**Selected Technique**

“"Aortic Balloon Molding"” during Ovation Endograft Implantation Expands Graft Use for Hostile Neck Anatomy

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**Background:** Challenging aortoiliac anatomy such as short neck and narrow access vessels is responsible for endovascular repair of abdominal aortic aneurysm (EVAR) ineligibility in up to 50% of cases. The Ovation stent graft helped widen the range of abdominal aortic aneurysms (AAAs) suitable for EVAR thanks to its low-profile delivery system and polymer-filled sealing rings. However, its advantages are offset by a tight sizing chart that can lead to increased risk of type Ia endoleak or endograft infolding from under- or oversizing, respectively. We sought to assess the safety and efficacy of a novel endovascular technique developed to expand the use of the Ovation endograft while avoiding these issues.

**Methods:** We conducted a retrospective review of all patients who underwent EVAR with the Ovation endograft at our institution between March 2019 and December 2020. ""Aortic Balloon Molding"" or ABM is a novel endovascular technique in which the graft is pre-cannulated and a compliant aortic balloon is inflated at the site of the graft’s sealing rings during polymer administration. The technique was preferentially performed in patients with hostile neck anatomy (HNA) defined as any or all of angulation > 60°, reverse taper configuration, > 50% circumferential thrombus, or calcification. Patients undergoing traditional deployment were compared to those in whom ABM was performed. End points included neck-related adjunctive procedures, technical success, type Ia endoleak at completion angiogram, and 1-year freedom from type Ia endoleak and migration.

**Results:** A total of 43 patients were included in the study, of which 26 (60.5%) were treated with the ABM technique. Mean follow-up was 7.9 ± 6 months. Patients in the ABM group were more likely to have a reverse taper neck (61.5% vs. 41.2%, \( P = 0.1 \)), have significant circumferential thrombus or calcium (23.1% vs. 5.9%, \( P = 0.1 \)), and be treated outside of the Ovation indications for use regarding anatomic characteristics (65.4% vs. 41.2%, \( P = 0.1 \)). Technical success was achieved in 100% of cases. However, patients in the ABM group were less likely to require a neck-related adjunctive procedure (7.7% vs. 23.5%, \( P = 0.1 \)). Only 1 type Ia endoleak was observed at completion angiogram in a patient treated without ABM. At 1 year, freedom from type Ia endoleak or migration was 100% for both groups.

**Conclusions:** ABM proves to be a safe and effective adjunctive technique for the treatment of AAAs with HNA using the Ovation stent graft. This may allow optimal endograft sizing to achieve adequate seal in complex aortic anatomies. Further research is warranted to evaluate the long-term outcomes of this technique.

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INTRODUCTION

The Endologix Ovation Abdominal Stent-Graft System is an FDA-approved device to treat abdominal aortic aneurysms (AAAs). It consists of a trimodular endograft with an aortic body and 2 iliac limbs. The graft has several key features—notably, it achieves fixation and sealing in independent locations on the graft. Fixation is achieved at the abdominal aorta using suprarenal stent anchors, while seal is achieved through an inflatable sealing ring that is filled with polymer. This innovative proximal sealing mechanism in part explains Ovation’s broader applicability for endovascular repair of abdominal aortic aneurysms (EVAR) when compared to other devices regarding anatomic requirements at the aortic neck. The Ovation endograft also has the lowest profile among the current options for EVAR, which makes it ideal for patients with unfavorable access site anatomy including small common femoral arteries or tortuous iliac arteries who would otherwise not be candidates for endovascular repair. Overall, the Ovation stent graft has seen success in early, mid, and long-term safety and efficacy end points.

Despite these features that make the Ovation endograft highly favorable, particularly in the setting of hostile neck anatomy (HNA) and unfavorable access site vasculature, there are several challenges that we have observed either in the literature or in our experience with the endograft. First, Ovation has the tightest sizing matrix among the currently available endograft options, meaning there is little room for variations in sizing. This can be challenging because undersizing increases the risk of type 1a endoleak (EL), while oversizing increases the risk of infolding within the graft, also risking a type 1a EL. Second, there are risks associated with the inflatable ring system for endograft sealing. These risks include immediate or late type 1a EL due to sizing issues, aortic stenosis, and ring rupture with leak of polymer at the time of repair. These kinds of issues can require neck-related adjunctive procedures such as ballooning, stenting, or graft extension either at the time of initial repair or in a delayed fashion, or graft explantation.

In the current study, we sought to address these challenges with a novel technique called “Aortic Balloon Molding” or ABM. In this technique, an oversized device is used and a balloon is inflated at the site of the sealing polymer rings to reinforce the seal by ensuring adequate apposition of the rings to the aortic wall and preventing pleating of the graft. We hypothesize that the use of ABM allows for more forgiveness in endograft sizing, decreases the risk of type 1a EL, and decreases the need for neck-related adjunctive procedures during EVAR in patients with HNA. In this study, we sought to evaluate the ABM technique for safety and early efficacy.

METHODS

Study Design and Setting

We performed a retrospective review of a prospectively maintained database of all patients who underwent EVAR with the Ovation TriVascular endograft between January 2019 and December 2020 at the University of California San Diego Sulpizio Cardiovascular Center or the San Diego Veterans Affairs Hospital under an institutional review board–approved protocol. Patients were followed with the goal of using computed tomography (CT) scans at set intervals per the Society of Vascular Surgery practice guidelines.

Study Eligibility Criteria

Patients undergoing standard deployment were compared to those in whom ABM was performed. The ABM technique was used more often in patients with HNA defined as any or all of the following: (1) angulation ≥60 degrees, (2) juxtarenal/reverse taper configuration with shorter than 7-mm parallel neck, and (3) >50% circumferential thrombus or calcification, similar to definitions by previous studies. Reverse taper was defined as gradual neck dilatation ≥2 mm within the first 10 mm after the most caudal renal artery in accordance with previous reports (Fig. 1). Additionally, the technique was considered in patients in whom a larger graft was chosen when the suggested graft diameter was on the border between 2 sizes. Patients with thoracoabdominal aortic aneurysm, pararenal AAA, or large common iliac aneurysm requiring EVAR were excluded from the study. Patients with ruptured aneurysms were also excluded. The attending of record made the final determination about whether to use the ABM technique.

Endovascular Technique

The ABM technique is utilized after graft deployment and before administration of the polymer.
1. The single oversized Endologix TriVascular Ovation iX Endograft is advanced into the aorta per the device’s indications for use (IFU).

2. To start the ABM process, a wire is snared from the contralateral limb using the up-and-over lumen. Usually, a 0.014-inch Nitrex wire is used (Fig. 2).

3. Next, a catheter is introduced and advanced to the end of the contralateral lumen.

4. Then a buddy wire is introduced up the contralateral lumen. We use a 0.018-inch Nitrex wire for added stiffness later in the procedure.

5. An angled catheter is spun within the aortic lumen and up through the uncovered stent to ensure intraluminal location.

6. This is then exchanged for a stiff wire.

7. A 12-French sheath is then advanced over the stiff wire and then a compliant balloon is placed at the level of the polymer sealing rings. We use a 32-Coda balloon through the 12-French sheath.

8. Once the balloon is in place at the site of the sealing polymer rings, a balloon test is performed to again ensure true lumen location of the balloon, looking for inappropriate deformation of the uncovered stent.

9. Once confirmed, the balloon is inflated up to the arterial wall and the polymer is infused. Shouldering, or flattening of the rings against the wall of the aorta, can be observed on fluoroscopy, indicating a longer length of ring contact with the aortic wall and better apposition to the wall (Fig. 3). The balloon remains inflated for a total of 13 min, the duration of polymer curing. Figure 4 shows a few examples of final polymer ring positioning on angiogram.

10. The balloon is then removed and the remainder of the procedure is performed according to IFU with extension of both limbs to the hypogastric arteries.

Figure 5 shows some representative angiographic images of key steps of the procedure. Figure 6 shows follow-up computed tomographic images of the same patient represented in Figure 5. Figure 6 demonstrates the smooth nature of the rings with a uniform thickness throughout the full circumference and no pleats, infolding, or aortic stenosis from the rings, which can be seen with the smaller sized Ovation grafts. We chose not to perform any other intraoperative imaging as we did not feel that this would add to the study but would increase costs.

End Points

The primary end point was use of a neck-related adjunctive procedure including proximal aortic cuff, unplanned snorkel, Palmaz stent, or high-pressure balloon angioplasty as a composite end point. The use of a neck-related adjunctive procedure was determined based on a retrospective review of operative reports and any follow-up procedures. Secondary end points included operative time, contrast use, technical success, type 1a EL at completion angiogram, and 1-year freedom from type 1a EL and stent migration. Operative time, contrast use, technical success, and type 1a EL at completion angiogram were determined based on a retrospective review of operative reports. Technical success was defined as successful delivery and deployment of the endograft, without unintentional coverage of renal or visceral arteries, followed by successful removal of the delivery system, and the absence of either a type I or type III (high pressure) EL. One year freedom from type 1a EL and stent migration was determined based on follow-up CT scan approximately 1 year after the initial procedure. All main body devices used in the ABM group were oversized compared to IFU sizing.

Statistical Analysis

Continuous and categorical covariates were analyzed using Student’s t-test, medians, Fisher exact test, and χ² test as appropriate. Event-free survival rates were estimated using Kaplan-Meier
methods. Due to the small sample size and exploratory nature of the analyses, we adopted the previously established convention of using a *P*-value of ≤0.1 for significance. Statistical analysis was performed using Stata/SE 16 software (StataCorp LLC, College Station, TX).

**RESULTS**

**Baseline Characteristics**

A total of 43 patients were included in the study, of which 26 (60.5%) were treated with the ABM technique. Mean follow-up was 7.9 ± 6 months. Patients in the ABM group were more likely to have hypertension (88.5% vs. 64.7%, *P* = 0.06) compared to the patients who underwent standard deployment. Other medical comorbidities were similar between the 2 groups with higher rates across the board for the ABM group, though none reaching statistical significance. Patients in the ABM group were slightly more likely to have all of the following: coronary artery disease (42.3% vs. 23.5%, *P* = 0.2), chronic obstructive pulmonary disease (26.9% vs. 11.7%, *P* = 0.2), chronic kidney disease (30.7% vs. 17.6%, *P* = 0.3), and congestive heart failure (15.4% vs. 5.9%, *P* = 0.3). The baseline characteristics are illustrated in Table I.

**Anatomic Characteristics**

Patients in the ABM group were more likely to have a reverse taper neck (61.5% vs. 41.2%, *P* = 0.1), a shorter parallel neck (14.6 ± 17 mm vs. 28.4 ± 21 mm, *P* = 0.02), significant circumferential thrombus or calcium (23.1% vs. 5.9%, *P* = 0.1), and to be treated outside of the Ovation IFU regarding anatomic characteristics (65.4% vs. 41.2%, *P* = 0.1). About 30% of the patients in the ABM group treated off IFU were cases where the parallel neck below the

![Fig. 2. Up-and-over snare. (A) This image is an illustration of the up-and-over technique in which a wire is snared from the contralateral limb using the up-and-over lumen, depicted in purple. This is performed after graft deployment and before administration of polymer. (B) This image shows the wire orientation on angiogram.](image)
renal arteries was <7 mm and an upsized graft was used. Thirty percent was due to landing in a previous endograft for relining. The last 40% was a combination of short neck and high angulation or short neck and relining endograft with a larger graft used. There were no statistically significant differences in AAA diameter, neck diameter, or angulation. Anatomic characteristics are detailed in Table II.

**Main Outcomes**

Intraoperative outcomes revealed no differences in the average operative time (236 ± 78 min vs. 251 ± 75 min, *P* = 0.54) between the 2 groups. There was a significant increase in contrast use in the standard EVAR group when compared to the ABM group (183 ± 52 mL vs. 112 ± 47 mL, *P* < 0.001) likely due to more injections trouble shooting proximal leaks. Technical success was achieved in 100% of cases. However, patients in the ABM group were less likely to require a neck-related adjunctive procedure (7.7% vs. 23.5%, *P* = 0.1). Only 1 type Ia EL was observed at completion angiogram in a patient treated without ABM. At 1 year, freedom from type Ia EL or migration was 100% for both groups. Outcomes are listed in Table III.

**DISCUSSION**

The Endologix Ovation stent graft has filled several anatomic niches thus far in the literature, likely due to its unique polymer ring sealing mechanism and low-profile delivery system. These features address the 2 most common reasons for EVAR ineligibility, HNA followed by inadequate access site vasculature. HNA in particular, poses significant challenges in EVAR patients due to increased technical difficulty and worse short-term outcomes. AbuRahma et al. found that reverse taper configuration was associated with early type 1a EL, and reverse taper configuration and short neck length were associated with aortic cuff use—a common neck-related adjunctive procedure. Additionally, Pitoulias et al. found that a reverse taper configuration was the best predictor of proximal EVAR

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**Fig. 3.** Polymer ring sealing with balloon technique. (A) This image shows the balloon inflated up to the wall of the aorta after a balloon inflation test to confirm intraluminal location by looking for stent deformation. (B) This image shows filling of the ipsilateral gate and the beginning of ring filling. (C) This image shows further ring filling with polymer, shouldering of the rings against the aortic wall, and aortic lumen preservation with the balloon inflation. (D) This image shows filling of the contralateral gate and shouldering of the rings up against the wall of the aorta just prior to balloon deflation.
failure. Women pose an additional challenge as they tend to have more challenging common femoral, iliac, and aortic anatomy, often rendering them ineligible for EVAR.\textsuperscript{19,20} However, a recent study by Ash et al.\textsuperscript{21} suggests that despite their more complex anatomy, women had comparable procedural and perioperative outcomes at 1 year following EVAR with the low-profile Ovation stent graft. Additionally, Varkevisser et al.\textsuperscript{22} used the ENCORE database and found similar 5-year freedom from type 1a EL

Fig. 4. Angiogram images with final ring position. This figure illustrates representative angiogram images of final ring positioning from 3 different angles and highlights a lack of infolding, aortic lumen preservation, and shouldering of the rings against the aortic wall.

Fig. 5. Pre- and postoperative representative imaging. (A) This image shows the initial angiogram with irregularities in the neck as well as conicity. (B) This image shows the “up-and-over” wire technique. (C) This image shows the contralateral catheter advanced up the aortic lumen and polymer filling the rings. (D) This image shows the completion angiogram.
between men and women using the Ovation endograft, despite more challenging neck anatomy in women. Overall, studies have suggested that use of the Ovation endograft device expands the range and complexity of AAAs that can be treated with endovascular repair.2,23

Despite these successes, the device does present its own set of challenges given its tight sizing matrix and potential issues with polymer ring seal. The ABM technique was implemented using oversized grafts to address both these challenges in the hope of being able to increase patient device eligibility further by expanding endograft use in more HNA. In our study, the patients who were treated with ABM were more likely to have challenging neck anatomy including reverse taper neck and short neck length, and were more likely to be treated off IFU regarding anatomic characteristics, yet our results suggest equivalent outcomes to non-ABM patients, despite the aforementioned challenges. This would suggest that the ABM technique further broadens the range of aneurysms that can reasonably be treated with endovascular repair using the Ovation endograft and allows for off IFU outcomes to come close to if not mimic on IFU outcomes in patients with HNA. The increased requirement of secondary neck-related interventions in the non-ABM group could also explain the increased use of contrast in these patients. Additionally, despite the added procedural steps for the ABM group, there was no difference in operative time between the groups and no complications secondary to the added steps of the procedure, including polymer leak.

On May 6, 2020, Endologix issued a recall of the Ovation iX citing risks of polymer leaks during implantation.24 These leaks had previously been thought to be due to incorrect use of the device; however, the manufacturer later cited material weakness as the cause of polymer leak. Following further study and modification of the materials, risks have been mitigated, but physicians are encouraged to factor the risk of polymer leak into determination of device selection.24 Interestingly, no polymer leak was noted in either arm of this study. Endologix’s newer device on the market, Alto, is thought to

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Fig. 6. Postoperative CT imaging. These images represent postoperative images from the case depicted in Figure 5. (A) This image shows the sagittal view on postoperative CT scan. (B) This image shows an axial view of the aortic neck. (C) This image shows an axial view of the distal aneurysm, shrinking from the original size of 58 mm in maximum diameter, with visualization of both iliac limbs.

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rectify some of the issues found with the Ovation iX endograft, such as the material weakness previously described. The Alto device also includes an aortic balloon, which is used to open up the crown of the graft, but this could also be used in an aortic balloon modeling technique, similar to the ABM technique that we describe but without the need to precannulate. This could be performed by inflating the Alto graft’s balloon during the time of polymer ring seal. Its use is theoretically easier than the ABM technique as the built-in nature of the balloon limits the more complex and potentially time-consuming up-and-over snare and advancement of catheter and sheath through the contralateral lumen that is necessary for the ABM technique. We have also found this useful in rupture cases as the sheath, aortic occlusion balloon, and aortic main body are all in 1 delivery system. This allows for aortic occlusion below the renal arteries while polymer is being administered and curing. This study provides some early efficacy of the balloon technique that could be used with the Alto device. A future area of study could include defining outcomes for the Alto device using the ABM technique. A registry will assist with this for high-risk neck anatomy and rupture cases.

### Limitations

One of the limitations of the ABM technique described in this study is the complexity that this adds to an already complex procedure. Based on our statistical analysis however, there was no

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### Table I. Baseline characteristics

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>ABM (N = 26, 60.5%)</th>
<th>Standard EVAR (N = 17, 39.5%)</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>75 ± 7.8</td>
<td>74 ± 8.3</td>
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<tr>
<td>Female sex</td>
<td>2 (7.7)</td>
<td>3 (17.6)</td>
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<tr>
<td>Smoking history</td>
<td>17 (65.4)</td>
<td>11 (64.7)</td>
<td>0.9</td>
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<tr>
<td>Hypertension</td>
<td>23 (88.5)</td>
<td>11 (64.7)</td>
<td>0.06</td>
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<tr>
<td>Diabetes</td>
<td>5 (19.2)</td>
<td>5 (29.4)</td>
<td>0.44</td>
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<td>Coronary artery disease</td>
<td>11 (42.3)</td>
<td>4 (23.5)</td>
<td>0.2</td>
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<td>Chronic obstructive pulmonary disease</td>
<td>7 (26.9)</td>
<td>2 (11.7)</td>
<td>0.2</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>8 (30.8)</td>
<td>3 (17.6)</td>
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<tr>
<td>Congestive heart failure</td>
<td>4 (15.4)</td>
<td>1 (5.9)</td>
<td>0.3</td>
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Bold is significance regarding P-value.

### Table II. Anatomic characteristics

<table>
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<th>Anatomic characteristics</th>
<th>ABM</th>
<th>Standard EVAR</th>
<th>P-value</th>
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<tbody>
<tr>
<td>AAA diameter (mm)</td>
<td>60 ± 16</td>
<td>58 ± 8</td>
<td>0.6</td>
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<tr>
<td>Reverse taper neck, n (%)</td>
<td>17 (65.4)</td>
<td>7 (41.2)</td>
<td>0.1</td>
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<tr>
<td>Neck length (mm)</td>
<td>14.6 ± 17</td>
<td>28.4 ± 21</td>
<td>0.02</td>
</tr>
<tr>
<td>Neck diameter (mm)</td>
<td>21.3 ± 4</td>
<td>20.9 ± 2</td>
<td>0.6</td>
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<tr>
<td>Infrarenal angulation ≥ 60</td>
<td>3 (11.5)</td>
<td>2 (11.7)</td>
<td>0.9</td>
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<tr>
<td>Thrombus/calcification ≥ 50%</td>
<td>6 (23.1)</td>
<td>1 (5.9)</td>
<td>0.1</td>
</tr>
<tr>
<td>Off Ovation IFU</td>
<td>17 (65.4)</td>
<td>7 (41.2)</td>
<td>0.1</td>
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Bold is significance regarding P-value.

### Table III. Outcomes

<table>
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<th>ABM</th>
<th>Standard EVAR</th>
<th>P-value</th>
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<tr>
<td>OR time (min)</td>
<td>236 ± 78</td>
<td>251 ± 75</td>
<td>0.54</td>
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<tr>
<td>Contrast (mL)</td>
<td>112 ± 47</td>
<td>183 ± 52</td>
<td>&lt; 0.001</td>
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<tr>
<td>Technical success</td>
<td>100%</td>
<td>100%</td>
<td></td>
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<tr>
<td>Type Ia EL at completion</td>
<td>0 (0)</td>
<td>1 (5.9)</td>
<td>0.21</td>
</tr>
<tr>
<td>Neck-related adjunctive procedure</td>
<td>2 (7.7)</td>
<td>4 (23.5)</td>
<td>0.1</td>
</tr>
<tr>
<td>One-year freedom from type Ia EL</td>
<td>100%</td>
<td>100%</td>
<td></td>
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<tr>
<td>One-year freedom from stent migration</td>
<td>100%</td>
<td>100%</td>
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</tbody>
</table>

Bold is significance regarding P-value.
significant change in the operative time between the ABM and non-ABM groups, and technical success was seen in 100% of patients in both groups, potentially because the ABM group required fewer neck-related interventions. Despite some promising findings, our study is limited in that it is a retrospective review without a formal control group or power analysis. Although the ABM group was compared to the non-ABM group in the statistical analysis, patients were not randomized and there could be inherent differences between the group that are not accounted for. The study is also limited by small sample size. Additionally, surgeries were performed by multiple attending vascular surgeons at both University of California San Diego and the Veterans Affairs Hospital. Although this limits the consistency of data, it may also offer more generalizability of findings. Longer term outcomes may be a focus of future research.

CONCLUSION

ABM is a safe and effective adjunctive technique for the treatment of AAA with HNA using the Ovation iX stent graft. The technique may allow for optimal endograft sizing and eliminates some of the anxiety associated with the precise sizing matrix relative to other endografts. The technique also ensures adequate seal in complex aortic anatomy, particularly in patients who do not meet IFU criteria for endovascular repair. These findings serve as a precursor to the newer Ovation endograft, Alto, which has an aortic balloon built into the device and offers further improved patient eligibility based on recent data. Further research is needed to evaluate long-term outcomes of the ABM technique.

REFERENCES


