Giampiero Esposito

INNOVATIVE GRAFTS FOR THE AORTIC ARCH REPLACEMENT

EDIZIONI MINERVA MEDICA
Thoracic aortic surgery represents today the ultimate compendium of all the techniques, the technology and the notions applied to cardiac and vascular surgery. The arguments that will make up this complex chapter are numerous, different but intriguing. Anyone who undertakes this type of surgery must be capable of dealing with different problems such as the reconstruction of valves and the myocardial revascularization since, in this area, the aortic valve, the aortic sinus and the coronary ostia are often involved. There are many facts that will be discussed and treated in this book.

The first point of interest is the myocardial protection. Considering the complexity and the length of the surgery, the myocardial protection must be considered and best resolved with all the techniques and strategies possible. One of the most important problems that needs to be faced is that of the cerebral perfusion and of the spinal cord protection, since in these diseases the supra aortic vessels and the arteries that supply blood to the spinal cord are often involved. In just a few years we have witnessed a great improvement from the generic and non-specific cerebral protection entrusted to deep hypothermia, to the selective perfusion of the carotid and subclavian arteries. It is precisely this change that has allowed an important evolution conducive to particular complications.

Another topic of discussion will be the splanchnic protection. We will see which techniques and, above all, which results and advantages were obtained in the intestinal and kidney area. Even in this case, we have gone from the hypothermic protection to the intraoperative perfusion of the abdominal and visceral thoracic district. It is absolutely necessary to be able to manage an extra corporeal circulation which, quite often, is quite complex, since in the central phase of the intervention it is necessary to ensure both the perfusion of different districts with different pressures and flows contemporaneously for very long times.

What is the reason and what are the elements that have induced, encouraged and prompted this change? The first consideration regards the objective that needs pursuing today. In the past few years the main goal of surgery has gone from simply saving a patient from a serious threat (and I am referring to the type A aortic dissection), accepting the complications that seem inevitable, to new a surgery that no longer has as its sole objective of momentanely saving the life of the patients but also try to give a complete recovery of the diseased aorta, at least in the district where the evolution is most dangerous and less controllable and with minor complications. All this has been made possible thanks to the inventions of a modern generation of prosthetic and endoprothetic materials, suitable and provided for both intraoperative and post surgical use. After years of evolution, a series of multibranched vascular grafts are available, giving the chance to cure different type of aortic diseases, recreating the anatomic design of the aorta and its branches. Hybrid aortic repair is a
real point of convergence between traditional vascular surgery and endoprosthesis technology. Is it an easy undertaking? No, it is not. It is much more complex but much more logical and quite definitive. It requires considerable experience, great mental order, customary surgical skills, much rationality and a mastery of techniques and different technologies.

The results, as we shall see, are absolutely thrilling both in the present and in the future. There is a new or numerous new paths to follow, to discover how to deal with a disease that was often just controllable and only for a limited period of time.

Not many years have passed since De Bakey and Crawford presented amazing repairs with the complete replacement of the entire aorta from its origin from the heart to the bifurcation in the iliac with segments of Dacron. Those were the results of acrobatic gestures by unique so-called wizards of the scalpel. The complications, at least a few of them, like paraplegia or cerebral and intestinal ischemia, however, seemed insuperable and the surgical gesture was, as mentioned previously, attributable to some extraordinary players who were technically gifted.

Today, as we shall see, by exploiting technique, reasoning, culture and technology, incredible results are within the reach of many and while so difficult to imagine only a few years ago, complications remain contained within percentages previously unthinkable. Gone are the days when we used to believe that there is no recovery or cure of vascular disease, aneurysm or dissection; that it cannot be healed because it is an intrinsic disease of the vessel wall. Today, it can finally be treated well, in the most uncompromising segments with lasting results in time without creating invalidity. It is no longer limited to those few “magicians” who remain those who historically have opened a road that still has a long way to go.

The techniques that are presented and discussed in the various chapters are, although sometimes complex, accessible to all and are the brilliant compendium of personal experience and technological evolution.

As always, the future comes from a critical observation of the past.

Vincenzo Arena
Specialist in Cardiology - Vascular Surgery and General Surgery, Senior Consultant Cardiac Surgery, Humanitas Gavazzeni, Bergamo (Italy)
In 1957 DeBakey and colleagues published the first successful surgical repair of an aortic arch aneurysm in a 56-year-old patient by replacing it with a homograft. Since then extraordinary progress in the treatment of this complex pathology has been made and nowadays the armamentarium of cardiovascular surgeons includes a wide spectrum of methods, ranging from conventional open procedures to minimally invasive, endovascular, hybrid and catheter-based procedures. It has been a dream of mine, as surgeon deeply involved in developing less invasive and more reproducible procedures in this field of aortic surgery, to edit a book where international experts could share with the medical community their efforts on improving existing conventional methods or innovative minimally invasive techniques in the hope of providing better care for our patients.

My dream has become a reality and I wish to express my sincere gratitude to all the involved colleagues: without their help this book would not be possible.

I deeply thank all the staff of Minerva Medica for their support and dedication to this project as well as the sponsor Jotec. A particular thank to Fabio Rocchi for his unbelievable medical engineering support in choosing the best way and the more adequate surgical/endovascular material to treat our patients with thoracic aortic disease.

Last but not least I thank my wife Linda, my sons Edoardo, Eugenia, Andrea and my mother Liliana in supporting me every day.

I dedicate this book to them as well as to all my patients.

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Hybrid approaches to aortic arch lesions were developed with the goal of treating patients at high risk for traditional open operations. These procedures were assumed to be safer because they avoided or limited the use of cardiopulmonary bypass (CPB) and hypothermic circulatory arrest (HCA). Extra-anatomic bypasses of the supra-aortic vessels were combined with endovascular techniques and early reports described the feasibility of such an approach with similar outcomes to conventional open repairs.\(^1\,^2\) As more experience has accumulated with these integrated procedures, the risk of neurovascular events, spinal cord injury, retrograde aortic dissections and endoleaks brings their value into question. Technical success has been reported to be 86%, with the most common cause of failure being type 1 endoleak (9%). Perioperative stroke and death averages approximately 16%.\(^3\)

As early as 2005, we performed these procedures at our institution with some excellent success in the highest risk patients, but we also encountered issues with stroke and retrograde dissection that have given us pause. We rarely perform a simple debranching procedure combined with landing thoracic endografts into zone 0 of the aorta at the Cleveland Clinic Aortic Center. Instead, we tailor the operation to the patient's anatomy and disease. We believe it is more effective to employ all of the tools at our disposal including the use of stent-graft devices and the use of CPB and cardiac arrest with or without HCA. When possible, we avoid landing a stent-graft into native proximal aorta. As long term follow-up of stent-grafts continues, it is not surprising to see that many patients require additional interventions at a later date, because other segments of their aorta frequently develop disease. Rather than simply providing a less invasive approach for higher risk patients, the hybrid approach to the aorta facilitates a more effective and potentially more durable repair for the complex aortic patient. It also allows for a scaled approach to the patient while maintaining quality with the potential for increased safety. The objective of this article is to review the current hybrid options to address lesions of the aortic arch and describe how we apply them in our practice.

### Conventional total arch repair

Advances in cannulation techniques, hypothermic circulatory arrest, cerebral perfusion monitoring and anesthesia have been revolutionary in the treatment of aortic arch pathologies. Outcomes continue to improve, and the procedures are becoming safer.\(^4\,^6\) The traditional open approach utilizes of CPB, cardiac arrest and HCA with selective antegrade brain perfusion to a core temperature of approximately 20 °C. A branched polyester graft is then anastomosed to the proximal descending thoracic aorta with separate grafts to the left subclavian artery (LSA), the left com-
mon carotid artery (LCCA) and the innominate artery. After a process of de-airing the graft and aorta, the cross-clamp is applied to the proximal graft, flow is restored and the patient is rewarmed while the proximal anastomosis is performed, with or without addressing any issues with the aortic valve.

Results for the open technique of total arch repair procedures are the gold standard and have yet to be improved upon by more complex but potentially less invasive hybrid techniques. At the same time, patients who were previously denied surgery because of comorbidities and prohibitive risk often being treated with a hybrid approach with similar results to conventional repair. Recent comparisons of hybrid versus open traditional repairs reveal no difference in outcomes despite the higher risk population that lends itself to the less invasive techniques, but these comparisons are generally under powered and biased by the heterogeneity of the population.\(^1,2,7,8\)

Hybrid arch repair classification

Hybrid arch repair in the literature has taken on a wide range of meanings. In many series hybrid arch repair includes procedures such as thoracic endovascular aortic repair (TEVAR) with coverage of the left subclavian artery before or after a carotid to subclavian artery bypass. They can also include patients with multisegment disease who have undergone sternotomy, CPB, HCA with total ascending and arch replacement with placement of traditional elephant trunk (ET) completed with TEVAR to address the distal arch and descending aorta. To simplify a discussion of hybrid arch repair, we use a classification system that focuses on the intensity of mechanical circulatory support to differentiate the various repair. Additionally, procedures can each be subdivided into single (S) or dual staged (D) repairs. The common element, is that both open and endovascular techniques are employed to repair the entire arch, resulting in a “hybrid” procedure. We do not include the simpler combination of left subclavian artery coverage and revascularization in our classification of hybrid arch repair since this is essentially a descending aorta repair. The specific approach for each patient is dictated by the surgeon’s preference, the patient’s particular anatomy and comorbidities. This classification scheme is illustrated in Figure 1.1.

Type I hybrid repairs are performed on a beating heart (with or without CPB) and utilize a side-biting clamp on the ascending aorta to facilitate debranching of the supra-aortic vessels to create a landing zone in the ascending aorta for a thoracic endograft, placed in a single (S) or dual (D) staged procedure, via an antegrade or retrograde approach, respectively.

Type II hybrid repairs are performed using CPB with cardiac arrest, but without HCA. These repairs include replacement of the ascending aorta with a surgical graft and debranching of the supra-aortic vessels, and landing a thoracic endograft in the replaced ascending aorta via a retrograde or antegrade approach in a single (S) or dual (D) staged repair.

Type III repairs require HCA and are typically performed in patients without a suitable proximal aortic landing zone even after debranching due to multi-segment disease. These repairs include the replacement of both the ascending aorta and the arch using a surgical graft and the creation of an elephant trunk. The elephant trunk may be stented- or frozen- and completed in a single (S) stage or completed endovascularly as a dual (D) staged repair.

Patient selection

Indications for aortic arch replacement include acute or chronic aortic dissection extending into the aortic arch, aortic arch aneurysm either in isolation or involving multi-segment thoracic disease, and congenital arch disease including aortic coarctation or Kommerel’s diverticulum.
Imaging and perioperative considerations

There is great variability in arch anatomy and morphology. When selecting patients for a hybrid arch procedure a clear understanding of the aortic anatomy is crucial to planning the operation. Preoperative contrast enhanced computed tomography (CT) of the chest, abdomen and pelvis with three dimensional reconstructions provides the necessary information. For type 1 and 2 repairs where the device is placed into the highly elastic ascending aorta, endograft selection is typically performed with oversizing around 20% to optimize sealing. For a type 3S repair, or frozen elephant trunk, the endograft device is fixated directly into the aorta with suturing so no oversizing is used to optimize fit and minimize wrinkling of the graft material. Measurements of the aortic diameter are made at the point of fixation within the arch and at the distal landing zone, perpendicular to the axis of blood flow using 3-dimensional multiplanar reconstructions. When there is any doubt about the landing zone measurements, intravascular ultrasound (IVUS) is a reasonable adjunct but will not necessarily provide a true center line measurement.
Serial imaging during follow-up is critical to monitor aortic remodeling and to assess for progression of disease or the need for re-intervention. Patients are monitored during follow-up for blood pressure control, and CT scans are reviewed at an initial 3-month interval followed by an annual study thereafter.

**Type I repairs**

Because of concern about the risk for type 1 endoleaks and retrograde dissection, we have reserved the use of this type of hybrid for the uncommon patient considered high risk for CPB, cardiac arrest and HCA. A typical patient that fits these criteria may be an elderly patient who presents with contained rupture of a focal arch aneurysm and refuses blood transfusion due to religious beliefs. The patient is brought to the operating room and a median sternotomy or hemisternotomy is performed. The supra-aortic vessels are exposed and mobilized. The ascending aorta is clamped tangentially just above the sinotubular junction and the main body of a multibranched graft is anastomosed to the right anterolateral aspect of the aorta. Care is taken to provide the most room possible for subsequent landing of a thoracic endograft stent by placing the surgical graft as close to the sinotubular junction as possible. The head vessels are then sequentially grafted starting at the left subclavian artery if it is accessible. We prefer to perform these as end-to-end anastomoses to limit the risk of atheroembolization. When the intrathoracic left subclavian artery is not accessible it can be addressed with a bypass to the supraclavicular portion of the subclavian artery. This can be performed at the time of the initial operation or at a later date using the left carotid artery as in flow. A left carotid to subclavian artery bypass may also be performed prior to the planned arch operation. If it is performed as a two staged repair, the thoracic stent graft is usually delivered in a retrograde fashion with femoral artery access. For the single stage repair, antegrade stent-graft delivery via a separate branch graft coming off the main body or via the ascending aorta itself is also feasible. If the indication is contained rupture, we prefer a single stage approach. If the length of coverage is extensive and the indication is less of an emergency, then staging the repairs may reduce the risk of spinal cord injury. Spinal cord protection is also addressed by maintaining mean arterial pressures from 80 to 100 mmHg postoperatively, and we have a low threshold to use cerebrospinal fluid drainage.

In our experience, placing an endograft in the native zone 0 aorta is not an ideal operation. It has been shown to be a risk factor for retrograde dissection of the ascending aorta, reintervention for endoleak, pseudoaneurysm formation, and stroke. Particularly, retrograde aortic dissection is a serious concern. The rate of retrograde dissection ranges from 0% to 24% (Tab. I.I). This is likely due to the nature of the diseased aorta, trauma from the placement of a side-biting clamp, and additional trauma from instrumentation of the native ascending aorta.

**Type II repairs**

Deploying a thoracic endograft within graft material eliminates the risk of retrograde ascending dissection. Type II hybrid repairs of aortic arch pathology aim to decrease morbidity by limiting the use of CPB and avoiding HCA. Like the type 1 repair, type 2 repairs include debranching the aortic arch but also included ascending graft replacement to providing a more reliable landing zone for a staged or simultaneous TEVAR delivery and deployment. The typical anatomy lending itself to the type II hybrid arch repair is that which involves a dilated or dissected ascending and proximal descending thoracic aorta. Because the heart is arrested for ascending repair, this approach is also applicable to patients with concomitant valve pathology requiring repair or replacement.

The patient is placed on CPB via central cannulation or right axillary artery cannulation. The aorta is cross clamped and the heart ar-
rested. Valve or coronary disease is addressed first, then the ascending aorta is replaced utilizing a main body graft anastomosed to the level of the cross clamp and the proximal ascending aorta at the sinotubular junction. The supra-aortic debranching is performed after removal of the cross clamp to optimize lie of the branch grafts. After debranching, a TEVAR may be deployed in the newly created ascending landing zone via an antegrade approach using an extra limb of the main body graft or via a traditional retrograde approach from the femoral arteries. This can be performed in a single or dual staged procedure.

### TABLE I. I. Results for hybrid arch repair.

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<th>Type</th>
<th>30-day mortality (%)</th>
<th>Stroke (%)</th>
<th>SCI (%)</th>
<th>RAD (%)</th>
<th>Endoleak (%)</th>
<th>HD (%)</th>
<th>Re-op bleeding</th>
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<td>Kent (2014)³⁴</td>
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<td>Andersen (2013)¹²</td>
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<td>Di Eusanio (2014)²⁵</td>
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<td>Shrestha (2015)²⁰</td>
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<td>Leontyev (2016)²⁶</td>
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SCI: spinal cord injury; RAD: retrograde aortic dissection; HD: hemodialysis.
Although the graft in the ascending aorta provides a safer and more reliable landing zone than the native aorta, we have found that the risk for type 1 endoleak is high if the length of the ascending graft is not sufficiently long enough to provide seal for at least 3-4 cm of parallel lie within that proximal landing zone. For this reason, we fashion the ascending graft to be as long as is feasible and create the origin of the branch grafts as proximal as possible. Some have advocated this repair for patients requiring reoperation after conventional ascending replacement for acute type A dissection. Although this is feasible, we have found that most of the time the old graft is too short to provide enough space for both debranching and as a reliable landing zone for the TEVAR.

**Type III repairs**

In 1983 Borst and colleagues pioneered the “elephant trunk procedure” that entailed leaving a graft in the descending aorta beyond the left subclavian artery for use in subsequent aortic repairs. Svensson later describe a modified elephant trunk technique that involved inverting the graft during the distal arch anastomosis. This was developed in an effort to reduce the risk of tearing and hemorrhage at the anastomotic site. These procedures have become safer through the years and recently, we have reported on our experience with prophylactic use of the ET procedure. The indications for the prophylactic ET included a descending aortic diameter of >4 cm, chronic dissection, or known aortitis or connective tissue disorder. We reported an operative mortality of 0.08% (1 of 117 patients), a stroke rate of 6%, hemodialysis for renal failure in 3.4% and respiratory failure requiring tracheostomy of 5.1%. Many of these patients have gone on to require endovascular elephant trunk completion procedures including some with emergency indications. The use of HCA when paired with antegrade brain perfusion is very safe. Although the carotid arteries can be directly cannulated for bilateral brain perfusion, right axillary cannulation is our preferred method for patients requiring redo surgery. Exceptions are patients with an aberrant right subclavian artery or other contraindication to right axillary cannulation. The type 3 hybrid repairs combining both HCA with antegrade brain perfusion and the use of stent-graft devices has become our preferred operation for treating complex thoracic aortic pathology involving the total arch. These tools allow for full exposure, secure reliable placement of the stent-graft device and a complete method of repair. We select the frozen elephant trunk single stage operation (type 3S hybrid) for patients with more limited disease and the two staged elephant trunk with endovascular elephant trunk completion TEVAR (type 3D hybrid) for patients with more extensive distal disease. As our experience has grown, use of the frozen elephant trunk (FET) technique is increasingly more common. The frozen elephant trunk has an advantage over the traditional elephant trunk due to the presence of the stents within the distal portion of the graft/repair. This is particularly helpful for patients with aortic dissection. Placing a stent graft in the true lumen of the dissected descending aorta allows for a supported structure that is better suited to withstand the small diameter of the true lumen and the forces exerted upon it by the flow in the false lumen. The frozen elephant trunk is easier to access at a later date, and is less prone to kinking or thrombus formation than the conventional elephant trunk graft. We are now performing most of our elephant trunk procedures as a frozen or stented type even when we anticipate that the extent of disease may require a subsequent second stage stent-graft extension. Currently the indications for the use of the FET technique are evolving but is applicable to patients with acute DeBakey type 1 aortic dissections with malperfusion or distal entry tears, post-dissection aneurysmal degeneration after type A repair, type B dissections where TEVAR is not an option (no landing zone, dilated arch, steep arch angulation), thoracic aortic aneu-
Current management of aortic arch lesions with hybrid procedures: a tailored approach to a progressive disease

INNOVATIVE GRAFTS FOR THE AORTIC ARCH REPLACEMENT

The graft is positioned at the edge of the aorta on the underside of the arch and secured here with a 4-0 polypropylene suture. The stent graft is then fenestrated with an eye cautery device under the orifice of the left subclavian artery and sometimes the left carotid artery too. If the arch branch vessels are also dissected then a separate 2.5-cm-long stent graft is placed through the fenestration directly into the branch artery and ballooned with a conformable balloon. The thoracic stent graft is then sutured circumferentially to the distal aortic arch to close the false lumen and secure the stent-graft to the aorta.

The distal aortic hemiarch anastomosis is then performed in the usual manner with a beveled surgical graft, reinforced with bovine pericardium externally. The stent graft is included in the anastomosis as a neointimal layer and helps to optimize hemostasis due to the radial force from the stents. The anastomosis is continued around the base of the origin of the innominate artery to complete the arch repair as a single distal anastomosis.

If the FET procedure is being performed as an elective operation for chronic dissection or aneurysm, the innominate and left common carotid arteries are usually reconstructed with separate grafts in an end to end fashion to each of two 8-10 mm side limbs from the surgical graft. The proximal anastomosis is then performed after complete de-airing, cross-clamping of the graft and initiation of rewarming and reperfusion are started. When performed in a dual staged procedure, the risk of paraplegia has been shown to be reduced.

Hybrid repairs for congenital aortic arch disease

Congenital arch anomalies also lend themselves to a hybrid approach and these techniques have evolved with the treatment of these patients in mind. Patients with previous coarctation of the aorta, in particular, are at risk for late aortic
complications and commonly have concomitant heart disease. This combination of pathology makes a hybrid repair attractive in that it enables you to treat the patient in one setting through an anterior approach while avoiding a reoperative field in the left chest. These patients are at risk for developing post repair aneurysms or pseudoaneurysms, often have bicuspid valve disease, and recurrent coarctation. In our study of hybrid repairs of aortic aneurysm in patients with a previous coarctation, the most common operation performed was a frozen elephant trunk.26 The patients undergo retrograde access with a 100-cm catheter from the femoral artery, across the often complex aortic pathology and a sternotomy is then performed. CPB and HCA is instituted. The endograft is deployed over the previously placed wire, across the abnormal segment of thoracic aorta and the proximal end of the device is sutured at the arch. Additional cardiac and proximal aortic disease can be addressed. Most commonly, we perform ascending replacement or patch angioplasty for a hypoplastic arch, with or without a valve or root procedure. Some patients with more extensive disease required a two-stage procedure that involves completion of the elephant trunk with a stent graft delivered retrograde from the iliofemoral vessels.

Some of these patients have particularly complex anatomy. We reported on one patient that underwent previous coarctation repair with an interposition graft at the age of 6 and subsequent left subclavian artery to descending aorta bypass for recurrent coarctation at the age of 25. The patient presented with a pseudoaneurysm originating at both the proximal and distal bypass anastomoses and persistent but minimal flow through the original interposition graft as well as a severely stenotic bicuspid aortic valve. For this challenging combination of problems, we devised a multicomponent hybrid repair that included redo-median sternotomy and CPB but not HCA. The procedure included an ascending to descending aortic bypass, aortic valve replacement with a bioprosthetic aortic valve, and stent-grafting from the arch into the left subclavian artery with a tapered iliac limb device, and stent-grafting into the previous interposition graft from below in order to seal the growing pseudoaneurysm in both an antegrade and retrograde fashion (Fig. 1.2). These hybrid repairs allowed for a less invasive repair solution to very complex and challenging anatomy that would otherwise have required multiple more invasive procedures. In our series of hybrid repair of post coarctation complications, there were no mortalities, neurologic complications, or renal failure. Three patients developed endoleak and two required endovascular reintervention. We will continue to follow these patients long term to better understand the durability of these interventions.26

The right-sided aortic arch is a rare congenital defect and is a result of the anomalous development of the embryonic aortic arches. It occurs in less than 0.1% of the general population.27-29 A Kommerell diverticulum is a diverticulum of the descending thoracic aorta, originally described with a left sided aortic arch and anomalous right subclavian artery.30 It is a less common finding of the right sided aortic arch and surgical indications for repair of a right sided arch include symptoms of tracheal or esophageal compression and asymptomatic patients with a descending thoracic aortic aneurysm/dissection or Kommerell diverticulum >2.5 cm.30-32 In-hospital mortality of open repair of a Kommerell diverticulum has been reported to be between 8.3% and 18%.27-29 This complex anatomic challenge can be approached with a hybrid strategy combining open surgery and stent-grafting. In our experience at the Cleveland Clinic Aortic Center we have reported the use of hybrid approaches for both right sided aortic arch with aneurysm and Kommerel's diverticulum.30,31 The benefit of the hybrid approach is that it avoids a thoracotomy and single lung ventilation. This approach utilizes either a median or hemi-sternotomy, central cannulation and CPB with HCA and a modified frozen elephant trunk operation to exclude
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Figure 1.2 • Antegrade stent-grafting with complex hybrid reconstruction. Illustration demonstrate pre- (A) and postoperative (B) anatomy before and after hybrid reconstruction. C, D) Volume-rendered computed tomography reconstruction of the same patient before and after the procedure, respectively. From Idrees et al.26