Endovascular approaches to complex aortic aneurysms

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CHAPTER 3

FENESTRATED ENDOGRAFTS FOR COMPLEX ABDOMINAL AORTIC ANEURYSM REPAIR

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Abstract

Since the introduction of fenestrated endovascular aneurysm repair (FEVAR) in 1996, great advances have been made in endograft development. Custom-made and off-the-shelf fenestrated and branched endografts have been used to treat patients with complex abdominal aortic and thoraco-abdominal aneurysms.

Most experience has been gained with the Cook Zenith® fenestrated endograft (Cook Medical Inc., Limerick, Ireland). The Cook Zenith® endograft is customized with fenestrations, (fixed) inner or outer branches, or a combination of them, to cover a wide range of complex aneurysms. There are limitations to the number, location, and size of the fenestrations and to the maximal angulation of the aorta. Because the production of a custom-made fenestrated endograft takes several weeks, and is therefore not available for emergency cases, off-the-shelf fenestrated endograft were developed. One of these grafts was the Endologix Ventana™ (Endologix, Inc., Irvine, California). This endograft was withdrawn from enrollment due to a high re-intervention rate. Vascutek Ltd. developed the custom-made Vascutek Fenestrated Anaconda™ endograft (Vascutek Ltd., Inchinnan, Scotland) to treat patients where other endografts were not suitable—like in a more tortuous aorta with an angulation up to 90°. Additionally, the unsupported proximal body enables a high number and large size of fenestrations if needed. First reports of custom-made fenestrated and (inner and outer) branched JOTEC E-xtra DESIGN ENGINEERING (JOTEC GmbH, Hechingen, Germany) for aortic aneurysms seem promising, but larger series need to be reported to be able to draw conclusions.

Both custom-made Cook Zenith® and Vascutek Fenestrated Anaconda™ endografts have good reported clinical outcomes with a perioperative mortality between 4.1 and 6.7% and a re-intervention rate of <10% at one year. Knowledge on the long-term outcome of both devices is still limited.
Introduction

An abdominal aortic aneurysm (AAA) is a life-threatening disease. The annual risk of a ruptured AAA is 3–15% when the aorta reaches a diameter of 5.0 to 5.9 cm, increasing in rapidly growing or larger aneurysms, necessitating aortic repair.\(^1\) Patients with an AAA are usually of older age with multiple comorbidities, which makes them susceptible to post-operative complications. In the early 1990s, Parodi et al. published the first case series of AAA patients that had been treated by endovascular means.\(^2\) The DREAM trial showed a 30-day mortality rate of 1.2% in elective endovascular aorta repair (EVAR) versus 4.6% in open aneurysm repair (OAR). Patients who underwent EVAR suffered less severe complications (i.e., 4.7% versus 9.8% in OAR).\(^3,4\) This benefit seemed to diminish in the long-term, without significant difference in one-year survival and beyond. Furthermore, EVAR has been associated with a higher reintervention rate and seems to be more expensive.\(^5\) One of the reasons for reintervention is an inadequate seal between the proximal attachment zone to the aortic wall, creating a type Ia endoleak. Challenging necks with an aortic diameter ≥28 mm, angulation ≥60°, length <10mm, circumferential thrombus, reversed tapered configuration, or neck with bulging make it more difficult to apposite the endograft to the aortic wall and are related to an increased risk of type Ia endoleak and reinterventions.\(^6\) These anatomic characteristics lead to the development of an endograft with fenestrations. It has been 20 years since Park et al. described two cases of AAA repair with a fenestrated endograft, one with a fenestration for a renal artery and one with a fenestration for the inferior mesenteric artery.\(^7\) In 1999, Faruqi et al. described the treatment of a type Ia endoleak after EVAR with an endograft containing a fenestration for the left renal artery and over-stenting of the right renal artery successfully sealing the type Ia endoleak.\(^8\) The formation of a para-anastomotic aortic or iliac aneurysm after OAR can occur with the chance of rupture. EVAR was first done to treat these para-anastomotic aneurysms in 1997.\(^9\) Subsequently, in 2005, the first three cases of fenestrated endografts for the treatment of paraanastomotic aortic aneurysms were described.\(^10\)

Similar outcomes have been published after fenestrated endovascular aneurysm repair (FEVAR) compared to regular EVAR.\(^11,12\) Chisci et al. evaluated 136 patients with a challenging neck treated with OAR, EVAR, or FEVAR. Neck anatomy between the three groups was comparable, except for a slightly shorter neck in the FEVAR group compared to the EVAR
group. Their study showed that EVAR was related to more sac expansion and reinterventions, although the latter was not significant. A slightly higher number of endoleaks was also observed in the EVAR-treated patients compared to the FEVAR-treated patients. Endoleaks were related to an angulated or short neck, suggesting a benefit of FEVAR.6

In the last decade, several advancements to the endograft have been made and increasing experience has resulted in treatment of complex AAAs, including those with a short infrarenal aortic neck, juxtarenal and suprarenal AAA, and thoraco-abdominal aortic aneurysms (TAAA). In this review, we focus on the assets and liabilities of the four fenestrated endografts that are currently used or have been used in the past and discuss the outcome.

Materials and methods

To write this review, a broad PubMed search was performed with MeSH-terms and titles or abstracts including “Aortic Aneurysm, Abdominal”, combined with “FEVAR”, “fenestrated/fenestrations”, or “fenestrated aneurysm repair”. This search resulted in 278 articles. Additional searches were done adding terms of specific endografts. “Cook” or “Zenith” led to 54 results, “Vascutek” or “Anaconda” led to six results, “Endologix” or “Ventana” led to six results, and “Jotec” or “E-xtra” led to two results. These articles were screened with focus on origin and development of the fenestrated endograft, technical details of the endovascular procedure and individual endografts, and results in case series. Through cross-referencing, additional reports were screened and another three reports were added. After the PubMed search, cross referencing, and three added reports, a total of 138 reports were fully screened. All case series were included, except for the series with the Cook Zenith® fenestrated endograft (Cook Medical Inc., Limerick, Ireland) where only the seven largest series were addressed. A total of 15 case series were eligible for comparative analysis between endografts.

Fenestrated endograft and stenting target vessels

Cook Medical Inc. was the first company to develop a commercially available custom-made endograft for FEVAR. In the 20 years thereafter, the original design has been modified several times. Obviously, stenting the fenestrations into the target vessels prevents shuttering of the target vessels by graft material,13,14 creates adequate apposition of the fenestrations to the aortic wall, and improves stability of the endograft preventing migration and rotation.15-17

To form a more adequate seal between endograft and bridging stent in the target vessel, the
fenestrations became reinforced with a nitinol ring. Originally, stenting the fenestrations was done with balloon-expandable bare-metal stents. Covered balloon-expandable stents have shown to be associated with a lower incidence of in-stent stenosis and are, therefore, now recommended for use in fenestrated endografts. Over time, alternative fenestrated devices have been developed by competitors, all with their own advantages and disadvantages.

**Considerations for treating patients with a fenestrated endograft**

The decision to treat a patient by OAR or FEVAR depends on the patient’s characteristics, the complexity of the aneurysm anatomy, and the experience of the whole team of professionals involved with the treatment. The aspect of the aorta is assessed on computerized tomography angiography (CTA) and analyzed using dedicated software. Important prerequisites regarding the aorta differ between endografts and include a maximum neck diameter of 31–40 mm and an angulation of 45–90° (Table I). To minimize renal infarction, important accessory or multiple renal arteries should be absent. The proximal landing zone requires a relatively healthy parallel aorta and a consistent diameter for proper seal. To prevent visceral and distal embolization, there should be a thrombus-free lumen.

Technical success is described as exclusion of the aneurysm with successful deployment of the planned endograft and successful stenting of the target vessels without type I or III endoleak on the first post-operative CTA. The biggest challenge in FEVAR is adequate alignment and stenting of the target vessels. Mesenteric artery embolization or occlusion (correlated with a high mortality rate) and renal impairment (even occasionally leading to dialysis) are two of the most frequent major complications after FEVAR.

Pre-operative chronic kidney disease, longer procedural time, and metformin use have a higher risk of post-operative acute renal failure. Although not statistically significant, the operative complexity, fluoroscopy time, contrast volume, and blood loss also seem to influence post-operative renal impairment. A very rare, but devastating complication is spinal cord injury due to over-stenting or embolization to lumbar arteries. The incidence is higher in more proximally placed endografts, especially above the celiac artery. Maintaining mean systemic blood pressure >80 mmHg and drainage of spinal fluid may prevent spinal injury in these cases.

After successful treatment of the abdominal aneurysm, close follow-up with CTA and/or duplex ultrasound and abdominal X-ray is mandatory. Endoleaks usually occur within the
first year of FEVAR, but can also develop later on and could lead to aneurysm sac enlargement and eventually rupture. Stent occlusion, stenosis, or fracture, leading to mesenteric ischemia or renal impairment, can occur years after implantation of the endograft.\textsuperscript{18,19}

**Technical details of procedure**

Patients with an AAA are preferably assessed with 0.75–1 mm multi-slice CTA, from at least the distal descending thoracic aorta to the common femoral arteries. Center-line-of-flow measurements are used to determine the anatomy of the aorta and visceral arteries. Diameter and length of the proximal landing zone are determined and, if present, also from the infrarenal neck. The amount of calcium and thrombus should be taken into account. The length of the infrarenal neck, the scheduled distance between the top of the stent and the proximal fenestrated component, and the distance between the top of the stent and the iliac bifurcation are measured. Diameters, clockwise location, and lengths and angles of the visceral vessels are also measured.\textsuperscript{27,28}

Fenestrated endografts consist of two or three components; whereas, the fenestrations are positioned in the proximal component, additional scallops or valley augmentations can be added to maximize device length. The fenestrated endograft is combined with a bifurcated component and limbs, or just two limb extensions, depending on the type of endograft.\textsuperscript{27,29}

Manufacturing of a custom-made fenestrated endograft takes careful planning and customizing to the patient’s anatomy. Design and production can take between three to seven weeks, depending on design complexity and urgency.

The procedure can be performed under general, spinal, or epidural anesthetics and through percutaneous or open femoral access.\textsuperscript{27} Heparin is used to establish an activated clotting time of 250–300 seconds. Depending on the accessibility of the femoral arteries, one side is used for insertion of the fenestrated component and the contralateral side is used for catheterization of the target vessels using a guiding sheath. Under fluoroscopy guidance, the fenestrated component is deployed and selective catheters are used to access the target vessel(s).\textsuperscript{28} After confirmation of a correct position, balloon-expandable covered stents are placed through the fenestrations into the target vessels and deployed.\textsuperscript{19} The proximal portions of the stents are flared with a larger size balloon in order to achieve complete apposition and seal and provide stability in the fenestrated device. Selective angiography into the target vessel is performed to verify patency and absence of dissection.

When applicable, the separate bifurcated component is introduced through the same side as the
fenestrated main component and deployed with adequate overlap with the main fenestrated component. Depending on the endograft, one or two of the iliac extensions are placed with preservation of the internal iliac artery. Balloon dilatation of the proximal and distal sealing zones, as well as overlap zones, are done to prevent endoleak. Completion angiography is performed to check for endoleak and patency. The procedure has been described in more detail by Moore et al., Oderich et al., and Verhoeven et al.\textsuperscript{27,28,30}

Fenestrated endografts

\textit{Cook Zenith\textsuperscript{*} fenestrated endograft}

To date, most experience has been gained with the Cook Zenith\textsuperscript{*} fenestrated endograft (Figure 1), which is a regulated CE marked product and is considered a standard endograft, customizable within certain parameters to remain CE marked based on previous testing. It consists of a proximal fenestrated body graft, a distal bifurcated body graft, and iliac legs as needed. The materials are constructed of full-thickness woven polyester fabric, sewn to self-expanding stainless steel Cook-Z\textsuperscript{*} stents, with braided polyester and monofilament polypropylene. The endograft is reduced in diameter by an independent wire tied to diameter-reducing ties. Additionally, the bare suprarenal stent, at the proximal end of the proximal endograft containing barbs for fixation, is constrained with a top cap and held by a trigger-wire. This way, it allows the graft to be manipulated within the aorta to allow accurate positioning of the endograft.

The covered part of the proximal body contains precisely located fenestrations and/or a cut-out scallop(s), all reinforced by a nitinol ring. The fenestrations can be small with a diameter of 6 mm wide and 6–8 mm in height, or large with a diameter of 8–12 mm combined with a single scallop of 10 mm wide and 6–12 mm in height. The large fenestration must have a minimum distance of 10 mm from the proximal edge of the endograft and may have struts crossing the fenestration. Small fenestrations are usually designed for the renal arteries. The scallop allows flow to the superior mesenteric artery (SMA) or when placed more proximally, to the celiac artery.

The CE mark limits the number of fenestrations, but the patient-specific custom-made endograft can be built outside the specific limitations of the CE mark exceeding three fenestrations with possible affixed branches.

The specifically designed Zenith\textsuperscript{*} fenestrated AAA endograft distal bifurcated body has one
long ipsilateral iliac limb and one short contralateral limb. An iliac extension limb is placed on the contralateral short limb. To facilitate correct placement of the bifurcated body graft and the extension limb, there are radiopaque markers for fluoroscopic visualization.

The endograft is restricted to patients with a proximal aorta diameter between 19 and 32 mm and a proximal landing zone of ≥15 mm. The angle is bound to a maximum of 45°, relative to the long axis of the aneurysm or to the axis of the suprarenal aorta. The distal fixation site of the ipsilateral common iliac artery has to be greater than 30 mm in length with a diameter between 9 and 21 mm. The diameter of the distal fixation site of the contralateral common iliac artery must be between 7 and 21 mm (Table I).²⁷,³⁰

Vascutek Fenestrated Anaconda™ endograft

The custom-made Vascutek Fenestrated Anaconda™ endograft (Vascutek Ltd., Inchinnan, Scotland) (Figure 2) is a modular bifurcated system constructed of woven polyester and independent nitinol stents.²⁹,³¹ The endograft consists of one main body and two separate iliac extension limbs to the common iliac arteries, an aortic uni-iliac endograft, or an aortic cuff. The proximal part of the main body consists of two peaks and two valleys, as well as three or four pairs of nitinol hooks for proximal fixation. The saddle shape formed by the peaks and valleys of the proximal sealing rings can accommodate cradling of a visceral vessel in a valley, typically the SMA or celiac artery. Oversizing of 10–20% is recommended to provide optimal sealing proximally.

The nitinol reinforced fenestrations are placed in the unconstrained region of the graft and, therefore, they are not compromised by circular stents of the endograft. Size and number of the fenestrations are only limited to the proximity of other fenestrations and the space to ensure flaring of stents. As a result, there is a possibility of one to five fenestrations and can be used for additional aortic branches, such as a large accessory renal artery.²⁹

Proximal aortic diameter of the landing zone should be between 17.5 and 31 mm. Healthy tissue of ≥15 mm in length is required to form adequate seal; however, due to the saddle shape of the top rings and the ability to locate a fenestration between the rings, visceral vessels can be located within this region. According to the instructions for use (IFU), a neck angulation up to 90° to the aneurysm sac can be treated. Limbs are available in lengths from 60 to 180 mm in straight, tapered, and flared designs facilitating a distal landing diameter from 8.5 to 21 mm with a length of ≥20 mm (Table I).³¹
Fenestrated endografts for complex AAA repair

Figure 1: The Cook Zenith® fenestrated endograft.

Figure 2: The Vascutek fenestrated Anaconda™ endograft (Illustrated).

Figure 3: The Endologix Ventana™ Fenestrated Proximal Extension Endograft (Illustrated).

Figure 4: The Jotec E-xtra™ Design Engineering.
The Vascutek Fenestrated Anaconda™ endograft has the ability to be constrained away from
the vessel wall to allow for repositioning after unsheathing. The endograft system allows for
cannulation of target vessels with a cranial approach. The guidewire has a magnet, assisting
contralateral limb cannulation and reducing time of joining the limb to the main body. The
company provides a customized 3D printed model AAA, based on the CTA, as a prototype of
the fenestrated endograft to evaluate the location of the fenestrations before implantation.

**Endologix Ventana™ fenestrated endograft**

The Endologix Ventana™ fenestrated proximal extension endograft (Endologix, Inc., Irvine,
California) (Figure 3) was an off-the-shelf endograft and was composed of a cobalt chromium
alloy self-expanding stent cage with an external thin-walled, high density expanded poly-
tetrafluoroethylene graft cover. The cover was attached proximally and distally to the stent
cage with polypropylene sutures, combined with an overize up to 11 mm making the cover
conform to the aortic anatomy. The Endologix Ventana™ fenestrated endograft was a proximal
extension used in combination with the bifurcated endograft of the AFX® Endovascular AAA
system (Endologix, Irvine, CA). The AFX® endograft consists of an aortic main body with two
attached iliac legs. Accessory limb extensions in straight, stepped, flared, and tapered configu-
rations are available. Before implanting the fenestrated component, the bifurcated endograft
must be implanted.

In the proximal fenestrated component, a scalloped section was made to maintain flow to
the SMA. The scallop had a fixed length of 4 cm from the most proximal edge, with variable
diameters of 24 to 36 mm. Because of the large scallop, it had a greater range of manipulation
within the aorta. The mid-section had two circular, 3 mm diameter fenestrations on either
side that could expand up to 8 mm for cannulation of the renal arteries and introduction of
covered stents. The expandable fenestrations permitted the fenestration to be moved during
implantation to accommodate renal artery locations that were up to 35 mm from the nominal
location. The fenestrations were limited to the renal arteries and were not to be used for the
SMA.

The Endologix Ventana™ fenestrated endograft was used in aneurysms that fit specific
anatomical characteristics. The proximal non-aneurysmal aortic neck below the SMA had
to have a diameter between 18 and 34 mm, a length of ≥15 mm, and an angle ≤60° to the
aneurysm sac. The common iliac artery distal landing zone had to have a length of ≥15 mm
and a diameter between 10 and 23 mm (Table I).\textsuperscript{34} Obviously, an off-the-shelf design saves time and cost compared to custom-made endografts. It has the potential to be used in emergency cases.\textsuperscript{34}

**JOTEC E-xtra DESIGN ENGINEERING fenestrated endograft**

When it comes to the E-xtra DESIGN ENGINEERING (JOTEC GmbH, Hechingen, Germany), JOTEC offers the option of having individual vascular implants produced which are tailor-made for the patients’ anatomy— for vessels ranging from the aortic arch to the thoracoabdominal aorta down to the pelvic arteries. One example of a custom-made JOTEC E-xtra DESIGN ENGINEERING endograft (Figure 4) consists of a single main body with individual self-expanding nitinol z-stent rings, individually sewn tightly to woven polyester fabric on the inside. The central part has the option to narrow and includes fenestrations and/or branches. The proximal and distal ends of the endograft can be of various lengths and diameters and serve either as a primary seal with the aortic wall or as an attachment zone for proximal or distal elongation. The proximal end of the endograft is uncovered and self-expanding to provide optimal proximal seal and fixation to the aortic wall or an additional thoracic endograft. Fenestrations have a minimum of 6 mm and a maximum of 12 mm and the branches have a minimum of 6 mm and maximum of 10 mm. Branches are added when fenestration with stenting will not have adequate apposition to the aortic wall. The branches can have individual up- or downward orientation.\textsuperscript{35} When the aortic aneurysm extends distally to the iliac arteries, the standard JOTEC E-vita ABDOMINAL XT (JOTEC GmbH, Hechingen, Germany) can be used. If there is proximal extension of the aneurysm into the thoracic aorta, a combination with the JOTEC E-vita THORACIC 3G (JOTEC GmbH, Hechingen, Germany) is done. Implanting the endograft is done through femoral access, together with cranial approach for cannulation of the target vessels. The JOTEC E-vita ABDOMINAL XT consists of a bifurcated body with an extended ipsilateral limb and a separate contralateral limb extension.

The JOTEC customized endograft from E-xtra DESIGN ENGINEERING can be used for treatment of suprarenal and more proximal aortic aneurysm while incorporating the visceral arteries. The diameter of the proximal aorta needs to be between 16 and 40 mm with a minimum neck length of 15 mm and maximum angulation of 60°. The diameter of the distal landing zone
of the ipsilateral leg has to be between 8 and 25 mm, and the contralateral leg extension is available between 50 and 105 mm. The length of the distal landing zone should be at least 15 mm.

**Results with and comparison of the endografts**

Treating patients with complex AAA with FEVAR results in a four-year survival of 62.5%. In patients with juxtrarenal AAA and type IV TAAA treated with FEVAR, survival diminishes in the years thereafter to only 20% at eight years post-operatively, of which only 2% of the deaths are related to the aortic aneurysm.24

During recent years, patients unsuitable for OAR, in particular, have been treated with FEVAR. They generally suffer from coronary artery disease, cardiac dysfunction, chronic obstructive pulmonary disease (COPD), renal impairment, and diabetes mellitus. Nevertheless, results with FEVAR compared to OAR were comparable with regard to mortality and renal impairment.5,36-39

Moreover, patients treated with FEVAR have less post-operative cardiac and pulmonary complications compared to OAR and have a median intensive care and hospital stay of 1.0 and 9.0 day(s) after FEVAR compared to 8.9 and 24.0 days after OAR, respectively.38

Selecting high-risk patients for FEVAR, however, creates a selection bias and the heterogeneity of the groups makes results not reliably comparable.40 Moreover, the technique of FEVAR is still in development which may have a positive effect on future outcome.

To review the applicability of the different endografts, we reviewed technical success, target vessel cannulation, procedure time, contrast volume, perioperative mortality, reintervention rate, target vessel loss, type I and III endoleak, and survival. Table II shows the largest patient case series treated with the different endografts for complex abdominal aortic aneurysms.

The largest case series on Cook Zenith® fenestrated endograft reports a technical success of 92 to 100%, including successful target vessel cannulation in 97 to 100%.6,18,28,41-44 These high success rates support the applicability of the Cook Zenith® fenestrated endograft. Kaplan-Meier analysis shows 89.2 to 97% one-year survival, while none of the deaths were reported to be aneurysm related. Reinterventions after one year were necessary in 9 to 12% of cases. Specific endograft-related reinterventions are due to target vessel loss—in 2 to 7%, or endoleak in up to 1.4%—and are important factors for the success of FEVAR. Reasons for non-endo-
Fenestrated endografts for complex AAA repair

Graft-related complications needing reinterventions are occlusion of existing bypasses, groin hematoma, type II endoleak, aneurysm sac enlargement without endoleak, necrosis due to peripheral artery disease, kinking of a target vessel stent, bleeding from the wound, pseudo-aneurysm of an artery, or infected hematoma.

The GLOBALSTAR Registry reported results of FEVAR with the Cook Zenith™ fenestrated endograft with a three-year survival of 89%, target vessel loss of 15%, and a reintervention rate of 30%, showing the necessity for follow-up, even after one year.

Recently, Verhoeven et al. studied a cohort of patients suitable for OAR in an experienced hospital and reported a technical success of 96.8% after FEVAR. They showed a low perioperative mortality rate of 0.7%, a three-year reintervention-free survival of 90%, and target vessel patency of 98.1% at three years. This suggests that both patient selection and extensive experience may lead to better outcomes.

Only four case series with more than 10 patients have been reported for Vascutek Fenestrated Anaconda™ endograft (Table II). In the reported series, a technical success of 84 to 100% was reached. Target vessel cannulation was achieved in 94.6 to 100% and the perioperative mortality rate was 0 to 8.5%. None of the studies reported a one-year outcome for survival, reintervention, target vessel patency, or type I or III endoleaks. Eighty-four percent technical success was reached in one of the first published studies by Dijkstra et al., with 25 patients included. This report described one occlusion of the SMA after 30 days due to malposition of the main body, eventually leading to death. Also, they describe three type Ia endoleaks on the completion angiogram, which all had spontaneously resolved on the one-month CTA. During follow-up, there were no new occlusions or endoleaks requiring reintervention.

Only one study showed results at six months, with a reintervention rate of 2.8%. Target vessel patency was 3% and one (0.7%) type Ib endoleak occurred, requiring iliac limb ballooning.

The case rehearsal service, with a customized 3D model of the AAA, allows the clinicians to perform an in-vitro deployment of the endograft in the model of the patient. Combined with the ability to partly collapse the endograft, it has the potential to lead to an even higher technical success.

Data on the Endologix Ventana™ fenestrated endograft are much more limited. In patients with complex anatomy AAAs, a significant number were not eligible for the off-the-shelf Endologix Ventana™ fenestrated endograft. Two studies have been done with the Endologix Ventana™ fenestrated endograft, reporting 46 cases. These studies had technical success rates of 97
to 100%. None of these reports mention target vessel cannulation or one-year survival. At one year, the reintervention rate was 12.5% with a 9.7% incidence of target vessel loss and a 3.2% type I or III endoleak incidence (Table II). In these small patient series, no perioperative deaths were seen. In a 13 month series by Quiñones-Baldrich et al., a similar reintervention rate for the Endologix Ventana™ fenestrated endograft compared to the other endografts was shown. The true reintervention rate is higher because the Endologix Ventana™ fenestrated trial urged the company to stop enrolling patients. Also, the reported target vessel loss and type I or III endoleak incidence are considerably higher with the Endologix Ventana™ fenestrated compared to the Cook Zenith® fenestrated (1.4 to 4.3% and 0 to 1.4%, respectively) as well as the Vascutek Fenestrated Anaconda™ endograft (3 and 0.7%, respectively) (Table II).

Between 2010 and 2012, the JOTEC E-vita THORACIC 3G endograft was customized for eight patients with proximal and distal scallops and small or large fenestrations, whether or not stented. These first selected cases were treated with a custom-made JOTEC endograft for juxtarenal AAA and had a maximal aortic angulation of 30°. This study reports a 100% technical success, no reinterventions, no type I or III endoleaks, or any target vessel occlusion after one-year follow-up. After the successful experience, the JOTEC custom-made fenestrated/branched was further developed and first reported on in 2014. Eight patients were treated with JOTEC E-xtra DESIGN ENGINEERING endografts for Crawford type I-IV TAAA, of which three were type IV. Technical success was 100% and successful target vessel cannulation occurred in 29/32 (90.6%) with the fenestrated and/or branched endografts. During placement of the endografts, it was not possible to cannulate both renal arteries in one patient, necessitating bilateral ilio-renal bypass and placement of endovascular plugs in both renal branches. After a median follow-up of 18 months, there were no deaths and four percutaneous reinterventions performed for type I or type III endoleaks. Further aortic interventions were anatomically distinct from the original aortic aneurysm. The population differed from populations studied with the other endografts because of the inclusion of type I-III TAAAs with cannulation of the celiac artery, SMA, and both renal arteries. This could well explain the longer procedure time and higher contrast volume. The reintervention rate was 50%, but did not lead to higher mortality. Another study reported 50 patients, of which nine underwent fenestrated and/or branched EVAR with JOTEC E-xtra DESIGN ENGINEERING endografts to treat an AAA. They reported a 100% technical success rate. Unfortunately, the authors did
not separately discuss each case. So far, the JOTEC E-xtra DESIGN ENGINEERING FEVAR shows acceptable results. Larger studies are needed to show reintervention rates and endograft-specific complications like type I or III endoleaks and target vessel patency.

To date, only one study has been published comparing the Cook Zenith® fenestrated with Vascutek Fenestrated Anaconda™ and Endologix Ventana™ fenestrated endograft. No differences for technical success were seen between the three endografts. No follow-up was done and only eight patients were treated with Vascutek Fenestrated Anaconda™ endograft and only nine patients with Endologix Ventana™ fenestrated endograft, making these results not useful for interpretation. Moreover, no comparing series have been reported between JOTEC E-xtra DESIGN ENGINEERING endografts and other fenestrated endografts.

The relatively small case series and variable time in follow-up make comparison of results for different endografts difficult. Nonetheless, the three currently available endografts (Table II) do not seem to have large differences in outcome or reintervention rates.

The Cook Zenith® fenestrated, Vascutek Fenestrated Anaconda™, Endologix Ventana™, and the JOTEC E-xtra DESIGN ENGINEERING endografts all have high technical success rates. In both Cook Zenith® fenestrated and the Vascutek Fenestrated Anaconda™ endografts, successful target vessel cannulation is reached in almost 100% of the cases. Between and amongst the studies reporting Cook Zenith® fenestrated, Endologix Ventana™, and Vascutek Fenestrated Anaconda™ endografts, there is a wide discrepancy for procedural time and contrast volume. With more experience over time, procedure time seems to shorten.
Discussion

The current literature review discusses the development of three different custom-made, and another off-the-shelf, fenestrated endografts that are used to treat complex AAA. The off-the-shelf Endologix Ventana™ fenestrated endograft has been withdrawn from enrollment. The custom-made Cook Zenith® fenestrated endograft and Vascutek Fenestrated Anaconda™ endograft seem to be a valid alternative for OAR. First results with JOTEC E-xtra DESIGN ENGINEERING endografts are also promising as a third custommade endograft for complex AAA.

The challenges of FEVAR are technical success, including cannulation of the target vessels and enduring patency with long term aneurysm exclusion, preferably without reinterventions. Results for technical success and success of target vessel cannulation are into the 90th percentile and are becoming higher with more experience and further development of endografts. Perioperative mortality is comparable for Cook Zenith® fenestrated endograft and Vascutek Fenestrated Anaconda™ endograft and is mostly related to patients’ characteristics. Published studies reporting on Endologix Ventana™ fenestrated and JOTEC E-xtra DESIGN ENGINEERING endograft have too small sample sizes to draw firm conclusions about their outcome.

Since the introduction of FEVAR, grafts with more fenestrations are used with a higher technical success. More complex procedures did not lead to longer procedure time, more contrast load, or more complications.42 Although the design, production, shipping, and delivery of the custom-made endograft can take up to six weeks, some patients with a symptomatic AAA can still be eligible for a custom-made endograft. However, if a suitable off-the-shelf device is available, this should be used in preference for symptomatic AAA.

Fenestrated devices, unfortunately, are not available around the globe and, although the exact number is unclear, all devices do have a turn down rate based on the aneurysmal anatomy. Besides FEVAR, alternative treatment options for complex AAA are chimney of parallel grafts in conjunction with either regular EVAR endograft (CHEVAR) or the newer endovascular aneurysm seal technology (CHEVAS).57

In selected cases and minimizing the number of target vessels, CHEVAR showed similar technical success, target vessel cannulation, and perioperative mortality compared to FEVAR.
### TABLE II: RESULTS OF THE FOUR FENESTRATED ENDOGRAFTS

<table>
<thead>
<tr>
<th>1st Author, year</th>
<th>No. Of patients</th>
<th>Technical success (%)</th>
<th>Target vessel cannulation (%)</th>
<th>Median procedure time (min)</th>
<th>Median contrast volume (mL)</th>
<th>Perioperative mortality (%)</th>
<th>Reintervention rate at 1 year (%)</th>
<th>Target vessel loss at 1 year (%)</th>
<th>Endoleak type I or III at 1 year (%)</th>
<th>Survival 1 year (%)</th>
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<tr>
<td>Cook Zenith® fenestrated</td>
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<td>52</td>
<td>94.2</td>
<td>-</td>
<td>266</td>
<td>288</td>
<td>5.7</td>
<td>-</td>
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<td>-</td>
<td>99</td>
<td>180</td>
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<td>2.8</td>
<td>1.4</td>
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<td>92.0</td>
<td>98</td>
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<td>195 (270a)</td>
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<td>4.3</td>
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<td>97</td>
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</table>

- Not clearly stated, a Concentration of iodine in mg/mL. When no concentration mentioned, it was not clearly stated in the paper. b At median follow-up of 6 months, c At median follow-up of 13 months, d Patients treated for Crawford type I-IV thoraco-abdominal aneurysms with visceral arteries as target vessels with fenestrated and/or branched endograft, e At median follow-up of 18 months.
Median follow-up of six to 14 months showed similar results for reintervention rate, endoleaks, and vessel patency.\textsuperscript{58,59} The reports especially recommended CHEVAR in patients unable to wait for the manufacturing of the fenestrated endograft. It should be kept in mind that the chimney prevents the aortic endograft from forming a circumferential apposition to the aortic wall and may lead to gutters along the chimney. These gutters potentially cause a type Ia endoleak and this incidence increases with the number of chimneys, but could be avoided using CHEVAS. Recently, a technique using a three-dimensional printer was presented which could make a fenestrated endograft on-site within two hours.\textsuperscript{60} Patients requiring an urgent intervention might benefit from this type of custom-made on-site fenestrated endograft.

With regard to cost-effectiveness, custom-made FEVAR is likely to be more expensive compared with OAR.\textsuperscript{36,38,39} However, lower severe complication rates and shorter intensive care and hospital stays with FEVAR might equalize the difference.

To write this review, we did a broad search, however, not systemic. The published reports all use a different approach to their analysis, making it difficult to compare or make a pooled analysis.

There are some flaws in the current literature. Nearly all studies show retrospective data and include patients unfit for OAR. Patient outcome depends on patient selection and the surgeons experience because of the learning curve, leading to heterogeneous groups, which renders any comparison with OAR or EVAR unreliable.

A randomized controlled trial comparing different fenestrated endografts must be done to analyze outcome.

**Conclusion**

Fenestrated endovascular aneurysm repair is a feasible procedure for aneurysm repair of complex abdominal aortic aneurysms and type IV thoracoabdominal aneurysms. Particularly in patients not eligible for open surgery, it is the treatment of choice instead of open aorta reconstruction. Both the Cook Zenith\textsuperscript{®} fenestrated endograft and the Vascutek Fenestrated Anaconda\textsuperscript{™} endograft are related to good and improving outcomes. The JOTEC Extra DESIGN ENGINEERING endografts also show some promising results, but too little research has been done to draw robust conclusions.
References


