Health Policy Advisory Committee on Technology

Technology Brief

Ovation® Abdominal Stent Graft System

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Australian Safety and Efficacy Register of New Interventional Procedures – Surgical

Royal Australasian College of Surgeons

HealthPACT

emerging health technology

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Summary of findings

The Ovation® Abdominal Stent Graft System is a percutaneously deployed device developed for the endovascular repair of abdominal aortic aneurysms (AAA). It was first developed by TriVascular Inc. (California, United States of America) but was acquired by Endologix Inc. (California, United States of America) in February 2016. The Ovation Abdominal Stent Graft System has FDA premarket approval and a CE mark. The updated version of this device, the Ovation Prime® Abdominal Stent Graft System, which includes modifications to the delivery system, is listed on the Australian Register of Therapeutic Goods.

The Ovation Abdominal Stent Graft System represents an additive technology to the endovascular treatment of AAA as there are other stent grafts commercially available. The innovation of the Ovation Abdominal Stent Graft System is in its mechanism to seal the proximal end of the stent graft with the aorta; this involves a polymer-filled sealing ring as opposed to the self-expanding system of traditional wire and fabric stent grafts.

Outcomes from three case series, one prospective and two retrospective, on the Ovation Abdominal Stent Graft System are described in this Technical Brief. All three studies were multicentre; two, including the one prospective study, enrolled 161 patients and the third enrolled 36. Losses to follow-up were large for one of the studies which enrolled 161 patients (20% loss). Definitions used in the studies for similar outcomes differ, making summation of results difficult. Technical success was 100 per cent for two of the studies and 98 per cent for the third. One study reported a primary clinical success rate at two years of 95 per cent whilst another reported a 99 per cent treatment success rate at one-year follow-up. With respect to safety, the two studies with at least two year-follow up reported no deaths due to AAA complications, whilst the study with one-year follow-up reported a one per cent AAA-related mortality rate. No patients in any of the three studies required conversion to open surgery. Reinterventions were required in two studies (range of 5–6%), mainly for type I and type II endoleaks. The durability of the Ovation Abdominal Stent Graft beyond two years is not reported.

The prospective study with 161 patients reported several conflicts of interest including the sponsor of the study by TriVascular (the lead author was a speaker/consultant for TriVascular Inc. and three authors received honoraria from TriVascular Inc).

Seven clinical trials of the Ovation or Ovation Prime Abdominal Stent Graft System that are either recruiting or ongoing were identified. Several of these are post-market registry studies. No clinical trials were identified comparing the Ovation Abdominal Stent Graft System to another endovascular stent graft system for AAA.

HealthPACT Advice

The innovative nature of the Ovation® abdominal stent system makes it suitable for patients that would otherwise qualify for endoluminal management (i.e. high-risk surgical patients) but who have short infra-renal neck aortic aneurysms not treatable using standard endoluminal devices. When used in the appropriate group of patients, the Ovation® has demonstrated that it is safe; however endovascular treatment is more expensive than open surgery. Although modest savings in the length of stay and quality adjusted life years (QALYs) were reported, these gains were not offset by the cost of device.

HealthPACT therefore recommends that the Ovation® abdominal stent system should only be used in the small proportion of patients, with short infra-renal neck aortic aneurysms, who cannot be treated by other methods and who would benefit from this device. No further review of the evidence on behalf of HealthPACT is warranted at this time.

Technology, Company and Licensing

Register ID	**WP234**
Technology name	**Ovation® Abdominal Stent Graft System**
Patient indication	**For the treatment of abdominal aortic aneurysms in patients with aortic morphology that is suitable for endovascular repair**

Description of the technology

The Ovation Abdominal Stent Graft System (Figure 1) is an endovascular device used to treat abdominal aortic aneurysms (AAA). The device works by relining the diseased aorta and providing an alternative channel for blood to flow through. In doing so it isolates the aneurysm, protecting the weakened aortic wall from the high pressure of blood flow and thus reducing the risk of vessel rupture.[1]

Figure 1 Ovation Abdominal Stent Graft System (printed with permission from Getz Healthcare)

The Ovation Abdominal Stent Graft System is comprised of the following parts:

- An aortic body stent graft and delivery catheter
- Iliac limb stent grafts and delivery catheters
- Iliac extension stent grafts and delivery catheters, as required
- A fill polymer kit
- An autoinjector.[1]

The aortic body of the Ovation Abdominal Stent Graft System is delivered by a flexible catheter (delivery system outer diameter: 14–15Fr). It consists of a low-permeability polytetrafluoroethylene (PTFE) graft (proximal diameter 20–34 mm) and a suprarenal nitinol stent with anchors to enable its fixation to the aortic wall. The aortic body has inflatable channels and sealing rings that are filled during deployment with a low-viscosity, radiopaque polymer (polyethylene glycol) that sets in place to create a seal with the patient's aortic neck. The iliac limbs of the Ovation Abdominal Stent Graft System consist of flexible nitinol

stents covered with low-permeability PTFE packaged in small diameter (13Fr to 14Fr outer diameter) delivery systems.[2]

Deployment of the Ovation Abdominal Stent Graft System is performed under local, regional or general anaesthesia and usually takes about one to two hours. The procedural steps are as follows:

1. A small incision is made in the groin area to access the femoral arteries (selected cases can be performed percutaneously with a closure device).
2. The aortic body, iliac limbs and iliac extension of the device are preloaded into delivery catheters.
3. The aortic body stent graft delivery system is inserted via the femoral artery and positioned in the aorta and deployed under fluoroscopic guidance.
4. The channels in the aortic body stent graft are filled with the polymer to create a seal against the aortic wall and provide support and visibility for the graft.
5. The contralateral limb of the device is inserted via the femoral artery into the aortic body leg using the same iliac limb delivery catheter.
6. Once the polymer has set within the graft rings and channels, the aortic body delivery catheter is removed.
7. The ipsilateral iliac limb is then inserted. If an iliac extension is required, it is inserted using the same method as used with the iliac limbs.
8. The position of and blood flow through the stent graft is confirmed using angiography.
9. The cuts in the groin are closed with sutures (or a closure device) and the procedure is complete.[3, 4]

There is a range of commercially available endografts for endovascular repair of AAA. What differentiates the Ovation Abdominal Stent Graft System from other endovascular aneurysm endografts is its fixation and sealing mechanism. Sealing and fixation by most commercially available endografts is achieved via radial force from nitinol stents pushing fabric (either polyester or PTFE) against the aneurysm wall in addition to anchoring hooks. In comparison, fixation and sealing with the Ovation endograft are separate actions. Fixation is achieved suprarenally (above the level of the renal artery) with a nitinol stent and anchors, whilst sealing is achieved infrarenally (below the level of the renal artery) with an inflatable ring filled with polymer. Once the polymer cures it does not exert chronic outward force on the aortic wall.[5, 6] The radial force exerted by self-expanding stents, which is alleviated with the novel fixation and sealing design of the Ovation Abdominal Stent Graft System, has been implicated in aortic neck expansion and degeneration after stent graft implantation.

Degeneration may lead to loss of seal, Type Ia (proximal) endoleaks (continuing blood flow through the aneurysm) and device migration.[7]

Another reported benefit of the Ovation Abdominal Stent Graft system is the length of the suprarenal stent (at the renal arteries), which is markedly longer than the suprarenal stent of other aortic stent grafts. This enables anchoring at the level of the superior mesenteric artery. This aortic segment is considered healthier than the juxta-renal artery area and carries a lower risk for future aortic degeneration and distention.[5]

Finally, the lack of nitinol skeleton in the Ovation Abdominal Stent Graft System means it has one of the lowest catheter diameters of stent grafts currently available.[8] The advantage of a smaller profile is that it enables access through tortuous and/or narrowed iliac vessels, thus expanding the number of patients with AAA who would be eligible for endovascular repair.

Based on user feedback regarding the original Ovation Abdominal Stent Graft System, the manufacturer released another version, the Ovation Prime® Abdominal Stent Graft System, which has an improved delivery system and include the following:

- A key fit locking mechanism proximal of the primary stent to improves orientation of the aortic body within the delivery system and incorporated improves orientation markers
- Both aortic body limbs were attached to the delivery system with a release-wire to prevent limb movement during cannulation and to improve iliac limb insertion and deployment
- The nose cone of the catheter is firmer and taper was improved (Personal communication, Getz Healthcare).

The latest iteration of the Ovation Abdominal Stent Graft System is the Ovation iX™ Abdominal Stent Graft (iX stands for integrated exchange). It was developed to improve physician ease of use and expand patient applicability. The modifications include:

- A less invasive, low-profile (12–15Fr outer diameter) integrated sheath (10–13 Fr internal diameter) designed to minimise vessel trauma
- An increase in iliac limb diameter (up to 28 mm)
- An increase in iliac limb length (up to 160 mm)
- A new built-in cross-over lumen providing an alternative to retrograde cannulation of the main body of the device.[9, 10]

Patients must meet the following anatomic criteria to be eligible for endovascular AAA repair with the Ovation Prime Abdominal Stent Graft System:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices and accessories

- A proximal aortic landing zone at least 7 mm long, with an inner wall aortic diameter ≥16 mm and ≤30 mm at 13 mm below the inferior renal artery and with an aortic angle of ≤60 degrees if the proximal neck is ≥10 mm and ≤45 degrees if the proximal neck is <10 mm
- A distal iliac landing zone ≥10 mm in length and with an inner wall diameter ≥8 mm and ≤20 mm.

The Ovation Abdominal Stent Graft System is contraindicated in patients who have a condition that threatens to infect the graft or who have known sensitivities or allergies to the device materials.[1]

Company or developer

Endologix, Inc., California, United States of America (acquired from Trivascular, Inc. in February 2016).

Reason for assessment

The Ovation Abdominal Stent Graft System is a novel endograft designed to overcome the limitations of currently available AAA stent grafts by accommodating a broader range of aortic morphologies and by utilising an enhanced seal mechanism to potentially reduce the risk of endoleak and aneurysm enlargement.[11] These developments are proposed to expand patient access to endovascular repair of AAA by 10 per cent.[5]

Stage of development in Australia

According to the distributor of the Ovation Prime Abdominal Stent Graft System in Australia there have been several patients implanted with the device in NSW (Personal communication, Getz Healthcare).

- ☐ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☒ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

Licensing, reimbursement and other approval

The Ovation Abdominal Stent Graft System received a Humanitarian Device Exemption (H100008) from the United States Food and Drug Administration (FDA) in November 2011 (20mm device) and premarket approval (PMA) in October 2012 (P120006) for all sizes.[12, 13] The Ovation Prime Abdominal Stent Graft System received a PMA in December 2012 (P120006/S001) and the Ovation iX Abdominal Stent Graft received a PMA in February 2015 (P120006/S015).[14, 15] Including the Ovation Prime and Ovation iX variations, there have been 19 supplemental approvals by the FDA following the initial PMA of the Ovation Abdominal Stent Graft System in November 2012, reflecting ongoing modifications to this device.[16]

In Europe, CE marks were provided for the Ovation Abdominal Stent Graft System, Ovation Prime Abdominal Stent Graft System and Ovation iX Abdominal Stent Graft in 2010, 2012 and 2015, respectively.[17, 18]

Australian Therapeutic Goods Administration approval

The Ovation Prime Abdominal Stent Graft System has Australian Therapeutic Goods Administration approval. There are six ARTG numbers associated with this device. The supplier of the Ovation Prime Abdominal Stent Graft System in Australia reports that they hope to have the Ovation iX Stent Graft available in Australia by the second quarter of 2017 (Personal communication, Getz Healthcare Pty Ltd, NSW, Australia).

☒ Yes ARTG number (s): 263492, 219803, 216715, 216705, 216665, 219752

☐ No

☐ Not applicable

Technology type	**Device**
Technology use	**Therapeutic**

Patient Indication and Setting

Disease description and associated mortality and morbidity

An AAA is a dilatation of the aorta, the main blood vessel that supplies blood to the abdomen, pelvis and legs. They predominantly occur in Caucasian men over 50 years of age. Women only account for 10 per cent of AAAs.[19]

AAAs result from a weakening of the aorta wall. It is not known what causes this weakening, although risk factors include smoking, high blood pressure and a family history of aneurysms. Increasing age and being male are the biggest risk factors.[20]

AAAs can develop over many years. In most cases they cause no noticeable symptoms. If an AAA becomes large, some people may develop a pain or pulsating feeling in their abdomen or persistent back pain. AAAs usually expand slowly over time (average rate of approximately 1–2 mm each year). Larger aneurysms expand more rapidly. When AAAs are greater than 5.5 cm in diameter in men and greater than 5.0 cm in women they are at risk of rupturing.[21] A ruptured aneurysm can cause massive internal bleeding which is usually fatal if untreated. Around 8 out of 10 people with a ruptured aorta either die before they reach hospital or do not survive surgery.[20] Symptoms of rupture include sudden, severe pain in the abdomen or back, passing out, clammy skin, dizziness, nausea and vomiting, rapid heart rate and shock.[22]

There are no formal screening programs in Australia for AAA as there are in other countries. AAAs are usually asymptomatic and are therefore often found during an examination for other unrelated health issues or during routine health examinations. An AAA is diagnosed

using an ultrasound or computed tomography (CT) scan.[19, 21] The prognosis for patients who have surgery to repair an aneurysm before it ruptures is very good and patients can maintain a normal lifestyle without the concern of rupture following the usual postoperative recovery period.[19]

Number of patients

In Australia's public hospital system from 2013 to 2014 there were 506 separations reported against the principal diagnosis of ruptured AAA and 3,384 separations reported against the principal diagnosis of AAA without rupture.[23] During the same time period, 208 patients in the Australian public hospital system underwent replacement of an infra-renal AAA with a bifurcation graft to the iliac arteries.[24]

In New Zealand 1,050 discharges for aortic aneurysm and dissection were recorded in the publicly funded hospital system between 2012 and 2013.[25] One study reported the age-standardised AAA mortality rate in New Zealand between 2005 and 2007 at 5.21 per 100,000 for men and 2.12 per 100,000 for women.[26]

Speciality	**Cardiovascular disease and vascular surgery**
Technology setting	**Specialist hospital**

Impact

Alternative and/or complementary technology

The Ovation Prime Abdominal Stent Graft System is an additive technology. It adds to the range of existing stent grafts already available for endovascular repair of AAAs.

It should be noted that typically AAA stent grafts are reserved for patients who are high risk or ineligible for open surgery (personal communication, HealthPACT).

Current technology

Since the first commercially available endovascular aortic stent grafts became available in 1994 there has been continual device innovation.[27] Including the Ovation Abdominal Stent Graft System, there are currently seven FDA-approved endovascular devices on the market for the endovascular treatment of AAA (Table 1). All have similar device design; they have a main body component to seal the proximal aortic neck, and if required, two limbs supplying the iliac vessels. With the exception of the Ovation device, sealing of the proximal neck is achieved through radial force. The devices differ in regards to: composition of graft and stent materials; methods for achieving proximal and distal fixation; and, range of anatomies for which they are indicated. No comparative trials have been performed to determine if one device is superior to another in terms of safety, clinical effectiveness or cost-effectiveness.[28]

It should be noted that not all patients with AAA are eligible for endovascular repair. One review revealed that of 220 patients presenting with AAA, 45 per cent were ineligible. The main reasons for ineligibility for endovascular repair included a short infrarenal neck (44% of patients) and large proximal neck diameter (25% of patients). As mentioned previously, one of the design features of the Ovation Prime Abdominal Stent Graft System is the absence of a nitinol skeleton enabling it to have one of the lowest catheter diameters of the stent grafts that are currently available. The advantage of this smaller profile is that it enables access through tortuous and/or narrowed iliac vessels, thus expanding the number of patients with AAA who would be eligible for endovascular repair.[29] Based on expert clinical opinion, approximately five per cent of AAA cases would be suitable for the Ovation AAA Stent Graft System that are not suitable for standard current grafts (personal communication, Professor Fitridge, Vascular Surgeon, University of Adelaide).

Table 1 Current FDA-approved endovascular grafts for the treatment of abdominal aortic aneurysms[28]

Device name	Aorfix	Ovation	Zenith	Endurant	AFX.	Excluder	Zenith
Manufacturer	Lombard Medical Technologies Inc.	TriVascular Inc.	Fenestrated Cook Medical	Medtronic	Endologix Inc	W.L. Gore and Associates, Inc.	Cook Medical
FDA approval date	2013	2012	2012	2012	2011	2002	2003
Graft material	Polyester	Low pressure PTFE	Polyester	High density multifilament polyester	Duraply high-density expanded PTFE	Multilayered low pressure expanded PTFE	Polyester
Suprarenal fixation	No	Yes	Yes	Yes	Yes	No	Yes
Neck length (mm)	≥15	≥7	Proximal length 4 mm. Unsuitable for non-fenestrated graft	≥10	≥15	≥15	≥15
Neck diameter (mm)	19–29	16–30	19–31	19–32	18–32	19–29	18–32
Neck angulation	≤90°	≤60°	≤45°	≤60°	≤60°	≤60°	≤60° relative to aneurysm, ≤45° relative to suprarenal aorta
Distal fixation length (mm)	≥15	≥10	>30	≥15	≥15	≥10	≥10
Iliac diameters (mm)	9–19	8–20	7–21	8–25	10–23	≤18.5	7.5–20
Main body sheath size (Fr)	22	14–15	20	18–20	17	16–18	18–22
Limb sheath size (Fr)	20	10–13	14–16	14–16	9	12–15	14–16

Fr: French scale; PTFE: polytetrafluoroethylene.

Diffusion of technology in Australia

The supplier of the Ovation Abdominal Stent Graft System in Australia reports that the following hospitals in NSW have used the system to date; Lake Macquarie Private, John Hunter, St George Private, St George, Lismore Base, St Vincent's Private Lismore, Nepean, Prince of Wales, St Vincent's General and Strathfield Private (Personal communication, Getz Healthcare).

International utilisation

The Ovation platform is reported to be available for sale in more than 35 countries around the world and to have been used in the treatment of over 7,000 patients.[30] The table below was produced based on information from ClinicalTrials.gov and from the supplier of the Ovation Abdominal Stent Graft System in Australia (Personal communication, Getz Healthcare).

Country	Level of Use		
	Trials underway or completed	Limited use	Widely diffused
Australia	✓		
Belgium	✓		
Brazil	✓		
Canada	✓		
Chile	✓		
Germany	✓		
Greece	✓		
Hungary	✓		
Italy	✓		
Hong Kong	✓		
Malaysia	✓		
Mexico	✓		
Netherlands	✓		
Poland	✓		
Singapore	✓		
Sweden	✓		
Switzerland	✓		
Thailand	✓		
Turkey	✓		
United Kingdom	✓		
USA	✓		

Cost infrastructure and economic consequences

The Diagnosis-Related Groups that the Ovation Prime Abdominal Stent Graft System is being used under are F15A and F15B. In addition to the cost of the device, inserting a stent graft requires a catheterisation laboratory. Also, patients require pre-procedure computed tomography for graft sizing and planning.

The Ovation Prime Abdominal Stent Graft System is on the Australian Department of Health Prostheses List.[31] Its associated costs and descriptions are provided in Table 2. Note, also listed on the prostheses list under bifurcated stent grafts, is the Endologix AFX AAA Stent Graft System (Endologix, Inc., California, USA). The minimum benefit for this stent graft system (including both iliac extensions) is also $12,405. Similarly, the cost of an iliac limb extension is also $3,308.. .

Table 2 Cost and associated codes of the Ovation Abdominal Prime Stent Graft System on the Australian Department of Health prostheses list[31]

Billing code	Product	Description	Size	Minimum benefit
ER191	Ovation Prime Abdominal Stent Graft System	Bifurcated Aortic System, PTFE graft, nitinol stent and markers	20, 23, 26, 29 and 34 mm	$12,405
ER192	Ovation Prime Abdominal Stent Graft System – Iliac Limb	Ovation Prime Abdominal Stent Graft System – Iliac Limb	Diameter: 10, 12, 14, 16, 18 and 22 mm. Length: 80–140 mm	$3,308
ER193	Ovation Prime Abdominal Stent Graft System – Iliac Extension	Ovation Prime Abdominal Stent Graft System – Iliac Extension	Diameter: 10, 12, 14, 16, 18 and 22 mm. Length: 45 mm	$3,308
ER194	Ovation Prime Abdominal Stent Graft System – Fill Polymer Kit	Ovation Prime Abdominal Stent Graft System – Fill Polymer Kit	NA	$680

NA: not applicable; PTFE: polytetrafluoroethylene.

Ethical, cultural, access or religious considerations

No ethical, cultural, access or religious considerations were identified that may limit the use of this technology.

Evidence and Policy

Safety and effectiveness

Three case series (level IV interventional evidence) describing the use of the Ovation Abdominal Stent Graft System were identified for inclusion in this Technology Brief. One non-randomised comparative study (level III-2 interventional evidence) was identified but was not included as its outcomes were deemed as not important (reported aortic neck morphology at follow-up and there were large numbers lost to follow-up) (Personal communication, Discipline of Surgery, The University of Adelaide). No studies were identified on the Ovation Prime Stent Graft System or the Ovation iX Abdominal Stent Graft.

An overview of the studies is provided in Table 3. It should be noted that studies without a comparator group, such as these case series, can only inform on the safety of the Ovation system rather than its effectiveness.

Table 3 Included study characteristics

Study details/location	Inclusion criteria	Exclusion criteria	Number of patients; length of follow-up; losses to follow-up	Conflicts of interest
de Donato et al 2016[32] Retrospective level IV interventional evidence Multicentre registry (13 sites) Italy	Patients who had undergone implantation of a TriVascular Ovation Stent graft for AAA at least 24 months previously	Patients with mycotic aneurysm or prior aortic reconstructive surgery	N = 161 length = median of 32 months (range 24–50 months) losses = 32 (17 died and 15 were lost to follow-up)	None
Ierardi et al 2015[33] Retrospective level IV interventional evidence Multicentre (2 sites) Italy and Greece	Patients presenting with an AAA requiring intervention and with aortoiliac characteristics suitable for treatment using the Ovation device	NR	N = 36 length = mean 27.7 months (range 24–37 months) losses = 0	None
Mehta et al 2014[2] Prospective level IV interventional evidence Multicentre (36 sites) United States, Germany and Chile	Patients presenting with AAA requiring intervention who were candidates for open surgery and had aortoiliac characteristics suitable for treatment with the Ovation stent, age ≥18 years, male or non-pregnant female, a proximal neck length of ≥7 mm and an inner diameter of between 16 and 30 mm, a juxtarenal aortic neck angulation of ≤60 degrees if the proximal neck length was ≥10 mm or ≤45 degrees if the proximal neck length was <10 mm, a distal seal zone of ≥10 mm and diameter between 8 and 20 mm, an AAA diameter of ≥5 cm, 1.5 times the adjacent non-aneurysmal aorta, or expansion of ≥0.5 cm in the previous 6 months	Dissecting or acutely ruptured aneurysm, concomitant thoracic aneurysm or dissection, acute vascular injury, need for emergent surgery, mycotic aneurysm or active systemic infection, unstable angina, MI or stroke in past 6 months, major surgical procedure planned ≤20 days of AAA procedure, connective tissue disease, bleeding disorder or refusal of blood transfusions, hypersensitivity or contraindication to anticoagulation or contrast media, allergy or intolerance to PTFE, polyethylene glycol-based polymers, fluorinated ethylene propylene or nitinol, body habitus hinders radiographic visualisation of the aorta, life expectancy <1 year, participation in another device or drug trial, medical, social or psychological conditions that preclude patient from receiving the procedure.	N = 161 length = one year losses = 9 (four died, four withdrew and one was lost to follow-up)	TriVascular Inc. provided funding for the study; Dr Mehta receives research grants and is a speaker/consultant for TriVascular Inc. Dr Mehta, Dr Nolte and Dr Valdez received honorariums from TriVascular Inc.

AAA: abdominal aortic aneurysm; MI: myocardial infarction; NR: not reported; PTFE: polytetrafluoroethylene.

de Denato et al 2016[32]

This multicentre, retrospective case series reported on the results of 161 patients who underwent implantation of an Ovation Abdominal Stent Graft for AAA between December 2010 and November 2012. It is not clear whether patient inclusion was consecutive. The patients, from 13 centres across Italy, were enrolled as participants in the TriVascular, Inc. Ovation Italian Study and had at least 24 months' follow-up data. Standard CT scans on each patient, available at a minimum of 24-months follow-up, were collected and sent for blind reading to a centralised core laboratory.

Outcomes evaluated in the study included primary clinical success, assisted primary clinical success, primary technical success, and assisted primary technical success. Clinical success, reported on an intention-to-treat basis, was defined as successful deployment of the device at the intended location without death as a result of aneurysm-related treatment, type I or type III endoleaks, graft infection or thrombosis (blood clot), aneurysm expansion (diameter ≥5 mm or volume ≥5%), aneurysm rupture or conversion to open repair. The presence of graft dilation of ≥20 per cent in diameter, graft migration, or a failure of device integrity also classified a case as a clinical failure. Primary clinical success was defined as clinical success without the need for additional or secondary surgical or endovascular procedure. Assisted primary clinical success was defined as clinical success achieved with the use of an additional or secondary endovascular procedure. Technical success was defined as peri-procedural events that occurred from the initiation of the procedure through to the first 24-hour postoperative period. Primary technical success, reported on an intention-to-treat basis, required the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks or graft limb obstruction. Assisted primary technical success was defined as technical success achieved with the use of unplanned endovascular or surgical procedures.

Safety

During a median follow-up of 32 months (range 24–50 months) 17 patients (11%) died[1]. No deaths occurred during the perioperative period and none of the deaths were said to be related to the AAA.

Effectiveness

Primary technical success was 98 per cent. The failures included two type Ia endoleaks and one graft occlusion. Assisted primary technical success was 99 per cent as two of the three primary technical failures were corrected intraoperatively. This included a balloon-expandable stent implantation to correct one of the type Ia endoleaks and an intraoperative femoral bypass to repair the iliac graft occlusion. The other type Ia endoleak was considered low risk and was not treated.

1 In addition 15 (9%) patients were lost to follow-up.

Primary clinical success at two years was 95 per cent. Failures included four graft thrombi and three type I or III endoleaks (Table 4). Assisted primary clinical success at two years was 100 per cent.

Table 4 Clinical success at two years following implantation with the Ovation Abdominal Stent Graft System (de Donato et al 2016)[32]

Event	Number (%)
Primary clinical success	95%
Aneurysm-related death	0
Type I or type III endoleak*†	3 (2%)
Aneurysm expansion†	0
Graft infection	0
Graft thrombosis†	4 (3%)
Conversion to open repair	0
Assisted primary clinical success	100%

*Type I endoleak: leak at graft ends (inadequate seal); Type III endoleak: leak through a defect in the graft fabric; † Assessed by computed tomography or ultrasound follow-up.

Ierardi et al (2015)[33]

This retrospective, multicentre case series evaluated the two-year safety and effectiveness outcomes of the Ovation Abdominal Stent Graft System in 36 patients with two-year follow-up data. The study was conducted in two centres from November 2009 to May 2011. It is not clear whether patient inclusion was consecutive.

Outcomes reported included endovascular repair feasibility, immediate technical success and effectiveness and safety. Feasibility was defined as the possibility of carrying out endovascular repair in patients with difficult iliac access (diameter <7 mm) and a short (<7 mm) and/or angulated proximal neck (≤60 degrees). Technical success was defined as successful deployment of the endograft, including absence of type I endoleak at the angiogram performed at the end of the procedure. Effectiveness was defined as the absence of type I endoleak, migration and aneurysm enlargement at CT performed during follow-up.

The main safety outcome measures were major and minor complications, mortality and serious adverse events (aneurysm enlargement, rupture, conversion to surgery and secondary interventions).

Patients had follow-up visits at 1, 6 and 12 months and then annually following surgery. The mean follow-up time was 27.7 months (range 24–37 months). There were no losses to follow-up.

Safety

No major complications, serious adverse events or deaths were recorded during or after the procedure, 30 days after graft deployment or during the follow-up period. The rate of minor

complications was 8 per cent (3/36). Two patients developed transient renal failure and one patient required an arterial patch at the access site.

Effectiveness

Endovascular repair was feasible and the Ovation Abdominal Stent Graft was successfully implanted in all 36 patients (technical success of 100%). No aneurysm ruptures, fractures or migrations of the endograft or type I endoleaks were observed, and none of the patients required conversion to open surgery.

During follow-up (mean of 27.7 months) none of the patients presented with type I, III or IV endoleaks. In 12 patients (33.3%), a type II endoleak was noted. One of the 12 endoleaks occurred in a patient with sac enlargement. This was not treated owing to the patient's refusal of further intervention. In eight patients with a type II endoleak, the aneurysmal sac remained stable or decreased in size, therefore no further treatment was required. In the remaining three patients with type II endoleaks detected at either the 6-month (N = 1) or 12-month (N = 2) CT scan, the leak was not be detected on the 24 month scan.

Mehta et al 2014[2]

This prospective, multicentre case series evaluated the one-year safety and effectiveness outcomes of the United States regulatory trial for the Ovation Abdominal Stent Graft System. From November 2009 to May 2011, 161 consecutively enrolled patients with AAAs (mean diameter 54 mm, standard deviation [SD] 9) from 36 sites across the United States of America (28 sites), Germany (7 sites) and Chile (1 site) were treated with the Ovation Abdominal Stent Graft System. Patients were followed up by physical examination, laboratory testing, contrast-enhanced spiral abdominal/pelvic CT and four-view X-ray imaging at discharge (CT was not performed at discharge), 30 days, 6 months and annually thereafter for 5 years. An independent imaging laboratory analysed all preoperative and postoperative CT scans and radiographs.

The primary device effectiveness outcome recorded was the proportion of patients who experienced treatment success at one year post-surgery. Treatment success was defined as technical success (successful delivery and deployment of the aortic body and both iliac limbs) and freedom from all of the following: type I and III endoleaks at one year; stent graft migration (defined as evidence of proximal or distal movement of the stent graft >10 mm relative to fixed anatomic landmarks compared with the one month CT scan) at one year; AAA enlargement at one year (defined as >5 mm AAA diameter increase compared with the AAA diameter on the one-month CT scan) and AAA rupture or conversion to open surgery during one year follow-up.

The primary safety outcome recorded was the Clinical Events Committee adjudicated major adverse events (MAEs) up till 30 days postoperatively. This was defined as death, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischaemia or

procedural blood loss of at least 1000mL. Other safety outcomes recorded included serious adverse events (SAEs) and mortality (all-cause and AAA related). AAA-related mortality was defined as death due to AAA rupture, due to any procedure intended to treat the AAA or any in-hospital death if hospitalisation was greater than 30 days. A serious adverse event was defined as any event that was fatal, life threatening, required prolonged hospitalisation (>48 hours), was a persistent or significant disability or incapacity, or was considered an important medical event. A Clinical Events Committee reviewed and adjudicated all device-related adverse events and SAEs and classified major adverse events (MAEs).

During the post-surgery follow-up year four patients died, four withdrew and one patient was lost to follow-up. Although it is stated that complete one-year follow-up is available for the remaining 152 patients, the denominator of many of the radiographic derived effectiveness outcomes at one year is less than 152 owing to only readable images being included.

Safety

Safety outcomes recorded at 30 days and one year post surgery are reported in Table 5. The 30-day MAE rate was three per cent and the MAE rate for the entire one-year follow-up was six per cent. There were no device-related MAEs during the one-year follow-up based on the Clinical Events Committee adjudicated data.

During the one-year follow-up there were four deaths (4/161 patients, 3%); however, it is unclear from the study whether these deaths were a result of the procedure. AAA related mortality accounted for one death. Causes of the deaths included disseminated intravascular coagulation (blood clots in the body's small blood vessels) and abdominal infection or sepsis (day 17), respiratory failure (day 95), multiple organ failure (day 178) and suspected thoraco-abdominal aneurysm rupture (day 359).

The death occurring within 30 days following surgery due to intravascular coagulation was the result of an unanticipated adverse device event in a 76-year-old woman. During the procedure the polymer injection tube disconnected from the aortic body stent graft and the fill material was injected intravascularly. An investigation revealed a defective component (distal stop) had allowed the port for the fill material to prematurely disconnect from the aortic stent graft catheter. This event was reported to the FDA. Modifications were subsequently made to the distal stop and to the 'instructions for use' before the trial continued.

Table 5 Safety outcomes at 30 days and one year post surgery following AAA treatment with the Ovation Abdominal Stent Graft System (Mehta et al 2014)[2]

Outcome	30 days % (n/N)	1 year % (n/N)
Death	0.6 (1/161)	3 (4/161)
SAEs	13 (21/161)	39 (62/161)
Injury, poisoning and procedural complications	4 (6/161)	9 (15/161)
Respiratory, thoracic and mediastinal disorders	3 (5/161)	8 (13/161)
Vascular disorders	3 (4/161)	7 (11/161)
Cardiac disorders	2 (3/161)	7 (11/161)
Gastrointestinal disorders	2 (3/161)	7 (11/161)
Neoplasms (abnormal tissue growth)	0	6 (10/161)
General disorders and administration site conditions	4 (6/161)	6 (9/161)
Infection and infestations	0.6 (1/161)	5 (8/161)
MAEs	2.5 (4/161)	6 (10/161)
Myocardial infarction	1 (2/161)	3 (4/161)
Procedural blood loss ≥1000 ml	1 (2/161)	1 (2/161)
Renal failure	1 (2/161)	1 (2/161)
Bowel ischaemia	0.6 (1/161)	1 (2/161)
Death	0.6 (1/161)	3 (4/161)
Respiratory failure	0.6 (1/161)	1 (2/161)
Stroke	0	0
Paraplegia	0	0

MAEs: major adverse events; SAEs: serious adverse events (categorised by System Organ Class using the Medical Dictionary for Regulatory Activities).

Effectiveness

Effectiveness outcomes recorded at 30 days and one year post-surgery are reported in (Table 6). Arterial access and device deployment was achieved in all 161 patients (technical success of 100%). Treatment success one year post surgery was 99 per cent. No AAA ruptures, conversions to open surgery, stent graft migrations or types I, III or IV endoleaks occurred during this time. AAA related secondary procedures, as reported by individual sites, were performed in 10 patients due to 12 findings. These included type I endoleaks (three), type II endoleaks (three), aortic main body stenosis (three) and iliac limb occlusion (two) and iliac limb stenosis (one). Of the two patients who had two findings each, one underwent two secondary procedures to resolve a type Ia (proximal) endoleak and aortic main body stenosis. The second patient also underwent two procedures, one to resolve a type Ia endoleak and the other to resolve a type Ib (distal) endoleak. None of the four patients with stent fractures required treatment.

Table 6 Effectiveness outcomes at 30 days and one year post surgery following AAA treatment with the Ovation Abdominal Stent Graft System (Mehta et al 2014)[2]

Outcome	30 days % (n/N)	1 year % (n/N)
Radiographic events*		
Endoleaks†	44 (68/153)	39 (55/143)
Type I endoleak	0 (0/153)	0 (0/143)
Type II endoleak	41 (62/153)	34 (49/143)
Type III endoleak	0 (0/153)	0 (0/143)
Type IV endoleak	0 (0/153)	0 (0/143)
Indeterminate origin	4 (6/153)	4 (6/143)
Stent graft migration‡	NA	0 (0/150)
AAA diameter change‡		
≥5 mm increase in AAA diameter	NA	0.7 (1/150)
<5 mm change AAA diameter	NA	67 (101/150)
≥5 mm decrease in AAA diameter	NA	32 (48/150)
Stent fracture	0.6 (1/157)	3 (4/146)
Clinical events§		
Access failure	0 (0/161)	NA
Deployment failure	0 (0/161)	NA
AAA rupture	0 (0/161)	0 (0/161)
Conversion to open surgery	0 (0/161)	0 (0/161)
AAA related secondary intervention	1 (2/161)	6 (10/161)

AAA: abdominal aortic aneurysm; NA: not applicable; *Patients with readable imaging were included in the denominator for each retrospective outcome; †Type I: leak at graft ends (inadequate seal); Type II: sac filling via branch vessel; Type III: leak through a defect in graft fabric (mechanical failure of graft); Type IV: porous graft; ‡Compared with one month baseline imaging; §As reported by individual sites through-out one year.

Economic evaluation

No studies on the economic evaluation of the Ovation Abdominal Stent Graft System were identified.

Ongoing research

A search of ClinicalTrials.gov and the Australian and New Zealand Clinical Trials Registry (Table 7) identified seven clinical trials on either the Ovation and/or Ovation Prime Abdominal Stent Graft System. No clinical trials were identified comparing the Ovation Abdominal Stent Graft System to another stent graft system and no clinical trials were identified on the Ovation iX Abdominal Stent Graft. No Australian or New Zealand clinical trials were identified.

Table 7 Details of clinical trials identified on the Ovation or Ovation Prime Abdominal Stent Graft System

Trial ID; location	Study design	Estimated enrolment	Intervention(s)	Outcome measure(s)	Status	Estimated completion
NCT01092117 United States	Case series Multicentre	150 patients	Ovation Abdominal Stent Graft System	Proportion of patients experiencing a major adverse event within 30 days, proportion achieving treatment success	Active, not recruiting	December 2017
NCT01980901 United States	Case series (post-market approval study) Single centre	320 patients	Ovation/Ovation Prime Abdominal Stent Graft System	Freedom from aneurysm-related mortality at 5 years, composite safety and performance endpoints	Ongoing, not recruiting	October 2020
NCT01372709 Germany	Case series (post-market registry) Multicentre	501 patients	Ovation or Ovation Prime Abdominal Stent Graft System	Treatment success at 12 months post-implantation/surgery (defined as a composite technical and clinical endpoint)	Ongoing, not recruiting	January 2019
NCT01082185 Chile	Case series Multicentre	20 patients	Ovation Abdominal Stent Graft System	Safety at 30 days (no other details provided)	Ongoing, not recruiting	May 2016
NCT02224794 United States	Case series (patient registry) Multicentre	250 patients	Ovation Abdominal Stent Graft System	Major adverse events at 30 days	Currently recruiting	June 2016
NCT02451566 Canada	Case series (patient registry) Single centre	20 patients	Ovation Prime Abdominal Stent Graft System	Major adverse events at 30 days	Currently recruiting	June 2016
NCT02479191 United States	Case series (post market registry) Multicentre	225 patients	Ovation Abdominal Stent Graft System	Major adverse events at 30 days	Currently recruiting	August 2018

EVAR: endovascular aneurysm repair.

Other issues

One of the three case series included in this Technical Brief (Mehta et al 2014)[2] reported conflicts of interest. These included funding of the study by TriVascular Inc. and the lead author being a speaker/consultant for TriVascular Inc. In addition, three of the authors received honoraria from TriVascular Inc.

An intention-to-treat model was not applied by Mehta et al (2014)[2] and de Donato et al (2016)[32] as values for missing data on outcomes were not imputed where they used the complete population as the denominator.

A review on the current market for endovascular aneurysm repair devices reported that at least five new devices are being evaluated for approval in the United States, some of which are already CE approved.

Number of studies included

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies:	3
Total number of Level IV studies:	3

Search criteria to be used (MeSH terms)

Ovation AND stent graft

TriVascular AND stent graft

Date searched

5/4/2016

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