Early Experience with the Talent™ Stent-Graft System

for Endoluminal Repair of Abdominal Aortic Aneurysms

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Endoluminal grafting for treatment of aortic aneurysms is the most exciting topic in vascular surgery today. It is anticipated that at least half of all aneurysms in the infrarenal abdominal and descending thoracic aorta will be repaired endovascularly in the near future.

Endovascular grafting procedures require a combination of surgical maneuvers and refined interventional skills. They are often difficult, and involve catheter techniques and imaging requirements that are not readily available in most vascular surgery practices today. Collaboration between surgeons and interventionists is often necessary and, occasionally, is mandated by the investigational protocol.

The most significant technological achievement to date has been the development of the modular, fully supported, bifurcated stent-graft (Fig. 1).[1,2] This device incorporates 2 features that are currently viewed as critical components of endovascular graft technology: 1) *modular design*—which joins 2 or more sections of the stent-graft within the aorto-iliac lumen—optimizes deployment and exclusion by enabling the addition of extensions both cephalad and caudad; and 2) *full-length support* achieves the columnar strength that is necessary for stability and integrity, preserving normal channel flow even when placed across tortuous vessels. Another design feature that has recently become the focus of attention is *suprarenal fixation* of the uncovered stent at its proximal end, which enables secure attachment to a segment of the aorta less prone to progressive dilatation.[3]

In September 1999, 2 stent-graft devices for the exclusion of abdominal aortic aneurysms received approval from the Food and Drug Administration: the Ancure® device (Guidant; Indianapolis, Ind) (Fig. 2), which is an early-design balloon-expandable, 1-piece bifurcated stent-graft; and the AneuRx™ device (Medtronic AVE; Santa Rosa, Calif), a self-expanding, modular-design, fully supported bifurcated stent-graft. Additionally, several other stent-grafts are now under clinical investigation, including the Vanguard™ (Boston Scientific Corp; Natick, Mass) (Fig. 3), Talent™ (World Medical, a division of Medtronic Vascular; Sunrise, Fla), Bifurcated EXCLUDER Endoprosthesis (W.L. Gore & Associates; Sunnyvale, Calif) (Fig. 4), and Zenith™ (Cook Inc.; Bloomington, Ind) (Fig. 5). They are all self-expanding, modular-design endoluminal grafts, made of nitinol or stainless steel stents covered by a Dacron or polytetrafluoroethylene (PTFE) fabric. A somewhat different design is being developed by Cordis Endovascular (Cordis Corporation, a Johnson & Johnson company; Warren, NJ): this is a bilateral, aortoiliac endoluminal graft configuration that may be deployed percutaneously, given its low-profile (13 F) delivery system. A clinical trial is set to begin in mid-2000.

Endoluminal repair of aneurysms in the descending thoracic aorta is another area under active investigation at this time.[4] Designers of the Talent™, AneuRx™, and EXCLUDER devices have developed endoluminal grafts configured for placement in the thoracic aorta (distal to the aortic arch branches). Some forms of aortic dissection[5] and traumatic rupture are also being managed with endovascular approaches, but available information is only preliminary at this time; a much larger clinical experience with longer follow-up will be necessary before a definitive view can be attained concerning the performance of these endoluminal grafts for treatment of aneurysmal and nonaneurysmal thoracic aortic diseases. It is our impression today that stent-graft repair of descending thoracic aortic aneurysms will rapidly become a

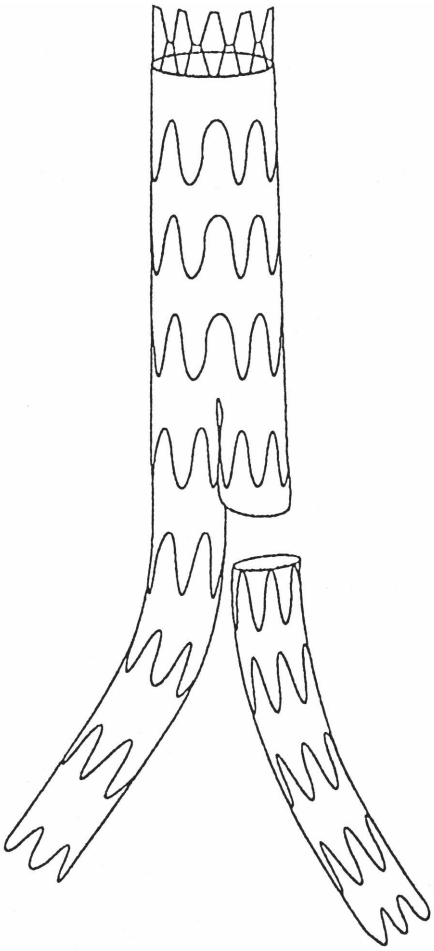

Fig. 1 *Modular, bifurcated, fully supported stent-graft.*

Fig. 2 *Ancure® stent-graft device.*

popular approach, given the extensive nature of conventional surgical treatment and the severe morbidity associated with it.

The Talent™ AAA Stent-Graft System

The Talent™ stent-graft is a modular, self-expanding prosthesis (Fig. 6) designed for endoluminal exclusion of aortic aneurysms. It consists of a series of serpentine nitinol stents embedded into woven Dacron fabric. The stents are spaced discontinuously along a full-length nitinol spine. The delivery system is a coaxial sheath with pusher rod and a compliant polyurethane balloon used to maximize attachment to the vascular wall and ensure full expansion throughout the length of the device. The outer diameter of the delivery system (containing the main section) ranges from 22 to 25 F (Table I). The more recently developed thinner Dacron fabric (Talent Low Profile System, or LPS™) has significantly reduced the outer diameter (Table II). For most AAA patients today, a 22-F system is used.

Salient features of the Talent device include the proximal bare spring (uncovered nitinol stent) (Fig. 7) and custom-manufacturing to fit a wide range of aorto-iliac sizes and configurations, as determined preoperatively by computed-tomographic (CT) imaging and angiography (Table III).

Device Implantation Techniques

The methods and technical principles described here are drawn from the senior author's (FJC's) personal experience with over 120 implants. Naturally, the opinion and advice of many investigators worldwide (who together have performed over 5,000 implants) and of Medtronic's engineering and technical team have had significant influence in the conception of these approaches.

The intervention often commences with percutaneous catheterization of the left brachial artery and placement of a 5-F sheath, as it has been found to be of great help during several steps of the implantation procedure (Table IV). After the guidewire has been steered along the correct pathway, the pigtail catheter is introduced and then "parked" in the proximal abdominal aorta, at the level of T12. Our own enthusiasm notwithstanding, most investigators prefer to use the brachial artery approach selectively, perhaps in less than 10% of procedures.

Systemic anticoagulation is induced with heparin, given intravenously in amounts adequate to prolong activated clotting time (ACT) to 300 to 400 seconds. The ACT is monitored and is maintained at this level throughout the implantation procedure by administering additional heparin as needed every 15 to 20 minutes.

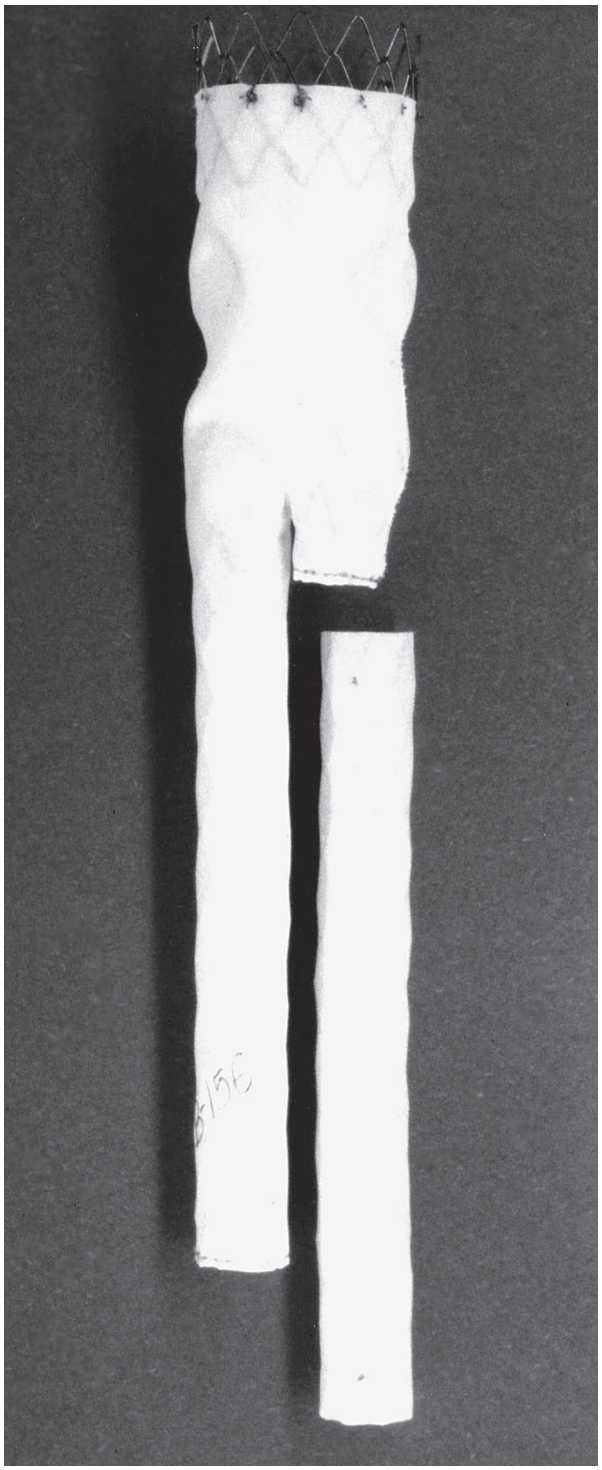

Fig. 3 *Vanguard™ stent-graft device.*

Fig. 4 *Bifurcated EXCLUDER Endoprosthesis.*

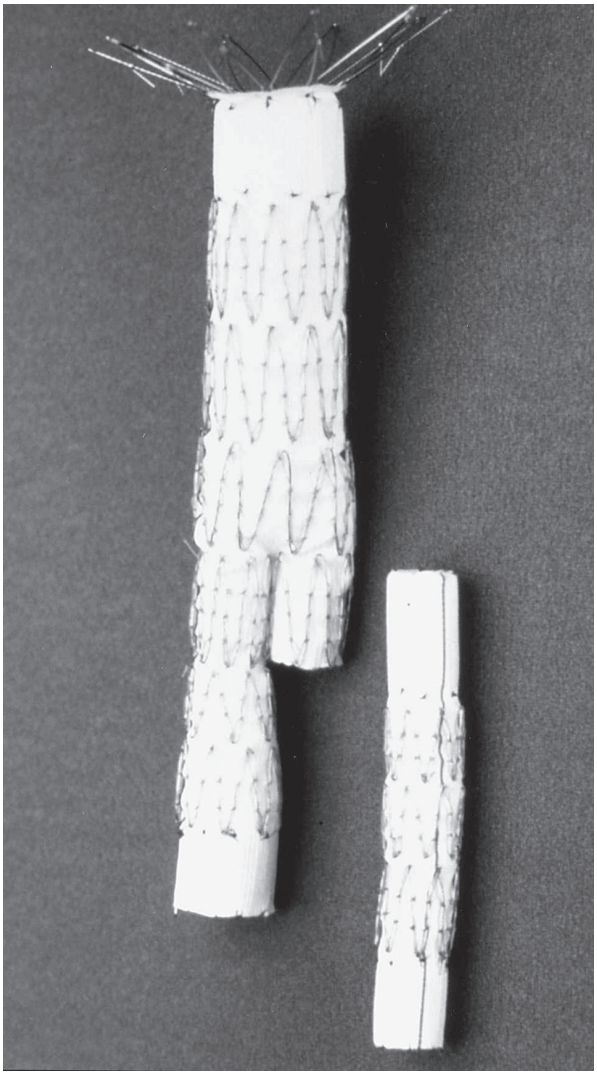

Fig. 5 *Zenith™ stent-graft device.*

Bilateral vertical groin incisions are made to surgically expose the full length of the common femoral artery (CFA) from the inguinal ligament to the femoral bifurcation.

An Amplatz Super Stiff™ (Boston Scientific) or Lunderquist (Cook) 0.035-inch guidewire, 260 cm in length, is inserted transfemorally by the exchange

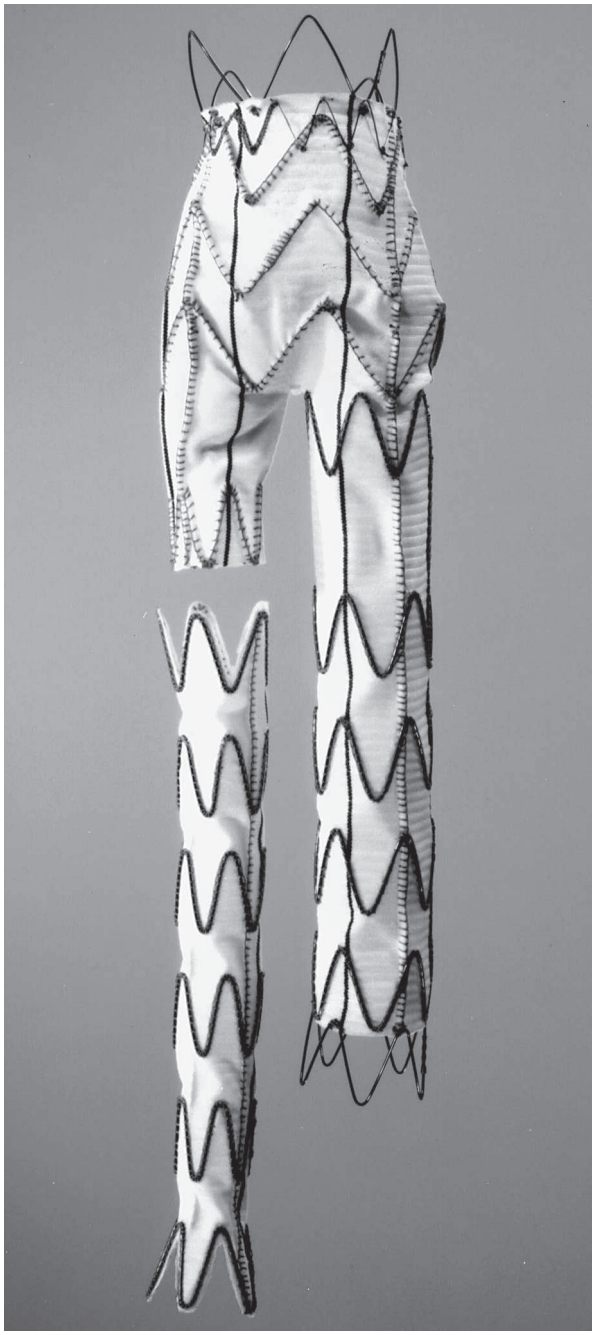

Fig. 6 *Talent™ stent-graft device.*

technique. The guidewire is advanced to the top of the aortic arch, where it is maintained until deployment has been completed. To prevent inadvertent advancement into the supra-aortic vessels or heart chambers, it is useful to have visual control of the wire's position at all times by relating it to an external reference point on the table (Fig. 8).

In preparation for introducing the sheath, a transverse arteriotomy is made at the site of the puncture. If the femoral arteries are thick-walled and diseased, longitudinal arteriotomy and subsequent patch repair may be more appropriate.

Table I. Talent™ AAA Stent-Graft System (Standard Graft Material)

	Aortic Graft Size	Delivery System Size
Bifurcated Grafts		
	20 mm	20 F
	22 to 30 mm	24 F
	32 to 36 mm	25 F

Table II. Talent LPS™ (Low Profile System)

	Aortic Graft Size	Delivery System Size
Bifurcated Grafts		
	20 mm	20 F
	22 to 30 mm	22 F
	32 to 36 mm	24 F
Tube Grafts		
	8 to 20 mm	18 F
	22 to 28 mm	20 F
	30 to 36 mm	22 F
	38 to 46 mm	24 F

Table III. Talent™ AAA Stent-Graft System: Sizes and Configurations

Main Section (usable on 14- to 34-mm aortas)	
Proximal neck diameter	16 to 36 mm
Length	5 to 12 cm
Iliac Extensions (usable on 8- to 18-mm vessels)	
Diameter	8 to 20 mm
Length	5 to 12 cm

The delivery sheath (containing the main body and ipsilateral limb of the endoluminal graft) is introduced over the Super Stiff wire and advanced carefully across the iliac artery into the aorta under fluoroscopic monitoring and guidance. We defer angiography until after the device has been introduced to the aorta, so that a *single contrast injection* will likely suffice for both anatomic definition and road-mapping. A push-pull wire technique ensures proper tension and facilitates transluminal tracking of the sheath; loss of wire access or excessive intraluminal advancement into the right side of the heart are avoided by the precautions described above. Very tortuous (but soft) iliac arteries can be appropriately straightened with brachial-femoral ("body floss") access, for which we prefer to use a 450-cm Glidewire® (Boston Scientific). When applying tension, we always protect the aortic arch and the left subclavian artery with a 5-F catheter over the wire (Fig. 9).

The sheath is advanced retrograde to the level of L1, and a power-injector angiogram is obtained via the brachial catheter. The image intensifier is centered on L1-L2 in order to center the fluoroscopic

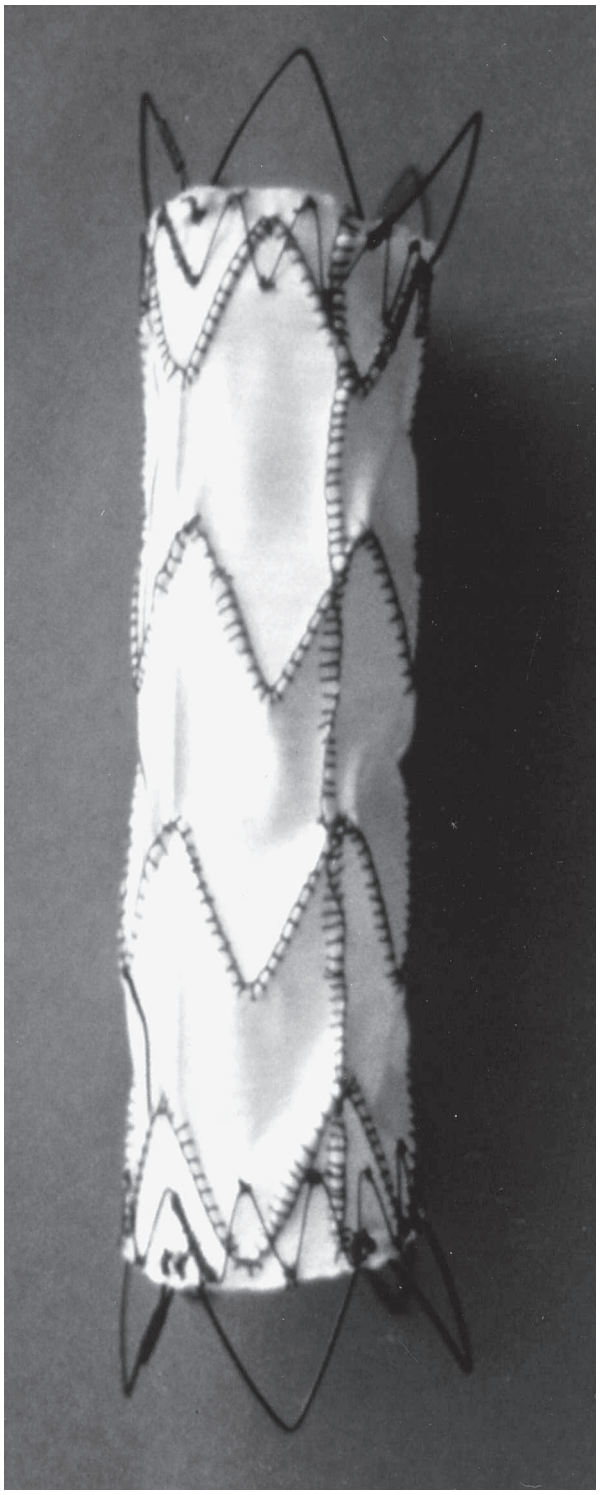

Fig. 7 *Note the bare spring (uncovered nitinol stent) at the top end of the Talent™ stent-graft.*

field on the juxtarenal aortic segment and thereby minimize parallax.

Deployment of the device is effected by gradually withdrawing the outer sheath as the pusher rod is held frozen in place. *We strongly recommend that deployment begin above the renal arteries.* Once the bare spring and 1st cloth-covered stent (corresponding to the 2 uppermost metal segments on fluoroscopy) are allowed to self-expand, the entire assembly is gently brought down to the juxtarenal position. "Ideal" placement consists of transrenal fixation of the bare spring, with the top end of the Dacron fabric 2- to 3-mm below the origin of the renal arteries. The fluoroscopic road-mapping technique is adequate to determine the proper proximal attachment level; if desired, a long 20g spinal needle can be inserted through the skin of the upper abdomen to mark the position of the renal arteries. When in doubt about possible coverage of 1 or both renal artery ostia by the Dacron fabric, a "puff angiogram" (through the brachial catheter) can easily and quickly provide clues in regard to whether the device should be pulled down to a lower level. Transrenal fixation may not be necessary when a long proximal neck is present.

Table IV. Uses of Brachial Artery Catheterization

Pre-deployment aortography
"Puff angio" to aid juxtarenal placement
Antegrade wire crossing of contralateral leg
Brachial-femoral access
Completion aortography

Once a satisfactory proximal level of attachment ("landing") has been achieved, the outer sheath is retracted fully to allow expansion of the rest of the device. Next, the balloon is inflated sequentially, all along the length of the body and the ipsilateral limb, to ensure proper expansion and embedding. Blood pressure control is not necessary during deployment of a self-expanding stent-graft.

Following removal of the delivery system, a long 9-F sheath with a radiopaque tip is placed (over the wire) through the arteriotomy to obtain a (limited) reflux angiogram that visualizes the adequacy of seal and the level of placement of the iliac limb. If these are satisfactory, the guidewire is removed, and the arteriotomy is repaired with interrupted sutures to quickly reestablish blood flow to the lower extremity. Inadequacies in the iliac-limb landing may be corrected by further balloon dilation, or by the addition of an iliac extension graft.

Access across the short leg is easily and quickly achieved from the top by passing a 300- to 450-cm long, 0.035-inch guidewire through the left brachial catheter. The wire is advanced antegrade into the aneurysm and out the iliac artery, down to the exposed common femoral artery. It can be extracted directly through the arteriotomy, or captured intraluminally with a goose-neck snare. Alternative access techniques can be used. Most investigators prefer the retrograde or contralateral ("over the top") approach for this ma-

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