

# Case Rehearsal in 3D Aortic Models Using Prototypes of the Fenestrated Anaconda™ Custom AAA Stent Graft System

How printing your patient's anatomy may help maintain high technical success of fenestrated endovascular aortic aneurysm repair.

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The Fenestrated Anaconda™ Custom AAA Stent Graft System (Vascutek Ltd.) is intended for the treatment of abdominal aortic aneurysms with an insufficient infrarenal landing zone. The endografts are custom made based on high-resolution, 1 mm slice CTA images. The planning and construction of a fenestrated endograft for complex aortic anatomy is critical when exact positioning of the graft is paramount to guarantee cannulation of the aortic branches. For every case, a non sterile prototype, as well as a 3D model, are constructed to allow the engineers, as well as the physician, to “test implant” the device and review the anatomic fit of the graft. Modifications to the initial graft design based on the results of prototype testing help maintain high technical success of fenestrated endovascular repair of pararenal aortic aneurysms.

## ENDOVASCULAR AORTIC ANEURYSM REPAIR

Compared to open aneurysm repair, endovascular aortic aneurysm repair (EVAR) may offer reduced peri-operative morbidity and mortality. Continuous improvement in graft design is among the important factors that have established EVAR as a viable and often-used option for aortic aneurysm repair with good long-term results.<sup>1,2</sup> Specific anatomic criteria have been defined for eligibility for endovascular treatment of an abdominal aortic aneurysm, and according to the current literature, a relatively large number of patients are actually not eligible for EVAR due to anatomic restrictions.<sup>3,4</sup>

The configuration of the proximal sealing zone (neck) is an important factor to consider when assessing the feasibility of EVAR. Whenever the proximal sealing zone is insufficient to allow for durable endovascular repair of an abdominal aortic aneurysm with off-the-shelf endografts, open aneurysm repair, hybrid procedures, off-label parallel

stent graft implantation, or fenestrated EVAR (FEVAR) may be considered as alternatives to conventional EVAR.

## FEVAR AND 3D AORTIC MODELS

Published results of fenestrated graft implantation have been encouraging<sup>3-7</sup> and one example of the available devices used to perform FEVAR is the Fenestrated Anaconda™ Custom AAA Stent Graft System. This custom-made device (Figure 1) is manufactured according to high-resolution 1 mm slice CTA images of the patient. As a “so-called” case rehearsal service, Vascutek provides a graft prototype and a 3D model of the specific patient's anatomy during the endograft design and manufacturing process. This is intended to allow *in vitro* visualisation of the *in vivo* anatomical fit of the custom-made



Figure 1. A representative device plan for a custom-made Fenestrated Anaconda™ Custom AAA Stent Graft System.

graft. To manufacture the 3D aortic models, the DICOM data in a patient's CT scan are utilised to establish a stereolithography (SLA) file, which will provide a pattern for an ultraviolet (UV) laser to transform photosensitive liquid polymer resin into a hard structure within the model. In a segmentation process, special software is used to allow isolation of the anatomical regions of interest held within the CT (usually, this involves the vascular structures starting a few centimetres above the coeliac trunk down to the iliac arteries). Initial segmentation will represent blood flow, and two more steps (creation of a wall and subtraction of the blood flow segmentation to achieve a representation of the blood vessel with a lumen) are necessary to create the final data set. Once transformed into an SLA format, the data can be sent to a 3D printer for aortic model creation.

SLA printing techniques are used to produce the models, which are transparent, rigid, solid structures made of UV light-cured epoxy resin, as previously described. Being transparent can be considered a valuable property when using the models for prototype testing, because it allows visualisation and evaluation of the deployed prototype inside the model. Over time though, if continually exposed to UV light, the SLA models can be prone to discolouration, which might reduce their transparency.

### PROTOTYPE TESTING IN AN AORTIC MODEL

An apparent benefit of using 3D aortic models during FEVAR planning is to verify that the device design is suitable for the patient. The engineers at Vascutek, as well as the physicians, can deploy a prototype of the graft within the anatomical model and assess the position of fenestrations relative to the ostium of renal and visceral target vessels (Figure 2). Wires and catheters can be used to cannulate the target vessels, which, apart from verifying that cannulation is not prohibited by a misaligned fenestration or "rucking" of the fabric, can help with technical considerations (eg. whether access via the subclavian artery may be necessary in addition to the usual access via the groin). The saddle shape that the proximal sealing rings assume at

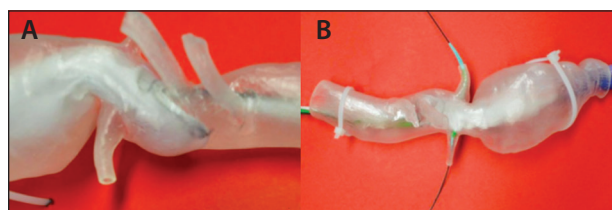
the proximal sealing zone can also be evaluated. Because the prototype contains the same markers as the final sterile endograft and the 3D model can also be used under fluoroscopy, the test procedure can be performed in the operating room. Naturally, changes can be made to the final graft design according to the information gathered during prototype testing, whether under fluoroscopy or simply by visually evaluating the prototype fit within the transparent model. Considering the potentially debilitating adverse events associated with a non optimal fit of a custom-made graft (eg. primary unconnected fenestrations with potential organ hypoperfusion or type I endoleaks), the possibility to test implant the device can be a valuable opportunity to improve the endograft design and prevent complications. Results from the engineers' test implantation are provided to the physician in a test summary. Additionally, physicians are able to test implant the device in a 3D aortic model themselves.

### WHY IS PROTOTYPE TESTING IN AORTIC MODELS INCLUDED IN THE GRAFT DESIGN PROCESS?

In the majority of cases, the initial prototype could be implanted with good technical success. Nonetheless, prototype testing in a 3D model offers the physician the possibility to modify and thereby optimise the final design, for instance, by moving a certain fenestration even by just a few millimetres. The possibility to test a non sterile prototype of the designed prosthesis in a 3D model of the patient's aorta can aid the design and construction processes by simulating *in vivo* fit of the designed stent graft in an *in vitro* setting. At our department, major changes (such as the inclusion of an additional fenestration into the graft design) have been made in approximately 20% of cases based on the results of prototype testing in an aortic model. Arguably, such modifications help maintain a high technical success rate in these procedures, which heavily relies on an ideal fit of the custom-made prosthesis.

### WHAT ARE THE LIMITATIONS OF PROTOTYPE TESTING IN AORTIC MODELS?

Many of the limitations of this *in vitro* fit test are related to the rigid design of the 3D model. Proximal sealing or any straightening of the vessels after introduction of stiff wires or the delivery system cannot reliably be simulated. Initially, iliac segments were also included in the prototype, but later omitted due to the rigid property of the material that prohibited advancement of the delivery system in tortuous vessels. In such cases, the iliac segment had to be sawn off to allow prototype deployment. Despite these limitations, use of rigid 3D models remains feasible, as the currently explored softer materials have been found to be



**Figure 2.** An example of prototype testing in a 3D model with assessment of the proximal seal with clearance between the superior mesenteric artery and the valve (A) and the ability to cannulate target vessels through fenestrations (B) on a double-fenestrated device.

easily damaged through repeated bench testing (eg. by small fixation hooks on the device).

## CONCLUSION

Technical success of FEVAR heavily depends on precise anatomical fit of the prosthesis. This is especially true for the Fenestrated Anaconda™ Custom AAA Stent Graft System, as the graft can be fully deployed and wall contact achieved prior to cannulation of fenestrations and branch vessels. A case rehearsal service provided by Vascutek during the endograft design and manufacturing process allows for *in vitro* testing of a non sterile prototype of the prosthesis in a 3D aortic model. The anatomical fit of the prosthesis can be assessed and, if necessary, adjusted by modifications such as movement of a fenestration. Anecdotal and according to currently unpublished data, this helps maintain a high technical success rate for this complex endovascular procedure. ■

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