Short-term results of physician-modified fenestrated endografts for treatment of failed infrarenal EVAR

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Disclosures

- Physician-Sponsored Investigational Device Exemption (G210245)

Background

Endovascular aneurysm repair (EVAR) has increased in prevalence since its advent

Failure after infrarenal EVAR increasingly common

- Loss of proximal seal

Increasing use of open conversion for late complications after endovascular aortic aneurysm repair

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ABSTRACT

Objective: Open procedures are often required for late complications after endovascular aneurysm repair (EVAR). Our aim was to describe the indications for open interventions and their postoperative outcomes and to specifically examine our experience with limited conversions in which problem endoleaks are targeted without endograft explantation.

Methods: We reviewed patients from 2002 to 2017 who underwent any surgical abdominal aortic operation after a previous EVAR. Baseline characteristics, preoperative imaging, procedural details, and postoperative outcomes were reviewed. The primary end point was 30-day mortality.

Results: There were 102 patients who underwent open conversion 3.8 ± 3.1 years after EVAR. The numbers increased significantly in recent years, with 18 cases performed in 2016; 48.5% of patients had undergone 1.9 ± 1.0 prior endovascular interventions. The indication for surgical conversion was an endoleak in 85 patients and infection in 15. One patient had a limb occlusion and another a proximal aneurysm. The 30-day mortality was 6.2% in 65 patients treated electively for endoleak but higher in 20 ruptures (40.0%) and 15 infections (40.0%). In a multivariate logistic regression model, independent predictors of 30-day mortality were rupture (odds ratio [OR], 6.70; 95% confidence interval [CI], 1.75-25.60; $P = .005$), endograft infection (OR, 8.48; 95% CI, 1.99-36.20; $P = .004$), and use of a supraceliac clamp (OR, 4.80; 95% CI, 1.47-15.66; $P = .009$). Transient acute kidney injury (12.8%) and prolonged intubation (11.8%) were the most common postoperative complications. In 65 patients treated for endoleak without rupture, 37 underwent endograft explantation, whereas 28 had a graft-preserving intervention (branch vessel ligation for type II endoleak in 26, external banding of the aneurysm neck for type IA endoleak in 8). Mortality was 8.1% when the endograft was explanted and 3.6% when it was not ($P = .63$). During 3.0 ± 3.5 years of follow-up, there was one reintervention after endograft explantation (for rupture secondary to type IB endoleak) and two reinterventions after graft preservation (for a new type IA endoleak and a new type II endoleak). Survival was 87.4% at 1 year and 70.9% at 5 years.

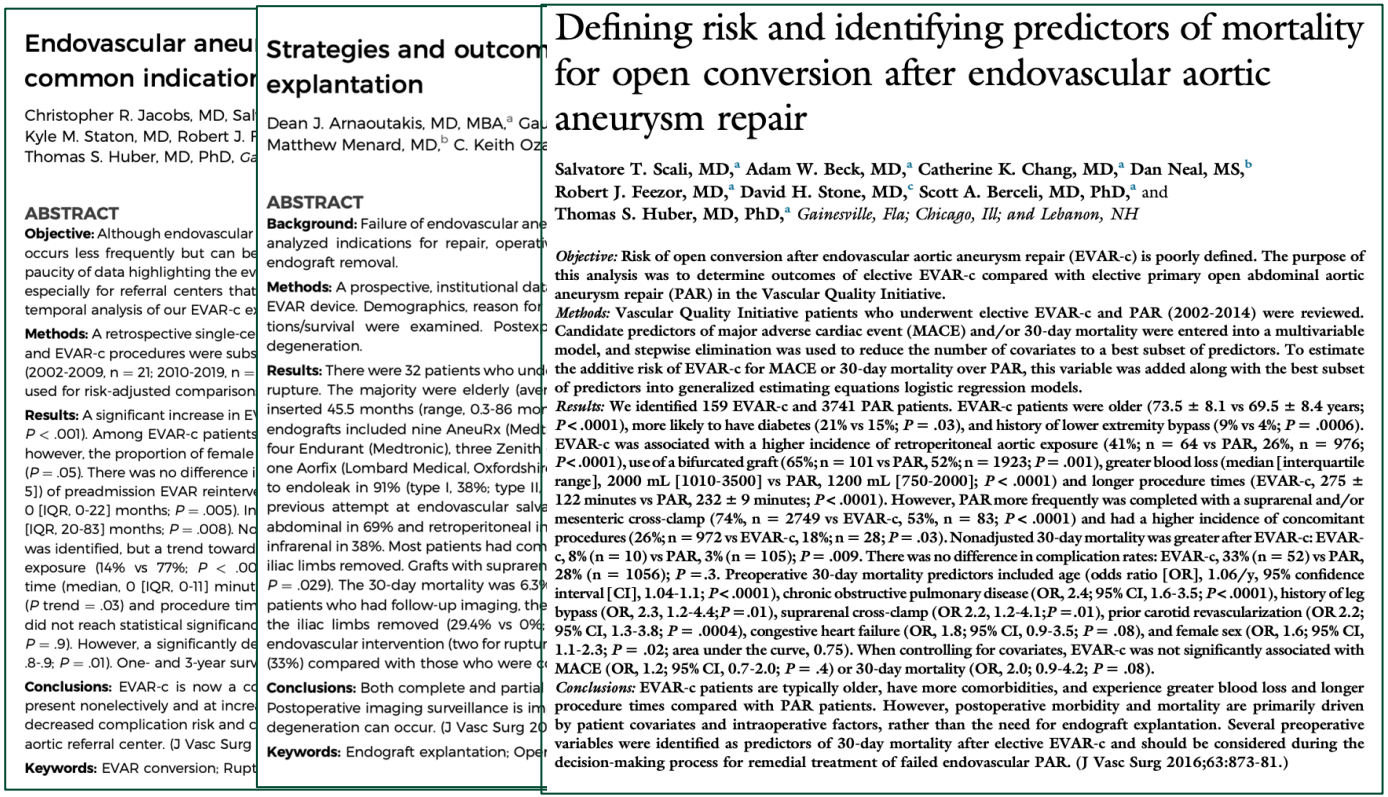
Conclusions: Open conversion is playing an increasing role in the management of late EVAR complications. Endoleaks treated electively by open conversion are reasonably safe and show good midterm durability, even with graft-preserving interventions that avoid endograft explantation. (J Vasc Surg 2019;69:1766-75.)

Keywords: Abdominal aortic aneurysm; Endovascular aneurysm repair; Open conversion; Endoleak; Aortic rupture

Treatment Options After Failed EVAR

- Open Explant
- Endovascular salvage
    1. Snorkels, Chimneys, graft extension
    2. Fenestrated Endovascular Aortic Repair (FEVAR)
        - Custom-made devices
    3. Physician Modified Endografts (PMEG)

EVAR Explant Outcomes



Endovascular aneu
common indicatior

Christopher R. Jacobs, MD, Sal
Kyle M. Staton, MD, Robert J. F
Thomas S. Huber, MD, PhD, Ga

ABSTRACT

Objective: Although endovascular
occurs less frequently but can be
paucity of data highlighting the ev
especially for referral centers that
temporal analysis of our EVAR-c ex

Methods: A retrospective single-ce
and EVAR-c procedures were subs
(2002-2009, n = 21; 2010-2019, n =
used for risk-adjusted comparison

Results: A significant increase in EV
$P < .001$). Among EVAR-c patients
however, the proportion of female
($P = .05$). There was no difference i
5]) of preadmission EVAR reinterve
0 [IQR, 0-22] months; $P = .005$). In
[IQR, 20-83] months; $P = .008$). No
was identified, but a trend toward
exposure (14% vs 77%; $P < .00$
time (median, 0 [IQR, 0-11] minut
(P trend = .03) and procedure tim
did not reach statistical significanc
$P = .9$). However, a significantly de
.8-.9; $P = .01$). One- and 3-year surv

Conclusions: EVAR-c is now a co
present nonelectively and at increa
decreased complication risk and c
aortic referral center. (J Vasc Surg

Keywords: EVAR conversion; Rupt

Strategies and outcom
explantation

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Matthew Menard, MD,[b] C. Keith Oze

ABSTRACT

Background: Failure of endovascular ane
analyzed indications for repair, operati
endograft removal.

Methods: A prospective, institutional dat
EVAR device. Demographics, reason for
tions/survival were examined. Postex
degeneration.

Results: There were 32 patients who und
rupture. The majority were elderly (aver
inserted 45.5 months (range, 0.3-86 mor
endografts included nine AneuRx (Medt
four Endurant (Medtronic), three Zenith
one Aorfix (Lombard Medical, Oxfordshir
to endoleak in 91% (type I, 38%; type II,
previous attempt at endovascular salva
abdominal in 69% and retroperitoneal in
infrarenal in 38%. Most patients had com
iliac limbs removed. Grafts with suprarer
$P = .029$). The 30-day mortality was 6.3%
patients who had follow-up imaging, the
the iliac limbs removed (29.4% vs 0%;
endovascular intervention (two for ruptur
(33%) compared with those who were c

Conclusions: Both complete and partia
Postoperative imaging surveillance is im
degeneration can occur. (J Vasc Surg 20

Keywords: Endograft explantation; Oper

Defining risk and identifying predictors of mortality for open conversion after endovascular aortic aneurysm repair

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Objective: Risk of open conversion after endovascular aortic aneurysm repair (EVAR-c) is poorly defined. The purpose of this analysis was to determine outcomes of elective EVAR-c compared with elective primary open abdominal aortic aneurysm repair (PAR) in the Vascular Quality Initiative.

Methods: Vascular Quality Initiative patients who underwent elective EVAR-c and PAR (2002-2014) were reviewed. Candidate predictors of major adverse cardiac event (MACE) and/or 30-day mortality were entered into a multivariable model, and stepwise elimination was used to reduce the number of covariates to a best subset of predictors. To estimate the additive risk of EVAR-c for MACE or 30-day mortality over PAR, this variable was added along with the best subset of predictors into generalized estimating equations logistic regression models.

Results: We identified 159 EVAR-c and 3741 PAR patients. EVAR-c patients were older (73.5 ± 8.1 vs 69.5 ± 8.4 years; $P < .0001$), more likely to have diabetes (21% vs 15%; $P = .03$), and history of lower extremity bypass (9% vs 4%; $P = .0006$). EVAR-c was associated with a higher incidence of retroperitoneal aortic exposure (41%; n = 64 vs PAR, 26%, n = 976; $P < .0001$), use of a bifurcated graft (65%; n = 101 vs PAR, 52%; n = 1923; $P = .001$), greater blood loss (median [interquartile range], 2000 mL [1010-3500] vs PAR, 1200 mL [750-2000]; $P < .0001$) and longer procedure times (EVAR-c, 275 ± 122 minutes vs PAR, 232 ± 9 minutes; $P < .0001$). However, PAR more frequently was completed with a suprarenal and/or mesenteric cross-clamp (74%, n = 2749 vs EVAR-c, 53%, n = 83; $P < .0001$) and had a higher incidence of concomitant procedures (26%; n = 972 vs EVAR-c, 18%; n = 28; $P = .03$). Nonadjusted 30-day mortality was greater after EVAR-c: EVAR-c, 8% (n = 10) vs PAR, 3% (n = 105); $P = .009$. There was no difference in complication rates: EVAR-c, 33% (n = 52) vs PAR, 28% (n = 1056); $P = .3$. Preoperative 30-day mortality predictors included age (odds ratio [OR], 1.06/y, 95% confidence interval [CI], 1.04-1.1; $P < .0001$), chronic obstructive pulmonary disease (OR, 2.4; 95% CI, 1.6-3.5; $P < .0001$), history of leg bypass (OR, 2.3, 1.2-4.4; $P = .01$), suprarenal cross-clamp (OR 2.2, 1.2-4.1; $P = .01$), prior carotid revascularization (OR 2.2; 95% CI, 1.3-3.8; $P = .0004$), congestive heart failure (OR, 1.8; 95% CI, 0.9-3.5; $P = .08$), and female sex (OR, 1.6; 95% CI, 1.1-2.3; $P = .02$; area under the curve, 0.75). When controlling for covariates, EVAR-c was not significantly associated with MACE (OR, 1.2; 95% CI, 0.7-2.0; $P = .4$) or 30-day mortality (OR, 2.0; 0.9-4.2; $P = .08$).

Conclusions: EVAR-c patients are typically older, have more comorbidities, and experience greater blood loss and longer procedure times compared with PAR patients. However, postoperative morbidity and mortality are primarily driven by patient covariates and intraoperative factors, rather than the need for endograft explantation. Several preoperative variables were identified as predictors of 30-day mortality after elective EVAR-c and should be considered during the decision-making process for remedial treatment of failed endovascular PAR. (J Vasc Surg 2016;63:873-81.)

30-day Mortality:

Overall: 6-14%

Elective: 3-10%

Non-elective: 14-40%

Major complications:

Overall: 31-46%

Respiratory events ~25%

Cardiac events~30%

ARF needing HD~18%

Chimney/Snorkel for failed EVAR

Technical Success ~ 90%

30-day Mortality ~ 3-9%

3-year patency ~ 94%

Endoleak rate ~ 5-30%

Collected Transatlantic Exp
the PERICLES Registry: Use
Grafts to Treat Post-EVAR
Endoleaks Shows Good Mid

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Giovanni Torsello, MD[3], Paul Kubilis, MD
Konstantinos P. Donas, MD[3], Felice Pecor

Abstract

Purpose: The aim of this retrospective analysis was to
treatment of type Ia endoleaks after standard endovascula
December 2014, 517 chEVAR procedures were perform
Thirty-nine patients (mean age 76.9±7.1 years; 33 men)
tomography angiography or magnetic resonance angiograp
used in the 20 cases. Single chimney graft placement was
70 visceral vessels were targeted for revascularization.
persistent type Ia endoleaks and 1 chimney graft occlusion
2.6%. Two other deaths (not aneurysm related) occurre
patency of the chimney grafts was 94.3% at 36 months.
no significant differences were observed regarding persist
[1/20 (5%) vs 0/19 (0%)]. **Conclusion:** The present series
Ia endoleaks has satisfactory results independent of the a
that chEVAR is an effective method for treating type Ia e

Keywords
abdominal aortic aneurysm, chimney graft, chimney techn
aneurysm, parallel graft, pararenal aortic aneurysm, perisc

Midterm Results with the Open Chimney Technique during Endovascular Aneurysm Repair

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Affiliations + expand

PMID: 30876807 DOI: 10.1016/j.jvir.2018.09.013

Abstract

Purpose: To report the midterm experience with chimney-endovascular aneurysm repair (Ch-EVAR) with the use of open self-expending stents for branch vessel preservation.

Materials and methods: From July 2010 to May 2017, 67 patients underwent open Ch-EVAR because their proximal landing zones were adjacent to, or covered, the renal or mesenteric arteries (Zones 7-9), and they were not suitable for standard or fenestrated endovascular aneurysm repair. The proximal landing zone was relocated below the highest renal artery in 46 cases, the superior mesenteric artery in 17 cases, and the celiac artery in 4 cases, using 84 open chimneys (131 stents). A subgroup analysis was performed between an early (2010-2014) and a later (2015-2017) time period. Thirty-two patients were treated during the early period, and 35 were treated during the later period. In the later period, open chimneys were strengthened by a second self-expanding stent.

Results: The primary technical success rate was 89.6%; the early mortality rate was 9.0%; and the median follow-up duration was 13 months (range, 1-76 months). The estimated actuarial survival rate was 85.7% in year 1 and 79.2% in year 2, and the estimated patency rate of open chimneys reached 95.2% at 2 years. Aneurysm sac regression >5 mm and sac stability rates were 39.0% and 57.6%, respectively. Freedom from aneurysm-related reintervention was lower in the later period (log-rank P = .04), while type Ia endoleaks tended to be twice as likely.

Conclusions: Midterm results of open Ch-EVAR show high technical success with acceptable midterm patency and lack of endoleak in appropriately selected patients. The advantages over covered stents are lower-profile delivery systems and maintenance of branch vessel patency in early bifurcations and overlying visceral vessels.

F/BEVAR for Failed EVAR

Endovascular rescue with Fenestrated EVAR (FEVAR) reported with success

- Custom-made devices
- limited access

30-day mortality ~ 3%

Results of fenestrated and branched endovascular aortic aneurysm repair after failed infrarenal endovascular aortic aneurysm repair

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ABSTRACT

Objective: Failure of infrarenal endovascular aneurysm repair (EVAR) due to loss of proximal seal is increasingly common. Open surgical conversion can be challenging and has been associated with significant morbidity and mortality. The aim of this study was to evaluate the use of fenestrated-branched EVAR (F/BEVAR) for the treatment of patients with prior EVAR failure.

Methods: Consecutive patients enrolled as part of the Aortic Research Consortium in six prospective, nonrandomized, physician-sponsored investigational device exemption studies evaluating F/BEVAR between 2012 and 2018 were included in this study. The cohort was stratified according to whether the F/BEVAR procedure was performed after EVAR failure. Demographics, operative details, perioperative complications, and length of stay were compared between groups. Postprocedural survival, type I or type III endoleak, target artery patency, target artery instability, and reintervention rates were calculated using Kaplan-Meier method and compared between groups.

Results: A total of 893 patients underwent F/BEVAR; 161 (18%) were treated after failed EVAR and 732 (82%) were treated without prior EVAR. Patients with failed EVAR were more often men (84% vs 66%; $P < .01$) with larger aneurysms (6.9 cm vs 6.4 cm; $P < .01$). There were no differences in aneurysm extent ($P = .20$) between groups; for the entire cohort, there were 19% juxtarenal, 9.2% suprarenal, and 72% thoracoabdominal aneurysms. The average number of targeted arteries per patient was 3.6 in both groups. The procedural technical success (99% vs 97%; $P = .15$) did not differ between groups, but radiation dose (4750 vs 2920 mGy; $P = .02$), dose-area product (154,572 vs 82,842 mGy·cm^2; $P < .01$), and operative time (5.2 vs 4.6 hours; $P < .01$) were significantly higher in the failed EVAR group. Median intensive care unit length of stay (2.9 days) and total length of stay (6.3 days) did not differ between groups. The 30-day mortality rate (failed EVAR, 2.5%; no EVAR, 1.1%; $P = .25$) and 30-day major adverse event rates did not differ between groups. Kaplan-Meier estimates of freedom from type I or type III endoleak (91.9% vs 92.5%; $P = .65$), target artery patency (97.3% vs 97.0%; $P = .91$), freedom from target artery instability (86.3% vs 88.8%; $P = .53$), and freedom from reintervention at 1 year (84.7% vs 88.7%; $P = .10$) did not differ between the failed EVAR and no EVAR groups, respectively. One-year survival was decreased in the failed EVAR group (86.3% vs 91.9%; $P = .02$), but this effect did not persist on multivariable analysis (hazard ratio, 1.52; 95% confidence interval, 0.88-2.62; $P = .14$).

Conclusions: In this multicenter study, F/BEVAR was safe and effective in patients with prior failed EVAR, with nearly identical outcomes to those of patients without prior EVAR. However, differences in procedural metrics indicate higher level of technical challenge in performing F/BEVAR in patients with prior failed EVAR. (J Vasc Surg 2020;72:849-58.)

Keywords: Fenestrated; Endovascular; Thoracoabdominal; Aneurysm

F/BEVAR with PMEG

Fenestrated/Branched EVAR with physician modified grafts

30-day Mortality~ 7%

30-day MAE ~ 17%

No IA or III endoleaks at 30 days

Procedural and perioperative results in patients treated with fenestrated endovascular aneurysm repair planned by automated software in a physician-sponsored investigational device exemption trial of physician-modified endografts

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ABSTRACT

Objective: Fenestrated endovascular aneurysm repair (FEVAR) has been used successfully to treat patients with juxtarenal abdominal aortic aneurysms (JAAAs). Barriers to wide adoption of FEVAR include complexity in planning of fenestration locations on endografts. The purpose of this study was to validate the use of automated planning software to design fenestrated endografts and to treat patients with complex abdominal aortic aneurysms.

Methods: Patients with JAAA who were not candidates for open repair were enrolled into the automated planning arm of an ongoing investigational device exemption clinical trial and treated with FEVAR. Patient-specific fenestration size and location were determined by automated planning software using patient imaging data and algorithms that account for the interaction between the endograft delivery system and angulated aortic anatomy. Standard, off-the-shelf abdominal aortic aneurysm endografts from multiple manufacturers were modified on the back table by the physician according to the automated graft plan in the form of a patient-specific three-dimensional printed cylindrical template. Endografts typically included fenestrations for the superior mesenteric artery and both renal arteries. Procedural, perioperative, and long-term clinical and imaging data were collected per protocol.

Results: Thirty nonoperative JAAA candidate patients (American Society of Anesthesiologists class ≥3) were consented and treated with fenestrated endografts planned by automated software. The mean age was 74 ± 7 (61-86) years. The mean aneurysm diameter was 61.3 mm (range, 49-96 mm), and the mean infrarenal neck length was 6.1 mm (range, 2-15 mm). At the index procedure, 100% (30/30) of the patient-specific, surgeon-modified grafts were implanted with preservation of 97% (84/87) of branch vessels and a mean final proximal seal zone length of 41.9 mm (range, 27.3-60.6 mm). Three renal arteries were not cannulated during the index procedure because of complications not related to graft planning. The 30-day mortality rate in these high-risk JAAA patients was 6.7% (2/30), and both deaths were unrelated to the aneurysm. The 30-day major adverse event rate was 16.7% (5/30). There were no type IA or type III endoleaks, ruptures, or conversions to open surgery through 30 days.

Conclusions: This automated FEVAR planning software accurately and efficiently identifies fenestration locations for vital branch arteries, thus simplifying the planning process and facilitating the FEVAR procedure. Validated automated FEVAR planning could help bring this beneficial therapy to most patients harboring JAAAs. (J Vasc Surg 2018;68:1297-307.)

Keywords: Aortic aneurysm; Juxtarenal aneurysm; Fenestration; Automated; Software; Seal zone; IDE

Objective

The purpose of this study was to evaluate the efficacy of physician-modified endografts for salvage of failed prior EVAR

Methods

Inclusion criteria:

- Patient with prior EVAR
  - IA endoleak
  - Proximal visceral degeneration
- Treated with PMEG
- 3/5/2021 to 3/31/2022

Analysis:

- Demographics
- Operative details
- Postoperative outcomes

Methods: Primary Safety Outcome

30-day Major Adverse Events (composite)

- Aortic-related mortality
- Major stroke
- Permanent Spinal Cord Ischemia
- Respiratory failure
  - Tracheostomy or >72 hrs intubated
- Myocardial Infarction
- Acute renal failure
  - Cr rise >0.5 or GFR inc >50% or post-op dialysis
- Bowel ischemia
- Lower extremity ischemia
- Blood Loss >1000mL

Methods: Primary Efficacy Outcomes

30-day Technical Success

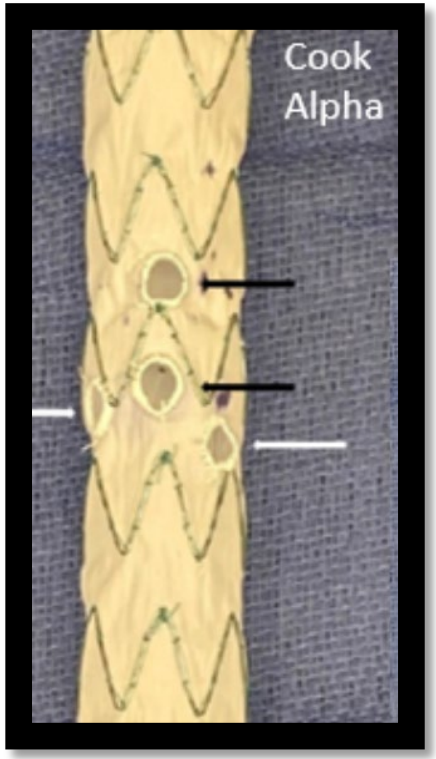
- Successful endograft delivery, deployment, and withdrawal
- Patency of all components
- Absence of inadvertent aortic branch vessel coverage

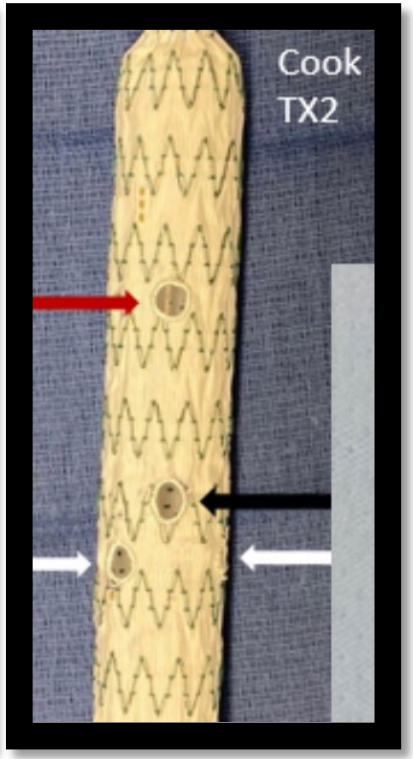
Methods: Secondary Outcomes

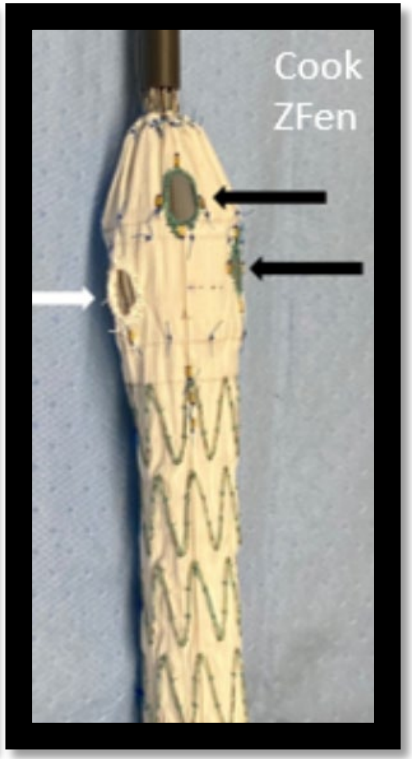
- Endoleak rates and types
- Bridging stent patency

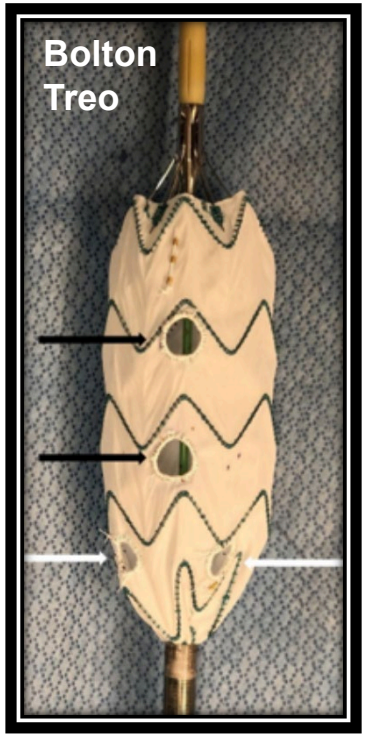
- Freedom from:
  - aortic enlargement >5cm
  - aortic rupture
  - type I or III endoleak requiring re-intervention
  - open conversion aneurysm-related mortality

Methods









Results

63 patients underwent PMEG from 3/5/21 to 3/31/22

- → 15 in setting of prior EVAR
  - → 13 (86%), Type IA (proximal) endoleaks
  - → 1 Extent IV TAAA with suprarenal aneurysmal degeneration
  - → 1 Pararenal AAA with suprarenal aneurysmal degeneration

Results: Demographics

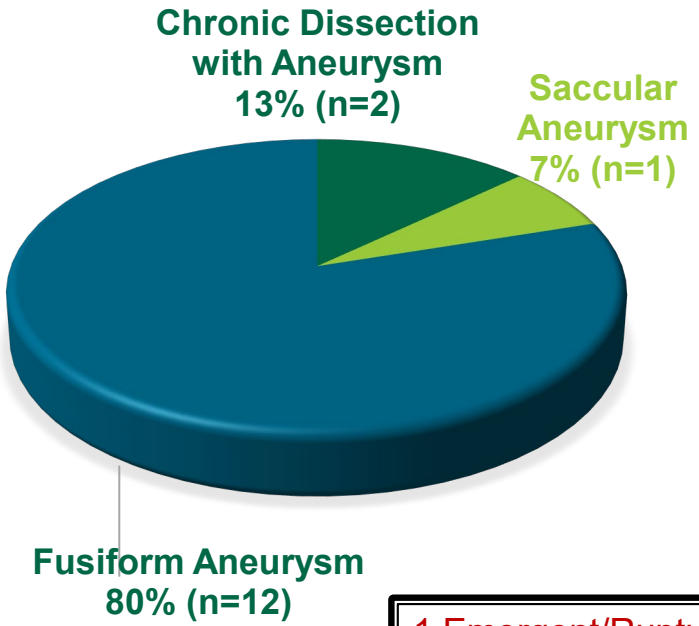
Demographic Characteristic	n=15 (%)
Age (yrs)	74.8±8
Males	13(87)
White	11(73)
Black	3(20)
Hispanic	1(7)
BMI	25±5.1
Functional status (n=12)	
Full	9(60)
Light work	3(20)
Self-care only	2(13)
Assisted care	1(7)

Comorbidities	n=15 (%)
CAD	11(73)
CABG	5(33)
PCI	5(33)
CHF	2(13)
EF (%)	52±6
HTN	15(100)
Arrythmia	4(27)
Diabetes	3(20)
CKD	2(13)
ESRD on dialysis	1(7)
COPD	11(73)
No medications	3(20)
On inhaler	6(40)
On oxygen	2(13)

Results: Aortic Characteristics

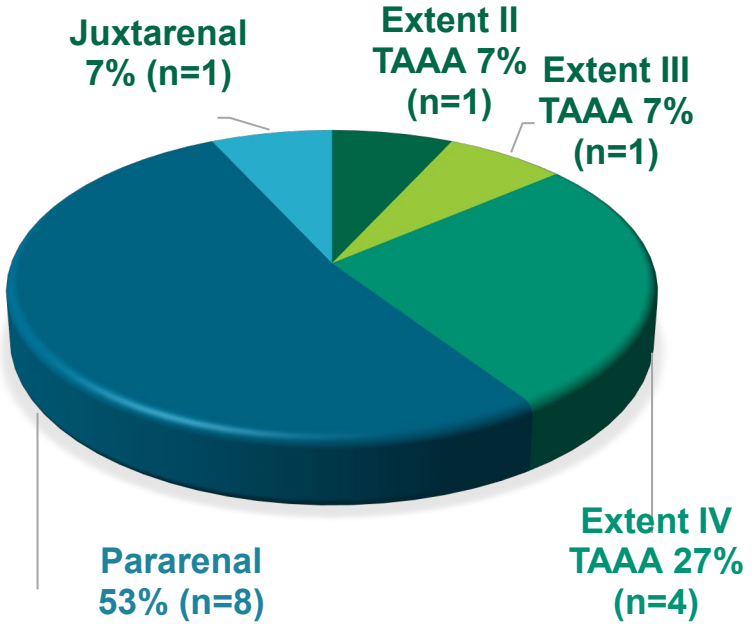
- Max aortic diameter: 65 mm ± 10.7 mm
- Median time to reintervention: 7.5 years (±4.8 years)

Aortic Pathology



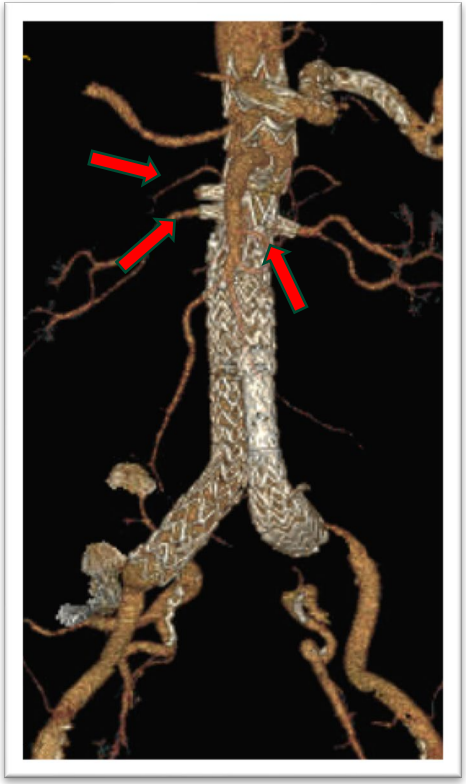
1 Emergent/Rupture
1 Urgent/Pending Rupture

Aneurysm Extent

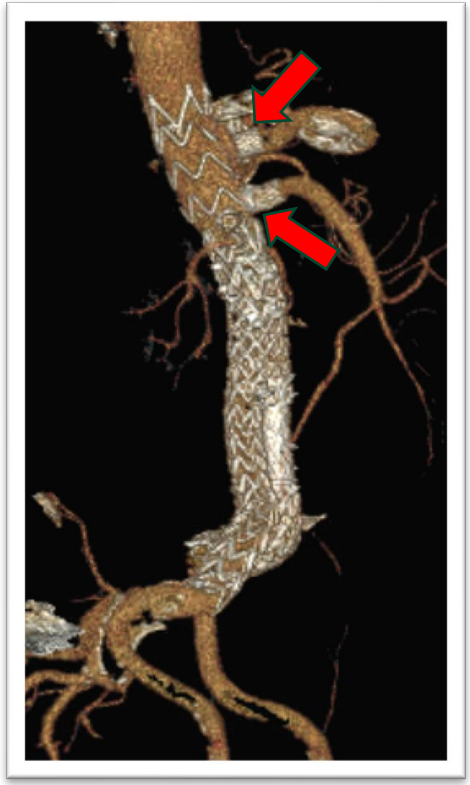


Results: Operative Details

*One patient underwent stenting of bilateral renal arteries & an accessory renal artery



Variable	PMEG N=15 (%)
PMEG Device Used	
Bolton TREO	10(67)
Cook Alpha	4(27)
Cook TX2	1(7)
Mean number of Fenestrations per Device	
Total Number of Fenestrations	54
Celiac artery	12
Superior mesenteric artery	15
Renal arteries	28*
Number of Fenestrations per Device	
Two-vessel	1(7)
Three-vessel	4(27)
Four-vessel	9(60)
Five-vessel	1(7)*
Target Vessel Bridging Stent	
Atrium iCAST	50(81)
Gore VBX	8(13)



Results: Operative Details

Variable	PMEG (N=15)
Adjunctive Fem-Fem Bypass	3(20)
Volume of Contrast Material (mL)	67±17
Dose-area Product (Gy/cm2)	348±155
Examination Dose (mGy)	2201±744
Fluoroscopy Time (min)	73±26
Total Procedure Time (min)	251±92
Estimated Blood Loss (mL)	303±262
RBC Transfusion (units)	1.3±1

Results: Primary Outcomes

Variables	N=14 (%)
30-day MAE Composite Outcome	
Aortic-related mortality	0
Major stroke	0
Permanent Spinal Cord Ischemia	1(7)
Respiratory failure (*tracheostomy or >72 hrs intubated*)	1(7)
Myocardial Infarction	0
Acute renal failure	1(7)
Bowel ischemia	0
Lower extremity ischemia	0
Blood Loss >1000	0
Total MAE	3(20)

Preop normal motor function → severe motor weakness of BLE

Preop Atrophic Left kidney with chronic renal insufficiency; required dialysis post-op

Results: Primary Outcomes

Variables	N=15 (%)
Technical Success	
Successful delivery and deployment	15(100)
Patency of all components	15(100)
Absence of inadvertent branch vessel coverage	15(100)

Results: Post-operative Details

Variable (%)	PMEG (n=15)
Hospital Length of Stay (days)	5.4±2.5
Extubated in <24 hours	14(93)
Access site complication	1(7)
30-day Readmission	2(13)*
30-day Mortality	0

Outpatient dialysis delay

Left femoral artery pseudoaneurysm repair

Results: Secondary Outcomes

Variables	N=14
Freedom from aortic enlargement >5cm	14(100)
Freedom from aortic rupture	14(100)
Freedom from type I or III endoleak requiring re-intervention	14(100)
Freedom from open conversion	14(100)
Freedom from aneurysm-related mortality	14(100)

Results: Endoleak Rates

Variables	N=14 (%)
~30-day endoleak rates	
Type Ia endoleak	*0*
Type Ib endoleak	*1(7)*
Type Ic endoleak	*1(7)*
Type II endoleak	*4(29)*
Type IIIa endoleak	*1(7)*
Total patients with endoleak	*4(29)*

Mean Follow up time: 119 days ± 81 days

Reintervention

Variables	N=15 (%)
Reinterventions	2 (13)
Mean time to reintervention	
Percutaneous approach	2(100)
Indication for reintervention	
Type Ic & Ib endoleak	*1(50)*
Type IIIa endoleak	*1(50)*

Mean Follow up time: 119 days ± 81 days

Future directions

- Surveillance imaging protocol: 30 days, 6 months, 12 months and yearly thereafter for 5 years

- Patient selection critical

Conclusions

- PMEG with FEVAR device is safe in setting of prior infrarenal EVAR

- Additional follow up for long-term success in this setting is needed to demonstrate efficacy
  - Surveillance: 30 day, 6 months, 12 months and yearly for 5 years
  - Patient selection is critical

Questions?