Home Made fenestration Vs. regular 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

- 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

- 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

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

Uflacker R¹, 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**
- **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%
Physician-modified endovascular grafts for the treatment of elective, symptomatic, or ruptured juxtarenal aortic aneurysms.

- **47 patients (mean age 75)**
  - 38 symptomatic/rapid aneurysm expansion
  - 40 ASA 3/4
  - Mean aneurysm diameter : 58 mm
- **82 fenestrations** : 58 renals, 16 SMAs, 3 CTs, 5 accessory renals
- **Mean time for device modification** : 48 min
- **1.75 reconstructed vessels/patient**
- **Technical success** : 98%
- **Freedom from aneurysm related death** : 98%
- **Complications** : access site (6%), 1 stroke, 1 permanent renal failure, 1 renal artery dissection
- **EL** : 13%
- **30-day mortality** : 2%
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
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 drawn 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

- 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

- Patient’s consent necessary
- If serial use is planned: IRB and IDE approvals required
The experience with HM-fenestrations in our center

- 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
Methods

- 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 cutting pen
- Snare used as a radio-opacifier and sewn with 5/0 prolène suture
- Device is resheathed

20 to 40 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
• 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
  • 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

15

ST group

single ST procedure

90
**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

**Significant differences:**

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

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<table>
<thead>
<tr>
<th>Variables</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency</td>
<td>6 (30)</td>
<td>0 (0)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cuff</td>
<td>2 (0.1)</td>
<td>3 (2.9)</td>
<td>0.14</td>
</tr>
<tr>
<td>ABI</td>
<td>17 (85.0)</td>
<td>101 (96.2)</td>
<td>0.048</td>
</tr>
<tr>
<td>AUI + bypass*</td>
<td>1 (5.0)</td>
<td>1 (0.9)</td>
<td>0.19</td>
</tr>
<tr>
<td>Hypogastric embolization</td>
<td>2 (0.1)</td>
<td>10 (9.5)</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Combined repair</strong></td>
<td>17 (85)</td>
<td>15 (14.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>56.1 ± 19.2</td>
<td>62.6 ± 31.4</td>
<td>0.47</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>196.3 ± 73.6</td>
<td>182.4 ± 87.5</td>
<td>0.51</td>
</tr>
<tr>
<td>Dosimetry (cGy/cm²)</td>
<td>13519±5793</td>
<td>18940±14032</td>
<td>0.18</td>
</tr>
<tr>
<td><strong>Contrast (mL)</strong></td>
<td>93.6 ± 22.0</td>
<td>130.6 ± 56.7</td>
<td><strong>0.006</strong></td>
</tr>
</tbody>
</table>

* femoro-femoral

**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

### Table: GFR

<table>
<thead>
<tr>
<th>Variables</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>GFR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J-1</td>
<td>71.8 ± 35.5</td>
<td>83.4 ± 24.7</td>
<td>0.081</td>
</tr>
<tr>
<td>J0</td>
<td>76.7 ± 43.8</td>
<td>76.1 ± 20.0</td>
<td>0.46</td>
</tr>
<tr>
<td>J1</td>
<td>79.9 ± 48.0</td>
<td>74.5 ± 26.3</td>
<td>0.61</td>
</tr>
<tr>
<td>J2</td>
<td>74.2 ± 49.4</td>
<td>75.8 ± 30.3</td>
<td>0.57</td>
</tr>
<tr>
<td>J5</td>
<td>74.8 ± 43.2</td>
<td>76.1 ± 27.7</td>
<td>0.23</td>
</tr>
<tr>
<td>J-1 vs. J0</td>
<td>p = 0.71</td>
<td>p = 0.035</td>
<td>-</td>
</tr>
<tr>
<td>J-1 vs. J5</td>
<td>p = 0.82</td>
<td>p = 0.065</td>
<td>-</td>
</tr>
</tbody>
</table>

### Table: GFR < 60

<table>
<thead>
<tr>
<th>Variable</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>J-1</td>
<td>9 (45.0)</td>
<td>14 (13.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>J0</td>
<td>9 (45.0)</td>
<td>31 (29.5)</td>
<td>0.18</td>
</tr>
<tr>
<td>J1</td>
<td>9 (45.0)</td>
<td>36 (34.3)</td>
<td>0.36</td>
</tr>
<tr>
<td>J2</td>
<td>11 (55.0)</td>
<td>35 (33.3)</td>
<td>0.07</td>
</tr>
<tr>
<td>J5</td>
<td>10 (50.0)</td>
<td>31 (29.5)</td>
<td>0.08</td>
</tr>
<tr>
<td>Pre-operative HD</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>0.68</td>
</tr>
<tr>
<td>Post-operative HF</td>
<td>1 (5.0)</td>
<td>2 (1.9)</td>
<td>0.42</td>
</tr>
<tr>
<td>Kidney infarction</td>
<td>6 (30.0)</td>
<td>27 (25.7)</td>
<td>0.69</td>
</tr>
</tbody>
</table>

### Table: AKI

<table>
<thead>
<tr>
<th>Risk</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>5 (25.0)</td>
<td>16 (15.2)</td>
<td>0.29</td>
</tr>
<tr>
<td>Injury</td>
<td>1 (5.0)</td>
<td>6 (5.7)</td>
<td>0.91</td>
</tr>
<tr>
<td>Failure</td>
<td>0 (0.0)</td>
<td>2 (1.9)</td>
<td>0.55</td>
</tr>
</tbody>
</table>

### Table: CKD

<table>
<thead>
<tr>
<th>Condition</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD improved</td>
<td>4 (20.0)</td>
<td>11 (10.5)</td>
<td>0.23</td>
</tr>
<tr>
<td>CKD stable</td>
<td>10 (50.0)</td>
<td>65 (61.9)</td>
<td>0.32</td>
</tr>
<tr>
<td>CKD decline x1</td>
<td>6 (30.0)</td>
<td>22 (20.9)</td>
<td>0.38</td>
</tr>
<tr>
<td>CKD decline x2</td>
<td>0 (0.0)</td>
<td>7 (6.7)</td>
<td>0.24</td>
</tr>
</tbody>
</table>
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

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### Intraoperative events

<table>
<thead>
<tr>
<th>Variables</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannulation failure</td>
<td>1 (4.8)</td>
<td>2 (1.0)</td>
<td>0.17</td>
</tr>
<tr>
<td>Target Vessel injury</td>
<td>1 (4.8)</td>
<td>0 (0.0)</td>
<td><strong>0.002</strong></td>
</tr>
</tbody>
</table>

### Early results (≤ 30 days)

<table>
<thead>
<tr>
<th>30 days mortality</th>
<th>HM group</th>
<th>ST group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 (15.0)</td>
<td>3 (2.9)</td>
<td><strong>0.021</strong></td>
</tr>
<tr>
<td>Multi-organ failure</td>
<td>0 (0.0)</td>
<td>1 (0.9)</td>
<td>0.68</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>2 (10.0)</td>
<td>2 (1.9)</td>
<td>0.062</td>
</tr>
<tr>
<td>Gastric hemorrhage</td>
<td>0 (0.0)</td>
<td>1 (0.9)</td>
<td>0.68</td>
</tr>
<tr>
<td>Respiratory complication</td>
<td>0 (0.0)</td>
<td>3 (2.9)</td>
<td>0.45</td>
</tr>
<tr>
<td>Rhabdomyolysis</td>
<td>0 (0.0)</td>
<td>1 (0.9)</td>
<td>0.68</td>
</tr>
<tr>
<td>Target vessel occlusion</td>
<td>1* (4.8)</td>
<td>3 (1.5)</td>
<td>0.30</td>
</tr>
<tr>
<td>Target vessel dissection</td>
<td>1 (4.8)</td>
<td>1 (0.5)</td>
<td>0.056</td>
</tr>
<tr>
<td>Access vessel dissection</td>
<td>0 (0.0)</td>
<td>2 (1.9)</td>
<td>0.42</td>
</tr>
<tr>
<td>Access vessel rupture</td>
<td>1 (5.0)</td>
<td>0 (0.0)</td>
<td><strong>0.023</strong></td>
</tr>
</tbody>
</table>

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

No significant difference at 12 months

Log-rank = 0.174

<table>
<thead>
<tr>
<th>Time to event (months)</th>
<th>Survival rate (CI-95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HM</td>
</tr>
<tr>
<td>0</td>
<td>95 (85-100)</td>
</tr>
<tr>
<td>1</td>
<td>85 (69-100)</td>
</tr>
<tr>
<td>3</td>
<td>85 (69-100)</td>
</tr>
<tr>
<td>6</td>
<td>85 (69-100)</td>
</tr>
<tr>
<td>12</td>
<td>85 (69-100)</td>
</tr>
</tbody>
</table>
Type I, II or III ELs: No significant difference at 12 months
At 12 months:
- $p = 0.052$
- Mean:
  - HM = $-1.8\% (-23 - 18\%)$
  - ST = $-9\% (-52 - 39\%)$
Primary patency of the target renal arteries

<table>
<thead>
<tr>
<th>Time to event (months)</th>
<th>Patency rate (CI-95%)</th>
<th>HM</th>
<th>ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100 (85-100)</td>
<td>99 (98-100)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>100 (85-100)</td>
<td>98 (97-100)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>100 (85-100)</td>
<td>97 (95-100)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>100 (85-100)</td>
<td>97 (95-100)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>100 (85-100)</td>
<td>97 (95-100)</td>
<td></td>
</tr>
</tbody>
</table>

Log-rank = 0.489

- 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

No significant difference at 12 months
In our experience:

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

- 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

BUT emergency procedures with hostile iliac access
When to do what?

**Patient at High-risk for OSR:**
- ASA ≥ 2
- Hostile abdomen
- COPD
- BMI > 25
- Cardiac insufficiency

**ST-fenestration is the first choice:**
- Safe
- Effective
- Good long-term results even in high-risk patients

**BUT some requirements need to be met...**
- **Favorable anatomy** due to limitations in the configuration design:
  - Fenestration locations
  - Number of fenestrations
- **Good bilateral iliac access:**
  - 18 to 24 Fr
- **Possibility to wait for the manufacturing delays of 6 to 12 weeks**
- **Only available in some centers, with a number of devices limited per year**
**HM-fenestration is an effective solution:**

- Device adaptability
- Available in 1 to 2 hours
- 100% tailored to patient’s anatomy
- Possible use of low profile devices in hostile iliac access
- Lower cost
- Similar technical success rate

**Patient uneligible for ST-fenestration:**

- **Emergent setting:**
  - Rapidly expanding AAA
  - Symptomatic AAA
  - (Contained) Ruptured AAA hemodynamically stable

- **ST-fenestrations quotas finished for the year with AAA > 70mm**

- **Unfavorable anatomy:**
  - Hostile iliac access ≤ 7mm
  - History of prior aortic surgery with anastomotic pseudo-aneurysm
  - < 15mm between SMA and highest renal

**With some limitations:**

- **Off-label:** inform patient and family, legal risk
- **Advanced endovascular skills**
- **High-quality imaging**
- **No long-term results:** Durability? Quality control? Increased risk of infection?

*estimated annual risk of rupture > 30%, Moll et al. Eur J Vasc Endovasc Surg 2011*
• THANK YOU FOR YOUR ATTENTION
Home Made fenestration Vs. regular fenestration: is there a difference?

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CHU Bordeaux