The Endurant Stent Graft System: 15-month follow-up report in patients with challenging abdominal aortic anatomies

Alexander Hyhlik-Dürr · Tim F. Weber · Drossos Kotelis · Fabian Rengier · Johannes Gahlen · Stefanie Böck · Jürgen Köhler · Christoph-M Ratusinski · Dittmar Böckler

Abstract
Objective The objective of this study is to report a 15-month follow-up with the Endurant Stent Graft System in patients with challenging aortic anatomies.
Methods At three German clinics, a consecutive series of 50 patients underwent endovascular abdominal aortic repair (EVAR) for challenging abdominal aortic aneurysm with the Endurant stent graft between November 2008 and May 2009. EVAR was elective in 48 cases and emergent in two. Patients had short (≤15 mm) aortic necks, severe suprarenal/infrarenal angulation, and/or small (<8 mm), calcified, severely angulated, or tortuous iliac or femoral access vessels. Additionally, a cohort of 40 patients without challenging anatomies were retrospectively analysed to clarify differences concerning technical success, mortality, and morbidity between these groups.
Results The primary technical success rate was 92% (46/50). The 30-day mortality rate was 2% (1/50), the death due to multiorgan failure. Intraoperative angiograms revealed three type I endoleaks (2 proximal and 1 distal), and one of those was persisting at 30 days (30-day rate, 2%). Postoperative imaging discovered no further type I or type III endoleaks. The 30-day rate of the type II endoleak was 6% (3/50). There were two cases of graft limb occlusion, both requiring reintervention within 30 days. Follow-up was available in all of the 50 patients (100%) over a median of 15 months (1–25). During this time, seven patients died (overall mortality, 16%; 8/50), besides the above-described patient, all of them unrelated to the procedure. Compared to the 30-day results with the Endurant stent graft in non-challenging anatomies (no type I endoleak; no graft limb occlusion; all-cause mortality, 0%), procedure-related complications in challenging anatomies are increasing.
Conclusion Early and 15-month results with the Endurant stent graft in patients with challenging aortic anatomies are encouraging.

Keywords Abdominal aortic aneurysm · Endovascular abdominal aortic repair · Short proximal aortic neck · Narrow, kinked, and calcified iliac access vessels · Iliac tortuosity · Endurant Stent Graft System

A. Hyhlik-Dürr (✉) · D. Kotelis · S. Böck · D. Böckler
Department of Vascular and Endovascular Surgery,
Ruprecht-Karls University,
Im Neuenheimer Feld 110,
69120 Heidelberg, Germany
e-mail: alexander.duerr@med.uni-heidelberg.de

T. F. Weber
Department of Diagnostic and Interventional Radiology,
Ruprecht-Karls University,
Heidelberg, Germany

F. Rengier
Department of Radiology, German Cancer Research Center (DKFZ),
Heidelberg, Germany

J. Gahlen
Department of Vascular and Endovascular Surgery,
Hospital Ludwigsburg,
Ludwigsburg, Germany

J. Köhler · C.-M. Ratusinski
Department of Vascular and Endovascular Surgery, Pius-Hospital,
Oldenburg, Germany

Introduction

Since the first endovascular treatment of abdominal aortic aneurysm (AAA) in the early 1990s, investigation has been

ongoing regarding the benefit of endovascular abdominal aortic repair (EVAR) compared to open surgical repair. The EVAR 1 [1] and Dutch Randomized Endovascular Aneurysm [2, 3] trials showed no mortality differences between both methods in the first year of follow-up but more reinterventions (9.8% vs. 5.8%) and in particular the correction of endoleaks (3.4% vs. 0.2%) [4]. Proximal aortic neck length and the nature of iliofemoral vessel access remain important concerns for EVAR procedures. The risk of type I endoleak increases with a short proximal stent–graft landing zone [5, 6]. Device delivery in EVAR could be hindered by challenging access vessels, associated with risk of graft limb occlusion [7].

In order to reduce the continuing incidence of complications and secondary reinterventions, continuing research and developing new devices of stent graft systems are of great interest for patients with challenging anatomies [3, 4, 7, 8]. Severe angulation at the proximal aortic neck and tortuous, calcified, and small iliac arteries are still recognized as important risk and exclusion factors for successful EVAR. Even so, EVAR is often the only surgical option for excluding AAA.

The aim of this study was to document early experience with the next-generation Endurant Stent Graft System (Medtronic Endovascular, Santa Rosa, CA, USA) in patients with the above-mentioned challenging anatomies. We report the results of collaboration between three German vascular surgical centres employing this stent graft in 50 consecutive difficult EVAR cases. Additionally, a cohort of 40 patients without challenging anatomies who were included into the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) were retrospectively analysed to clarify differences concerning technical success, mortality, and morbidity between these groups.

Methods

In a collaborative approach by three German clinics (Heidelberg/Oldenburg/Ludwigsburg), a consecutive series of 50 patients underwent EVAR for challenging AAA with the Endurant Stent Graft System. EVAR was elective in 48 of the patients, while in two cases, emergency EVAR was performed due to contained rupture. Inclusion criteria were short proximal aortic necks (≤15 mm in length) and/or small (<8 mm in diameter), calcified, and severely angulated or tortuous iliac access vessels. Patients with non-challenging anatomies were included in ENGAGE [9]. These indications (proximal landing zone, <15 mm; access vessel, <8 mm) allowed inclusion of cases outside the recommendations contained in the manufacturer's instructions for use [10].

The Endurant Stent Graft System

The modular Endurant Stent Graft System is an evolution of the Talent abdominal stent graft (Medtronic Endovascular) based on international engineer and physician feedback (Fig. 1) [11]. Positive results have recently been reported in a multicentre European trial [12]. The device was designed to provide both active fixation and flexibility. Proximal sealing of the graft is supported by M-shaped body stents for radial force. To secure suprarenal fixation, it is ensured by proximal springs with anchoring pins. Distally, a sinusoidal design enhances device flexibility. The small outside diameter and hydrophilic coating reduce friction and improve trackability in the access vessels.

Preoperative imaging and measurements

Preoperative work-up for procedure planning included a multislice computed tomography (MSCT) angiography according to general recommendations [13]. The reconstructed slice thickness ranged between 1 and 3 mm to allow high-resolution image postprocessing [14]. The decision to implant the Endurant stent graft was based on evaluation of the proximal aortic neck and the morphology of the iliac arteries by an independent radiologist and a vascular surgeon according to approved classifications. This was necessary because the outcome of EVAR is directly affected with anatomical morphology of the

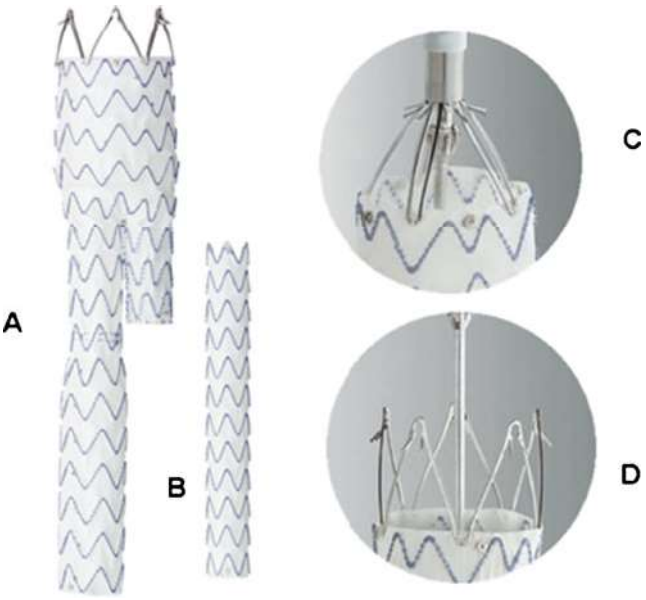

Fig. 1 The two primary components of the bifurcated modular Endurant Stent Graft System are the aorto-iliac bifurcated component (**a**) and a contralateral limb (**b**). **c** and **d** show the proximal stent graft component with it's delivery system and anchoring pins for active fixation in detail (Medtronic Vascular, Santa Rosa, CA, USA)

proximal aortic necks [15] which were assigned to categories concerning their morphologies (Fig. 2) [8].

Image postprocessing and quantitative evaluation were performed on a workstation providing centreline vessel analysis, semiautomated for precise evaluation of vessel diameters and lengths (3surgery Vascular Imaging workstation, version 4.0, 3mensio Medical Imaging, Bilthoven, the Netherlands). Diameter measurements were obtained perpendicular to the centreline beginning 0.5 cm above the lowest renal artery. The proximal aortic neck was measured at 4 points in order to characterize the morphology of the proximal landing zone. The length of the proximal aortic neck, the common and external iliac arteries, and the common femoral artery up to the femoral bifurcation were read out parallel to the centreline (Fig. 3). In double-oblique multiplanar reformations (MPR), the distance between the aortic and femoral bifurcations was determined and set into a ratio with the centreline length of the iliac and femoral arteries. This quotient served as an iliac tortuosity index (ITI) intended to express the magnitude of elongation and kinking of the iliac access vessels (Fig. 4).

Surgical approach and technique

All procedures were performed in operating theatres equipped with fluoroscopic and angiographic capabilities and carbon fibre operating tables. The procedures for surgical cutdown and access have been previously published [16, 17]. Digital subtraction angiography was performed with the breath-hold technique followed by injection of 20 mL of nonionic contrast medium (Iomeron 400 [iomeprol], AltanaPharma, Konstanz, Germany) administered by automated injection (Injector System Mark V ProVis KMP910G, Medrad, Indianola, PA, USA; Injektron 82 HP, Medtron, Saarbrücken, Germany). For stent graft diameter selection, 15% oversizing was applied. Technical success was defined according to the reporting standards for endovascular aortic aneurysm repair [18].

Follow-up

Follow-up included physical examination and postoperative monitoring for hypertension, fever, pain, and laboratory dysfunction (creatinine, urea, blood count, electrolytes). Computed tomographic (CT) or magnetic resonance (MR) angiography was performed prior to hospital discharge or between discharge and the 30-day follow-up examination, and after discharge annually. All patients were specifically assessed for type I endoleak and graft limb occlusion. Data were collected prospectively by the individual centres and stored in Microsoft Excel spreadsheets on password-protected computers.

Technical success was defined as successful implantation without conversion to open surgery, death, type I or III endoleak, or acute limb thrombosis, according to the established reporting standards for EVAR [18]. Endoleaks were categorized as described by White et al. [8]. Primary endoleaks were defined as apparent on intraoperative angiography or the CT or MR angiography performed before discharge (or <30 days postprocedure).

Results

Patient demographics

The 50 consecutive cases with challenging anatomies of EVAR with the Endurant stent graft, occurring between November 2008 and May 2009, included 22 patients at the Heidelberg clinic, 12 at the Oldenburg clinic, and 16 at the Ludwigsburg clinic. Between July 2009 and October 2010, 40 patients treated at the Heidelberg clinic were entered into ENGAGE. Patient demographics are detailed in Table 1. The median age was 75 (55 to 91) and 72 (57 to 88)years, respectively. Forty nine (98%) in the challenging anatomy cohort and 38 (95%) in the ENGAGE cohort were male. According to the distribution of comorbidities, the patient population overall was at high risk for open aortic surgery in the patients with challenging anatomies. Ninety per cent was under treatment for hypertension, 28% had a history of smoking, 32% had hyperlipidaemia, 26% had renal insufficiency, 38% manifested coronary artery disease, 22% had a history of myocardial infarction, and 26% had chronic obstructive pulmonary disease. Sixteen patients had undergone aortic surgical procedures.

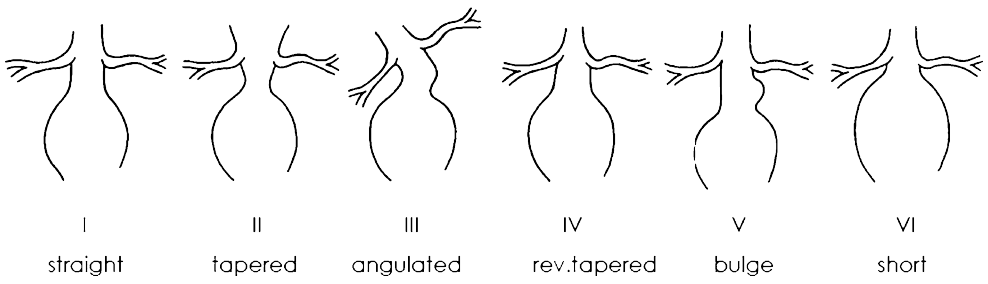

Fig. 2 Morphological classification of the proximal aortic neck with six types in abdominal aortic aneurysms (*rev. tapered*= reversed tapered)

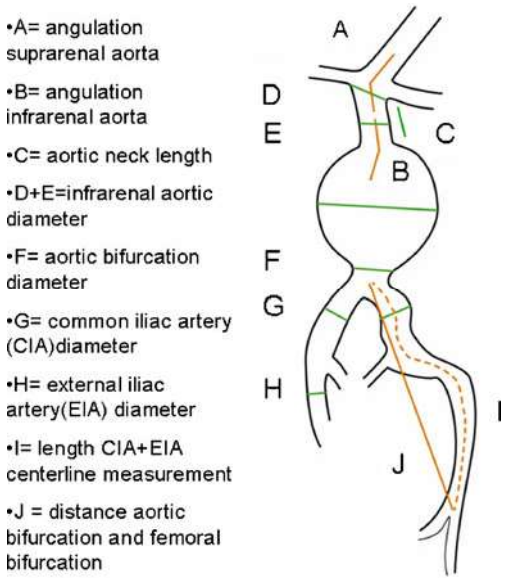

Fig. 3 Preoperative measurement protocol in the abdominal aorta and access vessels using MSCT, angiography, and image postprocessing on a workstation

Aortic neck and iliac artery configuration in patients with challenging anatomy

Morphological characteristics of the aortic neck and iliac artery configuration are shown in Table 2. The median aortic neck diameter at the level of the lowest renal artery was 22.3 mm (range, 16.9 to 30.7 mm). Overall, in the patient population with challenging anatomies, the median length of the proximal aortic neck was 12.0 mm (range, 5.0 to 48 mm). In the 31 treated patients (62%) who had an aortic neck ≤15 mm in length and were assessed as having type IV proximal aortic neck according to the classification demonstrated in Fig. 2, the median proximal aortic neck length was 10 mm (range, 5.0 to14 mm). The median aneurysm diameter was 56.6 mm (range, 48 to 82 mm). In 16 patients (32%), severe tortuosity of iliac arteries (ITI≥ 1.4) was observed. Twenty seven (54%) of the patients had narrowed and calcified iliac arteries, with a median iliac diameter in those patients of just 5.8 mm. Due to the presence of coexisting common or internal iliac artery aneurysm, two patients required a coiling of the internal iliac artery before the endovascular procedure. Most of these patients with challenging anatomy (66%) had a combination of both challenging aortic neck and difficult vascular access.

Aortic neck and iliac artery configuration in patients without challenging anatomy

Patients included in ENGAGE had a median length of the proximal aortic neck of 22.0 mm (range, 15.0 to 40 mm). In patients without challenging anatomies, the median aneurysm diameter was 58 mm (range, 46 to 81 mm), and the median diameter of the external iliac artery was 10 mm in the ENGAGE cohort. One patient required a coiling of the internal iliac artery before the endovascular procedure. These patients included in ENGAGE were treated according to the recommendations for use and had therefore no short aortic necks (<15 mm) or small (<8 mm) access vessels.

Procedural details and technical success in challenging anatomies

Forty-five patients received a bifurcated stent graft component. On the basis of their distal aortic neck diameters of <20 mm or occlusions of common iliac arteries, five patients received an aorto-uni-iliac graft component followed by crossover bypass. All procedures at the Oldenburg and Ludwigsburg clinics were performed under general anaesthesia. At the Heidelberg clinic, three of 22 procedures (13.6%) were performed

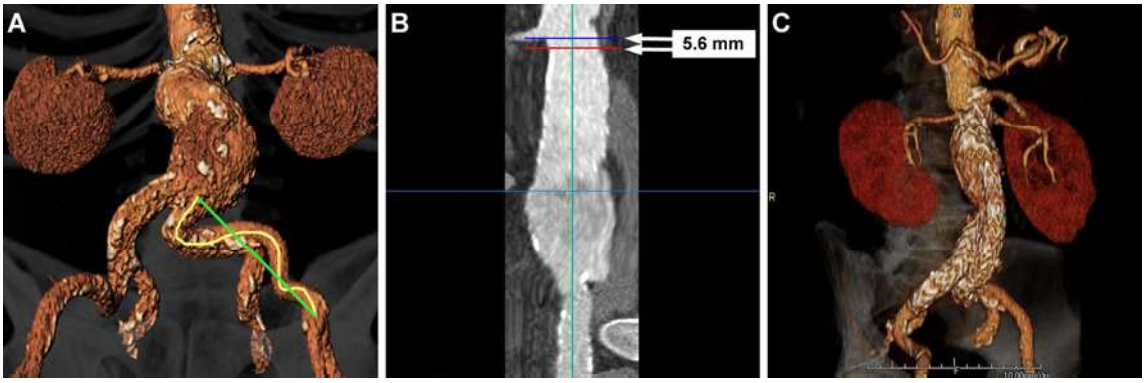

Fig. 4 **a** Volume-rendering CT angiography illustrates the ITI as the ratio between iliac lengths on double-oblique MPRs (*green line*) and centerline analysis (*yellow line*). **b** Centerline analysis was used for proximal neck length measurement (in the same patient as **a**). **c** Volume-rendering CT angiography after successful implantation of an Endurant Stent Graft System

Table 1 Patient demographics with (A, *n*=50) and without (B, *n*=40) challenging anatomies

Variable	A Number or median (% or range)	B Number or median (% or range)
Age (years)	75 (55–91)	72 (56–88)
Male	49 (98%)	38 (95%)
ASA classification	3 (2–4)	3 (2–3)
Hypertension	45 (90%)	27 (67.5%)
Smoking history	14 (28%)	14 (40%)
Diabetes mellitus	9 (18%)	2 (5%)
Hyperlipidaemia	16 (32%)	27 (67.5%)
BMI	27 (21–42)	Not available
Renal insufficiency	13 (26%)	5 (12.5%)
Manifest CAD	19 (38%)	15 (37.5%)
COPD	13 (26%)	5 (12.5%)
Previous infrarenal aortic surgery	4 (8%)	0
Previous thoracic aortic surgery	10 (20%)	0

ASA American Society of Anesthesiology, *BMI* body mass index, *CAD* coronary artery disease, *COPD* chronic obstructive pulmonary disease

under general anaesthesia, and 19 (86.4%) were performed under local or cerebrospinal anaesthesia (Table 3). The median intensive care unit (ICU) stay was 0 day (0 to 28). One patient had a prolonged ICU stay because of mesenteric ischaemia after the EVAR procedure. The median hospital stay was 5 days (3 to 28).

Primary technical success was achieved in 46 of 50 patients (92%). The four technical failures occurred as follows. One patient showed occlusion of a renal artery on intraoperative angiography, related to the proximal deployment. Interventional recanalisation with bailout stenting failed, and open conversion with renal bypass grafting was rejected because of severe comorbidities. Creatinine clearance decreased from 128.5 to 56 mL/min before discharge. After 6 weeks, renal function was restored with increase of the creatinine clearance to 75 mL/min.

Table 2 Morphological characteristics of patients with challenging (A, *n*=50) and without challenging anatomies (B, *n*=40)

Anatomical parameter	A Median or number (range or %)	B Median or number (range or %)
Aortic neck angulation by MPR (°)	19.9 (1–73.1)	–
Aortic neck angulation ≥60°	10.0 (20)	0
Diameter of the aneurysm (mm)	56.6 (48–82)	58 (range, 46 to 81)
Diameter of the common iliac artery (mm)		
Right	10.1 (4.5–17.5)	14 (9–20)
Left	9.4 (5–24.3)	15 (9–24)
Diameter of the external iliac artery (mm)		
Right	7.5 (3.3–13.3)	10 (7–13)
Left	7.3 (4.1–13.9)	10 (8–14)
Length of the proximal aortic neck (mm)	12.0 (5.0–48)	22 (14–40)
Aortic neck ≤10 mm	19.0 (38)	0
Iliac tortuosity index		
Right	1.3 (1–2)	Not available
Left	1.3 (1.1–2)	Not available
Indications[a]		
Short proximal aortic neck length (≤15 mm)	31 (62%); median, 10 mm (5.0–14)	
Severe iliac tortuosity (ITI≥1.4)	16 (32%)	
Narrowed access vessels	27 (54%)	
	Median, 5.8 mm (3.3–7.0)	

MPR multiplanar reformations, *ITI* iliac tortuosity index

[a] More than one indication possible

Table 3 Procedural details and perioperative morbidity and mortality in challenging (A, n=50) and without challenging (B, n=40) anatomies

	A Number or median (% or range)	B Number or median (% or range)
Primary technical success	46 (92%)	39 (97.5%)
30-day mortality	1 (2%)	0
Graft limb occlusion	2 (4%)	0
Primary endoleak	6[a] (8%)	13 (32.5%)
Type I	3[a] (6%)	1 (2.5%)
Type II	3[a] (6%)	12 (30%)
Cardiac complications	1 (2%)	0
Respiratory complications	0	0
Renal failure (≥1.2 mg/dL)	2 (4%)	2 (5%)
Stroke	1 (2%)	0
Intraoperative blood transfusion	3 (6%)	0
Conversion	0	0
ICU stay (days)	0 (0–28)	0
Hospital stay (days)	5 (3–28)	6 (4–49)
Reinterventions	5[b] (8%)	3 (7.5%)

ICU intensive care unit

[a] Two patients had both type I and II endoleaks

[b] One patient had two reinterventions

In the second patient with technical failure, gate cannulation of the contralateral limb with the guidewire did not succeed. A crossover manoeuvre and antegrade canalisation via a brachial access failed. Therefore, an aorto-uni-iliac endograft was implanted into the deployed bifurcated graft, and then, femoro-femoral crossover bypass was performed as a rescue manoeuvre.

The third technical failure occurred in a patient with a proximal aortic neck length of 8 mm who showed a persistent proximal type I endoleak on final angiography. In the fourth patient with technical failure, there was accidental overstenting of the internal iliac artery without buttock claudication. No surgical conversions were performed.

Procedural details and technical success in patients without challenging anatomies

Thirty-eight patients received a bifurcated stent graft component. Only two patients received an aorto-uni-iliac graft component followed by crossover bypass because of the same reasons mentioned above. Primary technical success in this cohort was 97.5%. In one patient, it was not possible to cannulate the contralateral limb through a femoral access. The cannulation was performed successfully via brachial access.

Morbidity and mortality through the 30-day follow-up in challenging anatomies

Overall mortality through 30 days was 2% (1/50). Morbidity through 30 days is detailed in Table 3. The one death was due to multiorgan failure after successful implantation of an aorto-uni-iliac endograft. The patient was found to have a severely calcified and narrowed iliofemoral access, which could still be passed by the Endurant stent graft. The Talent Occluder could not be placed in the contralateral common iliac artery without partially covering the internal iliac artery. The presence of a 3.7-cm common iliac aneurysm required coil embolisation of the contralateral right internal iliac artery before endovascular exclusion of the 6.7-cm AAA. On the first day after the implantation, the patient developed mesenteric ischaemia, necessitating subtotal colectomy. The death due to multiorgan failure occurred on day 28. Mortality through the 30-day follow-up in patients without challenging anatomies through 30 days was 0% (0/40).

Morbidity and mortality after 15 months of follow-up in challenging anatomies

Follow-up was available in all of the 50 patients (100%) over a mean of 15 months (1–25). During this time, seven patients died (overall mortality, 16%; 8/50), besides the above-described patient, all of them unrelated to the procedure (1 pneumonia, 2 myocardial infarctions, 2 malignant tumours, 1 sepsis, and 1 incarcerated hernia). There were no graft-related complications concerning the two patients contained to rupture. One of them with preexisting renal insufficiency creatinine advanced without the need for dialyses.

Primary endoleaks, graft limb occlusions, and reinterventions through the 30-day and midterm follow-ups in challenging anatomies

Intraoperative angiograms revealed two proximal type I endoleaks and one distal type I endoleak. All of them were

treated intraoperatively by means of balloon dilatation. There were no type III endoleaks. One persistent type I endoleak (2%) and five type II endoleaks (10%) were detected by CTA through the 30-day follow-up. All of the type II endoleaks have been treated conservatively. During follow-up, one persisting type I endoleak was treated with a fenestrated graft after unsuccessful ballooning. One type II endoleak occluded spontaneously; the others were persistent without expansion of the aneurysms.

Graft limb iliac thrombosis occurred in two patients (4%) during the 30-day follow-up. Surgical thrombectomy was required in association with stent implantation of the common and external iliac arteries. Both patients received a femoro-femoral crossover bypass because of persisting critical limb ischaemia.

Another major complication with complete thrombosis of an aorto-uni-iliac endograft was recorded 15 months after implantation. The patient was treated successfully with transfemoral thrombectomy and ballooning of the severe calcified and angulated aortic neck.

Primary endoleaks, graft limb occlusions, and reinterventions through the 30-day follow-up in patients without challenging anatomies

Intraoperative angiograms revealed one proximal type I endoleak which was treated successfully by means of balloon dilatation. There was no type III or IV endoleak. Twelve type II endoleaks (30%) were detected by CTA through the 30-day follow-up. Besides one embolisation, all of the type II endoleaks have been treated conservatively. Two of these endoleaks dissolved in the 1-year follow-up.

There were three (10%) major events during follow-up: one occlusion of a crossover bypass, one claudication because of new embolic limb stenosis in a patient with cardiac arrhythmia, and one stenosis of an external ilac artery which was treated by stenting to prevent occlusion.

Discussion

Since the first interventions in the early 1990s, the role of EVAR has expanded [19–21], with ongoing progress in the diagnosis and management of AAA and validation in randomized trials versus conventional open surgical repair [1–4, 22]. The evolution of stent grafts and endovascular delivery systems has substantially improved the application rate for and patient outcomes with EVAR [23, 24]. However, further development is needed in order to reduce the continuing incidence of complications and secondary reinterventions. The length of the proximal aortic neck as landing zone for the stent graft is the most important barometer of success. When the proximal aortic neck is short (≤15 mm), one of the most likely complications is a type I endoleak, which is associated with a high risk of rupture [5, 8, 15, 25].

We achieved acute technical success in 46 (92%) of our 50 challenging cases, with no need for primary surgical conversion. The cases in our series were indeed challenging by the established standards. For proximal aortic neck length, the median value was 12 mm, and the length was ≤15 mm in 31 (62%) of the patients (with a median value of 10 mm in those 31 cases). Nevertheless, type I endoleak was detected in only three instances, and there was only one type I endoleak (2%) that was persisting at 30 days. This case was treated with a fenestrated graft.

This 30-day outcome in terms of type I endoleak compares well with results recently reported for other EVAR devices [26–31]. Even in midterm follow-up, the Endurant stent graft achieved excellent outcomes (1.3% type I endoleak and freedom from type I endoleak of 97%) in patients with a short aortic or severely angulated neck. In our present series, only one type I endoleak (2%) occurred (primary endoleak) in a patient with a reversed tapered aortic neck (8 mm) combined with a relevant neck thrombus. These constellations were to be held responsible to affect the rate of type I endoleaks more than angulation of the aortic neck [32]. Due to differences in the device designs (Table 4) and the varying anatomical conditions in these trials, the data can be compared only with great circumspection.

One explanation for the low incidence of the type I endoleak in these series is the special proximal stent design of the Endurant graft with its great radial force and the addition of anchoring pins, these factors combining to promote more active fixation [11]. Another stent-design factor potentially affecting the rate of the type I endoleak is the tip capture mechanism that holds the suprarenal stent crowns and anchoring pins constrained while the stent graft is placed. Despite such cautionary findings, the rare occurrence of only one persisting primary type I endoleak in our cohort would seem to justify the more liberal use of the Endurant endograft in carefully selected patients.

Besides EVAR with a suprarenal fixed endograft like the Endurant Stent Graft System, fenestrated or branched endografts offer another treatment modality for these complex pathologies. The obvious advantage of fenestrated endografts for AAA is the prospect of a safer proximal fixation based on the stretching of the landing zone. Initial short-term reporting on the use of branched endografts shows a high rate of technical success (95%) [33]. Thus, it is imperative that training programmes have to be initiated in order to develop expertise in simple fenestrated graft implantation before this method is employed in complex pathologies. While the handling of these endografts must be simplified and their availability has to be increased to allow

Table 4 Comparison of diameter specifications among commercially available EVAR Stent Graft Systems

Stent graft (manufacturer)	Proximal aortic stent graft diameter (mm)	Catheter diameter (F)
Endurant (Medtronic)	23–25	18 outer diameter
	28–36	20 outer diameter
Talent (Medtronic)	24–28	22 outer diameter
	30–36	24 outer diameter
Zenith (Cook)	22–26	18 inner diameter
	28–32	20 inner diameter
	36	22 inner diameter
Excluder (Gore)	23–28.5	18 inner diameter
	31	20 inner diameter
Anaconda (Vascutek)	19.5–23.5	20 outer diameter
	25.5–34	22 outer diameter

a broader usage in both routine and emergency cases, the technique will nevertheless probably remain limited to highly specialized centres [34].

In addition to the active suprarenal fixation afforded by the Endurant stent graft in short aortic necks, other distinguishing features of the device design proved beneficial in our patients with difficult access vessels—characterized as narrow and calcified in 27 cases (54%) and tortuous in 16 (32%). The flexibility of the device allowed effective access through the calcified, narrowed, elongated, and kinked vessels. The low-profile Endurant delivery system currently has the smallest outside diameters available (Table 4) [11].

Indices of iliac tortuosity can be used to predict difficulties in passing the iliac region with the endograft. To quantify the tortuosity in iliac arteries, we introduced the ITI, which ranged from 1.0 to 2.0 with a mean of 1.3 in this cohort (Table 2). An acknowledged limitation of this index is the unsatisfying detection of great angulations occurring within a short distance, as were sometimes observed at the area of the distal aorta and the beginning of the common iliac artery. Further prospective studies will be required to validate the ITI and define a threshold corresponding to an angulated or tortuous iliac artery.

Small limb diameter and type of endograft have been identified as risk factors for iliac graft limb occlusion [7], and we have assumed that the tortuosity of access vessels could also predict this outcome (Table 5). One of the two graft limb occlusions in our series occurred in a case in which the contralateral limb was accidentally placed a long distance into the main body as a technical failure. In the second case of graft limb occlusion, the patient had small common (5.2 mm) and external (6.7 mm) iliac arteries, and a possible reason for this occlusion could be that the contralateral limb device component was much oversized. Nevertheless, the limb occlusion rate of 4% (2/50) in our series is comparable with the reported incidence (3.7% to 7.7%) in larger series [7, 22, 35].

The 30-day mortality rate of 2% (1/50) is in line with the range of 1% to 3% reported in the literature for other endografts of the current generation [2, 26, 27, 30], supporting the growing feasibility of EVAR in challenging anatomies. In our selected group of patients, a higher mortality rate was expected but was also not found in the

Table 5 Subgroup analysis (limb occlusion, endoleak, technical success, and mortality) concerning outcome in patients with (n=50) and without (n=40) challenging anatomies

Outcome parameters (n/%)	Short neck <10 mm	Angulation of the aortic neck <45	Angulation of the aortic neck >45 to <60	Angulation of the aortic neck >60	Small (<8-mm access vessel)	Total	ENGAGE[a]
Patients (n)	19	31	12	7	27	50	40
Limb occlusion	0	2	0	1	1	3 (6%)	0
Endoleak, type I, primary	2	2	0	0	0	3 (6%)	1 (2.5%)
Endoleak, type I, 30 day FU	1	1	0	0	1	1 (2%)	0
Technical failure	2	0	0	1	1	4 (8%)	1 (2.5%)
30-day mortality	1	1	0	0	1	1 (2%)	0

[a] Forty patients from the Heidelberg clinic were included in ENGAGE

2-year single-centre analysis with the Endurant stent graft in a similar cohort by Troisi (2.6%) [32]. For these patients, the surgeon's preference was for EVAR rather than open repair because of the high comorbidities. Compared to the excellent 30-day results with the Endurant stent graft in non-challenging anatomies (no type I endoleak; no graft limb occlusion; all-cause mortality, 1.7% (3/180)), procedure-related complications in challenging anatomies are increasing [9]. Nevertheless, EVAR in such patients with challenging anatomies can be an alternative method but cannot be deemed a completely safe procedure.

These early results are encouraging for application of EVAR in challenging anatomies. However, they have to endure the long-term follow-up in these patients. In general, at this time, of course, we cannot recommend treatment with the stent graft for indications beyond the device instructions for use.

Conflicts of interest There was financial support from Medtronic for patients included in ENGAGE.

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