Durability of abdominal aortic endograft with the Talent Unidoc stent graft in common practice: Core lab reanalysis from the TAURIS multicenter study

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Background/Objective: **Durability is the main concern of aortic endografting, but it is not clear to what extent trial results are applicable to "real world" patients. The purpose of this study was to assess the durability of a single model of aortic endograft in an unselected population with core lab analysis of morphological changes.**
Methods: **Computed tomography (CT) images of patients treated with Talent Unidoc (Medtronic, Santa Rosa, Calif) endografts from 2002 to 2006 in nine European centers with more than 1 year follow-up were centrally reviewed using a dedicated software with multiplanar and volume reconstructions. Images were checked for aneurysm growth ≥5 mm, neck enlargement >3 mm, graft migration ≥10 mm, endoleak, structural integrity. Morphological changes were defined clinically relevant when associated with reintervention or aneurysm-related death.**
Results: **A total of 349 patients (mean age 73.8 years, 90% males) were available for analysis; 1187 CT examinations were reviewed. Median abdominal aortic aneurysm (AAA) diameter was 56 mm (interquartile range [IQR] 49-62), neck length 20 mm (IQR 16-30), and neck diameter 25 mm (IQR 23-26). Mean follow-up was 25 months (range 12-60 months). During the study period, 10 late deaths (1 aneurysm-related, 0.3%) with a survival rate of 89.2% at 48 months and 33 reinterventions including 8 conversions (2.2%), 2 AAA ruptures (0.6%) and 1 (0.3%) loss of graft integrity were recorded. Cumulative reintervention rate was 6%, 8%, 13%, and 16% at 1, 2, 3, and 4 years, respectively. According to core lab analysis, 22 AAA grew, 169 were unchanged, and 158 shrunk, with a growing AAA rate of 3.1% patients/year. Five growths required reintervention, one for rupture. Forty-seven (6.5% patients/year) neck enlargements, three clinically relevant, 17 migrations (2.4% patients/year), five clinically relevant, and 70 endoleaks (9.7 % patients/year), 11 clinically relevant, were detected.**
Conclusion: **Data from this real world experience monitored with a centralized imaging review show that endovascular repair of abdominal aortic aneurysm with the latest generation of a single model of endograft is associated with low graft thrombosis and graft fatigue, and low late aneurysm rupture and related death risks. Neck enlargement although common after EVAR, is almost always without clinical consequences but a longer follow-up and prospective clinical studies are advisable to confirm the present results. (J Vasc Surg 2009;49:859-65.)**

Randomized trials (RCT) showed that endovascular repair of abdominal aortic aneurysm (EVAR) is associated with significant reductions in operative mortality but raised substantial concerns regarding the long-term durability of the benefit.[1,2] There continues to be a 10% to 20% reintervention rate,[1-5] in part secondary to endoleak or graft migration resulting in sac expansion. Furthermore, postoperative neck enlargement is reported in 10% to 35% of patients, warning for loss of proximal fixation resulting in graft instability.[6-8]

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Supported by a grant from Medtronic, Santa Rosa, Calif.
*Please see Appendix for list of coordinating and participating centers of the TAURIS Group.
Competition of interest: none.
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0741-5214/$36.00

doi:10.1016/j.jvs.2008.11.044

Whether and to what extent the RCT concerns are applicable to the real world of EVAR remains subject of debate for two main reasons. (1) Accurate morphology assessment of aortic repair after EVAR is not always systematically performed and maintained for the entire length of follow-up outside RCTs or IDE trials, leading to unreliable estimate of failure rates or other events as aneurysm growth, migrations, etc. in mid- and long-term. (2) Most of the criticism against EVAR durability is based on results obtained with old generation grafts. EVAR is an evolving technology and, since its first introduction, substantial improvement in material and design has changed the applicability and results of repair.

The Talent AAA (Medtronic, Santa Rosa, Calif) endograft system has been diffusely used in Europe and other non-American countries since 1996. The design has been changed and improved during time to encompass the adverse events detected in the mid and long term with earlier technologies. In 2002, the new Talent Unidoc (Medtronic) system was established but no reports have focused on the durability and stability of this device.

The aim of this study was to evaluate midterm morphological changes after the new generation Talent Unidoc device using core lab analysis of data.

METHODS

Patients treated for abdominal aortic aneurysm (AAA) with Talent Unidoc between January 1, 2002 and October 15, 2006 and with at least >12 months follow-up were included in the study. A total of 10 centers in Italy were enrolled as participants in the Talent Unidoc Retrospective Italian Study (TAURIS) group.

Full data sets and cross-sectional images of noncontrast and contrast computed tomography (CT) scans performed before hospital discharge and at each subsequent follow-up interval were reported in the TAURIS database. All data were considered "early" or "late" when occurring within 30 days or later.

Core lab review of morphological data was performed in all patients with at least one CT scan performed during follow-up at 12 months after the first postoperative CT evaluation. Comparisons were made between the immediate postoperative and latest follow-up scans.

CT images of the preoperative, the early postoperative, and at 12 months or more were sent for blind reading to a centralized core laboratory. All CT scans were reviewed by the same vascular surgeon (I.G. from the core lab group) with previous tested interobserver agreement in CT AAA measurement. Scans were obtained 1 cm above the celiac artery to the femoral arteries. Images were analyzed using a workstation with dedicated software for vascular reconstructions and volume rendering analyses (Aquarius TeraRecon Inc., San Mateo, Calif). Volumetric acquisition for visualization of vessel anatomy was also performed using a predefined module for vessel analysis of the target regions-of-interest.

When DICOM format was not available (40% of the cases), measurements were performed manually with a caliper using the smallest diameter in the largest axial image. We used the minor axis because is believed to be a more reliable measure and is commonly used in FDA trials on EVAR.[8,9]

Measurements and definitions. Length and diameter of aortic neck, stent graft patency and integrity, evidence of endoleak, and position of the stent graft in relation to the native arterial vasculature (aorta, renal arteries, and superior mesenteric artery) were assessed.

An increase or decrease of more than 5 mm in maximum aneurysm diameter compared with immediate postoperative CT imaging at any time during follow-up or between any two consecutive follow-up intervals was considered to be a significant change.

The proximal aortic neck was measured as the outer diameter in the minor axis at two different levels: at the level of the lowest renal artery and 5 mm distally.

Aortic neck dilation was defined as an increase of more than 3 mm in diameter at follow-up examination in any of the two abovementioned locations.

For device migration, the distance from the level of the superior mesenteric artery to the CT scan image containing at least one half of the proximal stent was measured. Graft migration was defined as dislocation of 10 mm or more with respect to the immediate postoperative CT.

Endoleak was classified as types I through IV according to standard definitions[10] and in compliance with reporting standards.[11] Endoleaks were defined "persisting" when present at two or more consecutive CT scan assessments.

All morphological changes with respect to the immediate postoperative assessment were considered clinically relevant when associated with any reintervention, aneurysm rupture, or related mortality.

Clinical evaluations are included as reported by each center regardless of whether core lab data were available for a visit interval.

Device. The Talent Unidoc device is a self-expanding modular endograft system composed of serpentine-shaped nitinol stents integrated into a woven polyester fabric. The stents are spaced along a full-length nitinol spine; a 15 mm long uncovered stent at the proximal end allows transrenal or suprarenal fixation and a mini-support spring in the exoskeleton at the proximal end of the graft reduces the risk of graft in-folding.

The Talent Unidoc technology implies two changes with respect to the original Talent AAA stent graft to further improve graft durability: (1) chemical treatment of nitinol to reduce corrosion and risk of fracture; and (2) iliac connecting bar moved from lateral to medial position to improve graft stability and conformability and decrease risk of kinking and thrombosis.

Statistical analysis. Statistical analysis was performed with SPSS software (version 11.0.1; SPSS Inc, Chicago, Ill). The χ^2 and Fisher exact test were used to analyze discrete variables. Results of categorical variables were reported as frequency and percentages, whereas continuous variables were expressed as mean and range for normally distributed variables and median and interquartile ranges (IQR) for skewed variables. Quantitative estimates of morphological outcomes (growth, endoleak, neck enlargement, migration) were calculated as annual incidence rates and displayed in patients/year percentages (IR_{ann} number of events/person-year at risk). The Kaplan-Meier method was used to assess the cumulative rates of reintervention and graft thrombosis. Differences were reported as significant when the *P* value was equal or less than .05.

RESULTS

During the study period, 557 patients with AAA underwent elective repair with the Talent Unidoc device. Patients with less than 12 months imaging were excluded for further morphologic analysis. There were 10 (1.8%) perioperative deaths. Twenty-four patients (4.3%) died from nonaneurysm related causes before reaching 1 year. Twelve patients (2.1%) who were converted to open surgery before completing 1 year follow-up were excluded. Finally, 162 (29%) additional patients did not have 1- or 12-month CT scans with adequate frames nor had CT

Table I. Risk factors of 349 patients

	N	*%*
Smoking	248	71
Hypertension	280	80
Hypercholesterolemia	206	59
Coronary artery disease	237	68
COPD	216	62
Diabetes	47	13
Renal disease	58	17
Cerebrovascular disease	108	31

COPD, Chronic obstructive pulmonary disease.

Table II. Anatomical features of 349 patients

	Median	*IQR*
AAA diameter (mm)	56	50-62
Neck length (mm)	20	16-30
Neck diameter (mm)	25	23-26
Neck thrombus	150 (43%)	—
Neck angulation > 60°	29 (8%)	—

AAA, Abdominal aortic aneurysm; *IQR,* interquartile range.

follow-up elsewhere and films were unavailable for review. When adequate follow-up imaging could not be obtained, the patients were excluded from further analysis.

Therefore, 349 patients who completed both the postoperative (1-month) and at least 12-month CT scans represent the study cohort and are the basis for all the further review of morphology by the core lab. The mean follow-up period for these 349 patients was 25 months (range 12-60 months).

One hundred eighty-five patients had a follow-up longer than 24 months and 85 longer than 36 months. A total of 1187 complete CT scan series were reviewed by the core lab.

There were 24 females and 325 males. Patients ages ranged between 45 and 90 years (mean 73.8 years). Patient characteristic and baseline anatomical features are reported in Tables I and II. There were 34 AUI and 315 bifurcated grafts. The device was oversized by a mean of 12.8%, with 95 cases <10%, 205 between 10% to 20%, and 49 >20% of the baseline neck diameter.

During the mean follow-up period of 25 months, 10 of the 349 patients included in the core lab analysis died, one for aneurysm rupture (0.3%). Two patients died from cardiopulmonary complications, six from cancer, and one from stroke. The cumulative survival rate at 48 months was 89.2%. Morphological outcome for these patients was evaluated until the time of death.

Overall, two AAA late ruptures (0.6%) were recorded, one fatal.

Fourteen (4%) early (within 30 days) reinterventions (seven endovascular) were recorded, including eight (2.3%) for limb graft thrombosis. These data are detailed in Table III.

Nineteen late (>30 days) reinterventions were performed, 8 (2.2%) were conversions to open repair, 3 femoro-femoral crossover bypass, and the other 8 were performed by endovascular route. Causes, details and types of late reintervention are shown in Table IV.

Table III. Perioperative reinterventions

Perioperative reinterventions (n = 14)	*N*	*Indication*
Fem-fem bypass	5	Iliac limb occlusion
Iliac angioplasty	3	Iliac limb occlusion
Iliac-femoral bypass	1	Iliac limb occlusion
Aorto-monoiliac endografting	1	Type I endoleak
Hypogastric artery embolization + distal cuff	1	Type II hypogastric endoleak
Aneurysmal sac embolization	1	Type II endoleak
Spleno-renal bypass	1	Renal artery occlusion
Percutaneous hematoma drainage	1	Retroperitoneal bleeding

Table IV. Late reinterventions

Late reinterventions (n = 19)	*N*	*Indication*
Conversion to OR	8	1 (type 3 + growth), 1 (migration + growth), 1 (migration + type 2), 1 (rupture, neck enlargement + growth + type 3), 1 (rupture, type 1), 1 (migration + neck enlargement), 1 (migration), 1 type 1)
Fem-fem by-pass	3	Iliac limb occlusion
Distal cuff	3	Distal type I endoleak
Proximal cuff	1	Migration + proximal type 1 endoleak
Renal artery stenting	1	Renal artery stenosis
Aneurysmal sac embolization	2	Type II endoleak
Aorto-monoiliac endografting	1	Type I endoleak

OR, Open repair.

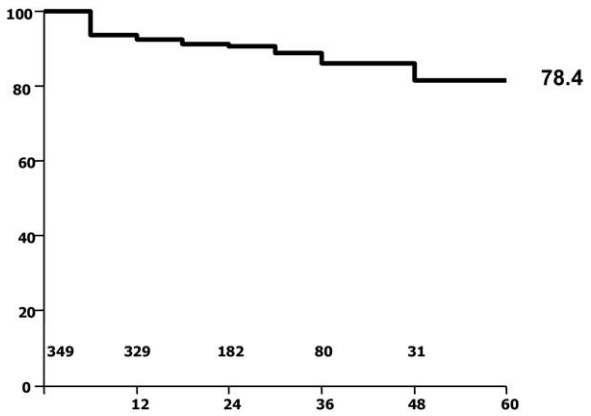

Fig 1. Freedom from reinterventions.

The incidence of any reintervention was 6% at 1 year, 8% at 2 years, 13% at 3 years, and 16% at 4 years. The corresponding Kaplan Meier estimates for freedom from reintervention rate (87% at 3 years and 73.9% at 4 years) and conversion rate are shown in Figs 1 and 2, respectively.

Morphological analysis. According to the core lab reanalysis of data, the median aneurysm diameter was 56

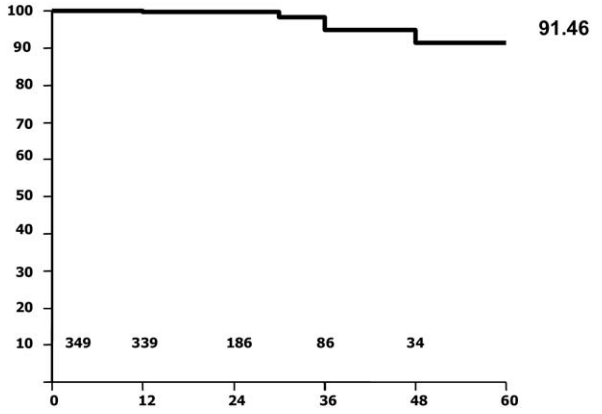

Fig 2. Freedom from conversion.

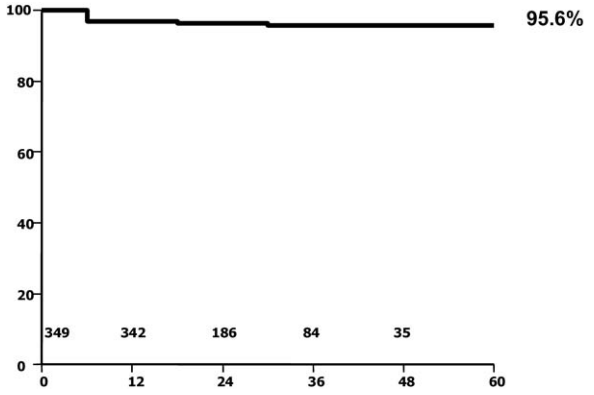

Fig 3. Freedom from graft limb occlusion.

mm (IQR 50-62) in the early postoperative assessment and 48 mm (IQR 39-54) at the latest examination ($P = .0001$). The maximum aneurysm diameter remains unchanged in 169 patients (48%) and decreased >5 mm in size in other 158 patients (45%). For 22 (6.3%) aneurysms, an increase >5 mm in diameter was detected for an overall growing AAA rate of 3.1% patients/year. In nine, AAA growth was 10 mm or more, and in 13 between 5 and 10 mm. All 22 aneurysms that enlarged were associated with one or more complications revealed on CT scan: 17 endoleaks, 2 migrations, 4 neck enlargements, and 1 graft thrombosis.

On the baseline assessment CT scan, aortic neck was 25 mm (IQR 23-26 mm) median diameter and 20 (IQR 16-30 mm) median length. Proximal neck diameter remained unchanged in 302/349 patients and increased >3 mm in 47/349 patients during the following assessment. The overall annual incidence rate for neck enlargement was 6.5% patients/year. In 20 patients, the enlargement was greater than 5 mm.

Seventeen grafts migrated for 10 mm or more during follow-up. The overall migration rate was 2.4% patients/year.

Eighty-two (23.4%) endoleaks were present at the immediate postoperative scan, 70 of type II, while 65 (18%) endoleaks were detected on the latest CT scan assessment, 50 of type II. Fifty-one endoleaks were persisting.

Overall, 13 limb graft thromboses occurred, eight early at the time of deployment and five (1.4%) later (>30 days). According to Kaplan Meier estimates, freedom from graft limb occlusion rate was 95.6% at 5 years (Fig 3). Finally, a single case of loss of graft integrity due to a hole in the graft was also detected during follow-up CT assessment.

Morphological changes detected by core lab were compared with clinical events recorded by each participating center during the same period. Of the 22 aneurysm growths >5 mm detected by the core lab, five were followed by reintervention, one due to aneurysm rupture (stent graft disconnection associated with endoleak). The only case of loss of graft integrity required conversion because of aneurysm rupture. Overall, 3/47 neck enlargements, 5/17 migrations, and 11/70 endoleaks were clinically relevant and associated with reintervention/conversion.

DISCUSSION

This is the first multicenter experience performed outside IDE or RCT that used a centralized core lab analysis to assess morphological changes after EVAR using a single model device in a postmarketing approval setting. The findings of the study are therefore generalizable to the "real world" population of patients undergoing EVAR.

All available CT scans from patients with the new generation Talent device implanted in separate vascular centers were archived for rigorous assessment in a centralized core laboratory. Core lab interpretation was used because it has a uniform methodology across sites. A standardized measurement protocol was designed to give the most accurate measurements of the aortic and stent graft morphology using a workstation with dedicated software for vascular reconstructions and volume rendering analyses. The use of automated reconstruction software and the training of the operator in manual or semiautomated measurements utilizing precise protocol improved the reliability of the study findings (Figs 4 and 5). Although DICOM reconstructions were not available in about 40% of the study cohort, and thus, in these, the measurements were performed directly from the CT image without centerline reconstruction, all study measurements were made by a single individual, limiting measurement variability and minimizing any effect on our results.

Our results showed that, as advised by RCT on EVAR durability, morphological changes in native anatomy after EVAR are common and probably inevitable. In spite of this, these changes can be seldom translated in stent graft failure with last generation devices. In particular, complication rates directly related to the graft structure, as limb occlusion or stent fracture, appeared to be significantly lower than those shown in previous studies reporting results of older generation endografts.

It is known that the infrarenal aortic neck in AAA tends to dilate and enlargements have been reported after EVAR of 10% to 35%.[6-8]

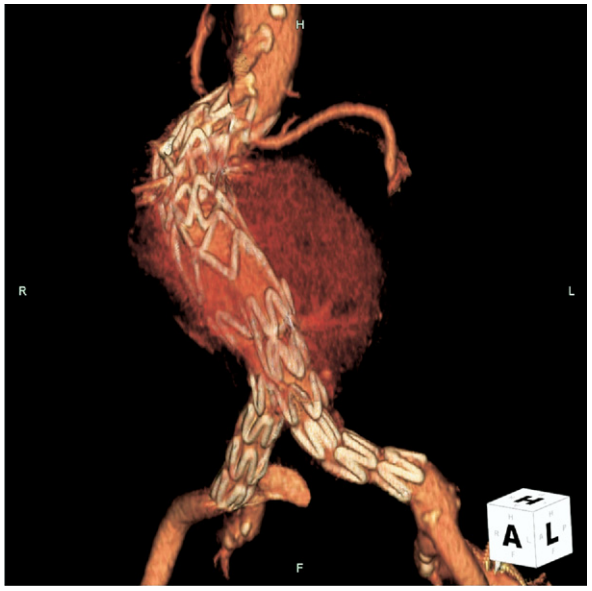

Fig 4. Volume rendering analysis (TeraRecon software) 24 months after endovascular aneurysm repair (EVAR) in patient with angulated proximal neck.

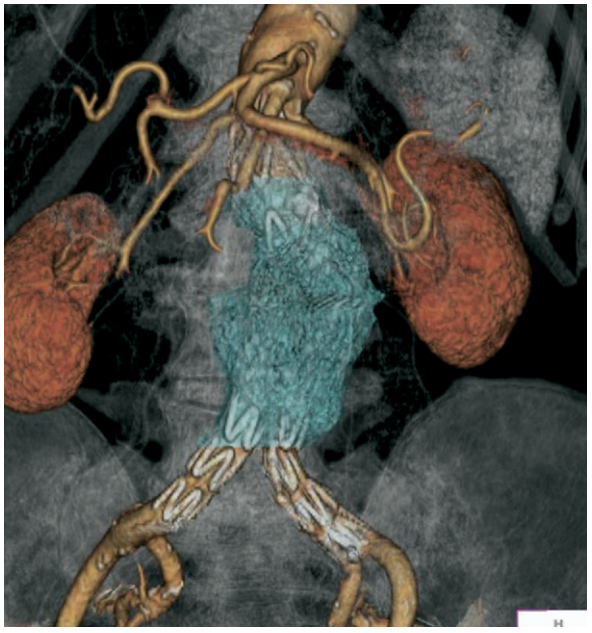

Fig 5. Volume rendering analysis with aneurysmal sac evaluation (TeraRecon software) 12 months after endovascular aneurysm repair (EVAR).

Other recent reports have identified a possible biphasic dilatation of aortic neck after EVAR, with an initial dilatation related to device oversizing and a progressive dilatation thereafter.[12] Rodway et al reported that changes in the area of aortic neck were significantly greater after 67 EVAR than after 56 open repairs in a subset of patients included in the EVAR trial.[13] Furthermore, in the EVAR subset, the median neck area significantly increased (>0.7 cm^2) in many patients (68%, 31/45) within 3 months, and additional increases occurred in more than a third (40%, 18/45) of patients after 3 months and up to 2 years. Unfortunately, the authors did not include any information about migration or clinical events related to these changes.

There is a clear association between neck enlargement and migration with literature data reporting that endografts migrated at a 10% to 40% rate.[6,8,14,15] Resch et al documented that 50% of patients with migration had significant neck enlargemen,[15] while we reported that 27% of patients with significant neck enlargement had graft migration.[6]

The observations regarding aortic neck dilatation and migration after EVAR were investigated in the TAURIS study through core lab measurements. We used 3 mm as a cut-off for significant neck enlargement in proximal neck diameter. Core lab analysis of data showed that aortic neck remained unchanged in 86% (302/349) of patients and increased >3 mm (>12%) in 13% (47/349) of patients at a maximum follow-up of 5 years. Accordingly, enlargement of more than 3 mm occurred in 6.7% patients/year after repair. However, this finding did not translate into a loss of fixation, probably due to graft oversizing and stability of proximal attachment zone.

In this regard, recently published data from a subset of patients included in EVAR 1 Trial, warning on an increased aortic neck dilation after EVAR rather than after open surgery, may be clinically irrelevant.[13] Indeed, in the present study, only three of 47 neck enlargements were associated with migration and there were few clinically detectable migrations (5/349). However, this lack of effect awaits confirmation by longer and larger studies. The overall migration rate (2.4% patients/year) in TAURIS is higher than that recently reported in other FDA trials with new generation devices.

The comparison of the Talent and Zenith Cook (Biaeverskow, Denmark) suprarenal devices in the patients randomized in the EVAR 1 trial showed that complications such as migration (2.7% vs 0.6%) or type I endoleak (4.8% vs 2.5%) were more frequent in the Talent group.[16] However, the difference was not significant and could be ascribed at least in part to different anatomical settings, rendering the comparison between graft-specific results unreliable. The selection of size, morphology, length, and angulation of aneurysm necks is a relevant factor in determining the risk of progressive neck enlargement and stability of endograft fixation, together with endograft oversizing. Indeed, data from the Zenith trial showed 14.1% migration at 12 months in patients with >30% oversizing, these findings were not confirmed in TAURIS.[8]

Loss of adherence of stringent anatomic criteria makes the comparison between our "common world" results and other published results on last generation devices within FDA or IDE trials poor. Indeed according to both the Excluder (W.L. Gore and Associates, Flagstaff, Ariz) and the Cook Zenith (Cook Inc., Bloomington, Ind) multicenter trials on last generation devices, the risk of migration

was trivial, with only two cases at 5 years in 739 Cook Zenith (99.6% freedom from) and no migration in 235 Excluder grafts, followed only for 12 months.[8,9] This exceptional low risk of migration is optimistically achievable in common patients.

In the EUROSTAR registry, where less stringent criteria were used, the migration rate was more similar to ours and was sensibly affected by adverse anatomy, ranging from 4.3% to 5.9% according to the presence or not of an adverse neck angulation.[6] Other studies showed that the application of commercially available devices outside specific instruction for use had an incremental negative effect on late results, with difference in outcomes that are non device-specific.[17]

Other studies report variable migration rates with newer generation grafts: a recent single center experience from Badger et al found no difference in migration rates between 29 patients treated with Zenith and 33 with Talent, both being as high as 17% at 3 years.[18]

Donayre et al in their institutional IDE clinical trial found 7 migrations over 47 Talent implanted in adverse neck anatomy in the period 1998-2001 and only one migration in 48 patients enrolled after 2002 using the newer generation LPS Talent.[19]

The high rate of reintervention after repair has often been recognized as the Achilles' heel of EVAR durability,[1-3,20] however, this is not the case if only minor, low risk reinterventions are required to ensure the primary goal to prevent AAA rupture and related death. The current version of Talent Unidoc stent graft included improvements as chemically imprinted nitinol and medial placement of the connecting bar implemented to improve fatigue resistance. In this series only one aneurysm-related death (0.3%) and two AAA ruptures (0.6%) after repair occurred during a mean follow-up of 25 months in 349 patients who were reviewed by the core lab. In addition, the need for late conversion to open repair was as low as 2.2% probably because of the fewer failures of substantial graft material fatigue.

Indeed, a number of complications related to graft material, identified in previous studies with older generation Talent device, were less frequently encountered in the TAURIS experience. In the TAURIS study, although freedom from reintervention rate was 78.4% at 5 years the reasons for reinterventions were not attributable to graft material weakness. Only one loss of graft integrity (0.3%) occurred and there was no longitudinal bar erosion or fracture for a crude rate of late graft thrombosis of 1.4%. The overall freedom from graft limb occlusion at 5 years (95.6%) was comparable to those showed within FDA trials of other last generation devices and also better than that reported in other non-FDA studies.[8-9] TAURIS results may support other experiences showing a superior patency in Talent devices. Within the EVAR 1 trial, thrombosis/stenosis rates were 3.8% with Zenith vs 1.1% with Talent devices.[16] Abbruzzese et al analyzed outcomes of three commercially available devices other than Talent (Cook Zenith [Cook Inc.], Excluder [W.L. Gore and Associates], or AneuRx [Medtronic, Santa Rosa, Calif]) applied outside the anatomical instruction for use, and showed that the 5-year freedom from graft related adverse event was 74% and was mainly affected by the high incidence of graft thrombosis.[17]

Limitations of the study. The TAURIS study retrospectively analyzed patients compliant with a minimum 1-year follow-up and complete sequential imaging, thus selection biases could not be avoided. Even if more representative of a real world population with respect to clinical trial, our patients were the results of a selection and therefore generalization of our results should be interpreted with caution.

The study was also limited to patients in whom a device had been successfully deployed. Therefore, we cannot analyze the overall effect on clinical outcomes.

Morphological suitability was not homogenous among centers, as it is in prospective studies with predefined criteria, but this can render the results of the present experience even more realistic and express the true outcomes of EVAR treatment in standard settings. Morphology status was determined in 40% on direct measurements from original CT scan hard copies without centerline reconstruction. This reflects the real world where many centers lack of digitally archived DICOM images. However, all study measurements were made by a single individual, which should limit measurements variability and thus minimize any affect on our conclusion.

Core lab morphologic interpretation is being reported because it has uniform methodology across the sites. However, clinical evaluations are included regardless of whether core lab data were available for a visit interval. Due to the recent introduction of the last generation of Unidoc technology, follow-up length could be assessed only at a mean of 25 months.

CONCLUSIONS

Data from this real world experience monitored with a centralized imaging review show that AAA endovascular repair with the latest generation of a single model of endograft is associated with low thrombosis and graft fatigue, and low aneurysm rupture and related death risks. Neck enlargement, and other morphology changes are common after EVAR, but might be almost always without clinical consequences. Longer follow-up is advisable to confirm the present results.

AUTHOR CONTRIBUTIONS

Conception and design: FV, PC, PDR, GP
Analysis and interpretation: GP, PDR, PC, FV
Data collection: GP and the TAURIS group
Writing the article: PDR, FV, GP, PC
Critical revision of the article: PC, PDR
Final approval of the article: PC
Statistical analysis: GP, FV, PDR
Obtained funding: PC
Overall responsibility: PC

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Submitted Aug 29, 2008; accepted Nov 11, 2008.

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