

Evolution of the Fenestrated Anaconda™ Custom AAA Stent Graft System

An overview of the clinical need that led to the design of this technology for use in patients who cannot be treated with conventional EVAR.

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Endovascular aneurysm repair (EVAR) is well established as an alternative to open repair of conventional infrarenal abdominal aortic aneurysm (AAA), the benefits of which are well documented for patients who are unable to undergo an open procedure. Original EVAR devices were based upon a neck length of 15 mm and < 60° angulation. Newer devices now available can treat 10 mm necks and/or 90° angulation. However, a number of AAA cases are not suitable for conventional EVAR. These are cases with anatomy such as short necks or juxtarenal, thoracoabdominal, and pararenal aneurysms that cannot be treated with conventional EVAR devices. Previously, the only way to treat these cases was through open repair, often in patients who were deemed too high risk for surgery.

Through the development of custom-made devices for fenestrated endovascular aneurysm repair (FEVAR), clinicians are now able to accommodate the renal and mesenteric vessels and, in turn, treat these patients by implanting devices higher up in the aorta where disease progression has occurred. The original devices had certain shortcomings, including limitations on the location of the fenestrations to accommodate the vessels and the ability to be cannulated from above.

DEVELOPMENT AND DESIGN OF THE FENESTRATED ANACONDA™ AAA STENT GRAFT SYSTEM

Following a request for a custom fenestrated version of the Anaconda™ AAA Stent Graft System (Vascutek Ltd.) by Dr. Peter Bungay of Royal Derby Hospital in the United Kingdom to treat a specific patient, Vascutek quickly developed the first Fenestrated Anaconda™ Custom AAA Stent Graft System that was successfully implanted in June 2010. Already a highly experienced user of the infrarenal Anaconda™ device, Dr. Bungay recognised the key design features that would make the device an excel-

lent base for a tailored fenestrated variant. These features included the flexible, unconstrained main body, conformable proximal sealing ring stents, and the fact that it is also fully repositionable. These design characteristics made it a very attractive option for use in FEVAR applications, as it provided a degree of control and versatility. Furthermore, due to the longer operating times and technical difficulty of the FEVAR procedures, the intrinsic magnet guidewire used for fast, easy cannulation of the main device body had the potential to reduce the length of the procedure, including fluoroscopy time. These key features were all available in the first customised Fenestrated Anaconda™ Custom AAA Stent Graft System.

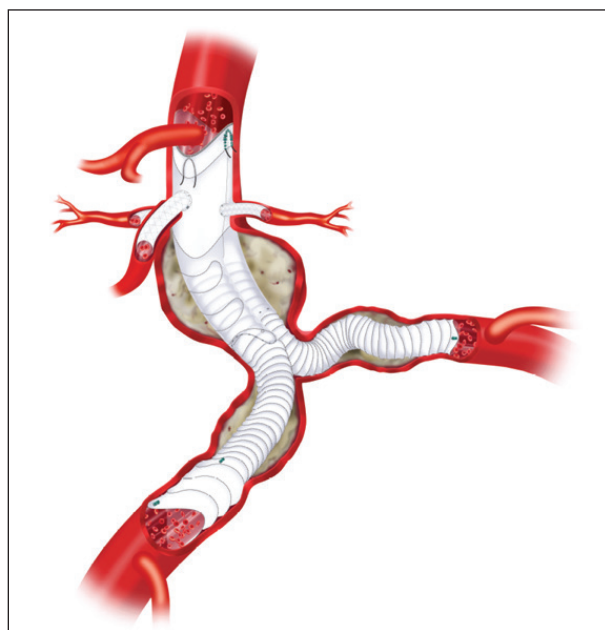


Figure 1. A representation of a deployed Fenestrated Anaconda™ Custom AAA Stent Graft System with the coeliac trunk accommodated in the anterior valley of the device.

The initial concept took full advantage of the proximal ring stent sealing arrangement, a distinguishing characteristic across the Anaconda™ platform, to accommodate visceral vessels. The ring stents form peaks and valleys when sealing in the aorta, with proximal fixation hooks attached at each peak and valley. With the standard infrarenal stent graft system, the peaks are orientated anterior/posterior, with the legs of the stent graft lateral. Rotating this configuration 90° moves the valleys of the ring stents to an anterior/posterior orientation, and the saddle shape of the oversized ring stents can be used to accommodate anteriorly positioned visceral vessels such as the superior mesenteric artery (SMA) or coeliac trunk, as illustrated in Figure 1.

There is often no requirement for an additional fenestration and subsequent branch stent due to the unique sealing characteristics of the ring stent design for patients in whom disease is present suprarenally and a suitable landing zone exists to accommodate the sealing ring stents. Figure 1 shows the coeliac trunk cradled in the anterior valley of the device with three fenestrations positioned in the main body to accommodate the SMA and both renal arteries.

Following the successful implantation of Dr. Bungay's initial case with a device designed with two renal fenestrations and the SMA accommodated in the anterior valley, Vascutek continued to review clinician requests for customised devices to treat other patients with similar anatomical challenges. In addition to the standard ring configuration, an "augmented valley" design was possible, where the proximal sealing ring stent was sewn to the fabric angled toward the anterior, thus reducing the distance between the proximal sealing rings at the anterior valley. This creates a scallop effect when the device seals in the oversized position and allows anatomies to be treated where there is greatly reduced clearance between the visceral vessels without resorting to additional fenestrations.

Other early developments included the "fenestrated valley" proximal ring configuration. Here, a fenestration is positioned between the two proximal sealing rings and is typically used to access and stent the SMA or coeliac trunk, depending on the nature of the specific patient anatomy. Again, the profile of the ring stent in the oversized position can be taken advantage of to allow a treatment solution where the renal arteries and SMA are in very close proximity; renal artery fenestrations can be positioned under the peaks of the second proximal sealing ring of the device while a fenestration accommodates the SMA between the proximal sealing rings.

Since the first successful implant of the Fenestrated Anaconda™ Custom AAA Stent Graft System, Vascutek

has delivered devices to treat more challenging anatomies, including a number of complex cases. Four and, on a few occasions, five fenestrated devices that sometimes call for an accessory renal artery or early branching of the coeliac trunk have been manufactured and successfully implanted. The unconstrained main body fabric has no interfering stent structures, and thus it is theoretically possible to position fenestrations anywhere across the device circumference. This allows a design that is tailored to match the anatomy of each individual patient. In addition to bifurcated devices, custom cuff and aortouni-iliac devices can be provided depending on the requirements of the specific patient. Custom leg devices have also been implanted.

SIZING AND PLANNING

Cases are reviewed on an individual patient basis, with the CT data assessed by the Vascutek planning team. An engineer then provides a custom device scheme outlining the proposed design for that patient based on critical measurements obtained from the CT data. Figure 2 shows a typical device scheme, which outlines visceral vessel positions and intended fenestration locations alongside the proximal sealing ring profile, which is calculated at the intended landing zone in the aorta with corresponding fixation hook locations. At this stage, the case planners and engineers can determine the most appropriate type of device design for the particular anatomy and quickly present this proposal to the clinician to agree on the initial intended device design.

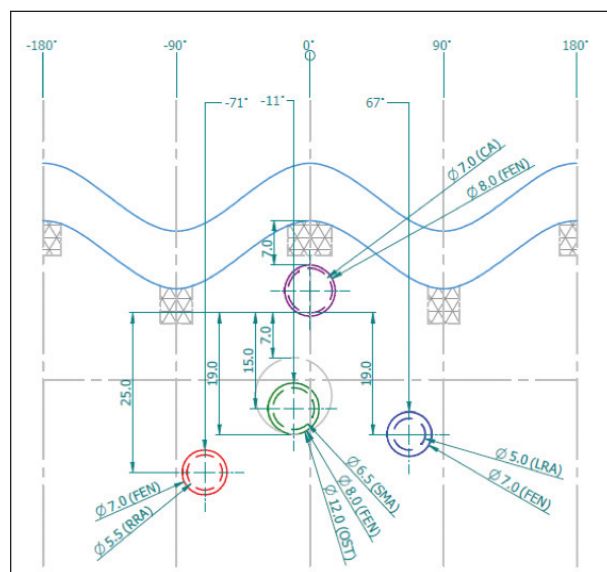


Figure 2. The Fenestrated Anaconda™ Custom AAA Stent Graft System device scheme.

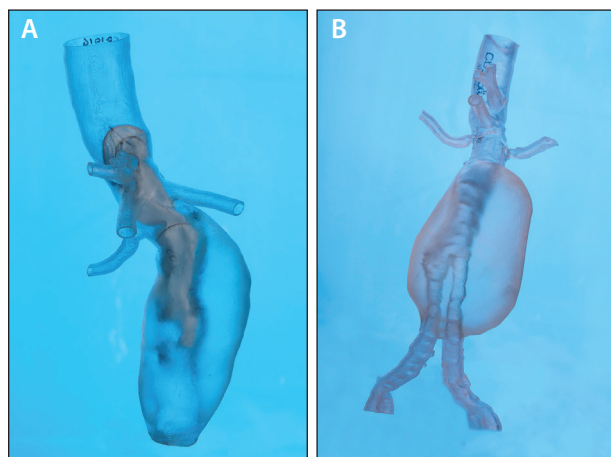


Figure 3. Examples of 3D printed anatomy models. The device deployed inside an anatomy model with four fenestrations (A). A printed model showing an *in situ* existing EVAR device (B).

The CT data are then used to produce a 3D printed model (Figure 3) of the patient's individual anatomy. A prototype device is manufactured and tested to verify the suitability of the design, allowing assessment of important aspects of the design and the forthcoming procedure. This process includes assessing the alignment of the fenestrations with branch vessel ostia, ease of cannulation, suitability of the sealing ring profile, ease of repositioning of the device, tortuosity of the aorta and branch vessels, and identification of any additional risks associated with the design.

The model and prototype are then sent to the clinician for evaluation. Clinician prototype testing is typically performed under fluoroscopy (Figure 4). This allows visualisation of the device in the 3D replica of the patient's anatomy to help evaluate the best approach to take during surgery and to determine the most appropriate equipment to use for cannulation. The sterile device is then manufactured within the agreed time frame, which is typically 3 weeks following approval.

CONCLUSION

Growing clinical evidence and experience with the Fenestrated Anaconda™ Custom AAA Stent Graft System coupled with continued utilisation of the lat-

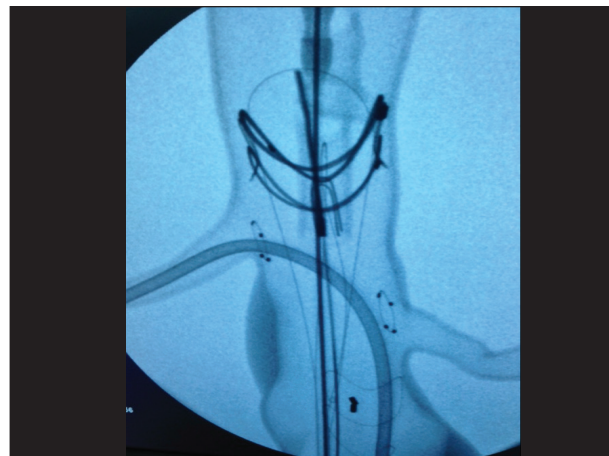


Figure 4. Clinician test deployment performed under fluoroscopy.

est 3D printing technology, computer-aided design, and clinical measurement software throughout the past 6 years have led to a number of further customisable opportunities in device design. Tapered and flared device configurations can be used to treat anatomical variants where significant changes in arterial diameters are identified at the planning stages. To date, over 1,600 Fenestrated Anaconda™ Custom AAA Stent Graft Systems have been implanted worldwide, and it is now a well-recognised treatment option for patients with complicated anatomy who cannot be treated with conventional EVAR. ■

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Disclosures: None.