

Variation in the shape and length of the branches of a thoracoabdominal aortic stent graft: Implications for the role of standard off-the-shelf components

Ki-Hyuk Park, MD,^a Jade S. Hiramoto, MD,^b Linda M. Reilly, MD,^b Matthew Sweet, MD,^b and Timothy A.M. Chuter, MD,^b *San Francisco, Calif*

Purpose: To describe variations in the shape, orientation, and length of the branches of multi-branched thoracoabdominal stent grafts.

Method: The branches were constructed in situ by attaching a covered stent (Fluency Plus Tracheobronchial Stent Graft; Bard Peripheral Vascular, Tempe, Ariz) to each of four caudally-oriented cuffs on custom-made stent grafts. Pre- and postoperative computed tomography (CT) scans of 38 consecutively treated patients were analyzed using a three-dimensional work station to give the orientation of celiac, superior mesenteric, and right renal and left renal orifices relative to the centerline of the aorta (planned cuff orientation [PCO]) and relative to the centerline of the stent graft (actual vessel orientation [AVO]). The orientation of each cuff (actual cuff orientation [ACO]) was also measured relative to the centerline of the stent graft. These values were used to assess the degree of stent graft malorientation (ACO-PCO), or cuff-to-artery misalignment (ACO-AVO), and combined with measurements of branch length to calculate the resulting lateral displacement (arc distance [AD]) between each cuff and its corresponding arterial orifice and the angle (longitudinal branch angulation [LBA]) between the long axis of the branch and the long axis of the aorta, all in the plane of the aortic surface.

Results: All 136 branches were inserted as intended. None has since migrated, disconnected, or kinked. In most cases, stent graft orientation was accurate, with a mean ACO-PCO of 18.4 + 12.1 degrees. Cuff-to-artery misalignment was correspondingly low, with a mean ACO-AVO of 19.8 + 14.0 degrees. More than 30 degrees of misalignment was present in 23.2% of branches, yet only 9% (n = 12) had an LBA of >30 degrees.

Conclusion: Moderate degrees of cuff-to-artery misalignment had no effect on the feasibility of multi-branched stent graft insertion. (J Vasc Surg 2010;51:572-6.)

Multi-branched endovascular repair of thoracoabdominal aneurysm (TAAA) is an emerging technique with great potential.¹⁻⁹ Until recently, all branched stent grafts were custom-made to reflect individual patient anatomy. However, customization, and the attendant delay in therapy, may not be necessary in every case.¹⁰ The self-expanding covered stents, which connect the cuffs of the stent graft with the visceral arterial branches of the aorta, can bend or overlap to varying degrees, creating branches of varying shape and length.²

This study examines the accuracy of stent graft deployment in a series of custom-made multi-branched stent

grafts, together with the effects on cuff-to-artery alignment, the feasibility of branch insertion, and branch morphology. The goal is to assess the extent to which intraoperative changes in branch morphology could potentially substitute for preoperative changes in stent graft design.

METHODS

The planning, manufacture, and insertion of a multi-branched stent graft. Multi-branched endovascular TAAA repair has already been described in articles spanning almost a decade.^{1,2,4,5} However, some aspects of stent graft design and implantation, relating to the causes and effects of branch misalignment, deserve emphasis here.

The stent grafts in this series all carried four caudally-oriented cuffs (Fig 1), which served as attachment points for the branches. The proximal end of each 18-mm-long cuff opened to the inside of the stent graft, and the distal end to the outside. Any catheter, or branch, exiting the outer end of the cuff passed in a caudal direction down the aorta on its way to the visceral artery orifice, curving clockwise or anti-clockwise, depending on the direction of cuff malorientation. The effects of cuff/artery misalignment are, therefore, manifest in both transverse and longitudinal planes.

From the Division of Vascular Surgery, Daegu-Catholic University,^a and the Division of Vascular Surgery, University of California San Francisco.^b

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Reprint requests: Tim Chuter, MD, Division of Vascular Surgery, UCSF, 400 Parnassus Ave, A-581, San Francisco, CA 94143 (e-mail: chutert@surgery.ucsf.edu).

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Fig 1. Photograph showing four caudally-oriented cuffs on a narrow (18-mm-wide) segment of the standard stent graft.

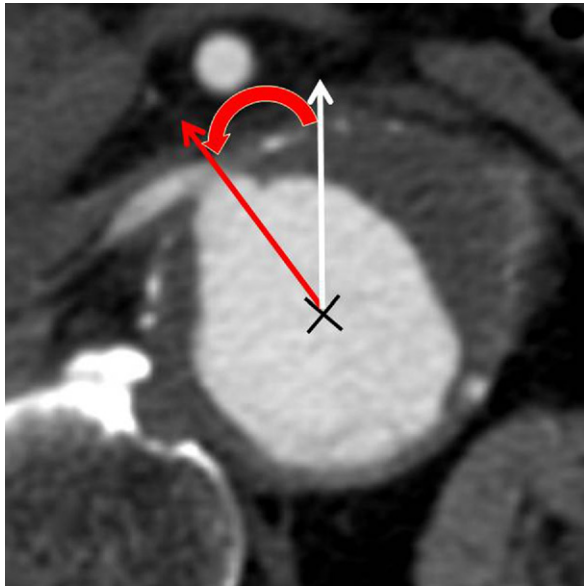


Fig 2. A transaxial representation of computed tomographic angiography (CTA), showing measurement of a planned cuff orientation (red arrow) relative to a line (white arrow) through the centerline of the aortic lumen.

These stent grafts were custom-made to reflect individual patient anatomy. One might, therefore, expect the orientation of each cuff on the stent graft to reflect the exact orientation of the target artery as shown on a preoperative computed tomographic angiography (CTA), but in practice, a precise match is rarely possible due to constraints on cuff position. Each cuff has to fit into one of 12 spaces between stent struts at 30-degree intervals around the surface of the stent graft. Moreover, adjacent 6 to 8 mm-wide cuffs have to be separated by at least 45 to 60 degrees for lack of space on the relatively narrow (18-mm) central cuff-bearing segment of the stent graft. A similar constraint applies to the longitudinal position of each cuff, which has to lie completely within the span of a single 18-mm-long stent.

Even greater disparities between planned cuff orientation and actual cuff orientation result from imperfect control over stent graft deployment. First, the planned cuff orientation assumes that the stent graft lies exactly on the centerline of the aorta, which is often not the case. Second, the axial orientation of the stent graft is sometimes difficult

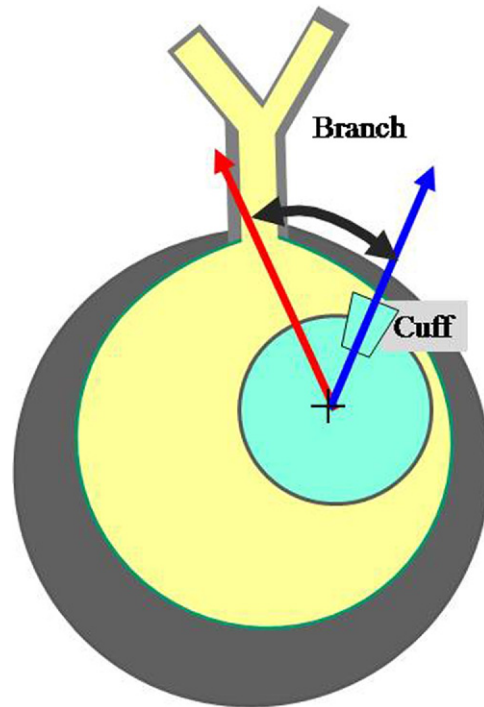


Fig 3. A diagram showing how the difference between actual cuff orientation (blue arrow) and actual vessel orientation (red arrow) projects to the surface of the aorta as an arc length (black arrow).

to control. The radio-opaque markers only provided reliable information on stent graft orientation after deployment, by which time any attempts at reorientation carry a risk of twisting the stent graft or dislodging mural thrombus.

Measurements. All measurements were made from reconstructed CTA images using the Aquarius three-dimensional (3D) work station (TeraRecon, Inc, v.3.7.0.7, San Mateo, Calif). We measured three angles, planned cuff orientation (PCO), actual cuff orientation (ACO), and actual vessel orientation (AVO), for the celiac artery (CA), superior mesenteric artery (SMA), and both left and right renal arteries (LRA and RRA). Each angle was measured on a single transaxial representation of 3D anatomy by degrees of rotation from the direct anterior (12 o'clock) orientation using the angle measurement function of the TeraRecon software. The PCO was measured relative to the center of

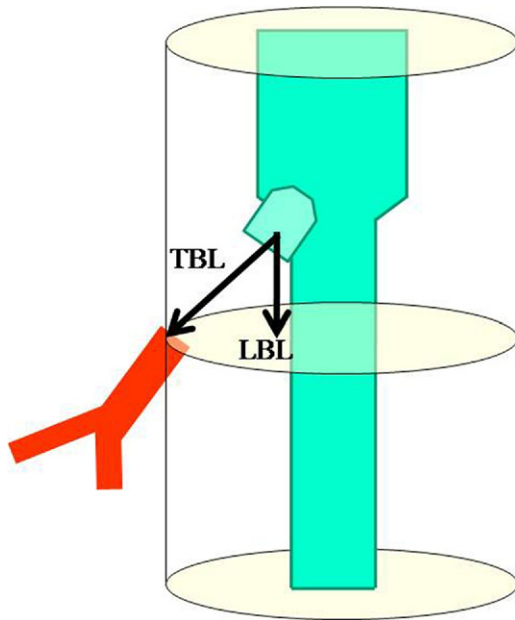


Fig 4. A diagram showing how true branch length (TBL) is measured as the distance between a marker at the outer end of the cuff and the orifice of the target artery, whereas longitudinal branch length (LBL) is measured as the axial displacement between these two landmarks.

the aortic lumen on a preoperative CTA (Fig 2). The other measurements (ACO and AVO) were made relative to the center of the cuff-bearing segment of the stent graft on the first postoperative CTA (Fig 3).

Analysis. In the absence of any real change in the axial orientation of visceral arterial orifices, PCO and AVO are essentially the same. The only difference between them is in the central reference point: PCO is measured relative to the center of the aorta, and AVO is measured relative to the center of the stent graft. The PCO was compared to ACO as a measure of deployment accuracy (ACO-PCO), whereas AVO was compared to ACO as a measure of cuff-to-artery alignment (ACO-AVO).

Branch length, the distance from a marker at the outer orifice of the cuff to the orifice of the visceral artery, was measured in two directions (Fig 4). True branch length (TBL) was the 3D length of the branch, derived using the centerline vessel length measuring function of the TeraRecon software. The longitudinal branch length (LBL) was the length of the branch in an axial direction, as displayed on a coronal, or sagittal, projection of the branch. This was the distance between the transaxial planes containing the proximal and distal ends of the branch. It was also the length one would see on fluoroscopy during deployment.

The angle ACO-AVO was projected out in a radial direction to the aortic surface to give an arc length (AL) between the angular positions of the cuff and the arterial orifice (Fig 2). The AL was used, in conjunction with LBL and BL, to calculate the longitudinal branch angle (LBA).

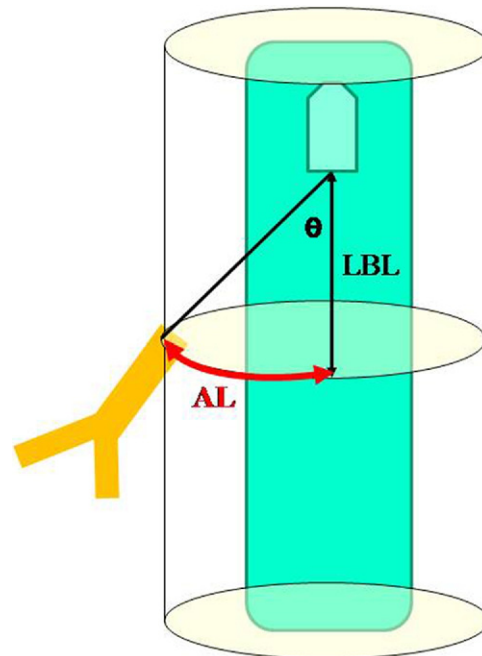


Fig 5. A diagram showing the longitudinal branch angle (LBA), the longitudinal branch length (LBL), and the arc length (AL).

As depicted in Fig 5, the LBA is the angle between the longitudinal orientation of the stent graft and the longitudinal orientation of the branch. A plot of AL on the x-axis against longitudinal branch length (LBL) on the y-axis (Fig 6) was used to display the relative positions of the cuffs, and visceral arteries projected outward onto the surface of the aorta.

All these calculations neglected z-plane effects on the grounds that the distance between the stent graft and the wall of the aorta was generally quite small, and the resulting branch angulation would be correspondingly small. Besides, z-plane effects lie beyond the scope of the current investigation because they are not addressed by the variable elements of a typical customized stent graft, which is designed to optimize the circumferential alignment of the cuffs relative to the visceral artery orifices, regardless of the radial displacement.

RESULTS

Between November 2005 and December 2008, 38 patients underwent multi-branched endovascular aortic aneurysm repair for TAAA using 136 caudally-oriented branches to 136 visceral arteries. All 136 were inserted as planned. None has since migrated, disconnected, or kinked.

The mean difference between the ACO-PCO cuff orientation is shown in the first column of the Table. The ACO-PCO was >30 degrees in 21.3% (29/136) of all branches and >45 degrees in 3.7% (5/136).

In most cases, the arc subtended by the transaxial angle between the cuff and the corresponding visceral orifice was

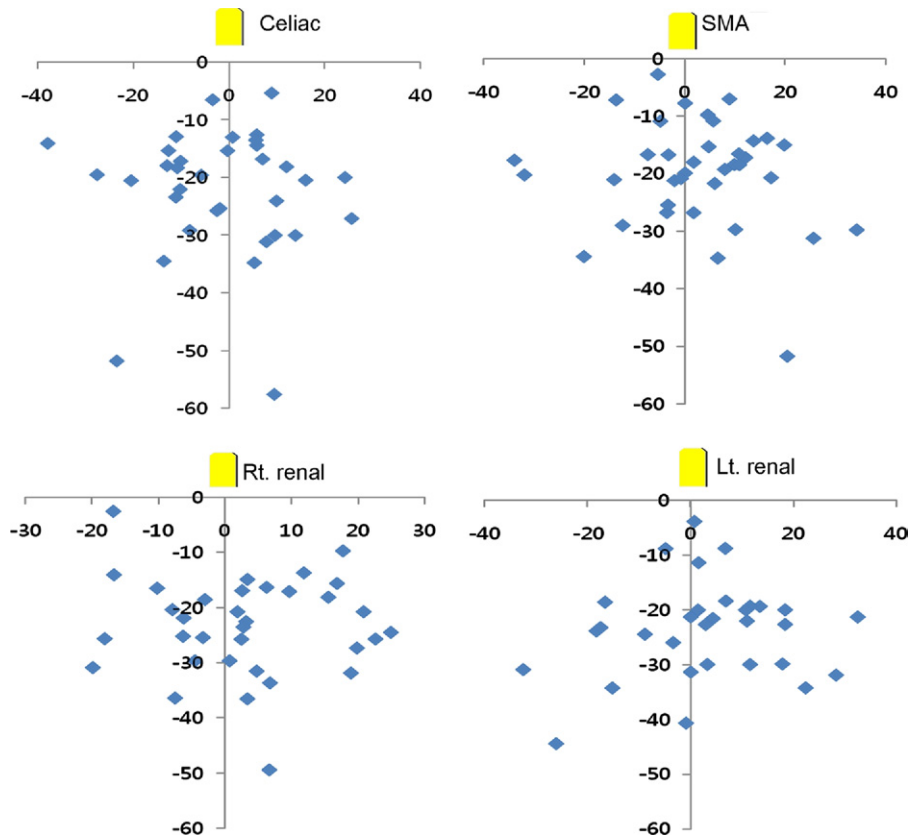


Fig 6. The positions of the arterial orifices relative to the corresponding cuffs.

Table. Branch length (mm) and various indices of branch angulation (degrees)

	<i>ACO-PCO</i> (mean + SD)	<i>ACO-AVO</i> (mean + SD)	<i>LBL (mm)</i>	<i>LBA</i> (mean + SD)
CA	18.1 + 11.6	18.9 + 11.6	22.2 + 10.9	15.3 + 11.0
SMA	18.2 + 11.4	20.3 + 15.5	19.9 + 9.4	16.2 + 12.2
RRA	16.9 + 12.3	17.9 + 13.4	23.9 + 8.9	14.4 + 14.4
LRA	20.5 + 13.4	21.2 + 15.8	23.7 + 8.9	13.0 + 8.6
All branches	18.4 + 12.1	19.8 + 14.0	22.3 + 9.6	14.8 + 11.7
Percent >30	21.3%	23.2%	17.2%	9.0%
Percent >45	3.7%	5.8%	3.0%	2.2%

ACO-PCO, Actual cuff orientation-planned cuff orientation; *ACO-AVO*, actual cuff orientation-actual vessel orientation; *LBL*, longitudinal branch length; *LBA*, longitudinal branch angle; *CA*, celiac artery; *SMA*, superior mesenteric artery; *RRA*, right renal artery; *LRA*, left renal artery.

ACO-PCO is a measure of the accuracy of stent graft orientation, *ACO-AVO* is a measure of branch angulation in a transaxial plane, and *LBA* is a measure of branch angulation in a longitudinal plane.

shorter than the corresponding branch of the stent graft. As a result, the degree of transaxial misalignment (*ACO-AVO*) was generally larger than the degree of *LBA*, as shown in the last two columns of the Table.

DISCUSSION

The findings of this study show how much cuff-to-artery misalignment the multi-branched stent graft can tolerate without compromising the repair. What this study cannot assess, in the absence of any failed attempts at

branch insertion, is what the technique will not tolerate and what extremes of misalignment are insurmountable. Nevertheless, given the observed range of variation in the relative positions of the visceral artery orifices¹⁰ and the demonstrated potential for intraoperative customization of branch morphology, the substitution of a standardized off-the-shelf stent grafts for the usual customized stent graft may be feasible in selected cases.

Clearly, one cannot advocate widespread use of an off-the-shelf stent graft based solely on observations in a

series of custom-made stent grafts. For one thing, the misalignment of a custom-made stent graft is caused solely by inaccurate deployment, whereas the misalignment of an off-the-shelf stent graft also results from a variable degree of mismatch between cuff distribution and visceral artery distribution.

An off-the-shelf alternative has several advantages, especially in patients with large, or symptomatic, aneurysms who cannot wait 2 months for a custom-made stent graft. The standardized off-the-shelf stent graft is also a better candidate for regulatory approval. The custom-made equivalent comes in many forms, and the need to stratify study results might make it difficult to achieve the necessary numbers. One cannot, for example, bundle branched stent grafts combining cuff-bearing stent grafts and caudally-oriented self-expanding covered stents with branched stent grafts combining fenestrated stent grafts and transversely-oriented, balloon-expanded, covered stents.^{3,6,7,9} Although both are modular multi-branched stent grafts, they perform quite differently. We believe axially-oriented cuffs increase the distance between the intercomponent attachment site and the target artery, allow greater variability in branch morphology, and have greater potential for off-the-shelf alternatives to customized manufacture.

AUTHOR CONTRIBUTIONS

Conception and design: JH, TC

Analysis and interpretation: JH, TC, KP, LR

Data collection: JH, KP, MS

Writing the article: KP, TC

Critical revision of the article: JH, LR, MS, TC

Final approval of the article: KP, JH, LR, MS, TC

Statistical analysis: JH, TC, KP, MS

Obtained funding: JH, TC

Overall responsibility: TC

REFERENCES

1. Chuter TA, Gordon RL, Reilly LM, Goodman JD, Messina LM. An endovascular system for thoracoabdominal aortic aneurysm repair. *J Endovasc Ther* 2001;8:25-33.
2. Chuter TA, Rapp JH, Hiramoto JS, Schneider DB, Howell B, Reilly LM. Endovascular treatment of thoracoabdominal aortic aneurysms. *J Vasc Surg* 2008;47:6-16.
3. Greenberg RK, Lytle B. Endovascular repair of thoracoabdominal aneurysms. *Circulation* 2008;117:2288-96.
4. Gilling-Smith GL, McWilliams RG, Scurr JR, Brennan JA, Fisher RK, Harris PL, Vallabhaneni SR. Wholly endovascular repair of thoracoabdominal aneurysm. *Br J Surg* 2008;95:703-8.
5. Imai M, Kimura T, Toma M, Saito N, Nakanoue T, Tadamura E, et al. Inoue stent-graft implantation for thoracoabdominal aortic aneurysm involving the visceral arteries. *Eur J Vasc Endovasc Surg* 2008;35:462-5.
6. Anderson JL, Adam DJ, Berce M, Hartley DE. Repair of thoracoabdominal aortic aneurysms with fenestrated and branched endovascular stent grafts. *J Vasc Surg* 2005;42:600-7.
7. Verhoeven EL, Tielliu IF, Bos WT, Zeebregts CJ. Present and future of branched stent grafts in thoraco-abdominal aortic aneurysm repair: a single-centre experience. *Eur J Vasc Endovasc Surg* 2009;38:155-61.
8. Ferreira M, Lanzotti L, Monteiro M. Branched devices for thoracoabdominal aneurysm repair: early experience. *J Vasc Surg* 2008;48(6 Suppl):30S-6S; discussion 36S.
9. Bicknell CD, Cheshire NJ, Riga CV, Bourke P, Wolfe JH, Gibbs RG, et al. Treatment of complex aneurysmal disease with fenestrated and branched stent grafts. *Eur J Vasc Endovasc Surg* 2009;37:175-81.
10. Sweet MP, Hiramoto JS, Park KH, Reilly LM, Chuter TA. A standardized multi-branched thoracoabdominal stent-graft for endovascular aneurysm repair. *J Endovasc Ther* 2009;16:359-64.

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