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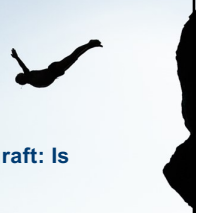

Current Status of the AFX2 Endograft: Is Increased Surveillance Indicated?

Presenter:

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Adjunct Investigator, KPNC Division of Research

November 21, 2024

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No Disclosures

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Background

- Increased data signal with AFX (Strata and Duraply)
- FDA communication (December 2022) recommending enhanced surveillance for AFX2 given lack of data beyond year three
- What is the data regarding the currently available AFX2 device?
- How do we define optimal surveillance?

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Midterm outcomes for 605 patients receiving Endologix AFX or AFX2 Endovascular AAA Systems in an integrated healthcare system

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Journal of Vascular Surgery
Volume 73, Number 3

Risk for surgical interventions following endovascular aneurysm repair with Endologix AFX or AFX2 Endovascular AAA Systems compared with other devices

Heather A. Prentice, PhD,[a] Elizabeth W. Paxton, PhD,[a] Jessica E. Harris, MS,[a] Joy Garg, MD,[b] Thomas F. Rehring, MD,[c] Nicolas A. Nelken, MD,[d] Homayon Hajarizadeh, MD,[e] Jeffrey H. Hsu, MD,[f] and Robert W. Chang, MD,[g,h] *San Diego, Redwood City, Fontana, South San Francisco, and San Francisco, CA; Denver, CO; Honolulu, HI; and Clackamas, OR*

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But…

- Institutional decision to halt AFX2 implantation in 2018
- Resulting AFX2 cohort for long-term surveillance is limited
- N=37

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Circulation

ORIGINAL RESEARCH ARTICLE

Comparison of Unibody and Non-Unibody Endografts for Abdominal Aortic Aneurysm Repair in Medicare Beneficiaries: The SAFE-AAA Study

Eric A. Secemsky, MD, MSc; Yang Song, MSc; Tianyu Sun, PhD; Carmen Gacchina Johnson, PhD; Megan Gatski, PhD; Li Wang, PhD; Andrew Farb, MD; Robert E. Lee, MD; Aurko Shaw, MTM; Jiaman Xu, MPH; Robert W. Yeh, MD MSc

Circulation. 2023;147:1264–1276.

Objective

To evaluate the composite outcome of late aneurysm rupture, endograft relining, endograft extension, conversion to open repair or all-cause mortality following infrarenal EVAR with a unibody endograft compared with other commercially available non-unibody endografts in Medicare fee-for-service insurance claims data.

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Methods

- Retrospective cohort study
- 2011-2017 (follow-up through 2019)
- 11,903 patients received unibody device
- 75,260 patients received non-unibody device
- Substudy of presumed AFX2 grafts based on date
- Noninferiority study design

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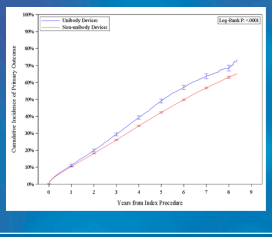
	Unibody (N=11,903)	Non-unibody (N=75,260)
Maximum Follow-Up Time, days	3,072	3,074
Median Follow-Up Time, days	1,218	1,250
Number of composite events, n	5,451	30,353
Cumulative Incidence of composite event at the End of Follow-Up, %	73.9%	65.0%
Adjusted Cumulative Incidence of composite event at the End of Follow-Up, %	73.4%	65.0%
Unadjusted HR (95% CI)	1.20 (1.17, 1.24)	
Adjusted HR (95% CI), NI p-value	1.19 (1.15, 1.22), NI p-value=1.00	



Circulation. 2023;147:1264–1276.

Event	Cumulative Incidence		*HR (95% CI)
	Unibody endograft (N=11,903)	Non-unibody endograft (N=75,260)	
All-cause mortality	64.3%	61.7%	1.06 (1.03, 1.09)
Conversion to open repair	2.1%	1.4%	1.70 (1.43, 2.02)
Endograft extension	8.9%	4.6%	2.05 (1.89, 2.23)
Graft relining	12.5%	2.3%	4.03 (3.67, 4.42)
Late aneurysm rupture	3.8%	1.6%	2.28 (1.97, 2.63)
Graft relining, endograft extension, or conversion to open repair	17.4%	6.9%	2.25 (2.10, 2.40)
Late aneurysm rupture, graft relining, or conversion to open repair	15.5%	4.6%	2.80 (2.60, 3.02)
Late aneurysm rupture, graft relining, endograft extension, or conversion to open repair	18.3%	7.5%	2.16 (2.03, 2.30)

Circulation. 2023;147:1264–1276.

But…

Median follow-up 3.4 years (2.6 y for sub group)

Risk for relining/extension---long-term question still exists

Claims data limitations

No imaging/aneurysm-specific details

True increase in reintervention rates vs. increased awareness?

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Five-year results of the LEOPARD trial of commercially available endografts

Christopher J. Kwolek, MD,[a] Kenneth Ouriel, MD,[b] Fred S. Stucky, MD,[c] Vikram K. Rao, MD,[d] Peter J. Pons, MD,[e] Samuel E. Wilson, MD,[f] *and* Scott W. Kujath, MD,[g] *Wellesley, MA; New York, NY; Huntsville, AL; Florence, AL; Willoughby, OH; Orange, CA; and North Kansas City, MO*

Journal of Vascular Surgery
Volume 78, Number 2

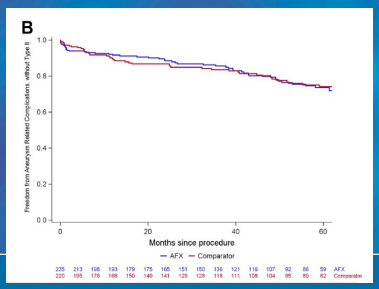
Objective

A prospective, randomized, multi-center trial was performed to compare the anatomically fixated AFX/AFX2 endograft system (Endologix) with other endografts.

The primary endpoint was freedom from composite endpoint consisting of perioperative death, rupture, conversion, postoperative endoleaks, migration, aneurysm enlargement, endograft limb occlusion, and reintervention.

Methods

- Real-world design
- 235 patients randomized, received Endologix
- 220 patients with other devices
- Surgeon-decision on suitability (34% outside IFU in both groups)
- 21 and 32 patients respectively LTFU at 1 year.



Journal of Vascular Surgery
Volume 78, Number 2

But…

Industry-sponsored trial

Possible enrollment bias

Limited LTFU information

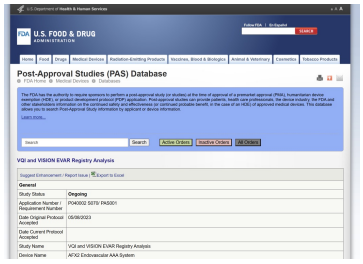
179 patients (235 start) censored by 60 months

30% ACM at 5 years, without consideration of competing risk analysis (vs K-M) which may overestimate freedom-from-events

No information on robustness of imaging component

Crude adverse events	AFX2
Total N	37
Longitudinal events	
Any non Type II endoleak	5
2-year cumulative event probability (95% CI)	5.4 (0.9-16.1)
6-year cumulative event probability (95% CI)	11.2 (3.4-24.0)
Revision	6
2-year cumulative event probability (95% CI)	8.1 (2.0-19.8)
6-year cumulative event probability (95% CI)	13.9 (4.9-27.4)
Reoperation	2
2-year cumulative event probability (95% CI)	2.7 (0.2-12.3)
6-year cumulative event probability (95% CI)	--
Conversion to open repair	0
2-year cumulative event probability (95% CI)	--
6-year cumulative event probability (95% CI)	--
Rupture	1
2-year cumulative event probability (95% CI)	2.7 (0.2-12.3)
6-year cumulative event probability (95% CI)	--
Overall mortality	18
2-year cumulative event probability (95% CI)	16.3 (7.7-32.8)
6-year cumulative event probability (95% CI)	44.5 (30.0-62.1)
Aneurysm-related mortality	1
2-year cumulative event probability (95% CI)	2.7 (0.4-17.7)
6-year cumulative event probability (95% CI)	--

Ongoing surveillance



Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION)

PRACTICE MANAGEMENT

The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices

Greg Tsougranis, BS,[a,b,c] Jens Eldrup-Jorgensen, MD,[d] Daniel Bertges, MD,[e] Marc Schermerhorn, MD,[f] Pablo Morales, MD,[g] Scott Williams, MS, RAC,[h] Roberta Bloss, MS,[i] Jessica Simons, MD, MPH,[j] Sarah E. Deery, MD, MPH,[k] Salvatore Scali, MD,[l] Graham Roche-Nagle, MD, MBA, ME,[m] Leila Mureebe, MD, MPH, MMC,[n] Matthew Mell, MD,[o] Mahmoud Malas, MD, MHS,[p] Brian Pullin, MS,[q] David H. Stone, MD, MS,[a,b] Misti Malone, PhD,[q] Adam W. Beck, MD,[q] Grace Wang, MD, MS,[r] Danica Marinac-Dabic, MD, PhD,[s] Art Sedrakyan, MD, PhD,[t] *and* Philip P. Goodney, MD, MS,[a,b] *Lebanon and Hanover, NH, White River Junction and Burlington, Vt, Portland, Me, Boston, Mass, Rockville, Md, Bloomington, Ind, Flagstaff, Ariz, Gainesville, Fla, Toronto, Ontario, Canada, Durham, NC, Davis, San Diego, Calif, Birmingham, Ala, Philadelphia, Pa, New York, NY*

Journal of Vascular Surgery, December 2020 Dec;72(6):2153-2160

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How VQI-VISION works….

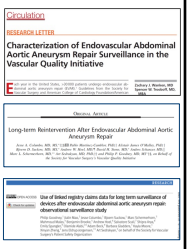
Start With VQI Data

Mr. Jones (name, SS#)
Clinical Factors (comorbidities)
Implant Data (Graft XY2)
Surgical Details (how it was placed)
Surgeon Details
Hospital Information
Short term complications

Data Linkages to Medicare Claims
The Dartmouth Institute

Measure Long-Term Events:

- **Survival**
- **Effectiveness of the Procedure**
- **Long-Term Device Failures/Revisions**
- **Cost**



The Long-Term EVAR Assessment and Follow-Up (LEAF) System

- **The AFX2 LEAF Study is an observational, retrospective and prospective, multicenter study to evaluate the performance of the AFX2 System using real world evidence from VQI-VISION. Further information on the study design is included in the VQI LEAF System Protocol.**
- **The primary objective of this study is to valuate the clinical performance of the AFX2 System patients against other commercially available EVAR devices and evaluate the Type III endoleak occurrence in AFX2 System patients through 5 years.**

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The Long-Term EVAR Assessment and Follow-Up (LEAF) System

- **Clinical Endpoint**
  - **Number of subjects: Minimum 2,000 AFX2 subjects and 18,000 comparator graft subjects**
- **Imaging Endpoint**
  - **Number of subjects: Minimum 315 AFX2 subjects evaluable at 5 years.**
  - **The AFX2 System population includes patients who underwent EVAR as their first abdominal aortic aneurysm repair within the VQI EVAR registry.**

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The Long-Term EVAR Assessment and Follow-Up (LEAF) System

- **Co Primary Endpoints**
  - **The primary clinical endpoint is the rate of the composite of AAA rupture, aortic-related reintervention, and mortality through 5 years.**
  - **The primary imaging-driven endpoint is the cumulative incidence of Type III endoleaks at 5 years.**
- **Secondary study endpoints:**
  - **Secondary endpoints through 10 years include:**
    - **AAA rupture**
    - **Aortic-related reintervention**
    - **Mortality**
    - **Rate of imaging with CT**

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The Long-Term EVAR Assessment and Follow-Up (LEAF) System

- **The AFX2 System population includes patients who underwent EVAR as their first abdominal aortic aneurysm repair within the VQI EVAR registry.**
- **Follow-up data of enrolled patients will be analyzed for the relevant cohorts through 5 years (primary endpoints) and 10 years (secondary endpoints).**
- **As this is an observational study using real world evidence, follow-up will be based on standard of care.**

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The Long-Term EVAR Assessment and Follow-Up (LEAF) System

Interim or Final Data Summary	
Actual Number of Patients Enrolled	24,020 in VQI-VISION EVAR Registry
Actual Number of Sites Enrolled	N/A
Patient Follow-up Rate	Follow-up data was provided through 3 years. There were 773 AFX2 subjects that reached 3 year follow-up.

VQI and VISION EVAR Registry Analysis Reporting Schedule

Reporting Schedule	Report Date Due	FDA Receipt Date	Applicant's Reporting Status
6 month report	11/06/2023	11/13/2023	Overdue/Received
1 year report	05/06/2024	05/03/2024	On Time
18 month report	11/06/2024	11/06/2024	On Time
2 year report	05/05/2025		
3 year report	05/06/2026		
4 year report	05/05/2027		

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Do we still need increased surveillance?

- The answer is not clear
- All endografts should be surveilled closely with efforts to minimize lost-to-follow-up
- Analytic techniques should account for non-aneurysm mortality when focusing on device specific outcomes
- Participation in registry and collective efforts are essential to long-term awareness of EVAR performance

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Thank you