

Endovascular Treatment of Various Aortic Pathologies: Review of the Latest Data and Technologies

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Abstract

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The technologies and innovations applicable to endovascular treatment for complex aortic pathologies have progressed rapidly over the last two decades. Although the initial outcomes of an endovascular aortic repair have been excellent, as long-term data became available, complications including endoleaks, endograft migration, and endograft infection have become apparent and are of concern. Previously, the indication for endovascular therapy was restricted to descending thoracic aortic aneurysms and abdominal aortic aneurysms. However, its indication has expanded along with the improvement of techniques and devices, and currently, it has become possible to treat pararenal aortic aneurysms and Crawford type 4 thoracoabdominal aortic aneurysm (TAAA) using the off-the-shelf devices. Additionally, custom-made devices allow for the treatment of arch or more extensive TAAs. Endovascular treatment is applied not only to aneurysms but also to acute/chronic dissections. However, long-term outcomes are still unclear. This article provides an overview of available devices and the results of endovascular treatment for various aortic pathologies.

The dawn of endovascular treatment was a report on the treatment for arteriosclerotic obstruction using a stainless steel spring coil in 1964 by Dotter and Judkins,¹ who invented the concept of a dilating a vessel using a catheter. The origin of endograft was derived from a report using a nitinol coil in 1983.^{2,3} Although the concept of a stent graft for aortic aneurysms was proposed previously, the first report of implantation involved an animal experiment by Balko et al in 1986.⁴ At the same time, Volodos et al⁵ succeeded in implanting an endograft for a traumatic descending aortic aneurysm. Parodi et al⁶ reported the first endovascular treatment of abdominal aortic aneurysms (AAAs). This report attracted widespread attention as a less invasive treatment for an aortic aneurysm, and the endograft was considered as an epoch-making development. Subsequent paradigm shifts were not limited to descending thoracic aortic aneurysms (DTAAs) and AAAs but also

branched endografts have enabled endovascular repair for aortic arch aneurysms and thoracoabdominal aortic aneurysms (TAAAs), and various technological innovations are still ongoing. The initial outcomes of endovascular aneurysm repair were excellent, but late complications including endoleaks, migration, or infection have become apparent and are increasingly becoming a clinical issue. The aim of this article is to provide an overview of current available endografts and to review the outcomes of endovascular treatment for various aortic pathologies.

Thoracic Aortic Aneurysm

In 1994, Dake et al⁷ reported the outcome of thoracic endovascular aortic repair (TEVAR) for 13 patients with traumatic DTAAs or chronic dissection aneurysms. The stent graft was a homemade device composed of stainless

steel self-expanding Z stent covered with a Dacron woven graft. The initial outcome was satisfactory with no 30-day mortality, a much lower rate of postoperative complications, and a shorter length of stay compared with conventional open repair. TEVAR, including the concept of a landing zone, has also been performed with a homemade endograft or branched endograft for thoracic aortic aneurysm in Japan.⁸⁻¹⁰

The development of an endograft for thoracic aortic aneurysm has improved since the TAG endograft (W.L. Gore & Associates, Flagstaff, AZ) was approved by the Food and Drug Administration (FDA) in 2005. Five-year outcomes of TEVAR using TAG for DTAA were excellent, including a lower aneurysm-related death (ARD) rate in the TAG group (TAG: 2.8% vs. open surgery: 11.7%, $p = 0.008$).¹¹ No statistical difference was observed in overall survival, but postoperative complications were significantly lower in the TAG group compared with the open repair group ($p = 0.001$). Initial outcomes of TX2 (Cook Medical, Bloomington, IN) and Talent (Medtronic, Minneapolis, MN) also reported satisfactory results, as did Gore-TAG.^{12,13} Furthermore, the 5-year outcomes of TX2 for DTAA were reported in 2014.¹⁴ The 30-day mortality in the TX2 group was lower than in the open surgery group (1.9 vs. 5.7%). Although long-term survival and rate of freedom from ARD were not significantly different between the two groups, the postoperative incidence of complications was lower in the TEVAR group than in open surgery group consistent with the TAG study ($p < 0.001$).

The thoracic endografts are divided into two configurations: those with or without a proximal bare stent. The TAG, TX2, and Relay plus NBS (Bolton Medical, Sunrise, FL) are devices that do not have a proximal bare stent, whereas Valiant (Medtronic, Minneapolis, MN), Relay (Bolton), Zenith α (Cook Medical), E-vita (Jotec GmbH, Hechingen, Germany), and C-TAG (W.L. Gore) have a proximal bare stent. The proximal bare stent is believed to improve endograft alignment in the aortic arch and strengthen the sealing to the proximal neck. Although previous devices caused retrograde type A dissection due to an extremely strong radial force of the proximal bare stent, recent devices are more conformable in terms of improving alignment and focused more on sealing rather than fixation.

Descending Thoracic Aortic Aneurysm

Endovascular treatment for DTAAAs has been more frequently performed due to the positive results of two clinical trials of involving the TAG and the TX2 as described earlier. Shortcomings of open repair for DTAA are not only higher mortality but also postoperative wound pain, and one report indicated that TEVAR patients were four times more likely to have a routine discharge to home compared with open repair.¹⁵ The less invasiveness of TEVAR is also highlighted by other studies that indicate a lower 30-day mortality and shorter length of hospitalization compared with open surgery.^{11,14,16} Additionally, TEVAR was superior to open repair in terms of a shorter length of intensive care unit stay or low incidences of postoperative complications. The occurrence rate of spinal cord ischemia (SCI), which is related to occlusion

of the intercostal artery and Adamkiewicz artery for the treatment of an extended aneurysm, is lower after TEVAR compared with open surgery.¹⁷ According to recent reports, the 30-day mortality rate following TEVAR was 4 to 4.7%, occurrence rate of stroke was 0.6 to 2.7%, and occurrence rate of SCI was 0.5 to 3.2%.¹⁸⁻²⁰ Although endoleaks, which are the most common cause of reintervention, occurred in 6.4 to 10.5% of cases, the long-term survival and freedom rate from ARD seem to be acceptable.

Based on the guidelines established by the European Society of Vascular Surgery (ESVS) in 2017,²¹ TEVAR is evaluated as class IIb, level B in the DTAA with an aneurysm size of 5.6 to 5.9 cm, TEVAR for DTAA with an aneurysm size exceeding 6.0 cm is class IIa, level B, and open surgery for DTAA is class IIa-b, level C. Furthermore, TEVAR for ruptured DTAA with its appropriate anatomy is listed as class I, level B. Therefore, TEVAR is the first-line treatment of DTAA with appropriate anatomy.²⁰⁻²² In contrast, some cases with poor access, an absence of a landing zone, young patients with connective tissue disorder including Marfan's syndrome, presence of metal or contrast agent allergy, and large symptomatic DTAA with dysphagia or dyspnea secondary to recurrent nerve injury are candidates for open repair.

Distal Arch and Aortic Arch Aneurysm

Although most current devices can be used up to zones 2 to 4 based on the instruction for use (IFU), the initial outcomes of zone 2 TEVAR is acceptable as well as TEVAR for DTAA.²³ In a zone 2 landing, the management of the left subclavian artery (LSA) is an important consideration. LSA coverage is one of the risk factors for perioperative stroke during TEVAR. In fact, the frequency of stroke during TEVAR with LSA coverage is 6.3%, whereas without LSA coverage, it is 3.2%.²⁴ Since some reviews of a comparison between LSA simple coverage and LSA reconstruction have reported that LSA reconstruction reduces the risk of perioperative stroke,²⁴⁻²⁶ LSA reconstruction may be desirable, although there is no level I evidence and further study is warranted. LSA reconstruction is not always necessary when there is a communication between the left and right vertebral arteries. However, in the absence of this communication, or in the presence of coronary bypass using left internal thoracic artery and of blood access for dialysis on the left hand, LSA reconstruction are required during TEVAR. Recently, a single branched device has been developed to preserve to the cervical branches. Valiant Mona LSA device aimed at preserving the LSA consists of a fenestrated endograft and a small diameter endograft. In a preliminary report involving a single-center study, LSA reconstruction could be performed in all cases, and the 30-day mortality was 0%.²⁷ A multicenter clinical trial using Gore Thoracic Branch Endoprosthesis (TBE, W.L. Gore & Associates) evaluated 22 patients undergoing TEVAR to preserve LSA in zone 2.²⁸ The primary end point of device delivery and branch vessel patency was achieved in 100% of the cases with no 30-day mortality. Although type 1 endoleaks were identified intraoperatively in four patients (18%), all were resolved by 1 month without reintervention.

TEVAR for aortic arch aneurysm involving distal arch aneurysm that requires landing for zones 0 to 1 is still a

challenging treatment option due to the difficulty of landing within the complex anatomy of the aortic arch and the necessity of reconstructing the neck vessels including the brachiocephalic artery (BCA) and left common carotid artery (LCCA). The procedures of complex TEVAR for aortic arch aneurysms involve totally endovascular therapy including branched, fenestrated endograft, or in situ fenestration, hybrid therapy with debranching, and staged TEVAR using frozen elephant trunk following total arch replacement (TAR). The 30-day mortality of debranching TEVAR is inconsistent and ranges between 0 and 25%.²⁹⁻³¹ The perioperative stroke also varies and is reported between 0.8 and 18%, which appears to be worse in comparison to TAR.^{32,33} Branched endograft for aortic arch aneurysm has been utilized since the development of the Inoue stent graft.^{8,9} Available industry-made fenestrated or branched endografts include the Najuta (Kawasumi Laboratories, Tokyo, Japan), a-Branch (Cook Medical), and dual-branch aortic arch graft (Bolton Medical). Initial outcomes using the Najuta endograft system (→**Fig. 1**) reported low 30-day mortality (0%) and stroke rates (3–5%). However, the reintervention rate was relatively high at 10%.^{34,35} The devices of both a-Branch and Bolton dual-branch aortic arch endografts have two inner sleeves for reconstructing the BCA and LCCA. The preliminary results of 26 patients undergoing branched TEVAR with Bolton dual-branch graft revealed a 30-day mortality of 7.7% and postoperative stroke in 3.8% of cases.³⁶ The inner sleeves of the a-Branch attached to the outside diamond marker on the main device are independent and allow to cannulate to the cervical branches from each sleeve. There were no cases of 30-day mortality in the initial results of 27 patients using the a-Branch in a multicenter trial, and a major stroke rate of 7.4% and a minor stroke rate of 3.7% were reported.³⁷

Additionally, since a stiff wire has to be inserted into the left ventricle at the time of inserting the delivery system of both devices, attention must be paid to prevent left ventricle perforation.

Other totally endovascular treatments include physician-modified fenestration endograft (PMEG), in situ fenestration, and the chimney method. PMEG TEVAR is a method in which a fenestration is created to an off-the-shelf approved endograft by a physician. However, large fenestrations seem to be the major cause of endoleaks and along with medicolegal risk, PMEG is suboptimal. Thus, in situ fenestration TEVAR is a method that makes it possible to provide appropriate fenestration by puncturing the graft following endograft deployment. One of the advantages of a PMEG or in situ fenestration is that they can be performed for emergency cases because it can be performed using off-the-shelf devices as opposed to custom-made endografts. The results of 22 cases using an excimer laser to fenestrate LSA demonstrated a 100% branch vessel patency and a 4.5% in-hospital death rate.³⁸ Other methods include radiofrequency catheter and a simple needle puncture method for fenestration, and best technique is yet to be determined.³⁹⁻⁴¹ The chimney method is a procedure in which retrograde stents via neck vessels are inserted into the ascending aorta to maintain the blood flow of the great vessels while the main endograft is inserted deeply into the ascending aorta covering the orifices of these branches. Gutter endoleak is an endoleak caused by the space between the chimney stent and the main endograft and is classified as a type 1a endoleak and its frequency seems to increase with higher number of chimney endografts. A single-center experience of 122 patients showed that chimney repair had an excellent 30-day mortality (0.8%). However, gutter endoleak was reported in 13 patients (10.7%).⁴² Although a



Fig. 1 Najuta endograft. Thoracic endovascular aortic repair for aortic arch aneurysm using custom-made fenestrated endograft.

recent systematic review also showed excellent chimney graft patency (97%) and 30-day mortality (4%), the occurrence rate of gutter endoleak was 11% and occurred higher with increasing number of chimneys.⁴³

The most important complication after TEVAR is stroke and type 1a endoleak. Our study, which enrolled 439 patients undergoing TEVAR, demonstrated that stroke occurred in 17 patients (3.9%), and multivariate analyses revealed the presence of coronary artery disease, history of stroke, shaggy aorta, and pull-through wire technique to be independent predictors of stroke.⁴⁰ Lack of landing zone is well known as a cause of type 1a endoleak. While TEVAR for zones 3 and 4 landing showed a low incidence of type 1a endoleak, TEVAR for zones 0 to 2 landing had a higher incidence of type 1a endoleak (13.1%). Additionally, risk factors affecting type 1a endoleak included zones 0 to 2 landing TEVAR, chimney TEVAR, proximal neck diameter > 38 mm, and excessive oversizing of the endograft (> 114%).⁴¹

TEVAR for Ascending Arch Aneurysm and Type A Dissection

Indication of TEVAR for ascending arch aneurysm is more restrictive than for aortic arch aneurysm. The most common reason TEVAR is not possible is the absence of an adequate landing zone. The proximal ascending aorta involves the sinotubular junction, the coronary sinus, and the aortic valve, and the distal ascending aorta involves BCA. For these reasons, TEVAR for ascending aortic pathologies is a very challenging procedure, and only select high-risk patients with pseudoaneurysm or localized type A dissection have been treated with TEVAR. A recent systematic review from 1995 to 2017 reported that TEVAR for the ascending aorta was performed in 118 patients.⁴⁴ The aortic pathologies treated involved type A dissection (50%), pseudoaneurysm (30%), and others (20%), including penetrating ulcer, and true aneurysm. The overall survival rate was 15.2%, and ARD rate was 5%. Type 1 endoleak was identified in 18.6% and most half required reintervention underscoring the difficulty of TEVAR in this region.

Acute and Chronic Type B Dissection

The first-line treatment option for acute type B aortic dissection (TBAD) has long considered to be best medical treatment (BMT) mainly consisting of antihypertensive therapy. Only complicated TBAD with organ ischemia or rupture were candidates for surgical intervention. However, since the outcomes of surgical intervention were not satisfactory, TEVAR has been sought for such condition. The initial prognosis of the patients undergoing TEVAR was excellent, and it revealed an enlargement of the true lumen accompanied with shrinkage of the false lumen and the overall aorta diameter which is termed positive remodeling.⁴⁵ The INSTEAD trial, a randomized controlled trial (RCT) enrolled 140 patients and aimed at comparing BMT with BMT + TEVAR (Talent, Medtronic), was designed to evaluate the safety and efficacy of the treatment of uncomplicated TBAD.^{46,47} Both overall survival and ARD for 2-year follow-up were comparable in the two groups, but TEVAR had a

higher incidence of aortic remodeling compared with BMT ($p < 0.001$). Additionally, TEVAR was superior to BMT in terms of survival and thrombosis of the false lumen at 5-year follow-up. The results of the ADSORB trial, a prospective and RCT aimed at comparing BMT and BMT + TAG (W.L. Gore & Associates) for uncomplicated TBAD, were reported in 2014.⁴⁸ Although mortality rate was equivalent in the two groups, the BMT + TEVAR group was superior to BMT alone in terms of aortic remodeling. A recent review concluded that the long-term results of BMT alone for the treatment of uncomplicated type B dissection were inferior to those of the complicated type and showed a high frequency of surgical intervention.⁴⁹ Based on these evidences, TEVAR for acute TBAD is listed as the first-line treatment option in the ESVS guidelines.²¹

Chronic TBAD, including a residual dissection after repair of an acute type A dissection, is defined as "chronic" when 2 weeks have elapsed from the onset. There are some reports that patients with a maximum diameter of > 40 mm after TBAD showed expansion of the false lumen in ~20 to 40% of cases, whereas in cases of < 40 mm at the time of onset, ~80 to 95% experienced spontaneous thrombosis of the false lumen.^{50,51} Other factors influencing the expansion of the false lumen were entry tear size (> 10 mm), location of the primary tear (proximal descending aorta), and Marfan's syndrome.⁵² There is no study comparing for open surgery versus TEVAR for chronic TBAD; however, since the results of an open repair for TBAD have improved, open repair is the standard option for low-risk patients including young patients.⁵³ Although there are few reports comparing open repair with TEVAR, a study enrolled 24 patients showed the 30-day mortality was 8% in open repair and 0% in TEVAR, and the subsequent survival rates within 1 year, following open repair and TEVAR, were 33 and 0%, respectively.⁵⁴ A recent review of TEVAR for chronic TBAD reported that mid-term mortality was 9 to 10% and reintervention commonly caused by endoleak from the re-entry was identified in 0 to 60% of cases.^{55,56} Evidence level is low and further development of devices and techniques as well as clinical investigation is warranted for chronic TBAD.

Thoracoabdominal Aortic Aneurysm

There are no commercially available branched endografts for TAAA involving the visceral branches, and therefore, open repair is the standard treatment for TAAA. However, it is highly invasive because the surgery involves opening of both the thoracic and abdominal cavities. Cardiac dysfunction, respiratory failure, renal failure, or redo aortic surgery predicts poor postoperative survival.^{57,58} Therefore, TAAA patients with severe comorbidity are not candidates for open repair and are ideally treated endovascularly. Endovascular treatments for TAAA, including fenestrated endovascular abdominal aortic repair (EVAR) (FEVAR), branched EVAR (b-EVAR), and PMEG, are required not only to exclude the aneurysm but also to maintain the visceral branches. While PMEG and other procedures such as snorkel (chimney) methods or debranching TEVAR can be performed in

emergency cases, industry-made fenestrated endografts and branched endografts take considerable time to procure. In a high-volume center experience, the 30-day mortality was 5 to 19%, and postoperative complications, of which paraplegia is the most common, occurred in 10 to 16% of cases. Severe perioperative complications were encountered most frequently following treatment of Crawford type II TAAAs.⁵⁸⁻⁶¹

Totally Endovascular Repair for TAAA

The most common type of FEVAR is composed of a Zenith platform (Cook Medical). The number of fenestrations is determined by the number of reconstructed branches, and iCAST (ATRIUM Corp, Hudson, NH) has often been used for reconstructing the visceral branches. Since the main device is commonly inserted via the common femoral artery (CFA) and the required number of sheaths for branched reconstruction is inserted from the contralateral CFA, common complications include limb ischemia due to prolonged sheath insertion and the occurrence of endoleaks from the junctions between the main endograft and the branch stents. Industry-made branched endograft is also consisted of Zenith (t-Branch, Cook Medical). This device has sleeves for the visceral branches, and the main device is inserted via the CFA, but unlike with FEVAR, the sheath for reconstruction of the visceral branches is inserted via the brachial or axillary arteries (► Fig. 2). Thus, there seems to be a lower incidence of limb ischemia compared with FEVAR. However, the cerebral infarction rate following b-EVAR is higher than for FEVAR because of the need to pass devices through the aortic arch region.⁶²

The outcomes of FEVAR and b-EVAR have been reported from various institutions.⁶²⁻⁷² Technical success was achieved in 90 to 97% of elective cases. The 30-day mortality was 0 to 9%, the occurrence rate of SCI was 4 to 12%, and the visceral vessel patency rate was 90 to 100%. Endoleak was

identified in 3 to 15% of cases, and the reintervention free rate at 3 years ranged between 80 and 90%. The outcomes of Crawford type II TAAA was accompanied with higher mortality and longer hospitalization compared with Crawford type III TAAA. The risk factors for poor long-term survival following TAAA treatment were old age, chronic pulmonary obstructive disease, and Crawford type II TAAA.⁶⁵ In a comparison between FEVAR/b-EVAR and open surgery for the treatment of TAAA including suprarenal and pararenal AAA, the mortality rates were 6.7 and 5.4%, respectively, with no statistical difference, but the cost-effectiveness of endovascular repair was overwhelmingly inferior to that of open surgery.⁷¹

Other techniques include the sandwich technique and TEVAR with celiac coverage. Although the first report of the sandwich technique was initially performed for iliac aneurysm, this technique can be applied to TAAA, especially in emergency cases.⁷² Recent reports showed that the technical success and 30-day mortality rates were 88 and 6.3%, respectively, and endoleaks and risk of visceral stent occlusion were more frequent as the number of chimney grafts increased.⁷³ TEVAR with CA coverage indicated for Crawford type I TAAA cases is safe and effective when the CA-SMA collateral circulation is present. Technical success was acceptable, but the 30-day mortality was 9.7% in a recent review, and the most common cause of death was visceral ischemia, which accounted for 30% of such cases.^{74,75}

Hybrid Repair of TAAA

Hybrid therapy usually termed as abdominal debranching TEVAR, which consists of endograft deployment across the visceral branches followed by extra-anatomical visceral artery bypass is an acceptable option for high-risk patients with TAAA. Both the iliac artery and aortic bifurcation are

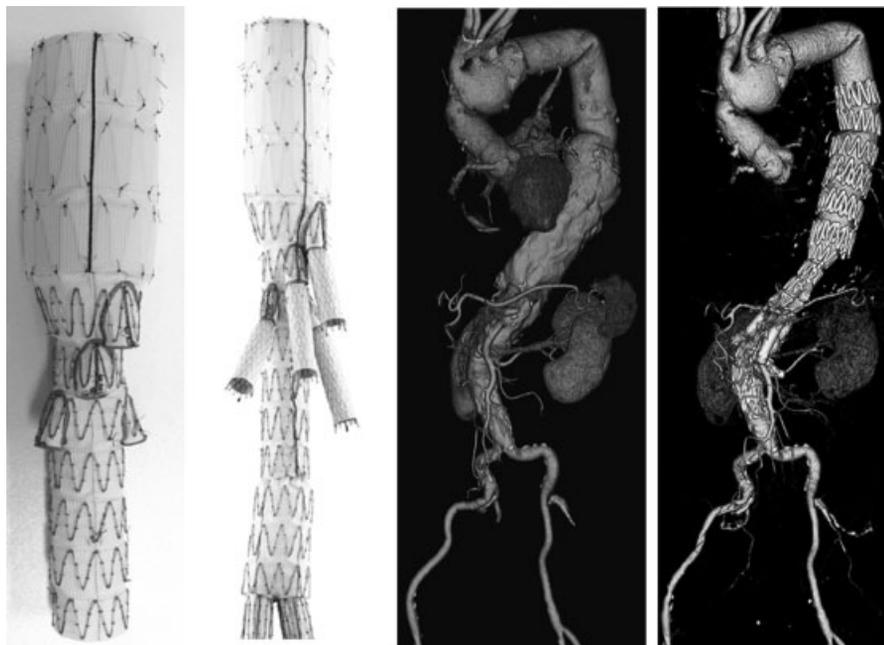


Fig. 2 t-Branch endograft. Endovascular treatment for thoracoabdominal aortic aneurysm using custom-made device.

generally used as a bypass inflow. Recent results were ~2 to 13% in terms of 30-day mortality, and the incidence of major complications was 7 to 29%, and endoleaks occurred in 5 to 17% of cases.⁷⁶⁻⁸⁰

Abdominal Aortic Aneurysm

Parodi et al⁶ were the first to report the use of an endograft for AAAs. At the time, only straight type endografts were available, but a modular graft was subsequently developed, and a clinical study was reported.⁸¹ The endograft for AAA differed from that for TAA in the industry developed and launched them during the early phase. Although a clinical trial using an industry-made device started mainly in Europe in 1995, the effectiveness of the treatment itself was threatened due to various complications following EVAR. However, second-generation endografts with improved performance was developed. Two randomized controlled clinical trials (EVAR trial 1 and DREAM trial) using second-generation endografts were undertaken in Europe.^{82,83} Both showed a remarkable 60 to 70% reduction in 30-day mortality with EVAR compared with open repair, and the EVAR was superior to the open repair in freedom from ARD at 4 years following surgical intervention. These favorable outcomes helped early adoption and penetration of EVAR as well as further development of next-generation endografts. These trials have recently reported their 15-year follow-up in results. According to these results, the advantage of EVAR was gradually lost after 8 years following treatment. Moreover, both ARD and cancer death were significantly higher following EVAR in the long-term period.⁸⁴ However, since the newer devices have largely resolved the short comings of prior generation endografts used in these trials, and also since both trials had poor imaging follow-up that led to missing the opportunity to detect and treat endoleaks, the long-term results of these trials need to be interpreted with great caution.

Infraarenal Abdominal Aortic Aneurysm

RCTs comparing EVAR and open repair along with the trials stated previously showed that the early outcomes including mortality were superior for EVAR, but the advantages of EVAR were gradually lost in the long term.⁸⁵⁻⁸⁷ The most common long-term complications of EVAR include endoleak, migration, infection, and late rupture. Even though there are such concerns of EVAR in the long term, more than half of the AAA cases worldwide are currently treated with EVAR.⁸⁸ Recent reports described that the 30-day mortality of EVAR was 0.5 to 1.7%, and that for open repair was 0.6 to 4.7%. Additionally, reintervention of EVAR was 5 to 9%, while that for open repair was 2 to 5%.⁸²⁻⁸⁷ The endografts can be classified into two types: those with a suprarenal stent and those without. Endografts with a suprarenal top stent are Endurant (Medtronic), Talent (Medtronic), Zenith (Cook Medical), Zenith LP, Ovation (Endologix, Santa Rosa, CA), InCraft (Cordis Corp, Bridgewater, NJ), and Treovance (Bolton), whereas those without a suprarenal stent are AneuRx (Medtronic), Excluder (Gore), Anaconda (Vascutek, Scotland,

UK), Aorfix (Lombard Medical, Irvine, CA), and AFX (Endologix).

Based on the IFU, the length of the proximal neck is required to be more than 10 to 15 mm and absence of severe angulation when performing EVAR. However, even in cases outside the IFU, including short proximal neck or severely angulated neck, EVAR can be performed by modifying the technique. However, it has been pointed out there is a difference in long-term outcomes between inside IFU (on label) and outside IFU (off label) cases.⁸⁹ Early type 1 endoleak and early reintervention rates were 7 and 10% for inside IFU versus 18 and 24% for outside IFU, respectively. In a multivariate analysis, a neck angle >60 degrees carried a risk of death, sac expansion, and early reintervention, a neck length <10 mm carried a risk of early/late reintervention and late death. The internal iliac artery (IIA) should not be occluded according to the IFU and to preservation of at least one IIA is also recommended by the SVS guidelines.⁹⁰ A systematic review of 2,671 patients was undertaken.⁹¹ IIA coverage was required in 15% of EVARs, and the overall incidence of buttock claudication was identified in 28% of cases. The occurrence rates of buttock claudication between unilateral and bilateral IIAs killed were comparable (unilateral 29.2 vs. 30.3% bilateral). Meta-analysis of 15 studies comprising 931 patients revealed that unilateral IIA killed was associated with a reduced incidence of buttock claudication compared with bilateral killed. In another study, buttock claudication was reduced when coils were placed in the proximal IIA ($p = 0.003$). Erectile dysfunction occurred in 10.2% of cases, with higher rates after coil embolization of the IIA. However, ischemic complications were very rare. Recently, new devices, such as Zenith IBD (Cook Medical) or Excluder IBE (Gore, **Fig. 3**), for preserving IIA have become commercially available and have shown excellent outcomes.^{92,93}

As mentioned previously, postoperative complications following EVAR include endoleaks, migration, and infection. Initially, types 1 and 3 endoleaks attracted much attention and were treated, but recently, problems related to sac enlargement with or without type 2 endoleak have been recognized as a weakness of EVAR. Although types 1 and 3 endoleaks should be resolved, the treatment of type 2 endoleaks remains controversial. The incidence of type 2 endoleaks within 6 months is 10 to 15%.⁹⁴ Factors affecting persistent type 2 endoleak include a patent inferior mesenteric artery, number and diameter of patent lumbar arteries, and anticoagulation therapy.^{95,96} Since a delayed type 2 endoleak may be associated with sac enlargement,⁹⁷ various treatments including laparoscopic ligation of the side branch vessels, coil embolization, and glue embolization are performed to resolve these type 2 endoleaks. However, more than 50% of the aneurysm sac treated for type 2 endoleaks continue to expand.^{98,99} Therefore, type 2 endoleaks remain difficult to treat. As such problems, an endograft capable of occluding side branches at the time of EVAR have been developed and have been termed as endovascular aneurysm sealing. With this system, side branches are occluded by injecting polymers into the aneurysm sac during EVAR to prevent type 2 endoleaks. Early results appear to be promising but the ultimate role and value of this system are yet to be proven.^{100,101}

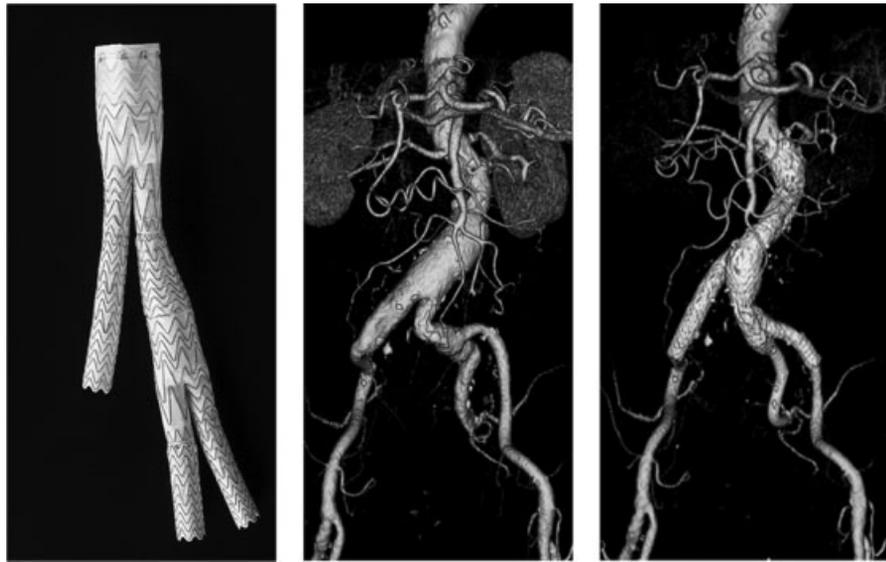


Fig. 3 Excluder IBE endograft. This is an off-the-shelf device allowing for the preservation of the internal iliac artery.

While a cut down is commonly required for the insertion of an endograft via the CFA, the feasibility of percutaneous EVAR has been reported with acceptable outcomes.¹⁰² However, wound complication is a rare occurrence during EVAR.¹⁰³ Endograft infection after EVAR is also rare (0.6%). Most patients underwent with endograft infection have undergone surgical treatment with a prosthetic graft or an allograft. The estimated 30-day/in-hospital mortality was 26.6% for all cases, and for the patients receiving conservative treatment, the mortality rate was alarmingly high (63.3%).¹⁰⁴ Therefore, late endograft infection is an unsolved and a difficult problem.

Ruptured AAA and Pararenal AAA

EVAR was expected to be a useful treatment option for ruptured AAA because it is less invasive.¹⁰⁵ However, the IMPROVE RCT trial,¹⁰⁶ which compared open repair and EVAR for ruptured AAA, failed to demonstrate the superiority of EVAR in terms of 30-day mortality and cost-effectiveness. However, EVAR was superior to open repair in length of stay and the possibility of home discharge. In addition, EVAR performed at high-volume centers showed improved mortality and outcomes.¹⁰⁷ The aorto-uni-iliac or Nellix devices are useful even in anatomically unsuitable cases. Since the outcomes of EVAR for ruptured AAA that follow a protocol are better than those without a protocol,¹⁰⁸ EVAR for ruptured AAA following a protocol at a high-volume center is considered desirable.

Since the treatment of pararenal AAA is not possible with a standard EVAR, a fenestrated graft or snorkel technique is required. The Zenith fenestrated graft (Cook Medical) has been approved by the FDA and has obtained CE mark.^a In a multicenter trial, there were no 30-day mortality and no ARD.¹⁰⁹ Recent studies have confirmed this excellent out-

come with a 0 to 7% 30-day mortality and 95 to 98% visceral vessel patency.^{110–112} On the contrary, the 30-day mortality and target vessel patency were 1 to 4% and 92 to 96%, respectively, with the snorkel EVAR.^{113–115}

Conclusion

Endografts have revolutionized the treatment of aortic aneurysms and have enabled treatment of otherwise inoperable patients. Although short comings of EVAR exist, its contribution is significant and EVAR is here to stay. Miniaturization and improving long-term outcome are remaining issues for endovascular repair of TAAs and AAAs, while much more development and accumulation of data are required for the treatment of ascending, aortic arch, thoracoabdominal aneurysm, as well as acute and chronic dissections. Conversely, the role and volume of surgical repair will most likely continue to diminish.

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^a CE mark is a standard conformity mark that products are attached to those that meet the criteria of all EU member states.

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