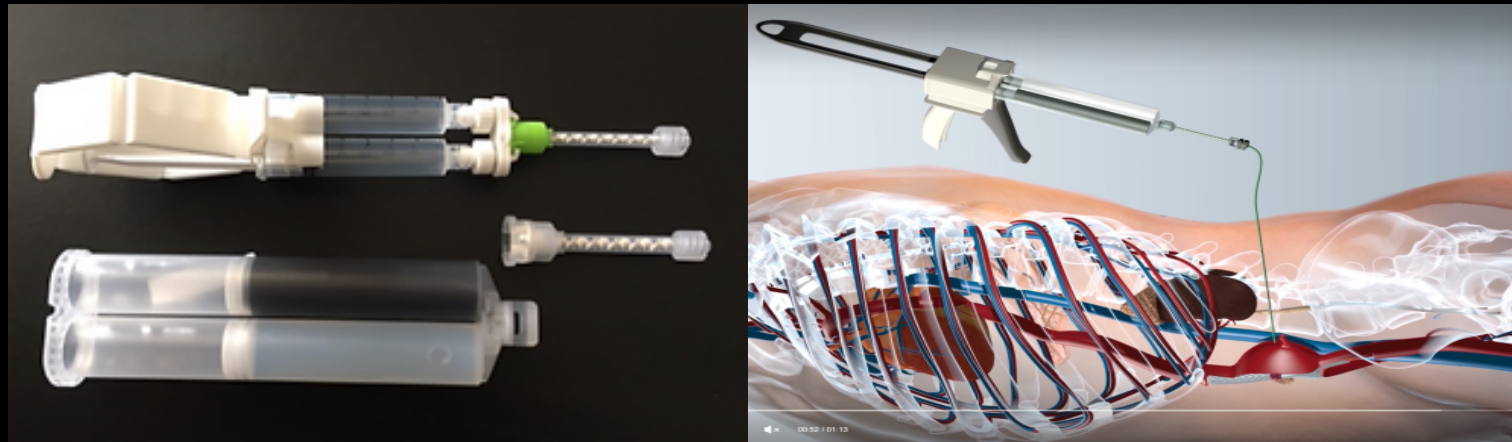




AneuFix: a novel treatment for type 2 endoleak

Short-term results of a multicenter pivotal trial

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Disclosure

Speaker name:

Stefan Smorenburg

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)

partly funded research by Philips

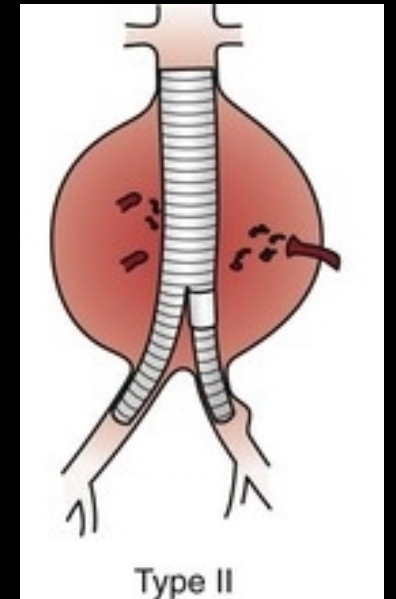
- ☐ I do not have any potential conflict of interest



- Type 2 endoleaks after EVAR are common (8-44%)
- Need for secondary interventions in up to 40% cases

Interventions for type 2 endoleak

- transarterial embolization
84% technical, 62% clinical success¹
- translumbar embolization (Onyx/Glues)
99% technical, 66% clinical success^{1,2}



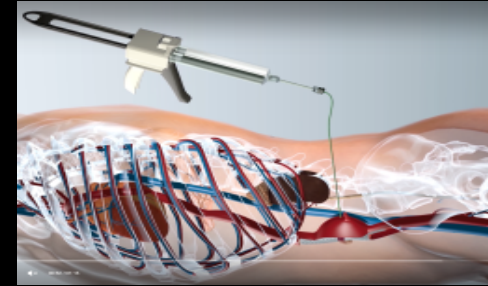
¹Ultee et al. 2018 *Eur J Vasc Endovasc Surg*

²Scallan et al. 2021 *J Vasc Surg*



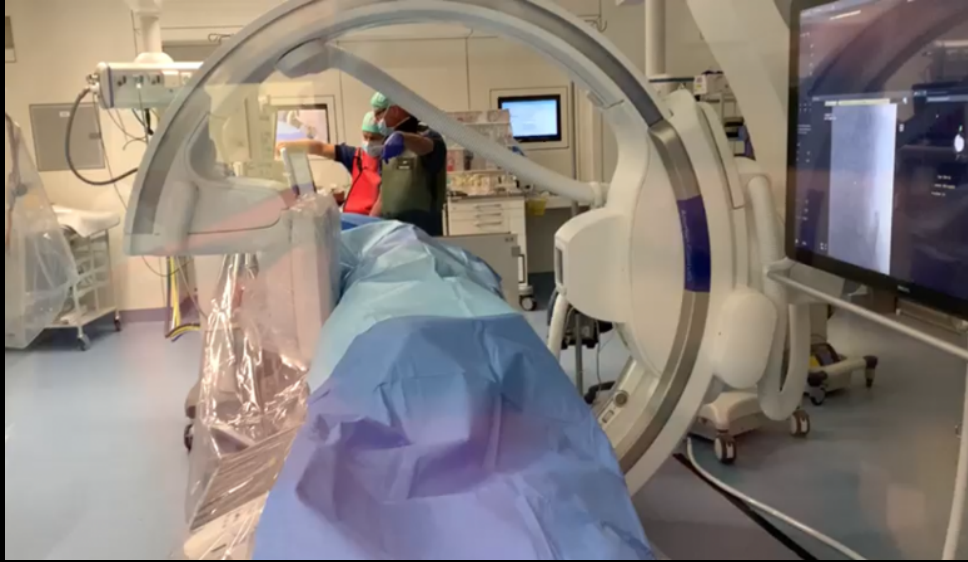
AneuFix is a novel elastic polymer designed to fill the endoleak cavity including a short segment of the feeding vessels

- low viscosity
- injected via translumbar access

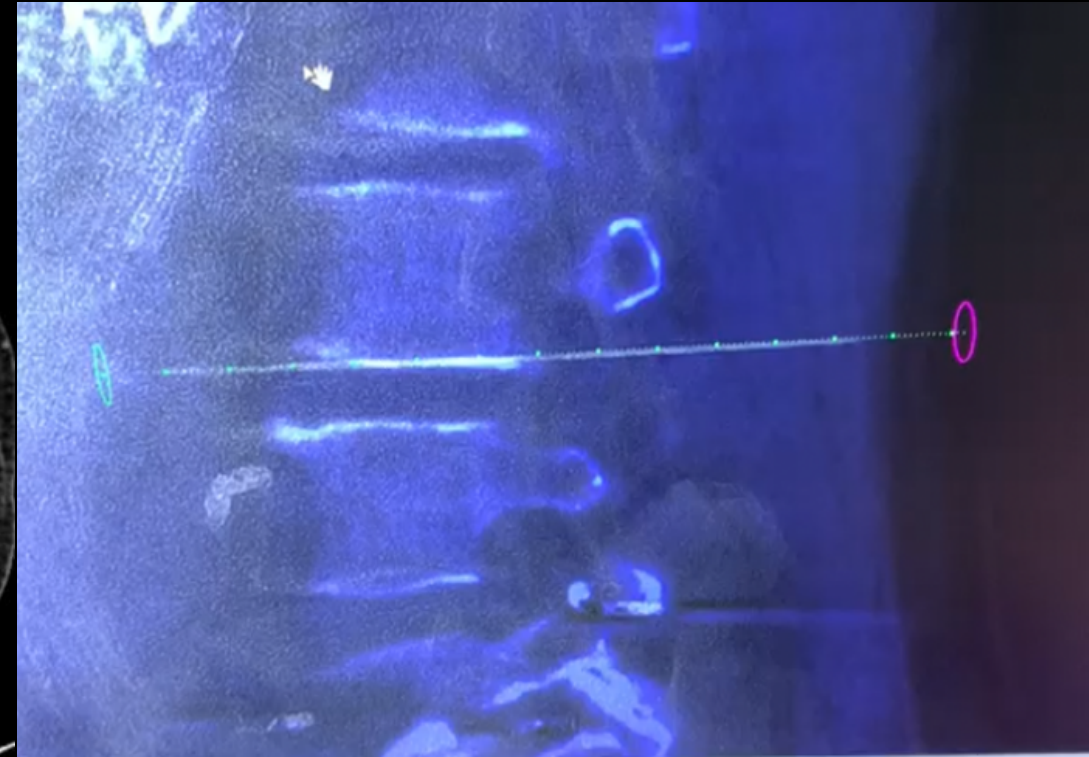


After being injected into the endoleak, AneuFix regains a very high viscosity and the cured AneuFix implant is **stable**, remains **flexible** and is **biocompatible**

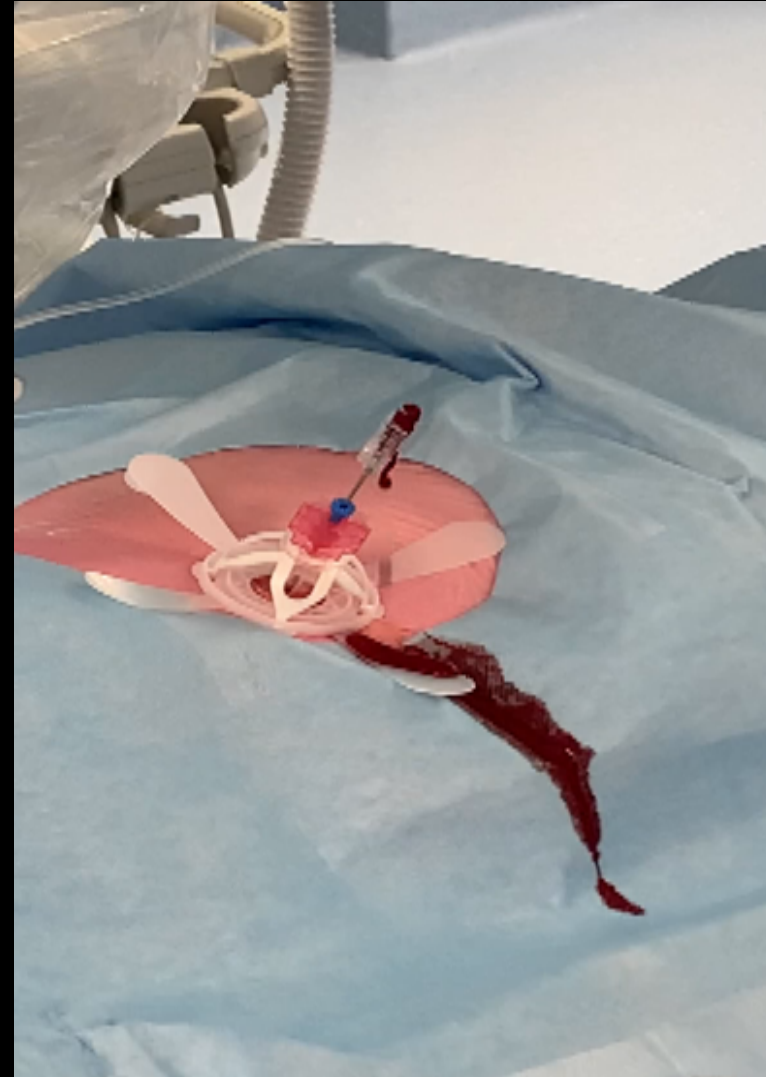
Cone-beam CT



Needle planning software

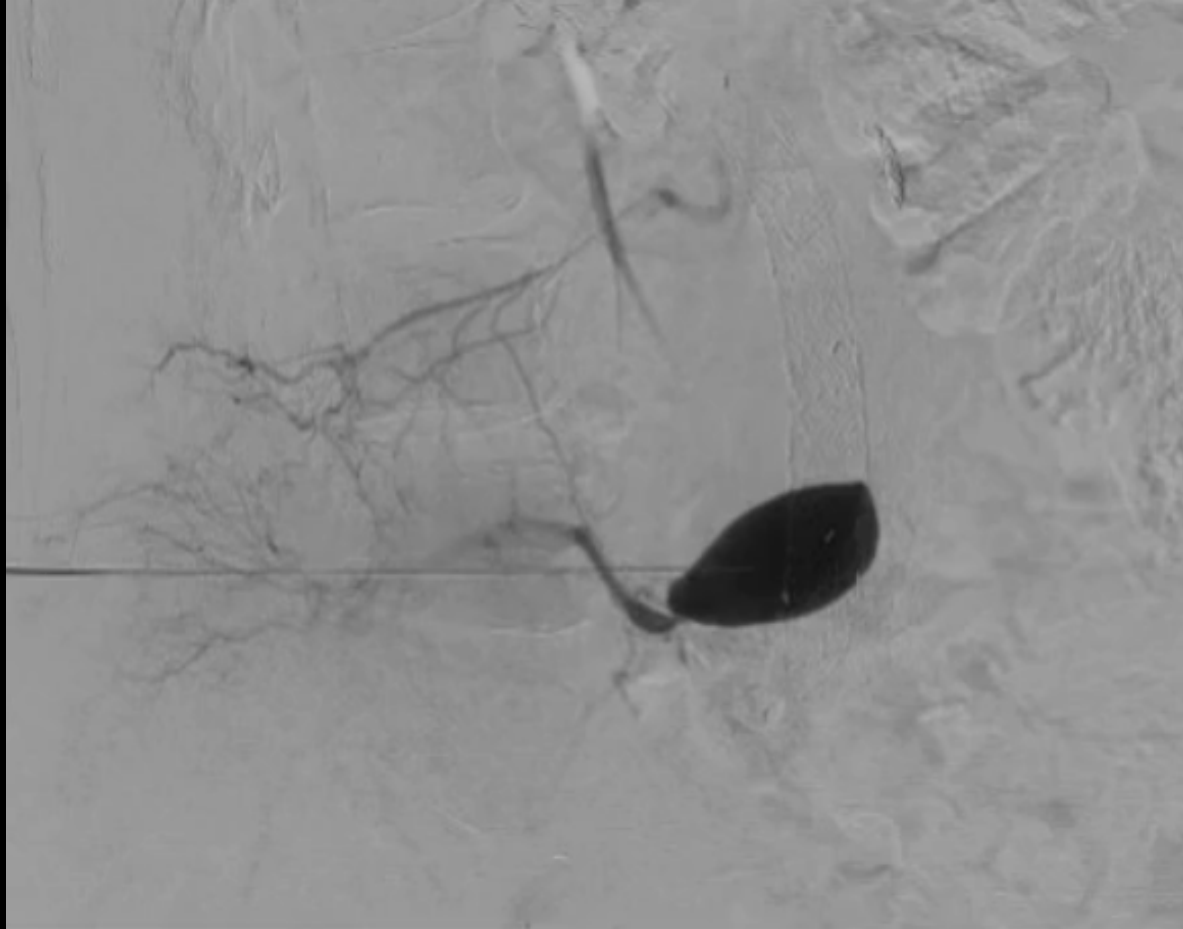


Translumbal puncture of endoleak cavity

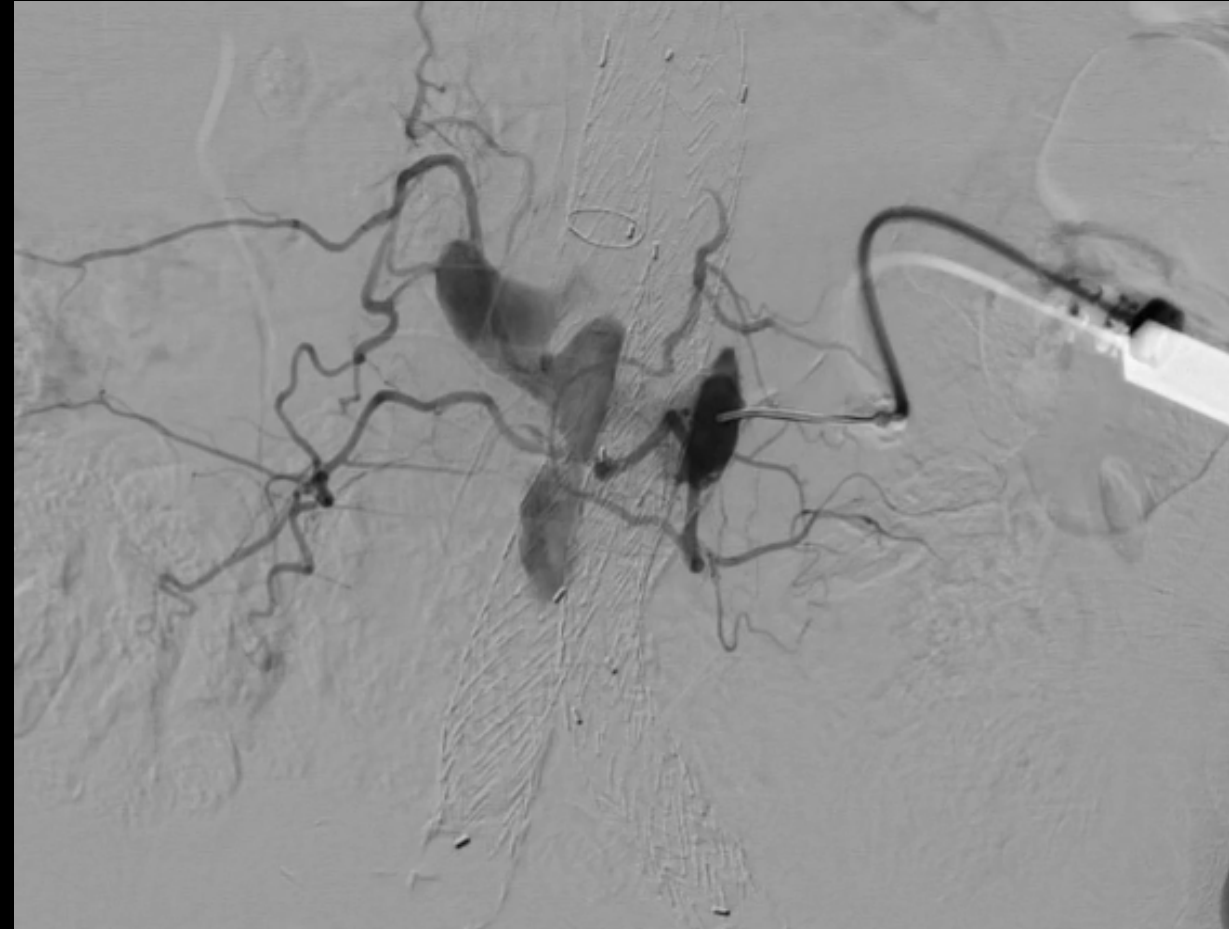




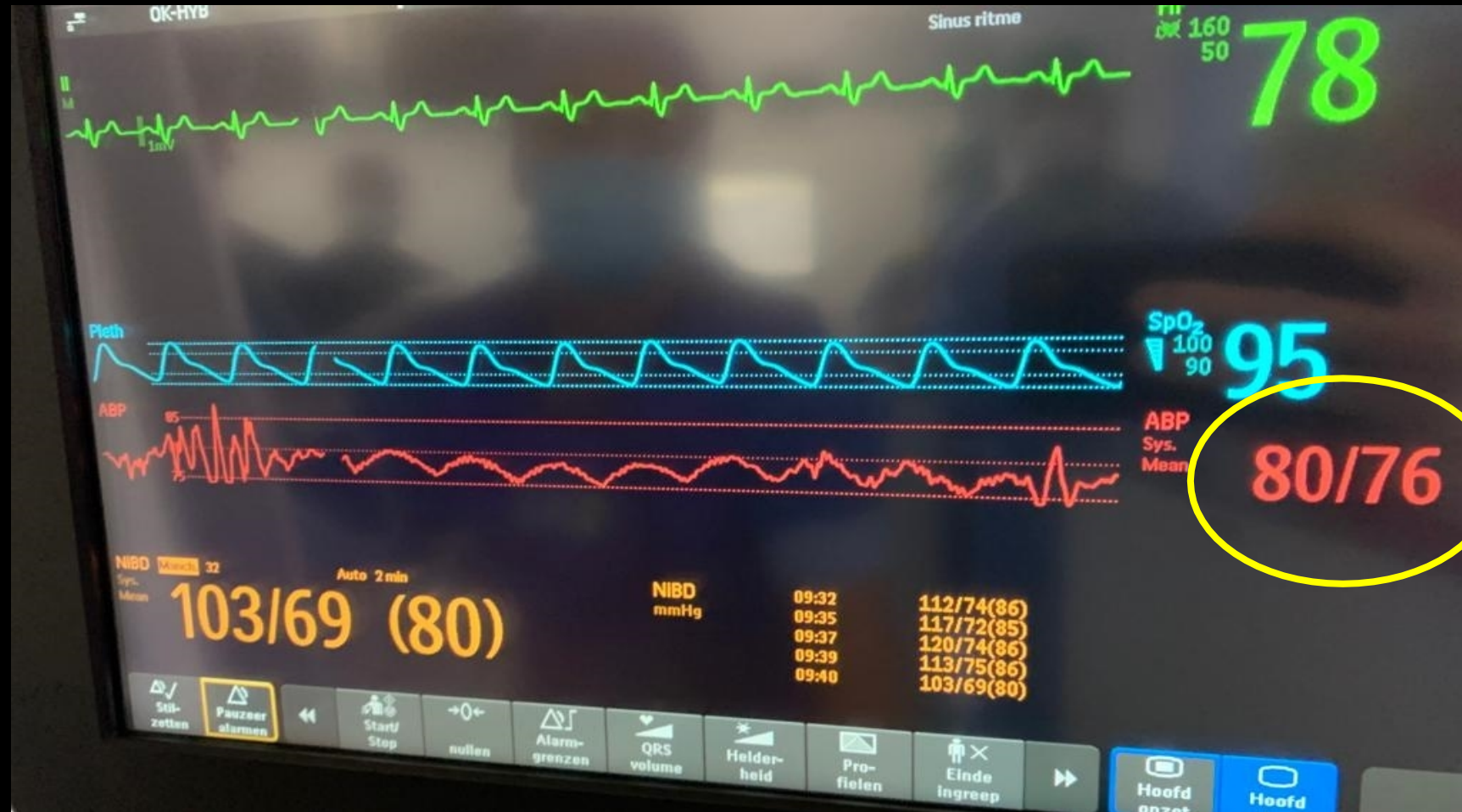
Direct angiography of endoleak



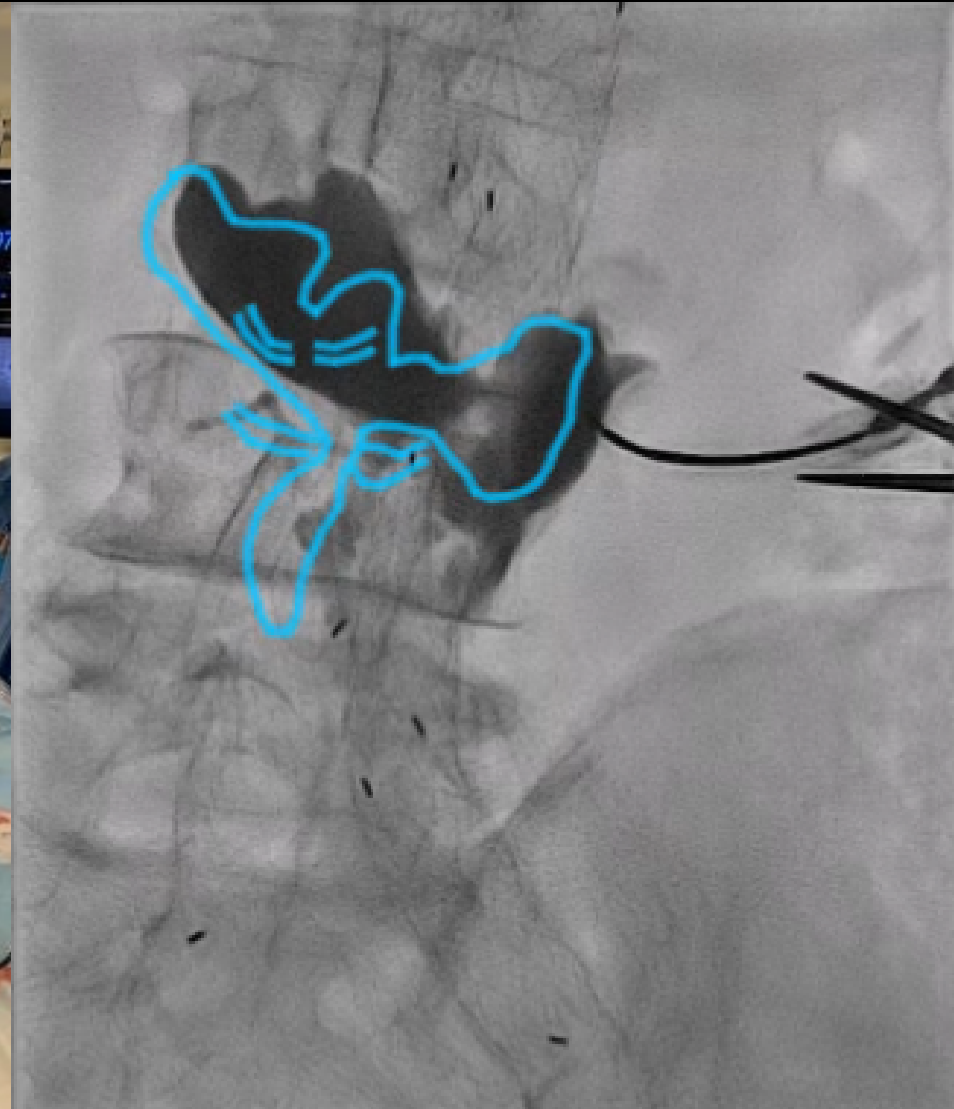
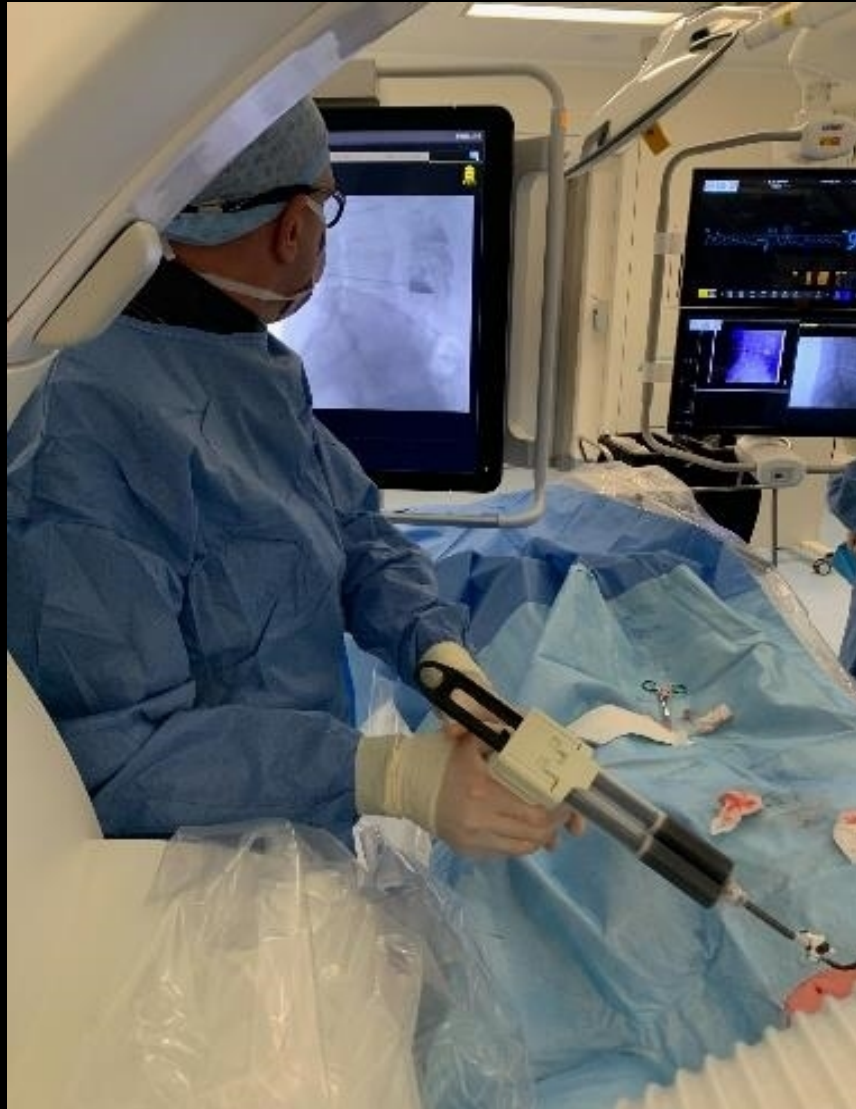
Multiple connected lumbar arteries

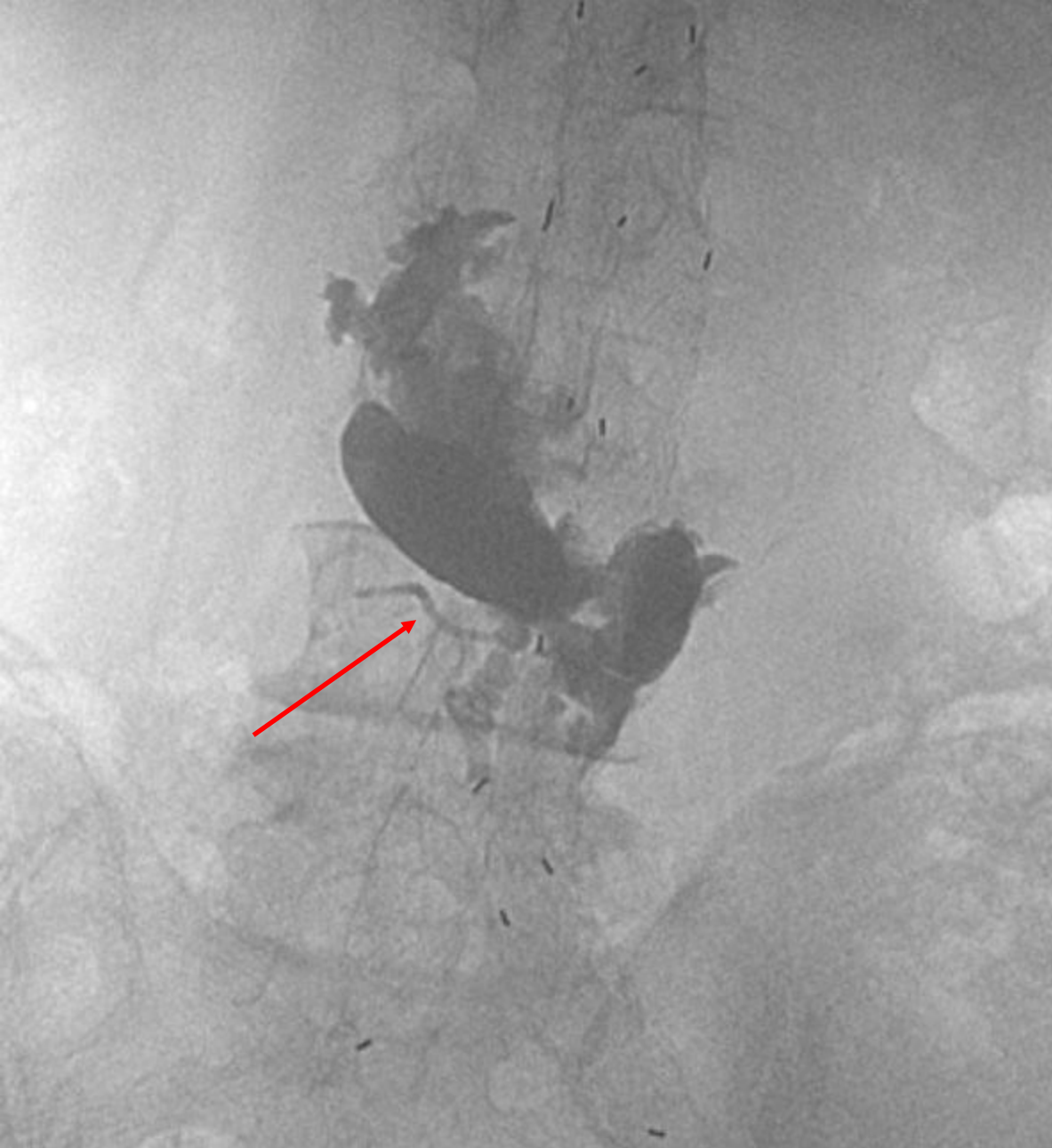


Aneurysm Sac pressure



AneuFix injected into Endoleak



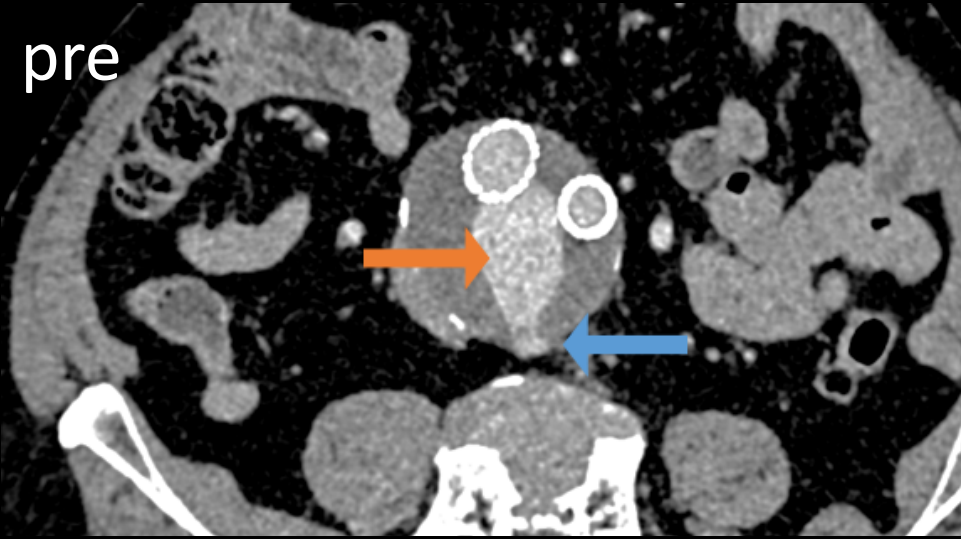


Endoleak filled with polymer

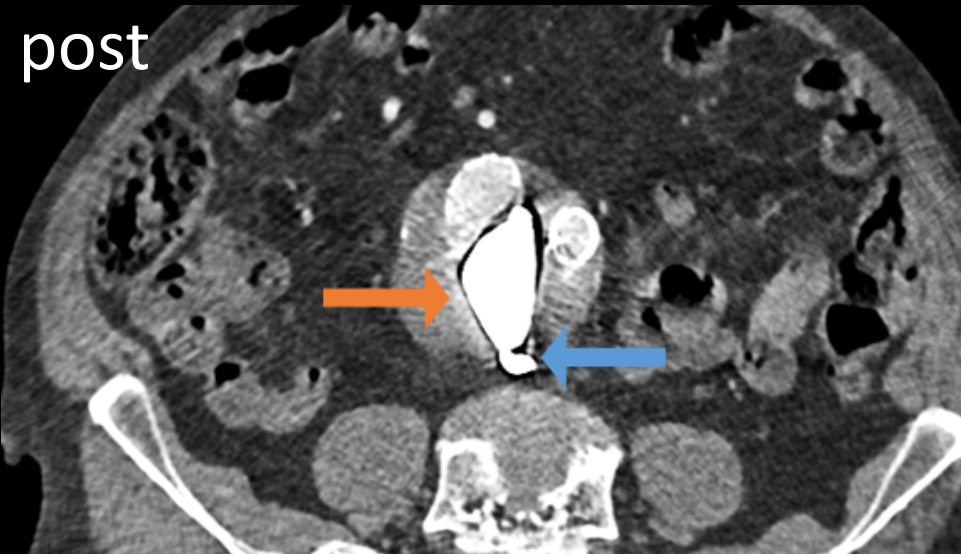
Note intended filled short segment
of feeding lumbar artery (arrow)

CTA

pre



post





AneuFix Trial

(*ClinicalTrials.gov: NCT02487290*)



Inclusion

- Type 2 endoleak and aneurysm growth >5mm

Exclusion

- Patients with patent inferior mesenteric artery connected to the endoleak



Primary endpoint

- Technical success:

Adequate puncture endoleak cavity and injection of AneuFix

Secondary endpoints

- Serious adverse events/reinterventions
- Clinical success at 6 months: *No further aneurysm growth*

Follow-up CTA after 1 day, 3/6/12 months



Results

- 16 men, 4 women, median age 78 years (IQR 76-81 years)
- median pre-AneuFix aneurysm diameter 79 mm (IQR 71-85 mm)
- median aneurysm growth after EVAR 16 mm (IQR 10-21 mm)



- 3 procedures general, 17 local anaesthesia

- **Technical success 94%**

18 out of 19 endoleaks filled with AneuFix polymer

- 1 failure (no endoleak visible on pre-procedural CT)



- Median Arterial Sac Pressure 85 mmHg (IQR, 71-90 mmHg)
- AneuFix volume injected 14 ml (IQR 10-20 ml)
- AneuFix injection time 5 min (IQR 5-8 min)
- Fluoroscopy time 9 min (IQR, 7-11 min)
- Total procedure time 1h 25 min (1h 10–1h 47 min)



- No serious adverse events/re-interventions
- Clinical success 80% (12/15)
 - 2 patients persistent aneurysm growth (insufficient endoleak filling)
 - 1 patient type 1a endoleak

In conclusion



First results of type 2 endoleak treatment with **AneuFix** elastic polymer in patients with growing aneurysms show that the technique is

- feasible and relatively simple
- local anaesthesia
- safe
- clinically effective at 6 months

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