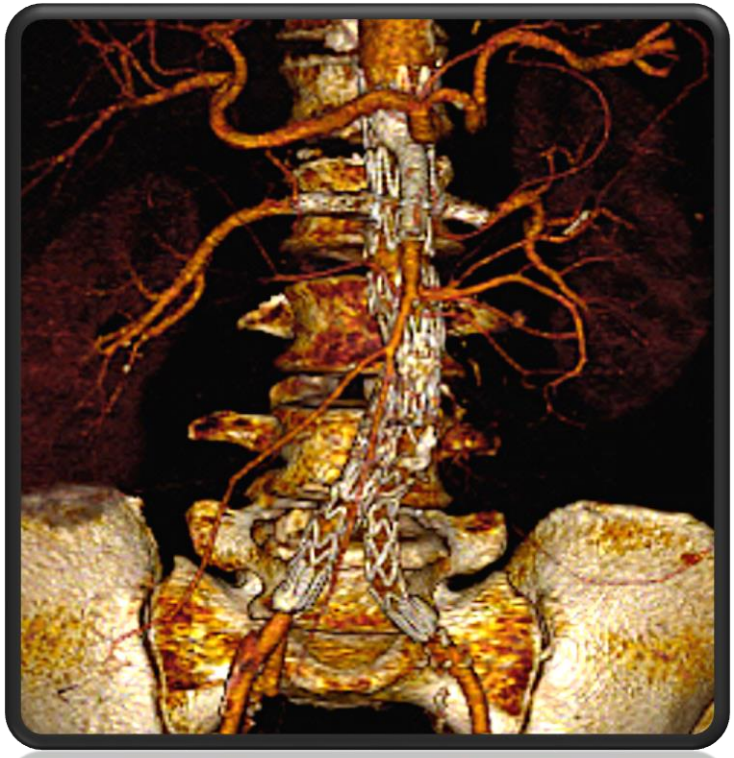

Home made or standard fenestration?

Is there a difference ?

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Disclosure

Speaker name:

.E Ducasse.....

- ■ I have the following potential conflicts of interest to report:
- ■ Consulting Cook, Gore, Medtronic
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest

We already know the early and mid-term results of ST-fenestrations

Ann Vasc Surg. 2013 Nov;27(8):1190-200. doi: 10.1016/j.avsg.2013.06.003. Epub 2013 Aug 22.

Fenestrated endovascular repair for pararenal abdominal aortic aneurysms: a systematic review and meta-analysis.

Di X[1], Ye W, Liu CW, Jiang J, Han W, Liu B.

- Meta-analysis : 12 studies / 776 cases between 2006-2011
- 30-day mortality : 2.52% (95% CI: 1.55-4.08)
- Technical success : 92.8% (95% CI: 87.5-96.0)
- 1-year target vessel patency : 94.5% (95% CI: 92.1-96.2)
- Postoperative reintervention rate : 17.6% (95% CI: 12.0-25.1)
- Postoperative permanent dialysis rate : 2.6% (95% CI: 1.5-4.4)

F-EVAR is a favorable option in high-risk patients with good early and mid-term outcomes

As well as the long-term results

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].

- Long term survival : 20% at 8 years
  - Negatively associated with increasing age, congestive heart failure, cancer, and previous aneurysm repair
- Aortic-related mortality: 2%
- Spinal cord ischemia : 1.2%
- Less complex designs = increased risk of type I EL over time
  - 10.4% for renal fenestrations only vs. 1.9% for others, $p < 0.01$

F-EVAR is safe and effective in long-term FU
Mortality is largely not aortic-related

What about HM-fenestrations?

- **2006 : first description in a series of 3 patients**

J Vasc Interv Radiol. 2006 Dec;17(12):1935-42.

Clinical experience with a customized fenestrated endograft for juxtarenal abdominal aortic aneurysm repair.

Uflacker R[1], Robison JD, Schonholz C, Ivancev K.

- Technical success : 100%
- FU 4-14 months :
  - No procedure-related complications
  - No EL

AT THE MOMENT VERY FEW STUDIES ARE AVAILABLE ON HM-FENESTRATIONS

Perspect Vasc Surg Endovasc Ther. 2009 Sep;21(3):157-67. doi: 10.1177/1531003509351594. Epub 2009 Dec 3.

Modified fenestrated stent grafts: device design, modifications, implantation, and current applications.

Oderich GS[1], Ricotta JJ 2nd.

- **30 patients from 2007-2009** vs.16 debranching + EVAR
- **85 fenestrations :** 50 renals, 33 SMAs, 2 hypogastric

- **Mean time for device modification : 45** min
- **2.8 reconstructed vessels/patient** in both groups

- **Technical success : 98%**
- **30 day mortality : 3.3%** (1 patient) vs. 19% (NS)
- **Complications :** 37% vs. 73% ($p<0.05$)

- **1-year :**
  - primary target vessel patency : **97%** vs. 98%
  - freedom from EL : 88% vs. 74%
  - survival : **72%** vs 71%

J Vasc Surg. 2013 Aug;58(2):311-7. doi: 10.1016/j.jvs.2013.01.029. Epub 2013 May 3.

Early report from an investigator-initiated investigational device exemption clinical trial on physician-modified endovascular grafts.

Starnes BW[1], Tatum B.

- 26 patients from 2011-2012
  - Mean aneurysm diameter : 62.5 mm
- 63 fenestrations : 48 renals, 15 SMAs (left unstented)

- Mean device modification time : 59.7 min
- Technical success : 100%
- 30-day mortality : 3.8%
  - 1 respiratory failure, 1 congestive heart failure

- MAEs : 11.5%
- EL :
  - Freedom from type I or III ELs : 87.5%
  - 15.4% of type II ELs

Eur J Vasc Endovasc Surg. 2015 Nov;50(5):583-92. doi: 10.1016/j.ejvs.2015.07.002. Epub 2015 Aug 7.

Early Results of Physician Modified Fenestrated Stent Grafts for the Treatment of Thoraco-abdominal Aortic Aneurysms.

Cochennec F[1], Kobeiter H[2], Gohel M[3], Leopardi M[4], Raux M[4], Majewski M[4], Desgranges P[4], Allaire E[4], Becquemin JP[4].

- 11 TAAA (mean age 73) from January 2012-June 2014
  - 8 ASA 3, 3 ASA 4
  - Mean diameter : 73 mm
- Median number of fenestration : 3

- Median device modification time : 2 hours with diameter reducing ties
- In hospital mortality : 9% (1 patient : colic ischemia)
- Complications : 36%
  - 1 paraparesis with complete resolution after spinal fluid drainage, 1 pneumonia, 1 acute prostatitis, 1 retroperitoneal hematoma at the site of a right iliac conduit deemed necessary because of hostile iliac access treated endovascularly
- Reinterventions : 45%
  - 3 type III ELs (additional covered stent deployment on target vessels), 1 covered stent for retroperitoneal hematoma, 1 type Ia EL (proximal stent component)

- Median FU : 6 months :
  - No additional complication or EL

J Endovasc Ther. 2015 Oct 23. pii: 1526602815611887. [Epub ahead of print]

Systematic Review of Off-the-Shelf or Physician-Modified Fenestrated and Branched Endografts.

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

- Meta-analysis from January 2001 through March 2015
- 15 articles on HM-fenestrations vs. 8 on off-the-shelf devices / 308 patients (mean age 72.93)
  - 1/3 operated on an emergency basis
  - Mean aneurysm diameter : 75.9 mm vs. 68.1 mm
- 458 vs. 478 target vessels

- MAEs : 12.8% (95% CI : 8.6-18.7) vs. 7.4% (95% CI : 3.7-14)
- Technical success : 91.4% (95% CI : 86.2-94.9) vs. 95% (95% CI : 89.1-98.0)

- Mortality : 3.2% (1.1% aneurysm related) vs. 0%
- Overall target vessel patency : 96.7% vs. 97.9%

Major conclusions on HM-fenestrations drawned from those limited series

- Perform similarly to commercially manufactured grafts in terms of :
  - Technical success
  - Mortality/Morbidity
  - ELs
  - and target vessel's patency at short-term follow-up

- Safe and effective in both the elective and acute settings for the treatment of complex aortic aneurysms in high-risk patients

- Reintervention is frequent = need for diligent FU

- Patients surviving the initial hospitalization of acute aortic disease can anticipate good long-term survival

Legal issues

J Vasc Surg. 2013 Mar;57(3):829-31. doi: 10.1016/j.jvs.2012.11.043.

A surgeon's perspective regarding the regulatory, compliance, and legal issues involved with physician-modified devices.

Starnes BW[1].

- Off-label use of medical devices occurs on a daily basis
- When performed by physicians it is both legal and unregulated
- Reimbursement might be denied citing that the device modifications are « investigational »
- Since the device has been modified after manufacturing process and used outside the IFUs, the manufacturer is exempt from any product liability claim

J Vasc Surg. 2013 Mar;57(3):832-3. doi: 10.1016/j.jvs.2012.12.026.

Advisory statement on clinical use of modified aortic endografts from the Society for Vascular Surgery®.

White RA[1].

- **Patient's consent necessary**
- **If serial use is planned : IRB and IDE approvals required**

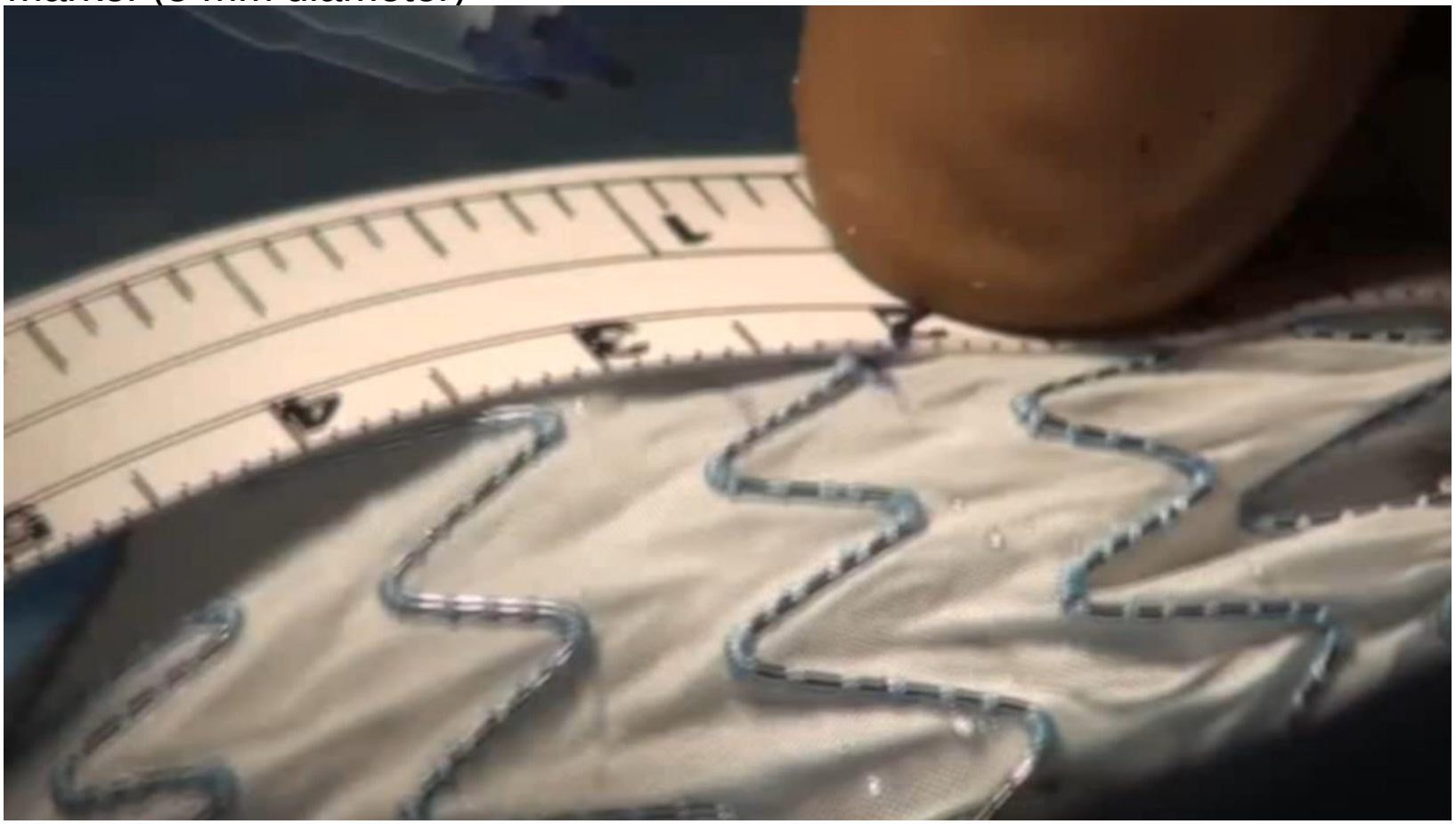
Our experience with HM-fenestrations

- 125 high risk-patients from January 2010-2015 :
  - **20** treated by HM-fenestration
  - vs. **105** by ST-fenestration
- Groups comparable except for :
  - Male : ST > HM
  - BMI : ST > HM
  - **History of prior aortic surgery :** HM> ST

Variables	*HM group n = 20*	*ST group n = 105*	*p*
Male	17 (85)	101 (96)	**0.048**
Age (years)	74.7 ± 6.9	71.3 ± 8.5	0.092
Coronary heart disease	5 (25)	41 (39)	0.24
Hypertension	15 (75)	85 (81)	0.55
Dyslipidemia	9 (45)	63 (60)	0.22
Diabetes	3 (15)	17 (16)	0.90
BMI	24,4 ± 3,1	26.3 ± 4.5	**0.008**
CVD	0 (0)	10 (10)	0.15
PAD	2 (10)	9 (9)	0.84
Prior aortic surgery	4 (20)	7 (7)	0.056
Hostile abdomen	6 (30)	20 (19)	0.27
Active smoking	8 (40)	25 (24)	0.13
COPD	7 (35)	24 (23)	0.25
ASA classification	-	-	0.21
1	1 (5)	5 (5)	-
2	8 (40)	47 (45)	-
3	8 (40)	50 (48)	-
4	2 (10)	3 (3)	-
5	1 (5)	0 (0)	-

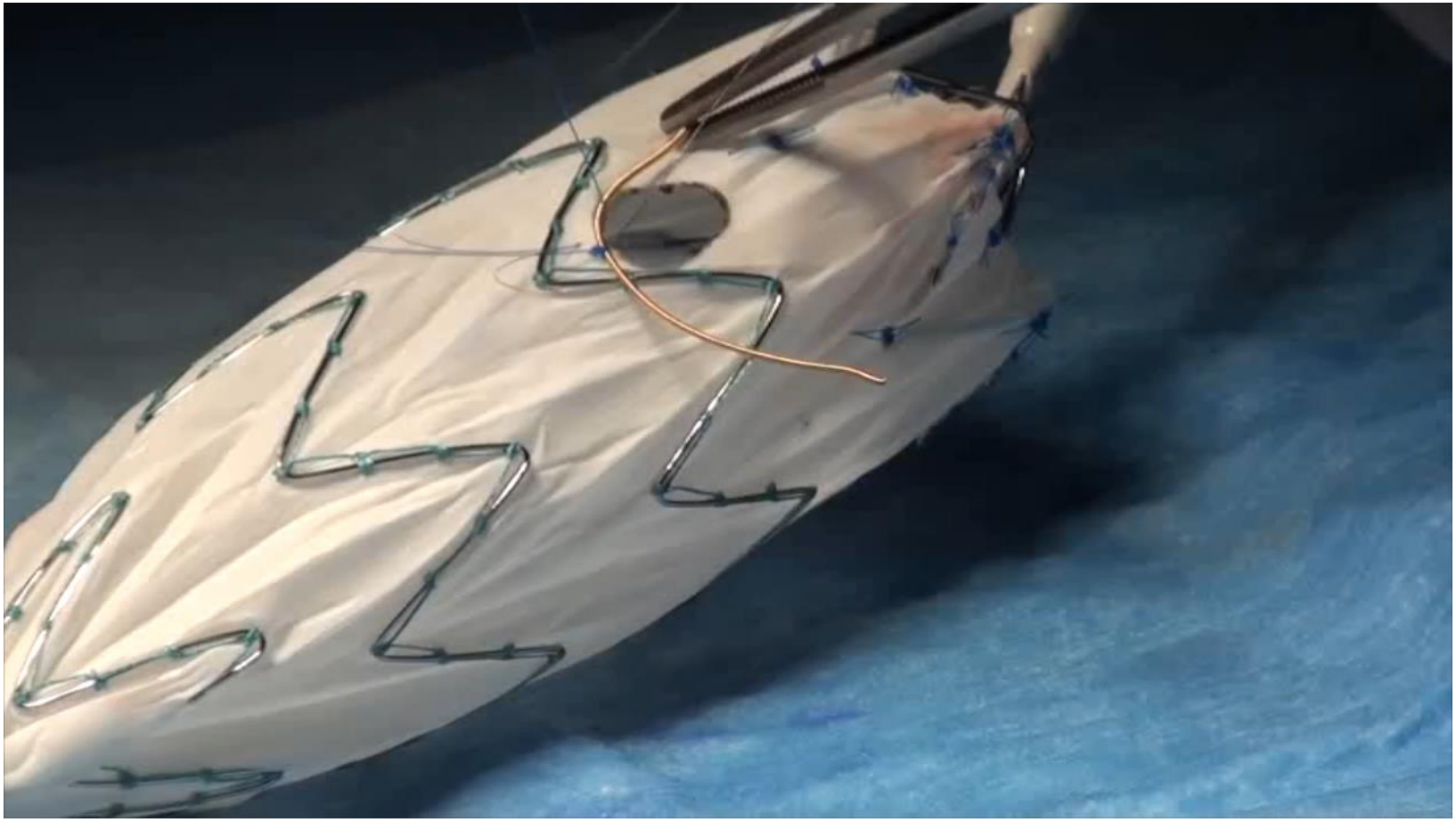
Device sizing

Graft is unsheathed on a back side table under sterile conditions
Location of the fenestrations is pre-marked between struts with sterile marker (5 mm diameter)



Hole created in the fabric with cuttering pen

Snare used as a radio-opacifier and sewn with 5/0 prolène suture



Diameter reducing ties are positioned

Device is resheathed

Total preparation time 50 to 80 min :

Coincides with the preparation of the patient from the anesthesiology team and while the graft is prepared by the primary senior surgeon, the assistant surgeon can work in parallel on surgical exposure

Anatomical caracteristics and implanted devices

- Groups comparable except :
  - Aortic neck and graft D : ST > HM
  - **Total nb of reconstructed vessels/patient :** ST> HM
- 23 HM-fenestrations :
  - 21 renals, 1 CT, 1 SMA
- 229 ST-fenestrations :
  - 194 renals, 27 SMAs, 8 CTs

Variables	*HM group*	*ST group*	*p*
Aneurysm D (mm)	63.0 ± 10.8	58.6 ± 9.9	0.078
Aortic neck D (mm)	24.4 ± 2.4	26.2 ± 2.9	**0.013**
Graft D (mm)	27.8 ± 2.2	30.7 ± 3.6	**0.001**
Oversizing (%)	12 ± 4	14 ± 5	0.12
Endografts	-	-	-
Medtronic®	4 (20)	0 (0)	-
Cook®	16 (80)	81 (77)	-
Vascutek®	0 (0)	24 (23)	-
Target vessel D (mm)	6.1 ± 0.8	6.0 ± 0.9	0.85
Target vessel stent D (mm)	6.7 ± 0.6	6.6 ± 0.7	0.54
Nb of reconstructed RA	21	194	-
Total nb of reconstructed vessels/patient	2.5 ± 0.7	3.0 ± 0.6	**0.002**

Target vessels stents :

- Advanta V12® = 20 HM / 226 ST
- Lifestream® = 1 HM / 3 ST
- Bentley® = 2 HM

Methods

HM group

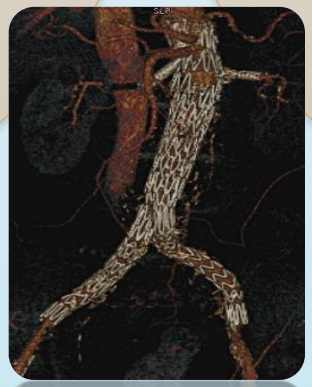
single HM procedure

3

Combined-repair

= Fenestration + Chimney

17

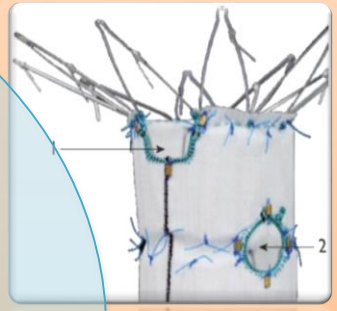


ST group

single ST procedure

90

15



reconstruction

- Indications for HM:
  - **Symptomatic aneurysm** : 30%
  - **D AAA > 70mm** : 4 patients
  - **Unfavorable anatomy :**
    - Prior aortic surgery with anastomotic pseudo-aneurysm : 4 patients
    - Hostile iliac access ≤ 7mm : 4 patients
    - < 15 mm between SMA/highest renal : 2 patients

Variables	*HM group*	*ST group*	*p*
Emergency	6 (30)	0 (0)	**<0.0001**
Cuff	2 (0.1)	3 (2.9)	0.14
ABI	17 (85.0)	101 (96.2)	**0.048**
AUI + bypass*	1 (5.0)	1 (0.9)	0.19
Hypogastric embolization	2 (0.1)	10 (9.5)	0.95
Combined repair	17 (85)	15 (14.3)	**<0.0001**
Fluoroscopy time (min)	56.1 ± 19.2	62.6 ± 31.4	0.47
Procedure time (min)	196.3 ± 73.6	182.4 ± 87.5	0.51
Dosimetry (cGy/cm^2)	13519±5793	18940±14032	0.18
Contrast (mL)	93.6 ± 22.0	130.6 ± 56.7	**0.006**

* *femoro-femoral*

- Significant differences :
  - **Contrast :** HM < ST but less reconstructed vessels/patient
  - **Combined-repair** : HM > ST

Mean hospital stay : NS

Renal function

- Only significant difference :
  - **Pre-operative renal failure** : HM > ST
- Only one shift towards hemodialysis: ST group
- (renal stents occlusions)

No significant difference in terms of post-operative
Acute renal failure
or Chronic renal insufficiency

Variables	*HM group*	*ST group*	*p*
GFR			
J-1	71.8 ± 35.5	83.4 ± 24.7	0.081
J0	76.7 ± 43.8	76.1 ± 20.0	0.46
J1	79.9 ± 48.0	74.5 ± 26.3	0.61
J2	74.2 ± 49.4	75.8 ± 30.3	0.57
J5	74.8 ± 43.2	76.1 ± 27.7	0.23
J-1 vs. J0	p = 0.71	**p = 0.035**	-
J-1 vs. J5	p = 0.82	p = 0.065	-
GFR < 60			
J-1	9 (45.0)	14 (13.3)	**0.001**
J0	9 (45.0)	31 (29.5)	0.18
J1	9 (45.0)	36 (34.3)	0.36
J2	11 (55.0)	35 (33.3)	0.07
J5	10 (50.0)	31 (29.5)	0.08
Pre-operative HD	0 (0)	1 (1)	0.68
Post-operative HF	1 (5.0)	2 (1.9)	0.42
Kidney infarction	6 (30.0)	27 (25.7)	0.69
AKI			
Risk	5 (25.0)	16 (15.2)	0.29
Injury	1 (5.0)	6 (5.7)	0.91
Failure	0 (0.0)	2 (1.9)	0.55
CKD			
CKD improved	4 (20.0)	11 (10.5)	0.23
CKD stable	10 (50.0)	65 (61.9)	0.32
CKD decline x1	6 (30.0)	22 (20.9)	0.38
CKD decline x2	0 (0.0)	7 (6.7)	0.24

Early post-operative results

- Cannulation failure : 1 HM vs. 2 ST
  - **Technical success : 90.5 vs. 99.0%**
- **30-days mortality : 15 vs. 2.9%**
  - HM : 1 external iliac rupture **only surgical conversion**
- Target vessel injury : HM > ST

BUT emergency procedures with hostile iliac access

Variables	*HM group*	*ST group*	*p*
Intraoperative events			
Cannulation failure	1 (4.8)	2 (1.0)	0.17
Target Vessel injury	1 (4.8)	0 (0,0)	**0.002**
Early results (≤ 30 days)			
30 days mortality	3 (15.0)	3 (2.9)	**0.021**
Multi-organ failure	0 (0.0)	1 (0.9)	0.68
Bowel ischemia	2 (10.0)	2 (1.9)	0.062
Gastric hemorrhage	0 (0.0)	1 (0.9)	0.68
Respiratory complication	0 (0,0)	3 (2.9)	0.45
Rhabdomyolysis	0 (0.0)	1 (0.9)	0.68
Target vessel occlusion	*1* (4.8)*	3 (1.5)	0.30
Target vessel dissection	1 (4.8)	1 (0.5)	0.056
Access vessel dissection	0 (0.0)	2 (1.9)	0.42
Access vessel rupture	1 (5.0)	0 (0.0)	**0.023**
Access site false aneurysm	0 (0.0)	1 (0.9)	0.68
Access site hematoma	1 (4.8)	2 (1.9)	0.42
Lower limb ischemia	0 (0.0)	3 (2.9)	0.45
Myocardial infarction	0 (0.0)	2 (1.9)	0.68
Regressive SCI	0 (0.0)	1 (0.5)	0.68

SCI, spinal chord ischemia

** Patient had a combined procedure and it was a chimney occlusion on the right renal artery and not a fenestration*

Reinterventions

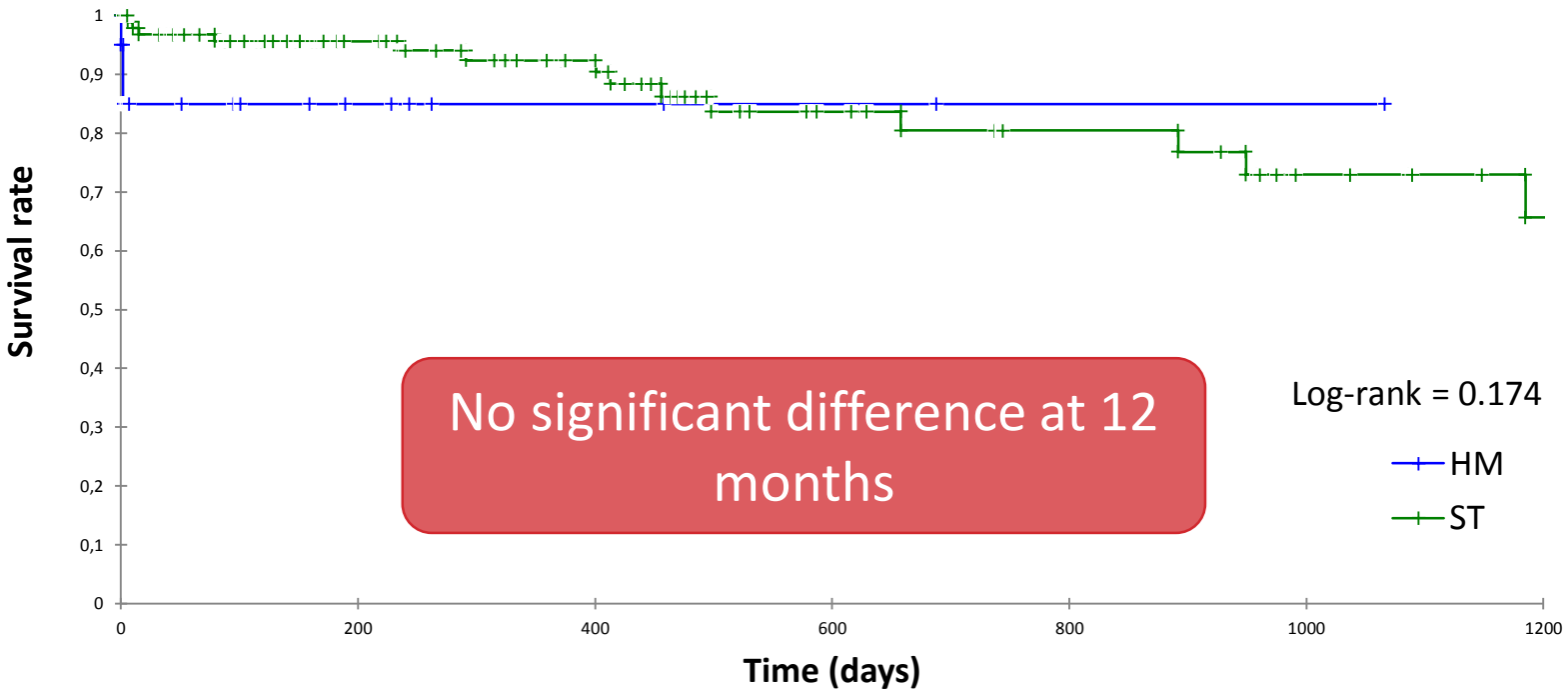
- HM :
  - 1 renal stent occlusion
  - 2 type Ia ELs
  - **BUT** due to the chimneys
- ST :
  - **1 type I EL = proximal cuff addition**

Variables	*HM group*	*ST group*	*p*
Target vessel occlusion	*1* (4.8)*	0 (0.0)	***0.002***
Limb occlusion/stenosis	1 (5.0)	1 (0.95)	0.19
Limb extension	0 (0.0)	4 (3.8)	0.38
Access complication	1 (5.0)	3 (2.9)	0.63
Type I EL	*2** (10.0)*	1 (0.95)	***0.016***
Type II EL	0 (0.0)	3 (2.9)	0.45
Type III EL	0 (0.0)	2 (1.9)	0.55
Chronic mesenteric ischemia	0 (0.0)	1 (0.95)	0.68
Acute mesenteric ischemia	2 (10.0)	2 (1.9)	0.062

** Patient had a combined procedure and it was a chimney occlusion on the right renal artery and not a fenestration*

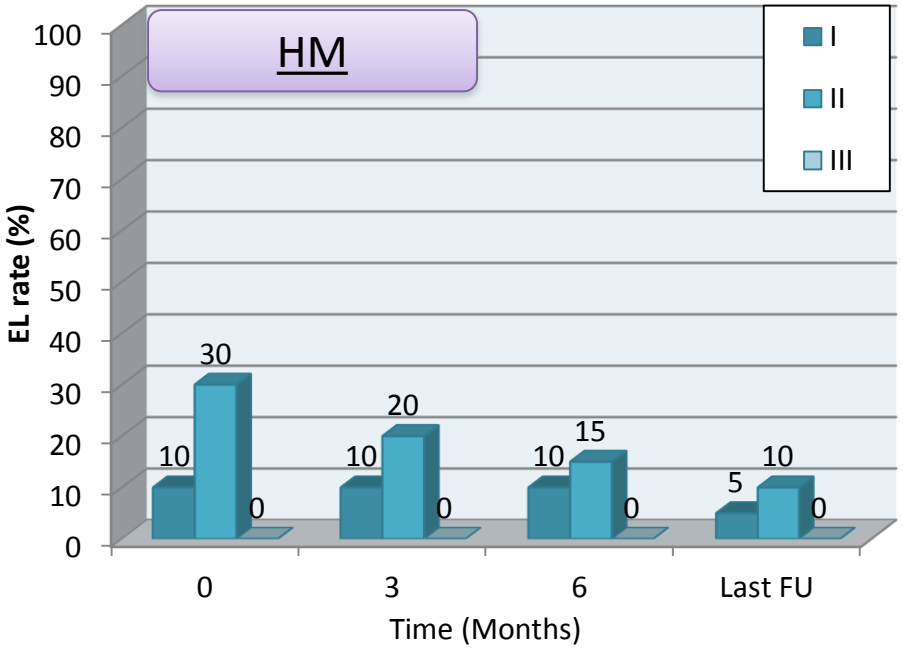
*** Patients had a combined procedure the type I EL was due to the open chimney in the left renal artery for the first patient and the open chimney in the SMA in the second that we chose to convert into covered chimneys*

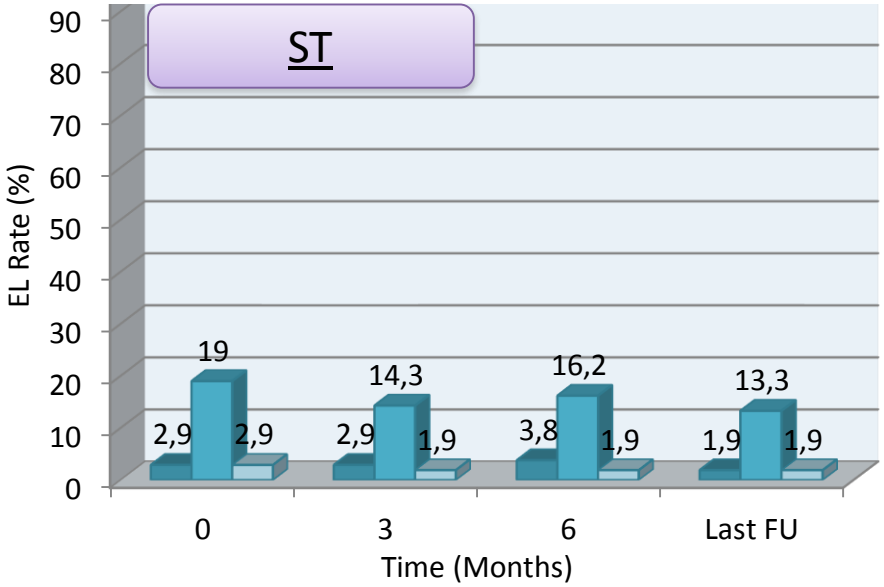
Survival curve



Time to event (months)	Survival rate (CI-95%)	
	HM	ST
0	95 (85-100)	-
1	85 (69-100)	97 (93-100)
3	85 (69-100)	96 (91-100)
6	85 (69-100)	94 (89-99)
12	85 (69-100)	92 (86-98)

ELs



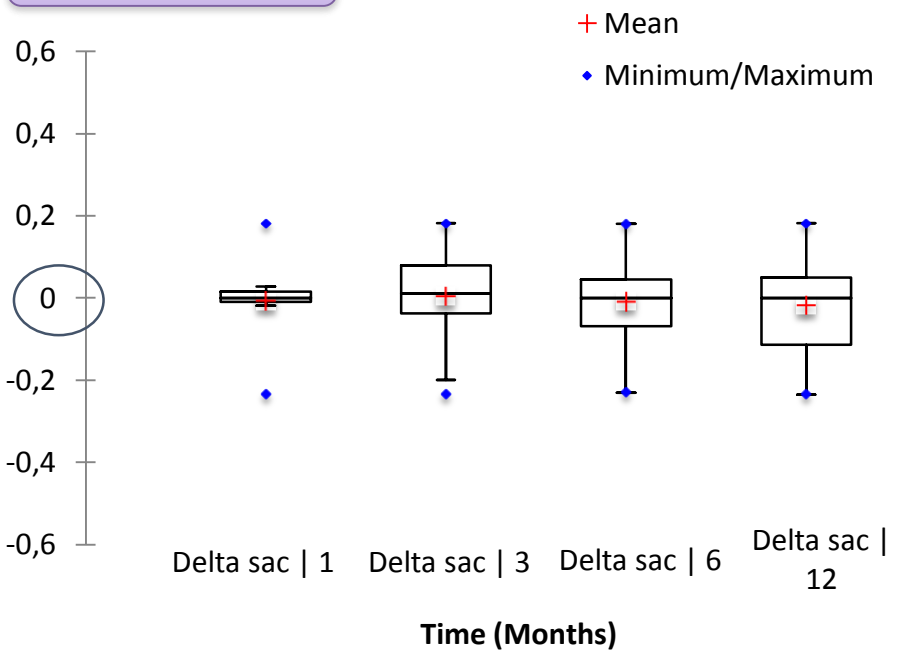


Variables	HM group	ST group	p
Post-operative	-	-	-
Type I EL	2 (10.0)	3 (2.9)	0.14
Type II EL	6 (30.0)	20 (19.0)	0.27
Type III EL	0 (0.0)	3 (2.9)	0.45
3 months follow-up	-	-	-
Type I EL	2 (10.0)	3 (2.9)	0.14
Type II EL	4 (20.0)	15 (14.3)	0.52
Type III EL	0 (0.0)	2 (1.9)	0.68
6 months follow-up	-	-	-
Type I EL	2 (10.0)	4 (3.8)	0.24
Type II EL	3 (15.0)	17 (16.2)	0.90
Type III EL	0 (0.0)	2 (1.9)	0.68
Last follow-up (days)	179 ± 269	448 ± 433	-
Type I EL	1 (5.0)	2 (1.9)	0.42
Type II EL	2 (10.0)	14 (13.3)	0.69
Type III EL	0 (0.0)	2 (1.9)	0.68

Type I, II or III ELs : No significant difference at 12 months

Evolution of the Aneurysmal sac

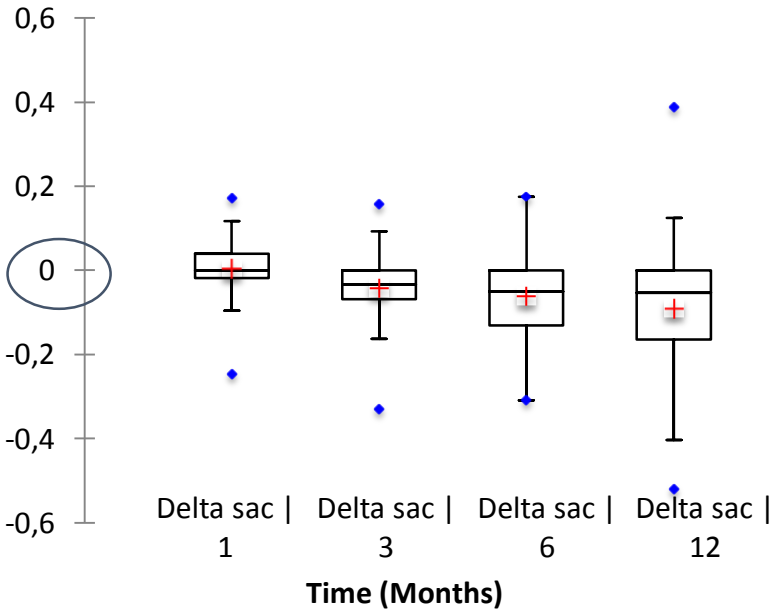
HM



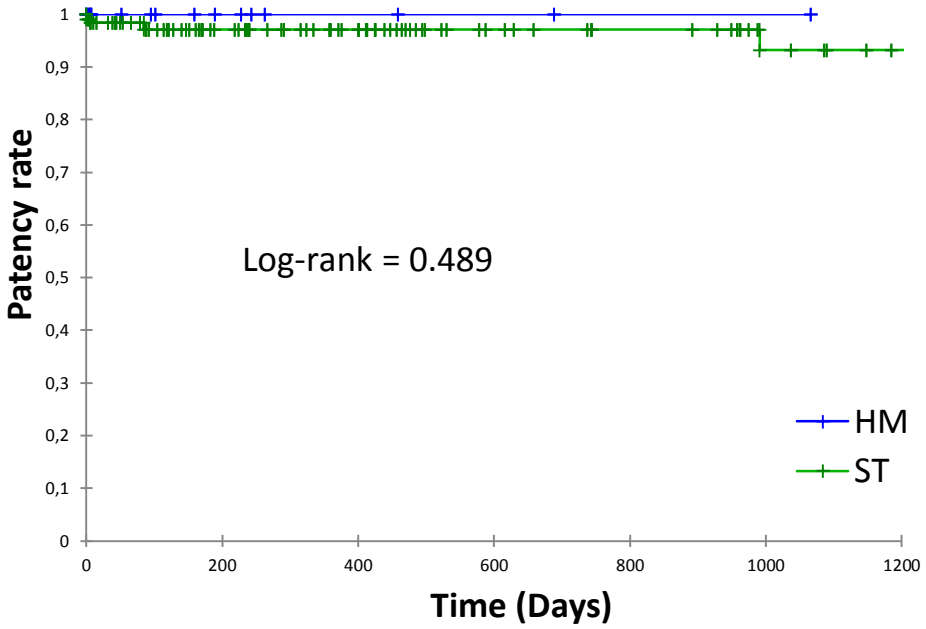
At 12 months :

- p = 0.052
- Mean :
  - HM = **-1.8%** (-23 – 18%)
  - ST = **-9%** (-52 – 39%)

ST



Primary patency of the target renal arteries



- ST group = 189/194
- **1** impossible to cannulate
- **2** early thrombosis
- **2** thrombosis at 3 months FU :
  - 1 in a patient who had already lost her left kidney (LRA impossible to cannulate) → only shift towards dialysis

Time to event (months)	Patency rate (CI-95%)	
	HM	ST
0	100 (85-100)	99 (98-100)
1	100 (85-100)	98 (97-100)
3	100 (85-100)	97 (95-100)
6	100 (85-100)	97 (95-100)
12	100 (85-100)	97 (95-100)

No significant difference at 12 months

In our experience :

- **Early results : HM-fenestrations < ST**
  - ↗ 30-days mortality, target vessel injury and liac rupture

BUT emergency procedures with hostile iliac access

- **At 6 and 12 months : NO SIGNIFICANT DIFFERENCE in terms of patency, renal function, ELs or survival**

- **HM-fenestrations :**
  - Perform similarly to ST-fenestrations
    - technical success, target vessel's patency, renal function, ELs and survival at short-term follow-up
  - Are safe and effective
    - In elective and acute settings
    - For complex aortic aneurysms in high-risk patients

- **Current design of off-the-shelf devices is theoretically applicable in 50-80% of anatomical configurations :**
  - some patients will still require an alternative