



Endovascular Juxtarenal Aortic Aneurysm Repair Using the ALTO Abdominal Stent Graft System: The First Case Series

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The ALTO abdominal stent graft system (Endologix Inc., Irvine, CA, USA) is a latest-generation polymer-based device used to treat patients with abdominal aortic aneurysms. The present study describes the first case series of patients with abdominal aortic aneurysms, including two patients with juxtarenal aneurysms, treated using the ALTO stent graft system. Six males were treated using the ALTO device at a single public center. All procedures were uneventful, and the dosimetric results recorded in terms of kerma-area product and fluoroscopy time were similar to those reported in previous studies. At the 1-month follow-up, computed tomography angiography showed no evidence of endoleak, device migration, thrombosis, or structural graft failure. This clinical series demonstrates that the use of the ALTO stent graft system is associated with promising patient outcomes. Lifelong postoperative imaging surveillance may highlight possible late failures and suggest potential graft improvements.

Key Words: Endovascular procedures, Aortic aneurysm, Polyethylene glycols, Polymers

Received January 20, 2022
Revised March 21, 2022
Accepted April 25, 2022
Published on June 24, 2022

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Cite this article; Vasc Specialist Int 2022. <https://doi.org/10.5758/vsi.220004>

INTRODUCTION

Expanding its portfolio of medical devices, Endologix recently introduced the ALTO abdominal stent graft system (Endologix Inc., Irvine, CA, USA), which is a latest-generation polymer-based graft system for endovascular aneurysm repair (EVAR) in patients with intact abdominal aortic aneurysms (AAAs). Owing to their short necks, juxtarenal aneurysms extending to just below the renal arteries present a great challenge to vascular surgeons and limit the use of currently commercially available devices in patients [1,2]. The ALTO device, in contrast to its predecessor the Ovation iX system, grants interventionalists the ability to treat AAAs with short, reverse-tapered (conical), or tapered proximal

necks, thus allowing more patients to be eligible for EVAR; the minimum infrarenal neck length requirement for the ALTO device is 7 mm. In addition, its CustomSeal polymer-based technology does not require traditional metallic stent frames to support the fabric [3,4]. Regarding its technical success, according to the FDA Summary of Safety and Effectiveness Data [5], 58 of 61 patients (95%) treated with the ALTO abdominal stent graft did not present any device- or aneurysm-related issues when evaluated 12 months post-operatively. Similar results (100% procedural and technical success rates) were recently reported in another case study [6].

The present study describes the main characteristics and deployment procedures of the ALTO device and early

operative outcomes of EVAR using the ALTO system in six patients with AAAs treated at the University Hospital of Patras in Greece. The study was approved by the Institutional Review Board of University Hospital of Patras (no. 29/11-07-2018). Informed consents were obtained from the patients.

CASES

Through standard bilateral groin incisions and common femoral artery cutdown, guidewires were advanced up to the thoracic aorta. Following heparin administration, the ALTO main body delivery system was introduced over a Lunderquist wire under fluoroscopic guidance. Following appropriate device orientation, the outer sheath was retracted, and the graft was uncovered. The mid-crown

segment was deployed, and the integrated balloon was inflated temporarily. Angiography was performed to visualize the renal arteries, and the proximal graft was deployed at the intended site by pulling the proximal deployment knob while steadily holding onto the delivery system. This action engaged the stent anchors, and the main body of the graft was fixed in place. Subsequently, a polymer was injected to fill the two sealing rings. The contralateral gate was cannulated, and the rest of the procedure was similar to that using a modular endograft with two docking limbs. After confirmation of aneurysm exclusion and graft patency, the case was concluded according to standard procedures.

The ALTO device was used in 6 males at the University Hospital of Patras between June 2021 and September 2021. Patient characteristics, risk factors, and comorbidities are presented in Table 1. The quantitative criterion of a ≥ 7 -mm

Table 1. Characteristics, risk factors, and comorbidities in six males who underwent endovascular repair of intact abdominal aortic aneurysms using the ALTO device

Variable	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age (y)	60	64	77	62	63	76
Body mass index (kg/m ²)	31.02	24.28	35.49	27.04	25.31	32.09
Smoking	Former	Former	Former	Yes	Former	Former
Alcohol consumption	Former	No	Yes	No	Former	Yes
Hypertension	Yes	No	Yes	Yes	Yes	Yes
Dyslipidemia	No	Yes	Yes	Yes	Yes	Yes
Diabetes mellitus	Type 2	No	Type 2	Type 2	No	No
Coronary artery disease	Yes	No	No	No	Yes	No
Chronic kidney disease	No	No	Yes	No	No	No
Cerebrovascular disease	No	No	No	No	No	No
Pulmonary disease	No	Yes	Yes	No	No	No
Previous surgery	Three coronary artery angioplasties/stentings	No	Coronary artery bypass grafting (18 y ago)	No	One coronary artery angioplasty/stenting	No

Table 2. Aneurysm characteristics and operative details

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Symptom	Asymptomatic	Asymptomatic	Symptomatic	Asymptomatic	Asymptomatic	Asymptomatic
Abdominal aortic aneurysm type	Juxtarenal	Infrarenal	Infrarenal	Infrarenal	Juxtarenal	Infrarenal
Aneurysm maximum diameter (cm)	6.0	7.8	6.0	5.1	6.4	5.3
Aneurysm neck length (mm)	7	29	36	29	8	40
Maximum juxtarenal angle (degree)	36	48	48	7	37	47
Anesthesia type	Local	General	General	General	Local	General
Contrast agent volume (mL)	270	140	160	125	125	210
Procedure duration (min)	215	180	170	150	135	165
Postoperative hospitalization (d)	1	2	3	1	1	1
Kerma-area product* (mGy·m ²)	4.57	3.98	5.33	1.85	2.54	4.09
Fluoroscopy time (min)	28.70	41.03	30.15	21.55	19.25	26.16

*The fluoroscopic equipment used was a mobile C-arm with a 12-inch image intensifier (Philips BV Pulsera; Philips Medical Systems, Eindhoven, the Netherlands).

aortic neck length was positive in all patients. The aortic neck lengths in the patients ranged from 7 to 40 mm, with a median value of 29 mm. All procedures were uneventful, and the median dosimetric results in terms of kerma-area product (KAP) and fluoroscopy time (FT) were 4.0 mGy·m² and 27.4 minutes, respectively. Postoperative hospitaliza-

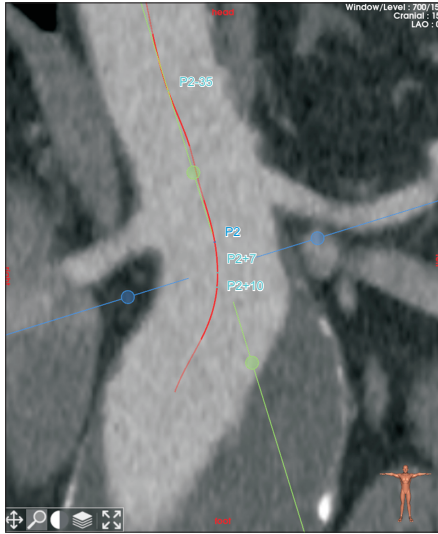


Fig. 1. A coronal reformatted computed tomography angiography image showed a juxtarenal abdominal aortic aneurysm. Reverse-tapered neck anatomy was evident.



Fig. 2. The final intraoperative angiography after the successful deployment of the ALTO endograft showed complete sealing of the aneurysm sac with no evidence of endoleaks and complete patency of the renal arteries. The suprarenal support mechanism of the endograft, polymer-filled rings, and crossed-limb “ballerina” configuration of the endograft legs were also observed.

tion was 1 day in four patients, 2 days in one patient, and 3 days in one patient. Aneurysm characteristics and operative details are shown in Table 2.

At the 1-month follow-up, computed tomography angiography (CTA) showed no evidence of endoleak, device migration, graft thrombosis, or structural graft failure in any of our patients. The representative case results are described below.

The first patient in the present case series had a 6.0-cm juxtarenal AAA (Fig. 1) with a 7-mm neck length and 3.2-cm aortic diameter at 1.0 cm below the renal arteries. The final intraoperative angiography after the successful deployment of the ALTO endograft showed complete sealing of the aneurysm sac with no evidence of endoleaks and complete patency of the renal arteries. The suprarenal support mechanism of the endograft, polymer-filled rings, and crossed-limb “ballerina” configuration of the endograft legs are shown in Fig. 2.

The fourth patient in the series had a 5.1-cm tapered-neck infrarenal AAA (Fig. 3) extending down to the aortic bifurcation. The aortic neck was of adequate length without severe angulation. Furthermore, atherosclerotic plaques were observed in the aneurysm walls. At the 1-month follow-up, CTA showed no evidence of endoleak, graft migration, or limb occlusion (Supplementary Fig. 1).

DISCUSSION

In this study, the technical success rate of the procedures was 100%, whereas the in-hospital mortality rate was 0%. No deaths, endoleaks, or reinterventions occurred during



Fig. 3. Three-dimensional reconstruction of a computed tomography angiography image showed an abdominal aortic aneurysm with a tapered neck.

follow-up. However, a long-term follow-up on a yearly basis after surgery is necessary because previous studies have reported proximal neck dilatation and graft migration after EVAR, especially in patients with greater longevity [7].

In the present study, we demonstrated the successful exclusion of two aneurysms fulfilling the European Society for Vascular Surgery criteria for a juxtarenal aneurysm, defined as an AAA with a <10-mm neck length [8]. Use of the ALTO device for juxtarenal AAA repair has not been previously reported in the literature. To our knowledge, this is the first independent study on juxtarenal AAA treatment using an infrarenal device, although a larger series with a longer follow-up is required.

Our results are similar to those reported by Holden and Lyden [6]. Their study included a full-year screening and clinical follow-up. At the 1-month follow-up, no type I or III endoleaks were observed; however, type II endoleaks were detected in two patients. In the present study, the mean procedure time was 169.2 minutes, which was longer than the 145-minute mean procedure time reported by Holden and Lyden [6]. The mean contrast agent volume used was 172 mL, which was similar to that (180 mL) reported by Holden and Lyden [6]. The results obtained at the 1-month follow-up in a study by de Donato et al. [9] correspond with those obtained in the present study, including a clinical success rate of 100% with no AAA-related mortalities. Type I or III endoleaks, polymer leakage, endograft migration, and sac expansion were not observed. The potential solutions for an intraoperative type I endoleak could be conversion to open repair, use of Onyx glue (Ev3 Inc., Irvine, CA, USA), or conversion to a branched endograft, depending on the clinical circumstances.

To our knowledge, no study has yet reported FT and KAP values for ALTO-related EVAR procedures. The recorded KAP and FT median values in the present study were 4.0 mGy·m² and 27.4 minutes, respectively. In a previous study, the median KAP and FT values were 2.7 mGy·m² and 17.0 minutes, respectively [10]. In that retrospective study, six procedures were performed using the Ovation iX device, and the median FT and KAP values were 37.4 minutes (36.5% higher than that recorded using the ALTO device) and 4.5 mGy·m² (10.9% higher than that recorded using the ALTO device), respectively. However, a direct comparison is inappropriate because the complexities of the procedures may differ.

Gregory et al. [11] stated that although existing published data on the ALTO device are limited, if more published data show short- to long-term results comparable to those obtained using the Ovation iX [12-19], then the ALTO device can be used more widely. However, whether ALTO devices can be successfully used in patients with more hostile aortic anatomies remains to be seen, considering the satisfac-

tory results of Ovation iX use reported by Sirignano et al. [17] and Morgan-Bates and Chaudhuri [19]. Short-term results may be identical between Ovation iX and ALTO device use, but a thorough comparison between the two devices would require long-term follow-ups of patients using ALTO devices. Nevertheless, the ALTO device has replaced the Ovation iX because it has several new features including a longer contralateral leg to facilitate contralateral gate cannulation, inclusion of webbing between the aortic body legs at the graft bifurcation, and incorporation of an integrated balloon into the delivery system.

The main limitation of this study is the relatively small sample size of patients treated at a single hospital. The inclusion of a larger sample of patients would have strengthened the results of this study. Moreover, as lifelong postoperative imaging surveillance is recommended for patients undergoing EVAR, the lack of a long-term follow-up is an additional limitation [20].

In conclusion, this clinical series demonstrates that the use of the ALTO stent graft system is associated with promising initial outcomes.

FUNDING

None.

SUPPLEMENTARY MATERIALS

Supplementary data can be found via <https://doi.org/10.5758/vsi.220004>.

CONFLICTS OF INTEREST

The Department of Vascular Surgery has received funding from the graft distributor, Hospital Line S.A.

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