Modular branched endograft system for aortic aneurysm repair: evaluation in a human cadaver circulation model

*Vascular and Endovascular Surgery*. 2007 41: 126-9

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ABSTRACT

Objective: to evaluate the deliverability, deployment, and acute performance of a modular branched endograft system in a human cadaver circulation model.

Methods: A circulation model was created in 6 non-aneurysmal human cadavers. Two fenestrations were created in an appropriately sized branched aortic endograft system. Under fluoroscopic guidance, the main endograft was advanced to the target site and the fenestrations were aligned with the ostia of the renal arteries. Branch grafts were placed through the fenestrations into the renal arteries. The outcome was evaluated by post implant angiography and autopsy.

Results: Eleven branch grafts were deployed at the target site. All targeted renal arteries showed good patency. At autopsy, all main endografts were adequately deployed, and 10 of 11 branch grafts were locked in place.

Conclusion: In this model, deliverability and deployment of the modular branch graft system is feasible in a reliable, predictable, and timely fashion.
Introduction

Endovascular aneurysm repair (EVAR) has emerged as a good alternative technique for the treatment of abdominal aortic aneurysms (AAAs). The current inclusion for endovascular AAA repair varies greatly from one institution to the other. The most common contraindication to EVAR is the length of the proximal neck.1-3 For these aneurysms that approach or involve the renal and visceral arteries, fenestrated and branched endografts have been designed.4-7 These endografts have been developed into successful clinical application and currently are a real option for high-risk patients; however, the procedures described have proven to be complex, technically challenging, and time consuming. Fenestrated and branched endografts are therefore not yet available in regular practice.

It is in this light that we are developing, in cooperation with a major endograft manufacturer, an easy-to-use branched aortic endograft system that is suitable for use in conventional endovascular units. The purpose of this study was to evaluate the deliverability, deployment, and acute performance of a modular branched endograft system in a human cadaver circulation model.

Methods

Endograft system

The device that was evaluated in this study is a modular system containing a main endograft and 2 separate branch grafts for the renal arteries. The main endograft is a tubular Talent endograft (Medtronic Inc., Santa Rosa, CA, USA). After creation of 2 fenestrations into the proximal part, the endograft is mounted on a modified 22F CoiITrac delivery system (Medtronic Inc) equipped with a partial deployment feature consisting of a bare top stent constrained by a spindle and sleeve. Restraining sutures have been placed around the main endograft to allow optimal maneuverability. When the device is unsheathed, it can still be rotated or moved proximally and distally for proper alignment of the fenestrations with the vessel ostia.

The separate branch grafts are composed of a 20-mm-long Bridge Assurant balloon-expandable stent (Medtronic Inc). The stent is covered with an extended tube of expanded polytetrafluoroethylene (ePTFE) over which is molded a silicone
flange. The ePTFE is held to the stent system by an additional constraining suture that breaks when the integrated stent is balloon expanded (Fig. 1). The silicone flanges are designed to easily slide into the fenestration, lock into place, and create a fluid-tight seal with the main endograft (Fig. 2).

**Model Preparation**

Six non-aneurysmal human cadavers (Table 1) were obtained through the Medical Education and Research Institute (Memphis, TN, USA) and prepared according to a procedure described by Garrett. In this procedure, a lifelike circulation model is established by isolating a section of the arterial tree containing the descending aorta and both femoral arteries. Inflow and outflow is achieved through catheters inserted at remote sites. Flow can be adjusted to simulate normal cardiac output or reduced to decrease the volume of radiopaque dye required for fluoroscopic visualization.

![Figure 1: The branch graft device is made of an expanded ePTFE tube over which is molded a silicone flange (arrow), the ePTFE is held to the 20-mm-long Bridge Assurant balloon-expandable stent system with a constraining suture (arrowhead).](image)
Modular branched endograft system in a circulation model

Figure 2: (A) Both branch grafts are deployed and seated within the fenestrations of the main graft. (B) The silicone flanges are designed to easily slide into the fenestration and lock into place, (C) to create a fluid-tight seal.

Table 1: Details of circulation model

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<th>Cadaver no.</th>
<th>Age (yr)</th>
<th>Sex</th>
<th>Weight (kg)</th>
<th>Diameter aorta (mm)</th>
<th>Size main endograft (mm)</th>
<th>Branch stent diam. (mm)</th>
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Endovascular Procedure

Both femoral arteries were exposed and isolated by cutdown procedures. A sizing catheter was advanced, and digital subtraction angiography was performed. The diameter of the aorta and both renal arteries was measured as well as the location of the renal ostia. Two fenestrations were created in an appropriately sized main endograft (Table 1), which was loaded into the delivery system and advanced to the target site under fluoroscopic guidance over a stiff 0.035-inch Back-up Meier guidewire (Boston Scientific, Natick, Mass). After the fenestrations were correctly aligned with the renal ostia, the main endograft was partially deployed.

A 22F Check-Flo introducer sheath (Cook Inc, Bloomington, Ind) was introduced into the contralateral femoral artery. A 0.035-inch Rosen curved guidewire (Cook) and a 6F Veripath directional catheter (Guidant Corp, St. Paul, Minn) were used to cannulate the renal artery through the fenestration in the main endograft. The flexible guidewire was replaced with a stiff 0.035-inch Back-up Meier guidewire and the side branch system was placed into the introducer sheath via a loading cartridge that folds the flange and reduces its profile. The side branch system was then tracked over the guidewire into the renal artery. Once the branch graft was in place, the integrated stent was balloon expanded (3 atm). The diameter of the branch grafts was oversized by 1 mm to achieve effective sealing (Table 1). The same procedure was performed for the contralateral renal artery. This was followed by complete deployment of the main endograft by unlocking the partial deployment mechanism and final balloon expansion with a noncompliant balloon to break any constraining sutures. Finally, post-implant angiography and autopsy were performed to evaluate patency and device positioning.

Results

The median time for the entire endovascular procedure was 119.5 minutes (range, 93 to 131 minutes). Main endograft delivery was successful in all trials. Eleven branch grafts were deployed at the target site. One branch graft could not be delivered because severe calcification of the renal artery made cannulation impossible. The median cannulation time for each deployed branch graft was 17 minutes (range, 12 to 27 minutes). On angiography, the 11 targeted renal arteries showed good patency (Fig. 3). Autopsy proved all main endografts to be adequately deployed, and 10 of the 11 placed branch grafts were locked into place, with intact connections between the main endograft and the branches.
Discussion

The development of fenestrated and branched aortic endografts has resulted in a wider range of abdominal aortic aneurysms (AAA) that are suitable for endovascular repair. Fenestrated endografts have been designed for AAA that approach but do not involve the renal and visceral arteries.9,10 By creating holes in the fabric of the graft, blood flow to the accessory arteries is preserved. The concept of graft fenestration has been developed from bench top studies into successful clinical application.4,5,11 Nonetheless, the procedure is associated with risk for adverse renal events,12 and when applied in the treatment of aneurysms with very short or absent infrarenal necks, the risk of endoleaks remains present.

For aneurysms that not only approach but also involve essential branch vessels, branched endografts with fluid-tight seals between the main and branch grafts are being developed. Several reports describe the successful clinical application of these endograft systems.5,13 These procedures have proven technically challenging and time consuming and are therefore probably less suitable for use in a conventional endovascular unit. Nonetheless, the modular branched endograft system described in this study, although still in preclinical development, has proved that it can be deployed in a reliable, predictable, and timely manner.14

For endovascular device testing, animals offer the advantage of a functional arterial circulation, but most animal vessels are too small to mirror conditions in human
patients. The reduced arterial size limits the sheath size that can be introduced and precludes testing of many devices large enough for use in human arteries. The human cadaver circulation model, as described in this study, proved an excellent alternative. This model offers a lifelike condition for testing endovascular devices and implanting endografts, with the advantage of a representative bifurcated aorta/iliac anatomy. On the other hand, using non-aneurysmal cadavers resulted in a decreased maneuverability of the endograft once the sheath was retracted.

Success of the procedure as described depends on the manufacture of a custom-made graft to obtain correct alignment of the fenestrations with the branch artery orifices and also by optimal positioning of the main graft during the procedure itself. Accurate preoperative measurements are essential, preferably with 3-dimensional (3D) imaging. During this study, no 3D imaging was available; in future studies, having better imaging such as CT, intravascular ultrasound, or patient-specific 3D computer models (Preview Treatment Planning Software, M2S, West Lebanon, NH), or a combination of these, will likely increase procedural success.

Difficulties were encountered in 2 cases while the branch grafts were being delivered. Fenestrations were prone to infolding caused by the necessary oversizing of the main endografts, which increased the amount of force necessary to deliver the silicone flange. This problem probably also resulted in 1 branch graft not completely locking into place, as revealed at autopsy. Even though post-implant angiography showed good patency, this could affect the durability of the branch graft and might increase the risk of endoleaks. Reinforced fenestrations in future designs might solve this problem.

**Conclusion**

In this model, deliverability and deployment of the modular branch graft system is feasible in a reliable, predictable, and timely fashion. For future use, it is too early to predict the role of this branch graft system. Theoretically, branch graft placement as described in this study need not be limited to the renal arteries, but can also be implemented in aortic arch branches, visceral arteries, and internal iliacs. When, with further study and development a system like this would become commercially available, it could potentially lead to a significant widening of the indication range for endovascular aortic aneurysm repair.
References


