

From the Peripheral Vascular Surgery Society

Incidence of and outcomes after misaligned deployment of the Talent Thoracic Stent Graft System

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Objective: Various types of device-specific adverse events can occur during deployment of thoracic stent grafts due to the high flow rate and severe aortic angulation that is often encountered in the thoracic aorta. This study assessed the incidence, etiology, and overall effect of misaligned deployment of the Talent Thoracic Stent Graft (TSG) System. Techniques to predict and avoid this complication are discussed.

Methods: Data collection included pivotal-trial follow-up, direct surveys of centers inside and outside the United States and principal investigators, a targeted literature search, and review of complaint files. Misaligned deployment was considered to occur when the proximal covered or uncovered stent apices of a thoracic stent graft folded back on itself and remained nonparallel to the wall of the aorta after deployment had been completed.

Results: Of about 20,305 deployments to date of the Talent TSG, 24 misaligned deployments were identified for an incidence of 0.1%. Nineteen (79%) events occurred during treatment of degenerative aneurysms or penetrating ulcers, four (17%) during treatment of dissections, and the underlying pathology could not be determined for one patient. The misalignment was noted at the proximal end of the stent graft in 15 patients (63%), and the other 9 events (37%) occurred at the graft overlap junction. Two events were treated intraoperatively, with a second overlapping device placed in one patient and a snare used to reposition the proximal stent in another. Adverse clinical events occurred in three patients and included a persistent type I endoleak, continued false lumen perfusion in a patient with dissection, and delayed retrograde type A dissection in a patient undergoing total arch repair. No intraoperative contrast extravasation or computed tomography evidence of perforation was noted. There were no perioperative deaths or cerebrovascular events, with one report of paraplegia among the 24 patients in this series.

Conclusion: Misaligned deployment is an unusual phenomenon that tends to occur in the context of certain well-defined anatomic conditions in the thoracic aorta. To date, most of these events have not led to significant adverse sequelae. However, careful patient selection, periprocedural imaging, and case planning can help to identify anatomies in which misaligned opening is likely to occur, allowing physicians to avoid this complication. (*J Vasc Surg* 2010;51:1096-102.)

In the experience with thoracic endovascular aneurysm repair (TEVAR), stent graft failure has been found to occur most frequently in the early perioperative period or during late follow-up.¹ The circumstances of TEVAR differ from those of endovascular abdominal aneurysm repair (EVAR) in terms of the tortuosity of the thoracic aorta, which cannot be easily corrected with stiff wires, the greater hemodynamic forces in the aortic arch, and the remoteness of the pathology from the procedure entry site leading to an

increased risk of device-related complications.² Early TEVAR failures involve delivery, deployment, and conformation to the local aortic anatomy. Deployment failures, which are rare but difficult to correct, usually occur in situations of severe aortic tortuosity and near the distal arch.¹

Misaligned deployment can occur when the proximal stent apices of a deployed stent graft retroflex and remain significantly nonparallel to the wall of the aorta after deployment has been completed. Potential clinical sequelae of misaligned deployment may range from negligible to significant and may present acutely or chronically.

The worldwide experience during the past decade with the Talent Thoracic Stent Graft (TSG) System (Medtronic Vascular, Santa Rosa, Calif) has been reported in numerous articles.³⁻⁹ The Talent device received the Conformite European (CE) mark in April 1998 and United States (US) Food and Drug Administration (FDA) approval in June 2008. Currently, 20,305 Talent TSG devices have been implanted in 7547 patients worldwide.

In the pivotal VALOR (Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms) trial, which enrolled 195 patients between December 2003 and June 2005, the bare spring segment of the most proximally implanted

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Competition of interest: Dr Kasirajan receives research support from Medtronic and W.L. Gore and Associates. Dr Kwolek receives research support from Medtronic, Cook, W.L. Gore and Associates, and Bolton. Dr Fairman is a consultant to Medtronic and receives research support from Medtronic, Cook, Aptus, Boston Scientific, and Abbott.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest.

0741-5214/\$36.00

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doi:10.1016/j.jvs.2009.11.071

Talent device was in zone 1 or zone 2 of the aortic arch in 33.5% of patients, and overall, no instances of misaligned deployment were reported.⁹ Nevertheless, a small number of reports of misaligned deployment events have been documented related to the proximal bare spring and the proximal covered stent, especially when deployed in tortuous anatomy. We report the results of a thorough program of data collection and event adjudication that was undertaken to evaluate the incidence and clinical significance of misaligned proximal stent deployment occurring during deployment of the Talent TSG System.

METHODS

Device description and deployment. The Talent TSG System is composed of a series of shaped sinusoidal nitinol wire rings acting as springs stacked in a tubular arrangement to form the self-expanding structure. These rings are covered by a sewn-on monofilament polyester woven graft with radiopaque markers attached. The overall design concept is modular, with additional main sections as well as proximal and distal extensions available for introduction separately for mating in vivo as necessary for completing thoracic aortic aneurysm (TAA) exclusion. The proximal end of the stent graft can be configured as a serrated proximal covered stent (open-web) or as an open bare-stent (free-flow) segment. The bare-stent configuration allows device implantation across the orifice of the left subclavian or common carotid artery while maintaining antegrade blood flow through these branch vessels.

The loaded delivery system is inserted most commonly through the femoral or iliac artery, tracks through the vasculature, and delivers the stent graft at the target site. Deployment of the proximal stent graft occurs as the outer sheath is withdrawn, initially exposing the proximal bare spring and first covered stent graft.

Data collection. The purpose of the data collection process was to assemble information about reports of misaligned deployment of the proximal portion of the Talent TSG device (also referred to as *bare spring flip* or *eversion*). Misaligned deployment was defined as occurring when the proximal stent apices of a deployed stent graft remained significantly nonparallel to the wall of the aorta after deployment was completed (Fig 1). Two levels of severity of misaligned deployment were defined. Severity level 1 was defined for cases of unresolved mild asymmetry or stent apex protrusion into the aortic wall without clinical effect, including no evidence of endoleak, graft narrowing or occlusion, perforation, or retrograde dissection. Severity level 2 was defined as unresolved misalignment or stent apex protrusion into the aortic wall with clinical effect, including evidence of endoleak, luminal narrowing of the endograft, perforation, or type A dissection.

The data collection included the follow-up of the population in the pivotal VALOR trial; direct surveys of centers within and outside of the United States (OUS), including participants in sponsor-investigator investigational device exemption (IDE) studies; a targeted literature search that included peer-reviewed medical journals and major medical

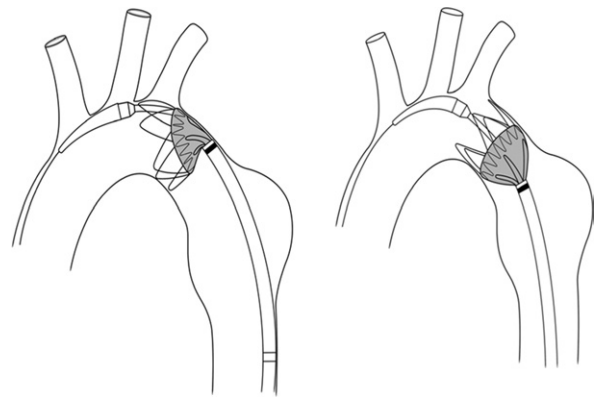


Fig 1. **Left,** Drawing depicts a case of misaligned opening of a Talent Thoracic Stent Graft. **Right,** Drawing depicts the pull-back procedure recommended in the Talent device instructions for use for mitigating a misaligned opening event.

association seminars and conferences; a review of all complaint files to Medtronic related to Talent TSG deployment in the thoracic aorta; and a reopening of field assurance research into relevant historical reports.

The survey of OUS centers involved a random sampling of qualifying facilities in Canada and Western Europe that were the highest volume users, defined as having used at least one Talent TSG device in the prior year. The survey plan required an initial sampling based on 3500 ordered stent grafts, and 96 hospital accounts were surveyed. The Medtronic OUS sales force and clinical research support staff were queried with a formal questionnaire regarding any knowledge of unreported instances of misaligned deployment.

Data updates from the seven US sponsor-investigator IDE studies of the Talent TSG were reviewed for incidents of misaligned deployment, aortic perforation, and type A retrograde aortic dissection, with screening for events that could be construed as including or related to these phenomena. The data updating included direct surveying of the principal investigators of the IDE studies.

A review was conducted to identify studies from recognized scientific publications in peer-reviewed journals. Articles were limited to those involving the treatment of human participants, with at least an abstract available in English. Bibliographies of the retrieved articles were searched for additional potentially relevant articles. The retrieved articles included clinical trial reports, review articles, retrospective analyses, experimental studies, and case reports.

The incidence was calculated using the total number of devices deployed because this is a device-specific event and not a patient-related event; for example, a single patient might experience this event twice if multiple pieces were used.

RESULTS

The data collection and review methods described identified 24 cases of misaligned deployment of the Talent

Table I. Adjudicated misaligned deployments of the Talent Thoracic Stent Graft by study or cohort

<i>Distribution cohort</i>	<i>Implants No.</i>	<i>Patients No.</i>	<i>Misalignment events No. (% of implanted)</i>
US feasibility studies	102	41	0
US VALOR studies	1056	359	0
US emergency/compassionate use	1226	316	0
US SI IDE studies ^a	1050 ^b	389	3 (0.29)
OUS commercial sales	15,041 ^c	5571 ^b	6 (0.03)
US commercial sales	1830 ^d	871	15 (0.81)
Total	20,305	7547	24 (0.1%)

OUS, Outside the United States; US SI IDE, United States sponsor-investigator investigational device exemption studies; VALOR, Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms.

^aAt the time, the Talent Thoracic Stent Graft was the subject of 7 US sponsor-investigator IDE studies.

^bThe number of implants was estimated on the basis of 2.7 devices per patient (used in the indexed procedure) experienced in the VALOR study.

^cApproximated, based on sales from January 2002 to November 8, 2006.

^dSales of the TALENT thoracic stent graft since commercial release in the US.

device (Table I). The literature search identified approximately 2500 references published through January 2009, of which 56 articles were determined to be relevant. Five of the retrieved articles included references to 10 cases of stent graft maldeployment: 3 with the Talent device (these are included in Table I) and 7 with other stent graft devices.¹⁰⁻¹⁴

Table II provides a summary of the 24 identified cases of misaligned deployment, according to the anatomic indications for stent graft treatment, the stent graft diameter, the location of the misaligned deployment, clinical sequelae, and presumed etiology. In four of these cases, the device was used to treat a type B aortic dissection (Fig 2). In one case, the implantation was used to treat a short length of proximal neck (<2 cm) used for the landing zone, and four other cases involved the use of stent grafts to treat ascending thoracic aorta or arch pathology. In one other patient, an abdominal aortic aneurysm was treated with a thoracic aortic device. The underlying pathology could not be determined for one event.

Overall, 15 of the 24 events (63%) occurred with use of large-diameter (≥ 40 mm) devices (Fig 3). No misaligned deployments were observed in devices <34 mm. Nine (38%) of the misaligned deployments occurred at the overlap of two stent grafts. Two events were treated intraoperatively with a second overlapping device in one and a snare repositioning in the other.

Adverse clinical sequelae were documented in relation to three cases. In one patient with a proximal neck <2 cm in length, a second stent was deployed to overlap the first graft, and then a third extension stent graft was incorporated into the second graft and was brought all the way to the celiac artery. The entire stent graft was then dilated with a 46-mm balloon. Despite these corrective measures, a

proximal type I endoleak was demonstrated on the postoperative computed tomography (CT) scan.

The second case involved treatment for a type B aortic dissection. The entry tear was inadvertently not covered during the initial deployment proximal to the left subclavian artery, and angiography revealed that three of the five proximal bare springs were "bent outward and folded over the stent graft," with notation of a type I endoleak in the false lumen and acute angulation of the graft in the aortic arch. A CT scan 1 week later revealed continued perfusion of the false lumen.

In the third patient, successful repositioning of the misaligned proximal bare spring was achieved through a transbrachial snare. The proximal bare spring located in the ascending aorta was used to treat an arch aneurysm after debranching. A retrograde type A dissection was reported at the 1-month follow-up CT scan, with no further intervention.

No intraoperative contrast extravasations or CT evidence of perforation was noted in any patients. There were no perioperative deaths or strokes, with a single report of paraplegia. The paraplegia was not directly related to the misaligned deployment because no hypotension or excess blood loss resulted from this event.

DISCUSSION

Collection of data on device malfunction is critically important, particularly as new users are exposed to these devices. These data are often underreported and difficult to collect, however, because of concerns about potential patient litigation, regulations protecting patient confidentiality, and the inconvenience of assembling and transmitting complete case data. We used multiple sources of data in an effort to analyze the true incidence and clinical significance of this event, including direct requests to physicians at centers inside and outside the United States who had experienced misalignment events.

We then reviewed all available clinical data, including correspondence from implanting physicians and sites, intraoperative arteriograms, operative dictations, postoperative CT scans and plain radiographs, and articles or presentations describing the incidence of these events. We believe that the thoroughness of this process allowed us to capture most of the misalignment events that have occurred to date.

Three thoracic stent grafts are currently approved for use in the United States. Each device is designed to deploy in a different fashion and has very specific recommendations for deployment. Additionally, the proximal end of each of these stent grafts differs, with unique fixation mechanisms. The TAG (W. L. Gore, Flagstaff, Ariz) was the only device available in the United States for almost 3 years, during which time most physicians became comfortable with its use. This device deploys by the use of a constraining expanded polytetrafluoroethylene cord that allows the stent graft to deploy from the middle of the graft outward. The deployment technique uses constant forward pressure on the guidewire to align the stent graft against the outer curvature of the aorta. However, this same technique

Table II. Summary of cases of misaligned deployment of the Talent Thoracic Stent Graft

Event	Treated etiology	Prox TSG diameter, mm	Location of misalignment	Adverse events
1	Indeterminate	Unknown	Unknown	None
2	TAA	42	Unknown	None
3	TAA	46	Unknown	None
4	Penetrating ulcer	36	LSA	None
5	TAA	34	LSA	None
6	Existing dissection	Unknown	LSA	Continued false lumen perfusion
7	Existing dissection	34	LSA	None
8	TAA. Off-label due to coverage of left common carotid artery	40	LCC	None
9	TAA. Off-label due to short length of proximal neck (<2 cm)	38	LSA	Type I endoleak
10	Ascending thoracic placement; total arch repair	46	Unknown	New, focal type A dissection with a tear just proximal to the sinotubular junction
11	TAA	46	LSA	None
12	Dissection of the thoracic aorta	44	Unknown	None
13	Dissection of the thoracic aorta	44	LCC	None
14	Ulcer at the innominate artery, ascending thoracic aorta	46	LCC	None
15	TAA	38	Unknown	None
16	TAA	42	LCC	None
17	TAA	44	LCC	None
18	TAA	34	Unknown	None
19	TAA	46	Unknown	None
20	TAA	46	Unknown	None
21	AAA	40	Unknown	None
22	TAA	40	Celiac	None
23	TAA	40	LSA	None
24	TAA	38	Unknown	None

AAA, Abdominal aortic aneurysm; LCC, left common carotid artery; LSA, left subclavian artery; TAA, thoracic aortic aneurysm; TSG, thoracic stent graft.

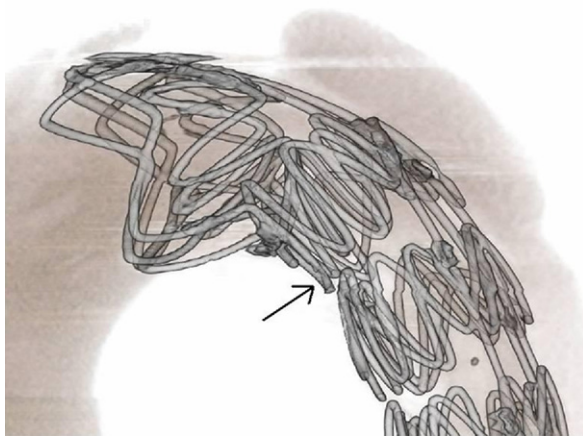


Fig 2. Misaligned deployment of the bare spring (*arrow*) is shown along the inner curvature of the aorta in a patient with dissection.

used to deploy the Talent TSG encourages the phenomenon of misaligned deployment. This is especially true in large-diameter aortas with short proximal necks. The continued outward pressure on the wire will force the stent graft to open in a nonparallel fashion so that the leading end may fold back on itself (Fig 1).

This deployment outcome may be avoided by allowing the Talent device to maintain the neutral centerline posi-

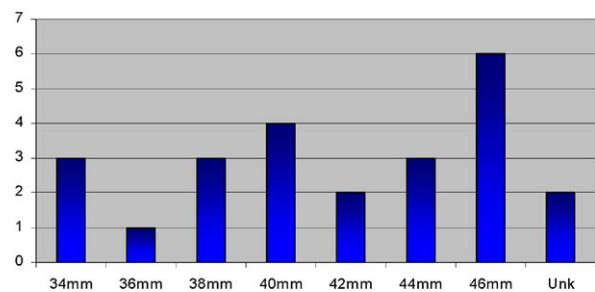


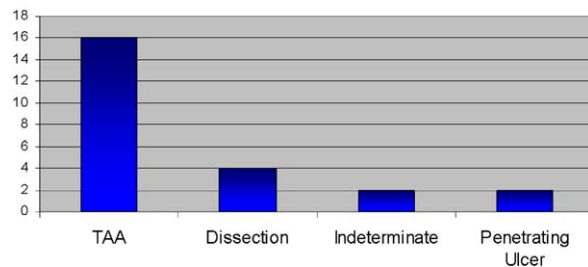
Fig 3. Stent graft diameters reported in the 24 patients with misaligned deployment.

tion during deployment. Almost all proximal type I endoleaks are related to failure of the graft to seal to the inner curvature of the aorta at the distal arch. The proximal bare springs of the Talent TSG are designed to overcome this possibility by hugging the inner curve of the distal arch. However, misaligned deployment can result when the Talent TSG is held away from the inner curvature of the aorta and pushed instead against the outer wall during deployment.

Misaligned deployment is often a predictable phenomenon. Two commonly observed causes for misaligned deployment of the Talent device involve (1) an uncorrected misaligned opening (failure of the stent graft to self-resolve

Table III. Techniques for avoiding misaligned deployment of the Talent Thoracic Stent Graft System

- Allow stent graft to maintain centerline position (neutral) during deployment
- Keep mean pressure <70 mm Hg
- Anti-impulse therapy for challenging neck anatomy (adenosine asystole, rapid ventricular pacing, controlled venous inflow occlusion)
- Avoid constant forward pressure on the guidewire
- Start deployment proximal to intended target and move back into position

**Fig 4.** Etiology treated in the 24 patients with misaligned deployment.

the misaligned opening or operator failure to correct the misaligned opening by retracting the stent graft distally, or both) and (2) the pushing proximally of a stent graft that is only partially opened (forcing the proximal edge of a partially deployed graft forward can force the graft to bend or buckle within the aorta).

Misaligned deployment is more likely to occur when the stent graft is used in larger-diameter proximal landing zones located in the curvature of the distal arch. Such a scenario can be avoided by selecting relatively healthy aortic necks with a minimum of 2-cm landing zone. With larger-diameter devices, a longer landing zone may be preferable, especially in areas of significant angulation. Table III describes additional techniques that can be used to prevent misaligned deployment in challenging proximal necks.

Misaligned deployment is a phenomenon that has been observed only rarely and infrequently produces adverse clinical sequelae. The phenomenon does not appear to have a propensity for a specific underlying thoracic pathology (degenerative aneurysms vs penetrating ulcers vs type B dissection; Fig 4). Of note, the Talent TSG is approved for dissection use OUS but remains an off-label indication in the United States.

One conclusion that can be drawn from the results of our extensive literature search is that misaligned deployment is not unique to the proximal bare spring component, since 9 of the 24 events (38%) occurred at the overlap zone between a proximal and distal components, involving the open-web proximal stent graft configuration that does not have any bare springs. However, misaligned deployment has been the focus of very few publications. Our literature search through January 2008 retrieved seven articles related

to devices other than the Talent and three related to the Talent.¹⁰⁻¹⁴

No instances of misaligned deployment were reported in the pivotal VALOR trial, which enrolled 195 patients between December 2003 and June 2005, despite the bare spring segment of the most proximally implanted Talent device being located in zone 1 or zone 2 of the aortic arch in 33.5% of the patients.⁹

Only three of the misaligned deployments found in this review had adverse clinical sequelae. One case resulted in a type I endoleak in a TAA patient, related to the misaligned deployment. The patient in another case continued to experience perfusion of the false lumen after implantation of the endograft for aortic dissection. The last patient sustained a delayed retrograde type A dissection. Our review determined that the continued perfusion of the false lumen might have been due to inappropriate landing-zone selection rather than to the misaligned deployment, but we had no additional information regarding clinical sequelae in this patient. In two of these cases with x-ray films available for review, we believe that the misaligned deployment might have been prevented by extending the graft more proximally, covering the left subclavian artery in order to land the device more proximally in undilated aorta.¹

We noted that nine of the events of misaligned deployment occurred at the overlap of two stent grafts, probably due to interaction of the overlapping and overlapped grafts during deployment. No clinical sequelae were reported in these cases, which involved the open-web proximal stent graft configuration rather than the bare spring.

In terms of adjudication of causes and potential treatment, we could not determine the exact cause for 3 of the 24 cases of misaligned deployment and therefore could not determine the appropriate steps necessary to prevent it. Our review of the remaining 21 events, however, suggested that the misaligned deployment could have been effectively prevented by introducing the stent graft proximal to the appropriate landing zone and then retracting the delivery system to the target location before complete stent graft deployment.

Among patients with complete data sets available, five of the cases were related to improper landing zone selection: insufficient landing zone in two and a landing zone proximal to the left carotid artery in three. Two other cases were related to inappropriate delivery technique: one case that could have been mitigated by retracting the delivery system before complete device deployment and one case that involved advancement of a partially deployed stent graft.

Once a misaligned deployment is noted, balloon dilatation inside the stent graft is not recommended to correct this phenomenon. On the contrary, balloon repositioning by means of inflation of an aortic balloon outside the thoracic device at the level of the everted stent ring may help reposition the misaligned deployment.

Study limitations. The main drawback is that this assessment is entirely retrospective on data collections not intended to investigate misalignment. The data sources

were derived from a commercial company and were often collected by sales and product persons employed by this company. There was no doctor or investigator accountability for the accuracy of procedure reporting of most of the cases. Hence, despite an aggressive effort to capture all misaligned deployment events, this report may represent an under reporting. Most misalignment events have no immediate adverse clinical sequel, so not all are reported or recognized. Because imaging studies were not yet available for most of the events reported in the postapproval phase of the data collection process, a complete analysis of the causes of those misalignment events has not yet been possible. In addition, no data are currently available on the long-term outcome of patients with these misaligned grafts.

CONCLUSION

Based on a thorough review of all reported cases of misaligned deployment of the Talent TSG, we believe that it is an unusual phenomenon that tends to occur in the context of specific well-defined circumstances and rarely has immediate clinical implications. It often occurs with the use of larger-diameter grafts placed in tortuous aortic anatomy. Attention to deployment technique along with proper patient selection, perioperative imaging, and case planning can help to identify the patients in whom misaligned deployment is more likely to occur and prepare physicians for using effective measures to prevent these events. Future device development is underway to prevent this phenomenon in the form of a "tip capture," which involves constriction of the proximal bare stent until the entire device is deployed.

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Submitted Jul 1, 2009; accepted Nov 2, 2009.

INVITED COMMENTARY

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The article by Kasirajan et al highlights misalignment of the Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, Calif). As they note in their article, misalignment can and does occur with all of the currently available thoracic stent graft systems. It is likely that this evaluation significantly underestimates the occurrence of this phenomenon, and it is clear that we do not have a real understanding of why this occurs in each instance.

Misalignment, as defined by a lack of alignment of the stent graft parallel to the walls of the aorta, occurs much more frequently than noted; however, confining the definition, as the authors have done, to "retroflexed" proximal stents, which could be considered severe misalignment, occurs much less frequently. There are several intriguing issues regarding the findings and several important points the authors note as well.

The incidence of this event appears to be much more frequent in the United States than in Europe, occurring in almost 2% of patients (1.7% per patient calculation) in the United States commercial sales. Even this incidence is probably under-representing the true incidence. In addition, although the authors note that this is more common to occur with larger graft sizes, without knowing the percentage of use of the larger devices, it is difficult to implicate

simply increased graft size as the issue. There is no information regarding the degree of over-sizing and no information regarding patient features alone, which may be responsible for these issues. Finally, although limited sequelae have been noted in these cases, the long-term events for these patients have not been defined, and it remains to be seen how individuals with these devices will fare, and in fact, how the devices themselves will fare when deployed in a manner that is completely outside the anatomic situation for which they were designed.

Significantly, the authors have pointed out a number of tips that can be used during deployment that can help to decrease the occurrence of this problem. Although it is important for any physician deploying implantable devices to understand how the device works and how the deployment system works, it is likely more important to understand how the device and its deployment mechanism fail and how this can be avoided or managed. The tips the authors have outlined here should be heeded by those using these devices, especially in tortuous aortic anatomy. Similar understanding of deployment mechanics and the failure modes of the deployment mechanics would be helpful to understand for all endovascular grafts, and it is only through publications such as this