

RECENT TECHNOLOGIES FOR EVAR PRESENTATION AND RESULTS

NELLIX® , ENDOLOGIX

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Why change the concept of EVAR ⇒ EVAS

Long-term outcomes of secondary procedures after endovascular aneurysm repair

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Number of Patients	1,768
Mean Follow-up [SD]	34 Months [30]
% with Secondary Intervention	19.2%
Type II Endoleak	40.1%
Type I/III Endoleak	16.5%
Migration	13.6%
Limb Occlusion	7.4%
Rupture, Device Defect, etc.	8.6%

Why change the concept of EVAR ⇒ EVAS

5-year Costs Following EVAR (\$US)

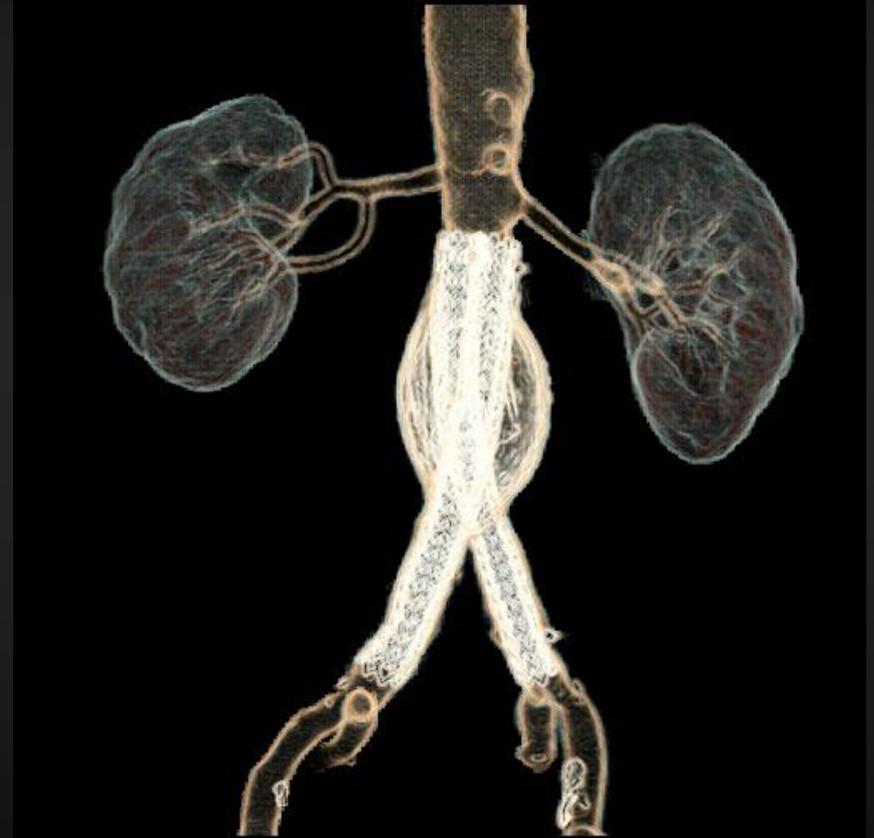
Event	No	Yes
Endoleak	\$5,706	\$26,739
Secondary Intervention	\$3,668	\$31,696

“Efforts aimed at minimizing cost should emphasize technical and device modifications aimed at reducing endoleaks and the need for secondary procedures.”

Noll RE, et al. J Vasc Surg 2007;46:9-15.

NELLIX design goals

- Address Challenging Proximal Neck Anatomies
 - Shorter lengths (<10mm)
 - Irregular (reverse conical)
- Treat Iliac Aneurysm Disease
 - Avoid IIA occlusion
- Lower Profile
- Reduce Rates of Reintervention
 - Minimize endoleaks
 - Prevent device migration



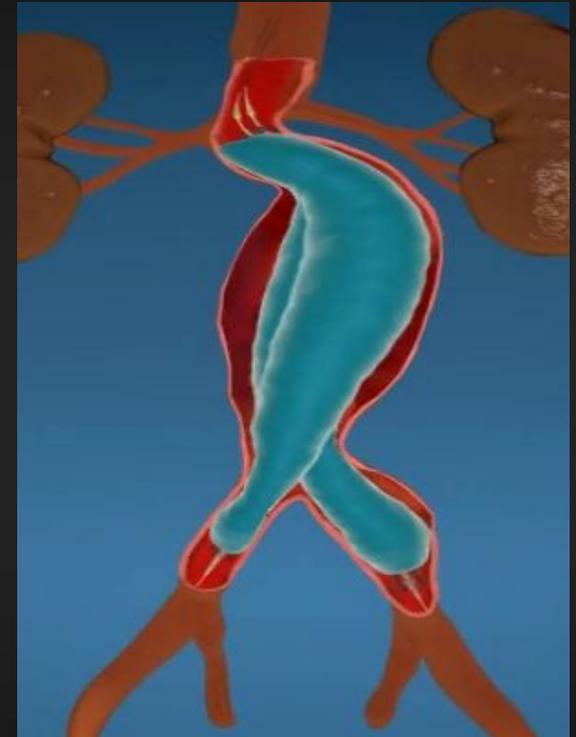
NELLIX sealing system



**Introduce both catheters
over .035" wires**



**Balloon expand both stents
(Chromium Cobalt)**

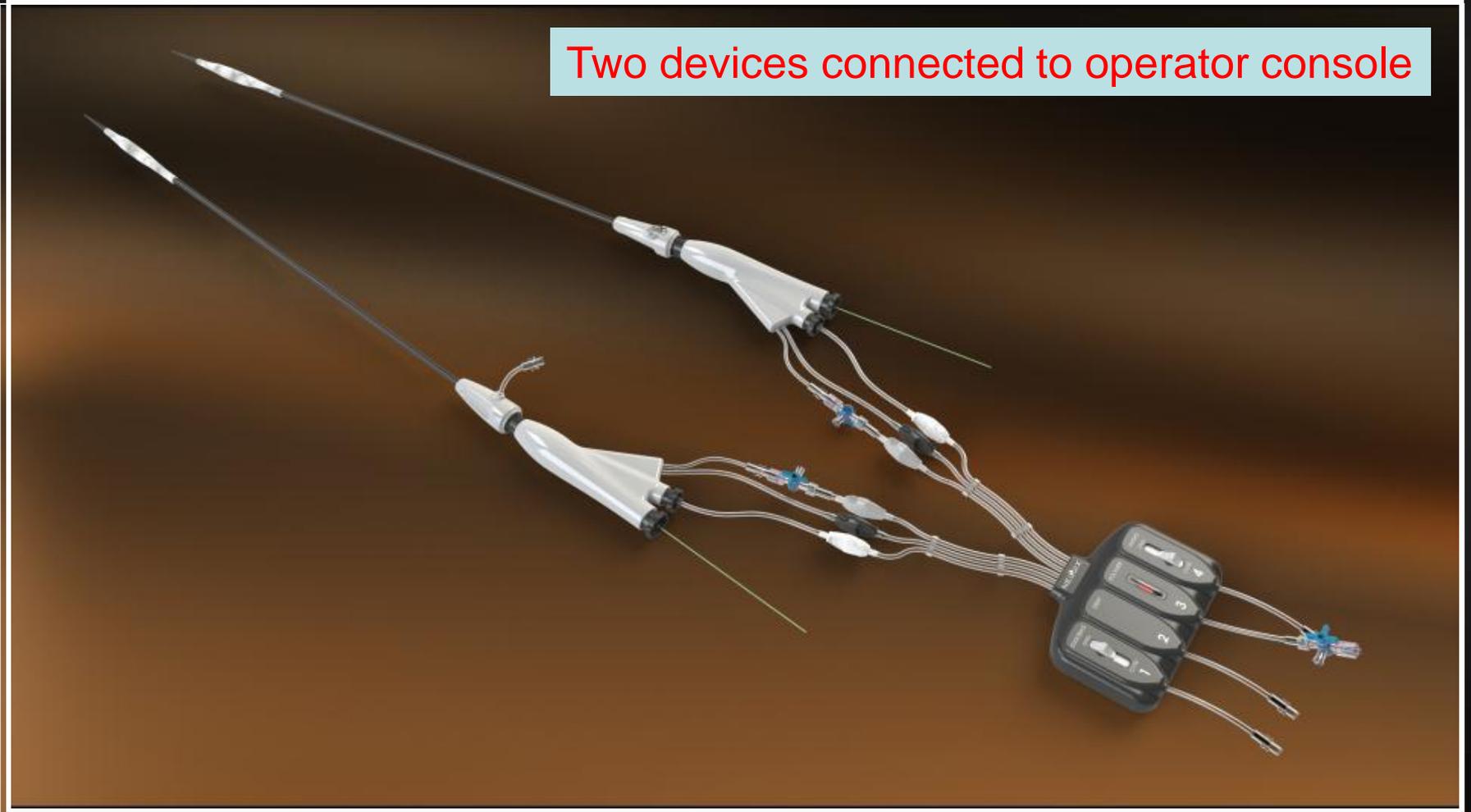


**Fill with Polymer using
pressure monitoring**

NELLIX sealing system

Angio-Tip (Hand or Power Contrast)

Two devices connected to operator console



NELLIX sealing system

- Step 1: device introducing

Video from Andrew Holden and Andrew Hill – Auckland, NZ

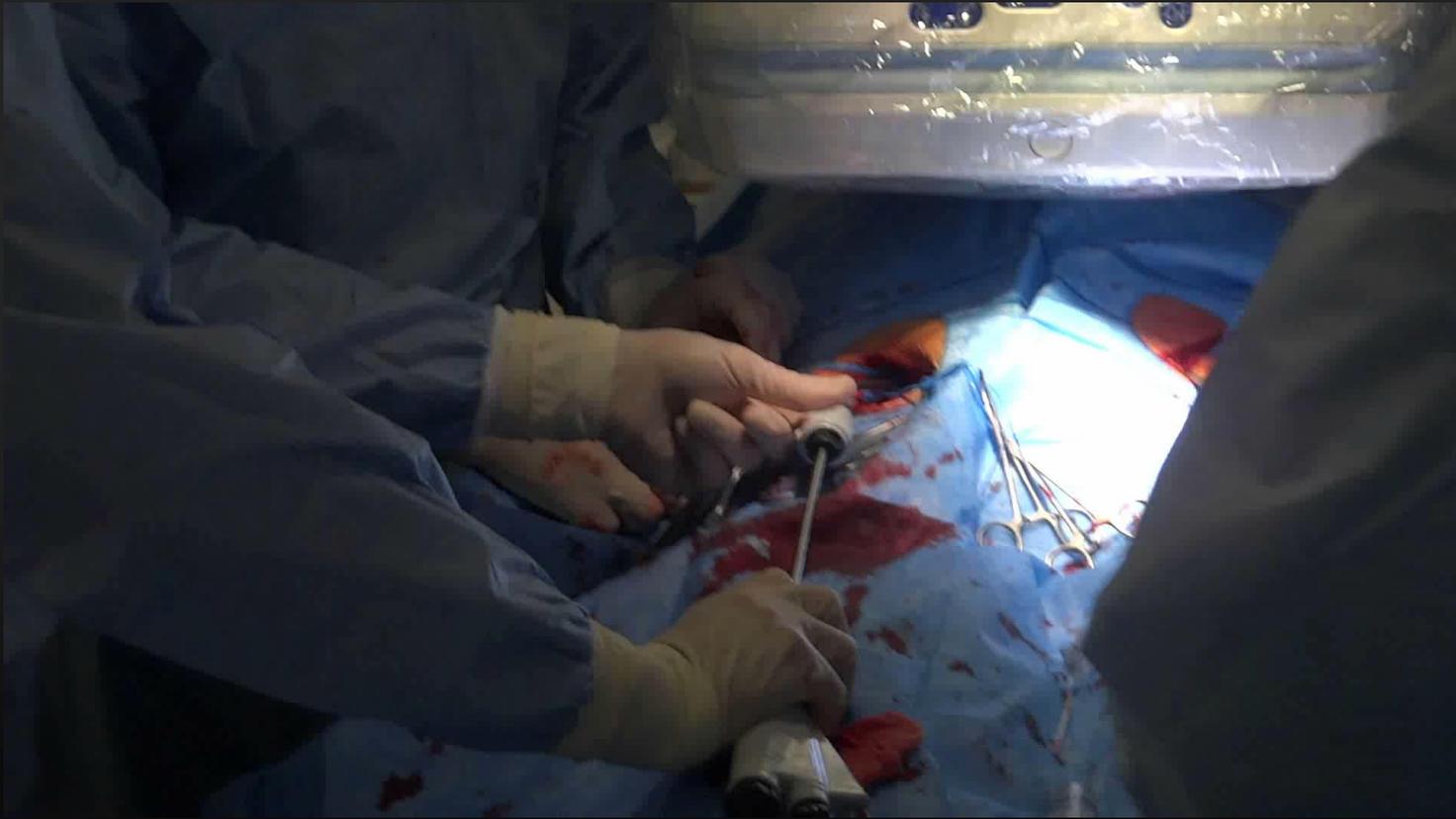


Personnal video



NELLIX sealing system

- Stent delivery
withdraw sheaths



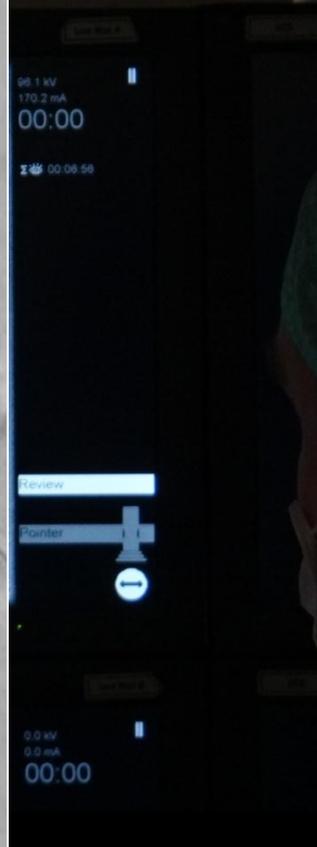
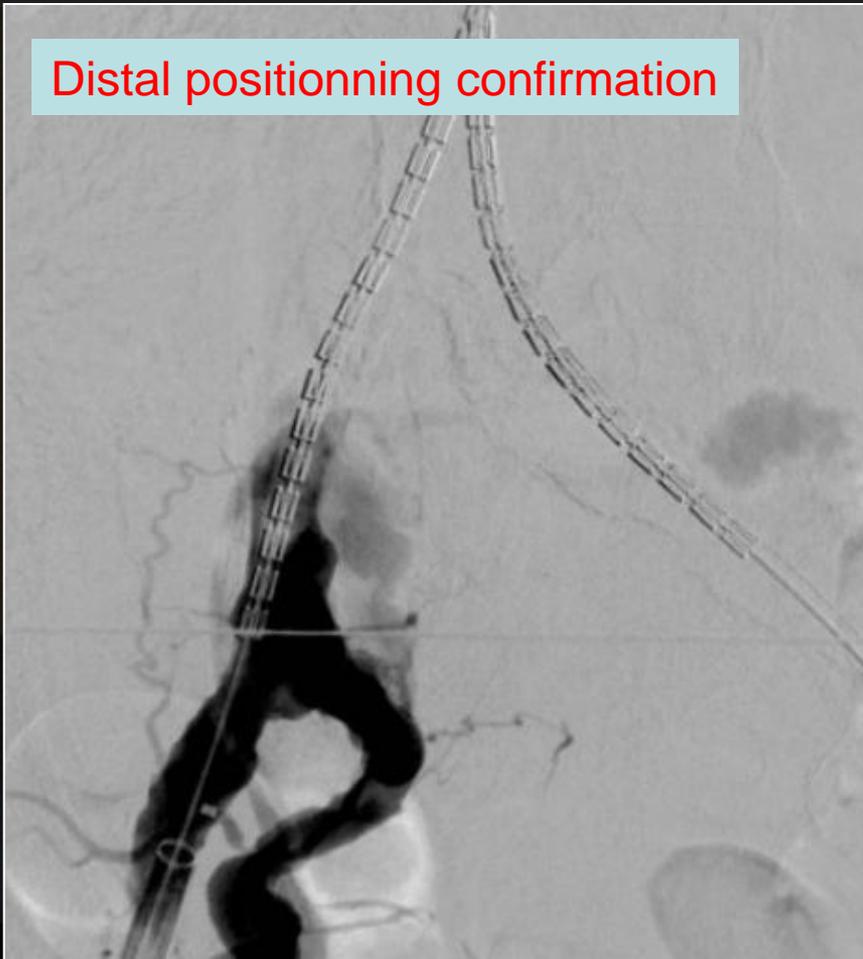
NELLIX sealing system



NELLIX sealing system

- Confirm the device position

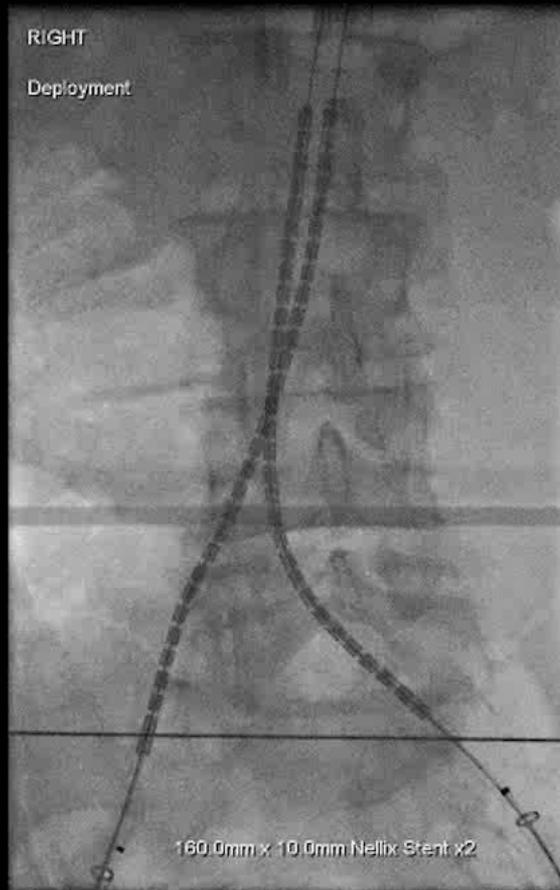
Distal positioning confirmation



NELLIX sealing system

- Deploy stent

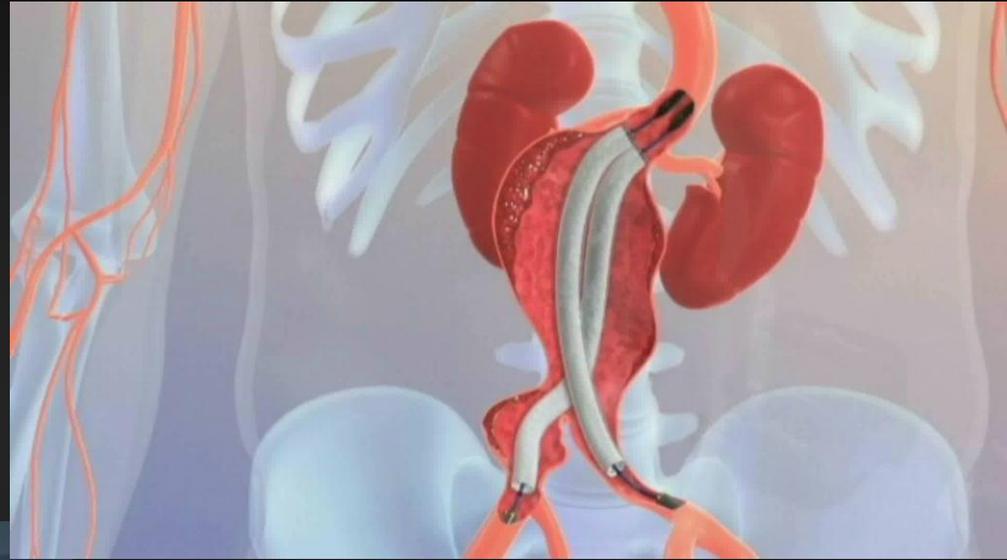
Video from Andrew Holden and Andrew Hill – Auckland, NZ



NELLIX sealing system

- Fill endobags with polymer with the pressure transducer

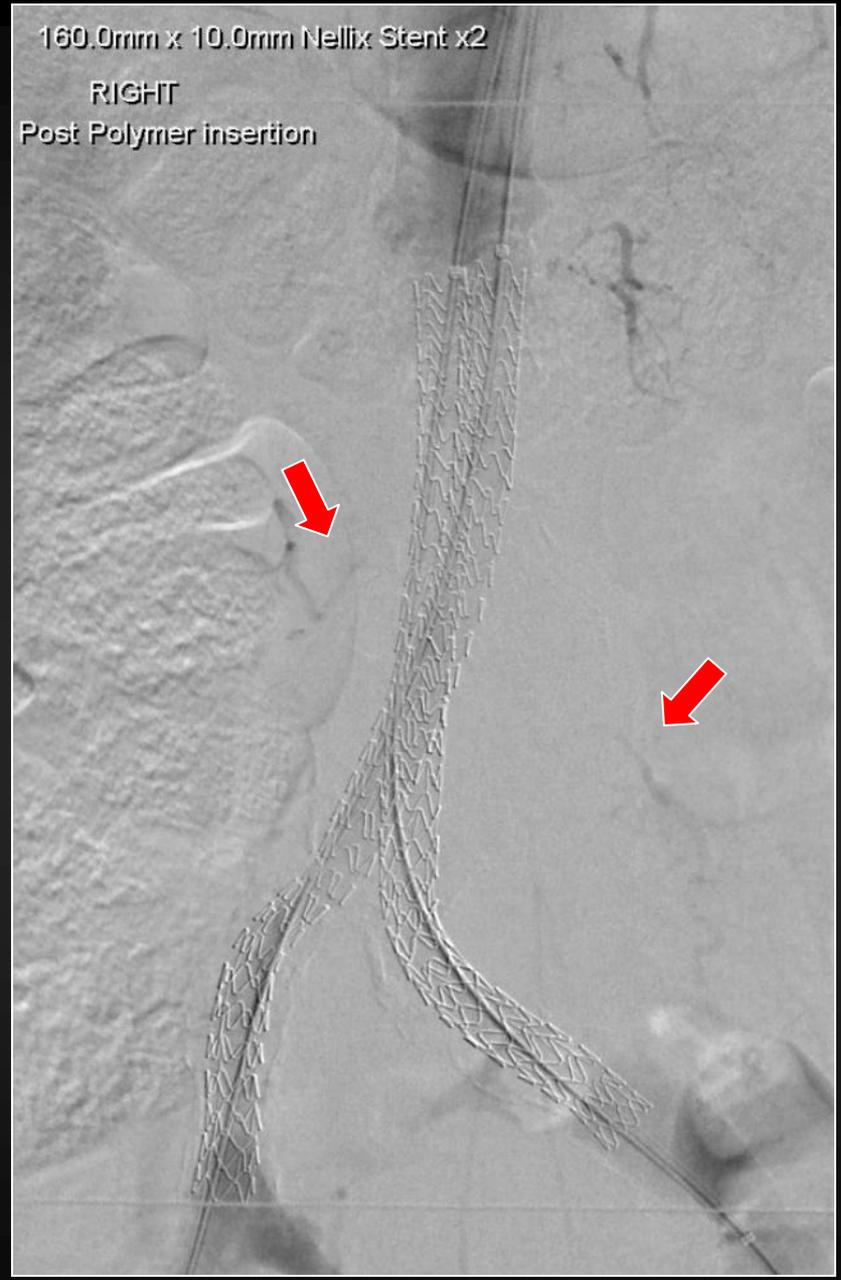
Personnal video



NELLIX sealing system

- Polymer acting in less than 5 minutes
- Possibility of reinjection (second line)





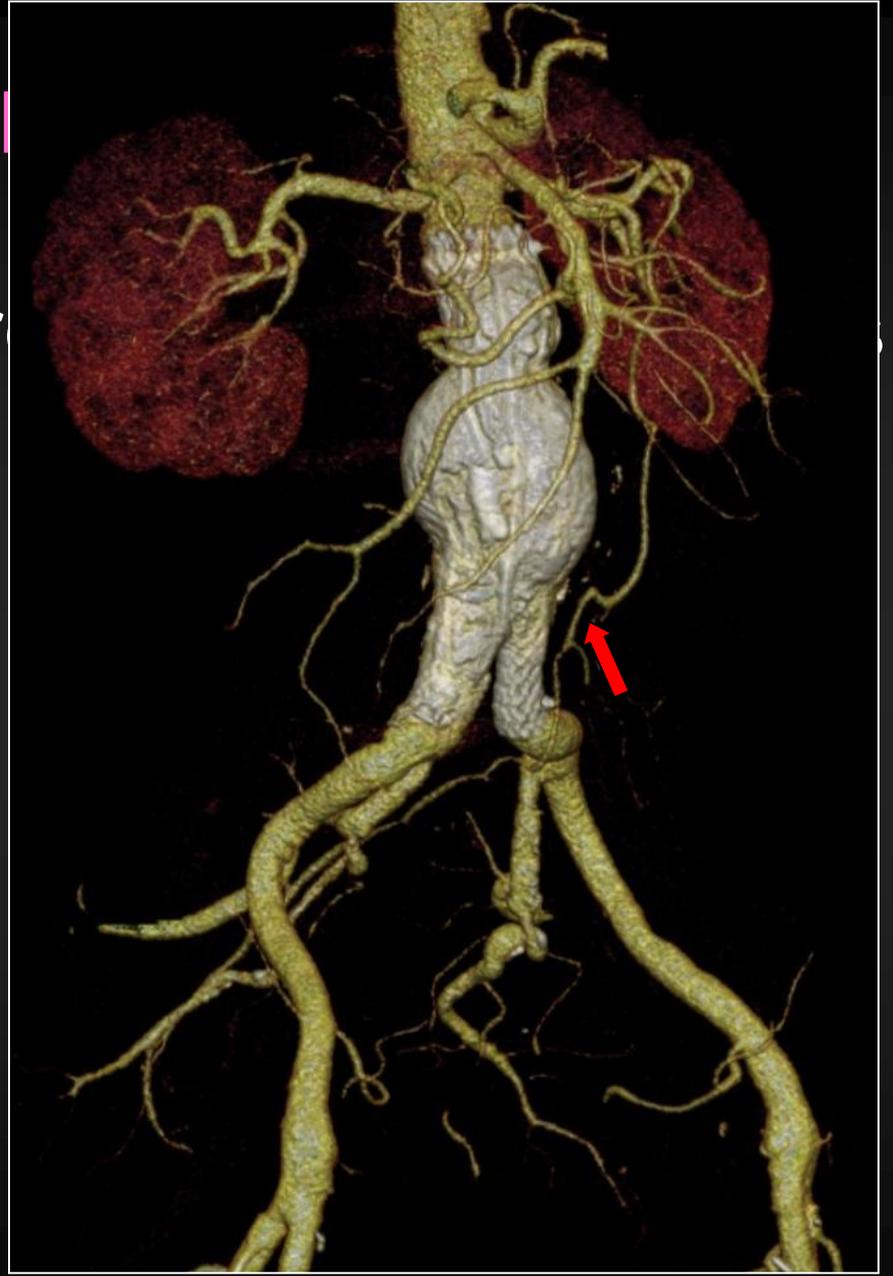
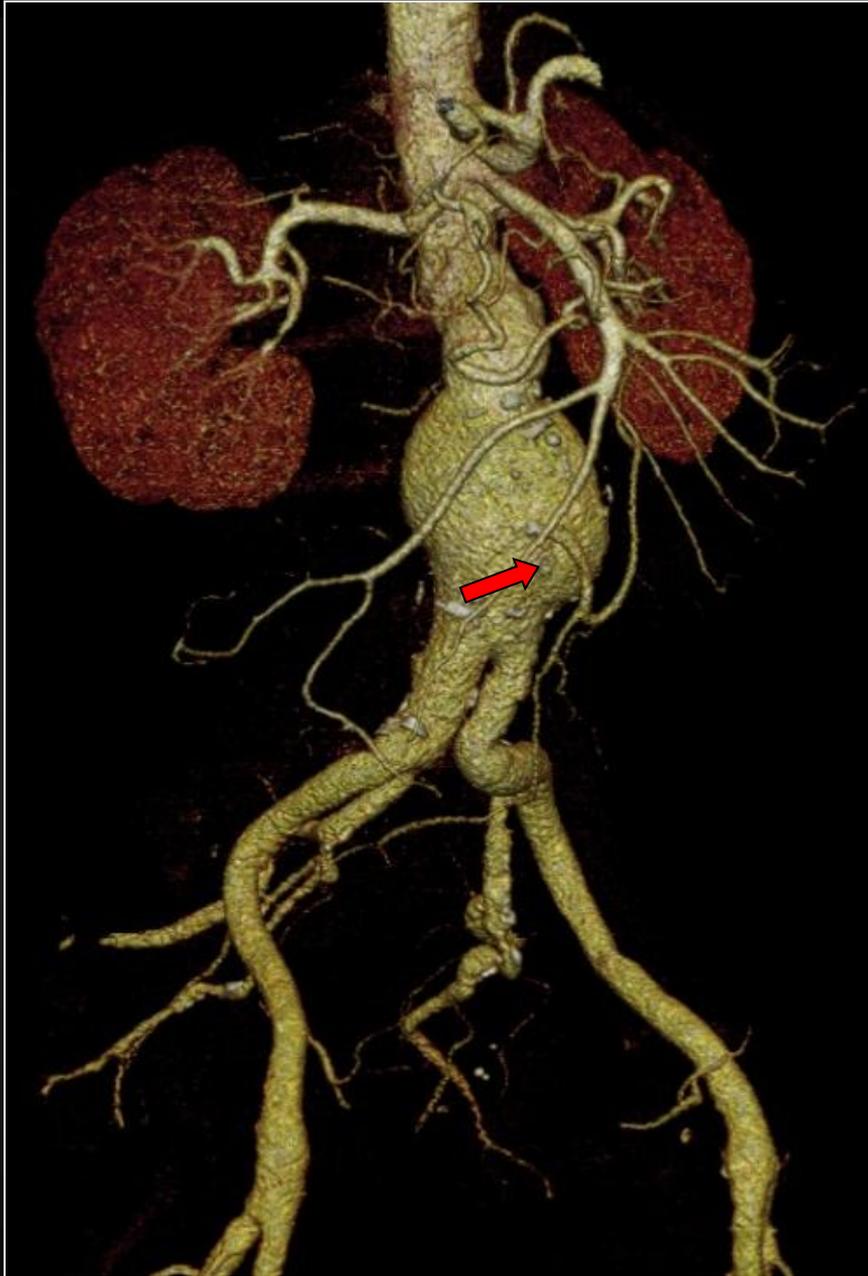
Results EVAS 1-NELLIX trial

Procedural Data	CE Trial Cohort (n = 34)	Continued Access Cohort 1 (n = 13)	Continued Access Cohort 2 (n = 8)	Total (N = 55)
Nellix indwelling time (min)	70 (33, 150)	47 (22, 83)	31 (23, 55)	52 (22, 150)
Polymer fill volume (mL)	73 (21, 79)	59 (21, 79)	63 (45, 90)	68 (21, 168)
Estimated blood loss (mL)	165 (35, 400)	195 (50, 630)	196 (95, 400)	179 (35, 630)
Fluoroscopy time (min)	33 (10, 70)	16 (4, 26)	11 (6, 30)	21 (4, 70)
Contrast volume (mL)	219 (105, 450)	220 (48, 390)	212 (85, 544)	210 (48, 544)
Total procedure time (min)	116 (33, 170)	95 (28, 104)	79 (43, 146)	105 (33, 170)
Time to hospital discharge (days)	3.8 (1, 9)	3.2 (1, 11)	3.3 (2, 6)	3.6 (1, 11)

Results EVAS 1-NELLIX trial

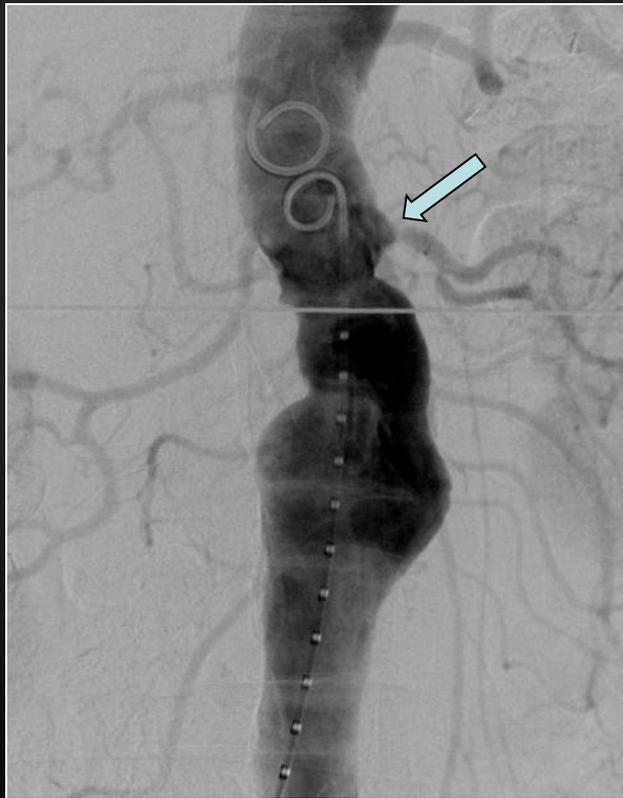
- Type 1A Endoleak resolved spontaneously within 60 days
- Type 1B Endoleak was due to improper device sizing (too short). A limb extension was added at 15 months which resolved the Endoleak
- Type II Endoleak resolved spontaneously within 60 days

Evaluation	30 Days (n = 54)	6 Month (n = 46)	1 YR (n = 40)	2 YRS (n = 29)	3 YRS (n=6)
Device Migration	0	0	0	0	0
Endoleak – Type 1A	1.8% (1)	0	0	0	0
Endoleak – Type 1B	1.8% (1)	1.8 (1)	3.1% (1)	0	0
Endoleak – Type II	1.8% (1)	0	0	0	0
Endoleak – Type III/IV	0	0	0	0	0



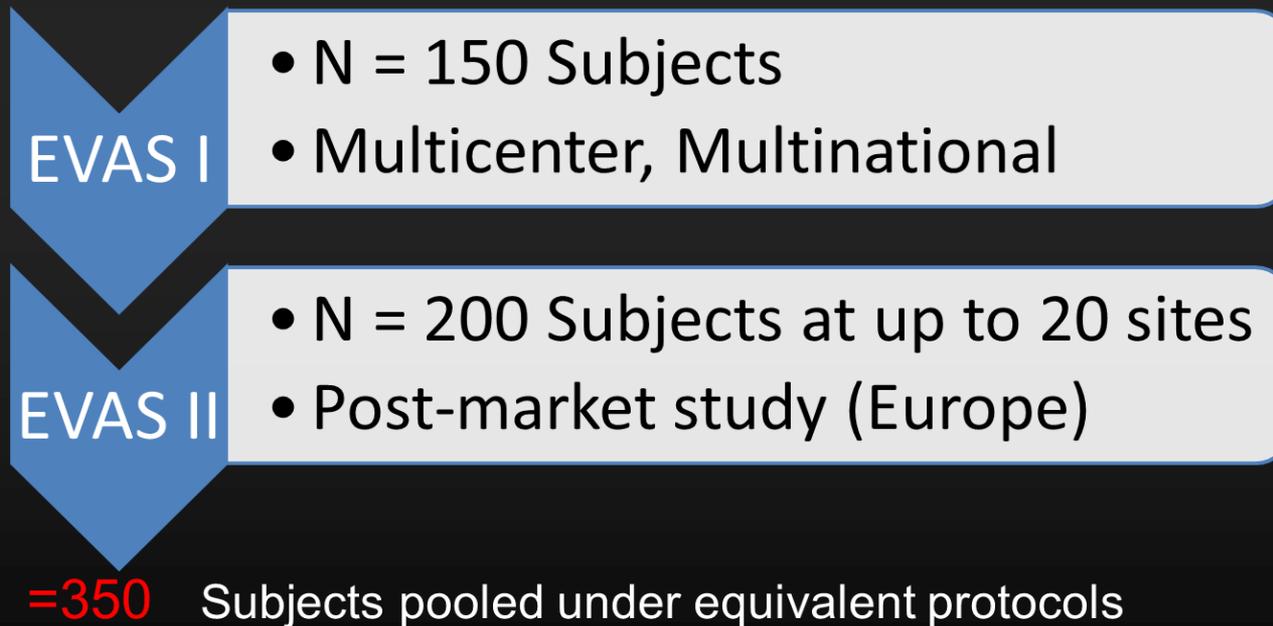
Summary – personal feeling

- Deal with very short neck – reverse conical neck ...with chimney...in emergency



Conclusion

- Very exciting and promising device
- Efficiency and durability need to be proved



Conclusion: polymer is fantastic !

