Improvement in conformability of the latest generation of thoracic stent grafts

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Objective: Poor aortic arch apposition increases the risk of technical failure after thoracic endovascular repair. The aim of this study was to assess the conformability of the latest generation of thoracic stent grafts in relation to the degree of device oversizing and aortic arch angulation.

Methods: A benchtop pulsatile flow model was designed to test stent graft anchorage in a 2-cm-long proximal landing zone at varying landing zone angles (from 140° down to 70°) and stent graft oversizing (12%-28%). The experiments were performed using 10 human thoracic cadaveric aortas and four stent grafts: C-TAG, Zenith TX2 Pro-Form, Valiant Captivia, and Relay. Device-wall apposition was measured as a function of landing zone angulation and oversizing during static and dynamic (60 pulses/min, 300/150 mm Hg) tests.

Results: The Valiant stent graft remained apposed to the aortic wall at each increment of neck angulation and device oversizing. Lack of apposition of the proximal anchorage segment was observed with the C-TAG above 120° landing zone angulation (1-2 mm) and with the Relay above 110° landing zone angulation (1-4 mm). Lack of “body” apposition (1-4 mm) was first observed with the Zenith Pro-Form stent graft above 110° angulation (P = .001). When the device was not apposed to the aortic wall, an increase in stent graft oversizing significantly (P = .01) decreased device-wall apposition.

Conclusions: The requirement for close conformability has influenced the design of next-generation devices. Manufacturers have modified devices and/or their deployment system to specifically address this problem. When compared with the results of our previous experimental test, this study demonstrates that these alterations have resulted in a marked improvement in the performance of commercially available stent graft systems. (J Vasc Surg 2013;57:1084-9.)

Clinical Relevance: The first decade of thoracic endovascular aortic repair has shown good midterm results. However, adequate sealing and stent graft conformability of the stent graft in angulated necks may still be a relevant problem when indications are extended to more proximal landing zones. Inadequate apposition to the lesser curvature of the arch is observed more frequently in stent grafts deployed in the presence of an acute aortic angle. Unfortunately, this situation may lead to late complications, including stent graft collapse, type I endoleak, and thoracic stent graft migration. The aim of this study was to assess the conformability of the latest generation of thoracic stent grafts as a function of oversizing and increasing aortic arch angulation.

The first decade of thoracic endovascular aortic repair (TEVAR) has demonstrated good short- and midterm outcomes. These results support endovascular repair as the procedure of choice for patients presenting with thoracic aortic diseases. Adequate sealing with good stent graft conformability in challenging proximal necks presents a problem, which is especially marked in more proximal landing zones. Inadequate apposition to the lesser curvature of the arch is observed more frequently in stent grafts deployed in the presence of an acute aortic angle (Fig 1). This situation may lead to late complications, including stent graft collapse, type I endoleak, and thoracic stent graft migration.

Previous work to assess proximal fixation in four commercially available thoracic stent grafts demonstrated that the major factors in stent graft design contributing to secure proximal anchorage appear to be radial force and the presence of a proximal open stent segment.1 Since then, manufacturers of thoracic stent grafts have attempted to modify devices and their deployment system to specifically address the problem of inadequate proximal conformability of the stent graft.

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graft material. The stent graft does not have a connecting

Individual stents are sutured to the outside of the polyester

fabric graft. A curved nitinol wire (torsion bar) is sutured to a polyester

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endograft remains the same. The Relay stent graft (Bolton Medical, Sunrise, Fla) is composed of self-expanding sinusoidal nitinol stents that are sutured to a polyester fabric graft. A curved nitinol wire (torsion bar) is sutured to the outer curve of the stent graft fabric to provide longitudinal support for optimal anatomic orientation and for transmission of torsion forces. The proximal end of this stent graft is an open bare stent.

The new delivery system features a nitinol inner catheter that provides improved self-alignment of the dual sheath system, which allows the graft to take the lesser curve without kinking.

“Body” and proximal anchorage segment of the stent graft. The “body” of each device was defined as the covered tubular part of the stent graft without the open bare or covered stent segment. The proximal anchorage

Hypotonic saline was infused into the aorta to maintain the diameter of the individual aortic segments measured 22.9 mm (range, 22-25 mm) before explantation. The aortas were immediately placed in ice and maintained at 

Methods

Harvesting and preparation of aortas. This study was approved by the departments involved and performed in accordance with French regulations. A total of 10 nonaneurysmal descending thoracic aortas were harvested en bloc at autopsy from seven men and three women (mean age, 44.9 years; range, 29-58 years) who had died a maximum of 4 days previously (mean, 1.9 days). The mean diameter of the individual aortic segments measured 22.9 mm (range, 22-25 mm) before explantation. The aortas were immediately placed in ice and maintained at 4° until required (mean delay <30 minutes). Sections of the aortas were sent to the Department of Pathology for analysis (staining with orcein and hematein/eosin) to ensure the presence of a three-layer aortic wall comparable to a fresh aorta.

Stent grafts. Four 100-mm-long commercial stent grafts (Fig 2) were evaluated.

Valiant Captivia stent graft. The Valiant stent graft (Medtronic Vascular, Santa Rosa, Calif) is composed of a nitinol stent framework between layers of polyester graft. Individual stents are sutured to the outside of the polyester graft material. The stent graft does not have a connecting bar between springs, and the proximal end features an open bare stent segment.

Zenith TX2 thoracic stent graft with Pro-Form. The Zenith TX2 thoracic stent graft with Pro-Form (Cook Medical, Bloomington, Ind) is made of Dacron fabric blended with self-expanding stainless steel Gianturco Z-stents.

To specifically address the problem of proximal neck-aortic wall apposition, a new release sequence has been added with a diameter-reducing suture (Tevdek II 5-0 polyester) linked to the trigger wires. In the new version, the trigger wires are attached to both the proximal and distal edges of the proximal sealing stent, holding the proximal end closed in a trifold fashion. This configuration maintains the proximal stent parallel to the aortic inner curvature during deployment. Once the stent graft is semideployed, the trigger wire release mechanism allows microadjustments while the proximal trifold configuration prevents the “windsock” effect. To accommodate a curved aorta, the manufacturers also introduced a circumferential “diameter-reducing” suture to the distal end of the first stent. Releasing the trigger wires allows the struts of the first stent to pleat into the second stent at the inner curvature.

Conformable TAG (C-TAG) stent graft. The TAG stent graft (W. L. Gore & Assoc, Flagstaff, Ariz) is composed of a symmetrically expanded polytetrafluoroethylene tube reinforced externally with a layer of expanded polytetrafluoroethylene. An exoskeleton consisting of nitinol stents is attached to cover the length of the graft.

The next generation of the Gore device was engineered for flexibility and conformability in tortuous anatomy. The flared scallops at the proximal and distal ends of the device (W. L. Gore & Assoc) have been replaced by a partially uncovered stent proximally, which is straight, not flared, and has outward radial force consistent with the entire length of the device. The bare stent ranges from 3 to 6.5 mm in length, depending on the diameter of the device. The diameter of the nitinol wire is increased to optimize the radial force. The nitinol is a single piece of wire that continues in a spiral throughout the length of the device. An extra apex has been added so that each circumference has nine apexes, which helps to distribute the load to increase the bending fatigue life of the wire. When placed in a curved position, the device shows no tendency to straighten and continues to stay in its given conformation. The reduction in length of the inner curvature is achieved by telescoping consecutive segments in the inner radius of the device throughout its length.

Relay stent graft with Plus delivery system. The endograft remains the same. The Relay stent graft (Bolton Medical, Sunrise, Fla) is composed of self-expanding sinusoidal nitinol stents that are sutured to a polyester fabric graft. A curved nitinol wire (torsion bar) is sutured to the outer curve of the stent graft fabric to provide longitudinal support for optimal anatomic orientation and for transmission of torsion forces. The proximal end of this stent graft is an open bare stent.

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“Body” and proximal anchorage segment of the stent graft. The “body” of each device was defined as the covered tubular part of the stent graft without the open bare or covered stent segment. The proximal anchorage

Fig 1. Computed tomographic scan demonstrating poor apposition of the stent graft along the inner curve of the aortic arch, with the stent graft protruding into the lumen of the aorta.
segment was defined as the open bare stent segment for the Relay, Valiant, and C-TAG devices. The Zenith TX2 was the only device with a proximal anchorage system but without an open bare or uncovered stent segment.

Model preparation and test procedure. All investigations were carried out with a custom-built, closed-system, benchtop pulsatile flow model. This experimental model and the test procedure have been reported previously (Fig 3).1 The test order for the commercial devices was random. The proximal end of each stent graft was placed at the tightest portion of each angled aorta and was held constant. The device landing zone was in the naturally angled distal aortic arch/proximal descending aorta along the anatomic curve. The stent graft was dilated after deployment with a low-pressure balloon.

Failure of device-wall apposition at various angulations was noted and measured, during static and dynamic (60 pulses/min, 300/150 mm Hg) tests. The aortic diameter was defined as the intraluminal diameter of the aortic neck.

The only modification to the previously described experimental protocol was that the proximal landing zone angulation was decreased from 140° to 70° in 10° increments. This change was performed to allow the best conformation of the devices for which the delivery system has been modified to address the problem of proximal lack of device-wall apposition. Indeed, the stent grafts were deployed in the most acute aortic arch angulation, and the new delivery systems should allow the most appropriate conformation of the device.

Statistical analysis. Categorical variables are presented as count (percentage) with 95% confidence interval. Continuous variables are given as mean (standard deviation) for normally distributed data and as median with interquartile range for nongaussian distribution. Normality was tested with the Shapiro-Wilk test. The Wilcoxon or Mann-Whitney nonparametric test was used for comparing continuous variables between two groups. Correlations were assessed with the Spearman coefficient. Differences were considered significant at P < .05. Statistical analysis was carried out using SAS software (version 9.1; SAS Institute, Cary, NC).

RESULTS

Histologic analysis of the harvested aortas at the start of the study revealed that all 10 aortas had a three-layer wall and were comparable to fresh aortas. During the dynamic tests, no stent graft collapse was seen. The Valiant stent graft body and proximal anchorage segment remained apposed to the aortic wall at each variation of neck angulation and degree of oversizing, with the springs always penetrating into the aortic wall (Fig 4). In the other stent grafts tested, lack of device-wall apposition was observed between the proximal anchorage segment and the inferior aortic wall (Table I). The Relay device demonstrated a lack of device-wall apposition at the proximal anchorage at an angulation >110°, and increased from 1 to 4 mm as the angulation and oversizing increased. Despite this, the body of the Relay device always remained well apposed. Macroscopically, the Relay stent graft did not appear to injure the aortic wall.

The C-TAG device demonstrated a lack of device-wall apposition of 1 to 2 mm between the bare stent of the proximal anchorage segment and the inferior aortic wall at angulations
The body of the C-TAG device always remained well apposed and did not appear to injure the aortic wall. The Zenith TX2 device demonstrated a lack of device-wall apposition between the stent graft “body” and the aortic wall beginning at an angulation of 110°, increasing from 1 to 4 mm as the proximal landing zone angle and oversizing increased. The barbs of the Zenith TX2 stent graft were associated with macroscopic transmural injury. Notably, the body of the Zenith TX2 was the only graft to lose apposition with the aortic wall (P < .001). An increase in stent graft oversizing for the C-TAG, Zenith TX2, and Relay devices significantly increased the lack of device-wall apposition (P = .01).

DISCUSSION

The technique of TEVAR is evolving. Concerns over long-term endograft durability remain given that up to 3.9% of patients require reintervention independent of the type of endograft implanted.² Lifelong surveillance is recommended to identify potential complications such as device failure, endoleak, and endograft migration, which may lead to aneurysm rupture.
Thoracic devices were initially developed from those used in the infrarenal aorta\textsuperscript{3}. It has long been recognized that thoracic devices perform well in the descending thoracic aorta, but conformation to the anatomy of the aortic arch poses a unique challenge. This is especially true when the angle of the arch is very acute. Stent grafts that do not conform to the contours of the aortic arch can sit above the inner curvature of the arch, displaying a "bird’s-beak" configuration on imaging. The risk of device collapse is proportional to the length of graft not in contact with the aorta, increasing the risk of type I endoleak or even sudden aortic occlusion and death\textsuperscript{4,5}. Preclinical testing has a limited ability to predict clinical failures, in part due to limitations inherent in ex vivo models. Synthetic materials are limited in their ability to simulate the native properties of the human aorta, such as wall compliance. Abel et al\textsuperscript{6} suggested that evaluation of proximal landing zone angle and oversizing was essential during preclinical testing of thoracic stent grafts. These authors recommended the use of “worse case” simulations to assess device performance under extreme anatomic conditions. In this study, efforts were made to approximate in vivo conditions as closely as possible, using cadaveric aortas that had histologic characteristics similar to aortas of living persons.

Previous work concluded that, in the face of severe aortic arch angulation, proximal hooks do not improve fixation\textsuperscript{1}. The major factors that ensure secure proximal anchorage appear to be radial force and the presence of a proximal open stent segment. Since the previous evaluation, three of the devices assessed have been further optimized for use in the aortic arch. Either the structure of the device has been modified (C-TAG, Zenith TX2) and/or the delivery system has been designed to maintain the proximal stent parallel to the aortic inner curvature during deployment (Relay stent graft with Plus delivery system, Zenith TX2 thoracic stent graft with Pro-Form).

As in previous studies, the Valiant stent graft remained apposed to the aortic wall at each increment of neck

### Table I. Lack of device-wall apposition of three stent grafts measured at various angulations and categories of diameter oversizing

<table>
<thead>
<tr>
<th>Oversizing, %</th>
<th>140°</th>
<th>130°</th>
<th>120°</th>
<th>110°</th>
<th>100°</th>
<th>90°</th>
<th>80°</th>
<th>70°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relay with Plus delivery system</td>
<td>3.8</td>
<td>3.4</td>
<td>2.8</td>
<td>2</td>
<td>1.7</td>
<td>0.7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C-TAG</td>
<td>2</td>
<td>1.7</td>
<td>1.3</td>
<td>0.3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zenith TX2 with Pro-Form</td>
<td>3.8</td>
<td>3.7</td>
<td>2.8</td>
<td>2.7</td>
<td>1.5</td>
<td>0.8</td>
<td>0.1</td>
<td>0</td>
</tr>
<tr>
<td>Valiant with Captivia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Data are presented as the mean. Proximal anchorage segments for the Relay (bare stent) and C-TAG (bare stent) devices and the body of the Zenith TX2 stent graft. An increase in stent graft oversizing for the C-TAG, Zenith TX2, and Relay devices significantly increased the lack of device-wall apposition ($R = .01$).

### Table II. Lack of device-wall apposition of the first generation of stent grafts measured at various angulations and categories of diameter oversizing

<table>
<thead>
<tr>
<th>Oversizing, %</th>
<th>140°</th>
<th>130°</th>
<th>120°</th>
<th>110°</th>
<th>100°</th>
<th>90°</th>
<th>80°</th>
<th>70°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relay</td>
<td>4.8</td>
<td>4.7</td>
<td>3.4</td>
<td>3</td>
<td>2.9</td>
<td>2.2</td>
<td>2</td>
<td>1.1</td>
</tr>
<tr>
<td>TAG</td>
<td>4</td>
<td>3.5</td>
<td>3</td>
<td>2.5</td>
<td>2</td>
<td>1.5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Zenith</td>
<td>4.2</td>
<td>4.1</td>
<td>3.6</td>
<td>3.2</td>
<td>3</td>
<td>2.7</td>
<td>1.9</td>
<td>1.2</td>
</tr>
<tr>
<td>Valiant</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Relay</td>
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<td>5</td>
<td>4.5</td>
<td>4.3</td>
<td>3.6</td>
<td>3</td>
<td>2.4</td>
<td>2</td>
</tr>
<tr>
<td>TAG</td>
<td>4.8</td>
<td>4.6</td>
<td>3.6</td>
<td>2.9</td>
<td>2.4</td>
<td>1.9</td>
<td>1.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Zenith</td>
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<td>Valiant with Captivia</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Data are presented as the mean. Proximal anchorage segments for the Relay (open springs) and TAG (scalloped flares) devices and the body of the Zenith TX2 with Pro-Form stent graft.
springs in the Relay (n = 7). We retrospectively analyzed and compared the endovascular repair of acute traumatic thoracic aortic transection, assessed the impact of stent graft design on the outcome of the arch, with increased proximal conformability of the stent graft.

The Relay stent graft conforms well in aortic arch angulation up to 110°. Above 110° of angulation, a lack of apposition of the bare stent was observed. Previously, this had occurred at angles >80°. Similarly, the Zenith TX2 with Pro-Form stent graft apposed well until 110° of angulation was induced, where previously this occurred at only 70° in the Zenith TX2 with Pro-Form delivery system. Of note, at an angulation >140°, the lack of device-wall apposition caused a hemodynamically significant stenosis.

The superior performance of the Valiant model compared with the other stent grafts may be explained by the delivery of more robust radial force and the high-amplitude joint between the spring and the peaked spring. The springs of the Valiant were also longer than the springs of the C-TAG and were greater in number (n = 8) than the springs in the Relay (n = 5).

The potential problems caused by a “bird’s-beak” configuration after stent deployment have influenced the commercial design of the latest-generation devices. This latest generation of devices has been tailored for use in the arch, with increased flexibility and conformability by improvement of either the device and/or its deployment system to specifically address the problem of inadequate proximal conformability of the stent graft.

The improvement observed during this experimental study has been confirmed by clinical results. We recently assessed the impact of stent graft design on the outcome of endovascular repair of acute traumatic thoracic aortic transection. We retrospectively analyzed and compared the outcomes of endoluminal treatment of acute traumatic aortic transection using first-generation vs second-generation stent grafts. Enhanced stent graft conformability has significantly decreased the morbidity (from 18.7% to 6.2%) of endovascular repair of acute traumatic transection of the thoracic aorta. Melissano et al. reported the results of 27 patients treated with the Zenith TX2 with Pro-Form. Postoperative computed tomography at 1 and 6 months confirmed 100% clinical success with the absence of device-related complications. No type I endoleak was documented. The proximal sealing stent fit well with the aortic profile in all cases except one, in which malapposition was seen in a severely angulated aorta at 6-month follow-up.

An important limitation of this study is that stent grafts were placed within nonaneurysmal aortas, so this model may more closely parallel a focal traumatic aortic injury rather than an aneurysm. Furthermore, during endovascular aneurysm repair, a long segment of the stent graft is unsupported as it traverses the sac, allowing the stent graft to conform to a “best-fit” situation.

CONCLUSIONS

Imperfect stent graft apposition, or “bird’s-beak” appearance after TEVAR of the aortic arch, increases the likelihood of poor clinical outcome. This has influenced the design of next-generation devices, and manufacturers have modified both devices and deployment systems to specifically address this problem. When compared with the results of our previous experimental test, this study demonstrates that improvements in design have resulted in greater graft conformability within the aortic arch in the setting of a human ex vivo model.

AUTHOR CONTRIBUTIONS

Conception and design: LC, PC, FJ, PB, CM, PA
Analysis and interpretation: LC, PA
Data collection: LC, PA
Writing the article: LC, PA
Critical revision of the article: LC, PC, FJ, PB, CM, PA
Final approval of the article: LC, PC, FJ, PB, CM, PA
Statistical analysis: LC
Obtained funding: PA
Overall responsibility: LC, PA

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