

# Guidelines for Development and Use of Transluminally Placed Endovascular Prosthetic Grafts in the Arterial System<sup>1</sup>

Frank J. Veith, MD, William M. Abbott, MD, James S.T. Yao, MD, Jerry Goldstone, MD, Rodney A. White, MD, Dorothy Abel, Michael D. Dake, MD, Calvin B. Ernst, MD, Thomas J. Fogarty, MD, K. Wayne Johnston, MD, Wesley S. Moore, MD, Arina van Breda, MD, George Sopko, MD, Paul Didisheim, MD, Robert B. Rutherford, MD, Barry T. Katzen, MD, and D. Craig Miller, MD, for the Endovascular Graft Committee<sup>2</sup>

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THE feasibility of placing prosthetic grafts within the arterial tree by inserting them via a remote site, guiding them intraluminally to the appropriate location, and fixing them there with attachment systems, such as a variety of expandable stents, has been demonstrated in animals and human subjects (1-3). There is a potential for these transluminally placed endovascular grafts (TPEGs)<sup>a</sup> to provide improved

treatment for a variety of arterial lesions including aneurysms, traumatic injuries, and arteriosclerotic occlusions. TPEG repairs of all three kinds of lesions have been carried out at various levels of the arterial tree with short-term success (1,4-17). Because TPEG repairs can be performed less invasively, their risks and costs may be less than those of standard vascular graft operations. They will, therefore, be extremely attractive to both patients and physicians, and consequently there will be enormous pressures to develop and use these devices rapidly.

The purpose of this document is to foster the development of safe, effective devices for performing TPEG repairs of various arterial lesions at all levels of the arterial tree. To this end, it will provide guidelines for the careful and structured evaluation and monitoring that is necessary to document the safety, efficacy, and effectiveness<sup>b</sup>

of these devices in various settings before they undergo widespread clinical use. Although these guidelines are not a regulatory document, they are intended to help avoid premature and potentially harmful usage of TPEGs.

## GENERALITIES

### Types of TPEGs

TPEGs can be divided into those that are *covered single stent devices*<sup>c</sup> and *end fixation devices*, which comprise a prosthetic graft fixed with a stent or other attachment system at both ends. Variants of the latter are bifurcated Y grafts or branched grafts with attachment devices at all three ends and long grafts stented at one end and with no stent or a suture anastomosis at the other end. Further division of TPEGs can be based on the *characteristics of the device*, specifically (a) the nature of the delivery system (eg, sheath/no sheath, over a wire/not over a wire, etc), (b)

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<sup>1</sup> These guidelines have also been published in the *Journal of Vascular Surgery* 1995; 21:670-685. **Address correspondence to** F.J.V., Department of Surgery, Montefiore Medical Center, 111 E 210th St, New York, NY 10467-2490.

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<sup>2</sup> See Appendix.

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<sup>a</sup> At present, these include a variety of graft-stent combinations. However, these guidelines apply to other devices that will have or develop blood impervious walls and that may be inserted via intraluminal routes to provide prosthetic support or replacement of a diseased arterial wall. Devices that involve autologous tissue (eg, stents and a vein graft) are also a variety of TPEG. Another variety is TPEGs used in the systemic and/or portal venous systems. Although some generalities in these guide-

lines apply to these autologous and venous TPEGs, they will not be dealt with specifically in this document. Throughout these guidelines the terms TPEG, stented graft, and stent graft are used interchangeably, although it is recognized that TPEG has a broader meaning since not all of these devices will necessarily include a stent component per se.

<sup>b</sup> *Safety* is defined as freedom from complications or intrinsic device failure; *efficacy* is defined as the ability of the device to restore the vascular wall and luminal integrity, to prevent aneurysm expansion and rupture, or to maintain luminal patency; and *effectiveness* is defined as the ability to extend patient

survival and limb or organ function by preventing aneurysm expansion and rupture or by maintaining arterial flow through the diseased segment of the artery.

<sup>c</sup> A covered single stent is one to which a prosthetic graft, which is or will become impervious to blood, is fixed so that the graft covers a portion or all of the internal or external surface of the stent after its expansion within a blood vessel. Some devices of this variety may incorporate stent-like components within a graft matrix to provide an *integrated unit*; others may consist of a stent alone that becomes impervious to blood.

the nature of the *attachment or fixation system and method* (balloon-expandable, spring-expandable, and/or mechanically expandable stent or other device, with or without hooks for fixation to the vessel wall, etc), and (c) the nature of the *graft or covering material component* (knitted polyester [Dacron]<sup>d</sup>, woven polyester [Dacron]<sup>d</sup>, polytetrafluoroethylene [PTFE] or other developmental prosthetic material).

### Usage Categories

Because different characteristics and properties of TPEGs may be required to treat different forms of arterial pathology in different parts of the arterial tree, usage must be defined based on *lesion location* and *lesion pathology*. Safety, efficacy and effectiveness must at least be considered separately for each device and each usage. This document provides guidelines for evaluating TPEGs according to usage categories defined by the following vessel sizes and locations: the *thoracic and suprarenal aorta, large arteries* (infra-renal aorta, iliac, innominate, common carotid and subclavian), and *medium-sized arteries* (femoral, popliteal, axillary, visceral, renal, coronary, vertebral, and carotid bifurcation and branches<sup>e</sup>) and for devices to be used to treat (a) aneurysms, (b) traumatic lesions (false aneurysms, arteriovenous fistulas, mural injuries), (c) stenotic and occlusive lesions, and (d) dissections and intramural hematomas.

Usage categories other than these may be required based on pathologic, anatomic, or physiologic characteristics of the patient or lesion being treated. For example, some aneurysmal, traumatic, or ulcerating atherosclerotic lesions may cause distal embolization as their only manifestation. The suitability of such lesions for

TPEG treatment might need to be evaluated separately.

For purposes of demonstrating safety, efficacy, and effectiveness, each specific device should be considered for evaluation in a specified sized artery in one or more locations with similar defined pathology. However, it is possible that a given device will be safe and effective in several different-sized arteries, in different locations and even for the treatment of different types of lesions. Accordingly, it will be acceptable to evaluate and demonstrate safety, efficacy, and effectiveness of a given device by studies in which that device is used in more than one location or for more than one type of lesion. In such circumstances a satisfactory rationale and justification for combining usage categories must be provided. All studies should be designed to demonstrate statistically valid conclusions within one or more subdivisions of this categorization system.

### Requirements for Developmental and Testing Centers

Because TPEGs require vascular surgical skills and catheter, guidewire, and imaging skills to insert and deploy, the clinical teams involved in their development and initial testing in patients should consist of individuals with the highest levels of expertise in both these modalities.<sup>f</sup> This means that individuals possessing skills and experience in vascular surgery<sup>g</sup> and interventional radiology must be involved in and responsible for the efforts of these developmental centers. Usually this combination of skills will require two or more individuals, a vascular surgeon and an interventional radiologist, who work smoothly together as a team, although it is possible that one individual will possess

the requisite skills and experience to perform all parts of the procedure. It is recommended that developmental or research centers testing these devices be staffed by integrated teams of vascular surgeons and radiologists, coordinated by a single individual who is familiar with vascular pathology and natural history and all standard treatment alternatives and who bears overall patient responsibility. To deal optimally with unexpected problems, procedures carried out on patients should be performed in a procedural room that is equipped with digital imaging fluoroscopy and that has all the appropriate equipment and personnel to carry out open arterial operations. In the light of current designs, approaches, and clinical experience and because the possibility that large artery injury, occlusion, or rupture may require immediate emergency operation, procedures conducted on the thoracic or abdominal aorta, the iliac arteries, or other aortic branches should be performed in a room that has appropriate imaging devices and equipment and staff to carry out emergency major vascular or cardiovascular surgery. (See Requirements for Facilities in Which TPEGs Should Be Used Clinically for further details regarding equipment.)

In addition, these centers should have inpatient radiological and vascular surgical services experienced in performing the full range of standard arteriography, catheter-directed angioplasty and stent placement, and all vascular and cardiothoracic operations. They should also have the outpatient facilities, noninvasive vascular diagnostic laboratories, radiology services and support staffs to perform the high-quality imaging techniques needed for accurate and thorough patient follow-up evaluation. Centers involved in these studies must demonstrate a commitment to long-term follow-up.

### Comparison between TPEGs and Standard Arterial Grafts and Stents

It should be recognized that some properties of TPEGs may differ from those required of standard grafts or stents used to treat similar lesions in similar locations. Because TPEGs will be inserted from a remote site and guided into position, there are clear

<sup>d</sup> Dacron is a registered trademark of E.I. duPont de Nemours. It refers to the polyester, polyethylene terephthalate. Throughout these guidelines the generic term, "polyester," will be used for this material.

<sup>e</sup> Coronary, carotid, and vertebral devices will have special problems relating to the end organs they supply and technical challenges to obtain access. Appropriate monitoring of end organ function, such as the heart or brain, will be required with devices used in these arteries.

<sup>f</sup> Separate training and credentialing guideline documents for individuals who can perform vascular surgery and endovascular procedures have been prepared by various specialty organizations (18–23). The general principles expressed in these documents should also apply to the present guideline document.

<sup>g</sup> Procedures performed for lesions of the thoracic aorta may require the participation of individuals skilled and credentialed in cardiothoracic surgery, especially if it appears that cardiopulmonary bypass may be necessary to manage device complications.

advantages to reducing their unexpanded cross-sectional diameter or "profile" as much as possible. In this way, the requirement that they be introduced through an open arteriotomy in a large-caliber artery will be minimized. Thus, devices with a low profile offer clear advantages in terms of feasibility and applicability. However, making the TPEG thin and flexible to achieve a low unexpanded profile may require a thinner graft with reduced strength.

Currently it is not known whether or not TPEGs need the same burst strength and/or porosity characteristics as a standard arterial graft. A TPEG that will be placed within the unsupported lumen of an aortic aneurysm must have adequate strength and durability to withstand aortic pressures and flows, although it may not have to meet the same safety factors required of standard aortic grafts with regard to these parameters. In addition, a TPEG intended for use in the treatment of unruptured aneurysms may not require the same porosity specifications as a standard graft used to treat the same condition. Since the endoluminally inserted device will be contained within the intact aneurysm sac, greater porosity may be tolerable since transinterstitial bleeding will be contained by the aneurysm wall until fibrin deposition occludes the pores. Moreover, a TPEG placed within a stenotic or occluded artery may receive structural support from the surrounding arterial wall, thereby allowing the use of grafts with different physical properties (eg, decreased wall thickness and strength). Long-term experimental and clinical studies will be required to settle these issues. In contrast, some endoluminally placed grafts may require unusual characteristics not needed with standard grafts. Examples would be physical properties that contribute to an intact and fixed friction seal at junction points with host arteries, to developing rapid and secure impermeability to blood in ruptured aneurysms and traumatic arteriovenous fistulas, or to resisting compression when a TPEG is placed within occluded arteries.

## DEVELOPMENTAL STUDY PROTOCOLS

When TPEGs and appropriate systems for their insertion are developed

and are thought to be suitable for treatment of specific lesions in specified locations, the following general guidelines are recommended for pre-clinical and clinical testing, *before* the devices are brought into widespread usage. For any device, the evaluation must consist of four phases: bench testing, (structural/mechanical), pre-clinical (animal) testing, clinical testing-feasibility, and clinical testing-comparative performance. However, in identifying appropriate testing for any device, consideration must be given to the mode(s) of failure and its/their effect on the performance of the device.

### Bench Testing

For the *graft portion* of the device, this should consist of essentially the same tests of physical properties, such as strength, durability, porosity, kink resistance, suture holding ability<sup>h</sup>, flexibility, longitudinal and radial stretchability, etc, as are required for a currently standard or a proposed new arterial prosthesis (24–26). The possibility also exists that modified requirements may need to be developed for new graft materials that may be developed and used for TPEGs. In addition, the *stent portion* or *attachment system* of a TPEG device will have to be evaluated for the various characteristics important to its function, for example, inertness in blood, lack of toxicity, absence of metal fatigue, flexibility, compression resistance, and other physical properties that contribute to a leak-proof seal and secure fixation at junction points with arteries (27). Finally, the *delivery system* of a device will require bench testing to demonstrate appropriate maneuverability, kink resistance, radiopacity, and marker visibility, etc, to be effective in the clinical setting in which it will be used.

### Animal Testing

Successful animal implantation of all TPEG devices, with use of the same introduction systems and localization and deployment methods that will be used in patients, should be required before clinical trials can be under-

taken. Successful implantation includes the ability to visualize and deploy the device with techniques similar to those that will be required in patients; the firm fixation of the device at the site of original implantation; and acceptable freedom from leakage, migration, vessel wall erosion, thrombosis, excessive intimal hyperplasia with luminal narrowing, and distal embolization. There should also be acceptable freedom from other complications related to the fixation component or stent, particularly those with hooks or spikes. The duration of observation in animal testing should be for a minimum of 6 months before clinical tests can be undertaken. Longer studies may be needed if synthetic materials not currently in use in the vascular system are involved.

The TPEG should be inserted in animal models at anatomic locations similar, although not necessarily identical to, those intended for use in patients. Every effort should be made to use animal models that mimic as closely as possible the clinical problem being addressed. Device insertion techniques and endpoints studied should parallel those that will apply in the clinical setting as much as possible. Imaging techniques, such as angiography or intravascular ultrasound (IVUS), that provide visualization and localization of the fixation device and the graft are important parameters to evaluate in these studies.

It is recognized, however, that animal models have several limitations in evaluating TPEGs. First, the commonly available large animal models (dogs, pigs, or sheep) have arteries that are smaller than comparable arteries in man. Calves are larger and their arteries better approximate the size of human arteries, but their rapid growth limits their utility for anything other than short-term studies. Second, it is not possible to produce in animals arterial lesions that are comparable to those in patients, with the possible exceptions of traumatic arteriovenous fistulas, false aneurysms, and aortic dissections (28). Although animal models with fusiform polyester cloth aneurysms have been described (2,3,29,30) and have some limited applicability, good models of true aneurysms and arteriosclerotic occlusive disease do not exist. Accordingly, animal studies have limited applicability

<sup>h</sup> If an open surgical anastomosis may be required at one end.



in predicting the outcome of TPEGs in treating some human arterial lesions. Furthermore, it may be necessary to test some devices in more than one animal model to address all concerns (eg, long-term study of implants in dogs with acute studies in calves to study clinical-sized devices). All animal studies should include gross and histologic evaluation and, if possible, angiographic evaluation, contrast-enhanced computed tomography (CT), magnetic resonance (MR) imaging, and/or IVUS to document device, luminal, and arterial wall morphology and relationships.

All the animals involved in these studies must receive humane care in compliance with the "Principles of Laboratory Animal Care" formulated by the National Society for Medical Research and the "Guide for the Care and Use of Laboratory Animals" prepared by the National Academy of Sciences.

### Clinical Testing

Clinical testing must demonstrate the safety, efficacy, and effectiveness of TPEGs in the treatment of human arterial diseases. Separate studies may be needed for each usage category and each artery size and lesion described previously. However, it is possible that some devices will be suitable for treating multiple categories of lesions. Therefore, it may be appropriate to combine lesion sites and pathologic categories for clinical testing when this can be supported and justified. This is particularly likely when treatment of uncommon lesions is being considered. Clinical testing will be divided into two phases: feasibility testing and comparative performance testing.

**Feasibility testing.**—Feasibility testing should demonstrate that insertion of a TPEG device is possible in a given disease state in a given location and that the device functions safely and effectively for at least 6 months. These tests must include comparative pre- and postprocedural noninvasive measurements of the distal circulation and, in the case of aneurysms, their size before and 3 and 6 months after TPEG placement. These measurements include (a) lower extremity segmental systolic pressures and pulse volume recordings

(or Doppler waveform measurements) and (b) ultrasound (US), contrast-enhanced CT, MR imaging, and/or IVUS measurements of aneurysm size.<sup>i</sup> They must be available in at least 10 patients and should be supplemented by appropriate imaging studies to demonstrate device patency, confinement of flowing blood to the graft lumen, and freedom from leakage, migration, and aneurysm enlargement.<sup>j</sup> Preplacement, completion, and 6-month postplacement arteriographic confirmation should be provided in at least one-half of the patients and preferably in all. However, if other less invasive modalities can provide accurate equivalent information, arteriographic study may be unnecessary.

There are two types of *feasibility studies*. In both, protocols should be consistent with Institutional Review Board (IRB) and Food and Drug Administration (FDA) standards and regulations.

In the first type of feasibility study, *standard usage*, the TPEG treatment is offered to patients who are candidates for standard operative abdominal aneurysm repair (31), standard operative graft or balloon angioplasty/stent treatment of occlusive lesions, or standard surgical repair of traumatic lesions or peripheral aneurysms for the usual indications. In this setting, the patient must be prepared for and willing to undergo the standard procedure if the TPEG placement is impossible or unsuccessful or has a complication. In general, if the aorta or iliac arteries are involved or if limb salvage is the indication, patients undergoing these initial TPEG procedures should have them performed in a location that is equipped and staffed for emergency operative repair.

In the second form of feasibility study, *high-risk usage*, patients who are unsuitable for or at high risk for the standard treatment may be offered the new TPEG treatment as an

option.<sup>k</sup> In the case of abdominal aneurysm repair, these can be patients with large threatening aneurysms whose operative risk is excessive (ie, in excess of three to four times normal) on the basis of cardiac, pulmonary, or hepatic disease or previous abdominal scarring or infection (31). In the case of occlusive lesions or peripheral aneurysms, the same risk factors and the presence of limb-threatening ischemia or a large aneurysm could be considered an indication to offer TPEG placement as a therapeutic option.

**Comparative performance testing: clinical trials.**—This phase of evaluation is designed to show that the TPEG device will perform essentially equivalent to or significantly better than standard treatment. There are several ways to test safety, efficacy, and effectiveness and to show equivalence or superiority. It is not the purpose of this document to specify how a clinical trial of a new TPEG device should be designed and conducted. This has been discussed in a recent editorial (32). However, such trials should be conducted in a fashion that is scientifically sound and that provides statistically valid data relating to the important criteria to be described below for the various usage categories. When it is feasible and appropriate, these studies should be designed to permit a valid comparison of the safety, efficacy, and effectiveness of a new TPEG device and current standard treatment(s) of similar arterial lesions in similar patients. In other circumstances, when it may not be feasible or in the interests of patients to obtain such valid comparative performance data, the clinical trial study protocol should clearly indicate the reasons for this and provide an acceptable alternative method for testing the hypotheses posed in the study and/or docu-

<sup>i</sup> These measurements should permit accurate definition of wall, clot, and lumen (flowing blood) dimensions.

<sup>j</sup> In the descending thoracic aorta, transesophageal echocardiography may be useful for these evaluations.

<sup>k</sup> There is some disagreement over the ethical merits of demonstrating feasibility in patients for whom no surgical rescue procedure is available if the untested device fails. These guidelines cannot resolve this disagreement. Ideally, some prior experience or other evidence should be available to suggest feasibility before high-risk usage of a new TPEG device is undertaken. High-risk usage protocols must have risk factors or criteria clearly defined and objectively documented to avoid overly liberal use.

menting the safety, efficacy, and effectiveness of the new TPEG device.<sup>1</sup>

Those responsible for the clinical trials of new TPEG devices should consult the appropriate office at the FDA (Office of Device Evaluation) prior to the design and conduct of a trial. By doing so, the investigator will become familiar with the requirements and recommendations of the FDA for premarket approval of a new medical device and how to design an appropriate trial that is likely to yield valid conclusions about the clinical performance of the TPEG device.

In general, the format recommended throughout these guidelines will entail (a) a *feasibility study* of at least 10 patients observed for 6 months, followed by (b) a *comparative performance study* with an adequate number of patients in the device test group followed up postprocedurally to allow statistically valid comparisons after 1–2 years with standard treatment in similar patients with similar stages of the disease process.<sup>m</sup> Comparative performance studies should include the primary criteria listed in **Table 1** with regard to procedural (30-day) morbidity and mortality and 1–2-year device safety and efficacy. The results should allow statistically valid and biologically meaningful conclusions indicating whether a given device provides results that are better than, worse than, or equivalent to standard treatment as measured by these criteria. Demonstration of statistically significant equivalence between two treatment groups may require unacceptably large numbers of patients so that comparative studies should be designed to show statistically signifi-

cant differences between the TPEG and standard treatment or *essential equivalence*, that is, no grossly apparent difference.

Every effort must be made in all clinical stages of testing to obtain postmortem examination of patients who die from any cause to determine the cause of death and to perform a complete explant analysis including a gross and microscopic examination of the device and the sites of device implantation and fixation to determine the morphology and histology of the proximal and distal vessel and of the aneurysm or other arterial lesion being treated.

It is recognized that some comparative performance trials may, when appropriately justified, evaluate a specific TPEG device in more than one location and/or for treatment of more than one type of lesion. However, since device requirements for different lesions and different locations may vary, the crucial data to be collected or criteria for seven distinct major types of trials are described separately in **Table 1** and the following text sections. These seven major types of trials are 1) infrarenal aortic aneurysms (tubular device required); 2) infrarenal aortic aneurysms with no distal neck or with iliac aneurysms (bifurcated device required); 3) peripheral aneurysms (femoral, popliteal, or other); 4) traumatic arterial lesions (false aneurysms, arteriovenous fistulas, or mural injuries); 5) iliac artery (common and external) occlusive disease with or without involvement of the distal aorta; 6) femoral and/or popliteal artery occlusive disease; and 7) descending thoracic aortic pathology (aneurysms, dissections, and traumatic injuries). Other data that should be collected and analyzed in addition to those listed in **Table 1** are duration of the procedure, time spent in an intensive care unit, length of hospital stay, and the number of units of homologous blood transfused. Systemic complications of these procedures (defined in **Table 2A**) and device-related failures or complications (defined in **Table 2B**) must also be documented and analyzed.

It is possible that other types of clinical trials will be required in other settings or with specific subgroups of patients. These other trials

can be based on the seven major types of trials described below.

### **Abdominal Aortic Aneurysm (Infrarenal): Tubular Devices**

Adequate data must be collected so that, after a group of patients<sup>n</sup> are treated with the TPEG device and compared to patients treated with standard operative repair with a prosthetic graft, it can be determined that the groups being compared are similar except for the form of treatment.

*Preprocedural data* should be collected on age, sex, ethnic origin, height, weight, diabetic status, cardiac function and risk factors, pulmonary function and risk factors, hepatic and renal function, hematologic values, lower extremity pulse status and ankle/brachial indexes (ABI), and previous abdominal operations and scars (**Table 3**). CT, MR imaging, US, and/or arteriography should be performed and data acquired with regard to aneurysm length and transverse and anteroposterior diameters; the extent and dimensions of intraluminal clot and flowing blood; the diameter, length, and degree of calcification of the normal infrarenal aortic segment (ie, the proximal and distal aortic “neck” or “cuff”); the diameter and tortuosity of the common and external iliac arteries (supplement with diagram); and the location and relationship to the aneurysm of patent renal arteries, lumbar arteries, and the superior and inferior mesenteric arteries. These data may be supplemented by MR imaging or CT three-dimensional aortic reconstructions showing aneurysm, neck, and branch morphology, including a definition of the areas occupied by intraluminal clot and flowing blood.

*Intraprocedural data* should be collected regarding the site of device placement, including that of the proximal and distal attachment, if appropriate, relative to the aorta/aneurysm; the relationship of the device, its stented and unstented portions, and its covered and uncovered portions to patent arter-

<sup>1</sup> In some exceptional circumstances in which no satisfactory treatment exists, a high-risk-usage study of a TPEG device may constitute appropriate evidence for the manufacturer to obtain approval to market and sell the device for a specific indication. An example would be use of a TPEG device in the treatment of a central arteriovenous fistula or false aneurysm in patients who would otherwise require a thoracotomy or laparotomy for standard surgical repair and in whom intercurrent heart and/or lung disease precludes administration of general anesthesia or makes its risk prohibitive.

<sup>m</sup> It is recognized that standard treatment group parameters may best be represented by a range of reported values. TPEG and standard treatment groups of patients must have equivalent systemic risk factors and disease morphology and complexity.

<sup>n</sup> Patient selection criteria will be based on device characteristics. However, all patients must be suitable candidates for standard operative repair of their aneurysm and must have appropriate indications for such a repair.

**Table 1**  
**Important Study Criteria for Each Category of Arterial Lesion/Location**

Study Criteria	Infrarenal AAA Tubular Device	Infrarenal AAA with Iliac Aneurysm Bifurcated Device	Peripheral Aneurysm Tubular Device	Traumatic Arterial Lesions	Aortoiliac Occlusive Disease	Femoro-popliteal Occlusive Disease	Descending Thoracic Aorta
Procedural mortality	++	++	+	+	+	+	++
Complications*							
Myocardial infarct	++	++	+	+	++	++	++
Other cardiac	++	++	+	+	++	++	++
Pulmonary	++	++	+	+	++	++	++
Renal failure	++	++	+	+	++	++	++
Bowel ischemia	++	++	—	—	++	—	++
Bowel obstruction	++	++	—	—	++	—	—
Procedural failure†	+	+	+	+	+	+	+
Leak	++	++	++	++	++	++	++
Device migration	++	++	++	++	++	++	++
Embolism	++	++	++	++	++	++	++
Thrombosis	++	++	++	++	++	++	++
Inadequate function‡	++	++	++	++	++	++	++
Limb loss	+	+	++	++	++	++	+
Paraplegia or paraparesis	+	+	—	—	—	—	++
Other‡	++	++	+	+	+	+	+
Mortality from rupture	++	++	—	++	++	—	++
Conversion to standard open operation	++	++	++	++	++	++	++
Increase in aneurysm size	++	++	++	+	—	—	++
Lack of increase in aneurysm size	++	++	++	—	—	—	++
Graft patency	++	++	++	++	++	++	++
Graft enlargement (>25%)	++	++	+	+	+	—	++
Persistent flow in sac or branch artery	++	++	+	+	+	+	++
Normal flow without leak, twist, or migration	++	++	++	++	++	++	++

Note.—AAA = abdominal aortic aneurysm, ++ = primary criterion, + = secondary criterion, — = recorded but probably not relevant.

\* Definitions provided in Table 2.

† Inability to insert device.

‡ Flow reduction without thrombosis.

§ Infection, bleeding, etc. Infection involving an endoluminal device is ++ in all categories.

ies; and the diameter and length of the stent(s) (when applicable) after deployment. Data should also include the length and diameter of the graft, the site and route of introduction, sheath configuration and diameters, blood loss, total fluoroscopy time, hematoma formation, and any problems associated with device insertion.

If balloons or stents other than those designated in the experimental protocol are used, the length, diameter, specifications, and manufacturer

should be recorded along with inflation volume, time, and pressure.<sup>o</sup> Data on any associated procedure that is

<sup>o</sup> A standardized delivery system should be used with each device being studied for a particular lesion in a particular location. Otherwise, stratification based on delivery system variation will be required. However, other balloons and materials may be required during the implantation procedure or for management or treatment of complications, and all such details should be recorded.

required, such as transluminal balloon angioplasty of the iliac vessels; placement of additional stents<sup>p</sup>, covered stents<sup>p</sup>, or stented grafts<sup>p</sup>; arterial repair; or thrombectomy should also be recorded. The type of anesthesia, med-

<sup>p</sup> If these are investigational devices, their use could confuse the results of a TPEG trial. Such use of adjunctive investigational devices should be identified and results with them reported separately from other results obtained without them.

**Table 2A**  
**Definitions of Systemic or Organ-related Complications**

Complication	Definition
Myocardial infarction	Significant elevation of CPK-MB, appearance of new significant Q wave or loss of R waves
Other cardiac	
Arrhythmia	Requiring treatment with drugs, cardioversion, or pacemaker
Congestive heart failure	Requiring tracheal intubation or ICU care
Pulmonary	Requiring tracheal reintubation, extension of ventilator support beyond 48 h, ICU beyond 3 d, or return to ICU
Renal failure	Creatinine level increase >30% or requiring dialysis
Bowel ischemia	Mucosal hemorrhage or requiring bowel resection or colostomy
Bowel obstruction	Requiring extended (>4 d) nasogastric intubation or laparotomy
Neurologic	
Stroke	New neurologic event lasting > 24 h
Transient ischemic attack	Neurologic event lasting < 24 h
Paraplegia or paraparesis	Lasting > 24 h
Limb loss	Major amputation at level of ankle or above

Note.—CPK-MB = creatinine phosphokinase-MB, ICU = intensive care unit.

**Table 2B**  
**Definition of Device Failures or Complications**

Device Failure or Complication	Definition
Device occlusion	Absence of flow through the device with or without intraluminal thrombosis
Stenosis	Device-related lumen reduction in, proximal to, or distal to the device associated with a reduction in flow or pressure
Leak	Flow of blood outside the lumen of a device when all such flows should be contained within its lumen
Migration	Displacement of the device sufficient to be associated with another complication, for example, occlusion, stenosis, or leak
Embolism	Formation of thrombus within the device with migration to a distal artery

ications required, the duration of the procedure, and a description or diagram of the procedure should be recorded and a hard copy of the completion arteriogram kept on file.

Any procedural complications such as device twisting, leakage, misplacement, migration, or failure should be recorded along with the endovascular or operative maneuvers required to manage the complication. If device removal is required, the steps involved should be detailed along with the outcome of these corrective efforts. Complications involving the native arterial tree and their management should also be documented.

*Early postprocedural data* (7–10 days) should include the duration of hospitalization, a description of wound

healing, an evaluation of device position, luminal patency, and complications (eg, leakage, migration, kinking, twisting, or obstruction). These device-related evaluations should be based on conventional radiographic, CT, MR imaging, IVUS, and/or color flow duplex imaging studies. Further evaluation with arteriography may be needed to exclude or further assess leakage, and US may be used to demonstrate shrinkage and pulsatility of the aneurysm wall.

Complications from the procedure or the device should be described along with the steps taken to manage these complications and the outcome. During this early postprocedural period, all preprocedural data relative to renal and hematologic function and

noninvasive evaluation of the peripheral circulation, aneurysm, and aortic morphology should be repeated. This will permit an assessment of early device safety and efficacy.

*Early midterm (6-month) postprocedural data* should include all those parameters evaluated in the first 7–10 days after device insertion and *must* include at least one adequate imaging technique (CT, IVUS, MR imaging, duplex US, or arteriography) to evaluate luminal patency, device integrity and localization, aneurysm size and pulsatility, and freedom from leakage. All these parameters plus a hematologic and biochemical evaluation of organ function should be studied approximately 6 months after device insertion, although it is understood that many of these tests, particularly those that can be performed noninvasively or by means of blood sampling, may be performed at more frequent intervals, specifically between 2 and 3 months after device insertion.

*Late midterm (1-year) postprocedural data* including all those parameters outlined for early midterm evaluation should be collected 1 year after device insertion. If a new device is as effective and as safe as standard operative aneurysm repair, according to the primary criteria in Table 1, for 1 year, the manufacturer of that device may seek clearance to market and sell it for specific indications (25).

The same data, including adequate imaging, should be collected at 6–12-month intervals thereafter for the life



**Table 3**  
**Prerequisite Information Regarding Risk Factors**

Systemic and Local Risk Factor	Preprocedural Data
Cardiac function	Left ventricular ejection fraction History of myocardial infarction Presence of significant Q waves Arrhythmias Thallium persantine stress test abnormalities History of angina pectoris History of congestive failure History of diastolic blood pressure >90 mm Hg or systolic pressure >160 mm Hg History of diabetes
Renal function	Serum BUN Serum creatinine
Pulmonary function	Arterial blood gases on room air FEV <sub>1</sub> Chest radiograph abnormalities Decreased exercise tolerance
Hematologic profile	CBC, platelet count, prothrombin time, partial thromboplastin time
Liver function	Serum albumin, bilirubin, SGOT, and SGPT levels Prothrombin time History of cirrhosis, hepatitis
Local risk factors	History of previous operations Description of scarring and infections (past, present)

Note.—BUN = blood urea nitrogen, CBC = complete blood cell count, FEV<sub>1</sub> = forced expiratory volume in 1 second, SGOT = serum glutamic oxaloacetic transaminase, SGPT = serum glutamic pyruvic transaminase.

of all patients receiving these devices. In that way, a determination can be made of long-term or *late postprocedural* (3–5 years) safety, efficacy, and effectiveness, and comparative performance of the device with regard to standard aneurysm repair can be determined. With this information and the data regarding adverse device effects, it will be possible to determine whether the TPEG device should be used as preferential treatment for selected high-risk patients, for patients now subjected to standard surgical repair, or even for some patients with smaller aneurysms not currently being treated. In addition, information will be obtained that will help determine when the device should not be used or its use restricted to certain anatomic situations, and whether or not it should be considered for use in circumstances other than those provided by an unruptured infrarenal aortic aneurysm, for example, anastomotic aneurysms, aortic aneurysms proximal to a previous aneurysm repair, ruptured aneurysms, or infected aneurysms.

#### **Abdominal Aortic Aneurysm (Infrarenal) with Iliac Involvement or Aneurysm(s): Bifurcated Devices**

TPEG repair of these aneurysms will require a bifurcated or branched device, although it is possible for some aortoiliac aneurysms to be repaired with a tubular TPEG device to revascularize one limb supplemented by femorofemoral bypass and occlusion of the opposite common iliac artery by some means. (This type of procedure is considered to be a subgroup of the aneurysms in the previous section.)

In general the feasibility testing; the preprocedural, intraprocedural, early postprocedural, midterm postprocedural, and late postprocedural data; and the design of comparative performance clinical trials will be similar to those outlined in the previous section addressing tubular devices for abdominal aortic aneurysms. The use of a bifurcated device may be more complicated and possess specific additional risks during device insertion and in the postprocedural period. With bifurcated devices, specific infor-

mation regarding the status and maintenance of perfusion in the internal as well as the external iliac arteries should be recorded before and at the various intervals after device insertion. Information regarding possible continued flow into the aneurysm from the internal iliac arteries and the status of the colonic circulation after the procedure should also be obtained.

#### **Peripheral Aneurysm (Femoral, Popliteal, and Others<sup>4</sup> in Comparably Sized Arteries): Tubular Devices**

In general, TPEG devices used to treat these lesions will have an expanded internal diameter from 6 to 16 mm. One possible design will have an attachment device at both ends, although in others a graft will be attached at one end with an endoluminally placed device and arterial continuity will be established at the other end by performing an open suture anastomosis. Other effective designs, such as grafts supported throughout their entire length, may also be developed.

*Feasibility testing* with these devices will be performed on patients who have indications for operative repair and who satisfy the general requirements for feasibility testing already outlined. These feasibility tests for aneurysms in these specific locations<sup>5</sup> should be carried out in at least 10 patients followed up for 6 months to demonstrate reasonable safety and efficacy with regard to the primary criteria specified in Table 1. Adequate preprocedural data should be collected to characterize the aneurysm, the distal circulation (ABI), and the patients' systemic and local risk factors (Table 3).

#### *Intraprocedural and early and early*

<sup>4</sup> These include isolated iliac, subclavian, and carotid artery aneurysms in patients with appropriate proximal and distal arterial anatomy for device fixation.

<sup>5</sup> It may also be possible to combine results of a given device used for similar lesions in several different locations to demonstrate feasibility with smaller numbers of device implantations. In such combined feasibility studies, data will have to be stratified by location and emphasis should be placed on the "worst case" or most difficult location to access and treat. Similar considerations may also apply to comparative performance testing of devices for treating peripheral aneurysms in these locations.



*midterm postprocedural data* should include a description of the following: the experimental device and the diameter and length of its components, the placement procedure including the route of access, the anesthesia, the insertion procedure, the location of the device and its components (supplement with diagram), any procedural complications or mishaps, the need to perform any surgical or interventional reparative procedure to deal with problems that were encountered, blood loss, and length of hospital stay. Data collected at 6 months should include repetition of preprocedural studies that are required to demonstrate exclusion of the aneurysm from the circulation and maintenance of luminal continuity and distal arterial circulation without device migration, leakage or other defects. These data should include ABI, duplex US and/or CT scans, MR images, or arteriograms.

Satisfactory completion of feasibility testing should be followed by *comparative performance testing*. Data similar to that for the feasibility testing should be collected. Postprocedural data collection should take place at 3, 6, 12, 18, and 24 months. TPEG devices proposed for *femoral aneurysms* and/or other peripheral aneurysms should be compared with standard prosthetic (PTFE or polyester fabric) or autologous grafts where appropriate. Several cooperating centers may be required to accumulate a sufficient group of patients to enable a statistically and scientifically valid judgment to be made regarding *safety* and *efficacy* (as described earlier) and *effectiveness* (ie, prevention of embolization, limb loss, and aneurysm rupture) for at least 1 year.

If the comparative performance trials demonstrate that the TPEG performs as well as or better than operatively placed grafts, the manufacturer may seek clearance to market and sell the device. However, the initial study patients should be followed up until long-term (3–5-year) data are available.

### Traumatic Arterial Lesions (False Aneurysms, Arteriovenous Fistulas, Mural Injuries)

The TPEG devices for treatment of these injuries will generally have expanded internal diameters of 6–25

mm depending on the artery that is injured and will probably consist of a 2–6-cm-long attachment device covered—except for 5–10 mm at its ends—by a tube of polyester fabric, expanded PTFE, or some other material.<sup>5</sup> These devices should be deployed to cover the defect in the arterial wall (false aneurysms or arteriovenous fistulas) or to reinforce the arterial wall and fix intimal flaps (mural injuries). Initially these devices will probably only be used to treat arterial injuries less than 4 cm in length because it is likely that longer injuries will be associated with sufficient soft-tissue damage and internal or external bleeding that standard operative repair will be required. However, it is conceivable that longer injuries could be treated by TPEGs.

After appropriate bench and animal testing for prosthetic grafts that might be used in comparable locations, human *feasibility testing* should be carried out in patients who would otherwise require a standard operative repair and who are stable enough to permit preprocedural angiographic definition of the vascular injury and the distal arterial circulation. Ideally, separate feasibility studies should be performed for injuries of the aorta and innominate artery, the iliac and common femoral arteries, the subclavian and axillary arteries, the superficial femoral and popliteal arteries, and the carotid and vertebral arteries. In each of these five arterial systems<sup>4</sup>, these feasibility studies should show that the device can safely be implanted in 10 patients and can maintain a satisfactory repair of the lesion with preservation of luminal continuity without distal embolization for at least 6 months.

*Preprocedural data* should be col-

lected to characterize the location and length of the arterial injury, the cause of the injury (blunt trauma, gunshot or knife wound, iatrogenic, or other injury), the nature of the injury, and associated injuries. *Intraprocedural data* should include the diameter and length of the graft and the attachment device, a description of the placement procedure, the route of access, whether the device was inserted percutaneously or by open operation, the location of the device and its components (supplement with diagram), any procedural complications or mishaps, the need to perform surgical or catheter-based corrective procedures, procedural blood loss, and the length of hospital stay. *Early and 6-month postprocedural data* should be similar to those already described for other TPEG devices and should demonstrate luminal continuity, correction of the arterial defect, maintenance of the distal circulation, and freedom from device migration, leakage, embolization, or aneurysm formation.

Satisfactory completion of feasibility testing in each location or system should be followed by *comparative performance testing* in each or a combination of the major arterial systems described above, recognizing the limited number of suitable patients available for inclusion in these trials. Ideally in each of these systems, TPEG device repairs should be characterized with regard to the criteria listed in Table 1 so that comparisons can be made with similar data for operative repair of similar lesions. The procedural and postprocedural data collected should be similar to those already described.

If the TPEG device proves equivalent or superior to standard repair for 1 year, the manufacturer may seek clearance to market and sell the device for these specific indications. Although the increased simplicity and minimally invasive nature of treating traumatic injuries of these arteries with nonautologous TPEGs is attractive, such treatment should be validated by patency studies extending at least to 5 years. Therefore, all patients in these studies should continue to be evaluated every 6 months for 5 years with use of the same parameters already described. In this way, the long-term effectiveness as well as the limitations and late complications of TPEGs can be determined. Particular

<sup>5</sup> This is one example. Other possible designs may be developed, such as a stent-like material incorporated uniformly within a graft matrix or some other combination of fixation device and graft.

<sup>4</sup> However, since these are uncommon lesions, it may be necessary to combine results of a given device used in several different locations to demonstrate feasibility with smaller numbers of device implantations. In such combined studies data will have to be stratified by location and emphasis must be placed on the "worst case" or most difficult location to access and treat. Because they involve arteries supplying the brain, devices for use in the carotid and vertebral arteries should be evaluated separately. Similar considerations may apply to comparative performance testing of devices for treating arterial trauma in these locations.

attention should be directed toward the patency results of these short devices in small-diameter arteries, such as the superficial femoral and popliteal, where the long-term patency of prosthetic grafts may be poor.

#### **Distal Aorta and Iliac Artery (Common and External) Occlusive Disease**

TPEGs that will be employed to treat these lesions will probably have an expanded internal diameter from 6 to 20 mm and either an attachment device at both ends of a tubular graft or a proximal fixation system and a distal suture anastomosis, although other configurations may be developed. A distal suture anastomosis may be necessary if the anatomic situation demands that the graft terminate at a point where two important patent artery branches originate (eg, the junction of the superficial and deep femoral arteries). The requirements for bench and animal testing for the grafts used in these devices should be similar to those required for standard grafts used in these locations (24–26). However, since the grafts will be placed within dilated or recanalized occluded arteries, it is possible that they may not need to have the same structural and porosity specifications as standard bypasses, but evidence supporting the safety of modified or new grafts should be presented.

*Feasibility testing* of these devices should be performed on patients who have indications for operative repair but who may also have a major systemic or local contraindication to such an operation. Contraindications to standard operative bypass grafting include severe cardiac and/or pulmonary disease or other systemic disorders that preclude general or major regional anesthesia, or factors such as scarring or infection, which would make an open arterial operation excessively difficult or dangerous. In addition, the lesions may be suitable for treatment by means of conventional percutaneous balloon angioplasty (PTA) with or without endoluminal stent placement, depending on the length or complexity of the occlusive and stenotic process. These feasibility tests should be carried out in at least 10 patients who are followed up for 6 months to demonstrate reasonable

safety and efficacy. Adequate *preprocedural data* should be collected to characterize the nature and extent of the patients' occlusive disease (arteriography), the status of the distal circulation (ABI, pulse volume recordings [PVR]) and the patients' systemic and local risk factors (Table 3). *Intraprocedural data* should include the diameter and length of the graft(s) and the attachment systems; a description of the placement procedure including the route of access and whether it was performed open or percutaneously, unilaterally or bilaterally; the location of the graft(s) and stent(s) within the arterial tree (supplement with diagram); a description of any procedural complications and the catheter-directed or surgical techniques required to correct the problem; and the length of hospital stay. *Postprocedural data* to demonstrate 6-month safety and efficacy, should include repetition of the preprocedural studies (ABI, PVR, arteriography and duplex US) to document graft patency, improved distal perfusion, and freedom from leakage, collateral or branch occlusion, or device migration. These data may be supplemented, when necessary, with imaging studies such as plain radiographs, CT scans, MR images, and IVUS scans.

Satisfactory completion of feasibility testing should be followed by *comparative performance testing* in which the new TPEG device is compared, with standard prosthetic bypass grafts (aortobifemoral, axillofemoral, iliofemoral, or femorofemoral) and against PTA alone or supplemented by stents. Because of the variability of the pathology in the aortoiliac segment, these will be complex studies to conduct. Many patients will have to be enrolled to eliminate or define confounding variables. It is likely that these studies will have many arms and will require multiple collaborating centers.

In these studies, adequate data should be collected on risk factors, the degree of ischemia, and the arterial pathology, as well as the local factors enumerated previously to be sure that the test groups receiving the new TPEG treatment and the standard therapy groups are well matched except for the treatment employed. Follow-up and data accumulation (using the criteria outlined in Table 1) on these patients should determine 1-year results and then be continued to deter-

mine long-term (3–5-year) safety, efficacy, effectiveness, and durability. In addition, these studies might provide an assessment of the relative effects of these new devices and standard treatments on the progression of atherosclerotic disease, and of how device complications and failures should best be managed.

#### **Femoropopliteal Occlusive Disease**

The TPEGs that will be used to treat these lesions will most likely have an expanded internal diameter from 4 to 8 mm. They may have an attachment system at one or both ends of a tubular graft, although the distal end may not require such a system, and either the proximal or distal anastomosis may be performed in the standard open-sutured fashion or a stent-like component may be incorporated in a graft matrix. These devices may be insertable percutaneously or via an open arteriotomy. The requirements for bench and animal testing are similar to those already described for iliac TPEG devices.

*Feasibility testing* of these devices for femoropopliteal occlusive disease should be carried out on patients who have indications for operative vein or prosthetic bypass and who also may have a major contraindication to such an operation (see Distal Aorta and Iliac Artery Occlusive Disease). In addition, the lesions may be suitable for a standard PTA by virtue of their length or complexity. Data collection before, during, and after the procedures up to 6 months should parallel those described in the previous section (Distal Aorta and Iliac Artery Occlusive Disease) and should be obtained in at least 10 patients to demonstrate safety and efficacy of the device for that length of time.

Satisfactory completion of feasibility testing can then be followed by *comparative performance testing* as described above for iliac occlusive lesions.<sup>4</sup> Because of the multiple variables in risk factors, degree of ischemia, and arterial pathology in

<sup>4</sup> TPEG results should be compared with standard surgical vein and prosthetic bypasses and possibly with PTA alone and PTA with stents (if the latter are shown to be safe and effective) in groups of patients suitable for treatment with PTA with or without stents.

this setting, adequate numbers of patients will have to be entered so that confounding variables can be eliminated. It is therefore likely that these studies will also require multiple collaborating centers and will have several arms. One obvious study group would be patients who do not have a useable autologous vein so that the performance of a TPEG procedure can be compared with that of a standard prosthetic graft. Data collection should permit evaluation of safety, efficacy, effectiveness, and durability of the new device at 1 year and ultimately after 4–5 years, which should allow valid comparisons with the more traditional operative and balloon angioplasty procedures as well as determination of the precise indications and contraindications for use of these TPEG devices.

### Descending Thoracic Aorta

The TPEG devices that will be used to treat lesions in this location will have expanded external diameters up to 45 mm or more. They may consist of a single or multiple contiguous stents covered by a graft, two separate stents or attachment systems at each end of a tubular graft, or have some other design. They may be used to treat acute or chronic aortic dissections, degenerative atherosclerotic aneurysms, traumatic or postoperative false aneurysms, ulcerating mural lesions, intramural hematomas, and possibly other lesions. They will probably be inserted in a fashion similar to devices used to treat infrarenal aortic aneurysms.

The requirements for bench and animal testing as well as feasibility and comparative performance trials will be similar to those already described for abdominal aortic aneurysm devices. However, because several pathologic processes will be treated in the thoracic aorta, it will probably not be feasible to perform separate trials on each before marketing approval for general clinical usage is requested.

Imaging of thoracic lesions with transesophageal echography and with color Doppler flow studies may be used to supplement the pre- and post-procedural evaluations recommended for abdominal aortic aneurysms (28). Experience to date dictates that TPEG procedures on the thoracic aorta be

performed in a procedural room in which the following are available: general anesthesia with endobronchial intubation, pulmonary artery catheterization, and, in some instances, the equipment and staff to perform emergency operation with complete cardiopulmonary bypass. When the latter is required, the participation of a cardiothoracic surgeon is mandatory.

### TPEG REGISTRY RECOMMENDATIONS

To maximize the knowledge gained from the widespread early experiences in the developing field of TPEGs, the data from all feasibility and comparative performance trials that are conducted should be collected, stored, and analyzed by a central databank or registry. Submission of all clinical trial data to such a registry should be mandatory and a requirement for obtaining marketing approval. Such a registry is being developed by the same Endovascular Graft Committee that wrote these guidelines. Additional information about this TPEG registry can be obtained from K. Wayne Johnston, MD, Toronto General Hospital, Toronto, Canada.

### TRAINING REQUIREMENTS FOR USAGE OF TPEGs

For initial clinical studies with each device, principal investigators will need to work with the manufacturer to develop appropriate training programs for all investigators. The teams that will be involved in the use of a given TPEG device must include an experienced vascular surgeon (or cardiothoracic surgeon for procedures on the thoracic aorta) and interventional radiologist, both of whom devote a major portion (>50%) of their activity to the management of noncardiac vascular disease.<sup>v</sup> The training program must include adequate large animal experience (or mock circulatory model) experience to ensure technical

proficiency with the usage of the device being evaluated. Although it is recognized that good animal models for human aneurysmal and occlusive disease do not exist, animal (or model) experience should be obtained by placing the device under fluoroscopic control in an anesthetized animal (or model) in arteries large enough to approximate those that will be encountered in human patients.

When individuals or teams have had this initial animal or model experience and then implanted the TPEG device in at least *three patients* with acceptable results, they may qualify as *instructors* for other individuals who desire to perform investigational procedures with the device in question. The individuals or teams being qualified in this way must possess the full knowledge of vascular disease and all its treatment methods and the requisite surgical and catheter-guide wire skills and experience, as already outlined. They must participate as assistants in at least *three procedures* that utilize the device and that are being carried out by the individual or group who are serving as instructors. These background and training requirements apply to individuals or teams at other centers wishing to join an ongoing comparative clinical testing protocol.

### REQUIREMENTS FOR FACILITIES IN WHICH TPEGs WILL BE USED CLINICALLY

Although it is probable that some of these devices may ultimately be suitable for safe and reliable percutaneous introduction (4,5), experience to date indicates that open vascular operations are required or may be required as a part of many TPEG insertion procedures or to treat complications or adverse events that may occur (1,6–15). Accordingly, it is mandatory that facilities in which these procedures are performed be suitable for the performance of open arterial operations as well as catheter-directed fluoroscopically guided techniques with high-quality imaging. Such facilities can take one of two forms. A standard operating room or comparable location may be equipped to perform open arterial operations, digital imaging fluoroscopy and arteriography, and cathe-

<sup>v</sup> Separate training and credentialing guideline documents for individuals who can perform vascular surgery and endovascular procedures have been prepared by various specialty organizations (18–23). The general principles expressed in these documents should also apply to the present guideline document.



ter-guide-wire manipulations at several levels of the arterial tree. There are a number of ceiling- and floor-mounted digital fluoroscopy/arteriography units and movable radiolucent operating tables that are ideally adapted to the performance of these procedures in an operating room setting. However, it is also possible to perform them adequately with an electrically operated radiolucent movable operating table and C-arm portable digital imaging and fluoroscopy with hard copy and videotape recording capability and, preferably, with last image hold and roadmapping. The procedural room should be equipped with conventional (525 line) or high-resolution (1000+ line) imaging chains capable of resolving at least 3.3 line pairs per millimeter in the 9-inch image intensifier. The image intensifier should have a high contrast ratio (20:1), provide manual collimation, and be of high conversion gain. The room should also be equipped with a power injector for adequate digital angiography.

Alternatively, a standard arteriography suite equipped for digital imaging fluoroscopy and catheter-guide-wire technologies can be modified to permit emergency sterile open operations according to standards from the Association of Operating Room Nurses (33). For procedures in which devices will be placed in the abdominal or thoracic aorta or iliac or visceral arteries, patient safety considerations and the possible need to deal with emergent complications mandate that they be performed in a room that is fully equipped and staffed with appropriate nursing and anesthesia personnel so that major vascular operations can be performed safely and expeditiously if required. For thoracic aortic procedures, perfusionists and equipment for instituting total cardiopulmonary bypass must also be immediately available.

In the future, different combinations of various imaging modalities other than fluoroscopy may prove equally effective and safe for the deployment of TPEGs and may be substituted for those described above to facilitate TPEG device insertion and evaluation in different treatment environments.

## RADIATION SAFETY REQUIREMENTS

Federal regulations regarding maximum fluoroscopic radiation exposure rates must be followed. If high level control (HLC) fluoroscopy is used, activation of this mode must be accompanied by a continuous audible signal and the output of the x-ray tube in HLC fluoroscopy should be closely monitored and measured and should not exceed 20 R/min. A cumulative monitor of fluoroscopy time should be present and the time should be recorded for each patient. The procedure room should meet the radiation protection standards of the National Council on Radiation Protection (34–37), and the workers should have awareness of the safety standards of the International Commission of Radiation Protection. All personnel within the room should wear lead aprons and individual state regulations regarding personnel dosimetry should be followed. Quality control charts should be maintained on the x-ray equipment and arrangements should be made for their routine maintenance. All quality control data should be reviewed by a medical physicist at least annually (37). The procedural room should have a safe, electrical primary wiring system, and proper electrical isolation of all equipment attached to the patient. With the addition of angiographic equipment and the presence of catheters within the vascular system, there should be periodic inspection of the electrical system which should have equipotential hardwired grounding. Electrical safety checks should be reviewed at least annually by a qualified medical physicist.

## MODIFICATIONS OF THESE GUIDELINES

The developmental paths of TPEGs, the optimal technology, their ultimate value, the complications of their insertion, their impact on various arterial disease processes, and the various modifications that may be introduced are presently unknown. It is therefore probable that these guidelines will evolve and change to encompass new treatment developments. Accordingly, future modifications and refinements of this document should be made as needed by the *Endovascular Graft Com-*

*mittee* of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery and the Society of Interventional Radiology.

## APPENDIX

The Endovascular Graft Committee is an Ad Hoc Conjoint Committee of the Joint Council of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery, North American Chapter\*, and the Society of Interventional Radiology<sup>†</sup>. The Committee includes representatives from the Food and Drug Administration<sup>‡</sup> and the National Heart, Lung and Blood Institute, National Institutes of Health<sup>#</sup>.

Committee members are Jerry Goldstone (Current Chairman)\*, Brian Thiele (Past Chairman)\*, William M. Abbott\*, Dorothy Abel<sup>‡</sup>, Michael D. Dake<sup>‡</sup>, Paul Didisheim<sup>#</sup>, Calvin B. Ernst\*, Thomas J. Fogarty\*, K. Wayne Johnston\*, Barry T. Katzen<sup>†</sup>, D. Craig Miller\*, Wesley S. Moore\*, George Sopko<sup>#</sup>, Arina van Breda<sup>†</sup>, Frank J. Veith\*, Rodney A. White\*, James S.T. Yao\*, Jacob Cynamon<sup>†</sup>, Richard H. Dean\*, Richard M. Green\*, Larry H. Hollier\*, Eric Martin<sup>†</sup>, Juan C. Parodi\*, Julio Palmaz<sup>†</sup>, Robert Vogelzang<sup>†</sup>, and Robert B. Rutherford\*.

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