

EVAS Global Registry Update

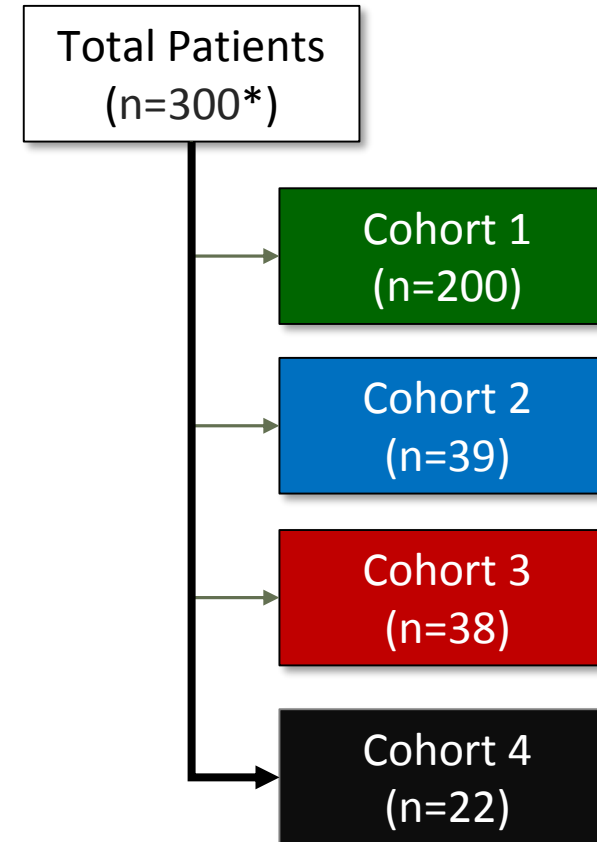
Jean-Paul P.M. de Vries

CRITICAL ISSUES, Lille

May 21st, 2016

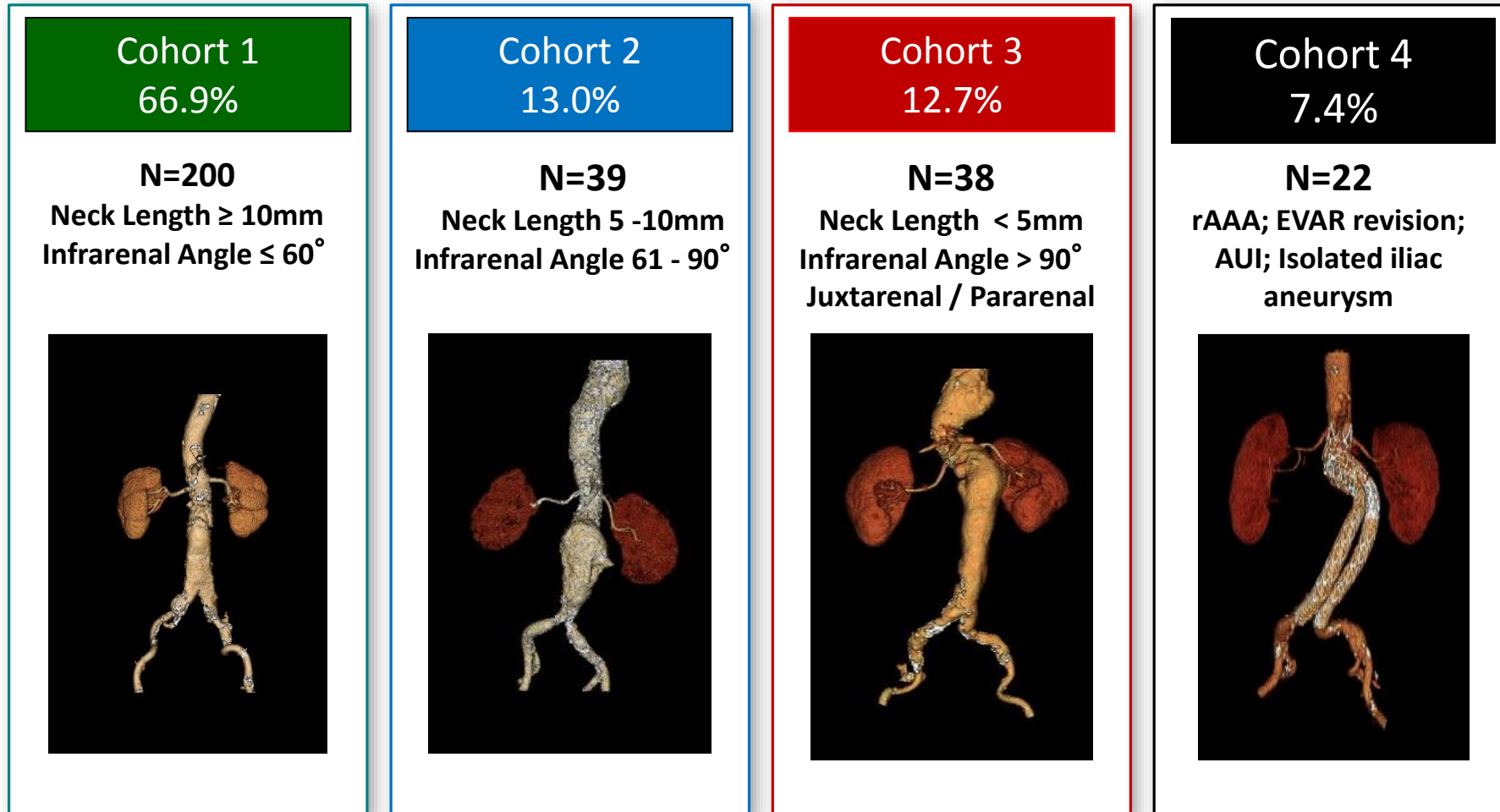
EVAS FORWARD Global Registry: Design and Status

- Principal Investigators
 - Andrew Holden, MBChB, *Auckland, NZ*
 - Matt Thompson, MD, *London, UK*
- 300 patients, 30 centers with five year follow-up
- Real-world experience; no prospective screening
- CT scan core lab analysis (Cleveland Clinic Core Lab)
- Independent adverse events adjudication
- Primary outcomes typical of EVAR therapy
- Mean follow-up of 20 months with longest follow-up beyond 2 years
 - Mean 20mo (0-28mo)
 - Median 21mo (25%ile=19mo, 75%ile=23mo)

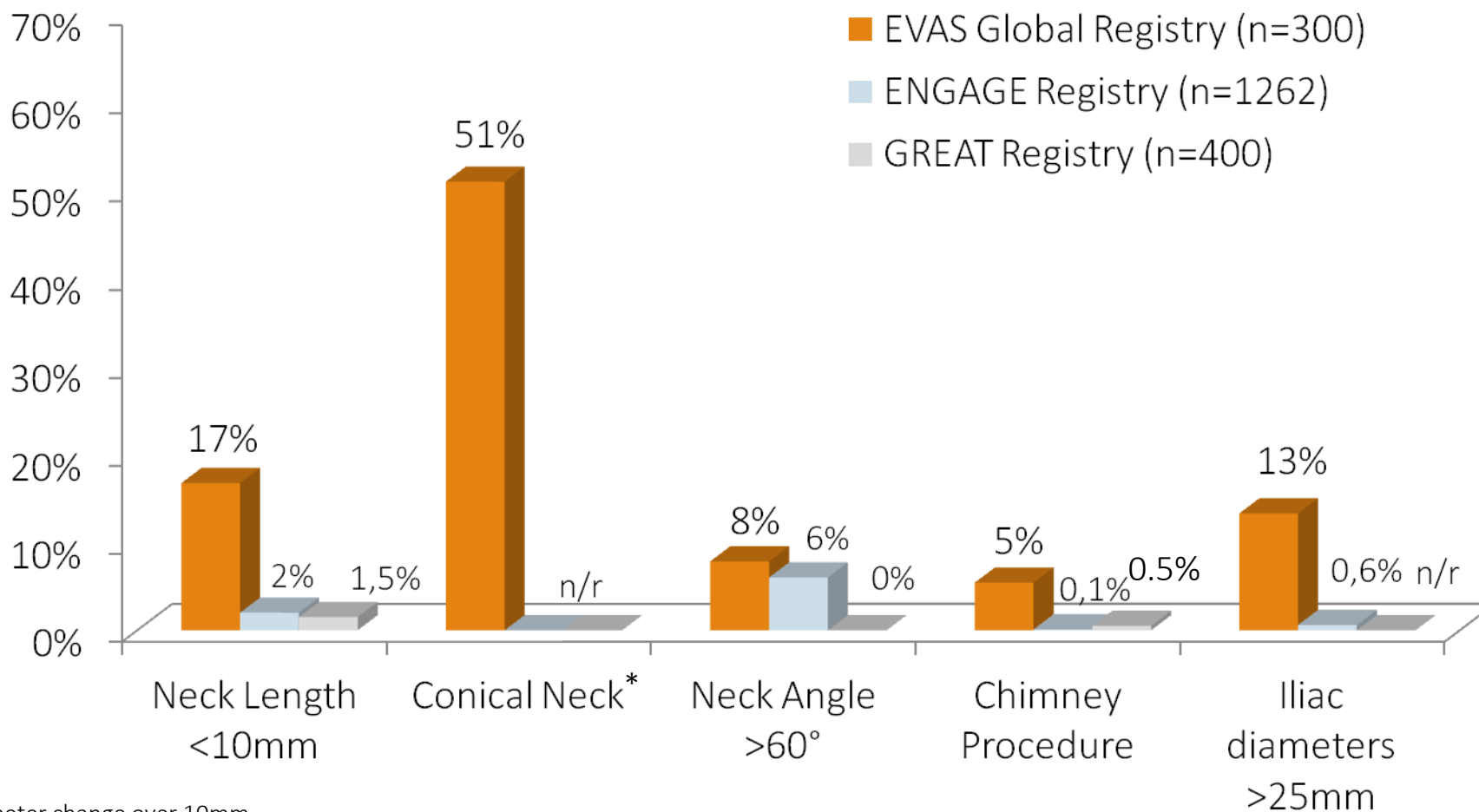


*One (1) consented patient did not receive implant

Cohorts



AAA Complexity across All-Comer Registries

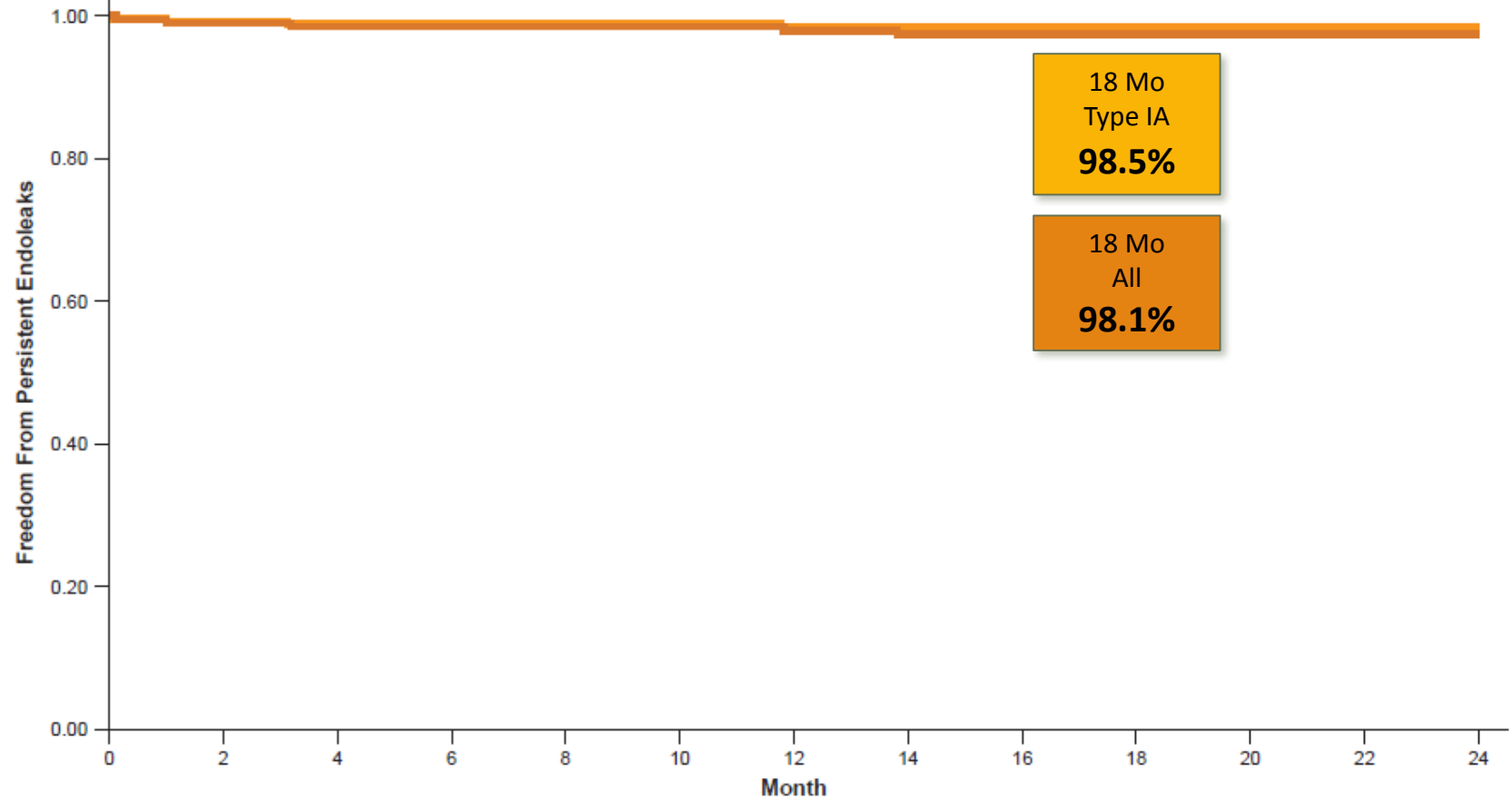


*Infrarenal 20% diameter change over 10mm

ENGAGE: Stokmans et al. *EJVES* 2012 / Broos et al. *J Vasc Surg* 2015

GREAT: Verhoeven et al. *EJVES* 2014

Freedom From *Persistent* Endoleak: Type IA and Overall



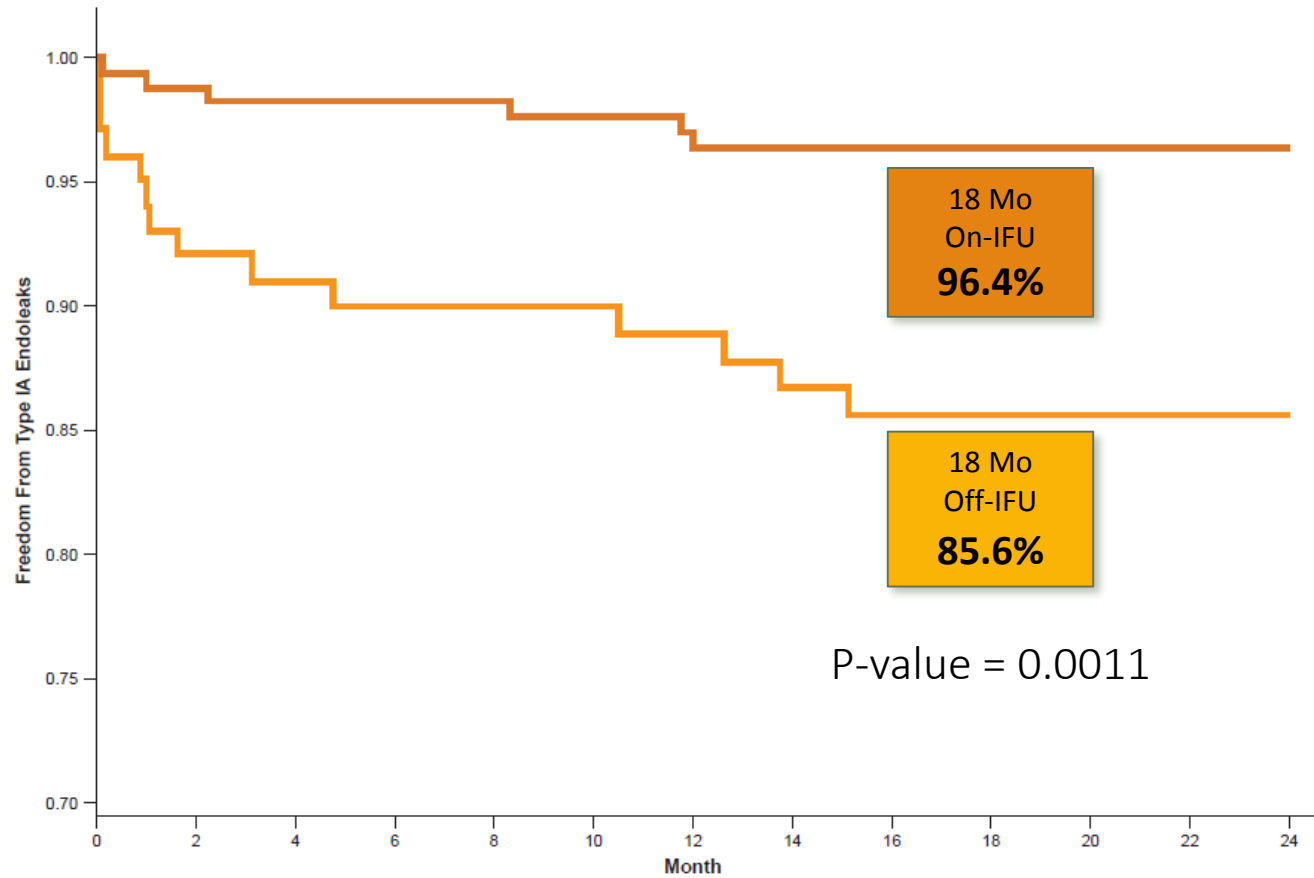
277	255	249	246	243	238	234	228	224	208	149	82	45	All Endoleaks
277	268	263	260	256	252	249	246	243	224	161	89	46	Type IA Endoleaks

Persistent Endoleak through Last Follow-Up

All Endoleak	1.9% (5)
Type IA	1.5% (4)
Type IB	-
Type II	-
Type III	-
Type Unknown	0.4% (1)

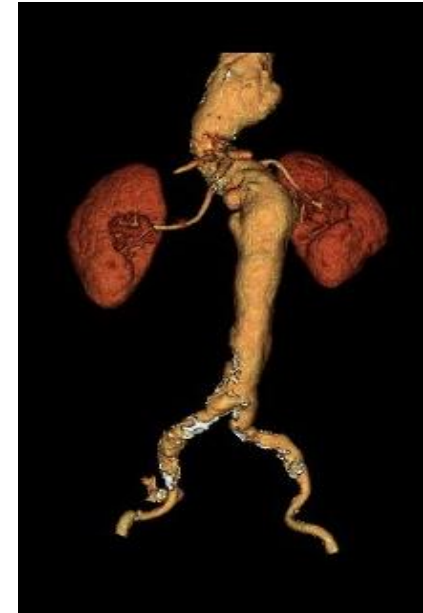
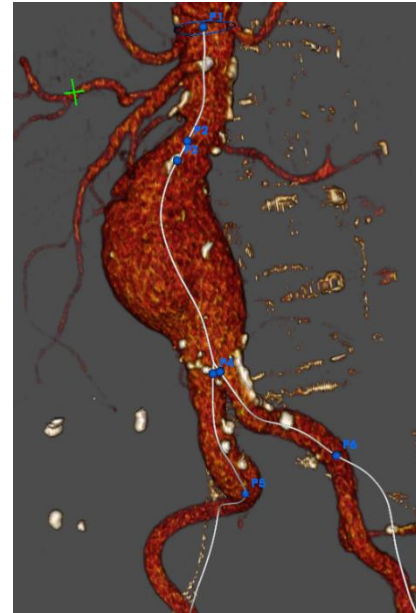
Mean follow-up 20 mo (0-28 mo)

Freedom From Type IA Endoleak: On- and Off-IFU



175	169	167	166	163	160	158	155	152	143	107	57	31	On-IFU
102	91	87	85	84	83	81	79	78	71	47	28	14	Off-IFU

Juxtarenal AAA Neck Angle > 60°

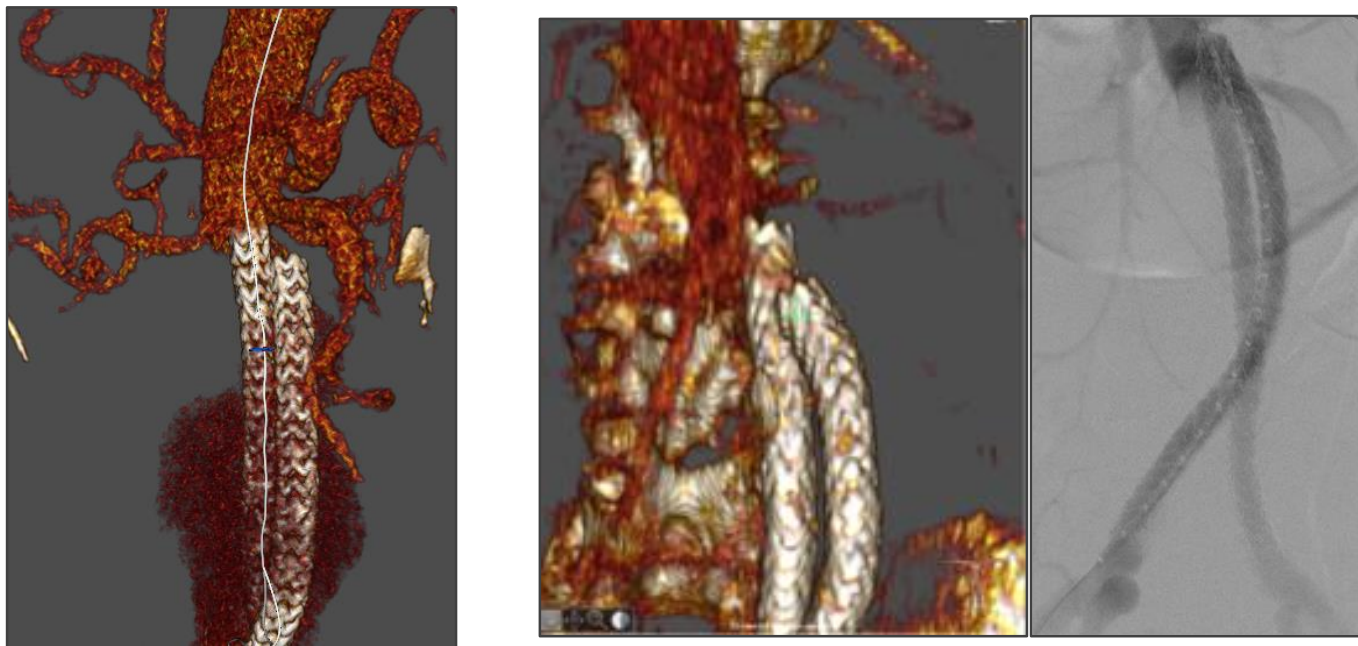


86% of off-label cases due to:

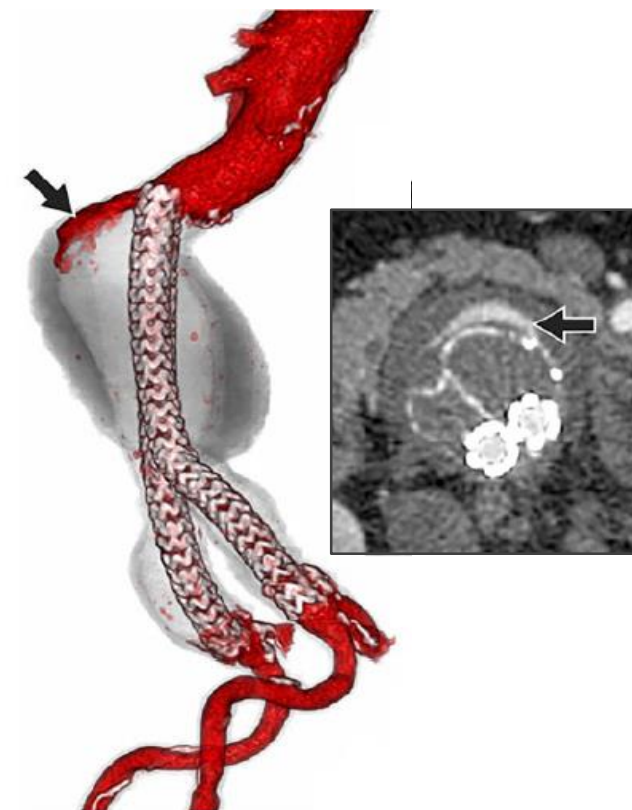
- Neck anatomy (short, angulated, wide)
- Large flow lumen
- Distal anatomy (large CIA, small access vessel)

Type IA Endoleak: Procedural Risk Factors

Procedural Stent Misalignment

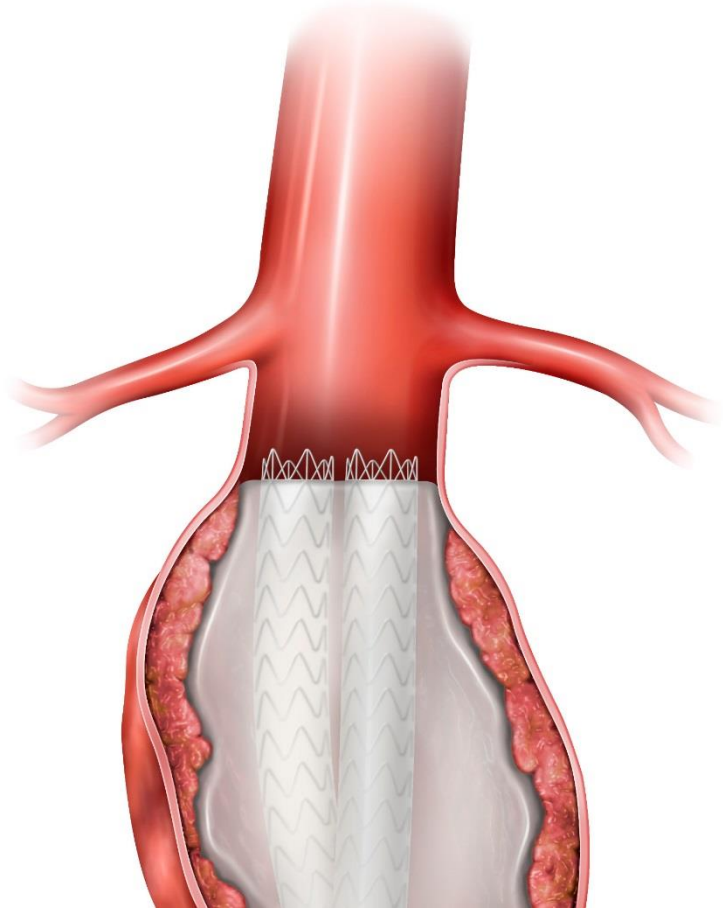


Procedural Low Stent Placement

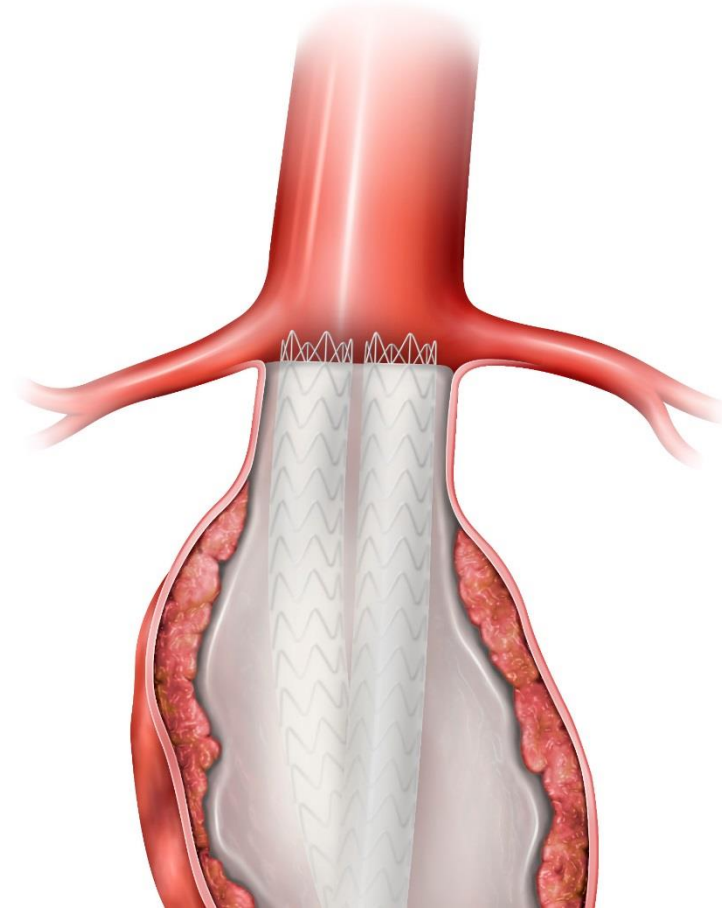


Nellix Stent Positioning to Maximize Proximal Seal

Too low

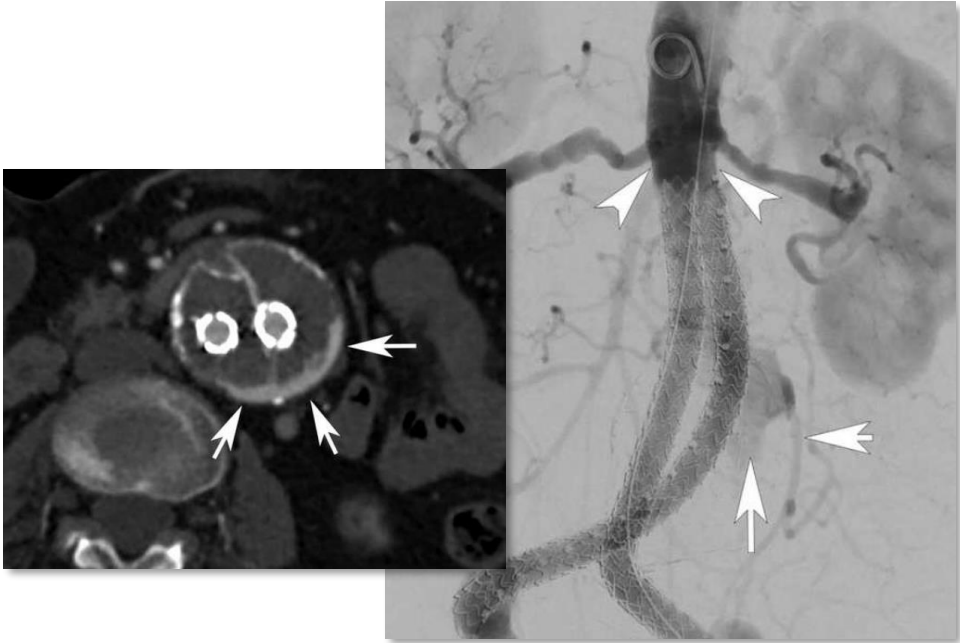


Ideal

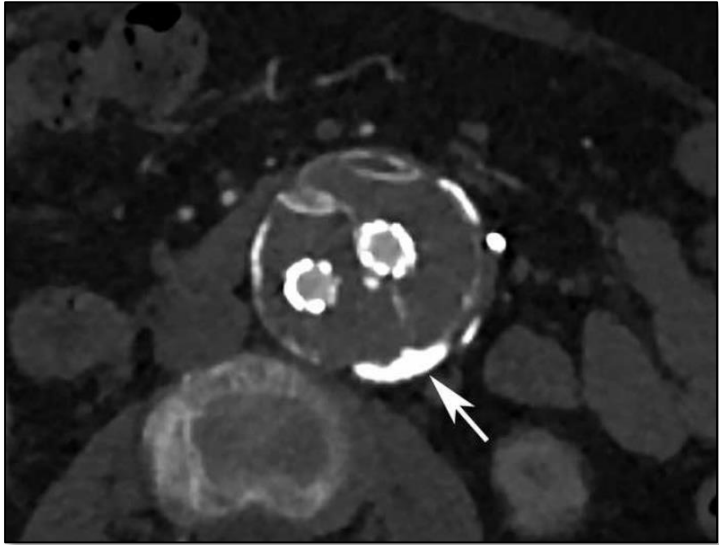


Successful Transcatheter Embolisation of Type IA Endoleak

Type IA Endoleak*



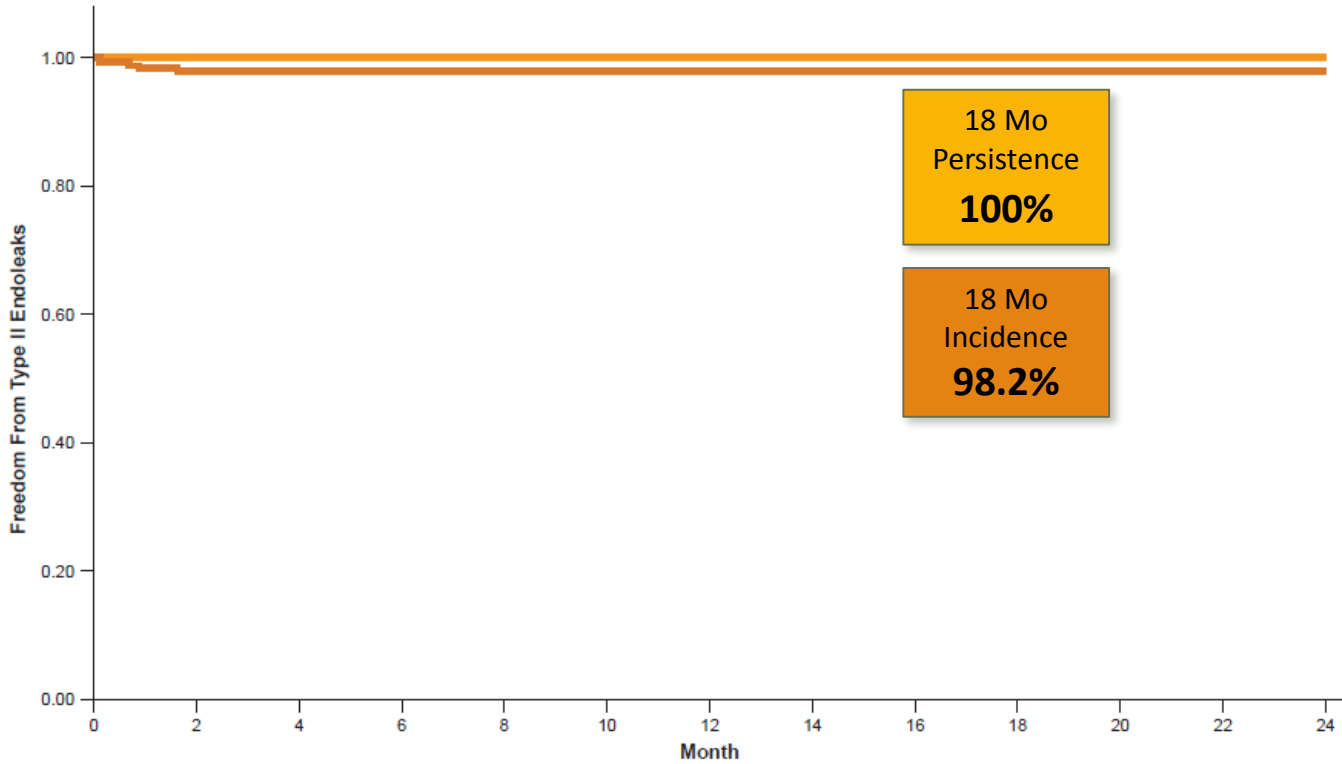
1 month post Transcatheter Embolization with Proximal Extensions



*95% of patients did not present with a recurring endoleak at follow-up

Harvey et al. *JVIR* 2016

Freedom From Type II Endoleak

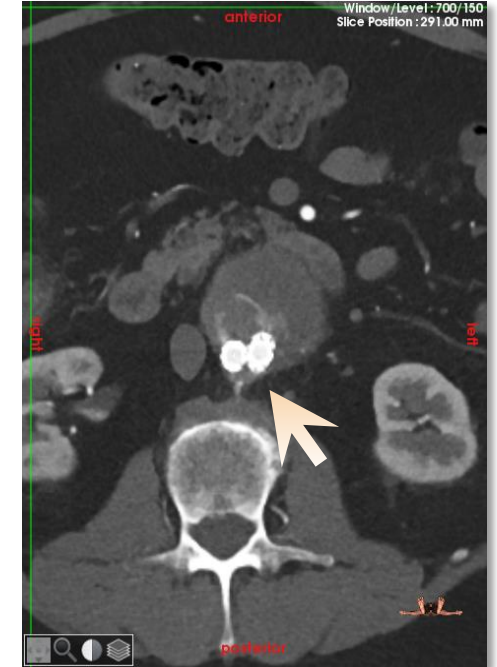


277	265	261	259	256	252	250	247	244	225	162	91	47	INCIDENCE
277	270	266	263	259	255	253	250	247	228	164	92	47	PERSISTENCE

30d



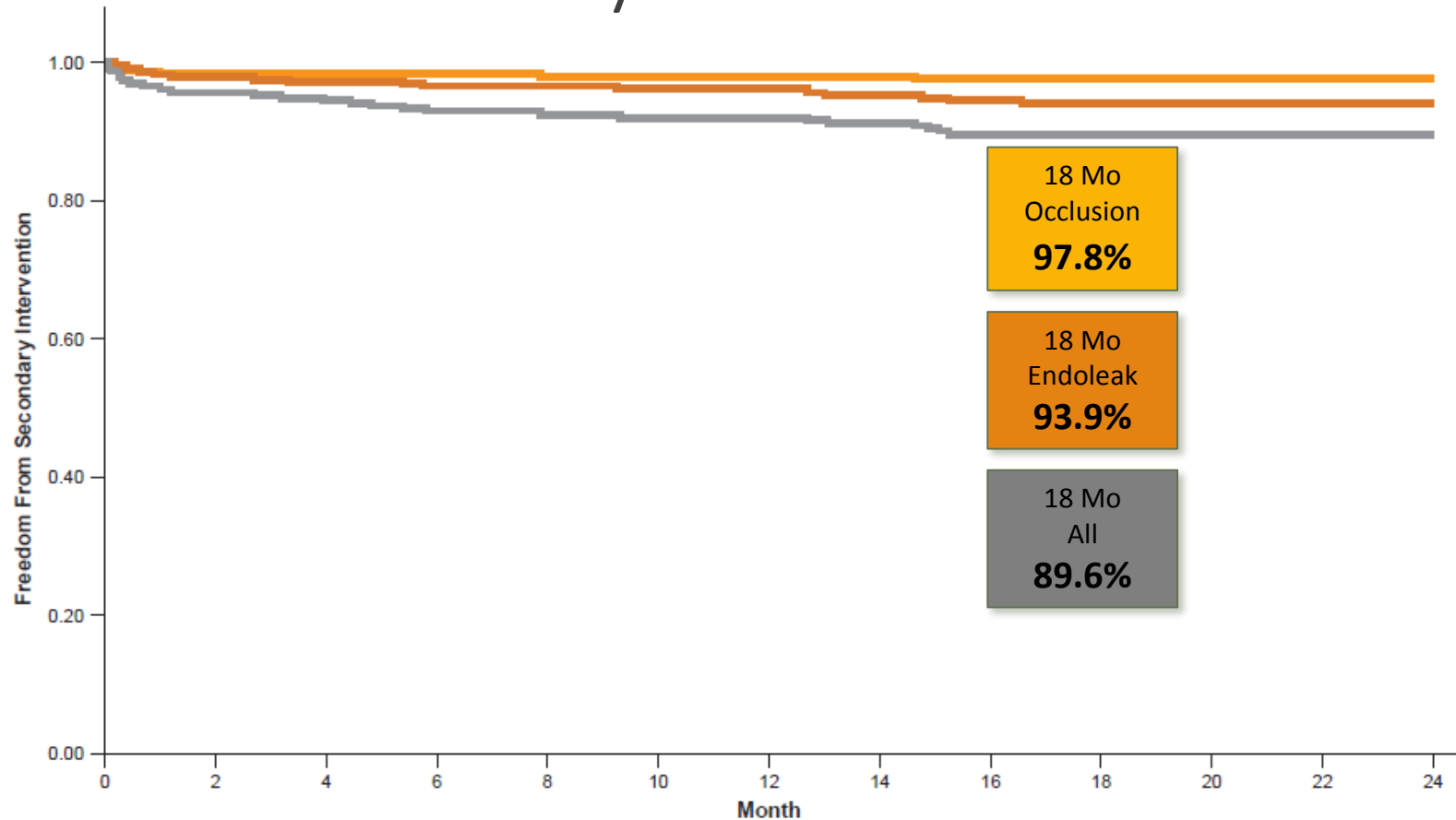
1yr



Endoleak Summary

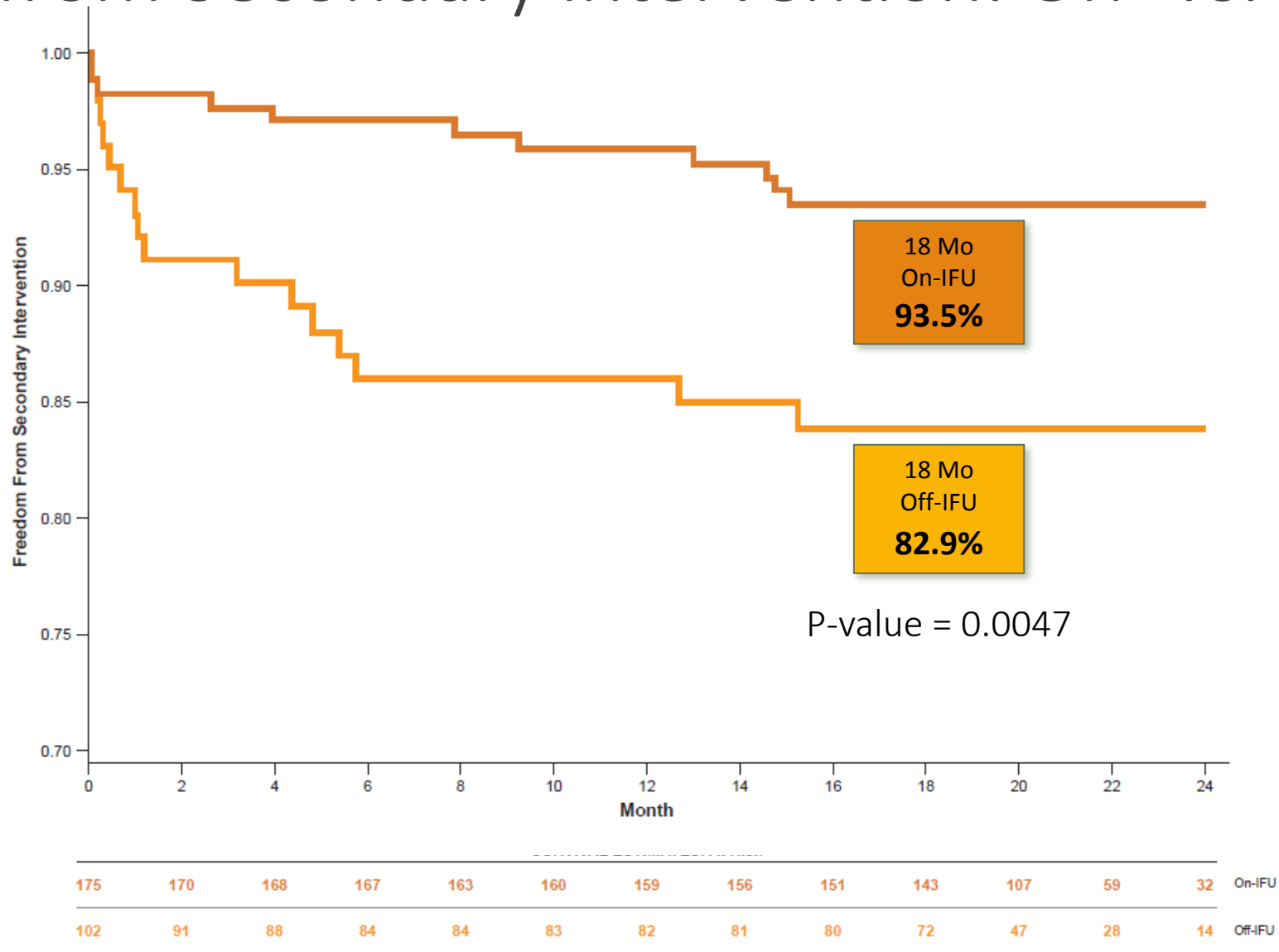
- Composite endoleak rates remain low through latest follow-up
- Type IA endoleak
 - Most occur in off-IFU patients
 - Can be effectively treated endovascularly
 - Successful outcomes driven by patient selection and procedural best practices
- No Type II endoleak present at latest follow-up

Freedom from Secondary Intervention

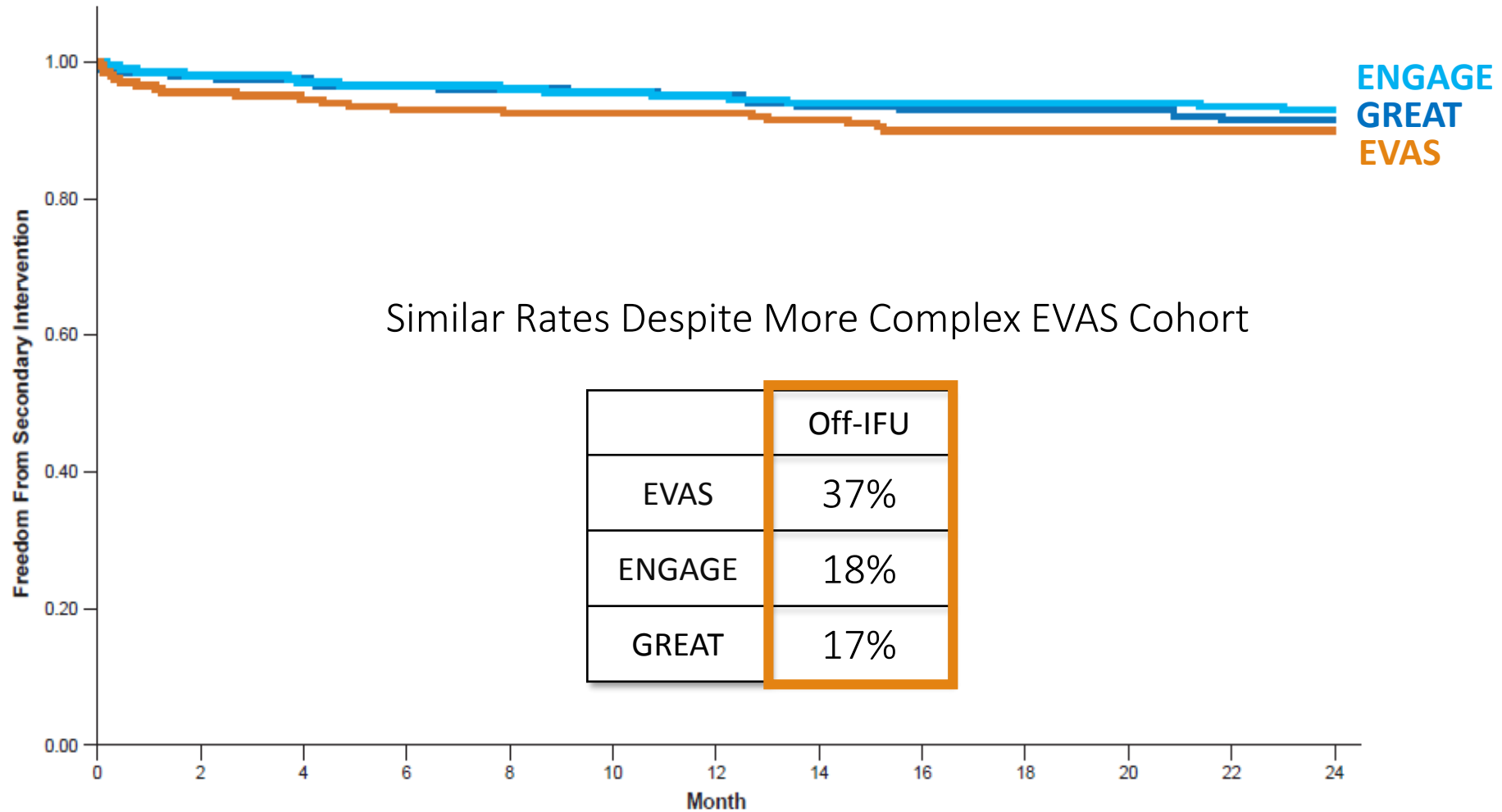


277	267	264	261	256	252	250	247	243	225	161	91	46	ALL
277	265	259	255	251	247	245	241	236	218	156	87	46	Endoleaks
277	261	256	251	247	243	241	237	230	214	154	87	46	Occlusion

Freedom from Secondary Intervention: On- vs. Off-IFU



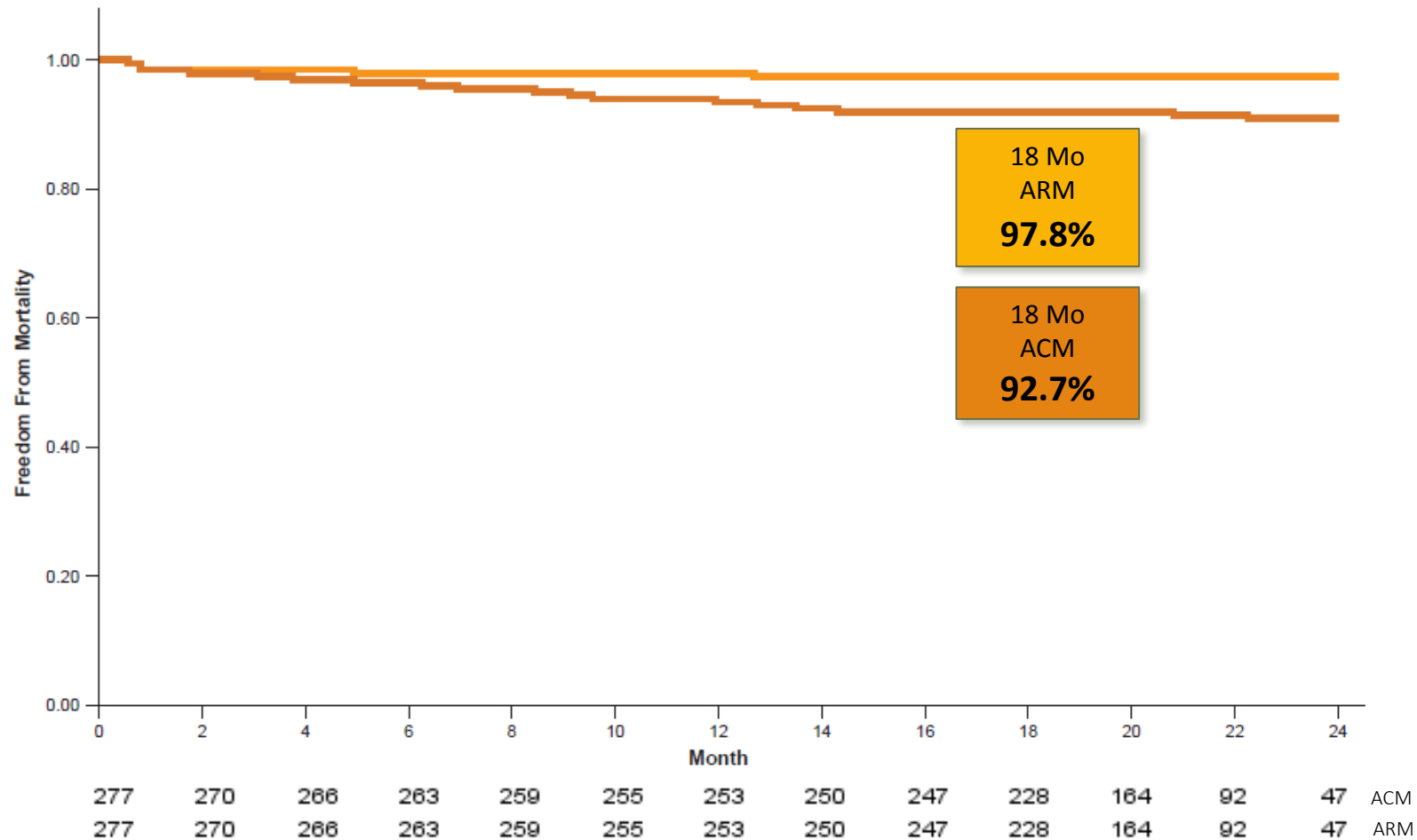
Freedom from Secondary Intervention



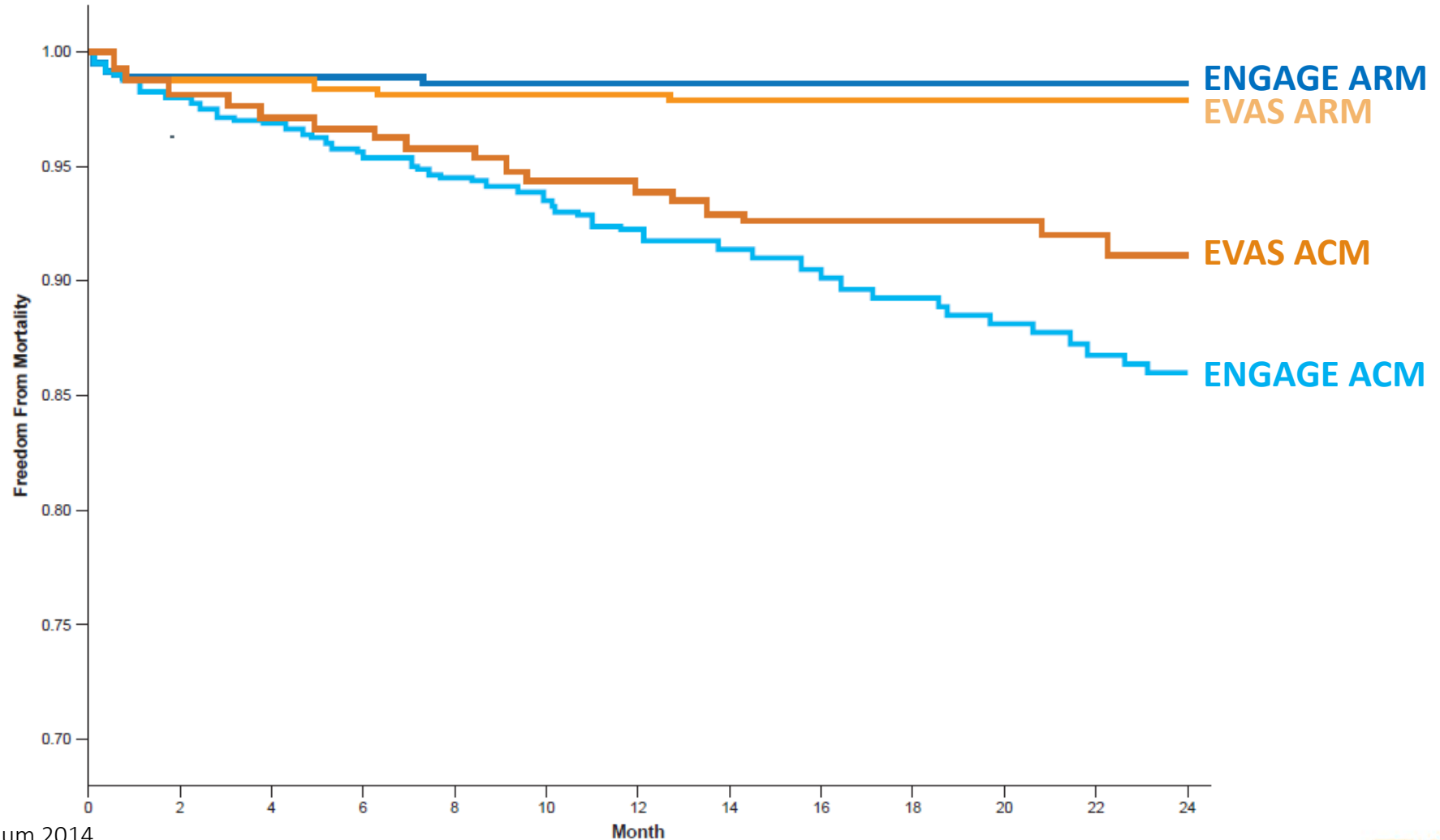
ENGAGE: Verhagen et al. LINC Symposium 2014.

GREAT: Verhoeven et al. *EJVES* 2014

Freedom from Aneurysm-Related and All-Cause Mortality



Freedom from Aneurysm-Related and All-Cause Mortality EVAS vs. ENGAGE



ENGAGE: Verhagen et al. LINC Symposium 2014.

Conclusions

- Encouraging results in the first-ever prospective, EVAS all-comers clinical study showing durability of repair at 20 months
- Low endoleak and reintervention rates in complex patient population
 - Patient selection and stent placement contribute to successful outcomes
 - Low rate of Type IA endoleak in on-IFU patients
 - Zero Type II endoleaks present at latest follow-up
- Excellent aneurysm-related and overall survival trends through latest follow-up