Custom Devices Can't Be Abandoned

Long-term data for off-the-shelf devices remain uncertain, and their durability for challenging anatomy should be considered.

BY TARA M. MASTRACCI, MD, AND ROY K. GREENBERG, MD

Off-the-shelf endovascular solutions for juxtarenal and thoracoabdominal aneurysms have been touted by many as the Holy Grail of modern aortic surgery, as well as the minimally invasive answer to every aortic surgeon's dreams. Much like the infrarenal endovascular revolution of the last 2 decades, the allure of a minimally invasive treatment for a disease that has conventionally required a debilitating repair is difficult to resist and has enchanted many. However, with our expanding understanding of aortic disease, the entry of off-the-shelf technology into our surgical repertoire may not be the panacea it was once hoped to be. The true benefit of off-the-shelf designs lies in the absence of any treatment delay required for the production of customized grafts and the potential to have cheaper devices, given that they can be mass produced. So what are the pitfalls of such a strategy?

Our current knowledge with respect to the long-term behavior (durability) of these devices is limited to a few studies. Many reports have indicated that there are very specific anatomic situations in which devices will perform at a substandard level. Examples include areas of marked tortuosity, misalignment between aortic components and target vessel stent grafts, and small target vessels. The technical aspects of the procedure also have serious implications on the success of the repair. Inadvertent arterial injuries, such as perforations or dissections, have potentially disastrous consequences.

With our expanding understanding of aortic disease, the entry of off-the-shelf technology into our surgical repertoire may not be the panacea it was once hoped to be.

To begin, one must question the definition of "off-the-shelf" design. Does this mean that there are two to four devices that will fit most patients and thus can be stocked in hospitals with reasonable volumes? Or, does it mean that a company can premanufacture several varieties of a given off-the-shelf device and have the ability to ship them out in a rapid manner? The bigger the matrix of production, the less feasible it is to actually provide devices to institutions for immediate use. Furthermore, a smaller matrix of production means that the range of potential treatable anatomies using a given device is larger, potentially creating situations in which access and stenting in target vessels can be done, but the relationship between the target vessel stent graft, aortic graft, and the target vessel may be under considerable strain.

Therefore, it seems reasonable to have a balanced view regarding both custom and off-the-shelf technologies. We do not consider off-the-shelf and custom devices to be an either/or situation. Rather, they

represent two important tools that can be selectively employed to manage patients individually. One must balance the desire for a quick fix with a device that may work for a patient at the fringe of acceptability criteria versus a delay for a device that is truly intended for a given patient's anatomy.

THE PITFALLS AND BENEFITS OF DEVICE CUSTOMIZATION

Over the course of the last 10 years, centers of excellence for aortic endovascular procedures have primarily been using one platform for the treatment of complex aortic pathology: the Zenith fenestrated/branched family of devices (Cook Medical, Bloomington, IN). Use of this device platform has required custom graft design and then a subsequent manufacturing delay, which can postpone intervention for up to 3 months. This process requires that the physician have access to adequate postprocessing software to design a suitable graft and that the rules of device design are learned and applied with accumulated experience (although much of this will be true with off-the-shelf devices as well). The designs are then submitted to the centralized manufacturer, constructed by hand, sterilized, and shipped. Given the perception of urgency with aneurysm disease, this delay can introduce risk to the patient and certainly limits the application of this technology to only the nonacute subset of the population.

Customization is also a challenge from a regulatory perspective, and it is likely that the lack of standardization is one factor that has contributed to the long delay in commercialization of this product in stricter regulatory environments, such as the United States. The highly variable nature of custom devices makes engineering testing challenging to perform and large populations of investigation data more important to collect.

Despite these drawbacks, customization of aortic devices has the advantage of creating a device that fits the patient's aorta, as opposed to requiring the aorta to conform to the device. The careful design and construction of these devices is likely one of the contributing factors to the evolution of our understanding of the applications for use and the relative durability of these repairs, long-term data for which are only beginning to be published. By understanding the interaction between aortic forces and the endograft, surgeons and engineers have been able to construct designs that are both durable and stable. For example, we have learned from experience the importance of overlap[1] and the benefits of covered stents in renal arteries[2] with regard to long-term benefits. These lessons have been incorporated into the development of standard devices and were derived from an analysis of long-term data; the same is true for the various aspects of device planning and patient selection.

> The endovascular era has brought with it an evolution of device technology that outpaces outcomes research, making evidence-based practice a challenge.

Critical factors can be accounted for in customized devices that have not been addressed in the available standard device platforms. The location of the proximal seal is first and foremost. The need to achieve a circumferential seal within a perceptibly healthy aorta is arguably the most important dictum when repairing aneurysms involving branches. Once the branches are present, any endovascular bailout procedure for leakage or migration as a result of proximal neck failure will be markedly more complicated than a primary procedure. Off-the-shelf platforms do not allow variability in the location of the proximal seal. The use of large scallops for the celiac or superior mesenteric arteries precludes circumferential apposition between the graft and aorta, which, in the setting of subtle disease, may result in serious complications during late follow-up.

STANDARDIZATION OF OFF-THE-SHELF DEVICES

With modern understanding of branched devices, numerous groups are now investigating the use of standard off-the-shelf devices. Relying on the accumulated data of known branch vessel anatomy,[3,4] similarities in anatomy for the majority of patients have been recognized, and it is with these data that off-the-shelf devices have been designed. Most authors who have studied the anatomic similarities between juxtarenal and thoracoabdominal aneurysms, however, note that in addition to a majority of patients with very similar presentations, there is a small subset with highly variable anatomy who are unlikely to derive benefit from a noncustomized device. Such outliers require special consideration, even with a customized design. Unlike the one-size-fits-all solution that the proverbial off-the-shelf device has come to represent, it is critically important to note that any of the proposed standardized devices might not be appropriate for these patients.

Each of the manufacturers has proposed several device diameters and a minimum of two standard configurations for the visceral vessels. Thus, there are 10 proximal components at a minimum. These must be mated with distal components, of which there are many variations. So, what is entailed in making a standardized off-the-shelf device? The answer is a lot of money and a very large stock room. For the patients on the fringe of acceptance criteria, and for patients who have common anatomical features that preclude the standard designs (ie, single or multiple renal arteries), custom devices may be preferred.

The ramifications of off-label or "off-IFU" (off instructions for use) placement of infrarenal endografts are only recently being recognized. In a recent study of imaging data from 10,228 patients entered into a large centralized database, only 42% met the criteria outlined in the manufacturers instructions for use for infrarenal endografts, and the rate of sac enlargement was 41%.[5] The investigators concluded that, within the limitations of the data available, associations could be made between the trend of ignoring device implantation parameters and the long-term failure of the repair. Certainly, this is echoed in earlier data provided for the Renu device (Cook Medical), which note proximal neck failure very early after implantation.[6] If proximal landing zone specifications for fenestrated devices are ignored in the interest of expanding the use of off-the-shelf devices for complex aneurysms, the ramifications could be greater.

Although there are endovascular solutions for failed infrarenal grafts, the complexity of converting a failed juxtarenal device is likely to be much greater and may require explantation of such failed devices until a suitable endovascular solution is found.

In addition to the pitfalls of using devices outside of their IFU, implantation of noncustomized devices could also result in stent grafts being deployed in aortic morphologies that might be better served with custom devices. We know from experience with iliac tortuosity in infrarenal endovascular repair that placement of stiff devices in an attempt to conform the aorta to the device largely results in device failure. However, similar evaluation using fenestrated devices has not been possible because customization removes the device:aorta mismatch that can cause long-term device failure. If this same concept can be extrapolated to tortuous or aberrant branch vessels and these devices are placed in challenging anatomy, this could result in a decrease in branch stent patency and therefore device durability. Many of the proposed off-the-shelf devices rely on the ability of the branch to accommodate a large spectrum of angles from a single fulcrum. However, as the degree of angulation becomes further from its custom counterpart, the impact on long-term durability is unknown. Although efforts have been made to assess the material fatigue, the extremes will always be a concern.

CONCLUSION

The endovascular era has brought with it an evolution of device technology that outpaces outcomes research, making evidence-based practice a challenge. When evaluating off-the-shelf devices, we must keep in mind that accommodation of the visceral branches into a fenestrated graft is simple, but the choice and extent of the landing zones is more critical and must take precedence over other clinical decisions. Although we are eager to adopt new technology, we must not completely abandon the devices and techniques that have allowed us to achieve the success we have today. ■

Tara M. Mastracci, MD, is a vascular surgeon in the Department of Vascular Surgery at the Cleveland Clinic Foundation in Cleveland, Ohio. She has disclosed that she provides proctoring and consultation for Cook Medical and serves on the Data and Safety Monitoring Board for Endologix. Dr. Mastracci may be reached at mastrat@ccf.org.

Roy K. Greenberg, MD, is a vascular surgeon in the Departments of Vascular Surgery and Thoracic and Cardiothoracic Surgery in the Sydell and Arnold Miller Heart & Vascular Institute at the Cleveland Clinic Foundation in Cleveland, Ohio. He holds joint appointments in the Imaging Institute Department of Diagnostic Radiology and the Lerner Research Institute Department of Biomedical Engineering. Dr. Greenberg is also Director of Endovascular Research and the Cleveland Clinic Peripheral Vascular Core Laboratory. He has disclosed that he has intellectual property licensed to and receives royalty fees from Cook, Inc. Dr. Greenberg may be reached at (216) 445-5306; greenbr@ccf.org.

1. Dowdall JF, Greenberg RK, West K, et al. Separation of components in fenestrated and branched endovascular grafting—branch protection or a potentially new mode of failure? Eur J Vasc Endovasc Surg. 2008;36:2-9.
2. Mohabbat W, Greenberg RK, Mastracci TM, et al. Revised duplex criteria and outcomes for renal stents and stent grafts following endovascular repair of juxtarenal and thoracoabdominal aneurysms. J Vasc Surg. 2009;49:827-837.
3. Azzaoui R, Sobocinski J, Maurel B, et al. Anatomic study of juxta renal aneurysms: impact on fenestrated stent-grafts. Ann Vasc Surg. 2011;25:315-321.
4. Conway BD, Greenberg RK, Mastracci TM, et al. Renal artery implantation angles in thoracoabdominal aneurysms and their implications in the era of branched endografts. J Endovasc Ther. 2010;17:380-387.
5. Schanzer A, Greenberg RK, Hevelone N, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation. 2011;123:2848-2855.
6. Jim J, Rubin BG, Geraghty PJ, et al. Midterm outcomes of the Zenith Renu AAA ancillary graft. J Vasc Surg. 2011;54:307-315.