



Branched Stent-Grafts for Endovascular Repair of Aortic and Iliac Aneurysms

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Endovascular technique, which gains access through indirect transarterial routes and isolates the aneurysm without interrupting flow, has particular advantages in aneurysms of the aortic arch and thoracoabdominal aorta. Yet progress has been slow. The necessary branched stent-grafts face several unique technical challenges. The simplest, most versatile approach involves assembling a modular stent-graft in situ from multiple parts. Techniques vary according to the presence or absence of an overlap zone, or cuff. The first cases of this type, reported over 4 years ago, had axially oriented cuffs. Recent efforts have seen the intercomponent attachment site reduced to a ring of Nitinol around a simple fenestration, with various hybrids of cuffed and fenestrated technique in between. Other advances, such as better sheaths, better covered stents, and commercial manufacture (Cook, Australia), have helped to extend the use of branched stent-grafts to a wider range of users and a wider range of aneurysms. Although their future role remains unclear, all these devices have gone beyond the proof of concept stage, and some, such as the bifurcated component for the endovascular iliac reconstruction, are ready to become standard parts of the endovascular.

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In general, a stent-graft needs one branch for every major artery that takes origin from the aneurysm. Otherwise, endovascular aneurysm exclusion results in branch artery occlusion and end organ infarction. Fortunately, all the indispensable branches of the aorta are clustered in the aortic arch and the proximal abdominal aorta, while aneurysms occur most often in the intervening segments where the only branches are small, duplicated, or well collateralized.

The simplest branched stent-graft bifurcates into two branches, one for each common iliac artery. Bifurcated stent-grafts take one of two forms, unibody or modular. Unibody stent-grafts are inserted whole, whereas modular stent-grafts are assembled in situ from multiple parts. Both types are available, but the modular approach predominates, because modular stent-grafts are simpler to make, simpler to insert, and more versatile. These advantages assume even greater importance as the number of branches increases. ^{1,2} The only theoretical disadvantage of a modular approach is a risk of component separation, which we have never seen in our

multi-branched stent-graft experience, and rarely seen in our bifurcated stent-graft experience.

The basic elements of a modular stent-graft design and insertion are the same, no matter the location or how many branches there are. The main body of the stent-graft has a single lumen proximally and two or more lumens distally, of which all but one are truncated so that they reside entirely within the aorta. All our devices are based on the Zenith design (Cook, Australia), which has a barbed, uncovered Z-stent at the proximal end for fixation, Z-stents within each graft orifice for sealing, and Z-stents all along the outer surface for kink-resistance.

The main body of the device is inserted first. Additional lines of insertion are then established by passing catheters and guidewires between the distal branches (or fenestrations) of the main body stent-graft and the corresponding branches of the aortic aneurysm. Short covered stents then follow these paths through the main body of the stent-graft to the target arteries. Once deployed, the covered stents bridge the gap between the branches of the main body and the branches of the aorta, thereby isolating the aneurysm while maintaining branch artery flow.

Downstream access to the branch artery simplifies the procedure enormously. In endovascular repair of the infrarenal aorta or aortic arch, the line of covered stent insertion passes from the access point and the target artery, then through the

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aorta and into the corresponding branch of the main body stent-graft. By contrast, inaccessible branches require remote access through another artery. In endovascular repair of thoracoabdominal or common iliac aneurysms, for example, the line of covered stent insertion passes from an access point in the brachial or contralateral femoral artery, through the trunk of the main body, through a branch (or fenestration) of the main body, through the aneurysm, and finally into the corresponding target artery. In these cases, the length and tortuosity of the path from the access point to the target artery largely determines the complexity of the procedure.

Fenestrated Stent-Grafts, Branched Stent-Grafts, and Hybrids

The type of connection between the main body stent-graft and covered stent not only determines the stability of the joint, but the shape, insertion technique, and implantation site of the entire system. However, some of the distinctions between fenestrated and externally cuffed devices reflect the developmental histories of the two approaches, rather than immutable features of each approach.

Fenestrations, ring-supported fenestrations, and internally cuffed fenestrations have no effect on the external profile of the main body. So long as the main body is made and positioned accurately, the fenestrations line up with the branch orifices and the surrounding stent-graft can be in direct apposition with the surrounding aortic wall. This allows for a mixture of fenestrated and branched technique with covered stents in places where the aorta is aneurysmal, and ordinary stents in places where the aorta is of normal caliber.³

External, axially oriented cuffs provide for longer overlap between components and a greater separation between the outer end of the cuff and the target branch artery. The multi-branched approach is in some regards less exacting than a fenestrated equivalent because the length and orientation of the covered stent can accommodate variations in the position and orientation of the main body. The longer overlap also provides additional intercomponent fixation and sealing, which is particularly important when long covered stents traverse large aneurysms. However, the external cuff does interfere with main body implantation in adjacent segments of aorta. The implantation site has to be above the cuffs and well above the most proximal of the branch arteries, which, in the thoracoabdominal aorta, is the celiac axis.

Fenestrated and externally cuffed main bodies generally employ different routes of access for covered stent insertion. In the fenestrated approach, 4,5 the covered stents are inserted through the femoral arteries downstream from the uncovered proximal stent. This route of insertion can be established while the proximal stent is still within its cap, the body of the stent-graft within a series is partially constraining ties, and the orientation and longitudinal position are still adjustable. Bridging catheters, sheaths, or balloons between the fenestrations and the target arteries are inserted while the stent-graft is in a partially expanded state. These then help to guide the second stage of stent-graft expansion by directing the fenestration to the branch

orifice. In the externally cuffed approach, the covered stents are inserted from a brachial approach, which is only possible once the proximal stent has been released from its cap and the stent-graft has been fixed in position.

Cuffed Modular Stent-Grafts for Thoracoabdominal Aortic Aneurysm (TAAA) Repair

Background

The thoracoabdominal aorta has branches to organs, such as the liver, kidneys, and intestines, which tolerate ischemia poorly. Furthermore, its location, high in the retroperitoneum under the dome of the diaphragm, impedes surgical exposure. Not surprisingly, the morbidity and mortality rates of open surgical repair remain high despite decades of improvement in surgical technique and perioperative care, hence, the appeal of endovascular technique, which avoids a large incision by employing a transarterial route to the aneurysm, and aortic clamping, by leaving the aneurysm intact. Despite these advantages, progress toward widespread endovascular AAA repair has been limited by the complexity of the technique and by a shortage of suitable adjunctive technology.

History

In the past year, there has been a growing experience of pararenal and TAAA repair using a variety of custom-made Zenith fenestrated stent-grafts and various covered stents, principally the balloon-expanded Jomed stent.³ However, the only long-term experience of endovascular TAAA repair has been with systems in which axially oriented cuffs on the main body stabilize intercomponent connections.⁷ This approach has proven both effective and durable, with more than 4 years of follow-up to date.

Device Design

The assembled stent-graft has two main classes of components: Zenith-style aorto-iliac stent-grafts, and small cylindrical covered stents. The main body has an uncovered barbed stent at its proximal end, and multiple caudally oriented cuffs arising from the tapered central segment between two unbranched terminal segments. The distribution of cuffs reflects the distribution of aortic branches. However, the intervals are not quite the same. The gaps between the cuffs are shorter than the gaps between the arteries, so that, with the celiac cuff in proper position, each of the other cuffs is sure to lie proximal to its corresponding artery. Radiopaque markers surround the orifices of each cuff, both proximally and distally. Additional markers on the trunk of the stent-graft indicate orientation, just as they do on the fenestrated Zenith stent-graft.

We insert the main body of the stent using a 22-French (ID) Zenith fenestrated stent-graft delivery system, if the aneurysm ends within 10 cm of the celiac artery. We use a 22-French (ID) Zenith thoracic (TX2) delivery system, if it extends more proximally. The fenestrated stent-graft delivery system is the more complex of the two. It has a proximal cap for the uncovered stent and constraining wires to maintain a

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