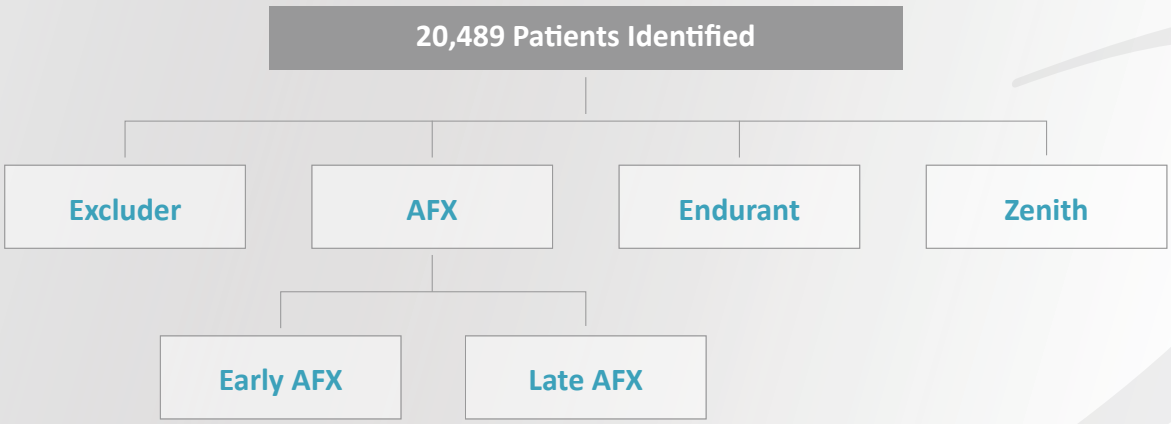
Publication Summary: Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study[1]

Goodney P, et al. Published in BMJ 2022

STUDY DESIGN

Observational surveillance study including 282 centers from the VQI-VISION dataset linked to United States Medicare claims from 2003 to 2018.



Due to AFX product modifications in late 2014, AFX patients were divided into 2 groups; early & late AFX, based on date before and after January 1, 2015.

MAIN OUTCOME MEASURES: REINTERVENTION AND RUPTURE OF ABDOMINAL AORTIC ANEURYSM POST-EVAR

Vascular Quality Initiative
(VQI)

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Vascular Implant Surveillance and Interventional Outcomes Network
(VISION)

- VISION links VQI registry data to Medicare claims to generate novel registry-claims linked datasets
- VQI-VISION framework will be considered by the FDA for long-term surveillance of EVAR patient outcomes to help prevent avoidable harm
- VISION data is also used to generate Survival, Reintervention and Surveillance (SRS) reports as well as to analyze device performance and long-term outcomes of surgical techniques[2]

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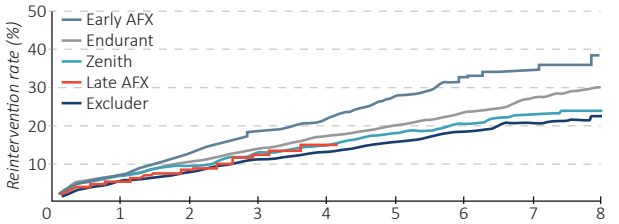
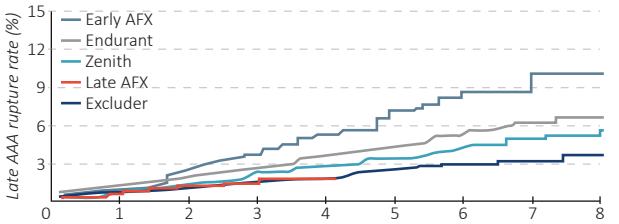
LATE AFX REINTERVENTION AND LATE RUPTURE RATES DID NOT DIFFER WHEN COMPARED TO THE THREE OTHER DEVICES DURING THE SAME PERIOD



No at risk									Years
Early AFX	942	770	669	551	472	244	128	51	20
Endurant	6606	4609	3256	2242	1455	903	498	241	108
Zenith	3281	2427	1865	1419	1014	648	363	197	110
Late AFX	1350	947	584	259	<11				
Excluder	8310	5576	3799	2602	1643	995	544	292	163



No at risk									Years
Early AFX	942	818	731	630	554	308	167	65	26
Endurant	6606	4872	3525	2483	1653	1049	591	298	142
Zenith	3281	2549	2006	1569	1145	750	437	239	127
Late AFX	1350	977	617	282	<11				
Excluder	8310	5779	4037	2834	1833	1144	652	359	204

"The manufacturer of the AFX stent graft, Endologix, has improved its device, and a later iteration—also evaluated by Goodney and colleagues, appears to be performing well."[3]

—Robert J Hinchliffe, BMJ 2022

PROPENSITY SCORE MATCHED COHORTS COMPARING LATE AFX TO OTHER INDIVIDUAL DEVICES

Hazard Ratios with 95% Confidence Intervals	**Late AFX** *v* Excluder	**Late AFX** *v* Endurant	**Late AFX** *v* Zenith
Reintervention	1.29 (0.95-1.75)	0.86 (0.66-1.12)	1.11 (0.84-1.46)
Late Rupture	2.33 (0.89-6.16)	0.71 (0.35-1.47)	1.25 (0.58-2.70)
Death	1.01 (0.84-1.22)	1.01 (0.84-1.22)	1.12 (0.92-1.36)

The conversion rates to open repair after EVAR also did not differ in patients treated with AFX devices and those treated with the other devices.

References

1. Goodney, P, Mao J, Columb J, Suckow B, Schermerhorn M, Malas M, et al. Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study. BMJ 2022;379:e071452.
2. https://www.vqi.org/data-analysis/vision/
3. Hinchliffe RJ. Tracking the performance of endovascular devices. BMJ 2022;379:o2448.

INDICATIONS FOR USE- US : The Endologix® AFX®2 Endovascular AAA Systems are indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair using a surgical vascular access technique or a bilateral percutaneous technique; a non-aneurysmal aortic neck between the renal arteries and the aneurysm: with length of ≥15mm, diameter ≥18 to ≤32mm and neck angle of ≤60° to the body of the aneurysm; aortic length ≥1.0cm longer than the body portion of the chosen bifurcated model; common iliac artery distal fixation site with length ≥15mm, diameter of ≥10 to ≤23mm, and with ability to preserve at least one hypogastric artery; and with an iliac angle of ≤90° to the aortic bifurcation. Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

CONTRAINDICATIONS- US: The Endologix® AFX®2 Endovascular AAA Systems are contraindicated for use in patents who have a condition that threatens to infect the graft and in patients with sensitivities or allergies to the device materials. Refer to the Instructions for Use for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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