Initial experience with polymer endovascular aneurysm repair using the Alto stent graft

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ABSTRACT

The Alto Abdominal Stent Graft System (Endologix Inc, Irvine, Calif) is the next-generation Ovation system for polymer endovascular aneurysm repair. The most significant design change relocates the sealing ring closer to the top of the fabric, but a number of additional design changes were made. This report describes the first seven patients treated with the Alto stent graft at a single center (Auckland Hospital, Auckland, New Zealand) from August 2016 to February 2017. There was 100% procedural technical success. At 12-month follow-up, no type I or type III endoleak, stent graft migration, abdominal aortic aneurysm rupture, abdominal aortic aneurysm-related mortality, or secondary intervention was reported. (J Vasc Surg Cases and Innovative Techniques 2020;6:6-11.)

Keywords: Alto; Ovation; Aortic aneurysm; Endovascular; EVAR; Stent graft

Even with continuing advancements in stent graft technology, only about 50% of patients requiring endovascular aneurysm repair (EVAR) meet the anatomic guidelines specified in the instructions for use.[1] In patients who ultimately undergo EVAR, only 42% to 69% are treated on-label.[2] Given the higher complication risks with open surgical repair[3,4] and off-label EVAR[2,5,6] compared with on-label EVAR, there remains a distinct clinical need to safely expand on-label anatomic indications to further increase EVAR eligibility.

The Ovation Abdominal Stent Graft System (Endologix Inc, Irvine, Calif) was developed to accommodate a wider range of anatomies on-label. On-label eligibility with the Ovation iX stent graft has been reported at 72% vs 35% to 63% with other stent grafts.[7] Since original Food and Drug Administration approval, some design modifications to the Ovation stent graft have occurred, including an integrated sheath with expanded limb size offerings (Ovation iX) and shorter polymer cure times. Alto is the latest generation Ovation stent graft system, with a proximal seal zone closer to the renal arteries while incorporating additional design enhancements to improve ease of use. This paper describes the Alto implant characteristics, differentiating features, and initial early clinical experience. Patients treated gave consent to participate in this case series and publication.

METHODS

The Alto stent graft system consists of an aortic body and two iliac limbs individually constrained within a flexible, hydrophilic-coated, 15F outer diameter catheter. The aortic body is composed of low-permeability graft material and suprarenal nitinol anchors that provide active fixation to the aortic wall. The aortic body contains a network of inflatable channels and sealing rings that are filled with a low-viscosity radiopaque liquid polymer during deployment that cures in situ. The intraprocedural delivery of polymer reduces device profile. The iliac limbs are composed of flexible nitinol stents encapsulated in low-permeability polytetrafluoroethylene, which makes them suited for narrow or tortuous iliac arteries. The iliac limbs are packaged in a 12F to 15F outer diameter delivery system and are available in lengths between 80 mm and 160 mm and diameters between 10 mm and 28 mm.

The Alto achieves circumferential seal at the level of the proximal sealing ring. The sealing ring is 6 mm in height and begins 4 mm distal to the proximal edge of the graft itself. Device sizing is calculated relative to the center of the ring, which is 7 mm below the top of the fabric. This is a significant difference relative to the Ovation iX, in which the sealing ring starts at 10 mm and centers at 13 mm (Fig 1).[8]

Other design improvements with Alto include the addition of an integrated compliant balloon (Fig 2). A marker on the proximal balloon is used to indicate the location of the sealing ring. During device deployment (Fig 3), the lower aspect of the uncovered fixation stent (termed mid-crown segment) and the endograft body are initially deployed. The fabric and mid-crown segment are

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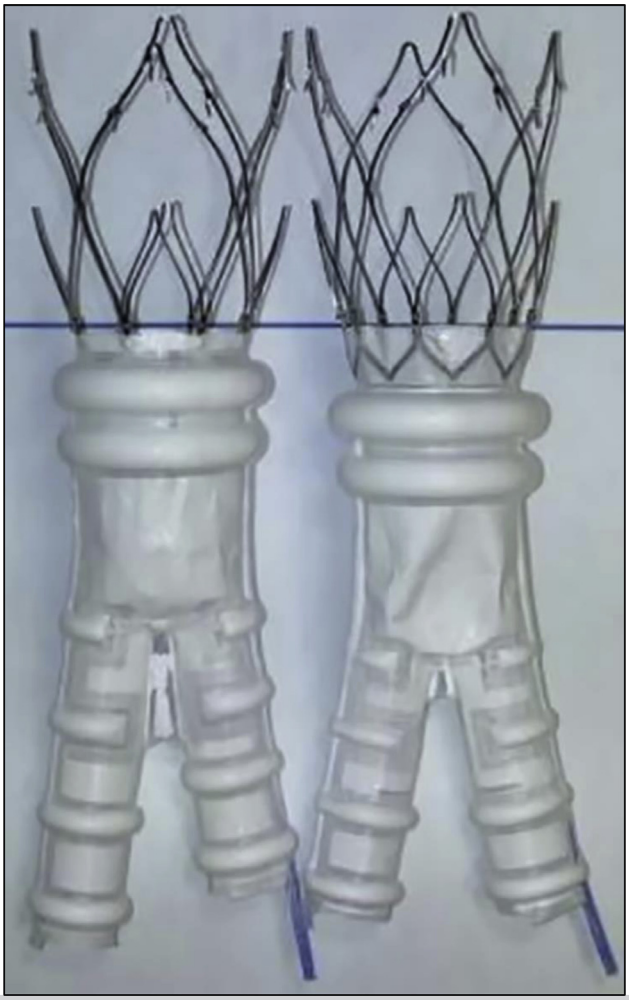

Fig 1. Comparison of Ovation Alto (*left*) and Ovation iX (*right*). Relative to the proximal stent graft edge represented by the *blue horizontal line,* the midpoint of the proximal sealing ring is 7 mm distal with Ovation Alto vs 13 mm distal with Ovation iX.

transiently expanded with the integrated compliant balloon. Eight radiopaque markers on stent struts at the base of the fixation stent provide accurate markers for the upper edge of the graft fabric. The upper aspect of the fixation stent remains constrained so the device can be safely and accurately repositioned before the entire fixation stent is deployed. The compliant balloon can also be used to postdilate the main body.

Three improvements were made to improve access to the limbs (Fig 2). Increased webbing was added at the device bifurcation to offset the limbs and to prevent prolapse of the contralateral limb during wire access. The inner diameter of the docking limb was increased to 11 mm and standardized across all device diameters. The aortic body limbs were also offset by 5 mm to improve identification between limbs.

Aortic neck sizing with Alto accommodates necks ≥7 mm in length, provided the aortic diameter is

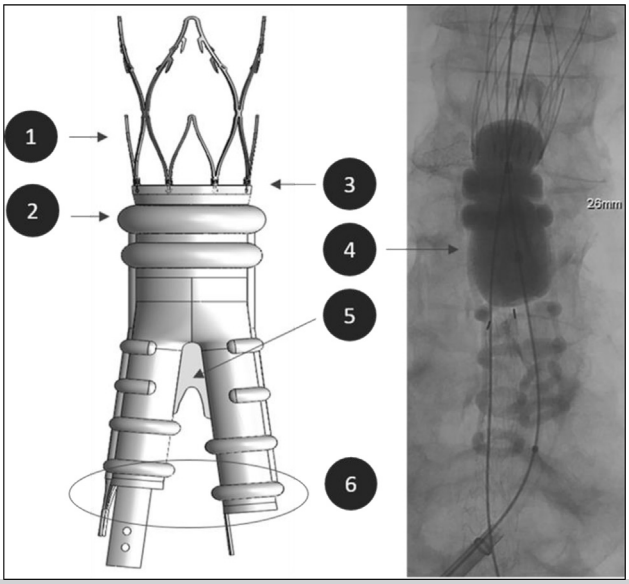

Fig 2. New device features of Alto. *1,* Mid-crown segment of proximal fixation stent. *2,* Sealing ring center 7 mm from the proximal polytetrafluoroethylene edge. *3,* Radiopaque markers mark upper aspect of endograft fabric. *4,* Integrated balloon. *5,* Webbing at graft bifurcation. *6,* Offset AB legs in endograft.

between 16 and 30 mm in diameter and angulation is ≤45 degrees. For necks with angulation of 45 to 60 degrees, neck length ≥7 mm is needed.

RESULTS

The initial clinical experience with the Ovation Alto stent graft occurred at a single institution (Auckland Hospital, Auckland, New Zealand). Seven patients (five men, two women) with a mean age of 78 years (75-82 years) were treated between August 2016 and February 2017. The anatomic characteristics of patients treated are presented in the Table. Calcification and beta angulation of the infrarenal neck were common findings (Fig 4). Technical and procedural success was 100%, with the device delivered and deployed in all cases. Mean procedure time was 145 minutes (90-185 minutes), and average contrast material volume was 180 mL (120-300 mL). All patients have survived beyond 12 months with no reintervention. No patient experienced a significant decline in renal function during the first 12 postoperative months. At 1-, 6-, and 12-month follow-up, there were no type I or type III endoleaks. There were two type II endoleaks at 1 month, one persistent at 12 months. The mean sac diameter was 56 mm (52-62 mm) before treatment, reduced to 53 mm (46-63 mm) at 6 months and 51 mm at 12 months (40-64 mm). Aneurysm sac size was stable or reduced in all patients with a mean sac reduction of 5.4 mm (−14 mm to +2 mm) at 12 months.

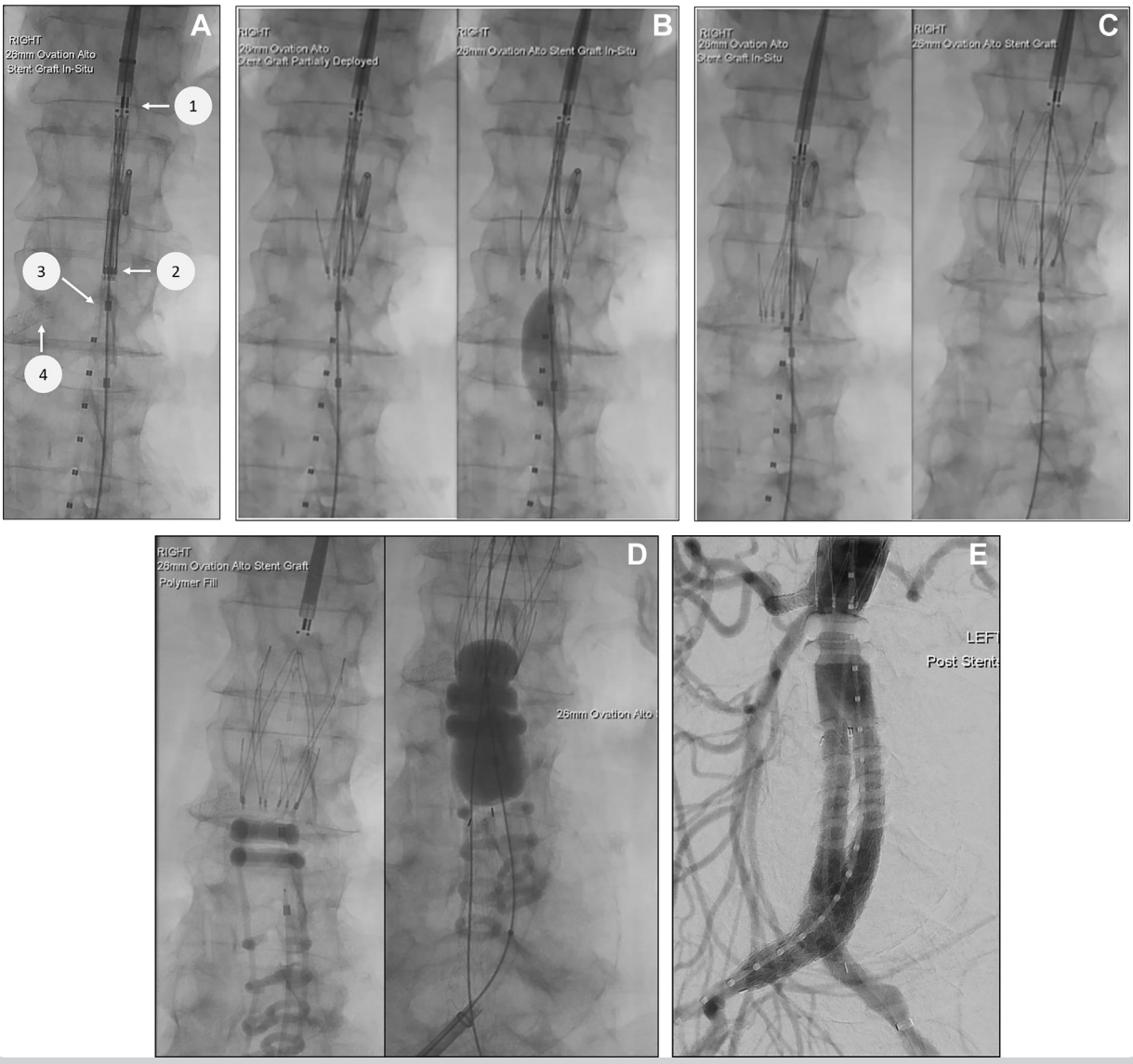

Fig 3. Initial deployment steps of the Alto device. Endoluminal repair performed in a 74-year-old woman with a solitary functional right kidney. A right main renal artery stenosis was treated with a stent at the beginning of the endoluminal procedure. **A,** Device introduced. A calibrated pigtail catheter has been introduced from the contralateral groin for angiographic control. Note the following features: *1,* "exclamation mark" configuration of the radiopaque markers on the delivery system marks the position of the contralateral limb; *2,* radiopaque markers on the base of the proximal fixation stent; *3,* upper radiopaque marker of the integrated compliant balloon; *4,* right renal stent. **B,** Deployment of the mid-crown segment of the proximal fixation stent. Note that this is deployed while the device is above the planned landing zone. Appropriate angulation of the image intensifier is performed to superimpose the eight upper fabric radiopaque markers (*left*). Compliant balloon is partially inflated to expand the mid-crown segment (*right*). **C,** Endograft is repositioned caudally so that endograft material lies immediately below the renal stent (*left*). Proximal, uncovered fixation stent is fully deployed (*right*). **D,** Sealing and limb rings are filled with polymer. Note that the top radiopaque marker of the integrated compliant balloon accurately marks the center of the sealing ring (*left*). Integrated compliant balloon is used to postdilate the main body (*right*). **E,** Completion angiography.

DISCUSSION

Almost half of patients in need of abdominal aortic aneurysm repair remain ineligible for on-label EVAR because of anatomy beyond the limitations of current stent grafts.[2] The Alto is designed to address this issue by allowing on-label EVAR in a wider range of aortic anatomies, primarily through proximal relocation of the unique sealing mechanism and the low-profile delivery system.

Conventional EVAR devices require a length of 10 to 15 mm of uniform-diameter healthy aortic neck because sealing occurs by graft-vessel wall apposition over a sufficient length. The Ovation system uses a polymer to fill a

Table. Anatomic characteristics of the patients treated

Patient	Infrarenal neck length, mm	Thrombus	Calcification	Beta angle, degrees	Alpha angle, degrees	Minimum EIA diameter, mm
1	35	Nil	Mild	38	0	4
2	14	Nil	Severe	47	0	6
3	14	Nil	Moderate	28	24	6
4	26	Mild	Severe	76	0	6
5	11	Nil	Moderate	30	12	8
6	28	Nil	Nil	67	0	11
7	20	Moderate	Mild	26	25	4
Mean (range)	21 (11-35)			44.5 (26-76)	8.7 (0-25)	6.4 (4-11)

EIA, External iliac artery.

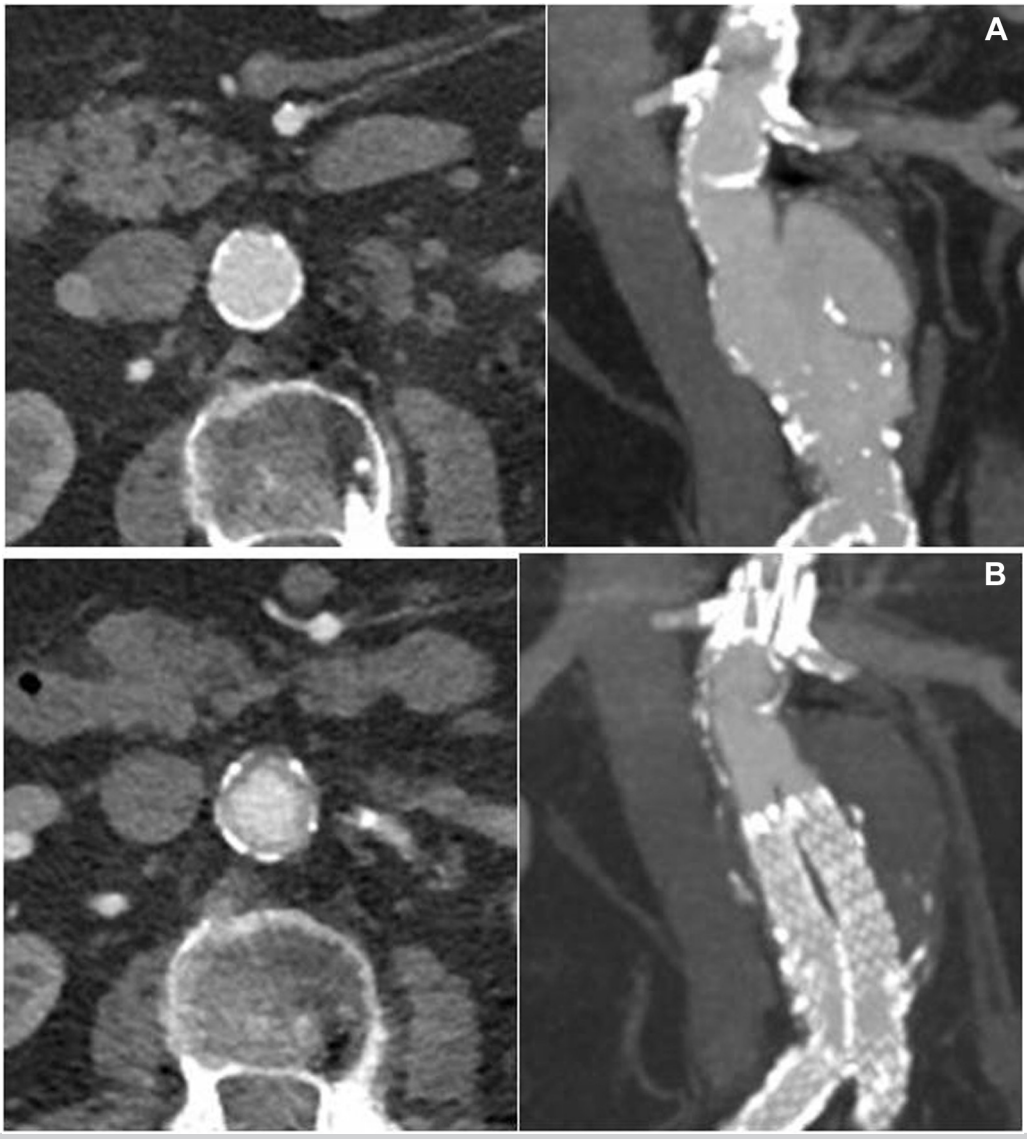

Fig 4. Ovation Alto repair of an aneurysm with a heavily calcified and mildly angulated infrarenal neck. **A,** Axial and coronal images from the preoperative computed tomography scan. **B,** Axial and coronal images from a 1-month postoperative computed tomography scan.

sealing ring that creates a sealing ring customized for each unique anatomy. In the Ovation iX system, the sealing ring is centered at 13 mm below the top of the fabric. In Alto, the sealing ring is relocated closer to the top of the fabric, shortening the neck length requirement to 7 mm. The polymer sealing ring starts 4 mm distal to the proximal edge of the graft and extends 6 mm, with the midpoint of the ring at 7 mm below the top of the graft. Proximal neck morphology is considered on-label provided the diameter is between 16 mm and 30 mm at this level.

Sealing for most traditional endografts is achieved not only by endograft to vessel wall apposition but also by radial force exerted on the aortic wall. Over time, the proximal neck may dilate to approximate the unconstrained diameter of the self-expanding stent.[9] A systematic review of standard EVAR grafts reported that neck dilation occurred in one of four patients and that the risk of type I endoleak, migration, and secondary intervention was higher in patients with neck dilation.[10] In contrast, Alto exerts no chronic outward radial force onto the aortic wall. The polymer sealing technology in Alto is the same as that used in the Ovation stent graft, for which freedom from neck dilation was identified through 5-year follow-up.[11]

The 15F outer diameter delivery system of Alto has a smaller profile than many commercially available stent grafts. A low-profile delivery system expands the ability to treat patients with small-caliber access vessels while remaining compliant with instructions for use. Percutaneous EVAR can also be performed in a higher percentage of patients with low-profile devices.[12] Numerous studies have reported higher technical success rates, less blood loss, fewer access-related complications, and shorter hospital stays with percutaneous EVAR compared with surgical cutdown.[12-19]

Excellent 5-year safety and effectiveness outcomes have recently been reported with the Ovation system of stent grafts, including a 97% freedom from secondary intervention for proximal endoleak and 99% freedom from rupture.[10] However, some potential deficiencies of earlier generations of the Ovation endograft have been addressed with Alto. The relocated sealing ring closer to the top of the fabric plus the integrated compliant balloon should optimize accurate positioning and minimize the risk of intraprocedural type IA endoleak. Device modifications, including the integrated crossover port, are designed to simplify contralateral gate cannulation. The initial experience with Alto is limited but positive, with excellent technical success and promising short-term results. Long-term results with Alto in a larger patient cohort is awaited. Alto is currently being evaluated in the Expanding Patient Applicability with Polymer Sealing Ovation Alto Stent Graft (ELEVATE) clinical trial, a Food and Drug Administration investigational device exemption study of 75 patients that completed enrollment in early 2018 and will observe patients through 5 years.

CONCLUSIONS

The indications for the Alto are the broadest of any stent graft. The first-in-human experience with this device demonstrated promising results.

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