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

F. Cochennec a,*, H. Kobeiter b, M. Gohel c, M. Leopardi b, M. Raux a, M. Majewski b, P. Desgranges a, E. Allaire a, J.P. Becquemina

a Department of Vascular Surgery, Henri Mondor Hospital, Créteil, France
b Department of Radiology and Medical Imaging, Henri Mondor Hospital, Créteil, France
c Department of Vascular Surgery Addenbrooke’s Hospital, Cambridge University Hospitals NHS Foundation Trust, UK

WHAT THIS PAPER ADDS
This article demonstrates that the treatment of high risk patients with thoraco-abdominal aneurysms by physician modified stent grafts is feasible and provides encouraging short-term results. Physician modified stent grafts may represent a valid alternative to “off the shelf” devices for patients unable to wait for a custom made fenestrated or branched device.

Objectives: The aim was to determine whether physician modified stent grafts (PMSGs) are safe and effective for the treatment of high risk patients with thoraco-abdominal aortic aneurysms (TAAAs).

Design: This was a retrospective single institution study.

Material: Consecutive patients with TAAA undergoing endovascular repair using a PMSG between January 2012 and June 2014 were evaluated.

Methods: Fenestrations to preserve branch vessels were created in TX2 thoracic (Cook Medical) stent grafts. Pre-intra- and post-operative data were recorded by means of a prospectively maintained database.

Results: Eleven high risk patients with TAAA (type I, n = 4; type III, n = 3; type IV, n = 3; type V, n = 1) underwent fenestrated endovascular repair using PMSGs. Indications were painful aneurysm (n = 5), >70 mm rapidly enlarging aneurysm (n = 4), saccular aneurysm (n = 1), and visceral patch false aneurysm after open repair of a type IV TAAA (n = 1). In four asymptomatic patients, an additional fenestration was created for temporary selective sac perfusion and occluded 2–4 weeks later. Median duration for stent graft modifications was 2 hours (range 1–3 hours). The median number of fenestrations was three (range 2–4). One patient died during the post-operative period from colonic ischemia, giving a 9% in hospital mortality rate. Four (36%) patients presented with moderate to severe complications. One (9%) patient presented with a paraparesis that resolved completely after spinal fluid drainage. Among surviving patients, four required early endovascular re-intervention for type III endoleak (n = 2), type Ia endoleak (n = 1), or target vessel cannulation failure (n = 1). The median follow up time was 6 months (range 3–20 months). During follow up, no other complications occurred and all target vessels remained patent. One patient presented with a persistent type II endoleak.

Conclusion: PMSGs provided acceptable short-term results and may be a management option for the treatment of TAAA in selected high risk patients. Durability concerns need to be assessed in additional studies with long-term follow up.

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Keywords: Thoraco-abdominal aortic aneurysm, Fenestrated stent grafting, Branched stent grafting, Endovascular repair of aortic aneurysm

INTRODUCTION
Manufactured fenestrated and branched stent grafts have gained widespread acceptance for the treatment of patients with thoraco-abdominal aortic aneurysms (TAAA). However, high device costs and long manufacturing delays (6–12 weeks) limit the overall applicability of this technique. Therefore, patients with symptomatic or large aneurysms are not ideal candidates for fenestrated/branched stent grafting using custom made commercial devices. Endovascular alternatives include “off the shelf” devices and parallel...
stenting approaches such as the “sandwich” technique. “Off the shelf” fenestrated and branched devices are being evaluated in a few expert centers.1–4 At present, they are not widely available and still limited by anatomical requirements. Parallel techniques remain complex off label procedures.5,6 Uncertain long-term patency of reconstructed renal/visceral vessels remains a concern, as well as the theoretical risk of type Ia endoleak. An alternative option is a physician modified fenestrated stent graft (PMSG). This involves deployment of a conventional stent graft device, creating customized fenestrations and reconstraining the device into the delivery system.7–10 Some centers have reported good short-term results for juxta- and supra-renal aneurysms,11,12 but there is a lack of data on their applicability for TAAA. Their use raises concerns on feasibility, poor quality control, and questionable durability.

The objective of this retrospective series was to report the authors’ experience with PMSG for TAAA in patients unfit for open repair and needing rapid treatment.

MATERIALS AND METHODS

Patient population
This experience with PMSGs started in January 2012. Consecutive patients with TAAA undergoing endovascular repair using a PMSG between January 2012 and June 2014 in the tertiary vascular unit were included. TAAAs were classified according to the Crawford classification.13 Patients were considered for open, hybrid, or endovascular repair in a multidisciplinary meeting. In the current series, all patients were deemed unfit for open or hybrid repair. Indications for a PMSG were painful aneurysms, rapidly enlarging >70 mm aneurysms, saccular aneurysms, and visceral patch false aneurysms after TAAA open repair. Rapidly enlarging aneurysms were defined as a >5 mm growth within 6 months. Demographic, anatomical, intraoperative, and post-operative data were recorded by means of a prospectively maintained database. All patients underwent computerized tomography (CT) scan preoperatively and before discharge. The follow up protocol included CT scan at 3, 6, and 12 months and yearly thereafter. Informed consent was obtained from all patients and this study was approved by the local ethics committee (Commission Nationale de l’informatique et des libertés). When patients were consenting, potential risks, and benefits of PMSGs and manufactured stent grafts were discussed in detail and without bias. The increased risk of infection associated with PMSGs, the lack of standardization, and the lack of mid- and long-term data were clearly explained.

Planning and sizing
Procedure planning and device sizing were performed using a dedicated three dimensional vascular imaging workstation (Aquarius WS; Terarecon Inc, Mateo, CA, USA) with centerline luminal reconstructions. Anatomic inclusion criteria are presented in Table 1.

Table 1. Anatomical inclusion criteria for physician modified fenestrated stent grafts.

<table>
<thead>
<tr>
<th>Anatomic criterion</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurysm sac</td>
<td>&gt;70 mm and rapidly enlarging</td>
</tr>
<tr>
<td></td>
<td>Sacular</td>
</tr>
<tr>
<td></td>
<td>Non-mycotic false aneurysm</td>
</tr>
<tr>
<td>Proximal neck</td>
<td>Diameter: 20–40 mm</td>
</tr>
<tr>
<td></td>
<td>Length ≥20 mm</td>
</tr>
<tr>
<td>Aortic angulation</td>
<td>≤45° in the visceral segment</td>
</tr>
<tr>
<td>Aortic wall</td>
<td>Absence of floating thrombus</td>
</tr>
<tr>
<td></td>
<td>Absence of aortic dissection</td>
</tr>
<tr>
<td>Iliac arteries</td>
<td>Diameter 8–20 mm</td>
</tr>
<tr>
<td></td>
<td>Absence of excessive tortuosity</td>
</tr>
<tr>
<td></td>
<td>Absence of significant occlusive disease</td>
</tr>
<tr>
<td>Target vessels</td>
<td>Diameter ≥5 mm</td>
</tr>
<tr>
<td></td>
<td>Absence of &gt;70% ostial stenosis</td>
</tr>
<tr>
<td></td>
<td>Absence of previous stenting</td>
</tr>
</tbody>
</table>

a As deemed by multidisciplinary evaluation.

Fenestrations were created in standard tubular or tapered Zenith TX2 proximal thoracic components (ZTEG, Cook Medical Inc, Bloomington, IN, USA). In some cases, custom made Zenith TX2 devices (CMD-ZTEG, Cook) were used, which can be ordered with custom made lengths, diameters, and shapes and delivered within 5 days. In contrast to standard TX2 devices, these can be provided without proximal barbs, which facilitates reloading into the existing delivery system.

The TX2 stent graft length was chosen to enable a proximal landing zone of at least 25 mm in healthy aorta and to ensure that planned fenestrations would not be on stent overlap zones. In cases where additional proximal thoracic components or bifurcated distal components were necessary, the length of the stent graft components and the position of fenestrations were calculated to ensure at least two stent overlap. Stent graft diameters in proximal and distal sealing zones were oversized by 15–20%.

To calculate the position of fenestrations, the superior mesenteric artery (SMA) ostium was considered the primary reference point. Lengths to other target vessel ostia and distance to the proximal edge of the modified TX2 device were determined on centerline reconstructions. Relative clock positions of target vessels were determined on coronal views, with the SMA ostium at 12 o’clock. For calculation of arc lengths, the circumference of the modified thoracic stent graft was divided into 48 units, each unit representing a quarter of an hour. For each target vessel, the theoretical arc length (TAL) from 12 o’clock (center of SMA ostium) was calculated according to the following formula:

$$TAL = N \times D \pi/48,$$

with $N$ representing the number of units and $D$ the diameter of the TX2 modified stent graft.

Posterior reducing ties were used to facilitate longitudinal and rotational movements of the PMSG, allowing adjustment of the position of fenestrations to facilitate cannulation of target vessels. Thus, the TAL was adjusted to
take into account the constraining effect. Assuming the posterior reducing ties reduced the graft diameter by 20—30% and essentially affected the position of lateral renal fenestrations, each renal TAL was reduced by 10—15%. Thus, a compromise between the positions of renal fenestrations before and after the release of diameter reducing ties was obtained. Modified devices included up to four fenestrations dedicated to renal and visceral vessels. Scallops were not used. Although the concept has not been definitely proven to significantly reduce the risk of spinal cord ischemia, an additional fenestration was created in the proximal thoracic component to ensure temporary sac perfusion in some patients with asymptomatic extended TAAAs (types I, II, or III). This fenestration was occluded under local anesthesia 2—4 weeks after stent graft deployment.

In one patient with >40° angulation of the visceral aorta, two fenestrations were created for the SMA and celiac trunk, and both renal arteries were revascularized using a snorkel technique.

**Device preparation**

Procedures were performed either in an endovascular suite equipped with a Philips FD20 fixed X-ray system or in an operating room equipped with a Philips Veradius C-arm. Stent graft modifications were performed on a back table. They were commenced before starting anesthesia. The anesthesiologists started to prepare the patient when the estimated time required to complete graft modifications was 30 minutes. The Zenith TX2 Cook device (standard ZTEG or CMD-ZTEG) was fully unsheathed. Proximal barbs of the standard ZTEG devices were transected. The distance between the SMA and the proximal edge of the stent graft was measured using a sterile ruler. The SMA fenestration position was marked on the fabric using a sterile marking pen. The other fenestrations were marked according to the predetermined distances from the SMA and adjusted TAL. If one fenestration was too close to a stent strut, the SMA fenestration position was adjusted, and other fenestrations re-marked so that all fenestrations were positioned in the spaces between stent struts.

Posterior reducing ties were created according to the technique described by Oderich. Briefly, one of the three proximal trigger nitinol wires was retrieved from the grey inner cannula and rerouted posteriorly using a needle, along the posterior border of the stent graft, through and through the fabric. Z-stents were constrained using two loops of 4-0 Prolene. A total of six to eight stent struts were constrained.

The final shapes of planned fenestrations were then marked on the fabric. Their diameter corresponded to the diameter of the covered stents selected for each target vessel. Where sac perfusion fenestrations were deemed necessary, these were created posteriorly next to the proximal segment of the aortic aneurysm and away from stent overlap zones. Fenestrations were created using a low temperature ophthalmology cautery (OASIS Medical, Glendora, CA, USA). They were reinforced using the radio-opaque distal tip of a 0.014" Asahi Miraclebros guidewire (Abbott Vascular, Abbott Park, IL, USA) or the loop of a snare (AmplatzGooseNeck, Covidien, MN, Minneapolis, USA), fixed on the fabric with four stitches of 5-0 Prolene and a running locking suture of CV-5 (Gore, Flagstaff, AZ, USA). The endograft was finally reloaded in the existing sheath using temporary 2/0 Vicryl loops to collapse each Z-stent. In cases where a bifurcated distal component was necessary, the proximal bare stent was removed in order to avoid any conflict with bridging stents dedicated to renal arteries.

**Modified stent graft implantation**

Under general anesthesia, both common femoral arteries were exposed using a standard cut down technique. Patients received 100 units/kg of heparin. One femoral access vessel was used to deliver the modified stent graft and the contralateral femoral was used for target vessel cannulation. The procedure followed the usual steps for a Cook fenestrated stent grafting procedure, as described previously.

Once target vessel access was secured with Flexor sheaths (Cook), trigger wires for the PMSG were removed to release the posterior reducing ties. For target artery stenting, V12 Advanta (Maquet) stents were removed. Each stent was flared using Mustang 10 or 12 mm × 2 cm balloons (Boston Scientific). Selective control angiograms were performed after insertion of Flexor sheaths in target vessels and after covered stent deployment.

In cases where a thoracic fenestration was created to maintain temporary sac perfusion, patients underwent endovascular re-intervention under local anesthesia 2—4 weeks after stent grafting. An occlusion balloon was inflated in the fenestration via a femoral puncture. After 30 minutes of balloon occlusion with no neurologic deficit, the fenestration was occluded. For fenestration occlusion, an Amplatzer device (St Jude) was deployed either directly through the fenestration or in a V12 Advanta (Maquet) stent inflated through the fenestration.

**RESULTS**

**Study population**

During the study period, a total of 51 TAAA patients underwent endovascular (n = 24), open (n = 22), or hybrid repair (n = 5). In the endovascular group, seven patients were treated using manufactured devices with branches and fenestrations, six patients were treated with manufactured branched grafts. PMSGs were used in 11 of 24 (46%) cases. Clinical and anatomical data of patients who underwent endovascular repair using PMSGs are summarized in Table 2. Indications for implantation of a PMSG were painful/tender aneurysm (n = 5), >70 mm and rapidly enlarging aneurysm (n = 4), and saccular aneurysm (n = 1). The remaining patient had a 65 mm false aneurysm arising from a visceral patch performed 5 years earlier as part of an open repair procedure for a type IV TAAA. As pre-operative
work up showed no sign of aortic infection, endovascular treatment using a PMSG was preferred. The median number of fenestrations was three (range 2–4). In five patients, four fenestrations (celiac trunk, SMA, and both renal arteries) were created. Six patients required fewer than four fenestrations due to pre-operative occlusion of visceral/renal arteries (n = 2), prior coil embolization of stenosed renal arteries with atrophic kidneys (n = 2), and common celiac/superior mesenteric origin (n = 1). In another patient with >40° angulation of the visceral aorta, both renal arteries were revascularized using a snorkel technique (Fig. 1). The median duration for stent graft modifications was 2 hours (range 1–3 hours).

Details of stent graft configuration and intra- and post-operative events are summarized in Table 3.

Complications and re-interventions

One ASA IV patient with a type III TAAA on chronic renal dialysis (Patient 4) died at day 31, giving a 9% in hospital mortality rate in this series. This patient presented with an acutely ischemic left leg on day 1, related to the occlusion of external iliac and common femoral arteries caused by a residual stenosis at the left common femoral access site. The patient underwent a left external iliac thrombectomy and a prosthetic iliofemoral bypass. Two days later, the patient underwent a left colectomy for colic ischemia. The etiology remained unclear. On a CT scan performed a few hours before the colectomy, hypogastric arteries, and bridging stents for the celiac trunk and SMA were fully patent. Pathological examination of the left colon showed multiple submucosal micro-thrombi. At day 15, the patient presented with a left groin infection requiring replacement of the prosthetic iliofemoral bypass using a contralateral saphenous vein. This bypass occluded 2 days later and a left transfemoral amputation was performed. The patient finally died from multi-organ system failure.

Four (36%) patients developed moderate to severe complications. None was directly related to stent graft modifications. One (9%) patient (patient 2) with a type I TAAA presented with paraparesis, with complete resolution after spinal fluid drainage. For this patient, temporary selective sac perfusion was not used and aortic stent grafting was performed as a single stage procedure. One patient developed pneumonia and another had acute prostatitis, resulting in a prolonged hospital stay. One patient (Patient 10) with a large type V TAAA treated using a four fenestration stent graft with an additional fenestration for temporary sac perfusion presented with a retroperitoneal hematoma secondary to anastomotic bleeding at the site of a right iliac conduit. In this patient, bilateral iliac conduits were deemed necessary because of calcified <7 mm external iliac access vessels. The anastomotic bleeding was treated successfully on day 1 by covered stent deployment under local anesthesia. One month after, the temporary fenestration was occluded but a post-operative CT scan showed a persistent proximal type I endoleak with a 6 mm aneurysmal sac enlargement. The patient underwent deployment of a proximal stent component via an axillary approach. On the last follow up CT scan, the type I endoleak had resolved but a type II endoleak persisted, with the aneurysm diameter remaining stable.

Three other patients required unexpected early endovascular re-interventions, giving a 45% (5 of 11) early re-intervention rate. One patient (patient 3) presented with a type III endoleak related to suboptimal flaring of the bridging stent to the right renal artery. The covered stent had been placed too far in the target vessel. The patient was successfully treated by additional renal covered stent deployment under local anesthesia (Fig. 2). Another patient (patient 5) who underwent a four fenestration stent graft required early endovascular re-intervention to treat a type III endoleak. A 10 mm bridging stent had been deployed in a 12 mm celiac trunk. Despite the use of a 12 mm balloon angioplasty to flare the covered stent, sealing in the celiac trunk was inadequate and the aneurysm still perfused. Under local anesthesia, an additional 12 mm covered stent was deployed more deeply in the celiac trunk. A CT scan performed after this re-intervention showed no residual endoleak. In the remaining patient (patient 7), the celiac trunk could not be cannulated via a femoral approach. Deployment of a celiac trunk bridging stent was achieved via a brachial approach during a secondary procedure.

With the exception of the patient who presented with a persistent type II endoleak (patient 10), aneurysm exclusion at discharge was achieved in all surviving patients.
Among surviving patients, the median follow up was 6 months (range 3–20 months). Two patients were lost to follow up after 3 months. Two patients were followed up beyond 1 year. No additional complications or endoleaks occurred during the follow up period. Target vessels and bridging stents remained patent. Aneurysm diameters remained stable.

**DISCUSSION**

With a 9% in hospital mortality rate and a 9% spinal cord ischemia rate, PMSG for TAAA provided acceptable short-term results for this high risk patient population. All surviving patients were alive and well with only one patient presenting with a persistent type II endoleak at the end of the follow up period. Cumulative data from previous
Table 3. Stent graft configuration, intra- and post-operative events.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Type of TAAA, anatomic details</th>
<th>Anatomic characteristics making patients unsuitable for an off the shelf t-branch device</th>
<th>Stent graft configuration</th>
<th>Intra-operative complications</th>
<th>Post-operative complications/re-interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Symptomatic (tender) 45 mm saccular type IV, SMA and CA occluded pre-operatively, IMA and left colonic arcade well developed</td>
<td>Two target vessels (SMA and CA occluded pre-operatively)</td>
<td>Modified ZTEG with two fn (RRA, LRA) deployed above the IMA</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>Asymptomatic 71 mm type I TAAA</td>
<td>Aortic diameter &lt;25 mm at the level of renal arteries</td>
<td>Proximal ZTEG + modified ZTEG with 4 fn (CA, SMA, RRA, LRA)</td>
<td>None</td>
<td>Incomplete paraplegia, regressive after SFD latrogenic meningitis</td>
</tr>
<tr>
<td>3</td>
<td>Asymptomatic 75 mm type I TAAA, previous aortic arch repair (frozen elephant trunk technique), CA occluded</td>
<td>Three target vessels (CA occluded) Target vessels not accessible from antegrade approach due to recent frozen elephant trunk technique</td>
<td>Modified proximal CMD-ZTEG (1 fn for temporary sac perfusion) + modified ZTEG with 3 fn (SMA, RRA, LRA)</td>
<td>None</td>
<td>Endovascular re-intervention for type III EL: deployment of an additional covered stent in the RRA</td>
</tr>
<tr>
<td>4</td>
<td>Symptomatic (tender) 65 mm type III TAAA</td>
<td>Two target vessels (bilateral renal embolization)</td>
<td>Renal embolization + modified ZTEG with 2 fn (SMA, CA) + Zenith AAA bifurcated stent graft</td>
<td>None</td>
<td>Lower limb ischemia, colic ischemia, death</td>
</tr>
<tr>
<td>5</td>
<td>Asymptomatic 65 mm false aneurysm of the visceral patch after OR for a type IV TAAA</td>
<td>None</td>
<td>Modified CMD-ZTEG with 4 fn (CA, SMA, RRA, LRA) + Zenith bifurcated stent graft</td>
<td>None</td>
<td>Endovascular re-intervention for type III EL: deployment of an additional covered stent in the CA</td>
</tr>
<tr>
<td>6</td>
<td>Symptomatic (tender) 130 mm type I TAAA; 45 mm aneurysm of the distal arch (left untreated)</td>
<td>Aortic diameter &lt;25 mm at the level of renal arteries</td>
<td>Proximal ZTEG + modified ZTEG with 2 fn (CA, SMA) + snorkel for RRA and LRA + distal ZTEG</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>Asymptomatic 75 mm type III TAAA, stenotic RRA with atrophic kidney</td>
<td>Target vessels not accessible from antegrade approach (gothic arch)</td>
<td>RRA embolization, modified proximal ZTEG (1 fn for temporary sac perfusion) + modified ZTEG with 3 fn (CA, SMA, LRA) + Zenith bifurcated stent graft</td>
<td>CA cannulation failure</td>
<td>Pneumonia, endovascular re-intervention for CA cannulation and bridging stent deployment</td>
</tr>
<tr>
<td>8</td>
<td>Asymptomatic 55 mm sacciform type IV TAAA</td>
<td>Three target vessels (common celiac/superior mesenteric origin)</td>
<td>Modified CMD-ZTEG with 3 fn (common celiac/superior mesenteric origin, RRA, LRA)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9</td>
<td>Asymptomatic 70 mm type I TAAA</td>
<td>Upward orientation of the left renal artery</td>
<td>Modified proximal ZTEG (1 fn for temporary sac perfusion) + modified ZTEG with 4 fn (CA, SMA, RRA, LRA)</td>
<td>None</td>
<td>Acute prostatitis</td>
</tr>
<tr>
<td>10</td>
<td>Asymptomatic 82 mm Type V TAAA, HIV encephalitis. CA occluded</td>
<td>CA occluded</td>
<td>Bilateral iliac conduits, modified CMD-ZTEG with 1 fn for temporary sac perfusion and 4 fn for CA, SMA, RRA, LRA, accessory LRA.</td>
<td>None</td>
<td>Re-interventions for retroperitoneal hemorrhage and type I endoleak. Persistent type II endoleak</td>
</tr>
<tr>
<td>11</td>
<td>Symptomatic (tender) 75 mm type III TAAA. 50 mm aneurysm of the distal arch (left untreated)</td>
<td>Aortic diameter &lt;25 mm at the level of visceral arteries</td>
<td>Modified ZTEG with 4 fn (CA, SMA, RRA, LRA) + Zenith bifurcated stent graft</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CA = celiac artery; CMD = custom made; EL = endoleak; fn = fenestration; IMA = inferior mesenteric artery; LRA = left renal artery; OR = open repair; RRA = right renal artery; SFD = spinal fluid drainage; SMA = superior mesenteric artery; TAAA = thoraco-abdominal aortic aneurysm; TX2 = TX2 (Cook) thoracic stent graft; ZTEG = Zenith TX2 proximal component (Cook).
publications and from the present series suggest this option deserves consideration in a selected group of high risk patients for whom aneurysm repair cannot be delayed.

The available options to treat high risk patients with TAAA in acute or subacute settings are limited. Even in high volume centers, open repair is associated with mortality rates of 5—15% and spinal cord ischemia rates of 3—15%\(^{17–21}\). In emergency cases, these mortality rates increase to 20—40%\(^{20,22}\). Hybrid procedures combining debranching of visceral arteries and aortic stent grafting have the theoretical advantage of avoiding aortic cross clamping and extracorporeal circulation. However, there is no evidence that hybrid procedures are superior to conventional open repair in terms of post-operative mortality and paraplegia. A recent meta-analysis including 507 patients from 19 publications showed that hybrid procedures were still associated with significant in hospital mortality (12.8%) and spinal cord ischemia rates (7.5%).\(^{23}\)

Parallel techniques such as the sandwich technique constitute purely endovascular alternatives. Encouraging short-term results have been reported in small series\(^{5,6}\) but type la endoleaks through the gutters and uncertainty regarding the long-term patency of visceral artery covered stents remains a concern. Standardization in such procedures is also lacking. During the last 10 years, fenestrated/branched stent grafts have played a growing role in the management of TAAA. Expert centers have reported low peri-operative morbidity and mortality rates and excellent mid-term results\(^{24–27}\). However, commercial custom made devices require at least 6—12 weeks to be manufactured, thereby precluding the treatment of patients requiring urgent intervention, or expedited treatment. Recently, off the shelf multi-branched devices have been introduced in order to offer an endovascular alternative to emergent patients\(^{1–4,28}\). These devices are still under evaluation and not widely available. In France, only one device (t-branch device, Cook) is financed by the Social Security system and the indications are limited to type IV TAAAs. However, off the shelf devices are likely to play a growing role in the management of TAAAs and may reduce the potential indications for PMSG. Preliminary series have provided good short-term results. Bisdas et al.\(^2\) recently reported their experience with custom made and off the shelf (t-branch) multi-branched Cook devices. The t-branch device showed 100% technical success and similar clinical outcomes to the custom made device. The current design is theoretically applicable in 50—90% of anatomical configurations\(^{28,29}\).

Therefore, some patients will still require custom made stent grafts. In their study, Bisdas et al.\(^2\) also identified the main obstacles that would make the t-branch unsuitable for

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Figure 2. Patient with a recent history of aortic arch aneurysm treated by a frozen elephant trunk technique using an open-Evita device (A). A post-operative computed tomography scan showed a 75 mm rapidly enlarging type I thoraco-abdominal aortic aneurysm (B). The celiac trunk was occluded. The patient was treated using a physician modified fenestrated stent graft with three fenestrations for the renal and superior mesenteric arteries. An additional temporary fenestration was created for temporary sac perfusion and occluded 3 weeks later using an Amplatzer Occluder (St. Jude) device (black arrow, C). A post-operative computed tomography showed a persistent type III endoleak (C,D) that resolved after placement of an additional right renal covered stent (E,F).
previous reports from pioneering centres, PMSGs and universal off the shelf stent grafts and on the basis of term branch occlusion. While awaiting the arrival of reliable increased risk of target vessel cannulation failure and long-term the target vessels. This could potentially lead to an occlusion could have been used for patients with only two or three patent target vessels. Using through and through wires for antegrade cannulation could have overcome the problem of angulated aortic arches.

PMSGs could have several theoretical advantages. In contrast to the fixed three stents of the t-branch, the number of stents in the proximal part can be chosen when using PMSGs. This could permit less coverage of the thoracic aorta. Moreover, in order to permit use of t-branch devices in a large number of patients, the ideal position for visceral branches is usually compromised for one or more of the target vessels. This could potentially lead to an increased risk of target vessel cannulation failure and long-term branch occlusion. While awaiting the arrival of reliable and universal off the shelf stent grafts and on the basis of previous reports from pioneering centres, PMSGs constitute a valid option for the treatment of TAAA in selected patients.

In this study, asymptomatic patients were candidates for a PMSG only when the aneurysm diameter exceeded 70 mm and was rapidly enlarging. These criteria are not evidence based as the natural history of TAAA disease is poorly understood. However, there are data in the literature to suggest that aortic aneurysms >70 mm should be treated rapidly. Coady et al. reported a drastic increase in the risk of rupture beyond 70 mm for aneurysms of the descending thoracic aorta. When looking at available data on abdominal aortic aneurysms, the annual risk of rupture for diameters >70 mm has been estimated to be >30%. Therefore, 70 mm was considered to be an acceptable threshold to offer patients the possibility of rapid treatment using a PMSG.

In the current series, one patient died and one presented with transitory paraplegia. The single death was related to a colonic ischemia and occurred in an ASA 4 patient with a tender aneurysm and multiple comorbidities. The cause of the colonic ischemia remained unclear but was probably multifactorial. The bridging stent dedicated to the SMA remained patent. Retrospectively, although this compassionate endovascular procedure was technically straightforward, the patient may have lacked the physiological reserve to recover from such a procedure. Nevertheless, the results are similar to contemporary short-term results of fenestrated/branched stent grafts for TAAA. In expert hands, fenestrated/branched stent grafting for TAAA using commercial devices has been associated with 30 day mortality rates ranging from 5% to 12% and spinal cord ischemia rates ranging from 3% to 17%. The group has recently pointed out that these results might not reflect “real-life” practice. Indeed, using commercial custom made or off the shelf devices in 24 TAAA patients, a 12.5% 30 day mortality was reported. Although the restricted number of patients does not allow a reliable statistical comparison, the short-term results using PMSGs to date have been at least comparable if not favorable.

To date, only a few centers have reported results with the use of PMSGs in the management of complex aortic aneurysms. This approach has been used predominantly for juxtarenal aneurysms. A case series published in 2012 reported outcomes in 47 high risk patients treated with PMSGs for symptomatic or rapidly enlarging juxtarenal aneurysms. Again, results were similar to those in the current literature on commercial custom made fenestrated stent grafts, with 30 day mortality and complication rates of 2% and 13% respectively. Encouraged by those initial results, a further 28 patients were included in an investigator sponsored device exemption study, with 30 day mortality rates and freedom from sac enlargement at 12 months of 3.8% and 87.5% respectively. Regarding the use of PMSGs for the treatment of TAAA, publications are scarce, consisting of a few limited series or individual cases. To our knowledge, the largest experience comes from the Mayo Clinic. Recently, Oderich et al. presented results comparing the use of 30 PMSGs with 16 hybrid repairs for high risk patients with complex aortic aneurysms. Proportions of TAAA patients were 47% in the PMSG group and 81% in the hybrid group. When compared with the hybrid group, PMSGs were associated with reduced blood loss, less fluid requirements and shorter total operative time. Postoperative mortality rates were 3.3% in the PMSG group and 19% in the hybrid group.

Although the use of PMSGs seems to be an effective alternative for selected patients with TAAAs, several disadvantages must be considered. The early re-intervention rate was high (45%). Even if still in the learning curve, it reflects the fact that this off label procedure is technically challenging and that graft modification lacks standardization, varying from one center and one operator to another. PMSGs cannot be applied in hemodynamically unstable patients. Indeed, the median duration for stent graft modification was 2 hours, taking up to 3 hours in some cases. Moreover, even if performed in sterile conditions, deploying the stent graft on a back table for modification could be associated with an increased risk of infection. This complication was not observed in the present series. Long-term results are poorly understood and this constitutes another restriction to PMSGs. Lastly, modifying an implantable medical device is associated with obvious legal risks as the physician becomes fully responsible for the modifications. Thus, the use of PMSGs should be restricted to patients unfit for open repair and at risk for rupture in the short-term, with the support of an experienced multi-disciplinary team.
Although the concept lacks evidence, branch grafts are usually preferred for large TAAAs, especially when the calculated distance between the deployed aortic device and the origin of the target vessel is >10 mm. In such cases, branches might reduce the risks of cannulation failure and long term bridging stent occlusion/disconnection related to aneurysm shrinkage. Although the feasibility of immediate stent graft modifications using perfusion branches was reported previously, perfusion of critical branch vessels was maintained using fenestrations rather than branches. This option was considered acceptable since, apart from one case (patient 8, 55 mm saccular type IV TAAA), the calculated distances between the deployed aortic device and the origin of target vessels did not exceed 10 mm. As regards patient 8, all target vessels remained patent at three months.

In the present series, one patient (patient 2) with an asymptomatic 71 mm type I TAAA presented with post-operative partial paraplegia, completely reversed after spinal fluid drainage. Subsequently, additional fenestrations were created to ensure temporary sac perfusion in patients with asymptomatic type III, type I, or type V aneurysms (there were no patients with type II TAAA in the present series). Although there is no evidence this strategy can significantly reduce the risk of paraplegia, the four patients treated using temporary fenestrations for selective sac perfusion remained free from spinal cord ischemia after closure of the fenestration.

CONCLUSION

Short-term results are promising using PMSGs for the treatment of TAAA.

Until reliable and applicable “off the shelf” stent grafts become widely available, PMSGs may be a valid option for high risk patients, unable to wait for a custom made fenestrated or branched device. However, long-term follow up is needed before fully endorsing this novel approach in the treatment of TAAA.

CONFLICT OF INTEREST

None.

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None.

REFERENCES


