CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

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Thinner and thinner: does the next generation endograft compromise durability?

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Disclosure

Speaker name:

Philippe Cuypers

☐ I have the following potential conflicts of interest to report:

☐ Other(s): Educational Grant Medtronic, Cook

"Thinner and thinner" ~ "Less is more"

'view that a minimalistic approach is more effective or more appreciated'

Wikipedia

“Less is more”

Less is more?

What are the possible benefits of lower profile introducer systems?

- Treat more patients?
- Make current EVAR procedures safer?
- More and safer percutaneous access?
- Marketing tool?

Treat more patients?

- Unsuitable: 10-40 %

- Reasons for unsuitability:
  - Neck issues: 70-80 %
  - Access issues: 20-30 %

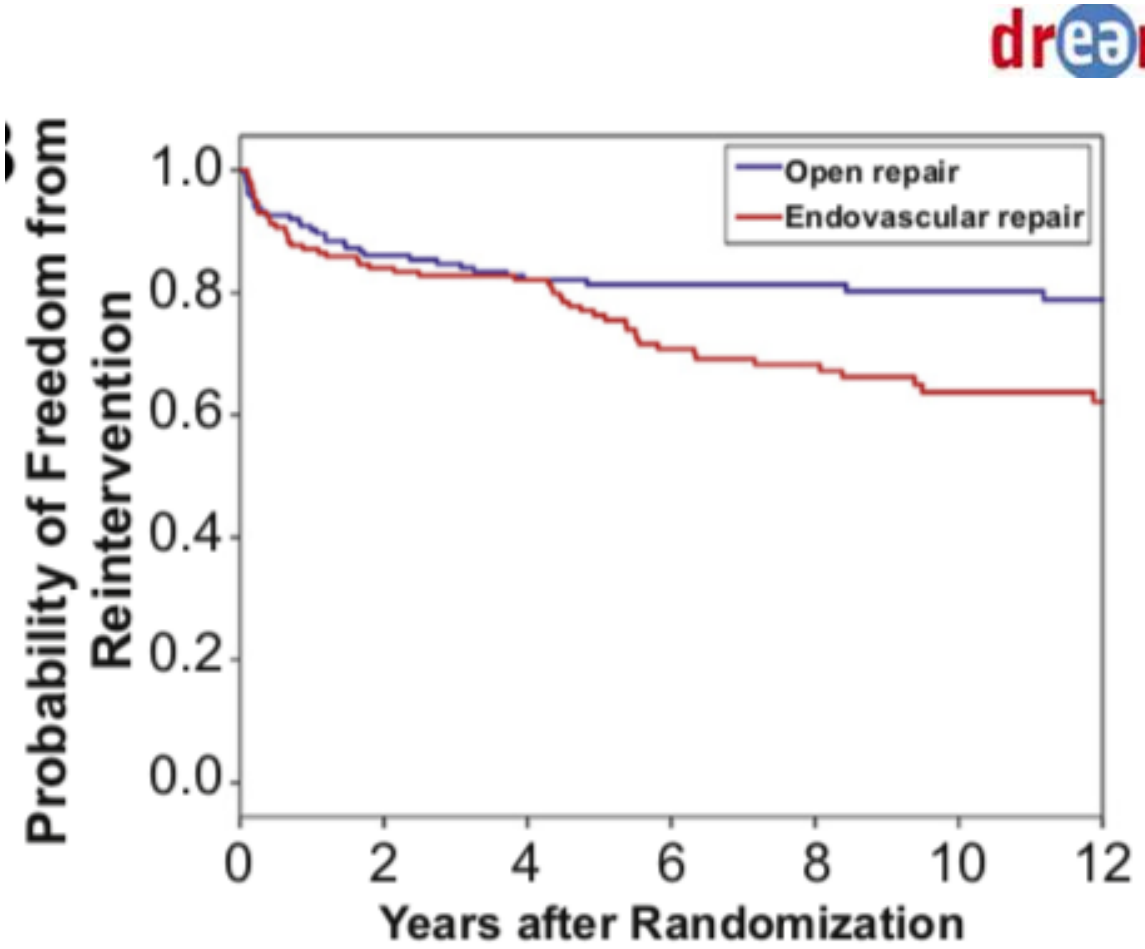
- Unsuitable because of access: 5-10%

Simons et al. JVS 2003;38:758-61
Zarins et al. Ann Surg 2000;232:501-7

Population dependent unsuitability?

- Persistent gender difference
  - Ulug et al. Lancet 2017 Jun 24;389:2482-2491: systematic review and meta-analysis
  - Suitability for EVAR was significantly lower for women (34%) than for men (54%)
- Racial difference
  - Banzic et al. Eur J Vasc Endovasc Surg. 2016 Jun;51(6):783-9
  - Length and diameters differs significantly between Caucasian and Asian population

Make EVAR procedures safer?

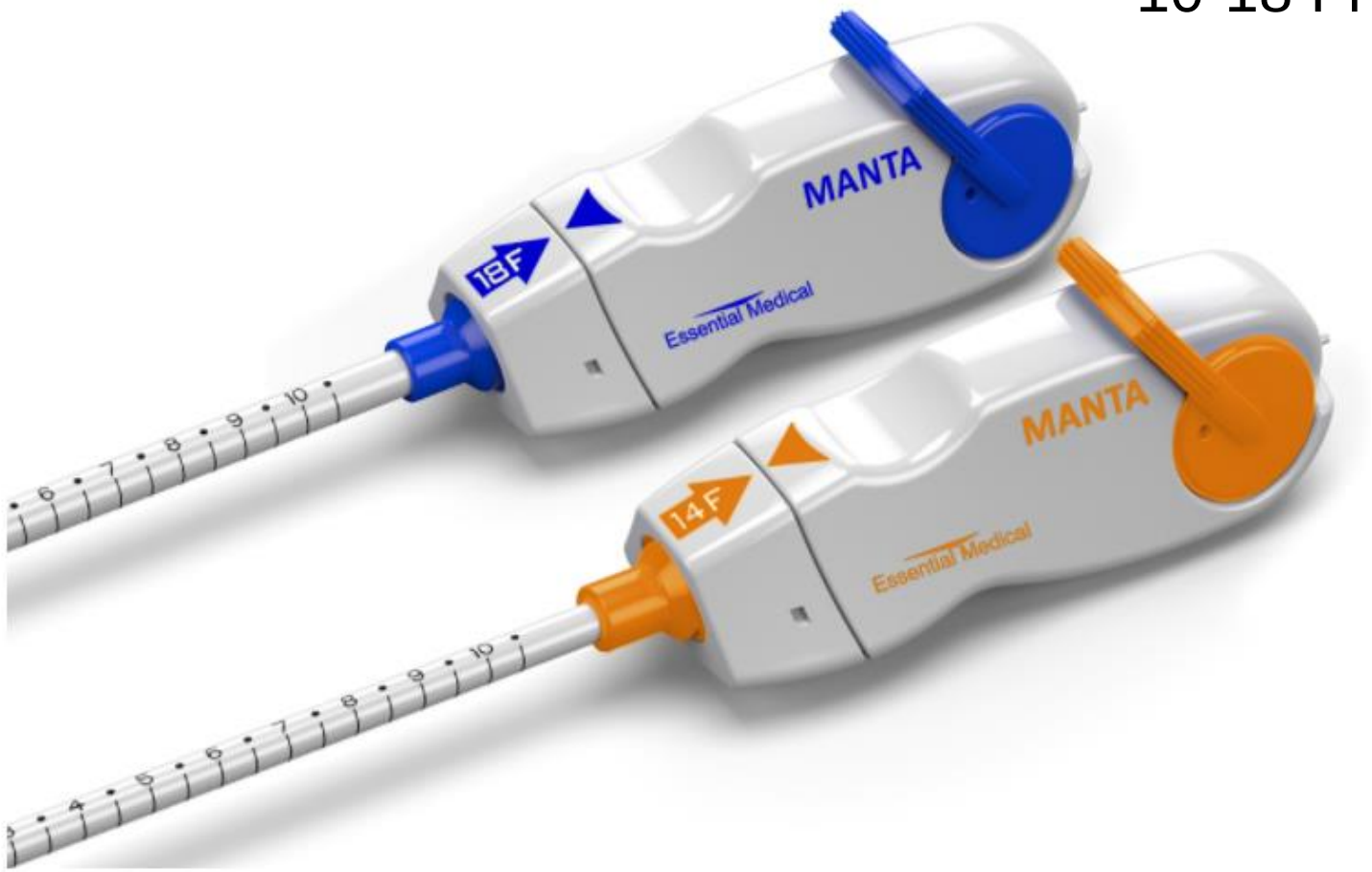


- No major safety issues during first 30 days
- Major concern is reintervention rate

More and safer percutaneous access?

- Patient comfort and recovery, cost-effectiveness
- Latest closure devices can easily deal with large profile devices

10-18 Fr



18-25 Fr

Marketing tool?

vascularnews

Low profile EVAR devices show encouraging results

Incraft low-profile endograft launched in Europe and Canada

vascularnews

Two new lower profile EVAR devices launched at ESVS

TriVascular launches the Ovation EVAR device at LINC

20th January 2011

At 14F outer diameter, Ovation is the lowest profile system on the market and expands the patient population suitable for EVAR.

What are the possible risks of lower profile introducer systems?

1. Manufacturer: inadequate device

2. Physicians: treat wrong patients

1. Device durability: how to reduce profile?

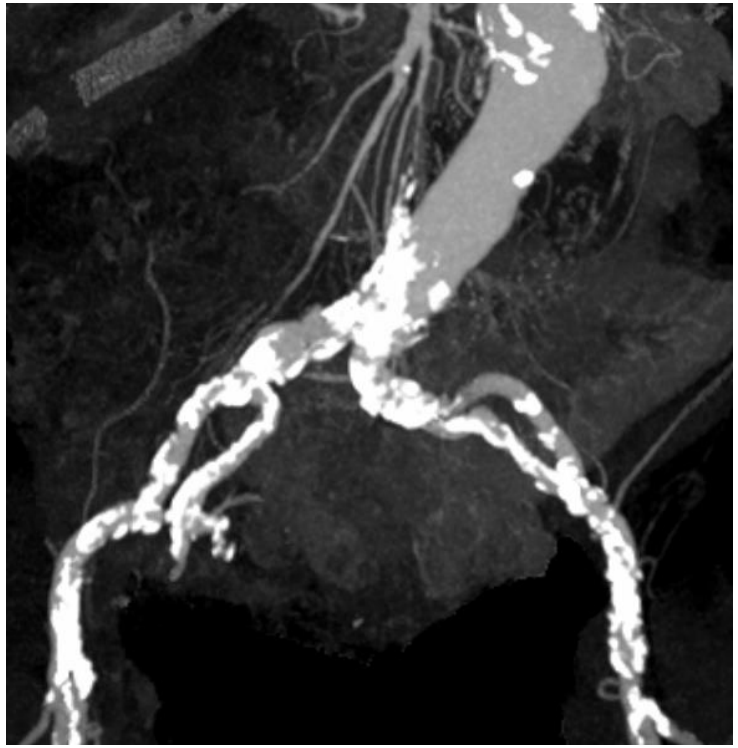
- Thinner graft material
- Change structure/thickness of stents
- Less markers
- Tri-fab construction
- Innovative design to reduce profile (Ovation, Nellix)

Potential drawbacks of low profile

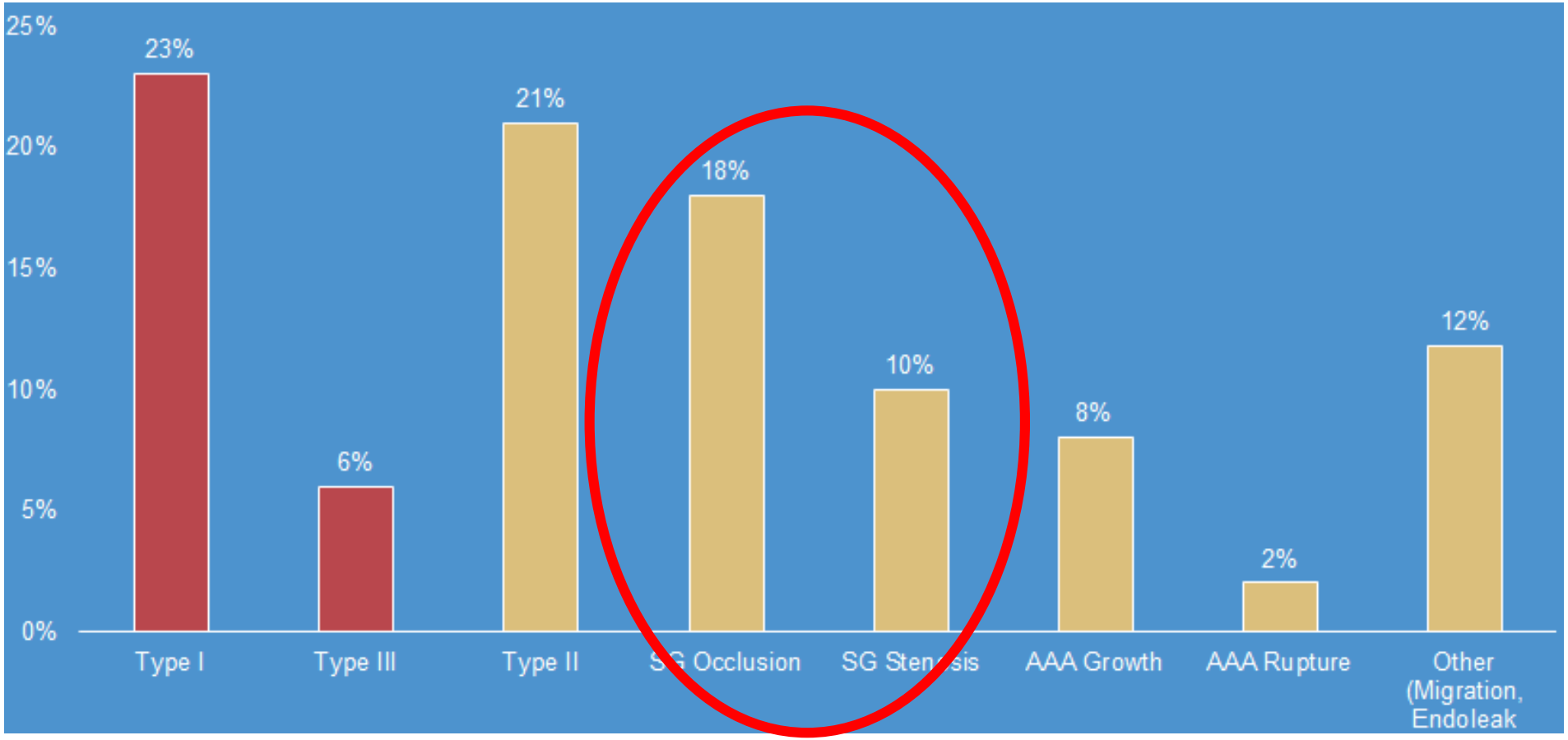
Recent experience with profile < 18 Fr:

- Zenith LP, Cook: 16-17 Fr
- Incraft, Cordis: 14 Fr
- Endurant EVO, Medtronic: 15 Fr

2. Allow physicians to perform EVAR in patients who should not have EVAR at all



5 yrs ENGAGE: reason for secondary interventions



Comparison of midterm results for the Talent and Endurant stent graft

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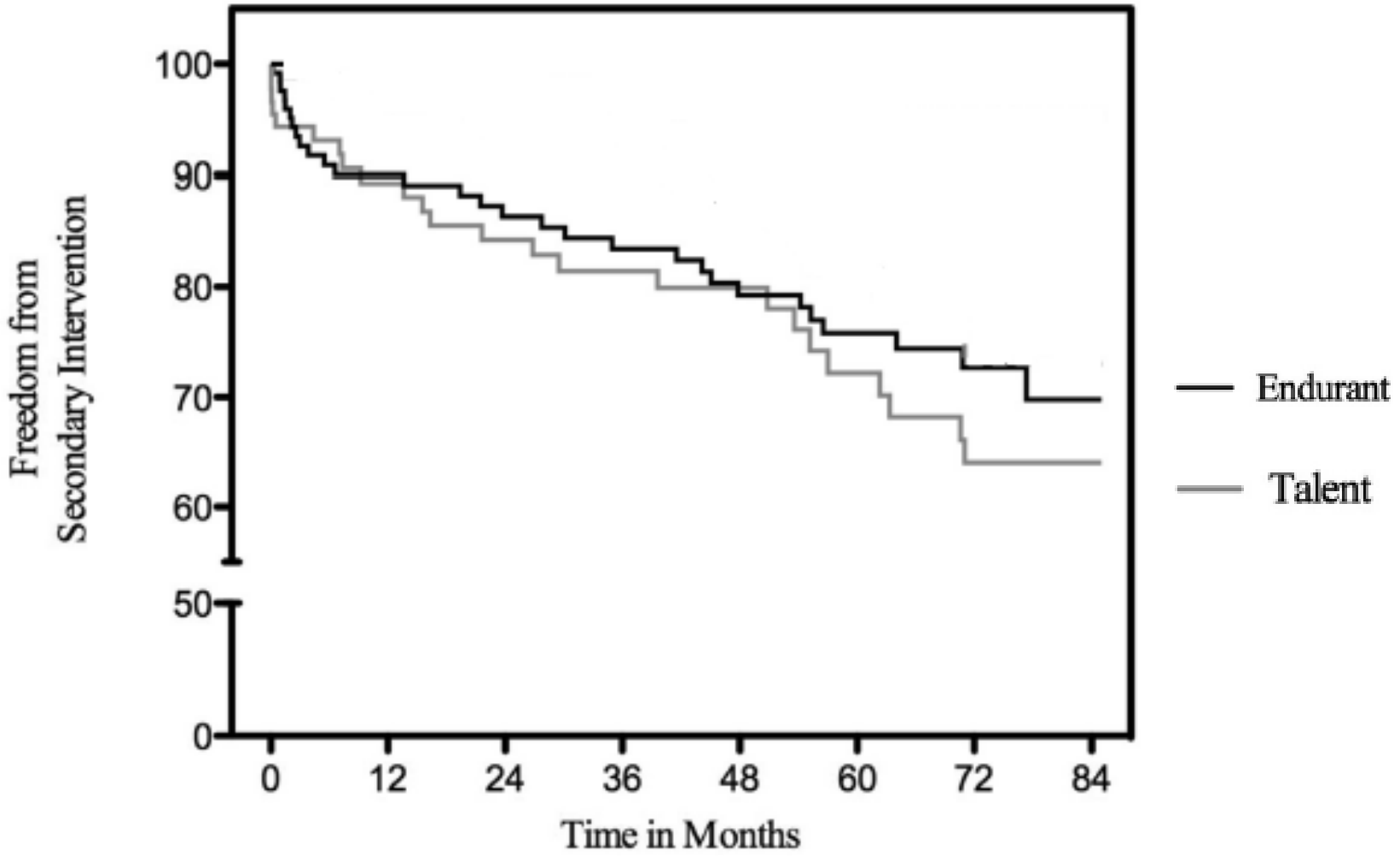
J Vasc Surg 2017;66:735-42

Variables	Talent (n = 90)	Endurant (n = 131)	*P* value
Age, years	73.0 ± 7.4	72.6 ± 8.0	.680
Male	93.3 (84/90)	85.5 (112/131)	.071
ASA class			.312
1	1.1 (1/88)	6.1 (8/131)	
2	68.2 (60/88)	66.4 (87/131)	
3	26.1 (23/88)	24.4 (32/131)	
4	4.5 (4/88)	3.1 (4/131)	

Variable	Talent (n = 55)	Endurant (n = 118)	*P* value[a]
Proximal neck length, mm	39 ± 12.8	32 ± 13.7	.183
Proximal neck diameter, mm	23 ± 2.6	23 ± 3.2	.505
Distal neck diameter, mm	24 ± 3.0	24 ± 3.7	.652
>32 mm (n)	1	2	
Suprarenal angulation, degrees	20 (14-28)	20 (14-35)	.565
Infrarenal angulation, degrees	48 ± 21.1	47 ± 25.3	.699
AAA diameter, mm	58 (54-65)	57 (53-62)	.354
Right CIA max,[b] mm	17 (14-21)	16 (13-19)	.047
Left CIA max,[b] mm	15 (13-19)	15 (13-18)	.141
Right EIA, mm	9 (9-10)	9 (8-10)	.089
Left EIA, mm	10 (8-11)	9 (8-10)	.199
Infrarenal neck outside IFU[c] (n/N)	18.2% (10/55)	16.1% (19/118)	.733

Freedom from secondary interventions



Variable	Talent patients (interventions)	Endurant patients (interventions)	*P* value
Secondary interventions	28.4% (25/88)	23.8% (30/126)	.449
Independent interventions			
Type Ia	10 (12)	6 (6)	.071
Type Ib	2 (2)	3 (3)	1.000
Type II	0	4 (4)	.145
Type III	1 (1)	3 (3)	.645
Graft migration	7 (8)	0 (0)	.002
Limb dislocation	2 (2)	1 (1)	.570
Occlusion	3 (3)	7 (7)	.531
Stenosis	0 (0)	6 (10)	.044
Marginal sealing	3 (3)	5 (5)	1.000
Other	7 (9)	1 (1)	
Intervention for proximal neck[a]	18.2% (16/88)	4.8% (6/126)	.001
Intervention for iliac limb[b]	3.4% (3/88)	7.9% (10/126)	.172

Endurant +

Talent +

Discussion

- Priority for physicians and patients is not treating “more” but treating “better”

- Longterm durability and further reduction of secondary intervention should be higher priority than reducing introducer profile

Conclusion

- Latter generation endografts do perform better in terms of durability, especiallly for proximal neck sealing

- Caution for profile < 18 Fr:
  - Physicians are tempted for use in patients who should not have EVAR at all
  - So far, manufacturers are not ready to guarantee durability