

ENDOVASCULAR STENT-GRAFTS FOR THORACIC ANEURYSMS AND DISSECTIONS

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Over the last 10 years, no new cardiovascular interventional technique, with the exception of gene therapy, has had as much unrealized clinical potential as thoracic aortic stent-grafting. Although the theoretical advantages of this less-invasive alternative to open repair are compelling, perhaps even more compelling than the recognized benefits of applying endograft technology to the management of abdominal aortic aneurysms, the potential of this attractive therapy essentially remains an unrealized cliché. It is hard to believe that after more than 10 years of clinical investigation with a variety of thoracic stent-grafts, the medical community interested in treating thoracic aortic diseases still has no access to a Food and Drug Administration approved device for patients with prohibitive operative risks.

Nevertheless, the consensual opinion of surgical and interventional authorities working in this field suggests that in the near future this technology will have an expanded role in the treatment of patients with thoracic aortic diseases and that it will eventually evolve into the primary therapy for selected pathologies in which clear benefits are identified. The traditional standard therapy for descending thoracic aortic aneurysm (TAA) is open operative repair with graft replacement of the diseased aortic segment. Despite important advances in surgical techniques, anesthetic management, and postoperative care over the last 30 years, the mortality and morbidity rates of surgery remain considerable, especially in patients at high risk for thoracotomy because of co-existing severe cardiopulmonary abnormalities or other medical diseases.

The advent of endovascular stent-graft technology provides an alternative to open surgery for selected patients with TAA. Following closely on the heels of early clinical experience with endografts for the treatment of patients with abdominal aortic aneurysms, the application of this new technology was initially focused on the

management of descending aortic aneurysms in high-risk surgical candidates.¹⁻⁵

The initial results of these feasibility studies suggest that stent-grafts offer an attractive alternative to open surgical repair that may potentially reduce the operative risk, hospital stay, and procedural cost in selected patients.⁵⁻⁷ Subsequently, clinical trials of commercially manufactured devices have been initiated to treat patients with descending TAA. Results will be compared with those achieved in an enrolled group of contemporary surgical controls to better determine the effectiveness of stent-graft therapy and quantitate any benefits. Unfortunately, the final results of these studies, including 1-year follow-up data, will not be available until 2002.

Since 1992, when the feasibility and safety of stent-graft therapy for TAA was initially investigated, there has been an increasing number of reports of the application of this technology to treatment of patients with a wide spectrum of thoracic aortic disease, including acute and chronic dissection; intramural hematoma; penetrating ulcer; traumatic injury; Marfan's syndrome; mycotic aneurysm; anastomotic aneurysm; rupture; and emboligenic aortic sources.⁵⁻¹⁴ This chapter describes experiences with stent-graft management of specific aortic disease, after a presentation of the currently available devices.

Devices

A detailed discussion of the various first-generation homemade devices is only of modest historical interest. Suffice it to say, most of these prototypical prostheses were self-expanding and based on a combination of polyester graft with a modified type of Gianturco Z stent. Most delivery systems were large (24 to 27 French), relatively rigid, and depending upon the anatomy as well as the length and diameter of the device, difficult to target and deploy due to a marked frictional resistance encountered

during withdrawal of the outer device-constraining sheath. Detailed descriptions of individual systems, components, fabrication processes, and deployment techniques are provided elsewhere.⁵⁻¹⁴

Currently, there are two commercially manufactured thoracic stent-grafts that are widely available. The Excluder (W.L. Gore and Associates, Flagstaff, AZ) and the Talent devices (AVE/Medtronic Inc., Santa Rosa, CA) have been each implanted in more than 500 patients with TAA worldwide. Both represent considerable improvements over the prior generation of institutionally fabricated stent-grafts, in terms of ease of use, reliability, and consistency of device manufacturing.

The Gore Excluder (Figure 39-1) is composed of a self-expanding nitinol stent lined with ultrathin wall polytetrafluoroethylene (PTFE) graft material. The PTFE graft has a 30-micron internodal distance similar to the pore size of conventional PTFE grafts used for peripheral vascular reconstructions. The ends of the device have a scalloped contour to enhance graft contact with the aortic wall over a wide range of aortic tortuosities and angulations.

The scalloped projections are covered with PTFE, and their length is directly proportional to the diameter of the graft. The device is very flexible radially and longitudinally.

Two S-shaped stabilization wires anchored 180° apart span the length of the graft to limit longitudinal compression.

The graft is axially compressed onto the end of the delivery catheter and constrained by a PTFE corset that is laced with PTFE suture. The suture runs the length of the



FIGURE 39-1. The two most commonly used commercially manufactured thoracic stent-grafts are the Gore Excluder (left) and the Talent device from AVE/Medtronic.

catheter and is attached to a deployment knob at the opposite end. Grafts are available in a range of diameters between 26 and 40 mm and in a selection of lengths between 7.5 and 40 cm. The sizes of the delivery system and compatible introducer sheaths vary according to the diameter of the device and scale over a range of 20 to 24 French.

After preliminary arteriographic studies define the preferred proximal and distal stent-graft “landing zones” and these targets are confirmed by transesophageal ultrasonography, the appropriately sized 30-cm-long introducer sheath is advanced over a guidewire to the infrarenal aorta. Alternatively, in certain situations, the catheter delivery system may be introduced over the guidewire without the use of a sheath. In either case, the device catheter is tracked over the wire until it reaches the selected target in a manner that bridges the aneurysm from proximal to distal necks. If more than one device is required because of excessive aneurysm length (> 16 cm) or a mismatch in diameters between proximal and distal necks > 4 mm, the smallest-diameter device is deployed first, irrespective of its location. Subsequently, the larger-diameter device is coaxially placed with at least a 3-cm overlap to enhance the interference seal between the grafts. If the anticipated diameters of multiple grafts are equal, the proximal device is usually deployed first, with additional coaxial devices placed successively distal.

In all cases, there must be sufficiently long proximal and distal aneurysm necks of at least 15 to 20 mm to ensure adequate wall contact for graft fixation and a tight circumferential seal.

After final positioning is completed, the device is deployed by pulling the knob adjacent to the catheter hub. As the knob is smoothly retracted, the attached suture is withdrawn, and opening of the corset occurs initially in the middle and then proceeds toward both ends. An instantaneous release of the underlying self-expanding stent-graft occurs. After deployment, the delivery catheter is removed and a trilobed balloon, designed exclusively to smooth any wrinkles or pleats in the graft without increasing the proximal arterial pressure, is introduced and expanded at the proximal and distal necks, as well as at any device overlap zones. This ensures full graft expansion. The procedure is complete if the desired position of the graft is achieved without arteriographic or transesophageal ultrasound imaging evidence of inadequate sealing and persistent flow within the aneurysm. However, if the device is poorly positioned or not fully expanded and there is a perigraft leak, supplemental maneuvers, including placement of additional stent-graft(s) or balloon expansion over the segment of aneurysm neck where the leak is suspected, may prove beneficial. Additional preprocedural considerations, imaging requirements, procedural techniques, postprocedural patient management, and follow-up issues were detailed earlier.

The second device currently available for treatment of patients with descending TAA is the Talent endoprosthesis (see Figure 39-1). The design of this product has evolved since its clinical introduction.

The current version has a lower profile and more flexible delivery catheter than did the original system. The prosthesis is composed of sinusoidal nitinol stent elements sandwiched between thin layers of polyester graft material. The individual stent forms are secured in place with oversewn sutures to prevent migration; however, they are not connected to one another, and there are segments of unsupported graft interposed between stents.

This design allows independent stent motion and confers a degree of longitudinal flexibility.

Similar to the Excluder device, the Talent uses two longitudinal wires to provide stabilization and prevent longitudinal compression.

A unique aspect of the device is its proximal margin with broad-based nitinol wire scallops. The wide uncovered interstices may be placed across the origin of the left subclavian artery in cases where there is a short proximal neck of between 10 and 20 mm. In this setting, placement of the uncovered stent across the left subclavian artery helps to optimally orient the graft, stabilize its position, and, during deployment, secure precise targeting of the graft material at the distal subclavian margin.

The stent-grafts are available in a wide range of diameters and lengths. In addition, custom fabrication of a prosthesis based upon an individual patient's anatomy is possible within 3 weeks. The delivery profile for Talent is between 22 and 27 French, depending on the diameter and length of the device.

The delivery catheter has a flexible conical tip. Set back from the tip is an integrated balloon that is used for smoothing the graft material and promoting adequate stent expansion following deployment of the self-expanding device. The prosthesis is collapsed over the distal segment of the delivery catheter and maintained in this packed configuration by an overlying transparent sheath. Proximal to the loaded stent-graft is a blunt metal stopper that functions as a brace to maintain the device position as the constraining sheath is withdrawn.

After the stent-graft is properly positioned, usually 1 to 3 cm proximal to the optimal landing zone to mitigate against an inadvertent downstream drift during deployment, the overlying sheath is slowly withdrawn.

As the initial uncovered stent elements cantilever open, gentle retraction of the device is applied until the exact desired position of the proximal graft margin is obtained. After the device is fully deployed, the balloon is withdrawn and expanded within the proximal and distal neck segments to fully expand the prosthesis. Subsequently, the final result is documented angiographically and the arteriotomy repaired surgically.

In an analysis of the relative merits of the devices, it is important to note that both devices have established

records of technical and clinical successes. However, in certain cases, the particular disease process and/or anatomy may recommend one over the other. The marked flexibility of the Excluder device and its delivery system, as well as its smaller introduction profile, make it better suited for patients with severely angled aortic anatomy or iliofemoral conduct arteries that are small, calcified, or tortuous.

In TAA cases with short (< 15 mm) proximal necks, or in aortic dissection where the primary entry tear is very close to the left subclavian artery, the Talent device may be preferred because of its leading segment of uncovered stent. In terms of ease of use, the Excluder has some advantages. The maximum graft length available is 20 cm as compared to 13 cm for an individual noncustom Talent device. This, in combination with its simple and straightforward deployment, makes it more efficient to treat patients with long aneurysms. In certain applications, such as aortic dissection, the relative radial force exerted by the prosthesis may be a consideration. In the acute setting, the lower hoop strength of the Excluder may allow adequate coverage of the entry site without causing an iatrogenic secondary tear in the thin fragile dissection flap. On the other hand, the greater radial force of the Talent may be beneficial in cases of chronic dissection to displace a thick and resistant dissection septum and, thus, to enhance the true lumen diameter.

Applications

Currently, the application with the greatest clinical experience remains descending TAA with an estimated 3,000 implementations worldwide (Figure 39-2). Results of controlled studies are not available, long-term data are limited, and comparison of experiences that typically employ a wide variety of prosthetic designs is problematic; however, a consensual pattern of outcomes from centers active in this field is emerging that defines a shared reality.

Irrespective of the device implanted (institutionally crafted first generation or commercially manufactured second generation), in series of more than 40 patients (range, 40 to 260) with nondissection-associated TAA, operative mortalities were between 0 and 4%, technically successful device deployments occurred in 98 to 100% of cases, and immediate aneurysm thrombosis was achieved in 90 to 100%.¹⁵⁻¹⁹ Paraplegia was a complication in 0 to 1.6%, and stroke occurred in a range of 0 to 2.8%. Conversion to open surgical repair occurred in 0 to 4% of cases, and late endoleaks were noted in 2 to 3%.

What have we learned from the experiences accumulated to date? First, it is clear that the ideal endovascular prosthesis for TAA is not yet available. Perhaps, it is unreasonable to expect that one device will be capable of optimally addressing all combinations of TAA etiologies, morphologies, and underlying vascular anatomy. In the end, the individual aspects of each case may dictate

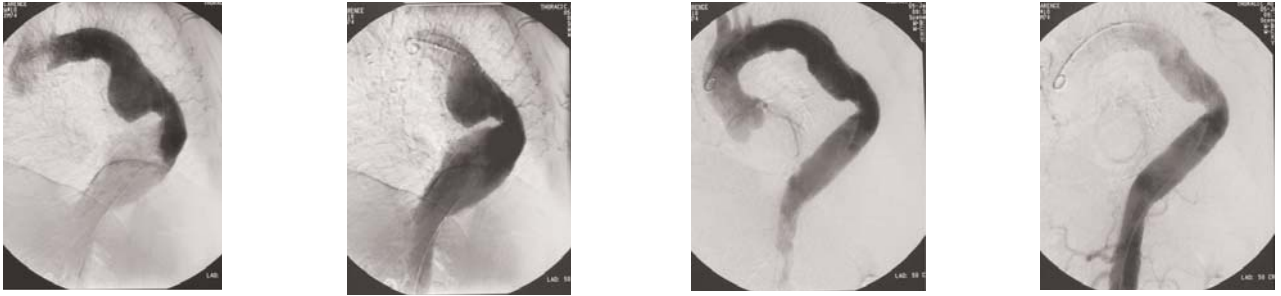


FIGURE 39-2. Aortograms of a 64-year-old man, performed before and immediately after stent-graft placement to isolate a descending thoracic aortic aneurysm.

selection of the best suited prosthesis from a medley of devices.

One factor (eg, short proximal neck, severely angled descending aorta, small or tortuous access arteries) may dominate the decision process. The factors considered in determining which device is preferred for implantation in a 20-year-old with an acute traumatic injury may be different than the factors considered when determining which device is best to deploy in an 80-year-old with a long tortuous degenerative aneurysm.

The reports from the first wave of experiences provide additional insights into the spectrum of results and frequency of complications, some of them unexpected. Indeed, the recorded frequencies for paraplegia are lower than most experienced clinicians would have predicted prior to the initiation of this therapy and are similar to the most favorable results from contemporary series of open surgical repair for TAA. The anticipated potential complication of device migration or kinking has been very rare and observed mostly with the use of “homemade” rigid or semirigid devices and prostheses with unsupported midgraft segments.

The experience with sequelae of stent-graft coverage and occlusion of the left subclavian artery is no longer limited to isolated case reports of inadvertent obstruction due to device misplacement within a short proximal neck segment. The practice of prophylactic left subclavian to left carotid artery transportation or bypass graft placement in patients with an insufficiently long proximal neck in order to avoid possible complications following endograft placement across the subclavian has given way to a trend toward expectant management. If arm, hand, or cerebral symptoms develop after coverage of the branch, then surgical revascularization of the subclavian artery is performed. Early results of this revised algorithm suggest that it is safe in the majority of patients; however, symptomatic malperfusion of the upper extremity requiring interventions occurs with a frequency that is yet to be defined.

In contradiction to the problem of an inadequate proximal neck segment, there are no easy management strategies to deal with a short distal neck above the celiac artery. Intentional coverage of the celiac is not an innocuous tactic despite a coexisting normal superior mesenteric

artery capable of supporting an apparently normal network of collateral flow. There are four known cases of death following intentional stent-graft coverage of the celiac artery during treatment of TAAs with short distal necks. Two of the patients died because of liver failure, and two from sepsis with pancreatic and splenic infarctions, respectively. In all cases, preprocedure catheter maneuvers, including selective arteriographic mapping of possible collateral pathways and hemodynamic pressure recordings, were performed in an effort to predict whether the patients would tolerate occlusion of the celiac artery. Unfortunately, there are no easy operative methods to solve the problem of the short suprarenal neck.

Another concern that still requires attention is the large delivery profile of current devices relative to the iliofemoral arteries. Injuries to conduit arteries and arterial access complications are common, and the clinical sequelae of these complications are often significant. Indeed, the frequency of these events and the more alarming reports of strokes, due in part to manipulations of large, bulky, and semirigid delivery systems within aortic arch, mandate immediate development of smaller, less-traumatic devices.

The issue of endoleaks after stent-graft treatment of patients with TAA is an interesting and important subject. It is now obvious that there are distinct differences between the relative frequencies, various types, and fates of endoleaks identified after stent-graft therapy of TAA and abdominal aortic aneurysm (AAA). There is a clear indication that endoleaks occur less frequently after TAA repair. When they are observed, TAA endoleaks occur more commonly at proximal or distal attachment sites (type 1 endoleak), where there is an incomplete seal between the graft and the proximal or distal aneurysm neck, rather than via retrograde aortic branch vessel flow into the aneurysm from collateral channels (type 2 endoleak). The majority of endoleaks diagnosed early after stent-graft repair of AAA are of the type 2 variety.

Although type 2 endoleaks via intercostal or bronchial arteries have been reported after TAA therapy, the incidence is very low. The reason for this difference is currently unclear.

It is generally accepted that the prognosis for type 1 endoleaks is more serious than the natural history of type

2 endoleaks. The effects from the force of aortic arterial pressure transmitted directly to a TAA after stent-graft placement are potentially lethal, and there are multiple isolated reports of early rupture occurring in this setting. Consequently, aggressive endovascular or surgical intervention is recommended if feasible when type 1 endoleaks are documented more than 2 to 4 weeks after the implantation procedure.

Another thoracic aortic stent-graft application that is receiving increasing attention is the treatment of patients with aortic dissection (Figure 39-3).

There is growing worldwide experience with this procedure in the setting of acute type B dissection and chronic dissection with coexisting descending aortic false lumen aneurysm.^{12-14,20,21}

In both pathologies, successful management is predicated on obliteration of the primary entry tear of dissection by placement of the prosthesis within the true lumen across the entry tear. Stent-graft coverage of the entry site closes the primary communication to the false lumen, and its flow is markedly reduced or choked off completely. In acute type B dissection, the true lumen immediately increases in diameter without a corresponding incremental change in the overall aortic diameter. Downstream, any dynamic branch vessel involvement of abdominal aortic true lumen arteries compromised by the dissection process is expeditiously reversed seconds after stent-graft placement.

In both cases of acute and chronic dissection, stagnant blood in the thoracic aortic false lumen clots, and in the majority of patients, progressive thrombosis of the false lumen proceeds from the proximal aspect of the involved thoracic aorta distally, irrespective of the primary tear location. The tempo of this process is variable and presumably based on the size of the false lumen, abdominal branch vessel distribution off the aortic lumens, and the amount of residual thoracic aortic false lumen flow via uncovered additional tears in the thoracic dissection flap, retrograde thoracic aortic false lumen branch vessel flow from collaterals, retrograde perfusion from the abdominal aortic false lumen, and similar considerations.

It is expected that residual isolated patency of the abdominal aortic false lumen will persist via natural fenestration in the dissection flap that exists at levels corresponding to abdominal branches off the false lumen. This phenomenon permits sufficient perfusion of abdominal aortic false lumen branches via true lumen transeptal flow after stent-graft obliteration of the primary thoracic communication to the false lumen. In cases of acute dissection, if thoracic aortic false lumen thrombosis occurs after stent-graft placement, progressive false lumen resolution may occur with a corresponding gradual enlargement of the thoracic true lumen. In this regard, follow-up imaging at 1 year has shown apparent "healing" of the dissection in a number of cases without computed tomography (CT) evidence of a residual thoracic aortic false lumen or dissection flap.^{12,13}

Early results from clinical series of stent-graft management in limited numbers of patients with acute type B and acute type A aortic dissection where the primary tear is identified distal to the left subclavian artery are encouraging.^{12,16-19,21} Obliteration of flow through the entry tear into the false lumen was achieved in more than 90% of cases, with associated complete thrombosis of the proximal thoracic aortic false lumen segment apparent in 80 to 100% of cases, and distal thoracic segment thrombosis noted less frequently. Progressive thoracic false lumen shrinkage at 1-, 6-, and 12-month follow-up imaging was observed in most cases.

Complications, including paraplegia, rupture, and iatrogenic extension of the dissection into the ascending aorta, were reported anecdotally in early experience with stent-graft placement in acute dissection.¹⁶⁻¹⁹

In terms of the procedure, there are some technical challenges related to the idiosyncratic morphologic manifestations of aortic dissection that are often discussed when stent-graft therapy is considered. Specifically, the optimal method to select the diameter and length of the prosthesis is a common issue. Because the true lumen is a fraction of the overall transaortic diameter and rarely cylindrical in shape, choosing the "right" device dimension is a unique logistical dilemma. Most practitioners base their selection on more than one measurement. Perhaps, the most compelling measurement is the diameter of the nondissected aorta immediately proximal to the entry tear. This is a good estimate of the original size of the proximal involved segment prior to the dissection. This measurement, plus an oversize factor of 20% to ensure secure anchoring and a tight circumferential seal, is the approximation of device size most frequently used in current practice.

Obviously, if there is retrograde proximal extension of the dissection from the entry site, other planning steps must be taken. These include calculation of the mean true lumen diameter from measurements of the maximum and minimum true lumen dimensions and selection of an arbitrary diameter corresponding to a value larger than the true lumen but smaller than the overall aortic diameter.

In terms of the device length, most investigators implant devices that are clearly longer than the entry tear and usually in the range of 10 to 15 cm long. This added length confers an appearance to the aortic morphology after implantation that is more normal anatomically, especially in the arch, than that observed following placement of a short device focally over the entry tear. In addition, the longer device promotes a more rapid tempo to the formation of thrombus within the proximal thoracic aortic false lumen. Longer extension of the overall device length into the distal one-third of the descending thoracic aorta, however, should be avoided in this setting because of an associated increased risk of spinal cord ischemia.

In cases of aortic dissection with a classic isthmus location of the primary entry site, the tear may be within

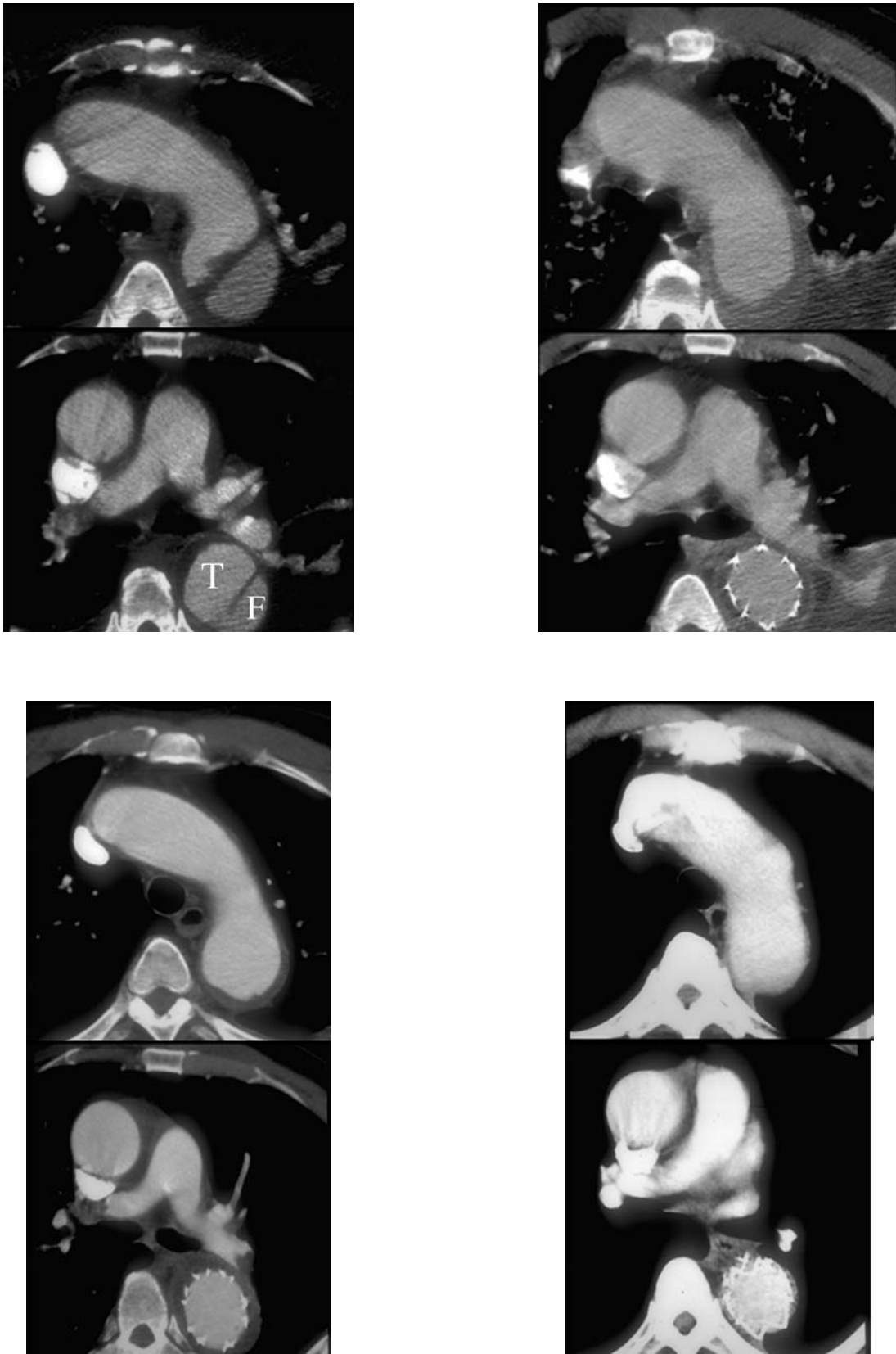


FIGURE 39-3. Series of CT scans performed at the same anatomic levels before and following stent-graft repair of a 53-year-old man with an acute type B aortic dissection complicated by abdominal branch vessel involvement. Immediately after stent-graft placement, there is an increase in the size of the true lumen (T) with resolution of the peripheral ischemia, and subsequently, progressive thrombosis and shrinkage of the false lumen (F).

10 mm of the left subclavian artery. In this situation, a device with a proximal segment consisting of a bare stent can be placed across the left subclavian artery to effectively maximize the length of graft contact with the aortic wall prior to the tear. However, in other settings, where there is retrograde proximal extension of the dissection from the tear to the subclavian artery, it may be necessary to place the graft over the branch, with its leading margin between the left carotid and subclavian arteries. In addition to carefully monitoring the patient post procedure for ischemic symptoms referable to the covered left subclavian, it is important to carefully image the thoracic aorta to exclude persistent perfusion of the false lumen via retrograde subclavian flow around the device into the arch.

Similar to acute type B dissection, experience is mounting with endograft management of chronic aortic dissection as an alternative to open surgical repair in patients with false lumen aneurysm. In this regard, multiple studies report rates of aneurysm, thrombosis, and subsequent false lumen shrinkage that mirror the results recorded in series of acute dissection.^{13–20,22} One controlled investigation that compared stent-graft therapy to open surgery in matched groups of patients with chronic type B dissection reported improved survival and decreased neurologic complications with the less-invasive procedure.¹³

Many other applications of stent-grafts for the treatment of patients with a wide variety of thoracic aortic pathologies have been published and are destined to receive increasing attention and clinical study in the future. Most noteworthy are traumatic aortic injury, mycotic aneurysm, aortic rupture, and aneurysms involving arch or abdominal branches.^{8–10,22} Details of these experiences are available in earlier publications.

Are there any trends currently evolving? Based on the experience accumulated thus far, and emboldened specifically by the relatively low frequency of paraplegia complicating treatment of TAA, the average stent-graft length appears to be increasing recently. This practice is intended to allow the device to be confidently secured within an ample segment of normal aorta proximal and distal to the aneurysm. It is hoped that this will help to avoid late complications such as endoleak due to degenerative changes within the aortic borders immediately adjacent to the aneurysm.

In conclusion, the recent development of endovascular stent-graft technology and its application as an alternative therapy to open surgical treatment of patients with a variety of thoracic aortic pathologies is an exciting and potentially valuable advance. The next major challenge that interventionists face is the important task of objectively elucidating the “real” benefits, risks, and complications of thoracic stent-grafts through rigorous, prospective, controlled investigations of each possible disease application. This type of controlled experience will no doubt help to better identify the most salutary indications, patients with the best chance for extended benefit, and the frequency

of long-term failures. Only after this level of scientific scrutiny is performed can clinicians confidently counsel patients with accurate information regarding their therapeutic options.

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