

# Understanding anatomical complexity and strategies to treat it

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## Disclosure

Speaker name: **Mauro Gargiulo**

**X I have the following potential conflicts of interest to report:**

- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company-sponsored speaker bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

**X Principal Investigator Expand Registry VBX 17-04**

**X Consulting : Cook Medical, WL Gore & Associates, Medtronic**



# EVAR - Challenging aortic anatomy



**neck**

aneurysm

iliac arteries



# Aortic Neck Anatomic Features and Predictors of Outcomes in EVAR



## Results: anatomical neck features related to the end points

- **Pts:** **594**
- Mean age: 75 years ( $\pm 7$ )
- AAA mean diameter: 57 mm ( $\pm 11$ )
- **AAA neck morphology**
  - diameter (mean): 23 $\pm$ 3 (> 28 mm: 22%)
  - length (mean): 21 $\pm$ 1 (<10 mm: 3.7%, < 15 mm 27%)
  - angle > 60°: 122 (20%)
  - thrombosis - calcification: 84 (14%) – 15 (2.5%)
  - tapered - reversed tapered: 12 (2%) – 66 (11%)
  - Chaickof score 3 (Severe): 231 (39%)

End-points	Univariate analysis	Multivariate analysis
<b>Intraoperative cuff</b>	Length < 15 mm Angle > 60° Chaickof 3	Length < 15 mm <b>Angle &gt; 60°</b> ←
<b>Technical success</b>	Angle > 60° Tapered neck Chaickof 3	<b>Angle &gt; 60°</b> ← Tapered neck
<b>EL Type IA (follow up)</b>	Length < 15 mm Diameter > 28 mm Tapered neck Reversed tapered neck Angle > 60° Chaickof 3	Length < 15 mm Tapered neck Reversed tapered neck Diameter > 28 mm
<b>REDO (follow up)</b>	Angle > 60° Tapered neck Reversed tapered neck	<b>Angle &gt; 60°</b> ← Tapered neck Reversed tapered neck

# Manufacturers' device IFU

## AAA neck

	Length (mm)	Diameter (mm)	Angle (infrarenal)	Calcifications Thrombosis
<b>Terumo - Anaconda</b>	$\geq 15$	17.5 - 31	$\leq 90^\circ$	non-significant
<b>Terumo - Treo</b>	$\geq 10$ $\geq 15$	17 - 32 <b>16 - 30</b>	$\leq 60^\circ$ <b><math>60^\circ - 75^\circ</math></b>	<b>non-significant</b>
<b>Gore - Excluder</b>	$\geq 15$	19 - 29	$\leq 60^\circ$	< 2mm and/or <25% circumference
<b>Medtronic - Endurant IIs</b>	4-10 (+Heli-FX) $\geq 10$ $\geq 15$	<b>19 - 32</b>	$\leq 60^\circ$ $\leq 60^\circ$ <b><math>60^\circ - 75^\circ</math></b>	<b>insignificant</b>
<b>Cook - Alpha Abdominal</b>	$\geq 15$	18 - 32	< $60^\circ$	< 50%



# Manufacturers' device IFU

## AAA neck

	Length (mm)	Diameter (mm)	Angle (infrarenal)	Calcifications Thrombosis
<b>Terumo - Anaconda</b>	≥ 15	17.5 - 31	≤ 90°	non-significant
<b>Terumo - Treo</b>	≥ 10	17 - 32	≤ 60°	non-significant
	≥ 15	16 - 30	60° - 75°	
<b>Gore - Excluder</b>	<b>≥ 15</b>	<b>19 - 29</b>	<b>≤ 60°</b>	<b>&lt; 2mm and/or &lt;25% circumference</b>
<b>Medtronic - Endurant IIs</b>	4-10 (+Heli-FX)	19 - 32	≤ 60°	insignificant
	≥ 10		≤ 60°	
	≥ 15		60° - 75°	
<b>Cook - Alpha Abdominal</b>	≥ 15	18 - 32	< 60°	< 50%



# Manufacturers' device IFU

## AAA neck

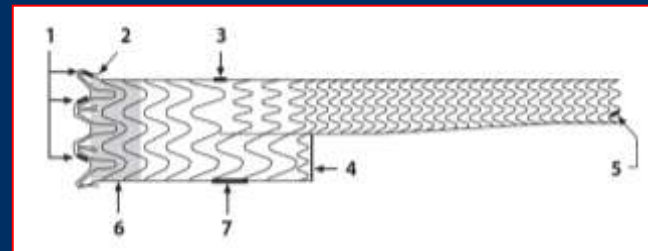
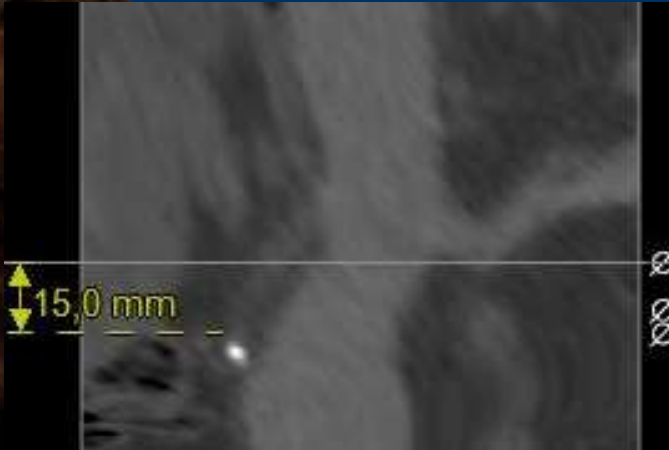
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<b>Gore - Excluder</b>	<b>≥ 15</b>	<b>19 - 29</b>	<b>≤ 60° / 60°-90° (?)</b>	<b>&lt; 2mm and/or &lt;25% circumference</b>
<b>Medtronic - Endurant IIs</b>	4-10 (+Heli-FX)	19 - 32	≤ 60°	insignificant
	≥ 10		≤ 60°	
	≥ 15		60° - 75°	
<b>Cook - Alpha Abdominal</b>	≥ 15	18 - 32	< 60°	< 50%





*AAA with severe neck angle (> 60°)*

EVAR with GORE® EXCLUDER® AAA Endoprosthesis (outside IFU)



Aortic Neck 3





# AAA – EVAR with GORE® EXCLUDER® AAA Endoprosthesis

- ✓ Prospective, monocentre
- ✓ 2011 – 2018
- ✓ AAA – EVAR
- ✓ GORE Excluder C3

## AIM

1. Overall experience
2. Results severe  $\beta$ -angle ( $\geq 60^\circ$ ) vs mild/moderate  $\beta$ -angle ( $< 60^\circ$ )



# AAA – EVAR with GORE® EXCLUDER® AAA Endoprosthesis

## Results - @ 30 - day

<b>End Points</b>	$\beta$ - Angle <b>severe (51 – 31%)</b>	$\beta$ - Angle <b>mild-moderate (116 - 69%)</b>	<b>p</b>
Repositionability (R)	45 %	18 %	.000
Proximal Oversize	30 %	18 %	.02
Proximal cuff (CP)	8 %	1 %	.03
Renal artery lost (RAL)	4 %	-	.09
Endoleak I A (ELIA)	4 %	-	.09
Composit Endpoint (almost one among CP/RAL/ELIA)	10 %	1 %	.01

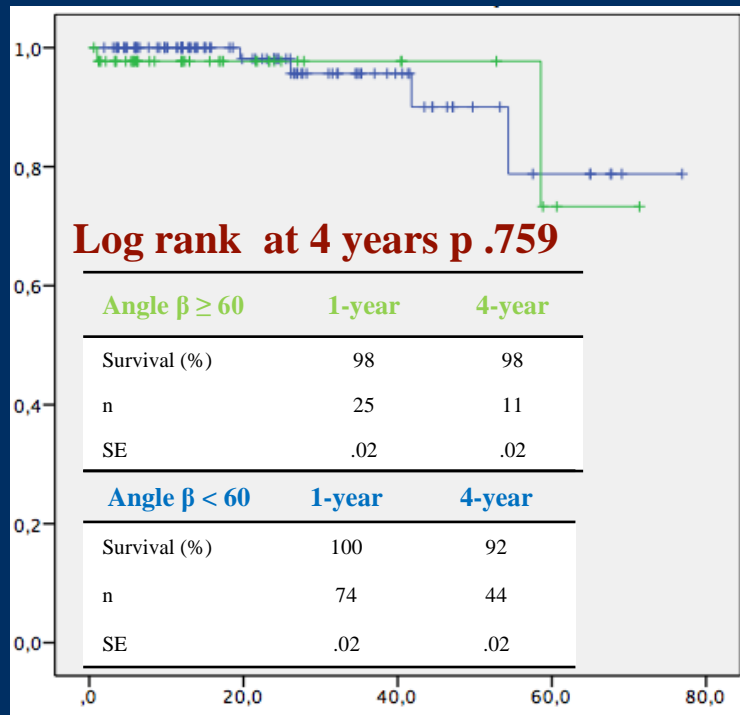


# AAA – EVAR with GORE® EXCLUDER® AAA Endoprosthesis

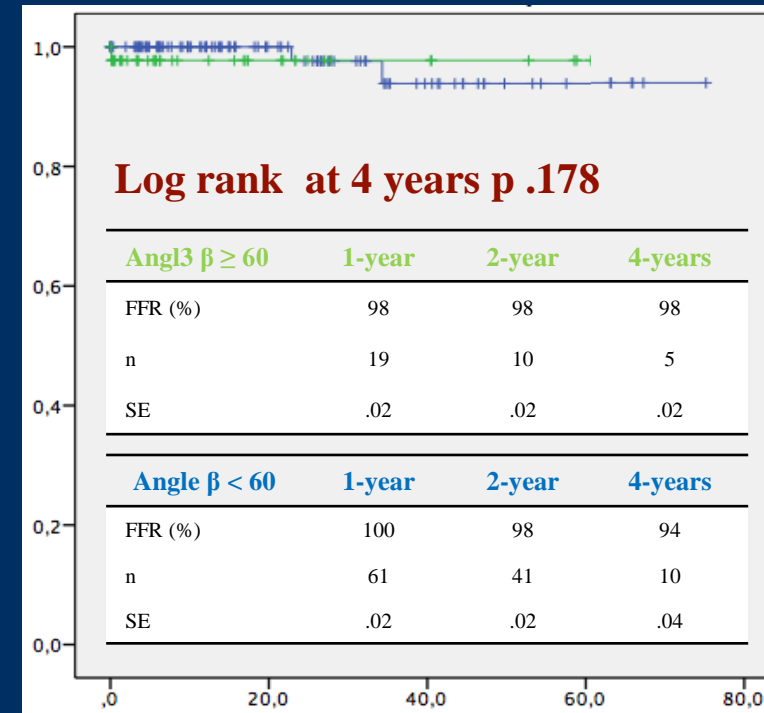
## Results – Follow up

	$\beta$ - Angle <b>Severe</b>	$\beta$ - Angle <b>mild-moderate</b>	p
<b>AAA-shrinkage (&gt;5mm)</b>	57%	54%	.86
<b>Endoleak IA</b>	4%	3%	1

### Survival



### Freedom from reintervention



# AAA – EVAR with GORE® EXCLUDER® AAA Endoprosthesis

*Severe  $\beta$ -angle ( $\geq 60^\circ$ ) vs mild/moderate  $\beta$ -angle ( $< 60^\circ$ )*

## Take Home Message

EVAR with repositionable endograft in **infrarenal fixation** with **severe  $\beta$  angle**:

- technically demanding  
(repositioning, cuffs, composite endpoint)
- no differences at mid-term vs mild to moderate  $\beta$  angle



# GORE® EXCLUDER® Conformable AAA Endoprosthesis

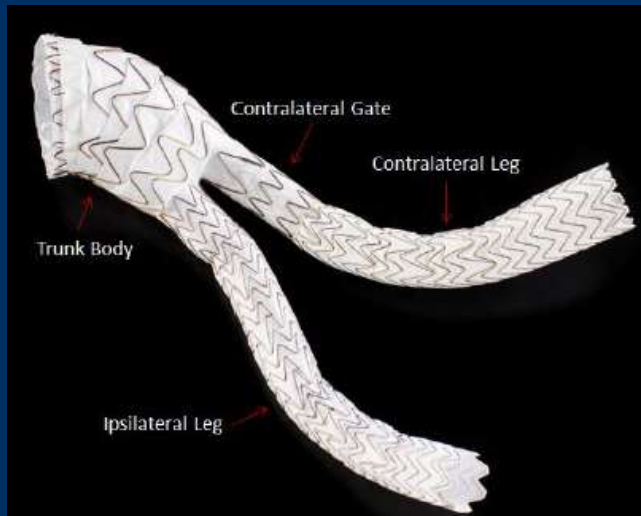


## Design inputs:

- 16 Fr for most trunks
- Ability to conform to proximal neck angles up to 90° similar to CTAG technology
- Achieve seal in short ( $\geq 10$  mm) proximal necks
- Ability to reposition the device
- Mechanism to control device angulation
  - Fully constrained and partially deployed
  - Orthogonal positioning



# GORE® EXCLUDER® **Conformable** AAA Endoprosthesis



**Table A. Anatomic measurement table and group specific**

	≥15 mm neck length	10-14 mm neck length	5-9 mm neck length	<5 mm neck length
≤60° neck angulation	Inside IFU	Inside IFU	Challenging Anatomy Cohort	Challenging Anatomy Cohort
61-90° neck angulation	Inside IFU	Designed for/ Under investigation	Challenging Anatomy Cohort	Challenging Anatomy Cohort
>90° neck angulation	Challenging Anatomy Cohort	Challenging Anatomy Cohort	Challenging Anatomy Cohort	Challenging Anatomy Cohort



# Treat a broad range of patients within IFU

	Standard neck <sup>*</sup>	Angulated neck <sup>†</sup>	Short neck <sup>‡</sup>	Small diameter neck <sup>§</sup>	Aorto-iliac Aneurysms <sup>  </sup>
<b>GORE® EXCLUDER®</b> Device family					
<b>MEDTRONIC ENDURANT®</b> Abdominal Stent Graft					
<b>COOK® ZENITH®</b> Endovascular System					

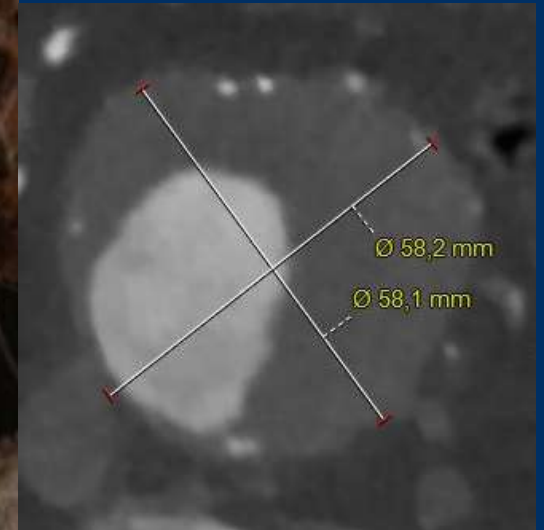
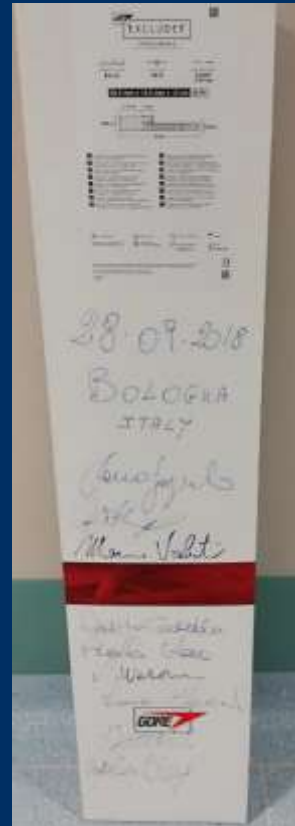
\* Standard neck > 15 mm - up to 60°.  
† Angulated neck up to 90°.  
‡ Short neck down to 10 mm.  
§ Small diameter neck down to 16 mm.  
|| On label option for Common Iliac diameters larger than 25 mm. Common Iliac Artery (CIA) Aneurysms are treatable with a bell bottom limb up to 25 mm; with this treatment higher rate of complications during follow-up are reported (vs the use of Iliac Branch Devices). Please note that Society Guidelines define aneurysmatic any CIA ≥ 18mm in men and ≥ 15mm in women. GORE® EXCLUDER® Iliac Branch Endoprosthesis is indicated for CIA larger than 17 mm.



# Gore® EXCLUDER® Conformable AAA Endoprosthesis

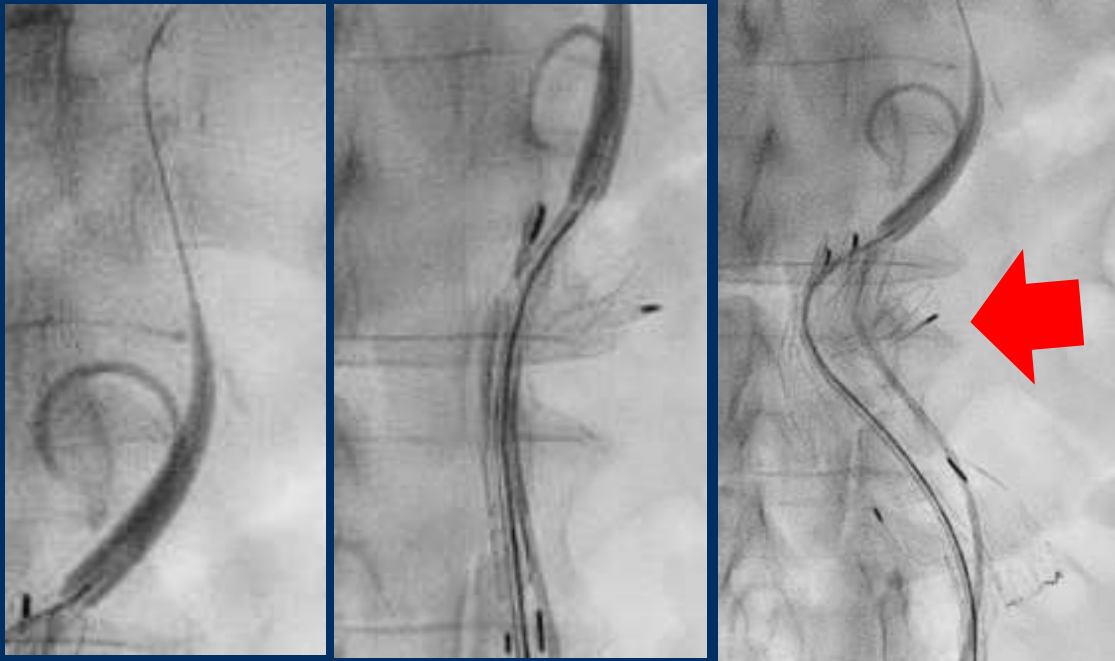
#1, T.L., f, 81 years

- Hypertension
- Dyslipidemia
- History of breast cancer
- AAA 58 mm
- ASA III
- Creatinine 1.3 mg/dl  
(VFG 37 ml/min)

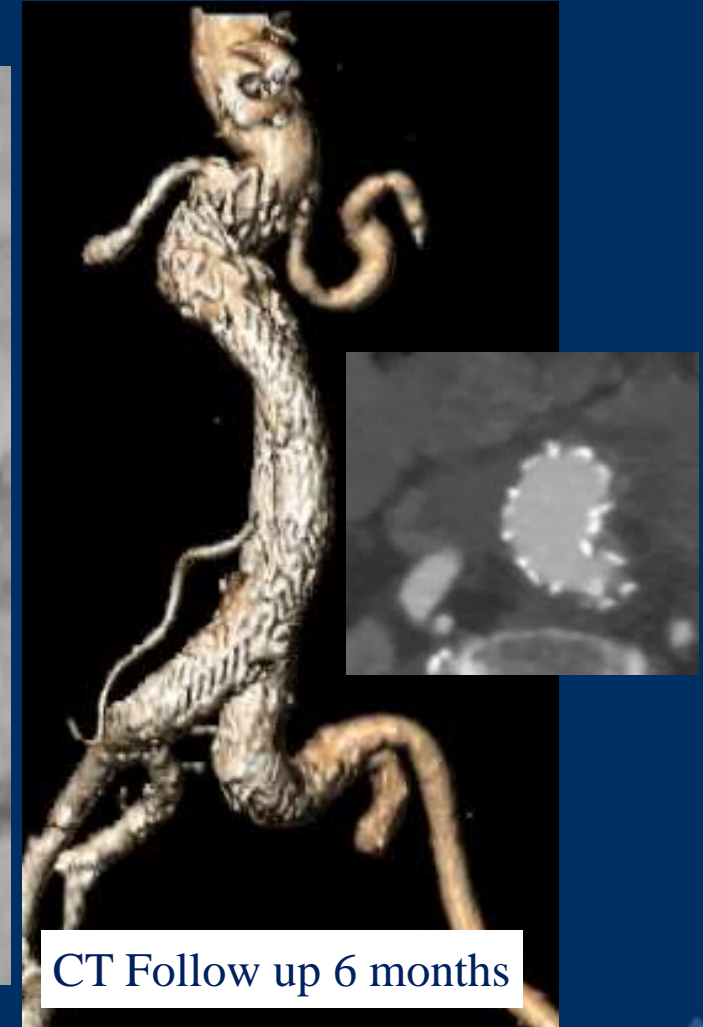
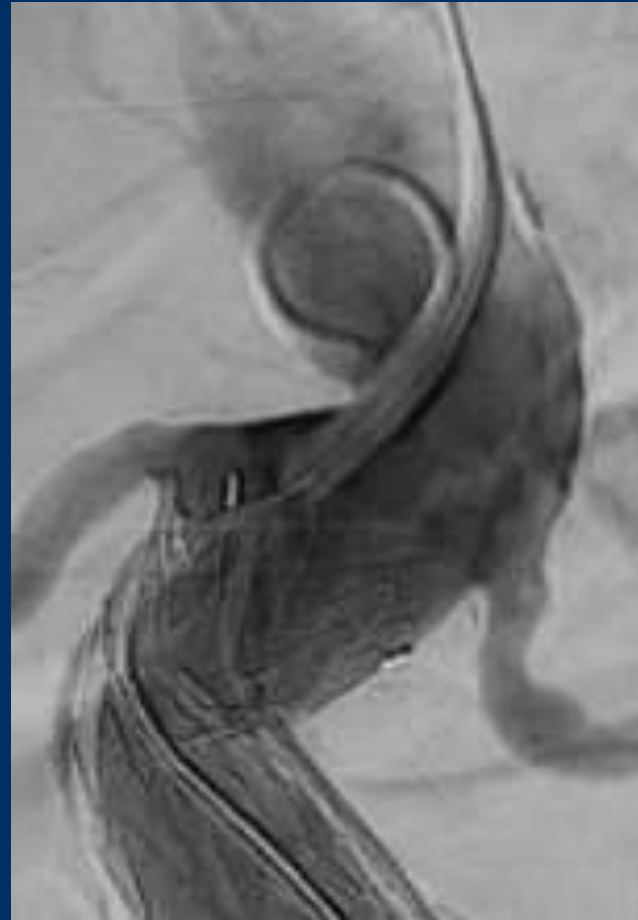


# GORE® EXCLUDER® Conformable AAA Endoprosthesis

#1, T.L., f, 81 years



Retracted  
Terumo stiff



CT Follow up 6 months



# GORE® EXCLUDER® **Conformable** AAA Endoprosthesis

- ✓ Prospective, monocentre
- ✓ September 2018 – December 2020
- ✓ AAA – EVAR
- ✓ GORE Excluder Conformable

## 26 EVAR

### GORE Excluder Conformable

Demographics	n	%
Sex (m)	18	69
Hpt	26	100
CIC	12	46
COPD	9	35
POAD	0	-
CRF	12	46
Active smoke	2	8
BMI > 30	3	11
ASA score ≥ 3	26	100
AOT	3	11
Double Ag	0	-
Statin therapy	21	81
	median	IQR
Age (y)	80	11
AAA diameter	60	12.5



# GORE® EXCLUDER® **Conformable** AAA Endoprosthesis

## Results – Infrarenal Neck Morphology

	median	IQR
Length (mm)	21	10
Diameter (mm)	22	2.6
	n	%
Length < 15 mm	2	8
Diameter > 28 mm	2	8
<b>β-angle ≥ 60°</b>	<b>26</b>	<b>100</b>
Calcification ≥ 50%	2	8
Thrombus ≥ 50%	4	15



# GORE® EXCLUDER® **Conformable** AAA Endoprosthesis

## Results – 30 days

	n	%		Morbidity	n	%
ELI/III	0	-		Cardiac	2	8
Renal artery coverage	0	-		Pulmonary	0	-
OR conversion	0	-		Renal Worsening*	1	4
Mortality	0	-				
<b>Technical Success</b>	<b>26</b>	<b>100</b>				

\*: GFR > 30% of the baseline value



# GORE® EXCLUDER® **Conformable** AAA Endoprosthesis

## Results – Follow up

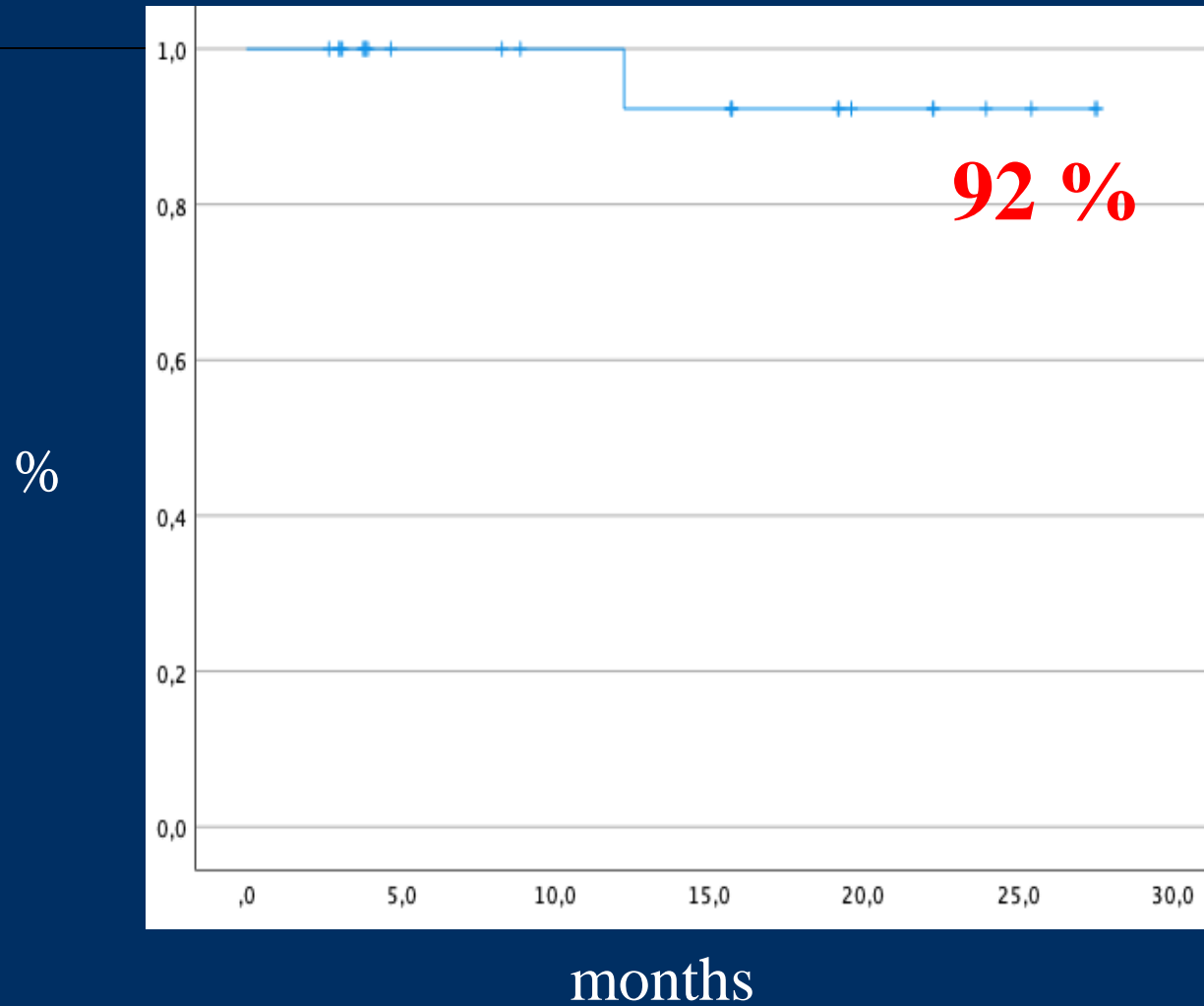
- Median : 11 months
- Range: 1 - 28 months

<b>F/up ≥ 6 months 16 pts</b>	<b>n</b>	<b>%</b>
ELI-III	0	0
ELII	2	12.5
Re-interventions	0	0
AAA-related mortality	0	0
AAA sac shrinkage	10	62.5



# GORE® EXCLUDER® Conformable AAA Endoprosthesis

## Results – Survival







# Vascular Surgery – Bologna University, Italy

## 2021

AAA neck lenght	Treatment
<b>&gt; 1.5 cm</b> angle < 60° angle ≥ 60°	<b>Repositionable delivery – GORE® EXCLUDER® AAA Endoprosthesis</b> <b>Repositionable delivery – GORE® EXCLUDER® <u>Conformable</u> AAA</b>
<b>1.5 – 1.0 cm</b> angle < 60° angle ≥ 60°	<b>Repositionable delivery – GORE® EXCLUDER® <u>Conformable</u> AAA, Endograft with suprarenal fixation</b> <b>Repositionable delivery – GORE® EXCLUDER® <u>Conformable</u> AAA, Surgery</b>
<b>1.0 - 0.7 cm</b> angle < 60° angle ≥ 60°	Fenestrated Endograft, Endograft with suprarenal fixation+Heli-FX, Chimney Surgery, Chimney
<b>≤ 0.7 cm</b> angle < 60° angle ≥ 60°	Fenestrated Endograft Surgery, Chimney