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Endovascular Aortic Repair: Why Long-Term Durability Should Not Be a Compromise

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How do you define "durable repair"?

Dr. Fatima: A durable repair is individualized to each patient, and ideally, it is one that lasts the lifetime of that patient. Although the general principles of attaining a durable repair remain unchanged (as alluded to below), age, physiology, frailty, and presentation of the patients may tailor the operative approach for needed durability. For instance, in the case of a young and healthy patient, a durable repair would warrant following all the rules of endovascular repair with minimal or no reintervention. Offering a repair in an old and frail patient with potential need for reintervention over time is acceptable durability, and getting the patient off the table alive may be the durability needed for a ruptured aneurysm.

Dr. Bechara: I am glad you asked this question. We really need to emphasize that we need to offer a durable endovascular repair that rivals open repair. Looking at 1-, 6-, and 12-month outcomes is important, but we need to examine the data and outcomes beyond those periods. Putting in a stent and seeing what happens should not be done; we are past that phase of learning about devices.

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The emphasis should be on what I need to do to provide a durable repair that will last the patient decades, like open surgery.

Dr. Maldonado: The National Institute for Health and Care Excellence (NICE) guideline entitled, "Abdominal aortic aneurysm: diagnosis and management (NG156)" was published on March 19, 2020, and recommended that open repair be considered as first-line treatment for elective unruptured abdominal aortic aneurysm (AAA).[1] The rationale for this was that, compared with open surgical repair, elective endovascular aneurysm repair (EVAR) "has medium- and long-term harms that outweigh the short-term benefits."[1] Not surprisingly, these guidelines prompted significant pushback and controversy from endovascular specialists because EVAR has become standard of care for most AAA patients. NICE guidelines remain biased against EVAR in large part because they draw conclusions from five randomized controlled trials (RCTs) (OVER, EVAR-1, ACE, EVAR-2, DREAM).[2-6] Although these trials are certainly important and elegant, they are likely inadequate to answer the question at hand: What is the safest and most durable intervention for AAA in 2021?

In the short term, technical success is clearly defined by exclusion of sac from systemic arterial pressure. Most would agree that any durable repair is one that is free of type I endoleak. Indeed, secondary interventions to treat type I endoleak due to graft migration or aortic remodeling/neck dilatation resulting in loss of proximal or distal seal are reflective of poor durability. Poor durability would also be defined as loss of graft integrity, as in type IV endoleak or stent fracture. Perhaps less clear is whether treatment of type II endoleak in the setting of sac expansion should be regarded as a reflection of a failed EVAR (poor durability), as it has little to do with the index procedure.

The majority of AAA patients in the four RCTs cited by Powell et al fail to live past 9 years.[7] Hence, the argument that EVAR should be abandoned in favor of open surgery only to protect the small group of survivors approaching their ninth decade of life, while denying the proven early survival advantages of EVAR to the entire cohort, seems to place undue worth on the later time period. This approach may further undervalue the importance patients place on superior early outcomes, specifically survival in the first 4 years after EVAR. Hence, defining a durable repair as any repair that can last 10 years would be reasonable. Nonetheless, as the NICE guidelines remind us, our task as endovascular specialists is to carefully screen our EVAR patients and remember that open repair may be the better option for some of our patients with inadequate anatomy for EVAR. Careful patient selection (including a balanced assessment of patient comorbidities and life expectancy) will optimize our chance of durable endovascular repair.

Dr. Mastracci: How long is a piece of string? In fact, the durability of the repair depends entirely on the life expectancy of the patient into whom it's being implanted. In much the same way that we gauge appropriateness of aortic repair based on a minimum expected life expectancy of a patient, I think the collective 27-year experience with endovascular surgery now allows vascular surgeons to gauge the aggressiveness of their approach with the maximum life expectancy of the patient. For the patient who is 70 years old and has the combination of poor landing zone distal to the renal arteries and no other comorbidities threatening their life expectancy, you can be almost certain that an infrarenal EVAR will evolve to type I endoleak and require reintervention within the patient's lifetime. I usually quote an average of 5 to 7 years to failure, but this can be shorter in really bad landing zones. Thus, a complex stent graft that lands through the visceral segment is most likely to provide the level of durability that is needed for a repair to last longer than the patient. Conversely, an 80-year-old patient with a similar landing zone may warrant a less aggressive approach.

The best aortic repair strategy would be to plan a repair that outlives the patient, without shortening their life expectancy with an unacceptably high perioperative risk of overly aggressive repair in the process.

When reviewing a patient for EVAR, what factors go into your decision-making to provide that patient with a durable repair?

Dr. Fatima: I believe a durable repair is reliant broadly on the interplay between patient- and device-specific factors. One must pay great attention to the anatomic details of the aorta when evaluating for EVAR—in particular, the characteristics of the landing zones for adequacy of seal. A durable seal requires landing in a healthy parallel segment of aorta. Hostile characteristics, such as short, angulated, wide, tortuous, calcified, or thrombus-laden neck, compromise the durability of the repair, and alternate ways/techniques or additional adjuncts should be considered when the aortic anatomy is fraught with these. Additionally, the device characteristics, such as its conformability and integrity, active fixation to the aortic wall, and resistance to migration or fracture in challenging anatomy, are important considerations in determining what may be the best device for each patient.

Dr. Bechara: I try to simplify the process as much as I can; our patients are complex enough! When I review images and see a patient with an aneurysm, I look at the

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patient's overall health status, aneurysm anatomy, and access. I will elaborate on each. Patient age is important, but we see healthy, very active patients who are well into their 80s with aneurysms. I look more at their quality of life. As an example, for a patient who does not leave the house and is on home oxygen or with severe dementia with no support, I would probably never offer surgery. Taking into account physical activity, health, patient longevity, and quality of life are important.

When looking at aneurysm anatomy, it is more than just diameter. Having said that, if a patient has a poor health status, I would probably wait until the aneurysm is > 6 cm before I would offer surgery to justify the risk of surgery over rupture. It is all about risk and benefit. Another thing I look at is whether this is a straightforward endovascular repair with healthy neck that I could potentially do under local anesthesia or whether it is a complex endovascular case. If complex, I start looking at visceral anatomy, angulation, calcifications, length of coverage, risk of spinal cord ischemia, access issues, etc. Access issues could lead to severe complications like colon, lower extremity, and pelvic ischemia, with prolonged large sheath-insertion, and these need to be considered too when planning a case. Finally, always include open surgery in your algorithm. It sounds like a lot of information to take into account, but that is what goes through my mind, and now I am able to process it quickly.

Dr. Maldonado: Patient selection (specifically, patient aortic anatomy) is paramount to provide patients with the best chance of a durable endovascular repair. Distal seal can generally be achieved, whether with an iliac branch device or simple internal iliac embolization and external iliac extension, but proximal seal must never be compromised at index procedure if one is to achieve the most durable repair. Hostile neck anatomy (ie, short, angulated, concentric thrombus, and heavy calcification) should be avoided when possible, as these have been shown to result in sac expansion.[8,9] Sac remodeling and neck dilatation can result in graft migration and type I attachment-site endoleak. Additional factors have been shown to contribute to neck dilatation, including larger neck diameters, self-expanding stents, and excessive oversizing.

When obtaining the best seal in healthy aortic neck, ideally > 20 mm in length and with minimal calcium, thrombus, and angulation should be the ideal. As such, in the absence of such infrarenal anatomy, one should not hesitate to obtain seal more proximally. Indeed, these hostile-neck, infrarenal AAAs are more accurately defined as "pararenal" or "juxtarenal." In my practice, I am more liberal in relying on fenestrated technology to ensure the healthy 20 mm of proximal seal, even if standard EVAR might yield acceptable completion angiogram. In fact, others have shown higher incidence of late sac expansion (12.2% vs 1.9%; $P = .036$) between EVAR and fenestrated EVAR (FEVAR), due largely to what appears to be a compromise on "healthy infrarenal aortic neck" in the standard EVAR cohort.[8]

Dr. Mastracci: I think looking at both aortic and physiologic factors is important. Anatomy plays a large role in the decision-making. Choosing a long landing zone (> 2 cm) that doesn't end in the middle of the visceral segment (ie, either an infrarenal device or a device with four fenestration/branches) has been an approach that has served me well. Ultimately, the goal is to design something that won't fail, but if it does, it "fails well." This means that it would be easy to repair the second time around.

Another thing I think about is the number of vessels to incorporate in a complex repair. Although old wisdom used to be to stay away from the celiac because it was tricky, I think that view has largely been abandoned. Incorporating fewer than all four visceral vessels makes failure a lot trickier to manage, and in reviewing our centers' experience, we've recently found that sealing above the celiac artery makes a much more long-term stable device.

Finally, I think it's critical to pay close attention to distal sealing zone. It is sometimes tempting to place bell-bottom devices in ectatic iliac arteries, especially after a long and difficult proximal procedure. However, distal endoleak is not uncommon when large-diameter iliac devices are placed, and so centers should consider iliac branch devices when possible to create a durable repair, or keep in mind that this is a staged repair with the intention of converting to iliac branches in a year or so.

We sometimes hear "the final run looks great" after an endovascular aortic repair; what concerns do you have about this comment and why?

Dr. Fatima: The "final run" is a two-dimensional (2D) angiographic evaluation that is prone to missed endoleaks, specifically, an occult type Ia endoleak. Additionally, the inference of data from the run relies on whether the run was completed with the wires in place or without them, which can often alter the conformation of the endograft to the aortic wall. I always tell my trainees that > 90% of the case is done in the planning phase. Planning, ideally using TeraRecon software, should be done with such precision that one has accounted for any anticipated challenges that the case may present. A compromised plan may result in a 2D picture that seemingly looks great but may have downstream implications, with a potentially more complex remediation. When any of the

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challenging anatomic features are encountered, one should consider extending the repair to a healthy aortic segment. Additionally, one may couple the final run with adjuncts such as intravascular ultrasound to assess for satisfactory apposition of the graft to the aortic wall. Alternatively, an on-table cone-beam CT may give a more definitive confirmation of adequacy of repair and the opportunity to remediate the leak in the same setting.

Dr. Bechara: Luckily, most times that holds true, but a final cone-beam CT can provide us with more information. If you have that technology, use it. It saves on contrast and omits the first post-CT scan. If relying only on angiography, make sure you do a prolonged injection and in anteroposterior and oblique views. When dealing with complex cases, the final cone-beam CT should look great—not just the final angiogram. There is no reason to learn of a crushed or occluded renal or superior mesenteric artery stent on day 1 after surgery when it could have been identified intraoperatively and dealt with.

Dr. Maldonado: The goal of a completion angiogram should not only be to assure lack of type I endoleak but also to confirm the operative plan was indeed achieved. To this end, multiple completion angiograms should be obtained under a variety of oblique projections to properly interrogate the neck for leak, remove parallax, and assure proper positioning of the proximal stent relative to the seal zone. Careful attention should be paid to the completion angiogram in the context of the underlying aortic anatomy and the operative plan. For example, inadvertently deploying a standard EVAR stent 5 mm distal to the lowest renal in a 10-mm neck is, at best, a tenuous seal. Such a scenario would warrant either placement of a proximal aortic extension cuff and/or careful, more vigilant surveillance for stent migration and type I endoleak.

However, the primary endpoint to any endovascular repair should not be the completion angiogram but rather the long-term durability of the repair. Specifically, the freedom from sac expansion and/or type I endoleak. Type II endoleaks are more controversial and may not necessarily be considered a failure of treatment by some. Hence, a completion angiogram in the setting of an operative plan that relies on a seal in an unhealthy aortic neck should also be scrutinized more carefully intraoperatively and in follow-up.

Dr. Mastracci: Over the years, experience has taught us that a sealed device at the time of implantation does not necessarily predict long-term durability. When devices are landed in "vulnerable" aorta (ie, aorta that has a lot of risk factors to dilate further in the future), follow-up CT scans will likely reveal type Ia endoleaks as the aorta continues to grow beyond the diameter of the sealing stents. This was proven by my colleague Dr. O'Callaghan in 2015.[10] The ability of stent grafts to seal in unhealthy aorta is one of their characteristics that we can exploit for good—using endografts in ruptured aneurysms with bad but "sealable" necks is great as a bridge to destination therapy. It gets the patient through a difficult rupture and allows us to plan definitive treatment. However, I'd say this is the only time it would be advisable to land in unhealthy sealing zone, because even though we might get a seal, it won't last long.

Sac regression has been shown to be linked to longer-term survival rates.[11] How has this played into your decision-making when choosing an aortic stent graft?

Dr. Fatima: Optimal sac behavior is incumbent on (1) good apposition of the endograft in a healthy parallel aortic segment and (2) absence of endoleaks. An endograft that has the flexibility to conform to the aortic wall and anchors to fixate it at the intended location can be instrumental in optimizing seal and durability. In the thoracic segment, a tapered graft can be particularly useful to avoid excessive oversizing when there is significant discrepancy in the proximal and distal landing zone diameters, therefore avoiding infolding of endograft. A longer endograft can avoid multiple short pieces and, as such, mitigate the potential risk of endoleak. An endograft should be carefully selected based on the individualized anatomic needs of each patient and thereby facilitate sac regression and ultimately enhance durability of repair.

Dr. Bechara: Sac regression is important for long-term survival, but achieving sac regression is more complex than just choosing a stent graft. Stent graft design, graft porosity, and graft thickness play a role as well, which some link to the severity of the postimplantation inflammatory state. Further investigation is needed on the role of inflammation and inflammatory markers with aneurysms and stent grafting, particularly those with endoleaks, and their effect on sac regression. I have treated endoleaks (endo or open) in patients who felt better afterwards! There must be a relationship between endoleaks and thrombus in the sac causing an inflammatory state. Another thing to consider is if preoperative embolization of large lumbars and the inferior mesenteric artery causes sac regression. Patient sex, thrombus burden, and statin therapy are other risk factors influencing sac behavior. We need more research in this area to be able to answer that question.

Dr. Maldonado: Sac stabilization (static diameter or shrinkage) has traditionally been regarded as evidence of

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successful EVAR repair. In many ways, it is not surprising that recent data show sac regression to have been linked to longer-term survival rates and hence should be regarded as the best metric for successful repair. Achieving sac regression may be multifactorial and implicate type II endoleak, sac remodeling, loss of proximal seal due to neck dilatation, and/or stent migration. Recent data have suggested that fenestrated repair can result in significant sac regression.[12] Although few studies directly compare standard EVAR to FEVAR, current studies presented at this year's Vascular Annual Meeting (VAM) report higher incidence of sac regression in FEVAR compared to EVAR.[13] Curiously, FEVAR does not appear to have a lower incidence of type I endoleak compared to standard EVAR. Rather, some hypothesize that FEVAR may achieve better seal than EVAR, resulting in less endotension, which leads to protection from sac growth and even induces sac regression. As a result, in patients whose anatomy might otherwise achieve a proximal seal with standard EVAR but whose proximal aortic neck is anatomically hostile, I believe in more liberal use of FEVAR to minimize endotension and induce sac regression. Ultimately, this translates into more durable repair in my opinion. A caveat to this approach/philosophy is that one must not compromise on renal or visceral vessel anatomy when considering fenestrated technology.

Dr. Mastracci: Similar to answers to the questions above, the decision is most closely related to the amount of coverage needed for each individual patient. If you can design a stent that has durable seal, it is far more likely that you'll achieve sac regression.

Durability of devices has emerged as a key topic in achieving successful aortic repair; how has it changed the way you approach treating aortic disease? If it hasn't, why not?

Dr. Fatima: Over time, we have learned more about the role of native aortic processes and device impact on landing zones, particularly in short, diseased, or hostile seal zones. We have gained more data and knowledge regarding the increased frequency of aortic neck dilatation as we push the envelope in complex/challenging anatomy. It seems only prudent to be more aggressive up front regarding building up into a healthier segment of aorta. I am more liberal in my use of fenestrated and branched technology in short or otherwise compromised neck to attain adequate seal and improve long-term durability. Additionally, it is important to understand failure modes of devices that can result in disruption of stent architecture, fabric tears, and increase the risk of endoleaks. Long-term durability data are instrumental in understanding these and selecting grafts that may be less susceptible to such adverse events.

Dr. Bechara: I believe that devices overall have improved tremendously since the ones I used in training. When planning a case, we need to make sure we have adequate seal proximally and distally, and this should never be compromised. I believe we have done a tremendous job teaching our trainees to think that way too; I experience it personally when fellows and junior faculty discuss cases with me. Also, social media has brought us closer. Finally, I always tell my trainees they need to know any device or stent they use very well. Always read the instructions that come with any device. I tell them that they not only need to know how the device works but also how it fails. If you do not know how it fails, then you will be seeing and dealing with more failures during your career.

Dr. Maldonado: The advent of EVAR technology in the late 1990s and early 2000s invited a wave of naïve optimism and, at times, blind trust in the device integrity and durability. In the recent decade, endovascular specialists and ultimately patients have become all too well-informed and familiar with the delayed failures of certain stent graft technology. Fabric porosity/tears, stent fractures, and fabric fatigue are all painful reminders that design failures must be reckoned with and are best avoided altogether if possible. For this reason, certain established devices may reap the benefit of building on time-tested platforms. Conversely, new devices are burdened by a higher standard to prove safety, efficacy, and durability. The latter being a function of time that no benchtop test or clinical trial can predict or produce. For these reasons, in my practice, I am certainly more wary of devices that are not based on established design platforms.

Dr. Mastracci: I think focusing on durability means changing your mindset from short- to long-term outcomes. In practice, this means relying on feedback from surveillance clinics rather than completion angiography to guide the appropriateness of surgical judgment over time. Having a robust audit system, keeping track of outcomes, and being able to draw a line between intraoperative decision-making and findings on follow-up CT scans after many years is really crucial to designing for durability. This shifts the focus in our multidisciplinary team discussions considerably and makes the clinical research we do imperative to patient care. Also, because this sort of feedback can be years in the making, we are increasingly more enthusiastic about follow-up strategies that help us refine surgical decision-making.

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What role do long-term data play in the future of current or next-generation aortic stent grafts?

Dr. Fatima: It is important for any device to have long-lasting integrity of its fabric and infrastructure. Most devices on the shelf have gone through extensive bench testing to prove resistance to mechanical device failures; however, whether their performance upholds in clinical setting will warrant evaluation through clinical trials and long-term follow-up. Long-term data are critical to establish long-term durability of these devices, but the device industry has been and will continue to evolve to reduce device delivery profile and improve graft material for enhanced flexibility to better accommodate the anatomic needs of aortic pathology. Therefore, these long-term data should be used as a platform to learn from the previous-generation devices to allow for efficient, effective engineering of next-generation devices.

Dr. Bechara: We really need to look beyond 1- to 2-year data. It is our duty to track long-term data for 10 to 20 years; we owe it to our patients. Having registries is one way of achieving this. As for next-generation grafts, we learned again and again that we cannot compromise device integrity and durability over a lower profile. The other issue is how we convince patients to get their follow-up studies and send them reminders to get their yearly duplex or CT. Many studies have shown that patients who are lost to follow-up have worse outcomes. One thing I found helpful in my practice is to ask my patients to get their studies done locally or whatever is convenient for them and to send the images, not just the report, to me for review. Patients appreciate that and are more compliant when they are able to get their studies locally. However, not all vascular labs are familiar with endoleaks and diagnosing them. I find myself ordering more CT scans, but at least I am able to track more patients.

Dr. Maldonado: Long-term data were woefully absent in the early days of EVAR. Presently, new EVAR technology continues to rely on 5-year data from clinical trials. Longer, more robust, and arguably more relevant data exist in the form of registries, albeit less controlled. Interestingly, the majority of patients enrolled in the four clinical trials cited by Powell et al failed to live past 9 years after EVAR.[7] The question remains regarding the appropriate duration for capturing long-term data to assure safety and efficacy of new EVAR technology. Although 5-year data seem too short, 20-year data would seem excessive or even impossible for this patient population. Ten-year data seem appropriate for next-generation stent grafts, especially those that do not build on established time-tested platforms.

Dr. Mastracci: Long-term data are the key to designing stent grafts that last, so it is imperative that no data point is wasted. In an ideal world, all centers would be collecting data about outcomes and complications and analyzing the work they do so we can share collected experience. Rare events, or those that take a long time to mature, are not commonly seen in sponsored trials and are best captured in real-world experience. Large databases may be the key to iterating technology to ensure that we don't repeat the errors of generations past and evolve devices and practice to improve quality of care. ■

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