CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE

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CHU Hôpitaux de Bordeaux

FEVAR

FIFTEEN YEARS OF EFFICIENCY

E.DUCASSE

MD PHD FEBVS

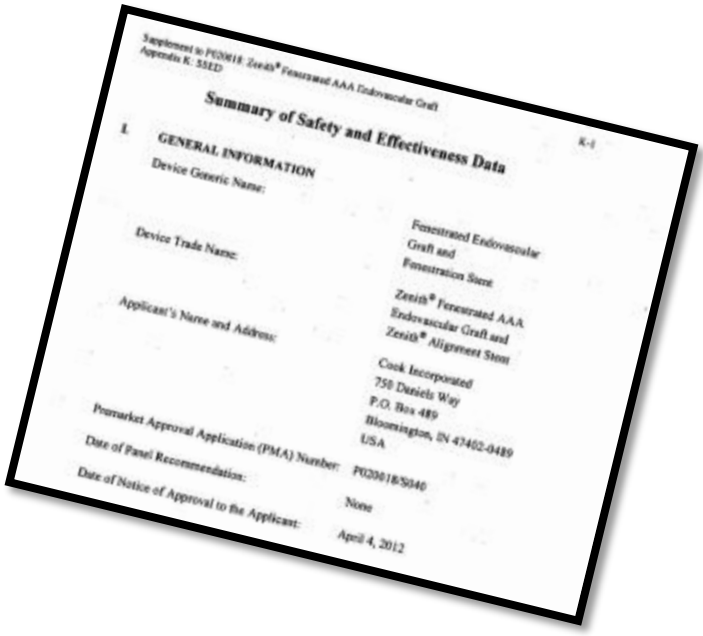
CHU DE BORDEAUX

2018

GETINGE ✱ Symposium
Importance of durable ancillary products in complex endovascular procedures
Moderator: Jean Paul de Vries
FEVAR fifteen years of efficiency, Eric Ducasse
What are the latest findings after the PERICLES Registry about CHEVAR, Konstantinos Donas

CX Great Debate
"FEVAR is best for juxtarenal aneurysmal repair"
AGAINST the motion
co-speakers : Eric Ducasse, Konstantinos Donas

A BIT OF HISTORY


Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION

Device Generic Name: Fenestrated Endovascular Graft and Fenestration Stent

Device Trade Name: Zenith® Fenestrated AAA Endovascular Graft and Zenith® Alignment Stent

Applicant's Name and Address: Cook Incorporated, 750 Daniels Way, P.O. Box 489, Bloomington, IN 47402-0489 USA

Premarket Approval Application (PMA) Number: P020018/S040

Date of Panel Recommendation: None

Date of Notice of Approval to the Applicant: April 4, 2012

- **First use of F-EVAR : 1990s**
  - Park et al. J Vasc Interv Radiol. 1996;7:819-823.
  - Faruqi et al. J Endovasc Surg. 1999;6:354-358.
  - Browne et al. Eur J Vasc Endovasc Surg. 1999;18:445-449.
  - Kinney et al. J Endovasc Ther. 2000;7:192-197.
- **First series of patients from Australia : 2001**
  - Anderson et al. J Endovasc Ther. 2001;8:3-15.
- **Early experience in the US with physician-sponsored (PS)-IDE trials : 2005**
  - Much of procedural protocols, device enhancements, and understanding of device and repair durability have arisen from these assessments
  - **Roy Greenberg and the Cleveland Clinic**
    - First fenestrated endograft : 2001
      - more rudimentary than those employed in the US ZFEN clinical trial, as they lacked reinforced fenestrations
    - First report : 2004 (**22** patients)
      - Greenberg et al. J Vasc Surg. 2004;39:279-287.
    - Second report : 2006 (**119** patients, 302 renal and visceral vessels)
      - O'Neill et al. Eur J Vasc Endovasc Surg. 2006;32:115-123.
- **April 2012 : FDA approval of the ZFEN system (Cook Medical) in the US** for short infrarenal necks (4–14 mm)

- **Long-term results : 2015** (**607** patients with a mean follow-up of 8 years)
  - Mastracci et al. Twelve-year results. J Vasc Surg. 2015;61:355-364.

MAIN RESULTS : *VS OSR*

Eur J Vasc Endovasc Surg. 2009 Jul;38(1):35-41. doi: 10.1016/j.ejvs.2009.02.012. Epub 2009 Apr 5.

Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair--a systematic review.

Nordon IM[1], Hinchliffe RJ, Holt PJ, Loftus IM, Thompson MM.

No randomised studies were identified

F-EVAR

8 cohort studies
368 patients

OSR

12 cohort studies
1164 patients

OSR vs F-EVAR	P value	RR
30-day mortality ↗ 2%	0.02	1.03 (95%CI: 1.01-1.04)
Postoperative permanent dialysis	1	1.00 (95%CI:
Transient renal failure ↗	0.03	1.06 (95%CI:
Early reintervention ↘	0.0001	0.87 (95%CI:

BUT

Table 1 Grouped preoperative demographics and co-morbidities in open and f-EVR cohorts (where data available).

	f-EVR	Open	Sig
Gender (F/M)	51/300	200/881	0.09
Age (yr (±SD))	71.8(±2.4)	73.8(±1.9)	0.0001
Ischaemic heart disease	55%	58%	0.35
Renal disease	24%	22%	0.5

MAIN RESULTS : *VS OSR*

J Vasc Surg. 2014 Oct;60(4):858-63; discussion 863-4. doi: 10.1016/j.jvs.2014.04.011. Epub 2014 May 15.

A propensity-matched comparison of outcomes for fenestrated endovascular aneurysm repair and open surgical repair of complex abdominal aortic aneurysms.

Raux M[1], Patel VI[2], Cochennec F[3], Mukhopadhyay S[4], Desgranges P[3], Cambria RP[4], Becquemin JP[3], LaMuraglia GM[4].

Table I. Clinical and demographic features

	Unmatched cohort		
Variable	*FEVAR (n = 55)*	*OSR (n = 319)*	P
Age, mean ± SD, years	73 ± 9.3	74 ± 8.0	.8
Male sex, %	91	70	.001
History of aneurysm, %	7.3	5.3	[illegible]
Hypertension, %	65	90	<.0001
MI, %	35	34	.9
CHF, %	24	7.5	.0002
CAD, %	56	23	<.0001
COPD, %	44	24	.003
CVA, %	11	7.9	.1
Diabetes, %	22	11	.02
Smoking, %	60	78	.005
CRI, %	24	19	.5
Clamp, %			
Suprarenal	53	76	.0003
Supravisceral	47	24	.0003

OSR and F-EVAR

are offered to **different population targets**

*may be secondary to the selection bias of **F-EVAR** being offered to **high-risk** patients?*

MAIN RESULTS : *VS OSR*

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Table I. Clinical and demographic features

	Unmatched cohort			*Propensity-matched cohort*		
Variable	*FEVAR (n = 55)*	*OSR (n = 319)*	P	*FEVAR (n = 42)*	*OSR (n = 147)*	P
Age, mean ± SD, years	73 ± 9.3	74 ± 8.0	.8	73 ± 10	73 ± 7.8	.8
Male sex, %	91	70	.001	88	82	.4
History of aneurysm, %	7.3	5.3	.2	4.8	5.4	.3
Hypertension, %	65	90	<.0001	74	80	.4
MI, %	35	34	.9	26	36	.2
CHF, %	24	7.5	.0002	14	12	.6
CAD, %	56	23	<.0001	43	34	.3
COPD, %	44	24	.003	36	25	.2
CVA, %	11	7.9	.1	7.1	7.5	.3
Diabetes, %	22	11	.02	19	14	.5
Smoking, %	60	78	.005	67	71	.6
CRI, %	24	19	.5	26	20	.4
Clamp, %						
Suprarenal	53	76	.0003	57	63	.5
Supravisceral	47	24	.0003	43	37	.5

CAD, Coronary artery disease; *CHF*, congestive heart failure; *COPD*, chronic obstructive pulmonary disease; *CRI*, chronic renal insufficiency; *CVA*, cerebrovascular accident; *FEVAR*, fenestrated endovascular aneurysm repair; *MI*, myocardial infarction; *OSR*, open surgical repair; *SD*, standard deviation.

Circulation. 2012 Jun 5;125(22):2707-15. doi: 10.1161/CIRCULATIONAHA.111.070334.

Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom.

British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry[1].

GLOBALSTAR
F-EVAR

UK Multicentric study (14)
Retrospective
January 2007-December 2010
318 patients

Table 3. Target Vessels

S

CA

SMA

89 (670)

callop;

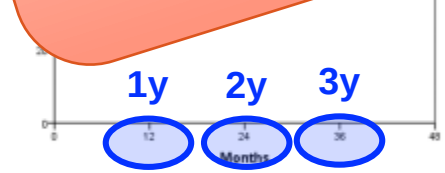
right;

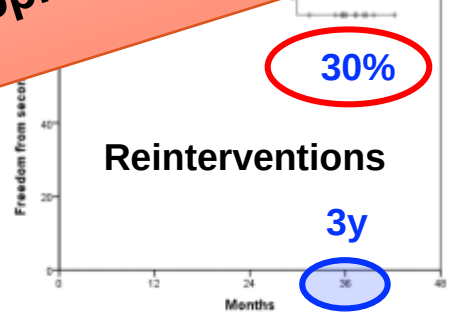
Median FU : 6 m

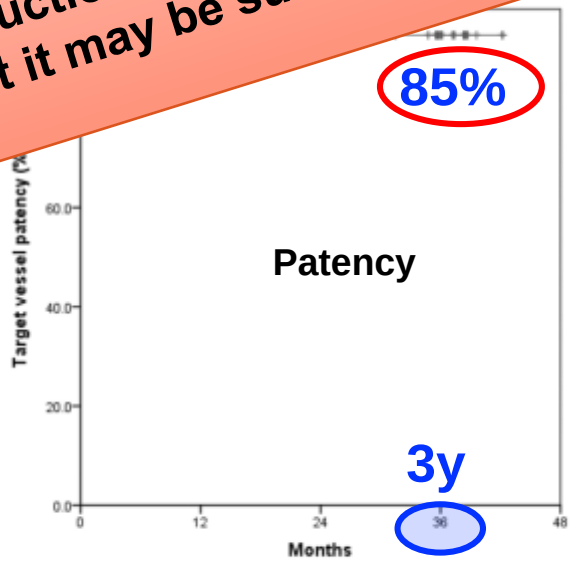
Tech

Using V-POSSUM Scoring System and Predicted Risk of Open Repair
27 perioperative deaths **(11%)** were estimated for open repair in the cohort that underwent F-EVAR

This study has estimated the potential risk reduction associated with an endovascular approach and suggests that it may be substantial







Eur J Vasc Endovasc Surg. 2010 May;39(5):537-44. doi: 10.1016/j.ejvs.2009.12.008. Epub 2010 Jan 25.

Fenestrated endovascular grafting: the French multicentre experience.

Amiot S[1], Haulon S, Becquemin JP, Magnan PE, Lermusiaux P, Goueffic Y, Jean-Baptiste E, Cochennec F, Favre JP; Association Universitaire de Recherche en Chirurgie Vasculaire.

F-EVAR
French Multicenter Restrospective

May 2004-January 2009
134 patients

403 visceral vessels

Patency 97%

Target vessel occlusion during follow-up.

	Vessel occluded	Preoperative stenosis	Stent fracture	Secondary proced…	…ve	Post-occlusion GFR
1	Right renal artery	Yes				57
2	Left renal artery					69
3	Left renal					2

Median FU : 15 months	F-EVAR
1 intraoperative conversion to OSR	
30-day mortality	
Re…	

…its had sac enlargement
…ciated with a persistent EL

	F-EVAR
Transient Dialysis	3% (4)
Permanent Dialysis	1% (2)

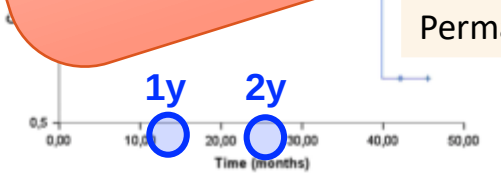


Table 4 Secondary interventions during follow-up.

Complication diagnosed	Secondary intervention (*n*)
Type IA endoleak	Chimney SMA covered stent + aortic cuff (1)
Type IB endoleak	Palmaz stent implantation (1)
Type II endoleak	Embolisation (2)
Type III endoleak	Covered renal stent (1)
Type III endoleak	Aortic cuff (1)
Renal stent fracture	Renal artery stenting (4)
Renal stent fracture	Hepato-renal bypass (1)
Ilio-femoral bypass proximal stenosis	Angioplasty (1)

F-EVAR is safe and effective in preventing rupture in the mid-term

A predictable high mortality rate was depicted during FU in this high-risk cohort

Meticulous FU to assess sac behaviour and visceral ostia is critical to ensure optimal results

Eur J Vasc Endovasc Surg. 2010 May;39(5):529-36. doi: 10.1016/j.ejvs.2010.01.004. Epub 2010 Mar 3.

Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience.

Verhoeven EL[1], Vourliotakis G, Bos WT, Tielliu IF, Zeebregts CJ, Prins TR, Bracale UM, van den Dungen JJ.

F-EVAR IDE protocole
Retrospective study
In a tertiary referral centre

November 2001-April 2009
100 patients

Median FU : 24 mont

Technical

F-EVAR for short-necked and JRAs demonstrates promising results in the **mid-term**

Renal function deterioration is a concern in a substantial number of patients

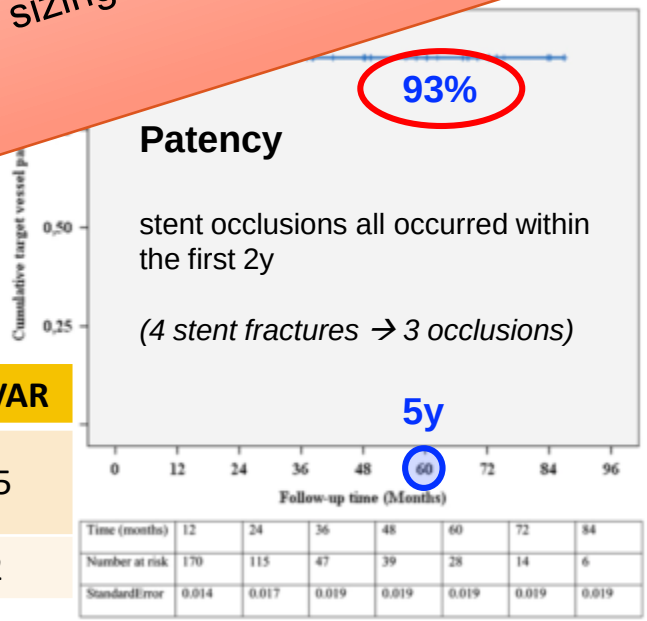
To allow widespread application of the technique, continuous efforts must be placed in **training new centres** on patient selection, device sizing and the development of new materials and techniques

Table 2 Distribution of vessels incorp… the fenestrated stent graft and type …

Target vessel Type …

Time (months)	12	24	36	48	60	72
Number at risk	73	50	28	19	14	7
Standard Error	0.031	0.040	0.057	0.070	0.081	0.100

	F-EVAR
↗ serum creat. clear. >30%	25
Dialysis	2



Time (months)	12	24	36	48	60	72	84
Number at risk	170	115	47	39	28	14	6
StandardError	0.014	0.017	0.019	0.019	0.019	0.019	0.019

J Vasc Surg. 2014 Dec;60(6):1420-8.e1-5. doi: 10.1016/j.jvs.2014.08.061. Epub 2014 Sep 5.

Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms.

Oderich GS[1], Greenberg RK[2], Farber M[3], Lyden S[2], Sanchez L[4], Fairman R[5], Jia F[6], Bharadwaj P[6]; Zenith Fenestrated Study Investigators.

F-EVAR
US Multicenter (14) Prospective

2005-2012
67 patients

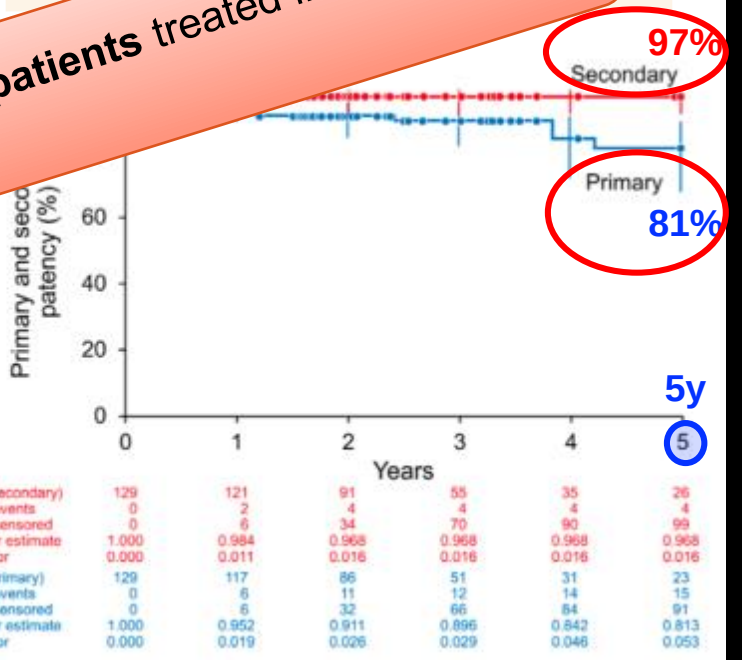
178 visceral vessels

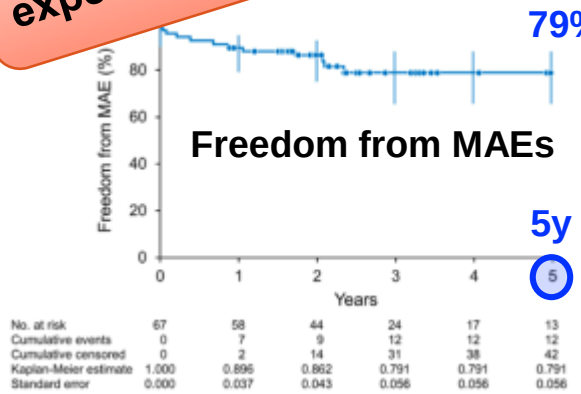
Patency

	F-EVAR
Occlusion	
Stenosi	

Mean FU : 37 months	F-EVAR
Technical success	100%
30-day mortality	
Migration >10mm	
Reinte	22% (15)

Mortality and morbidity are low in properly selected patients treated in **centers with experience** in these procedures





Freedom from MAEs

Survival 91%
No rupture

Freedom from AKI **100%**
Despite **10%** of radiographic evidence of renal embolization

J Vasc Surg. 2015 Feb;61(2):355-64. doi: 10.1016/j.jvs.2014.09.068.

Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms.

Mastracci TM[1], Eagleton MJ[2], Kuramochi Y[2], Bathurst S[2], Wolski K[2].

607 patients

Table I. Outcome through the entire follow-up period according to device design

Variables	*Supraceliac (n = 58), No. (%)*	*Celiac scallop (n = 190), No. (%)*	*SMA or lower (n = 282), No. (%)*	*Renal or lower (n = 77), No. (%)*	P *value*
Classification					
Group IV	57 (98.3)	187 (98.4)	96 (34.0)	9 (11.7)	<.001
Juxtarenal	1 (1.7)	3 (1.6)	186 (66.0)	68 (88.3)	
Additional procedures	16 (27.6)	47 (24.7)	74 (26.2)	21 (27.3)	.96
Additional procedures					
None	42 (72.4)	143 (75.3)	208 (73.8)	56 (72.7)	
1	14 (24.1)	34 (17.9)	53 (18.8)	16 (20.8)	
2	0 (0.0)	10 (5.3)	18 (6.4)	2 (2.6)	
≥3	2 (3.4)	3 (1.6)	3 (1.1)	3 (3.9)	
Patients with endoleak					
Type I	2 (3.4)	2 (1.1)	6 (2.1)	8 (10.4)	.002
Type II	10 (20.0)	32 (18.5)	43 (16.4)	12 (16.0)	.88
Type III	5 (10.0)	9 (5.2)	7 (2.7)	7 (9.3)	.03
Type IV	0 (0.0)	0 (0.0)	2 (0.8)	1 (1.3)	.44
Unknown type	3 (6.0)	0 (0.0)	4 (1.5)	2 (2.7)	.02
Occlusion during follow-up	12 (23.5)	14 (8.0)	21 (7.9)	4 (5.3)	.002
Left renal	0 (0.0)	5 (2.9)	10 (3.9)	1 (1.4)	.56
Right renal	0 (0.0)	2 (1.2)	8 (3.0)	3 (4.2)	.29
SMA	0 (0.0)	3 (1.7)	3 (1.1)	0 (0.0)	.85
Celiac	2 (3.4)	3 (1.6)	0 (0)	0 (0)	.02
Stent fracture	0 (0.0)	3 (1.6)	8 (3.0)	3 (4.1)	.44
Component separation	1 (1.9)	1 (0.5)	2 (0.8)	3 (4.2)	.08
Aneurysm growth	3 (5.2)	4 (2.1)	13 (4.6)	2 (2.6)	.42
Stent migration	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	.22
Rupture	3 (5.2)	2 (1.1)	8 (2.8)	1 (1.3)	.22

SMA, Superior mesenteric artery.

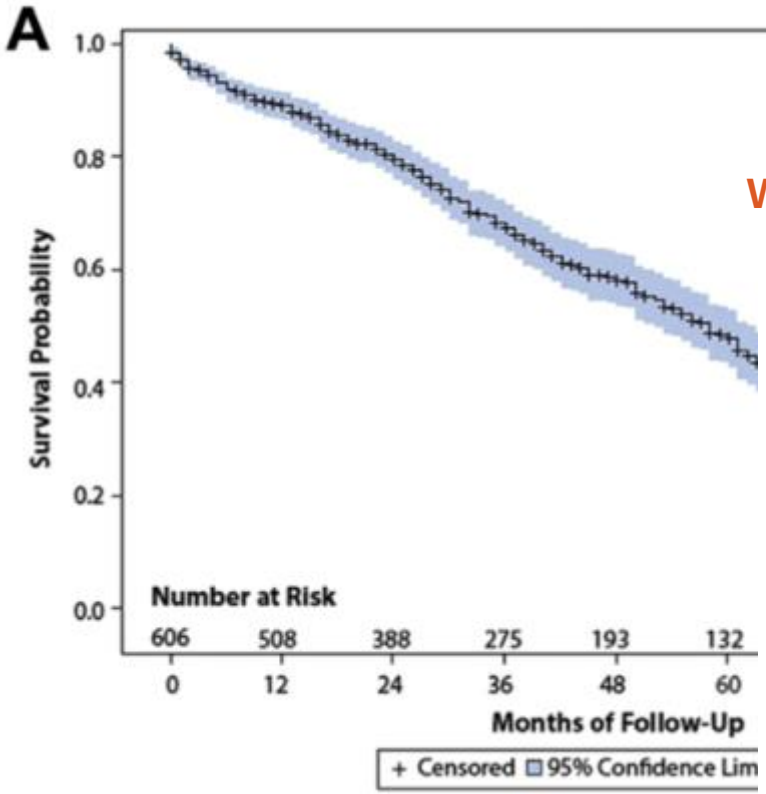
J Vasc Surg. 2015 Feb;61(2):355-64. doi: 10.1016/j.jvs.2014.09.068.

Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms.

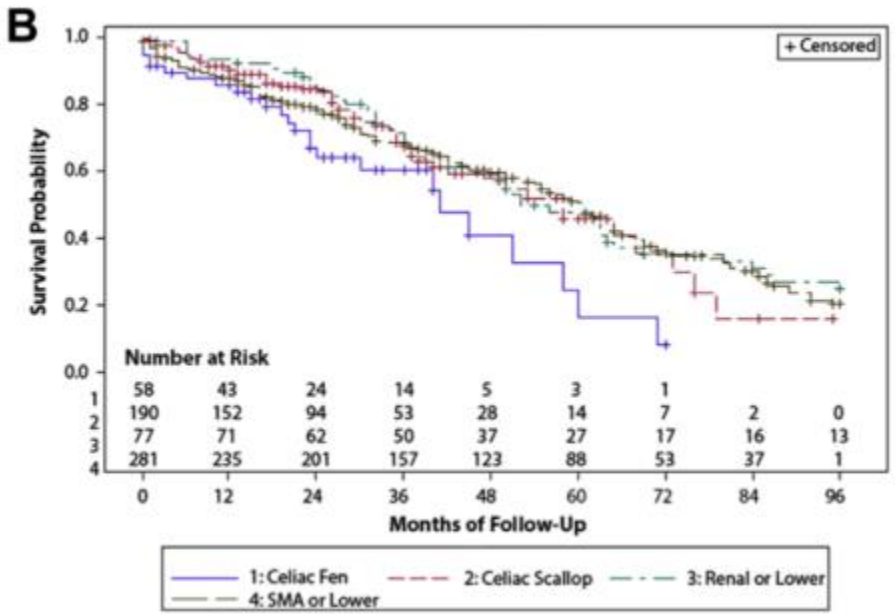
Mastracci TM[1], Eagleton MJ[2], Kuramochi Y[2], Bathurst S[2], Wolski K[2].

20% Overall Survival rate @ 8 years

With 2% aortic-related mortality



Worse survival for patients requiring Celiac Fen



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OVER TIME:

↘Celiac fen configurations

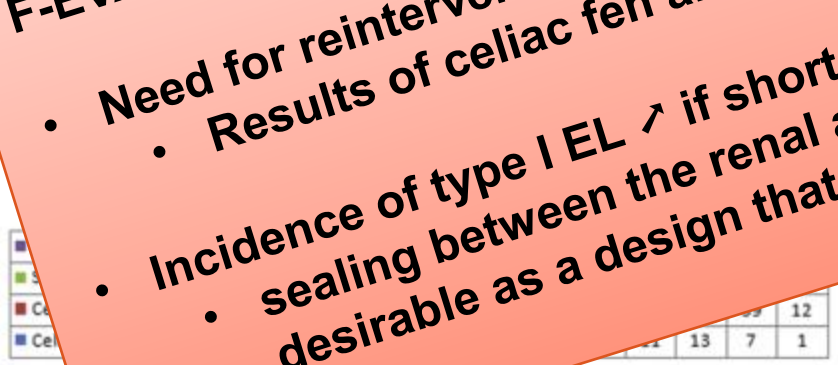
↗Celiac scallop configurati

RI

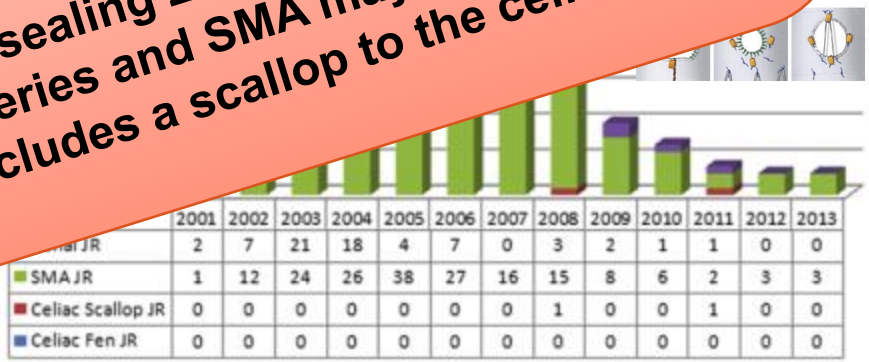
tions

A

- **F-EVAR is safe over the long-term**
  - **Need for reinterventions ↗ with complexity of design**
  - **Results of celiac fen are of concern**
- **Incidence of type I EL ↗ if shorter sealing zones are chosen**
  - **sealing between the renal arteries and SMA may not be as desirable as a design that includes a scallop to the celiac artery**



													12
										13	7	1	



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
[illegible] JR	2	7	21	18	4	7	0	3	2	1	1	0	0
SMA JR	1	12	24	26	38	27	16	15	8	6	2	3	3
Celiac Scallop JR	0	0	0	0	0	0	0	1	0	0	1	0	0
Celiac Fen JR	0	0	0	0	0	0	0	0	0	0	0	0	0

OVERALL…

Vasc Med. 2016 Jun;21(3):223-38. doi: 10.1177/1358863X16631841. Epub 2016 Mar 24.

Fenestrated stent grafts for the treatment of complex aortic aneurysm disease: A mature treatment paradigm.

Georgiadis GS[1], van Herwaarden JA[2], Antoniou GA[3], Giannoukas AD[4], Lazarides MK[5], Moll FL[2].

	Outcome measures after F-EVAR
Technical failure • *inadequate device design* • *suboptimal procedure planning*	1.1-2.1% in specialized centers
30-day mortality	1-3% in specialized centers
Overall Survival	76% @ 3y 60% @ 5y 46% @ 10y
Aneurysm rela	
Target vesse	
Migration ⩾ 10	
Reinterventions	**29% EL rela** 26% target 13% graft li

Minimally invasive
- *No laparotomy*
- *No suprarenal cross-clamping*

Long-term Results are now reported
in specialized centers
importance

Covered bridging stent use was associated with a lower rate of renal artery stenosis compared to bare-metal stents

However, there was no difference in branch vessel occlusion rates

This has led to the primary use of covered stents when performing F-EVAR, regardless of the need to obtain a seal with the fenestration at that location

→

BUT Excel
- **Second**
  EL deve
  - **0**
  - **4**
  - **6**
  - **5**
- **Freedor**

Mastracci et

Stent
can be catastrophic

eterioration
permanent dialysis

m in order to
ailure

VAR given the
stiff stent systems
- ↗ PSV to >280 cm/sec to identify 60-99% renal artery stenosis

→ improved Se (93%), Sp (100%) and PPV/NPV (99%)

Mohabbat et al. J Vasc Surg. 2009;49:827-837

OVERALL…

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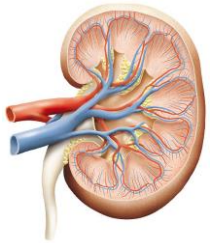
30-day mortality	1-3% in specialized centers
Overall Survival	76% @ 3y 60% @ 5y 46% @ 10y
Aneurysm related death	9% @ 10y
Target vessel patency	**91**-98% @ 1y 93-98% @ 5y
Postop renal impairment Need for hemodialysis	0-**29%** 0-6%
Type I EL	3%
Type II EL	16%
Type III EL	4.6%
	29% @ 1y



- 16% of patients without preoperative renal insufficiency
- 39% of those with chronic renal disease
  - ↗ incidence of permanent dialysis
  - ↗ mortality.

eGFR stabilize within 6months of index surgery with a 14% ↘ @3y

Mastracci et al. J Vasc Surg. 2015;61:355-364.

One of the greatest concerns :

- Manipulation and stenting of the renal arteries
- Use of iodinated contrast during the procedure and repeated FU imaging

However, similar rates have been observed after OSR and EVAR

Martin-Gonzalez et al. J Vasc Surg. 2015;62:569-577.

OVERALL…

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Target vessel patency	**91**-98% @ 1y 93-98% @ 5y
Postop renal impairment Need for hemodialysis	0-**29%** 0-6%
Reinterventions	

Longevity of the repair?

- F-EVAR requires more re-interventions in the long-term vs OSR
  - 12.7% vs 4.9%, $p < 0.0001$
- Poor patient seletion
- Disease progression +++
  - 2-3% will develop a pr

O'Callaghan et al. J Vasc Surg. 201

↗ type I EL in patients receiving device configurations with only renal fenestrations

We first attempted to treat patients with the shortest amount of coverage possible (≈15-mm)

→ **We now search for Higher sealing zones**

- Currently, we attempt to achieve a 2- to 3-cm landing zone when extending a repair into the visceral aortic segment while balancing the risks of developing other complications such as spinal cord ischemia

OVERALL…

Vasc Med. 2016 Jun;21(3):223-38. doi: 10.1177/1358863X16631841. Epub 2016 Mar 24.

Fenestrated stent grafts for the treatment of complex aortic aneurysm disease: A mature treatment paradigm.

Georgiadis GS[1], van Herwaarden JA[2], Antoniou GA[3], Giannoukas AD[4], Lazarides MK[5], Moll FL[2].

	Outcome measures after F-EVAR
Technical failure • *inadequate device design* • *suboptimal procedure planning*	1.1-2.1% in specialized centers
30-day mortality	1-3% in specialized centers
Overall Survival	76% @ 3y 60% @ 5y 46% @ 10y
Aneurysm related death	9% @ 10y
Migration ⩾ 10 mm	1-13%
Reinterventions	**29% EL related** 26% target vessel related 13% graft limb related

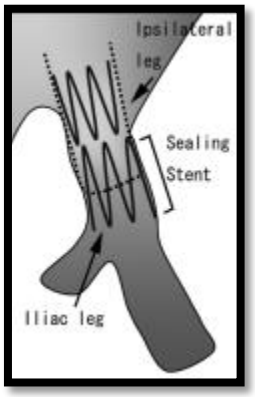
Most of these patients had < 2-stent overlap

An algorithm was developed to assess the risk of potential component separation

- It predicted the maximum amount of possible intercomponent movement
- thereby deriving the minimum overlap required

A new baseline at attempting to achieve three- to four-stent overlap was determined

Dowdall et al. Eur J Vasc Endovasc Surg. 2008;36:2-9.

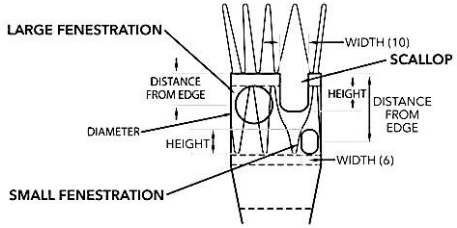


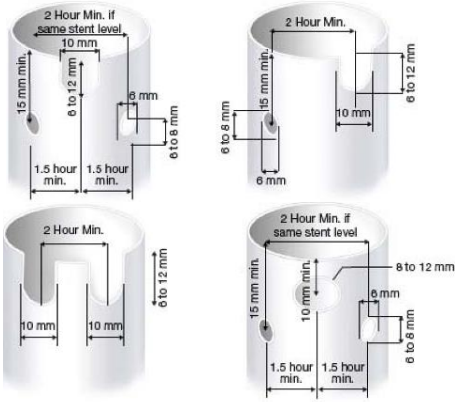
Risk of
- Target vessel/Limb stent crushing and occlusion
- Rupture

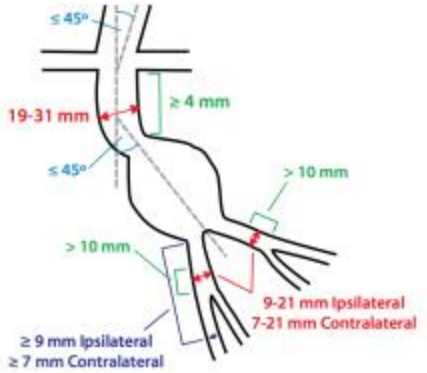
BUT....

A lot of Patient remain uneligible for CM F-EVAR :

- **Elective only (6-8 weeks delay)**
  - **NOT FOR Life threatening aneurysms :**
    - *Rapidly expanding*
    - *Symptomatic / Ruptured*
    - *Diameter ≥ 70mm**
- **Limited availability & Elevated cost**
  - **Requires Advanced endovascular skills**
    - *Learning curve during which deaths because of technical errors or intraoperative complications are not uncommon*
  - **Only available in expert centers**
- **REQUIRES Favorable anatomy, NOT FOR:**
  - 1/ Hostile iliac access
    - *20/22 Fr sheaths = minimum 7.7/8.5 mm outer diameter*
  - 2/ Caudal-directed renal arteries (≤ -30°)
  - 3/ Target vessel small diameter (≤ 5mm)
  - 4/ Close proximity of SMA and highest renal (≤ 15mm)
  - 5/ Prior aortic reconstruction
    - *anastomotic pseudo-aneurysm or type Ia EL*
  - 6/ Tortuous aortic neck (> 45°)
  - 7/ Outcomes strongly correlated to the level and proximal extension of aneurysm disease
    - *poorer long-term outcomes with a device that requires coverage above the celiac artery*







TAKE HOME MESSAGE

- **Available results in specialized centers clearly demonstrate successful use of F-EVAR**
  - More complex designs
    - → *Lower rates of type I EL*
    - → *98% freedom from aneurysm-related mortality*
    - → *BUT higher rates of reintervention*
- **F-EVAR is still in its early phases even though it has the longest reported outcomes compared to other endovascular strategies in JRAs**
- **The current FDA-approved device has limitations and many patients still cannot be treated at this time**
- **There is the need for more advanced devices**
  - easier to use
  - allowing for the incorporation of more visceral vessels and more cephalad extension for improved durability with the same efficacy and safety of use
- **Failure modes are better understood, but in the light of recent findings related to the long-term outcome of infrarenal EVAR, defining the long-term outcome of F-EVAR should remain a priority**

THANK YOU FOR YOUR ATTENTION