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Structural implications of fenestrated stent graft misalignment

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ABSTRACT

Background: Endovascular aneurysm repair is a minimally-invasive method for the treatment of abdominal aortic aneurysms. For aneurysms that involve the visceral arteries, a custom-made stent graft with fenestrations for the branch arteries is required. The purpose of the current study is to evaluate the structural impact of misaligned fenestrations with respect to luminal patency and proximal aortic neck apposition in an *in vitro* model.
Methods: A custom apparatus was used to evaluate seven Anaconda and three Zenith fenestrated stent grafts. All stent grafts were evaluated at 10° increments of stent/fenestration misalignment up to 80°. Images were captured at each interval and the luminal cross-sectional area and wall apposition were measured.
Results: The Anaconda stent graft, which has an unsupported main body, demonstrated a linear reduction in luminal patency at increasing angles of misalignment ($P < 0.0001$). Stent/fenestration misalignments of 20° and 80° resulted in decreases in mean luminal patency of 14% and 54% respectively. The Zenith stent graft demonstrated a similar decrease in luminal patency, starting at misalignments of ≥40° ($P < 0.0001$). However, with stent/fenestration misalignments of ≥30°, apposition between the Zenith stent graft and the simulated aortic neck was compromised suggesting the creation of a type Ia endoleak.
Conclusions: Both the Anaconda and Zenith devices behave adversely at extreme angles of misalignment with luminal narrowing in the Anaconda device and loss of wall apposition in the Zenith device; however, both stent grafts appear to be equivalent at low angles of misalignment.

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Introduction

Endovascular aneurysm repair is a minimally-invasive method for treatment of abdominal aortic aneurysms (AAAs) in which the diseased aortic segment is excluded from the circulation through the placement of a stent graft. While the majority of AAAs can be treated with a conventional stent graft, aneurysms near or encompassing the visceral vessels require the creation of a custom-made graft. This custom-made graft incorporates patient-specific fenestrations aligned with the target visceral vessels, as defined by pre-operative imaging.[1] This modular main body is then connected *in vivo* to the target artery via these fenestrations with covered stents to maintain end organ perfusion. Technical success of this procedure requires careful pre-operative planning to ensure that there is no misalignment or angulation between the fenestration and the target artery.

Custom-made fenestrated devices currently require a 6–12 week lead time for the pre-procedural planning and manufacture of the stent graft. This lead time can pose significant challenges in the treatment of these patients including the risk of aneurysmal rupture while waiting for the device to be manufactured. This lead time also precludes the use of custom-made devices in the setting of ruptured or symptomatic complex AAAs. This limitation has led to the development of 'off-the-shelf' fenestrated and branched devices such as the Cook p-Branch and t-Branch as well as the Endologix Ventana.[2] Other methods for urgent endovascular repair of complex aneurysms include physician modified stent grafts as well as chimney grafts, which have both been shown to be potentially viable with the appropriate expertise.[3–7]

Another potential option for the repair of a symptomatic or ruptured complex AAA is the use of an 'in-stock' custom-made stent graft. Occasionally, patients awaiting the manufacture of a custom-made stent graft may pass away prematurely for various reasons (including rupture of their aneurysm), leading to a custom-made device without a target patient. The use of these 'in-stock' stent grafts may be acceptable in the urgent setting despite small misalignments between the fenestration and target artery. Previously, Barilla et al. have reported their experience with the implantation of an 'in-stock' custom Cook branched stent graft and similarly our institution recently successfully implanted an 'in-stock' fenestrated Anaconda stent graft.[8]

The structural implications of having radial misalignments between the fenestration and the target artery has not been previously studied and has implications not only for 'in-stock' custom stent grafts but also for misalignments that occur during the routine deployment of custom-made stent grafts. This study evaluated two devices that represent different platforms – one that is fully supported by Z-stents (Cook Zenith), and one that has an unsupported main body (Vascutek Anaconda). For both devices, luminal patency and proximal aortic neck apposition were quantified as a function of the angle of misalignment.

Methods and materials

Seven fenestrated Anaconda grafts (Vascutek, Glasgow, UK) and three fenestrated Zenith grafts (Cook Medical, Bloomington, IN, USA) were evaluated. All seven Anaconda devices were 2-vessel fenestrated stent grafts. Two of the Zenith devices had 2-vessel fenestrations with an SMA scallop (Devices 1 and 3, Table 1) and the third Zenith device was a 3-vessel fenestrated graft (Device 2, Table 1). Complete device specifications are provided in Table 1. The deformation of the proximal stent graft secondary to aortic oversizing was simulated by a ½" circular hose clamp (McMaster-Carr, Elmhurst, IL, USA) adjusted to 90% of the stent diameter. The evaluation of the fenestration angle was carried out on a custom developed testing apparatus as illustrated in Fig. 1. The developed apparatus had a radial fulcrum point within the center of the stent graft and utilized exchangeable stainless steel rods of different diameters (McMaster-Carr, Elmhurst, IL, USA), which were passed through the fenestration to simulate a rigid stent. The diameter of the stainless steel rod was selected to match the size of the fenestration. Each renal artery fenestration was tested independently. On mounting of the stent graft to the testing apparatus, the position of the opposing renal artery fenestration, circular clamp, and distal aspect of the stent graft are fixed. The height and angle of the stainless steel rod are then adjusted to match the native alignment of the tested fenestration. This position represents 0° of angulation.

Table 1 – Anaconda and Zenith device measurements.

Device no.	RRA diameter (mm)	LRA diameter (mm)	Anterior renal artery angle (°)	Top of right renal artery – top of graft (mm)	Top of left renal artery – top of graft (mm)	Graft diameter (mm)
				Vascutek anaconda devices		
1	7	7	162	9	11	30
2	6	6	141	8.8	5.4	32
3	5	5	160	16	10	32
4	7	6.5	111	4	7	34
5	6	6	148	8	15	30
6	5.5	6	198	12	17	28
7	6	5.5	181	13	12	32
				Cook Zenith devices		
1	6	6	153	6	7	30
2	6	6	152	9	13	23
3	5.5	6	159	10	10	35

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