

Initial Experience With Abdominal Aneurysm Repair Using the E-vita Abdominal Stent- Graft: A Single-Center Study

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◆ CLINICAL INVESTIGATION ◆

Initial Experience With Abdominal Aneurysm Repair Using the E-vita Abdominal Stent-Graft: A Single-Center Study

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Purpose: To evaluate the feasibility and midterm results of a new stent-graft for infrarenal endovascular aneurysm repair (EVAR) in a non-selected population.

Methods: Nineteen consecutive patients (19 men; mean age 70 years, range 58–87) who presented within an 8-month period with abdominal aortic aneurysms (AAA) suitable for EVAR were treated with the new E-vita abdominal stent-graft. Most of the patients (13, 68%) were ASA grade 3 or higher; the maximum AAA diameter was 57 mm (40–75), and hostile necks were present in a third and tortuous iliac arteries in half. Most of the cases (18, 95%) were elective; 1 was performed for a contained rupture. Seventeen procedures were primary implantations and 2 were secondary repairs of failing endografts.

Results: All stent-grafts were implanted at the intended position; no conversions to open surgery were necessary and no type I endoleak was noted. Fifteen bifurcated and 4 straight stent-grafts were implanted; the majority of the vascular accesses (29/35, 83%) were percutaneous. There was no 30-day mortality. In the mean 10-month follow-up (range 4–17), no stent fractures, migrations, or secondary endoleaks were noted. Aneurysm diameter was reduced in 8 (42%) and remained unchanged in 11 (58%) patients. One patient required open surgery at 1 year for thrombotic occlusion of the stent-graft. Two octogenarian patients died during follow-up.

Conclusion: The E-vita abdominal stent-graft appears safe and effective in this initial midterm clinical experience. This device appears especially suitable to challenging aneurysm anatomy, such as severely angulated necks or tortuous and dilated iliac arteries.

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Key words: Abdominal aortic aneurysm, endovascular aneurysm repair, stent-graft, hostile neck, iliac arteries, outcome analysis, complications, endoleak

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Endovascular aneurysm repair (EVAR) has evolved into a routine procedure for treatment of abdominal aortic aneurysms (AAA).¹ Numerous devices are on the market, with some first- and second-generation stent-grafts having already disappeared due to improvements in the next generation.² We

started our endovascular program in 1994³ and have since implanted 261 AAA stent-grafts, including Zenith, Talent, Anaconda, AneuRx, Aorfix, and several models no longer on the market. All stent-graft systems have their special advantages and disadvantages in terms of fixation, flexibility, struts, graft

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fabric, and deployment precision. Therefore, it is valuable to test a newly designed stent-graft with special features of deployment in all variations of AAA anatomy. The E-vita abdominal stent-graft was developed by collaboration of industry and physicians drawing on daily clinical experience.

METHODS

Study Design

The first clinical implantations of the E-vita abdominal stent-graft (Jotec, Hechingen, Germany) began at our clinic in January 2008 under a protocol designed to include all patients with AAA anatomy suitable for standard EVAR (not requiring fenestrated or branched endografts). Suitability was based on an aneurysm diameter >5 cm; those with a diameter <5 cm were eligible if (1) the aneurysm had increased by >0.5 cm in the prior 6 months or (2) the configuration was saccular. The only exclusion criterion for standard EVAR was a proximal neck <15 mm long; angulation, calcification, or thrombus in the proximal neck were not contraindications to EVAR. Additional exclusion criteria for the E-vita abdominal device were proximal necks >30 mm wide and iliac arteries measuring >24 mm in diameter without a distal landing zone in front of the iliac bifurcation (EUROSTAR type E⁴). The study was approved by the institutional ethics committee; written informed consent was obtained from the participants. Data were collected prospectively in a database.

Preoperative aortic measurements were performed in all cases with contrast-enhanced helical computed tomography (CT) with 1.5- to 3-mm slices. All patients underwent coronary artery angiography before the procedure with subsequent percutaneous coronary intervention (PCI) or coronary bypass surgery (CABG) prior to the AAA procedure in the case of significant coronary artery disease. In 17 (89%) cases, aortography combined with coronary arteriography yielded additional information on aortic morphology. Hostile neck anatomy was defined as (1) short neck: ≤ 10 mm between the most caudal renal

artery and the beginning of an aneurysm >26 mm in diameter, (2) neck bulge: a focal enlargement of the aneurysm neck of at least 3 mm within the first 15 mm after the most caudal renal artery, (3) reverse taper: gradual neck dilation ≥ 2 mm within the first 10 mm after the most caudal renal artery, (4) angulated neck: aortic angle $\geq 60^\circ$ within the first 30 mm after the most caudal renal artery, and (5) significant neck thrombus: $>50\%$ coverage of the circumference of the proximal neck.^{5,6}

Stent-Graft and Delivery System

The self-expanding E-vita abdominal stent-graft, which was approved for the European market in January 2008, was derived from the E-vita thoracic device, which has been in clinical use since 2004.⁷ The abdominal model consists of a special low porosity woven polyester graft with nitinol springs sutured in the inner side of the stent-graft in a tip-to-valley fashion in the trunk and in a tip-to-tip configuration in the limb. The lack of a connecting bar makes the graft flexible. Four components can be combined: a bifurcated main body, a contralateral limb, an iliac extension, and an aortic extension cuff (Fig. 1A). The bifurcated main body and the aortic extension cuff have bare springs at the proximal end for suprarenal fixation. The number of spring tips in the trunk has been adapted to the stent-graft diameter (1) to maintain constant radial force independent of stent-graft diameter and (2) to optimize contact between the polyester fabric and vessel wall, thus optimizing sealing and anchoring to reduce the risk of type I endoleak (Fig. 1B).

The bifurcated main body is available in 150 and 170 mm ipsilateral lengths and in body lengths of 80 and 100 mm to the end of the 14-mm-diameter contralateral connection socket. Proximal diameters range from 24 to 34 mm and iliac diameters from 12 to 24 mm. The 16-mm proximal diameter contralateral limbs have corresponding distal diameters and lengths of 50, 70, 90, and 105 mm. Iliac extensions are 50 mm long and 14 to 26 mm in diameter. Three radiopaque marker rings are attached to the stent-graft: one at the proximal end of the fabric in the main body and the others at the distal end of the socket

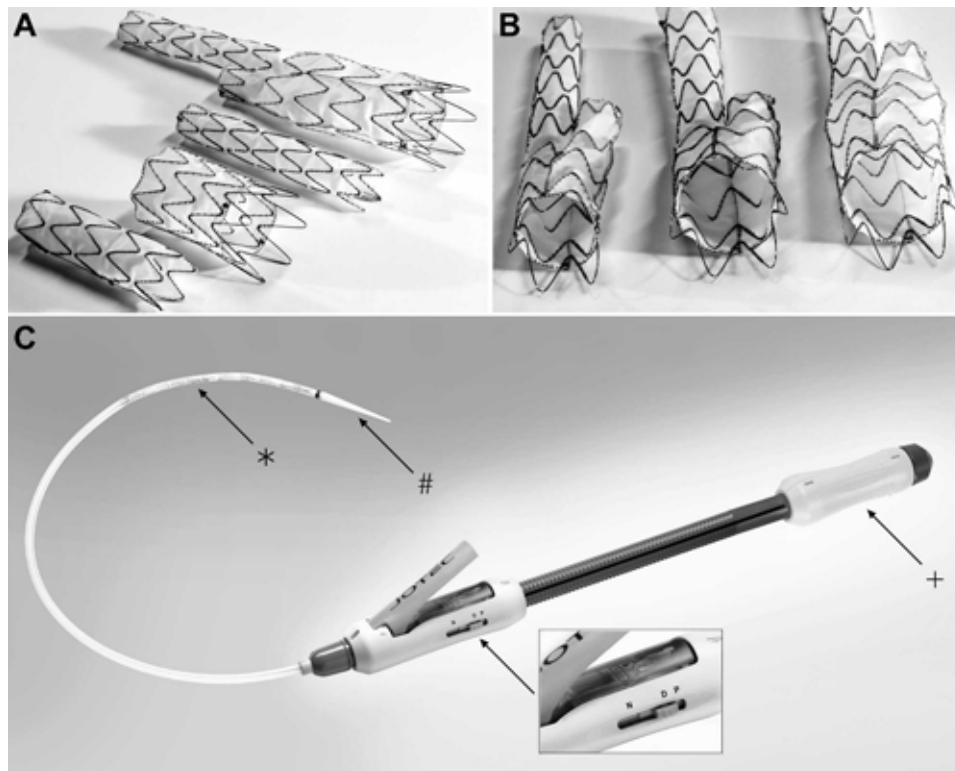


Figure 1 ♦ (A) E-vita abdominal stent-graft components. From top to bottom: bifurcated main body, contralateral limb, aortic extension cuff, and iliac extension. (B) Three E-vita abdominal main bodies of 24-, 28-, and 34-mm diameter from left to right: the number of a spring tips increases from 5 to 7 with diameter, resulting in identical angles of the springs. Thus, radial force of the sealing zone is constant and independent of diameter. (C) E-vita abdominal delivery catheter: pusher and pullback sheath mechanism consisting of a transparent PTFE sheath containing the loaded stent-graft (*arrow), silicone tip (#arrow), position control grip (+arrow), and the release grip (arrow, insert), which works in 3 modes to be shifted with the gear at the side of the grip.

and of the iliac leg. The proximal markers in the contralateral limbs and iliac extensions indicate the minimal recommended overlap when matched to the distal marker of the proximal component.

The delivery catheter (Fig. 1C) consists of a pusher and pullback sheath mechanism. The outer sheath is made of transparent polytetrafluoroethylene (PTFE), allowing rotational orientation of the main body by direct vision before entering the vessel. The soft silicone tip is designed to smoothly follow the curves of tortuous iliac arteries. A mechanical aid in the release grip helps to deploy the graft without applying direct force, so the level of the stent-graft can be held and precisely adjusted during deployment with the position control grip. If deemed necessary, the graft can be released in

the conventional pullback manner at any stage of delivery. The outer diameter is 20 F to 22 F for the main body and 16 F to 18 F for the contralateral limbs and iliac extensions, depending on the size of the loaded stent-graft. The delivery catheter is designed for direct implantation into the vessel. In case of access problems in tortuous or calcified access vessels, a 20-F or 22-F sheath (E-asy; Jotec) is provided,⁷ as is a crossover supporting catheter (E-asyCross; Jotec) in the case of difficult retrograde cannulation.

Sizing

The diameter of the stent-graft is oversized in relation to the outer diameter by ~20% at the proximal fixation zone and by ~10% in the

common iliac arteries (CIA). The length of the main body should be the longest possible main body so that the flow divider can be placed more distally in the aneurysm to lower the displacement forces acting on the stent-graft^{8,9} and facilitate cannulation of the contralateral socket when it is closer to the natural bifurcation.

Most AAAs can be treated with a 2-piece bifurcated E-vita abdominal stent-graft if the iliac arteries are non-aneurysmal. When the stent-graft must be placed directly in front of the ostium of the hypogastric artery in EUROSTAR C and D anatomy,⁴ the appropriate stent-graft length can be achieved only by using the trombone technique with intraoperative length measurement made using a calibrated catheter after the main body has been placed. If the CIA is elongated, a 14-mm ipsilateral limb is chosen and extended by a prefabricated contralateral limb of the appropriate size.

Implantation Technique

The first 3 procedures were performed in a standard operating room with a surgical C-arm and angiography equipment (BV 300; Philips, Eindhoven, The Netherlands) for intraoperative imaging. The next 16 procedures were performed in a new hybrid operating room equipped with a fixed angiography unit and integrated angiography table (Artis; Siemens, Erlangen, Germany). General anesthesia was used in all cases.

For access, the side with less tortuosity and calcification of the iliac arteries was chosen for delivery of the main body. Access was achieved with bilateral surgical exposure of the common femoral arteries using a small oblique incision, or for non-calcified femoral arteries, a percutaneous technique with a 10-F vascular suture device (Prostar XL; Abbott Vascular Devices, Redwood City, CA, USA). Details have been presented previously.^{7,10}

The target angiogram for correct location of the renal arteries was performed through a contralateral 5-F or 8-F pigtail catheter, which remained in place until the main body was finally deployed. On the ipsilateral side, a 0.035-inch smooth Radiofocus hydrophilic

guidewire (Terumo) and a 5-F headhunter catheter (William Cook Europe) were positioned in the ascending aorta. The smooth wire was exchanged inside the catheter for an ultra-stiff guidewire (E-wire; Jotec). The delivery system was advanced in the retrograde direction over this wire. Before entering the artery, the contralateral socket, which was visible directly through the transparent sheath, was placed 45° anterior to the contralateral side. This position was adjusted under fluoroscopy when the delivery catheter was advanced to the level of the renal arteries.

The C-arm was positioned with the renal arteries in the center and angled in the cranial position according to the course of the infrarenal neck determined on the sagittal CT reconstruction. Target angiography was performed through the pigtail catheter from the contralateral side. The contours of the aorta and the renal arteries were drawn on the screen with a surgical marker pen. The gear of the release grip was shifted into position D, which moved the handle into the working position, and the stent-graft was deployed according to the landmarks on the screen by gently squeezing the handle of the grip; the speed of deployment was varied by changing the squeezing frequency. The position of the stent-graft was controlled during deployment by the other hand on the position control grip (Fig. 1C). The stent-graft was opened in this way until the contralateral socket was released; angiography was performed to check the position and patency of the renal arteries. Leaving the ipsilateral leg sheathed allowed further manipulation of the stent-graft if necessary.

The pigtail catheter from the contralateral side was stretched and pulled back into the aneurysm. The contralateral socket was entered with the wire guided by the pigtail catheter in combination with the long 12-F sheath (in a percutaneous approach) or a headhunter, Cobra, or Van Schie 5 catheter (William Cook Europe). The correct position inside the stent-graft was ensured by proper configuration of the guiding catheter in the aneurysm neck when the wire was retracted and by free movement and rotation of the catheter in the neck. The Terumo wire was then replaced inside the catheter by another

super-stiff E-wire. The origin of the hypogastric artery was identified by retrograde contrast injection from the sheath in 30°–45° oblique projection. If critical, the distance from the socket to the hypogastric artery was measured with a calibrated catheter. A contralateral limb of appropriate length was advanced over the wire and deployed in the same technique as the main body. The correct overlap between socket and limb was achieved by keeping the corresponding markers at the same level. The delivery system was closed after shifting the gear to N by retracting the position grip while the release grip is held. If the nose cone became stuck during retraction through the limb, this was solved by gentle back and forth maneuvers. If there was a suspicion that the position of the main body had changed during these manipulations, angiography was again performed to check the renal arteries; then the ipsilateral leg was deployed, and the nose cone was retracted in the same manner. Distal extensions, if necessary, were implanted. Balloon molding of the stent-graft was performed in all cases with a large compliant balloon (Reliant; Medtronic Vascular, Santa Rosa, CA, USA) in the proximal neck, at all connection sites of the modular graft, and along the entire length of the CIAs. The result was checked with a final angiogram. Catheters and sheaths were removed, and the access site arteries were closed with 5-0 Prolene sutures or the vascular closure device.

Postoperative Care and Follow-up

Patients were extubated at the end of the procedure or artificially ventilated for a few hours. They were transferred either directly to the normal ward or to the intensive care unit (ICU) for <24 hours and were mobilized on the first postoperative day; longer ventilation and ICU times were seen in patients with severe comorbidity or sequelae of aortic rupture. Imaging was performed before discharge in all patients to assess the postoperative result. Complications, endoleaks, and technical success were assessed according to the SVS/AAVS (Society for Vascular Surgery/American Association for Vascular Surgery) reporting standards for endovascular aortic aneurysm repair.¹¹

Follow-up data were collected from office visits with CT or magnetic resonance imaging (MRI) scans scheduled at 3 and 12 months and yearly thereafter. For patients who did not come to the office visits on time, letters from other hospitals or inquiries of the local citizen registration authorities were made to assure continued survival; their primary care physicians were contacted for information to verify all events.

Patient Sample

From January to August 2008, 38 patients presented with AAA; 6 were treated with Zenith iliac side branch devices, 7 with open repair, and 6 with other endovascular devices owing to logistical problems at the start of the study. The remaining 19 consecutive EVAR-eligible patients (all men; mean age 70 years, range 58–87) were included in the study. Risk factors and comorbidities are presented in Table 1; of note, coronary artery disease was present in 89%, previous cardiac surgery in 26%, and previous PCI in 37%. Thirteen (68%) patients were ASA class 3 or higher.¹² The mean maximum AAA diameter (Table 2) was 57 mm (range 40–75). Six (32%) patients had hostile neck anatomy (Fig. 2). Eighteen (95%) procedures were elective; 1 patient presented in shock with contained rupture due to a type III endoleak 2 years after previous repair with a Zenith fenestrated stent-graft. Another repeat intervention was for sac enlargement owing to proximal migration of a Lifepath stent-graft implanted 55 months before.

RESULTS

Operative details are given in Table 3 and information on endograft configuration and vascular access in Table 4. The percutaneous vascular approach was used in 29 (83%) of the 35 access sites, but surgical exposure of the common femoral artery was ultimately required in 6 (21%). Fifteen (79%) bifurcated and 4 (21%) tube grafts were implanted (technical success rate 100%); no conversion to open surgery was necessary. Two of the tube grafts were implanted in the repeat procedures described above. The type III endoleak was repaired successfully with a 26-mm E-vita

TABLE 1
Patient Demographics, Risk Factors,
and Comorbidities

Median age, y	70 (58-87)
Men	19 (100%)
ASA class \geq III ¹²	13 (68%)
Coronary artery disease†	17 (89%)
Previous cardiac surgery	5 (26%)
Previous PCI	7 (37%)
Pacemaker/ICD	2 (11%)
SVS/AAVS risk score ¹¹	7.9 (1-13)
Diabetes	4 (21%)
Smoking	15 (79%)
Hypertension	19 (100%)
Hyperlipidemia	15 (79%)
Carotid disease	2 (11%)
Cardiac disease	16 (84%)
Cardiac grade 3*	2 (11%)
Renal disease	5 (26%)
Pulmonary disease	2 (11%)
BMI, kg/m ²	28 (21-41)
Obesity (BMI >30 kg/m ²)	6 (32%)

Continuous data are presented as the mean (range) unless stated otherwise; categorical data are given as counts (percentages).

ASA: American Society of Anesthesiologists, PCI: percutaneous coronary intervention, ICD: implantable cardioverter defibrillator, SVS/AAVS: Society for Vascular Surgery/American Association for Vascular Surgery, BMI: body mass index.

* Defined as unstable angina, symptomatic or poorly controlled arrhythmia, poorly compensated congestive heart failure, myocardial infarction within 6 months, and/or left ventricular ejection fraction <25%.¹¹

† All patients had preoperative coronary angiography.

abdominal iliac extension (Fig. 3). The migrated Lifepath stent-graft was relined with a 30-mm-diameter E-vita abdominal proximal aortic extension cuff and a 50-mm iliac limb after the limb of the Lifepath had separated from the main body due to the manipulations. Two other custom-made tube grafts were implanted for false aneurysms (Fig. 4) due to penetrating ulcers in severely atherosclerotic infrarenal aortas.

Details of the in-hospital course are given in Table 5. Only the ruptured AAA patient required ventilation for >6 hours (22 hours). Ten (53%) patients were transferred to the ward directly; 3 (16%) stayed in the ICU for <12 hours, 4 (21%) for up to 24 hours, and 2 (10%) for up to 48 hours. The median length of hospital stay

TABLE 2
AAA Morphology

AAA maximum diameter, mm	57 (40-75)
Proximal neck	
Diameter, mm	26 (18-30)
Length, mm	35 (19-60)
Angulation, °	39 (0-110)
Moderate (30°-60°)	11 (58%)
Severe (>60°)	5 (26%)
Thrombosis	3 (16%)
Calcification	2 (11%)
Hostile neck ⁵	6 (32%)
Iliac arteries (n=38)	
CIA landing zone diameter, mm	16 (10-26)
Angulation, °	58 (10-120)
Moderate (30°-60°)	6 (17%)
Severe (>60°)	18 (50%)
Thrombosis	4 (11%)
Calcification	22 (58%)

Continuous data are presented as the mean (range) unless stated otherwise; categorical data are given as counts (percentages).

CIA: common iliac artery.

All measurements except maximal diameter and iliac angulation given only for primary implantations; in redo operations, the actual diameter before redo surgery was used.

was 9 days (mean 17.7±26.7, range 3-120). Length of hospital stay was \leq 7 days in 7 (37%), 7 to 14 days in 7 (37%), 14 to 30 days in 1 (5%), and >30 days in 4 (21%) patients.

Endoleaks and Complications

No type I endoleak was noted at the end of the procedures, but a type Ib endoleak arose after a failed attempt to provide additional seal of the distal leg in an aneurysmal CIA. In this case, deployment of a Palmaz stent resulted in a perforation, which was sealed by a distal extension into the external iliac artery. This was the only case in which a patent hypogastric artery was occluded.

All patients had CT or MRI examinations before discharge. In these scans, 6 of the 12 type II leaks seen on the completion angiogram had occluded, leaving 6 (32%) type II endoleaks at discharge.

Secondary occlusion of a renal artery was noted in 2 cases. In the first, a 61-year-old obese patient, dissection of the ostium of

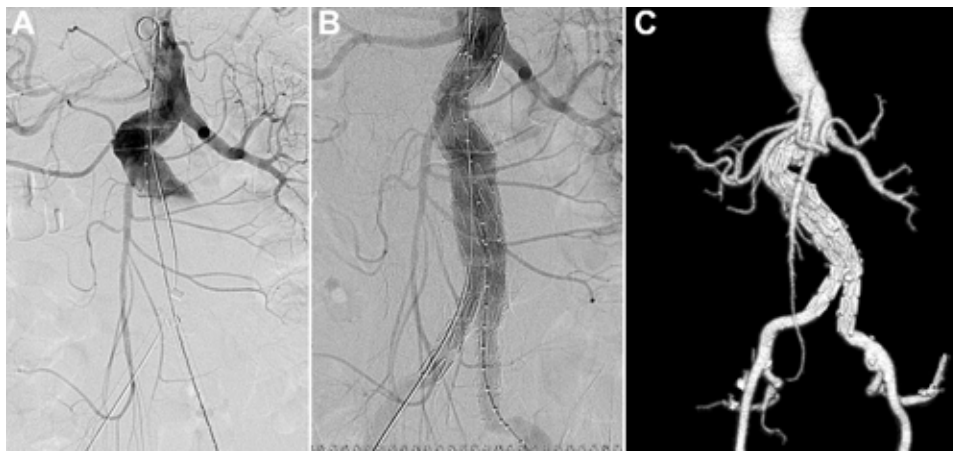


Figure 2 ♦ Example of hostile neck anatomy in a 65-year-old patient with a 68-mm AAA. (A) Intraoperative angiography shows a double kinked aneurysm neck with a 60° angle at the left renal artery and a 90° bend in the middle of the neck. (B) The completion angiogram demonstrates exclusion of the aneurysm and a moderate straightening of the 2 kinks by the flexible stent-graft. (C) CT reconstruction at 3 months shows the unchanged position of the stent-graft and sustained exclusion of the AAA.

the left renal artery had been seen in the intraoperative angiogram before and after implantation of the stent-graft, which was positioned close beneath the renal arteries.

This dissection probably induced the secondary occlusion. An attempt was made to reopen this artery with angioplasty, but it was impossible to cannulate the ostium. An attempt was also made to pull down the graft with a wire across the flow divider, but the fixation of the stent-graft in the neck was too

TABLE 3
Operative Details

Indication	
Elective	18 (95%)
Contained rupture	1 (5%)
Redo intervention	2 (11%)
Implantation success	19 (100%)
Conversion to open procedure	0 (0%)
Endoleak at end of the procedure	
Type I	0 (0%)
Type II	12 (63%)
Type IV	1 (5%)
Device-related complications	
Occluded iliac artery	1 (5%)
Perforated iliac artery	1 (5%)
Occluded accessory renal artery	1 (5%)
Additional procedures	
Crossover bypass	1 (5%)
Stent	1 (5%)
Duration of procedure, min	132 (50–375)
Fluoroscopy time, min	20 (5–50)
Volume of contrast agent, mL	120 (29–320)

Continuous data are presented as the median (range) unless stated otherwise; categorical data are given as counts (percentages).

TABLE 4
Endograft Configuration and Vascular Access

Endograft configuration	
Bifurcated	15 (79%)
Tube	4 (21%)
Aortomonoiliac	0 (0%)
Segments implanted	2.4 (1–5)
Endograft fixation proximal neck	
Suprarenal	18 (95%)
Infrarenal	2 (11%)
Stent-graft diameter (median)	30 (22–34)
Endograft fixation distal sites	
Abdominal aorta	4 (12%)
Common iliac artery	29 (85%)
External iliac artery	1 (3%)
Stent-graft diameter (median)	18 (12–26)
Vascular access mode	
Cutdown	6 (17%)
Percutaneous	29 (83%)
Percutaneous converted	6 (21%)

Continuous data are presented as the mean (range) unless stated otherwise; categorical data are given as counts (percentages).

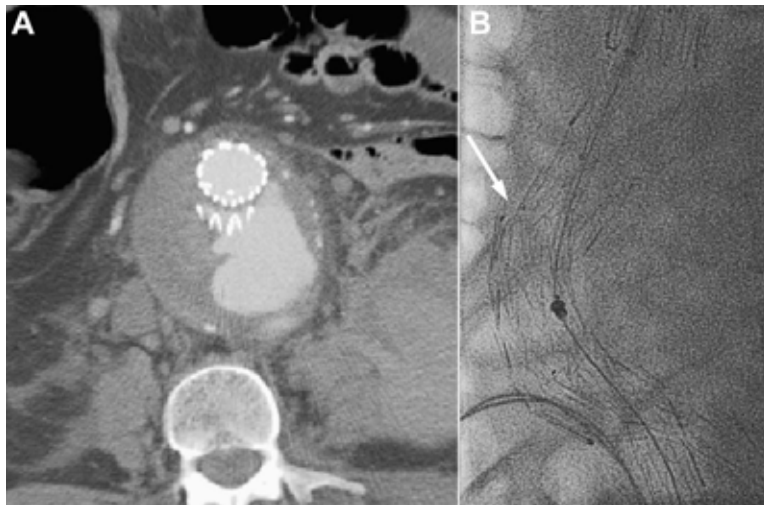


Figure 3 ♦ AAA rupture after type III endoleak of a fenestrated Zenith stent-graft in an 81-year-old patient. (A) CT scan on admission shows the endoleak at the spot of the separated proximal and distal segments and an extensive retroperitoneal hematoma. (B) Intraoperative fluoroscopy in lateral projection shows the 50-mm-long iliac extension before deployment to bridge the 2 separated components (arrow).

tight. The patient refused conversion to open surgery and bypass to the renal artery.

In the second case, the stent-graft was placed into a 65° angled neck very close to the right renal artery; the completion angiogram showed the artery to be open, but in the postprocedural MRI, it was occluded. Retrospective viewing of the intraoperative images showed that the fabric was already positioned

above this renal artery. No further treatment was undertaken because it was deemed impossible to solve the problem endovascularly, and the patient was deemed unfit for open surgery (bleeding from a bladder tumor).

Free intra-abdominal air indicative of a late colon perforation was found incidentally on the routine CT scan 13 days after the

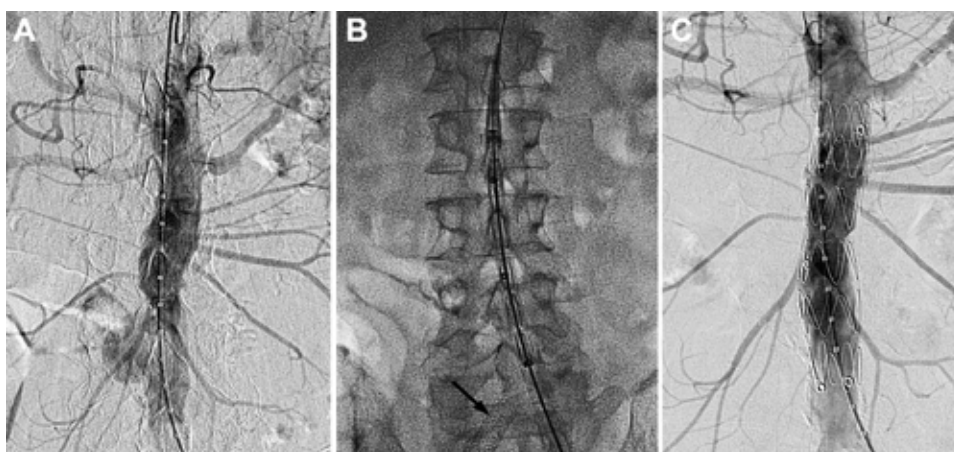


Figure 4 ♦ Example of an infrarenal tube stent-graft in a 68-year-old patient. (A) Intraoperative angiography shows a penetrating ulcer in a severely atherosclerotic aorta. (B) An E-vita thoracic delivery catheter was used to deploy a custom-made stent-graft; note a previously implanted bare metal stent (arrow) in the calcified right CIA. (C) Completion angiography shows exclusion of the false aneurysm.

TABLE 5
In-Hospital Results

30-day mortality	0 (0%)
Hospital stay, d	9 (3–112)
Technical success	100%
ICU stay, h	0 (0–48)
Ventilation, h	0 (0–22)
Endoleak at discharge*	6 (32%)
Procedure-related complications†	2 (11%)
Systemic complications	
Late colon perforation	1 (5%)
Bleeding from a bladder tumor	1 (5%)
Renal‡	3 (16%)
Cardiac‡	1 (5%)
Cerebral§	1 (5%)
Re-interventions	4 (21%)
Conversion	0 (0%)
Renal artery angioplasty	1 (5%)
Access site	1 (5%)
Bowel resection	1 (5%)
TUR for bladder tumor	1 (5%)

Continuous data are presented as the median (range) unless stated otherwise; categorical data are given as counts (percentages).

TUR: transurethral resection.

* All type II based on CT or MRI available in all patients.

† Renal artery occlusion.

‡ Grade 1.

§ Grade 2.

procedure in an 87-year-old patient. Sigmoidectomy was performed, and the specimen revealed chronic inflammation of the sigmoid colon and rectum with a small wall defect, so it was considered unlikely that the stent-graft implantation had caused an ischemic colon perforation.¹³ The patient suffered several late complications from the laparotomy, was unable to be mobilized, and died 4 months after the procedure in another hospital. Because the precipitating event occurred in hospital after the stent-graft implantation, this death was considered procedure-related.

Follow-up

There was no 30-day mortality, and no patient was lost to follow-up (mean 10 months, range 4–17). Sixteen patients had a 3- or 6-month CT or MRI and 2 patients completed 12-month follow-up (Table 6).

TABLE 6
Follow-up Results

Follow-up time, mo	10 (4–17)
Lost to follow-up	0 (0%)
Mortality	3 (16%)
Procedure-related	1 (5%)
Non-related	2 (10%)
AAA diameter, mm*	55 (35–80)
Reduction	8 (42%)
Unchanged	11 (58%)
Expansion	0 (0%)
Endoleak* (all type II)	4 (21%)
Procedure-related complications†	1 (5%)
Systemic complications	
Cardiac‡	1 (5%)
Cerebral§	1 (5%)
Re-interventions¶	1 (5%)

Continuous data are presented as the mean (range) unless stated otherwise; categorical data are given as counts (percentages).

* Aneurysm size and endoleak recorded from last available CT/MRI.

† Stent-graft occlusion

‡ Grade 2.

§ Grade 3.

¶ Conversion.

Eighteen stent-grafts were patent with no stent fractures or migrations. Maximum aneurysm diameter was reduced in 8 (42%) and remained unchanged in 11 (58%) patients. No secondary enlargement of the aneurysm sac was noted. Two type II endoleaks had occluded, leaving 4 (32%) open; no new secondary endoleak was noted.

One patient presented complete thrombotic occlusion of the stent-graft and the iliac arteries at the routine visit at 5 months. He had suffered sudden onset of bilateral claudication a few days after discharge, but did not relate this symptom to the procedure. Retrospective review of intraoperative imaging identified kinking of both limbs in the tortuous iliac arteries, which had been patent in the completion angiogram. Explantation of the stent-graft and open repair with a bifurcated graft was performed 12 months after the procedure. No other secondary endovascular or open procedures were required.

Three patients died during follow-up, including the colon ischemia case described

above. A 68-year-old patient died 11 months after the procedure from metastasizing bronchial carcinoma, which had been detected at the first postoperative CT scan. An 84-year-old patient committed suicide 6 months after the procedure.

DISCUSSION

This prospective study of the E-vita abdominal stent-graft system was conducted to gain experience with the new device and to challenge it with all anatomical variations in EVAR-eligible patients. Selection bias between different devices was overcome by using the new device consecutively in a defined period of time. Thus, this study was not a prospective trial of selected patients; rather, it represented daily clinical practice.

The new stent-graft met our expectations. Due to its unique delivery mechanism, it was easy to deploy in all cases. The deployment handle is operated with 2 fingers, even in highly curved anatomy, and the speed of the delivery can be continually adjusted. Therefore, no longitudinal force has to be applied to the catheter as with conventional push/pullback delivery catheters and no rotational momentum is necessary as would be needed to unscrew mechanical aids. These advantages reduce the risk of intraoperative migration caused by the operator.

Cannulation of the contralateral socket was performed without difficulties using simple retrograde guiding catheter/wire combinations; no crossover maneuver was necessary. The practice of choosing the longest possible main body for the individual case and thus bringing the socket as close as possible to the natural bifurcation seemed to make cannulation easier. Moreover, having shorter stiff limbs inside the aneurysm owing to a longer main body transmits the dynamic forces acting on the bifurcation more into the iliac arteries, which lowers the displacement forces acting on the stent-graft.^{8,9}

Our 100% rates of immediate procedural success without conversion and technical success without type I endoleak attested to the safety and efficacy of the new stent-graft system. Primary seal at the proximal aneurysm neck was achieved in all cases without

additional stents¹⁴ or cuffs despite adverse neck anatomy in many cases. The unique configuration of the proximal end of the stent-graft seems to provide excellent sealing. The case in which we unsuccessfully tried to pull down the stent-graft with a crossover wire with reasonable force demonstrated how tight these grafts are anchored into the aneurysm neck. Our 0% 30-day mortality rate and minimal secondary procedures (only 1 for an access site hematoma) compare favorably with studies of other stent-grafts that are now well established.¹⁵⁻¹⁸

Challenging anatomy of the infrarenal aneurysm neck and the iliac arteries beyond the typical inclusion criteria of multicenter clinical trials is a clinical reality in EVAR. Adverse neck anatomy implies a risk of early and secondary proximal type I endoleak and migration. In a EUROSTAR analysis, neck angulation $>60^\circ$ was clearly associated with proximal type I endoleak, but the relationship to stent-graft migration was not definite.¹⁹ Dillavou et al.⁵ and Chaikof et al.⁶ defined the term "hostile neck anatomy," which was present in a third of our patients. Regardless, implantation was performed with excellent results in all these cases due to the flexibility of the E-vita device and the precision of the delivery system, which allows the operator to stop, check, and make adjustments at any stage.

Choosing the longer main body was helpful in achieving complete wall opposition throughout the angulated necks. In tapered necks, the grafts were sized according to the largest diameter, which did not impair sealing at the narrower part of the neck. Due to its flexibility, the stent-graft adapts well to the curved anatomy without violating it (Fig. 2). It avoids implanting additional Palmaz stents, which is recommended to achieve sealing of other stent-grafts,²⁰ and significant straightening of the neck, as we have observed with the Talent device. In our experience, these bent aneurysm necks can regain their kinked shape in follow-up, with subsequent downward migration of the implanted stent-graft.

Another challenge is iliac tortuosity. Angulation of $>60^\circ$ was present in 50% of the iliac arteries. The E-vita abdominal stent-graft met these challenges as well except in the patient who developed bilateral stent-graft

thrombosis. The event was probably due to kinking of both limbs in the kinked iliac arteries, although the completion angiogram had shown good flow. Limb thrombosis is an identified problem in all types of bifurcated AAA stent-grafts with interrupted Z stents in the limbs^{2,15,18,21} or unsupported limbs.^{2,22} Even the Anaconda, which has nitinol rings instead of Z stents to provide greater limb flexibility, is not immune.^{23,24} Only the Aorfix (nitinol spirals in the limbs²⁵) and the Lifepath (balloon-expandable stents)²⁶ have had no limb occlusions reported to date in the limited literature available. In our case, the kink of the stent-graft limbs was probably induced by sharp 90° and 100° angles, respectively, of the iliac arteries from the bifurcation. A more critical view of the final angiogram and visualization of the metal structures would probably have identified the problem early enough for it to have been fixed by flexible self-expanding bare metal stents.

At least one of the two renal artery occlusions was a consequence of our practice of placing the stent-graft as close as possible to the renal arteries to achieve optimal sealing and fixation. In the completion angiogram, apparently good flow in the renal arteries may mask partial obstruction, which can cause subsequent thrombotic occlusion of the vessel.

The 21% rate of tube graft use in the infrarenal position in this small series is unusual. In 2 cases, the prefabricated tubes from the E-vita system were implanted as sealing cuffs for failing stent-grafts. The E-vita abdominal stent-graft was chosen in one case because the original stent-graft was no longer available; in the second case, one involving acute rupture, the appropriate component from the previously implanted fenestrated Zenith stent-graft was not available in the short time. The other 2 cases were obviously penetrating ulcers with long distal necks and, in one case, an unsuitable right iliac artery. The aortic tube configuration is very rare, as all manufacturers have stopped producing tube grafts for infrarenal purposes after the adverse results of the first-generation devices. Implanting a bifurcated or an aortomonoiliac stent-graft in these 2 cases would have imposed unnecessary additional

difficulties, however. Custom-made short tube grafts loaded in an E-vita thoracic delivery catheter were implanted quickly with good success.

In a relatively short follow-up period, a third of the aneurysms had already started to reduce in size and the others remained unchanged (3 patients with only the pre-discharge CT scan in the latter group). No secondary endoleaks were noted, which underlines the good sealing capacity of the stent-graft and represents excellent early results.

Approximately 20% of the patients had persisting endoleaks at the follow-up evaluation, all type II; no secondary endoleaks were observed. Twelve type II endoleaks had been recognized in the completion angiograms; half of them had occluded in the pre-discharge CT scans and 2 more occluded during follow-up. It remains unclear whether the incidence of type II endoleaks is device-specific.²² However, there have been differing endoleak rates for other stent-grafts, at least in the first year of implantation. For example, Talent had a lower rate of type II endoleak compared to the average within the first 6 months, while Excluder had significantly higher rates. These differences disappeared with longer observation.²⁷ The rapid closure of the leaks in our study suggests that the E-vita abdominal stent-graft may have a positive impact on the early incidence of type II endoleaks.

Ongoing Technical Improvements

This study represents the very first clinical practice with this new stent-graft. Some of our experiences and observations gave rise to technical improvements and modifications in the next version of the stent-graft, which will be issued in September 2009, or to changes in the implantation guidelines of the manufacturer.

The iliac limbs of the modified version will have shorter stents and wider gaps to improve flexibility and avoid kinking in narrow and angulated iliac arteries. The radiopaque markers at the proximal end will be improved for better 3-dimensional visualization.

The nose cone of the current delivery catheter is made of soft silicone to better follow every curve of the arteries, but the soft tip is sometimes difficult to handle when pushed directly into the artery, especially in the percutaneous technique. The soft silicone is sticky and adds friction to the surface, which makes retraction through the graft into the sheath after deployment sometimes difficult. The tip has been slightly modified and is now stiffened gradually from the inside. In the next version, the nose cone will be made of polyurethane, which glides better and will further improve pushability.

Intraoperative fluoroscopy and angiography depicted a phenomenon that is not common in other second-generation stent-grafts. In order to achieve a small profile for the delivery catheter without losing strength and durability of the material, the engineers utilized nitinol with a transition temperature set at 25°C,²⁸ which means that the nitinol springs are compressed at room temperature and will then expand to their preset shape and diameter at body temperature after deployment. Hence, it is not necessary to rinse the delivery catheter with ice water before introduction as was recommended for the Stentor and Vanguard first-generation devices. However, the expansion is slow, and immediate complete wall apposition is not obtained after deployment. Therefore, the graft has to be expanded with a compliant balloon to achieve final fixation and sealing and to secure the connections of the modular graft. This has been added to the manufacturer's recommendations after our initial experience. Aorfix, another newer generation device, also uses the nitinol thermal shape-memory effect; the manufacturer recommends balloon dilation of the stent-graft over its entire length.²⁵

Limitations

All conclusions have to be considered preemptive because of the small number of patients and the heterogeneous anatomy in this initial clinical experience. Further evaluation of a larger number of patients and for longer times is required.

Conclusion

The E-vita stent-graft has proven in our hands to be a safe and reliable device for EVAR. With a unique delivery catheter, it is easy to deploy with precision. It offers the possibility of treating more complex and anatomically challenging cases with adverse neck anatomy and tortuous iliac arteries. The device can be used in all cases suitable for EVAR except in those that need fenestrated or branched endografts. Midterm follow-up results are excellent.

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