Latest Clinical Results from INCRAFT AAA Stent Graft: Five Years of Data

Giovanni Torsello MD

On behalf of the INNOVATION trial participants

Disclosure

Speaker name:

.....G.Torsello.....

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s): The Innovation study was supported by the Cordis Company

☐

The INNOVATION Study

OBJECTIVE

- To assess the technical success and safety of the Cordis INCRAFT® Stent Graft System in subjects with AAA

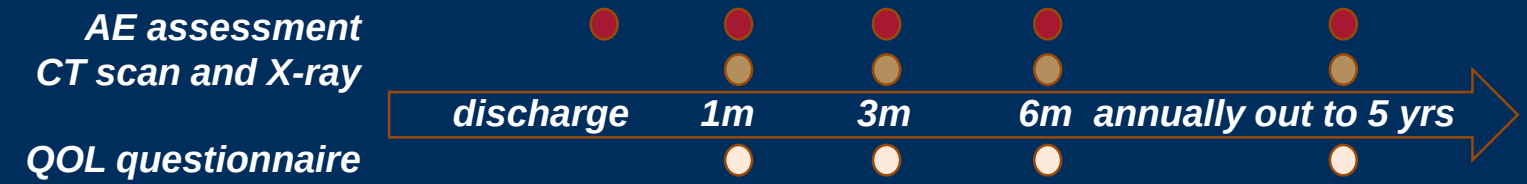
PRIMARY ENDPOINTS

- Successful deployment at desired location and absence of Endoleaks (I, III or IV) at conclusion of procedure
- Absence of device or procedural related major adverse events (MAE) 1 month post-procedure

MAJOR SECONDARY ENDPOINTS

- Absence of aneurysm enlargement ≥5 mm
- Absence of stent graft migration ≥10 mm
- QOL
- Absence of stent graft fracture
- Absence of MAE and Endoleaks (I, III, or IV) at 3, 6 and 12 months and annually out to 5 years post-procedure

FOLLOW-UP



Hostile anatomy distribution

(based on CoreLab assessments)

	HOSTILE ANATOMY ATTRIBUTE	CATEGORIZATION*	ABSENT	MILD	MODERATE	SEVERE
PROXIMAL	Neck length (mm)	*(>25; 25-15; 15-10; <10)*	60%	23%	8%	8%
	Infra-renal angle (°)	*(<20; 20-40; 40-60; >60)*	13%	57%	25%	5%
	Supra-renal angle (°)	*(<20; 20-40; 40-60; >60)*	85%	13%	2%	0%
	Aortic thrombus	*(Subjective analysis)*	5%	73%	17%	5%
	Aortic calcification	*(Subjective analysis)*	7%	82%	12%	0%
DISTAL	Minimal aortic bifurcation ø	*(>22; 22-20; 20-18; <18)*	38%	10%	18%	33%
	Left iliac sealing length (mm)	*(>30; 30-20; 20-10; <10)*	15%	12%	33%	40%
	Right iliac sealing length (mm)	*(>30; 30-20; 20-10; <10)*	18%	20%	30%	32%
	Left minimal access ø (mm)	*(>10; 10-8; 8-7; <7)*	2%	29%	24%	46%
	Right minimal access ø (mm)	*(>10; 10-8; 8-7; <7)*	2%	30%	24%	44%
	Iliac Tortuosity (τ)	*(<1,25; 1,25-1,5; 1,5-1,6; >1,6)*	85%	12%	0%	2%

INCRAFT® System Early outcomes

	Operative	30 days (58/60)
Successful deployment at desired location	98.3% (59/60)	-
Freedom from Endoleak		
Type I	98.3%*(59/60)	96.6%‡ (56/58)
Type III	100% (60/60)	100% (58/58)
Stent graft patency	100% (60/60)	100% (58/58)
Freedom from Migrations	NA	100% (58/58)
Freedom from Fracture	NA	100% (58/58)
Freedom from Sac Enlargement	NA	100% (58/58)
Freedom from MAE (death, QMI, CVA, renal failure)	100% (60/60)	100% (58/58)

* Type I endoleak due to severe calcification in aortic neck, resolved after additional endovascular intervention on day 61
‡Type I endoleak was present at 30 day follow-up and resolved after additional endovascular intervention on day 278

Is there a trade-off with low profile stentgrafts?

- Will lighter fabrics and stent material decrease EVAR durability?

- Will the rate of type III/IV endoleak increase in the future?

- Will the need for secondary procedures increase in the future?

INCRAFT® System Long-term outcomes

Event	4 Years	5 Years
Freedom from Endoleak*		
Type Ia	100% (39/39)	100% (39/39)
Type Ib	97.4% (38/39)	97.4% (38/39)
Type III	100.0% (39/39)	100% (39/39)
Stent Graft Patency	97.6% (40/41)	97.4% § (38/39)
Freedom from Migrations	100.0% (38/38)	100% (37/37)
Freedom from Fracture	97.5% (39/40)	97.4% ¥ (38/39)
Freedom from Sac Enlargement	89.7% (35/39)	92.1% # (35/38)
Freedom from MAE (death, QMI, CVA, renal failure)	82.4% (42/51)	76.0% ‡ (38/50)

* Any Endoleak: contains Types I and III endoleaks that are site-reported and CEC adjudicated.

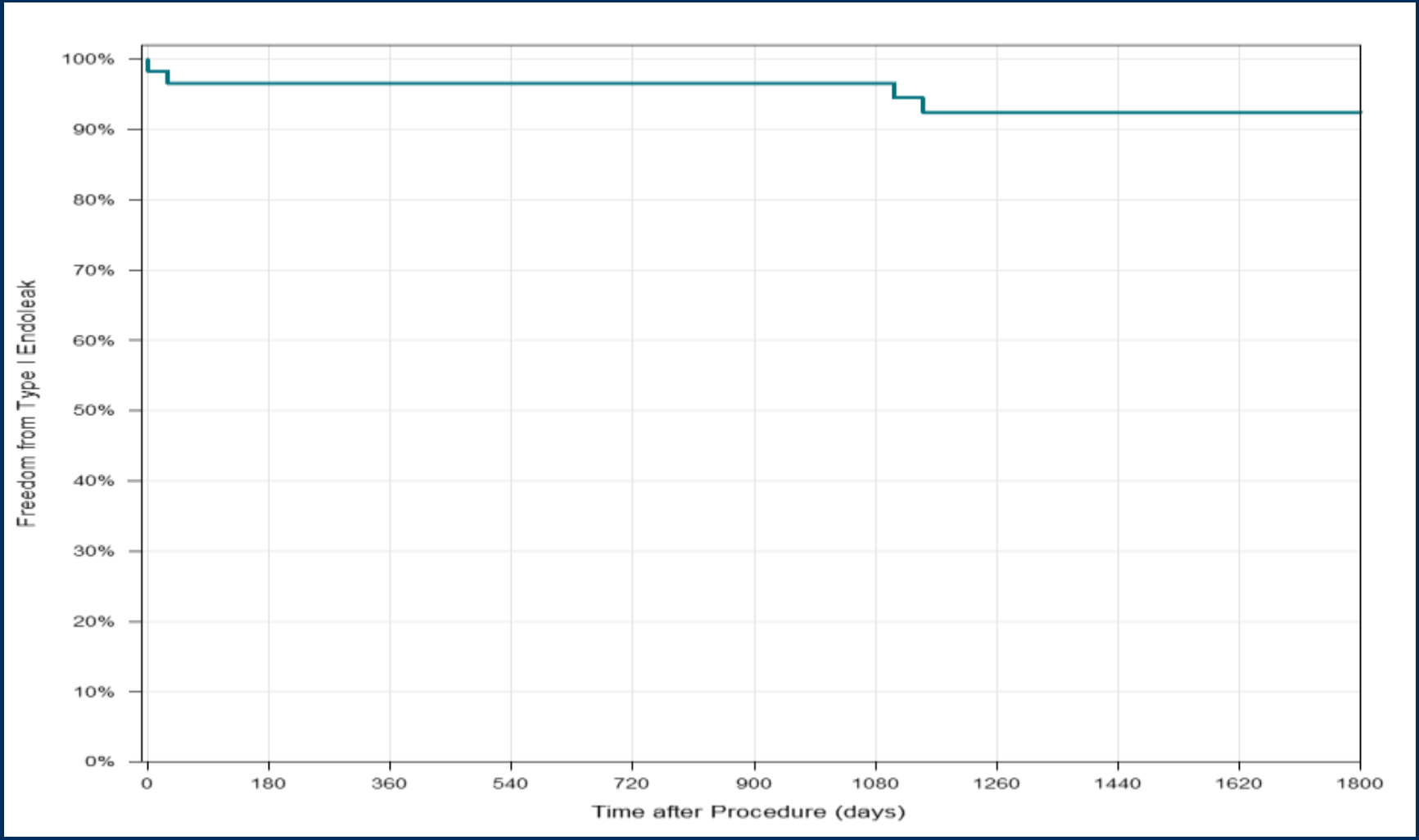
§ Endoleg non-patency occurred in one subject at 3YFU and is ongoing at 5YFU.

Both aneurysm enlargement and main body stent-graft migration are defined as being compared to the 30 day baseline CT assessment. One subject did not have 30 day CT and therefore could not be evaluated.

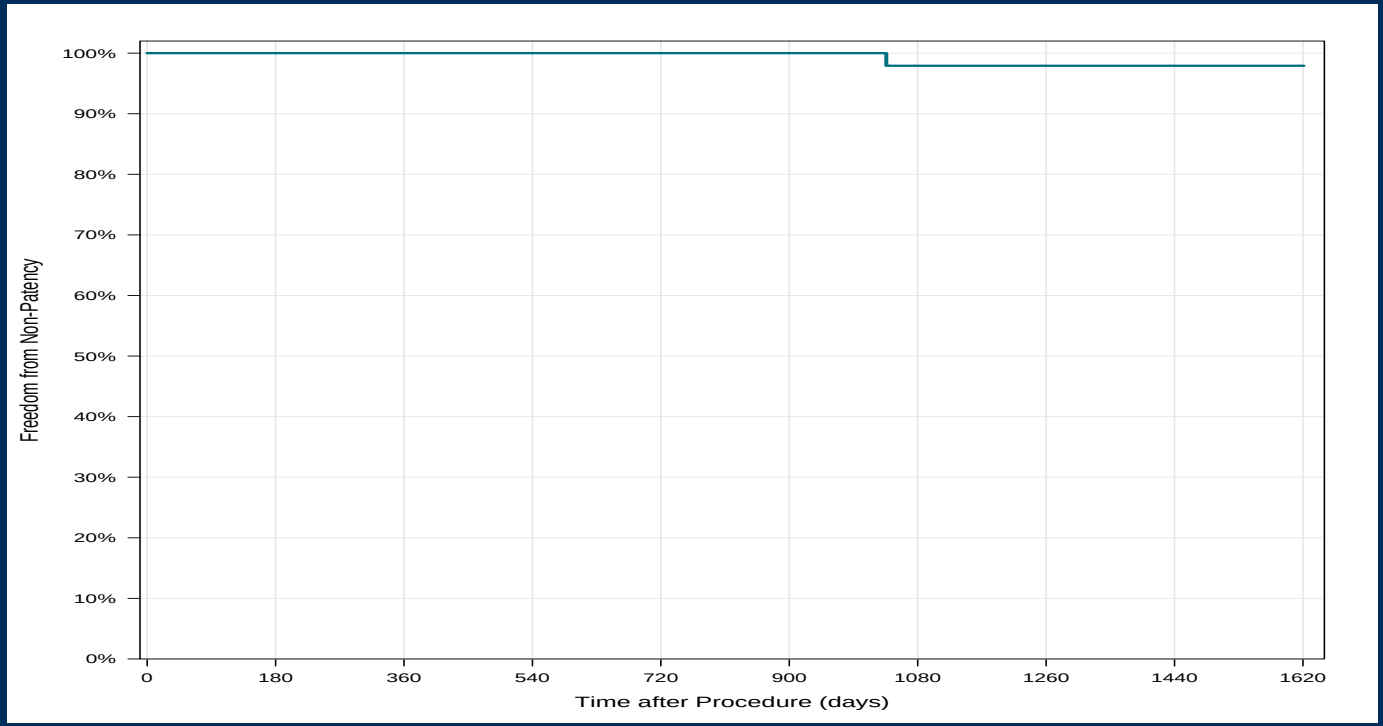
¥ Stent-graft fracture is defined as stent skeleton fracture and barb separation and identified through X-ray. Fracture occurred in one subject at 3YFU and is ongoing at 5YFU. For 7 subjects, X-rays were missing however no fractures were reported through other site imaging.

‡ 1 death occurred within up to 1 year, 5 within the 2 year timeframe, 1 within 3 year timeframe, 2 within 4 year timeframe, 3 within 5 year timeframe, all non-AAA related

INCRAFT® System
Endoleaks I – through 5 years

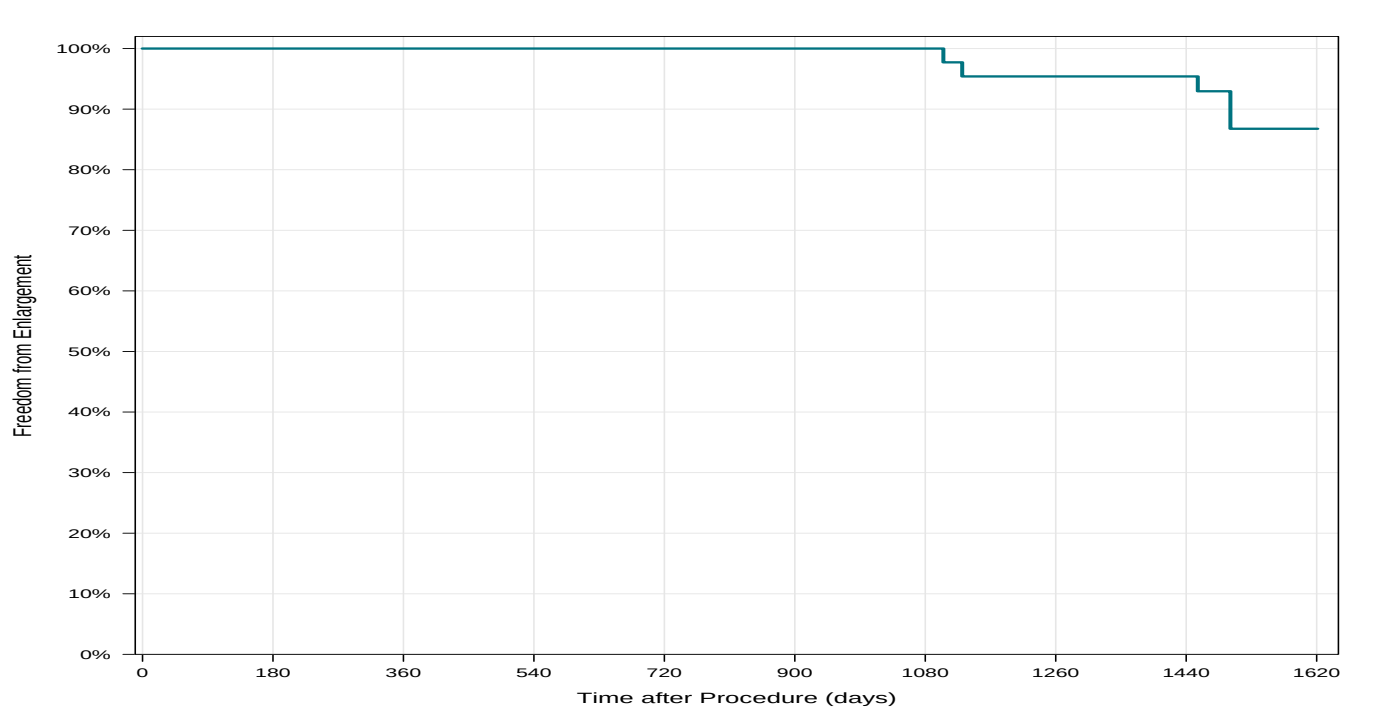


INCRAFT® System - Patency



	Time after Procedure (Days)									
	0	180	360	540	720	900	1080	1260	1440	1620
# Entered	59	59	56	54	51	50	48	44	40	40
# Censored	0	3	2	3	1	2	3	4	0	32
# at Risk	59	59	56	54	51	50	48	44	40	40
# of Events	0	0	0	0	0	0	1	0	0	0
% Survived	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	97.9%	97.9%	97.9%	97.9%
SE1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.1%	2.1%	2.1%	2.1%

INCRAFT® System
Freedom from AAA enlargement



	Time after Procedure (Days)									
	0	180	360	540	720	900	1080	1260	1440	1620
# Entered	56	56	56	54	51	50	48	45	40	40
# Censored	0	0	2	3	1	2	3	3	0	29
# at Risk	56	56	56	54	51	50	48	45	40	40
# of Events	0	0	0	0	0	0	0	2	0	2
% Survived	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	95.4%	95.4%	86.8%
SE1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3.2%	3.2%	7.0%

INCRAFT® System Conclusions

- The INCRAFT performs well on long-term while overcoming more difficult access morphologies
- The Endograft can be utilized in patients with demanding access vessel morphology, further extending its applicability
- The post-market INCRAFT® study (INSIGHT) is on going

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Thank you !

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