In situ fenestrations of aortic endografts

Friday November 4th, 2016

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In situ fenestrations of aortic endografts

…Where endovascular surgery meets … architecture
Fenestration: an opening in a surface (as a wall or membrane)

Merriam Webster dictionary

architecture
In situ fenestrations of aortic endografts

- Fenestration: an opening in a surface (as a wall or membrane)  
  Merriam Webster dictionary

- In Situ: In Vivo – Ex Vivo (PMEGs – smFBSGs)

- Why in situ? NEED

- How -? Materials – familiarity of 3D Reconstruction techniques and measurements, is fundamental

- FACTORS affecting durability

- Its durability?

- Is it a safe alternative?

- Thoracic aorta endografts, urgent / emergent or elective (Retrograde)
- Abdominal aorta endografts for covered splanchnic arteries (Anterograde)
- Iliac artery endografts for covered hypogastric arteries
Why in situ fenestrations of aortic endografts?

Extent landing zones for TEVAR proximal to LSA – first human case preserve LSA (2004 AUS)

Rescue inadvertently covered LSA

Endovascular Total Arch Repair (Type A dissection)

Symptomatic pts – acute aortic syndromes – ruptures – lack of “off - the self - devices”

High risk pts – time elapse for custom made devices

Rescue inadvertently covered abdominal visceral vessels (bailout operation)

ThoracoABDOMINAL aorta – surgeons modified branched – fenestrated devices
In situ fenestrations of aortic endografts

Bench studies  
(retrograde: McWilliams RG et al, J EVT 2003;10:946–952)  
(anterograde: Ruthrauff AA et al, J Vasc Interv Radiol 2015;26:1551–8)

Animal studies  
(retrograde: McWilliams RG et al, J EVT 2003;10:946–952)  
(anterograde: Tse LW et al, J EVT 2007;14:158–167)

In Situ: In Vivo Retrograde  
(McWilliams RG et al, J EVT 2004;11:170–174)

Anterograde  
(4 successful human cases)

Ex Vivo – In situ:  PMEGs - sm-FBSGs
In situ fenestrations of aortic endografts

Retrograde in vivo access to intended vessel

deployment of the thoracic endograft

puncture of the fabric of the stent graft with a needle

energy based device: Laser or RF cautery

Anterograde in vivo cases to rescue inadvertently covered abdominal visceral vessels (bailout operation)
In situ (In Vivo) fenestrations of aortic endografts - evidence

From 118 articles – 28 studies - 16 clinical papers (2 case series – 14 case reports)

46 fenestrations aortic branch vessels in 44 pts

LSA 72%, Aortic aneurysm 43%

Technical success 96%

7% combined perioperative mortality, stroke, paralysis

Talent 54%, Zenith 37% (strongest in postfenestration mechanical testing, most resistant to balloon dilatation), TAG 9%

In vitro benchtop evaluation (one year of pulsatile fatigue testing): minimal changes in fenestration size

Energy based fenestrations better than needle ones
**Table I. Summary of included in situ fenestration animal and benchtop studies**

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Model</th>
<th>Percutaneous method</th>
<th>Stent graft</th>
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<tbody>
<tr>
<td>Canalis</td>
<td>2014</td>
<td>Benchtop</td>
<td>Needle</td>
<td>Valiant, TAG</td>
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<td>Kadosh</td>
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<td>Radiofrequency</td>
<td>Zenith, Fenestron, Talent, ePTFE</td>
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<td>Lin</td>
<td>2010</td>
<td>Benchtop</td>
<td>Needle and catheter</td>
<td>Talent, AneuSeal, Zenith</td>
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<td>McWilliams</td>
<td>2003</td>
<td>Canine</td>
<td>Guidewire</td>
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<td>Nannan</td>
<td>2008</td>
<td>Porcine</td>
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<td>Rigs</td>
<td>2009</td>
<td>Porcine</td>
<td>Needle</td>
<td>Zenith</td>
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<tr>
<td>Rigs</td>
<td>2013</td>
<td>Benchtop</td>
<td>Needle</td>
<td>Talent, Zenith, EndoStent</td>
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<td>Rothrauff</td>
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<td>Benchtop</td>
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<td>Endurant, Zenith</td>
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<td>Sazi</td>
<td>2011</td>
<td>Benchtop</td>
<td>Needle</td>
<td>Endurant, TAG, Talent, Valiant, Zenith</td>
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<td>Sazi</td>
<td>2012</td>
<td>Porcine</td>
<td>Needle</td>
<td>Endurant, Talent</td>
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<tr>
<td>Soisson</td>
<td>2012</td>
<td>Porcine</td>
<td>Needle</td>
<td>Endurant</td>
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<tr>
<td>Tse</td>
<td>2007</td>
<td>Canine</td>
<td>Needle</td>
<td>Endurant</td>
</tr>
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</table>

(PTR, Expanded polytetrafluoroethylene)

**Table II. Summary of included in situ fenestration clinical studies**

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>No. of patients</th>
<th>Percutaneous method</th>
<th>Stent graft</th>
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<tbody>
<tr>
<td>Biemans</td>
<td>2012</td>
<td>1</td>
<td>Needle</td>
<td>TAG</td>
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<tr>
<td>Eid Leicht</td>
<td>2008</td>
<td>2</td>
<td>Needle</td>
<td>Zenith</td>
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<tr>
<td>Eisani</td>
<td>2014</td>
<td>2</td>
<td>Needle</td>
<td>Zenith</td>
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<tr>
<td>Elongo</td>
<td>2014</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
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<td>Elongo</td>
<td>2011</td>
<td>1</td>
<td>Needle</td>
<td>TAG</td>
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<tr>
<td>Elongo</td>
<td>2011</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
</tr>
<tr>
<td>Kassim</td>
<td>2012</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
</tr>
<tr>
<td>Koeberl</td>
<td>2012</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
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<td>Mannig</td>
<td>2010</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
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<td>McWilliams</td>
<td>2004</td>
<td>2</td>
<td>Needle</td>
<td>Zenith</td>
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<td>Murphey</td>
<td>2009</td>
<td>1</td>
<td>Laser</td>
<td>Talent</td>
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<td>Redberger</td>
<td>2015</td>
<td>22</td>
<td>Laser</td>
<td>Talent, Zenith</td>
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<td>Socious</td>
<td>2000</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
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<tr>
<td>Tse</td>
<td>2015</td>
<td>8</td>
<td>Radiofrequency</td>
<td>Talent/Zenith</td>
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<tr>
<td>Tschudi</td>
<td>2016</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
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<tr>
<td>Wheeler</td>
<td>2012</td>
<td>1</td>
<td>Needle</td>
<td>TAG</td>
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<tr>
<td>Xiong</td>
<td>2015</td>
<td>1</td>
<td>Needle</td>
<td>Zenith</td>
</tr>
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**Table IV. Demographics, indication, and target fenestrated vessel in patients undergoing in situ fenestration**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (range) or percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>62 (37-85)</td>
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<tr>
<td>Male sex (n = 29)</td>
<td>66</td>
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<tr>
<td>Maximal aortic diameter, mm</td>
<td>55.6 (28-94)</td>
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<tr>
<td>Follow-up, months</td>
<td>11 (0-72)</td>
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<tr>
<td>Urgency</td>
<td></td>
</tr>
<tr>
<td>Symptomatic (n = 23)</td>
<td>52</td>
</tr>
<tr>
<td>Elective (n = 15)</td>
<td>24</td>
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<tr>
<td>Ruptured (n = 6)</td>
<td>14</td>
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<td>Indication</td>
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<tr>
<td>Degenerative aneurysm (n = 20)</td>
<td>45.5</td>
</tr>
<tr>
<td>Chronic type B dissection (n = 10)</td>
<td>22.7</td>
</tr>
<tr>
<td>Intramural hematoma (n = 6)</td>
<td>13.6</td>
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<tr>
<td>Acute type B dissection (n = 5)</td>
<td>11.4</td>
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<tr>
<td>Other (n = 8)</td>
<td>6.8</td>
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<tr>
<td>Fenestrated target vessel</td>
<td></td>
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<tr>
<td>LSA (n = 58)</td>
<td>71.7</td>
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<tr>
<td>Left common carotid artery (n = 5)</td>
<td>10.9</td>
</tr>
<tr>
<td>Brachiocephalic artery (n = 4)</td>
<td>8.7</td>
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<tr>
<td>Renal artery (n = 2)</td>
<td>4.3</td>
</tr>
<tr>
<td>Internal iliac artery (n = 1)</td>
<td>2.2</td>
</tr>
<tr>
<td>Common iliac artery (n = 1)</td>
<td>2.2</td>
</tr>
</tbody>
</table>

**Table V. Complications of in situ fenestration**

| Type II endoleak        | 4 | Endoleak from target fenestrated vessel requiring intervention |
| Access-related complications | 2 | Postoperative hematoma requiring surgical evacuation |
| Death                   | 2 | Presented with aortoesophageal and aortobronchial fistulas |
| Aortic dissection       | 1 | Retrograde aortic dissection caused by deployment of aortic stent graft |
| Paraplegia              | 1 | Immediate postoperative paraplegia after repair of ruptured aortic dissection |
FU mean 11 months (0-72) – no reported occlusions of the fenestrated vessels

Two (4.5%) pts access – related complications (brachial – subclavian artery hematoma – surgical evaluation)

Four (9.1%) pts Endoleak Ic from the fenestrated vessel (coil embolization)

AD: 1, Permanent paraplegia :1, Death: 2 (related to pre-existing aortoesophageal and aortobronchial fistulas)

Conclusions:
In the short to moderate term, in situ fenestration appears to be a reasonable and effective method to extend the proximal landing zone for revascularization of the left subclavian artery. However, longer follow-up is needed to fully assess the long-term durability of this procedure.

Based on studies of material properties, an energy-based fenestration technique (radiofrequency or laser) is recommended, along with the avoidance of cutting balloons for dilation of the fenestration.

Tzilalis VD
Retrograde in situ (in vivo) fenestration technique

Unknown long-term durability of an unreinforced fenestration – absence of a nitinol or stainless steel ring

Fenestration depends only on the fabric composition and the quality of the created fenestration.

Factors:
- Fenestration technique (needle, RF or laser) – angle of “fenestrating instrument” to the graft
- Choice of dilatation (conventional or cutting balloon)
- Fabric composition of the graft

Fenestration technique

Angioplasty balloon
- Laser fen: 2-3 mm – balloon 6 mm
- RF or needle: 1 mm – predilatation 3-4 mm
- Balloon: 2 – 12 mm (76% 6 mm balloon)

Bridging stent selection: 6-12 mm iCast/V12 covered(Atrium) – flaring (10-14 mm angioplasty balloon)
Endovascular Total Arch Repair Using In Situ Fenestration for Arch Aneurysm and Chronic Type A Dissection


Japan Dec 2012 – March 2014:

- 7 pts
- Type A AD: 3
- Thoracic aneurysm: 4

Success 85.7% (one Ax-Ax bypass)

No endoleaks (17.6 +/- 9.4 months)

Two strokes

Late death 2: pneumonia and advanced colon cancer

PTC needle, Hakko, Japan

Fig 1. Details of cardiopulmonary bypass system. The main circuit was reserved as a spare circuit for open conversion, and one of the selective cerebral perfusion circuits was also reserved for left common carotid artery (LCCA) perfusion if transposition was to be performed. (Lt. left; Rt. right.)
Physician Modified Endovascular Grafts (PMEGs)

- For chronic aortic dissection involving the arch branches (Qingsheng Lu, et al J Thorac Cerdiovasc Surg 2015;150:1631-8)

Shanghai, China 2009-2014:
- 51 pts AD (FU 14-66 months, mean 44)
- Type A: 7
- Type A retrograde: 22
- Type B: 22

- 53 branched sections
- 37 fenestrations (6 stented: 16.2%)

- Cervical bypasses: 11 (21.6%)
- Zone 0 Landing: 33 (64.7%)
- Zone 2 Landing: 18 (35.3%)

FU median 44 months (14-66)
No stroke, 6th day one death (retrograde Type A)
All: complete thrombosis of false lumen – significant true lumen recovery
False lumen shrinkage in different levels of aorta (CTA one year)
Physician Modified Endovascular Grafts (PMEGs)

In situ – ex vivo fenestrations of aortic endografts - evidence

In January 2011, the University won unconditional approval from the FDA to conduct a 150 patient trial of PMEGs for juxtarenal aortic aneurysms. At this point, UW Medicine is the only US provider permitted by the FDA and CMS to offer this uniquely promising procedure.

Use of Physician-Modified Stents Presents Serious Risk to Patients

More than a million people are living with an aortic aneurysm, and most don’t know it. An aortic aneurysm is a bulge in a section of the aorta (the body’s “trunk” artery). The area around the aneurysm becomes weak and overstretched, which can cause the aorta to burst, leading to internal bleeding and possibly death.

Aortic aneurysms are traditionally repaired with a well-established open surgical procedure, whereby the physician makes an incision, removes the damaged portion of the artery, and replaces it with a man-made graft.

In more recent years, however, less invasive endovascular procedures have been developed, whereby a tube called a stent graft is inserted through an artery in the groin. While this option has the appeal of avoiding some of the risks and complications of major open surgery, the long-term efficacy of such procedures is still not well-established.

Physicians treating aortic aneurysms frequently modify the stent grafts manufactured by industry to meet the needs of a particular patient. This can be a highly dangerous course of treatment (one that has not been adequately assessed through well-designed and executed clinical studies), the failure of which can lead to such serious consequences as kidney failure and death.

Perhaps recognizing the widespread use of this technique, a senior FDA official has recently warned of senior vascular surgeons concerning the inappropriate use of physician-modified endovascular grafts (PMEGs).
Mean FU 607 days (425-1460)

Contrast mean 98 ml
Fluro time mean 48 min

Technical success 98%
Complications 13%
  3 (6%) access related
  3 (6%) procedure related
stroke
renal failure

Conclusions: PMEG is a safe and effective alternative for treating patients with juxtarenal aneurysms who have no other alternatives for repair. Longer-term follow-up is needed to assess the durability of repair and potential for device-related complications. (J Vasc Surg 2012;56:601-7.)

FU: 6 pts (13%) Endoleak, 1 type I, 5 type II

In hospital and 30 day mortality: 1 (2%) aspiration

FU 2 deaths: cessation of dialysis 58 days, stent migration SMA occlusion 485 days
First year two deaths
Second year one death
One pt with endoleak (2%) secondary intervention – sac expansion
An ophthalmic Bovie cautery device (Medtronic, Minneapolis, Minn) was used to carefully burn the Dacron fabric to create all fenestrations and thus avoid fabric fraying. Gold, 15-mm Amplatz Gooseneck Snares (ev3 Endovascular Inc, Plymouth, Minn) were then used to reinforce all fenestrations. These were hand-sewn into place using 4-0 Prolene suture in a 720 degree running fashion.

Table I. Demographics and patient characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>N (%)</th>
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<tbody>
<tr>
<td>Male</td>
<td>27 (57.4)</td>
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<tr>
<td>Coronary artery disease</td>
<td>23 (48.9)</td>
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<tr>
<td>Congestive heart failure</td>
<td>13 (27.7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>45 (95.7)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>16 (34.0)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>10 (21.3)</td>
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<tr>
<td>Hyperlipidemia</td>
<td>34 (72.3)</td>
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Table II. Physician-modified endovascular graft procedure details

<table>
<thead>
<tr>
<th>Procedural details</th>
<th>Mean or % (range)</th>
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<tbody>
<tr>
<td>Operative time</td>
<td>185 minutes (66-349 minutes)</td>
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<tr>
<td>Fluoroscopy time</td>
<td>48 minutes (4.1-119.2 minutes)</td>
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<tr>
<td>Contrast usage</td>
<td>98 mL (30-204 mL)</td>
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<tr>
<td>Estimated blood loss</td>
<td>119 mL (50-750 mL)</td>
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<tr>
<td>General anesthesia</td>
<td>94%</td>
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</table>

Fig 3. A typical physician-modified endovascular graft (PMEG) prior to device repackaging (A). Fenestrations for the superior mesenteric artery (SMA) (struts present) and left and right renal arteries (strut-free) were created for this particular patient. B, Rerouting of the trigger wire to allow for placement of graft constraining ties.
Early report from an investigator-initiated investigational device exemption clinical trial on physician-modified endovascular grafts

Benjamin Ware Starnes, MD, and Billi Tatum, RN, CRCC, Seattle, Wash

April 2011 – August 2012: 16 month study period

Aneurysm diameter mean 62.5 mm
Proximal neck length 4.4 mm
Graft manufacture time 59.7 minutes
Procedure time 169 min
Contrast 63 ml
Fluro time 42.8 min
Estimated blood loss 221 mL

Technical success: No MAE, only one single minor (successful reintervention)

30 days: 4 type II endoleaks
Two deaths: One day 23 respiratory failure, (3.8% in hospital and 30 day mortality) and one day 210 from urosepsis and CHF

MAE in 30 days: 11.5%, Technical success rate: 100%, Freedom from migration: 100%, Freedom from rupture or conversion: 100%
Freedom from type I or III endoleaks: 87.5%, Freedom from sac expansion: 87.5%

Conclusions: These preliminary data suggest that endovascular repair with PMEG is safe and effective for managing patients with juxtarenal aortic aneurysms. Endovascular repair with PMEG has acceptable early rates of morbidity, mortality, and endoleak. This endovascular aortic strategy is particularly appealing for those patients presenting with symptomatic or ruptured aortic aneurysms until reliable off-the-shelf solutions become widely available. (J Vasc Surg 2013;58:311-7.)

Investigator-sponsored Investigational Device exemption study (IDE) with the approval of the FDA

28 pts consented – 26 PMEGs
38 (80%) symptomatic or rapid aneurysm expansion
63 fens for 48 renal art, stented 96%
15 SMA unstented

PMEGs: Starnes BW, Tatum B, JVS 2013;58: 311-7
PMEGs: Starnes BW, Tatum B, JVS 2013;58: 311-7

In situ - Ex Vivo

Fig 1. Arc length example. The length measurement is between the superior mesenteric artery (SMA) and the left renal artery.

Fig 3. Summary and flow chart of subject enrollment to date.
Nonrandomized, prospective, consecutively enrolling, April 1, 2011 – May 31, 2015
MAE within 30 days, primary efficacy end point: treatment success
Successful delivery and deployment PMEG – preservation of branch vessels
Freedom from type I and III endoleak, stent graft migration > 10mm, sack >5mm
Aortic aneurysm rupture and open conversion

50 months – 64 pts enrolled
60 began and 59 received PMEG

145 fenestrations for:
110 renal art (93% stented)
38 SMA
30 day mortality 5.1 % (3/59)
No open conversion or explantations
Type la: 0
Type lb: 1 (successful reintervention - SE)
Type III endoleaks: 2 (SE)
Overall MAE at 30 days: 11.9%
Primary efficacy end point: 94.1%

Table I. Anatomic inclusion criteria

<table>
<thead>
<tr>
<th>Anatomic criterion</th>
<th>Parameter</th>
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<tr>
<td>Proximal neck diameter, mm</td>
<td>20-32 (OD)</td>
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<tr>
<td>Proximal neck length, mm</td>
<td>≥2</td>
</tr>
<tr>
<td>Juxtarenal aortic angle, degrees</td>
<td>60</td>
</tr>
<tr>
<td>Iliac diameter, mm</td>
<td>8-20 (OD)</td>
</tr>
<tr>
<td>Iliac length (distal seal zone) mm</td>
<td>≥15</td>
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<td>OD: Outer diameter</td>
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Table II. Demographics and patient comorbidities

<table>
<thead>
<tr>
<th>Demographics</th>
<th>No. (%) or mean ± SD (range)</th>
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<tbody>
<tr>
<td>Age, years</td>
<td>74.8 ± 7.9 (59-90)</td>
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<tr>
<td>Male</td>
<td>45 (76)</td>
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<tr>
<td>Coronary artery disease</td>
<td>26 (44.1)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>5 (8.4)</td>
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<tr>
<td>Hypertension</td>
<td>54 (91.5)</td>
</tr>
<tr>
<td>COPD</td>
<td>26 (44.1)</td>
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<tr>
<td>Diabetes mellitus</td>
<td>15 (25.4)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>48 (81.4)</td>
</tr>
<tr>
<td>ASA 3</td>
<td>55 (93.2)</td>
</tr>
<tr>
<td>ASA 4</td>
<td>4 (6.8)</td>
</tr>
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</table>

ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; SD, standard deviation.

Table III. Physician-modified endovascular graft (PMEG) procedure details

<table>
<thead>
<tr>
<th>Procedural details</th>
<th>Mean (range) or %</th>
</tr>
</thead>
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<tr>
<td>Craft manufacture time, minutes</td>
<td>55.1 (13-59)</td>
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<tr>
<td>Operative time, minutes</td>
<td>156.8 (91-427)</td>
</tr>
<tr>
<td>Fluoroscopy time, minutes</td>
<td>39.6 (16-164)</td>
</tr>
<tr>
<td>Contrast material use, mL</td>
<td>75.3 (30-162)</td>
</tr>
<tr>
<td>Estimated blood loss, mL</td>
<td>213 (20-1000)</td>
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<tr>
<td>General anesthesia</td>
<td>96.3%</td>
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</table>

Table IV. Anatomic details of treatment group

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean ± SD (range)</th>
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<tbody>
<tr>
<td>Maximum aneurysm diameter, mm</td>
<td>65.9 ± 12.2 (69-104)</td>
</tr>
<tr>
<td>Proximal aortic neck length, mm</td>
<td>5.4 ± 3.2 (2-13)</td>
</tr>
<tr>
<td>Proximal seal zone length, mm</td>
<td>40.8 ± 6.7 (18.9-72)</td>
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</tbody>
</table>
**Table V.** Mortality and lengths of stay

<table>
<thead>
<tr>
<th></th>
<th>No. (%) or mean ± SD (range)</th>
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</thead>
<tbody>
<tr>
<td>Thirty day mortality</td>
<td>3 (5.1)</td>
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<tr>
<td>ICU length of stay, days</td>
<td>2.2 ± 3.3 (0.5-19.7)</td>
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<tr>
<td>Hospital length of stay, days</td>
<td>4.1 ± 4.2 (1.1-27.4)</td>
</tr>
</tbody>
</table>

*ICU: Intensive care unit; SD: standard deviation.*

**Table VI.** Primary effectiveness end point: Treatment success

<table>
<thead>
<tr>
<th>Criteria</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>57/60 (95)</td>
</tr>
<tr>
<td>Freedom from migration at 12 months</td>
<td>44/44 (100)</td>
</tr>
<tr>
<td>Freedom from rupture or conversion at 12 months</td>
<td>44/44 (100)</td>
</tr>
<tr>
<td>Freedom from type I or III endoleaks at 12 months</td>
<td>42/44 (95.5)</td>
</tr>
<tr>
<td>Freedom from sac enlargement at 12 months</td>
<td>43/44 (97.7)</td>
</tr>
</tbody>
</table>

At 12 months, 94.1% of patients met the primary effectiveness end point; 93.2% of patients with 1-year follow-up met all four composite end points.

**Table VII.** Primary safety end point: Major adverse events (MAEs) within 30 days

<table>
<thead>
<tr>
<th></th>
<th>Postprocedure</th>
<th>One month</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of subjects</td>
<td>59</td>
<td>56</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>3 (5.1%)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>3 (5.1%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>3 (5.1%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>1 (1.7%)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0</td>
<td>1 (1.7%)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>0</td>
<td>4 (6.8%)</td>
</tr>
<tr>
<td>Paralysis</td>
<td>1 (1.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>1 (1.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Procedural blood loss</td>
<td>1 (1.7%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Within 30 days, 11.9% of patients experienced one or more MAEs.

*Four events in the same subject.*

*Five events in the same subject.*
**PMEGs:** Starnes BW, Heneghan RH, Tatum B.
*JVS in press* Submitted Apr 11, 2016; accepted Jul 24, 2016

*In situ - Ex Vivo*

**Fig 5.** Freedom from reintervention.

**Fig 4.** Kaplan-Meier survival curves for physician-modified endovascular graft (PMEG). Freedom from all-cause mortality (blue) and aneurysm-related mortality (ARM; red) to 4 years. One patient died of rupture 1 day before being treated.

**Fig 2.** Endoleaks by type and number throughout the study period (60 months).

**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 2016;11:9)
Fig 6. Seal zone length in standard endovascular aneurysm repair (EVAR; left) compared with physician-modified endovascular graft (PMEG; right).

In situ - Ex Vivo

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 2016;1-9)

Fig 7. A typical example of a physician-modified endovascular graft (PMEG) device that cannot be manufactured or sold within the United States as a ZFEN device but is easily available under our investigational device exemption (IDE) clinical trial. A. Intraoperative photograph of the actual graft created for a patient with a solitary right kidney and a superior mesenteric artery (SMA) origin that is close to the origin of the right renal artery. B. Preoperative computed tomography angiography axial image. C. Intraoperative angiogram showing successful implantation. D. Axial image at 1 year demonstrating a widely patent SMA and right renal artery.
Vascular surgeon Dr. Benjamin W. Starnes pioneered a new treatment for abdominal aortic aneurysms. Now he is using 3D printing to perfect it.

A 3D printed replica of patients' aortas helps doctors create precise fenestrations in stent grafts.

A 3D printer creates an exact replica of a patient's aorta from a digitized CT scan. Starnes then makes precise fenestrations, using the 3D mold as a guide.
Custom fenestration templates for endovascular repair of juxtarenal aortic aneurysms

Daniel F. Leotta, PhD, a and Benjamin W. Starnes, MD, b Seattle, Wash

Physician-modified endovascular grafts, with fenestrations added to accommodate major branch vessels, provide a means for endovascular treatment of abdominal aortic aneurysms that are adjacent to the renal arteries. Manual measurements of vessel origin locations from computed tomography images, however, take time and can lead to errors in the positions of the fenestrations. To make the fenestration process faster and more accurate, we have developed a procedure to create custom templates that serve as patient-specific guides for graft fenestration. We use a three-dimensional printer to create a clear rigid sleeve that replicates the patient’s aorta and includes holes placed precisely at the locations of the branch vessels. The sleeve is slipped over the graft, the locations of the openings are marked with a pen, and the fenestrations are created after the sleeve is removed. Custom fenestration templates can potentially save procedural costs and make minimally invasive aortic aneurysm repair available to more patients. (J Vasc Surg 2015;61:1637-41.)
Custom fenestration templates for endovascular repair of juxtarenal aortic aneurysms

(F Vasco Surg 2015;61:1637-41.)

Fig 1. Three-dimensional (3D) display of the traced lumen contours of the abdominal aortic aneurysm (AAA) proximal neck for the demonstration data set. The branch vessel origin locations are displayed as spheres.

Fig 2. Fenestration template computer-assisted design model. The lumen contours shown in Fig 1 were converted to a solid model format compatible with a three-dimensional (3D) printer. A, Polygon model of the aneurysm proximal neck. B, Combined display of the proximal neck model and cylinders at each of the branch vessel origins. The cylinder diameters are set to match the branch vessel opening diameters as measured from the original computed tomography (CT) images. SMA, Superior mesenteric artery. C, The result of the Boolean difference between the proximal neck object and each cylinder is a hole in the aorta model at the location of each of the branch vessel origins.
Custom fenestration templates: Leotta DF, Starnes BW

(J Vasc Surg 2015;61:1637-41.)
Physician-sponsored Investigational Device exemption study (IDE) with the approval of the FDA

Physician Modified Endovascular Grafts (PMEGs) and

Surgeon – modified Fenestrated - Branched Grafts (sm-FBSGs)

Surgeon-modified fenestrated-branched stent grafts to treat emergently ruptured and symptomatic complex aortic aneurysms in high-risk patients

(J Vasc Surg 2012;56:1535-43.)

Joseph J. Ricotta, II, MD, MS, and Nikolaos Tsilimparis, MD, Atlanta, Ga

12 pts (9 men) – 7 ASA IV – 5 ASA III
7 symptomatic – 5 ruptures
71 years mean (52-86) – aneurysm size 8.1 cm (5-12)
50 prior aortic surgery or hostile abdomen
Treated: 3 visceral arteries (2-4) per patient – 35 targeted
All sm-FBSGs successfully implanted
No stroke – no paraplegia - no intraoperative death

One (8.3%) died subarachnoid hemorrhage ≤ 30 days
Reintervention for 2:
Type III endoleak and for retroperotopneal hematoma
One MI , one transient respiratory failure and one RF not requiring dialysis
Mean postop stay 4 days ICU – 8 in the hospital
Mean FU 9 months (3-18) 2 deaths (non - aneurysm related)
Branch vessel patency 100% - one type II endoleak

Tzilalis VD
Physician-sponsored Investigational Device exemption study (IDE) with the approval of the FDA

Surgeon-modified fenestrated-branched stent grafts to treat emergently ruptured and symptomatic complex aortic aneurysms in high-risk patients

(J Vasc Surg 2012;56:1535-43.)

Joseph J. Ricotta, II, MD, MS, and Nikolaos Tselimparis, MD, Atlanta, Ga

Conclusions: Sm-FBSG may play an important role in the treatment of select patients with symptomatic or ruptured complex aortic aneurysms who are at prohibitive risk for open surgery and in whom endovascular repair cannot be delayed to allow implantation of a custom-made commercial device. Until an off-the-shelf fenestrated-branched device is created that does not require a prolonged waiting period, this may be the best option to treat patients with symptomatic ruptured complex aneurysms that are at excessively high surgical risk. (J Vasc Surg 2012;56:1535-43.)
Physician Modified Endovascular Grafts (PMEGs) and

Surgeon – modified Fenestrated - Branched Grafts (sm-FBSGs)

Physician-sponsored Investigational Device exemption study (IDE) with the approval of the FDA

TX2 Zenith, AAA Zenith (Cook)
AAA Endurant (Medtronic)

In situ - Ex Vivo

Fig. 1. A, A computed tomography (CT) scan demonstrates contained rupture of a type IV thoracoabdominal aortic aneurysm (TAAA) (arrow). B, Centreline of flow analysis reconstruction of a CT scan demonstrates rupture and preoperative measurements made to plan construction of a four- vessel fenestrated branched device. C, Surgeon-modified Zenith TX2 endograft with four reinforced fenestrations to revascularize the visceral vessels.

Fig. 2. A, An intraoperative angiogram demonstrates rupture of the thoracoabdominal aorta. B, Intraoperative fluoroscopy shows all four fenestrations and target visceral vessels cannulated with sheaths and wires before release of diameter-reducing ring and complete deployment of the fenestrated endograft. C, Completion angiogram after successful repair of ruptured type IV thoracoabdominal aortic aneurysm (TAAA) shows patency of all four branch-stems in place in the target vessels and no evidence of endoleak.
Retrograde Fenestration of Endoluminal Grafts
From Target Vessels: Feasibility, Technique, and Potential Usage

Richard G. McWilliams, FRCS, FRCSI; Shirley J. Fearn, FRCS, PhD;
Peter L. Harris, MD, FRCS; David Hartley, FRCS; James B. Semmens, MSc, PhD;
and Michael M. D. Lawrence-Brown, FRACS

1Royal Liverpool University Hospital, Liverpool, England, UK. 2Centre for Health Services Research, School of Population Health, The University of Western Australia, Nedlands, Western Australia. 3Department of Vascular Surgery, Royal Perth Hospital, Perth, Western Australia.

Purpose: To report initial experiments involving a new method for percutaneous intraprocedural stent-graft fenestration from the target vessel.

Technique: In bench and canine models, the fabric of an implanted Zenith endograft was punctured easily using the stiff end of a coronary 0.014-inch guidewire delivered through the target vessel (e.g., renal or iliac artery). A 20-G cutting needle was passed over the coronary wire to enlarge the puncture site, followed by a cutting balloon to create a fenestration that was of sufficient size to allow deployment of a stent.

Conclusions: In vivo endograft fenestration of a Zenith endograft is feasible. In addition to providing a percutaneous means of intentionally fenestrating a stent-graft from the artery to be perfused, the technique has potential application as a bailout maneuver after inadvertent side branch occlusion. Although the time to achieve successful fenestration in the experimental model was long, refinement may achieve performance times adequate to maintain viability of the end organ.
How things started in 2003

Figure 1: (A) Side view of a Zenith endograft and the application of a cutting balloon to create a fenestration in the fabric. (B) The fenestration has been stented with a 3.5-mm coronary stent.

Figure 2: An example of in vivo renal artery fenestration tested in a canine model. (A) A 5-mm angioplasty balloon shows a waist at the level of the fabric during attempted enlargement of the fenestration created by a cutting balloon. (B) The graft has been explanted and opened to show the stented luminal surface of the in vivo renal artery fenestration.

Figure 3: (A) Retrograde angiogram from the left iliac artery shows exclusion of the artery from antegrade flow by a stent-graft deployed from the aorta into the right iliac artery. (B) The fabric has been punctured using the stiff end of a coronary guidewire from the left iliac artery. The wire tip is now within the lumen of the graft at the aortic level. (C) A 4-mm cutting balloon is fully inflated at fabric level with no waist. (D) An AVE Bridge stent is inflated fully across the fenestration. (E) Completion angiogram shows restoration of antegrade flow to the left leg. The graft delivery sheath fills the right iliac system, which shows no flow.

Figure 4: (A) The explanted graft with AVE stent through the fenestration in the fabric. (B) The luminal surface of the fenestration. There has been deliberate intraprocedural flaring of the aortic portion of the AVE stent using a compliant balloon.
TX1 Zenith Cook - A 7-mm balloon was passed through the 6-F sheath in the LSA and positioned against the fabric of the thoracic graft where it covered the LSA ostium. The balloon was inflated and the fabric punctured with the reversed end of a SV-5, 0.018-inch guidewire (Cordis Endovascular, Miami, FL, USA) introduced through the guidewire lumen of the balloon.
Conclusion: This radiofrequency device allowed successful fenestration but was difficult to control. Technical improvements are required to improve clinical success and patency.
Antegrade In Situ Stent-Graft Fenestration for the Renal Artery Following Inadvertent Coverage During EVAR

Tilo Kölbl, MD, PhD; Sebastian William Carpenter, MD; Holger Diener, MD; Sabine Wipper, MD, PhD; Elke Sebastian Debus, MD, PhD; and Axel Larena-Avellaneda, MD, PhD

University Heart Center Hamburg Eppendorf, Hamburg, Germany.

Purpose: To report the use of antegrade in situ fenestration as a bailout technique to rescue a renal artery after inadvertent coverage during endovascular aneurysm repair (EVAR).

Technique: The technique is demonstrated in a patient with a 6-cm infrarenal abdominal aortic aneurysm (AAA) and a short, angulated proximal neck. A type I endoleak persisted on completion angiography after implantation of a bifurcated Zenith stent-graft despite dilation with a compliant balloon. A Giant Palmaz stent mounted on a large compliant balloon successfully resolved the endoleak. After placing the stent, the left renal artery was covered completely by the main aortic graft material, leading to only marginal opacification on angiography. To preserve flow to the renal artery, a transseptal sheath and transseptal needle were introduced from the right femoral artery and used to puncture the abdominal stent-graft antegrade at the site of the left renal artery. A 0.018-inch guidewire could then be introduced into the left renal artery; following a number of maneuvers, a balloon-expandable stent was placed through the fenestration into the target vessel. On computed tomographic angiography 4 days postoperatively, the AAA remained excluded and both renal arteries were patent, with all side branches fully preserved. Renal function was completely restored.

Conclusion: Antegrade in situ fenestration can facilitate immediate revascularization of inadvertently covered side branches in EVAR using a transseptal sheath and needle. If the anatomical features are supportive, antegrade in situ fenestration can be a useful bailout technique.
In Situ Fenestration of the Internal Iliac Artery as a Bailout Technique Associated With Endovascular Repair of an Abdominal Aortic Aneurysm: Long-term Follow-up

Grayson H. Wheatley III, MD
Department of Cardiovascular Surgery, Arizona Heart Institute, Phoenix, Arizona, USA.

Purpose: To describe a bailout technique for in situ fenestration of an inadvertently covered internal iliac artery (IIA) associated with endovascular repair of an abdominal aortic aneurysm (AAA).

Technique: The procedure is demonstrated in a 76-year-old patient who underwent elective repair of a 5-cm infrarenal AAA using an Excluder endovascular graft 2 years following thoracic aortic stent-graft repair of a chronic type B aortic dissection. A completion angiogram demonstrated unintentional coverage of the left IIA. The iliac limb of the stent-graft was not able to be displaced away from the ostium, so to preserve IIA perfusion in a patient with prior thoracic aortic stent-grafting, a bailout technique was performed using an Outback re-entry device to successfully fenestrate the polytetrafluoroethylene graft material. An iCast balloon-expandable stent was placed across the fenestration creating a patent side branch to maintain patency. Six-year follow-up demonstrates a stable repair.

Conclusion: In situ fenestration of a stent-graft overlying the internal iliac artery can be a useful bailout technique when other options are unsuccessful.


Figure (A) Angiogram demonstrating a patent contralateral limb of an Excluder endoluminal graft obstructing flow to the left IIA (arrow). (B) Angiogram demonstrating successful in situ fenestration of the endoluminal graft and deployment of a covered stent into the IIA, restoring flow (arrow). (C) Six-year follow-up computed tomography scan of the abdominal aorta documenting a patent branch graft into the left IIA (arrow) created using an in situ fenestration technique.
Ross modified Colapinto needle from a transjugular intrahepatic access set. The hole in the fabric is then enlarged with a cutting balloon and a high-pressure noncompliant balloon. Two balloon-expandable covered stents are positioned and simultaneously deployed.

To date, this technique has been successfully used in 4 patients with satisfactory short-term results. **Conclusion:** This technique represents another application of endograft in situ fenestration. This strategy provides a bifurcated repair in cases where bifurcated stent-grafts are usually precluded, such as a narrow distal aorta, ruptured abdominal aortic aneurysm, or combined aortoiliac occlusive disease.
In situ fenestration of aortic stent grafts has the potential to allow for continued perfusion of supra-aortic trunks, without the need for extra-anatomic bypass, and without the need for custom-made devices. Angulation of the target vessel relative to the arch is an obstacle to success with this technique. In this report, we describe a case of successful in situ fenestration of the left subclavian artery (LSA) in a patient with an aortic arch aneurysm, treated with an endovascular stent graft. We outline a novel technique using through and through wire access and a pre-curved semi-rigid sheath, which allows successful access to the lumen of the aortic stent graft, despite an acute angle at the take-off of the LSA. (J Vasc Surg 2010;52:491-4.)
To overcome the problem, the cephalad portion of the proximal disconnected limb overlying the main body gate was successfully fenestrated with an endoscopic FNA needle and continuity restored with a Viabahn stent-graft across the balloon-modeled fenestration.
Antegrade in situ fenestration was carried out with radiofrequency puncture followed by balloon dilation with either conventional or cutting balloons. Renal covered stents were deployed and flared. Specimens were mounted onto an accelerated fatigue tester for 40 Mcycles (1 patient life-year), and evaluated with microscopy, caliper measurements, and fabric counts.
Results: Cutting balloons resulted in more fabric fraying. None of the fenestrations grew beyond the targeted 6-mm diameter despite accelerated fatigue. Fluoroscopic images demonstrated a very prominent waist of the renal fenestration in the Cook device when a conventional balloon was used compared with a cutting balloon. The average fenestration diameter for the Cook device was only 3.1 mm with the conventional balloon compared with 4.8 mm with the cutting balloon. The average fenestration diameter for the Medtronic device was 3.8 mm with the conventional balloon compared with 5.1 mm with the cutting balloon. The fabric counts suggested crowding of yarns around the fenestrations with conventional balloons but less with cutting balloons.
Conclusions: This experimental work suggests that the size of in situ renal fenestrations does not expand beyond the target diameter despite cyclic fatigue. Although the small number of devices tested and selected aortorenal anatomy in this study may limit conclusions, textile analysis suggests that cutting balloons should be used for the Cook Zenith device, whereas conventional balloons should be used for the Medtronic Endurant device when performing in situ fenestration.
More fenestrated grafts
Decrease cost
Increase availability
More anatomic configuration

Objectives: In situ fenestration of endovascular stent grafts is a technique that is becoming more common, as it has the advantages of decreased cost, increased availability, and more anatomic configuration than other methods of branch revascularization. However, a significant concern is the short- and long-term durability of the stent graft fabric during and after fenestration.

Short and long term durability

Methods: This study utilizes the textiles analysis techniques of macro- and microscopic imaging, tear strength testing, burst strength testing, and accelerated cyclic fatigue testing on the fabrics of the Cook Zenith, Medtronic Talent, and Medtronic Endurant stent grafts (three polyester grafts), as well as two different expanded polytetrafluoroethylene (ePTFE) membranes. Specimens were punctured using radiofrequency, and serially dilated with angioplasty balloons (3, 5, and 7 mm). For each type of fabric, three groups were analyzed: control, radiofrequency (RF) puncture only, and balloon dilated.

Δύναμη για πρόκληση ρήγματος
Δύναμη διάρρηξης
Επιταχυνόμενες δοκιμές κυκλικής κόπωσης
Zenith Cook  (polyester)
Talent Medtronic   ..
Endurant Medtronic  ..
Two different membranes  ePTFE

RF, angioplasty balloons 3,5,7mm
Graft Durability and Fatigue after In Situ Fenestration of Endovascular Stent Grafts Using Radiofrequency Puncture and Balloon Dilatation

L.A. Eadie a, G. Soulez b, M.W. King a,c, L.W. Tse d, e

European Journal of Vascular and Endovascular Surgery


Figure 4. Images from the stereoscopic zoom microscope showing ballooned fenestrations in (A) Zenith (×30); (B) Endurant (×8), and (C) Talent (×8) fabrics; (D) conventional ePTFE (×8) and (E) prototype ePTFE (×8) membranes.

Results: A total of 110 specimens were analyzed, with 80 of them having been fenestrated. The Zenith fabric had the greatest strength after fenestration, but was limited by the inability to fully dilate the fenestration with the conventional balloons, which only achieved 26–29% of their nominal balloon diameter. While the Talent and Endurant grafts could be dilated with balloons, the orifices were markedly elliptical not circular. After accelerated fatigue testing, there was an increase in the size of fenestrations of the Talent fabric. There was no increase in fenestration size for the Endurant fabric, Zenith fabric, or the ePTFE fabrics, after fatigue testing.
Overall, the Zenith fabric had the greatest strength with respect to tearing strength and bursting strength, both before and after RF puncture and balloon expansion. However, the inability to achieve a large enough fenestration diameter precludes its use with conventional angioplasty balloons. Further work with stents, cutting balloons, and high-pressure balloons would be required for the Zenith fabric. The high variability observed in the ePTFE samples makes it more difficult to predict their in vivo performance. However, for all the materials selected, except the Talent sample, there was no increase in fenestration dimensions during fatigue testing after in situ fenestration using RF puncture and balloon angioplasty.
In-situ fenestration of stent-grafts: an in-vitro study of the influence of different fabric structures

Jing Lin¹, Naval Udgiri², Jia Du¹, Lu Wang¹, Robert Guidoin³, Mark Nutley⁴, Jean Panneton² and Yvan Douville³

¹ Donghua University, Key Laboratory of Textile Science and Technology of Ministry of Education and College of Textiles, China
² Eastern Virginia Medical School, Division of Vascular Surgery, United States
³ Laval University and Québec Biomaterials Institute, Departments of Surgery and Radiology, Canada
⁴ Peter Lougheed Health Centre and The University of Calgary, Division of Vascular and Endovascular Surgery and Department of Diagnosis Imaging, Canada

**Materials and methods:** Three types of aortic stent-grafts, the Zenith TX2 (multifilament woven fabric), the Anaconda (multifilament woven fabric) and the Valiant (monofilament woven fabric) were used to perform an in-situ fenestration in vitro. The perforation was initially performed using a laser probe with 1.7 mm, 2.0 mm or 2.3 mm in diameter which was then dilated by an angioplasty balloon with 8 mm, 10 mm or 12 mm in diameter. The fenestrations were observed by gross observations, light microscopy and SEM. The MIXED procedure of the SAS program was used for statistical analysis after the area and the maximal length (in warp and weft of fabrics) of the fenestrated ostia was measured (Figure 1).

Figure 2. Fenestration with laser probe in 2.3 mm followed balloons. (a) Zenith TX2; (b) Anaconda; (c) Valiant
In-situ fenestration of stent-grafts: an in-vitro study of the influence of different fabric structures

Jing Lin¹, Naval Udgeir², Jia Du¹, Lu Wang¹, Robert Guidoin³, Mark Nutley⁴, Jean Panneton² and Yvan Douville²

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² Eastern Virginia Medical School, Division of Vascular Surgery, United States
³ Laval University and Quebec Biomaterials Institute, Departments of Surgery and Radiology, Canada
⁴ Peter Lougheed Health Centre and The University of Calgary, Division of Vascular and Endovascular Surgery and Department of Diagnosis Imaging, Canada

Figure 1. Schematic diagram illustrating the surface areas and the lengths of the fenestrations.

Conclusions: The area and length of fenestration was more predictable with the 8 mm angioplasty balloon. The fabric of Valiant was easier to tear and caused an over enlarged fenestration compared other devices. Thus, the surgeon should make a prudent selection on the stent-grafts and the instruments of fenestration. The in-situ fenestration must currently be restricted to urgent and emergent cases using laser probe and an 8 mm diameter balloon.

This project was supported by the 111 Project (B07024) and Shanghai Construction of College Experimental Technique Team Project (101-07-0053014).
Laser Generated *In situ* Fenestrations in Dacron Stent Grafts

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**WHAT THIS PAPER ADDS**

There is an ongoing discussion around whether or not it is safe to cover the left subclavian artery (LSA) during thoracic endovascular aneurysm repair. The standard technique for LSA revascularization is either carotid—subclavian bypass or transposition. These sometimes demanding procedures are associated with a 6—13% mortality/stroke rate. Evolving endovascular techniques for LSA revascularization include *in situ* fenestration. In this experimental porcine model, an excimer laser was used to fenestrate Dacron stent grafts to determine whether graft fabric or coagulated blood embolized during the procedure. No macroscopically visible emboli/clot could be detected. This might indicate safe usage of laser created fenestrations in the arch vessels.

**Conclusion:** Creation of laser generated, *in situ* fenestrations do not produce macroscopically visible emboli/clot. This might indicate safe usage of laser created fenestrations for endovascular arch repair and left subclavian artery revascularization.

OTW laser catheter (.0014 or .0018, 2.0 Turbo Elite OTW; Spectranetics, Colorado Springs, CO, USA). The use of the IM guiding catheter allowed the laser catheter to be steered and positioned optimally in relation to the intended fenestration site. The laser catheter was connected to a CVX-300 Excimer Laser (Spectranetics). This is a “cold” laser operating at 308 nm in the ultraviolet (UV) wavelength.
In Vitro Fenestration of Aortic Stent-Grafts: Implications of Puncture Methods for in Situ Fenestration Durability

Celia V. Riga, MD, MRCS\textsuperscript{1,2}; Colin D. Bicknell, MD, FRCS\textsuperscript{1,2}; Melvinder Basra, BS\textsubscript{0}, MRCS\textsuperscript{2}; Mohamad Hamady, FRCR\textsuperscript{3}; and Nicholas J.W. Cheshire, MD, FRCS\textsuperscript{1,2}

\textsuperscript{1}Department of Surgery and Cancer, Imperial College London, and \textsuperscript{2}Imperial Vascular Unit and \textsuperscript{3}Department of Interventional Radiology, Imperial College Healthcare NHS Trust, London, UK.

Talent monofilament, Zenith multifilament, Endofit thin wall ePTFE.

Punctures were made at 30\textdegree, 60\textdegree, and 90\textdegree angles using a 20-G needle and dilated using 6-mm standard and 7-mm cutting balloons; at least 6 fenestrations were made at each angle with standard balloons and at least 6 with cutting balloons.

Results: PTFE grafts were easier to puncture/dilate, resulting in larger, elliptical fenestrations with overall better quality than the Dacron grafts; however, the puncture/dilation angle made an impact on the shape and quality of fenestrations. A significant number of fabric tears were observed in PTFE fabric at <90\textdegree puncture/dilation angles compared to Dacron grafts. In Dacron grafts, fenestration quality was significantly higher with 90\textdegree puncture/dilation angles (higher in Talent grafts). Cutting balloon use resulted in significantly more fabric tears and poor quality fenestrations in all graft types.

Conclusion: Different endografts behave significantly differently when fenestrations are fashioned. Optimum puncture/dilation is important when considering in vivo fenestration techniques. Improvements in instrumentation, materials, and techniques are required to make this a reliable and reproducible endovascular option.

Attention! for future endoleaks III
Magnetic apparatus for in situ location of a graft fenestration site and method of using same

WO 2009056644 A1
Radiofrequency In Situ Fenestration for Aortic Arch Vessels During Thoracic Endovascular Repair

Leonard W. Tse, MD, FRCSC, MASc¹, Thomas F. Lindsay, MDCM, MSc, FRCSC¹, Graham Roche-Nagle, MD, MBA, FRCSI, EBSQ-VASC¹,
George D. Oreopoulos, MD, MSc, FRCSC¹, Maral Ouzounian, MD, PhD, FRCSC¹, and Kong Teng Tan, MD, FCRS, FRCR, FRCPC¹

2011 – 2013: 40 TEVAR - 10 (Valiant 5, Zenith TX2 5) in situ fenestrations
6/10 technical success
0.035-inch PowerWire RF (Baylis),
brachial approach LSA:9, LCCA:1, fens dilation to 6 mm, Advanta V12
No fenestration-related complications but:
Case of paraparesis CSFD, one death of preexisting aortoesophageal fistula.
No postoperative strokes - Patent fenestrations 12 month FU (1-13) – no endoleaks
transseptal BRK™ needle (St. Jude Medical, Inc., St. Paul, Minnesota), in situ fenestration was performed 2 cm below the top of the graft while it was positioned well within the aneurysm sac to ensure that no aortic injury occurred. A .014” wire was then advanced across the aneurysm sac into the left renal artery, followed by a Quick-Cross catheter (Spectranetics, Colorado Springs, CO).
Surgical Technique

Pump-Assisted Total Arch Replacement Using an In Situ Stent Graft Fenestration Technique

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Abstract We describe an endovascular technique using in situ stent graft fenestration and pump assist to repair a pseudoaneurysm of the transverse arch following previous ascending aortic and transverse arch replacements. doi: 10.1111/jocs.12395 (J Card Surg 2014;29:816-820)

Figure 4. Schematic drawing of the surgical plan. Right femoral cutdown was used for insertion of stent (femoral artery) and RA cannula insertion (femoral vein).
Endovascular total aortic arch replacement by in situ stent graft fenestration technique

TECHNICAL NOTE

Björn Sönesson, MD, PhD, Tim Resch, MD, PhD, Mats Allers, EBCP, and Martin Malina, MD, PhD, Malmö, Sweden

Open surgical total aortic arch replacement is a demanding procedure which carries a substantial morbidity and mortality. A less invasive endovascular option is endovascular stent grafting using in situ fenestrations. After thoracic stent graft deployment in the arch, fenestrations are made for the major arch vessels. During this procedure, antegrade cerebral perfusion is maintained using a temporary bypass from the left femoral artery to both carotids perfusing both the anterior and posterior cerebral circulation. The endovascular technique and devices used are herein described. (J Vasc Surg 2009;49:1589-91.)
A thoracic stent graft COOK ZTEG-2P-42-216, Bjaereskov, Denmark) was introduced percutaneously through the right CFA and positioned 1.5 cm above the coronary artery ostia.

A 20-cm long, 20-gauge special needle (Mediplast, Malmö, Sweden) was used to puncture the stent graft through the left 6F CCA introducer. A 0.014 coronary wire (Shinobi, Cordis, Miami, Fla) was then passed into the stent graft. The graft perforation was sequentially dilated with a 2-mm balloon (Maverick, Boston Scientific, Galway, Ireland) and a 3-mm cutting balloon (Boston Scientific, Letterkenny, Ireland). After this, a percutaneous nephrostomy access set (COOK) was placed into the stent graft to exchange the 0.014 wire to a 0.035 wire (Amplatz super stiff, Boston Scientific, Natick, Mass) placed in the ascending aorta. The 6F introducer was exchanged for a 7F Flexor sheath (COOK) and a balloon-expandable stent (Visi-Pro 8/37, EV3, Plymouth, Mass) was deployed through the fenestration. Due to proximity of the stent to an aortic stent graft strut, some waisting occurred but this resolved after high pressure PTA (Conquest 8 mm, Tempe, Ariz). For reinforcement, another Visi-Pro stent was placed inside the first.
VASCULAR AND ENDOVASCULAR TECHNIQUES

Peter F. Lawrence, MD, Section Editor

New temporary internal introducer shunt for brain perfusion during total endovascular arch replacement with in situ fenestration technique

Björn Sönnasson, MD, PhD, Tim Resch, MD, PhD, Nuno Dias, MD, PhD, and Martin Malina, MD, PhD, Malmö, Sweden

Complete endovascular arch replacement by in situ fenestration technique requires maintenance of cerebral perfusion during the fenestration procedure by an extracorporeal femoral-carotid bypass. The bypass has the disadvantages of being invasive, requiring a pump, and shunting blood extracorporeally. This report describes bench testing and an in vivo experimental animal setup with an endovascular, temporary introducer shunt. This technique represents an adjunctive step toward a complete endovascular repair for the aortic arch. (J Vasc Surg 2012;56:1162-5.)

Fig 1. Schematic drawing of the introducer shunt shows that when the aortic stent graft is deployed, the flow (arrows) will go from the descending aorta into the introducer shunt and innominate and left carotid arteries.

APPENDIX. POISEUILLE’S LAW

\[ Q = \pi r^4 \left( P_1 - P_2 \right) / 8 \eta L \]

Where \( Q \) = flow; \( r \) = inner radius of the introducer; \( P_1 - P_2 \) = pressure difference (eg, innominate/left carotid and descending aorta distal to the aortic stent graft; \( L \) = length of the introducer (30 cm); and \( \eta \) = viscosity, at a normal hematocrit of 40%, the relative viscosity of blood is \( = 4. \)
Novel temporary endovascular shunt technique to assist in situ fenestration for endovascular reconstruction of the distal aortic arch

Jiang Xiong, MD, Wei Guo, MD, Xiaoping Liu, MD, Xin Jia, MD, Xiaohui Ma, MD, and Lijun Wang, MD, Beijing, China

Thoracic endovascular aortic repair (TEVAR) of arch pathology presents special challenges for revascularization. To obtain an anatomic reconstruction of the arch arteries, in situ fenestration with extra-anatomic bypass has been increasingly used in TEVAR. We report a case involving TEVAR for a pseudoaneurysm at zone 2 of the thoracic aorta in a 37-year-old man with the use of in situ fenestration assisted by a temporary endovascular shunt technique. (J Vasc Surg 2015;62:226-8.)

two 9F 85-cm sheaths (Starway Medical Technology, Inc, Beijing, China) with an oval side port (2 10 mm and 30 cm to the tip) made during the procedure were used to establish a TES 32 160-mm Zenith TX2 SG – Jotec covered
Through a retrograde left brachial artery access, an 8-F Lamp sheath (St. Jude Medical, St. Paul, MN, USA) with preformed angle at the tip was placed. A 2.0 to 2.5-mm Turbo Elite laser catheter (Spectranetics, Colorado Springs, CO, USA) over a 0.018-inch Platinum Plus wire (Boston Scientific, Natick, MA, USA) was placed at the ostium of the left LSA perpendicular to the endograft. After the Dacron thoracic endograft was deployed, laser energy was applied in conjunction with gentle laser endograft contact pressure for 3 to 5 seconds to create a fenestration.
In Situ Laser Fenestration for Revascularization of the Left Subclavian Artery During Emergent Thoracic Endovascular Aortic Repair

Sadaf S. Ahanchi, MD; Babatunde Almaroof, MD; Christopher L. Stout, MD; and Jean M. Panneton, MD

Division of Vascular Surgery at Eastern Virginia Medical School, Norfolk, Virginia, USA.
In situ laser fenestration during emergent thoracic endovascular aortic repair is an effective method for left subclavian artery revascularization

Richard E. Redlinger Jr, MD, Sadaf S. Ahanchi, MD, and Jean M. Pannecon, MD, Norfork, Ya

September 2009 through August 2012 TEVAR was performed with deployment of a Talent or Valiant (Medtronic Inc, Santa Rosa, Calif), TX2 (Cook Inc, Bloomington, Ind), or TAG (W. L. Gore & Associates, Flagstaff, Ariz) grafts.

An 8F Lamp sheath (St. Jude Medical, St. Paul, Minn), with a preformed angle at the tip, was placed through retrograde left brachial artery access at the ostium of the LSA. A 2.0- to 2.5-mm Turbo Elite laser catheter (Spectranetics, Colorado Springs, Colo) was placed at the ostium of the LSA perpendicular to the endograft over a 0.018-inch Platinum Plus wire (Boston Scientific, Natick, Mass).

TEVAR with laser fenestration was successfully performed in 22 patients (12 men; mean age, 57 years) in an urgent or emergent setting secondary to unremitting symptoms or rupture.

Twelve patients had large symptomatic thoracic aortic aneurysms (eight secondary to chronic dissection); four patients had acute symptomatic type B aortic dissection, and six patients had an intramural hematoma or penetrating aortic ulcer, or both.

An average of two endografts (range, 1-4) were deployed. LSA-covered stents were 8 to 10 mm in diameter. Mean operative time was 154 ± 65 minutes.
Average hospital length of stay was 12 ± 7 days. No major fenestration-related complications occurred. One patient developed postoperative paraplegia. One patient died in the postoperative period, for an in-hospital mortality rate of 4.5%. Two patients died of non-TEVAR-related causes at a mean follow-up of 10 months (range, 1-40 months). Follow-up computed tomography angiography imaging demonstrated a 100% primary patency for the LSA stents. One patient had an asymptomatic LSA stent stenosis. Type II endoleaks from the LSA in two patients required endovascular coil embolization. No fenestration-related type I or III endoleaks were noted.

**Conclusions:** In situ retrograde laser fenestration is a feasible and effective option for LSA revascularization during TEVAR involving a spectrum of acute thoracic aortic pathology. Laser fenestration provides a rapid, reproducible method of fenestrating the endograft material. The high technical success, low fenestration-related morbidity, and excellent midterm patency support this technique of intraoperative endograft modification. (J Vasc Surg 2013;58:1171-7.)
Energy based

Turbo-Elite Laser Atherectomy Catheter

Instructions for Use >

ENHANCED PERFORMANCE AND EFFECTIVENESS

Pre-Procedure

Post-Procedure

Tzilalis VD
The transjugular intrahepatic portosystemic shunt procedure

TIPS is a conduit for portal venous blood to bypass the ineffective liver and thereby relieve portal hypertension. The transjugular variety of this procedure has existed. After Joseph Rösch’s group perfected the procedure in about 40 dogs, it took another eleven years for it to be unleashed on cirrhotic humans (Colapinto et al, 1982).

The procedure itself

In its modern form, the procedure takes 1-2 hours. Its history is well described by Harold Conn (1993). The first human study reported using a Gruntzig balloon catheter, which is a standard angioplasty balloon dilation device. A catheter is passed through the jugular vein (that’s the “transjugular” component) and introduced into the middle hepatic vein. Over this catheter, a modified Ross needle (these days called a Colapinto needle) is stabbed through the liver parenchyma and into the left portal vein.

At this stage, one is able to measure the portal pressure directly, which is a rare opportunity. The hole between veins is then dilated with the balloon, usually 9-10mm in diameter. In the original paper, the balloon was left in situ for up to 12 hours, and then deflated. Colapinto et al would have called it a day at this stage. These days, we finish by placing a mesh stent through the defect, thereby maintaining patency of the shunt.

The procedure itself is improved if the patient has recently had their ascites drained (this places the liver in a more favourable position). A CT should be performed to map the anatomy. Furthermore, a TTE should be performed to confirm that there is no severe right heart failure, and that a vigorous tricuspid regurgitation jet is not going to con-
Percutaneous Transhepatic Cholangiography

(PTC) Needle

Outback needle

transseptal BRK™ needle

(St. Jude Medical)

FNA needle beveled Echotip

Tzilalis VD

Transeptal Needle (Cook)
Cauterries

Ophthalmic cautery

Stainless steel thermal cautery

A

B

C

D

E
After successful bench testing 34 fenestrations in 18 pts
31/38 success (91%)
Endoleaks type III: 2
One fenestration unused
No perioperative mortality, no stroke, embolization, vessel dissection, RF or graft infection
Excellent 1 year FU

Figure 1: (A) Stent-graft fenestrators with diameters of fenestrating heads ranging from 3 to 10 mm. (B) Fenestrator head being heated over a spirit lamp flame. (C) Fenestration for the left subclavian artery being created in a partially deployed Valiant Captivia thoracic stent-graft. The stent-graft fabric was kept stretched during this process by applying traction on temporary polypropylene sutures passed around stent struts on either side of the fenestration point. (D) Fenestration edge being strengthened using interlocking polypropylene sutures taken around a radiopeaque 0.014-inch flexible nitinol wire. (E) Fenestrations for the innominate (larger) and left common carotid (smaller) arteries made in a Zenith TX2 thoracic stent-graft that was subsequently used in case 15 (Table 2).
A Novel Cautery Instrument for On-Site Fenestration of Aortic Stent-Grafts: A Feasibility Study of 18 Patients

Edwin Stephen, MS; George Joseph, DM; Indrani Sen, MS; Sujith Chacko, DM; Prabhu Premkumar, MS; Lijo Varghese, DM; and Dheepak Selvaraj, MS

Departments of 1Vascular Surgery and 2Cardiology, Christian Medical College, Vellore, India.

J Endovasc Ther. 2013;20:638–646

**Conclusion:** This simple-to-use instrument makes on-site creation of aortic stent-graft fenestrations easy, accurate, and precise. The instrument is inexpensive, robust, and easily sterilized.
Figure 4. Placement of a constraining wire using the available pre-loaded wire that secures the top cap and uncovered stent. The wire is carefully removed from inside of the device (A), rerouted posteriorly and introduced into a 20 gauge spinal needle (B). The wire is secured to the Z stents with 4-0 prolene loops that are calibrated using a 5 French dilator (C). Once the spinal needle is removed, the constrained device is resheathed in a retrograde fashion (D).
Modified Fenestrated Stent Grafts: Device Design, Modifications, Implantation, and Current Applications

Gustavo S. Oderich, MD and Joseph J. Ricotta II, MD

Figure 5. Resheathing of the stent graft is done in a retrograde fashion using 1-0 silk sutures to collapse the Z stents. These sutures are serially removed once the device is resheathed. Note that an endarterectomy spatula may facilitate resheathing of struts, fenestrations, and barbs (inset).
Tips and tricks … and multiple wires!

Externalized Guidewires to Facilitate Fenestrated Endograft Deployment in the Aortic Arch

George Joseph, DM¹, Prabhu Premkumar, MS², Viji Thomson, DM¹, Mithun Varghese, DM¹, Dheepak Selvaraj, MCh², and Raj Sahajanandan, MD³

Figure 1. (A) Valiant Captivia endograft with a single fenestration cannulated with a nitinol guidewire. (B) Schematic diagram of the modified endograft delivery system: Key: (1) radiopaque figure-8 mid-body marker, (2) fenestration, (3) endograft, (4) tapered tip, (5) nitinol guidewire, (6) central guide wire lumen, (7) stent stop, (8) needle hole in introducer sheath, (9) needle hole in stent stop, and (10) introducer sheath.
Externalized Guidewires to Facilitate Fenestrated Endograft Deployment in the Aortic Arch

George Joseph, DM¹, Prabhu Premkumar, MS², Vijji Thomson, DM¹, Mithun Varghese, DM¹, Dheepak Selvaraj, MCh², and Raj Sahajanandan, MD³

Tips and tricks … and multiple wires!

Figure 5. (A) Valiant Captivia endograft with fenestrations made for the left subclavian artery (LSA-f), left common carotid artery (LCCA-f), and innominate artery (IA-f); the LSA-f and LCCA-f are made in line with the figure-8 radiopaque marker (“8”), and the 0.014-inch nitinol guidewires (NGw) pass through them. (B) After resheathing the endograft, the 2 NGws exit the top of the introducer sheath together and in line with the LSA-f and LCCA-f.

Figure 6. Setting the stage for delivery of a triple-fenestrated precannulated endograft into the aortic arch. (A) A hydrophilic guidewire (HGw) introduced from the left common carotid artery (LCCA) is passed through a left subclavian artery (LSA) snare loop in the aortic arch; it is then caught by another snare in the ascending aorta and exteriorized from the right femoral artery (RFA). (B) A Judkins right guiding catheter (JRGC) with a side hole near its tip is tracked over the HGw from the RFA and enables delivery of a Lunderquist guidewire (LGw) into the ascending aorta without the latter passing through the LSA snare loop or the triangle (T) formed by the LSA snare, the HGw, and the outer curve of aortic arch. (C) The endograft delivery system (EDS) is introduced into the aorta over the LGw, while the 2 nitinol guidewires (NGws) that traverse the fenestrations in the endograft pass through a multipurpose catheter (MPC) that was earlier passed over the HGw from the LCCA and exteriorized from the RFA.
Externalized Guidewires to Facilitate Fenestrated Endograft Deployment in the Aortic Arch

Technical Note

Figure 7. Case 2. (A) Balloon occlusion of the innominate artery (IA), left common carotid artery (LCCA), and left vertebral artery (LVA) during advancement of an endograft (wide white arrow) having fenestrations for each of the 3 arch branches into the aortic arch. (B) Covered stent deployment in the IA fenestration (wide white arrow); a 6-F left subclavian artery (LSA) snare encircles nitinol guidewires (NGw, black arrows) that traverse the 2 other fenestrations and are exteriorized from a LCCA sheath. (C) Introduction of a hydrophilic guidewire (HGw) into the LCCA through a guiding catheter (wide white arrow) passed from the right femoral artery over the NGw traversing the LCCA fenestration. The HGw must not pass through the 6-F LSA snare loop that encircles the NGws (black arrows). (D) HGw in the LCCA caught by a 4-F snare, which then exteriorizes it from the LCCA sheath. (E) The NGw traversing the LCCA fenestration has been removed; pulling back on the LSA snare at this stage helps exteriorize the NGw traversing the LSA fenestration (black arrows). (F) Covered stent deployment in the LCCA fenestration (wide white arrow); the NGw traversing the LSA fenestration (black arrows) can be seen coursing directly into the LSA.
Use of precannulated fenestrated endograft system described is feasible and has potential to make aortic arch endovascular repair simpler, more reliable, and safer.
“Squid-Capture” Modified In Situ Stent-Graft Fenestration Technique for Aortic Arch Aneurysm Repair

Norio Hongo · Shinji Miyamoto · Ricko Shuto · Tomoyuki Wada · Noritaka Kamei · Aiko Sato · Shunro Matsumoto · Hiro Kiyosue · Hiroma Mori
Experimental Evaluation of Complete Endovascular Arch Reconstruction by In Situ Retrograde Fenestration


Ludovic Canaud, MD, PhD, Elsa Madeleine Faure, MD, Pascal Branchereau, MD, Baris Ata Ozdemir, BS, MRCS, Charles Marty-Ané, MD, PhD, and Pierre Alric, MD, PhD

Department of Thoracic and Vascular Surgery, Arnaud de Villeneuve Hospital, Montpellier; and INSERM U 1046, Montpellier, France

Methods. The experiments were performed using 8 cadaveric human thoracic aortas (aortic arch) using 2 different stent-graft types: woven polyester (Valiant Captivia; Medtronic Vascular, Santa Rosa, CA) and expanded polytetrafluoroethylene (conformable [C]-TAG; W.L. Gore & Associates, Flagstaff, AZ).

Conclusions. Total endovascular repair of the aortic arch through in situ retrograde fenestration of stent-grafts is feasible. The behavior of the 2 types of stent-graft was significantly different while the fenestrations were fashioned, but stent-graft material had no impact on the quality of fenestrations.

20-gauge Needle - dilation of the fenestration with a standard 4-mm angioplasty balloon - a balloon-expandable covered stent (Atrium)

Tzilalis VD
Inoue et al. 1999; Circulation 100:316-21
1995-1998, 15 pts, 14 single branch – 1 triple, **outer branches**, traction wire

SHIN ISHIMARU et al, NOVEMBER 2007 | ENDOVASCULAR TODAY

Chuter et al. 2007;
Perspect Vasc Surg Endovasc Ther19(2):188-92

Tzilalis VD
During the 18 month study period, 27 patients were treated in the three centers.
The FASG is found to be safe and convenient in this preclinical study with swine.
Upcoming Technology for Aortic Arch Aneurysms

Devices on the horizon that will allow near-total endovascular techniques to become a reality.

BY CHERRIE Z. ABRAHAM, MD, AND VICTOR M. RODRIGUEZ, MD

NOVEMBER 2015, ENDOVASCULAR TODAY

Figure 3. The Double Branch Arch system.

Figure 2. The Valiant Mona LSA thoracic branch stent graft system.

Figure 4. The Zenith arch branched graft in the superior view (A), lateral view (B), and proximal view (C). I = innominate branch; C = left common carotid branch.
Our Cases in 401 GAH – Cardiovascular Surgery - Endovascular Surgery

“Christmas ball” One – Hybrid but …

Alternative: in situ fenestration (LCCA – LSA bypass)
“Christmas ball” Two – Hybrid but …

Alternative: in situ fenestration (LSA)
Not only can variation in the shape and length of the branch accommodate errors in planning or placement, it can also accommodate an imperfect match between cuff distribution and visceral artery distribution. The resulting 
in situ customization permits the treatment of a wide range of patients using a narrow range of pre-made stent-grafts, which has the potential to expand the scope of multi-branched endovascular reconstruction by eliminating manufacturing delays.

Until these limitations are overcome and the appropriate tools manufactured for antegrade in situ fenestration, custom-made prefenestrated endografts may be the better choice. However, the authors should be encouraged to continue their work and congratulated for their forward-thinking development of antegrade stent-graft fenestration for use in aneurysms that are not suitable for standard endovascular aneurysm repair.

**Surgeon-Modified Multi-Branched Stent-Grafts: The Options Abound**

Jade S. Hiramoto, MD, MAS
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**In Pursuit of an Off-the-Shelf Fenestrated Stent-Graft: Radiofrequency Perforation for In Vivo Antegrade Fenestration**

Frank R. Arko III, MD
Department of Vascular and Endovascular Surgery, University of Texas Southwestern Medical Center, Dallas, Texas, USA.
Conclusions:

Open surgery

Hybrid procedures

Total endovascular procedures

Off - the self - endovascular grafts

In situ fenestrations

Custom made fenestrated – branched endografts (delay)

Reasonable and effective method to extend the landing zones

Bailout procedures

Energy-based fenestration technique better / 90 degrees

Experienced Team – Endovascular SUITE – CardioVascular department (arch) – Imaging – Imagination

Long term FU
BUT

Requires **experience** (high volume complex endovascular / hybrid / open cases – fenestrated, branched, different types of grafts)

**Endovascular Suite** – multidisciplinary approach (**endovascular specialists**, companies, materials, support)

Vascular surgery - Endovascular surgery – **CardioThoracoEndovascular Center** – Cardiovascular surgery – Interventional radiology

**Imaging** (TerraRecon, 3Mensio, M2S,, Osirix MD, etc) and … **Imagination**