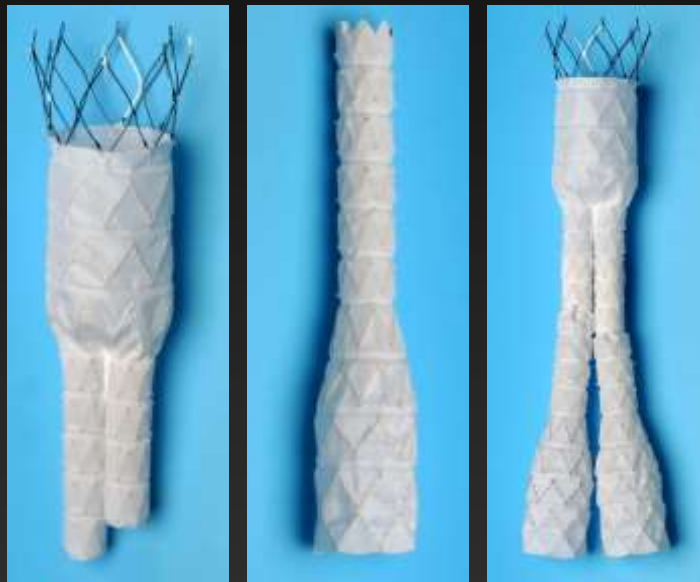
Trivascular Ovation

Sealing Rings Advantageous for Snorkeling



INCRAFT Low Profile AAA Endograft

Inspired by the “few-fits-most” surgical concept

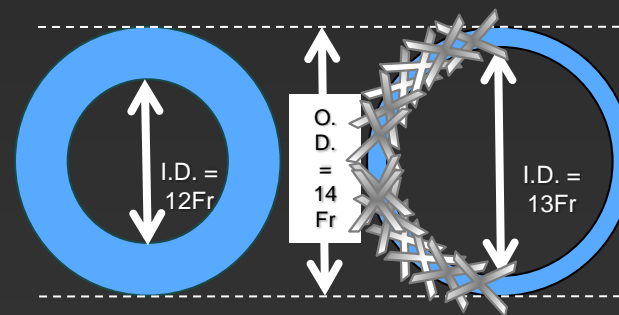


4 bifurcates

19 limbs

23 codes

- Reduces planning and procedural complexity
- Minimizes product inventory
 - Only 23 main components
- Provides broad anatomic coverage
 - 17-31mm aortic diameters
 - 7-22 mm iliac diameters
 - 12-21 cm overall treatment lengths



Severe Morphologies in Innovation

Challenging Necks

Challenging Iliac/Neck

Challenging Access

Screening CT



6 Month Follow-up



INCRAFT Proximal Neck Deployment Accuracy

Definition:

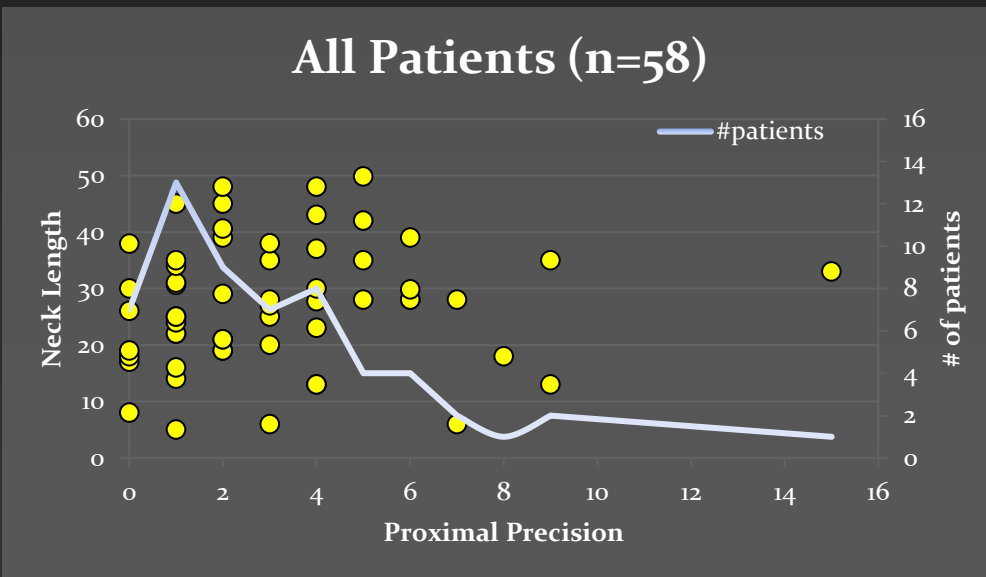
- Distance from lowest renal to bottom of first two cranial graft edge markers

Results*:

- Median distance from renal artery 2 mm
- In those patients with short and difficult necks (n=8) mean distance also 2 mm



Distance to the Lower RA:
1M FU = 0 mm; 1Y FU = 0 mm



*Excluding those patients where placement was intentionally below the renal artery

GORE Excluder Iliac Branch Endoprosthesis (IBE)

Iliac Branch Component

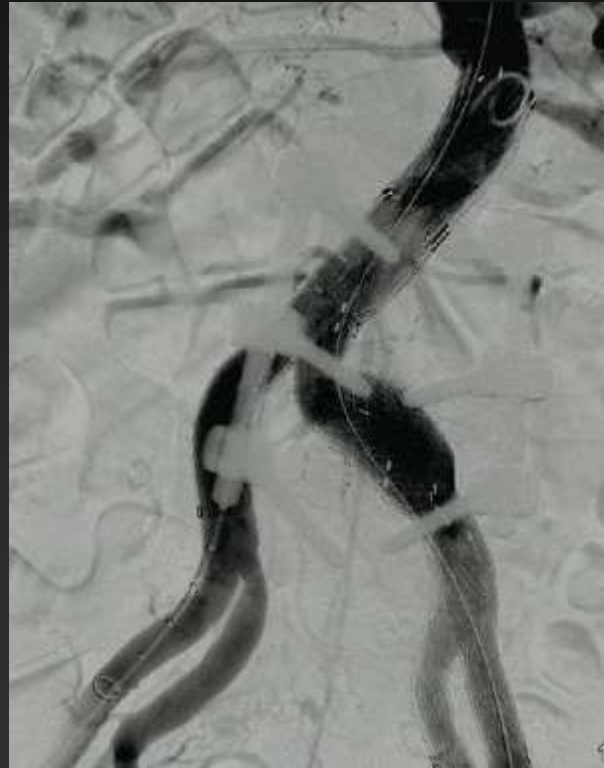
- 16 Fr compatible
- 6.5 – 25 mm External Iliac treatment range (with EXCLUDER® Iliac Extenders)
- Two-stage deployment
- Repositionable
- Pre-cannulated internal iliac gate

Internal Iliac Component

- 12 Fr compatible (with 0.035" buddy wire)
- 6.5 – 13.5 mm Internal Iliac treatment range
- Deploys Hub-to-Tip



GORE Excluder Iliac Branch Endoprosthesis (IBE)



- Tech success: 93%(14/15)
- No Type I endoleak
- 4 Type II endoleaks
- No re-interventions
- No buttock claudication
- No iliac occlusions

Next Generation Endografts

Conclusions

- The latest generation EVAR devices provide iterative improvements in profile, and 14F appears to be about the lowest attainable
- F-EVAR devices are transforming our ability to seal adverse necks with few type I leaks and good visceral branch graft patency
- Endostapling, sealing rings and endobags are also transforming our ability to provide endovascular solutions for hostile neck anatomy
- The IBE device now provides a solution for iliac aneurysms with preservation of the internal iliac artery