What is the real benefit of low profile endografts, if any?

Timothy Resch, MD PhD

Professor of Vascular Surgery

Copenhagen University Hospital - Rigshospitalet

Disclosures

- COOK Medical Inc – Consulting, IP
- JOTEC/Cryolife – Consulting
- Bentley Innomed – Consulting
- GORE – Speaker
- Medtronic – Advisory Board

Why Low Profile?

- Access Issues
  - Women (TEVAR)
- PEVAR
  - EVAR in LA
  - Wound infection
- Outflow Issues?
- Material fatigue
  - Endoleaks
  - Stent fracture

Is access limiting?

- Up to 50% of patients present with poor iliac access inhibiting EVAR*
- 15 % of conduits in TEVAR / EVAR**

Elkouri et al,Vasc Endovasc Surg 2004;38:401-412
** *Peterson et al*, J Vasc Surg. 2008 Feb;47(2):441-5
Abu-Ghaida et al, J Vasc Surg. 2002 Jul; 36(1):111-7

Influence of gender on outcomes after thoracic endovascular aneurysm repair

George J. Arnaoutakis, MD,a Eric B. Schneider, PhD,b Dean J. Arnaoutakis, MD, MBA,a

James H. Black III, MD,a Ying Wei Lum, MD,a Bruce A. Perler, MD, MBA,a Julie A. Freischlag, MD,a and Christopher J. Abularrage, MD, *Baltimore, Md*

Conclusions: Thirty-day unadjusted mortality after TEVAR for nonruptured thoracic aortic aneurysms is increased in women compared with men, but this univariate finding did not persist after risk adjustment. Multivariable analysis showed need for iliac artery exposure, age, and emergency surgery were independently associated with higher mortality rates. These results suggest a need for decreased device delivery size and improvements in endovascular technology.

(J Vasc Surg 2014;59:45-51.)

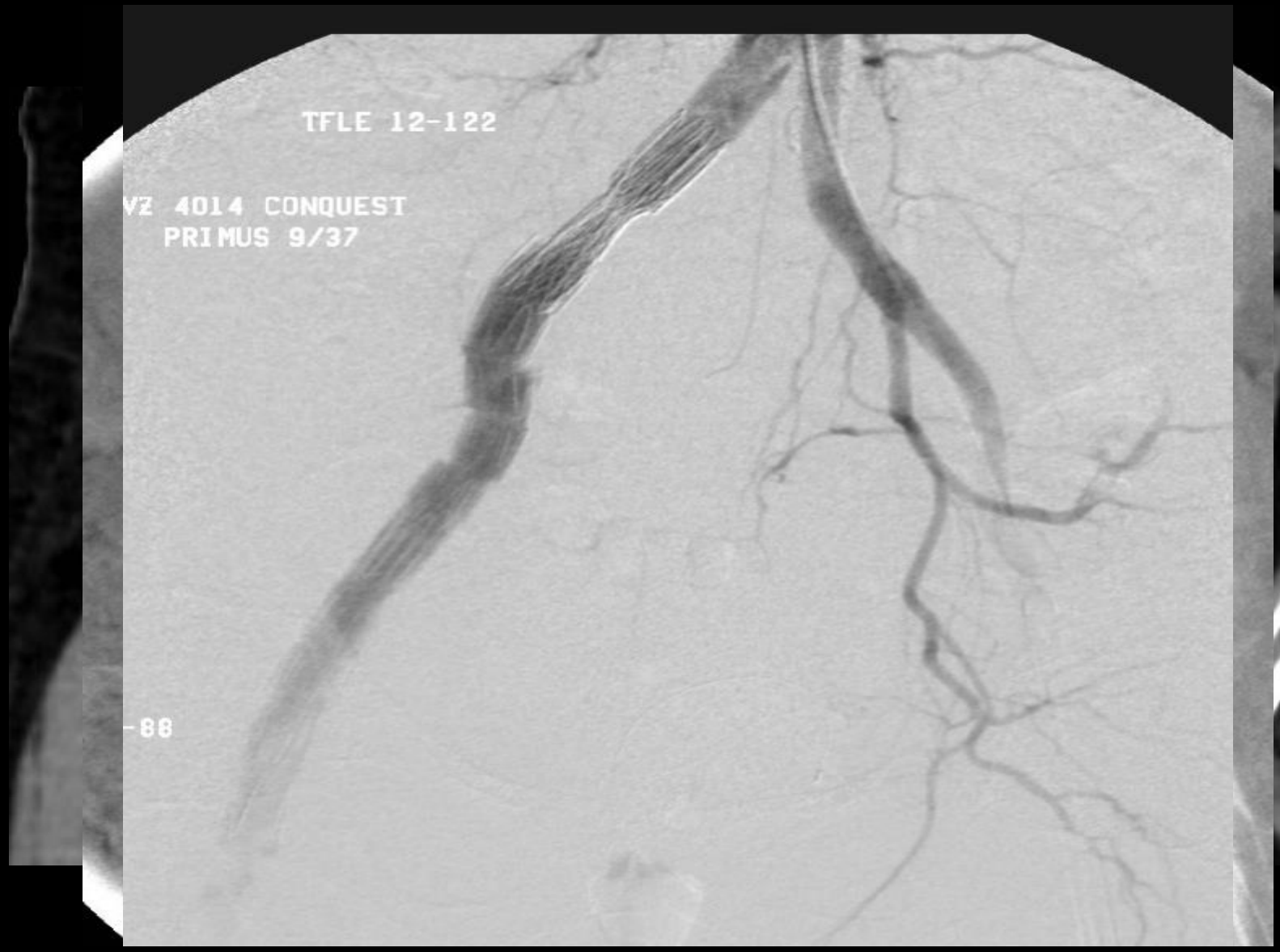
Does Profile affect suitability?

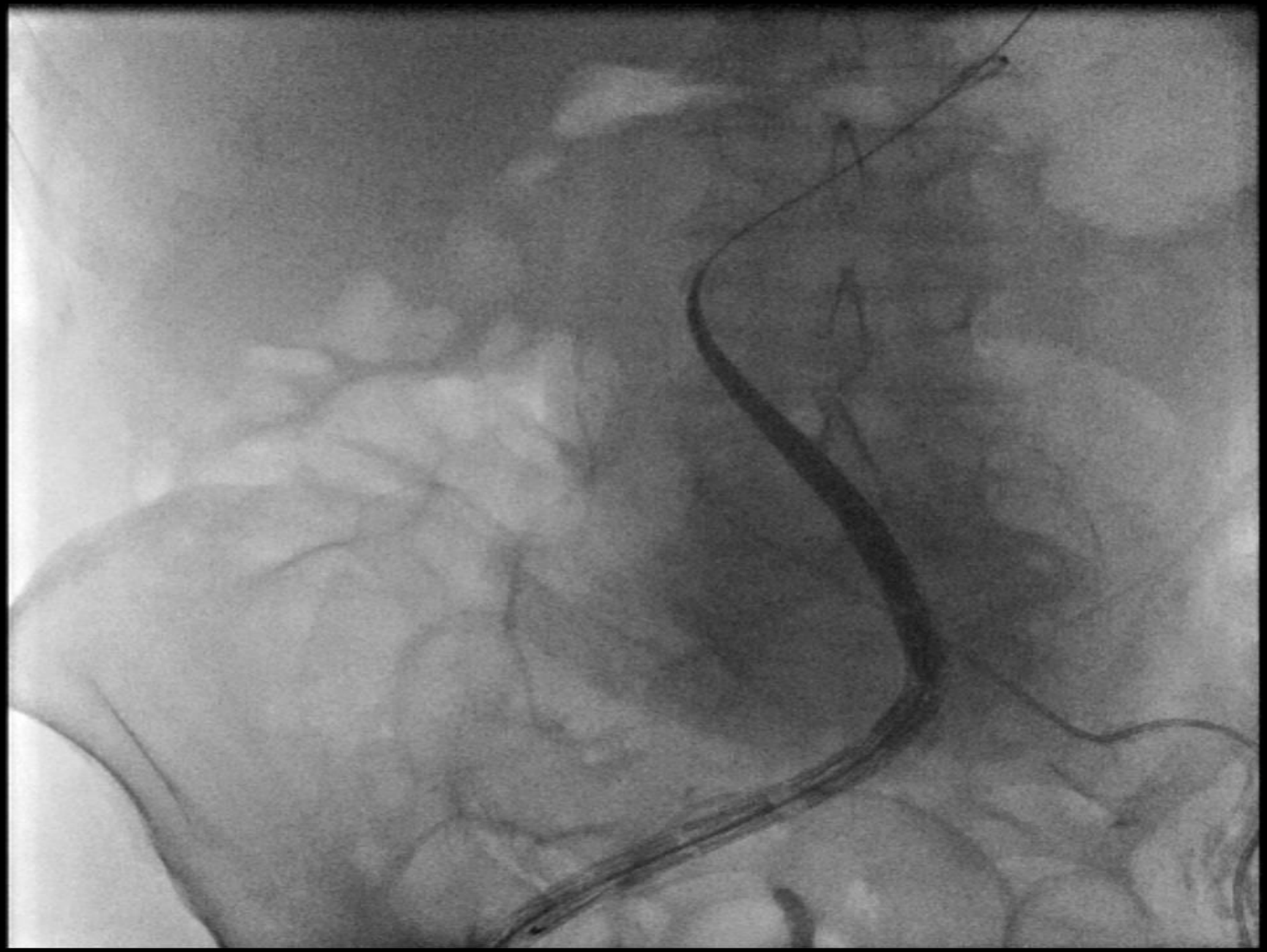
	IFU	Iliac diameter 4-6mm
Zenith Flex	28,6%	56,7%
Excluder	25,7%	58,9%
Endurant	48,1%	60,2%

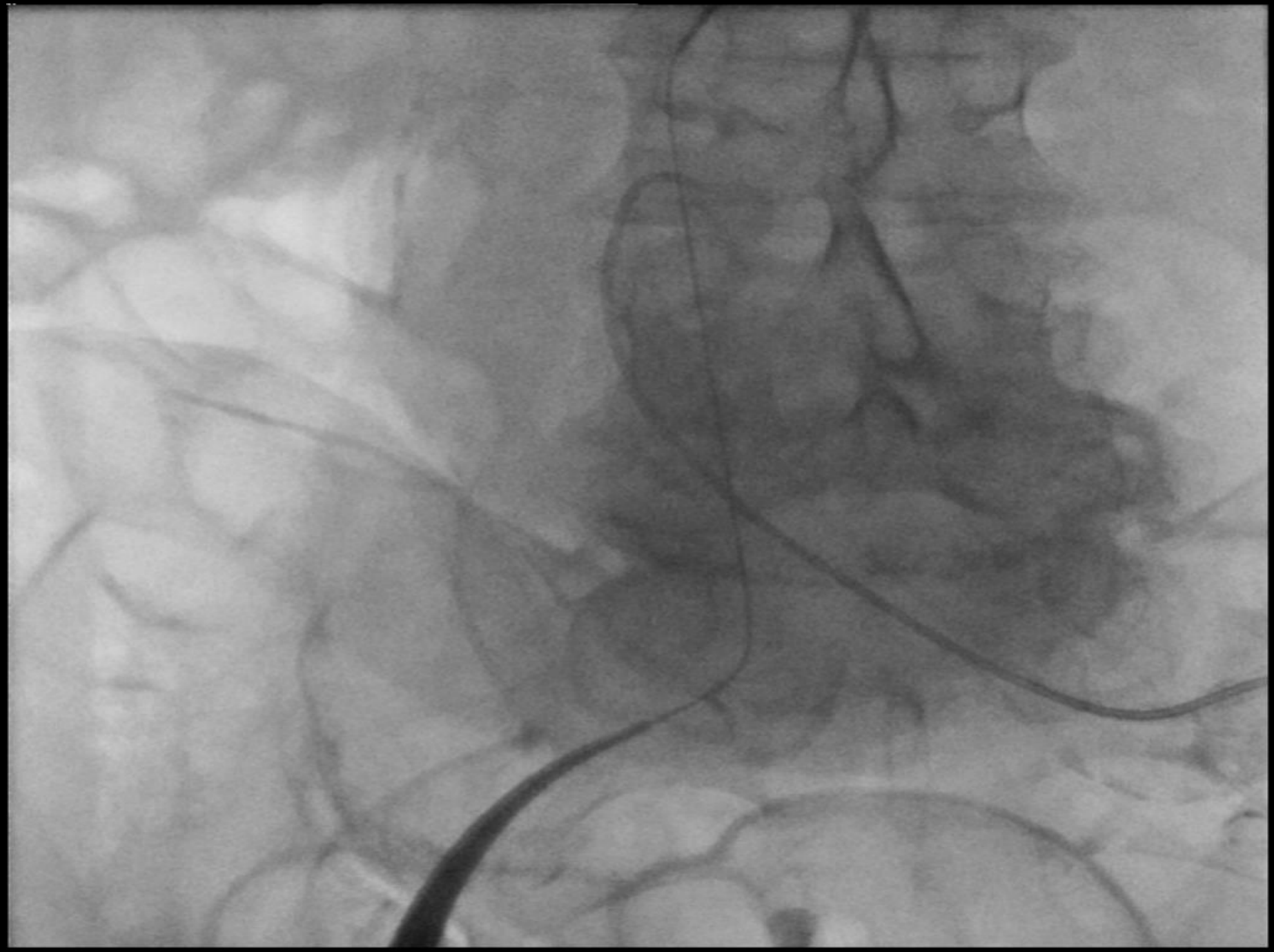
Kristmundsson et al. Vascular 2014 Apr;22(2)

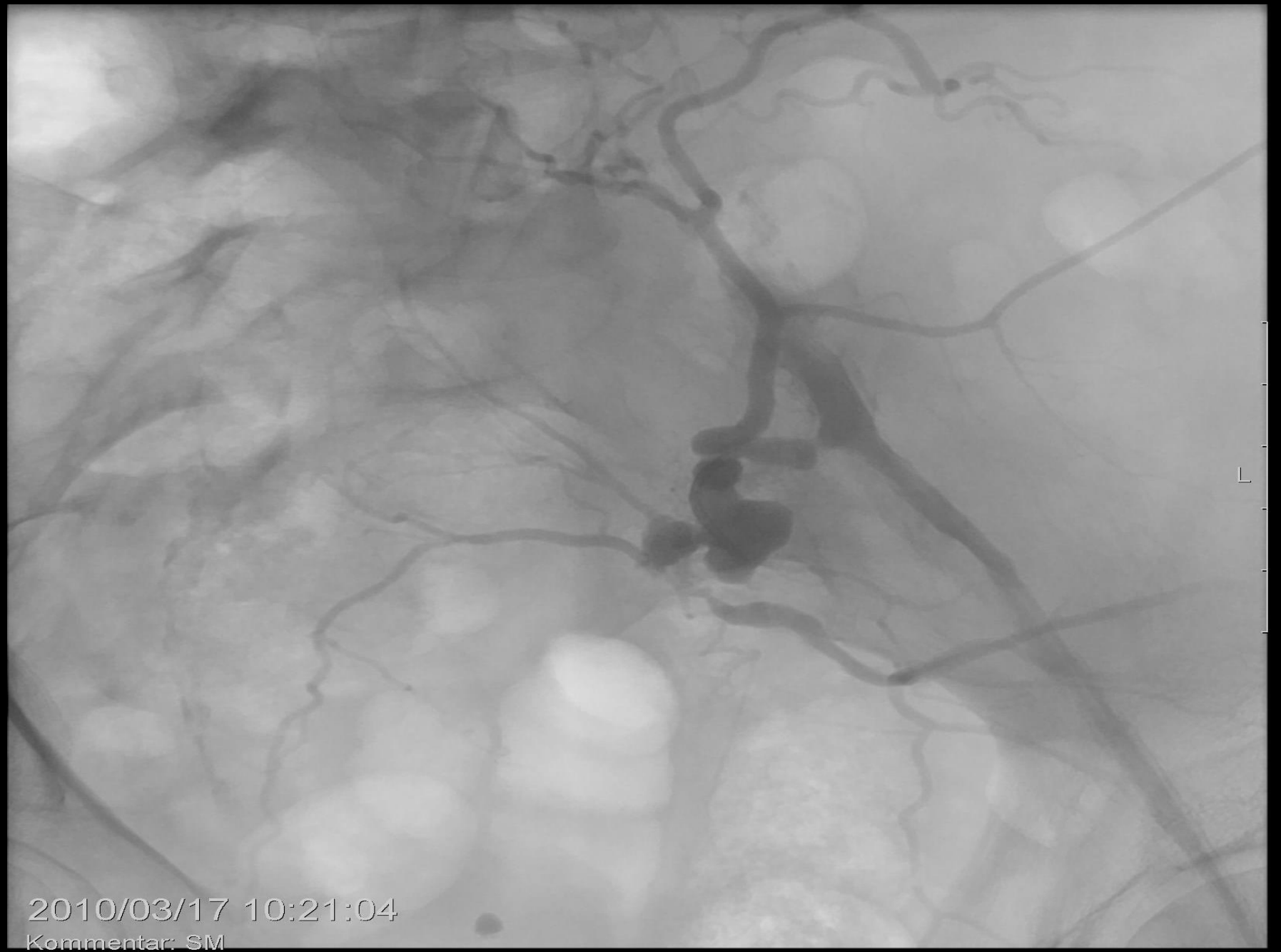
< 4mm (12F) no further advantage

Access problems





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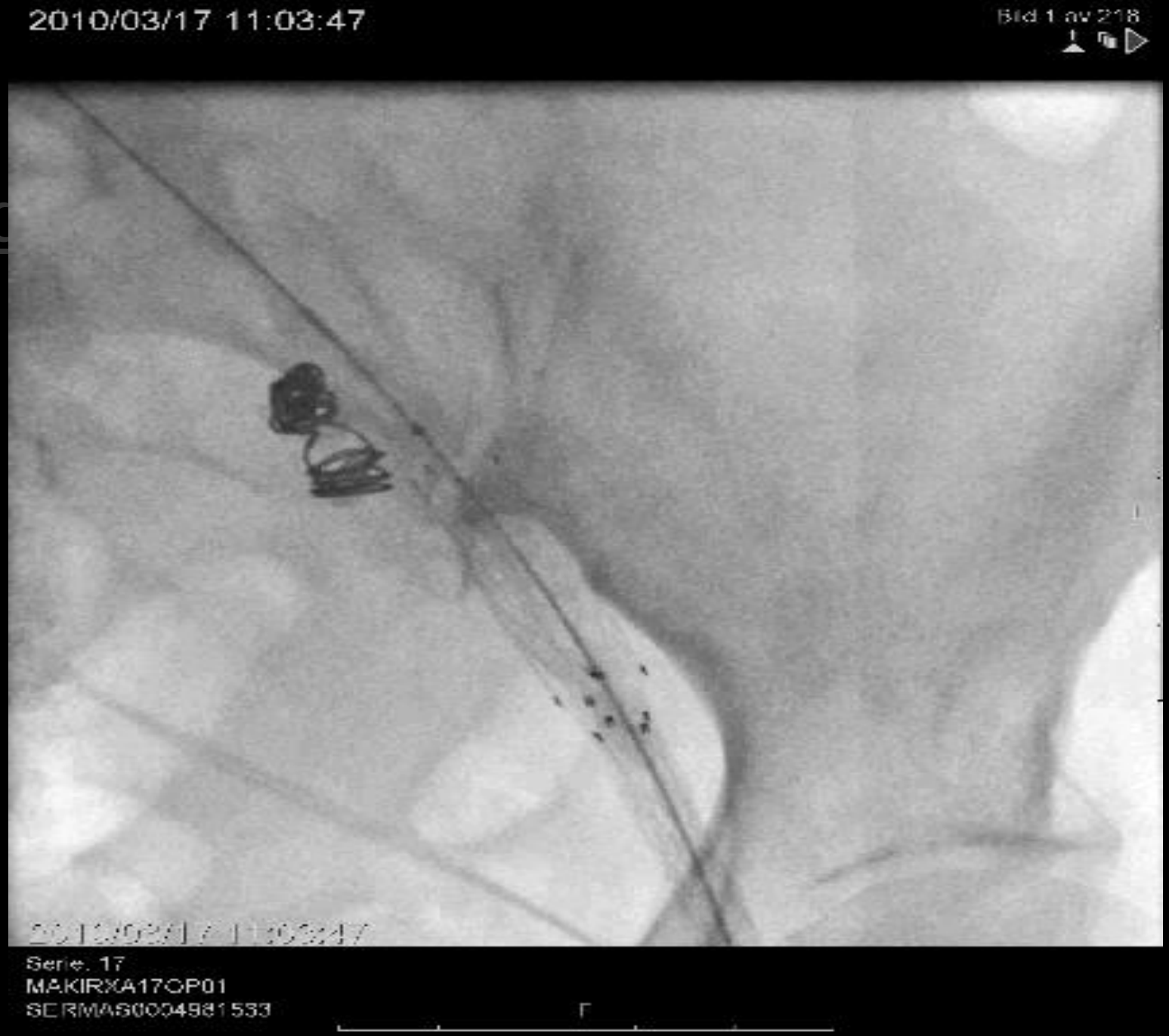
Paving and Cracking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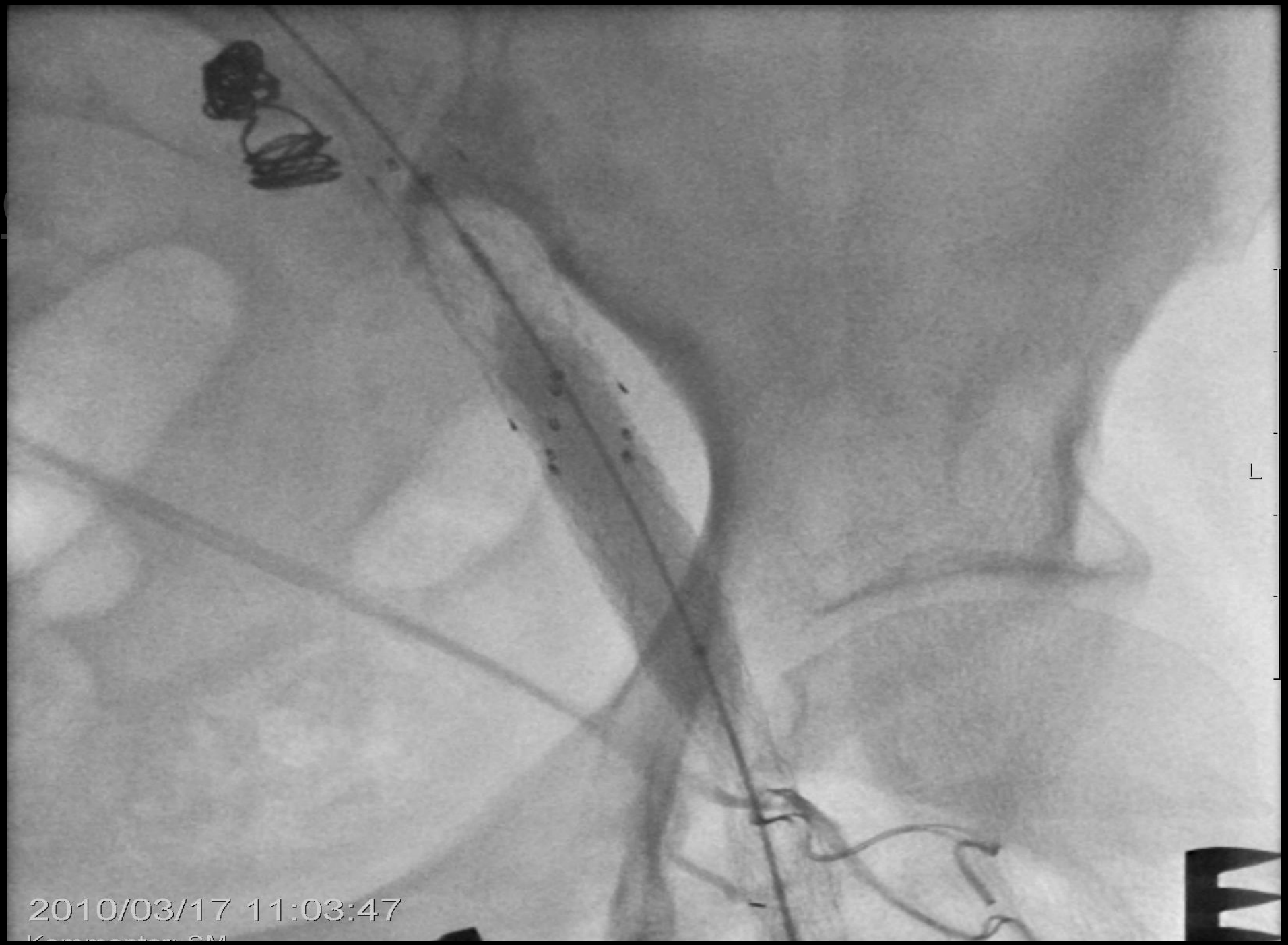
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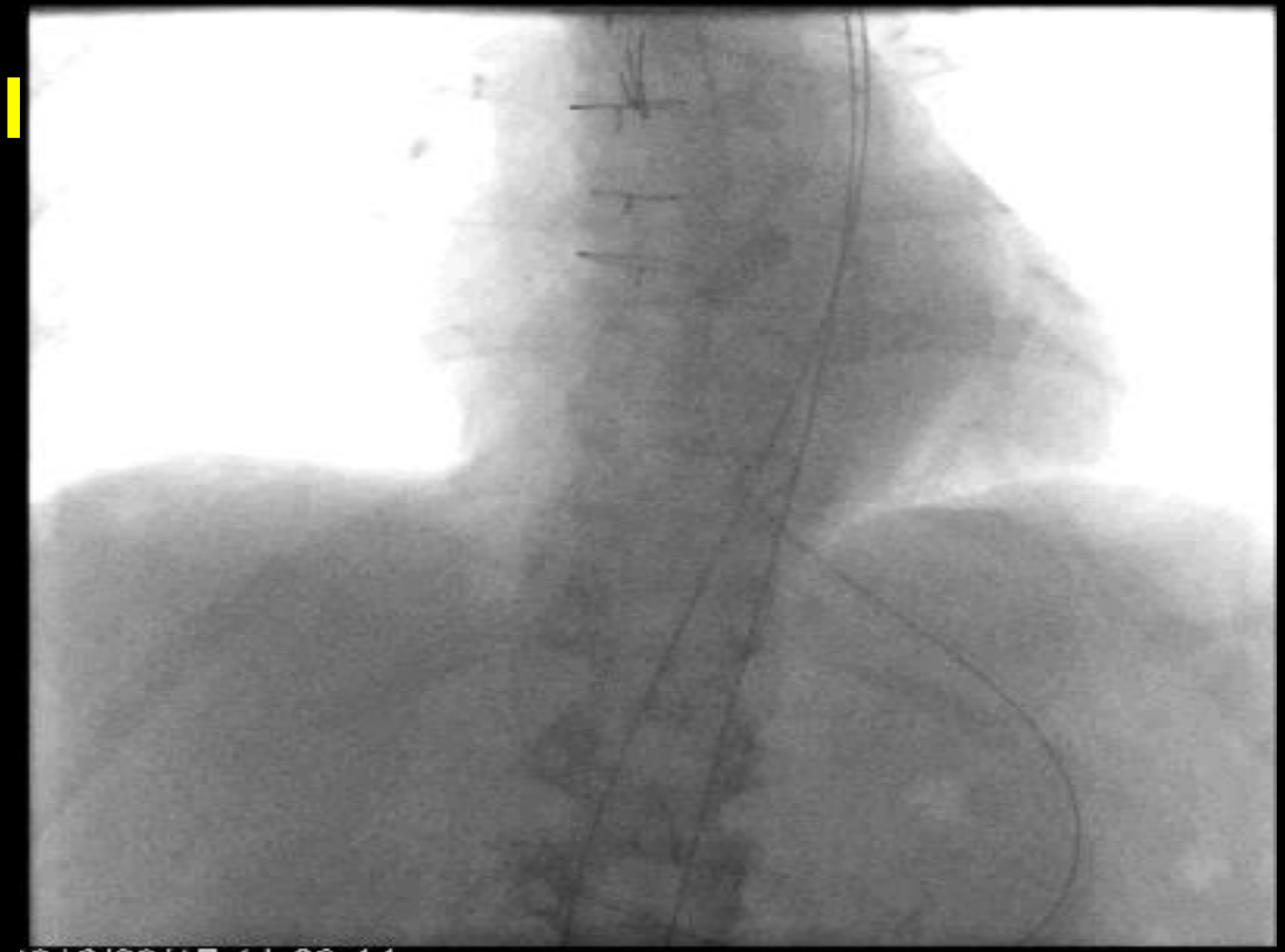
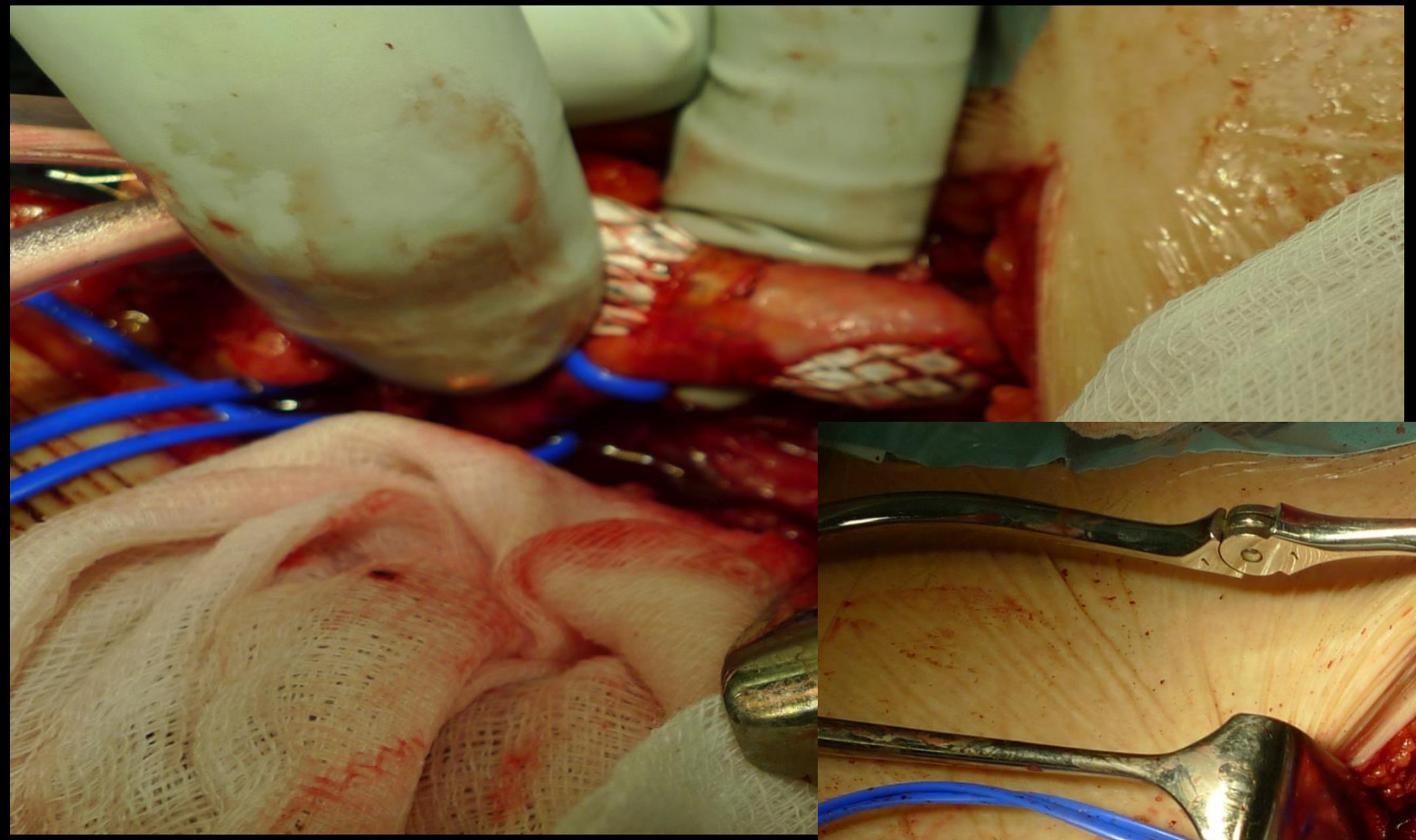




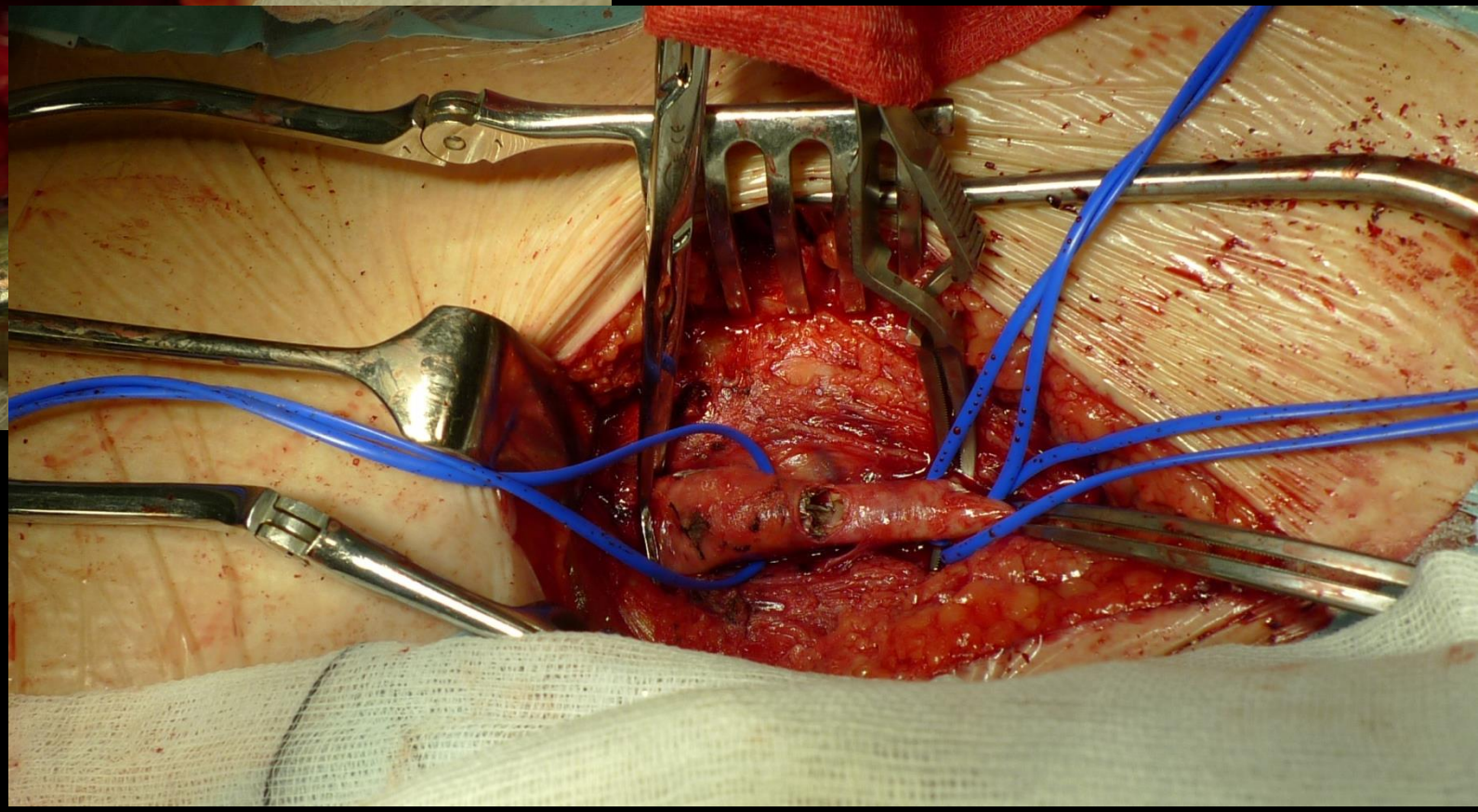


TABLE 1. EXAMPLES OF EVAR DELIVERY DEVICE DIAMETERS

Device	Manufacturer	Outer Diameter (F)*	CE Mark Approval	FDA Approval
Incraft	Cordis Corporation	14	Yes	No
Ovation	Endologix	14	Yes	Yes
Nellix	Endologix	17	Yes	No
AFX	Endologix	17	Yes	Yes
Zenith Alpha AAA	Cook Medical	18	Yes	No
Endurant II	Medtronic	18	Yes	Yes
Excluder	Gore & Associates	20.4†	Yes	Yes

Abbreviations: CE, Conformité Européenne; EVAR, endovascular aneurysm repair; FDA, US Food and Drug Administration.
*Size represents the majority of the main body devices in the product range.
†Outer diameter of 18-F introducer sheath.

Profile Comparison

Proximal Diameters (Fr size OD)

Graft Dia. (mm)	Zenith Alpha™ TAA	Medtronic Valiant	Gore C-TAG	Bolton Relay
18	**19 Fr**			
20	**19 Fr**			
21			21 Fr	
22	**19 Fr**	22 Fr		22 Fr
24	**19 Fr**	22 Fr		22 Fr
26	**19 Fr**	22 Fr	23 Fr	22 Fr
27			23 Fr	
28	**19 Fr**	22 Fr	23 Fr	22 Fr
30	**19 Fr**	22 Fr	25 Fr	22 Fr
31			25 Fr	
32	**21 Fr**	22 Fr		23 Fr
34	**21 Fr**	24 Fr	25 Fr	23 Fr
36	**21 Fr**	24 Fr	27 Fr	24 Fr
37			27 Fr	
38	**21 Fr**	24 Fr		24 Fr
40	**23 Fr**	24 Fr	27 Fr	25 Fr
42	**23 Fr**	25 Fr		25 Fr
44	**23 Fr**	25 Fr		25 Fr
45			27 Fr	
46	**23 Fr**	25 Fr		26 Fr

Review > Vasa. 2018 Apr;47(3):209-217. doi: 10.1024/0301-1526/a000688. Epub 2018 Feb 5.

Loco-regional versus general anaesthesia for elective endovascular aneurysm repair – results of a cohort study and a meta-analysis

Shahin Hajibandeh [1 2], Shahab Hajibandeh [1 2], Kelvin Adasonla [1], Stavros A Antoniou [1], Janet Barrie [3], Manmohan Madan [1], George A Antoniou [1]

- Reduced LOS
- Reduced morbidity and Mortality

Review > Vascular. 2016 Dec;24(6):638-648. doi: 10.1177/1708538116639201. Epub 2016 Mar 21.

Percutaneous access for endovascular aortic aneurysm repair: A systematic review and meta-analysis

Shahin Hajibandeh [1], Shahab Hajibandeh [2], Stavros A Antoniou [3], Emma Child [4], Francesco Torella [2], George A Antoniou [5]

- Shorter LOS
- Shorter OR Time
- Less Groin infection

Meta-Analysis > Eur J Vasc Endovasc Surg. 2021 Mar;61(3):383-394.
doi: 10.1016/j.ejvs.2020.11.008. Epub 2020 Dec 10.

Editor's Choice – Percutaneous Access Does Not Confer Superior Clinical Outcomes Over Cutdown Access for Endovascular Aneurysm Repair: Meta-Analysis and Trial Sequential Analysis of Randomised Controlled Trials

George A Antoniou [1], Stavros A Antoniou [2]

- No difference groin infection or LOS
- Shorter procedure time
- Less lymph leak

How have cell phones changed over time?

Device size

????

Why Low Profile?

- Access Issues
  - Women (TEVAR)
- PEVAR
  - EVAR in LA
  - Wound infection

- Outflow Issues?
- Material fatigue
  - Endoleaks
  - Stent fracture

Clinical Trial > J Vasc Surg. 2021 Mar;73(3):867-873.e2. doi: 10.1016/j.jvs.2020.06.128. Epub 2020 Jul 21.

Five-year results of the INSPIRATION study for the INCRAFT low-profile endovascular aortic stent graft system

Nathan L Liang [1], Takao Ohki [2], Kenneth Ouriel [3], Corey Teigen [4], Dennis Fry [5], John Henretta [6], Kimihiro Komori [7], Kimihiko Kichikawa [8], Michel S Makaroun [9], INSPIRATION Investigators

MedTech

Medtronic suspends recruitment for stent graft study for aortic aneurysm repair

by Emily Wasserman | May 10, 2016 10:25am

Back in April 2015, Medtronic ($MDT) launched a clinical study of its Endurant Evo AAA stent graft system. Now, the company is suspending recruitment on the trial after encountering a setback.

The Minnesota device giant had only one patient left to enroll but decided to stop the study so it could look into unanticipated stent fractures, *The Gray Sheet* reports. The study was designed to look at how well the device could treat abdominal aortic aneurysms, according to a recent filing at ClinicalTrials.gov.

In April 2015, Medtronic kicked off a clinical study to evaluate the system's safety and effectiveness with plans to enroll 140 patients at 30 sites in the U.S. and Europe. Endurant Evo AAA offers an alternative to open surgical repair for patients with abdominal aortic aneurysms.

Endurant stent graft system--
Courtesy of Medtronic

Medtronic Recalls Valiant Navion Thoracic Stent Graft System Due to Risk of Stent Fractures and Type III Endoleaks

Medical Device Recalls

2021 Medical Device Recalls

2020 Medical Device Recalls

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Medtronic Valiant Navion Thoracic Stent Graft System
- Model Number, Product Codes, Catalog or Lot numbers: Please See Links Below.
- Distribution Dates: November 12, 2018 to February 10, 2021
- Devices Recalled in the U.S.: 14,237
- Date Initiated by Firm: February 4, 2021

Device Use

The Valiant Navion Thoracic Stent Graft System is designed to repair lesions of the descending thoracic aorta, located in the body's largest artery (aorta) which passes through the lower part of the chest. A surgeon uses a long tube-like device (catheter) to place the stent graft inside the aorta. Once placed, the stent expands to fit within the aorta to provide a new path for blood to flow from the heart to the lower part of the body.

Reason for Recall

Content current as of:
04/09/2021

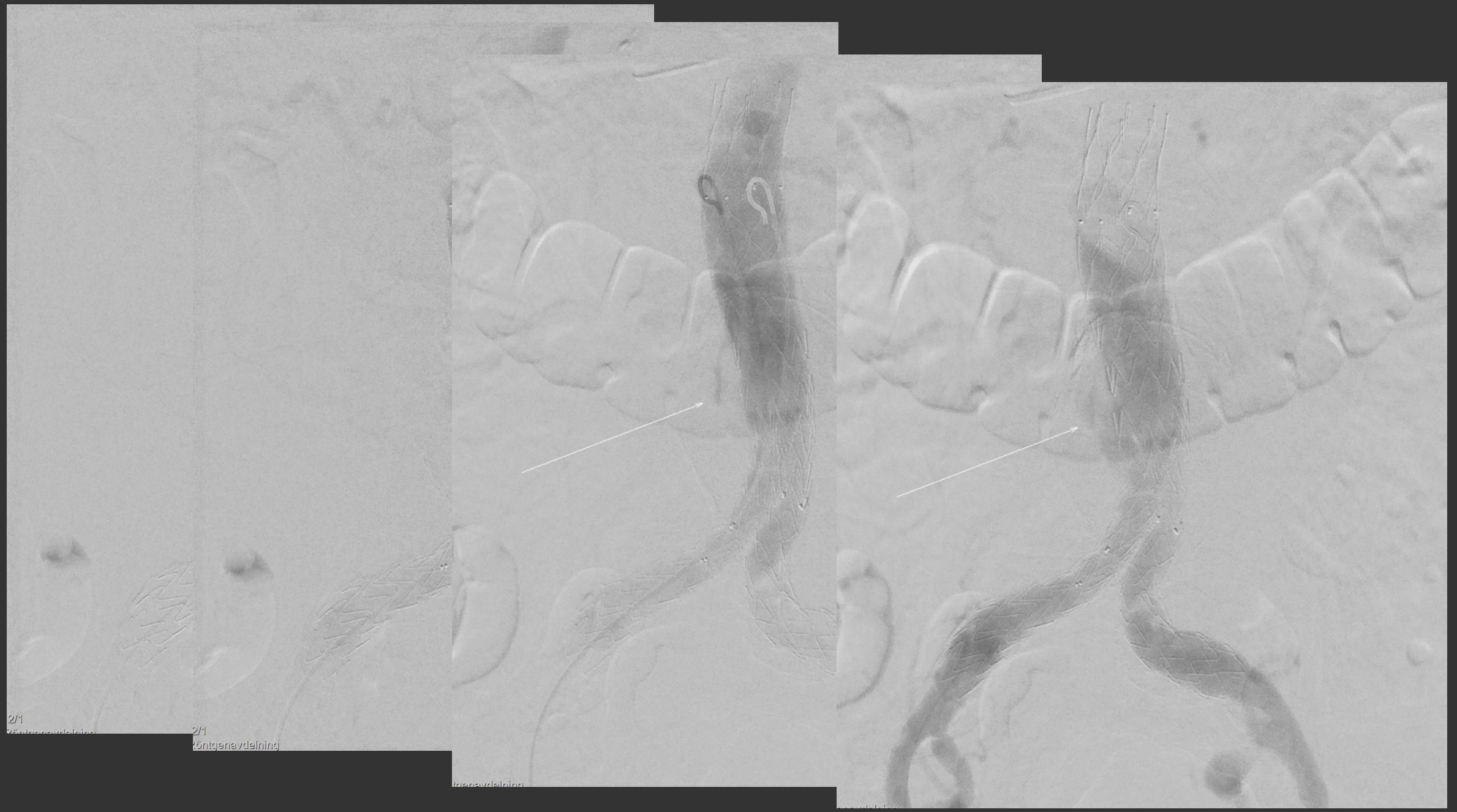
Regulated Product(s)
Medical Devices

DIVE BRIEF

Endologix AAA graft to go before FDA panel over potential life-threatening leak risk

Published Dec. 7, 2020

By Susan Kelly
Contributor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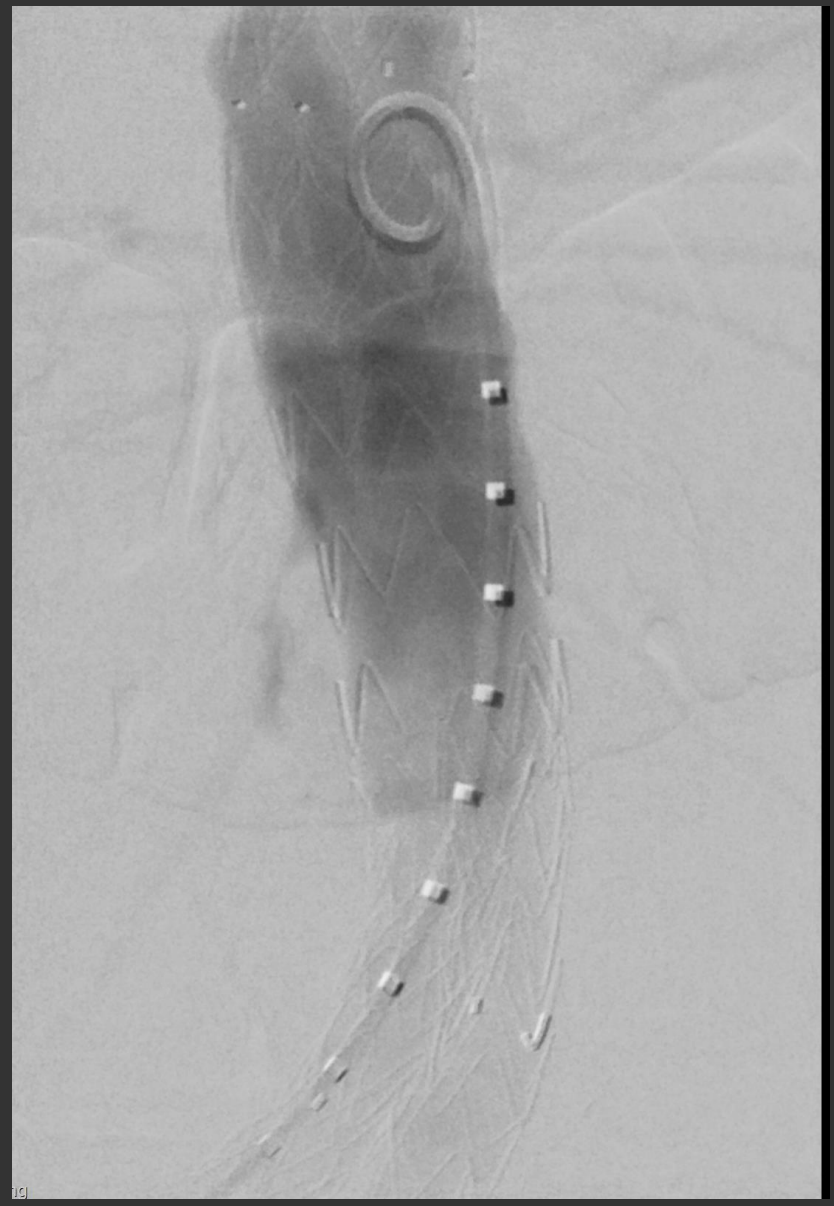

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FULL LENGTH ARTICLE | VOLUME 62, ISSUE 4, P532-539, OCTOBER 01, 2021

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Results

A total of 924 patients were included. The majority were male (84%), the mean age was 76 years (± 7.5 SD), and median AAA diameter was 59 mm (IQR 55, 67). Patients were treated with Zenith Alpha (*n* = 315, ZISL limbs), Excluder (*n* = 152, PLC/PXC limbs), and Endurant (*n* = 457, ETLW/ ETEW limbs). During median follow up of 37 months (IQR 21, 62), 55 occlusions occurred (5.9%); 39 with Zenith Alpha (12.4%), one with Excluder (0.7%), and 15 with Endurant (3.3%). In the NCC analysis, the Zenith Alpha device (OR 5.31, 95% CI 1.97 – 14.3), external iliac artery (EIA) landing (OR 5.91, 95% CI 1.30 – 26.7), and EIA diameter < 10 mm (OR 4.99, 95% CI 1.46 – 16.9) were associated with an increased risk of LGO.

Conclusion

Endograft device type is an independent risk factor for LGO after EVAR. Specifically, the Zenith Alpha demonstrated an increased risk of LGO compared with the Endurant and Excluder devices. In addition, a narrow EIA and landing zone in EIA are also risk factors for LGO.

Tables

Related Articles

NCC analysis, the Zenith Alpha device (OR 5.31, 95% CI 1.97 – 14.3), external iliac artery (EIA) landing (OR 5.91, 95% CI 1.30 – 26.7), and EIA diameter < 10 mm (OR 4.99, 95% CI 1.46 – 16.9) were associated with an increased risk of LGO.

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LP devices.pdf | Case rAAA type 2....pptx | Vis alle

Reason for Recall

Endologix, Inc. is recalling the Ovation iX due to risks of liquid polymer leaks during implantation. Previously on August 6, 2018, Endologix, Inc. issued an Important Safety Update to their customers reporting the polymer leaks were due to incorrect use of the device. By issuing the recall on May 6, 2020, Endologix is clarifying that the root cause for most polymer leaks is a material weakness caused during the manufacturing process. The weakened area may gap or open during use, which can cause liquid polymer to leak outside of the device as it is filled. If there is not enough liquid polymer in the device to

Why different outcomes for different LP grafts?

- On vs Off IFU
  - Reveals device weak points be it limbs, fabric, metal structure
- Poor planning
  - Right device for the right patient
- Improper expectations?
  - Has the outflow been treated after EVAR?

Summary

- Low Profile improves
  - Suitability
  - Deliverability
  - Percutaneous Approach
- Reduces iliac complications
- Late failure – durability?