"Off-the-shelf" devices for complex aortic aneurysm repair

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Background: **Fenestrated devices currently require a 3- to 4-week manufacturing period before implantation; as such, there have been efforts to develop "off-the-shelf" (OTS) devices to reduce the time before definitive treatment can be accomplished. We examined all patients treated for complex aortic problems at our institution during the past 12 months to evaluate the suitability and early outcomes of the OTS devices vs commercially available endovascular options.**

Methods: **Between July 2012 and September 2013, patients undergoing aortic aneurysm repair were extracted from a prospectively managed aortic database. Two OTS devices, the Cook (Bloomington, Ind) p-Branch and the Endologix (Irvine, Calif) Ventana device, were being evaluated through clinical trials during this time frame. The custom Cook Zenith fenestrated endovascular (ZFEN) device was also available and approved by the U.S. Food and Drug Administration (FDA) during the study period.**

Results: **Of 224 aortic aneurysms treated at our institution during this period, there were a total of 85 patients with type IV thoracoabdominal aneurysms including juxtarenal aneurysms. Only 23 patients (27%) met anatomic criteria for OTS devices, with 16 patients having these investigational devices implanted. The major exclusion criterion for the p-Branch device was renal axial or circumferential position; the limiting factor for Ventana was infrasuperior mesenteric artery neck length restriction. Five of the patients who would have fit criteria for an OTS device had an FDA-approved (ZFEN) device implanted instead, and two patients opted for open repair as a result of follow-up requirements. An additional 25 patients received custom-designed (ZFEN) devices (n = 30; 35%), whereas 37 (44%) others did not meet criteria for any available endovascular device and were repaired with alternative management strategies. The mean age and maximal aortic diameter of the two cohorts (OTS and ZFEN) were 71.8 years and 72.7 years (P = NS) and 61.3 mm and 58.5 mm (P = NS), respectively. Technical success was 100%, with an overall 30-day mortality of 2.1% (n = 1, ZFEN). Major complications occurred in eight patients (17%; two OTS, six ZFEN).**

Conclusions: **Whereas OTS device strategies will reduce the waiting times for patients with complex aortic aneurysmal disease, a significant number will still require custom-made device repair until additional device designs become available. Early experience with OTS devices does not demonstrate any significant renal risks; however, the treatment numbers are low and should be interpreted with caution until larger confirmatory studies are published. Further studies comparing the outcomes of these techniques are required to establish the best approach to handle endovascular repair of complex aortic aneurysm. (J Vasc Surg 2014;60:579-84.)**

In April 2012, the U.S. Food and Drug Administration (FDA) granted approval for the Cook (Bloomington, Ind) Zenith fenestrated endovascular (ZFEN) graft, providing technology to the United States that has been routinely available in Europe and other parts of the world for the better part of 5 to 8 years. Critical factors in the use of this graft are procedural expertise, precise planning of the fenestration locations, and approximately 1 month of manufacturing time for the device. For asymptomatic elective aneurysms, this rarely creates an issue with respect to patient care. However, patients with symptomatic complex aortic aneurysms may be placed at increased risk of rupture if they are expected to wait 4 weeks before receiving definitive treatment. In an effort to address this shortcoming, "off-the-shelf" (OTS) device configurations have been designed. Initial data used to justify their configurations and design features were based on a subset of patients already accepted for Zenith fenestrated devices in Europe and predicted that 70% of patients may be suitable for this treatment modality.[1] In addition, Endologix (Irvine, Calif) has developed an alternative design based on no prior fenestrated device implant experience.[2] We report our experience using these two devices for all patients referred to our tertiary referral center for the evaluation and treatment of complex aortic aneurysms with respect to applicability and generalized outcomes.

METHODS

A prospectively maintained database of aortic procedures was analyzed for patients treated for aortic aneurysms during the period of July 2012 to September 2013, and data analysis was conducted through October 2013. Juxtarenal and pararenal aneurysms were categorized along with type IV thoracoabdominal aortic aneurysms (TAAAs) as was initially described with the categorization of TAAA.[3]

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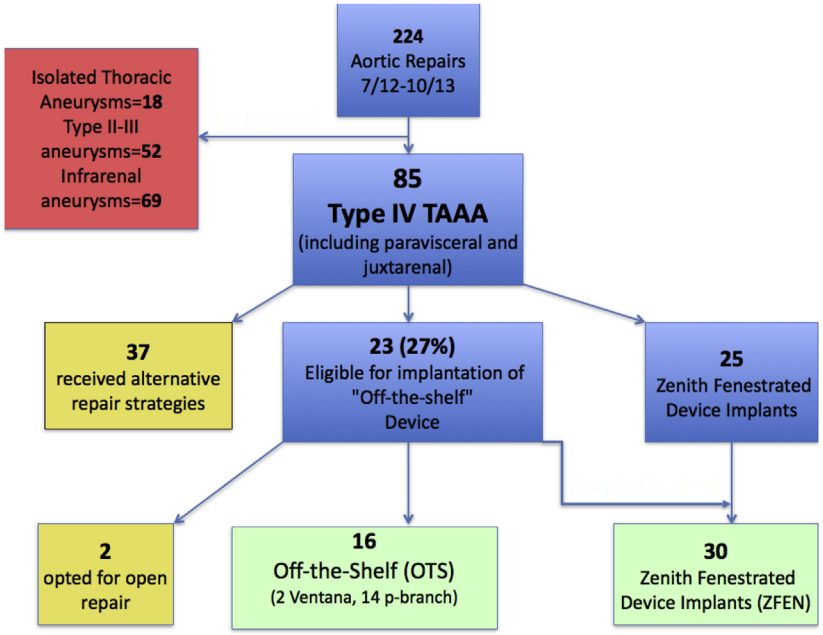

Fig. Flow chart showing mechanisms of repair of aneurysms presenting to University of North Carolina Hospitals from July 2012 to September 2013. *TAAA,* Thoracoabdominal aortic aneurysm; *zFEN,* Zenith fenestrated endovascular.

During a similar period, there were two devices undergoing clinical investigation through investigational device exemption trials: the Cook p-Branch and Endologix Ventana device. Patients' anatomic characteristics were examined to determine their suitability for each device. Those patients who were not candidates or chose not to enroll in the trials were offered alternative treatment strategies, including the commercially available ZFEN device if applicable on the basis of manufacturing guidelines. All measurements were completed on iNtuition software (version 4.4.8; TeraRecon, San Mateo, Calif) with centerline analysis, and results were assessed with SAS version 9.3 (SAS Institute, Cary, NC) statistical analysis software. Reporting standards for the Society for Vascular Surgery were used in the analysis. The study was approved by the institutional review board and the FDA (IDE#-G110101). Patients were exempted from informed consent for this report based on its retrospective design.

RESULTS

There were 224 aortic repairs completed during this 15-month period (Fig). This included type II to type IV TAAAs, thoracic dissections, acute traumatic aortic injuries, and infrarenal abdominal aortic aneurysms. Excluded from analysis were isolated thoracic lesions (n = 18), type II and type III TAAAs (n = 52), and infrarenal repairs (n = 69). The remaining 85 (38%) type IV TAAAs underwent repair with the following treatments. Twenty-three patients (27%) were eligible for OTS devices on the basis of their anatomy. However, only 16 patients underwent implantation of an OTS device because five chose an FDA-approved device and two chose open repair owing to follow-up requirements. Twenty-five additional patients received an FDA-approved ZFEN device, whereas 37 others (44%) did not meet criteria for any available endovascular device and were repaired with alternative management strategies, including but limited to hybrid and open repair, to protect against rupture.

Thirty-seven patients (44%) were excluded primarily for proximal extension of disease that would compromise the sealing zone with either a ZFEN or OTS device. Of the remaining 48 patients, exclusion for OTS devices (Table I) was a result of severe neck angulation (>60 degrees) in six patients (13%). Overall, only 21% (n = 10) of the patients met the instructions for use requirements for the Ventana device; patients were excluded mainly because of either an insufficient proximal sealing region below the superior mesenteric artery (SMA; <15 mm; n = 31; 65%) or renal anatomic criteria (n = 6; 13%). Conversely, the Zenith p-Branch device had a high exclusion because of renal axial or circumferential position (n = 29; 56%) and more commonly involved exclusion because of right renal artery position.

The 46 patients treated with either ZFEN or OTS devices represent the cohort analyzed for outcomes in this study, with 30 and 16 patients in the respective groups. Covered stents were routinely used for all fenestrations in the OTS devices and all ZFEN devices unless early bifurcations prevented their implantation to preserve perfusion. Self-expanding stents were used to manage branched vessel kinking at the distal aspect of balloon-expandable stents at the discretion of the implanting physician. The male-to-female ratio was approximately 3:1 (76%:24%), with a similar mean age (M:F, 72.2:73.1 years). Octogenarians represented 20% of the patients. The maximal aortic diameter based on orthogonal measurement was 59.5 mm. The

Table I. Reason for exclusion from off-the-shelf (OTS) devices for 48 patients undergoing complex aneurysm repair

Reason for exclusion[a]	*p-Branch (eligibility: 40%)*	*Ventana (eligibility: 21%)*
Neck angulation >60 degrees	13%	13%
Infra-SMA length <15 mm	0%	65%
Renal position	56%	13%

SMA, Superior mesenteric artery.
[a]Patients may have had more than one exclusion.

past medical history is listed in Table II and is notable for pre-existing renal insufficiency (17%), hypertension (85%), hypercholesterolemia (70%), and chronic obstructive pulmonary disease (59%).

Technical success for the entire cohort was 100%, with a 30-day mortality of 2.1% (n = 1; ZFEN) secondary to a ruptured hepatic artery aneurysm. No patient experienced renal failure. Worsening renal function was defined as an abnormal creatinine concentration with a sustained decrease in estimated glomerular filtration rate >30% for more than 3 months. Complications occurred in 18.7% of the OTS cohort and 16.7% of the ZFEN group and included pneumonia (n = 1) and worsening renal insufficiency (n = 2) secondary to a procedural renal artery dissection and renal emboli, both in the OTS cohort. In the ZFEN group, the complications included the hepatic artery aneurysm rupture as well as SMA dissection (n = 1), evacuation of groin hematoma (n = 1), retroperitoneal hematoma requiring exploration (n = 1), arrhythmia (n = 1), groin lymphatic leak (n = 1), and prolonged oxygen requirement (n = 1).

Mean follow-up for the cohort was 6.5 months, with one additional nonaneurysm-related mortality at 72 days. Device-related secondary interventions (Table III) occurred in 13% of the patients and did not differ between groups (P = NS). There were no type I and two type III endoleaks during the follow-up period. This included a renal artery fenestration endoleak treated with angioplasty and a misdiagnosed type III endoleak from a previous infrarenal device managed immediately after the index procedure with extension of the main aortic fenestrated component device.

There were three additional renal artery procedures, including one renal artery stent extension for distal renal artery kinking and treatment for severe renal stent stenosis/occlusion in two patients. Secondary interventions were attempted in both instances, with successful restoration of perfusion and maintenance of renal function in both patients. Imaging analysis demonstrated that these renal complications were likely the result of a procedure-related proximal stent kink (managed with tissue plasminogen activator and balloon angioplasty) and distal renal artery kinking (treated with a distal self-expanding stent extension). The additional secondary interventions included implantation of an SMA stent for extension in one scallop that was determined to be partially misaligned, SMA stent insertion for a dissection (n = 1) or proximal extension (n = 1), and embolizations for type II endoleaks in two patients. Nondevice-related secondary procedures (13%; n = 6) included two diagnostic arteriograms obtained for suspicion of visceral artery stenosis based on duplex surveillance, hypogastric aneurysm exclusion, treatment of an isolated intramural hematoma, carotid endarterectomy, and wound vacuum placement for control of a groin lymphatic leak.

Table II. Demographics and comorbid conditions of 46 patients undergoing endovascular repair with either an off-the-shelf (*OTS*) or Zenith fenestrated (*ZFEN*) device

	OTS (n = 16), No. (%)	*ZFEN (n = 30), No. (%)*	P *value*
Mean age ± SD, years	72 ± 6.4	73 ± 7.5	NS
Male	14 (87.5)	21 (70)	NS
CAD	7 (43.8)	13 (43.3)	NS
AFIB	2 (12.5)	4 (13.3)	NS
MI	4 (25)	7 (23.3)	NS
CHF	1 (6.3)	1 (3.3)	NS
CABG/PTCA	5 (31.3)	8 (26.7)	NS
Hypertension	13 (81.3)	26 (86.7)	NS
Hypercholesterolemia	10 (62.5)	22 (73.3)	NS
COPD	10 (62.5)	17 (56.7)	NS
Home oxygen	1 (6.3)	3 (10)	NS
CRI	3 (18.7)	5 (16.7)	NS
Dialysis	0	1 (3.3)	NS
Maximal orthogonal aortic diameter ± SD, mm	61.3 ± 16.1	58.5 ± 7.9	NS

AFIB, Atrial fibrillation; *CABG/PTCA,* coronary artery bypass grafting/percutaneous transluminal coronary angioplasty; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CRI,* chronic renal insufficiency; *MI,* myocardial infarction; *NS,* not significant; *SD,* standard deviation.

DISCUSSION

Complex aortic repair is gaining rapid acceptance in the United States since approval of the Zenith fenestrated device in April 2012, with more than 500 implants completed. There is an inherent delay in treatment, however, given the custom design nature of the device. Although it is relatively small, a 1-month delay in treatment of a 6-cm aneurysm would result in an estimated 0.5% to 1% mortality risk in this population, assuming yearly rupture risk of 6% to 12%.[4] This is not insignificant, however, when one considers that the treatment risk in most experienced hands is 0% to 5% for fenestrated repairs.[5] In an effort to reduce the overall risk as low as possible, OTS device designs have been proposed and are in early clinical trials. To reduce the mortality risk associated with a delay in treatment, however, the devices must be able to treat a significant portion of the patients for whom they are designed without significantly increasing the other risks associated with the repair.

Initial design efforts were based on patients being treated with a custom-designed ZFEN device[1] and estimated 70% applicability in the patient population. This, however, was based on a preselected group. In our tertiary

Table III. Secondary interventions among 46 patients undergoing endovascular repair with either an off-the-shelf (OTS) or Zenith fenestrated (ZFEN) device

Device related: 13%	
Type III repair, distal aortic extension: 1	3 days
Renal artery interventions: 4	
PTA for type III endoleak: 1	1.5 months
RA stent extension for kinking: 1	6 months
Severe stent stenosis/occlusion[a]: 2	1 month, 4 months
SMA stent for extension or malalignment: 2	5 months, 6 months
SMA stent extension for dissection: 1	3 hours
Type II endoleak embolization: 2	7 months, 12 months
Other: 13%	
Diagnostic visceral angiogram: 2	4 months, 9 months
Thoracic IMH treatment: 1	1 month
Hypogastric aneurysm exclusion: 1	2 months
Carotid endarterectomy: 1	7 months
Wound vacuum placement for control of lymphatic leak: 1	1 month

IMH, Intramural hematoma; *PTA,* percutaneous transluminal angioplasty; *RA,* renal artery; *SMA,* superior mesenteric artery.

[a]Primary procedure-related stent kinking; both treated with tissue plasminogen activator and angioplasty.

referral center for complex aneurysms, we evaluated all patients undergoing treatment at our institution. After excluding isolated thoracic aneurysms, type II and type III TAAAs, thoracic transection, and infrarenal pathologic processes, we were left with 85 potential candidates with type IV TAAAs, including pararenal and paravisceral subtypes. Analysis in this cohort resulted in an applicability percentage of 27%, which is vastly different from that originally reported. To aid in future device development, it is important to understand why exclusions occurred. For a device designed to treat paravisceral aneurysms (Zenith p-Branch), restrictions in the renal treatment zone occur because the design is based on a fixed SMA position. The specifics of the device have been previously reported.[6] This is an intentional design feature to ensure patency of the most critical visceral vessel, which is always treated with a covered stent through the fenestration. In contrast, a design that targets pararenal aneurysms (Endologix Ventana device) has significant limitations in treating more extensive proximal disease but liberates the strict anatomic criteria seen in a paravisceral device. Whereas each device had its design advantages and disadvantages, the p-Branch device can be adapted to more patients (40%) compared with the Ventana device (21%). These findings are similar to those reported by Oderich et al[7] and do not include patients presenting with type IV TAAAs in which the proximal extent of disease extended cranially above the level of the SMA (n = 37). This is a reflection of our conservative philosophy concerning endovascular management of patients with aortic disease. Our belief is that aortic enlargement as one progresses caudally down the aorta of more than 10% represents early aneurysmal disease, and this region should be avoided as the intended sealing zone in patients and the device implanted more proximally. This suggests that nearly half (43%; 37 of 85) of those patients diagnosed with type IV TAAAs would require devices that use a sealing region in the distal descending thoracic aorta and incorporate all four visceral vessels into the treatment strategy. This type of configuration is not currently available in the United States, even with custom-designed configurations. In addition, the only OFS solution in management of these patients as well as of patients with type II and type III TAAAs appears to be the standardized thoracic branched device described by Chuter.[8] This is not without controversy, however, as some individuals believe that upward-angled renal vessels can be problematic with caudally oriented branches.[9]

There has always been some concern that more extensive fenestrated endovascular aortic aneurysm repair would lead to a high incidence of complications. We experienced branched stent event rates in the OTS and ZFEN cohorts of 6.5% (3 of 46) and 5.9% (4 of 68), respectively. This is in the range of previously published reports (5%-25%)[8,10] and highlights the importance of close postoperative surveillance and attention to detail in this group of complex patients. Whereas we report no renal occlusive event in our custom fenestrated population, they have previously been reported.[9] The two renal occlusive events in the OTS cohort can be attributed to the learning curve of new devices. The severe stenosis that was observed at 1-month follow-up in the p-Branch device was procedure related. Review of the primary procedure revealed an anterior to posterior crushing of the left renal stent during insertion of the distal aortic component. This was treated with a short period of tissue plasminogen activator and redilation of the proximal renal stent. The patient's renal function has remained below his baseline at his 6-month follow-up visit. Since this event, we have changed our practice either routinely to re-balloon the renal stents at risk for crushing or to perform a completion 3D/Dyna-CTA (Siemens Medical Solutions, Erlangen, Germany) to confirm that no branched stent vessel issues exist before completing the primary procedure. In the second instance, renal occlusion occurred at 3 months in a patient with a Ventana device. Imaging analysis of the procedure and postoperative films suggested kinking at the distal end of the stent despite normal renal velocity criteria. Reintervention was again successful in re-establishing perfusion of the patient's renal function, with normalization of his renal function at 3 months.

Additional efforts at decreasing delays in treatment are forthcoming. Type II and type III TAAAs can potentially be managed with either an OTS four-vessel branched device or a hybrid device using both fenestrations and branches.[8,11] For pararenal and paravisceral subtypes, however, additional efforts may need to be targeted at additional configurations of devices. The p-Branch device is currently offered in two different options: one with the renal artery pivot fenestrations at the same level and the second with the left renal artery positioned lower. Exclusion analysis reveals that many right renal arteries are within 5 mm longitudinally of the base of the SMA. Adjustments

to the aortic stent component may be necessary to enable treatment of these patients.

Whereas the current Ventana device trial is on hold as of this writing, our data suggest that future design efforts should be targeted at improvement in the proximal sealing region in an attempt to treat paravisceral aneurysms because it appears to have a sufficient incorporation of renal vessel locations. Attempting to use OTS devices outside their intended instructions for use would definitely increase the eligibility of patients but in our opinion significantly increases the risk of device-related complications. Each of the aforementioned OTS devices differ in the intended proximal sealing regions. The p-Branch device is able to treat paravisceral aortic disease that extends to the base of the SMA by using a fenestration for the SMA and a scallop for the celiac artery. The Ventana device, on the other hand, needs a 15-mm infra-SMA neck length because of the large scallop configuration, limiting it to the treatment of pararenal aneurysms.

There were some limitations of this study. There were a limited number of patients who had OTS implants. Further studies with increased sample size and longer follow-up are needed to prove that these devices are safe. We evaluated only complex aneurysms referred to our center. Types of aneurysms referred may be different at other institutions and may have changed the results of our analysis. The implants were also done at an institution with vast experience in performing complex fenestrated endovascular repair. These results and the learning curve may be different in less experienced hands.

CONCLUSIONS

Whereas OTS device strategies will reduce the waiting times for patients with complex aortic aneurysmal disease, a significant number will still require either complex open or endovascular custom-made devices until additional device designs become available. Early experience with OTS devices does not demonstrate any significant renal risks; however, the treatment numbers are low and should be interpreted with caution until larger confirmatory studies are published. Further studies comparing the outcomes of these techniques are required to establish the best approach to handle endovascular repair of complex aortic aneurysm.

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AUTHOR CONTRIBUTIONS

Conception and design: MF, RV
Analysis and interpretation: MF, RV, WM
Data collection: MF, RV
Writing the article: MF, RV, WM
Critical revision of the article: MF, RV, WM
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DISCUSSION

Dr Adam W. Beck (*Gainesville, Fla*). Mark, thank you for an excellent presentation, and congratulations on a nice manuscript.

This study demonstrates the difficulties that device engineers and surgeons alike will have with expanding endovascular repair to the branched segments of the aorta, particularly with finding devices that do not have to be customized to the patient's individual anatomy.

Because of the wide variation in aneurysm location and the variability of the visceral vessel anatomy, Dr Farber has demonstrated that the current configurations of off-the-shelf (OTS) devices are unable to treat the majority of patients for whom they were designed. He has also demonstrated that when these devices do accommodate the patient's anatomy within their intended configuration, they do a nice job of providing an adequate repair in early follow-up.

Mark, I have two questions for you:

1. Where are these OTS devices going to go in the future? With the current technology used in these devices, do you think we will ever be able to reach the device companies' goal of treating 60% to 70% of patients?

2. As these devices allow you to move more proximal on the aorta, we are obviously worried about whether you can successfully complete the repair with regard to the visceral and renal anatomy, but what is your philosophy about what constitutes good aorta for a landing zone proximally? For example, with juxtarenal and suprarenal aneurysms, why not always use the distal thoracic aorta as a landing zone to ensure that you are providing a good zone of seal and fixation? Is there any downside to that?

Dr Mark A. Farber. Thanks, Adam. I think I will handle your second question first about the scallops. First a comment—not all scallops are the same. If you look at the Ventana device, it is a very large, wide scallop. It is what most of us would probably refer to as a double-wide scallop. It is on the order of 20+ mm in width and very deep. The current custom ZFEN device is a very narrow scallop of only 10 mm. We as well as others in the United States have changed our practice about how we manage very small scallops. They can be malaligned, needing a superior mesenteric artery stent, which is not the case for double-wide scallops. So we have to be careful about saying scallops are all the same. I think all of us know that as you become more comfortable doing these procedures moving up into the SMA and the celiac, it does not add significant risk. It does not add that much more time, and it is more about selecting the right patient. If you take some of the early data from the Cleveland Clinic, their failures were in patients who already had some minor dilation of the aortic neck in the paravisceral section at the SMA, and so we have used centerline flow analysis to plan; and whenever any significant change is seen, 10% or posterior disease in the aorta, we move our sealing zone up into the distal thoracic aorta to try to get away from that. The problem is access to devices that accomplish this, and if people try to shoehorn a device in a problem area, it is going to be more prone to fail. I am sure your institution and many referral institutions are the same. We see failed infrarenal devices, and if you go back to the original imaging, the device was put in an already diseased infrarenal neck, and that goes on to dilate and fail. I think from that standpoint and to where we are going in the future, it ties into your first question. We will move up, but we will move up when the devices are available, and doing a four-vessel fenestration, thereby giving yourself a 3-cm landing zone above the celiac, means that any future repair is going to be much easier because you can attach that into a tube graft.

Your last question, what is the FDA thinking? Well, I do not really know what the FDA is thinking. To say that it will let us do these OTS devices I think is a little stretch. They are done under investigational device exemption protocols, and I think we do have to look at outcomes. If we take OTS devices that have a limitation where you can put the renals and the SMA and say "we are going to cheat on that and maybe we will move it here" for an urgent or emergent case and we cannot wait for a custom-designed device to fit the patient specifically, then we have to assess the risks. If the risks are that the patient has one renal and the renal does not fit and that the patient is going to go into renal failure if the device does not fit, then I think that is a lot different from someone who says "well, there is an accessory renal and we are going to lose part of a kidney function, not the whole function, and we can deal with that." I think this is going to be up to the individuals about how to use it. If we use the devices inappropriately, eventually it is going to ultimately hurt us in the outcome. I think most of us believe that custom devices are still going to play a role, and in our practice I think it is probably going to be 50/50 custom devices vs OTS devices, unless we can get more designs to fit more people, then that may increase to 70%. The original 70% estimate on applicability was based only on devices that were ordered out of Tim Resch's group in Sweden for a custom device. So he already took out the pararenal, the paravessels, and unusual cases. What we tried to look at is what comes to our practice because our goal is to send a message to the corporations that this is what we need to treat more patients in an off-the-shelf fashion. We have to look at the renals closely, of which the right renal artery is the most problematic. It actually comes up very high, and for the p-Branch device, that interferes with the SMA stent, and then the Ventana device does not extend high enough into the aorta because of that wide scallop. So the message will be different per device as to what needs to be modified to treat more patients, but that is really what we are after.