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# Comparison of midterm results for the Talent and Endurant stent graft



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# ABSTRACT

**Objective:** Stent graft evolution is often addressed as a cause for improved outcomes of endovascular aneurysm repair for patients with an abdominal aortic aneurysm. In this study, we directly compared the midterm result of Endurant stent graft with its predecessor, the Talent stent graft (both Medtronic, Santa Rosa, Calif).

**Methods:** Patient treated from January 2005 to December 2010 in a single tertiary center in The Netherlands with a Talent or Endurant stent graft were eligible for inclusion. Ruptured abdominal aortic aneurysms or patients with previous aortic surgery were excluded. The primary end point was the Kaplan-Meier estimated freedom from secondary interventions. Secondary end points were perioperative outcomes and indications for secondary interventions.

**Results:** In total, 221 patients were included (131 Endurant and 90 Talent). At baseline, the median aortic bifurcation was narrower for the Endurant (30 mm vs 39 mm; P < .001). Median follow-up was 64.1 ± 37.9 months and 59.2 ± 25.3 months for Talent and Endurant, respectively. The estimated freedom from secondary interventions at 30 days, 1 year, 5 years, and 7 years was 94.3%, 89.4%, 72.2%, and 64.1% for Talent and 96.8%, 89.3%, 75.2%, and 69.2% for Endurant (P = .528). The indication for secondary interventions does differ; more patients required an intervention for a proximal neck-related complication (type Ia endoleak or migration) in the Talent group (18.2% vs 4.8%; P = .001), whereas more interventions for iliac limb stenosis were seen in the Endurant group (0.0% vs 4.8%; P = .044). In a binomial regression analysis, suprarenal angulation, infrarenal neck length, and type of stent graft were independent predictors of neck-related complications.

**Conclusions:** Evolution from the Talent stent graft into the Endurant has resulted in significant reduction of infrarenal neck-related complications; on the other hand, iliac interventions increased. The overall midterm secondary intervention rate was comparable. (J Vasc Surg 2017;66:735-42.)

Since the first endovascular aneurysm repair (EVAR), reported by Parodi et al and Volodos et al independently of each other, materials and techniques have changed tremendously.<sup>12</sup> Early physician-made grafts were rapidly replaced by commercially produced stent grafts, allowing the majority of aneurysm patients to be treated by EVAR.

To allow all abdominal aortic aneurysm (AAA) patients to be treated by EVAR, some anatomic challenges, particularly the infrarenal neck and iliac artery morphology, have to be overcome. Therefore, stent graft development has focused on reducing the sheath profile, increasing graft flexibility, and optimizing deployment precision. Stent graft evolution resulted in more

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liberal instructions for use (IFU) and an overall improvement of short-term technical and clinical outcomes.<sup>3-5</sup>

However, studies on stent graft evolution compared large groups of different manufacturers.<sup>3,6</sup> By combining data into stent graft eras, the cause of differences is difficult to determine; evolution, natural selection, or operator experience can be responsible for the results.<sup>3,6</sup> A randomized controlled trial, comparing various manufacturers over time, would be preferred; however, this kind of study is subjected to a high number of stent graft and introducer variations. Consequently, the outcomes are nearly impossible to analyze specifically. Therefore, our aim was to directly compare two widely used stent graft systems, the Endurant AAA Stent Graft and the predecessor Talent Abdominal Stent Graft (both Medtronic, Santa Rosa, Calif). A previous study by Mensel et al showed encouraging 30-day results in a small population.<sup>7</sup> In this study, we present midterm data to determine if durability in addition to short-term outcomes has improved as this remains one of the major drawbacks of EVAR.

#### **METHODS**

**Stent design**. The Talent and Endurant stent grafts are both a two-piece design with a nitinol-based wireframe covered with a polyester fabric. There are several design features fundamentally different between the grafts. Proximal anchoring pins are added to the suprarenal

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stent to increase proximal stability of the Endurant stent graft. Furthermore, the main body is constructed of smaller and closely positioned M-shaped stents, increasing flexibility and conformability of the Endurant.

Longitudinal connecting rods in the iliac limbs were removed, further increasing flexibility and reducing the risk of kinking. The amplitude of the iliac stents was reduced and they were positioned closely together. The introducer mechanism remained similar, but profile size was reduced from 22F to 18F for a bifurcated graft.

The Talent stent graft was suitable for infrarenal necks of  $\geq$ 10 mm and an angulation of  $\leq$ 60 degrees. The Endurant IFU were slightly adapted to an infrarenal neck  $\geq$ 10 mm with an infrarenal angulation of  $\leq$ 60 degrees and suprarenal angulation of  $\leq$ 45 degrees. For proximal necks of  $\geq$ 15 mm, an infrarenal angulation of  $\leq$ 75 degrees and suprarenal angulation of  $\leq$ 60 degrees is accepted.

**Study population.** A retrospective study included patients who were treated with either a Talent Abdominal Stent Graft or an Endurant Stent Graft System in a single tertiary referral hospital in The Netherlands. Patients treated for a nonruptured aneurysm, including symptomatic, from January 2005 to December 2010 were eligible. The stent grafts were used alongside each other for a short period; the first Endurant was implanted in February 2008, and the last Talent was used in September of that year. Patients with ruptured AAAs, fistulas, or treated as part of a secondary intervention were excluded. If only an iliac limb was implanted, patients were also excluded. Patients treated later than 2010 were not included to ensure sufficient follow-up in both groups. Stent graft selection was at the operator's discretion.

Data collection. The local EVAR database was consulted to identify patients and to collect demographics, preoperative characteristics, comorbidities, and procedure details. The data were retrospectively completed. Three-dimensional sizing software (3mensio; Pie Medical Imaging BV, Maastricht, The Netherlands) was used for aortic measurements. All procedures were performed by or under the direct supervision of four vascular surgeons; all operators had previously obtained a minimum of 5 years of EVAR experience. Retrospective "patient's files" research is not in the scope of the Dutch WMO (Wet Mensgebonden Onderzoek: law human bound research), and Investigational Review Board approval was therefore not required. As a consequence, informed consent of the patients was not obtained. Patients' data were analyzed anonymously.

Routine follow-up was performed at 1 month, 6 months, and 1 year and yearly thereafter. At 1-month follow-up, computed tomography angiography (CTA) was routinely performed, followed by duplex ultrasound examination by specialized vascular technicians or CTA at subsequent

# **ARTICLE HIGHLIGHTS**

- **Type of Research:** Retrospective single-center controlled study
- **Take Home Message:** Use of the newer generation Endurant stent graft compared with the older Talent (both Medtronic, Santa Rosa, Calif) resulted in fewer proximal neck complications but increased iliac limb stenosis and similar secondary intervention rates.
- **Recommendation:** The authors suggest that new stent graft modifications improve aspects of older designs but sometimes introduce new vulnerabilities.

follow-up visits. Referring physicians were contacted to collect follow-up data. The date of death was retrieved from hospital records or, if absent, from the municipal personal records. Patients who were not registered in The Netherlands were censored at last date of follow-up.

**Outcomes.** Technical success was defined as a successful introduction and deployment and the absence of a type I or type III endoleak at completion angiography. Assisted technical success was defined if an endoleak resolved with an additional procedure at the time of implantation. Secondary interventions were defined as any intervention, surgical or endovascular, required to resolve stent graft complications. A type Ia endoleak or proximal migration was registered as an infrarenal neck-related complication. Displacement of the stent graft >10 mm or requiring any intervention was defined as migration. Type II endoleaks that caused aneurysm sac expansion were considered for treatment. Obstructive iliac complications, stenosis or occlusion, were diagnosed on the basis of clinical signs of ischemia.

Aneurysm-related mortality included 30-day mortality and death caused by a rupture or resulting from a secondary intervention.

Statistical analysis. Categorical variables are presented as frequencies with percentages. Continuous variables are presented as mean  $\pm$  standard deviation or as median and interguartile range (IQR) in case of skewed data. The  $\chi^2$  or Fisher exact test was used for categorical variables, depending on sample size. For continuous variables, a t-test or a Mann-Whitney U test in case of skewed data was performed. Statistical difference for Kaplan-Meier curves was tested by means of log-rank. A *P* value < .05 was considered statistically significant. Risk factors for complications were determined with a binominal logistic regression analysis that included all univariate significant factors. Only patients with a full set of morphologic data were eligible for analysis. Statistical analyses were performed using SPSS version 21 for Mac (IBM Corp, Armonk, NY).

#### Table I. Baseline characteristics

Variables	Talent (n = 90)	Endurant (n = 131)	<i>P</i> value
Age, years	73.0 ± 7.4	72.6 ± 8.0	.680
Male	93.3 (84/90)	85.5 (112/131)	.071
Risk factors			
Tobacco use	43.3 (39/90)	30.0 (39/130)	.042
Hypertension	81.1 (73/90)	80.9 (106/131)	.971
Hypercholesterolemia	56.7 (51/90)	45.7 (59/129)	.111
Diabetes	13.3 (12/90)	13.0 (17/131)	.939
History of cancer	21.1 (19/90)	16.8 (22/131)	.417
Cardiac disease	66.7 (60/90)	63.8 (83/130)	.666
Carotid disease	28.9 (26/90)	20.3 (26/128)	.144
Pulmonary disease	30.0 (27/90)	24.8 (32/129)	.394
Renal insufficiency	36.7 (33/90)	23.8 (31/130)	.040
ASA class			.312
1	1.1 (1/88)	6.1 (8/131)	
2	68.2 (60/88)	66.4 (87/131)	
3	26.1 (23/88)	24.4 (32/131)	
4	4.5 (4/88)	3.1 (4/131)	

ASA, American Society of Anesthesiologists

Values are reported as mean  $\pm$  standard deviation or frequencies (%) (n/N).

# RESULTS

Between 2005 and 2010, a Talent or Endurant stent graft was implanted in 264 patients. A total of 221 (90 Talent, 131 Endurant) patients met the inclusion criteria, accounting for 63.3% of all electively implanted endografts. Other devices were used during the study period; graft selection was not based on aneurysm morphology.

Baseline characteristics, depicted in Table I, are similar for both groups.

Preoperative CTA was analyzed in 173 patients (55 Talent, 118 Endurant); for 47 patients, no imaging was available as they were referred. For one patient, only a magnetic resonance imaging data set was available that could not be assessed in 3mensio. The results of central lumen line measurements are reported in Table II. The aortic bifurcation of patients in the Endurant group was significantly smaller (30 mm vs 39 mm; P < .001).

Procedural characteristics are depicted in Table III. Initial technical success was comparable (90.1% for Talent vs 93.8% for Endurant; P = .313). After additional procedures, the assisted technical success increased to 93.3% for Talent and 97.7% for Endurant (P = .116). In addition to procedures to resolve endoleaks, 11.8% required an iliac intervention either to allow device implantation or to optimize the end result on completion angiography. Rates were not significantly different between Talent and Endurant (15.6% and 9.2%, respectively; P = .202). In total, five patients were not treated by EVAR; two procedures were aborted, and three patients were directly converted to open repair. Iliac

Table II.         Morphologic data when a preoperative computed
tomography angiography (CTA) study was available

Talent Endurant					
Variable	(n = 55)	(n = 118)	P value <sup>®</sup>		
Proximal neck length, mm	39 ± 12.8	32 ± 13.7	.183		
Proximal neck diameter, mm	23 ± 2.6	23 ± 3.2	.505		
Distal neck diameter, mm	24 ± 3.0	24 ± 3.7	.652		
>32 mm (n)	1	2			
Suprarenal angulation, degrees	20 (14-28)	20 (14-35)	.565		
Infrarenal angulation, degrees	48 ± 21.1	47 ± 25.3	.699		
AAA diameter, mm	58 (54-65)	57 (53-62)	.354		
Bifurcation diameter, mm	39 (30-47)	30 (23-38)	.000		
Right CIA max, <sup>b</sup> mm	17 (14-21)	16 (13-19)	.047		
Left CIA max, <sup>b</sup> mm	15 (13-19)	15 (13-18)	.141		
Right EIA, mm	9 (9-10)	9 (8-10)	.089		
Left EIA, mm	10 (8-11)	9 (8-10)	.199		
Infrarenal neck outside IFU <sup>c</sup> (n/N)	18.2% (10/55)	16.1% (19/118)	.733		
<10 mm	2	1			
10-14 mm <sup>d</sup>	1	2			
>15 mm <sup>e</sup>	7	16			
AAA. Abdominal aortic aneurysm; <i>CIA</i> , common iliac artery; <i>EIA</i> , external iliac artery; <i>IFU</i> , instructions for use. Values are reported as mean $\pm$ standard deviation or median (inter- quartile range [IQR]). <sup>a</sup> The <i>t</i> -test if mean $\pm$ standard deviation are presented; Mann-Whitney <i>U</i> test if median and IQR are presented. <sup>b</sup> Largest common iliac artery diameter measured. <sup>c</sup> IFU of the Endurant stent graft.					

Infrarenal angulation >60 degrees or suprarenal angulation >45dearees

 $^{e}$ Infrarenal angulation >75 degrees or suprarenal angulation >60 degrees.

access was the reason for failure in four cases; the fifth case was converted because of unintended renal coverage.

More bifurcated grafts were implanted in the Endurant group, and in general the procedure was quicker. When focusing only on bifurcated grafts, the difference in median procedure time was 127 minutes (IQR, 110-168 minutes) vs 94 minutes (IQR, 80-116 minutes; P < .001) for Talent and Endurant.

Thirty-day mortality was 0.0% (0/90) for Talent and 1.5% (2/131) for Endurant. One patient died of a perforated gastric ulcer and the second as the result of cardiac failure.

Follow-up and secondary interventions. Follow-up was available for 214 patients (126 Endurant and 88 Talent, excluding 30-day mortality and no-implant). Overall mean follow-up was  $61.2 \pm 31.1$  months. The follow-up for Talent and Endurant was 64.1  $\pm$  37.9 months and 59.2  $\pm$  25.3 months, respectively.

During follow-up, a total of 80 secondary interventions were performed on 55 patients. Fig 1 shows the Kaplan-

#### Table III. Procedural details

Variable	Talent (n = 90)	Endurant (n = 131)	<i>P</i> value		
Symptomatic AAA	15.6 (14/90)	13.0 (17/131)	.588		
Duration of procedure, minutes		95 (80-119)	<.001		
Anesthesia			.165		
General	26.7 (24/90)	38.9 (51/131)			
Regional	72.2 (65/90)	60.3 (79/131)			
Local	1.1 (1/90)	0.8 (1/131)			
Planned stent graft configuration			.004		
Bifurcated	83.3 (75/90)	95.4 (125/131)			
AUI	16.7 (15/90)	3.8 (5/131)			
Tube	0.0 (0/90)	0.8 (1/131)			
Distal sealing EIA	11.1 (10/90)	15.3 (20/131)	.375		
Procedural outcome					
Technical success	90.0 (81/90)	93.1 (122/131)	.403		
Assisted technical success	93.3 (84/90)	97.7 (128/131)	.106		
No implant	2.2 (2/90)	2.3 (3/131)	—		
Type Ia endoleak	4.4 (4/90)	0.0 (0/131)			
30-day mortality	0.0 (0/90)	1.5 (2/131)	.515		
AAA, Abdominal aortic aneurysm; AUI, aortic-uni-iliac; EIA, external iliac artery. Values are reported as frequencies (%) (n/N) or median (interquartile range [IQR]).					

Meier curve representing freedom from secondary interventions. The Kaplan-Meier freedom from secondary interventions estimate at 30 days, 1 year, 5 years, and 7 years is 94.3%, 89.4%, 72.2%, and 64.1% for the Talent and 96.8%, 89.3%, 75.2%, and 69.2% for the Endurant (log-rank, P = .528).

The indications for secondary interventions are displayed in Table IV. Significantly more Talent patients required a secondary intervention for proximal neck complications (P = .001), either migration or a type la endoleak. This difference remains significant if it is adjusted for time in a Kaplan-Meier curve (Fig 1). More patients in the Endurant group required an intervention for a stenosis (0% vs 4.8%; P = .044); when combining patients with either a stenosis or an occlusion, no difference was recorded (3.4% vs 7.9%; P = .172).

To identify influencing factors for the risk of proximal complications, all 168 (55 Talent, 113 Endurant) patients with both a full morphologic data set and follow-up were included. A total of 15 of these patients had proximal neck complications. Off-label use, type Ia endoleak on completion angiography, infrarenal neck length, and suprarenal angulation were significantly different in addition to the type of stent graft. Binomial logistic regression analyses showed that the Talent stent graft (odds ratio [OR], 6.727; 95% confidence interval [CI], 1.653-27.382), suprarenal angulation (OR, 1.036; 95% CI,

1.001-1.071), and infrarenal neck length (OR, 0.943; 95% CI, 0.982-0.997) were statistically significant predictors of proximal neck complications.

Overall survival and AAA-related survival of patients after stent implantation are depicted in Fig 2. In case no stent graft was implanted, patients were censored at the day of discharge. The Kaplan-Meier estimate of the overall survival at 1 year, 5 years, and 7 years is 94.3%, 62.9%, and 53.6% for Talent and 93.0%, 72.7%, and 65.6% for Endurant (P = .119).

In the Endurant group, three AAA-related fatalities were recorded, two within 30 days and one after ruptured AAA due to a type III endoleak. Six AAA-related deaths occurred in the Talent group; one was the result of a ruptured AAA, and the other five were related to a secondary intervention. Of the secondary interventions, two were performed endovascularly; the other three patients required a laparotomy. The AAA-related survival estimates at 30 days, 1 year, 5 years, and 7 years are 100%, 98.9%, 93.1%, and 91.3% for Talent and 98.4%, 98.4%, 97.6%, and 97.6% for Endurant (P = .104).

#### DISCUSSION

Stent graft evolution is often addressed as an argument as to why results of previous research cannot be applied to today's devices. However, there is little evidence to show that changes in stent graft design, independent of other factors, resulted in improved outcomes. In this study, we showed that there is no significant difference in the rate of secondary interventions between the groups, but vulnerabilities (such as infrarenal neckrelated complications) have been successfully addressed.

First, this study shows no overall reduction in the secondary intervention rate after the introduction of a new stent graft. In accordance with our results, studies that compared graft generations reported no significant difference in secondary intervention rates.<sup>3,4,8</sup> Other papers that studied both stent grafts showed similar freedom from secondary intervention rates.<sup>9-11</sup> On the other hand, comparisons of the Talent and Endurant showed that the performance of the latter appears to be better.<sup>7,12</sup> The results of the U.S. regulatory pivotal trials of the Endurant and Talent were compared, showing favorable outcomes for the Endurant.<sup>12,13</sup> Although both these trials are similar in design, they are divided by a 5-year inclusion gap and have different participating centers. Furthermore, the strict inclusion criteria limit the applicability of the trial results to a real-world population. It is likely that design changes do improve performance in a well-controlled population, but they are not directly translated to the average AAA patient.

One important indication that evolution does improve treatment results in our population is a shift in the indication for secondary interventions. The most significant change is a reduction of infrarenal neck-related

Freedom from Secondary Intervention		2 24	"' " "		72 84		
		Day 0	30-days	1-year	5-years	7-years	
	ent overall ents at risk (SE)	88	81 (.025)	72 (.034)	36 (.055)	31 (.062)	
	urant overall ents at risk (SE)	126	120 (.016)	104 (.028)	65 (.042)	8 (.052)	
	ent proximal ents at risk (SE)	88	85 (.011)	76 (.021)	40 (.049)	30 (.060)	
Pati	urant proximal ents at risk (SE)	126	124 (.000)	115 (.012)	82 (.021)	13 (.021)	

**Fig 1.** Freedom from secondary interventions and freedom from infrarenal neck-related interventions. *AAA*, Abdominal aortic aneurysm; *SE*, standard error.

complications, migration or proximal endoleaks, in comparable infrarenal necks. Binomial regression analysis showed that the type of stent graft significantly influences the risk of infrarenal neck-related complications. The risk of proximal complication with the Talent is significantly higher (6.727; 95% CI, 1.653-27.382) compared with its successor. One explanation for this improvement comes from research in cadaveric models that demonstrated more force was required to dislocate a stent graft with fixation pins as opposed to a device without.<sup>14</sup> Whether the changed wireframe design contributes to the described reduction is unclear. Current wireframe designs vary greatly between devices; consequences of these differences are elucidated.

Benefits of improved proximal stability appear to be countered by iliac challenges. In our population, 5.6% of Endurant patients had an iliac occlusion and 4.8% had a stenosis. This is fairly higher than the 3.4% occlusion and 0.0% stenosis rates in the Talent group. In other studies, occlusion rates between 2.7% and 4.0% for the Endurant stent graft have been reported.<sup>9,15-17</sup> Known risk factors for iliac complications are narrow iliac arteries, tortuous vessels, and a landing zone in the external iliac artery.<sup>16,18</sup> In the IFU of stent grafts, iliac access is addressed only with regard to diameters and minimum sealing length. There is no widely accepted technique to assess iliac complexity, hampering research, objective comparisons, and specifying IFU limitations. Increasing applicability, by reducing stent graft profile and increasing flexibility, stimulates the implantation in narrow and tortuous iliac arteries.<sup>8,19</sup> In addition to patient factors, increased stent graft flexibility increases the risk of compression.<sup>15</sup> The longitudinal rod in Talent iliac limbs has the tendency to kink but also enhances the visibility of kinking on fluoroscopy.<sup>18</sup> Therefore, it is likely that challenging iliac situations were avoided or quickly addressed. A more aggressive intraoperative and postoperative intervention strategy is suggested to improve stent graft patency if there is a suggestion of iliac compression in modern devices.<sup>17</sup> Performing the final

<b>Fable IV.</b> Total number of individual interventions and number of affected patients
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Variable	Talent patients (interventions)	Endurant patients (interventions)	P value
Secondary interventions	28.4% (25/88)	23.8% (30/126)	.449
Independent interventions			
Туре Іа	10 (12)	6 (6)	.071
Type Ib	2 (2)	3 (3)	1.000
Туре II	0	4 (4)	.145
Type III	1 (1)	3 (3)	.645
Graft migration	7 (8)	O (O)	.002
Limb dislocation	2 (2)	1 (1)	.570
Occlusion	3 (3)	7 (7)	.531
Stenosis	O (O)	6 (10)	.044
Marginal sealing	3 (3)	5 (5)	1.000
Other	7 (9)	1 (1)	
Intervention for proximal neck <sup>a</sup>	18.2% (16/88)	4.8% (6/126)	.001
Intervention for iliac limb <sup>b</sup>	3.4% (3/88)	7.9% (10/126)	.172
Endovascular interventions	68.4% (32/40)	90.0% (36/40)	

<sup>a</sup>Intervention for either graft migration or type Ia endoleak.

<sup>b</sup>Intervention for either stenosis or occlusion.

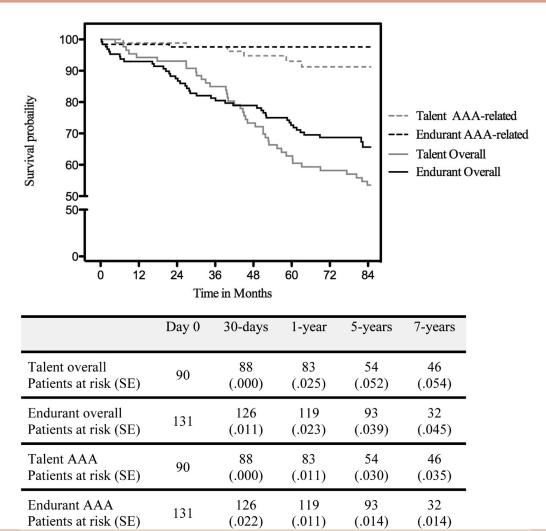


Fig 2. Overall survival and freedom from abdominal aortic aneurysm (AAA)-related mortality, intention-to-treat basis. SE, Standard error.

two-directional angiography after removal of stiff guidewires and measuring iliac pressure can aid in improving recognition of stenosis.<sup>17</sup> Other techniques, like duplex ultrasound and intravascular ultrasound, can be applied to quantify a stenosis. For the new-generation Endurant, Endurant Evo, the design of the iliac limbs has changed. The current stent rings are replaced by a helical stent design for the iliac limbs.<sup>20</sup> Expanding EVAR suitability is associated with a risk of iliac complications and therefore requires vigilance, in both planning and surgery. A validated technique to assess iliac complexity, similar to infrarenal neck measurements, can assist in

comparing outcomes and planning of treatment. One of the implications of our results is that different stent grafts have specific vulnerabilities. However, proposed follow-up regimens and imaging modalities are the same for all grafts, regardless of manufacturer or model.<sup>21,22</sup> A review by Wilt et al showed that secondary intervention rates range from 3.8% to 55%, and there are large differences in endoleak rates between grafts.<sup>23</sup> Although reviews are influenced by large study variations, it is clear that complications differ between stent grafts.<sup>6,8,23,24</sup> Cost-effectiveness of EVAR is widely debated, and follow-up is a significant contributor to the costs. Several studies have attempted to base follow-up on the risk of complications; the type of stent graft was not included in these models.<sup>25,26</sup> Therefore, large cohorts with a substantial number of different grafts are needed to determine a device-specific complication profile required to design an efficient and evidence-based surveillance.

A retrospective study of consecutive stent grafts has several limitations. Because patients were included during a 5-year period, the more recent patients could have benefited from increased experience. However, all operators had extensive EVAR experience before 2005, and the deployment systems of the Endurant and Talent are similar. Nevertheless, initial results and specific complications of a new device are included that might be avoided in the future. A relatively low rate of secondary interventions makes it difficult to determine specific risk factors for each complication.

## **CONCLUSIONS**

Evolution of the Talent stent graft into the Endurant has resulted in a significant reduction of infrarenal neckrelated complications in similar morphology. Improved handling likely encouraged application in more challenging iliac anatomy, not reducing the overall midterm intervention rate because of an increased rate of iliac complications.

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## REFERENCES

- 1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
- Volodos NL, Karpovich IP, Troyan VI, Kalashnikova YuV, Shekhanin VE, Ternyuk NE, et al. Clinical experience of the use of self-fixing synthetic prostheses for remote endoprosthetics of the thoracic and the abdominal aorta and iliac arteries through the femoral artery and as intraoperative endoprosthesis for aorta reconstruction. Vasa Suppl 1991;33: 93-5.
- Tadros RO, Faries PL, Ellozy SH, Lookstein RA, Vouyouka AG, Schrier R, et al. The impact of stent graft evolution on the results of endovascular abdominal aortic aneurysm repair. J Vasc Surg 2014;59:1518-27.
- 4. Verzini F, Isernia G, De Rango P, Simonte G, Parlani G, Loschi D, et al. Abdominal aortic endografting beyond the trials: a 15-year single-center experience comparing newer to older generation stent-grafts. J Endovasc Ther 2014;21: 439-47.
- Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-55.
- 6. Ouriel K, Clair DG, Greenberg RK, Lyden SP, O'Hara PJ, Sarac TP, et al. Endovascular repair of abdominal aortic aneurysms: device-specific outcome. J Vasc Surg 2003;37: 991-8.
- 7. Mensel B, Kuhn JP, Trager T, Duhrkoop M, von Bernstorff W, Rosenberg C, et al. Technical and clinical outcome of Talent versus Endurant endografts for endovascular aortic aneurysm repair. PLoS One 2012;7:e38468.
- 8. Maudet A, Daoudal A, Cardon A, Clochard E, Lucas A, Verhoye JP, et al. Endovascular treatment of infrarenal aneurysms: comparison of the results of second- and thirdgeneration stent grafts. Ann Vasc Surg 2016;34:95-105.
- Zandvoort HJ, Goncalves FB, Verhagen HJ, Werson DA, Moll FL, de Vries JP, et al. Results of endovascular repair of infrarenal aortic aneurysms using the Endurant stent graft. J Vasc Surg 2014;59:1195-202.
- Verhoeven BA, Waasdorp EJ, Gorrepati ML, van Herwaarden JA, Vos JA, Wille J, et al. Long-term results of Talent endografts for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2011;53:293-8.
- Donas KP, Torsello G, Weiss K, Bisdas T, Eisenack M, Austermann M. Performance of the Endurant stent graft in patients with abdominal aortic aneurysms independent of their morphologic suitability for endovascular aneurysm repair based on instructions for use. J Vasc Surg 2015;62: 848-54.
- 12. Singh MJ, Fairman R, Anain P, Jordan WD, Maldonaldo T, Samson R, et al. Final results of the Endurant Stent Graft

System in the United States regulatory trial. J Vasc Surg 2016;64:55-62.

- 13. Turnbull IC, Criado FJ, Sanchez L, Sadek M, Malik R, Ellozy SH, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. J Vasc Surg 2010;51:537-44. 544.e1-2.
- 14. Melas N, Saratzis A, Saratzis N, Lazaridis J, Psaroulis D, Trygonis K, et al. Aortic and iliac fixation of seven endografts for abdominal-aortic aneurysm repair in an experimental model using human cadaveric aortas. Eur J Vasc Endovasc Surg 2010;40:429-35.
- Makaroun MS, Tuchek M, Massop D, Henretta J, Rhee R, Buckley C, et al. One year outcomes of the United States regulatory trial of the Endurant Stent Graft System. J Vasc Surg 2011;54:601-8.
- 16. Faure EM, Becquemin JP, Cochennec F; ENGAGE collaborators. Predictive factors for limb occlusions after endovascular aneurysm repair. J Vasc Surg 2015;61:1138-45.e2.
- van Zeggeren L, Bastos Goncalves F, van Herwaarden JA, Zandvoort HJ, Werson DA, Vos JA, et al. Incidence and treatment results of Endurant endograft occlusion. J Vasc Surg 2013;57:1246-54; discussion: 1254.
- Carroccio A, Faries PL, Morrissey NJ, Teodorescu V, Burks JA, Gravereaux EC, et al. Predicting iliac limb occlusions after bifurcated aortic stent grafting: anatomic and device-related causes. J Vasc Surg 2002;36:679-84.
- Sobocinski J, Briffa F, Holt PJ, Martin Gonzalez T, Spear R, Azzaoui R, et al. Evaluation of the Zenith low-profile abdominal aortic aneurysm stent graft. J Vasc Surg 2015;62:841-7.
- 20. Medtronic starts clinical study of Endurant Evo AAA stent graft system for endovascular treatment of abdominal aortic

aneurysms [press release]. Available at: http://newsroom. medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle& ID=20403572015. Accessed August 25, 2016.

- Moll FL, Powell JT, Fraedrich G, Verzini F, Haulon S, Waltham M, et al. Management of abdominal aortic aneurysms: clinical practice guidelines of the European Society for Vascular Surgery. Eur J Vasc Endovasc Surg 2011;41 (Suppl 1):S1-58.
- 22. Chaikof EL, Brewster DC, Dalman RL, Makaroun MS, Illig KA, Sicard GA, et al. The care of patients with an abdominal aortic aneurysm: the Society for Vascular Surgery practice guidelines. J Vasc Surg 2009;50(Suppl):S2-49.
- 23. Wilt TJ, Lederle FA, Macdonald R, Jonk YC, Rector TS, Kane RL. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. Evid Rep Technol Assess (Full Rep) 2006;144:1-113.
- 24. van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, Harris PL, Buth J, Laheij RJ, et al. Risk-adjusted outcome analysis of endovascular abdominal aortic aneurysm repair in a large population: how do stent-grafts compare? J Endovasc Ther 2005;12: 417-29.
- 25. Karthikesalingam A, Holt PJ, Vidal-Diez A, Choke EC, Patterson BO, Thompson LJ, et al. Predicting aortic complications after endovascular aneurysm repair. Br J Surg 2013;100:1302-11.
- **26.** Barnes M, Boult M, Maddern G, Fitridge R. A model to predict outcomes for endovascular aneurysm repair using preoperative variables. Eur J Vasc Endovasc Surg 2008;35: 571-9.

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