SOCIETY FOR VASCULAR SURGERY® DOCUMENT

Reporting standards for thoracic endovascular aortic repair (TEVAR)

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INTRODUCTION

Reporting standards for studies involving endovascular repair of infrarenal abdominal aortic aneurysms were introduced by the Society for Vascular Surgery in 1997 and revised in 2002.[1-3] Although the 2002 standards addressed endovascular aortic aneurysm repair in a more general sense, they did not focus on thoracic endografts. With the development of endovascular grafts to treat thoracic aortic pathology, there is a need for reporting standards specific to this procedure. Many of concepts and definitions of success are extrapolated from the prior publications regarding standards for endovascular abdominal aortic aneurysm repair (EVAR). Nonetheless, thoracic endovascular aortic repair (TEVAR) incorporates some unique aspects, ranging from specific anatomic issues to the differing etiologies of diseases affecting the thoracic aorta, such as dissection, traumatic injury, penetrating ulcer, and pseudoaneurysm. The framework for TEVAR reporting will be addressed in this article. The reporting standards for aortic dissection are particularly complex and will be addressed in more detail in a separate publication.

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CLASSIFICATION CRITERIA FOR THORACIC AORTIC PATHOLOGY

Classification of thoracic aortic pathology is recommended with respect to a combination of factors, including (1) site, (2) etiology, and (3) clinicopathologic manifestations. In any one specific report, the selection of only one of these factors as the basis for classification may be appropriate.

Anatomic classification. All reports should classify aortic aneurysms on the basis of site and extent of disease (Table I). Classification may require inclusion of multiple sites, as listed in the table. Notably, the classic definitions of type I to IV thoracoabdominal aortic aneurysm by Crawford are not consistently interpreted in the literature, partly because the illustrations from the original articles show the worst case of the type IV variant.[4-9] Reports involving thoracoabdominal aortic pathology need to use a clear definition, including the number of branch vessels treated (if any). Other pathology, such as dissection, *penetrating aortic ulcer*, and *intramural aortic hematoma*, should also be reported on the basis of site and extent, but penetrating aortic ulcer and intramural aortic hematoma require additional information with regard to depth of the ulceration, thickness of the associated hematoma, and the presence or absence of symptoms.

One challenging issue with thoracic aortic pathology is the ability to differentiate penetrating aortic ulcer, intramural aortic hematoma, dissection, and aneurysm. Clinical differentiation is further complicated because the diagnosis is time-dependent as one type of pathology can evolve into others. Reports should attempt to classify the aortic pathology based on the primary process and avoid reports that group multiple pathologic types without distinction of etiologies and outcomes. Once a patient's pathology has been classified for data collection, it should not appear in another manuscript under a different classification to avoid problems with meta-analysis.

In all pathologic entities, the diameter of the aorta is of interest and should be recorded in a standard fashion. Given the inherent tortuosity of the thoracic aorta after pathologic changes have occurred, diameter assessments

Table I. Classification of aortic aneurysms by anatomic site

Ascending thoracic
Arch
Descending thoracic
Thoracoabdominal (Crawford types I to IV)[4]
• Type I: begins in the proximal half of the descending thoracic aorta (equivalent to "above T6 disc space"), involves the remainder of the descending thoracic aorta and transcends the diaphragmatic boundary, involving the upper abdominal aorta without extending below the renal arteries.
• Type II: begins in the proximal half of the descending thoracic aorta ("above T6 disc space"), involves most or all of the descending thoracic aorta and most or all of the abdominal aorta, extends below the renal arteries.
• Type III: involves the distal half (equivalent to "below T6 disc space") of the descending thoracic aorta and involving varying segments of the abdominal aorta.
• Type IV: includes most or all of the entire abdominal aorta, including the renal arteries. These definitions adapted by Crawford,[4] eliminate the Type V category.
Abdominal
• Juxtarenal: aneurysm abuts the renal arteries, but does not involve the renal arteries (no normal aorta between upper extent of aneurysm and renal arteries)
• Infrarenal
Iliac involvement (with either thoracoabdominal or abdominal aortic aneurysm)

should be obtained by using images reformatted *orthogonal* (on a perpendicular plane) to the centerline of the vessel using three-dimensional (3-D) reconstructions. For cases in which a diameter perpendicular to the vessel centerline is not available, the minor and major axis diameter of the aneurysm should be recorded and the minor axis diameter reported as the representative diameter. In cases where length is recorded to define the extent of treatment, the tortuous diseased aorta should be measured in 3-D reconstructions using the central lumen of the vessel, the vessel center (including extraluminal components), or a specifically defined path. Aortic pathology (eg, calcific plaque or irregularities) or bony landmarks close to the aortic aneurysm may be used as adjunctive landmarks for measurements.

It must be stressed that axial computed tomography (CT) measurements alone are undesirable for these purposes, and that new studies must use one of the many available types of 3-D reconstruction. Further details are included in the section "Classification and measurement of treatment effects related to TEVAR" and in the Appendix (online only).

Etiologic classification. It is recommended that reports identify the etiology of the aortic pathology to the extent possible, in keeping with a classification that includes anatomy, etiology, and clinicopathologic manifestations (Table II). With regard to arterial aneurysms, distinction should be made between degenerative (arteriosclerotic), anastomotic, infectious, inflammatory (noninfectious), traumatic, connective tissue disorder, chronic dissection, and congenital aneurysms. Standard naming terminology is

Table II. Descriptors of thoracic aortic pathology in thoracic endovascular aneurysm repair

Aneurysm
Anatomy—See Table I
Etiology—Degenerative (arteriosclerotic), anastomotic, infectious, inflammatory (noninfectious), traumatic, dissection, connective tissue disorder, and congenital aneurysms
Clinicopathologic manifestations—Chronic pain, acute severe pain, emboli, acute rupture, chronic contained rupture, fistula, compression or erosion of adjacent structures
Traumatic aortic injury
Anatomic location, associated dissection length, aneurysm, or pseudoaneurysm diameter
Etiology—Blunt, penetrating
Time from injury
Clinicopathologic manifestations—Aneurysm, dissection, rupture, emboli
Dissection
Anatomy—Identify location in ascending, arch, or descending aorta, or use a standard classification scheme (eg, Stanford, DeBakey)
—Include as much precision on length, location, and involvement of aortic branches as possible
Etiology—Spontaneous dissection due to hypertension, Marfan syndrome, or other connective tissue disorder, or traumatic dissection (blunt, sharp, iatrogenic)
Time course—Acute or chronic, using 14-day criterion[42]
Clinicopathologic manifestations—Pain, ischemia, aneurysm, rupture
Penetrating aortic ulcer
Anatomy—Site, extent, depth of the ulceration, maximum aortic diameter
Etiology—Degenerative, infectious, iatrogenic
Time course—If acutely manifesting (eg, rupture, emboli)
Clinicopathologic manifestations—Pain, emboli, rupture
Intramural hematoma
Anatomy—Site, extent, thickness of the associated hematoma, maximum aortic diameter
Etiology—Hypertension, iatrogenic, penetrating ulcer, aneurysm (see co-existing pathology below)
Time course—If acutely manifesting (eg, rupture)
Clinicopathologic manifestations—Pain, aneurysm, rupture, compromise of branch arteries
Aortic diverticulum
Anatomy—Standard naming terminology is appropriate (eg, Kommerell's diverticulum)
—Anatomic description of location appropriate to make the pathology and location clear
—Dtudies demonstrating compressive effect (computed tomography, magnetic resonance, esophageal area, endoscopy findings)
Associated abnormalities—Right-sided aortic arch, aberrant subclavian artery, etc
Clinicopathologic manifestations—Dysphagia, emboli, pain, etc, including severity
Coexisting pathology
—All pertinent should be listed
—The primary pathologic entity should be designated accordingly
—Standard classifications of type, etiology, time course and clinicopathologic manifestations
—All types of pathology should be accompanied by hemodynamic status at presentation/repair: stable, unstable, vital signs, associated cardiac arrest

appropriate for aortic diverticulum (eg, Kommerell's diverticulum) but should be accompanied by a brief anatomic description to make the pathology clear, as well as associated abnormalities such as right-sided aortic arch and aberrant anatomy of other arch vessels. When multiple types of pathology coexist and are pertinent to repair, such as dissection with a corresponding aneurysm, the primary pathologic entity should be designated in addition to describing other pertinent pathology.

Clinical classification. Aneurysms and other pathologic entities should be categorized by clinical presentation as asymptomatic or symptomatic. Pertinent *symptoms*, *time course*, and *severity* should be documented, including those related to compression or erosion into neighboring structures, thrombosis, embolization, or end-organ ischemia. Rupture should distinguish between a free or contained rupture and fistulization into adjacent structures. In this regard, hemodynamic status of the patient should be reported, including blood pressure and response to the initial resuscitation (*stable, unstable, cardiac arrest*). Reports on intramural hematomas or dissections should include the elapsed time between onset and therapy, with a clear definition of *acute* and *chronic*. Patients presenting with symptoms occurring ≤2 weeks of a clearly defined new pathologic entity may be considered acute, whereas those treated thereafter are considered chronic. Although this time frame is arbitrary for intramural hematoma, it is to be consistent with the definition of acute for dissections, based on autopsy studies showing that 74% of patients who die of aortic dissections do so within the first 14 days.[10] Dysphagia or other compressive effects due to the aortic pathology should be described by time course and severity.

CATEGORIZATION OF OPERATIONS AND PROCEDURES

Operative and procedural details, including all the additional procedures necessary to maintain a clinically durable result, will determine the magnitude, complexity, and expense of TEVAR. Therefore, careful reporting will assist in efforts designed to enhance treatment efficacy with revision of patient selection criteria, improvement of intraoperative adjuncts, or refinement of device design. In all cases, identification of procedural goals, maneuvers, device components, and configurations is important.

Categorization of endograft configurations and components. Precise description of the configuration, modularity, fabric, support, and fixation structures of the endograft system should be provided, if not detailed in a prior report. There must also be an accounting of all adjunctive components, devices, and maneuvers. Recommendations regarding uniform reporting of device configuration and components are outlined in Table III and are detailed in the online Appendix.

Table III. Categorization of endograft configurations and components

- Configuration
  - Location: Proximal (zones 0-7, see text), distal (relative to visceral aortic branches, zones 4-11, see text)
  - Length of coverage: Length (cm) or proportion of descending thoracic aorta covered
  - Modularity: Single or multiple components
  - Diameter: Straight or tapered
  - Branch vessel treatments to an aortic stent graft:
    - Scallop, fenestration, stented fenestration, fenestrated branch, side-arm branch (see text for definitions)
    - Number of vessels treated (intent to treat)
    - Type and number of components (eg, balloon-expandable or self-expanding stent grafts)
      - Retrograde, antegrade branches
      - Branch vessel adjuncts (eg, chimney or snorkel technique, debranching—see text)
- Endograft fabric (eg, polytetrafluoroethylene, polyester, combination, fabric "generation")
- Support system
  - Full or partial support
  - Balloon-expandable or self-expanding
  - Stent framework luminal or abluminal in relation to the fabric
  - Supporting framework fixed to the graft with stitches or otherwise bonded, attached
  - Geometric configuration
  - Material composition (eg, nitinol, stainless steel, Elgiloy); describe nonstandard alloys
- Fixation components and techniques
  - Integral part of the support skeleton or a separate or unique element of the endograft system
  - Configuration (hooks, barbs, screws, pins, scales, or other means)
  - Balloon or self-expanding
  - Intended placement of a fixation system (eg, proximal or distal to branch vessel origins)
  - Endograft extensions and intraluminal stents
  - Adjunctive devices to assure proper fixation, sealing, patency, and positioning of the endograft (eg, adjunctive intraluminal balloon-expandable or self-expanding stents, unplanned stent raft components of another manufacturer, extensions that would not be typical of the device, or unplanned extensions)
- Graft size relative to the native aorta
  - Percentage of graft oversizing relative to the host artery diameter at the intended fixation sites
  - Oversizing relative to lumen or outer vessel wall
  - Reported as an absolute number or preferably as a range and average percent of over-sizing

Configuration: Branch treatments, branched and fenestrated endografts. The newest and most complex issue in reporting TEVAR stent graft configuration is for branch vessel treatment. The aortic stent graft configuration may be modified in a number of ways to treat aortic branch vessels. The term *scallop* refers to a portion of aortic graft material removed to accommodate an aortic branch at the proximal or distal end of the aortic repair, thus allowing some fabric to extend further proximally or distally than a simple cylindrical configuration would allow. The term *fenestration* or *fenestrated* may be used to indicate the presence of openings purposely created within the endograft to allow perfusion of visceral or brachiocephalic arteries in the region otherwise covered by the aortic endograft. If stents are placed within fenestrations, the frequency should be noted and designated by a term such as *stented fenestrations.* If a stent graft is placed within a

fenestration, but not required for sealing, the proper term would still be stented fenestration.

The prefix *branched* is used to indicate the presence of stent graft side arms intended to connect the primary aortic endograft to visceral or brachiocephalic arteries in the region otherwise covered by the aortic endograft. The implication is that a stent graft *branch* is required for sealing across a gap between the primary aortic endograft and the target visceral or arch vessel (ie, a fenestration or stented fenestration would allow flow or pressurization of the aneurysm sac). A *fenestrated branch* seals into a fenestration that has been reinforced to allow sealing, and a *side-arm branch* implies a side arm has been sewn onto the aortic stent graft component to allow sealing. The type of branch should be reported, as well as whether the branch is oriented antegrade or retrograde. For branches and fenestrations, the vessels intended to receive scallops, fenestrations, stented fenestrations, or stent grafts should be described, as well as the total number of stent grafts or stents required.

Other treatments for aortic branches may affect the primary aortic stent graft(s). As such, they must be reported, and the definition is included with graft configuration even though the treatment may not technically modify the primary aortic endograft configuration. Branch treatments include *debranching* of the visceral or arch vessels, which is defined as a surgical bypass performed to originate perfusion of the aortic branch artery from a location that will not be covered by the intended aortic stent graft (eg, iliac-renal bypass, carotid-subclavian bypass). The other commonly described branch treatment is the placement of a stent or stent graft in an aortic branch artery that is covered or partially covered by the aortic stent graft, typically referred to as the *chimney* or *snorkel* technique. Reports of these treatments should include the number and type of stents, stent grafts, or grafts used and whether the treatment was planned or unplanned.

Zones of attachment. The location of attachment and length of coverage relates to the risk and complexity of the procedure as well as component selection and stresses on the devices. A system is already in place to describe the proximal *zones of attachment*, originally proposed to describe the ascending aorta, arch, and proximal descending aorta (zones 0-4).[11,12] Reporting the proximal attachment zone is particularly important when reporting neurologic outcomes, because cerebrovascular outcomes appear to be related to the proximal attachment site zone.[11,13] Both the proximal and distal attachment zone likely affect patient risk, device selection, complexity of the procedure, and stresses on devices,[14] so an extended "zone" system is described here that allows for a complete description of both proximal and distal attachment site by zone. See the Fig in addition to the following:

- *Proximal attachment zone:* Proximal endograft attachment site, defining the proximal edge of covered endograft. Zone 0 = the proximal edge of the covered endograft is proximal to the innominate artery origin; 1 = distal to the innominate but proximal to the left common carotid artery (LCCA) origin; 2 = distal to the LCCA but proximal to the subclavian artery; 3 = ≤2 cm of the left subclavian artery without covering it; 4 = proximal extent of the endograft is >2 cm distal to the left subclavian artery and ends within the proximal half of the descending thoracic aorta (T6 approximating the midpoint of the descending thoracic aorta); 5 = starts in the distal half of the descending thoracic aorta but proximal to the celiac artery; 6 = celiac origin to the top of the superior mesenteric artery (SMA); and 7 = SMA origin, suprarenal aorta. For devices with bare stents, it is useful to differentiate the covered and noncovered end point.
- *Distal attachment zone:* Distal endograft attachment site, defining the distal edge of covered endograft. Zone 4 = distal extent of the endograft is >2 cm distal to the left subclavian artery and within the proximal half of the descending thoracic aorta (T6 approximating the midpoint of the descending thoracic aorta); 5 = ends in the distal half of the descending thoracic aorta but proximal to the celiac artery; 6 = covers the celiac, ends proximal to the SMA; 7 = covers the SMA,

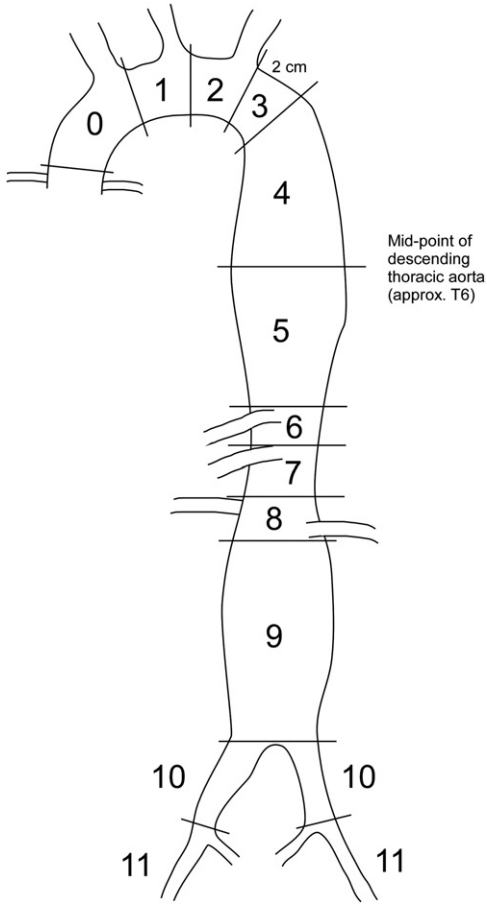

Fig. Zones of attachment. See text in the main document and the online Appendix for more details.

ends proximal to renal arteries; 8 = covers at least 1 renal artery; 9 = infrarenal; 10 = common iliac; 11 = external iliac. For iliac arteries, the zone can be reported separately or by the most distal site (eg, if one side ends in the common iliac artery and the other ends in the external iliac artery, use zone 11). For devices with bare stents, it may be useful to differentiate the covered and noncovered end point. For extensive repairs, the *status of both internal iliac arteries should be reported* (patent, chronically occluded, or coiled/covered by the repair).

Alternatively, the distal attachment location may be reported relative to the anatomic segment, namely descending thoracic aorta (eg, proximal third, middle third, or distal third), the visceral aortic segment (describing the branches that are covered), the infrarenal aorta, the common iliac, or the external iliac arteries. For extensive repairs, the status of the internal iliac arteries should be reported (patent, chronically occluded, or coiled/covered by the repair).

Other aspects. Other aspects of stent graft configuration, including location, length, modularity, fabric, support system, fixation, as outlined in Table III, are described in detail in the online Appendix.

Description of the principle or primary procedure. A *principal procedure* is one that the surgeon believes contributes most to treatment of the aortic pathology and therefore involves placement of the aortic endograft components in reports of TEVAR. The primary pathologic entity designated for treatment must be described as detailed in "Classification criteria for thoracic aortic pathology" and Table II. For most reports, the procedure will also largely be described by the categorization of the device configuration (eg, location, branch treatments, etc) as reported in Table III and the adjunctive procedures as described below and in Table IV.

Adjunctive maneuvers and concomitant or staged procedures: Preoperative, intraoperative, and postoperative. A *principal procedure* is one that the surgeon believes to contribute most to treatment of the aortic pathology, and therefore involves placement of the aortic endograft components in reports of TEVAR. An *adjunctive procedure* is any other procedure that is designed to augment the effects of the principal procedure, such as debranching an aortic segment by a bypass (eg, carotid-carotid artery bypass, iliac-celiac artery bypass), stenting a branch artery (eg, for a pre-existing stenosis), or use of a stent, conduit, or bypass as an aide to device delivery (eg, 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). Adjunctive procedure types are outlined in Table IV. Such procedures may occur in the preoperative, intraoperative, or postoperative periods and should be designated in like manner.

Primary procedures refer to all interventions performed during the initial aortic endovascular repair and serve as the reference point for these designations. Adjunctive procedures can be "preoperative" if the procedure is staged (eg, debranching before aortic stent grafting). "Intraoperative" adjuncts may also be designated as *concomitant procedures*, and should be further described as *planned* or *unplanned* when appropriate. Adjunctive procedures would rarely be designated as "postoperative," because postoperative adjuncts would typically be unplanned secondary interventions designed to treat a problem with the primary repair. One example of a postoperative adjunctive procedure would be a carotid-subclavian bypass that was planned for the primary procedure but was staged in a delayed fashion due to patient instability at the time of the primary procedure. Thus, *secondary procedures* include essentially all operations or endovascular interventions performed at a later date.

Table IV. Categorization of adjunctive procedures

Hemodynamic adjuncts
Lowering systemic blood pressure
Altering cardiac inflow (eg, atrial balloon)
Cardiac slowing or arrest (eg, Adenosine)
Rapid cardiac pacing
Branch adjunct
Occlusion
Coiling
Endograft "plugs"
Other occlusion devices
Stent or stent graft
Treating occlusive disease
Treating dissection
Debranching
Cervical (cerebrovascular)
Visceral (mesenteric, renal)
Chimney procedure
Stent, stent graft
Branch
Typically part of the primary procedure for branched endografts
Aortic attachment adjuncts
Bare stents, stent graft extensions, external wraps
Aortic sac adjuncts
Coils, glue, or other pharmacologic treatment
Monitoring or therapeutic adjuncts
Pressure monitoring devices
Cerebrospinal fluid drainage
Somatosensory or motor-evoked potentials
Adjuncts for device delivery
Stent
Internal conduit (stent graft)
Temporary surgical conduit
Bypass (for delivery conduit)

Conversion to open surgical repair. Conversion from endovascular to open repair may be required at the original operation (*primary conversion*) or on a subsequent occasion (*secondary conversion*). Secondary conversion also should be classified as *urgent* or *elective*. For example, secondary conversion for persistent endoleak in an asymptomatic aneurysm is an elective procedure, and conversion precipitated by aneurysm rupture is an urgent or emergent intervention. Details of conversion should be reported, including indication, site of aortic control, and other relevant operative information. Open surgical aortic arch repair

performed for dissection or aortic degeneration thought to be caused by stent graft placement would be categorized as a complication with secondary open intervention. Although the latter would not be classified as an open surgical conversion, it would be of equivalent significance and should be reported clearly.

CLASSIFICATION AND MEASUREMENT OF TREATMENT EFFECTS RELATED TO TEVAR

The primary goal of TEVAR for any pathologic entity is to prevent death secondary to the pathology or related interventions. Death or rupture may occur in quite a delayed fashion, even in ineffective repairs, so surrogates of device efficacy that can be measured in the near term are desirable. The aneurysm sac in EVAR is left intact, and this feature is important in outcome assessment. Specifically, clinical correlation suggests that aneurysm expansion after EVAR is an indicator of incomplete aneurysm exclusion, continued risk of aneurysm rupture, and a presumed treatment failure.[2] Because variations in size occur in three dimensions, both sac diameter and volume are relevant parameters for defining changes in aneurysm size. It is noteworthy that relatively small diameter shifts of 1 to 2 mm, which may otherwise be difficult to accurately measure with conventional imaging techniques, may be correlated with a significant change in aneurysm volume.[2,15-18] Other pathologies can be evaluated, at least partially, using similar techniques. For intramural hematoma, measurement of the longitudinal extent and thickness are important and may be captured and/or measured in similar fashion to aneurysm diameter and volume. Similarly, traumatic aortic injury and dissection are often associated with aneurysm, and changes in the aneurysm size may be a secondary outcome measure as a surrogate of treatment effect in these cases.

Measurement of device migration, attachment site apposition length, device diameter, modular component overlap, and angulation are analogous to surrogate end points involving the aneurysm sac and may serve as indicators of device stability in all types of TEVAR. Measures of branch vessel change are critical in branched endograft repair of thoracoabdominal or thoracic aneurysm, but may be important in traumatic aortic injury, dissection, or even relatively straightforward TEVAR for aneurysm.

Thus, reports pertaining to the implementation of TEVAR may include measures of diameter, length, volume, endoleak, attachment site dimensions, migration, tortuosity, and branch vessel morphology, as outlined in Table V. Recommendations regarding the methodology for calculating key measurements are included in the online Appendix. Some of these parameters are more pertinent for clinical trials of new devices or research studies, but at a minimum, reports of TEVAR must include a measure of aortic size (covered below), exclusion of the pathologic entity of *endoleak* (Table VI and online Appendix), *device stability,* including *migration* (online Appendix), and *device integrity* (covered in the next section).

Changes in aneurysm dimension. Measurable changes in aortic and aneurysm dimensions have been reported immediately after endograft deployment. Therefore, changes in size should be referenced to measurements obtained from the first set of postoperative images. At each time point, aneurysm size should be expressed as maximum diameter measured orthogonal (perpendicular) to the lumen centerline or vessel centerline. If available, aneurysm size should also be reported for sac volume, which appears to be more sensitive for detecting aneurysm size change.[2,15-18] Volume can be measured by total volume or by measuring the device and sac volumes as separate components (Table V and online Appendix). Deviations from this method of measurement should be detailed in any report.

Comparisons between time points should use a potential measurement error of 5 mm diameter or 10% change for volume measurements, unless data supporting alternative intraobserver or interobserver variability is reported based on percent change or absolute value in mL. Modality, method, and definitions should be clearly described, and comparisons should only be made between identical meth-

Table V. Key measurements for reports pertaining to thoracic endovascular aneurysm repair

1. Diameter: Measured perpendicular to 3-D centerline flow or minor axis of axial computed tomography
2. Volume: Documented to be more sensitive to aneurysm size change than diameter Preferably measured external to the lumen of the endograft, as a percentage of baseline measurement or in cubic centimeters
3. Length of the aneurysm and/or dissection: 3-D centerline measurement from vessel centerline or lumen centerline
   a. Distance between two reproducible anatomic aortic landmarks on the imaging study
   b. Anatomic non-aortic landmarks found on adjacent structures
   c. Requires a measure of stability of the total aortic length (including untreated segment)
   d. Can be expressed in simple absolute measurements (ie, mm) and as a percentage of total length between two defined landmarks (eg, subclavian and celiac artery branches)
4. Endoleak: See Table VI and online Appendix.
5. Aortic attachment site diameter change: Perpendicular to vessel/lumen centerline or minor axis of axial computed tomography
6. Aortic attachment site apposition length (seal zone): 3-D centerline measurement
7. Device migration: 3-D centerline measurement
   a. Distance between two reproducible anatomic aortic landmarks on the imaging study
   b. Anatomic nonaortic landmarks found on adjacent structures
   c. Requires a measure of stability of the total aortic length (including untreated segment)
8. Intercomponent relationships (eg, changes in overlap, attachment)
9. Aortic or device tortuosity, angulation, or radius of curvature
10. Adjacent aortic branch vessel change
    a. Diameter: Perpendicular to vessel/lumen centerline or minor axis of axial computed tomography
    b. Angle: 3-D measurement strongly preferred
    c. Stenosis or occlusion

The above measurements should be reported in mm or to the tenth of a cm (eg, 6.2 cm) unless otherwise specified. Recommendations regarding the methodology for calculating key measurements are included in the online Appendix.

Table VI. Endoleak definitions

Type I:
- a. Leak at the proximal graft attachment site
- b. Leak at the distal graft attachment site
- c. Leak around a fenestration, branch end point, or branch occluding plug (eg, plug occluding a subclavian artery or iliac artery to prevent flow into an aneurysm sac[2])

Type II: Retrograde flow from branch arteries arising from the excluded segment

Type III:
- a. Modular disconnect or apposition failure (including branch junctions)
- b. Fabric tear

Type IV: Flow through porous fabric (generally resolves within a short time period, typically less than 24 hours)

Type V: No detected endoleak, but aneurysm expansion (thus presumed failure to detect the endoleak or presumed pressure transmission through thrombus without blood flow)

Note: Endoleaks must be stratified by
1. Time of endoleak occurrence (primary, secondary, recurrent)
2. Site of endoleak origin
3. The proportion of patients with an endoleak and confirmed aneurysm expansion
4. The proportion of patients without detectable endoleak with demonstrable aneurysm expansion (ie, possible endotension)

The number of patients available for analysis must be specified at each time point. Full definitions of endoleak types and reporting methods are included in the online Appendix.

ods of measurement. Refer to the online Appendix for further discussion of these measurements and other measurements, including endoleak and migration.

Imaging modalities and follow-up sequence for measuring changes in aneurysm morphology and categorizing outcomes. Imaging studies are currently recommended at discharge or at least ≤1 month of the procedure, and periodically thereafter. At a minimum, annual follow-up studies were conducted by all of the prospective U.S. clinical trials. Follow-up studies typically include high-resolution, contrast-enhanced spiral CT studies of the chest and abdomen. The study should cover the device from start point to end point, and initially the delivery system access site should ideally be imaged by CT or duplex ultrasound imaging. Follow-up studies also typically include plain radiographic images of the appropriate anatomic region to assess thoracic device fracture. Although noncontrast CT studies can be used to assess aneurysm size, the presence or absence of an endoleak can only be determined with a contrast-enhanced imaging study. Magnetic resonance imaging (MRI) may be substituted for CT scans if the signal void created by the implanted device is minimal (<2 mm). Recommendations for follow-up and MRI compatibility should be found in the *instructions for use* for any device.

Methodology for documenting the integrity of an endoprosthesis. The integrity of the endovascular device may be compromised at the time of deployment (early device failure) or later after graft implantation (late device failure). If disruption of a component of the prosthesis is observed at deployment, the role of delivery system failure and operator error should be noted, including inappropriate patient selection or technical misjudgment. Failure of the delivery system and related adjuncts should be reported separately as access or delivery system issues, and not grouped with failures of the implanted endoprosthesis. Late deformation of endografts should be defined by whether there is associated device obstruction or component module disconnection. A progressive change in angulation over time remains an area of investigation, and if reported, it should include the initial angulation and the change in angulation over time based on a clear definition. The site of angulation should be specified by proximity to anatomic landmarks, the distance from graft attachment, and the length over which the angulation is measured. Angulation is best measured on 3-D reconstructions of the endograft, because plain radiographs tend to underestimate angulation or cause ambiguities in measurement.

Noninvasive assessment of the integrity of metallic graft components is typically determined by plain radiographs obtained in the anteroposterior, lateral, and oblique positions. High-resolution spiral CT scan imaging can be used as a supplement to plain radiographs or may substitute for plain radiographs if 3-D reconstructed views allow for proper assessment of the metallic components of the device (if resolution is adequate and demonstrated by validation vs conventional radiography in the same report or a prior report). All imaging methods have limited ability to detect fabric failure, and the methodology for detection should be described (eg, delayed contrast CT angiography or MR angiography, conventional angiography, angiography with outflow occlusion to create a standing column of contrast within the implant, or explant). The prevalence of a fabric or metallic structural failure in a carefully studied, unselected, and numerically significant subset of implanted devices can serve as an estimate of device failure.

Grading system for reporting device failures. The clinical significance of reported device failures should be stratified as:

0—not associated with an adverse clinical event or necessitating increased surveillance or intervention;
1—necessitating increased surveillance but without clinical event;
2—necessitating intervention to control or manage;
3—resulting in conversion, rupture, major complication, or death.

Reports of late device failure should also include potentially relevant clinical, anatomic, and hemodynamic parameters, such as implant duration, associated changes in aortic or implant morphology, and blood pressure.

OUTCOME CRITERIA AND DEFINITIONS

The motivation for treatment of thoracic aortic pathology is to minimize the mortality and morbidity associated with the pathology. The method of accomplishing this goal varies slightly, depending on the pathologic entity, but is primarily designed to reduce or eliminate the risk of aortic

Table VII. Primary and secondary outcome criteria for thoracic endovascular aneurysm repair

Primary outcome criteria
1. Prevention of rupture of aortic aneurysm or other aortic pathology
2. Prevention of death from aneurysm rupture or other aortic pathology (including end-organ ischemia)
3. Prevention of death associated with primary or secondary treatment of the original aortic pathology, including operative or endovascular intervention for rupture, dissection, or end-organ ischemia (eg, stroke, transient ischemic attack, mesenteric or renal infarction or ischemia, upper or lower extremity ischemia)
Secondary outcome criteria (surrogate markers and markers of patient morbidity)
1. New, expanding, or progressing: aneurysm, dissection, ulceration, or hematoma
2. Device migration
3. Device degradation (eg, stent fracture, fabric erosion)
4. Endoleak presence (for aneurysm)
5. Endoleak requiring intervention
6. Hospital admission for medical treatment of the original pathology or its sequelae
7. Neurologic events (stroke, transient ischemic attack, paraplegia, paraparesis)
8. Embolic phenomena
9. Ongoing ischemia (eg, mesenteric ischemia, renal failure, claudication)
10. Complications of adjunct procedures performed to facilitate the implantation of the endograft (eg, occlusion of debranching bypass graft)
11. Conversion to open repair

rupture, end-organ ischemia secondary to embolization or malperfusion, new or progressive dissection, paraplegia, and death. The indications for treatment and the resulting outcomes must be reported, because they are critical for comparison of studies and for meta-analysis.

Primary and secondary outcome criteria. The goal of minimizing patient morbidity and mortality is, of course, related to the interventions as well as to the pathologic entity. Therefore, by definition, the *primary outcome criteria* for TEVAR includes the prevention of rupture and death related to the primary pathologic entity or to a procedure designed to treat it (Table VII).

It is initially difficult to determine whether placement of an endovascular graft has prevented or reduced the risk of rupture or death, however, because these outcomes may only occur after substantial time has passed. Thus, surrogate markers that suggest a continuing or increasing risk from the original pathology may play a critical role in the overall assessment of the effectiveness of endovascular treatment strategies. Surrogate markers and markers of patient morbidity should be designated as *secondary outcome criteria* and may include the conditions listed in Table VII. Conversion to open repair of the pathology represents a special type of failure of the endovascular technique and should be reported clearly and uniquely from other types of secondary intervention. Significant value exists in reporting an accepted and unifying measure of clinical success that combines the most significant primary and secondary outcome criteria, which reflect the goals of this treatment method (see also "Reporting deaths and complications" below).

Definition of success. Defining the success of TEVAR remains dependent on a consideration of both clinical and radiographic criteria that exist within the context of historical standards established by open surgical repair as well as by EVAR. For direct analogy to open repair, a similar result can only be accomplished with an endograft if complete exclusion of the pathology from the circulatory system is achieved. Some investigators, however, have suggested that the presence of a persistent type II endoleak after EVAR may or may not be a predictor of late adverse outcomes, including aneurysm expansion and rupture.[19-21] Less data exist regarding type II endoleak after TEVAR than after EVAR. In the absence of definitive data, the relative predictive value for endoleak and other surrogate outcome markers remain incompletely defined and should continue to be reported with all reports pertaining to TEVAR.

Definition of technical success. *Technical success* relates to immediate periprocedural events that occur from the initiation of the procedure and extend through the first 24 hours postoperatively. *Primary technical success* is defined on an intent-to-treat basis that begins with the implantation procedure and requires the successful introduction and deployment of the device in the absence of surgical conversion to open repair, death ≤24 hours, type I or III endoleaks as evidenced by procedural angiography, or graft obstruction. A technical success thus implies the following qualifying details are all met:

1. successful access to the arterial system using a remote site (ie, the femoral, external iliac, common iliac, abdominal aorta, or brachiocephalic arteries with or without use of a temporary or permanent prosthetic conduit to access these arteries);
2. successful deployment of the endoluminal graft at the intended location;
3. absence of a type I or III endoleak (angiographically detected);
4. patent endoluminal graft without severe obstruction (ie, the mean pressure gradient should be <10 mm Hg by intraoperative measurements).

Secondary technical end points should be reported, such as procedure time, blood loss, blood transfusion, fluoroscopy time, contrast load, range and average number of days in an intensive care unit, and hospital length of stay (preferably mean, median, and range). These parameters do not enter into the consideration of the primary technical success rates.

Definitions of clinical success. *Primary clinical success* should be reported on an intent-to-treat basis and initially requires successful deployment of the endovascular device at the intended location. *Ongoing primary clinical success* is further defined as freedom from the need for an unplanned additional (secondary) surgical or endovascular procedure targeted at the pathology that was initially treated or targeted at new pathology caused by the index

procedure. Clinical success can only occur without any of the following: death as a result of treatment or as a result of the original pathology that was treated; type I or III endoleak, infection or aortic thrombosis; aneurysm expansion (diameter ≥5 mm, volume ≥10% or greater than two times interobserver variability) or rupture; conversion to open repair; or failure to arrest the original pathologic process (eg, embolization from penetrating ulcer) or causing a new thoracic aortic pathology as a result of the intervention (eg, pseudoaneurysm, dissection, intramural hematoma).

Assisted primary clinical success is defined as clinical success achieved initially and continuously maintained, but only with the use of an additional procedure deemed necessary to prevent failure of the initial implant(s).

Secondary clinical success is defined as clinical success obtained initially but temporarily interrupted by a failure that is corrected with the use of an additional, secondary surgical procedure; for example, a type I endoleak develops in an initially excluded aneurysm due to endograft migration at 2 years and is corrected by placement of a new, more proximal endograft. Conversely, clinical failure includes death as a result of treatment or as a result of the original pathology that was treated or a pathology caused by the initial procedure (eg, aneurysm rupture, or dissection extending to cause mesenteric ischemia and resulting in death), type I or III endoleak, graft migration, infection, or thrombosis, aneurysm expansion (as defined elsewhere in this document; aneurysm rupture), conversion to open repair, failure to arrest the original pathologic process, or appearance of a new thoracic aortic pathology as a result of intervention.

Endograft integrity problems should be reported separately and include graft dilatation of ≥20% by diameter relative to nominal size at implant, wire fracture, graft migration, or other failure of device integrity. Clinical success can be claimed for those cases with a type II endoleak only in the absence of aneurysm expansion.

Definitions of success relative to length of follow-up. The presentation of clinically meaningful success rates mandates that the data are statistically valid for the time period in question. Specifically, the *standard deviation of life-table or Kaplan-Meier estimates should not exceed 10%,* as noted in other Society for Vascular Surgery reporting standards. The following temporal characterization of clinical success is consistent with the EVAR standards. *Initial or 30-day clinical success* is defined to encompass data ≤30 days after the procedure. *Short-term clinical success* includes outcome measures reported from 30 days to 6 months. *Midterm clinical success* refers to all outcome measures that are statistically significant ≤5 years after endograft implantation. *Long-term clinical success* includes all outcome measures that are statistically significant >5 years.

Aortic rupture or aneurysm rupture should be reported as a procedure-related rupture (eg, perforation of the aorta or aneurysm during the course of the implantation procedure) or as a late rupture that occurs in delayed fashion (>24 hours) after completion of the procedure.

Reporting deaths and complications. Standardized reporting of deaths and complications is necessary to establish TEVAR as a safe and effective therapy for aortic pathology and to compare TEVAR between different devices or with conventional surgery for patients at low and high risk. Deaths and complications should be reported on an intent-to-treat basis. *Intent-to-treat* should be considered initiated by any maneuver directed at treating the aneurysm with an endovascular approach or the first adjunctive procedure (eg, debranching) in a staged approach.

Deaths. All deaths that occur ≤30 days of the operative procedure should be categorized as *TEVAR-related deaths* (ie, aneurysm-related deaths in the case of aneurysm repair), and classified as either *procedure-related* or *device-related*. Deaths that occur >30 days should be considered *late deaths,* with the additional categorization of *in-hospital late death* for those patients who died >30 days after the procedure but never left the hospital. The cause of late death and its relationship to the implanted device or procedure should be noted. *TEVAR-related deaths* should be reported explicitly and are defined as all deaths due to the treated pathology, including aneurysm rupture, a primary or secondary procedure, surgical conversion, or complications of TEVAR leading to new aortic pathology (eg, retrograde dissection leading to fatal cardiac tamponade).

The cause of death should be classified as verified if determined 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 unavailable, the cause and its relationship to the procedure and device should be classified as *probable* if the clinical picture is consistent and documented with reliable observations during the terminal illness. When these criteria cannot be met, the cause of death should be considered *indeterminate*.

Complications and complications grading system. Complications should be assigned a severity score so that degrees of morbidity can be assessed and compared. A specific complication and morbidity grading system already exists in the EVAR standards, and can be used for TEVAR.[2] See also "Other key aspects" below.

Grading system for spinal cord ischemia. One recommended modification to the existing EVAR standards is for the *spinal cord ischemia grading system:*

0 = none;
1 = resolved with minimal sensory deficit, able to walk independently;
2 = minor motor deficit, able to walk with assistance or independently (implies the ability to move against gravity);
3a = nonambulatory (wheelchair bound), able to move against gravity;
3b = nonambulatory (wheelchair bound), able to move the extremity laterally but not against gravity; and
3c = nonambulatory (wheelchair bound), minimal or no movement.

This system allows incorporation of more detailed systems,[22] while maintaining the standard, clinically useful "mild, moderate, or severe" grading system (see next section). Complications such as paraplegia or paraparesis are most appropriately expressed in status at a particular time point (eg, 1 month postoperatively, 1 year postoperatively), and progression from one level of severity to another can be noted.

Grading system for complications without an existing grading system. The following scoring system has been modified from Rutherford et al[23] for uncommon complications without a specific grading system and is consistent with the EVAR reporting standards[2,3]:

- *Mild* indicates the complication occurred but resolved spontaneously or with nominal intervention, did not prolong hospital stay, and did not cause permanent impairment.
- *Moderate* indicates the need for significant intervention, prolongation of hospitalization >24 hours, and at 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 convalescence, is usually accompanied by prolonged or permanent disability, and may result in death.[2,24]

Other key aspects. All complications should be classified as procedure-related or device-related, and anatomic site and presumed etiology should be reported where appropriate. All complications graded as moderate (2) or severe (3) are considered *major* complications, and those graded as mild (1) can be considered *minor* complications.

Longitudinal reporting of clinical outcome measures. The following parameters are recommended for inclusion in any comprehensive report of TEVAR: *survival, rupture-free survival, aneurysm-related death, freedom from aneurysm expansion, freedom from type I and III endoleaks, prevalence of type II endoleak, prevalence of secondary endoleak, endograft patency,* and *technical and clinical success rates.* Aneurysm rupture may be uncommon for other types of pathology but should still be reported (rupture can occur with traumatic injury, dissection, penetrating ulcer, intramural hematoma, and diverticula). All pathologic entities should also have survival free from death or major morbidity related to the pathology (eg, freedom from emboli, neurologic events, end-organ ischemia).

Life tables or Kaplan-Meier curves should be calculated when reporting survival, rupture-free survival, maintenance of clinical success, freedom from death related to the aortic pathology (aneurysm, dissection, etc), as well as for freedom from surrogate end points such as aneurysm expansion, type I or III endoleaks, and new or progressing dissection, embolization, among others, as defined previously. Because all thoracic repairs are adjacent to or may involve major branch vessels, a separate analysis should be considered that reports parameters relevant to long-term branch artery patency or occlusion, such as stroke, arm symptoms, mesenteric ischemia, unintended weight loss, segmental renal infarcts, glomerular filtration rates, hypertension, dialysis, claudication, and amputation. Reports of *endograft patency* should use life-table or Kaplan-Meier format and standard definitions of primary, assisted primary, or secondary patency, depending on the use of additional endovascular or surgical procedures.

Longitudinal reporting of morphologic changes. Although the life-table format is ideal for reporting binary outcomes (eg, freedom from mortality, freedom from aneurysm expansion), a format that allows multiple outcomes may be best to present the details of morphologic changes. In the case of aneurysm sac morphology, for example, a complete report should include the percentage of aneurysms that have significant sac shrinkage as well as sac expansion or lack of significant change. *Nonbinary outcomes* in aneurysm or lumen dimension should be reported as the number of available individuals at each time period; for example:

> Of 100 implanted devices, 80 had appropriate imaging for evaluation at 1 year. At 1 year, there were 20 aneurysms with significant reduction in sac diameter (>5 mm), 10 with significant enlargement (>5 mm), and 50 with no significant change in aortic aneurysm diameter or volume.

Data of this type can be displayed as a stacked bar graph, stacking the multiple outcome types (in this case, expansion, shrinkage, no change) for each bar to clearly display the number of aneurysms with the outcome at each designated time point. The *stacked bar format* thus displays the total number of cases at each time point as well and permits data display for multiple years, without requiring a large amount of explanatory text.

For research reports in particular, other methods to describe morphologic changes over time may be useful (eg, to report neck angulation or aortoiliac tortuosity, where binary or tertiary outcome standards have been suggested but not defined).[2,3] In these cases, the mean and standard deviation, or median, range, and quartile values may be reported to describe morphologic characteristics at specific time points. In each case, however, the number of cases being evaluated at each time point must be clearly stated. For reports of this type, attempts to *categorize anatomic variables into nominal groupings* (eg, mild, moderate, severe) are encouraged if the goal is to define a variable that may predict outcome.[3]

Comparing the clinical success of endovascular with open surgical repair. Investigations that compare open surgical repair with endovascular repair should report primary outcome criteria for both treatment groups, as previously defined. The use of related, although distinct, definitions of clinical success are necessary for patients treated with open surgery. *Primary technical success for open surgical repair* should be reported on an intent-to-treat basis (beginning with the onset of the operative procedure) and should require replacement or bypass of the pathologic segment with a prosthetic graft in the absence of death,

graft thrombosis, or malperfusion during surgery or during the initial 24-hour postoperative period.

The definition of *clinical success for open surgical repair* includes the absence of death as the result of the procedure, graft infection or thrombosis, failure of device integrity, including graft dilatation ≥20% compared with the nominal diameter, and para-anastomotic aneurysm formation. Should open repair consist of aneurysm exclusion and bypass grafting, rupture or expansion of the treated aneurysm (diameter ≥5 mm, volume ≥10% or twice interobserver variability) would classify a case as a clinical failure. Definitions of initial (30-day), short-term, midterm, and long-term clinical success and of primary, assisted primary, and secondary clinical success otherwise remain as described elsewhere in this document, as do recommendations for longitudinal reporting of clinical data.

Other significant outcome variables, such as device integrity, quality of life, and cost effectiveness can be compared with guidelines outlined below. Likewise, *grading schemes for reporting complications and their severity*, although primarily focused on endovascular treatment in this report and prior standards documents,[2,3] can be adapted with little modification for open repair. Finally, when two or more patient populations treated with open surgery and endovascular approaches are compared, *adjusting for case severity mix*, particularly with respect to comorbid medical conditions, can be performed with schemes described elsewhere.[2,3]

Quality of life and cost-effectiveness studies. The benefit provided by new interventions must be weighed against their expense. Therefore, studies designed to evaluate aortic endograft technology may include an assessment of both the cost of this technology and the quality of life of the treated patient. Examples of variables that should be evaluated for the use of endografts with respect to open surgery include hospital stay, mortality and morbidity, *discharge to home vs a skilled nursing facility or rehabilitation facility*, perioperative and long-term *quality of life*, return to normal activity, need for reintervention, and psychologic stress. Quality of life must be assessed frequently enough to capture the earlier postoperative rise of endovascular repair and also the later postoperative rise of open repair. For an *economic analysis*, cost rather than charge data should be gathered and analyzed and should include as many of the total costs as possible, including preadmission imaging, postimplantation surveillance, and late secondary procedures. The *costs of rehabilitation stays, skilled nursing facility, outpatient visits,* and *reinterventions* should be captured. The *cost of nonvascular reintervention* (eg, incisional complications such as wound infection, hernia, intervention or hospitalization for bowel obstruction secondary to adhesions, etc) should be captured for both EVAR and open repair. In regional or national population-based economic studies, investigators should consider the additional costs of endovascular intervention compared with the *costs and consequences of rupture without therapy* for patients who would not otherwise be candidates for open surgery.

INVESTIGATOR DISCLOSURE AND CONFLICT OF INTEREST

The International Committee of Editors of Biomedical Journals has established guidelines for disclosure of conflicts of interest.[25] On the basis of these guidelines, the *Journal of Vascular Surgery* has published its formal requirements for all authors of a submitted article.[26,27] The standards for EVAR also include a statement about conflict of interest.[2] These guidelines should be followed by all listed authors, with a standard form provided by the publisher or as a formal statement in the body of the text or a footnote.

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APPENDIX. Methodology and reporting of anatomic measurements, endoleak, and endograft configurations

METHODOLOGY AND REPORTING OF ANATOMIC MEASUREMENTS

Methodology for measuring changes in aneurysm diameter, volume, and length diameter. Aneurysm size should be expressed as maximum diameter and should include volume data if available. Modality, method, and definitions should be clearly described, and comparisons should only be made between identical methods of measurement. Given the inherent tortuosity of much of the thoracic aorta, the maximum aortic or aneurysm diameter should be measured perpendicular (orthogonal) to the central lumen line or the centerline of the vessel (which are not identical in all cases due to asymmetrical thrombus, plaque and/or dissection), using three-dimensional reconstructions of computed tomographic (CT) or magnetic resonance (MR) scan images. Because aneurysm cross sections may appear elliptical on axial images, the minor axis of the ellipse (smaller diameter) is generally a closer approximation of true maximum aneurysm diameter if digital images are not available for three dimensional reconstruction.[28-30] The intraobserver and interobserver variability of diameter measurements obtained from CT scan images range between 2 and 5 mm or 5% and 15%.[31-33] Therefore, a diameter change of 5 mm or more is considered significant. Blinding of observers and datasets are recommended to minimize bias.

Volume. Total aortic volume or total aneurysm volume is defined as the volume within the native aortic wall, and should be defined to begin and end at a reproducible landmark, such as "from just distal to the left subclavian artery origin to the first CT slice containing the celiac artery origin". Lumen volume is defined as the volume circumscribed by the endograft and the true lumen in the case of dissection, while nonlumen volume is comprised of thrombus external to the prosthesis (if present), endoleak, and false lumen of a dissection if present. Endograft dilatation may be associated with an increase in lumen volume, while reduction in aneurysm size is principally related to a decrease in nonlumen volume. Stent graft expansion may obscure changes of the sac when TEVAR is used to treat small aneurysms or pseudoaneurysms, therefore extraluminal sac volume may be used to better evaluate sac behavior over time. The term complete aneurysm resolution may be used if the nonlumen aneurysm volume is less than 10% of the original nonlumen volume measured after endograft implantation. The intraobserver and interobserver variability for volume measurements have ranged between 3% and 8%, with a volume change of 5% or 10% typically considered significant.[2,3,15-18] A percentage may not be ideal for small aneurysms, and the threshold validation range should be known, along with the minimum detectable size change for small-volume aneurysms. Ideally the interobserver variability and minimum detectable size change will be known and stated within the report. Blinding of observers and datasets are recommended to minimize bias.

Length. Alterations in aortic length have been noted. Shortening has occurred in the setting of a reduced aneurysm size and may be associated with morphologic changes in the endovascular prosthesis such as endograft buckling, kinking, and component dislocation.[34] Aortic lengthening may occur in the presence of a pre-existing aortic prosthesis such as an aortic arch repair, following endovascular completion of elephant trunk graft repairs, and in the setting of conventional treatment with an endovascular stent graft.[35,36] Thus aortic length is recommended to be measured between two reproducible endpoints, such as the subclavian and celiac artery, along the central lumen line or vessel centerline, as depicted in three-dimensional reconstructions from CT or MR scan images.[2,3,36,37] Aortic length should also be measured from the proximal reproducible endpoint to the proximal endograft (eg, left carotid or subclavian to top-of-graft) and from the distal reproducible endpoint to the distal endograft (eg, celiac to distal end-of-graft). Temporal comparisons of length measurements should occur only when the same method for measurement is used for each length calculation. In the absence of three-dimensional reconstruction, aneurysm length is underestimated as determined from axial CT scan images.[38,39] Axial or straight-line measurements may be of limited value only as an adjunct to centerline measurements in an effort to describe complex three-dimensional relationships (eg, tortuosity index).[3] It should be noted that limitations exist for angiography performed with a calibrated marker catheter, and this is not the preferred method for reporting, especially since it does not lend itself to serial follow-up measurements.

Migration measurements

Image acquisition and reconstruction. Imaging studies are recommended at discharge or at least within 1 month of the procedure, 6 months postoperative, 12 months postoperative and yearly thereafter. High-resolution contrast enhanced spiral CT studies of the chest and abdomen are required to properly assess thoracic device stability. For analysis of migration and other morphologic changes, images should be acquired using a collimation appropriate to allow for reconstructions with a longitudinal (axial or "Z") resolution of 3 mm or better, and have a pixel size (X-Y) of 1 mm or less. The collimation or beam thickness should not be confused with the reconstruction interval (reformat interval). A collimation or beam thickness of 1.5 mm or less is preferred, which requires a multi-detector row CT scanner. A slice reconstruction interval or reformat interval of 0.75-1 mm is preferred for optimal resolution of branches, smaller vasculature, and aneurysm shape and size. The inherent tortuosity of the thoracic aorta precludes two-dimensional image analyses to conduct migration assessment, other than gross device movement. Thus, digital data coupled with three-dimensional analysis tools are mandatory for this aspect of device reporting.

Initial screen for migration. A centerline of flow or central lumen line (CLL) pathway should be generated using a validated technique (automated, semi-automated or manual) to identify the center of the contrast-enhanced lumen. Images orthogonal to the CLL are used to identify

a proximal native vasculature reference point (LCCA, left common carotid artery) and distal reference point (CA, celiac artery). An intermediate stable anatomic landmark in closer proximity to the device may also be used (eg, a readily identified calcified plaque). The CLL distance between the LCCA and CA is assessed to determine the stability of the thoracic aortic length. If the length of the thoracic aorta is noted to be temporally stable, then additional CLL measurements can be calculated from these reference landmarks as described below. If the length is noted to be unstable or cannot be calculated, then an alternative migration assessment with local landmarks should occur (see next section). Assuming aortic length stability, the CLL distances are calculated from the LCCA or proximal anatomic landmark to the proximal stent tip (PST, most proximal visualization of the stent) and proximal stent circumferential (PSC, most proximal point where the full circumference of the stent is first seen). Similar measurements are taken from the CA or distal anatomic landmark to the distal stent tip (DST, most distal visualization of the stent) and distal stent circumferential (DSC, most distal point where the full circumference of the stent is first seen) appearance. A CLL length change in excess of 10mm of the PST and PSC from the proximal anatomic landmark implies proximal stent migration. CLL length changes in excess of 10mm of the PST or PSC (but not both) from the LCCA implies angulation of the proximal stent. CLL length measurement changes in excess of 10mm between the CA and DST and DSC implies migration of the distal stent, while CLL length alterations greater than 10mm to either the DST or DSC (but not both) implies angulation of the distal stent. Patients that meet any of the screening test endpoints listed above including migration or angulation of the proximal or distal stent should then undergo migration adjudication analysis.

Migration adjudication analysis. This analysis requires a visual assessment of the reconstructed aortic segment from which a specific fixed landmark (fiducial, or fixed point of comparison) must be identified within the aortic wall (eg, calcifications) or attached to the aorta or surgically implanted aortic prostheses (eg, hemaclips), in close proximity to the proximal or distal stent graft. If aortic landmarks are not present, an adjacent bony landmark may be used, but requires axial CT reformats in conjunction with a three-dimensional reconstruction in order to perform the evaluation. Distance measurements of the PST and PSC or DST and DSC to landmarks closer than the fixed arterial branches (LCCA or CA) will help to differentiate between global aortic length changes from device movement relative to the initial implantation site. Movement in excess of 10 mm from these local proximal landmarks to the PST and PSC, or distal landmarks to the DST and DSC implies device migration.

Methodology for measuring changes in neck dimension. Long-term aneurysm exclusion and device stabilization is dependent on the maintenance of an effective attachment and seal between the endograft and the host aorta. Therefore, dilatation of the aorta at the site or sites intended for primary endograft fixation may lead to treatment failure either with device migration or via the occurrence of a new endoleak with aneurysm expansion.[17,40,41]

Both diameter and cross-sectional area of the aortic neck at the sites intended for sealing or graft attachment are reportable parameters, and such measurements should be made using images reformatted to assess diameters perpendicular to the lumen or vessel centerline. In the rare instance that multiplanar CT reformats and 3-D reconstruction are not available, the smallest diameter (minor axis of the elliptical cross section) is generally the best approximation of the actual neck diameter.[2,3,40] This statement is not universally true, however, and assessment with axial images should be avoided. Notably, the outer perimeter of the aortic wall should be used as the reference point for all measurements. If the lumen diameter is the focus of the study, it may be reported in addition to the corresponding outer wall measurement. Modality, method, and definitions should be clearly described, and comparisons should only be made between identical sources (CT to CT, MR to MR).

Changes in the dimension of aortic branch arteries. Progressive angulation of the aortoiliac segment leading to distortions of the endograft can accompany reductions in aneurysm size for thoracic and thoracoabdominal aortic aneurysms. This may result in endograft disruption, stenosis, and branch or limb occlusion for hybrid de-branching limbs and for branched and fenestrated endografts. Alterations in branch artery angulation and size after endovascular grafting and the consequent responses of the prosthesis may be important determinants of outcome. At the time of this report, there are no standards for de-branching procedures, branched and fenestrated endografts. Reports directed at characterizing outcomes of interest for these procedures are encouraged, following general principles outlined for TEVAR thus far. Further potential considerations follow, pending more data for future reporting standards directed specifically at these issues.

Methodology for measuring changes in branch artery diameter and tortuosity. Three-dimensional image analysis with appropriate anatomic referencing is recommended for accurate determination of branch artery angulation. Measures derived from plain abdominal x-rays are discouraged, as variations in position, angulation, and equipment may have a significant impact on the reproducibility of derived measures. Definitions and categorization of iliac tortuosity and angulation have been detailed elsewhere, as have potential model methods for describing visceral branch arteries.[3,42]

Methodology for reporting sequential changes in aortoiliac morphology. After placement of an endovascular prosthesis, the local biomechanical and hemodynamic environments of the native aorta are altered. As a consequence, dynamic changes in morphology of the aorta and branch arteries can be observed over time. The rate, magnitude, and direction of this response will be influenced by properties inherent to the chosen device and host aorta. Capturing the time course and the direction of these asso-

ciated morphologic changes may be a direction for future research.

ENDOLEAK

Endoleak is defined by the persistence of blood flow outside the lumen of the endoluminal graft but within the aneurysm sac, most likely resulting from an incomplete exclusion of the aneurysm from the circulation, as determined by an imaging study.[43] To simplify the following discussion, the term "aneurysm" will be understood to imply any contained segment of aortic pathology that may dilate following endovascular repair. This definition is not directed at primary dissection, as continued perfusion of the false lumen is a special circumstance that may not be directly analogous to endoleak. For example, there may be a difference in outcome for proximal or thoracic false lumen thrombosis versus distal or abdominal false lumen thrombosis. The status of the false lumen is an area for potential clinical investigation, and may be addressed in a set of reporting standards directed specifically for dissection.

Classification of endoleak. An endoleak can be classified according to time of occurrence relative to the operative procedure and site of origin.[2,43,44] An endoleak first observed during the perioperative (≤30 days) period is defined as a primary endoleak, and if the initial detection occurs more than 30 days following the procedure (or on the second postoperative study) it is termed a secondary endoleak.[2,43,44] The reappearance of an endoleak either after spontaneous resolution or after an intervention that was considered successful is defined as a recurrent endoleak. Further categorization requires precise information regarding the course of blood flow into the aneurysm sac. The definitions of endoleak types are well known and can be summarized as (Table VI):

Type I:

A – Leak at the proximal graft attachment site

B – Leak at the distal graft attachment site

C – Leak around a branch occluding plug (eg, occluding a subclavian artery arising from the aneurysm sac to prevent Type II branch flow into the sac)

Type II: retrograde flow from branch arteries arising from the excluded segment

Type III:

A – Modular Disconnect

B – Fabric tear

Type IV: Flow through porous fabric (generally resolves within a short time period, typically less than 24 hours)

Type V: No detected endoleak, but aneurysm expansion (thus presumed failure to detect the endoleak or presumed pressure transmission through thrombus without bloodflow)

Methodology for measuring the presence, source, magnitude, and physiologic significance of endoleak and endotension. Endoleak detection is most commonly performed using a contrast-enhanced CT scan, which may require comparison to a noncontrast imaging study. CT imaging may fail to identify an endoleak if delayed-contrast images are not obtained after infusion of contrast medium.[45] MR imaging, especially delayed imaging with gadolinium or blood-pool contrast enhancement, has been reported to be particularly sensitive and useful as a means of detecting endoleak.[46,47] The sensitivity and specificity of available imaging methods for endoleak detection have not been characterized well, in part because some stent grafts are not MR-compatible. Dynamic CT or dynamic MR can quantify aneurysm morphology over time, and have been suggested as another means to evaluate for potential sac pressurization.[48-50] Reports involving dynamic CT or MR should describe the methods in detail, including slice thickness, gating methods, volume covered, and radiation dose.

Although intra-sac pressure may approach systemic arterial pressure in the presence of an endoleak, some type II endoleaks have been associated with shrinking aneurysms and intrasac pressures that are substantially less than systemic values.[51] If pressure measurement techniques are utilized, details regarding the specific method by which the measurements were obtained as well as their relationship to systemic pressures should be provided.

Characterizing the frequency of endoleak in a study population during a defined observation period. Reports should include the prevalence (%) of endoleak over the duration of the implant period. Endoleaks must be stratified by:

1) time of endoleak occurrence (primary, secondary, recurrent);
2) site of endoleak origin;
3) the proportion of patients with an endoleak and confirmed aneurysm expansion; and
4) the proportion of patients without detectable endoleak with demonstrable aneurysm expansion (ie, possible endotension).

The number of patients available for analysis must be specified at each time point.

In characterizing the absence of endoleak at any time during a study period, life table or Kaplan-Meier analysis should be used for data presentation, as in "freedom from endoleak or endoleak-free survival". In order to allow comparison of studies with pre-discharge studies and studies only at 30 days, life tables for endoleak may start at the 1 month post-operative CT scan. In this regard, primary, assisted primary, and secondary "absence of endoleak" curves, which are distinguished on the basis of whether or not a secondary surgical or catheter-based intervention was performed, can be used to assess the role of endoleak-directed intervention, but these should alter the life table whether within the first 30 days or not. In this manner, early interventions are not missed or under-reported.

CATEGORIZATION OF ENDOGRAFT CONFIGURATIONS AND COMPONENTS

Precise description of the configuration, modularity, fabric, support, and fixation structures of the endograft system should be provided, if not detailed elsewhere, in

addition to an accounting of all adjunctive components, devices, and maneuvers. Recommendations regarding uniform reporting of device configuration and components are outlined in Table III.

Configuration: Location, length, modularity, and diameter

Location and zones of attachment. The location of attachment relates to the risk and complexity of the procedure as well as component selection and stresses on the devices. A system is already in place to describe the proximal zones of attachment, originally proposed to describe the ascending aorta, arch and proximal descending aorta (Zones 0-4).[11,12] Reporting the proximal attachment Zone is particularly important when reporting neurologic outcomes, as cerebrovascular outcomes appear to be related to the proximal attachment site Zone.[11,13] Both the proximal and distal attachment zone likely affect patient risk, device selection, complexity of the procedure and stresses on devices,[14] so an extended zone system is described here that allows for a complete description of both proximal and distal attachment site by zone. See Fig 1 in the on-line appendix in addition to the following text.

Proximal attachment zone. Proximal endograft attachment site, defining the proximal edge of covered endograft. Zone 0= the proximal edge of the covered endograft is proximal to the innominate artery origin; 1= distal to the innominate but proximal to the left common carotid artery origin; 2= distal to the left common carotid but proximal to the subclavian artery; 3= within 2 cm of the left subclavian artery without covering it; 4=proximal extent of the endograft is >2 cm distal to the left subclavian artery and ends within the proximal half of the descending thoracic aorta (T6 approximating the mid-point of the descending thoracic aorta); 5= starts in distal half of the descending thoracic aorta but proximal to the celiac artery; 6=celiac origin to top of SMA; 7=SMA origin, suprarenal aorta. For devices with bare stents, it may be useful to differentiate the covered and noncovered endpoint.

Distal attachment zone. Distal endograft attachment site, defining the distal edge of covered endograft. Zones 4=distal extent of the endograft is >2 cm distal to the left subclavian artery and within the proximal half of the descending thoracic aorta (T6 approximating the mid-point of the descending thoracic aorta); 5= ends in the distal half of the descending thoracic aorta but proximal to the celiac artery; 6=covers celiac, ends proximal to SMA; 7=covers SMA, ends proximal to renal arteries; 8=covers at least 1 renal artery; 9=infrarenal; 10= common iliac; 11=external iliac. For iliac arteries, the zone can be reported separately or by the most distal site (eg, if one side ends in the common iliac artery and the other ends in the external iliac artery, use zone 11). For devices with bare stents, it is useful to differentiate the covered and noncovered end point.

For extensive repairs, the status of both internal iliac arteries should be reported (patent, chronically occluded, coiled/covered by the repair). Note also that by using a definition that T6 approximates the mid-point of the descending thoracic aorta, the "zone" system can be used to correlate with the traditional Type I-IV Crawford-type classification system, but with more precision.

Alternatives. Alternatively, the distal attachment location may be reported relative to the anatomic segment, namely descending thoracic aorta (proximal half, distal half), the visceral aortic segment (describing the branches that are covered), the infrarenal aorta, the common iliac or external iliac arteries. For extensive repairs, the status of the internal iliac arteries should be reported (patent, chronically occluded, coiled/covered by the repair). In general, it is best to be as specific as possible when reporting anatomic coverage (zones of attachment) or use more traditional classifications (Crawford classifications).

Length of coverage. Length of coverage is a risk factor for paraplegia, and is thus of interest in TEVAR reports. Length of coverage may be recorded in terms of absolute length (cm) or the proportion of coverage of the descending thoracic aorta. For example, the coverage may be described as less than one-third of the descending thoracic aorta, one-third to two-thirds, or greater than two-thirds of the descending thoracic aorta. Beyond such descriptions, the start and endpoints using the Zone designation (see above) is also a potential method to determine the length of coverage. The best method to report length of coverage is not yet determined, but one of these methods should be used.

Modularity. Endografts should be categorized as comprised of a single endograft or modular components, which are assembled in situ within the vasculature of the patient. Modular grafts must have overlapping junctions between components. Any methods utilized to enhance or alter the attachment of one component to another should be reported (eg, staples, balloon-expandable stents, etc). If a standard method of overlapping is used (eg, a minimum length in cm or always overlapping devices completely within the sac), it should be reported.

Diameter. When the diameter of the graft is reported, the largest and smallest diameters of the aortic graft(s) may be of interest. Such reports should describe whether the device is straight or tapered (in which case both the largest and smallest diameters are reported) and whether multiple devices are used (in which case the various aortic devices may have a range of sizes). In such cases the largest and smallest devices for the individual repair may be described, or a standard taper configuration may be reported (eg, 4 mm from top to bottom) or a standard diameter change between components may be described (eg, no more than 4 mm difference between components).

Configuration: Branch treatments including branched endografts. The newest and most complex issue in reporting TEVAR stent graft configuration is for branch vessel treatment. The aortic stent graft configuration may be modified in a number of ways to treat aortic branch vessels. The term "scallop" refers to a portion of aortic graft material removed to accommodate an aortic branch at the proximal or distal end of the aortic repair, thus allowing some fabric to extend further proximally or distally than a simple cylindrical configuration would allow. The term

"fenestration" or "fenestrated" may be used to indicate the presence of openings purposely created within the endograft to allow perfusion of visceral or brachiocephalic arteries in the region otherwise covered by the aortic endograft. If uncovered stents are placed within fenestrations, the frequency should be noted and designated by a term such as "stented fenestrations". If a stent graft is placed within a fenestration, but not required for sealing, the proper term would still be stented fenestration. Thus, the prefix "branched" is only used for aneurysms that involve a target vessel whereby the use of mating stent grafts are required to form a seal. The prefix "branched" is used to indicate the presence of stent graft side-arms intended to connect the primary aortic endograft to visceral, renal, or brachiocephalic arteries in the region otherwise covered by the aortic endograft. The implication is that a stent graft branch is required for sealing across a gap between the primary aortic endograft and the target visceral or arch vessel (ie, a fenestration or stented fenestration would allow flow or pressurization of the aneurysm sac). A "fenestrated branch" seals into a fenestration which has been reinforced to allow sealing, and a "side-arm branch" implies a side-arm has been sewn onto the aortic stent graft component to allow sealing. The type of branch should be reported, as well as whether the branch is oriented antegrade or retrograde. For branches and fenestrations, the vessels intended to receive scallops, fenestrations, stented fenestrations or stent grafts should be described, as well as the total number of stent grafts or stents required.

Other treatments for aortic branches may affect the primary aortic stent graft(s). As such, they must be reported, and the definition is included with graft configuration even though the treatment may not technically modify the primary aortic endograft configuration. Branch treatments include debranching of the visceral or arch vessels. De-branching is defined as a procedure in which a surgical bypass is performed to originate perfusion of the aortic branch artery from a location that will not be covered by the intended aortic stent graft (eg, iliac-renal bypass, carotid-subclavian bypass). The other commonly described branch treatment is the placement of a stent or stent graft in an aortic branch artery that is covered or partially covered by the aortic stent graft, typically referred to as the "chimney" or "snorkel" technique. With these treatments, the report should include the number and type of stents, stent grafts or grafts utilized, and whether the treatment was planned or unplanned.

Endograft fabric. The nature of the graft material should be identified. For example, the material may be expanded polytetrafluoroethylene, knitted or woven polyester fabric, some other material, or combination thereof. If a change in fabric composition occurs over the study period, the "generation" of the fabric should be noted.

Support system. For the initial report of a new device, the nature of the support system of the device also should be defined. Reports should state whether the system fully or partially supports the graft, whether it is balloon expandable or self-expanding, luminal or abluminal in relation to the fabric, and whether the supporting framework is fixed to the graft with stitches or otherwise incorporated within the graft. Likewise, the geometric configuration and the material composition of the metallic stent framework should be specified. Nonstandard alloys should be described. Subsequent reports may reference the initial report of the device structure, but must note any modifications of the device.

Fixation components and techniques. Reports should specify whether graft fixation is achieved with a component that is an integral part of the support skeleton or a separate or unique element of the endograft system. The geometric configuration of these components should be described, including whether hooks, barbs, screws, pins, scales, or other means are used and whether fixation is to be achieved with balloon or self-expanding stents or by a means separate from endograft deployment. Finally, the intended placement of a fixation system, proximal or distal to vessel orifices (eg, subclavian artery) should be noted.

Endograft extensions and intraluminal stents. The nature of adjunctive devices to assure proper fixation, sealing, patency, and positioning of the endograft should be described. For example, reports should include details of graft extensions and the use of adjunctive intraluminal balloon expandable or self-expanding stents or stent grafts, unplanned stent graft components of another manufacturer, extensions that would not be typical of the device, and unplanned extensions.

Graft sizing relative to the native aorta. The amount of graft over-sizing relative to the host artery diameter at the intended fixation sites should be reported, because this may affect attachment and sealing. The degree of oversizing should be reported as an absolute number and/or as a range and average percent of oversizing. It should be specified as to whether oversizing is relative to the vessel lumen or to the outer vessel wall. If over-sizing is reported relative to the lumen, the report must specify the acceptable threshold of thrombus, noncalcified plaque or calcified plaque in terms of both thickness (mm) and circumference (as a percentage of the total circumference).