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Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries

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ABSTRACT

Endovascular aortic aneurysm repair of complex aortic aneurysms requires incorporation of side branches using specially designed aortic stent-grafts with fenestrations, directional branches or parallel stent-grafts. These techniques have been increasingly utilized and reported in the literature. The purpose of this document is to clarify and update terminology, classification systems, measurement techniques and end-point definitions that are recommended for reports dealing with endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms involving the renal and mesenteric arteries.

INTRODUCTION

Endovascular aortic aneurysm repair is currently the most frequently used treatment in patients with abdominal (EVAR) and thoracic aortic aneurysms (TEVAR), who have suitable anatomy and appropriate risk.(1-9) In patients with complex aortic aneurysms that do not fit the basic anatomical requirements consistent with the Instructions for Use (IFU) of available devices , a variety of innovative techniques have been described to expand the indications of EVAR and TEVAR.(10, 11) These techniques require side branch incorporation using specially designed aortic stent-grafts with fenestrations and/or branches and parallel stent-grafts.(12-31) Fenestrated and branched stent-grafts and parallel graft techniques have been increasingly utilized and reported in the literature.(12, 14, 16, 18, 20, 28, 29, 32-34) The Society for Vascular Surgery (SVS) 2002 and 2010 EVAR and TEVAR recommended reporting standards provide general and basic definitions that can be extrapolated to more complex repairs.(35, 36) However, endovascular aortic repair using fenestrated, branched and/or parallel stent-grafts introduces unique aspects, ranging from specific terminology, classification systems, measurement techniques to the necessity of coupling aortic repair with bridging stents in a variety of patient specific or off-the-shelf device designs that are not covered in the EVAR and TEVAR reporting standards. The increasing use of these techniques in clinical practice and investigational studies mandates for standardization of terminology and outcome measures to facilitate comparisons between studies and stent-graft designs.(37) Although fenestrated and branched technology can be applied to any anatomical location, the framework of this document focuses on incorporation of renal and mesenteric branches during repair of complex abdominal (AAA) and thoracoabdominal aortic aneurysms (TAAAs).

PATIENT ASSESSMENT

One of the basic tenets in the patient's pre-operative evaluation is a detailed evaluation of the aortic aneurysm anatomy coupled with a thorough assessment of the patient's comorbidities (i.e. cardiac, pulmonary and renal function). This should be conditioned by the surgeon's experience and the endovascular environment and resources available. The extent of aneurysmal disease and a comprehensive clinical risk assessment should be integral components of reports addressing complex aortic aneurysms to allow for a meaningful comparison between reports evaluating various and diverse techniques. In general, most patients with complex aortic aneurysms undergo a comprehensive pre-operative medical evaluation that is guided by cardiovascular risk factors, pre-existing symptoms and medical history.(35, 36)

Clinical comorbidity score systems

Cardiac complications remain one of the main outcome measures and several clinical scoring systems have been developed to assess risk of cardiac events.(35, 38, 39) Previously described cardiac scoring systems include several overlapping clinical conditions, including prior myocardial infarction, history of angina and prior congestive heart failure, which have been found to be associated with higher rates of perioperative cardiac events. The American Association of Anesthesiology (ASA) grading system has been widely utilized for endovascular procedures and has advantages in terms of simplicity, but mainly relies on subjective parameters and lacks detailed information about specific metrics that affect outcomes. This report recommends the adoption of the current SVS/AAVS medical comorbidity grading system (**Table I**) to describe the severity of medical co-morbidities in patients with complex aortic aneurysm disease.(35) However, we acknowledge that the current SVS/AAVS system has yet to be

validated in prospective studies or in a large cohort of patients treated for aortic disease. Importantly, the current SVS/AAVS grading system evaluates not only the presence but also the severity of cardiac, pulmonary and renal diseases that affect treatment selection and outcomes in patients with complex aortic disease and allow for stratification of cardiovascular co-morbidities. In addition, pulmonary complications are common after open and endovascular repair of complex aortic aneurysms. The severity of underlying pulmonary disease is an important predictor of long-term survival amongst patients with complex aortic aneurysms. The Vascular Study Group of New England (VSGNE) modified score scheme (**Table I**), recently proposed in the AAA clinical practice guideline assess seven variables to predict mortality risk in low-risk (0.12 to 1%), intermediate risk (1.7 to 4.9%), high risk (8% to 20%) and prohibitively high-risk patients (31% to 70%).(40-42) This system was validated for infra-renal aneurysms and has not been evaluated for complex aortic aneurysms.

IMAGING ASSESSMENT AND PROCEDURE PLANNING

Endovascular repair of complex aortic aneurysms requires meticulous and precise planning using cross-sectional imaging.(43) The implantation plan requires analysis of the aorta from the arch to the femoral arteries and comprises the evaluation of access sites, aneurysm extent, the three dimensional (3D) course of the aorta, branch vessel anatomy and atherosclerotic burden. The design of an off-the-shelf or a patient-specific fenestrated and/or branched stent-graft is based on anatomical measurements to achieve optimal implantation and to avoid misalignment between the fenestrations and branches and the target vessels. In the case of an off-the-shelf configuration, analysis of branch vessel anatomy is necessary to discern the minimum requirements for successful branch vessel cannulation and stent placement.(20, 44-48)

This is important not only for successful cannulation but also to reduce procedural time, radiation exposure and contrast utilization. For custom made devices (CMDs), the positions and location of the fenestrations and/or branches must be at precise distances from each other in a longitudinal plane for vertical alignment and located at precise circumferential positions for rotational alignment. Branches should also be properly located to allow access to target vessels, while providing a minimum distance from the aortic stent-graft to the target ostium. These measurements should be made using computed tomography angiography (CTA) with multi-slice cuts of ≤ 1 to 3mm. As explained below, measurements include distances, diameters, axial location reported as clock position and arc lengths. CTA images are analyzed in a 3D workstation for multi-planar (MPR) and curved-planar reconstruction (CPR) views using centerline of flow (CLF). The type of workstation and software should be reported. Examples of these systems include Aquarius iNtuition (Terarecon, Foster City, CA), OsiriX viewer (Pixmeo SARL, Bernex, Switzerland), EVAR Assist and Advantage Window (AW, GE Healthcare, Chalfont St Gilles, United Kingdom), 3Mensio Vascular (Bilthoven, Netherlands), or M2S (West Lebanon, NH).

Basic principles

Aortic diameters and length measurements of the intended proximal landing zone should be reported in millimeters to guide the choice of the main aortic stent-graft and to assess the adequacy of the proximal landing zone as predetermined by IFU. Other proximal neck characteristics, such as angulation, thrombus burden, geometric configuration (i.e. parallel walls) and calcification should also be included. The definitions, grading and categorization for the proximal landing zone should follow the recommendations of the SVS Reporting Standards for EVAR.(35, 36, 42)

Sizing and planning of branch incorporation require precise distance measurements based on CPR views and/or straightened CLF MPR reconstructions (sMPR). The *zero reference* point needs to be specified. This is often used to allow measurements between target vessels or to estimate the length of stent-graft coverage above each intended target vessel. There is variation on which reference point is selected. For example, most operators use as reference point the center of the uppermost target vessel (e.g. celiac axis) or the proximal edge (PE) of the stent-graft fabric. Alternatively, the center of the SMA may be used as reference point when measuring off-the-shelf devices.

The minimum recommended sealing zone for planning a fenestrated and/or branched endovascular repair should be specified and ranges between 15 to 25mm in most publications. In recent years, several investigators have proposed using longer sealing zones to prevent late complications from disease progression. It is recommended that investigators specify the *minimum recommended seal zone*, the *total effective seal zone* and the *total used seal zone*, which is often significantly longer than the minimum recommended seal zone (**Figure 1**). The *minimum recommended seal zone* is defined by the minimum length of normal aortic segment that should be used to provide seal. The *total effective seal zone* is defined as the length of seal that has circumferential fabric opposing the aortic wall. The *total used seal zone* is the length from top of the fabric to the start of the aneurysm. For example, if an adequate length of seal zone is present inferior to the superior mesenteric artery (SMA) and a scallop is chosen, the distance from the bottom of the SMA to the start of the aneurysm represents the total effective seal zone. In this case, the scalloped segment does not provide a 360-degree sealing zone and should not be considered an effective seal zone. However, it does contribute to some degree of sealing and should be included in the total seal zone. Alternatively, if a fenestration is planned

for the SMA, the measurement of effective seal zone should be obtained from the top of the fabric to the start of the aneurysm. Distance measurements from the bottom of the lowest renal artery to the aortic bifurcation and to the iliac bifurcation should also be defined to determine selection of distal bifurcated component and iliac limb extensions. These measurements determine the longitudinal positions of fenestrations in the endograft and are adjusted accordingly if the reference point for the proximal edge of the graft is positioned proximal or distal to the bottom of the celiac, as required. Importantly, the final used sealing zone may differ from the preoperative planning if the device is deployed above or below the intended target.

In addition to the distance measurements, circumferential positions of the target vessels and/or fenestrations must be determined and reported.(49) Multi-planar views by adjusting the axis of the sagittal and coronal views to obtain a true axial cut of the visceral aorta are used. The axial location is determined using clock face positions in hours with 15 minutes increments or as 0 to 360 degree angle of origin, where each 15-minutes correspond to a 7.5-degree angle (**Figure 1**). The location of the celiac axis, SMA and renal vessels are determined from this viewpoint. For example, the origin of the left renal artery at 3:00 o'clock position would coincide with a 90-degree angle. Measurements of arc lengths are useful to allow proper location of fenestrations relative to the inner vessel diameter (IVD) at the intended location. Such arc lengths may be measured directly using the line segment feature of the software or may be calculated based on clock position and the intended IVD of the aorta (**Figure 2**). This measurement is used by the device manufacturer to position the fenestration for appropriate alignment with the vessel orifice. The aortic diameter at the level of the target vessels is measured to determine the circumferential distance from the 12 o'clock position at which the scallop and fenestrations are placed. Since the aortic diameter at the renal arteries will be different than the diameter of the graft on which the

fenestrations will be placed, the aortic diameter and clock positions are critically important to calculate the circumferential distance or arc length from the 12 o'clock position. As a general rule, the corrected arc length should be based on the IVD at the intended location of the fenestration. In this scenario the corrected IVD should never be larger than the diameter of the selected stent-graft. For example, if the fenestration is created at three o'clock (or 90 degree) position in a 30 mm diameter stent-graft, but the actual IVD in that location is 40mm, the corrected IVD should be 29mm (Corrected IVD = Diameter of graft – 1). Otherwise, the fenestration would be cut for a 40mm graft which would result in misalignment of the fenestration and target vessel. In cases with significant angulation in the anterior, posterior or lateral axis, the automated center line creation by the 3D workstation software may need to be readjusted, as the aortic endograft and stiffer guidewire systems will not follow the center lumen and instead will follow the contours of the angulated aorta typically resulting in a shorter distance than the centerline. The difference in centerline measurement may significantly affect the calculated distances from the top of the stent-graft to each fenestration or within the origin of vessels themselves. In these cases, it is essential to report the degrees of angulation above and below the visceral segment, as well as within the infrarenal segment of the aorta. Centerline and multiplanar views are useful here to assess the distances and circumferential measurements. If significant discrepancies are evident, the different values should be reported as well as the chosen measurements used for the design of the fenestrated endograft. Target vessel measurements include the nominal diameter in the first 15mm and the length to vessel bifurcation.

Renal artery tortuosity and angulation

Renal artery angulation and tortuosity has been analyzed as an important factor associated with branch-related outcomes.(50, 51) The *renal artery origin angle* is measured between a longitudinal aortic axis and a transverse axis placed at the level of the origin of each of the renal arteries (**Figure 3**).(50) The angle of origin is measured relative to the transverse axis. A positive angle is defined as any angle above the horizontal or transverse axis perpendicular to the aortic axis, and corresponds to upward-oriented renal arteries. A negative angle is defined as an angle measured below the transverse axis and corresponds to downward-oriented renal arteries. *Renal artery tortuosity index* (RATI) is measured using similar methodology as applied for the iliac arteries (**Figure 4**).(35, 51) The index is defined as RATI = L1/L2 where L1 is the distance along the centerline of flow measurement between the distal end of the directional branch or origin of the fenestration (P1) and the distal end of the stented segment(P3). The *renal artery distal target angle* is defined as the angle measured between the proximal and distal segments based on the distal end of the target vessel stent. We recommend using the distance to the first branch point when measuring length of bridging stents.

Renal parenchymal volume

Measurement of renal parenchyma has been used to estimate perfusion and volume size of perfused kidney parenchyma.(52) Volumetric analysis can be done using proprietary software and digital datasets of CTA to estimate kidney parenchyma and total renal volume. For example, to identify the kidney area perfused by an accessory renal artery (ARA), the trajectory of the ARA and main renal arteries are followed in the axial, coronal and sagittal planes and the volume of perfused tissue in the respective segment was estimated. The estimated volumetric kidney parenchyma (VKP) is obtained by dividing the segment volume from the total kidney

volume. Accessory renal arteries can be classified in one of three groups based on VKP estimates: VKP < 25% and/or ARA diameter < 3 mm diameter, VKP 25-40% or VKP > 40% **(Figure 5).**

Aortic wall thrombus

The term "shaggy aorta" has been used to describe diffuse aortic involvement by circumferential atherosclerotic debris. Aortic wall thrombus (AWT) has been quantified as a measure to predict risk of embolization during endovascular procedures.(53, 54) Volumetric measurements can be obtained using CTA and proprietary Software (**Figure 6**) in non-aneurysmal aortic segments of the ascending aorta and arch (Segment A), descending thoracic aorta (Segment B) and renal-mesenteric aorta (Segment C). An index is calculated using the proprietary software volumetric tool to measure AWT burden in the three segments and in the entire length of aorta starting at the aortic annulus and extending 1-cm below the renal arteries. The infra-renal aorta, which is typically affected by large aneurysm and extensive laminated thrombus, is not measured. As it is not possible to measure the volume of the thin walled intima, media and adventitia, an AWT index is calculated by subtracting the volume of the aortic lumen from the total aortic volume, which includes the aortic lumen, any AWT, and the intima, media and adventitia. Therefore, the AWT index is representative of the solid portion of the aortic wall after excluding the blood volume. The AWT index is presented as a percent value (AWT Index = [Total Aortic Volume – Aortic Lumen Volume/Total Aortic Volume] x 100).

In order to facilitate assessment of AWT in clinical practice, Ribeiro and colleagues proposed a novel classification system using a scoring system from 0 to 10 to quantify thrombus type (i.e. smooth or irregular), thickness, area of involvement, circumference and number of affected segments (**Figure 7**).(53) For purposes of this scoring system, the most severely

affected segment of the aorta is analyzed using axial cuts. The area is selected after examination of the entire length of the aorta. The final score may be correlated with the AWT volume index measured in the three aortic segments and in the entire aorta to validate the classification.

Iliac access

As with any aortic endovascular procedure, iliofemoral access is evaluated to determine the feasibility of delivering the device, which currently requires 18Fr to 24Fr introducer sheath depending on the manufacturer. A significant proportion of adverse events during EVAR and TEVAR are related to access complications. To avoid such complications, iliac and femoral artery diameters, lengths and other morphologic features need to be assessed and reported. Additionally, length measurements of the iliac arteries should take into consideration that the proximal end of the bifurcated component will be positioned a few centimeters below the lowest target vessel when it docks in the proximal fenestrated or branched component. The distances to the iliac bifurcation and diameters of the bifurcated components should be included. Other definitions and categorizations relevant to the aortic aneurysm, iliac arteries and branch vessels in terms of diameters, length, angles, tortuosity, morphology, degree of calcification and thrombus burden should follow the SVS reporting standards for EVAR.(35)

ANEURYSM CLASSIFICATION

Aortic aneurysm classification requires uniform terminology that can be compared with prior and future reports dealing with open or endovascular techniques of complex aortic aneurysmal repair.(35) Important determinants of clinical outcomes include specific aneurysm etiology (e.g. degenerative, dissection, mycotic), presentation (e.g. asymptomatic, symptomatic-not ruptured and symptomatic - ruptured) and the extent of the aneurysm. More recently,

endovascular repair has also been used in select patients with genetically triggered aortic diseases.(55-66) The extent of endovascular repair may differ from the traditional anatomical classifications described for open surgical repair because sealing zones are selected in healthy aortic segments, more proximal and distal to the extent of aneurysm.

Etiology

It is recommended that reports dealing with complex aortic aneurysms describe the specific aneurysm etiology using detailed terminology proposed in the SVS TEVAR reporting standards (**Table II**).(36) Given the evolving role of genetically triggered aortic diseases, future publications should also include as much detailed information about the familial nature of these aneurysms, as well as specific genetic abnormalities that were identified within the study population. This is particularly important for comparisons with open surgical reports, given that a large proportion of patients treated for complex aortic aneurysms by open surgery are young and have identified connective tissue disorders. A recent updated classification of the most common genetic disorders, gene mutations and protein abnormalities are provided in **Table III**. Information about genetic testing and genetic counseling should also be described when available. The presence of family history of aortic aneurysm or dissection (number of first degree or second-degree relatives with known aneurysms or known ruptured aneurysms) has been demonstrated to affect the incidence of aneurysms involving almost every segment of the aorta and multiple aortic segments. As knowledge of the phenotypic classifications of aneurysms evolves, this aspect of documentation should also become more detailed.

Clinical presentation

Complex aortic aneurysms are categorized by clinical presentation as asymptomatic or symptomatic. Specific presentation in the symptomatic group needs to be further described with

respect to timing, progression and severity. The most common symptoms are attributed to acute changes in the aneurysm such as compression or erosion to adjacent structures, thrombosis, embolization, or end-organ ischemia. The presence of a ruptured aneurysm needs to be further classified into free or contained rupture, with or without hemodynamic instability. In this regard, the hemodynamic status of the patient should be reported with respect to systolic blood pressure, response to fluid resuscitation and/or presence of cardiac arrest. Most reports define *hemodynamic instability* as cardiopulmonary arrest or inability to achieve and maintain a stable systolic blood pressure ≥90 mmHg despite appropriate fluid resuscitation.(67, 68) Because endovascular repair has been increasingly utilized to treat acute aortic syndromes (i.e. dissections, intramural hematoma, and penetrating aortic ulcers), a description of the time elapsed between the initial event and treatment is also important. This report recommends a revised classification of timing of presentation, initially proposed by the TEVAR reporting (67, 68)standards.(36) This includes acute presentation as within less than 14 days, subacute presentation within 15 days to 3 months and chronic presentation if beyond 3 months. The description of timing of presentation is particularly important for reports dealing with aortic dissections or ruptures.(69, 70)

Normal aortic segment

Durable endovascular aneurysm exclusion requires placement of the stent-graft within healthy segments of the aorta and/or iliac arteries. Recommendations of approved devices are based on the IFU derived from clinical trials evaluating the safety and effectiveness of the respective devices. These recommendations approved by the United States Food and Drug Administration (FDA) include minimum requirements for proximal and distal landing zone diameter and length, which are specified under the IFU. The term “healthy” or “normal” aortic

neck has been coined to describe a segment of aorta with parallel aortic wall with minimal (<10%) or no difference in diameter and no atherosclerotic debris, thrombus or calcification. The maximum proximal landing zone diameter for abdominal aortic stent-grafts is typically 32mm and for thoracic stent-grafts is 42mm, depending on the manufacturer.(71, 72) Typical accepted minimum lengths are 10 to 15mm for the infra-renal aorta and 20 to 25mm for the thoracic aorta. It is recommended that reports dealing with complex aortic aneurysms specify the anatomic criteria used for selection of landing zones, including the minimum length and diameters as well as use of devices outside their IFU.(11)

Anatomical classification

Traditional classifications used to describe aneurysm extent based on reports dealing with open surgical repair do not necessarily correlate with the extent of endovascular repair when techniques of branch incorporation are used. It is recommended that reports dealing with complex endovascular techniques provide information on traditional aneurysm classification for comparisons with open surgical techniques, but also outline the extent of endovascular repair. For example, an anatomic Extent IV thoracoabdominal aortic aneurysm (TAAA) may require more extensive thoracic aortic coverage, changing to an Extent III endovascular repair. Similarly, an anatomic Extent I TAAA often requires extension of the stent-graft to the infrarenal aorta, changing the Extent II endovascular repair.

Thoracoabdominal aneurysm

A classification of TAAAs proposed by Stanley E. Crawford in 1986 continues to be widely accepted and utilized in many reports (**Figure 8**).(73, 74) This classification describes the extent of complex aortic aneurysm based on the proximal and distal anatomical extension and involvement of the visceral arteries. The aneurysm extent affects surgical approach, clamp site

and methods of reconstruction. A modification of the Crawford classification was proposed by Hazim Safi and colleagues (**Figure 9**).(75, 76) In this modified classification, the original category of Extent III TAAA, which was defined by a TAAA starting below T6 with involvement of the visceral arteries, was further divided into two groups. Extent III was maintained for aneurysms extending from T6 to the infrarenal aorta or iliac arteries, but Extent V was created to describe aneurysms that extend from T6 to the level of the renal arteries and do not involve the infra-renal aorta.

This categorization has been useful for reports dealing with conventional open surgical repair because it provides a description of surgical approach, extent of aortic repair, prognosis for the risk of spinal cord ischemia, and other perioperative morbidities, whose risk assessment is largely based on the extent of aortic involvement. However, this classification system assumes that the clamp site and anastomotic line is close to the level of repair, which is typically not the case for endovascular therapy. During endovascular repair, a a long, healthy and parallel-walled landing zone is selected several centimeters above or below the proximal and distal anastomotic lines. This means that aneurysms require that the aortic repair is extended more proximally (often into the thoracic aorta) than what is typically performed during open surgical repair. As such, for the same extent of aortic disease, the segment to be replaced may differ depending on the choice of open versus endovascular technique, as well as in the design of the stent-graft predominantly with fenestrations or branches. Therefore, conventional open surgical and endovascular repair significantly differ because covering a larger segment of the proximal aorta (with an endovascular approach) will intuitively infer greater risk than the anatomical classification would imply, although this does not necessarily translate into greater clinical risk. **Table IV** and **Table V** exemplifies the typical correlation between the anatomical classification

and extent of endovascular repair based on segment of proximal landing zone and aortic coverage. For patients who have previously undergone open or endovascular repair of the ascending aorta, arch, thoracic or abdominal aorta, it is recommended to use the term *completion* and the classification that encompasses the total extent of treated aorta. For example, if the proximal thoracic aorta was treated by open graft replacement, distal endovascular repair to the level of the infrarenal aorta would be described as a *completion Extent II TAAA repair*.

Complex abdominal aortic aneurysms

Complex abdominal aortic aneurysms (**Figure 10 and Table II**) are defined as aneurysms that involve the renal and/or mesenteric arteries and extend up to the level of the celiac axis or diaphragmatic hiatus, but do not extend into the thoracic aorta.(35) An anatomic classification system has been frequently utilized in reports dealing with complex abdominal aortic aneurysms, which describes the most proximal extent of the aneurysm in relation to the location of the renal and mesenteric vessels. This classification system includes the description of short-neck infra-renal aortic aneurysms, defined by the presence of an infra-renal aortic neck of 4-10 mm in length (77-82) and juxtarenal aortic aneurysms, defined by infra-renal neck ≤4 mm in length with aneurysm extension up to but not beyond the renal arteries.(16, 21, 24) These two subgroups imply that the renal arteries originate from normal aortic segments and are not involved with the aneurysm. Pararenal aortic aneurysms involve at least one of the renal arteries and extend up to but not cephalad to the superior mesenteric artery (SMA). Para-visceral aortic aneurysms involve the renal arteries and SMA but not the celiac axis. The term suprarenal aortic aneurysm is often used and combines pararenal and para-visceral aortic aneurysms into a single category. Extent IV TAAA is defined by proximal extension of the aneurysm to the celiac axis (CA) or diaphragmatic hiatus.

Aortic dissections

Complex endovascular techniques have been increasingly utilized to treat patients with aortic dissections and chronic post-dissection TAAAs. Reports should describe the extent of the dissection using the classification system proposed by DeBakey (**Figure 11**) and Daily (**Figure 12**) in 1965 and 1970, known as the DeBakey and Stanford classifications, respectively.(83, 84) For reports dealing with side branch incorporation, a description of the vessel involved and its location in relation to the true or false lumen is recommended. The timing of repair (acute, subacute or chronic) should be reported as proposed by the TEVAR reporting standards.(36) The *DISSECT clinical* classification system was proposed in 2013 by Dake and colleagues and encompasses five features characterized by the mnemonic DISSECT: **d**uration, **i**ntimal tear, **s**ize of aorta, **s**egment **e**xtent of involvement, **c**linical complications and **t**hrombosis of the false lumen.(85)

1. *Duration* of dissection is defined as time from onset of symptoms and includes acute (Ac, < 2 weeks), subacute (Sa, 2 weeks to 3 months) and chronic (Ch, > 3 months)
2. *Intimal tear* is defined by the location of the primary tear within the aorta and includes the ascending aorta (A), aortic arch (Ar), descending aorta (D), abdominal aorta (Ab) and unknown location (Un).
3. *Size* of aorta is based on the maximum trans-aortic diameter measured by the centerline analysis in millimeters at any level within the dissected segment.
4. *Segmental extent* of aortic involvement describes the extent from proximal to distal boundaries: ascending aorta exclusively (A), aortic arch exclusively (Ar), descending aorta exclusively (D), abdominal aorta exclusively (Ab), Ascending to arch (AAr),

ascending to descending (AD), Ascending to abdomen (AAb), ascending to iliac (AI), arch to descending (ArD), arch to abdomen (ArAb), arch to iliac (ArI), descending to abdomen (DAb), and descending to iliac (DI).

5. *Clinical complications* related to the dissection should be described as complicated (C), including aortic valve involvement, cardiac tamponade, rupture, branch vessel malperfusion, progression of aortic involvement, and other problems (e.g. uncontrollable hypertension). Uncomplicated (UC) is defined by absence of complications listed above.

6. *Thrombosis* of the false lumen within the dissected segments is graded as patent (P) if there is evidence of flow or opacification within the false lumen throughout the entire length, complete thrombosis (CT) if the false lumen is completely thrombosed, or partial thrombosis (PT) if there is only portion of the false lumen that is thrombosed. Importantly, determination of false lumen flow requires careful timing relative to contrast injection.

The SVS and Society for Thoracic Surgery (STS) reporting standards for type B aortic dissections have recommended using the Stanford classification (A and B) coupled with the aortic zones of attachment described below.(86) Type A dissections have entry tear starting in Zone 0 with distal extension into Zone 1-11 (e.g. TypeA0-11). Type B dissections have entry tear starting at Zone ≥1 and extending into Zone 2-11. (e.g. Type B3-11).

Zones of attachment

The zones of aortic attachment have been well described in the SVS TEVAR reporting standards and should be utilized in reports dealing with complex aortic aneurysms and dissections (**Figure 13**).(36) For the purposes of reporting standards, it is recommended to

indicate the location of proximal and distal sealing zones and the aortic segments covered. **Table IV** and **Table V** shows the discrepancy from anatomic classification to extent of endovascular aortic repair as compared to extent of open surgical repair. The purpose of a classification for treating aneurysms in scientific papers is to confer a prognostic risk and to allow comparison with other treatment options. As such, reports should specify both the anatomic classification but also the extent of endovascular repair using the numerical system.

Recent reports have recommended the use of more extensive supra-celiac sealing zones for complex abdominal aortic aneurysms. It is recommended to specify the length of supra-celiac coverage, which may be associated with added risk of spinal cord injury. Mastracci and colleagues identified higher rates of spinal cord injury with fenestrated grafts designed with ≥5cm supra-celiac coverage.(87) A simplified classification system defines supraceliac coverage in three categories. Infra-celiac coverage implies sealing in segment 6 or 7, but not extending above the uppermost limit of the celiac axis origin. *Low or high supraceliac* coverage indicates coverage of < or ≥5-cm (or equivalent to two sealing stents) above the uppermost margin of the celiac axis (**Figure 14**).

DESCRIPTIONS OF TYPE OF INCORPORATION

A description of the types of incorporation has been previously included in the TEVAR reporting standards but is revised in this document (**Table VI**).(36, 54) The term *fenestrated endovascular repair* (FEVAR) is applied when a stent-graft with fenestrations is used to incorporate target arteries into the repair using fenestrations (**Figure 15**). In these cases, there may be a gap or no gap between the fenestration and the target vessel (49, 104). Alignment stents

are typically used to prevent target vessel occlusion or stenosis from any misalignment between the fenestration and the origin of the vessel. Originally, bare metal alignment stents were utilized, but these have largely been replaced in most series by covered stents because of reduced risk of neointimal hyperplasia and vessel occlusion as well as potential endoleak. The term *branched endovascular repair* (BEVAR) has been used to describe endovascular repair of aneurysms with involvement of side branches using stent-grafts designed with directional branches. In these cases, the target vessels usually originate from the aneurysmal aorta and therefore a gap exists between the main aortic stent-graft and the origin of the branch vessel in the aortic wall. The terms directional branch, cuff or portal have been applied to that describe pre-sewn side branches that serve as a docking gate for placement of bridging stents that connect the aortic stent-graft to the target vessel. Although branched endovascular repair has been used as synonymous of a directional branch, it is important to note that branched endovascular repair can be performed with internal, internal/external or external directional branches. The term *fenestrated-branched endovascular repair* (FBEVAR) applies when a combination of fenestrations and branches is used within the same device, which may be related to specific anatomic features or operator preference. Although the term fenestrated-branches has been used to denote the use of reinforced fenestrations that are bridged by balloon-expandable covered stents to seal the fenestration along with the space between the aortic stent-graft and aortic wall, this type of incorporation should be considered a fenestrated repair. In this regard, all analysis should specifically be based on whether fenestrations or branches are used for each target artery.

Other types of procedures have been used to incorporate the renal and mesenteric arteries. One of the first methods to be described was the *hybrid* or *visceral debranching* procedure, which combines extra-anatomic reconstruction of the renal and mesenteric vessels via midline

laparotomy, followed by endovascular aortic repair performed in one or two stages. *Parallel stent-grafts* include a wider variation of stent-graft configurations with several accepted terms in the literature (**Figure 16**). These techniques have in common the placement of stent-grafts side by side in parallel or oblique configuration, without a specially designed seal mechanism with the main aortic component. To describe a wider variation of these techniques, the term *CHIMPS* has been used to include chimneys, periscopes and sandwich techniques. The term *chimney or snorkel* stent denotes placement of a stent using antegrade approach to maintain perfusion into the renal-mesenteric arteries.(27, 107) These stents are oriented superiorly and provide antegrade flow into the vessel. *Periscope* technique is described by placement of a stent in retrograde configuration, typically from a trans-femoral approach.(29, 108-110) A *sandwich* stent-graft technique implies use of bridging stents between two aortic stent components, typically using combined antegrade or retrograde approaches to treat a TAAA.(31, 111) Because these techniques are off-label and there is no standardization on best practices between centers, it is important to recognize that physicians reporting on parallel grafts specify length of overlapping segments, stent-graft oversizing, and which specific stent-graft components were selected for the aortic stent(s) and bridging stents.

CATEGORIZATION OF BRANCH INCORPORATION, OPERATIONS AND PROCEDURES

Endovascular repair of aneurysms involving the renal-mesenteric arteries require use of modular systems that increase complexity of planning, design and implantation techniques. Understanding and describing device components is of paramount importance when performing endovascular repair of pararenal and TAAAs. These procedures may require one or more

proximal aortic components in the thoracic aorta or arch, a middle component with fenestrations and/or directional branches for the renal-mesenteric vessels and a distal bifurcated stent with iliac limb extensions (**Table VII**). In addition, these procedures require adjunctive bridging stents that direct blood flow and perfusion to the renal and mesenteric vessels. Given the wide variation and combination of bridging stent options, detailed description is important to allow future comparison between reports dealing with renal-mesenteric incorporation.

Proximal thoracic extensions

Depending on the extension of the aneurysm into the thoracic aorta, one or more proximal thoracic extensions may be needed to the seal the aneurysm in a healthy aortic segment within the thoracic aorta or distal arch. The proximal aortic stents may be deployed in a single stage procedure in conjunction with the fenestrated or branched aortic component that addresses the renal-mesenteric segment, or as a staged operation days or weeks prior to the primary fenestrated-branched procedure. The location of the proximal landing zone, extent of coverage, modularity (single or multiple) and specific diameters of the stent need to be specified.

Fenestrated, branched or parallel stent component

The main device or main body harboring the fenestrated and or branched segment is the component that is placed in the renal-mesenteric segment of the aorta. Specific characteristics of the device that need to be specified include the type of fabric (woven polyester or expanded PTFE), metallic support structure (nitinol or stainless steel), presence of an uncovered proximal stent and active fixation and profile (standard or low-profile). The fenestrated or branched device comes in various lengths and diameters and is meant for precise delivery at the renal-mesenteric segment and thus extends short of the aortic bifurcation. In the case of a pararenal aneurysm or

Extent IV TAAA, the fenestrated or branch component is typically the most proximal component. However, for Extent I to III TAAAs, additional proximal thoracic extensions may be needed. The fenestrated or branched component incorporates the side branches by maintaining perfusion to the celiac axis, SMA and renal arteries, depending on the extent of repair. Vessel incorporation can be achieved with one of three main configurations: fenestrations, directional branches and parallel stent-grafts. *Fenestrations* are circumferential windows within the device. Important characteristics of a fenestration need to be specified, including dimensions in the longitudinal and lateral axis (e.g. 6x8 or 6x6 mm), reinforcement, mobility and configuration (e.g. pivot fenestrations). *In situ fenestrations* denote creation of a fenestration in the aortic component at the time of device implantation using guidewire, TIPS needle, biopsy needle, radiofrequency energy or endovascular laser.(112-115) These can be done retrograde as in the case of arch in situ fenestrations of supra-aortic trunks, or antegrade with assistance of onlay fusion or preemptive stenting. *Self-sealing fenestrations* apply fabric to allow temporary access into the device for placement of a side branch stent. After the sheath and catheter are removed, the fenestration is sealed by fabric that is pushed shut by antegrade blood flow to cover the fenestration and prevent an endoleak. *Scallops* are "U" shaped cutouts extending from the top edge of the graft downwards, which are intended for incorporation of a larger vessel or for access into the device using pre-loaded catheters or guidewire systems (e.g. *access scallops*). Dimensions of scallops should be specified in millimeters including width and depth. *Directional branches* are specifically designed cuffs or portals, which provide overlap for bridging stents intended for target vessels. Specific characteristics of branches include its location relative to the aortic device (e.g. internal or inner, external, internal/external), configuration (e.g. straight, helical), orientation (e.g. downward, upward, antegrade or retrograde), diameter and length.

Internal branches can be coupled with large diamond-shaped or oblong fenestrations. All are meant to allow a connection of the main device to the target artery (renals, SMA, celiac) in order to maintain perfusion to the target organ. Although most branches are intended for specific target vessels, *perfusion branches* can be designed to maintain sac perfusion temporarily. The number of perfusion branches and time until closure should be reported. Fenestrated or branched stent-grafts can be patient-specific or custom-made devices (CMDs) by the manufacturer or can be off-the-shelf. *Preloaded catheters or guidewires* involve use of adjunctive catheters/guidewires within the original delivery of the fenestrated and/or branched stent-graft, which allow direct access to specific fenestration or branch via femoral or brachial access. The term *inverted limb* has been used to describe bifurcated component with a short length contra-lateral limb, which is inverted within the main body of the bifurcated device. The term *physician-modified endovascular graft* (PMEG) should be used to describe on-table modification of a manufactured device by a physician to create fenestrations or branches and the presence of an investigational device exemption (IDE) protocol should also be stated.(116-122) These devices should only be used in the setting of an IDE.

Distal bifurcated device, iliac limb extensions and iliac branch devices

The first descriptions of a fenestrated repair were done using modifications of a commercially available bifurcated device, but it became evident that creating separate fenestrated and distal bifurcated components had several potential advantages including easier catheterization and avoiding risk of excessive migration forces of the renal stents. In most designs of fenestrated and branch technology, a distal bifurcated device and iliac limb extensions are used to bridge the aortic stent-graft to the iliac arteries. This may be unnecessary if there is a distal landing zone in the infra-renal aorta or in a previously placed aortic graft or stent-graft. If

the distance between the renal arteries and the aortic bifurcation is shortened by placement of a bifurcated stent-graft or surgical graft, custom made bifurcated devices may require use of an *inverted iliac limb*.(123, 124) Iliac branch devices (IBDs) or endoprosthesis (IBEs) have been used for incorporation of the internal iliac arteries.

Bridging stents and stent-grafts

Techniques of endovascular incorporation of renal-mesenteric arteries require use of bridging stents to connect the aortic device to each specific target artery (**Table VIII**). These stents are defined as additional separate components and are important to maintain vessel perfusion, prevent vessel occlusion and to create adequate seal in cases where the vessel originates from aneurysmal segments. It is important to acknowledge the specific characteristics of bridging stents, including manufacturer, material, self-expandable or balloon-expandable, diameter and length.(50, 51, 87, 92, 125-128) Most often, balloon-expandable stents used for fenestrations are flared at the origin using an oversized balloon. This provides better attachment, fixation, and facilitates re-catheterization if future intervention is needed. This also helps prevent migration of the stent out of the aortic stent graft and minimizes a junctional endoleak. The specifications of balloon flaring should be provided in reports dealing with fenestrated stent-grafts. The length and diameter of the bridging stent is determined by the construct and should be specified. Additional stents may be deployed into the target vessel in conjunction with the main bridging stent. For example, a self-expanding stent may be added at the distal edge of a balloon-expandable stent to manage angulation and kinks. A balloon-expandable stent may be used in conjunction with self-expandable stent-grafts to increase radial force at the proximal attachment site of directional branches. These self-expanding stents should extend from the bridging stent

into the target artery. In parallel graft techniques, bridging stents should be specified as described above for fenestrated and branched endografts.

Description of the primary or principal procedure

Staged and adjunctive procedures (**Table IX**) have been increasingly utilized to extend landing zones or minimize risk of complications such as spinal cord injury.(99, 129-137) A description of these types of procedures will be defined as:

Primary procedure

The principal or primary procedure is the one that contributes the most or contributes primarily to the treatment of the aortic pathology for which the operation is being performed, in this case typically the procedure that involves incorporation of the renal-mesenteric arteries, independent of which technique is selected. The primary procedure may be performed in one operative session (single stage) or in two (two-stage) or multiple sessions (>2 sessions), including planned subsequent interventions such as occlusion of a temporary aneurysm sac perfusion (TASP) branch.(99, 132) These subsequent anticipated procedures should not be described as “planned secondary interventions”, as they are intended procedures and are integral part of the staged and planned concept of repair.

Single, two or multiple stage procedures

Single-stage procedure is used to describe treatment of aortic pathology in a single operation. A *two-stage procedure* is defined by use of a second adjunctive operation before or after the principal procedure. *Multiple-stage procedure* is defined by use of greater than two operations to treat the aortic pathology. In these cases, it is recommended to specify the principal operation as described above, as well as specific indications for the secondary operations.

Adjunctive procedures

An adjunctive procedure is any other procedure that is designed to augment the effects of the principal procedure, such as surgical debranching of an aortic segment by a bypass (e.g. carotid-carotid artery bypass, iliac-celiac artery bypass), stenting a branch artery (e.g. for a pre-existing stenosis), embolization of an intercostal artery, enhancing proximal fixation with the use of stents or anchors or use of a stent, conduit, or bypass to allow for device delivery (e.g. treating an iliac artery stenosis with stenting, placement of an internal iliac conduit, or a bypass graft used as a conduit for the delivery system). These procedures should be temporally designated as occurring in the preoperative, intraoperative, or postoperative periods. These procedures should also be classified as "staged" that is planned adjunctive procedures performed to achieve the therapeutic goal or as "unplanned" if the adjunctive procedure is performed to correct consequences of an unanticipated problem or to supplement the primary procedure.

The *primary procedure* is the reference point for analysis of primary and secondary end-points. For example, the primary procedure may be preceded by adjunctive procedures such as debranching or TEVAR in a staged fashion, as in the case of an extensive TAAA treated in multiple stages (**Figure 17**). Intraoperative adjuncts may be described as *concomitant procedures* and should be further described as *planned* or *unplanned*. (99, 129, 132) The term *secondary procedure* refers to all other interventions performed after the initial aortic endovascular repair, which are not considered staged and may include adjunctive procedures.

Conversion to open surgical repair and abandonment

Conversion to open surgical repair is a change in procedure from endovascular to open repair of the primary aortic pathology at any time after initiation of the primary procedure. It is important to differentiate *conversion to open aneurysm repair* (which implies repairing the aneurysm by open approach) from an open surgical approach that is used before, during or after

the primary operation for indications other than repair of the primary aortic pathology. Examples are an exploratory laparotomy or surgical exposure for repair of branch vessel or extra-anatomic revascularization, where there was no change in primary strategy of repair from endovascular to open approach. Timing of conversion should be stated with *early conversion* defined as within the first 30 days or during the hospital stay and *late conversion* beyond 30 days or after hospital dismissal if longer than 30 days.

Abandonment of repair is the termination of the primary endovascular procedure at any time after initiation of the primary procedure. In these cases, the specific indications and maneuvers that were used prior to abandonment should be described.

ASSESSMENT OF OPERATIVE METRICS AND RADIATION EXPOSURE

Procedural metrics are often reported to estimate technical difficulty, compare different techniques or estimate variations in early or late clinical experience.(88, 89) (88, 90-101) For complex endovascular procedures, operative metrics frequently reported include type of anesthesia, operating room setting (hybrid room with fixed imaging, portable c-arm), operative time metrics, fluid requirements and estimated blood loss (**Table X**). The *total anesthesia time* is defined as time from induction of anesthesia to extubation if this is done in the operating room, or wheels out for patients who are transferred to recovery room or intensive care unit intubated. *Total operating time* is the skin-to-skin time defined from skin incision to closure. The *total endovascular time* focuses on the endovascular segment of the operation and is defined from initial arterial puncture (needle in) to removal of access sheath, and excludes any initial surgical exposure or the time spend with skin closure. *Total fluoroscopic time* is the foot-on-pedal time

and is typically capture by the imaging unit. Radiation exposure, contrast volume and concentration should also be reporte.

ASSESSMENT OF CLINICAL AND MORPHOLOGICAL OUTCOMES

The primary goal of complex endovascular aortic repair is to prevent death secondary to the aortic pathology or related interventions. Because the aneurysm sac is left intact, treatment failure can be manifested several years before aneurysm rupture or death. Therefore, it is important to describe other surrogates of treatment success and device efficacy that indicate treatment failure before rupture occurs. These end-points can occur intra-operatively or at any point after the procedure. For example, successful aneurysm sac exclusion requires by definition, absence of a Type I or Type III endoleak, and a stable aneurysm sac diameter or volume. Evidence of aneurysm sac enlargement is indicative of incomplete aneurysm exclusion and implies continued risk of aneurysm rupture. Changes in aneurysm sac dimensions (diameter, volume) are important, although minor differences in diameter can reflect different measurement techniques and may not be significant in clinical practice.

Progression of aortic disease can be manifested by changes in the area selected for sealing zone ("aortic neck"), or by changes in aneurysm sac diameter and morphology. Measurements of device migration, stent-graft apposition and side branch configuration, and modular component overlap or separation serve as indicators of device stability in all types of complex endovascular repairs. In these cases, it is important to specify surrogate measurements of side branch preservation including patency, target vessel endoleak and integrity of modular components. **Table XI** summarizes important measurements of morphological and technical outcomes including measures of diameter, length, volume, endoleak, attachment site dimensions,

migration, tortuosity and branch vessel morphology.

Primary and secondary outcome criteria

Primary outcome criteria of complex endovascular repair, described as treatment efficacy, is prevention of aneurysm rupture and death related to the primary aortic pathology or to the operation or a secondary intervention indicated to treat the disease. *Secondary outcome criteria* are described in **Table XII** and include other issues associated with disease progression, device failure (e.g. migration, degradation, limb thrombosis), endoleak, secondary interventions and other life-style limiting or disabling complications (e.g. paraplegia, stroke). Conversion to open surgical repair to treat the primary aortic pathology represents a special type of failure of endovascular aortic repair.

Treatment success

The definition of treatment success of complex endovascular repair should take into consideration both clinical and radiographic criteria and prior definitions for reporting standards dealing with EVAR, TEVAR and open surgical repair.(35, 36, 138)

Technical success

Technical success relates to the events that occur from the initiation to the end of the endovascular procedure. This end-point refers to the ability to deliver the aortic component and all intended side branch components that are necessary to complete the intended target vessel incorporation, which is needed to treat a complex aneurysm. In addition, successful aneurysm sac exclusion is an integral part of the definition of technical success. Since its original description in prior versions of reporting standards, it became evident that some patients with intraoperative type I or III endoleak may have spontaneously resolution of the endoleak early within the same hospital stay or in the first weeks postoperatively. Therefore, a modified

technical success definition is proposed, which implies the following qualifying criteria are all met:

a. Successful access to the arterial system using remote arterial exposure, percutaneous technique or open surgical conduits.
b. Successful delivery and deployment of the aortic stent-graft and all modular stent-graft components.
c. Successful side branch catheterization and placement of bridging stents with restoration and maintenance of flow in all intended target vessels.
d. Absence of type I or type III endoleaks at completion angiography that extends beyond 30 days by confirmatory imaging (computed tomography angiography, magnetic resonance angiography or duplex ultrasound).
e. Patency of all aortic modular stent-graft components and intended side branch components.

Primary technical success is defined on an "intent-to-treat" basis and requires the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleak, branch occlusion or graft limb obstruction.

Primary technical success can include the use of additional modular components, stents, or angioplasty, and adjunctive surgical procedures at the time of the primary procedure. The terms assisted primary or secondary technical success are applied to describe any unplanned endovascular or surgical procedures that are necessitated, respectively. A special clarification is needed for 'gutter' endoleaks (in the case of parallel grafts), which should be considered as type IA endoleaks. The timing of the endoleak should be described, considering that 'gutter' endoleaks may be present at initial angiography and spontaneously resolve in the first 30 days

upon evaluation by CTA. Several studies, including industry-sponsored feasibility trials, have proposed the definition of technical success using CTA evaluation of type I and III endoleaks at 30-days. If used, this definition needs to be clarified in the methods section of the report.

Clinical or treatment success

Primary treatment or clinical success is defined using intention-to-treat analysis and requires successful deployment and implantation of the aortic modular components and side branches with the criteria described above for technical success in addition to absence of important disabling permanent clinical sequela. These include death, aneurysm rupture, graft infection, conversion to open surgical repair and complications such as permanent paraplegia, disabling stroke and permanent dialysis. *Ongoing primary clinical success* is further defined as freedom from an unplanned secondary surgical or endovascular procedure targeted at the aortic pathology that was initially treated with the complex endovascular aortic repair. With respect to secondary procedures, it is important to exclude planned secondary procedures for *intentional endoleaks* such as closure of temporary aneurysm sac perfusion branches to prevent spinal cord injuries during extensive TAAA repair. Clinical success requires that all the following criteria be met:

a. Technical success
b. Absence of death from the initial procedure, secondary intervention or aortic-related cause.
c. Absence of persistent type I or III endoleaks
d. Absence of aneurysm sac expansion >5 mm
e. Absence of device migration >10mm
f. Absence of failure due to device integrity issues

g. Absence of aneurysm rupture

h. Absence of conversion to open surgical repair

i. Absence of permanent paraplegia, disabling stroke or dialysis that resulted from the initial operation or a secondary intervention to treat the original aortic pathology.

Assisted primary clinical success is defined by clinical success that is obtained initially and continuously maintained with additional secondary re-interventions to achieve the above-mentioned goals, thus there is not an interruption of the initial clinical success. *Secondary clinical success* is defined by initial clinical success that is interrupted by a treatment failure and is successfully corrected with a secondary intervention. For example, a patient that undergoes successful treatment of a type I, II or III endoleak. Conversely, *clinical or treatment failure* is defined as death from complications of the initial operation or a secondary intervention, aneurysm rupture, conversion to open surgical repair, persistent type I or III endoleak, sac expansion >5 mm, device migration >10mm, infection or thrombosis.

Definitions of treatment period

Clinical outcomes that are time-dependent end-points need to be described in the context of pre-defined treatment periods. We recommend using the definitions previously described in the EVAR and TEVAR reporting standards.(35, 36) For time-dependent outcomes, results are presented using life-table analysis. The standard deviation of life-table or Kaplan-Meier estimates should not exceed 10% and the number of patients at risk and the number of events should be specified at each time interval in graph or tabular format. *Early period* or within 30-day results are defined as any event occurring within the first 30 post-operative days or within the hospital stay if longer than 30 days. *Short-term* results encompass outcomes between 30 days

to 6 months of follow up. *Mid-term* results refer to outcome measures that occur within 6 months to 5 years of follow up. *Long-term* results include outcomes after 5 years of follow up.

CLINICAL OUTCOME DEFINITIONS

Primary and secondary outcome definition

The primary goal of treatment of complex aortic disease is to minimize the mortality and morbidity associated with the pathology. Although there are significant variations in the techniques used to treat the aortic pathology, all are designed to reduce or eliminate the risk of aortic rupture and other complications (i.e. end-organ ischemia, embolization, dissection, paraplegia and death). It is recommended that indications and the resulting outcomes be reported to allow critical comparison with alternative open surgical and endovascular techniques.

Table XII summarizes important primary and secondary outcome criteria for complex endovascular aortic repair. The definition of the primary end-point is variable depending of a specific question to be answered by the investigative study. It is recommended that this is clarified in the methods section of the study. *Primary outcome criteria* need to be specified in the study methods and should include the main end-point measure that is being investigated. *Secondary outcome criteria* may include other important end-points that are evaluated in the study, but do not constitute the primary question that is being evaluated.

Mortality and morbidity

Standardized documentation of mortality and morbidity is recommended for any reports dealing with complex endovascular aortic repair.(10) Deaths and complications should be reported in an intention-to-treat basis, which should be considered with any adjunctive or staged procedure that is done in anticipation of the principal procedure to repair the aortic pathology.

Mortality

Procedure-related mortality should include any death that occurs within the first 30-days or within the hospital stay if >30 days, or that result from a secondary intervention to treat a complication of the initial aortic device and its side branches that were used to treat the primary aortic pathology.(10) *Device-related mortality* is defined as death which occurs during implantation of the device or from a complication triggered by any of the device components. Examples would be mortality from end-organ damage caused by side branch occlusion, arterial disruption or dissection that is caused during device implantation. Deaths beyond 30 days in patients discharged from the initial hospital stay are usually considered as a *late mortality,* but the terms short-term, midterm and long-term are recommended to further define time period. *Aneurysm-related mortality* is defined by any death that occurs within the first 30 days or any death that results from aneurysm rupture, aortic-related complications (e.g. infection, occlusion, dissection, hematoma) or from a complication of a secondary intervention. *All-cause mortality* is a broad definition that includes all deaths independent of the specific cause.

The cause of death should be reported and its relationship with the procedure and device should be established using the aforementioned definitions. Determination of cause of death should be verified on the basis of autopsy findings, direct surgical observation that defines the status of the aneurysm, or definitive imaging studies of the endograft obtained during the patient's terminal illness. When this level of information is not available, the cause of death and its relationship to the procedure and device should be classified as *probable* if there is clinical evidence supporting a specific diagnosis, or as *indeterminate* if there is no available clinical information to establish a diagnosis.

Patient survival

Longitudinal assessment of patient survival is fundamental for evaluation of treatment efficacy and should be reported using life-table analysis with Kaplan-Meyer methods. Survival can also be reported as separate analysis of *aneurysm-related* and *all-cause mortality.*(36)

Morbidity

It is recommended that complications be reported using a defined follow-up interval and device-related definitions specified above. In addition, we recommend using the scoring system proposed in the EVAR and TEVAR reporting standard documents.(35, 36) Specific definitions are recommended to describe major adverse events, neurologic and renal complications, which are main end-points in reports dealing with complex endovascular aortic repair.

Spinal cord injury

A description of spinal cord injury is especially important for reports dealing with complex endovascular aortic repair. It is recommended to consider all injuries, independent of cause or mechanism (e.g., embolization, hemodynamic compromise, epidural hematoma from drain placement). The same grading system proposed by the TEVAR reporting standards is recommended for reports dealing with complex open or endovascular aortic repair (**Table XIII**).(36) The deficit should be graded based on peak of injury in the worst extremity if asymmetric. It is useful to document the peak injury and improvement at 30-days follow up. *Paraplegia* is defined by any Grade 3 spinal cord injury (A to C) in a patient who is non-ambulatory. *Paraparesis* describes spinal cord injuries causing motor deficit in patients with Grade 2 injuries. *Temporary injury* is defined by any spinal cord injury that has complete resolution and expected return to baseline or Grade 0. *Permanent injury* is defined by any injury that has partial or no improvement compared to baseline examination. In addition to these definitions, reports should specify temporal relationship with the specific procedure. *Immediate*

spinal cord injury is defined by any injury occurring during the operation and identified at the end of the procedure or in the first examination after the operation. Patients that have a normal exam after the operation but develop a spinal cord injury beyond that should be described as having a *delayed* spinal cord injury. It is recommended to report the specific postprocedural day that the patient developed the neurologic deficit.

Stroke

The ability to diagnose and quantify the extent of a transient or permanent neurologic deficit is critically important in these cases. The National Institutes of Health Stroke Scale (NIHSS) is a validated tool that can objectively quantify stroke impairment.(139) The NIHSS has been found to be a valuable predictor of patient outcomes, including probability of recovery and death. This grading system proposed by the TEVAR reporting standards is recommend for reports dealing with complex open or endovascular aortic repair.(36) When administering the NIHSS patients should not be assisted during the assessment. For each item that is assessed, the examiner should score the patient's initial effort or response. However, for language assessment the best effort should be recorded. Eleven defined categories are independently assessed and a single score calculated. The eleven categories and individual scoring are summarized in **Table XIII**. The NIHSS is widely accepted and the reliability has been proven by consistency of inter-examiner and test-retest scenarios. Clinical research typically utilizes a baseline score followed by repeated examinations at regular intervals. A baseline score of >16 indicates a high likelihood of death, while a baseline score of <6 predicts a favorable outcome.

The Rankin stroke scale is a simplified classification often utilized. The classification focuses on the description of clinical disability and is useful for definition of major neurological

events but provide less detailed information than the modified NIHSS. The Rankin classification is described below:

0	Asymptomatic
1	No significant disability despite symptoms: able to carry out all usual duties and activities
2	Slight disability: Unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability: requiring some help, but able to walk without assistance
4	Moderately severe disability: unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability: bedridden, incontinent, and requiring constant nursing care and attention
6	Death

Renal function deterioration

It is recommended to use the RIFLE classification system that was originally published in 2004 to standardize the definition of acute kidney injury (AKI) is summarized in **Table XIV**.(28, 53, 92, 140-146) The classification is based on variations in serum Creatinine and urinary output, and the acronym indicates *risk* of renal dysfunction, *injury* to the kidney, *failure* of kidney function, *loss* of kidney function and *end-stage* renal disease.

In addition, clinical studies detailing renal outcomes should also incorporate the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) classification for chronic kidney disease (CKD) stages prior to and after surgery (**Table XV**).(140, 143, 147-151) This classification grades severity of kidney loss based on levels of estimated glomerular

filtration rate (eGFR). Freedom from renal function deterioration is define as >30% decline in baseline eGFR. Other important anatomical renal outcomes should also be described including infarcts, defined by area of lack of perfusion in the kidney parenchyma using contrast angiography, CTA or MRA, kidney length and patency of targeted and non-targeted accessory renal arteries.

Major adverse events

A definition of *major adverse events* (MAEs) have been frequently utilized in device trials to describe a composite of death or any major complications that result in escalating level of care or severe disability.(10, 19, 118, 152) Major adverse events should be reported using the definitions of follow up time interval as specified above and include the following:

a. All-cause mortality
b. Myocardial infarction
c. Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation
d. Renal function decline resulting in >50% or estimated Glomerular Filtration Rate or new-onset dialysis
e. Bowel ischemia requiring surgical resection or not resolving with medical therapy
f. Major stroke
g. Paraplegia (Grade 3)

Adverse Events

The 2011 ISO 14155 guidelines define an adverse event as an “untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical

device.(10) Adverse events are classified by whether they are device-related, procedure-related, or neither (non-device, non-procedure related). Device-related adverse events include those events directly attributable to the device, for example, peripheral stent or bypass graft thrombosis. Procedure-related adverse events are those events that occur from the procedure, irrespective of the device, such as an external iliac artery dissection upon cannulating the vessel. Finally, access-related complications (i.e. pseudoaneurysm, hematoma, thrombosis, unplanned reintervention) should be consider as procedure-related complications.

Serious Adverse Events

Serious Adverse Events (SAEs) are defined as those adverse events where the outcome is one of the six specific occurrences : 1) Death, 2) Life-threatening, where the patient was at substantial risk of dying or continued use of the product might have resulted in death, 3) Hospitalization or prolongation of an existing hospitalization, 4) Disability or permanent damage, interfering with the patient's ability to conduct normal life functions, 5) Congenital anomaly or birth defect, 6) Required intervention to prevent permanent impairment.(10)

System specific complications

Postoperative complications should be reported in a systematic manner using the recommendations of prior reporting standard documents. These complications should be described using specific follow up time intervals and should be classified with respect to procedure or device association.(35, 36) A scoring system consistent with the EVAR and TEVAR reporting standards include the following classification:

- Mild- indicates a complication that occurred but resolved spontaneously or with nominal intervention without prolongation of hospital stay or permanent impairment

- Moderate- indicates a complication that required significant intervention, prolongation of hospitalization >24 hours, and that resulted at the most minor permanent disability that does not preclude normal daily activity
- Severe- indicates the need for major surgical or medical intervention, may be associated with prolonged recovery time and is usually associated with prolonged or permanent disability or has resulted in death

Secondary interventions

Secondary interventions are defined as any repeat vascular or non-vascular procedure on the index device and/or its branches. Re-interventions can be divided into major and minor categories to reflect the magnitude of the procedure and its presumed impact on the patient. Major re-interventions include deployment of proximal and/or distal extensions involving larger diameter sheaths, removal of the device, use of thrombectomy or thrombolysis and any major open surgical procedure. Minor secondary interventions include endovascular procedures (PTA, atherectomy, stenting) without thrombectomy/thrombolysis, interventions to treat branch vessel stenosis, interventions to treat type II endoleak or branch-related endoleaks, and minor surgical revisions (patch angioplasty) of the access vessels. Re-interventions that are non-vascular should also be described including access-related, wound debridement, hernia or laparotomy-related interventions or other procedures.

ANEURYSM AND STENT-GRAFT RELATED OUTCOME DEFINITIONS

Endoleaks

The classification of endoleaks has been proposed in the EVAR reporting standards.(35, 36, 138) Development of newer technology to incorporate side branches requires a revision of

the original classification system to adapt to additional failure mechanisms that can occur with modular devices based on fenestrations, directional branches or parallel stent-grafts.(153) The revised classification system is summarized in **Figure 18**.

Endoleaks should be classified as *primary endoleaks* if present at the initial completion angiography or at the first cross-sectional imaging evaluation using either CTA or MRA. *Secondary endoleaks* are described as development of a new endoleak detected by CTA after the original procedure and after the first follow-up CTA or MRA has demonstrated absence of an endoleak. The reappearance of an endoleak after spontaneous resolution or successful intervention is termed a *recurrent endoleak.* Further categorization of endoleaks requires precise information regarding the course of blood flow into the aneurysm sac.

Type I endoleaks

Type I endoleaks by definition involve a persistent perigraft channel and therefore inadequate sealing at attachment sites of the aortic stent-graft and its modular components. The newer proposed classification uses subscripts *A, B* and *C* to indicate proximal, distal and target vessel fenestrated, branched or parallel graft attachment sites. The Type IC endoleak classification adds to the prior definition of endoleak related to iliac occluders, which are infrequently utilized. In this classification system, “gutter” endoleaks are considered Type IA endoleaks, since the endoleak involves the proximal landing zone due to lack of stent-graft apposition in the parallel stent segment.(154)

Type II endoleaks

A type II endoleak is attributed to retrograde flow into the aneurysm sac. This often involves a complex endoleak with multiple inflow and outflow channels. Retrograde flow can occur from lumbar arteries, inferior mesenteric artery (IMA), accessory renal arteries or other

collateral vessels. As there is a robust collateral pathway between the SMA and celiac artery, a type II endoleak can occur from the celiac axis if the vessel is not targeted by a fenestration or branch and is left without a stent. Origin and outflow of the endoleak should be described whenever possible, understanding the limitations that this requires a dynamic study to demonstrate flow pattern.

Type III endoleaks

Type III endoleaks are described as those occurring due to stent disconnection, inadequate overlap, fabric tears or disconnections, or graft disintegration. A distinction between which specific modular component is affected by endoleak also uses the subscripts *A, B* and *C.* *Type IIIA* endoleak is used to describe insufficient overlap or apposition between any of the aortic or iliac modular components, including any proximal thoracic stent-graft, fenestrated or branch component, distal bifurcated device or iliac limb extensions. The definition of *Type IIIB* endoleak remains unchanged and implies a fabric tear, which may be further described as minor (<2mm) or major (≥2mm). Finally, the new *Type IIIC* category is defined by insufficient overlap, apposition or a separation between the one or multiple bridging target vessel stents or between the bridging target vessel stent and the cuff or fenestration of the aortic device.

Type IV endoleaks

Type IV endoleaks are defined by blood flow through an intact aortic stent-graft attributed to porous fabric and observed within the first 30 days after the procedure. This designation is not applicable to fabric tears, disruptions or persistent flow through the fabric beyond 30 days, which should be classified as type IIIB endoleak.

Indeterminate endoleak

Indeterminate endoleaks are defined by endoleaks that are visualized on imaging studies without a defined source.

Endotension

Aneurysm sac enlargement >5 mm with no imaging evidence of an endoleak is classified as endotension. This may represent an endoleak that may not be evident because of inadequate imaging or limitations of currently available imaging modalities.

Aneurysm sac changes

Changes in aneurysm sac diameter should be described by specific follow-up time interval. Clinical correlation of aneurysm sac diameter and presence of endoleaks or other complications should also be specified in reports dealing with complex endovascular aortic repair. Because variations in size occur in three dimensions, both sac volume and diameter are relevant parameters. In addition, comparisons between studies at different time intervals are needed to determine sac changes. Relatively small diameter shifts usually don't have clinical significance and may be difficult to accurately measure. The definition of *aneurysm sac enlargement* or *shrinkage* is an increase or a decrease in diameter >5 mm or >5% in volume measurements, respectively. It is recommended that measurement of sac changes is performed by comparison with prior studies using same imaging modality at standardized aortic segments.

Device migration

Device migration should be established using sequential imaging studies with specific anatomic landmarks (e.g. distance from lower edge of renal arteries). Migration is defined by movement of the main aortic stent-graft or any of its modular components of >10 mm. A description of type of movement includes *cranial*, *caudal* or both. Because migration may lead to

compromise of targeted vessels, it is important to report its association with other branch-related outcomes such as kink, stenosis, occlusion or endoleaks.

Separation or movement of components

The addition of modular components is submitted to aortic remodeling or displacement forces that may lead to movement or separation of components over time. *Separation* of component is defined by lack of attachment in a previously attached stent-graft or side branch. *Inter-component movement* is defined by displacement of a component that is still attached and is not disconnected from its initial deployment location.(155) It is important to the length of movement and its relationship with occurrence of other stent-graft related complications including migration, stenosis, kink, occlusion or endoleaks. The intercomponent movement should be specified in millimeters or number of stents in the overlapping segment.(155) Over time the branch stent may disengage from the target vessel creating an endoleak and potential vessel occlusion. It is important to note any withdrawal of the branch stent from the target vessel.

Device integrity

Integrity of a device may be compromised at the time of deployment or during any point in follow-up. These problems include fractures of stents, barbs, hooks and disruption of fabric or suture material. Reports should distinguish if the specific failure mechanism affected the delivery system, endograft or adjunctive mechanisms. It is important to specify if the device was implanted under specific instructions for use and to describe any variations from anatomic recommendations. It is recommended to use the methodology reported in the EVAR and TEVAR reporting standards:(10, 35, 36)

Grade 0: device integrity issue with no adverse clinical event and that does not require additional surveillance or an intervention

Grade 1: Device integrity issue with no clinical event that requires increased surveillance but does not require intervention

Grade 2: Device integrity issue that requires medical or surgical intervention

Grade 3: Device integrity issue that requires conversion to open repair or leads to rupture, major complications or death

Progression of aortic disease

Disease progression has been increasingly recognized as an important clinical outcome that affects durability of repair or may require future additional intervention. There is evidence that aortic diameter at the sealing site or in areas that were not treated continue to enlarge after open or endovascular repair. Changes in aortic configuration and diameter may or may not lead to clinical events, re-interventions and compromise of the initial aortic repair. These changes can occur proximal or distal to the initial repair and must be reported and the therapy/intervention required to treat them.

Graft instability

The term graft instability can be used to describe a composite end-point of any event related to the aortic graft component that is associated with patient death, aneurysm rupture, infection or reintervention, excluding target vessel related events, which are described under the definition of target-vessel instability. Examples include device migration, component separations, integrity issues such as type III endoleak or stent fracture. Progression of aortic disease with loss of proximal or distal seal should also be accounted.

SPECIFIC BRANCH-RELATED OUTCOMES

End-points for standardized reporting on side-branch incorporation are summarized in **Table XVI**. These end-points are defined using objective imaging assessment and clinical criteria.

Patency

Patency of a graft or stent should be based on objective imaging assessment. Surveillance protocols after complex endovascular aortic repair typically include longitudinal follow-up with duplex ultrasound and/or computed tomography angiography to evaluate the aortic stent-graft, its modular components, the aneurysm sac and any untreated segments of the aorta.(16, 21, 24) Patency should be reported for all side branches, for each specific side branch (celiac, SMA and renals) and for specific method of incorporation (e.g. fenestration, directional branch, parallel graft, antegrade, retrograde configuration). A side-branch or any of the modular components may be considered patent when one of the two criteria is met:

1. Demonstrable patency of stent or stent-graft and target vessel by accepted vascular imaging technique, including duplex ultrasound (with or without contrast), computed tomography angiography, magnetic resonance angiography and/or contrast angiography.
2. Direct observation of patency at operation or postmortem examination.

Occlusion of a side branch is defined as an absence of demonstrable flow in any of the modular components including the side branch, stent, stent-graft or the native segment of the target vessel. *Stenosis* is defined by the presence of narrowing with demonstrable flow in any of these components. *Stenosis* can be graded to demonstrate severity using contrast angiography. Use of computed tomography angiography or magnetic resonance angiography to grade a

stenosis in the stented segment has not been validated and is limited by metallic artifact. A *hemodynamically significant stenosis* is defined by a decline in the systolic pressure measurement of at least 10 mmHg across the narrowed segment, which can be measured using pressure gradients. *Kink* can be a cause of stenosis and is defined by demonstrable angulation in any of the stent components or native target vessel.

Surveillance programs are designed to detect any stenosis or kink that can put the side branch or native artery at risk; reinterventions may be indicated to maintain stent patency. It is recommended that reports use the same standardized nomenclature that was proposed for reports dealing with other types of revascularization procedures to define patency. A side branch is considered to have *primary patency* if it has had *uninterrupted* patency with either no procedure performed to maintain patency within the stented segment or with the native artery beyond the stent if there is a new lesion due to progression of occlusive disease or development of neointimal hyperplasia. Thus, the only exceptions that would not disqualify for primary patency are procedures performed to treat endoleak, bleeding, disconnection or stent disruption, where the vessel remains patent by contrast angiography, surgical or postmortem examination. The denomination of *assisted primary patency* has been extensively used for lower extremity revascularizations and to a lesser extent for endovascular procedures involving aneurysm repair. *Assisted primary patency* of a side branch stent or stent-graft is defined by endovascular intervention (e.g. percutaneous transluminal angioplasty, stent or stent-graft placement) that is performed to maintain patency in the presence of a stenosis, kink before occlusion occurred. *Secondary patency* is defined by successful endovascular restoration of patency after occlusion of the side branch, stent or stent-graft has already occurred. Secondary patency is lost if

restoration of patency is not possible using endovascular technique or if conversion to open surgical reconstruction is needed to restore vessel patency.

Vessel complication

Catheter manipulation that is needed to perform complex endovascular aortic repair may result in inadvertent injury to the target vessel with potential risk of hemorrhage or loss of vessel patency. It is recommended that reports use standardized definitions to describe these complications, including dissection, intramural hematoma, perforation, occlusion or distal embolization. Adjunctive procedures and loss of organ or permanent clinical sequela (e.g. kidney loss) should be specified.

Target vessel instability

The term branch instability has been coined by Mastracci and colleagues to describe a composite end-point of any branch-related complication leading to aneurysm rupture, death, occlusion, component separation or a reintervention to main branch patency or treat a branch-related component separation or endoleaks.(125) In order to avoid confusion between outcomes of fenestrated and directional branches, we recommend using the term *target vessel instability* instead of branch instability. It is recommended that reports dealing with complex endovascular aortic repair describe longitudinal freedom from any branch instability.

END-POINT DEFINITIONS

Durability outcomes

Durability end-points include those that evaluate the structural integrity of the device and its modular components with respect to the ability to maintain effective treatment of the primary aortic pathology and target organ perfusion whilst preventing the need for additional procedures. Examples of durability end-points would be decay curves of freedom from reinterventions, target

vessel instability, primary and secondary patency and conversion to open surgical repair. A detailed specification of aortic and non-aortic reinterventions should be noted.

Safety outcomes

Safety end-points include those that describe the ability of a repair to prevent death, complications and end-organ damage. These include mortality and adverse events. A distinction of serious (SAEs) and non-SAEs has been proposed by the ISO and FDA.(10) *Serious adverse events* are defined by an adverse event that results in one of the following: death, life-threatening risk, hospitalization or prolongation of existing hospitalization, disability or permanent damage, congenital anomaly or birth defect or required intervention. The term unanticipated adverse device effect (UADE) has been defined by a serious adverse effect on health or safety or any life-threatening complication or death caused by, or associated with a device, if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan.(10)

Effectiveness

Effectiveness measures if the proposed treatment has decreased or eliminated risk of death or aortic complication due to progression of primary aortic pathology. Examples of effectiveness end-points include: technical success, treatment success, quality of life measures, morbidity, mortality, device integrity, durability and rupture.

QUALITY OF LIFE AND COST-EFFECTIVENESS ANALYSIS

Analysis of quality of life and cost-effectiveness have been increasingly used to describe the impact of treatment on patients activity of daily leaving and physician well-been as well as the benefit of new interventions weighted against its expense.(156-160) Studies designed to

evaluate novel side branch technology may include an assessment of the cost of this technology and its surveillance program, as well the impact the treatment had on patients' quality of life. Examples of end-points that impact on both these measures are: length of hospital stay, morbidity and mortality, major disability, return to work, type of discharge (e.g. home versus skilled nursing facility, or rehabilitation), perioperative and long-term quality of life, return to normal physical activities, need for reintervention, and psychological stress. For assessment of quality of life measures, it is important to establish a baseline before the treatment was applied, and to reassess frequently enough to capture the earlier perioperative rise of endovascular repair and also the later postoperative rise of open repair. Financial analysis requires measurement of cost rather than charge data. Cost analysis needs to be comprehensive including all pre-operative and postoperative evaluation, as well as the cost of the endovascular and open repair used to treat the aortic pathology. It is important to capture the costs of rehabilitation, skilled nursing facilities, outpatient visits, and re-interventions. The cost of non-vascular re-interventions (e.g. incisional complications such as infection, seroma, hernia, intervention or hospitalization to treat bowel obstruction) should be captured.

SUGGESTED STATISTICAL METHODS

It is recommended that studies evaluating complex endovascular repair describe specific design methodology (e.g. retrospective, prospective, cross-sectional, case-control). Other important information includes descriptions of specific database and statistical software. The reporting standards used to define outcome variables should be included as specific definitions of primary and secondary endpoints.(35, 36) Specific statistical tests and methods as well as levels of statistical significance should be specified. The methods of how data is presented need to be

mentioned.

Early outcomes

Clinical data on complex endovascular repair is rapidly evolving with newer reports from industry sponsored clinical trials, multi-center registries and single center retrospective reviews. Description of early results support the safety and efficacy of complex endovascular repair. It is recommended that these results are separated from other longitudinal mid-term or long-term outcomes. The early result section usually describes basic demographics and clinical characteristics, such as clinical presentation, cardiovascular risk factors, anatomical measurements and pertinent pre-operative laboratory studies (**Table XVII**). For comparisons between groups, it is recommended to report the variables for the entire cohort and for each treatment arm.

Most studies include a description of early mortality and major adverse events.(10) The reporting standards for adverse events after medical device use in the peripheral vascular system provides a useful source for standardized definitions used in clinical trials. The United States Food and Drug Administration (FDA) regulates clinical trials under section 520(g) of the Federal Food, Drug and Cosmetic Act. Part 812 of title 21 specify medical device regulations, which mandate reporting of adverse events to ensure the protection of human subjects in clinical trials. In an effort to minimize disparity of reporting with other national agencies, the Global Harmonization Task Force (GHTF) in 1992 and the International Organization for Standardization in 2003 provided documents to achieve conformity in the assessment of medical devices.

Several other important end-point measures should be described in the early outcome section. Changes in renal function can predict early and late mortality and should be described

using the proposed classification for acute kidney injury. A description of early secondary interventions, which are usually associated with technical problems should be included and separated from late secondary interventions. Reports should also include a description of objective imaging if obtained within the first 30 days to assess patency, endoleak and integrity issues. Other customary end-points in the early outcome section are length of stay in the intensive care unit, length of stay in the hospital and disposition, such as dismissal to home, rehabilitation unit or nursing home.

Longitudinal reporting of short-term, midterm and long-term outcomes

Longitudinal reporting should use relevant time frames divided into short-term, midterm and long-term, proposed and used in a number of SVS reporting documents, including the EVAR and TEVAR reporting standards.(35, 36) Description of longitudinal outcomes can be done using tabular format or Kaplan-Meier survival curves. It is important to clearly describe the number of patients at risk, events and number of patients lost to follow up at each time interval (**Figure 19**). Whereas some events may be reported using either method, others are better described in tabular format. These are the events which may change category multiple times during the follow up interval, such as endoleak presence and classification, change in sac diameter or chronic kidney disease category. For example, a patient may have a type II endoleak treated, but this may reappear in late follow up. In these cases, a survival curve of freedom from endoleak may not accurately represent the efficacy of treatment or demonstrate the reoccurrence of the event.

The following parameters are particularly important for reports dealing with endovascular repair of complex aneurysms: patient survival or freedom from all-cause mortality, freedom from aneurysm-related death, freedom from aneurysm rupture, freedom from any aneurysm sac expansion, freedom from any type I or III endoleak, prevalence and classification of endoleak,

classification of changes in sac diameter and freedom from device migration, freedom from secondary intervention. Outcomes describing target vessel events are particularly important. These include primary, primary-assisted and secondary target vessel patency and freedom from target vessel instability. It is important to describe target vessel outcomes with granular information to allow comparison between studies, including a description by specific vessel (e.g. celiac, SMA, right and left renal) and type of incorporation (e.g. fenestration versus directional branch) or bridging stent (e.g balloon-expandable versus self-expandable).

Time dependent outcomes should be described using life tables or Kaplan-Meier curves. These include reports of survival, rupture-free survival, maintenance of clinical success, freedom from aortic-related death and freedom from secondary interventions. The later should be further described in freedom from any reintervention, any aortic-related and non-aortic related reinterventions. A description of non-aortic related reinterventions is particularly important in reports dealing with comparisons to open surgical repair. Several studies have shown a high rate of wound complications and laparotomy-related problems, which are not factored under the classification of aortic related reinterventions. It is recommended to include in life table analysis the number of patients at risk, events and the standard deviation at each time interval. As a general rule, intervals with standard error of the mean (SEM) ≥10% should be identified as a dotted line or other. Differences between groups should be assessed using log rank test. For multivariate analysis of longitudinal events, cox regression model should be used.

Events that are not binary and that have multiple categories (e.g. endoleaks) or that may reoccur multiple times during follow up are best described using tabular format or stacked bar graphs. The stacked bar graphs should describe the number of patients at risk during each time interval and the event category. These descriptions are useful by displaying granular data

longitudinally, including all the event categories and percentages, without requiring a large amount of explanatory text. Reports often summarize longitudinal measures of continuous variables, such as maximum aneurysm diameter, serum creatinine or eGFR. For measures of continuous variables, it is recommended to report the mean and standard deviation, or median, range, and quartile values may be reported to describe characteristics at specific time points.

OPEN SURGICAL CONTROLS

Comparative analysis of open surgical and endovascular techniques should take into consideration a detailed description of treatment algorithms, clinical and anatomical components affecting decision of type of repair and approach. It is recommended that the same standards are used to describe clinical comorbidities, aneurysm classification, early and late outcome measures in both groups. Follow up should be described in the open surgical group, including objective imaging assessment of the repair and aortic side branches. A description of non-aortic, wound or laparotomy-related complications, such as wound infection, incisional hernia or bowel obstruction is important to provide full analysis of treatment-related end-points in the open surgical group. Primary technical success should be reported on an intention-to-treat basis, which is initiated at the time of surgical incision. A technically successful open surgical repair requires successful replacement or bypass of the aorta without death, graft or side branch thrombosis, target organ or lower extremity malperfusion or reoperation in the first postoperative day. Therefore, if the operation is not concluded because of intra-operative death, even prior to aortic replacement or bypass (or implantation of a device with endovascular procedures), the subject should still be included in the open surgical group as a technical failure. The definition of clinical success for open surgical repair should take into consideration the same proposed end-points as

defined for endovascular repair. A clinically successful procedure implies absence of death, graft infection or thrombosis or para-anastomotic aneurysm.

PROSPECTIVE STUDIES AND INVESTIGATIONAL DEVICE EXEMPTION STUDIES

Endovascular repair of complex aortic aneurysms has been rigorously evaluated in industry and physician-sponsored clinical trials.(17, 92, 121, 127, 159, 161-163) It is important to recognize differences in level of evidence from clinical trials evaluating outcomes of fenestrated-branched stent-grafts with that obtained from retrospective studies, prospectively maintained institutional databases and registries. Investigational device exemption (IDE) protocols and industry-sponsored clinical trials have a higher standard of data acquisition, monitoring and oversight. The reliability of clinical trial data reported by investigative sites has improved as a result of standardized guidelines. Independent monitoring by outside agencies or internal, independent departments have not only increased the accuracy of reporting, but also provided uniformity and standardization. Clinical monitoring by clinical research associates (CRAs) may be employed by the industry or physician sponsors or may be available in some institutions by independent regulatory research departments. The monitor has responsibility to evaluate patient consenting, adherence to protocol inclusion and exclusion criteria, completion of case report forms, and accurate assessment and reporting of adverse events. The monitor may identify clinical events which were missed in case report forms by the primary investigator. Therefore, the sensitivity and accuracy of event recording is significantly improved in studies with independent monitoring.

Prospective clinical studies often include independent core lab or imaging review committee, data safety monitoring board (DSMB) and clinical event committee (CEC). It is recommended that prospective studies evaluating novel stent-graft technology have these

independent, impartial committees to assess safety end-points. The trials often have recommendations for *warning* and *stopping rules,* which are based on estimates from pooled reviews of the literature. End-points often selected include 30-day mortality, major adverse events, target vessel occlusion and events associated with permanent disability, such as stroke, paraplegia or dialysis. The CEC is responsible for adjudication of clinical events and end-points (e.g. procedure-related, device-related, aortic-related, etc), whereas the DSMB is responsible to monitor the overall safety of the study with respect to *warning* and *stopping rules*. These committees are organized by individuals with experience and knowledge in conducting clinical trials and a biostatistician. It is recommended that these individuals are free of any financial and other conflicts of interest and are not investigators in the study. Publications reporting on outcomes of endovascular therapies for complex aortic aneurysms need to mention type of auditing, DSMB and CEC used, if any, and rules for advent adjudication. Retrospective studies should describe methodology used for imaging surveillance, anatomical review and intra or inter-observer consistency.

LEVELS OF EVIDENCE

It is recommended that authors use the **GRADE framework** to evaluate and grade the strength of any recommendation and quality of evidence.(164) High quality of evidence is derived from prospective randomized trials, whereas evidence from observational studies is initially rated as low. The GRADE domain is then used to modify the initial rating after assessment of risk of bias, consistency of results across studies, homogeneity of the study population and interventions, precision of the estimates of end-points and size of the observed end-point. When the evidence clearly demonstrates that the benefits of an intervention outweigh

its risks or vice-versa, a **strong recommendation** is issued. However, if the evidence points towards uncertain risk-benefit ratio, because of low-quality evidence, or because of high-quality evidence indicating that the risk-benefit ratio is closely balanced, a **weak recommendation** is recorded. This classification system is used in the development of practice guidelines. As such, the guideline writing committee uses the term "we recommend" to describe strong recommendations, whereas the term "we suggest" is applied for weaker recommendations. The **quality of evidence** is rated **high** when evidence from additional prospective studies is unlikely to change the estimation of effect, **moderate** when further research is likely to provide additional information on estimation of effect and **low** when additional research is likely to change the estimation of effect.

DISCLOSURES AND CONFLICT OF INTEREST

It is imperative that all authors and institutions disclose all financial relationships, particularly those related to studies based on data acquired through industry-sponsored registries or clinical trials. Although disclosures may not resolve all biases involved with a particular study, the information provided to the readers may allow them to interpret the results at their discretion. The International Committee of Editors of Biomedical Journals, which includes the Journal of Vascular Surgery, has established specific guidelines for disclosure of conflicts of interest and formal requirements for all submissions. Disclosures should include institutional and corporate relationships, sources of funding and sponsorship received for the reported study and other related research projects within 3 years of manuscript acceptance and potential financial conflicts, including consulting agreements, board membership or employment, royalties, stock

holdings, or honoraria with the company relating to the publication or its competitors. Proctor, principal investigator and consulting agreements should be listed, and financial income should be specified if directed to the physician, hospital or third party. Besides disclosures, the Methods section of a manuscript should include specific information related to the respective roles of study sponsors and investigators in study design, conduct of the study, data collection and analysis, data interpretation, writing of the manuscript and the decision regarding where and when to submit the report for publication. All listed authors should provide their disclosures with a standard form, usually provided by the publisher, or as a formal statement in the manuscript. Finally, details of institutional review board approval, informed consent process and clinical trial registration should be provided, as appropriate.

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FIGURE LEGENDS

FIGURE 1. Illustration of minimal, effective and total seal zone for complex endovascular repair. Note the location of target vessel origin should be described using clock position or angle. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 2. Illustration of calculation of arc lengths based on measurement from 12:00 o'clock position to the center of the target vessel ostia. Note that for grafts larger than the aorta in a given segment, the actual inner vessel diameter (IVD) should be used. However, for grafts that are smaller than the aortic luminal diameter (e.g. large thoracoabdominal aneurysm), the IVD should not exceed the diameter of the graft at that segment. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 3. Technique of measurement of renal artery angle. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 4. Technique of measurement of renal artery tortuosity index. P1 indicates distal end of branch cuff or fenestration, P2 origin of target vessel, P3 distal end of covered stent and P4 distal end of bare metal stent. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 5. Volumetric measurement of renal parenchyma used for estimates of renal infarct size or perfusion by accessory renal artery. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 6. Volumetric measurement of aortic wall thrombus (AWT). Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 7. Measurement of aortic wall thrombus using qualitative assessment of computed tomography angiography based on number of segments affected by thrombus and the type, thickness, area and circumferential measurements of thrombus. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 8. Classification of thoracoabdominal aneurysm extent based on Crawford. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

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FIGURE 10. Classification of abdominal aortic aneurysms including short neck (<10mm) infrarenal (A), juxtarenal (B), pararenal (C), paravisceral (D) and Extent IV thoracoabdominal aortic aneurysm (E). Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 11. Classification of aortic dissection proposed by DeBakey. *DeBakey Type I* dissection is defined as a dissection that starts at the ascending aorta and propagates at least to the aortic arch and often beyond to the thoracic or thoraco-abdominal segment. *DeBakey Type II* dissections originate in ascending aorta and are confined to the ascending aorta. *DeBakey Type III* dissections start beyond the origin of the descending thoracic aorta and can be further classified into IIIA (to the level of the diaphragm) or IIIB (beyond the diaphragm). Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 12. Stanford classification of aortic dissection. Stanford Classification, was introduced one year after the DeBakey classification and includes two categories, A and B, depending on whether the ascending aorta is involved. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 13. Zones of attachment. The proposed classification includes Zones 0 to 3 (ascending aorta to distal aortic arch), 4 to 5 (proximal to distal thoracic aorta), 6 to 8 (visceral aorta), 9 (infra-renal aorta) and 10 to 11 (iliac arteries). Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 14. Proposed classification for supraceliac coverage including high supraceliac (HSC), low supraceliac (LSC) and infraceliac (IC) sealing zones. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

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FIGURE 17. Strategies for staged endovascular repair of thoracoabdominal aortic aneurysms including sequential thoracic coverage or use of temporary aneurysm sac perfusion via incomplete repair or perfusion branches. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 18. Classification of endoleaks. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

FIGURE 19. Example of Kaplan-Meier survival estimates for primary target vessel patency. Image reproduced with permission of Mayo Foundation for Medical Education and Research.

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TABLES

Table I. Society for Vascular Surgery clinical comorbidity score system

Score	Description of Score	Weighting
Major components		
Cardiac status		X4
0	Asymptomatic with normal echocardiogram	0
1	Asymptomatic but with either remote myocardial infarction by history (>6 months), occult myocardial infarction by electrocardiogram, or fixed defect on dipyridamole thallium or similar scan	4
2	Any of the following: stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (1% of time) on holter monitoring, ejection fraction of 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated	8
3	Any one of the following: unstable angina, symptomatic or poorly controlled ectopy/arrhythmia (chronic/recurrent), poorly compensated congestive heart failure, ejection fraction less than 25%, myocardial infarction within 6 months	12
Pulmonary status		X2
0	Asymptomatic, normal chest radiograph, pulmonary function tests within 20% of predicted	0
1	Asymptomatic or mild dyspnea on exertion, mild chronic parenchymal radiograph changes, pulmonary function tests 65% to 80% of predicted	2
2	Between 1 and 3	4
3	Vital capacity less than 1.85L, FEV1 less than 1.2L or less than 35% of predicted, maximal voluntary ventilation less than 50% of predicted, PCO2 greater than 45 mmHg, supplemental oxygen use medically necessary, or pulmonar hypertension	6
Renal status		X2
0	No known renal disease, normal serum Creatinine level	0
1	Moderately elevated Creatinine level, as high as 2.4 mg/dL	2
2	Creatinine level of 2.5 to 5.9 mg/dL	4
3	Creatinine level greater than 6.0 mg/dL, dialysis or kidney transplant	6
Minor componentes		
Hypertension		X1
0	None (cutoff point, diastolic pressure usually < 90 mmHg	0
1	Controlled with single drug	1
2	Controlled with two drugs	2
3	Requires more than two drugs or is uncontrolled	3
Age		X1
0	< 55 years old	0
1	55 to 69 years old	1
2	70 to 79 years old	2
3	>80 years old	3
Total		30

Vascular Study Group of New England Modified Score Scheme

Type of repair	
0	EVAR

1	Open surgical repair with infrarenal clamp
2	Open surgical repair with supra-renal clamp
Aneurysm diameter	
0	<65mm
1	≥65mm
Age	
0	≤75 years-old
1	>75 years-old
Gender	
0	Male
1	Female
Comorbidities	
1	Myocardial infarction
2	Chronic obstructive pulmonary disease
0	Serum creatinine <1.5 mg/dL
1	Serum creatinine 1.5 to 2.0 mg/dL
2	Serum creatinine ≥2 mg/dL

Predictive risk of mortality

Sum score		Mortality
0 to 4	Low risk	0.12 - 1%
5 to 7	Intermediate risk	1.7 - 4.9%
8 to 10	High risk	8 – 20%
≥11	Prohibitive high risk	31-70%

Table II. Proposed classification of aortic pathology by anatomical site and etiologic mechanism

Classification
Anatomical location
Ascending aorta
Aortic arch
Descending thoracic aorta
Type A: from subclavian artery to T6
Type B: from T6 to the celiac axis
Type C: from subclavian artery to celiac axis
Thoracoabdominal aorta
Crawford classification
Extent I: from above T6 to the level of the renal arteries
Extent II: from above T6 to below the level of the renal arteries
Extent III: from below T6 to the level or below the level of the renal arteries
Extent IV: abdominal aneurysm extending up to the celiac axis
Safi classification
Extent I: from above T6 to the level of the renal arteries
Extent II: from above T6 to below the level of the renal arteries
Extent III: from below T6 to below the level of the renal arteries
Extent IV: abdominal aneurysm extending up to the celiac axis
Extent V: from below T6 to the level of the renal arteries
Abdominal aorta
Infrarenal: minimum sealing zone below the renal arteries ≥ 4mm
Juxtarenal: aneurysm abuts, but does not involve the renal arteries with sealing zone ≤4 mm
Pararenal: aneurysm involves at least one renal artery and abuts, but does not involve the superior mesenteric artery
Paravisceral: aneurysm involves the superior mesenteric artery and abuts, but does not involve the celiac axis
Iliac arteries
Etiology

Degenerative, anastomotic, infectious, inflammatory (noninfectious), traumatic, dissection, connective tissue disorder, genetically triggered, congenital

Clinicopathologic manifestations

Chronic pain, acute severe pain, acute rupture, chronic contained rupture, fistula, compression or erosion of adjacent structures

Traumatic aortic injury

Anatomical location, associated dissection, aneurysm, rupture or emboli

Etiology: blunt, penetrating

Time from injury

Clinicopathological manifestations: aneurysm, dissection, rupture and emboli

Classification

Grade I: intimal tear

Grade II: intramural hematoma or large intimal flap

Grade III: pseudoaneurysm

Grade IV: free rupture

Dissection

Anatomy: identify location in ascending, arch, descending thoracic or abdominal aorta, or use standard classification scheme (Stanford, DeBakey)

Etiology: spontaneous, associated mechanism (e.g hypertension, cocaine use), associated with genetically triggered aortic disease (e.g. Marfans, Ehlers-Danlos), traumatic (blunt, penetrating, iatrogenic, catheter-related)

Timing: acute, subacute, chronic

Clinicopathological manifestation: pain, ischemia, aneurysm, rupture, malperfusion

Penetrating aortic ulcer

Anatomy: site, extent, depth of the ulceration, maximum aortic diameter

Etiology: degenerative, infectious, iatrogenic

Time course: acute, chronic

Clinicopathological manifestation: pain, ischemia, aneurysm, rupture, emboli

Intramural hematoma

Anatomy: site, extent, thickness of the associated hematoma, maximum aortic diameter

Classification: Type A (ascending) or Type B (descending)

Etiology: Hypertension, iatrogenic, penetrating ulcer, aneurysm

Time course: acute, chronic

Clinicopathological manifestation: pain, aneurysm, rupture, compromisse of side branches

Coexisting pathology

All pertinent pathology should be listed

The primary pathology entity should be designated

Standard classifications of type, etiology, time course and clinopathological manifestations

All types of pathology should be accompanied by hemodynamic status at presentation, repair: stable, unstable, vital signs, associated cardiac arrest

Table III. A summary of Familial Thoracic Aortic Aneurysm and Dissection (FTAAD) genes, including year of discovery, number of discovered mutations within the gene, affected protein and associated connective tissues disorders and syndromes

Gene	Year	# of mutations	Protein	Associated Syndrome	Associated Pathology
Mutations affecting the TGF-β-beta signaling pathway					
FBN1	1991	1,300	Fibrillin-1	MFS	Ocular, skeletal involvement
TGFβR1/ TGFβR2	2005	110	TGFβ receptors 1 and 2	LDS	Skeletal manifestations, craniofacial abnormalities, tortuous arteries, cutaneous anomalies
SMAD3.	2011	11	SMAD3	AOS	Arterial aneurysms/tortuosity, mild craniofacial, skeletal, cutaneous anomalies, early-onset osteoarthritis
TGF-β2	2012	14	TGFβ2		Intracranial aneurysms, subarachnoid hemorrhages
SLC2A10	2006	19	Glucose transporter GLUT10	ATS	
Mutations affecting collagen					
Col3A1	1986	700	Procollagen III	VEDS	Risk of bowel and uterine rupture

Mutations affecting smooth muscle cell proteins				
ACTA2	2009	30	ACTA2	Early onset coronary artery disease, strokes, Moyamoya disease, livedo reticularis
MYH11	2006		MYH11	Patent ductus arteriosus
MLCK	2010		Myosin light chain kinase	
PRKG1	2013		PKGI	

MFS, Marfans Syndrome; *LDS*, Loyes-Dietz syndrome; *AOS*, aneurysm-osteoarthritis syndrome; *ATS*, arterial tortuosity syndrome; *VEDS*, Vascular Ehlers-Danlos Syndrome

Table IV. Correlation of anatomical classification of aneurysm and extent of aortic repair based on aortic segments covered

Anatomic Extent of Aortic Disease	Minimum estimated Proximal Sealing Zone	Estimated Segments Covered	Endovascular Extent of Aortic Repair
Abdominal aneurysm			
Infrarenal aneurysm	9	9-10	Infrarenal
Juxtarenal aneurysm	7	8-10	Pararenal
Pararenal aneurysm	6	6-10	Extent IV
Thoracoabdominal aneurysm			
Extent IV	5	5 to 10	Extent III
Extent III	4	4-10	Extent II
Extent II	3	3-10	Extent II
Extent I	3	3-9	Extent II

Table V. Classification of complex abdominal aortic aneurysms and correlations with open surgical and endovascular repair

Extent of Aortic Disease	Extent of open repair (segment of anastomosis)	Extent of endovascular repair (segment of stent sealing zone)
Infrarenal aneurysm	Infrarenal (Zone 9)	Infrarenal (Zone 9)
Juxtarenal aneurysm	Juxtarenal (Zone 8)	Pararenal (Zone 7)
Pararenal aneurysm	Pararenal (Zone 7)	Extent IV (Zone 6)
Extent IV	Extent IV (Zone 6)	Extent III (Zone 5)
Extent III	Extent III (Zone 5)	Extent II (Zone 4)
Extent II	Extent II (Zone 3)	Extent II (Zone 3)
Extent I	Extent I (Zone 3 to 8)	Extent II (Zone 3 to 9)

Table VI. Proposed terminology to describe type of endovascular incorporation

Terminology	Definition
Fenestrated and branched endovascular aortic repair	
Fenestrated repair	Vessels targeted by fenestrations
Branched repair	Vessels targeted by directional branches
Fenestrated-branched repair	Vessels targeted by fenestrations and directional branches
Fenestrations	Small or large circular or oval shaped openings usually aligned by stent to target vessels originating from normal or mildly enlarged aortic segments
Scallops	Single or doublewide "U-shaped" openings in the top of the device usually not aligned by stents
Directional or cuffed branches and portals	Pre-sewn side branches, cuffs or portals that serve as gate areas for placement of bridging stents that connect the aortic stent-graft to the target vessel
External branch or portal	Cuff or portal located in the external portion of the aortic stent-graft
External-internal branch or portal	Cuff or portal located partially in the internal and partially in the external portion of the aortic stent-graft
Internal branch or portal	Cuff or portal located in the internal portion of the aortic stent-graft
Helical branch or portal	Cuff or portal with helicoidal configuration
Straight branch or portal	Cuff or portal with straight configuration
Antegrade branch or portal	Cuff or portal with antegrade, down-going configuration accessed from brachial approach
Retrograde branch or portal	Cuff or portal with retrograde, upgoing configuration accessed from femoral approach
Bifurcated device with inverted iliac limb	Contra-lateral iliac limb is inverted and placed inside the main body of the bifurcated device, allowing short distance from top of the fabric to the contra-lateral gate
Iliac branch device or endoprosthesis	Specially designed device with directional branch for internal iliac artery incorporation
Hybrid visceral debranching	Combines extra-anatomic reconstruction of the renal and mesenteric vessels via midline laparotomy with endovascular aortic repair
Parallel graft endovascular aortic repair	
CHIMPS	Term used to describe chimney, periscope and sandwich graft technique
Chimney stent-graft	Parallel stent-graft positioned in antegrade down-going configuration between the aortic wall and aortic stent-graft
Periscope stent-graft	Parallel stent-graft positioned in retrograde up-going configuration between the aortic wall and aortic stent-graft
Sandwich stent-graft	Parallel stent-graft positioned in antegrade or retrograde between two aortic stent-grafts

Octopus stent-graft	Parallel stent-graft technique using multiple parallel stent-grafts positioned inside iliac limb or gate of bifurcated stent-graft to treat thoracoabdominal aortic aneurysms

Table VII. Proposed terminology for descriptions of stent components and branch incorporation

Category	Specifications
Configuration	
Proximal sealing zone	0 to 7
Distal sealing zone	4 to 11
Length of aortic coverage	cm or proportion of descending thoracic aorta
Modularity	Single or multiple components
Branch vessel incorporation	Refer to Table 7 Scallop, fenestration, directional branch Number of vessels treated Type of bridging stent component (balloon versus self-expandable stent-grafts) Antegrade versus retrograde branches Parallel, chimney, periscope or sandwich grafts
Delivery system adjuncts	Preloaded catheter or guidewire systems, femoral or brachial access Hydrophilic coating
Endograft fabric	Polytetrafluoroehylene, polyester, combination, fabric "generation"
Diameter change	Tapered, reverse tapered
Temporary diameter reducing mechanism	Posterior reducing ties, sleeve, circular ties
Bifurcated device	Standard universal, inverted iliac limb
Design	Off-the-shelf, patient-specific, custom manufactured
Profile	Standard or low profile
Support system	Full or partial support Balloon-expandable or self-expandable Stent framework luminal or abluminal in relation to fabric Supporting framework fixed to the graft with stiches or otherwise bonded, attached Geometric configuration Material composition (e.g. nitinol, stainless steel, elgiloy)
Fixation componentes and techniques	
Configuration	Hooks, barbs, screws, pins, scales, or other means Balloon-expandable or self-expandable
Location	Proximal or distal to stent-graft fabric
Graft size relative to native aorta	
Oversizing	Percentage relative to intended aortic diameter at sealing zone Indicate oversizing relative to luminal or outer aortic wall diameter Indicate absolute number or range

Table VIII. Proposed variables to describe branch stent construction during fenestrated and branched endovascular aortic repair

Variables	Specifications
Intended target vessel	Specify target vessel: innominate artery, left common carotid artery, left subclavian artery, celiac axis, superior mesenteric artery, right renal artery, left renal artery, accessory renal artery, right internal iliac artery, left internal iliac artery
Type of incorporation	Refer to Table VII (e.g. scallop, fenestration, directional branch, parallel graft)
Bridging stent type	Balloon-expandable or self-expandable stent-graft Manufacturer
Dimension	Diameter and length relative to target vessel
Orientation	Antegrade, retrograde, straight, helical
Adjuncts	Reinforcement with self-expandable bare metal stent, drug-elluting stent
Flaring	Diameter (mm) and angulation (e.g 90-degree, 60-degree)
Oversizing	Diameter of the stent relative to nominal diameter of the target vessel
Target vessel landing zone lenght	Length of landing zone within the target vessel (mm)

Table IX. Proposed terminology to describe primary procedure, staged and adjunctive procedures

Terminology	Definition
Aortic repair procedures	
Principal or primary procedure	Procedure involving exclusion of the aneurysm, typically including incorporation of the renal-mesenteric segment
Adjunctive procedures	Adjunctive or staged procedures performed before or after the primary procedure to achieve aneurysm exclusion in stage fashion or revise the primary procedure
Single stage	Endovascular aneurysm exclusion is achieved in single procedure
Two or multiple stage	Endovascular aneurysm exclusion is achieved in two or more procedures
Staging strategies	Proximal thoracic endovascular repair Temporary aneurysm sac perfusion (TASP) branches Incomplete primary procedure Planned or unplanned
Adjunctive procedures	
Branch related	Debranching: extra-anatomic bypass performed to extend proximal landing zone prior to primary aortic procedure (e.g. carotid-subclavian bypass) Occlusion (e.g. coils, plugs, other) Stenting for occlusive disease or dissection
Aortic sac adjuncts	Coil embolization, liquid agentes, “candy” plug, other
Conduits	Permanent or temporary, iliac or femoral, open surgical or endovascular
Hemodynamic maneuvers	Induced hypotension, rapid ventricular pacing, caval balloon occlusion
Monitoring	Neuromonitoring (motor evoked and somatosensory evoked potentials), near infrared spectroscopy (NIRS), cerebrospinal fluid drainage
Timing	Pre or post primary aortic procedure Planned or unplanned

Table X. Proposed variables for reporting operative metrics and radiation exposure

Variable	Definition	Value
Anesthesia and operative time		
Total anesthesia time (min)	Induction to extibation or wheels out if patient not extubated in the OR	Mean (SD)
Total operating time (min)	Skin incision to closure	Mean (SD)
Total endovascular time (min)	Arterial access (needle in) to removal of arterial access (sheath out)	Mean (SD)
Contrast dose and volume		
Total contrast dose (mg)	Total contrast concentration	Mean (SD)
Total contrast volume (ml)	Volume of contrast	Mean (SD)
Indirect measurements of adiation exposure		
Total fluoroscopy time (min)	Time spent on pedal using fluoroscopy	Mean (SD)
Dose Area Product (DAP) or Kerma Area Product (KAP) ($Gy.cm^2$)	Product of air kerma (energy extracted from x-ray beam per unit mass of air) by the area of the cross section of the x-ray beam. It measures the entire amount of energy delivered to the patient	Mean (SD)
Cummulative Air Kerma (CAK, mGy) or cumulative dose	Air Kerma accumulated at a specific reference point relative to the fluoroscopic gantry. The aim of CAK is to provide an estimate of the dose at the patient's skin entry. The location of the reference point changes with gantry rotation	

Table XI. Proposed morphological variables for assessment of outcomes of fenestrated and branched endovascular aortic repair

Variable	Definition
Aneurysm sac changes	Measurements of maximum and minimum aneurysm diameter, length and volume should be obtained using same technique in same location
Enlargement	>5mm enlargement in sac diameter compared to baseline study obtained immediately prior or after (1 month) stent-graft implantation
Shrinkage	>5mm decrease in sac diameter compared to baseline study obtained immediately prior or after (1 month) stent-graft implantation
Stable	<5mm changes in sac diameter
Volume	Total aneurysm volume measured within native aortic wall
Complete aneurysm resolution	Term used to describe aneurysm sac volume within less than 10% of baseline of the original volume
Endoleak classification	(See Figure 19)
Type IA	Proximal aortic sealing zone
Type IB	Distal aortic or iliac sealing zone
Type IC	Target vessel sealing zone or occluding aortic side/iliac branch plug (e.g subclavian or iliac occlusion plug)
Type II	Retrograde endoleak via patent aortic side branch (e.g. lumbar, intercostal, accessory renal artery or inferior mesenteric artery)
Type IIIA	Modular disconnection or apposition failure in the main aortic component, bifurcated device or iliac limb
Type IIIB	Fabric tear
Type IIIC	Target vessel bridging stent disconnection or apposition failure
Type IV	Flow from porous fabric <30 days after graft placement
Indeterminate	Flow visualized but source unidenfified
Complex or mixed	Multiple sources of endoleak identified (e.g Type I and III)
Migration	>10 mm movement, proximal or distal

Table XII. Recommended primary and secondary outcome criteria for reports dealing with fenestrated, branched and parallel stent-grafts

End-point	Description
Primary outcome criteria	
Mortality related to primary aortic pathology	
Reinterventions designed to treat the underlying aortic disease	Open conversion, endovascular or open intervention for endoleak
Aneurysm rupture	
All-cause mortality	
Secondary Outcome Criteria	
Evidence of aortic disease progression	Aneurysm growth ≥5mm
Device failure	Migration ≥10mm, device degradation, loss of device integrity
Endoleaks	
Secondary reinterventions	Treatment of branch vessel stenosis or occlusion, embolization

Significant life-style limiting or disabling complications	Stroke, paraplegia
Cardiac dysfunction	Myocardial infarction, congestive heart failure, cardiac ischemia requiring intervention
Renal events	Renal infarction, deterioration of renal function, renal failure
Mesenteric events	Ischemia, resection
Respiratory events	Failure, prolonged intubation

Table XIII. Recommended classification for defining spinal cord injury and stroke following complex endovascular aortic repair

Grading or score	Description
Spinal cord injury classification	
Grade 0	No neurologic deficit
Grande 1	Minimal sensory deficit with no motor deficit and ability to walk independently
Grade 2	Paraparesis; minor motor deficit with ability to walk with assistance or independently. This definition implies the patient is able to move the extremity against gravity.
Grade 3	Paraplegia, severe motor deficit causing inability to walk (wheelchair bound), should be further classified:
3A	non-ambulatory with ability to move extremities against gravity
3B	non-ambulatory with ability to move extremity laterally but not against gravity
3C	non-ambulatory with minimal or no movement
Stroke	
National Institute of Health Stroke Scale (NIHSS)	
0	no stroke symptoms
1 to 4	Minor stroke
5 to 15	Moderate stroke
16 to 20	Moderate to severe stroke
21 to 42	Severe stroke
Level of consciousness	The level of consciousness testing is divided into three sections; scores for responsiveness, questions and commands are collected.
Responsiveness	
0	Alert, responsive
1	Not alert, verbally arousable
2	not alert; responsive to repeated or strong/painful stimuli
3	totally unresponsive; responds with reflexes or areflexic
Questions	

0	correctly answers both questions
1	correctly answers one question
2	unable to correctly answer either question
Commands	
0	correctly performs both tasks
1	correctly performs 1 task
2	unable to perform either tasks
Horizontal eye movement	This task evaluates the patient's ability to track a finger or pen side to side only using their eyes and assesses the motor ability to gaze towards the opposite hemisphere.
0	normal; successfully follows finger or pen movements
1	partial gaze palsy
2	total gaze palsy
Visual field test:	Each eye is tested individually and assessment of each visual field is included:
0	no visual field loss
1	partial hemianopia or complete quandrantopia
2	complete hemianopia
3	bilateral blindness
Facial palsy	Inspecting the symmetry of each facial expression includes: asking the patient to grin, close their eyes tightly, open their eyes and raise their eyebrows.
0	normal, symmetrical facial movements
1	minor paralysis (i.e. flattened nasolabial fold, smile asymmetry)
2	partial paralysis
3	complete facial hemiparesis
Motor arm	Observation of downward arm drift during a 10 second cycle for each arm is performed. The examination begins with palms facing down, one arm extended 90 degrees in front of the patient if seated and 45 degrees out front if the patient is lying down.
0	no arm drift for the full 10 seconds
1	intermediate position drift, does not rely on support
2	limited effort against gravity, arm drifts, support needed
3	no effort against gravity, arm falls immediately, limited movement
4	no ability to enact voluntary movements
Motor leg:	This study includes evaluation of downward leg drift

	during a 5 second cycle while the patient resides in the supine position. Each limb is score independently and starts at a position 30-degrees above horizontal.
0	no leg drift
1	leg drift to an intermediate position, limb doesn't touch the bed
2	limited effort against gravity, unable to obtain starting position
3	no effort against gravity, some degree of movement is present
4	no movement
Limb ataxia	Assessing for a difference between weakness and incoordination (if present) may determine the presence of a unilateral cerebellar lesion. The patient is instructed to touch their index finger to the examiners index finger and then touch their own nose, repeating this movement 3-4 times. The second component requires the patient to move their heel up and down the contralateral shin.
0	normal coordination
1	ataxia present in 1 limb
2	ataxia present in 2 or more limbs
Sensory	Pinpricks are used to assess sensation in all four limbs. A side to side comparison should be included.
0	no sensory loss
1	mild to moderate sensory loss, dullness to sensation
2	severe or total sensory loss
Language	Language skills are objectively assessed by having the patient explain a scenario depicted in a picture, read a list of simple sentences and name each depicted objects in a picture.
0	no speech déficit
1	mild to moderate aphasia, loss of fluency
2	severe aphasia, fragmented speech
3	unable to speak or be understood
Speech	Dysarthria is defined as a lack of motor skills to create understandable speech. Strokes can impact vital regions of the brain which controls the motor function of the tongue, throat, lips and/or tongue. To perform this test, patients are asked to read a list of words while the examiner assesses articulation and clarity of speech.

0	normal, clear and smooth speech
1	mild to moderate dysarthria, slurring of speech
2	severe dysarthria, unable to understand
Extinction and inattention	An adequate assessment of this item may have been obtained while assessing items 1-10. If uncertain, the examiner should perform the double simultaneous stimulation test. This is performed by having the patient close their eyes and asking them to identify which side is being touched. This test should be repeated on the face, arms and legs. To test extinction of vision, the examiner should hold up 1 finger in front of each of patient's eyes and inquire which finger is being wiggled
0	Normal
1	inattention on one side, one modality
2	hemi-attention, doesn't recognize stimuli using >1 modality

Table XIV. RIFLE Classification for Acute Kidney Injury

Stage	GFR criteria	Urine Output Criteria
Risk	SCr increased 1.5-2x baseline or GFR decreased >25%	UO <0.5 mL/kg/h for <6 hours
Injury	SCr increased 2-3x baseline or GFR decreased >50%	UO <0.5 mL/kg/h for >12 hours
Failure	SCr increase >3x baseline, GFR decreased >75%, SCr ≥4 mg/dL; acute rise ≥0.5 mg/dL	UO <0.3 mL/kg/h for 24 hours Oliguria Anuria for 12 hours
Loss of function	Persistent acute renal failure: complete loss of renal function >4 weeks (requires dialysis)	
End stage renal disease	Complete loss of renal function >3 months (requires dialysis)	

Table XV. National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) classification for chronic kidney disease (CKD)

Chronic Kidney Disease Stage	Glomerular Filtration Rate (GFR)	Description
I	>90 ml/min/1.73 m^2	Normal renal function but positive urine findings, structural abnormalities or genetic disease
II	60-89 ml/min/1.73 m^2	Mildly reduced renal function and associated findings in stage I
III	30-59 ml/min/1.73 m^2 a) 45-59 ml/min/1.73 m^2 b) 30-44 ml/min/1.73 m^2	Moderately to severely reduced renal function
IV	15-29 ml/min/1.73 m^2	Severely reduced renal function
V	<15 ml/min/1.73 m^2 or dialysis	Renal failure or end stage kidney

Table XVI. Proposed end-points to evaluate target vessel related outcomes

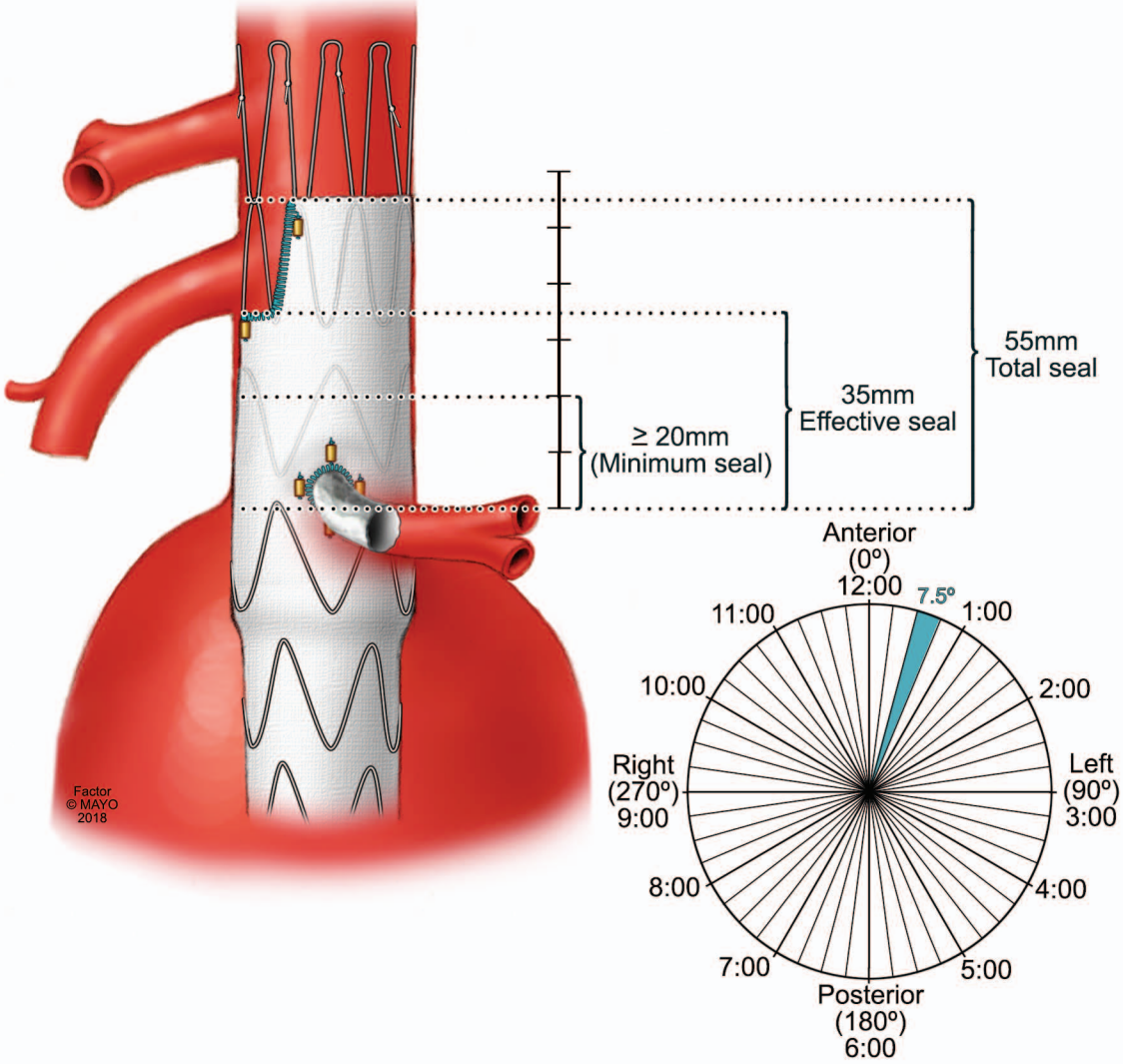
End-points	Definition
Target vessel technical success	Technical success for target vessel stenting is defined by successful catheterization and stent placement in all intended target vessels
Vessel patency	
Occlusion	Objective documentation by angiography, computed tomography or ultrasound of complete occlusion or minimal flow into a targeted vessel
Stenosis	Objective documentation by angiography, computed tomography or ultrasound of stenosis into a targeted vessel
Kink	Objective documentation by angiography, computed tomography or ultrasound of kink in the stented or native segmento of a targeted vessel
Primary patency	Uninterrupted patency with no occlusion or procedure performed to maintain patency on the stent or native target vessel. Interventions intended to treat endoleak or stent disconnection do not count as loss of primary patency
Primary assisted patency	Endovascular intervention performed to maintain patency in the presence of a stenosis before occlusion
Secondary patency	Endovascular restoration of patency after occlusion of the side branch, stent or stent-graft has already occurred. Conversion to bypass or inability to treat by endovascular means defines loss of secondary patency
Target vessel instability	Composite end-point used to define any death or rupture related to side branch complication (e.g. endoleak, rupture) or any secondary intervention indicated to treat a branch-related complication, including endoleak, disconnection, kink, stenosis, occlusion or rupture.
Intraprocedural complications	Any vessel perforation, dissection or occlusion during target vessel stenting

Table XVII. Proposed format for description of Table of clinical characteristics to describe demographics, cardiovascular risk factors, clinical presentation, labortatory and pertinent anatomical measurements. Adapted from Oderich and associates (J Vasc Surg 2017;

Variable	All	Pararenal	Type IV TAAA	Type I-III TAAA	P value
	n = 127	n = 47	n = 42	n = 38	
n= number of patients	*N and (Percent) or Mean ± Standard Deviation*				
Demographics					
Age (years old)	75 ± 10	76 ± 13	75 ± 7	73 ± 7	0.55
Age > 80 years old	30 (24)	18 (38)	10 (24)	7 (18)	0.16
Male gender	91 (72)	33 (70)	34 (81)	24 (63)	0.2
Cardiovascular risk factors					
Cigarette smoking	112 (88)	40 (85)	36 (86)	36 (95)	0.33
Hypertension	110 (87)	38 (81)	37 (88)	35 (92)	0.30
Hypercholesterolemia	103 (81)	37 (79)	35 (83)	31 (82)	0.85
Coronary Artery Disease	67 (53)	21 (45)	24 (57)	22 (58)	0.38
COPD	47 (37)	16 (34)	15 (36)	16 (42)	0.73
Myocardial Infarction	42 (33)	14 (30)	17 (40)	11 (29)	0.46
Peripheral arterial disease	37 (29)	9 (19)	14 (33)	14 (37)	0.16
CKD Stage III-V	22 (17)	6(13)	9(21)	7(18)	0.55
Stage III	17 (13)	4 (9)	8 (19)	5 (13)	
Stage IV	5 (4)	2 (4)	1 (2)	2 (5)	
Stage V	0	0	0	0	
Diabetes Mellitus	20 (16)	7 (15)	10 (24)	3 (8)	0.15
Congestive Heart Failure	15 (12)	3 (6)	9 (21)	3 (8)	0.06
Arrhythmia	12 (9)	3 (6)	7 (17)	2 (5)	0.15
Stroke/TIA	12 (9)	4 (9)	3 (7)	5 (13)	0.63
Other medical history					
Prior laparotomy	55 (43)	16 (34)	19 (45)	20 (53)	0.22
Prior aortic repair	38 (30)	7 (15)	10 (24)	21 (55)	<0.001
History of malignancy	28 (22)	13 (28)	7 (17)	8 (21)	0.45
Family history of aortic aneurysm	19 (15)	7 (15)	5 (12)	7 (18)	0.97
Preoperative evaluation					
Positive Cardiac Stress Test	24 (20)	10 (21)	10 (26)	4 (11)	0.33
Ejection fraction (%)	58 ± 11	59 ± 12	55 ± 11	60 ± 10	0.1
Serum Creatinine (mg/dl)	1.2 ± 0.7	1.2 ± 0.3	1.2 ± 0.3	1.3 ± 1.2	0.56
eGFR (mL/min/1.73 m^2)	62 ± 20	61 ± 19	62 ± 20	63 ± 21	0.91
Body Mass Index (kg/m^2)	28 ± 5	29 ± 5	29 ± 6	26 ± 4	0.07

Risk assessment and comorbidity scores					
ASA classification					0.34
Class I	20 (16)	10 (21)	6 (14)	4 (11)	
Class II	83 (65)	31 (66)	26 (62)	26 (68)	
Class III	22 (17)	6 (13)	8 (19)	8 (21)	
Class IV	2 (2)	0	2 (5)	0	
Class V	0	0	0	0	
SVS Total Score (0-30)	12 ± 4	12 ± 4	13 ± 4	12 ± 3	0.09
Cardiac Score	13 ± 7	12 ± 7	15 ± 7	12 ± 7	0.025
Pulmonary Score	14 ± 10	15 ± 10	13 ± 10	13 ±8	0.79
Renal Score	3 ± 6	3 ± 4	4 ± 7	3 ± 7	0.63
Hypertension Score	17 ± 10	17 ± 10	18 ± 10	16 ± 9	0.63
Age Score	21 ± 7	23 ± 7	20 ± 7	19 ± 7	0.038
Anatomical measurements(mm)					
Max aortic diameter	59.0 ± 17	55.8 ± 19.2	59.7 ± 15.4	62.2 ± 15.3	0.3
Max R CIA diameter	15.4 ± 6.4	15.1 ± 4.0	17.2 ± 9.4	14.0 ± 4.5	0.1
Max L CIA diameter	15.6 ± 7.2	15.2 ± 5.5	17.8 ± 9.7	13.8 ± 5.3	0.044
Celiac artery diameter	7.6 ± 1.4	7.4 ± 1.1	7.5 ± 1.3	7.9 ± 1.7	0.25
SMA diameter	7.5 ± 1.0	7.2 ± 0.9	7.6 ± 0.9	7.6 ± 1.3	0.09
R renal diameter	5.5 ± 1.0	5.6 ± 0.8	5.6 ± 1.1	5.2 ± 1.1	0.16
L renal diameter	5.8 ± 0.8	5.7 ± 0.8	5.9 ± 0.7	5.6 ± 0.8	0.2
Target vessel incorporation					
total target vessels	**n = 496**	**n = 181**	**n = 165**	**n = 150**	
Fenestrations	352 (71)	160 (88)	143 (87)	49 (33)	<0.001
Directional branches	125 (25)	2 (1)	22 (13))	101 (67)	<0.001
Doublewide Scallops	19 (4)	19 (11)	0	0	<0.001
Total celiac axis	123 (25)	45 (25)	42 (25)	36 (24)	0.96
Doublewide scallop	19 (4)	19 (10)	0	0	<0.001
Large fenestration	63 (13)	25 (14)	34 (21)	4 (3)	<0.001
Directional branch	41 (8)	1 (1)	8 (5)	32 (21)	<0.001
Total SMA	126 (25)	46 (25)	42 (25)	38 (25)	1
Large fenestration	86 (17)	45 (25)	35 (21)	6 (4)	<0.001
Directional branch	40 (8)	1 (1)	7 (4)	32 (21)	<0.001
Total R renal artery	120 (24)	45 (25)	38 (23)	37 (25)	0.91
Small fenestration	98 (20)	45 (25)	35 (21)	18 (12)	0.01
Directional branch	22 (4)	0	3 (2)	19 (13)	<0.001
Total L renal artery	120 (24)	44 (24)	40 (24)	36 (24)	1
Small fenestration	101 (20)	44 (24)	36 (22)	21 (14)	0.06
Directional branch	19 (4)	0	4 (2)	15 (10)	<0.001
Other vessels	7 (1)	1 (1)	3 (2)	3 (2)	0.47
Small fenestration	4 (1)	1 (1)	3 (2)	0	0.18
Directional branch	3 (1)	0	0	3 (2)	0.03
Other	**n=127**	**n=47**	**n=42**	**n=38**	

Vessels per patient	3.9± 0.5	3.9±0.6	3.9±0.7	3.9±0.4	0.68
≥4 target vessels	111 (89)	39 (83)	38 (90)	34 (89)	0.51
Access scallops	61 (48)	26 (55)	32 (76)	3 (8)	<0.001
Pre-loaded catheters	79 (62)	27 (57)	34 (81)	18 (47)	0.006
Vessels aligned by stents	**n = 470**	**n = 161**	**n = 162**	**n = 147**	
Celiac axis	104 (22)	26 (16)	42 (26)	36 (24)	0.08
Fluency stent-graft	21 (5)	0	2 (1)	19 (13)	<0.001
Viabahn stent-graft	9 (2)	1 (1)	1 (1)	7 (5)	.01
iCAST stent	69 (15)	25 (16)	36 (22)	8 (5)	<0.001
Other	5 (1)	0	3 (2)	2 (1)	0.25
SMA	126 (27)	46 (29)	42 (26)	38 (26)	0.82
Fluency stent-graft	28 (6)	0	5 (3)	23 (16)	<0.001
Viabahn stent-graft	6 (1)	1 (1)	0	5 (3)	0.02
iCAST stent	89 (19)	45 (28)	36 (22)	8 (5)	<0.001
Other	3 (1)	0	1 (1)	2 (1)	0.33
R renal artery	120 926)	45 (28)	38 (23)	37 (25)	0.65
iCAST stent	104 (22)	45 (28)	37 (23)	22 (15)	0.02
Viabahn stent-graft	16 (3)	0	1 (1)	15 (10)	<0.001
L renal artery	120 (26)	44 (27)	40 (25)	36 (24)	0.81
iCAST stent	104 (22)	44 (27)	36 (22)	24 (16)	0.07
Viabahn stent-graft	16 (3)	0	4 (2)	12 (8)	<0.001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Total seal
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Effective seal
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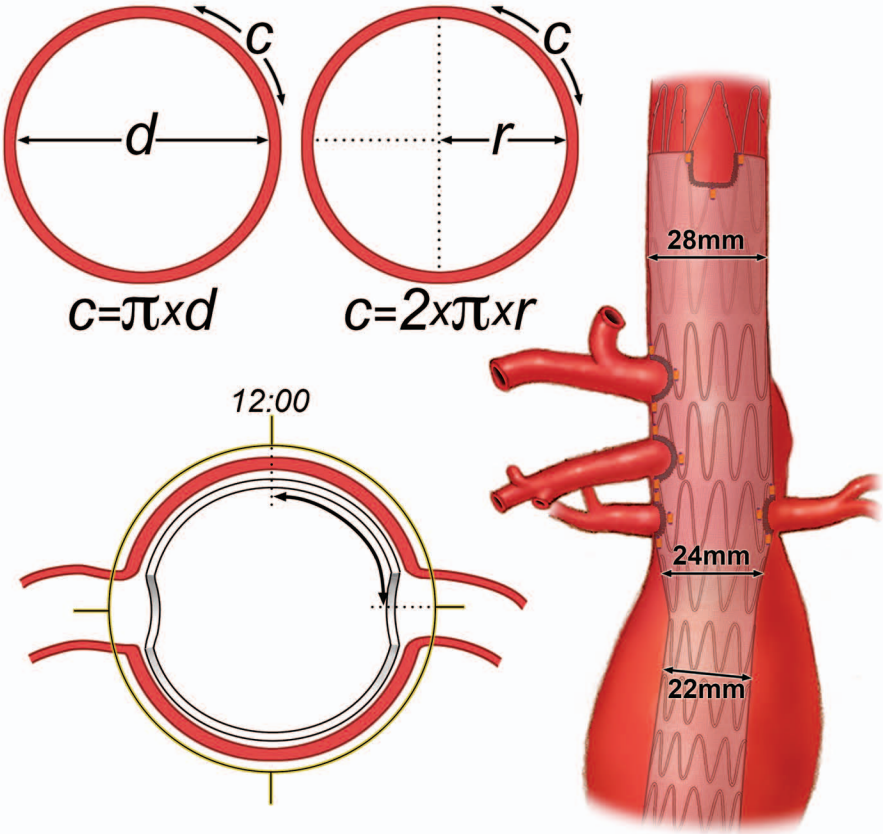
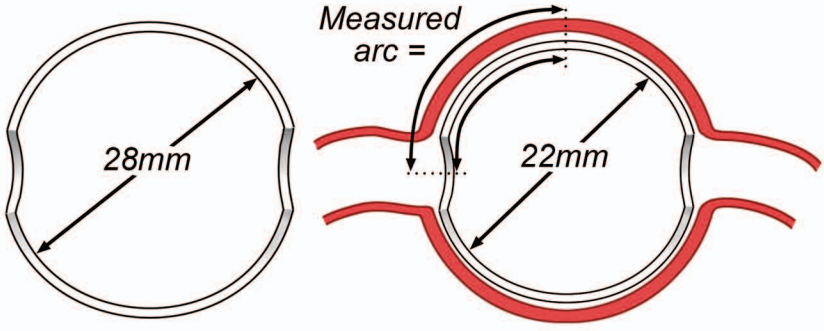
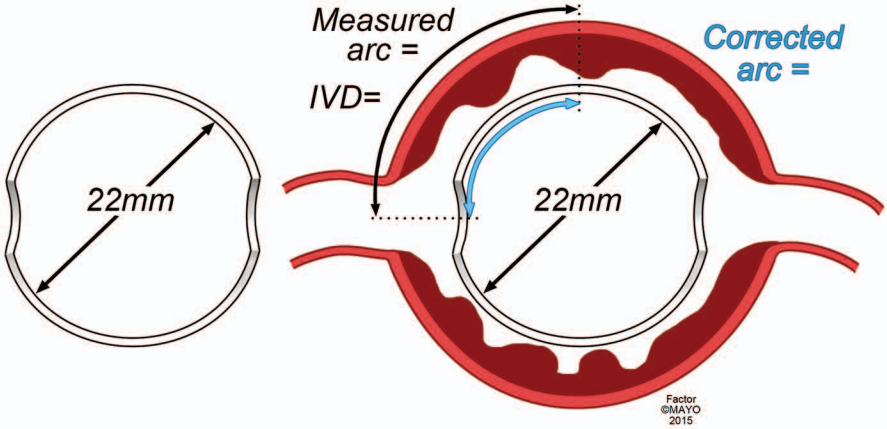
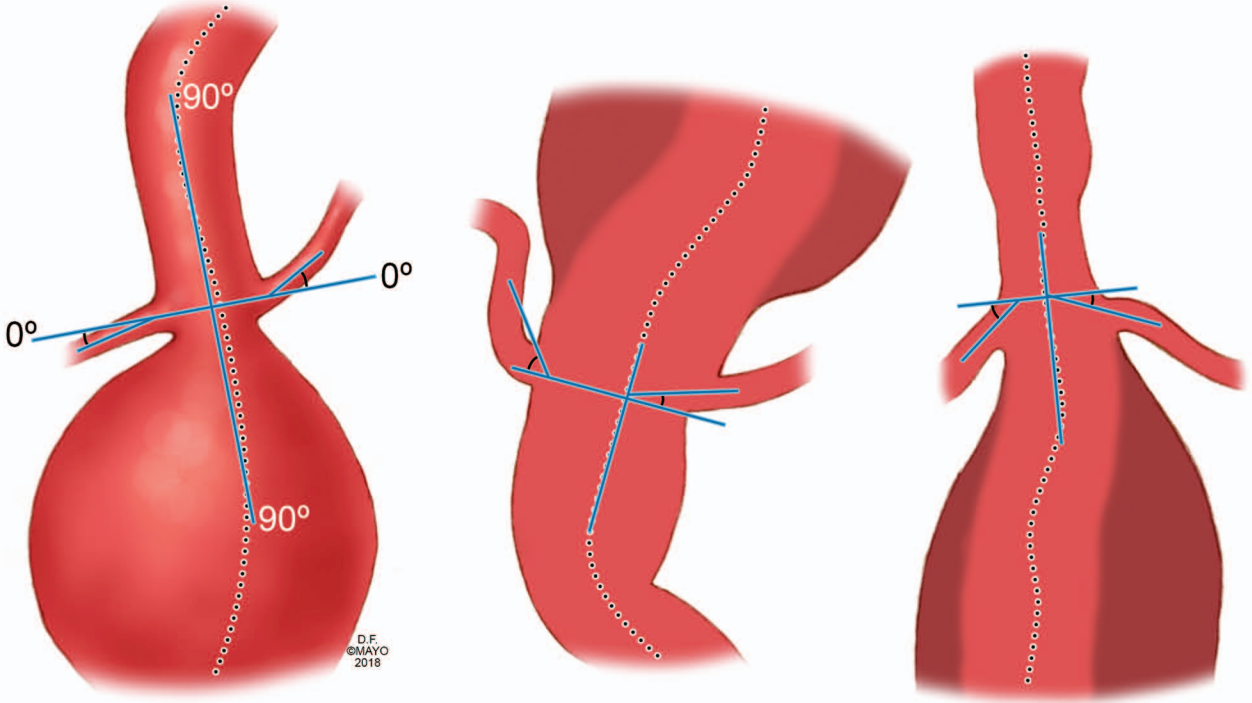


GRAFT LARGER THAN AORTA



AORTA LARGER THAN GRAFT

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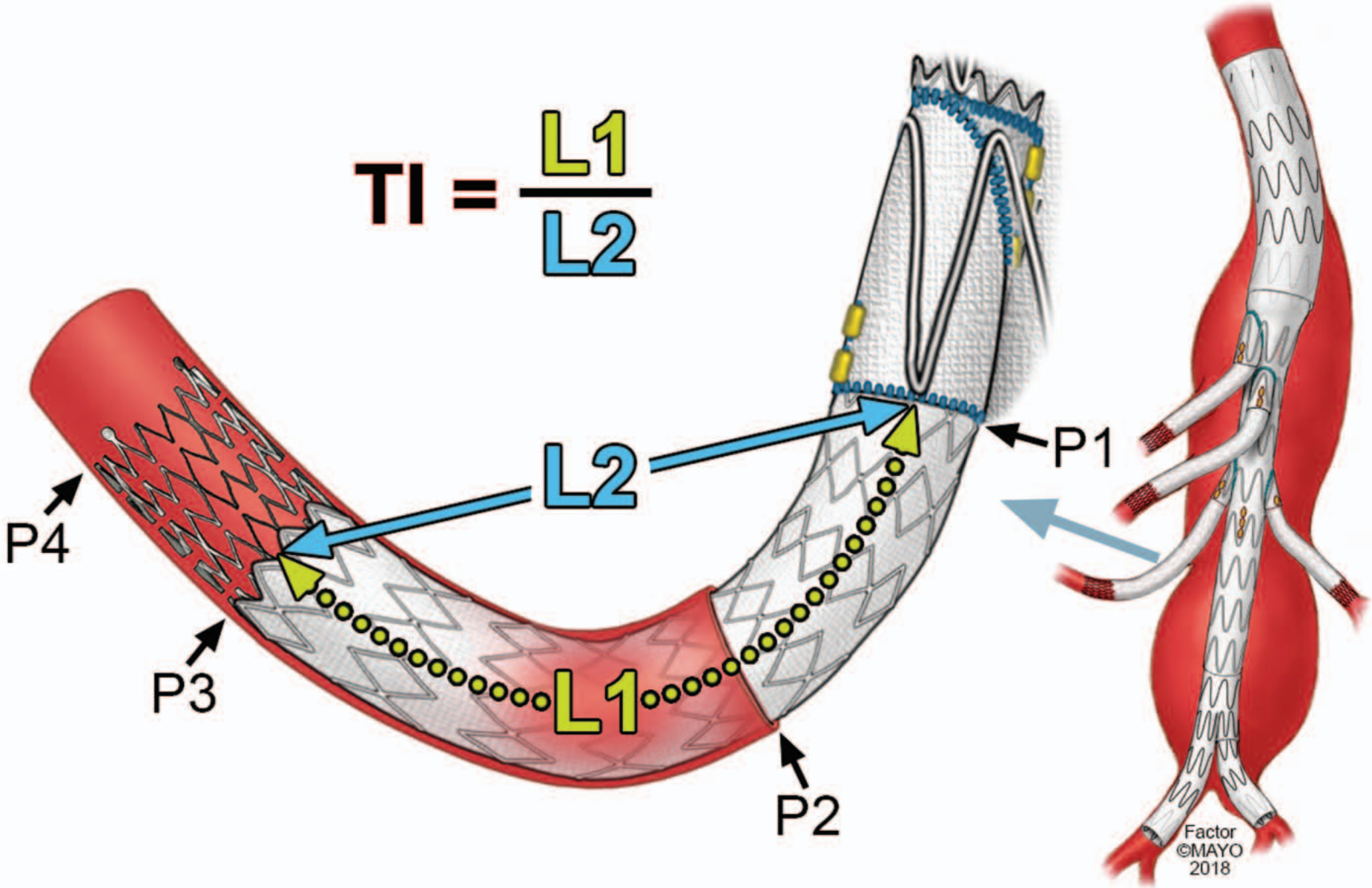
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L1
P1
P2
P3
P4
Factor
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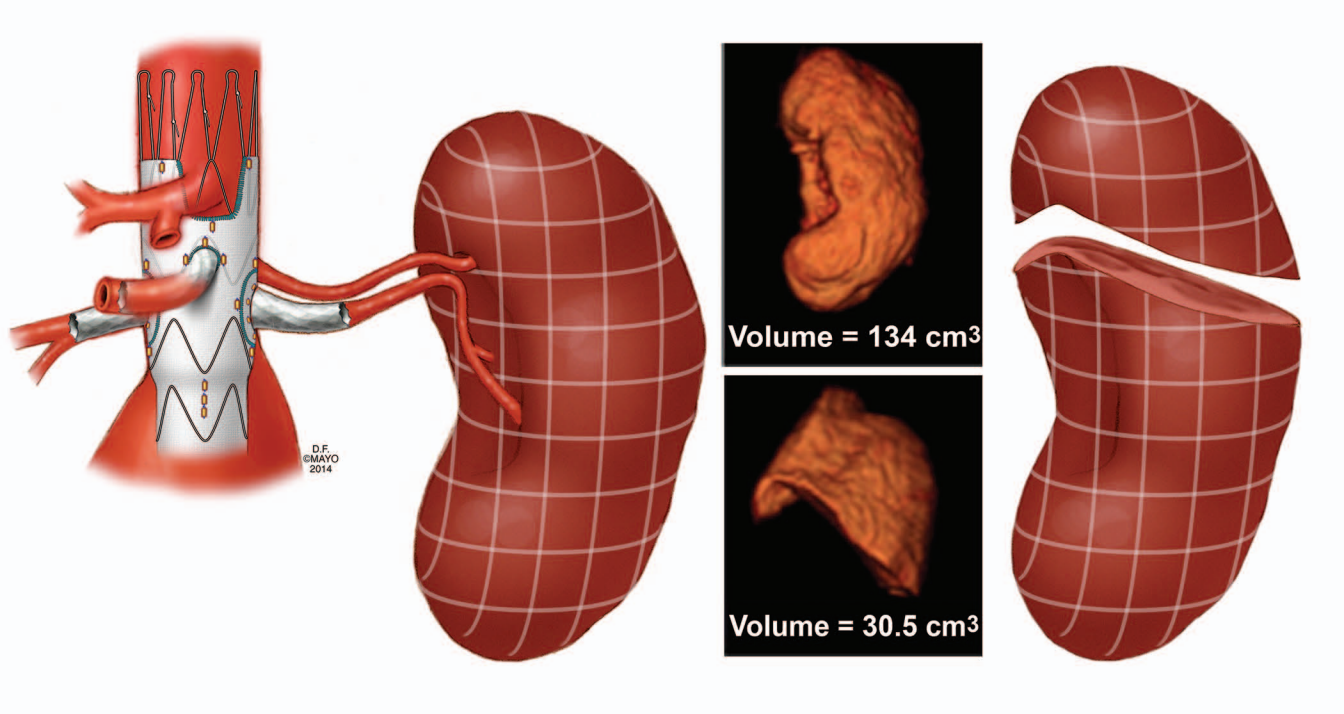
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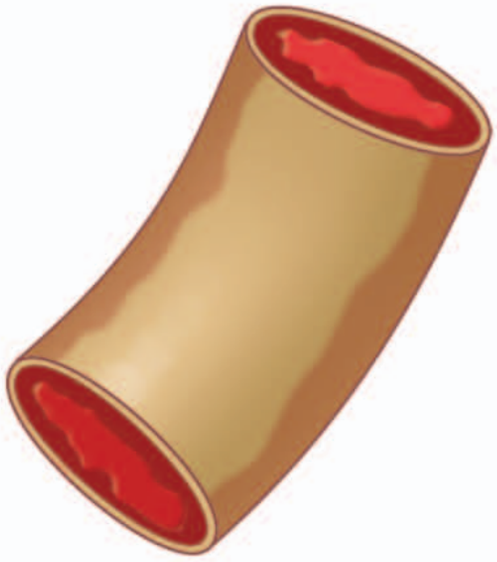
Volume = 134 cm3
Volume = 30.5 cm3

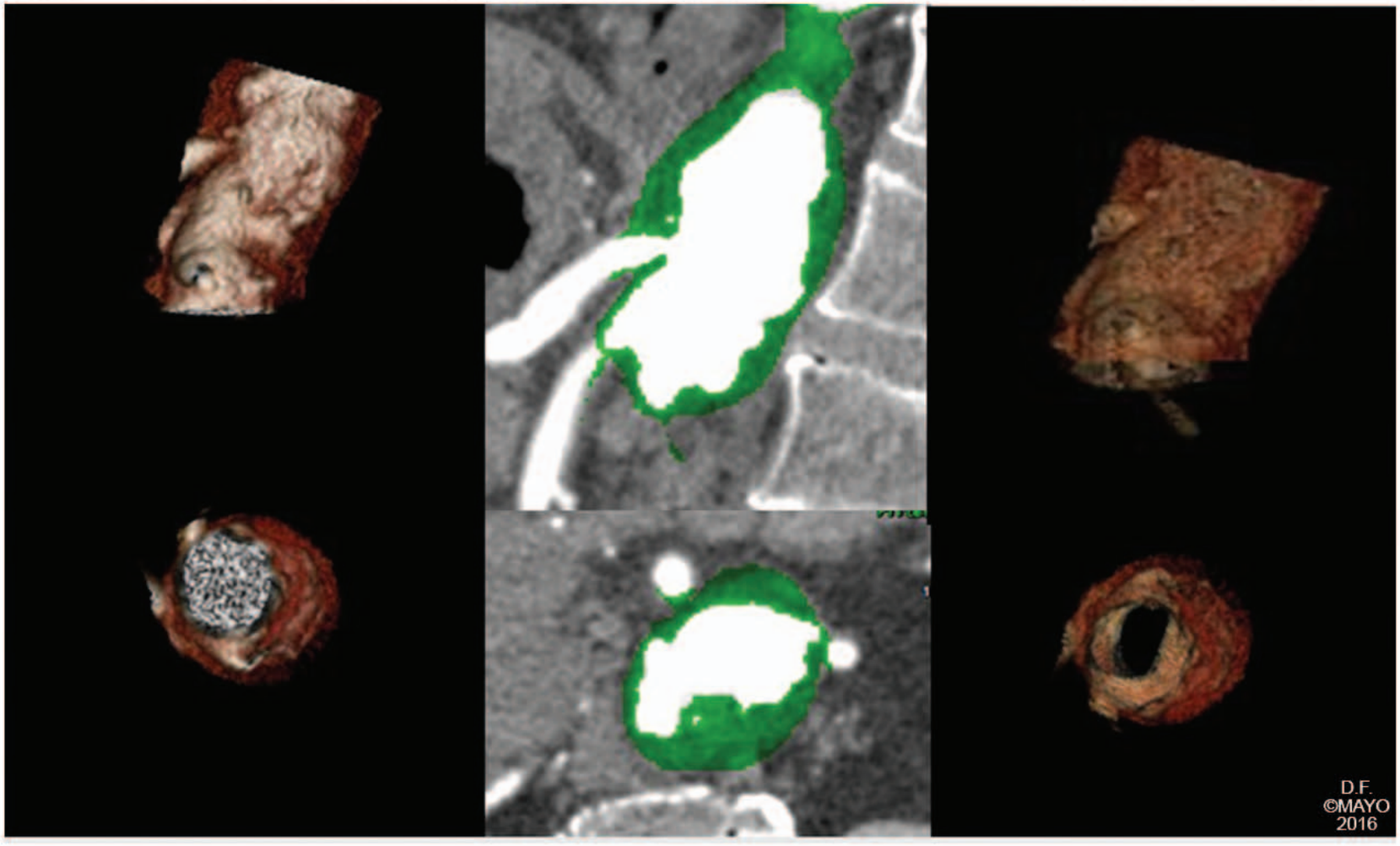
VOLUMETRIC ANALYSIS



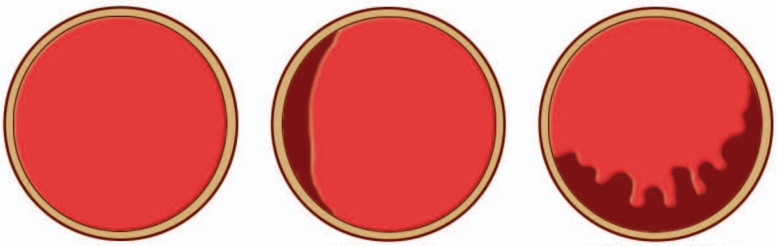
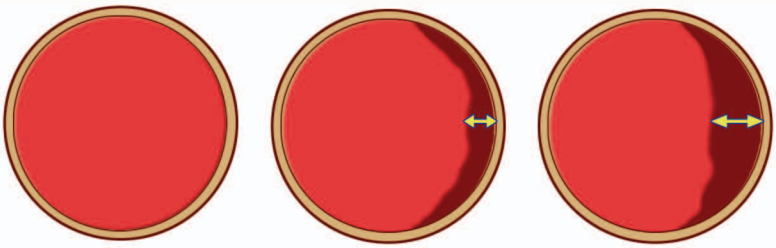
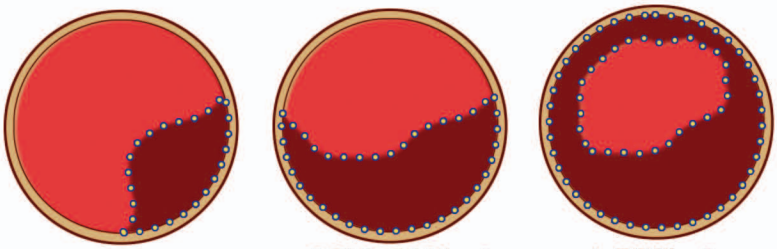
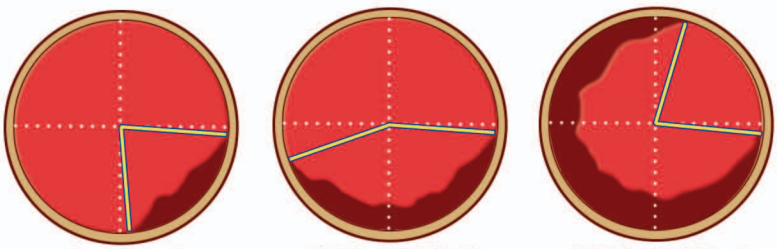
STEP 1
Measurement of total aortic volume
(Wall+Thrombus+Lumen)

STEP 2
Subtraction of the luminal volume

STEP 3
Residual volume of aortic wall and thrombus
(AWT volume)



QUALITATIVE ANALYSIS

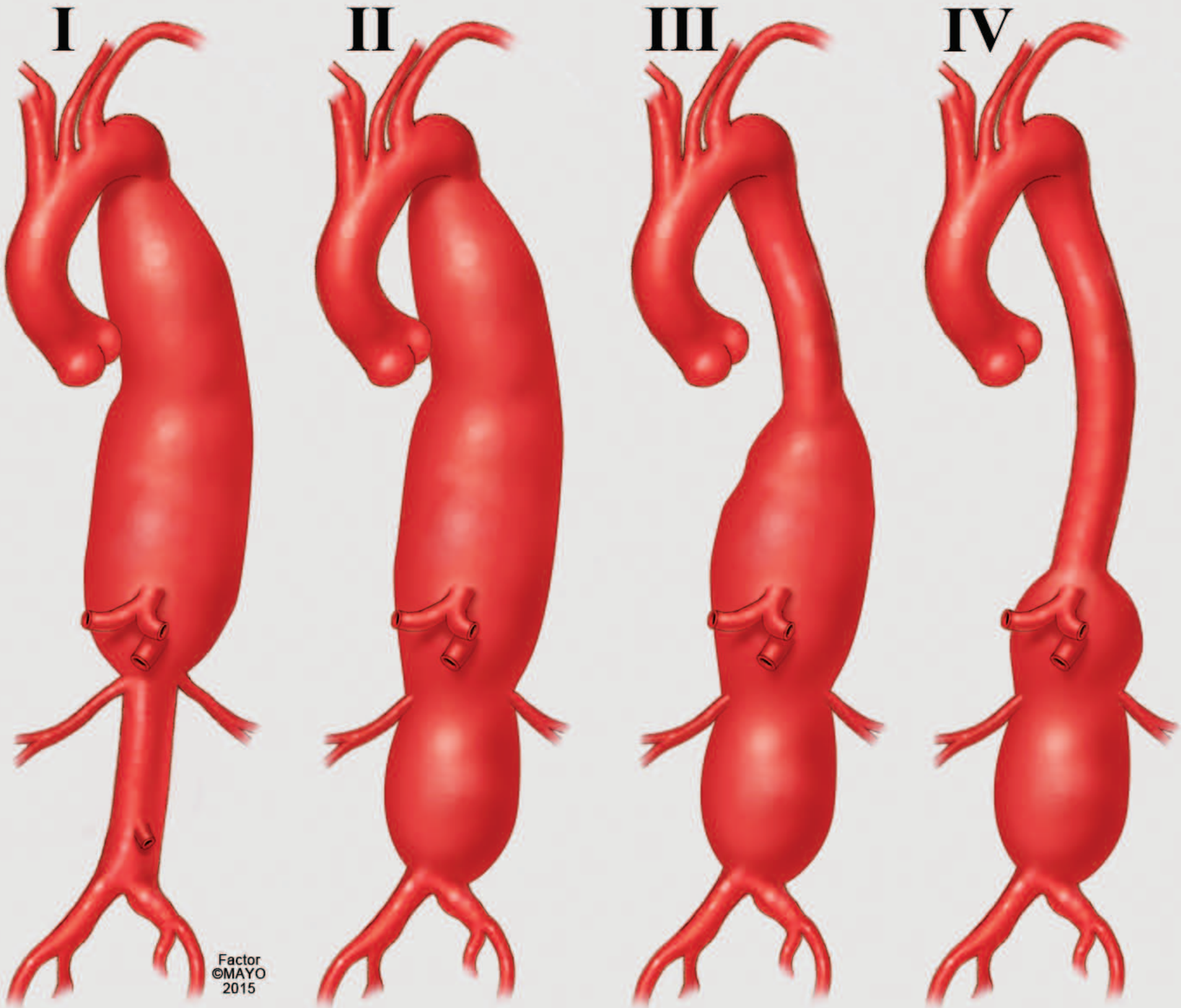
SEGMENTS (A,B, & C)	 None=0	1 segment=1	2-3 segments=2	2
THROMBUS TYPE	 None=0	Smooth lining=1	Finger-like projections=2	2
THICKNESS	 None=0	1-4mm=1	≥5mm=2	2
AREA	 0-24%=0	25%-50%=1	≥50%=2	2
CIRCUMFERENCE	 0-90º=0	91º-179º=1	180º-360º=2	2
				Total 0-10

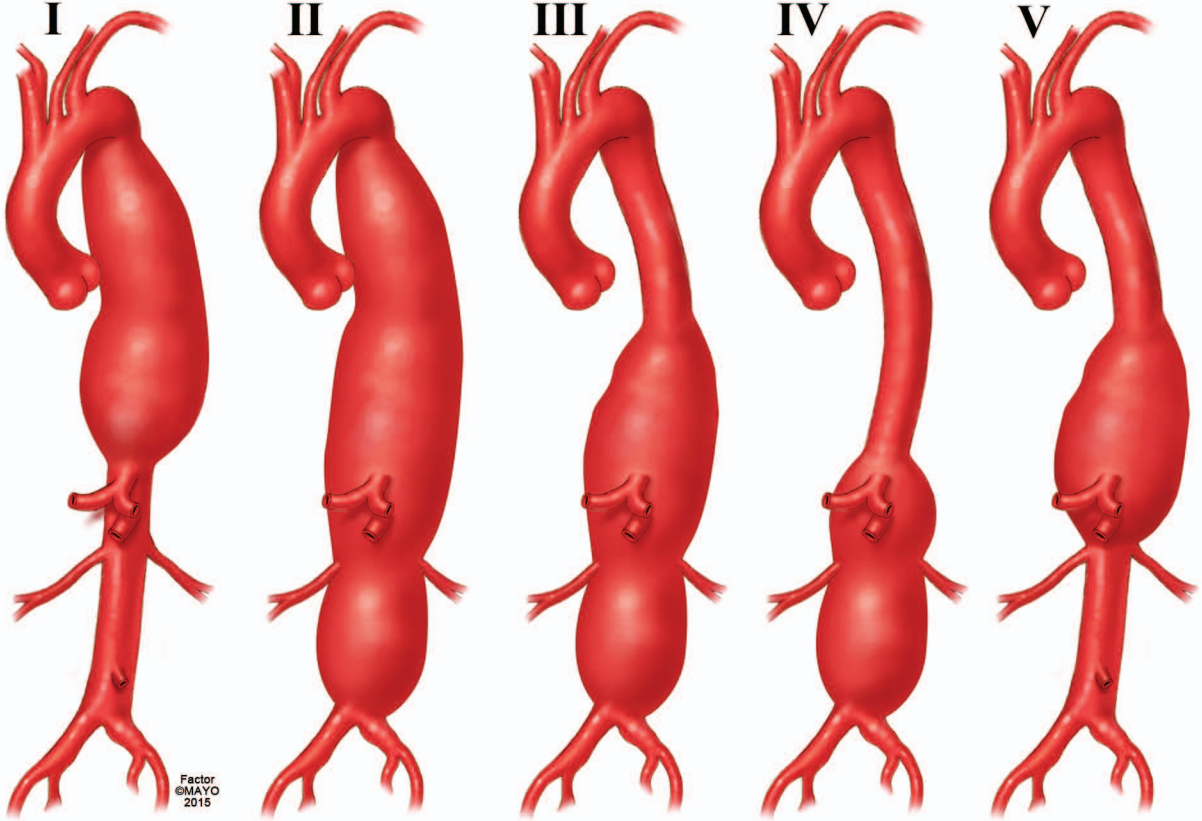
Factor ©MAYO 2016

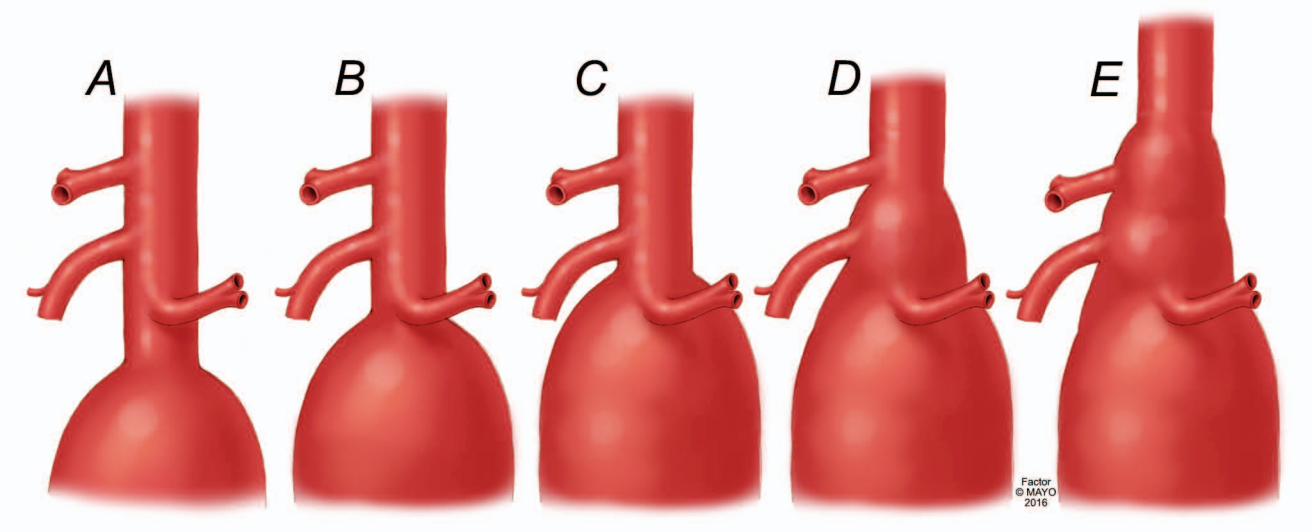
MILD 0-3

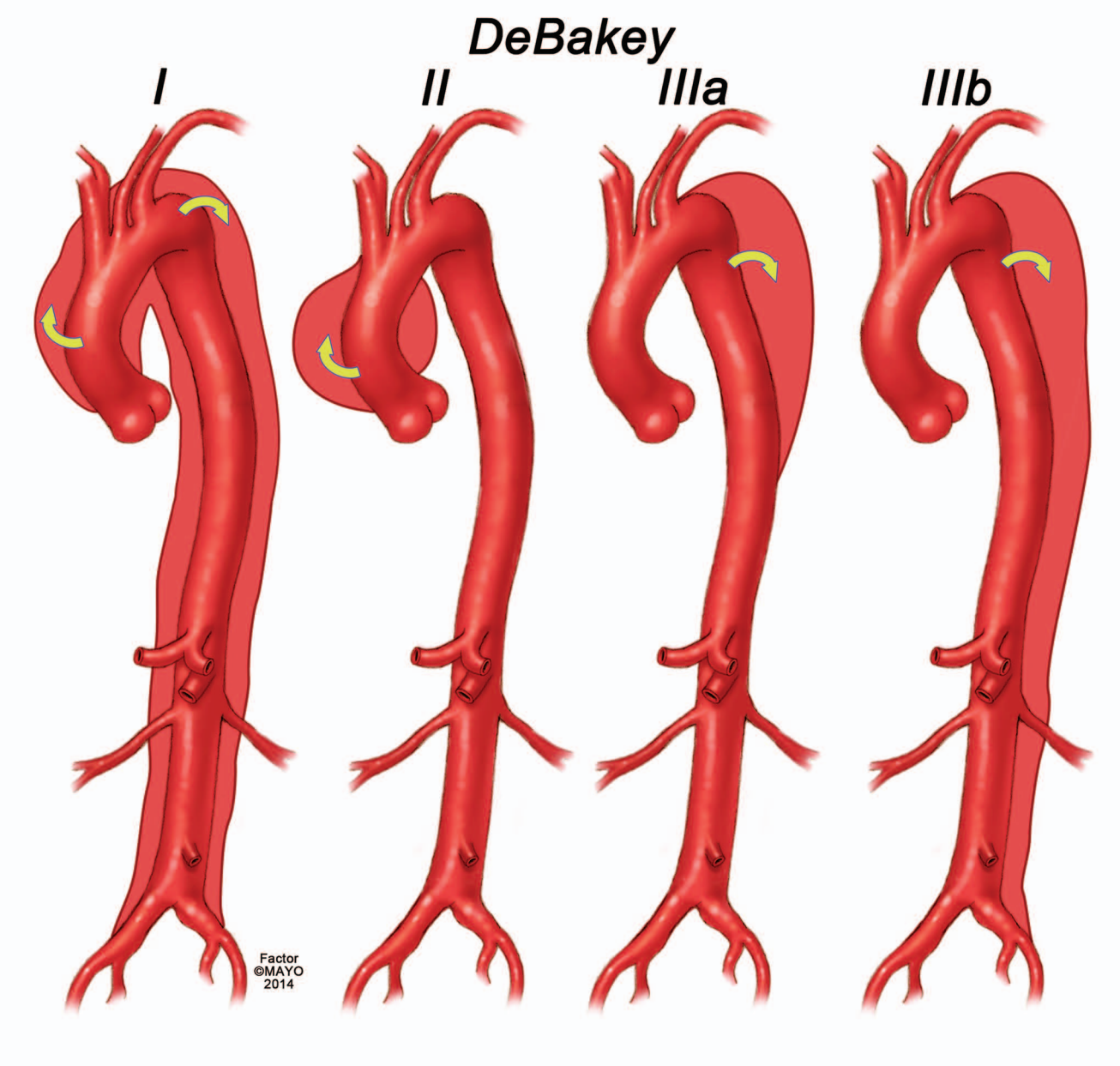
MODERATE 4-8

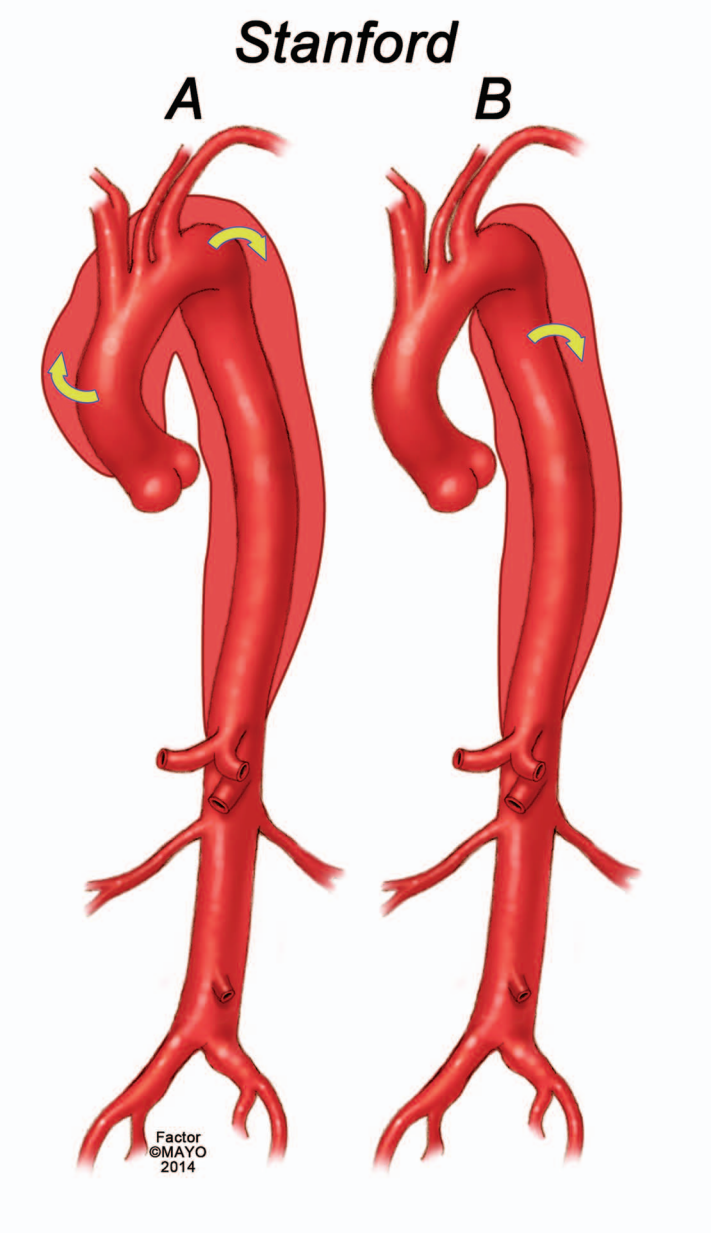
SEVERE 9-10

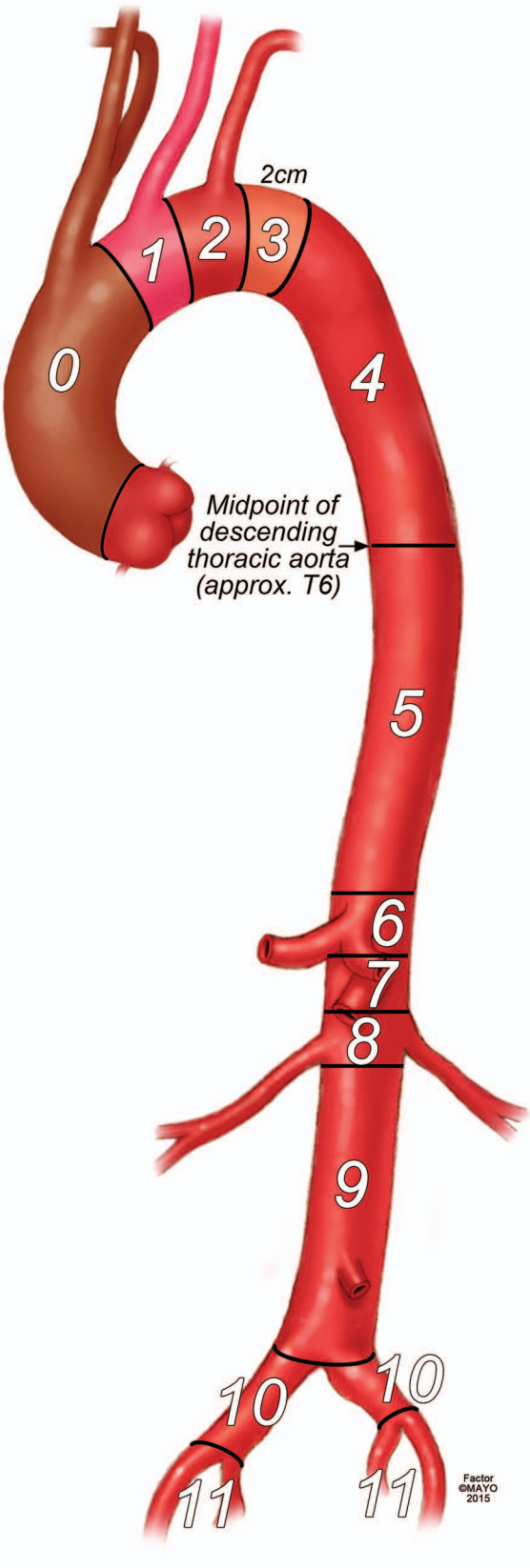

I
II
III
IV
Factor
©MAYO
2015

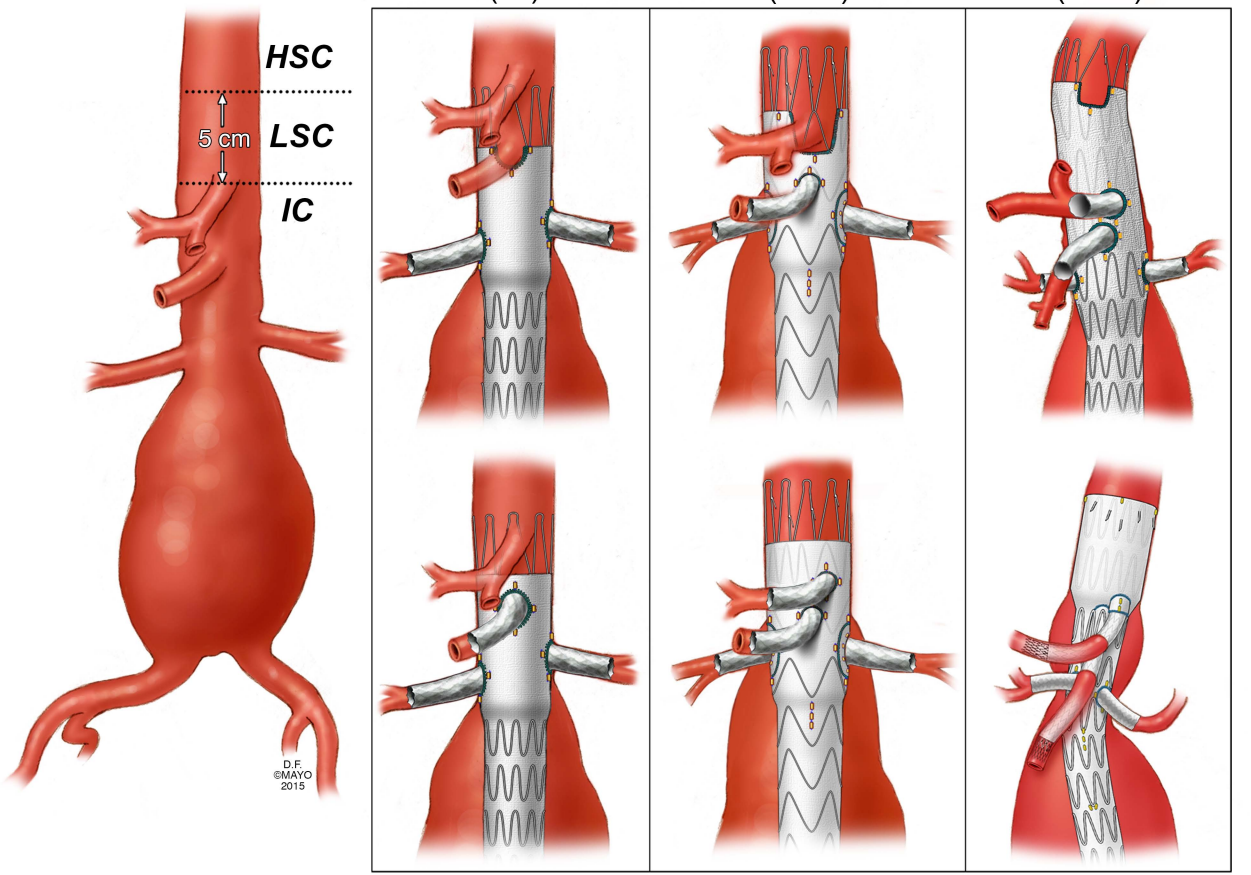

I
II
III
IV
V
Factor
©MAYO
2015

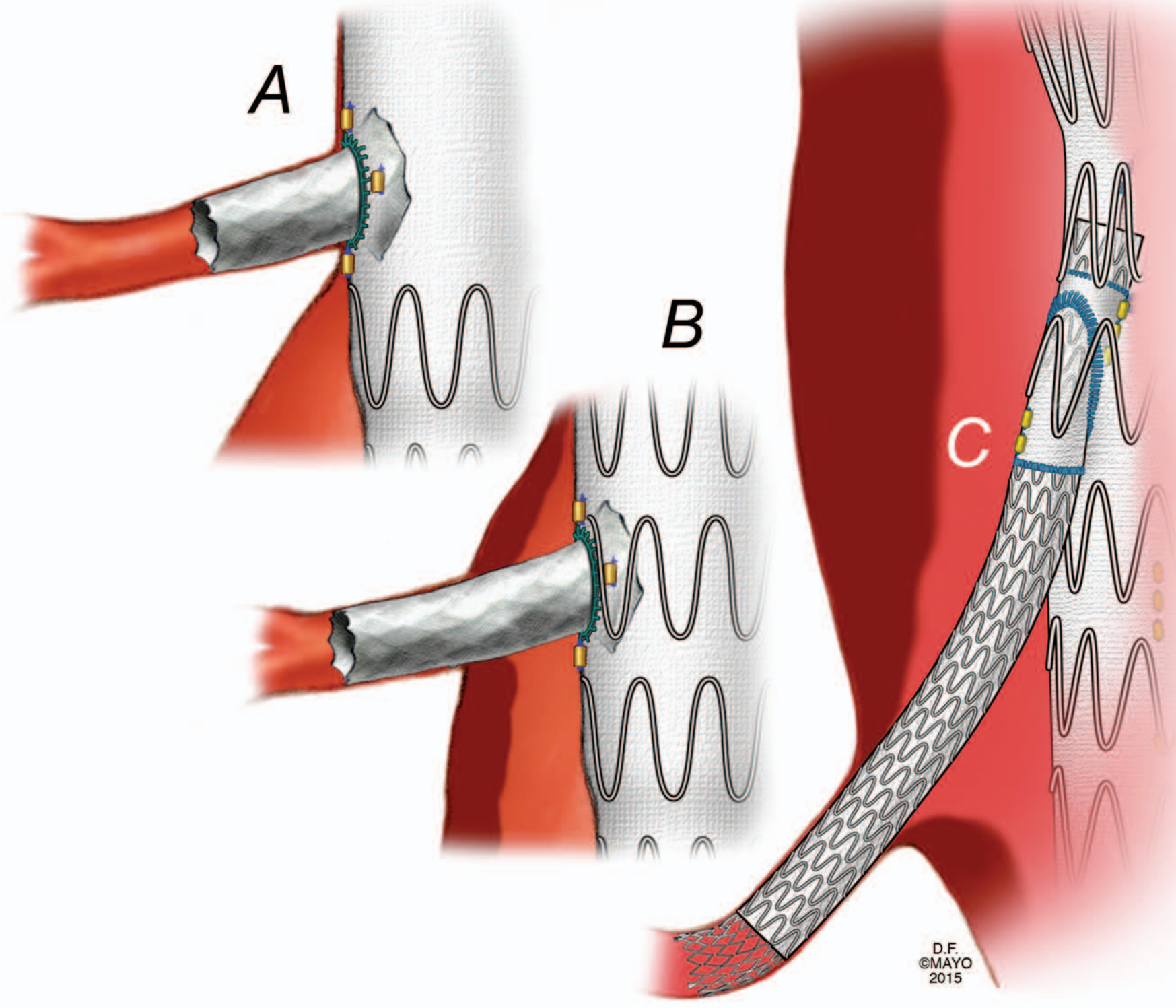

A
B
C
D
E
Factor
© MAYO
2016

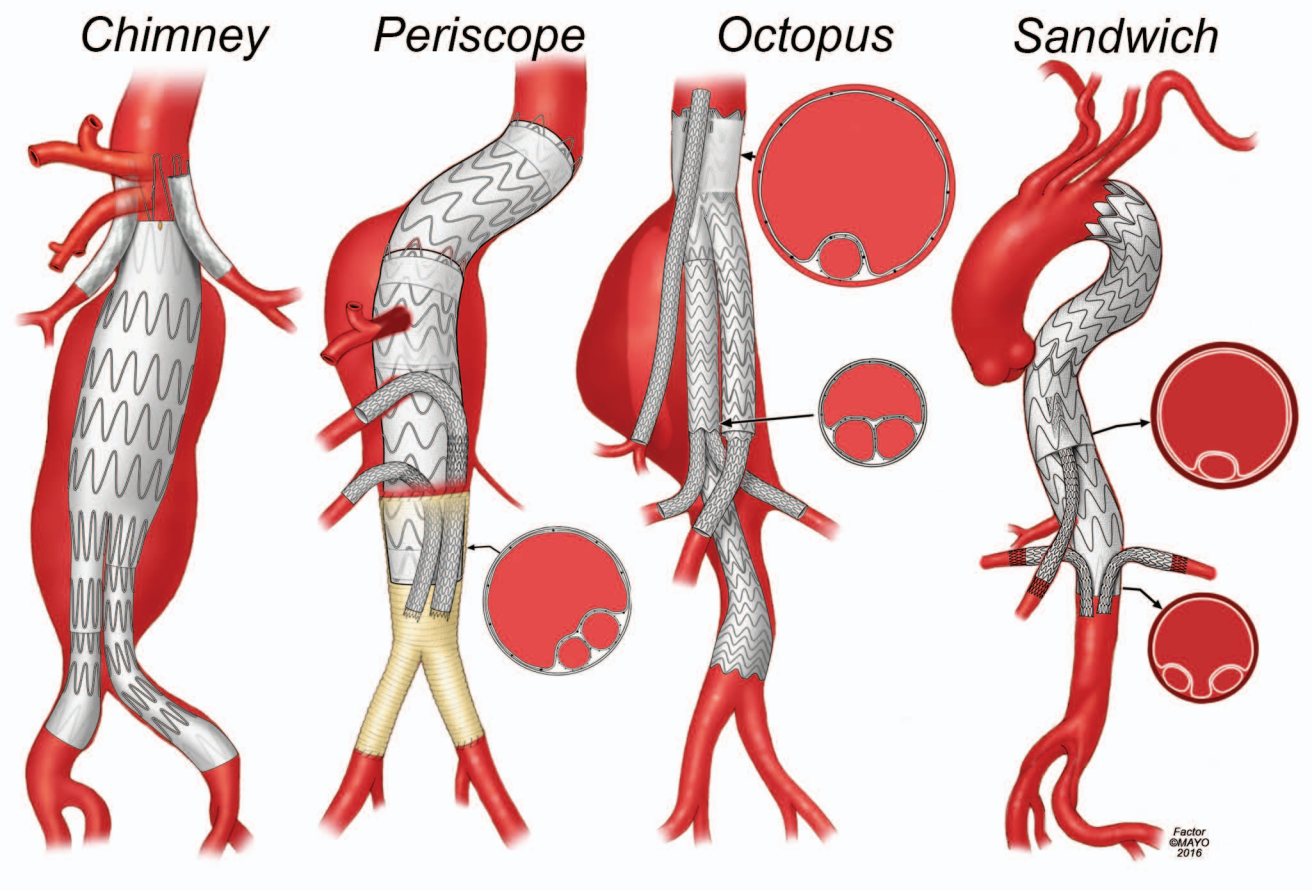

DeBakey
I
II
IIIa
IIIb
Factor
©MAYO
2014

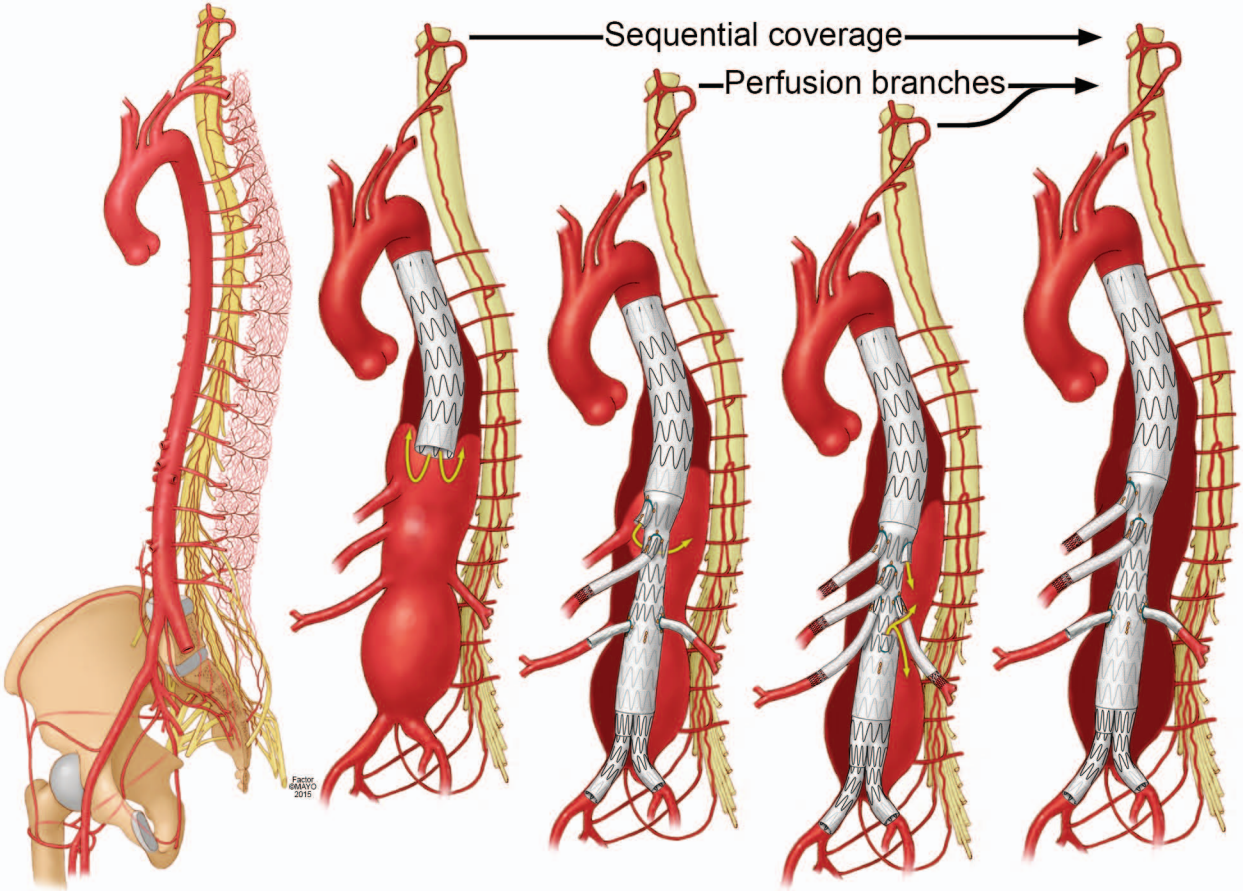

Stanford
A
B
Factor
©MAYO
2014

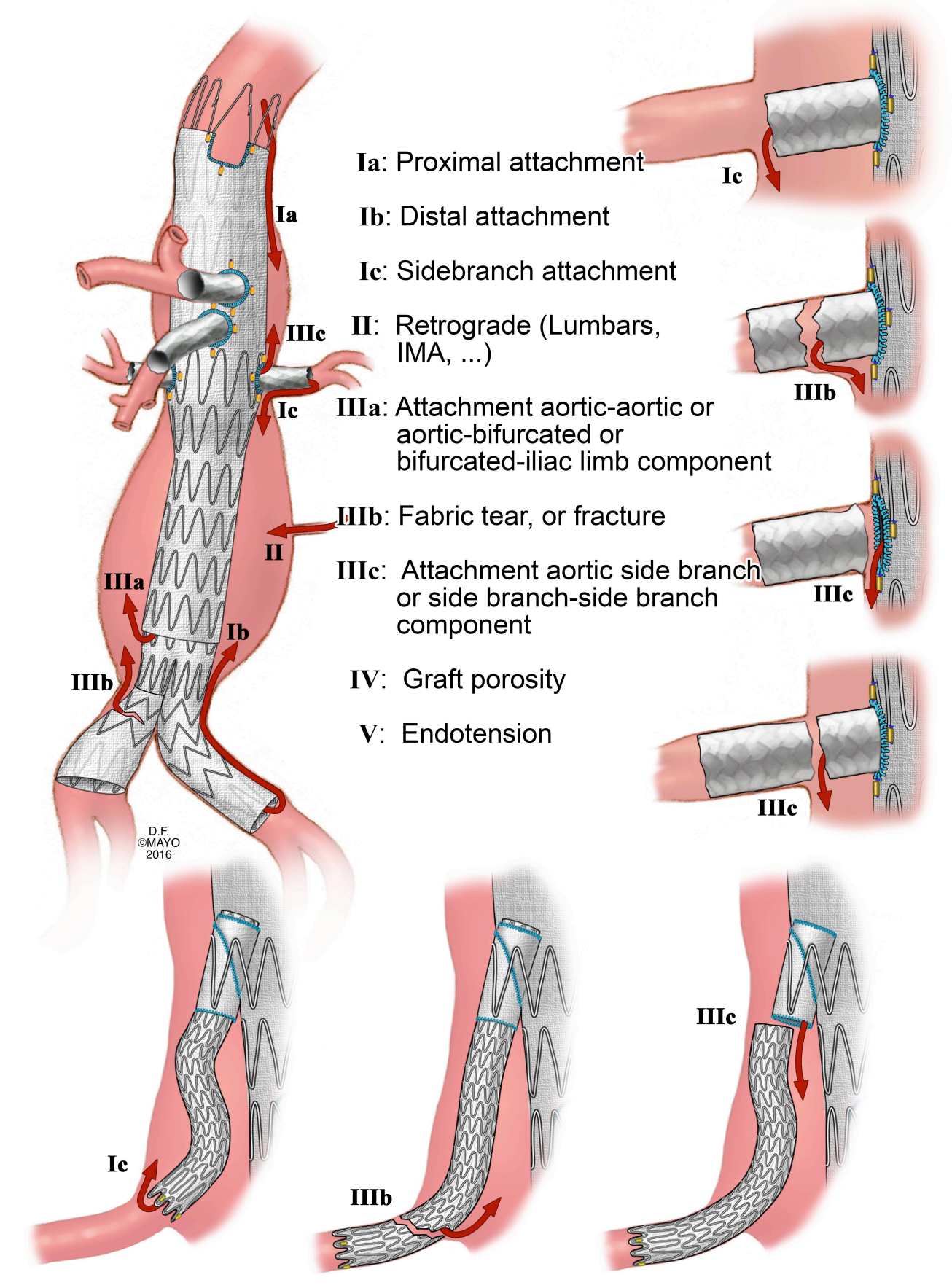

2cm
0
1
2
3
4
Midpoint of
descending
thoracic aorta
(approx. T6)
5
6
7
8
9
10
10
11
11
Factor
©MAYO
2015

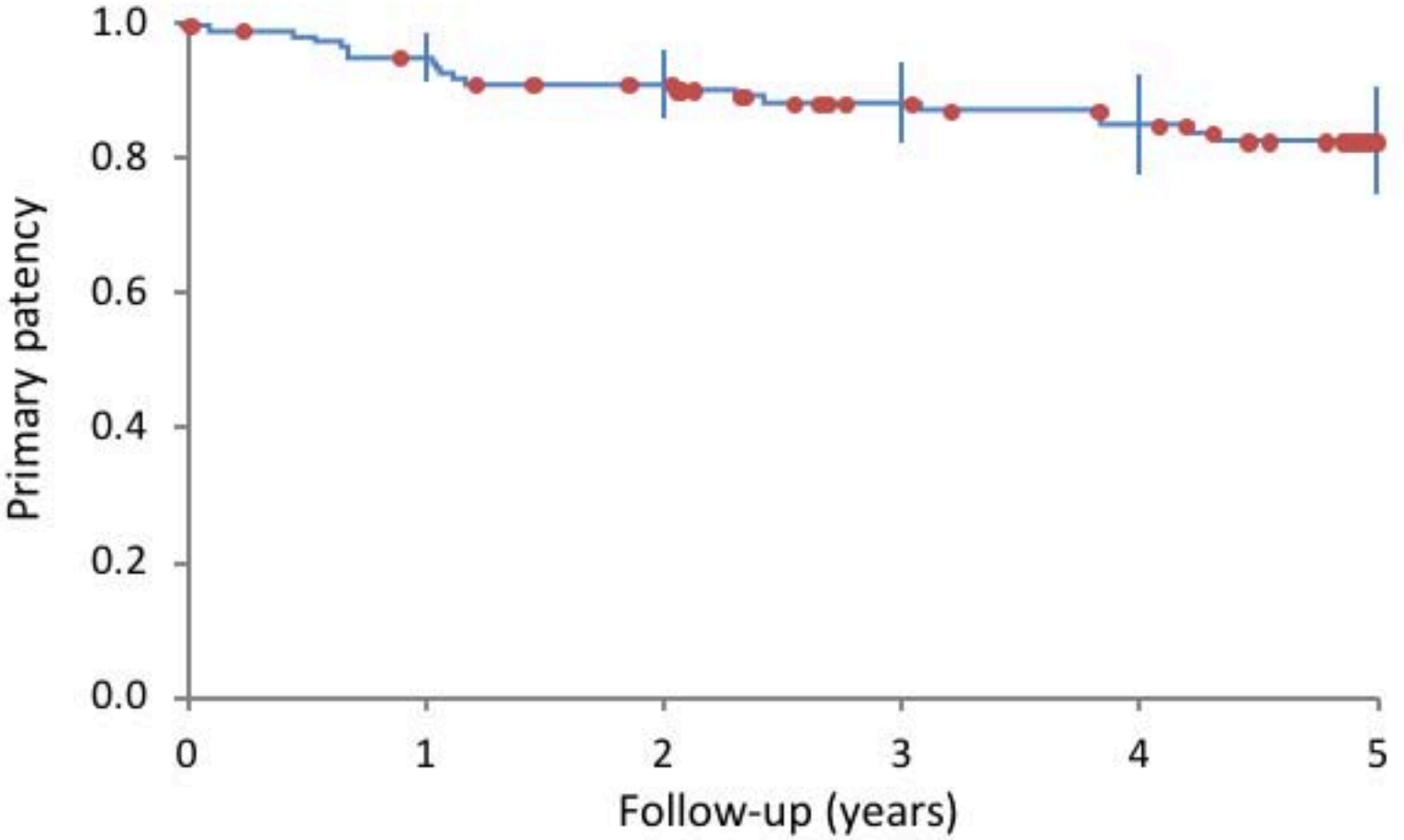

Infra-celiac
(IC)
Low
Supra-celiac
(LSC)
High
Supra-celiac
(HSC)
HSC
5 cm
LSC
IC
D.F.
©MAYO
2015


A
B
C
D.F.
©MAYO
2015


Chimney
Periscope
Octopus
Sandwich
Factor
©MAYO
2016


Sequential coverage
Perfusion branches
Factor
©MAYO
2015


Ia
IIIc
Ic
II
IIIa
Ib
IIIb
D.F.
©MAYO
2016
Ia: Proximal attachment
Ib: Distal attachment
Ic: Sidebranch attachment
II: Retrograde (Lumbars, IMA, ...)
IIIa: Attachment aortic-aortic or aortic-bifurcated or bifurcated-iliac limb component
IIIb: Fabric tear, or fracture
IIIc: Attachment aortic side branch or side branch-side branch component
IV: Graft porosity
V: Endotension
Ic
IIIb
IIIc
IIIb
IIIc
IIIc



Parameter						
Number at risk	129	117	106	85	76	49
Cumulative events	0	6	11	14	17	19
Cumulative censored	0	6	12	30	36	61
Kaplan-Meier estimate	1.000	0.952	0.911	0.884	0.851	0.827
Standard error	0.000	0.019	0.026	0.031	0.037	0.041