Evaluation of the redesigned conformable GORE TAG thoracic endoprosthesis for traumatic aortic transection

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Objective: **To evaluate the safety and effectiveness of the conformable GORE TAG thoracic endoprosthesis (CTAG) device (W. L. Gore and Associates, Flagstaff, Ariz) for the endovascular repair of traumatic aortic transections.**

Methods: **A prospective, nonrandomized, multicenter trial was conducted at 21 sites. Primary safety end points included 30-day all-cause mortality. The effectiveness end point was freedom from a major device event requiring reintervention through 1-month follow-up.**

Results: **Fifty-one subjects were enrolled between December 2009 and January 2011 with polytraumatic injuries and a mean Injury Severity Score of 32 ± 14. The proximal mean intimal aortic diameter measured 24 mm, while the mean distal intimal diameter was 22 mm. A total of 57 CTAG devices were implanted (mean, 1.1/subject; range, 1-2) with a mean patient age of 44 years (range, 21-87) and a male-to-female ratio of 2:1. Technical success was 100% with an operative mortality of 0%. Femoral access was utilized in 96% of patients. The mean procedure time and blood loss was 105 minutes and 148 mL, respectively. All subjects required admission to an intensive care unit with a mean hospital stay of 14.6 days. Adjuvant techniques (ie, lumbar drains and induced hypertension) to prevent paraplegia were used in only 7.8% of patients. No patient developed paraplegia despite 63% having complete or partial left subclavian artery coverage and only 9% of those receiving left subclavian artery revascularization. In addition, there were no device compressions or major device events reported. Overall mortality at 30 days was 7.8%, and all were adjudicated by the clinical events committee as not being device or procedure related. Serious adverse events occurred in 39.2% of patients through 30 days. To date, there have been no conversions to open repair. Two site-reported endoleaks were detected during the mean follow-up of 4.2 months, which did not require reintervention.**

Conclusions: **The CTAG device was demonstrated to be a safe and effective treatment for traumatic aortic transection based on 30-day outcomes. There were no device-related serious adverse events. (J Vasc Surg 2013;58:651-8.)**

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The treatment of blunt aortic injury (BAI) has seen many changes over the last half-century. Despite its not being approved for this indication, most major trauma centers began employing its use after thoracic endovascular aortic repair (TEVAR) approval for aneurysmal disease in 2005.[1] By 2010 estimates, more than 64% of injuries were being managed through endovascular techniques instead of traditional open repair. It has become recognized that despite its acute benefit in reducing operative mortality and complications, device complications with the TAG device (W. L. Gore and Associates, Flagstaff, Ariz) were occurring that hindered its more universal acceptance.[2,3] Device redesign was therefore necessary to address these complications that were observed when treating patients with TEVAR for BAI. The result of these efforts was an improved stent-graft device: the conformable GORE TAG thoracic endoprosthesis (CTAG) device (W. L. Gore and Associates). The primary objective of this study was to determine the short-term safety and effectiveness of the CTAG device for treatment of subjects with traumatic aortic transection. This report details the premarket approval submission data for the treatment of

Table I. Inclusion and exclusion criteria for the TAG 08-02 study

Inclusion criteria
(1) Traumatic transection of the descending thoracic aorta that requires repair, determined by the treating physician
(2) Traumatic aortic transection location between, but does not include, the left subclavian artery and celiac artery
(3) Endovascular repair with the GORE conformable TAG device performed ≤14 days after aortic injury
(4) Age ≥18 years
(5) Proximal and distal landing zone length ≥2.0 cm
- Landing zones must be in native aorta
- Landing zone may include left subclavian artery, if necessary

(6) All proximal and distal landing zone inner diameters are between 16-42 mm
- Diameter assessed by flow lumen and thrombus, if present; calcium excluded

(7) Subject capable of complying with study protocol requirements, including follow-up
(8) Informed consent form signed by subject or legal representative

Exclusion criteria
(1) Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements (sizing guide) for a single endoprosthesis diameter and the inability to use devices of different diameters (in adherence to the sizing guide) to compensate for the taper
(2) Tortuous or stenotic iliac and/or femoral arteries and inability to use a conduit for vascular access
(3) Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
(4) Infected aorta
(5) Subject has a systemic infection and may be at increased risk of endovascular graft infection
(6) Planned coverage of left carotid or celiac arteries with the device
(7) Known degenerative connective tissue disease (eg, Marfan or Ehler-Danlos syndrome)
(8) Treatment in another drug or medical device study within 1 year of study enrollment
(9) Known history of drug abuse
(10) Pregnant female
(11) Moribund patient not expected to live 24 hours with or without operation, determined by the treating physician
(12) ISS of 75
(13) Subject has known sensitivities or allergies to the device materials

ISS, Injury Severity Score.

traumatic aortic transections that led to Food and Drug Administration (FDA) approval to treat isolated thoracic aortic lesions.

METHODS

This study was a prospective, multicenter, single-arm evaluation designed to assess the safety and effectiveness of the CTAG device in subjects with traumatic aortic transection. A maximum of 30 investigative sites and 51 subjects were planned for participation. Lesions were classified into one of four categories: intimal tear <1 cm, no hematoma; tear ≥1 cm; circumferential disruption; and other. Specific inclusion and exclusion criteria are listed in Table I. Subjects were scheduled for evaluation through hospital discharge and follow-up visits at 1 month, 6 months, and annually through 5 years post-treatment. During the 13-month enrollment period, there were four amended protocol changes. The first two changes were used to update imaging guidelines, whereas the third clarified the definition of anesthetic classification for inclusion and exclusion. The last amendment was enacted to allow for continued access. This report does not include data from the patients treated under emergency use provisions or the continued access arm of the study.

The primary safety end point of this study was all-cause mortality incidence through 30 days post-treatment. Subjects who could not be confirmed as alive through 30 days postimplant were counted as lost to follow-up. The primary effectiveness end point was freedom from any major device event (MDE) requiring reintervention through the 1-month follow-up visit. An MDE was defined as endoleak, migration, wire fracture, compression, erosion, extrusion, aortic dilatation, endograft infection, or aortic rupture that required significant therapy, including unplanned increase in the level of care, permanent sequelae, hospitalization, or death per reporting standards.[4]

Statistical methods. The sample size was determined assuming a 30-day mortality incidence of 0.10 and was designed to provide a confidence interval with a half-width of <0.085. This provides a two-sided 95% score confidence interval around the estimate of ± 0.084. Statistical calculations were performed using SAS v. 9.2 (SAS Institute, Cary, NC).

Device description. The device has undergone specific changes from the original TAG device and was based upon detailed computational analysis surrounding aortic velocities and anatomy encountered in younger individuals more likely to be treated with an endoprosthesis for blunt traumatic aortic injury. Specific changes include modification to the stent frame to increase durability and compression resistance (change from eight to nine stent apices around the circumference of the device, increased wire diameter, and removal of the flares on both the proximal

Fig. GORE TAG device (*left*) and conformable GORE TAG device (*right*).

and distal end) and optimization of the graft material and stent attachment pattern to enhance conformability of the device. The Fig depicts the two different iterations of the device that have received FDA approval.

RESULTS

Eighty-seven patients were screened for enrollment and 36 were excluded for inappropriate landing zones (9), study informed consent form not signed (8), inability to comply with protocol follow-up/drug abuse (8), American Society of Anesthesiologists (ASA) V (4), repair not within 14 days (3), under 18 years of age (3), and unknown (1). The resultant 51 subjects had polytraumatic injuries and were enrolled between December 2009 and January 2011 at 21 sites. Seven additional sites were involved with the study but did not enroll patients.

Subject compliance. Three patients (5.9%) died prior to their 1-month evaluation, and no subject discontinued their follow-up (Table II). Computed tomography (CT) scans were obtained in 93.8% of the eligible patients at 1 month but only 76.7% at the 6-month follow-up interval. In those patients eligible for their 12-month visit, only one patient (14.3%) was noncompliant in obtaining an axial CT scan.

Demographics. There were 34 males and 17 females enrolled (ratio 2:1) with a mean age for the cohort of 44.1 ± 19.9 years (range, 21-87). The majority of patients were Caucasian (82.4%) and possessed a significant medical history of smoking, hypertension, and/or hypercholesterolemia (Tables III and IV). The cohort had an ASA classification of either III or IV in 80.4% of the patients and a mean Injury Severity Score (ISS) of 32 ± 14 (range, 9-66) (Table V). Fifty of the 51 patients had either a tear greater than 1 cm, circumferential disruption, or pseudoaneurysm. Median time from injury to treatment was 21 hours with a range of 3 to 334 hours. The median blood pressure upon presentation for the cohort was 130/70 mm Hg. Motor vehicle collision was the etiology in most patients (84.3%) with 2% of the patients sustaining their injury from a fall. Table VI comprises a list of the common concomitant injuries that were predominantly thoracic in nature. Also included were pulmonary, upper torso, and extremity fractures.

Aortic and procedure details. The mean intimal aortic diameter at the proximal implantation site measured 24.1 ± 3.7 mm (range, 17-33), whereas the mean distal intimal diameter was 21.8 ± 3.8 mm (range, 16-34). The average lesion diameter was 29.2 ± 6.3 mm (range, 18-47). Mean proximal neck length distal to the left common carotid artery was 38 mm. Implantation zones are listed in Table VII. Fifteen patients (29.4%) had partial left subclavian artery (LSCA) coverage without revascularization. An additional 17 patients (33.3%) had complete LSCA coverage with three of these receiving revascularization (transposition, 1; bypass, 2) at the discretion of the implanting physician. Patient-specific revascularization was physician dependent and the indication for revascularization was not documented. Snorkels and chimneys were excluded in the trial. General anesthesia was used for the procedure in the majority of patients (92.2%). Femoral access was utilized in 96.1% of patients. The median external iliac diameter was 8 mm, regardless of laterality. Percutaneous access was left to discretion of the investigator and comprised 31.4% of the insertion methods. There was one iliac artery access exposure and one infrarenal aortic conduit.

Safety evaluation. A total of 57 CTAG devices (Table VIII) were implanted (mean, 1.1/subject; range, 1-2) with 88.2% of patients requiring one device for lesion exclusion (10-cm treated length). Six patients (12%) had two devices implanted to treat their injury. Reasons for additional implants included long lesion length in two subjects, device deployment distal to intended location in three subjects, and one subject required a second implant for a presumed type III endoleak. Technical success was 100%, operative mortality was 0%, and no secondary procedures were required during follow-up. The mean procedure time and blood loss were 105 minutes and 147.9 mL, respectively. Adjuvant techniques to prevent paraplegia were used in only 7.8% of patients: cerebrospinal fluid drainage, 1; hypertension, 2; and steroids, 1. No patient developed paraplegia, and only one patient with partial subclavian coverage developed left arm claudication at 4 months. This was despite 62.7% of the patients having complete or partial LSCA coverage and only 5.9% receiving

Table II. Subject disposition and compliance by study interval

		Follow-up compliance				*Events prior to next interval*		
Study period	*Eligible for follow-up, No.*	*Eligible for follow-up and completed study period,*[a] *No. (%)*	*Subjects with visit in window,*[a] *No. (%)*	*CT scan performed,*[a] *No. (%)*	*X-ray performed,*[a] *No. (%)*	*Death,*[a] *No. (%)*	*Discontinued,*[a] *No. (%)*	*Not due for next follow-up,*[a] *No. (%)*
Procedure	51	51 (100.0)	-	-	-	0 (0.0)	0 (0.0)	0 (0.0)
Postprocedure	51	51 (100.0)	-	-	-	3 (5.9)	0 (0.0)	0 (0.0)
1 month	48	48 (100.0)	47 (97.9)	45 (93.8)	43 (89.6)	2 (4.2)	0 (0.0)	0 (0.0)
6 months	46	30 (65.2)	26 (56.5)	23 (50.0)	24 (52.2)	1 (2.2)	0 (0.0)	23 (50.0)
12 months	22	7 (31.8)	7 (31.8)	6 (27.3)	6 (27.3)	0 (0.0)	0 (0.0)	22 (100.0)
24 months	0	-	-	-	-	-	-	-
36 months	0	-	-	-	-	-	-	-
48 months	0	-	-	-	-	-	-	-
60 months	0	-	-	-	-	-	-	-

CT, Computed tomography.
Study period definitions: procedure (0-0 days); postprocedure (1-14 days); 1 month (15-59 days); 6 months (60-242 days); 12 months (243-546 days); 24 months (547-911 days); 36 months (912-1275 days); 48 months (1276-1640 days); 60 months (1641-2006 days).
[a]Percentages are based on number of subjects eligible for follow-up. Completed study period is defined as any of the following: through window without visit, death or discontinuation during window, or visit completed in study window.

Table III. Subject demographics

	CTAG cohort
Number of enrolled subjects	51
Sex, No. (%)	
Male	34 (66.7)
Female	17 (33.3)
Ethnicity, No. (%)	
Not Hispanic or Latino	49 (96.1)
Hispanic or Latino	2 (3.9)
Race, No. (%)	
White or Caucasian	42 (82.4)
Black or African American	5 (9.8)
Asian/Oriental	2 (3.9)
American Indian or Alaskan Native	1 (2.0)
Native Hawaiian or Other Pacific Islander	1 (2.0)
Age, years	
No.	51
Mean (SD)	44.1 (19.9)
Median	40.0
Range	21.0-87.0

CTAG, Conformable GORE TAG thoracic endoprosthesis; *SD,* standard deviation.

Table IV. Previous medical history of enrolling subjects

	CTAG cohort, No. (%)
Number of enrolled subjects	51
Cigarette smoking	15 (29.4)
Hypertension	13 (25.5)
Hypercholesterolemia	7 (13.7)
CAD	4 (7.8)
Diabetes mellitus	4 (7.8)
COPD	3 (5.9)
CABG	2 (3.9)
Renal insufficiency	2 (3.9)
CHF	1 (2.0)
Carotid disease	1 (2.0)
Stroke	1 (2.0)
TIA	1 (2.0)
Peripheral vascular disease	0 (0.0)

CABG, Coronary artery bypass graft; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CTAG,* conformable GORE TAG thoracic endoprosthesis; *TIA,* transient ischemic attack.

LSCA revascularization. Partial coverage of the LSCA was defined as any portion of the device proximal to the distal aspect of the LSCA orifice but not completely occluding the artery. All patients were admitted to the intensive care unit and had a mean intensive care unit and hospital stay of 8.2 and 14.6 days, respectively.

Overall mortality at 30 days was 7.8%, and all were adjudicated by the clinical events committee (CEC) as not being device or procedure related. Serious adverse events occurred in 39.2% of patients (Table IX). During a mean follow-up of 4.2 months, there were no device compressions, retrograde dissections or MDEs reported; however, two additional deaths occurred at 57 and 204 days related to traumatic brain injury and drug toxicity, respectively. Neurologic complications were notably absent beyond the 30-day follow-up interval; however, there were two reported cerebral events related to hypoxic encephalopathy and an ischemic stroke during the perioperative time frame. The encephalopathy resolved prior to discharge in the first patient and the remaining patient with an ischemic stroke died 24 hours after the repair from splenic hemorrhage. To date, there have been no conversions to open repair. The primary safety end point was therefore achieved in 92.2% of cases.

Effectiveness evaluation. No MDEs were reported for the entire cohort. Two endoleaks were reported. The first involved a site-reported type II endoleak on postoperative day 14, required no treatment, and was resolved

Table V. Pretreatment risk summary

	CTAG cohort
Number of enrolled subjects	51
ASA classification, No. (%)	
I	5 (9.8)
II	5 (9.8)
III	10 (19.6)
IV	31 (60.8)
V	0 (0.0)
ISS	
No.	51
Mean (SD)	31.8 (14.2)
Median	29.0
Range	9.0-66.0
ISS polytrauma, No. (%)	
Polytrauma (ISS >17)	43 (84.3)
No polytrauma (ISS ≤7)	8 (15.7)
Glasgow Coma Scale, No. (%)	
Minor ≥13	41 (80.4)
Moderate 9-12	5 (9.8)
Severe ≤8	4 (7.8)
Missing	1 (2.0)

ASA, American Society of Anesthesiologists; *CTAG,* conformable GORE TAG thoracic endoprosthesis; *ISS,* Injury Severity Score; *SD,* standard deviation.

at subsequent follow-up imaging. The other encompassed an investigator-reported type III endoleak (fabric defect), which was reported to have continued through discharge despite a secondary device being deployed at the time of treatment. As a result of the rarity of the event, a CEC review was undertaken that reached the consensus that it was an indeterminate endoleak, which was resolved at the completion of the procedure. Neither the CEC nor the core lab detected an endoleak at discharge or 1-month follow-up imaging. Lesion diameter characteristics have demonstrated no increase in diameter >5 mm during follow-up based on orthogonal imaging. There have been no identified wire frame fractures, compression, obstruction, or thrombus-related events. There was one core lab-reported migration of ≥10 mm at 6 months without clinical sequelae or impact on lesion exclusion. Subsequent imaging demonstrated no migration (<10 mm) at 12 months compared with baseline and may be related to respiratory or imaging variation. The primary effectiveness end point was achieved in 100% of cases.

DISCUSSION

"Off-label" use of endovascular devices has been occurring for many years and is in excess of 40%.[5] Analysis of outcomes in this patient population has met with mixed results with poorer outcomes occurring when devices are implanted in patients with pathologies other than aneurysmal disease.[6] BAIs are no exception with endovascular treatment gaining widespread acceptance despite the lack of FDA approval and the rigors of a clinical trial. Significant limitations have been reported, however, with the first-generation TEVAR devices when used in treating patients with BAI.[1,7] The most recognized of these limitations is device collapse.[8] Despite the widespread preference over conventional repair, the potential benefits of TEVAR over open repair remain controversial.[9,10] As with many other minimally invasive techniques, endovascular management of thoracic transections has the potential to reduce

Table VI. Concomitant injuries reported in >5% of study subjects

	CTAG cohort, No. (%)
Number of enrolled subjects	51
Any concomitant injury	50 (98.0)
Thoracic cage fractures and dislocations	41 (80.4)
Pneumothorax and pleural effusions NEC	33 (64.7)
Skin injuries NEC	30 (58.8)
Abdominal injuries NEC	24 (47.1)
Spinal fractures and dislocations	23 (45.1)
Upper limb fractures and dislocations	22 (43.1)
Chest and lung injuries NEC	20 (39.2)
Lower limb fractures and dislocations	16 (31.4)
Pelvic fractures and dislocations	16 (31.4)
Parenchymal lung disorders NEC	11 (21.6)
Skull fractures, facial bone fractures and dislocations	11 (21.6)
Non-site-specific injuries NEC	8 (15.7)
Hemorrhages NEC	7 (13.7)
Mediastinal disorders	7 (13.7)
Site-specific injuries NEC	7 (13.7)
Anemias NEC	6 (11.8)
Limb injuries NEC (including traumatic amputation)	6 (11.8)
Central nervous system hemorrhages and cerebrovascular accidents	5 (9.8)
Renal and urinary tract injuries NEC	5 (9.8)
Renal structural abnormalities and trauma	5 (9.8)
Urinary abnormalities	5 (9.8)
Vascular hypotensive disorders	5 (9.8)
Adrenal gland disorders NEC	4 (7.8)
Cerebral injuries NEC	4 (7.8)
Paralysis and paresis (excluding cranial nerve)	4 (7.8)
Peritoneal and retroperitoneal hemorrhages	4 (7.8)
Renal vascular and ischemic conditions	4 (7.8)
Respiratory failures (excluding neonatal)	4 (7.8)
Skin and subcutaneous conditions NEC	4 (7.8)
Vascular hypertensive disorders NEC	4 (7.8)
Cardiovascular injuries	3 (5.9)
Pain and discomfort NEC	3 (5.9)
Rate and rhythm disorders NEC	3 (5.9)
Renal failure and impairment	3 (5.9)
Spinal cord and nerve root disorders NEC	3 (5.9)

CTAG, Conformable GORE TAG thoracic endoprosthesis; *NEC,* not elsewhere classified.

Table VII. Zone of device implantation

Zone	*No. (%)*
0	Excluded
1	Excluded
2	32 (63)
3	18 (35)
4	1 (2)

Table VIII. Implanted device sizes

Device size	*No. (%)*
21	5 (8.8)
26 × 21	11 (19.3)
26	12 (21.1)
28	10 (17.5)
31 × 26	8 (14.0)
31	5 (8.8)
34	4 (7.0)
37	2 (3.5)
40	0 (0.0)
45	0 (0.0)

major complications and morbidity associated with this severe injury. Although many overwhelming positive early reports exist, complications have occurred raising the need for evaluation of device performance in this disease-specific condition.

As previously reported, the mean age of patients suffering BAI is considerably younger than that being treated by TEVAR for aneurysmal disease. The mean age of our cohort was 44.1 years. This is similar to other published series on the subject.[10] The mortality rate observed in this cohort, however, was less than expected based on their ISS score of 33. This may be related to the young age of this cohort or other aspects of their injuries not investigated during this study. Correspondingly, the aortic diameter in these patients is also smaller but appears larger than that previously reported.[11] Device size selection was based on the CT intimal diameter as dictated by the instructions for use, however, no guidelines were given with respect to determining the impact of hypotension on this measurement. Additional modalities such as intravascular ultrasound were used at the discretion of the implanting physician to aid in procedural planning.

The original TAG device was designed with an oversizing window of 6%-22%. The treating physician needed to account for the degree of hypotension-induced aortic contraction, orthogonal centerline adjustments, and aortic curvature so that the appropriately sized device could be implanted. Small errors in these calculations led to potential procedural- and device-related complications that exposed the patients to the life-threatening situation of device compression.[3] Secondary procedures were then required to remedy the situation.[12] In contrast, the redesigned device has generous oversizing windows (6%-33%), which allow the treating physician to choose among several devices for implantation. Device selection under this design approach provides a wider margin of variance, thereby reducing the risks of sizing/implantation complications by the physician. Analysis of CT scan diameter measurements in this cohort revealed that 73% of the patients did not meet sizing criteria for the original TAG device. Fifty-nine percent of patients needed a smaller device (less than 23 mm), and an additional 14% of subjects enrolled were too tapered for the TAG device sizing guidelines. It should be noted that tapered device configurations accounted for the majority of the increase in patient applicability and seem most useful in patients with BAI. Additionally, no adjustments were made when calculating the aortic diameters to compensate for hypotension-induced aortic contraction. The impact of the CTAG device oversizing window cannot be emphasized enough, as it significantly increases the applicability of the device to the patient population impacted most by blunt aortic trauma.

The median delay prior to treatment was 21 hours. This is similar to the report in 1997 of 16 hours (injury

Table IX. Summary of serious adverse events through 30 days

	CTAG cohort, No. (%)
Number of enrolled subjects	51
Any serious event	20 (39.2)
Pleural effusion	3 (5.9)
Respiratory failure	3 (5.9)
Anuria	2 (3.9)
Hypotension	2 (3.9)
Hypoxia	2 (3.9)
Ileus	2 (3.9)
Pneumonia	2 (3.9)
Pyrexia	2 (3.9)
Abnormal weight gain	1 (2.0)
Acute respiratory distress syndrome	1 (2.0)
Acute respiratory failure	1 (2.0)
Anemia	1 (2.0)
Angina pectoris	1 (2.0)
Atrial fibrillation	1 (2.0)
Blood culture positive	1 (2.0)
Cardio-respiratory arrest	1 (2.0)
Cerebral hypoperfusion	1 (2.0)
Dyspnea	1 (2.0)
Enterococcal infection	1 (2.0)
Fat embolism	1 (2.0)
Hematemesis	1 (2.0)
Hematocrit decreased	1 (2.0)
Hemodynamic instability	1 (2.0)
Heart rate increased	1 (2.0)
Hypertension	1 (2.0)
Hypoxic-ischemic encephalopathy	1 (2.0)
Ischemic stroke	1 (2.0)
Joint contracture	1 (2.0)
Leukocytosis	1 (2.0)
Noncardiac chest pain	1 (2.0)
Pneumothorax	1 (2.0)
Postoperative wound infection	1 (2.0)
Renal failure	1 (2.0)
Respiratory tract infection	1 (2.0)
Septic shock	1 (2.0)
Shock	1 (2.0)
Skin infection	1 (2.0)
Splenic hemorrhage	1 (2.0)
Splenic injury	1 (2.0)
Supraventricular tachycardia	1 (2.0)
Tachycardia	1 (2.0)
Traumatic brain injury	1 (2.0)
Traumatic liver injury	1 (2.0)
Wound infection, staphylococcal	1 (2.0)

CTAG, Conformable GORE TAG thoracic endoprosthesis.

to thoracotomy) by the original American Association for the Surgery of Trauma publication[13] and significantly less than 55 hours reported in the subsequent American Association for the Surgery of Trauma study in 2008.[1] Whether this is related to changes in practice patterns, device availability, or a trend away from delayed repair with endovascular techniques is difficult to determine.

Exclusion criteria was not based on the radius of curvature in this study. As such, device conformability was not calculated. While it is extremely difficult to quantify the degree of conformability of a device to the inferior aspect of the aortic arch, it has been the general perception by the implanting physicians that this device conforms better than the previous iteration. Prior publications have emphasized the impact of "bird-beaking" on device outcomes.[14] There was a decreased number of type I endoleaks reported in the TAG 08-03 aneurysm study. Type Ia endoleaks (major and minor) were present in 6.5% of TAG 08-03 patients through 30 days compared with 9.4%, 8.0%, and 12.9% of patients in the original TAG trials (TAG 99-01, TAG 03-03, and TAG 04-02, respectively). Multifactorial issues including patient selection, physician experience, and improved preoperative imaging are also likely causative factors for this observation, however, enhanced device conformability cannot be ignored and was specifically targeted as a new design feature with the device.

Specific design features were engineered into the CTAG device by altering the fabric and wire components and were confirmed through computational analysis. The original TAG device was prone to device compression when excessive oversizing or poor conformability existed.[3,8] Compression complications with the original TAG device occurred more commonly with treatments involving blunt aortic injuries with an overall incidence of 0.4% and occurring at a median and mean follow-up of 9.5 and 76 days, respectively (range, 0-2190).[3] To date, no device compressions have been reported in either of the two trials, and no compression events have been reported to the company in over 10,000 implants worldwide suggesting that the new engineering design has mitigated this problem significantly if not completely.

Revascularization of the left subclavian artery during TEVAR has been debated ever since its introduction. Recent recommendations from the SVS,[15] state "*…revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C)*." Of note, only 9% of patients who required LSCA coverage underwent planned revascularization, despite 63% having either partial or complete coverage of their LSCA. No data were available concerning vertebral imaging in this group of patients. No patient experienced paraplegia, and the only patient who developed arm symptoms had a partially covered left subclavian artery and presented for treatment approximately 4 months after their procedure. The symptoms resolved after placement of a left subclavian stent. No other delayed revascularizations were performed. Subclavian revascularization is more difficult to perform in the trauma population because, in most instances, the cervical spine has not been cleared prior to the need for repair of the aortic injury. Given the short coverage length needed for exclusion (generally 10 cm), there appears to be little risk of inducing paraplegia. To date, there have been only two reported cases of paraplegia associated with TEVAR for BAI in the literature.[16] Although the potential risk of a spinal cord ischemic complication appears extremely low, other potential complications remain a concern.

It should be noted that not all devices in the TAG 08-02 study were implanted completely distal to the left common carotid artery. Despite this, no strokes have occurred beyond the 30-day follow-up period. The proximal configuration of the devices does possess partially uncovered stents that allow perfusion, however, the constraining sleeve extends into this region and can obstruct flow. It should be noted that there have been no aortic complications in this trial, such as retrograde dissection, from the partially uncovered stent of the device on the proximal end. Two cerebral events were documented during the trial that warrant special mention. An ischemic stroke was suspected in an elderly patient; however, the evaluation was limited because the patient expired from splenic hemorrhage on the first postoperative day. The second patient was diagnosed with hypoxic-ischemic encephalopathy, which fully resolved after 37 days. The CEC determined that neither of these events was related to the device.

Finally, there are several criticisms of the study that should be noted. Although the specific grading classification from Azizzadeh[17] was not used, a categorization was used to denote intimal and nonintimal injuries. The vast majority of patients were not treated for intimal injuries. Determination as to whether the patient required treatment was left to the discretion of the treating physician. The trial was conducted specifically in this fashion to avoid controversies in this respect since there is no current standard of practice. Although it is generally accepted that grade I injuries can be observed safely, no requirement was dictated in the trial. There was, however, a restriction in the ISS, with respect to enrollment in the trial. Those patients with an ISS of 75 were excluded. An ISS score of 75 was assigned to any patient with at least one body region that had an unsurvivable injury or if at least three body regions had critical injuries. Subjects with an ISS of 75 were excluded from TAG 08-02 to allow for the enrollment of subjects who were likely to survive the endovascular procedure and provide follow-up. Lastly, the timing of repair was determined by the treating facility. The mean length of time from injury to treatment was 21 hours (range, 3-334). There was a fairly wide range, which is most likely related to concomitant patient injuries; however, the reasons for not undergoing immediate repairs were not tabulated.

CONCLUSIONS

The conformable GORE TAG device was specifically designed for the treatment of blunt aortic injuries.

Available device sizes and configurations allow for significantly more patients to be treated within the sizing guidelines. There have been no reports of device collapse in clinical studies or commercial use of the device. The CTAG device appears to be a safe and effective treatment modality for traumatic aortic transection based on 30-day outcomes with no device-related serious adverse events. As a result of these data, in conjunction with prior supporting studies, the FDA has approved this device for the treatment of isolated lesions of the descending thoracic aorta.

AUTHOR CONTRIBUTIONS

Conception and design: MF
Analysis and interpretation: MF, JG, BS, SS, JH, RC, JM
Data collection: MF, JG, BS, SS, JH, RC, JM
Writing the article: MF
Critical revision of the article: MF, JG, BS, SS, JH, RC, JM
Final approval of the article: MF
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Overall responsibility: MF

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