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Ultra-low profile polymer-filled stent graft for abdominal aortic aneurysm treatment: a two-year follow-up

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Abstract
Purpose This study evaluated 2 years of follow-up of the Ovation Abdominal Stent Graft System (TriVascular Inc., Santa Rosa, CA, USA) for endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs).
Materials and methods This retrospective multicentre study included 36 patients (median age, 73.6 year) with AAAs (mean diameter, 5.65 cm) treated with the Ovation stent graft and followed up for at least 2 years. Safety and effectiveness of the Ovation stent graft were evaluated. Indications for EVAR were the following: AAA ≥5 cm, neck length ≥7 mm, angulation ≤60° and diameter <30 mm; the presence of neck calcification and thrombosis was not considered a contraindication; distal iliac landing zone length of 10 mm, and diameter between 5 and 20 mm. Patients were treated under a common protocol, including clinical and imaging follow-up at discharge, 30 days, 6 months, and annually for 5 years. Adverse events, clinical and imaging data and possible re-intervention were recorded.
Results The Ovation stent graft was implanted successfully in 36 patients (100 %). None of the patients required conversion to open surgery, and none presented with an aneurysm rupture. Endograft stent fracture or migration was not observed in any case. No type I, III or IV endoleaks were observed; in 12 patients (33.3 %), a type II endoleak was noted, in one case with sac enlargement but not treated due to concomitant comorbidities and the patient's decision.
Conclusions The 2-year results of the Ovation Abdominal Stent Graft System demonstrate excellent safety and effectiveness in the treatment of patients with AAAs, particularly in those with challenging anatomical characteristics.

Keywords EVAR · Low-profile endograft · Ovation · Follow-up

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Introduction

Endovascular aortic aneurysm repair (EVAR) for suitable abdominal aortic aneurysms (AAAs) has gained wide acceptance in the past decade. In spite of its increasing popularity, technical aspects of graft placement, related to anatomical considerations (arterial diameter, neck length, or angulations), often preclude successful endovascular repair in many patients [1]. EVAR of AAAs not fulfilling the anatomical criteria for the neck is associated with an increased incidence of type I endoleak, migration of

the endograft and aortic neck dilatation [2, 3]. Furthermore, anatomically smaller iliac arteries (such as in short females) where iliac diameter may be less than 1 cm or in patients with concomitant iliac occlusive disease causing iliac artery stenosis with a residual lumen between 5 and 8 mm are usually excluded for EVAR with conventional devices [3]. Thus, decreasing profile and simplifying delivery systems should increase the number of candidates for endovascular repair. The Ovation Abdominal Stent Graft System (TriVascular Inc, Santa Rosa, Calif) is a new device that is designed to overcome the limitations of currently available stent grafts and can accommodate a broad range of aortoiliac characteristics, navigate through complex iliac and femoral access, and provide a seal in complex proximal infrarenal aortic neck morphology. The main body is a modular two-docking limb device with a 14F outer diameter delivery system, active suprarenal fixation, and polymer-filled proximal rings that accommodate the aortic neck for seal.

The aim of this study was to evaluate the 2-year safety and effectiveness outcomes of the Ovation Abdominal Stent Graft System (TriVascular Inc, Santa Rosa, CA, USA) for endovascular repair of abdominal aortic aneurysms (AAAs).

Materials and methods

Patients

All patients gave informed consent according to the practice in two Institutes. All patients presented with an AAA requiring intervention and with aorto-iliac characteristics suitable for treatment using the Ovation device. This retrospective study was conducted in two centres from November 2009 to May 2011, and involved 36 patients (33 men and 3 women; median age 73.6; range 56–85 years) with AAAs (mean diameter, 5.65 cm) treated with the TriVascular Ovation device (Table 1). The procedures were performed through common femoral artery puncture after surgical arteriotomy. Patients were monitored throughout their hospitalisation and at regular follow-up visits with contrast-enhanced computed tomography (CT) performed at 1 and 12 months after the endovascular procedure. Mid-term follow-up was performed at 6 months with contrast-enhanced ultrasound (CEUS) and, in the event of endoleak detection, a contrast-enhanced CT examination. After the first year, the protocol involved annual CT scans.

Baseline imaging and treatment procedure

All patients underwent preoperative evaluation of their aneurysm with conventional contrast-enhanced CT imaging with thin (1 mm) slice thickness and with intravenous administration of iodinated contrast media. Optimal arterial enhancement on contrast-enhanced CT scan was achieved using the bolus-tracking technique, with a region of interest (ROI) placed on the abdominal aorta (at the supra-renal level) and considering a threshold 100 HU higher than baseline density. A venous phase was performed 90 s after contrast medium administration. Patients were eligible for the procedure if they were considered to have a low-to-moderate risk for elective open repair of a non-ruptured AAA or aortoiliac aneurysm according to the Society for Vascular Surgery (SVS)/International Society for Cardiovascular Surgery (ISCVS) scores of 0, 1, or 2 [3, 4]. The primary inclusion criteria were: (1) age >18 years old; (2) a proximal neck length of ≥7 mm and an inner diameter of between 15 and 30 mm; (3) a juxtarenal aortic neck angulation of ≤60° if the proximal neck length was ≥10 mm or ≤45° if the proximal neck length was <10 mm; (4) a distal seal zone of ≥10 mm and diameter between 5 and 20 mm, with severe bilateral iliac artery disease; (5) an AAA diameter of ≥5.0 cm, 1.5 times the adjacent nonaneurysmal aorta, or expansion of ≥0.5 cm in the previous 6 months. The exclusion criteria were: (1) subjects with high probability of non-adherence to physician's follow-up requirements, or (2) with current participation in a concurrent randomised control trial or investigational device/drug study which could confound the study results; (3) life expectancy less than 1 year; (4) pregnancy; (5) patients with poor renal function as indicated by a serum creatinine >2.5 mg/dL; (6) patients with a condition likely to infect the graft and patients with known sensitivities or allergies to the device materials [including polytetrafluoroethylene (PTFE), polyethylene glycol (PEG)-based polymers, fluorinated ethylene propylene (FEP) or nitinol].

Device description

The TriVascular Ovation stent graft is a low-profile endovascular device designed to overcome the limitations of previous stent grafts by accommodating a broader range of aortoiliac anatomy with a 14F outer diameter (OD) delivery system and a proximal aortic neck seal mechanism designed to conform to and accommodate the aortic neck. The Ovation stent graft is characterised by a trimodular design (comprised an aortic body section and two iliac limbs); the aortic body consists of a flexible hydrophilic-coated 14F OD catheter, the smallest profile of any currently commercially available stent graft. The aortic body consists of a low-permeability PTFE graft and a suprarenal nitinol stent with integral anchors to achieve active fixation to the aortic wall. The aortic body contains a network of inflatable channels and sealing rings that are filled during deployment with a low-viscosity, radiopaque fill polymer [PEG-based fill polymer, contrast agent (Visipaque 320,

Table 1 Characteristics of the abdominal aortic aneurysms, follow-up and complications

Pt and sex	Age	Pre-op AAA size (cm)	Pre-op il aneurysm size (cm)	F-U months	CT 24 months	AAA size (cm)	Additional therapeuticalprocedures	Graft patency/ occlusion	Pt status
BF, M[a]	64	5		36	No EL	3		Patent	Alive
IP, M[a]	68	5		28	Type II EL after 12 m; disappeared at 24 m	4.6	None required	Patent	Alive
AL, M[a]	80	5.8		28	Type II EL (decrease of sac)	5.1	None required	Patent	Alive
GF, M[a]	67	5		30	No EL	5.3		Patent	Alive
MAB, F[a]	76	6.4		32	Type II EL after 6 m; disappeared at 24 m	4.5	None required	Patent	Alive
GDM, M[a]	73	5.5		26	Type II EL after 12 m; disappeared at 24 m	4.5	None required	Patent	Alive
MRB, M[a]	77	6.2		28	No EL	4.2		Patent	Alive
VP, M[a]	82	6		33	No EL	4		Patent	Alive
SG, M[a]	82	5		30	No EL	3.8		Patent	Alive
LZ, F[a]	75	5		24	Type II EL (decrease of sac)	4.7	None required	Patent	Alive
BB, M[a]	78	6.4		28	No EL	6		Patent	Alive
MT, M[a]	78	5.6		30	Type II EL (stable sac)	5.5	None required	Patent	Alive
GA, M[a]	81	5.9		24	Type II EL (decrease of sac)	5	None required	Patent	Alive
SS, M[a]	72	5.8		26	Type II EL (decrease of sac)	5.2	None required	Patent	Alive
GV, M[a]	81	6		27	Type II EL (decrease of sac)	5.6	None required	Patent	Alive
GDZ, M[a]	72	6.5		24	No EL	5		Patent	Alive
GP, M[a]	78	5.7		26	No EL	5.5		Patent	Alive
LP, M[a]	84	5.8		24	No EL	4.2		Patent	Alive
RB, M[a]	67	5.7		26	No EL	4		Patent	Alive
TC, M[a]	66	6		28	No EL	4		Patent	Alive
KM, M[b]	74	5.5		37	No EL	4.5		Patent	Alive
EC, F[b]	71	5.5	3.7	37	No EL	4.3		Patent	Alive
AB, M[b]	74	6.2		35	No EL	4.2		Patent	Alive
AX, M[b]	74	5.5		34	No EL	5		Patent	Alive
EF, M[b]	74	5.5		33	No EL	5		Patent	Alive
TE, M[b]	85	6.6		33	Type II EL, AAA enlargement	7.8	Patient refused further intervention due to chronic renal failure, deteriorated health and age (88)	Patent	Alive
EP, M[b]	65	5.5		31	No EL	3.5		Patent	Alive
ZG, M[b]	75	5.5		31	No EL	3.5		Patent	Alive
SS, M[b]	77	5.5		30	No EL	5		Patent	Alive
AS, M[b]	77	6.0		28	No EL	5		Patent	Alive
GP, M[b]	68	5.8		27	No EL	5		Patent	Alive
SK, M[b]	65	5.5		27	No EL	4.3		Patent	Alive

Table 1 continued

Pt and sex	Age	Pre-op AAA size (cm)	Pre-op il aneurysm size (cm)	F-U months	CT 24 months	AAA size (cm)	Additional therapeuticalprocedures	Graft patency/ occlusion	Pt status
PK, M[b]	80	5.5	3.6	27	Type II EL, decrease of sac	3	None required	Patent	Alive
SM, M[b]	56	6.5		27				Patent	Alive
AL, M[b]	63	5.5		27	Type II EL, decrease of sac	5.0	None required	Patent	Alive
GM, M[b]	70	5.6		26				Patent	Alive

Pt patient, *pre-op* pre-operative, *AAA* abdominal aortic aneurysm, *F-U f*ollow-up, *EL* endoleak, *m* months

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GE Healthcare, USA), and a buffer] that cures in situ to create a conformable seal to the patient's aortic neck. The graft has an inflation fill port that connects the inflation network of the graft to the delivery catheter. The Ovation iliac limbs consist of highly flexible nitinol stents encapsulated in low-permeability PTFE that are packaged in low-profile 13F to 14F OD delivery systems. Stent radial force provides both fixation and sealing of the interface between the aortic body and each iliac limb. Radial force of the stent also provides fixation and sealing between the iliac limb and the distal landing zone of the iliac artery (Fig. 1).

Follow-up

Patients were monitored until hospital discharge and returned for follow-up visits at 1, 6, 12 months and then annually. The actual follow-up period was between 24 and 37 months (mean, 27.7 months). At each follow-up visit, patients underwent a physical examination, blood chemistry, evaluation of concomitant medications, and collection of adverse events. Contrast-enhanced CT was performed at 1 and 12 months after the intervention. Mid-term follow-up was performed at 6 months with contrast-enhanced ultrasound (CEUS) and, if an endoleak was detected, then a contrast CT scan was also performed. After the first year, follow-up consisted of annual CT scans (Fig. 2).

Outcomes

Outcomes were evaluated in terms of EVAR feasibility in selected patients, immediate technical success, and effectiveness and safety.

Feasibility was defined as the possibility of carrying out EVAR in patients with difficult iliac access (diameter <7 mm), with short (but ≥7 mm) and/or angulated proximal neck (≤60°).

Technical success was defined as successful deployment of the endograft, in particular absence of type I endoleak at the angiogram performed at the end of the procedure.

Effectiveness was defined as the absence of type I endoleak, migration and aneurysm enlargement at CT performed during follow-up. The main safety outcomes measured were mortality and serious adverse events (aneurysm enlargement rupture, conversion to surgery, and secondary interventions), in accordance with the classification system of the Society of Interventional Radiology [5].

Results

EVAR was feasible in all selected patients. The Ovation stent graft was implanted successfully in 36 patients (100 %). Technical success was 100 %. None of the patients

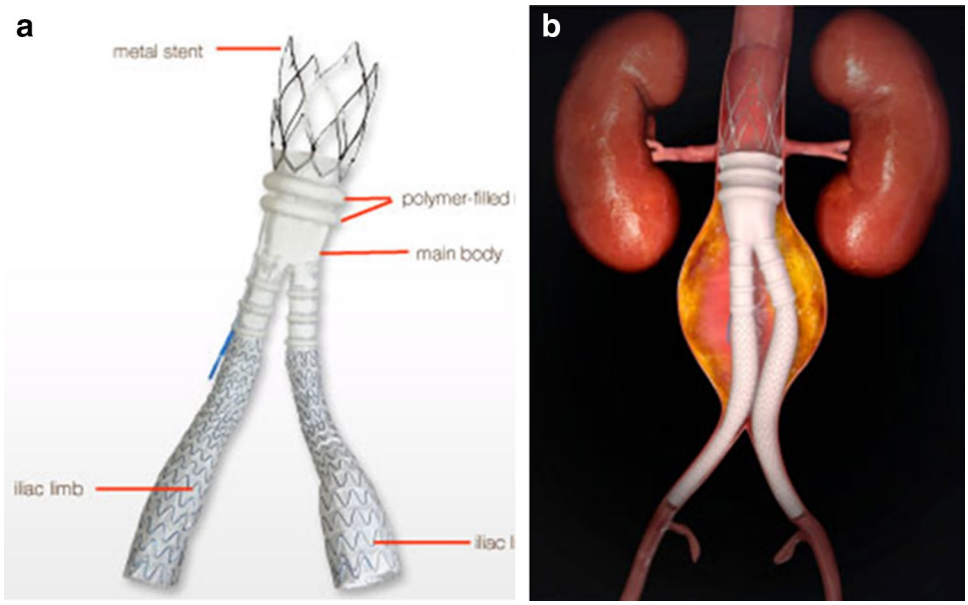

Fig. 1 Ovation stent graft is an implantable device made up of three parts: a main body and two limbs. The main body of the stent graft uses two polymer-filled rings to provide seal against the wall of the aorta, while the metal stent provides fixation of the stent graft to the aorta (**a**); schematic image of the stent graft implanted in an abdominal aortic aneurysm (**b**)

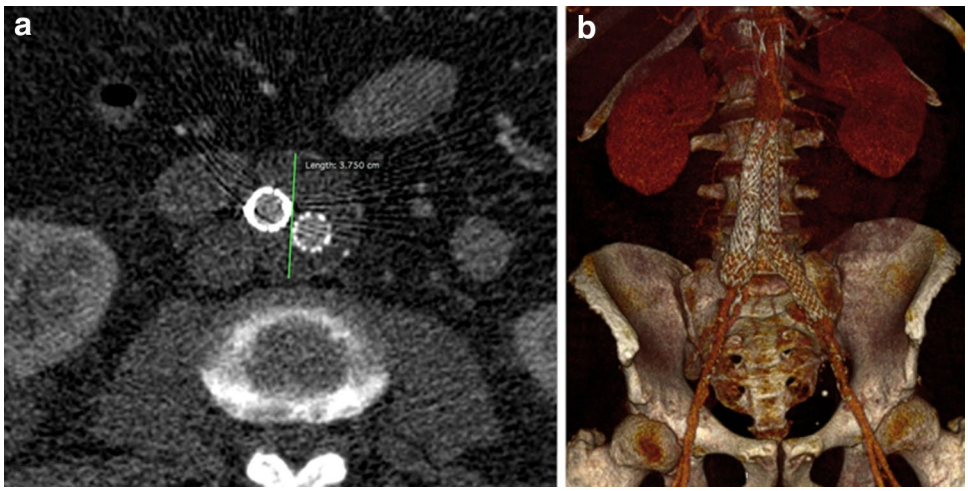

Fig. 2 Computed tomography (CT) scan performed after 24 months reveals reduction of the sac diameter (G); volume rendering (VR) reconstruction of the same examination (**b**)

required conversion to open surgery, and no aneurysm rupture, fracture, or migration of the endograft were observed. Moreover, in all patients, post-procedural angiography documented the absence of type I endoleak. Mean follow-up duration was 27.7 months (range, 24–37 months). During follow-up, none of the patients presented type I, III or IV endoleaks. In 12 patients (33.3 %), a type II endoleak was noted; only one patient had sac enlargement which was not, however, treated because the patient refused further intervention due to chronic renal failure, deteriorated health and advanced age (88 years); in eight patients with type II endoleak, the aneurysmal sac remained stable or decreased in size and thus no treatment was required (Fig. 3). In three patients, a type II endoleak was detected at CT scan after 12 months ($n = 2$) and 6 months ($n = 1$), respectively, but disappeared at CT scan performed after 24 months. During follow-up, no occlusion of the main body or of the branches was observed (Table 1). No major or minor complications, serious adverse events or deaths were recorded during or after the procedure, 30 days after graft deployment or during the follow-up period. The rate of minor complication was 8.3 % (3/36): in detail, two patients developed a transient renal failure (serum creatinine value >2 mg/dL) and one patient required an arterial patch at the access site.

Discussion

Since the introduction of EVAR in 1991, endovascular treatment with newer stent grafts has assumed a prominent role in the clinical management of AAA with reduced perioperative mortality and an equivalent mid-term

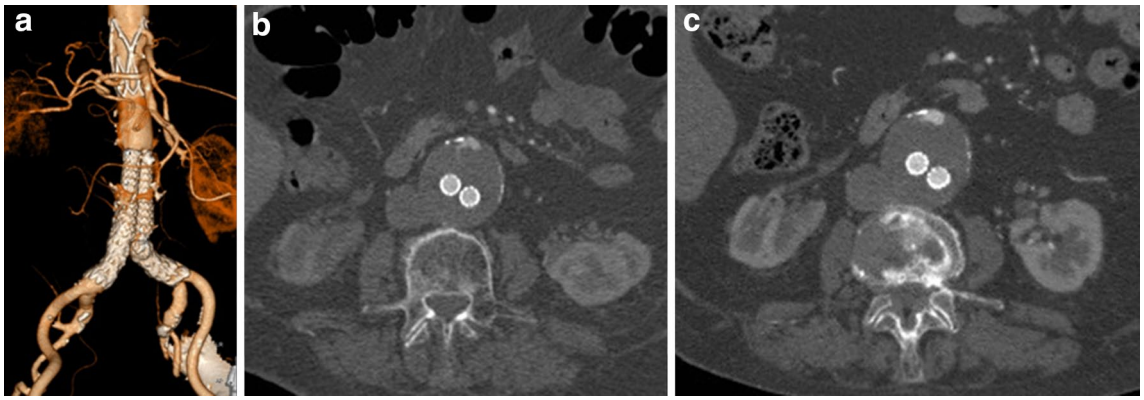

Fig. 3 Volume rendering reconstruction of a CT scan performed during follow-up in a patient with Ovation stent graft (**a**); CT scan performed after 1 year revealed type 2 endoleak (**b**); type 2 endoleak and the diameter of the sac remained stable (**c**)

outcome, compared to open surgery [6]. The angulation of the aneurysm neck, defined as the angle between the suprarenal aorta and the first portion of the aneurysm neck (within the first 3 cm), must be considered [7]. An angle greater than 60° is a relative contraindication since this is associated with a greater complication rate (primarily type I endoleaks). Even with an initially good result, the risk of migration, stent fracture, or separation of the prosthesis components in the case of angulation >60° is significantly increased [2, 8]. In our study, we did not observe any stent migration with the Ovation, most likely due to the suprarenal fixation bare stent. The prerequisites for successful endovascular treatment are complication-free passage of the stent graft through the iliac access vessels and anchoring in an adequate distal landing zone [7, 9, 10]. In the case of arterial occlusive disease, the vascular segment may need to be treated pre-interventionally via stent angioplasty [9].

On the basis of the characteristics described, a great deal of attention and research has focused on endovascular aortic repair devices to accommodate patients with hostile necks as well as concomitant iliac stenosis which may exclude larger profile devices.

The Ovation stent graft is characterised by a trimodular design: the aortic body is composed of a low-permeability PTFE graft with a suprarenalnitinol stent with anchors that provide active fixation. Unlike the previous stent grafts, the Ovation aortic body contains a network of inflatable sealing rings and channels that are filled with a low-viscosity radiopaque polymer during stent graft deployment. As the polymer cures in situ, it conforms to aortic necks of various shapes and provides proximal stent graft seal. The Ovation main body is delivered through a flexible hydrophilic-coated 14F OD catheter, the smallest profile of any currently commercially available stent graft. The Ovation iliac limbs are composed of highly flexible nitinol stents encapsulated in low-permeability PTFE that are packaged in low-profile 13F to 14F OD delivery systems that allow access in iliac arteries as small as 4.7 mm [11, 12].

With these design characteristics, the first publications revealed that the Ovation stent graft was implanted successfully in 100 % of patients, without any access failures, type I or III endoleaks, stent graft migration, explant, or aneurysm rupture [11, 12].

Mehta et al. [12] observed that even in patients with challenging anatomy, the Ovation stent graft yielded excellent results, including 100% technical success, 97% freedom from major adverse events through 1 year, and 3.2 % freedom from major adverse events with AAA-related secondary procedures. The Ovation stent graft has the ability to treat a wider range of patients compared with other stent grafts, especially those with narrow access vessels and short proximal necks, without sacrificing patient safety or device effectiveness. In 1 year of follow-up, type II endoleaks were identified in 34 % of patients; this endoleak rate, although higher than anticipated, is within the typically reported range [13]. These data are in accordance with our results (33.3 %). Given the positive relationship between endoleak volume and aneurysm wall pressure, these small type II endoleaks may portend a benign clinical course [14, 15]. As Mehta et al. [12] concluded, even in our series, the long-term trajectory of these endoleaks will be monitored and remains to be determined as patients undergo regular surveillance annually for 5 years under the study protocol.

The study presented is the first with a series of patients with at least 2 years of follow-up available. This study also had several limitations. It was a relatively small study, with only 36 patients garnered from two referral centres. It was a non-controlled study and, therefore, comparative performance of the Ovation stent graft with alternative AAA treatments could not be directly evaluated.

As in the patient group reported by Mehta et al. [12], women accounted for a minority of patients enrolled in our study (3 out of 36). An additional study with more patients will be required to elucidate the long-term outcomes.

At the moment, we can conclude that the Ovation stent graft may help to expand the patient population eligible for EVAR by accommodating a wider range of aorto-iliac anatomies with promising safety and effectiveness.

Conflict of interest The authors have no conflicts of interest or financial ties to disclose.

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