A novel endovascular debranching technique using physician-assembled endografts for repair of thoracoabdominal aneurysms

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Objective: **The objective of this study was to demonstrate a technique that uses physician-assembled endografts to make use of the benefits of parallel grafts while also providing for circumferential seal and fixation in repair of thoracoabdominal aneurysms in inoperable patients.**
Methods: **A single-center all-comers retrospective analysis of 14 patients was performed that looked at the early outcomes of patients treated for thoracoabdominal aneurysms. Three Crawford type II, four type III, four type IV, and three type V thoracoabdominal aneurysms were treated. Contrast material, fluoroscopy time, length of stay, clinical success, and technical success were measured.**
Results: **There was no in-hospital, 30-day, or 6-month mortality. We found two type III endoleaks in the early design. One required coil embolization. Average volume of contrast material and average fluoroscopy time were 76.9 mL and 119.1 minutes, respectively. Average length of stay was 10.5 days, and average procedure time was 251.2 minutes. Clinical success was observed in 78.6% of patients to date, and technical success was observed in 85.7% of patients.**
Conclusions: **Short-term results show that this approach is safe. The device can be safely implanted, is off-the-shelf, and can treat each of the Crawford thoracoabdominal aneurysm types. Finally, the assembly of off-the-shelf components may shorten the regulatory path for this physician-assembled endograft. (J Vasc Surg 2014;60:1177-85.)**

Open repair of thoracoabdominal aortic aneurysms (TAAAs), especially in patients with pre-existing comorbidities, is fraught with complications. A meta-analysis of 7833 open repairs of TAAAs from 2000 to 2010 found a 30-day mortality rate of 7%, in-hospital mortality rate of 10%, spinal cord ischemia rate of 7.5%, renal failure rate of 19%, and pulmonary dysfunction rate of 36%.[1] Predictors of adverse events after elective open repair based on pre-existing comorbidities have been established. Advanced age (>70 years),[2-5] respiratory disease,[4] renal insufficiency,[6] coronary artery disease,[2,5] symptomatic aneurysms, extent I and II aneurysms,[7-10] and diabetes[11] are reported to be predictors of 30-day mortality. Cardiac function,[12] extent I and II aneurysms,[8,13-15] symptomatic cases,[15] and diabetes[11] are reported to be predictors of paraplegia.

The outcomes reported are in a low- to moderate-risk patient population. It is a logical extension to assume that the outcomes in moderate- to high-risk patients would be worse, so patients deemed to be at moderate to high risk on the basis of pre-existing comorbidities or emergent status need an off-the-shelf technique for endovascular repair. Whereas good results have been achieved with branched and fenestrated devices, the custom build and manufacture lead times limit the availability, so these devices are not available for all patients with emergent status. Two clever sandwich techniques have been proposed to care for patients with an off-the-shelf approach. The first used dual bifurcated infrarenal grafts in the descending thoracic aorta.[16] The second used three or four bridging stents sandwiched with a thoracic graft in the descending thoracic aorta.[17] Although these sandwich techniques can be used off-the-shelf, they do not provide for circumferential seal and fixation, and long-term durability is in question.

Here we propose a technique that requires only one measurement for the main body grafts: the proximal seal zone diameter. It also provides for circumferential seal and fixation at the seal zone and each of the modular junctions in the assembly while still making use of the advantages of parallel grafts. In the period during which these 14 patients were treated, the closest investigational site for the Cook t-Branch was roughly 1000 miles away from our center. The travel required for that investigational device is not realistic. Because of this, several of the patients were not candidates. Of our 14 patients, none were candidates for a custom fenestrated device because none of them

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Author conflict of interest: P.W.K.'s institution has filed for patents associated with the device discussed, and the patents are currently pending. If the patents are awarded, there is a possibility that P.W.K. could license the device to manufacturing companies. The invention is P.W.K.'s, and none of the inventions were made by industry. P.W.K. has not received any financial compensation to date from any company for use of the device.
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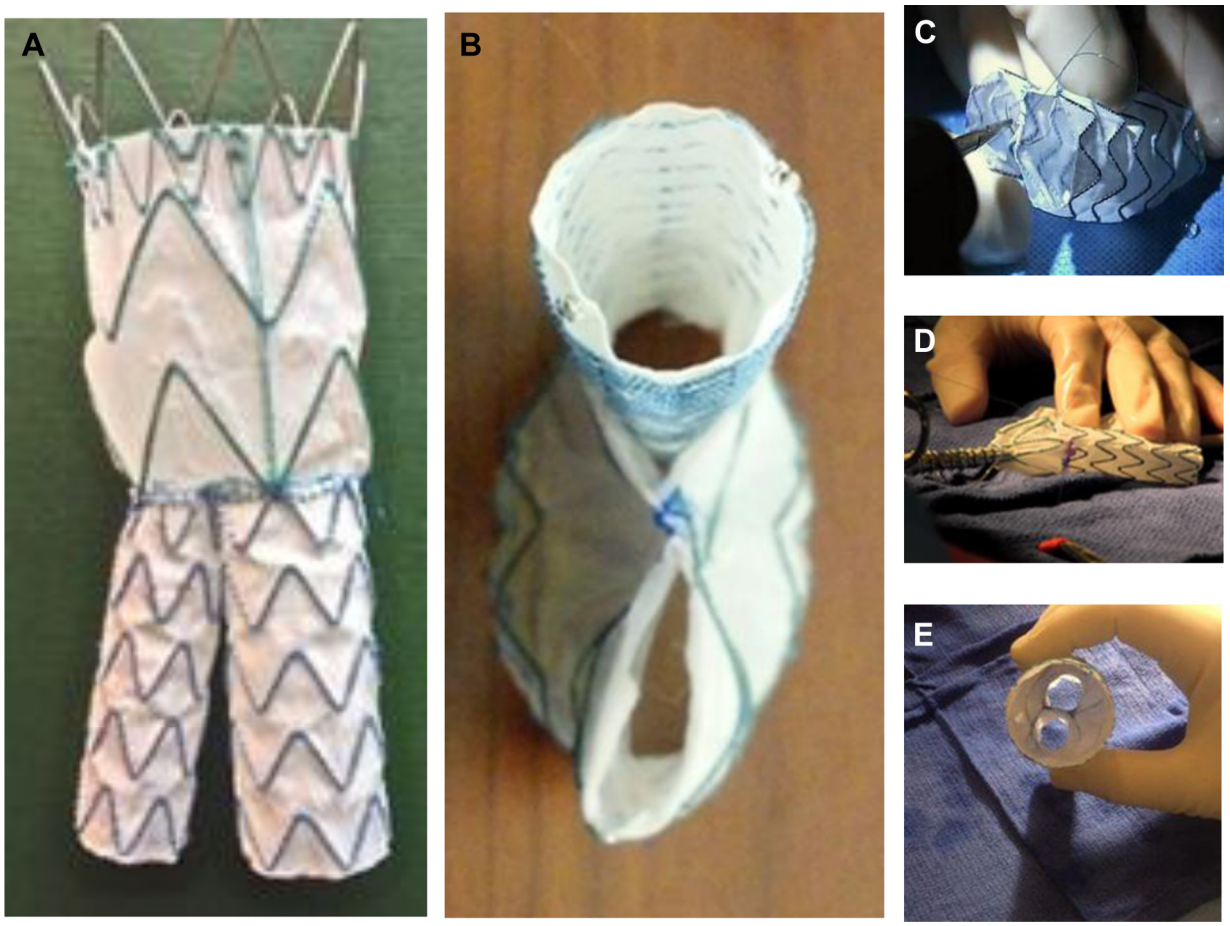

Fig 1. Sequence of constructing **(A)** the thoracic bifurcation graft (early configuration shown in **B**), including **(C)** sewing the common seam and **(D)** sewing the end-to-end anastomosis between the Valiant and the two Endurant limbs. **E,** Top view of the thoracic bifurcation showing no gutters.

met the anatomic requirement of a 4-mm neck. Once the first patient had been observed for 9 months and the second patient had been observed for 3 months, we decided to begin offering this treatment more widely and to begin pursuing a sponsor-investigator investigational device exemption that will allow us to collect prospective data of both elective and symptomatic patients treated with this physician-assembled endograft (PAEG).

METHODS

Physician-assembled stent grafts. Two custom grafts were assembled for this procedure. The first stent graft, referred to as the thoracic bifurcation (Fig 1, *A*) stent graft, was originally made with a vertical seam spanning half the length of the Valiant, dividing the distal end into two lumens (Fig 1, *B*). After the second patient, the design was modified and consisted of a Valiant straight thoracic graft (Medtronic Endurant, Minneapolis, Minn) size matched to the thoracic aorta and shortened to approximately 50 mm in length, a 20 × 82-mm iliac extender limb, and a 16 × 82-mm iliac extender limb (Medtronic), which were both eventually shortened to 50 mm as well. The iliac extender limbs were then sutured together, forming a common seam (Fig 1, *C*). From here, the 20-mm iliac limb was slid onto the Valiant deployment shaft. Approximately 2 cm of the proximal end of the Valiant graft was deployed but constrained with 20-gauge surgical wire. The remaining graft was then deployed and trimmed to approximately 50 mm (Fig 1, *D*). Cut ends were heat sealed to avoid fraying. The seam of the Valiant graft was salvaged, tied, and reinforced with 5-0 Prolene sutures. The paired iliac extenders were then sutured end to end to the shortened end of the Valiant with 6-0 Prolene by a running locked stitch in such a way that there were no gutters formed (Fig 1, *E*). The thoracic bifurcation requires one Valiant and two Endurant limbs. For final seal, the thoracic bifurcation is extended distally to either healthy infrarenal aorta in the case of a Crawford type I or type V aneurysm or to the infrarenal graft in all other Crawford types. Endurant extension limbs are used for this purpose.

The second graft, referred to here as the visceral manifold (Fig 2, *A*), was assembled from a modified 23 × 13 × 82-mm Endurant stent graft (Medtronic) and four 7-mm Viabahn stent grafts (W. L. Gore & Associates, Flagstaff,