

Endovascular and Hybrid Management of the Thoracic Aorta

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A Case-based Approach

by

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 **WILEY-BLACKWELL**

A John Wiley & Sons, Ltd., Publication

This edition first published 2008, © 2008 by Blackwell Publishing Ltd

Blackwell Publishing was acquired by John Wiley & Sons in February 2007. Blackwell's publishing program has been merged with Wiley's global Scientific, Technical and Medical business to form Wiley-Blackwell.

Registered office: John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK

Editorial offices: 9600 Garsington Road, Oxford, OX4 2DQ, UK
The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK
111 River Street, Hoboken, NJ 07030-5774, USA

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Library of Congress Cataloguing-in-Publication Data

Endovascular and hybrid management of the thoracic aorta / by Edward B. Diethrich . . . [et al].
p. ; cm.

Includes bibliographical references and index.

ISBN 978-1-4051-7535-7 (alk. paper)

1. Aorta—Surgery. 2. Thoracic arteries—Surgery. 3. Endarterectomy. I. Diethrich, Edward B., 1935—

[DNLM: 1. Aorta, Thoracic—surgery—Case Reports. 2. Aortic Diseases—surgery—Case Reports.

3. Vascular Surgical Procedures—methods—Case Reports. WG 410 E557 2008]

RD598.65.E53 2008

617.4'13—dc22

2008010765

ISBN: 9781405175357

A catalogue record for this book is available from the British Library.

Set in 9.5/12pt Minion by Aptara Inc., New Delhi, India

Printed in Singapore by COS Printers Pte Ltd

1 2008



Contents

Preface, viii

Foreword (Patrick M. McCarthy), ix

Foreword (Rodney A. White), x

Acknowledgments, xi

Introduction: Current status of thoracic endografting, 1

Section I Thoracic aortic aneurysms, 9

CASE 1 Endovascular repair of descending thoracic aortic aneurysms using the Gore TAG stent graft, 11

CASE 2 Endovascular management of thoracic aortic aneurysm using a Cook Zenith TX2 endograft, 18

CASE 3 Endovascular management of a thoracic aortic aneurysm using a Medtronic Talent thoracic graft (VALOR trial), 24

CASE 4 Endovascular management of thoracic aortic aneurysms with coverage of the left subclavian artery, 30

CASE 5 Endovascular management of a thoracic aortic aneurysm with tortuous aorta and calcified iliac arteries using the brachiofemoral wire approach, 38

CASE 6 Endovascular management of a thoracic aortic aneurysm with small tortuous calcified iliac vessels (retroperitoneal conduit), 45

CASE 7 Endovascular management of a ruptured thoracic aortic aneurysm, 50

CASE 8 Total percutaneous endovascular management of a thoracic aneurysm

with severe iliofemoral occlusive disease: use of an endoconduit in a high-risk patient, 54

CASE 9 Complete endovascular management of a patient with multilevel aortic disease, 59

CASE 10 Endovascular repair of a descending thoracic aneurysm with previous open resection of abdominal aortic aneurysm, 65

Section II Penetrating aortic ulcers, 71

CASE 11 Endovascular management of penetrating aortic ulcer, 73

CASE 12 Endovascular management of a penetrating aortic ulcer with rupture, 77

Section III Traumatic aortic injuries, 85

CASE 13 Endovascular management of thoracic aortic disruption, 87

CASE 14 Endovascular management of a traumatic pseudoaneurysm postcoarctation repair, 92

CASE 15 Endovascular management of a traumatic pseudoaneurysm of the thoracic aorta, 96

Section IV Thoracic aortic dissections, 103

CASE 16 Endovascular management of acute Stanford type B dissection, 105

CASE 17 Endoluminal graft repair of chronic type B dissections, 114

CASE 18 Endovascular management of the aneurysmal false lumen distal to an interposition graft placed for ruptured Stanford type B dissection, 120

CASE 19 Hybrid management of type A dissection with malperfusion of the lower extremities, 126

CASE 20 Endovascular management of a type B dissection complicated by renovascular hypertension, 134

CASE 21 Endovascular management of a chronic type B dissection complicated with a new dissection and left renal artery compromise, 137

CASE 22 Hybrid management of a retrograde type B dissection after endoluminal stent grafting, 145

Section V Thoracic aortic pseudoaneurysms, 153

CASE 23 Endovascular management of thoracic aortic pseudoaneurysms, 155

CASE 24 Endovascular management of thoracic mycotic aneurysms, 159

Section VI Extending proximal landing zones, 169

CASE 25 Hybrid management of an arch aneurysm with a carotid–carotid bypass and deployment of an endoluminal graft, 171

CASE 26 Endovascular management of transverse arch aneurysms, 176

CASE 27 Hybrid endovascular management of an arch pseudoaneurysm using an antegrade deployment approach, 182

CASE 28 Hybrid management of a retrograde type B dissection, 187

CASE 29 Hybrid management of a chronic type B dissecting aneurysm with ascending aortic aneurysm, 193

Section VII Extending distal landing zones, 199

CASE 30 Hybrid repair of Extent II thoracoabdominal aneurysms, 201

CASE 31 Hybrid repair of an extent V thoracoabdominal aneurysm, 208

CASE 32 Hybrid (combined open and endovascular) repair of thoracoabdominal aneurysms, 215

Section VIII Thoracic aortic coarctations, 225

CASE 33 Endovascular management of adult primary coarctation of the aorta, 227

CASE 34 Endovascular management of the small thoracic aorta with postcoarctation pseudoaneurysm, 234

CASE 35 Recurrent coarctation of the thoracic aorta, 239

Section IX Thoracic aortobronchial fistula, 245

CASE 36 Endovascular management of aortobronchial fistulas, 247

Section X Complications of thoracic aortic endografting, 253

CASE 37 Endovascular management of a type I endoleak, 255

CASE 38 Endovascular management of a type II endoleak, 260

CASE 39 Retrograde dissection following endovascular management of thoracic aortic aneurysm, 264

Section XI Ascending aortic pathologies, 269

CASE 40 Endovascular management of an ascending aortic pseudoaneurysm, 271

- CASE 41 Endovascular management of aneurysm of a right coronary vein graft using an ascending aorta endoluminal graft, 277

Section XII Supra-aortic thoracic aortic aneurysms, 283

- CASE 42 Hybrid approach to the management of a type C innominate artery aneurysm, 285

Section XIII Future of thoracic aortic endografting, 291

- CASE 43 Remote wireless pressure sensing for postoperative surveillance of thoracic endoluminal grafts, 293
- CASE 44 Zenith® Dissection™ Case Study, 297
- The Road Ahead... , 300
- Index, 303



Preface

When the Arizona Heart Institute's endovascular program was initiated well over two decades ago, no one could have envisioned its current acceptance by all disciplines given its checkered beginning, with skepticism and resistance to move from traditional therapies. Today, radiologists, vascular surgeons, vascular medicine specialists, cardiologists, and more recently cardiovascular surgeons have all recognized the enormous benefits of the endovascular approach to cardiovascular disease. Interventional technology has been proven to shorten hospitalization, reduce morbidity and mortality, speed recovery, and hasten return to normal life. Clinical investigations have shown these procedures to be favorable over open surgical techniques in most situations.

Despite these findings and the worldwide movement toward less invasive techniques, our training and educational programs have lagged behind the technology explosion. The core curricula in our current training residencies and fellowships in the majority of cases were not designed to easily accommodate the rapid evolution in endovascular technology. Hence, the need to revamp and expand our educational process to assure that current and future endovascular interventionalists will have adequate fundamental knowledge and skill sets.

Didactic lectures, simulations, hands-on training, and observation of the experts are all essential in this training paradigm. Importantly, learning by case example has been a hallmark in cardiovascular surgery training for decades. To assure an optimum result, the pathophysiology and anatomy of the disease process must be appreciated. Modern diagnostic tools, particularly new imaging modalities, must be understood and applied appropriately. Interventionalists today must have not only an acquaintance with the growing variety of endovascular techniques, but also a working knowledge of

their efficacy. In an effort to address these needs, we have called upon our vast endovascular experience to assemble this textbook of thoracic endovascular interventions. It is important to note that most cases in this textbook were performed under an investigational protocol with Institutional Board Review oversight. We earnestly believe that informed patients who adhere to a follow-up protocol will generate the much-needed data that can help us address the pressing questions in this blossoming field.

We recognize that certain limitations exist currently regarding thoracic endografting techniques and their application to thoracic aortic pathologies. There is every indication, however, that most thoracic aortic pathologies will be treated with these less invasive procedures in the future, and so this textbook should prove useful as this segment of the field expands. Our particular institution has been fortunate enough to be at the forefront of this technological revolution.

With this in mind, the textbook has been organized to begin with the currently accepted procedures and progress to those techniques for which proof of principle exists. It then proceeds to evolving areas of treatment in which further understanding and investigation are needed. The final chapters address the challenges of the ascending aortic arch, with recommendations for future endovascular technology. There is no substitute for learning from experience. It is our hope that endovascular management of the thoracic aorta with its case study approach will provide a useful tool for practitioners as they plan and execute treatment of patients with these thoracic aortic pathologies.

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Foreword

How do you teach new procedures involving brand-new, still evolving technologies to a diverse group of physicians? Dr Ted Diethrich and colleagues from the Arizona Heart Institute have successfully addressed this daunting problem in their comprehensive new textbook. Endovascular and hybrid management of thoracic aortic diseases have been rapidly advancing and these practitioners are clearly at the leading edge of this revolution. The authors use an interesting “case based” approach of approximately 50 cases that are very well illustrated with appropriate references. They range from relatively common problems, such as thoracic aortic aneurysms and chronic Type B aortic dissections, to more rare and challenging problems such as ascending aortic pseudoaneurysms. The authors make use of their outstanding background and clinical experience with the surgical treatment of aortic pathology add in new advanced imaging techniques such as 64-slice CT imaging and intravascular ultrasound, and show how endovascular and hybrid approaches can be applied to a variety of pathological conditions. The text itself is very well written and

well illustrated and for those learning about this new field or those already with some experience, this is an important reference.

The publication is timely because of the rapid advancement and expansion of these approaches outside of traditional academic medical centers to a variety of clinical practices. The text should be of great interest to cardiovascular surgeons, cardiologists, vascular medicine specialists, and interventional radiologists. Dr Diethrich and his colleagues have done a tremendous service dedicating the time and effort into amassing this clinical experience and disseminating it through the medical community at this early phase using this new technology.

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Foreword

The authors have presented a comprehensive, state-of-the-art review of the current status of thoracic aortic endografting. The format of the book is based on case reviews including indications for the procedure, concise discussions of therapeutical alternatives, and methods used during the procedure. The book covers the entire spectrum of thoracic pathologies and therapeutic options from fully endovascular repairs to the hybrid inventions combining endovascular approaches and conventional vascular surgical techniques. The text has excellent illustrations demonstrating not only the pathology being addressed, but appropriately selected procedural and post-intervention studies that illustrate not only the techniques and outcomes but also appropriate imaging modalities and imaging quality that is required for optimal outcomes.

The text contains approximately 50 case discussions. The text begins with a review of the approved Gore TAG device and the Food and Drug Administration–approved indications. This device is used in the majority of patients treated in the case studies. Other devices are described as they were used as part of ongoing clinical trials that were not completed at the time of the publication. The Gore TAG chapter outlines the approved indications and follow-up data regarding the outcomes that are available. The subsequent chapters each deal with a major thoracic pathology or with techniques that can be used to extend the utility of thoracic endoluminal devices, such as extending the proximal and distal landing zones and describing utility

of hybrid techniques. There is also sections dealing with complications and addressing associated additional pathologies including ascending aortic and transverse thoracic arch pathologies. The text fully addresses all the approved current indications, developing therapies, and future indications for application of thoracic endografts.

The text is written with a style and excellence that characterizes the Arizona Heart Institute. It contains well-illustrated cases and discussions as well as easily assimilated and exceptionally well-illustrated teaching modules. The comprehensive nature of the pathologies and endovascular techniques displayed can only be exhibited in this manner by the team at Arizona Heart Institute lead by Dr Ted Diethrich.

The development of thoracic endograft technologies promises to be a major advance in medical therapy significantly reducing patient morbidity and mortality in the critical spectrum of pathologies, including aneurysm, dissections, and traumatic lesions. The publication is an exceptionally well-written and timely endeavor and provides an easily assimilated, comprehensive view of the subject for all who are interested in this rapidly developing field.

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Acknowledgments

The authors would like to recognize the following people whose contributions to this project made this book possible: Dr John A. Sutherland, Director of Imaging Services, Arizona Heart Institute; and James P. Williams, Research Coordinator, Arizona Heart Institute.

INTRODUCTION

Current status of thoracic endografting

Gore TAG thoracic endoprosthesis

The Gore Excluder thoracic endoprosthesis (W.L. Gore & Associates, Flagstaff, AZ) was the first thoracic endograft to enter clinical trials in the United States in 1998 with a feasibility trial. This was followed by the pivotal study in 1999. The Gore TAG excluder device gained Food and Drug Administration (FDA) approval in March 2005 for the commercial use for the treatment of thoracic aortic aneurysms (Figure 1).

Device design

The TAG endoprosthesis is a symmetrical expanded polytetrafluoroethylene (ePTFE) tube reinforced with ePTFE/FEP (fluorinated ethylene propylene) film and an external nickel–titanium (nitinol) self-expanding stent along the entire surface of the graft (Figure 2). The stent is attached to the graft with ePTFE/FEP bonding tape. A circumferential PTFE sealing cuff is located on the external surface of the endograft at the base of each flared, scalloped end. Flares are designed to help with conforming to tortuous anatomy. Each cuff is circumferentially attached on one edge with FEP, thus allowing the other end to remain free to enhance sealing of the endoprosthesis to the aortic wall and help eliminate endoleaks.

The original TAG device graft material was constructed from two ePTFE layers with two longitudinal wires for support during deployment. The modified TAG device is constructed from three ePTFE layers. The additional layer, similar to that incorporated into the excluder bifurcated endoprosthesis, is sandwiched between the two original layers and provides support that was formerly provided

by the deployment wires. At the base of the flares are two radiopaque gold bands, which serve as a guide during implantation and in follow-up. The devices are available in 26–40 mm diameters that accommodate aortic diameters between 23 and 37 mm and require 20-F (20-French) through 24-F introducer sheaths, depending on the device size. Recently a 45-mm-diameter device has been introduced under investigational device protocol.

Deployment of the TAG device is unique. A sleeve made of ePTFE/FEP film is used to constrain the endograft. A deployment knob is located at the control end of the delivery catheter and has a deployment line that runs the entire length of the catheter connecting it to the sleeve. Turning and pulling the deployment knob removes the deployment line from the endograft, thereby deploying it. The device is deployed rapidly from the middle of the endograft toward both ends of the prosthesis. The device is then secured in position with a specially designed trilobed balloon, which allows continuous blood flow during inflation.

Feasibility study

The first trial to be conducted in the United States was the feasibility study to establish preliminary device safety data. This study was performed at two sites in the United States and enrolled a total of 28 patients between 1998 and 1999. The 30-day mortality rate was 3.6% ($n = 1$). At 1 year, the mortality rate was 21% without any paraplegia or stroke. Renal failure and myocardial infarction were noted in 1 patient each (3.6%). Through a 5-year follow-up period, two additional adverse events were reported between 2 and 5 years. All-cause mortality at 5 years was 25%. Endoleaks were noted at

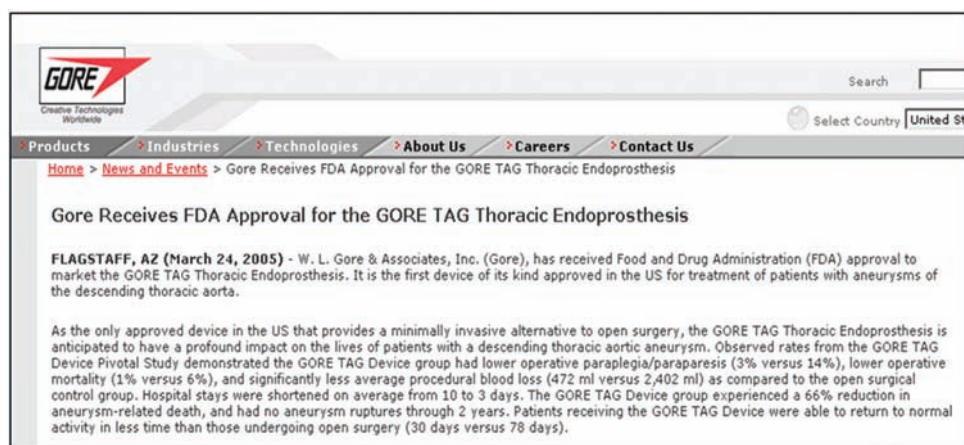


Figure 1 Federal drug administration approves use of thoracic endoluminal graft for treatment of thoracic aneurysms.

any time in 21% of the patients, and aneurysm sac growth was noted in 18%. Stent fractures were noted in 32%. There was one conversion and there were two reinterventions over time to place additional devices. No aneurysm ruptures, device migration, extrusion, erosion, lumen obstruction, or branch vessel occlusions were reported.

Once device safety was demonstrated with the feasibility study, the pivotal phase II trial was undertaken.

Pivotal (phase II) trial

Objectives and hypotheses

The objectives were to determine the safety and efficacy of the TAG endoprosthesis for the treatment of descending thoracic aneurysm as compared with open surgical repair controls. The primary safety hypothesis was that the percentage of subjects with one or more major adverse events (MAEs) through 1 year after treatment would be lower in the TAG group as compared with the surgical control group. The primary efficacy hypothesis was that freedom from any major device-related events through 1 year

of follow-up for the TAG device group would be better than 80%. A predefined point estimate of 80% for the endovascular group was considered to be a reasonable efficacy outcome, because the device was expected to show a considerable improvement in safety profile. The efficacy for the surgical procedure was assumed to be 100%. The secondary hypotheses were that the procedural blood loss, intensive care unit (ICU) and hospital stay, and convalescence to normal activities would be lower in the TAG device group as compared with the surgical control group. The primary efficacy end point of this pivotal study was the percentage of subjects who were free from major device-related events through 1 year of follow-up for the TAG device group.

Study design

This study was a prospective, nonrandomized, controlled multicenter trial. The study enrolled 140 study patients and 94 control subjects between September 1999 and May 2001 through 17 clinical sites in the United States. The control group consisted of 44 patients acquired prospectively during the study and 50 historical patients acquired by

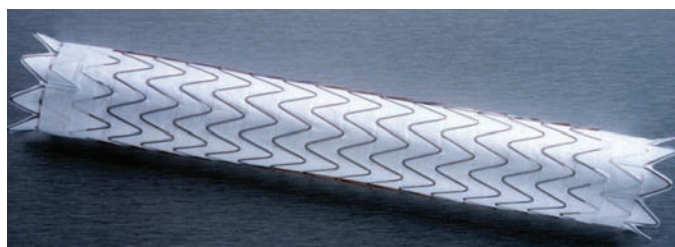


Figure 2 Gore TAG thoracic endoprosthesis.

Table 1 Inclusion criteria.

<i>Criterion</i>	<i>Gore TAG</i>
Age (yr)	>21
Women	Must be infertile
Open surgical candidate	Yes
Neck length	Minimal 2 cm proximal and distal
Aneurysm	Fusiform descending thoracic aorta at least twice the size of normal thoracic aorta; saccular
Penetrating ulcer	No
Proximal landing zone location	20 mm distal to left common carotid artery
Distal landing zone location	20 mm proximal to celiac axis
Landing zone diameter (mm)	23–37

selecting the most recent surgical patients in reverse chronological order. Inclusion and exclusion criteria are detailed in Tables 1 and 2.

Follow-up

All patients are to be followed for 5 years. Computed tomography (CT) scans, plain radiographs, and

physical examinations were obtained at 1-month, 6-month, and 12-month intervals and yearly thereafter. A 3-month visit with a CT scan was conducted for patients with early endoleaks. A core laboratory reviewed all imaging studies. Clinical data were reported by individual centers and monitored by sponsor representatives. Major adverse effects were adjudicated by the Clinical Events Committee and defined as clinical events that required therapy or that resulted in an unintended increase in the level of care, prolonged hospitalization, permanent adversity, or death [5]. Minor adverse events were those that did not require any therapy or those with no consequences.

Results of the pivotal study

Clinical materials

The TAG group and the surgical group were very similar in all major demographic and clinical variables (Table 3). The average age of the patients was 71 years in the TAG group and 68 years in the control group. Men accounted for 58% of the patients in the TAG group and 51% in the control group.

Baseline aortic morphology was also well matched between the groups, except for the smaller diameter of the proximal and distal necks in the TAG device group, which was expected because of the requirements for sealing. Baseline comorbidities were also quite similar between the TAG device group and the control group (Table 4). Although coronary artery disease seemed to be more prevalent among the TAG group, this difference was not significant. Symptomatic aneurysms, however, were significantly more prevalent in the control group than in the TAG group. The risk classifications performed on the basis of the standard American

Table 2 Exclusion criteria.

<i>Criterion</i>	<i>Gore TAG</i>
Creatinine (mg/dL)	>2.0
Unstable rupture	Yes
Mycotic aneurysm	Yes
Connective tissue disease	Yes
Significant landing zone thrombus	Yes
Previous descending aortic surgery or endovascular repair of descending thoracic aneurysm or abdominal aortic aneurysm	N/A
Aortic dissection	Yes
Coagulopathy	Yes
Myocardial infarction/cerebrovascular accident	<6 wk
Major operation within 30 days	Yes
Participation in another investigational study	<1 yr

N/A, not applicable.

Table 3 Patient demographics.

<i>Variable</i>	<i>TAG group</i>	<i>Surgical control</i>
Male (%)	57	51
Age (yr)	71	68
Ethnicity (%)		
White	87	86
Black	8	10
Other	5	4
Height (cm)	170	170
Weight (kg)	76	78

Table 4 Comparison of early complications between TAG and open surgical controls in the Gore pivotal study.

<i>Variable</i>	<i>TAG device (%)</i>	<i>Surgical control (%)</i>	<i>p value</i>
Coronary artery disease	49	36	.06
Cardiac arrhythmia	24	31	.23
Stroke	10	10	>.95
PVOD	16	11	.33
Prior vascular intervention	45	55	.14
Symptomatic aneurysm	21	38	<.01
Other concomitant aneurysms	28	28	>.95
COPD	40	38	.89
Smoking	84	82	.86
Renal dialysis	1	0	.52
Hepatic dysfunction	2	1	.65
Paraplegia	1	0	>.95
Cancer	19	13	.21

PVOD, peripheral vascular occlusive disease; COPD, chronic obstructive pulmonary disease.

Society of Anesthesiologists classification and the Society of Vascular Surgery risk score showed no significant difference in either classification.

Operative data

Of 142 patients recruited (140 in the pivotal trial and 2 extended access), 139 (98%) underwent successful implantation of the TAG device. The three failures were all due to poor iliac access. A conduit was placed to facilitate access in 21 patients (15%). More than one device was used in 77 patients (55%): 61 patients (44%) received two devices, 11 patients (8%) received three devices, and 5 patients (4%) received four devices.

Prophylactic left carotid/subclavian bypass grafting was performed in 28 patients in preparation for planned left subclavian artery coverage with the device. Unplanned subclavian artery and visceral artery coverage occurred in one patient each. The latter underwent an open abdominal explantation of the device and redeployment of a new device without sequelae.

Early adverse events

Mortality

Operative mortality, defined as death within 30 days of the procedure or on the same hospital admission, occurred in 3 patients (2.1%) after TAG implantation (Table 5). One death was due to a postoperative

stroke and another to a cardiac event that occurred on postoperative day 11. The third death occurred after 7 months of a protracted hospital course as a result of anoxic brain injury after a respiratory arrest. The patient died of septic complications from an aortoesophageal fistula. Six deaths (6.4%) occurred in the surgical control group.

Spinal cord ischemia

Spinal drainage was not routinely used in either group. In the TAG group, spinal cord ischemia (SCI) was noted in 4 patients. One was noted immediately after the procedure, and the deficit persisted despite all supportive measures. Three were delayed in onset, and all these regained motor function (one complete and two partial) and were ambulatory at last follow-up. It should be noted that multiple pieces of TAG endografts were used in 3 of 4 patients and that 2 of 4 patients had had previous infrarenal aortic aneurysm repair. The incidence of SCI did not differ between those with and without

Table 5 Operative complications.

<i>Variable</i>	<i>TAG</i>	<i>Open surgical</i>
Death	2.1%	11.7%
Paraplegia/paraparesis	3	14
Stroke	4	4

prior abdominal aortic aneurysm repair (4.7% vs 2%, respectively). The incidence of SCI in the control group was significantly higher (13.8%). Of 13 patients, 8 had paraplegia, of whom 6 died. One case of paraplegia resolved completely.

Cerebrovascular accidents

Perioperative stroke was noted in 5 patients (3.5%). One was fatal. Three were right-sided. Four of the five strokes occurred in patients who had proximal aneurysms requiring extension of the TAG to the left carotid and coverage of the subclavian artery; all four underwent carotid/subclavian bypass. Of the 28 patients with proximal aneurysms who had planned subclavian artery coverage, 4 (14%) had a stroke, compared with 1 (1%) of 114 with disease distal to the subclavian artery ($p < .001$). The overall incidence of cerebrovascular accident (4.3%) was similar in the two groups.

Endoleaks

Early endoleaks were seen in 5 patients. One patient had a proximal type I endoleak and was treated with endovascular revision and additional grafts. The remaining endoleaks were thought to be type II.

Other MAEs

The other most common MAEs were bleeding, cardiopulmonary events, and intraoperative vascular injury. Both bleeding and pulmonary events were significantly reduced in the TAG group compared with the surgical control group, due to a high percentage of procedural bleeding and respiratory failure in the latter.

The incidence of vascular injuries was 14% in the TAG group, which was significantly higher than in the control group (4%). This was related to the introduction of large introducer sheaths through the iliac system.

Hospital length of stay

The average ICU stay was significantly shorter in the TAG group compared with the control group (2.6 ± 14.6 days vs 5.2 ± 7.2 days; $p < .001$), as was the total length of stay (7.4 ± 17.7 days vs 14.4 ± 12.8 days; $p < .001$).

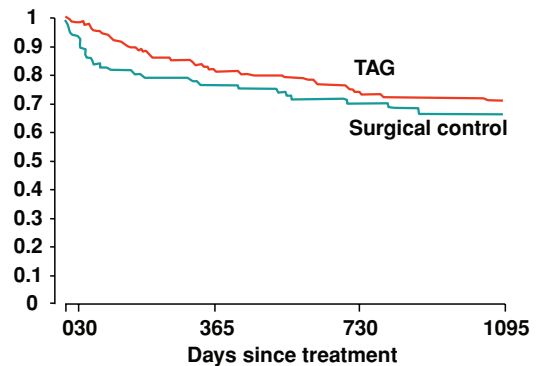


Figure 3 Comparison of Kaplan-Meier estimates for all-cause mortality through the 3-year follow-up between the Gore TAG and surgical control groups.

Late outcome

Late survival

All-cause mortality through 3 years did not differ in the two groups (Figure 3). The causes of death were commensurate with associated comorbidities in this elderly population. No ruptures have been reported.

With respect to aneurysm-related mortality, defined as death before hospital discharge, death within 30 days of the primary procedure or within 30 days of any secondary procedure to treat the original aneurysm, or death due to aneurysm rupture, there was one late death in the TAG group. This patient had an aneurysm growth in the setting of graft infection at 2 months. The patient underwent an open conversion and was found to have an aortoesophageal fistula, which was treated by graft excision and an extra-anatomic bypass, only to experience a respiratory arrest on postoperative day 13 with resultant anoxic brain injury. The patient died 3 days later. In the open surgical group, three additional deaths occurred during the first 6 months of follow-up. Freedom from aneurysm-related mortality through 3 years was 97% for the TAG device group and 90% for the open surgical controls ($p = .024$). No mortalities were noted in either group after the first year (Figure 4).

Major adverse events

The Kaplan-Meier estimates of the probability of freedom from MAEs were significantly higher with TAG treatment (58%) than with open surgical

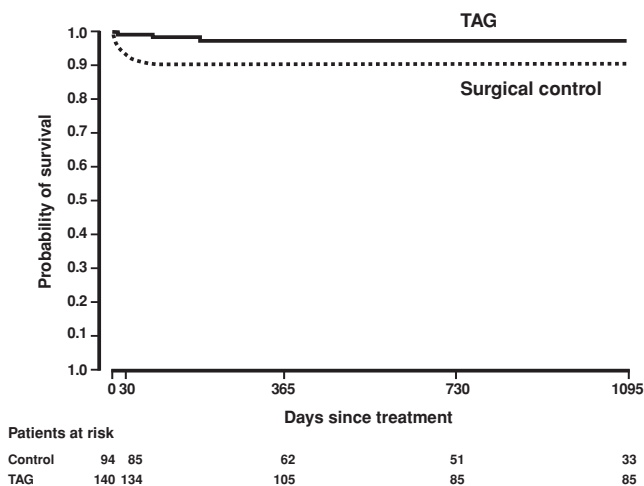


Figure 4 Comparison of Kaplan-Meier estimates for aneurysm-related mortality through 3-year follow-up between the Gore TAG and surgical control groups.

controls: 48% versus 20% at 3 years, respectively (Figure 5). In fact, 70% of all MAEs occurred within 30 days of the original procedure. A similar observation was made in the feasibility study, in which 63% of all events over 5 years were noticed in the first 30 days.

Device-related events

During a 3-year follow-up, 5 patients underwent endovascular revisions and 1 patient underwent surgical conversion. Three of the revisions occurred after 24 months of follow-up. Device migrations, three proximal and four components, were noted without clinical compromise at the 2-year follow-up. Sac shrinkage of greater than 5 mm was observed in 38% (24/64) and sac expansion in 17% (11/64) of patients. Three of the 11 patients with sac enlargement had endoleaks at some point during follow-up. Twenty fractures were noted in 19 patients: 18 in the longitudinal spine and 2 in the apical nitinol support rings. Clinical sequelae developed in only 1 patient, who developed a type III endoleak that was treated with an endograft. No ruptures were noted at a follow-up extending to 2 years. No device-related deaths were noted through 3 years.

Confirmatory study

Objectives and hypotheses

The confirmatory study was launched to demonstrate that deployment and early results with the modified device are comparable to those with the

original device. The safety and efficacy hypotheses were the same as in the pivotal trial except for using a 30-day end point. This earlier safety end point was chosen as an appropriate measure on the basis of the results of the pivotal study, in which most MAEs occurred within the 30-day period. Almost all major device-related events were also identified in the first 30 days during the pivotal trial. Although 30-day study end points were used, all patients are to be followed up to 5 years. Inclusion and exclusion criteria were identical to those used in the pivotal study.

Study design

The confirmatory study was a prospective, nonrandomized trial with all test subjects treated with the modified TAG device. The study was performed at 11 sites, all but one of which had participated in the pivotal trial. Fifty-one patients were enrolled in this study, and their results were compared with the same 94 control subjects used in the pivotal study.

Results of the confirmatory study

Clinical materials

Baseline demographics and aortic morphology were quite similar in the TAG device group and the surgical control group. Comorbidities were also well matched. In this comparison, the symptomatic aneurysm difference did not reach statistical

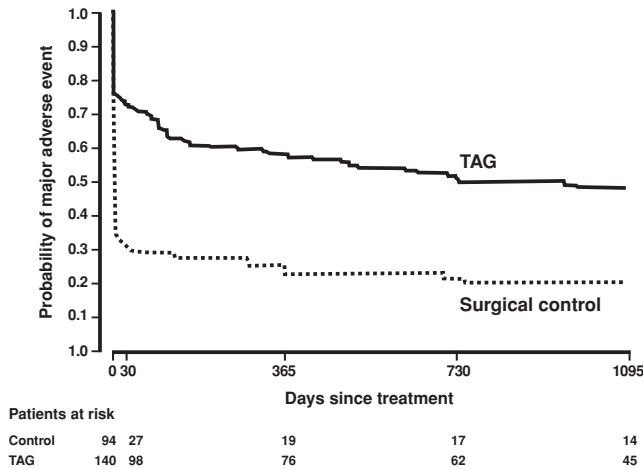


Figure 5 Comparison of Kaplan-Meier estimates for freedom from MAEs through the 3-year follow-up between the Gore TAG and surgical control groups.

significance. However, there was a higher prevalence of cancer or a history of cancer in the TAG device group compared with the surgical control group. Risk classification according to the American Society of Anesthesiologists was very well matched between the TAG and the surgical control groups. The Society of Vascular Surgery risk score was slightly higher in the TAG device group, and this was significant.

Early MAEs

At 30 days, the incidence of MAEs was 12% in the TAG group and 70% in the controls, a highly significant difference corresponding to an 83% risk reduction for those treated with the TAG device. No early deaths were noted in the TAG group. The rate of vascular complications was not significantly different in this cohort compared with the surgical controls.

Kaplan-Meier estimates of the probability of freedom from MAEs through 30 days showed a significant advantage for the TAG device group compared with the surgical control group ($p < .001$).

Device-related events

No major device-related events were reported through the 30-day follow-up in the test subjects compared with six (4%) reported for the pivotal study test subjects.

Hospital length of stay was shorter with the TAG device compared with the control group (3 days vs

10 days, respectively). The time to return to normal activities was shortened in the TAG group to 15 days versus 78 days for the control group.

Results from the Gore TAG trials [1, 2] have shown that the safety of endovascular repair of thoracic aortic aneurysm is superior to open surgical repair at short-term and mid-term results, with operative mortality and morbidity and SCI lower than those observed for open surgical repair. Patients treated with the endovascular approach had a lower length of hospital stay, lower length of ICU stay, lower blood transfusions, rapid recovery rates, lower aneurysm-related deaths, and fewer device-related complications.

The incidence of SCI though lower than with open surgical repair is still a major source of morbidity and mortality. Potential risk factors include extensive coverage of the descending thoracic aorta, open abdominal aneurysm repair with extensive coverage of descending thoracic aorta [3–5], and possibly coverage of the left subclavian artery with extensive coverage of the descending thoracic aorta.

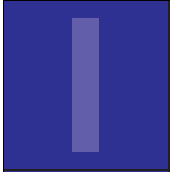
Vascular complications were more frequent in the endovascular group compared to the open surgical group. Small access vessels especially in females who comprised 50% of the thoracic aneurysm group are at risk of potential rupture when large sheaths are inserted. Conduits should be readily used as prophylactic procedure when small, tortuous, and calcified vessels are anticipated.

The risk of endoleak requires lifelong surveillance of patients with regular chest roentgenogram to detect device-related complications like migration or stent fracture and CT scans to follow endoleaks, aneurysm sac regression, or expansion.

In conclusion, the Gore TAG US trial has shown the efficacy of the Gore TAG excluder device for the treatment of thoracic aortic aneurysm. The application of this technology to other aortic pathologies is still under investigative trial protocols. Long-term data are required to establish better outcomes in the management of patients with thoracic aortic aneurysms. The evolution of more flexible end grafts, smaller delivery sheaths, and branched endografts would expand the application of this technology to patients with varied thoracic aortic pathologies.

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SECTION I

Thoracic aortic aneurysms

CASE 1

Endovascular repair of descending thoracic aortic aneurysms using the Gore TAG stent graft



Introduction

A descending thoracic aneurysm (DTA) is defined as a localized or diffuse dilation of an artery with a diameter at least 50% greater than an adjacent normal size artery. Thoracic aortic aneurysms are estimated to affect 10 per 100,000 elderly adults with 30–40% of those occurring in the descending portion of the thoracic aorta. The consensus size for intervention is generally 5.5 cm in the ascending aorta and somewhere in the range of 6.0–7.0 cm in the descending aorta. The most common risk factors include smoking, hypertension, atherosclerosis, bicuspid or unicuspid aortic valves, and genetic disorders. Potential symptoms from DTAs include back pain localized between the scapulae and midback and epigastric pain located at the level of the diaphragmatic hiatus. DTAs and thoracoabdominal aneurysms may compress the trachea or bronchus, cause stridor, wheezing, or dysphagia through compression of the esophagus. Erosion into surrounding structures may result in hemoptysis, hematemesis, or gastrointestinal bleeding. Erosion into the spine may cause back pain or instability. Spinal cord compression or thrombosis of spinal arteries may result in neurologic symptoms of paraparesis or paraplegia. DTAs may thrombose or embolize clot and atheromatous debris distally to visceral, renal, or lower extremities. The most common complications of thoracic aortic aneurysms are acute rupture or dissection. Some patients present with tender or painful non-ruptured aneurysms. Although debate continues,

these patients are thought to be at increased risk for rupture and should undergo surgical repair on an emergent basis. Endovascular stent grafting is fast becoming the accepted treatment modality for managing DTAs [1, 2] and has been approved for the US market since March 2005 (Figure 1).

Case scenario

A 71-year-old lady was diagnosed with a DTA of 4.4 cm × 5.2 cm approximately 18 months before intervention. She was now symptomatic with a complaint of chest pain that would radiate to the back. Her medical history was significant for hypertension, emphysema requiring nocturnal oxygen supplementation and a 120-pack year smoking history. Her medications included a couple of anti-hypertensive medications and inhalers for her emphysema. The remainder of her history and physical examination were essentially normal. A CT scan of the chest conducted within 3 months of intervention demonstrated a DTA of 6.0 × 5.3 cm (Figure 2a and 2b). Due to the expansion of the aneurysm and her prohibitive medical history, she was referred for endovascular repair.

Recommendation

Due to the patient's requirement for home oxygen and other severe comorbidities, she was felt to be a prohibitive risk for open surgery. Measurements

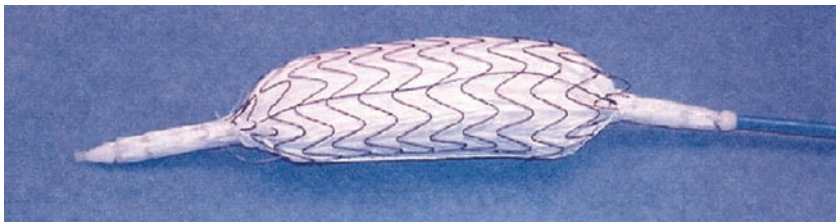
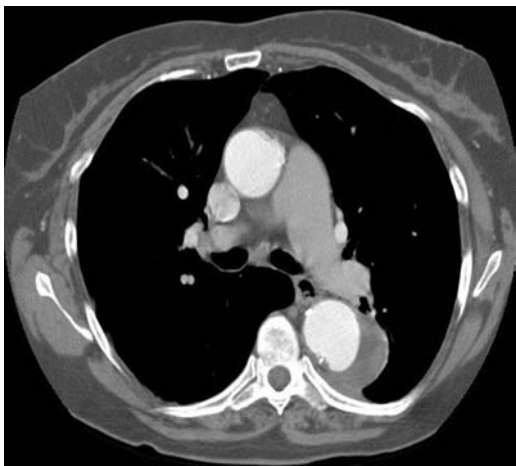
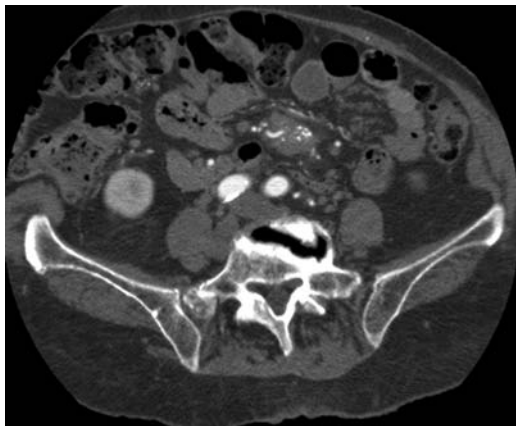


Figure 1 Illustration of a partially deployed Gore-TAG device.



(a)



(c)

Figure 2 (a) A CT scan of the chest with IV contrast demonstrating a DTA with mural thrombus measuring 6.0 cm × 5.3 cm in diameter. (b) A 3-D reconstruction showing the patient's anatomy and dimensions of the proximal and



(b)

distal landing zones. (c) An axial CT image demonstrating adequate-sized iliac arteries with mild calcification in the posterior wall of right iliac artery.

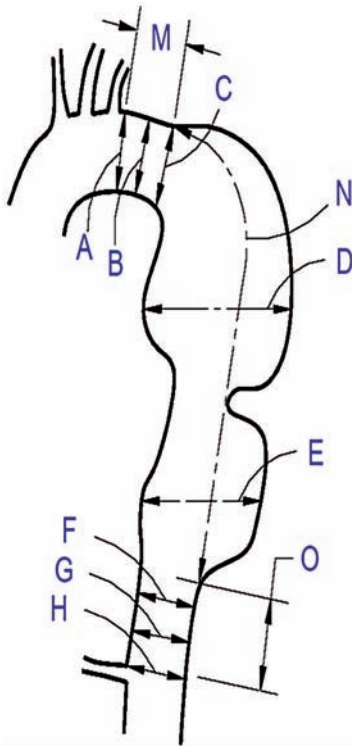


Figure 3 A preoperative worksheet to evaluate the candidacy for stent-graft placement. A, proximal implantation site, 30 mm; B, 1 cm proximal to implantation site; C, 2 cm from implantation site, 32 mm; D, aneurysm diameter, 60 mm; E, secondary aneurysm N/A; F, 2 cm distal to implantation site; G, 1 cm from distal implantation site, 29 mm; H, distal implantation site, 28 mm; N, distal neck, distance from aneurysm to celiac axis, 3 cm; O, total treatment length 9 cm.

obtained from the diagnostic CT scans of the chest, abdomen, and pelvis indicated that the patient met the criteria for endoluminal stent grafting using the preoperative work sheet (Figure 3). A Gore TAG endoluminal graft (W.L. Gore & Associates, Flagstaff, AZ) 34 mm × 15 cm would provide a 10–15% oversizing in the landing zones (Table 1) and would be adequate in length to exclude the aneurysm. A CT scan of the pelvis helped assess the size, tortuosity, and amount of calcification of the iliac vessels. The iliac arteries were 10 mm in diameter and free of significant disease or tortuosity (Figure 2c) and were adequately sized for deployment of an endograft (Table 2).

Table 1 Gore TAG sizing chart.

Device diameter (mm)	Vessel diameter (mm)	Oversizing (%)
26	23–24	8–14
28	24–26	8–17
31	26–29	7–19
34	29–32	9–16
37	32–34	9–16
40	34–37	9–18

Procedure

Under general anesthesia, open retrograde cannulation of the right common femoral artery was performed with an 18-G needle and a 0.035-in. soft-tip angled glide wire (Medi-tech/Boston Scientific, Natick, MA) was passed into the distal thoracic aorta and exchanged to a 9-F (French) sheath under fluoroscopic visualization. Percutaneous access of the left common femoral artery was similarly performed with a 5-F sheath. Five thousand units of heparin were given to keep the activated clotted time greater than 200 seconds. A 5-F pigtail catheter was advanced through the left groin sheath into the thoracic aorta. The fluoroscopic C-arm was positioned in a left anterior oblique angle, and an oblique thoracic arch aortogram was performed to visualize the arch vessels and the descending thoracic aortic aneurysm (Figure 4). Intravascular ultrasound (IVUS) is routinely performed in our institution using an IVUS 8.2-F probe (Volcano Therapeutics, Inc., Rancho Cordova, CA). The IVUS probe was advanced through the right groin sheath to confirm the size of the aneurysm, presence or absence of thrombus, proximal neck diameter and length, and distal neck diameter and length. The 34 mm × 15 cm

Table 2 Recommended iliac diameter for the introduction of Gore delivery sheaths.

Size (F)	ID (mm)	OD (mm)
20	6.7	7.6
22	7.3	8.3
24	8.1	9.1

ID, inner diameter; OD, outer diameter.

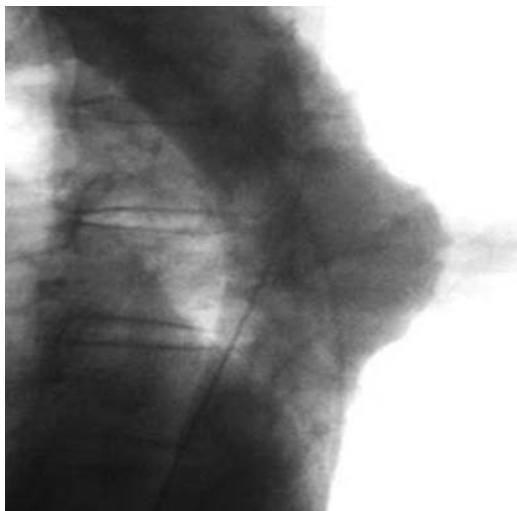


Figure 4 An aortogram demonstrating a descending thoracic aortic aneurysm with adequate proximal and distal neck length.

TAG stent graft was chosen (Figure 5). The IVUS catheter was exchanged for an extra-stiff 260-cm double curve Lunderquist wire (Cook Inc., Bloomington, IN). The right 9-F sheath was exchanged for a 22-F Gore sheath and a 34 mm × 15 cm TAG stent-graft device was advanced through the Gore sheath (Figure 6). Prior to deployment, the proximal and distal landing zones were identified and marked on angiographic road map. At the time of deployment

of the endoluminal graft, a systolic blood pressure of 90 mm Hg is achieved to decrease the “windsock” effect in the thoracic aorta. We have not felt the need for adenosine-induced asystole. A Gore trilobe balloon (Figure 7) was used to perform post-deployment balloon angioplasty to both the proximal and distal segments of the graft for good fixation. A completion angiogram demonstrated exclusion of the aneurysm with no endoleak (Figure 8). All wires and sheaths were removed from the right common femoral artery with the incision closed in a transverse fashion. A 6-F angioseal vascular closure device (St. Jude Medical, Inc., St. Paul, MN) was deployed to the left common femoral artery. At the end, the patient had bilateral peripheral pulses was extubated prior to leaving the OR and transferred to the recovery room. She was discharged on post-operative day (POD) 2 in satisfactory condition. A CT scan of the chest performed on POD 1 showed exclusion of the 6-cm aneurysm with no evidence of an endoleak (Figure 8a and 8b).

Discharge CT scan

Discussion

The management of DTAs has traditionally been by open surgical repair. Open surgical repair requires performing a left thoracotomy, aortic cross clamping, possible left heart bypass, and some degree of

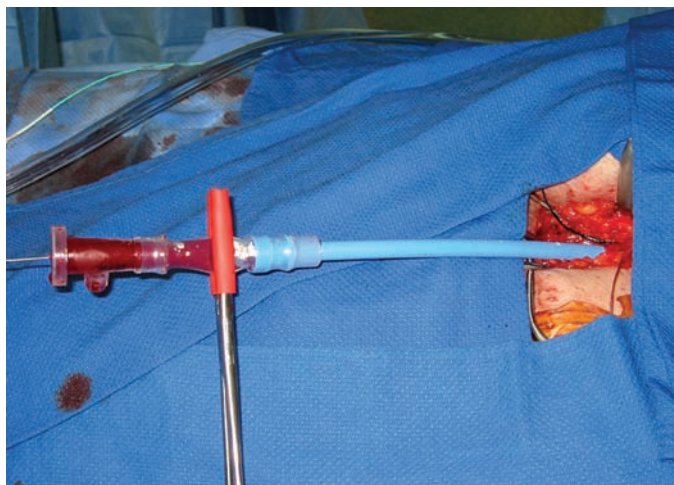


Figure 5 A 22-F Gore delivery sheath introduced through the femoral artery for deployment of endoluminal graft.

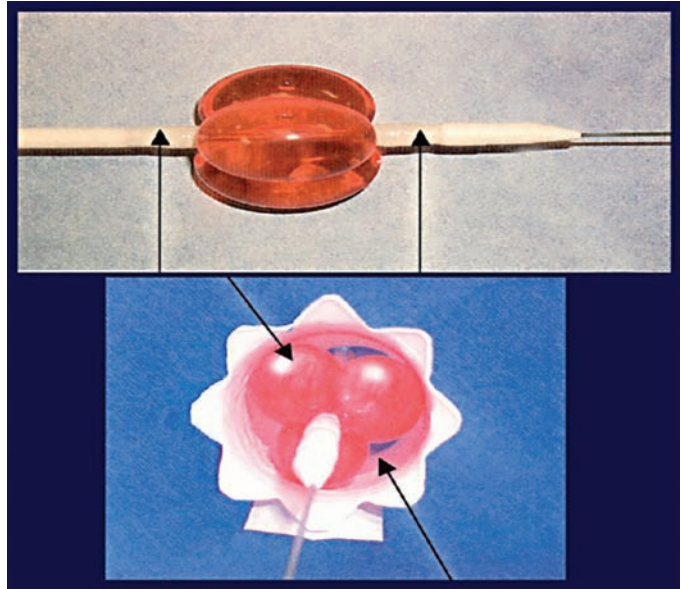


Figure 6 Gore trilobed balloon used for profiling the Gore TAG stent graft.

hypothermia that can increase the morbidity and mortality of the procedure. Thoracic endoluminal grafting has recently gained wide acceptance as a treatment modality for managing various aortic pathologies including DTAs [2–4]. From September

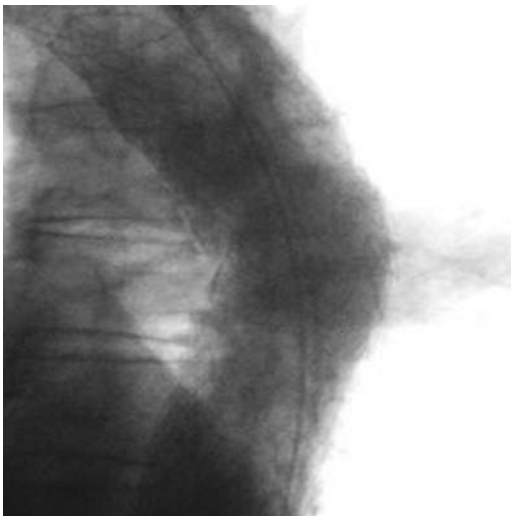


Figure 7 A postdeployment angiogram demonstrating exclusion of the thoracic aneurysm.

1999 through May 2001, 140 patients with DTAs were evaluated and enrolled at 17 sites across the United States. An open surgical control arm consisting of 94 patients was identified by enrolling both historical controls and concurrent subjects. Results of this US multicenter comparative trial (TAG 99-01) [5] showed a perioperative mortality in the endograft arm of 2.1% ($n = 3$) versus 11.7% ($n = 11$, $p < .001$) in the open surgery cohort. A 30-day analysis revealed a statistically significant lower incidence of the following complications in the endovascular cohort versus surgical cohort: spinal cord ischemia (3% vs 14%), respiratory failure (4% vs 20%), and renal insufficiency (1% vs 13%). The endovascular group had a higher incidence of peripheral vascular complications (14% vs 4%). The mean intensive care and hospital stay were shorter in the endovascular cohort group. Accepted, commercial indications for a thoracic endoluminal graft include DTAs deemed to warrant surgical repair, fusiform aneurysm greater than two times diameter of normal adjacent aorta, and saccular aneurysms. A minimum of 2-cm nonaneurysmal segment in both the proximal and distal landing areas are needed for successful deployment of a thoracic endoluminal graft. Angles less than 60°

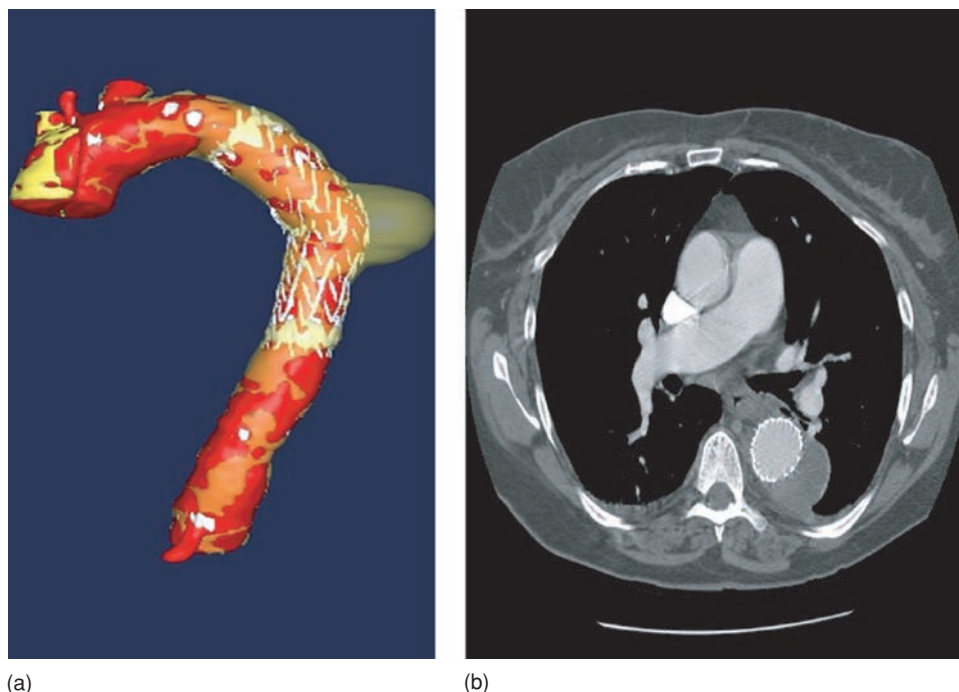


Figure 8 (a and b) A CT scan showing successful exclusion of the DTA.

between the aortic arch and the descending thoracic aorta may require additional length of nonaneurysmal segment, and coverage of the left subclavian artery may be required. Late complications associated with endografting include aortic wall perforation from the proximal bare spring configuration of earlier devices, device collapse from oversizing the endograft greater than 20% of the thoracic aortic neck diameter metal fracture, fabric erosion, and suture breakage associated with circumferential, radial, and tensional stresses from repetitive aortic pulsations [6]. Two-year follow-up data from the TAG 01 US multicenter trial showed a 6% endoleak rate detected at 1 year and 9% endoleak at 2 years postprocedure. During that time, three reinterventions in the endograft cohort were done with none in the open surgical cohort [7]. Five-year follow-up data show freedom from device-related complications to be very low with no aneurysm-related deaths, conversions, or ruptures for the control subjects enrolled in the pivotal and confirmatory studies (TAG 99-01 and TAG 03-03) [8]. Recommendations for endograft surveillance include a 4-view chest X-ray to assess for device

migration or stent fracture and a CT scan of the chest at periodic intervals (1 mo, 6 mo, 1 yr, and annually thereafter).

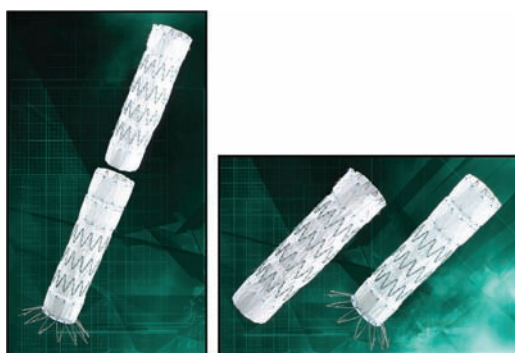
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CASE 2

Endovascular management of thoracic aortic aneurysm using a Cook Zenith TX2 endograft



Introduction

With the introduction of the first commercially available endograft, two additional endoprostheses are in the process of being evaluated for Food and Drug Administration approval. The Cook TX2 stent graft is designed as a two-piece system that incorporates hooks and barbs, distal fixation, and a proximal controlled deployment. Thoracic stent-graft treatment of thoracic aortic pathologies, including thoracic aortic aneurysms, has been associated with migration of both proximal and distal fixation points [1], erosion of uncovered proximal portion through the aortic arch [2], component separation with modular devices [2, 3]. These problems have been described with most of the thoracic endoprosthesis implanted for thoracic aortic pathologies [3–5]. The ideal thoracic stent graft currently does not exist but would need to be flexible enough to accommodate the tortuosity of the arch, incorporate a fixation system that is secure both proximally

and distally, seal within both straight and tortuous segments, be readily deliverable and have favorable effects on the excluded region of the aorta. Additionally, delivery of the device would optimally not require the induction of hypotension or bradycardia even in the setting of extreme tortuosity. The Cook TX1 and TX2 device has been designed to attempt to solve some of these issues but currently at this time is not approved as a commercial device in the United States.

Device description

The Zenith endograft is a one-piece (TX1) or two-piece (TX2) modular endovascular graft (Figure 1). The device composition is of Dacron (DuPont, Wilmington, DE) fabric sewn to self-expanding stainless steel Z-stents with braided polyester and monofilament polypropylene sutures. The graft is fully stented with an intention to provide columnar stability and expansile force. It consists of a