Real world experience with the TREO device in standard EVAR: Mid-term results of 150 cases from a German Multicenter study

Sebastian Zerwes[1], Ana-Maria Ciura[1], Hans-Henning Eckstein[2], Oksana Heiser[2], Johannes Kalder[3], Paula Keschenau[3], Mario Lescan[4], Bartosz Rylski[5], Stoyan Kondov[5], Jörg Teßarek[6], Hans-Kees Bruijnen[1], and Alexander Hyhlik-Dürr[1]

[1] Clinic for vascular and endovascular surgery, Medizinische Fakultät, Universität of Augsburg, Germany
[2] Clinic for Vascular and Endovascular Surgery, University Clinic, Klinikum rechts der Isar, Munich, Germany
[3] Department of Adult and Pediatric Cardiovascular Surgery, University Hospital Gießen, Germany
[4] Section of Vascular and Endovascular Surgery, University Clinic Tübingen, Germany
[5] Clinic for Heart and Vascular Surgery, University Heart Center Freiburg, Bad Krotzingen, Germany
[6] Department for Vascular Surgery, Bonifatius Hospital Lingen, Germany

Summary: *Background:* The objective of the study was to analyze mid-term results of unselected patients treated with the TREO (Terumo Aortic, Florida, USA) device at six German hospital sites. *Methods:* A multicenter, retrospective analysis of patients treated within and outside instructions for use (IFU) from January 2017 to November 2020 was performed. Primary outcomes were technical success, mortality and endograft related complications according to IFU status. Secondary outcomes were aneurysm/procedure related re-interventions. *Results:* 150 patients (92% male, mean age 73 ±8 years) were treated (within IFU 84% vs. outside IFU 16%) with the TREO device for abdominal aortic aneurysms (n=127 intact, n=17 symptomatic and n=6 ruptured; p=0.30). Technical success was achieved in 147/150 (within IFU 99% vs. outside IFU 92%, p=0.08). 30-day mortality was 2%, one year and overall mortality was 3% and 5%. During a mean follow-up of 28.4 months (range: 1–67.4 months), 35 (25%; within IFU 23% vs. outside IFU 35%, p=0.23) patients suffered from endoleaks. The majority were endoleaks type II (n=33), the remaining type Ia (n=5) and type Ib (n=3). No endoleaks type III-V, migrations or aneurysm ruptures occurred. Overall, 19 patients (13%; within IFU 13% vs. 15% outside IFU, p=0.70) received a secondary intervention: nine endoleak related endovascular procedures, three open conversions, two endograft limb related interventions, four surgical revisions of the femoral access sites and two bowl ischemia related procedures, respectively. *Conclusions:* This non industry-sponsored, multicenter trial indicates that using the TREO device in a real-world setting (both within and outside IFU) seems feasible in the treatment of patients suffering from AAA. While the rate of complications and secondary interventions is in line with previously published data, the findings highlight the fact that standard EVAR is associated with serious adverse events.

Keywords: TREO, Endovascular Aortic Repair, EVAR

Introduction

Endovascular aneurysm repair (EVAR) is often considered as the first-choice treatment modality for the therapy of infrarenal abdominal aortic aneurysms (AAA), as it is associated with lower 30-day perioperative morbidity and mortality and a shorter hospital stay [1, 2, 3]. However, given the long-term durability issues compared with open aortic repair, there has been an ongoing evolution of EVAR devices characterized by modifications and advancements in aortic endograft design to improve mechanical stability, practicality and clinical durability [4, 5]. A relative newcomer to the modern endovascular prosthesis market is the trimodular abdominal aortic stentgraft system TREO (Terumo Aortic, Florida, USA), which received its CE mark in September 2015 [6]. One of the novel features of this stentgraft is a so called "lock stent technology", which is designed to tackle endoleaks type III by preventing parting of the endograft limbs from the main body [6]. A relatively small number of early studies have shown promising results, among the largest the ITAlian North-East Registry of ENDOvascular Aortic Repair With the BOltOn Treo Endograft (ITA-ENDOBOOT), including a total of 137 patients [7, 8, 9, 10, 11].

Since the clinical performance of the TREO stent graft system has been underreported to date, the objective of the present study was to analyze mid-term results of a multi centric cohort, consisting of 150 consecutive, unselected patients, that were treated with the TREO device at six German hospital sites (five university centers and one community hospital). The study will focus on technical success of the procedures, 30-day, one-year and overall mortality, endograft related complications, as well as all aneurysm/procedure related re-interventions, with the aim to shed light on the real-world performance of this new device, in particular according to its usage within and outside instructions for use.

Methods

Study design and patient sample

This study was conducted in accordance with the STROBE (The Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [12]. This was a multicenter, retrospective case series study of patients treated with the TREO device at six German hospital sites. The inclusion criterion was therapy with the TREO stentgraft for the treatment of infrarenal abdominal aortic aneurysm (AAA) from January 2017 to November 2020. In order to allow for a group of patients resembling daily practice, both elective and non-elective cases (symptomatic and/or ruptured) were included. All consecutive patients meeting the entry criterion were included in the study. All data was retrospectively evaluated by each participating center going through the electronic patient files and put into a standardized excel data base (Microsoft cooperation, Redmond, Washington, US).

Each hospital (five university hospitals, one non-university hospital) had to include 25 consecutive patients during the abovementioned period, resulting in a total number of 150 cases. Patients were divided according to their instructions for use (IFU) status into within IFU and outside IFU. Instructions as published by the manufacturer are as follows [13]:

- adequate iliac or femoral access compatible with the required delivery system
- suprarenal neck angle of less than 45 degrees
- infrarenal landing neck length of:
  - 10 mm or greater with an infrarenal angle of less than 60 degrees and an inside diameter of 17 mm–32 mm, or
  - 15 mm or greater with an infrarenal angle between 60 and 75 degrees and an inside diameter of 16 mm–30 mm
- distal iliac landing neck of inside diameter:
  - 8 mm–13 mm and a length of at least 10 mm, or
  - >13 mm–20 mm and a length of at least 15 mm

Collected procedure associated data included duration of surgery (i.e. whole procedure time from cut-down/percutaneous puncture to wound/percutaneous closure), type of anesthesia (local vs. general), type of access (cut-down vs. percutaneous), size and number of stent grafts used (main body, contralateral and ipsilateral extension), blood loss, amount of contrast medium and intraoperative complications (endoleak, bleeding, rupture). All patients received a first postoperative control with CT scan. Further follow-up was performed with ultrasound after 3 and 6 months, and with CT scans after 12 months, followed by annual ultrasound controls.

The local ethics committee approved the collection, evaluation, and publication of the retrospectively collected and anonymized data used in this analysis (Nr. 22-0795).

Outcome measures

The main outcome measures were technical success (defined as successful stentgraft placement resulting in complete sealing with no type I or type III endoleak and without the need of conversion to open surgery), 30-day, one-year and overall mortality, as well as endograft related complications (endoleak, migration, aneurysm growth, aneurysm rupture) [14]. Migration was defined as any stent-graft movement $\geq$5 mm related to a predefined reference vessel or any migration leading to an endoleak [15]. Secondary outcomes were all aneurysm/procedure related re-interventions due to surgical access site complications, endoleaks, migrations or aneurysm growth. Complications were collected both during and after the hospital stay. All patients were followed up to their last hospital visit and in addition called up to see whether they were still alive.

Statistical analysis

Continuous data are given as the means ± standard deviation or median ([interquartile range: Q1, Q3] (absolute range)); categorical data are presented as the counts (percentage). Nominal variables were analyzed using the Fisher exact test, while numeric variables were compared with the Mann-Whitney U test due to the mostly not normal distribution. The threshold of statistical significance was set to $p<0.05$. Statistical analyses were performed using StatsDirect (version 3.1.8; StatsDirect Ltd, Altrincham, UK) [16]. Kaplan-Meier curves were calculated to graphicly display the cumulative survival, endoleak-free survival and endoleak-free survival excluding endoleaks type II, according to IFU status, respectively.

Results

Collected patient characteristics and anatomical features at the initial TREO implantation, can be found in Tables I and II, respectively. Most patients (n=127; 85%) were asymptomatic at the time of the endograft implantation (Table III), hence the procedure was carried out in an elective setting. Of the remaining patients, 17 (11%) presented with symptoms and six (4%) with an acute rupture, requiring emergent treatment.

125 (83%) procedures were performed under general anesthesia, while 25 (17%) under local anesthesia. The type

Table I. Patient demographics and comorbidities[a]

Patient characteristics	Total 150 (100)	Within IFU 124 (84)	Outside IFU 26 (16)	p-value
Age, y	73 (46–83)	75 (46–86)	71 (53–86)	0.56
Men	135 (90)	111 (90)	24 (92)	>0.99
Comorbidities				
BMI >30 kg/m^2	39 (26)	33 (27)	7 (27)	0.89
Hypertension	127 (85)	106 (85)	21 (88)	0.77
CAD	72 (48)	62 (50)	10 (38)	0.36
Arrhythmia	29 (19)	25 (20)	4 (15)	0.79
CABP	17 (11)	15 (12)	2 (8)	0.74
COPD	23 (15)	19 (15)	4 (15)	>0.99
Stroke	21 (14)	18 (14)	3 (11)	>0.99
PVD	33 (22)	27 (22)	6 (23)	0.81
Diabetes	35 (23)	30 (24)	4 (19)	0.66
Smoking	82 (55)	68 (55)	14 (54)	0.92
Renal insufficiency[b]	46 (31)	37 (30)	10 (38)	0.39
Hyperlipidemia	79 (53)	66 (53)	13 (50)	0.91
Previous abdominal surgery/trauma	46 (31)	39 (31)	4 (15)	0.12
ASA				
I	2 (1)	1 (1)	1 (4)	
II	43 (29)	35 (28)	8 (31)	
III	93 (62)	79 (64)	14 (54)	0.17
IV	11 (7)	9 (7)	2 (8)	
V	1 (1)	0	1 (4)	

Notes. ASA: American Society of Anesthesiologists; BMI: body mass index; CABG: coronary artery bypass graft; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; PVD: peripheral vascular disease.
[a]Continuous data are presented as the median (range); categorical data are given as the counts (percentage).
[b]Creatinine >2.0 mg/dL.

Table II. Preoperative anatomic features of the aneurysms within and outside instructions for use (IFU)[a]

Preoperative anatomic features of the aneurysms	Within IFU Median [interquartile range Q1, Q3] (absolute range)	Outside IFU Median [interquartile range Q1, Q3] (absolute range)	p-value
Aneurysm diameter (mm)	55 [51–60,4] (48–103)	57.5 [54–65] (46–105)	0.03
Proximal neck diameter (mm)	22.35 [20–25] (12.9–30)	22.1 [20.5–27] (13–33)	0.77
Proximal neck length (mm)	27.5 [19–38.55] (10–78)	31.5 [22–42] (6–62)	0.26
Proximal neck angulation (°)	26.3 [15–41,5] (0–72)	22.45 [12–36] (0–76)	0.34
Right CIA diameter (mm)	17.25 [13–17.25] (8,2–20)	17 [15–21] (8–35)	0.0025
Left CIA diameter (mm)	14.95 [13–16.9] (9–20)	19.5 [15–22.4] (7–37)	<0.0001
Right CIA length (mm)	58 [47–70] (26–158)	60.8 [50–66] (32–118)	0.71
Left CIA length (mm)	60 [51–72] (11.4–143)	52 [38–59] (11–92)	0.0022

Notes: CIA: common iliac artery. [a]Data are presented as the median [Q1, Q3] (absolute range).

Table III. Instructions for use (IFU) and case status

Case status	Total 150 (100%)	Within IFU 124 (84%)	Outside IFU 26 (16%)	p-value
Elective	127 (85%)	107 (86%)	20 (77%)	0.30
Symptomatic	17 (11%)	13 (10%)	4 (15%)	
Ruptured	6 (4%)	4 (3%)	2 (8%)	

of access was percutaneous in 101 (67%) and cut down in 49 (33%) cases. The surgeries lasted a median of 107.5 minutes (IQR 87,141; range 36–340), with a median blood loss of 120 ml (IQR 100,200; range 0–6000); the blood loss of 6000 ml was recorded in a patient with a ruptured aortic aneurysm that required open conversion. The median amount of contrast media used was 90 ml (IQR 58,120; range 0–244); 13 cases were carried out using

Table IV. Clinical outcomes and secondary aneurysm-/procedure related interventions according to instructions for use (IFU) status

	Total n=150 (100%)	Inside IFU n=124 (84%)	Outside IFU n=26 (16%)	p-value
Technical success	147/150 (98%)	123 (99%)	24 (92%)	p-value
Intraoperative death	1	0	1	0.08**
30-day mortality	3/150 (2%)	2	1	0.17**
All-cause mortality	8 (5%)	5	3	0.52**
Aneurysm/procedure related mortality	2	1	1	0.17**
Any endoleak	38/150 (25%)	29 (23%)	9 (35%)	0.32**
Endoleak type Ia	5	4	1	0.23
Endoleak type Ib	3	1	2	>0.99**
Endoleak type II	33 (22%)	25 (20%)	8 (31%)	0.078**
Endoleak type III	0	0	0	0.24
Endoleak type IV	0	0	0	–
Endoleak type V	0	0	0	–
Aneurysm growth	0	0	0	–
Aneurysm rupture	0	0	0	–
Migration	1	1	0	–
Other procedure-/aneurysm-related complications	13/150 (9%)	9 (7%)	4 (15%)	>0.99**
Access complication	5	4	1	0.24**
Endograft limb thrombosis	2	1	1	>0.99**
Endograft limb stenosis	1	1	0	0.32
Bowl ischemia	2	2	0	>0.99**
Miscellaneous	3	1	2	>0.99**
Secondary aneurysm-/procedure related interventions	19/150 (13%)	15/124 (13%)	4/26 (15%)	0.70
Endoleak related *endovascular* re-intervention	9*	7	2	0.65
Endoleak related *open conversion*	3*	2	1	0.44
Endograft limb (thrombosis/stenosis) related re-intervention	2	2	0	>0.99
Femoral access site related re-intervention	4	3	1	0.54
Bowl ischemia related re-intervention	2	2	0	>0.99

*One patient with an endoleak related **endovascular** re-intervention, later also received an endoleak related **open** conversion.
**Fisher-Freeman-Halton exact, otherwise Chi square test.

intravascular ultrasound (IVUS). In the majority of cases (87%; 131/150) one TREO main body (with a proximal diameter of 28 mm and a length of 80 mm being the most frequently used), one ipsilateral and one contralateral limb were used.

Technical success and mortality

Technical success was achieved in 147/150 procedures. Three cases were viewed as technically unsuccessful. Two endoleaks type Ia: one due to wrong measurement resulting in too much oversizing (within IFU) and one due to neck angulation (outside IFU), respectively. The third patient required open conversion right after endograft implantation, with insufficient aneurysm exclusion (due to endoleak type II) in the setting of acute rupture. The patient did not survive the conversion to open surgery, resulting in an intraoperative mortality of 1% (1/150). 30-day mortality was 2% (3/150): Aside from the intraoperative death, two other patients died. The first patient developed paraplegia directly after the EVAR procedure. Which was first interpreted as a rare case of spinal cord ischemia post EVAR, turned out to be a coincidental tumor in the spinal canal. This tumor was detected in postoperative magnetic resonance imaging (MRI) but had not been described in the computer tomography (CT) scan prior to the EVAR procedure. The patient was emergently operated by the department of neurosurgery and died due to massive intraoperative hemorrhage from the tumor. Accordingly, the death was not counted as procedure related. The second patient who died was an octogenarian who experienced an access complication necessitating femoral patch plasty during the primary EVAR procedure. He then developed a post operative urinary tract infection with a fatal sepsis. His death was counted as procedure related.

During a median time of follow-up of 28.4 months (range 1–67.4), all-cause mortality amounted to 3%, 3% and 5% at one, two and five years, respectively. Overall, 8/150 patients died: Aside from the above-mentioned three deaths, five patients died during follow-up: two cardiac-, one cancer-, one Covid-19- and one cerebral hemorrhage-related, respectively. Table IV gives an overview of the technical success and the mortality according to IFU status, while Figure IA displays the Kaplan-Meier curve for cumulative survival. Please note that only two deaths were viewed as aneurysm-/procedure related (one within, one outside IFU).

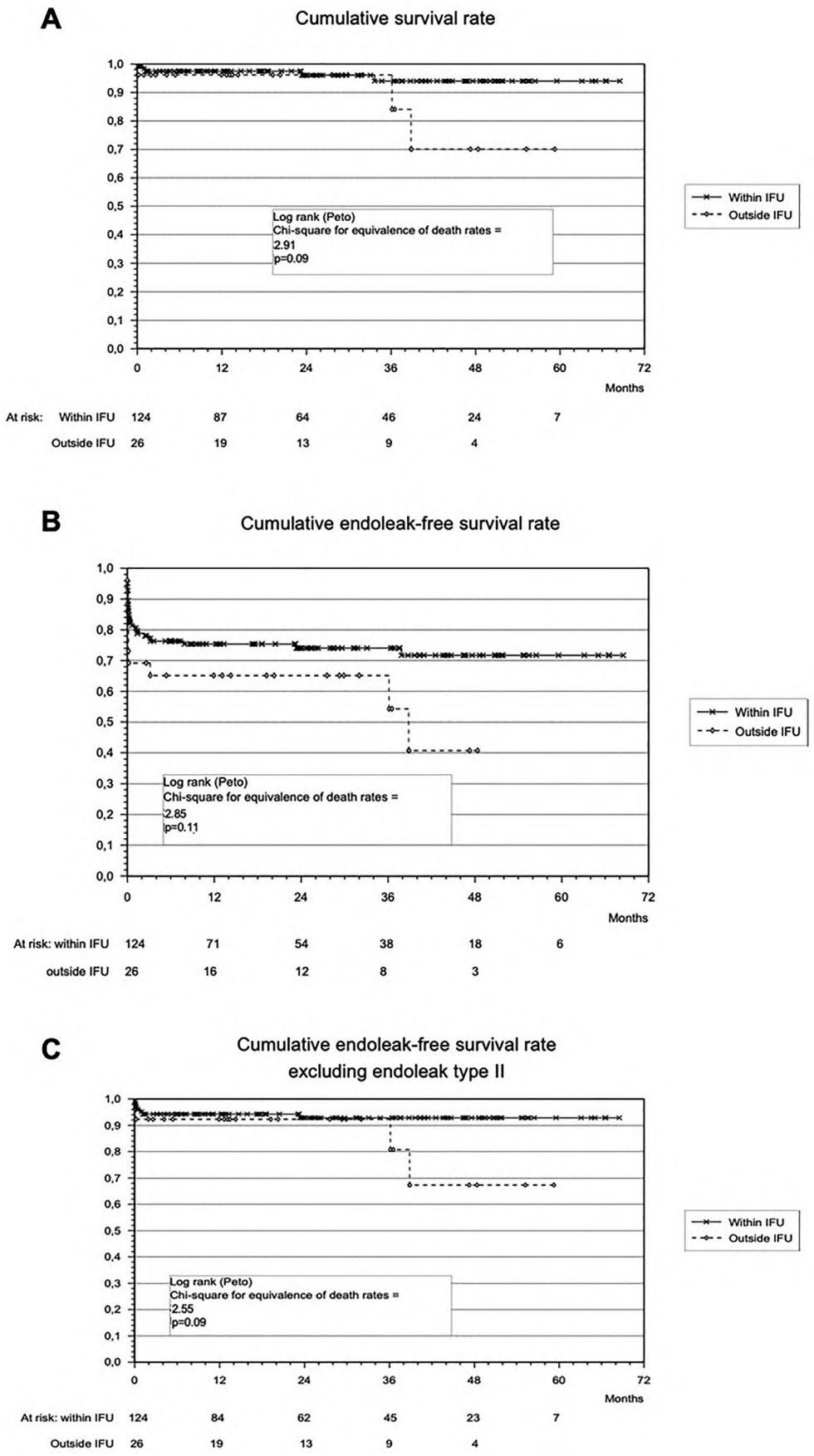

Figure 1. Kaplan-Meier curves for (A) cumulative survival, (B) endoleak-free survival and (C) endoleak-free survival excluding endoleaks type II; IFU, instructions for use.

Endoleaks, aneurysm growth/rupture and migration

In total, 38 patients were affected by one or more endoleaks. By far the most frequently observed endoleaks, were endoleaks type II, which were present in 33/38 (87%) patients. The remaining endoleaks were five type Ia and three Ib. Two patients were affected by combined endoleaks: one type II in combination with an endoleak type Ia and Ib, one type II in combination with Ia, respectively. While no endoleaks type III-V, no aneurysm growth and no ruptures were observed, one patient did suffer from a 7 mm endograft migration. The migration did not result in an endoleak. The exact distribution of the endoleaks according to the IFU status can be found in table IV, while Figure IB and IC display the Kaplan-Meier curves for cumulative endoleak-free survival and cumulative endoleak-free survival excluding endoleak type II.

Other procedure-/aneurysm-related complications

In total, 13 patients were affected by other procedure-/aneurysm related complications. These included five access complications (three delayed wound healings and two false aneurysm of the common femoral artery), two endograft limb thrombosis (one symptomatic, the other asymptomatic due to poor cardiac output) and one endograft limb stenosis due to kinking.

Two patients developed a bowl ischemia directly after the endograft implantation. Both had had patent inferior mesenteric arteries before the procedure. In addition, a total of three patients were affected by miscellaneous complications, including the above-mentioned case of the tumor in the spinal canal. The other two patients suffered from a minor posterior stroke (the patient did not want further evaluation due to lack of symptoms) and an acute on chronic renal failure (which resolved after temporary dialysis), respectively. Table IV gives an overview of all complications according to IFU status.

Procedure-/aneurysm-related secondary interventions

During follow-up, a total of 19 patients received a secondary intervention. The most frequent re-interventions were endoleak-related endovascular procedures carried out in 9/150 (6%) patients. These included four successful re-interventions for endoleak type Ia treatment: one plain proximal balloon angioplasty, one coil embolization procedure, one fixation with endoanchors and one chimney (left renal artery) procedure in combination with a proximal cuff. Three patients were effectively treated for endoleak type Ib: two with distal endograft limb extension and one with Histoacryl (B. Braun, Melsungen, Germany) glue embolization around the distal end of one endograft limb, respectively. Four patients were successfully treated for endoleak type II: three with coil embolization (one in combination with Histoacryl glue embolization for treatment of a concomitant endoleak type Ib) and one with balloon angioplasty of the endograft limbs near the endoleak feeding median sacral artery. All type II endoleaks had been large in size.

A total of three patients (2%) received an open conversion due to endoleak type II. Two patients suffered from insufficient aneurysm exclusion after TREO implantation for a ruptured AAA: one of the patients was converted on the operating table and deceased (as described above), while in the other the postoperative CT scan revealed a persisting aneurysm perfusion due to a large endoleak type II, leading to an open conversion four days after the initial endograft implantation. The patient survived without further complications. The third patient received an elective, semi-open conversion with aneurysm sac revision by means of ligature of four lumbar arteries, successfully excluding the endoleak type II. During the time of FU, no further interventions regarding endoleaks were performed.

Two patients (1%) had a secondary intervention due to endograft limb issues: One had a limb stenosis which was treated endovascularly by stenting, the other suffered from a limb occlusion which was treated with a femoral cross-over bypass.

Four patients (3%) received open surgical revisions due to femoral access complications. Two were treated with negative wound pressure therapy, one with surgical revision; all three had developed a delayed wound healing. Aside from these, one patient presented with a false aneurysm of the common femoral artery, which was treated with open surgical revision.

In addition to above mentioned secondary interventions, two patients received a hemicolectomy due to bowl ischemia. Both patients survived this complication. An overview of all aneurysm-/procedure related secondary interventions is displayed in table IV.

Discussion

The present study that included 150 patients, represents one of the largest multicenter studies to date evaluating the real-world performance of the TREO stentgraft system. Contrary to an industry-sponsored trial, it contains an unselected, consecutive group of patients that received a TREO implantation for treatment of AAA [17]. As such it not only included patients treated within (n=124) and outside (n=26) IFU, but also six cases of ruptured and 17 cases of symptomatic aneurysms, making this a truly relevant patient cohort, as it resembles honest data from a bouquet of patients that clinical vascular surgeons encounter in their everyday life. Afterall, while EVAR is generally seen as the first-choice treatment modality for the therapy of infrarenal AAA, due to its low 30-day perioperative morbidity and mortality and a shorter hospital stay, it remains mandatory to analyze new stentgraft designs with close scrutiny, making sure that they live up to the expectations [1, 2, 3].

Since the clinical performance of the TREO stent graft system has been underreported to date, the aim of the present study was to reduce that knowledge gap [6, 7, 8, 9, 10, 11].

Technical success and mortality

Technical success was achieved in 147/150 procedures. These findings are in line with technical success rates described in the literature, ranging from 93–100% [8, 9, 18]. In the present cohort, the procedures seen as technically unsuccessful were two endoleaks type Ia and one patient requiring open conversion right after endograft implantation due to persistent aneurysm perfusion (from an endoleak type II) in the setting of a ruptured aneurysm. While the presence of an endoleak type II does not deem a case to be technically unsuccessful, this changes in a rupture in which the endoleak type II inhibits sufficient aneurysm exclusion, resulting in hemodynamic instability of the patient [14]. In such scenarios, open conversion is unavoidable and often fatal, as was the case in this patient who did not survive the procedure, resulting in an intraoperative mortality of 1% [19]. Of note, this was the only patient out of six ruptured cases, that did not survive the EVAR procedure.

30-day mortality was 2% (3/150): aside from the intraoperative death, two other patients died within 30 days. As previously described, this included one patient with a tumor in the spinal canal (who did not survive the neurosurgery and was accordingly not counted as aneurysm related death) and an octogenarian who experienced an access complication necessitating femoral patch plasty during the primary EVAR procedure and later developed a fatal sepsis due to urinary tract infection. Hence, while a 30-day mortality of 2% seems high for standard infrarenal EVAR procedures, this is put into perspective when considering that one of the deaths occurred in the setting of aneurysm rupture, while another death was due to a coincidental tumor and not related to the aneurysm [1, 20]. This also holds true when taking a closer look at the overall all-cause mortality of 5% during a follow-up of 28.4 months (range 1–67.4): considering that only two deaths were classified as aneurysm/procedure related, these findings are very much in line with previously published data regarding mortality rates post EVAR [4, 20]. After all, this cohort represents a severely diseased group of patients, as evident by the fact that over two thirds were classified ASA III or IV, generally resulting in increased overall mortality rates, even after the successful treatment of AAA, as published by Bastos Goncalves et al. [21].

Complications and their management

Complications post EVAR are common and range from 16% to over 40% [22]. By far the most frequently observed complication in the present cohort, were endoleaks type II, which occurred in 22% of patients. These findings mirror previous studies describing endoleak type II rates ranging from 8–44% after infrarenal EVAR [23, 24]. While the presence of endoleaks type II in the acute setting of a rupture often warrants immediate action, dealing with the same endoleaks in an elective setting continues to be a controversy [23, 24]. Most authors would agree that indication for treatment of these endoleaks is either an aneurysm growth over time, or the presence of multiple feeding arteries, resulting in a large type II endoleak, unlikely to resolve spontaneously [23]. In the present study, four patients were successfully treated endovascularly, with the indication for treatment being the large size of the endoleak type II in all four cases. In addition, as described in the results section, three patients (2%) received an open conversion due to endoleak type II: two patients had a complete explantation of the endografts, while the third patient was treated with an elective, semi-open conversion with aneurysm sac revision by means of ligature of four lumbar arteries, successfully excluding the endoleak type II. While complete explantation of the endograft due to endoleak type II can occur in the setting of acute rupture or after prolonged aneurysm growth, open ligation of the feeding arteries also represents a well described procedure [19, 25]. Regardless of the type of repair, these findings highlight the fact that endoleaks type II are still the most common endoleaks after EVAR and do remain an issue, which could potentially be addressed by some sort of active sac management, as attempted in the ongoing EVAR SE (sac embolization) study [26]. In the addition, the relevance and impact of endoleaks type II on the clinical outcome becomes very evident when taking a closer look at Figure IB and IC, displaying the Kaplan-Meier curves for cumulative endoleak-free survival and cumulative endoleak-free survival excluding endoleak type II: the two graphs change significantly for the better once endoleaks type II are taken out of the equation.

In total, 3% and 2% of patients were affected by an endoleak type Ia or Ib, a finding in line with previously published data [6, 10, 11, 17, 27]. Interestingly, there was no significant difference in endoleak occurrence according to whether the patients had been treated within or outside IFU. The absence of statistically significant findings is most likely due to the low rate of endoleaks type Ia and Ib and the resulting small sample size. Of note, all type Ia and Ib (except for one, in which the patient refused treatment) were managed successfully via an endovascular approach.

While most complications and reinterventions post TREO, both in the present cohort and after EVAR in general, were endoleak related, patients did also suffer from other adverse events and the associated secondary interventions [28]. In total, 13 patients were affected by other procedure-/aneurysm related complications, including two endograft limb thrombosis, one endograft limb stenosis due to kinking and two cases of bowl ischemia.

While these numbers all mirror the current literature, they once again highlight the fact that even standard EVAR is associated with significant complications [29]. Fortunately, none of the abovementioned (non-endoleak related) complications resulted in an increased mortality. This includes the two cases of bowl ischemia, which is

among the most dreaded EVAR complications and has been reported to occur in 1–3% patients [30]. Both had had a patent inferior mesenteric arteries before the TREO implantation, suggesting that the most probable cause of this complication was microembolization during the procedure; both patients were successfully treated with a hemicolectomy.

Limitations

While the 150 patients represent one of the largest multicenter series on the TREO device, only limited conclusions can be drawn from a cohort this size. One example is the fact that while patients treated within the IFU tended do to better than those treated outside (both regarding the occurrence of complications and the number of secondary interventions), none of the findings reached statistical significance. Also, since endoleaks type III occur very seldomly per se, the study was not able to prove or confound whether the "stent-lock technology" of the TREO stentgraft system truly represents an advantage over existing devices in the prevention of endoleaks type III [1, 2]. Consequently, further data and prospective collection on a much larger scale are needed to gain a better understanding of this relatively new device. Taken all the above into consideration and given the sparse number of publications regarding the TREO device, the present study ought to be seen as one puzzle piece adding to the greater picture.

Conclusions

This non industry-sponsored, multicenter trial with 150 patients, indicates that EVAR using the TREO device in a real-world setting (both within and outside IFU) seems to be safe and effective in the treatment of unselected patients suffering from intact, symptomatic or ruptured AAA. While the rate of mortality, complications and associated secondary interventions is in line with previously published data, the findings of the present study highlight the fact that even standard EVAR is associated with serious adverse events. In the present study, patients treated within the IFU tended do to better than those treated outside (both regarding the occurrence of complications and the number of secondary interventions), however, none of the findings reached statistical significance. Hence, further data and prospective collection on a much larger scale are needed to gain a better understanding of this relatively new device.

References

1. Powell JT, Sweeting MJ, Ulug P, Blankensteijn JD, Lederle FA, Becquemin JP, et al. Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years. Br J Surg. 2017;104(3):166–78.
2. Budtz-Lilly J, Venermo M, Debus S, Behrendt CA, Altreuther M, Beiles B, et al. Editor's Choice – Assessment of International Outcomes of Intact Abdominal Aortic Aneurysm Repair over 9 Years. Eur J Vasc Endovasc Surg. 2017;54(1):13–20.
3. Schanzer A, Oderich GS. Management of Abdominal Aortic Aneurysms. N Engl J Med. 2021;385(18):1690–8.
4. Antoniou GA, Antoniou SA, Torella F. Editor's Choice – Endovascular vs. Open Repair for Abdominal Aortic Aneurysm: Systematic Review and Meta-analysis of Updated Peri-operative and Long Term Data of Randomised Controlled Trials. Eur J Vasc Endovasc Surg. 2020;59(3):385–97.
5. Colvard B, Georg Y, Chakfe N, Swanstrom L. Current aortic endografts for the treatment of abdominal aortic aneurysms. Expert Rev Med Devices. 2016;13(5):475–86.
6. Georgakarakos E, Kratimenos T, Koutsoumpelis A, Georgiadis GS. The Bolton Treo endograft for treatment of abdominal aortic aneurysms: just another trimodular platform? Expert Rev Med Devices. 2018;15(1):5–14.
7. D'Oria M, Galeazzi E, Veraldi GF, Garriboli L, Saccà S, Farneti F, et al. Impact of Proximal Neck Anatomy on Short-Term and Mid-Term Outcomes After Treatment of Abdominal Aortic Aneurysms With New-Generation Low-Profile Endografts. Results From the Multicentric "ITAlian North-East Registry of ENDOvascular Aortic Repair With the BOltOn Treo Endograft (ITA-ENDOBOOT)". Ann Vasc Surg. 2022;80:37–49.
8. Marone EM, Marazzi G, Brioschi C, Rinaldi LF. Five-Year Outcomes of Endovascular Aortic Repair With the TREO Abdominal Endograft. J Endovasc Ther. 2023;15266028231170161.
9. Georgakarakos E, Karaolanis GI, Argyriou C, Papatheodorou N, Karangelis D, Georgiadis GS. Update on the TREO endograft device: overview of its safety and efficacy. Expert Rev Med Devices. 2022;19(1):31–5.
10. Eagleton MJ, Stoner M, Henretta J, Dryjski M, Panneton J, Tassiopoulos A, et al. Safety and effectiveness of the TREO stent graft for the endovascular treatment of abdominal aortic aneurysms. J Vasc Surg. 2021;74(1):114–23.e3.
11. Marone EM, Rinaldi LF, Lovotti M, Palmieri P, Argenteri A. The Bolton Treo Endograft: A Single-Center Preliminary Experience. Ann Vasc Surg. 2019;56:139–46.
12. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344–9.
13. Boitano L, Eagleton MJ. The TREO abdominal aortic stent-graft system. Future Cardiol. 2021;17(5):805–10.
14. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg. 2002;35(5):1048–60.
15. Greenberg RK, Turc A, Haulon S, Srivastava SD, Sarac TP, O'Hara PJ, et al. Stent-graft migration: a reappraisal of analysis methods and proposed revised definition. J Endovasc Ther. 2004;11(4):353–63.
16. Zerwes S, Kiessling J, Liebetrau D, Jakob R, Gosslau Y, Bruijnen HK, et al. Open Conversion After Endovascular Aneurysm Sealing: Technical Features and Clinical Outcomes in 44 Patients. J Endovasc Ther. 2021;28(2):332–41.
17. Uberoi R, Setacci C, Lescan M, Lorido A, Murray D, Szeberin Z, et al. Global Post-Market Clinical Follow-up of the Treovance Stent-Graft for Endovascular Aneurysm Repair: One-Year Results From the RATIONALE Registry. J Endovasc Ther. 2018;25(6):726–34.
18. Sirignano P, Ceruti S, Aloisi F, Sirignano A, Picozzi M, Taurino M. Is Evar Feasible in Challenging Aortic Neck Anatomies? A Technical Review and Ethical Discussion. J Clin Med. 2022;11(15):4460.
19. Ben Abdallah I, El Batti S, Abou-Rjeili M, Fabiani JN, Julia P, Alsac JM. Open Conversion After Endovascular Abdominal Aneurysm Repair: An 8 year Single Centre Experience. Eur J Vasc Endovasc Surg. 2017;53(6):831–6.
20. Tzani A, Doulamis IP, Katsaros I, Martinou E, Schizas D, Economopoulos KP. Mortality after endovascular treatment of

infrarenal abdominal aortic aneurysms – the newer the better? Vasa 2018;47(3):187–96.
21. Bastos Gonçalves F, Ultee KH, Hoeks SE, Stolker RJ, Verhagen HJ. Life expectancy and causes of death after repair of intact and ruptured abdominal aortic aneurysms. J Vasc Surg. 2016;63(3):610–6.
22. Daye D, Walker TG. Complications of endovascular aneurysm repair of the thoracic and abdominal aorta: evaluation and management. Cardiovasc Diagn Ther. 2018;8(Suppl 1):S138–S156.
23. Ultee KHJ, Büttner S, Huurman R, Bastos Gonçalves F, Hoeks SE, Bramer WM, et al. Editor's Choice – Systematic Review and Meta-Analysis of the Outcome of Treatment for Type II Endoleak Following Endovascular Aneurysm Repair. Eur J Vasc Endovasc Surg. 2018 Dec;56(6):794–807.
24. Gelfand DV, White GH, Wilson SE. Clinical significance of type II endoleak after endovascular repair of abdominal aortic aneurysm. Ann Vasc Surg. 2006;20(1):69–74.
25. Onitsuka S, Ito H. Surgical Treatment of Sac Enlargement Due to Type II Endoleaks Following Endovascular Aneurysm Repair. Ann Vasc Dis. 2023;16(1):1–7.
26. Knappich C, Kirchhoff F, Fritsche MK, Egert-Schwender S, Wendorff H, Kallmayer M, et al. Endovascular aortic repair with sac embolization for the prevention of type II endoleaks (the EVAR-SE study): study protocol for a randomized controlled multicentre study in Germany. Trials. 2024;25(1):17.
27. Perini P, Bianchini Massoni C, Mariani E, Ucci A, Fanelli M, Azzarone M, et al. Systematic Review and Meta-Analysis of the Outcome of Different Treatments for Type 1a Endoleak After EVAR. Ann Vasc Surg. 2019;60:435–446.e1.
28. Sharma A, Sethi P, Gupta K. Endovascular Abdominal Aortic Aneurysm Repair. Interv Cardiol Clin. 2020;9(2):153–68.
29. Qrareya M, Zuhaili B. Management of Postoperative Complications Following Endovascular Aortic Aneurysm Repair. Surg Clin North Am. 2021;101(5):785–98.
30. Becquemin JP, Majewski M, Fermani N, Marzelle J, Desgrandes P, Allaire E, et al. Colon ischemia following abdominal aortic aneurysm repair in the era of endovascular abdominal aortic repair. J Vasc Surg. 2008;47(2):258–63; discussion. 263.

Conflict of interest
The following authors declare a potential conflict of interest: Speaker/Proctor for Terumo Aortic: Zerwes S, Kalder J, Keschenau P, Lescan M, Rylski B, Teßarek J and Hyhlik-Dürr A.

ORCID
Sebastian Zerwes
https://orcid.org/0000-0001-5475-6696
Ana-Maria Ciura
https://orcid.org/0009-0001-9909-5614
Oksana Heiser
https://orcid.org/0009-0006-2904-8229
Johannes Kalder
https://orcid.org/0000-0002-0606-2814
Paula Keschenau
https://orcid.org/0000-0002-2823-8091
Mario Lescan
https://orcid.org/0000-0002-3124-4994
Bartosz Rylski
https://orcid.org/0000-0001-6890-2172
Stoyan Kondov
https://orcid.org/0000-0002-1892-1487
Hans-Kees Bruijnen
https://orcid.org/0009-0001-1023-3516
Alexander Hyhlik-Dürr
https://orcid.org/0000-0002-4217-7758

Correspondence address
Dr. Sebastian Zerwes
Clinic for Vascular and Endovascular Surgery
Universitätsklinikum Augsburg
Stenglinstr. 2
86156 Augsburg
Germany

sebastian.zerwes@gmx.net