# Long-Term Results Of F/EVAR For Juxta- And Pararenal AAAs: Data From ARC Show That It Should Be The Procedure Of Choice


*Andres Schanzer, MD*

November 21st, 2024
Veith Symposium, New York, NY

## Disclosures

- Cook Medical, Phillips Imaging, Cryolife
  - Research grants
  - Case proctor
  - Consult

All compensation goes to UMass Memorial Foundation and none to me personally.

## Open Surgical Repair of Complex AAA in Large Single Center Studies

| Author (Reference) | n | 30-day Mortality | Renal Injury | Dialysis |
|---|---|---|---|---|
| Giulini et al (Eur JVES 2000) | 56 | 3.6% | - | 2% |
| Ayri et al (Ann Vas Sur 2001) | 53 | 11% | - | - |
| Sarac et al (J Vasc Surg 2002) | 138 | 5.1% | 22% | 3% |
| Shortell et al (J Vasc Surg 2003) | 112 | 6% | 12% | 3% |
| Bicknell et al (Eur JVES 2003) | 44 | 6.8% | - | - |
| Kudo et al (J Vasc Surg 2008) | 18 | 0 | 17% | 5.6% |
| Chiesa et al (J Vasc Surg 2006) | 119 | 7.6% | 18% | 5.8% |
| West et al (J Vasc Surg 2006) | 243 | 2.5% | 22% | 2% |
| Knott et al (J Vasc Surg 2007) | 126 | 0.8% | 22% | 1% |
| | **1202** | **4.2%** | **19%** | **3.8%** |

## Open vs Fenestrated Repair for Complex AAA in the United States

Review of NSQIP Database on Juxtarenal Aneurysms

| | Open Repair n = 598 | Fenestrated Repair n = 629 patients |
|---|---|---|
| Mean age | 73 | 71 |
| 30-day mortality | **4.5%** | **2%** |
| Dialysis | **6%** | **2%** |
| Return to OR | | |
| Re-intervention | | |
| Branch patency | | |

**2x↑ mortality**
**3x↑ dialysis**

Linsen et al. J Vasc Surg 2012

## Systematic Review of Open vs Fenestrated Repair for Complex AAA

| Systematic | Open Repair (n = 1164) | | Fenestrated Endografts (n = 368) | | RR (95% CI) | P value |
|---|---|---|---|---|---|---|
| 30-day mortality | **3.6%** | 2.7-4.9 | **1.4%** | 0.4-3.1 | 1.03 (1.01-1.04) | .02 |
| Renal impairment | **20%** | 17.9-22.5 | **15%** | 11.5-18.7 | 1.01 (1.01-1.12) | .03 |
| Dialysis | | | | | | |
| Primary endoleak | | | | | | |
| Vessel patency | | | | | | |
| Re-intervention | **2.6%** | 1.5-4.4 | **15%** | 11.5-18.7 | 0.87 (0.83-0.91) | .0001 |

**2x↑ mortality**
**5x↓ reinterventions**

Nordon et al. Eur J Vasc Surg 2009

## Outcomes of Open Surgical Repair and Fenestrated Repair of CAAAs in the SVS VQI

| | Age <65 | | | | Age 65-75 | | | |
|---|---|---|---|---|---|---|---|---|
| | FEVAR | OSR | OR (95% CI) | P value | FEVAR | OSR | OR (95% CI) | P value |
| 30-day mortality | | | | | 2.2% | 5.0% | 0.50 (0.30-0.79) | .004 |
| Dialysis | | | | | 1.2% | 5.4% | 0.60 (0.35-0.89) | <.001 |
| Cardiac complications | | | | | 2.5% | 7.6% | 0.42 (0.28-0.62) | <.001 |
| Pulmonary complications | | | | | 2.5% | 12% | 0.29 (0.28-0.62) | <.001 |
| Any complication | | | | | 8% | 23% | 0.38 (0.26-0.42) | <.001 |

**For age > 65**
**2x↑ mortality**
**3x↑ dialysis, cardiac, pulmonary complications**

Rastogi et al. Eur J Vasc Endovasc Surg 2023

## Open vs Fenestrated Repair for Complex AAA in France

Review of 2 High Volume Centers on CAAA

| | Open Repair n = 102 | Fenestrated Repair n = 102 patients | p-value |
|---|---|---|---|
| Long-term overall mortality | 36.3% | 40.2% | **0.40** |
| Aneurysm-related mortality | 5.8% | 6.8% | **0.30** |
| Late renal function decline | **47.4%** | 27.8% | <0.01 |
| Reinterventions | 5.1% | **23.5%** | <0.01 |

**2x↑ renal function decline**
**4x↓ Reinteventions**

Tinelli et al. Eur J Vasc Endovasc Surg 2024

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SYSTEMATIC REVIEW

## Long Term Outcomes and Durability of Fenestrated Endovascular Aneurysm Repair: A Meta-analysis of Time to Event Data

Aurélien M. Guirreti [a,*], Aisha Bashir [a], Bilal Ashur [a], James Budge [a], Iain Roy [a], Ian Loftus [a], Peter Holt [a]
[a] St George's Vascular Institute; St George's, University of London, UK

**Objective:** Despite widespread use, long term outcomes for fenestrated endovascular aneurysm repair (FEVAR) are uncertain. This meta-analysis reports long term survival, freedom from re-intervention, target vessel patency, and one year sac regression after FEVAR.
**Data Sources:** Systematic review and meta-analysis to pool time to event data according to PRISMA guidelines. The study was registered with the international prospective register of systematic reviews (PROSPERO) (ID: CRD42023401468).
**Review Methods:** Medline, Embase, and Cochrane databases were searched from 1992 – 2023; articles were independently screened by two authors. Publication of complete time to event data for any outcome of interest was an inclusion criterion. Raw Kaplan–Meier probabilities were directly extracted from published curves and pooled by random effects. Risk of bias was assessed using ROBINS I and certainty with GRADE.
**Results:** A total of 3 569 records were retrieved, 2 869 screened after duplicate removal, yielding 37 included studies ($n = 4\ 371$). The pooled mean age was 73.2 years (interquartile range [IQR] 72.2, 73.7) and 87.4% were male (95% confidence interval [CI] 85.8 – 88.9). Pooled Kaplan–Meier estimated probabilities of survival ($n = 34$ studies, $n = 4\ 192$ patients) at one, three, and five years were 91.6% (95% CI 90.2 – 92.9), 80.8% (95% CI 78.0 – 83.2), and 65.1% (95% CI 60.9 – 69.1). For freedom from re-intervention ($n = 24$, $n = 3\ 211$ patients) at one, three, and five years these were 90.2% (95% CI 87.3 – 92.7), 80.9% (95% CI 76.5 – 84.9), and 73.8% (95% CI 67.1 – 79.6). For target vessel patency ($n = 13$, $n = 5805$ target vessels) at one, three, and five years, these were 96.6% (95% CI 94.9 – 98.0), 94.5% (95% CI 91.7 – 96.7), and 93.1% (95% CI 89.3 – 96.0). Pooled estimate of sac regression ($n = 8$, $n = 560$) at one year was 40.2% (95% CI 28.9 – 52.7). Risk of bias was judged as moderate in 11 studies and low for the remaining 26.
**Conclusion:** There are moderate to low certainty data supporting reasonable long term outcome estimates following fenestrated endovascular aneurysm repair. Beyond five years there is a lack of data in the literature.

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*This meta-analysis in context*

The somewhat controversial NICE guidelines for the management of AAAs describe the evidence for FEVAR as limited in quantity and quality.[1] The ESVS guidelines make the recommendation (no. 96) that for juxtarenal aneurysms FEVAR should be the preferred complex EVAR option if feasible;[2] however, the cited literature to support this recommendation were systematic reviews[14] and a multicentre study ($n = 318$), for which the median follow up was only six months.[24]

High level evidence in the form of a randomised controlled trial (RCT) does not currently exist for FEVAR; this is in contrast to EVAR for infrarenal AAAs, which has been the subject of several key RCTs.[25] A FEVAR RCT will be challenging to deliver: currently, there is insufficient equipoise on treatment among specialists;[26] aneurysms suitable for FEVAR are relatively rare and heterogeneous, not to

Looking to the future, preliminary results of the UK COMPlex AneurySm Study (UK-COMPASS)[26] have been presented recently and their publication is imminent. UK-COMPASS is a risk adjusted and anatomically stratified cohort comparison study of OSR, FEVAR and infrarenal EVAR for juxtarenal AAAs. Its results will provoke discussion

"RCT for FEVAR does not exist."
"Equipose does not exist."
"UK-COMPASS publication is imminet."

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Editor's Choice – Comparison of Open Surgery and Endovascular Techniques for Juxtarenal and Com… AneurySm Study (U…

Srinivasa R. Vallabhaneni [a,b,*], Shaneel …, Michael P. Jenkins [c], David C. Ormesh…

**Objective:** Treatment of juxt… endovascular rather than op… precision. UK-COMPASS is a … an AAA unsuitable for stand…
**Methods:** All procedures for … assessed in a Corelab, peri-… suitable for either endovasc… mm, 5 – 9 mm, or ≥ 10 … remainder standard risk. … fenestrated EVAR (FEVAR) ar…
**Results:** Among 8 994 patie… Propensity score stratificatio… of standard EVAR devices … for EVAR (1.2%; $p = .00$… neck, the mortality rat… with a neck length ≥… 20.7% in the whole… However, in the 0… was equivalent by… treat…
**Conclusion:** FE… proves notably… neck length), with comparable midterm survival. For patients with short neck (5 – 9 mm) and complex neck (≥ 10 mm) AAAs, overall survival was worse in endovascularly treated patients compared with OSR despite relative peri-operative safety. This warrants further research and a re-appraisal of the current clinical application of endovascular strategies, particularly in patients with poor general survival outlook owing to comorbidity and age.

mortality rate did not hold the assumption of proportional hazards owing to a reversal of treatment effect direction during the follow up period (Fig. 4). Specifically, there is a peri-operative survival benefit for endovascular techniques but a later disadvantage. This crossover of direction occurred at 10.3 months for EVAR *vs.* OSR and 12.1 months for FEVAR *vs.* OSR. Statistically, non-proportional hazards were confirmed with an assessment of Schoenfeld residuals against the rank of time giving a $p$ value of $< .001$. Like to the late all cause mortality results, the overall survival benefit with OSR over endovascular techniques was not seen in the 0 — 4 mm neck length group. For these patients, overall survival between EVAR *vs.* OSR and FEVAR *vs.* OSR was equivalent at 3.5 years of follow up. Kaplan—Meier graphs showing comparative overall survival data for the six subgroups are shown in Figure 5. Comparative analysis results by subgroup are presented in Table 5 and the

Eur J Endovasc Surg. 2024

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## 2019 ESVES AAA guidelines

| | Recommendation | Class | Level |
|---|---|---|---|
| 95 | In patients with CAAAs, **open repair or complex endovascular repair should be considered** based on patient status, anatomy, local expertise, team experience and patient preference | IIa | C |
| 96 | In complex endovascular AAA repair, **FB-EVAR** should be considered the **preferred option** when feasible | IIa | C |
| 97 | In complex endovascular AAA repair, parallel grafts, endo-stables, in situ fenestrations may be considered in the **emergency setting** when fenestrated grafts are not indicated or available or as a bail out, ideally restricted **to ≤2 parallel grafts** | IIa | C |
| 98 | In patients with CAAAs, **new techniques or concepts** (EVAS, in situ, etc) **are not recommended as first line of treatment** | III | C |
| 99 | In patients with **ruptured CAAAs**, **open repair or complex endovascular repair** (with PMEGs, off the shelf or parallel grafts) may be considered based on patient status, anatomy, local experience, team experience and patient preference | IIa | C |

Wanhainen A, et al. Eur J Vasc Endovasc Surg 2019

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CLINICAL PRACTICE GUIDELINE

## 2022 ACC / AHA Guideline for the Diagnosis And Management of Aortic Disease

**Complex Abdominal Aortic Aneurysms**

**INTACT**

Repair **is recommended** when diameter is **≥ 5.5-cm in men and ≥ 5-cm (Class 1)**

In **low-moderate risk** patients with suitable anatomy for **open or endo** repair, **shared decision making is recommended** weighting risks/ benefits of each option **(Class 1)**

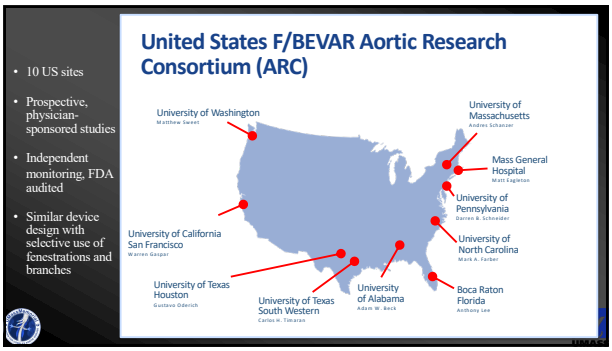
In **high risk patients** with CAAAs and suitable anatomy, **FB-EVAR is reasonable** over open repair **(Class 2a)**

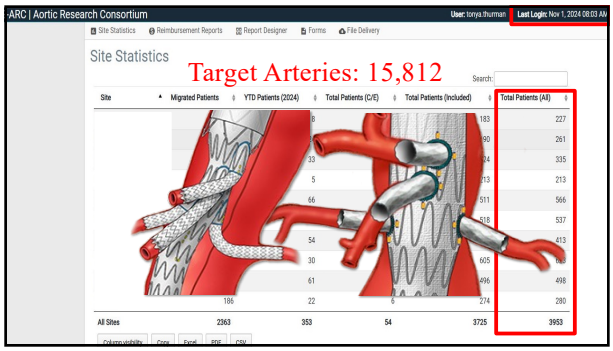
**RUPTURED**

In patients with Ruptured AAA and **suitable anatomy, EVAR is recommended** over open repair **(Class 1)**

**In stable patients with CAAAs endovascular repair is reasonable** in centers with expertise and access to devices **(Class 2b)**

Isselbacher E et al. Circulation and JACC 2022



| | Total n=3453 | TAAA (1-5) n=2357 | Complex AAA n=1096 | p-value |
|---|---|---|---|---|
| Age at index procedure, mean (std) | 73.5 (8.3) | 72.8 (8.6) | 75.1 (7.5) | <0.0001 |
| Male sex | 2423 (70) | 1546 (66) | 877 (80) | <0.0001 |
| Race (can select more than one) | | | | |
| White | 2954 (86) | 1962 (83) | 992 (91) | <0.0001 |
| Black | 278 (8.1) | 226 (9.6) | 52 (4.7) | <0.0001 |
| Asian | 36 (1.0) | 22 (0.9) | 14 (1.3) | 0.35 |
| American Indian or Alaska Native | 13 (0.4) | 7 (0.3) | 6 (0.6) | 0.37 |
| Native Hawaiian or Pacific Islander | 2 (0.1) | 2 (0.1) | 0 (0) | 0.99 |
| Other/unknown | 91 (2.6) | 71 (3.0) | 20 (1.8) | 0.043 |
| Hispanic ethnicity | 77 (2.2) | 63 (2.7) | 14 (1.3) | 0.010 |
| Comorbidities | | | | |
| CAD | 1647 (48) | 1062 (45) | 585 (54) | <0.0001 |
| COPD | 1211 (35) | 809 (34) | 402 (37) | 0.19 |
| Renal failure requiring dialysis | 61 (1.8) | 53 (2.3) | 8 (0.7) | 0.002 |
| Diabetes | 523 (15) | 334 (14) | 189 (17) | 0.019 |
| Hypertension | 3169 (92) | 2176 (92) | 993 (91) | 0.06 |
| Current tobacco use | 933 (27) | 624 (27) | 309 (28) | 0.3 |
| Prior EVAR | 531 (16) | 304 (13) | 227 (24) | <0.0001 |
| Technical success | 3327 (97) | 2259 (96) | 1068 (98) | 0.030 |
| ICU LOS days, mean (std) | 3.3 (5.4) | 3.8 (6.0) | 2.0 (3.4) | <0.0001 |
| Total LOS days, mean (std) | 6.4 (9.4) | 7.2 (9.3) | 4.8 (9.4) | <0.0001 |

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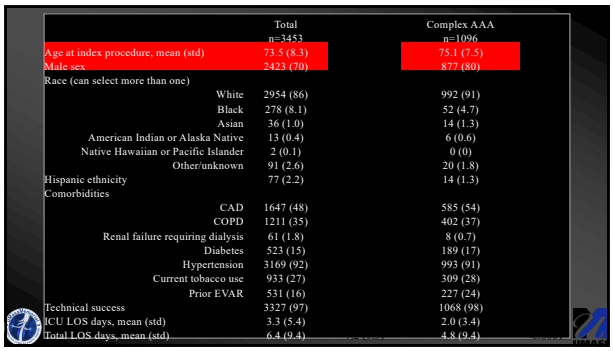
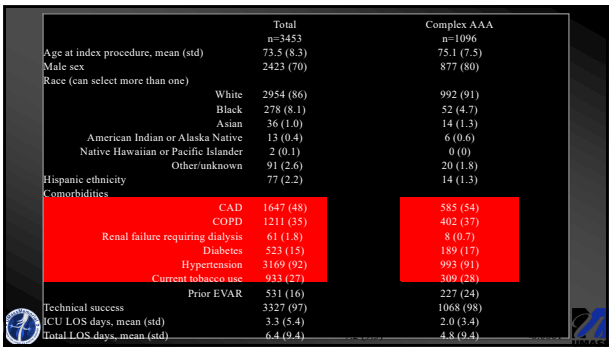
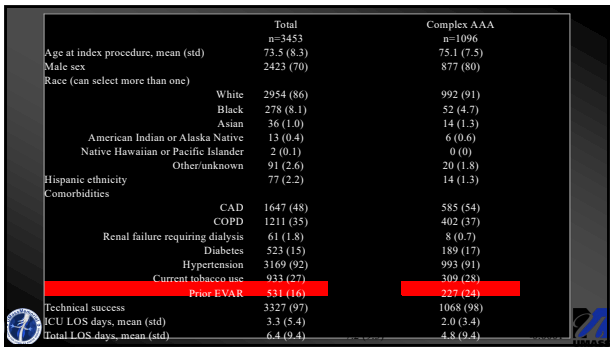
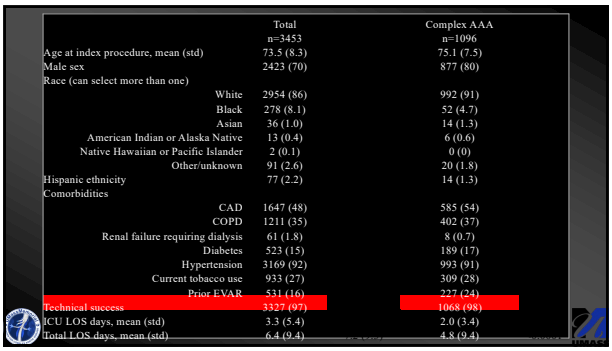
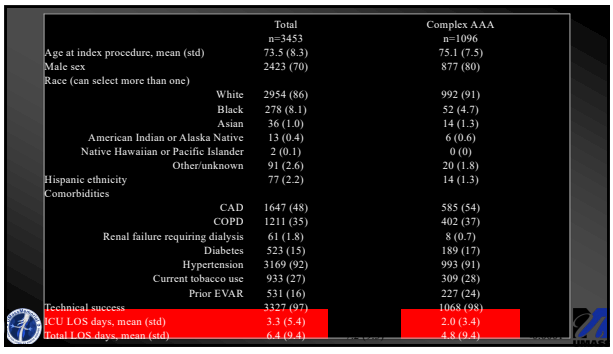










30-day or in-hospital mortality (n=3481)

**30-Day Mortality (11/13/24): 101/3481 =**

**2.9%**

A Quarter Century of Organ Protection in Open Thoracoabdominal Repair

*Anthony L. Estrera, MD, Harleen K. Sandhu, MD, MPH, Kristofer M. Charlton-Ouw, MD, Rana O. Afifi, MD, Ali Azizzadeh, MD, Charles C. Miller III, PhD, and Hazim J. Safi, MD*

Ann Surg. 2015.

Dr. Safi– 1896 patients
30 Day Mortality 16%

**Outcomes of 3309 thoracoabdominal aortic aneurysm repairs**

Joseph S. Coselli, MD,[a,b,c] Scott A. LeMaire, MD,[a,b,c,d,e] Ourania Preventza, MD,[a,b,c] Kim I. de la Cruz, MD,[a,b,c] Denton A. Cooley, MD,[f] Matt D. Price, MS,[a,d] Alan P. Stolz, MEd,[a,d] Susan Y. Green, MPH,[a,d] Courtney N. Arredondo, MSPH,[a] and Todd K. Rosengart, MD[a,b,c,d,e]

J Thorac Cardiovasc Surg. 2016.

Dr. Coselli – 3,309 patients
30 Day Mortality 7%

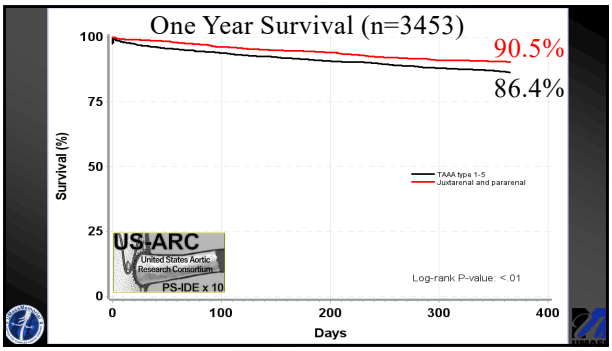
Durability of open surgical repair of type I-III thoracoabdominal aortic aneurysm

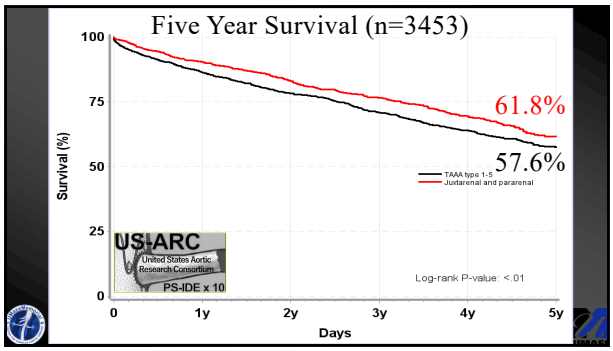
Christopher A. Latz, MD,[a] Richard P. Cambria, MD,[b] Virendra I. Patel, MD, MPH,[c] Jahan Mohebali, MD,[a] Emel A. Ergul, MS,[a] R. Todd Lancaster, MD, MPH,[a] Mark F. Conrad, MD, MMSc,[a] and W. Darrin Clouse, MD,[a]

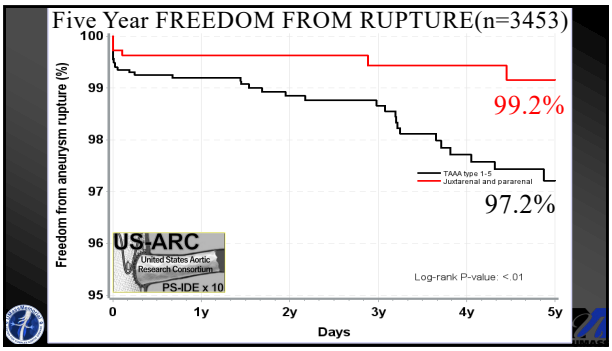
*Boston and Brighton, Mass; and New York, NY*

J Vasc Surg. 2019.

Dr. Cambria – 516 patients
30 Day Mortality 8%




## 1,681 Patients / 6,349 Target Vessels

Mid-term Renal and Mesenteric Artery Outcomes During Fenestrated and Branched Endovascular Aortic Repair for Complex Abdominal and Thoracoabdominal Aortic Aneurysms in the United States Aortic Research Consortium

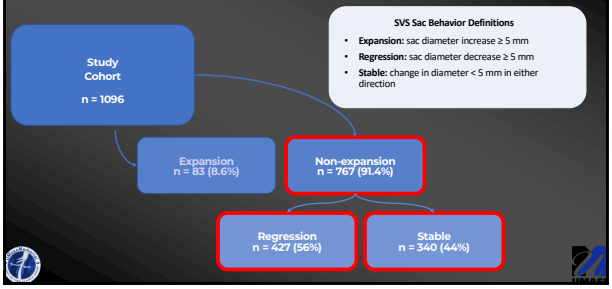
*Emanuel R. Tenorio, MD, PhD,* Andres Schanzer, MD,† Carlos H. Timaran, MD,‡ Darren B. Schneider, MD,§ Bernardo C. Mendes, MD,‖ Matthew J. Eagleton, MD,¶ Mark A. Farber, MD,# Federico Ezequiel Parodi, MD,# Warren J. Gasper, MD,** Adam W. Beck, MD,†† Matthew P. Sweet, MD,‡‡ Ying Huang, MD, PhD,* Gustavo S. Oderich, MD,*§§*

*and on behalf of the U.S. Fenestrated and Branched Aortic Research Consortium§§*

| Renal target artery stents 5-year Kaplan-Meier Estimates (%) | Fenestration n = 2166 | Branch n = 989 | P value |
|---|---|---|---|
| Primary patency | 94±1 | 83±3 | <.001 |
| Secondary patency | 97±1 | 89±2 | <.001 |
| Freedom from target vessel Instability | 88±2 | 80±2 | .001 |

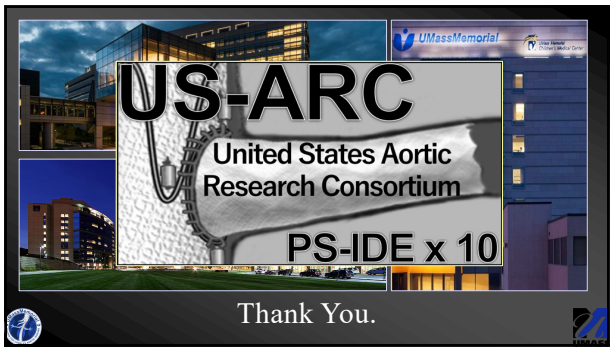
Tenorio E et al. Ann Surg 2023

## Juxta/Para Sac Behavior (n = 1096)



## Conclusions

- F/BEVAR is associated with lower morbidity and mortality compared to open surgical repair for complex AAA (despite being used in older and higher risk patients)
- Protection from rupture and from sac enlargement is excellent
- "Open repair is the gold standard." Really??? Enough is enough, it no longer is.
- Limitations of F/BEVAR are important to acknowledge: secondary intervention, limited access, regulatory hurdles, cost, and need for surveillance
- The US ARC has established a higher level of evidence supporting use of FB-EVAR in most patients with cAAA (and TAAAs)




Thank You.