# Five-year results of endovascular treatment with the Gore TAG device compared with open repair of thoracic aortic aneurysms

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***Objectives:*** **Report the results of a phase II multicenter, prospective trial comparing endovascular treatment of descending thoracic aneurysm (TEVAR) with the TAG device to surgical controls after 5 years of follow-up.**
***Methods:*** **The Gore TAG trial compared the TAG endograft patients (n = 140) with standard open surgical controls (n = 94) with enrollment from September of 1999 to May of 2001. An additional 51 patients were enrolled in 2003 after revision of the endograft. Follow-up consisted of patient visits, computed tomography (CT) scans and x-rays at 1, 6, and 12 months and yearly. Significant sac size change was defined as ≥5 mm increase or decrease from the 1 month baseline measurement. Migration was defined as ≥10 mm cranial or caudal movement of the device inside the aorta. Significance was determined as $P \leq .05$.**
***Results:*** **At 5 years, aneurysm-related mortality was lower for TAG patients at 2.8% compared with open controls at 11.7% ($P = .008$). No differences in all-cause mortality were noted, with 68% of TAG patients and 67% of open controls surviving to 5 years ($P = .43$). Major adverse events at 5 years were significantly reduced in the TAG group; 57.9% vs 78.7% ($P = .001$). Endoleaks in the TAG group decreased from 8.1% at 1 month to 4.3% at 5 years. Five TAG patients have undergone major aneurysm-related re-interventions at 5 years (3.6%), including one arch aneurysm repair for type 1 endoleak and migration, one open conversion and five endovascular procedures for endoleaks in three patients. There were fewer secondary procedures not directly related to aneurysm repair in the TAG vs the open repair group at 5 years, 15.0% vs 31.9%, ($P = .01$). For TAG patients, sac size at 60 months decreased in 50% and increased in 19% compared with the 1-month baseline. Comparison with the modified low-porosity device at 24 months showed sac increase in 12.9% of original vs 2.9% in modified grafts ($P = .11$). At 5 years, there have been no ruptures, one migration, no collapse, and 20 instances of fracture in 19 patients, all before the revision of the TAG graft.**
***Conclusions:*** **In anatomically suitable patients, TAG treatment of thoracic aneurysms is superior to surgical repair at 5 years. Although sac enlargement is concerning, early modified device results indicate this issue may be resolved. (J Vasc Surg 2008;47:912-8.)**

Descending thoracic aneurysm (DTA) repaired by the traditional open surgical procedure has long been recognized as having high morbidity and mortality, even in centers of excellence.[1,2] Thoracic endografting has been introduced as a means to exclude thoracic aneurysms with morbidity and mortality equal to or less than traditional surgical approaches.[3-8] Early reports of thoracic endovascular aneurysm repair (TEVAR) have been favorable,[3-8] even when high-risk patients were included.[6,7] The Gore TAG (W. L. Gore & Associates, Flagstaff, Ariz) device is currently the only thoracic endoprosthesis approved by the FDA for commercial use in the treatment of DTA. Early results of the regulatory trial have been reported previously.[3,4] Despite the excellent short-term results of TEVAR, there is concern for morbidity related to late interventions and prosthesis failure. This report details the results of the Gore TAG phase II multicenter trial at 5 years after DTA treatment either with the TAG device or open repair.

The primary aims of this nationwide multicenter device trial were to evaluate the safety and efficacy of the TAG endoprosthesis in comparison with open surgical repair as treatment for descending thoracic aortic aneurysms at 1 year, with follow-up scheduled to reach 5 years. Safety was determined by comparing the occurrence of major adverse events between the two treatment groups. Efficacy was measured by the incidence of major device-related events that required intervention. Secondary endpoints of the study were comparisons of the early clinical parameters of blood loss, ICU, and hospital stays and time to return to normal activities.

## METHODS

Details of study methods as well as inclusion and exclusion criteria have been previously described.[3,4] Briefly, the Gore TAG pivotal trial was a multicenter, prospective, nonrandomized phase II study that recruited surgical can-

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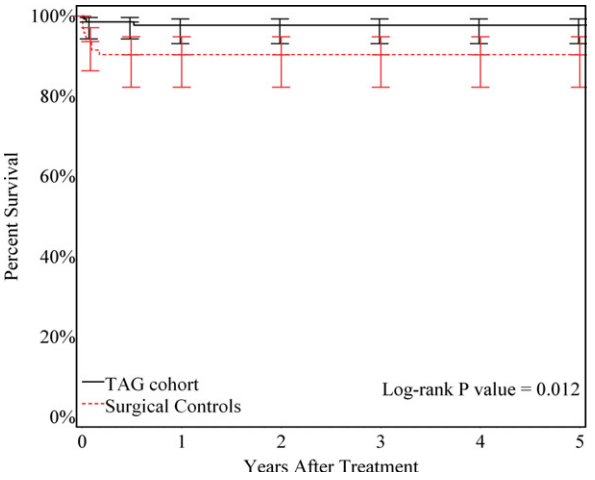
didates with DTA from September of 1999 through May of 2001. One hundred forty endovascular patients were enrolled. Ninety-four patients with DTA treated by open surgery were used as a control group. Of the 94 open surgical control patients, 44 were concurrent subjects and 50 were historic controls from the enrolling institutions. Details on the two populations have been previously published.[3] The groups were not significantly different on preoperative comorbidities or presentation other than there were more symptomatic aneurysm patients in the open surgical group (38% vs 21%, $P = .007$), and there were marginally more patients with cardiac histories in the TAG group (49% vs 36%, $P = .06$) In May of 2001, fractures of the longitudinal spine of the TAG graft were noted. The device was modified by eliminating the longitudinal wire and introducing a new stronger and less porous polytetrafluoroethylene (PTFE) material.[4] From January 2004 to June 2004, an additional 51 TEVAR patients were enrolled in a confirmatory TAG arm using the modified device, which is the currently marketed device.

Patients with DTA of at least twice the diameter of the normal thoracic aorta and with 2 cm of nonaneurysmal neck for sealing distal to the left carotid artery and proximal to the celiac artery were eligible for endovascular treatment. TAG devices ranged from 26 to 40 mm in diameter. Open repair was performed according to local protocols at the participating institutions. The extent of the open repair could not extend more proximally than the left carotid artery and more distally than the celiac axis. There were no mandates regarding use of spinal cord protection strategies or use of left heart bypass. High-risk patients, including those with dissection, ruptures, mycotic aneurysms, and trauma were excluded, as were medically high-risk patients.[3,4] Follow-up exams, four-view chest x-rays and spiral computed tomography (CT) scans were performed at 1, 6, and 12 months and yearly thereafter. These assessments were performed at 3 months if an endoleak was present. Five-year follow-up was concluded for all available patients in August of 2006.

**Adverse events.** Major adverse events (MAE) as defined per Sacks criteria,[9] were reported by the study sites and verified by clinical events coordinators. MAEs were those that resulted in a prolongation of treatment, new hospitalization, major disability, or death. Major and minor adverse events were adjudicated by a clinical events committee. Aneurysm-related deaths were those deaths which occurred in hospital or within 30 days of the initial procedure or any reinterventions, or a death due to the aneurysm or the treatment device. Pre and postoperative DTA measurements and endoleak assessments were performed at the study sites. Significant sac size change was defined as ≥5 mm change of the largest diameter of the aneurysm from the baseline 1-month measurement. Migration was defined as a graft shift ≥10 mm either cranial or caudal in the aorta.

**Statistical analysis.** Methods of statistical comparison have been previously described.[3,4] Kaplan-Meier curves and log-rank tests were used to construct survival curves, judge significance and track events over time. $\chi^2$ and the Fisher exact test were used to compare nominal data. Continuous variables were compared with 2-sample *t* test in a normal distribution or the Wilcoxon rank sum test in a non-normal distribution. $P \leq .05$ was considered significant.



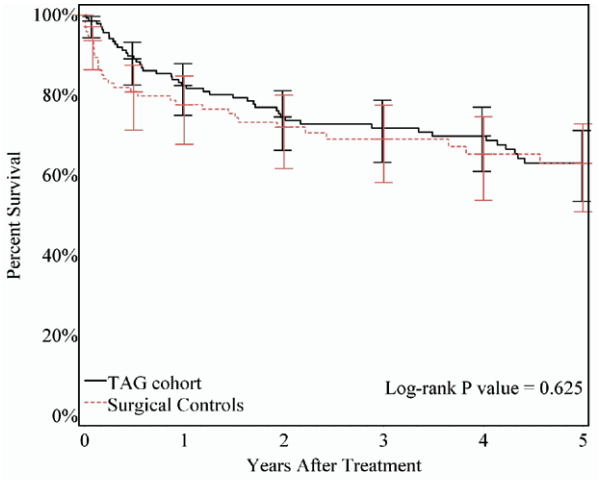

| | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|
| 95% C.I. TAG | .931, .993 | .931, .993 | .931, .993 | .931, .993 | .931, .993 |
| 95% C.I. Control | .822, .949 | .822, .949 | .822, .949 | .822, .949 | .822, .949 |

**Fig 1.** Freedom from aneurysm-related death to 5 years.

## RESULTS

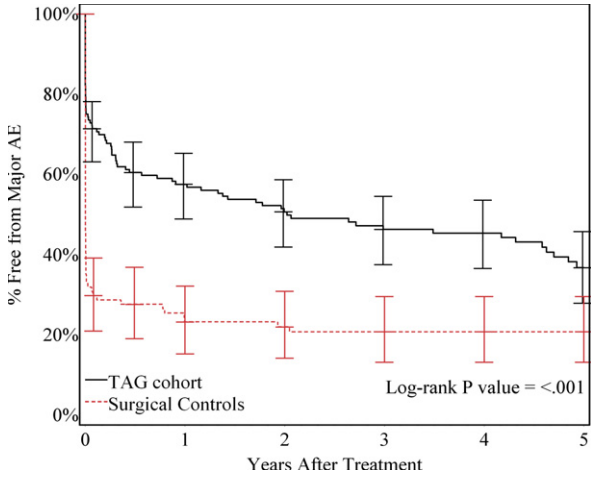
Two hundred thirty-four patients were treated for descending thoracic aneurysms in the pivotal TAG trial and underwent either thoracic endografting (n = 140) or standard open repair (n = 94). One hundred thirty-seven of 140 patients (98%) successfully received the TAG device in the pivotal trial, with three access failures. An additional 51 patients were enrolled in the confirmatory arm of the TAG trial after revision of the device with a follow-up of 2 years.

**Mortality.** Aneurysm-related mortality was concentrated in the early follow-up period with no late deaths related to rupture or reinterventions in either group. In up to 66 months after DTA repair, there have been four aneurysm-related deaths (2.8%) in the TAG group, and 11 aneurysm-related deaths (11.7%) in the open surgical group ($P = .008$). In the TAG cohort, three of these deaths were within the original hospitalization, resulting form stroke, cardiac causes, and sepsis. One later death occurred 2 months after TAG placement when the patient was found to have an aorto-esophageal fistula. He underwent successful conversion but suffered a respiratory arrest and anoxic brain injury on postoperative day 13. In the open surgical group, deaths were due to respiratory failure (n = 6), stroke (n = 3), cardiac causes (n = 1), and aorto-esophageal fistula (n = 1). All deaths occurred within the first year after treatment. The probability of freedom from aneurysm-related death was significantly higher ($P < .01$) in the TAG endograft arm vs surgical controls 5 years after treatment (Fig 1). The aneurysm-related survival advantage was clearly




| | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|
| 95% C.I. TAG | .749, .879 | .662, .811 | .632, .787 | .609, .770 | .534, .712 |
| 95% C.I. Control | .677, .848 | .617, .800 | .582, .776 | .538, .746 | .509, .728 |

**Fig 2.** Freedom from all-cause mortality 5 years after DTA.




| | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|
| 95% C.I. TAG | .488, .652 | .419, .586 | .375, .544 | .366, .535 | .279, .457 |
| 95% C.I. Control | .152, .322 | .142, .309 | .132, .296 | .132, .296 | .132, .296 |

**Fig 3.** Freedom from major adverse events over time.

**Table I.** Causes of death after descending thoracic aneurysm repair out to 5 years

*Aneurysm-related deaths*

| *Cause of death* | *TAG cohort (number of patients)* | *Surgical controls (number of patients)* |
|---|---|---|
| Respiratory failure | | 6 |
| Stroke | 1 | 3 |
| Cardiac arrest | 1 | 1 |
| Aorto-esophageal fistula | 1 | 1 |
| Respiratory failure after conversion | 1 | |

*All-cause mortality*

| *Cause of death* | *TAG cohort* | *Surgical controls* |
|---|---|---|
| Cardiac arrest/MI | 17 | 6 |
| Cancer | 4 | 2 |
| Respiratory failure | 5 | 8 |
| Pneumonia | 3 | 1 |
| CHF | 4 | |
| Stroke | 3 | 4 |
| Paraplegia | | 1 |
| Sepsis | 4 | 3 |
| Pulmonary embolism | 1 | |
| Ruptured AAA | 1 | |
| Mesenteric ischemia | 1 | |
| Trauma | | 1 |
| Unknown | 2 | 5 |
| Total | 45 | 31 |

*MI*, Myocardial infarction; *CHF*, congential heart failure; *AAA*, abdominal aortic aneurysm.

due to perioperative survival, but it is noteworthy to observe that there were no late deaths related to endoleak, stent fracture, material fatigue, or other graft-related problems.

Death from all causes was similar between the TAG and open surgical groups (Fig 2). Over 60 months, there were 45 deaths in the TAG group and 31 deaths in the surgical cohort, resulting in respective survival rates of 68% and 67% (log rank test $P$ value = .433). Table I lists all causes of death. Cardiac events, respiratory failure, stroke, and malignancy were the leading causes of death in both groups. There were no known cases of aneurysm rupture in either group although autopsy studies were rarely performed.

**Adverse events.** Major adverse events (MAE) after DTA repair primarily occurred in the immediate postoperative period, where 28% of TAG patients and 70% of surgical controls had at least one MAE ($P < .001$). The early advantage of fewer TAG MAEs continued throughout follow-up, with 12-month MAE rates of 42% in the TAG group and 77% in the surgical cohort ($P < .001$). Kaplan-Meier analysis demonstrated a log-rank value of $P = .001$ for differences in the occurrence of MAEs between the TAG and surgical control patients out to 5 years, with 57.9% of TAG and 78.7% of open patients having at least one MAE (Fig 3). At 5 years, TAG patients were significantly less likely to have had any bleeding, pulmonary, renal, wound, or neurologic complications. TAG patients were more likely to have had vascular complications ($P = .004$). Secondary procedures related to vascular complications are listed below. There were no late instances of renal failure. Cumulative MAE rates, which plot each MAE rather than the number of patients who had any MAE, showed that the average number of MAEs per patient at 5 years was 2.1 for TAG patients and 3.1 for surgical

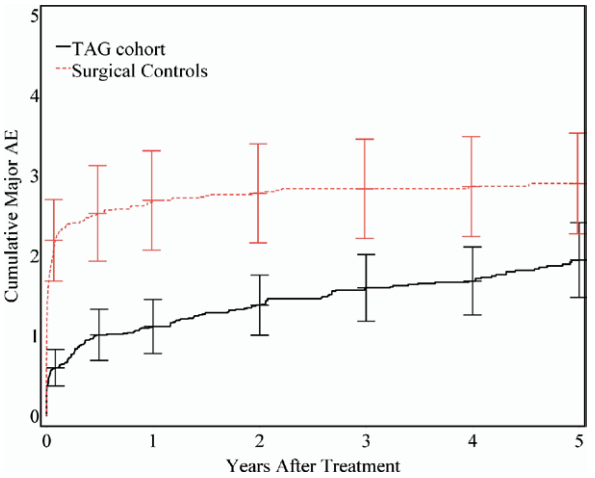



**Fig 4.** Cumulative major adverse events (MAEs) per patient over time.

controls (Fig 4). Endoleaks detected at any time were counted as MAEs.

**Endoleaks, reinterventions and secondary procedures.** Endoleaks occurred in 10.6% of pivotal TAG patients at some point during 5 years of follow-up (Table II). Remarkably, very few were suspected to be type II from intercostal arteries, and none of these were treated directly. Most endoleaks were thought to be type I at the attachment sites. Five TAG patients have had additional thoracic reinterventions directly related to the DTA treated (Table III). Three patients have required a total of five endovascular reinterventions for endoleaks. These additional procedures took place from 45 to 1525 days after the original repairs. One of the patients who had an endovascular reintervention had a spine fracture in the original endoprosthesis used. This patient also had a carotid-subclavian bypass to allow for TAG extension and developed hematoma complications from this at the neck and groin. There have been 20 spine fractures seen in 19 TAG patients, with only one patient (described above) requiring treatment. No new spine fractures were detected in any patients after 24 months of follow-up. One patient underwent conversion to open repair after discovery of an aorto-esophageal fistula 73 days after TAG placement. He died of respiratory and multisystem failure after the open procedure. The fifth patient had an open arch aneurysm repair for type 1 endoleak and migration at 5 months. This case of migration was the only one seen in 5 years, and was probably related to poor proximal neck anatomy (migration incidence 0.7%). The rate of major, direct aneurysm-related reinterventions in the TAG group at 5 years follow-up was 5/140 (3.6%). Reinterventions directly related to open aneurysm repair occurred in two patients, with one having a proximal anastomotic collection drained and one having debridement and drain placement for an aorto-esophageal fistula. The aneurysm reintervention rate was 2.1% for open controls.

There were six patients in the TAG group who needed secondary vascular procedures. Four of these took place on postoperative day 1. Three were related to acute leg ischemia and one was an evacuation of a brachial artery hematoma. Another patient had hematoma complications after carotid-subclavian bypass and extension of the TAG device. The final patient had thrombosis of an iliofemoral conduit on postoperative day 127 and underwent femoral to femoral bypass.

The total number of TAG patients with at least one secondary procedure following but not directly related to the aneurysm repair was 21/140 (15.0%). There have been 30 patients with additional secondary procedures in the surgical control group (31.91%). Most of these procedures are related to perioperative complications (Table III). There was one TAG patient who had a secondary procedure not directly related to aneurysm treatment more than 30 days after the DTA repair. This was a thrombosis of an iliofemoral conduit and is described above. In the surgical control group, there were six secondary procedures which took place more than 30 days after DTA repair, five related to wound issues, and one patient with axillary aneurysm repairs. At 5 years, there were significantly fewer aneurysm-related secondary procedures in the TAG group ($P$ = .011). Fig 5 shows all secondary procedures and reinterventions at 5 years.

**Sac diameter.** Change in the aneurysm sac diameter was assessed at each follow-up timepoint, and most aneurysms were found to increase or decrease over time, with a small percentage remaining stable out to 5 years (Table IV). In the pivotal trial, 19% of patients at 5 years had 5 mm or more of sac enlargement compared with a 1-month baseline, and 50% had ≥5 mm of sac shrinkage. Between 9.1% and 12.5% of all patients with sac enlargement were noted to have endoleaks between 1 month and 60 months postoperatively. The confirmatory patient cohort, treated with the revised low-porosity TAG endograft, exhibited no sac enlargement at 1 year ($P$ = .0548 vs earlier TAG patients at 1 year), and 2.9% exhibited ≥5 mm sac enlargement at 2 years ($P$ = 0.11 vs earlier TAG patients at 2 years) (Fig 6). Further follow-up data is not yet available for the confirmatory arm. The currently available commercial device is the low-porosity endograft.

**Follow-up.** TAG group follow-up was from 3 days to 66 months with a mean of 37 months. Surgical controls were compared with this group with a follow-up of 1 day to 73 months, mean 33 months. Twenty-six percent of TAG patients did not complete 5-year follow-up as they refused or were lost to follow-up. This was the case for 33% of open controls. These patients were followed for an average of 29 months (TAG) and 30 months (open). Death occurred in 32% of TAG and 33% of open controls during follow-up. Thirty-six percent of TAG and 24.5% of open patients completed the 5-year follow-up as outlined in the trial protocol. Outside of the patients who died or were lost to follow-up, there were a small percentage of patients who missed appointments or had appointments that fell outside of the accepted window for each timepoint. For example, a

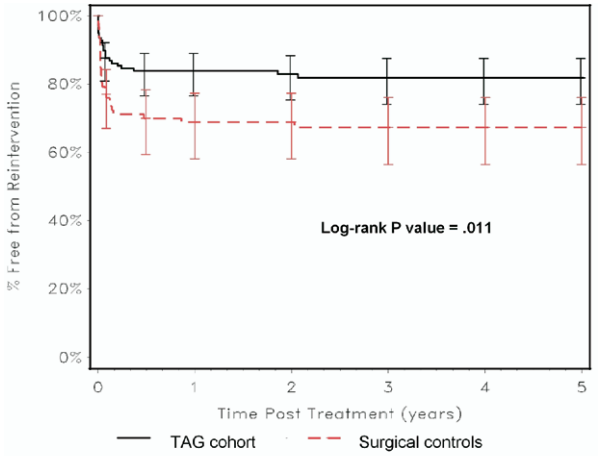
**Table II.** Endoleaks over time

| | *Periop* | *1 mo* | *6 mo* | *12 mo* | *24 mo* | *36 mo* | *48 mo* | *60 mo* |
|---|---|---|---|---|---|---|---|---|
| Patients available for follow-up | 81 | 123 | 108 | 103 | 80 | 64 | 57 | 47 |
| Patients with endoleaks | 7 (8.6%) | 10 (8.1%) | 7 (6.5%) | 4 (3.9%) | 5 (6.3%) | 2 (3.1%) | 3 (5.3%) | 2 (4.3%) |
| Type Ia | 3 | 5 | 4 | 1 | 1 | — | 1 | 1 |
| Type Ib | 1 | 1 | 1 | 1 | 1 | 2 | 2 | — |
| Type II | 1 | 1 | 1 | 1 | 1 | — | — | 1 |
| Type III | 1 | 1 | — | — | 1 | — | — | — |
| Type IV | — | — | — | — | — | — | — | — |
| Indeterminate | 1 | 2 | 1 | 1 | 1 | — | — | — |

*Type Ia*, Proximal attachment site; *Type Ib*, distal attachment site.

**Table III.** All secondary procedures and direct aneurysm reinterventions, reported as number of patients affected. Patients may have had more than one procedure

| | *TAG* | *Controls* |
|---|---|---|
| All secondary procedures | | |
| Additional thoracic aortic procedures | 3 | 2 |
| Empyema/chest wall reconstruction | 0 | 5 |
| Procedures for minor wound complications | 8 | 8 |
| Lumbar drain placement | 2 | 2 |
| Tracheostomy | 3 | 10 |
| Endoscopy or laparotomy for GI issues related to surgery | 1 | 9 |
| Evacuation retroperitoneal bleed | 1 | 0 |
| Cardiac conversion for atrial fibrillation | 0 | 3 |
| Surgery for vocal card paralysis | 0 | 2 |
| Placement dialysis catheter | 1 | 1 |
| Resection of ischemic bowel | 0 | 1 |
| Vascular reconstructions | 6 | 0 |
| Miscellaneous | 0 | 4 |
| Direct aneurysm reinterventions | | |
| Conversion/treatment of graft infection | 1 | 1 |
| Drainage of peri-anastomotic collection | | 1 |
| Extension for endoleaks | 3 | 0 |
| Evacuation of hematoma after carotid-subclavian bypass, repair of femoral pseudoaneurysm after TAG extension (all same patient as counted above) | 1 | |
| Conversion for migration | 1 | 0 |




| | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|
| 95% C.I. TAG | .766, .891 | .754, .883 | .741, .875 | .741, .875 | .741, .875 |
| 95% C.I. Control | .581, .773 | .581, .773 | .564, .761 | .564, .761 | .564, .761 |

**Fig 5.** Freedom from reintervention in TAG and surgical controls at 5 years.

"baseline" 1 month CT had to be performed between days 23 and 60 after the procedure, and only 123/140 patients fell within this time window. Without this CT no sac size change measurements could be conducted within the study protocol. Although these patients were followed as thoroughly as possible depending on their compliance, they were not counted as meeting protocol requirements.

## DISCUSSION

This work represents the first long-term results in a large patient population after thoracic endografting and in comparison with an open repair cohort. We illustrate that the significant perioperative advantages of the TAG thoracic device over open repair persist for more than 60 months after treatment. The advantages of the TAG system over open DTA repair include significantly lower rates of aneurysm-related deaths and major adverse events. An integral component of the long-lasting efficacy of the TAG has been the low incidence of graft-related complications, including few endoleaks, low rates of reintervention, and 1 of 140 patients with migration. The higher rate of perioperative and late secondary procedures within the surgical control group was surprising, and this was predominately related to wound complications. This does illustrate, however, that open surgical patients do have continuing and new problems related to DTA repair months and years after the original surgery. TAG patients also had late complications, mostly related to endoleaks and therapy for these. Also, there have been events related to comorbidities that appear to have manifested early in the open group and later in the TAG group. There have been no known ruptures in patients treated with TAG devices in this trial. Finally, the TAG phase II trial report is also significant in that the excellent results obtained were from a variety of practitioners across 17 institutions.

Despite these excellent results that persist to 5 years, we saw no difference in overall survival between the treatment

**Table IV.** Aneurysm sac size change over time in TAG group

| *Change in aneurysm size* | *1 to 6 mo (N = 85)* | *1 to 12 mo (N = 87)* | *1 to 24 mo (N = 71)* | *1 to 36 mo (N = 57)* | *1 to 48 mo (N = 50)* | *1 to 60 mo (N = 26)* |
|---|---|---|---|---|---|---|
| Decrease | 31 (35%) | 37 (43%) | 32 (46%) | 29 (53%) | 23 (45%) | 21 (50%) |
| No change | 49 (56%) | 41 (48%) | 29 (41%) | 17 (31%) | 17 (33%) | 13 (31%) |
| Increase | 8 (8%) | 8 (9%) | 9 (13%) | 9 (16%) | 11 (22%) | 8 (19%) |

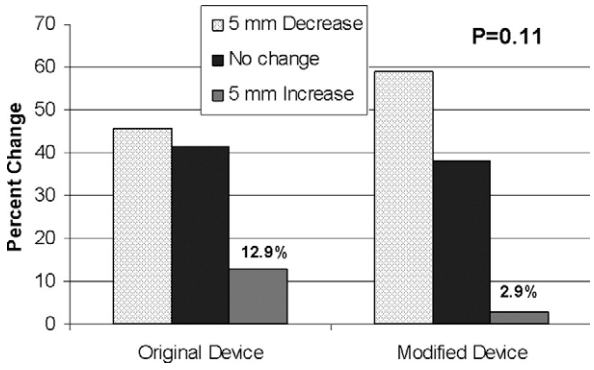



**Fig 6.** Original and modified low-porosity TAG endograft sac shrinkage at 2 years.

groups. The 5-year all-cause survival rate after either open or endovascular treatment was approximately 60%, with a 4-year survival of approximately 70%. This is not significantly different than 4-year survival rates after abdominal EVAR as seen in the EVAR I and II trials.[10] These survival rates reflect the aged population and comorbidities seen in aneurysm patients. Natural history studies have estimated a 14% annual rate of death, dissection, or rupture with a DTA of greater than 6 cm.[2] Additionally, since this is not a randomized study, there was a trend toward more TAG patients having a preoperative history of cardiac events. The higher cardiac death rate in TAG patients vs open controls after DTA probably is a reflection of the less invasive nature of the surgery, with TEVAR allowing these patients to survive longer with significant cardiac disease but having a higher long-term cardiac mortality.

Previous single-center reports have detailed midterm results after thoracic endografting. Ellozy[5] described the results of TAG and Talent endografts (Medtronic/AVE, Santa Rosa, Calif) used out to 52 months (mean follow-up 15 months). This series of patients within a mixture of clinical trials (26% treated with TAG devices and 74% treated with Talent devices) showed a higher operative mortality (6%) and a 6% rupture rate. At a mean follow-up of 18 months, Criado showed a 2.1% mortality rate and 17% incidence of MAEs, with one rupture 60 days after treatment using the Talent graft.[6] Demers et al's follow-up out to 10 years (mean 4.5 years) showed an 11% rupture rate overall and an approximate 20% reintervention rate at 48 months using a homemade device.[7] These collective results illustrate a trend toward ever-improving results as commercial devices are available and practitioners gain more experience.

Results out to 5 years after the phase II TAG study show improvement over the early TAG feasibility study which enrolled patients from 1998 to 1999. In this early study of device safety, 28 patients received the TAG device and had an aneurysm-related mortality of 3.6%. Endoleaks were noted in 21% of the patients at some time in follow-up, and 32% of the recipients had a stent fracture. There was a 10.7% rate of reinterventions/conversions, but no reports of rupture.[11] The current study shows improvement over these results in several areas, which speak to continuing evolution of the TAG endograft. The revision of the TAG device in 2004 and elimination of the spine of the graft has significantly decreased late graft-related complications and made following TAG endografts more straightforward.

In contrast to endoleaks seen after endovascular repair of infrarenal aneurysms, the endoleaks seen after TAG endografting were predominately type I. The overall rate of endoleak was low, but the high incidence of attachment site leaks reminds practitioners to be judicious in patient selection, vigilant with follow-up, and aggressive in treatment when appropriate. In some regards, the preponderance of attachment site leaks is welcome news, as extension of the endoprosthesis is a less technically difficult solution, rather than the more challenging and potentially dangerous prospect of coiling intercostal vessels. Thus far in follow-up, spine fractures have not been a major cause of endoleak, with only one patient needing treatment.

Sac expansion continues to be an issue with Gore endografts used prior to the introduction of the low-porosity fabric. Both in the treatment of abdominal aneurysms[12] and this series, we see a significant number of patients with sac expansion that is not related to endoleak. Although there has yet to be reported an incidence of rupture associated with sac expansion in the absence of endoleak with the Gore prosthesis, continued sac enlargement is worrisome. The early results from the low porosity TAG are encouraging, showing fewer than 3% of patients with sac expansion at 2 years. These results are even more dramatic in early analysis of infrarenal Gore Excluder use with the low-porosity devices having significantly more sac regression compared with original devices at 12 months.[13] Longer follow-up will be needed to determine if these early results are predictive of long-lasting sac shrinkage.

A final note should mention the difficulty seen in complete follow-up for TAG patients. More than 25% of TAG patients were lost to or refused follow-up during this trial. This is a disturbingly high number, especially knowing that dedicated teams of local and national coordinators were working to ensure compliance with trial protocol.

This finding should cause all of us to take a patient's capacity for follow-up compliance into account prior to performing TEVAR, and make sure that the patient is aware of his/her responsibility in this regard. Additionally, this could have had an effect on our overall results of open vs endovascular repair, as it is possible that patients with complications were lost to follow-up and never diagnosed. However, it is important to note that there was also relatively poor follow-up for the open surgical group, so additional problems with the open group could have been undetected as well.

## CONCLUSIONS

At 5 years follow-up, TAG thoracic endografting is a safe and effective method of DTA repair and is superior to open repair, with lower aneurysm-related death and major adverse events rates. The rate of reintervention or secondary procedures after any DTA repair is higher after open surgery compared with endografting. There have been no instances in post-repair DTA rupture in either patient cohort, and the risk of endoleak or migration after TEVAR is very low. Modification of the TAG device appears to have significantly decreased the late morbidity related to fractures within the TAG device and late sac expansion. Continued vigilant follow-up of the TEVAR population is needed to monitor for late complications.

## AUTHOR CONTRIBUTIONS

Conception and design: MM, RC, GW, ED
Analysis and interpretation: MM, ED
Data collection: MM, ED
Writing the article: ED
Critical revision of the article: MM, ED, RC, GW
Final approval of the article: MM, ED, RC, GW
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: MM

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