Expanding the Indication for EVAR

With proven clinical history and versatility, Medtronic's Talent™ Abdominal Stent Graft enables endovascular repair in more of today's aneurysm patients.
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do not often use the first person when writing a journal article, but this is different. Being a part of the Talent (Medtronic Vascular, Santa Rosa, CA) project has been so significant in my professional and personal life, and for so long, that it would feel somewhat insincere not to do so.

THE HISTORICAL DEVELOPMENT OF TALENT

My involvement with the project resulted from a meeting and discussions held in Sydney, Australia at the International Endovascular Symposium in December 1995. It was then that I met Howard Leonhardt, the real engine behind the project, who invited me to join the Talent team. In the summer of 1996, I became the national Principal Investigator for the US clinical trials. Little did I know then what a long and arduous road lay ahead.

Table 1 summarizes the historical evolution and development of the Talent Abdominal Stent Graft system from inception to the present time. Beginning in 1997, the Talent Abdominal Stent Graft system was tested in various clinical trials (Table 2); there were seven studies in total. Patient outcomes from the initial phase 1 trial were reported in 1998. Results from the first pivotal trial were published in 2003. A subsequent, confirmatory pivotal trial became necessary when the Talent Low-Porosity System (LPS) endograft evolved into the eLPS graft featuring several important enhancements (Figure 1). Patient enrollment for the latter trial (n=166) was completed in 2003, generating the dataset that would eventually support approval by the FDA for release and commercialization in the US.

Over the years, Talent proved its value and versatility, bringing benefit to countless AAA patients around the globe. It became, and remains a leading device worldwide. Unfortunately, patients and physicians in the US would not enjoy the benefits of this useful technology for many years to come. The complexity and unusually high number of clinical studies (Table 2) and corporate transitions (Table 3) all contributed to the delay of US FDA approval. An editorial commentary published in 2005 reflected on the resultant frustration. Almost incredibly, however, all of that is now ancient history because Talent received final FDA approval on April 15, 2008. Well-deserved recognition should go to the Medtronic team and leadership for their tireless work, their commitment through thick and thin, and their belief in the Talent technology and the therapy overall.
APPROVAL FOR AAA REPAIR: ON-LABEL INDICATIONS

The Talent Abdominal Stent Graft is the only abdominal aortic aneurysm (AAA) stent graft approved with an on-label indication for a proximal neck length as short as 1 cm. Table 4 lists the most significant on-label indications for use. They accurately reflect the impressive capabilities of this endograft, which has proven quite effective and versatile in the treatment of a broad range of aortic anatomies.

FEATURES OF THE TALENT ABDOMINAL STENT GRAFT

Figure 1 depicts the principal features of the Talent Abdominal Stent Graft—most prominently: surface treatment of the nitinol wire through chemical polishing to achieve a very smooth surface and prevent fractures; medial—instead of lateral—placement of the connecting bar (C-bar) in the iliac limb; the unidoc configuration for universal fitting of any limb or extension into the contralateral gate; and the flared configuration of the iliac limbs. Figure 2 highlights its most defining characteristics: the FreeFlo proximal bare spring for transrenal fixation; large diameters, up to 36 mm at the top end; and a very simple, intuitive delivery system and deployment mechanism. The Talent Abdominal Stent Graft delivery system has also evolved over time (Figure 3), with the most recent Xcelerant iteration that is currently available outside the US.

OVERVIEW

Physicians around the world have frequently chosen to use the Talent Abdominal Stent Graft to treat their patients for longer than 11 years, with an impressive overall cumulative caseload of more than 45,000 implants. This clinical experience is supported by more than 115 peer-review publications reporting data on 7,000 patients with up to 7 years of follow-up.

TABLE 2. CLINICAL STUDIES USING TALENT

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Risk Level</th>
<th>No. of Patients</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>High risk</td>
<td>n=26</td>
<td>1997</td>
</tr>
<tr>
<td>Phase II</td>
<td>High risk</td>
<td>n=130</td>
<td>1997–1998</td>
</tr>
<tr>
<td>Phase II</td>
<td>Low risk</td>
<td>n=151</td>
<td>1997–1998</td>
</tr>
<tr>
<td>Emergency/compassionate</td>
<td></td>
<td>n=536</td>
<td>1996–2004</td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
<td>n=148</td>
<td>1999–2002</td>
</tr>
<tr>
<td>LPS</td>
<td></td>
<td>n=240</td>
<td>1999–2001</td>
</tr>
<tr>
<td>eLPS</td>
<td></td>
<td>n=166</td>
<td>2002–2003*</td>
</tr>
</tbody>
</table>

*Pivotal dataset.

TABLE 3. CORPORATE TRANSITIONS AFFECTING THE TALENT PROJECT

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>WMMC acquired by AVE (Dec 14, 1998)</td>
</tr>
<tr>
<td>1999</td>
<td>AVE acquired by Medtronic (Feb 28, 1999)</td>
</tr>
</tbody>
</table>

TABLE 4. ON-LABEL INDICATIONS FOR TALENT ABDOMINAL STENT GRAFT

<table>
<thead>
<tr>
<th>Proximal Neck</th>
<th>Iliac Arteries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length ≥1 cm</td>
<td>Fixation length ≥15 mm</td>
</tr>
<tr>
<td>Angulation ≤60°</td>
<td>Diameter 8 to 24 mm</td>
</tr>
<tr>
<td>Diameter 18 to 32 mm</td>
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</tr>
</tbody>
</table>

Figure 2. Defining characteristics of the Talent Abdominal Stent Graft: bare spring (FreeFlo), suprarenal fixation, large sizes, and simple deployment.
years of follow-up. The Talent Abdominal Stent Graft has evolved over time and is now in its fourth generation of design (Figure 4), incorporating the most recent advancements in endovascular stent graft technology, including the most recent iteration of the Xcelerant delivery system, which is available outside the US.

The April 2008 regulatory approval of this device will allow commercialization in the US, bringing benefit to many AAA patients—and their physicians—who will no doubt derive significant benefit from the availability of such a useful and versatile stent graft device.

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Abdominal aortic aneurysms (AAAs) represent a chronic, degenerative disease of the abdominal aorta. Epidemiological studies estimate AAA prevalence to be 60 per 1,000 in the general population. In addition, AAA incidence appears to be increasing in industrialized countries independent of increased patient longevity, and the disease is responsible for considerable morbidity, mortality, and cost to society. More than 15,000 deaths due to AAA rupture occur in the US each year. The overall mortality rate for a ruptured AAA has been estimated to exceed 90%. In patients with intact AAAs, the rate of aneurysm rupture and death may exceed 60% within 3 years of the initial diagnosis depending on AAA size.

The technique for endovascular aneurysm repair (EVAR), as initially developed by Parodi et al, employs a transfemoral route of delivery and uses a balloon-expandable stent graft to achieve AAA sac exclusion from the systemic circulation, thereby reducing the risk of continued expansion and rupture. Numerous endovascular devices have been developed and tested for the treatment of AAA, with reproducible safety and efficacy profiles. However, treatment failures continue to occur despite the relative safety and efficacy of EVAR.

The Talent Abdominal Stent Graft (Medtronic Vascular, Santa Rosa, CA) is a self-expanding endoprosthesis composed of a Dacron graft with a nitinol frame. The proximal aortic fixation end has a 1.5-cm uncovered nitinol frame that allows for transrenal fixation of the device. These characteristics may allow increased potential for treating patients with challenging aortic neck configurations. The stent graft is preloaded in a delivery system that has since undergone changes as the device features have evolved, with the goal of improving treatment outcomes and reducing failures. This study sought to determine the immediate safety and efficacy profiles of the bifurcated Talent Abdominal Stent Graft using the CoilTrac delivery system in patients considered to be at increased risk for open surgical repair.

METHODS
Patient Characteristics
This study was a single-center, prospective analysis of the bifurcated Talent Abdominal Stent Graft using the CoilTrac delivery system. Data were obtained on 137 patients who were enrolled from April 2003 to November 2006. Inclusion criteria were age ≥ 18 years, medical comorbidities that preclude standard surgery, proximal implantation zone ≥ 1.5 cm, distal implantation zone ≥ 1 cm, and access vessel >0.8 cm. Exclusion criteria were weight ≥ 350 lbs, women of childbearing age, and patent inferior mesenteric artery in association with superior mesenteric artery disease and/or iliac artery disease with collateral mesenteric circulation. Patients were enrolled under a Sponsor-Investigator Investigational Device Exemption study through the FDA that was approved by the Institutional Review Board.

Perioperative Characteristics
Preoperative assessment in all patients consisted of conventional angiography and helical computed tomographic scan, with intravenous contrast and images acquired at 3-mm intervals. All procedures were carried out in an operating room equipped with fluoroscopic capabilities. Intraoperative and perioperative 30-day endpoints consisted of acute function of the delivery system; conversion to open repair; presence of endoleak; vessel or graft limb occlusion; mortality and morbidity, including cardiopulmonary, neurologic, and peripheral vascular complications; bowel ischemia; renal insufficiency; and wound complications. Secondary endpoints of the acute procedural analysis included procedure time, estimated
blood loss, blood transfusion, contrast load, time in an intensive care unit, and hospital length of stay.

For the analysis of the acute function of the delivery system, a successful delivery and deployment was defined as an initial implant procedure that was not aborted and did not involve delivery system malfunction. Primary technical success was defined as a successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction. All relevant adverse events were reviewed by an independent Clinical Events Committee and adjudicated as either aneurysm related, procedure related, and/or device related. The Harvard Clinical Research Institute served as the Clinical Events Committee.

Device Characteristics

The mechanical conformation of the Talent Abdominal Stent Graft with the CoilTrac delivery system is as follows: The CoilTrac catheter tip (Figure 1) is constructed from a soft, siliconized material and is equipped with a centrally bored lumen that interfaces midway in the tip to a catheter connected to an external hub. The flexible catheter tip is designed to securely interface with the cephalad end of the delivery catheter to create a tapered end without a sharp edge exposed to the arterial surface. The caudal end of the flexible tip accepts the cephalad end of an external polytetrafluoroethylene delivery sheath. The external sheath is also equipped with a radiopaque band, which marks the end of the catheter to facilitate fluoroscopic positioning.

The catheter interfaces with the flexible delivery system tip and contains a nitinol wire shaft that provides stiffness and flexibility; it is bonded to the proximal portion of the flexible tip, and there is a compliant balloon attached just below this bond. The balloon is present for postdeployment dilation of the graft-artery interface to ensure approximation of the stent graft to the arterial wall. The external stent graft encasement catheter is constructed from polytetrafluoroethylene and is terminated at its caudal end with a hemostatic valve. A pusher catheter is positioned coaxial to the guidewire catheter and stent graft encasement catheter. The cephalad end of the pusher catheter contains a stainless steel coil that is designed to engage the caudal end of the endovascular graft to stabilize it during encasement sheath retraction and stent graft deployment. The caudal end of the catheter is terminated in a Tuohy-Borst valve and bonded connector.

Additional features of the device include a flush port on the caudal end of the encasement sheath with a two-way valve. The caudal end of the guidewire catheter is terminated in a bifurcated manifold that accepts a 0.035-inch guidewire and permits controlled postdeployment balloon inflation.

RESULTS

Patient Demographics

The mean age was 75.4 years (range, 51–93 years), and males comprised 86.1% of the study population. The distribution of cases based on the American Society of Anesthesiologists classification showed that the majority of cases corresponded to class 3 (75.9%), followed by class 4 (19.7%). By grouping the comorbidities into body systems, the cardiovascular-associated illnesses were the most prevalent; 97.1% of the patients were found to have at least one condition that falls in this category. The most common associated risk factors were hypertension (84.7%) and tobacco use (86.9%) (Table 1). On computed
tomography, maximum baseline AAA diameter averaged 61.3±10.5 mm (range, 35–100 mm). The distribution of cases based on the maximum AAA diameter showed the higher percentages for sizes between 50 to 59 mm (39%) and 60 to 69 mm (36.8%).

Immediate Safety and Efficacy of the CoiTrac Delivery System

The delivery and deployment of the Talent Abdominal Stent Graft using the CoiTrac delivery system was achieved in all 137 cases (100%). There were no reports of aborted procedures or conversions to open repair.

Perioperative Endpoints

General anesthesia was required in only 1.5% of cases. Average duration of the procedure was 245.1 minutes (range, 108–748 minutes). In the case in which the length of the procedure reached 748 minutes, the intraoperative difficulties were related to a difficult access secondary to severe aortoiliac disease. The amount of contrast media used during the procedure averaged 311.5±128.2 mL. The average estimated blood loss was 317.6±242.8 mL, and transfusion was required in 24 (17.5%) patients. Average length of stay was 1.6±3.2 days (Table 2).

Endoleak was present in 12 (8.8%) cases: seven type I endoleaks (5.1%) and five endoleaks of undefined origin (3.7%). Stent graft occlusion occurred in two cases (1.5%) and was treated successfully. There were no events of branch vessel occlusion or stent graft migration. Wound complications were reported in eight (5.8%) patients; these corresponded to three wound infections (2.2%) and five cases of hematoma (3.6%). Major adverse events were reported for six patients; these included all-cause mortality (1.5%), procedural blood loss ≥1000 mL (2.9%), and respiratory failure (0.7%). There were no reported events of AAA rupture, conversion to open repair, myocardial infarction, neurological deficits, bowel ischemia, or renal failure (Table 3).

The reported operative deaths were adjudicated by the Clinical Events Committee as unrelated to the aneurysm, the device, or the procedure. One was a patient who died on postoperative day 18 from cardiopulmonary arrest secondary to congestive heart failure and severe aortic stenosis. The other reported death was due to aspiration pneumonia 24 days after EVAR. In both cases, there were no difficulties with the delivery system or deployment of the stent graft during the implant procedure, the immediate recovery was uneventful, and the patients were discharged within 48 hours from admission.

DISCUSSION

In this study, successful deployment of the stent graft was achieved in all 137 patients (100%), with no events of acute malfunction of the CoiTrac delivery system. There were 4.4% major adverse events, including two perioperative deaths, which were considered not related to the device. This study demonstrated satisfactory 30-day outcomes with the Talent Abdominal Stent Graft using the CoiTrac delivery system in medically high-risk patients.

To exclude the aneurysm sac successfully using endovascular repair, there are specific anatomic characteristics that must be fulfilled. Typically, these characteristics include aortic neck diameter <28 mm, aortic neck length >15 mm, aortic neck angulation <60°, and access artery diameter >7 mm. In addition, iliac tortuosity and calcification and the extent of aortic neck thrombus can limit the application of EVAR. These criteria have been modified as the techniques and devices for EVAR have evolved.16 Adherence to these parameters limits the number of

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### TABLE 2. ACUTE PROCEDURAL OUTCOME: SECONDARY ENDPOINTS

<table>
<thead>
<tr>
<th>Acute procedural data</th>
<th>Mean±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of procedure (min)</td>
<td>245.1±82.7</td>
<td>107–748</td>
</tr>
<tr>
<td>Amount of contrast media (mL)</td>
<td>311.5±128.2</td>
<td>110–855</td>
</tr>
<tr>
<td>Estimated blood loss (mL)*</td>
<td>317.6±242.8</td>
<td>50–1,800</td>
</tr>
<tr>
<td>Length of hospital stay (d)</td>
<td>1.6±3.2</td>
<td>1–36</td>
</tr>
<tr>
<td>Length of ICU stay (h)</td>
<td>6.8±7.3</td>
<td>0–864</td>
</tr>
</tbody>
</table>

*Blood transfusion required in 24 patients (17.5%).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful delivery and deployment</td>
<td>137 (100)</td>
</tr>
<tr>
<td>Primary technical success</td>
<td>128 (93.4)</td>
</tr>
<tr>
<td>Conversion to open repair</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Primary endoleak</td>
<td>12 (8.8)</td>
</tr>
<tr>
<td>-Endoleak type I</td>
<td>7 (5.1)</td>
</tr>
<tr>
<td>-Endoleak type III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>-Endoleak of undefined origin</td>
<td>5 (3.7)</td>
</tr>
<tr>
<td>Stent graft occlusion</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Major adverse events</td>
<td>6 (4.4)</td>
</tr>
<tr>
<td>Mortality (within 30 d)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Procedural blood loss &gt;1000 mL</td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Wound infection/hematoma</td>
<td>8 (5.8)</td>
</tr>
</tbody>
</table>
patients that are eligible for EVAR. It is estimated that up to 50% of patients evaluated for AAA repair are ineligible for EVAR based on anatomic criteria. The success of EVAR depends on complete exclusion of the aneurysm sac from systemic circulation. Incomplete exclusion exposes the aneurysm wall to systemic arterial pressures from continued arterial perfusion of the aneurysm sac, defined as endoleak. The increased intraluminal blood pressure transmitted to the aneurysm wall and may lead to continued aneurysm expansion and a significant risk of rupture, conversion to open repair, or death.

Experience with the Talent Abdominal Stent Graft has been published previously with deployment success rates ranging from 94% to 99%. The potential to use this device in patients with challenging aortic configurations is an advantage that can be particularly beneficial to patients with severe medical conditions that prohibit open repair. Earlier reports describing the use of EVAR in patients who are considered high-risk and unfit to undergo open repair have yielded satisfactory outcomes.

CONCLUSION
In this study, the bifurcated Talent Abdominal Stent Graft using the CoiTrac delivery system was efficiently employed to treat AAA in patients considered unfit for open repair due to the presence of severe comorbidities. Immediate safety of the device and successful procedural and clinical results in the 30-day perioperative period were observed in the majority of cases. The ongoing modifications to the devices employed in endovascular procedures aimed to improve their performance may also contribute to increase the number of suitable cases for this type of repair. The availability of endovascular procedures for medically high-risk patients is an important contributory factor to decrease the mortality rates associated with AAA disease.

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Endoluminal stent grafting continues to evolve as new device designs appear to simplify the deployment process and to deal with failure modes encountered with long-term data analysis of collected data. Aneurysm neck morphology, which has been extensively studied, is a vital component to the success of endovascular aneurysm repair (EVAR). Aortic necks that are large in diameter (>28 mm) or short in length (<15 mm) have been addressed by relying on passive or active suprarenal fixation. One of the endografts used to treat abdominal aortic aneurysms (AAAs) with adverse neck anatomy has been the Talent Abdominal Stent Graft (Medtronic Vascular, Santa Rosa, CA). We will review its performance at our institution and in long-term studies in the US and abroad.

**HARBOR/UCLA EXPERIENCE**

Between 1998 and 2001, as part of our own institutional Investigational Device Exemption (IDE), we identified 47 consecutive patients (41 men; mean age, 74; range, 55–84) with aortic neck diameters >28 mm. Their anatomic criteria precluded aneurysm exclusion with the then FDA-approved endografts, AneuRx (Medtronic Vascular, Santa Rosa, CA) and Ancure (formerly Guidant Corporation, Indianapolis, IN). Mean baseline aneurysm morphology included suprarenal 27.6 mm (range, 18–34), and infrarenal 28.1 mm (range, 24–34) neck diameters; the infrarenal neck length was 26±16 mm with an angulation of 37º±18º. These patients were treated with earlier-generation designs of the bifurcated Talent Stent Graft System, the Open Web (for infrarenal placement) or FreeFlo (bare uncovered nitinol framework [for transrenal or suprarenal placement]) proximal configurations (Figure 1).

Forty-five (96%) patients were successfully treated; in two, the device could not be introduced due to access issues. The site of fixation chosen according to anatomic neck characteristics was suprarenal in 26 patients, transrenal in five patients (bare spring covering only one renal orifice), and infrarenal in 14 patients. Eight patients (20%) had neck lengths <15 mm, and 15...
patients (38%) had a conical neck configuration. Forty patients had complete CT data to provide a mean follow-up of 17 months (range, 6–36 months) and comprised our study group.

Distal stent-graft migration >1 cm (mean, 18.5±6.6 mm) occurred in 7 patients (17.5%): three patients within 6 months and the others at 1, 2, and 3 years. Analysis of aortic neck morphology revealed that the migration group had a shorter neck (23.2 vs 28.6 mm), but this was not statistically significant. Not surprisingly, suprarenal fixation was more common in AAAs with shorter necks. Further analysis showed that a shorter neck (15 mm) was not predictive of eventual migration ($P= .4$). Postoperative suprarenal neck diameters remained fairly constant in both migration and no-migration groups. After an initial mean increase of 1.3 mm, the infrarenal neck diameters remained constant in patients with no migration. In contrast, significant increase was seen in the migration group reaching 2 mm at 2 years. The average rate of neck dilatation was tenfold lower in the nonmigration cohort, but patients with device migration did exhibit the standard expansion rate of 1 to 2 mm per year, which has been reported irrespective of device composition or preoperative neck size.

Three type I endoleaks were encountered, all in the migration group. Type II endoleaks were found in five patients (12.5%) at 6 months, and three patients (7.5%) at 1 and 2 years. One required inferior mesenteric embolization. None of the patients with type II endoleaks exhibited significant migration.

Six secondary procedures, five of which were in the migration group, were performed during the study period, with no mortalities or major complications. Aortic cuffs were deployed to reaffirm fixation in two patients with proximal bare spring fractures (only one was associated with proximal migration) and in three patients to seal the type I endoleaks. Two of the patients with endoleak had only infrarenal fixation and retrospectively may have benefited from suprarenal fixation. One patient also received aortic cuffs to achieve a secure proximal fixation and arrest further migration. Significant aneurysm sac shrinkage was seen in the nonmigratory group during the follow-up period but was not seen in the patients with migration until the proximal aortic cuffs were deployed.

An early configuration of the Talent abdominal stent graft was successfully deployed in 96% of patients with adverse neck anatomy, with no ruptures or need for conversion. Careful follow-up identified significant migration associated with type I endoleaks, which were treated by deploying aortic cuffs to ensure a secure proximal fixation and continued aneurysm sac shrinkage and exclusion. Important associations with postop-

Figure 2. Infrarenal AAA (6.2 cm in diameter) with a 27.9-mm aortic neck and angulation of 34.1° excluded with a Talent eLPS 36 mm in diameter (16.5 cm in length).
operative changes in aneurysm morphology were revealed. Infrarenal neck dilatation and delayed aneurysm sac regression were more prevalent in endografts that migrated, especially when not associated with suprarenal fixation.

Since 2002, as part of our FDA-approved physician-sponsored study (IDE #G01304), 48 patients have been enrolled to undergo endoluminal exclusion of their AAAs with the eLPS Talent abdominal stent graft, the current generation of the Talent stent graft. The data are currently undergoing careful and complete CT analysis (Figures 2 and 3, Table 1). We have had no ruptures, but two patients have required an open conversion. Significantly, we have only encountered one migration in this group of patients.

THE EUROPEAN EXPERIENCE

A total of 165 patients were treated with a Talent endograft in nine German centers between October 1996 and December 1998. The mean diameter of the aneurysm sac was 55.9±10.3 mm, with a neck diameter of 24.6±3.1 mm. The site of proximal fixation was suprarenal in 141 patients (85.5%) and infrarenal in 24 patients (14.5%). CT imaging revealed a decrease (>5 mm) in maximum aneurysm diameter in 106 patients (75.2%), an increase in 14 patients (9.9%), and no change in 21 patients (14.9%). Of the group with aneurysm expansion, 12 patients underwent open conversion because of type I endoleak (n=6), persistent type II endoleak (n=4), and rupture (n=2). Overall, the aneurysm sac diameter significantly decreased to 46.4±13.3 mm, whereas the aneurysm neck diameter increased to 25.1±8.8 mm. Distal migration by more than 1 cm occurred in seven patients (4.2%), with four patients undergoing open conversion. Three patients were treated successfully with endovascular techniques. Reasons for the migration were minimal oversizing (n=2), reverse conical neck (n=2), significant increase in neck diameter (n=2), and low deployment of the endograft (n=1). However, adverse neck anatomy, defined as neck diameter >28 mm, neck length <15 mm, and five patent aortic branches, did not significantly influence the aneurysm sac shrinkage rate, the risk for a secondary procedure, or the clinical success rate. Implantation of early prototypes of the Talent endograft was successful in most patients and even in those with adverse anatomy.

TALENT ABDOMINAL STENT GRAFT PMA SUBMISSION

The current version of the Talent stent graft, including improvements such as chemically etched nitinol and medial placement of the connecting bar implemented to improve fatigue resistance was named eLPS and served as the test group in the Talent Abdominal PMA. However, these 166 patients were treated with an older

| TABLE 1. MORPHOLOGICAL CHANGES IN AAAs TREATED WITH eLPS TALENT ABDOMINAL STENT GRAFT |
|----------------------------------|----------------------------------|------------------|------------------|------------------|
| AAA                              | Diameter (mm) | Volume (mL) | Renal Level | 1.5 cm Below Renals |
| Preoperative                     | 61.6          | 210.6        | 27.9         | 33.6             |
| 2004 (1 mo)                      | 59.7          | 229          | 30.5         | 36.6             |
| 2004 (6 mo)                      | 55.5          | 194.8        | 30.8         | 36.5             |
| 2005                             | 50            | 178.4        | 30.6         | 34               |
| 2006                             | 47.9          | 176.4        | 30.5         | 36               |
| 2007                             | 47.6          | 162.1        | 32.9         | 38               |

AAA diameter decreased 23%, and its volume decreased 24%, while the aortic diameter at the renal level increased 18% (5 mm), and the diameter 1.5 cm below the lower most renal artery increased 13% (4.4 mm).
The Talent stent graft, including its early prototypes in Europe and the US, reinforces its efficacy in endoluminal exclusion of infrarenal AAAs with adverse neck anatomy. However, continued postoperative changes in aneurysm morphology such as aortic neck dilation and elongation, mandate a careful and long-term follow-up to prevent aneurysm-related deaths or ruptures.

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Currently, there are concerns that the long-term outcomes of endovascular abdominal aortic aneurysm repair (EVAR) may not be as durable as those of open repair. The risks of complications and costs associated with intensive follow-up and secondary procedures in the long term may offset the initial survival benefit observed with endovascular repair.

Whether these concerns apply to the latest generation of EVAR devices used in unselected patient populations remains an object of debate because investigations with long-term follow-up after EVAR are scarce. In addition, patients enrolled in European randomized clinical trials that compare open versus endovascular repair in abdominal aortic aneurysms (AAAs) are highly selected, and experience may not reflect the actual practice.1-2

The Talent Abdominal Stent Graft (Medtronic Vascular, Santa Rosa, CA) was first introduced in 1995 and has been deployed in more than 45,000 patients worldwide. There are a number of studies, single-center or multicenter registries, that investigated late outcomes after Talent repair.3-10 The device is a self-expanding modular system composed of serpentine-shaped nitinol stents integrated into a woven polyester matrix and provided with a 15-mm-long proximal uncovered stent for suprarenal fixation (Figures 1 and 2).

Since its original introduction, the graft has been modified to include the use of a thinner, low-profile graft fabric to create the Talent Low-Porosity System (LPS). Later, the Talent stent graft nitinol springs were chemically treated to enhance durability, and the position of the iliac longitudinal connecting bar was moved from lateral to medial (to improve conformability and decrease risk of kinking and thrombosis), resulting in the latest-generation Talent eLPS device.

WORLDWIDE RESULTS

Published worldwide reports and US FDA trials are evaluating the safety and efficacy of EVAR with Talent and suggest good outcomes in both high-risk and low-risk patients and in difficult anatomy, even though few long-term data have been provided. In the largest multicenter prospective trial, Faries et al showed a perioperative mortality rate of 1.9% (7/368) with only two late aneurysm-related deaths at 18 and 23 months in 368 high-risk patients treated with Talent LPS.4 The pivotal Talent LPS multicenter (nonrandomized) prospective investigational device exemption trial, comparing 237 low-risk patients receiving the Talent device with 126 open surgical controls, showed similar, very low perioperative mortality rates (0.8% vs 0%). Open surgical conversion after EVAR was required in six cases (one intraoperative), and none in 26 late deaths (20 in the Talent group, six in the surgery group) were aneurysm related.5

Figure 1. Thirty-six-month follow-up CT scan after EVAR with bifurcated Talent device and left renal stenting. Complete exclusion of abdominal sac and renal stent patency.
The performance of the Talent Abdominal Stent Graft was also measured against other devices. According to the comparison of Ouriel et al on five different endograft models in 703 patients (included in IDE or other multicenter trials on EVAR), no AAA ruptures or migration occurred. The lowest rates of endoleak (19±7.1%) and one of the greatest frequencies of sac shrinkage (52±9.7%) at 12 months were detected with Talent devices.11

In the longest of these worldwide studies, Espinosa et al demonstrated good resistance from material fatigue in 193 patients treated with Talent LPS, showing no fracture, no aneurysm rupture, no limb occlusion, and only one fatal disconnection at 6 years.6 Furthermore, progressive shrinkage of the aneurysm sac, reaching 14 mm in average diameter decrease, occurred during that time. Single-center and multicenter series focused on the Talent device are reported on Table 1.

EUROPEAN EXPERIENCES

Three single-center and four multicenter European studies have recently reported on late results with Talent. All studies reported outcomes after 1 year and up to 7 years, with a mean follow-up ranging from 25 to 53 months. Study population varied from a minimum of 33 in single centers to 1,796 in the largest EUROSTAR (European Collaborators on Stent graft Techniques for Abdominal Aortic Aneurysm Repair) reports.

Single-Center Studies

Despite smaller populations, data from monocenter experiences may be valuable because of the high accuracy and uniformity in collecting and reporting. Coppi et al recently reported late results of 50 patients treated with the Talent LPS endograft between 1997 and 2001, with a mean follow-up of 47.7±27.4 months.9 The device was used in high-risk patients (25% unfit for open repair, 58% American Society for Anesthesiology class III–IV), many with unfavorable neck morphology (32% short: <15 mm; 16% angulated: 30°–60°, 6% large: >28 mm; and 14% tapered or bulging aortic neck) or iliac ectasia (32%). Implantation success was achieved in 96% (48/50); four (8%) patients died within 30 days. A Kaplan-Meier estimate of any-cause mortality was 51% at 5 years. There were two late (4%) aneurysm-related deaths. Eight (16%) secondary interventions were necessary, including three conversions to open repair, for a freedom from secondary procedures rate of 88% at 5 years. Furthermore, nine (18%) endoleaks, two migrations (4%), and a single case of stent graft fracture (2%) were detected. The reintervention and complication rates at 5 years compared well with other devices used in the same period by the investigators and supported the good performance of the device despite the use of Talent in adverse anatomical settings. The overall high mortality rates (either perioperative or late) could be explained by old age (average, 79.5 years) and multiple comorbidities (average, 3.5).

Quite differently from the previously mentioned experience, no 30-day mortality was found by Seriki et al (2006) in 68 patients treated with Talent between 1998 and 2002.10 All patients had at least 2-year follow-up (mean, 39 months; range 24–72). The cumulative mortality rate was 24.3% at 2 years; two (2.9%) late deaths due to rupture were aneurysm related. Two late conversions to open repair and 10 other reinterventions (12/68, 17.6%) were performed. Late complications included 24 endoleaks (four persistent), two (3%) stent wire fractures, three (4.4%) migrations, and one (1.5%) limb thrombosis. The 3-year freedom from persistent endoleak rate was 92.3%.

In a smaller UK series of 33 patients with at least 3 years of follow-up, the Belfast group reported a progressive aneurysm shrinkage at a mean of 3.3 years (range, 3–4 years).12 Despite the shorter preoperative neck, the investigators did not find differences between the rates of migration of Talent compared to other 29 Zenith devices (Cook Medical, Bloomington, IN) with 83% in both groups free from 10-mm migration at 3 years. Reintervention rates were also similar in the two groups in the range of 18%, and all were performed by endovascular route.
Multicenter Studies

Most of the longitudinal data on aortic endografts used in Europe come primarily from multicenter studies or registries, which often report cumulative data without accounting for diverse experience of participating centers. In some cases, such as voluntary registries, results may include a high patient dropout rate and do not account for the evolution of endograft material over time.

Currently, the longest data with Talent LPS devices are provided by the multicenter Talent AAA Retrospective Long-term (TARL) study, reporting outcomes of 165 patients treated in nine German centers before December 1998 with a mean follow-up as long as 53.2±20 months (range, 1–84). Results showed that the device provided low aneurysm-related mortality (0.6% late death) and high stability in fixation (4.2% migration) at 7 years from repair. During follow-up, there was a significant decrease in mean AAA diameter, from 55.9 to 46.4 mm (P<.001), regardless of adverse anatomy (ie, neck diameter, length, tortuosity). Two patients (1.2%) died at 30 days, and an additional 28 patients died during follow-up, but only one death was aneurysm related. Overall survival rates were 78.1±3.6% at 5 years and 76.2±4.1% at 7 years. During follow-up, 47 (28%) secondary procedures were performed, including 13 (7.8%) late conversions. Two were for aneurysm rupture (2/165; 1.2%).

According to life-table analysis, freedom from secondary intervention rates were 94.7±1.8%, 81.7±3.3%, and 77.4±3.6% at 1, 3, and 7 years, respectively. Late complications included endograft thrombosis (10/165, 6.1%), persisting endoleak (15/165, 9%), graft infection (1/165, 0.6%), graft migration (7/165; 4.2%), and loss of integrity (9/165; 5.4%) including four graft kinkings, two fractures of metallic stents, two erosions of longitudinal bar, and one modular separation). The quite disturbing rates of 6.1% endograft thrombosis and 5.4% graft changes in integrity were reasons for concern such that the investigators suggested to re-evaluate after the introduction of the next-generation Talent device (Talent eLPS), which was shown to have a better resistance to metal fatigue.

Rates of thrombosis and other complications related to graft structural failure were almost absent with the latest-generation Talent device, according to the recent multicenter Talent Unidoc Retrospective Italian Study (TAURIS). According to a core lab assessment of computed tomography (CT) scans of 349 patients, all treated after 2002 with the Talent eLPS device and with at least 1 year of follow-up, there was only one case (0.3%) of proximal stent graft fracture, 3.7% (13/349) graft thrombosis, and no metallic erosion at mean follow-up of 25 months (range, 12–60 months) (unpublished data). This multicenter study enrolled patients from nine Italian centers to provide an accurate morphologic analysis of complications after EVAR. Collected data supported the stability of Talent in terms of low risk of migration and conversion rates. However, follow-up time was shorter than that reached with the previous model of the Talent device used in TARL and requires careful and extended surveillance in the future.

EUROSTAR is the largest multicenter registry on aortic endografts in Europe. In 2005, van Marrewijk et al provided a device-adjusted analysis of outcomes from 6,787 stent grafts included in the EUROSTAR registry; results of 1,579 Talent devices over an observation period of 21 months (range, 0–108 months) were compared to other devices. Aneurysms treated with the Talent device had shrinkage rates of 30% per year and rare occurrences of graft occlusion, at 2.3% per year. Talent was associated

### Table 1. Single-Center and Multicenter Series Focused on the Talent Device

<table>
<thead>
<tr>
<th>Investigators</th>
<th>No. of Patients</th>
<th>Mean Follow-Up (mo)</th>
<th>30-Day Death (%)</th>
<th>30-day Conversion (%)</th>
<th>Late Rupture (%)</th>
<th>Late Conversion (%)</th>
<th>Migration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faries (2002)</td>
<td>368</td>
<td>7.3</td>
<td>1.9</td>
<td>1.1</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
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<tr>
<td>Cowie (2003)</td>
<td>38</td>
<td>12.5</td>
<td>0</td>
<td>0</td>
<td>2.6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Espinosa (2005)</td>
<td>193</td>
<td>36</td>
<td>3.7</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>n/a</td>
</tr>
<tr>
<td>Torsello (2006)</td>
<td>168</td>
<td>53.2</td>
<td>1.2</td>
<td>1.2</td>
<td>1.1</td>
<td>7.8</td>
<td>4.2</td>
</tr>
<tr>
<td>Coppi (2008)</td>
<td>50</td>
<td>47.7</td>
<td>8</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Serki (2006)</td>
<td>68</td>
<td>39</td>
<td>0</td>
<td>1.5</td>
<td>2.9</td>
<td>2.9</td>
<td>4.4</td>
</tr>
<tr>
<td>TAURIS study</td>
<td>349</td>
<td>25</td>
<td>n/a</td>
<td>n/a</td>
<td>0.6</td>
<td>2.3</td>
<td>4.8</td>
</tr>
</tbody>
</table>
with a lower risk of migration, kinking, occlusion, and secondary intervention when compared to older-generation (Vanguard, Boston Scientific Corporation, Natick, MA) devices. When compared to Zenith grafts (n=1988), risk of limb occlusion (2.3% vs 3.5% patients per year; hazard ratio [HR], 0.67; 95% confidence interval [CI], 0.5–1), and type II endoleak (4.6% vs 7% patients per year; HR, 0.7; 95% CI, 0.5–0.9) was lower for Talent. However, Talent performed worse with respect to risk of migration (2.4% vs 0.7% patients per year; HR, 3.6; 95% CI, 2.1–6.4), need for conversion (2.1% vs 0.6% patients per year; HR, 3.5; 95% CI, 1.9–6.3), and secondary interventions (6.6% vs 5.3% patients per year; HR, 1.3; 95% CI, 1–1.6). Another recent report from the EUROSTAR database questioned the risk of migration in aneurysms with severe (>60°) adverse neck angulation using different grafts. Hobo et al provided a subgroup analysis of severe adverse neck angulation that involved about one fifth of the 1,796 Talent grafts included in the EUROSTAR database. In patients with severe adverse neck angulation and the Talent device, there was an increased long-term risk (19.9±18 months) of proximal endoleak (as with other graft brands) and proximal neck dilation but not of migration. UK EVAR trial investigators analyzed late outcomes in the subgroup of 221 patients with Talent devices enrolled in the randomized EVAR 1 (n=187) and EVAR 2 (n=34) trials. At a mean of 3.8 years, the secondary intervention rate was 9.4% patients per year (52/221), aneurysm-related mortality rate was 1.4% patients per year (9/221), and all-cause mortality rate was 10.3% patients per year (68/221). Reintervention rates with the Talent Stent Graft were compared. There were no statistically significant differences; however, the direction of results was slightly in favor of Zenith in risk of migration (2.7% vs 0.6%, Talent vs Zenith) and type I endoleak (4.8% vs 2.5%, Talent vs Zenith) and in favor of Talent in risk of graft thrombosis (1.1% vs 3.5%, Talent vs Zenith). Anatomical selection and operator experience biases to use one or the other device made the comparison futile. However, the analysis provided interesting insight in long-term results of the currently most widely used endograft models in Europe.

CONCLUSIONS

Late results from published experiences worldwide suggest that the Talent Abdominal Stent Graft may be used successfully up to 7 years after deployment. The risks of loss of stability, migration, aneurysm rupture, and aneurysm-related death are low even in the subset of patients with complicated neck anatomy. Recent improvements in device design and material further reduced complication rates related to material fatigue and expectantly will improve future outcomes. However, accurate and prolonged monitoring of device performance in all patients is needed to ensure long-term benefit of Talent, as well as any other endograft model for AAA repair.
Endovascular aneurysm repair (EVAR) has emerged as an appealing alternative to open surgery. There is a need for lifelong surveillance due to complications such as endoleaks, endotension, limb occlusion, and device migration. The most common complication is endoleak, which is defined as continued perfusion of the excluded aneurysm sac after EVAR. This can result in increased intra-aneurysmal pressure, prevention of aneurysmal regression, and increased risk for rupture. It is important to detect and classify endoleaks as early as possible.

There are numerous types of endoleaks, including types I through IV. It is imperative to differentiate among the classes of endoleaks because each has its own unique follow-up and management protocol. Current practice has been to treat type I (attachment site) leaks and type III (fabric tear or modular component separation) leaks urgently and type II (retrograde side branch) leaks conservatively, using imaging surveillance to ensure the stability of the size of the aneurysm. Therefore, appropriate patient follow-up and management necessitates accurate endoleak classification.

The most commonly used imaging modality for postoperative surveillance of endoleaks is currently computed tomography angiography (CTA). CTA has been shown to be more sensitive and specific than digital subtraction angiography (DSA) in detecting endoleaks. Although DSA has previously been considered the gold standard, it is not without its drawbacks such as invasiveness, patient exposure to radiation and contrast, and a recognized morbidity. CTA has an inherent limitation in classifying endoleaks, particularly type II, because of its inability to identify the direction of blood flow.

Magnetic resonance angiography (MRA) has demonstrated greater sensitivity than CTA in detecting endoleaks, especially type II, and has been established as a single-center experience with this useful tool for identifying and classifying endoleaks after EVAR.

BY SALMAN S. SHAH, MD, AND ROBERT A. LOOKSTEIN, MD

Time-Resolved MR Angiography After EVAR Using the Talent Stent Graft

A single-center experience with this useful tool for identifying and classifying endoleaks after EVAR.

BY SALMAN S. SHAH, MD, AND ROBERT A. LOOKSTEIN, MD

Figure 1. The Talent Abdominal Stent Graft System (A) (Image courtesy of Medtronic Vascular). Coronal maximal-intensity-projection (MIP) image from a contrast-enhanced MRA (Siemens Medical Systems, Malvern, PA) (B).
an acceptable imaging modality in patients who have undergone EVAR.\(^{16,17}\) Contrast-enhanced time-resolved MRA (TR-MRA), which was first described in 1996, has provided the ability to directly visualize changes in direction of blood flow during an MR examination.\(^{18-20}\) This produces dynamic MR imaging with a series of images that can be viewed similar to a conventional flush aortogram.\(^{6,21}\) TR-MRA has shown the ability to identify the source of inflow and outflow to an endoleak and is a valued imaging modality in the surveillance of post-EVAR patients.\(^{6,21,22}\)

The purpose of this study was to evaluate TR-MRA in characterizing endoleaks after EVAR. We examined patients who had undergone EVAR with the Talent Abdominal Stent Graft (Medtronic Vascular, Santa Rosa, CA), which is comprised of a woven polyester fabric frame supported along its entire length with self-expanding nitinol stents joined by a nitinol spine (Figures 1 and 2).

### METHODS

The TR-MRA technique was developed and evaluated with a protocol approved by the Mount Sinai Medical Center Institutional Review Board, which is summarized in Table 1.

Between January 1999 and March 2008, 53 patients underwent MRA for surveillance post-EVAR with the Talent abdominal stent graft. The group included 46 men and seven women (mean age, 73 years; range, 47–87 years). Indications for MRA included renal insufficiency and incomplete characterization of the endoleaks by CTA or duplex. All patients gave informed consent. The patients underwent contrast-enhanced MRA on a

### TABLE 1. MOUNT SINAI MRA TECHNIQUE FOR ENDOLEAK CHARACTERIZATION

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TruFisp (2D)</th>
<th>Time-Resolved MRA (3D)</th>
<th>Conventional MRA (3D)</th>
<th>Flash (2D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repetition time (msec)</td>
<td>3.17</td>
<td>2.9</td>
<td>5.7</td>
<td>230</td>
</tr>
<tr>
<td>Echo time (msec)</td>
<td>1.59</td>
<td>0.9</td>
<td>1.9</td>
<td>2.48</td>
</tr>
<tr>
<td>Flip angle (degrees)</td>
<td>60</td>
<td>19</td>
<td>22</td>
<td>90</td>
</tr>
<tr>
<td>Partition thickness (mm)</td>
<td>8</td>
<td>3</td>
<td>1.4</td>
<td>6</td>
</tr>
<tr>
<td>Matrix size</td>
<td>265 X 176</td>
<td>256 X 182</td>
<td>384 X 292</td>
<td>512 X 141</td>
</tr>
<tr>
<td>Imaging time for each date set (sec)</td>
<td>18–20</td>
<td>2.4</td>
<td>18–20</td>
<td>20</td>
</tr>
</tbody>
</table>

Figure 2. Coronal MIP image from contrast-enhanced MRA (A) and axial gradient-echo postcontrast (B) image at the bifurcation showing no leak after EVAR with the Talent Abdominal Stent Graft.
1.5 Tesla (T) MR scanner (Magnetom Sonata or Avanto, Siemens Medical Solutions, Malvern, PA) with multi-phase acquisitions, including arterial, venous, and delayed venous. Steady state free procession (SSFP) imaging (Fiesta, GE Healthcare, Wauwatosa, WI; TruFisp, Siemens Medical Solutions) was used to categorize the contents of the excluded aneurysm sac (Figures 3 and 4).

RESULTS
All patients underwent successful MRA without complication. The stent graft lumen was able to be visualized in 50 patients. In three cases, the stent graft lumen and aneurysm sac was obscured by metallic artifact from previous embolization procedures involving stainless steel coils. Embolization procedures with platinum coils did not affect the visualization of the stent graft lumen or aneurysm sac in four patients (Figure 5). In 22 cases, SSFP was able to characterize the aneurysm sac as having continued blood flow or endoleak without intravenous contrast. An endoleak was visualized in the same 22 cases after the intravenous administration of gadolinium including eight type II leaks, 13 type I leaks, and one type III leak. Time-resolved MRA correctly characterized all 22 endoleaks when those patients went on to have conventional angiography. In addition, MRA was able to identify one patient with an iliac limb occlusion and two patients with renal artery stenosis.

DISCUSSION
This study shows MRA to be a valuable diagnostic modality in the follow-up of patients who have undergone EVAR with the Talent Abdominal Stent Graft. Previous studies have shown MRA to be at least as sensitive as CTA for the detection of endoleaks and in several instances even more sensitive than CTA. MRA

Figure 3. Follow-up contrast-enhanced CTA in a post-EVAR patient with the Talent Abdominal Stent Graft demonstrates no leak (A). A TruFisp axial image shows a bright signal in the aneurysm sac, suggesting persistent pressure and nonorganized thrombus (B). After administration of intravenous gadolinium chelate, an axial Flash image demonstrates an endoleak (type II, lumbar) (C).

Figure 4. Coronal reformatted images from the TR-MRA of the same patient as Figure 3 shows a type II endoleak supplied from a right iliolumbar artery (arrow) and delayed enhancement of the aneurysm sac (arrowhead).
is a useful alternative imaging modality in patients who have renal insufficiency or an allergy to iodinated intravenous contrast.

One limitation of MRA that we also encountered in our study is that patients with stainless steel stent grafts and embolization coils produce significant metallic artifact and cannot be imaged with MR. In the appropriate patient population, MRA is a useful tool for surveillance in patients who have undergone EVAR with the Talent Abdominal Stent Graft.

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