



# Technical Characteristics of the Ovation Alto for the Treatment of Abdominal Aortic Aneurysms: Application to Challenging Anatomies

Efstratios Georgakarakos, MD, MSc, PhD<sup>1</sup> Konstantinos Dimitriadis, MD, MSc<sup>1</sup>  
 Christos Argyriou, MD, MSc, PhD<sup>1</sup> Gioultzan Memet Efenti, MD<sup>1</sup> Damianos Doukas, MD<sup>1</sup>  
 George S. Georgiadis, MD, PhD<sup>1</sup>

<sup>1</sup> Department of Vascular Surgery, University Hospital of Alexandroupolis, Democritus University of Thrace, Alexandroupolis, Greece

Address for correspondence Efstratios Georgakarakos, MD, MSc, PhD, Department of Vascular Surgery, Democritus University of Thrace, 68100 Dragana, Alexandroupolis, Greece (e-mail: efstratiosgeorg@gmail.com).

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## Abstract Keywords

- Ovation Alto
- abdominal aortic aneurysm
- endovascular aneurysm repair
- wide neck
- juxtarenal aneurysm

The Ovation Alto design repositions the maximum diameter of the proximal sealing ring at 7 mm below the lowermost renal artery. Although it has been introduced to address abdominal aortic aneurysms with short necks  $\geq 7$  mm, we present further applications of Alto in other neck irregularities, presenting four representative challenging cases with a short, wide, and conical neck, as well a juxtarenal aneurysm. At 1-month follow-up, there was 100% technical and clinical success.

## Introduction

Endovascular aneurysm repair (EVAR) was introduced in the early 1990s as an alternative method to open surgery for the treatment of abdominal aortic aneurysm (AAA).<sup>1</sup> Nowadays, EVAR comprises the first-choice treatment for the majority of patients and accounts for  $>75\%$  of AAA repairs.<sup>1</sup> Multiple randomized trials have documented the lower postoperative morbidity and mortality, faster discharge, and fewer complications of EVAR compared with open surgical AAA repair in the early period, enabling repair in an increasing number of patients with comorbidities as well as application in the emergency setting of ruptured AAA. Despite the documented advantages of EVAR, there is concern regarding the higher late reintervention rates and the need for lifelong monitoring due to potential compli-

cations. The preservation of a successful seal between the aortic endograft and the infrarenal aortic neck determines the long-term durability of EVAR.

Some aortic neck characteristics contribute to the definition of “hostile neck,” particularly length  $\leq 10$  to 15 mm, large diameter  $>32$  mm, tapered or reverse tapered anatomy, mural thrombus, circumferential calcification, and angulation.<sup>2</sup> Hostile neck morphology is generally associated with higher rates of endoleak, stent migration, and reintervention.<sup>3</sup> The off-label use of standard EVAR is sometimes applied for patients who are not eligible for open surgery. Up to 44% of EVAR cases are performed using stent-grafts outside their Instruction-For-Use (IFU; off-label).<sup>4</sup> In such cases, higher rates of Type I endoleaks may be expected, mainly in short necks; yet for patients with severe angulation or high thrombus load in the proximal neck, results of

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outside IFU EVAR seem comparable to the results of inside IFU.<sup>5</sup>

## The Ovation Alto: Application to Short Necks

The Ovation (Endologix Inc. Irvine, CA) aortic endograft combines active suprarenal fixation via a long nitinol stent and a pair of polymer-filled inflatable rings to accommodate effectively even a wide range of infrarenal neck irregularities, including conical morphology, circumferential calcification, and significant thrombus onto the neck surface. The recently FDA approved Ovation Alto design lacks the nitinol-containing fabric of the previous Ovation iX platform, repositioning the maximum diameter of the proximal sealing ring 7 mm below the lowermost renal artery.<sup>6</sup> The key-point in the Alto design is the inflation of a compliant balloon integrated in the delivery system to accomplish the deployment of the sealing rings and their optimal apposition immediately after the polymer filling. The accommodation of the sealing rings immediately below the renal arteries provides the shortest sealing zone for EVAR, thus broadening the indications to include more complex AAA.

There is only scarce data in the current literature focusing on the applicability and technical success of the new Alto design. The recently published data by Holden and Lyden report excellent technical success, yet in AAA with an adequate length to the infrarenal neck of 11 to 35 mm.<sup>6</sup> Additionally, de Donato et al<sup>7</sup> documented satisfying technical results with the use of the new Ovation Alto platform in 11 AAA cases, mainly with short necks  $\leq 10$  mm. The aim of this manuscript is to analyze the unique technical features of this innovative endograft design and discuss their applicability to

some AAA anatomies whose treatment presents a surgical challenge.

## Materials and Methods

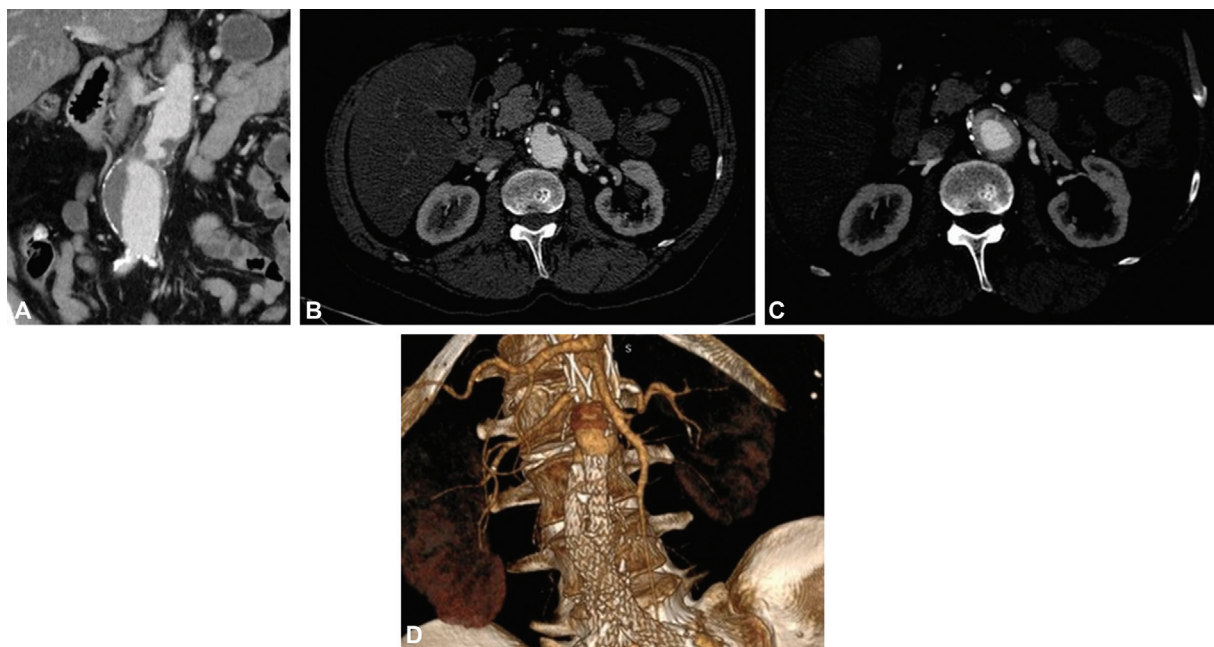
We demonstrate four representative examples of challenging AAA where the use of Ovation Alto offers a promising solution confronting anatomical issues not amenable to standard Nitinol-based endografts. The treated AAA were chosen at the authors' discretion, representing cases of challenging anatomies reaching or falling outside the IFU of other endografts.

Informed consent has been obtained from all patients for publication of the cases and the accompanying images. This study was conducted in accordance with the ethical standards of the institutional and national research committees and in accordance with the 1964 Helsinki Declaration. The internal scientific review committee approved the aim and methodology (retrospective review of surgical records).

## Case Presentation

### Case 1

A 63-year-old male patient presented with a 52-mm AAA (**►Fig. 1A**) with a 30-mm wide neck at 7 and 10 mm below the lowermost renal artery (**►Fig. 1B**) with an infrarenal angulation of 54 degrees. The patient was treated with a 34 mm Alto endograft with a distal diameter of the right and left iliac limbs of 18 and 14 mm, respectively. The 1-month follow-up computed tomography angiography (CTA) documented completely adequate postoperative sealing (**►Fig. 1C**) and absence of endoleaks (**►Fig. 1D**).



**Fig. 1** (A) Case 1 aneurysm with wide neck. (B) The proximally angulated infrarenal neck at 10 mm below the renal level. (C) Efficient sealing relies on the adjusted apposition on the conical neck irregularities. (D) The postoperative computed tomography angiography at one month shows efficient apposition of the inflatable rings at the sealing level, with no endoleaks.



**Fig. 2** The juxtarenal aortic aneurysm of case 2. The arrowhead shows the pair of sealing rings accommodated against the thrombus surface in this computed tomography with IV contrast.

### Case 2

A 71-year old female presented with a juxtarenal AAA of 55 mm. The infrarenal neck was aneurysmatic starting immediately below the renal arteries. The external diameter (outer-to-outer) of the neck at the level 7 mm below the lowermost renal artery was 3.3 to 3.7 mm. Interestingly, due to the heavy intraluminal thrombus burden, the true lumen dimensions were estimated 1.9 to 2.5 mm. It is crucial to delineate that the sizing philosophy of the Ovation sealing rings takes into account the lumen diameter plus half the

thrombus thickness on both sides but to a maximum value of 2 mm. Hence the patient was treated with a 26-mm endograft, achieving excellent intraoperative sealing at completion angiography, as well as in the 1-month postoperative CTA (►Fig. 2).

### Case 3

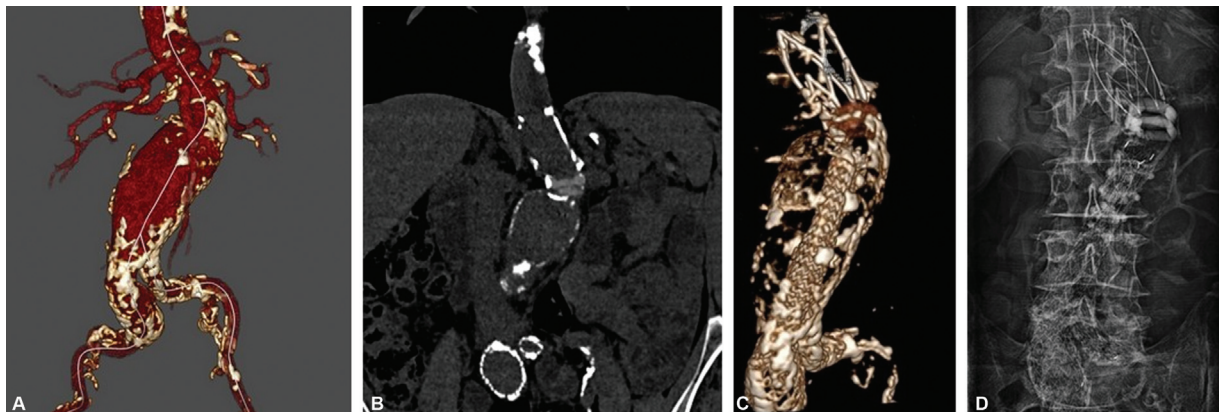
A 66-year-old male patient was admitted with a 53-mm AAA of angulated and short neck of 10-mm length and 26-mm diameter (►Fig. 3A). The patient was treated with a 29 mm Ovation Alto. The radiopaque inflatable rings showed excellent conformability on the short angulated infrarenal neck (►Fig. 3B–D) and proper sealing in the 1-month postoperative CTA.

### Case 4

A 66-year-old male patient was admitted with a 53mm AAA of conical (reverse tapered) neck with neck diameter increasing from 20 mm immediately infrarenally to 23 at 10 mm below the lowermost renal artery (►Fig. 4A). The patient was treated with a 26-mm Ovation Alto. The radiopaque inflatable rings showed excellent conformability on the irregular neck surface and efficient sealing in the 1-month postoperative CTA (►Fig. 4B).

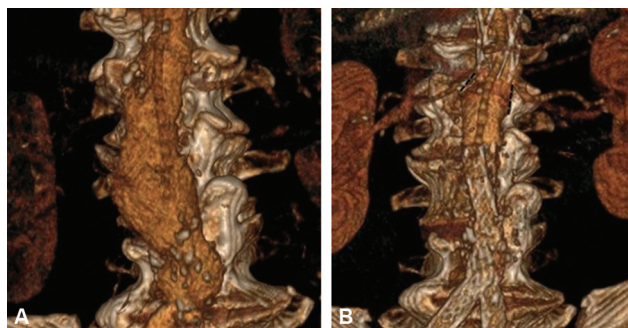
## Discussion

While certain anatomical parameters, that is, neck angulation, short length, and wide diameter are well documented to limit the successful sealing and/or its long-term preservation, the term “hostile neck” is still ill-defined, since other parameters, such as the morphology of infrarenal neck, the percentage of calcification, and the thickness/circumference of intraluminal thrombus have not been adequately delineated. The role of neck thrombus is quite ambiguous, although a multivariate analysis in a study group from the ANCHOR registry identified a potential risk for neck thrombus based on its thickness and circumference >11 degrees.<sup>8</sup> While a combination of the aforementioned parameters can



**Fig. 3** (A) The short-necked aneurysm of case 3. Note the infrarenal angulation of the neck. (B) Coronal plane of the 1-month no-contrast postoperative follow up, showing the accurate apposition of the sealing rings immediately infrarenally. (C) The lack of any fabric zone between the proximal bare stent and the sealing rings does not restrict the flexibility of the endograft to adjust efficiently in this short and angulated neck. (D) The endograft adapts efficiently to the curvature between the supra- and infrarenal angulation despite the long proximal stent and the short main body.





**Fig. 4** (A) The aortic aneurysm of the fourth case with reverse tapered neck. (B) The pair of sealing rings in the 1-month postoperative follow-up accommodating perfectly in the conical neck configuration (dashed lines).

be associated with intraoperative challenges and adverse effects, the Alto unique sealing philosophy surpasses these reservations, challenging the aforementioned traditional definitions.

While the initial indication for Alto refers to short necks, a careful appreciation of its sealing mechanism and the perception of the exact apposition sites of the inflatable rings may further prove beneficial for other anatomical constraints. The ability of gradually inflated rings that accommodate perfectly onto noncylindrical lumen appears ideal for conical-shaped necks, an anatomical feature associated with proximal failure of other conventional endografts.

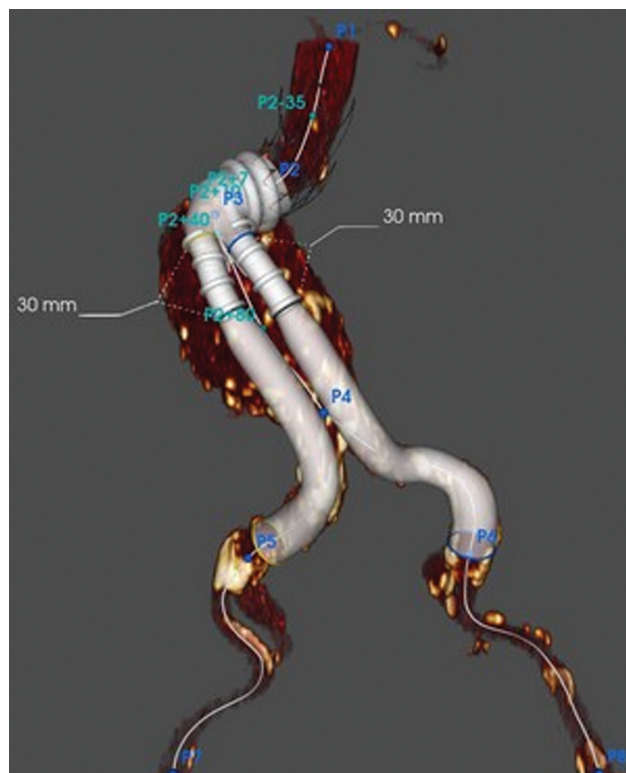
The unique Alto design may also prove beneficial in cases of wide necks  $\geq 30$  mm, which comprise an independent risk factor for neck-related adverse events even in midterm follow-up, with endoleak Type 1a being predominant. Since the causes of post-EVAR aortic neck dilatation have not been recognized, factors such as the nitinol-based continuous radial force have been implicated along with the degree of graft oversizing and the ongoing degenerative aneurismal process. While none of these has been identified to be a dominant and independent factor, it seems yet that the wide necks are affected to a greater degree from the aforementioned and have a greater rate of dilatation over time. Notably, although there has been no strong association with this regard in the literature, a short neck correlates more likely with wider neck diameter. Therefore, a new concept of more proximal sealing with minimal radial force provided by Alto seems appealing also for wide necks. Most importantly, the unique concept and advances of the Ovation Alto can be an alternative to the more technically demanding solutions of fenestrated EVAR and parallel grafts for certain juxta or pararenal AAA.

Typically, the new Alto design is currently the only endograft approved for AAA with necks  $\geq 7$  mm. Notably, in conical neck configurations, as defined by  $>10\%$  difference in neck diameter from the inferior renal artery to the level 7 mm caudally or a gradual neck dilation  $>2$  mm (reverse taper anatomy), or “barrel-shaped” neck shapes, the neck diameter measurements may not apply to a unique endograft size; for example, a neck diameter discrepancy from 22 mm at the renal level to 24.5 mm at 7 mm caudally applies

to the 26- and 29-mm endograft size, respectively. Hence, it is imperative that the physician studies thoroughly the apposition sites of the rings to choose the optimal endograft size.

Technically, since the use of the Alto platform is applied in very challenging necks with, by definition, short necks and irregular shapes, it is imperative to ensure that the apposition and inflation of the sealing rings will be conducted in the exact proper position, leaving practically no place for the slightest misplacement. Normally, the configuration of infrarenal neck can be straightened due to presence of super-stiff guidewires, leading to polymer infusion and sealing in a neck shape that will be altered after removal of the guidewires with consequent loss of any marginal sealing. Therefore, it is preferred to withdraw the super-stiff guidewire supporting the endograft until its soft proximal end approaches the nose cone of the delivery system. This maneuver facilitates the ring's inflation in a “neutral” infrarenal neck, avoiding any postoperative tension and strain on the neck surface.

Caution should be paid when using Ovation Alto in AAA with significant suprarenal and infrarenal angulation due to the short length of the endograft's main body, especially if the caudal end of the unsupported fabric segment and the origin of the iliac limbs gates are to be located at the verge of significant angulation, predisposing to kinking (**Fig. 5**). Therefore, additional caution may be needed when treating AAA of short and angulated necks with Ovation Alto.



**Fig. 5** Representation of deployment of Ovation Alto in an abdominal aortic aneurysm with significant infrarenal neck angulation. The narrow distance between the unsupported main body and the limb gates can lead to positioning of the latter at a site of steep angle, predisposing to kinking.

Certain points uniquely related to the Ovation platform should be taken into consideration: while the outer-to-outer wall diameter determines the size in Nitinol-based endografts, the Ovation graft is also influenced by the lumen diameter and the thrombus thickness as well (i.e., the lumen diameter plus half the thrombus thickness on both sides but not exceeding a maximum value of 2 mm). Given that the thrombus layers are not of equal density or mechanical properties, the Ovation size achieves optimal apposition of the rings against a partially compressed thrombus. These tactics, along with the quite immediate origin of sealing rings below the suprarenal stent, enable the application of Ovation Alto to para- or juxtarenal AAA, as in case 2, where the sealing relies exclusively on the positioning onto the thrombus surface (→ Fig. 2), since the typical infrarenal sealing zone can be absent, short, and/or wide and carrying a significant burden of intraluminal thrombus. In such off-label cases, the use of Ovation Alto is very ambitious and challenging, especially when taking into consideration that the current guidelines of the European Society for Vascular Surgery dictate the fenestrated approach for juxtarenal or pararenal AAA, leaving as a bailout solution the option of parallel grafts (periscope/chimney technique), as long as these are limited to a maximum of two parallel grafts. Long-term results on the durability of this Ovation Alto sealing concept are mandatory to confirm whether this management of complex AAA comprises a fair alternative.

As previously described in the literature, a great concern associated with the use of Ovation in EVAR remains the limitation and applicability of solutions to manage central endoleaks, since the stiffening of the sealing rings precludes the effective use of central cuffs or stents due to the polymer solidification. The sealing agents most effectively used are glue and coil embolization for Type-Ia endoleaks. Therefore, especially with the new Ovation platform, the best way to manage such a complication is avoiding creating it, by careful selection of patients and very meticulous preoperative planning with a thorough identification of the sealing sites.

## Conclusion

The Ovation Alto design is the evolution of previous Ovation platforms relocating the unique polymer-filled sealing rings more proximally and omitting the nitinol-containing zone in-between, enabling treatment of AAA with short or conical-shared necks. While the initial FDA-approved indication

is strictly limited to AAA with proximal parallel necks of length  $\geq 7$  mm with angulation  $\leq 60$  degrees, other neck irregularities or challenging anatomies such as wide diameter  $\geq 28$  mm or juxtarenal morphologies could be hypothetically addressed with the new design in carefully selected patients by experienced physicians.

### Funding

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### Conflict of Interest

The authors declare no conflict of interest related to this article.

### Acknowledgments

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