The transition from custom-made to standardized multibranched thoracoabdominal aortic stent grafts

Timothy A. M. Chuter, MD,[a] **Jade S. Hiramoto, MD,**[a] **Ki-Hyuk Park, MD,**[b] and **Linda M. Reilly, MD,**[a] *San Francisco, Calif; and Daegu, Korea*

Objective: **The purpose of this study was to compare the branch morphology and short-term outcome of endovascular aneurysm repair using multibranched thoracoabdominal custom-made stent grafts (CSGs) vs standard stent grafts (SSGs).**

Methods: **Data on patient demographics, aortic morphology, component use, and outcome were collected prospectively. Final branch length (cuff to target artery orifice) and branch angle (cuff orientation to target artery orientation) were determined using 3-D reconstruction of computed tomographic angiograms (CTAs).**

Results: **Between January 2008 and March 2010, 28 patients underwent endovascular aneurysm repair using 14 CSGs and 14 SSGs. Two patients were excluded from analysis: one patient in the CSG group had yet to undergo CTA, and one patient in the SSG group had crossed renal branches due to problems traversing a previously reconstructed aortic arch. All the stent grafts were implanted successfully. There were no perioperative deaths. There were no statistically significant differences between the CSG (n = 13) and SSG (n = 13) groups in terms of patient age (74.4 ± 7.9 years vs 73.5 ± 6.0 years), aneurysm diameter (66.1 ± 9.0 mm vs 71.2 ± 9.0 mm), operative time (311 ± 94 minutes vs 286 ± 57 minutes), fluoroscopy time (108 ± 43 minutes vs 101 ± 30 minutes), contrast volume (98 ± 39 minutes vs 91 ± 27 minutes), blood loss (458 ± 205 mL vs 433 ± 193 mL), mean branch angle (22.8 ± 19.0 degrees vs 22.0 ± 17.6 degrees), or branch length (25.3 ± 12.1 mm vs 23.4 ± 10.2 mm).**

Conclusion: **The substitution of SSG for CSG had no effect on the complexity of the procedure, the branch morphology, or the perioperative outcome. The availability of an off-the-shelf SSG will broaden the application of endovascular thoracoabdominal aortic aneurysm repair by eliminating manufacturing delays. (J Vasc Surg 2011;■■:■■■.)**

The first branched stent grafts for endovascular repair of thoracoabdominal aortic aneurysm (TAAA)[1] were inserted whole with their branches already attached. Because nothing could be done to change the length and position of any branch at the time of operation, each of these unibody stent grafts had to be custom-made to match individual patient anatomy. This constraint does not apply to modular multibranched stent grafts. Modular stent grafts are assembled in situ from multiple components, each of which can vary in shape, length, and overlap to match the arterial anatomy encountered at operation. The resulting variability in branch morphology amounts to a form of intraoperative customization, which has the potential to eliminate, or reduce, the need for preoperative customization.

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

Conflict of interest: Dr Chuter receives the following support from Cook Medical, the manufacturer of the multibranched thoracoabdominal stent graft: royalties from licensed patents, travel expenses, and research funding.

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

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

doi:10.1016/j.jvs.2011.03.005

Modular multibranched stent grafts vary widely according to the type of intercomponent connection and the type of covered stent used to construct the branches.[2-7] We use a tapered thoracoabdominal stent graft with multiple axially oriented cuffs that serve as the attachment sites for multiple self-expanding branches.[8,9] A decade of experience has shown that while malposition of a cuff relative to the corresponding visceral artery may affect the length and shape of the branch that connects them, it never prevents branch insertion or destabilizes branch position.[10] Moreover, most cases of TAAA eligible for treatment using a custom-made stent graft (CSG) would also have been eligible for treatment using a standard stent graft (SSG), given a sufficiently wide range of branch morphology.[11]

In December 2008, emboldened by the above findings, we began to substitute an SSG for CSGs, relying on the branches to accommodate any mismatch between cuff distribution and visceral artery distribution. The current study was undertaken to assess the effects of this evolution in the implantation procedure on the branch morphology and the short-term outcome.

METHODS

This study was performed under an investigational device exemption protocol approved by the Food & Drug Administration (FDA) and the institutional committee on human research. All patients gave informed consent. Data

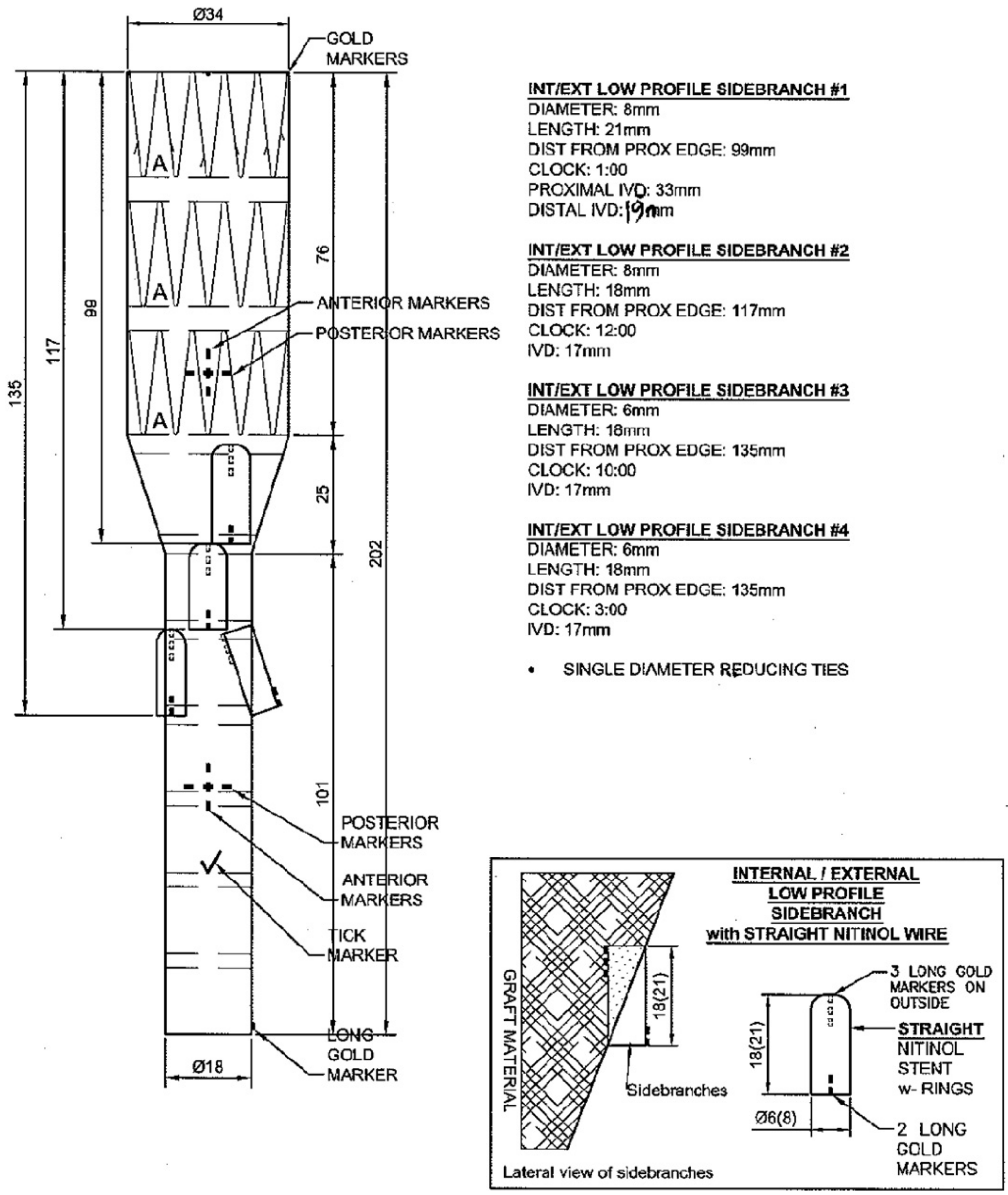

Fig 1. The cuff-bearing thoracoabdominal component.

on patient demographics, arterial anatomy, stent graft design, component use, stent graft implantation, and outcome were collected prospectively.

Patient selection. The main inclusion criteria for multibranched thoracoabdominal endovascular aneurysm repair were an estimated mortality rate from open repair >20%, aneurysm diameter >60 mm for men and 55 mm for women, and arterial anatomy suitable for treatment using a multibranched stent graft. This last criterion changed as the study progressed, the technique evolved, and the scope of endovascular repair expanded. In addition, many patients underwent preliminary operations such as iliofemoral bypass or renal stenting to eliminate anatomic obstacles to subsequent multibranched stent graft implantation.

The criteria by which some patients were selected for customized stent grafts while others were selected for the SSG also changed. In retrospect, there appear to have been three phases: at first, all repairs used CSGs; then there were some of each; and finally, all repairs used SSGs. The patterns of visceral artery anatomy among the patients in the second phase were examined closely to assess the extent to which this triage process represented a potential source of selection bias.

JOURNAL OF VASCULAR SURGERY
Volume ■■, Number ■

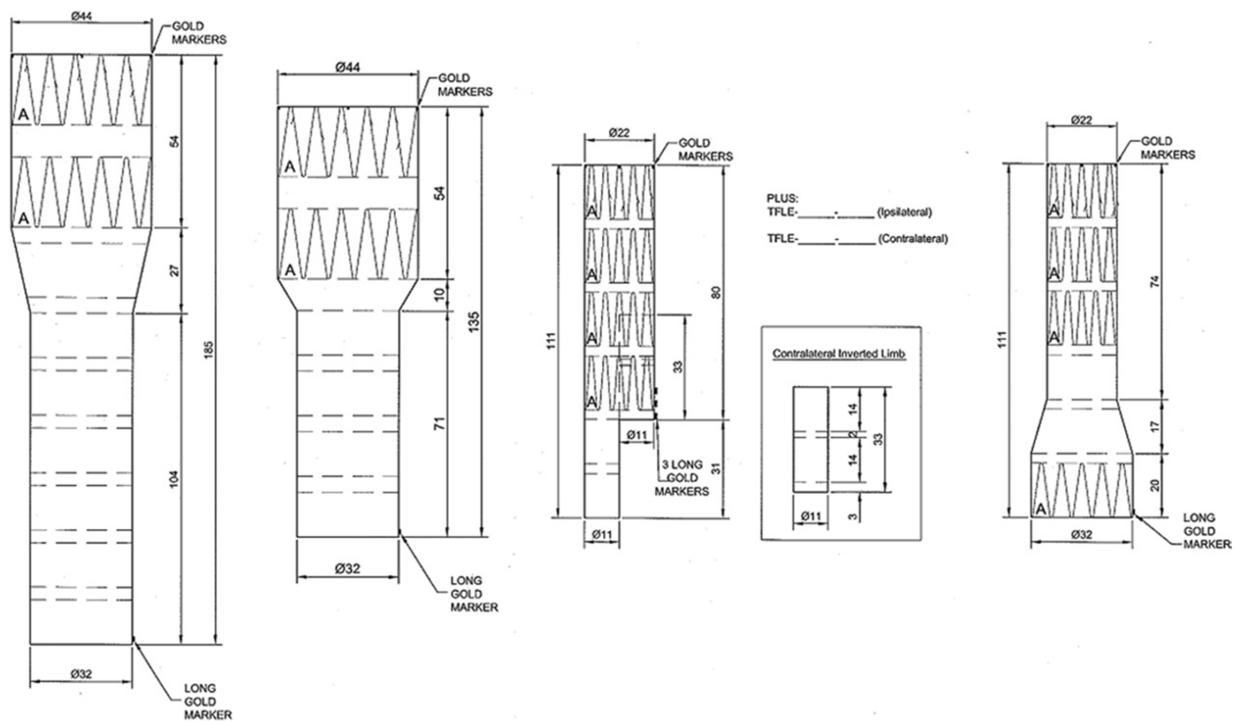

Fig 2. Four standard extensions: tapered proximal extensions of different lengths, a bifurcated distal extension, and a flared distal extension.

The stent graft. The multibranched thoracoabdominal stent graft has been described in detail elsewhere.[9-11] In brief, the trunk consists of a tapered stent graft with an exoskeleton of stainless steel z-stents and usually four short axially-oriented branches (cuffs), each of which serves as the attachment site for a self-expanding covered stent. None of the stent grafts in either arm of this study had fenestrations. Two of the CSGs had cranially oriented cuffs for branches to the renal arteries. All the other cuffs were caudally oriented. All the cuffs measured 18 mm in length and 6 mm (renal) or 8 mm (celiac and superior mesenteric) in diameter. The caudally oriented cuffs of the SSG were distributed over the surface of the tapered portion of the stent graft as illustrated in Fig 1. Each cuff had a cluster of three radio-opaque markers at its proximal (inner) end and two at its distal (outer) end.

Variation in the size and location of the proximal and distal aortic implantation sites was accommodated using a range of standard proximal and distal stent graft extensions: two tapered proximal extensions, one flared distal extension and one bifurcated distal extension (Fig 2). Many cases also used SSG components of the TX-2 or Zenith (Cook Medical Inc, Bloomington, Ind) abdominal aortic aneurysm (AAA) inventory. All these stent grafts had barbs projecting through the fabric around the proximal stent. Since stent graft insertion proceeded from proximal to distal, all the sites of overlap were secured by barbs and all the barbs traversed at least two layers of graft fabric.

With rare exceptions, the branches consisted of self-expanding polytetrafluoroethylene-covered Fluency (Bard Peripheral Vascular, Tempe, Ariz) stents, measuring 60 to 80 mm in length and 6 to 10 mm in diameter. Each covered stent had a lining of uncovered stent, usually a Wallstent (Boston Scientific, Natick, Mass) projecting from both ends.

Insertion procedure. The aortic and aortoiliac stent grafts were all inserted through surgically exposed femoral arteries or previously constructed bypass grafts originating on a common iliac artery. The cuff-bearing stent graft was deployed relative to the position of a catheter in one of the visceral arteries. The usual goal was to place the distal end of each cuff approximately 20 mm above, and never below, the proximal margin of the corresponding visceral artery orifice.

In the case of a CSG, the longitudinal spacing of the cuffs matched the longitudinal spacing of the visceral arteries, and any visceral target could be used as a reference point, because if one cuff was at the right level, they all were. In the case of an SSG, one of the visceral arteries was always a little cephalad (relative to the other visceral arteries) than the corresponding cuff (relative to the other cuffs). This was the artery at greatest risk of becoming inaccessible to catheterization if the corresponding cuff deployed caudal to its orifice. Therefore, this was the artery we used as the reference point when deploying the standard cuffed stent graft component.

The sequence of maneuvers has changed slightly as the study has progressed. Our current practice is to insert the aortic and aortoiliac stent grafts and close the primary femoral access site before proceeding with branch insertion.

Fig 3. An intraoperative photograph showing a 0.014-inch brachiofemoral guidewire (*white arrow*) and a micropuncture needle (*black arrow*) entering separate puncture sites in the valve of the left brachial sheath. Note the rubber loop through the handle of the clamp, which is applying traction to the brachial end of the wire.

The branches were all inserted through the surgically exposed left brachial artery. Two coaxial sheaths, one inside the other, and a fine (0.014-inch) brachiofemoral guidewire in between helped stabilize the route of access to the visceral arteries, mainly by preventing the formation of redundant loops at bends in the path of covered stent insertion such as the left subclavian orifice. This wire was tensioned using rubber loops (Fig 3). Since the brachiofemoral wire occupied the center of the valve of the left brachial sheath, the periphery of the valve was punctured to establish a second access site for branch insertion. The other end of the brachiofemoral wire exited through a small-caliber sheath in the contralateral femoral artery.

In CSG cases, the number of cuffs matched the number of target arteries, but in SSG cases, the number of cuffs sometimes exceeded the number of target arteries. After all the branches had been placed, the redundant cuff was occluded using an Amplatzer II plug (AGA Medical Corporation, Plymouth, Minn), as described by Ferreira et al.[12]

Branch morphology. The study protocol required contrast-enhanced computed tomography angiography (CTA) before repair and at 1 week, 1 month, 6 months, 12 months, and annually thereafter. Of these, only the 1-week CTA was consistently performed on a 64-slice scanner after a well-timed bolus of contrast. Contrast loads varied, depending mainly on postoperative renal function. A standalone workstation (TeraRecon, Santa Rosa, Calif) was used to generate multiple three-dimensional reconstructions of volumetric data sets from the first postoperative CTA. Branch length, vessel orientation, and cuff orientation were measured by a single observer.

Visceral artery orientation was measured relative to a line extending anteriorly from the centerline of the aorta (Fig 4). Cuff orientation was measured in a similar way, except the reference line extended anteriorly from the centerline of the stent graft (Fig 5). Deviation to the right of anterior was assigned a positive value, and deviation to the left was a negative value. Cuff orientation was subtracted from vessel orientation to give branch deviation. Therefore, clockwise rotation of a branch (as it descended from the cuff to the artery) had a positive value for branch deviation, whereas counterclockwise rotation had a negative value. However, subsequent analysis considered only the magnitude of branch deviation, not its direction (positive or negative). Otherwise, large deviations in one direction would have negated large deviations in the other direction. This method of measuring angular deviation focused on differences in the relative orientation of the cuff and target artery, not differences in their relative position, thereby excluding the effects of severable uncontrolled variables, such as the size and shape of the aneurysm and the position of the stent graft within the aortic lumen.

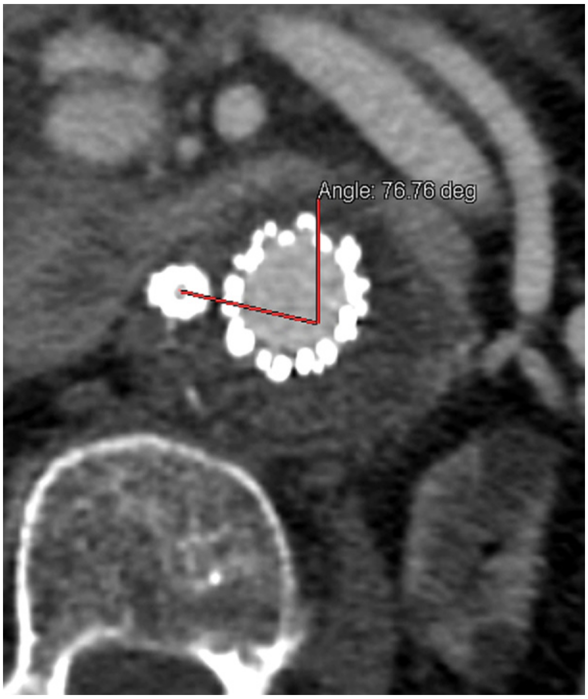

Fig 4. Measurement of the visceral orientation, relative to the center of the aorta.

The measurement of branch length was sometimes complicated by the multidirectional/multiplanar paths of some branches and by occasional difficulty in identifying the point at which the branch left the aorta to enter the visceral artery. Most measurements were made on multiplanar reconstructions using a pair of radio-opaque markers to show the outer end of the cuff and changes in the direction or caliber of the branch to show the point of exit from the aorta (Fig 6).

Statistical analyses. All statistical analyses were performed using Stata version 10.0 (StataCorp, College Station, Tex). Measured values are reported as percentages or

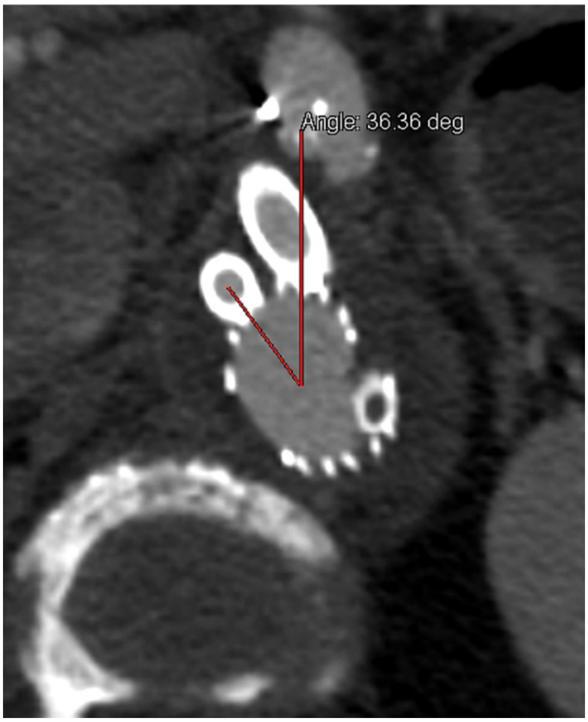

Fig 5. Measurement of the cuff orientation, relative to the center of the stent graft. Note the nonopacified (thrombosed) left renal cuff. This patient had an occluded left renal artery and needed only three of the four cuffs on a standard stent graft.

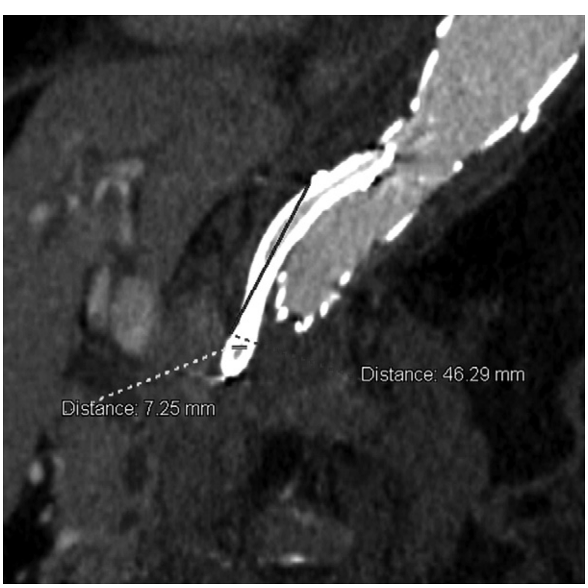

Fig 6. Measurement of distance (branch length) between two radio-opaque markers at the outer end of the cuff and a line drawn across the orifice of the renal artery.

means ± SD. The t test was used to compare the means of continuous variables, and the Pearson χ^2 and Fisher exact tests were used to compare categorical variables. A *P* value of ≤ .05 was considered statistically significant.

Fig 7. An intraoperative angiogram, showing crossed renal branches.

Table I. The number of custom-made and standard multibranched thoracoabdominal stent grafts used each year since January 2008

Year	*Custom*	*Standard*	*Total*
2008	10	1	11
2009	4 (3)	9 (8)	13 (11)
2010	0	4	4
Combined	14 (13)	14 (13)	28 (26)

In parentheses are the number of patients included in the current study.

RESULTS

Between January 2008 and March 2010, we performed endovascular aneurysm repair using multibranched thoracoabdominal stent grafts in a total of 28 patients, two of whom were excluded from the current analysis. One of the excluded patients had poor renal function, which precluded postoperative CTA. The other had the left renal branch attached to the right renal cuff and the right renal branch attached to the left renal cuff (Fig 7) due to problems traversing a previously reconstructed aortic arch. Of the remaining 26 patients (Table I), CSGs were used in 13 patients (11 men and two women), and SSGs were used in 13 patients (11 men and two women).

Two patients in the CSG group had aneurysmal degeneration of aortic dissections; all the others had atherosclerotic aneurysms. One patient in the SSG group underwent urgent repair for contained aneurysm rupture; all the other repairs were performed electively.

The first repair using an SSG was performed in December 2008 and the last repair using a CSG was performed in

Table II. Baseline characteristics of the two study groups (mean ± SD)

	Custom	*Standard*	P *value*
Age	74.4 (7.9)	73.5 (6.0)	.74
Baseline creatinine	1.4 (0.6)	1.3 (0.5)	.69
Aneurysm diameter	66.1 (9.4)	71.2 (7.4)	.13

Table III. Indicators of operative complexity (mean ± SD)

	Custom	*Standard*	P *value*
Operation time (minutes)	311 ± 94	286 ± 57	.43
Fluoroscopy time (minutes)	108 ± 43	101 ± 30	.64
Contrast volume (mL)	98 ± 39	91 ± 27	.50
Estimated blood loss (mL)	458 ± 205	433 ± 193	.76

July 2009. During this period of transition from an all-custom approach to an all-standard approach, four study patients were treated with CSGs: one patient had small (6 mm) superior mesenteric and celiac arteries and a right renal artery at the same level as the superior mesenteric artery; one patient had widely spaced arteries with 62 mm of aorta between the celiac artery and the renal arteries; one patient had a single renal artery; and one patient had a lumbar artery wide enough for its own branch from the stent graft.

Of the 13 patients in the CSG group, seven patients (54%) underwent staged repair, consisting of iliofemoral bypass in three patients, renal or visceral stents in four patients, carotid subclavian bypass in one patient, and fenestration of an interluminal septum in one patient. Of 13 patients in the SSG group, four patients (31%) underwent staged repair, consisting of iliofemoral bypass in all four patients. Everyone who underwent preparatory surgery during the period of the study also underwent stent graft implantation.

There were no significant differences between the custom and standard groups in mean age, mean preoperative creatinine, and mean aneurysm diameter (Table II). Nor were there any differences in the use of proximal extensions, bifurcated aortoiliac distal extensions, and flared aorto-aortic distal extensions. Mean operative time (minutes), fluoroscopy time (minutes), contrast volume (mL), and estimated blood loss (mL) were all higher in the custom group but not significantly so (Table III). The two groups were identical in the need for proximal extension (four of 13 patients), bifurcated aortoiliac distal extension (eight of 13 patients), and flared aortic distal extension (four of 13 patients).

All of the stent grafts were inserted as intended. There were no perioperative deaths, and no patients required dialysis in either group. One patient in the custom group suffered paraplegia together with cutaneous signs of micro-embolism. Postoperative CT scan showed two instances of type I endoleak in the SSG group. Both have now undergone catheter angiography. One was found to be leaking around the distal end of the superior mesenteric branch,

Table IV. Angular deviation in degrees (mean ± SD)

Branch	*Custom*	*Standard*	P *value*
CA			
Mean	14.5	21.6	.15
SD	13.3	10.7	
Maximum	45.6	36.7	
Minimum	0.4	4.6	
SMA			
Mean	25.6	15.3	.14
SD	18.6	15.2	
Maximum	53.5	44.5	
Minimum	1.3	1.2	
RRA			
Mean	25.3	21.3	.55
SD	19.9	13.7	
Maximum	63.4	52.9	
Minimum	4.0	5.0	
LRA			
Mean	26.1	30.7	.66
SD	23.0	26.4	
Maximum	76.4	77.0	
Minimum	0.6	0.47	
Combined			
Mean	22.8	22.0	.84
SD	19.0	17.6	
Maximum	76.4	77.0	
Minimum	0.4	0.47	

CA, Celiac artery; *LRA,* left renal artery; *RRA,* right renal artery; *SMA,* superior mesenteric artery.

which was not unusually long (21.8 mm). Although the other had no angiographically identifiable leaks, we took advantage of the opportunity to extend the superior mesenteric and celiac branches, which measured 20 mm and 16 mm, respectively. A single instance of type III endoleak occurred in the CSG group at the intercomponent junction of a bifurcated iliac stent graft. Treatment involved the insertion of an additional covered stent to channel all flow to the external iliac limb of the stent graft. One patient in the standard group underwent deliberate creation of a temporary (3 months) type Ib endoleak to restore lumbar perfusion and relieve symptoms of spinal ischemia.[13]

One of the two cranially oriented renal branches in the custom group was found to be occluded a year after implantation. All the other branches remain patent. There have been no cases of migration, component separation, secondary endoleak, aneurysm dilatation, or rupture in either group. Mean follow-up is 13.3 months in the standard group and 24.1 months in the custom group.

The analysis of branch morphology showed a wide range of values for both angular deviation (Table IV) and branch length (Table V). There were no significant differences between the SSG and CSG groups, or between different branches.

DISCUSSION

The transition from custom-made to standard components for multibranched endovascular aneurysm repair represents the last stage in a decade-long process of device evolution characterized by steadily increasing modularity.

Table V. Branch length in mm (mean ± SD)

Branch	*Custom*	*Standard*	P *value*
CA			
Mean	25.2	23.1	.70
SD	15.7	11.2	
Maximum	64.7	51.5	
Minimum	9.0	11.4	
SMA			
Mean	27.0	20.6	.10
SD	12.5	4.8	
Maximum	56.7	34.2	
Minimum	8.2	15.6	
RRA			
Mean	23.5	25.1	.75
SD	11.3	12.9	
Maximum	47.1	51.0	
Minimum	7.5	11.3	
LRA			
Mean	25.3	25.1	.94
SD	8.3	10.6	
Maximum	38.0	45.1	
Minimum	6.3	8.4	
Combined			
Mean	25.3	23.4	.41
SD	12.1	10.2	
Maximum	64.7	51.5	
Minimum	6.3	8.4	

CA, Celiac artery; *LRA,* left renal artery; *RRA,* right renal artery; *SMA,* superior mesenteric artery.

The original cuff-bearing thoracoabdominal stent graft varied widely in diameter, length, and shape, depending on the extent of the aneurysm. When we realized that long stent grafts were difficult to insert accurately, we began to use multiple short overlapping stent grafts, each positioned relative to a single anatomic feature. The proximal component targeted the proximal implantation site, the distal component targeted the distal implantation site, and the cuff-bearing component targeted the visceral arteries. We also realized that axially oriented branches, originating from axially oriented cuffs, are capable of accommodating disparities between cuff distribution and visceral artery distribution[10] and that a single stent graft design could be used to treat many patients.[11] Our response was to substitute SSGs for CSGs in a steadily increasing proportion of cases, as shown in Table I. We have not used a CSG since July 2009.

Based on the results of this study, the recent transition from an all-custom approach to an all-standard approach seems to have had no discernible effect on the implantation procedure, the short-term outcome, or the branch morphology. That is not to say that the two approaches are equivalent and interchangeable. As in all nonrandomized comparisons, this study suffers from potential selection bias, especially during the transition period when some patients received SSGs while others received CSGs. One has to wonder what would have happened if the patients who underwent repair using a CSG during the transition period had received instead an SSG and how this would have affected the findings of the study. However, any effect would have been limited by the small number of patients (n = 4) in this subgroup and the relatively minor differences between the CSG and an SSG in two of these cases. The other two patients had more unusual patterns of anatomy and more radically customized stent grafts. One had widely spaced arteries, and an SSG would have required very long renal artery branches. The other had a very large lumbar artery, and an SSG would have necessitated sacrifice of a potential route source of spinal perfusion.

The sequential nature of the two study groups is another potential source of bias. All 13 patients in the SSG group, but only four patients in the custom group, were treated in the past 2 years. Only patients in the SSG group could have benefitted from recent improvements in the technique of stent graft implantation. However, at this stage, significant changes in operative technique are unlikely. We have had many years to practice branched stent graft implantation, and, although we continue to discover new ways to improve the procedure, we also continue to discover new technical challenges. Although we saw some evidence of improving technique in the operative time, fluoroscopy time, contrast load, and blood loss, none of these differences reached statistical significance. However, this extraneous factor would probably have exerted a far greater effect had we included the entire series, starting in 2005.

This study focused on the short-term outcome, because most of the standard cases were too recent for long-term data. There is no reason to think that the branches of stent grafts in the standard group will behave any differently than the branches of stent grafts in the custom group, given the absence of any significant difference in branch morphology.

The lack of a difference in branch morphology between the custom and standard groups has several possible explanations. First, the system has a lot of noise: branch length and deviation vary widely, even in custom cases.[10] Second, the standardization of cuff distribution was accompanied by a shortening of the cuff-bearing stent graft, which probably increased the accuracy of cuff deployment. Third, the relative positions of the visceral branches generally vary much less than their absolute positions. If the celiac artery arises from the left side of the aorta, there is a good chance the superior mesenteric artery will too, in which case the SSG can be deployed with its cuffs rotated to the left. To put it another way, the relative positions of cuffs on the SSG are fixed, but one can still adjust their absolute positions by adjusting overall stent graft position and orientation.

One cannot deny that the widespread use of an SSG restricts the range of alternative branch attachment sites such as cranially oriented cuffs and fenestrations. We have in the past used cranially oriented cuffs, for example, in cases with cranially oriented renal arteries; but we stopped doing this more than 2 years ago, having concluded that cranially oriented renal branches fare poorly. They seem to be prone to occlusion, and, even when they remain patent, the size and function of the downstream kidney often declines. Out of more than 100 branches in the current study, the only one to occlude was a cranially oriented renal branch (of which there were only two). Furthermore, most renal arteries bend in a posterior direction more than they bend upward or downward, and stent-lined, self-expanding, caudally oriented branches seem to follow a curved path surprisingly well, unless the renal artery was implanted into the wall of a surgical graft at a prior operation and fixed in place by subsequent scarring.

Fenestrations have a theoretic advantage over cuffs when part of the aortic lumen is small enough to constrict the perigraft space. Nevertheless, it is now more than 4 years since we last used a fenestration as a branch attachment point in a thoracoabdominal stent graft. During this time, we have treated many patients in whom some part of the visceral aortic lumen was narrower than 25 mm. The most extreme example was a case of thoracoabdominal aneurysm complicating chronic type B dissection in which the true lumen measured only 12 mm × 25 mm preoperatively. Although fenestrations have been used successfully as attachment sites for the branches of a thoracoabdominal stent graft,[2-7] we prefer cuffs for two reasons. First, branch placement may be impossible in the presence of any mismatch between the position of a fenestration and the position of the target artery. Consequently, any attempt at standardized off-the-shelf use of a fenestrated stent graft[14] is limited to a several sizes fit most approach. Second, unlike the caudally oriented, stent re-enforced, self-expanding branch of a cuffed stent graft, the transversely oriented, balloon-expanded branch of a fenestrated stent graft cannot bear much load. The cuffed stent graft may be subject to large caudally directed forces, due to its taper, but we have never seen one migrate, and we have never seen its branches collapse or fall out, as branches sometimes do when attached to the narrow rim of a fenestration.[3]

Our initial exploration of the standardized approach was prompted by two patients: one died from rupture while waiting for a CSG; the other made a quick recovery after repair of a ruptured thoracoabdominal aortic aneurysm using a stent graft that had been made for someone else (with the approval of the institutional review board). A standard cuff-bearing stent graft is definitely a good thing to have in stock for off-the-shelf use in urgent cases, even if one does not adopt its wholesale use in elective cases. The standard multibranched stent graft has less obvious but equally important advantages relating to the manufacture, preclinical testing, clinical study, and regulatory approval of a device for widespread use. It is expensive to make and difficult to study a family of devices with multiple alternative features. Another custom-made device, the fenestrated stent graft, has been in a state of regulatory limbo for years. Meanwhile, surgeons in the United States, with patients in need of multibranched thoracoabdominal stent grafts, have little choice but to add cuffs and fenestrations themselves.[15]

AUTHOR CONTRIBUTIONS

Conception and design: TC, JH, LR
Analysis and interpretation: TC, JH, KP, LR
Data collection: TC, KP, LR
Writing the article: TC
Critical revision of the article: TC
Final approval of the article: TC, JH, LR
Statistical analysis: JH, LR
Obtained funding: TC
Overall responsibility: TC

REFERENCES

1. 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.
2. 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.
3. Verhoeven EL, Tielliu IF, Bos WT, Zeebregts CJ. Present and future of branched stent grafts in thoraco-abdominal aortic aneurysm repair: a single-center experience. Eur J Vasc Endovasc Surg 2009;38:155-61.
4. Ferreira M, Lanziotti L, Monteiro M. Branched devices for thoracoabdominal aneurysm repair: early experience. J Vasc Surg 2008;48(6 Suppl):30S-6S; discussion 36S.
5. Greenberg RK, Lytle B. Endovascular repair of thoracoabdominal aneurysms. Circulation 2008;117:2288-96.
6. Bicknell CD, Cheshire NJ, Riga CV, Bourke P, Wolfe JH, Gibbs RG, et al. Treatment of complex aneurismal disease with fenestrated and branched stent grafts. Eur J Vasc Endovasc Surg 2009;37:175-81.
7. Bakoyiannis CN, Economopoulos KP, Georgopoulos S, Klonaris C, Shialarou M, Kafeza M, et al. Fenestrated and branched endografts for the treatment of thoracoabdominal aortic aneurysms: a systematic review. J Endovasc Ther 2010;17:201-9.
8. 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.
9. 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.
10. Park KH, Hiramoto JS, Reilly LM, Sweet M, Chuter TA. 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. J Vasc Surg 2010;51:572-6.
11. 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.
12. Ferreira M, Monteiro M, Lanziotti L. How to occlude a side branch on a branched stent-graft during an endovascular thoracoabdominal aortic aneurysm repair. J Endovasc Ther 2009;16:454-6.
13. Reilly LM, Chuter TA. Reversal of fortune: induced endoleak to resolve neurological deficit after endovascular repair of thoracoabdominal aortic aneurysm. J Endovasc Ther 2010;17:21-9.
14. Arthurs ZM, Pannuccio G, Clair D. SS28. A 3-dimensional analysis of juxtarenal, pararenal, and suprarenal abdominal aortic aneurysms [Abstract]. J Vasc Surg 2010;51(6 Suppl):18S.
15. Oderich GS, Ricotta JJ 2nd. Modified fenestrated stent grafts: device design, modifications, implantation, and current applications. Perspect Vasc Surg Endovasc Ther 2009;21:157-67.

Submitted Dec 13, 2010; accepted Mar 1, 2011.

DISCUSSION

Dr R. Scott Mitchell (*Palo Alto, Calif*). Dr Chuter, congratulations on a great presentation of some truly groundbreaking research. Most of us doing these extensive operations realize that we exact a significant toll on these elderly patients, with probably fewer than 50%

of survivors returning to their previous lifestyle. We would all welcome a less-invasive alternative; which leads me to my questions.

1. What is the next step? Do you think this device is ready for a prospective trial aimed toward FDA approval?
2. Since you are one of the visionaries who are helping to shape the future, do you envision this as the treatment of choice which anatomic factors constitute the more challenging patient?
3. Last, chronic dissections with branch vessels arising from both true and false lumens have precluded endovascular methods. Do you foresee the means to manage these complex patients?

Again, my thanks to the Program Committee for allowing me to discuss this interesting manuscript.

Dr Timothy A. M. Chuter

1. The development of a standard stent graft facilitates both preclinical and clinical testing of device performance, which should speed progress toward FDA approval of branched stent graft technology. It is much harder to study a family of customized devices, as evidenced by the long delayed approval of the fenestrated Zenith stent graft.
2. Some patients are indeed easier to treat than others, and sometimes we need to do a little preparatory work in the form of an iliofemoral bypass, balloon angioplasty of a stenotic renal artery, or carotid-subclavian bypass. However, few patients lack the anatomic substrate for repair. It is not so much a question of who we *can* treat, but of who we *should* treat. For example, we still have too little long-term data to recommend multibranched endovascular repair in good-risk patients, especially those with type IV TAAAs for whom conventional open repair has low rates of death and paraplegia. We are also hesitant to recommend this form of repair in women who seem to have higher complication rates than men, although the recent development of a low-profile (18F) version of the system may help to eliminate the gender gap. Men, on the other, hand do well with multibranched thoracoabdominal endovascular repair, regardless of aneurysm extent. We have used the current technique to treat over 40 men without a single case of death or paraplegia. Putting all this together, endovascular repair is the preferred treatment for a sick old man with a large type II TAAA.
3. The multibranched endovascular repair of TAAA complicating chronic dissection is difficult for several reasons. First, branches that originate from the false lumen may be inaccessible from the true lumen where the stent graft lies. We have occasionally fenestrated the septum between one lumen and the other, but the necessary maneuvers were neither easy nor risk free. Second, a compressed true lumen has the potential to restrict the perigraft space and complicate branch insertion. Third, common iliac artery involvement makes it difficult to preserve both internal iliac arteries, which are important sources of collateral flow to the spine. Fourth, distal arch involvement makes it difficult to preserve the left subclavian artery, another important source of collateral flow to the spine. All of these problems are surmountable, but we believe that multibranched endovascular repair of a chronic thoracoabdominal aortic dissection is not yet ready for widespread use. Fortunately, isolated (unbranched) endovascular repair of the proximal descending thoracic aorta is often enough to induce false lumen thrombosis in the area where the aneurysm is widest, thereby preventing further dilatation and reducing the medium-term risk of rupture.