Is 16 F Small Enough? Will < 16 F Be Durable?

Experts discuss the impact of low-profile devices and the challenges to further reducing profile size.

Michael D. Dake, MD
Thelma and Henry Doelger Professor (III)
Department of Cardiothoracic Surgery
Stanford University School of Medicine
Falk Cardiovascular Research Center
Stanford, California
mddake@stanford.edu
Disclosures: None.

After observing the evolution of endovascular aneurysm repair (EVAR) technology over the last 2 decades, I started to believe about 5 years ago that devices in the range of 14- to 16-F outer diameter were not only feasible, but would also ultimately prove to be a workhorse size that would open the door to percutaneous procedures in nearly all patients—a true paradigm shift in practice. Now, the development of mid-range and large-bore closure devices in conjunction with mounting experience with percutaneous EVAR in select patients has us poised on the threshold of a new era, waiting only for the general acceptance of the proven effectiveness and durability of the smaller stent grafts. The convergence of decreasing graft sizes combined with the development of safe, simple, reliable closure devices focused on managing increasingly larger (double-digit French sizes) access has met comfortably at 16 F.

Is further concentration on reducing device profile warranted? Possibly, but there are diminishing returns from further size reduction below a 16-F outer diameter. Most would regard this pursuit as intriguing, but it is unlikely to provide additional clinical benefits and will require a sizeable investment to create a totally new technologic platform beyond the current metallic stent and graft design to achieve safe and effective smaller devices in the 10- to 12-F range. Even in the future, it is likely that interventionists will regard a 16-F EVAR device as asymptotically approaching the sweet spot of what is technically possible and clinically reliable—and that's not bad.

Jonathan S. Deitch, MD, FACS
Chief, Vascular and Endovascular Surgery
Associate Chairman
Department of Surgery
Staten Island University Hospital
Northwell Health System
Staten Island, New York
JDeitch@northwell.edu
Disclosures: None.

As scientists, clinicians, and engineers, we should never limit our ability to do better for our patients. We should continue to challenge ourselves and push the limits of what we can achieve technologically, or we will be at a standstill. I don't think many practicing vascular surgeons would have foreseen the day when 90% of abdominal aortic aneurysms (AAAs) could be repaired by endovascular means or percutaneous approaches to critical limb ischemia would be so successful or widely practiced. From this standpoint, we should continue to push the boundaries of percutaneous AAA treatment to < 16 F.

With some devices presently compatible with 14-F access (Ovation, Endologix), we have done a true service to our patients. Significant iliac occlusive disease, affecting about 15% of our AAA patients, is rarely a barrier for EVAR today because of reduced-diameter devices. Complications such as "iliac-on-a-stick" are now uncommon, and the need for iliac conduits has become less frequent. Furthermore, as many practitioners have routinely adopted percutaneous EVAR as their standard approach, many complications related to groin cutdowns (eg, groin infections, lymphocele formation, and saphenous neuropathy) have diminished in frequency. Along with 16-F EVAR, even the most conserva-

tive practitioners have growing confidence in percutaneous access. So, in the broadest sense, reducing access to < 16 F will be good for our patients. The days of ambulatory EVAR are just around the corner.

However, I must caution that the "buyer beware" because a reduction in device profile comes with a sacrifice in material diameter and strength. One can expect a higher rate of type III and IV endoleaks related to device integrity and porosity as device profiles are reduced below 16 F. However, I don't believe that this will be an engineering barrier at > 14 F because there are presently devices available at this profile without demonstrable fabric failure rates. Additionally, challenging iliac access, which will likely be overcome by EVAR with devices < 16 F, will likely come at the cost of increased graft limb occlusions due to severe concomitant occlusive disease. As such, I think that low-profile devices may come at a risk. Just as we saw runners break the 4-minute mile barrier with better training and conditioning, we can equate this to the EVAR with 16-F devices; I don't think that we will ever see runners break the 3-minute barrier, nor do I believe that EVAR with devices < 14 F will likely be encountered without newer materials.

Eric L.G. Verhoeven, MD, PhD
Chief, Department of Vascular and Endovascular Surgery
Klinikum Nuernberg
Paracelsus Medical University Nuernberg
Nuernberg, Germany
eric.verhoeven@klinikum-nuernberg.de
Disclosures: None.

The one word that jumps into my mind regarding smaller profile is "durability." Patients deserve a treatment that excludes the aneurysm and provides them with a safe feeling for the rest of their lives. This durability not only depends on the quality of the stent graft inserted but also on the correct indication. Too many stent grafts are being inserted into anatomies that would benefit from a different approach (eg, open or fenestrated). Too many operators are happy with the early result but forget to take into account that aneurysmal disease is progressive, especially in borderline-suitable anatomy. Too many presenters continue to boast about good short-term results in borderline anatomy. This has to change!

When we discuss new stent grafts and technical approaches, we also need to realize that durability is only tested in vitro, and we have been proven wrong many times in vivo. Nevertheless, I think that the companies are progressing with both the quality of their products and the quality of their testing.

Lower profile has been the Holy Grail for companies in order to compete with and surpass their competitors. All stent grafts are now available with smaller introduction systems, which present advantages during the procedure, including better and safer introduction through smaller arteries, less risk of iatrogenic injury and embolization, and making the option of percutaneous approach more logical.

With 16 F, we have now reached a profile that enables treatment of all patients. Perhaps the profile is already too low and we treat patients who may benefit more from an aortobifemoral graft? Most grafts are now made of nitinol stents instead of stainless steel, which is compatible with magnetic resonance angiography. The price we pay is somewhat lower visibility, lower radial force, higher thrombogenicity, and lower durability in the longer term, which should force us to be a bit more cautious with the indications, as previously discussed.

We do have a choice between many stent grafts, some of which now have proven long-term durability (eg, Zenith Tri-Fab, Cook Medical; Excluder, Gore & Associates), and we need to carefully balance when and why we use new concepts or newer, low-profile stent grafts in specific patients.

Edward Y. Woo, MD
Director, MedStar Vascular Program
Chairman, Department of Vascular Surgery
Professor of Surgery
Georgetown University School of Medicine
Washington, DC
Edward.y.woo@medstar.net
Disclosures: None.

The last 25 years in vascular surgery have been astounding in regard to the development of new technologies to treat vascular disease processes. Innovation has not only transformed vascular surgery but also cardiology, radiology, and cardiac surgery. Although nascent techniques for intravascular treatment were performed, it was not until Dr. Parodi introduced EVAR that the true endovascular era began. With EVAR came bold ingenuity, significant industry investment, and the courage to push the envelope far beyond the standard. It would be fair to say that EVAR has been at the forefront of vascular innovation for the last 25 years.

Technology has continued to advance EVAR as well. Stent and fabric design have evolved to improve fixation and seal. As a result, a larger number of patients can be treated and experience improved durability. Reduction in profile to allow easier graft delivery, trackability through almost all vessels, and smaller arterial access have been clear objectives. Devices now range from 14 to 22 F, with the most commonly used devices ranging from 18 to 20 F in outer diameter. Although this is still seemingly quite large and not markedly smaller than first-generation devices, sheath and coating technology, stiffer wires, and other technical innovations have ensured that almost all patients can be treated with these devices. In addition, suture-mediated closure devices have been successful in closing arterial puncture sites in this size range with minimal complications, thus facilitating percutaneous delivery of the stent grafts.

Although the appeal of smaller-profile devices is convincing, the reality is that it may be difficult to achieve. Reduction in access size is based on changes in fabric and stent structure/composition, which ultimately can lead to issues with durability. Over the last several years, we have seen some challenges in clinical trials evaluating low-profile devices. This may be a testament to difficulties in reducing profile and the sacrifices in doing so.

Ultimately, access profile will continue to decrease, but it may take a novel fabric, metal, and/or design to achieve a marked reduction while preserving durability. With the current array of stent grafts, closure devices, and techniques, we are able to offer more than adequate endovascular options for patients. ■