

# Performance of Bridging Stent Grafts in Fenestrated and Branched Aortic Endografting

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## WHAT THIS PAPER ADDS

This study provides details of the performance of bridging stent grafts used in fenestrated and branched endografting for the treatment of thoracoabdominal aortic aneurysm. It may help in planning the procedure and in addressing future device developments.

**Objective/Background:** Bridging stent grafts (BSGs) are used to connect the target vessel with the main body during fenestrated or branched aortic endografting (f/bEVAR). No dedicated devices are available for BSG. The aims of this study were to assess the performance of BSGs.

**Methods:** Between January 2004 and May 2014 the data of patients treated with f/bEVAR were prospectively collected. Only patients treated after January 2010 were included. The main measurement outcome was any BSG related complications. A logistic regression analysis, including target vessel type, type of joint (fenestration or cuff), and type of BSG identified potential risk factors.

**Results:** One hundred and fifty consecutive patients underwent f/bEVAR, and 523 target vessels were involved. These included 104 celiac, 140 superior mesenteric, 275 renal, and four other arteries. The technical success rate was 99% (520/523 target vessels). Balloon expandable BSGs were mainly used ( $n = 494$ ; 95%), and in 336 (65%) relining stents were combined. The primary reasons for technical failure were the dislocation of the main body ( $n = 1$ ) and unsuccessful cannulation ( $n = 2$ ). One was revascularized by means of the periscope technique. Four target vessel injuries were recorded and four renal arteries occluded peri-operatively. After a median follow up of 14 months (interquartile range 5.5–23.0), 13 (2%) BSGs occluded and 19 (4%) required re-interventions. Two SMA occlusions occurred, leading to death in both patients. The patency and freedom from re-intervention rates at 3 years amounted to 85% and 91%, respectively. Use of a branched main body was the only independent risk factor for re-intervention and for the composite event (hazard ratio [HR] 3.5, 95% confidence interval [CI] 1.3–9.9 [ $p = .02$ ]; and HR 2.8, 95% CI 1.2–7.0 [ $p < .01$ ], respectively). Of note, the use of relining stents seemed not to prevent BSG related complications.

**Conclusion:** The currently used BSGs had low occlusion and re-intervention rates. Modifications of the branched design or dedicated BSG devices may improve outcome, especially after bEVAR.

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## INTRODUCTION

Aortic branch devices have been proposed by Browne et al.,<sup>1</sup> for the treatment of complex aortic aneurysms involving the visceral segment since the late 1990s.

The safety, feasibility, and effectiveness of these devices have been demonstrated in different reports, and >7,000 patients worldwide have been treated.<sup>2</sup>

In general, a modular strategy is used to connect different devices with an aortic main body (AMB). This is characterized by a dedicated region working as junction point. The most extensive experience has been with a single main body platform (Cook Medical, Brisbane, Australia); however, recently, two other companies have produced devices — the Fenestrated Anaconda™ (Vascutek, Paisley, Scotland) and the Ventana™ Fenestrated System (Endologix, Irvine, CA, USA).<sup>3,4</sup>

Over the last 15 years evolution of the AMB has taken place. First came fenestrations with different diameters, with or without nitinol ring structures, and then came

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helical and axial branches, directed up or downward, and internally or externally placed.

Moreover, to overcome the necessity of AMB customization, an off the shelf device, able to fit different anatomies, has recently been presented.<sup>5</sup>

Self and balloon expandable stent grafts have been used to connect the AMB with the visceral vessels. They work as a bridge (bridging stent graft [BSG]) between the AMB and the target visceral vessel. The modular device resulting from AMB and BSGs has to exclude the aneurysm while preserving organ perfusion. The system requires a degree of flexibility in order to follow physiological movement and any vessel modification related to aortic elongation or aneurysm shrinkage.

At present, no studies are available comparing the performance of all the different options. To inform the debate, this article provides details on the performance of BSGs, analyzing possible risk factors leading to adverse events.

## MATERIAL AND METHODS

Between January 2004 and May 2014, based on prospectively collected data, all medical records of patients suffering from thoracoabdominal (TAAAs) or pararenal aortic aneurysms (PAAs), and treated by means of a fenestrated or multi-branched endograft (f/bEVAR), were reviewed. Only patients treated after January 2010 were included in this study.

### Devices

The BSGs for the AMB may be suited to branches or fenestrations, or both. Proximal to the AMB, a thoracic endograft can be used, and distally either an abdominal tube or a bifurcated endograft with or without iliac side branch devices.

In all cases, the AMB was based on the Zenith stent graft platform (Cook Medical), suitable for each patient's anatomy. Details of the planning of custom made f/bEVAR have been described extensively elsewhere.<sup>6,7</sup>

In all patients, a dedicated workstation (Aquarius iNtuition; TeraRecon Inc., Foster City, CA, USA) was used for the planning of the custom made AMB. The planning was further tested and confirmed by a company sponsored dedicated core laboratory; manufacturing time took approximately 8–10 weeks.

The AMB was usually customized using three different options to maintain the perfusion of the reno-visceral arteries: (i) normal or double wide scallop; (ii) small and large nitinol reinforced fenestration; (iii) straight caudally or cranially directed cuff or spiral cuff. The latter two options work as the joint point between the AMB and the BSG. They ensure an adequate sealing zone and stability between different devices.

Scallops are intended to preserve vessel perfusion with aneurysm exclusion without the use of further devices. Thus, this option was excluded from analysis.

The number of joints per AMB depended on the aneurysm type and the number of target vessels. The combination of fenestrations and branches in the same AMB was favored in narrow or angulated reno-visceral aortic segments.

The target vessels consisted of celiac trunk (CT), superior mesenteric artery (SMA), left and right renal arteries (LRA and RRA, respectively) and, rarely large accessory renal arteries or separate origins of the CT branches. Pre-operative ostial stenosis and/or dissection of the target vessel were grouped together and defined as a “challenging target vessel”.

In November 2012, an off the shelf multi-branched endograft (t-branch model; Cook Medical),<sup>5</sup> characterized by four caudally directed branches in a standard position, was introduced.<sup>8</sup> It was used according the instruction for use and not off label.

Appendix 1 provides an overview of the different balloon or self expandable BSGs used alone or in combination to build the joint for each target vessel.

### Implantation technique

The implantation technique has been described extensively in previous reports.<sup>9</sup>

Briefly, all interventions were performed in a hybrid operating room under fluoroscopic control (Axiom Artis FA; Siemens Medical Solutions, Forchheim, Germany). All patients underwent general anesthesia, and a totally percutaneous approach using the Prostar XL 10 French vascular closure device (Abbott Vascular, Redwood City, CA, USA) was favored.

Surgical exposure of the left axillary artery was normally used for the delivery and deployment of cuffs, while the contralateral limb was generally preferred for fenestrations.

The AMB was deployed using a road mapping technique and latterly, assisted by a three dimensional (3D) road mapping tool (Siemens, Munich, Germany) using pre-operative computer tomography angiography (CTA). Prior to the introduction of the 3D road mapping, pre-cannulation of the target vessels was done routinely.<sup>7</sup> In the case of AMB with cuffs only, the device was completely deployed with restoration of limb perfusion prior to the trans-axillary delivery of the BSGs. The aim of this maneuver was to reduce ischemia, not only of both extremities, but also of both hypogastric arteries. Considering that repositioning of the fenestrated graft remains essential for the successful catheterization of the target vessels, this technique was not used with fenestrations.

It was always intended that placement of the AMB and BSGs should be completed in a single stage. In order to reduce the risk of spinal cord ischemia, staged approaches were preferred for Crawford type II or III TAAAs.<sup>10</sup> First, a proximal endovascular thoracic aortic component was implanted at the level of an adequate proximal landing zone, and the AMB was delivered approximately 6–8 weeks later.

### Surveillance protocol

Follow up clinical assessment, laboratory testing (including evaluation of the glomerular filtration rate [GFR]), and CTA were obtained at 1 and 12 months, and annually thereafter. In patients with renal impairment (GFR < 60 mL/minute/1.73 m<sup>2</sup>), post-operative CT scans were performed using an intra-arterial bolus of 30 mL contrast agent through a

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