◆ ISES ENDOVASCULAR RESEARCH COMPETITION, SECOND PLACE ◆

A Standardized Multi-Branched Thoracoabdominal Stent-Graft for Endovascular Aneurysm Repair

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Purpose: To assess the feasibility of endovascular thoracoabdominal aortic aneurysm (TAAA) repair using a standard off-the-shelf multi-branched stent-graft.

Methods: The aortic anatomy of 66 patients (45 men; mean age 74 years, range 57–87) referred for endovascular repair of TAAA was measured using 3-dimensional reconstructed images from computed tomographic angiograms. In particular, the orientation and longitudinal position of the orifice of each celiac artery, right renal artery, and left renal artery were measured relative to the location of the superior mesenteric artery (SMA) orifice. Based on prior experience, branch insertion with a standard endograft was considered feasible under the following conditions: (1) no more than 4 indispensable (target) arteries to the abdominal viscera, (2) the celiac artery and SMA were 6 to 10 mm in diameter, (3) the renal arteries were 4 to 8 mm in diameter, (4) all target arteries were accessible from a transbrachial approach, (5) the distance between each cuff and the corresponding arterial orifice was $\leq$50 mm, and (6) the line between the cuff and the orifice deviated by $\leq 45^{\circ}$ from the long axis of the aorta.

Results: Seven (11%) of 66 patients violated conditions 1 through 4: 2 had target arteries that were either too wide or too narrow, 2 had $>$4 indispensable visceral or renal branches, and 3 patients had inaccessible upward directed renal artery branches. Three of the remaining 59 patients had renal arteries outside the boundaries defined by conditions 5 and 6 when the hypothetical stent-graft was positioned with its SMA cuff 25 mm proximal to the corresponding SMA orifice. However, if the stent-graft were deployed in a more caudal location, only 1 of these 3 renal arteries would have been out of range. Therefore, 58 (88%) of 66 patients met all the eligibility criteria for repair using the off-the-shelf stent-graft.

Conclusion: A standardized, off-the-shelf, multi-branched stent-graft is applicable in 88% of cases of TAAA that would otherwise have been treated using customized stent-grafts. The use of a pre-made stent-graft has the potential to eliminate long manufacturing delays and expand the scope of endovascular repair of TAAA.

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Thoracoabdominal aortic aneurysms (TAAA) are potentially lethal if left untreated.[1,2] Open surgical repair is complicated by the inaccessible location of the proximal abdominal aorta and by the presence of branches to the abdominal viscera. Morbidity and mortality rates vary according to the extent of the disease and the expertise of the surgeon.[3] Statewide audits provide a sobering picture of overall results, with 30-day mortality approaching 20%.[4]

Minimally-invasive endovascular repair of TAAA has the potential to reduce mortality and morbidity.[5–8] In this approach, a cuffed or fenestrated stent-graft forms the trunk and separately inserted covered stents become the branches of a multi-branched thoracoabdominal stent-graft. The central cuff-bearing stent-graft is often combined with various proximal and distal extensions. At present, this cuff-bearing segment is custom made so that the distribution of the cuffs reflects the distribution of the visceral arteries as closely as possible. However, experience has shown that precise customization may not be necessary. Variation in the length and orientation of the covered stent branch can accommodate disparities between the positions of the cuff and the corresponding visceral artery orifice.

The goals of this study were: (1) to determine the size and distribution of renal and visceral branches in patients with TAAA and (2) to determine the applicability of a standard off-the-shelf stent-graft among patients eligible for customized stent-graft repair.

METHODS

Study Design

Between November 2005 and October 2008, 66 patients (45 men; mean age 74 years, range 57–87) were considered suitable for endovascular repair using a customized multi-branched thoracoabdominal stent-graft based on radiographic assessment of the visceral artery anatomy. Demographic data were abstracted from the medical record (Table 1).

The study, which was approved by the Committee for Human Subjects Research at the University of California San Francisco, consisted of 2 parts. First, the orientation and longitudinal position of each celiac artery (CA), right renal artery (RRA), and left renal artery (LRA) were mapped relative to the position of the superior mesenteric artery (SMA). Second, the percentage of patients eligible for customized stent-graft repair who would qualify for treatment using a standard branched endograft under clinically derived boundary conditions was determined.

TABLE 1
Demographics and Branch Measurements

Demographics	
Mean age, y	74 (57–87)
Men	45 (68%)
Prior aortic operation	21 (33%)
Accessory renal artery	11 (17%)
TAAA type	
I	4 (6%)
II	20 (31%)
III	9 (14%)
IV	24 (38%)
Pararenal	7 (11%)
Median branch measurements	
Celiac artery	
Diameter, mm	8 (5–10)
Axis, °	15 (−45 to 60)
SMA	
Diameter, mm	8 (4–10)
Axis, °	0 (−30 to 60)
Right renal artery	
Diameter, mm	6 (4–7.5)
Axis, °	−60 (−100 to −20)
Left renal artery	
Diameter, mm	6 (4–9)
Axis, °	90 (15 to 140)

Continuous data are presented as the mean or median (range); categorical data are given as counts (percentages).
TAAA: thoracoabdominal aortic aneurysm, SMA: superior mesenteric artery.

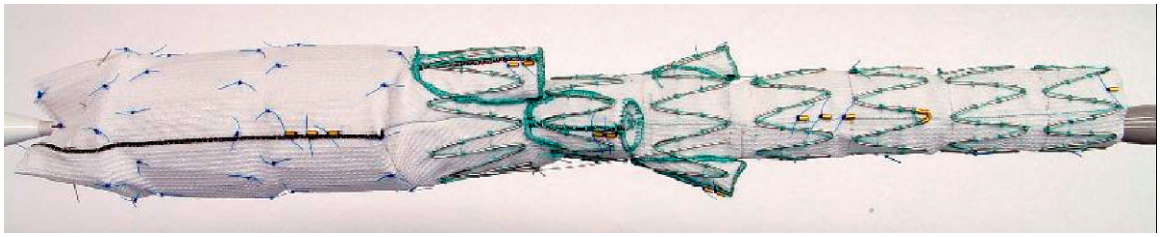

Figure 1 ◆ Photograph of the standard endograft.

Branch Measurements

All aneurysm measurements were made from reconstructed computed tomographic angiography (CTA) images using the Aquarius 3-dimensional (3D) work station (version 3.7.0.7; TeraRecon, Inc., San Mateo, CA, USA). As a 2D representation of a 3D object (similar to a map of the earth), the map of arterial distribution was constructed so that the aorta was opened longitudinally opposite the superior mesenteric artery (SMA) and laid flat. Each visceral orifice was assigned x and y coordinates representing the transverse and longitudinal distances between the location of the visceral artery orifice and the SMA orifice. The y-coordinate (cranial/caudal) was the longitudinal distance between the transaxial (orthogonal) plane containing the visceral artery and the transaxial (orthogonal) plane containing the SMA. The x-coordinate was the transverse distance (over the surface of the aorta) in the transaxial plane; it depended on the axial orientation of the arterial orifice and diameter of the aorta. No attempt was made to incorporate z-plane (radial distance) measurements into the analysis.

The longitudinal position (y-coordinate) of each visceral artery was measured from the proximal margin of its orifice. The longitudinal position (y-coordinate) of each cuff was measured from its distal (outer) end. The orientation of each branch was initially measured in degrees of rotation from anterior (12:00 o'clock) and subsequently expressed in degrees of rotation from the orientation of the SMA. The branch vessel diameters were measured at the anticipated site of covered stent implantation.

The off-the-shelf cuff-bearing stent-graft component (Cook Medical Inc., Brisbane, Australia) tapers from 34 mm proximally to 18 mm in the region of the visceral arteries (Fig. 1). Four 18-mm-long cylindrical cuffs are sewn into its surface. The proximal end of each cuff opens to the inside of the stent-graft and the distal end to the outside. The cuffs are therefore downward directed (caudally-oriented) in that the inner end of each cuff is accessible only from above. The cuffs occupy sequential stent levels, with the CA cuff one stent length above the SMA cuff and the SMA cuff one stent length above the renal artery cuffs. The CA cuff is 30° to the left of the SMA cuff, the RRA cuff is 60° to the right of the SMA cuff, and the LRA cuff is 90° to the left of the SMA cuff. The CA and SMA cuffs measure 8 mm and the renal cuffs measure 6 mm.

Based on prior experience with endovascular TAAA repair, branch insertion with a standard endograft was considered feasible under the following conditions: (1) there were no more than 4 indispensable (target) arteries to the abdominal viscera, (2) the CA and SMA were 6 to 10 mm in diameter, (3) the renal arteries were 4 to 8 mm in diameter, (4) all target arteries were accessible from a transbrachial approach, (5) the distance between each cuff and the corresponding arterial orifice was no greater than 50 mm, and (6) the line between the cuff and the orifice deviated by no more than 45° from the long axis of the aorta.

These criteria depended on several assumptions. While it would not be possible to add a cuff, unused cuffs could be closed using an occluder plug; hence, cases with fewer than 4 visceral arteries were included. The inferior mesenteric artery was considered dispensable. Small accessory renal arteries were ignored, unless the loss of downstream renal parenchyma would have caused a significant decline in renal function.

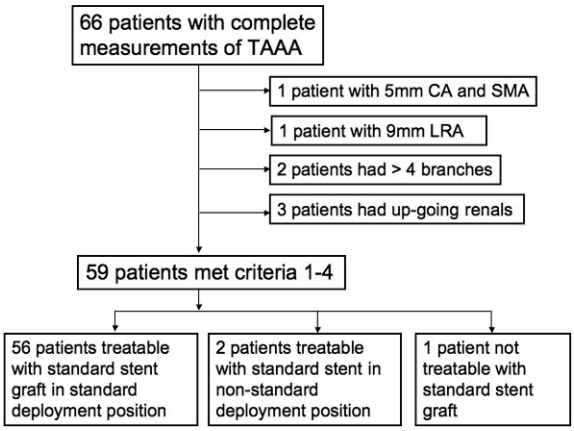

Figure 2 ◆ Flow diagram of the cohort with determination of applicability of the standardized multi-branched stent-graft.

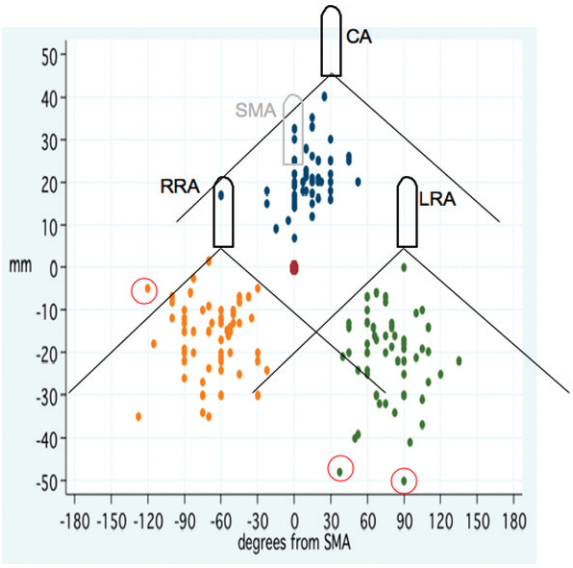

Figure 3 ◆ Scatter plot of branch position of the 59 patients meeting the initial 4 criteria with standard endograft overlaid. The angled lines indicate the boundary conditions as outlined in the text. The 3 branches that fall outside the boundary conditions are circled. CA: celiac artery, SMA: superior mesenteric artery, RRA: right renal artery, LRA: left renal artery.

All patients who met criteria 1 through 4 were included in further assessment of feasibility, in which arterial and cuff coordinates were plotted on the same grid to show their relative positions. Two lines radiating 50 mm in a caudal direction from each cuff, one 45° to the left of the long axis and the other 45° to the right, bounded 4 conical areas. All visceral artery orifices inside these conical areas met conditions 5 and 6 from the above list of feasibility criteria. This mode of analysis assumed that the SMA cuff was exactly 25 mm proximal to the SMA orifice in every case. A second method of analysis allowed the relative positions of the SMA cuff and orifice to vary (within the boundaries set by criteria 5 and 6), the goal being to bring the maximum number of visceral orifices within range of their corresponding cuffs.

RESULTS

The branch diameters were normally distributed, with only 5 (2%) of 251 branches deviating by >2 mm from the median value. The criteria relating to the number, shape, and size of the target arteries (criteria 1–4) were met by 59 (89%) of the 66 patients. One patient had a 5-mm-wide CA and a 5-mm-wide SMA, one patient had a 9-mm-wide single renal artery (the left), 2 patients had more than 4 target arteries, and 3 patients had upward directed renal arteries (Fig. 2). The criteria relating to the distribution of target arteries (criteria 4 and 5) were met by 56 to 58 of the remaining 59 patients, depending on the method of analysis. Figure 3 shows an overlay of cuff and visceral artery positions, with the SMA cuff located in a fixed position 25 mm above the SMA orifice. Based on this analysis, 3 patients had renal orifices outside the pre-specified boundaries. However, this constraint on deployment position is artificial; in practice, the stent-graft can be higher or lower, depending on the needs of the case. Individualized deployment, with the stent-graft in a more caudal location, would have brought the renal arteries within range in 2 of the 3 cases. Only one patient was considered completely unsuitable based on this assessment of visceral artery distribution.

Assuming a 45° limit on branch angulation and a 50-mm limit on branch length, 58 (88%) of the original 66 patients were eligible for treatment using the off-the-shelf version of the multi-branched stent-graft, while all 66 would have been eligible for treatment using customized versions of the multi-branched stent-graft.

TABLE 2
The Role of Boundary Conditions: A Comparison of Changes in Branch Length With Angulation

	Angle, °		
Length, cm	15°	30°	45°
5	18%	68%	85%
7.5	18%	71%	88%
10	18%	71%	88%

The numbers indicate the percentage of patients who could be treated with the standard graft at the stated boundary conditions.

Boundary Limits

Table 2 shows the effect on eligibility of varying the limits of branch angulation and branch length. Changes in the permissible degree of angulation had a more significant impact on the number of aneurysms that could be treated with the standard graft than changes in branch length. No added benefit was seen when branch length exceeded 75 mm.

DISCUSSION

Multi-branched endovascular stent-grafts have many implantation sites, each of which adds additional dimensions to the matrix of possible stent-graft sizes. No inventory of sizes could possibly accommodate all these sources of variation. Some form of customization is always needed. Our modular approach relies on mixing and matching multiple components to vary the shape and size of each part of the resulting multi-branched stent-graft. The off-the-shelf version of the cuff-bearing stent-graft does not eliminate customization; it substitutes intraoperative customization for preoperative customization. The boundary conditions applied in our assessment of versatility represent the limits of intraoperative customization.

The versatility of the off-the-shelf modular thoracoabdominal stent-graft depends on the orientation of the cuffs and the branches that originate from those cuffs. The current design of the standard multi-branched stent-graft allows each axially oriented branch to pass down and around the aorta for whatever distance and angle that the relative positions of the cuff and artery require. If the cuffs were oriented in a transaxial plane, the branches would have to take a more direct route to the corresponding arterial orifices, and the variability of length and orientation would be lost. The complete absence of cuffs, as in a fenestrated stent-graft, has a similar effect because every branch has to occupy a transaxial plane to optimize sealing at the narrow ring of inter-component contact.[9,10] Consequently, the distribution of fenestrations over the surface of the aortic stent-graft has to match the distribution of arterial branches over the surface of the aorta precisely, making customized manufacture an absolute requirement.

The limits we imposed on the length and angle of each branch of the stent-graft (the boundary conditions) are the product of experience with a customized version of the cuff-bearing component.[5] Short-term results have shown that a 45° angle between the longitudinal orientation of the aorta and the longitudinal orientation of the path from the cuff to the corresponding arterial orifice will not preclude branch insertion. Medium-term results have shown that a 5-cm-long branch is just as stable as a 2-cm-long branch. In a 3-year experience with 40 stent-grafts and more than 150 branches, we have never failed to insert a branch as intended and have never seen migration, component separation, or kinking.

This variability in branch orientation and position had two main sources: inaccurate deployment and the design constraints of cuffed stent-graft manufacture. An axially-oriented cuff fits into the sinusoidal spaces between stent struts only if it occupies the plane of the stent. A cuff cannot be moved up or down the stent-graft any less than one stent length (usually 18 mm). The precise matching of branch distribution is simply not feasible when the components are connected by axially-oriented cuffs. Most of the cuffs have to be a little higher or a little lower than one would like, even with customized manufacture.

The current analysis focuses on the effects of variations in cuff and arterial distribution because these are the primary impetus to customized manufacture. The most important aspect of the results relates the number of patients who would be considered treatable with the off-the-shelf components to the

number treatable with customized components. We showed that 88% of all patients eligible for treatment with a custom manufactured version of this stent-graft could have been treated with the off-the-shelf version.

Conclusion

Standardized off-the-shelf components have the potential to eliminate the delay of customized manufacture in most cases of TAAA. This would permit endovascular repair of very large or symptomatic aneurysms, for which the risk of rupture during an obligatory 2- to 3-month manufacturing delay is unacceptably high. Standardization also has the potential to simplify the systematic study of stent-graft performance, which will hopefully smooth the regulatory path to market access in the United States, where no such devices are currently available.

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