Performance of Newer Generation Endografts Anatomically Fixed on the Aortic Bifurcation for AAA Repair: Long-Term Outcomes in the Medicare Population

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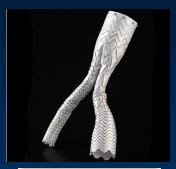
Disclosures

- Member Clinical Events Committee – Bard Endovascular
- Consultant, CEC member – Medtronic
- Consultant - Endologix

Background






Background

Benefits of Unibody Design
- Mimics natural aorta
- Separates graft fixation from proximal sealing zone
- Preserves native bifurcation

Anatomies
- Reverse taper necks
- Narrow Distal Aorta
- Narrow Iliacs

Evolution of AFX

2011 – AFX Strata: Original graft had concern for Type IIIa leaks

2013 – Longer bifurcated lengths and change in IFU – now with increase in type IIIb endoleaks

2014 – AFX Duraply: New material to decrease IIIb endoleaks

2016 - AFX2: Thicker graft material and updated design/manufacturing

Background

From the Society for Clinical Vascular Surgery

Late type III endoleaks are common in early generation Endologix AFX stent grafts

ORIGINAL RESEARCH ARTICLE

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

Incidence, Long Term Clinical Outcomes, and Risk Factor Analysis of Type III Endoleaks Following Endovascular Repair of Abdominal Aortic Aneurysm

Study Goal

Goal of this study was to compare the outcomes of EVAR with endografts that use proximal fixation to those that use anatomic fixation in the Medicare population at three consecutive time periods that represent different iterations in the unibody design to see how these changes relate to durability

Methods - Patients

Review of Medicare Fee for Service administrative claims database – 100% of Medicare beneficiaries

All EVAR for AAA from 1/1/2013 – 12/31/2017

2018 – changed CPT coding so could not differentiated type of device implant

Exclusion

- thoracoabdominal aneurysms
- ruptures
- aortic dissections

Methods - Endpoints

Primary outcomes

- All cause mortality (ACM)
- Aneurysm related reintervention
  - aneurysm disease
  - EVAR complication after discharge
- post-EVAR aortic rupture

30-day

Long-term

Methods - Cohorts

3 Study Cohorts

- Cohort 1: 1/1/2012 – 7/20/2014 – AFX unibody with Strata fabric
- Cohort 2: 7/21/2014 – 5/9/2016 – Mixture of AFX with new Duraply fabric, AFX strata and AFX 2 (ratio 26:3:1) – mostly Duraply
- Cohort 3: Mixture of AFX2 and AFX with Duraply (ratio 15:1) – mostly AFX2

Cohorts were compared to grafts with proximal fixation and docking limbs during each time period

Results

Cohort	Total	AF	PF
Total	32,034	4,720 (15%)	27,305 (85%)
Cohort 1	9,754	1,498 (15%)	8,256 (85%)
Cohort 2	11,103	1,713 (15%)	9,390 (85%)
Cohort 3	11,174	1,518 (14%)	9,656 (86%)

Results - Demographics

	Cohort 1: Patients Undergoing EVAR before July 21, 2014			Cohort 2: Patients Undergoing EVAR between July 21, 2014 and May 9, 2016			Cohort 3: Patients Undergoing EVAR after May 9, 2016		
	AF N=1498	PF N=8256	P-value	AF N=1713	PF N=9390	P-value	AF N=1518	PF N=9656	P-value
Length of follow up - y	2.59 (2.35)	2.64 (2.38)	0.45	2.20 (1.84)	2.21 (1.80)	0.83	1.66 (1.31)	1.65 (1.28)	.78
Age - y	76.3 (7.5)	76.3 (7.4)	1	75.7 (7.8)	76.0 (7.4)	0.14	75.2 (7.7)	75.7 (7.5)	.016
Female	343 (22.9%)	1549 (18.8%)	<0.0001	391 (22.8%)	1720 (18.3%)	<0.0001	349 (23.0%)	1757 (18.2%)	<.0001
White	[illegible] (93.0%)	[illegible] (93.5%)	[illegible]	[illegible] (92.4%)	[illegible] (91.9%)	0.44	[illegible] (91.6%)	8882 (92.0%)	.58
Black	62 (4.1%)	300 (3.6%)	0.34	69 (4.0%)	415 (4.4%)	0.46	65 (4.3%)	418 (4.3%)	.93
Myocardial Infarction	442 (29.5%)	2301 (27.9%)	0.19	481 (28.1%)	2401 (25.6%)	0.03	388 (25.6%)	2348 (24.3%)	.3
Valvular disease	431 (28.8%)	2202 (26.7%)	0.09	487 (28.4%)	2520 (26.8%)	0.17	424 (27.9%)	2467 (25.5%)	.049
CHF	367 [illegible]	1755 [illegible]	0.005	372 [illegible]	1955 [illegible]	0.4	340 [illegible]	2020 (20.9%)	.19
Peripheral vascular disease	682 (45.5%)	3042 (36.8%)	0.00001	758 (44.2%)	3520 (37.5%)	<0.0001	681 (44.9%)	3358 (34.8%)	<.0001
Neurovascular disease	[illegible] (38.7%)	[illegible] (36.7%)	[illegible]	[illegible] (38.2%)	[illegible] (35.4%)	[illegible]	[illegible] (33.4%)	[illegible] (31.5%)	.13
Hypertension	1383 (92.3%)	7565 (91.6%)	0.37	1568 (91.5%)	8517 (90.7%)	0.27	1406 (92.6%)	8663 (89.7%)	.0004
Diabetes	523 (34.9%)	2629 (31.8%)	0.19	545 (31.8%)	2764 (29.4%)	0.05	215 (14.2%)	1229 (12.7%)	.12
COPD	798 (53.3%)	4145 (50.2%)	0.29	846 (49.4%)	4480 (47.7%)	0.2	707 (46.6%)	4132 (42.8%)	.006
Renal Failure	185 (12.3%)	1088 (13.2%)	0.38	212 (12.4%)	1213 (12.9%)	0.53	202 (13.3%)	1267 (13.1%)	.84
ESRD	22 (1.5%)	176 (2.1%)	0.09	26 (1.5%)	205 (2.2%)	0.03	39 (2.6%)	168 (1.7%)	.26
Obesity	265 (17.7%)	1263 (15.3%)	0.019	300 (17.5%)	1573 (16.8%)	0.4	310 (20.4%)	2061 (21.3%)	.41

30-Day Mortality

Cohort	AF	PF	P Value
Cohort 1	27 (1.8%)	157 (1.9%)	0.79
Cohort 2	25 (1.5%)	147 (1.6%)	0.73
Cohort 3	27 (1.8%)	154 (1.6%)	0.63

30-Day Readmission

Cohort	AF	PF	P Value
Cohort 1	159 (10.6%)	874 (10.6%)	0.97
Cohort 2	175 (10.2%)	996 (10.6%)	0.63
Cohort 3	141 (9.3%)	944 (9.8%)	0.48

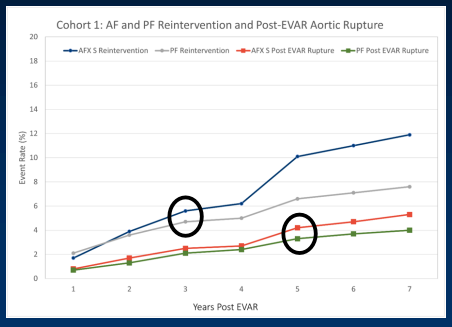
4-Year All Cause Mortality

Cohort	AF	PF	P Value
Cohort 1	517 (34.5%)	2633 (31.9%)	0.05
Cohort 2	571 (33.3%)	2921 (31.1%)	0.07
Cohort 3	455 (30%)	2673 (27.7%)	0.07

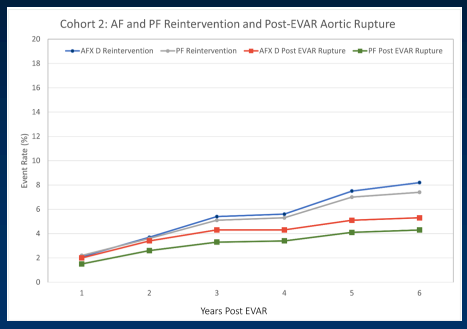
4-Year Endo AAA Repair

Cohort	AF	PF	P Value
Cohort 1	37 (2.5%)	20 (0.2%)	<0.001
Cohort 2	22 (1.3%)	56 (0.6%)	0.002
Cohort 3	28 (1.8%)	128 (1.3%)	0.11

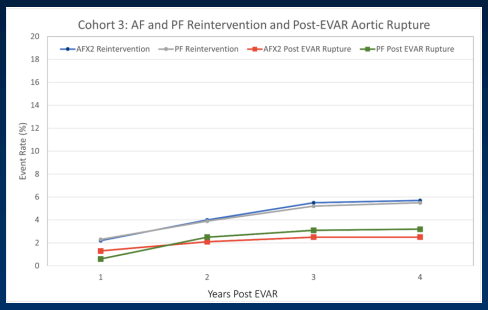
Cohort 1 Long-Term



Cohort 2 Long-Term



Cohort 3 Long-Term



Conclusion

Higher rates of aortic rupture and reintervention seen with AFX in the strata cohort did not persist with duraply and AFX2

Contemporary version of AFX2 has a durability similar to grafts that use proximal fixation

It is safe to use unibody grafts for AAA repair and this can be a valuable tool for treating difficult anatomies