

Branched Thoracic Stent Grafts

Experiences and insights on treating arch and thoracoabdominal aortic aneurysms with branched grafts.

BY TIMOTHY A. M. CHUTER, MD; ROY K. GREENBERG, MD; AND DAVID HARTLEY

Aneurysms of the unbranched descending thoracic and infrarenal abdominal segments of the aorta can be treated using a standard commercial tube or bifurcated stent grafts. On the other hand, aneurysms of the aortic arch and visceral aorta are far more difficult to treat because branches to the brain or abdominal viscera cannot be excluded from the circulation without dire consequences. Flow to these indispensable arteries must be maintained through branches of the stent graft, surgical bypass (debranching), or some combination of the two. Although the same basic principles apply to the endovascular repair of both areas, important differences in the technique of endovascular repair reflect the accessibility of the branch arteries and the ischemic tolerance of the downstream organs.

The inaccessibility of visceral aortic branches complicates both branched graft insertion and surgical bypass. The combination of surgical bypass to the celiac, superior mesenteric, and renal arteries, followed by endovascular aortic exclusion, is a large operation. Patients who are too sick to undergo the conventional surgical repair of thoracoabdominal or pararenal aneurysms may also be too sick for the hybrid open/endovascular alternative. Under these circumstances, the less-invasive branched endovascular reconstruction may be the only option.

The brain is very susceptible to ischemic injury. The endovascular portions of any operation to reconstruct the aortic arch have to be quick, atraumatic, and uniform-

"... branches to the brain or abdominal viscera cannot be excluded from the circulation without dire consequences."

ly effective, which is to say, as simple as possible.

Fortunately, surgical rerouting of flow from the right side of the aortic arch to the left can be performed through extracavitary (neck) incisions. Once this has been done, a bifurcated stent graft with one branch to the innominate artery provides inflow to both arms and both sides of the brain.

Inoue et al long ago demonstrated the feasibility of using unibody stent grafts to repair both the aortic arch¹ and thoracoabdominal aorta.² A multibranched stent graft of unibody design is inserted whole and guided into position by a system of catheters. Because catheters pull better than they push, this technique is somewhat easier in the aortic arch where one has downstream branch artery access. Nevertheless, the high rates of embolism in multibranched arch repair are probably attributable to the complexities of multibranched unibody stent graft deployment. We prefer the modular approach, in which components are assembled in situ, because modular stent grafts tend to be simpler and easier to insert than their

unibody counterparts. The only disadvantage of the modular approach is the potential for subsequent disassembly.

THORACOABDOMINAL AND PARARENAL AORTA

Despite obvious similarities, the fenestrated^{3,4} and multibranched⁵ approaches developed independently and synchronously. Both techniques were first described side-by-side in the same February 2001 issue of the *Journal of Endovascular Therapy*. As originally conceived, the fenestrated stent grafts had holes (the fenestrations) through which blood flowed to branch arteries. These fenestrations were positioned using bridging catheters, balloons, or sheaths, and were held in position using bridging stents. Instead of fenestrations, the multibranched stent grafts had axially oriented cuffs, which served as routes of insertion for branch artery catheterization and attachment sites for bridging stent grafts. In the original fenestrated repair, the seal was obtained between the trunk of the primary stent graft and the margin of the branch artery orifice, whereas in branched repair, the seal was obtained between the outer wall of the covered stent and the inner wall of the branch artery lumen.

The two techniques are both based on the Zenith stent graft (Cook Incorporated, Bloomington, IN), and both have self-expanding stainless steel Gianturco Z-stents, polyester fabric, and barb-mediated aortic attachment. The distinctions between the fenestrated and multibranched approaches have been blurred by a process of convergent evolution, which has produced a spectrum of hybrid devices with overlapping technology, performance

characteristics, and indications. Fenestrations have been used as attachment sites for covered stents and the stent graft/covered stent junction enhanced by nitinol rings or small cuffs.⁶ The original axially oriented, externally mounted cuffs of the multibranched device have been supplemented by a range of spiral, tilted, internal, external, and upside-down cuffs, as well as a variety of short internal cuffs, known as a capped fenestration. Moreover, cuffs and fenestrations have been incorporated into hybrid fenestrated/branched devices.

The lack of a suitable covered stent for use as a branch extension has been a rate-limiting step in the adoption of the multibranched approach. The fenestrated approach suffered no such impediment. Several suitable uncovered stents have long been available. In addition, fenestration helped address a common problem, the short neck. These factors contributed to the widespread application of renal artery fenestration for cases of juxtarenal aneurysm.

Fenestration Alone

The simple fenestration has no effect on the external profile of the stent graft, so the wall of the graft can expand onto the wall of the aorta, creating a seal. Indeed, the seal depends on close apposition between the margin of the fenestration and the margin of the branch artery orifice. The lack of external projections also facilitates positioning and repositioning of the stent graft during implantation. When combined with constraining ties and a top cap, the partially opened stent graft retains partial mobility. It need not become fixed in position until a

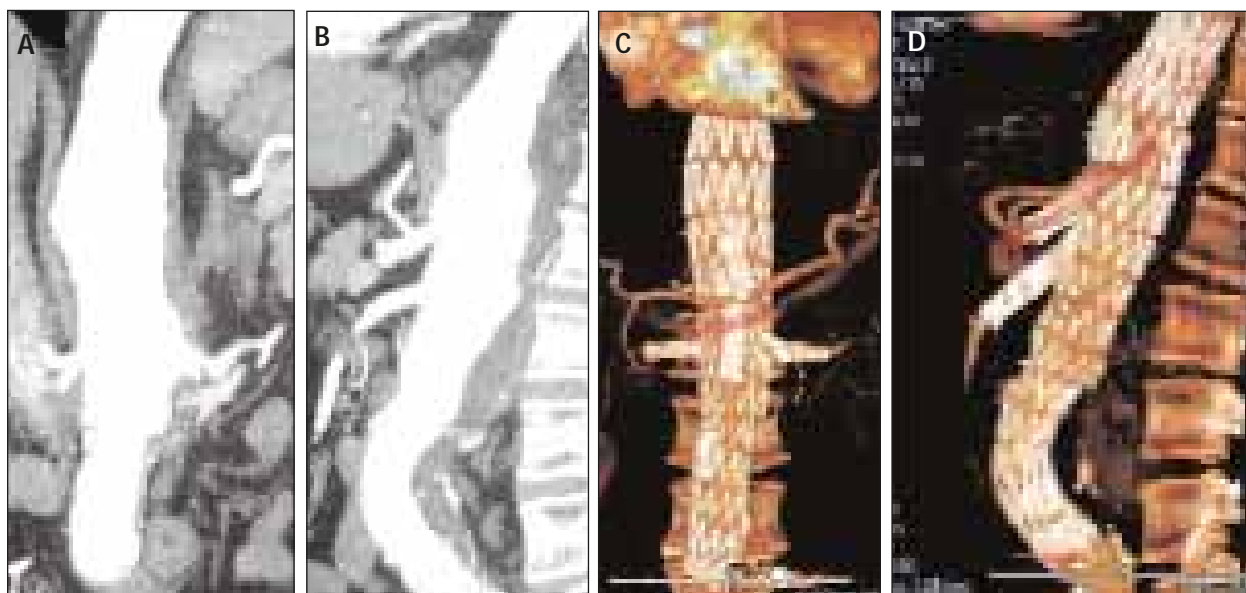


Figure 1. Coronal section from preoperative CT of a thoracoabdominal aortic aneurysm (A). Sagittal section from preoperative CT in the same patient (B). Lateral shaded surface display of postoperative CT in the same patient (C). Anterior shaded surface display of postoperative CT in the same patient (D).

bridging catheter, balloon, or sheath ensures that the fenestration will be directed correctly to the target arterial orifice.

Fenestration With Covered Stents

The substitution of a covered stent for the usual bridging stent has allowed fenestrated stent grafts to be used in cases of pararenal or thoracoabdominal aneurysm. The covered stent acts as a conduit between the primary stent graft and the branch artery, and this combination functions as a branched stent graft. The covered stent is generally bulkier and stiffer than the uncovered equivalent, and it is consequently more difficult to insert. In the long-term, the main disadvantage of the combination of a fenestrated primary aortic stent graft with a covered stent is the tenuous nature of the intercomponent connection.

"The axially oriented cuff takes advantage of the space that is available up and down the long axis of the aorta."

A nitinol ring around the fenestration provides some additional security by supporting the margin of the fenestration and allowing more forceful dilatation of a balloon-expanded stent graft to create a flanged junction. No self-expanding covered stents expand so forcibly or deform in this way, and the intercomponent connections generated by self-expanding covered stents are neither hemostatic nor secure enough for this application.

Because the covered stents project into the lumen of the stent graft, they are vulnerable to injury during subsequent manipulations, such as removal of the delivery system or balloon dilatation of the primary stent graft. Moreover, balloon-expanded stents do not yield and rebound; they deform and stay deformed. The usual result is a disturbance of the seal between the covered stent and the primary stent graft, causing type III endoleak, which may go unnoticed until completion angiography is performed at the end of the operation. At this point, corrective measures require recatheterization of the covered stent. Fortunately, it is easier to regain access into a covered stent than into the bare stent equivalent.

Capped Fenestration

In the capped fenestration, a large external fenestration is connected to a small downward-facing, internal fenestration by a short, curved cuff. The inner end of the cuff provides a site for branched stent graft attachment,

whereas the outer end of the cuff provides some latitude in positioning and catheter manipulation. The problem is, balloon-expanded stent grafts are deployed in the position adopted by the inflated balloon, which seldom conforms well to the curve of the cuff.

Axial Cuffs

The original branched stent grafts had axially oriented cuffs, not fenestrations, as branch attachment sites. The axially oriented cuff takes advantage of the space that is available up and down the long axis of the aorta. Experience in small numbers of patients has shown this approach to be versatile, effective, and durable.

These cuffs are typically 15 mm or longer, which seems to be long enough for secure hemostatic implantation of self-expanding covered stents. Indeed, there have never been any cases of intercomponent leakage or intercomponent separation after the use of self-expanding covered stents in combination with axially oriented cuffs, with up to 4 years of follow-up. Balloon-expanded covered stents, on the other hand, may be less secure because the fabric of the cuff limits expansion, and subsequent recoil of the covered stent can leave a gap. We have seen attachment failure, separation, and endoleak where balloon-expanded covered stents join the main stent graft and where balloon-expanded covered stents join other covered stents.

Externally cuffed stent grafts are usually designed so that the external orifice of the cuff lies well above (or, in the case of an upward-pointing cuff, well below) the level of the target artery. The additional distance provides the space for catheter manipulation, which can take any direction toward the target arterial orifice. The resulting curved path from the external end of the cuff has no predefined limits and allows the most latitude of any of the cuff designs. The exact position of the cuff need not be as precise as with the fenestrated approach. Consequently, the stent graft need not be so highly customized, and many patients may be treatable using some form of generic, premade inventory.

Helical Cuffs

The spiral cuff is a relatively long cuff that is designed to minimize the potential for kinking of the mating stent graft and reduce the stress placed on the modular joint between the aortic device and mating stent graft. By definition, a helical cuff does not maintain the same orientation relative to the trunk of the primary stent graft, but winds around the inner or outer surface of the aortic graft. The resulting branch directs catheters, wires, sheaths, covered stents, and blood flow away from the long axis of the aorta. This is intended to simplify access into the target vessel once sheath access into the branch is established. However, it is

important to realize that the orientation of a helical cuff is more critical than the orientation of an axially oriented cuff and less critical than the orientation of conventional fenestration. Ongoing clinical studies will address the technical issues involved in marking, loading, and catheterization of multiple overlapping helical cuffs, but to-date experience has been confined to the use of single helical cuffs in combination with multiple fenestrations.

Tilted Cuffs

The tilted (inside/outside) cuff maintains its axial position on the primary stent graft, but tilts in the radial direction so that the lumen projects out at an angle to the long axis of the aorta. The exact angle of projection depends on the length and diameter of the cuff because the inner orifice of the cuff abuts the inner wall of the stent graft trunk, and the outer orifice of the cuff abuts the outer wall of the stent graft trunk. Because none of the cuff lies completely outside the wall of the primary stent graft, it is well-supported and immune to twisting or kinking. In addition, the angulation of a tilted cuff may have some role in directing catheters, sheaths, and covered stents out toward the target artery.

Current Approach

Compared to fenestrations, cuffs often provide an easier route to the target artery and a more secure and hemostatic attachment site for covered stent implantation. These advantages are particularly important in large empty aneurysms of the thoracoabdominal aorta, in which we prefer to employ four axially oriented cuffs and four self-expanding covered stents (Figure 1). Tapering the central segment of the stent graft produces space savings in the delivery system and allows greater freedom of movement within the visceral segment of the aorta.

Covered stents to down-going visceral arteries are generally inserted from a left brachial approach through a system of coaxial sheaths. The route of insertion for covered stents to the renal arteries depends on renal artery orientation and aortic size at the level of the renal orifices. If the renal arteries arise from a relatively nondilated segment of aorta, we tend to substitute fenestrations for cuffs.

AORTIC ARCH

Our preferred approach to arch reconstruction combines surgical bypass to the left carotid and left subclavian arteries with endovascular arch exclusion using a bifurcated endovascular stent graft.^{7,8} The bifurcated stent graft has a branch to the innominate artery as a source of arterial inflow, thereby avoiding median sternotomy and aortic clamping. The substitution of surgical bypass for multiple branching of the stent graft greatly simplifies the endovas-

cular portion of the operation to the point where all stent graft implantations can be performed during short periods of adenosine-induced cardiac arrest.

“Compared to fenestrations, cuffs often provide an easier route to the target artery and a more secure and hemostatic attachment site for covered stent implantation.”

The operation is performed under general anesthesia with the patient in the supine position. Incisions in the posterior triangles of the neck afford access to the common carotid and subclavian arteries. We perform carotid-carotid bypass, followed by carotid-subclavian reimplantation or bypass, so as to preserve flow to the left internal mammary and vertebral arteries. The site of bifurcated stent graft insertion depends on the size of the delivery system, which depends in turn on the size of the ascending aorta. With conventional graft materials, any stent graft larger than 40 mm in diameter has to be delivered through a 24-F sheath, which is too large for the right common carotid artery. Instead, we use a conduit anastomosed to a longitudinal arteriotomy from the distal innominate artery to the proximal right common carotid artery. One of the femoral arteries serves as a second access site. Pigtail catheters are inserted through small sheaths in both access sites. The cervical catheter is advanced through the aortic valve into the left ventricle, while the femoral catheter is left in the ascending aorta for angiography.

After the intravenous administration of large doses of heparin, we replace the cervical catheter and sheath over a stiff wire (Lunderquist, Cook Incorporated) for the bifurcated stent graft delivery system. We advance the tip of this short delivery system into the left ventricle and orient the short wide leg of the stent graft toward the inner curve of the aortic arch. We perform sheath withdrawal, stent graft expansion, and stent graft release during a brief period of cardiac arrest. Even in the absence of any apparent kinking, we insert a large (18-mm) Wallstent (Boston Scientific Corporation, Natick, MA) into the long, narrow (16-mm) innominate limb of the stent graft.

We replace the femoral pigtail with a directional end-hole catheter and gain access to the short, wide limb of the stent graft for the implantation of a second stent graft. This cylindrical component extends the conduit around the arch to the implantation site in the descending thoracic aorta. A two-stent overlap and multiple barbs help to secure this intercomponent connection. We then ligate the proximal left subclavian and/or carotid arteries to

complete exclusion of the aortic arch before performing completion angiography.

LIMITATIONS OF MODULAR BRANCHED STENT GRAFTS

The ultimate role of branched stent grafts will be determined not by their advantages, which are obvious, but by their failings, which remain largely unexplored.

The chief practical limitation is an inevitable delay between evaluation and treatment. At this point, these highly customized devices cannot be kept in inventory. Although we are developing a standardized approach to design and manufacture, each device differs from every other device. However, the longitudinally cuffed versions of this approach require less customization. The variability in the size and location of the visceral arteries is accommodated by variation in the diameter, length, and position of the covered stent, not by the primary aortic component. In addition, variation in the size and location of the proximal and distal attachment sites can be accommodated by additional aortic components. This advantage of the modular approach may make it possible to treat a large proportion of cases from a small inventory of standard devices.

The primary disadvantage of any modular device is the potential for component separation. Balloon-expandable covered stents seem to be more prone to both primary leakage and late separation than the self-expanding equivalents. The presence of a cuff, especially a long axially oriented cuff, seems to enhance stability. We have never seen separation at the junction between a cuff and a self-expanding stent. This apparent stability is not just the product of friction between components, but also of stent graft rigidity. The short, stiff self-expanding covered stent just does not have the freedom of movement to flip out of position.

Of course, all these procedures are long and taxing. There is a lot to be done. However, the procedure is really only as difficult as its most difficult part. In that regard, the modular approach simplifies implantation enormously by breaking the operation down into bite-sized parts. One can stop the procedure to change the access site or room setup. One can even pause for a day or two to get additional components, sheaths, and wires.

All the components of modular branched stent grafts are expensive. One has to weigh this cost against the cost of prolonged intensive care following open repair. Of course, the cheapest approach is to do nothing, and that may also be the safest approach for patients who have aneurysms of borderline dimensions, or have limited life expectancy.

The one vital artery that is too small for its own branch is the distal thoracic intercostal that feeds the spine. We still have too little experience to comment on the risk of

paraplegia after endovascular thoracoabdominal aortic aneurysm repair. The relative risks of endovascular versus open repair will be determined by the relative importance of complete intercostal exclusion versus reperfusion, hypotension, blood loss, and visceral ischemia.

CONCLUSION

Modular systems of branched and multibranched stent graft construction allow one to apply endovascular techniques of aneurysm exclusion to branched segments of the aorta, such as the aortic arch and thoracoabdominal aorta. With the possible exception of the covered stents used in thoracoabdominal aortic aneurysm repair, all these modular stent grafts and their delivery systems are constructed using long-tried components, and they are all implanted using long-tried techniques. Although specific combinations are still evolving, it is now clear that the minimally invasive aspects of endovascular reconstruction will ensure a role for these techniques in the management of patients who have aneurysms of the thoracoabdominal aorta and aortic arch and who are often too sick to withstand the open surgical alternatives. ■

Timothy A. M. Chuter, MD, is with the Division of Vascular Surgery, University of California, San Francisco, California. He has disclosed that he is a paid consultant to and receives royalties from Cook Incorporated. Dr. Chuter may be reached at (415) 476-2381; chutert@surgery.ucsf.edu.

Roy K. Greenberg, MD, is Director of Endovascular Research, The Center for Aortic Surgery, Departments of Vascular and Cardiothoracic Surgery, The Cleveland Clinic Foundation, Cleveland, Ohio. He has disclosed that he is a paid consultant to and receives royalties from Cook Incorporated. He receives research funding from Sulzer-Vascutek, Gore & Associates, and Cook. Dr. Greenberg may be reached at (216) 445-5306; greenbr@ccf.org.

David Hartley is with the Research and Development Laboratories, Cook Incorporated, Australia. He has disclosed that he is a paid consultant for and receives royalties from Cook Incorporated.

1. Inoue K, Hosokawa H, Iwase T, et al. Aortic arch reconstruction by transluminally placed endovascular branched stent graft. *Circulation*. 1999;100S:II316-321.
2. Hosokawa H, Iwase T, Sato M, et al. Successful endovascular repair of juxtarenal and suprarenal aortic aneurysms with a branched stent graft. *J Vasc Surg*. 2001;33:1087-1092.
3. Stanley BM, Semmens JB, Lawrence-Brown MM, et al. Fenestration in endovascular grafts for aortic aneurysm repair: new horizons for preserving blood flow in branch vessels. *J Endovasc Ther*. 2001;8:16-24.
4. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. *J Endovasc Ther*. 2001;8:3-15.
5. Chuter TAM, Gordon RL, Reilly LM, et al. An endovascular system for thoracoabdominal aortic aneurysm repair. *J Endovasc Ther*. 2001;8:25-33.
6. Anderson JL, Berce M, Hartley D. Endoluminal grafting of thoracoabdominal aneurysms. *J Endovasc Ther*. 2004;11:1-3.
7. Chuter TA, Buck DG, Schneider DB, et al. Development of a branched stent graft for endovascular repair of aortic arch aneurysms. *J Endovasc Ther*. 2003;10:940-945.
8. Schneider DB, Curry TK, Reilly LM, et al. Branched endovascular repair of aortic arch aneurysm. *J Vasc Surg*. 2003;37:855.