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Outcomes of Endovascular Aneurysm Repair using the Ovation Stent Graft System in Adverse Anatomy

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WHAT THIS PAPER ADDS

The Ovation stent graft has broader instructions for use (IFU) than traditional endograft platforms and is known to be effective in abdominal aortic aneurysm exclusion in the short term. This retrospective study demonstrates that this effect is extended into the midterm even in aneurysms with adverse anatomical characteristics. Based on its design, the range and complexity of aneurysms that can be treated with standard infrarenal EVAR is increased.

Objective: The aim was the evaluation of mid-term efficacy and safety outcome measures for the Ovation (Endologix, Santa Rosa, CA, USA) stent graft system in the management of infrarenal abdominal aortic aneurysms (iAAA) with adverse anatomy.

Methods: A retrospective observational study of all patients undergoing elective iAAA repair was carried out from 2012 to 2017 using Ovation Prime or iX stent grafts with a minimum of 3 months follow-up at a single UK vascular centre. Post-operative surveillance involved computed tomography scans at 3 months and 1 year, with duplex ultrasound yearly thereafter. Outcome measures were established with retrospective analysis of pre- and post-operative imaging, and included peri-operative mortality, major adverse events, limb complications, aneurysm diameter change, and endoleak rates. All patients were within Ovation instructions for use (IFU), and assessment was made to determine whether aneurysms had anatomical features considered adverse for other commonly used stent graft platforms.

Results: Ovation stent grafts were implanted in 52 patients (79% male, mean age 75.7 years) with a mean aneurysm diameter of 62.5 mm (range 55–107 mm). There was 100% technical deployment success. The 30 day mortality was 0% and there was no aneurysm related mortality during follow-up (median 24 months, range 3–48 months). There were no type I or III endoleaks, but 19% developed type II endoleaks with one patient requiring re-intervention. No iliac limb occlusions were identified but one case required relining for limb kinking. All 52 cases were within the IFU for Ovation but only 12% met the IFU criteria for the Cook and Medtronic devices.

Conclusions: The mid-term experience with Ovation demonstrates safe, durable treatment of iAAAs, including those with unfavourable anatomy, frequently off IFU for other commonly used devices.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) has become the treatment of choice in the management of most infrarenal abdominal aortic aneurysms (iAAAs).[1,2] The ratio of EVAR to open repair has increased, with the UK National Vascular Registry recording 4198 iAAA repairs in 2015 of which 69% were EVAR and 31% open surgery.[3] However, many cases remain anatomically unfavourable for EVAR because of hostile neck sealing zones and narrow or tortuous iliac access vessels.[4–10] The Human Aortic Anatomy Project studied computed tomography (CT) scans of 1063 iAAAs and found neck length less than 15 mm in 47% of men and 63% of women.[2,11] Furthermore, only 32% of men and 12% of women met the classical EVAR instructions for use (IFU) criteria (infrarenal neck angulation $\leq$ 60°, neck length $\geq$ 15 mm, infrarenal neck diameter 18–32 mm, and iliac access diameter $\geq$ 6 mm). EVAR in the 68% of unsuitable patients would be considered off IFU, which often requires more adjunctive procedures to achieve a proximal seal.[2] In such cases there is a twofold increased risk of 30 day morbidity and fourfold increased risk of type I endoleak related mortality within 1 year.[2,12,13] Furthermore, progressive dilatation of the infrarenal aneurysm neck has been reported after EVAR.[14–17] This is likely to represent ongoing

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disease progression but is contributed to by the chronic outward radial force exerted by nitinol within stent grafts. Thus the very essence of conventional stent graft fixation contributes to its failure, resulting in late stent migration and type I endoleaks, necessitating re-intervention. Hence there remains a clinical need for continued advances in stent graft technology that can accommodate a wider range of aortoiliac morphology to extend the IFU criteria and offer sustained iAAA exclusion.[1]

The Ovation stent graft system (Endologix, Santa Rosa, CA, USA) is a trimodular endoprosthesis for treatment of iAAA that is delivered through a 14F system (Fig. 1).[1,2] Unlike traditional devices that use self-expanding Nitinol to generate chronic outward radial force in order to fix and seal the stent graft in position, the Ovation device uncouples these two processes.[2] Fixation is achieved suprarenally with 35 mm long rigid nitinol anchoring stents that fix the device at the level of the superior mesenteric artery (SMA), where aortic tissue is considered "healthier" and at lower risk of subsequent dilatation. Sealing occurs via a series of inflatable channels and rings in the main body which is otherwise free of metal and made of PTFE. During deployment, these channels are filled with a low viscosity, radiopaque polymer that cures in situ in order to conform to patient specific aortic neck anatomy.[1] The sealing rings create circumferential apposition 13 mm below the lowest renal artery with minimal chronic outward radial force that isolates the aortic neck from the effects of sustained systolic blood pressure thereby preventing dilation over time.[14] These characteristics expand the range of anatomy that can be treated to include aneurysms that would be considered unfavourable for traditional device platforms.

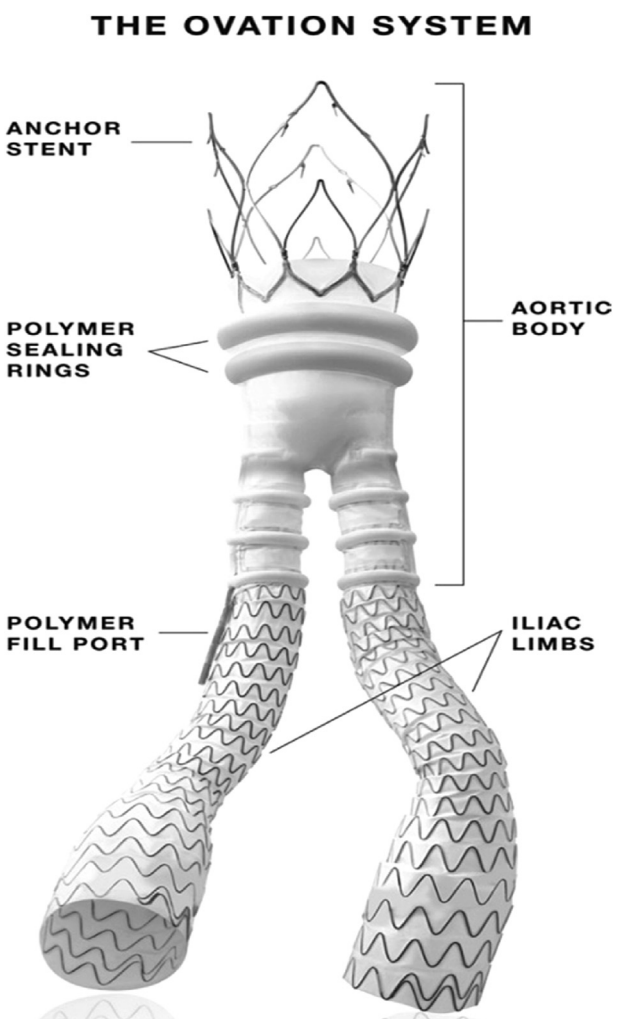

Figure 1. Image of deployed Ovation stent graft system (sourced from http://getfilings.com/sec-filings/150309/TriVascular-Technologies-Inc_10-K/).

Ovation was identified as a device that enabled off the shelf EVAR in the presence of hostile anatomy that would in some circumstances require off-IFU use of traditional infrarenal devices or complex EVAR. This retrospective study assesses mid-term clinical outcomes after EVAR with the Ovation stent graft in a large case series over 5 years in a single UK institution.

METHODS

All patients undergoing elective iAAA repair from 2012 to February 2017 at a single UK institution (Wythenshawe Hospital, Manchester, UK) using Ovation Prime and iX stent grafts with a minimum of 3 months follow-up were included in the study. The study end date for follow-up was July 6, 2017.

Eligible patients meeting inclusion criteria (Supplementary Table 1) for elective iAAA intervention and Ovation IFU underwent routine work up, including cardiopulmonary exercise testing. Every case was discussed in a multidisciplinary team meeting before a final decision on treatment modality was reached. Cases with standard aneurysm anatomy were treated according to the discretion of the operating vascular specialist. Conversely, treatment with Ovation was considered for cases with challenging anatomy; those outside the IFU were treated by alternative means. Hostile aneurysm anatomy was considered to include: infrarenal neck angulation $\geq 60^{\circ}$, neck length ≤ 15 mm, infrarenal neck diameter ≤ 18 mm or ≥ 32 mm, iliac access diameter ≤ 6 mm, significant thrombus or calcium load at the aortic neck, unfavourable neck shape, for example conical. Devices were implanted by a consultant vascular surgeon and a consultant interventional radiologist working together.

Retrospective analysis of pre- and post-operative CT angiogram and duplex imaging was used to establish defined outcome measures. All measurements were performed using Syngo Via multiplanar reconstruction software (Siemens Healthcare Limited, Camberley, UK) or with duplex ultrasound in the Vascular Studies department of Wythenshawe Hospital. Syngo measurements were performed by three assessors separately and the results averaged. Any significant discrepancies in measurements were reviewed by the group collectively before a final decision was made.

All EVAR patients at the institution had routine post-operative follow-up via arterial phase computed tomography (CT) at 3 months and 1 year, and annual duplex ultrasound thereafter. Additional CT $\pm$ contrast enhanced duplex

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