Supplement to

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VASCULAR INTERVENTIONS

ADVANCING THE CONVERSATION

AORTIC THERAPIES • PAD THERAPIES • EMBOLIC THERAPIES
VENOUS OBSTRUCTION THERAPIES

VASCULAR INTERVENTIONS

ADVANCING THE CONVERSATION

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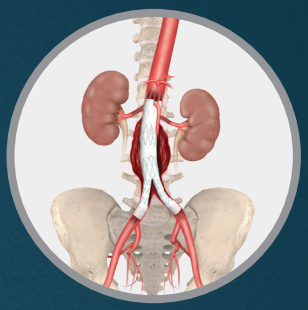

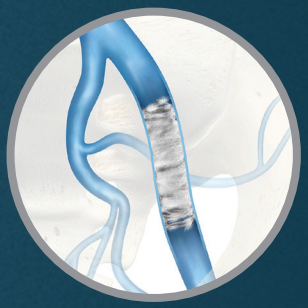

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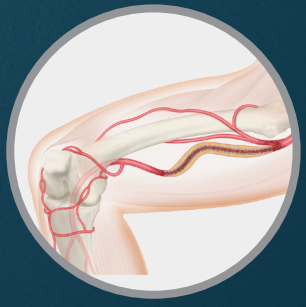

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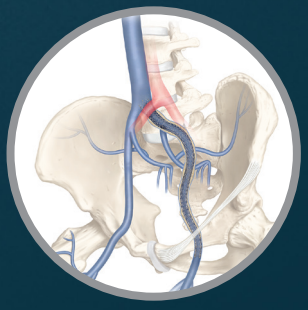

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Providing a Comprehensive Approach to Vascular Disease

Cook Medical is committed to helping physicians treat vascular diseases. We can provide physicians with the devices, therapies, and training that they need to approach these diseases comprehensively. We know there is increasing pressure to provide optimal results for patients, understand the economic value of the products used during procedures, and know more about the data behind the products. We recognize this and have decided to focus the topics in this supplement on the issues and conversations around these pressures and key issues that physicians face in the vascular space.

First, Javairah Fatima, MD; Carlos F. Bechara, MD; Thomas S. Maldonado, MD; and Tara M. Mastracci, MD, discuss endovascular aortic repair. Next, Scott O. Trerotola, MD, moderates a discussion on the clinical and economic power of pushable coils, with Sarah White, MD; Daniel Brown, MD; Riad Salem, MD; and Alan H. Matsumoto, MD, sharing their thoughts. Then, John Phillips, MD; Venita Chandra, MD; and Michael Wilderman, MD, talk about data transparency and how data help drive decision-making. Finally, the supplement is wrapped up with Stephen Black, MD; Kush R. Desai, MD; and Paul Gagne, MD, discussing venous obstruction and what factors are important to consider when diagnosing and treating a patient in order to achieve optimal outcomes.

We should continue these crucial conversations at symposia, in the hospitals and labs where we work with physicians and partners, and on social media. We will continue to listen and ensure we are thinking critically about how we can be an innovative partner and provide better outcomes for patients. We thank all of you for continuing to provide us feedback and for providing exceptional patient care during these challenging times. There is a lot of work to be done, but we are certain our readers can expect more from us.

Mark Breedlove
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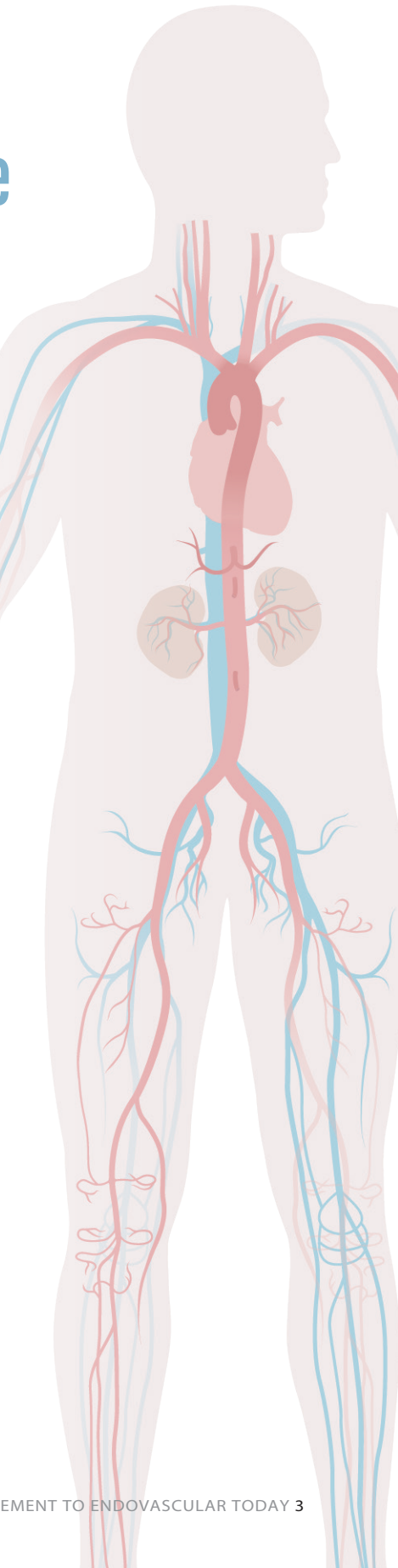

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AORTIC

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

With Javairiah Fatima, MD, FACS, RPVI, DFSVS; Carlos F. Bechara, MD, RPVI, FACS, DFSVS; Thomas S. Maldonado, MD, FACS; and Tara M. Mastracci, MD, FRCSC, FACS

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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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EMBOLIZATION

Harnessing the Clinical and Economic Power of Pushable Coils

Moderator: Scott O. Trerotola, MD
Panelists: Sarah White, MD; Daniel Brown, MD; Riad Salem, MD, MBA; and Alan H. Matsumoto, MD, FACR, FSIR, FAHA

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Dr. Trerotola: How do you feel about pushable versus detachable coils?

Dr. Brown: I use pushable coils basically as much as I can. I reserve detachables for a set situation when I'm worried that a pushable coil might prolapse back into the main artery.

Dr. Matsumoto: I reserve detachable coils for situations like Dr. Brown mentioned but also when I'm worried about them flying somewhere, like in a pulmonary arteriovenous malformation blowing through the big nidus. That's always nerve-wracking. I prefer to use pushable coils whenever possible and even in the case of a safe situation and location, I will inject them so I don't have to use a pusher wire.

Dr. Salem: I use mostly pushable coils, but I might use a detachable if I need explicit position of the coil (eg, for a gastroduodenal or a right gastric in the internal oncology space or for tumor redistribution). However, in general, I use pushables.

Dr. White: I think it depends a lot on location and vessel tortuosity. If there's a lot of tortuosity, a detachable coil may have a hard time navigating the turns. In that case, I may use a pushable coil. If I need exact deployment, I might use a detachable rather than a pushable. For the most part, pushables are my go-to coils because of their ease of use, cost, and variety of sizes.

Dr. Trerotola: When you use detachable coils, what percentage of the time do you actually reposition them?

Dr. Brown: I reposition them infrequently. To be honest, when I make the decision to use them, I usually end up putting two in rather than one; sometimes, I wonder if I could have gotten away with another pushable before making that decision.

Dr. Matsumoto: Probably < 10%. I find that I have to reposition a coil when it starts to migrate through a fistula or if the stability of my catheter position is tenuous. I also use detachable coils when I'm trying to create a coil nest within an aneurysm with a relatively wide neck, so if the coil begins to prolapse out of the aneurysm into the parent artery, I can reposition it.

Dr. Salem: Very rarely; < 5%, if ever, to be honest with you. Retracting the coil may be associated with losing the access you worked hard to get. You have to balance taking what you've gotten compared to repositioning and potentially losing that access.

Dr. White: I would agree with < 5%. When I need to reposition, I will retract it and get it to break in a different way.

Dr. Trerotola: How much do you think that fiber matters on coils?

Dr. White: I think fibers make a big difference. Even if I'm using a detachable coil for bleeding, for example, I know that I'll need to use a pushable because it has more fibers and will cause vessel occlusion. The fibered detachable coils don't have as many fibers as the Nester and Tornado coils (Cook Medical). If you do use a detachable, it becomes much more necessary to use more coils because you need to tightly pack them in. I think you need to have fiber, unless you have the ability to pack it in tightly, which is often not the case in a bleeding situation.

Dr. Salem: I speculate that for a larger vessel, it's probably helpful to a certain extent. I don't think it matters for smaller vessels because you're physically occluding the lumen but also hopefully distorting that vessel itself and injuring it, thereby causing thrombosis. I think there are multiple ways you get that occlusion in the small vessels. In a larger vessel, I prefer fiber.

Dr. Matsumoto: I prefer fibered coils because they stimulate an inflammatory reaction and cellular ingrowth and are less likely to recanalize, although they're a little bit more likely to compact over time. I think fiber does help for durability and reducing the incidence of recanalization through the coil.

Dr. Brown: I prefer fibered coils. Looking at when we did gastroduodenal artery embolization, before Yttrium-90 and before Nester was out, there was a case where I used about 20 to 25 pushable metal coils. When Nesters came on the market the first time, I used them. I did two cases and used a total of 12 coils, and we put them in the inventory the next day.

Dr. Trerotola: Are you under pressure to reduce the costs of the disposables you use?

Dr. White: Supply chain is putting more and more pressure on us to decrease our overall cost.

Dr. Salem: As Chair of our Value Added Committee, I have to say yes. On a system level, we certainly look at standardization and getting the best pricing with vendors.

Dr. Matsumoto: Yes, absolutely. Margins are shrinking, we're all being asked to eliminate waste, and value-based purchasing and care are here. In fact, as Chair, I try to

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reduce costs and overhead for device inventory, with hopes that we'll be provided with extra nurses, technical staff, or maybe another ultrasound machine. It's critically important as the margins shrink that we are aligned with reducing the costs related to our supplies. It's ultimately one bucket: You spend more on supplies, and the system has less revenue to pay for staff.

Dr. Brown: We haven't gotten to the granularity of case by case and people asking me why I used what I did, but there's definitely a move to cut budgets and make supplies cheaper.

Dr. Trerotola: Are you aware that sometimes the procedures we do actually exceed the reimbursement of the procedure?

Dr. Brown: This situation can absolutely occur. This event is especially true if a large number of detachable coils were used when pushables were feasible.

Dr. Matsumoto: Absolutely. All the people on this panel work in academic medical centers. It's oftentimes hard for us to exactly track our costs, what our margins are, and what we lose or make per procedure. If you're in an office-based lab or in a practice and someone says, "I'm going to give you a bundled payment for this procedure," you will surely start doing the math and figuring out how to trim your costs to increase your margin. Those of us on the panel have been lucky in that we've been practicing in academic medical centers, so we get to play around sometimes with newer and more expensive tools. We need to change our behavior and start assuming accountability for the overhead and costs associated with a procedure, including the devices being used.

Dr. White: I think about the cost of coils, and I even know how much each detachable coil on my shelf costs. If I need to use one of the expensive ones that we stock here, I make certain its use is justified. The most important thing is to get the patient what they need. If I have to exceed cost, then that's fine; but, I certainly think about it twice if I have to pull the really expensive ones off the shelf.

Dr. Trerotola: If I could give you a sheet of paper at the end of each case that showed how much you spent on a case, broken down by the devices, would that change your behavior?

Dr. White: Absolutely.

Dr. Salem: Yes.

Dr. Matsumoto: Sometimes.

Dr. Brown: Most of the time, yes. ■

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PERIPHERAL ARTERIAL DISEASE

Satisfying the Practitioner's Need for Long-Term Data, Transparency

With John Phillips, MD; Venita Chandra, MD; and Michael Wilderman, MD, FACS

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Is data transparency important when choosing a superficial femoral artery treatment?

Dr. Phillips: Certainly, but the devil is in the details. Thankfully, we have a lot of options when treating the femoropopliteal region, but at the end of the day, we want to know the intervention will be safe, efficacious, and durable. There are a lot of data out there—some of it good, some of it not so good. Physicians have a fiduciary responsibility to be as informed as possible. Likewise, our industry colleagues have the responsibility to provide us with the highest level of quality data with the longest possible time frame. If we have learned nothing else from the paclitaxel mortality concern, it is that we need more patient-level data and more long-term follow-up with any treatment modality we use.

Dr. Chandra: Data transparency is always important. It is so easy to shape data or present data in a way to make a point, but it is our responsibility as vascular interventionalists/surgeons to look closely at the data and make our own decisions about what they mean and how they will impact our practice.

Dr. Wilderman: Every time I take care of a patient, I care about both the short- and long-term outcome. This is even more important when I'm implanting a stent inside a patient. For any given clinical scenario, I am to use the device with the best short- and long-term results. Therefore, clinical data and personal experience are of the utmost importance to me. One of the challenges in the peripheral vascular space is that not all trials use the same endpoints or time lines. It can be difficult to compare devices head to head because of many confounding factors. Therefore, the better, longer, and more transparent a particular data set is, the easier it is for me to interpret and take to clinical practice.

How has the fear of increased paclitaxel mortality impacted your practice?

Dr. Phillips: My practice and the practice of our health system were initially impacted, as I imagine most were. However, as more patient-level data came out and the hazard ratio continued to shrink, my fears with respect to increased mortality risk when using paclitaxel, whether it be with a balloon or stent, were assuaged. Ultimately, in my opinion, the recently published data in the SWEDEPAD trial put this issue to rest for me.[1] I have always believed that the use of paclitaxel in either a balloon or stent produces more durable results with a similar safety profile to nonpaclitaxel–based products.

Dr. Chandra: It no longer affects my practice. Certainly, when the Katsanos et al paper first came out,[2] everyone

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needed to pause and take a deep dive into the issue. Ultimately, I think with larger amounts of patient-level data, there really is no longer any sign of a concerning signal when it comes to mortality. Given the significant efficacy data, my practice has gone back to the liberal use of drug-eluting technologies.

Dr. Wilderman: When Katsanos and his team reported an increase in late all-cause mortality in patients treated with paclitaxel-coated devices, the peripheral vascular world was shaken. We knew that these devices clearly outperformed noncoated devices in terms of patency, but increased mortality? The FDA issued a warning letter, hospitals were pulling products, and patients were concerned. Since then, the data has been reevaluated. In the Zilver PTX trial from Cook Inc., the initial published mortality results were reported based on the primary randomization and grouped based on the initial intent-to-treat groupings. The investigators later reported that 40% of the primary angioplasty group were actually treated with Zilver PTX (Cook Medical) in secondary randomization and crossover. If these patients were actually placed in the PTX group, there would have been no difference in mortality between the two groups.[3] Moreover, since that paper, others have found no increased mortality with paclitaxel-coated devices. As more and better data have become available, it has become easier to ease our patient's fears and concerns. Most patients now want me to do whatever I think is best for them, even if that means using a drug-coated device.

Do you feel like you have all the tools you need to treat critical limb ischemia (CLI)?

Dr. Phillips: I believe we are getting close, and the future is bright for treating CLI, particularly below the knee. I would like to see a dedicated scaffold with an antiproliferative agent for the tibial vessels. However, in general, I feel that both the wire technology and crossing catheter advances have truly changed our ability to cross these long, complex lesions. Also, the ability to modify the plaque, whether it be with a specialized balloon or atherectomy device, continues to improve our short-term results. Finally, we now have a dedicated device to treat dissections that occur after balloon angioplasty, and hopefully more devices will come to market to provide even more durable results. Ultimately, I believe we are much better off now than we were 5 years ago, and these patients who are the sickest of the sick with the highest mortality rate are the ones who are benefiting the most.

Dr. Chandra: We have made great strides and dramatically evolved our armamentarium of tools for CLI patients, but we still have a long way to go. Durable management of long chronic total occlusions and heavily calcified lesions and management of significant distal small-vessel disease/pedal arch disease are areas where we continue to need new tools.

Dr. Wilderman: CLI is a challenge, and unfortunately, many patients present too late in their disease course. We are still missing certain tools, the main being stents (with or without drug coating) designed for tibial vessels. Although some people prefer drug-coated balloons and atherectomy devices, I think that durable stents made for tibial vessels will be of great clinical significance to outcomes in the treatment of CLI.

Eluvia (Boston Scientific Corporation) 3-year data have still not been presented; has this affected your practice?

Dr. Phillips: Not at this point. However, the Zilver PTX stent is the torchbearer for drug-eluting stents (DESs) in the femoropopliteal segment. It has been on the market the longest and therefore has the most longitudinal data. Because of this, all other stents with paclitaxel, and balloons for that matter, will be judged against the Zilver PTX DES. We now have two paclitaxel DESs for this region, both of which have raised the bar in terms of patency and reduction of clinically driven lesion revascularization rates. In my opinion, these facts cannot be understated and should be celebrated as we continue to move forward to develop durable technology to treat this very complex anatomy.

Dr. Chandra: It is difficult to be the later player in the field. As such, Eluvia does not have a significant role in my practice because (A) it was not the first tool out there, and (B) its lack of longer-term data can't compete with the current players that are clearly proven to be safe and efficacious.

Dr. Wilderman: I have had great long-term success with Zilver PTX when I wish to use a drug-coated stent. The investigators have published outstanding 5-year data, and I have a large personal series as well with outstanding outcomes. For me to change to a new device, I would want to see as good, if not better, long-term outcomes in their clinical trial. Moreover, I would also want to see real-world data. The fact that the medium- and long-term Eluvia trial data have not yet been published makes me pause when selecting that stent over others with more long-term follow-up data.

Has concern of hypoechogenic halo, aneurysmal degeneration, persistent inflammation, negative

late lumen loss, persistent shadowing, positive remodeling, or aneurysm formation influenced your DES decision?

Dr. Phillips: Any time there are possible concerns raised about the durability of a device and/or negative architectural changes that may occur within said device or the surrounding vessel, we should take pause and reassess things. I believe we should look at the data closely and make the most informed decision on a case-by-case basis regarding what type of DES to implant. Although the data are statistically similar through 2 years, the Eluvia stent and Zilver PTX stent have differences with respect to their design and elution of paclitaxel. I do not believe that we have cornered the market on what the perfect antiproliferative agent is, how it should be impregnated on a stent, or how it is eluted over time. However, great strides have been made with respect to this technology, and we will continue to improve and develop new treatment modalities for the femoropopliteal segment and the tibial arteries.

Dr. Chandra: Yes, these findings are certainly concerning. It will be important to see the longer-term sequelae of these issues. As we have seen with the Katsanos et al paper, concerns occasionally present themselves and are later realized to not be an issue. However, it is hard to argue that such findings are acceptable. For now, I would not readily use a DES with such complications, especially when there are data on another commercially available DES with long-term efficacy and safety data.

Dr. Wilderman: Any device can have complications associated with it, and peripheral stents are no different. There have been reports of aneurysmal degeneration and halos after DES placement, but I have not seen it in clinical practice. I have placed hundreds of DESs over the years, and we participated in a large single-center registry. Our real-world results were similar to other large registries, and we did not have any patients with aneurysmal degeneration. For me, the most important thing is stent patency and freedom from symptoms and reinterventions. In my practice, DESs have performed the best, and I am not willing to compromise. ■

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2. Katsanos K, Spiliopoulos S, Kitrou P, et al. Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: a systematic review and meta-analysis of randomized controlled trials. J Am Heart Assoc. 2018;7:e011245. doi: 10.1161/JAHA.118.011245
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VENOUS

Venous Obstruction: Achieving Optimal Outcomes

With Stephen Black, MD, FRCS (Ed), FEBVS; Kush R. Desai, MD; and Paul Gagne, MD, FACS

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What are the most important factors you consider when diagnosing and preparing to treat a patient with venous obstruction?

Dr. Desai: It's about setting expectations. Venous disease remains a disease you manage. It's not something that you necessarily cure. Once you have identified what the pathophysiology is and what measures you need to take to treat the patient, you need to set the appropriate expectations. The diagnosis part is challenging, and we talk about it on a daily basis. But what I think is missed sometimes is making sure you set appropriate expectations, including that the patient needs to play an active role in their own care. They have to be compliant with their compression, compliant with their anticoagulation, and, when necessary, have to help you help them.

Prof. Black: I agree with Dr. Desai that it is important to manage expectations. We generally make patients better, but there are very few people who we make completely fine. We can't undo damage in its entirety. A stent in a vein is not natural; it overcomes a problem of obstruction, but it doesn't return a vein to what it was before. We're trying to improve people's symptoms and quality of life. As part of having a comprehensive practice, you need to look at every part of the venous system. There isn't a diagnostic test that says "yes" or "no" in a binary fashion. It's about putting history and diagnostics together in a way that makes sense to treat the venous obstruction first. However, there may be other things you might have to treat afterward or perhaps leave. If you have a comprehensive practice, you avoid a confirmation bias like, "It must be varicose veins."

Dr. Gagne: Taking a very careful history and physical is critical. It also helps to go down the checklist of a differential diagnosis. We know that the list of potential diagnoses for leg swelling is long. You can have skin damage and discoloration from a variety of pathologies that are not just venous related. So, appreciating the differential diagnosis of some of the key findings in both history and physical exam is important. Two diseases can look the same but are not the same. They share some similar characteristics. A careful history and physical exam, along with considering the differential diagnosis, helps you arrive at the right diagnosis more times than not.

For patients with deep venous obstruction, how do you gauge outcomes?

Prof. Black: We don't have a standard measure of outcome. There's so much variation in what people are using. We need a much more defined standard set of measures that quantifies what regulators, payers, and patients want. We're working with the International Consortium for Healthcare Outcomes Measurement to define a standard set of outcomes. We need an objective measure, such as vessel patency on duplex scan. If you don't have a patent vessel, then everything else falls apart. We also need a clinical scoring system like the Venous Clinical Severity Score (VCSS) or the Villalta score and a patient-reported outcome measure that includes quality of life. Then, we need everyone to report outcomes in a consistent fashion.

Dr. Gagne: Patency and quality of life are hallmarks, but I also look at durability. I don't want to have a patient who feels pretty good the month after their procedure and then 6 months later says, "I'm right back where I started." You either had a placebo effect, or you treated the wrong problem with the same persisting symptoms. I think durability is an important part of the equation. One of the benefits of tracking quality-of-life outcomes is that it gives us a point of discussion with payers. It helps us and the patients, and it helps the payers understand where to put their dollars.

Dr. Desai: Get the patient to that expectation that you helped set. We tell them we're going to improve their baseline level of function and make it easier to get through their day-to-day necessities. Of course, we're going to assess patency. However, we want the patient to say, "I'm so much better." Then, we can remind them that they must continue doing their part to make sure they stay better. We know that the quality of metrics is important because we know that research data are the building blocks to push the field forward. From the general practitioner's perspective, they don't want to spend a lot of time collecting outcome measures. However, you want to get a keen sense of what measures are meaningful for the patient. I advocate that everybody uses VCSS and Villalta, which are important for tracking your own outcomes internally.

During the interventional procedure, what things are you most concerned about?

Dr. Gagne: The two things I'm most concerned about are proper sizing and creating good flow. Whether it's a compression lesion or a post-thrombotic syndrome (PTS) lesion, you need enough lumen and inflow to make sure the stent stays open. Aggressive ballooning of the lesions before stenting is important where there may be fibrosis. Then, the stent along with postdilation will give you the expansion you need. As far as sizing the stent properly, in long-segment PTS lesions, the stent tends to be sized to the size of the balloon. With vein recoil, those stents are well fixed and don't embolize. For compression lesions, the vein on the contralateral side has too much variation. Instead, it's important to have the concept of anchoring to prevent migration. It's all about proper sizing, and intravascular ultrasound is probably the best way to do that.

Dr. Desai: One of the things I think about is why stents fail. They fail because of poor inflow and incomplete coverage of the disease. You want to ensure that inflow is sufficient to support a stent which crosses through the diseased iliofemoral segment; this is a more significant issue in post-thrombotic obstruction relative to non-thrombotic obstruction. Sizing is critical in non-thrombotic iliac vein lesions (NIVLs) because migration can be an issue, so you need to be diligent about how you size your stents and ensure you place stents on the longer side. As we're about to see from the work Prof. Black, I, and others have done, short and small-diameter stents can migrate. This is something that turns an outpatient procedure into a potentially catastrophic procedure. You also need to be aware of fracture and other complications to ensure you've optimized your procedure to the greatest extent possible and minimize those issues from occurring.

Prof. Black: The sizing decision is about risk mitigation. For acute and chronic patients, extensive scar tissue often holds the stent in place. I'm not that worried about migration. I'm trying to create a lumen that is big enough to compensate for the symptoms of the patient. In chronic PTS patients with long occlusions, I've ended up using 14-mm stents the majority of the time. My matrix has changed from using predominantly 16- to predominantly 14-mm–diameter stents. It's normal for us to take a 14-mm stent all the way from the groin to the confluence. There

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are no data to support that, but the risk of migration is not high. Our primary driver is creating a lumen that matches inflow vessels as much as possible and has smooth drainage of the leg.

With NIVL patients, the predominant risk is migration. I size those patients on the normal segment of the external iliac vein (EIV). I think the biggest conceptual problem is choosing a size based on the prestenotic dilation of the common iliac vein. Aortic disease is the analogy for me. We never size grafts for aneurysms based on aneurysm size. Why don't we do that in veins? According to the first principles of vascular surgery, I size the stent for the normal segment of vein, and we get a good anchoring point in the EIV. In practice, we end up with 16 mm for most NIVL patients. If you need an 18- or 20-mm stent, you have to ask yourself if this is genuinely an NIVL. If you can pass a 16-mm balloon through the lesion, I don't see how that causes significant venous outflow obstruction, even with a 50% stenosis.

What do you think are the most important factors in achieving optimal outcomes?

Dr. Desai: I split it up into non-thrombotic and post-thrombotic patients. In non-thrombotic patients, the most important factor is ensuring you've excluded other causes and that compression is probably the cause of their symptoms. Treating non-thrombotic patients is pretty straightforward. On the post-thrombotic side, patient compliance is a big factor. The two other important things are proper inflow to the stent and complete coverage of the disease. When you have all three, the patient will probably do a lot better for a lot longer.

Dr. Gagne: When talking about inflow and outflow, I don't think there's much difference between venous and arterial. In the venous system, you're going from a small vessel to a big vessel. In the arterial system, you're going from a big vessel to a small vessel. It's really about resistance to flow. If there is no resistance into and out of your stent, you typically have a successful, durable reconstruction. On the venous side, I think outflow is less spoken about because it's usually fixable. You can even extend up through an occluded vena cava to the level of the renal veins. On the other hand, inflow is not always fixable.

Prof. Black: For acute thrombotic and chronic post-thrombotic patients, it is flow, flow, flow. If you have good inflow, stents do well. All the data we have and all the publications say that if you have a relatively normal common femoral vein and good inflow, stents will do well. For non-thrombotic patients, the two most important factors are (A) getting a diagnosis and diagnosing correctly so you don't stent patients who don't need stents, and (B) avoiding stent migration because it's literally the only thing that can go wrong. That's why stent sizing is important, because flow is not an issue. If a stent is placed for the right indications and properly sized and anchored, you will get great results.

Why do you think Zilver Vena (Cook Medical) is well suited to treat your patients?

Dr. Gagne: I like Zilver Vena in part because of its flexibility. Some stents do a good job of gaining lumen but also distort the veins because they're relatively stiff and want to get straight, rather than allowing for flexibility and conformability. Zilver Vena seems to be adequate for doing the job I ask it to do and not cause new or other headaches. That is where I've found it to work very well for my patients.

Dr. Desai: I take a lot of solace in the VIVO-US trial data,[1] which reflected a true, heterogeneous venous population. The trial included acute deep vein thrombosis, PTS, and NIVL, which reflects what comes in my door on a day-to-day basis. The trial showed outcomes in all three patient subsets. I can use that to not only consult patients but also know what kind of outcomes I can expect. Zilver Vena is a flexible stent that comes in a variety of lengths, allowing me to minimize the number of devices I need to place. From an economic standpoint, this also very compelling.

Prof. Black: We're dealing with a heterogeneous patient population. The data from the trials showed that all of the stents performed equally in a heterogeneous population. We need to improve at making decisions about why we choose different qualities of stents for different areas. There are pros and cons to the different devices. Having stents that are more flexible and less rigid and stents that are stronger and less flexible gives you choices when looking at different types of patients. If you have a patient with post-thrombotic disease in the groin who is an athlete and will be exercising a lot and stressing the stent, then you want something more flexible. Zilver Vena allows us to have that very flexible stent to focus on that group of patients who will benefit from greater flexibility. ■

1. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED): Zilver Vena venous self-expanding stent. Accessed September 8, 2021. http://www.accessdata.fda.gov/cdrh_docs/pdf20/P200023B.pdf

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CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microcoils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel. • Nester Embolization Coils and Microcoils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter. • If difficulties occur when deploying the embolization coil, withdraw the wire guide, coil and angiographic catheter simultaneously as a unit.

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AB_T_NEC2_REV0

Tornado® Embolization Coils and Microcoils

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INTENDED USE: Tornado Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microcoils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel. • Tornado Embolization Coils and Microcoils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter. • If difficulties occur when deploying the embolization coil, withdraw the wire guide, coil and angiographic catheter simultaneously as a unit.

PRECAUTIONS: The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed. • Perform an angiogram prior to embolization to determine correct catheter position. • Prior to introduction of the embolization coil, flush the angiographic catheter with saline. • **If using a .018 inch Tornado Embolization Microcoil, ensure that the delivery catheter has an internal diameter (ID) of .018 to .025 inch.**

See instructions for use for full product information.

AB_T_TEM2_REV0

Zilver® PTX® Drug-Eluting Peripheral Stent

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INDICATIONS FOR USE: The Zilver® PTX® Drug-Eluting Peripheral Stent is indicated for improving luminal diameter for the treatment of *de novo* or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 7 mm and total lesion lengths up to 300 mm per patient.

CONTRAINDICATIONS: Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive a Zilver PTX Drug-Eluting Peripheral Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system.

WARNINGS: A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. See SUMMARY OF CLINICAL INVESTIGATIONS section in the complete Instructions for Use for further information. • Persons with allergic reactions to nitinol, or its components, nickel and titanium, may suffer an allergic reaction to this implant. • Persons allergic to paclitaxel or structurally-related compounds may suffer an allergic reaction to this implant. • The inner package should not be opened or damaged prior to use to maintain sterility; do not use if inner package is opened or damaged. • The use of this Drug-Eluting Peripheral Stent carries the risks associated with peripheral artery stenting, including vascular complications, and/or bleeding events. • The safety and effectiveness of implanting multiple Zilver PTX Drug-Eluting Peripheral Stents with a total drug coating quantity of greater than 3 mg paclitaxel (i.e., an additive stent length greater than 160mm per limb) has not been established.

PRECAUTIONS: To avoid involvement of the common femoral artery, the most proximal stent end should be placed at least 1 cm below the origin of the superficial femoral artery. To avoid involvement of the below-the-knee popliteal artery, the most distal stent end should be placed above the plane of the femoral epicondyles. • This product is intended for use by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed. • Manipulation of the Zilver PTX Drug-Eluting Peripheral Stent requires fluoroscopic control. • Do not try to push the delivery system through stenoses that cannot be dilated to permit passage of the introducer catheter. • If resistance is met during advancement of the delivery system, do not force passage. Remove the delivery system and replace with a new device. • Do not try to remove the stent from the introducer system before use. • Ensure that the red safety lock is not inadvertently depressed before stent deployment is desired. • A 0.035 inch (0.89mm) diameter wire guide should be used during tracking, deployment, and removal in order to ensure adequate support of the system. If hydrophilic wire guides are used, they must be kept fully activated. • Do not use excessive force to deploy the stent. If excessive resistance is felt when beginning deployment, remove the delivery system without deploying the stent and replace with a new device. • Do not expose the delivery system to organic solvents (e.g., alcohol). • Do not use power injection systems with the delivery system. • Do not torque the delivery system during introduction or deployment. • The device is intended for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease. • Appropriate antiplatelet/anticoagulant therapy should be administered pre- and post-procedure (**see section entitled PRE- and POST-PROCEDURE ANTIPLATELET REGIMEN in the complete Instructions for Use**). Use in patients who are unable to tolerate the appropriate antiplatelet therapy is not recommended. • Safety and effectiveness of the Zilver PTX Drug-Eluting Peripheral Stent has not been demonstrated in patients with a history of bleeding disorders. • Use of the Zilver PTX Drug-Eluting Peripheral Stent in an arterial vessel where leakage from the artery could be exacerbated by placement of the stent is not recommended. • A low incidence of stent fracture has been reported (0.9% at 12 months in the randomized pivotal study). Although no clinical sequelae were associated with stent fracture in the randomized study through 12 months, the long-term clinical consequence of stent fracture is not yet established. The majority of stent fractures were associated with stent elongation ≥ 10% at deployment. Therefore, care should be taken when deploying the stent to minimize the risk of stent fracture due to elongation at implant. • After stent deployment begins, the stent retraction sheath cannot be re-advanced and the stent cannot be re-captured. • If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). • Do not use the stent after the "Use By" date specified on the package. • Flow restrictions remaining after stent deployment (e.g., residual proximal or distal stenosis or dissection, or poor distal outflow) may increase the risk of stent thrombosis. Inflow and outflow should be assessed at procedure completion and additional measures considered (e.g., additional PTA, adjunctive stenting, or distal bypass) if necessary to maintain good inflow and outflow. • Following stent deployment, if resistance is met during the withdrawal of the delivery system, carefully remove the delivery system and wire guide as a unit. If resistance is still encountered during removal of the delivery system and wire guide as a unit, remove the wire guide, delivery system and introducer sheath together as a unit.

POTENTIAL ADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to, the following: Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol • Atheroembolization (Blue Toe Syndrome) • Arterial aneurysm • Arterial rupture • Arterial thrombosis • Arteriovenous fistula • Death • Embolism • Hematoma/hemorrhage • Hypersensitivity reactions • Infection • Infection/abscess formation at access site • Ischemia requiring intervention (bypass or amputation of toe, foot, or leg) • Pseudoaneurysm formation • Renal failure • Restenosis of the stented artery • Stent embolization • Stent malapposition • Stent migration • Stent strut fracture • Vessel perforation or rupture • Worsened claudication/rest pain. Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel. Potential adverse events, not described in the above source, may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to the drug coating • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis • Myalgia/Arthralgia • Myelosuppression • Peripheral neuropathy

See Instructions for Use for full product information.

AB_IFU0118_REV4

Zilver® Vena™ Venous Self-Expanding Stent

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INDICATIONS FOR USE: The Zilver® Vena™ Venous Stent is indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction.

CONTRAINDICATIONS: The Zilver Vena Venous Self-Expanding Stent System is contraindicated for use in: • Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system. • Patients who cannot receive intraprocedural anti-coagulation therapy.

WARNINGS: Nitinol (nickel-titanium) may cause allergic reactions in some patients. • The device is designed for single use only. Attempts to reprocess, re-sterilize, and/or reuse may lead to device failure and/or transmission of disease. This may also increase the risk of contamination. • Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Inspect the product to ensure no damage has occurred. • This device is a permanent implant.

PRECAUTIONS: This product should only be used by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed. • Manipulation of the Zilver Vena Venous Stent requires high-resolution fluoroscopic control. • Do not use power injection systems with the delivery system. • Prior to the procedure, the patient's underlying condition should be assessed for compatibility with anticipated procedural and post-procedural antiplatelet/anticoagulation therapy. • Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately premedicated. • Safety and effectiveness of the Zilver Vena Venous Stent for use in the arterial system has not been established. • When more than one stent is required, resulting in stent-to-stent contact, stent materials should be of similar composition to avoid the possibility of dissimilar metal corrosion. • The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects. **Stent Handling** • Do not attempt to remove the stent from the delivery system before use. • Do not expose any part of the delivery system to organic solvents (e.g., alcohol). • Use the stent system prior to the expiration date specified on the package. **Stent Placement** • Ensure that the safety lock is not inadvertently removed prior to stent release. • Do not rotate any part of the system during deployment. • Repositioning of the device once deployment has begun (i.e., the stent markers begin to flower) is not possible because the outer sheath cannot be re-advanced over the stent. • Repositioning of the delivery system to the intended deployment location can be carried out up until the stent markers begin to flower. • If excessive resistance is felt when beginning deployment, do not force deployment. Remove the delivery system without deploying the stent and replace with a new device. • Ensure the handle remains in a stabilized position while deploying the stent. Tension to remove the slack outside the patient's body should be applied; however, do not apply excessive tension on the system as stretching of the stent may occur. • Once stent deployment has begun, the stent must be fully deployed. **Stent/System Removal** • Do not advance outer sheath after stent has been deployed. Delivery system can be removed without the need to recapture tip. **Post Implant** • Antiplatelet/anticoagulant therapy should be administered during and after procedure according to institutional standard of care. • Use caution when re-crossing a stent to avoid stent damage or migration (i.e., the use of a balloon has the potential to get caught).

POTENTIAL ADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to, the following: • Abdominal or back pain • Abrupt stent closure • Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol (nickel-titanium) • Amputation • Aneurysm • Arrhythmia • Arteriovenous fistula • Bleeding associated with anticoagulation • Death • Embolism • Fever • Hematoma/hemorrhage at access site • Hypersensitivity reactions • Hypertension • Hypotension, nausea or symptoms of a vasovagal response • Infection/abscess formation at access site • Intimal/injury/dissection • Myocardial infarction (MI) • Pseudyaneurysm formation • Pulmonary embolism • Renal failure • Restenosis, occlusion, or thrombosis of the stented vein • Septicemia/bacteremia • Stent malapposition • Stent migration or embolization • Stent strut fracture • Stroke • Tissue necrosis • Vasospasm • Vessel perforation/rupture • Worsened pain

See Instructions for Use for full product information.

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