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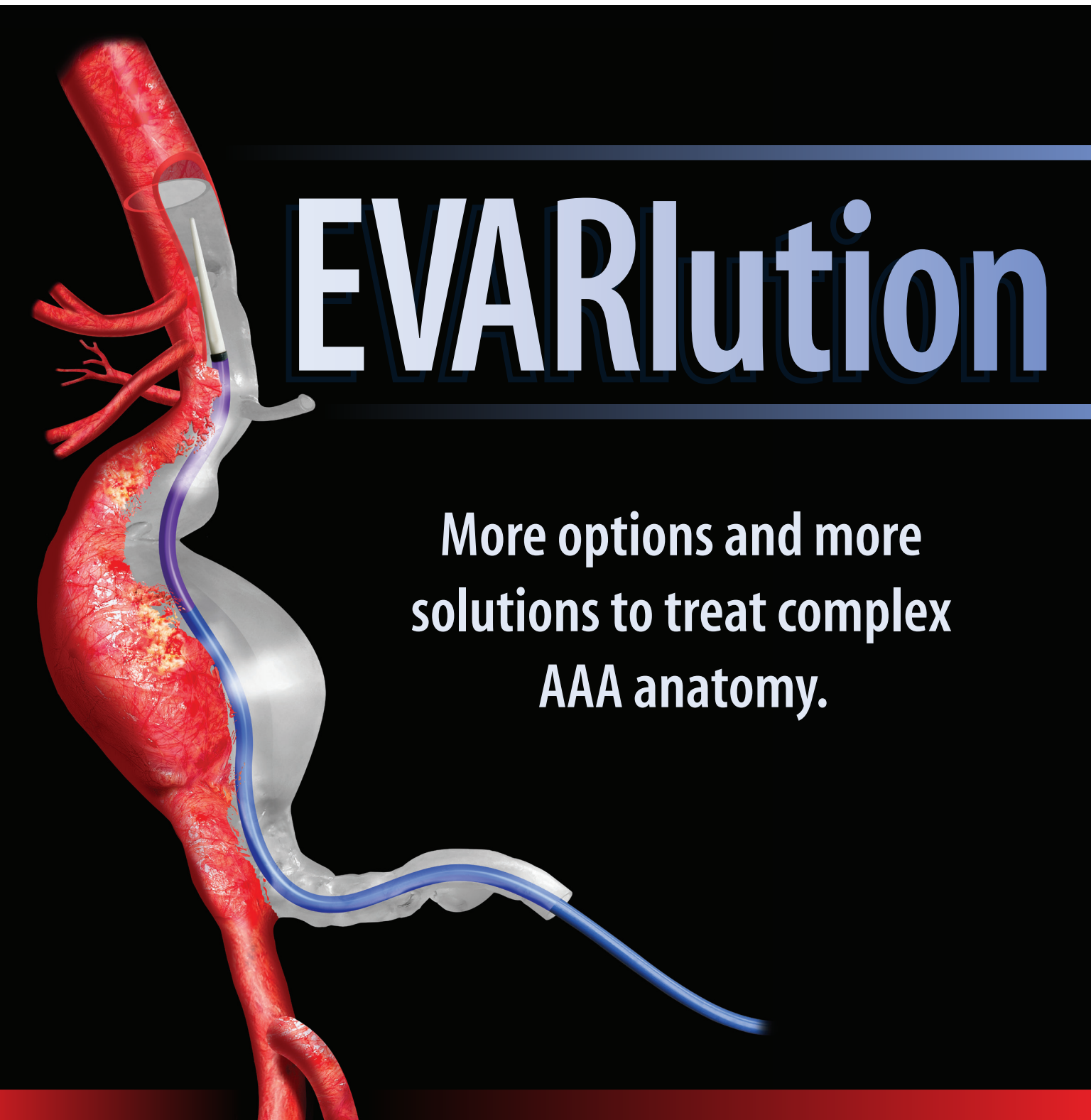

EVARlution

More options and more solutions to treat complex AAA anatomy.

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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.

BY ALUN H. DAVIES, MA, DM, DSc, FRCS, FHEA, FEBVS, FACPH

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 excellent 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.

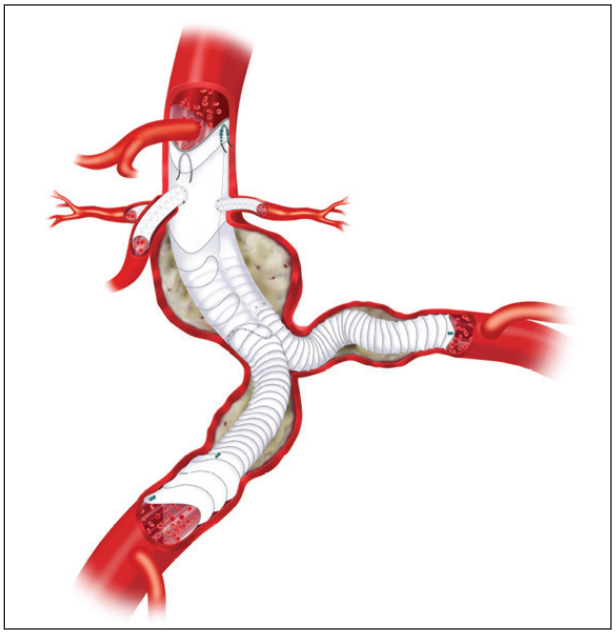

Figure 1. A representation of a deployed Fenestrated Anaconda™ Custom AAA Stent Graft System with the coeliac trunk accommodated in the anterior valley of the device.

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.

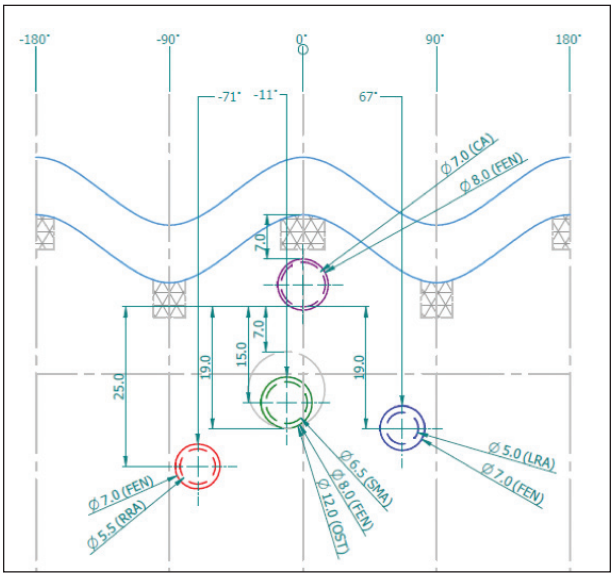

Figure 2. The Fenestrated Anaconda™ Custom AAA Stent Graft System device scheme.

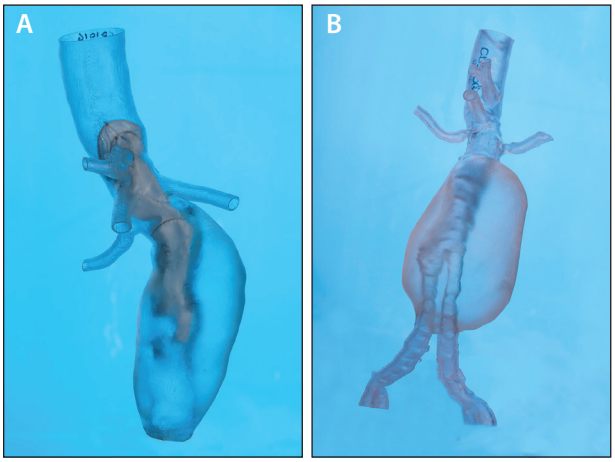

Figure 3. Examples of 3D printed anatomy models. The device deployed inside an anatomy model with four fenestrations (A). A printed model showing an *in situ* existing EVAR device (B).

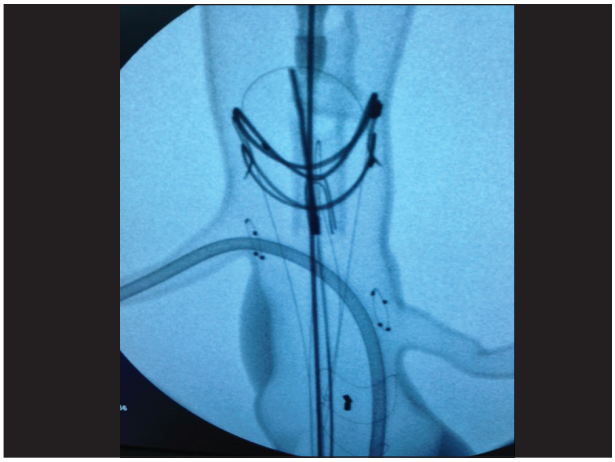

Figure 4. Clinician test deployment performed under fluoroscopy.

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 latest 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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Fenestrated Anaconda™ Custom AAA Stent Graft System for Pararenal Aortic Aneurysmal Disease

How the novel features of this device can optimise results in challenging pararenal aortic aneurysm cases.

BY RANDY D. MOORE, MD, MSc, FRCSC, FACS, AND DARSHAN BAKSHI, MD, FRCPC

The management of juxtarenal and/or pararenal aortic aneurysmal disease remains a challenge, with open surgical morbidity and mortality rates that are increased threefold compared to standard infrarenal aortic repair.[1] Only recently have endovascular strategies been developed to expand the indications for endovascular aortic repair in the juxtarenal/pararenal vascular beds. Early innovators expanded the use of commercially available devices to include novel strategies, such as snorkel or chimney techniques, or on-table fenestrations to allow for endovascular repair. These off-label uses have demonstrated short-term success but can be associated with significant long-term failure and reintervention rates.[2] Although chimney or parallel graft technique outcomes continue to improve, fenestrated endovascular repair of juxtarenal aortic aneurysms has demonstrated similar outcomes to open repair, with reductions in peri-operative mortality and morbidity, as well as length of hospital stay.[3] The Fenestrated Anaconda™ Custom AAA Stent Graft System (Vascutek Ltd.) has been uniquely configured to allow safe placement of endovascular devices in the juxtarenal/pararenal location and has demonstrated excellent short-term results.[4] Next, we present a case report that illustrates pararenal deployment with the Fenestrated Anaconda™ Custom AAA Stent Graft System.

CASE REPORT

A 68 year old man was referred to our centre for management of a symptomatic, 5.6 cm abdominal aortic aneurysm with an absent infrarenal aortic neck, reverse-tapered pararenal configuration, and 90° anteroposterior angulation (Figure 1). The patient was deemed to be an unsuitable anatomic candidate for standard infrarenal aortic repair and was classified as high risk for open repair due to his comorbidities, including hypercoagulable syndrome (lupus anticoagulant positive), abdominal obesity, and a hostile abdomen due to multiple previous laparotomies (diverticular disease). His anatomy was reviewed by the planning team for fenestrated repair, and he was approved for device prototype manufacture. After mock deployment with the prototype in the 3D anatomical model was completed, he was fast-tracked

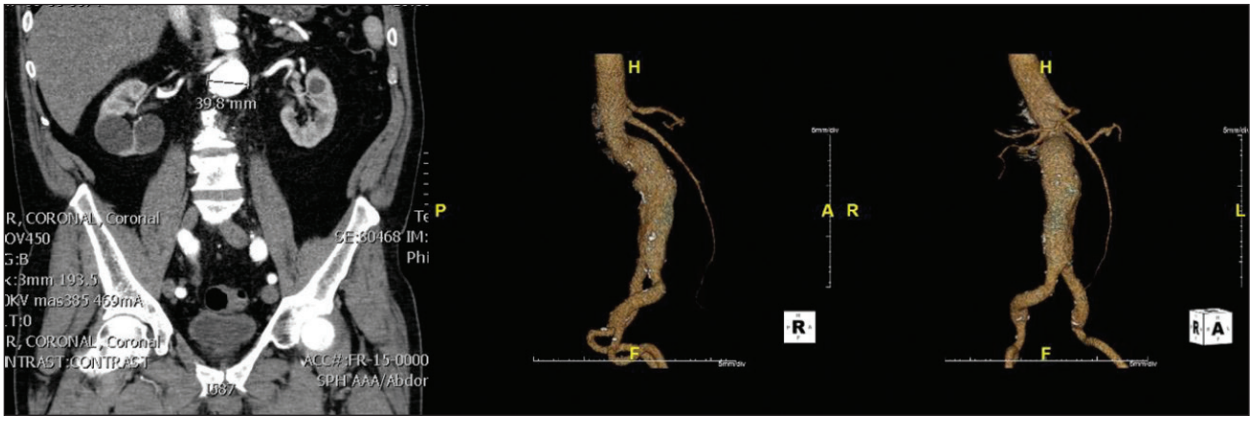

Figure 1. Pararenal aortic aneurysmal disease with an absent infrarenal neck and a short distance (< 10 mm) between the renal and visceral artery branches.

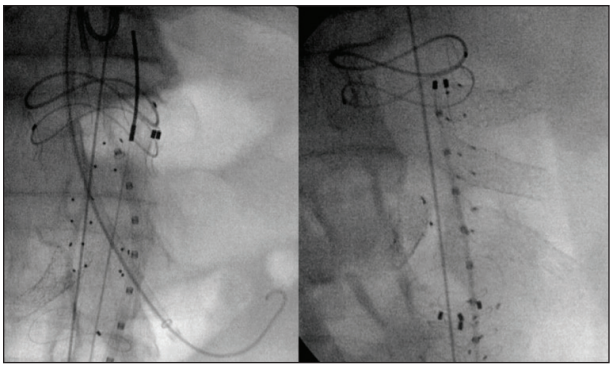

Figure 2. Intra-operative visceral branch access from the left axillary artery. All branch vessel stents in position after main body deployment (right).

for device production and was brought to the operating room 4 weeks after initial planning submission. Due to the absent infrarenal neck and the relative crowding of the perivisceral segment vessels, a four-branch fenestrated device was used.

Intra-operative challenges included the patient's obesity and the acute downward angulation of the renal arteries. Left axillary arterial access was achieved via ultrasound, and a 7 F, 80 cm Destination sheath (Terumo Interventional Systems) was placed into the descending thoracic aorta to allow for selective cannulation. Bilateral common femoral arterial access was achieved via percutaneous ultrasound guidance, and "preclosure" was completed with a Perclose ProGlide device (Abbott Vascular). Branch arteries were selectively catheterised and stented from above, starting with the coeliac axis and working downward to the renal arteries. Advanta V12 stents (Maquet Medical Systems) were utilised to sequentially stent each branch vessel, with postdeployment dilation using non compliant balloons to ensure proper mating to the stent graft fenestrations (Figure 2).

Completion aortography performed while the patient was fully anticoagulated demonstrated a late type II endoleak. Percutaneous closure devices were used to complete the arteriotomy repairs, with a total operative time of 180 minutes and a fluoroscopy time of 23 minutes (Figure 3).

The patient was discharged on the second postoperative day, with dual-antiplatelet therapy to ensure branch vessel patency. CT imaging at 1 and 2 year follow-up demonstrated no signs of residual endoleak, with marked reduction in aneurysm sac size and wide patency of all branch target vessel stents (Figure 4).

DISCUSSION

The Fenestrated Anaconda™ Custom AAA Stent Graft System has revolutionised the treatment of juxtarenal and pararenal aortic aneurysmal disease. The O-ring with unsupported body stent design eliminates the constraints on fenestration placement that is associated with the Z-stent design and allows for full customisation to patient anatomy and reduced seal zone length requirements. The device's retractable constraining collar and

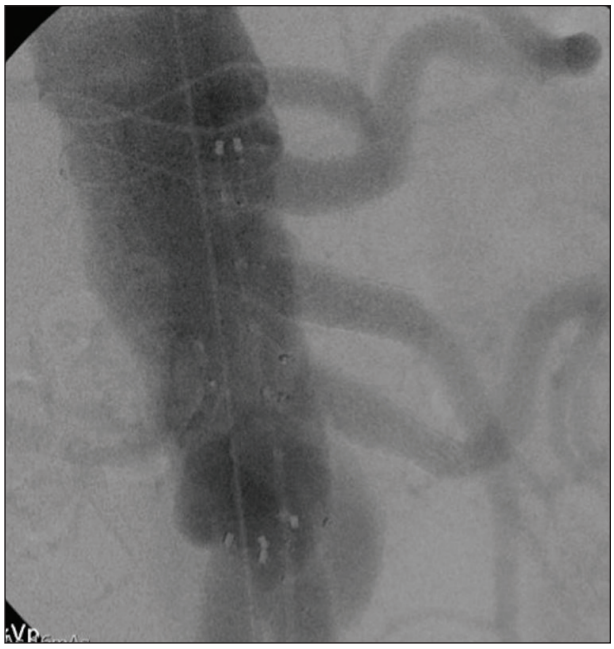

Figure 3. Completion aortogram demonstrating wide patency of all branch vessels and a delayed type II endoleak.

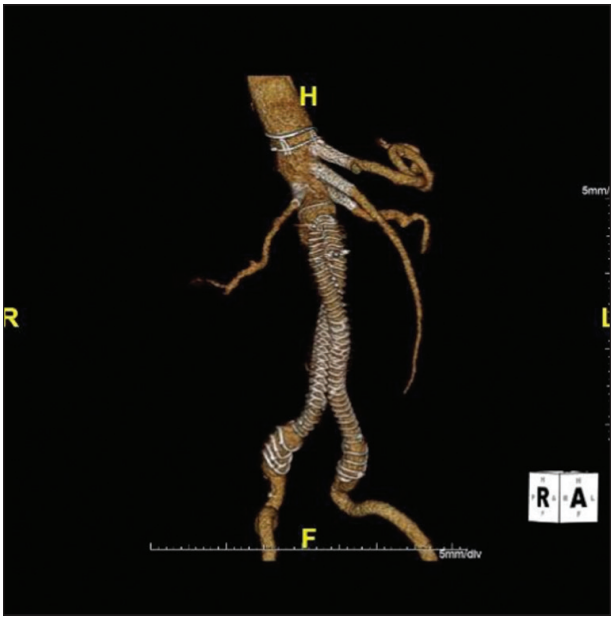

Figure 4. Two year follow-up CT scan demonstrating wide patency of all target vessels. The aneurysm sac has almost completely regressed.

minimally supported fabric allows for repositioning of the device during sequential cannulation, which markedly improves the ability to align fenestrations with branch vessels. Each branch can be selectively cannulated and stented before moving on to the next, which shortens cannulation times, reduces radiation exposure, and eliminates sheath and wire crowding inside the main body of the device.

As well as incorporating novel features inherent on standard Anaconda™ devices, such as the magnet wire cannulation system for the contralateral gate that also shortens operative times, there are a number of potential customisable options for Fenestrated Anaconda™ devices. These include additional wire supports for the fenestrations to prevent fabric "rucking" or folding in certain situations where, at the planning stage, there is increased risk of interference with cannulation as well as tapered or flared devices with differing device diameters to accommodate narrow aortic regions or allow for placement in fully aneurysmal pararenal segments. ■

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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.

BY FADI TAHER, MD; JÜRGEN FALKENSAMMER, MD; AND AFSHIN ASSADIAN, MD

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.[1,2] 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.[3,4]

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[3-7] 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

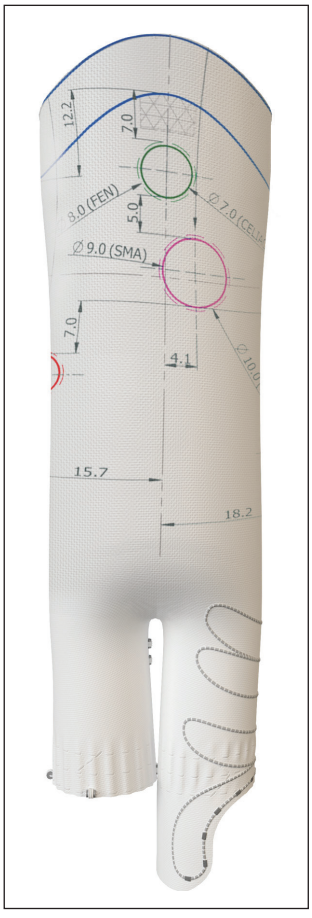

Figure 1. A representative device plan for a custom-made Fenestrated Anaconda™ Custom AAA Stent Graft System.

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.

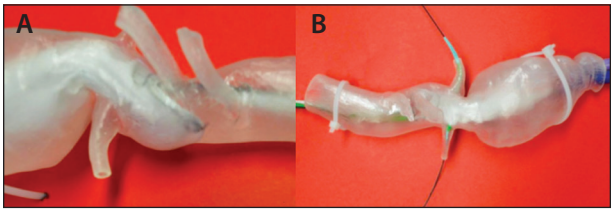

Figure 2. An example of prototype testing in a 3D model with assessment of the proximal seal with clearance between the superior mesenteric artery and the valley (A) and the ability to cannulate target vessels through fenestrations (B) on a double-fenestrated device.

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

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. Anecdotally and according to currently unpublished data, this helps maintain a high technical success rate for this complex endovascular procedure. ■

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Anaconda™ AAA Stent Graft System for Challenging AAA Anatomy

How endograft platforms perform in infrarenal neck angulations up to 90°.

BY ROBERT H. GEELKERKEN, MD, PHD; ROLAND J. BEUK, MD, PHD; AND ROBBERT MEERWALDT, MD, PHD

The large randomised clinical trials[1-5] comparing endovascular aneurysm repair (EVAR) with traditional open surgical repair (OSR) in elective infrarenal abdominal aortic aneurysm (AAA) treatment point out that in the first years after treatment, EVAR gives rise to better outcomes. After this initial finding, stent graft migration, ephemeral sealing between the vessel wall and the stent graft, stent breakage, stent component disconnection, prosthetic tearing, and limb occlusion were the causes of increased EVAR failure. Learning from the experience with the first-generation endografts and due to technological advances, there has clearly been improvement in the next generation of commercially available stent grafts. It is fairly reasonable to assume that the present generation of stent grafts allows a more durable outcome in the same circumstances, compared to the first generation used in the randomised clinical trials of the 1990s.

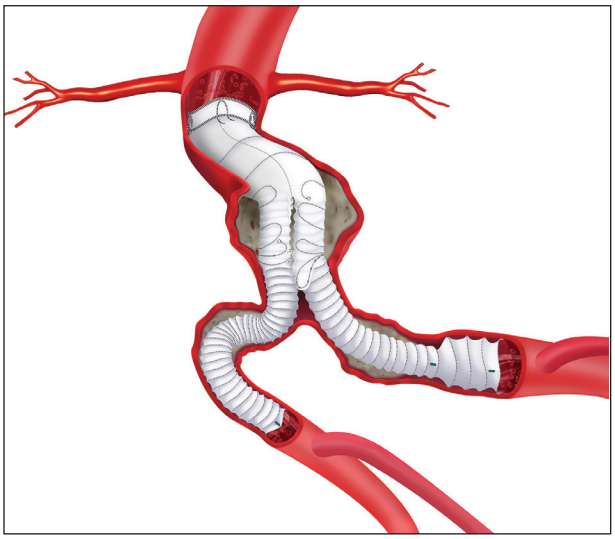

Figure 1. The Anaconda™ AAA Stent Graft System with ONE-LOK™ platform is composed of a three-piece modular track design.

THE ROAD TO THE ANACONDA™ ONE-LOK™ DESIGN

The Anaconda™ AAA Stent Graft System (Vascutek Ltd.) has been designed with the intention of addressing the failure modes observed in the 1990s designs. The first experiences with the Anaconda™ AAA Stent Graft System were encouraging; migration and type I or III endoleak were rarely observed.[6,7] In 2009, the Anaconda™ AAA Stent Graft System's design was upgraded to the ONE-LOK™ platform, which addressed, among other things, the relatively increased chance of early leg occlusion observed when smaller bodies were combined with larger legs. This version of the Anaconda™ ONE-LOK™ had a three-piece modular track design. The body with two short legs was characterised by two independent proximal sealing rings composed of multiple turns of fine nitinol, active fixation on the second ring due to four independent pairs of nitinol hooks, and zero body column strength in combination with additional body supporting ring stents (Figure 1). During placement, the proximal rings of the body were reconstrainable, allowing multiple rotational and upstream or downstream repositioning. The contralateral gate was preloaded with a magnet-bearing wire, which made contralateral limb cannulation quite simple. The legs were constructed of six to 10 individual turns of nitinol wires in a vacuum cleaner hose of tapered, straight, or flared design creating flexibility and kink resistance. The design of this system creates a convenient platform for challenging cases such as ruptured AAAs (rAAAs) with severely angulated infrarenal necks.

A CASE ON THE FRONTIER OF RAAA TREATMENT

In 2010, an 84 year old man who appeared to be very healthy visited our outpatient department, presenting with a 50 mm asymptomatic AAA. After shared decision making and discussing the option of elective AAA repair, a watchful waiting approach was chosen. The

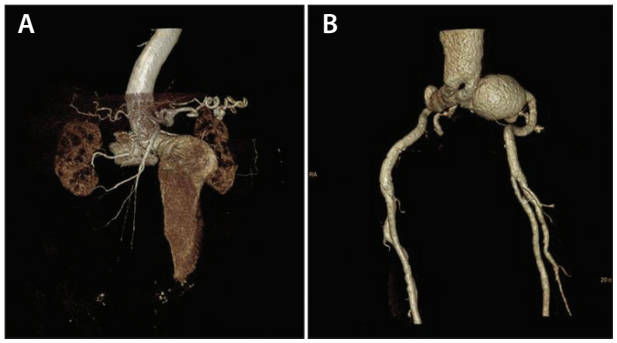

Figure 2. A 3D reconstruction of the proximal AAA anatomy (A) and distal AAA anatomy (B). Due to low flow, two separate CTAs were necessary.

patient did not attend regular visits, including recommended abdominal ultrasound examinations. In 2016, the patient was still living independently. His family doctor admitted him to our emergency department with increasing pain in his back and a painful pulsating abdominal mass.

At admission, the patient was conscious, but his blood pressure dropped to 90/60 mm Hg. He noted that if he was eligible, he preferred EVAR over OSR. An emergency CTA revealed a contained rupture of a 104 to 107 mm rAAA with an infrarenal neck diameter of 20 mm, neck length of 14 mm, and angulation of 75°. Furthermore, both common iliac arteries (CIAs) were very elongated, and the left CIA measured 51 mm in diameter (Figure 2).

Using CT fusion imaging (Discovery IGS 740, GE Healthcare) in our hybrid operating room, we performed ruptured EVAR (rEVAR). The main body delivery system was raised up to the level of the renal arteries, and the body of the Anaconda™ AAA Stent Graft System was released close to the origin of the lowest right renal artery (Figure 3). Thereafter, with three leg components on the left side and two leg components on the right side, the rAAA and the left CIA aneurysm were sufficiently excluded (Figure 4). The patient was admitted to the intensive care unit. He recovered well and was discharged on post-operative day 11 to a rehabilitation centre to prepare for his return home.

TIPS AND TRICKS FOR USING THE ANACONDA™ AAA STENT GRAFT SYSTEM IN CHALLENGING ANATOMY

Our first recommendation is to perform EVAR procedures in a hybrid operating room equipped with a CT fusion imaging system. This technique assists in better understanding of the images, simplifies the procedure, and, consequently, significantly reduces radiation and contrast exposure.[8] When using this system in AAAs with challenging anatomy, one must be aware of some additional tips and tricks that may be helpful in introducing and placing the stent graft. In cases with severe infrarenal neck angulation, it can be beneficial to aim for a relatively higher oversizing of the body in relation to the infrarenal neck diameter because the release of the body exactly perpendicular to the central lumen line is not achieved in all cases.

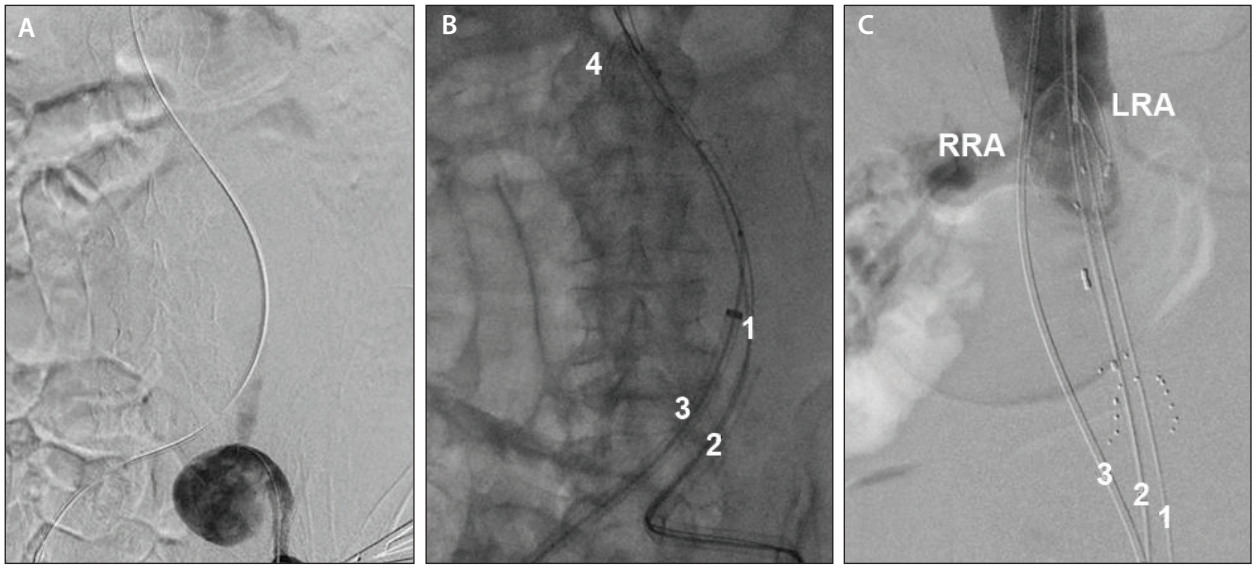

Figure 3. Panel A shows challenging left iliac access. Panel B shows two stiff wires on the left side (1), Check-Flo large introducer sheath (Cook Medical) (2), delivery device (3), and body of the Anaconda™ AAA Stent Graft System (4). Panel C shows a second stiff wire on the left side (1), a stiff wire on the right side of the body delivery system (2), and a straight flush catheter (3).

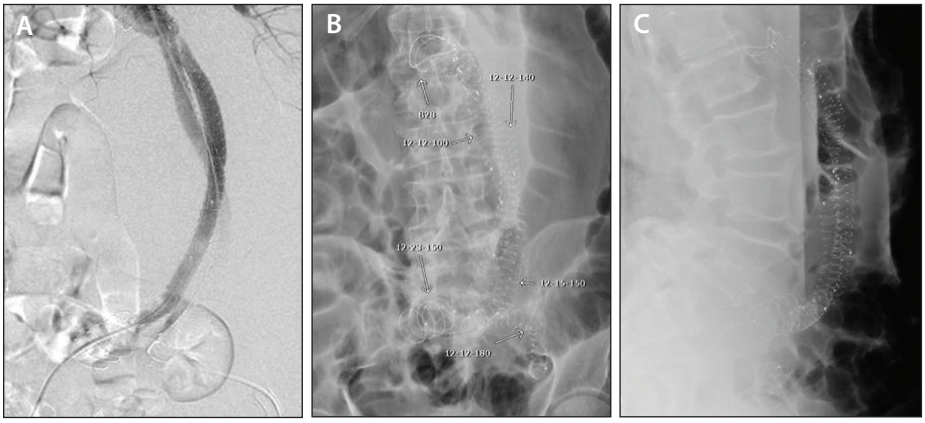

Figure 4. Completion angiogram (A), anteroposterior view of the six components (B), and lateral view (C).

Implantation starts with the routine technique of achieving access in both common femoral arteries by surgical cutdown or by a percutaneous Seldinger approach. Anticoagulation therapy is administered in accordance with the local standard for endovascular procedures. On both sides, one or two stiff wires are introduced up to the aortic arch. To stretch the iliac and aorta angulations further, starting on the contralateral iliac side or on both iliac sides, an 18 or 24 F (inner diameter), 20 to 25 cm long introducer sheath is placed up to the level of the AAA. Next, place the body juxtarenal in a rotated position with no legs in an inner or outer position in relation to the infrarenal angulation (in most cases, one of the legs is situated behind the other in an anteroposterior view). This prevents the outer leg from compressing the inner leg at the level of the neck angulation.

Next, access to the contralateral gate with the magnet wire system is achieved. In up to 95% of cases, contralateral gating is achieved within a few minutes.[9] The contralateral guiding catheter is pushed forward, up to the level of the visceral arteries, and the magnet wire is interchanged for one or both stiff wires. If there is still a sharp angulation, the contralateral 18 F introducer sheath is pushed forward, up to the level of the infrarenal neck. Through the contralateral guiding catheter or a regular angiography catheter, digital subtraction angiography is performed to visualise the renal artery orifices. The body of the Anaconda™ AAA Stent Graft System could be repositioned upstream or downstream, if indicated.

The marker ring at the top of the contralateral guiding catheter is then placed at the level of the flow splitter 8 marker on the Anaconda™ body, and the length of the contralateral leg is defined using the pull-back technique to the expected level of the CIA bifurcation. The contralateral guiding catheter is removed, and the delivery device with the appropriate contralateral leg is introduced up to the level of the renal arteries. The release wires of the body are pulled out, and the delivery device of the body is removed. The delivery device with the chosen leg on the ipsilateral side is introduced. The large introducer sheaths are simultaneously withdrawn up to the level of both CIA origins, and both legs are released (similar to the kissing stent technique) with the proximal markers of both legs just below the second body sealing and fixation ring. At the level of the CIAs, the introducer sheaths are withdrawn ahead of the releasing legs. The body and both legs are gently ballooned, and final angiography is performed to assess the patency of the renal arteries, endograft, internal iliac arteries, as well as any early or late endoleaks.

OUTCOMES OF VARIOUS STENT GRAFT SYSTEMS IN CHALLENGING ANATOMY

Anatomical characteristics of AAAs are the most critical factors in achieving successful EVAR outcomes. Challenging anatomy is characterised by > 60° infrarenal angulation or > 90° iliac axis tortuosity, short (< 15 mm) infrarenal neck, or reversed conical and bell-shaped necks. Of these, severe proximal aortic neck angulation has the greatest potential for fixation failure, a situation that may lead to complications including type I endoleak and late rupture. Bench test studies identified that the relative stiffness of a stent graft was responsible for its inability to conform to neck angulation, therefore creating leaks through gaps between the stent graft and the neck. Several publications have discussed the application of endografts in challenging anatomies.

Anaconda™ AAA Stent Graft System

Freyrie et al[10] published a series of 44 AAA patients treated with the Anaconda™ AAA Stent Graft System. All patients had severe angulation of the proximal aortic neck (> 60° angulation) and/or of the iliac arteries (> 90° angulation). Primary technical success was achieved in 100% of patients. At 24 months, survival, primary clinical success, and assisted clinical success rates were 94.2%, 88.2%, and 91.3%, respectively. Two year iliac limb paten-

cy in severely angulated iliac axes was 96.7%. Only one proximal type I endoleak was noted.

In a prospective multi-centre cohort study, Rödel et al[11] evaluated the midterm outcomes of using the Anaconda™ system for treating infrarenal AAAs with angulated necks. In a 5 year period, a total of 36 AAA patients with a mean infrarenal neck angulation of 82° were included. Primary technical success was achieved in 30 of 36 patients (83%). Four year primary clinical success was 69%. There was no aneurysm-related mortality. Four patients required conversion to open AAA exclusion. In six of the 36 patients, one or more reinterventions were indicated; five were due to occlusion of one leg or the complete body. The investigators concluded that using the Anaconda™ system to treat AAAs with severely angulated infrarenal necks is feasible, but comes with side effects.

The Anaconda™ ONE-LOK™ platform is also feasible for the management of short-neck infrarenal and juxtarenal aortic aneurysms with fenestrated EVAR (FEVAR). The first Dutch experience including 23 patients who were treated for juxtarenal aneurysms and two patients with short-neck AAAs were reported by Dijkstra et al.[12] A total of 56 fenestrations were incorporated, and 94.6% were successfully cannulated and stented. On completion angiography, three type I endoleaks and seven type II endoleaks were observed. At 1 month follow-up, all endoleaks had spontaneously resolved. There were no aneurysm ruptures or aneurysm-related deaths and no reinterventions. Primary patency at 1 month of cannulated and stented target vessels was 96%.

Aorfix Stent Graft

Sbarzaglia et al[13] reviewed the available data in the literature regarding the Aorfix stent graft (Lombard Medical, Inc.). They concluded that the high performance of the Aorfix stent graft did not present any significant difference between necks > 60° and < 60°, and in a personal series of 27 patients, they reported a primary technical success rate of 96.3% and an assisted primary technical success rate of 100%.

Powerlink Stent Graft

Experience using the Powerlink stent graft (Endologix, Inc.) has been reported by Qu et al.[14] In a single-centre study, 519 patients underwent EVAR using the Powerlink endograft. There were 54 cases in the short neck group, with lengths of 11 to 15 mm, and 26 cases involving very short necks, with lengths ≤ 10 mm. Angulated necks (37 patients) were defined as ≥ 60° between the longitudinal axis of the infrarenal aorta and the aneurysm. The technical success rate in these 177 challenging anatomy cases was 97.4%. Intraoperative complications included three conversions due to delivery access problems and six proximal type I endoleaks. The 30 day mortality rate was 1.7%. During follow-up, four proximal type I endoleaks were revised with a proximal cuff and/or Palmaz stent (Cordis Corporation). Limb occlusion occurred in two cases, and the total reintervention rate was 5.3%. There were no stent graft distal migrations, and no post-EVAR ruptures. The investigators concluded that the Powerlink stent graft platform proved safe and effective in treating AAAs with short and angulated necks.

Zenith Endovascular Graft

Forbes et al[15] reported their 5 year, single-centre outcomes in relation to neck length after elective placement of a Zenith endovascular graft (Cook Medical) in 318 patients. They concluded that patients with shorter infrarenal necks (4–15 mm in length) can be treated as effectively as those with longer necks using the Zenith endovascular graft, unless the necks are angulated or dilated.

Endurant Stent Graft System

The Endurant stent graft system (Medtronic) is also part of the next-generation systems designed to expand the applicability of EVAR in challenging anatomy. Verhagen et al[16] and Baston Goncalves et al[17] presented the preliminary results on the Endurant stent graft platform. Technical success was achieved in 90.3% of the patients. No device-related serious adverse events and no device-related deaths were seen during the early follow-up period. Their results support the adequacy of the Endurant stent graft system in the face of adverse neck anatomy. Neck length was the most relevant anatomical limitation for EVAR.

OUTCOMES IN CHALLENGING CASES

In a series of 439 patients treated with EVAR, the observed occlusion rate was 8.8% for those treated with Endurant, 5.8% for Zenith, 2.7% for the Anaconda™ system, and 2.2% for the Excluder endoprosthesis (Gore & Associates), with no statistical differences between these rates.[18] Significant angulation and excessive calcification were independent predictors of leg occlusion.

In the last 50 years, OSR for rAAA has a mortality rate of up to 50% despite rapid hospital transportation, early diagnosis, resuscitation, and improvements in anaesthesia and intensive care treatment.[19-21] Evidence was raised in several cohort studies that treating patients with rAAAs, including rEVAR whenever possible, achieved good results.[22-25] Three randomised clinical trials including rAAAs were published[26-28]; however, the mutual agreement between these trials was that

rEVAR does not improve survival. Remarkably, there was a prominent variance in 30 day mortality in these three trials between 18% to 53% in the rEVAR cohort and between 24% and 53% in the OSR cohort. It seems quite self-evident that study design, patient selection, and 24/7 presence of an experienced EVAR team are the drivers of this huge difference in 30 day mortality between the randomised clinical trials.

A recent systematic review concluded from the available data that there is no difference in the outcomes between rEVAR and OSR, but extrapolation to daily practice is limited by the paucity of data.[29] In the last decade, several vascular centres reported their results of treating patients with rEVAR whenever possible. Our experience with rEVAR is reflected in the publication by Rödel et al.[30] During a 4 year enrolment period, all 117 consecutive patients presenting with infrarenal rAAAs were assessed for preferential rEVAR treatment. Patients with challenging anatomy (infrarenal neck length < 15 mm and neck angulation > 60°) were included as part of a "damage control" concept. Thirty-five patients (33% of all admitted rAAA patients) were treated with rEVAR; 42% of them were considered haemodynamically unstable (systolic blood pressure < 100 mm Hg), and 30% had challenging AAA anatomy. The 30 day mortality in the rEVAR group was 17%. After a median follow-up of 3.4 years, mortality in the rEVAR cohort was 34%. All deaths were non AAA related. Our study shows that rEVAR is feasible in challenging AAA anatomy regardless of haemodynamic condition and that it is associated with relatively low mortality rates.

Nevertheless, six to seven out of 10 patients remain unsuitable for rEVAR because of inappropriate anatomy. Our preferential rEVAR treatment is also supported by other institutions. Ten Bosch et al[31] concluded that in EVAR-suitable rAAA patients, an absolute peri-operative mortality reduction of 25.5% with rEVAR versus OSR was achieved, which was still present at 6 months follow-up. In 2013, the nationwide Dutch Surgical Aneurysm Audit was started.[32] At the end of 2015, a total of 9,357 patients were included, with 15% rAAAs among them. Roughly 35% of the rAAAs were treated with rEVAR, and the 30 day mortality rate was approximately 26%.

CONCLUSION

The case presented and the literature discussed in this article underline the suitability of the Anaconda™ ONE-LOK™ platform in challenging anatomies. But using FEVAR in these cases challenged the EVAR team in more than one way. Dedicated endovascular skills were needed to compensate geometrical difficulties during stent placement. The operative procedures were customised to the patient in nearly every individual case. The features of the Anaconda™ AAA Stent Graft System including the repositionability of the two proximal ring stents during deployment, the unsupported and therefore more flexible main body, the three-piece modular platform, and the magnet system all expand the applicability of EVAR in challenging circumstances. ■

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Anaconda™ AAA Stent Graft System for Infrarenal Neck Angulations Up to 90°

A clinical case report demonstrating endovascular aneurysm repair in an elderly patient with hostile neck anatomy.

BY ANTONIO GIMÉNEZ-GAIBAR, MD; ELENA GONZÁLEZ-CAÑAS, MD; TERESA SOLANICH-VALLDAURA, MD; AND CAROLINA HERRANZ-PINILLA, MD

In 2013, approximately 75% of patients with abdominal aortic aneurysms (AAAs) were treated with endovascular aneurysm repair (EVAR) in the United States, but the potential advantages of this less-invasive approach are limited by the anatomical morphology of the aneurysm.[1] Approximately 20% of patients with AAAs have hostile neck anatomy that is inadequate for current stent grafts,[2] and some studies report that non favourable neck anatomy may result in exclusion from EVAR for approximately 60% of patients.[3]

CLINICAL CASE REPORT

An 84 year old woman without toxic habits but with a history of hypertension, asthmatic bronchitis, hiatal hernia, and cholelithiasis had undergone surgery for varicose veins and cataracts. Abdominal CT performed at another centre 6 months earlier showed a AAA with a diameter of 5.5 cm, but due to the patient's age, a conservative approach was adopted.

The patient presented to the emergency department with pain in the upper abdominal area, without nausea or vomiting. CTA revealed a AAA that was 6.6 cm in diameter, no mural thrombus, hostile neck with a 90º angle, 27 mm right common iliac artery aneurysm, and 15 mm left common iliac artery (Figure 1). Given the patient's clinical situation and rapid enlargement of the aneurysm, she was referred to our centre to assess the possibility of endovascular treatment of the aortic aneurysm.

The Anaconda™ AAA Stent Graft System (Vascutek Ltd.) with a bifurcated configuration was used for endovascular repair. First, embolisation of the right hypogastric artery was performed using an occlusion device (Amplatzer, St. Jude Medical, Inc.). The main body of the stent graft was placed in the infrarenal position, and the diameter used was 25 mm. A 19 mm left iliac extension was implanted in the common iliac artery, and subsequently, an endograft extension was placed in the right external iliac artery. Intra-operative angiography revealed the patency of the endoprosthe-

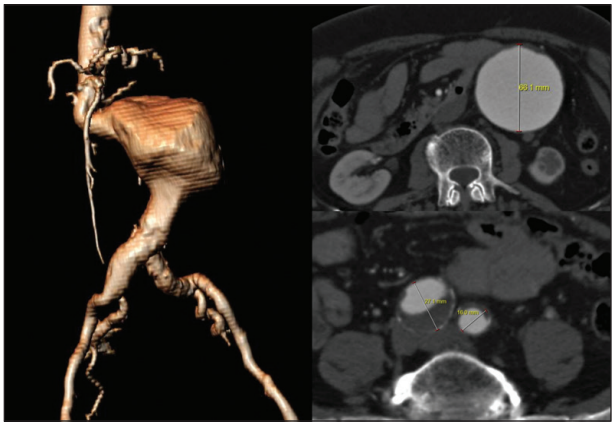

Figure 1. Pre-operative CTA.

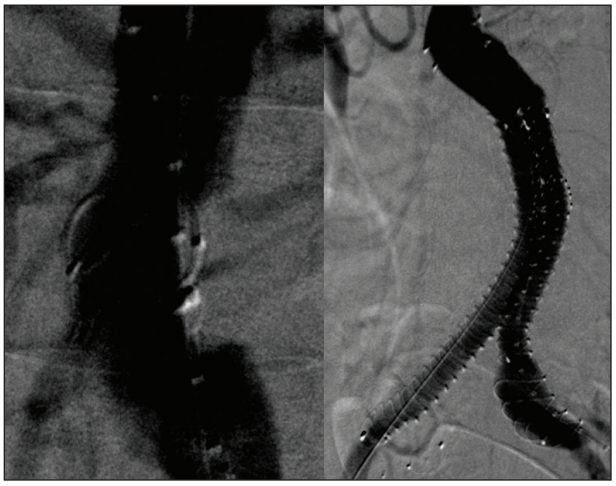

Figure 2. Intra-operative angiogram.

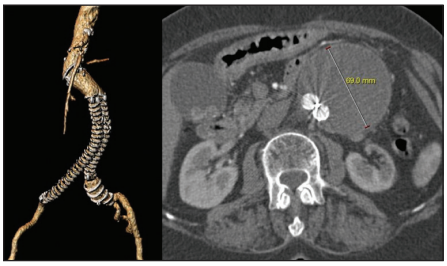

Figure 3. CTA at 1 month.

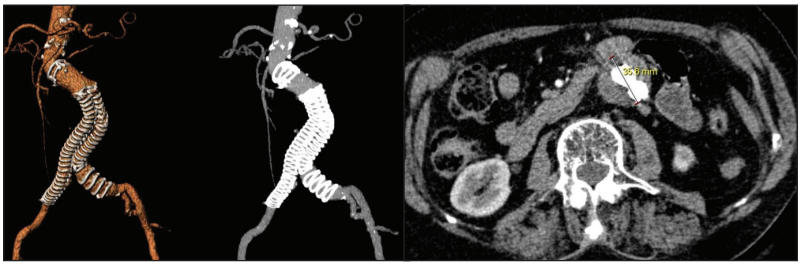

Figure 4. CTA at 5 years.

sis and visceral vessels, without endoleaks (Figure 2). Post-operative evolution was uneventful with remission of pain, and the patient was discharged after 72 hours. Follow-up CTA performed at 30 days (Figure 3), 12 months, and yearly thereafter has not shown any abnormalities, endoleaks, or migration, with a reduction in the diameter of the aneurysm sac to 38 mm at 5 years (Figure 4).

EVAR IN HOSTILE NECKS

Numerous authors have reported poor results with hostile AAA neck anatomy, but these often include a variety of grafts, techniques, and patient selection. A study by the EUROSTAR collaborators[4] revealed that the group of patients with the most severe neck angulation had the worst early and late results, but this was also the least healthy group of patients. On the other hand, Dillavou et al[5] considered that with careful selection, many patients with classic hostile necks may be successfully treated using an unsupported unibody endograft with active proximal fixation. In a meta-analysis of the literature, Antoniou et al[6] concluded that EVAR could be used in patients with unfavourable neck anatomy, but suggested that this approach should only be applied in patients at high surgical risk in whom all other alternative treatments are not feasible.

CONCLUSION

In cases with severely angulated proximal necks, adequate apposition between the stent graft and the native aortic neck wall is essential to maintain a circumferential seal and to reduce the risk of endoleak and distal migration. The features of Anaconda™ AAA Stent Graft System include the lack of suprarenal stent, full repositionability, and dual proximal ring stents with hooks. These are qualities to take into account when selecting an endoprosthesis for treating AAAs with angulated necks. ■

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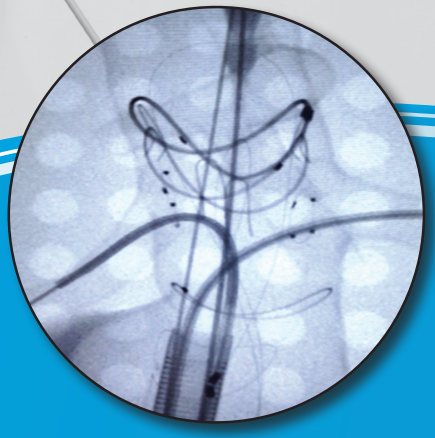

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References available on request.

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