CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE

How to Categorize the Infrarenal Neck Properly?

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Disclosure

Speaker name: Isabelle Van Herzeele

I have the following potential conflicts of interest to report:

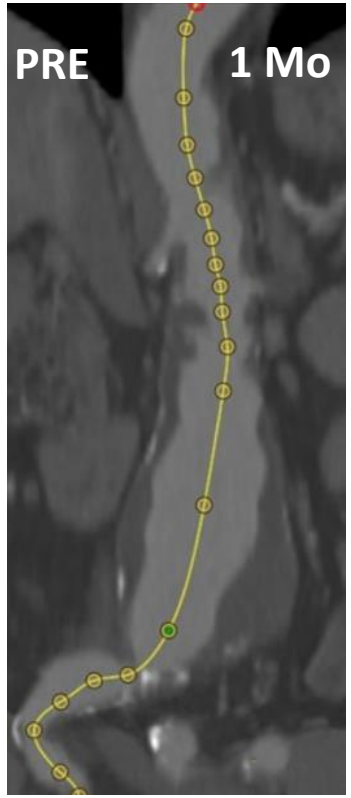
- Consulting:

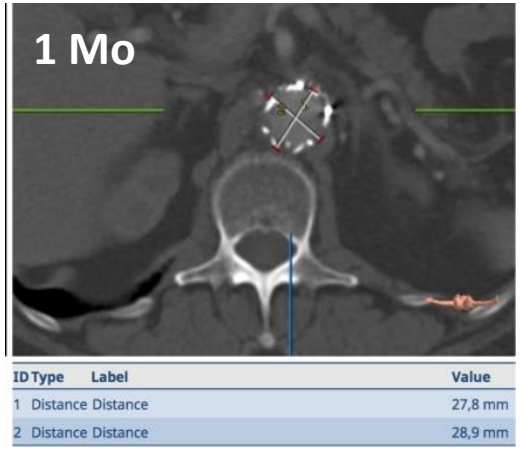
Medtronic Academia, Tolochenaz, Swiss

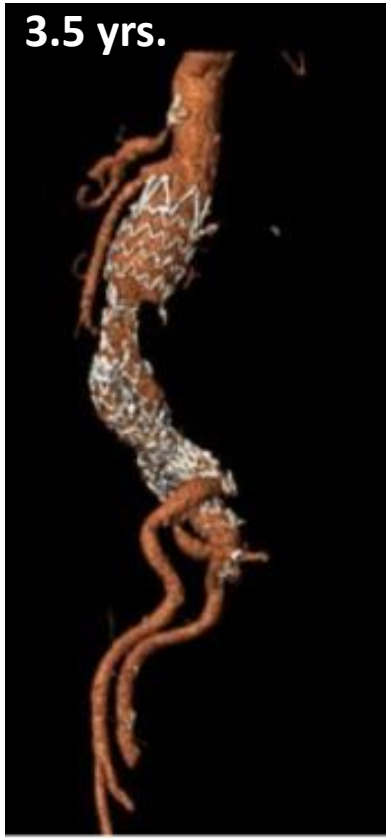
Silkroad Medical, Sunnyvale, CA, USA

Goal of EVAR: Prevent Aneurysm Rupture

Proximal Sealing and Fixation







Definition

- *Infrarenal neck* = « segment of the aorta from the most caudal main renal artery to the onset of the aneurysm »
- *Categorize* = « to put people or things into groups with ***same features*** »
- *Properly*= « in a manner suitable for the occasion or purpose »

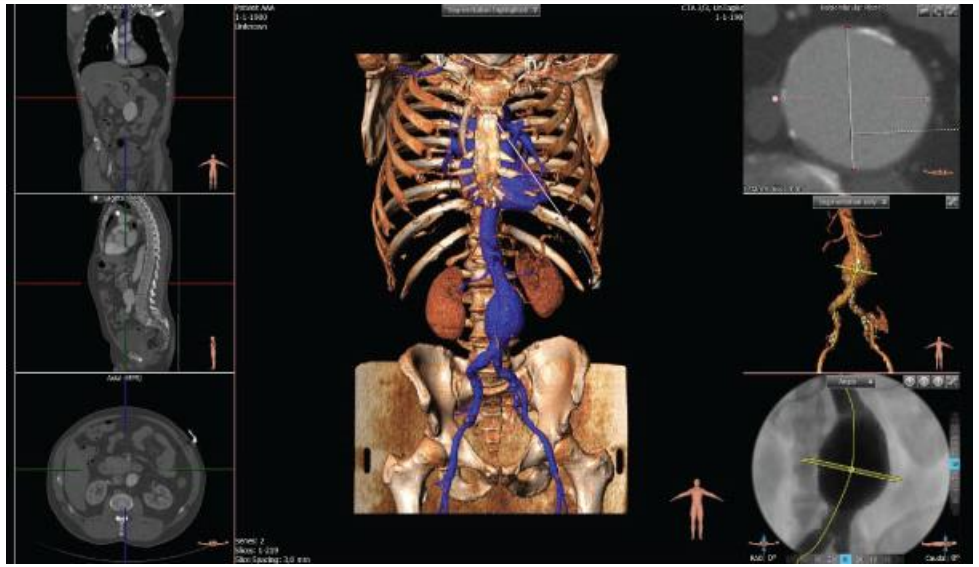
Standardized Assessment of Proximal Aortic Neck

Accurate Measurement

- Dedicated workstations
- Central lumen line
- REAL Neck
- *By Implanter*
- Planning
  - Oversizing
  - C-arm angulation

The Benefits of EVAR Planning Using a 3D Workstation CME

J. Sobocinski, H. Chenorhokian, B. Maurel, M. Midulla, A. Hertault, M. Le Roux, R. Azzaoui, S. Haulon*
Vascular Center, Hôpital Cardiologique, Lille University Hospital, France



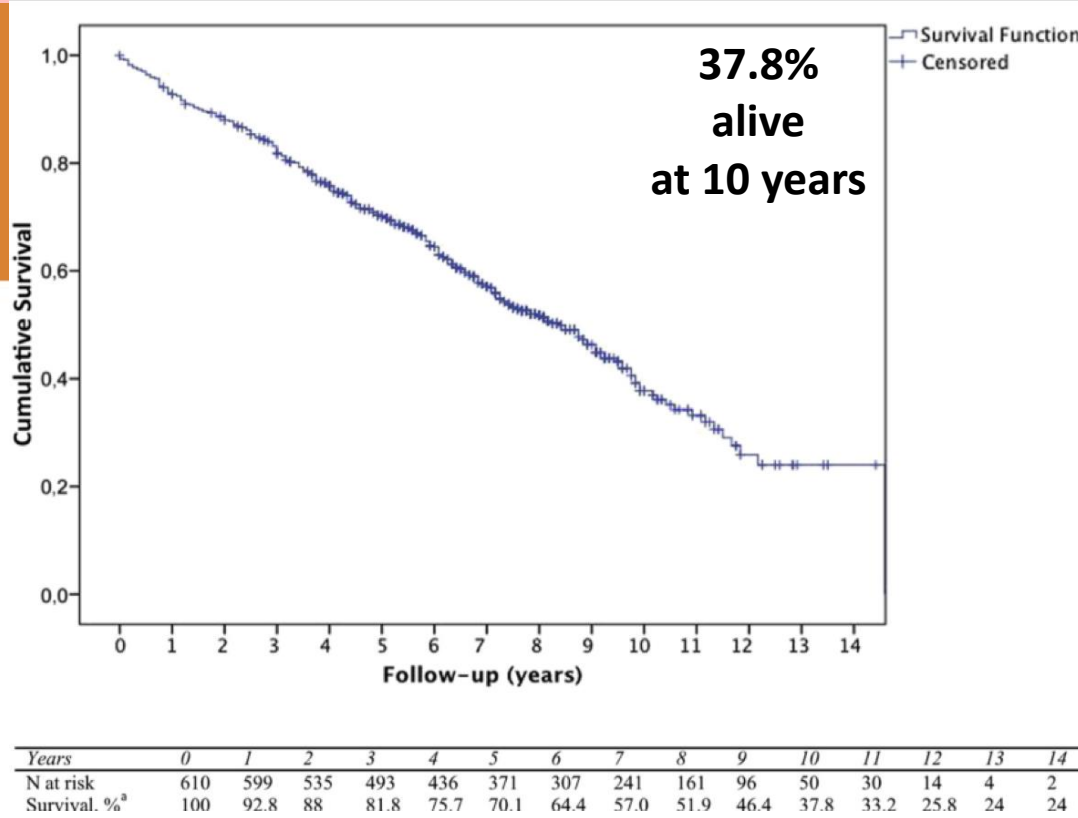
Eur J Vasc Endovasc Surg *2013; 46(4): 418-23*

400 million cycles

IFU

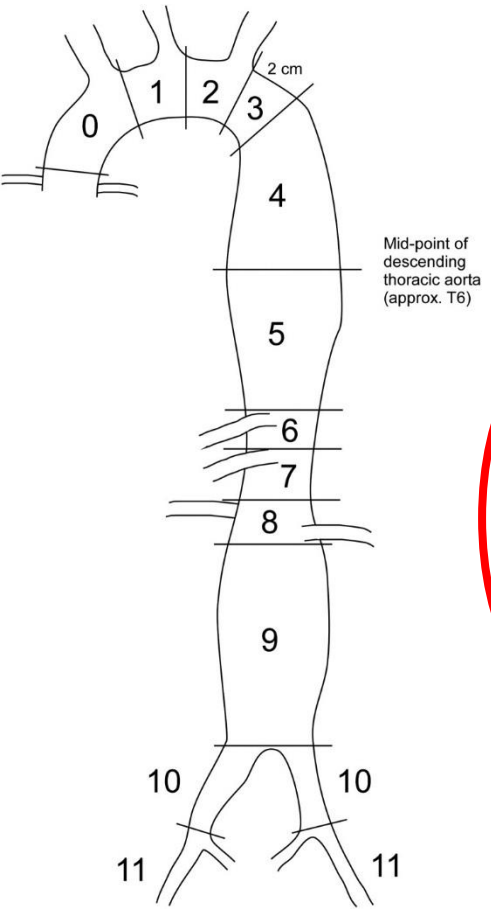
Proximal Neck

- Length
- Angulation
- Composition *calcification, trombus*
- Shape
- Diameter



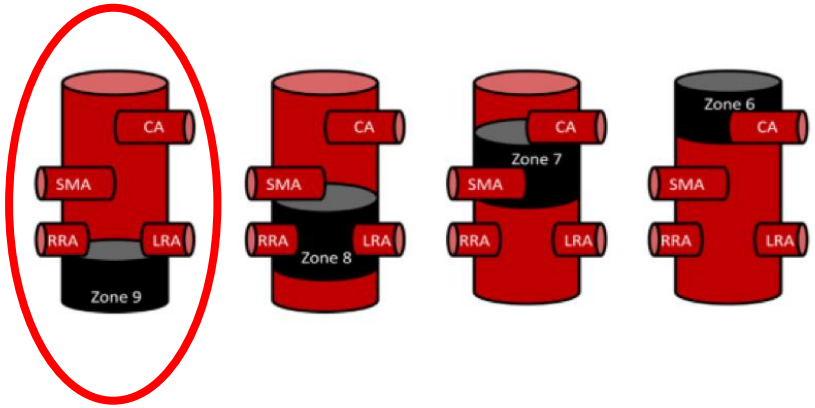
Years	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
N at risk	610	599	535	493	436	371	307	241	161	96	50	30	14	4	2
Survival, %[a]	100	92.8	88	81.8	75.7	70.1	64.4	57.0	51.9	46.4	37.8	33.2	25.8	24	24

F Verzini et al J Vasc Surg 2017; 65: 319-29



ESVS guidelines

Eur J Vasc Endovasc Surg 2011; 41: S1-58



Neck diameter >17 mm, < 32 mm
Angle between the suprarenal aorta and the juxtarenal aorta <60°
Angle between the juxtarenal aorta and the long axis of the aneurysm sac <60°–90°
Neck length >10 mm;
Neck thrombus covering <50% of the proximal neck circumference
Neck dilated <3 mm within 10 mm of the most caudal renal artery
Focal neck enlargement <3 mm within 15 mm from the most caudal renal artery
Neck calcification <50% of the proximal neck circumference

SVS guidelines

J Vasc Surg 2018; 67(1): 2-77

Device specific IFU
Infrarenal fixation: diameter <32 mm, length >15 mm, <60° angulation
Suprarenal fixation … when the morphologic features of the proximal neck are unfavorable...

- Chaikof *J Vasc Surg 2002; 35(5): 1061-6*

Infrarenal Neck	Absent = 0	Mild= 1	Moderate = 2	Severe = 3
Length (mm)	>25	15-25	10-15	<10
Diameter (mm)	<24	24-26	26-28	**>28**
Angulation °	>150°	135-150°	120-135°	<120°
Composition	<25%	25-50%	>50%	-

Based on " best current opinion" …

Hostile Neck?

- Schanzer *Circulation 2011; 123(24): 2848-55*

Conserv IFU	Liberal IFU	Outside liberal IFU
>15 *57.8%*	10-15 *17.8%*	<10 *24.4%*
<28 *91.4%*	28-32 *6.6%*	**>32** *2.2%*
<45 *72.7%*	45-60 *19.6%*	>60 *7.7%*

Hostile Neck?

Multicentre observational study …

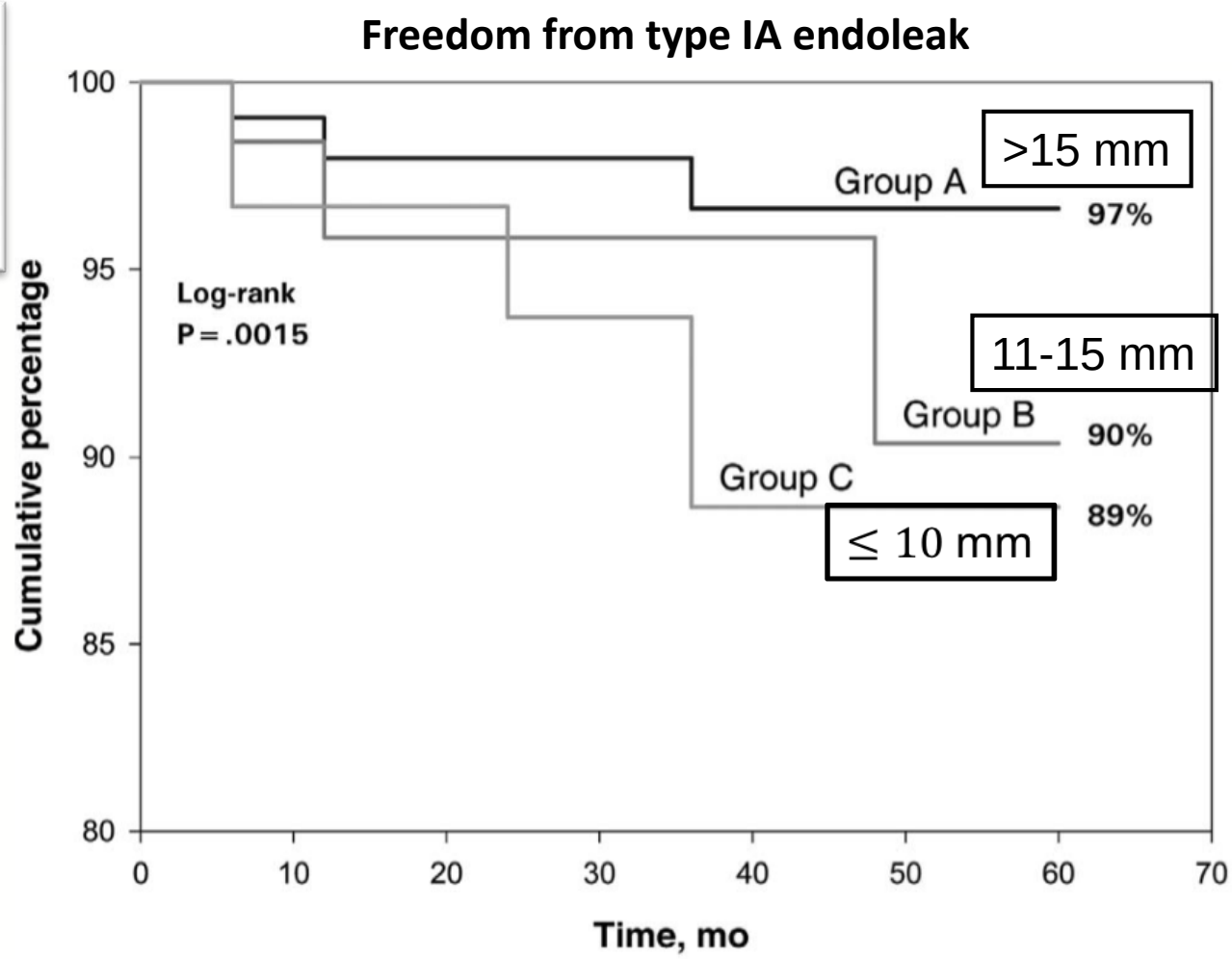
I. Neck length >15 ,10-15 or 4-10???

Influence of Infrarenal Neck Length on Outcome of Endovascular Abdominal Aortic Aneurysm Repair

Lina J. Leurs, MSc[1]; Jur Kievit, MD[1]; Pieter C. Dagnelie, PhD[2]; Patty J. Nelemans, MD, PhD[2]; and Jacob Buth, MD, PhD[1] on behalf of the EUROSTAR Collaborators

JEVT 2006; 13: 640-8

- N= 3499
- Suprarenal fixation: Talent or Zenith



Results of standard suprarenal fixation endografts for abdominal aortic aneurysms with neck length ≤10 mm in high-risk patients unfit for open repair and fenestrated endograft

Enrico Gallitto, MD, Mauro Gargiulo, MD, Antonio Freyrie, MD, Claudio Bianchini Massoni, MD, Rodolfo Pini, MD, Chiara Mascoli, MD, Gianluca Faggioli, MD, and Andrea Stella, MD, *Bologna, Italy*

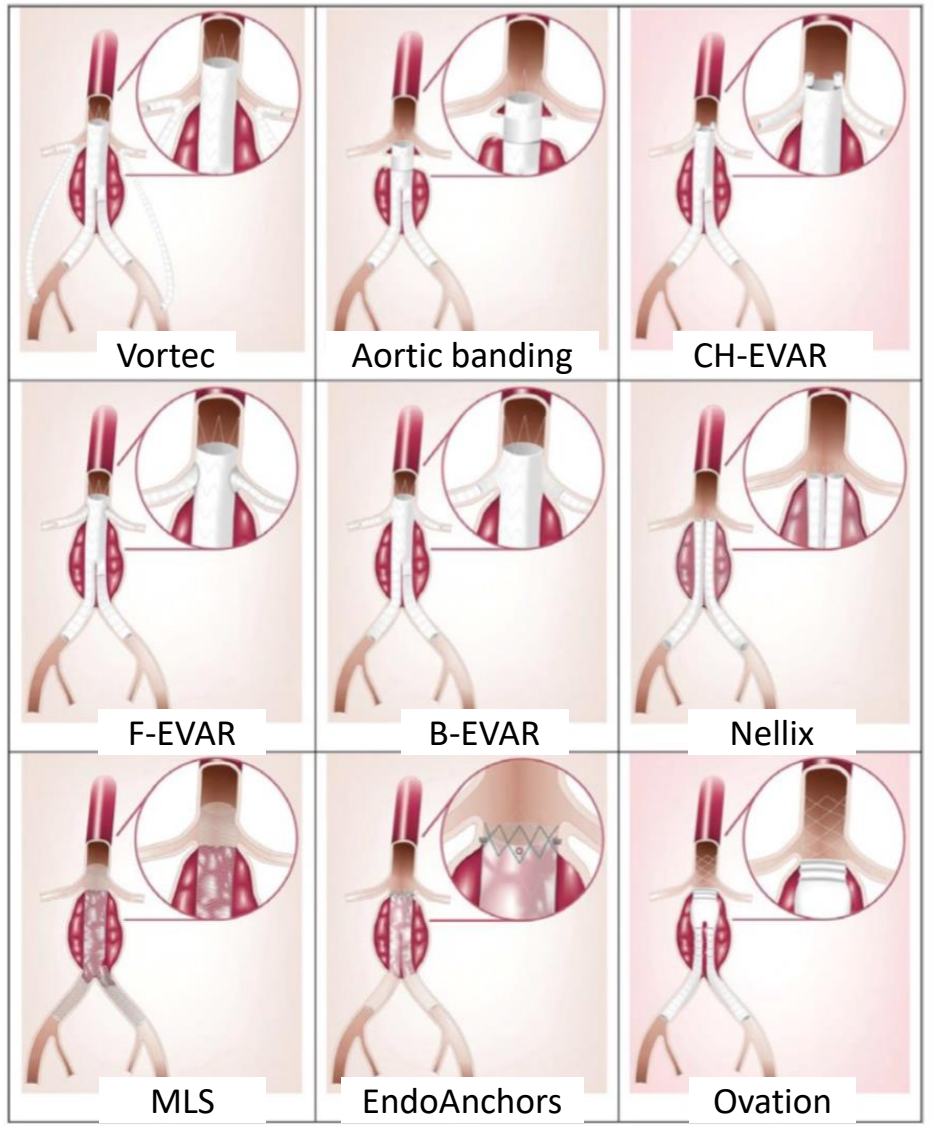
J Vasc Surg 2016; 64: 563-70

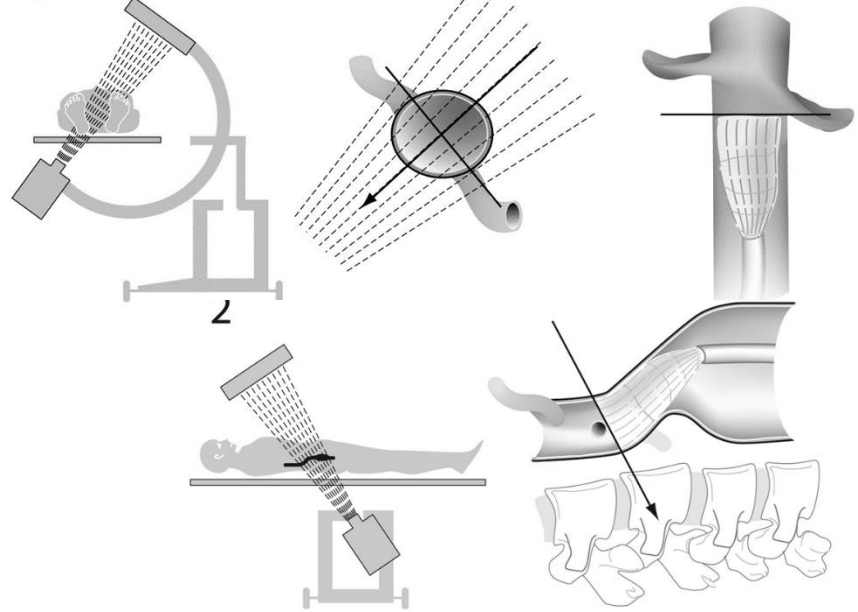
- 60 patients - ASA III-IV
- 70% 5 yrs. survival
- Neck length: mean 8.4 mm SD 1.6
- Neck diameter: mean 23.5 mm SD 3

	Univariate Cox analysis			*Multivariate Cox analysis*		
	HR	*95% CI*	P	*HR*	*95% CI*	P
Proximal type I endoleak						
Neck length <7 mm[a]	2.82	0.25-31.4	.40	—		
α ≥ 60 degrees	25.8	2.20-302	.01	25.8	2.20-302	.01
β ≥ 60 degrees	NE[b]	—	.01[d]			
Severe NC	2.42	0.22-26.7	.47	—	—	—
Severe NT	6.00	0.54-66.4	.14	—	—	—
Oversize <15%	NE[c]	—	.33[d]			
Reinterventions						
Neck length <7 mm[a]	5.56	1.21-25.6	.03	6.78	1.41-32.6	.02
α ≥ 60 degrees	11.7	1.58-86.4	.03	15.5	1.90-127	.01
β ≥ 60 degrees	1.70	0.42-6.96	.46	—	—	—
Severe NC	0.99	0.12-8.39	.99	—	—	—
Severe NT	1.37	0.26-7.11	.71	—	—	—
Oversize <15%	NE[c]	—	.11[d]			

≥4 <10 mm infrarenal neck…

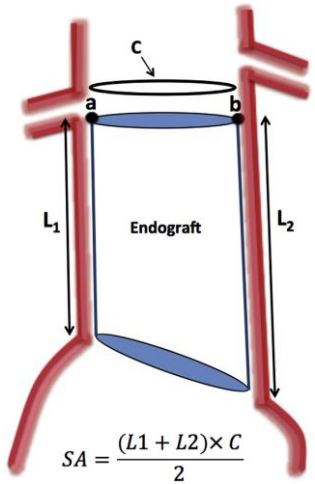
- Need for OR or advanced endovascular techniques
- Strict surveillance
- Disease progression…
- Time will tell!!!





Keep in mind!!!

- Sealing zone is shorter than neck length
- Technical Accuracy:
  - Adequate imaging for precise placement
  - Fabric is classically placed 2-3mm below lowest renal artery
  - Angulated necks: get rid of parallax to avoid loss of sealing zone
  - Planning and Rehearsal

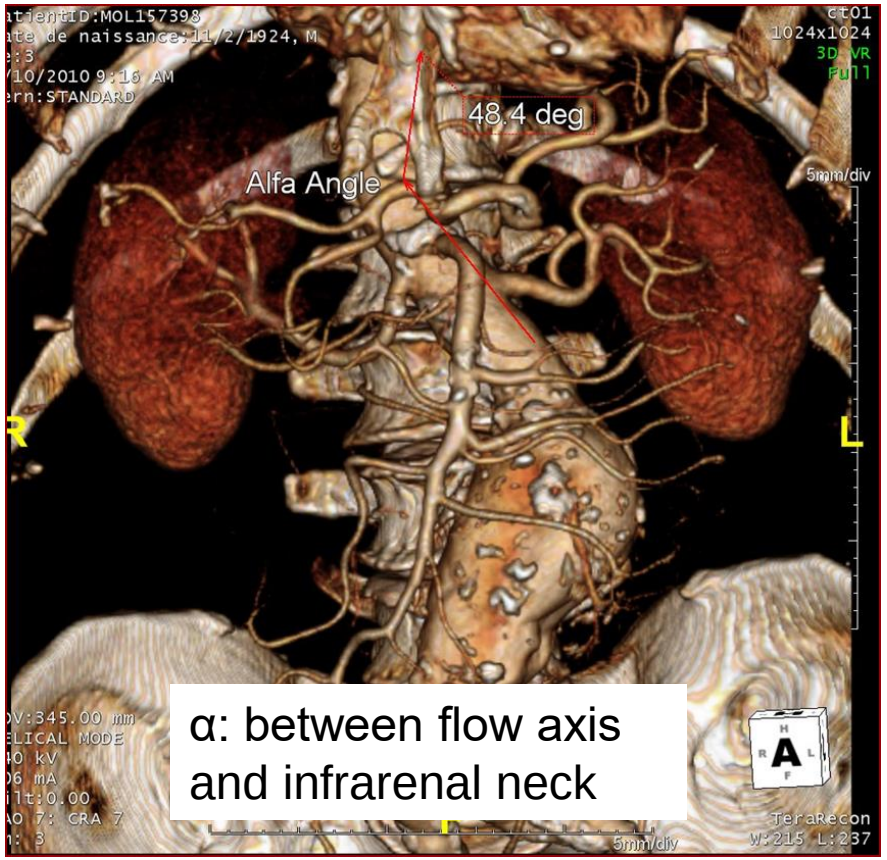


Acceptable (score 1 or 2)
- Partial renal artery coverage <= 2 mm OR
- <= 2-4 mm distal to the renal artery orifice

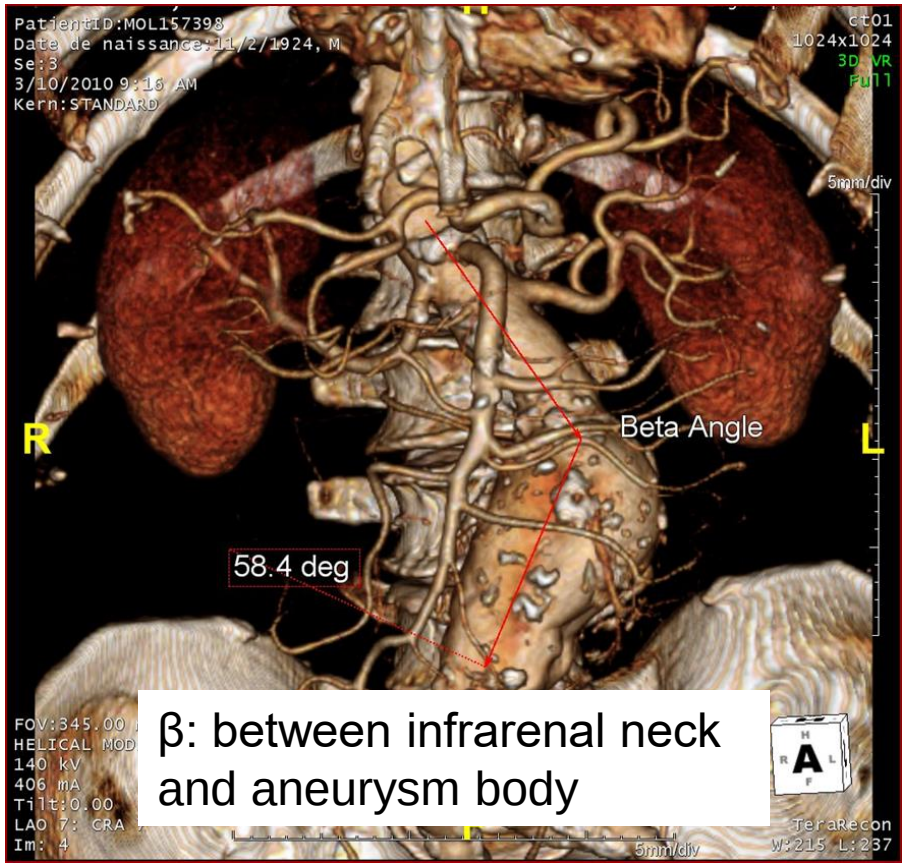
Unacceptable (score 3 or 4)

AH Kim et al. J Vasc Surg 2016; 64(1): 251-8

II. Neck angulation ∝<45°, β<60°

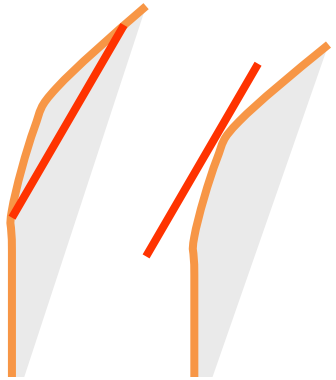


α: between flow axis and infrarenal neck

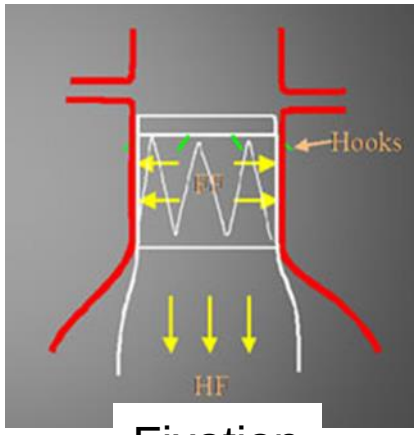


β: between infrarenal neck and aneurysm body

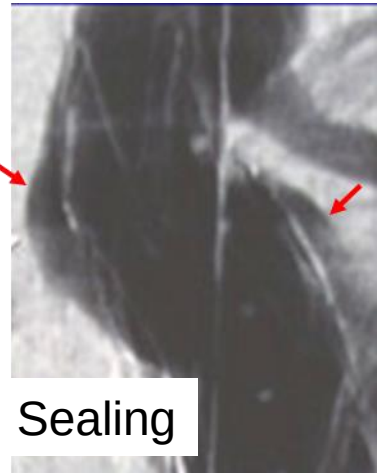
Angulation <60°



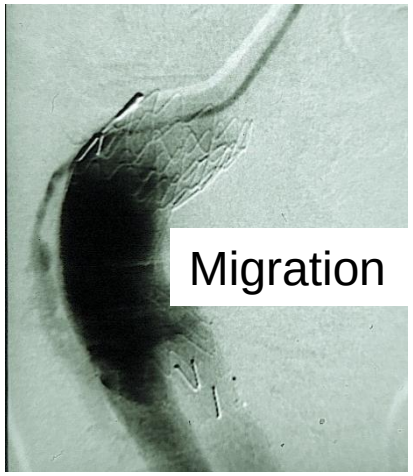
Apposition



Fixation



Sealing



Migration

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

10228 patients post-EVAR

Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

Covariates	Hazard Ratio (95% Confidence Interval)	*P*
Conical neck	1.17 (0.97–1.42)	0.10
Aortic neck angle, °		
<45	Reference	
45–60	1.04 (0.90–1.21)	0.58
>60	1.96 (1.63–2.37)	<0.0001

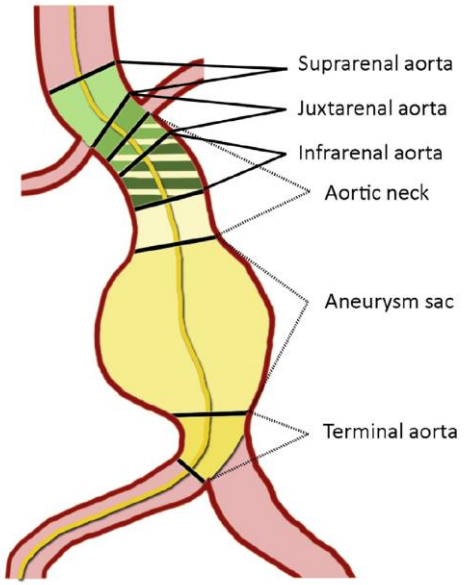
(*Circulation*. 2011;123:2848-2855.)

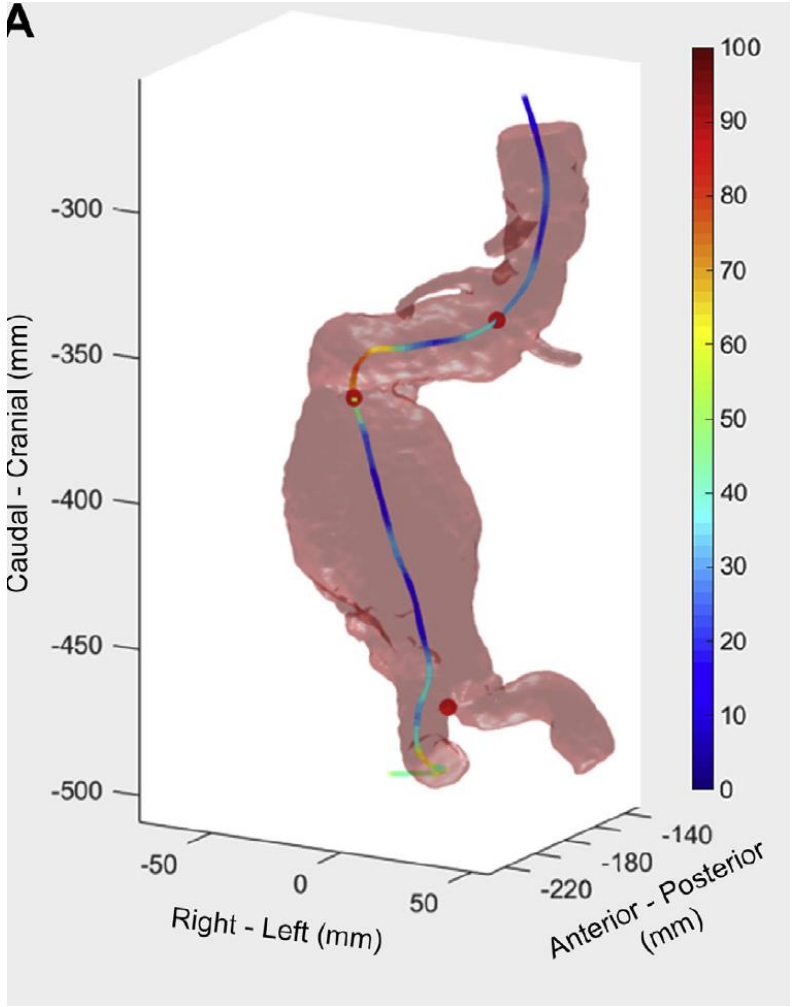
Aortic curvature as a predictor of intraoperative type Ia endoleak + Late type IA endoleak and Migration

Richte C. L. Schuurmann, MS,[a,b] Kenneth Ouriel, MD,[c] Bart E. Muhs, MD, PhD,[d] William D. Jordan Jr, MD,[e] Richard L. Ouriel, BS,[c] Johannes T. Boersen, MS,[a,b] and Jean-Paul P. M. de Vries, MD, PhD,[b] *Enschede and Nieuwegein, The Netherlands; New York, NY; New Haven, Conn; and Birmingham, Ala*

J Vasc Surg 2016; 63: 596-602
JEVT 2017; 24; 411-7

Variable[a]	*Controls (n = 79)*	*Endoleak (n = 64)*	P *value*
Diameter at lowest renal artery, mm	25.6 (5.4)	26.3 (4.8)	.233
Neck length, mm	23.2 (18.2)	26.3 (4.8)	.014[b]
Maximum aneurysm sac diameter, mm	54.3 (17.0)	55.7 (9.6)	.611
Angulation, °			
Suprarenal	14.0 (14.0)	15.0 (12.0)	.277
Infrarenal	25.0 (21.0)	26.0 (23.0)	.824
Infrarenal to bifurcation	35.0 (20.0)	35.5 (20.8)	.873
Neck variables			
Tortuosity index, –	1.05 (0.06)	1.05 (0.06)	.710
Thrombus thickness, mm	0.0 (0.0)	0.0 (0.0)	.153
Thrombus circumference, °	0.0 (0.0)	0.0 (0.0)	.346
Calcification thickness, mm	0.0 (2.0)	1.6 (2.4)	.044[b]
Calcification circumference, °	0.0 (35.0)	14.9 (48.7)	.029[b]
Maximum curvature, m^{-1}			
Aortic neck	31.7 (18.2)	34.1 (18.1)	.037[b]
Suprarenal	18.9 (12.1)	27.0 (17.3)	.018[b]
Juxtarenal	26.3 (18.2)	34.2 (22.3)	.002[b]
Infrarenal	35.0 (20.6)	35.8 (25.9)	.042[b]
Aneurysm sac	41.5 (19.4)	49.3 (27.5)	.001[b]
Terminal aorta	33.3 (27.7)	49.4 (34.9)	<.001[b]
Average curvature, m^{-1}			
Aortic neck	24.2 (16.6)	27.3 (15.8)	.017[b]
Suprarenal	15.1 (8.8)	18.4 (13.7)	.115
Juxtarenal	20.7 (14.4)	25.9 (16.8)	.001[b]
Infrarenal	27.6 (15.8)	27.4 (20.1)	.028[b]
Aneurysm sac	21.6 (10.1)	26.2 (11.4)	<.001[b]
Terminal aorta	22.5 (19.2)	35.3 (21.9)	<.001[b]
Outside IFU, %	36.7	54.7	.032[b]
Type stent graft,			<.001[b]





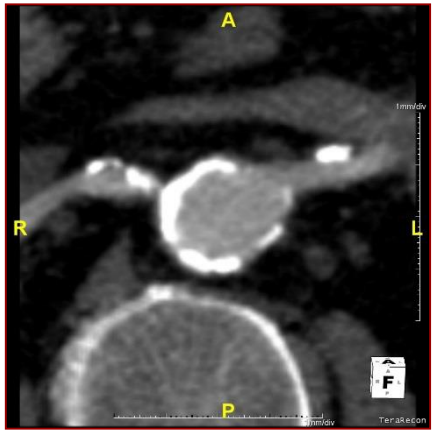
III.Neck Composition: Calcification/Trombus

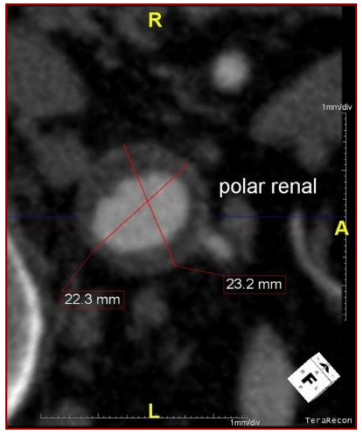
- Inhibits fixation?
- Promotes migration?
- Definition?: Threshold **>2 (3) mm** thick – circumference ***>25%*** (50%) *in at least 3 consecutive slices*

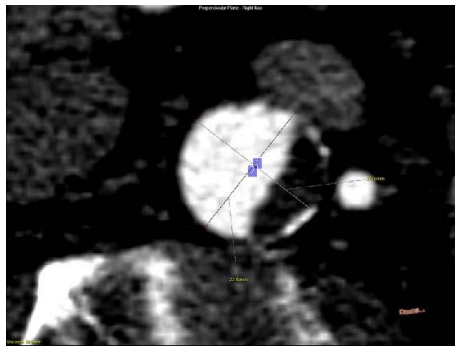
The influence of neck thrombus on clinical outcome and aneurysm morphology after endovascular aneurysm repair

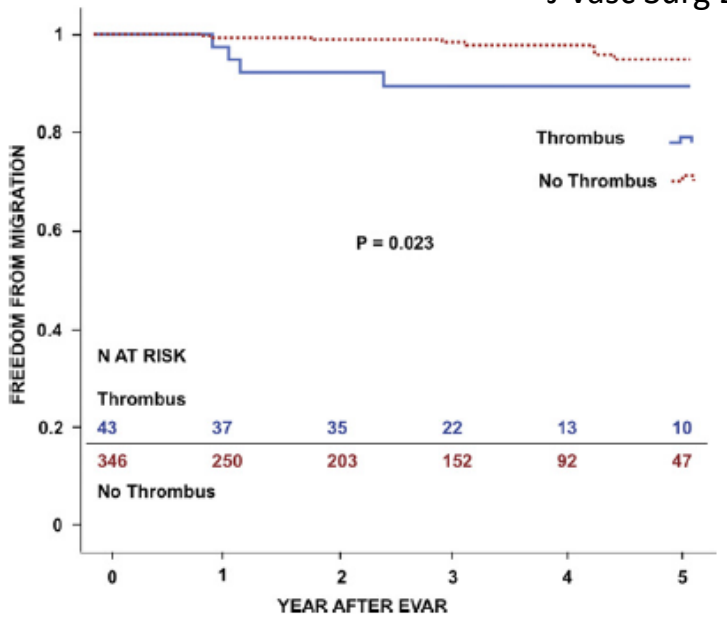
Frederico Bastos Gonçalves, MD,[a,b] Hence J. M. Verhagen, MD, PhD,[a] Khamin Chinsakchai, MD,[c] Jasper W. van Keulen, MD,[c] Michiel T. Voûte, MD,[a] Herman J. Zandvoort, MD,[c] Frans L. Moll, MD, PhD,[c] and Joost A. van Herwaarden, MD, PhD,[c] *Utrecht and Rotterdam, The Netherlands; and Lisbon, Portugal*

J Vasc Surg 2012; 56: 36-44

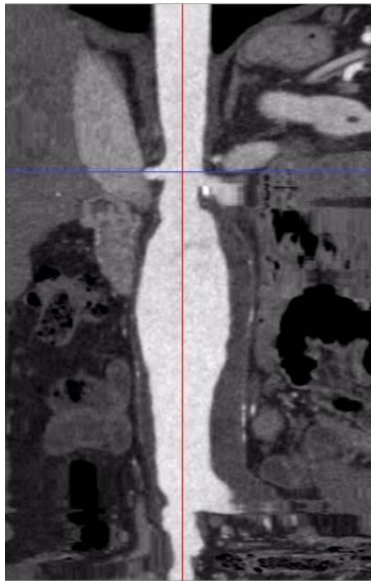








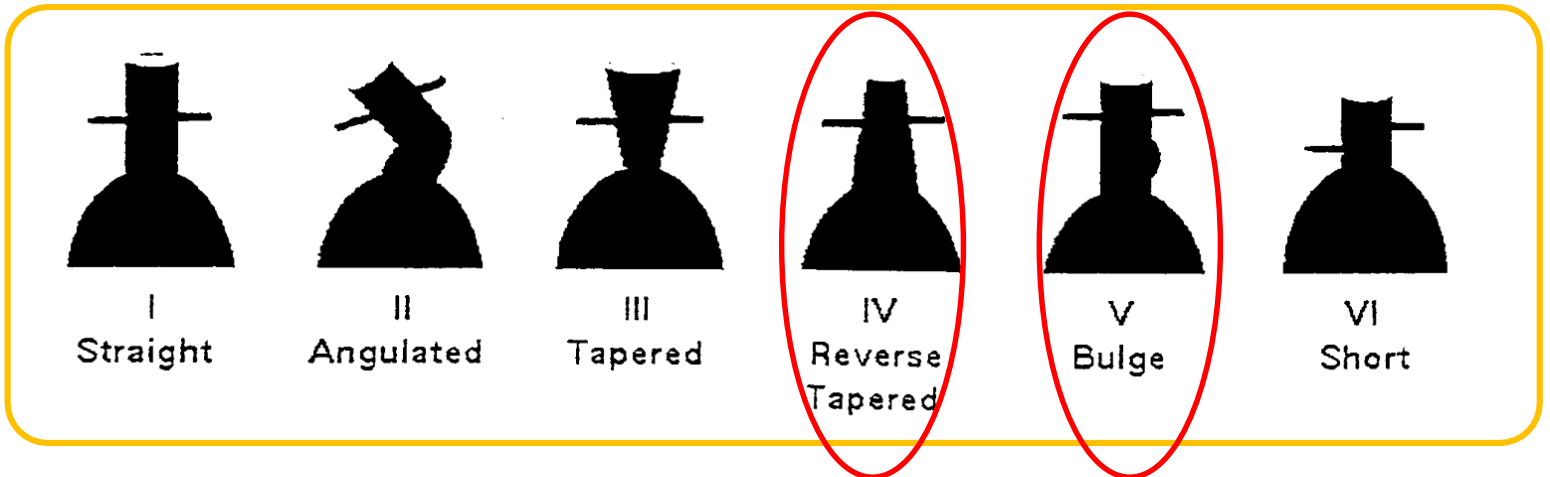
IV. Neck Shape: Conical necks



- Definition ? Gradual neck dilatation >2 (3) mm first 10 mm
- Negatively influences fixation and sealing -> migration

Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

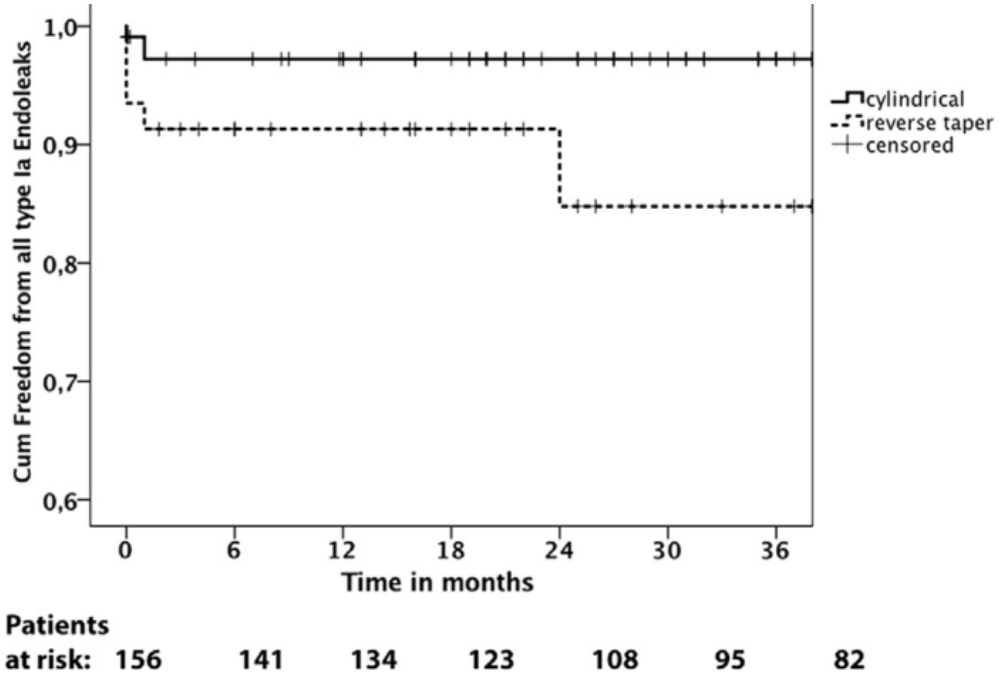
Covariates	Hazard Ratio (95% Confidence Interval)	*P*
Conical neck	1.17 (0.97–1.42)	0.10
Aortic neck angle, °		
<45	Reference	
45–60	1.04 (0.90–1.21)	0.58
>60	1.96 (1.63–2.37)	<0.0001



Conical neck is strongly associated with proximal failure in standard endovascular aneurysm repair

Georgios A. Pitoulias, MD, PhD,[a] Andrés Reyes Valdivia, MD, FEBVS,[b] Suteekhanit Hahtapornsawan, MD,[c,d] Giovanni Torsello, MD, PhD,[c] Apostolos G. Pitoulias, MD,[a] Martin Austermann, MD,[c] Claudio Gandarias, MD, PhD,[b] *and* Konstantinos P. Donas, MD, PhD,[c] *Thessaloniki, Greece; Madrid, Spain; Münster, Germany; and Bangkok, Thailand*

J Vasc Surg 2017; 66: 1686-95



- N= 156 EVAR neck <15 mm
- Endurant
- Mean FU 41 Months
- Primary outcome: Type IA endoleak 5.8%
  - Intraop - 4 (2 cuff, 1 palmaz, 1 coiling)
  - 1 month: 3 (2 cuff)
  - 2 years: 2 (2 palmaz)

- Multiple regression and cox regression: ***conical neck (>2 mm) (P<0.012)***

V. Neck Diameter – Large >32 or >28 mm?

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

Covariates	Hazard Ratio (95% Confidence Interval)	*P*
Aortic neck diameter		
Diameter at lowest renal artery <28 mm	Reference	
Diameter at lowest renal artery 28–32 mm	1.80 (1.44–2.23)	<0.0001
Diameter at lowest renal artery >32 mm	2.07 (1.46–2.92)	<0.0001

2013

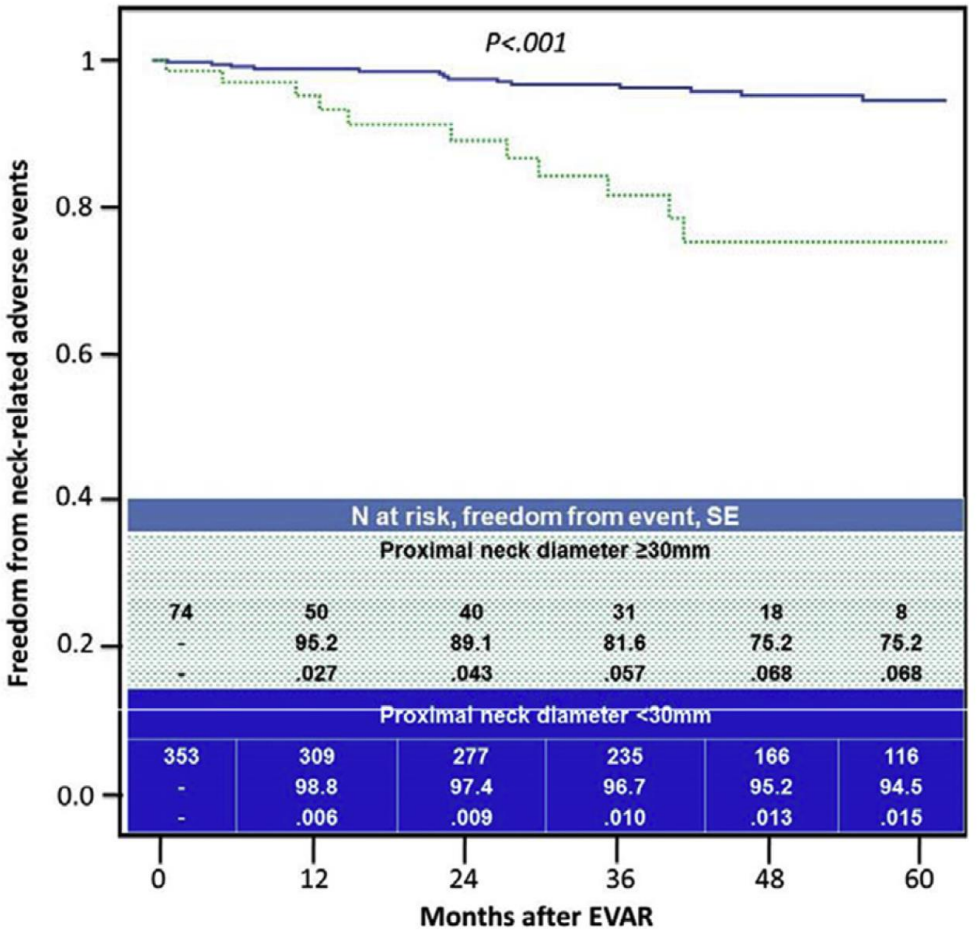
2016

Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events

Nelson F. G. Oliveira, MD,[a,b] Frederico M. Bastos Gonçalves, MD, PhD,[a,c] Marie Josee Van Rijn, MD, Quirina de Ruiter, MSc,[d] Sanne Hoeks, PhD,[e] Jean-Paul P. M. de Vries, MD, PhD,[f] Joost A. van Herwaarden, MD, PhD,[d] *and* Hence J. M. Verhagen, MD, PhD,[a] *Rotterdam, Nieuwegein and Utrecht, The Netherlands; and Azores and Lisbon, Portugal*

J Vasc Surg 2017; 65(6): 1608-16

- 427 patients – N=74 neck ***≥ 30 mm***
- Neck-related AE at 4 yrs.: 25% vs. 5%
- Type 1a endoleak: 9.5% vs. 2.8%
- Neck-related secondary interventions: 9.5 vs 3.7%



Late graft explants in endovascular aneurysm repair

Eric J. Turney, MD, Sean P. Steenberge, MS, Sean P. Lyden, MD, Matthew J. Eagleton, MD, Sunita D. Srivastava, MD, Timur P. Sarac, MD, Rebecca L. Kelso, MD, and Daniel G. Clair, MD,
Cleveland, Ohio

Objective: With more than a decade of use of endovascular aneurysm repair (EVAR), we expect to see a rise in the number of failing endografts. We review a single-center experience with EVAR explants to identify patterns of presentation and understand operative outcomes that may alter clinical management.
Methods: A retrospective analysis of EVARs requiring late explants, >1 month after implant, was performed. Patient demographics, type of graft, duration of implant, reason for removal, operative technique, length of stay, complications, and in-hospital and late mortality were reviewed.
Results: During 1999 to 2012, 100 patients (91% men) required EVAR explant, of which 61 were placed at another institution. The average age was 75 years (range, 50-93 years). The median length of time since implantation was 41 months (range, 1-144 months). Explanted grafts included 25 AneuRx (Medtronic, Minneapolis, Minn), 25 Excluder (W. L. Gore & Associates, Flagstaff, Ariz), 17 Zenith (Cook Medical, Bloomington, Ind), 15 Talent (Medtronic), 10 Ancure (Guidant, Indianapolis, Ind), 4 Powerlink (Endologix, Irvine, Calif), 1 Endurant (Medtronic), 1 Quantum LP (Cordis, Miami Lakes, Fla), 1 Aorta Uni Iliac Rupture Graft (Cook Medical, Bloomington, Ind), and 1 homemade tube graft. Overall 30-day mortality was 17%, with an elective case mortality of 9.9%, nonelective case mortality of 37%, and 56% mortality for ruptures. Endoleak was the most common indication for explant, with one or more endoleaks present in 82% (type I, 40%; II, 30%; III, 22%; endotension, 6%; multiple, 16%). Other reasons for explant included infection (13%), acute thrombosis (4%), and claudication (1%). In the first 12 months, 23 patients required explants, with type I endoleak (48%) and infection (35%) the most frequent indication. Conversely, 22 patients required explants after 5 years, with type I (36%) and type III (32%) endoleak responsible for most indications.
Conclusions: The rate of EVAR late explants has increased during the past decade at our institution. Survival is higher when the explant is done electively compared with emergent repair. Difficulty in obtaining a seal at the initial EVAR often leads to failure ≤1 year, whereas progression of aneurysmal disease is the primary reason for failure >5 years. (J Vasc Surg 2014;59:886-93.)

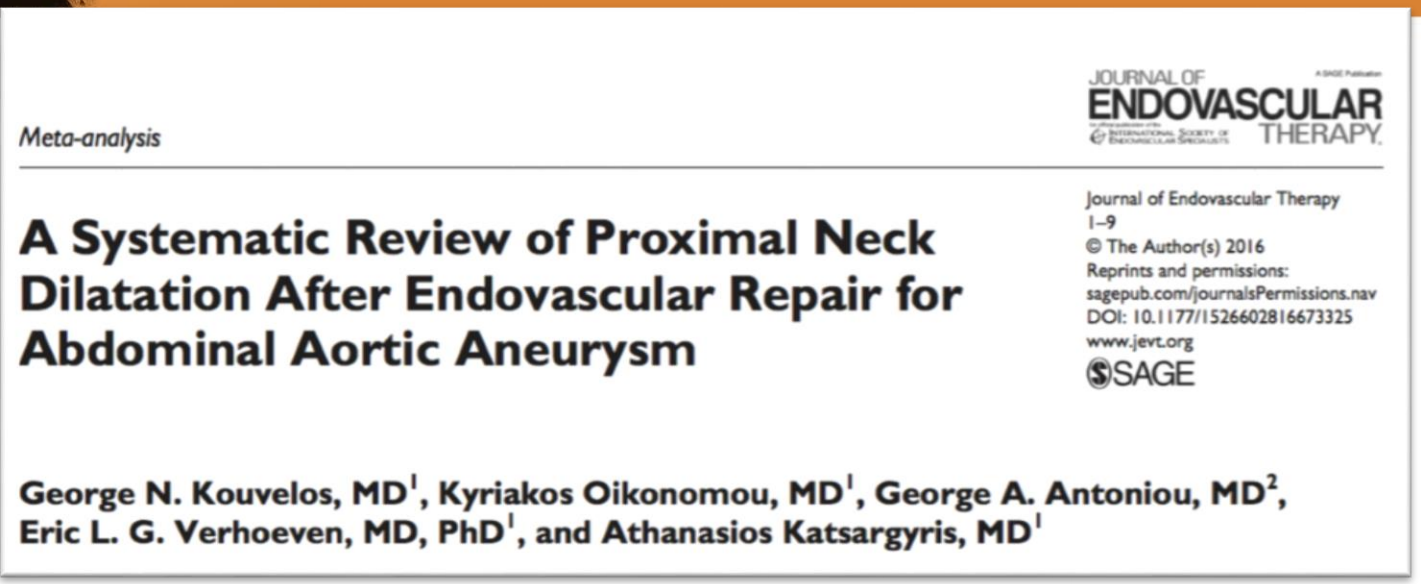
J Vasc Surg 2014; 59: 886-93

82% of patients had one or more endoleak

Type 1 (40), Type 2 (30), Type 3 (22), Type 5 (6)

30 Day mortality – 17%

	1 year N (%)	1-5 years N (%)	>5 years N (%)
Type I endoleak	11 (38)	19 (35)	8 (36)
Initial seal	7	5	1
Migration	3	4	1
Disease progression	1	10	6



Meta-analysis

JOURNAL OF ENDOVASCULAR THERAPY

A Systematic Review of Proximal Neck Dilatation After Endovascular Repair for Abdominal Aortic Aneurysm

Journal of Endovascular Therapy
1–9

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www.jevt.org
SAGE

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- 1991 – Sept 2015
- N= 26 studies
- N= 9721 pts., 71.8 yrs.
- AND vs. no AND: 26% vs. 2% clinical events

Neck Dilatation

- Definition AND >2, >2.5, >3 mm increase
- Measurement – 1, 2, 3, 4 points
- Time intervals? T_0 – **T_1** vs. T_{FU}
- FU 15 Mo – 9 Yrs.
- **24.6% AND**
- **Predisponing factors?**

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

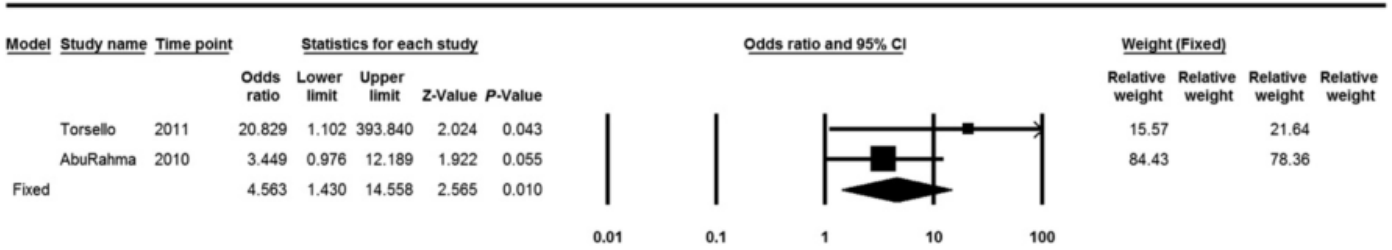
George A. Antoniou, MD, PhD,[a] George S. Georgiadis, MD,[b] Stavros A. Antoniou, MD,[c] Ganesh Kuhan, MD, FRCS,[a] and David Murray, MD, FRCS,[a] *Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany*

J Vasc Surg 2013; 57: 527-38

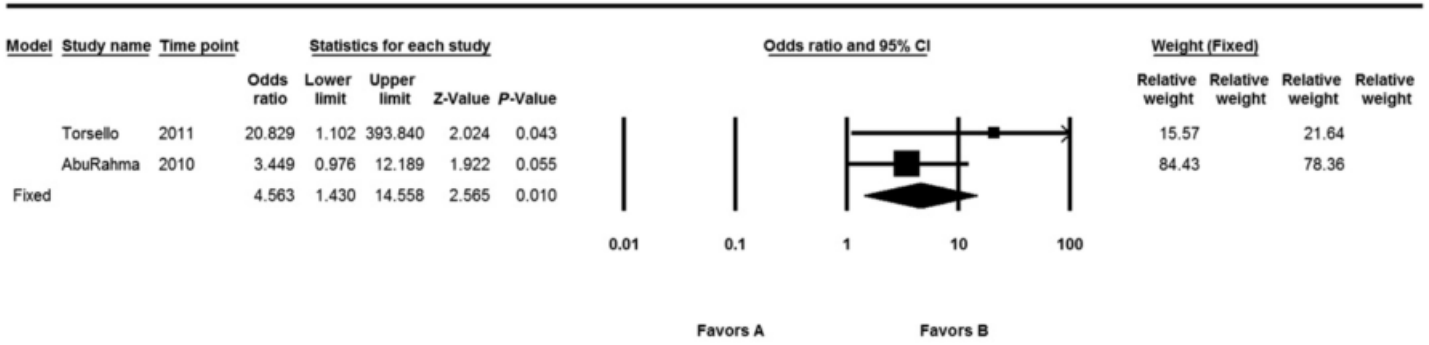
7 studies

1559 pts: 845 FNA, 714 HNA

Definition HNA varied



Type IA endoleak at 1 yr:
4.5 times higher



Aneurysm-related mortality at 1 yr:
9 times higher

Endovascular Aortic Aneurysm Repair in Patients with Hostile Neck Anatomy

Philip W. Stather, MRCS; John B. Wild, MRCS; Robert D. Sayers, MD, FRCS; Matthew J. Bown, MD, FRCS; and Edward Choke, FRCS, PhD

J Endovasc Ther 2013; 20: 623-37

16 studies

8920 FNA – 3039 HNA

	Favorable/ Hostile Neck	Criteria for Hostile Neck Anatomy					
		Length, mm	Diameter, mm	Angulation, °	Thrombus	Taper	Other
Greenberg 2000[26]	42/13	<10	N/A	N/A	N/A	N/A	N/A
Sternbergh 2002[24]	71/10	N/A	N/A	>60	N/A	N/A	N/A
Dillavou 2003[30]	115/91	<10	N/A	>60	>50%	>2-mm reverse	Focal bulge in neck >3 mm
Greenberg 2003[29]	352/141	<15	>28	>60	N/A	N/A	Aortoiliac tortuosity (≥2 90° angulations), iliac diameter <8 mm, inability to preserve IIA
Fairman 2004[27]	71/166	<15	>28	>45	>50%	N/A	N/A
Fulton 2006[12]	59/25	<15	>25	>45	N/A	N/A	N/A
Choke 2006[31]	87/60	<10	>28	>60	>50%	N/A	N/A
Leurs 2006[21]	2822/G2: 485, G3: 192	G2: 11–15; G3: ≤10	N/A	N/A	N/A	N/A	N/A
Hobo 2007[9]	4031/1152	N/A	N/A	>60	N/A	N/A	N/A
Abbruzzese 2008[7]	343/222	DS	DS	DS	DS	DS	N/A
AbuRahma 2009[8]	195/G2: 24, G3: 17	G2: 10–15; G3: <10	N/A	N/A	N/A	N/A	N/A
Georgiadis 2011[25]	43/34	<12	N/A	>60	N/A	N/A	Iliac axis >60°
Hoshina 2011[28]	80/49	<15	N/A	>60	N/A	N/A	N/A
Torsello 2011[33]	121/56	<10	N/A	>60	N/A	N/A	N/A
AbuRahma 2011[34]	89/149	<10	>28	>60	>50%	Reverse	>50% calcified neck
Stather 2012[6]	353/199	<15	>28	>60	>50%	Reverse	N/A

Hostile Neck =

Length <15 mm, Angulation>60° and Diameter >28 mm

Outcome	N	Hostile Neck	Favorable Neck	Odds Ratio	P
30d Mortality	5	771 (1.4%)	1224 (1.5%)	0.86 (0.38, 1.95)	0.72
Late aneurysm related mortality	2	421 (6.7%)	696 (0.9%)	8.82 (0.05, 1,428)	0.40
Primary Technical Success	2	***259 (93.8%)***	***440 (97.5%)***	***0.41*** (0.18, 0.93)	***0.03***
Intraoperative adjuncts	2	***209 (21.1%)***	***176 (9.7%)***	***2.43*** (1.31; 4.54)	***<0.01***
Sac Expansion	3	408 (8.1%)	529 (10.2%)	0.86 (0.53, 1,39)	0.55
30d Migration	2	421 (2.1%)	696 (2.3%)	0.95 (0.42, 2.19)	0.91
Aortic rupture	2	***421 (2.6%)***	***696 (0.9%)***	***3.16*** (1.16, 8.63)	***0.02***
Secondary intervention	5	771 (11.9%)	1224 (9.8%)	1.16 (0.83, 1.62)	0.39
Early Type I	3	149 (12.1%)	529 (0.9%)	2.28 (0.76, 6.82)	0.14
Late Type I	3	***408 (9.6%)***	***529 (4.9%)***	1.92 (1.14, 3.23)	**0.01**

Aortic Neck Anatomic Features and Predictors of Outcomes in Endovascular Repair of Abdominal Aortic Aneurysms Following vs Not Following Instructions for Use

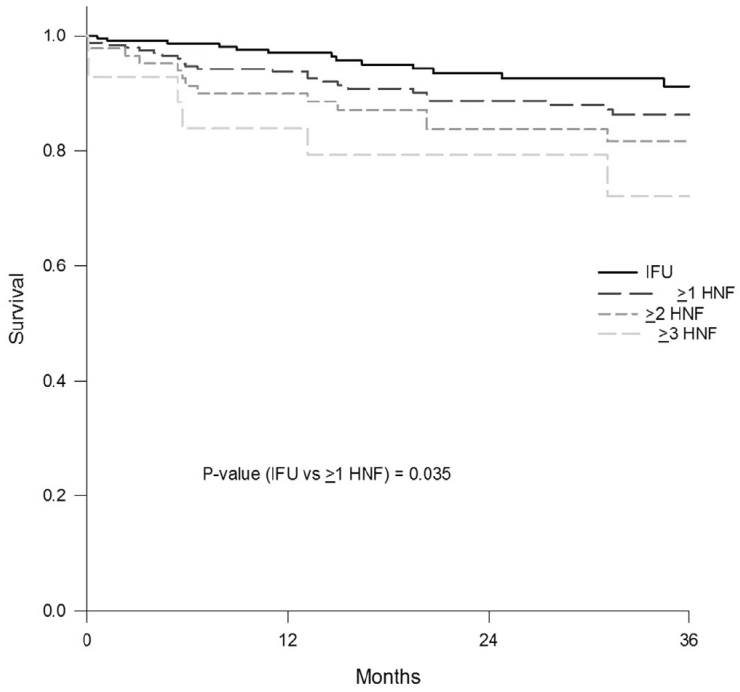
Ali F AbuRahma, MD, FACS, Michael Yacoub, MD, Albeir Y Mousa, MD, FACS, Shadi Abu-Halimah, MD, FACS, Stephen M Hass, MD, FACS, Jenna Kazil, MD, Zachary T AbuRahma, DO, Mohit Srivastava, MD, L Scott Dean, PhD, MBA, Patrick A Stone, MD, FACS

J Am Coll Surg 2016; 222: 579-89

	Outside IFU N = 275/526	
	N	%
Neck angle >60°	49	18
Neck length < 10 mm	35	13
Neck diameter >31 mm	16	6
Neck Calcium ≥ 50%	51	19
Neck Trombus ≥ 50%	135	49
Reverse taper	133	48

	IFU (n = 251)		Outside IFU (n = 275)		
Endoleak/intervention	n	%	n	%	p Value
Early type I	18	7	50	18	0.0002
All early endoleak and type					
0	177	71	176	64	
1	18	7	50	18	
2	52	21	47	17	
4	4	2	2	0.7	
Aortic proximal cuff	13	5	43	16	0.0001
Proximal aortic stent	12	5	20	7	0.2324
All early intervention	25	10	66	24	< 0.0001
Late type I endoleak	5	2	14	6	0.0477
All late endoleak and type					
0	191	80	212	83	
1	5	2	14	6	
2	44	18	27	11	
3	0	–	1	0.4	
Late intervention	9	4	14	6	0.3529
Sac expansion	17	7	14	6	0.4716

IFU, instructions for use.



IFU			1+ HNF			2+ HNF			3+ HNF		
N	%	SE	N	%	SE	N	%	SE	N	%	SE
174	97	1.2	171	93.7	1.63	65	90	3.37	18	84	7.4
104	93.5	1.93	118	88.8	2.3	45	83.8	4.33	13	79.3	8.33
62	89.8	2.86	91	86.3	2.65	32	81.7	4.72	7	72.1	10.2

Conclusions

- Categorization infrarenal aortic neck already EXISTS!!!
  - ***Standardized*** definitions, measurement and reporting outcomes
  - Add aortic curvature?

- ***High Quality*** and ***Validated Large*** Registries !!!
- Individual decision making – focus on a landing zone within "normal" morphological aorta = "THE" treatment goal!!!!