The usage of covered balloon expandable stents in ch-EVAS procedures

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Disclosures:

Consultant for Medtronic, Endologix

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Speaker fee: Maquet Getinge Group

Endovascular Treatment Juxta-Renal AAA

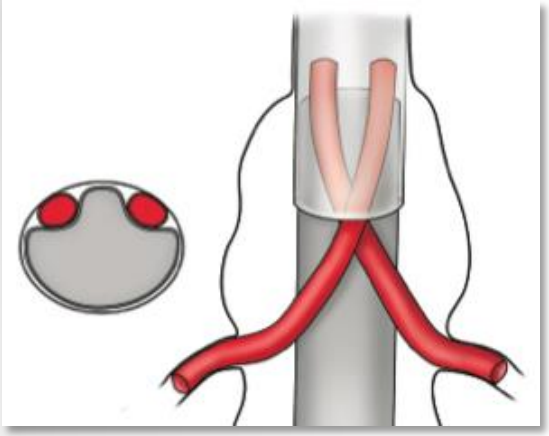
- CMD “gold-standard” but temporal and manufacturing constraints
- Significant “turndown” rate
- 7% early reintervention, 28% mortality in sealing zone 6

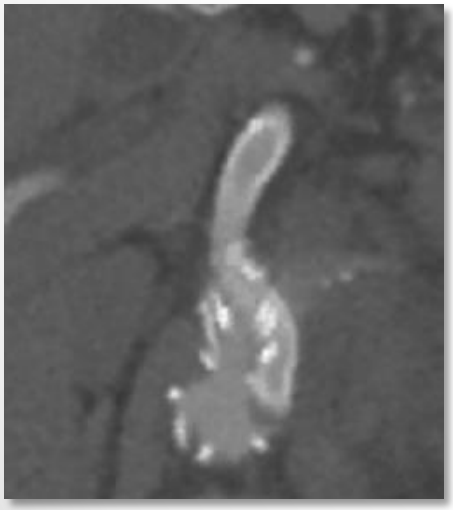
Banno et al JVS 2014; 60: 31

Globalstar Circulation 2012; 125: 2707

Patel et al JVS 2015; 62: 319

EVAR and Parallel Grafts for Juxta-Renal AAA

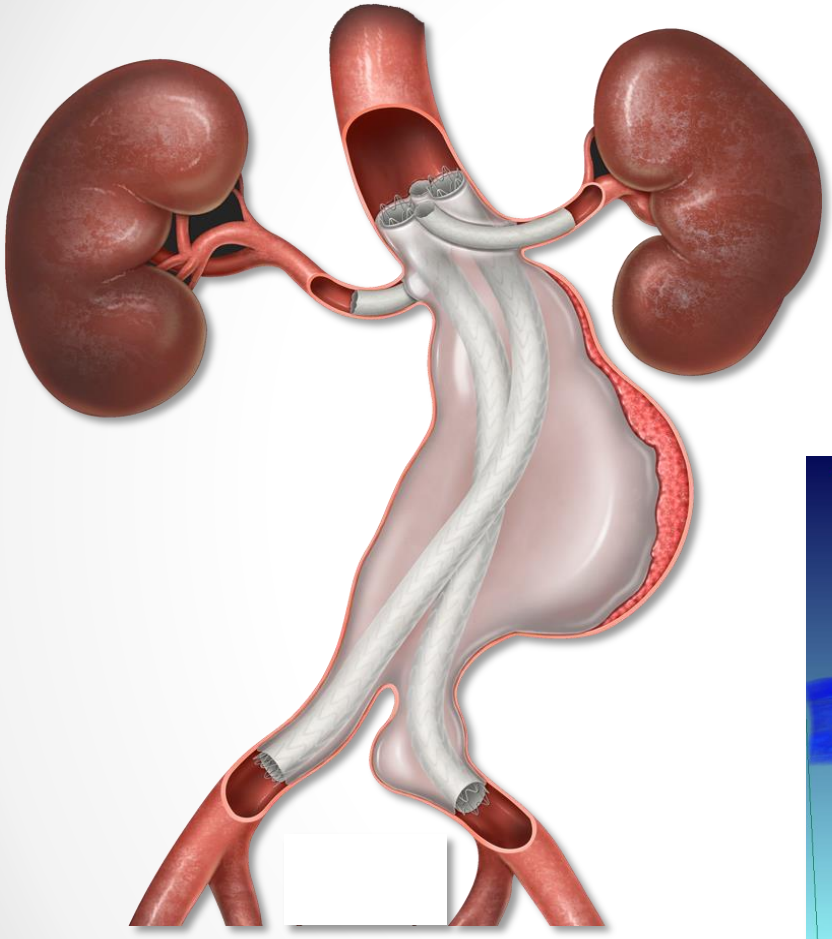


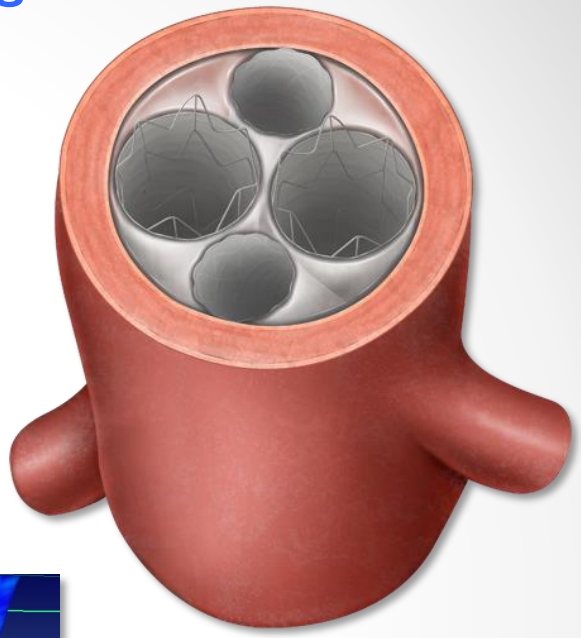


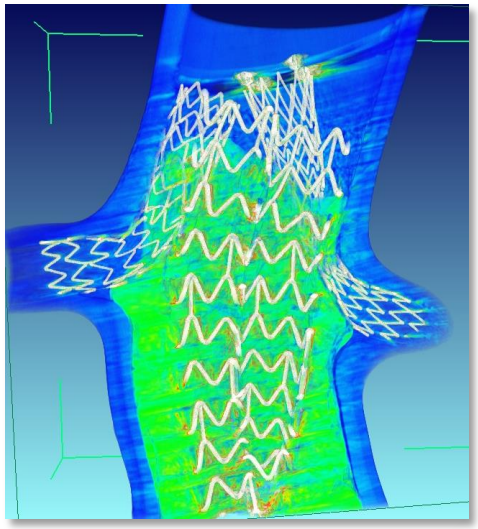
- Near universal applicability
- Early results better than expected – durability?
- Issue is seal – gutters / endoleaks
- 13% early endoleak
- Improved seal with polymer based technology?

Linblad et al EJVES 2015; 50: 722

EVAS and Parallel Grafts







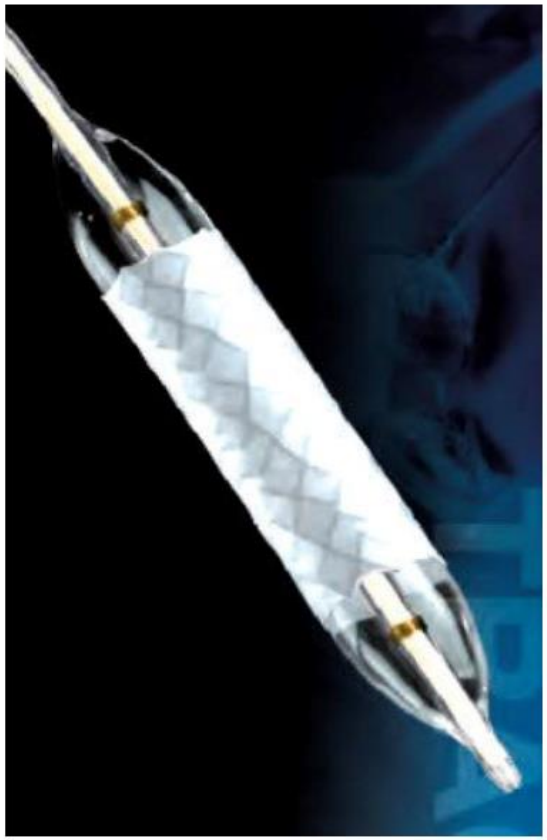
Parallel Grafts and EVAS – Technique

- Plan to increase sealing zone to at least 2cm
- 7F sheaths placed in target vessels
- Inflate Nellix stents first and then visceral stents
- Keep balloons inflated whilst endobags filled and polymer cures

Chimney stentgrafts

Balloon-expandable (Advanta V12)

- Double PTFE layer
- 5mm - 8mm diameter
- over 6/7F sheath
- 22mm, 38mm and 59mm length



Chimney stentgrafts

Self-expanding (Viabahn)

- PTFE layer
- 5mm - 8mm diameter
- over 7F/8F sheath
- length (50-250mm)

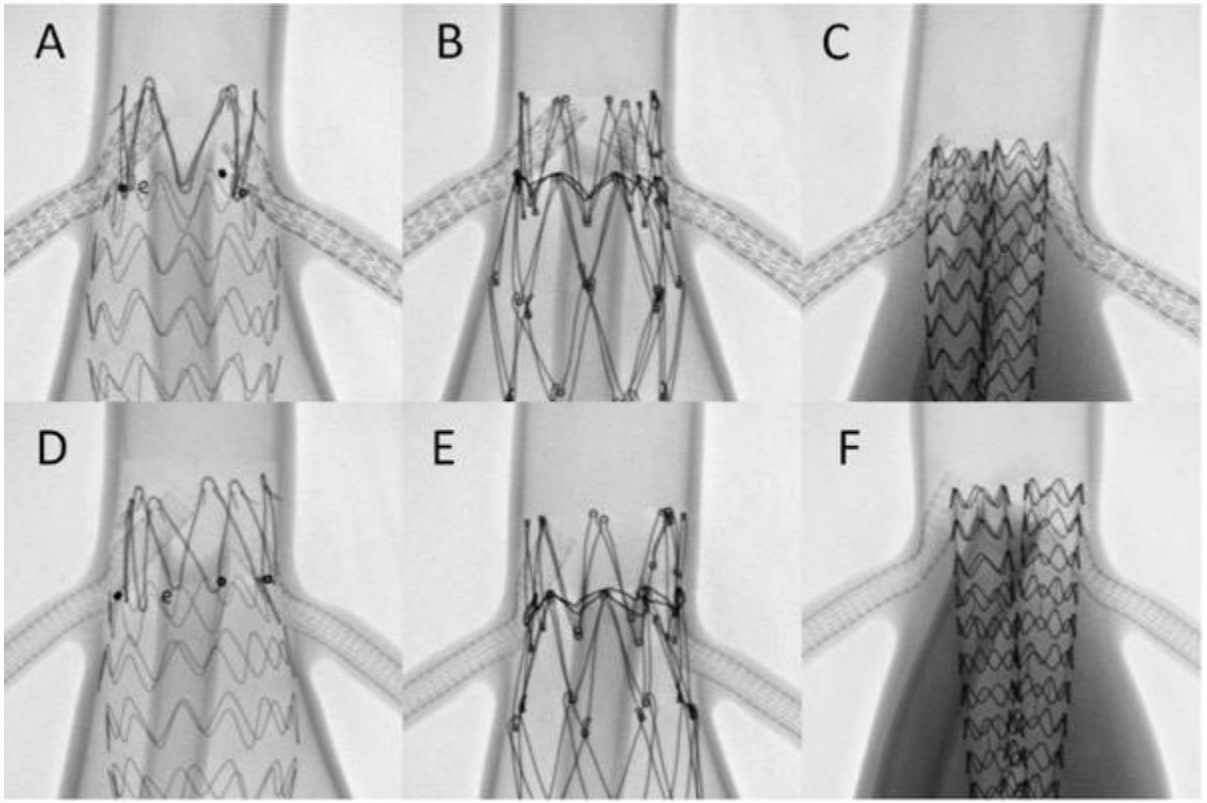
Why V12?

- Fluoroscopic visualization
- Precise placement
- Radial force
- Evidence in the literature

Why V12?

- Flexibility of the skeleton of the abdominal devices
- Radial force of the chimney devices

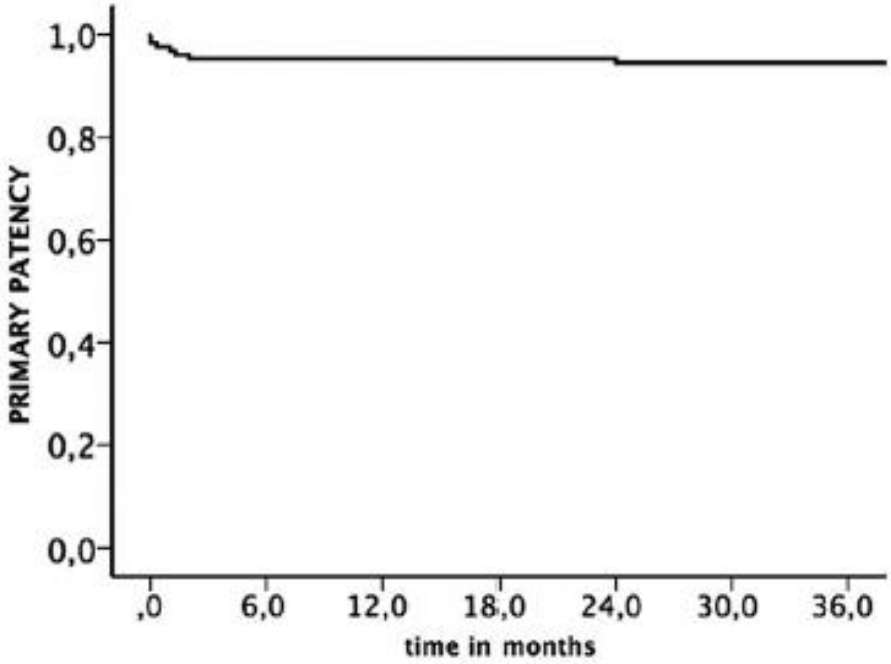
In-vitro analysis shows V12 less compressed with Nellix



The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique

J Vasc Surg 2016;63:1-7.

Konstantinos P. Donas, MD,[a,b] Giovanni B. Torsello, MD,[a,b] Gianluca Piccoli, MD,[c] Georgios A. Pitoulias, MD,[a,b,d] Giovanni Federico Torsello, MD,[c] Theodosios Bisdas, MD,[a,b] Martin Austermann, MD,[a,b] and Daniele Gasparini, MD,[c] *Münster, Germany; Udine, Italy; and Thessaloniki, Greece*



patients at risk:	128	105	92	84	64	52	38
chimney's at risk:	187	152	138	125	93	75	52
standard errors:	0,04	0,04	0,04	0,04	0,04	0,04	0,03

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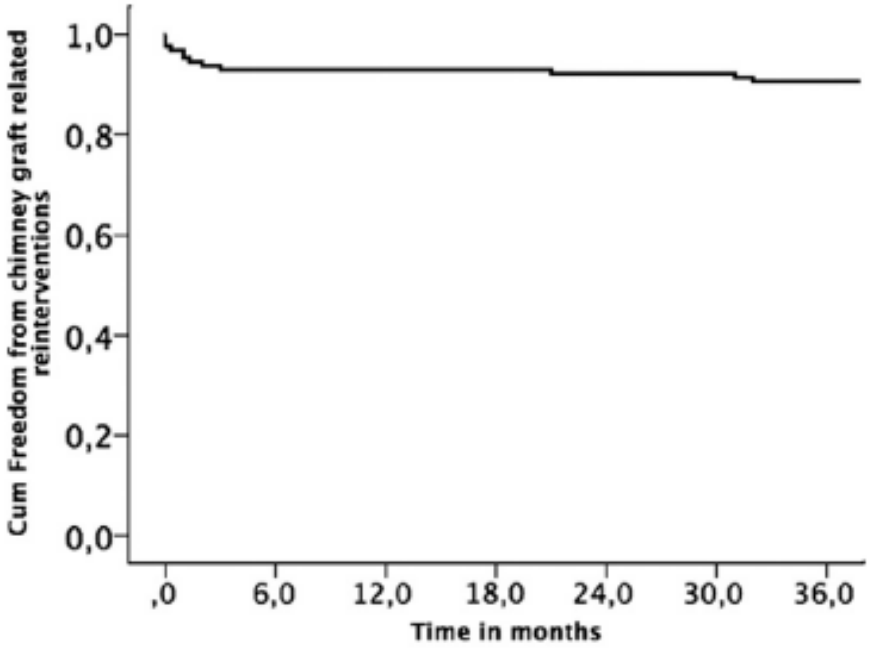

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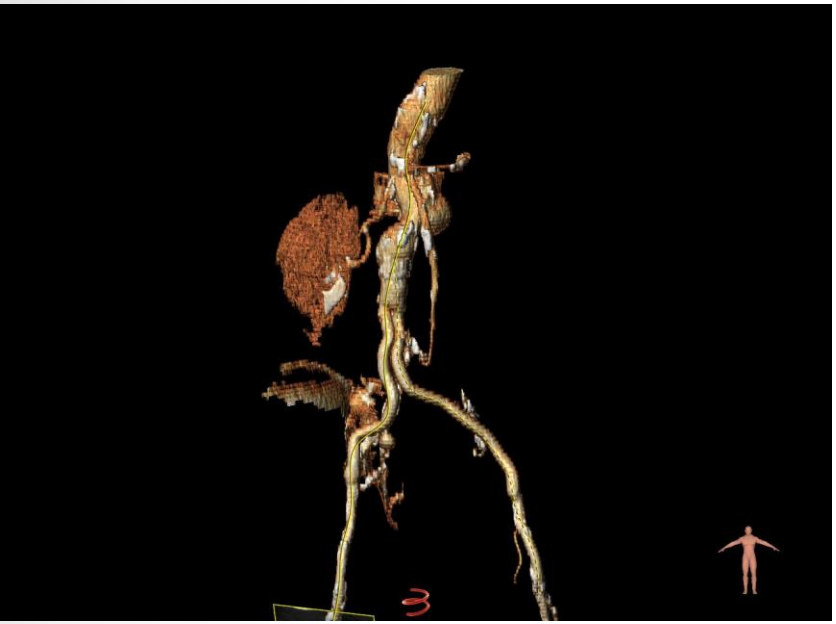
Case example #1

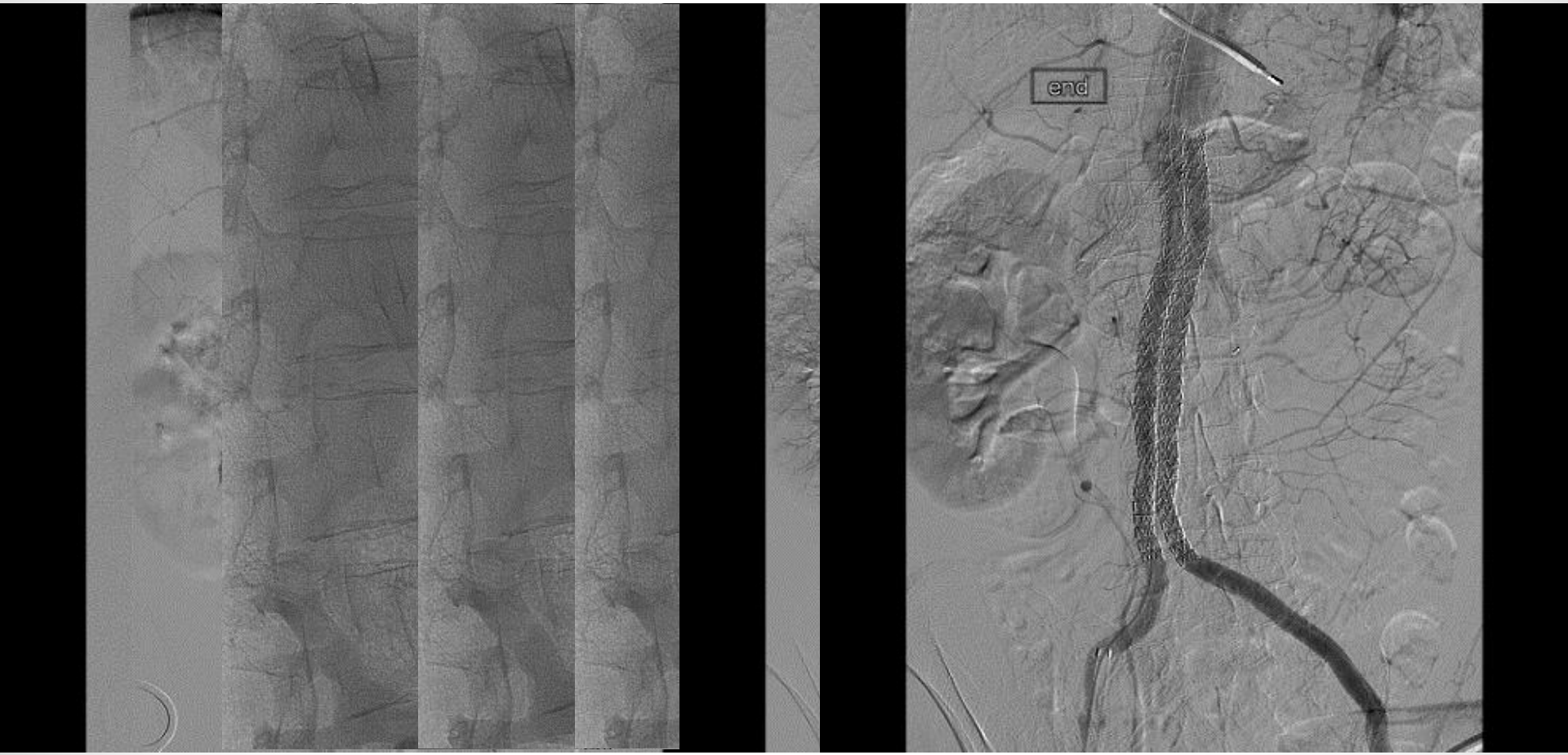


Male, 76 years

Former nephrectomy left, aorto-bi-iliac prosthesis

Sacculair proximal anastomotic aneurysm, 6.1 cm

Case example #1



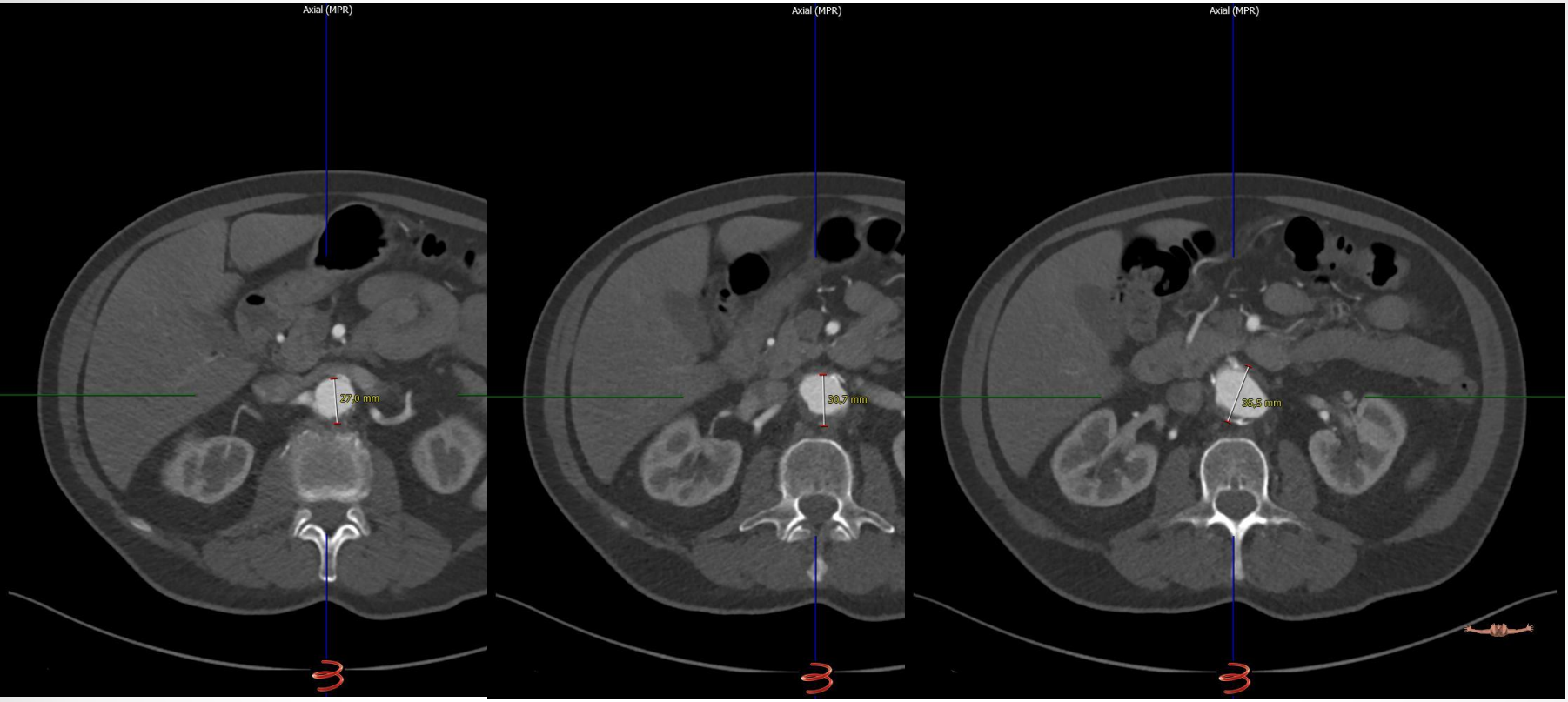
Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)

- Advanta stentgrafts, proximal at level of bare stents Nellix

Case example #1

Case example #1

Case example #2

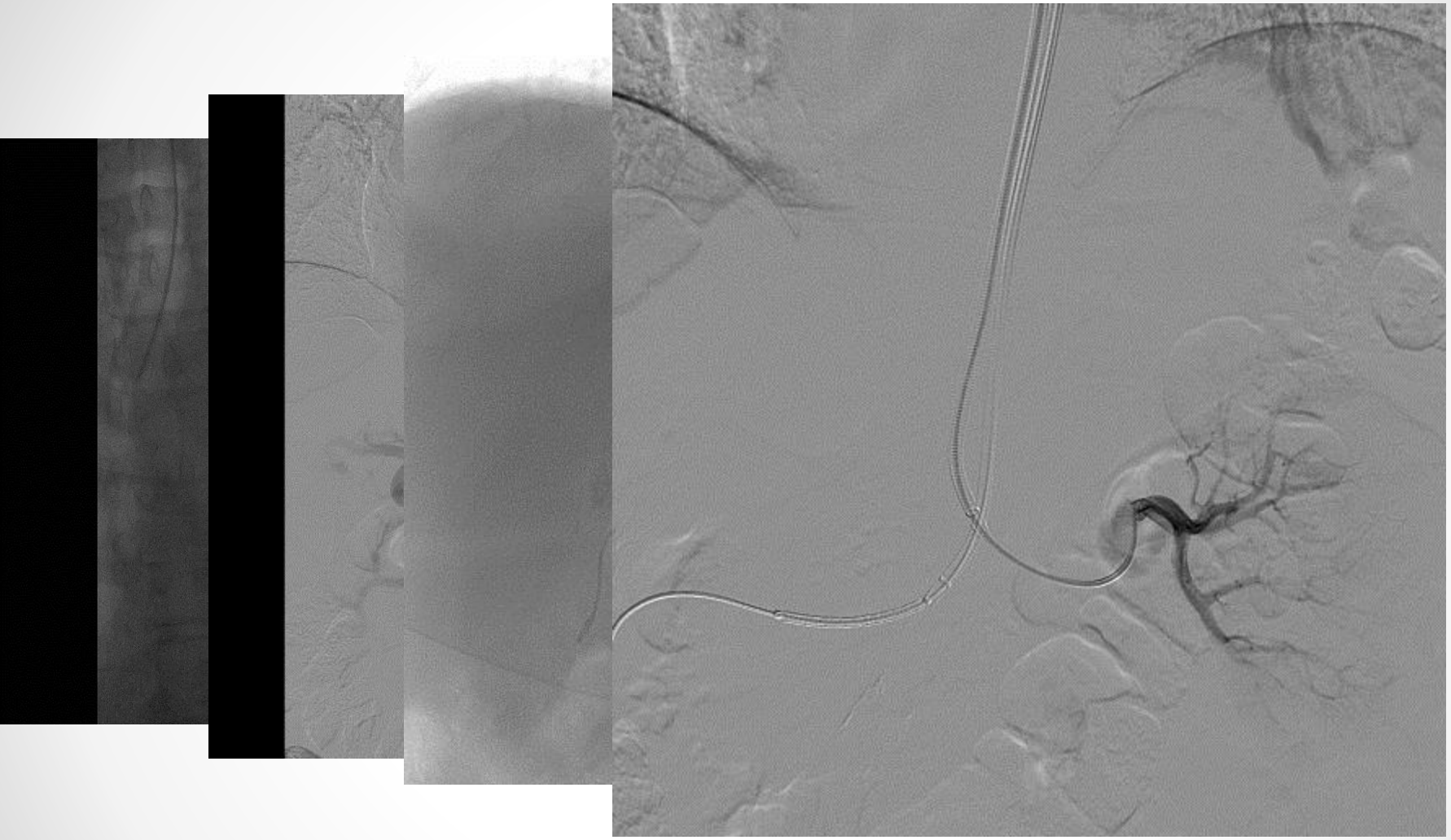


Male, 73 years

Conical neck (27 → 33 mm)

Former abdominal surgery (complicated diverticulitis)

Case example #2



Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)

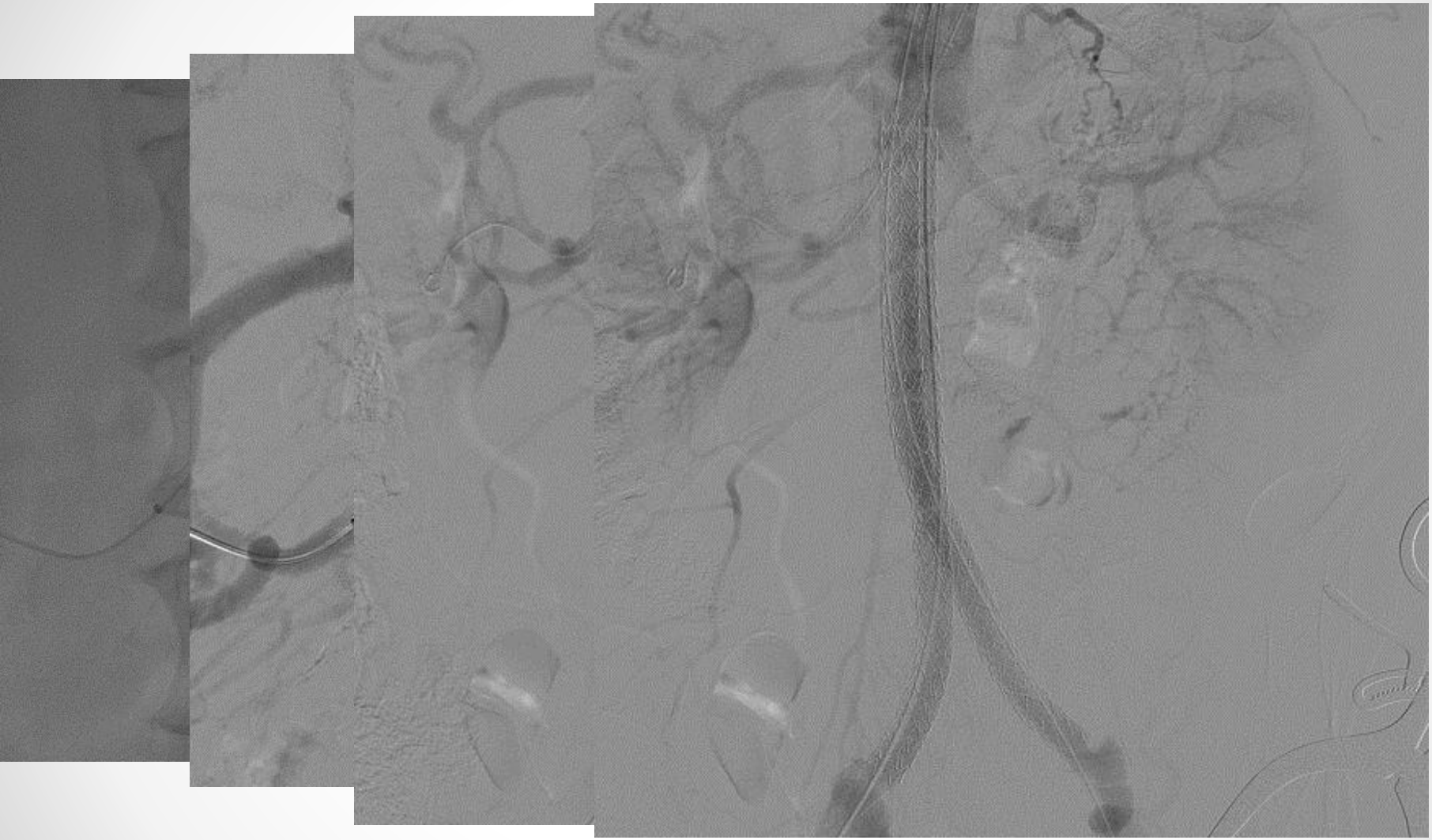
Case example #2

Balloon support

Case example #2

Length measurement (Nellix)

Case example #2



Bilateral brachial access (percutaneous), 7 fr sheaths, fixed-core wires (Cook)

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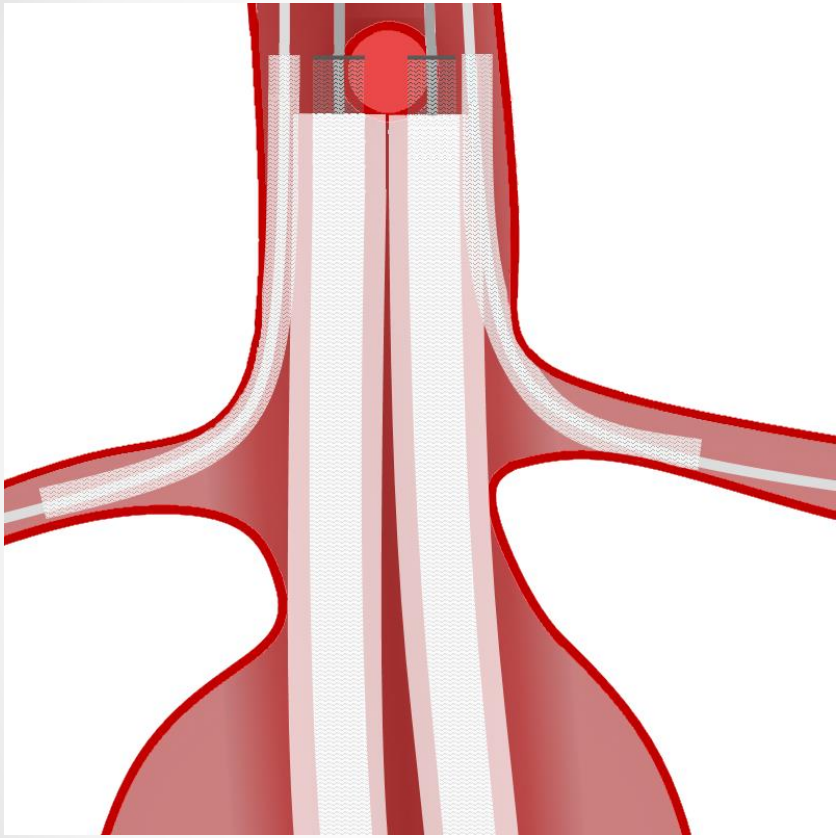
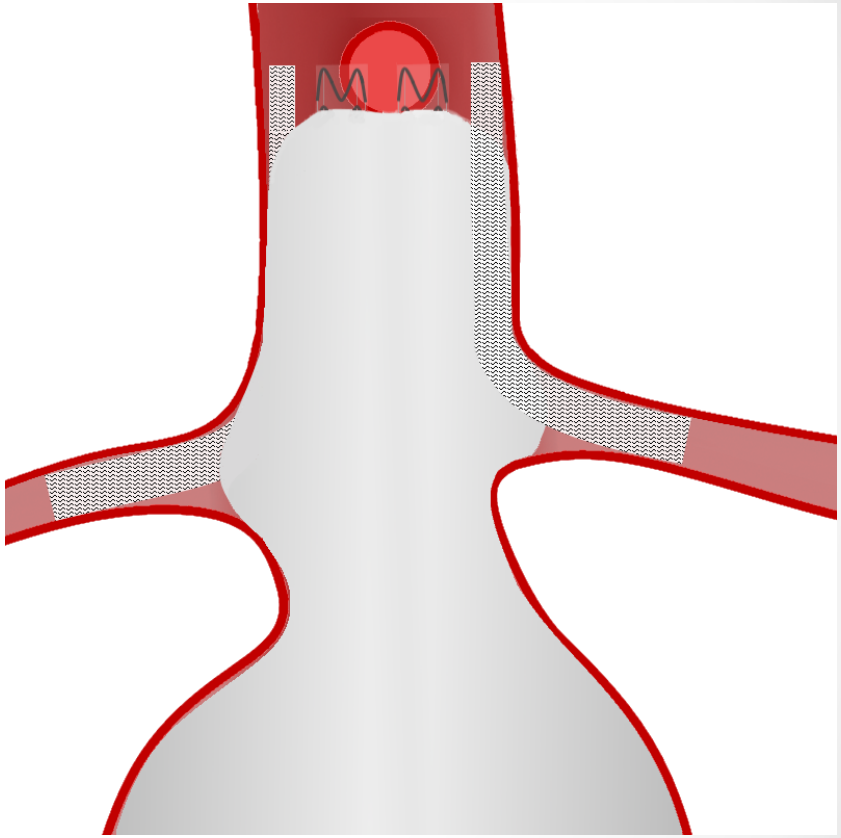
Position of Advanta stentgrafts / Nellix stentframes





Top of Advanta stentgrafts = Top of the (bare) stent of the Nellix

ASCEND

Aneurysm Sealing for Complex AAA: Evaluation of Nellix Durability

- Post-market registry of the Nellix System with Chimney Stents
  - Open-label, single-arm, no prospective screening
  - 200 patients, up to 10 international centers with 5y F/U
  - 187 patients (154 primary, 9 rAAA, 25 EVAR, 5 EVAS)
  - Endpoints typical of EVAR therapy in complex AAA

De Novo Procedures (154)

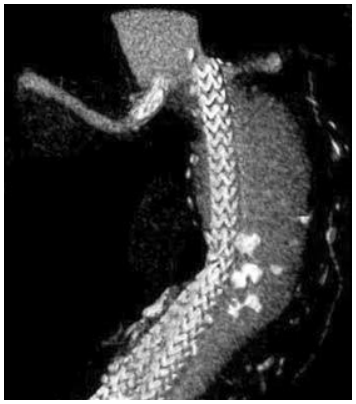
Single
40.3%

N=62

LRA = 33, RRA = 27

SMA = 1

Not Specified = 1



Double
35.1%

N=54

Both RA = 49

RA and SMA = 4

Not Specified = 1

Triple
17.5%

N=27

Both RA, SMA = 24

RA, SMA, CA = 2

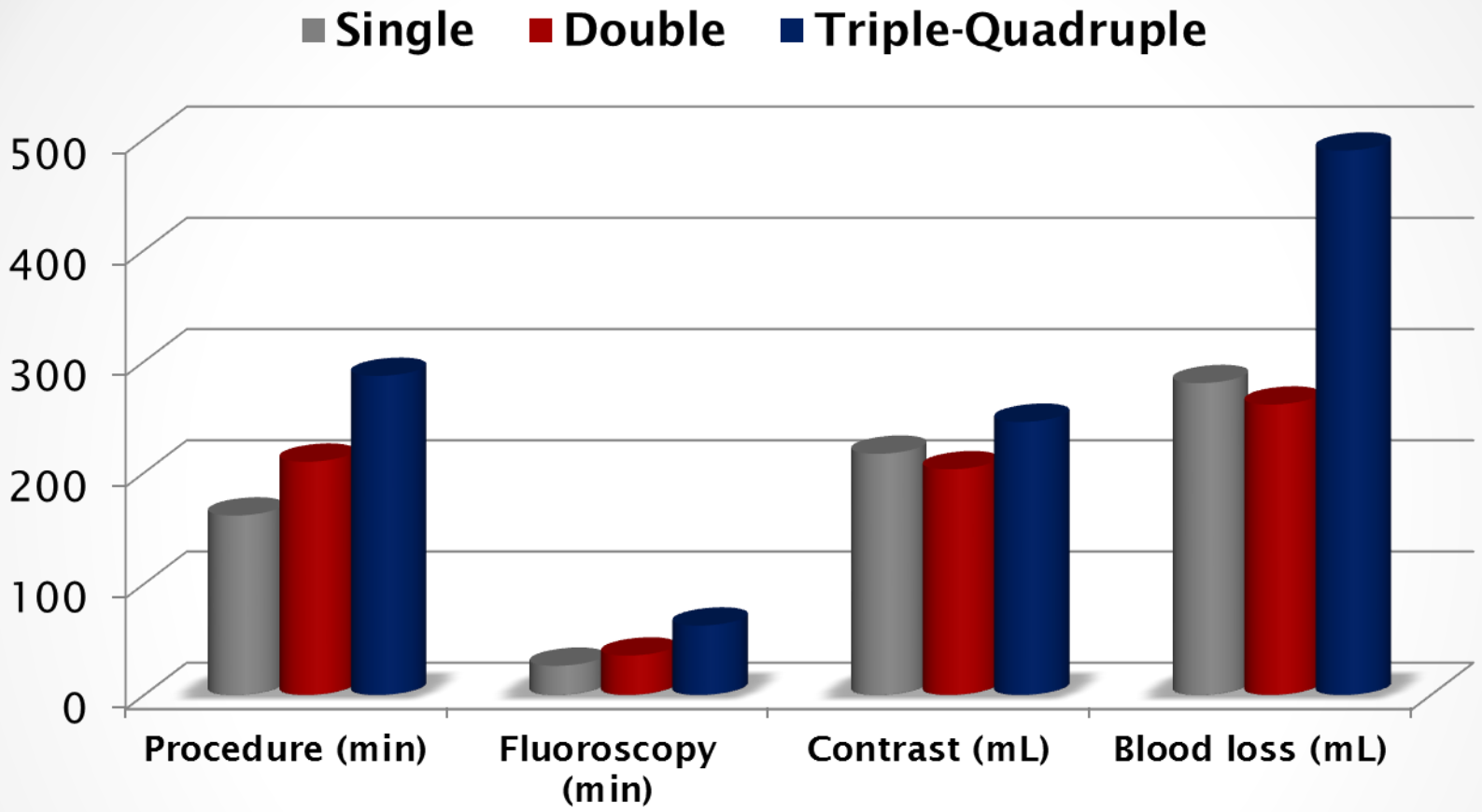
Not Specified = 1

Quadruple
7.1%

N=11

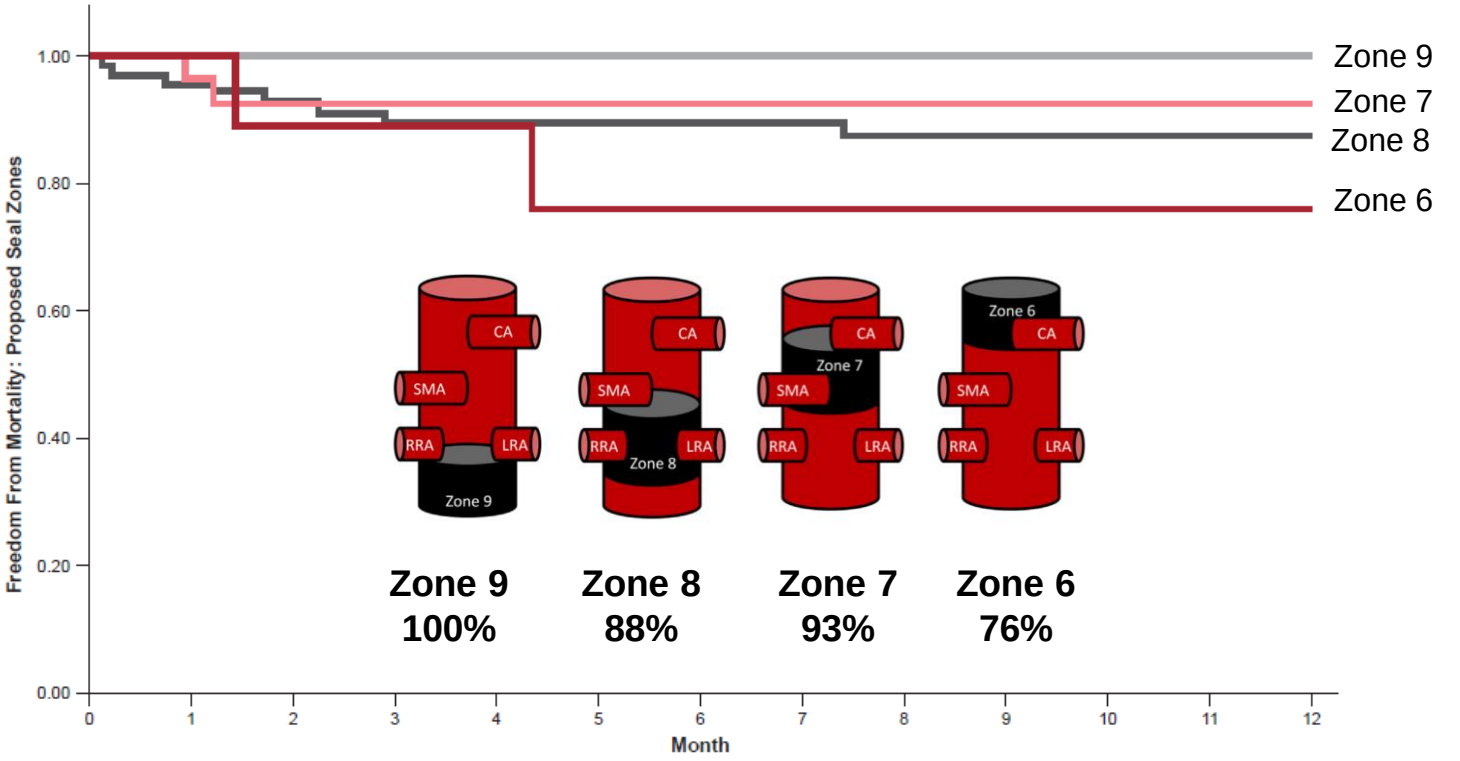
Both RA, SMA, CA

Procedural Characteristics



78% balloon expandable stents / **22%** self expanding stents

Freedom from Mortality By Seal Zone

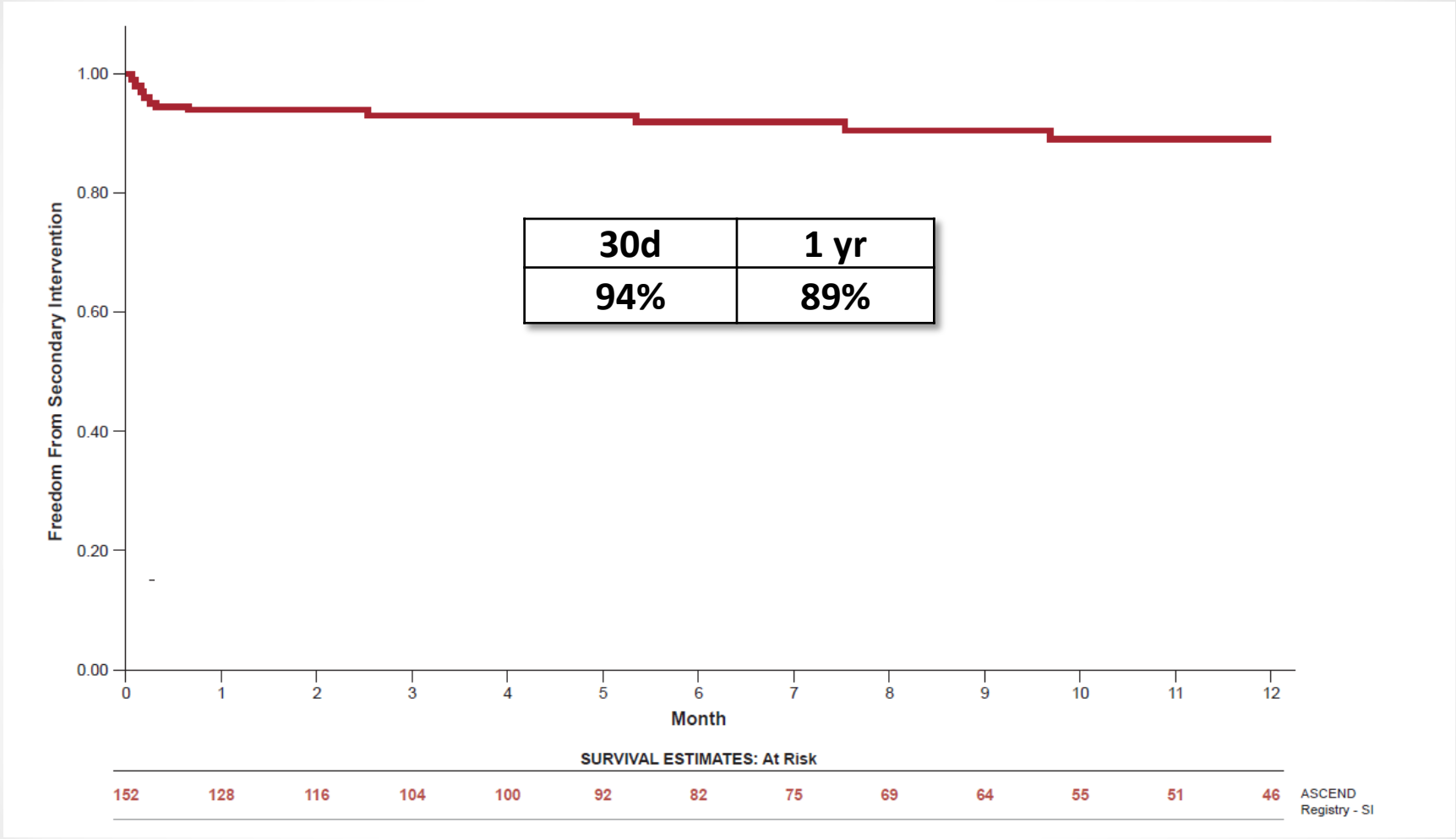


SURVIVAL ESTIMATES: At Risk

9	9	8	7	7	5	4	4	3	2	2	2	2
30	26	23	21	21	21	18	17	16	15	12	11	10
71	67	62	55	54	49	47	43	41	39	35	32	30
12	9	9	9	7	7	7	5	4	4	4	4	4

ASCEND Registry - Zone 6
ASCEND Registry - Zone 7
ASCEND Registry - Zone 8
ASCEND Registry - Zone 9

Freedom from Secondary Intervention

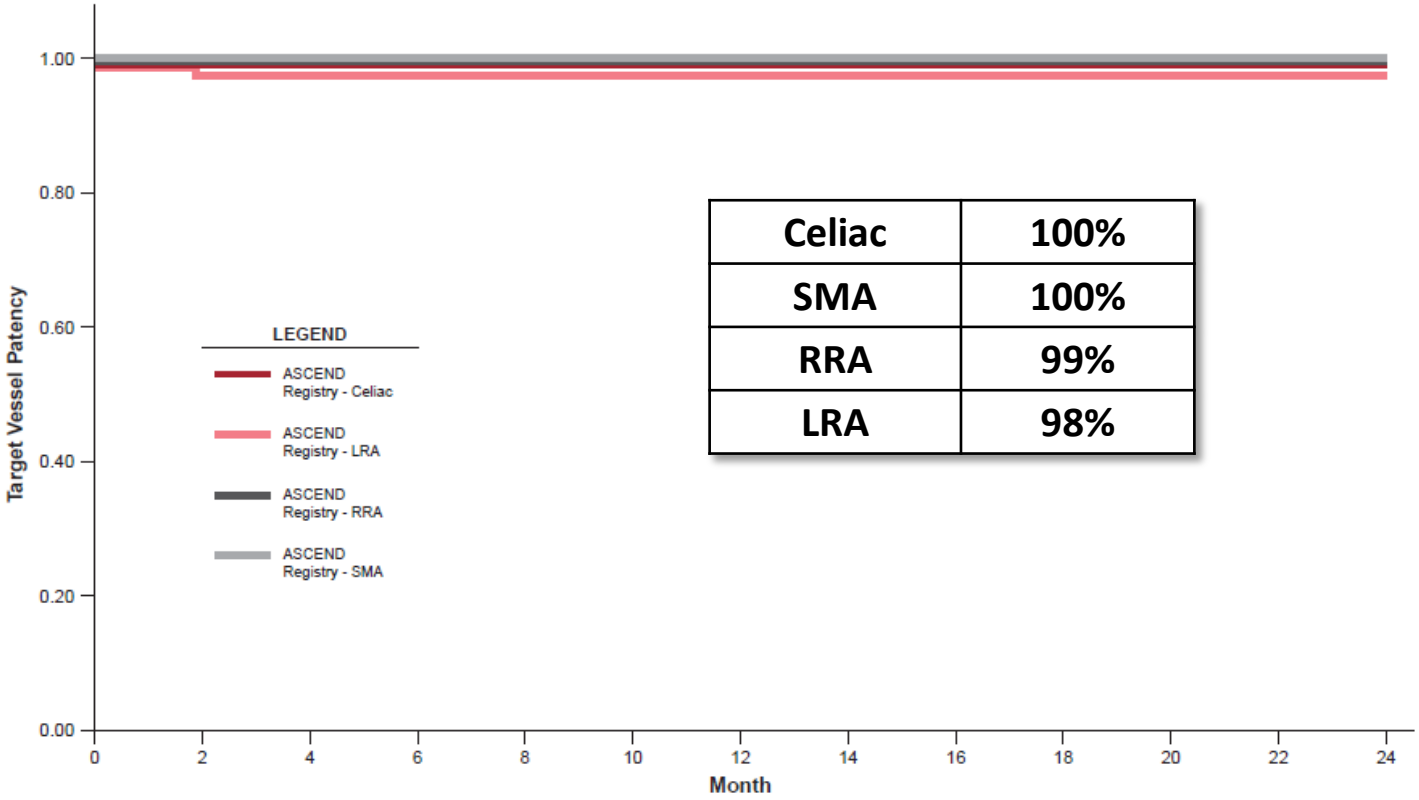


30d	1 yr
94%	89%

Secondary Intervention

	Endoleak	Chimney Stent	Nellix
Early (n=154)	1.9% (3)	2.6% (4)	1.9% (3)
Late (n=142)	2.8% (4)	3.5% (5)	0.7% (1)

Target Vessel Patency



Celiac	100%
SMA	100%
RRA	99%
LRA	98%

SURVIVAL ESTIMATES: At Risk

154	95	65	51	33	24	23	18	16	14	8	5	3	ASCEND Registry - Celiac
154	94	64	50	33	24	23	18	16	14	8	5	3	ASCEND Registry - LRA
154	95	65	51	33	24	23	18	16	14	8	5	3	ASCEND Registry - RRA
154	95	65	51	33	24	23	18	16	14	8	5	3	ASCEND Registry - SMA

Ch-EVAS with V12 stentgrafts in pararenal AAAs

- Promising use of new technology
- Theoretical advantages in using polymer based sealing
- Early results acceptable
- Long term results and endograft durability

V12 stentgrafts ~ SEG in ch-EVAR/S

- Necessary radial force
- Better visualization
- Shorter lengths
- Limitation: tortuous visceral arteries

Total Enrollment* = 187

Centre	Investigator	Enrolled
St George's Hospital	**Matt Thompson (ASCEND PI)**	50
Auckland City Hospital	**Andrew Holden (ASCEND PI)**	16
University Hospital Mainz	Marwan Youssef	35
Augsburg Hospital	Rudolf Jakob, Sebastian Zerwes	30
Arnhem Hospital	Michel Reijnen	19
Vascular Clinic IHT - Warszawa	Piotr Szopinski	15
Marien Hospital Kevelaer	Patrick Berg	12
University Hospital Posznan	Gregrorz Oszkinis	10

*Data cut April 14, 2016