The Fenestrated Anaconda™ for the Treatment of Complex Abdominal Aortic Aneurysms

An overview of the design, applicability, and clinical success of the Fenestrated Anaconda™ System for complex abdominal aortic aneurysm repair.

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Endovascular aneurysm repair (EVAR) for the treatment of abdominal aortic aneurysms (AAAs) has developed significantly since its introduction in the early 1990s. Applicability of standard EVAR is restricted to anatomic configurations. Features such as a short neck (< 10 mm), a neck angle over 60°, neck thrombus or calcification, nonparallel neck configuration, or large neck diameter jeopardize an adequate sealing, consequently increasing the risk of migration, type Ia endoleak, and reinterventions. To treat patients with hostile neck anatomy, endografts were developed with fenestrations to the renal arteries, superior mesenteric artery (SMA), and/or celiac artery (CA). Stenting of the fenestrations with balloon-expandable covered stents into the target vessel instead of bare-metal stents has improved apposition and prevented blockage of fenestrations by graft material and main device rotation and migration. To support the target vessels’ stents and prevent ripping of the fabric, fenestrations were reinforced with a nitinol ring. The large variation in visceral artery configuration requires customization of fenestrated endografts to the patients' anatomy. One of the current commercially available and extensively used customized endografts is the Fenestrated Anaconda™ (Vascutek Ltd.).

THE FENESTRATED ANACONDA™ Design

Planning is done by preoperative computed tomography angiography (CTA) scanning of the total aorta and iliac arteries with a recommended maximum of 1-mm slides. Using dedicated software, clock positions and angles of the aorta, aortic side branches, and access vessels are measured. After preliminary design, an acrylic 3D model of the aneurysm is printed to test the custom-made endograft, allowing minor modifications to the final design (Figure 1).

The Fenestrated Anaconda™ consists of independent circular nitinol stents and woven polyester graft material. The proximal end of the main body consists of two lateral peaks and two valleys. The two proximal rings are specifically designed to deliver the appropriate radial force on each aortic diameter and can be oversized to achieve optimal sealing. The proximal rings can be parallel (Figure 2A and 2C) or augmented (Figure 2B) in case of planned sealing between the SMA or CA. To prevent migration, three or four pairs of hooks are attached to these proximal rings (Figure 2A–2C). The standard endograft requires a landing zone of at least 15 mm in length and an aortic diameter between 17.5 and 31 mm, and the design allows a landing zone angle up to 90°. With Fenestrated Anaconda™, however, the custom-made device remains connected to the delivery device (purple), while fenestrations and target vessels are cannulated with guidewire and catheter (green) to check for any mismatch. Permission for use granted by Vascutek Ltd.
proximal sealing configurations with an augmented valley allow for a greatly reduced landing zone between visceral vessels; this is dependent on the geometry of the specific anatomy being treated. The unsupported region below the rings contains the nitinol-reinforced fenestrations (Figure 2A). The absence of stents in this area enables the potential for an unlimited number of fenestrations at any location but can also make it susceptible to folding of the graft. To prevent this, reinforcement rings can be placed around one (halo configuration, Figure 2B) or a combination of two proximate fenestrations (jelly bean configuration, Figure 2C). In addition, endografts can be pleated to remove excess fabric where deemed appropriate; the pleats also add an element of columnar stiffness and rigidity to the main body (Figure 2B). The endograft can be recollapsed after deployment or when required and can be repositioned at the desired location. The delivery system (ONE-LOK™) enables easy access in the contralateral limb by magnetically linking the guidewires, potentially reducing cannulation time.

After cannulation of the contralateral limb, the fenestrations and target vessels are cannulated and stented with balloon-expandable covered stents. The stents are flared to prevent type III endoleak. The system enables cannulation from femoral and/or brachial or axillary access without releasing the main device. The endograft can be designed as a cuff, uni-iliac, or bi-iliac endograft. Limb extension(s) can be tapered, straight, or flared to be sized to the iliac diameter. These extensions consist of multiple independent circular nitinol rings, allowing them to be used in very tortuous iliac arteries. Figure 3 shows a CTA and 3D reconstruction of a complex AAA before and after implantation of the Fenestrated Anaconda™. Fenestrated variants of the limb extensions have also been provided upon request as custom devices.

Study Results
Since the first report by Bungay et al in 2011,11 a number of case series evaluating the Fenestrated Anaconda™ have been published (Table 1 and Table 2).11-20 Although these studies include over...
Table 1. Preoperative Patient Characteristics

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Number of Patients</th>
<th>Age (years)</th>
<th>Gender (M/F)</th>
<th>ASA Classification (mean)</th>
<th>Hypertension (%)</th>
<th>Hypercholesterolemia (%)</th>
<th>Diabetes Mellitus (%)</th>
<th>History of Cerebrovascular Disease (%)</th>
<th>Cardiac History (%)</th>
<th>Pulmonary History (%)</th>
<th>Renal Disease (%)</th>
<th>Estimated Glomerular Filtration Rate (ml/min/1.73m²)</th>
<th>Peripheral Vascular Disease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bungay, 2011⁸</td>
<td>4</td>
<td>76.5</td>
<td>3/1</td>
<td>2.5</td>
<td>100</td>
<td>0</td>
<td>50</td>
<td>0</td>
<td>0</td>
<td>50</td>
<td>0</td>
<td>25</td>
<td>—</td>
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<tr>
<td>Dijkstra, 2014¹²</td>
<td>25</td>
<td>73</td>
<td>22/3</td>
<td>2.6</td>
<td>60</td>
<td>36</td>
<td>12</td>
<td>—</td>
<td>72</td>
<td>12</td>
<td>32</td>
<td>61</td>
<td>—</td>
</tr>
<tr>
<td>Rolls, 2014¹³</td>
<td>13</td>
<td>75</td>
<td>8/5</td>
<td>3.1</td>
<td>100</td>
<td>23.1</td>
<td>7.7</td>
<td>7.7</td>
<td>46.2</td>
<td>23.1</td>
<td>7.7</td>
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<tr>
<td>Gallitto, 2016¹⁴</td>
<td>5</td>
<td>78.4</td>
<td>—</td>
<td>3.2</td>
<td>100</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>40</td>
<td>80</td>
<td>20</td>
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<tr>
<td>Shahverdyan, 2016¹⁵</td>
<td>48</td>
<td>73</td>
<td>37/11</td>
<td>2.8</td>
<td>77.1</td>
<td>—</td>
<td>8.3</td>
<td>—</td>
<td>—</td>
<td>20.8</td>
<td>18.8</td>
<td>92</td>
<td>43.8</td>
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<tr>
<td>Kotelis, 2016¹⁶</td>
<td>39</td>
<td>74</td>
<td>36/3</td>
<td>3</td>
<td>87</td>
<td>—</td>
<td>13</td>
<td>—</td>
<td>61</td>
<td>17</td>
<td>41</td>
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<tr>
<td>Blankensteijn, 2017²⁸</td>
<td>60*</td>
<td>72</td>
<td>52/8</td>
<td>2.7</td>
<td>65</td>
<td>56.7</td>
<td>13.3</td>
<td>—</td>
<td>55</td>
<td>26.7</td>
<td>28.3</td>
<td>60</td>
<td>—</td>
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<td>Falkensammer, 2017²⁸</td>
<td>94</td>
<td>73</td>
<td>76/18</td>
<td>2.7</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<td>—</td>
<td>—</td>
<td>59.6</td>
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<tr>
<td>Colgan, 2017²⁰</td>
<td>101</td>
<td>76</td>
<td>86/15</td>
<td>2.9</td>
<td>71</td>
<td>—</td>
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<td>8</td>
<td>52</td>
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<td>39</td>
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<tr>
<td>Midy, 2017²⁰</td>
<td>86</td>
<td>73.4</td>
<td>82/4</td>
<td>2.8</td>
<td>76.7</td>
<td>68.6</td>
<td>22.1</td>
<td>4.7</td>
<td>60.5</td>
<td>41.3</td>
<td>15.1</td>
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<td>41.9</td>
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<tr>
<td>Pooled results†</td>
<td>450</td>
<td>73.9</td>
<td>380/65</td>
<td>2.8</td>
<td>75.7</td>
<td>57.8</td>
<td>11.8</td>
<td>6.8</td>
<td>55.6</td>
<td>29.5</td>
<td>27.4</td>
<td>67.9</td>
<td>36.7</td>
</tr>
</tbody>
</table>

Abbreviations: —, not clearly stated; 30-day, within 30-day postoperative period; ASA, American Society of Anesthesiologists; EL, endoleak.
*Partially including the same patients from Dijkstra et al.¹²
†Pooled analysis excluding Dijkstra et al.¹² Number of patients, fenestrations, and gender are presented in totals.

Figure 4. Graph showing the total number of endograft implants worldwide with a specific number of fenestrations for each fiscal year (April to April) from 2012 to 2017. More implants have been performed each year up to 2016 (light blue line), and there is a trend toward more Fenestrated Anaconda™ endografts including more fenestrations. ²⁰²¹ data does not include Q4 implants.

450 patients, the total number of implantations worldwide already exceeds 2,200 cases. All of these published studies include both results of primary AAA repair and redo after previous EVAR, either with a cuff, uni-iliac, or bi-iliac endograft. Pooled technical success was 89.3%, and successful target vessel cannulation was 96.7%. Despite the increasing number of fenestrations over time (Figure 4), the procedural time and contrast volume remained the same. The pooled percentage of accepted type Ia endoleaks at completion angiography can be observed in 8.6% of cases, but in only 1.5% of cases at 30 days postprocedure. At 30 days postprocedure, pooled mortality was 4.7% (Table 2).

Survival, reintervention-free survival, and target vessel patency were analyzed in four studies. At 1 year, pooled patient survival, reintervention-free survival, and target vessel patency was 88.9%, 91.4%, and 97%, respectively (Table 2). Three of these studies also presented 3-year analysis for patient survival (pooled rate, 84.7%) and reintervention-free survival (pooled rate,
In one study, 3-year target vessel patency was 96.3%.  

DISCUSSION

The current available data on the Fenestrated Anaconda™ demonstrate a satisfying technical success rate and high patient survival, reintervention-free survival, and target vessel patency rates during follow-up.

Technical success is described by Chaikof et al as successful access and planned deployment of the endograft without any type I or III endoleak.  

The tendency for the Fenestrated Anaconda™ to have a
lower technical success rate is due to higher prevalence of immediate type Ia endoleaks. As mentioned by Dijkstra et al and Blankensteijn et al, the Fenestrated Anaconda is designed with proximal nitinol rings, and it seems they need time to fully expand. This overview supports this theory by demonstrating the high percentage of type Ia endoleaks at completion angiography and their spontaneous disappearance at early follow-up (Table 2).

A perioperative mortality rate around 4% seems inevitable, because patients are usually older and have multiple comorbidities (Table 1). Adequate case selection, both based on anatomical configuration and the patient’s clinical state, is crucial. Open surgery should always be considered as an alternative for fit patients; consequently, patients treated with a fenestrated endograft have more preoperative comorbidities, and postoperative outcomes might be altered.

Katsargyris et al showed that more complex cases including three or more fenestrations did not influence perioperative outcomes for technical success (96.2% vs 98% in “standard” double-fenestrated endografts) and 30-day mortality (0.5% vs 0.5%, respectively). Nor was there any statistically significant difference in 1-year patient survival (94% vs 95%, respectively), reintervention-free survival (95% vs 98%, respectively), or target vessel patency (99% vs 99%, respectively). The presented data in this study support an increased experience over recent years, as reflected by the higher number of complex cases with more fenestrations, without an altered technical success rate, operating time, or contrast volume in the later and larger studies (Table 2).

Follow-up results from the literature are similar to the available custom-made Zenith Fenestrated graft (Cook Medical). The 1-year pooled results with the Zenith Fenestrated graft for patient survival, reintervention-free survival, and target vessel patency are 93%, 91%, and 98%, respectively. The 1-year patient survival of 89% seems slightly lower with Fenestrated Anaconda. Preoperative patient characteristics possibly influenced this difference, because it is not reflected by a difference in reintervention-free survival and target vessel patency (Table 1). This could also be due to case complexity; however, there are no available comparisons on number of device fenestrations used in each case.

Falkensammer et al separated reinterventions from primary cases but did not find any obvious difference, potentially related to the small sample size of the redo cases. The other presented studies analyzed a mixed population of primary AAA repair and reinterventions after failed EVAR, leading to heterogenic groups and consequently influencing outcome, as revision cases are generally more challenging. An individual patient data analysis could tell us more about the results in primary cases.

One of the advantages of the Fenestrated Anaconda is the case rehearsal service offered for each fenestrated custom device request. This involved a prototype device being produced alongside an accurate 3D-printed model of the patient’s anatomy and allows for testing and evaluation of the proposed design in the specific anatomy being treated. Evaluation is performed by engineers at Vascutek and subsequently by the requesting clinician. Following the evaluation, changes can be made to the design of the device prior to final manufacturing to ensure it is optimized for use in the specific anatomy being treated. Changing the custom design has been shown to lead to good results and might prevent unexpected misalignment by design.

Although recent data show good results of the Fenestrated Anaconda system, the number of studies is still few and have limited follow-up compared to published data of the commercially available Zenith Fenestrated AAA endovascular graft. Larger studies are awaited, and recently a prospective study (the Global Fenestrated Anaconda Clinical Study [Global FACT]) has been initiated to evaluate global, multicenter outcomes.

**CONCLUSION**

The custom-made Fenestrated Anaconda is applicable in the treatment of complex AAAs with good surgical outcomes, technical success, and low postoperative reintervention rates, and high patient survival, reintervention-free survival, and target vessel patency rates at midterm follow-up. Longer follow-up that includes individual patient analysis should be performed to further support current results.


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