


One-Year Outcomes Of The Fenestrated Anaconda (Terumo Aortic) Endograft For Treating Complex AAAs From The GLOBAL FACT Study: What Makes This Endograft Different: Advantages And Limitations

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Disclosures




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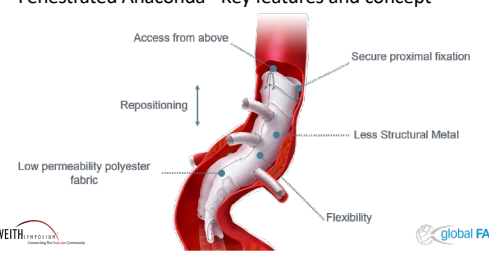




Fenestrated Anaconda - Anatomical prerequisites

- Suitable landing zone with non-significant calcification and/or non-significant thrombus
- Native proximal aortic diameters 17.5-32.5 mm
- Aortic angulation in the region of the proximal landing zone $\leq 90^\circ$
- Adequate iliac or femoral vessel access
- Minimum native iliac artery diameters 8.5 mm
- Distal fixation length of ≥ 20 mm

Fenestrated Anaconda - Key features and concept




GLOBAL FACT - Multicenter prospective registry

Global Fenestrated Anaconda™ Clinical Study

Enrollment Sites	% (n/N)
Arnhem, NL	22.3% (23/103)
Calgary, CA	4.9% (5/103)
Enschede, NL	5.8% (6/103)
Frimley Park, UK	24.3% (25/103)
Groningen, NL	6.8% (7/103)
London Imperial, UK	6.8% (7/103)
Melbourne, AU	1.0% (1/103)
Newcastle, UK	5.8% (6/103)
Newengton, NL	2.9% (3/103)
Perth Hollywood, AU	1.0% (1/103)
Vienna, AT	18.4% (19/103)



A total of **11 sites enrolled 103 subjects** in the **Global FACT** registry

Current Countries: Australia, Austria, Canada, France, Italy, Netherlands, UK

GLOBAL FACT - Key selection criteria



Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Patient has a juxtarenal or suprarenal abdominal aortic aneurysm • AAA with maximum sac diameter ≥ 5.5cm, or an AAA ≥ 4.5 cm which has increased by > 1.0 cm in the past year • Patient is anatomically suitable for a bifurcated Fenestrated Anaconda™ device 	<ul style="list-style-type: none"> • Patient has a ruptured, leaking, or mycotic aneurysm • Patient has a serum creatinine (5-Cr) level > 2.0 mg/dl (177 $\mu\text{mol/L}$) • Patient has a CVA or MI within three months of enrollment or treatment • Patient has a connective tissue disease (e.g., Marfan Syndrome) • Patient has had a previously inserted endovascular stent in the abdominal aorta • Patient has a life expectancy < 2 years, as judged by the investigator

GLOBAL FACT - Demographics and comorbidities

Baseline data




- 103 patients
- 94 male (91.3%), 9 female (8.7%)
- Mean age 74.2 ± 7.2 years (range 54-89)
- Mean BMI 27.6 ± 4.3 kg/m² (range 17-42)
- Current or former smoker 85%
- Hypertension 75%
- Diabetes mellitus 15%
- Cerebrovascular disease 18%
- Ischemic cardiac disease 42%
- Congestive heart failure 4%
- Chronic renal impairment 17%
- ASA score
 - II 16 (16%)
 - III 83 (81%)
 - IV 4 (4%)

GLOBAL FACT - multicenter prospective registry

Anatomical and surgical details

- Maximal AAA sac diameter (mean) 64.7 ± 10.7 mm
- Prior aortic surgery 10 (9.7%)
- Thoracoabdominal aneurysm 9 (8.7%)
- Saccular aneurysm 9 (8.7%)
- Iliac aneurysm 10 (9.7%)
- Occlusive aortoiliac disease 1 (1.0%)

GLOBAL FACT - Device details

STANDARD
Evening spacing and %
size of fenestration
Minimum oversize of 10% required

BICHOUDVALLEY
Smaller size of first proximal ring
with distal limb removed
Minimum oversize of 8% required

ADDITIONAL FENESTRATION SUPPORT
Boundary of Nitinol wire around each
fenestration. This is designed to prevent any
rubbed fabric partially occluding the
fenestration



LENZBACHVALLEY
Fenestration placed between proximal
rings with anterior limb removed
Minimum oversize of 10% required

Number of fenestrations

3	19	23	52	6
1	2	3	4	5




Used covered stents for side branches

- Atrium Advanta 317
- Bentley BeGraft 19
- Gore VBX 11
- Bard Lifestream 2




GLOBAL FACT - procedural details

- General anesthesia 99 (96.1%)
- Procedural time (min) 246.5 ± 108.8
- Fluoroscopy time (min) 66.3 ± 36.7
- Contrast volume (mL) 192.7 ± 116.4
- Device repositioning used
 - >1x times n=11 (10.7%)
- Device deployed in planned location n=103 (100%)
- Conversion to open repair n=1 (1.0%)

GLOBAL FACT - technical success and early mortality

- Unintentional coverage of an internal iliac artery 2
- Thrombosis of an iliac artery 2
- Endoleaks at completion angio
 - Type IA 5 (4.8%)
 - Type III. Contrast volume (mL) 3 (2.9%)
- 30-day mortality 3/103 (2.9%)
 - Conversion due to iliac artery rupture (POD 0)
 - Pulseless electric activity (POD 0)
 - Ischemic Heart disease (POD 0)

GLOBAL FACT - follow-up at one year

Mortality 5/103 (4.8%)
Two additional deaths to one year after 30 days

Causes of death



- 1 metastatic disease
- 1 procedure related
- 1 ischaemic heart disease
- 2 unknown cause (natural causes)

Morbidity

- Renal failure 2/103 (2%)
- Bowel ischemia 1/100 (1%)
- Paraplegia 1/100 (1%)
- Myocardial infarction 2/103 (2%)

16/100 patients required 19 secondary reinterventions through 1 year

- 6 occlusions/stenosis
- 4 endoleak
- 2 access related
- 2 target artery additional stenting
- 1 migration
- 1 to control bleeding (renal parenchyma)
- 1 focal dissection (limb extension)
- 1 leg ischemia
- 1 embolectomy (SFA)






GLOBAL FACT - follow-up: endoleaks

	First Post Discharge	1 Year	Total
No. of Adequate Imaging	82	62	103
No. of Total Type I and III Endoleaks	6.1% (5/82)	3.2% (2/62)	6.8% (7/103)
Type I			
New	0%	0%	0
Persistent			
Type III			
New	6.1% (5/82)	3.2% (2/62)	7
Persistent			

(corelab reported)

- Core Laboratory Reported
- No Type Ia, Type Ib, or Type IV endoleaks were observed and reported by the Core Laboratory.
- First Post Discharge:** Most Type III's were either at the junction of the right renal (n=2), left renal (n=2), or at the aortic (n=1) limb extensions.
- 1 Year:** Type III were at celiac junction and right renal extension






GLOBAL FACT - follow-up: patency

	First Post Discharge	1 Year
Device Integrity & Patency Observations		
Device Positional Stability	NA	0% (0/63)
Kinking/Twisting	NA	0% (0/64)
Ring Stent Fracture	NA	0% (0/59)
Graft Dilatation	NA	0% (0/62)
Graft Patency		
Main Body	0% (0/82)	0% (0/62)
Limb Occlusions	0% (0/82)	4.8% (3/62)
Target Vessel Occlusions		
Vessel I	1.2% (1/82)	2.4% (2/62)

(corelab reported)

- No reported positional stability, migration, kinking, ring-stent fractures, or graft dilatation.
- First Post Discharge:** Occluded fenestrations were observed at Vessel I:
 - 2 at the left renal artery stent (POD 47 and POD 205)
 - 1 at the right renal artery stent (POD 56)
- 1 Year:** Limb occlusions were observed in the right (n=2) and left (n=1) limbs.
- No occluded fenestrations were observed for the SMA or Celiac.

GLOBAL FACT - follow-up: aneurysm size change



	First Post-Discharge	1 Year
No. of subjects with imaging adequate to assess aneurysm size change	85	56
Increase (>5mm)	NA	8.9% (5/56)
Stable	NA	60.7% (34/56)
Decrease (>5mm)	NA	30.2% (17/56)

(corelab reported)

91.1% (51/56) have a stable or decrease (>5mm) in the maximum aneurysm diameter at 1-year follow-up



Subjects with an increase in max aneurysm diameter of >5mm (n=5)

- 2 subjects (40.0%, 2/5) had CL reported Type II endoleaks
- 2 subjects (40.0%, 2/5) had CL reported Type III
- And 1 subject (20.0%, 1/5) did not have any EL, interventions, patency or device integrity related observations (Core-Lab reported)
- Of these, 1 subject (20.0%, 1/5), had a secondary intervention (POD 575), to resolve an aneurysm sac expansion

Conclusions

- Early to one-year results with the fenestrated Anaconda are satisfactory so far with regard to aneurysm exclusion, patency rates, endoleaks and sac remodeling.
- Higher percentage of endoleaks, although lower than previous reports, and most of them resolve spontaneously.
- Longer-term experience in Global FACT in line with published experience.

Global Fact Study Group:

- Dr David Gerrard, Frimley Park Hospital, Surrey, UK
- Professor Jürgen Fallensammer and Professor Alois Asaad, Wilhelmsklinik, Vienna, Austria
- Dr Nick Burris, St Mary's Hospital, London, UK
- Dr Rob Williams and Mr James McCulloch, Freeman Hospital, Newcastle, UK
- Dr Robbert Akerwal, Medisch Spectrum Twente, Enschede, Netherlands
- Dr Randy Moore, Peter Lougheed Centre, Calgary, Canada
- Dr Rajeev Roganan, St Antonius Ziekenhuis, Nieuwegein, Netherlands
- Mr Rochore Sauranane, Hollywood Medical Center, Perth, Australia
- Mr Peter Chu, Spaworth Richmond Private Hospital, Melbourne, Australia
- Professor Michel Reijnen, Rijnstate Arnhem, Netherlands
- Professor Clark Zeebregts, University Medical Center Groningen, Groningen, Netherlands

Thank you for your attention !

