The Evidence for Chimneys is Poor: Fenestrated is the Gold Standard

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Disclosures and Affiliations

Cook Medical Inc, consultant and proctor

Siemens Medical, research collaboration

CYDAR Medical, research collaboration

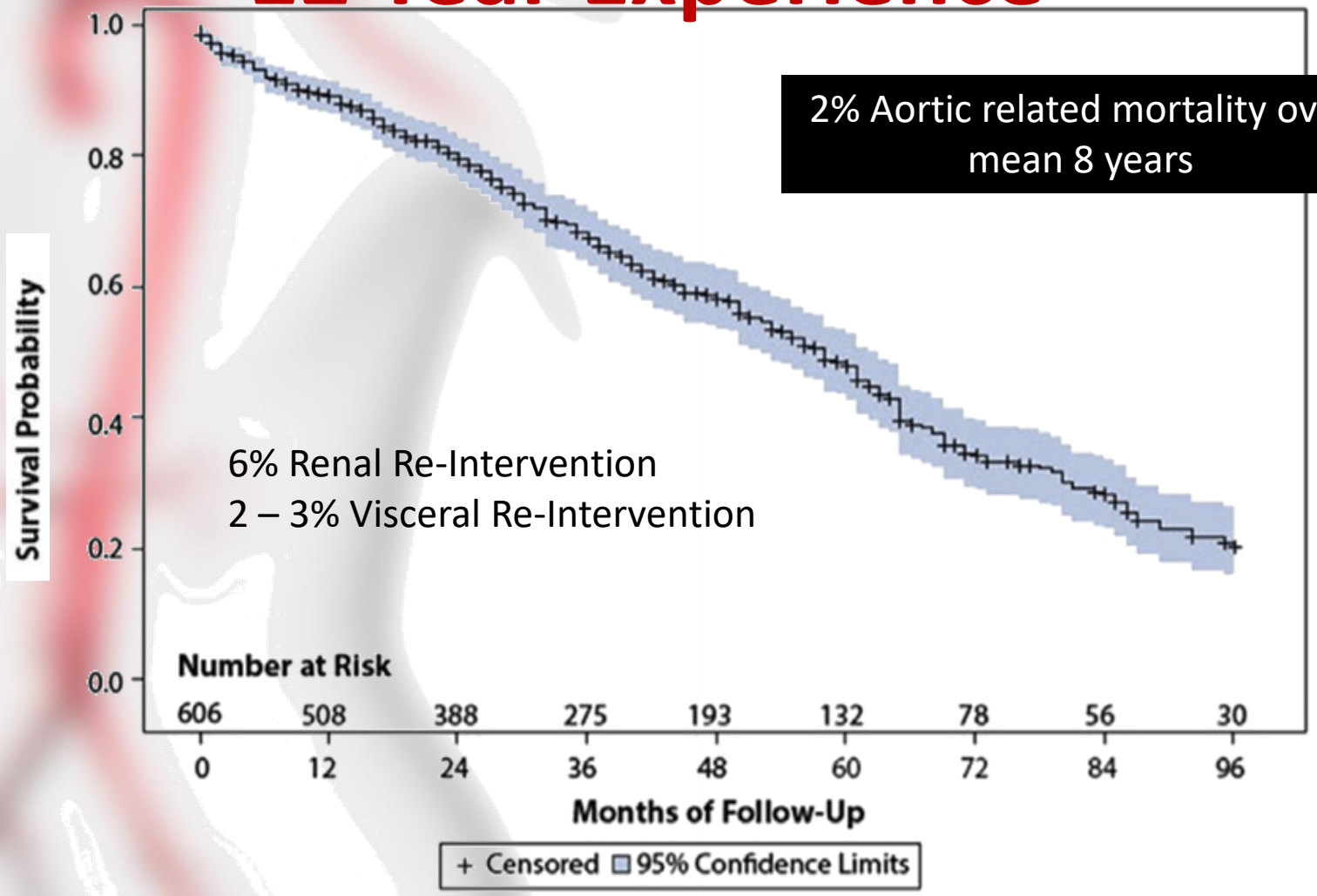
Proceeds generated from activities associated with industrial activities are donated to the Royal Free Aortic Charity, which is used to fund educational and clinical activities for the Aortic Team at the Royal Free London.

I DO NOT Believe in Parallel Grafts

- Branch stents were not tested to be radially/externally compressed
- Aortic stents were not mean to be deformed
- There is no such thing as a ‘mild type I endoleak’
- There will always be gutters

- We have a better alternative.

FEVAR: The Evidence:
12 Year Experience



2% Aortic related mortality over mean 8 years

6% Renal Re-Intervention
2 – 3% Visceral Re-Intervention

Mastracci et al, JVS 2014

Royal Free London NHS
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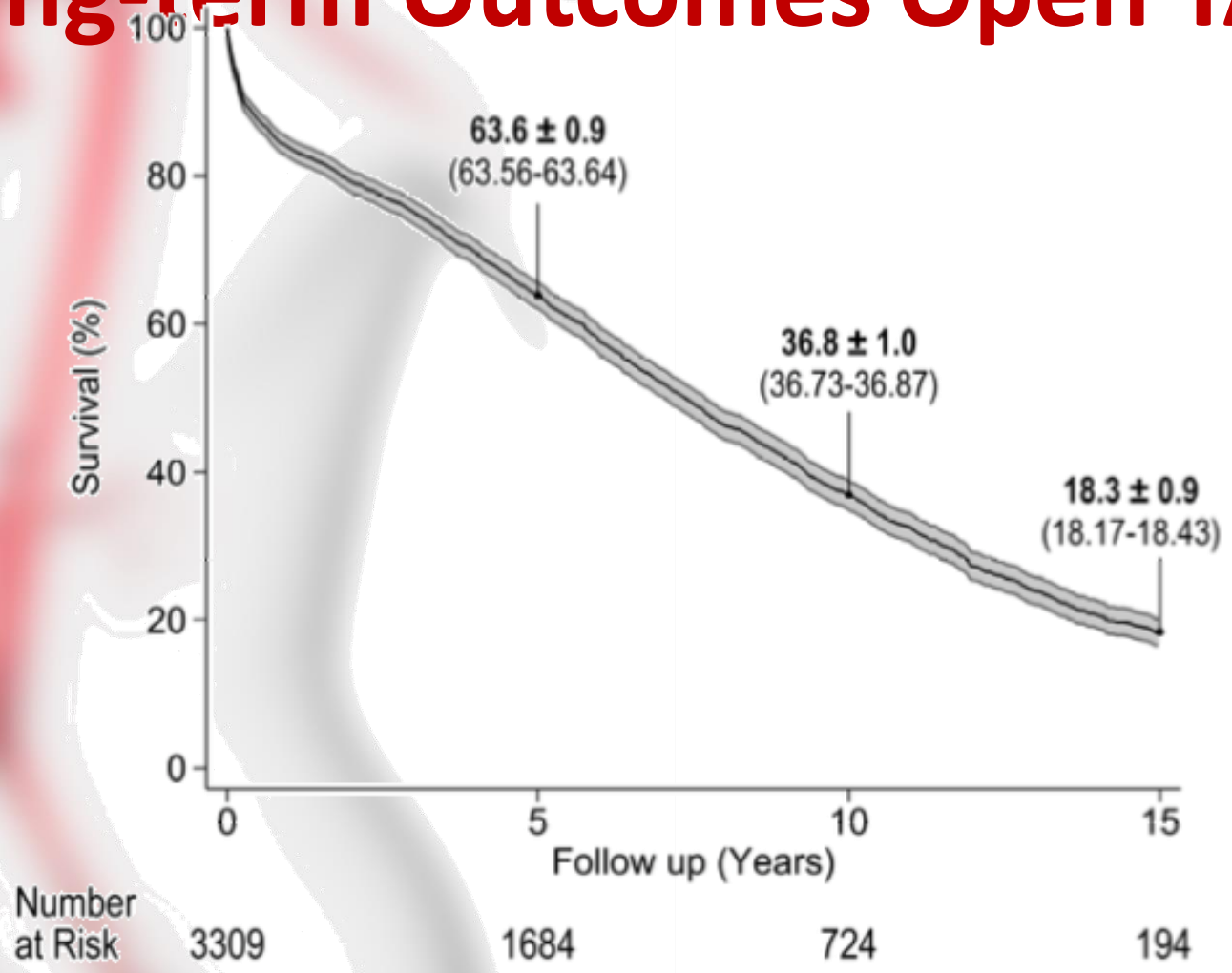
world class expertise vascular care

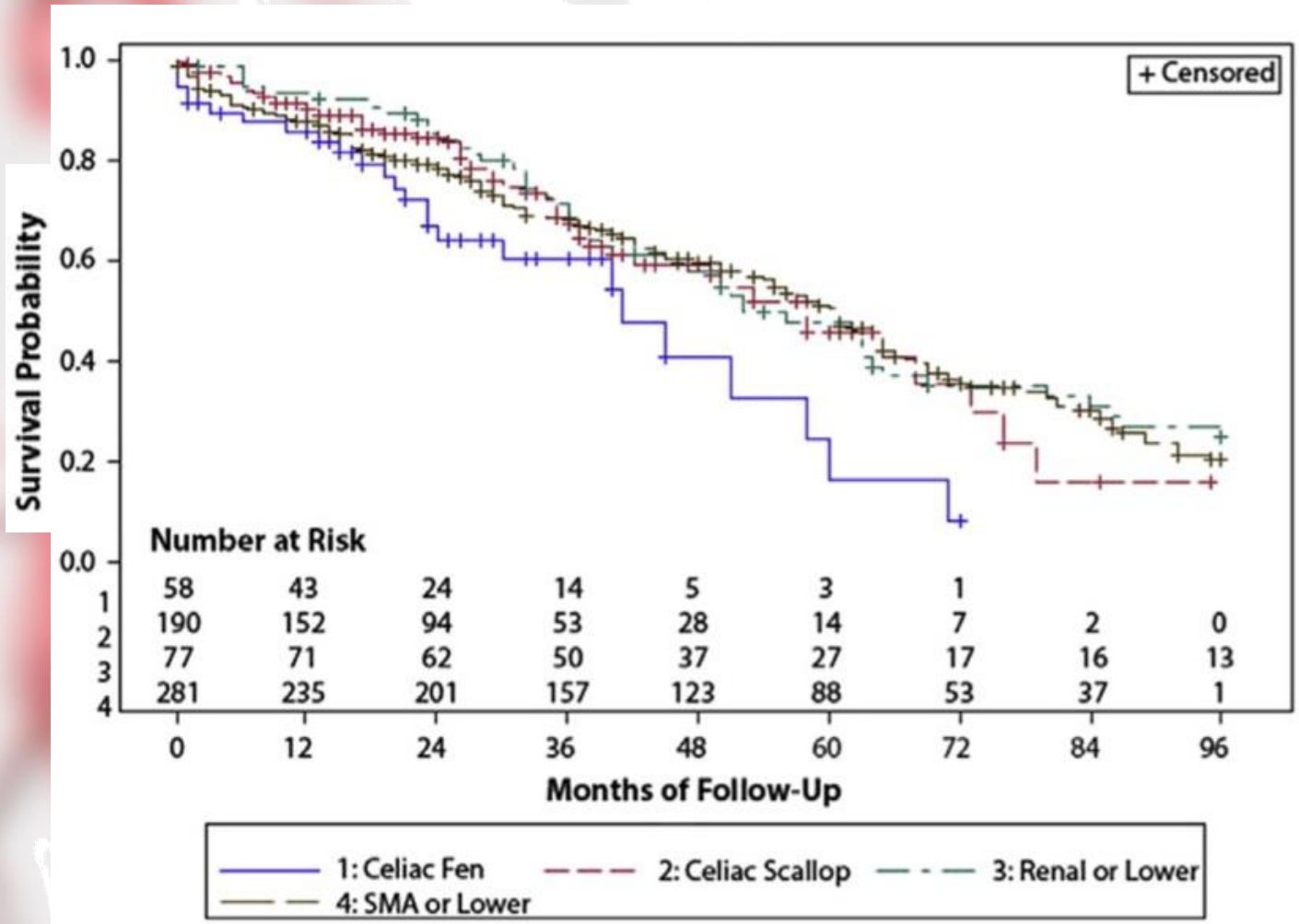
FEVAR: The Evidence:

Long-term Outcomes Open TAAA



Coselli et al, JTCVS 2016

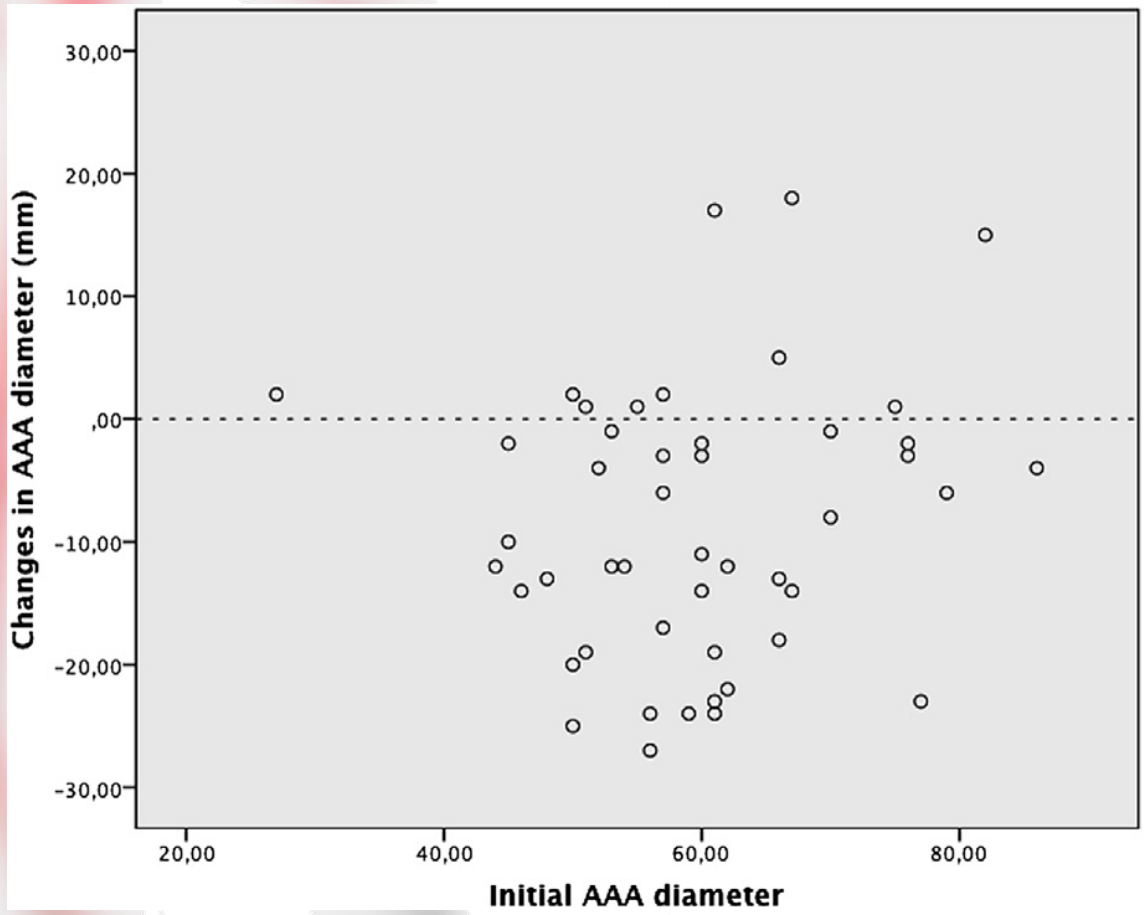
FEVAR: The Evidence
Number of Fenestrations



Mastracci et al, JVS 2014

FEVAR: The Evidence

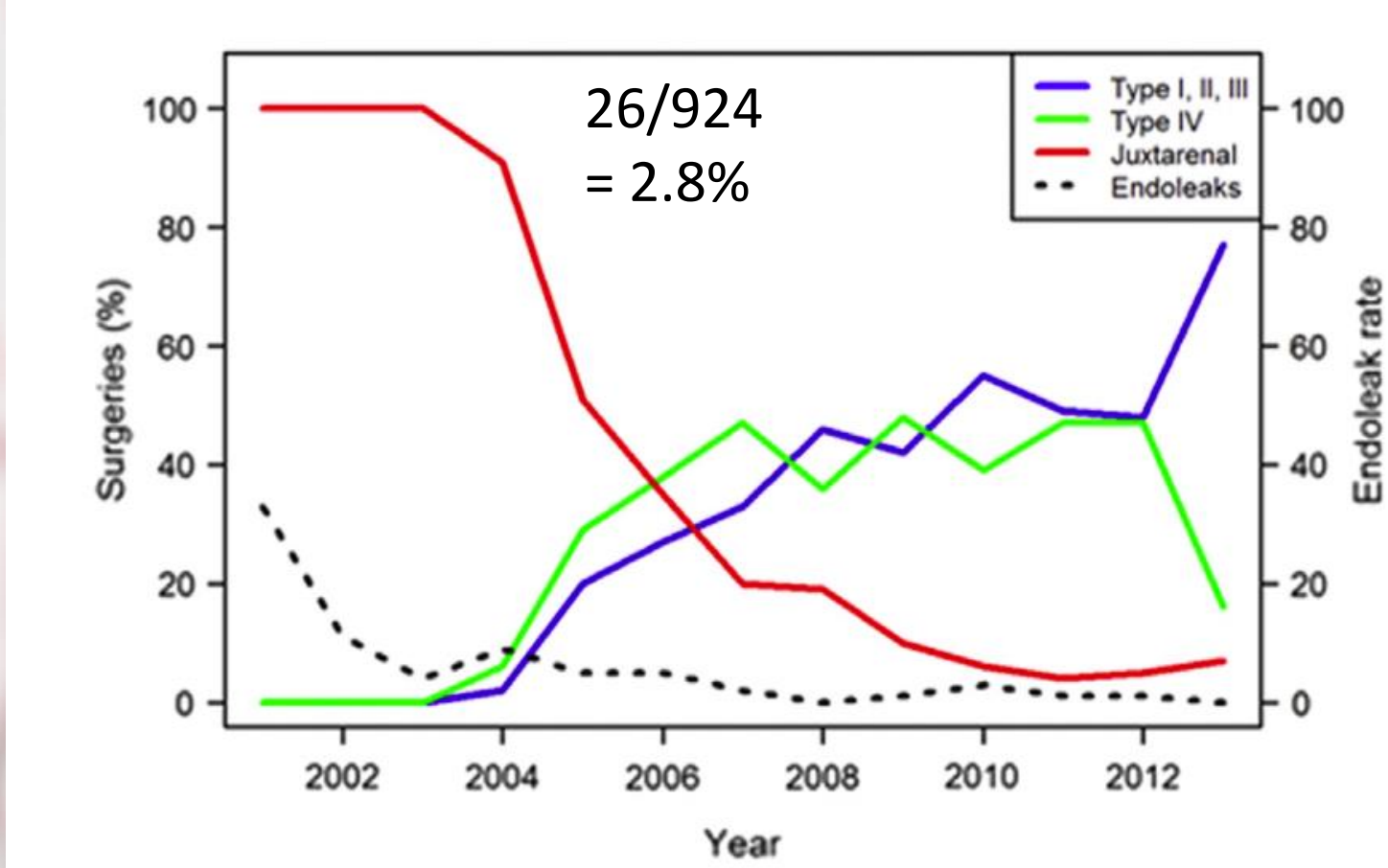
Change in Aortic Diameter over Time



Kristmundsson et al, 2014

FEVAR: The Evidence

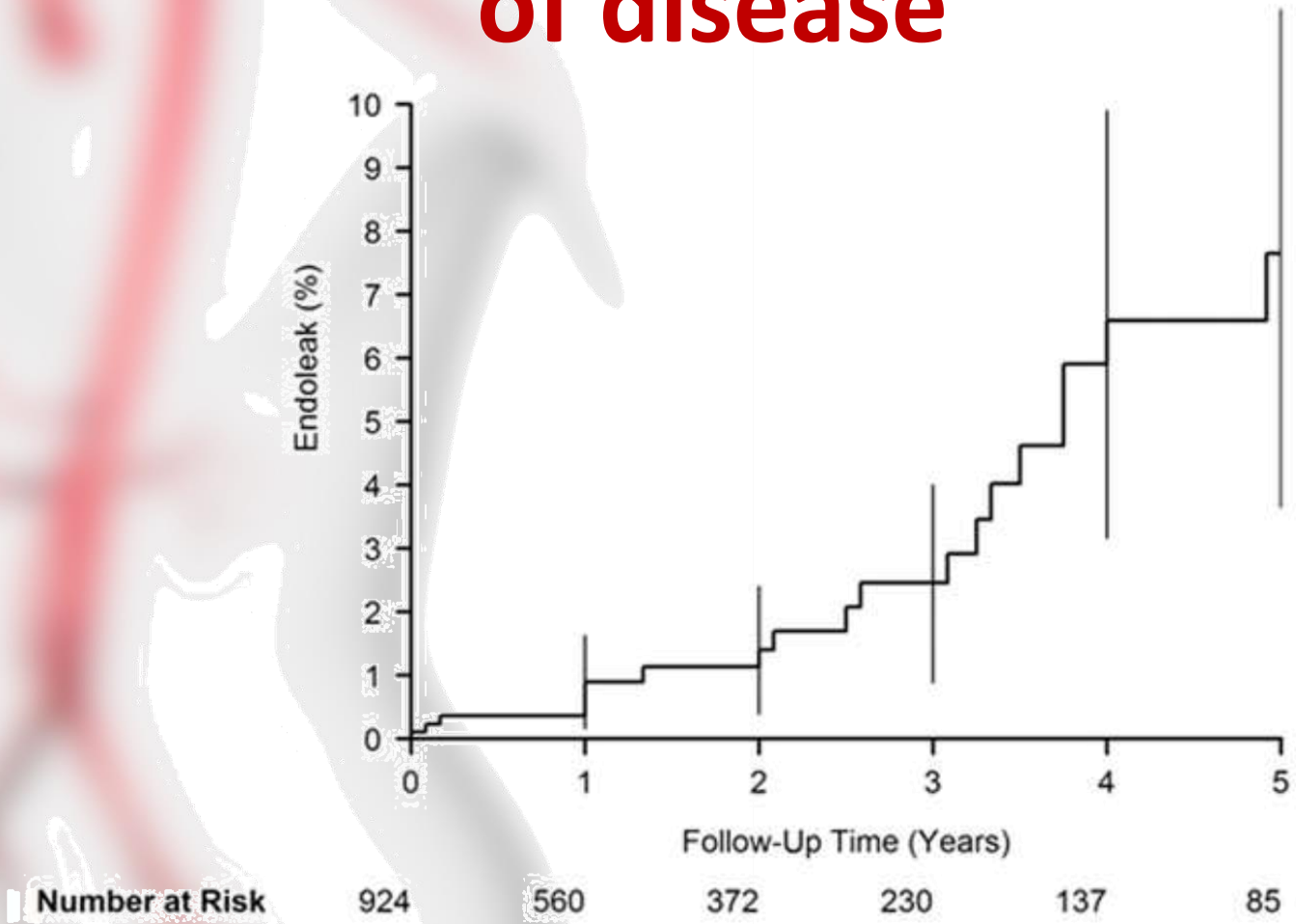
Type Ia Endoleak in Fenestrated



O'Callaghan et al JVS 2015

FEVAR: The Evidence

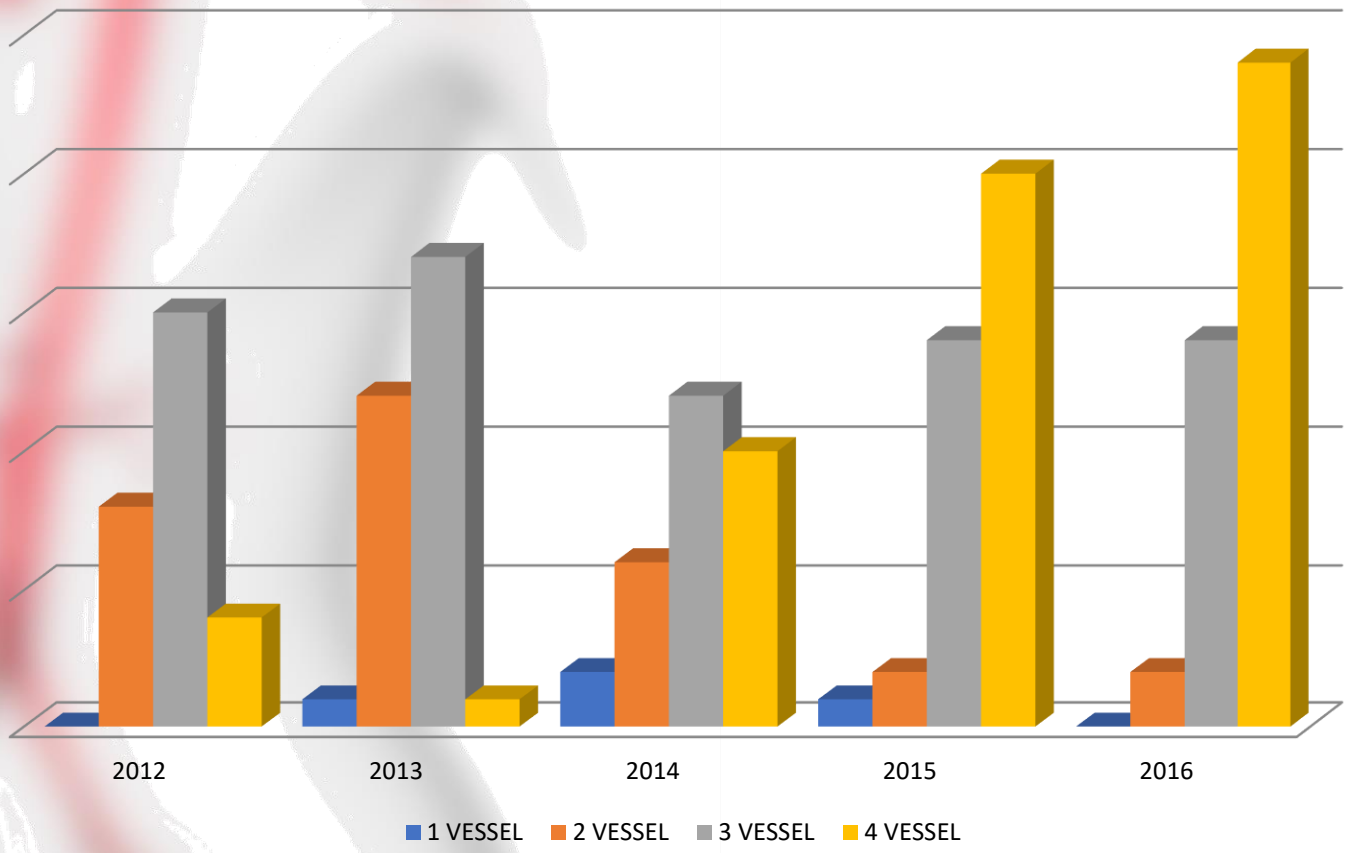
Type Ia endoleaks = progression of disease



O'Callaghan et al JVS 2015

FEVAR: The Evidence

More Vessels with Even Better Outcomes



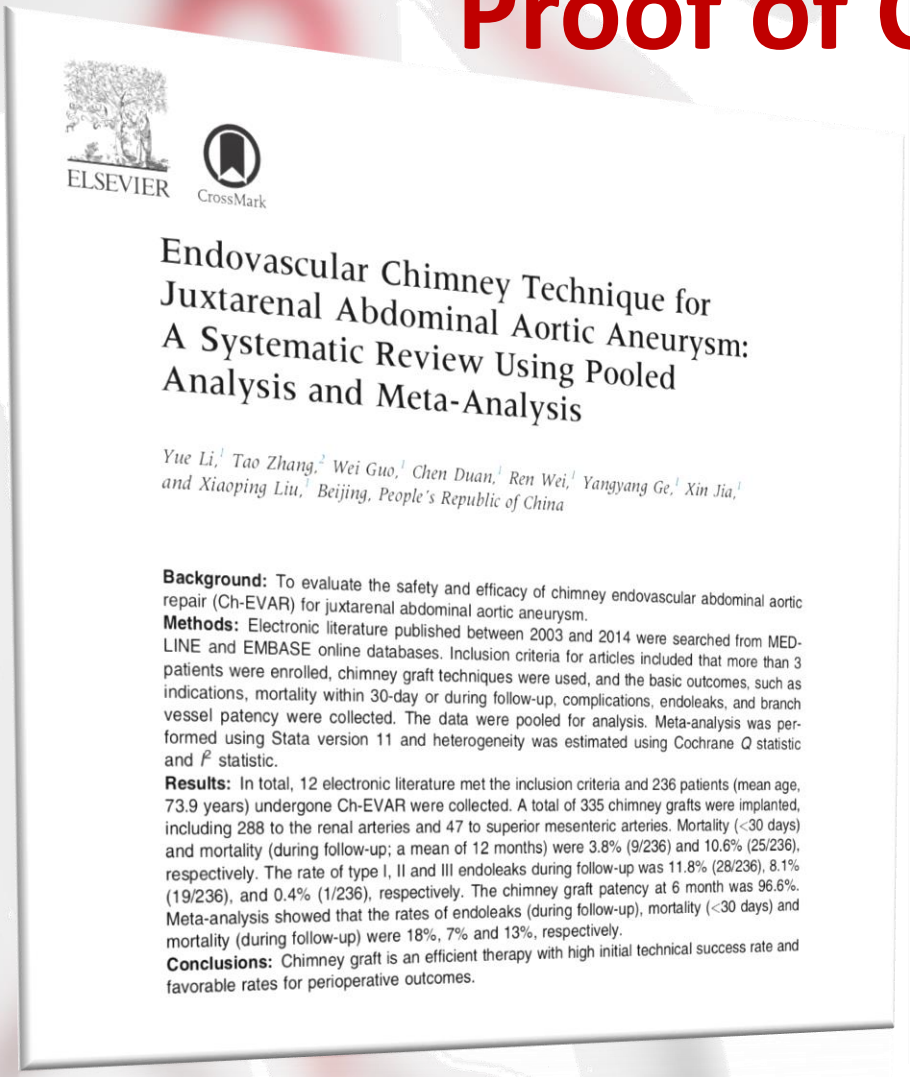
El Batti, Mastracci Submitted SVS 2018

Why Wouldn't you use FEVAR?

- ~~Skill?~~
- ~~Cost?~~
- ~~Facility requirements?~~
- ~~Ancillary devices?~~
- Manufacturing Delay?

Should we close our eyes, hold our breath, and start using Chimneys?

Parallel Grafts: The Evidence
Proof of Concept



ELSEVIER CrossMark

Endovascular Chimney Technique for Juxtarenal Abdominal Aortic Aneurysm: A Systematic Review Using Pooled Analysis and Meta-Analysis

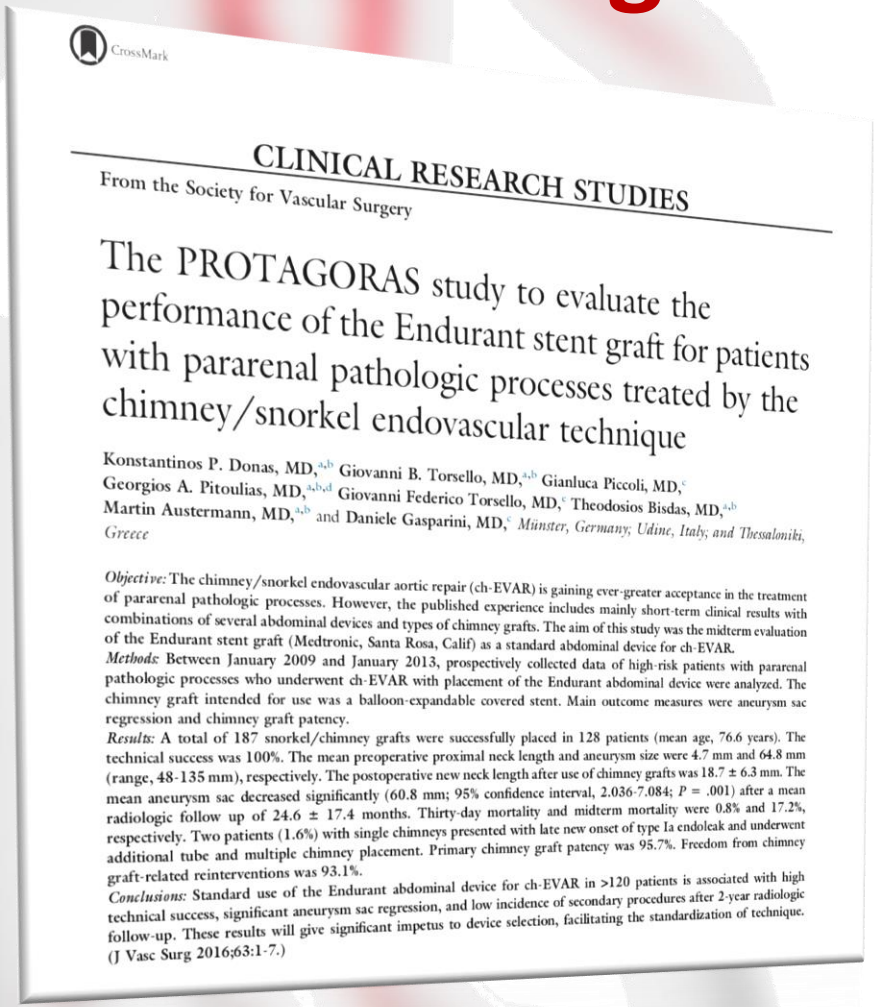
Yue Li,[1] Tao Zhang,[2] Wei Guo,[1] Chen Duan,[1] Ren Wei,[1] Yangyang Ge,[1] Xin Jia,[1] and Xiaoping Liu,[1] Beijing, People's Republic of China

Background: To evaluate the safety and efficacy of chimney endovascular abdominal aortic repair (Ch-EVAR) for juxtarenal abdominal aortic aneurysm.
Methods: Electronic literature published between 2003 and 2014 were searched from MEDLINE and EMBASE online databases. Inclusion criteria for articles included that more than 3 patients were enrolled, chimney graft techniques were used, and the basic outcomes, such as indications, mortality within 30-day or during follow-up, complications, endoleaks, and branch vessel patency were collected. The data were pooled for analysis. Meta-analysis was performed using Stata version 11 and heterogeneity was estimated using Cochrane *Q* statistic and I^2 statistic.
Results: In total, 12 electronic literature met the inclusion criteria and 236 patients (mean age, 73.9 years) undergone Ch-EVAR were collected. A total of 335 chimney grafts were implanted, including 288 to the renal arteries and 47 to superior mesenteric arteries. Mortality (<30 days) and mortality (during follow-up; a mean of 12 months) were 3.8% (9/236) and 10.6% (25/236), respectively. The rate of type I, II and III endoleaks during follow-up was 11.8% (28/236), 8.1% (19/236), and 0.4% (1/236), respectively. The chimney graft patency at 6 month was 96.6%. Meta-analysis showed that the rates of endoleaks (during follow-up), mortality (<30 days) and mortality (during follow-up) were 18%, 7% and 13%, respectively.
Conclusions: Chimney graft is an efficient therapy with high initial technical success rate and favorable rates for perioperative outcomes.

- 2003 – 2014
- 236 patients, 12 studies, 12 months follow up
- ?? Number of vessels incorporated?
- 11.8% type I endoleak

Li et al, Ann Vasc Surg 2014

Parallel Grafts: The Evidence
Landing Zone is Important



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CLINICAL RESEARCH STUDIES

From the Society for Vascular Surgery

The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique

Konstantinos P. Donas, MD,[a,b] Giovanni B. Torsello, MD,[a,b] Gianluca Piccoli, MD,[c] Georgios A. Pitoulias, MD,[a,b,d] Giovanni Federico Torsello, MD,[c] Theodosios Bisdas, MD,[a,b] Martin Austermann, MD,[a,b] and Daniele Gasparini, MD,[c] *Münster, Germany; Udine, Italy; and Thessaloniki, Greece*

Objective: The chimney/snorkel endovascular aortic repair (ch-EVAR) is gaining ever-greater acceptance in the treatment of pararenal pathologic processes. However, the published experience includes mainly short-term clinical results with combinations of several abdominal devices and types of chimney grafts. The aim of this study was the midterm evaluation of the Endurant stent graft (Medtronic, Santa Rosa, Calif) as a standard abdominal device for ch-EVAR.

Methods: Between January 2009 and January 2013, prospectively collected data of high-risk patients with pararenal pathologic processes who underwent ch-EVAR with placement of the Endurant abdominal device were analyzed. The chimney graft intended for use was a balloon-expandable covered stent. Main outcome measures were aneurysm sac regression and chimney graft patency.

Results: A total of 187 snorkel/chimney grafts were successfully placed in 128 patients (mean age, 76.6 years). The technical success was 100%. The mean preoperative proximal neck length and aneurysm size were 4.7 mm and 64.8 mm (range, 48-135 mm), respectively. The postoperative new neck length after use of chimney grafts was 18.7 ± 6.3 mm. The mean aneurysm sac decreased significantly (60.8 mm; 95% confidence interval, 2.036-7.084; $P = .001$) after a mean radiologic follow up of 24.6 ± 17.4 months. Thirty-day mortality and midterm mortality were 0.8% and 17.2%, respectively. Two patients (1.6%) with single chimneys presented with late new onset of type Ia endoleak and underwent additional tube and multiple chimney placement. Primary chimney graft patency was 95.7%. Freedom from chimney graft-related reinterventions was 93.1%.

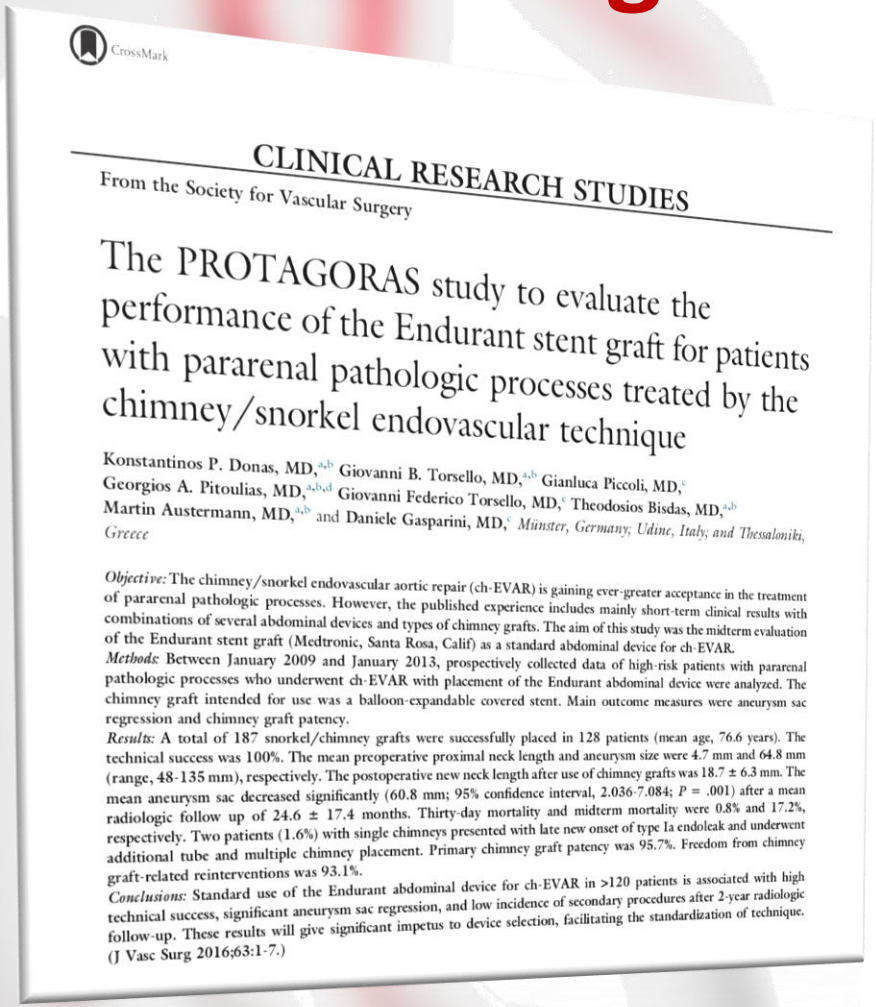
Conclusions: Standard use of the Endurant abdominal device for ch-EVAR in >120 patients is associated with high technical success, significant aneurysm sac regression, and low incidence of secondary procedures after 2-year radiologic follow-up. These results will give significant impetus to device selection, facilitating the standardization of technique.

(J Vasc Surg 2016;63:1-7.)

- 128 patients, 24 m f/u
- 64% only 1 chimney
- Pre op 64.8+/-14.6 mm (range, 48-135 mm), decreasing to 60.1+/-16.3 mm during follow-up.
- Type I endoleak 1.6% (2/128)

Donas et al, 2016

Parallel Grafts: The Evidence
Landing Zone Is Important



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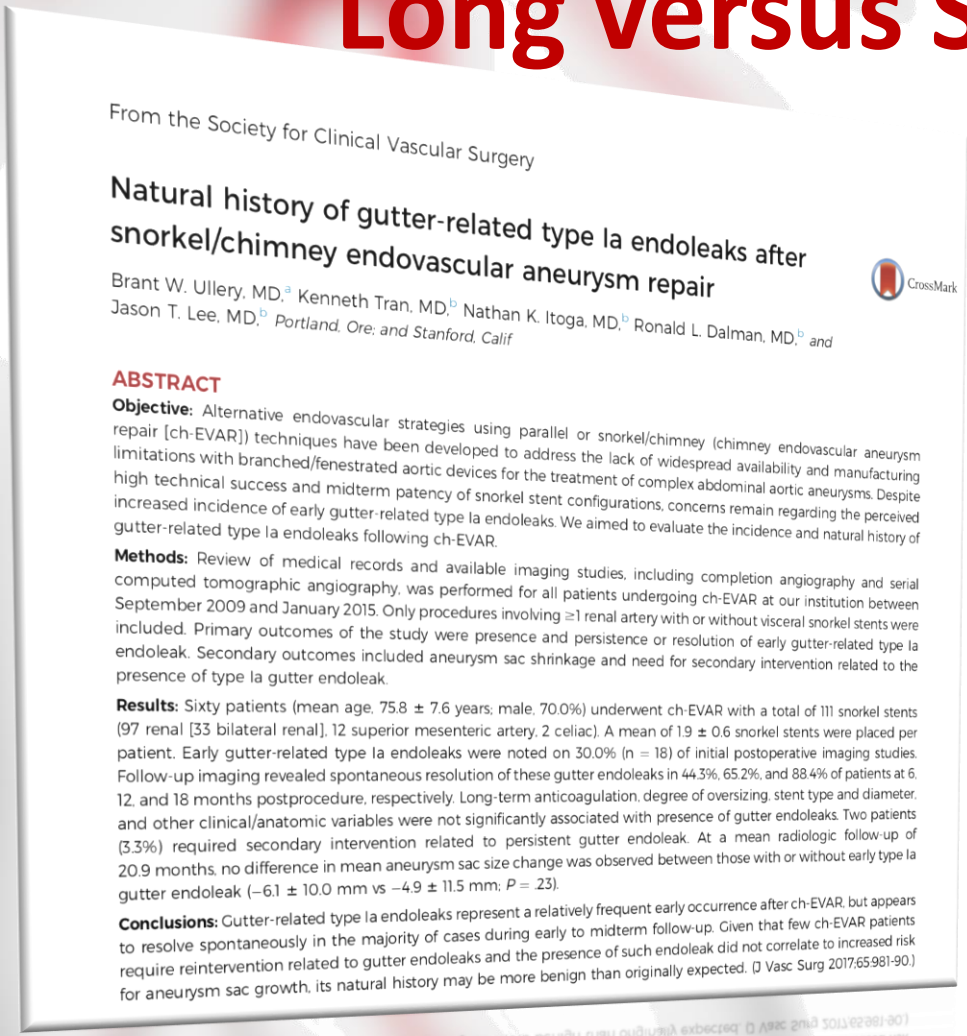
- 128 patients, 24 m f/u
- 64% only 1 chimney

- "It seems that creation of a proximal landing zone of >15 mm is sufficient to reduce the risk for late type Ia endoleak and the need for reintervention."

Donas et al, 2016

Parallel Grafts: The Evidence
Long versus Short Gutters



From the Society for Clinical Vascular Surgery

Natural history of gutter-related type Ia endoleaks after snorkel/chimney endovascular aneurysm repair

Brant W. Ullery, MD,[a] Kenneth Tran, MD,[b] Nathan K. Itoga, MD,[b] Ronald L. Dalman, MD,[b] and Jason T. Lee, MD,[b] *Portland, Ore; and Stanford, Calif*

ABSTRACT

Objective: Alternative endovascular strategies using parallel or snorkel/chimney (chimney endovascular aneurysm repair [ch-EVAR]) techniques have been developed to address the lack of widespread availability and manufacturing limitations with branched/fenestrated aortic devices for the treatment of complex abdominal aortic aneurysms. Despite high technical success and midterm patency of snorkel stent configurations, concerns remain regarding the perceived increased incidence of early gutter-related type Ia endoleaks. We aimed to evaluate the incidence and natural history of gutter-related type Ia endoleaks following ch-EVAR.

Methods: Review of medical records and available imaging studies, including completion angiography and serial computed tomographic angiography, was performed for all patients undergoing ch-EVAR at our institution between September 2009 and January 2015. Only procedures involving ≥1 renal artery with or without visceral snorkel stents were included. Primary outcomes of the study were presence and persistence or resolution of early gutter-related type Ia endoleak. Secondary outcomes included aneurysm sac shrinkage and need for secondary intervention related to the presence of type Ia gutter endoleak.

Results: Sixty patients (mean age, 75.8 ± 7.6 years; male, 70.0%) underwent ch-EVAR with a total of 111 snorkel stents (97 renal [33 bilateral renal], 12 superior mesenteric artery, 2 celiac). A mean of 1.9 ± 0.6 snorkel stents were placed per patient. Early gutter-related type Ia endoleaks were noted on 30.0% (n = 18) of initial postoperative imaging studies. Follow-up imaging revealed spontaneous resolution of these gutter endoleaks in 44.3%, 65.2%, and 88.4% of patients at 6, 12, and 18 months postprocedure, respectively. Long-term anticoagulation, degree of oversizing, stent type and diameter, and other clinical/anatomic variables were not significantly associated with presence of gutter endoleaks. Two patients (3.3%) required secondary intervention related to persistent gutter endoleak. At a mean radiologic follow-up of 20.9 months, no difference in mean aneurysm sac size change was observed between those with or without early type Ia gutter endoleak (−6.1 ± 10.0 mm vs −4.9 ± 11.5 mm; $P = .23$).

Conclusions: Gutter-related type Ia endoleaks represent a relatively frequent early occurrence after ch-EVAR, but appears to resolve spontaneously in the majority of cases during early to midterm follow-up. Given that few ch-EVAR patients require reintervention related to gutter endoleaks and the presence of such endoleak did not correlate to increased risk for aneurysm sac growth, its natural history may be more benign than originally expected. (J Vasc Surg 2017;65:981-90.)

- 66 patients, single centre
- 73% 2 vessels incorporated
- 21/60 = early type Ia endoleak on angio,
- 18/60.= Type Ia on CT scan

Ullery et al, JVS 2017

Parallel Grafts: The Evidence
Long versus Short Gutters

From the Society for Clinical Vascular Surgery

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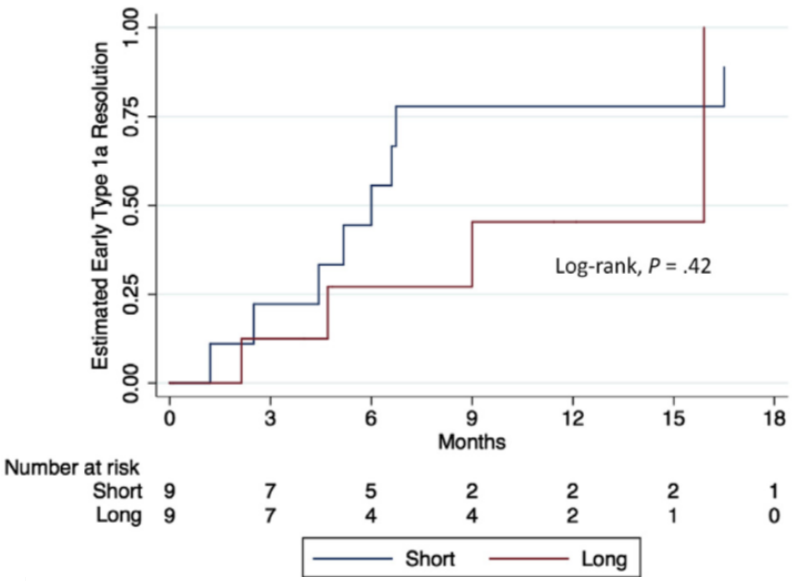
- Early ELs Resolved…



- Longer gutters less likely to resolve

Ullery et al, JVS 2017

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Parallel Grafts: The Evidence
Impact on Natural History

PAPERS OF THE 135TH ASA ANNUAL MEETING

Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of Complex Aortic Pathologies

The PERICLES Registry

Konstantinos P. Donas, MD, Jason T. Lee, MD,† Mario Lachat, MD,‡ Giovanni Torsello, MD, PhD,§ and Frank J. Veith, MD,¶ on behalf of the PERICLES investigators*

Objectives: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

Background: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

Methods: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

Results: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1–70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

Conclusions: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

Keywords: abdominal aortic aneurysm, endovascular, fenestrated, thoracoabdominal, vascular

(*Ann Surg* 2015;262:546–553)

The snorkel/chimney technique is an endovascular therapeutic modality for branch revascularization in complex aortic pathologies that has gained increasing popularity since the first publications in 2003 and 2007.[1,2] These techniques have emerged from the basic

- 517 Patients
- Multinational Study
- 17.1m follow up
- 7.9% Type 1a Endoleak

Donas et al, Ann Surg 2105

Parallel Grafts: The Evidence
Impact on Natural History

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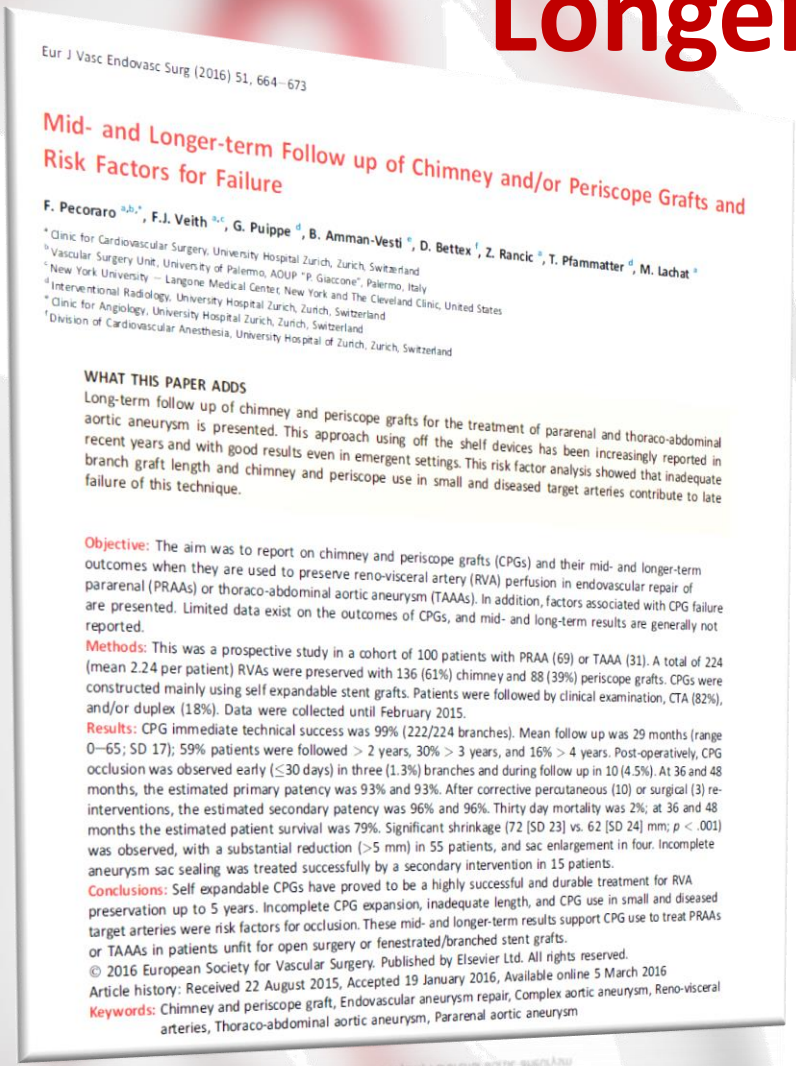
- 517 Patients
- Pre operative diameter 65.9 +/- 16.5
- Post operative diameter 61.2 ± 19.7 mm

Total chimney grafts, n	898
Right renal	342
Left renal	316
Accessory renal	34
SMA	156
Celiac	50

Donas et al, Ann Surg 2105

Parallel Grafts: The Evidence
Longer Follow UP



Eur J Vasc Endovasc Surg (2016) 51, 664–673

Mid- and Longer-term Follow up of Chimney and/or Periscope Grafts and Risk Factors for Failure

F. Pecoraro [a,b,*], F.J. Veith [a,c], G. Puippe [d], B. Amman-Vesti [e], D. Bettex [f], Z. Rancic [e], T. Pfammatter [d], M. Lachat [a]

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[b] Vascular Surgery Unit, University of Palermo, AOUP "P. Giaccone", Palermo, Italy
[c] New York University – Langone Medical Center, New York and The Cleveland Clinic, United States
[d] Interventional Radiology, University Hospital Zurich, Zurich, Switzerland
[e] Clinic for Angiology, University Hospital Zurich, Zurich, Switzerland
[f] Division of Cardiovascular Anesthesia, University Hospital of Zurich, Zurich, Switzerland

WHAT THIS PAPER ADDS

Long-term follow up of chimney and periscope grafts for the treatment of pararenal and thoraco-abdominal aortic aneurysm is presented. This approach using off the shelf devices has been increasingly reported in recent years and with good results even in emergent settings. This risk factor analysis showed that inadequate branch graft length and chimney and periscope use in small and diseased target arteries contribute to late failure of this technique.

Objective: The aim was to report on chimney and periscope grafts (CPGs) and their mid- and longer-term outcomes when they are used to preserve reno-visceral artery (RVA) perfusion in endovascular repair of pararenal (PRAAs) or thoraco-abdominal aortic aneurysm (TAAAs). In addition, factors associated with CPG failure are presented. Limited data exist on the outcomes of CPGs, and mid- and long-term results are generally not reported.

Methods: This was a prospective study in a cohort of 100 patients with PRAA (69) or TAAA (31). A total of 224 (mean 2.24 per patient) RVAs were preserved with 136 (61%) chimney and 88 (39%) periscope grafts. CPGs were constructed mainly using self expandable stent grafts. Patients were followed by clinical examination, CTA (82%), and/or duplex (18%). Data were collected until February 2015.

Results: CPG immediate technical success was 99% (222/224 branches). Mean follow up was 29 months (range 0–65; SD 17); 59% patients were followed > 2 years, 30% > 3 years, and 16% > 4 years. Post-operatively, CPG occlusion was observed early (≤30 days) in three (1.3%) branches and during follow up in 10 (4.5%). At 36 and 48 months, the estimated primary patency was 93% and 93%. After corrective percutaneous (10) or surgical (3) re-interventions, the estimated secondary patency was 96% and 96%. Thirty day mortality was 2%; at 36 and 48 months the estimated patient survival was 79%. Significant shrinkage (72 [SD 23] vs. 62 [SD 24] mm; $p < .001$) was observed, with a substantial reduction (>5 mm) in 55 patients, and sac enlargement in four. Incomplete aneurysm sac sealing was treated successfully by a secondary intervention in 15 patients.

Conclusions: Self expandable CPGs have proved to be a highly successful and durable treatment for RVA preservation up to 5 years. Incomplete CPG expansion, inadequate length, and CPG use in small and diseased target arteries were risk factors for occlusion. These mid- and longer-term results support CPG use to treat PRAAs or TAAAs in patients unfit for open surgery or fenestrated/branched stent grafts.

Article history: Received 22 August 2015, Accepted 19 January 2016, Available online 5 March 2016
Keywords: Chimney and periscope graft, Endovascular aneurysm repair, Complex aortic aneurysm, Reno-visceral arteries, Thoraco-abdominal aortic aneurysm, Pararenal aortic aneurysm

- 224 Patients
- 29 months f/u (16%>4 years)

Number of CPG	1	21
	2	47
	3	19
	4	13

- 56% had reduction in diameter over f/u

Pecaro et al, 2016

Royal Free London NHS
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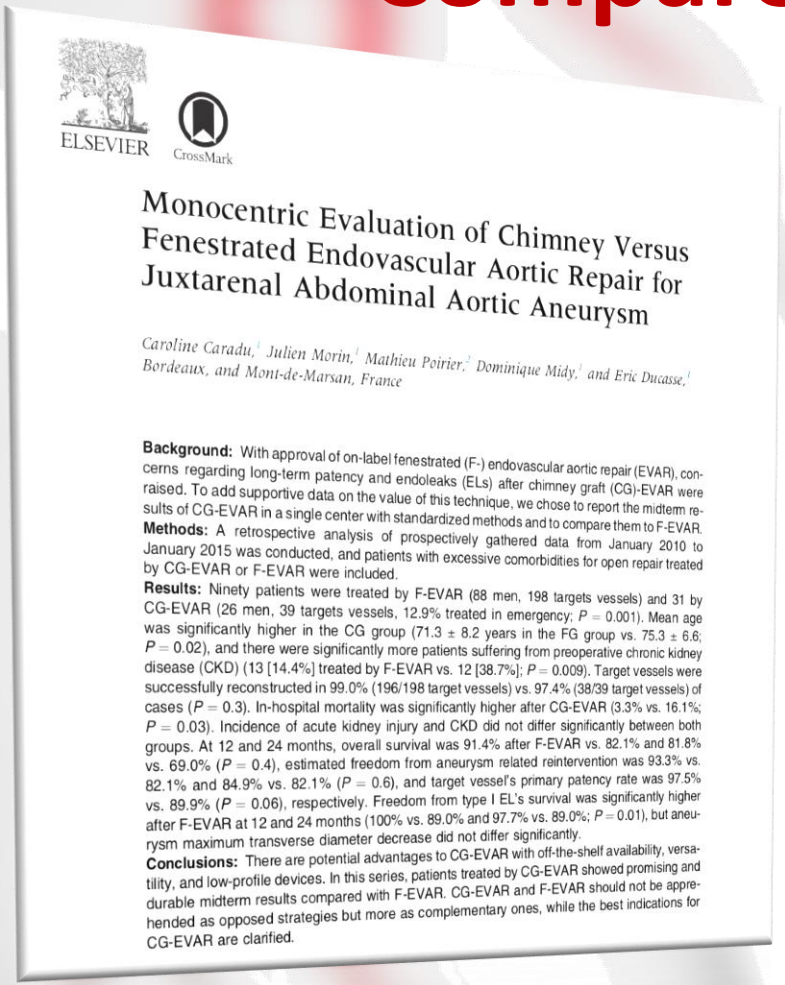
Parallel Grafts: The Evidence
Compared with FEVAR



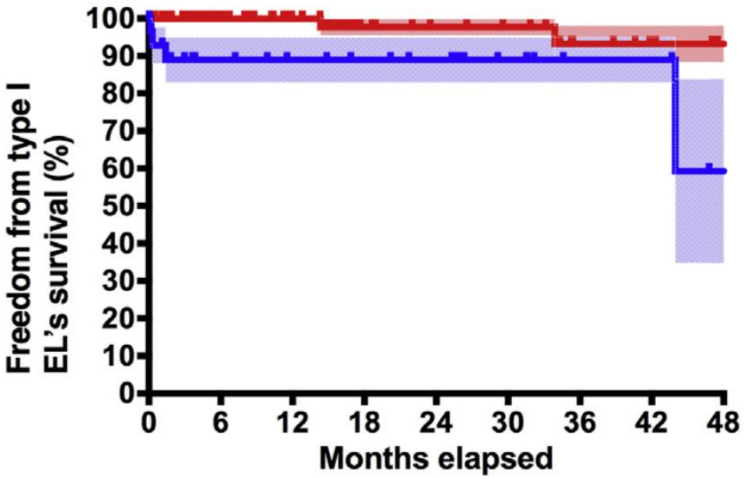
ELSEVIER CrossMark

Monocentric Evaluation of Chimney Versus Fenestrated Endovascular Aortic Repair for Juxtarenal Abdominal Aortic Aneurysm

Caroline Caradu,[1] Julien Morin,[1] Mathieu Poirier,[1] Dominique Midy,[1] and Eric Ducasse,[1] Bordeaux, and Mont-de-Marsan, France

Background: With approval of on-label fenestrated (F-) endovascular aortic repair (EVAR), concerns regarding long-term patency and endoleaks (ELs) after chimney graft (CG)-EVAR were raised. To add supportive data on the value of this technique, we chose to report the midterm results of CG-EVAR in a single center with standardized methods and to compare them to F-EVAR.
Methods: A retrospective analysis of prospectively gathered data from January 2010 to January 2015 was conducted, and patients with excessive comorbidities for open repair treated by CG-EVAR or F-EVAR were included.
Results: Ninety patients were treated by F-EVAR (88 men, 198 targets vessels) and 31 by CG-EVAR (26 men, 39 targets vessels, 12.9% treated in emergency; $P = 0.001$). Mean age was significantly higher in the CG group (71.3 ± 8.2 years in the FG group vs. 75.3 ± 6.6; $P = 0.02$), and there were significantly more patients suffering from preoperative chronic kidney disease (CKD) (13 [14.4%] treated by F-EVAR vs. 12 [38.7%]; $P = 0.009$). Target vessels were successfully reconstructed in 99.0% (196/198 target vessels) vs. 97.4% (38/39 target vessels) of cases ($P = 0.3$). In-hospital mortality was significantly higher after CG-EVAR (3.3% vs. 16.1%; $P = 0.03$). Incidence of acute kidney injury and CKD did not differ significantly between both groups. At 12 and 24 months, overall survival was 91.4% after F-EVAR vs. 82.1% and 81.8% vs. 69.0% ($P = 0.4$), estimated freedom from aneurysm related reintervention was 93.3% vs. 82.1% and 84.9% vs. 82.1% ($P = 0.6$), and target vessel's primary patency rate was 97.5% vs. 89.9% ($P = 0.06$), respectively. Freedom from type I EL's survival was significantly higher after F-EVAR at 12 and 24 months (100% vs. 89.0% and 97.7% vs. 89.0%; $P = 0.01$), but aneurysm maximum transverse diameter decrease did not differ significantly.
Conclusions: There are potential advantages to CG-EVAR with off-the-shelf availability, versatility, and low-profile devices. In this series, patients treated by CG-EVAR showed promising and durable midterm results compared with F-EVAR. CG-EVAR and F-EVAR should not be apprehended as opposed strategies but more as complementary ones, while the best indications for CG-EVAR are clarified.

- 90 FEVAR vs 31 Chimney
- 19m f/u



F-EVAR									
# at risk	90	61	48	32	28	25	19	16	13
% survival	100.0	100.0	100.0	97.7	97.7	97.7	93.3	93.3	93.3
CG-EVAR									
# at risk	30	20	17	15	13	9	5	5	2
% survival	96.6	89.0	89.0	89.0	89.0	89.0	89.0	89.0	59.3

Caradu et al, Ann Vasc Surg 2017

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- 90 FEVAR vs 31 Chimney

"A significant reduction in aneurysm maximum transverse diameter was observed between preoperative and last CTA in 51 (67.1%) vs. 16 patients (69.6%)"

Caradu et al, Ann Vasc Surg 2017

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Despite their convenience and improving outcomes over the years, Parallel grafts are NOT superior to FEVAR

Parallel Grafts: The Alternative

PMEG versus FEVAR

From the Society for Vascular Surgery

Fenestrated endovascular aortic aneurysm repair using physician-modified endovascular grafts versus company-manufactured devices

Shernaz S. Dossabhoy, MS, MBA, Jessica P. Simons, MD, MPH, Julie M. Flahive, MS, Francesco A. Aiello, MD, Parth Sheth, MD, Edward J. Arous, MD, Louis M. Messina, MD, *and* Andres Schanzer, MD, *Worcester, Mass*

ABSTRACT

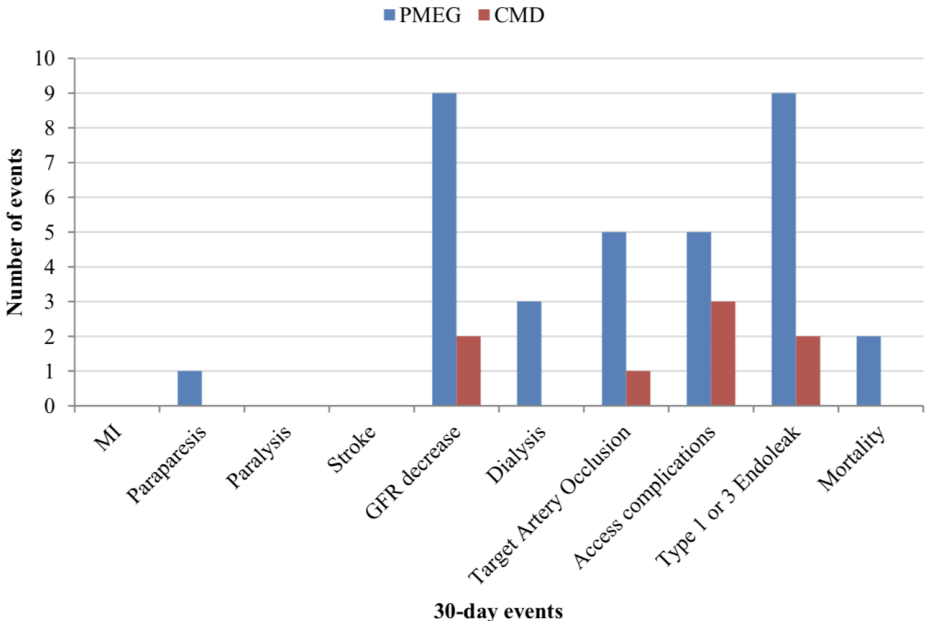
Objective: Fenestrated endografts are customized, patient-specific endovascular devices with potential to reduce morbidity and mortality of complex aortic aneurysm repair. With approval from the U.S. Food and Drug Administration, our center began performing fenestrated endovascular aneurysm repair through a physician-sponsored investigational device exemption (IDE #G130210), using both physician-modified endografts (PMEGs) and company-manufactured devices (CMDs). Because these techniques are associated with specific advantages and disadvantages, we sought to investigate differences in outcomes between PMEG and CMD cases.

Methods: A single-institution retrospective review of all fenestrated endovascular aneurysm repairs was performed. The cohort was analyzed by device type (PMEG or CMD) after matching of cases on the basis of (1) number of target vessels intended for treatment, (2) extent of aneurysm, (3) aneurysm diameter, (4) device configuration, and (5) date of operation. Outcomes of ruptures, common iliac artery aneurysms, and aortic arch aneurysms were excluded. Demographics, operative details, perioperative complications, length of stay, and reinterventions were compared. For patients with >1 year of follow-up time, survival, type I or type III endoleak rate, target artery patency, and reintervention rate were estimated using the Kaplan-Meier method.

Results: Between November 30, 2010, and July 30, 2016, 82 patients were identified and matched. The cohort included 41 PMEG and 41 CMD patients who underwent repair of 38 juxtarenal (PMEG, 17; CMD, 21; $P = .38$), 14 pararenal (PMEG, 6; CMD, 8; $P = .56$), and 30 thoracoabdominal type I to type IV (PMEG, 18; CMD, 12; $P = .17$) aneurysms. There were significant differences in presentation requiring urgent aneurysm repair (PMEG, 9; CMD, 0; $P = .002$), total fluoroscopy time (PMEG, 76 minutes; CMD, 61 minutes; $P = .02$), volume of contrast material used (PMEG, 88 mL; CMD, 70 mL; $P = .02$), in-operating room to out-of-operating room time (PMEG, 391 minutes; CMD, 319 minutes; $P = .001$), incision to surgery end time (PMEG, 276 minutes; CMD, 224 minutes; $P = .002$), and 1-year reintervention rate (PMEG, 37%; CMD, 13%; log-rank $P = .04$). No differences in perioperative complications, overall length of stay, type I or type III endoleak, or survival were observed between PMEG and CMD. For the entire cohort including both PMEG and CMD, the overall rate of any 30-day post-operative complication was 39%, and the Kaplan-Meier estimate of survival at 1 year was 86%.

Conclusions: In this single-institution experience of fenestrated endovascular aneurysm repair, the primary differences between PMEG and CMD related only to operative metrics and the need for postoperative reinterventions. No statistically significant advantage was found for one approach over the other; we therefore cannot conclude that one approach is better than the other. Both remain viable options that may compare favorably with open repair of complex aortic aneurysms. Further studies are necessary to determine whether this relative equivalence represents a type II error or lack of long-term durability data or whether true equivalence between PMEG and CMD approaches exists. (J Vasc Surg 2017;■:1-11.)

- 41 PMEG v 41 CMD



Dossabhoy et al, JVS 2017

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Parallel Grafts: The Alternative

PMEG versus FEVAR

From the Society for Vascular Surgery

Fenestrated endovascular aortic aneurysm repair using physician-modified endovascular grafts versus company-manufactured devices

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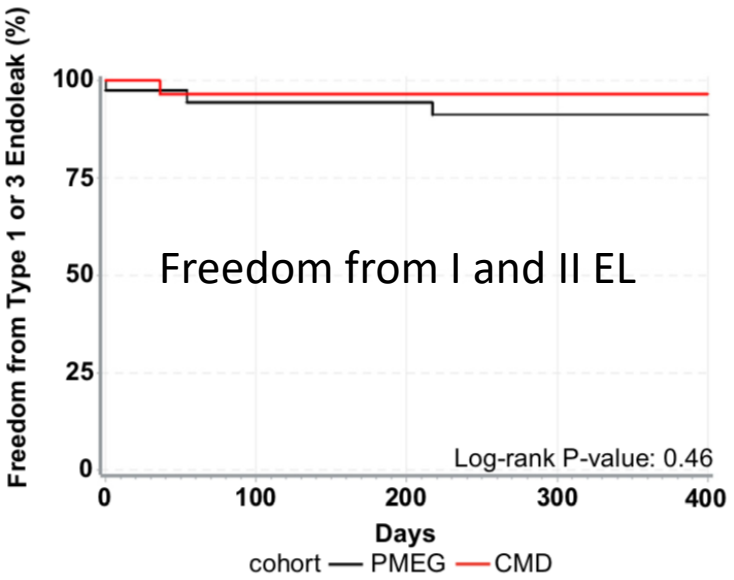
- 41 PMEG v 41 CMD



Days:	0	100	200	300	400
CMD # at risk:	41	24	15	12	10
CMD SE:	0	0.034	0.034	0.034	0.034
PMEG # at risk:	41	30	29	28	20
PMEG SE:	0	0.038	0.038	0.049	0.049

Dossabhoy et al, JVS 2017

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Parallel Grafts: The Alternative

Long Term PMEG

CLINICAL RESEARCH STUDIES

From the Western Vascular Society

Midterm results from a physician-sponsored investigational device exemption clinical trial evaluating physician-modified endovascular grafts for the treatment of juxtarenal aortic aneurysms

Benjamin W. Starnes, MD, Rachel E. Heneghan, MD, *and* Billi Tatum, RN, *Seattle, Wash*

ABSTRACT

Objective: The objective of this study was to report midterm results of an ongoing physician-sponsored investigational device exemption pivotal clinical trial using physician-modified endovascular grafts (PMEGs) for treatment of patients with juxtarenal aortic aneurysms who are deemed unfit for open repair.

Methods: Data from a nonrandomized, prospective, consecutively enrolling investigational device exemption clinical trial were used. Data collection began on April 1, 2011, and data lock occurred on May 31, 2015, with outcomes analysis through December 31, 2015. Primary safety and efficacy end points were used to measure treatment success. The primary safety end point was defined as the proportion of subjects who experienced a major adverse event within 30 days of the procedure. The primary efficacy end point was the proportion of subjects who achieved treatment success. Treatment success required the following at 12 months: technical success, defined as successful delivery and deployment of a PMEG with preservation of those branch vessels intended to be preserved; and freedom from type I and III endoleak, stent graft migration >10 mm, aortic aneurysm sack enlargement >5 mm, and aortic aneurysm rupture or open conversion.

Results: During the 50-month study period, 64 patients were enrolled; 60 began the implant procedure and 59 received the PMEG implant. Aneurysm anatomy, operative details, and lengths of stay were recorded and included aneurysm diameter (mean, 65.9 mm; range, 49-104 mm), proximal seal zone length (mean, 40.8 mm; range, 18.9-72.2 mm), graft manufacture time (mean, 55.1 minutes), procedure time (mean, 156.8 minutes), fluoroscopy time (mean, 39.6 minutes), contrast material use (mean, 75.3 mL), estimated blood loss (mean, 213 mL), and length of hospital stay (mean, 4.1 days) with intensive care unit length of stay (mean, 2.2 days). There were 145 fenestrations made for 110 renal arteries and 38 superior mesenteric arteries (SMAs). One patient had an SMA stent placed before the procedure for severe stenosis, and one subject had the SMA stented during the procedure. Renal arteries were stented whenever possible (93%). There were 102 stented renal arteries in 58 patients. There were no open conversions or explantations. Thirty-day mortality was 5.1% (3/59). There were zero type Ia, one type Ib, and two type III endoleaks during follow-up treated with successful reintervention. The overall rate of major adverse events at 30 days was 11.9%. The primary efficacy end points were achieved in 94.1% of patients.

Conclusions: These midterm results are favorable and verify our early report that endovascular repair with PMEG is safe and effective for managing patients with juxtarenal aortic aneurysms. PMEG has exceptional midterm rates of morbidity, mortality, and endoleak and may outperform standard endovascular aneurysm repair with favorable anatomy. In patients who are poor open surgical candidates who present with symptomatic or ruptured juxtarenal aortic aneurysms, PMEG continues to be an extremely appealing option as reliable off-the-shelf solutions are not widely available. Preoperative planning remains the key ingredient for success with use of these techniques. (J Vasc Surg 2017;65:294-302.)

- 64 patients
- 27 month f/u
- 0 Type 1a endoleak
- 3 patients with ‘sac enlargement’

Starnes et al, JVS 2017

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FEVAR is Definitely Superior to Parallel Grafts

- Fewer early endoleaks
- Fewer late endoleaks
- Longer evidence of follow up
- Feasibility to incorporate more vessels

- (better target vessel patency)

FEVAR is Definitely Superior to Parallel Grafts

- But in the context of manufacturing delay, the big question is… which alternative is acceptable?
  - Chimney?
  - Home-made FEVAR?
  - Laser-in situ FEVAR?

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