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MODERN PAD DECISIONS: From Access to Outcomes

Strategizing for long-term success.

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Modern PAD Access Strategies: Planning, Techniques, and Troubleshooting

With Katherine K. McMackin, MD, MS, and Constantino S. Peña, MD

CHOOSING AN ACCESS APPROACH

How important is access for peripheral artery disease (PAD) intervention?

Dr. McMackin: Planning access is a huge part of cases. To start, I'm thinking about: What has the patient had done before? Have they undergone any other surgeries? Is there any scarring? Where am I trying to get to? What's the easiest way to get there? The answers to these questions give you an idea of where you should start, and then you can determine your backup plan and plan C in some cases.

Dr. Peña: Each plan is tailored to your patient, having an idea of what you *think* you're going to do (you're never 100% sure) and which access you think is the safest, best access with which to start. However, you need to be ready to pivot to other types of access if needed.

What is your most common access site for PAD?

Dr. Peña: Our most common access would be common femoral artery (CFA) access, whether it's retrograde (going up toward the aorta) or antegrade (down toward the foot). Our choice of antegrade or retrograde access will depend on what we're going to treat. In certain situations, we go on the other extremities. For instance, we'll go retrograde on the right leg to treat a left leg PAD, depending on where we think we need to treat and what the clinical situation is.

Dr. McMackin: I would say the same: CFA access. I think safety is the biggest reason. Complications can occur, and the CFA is a large artery. One of the great things about the vascular space is that there are a lot of different thought leaders working in it, and that gives you different perspectives. Along with vascular surgery and interventional radiology, interventional cardiology also works in this space and they're using a lot of radial access, which I've recently started using in my practice. This gives you multiple different ways to treat disease and look at it from different avenues.

POTENTIAL ACCESS SITES FOR INTERVENTION

- Common femoral artery
- Radial artery
- Brachial artery
- Subclavian artery
- Popliteal artery
- Tibial artery
- Pedal artery
- Anywhere with a pulse

What approaches do you use other than CFA access?

Dr. McMackin: Depending on what you are doing and where you need to go, you can think upper extremity, radial, brachial, or subclavian. Usually, I go with either radial or subclavian. Brachial has some issues with postprocedural hematoma, which makes it a little bit more difficult. Then, you can work your way down. Everywhere you can feel a pulse theoretically is a good access site—femoral, popliteal (although most people don't use popliteal access), dorsalis pedis, or posterior tibial all give you ways to access this highway system to treat disease.

Dr. Peña: I agree with Dr. McMackin in terms of alternative access. I think radial is probably one of the most common as an alternative access. In my practice, if the groins are hostile, then I'll go ahead and do radial. If I'm doing something in the upper extremity or in the celiac or renal arteries, I may go radial just from the angles. There are a lot of alternative access approaches. Popliteal access is something we used to do a lot of—and we still do—and there are two ways you can do that. You can use frog legs, so you don't need to move the patient or have the patient prone. You can do tibial access or pedal access. I typically avoid brachial access; we do it when we have to.

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CHALLENGES TO ACCESSING SFA OR POPLITEAL LESIONS

- Caliber/size of access site
- Angles
- Distance to disease
- Lesion characteristics
- Flexibility versus pushability of the device

When treating superficial femoral artery (SFA) or popliteal artery PAD, what are some of the biggest challenges when it comes to access and reaching that lesion?

Dr. McMackin: Any time you're starting to work your way down the leg, you're talking about longer devices. If you're going contralateral, you'll need to go up and around the aortic bifurcation, so you need something that can make a turn but then also has that stiffness to provide pushability as you're getting through disease. Sometimes it's nice when you can do the antegrade access. It gives you that straight shot down the leg, and it's the same thing with the pedal access, the straight shot up the leg. It all depends on your angles, your pushability, and what the lesion looks like that help you decide which one of those you're going to use.

Dr. Peña: The aim is to be as direct as possible into the lesion you're treating. I think we've talked about which access site to choose, but you also have to think about the caliber or size of the access site. Is it going to require a 7-F sheath, a 6-F sheath, or can you do it with a 4-F sheath if you're looking for tibial work? The bigger the sheath, the greater risk of bleeding in terms of an access closure. All those things should be considered, but aiming to create a straight line to what we're trying to treat is ideal. Sometimes we have to go up and over and add some more angles, but we basically try to overcome those by using stronger devices and stiffer wires to help us achieve that and still have the pushability.

When you're obtaining access, how do you address tortuous or hostile vessels during PAD interventions?

Dr. Peña: We can't lose sight of the fact that when you're treating a patient with PAD, it's a systemic process. All the arteries are going to be diseased to some extent. As you start planning, it is important that you pick the best vessel, the healthiest vessel and area you can control, somewhere that you can then deliver the planned therapy. Maybe even start off with a microaccess system to see what you see, and then you may make a decision to go somewhere else. Being able to pivot is important.

Dr. McMackin: I think that the pivoting point is very well taken, and you really need some flexibility because your preoperative noninvasive imaging can only tell you so much. It's not until you start the case and see what that tortuosity is, does it straighten out when you put a wire or a sheath across? Some of those things you're not going to be able to tell preoperatively. It's all about really listening to the patient, listening to what that patient's anatomy is telling you, and letting that guide your case.

How do you approach closure? Do you use a closure device, or do you hold manual pressure?

Dr. McMackin: Everyone who's accessing the vascular space needs to know how to hold good manual pressure. There will be times when an access or a closure device works really well and times when it doesn't. You should always pick an access site where you know you can hold manual pressure in case of a closure failure. I personally like closure devices; they can get the patient ambulatory much faster, and they have low complication rates. So, depending on the access, factors like how big the sheath is, how big the vessel is, and how clean the stick was will help determine which closure device I'll use at the end. For me, ideally closure device is plan A, and then manual pressure is usually plan B.

Dr. Peña: I would agree with that. You should have skill for manual closure as well as multiple closure devices. Each closure device functions differently, and you need to understand when to use one over another. The quality of your puncture and how well that patient is responding are also important as you start choosing what you're going to use. If you have a very small artery, a closure device may not be ideal. But, maybe you have someone who's anticoagulated, at high risk for bleeding, and you need to determine the risk/benefit, and then you might go ahead and close. That's exactly what you have to go through in deciding when you're going to close and when you're not. Generally, we use closure devices for most of our arterial punctures.

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MANAGING PAD ACCESS COMPLICATIONS

What are some of the most common complications you encounter with an access site?

Dr. Peña: An access site complication could occur when you start accessing the artery. You may get spasm, or the needle may be in the wall instead of the lumen and cause a focal dissection. You may even get some bleeding around the wall during your puncture. These are things that we can often see with ultrasound, and a lot of these complications are very treatable. Many of these are self-limited and heal by themselves.

You may end up in a situation where when you're puncturing the artery, you go through the vein to get to the artery. This can create a fistula or communication between the artery and the vein. Use of ultrasound helps minimize a lot of these access-related complications, allowing us to see the artery or vein and evaluate its quality. Is it clean or is there plaque? Then, you can choose an ideal place to puncture and watch the needle go in.

When we are finishing these procedures, a fistula may be created or a pseudoaneurysm can occur, which means the artery where we placed the hole may not have healed completely. We treat these with compression or by injecting the area where that pseudoaneurysm is so that it will thrombose or clot off and heal.

Dr. McMackin: When you're planning your case, access site complications are something you consider. Large series tell us that 5% to 7% of cases are going to have access complications. It starts with the first stick. Knowing exactly what your needle is doing can help minimize the potential risk for those complications. Then, have everyone on the team know what to look out for when the patient is in the recovery area, so if there is a complication, they can catch it early.

How do you mitigate or reduce those risks?

Dr. McMackin: In any access, ultrasound is extremely helpful. There's no reason to guess where the artery is when you can see it on ultrasound; you can see your needle tip entering exactly into that vessel, and it helps identify if the vessel is healthy or if the vessel is spasming. Preoperative imaging can give you a good idea on plaque burden or if it's a short or long CFA. In the case of a long CFA, there is an increased risk of sticking too low, and if you have a short CFA, you could accidentally stick in the iliac.

Dr. Peña: To minimize the risk of a complication, we need to understand where we puncture, use our landmarks, and note where we think the CFA is going to be. Confirm that with ultrasound—find a good target when your wire goes in—and use fluoroscopy as you advance your wire. All these things add up to try to minimize the chance of a complication.

COMMON ACCESS SITE COMPLICATIONS

- Spasm
- Focal dissection
- Bleeding around the wall
- Fistula
- Pseudoaneurysm

Do you think using a microaccess system aids in reducing some of those access-related complications?

Dr. Peña: I think that a microaccess system helps reduce complications. When you have a smaller needle, you may not get the same back bleeding that you would get with, for example, an 18-gauge needle. With ultrasound, you can see that you're in, and then you can slowly advance the wire and then with fluoroscopy see that you're in the vessel. I would say that 99.9% of our access is now started with a microaccess system and an introducer system using ultrasound and fluoroscopic guidance.

Dr. McMackin: Having the microaccess system with a small needle and 0.018-inch wire, you can still have that tactile feel to know where you are—although it won't be as strong as if you're using a 0.035-inch wire and a larger system. I like to do a hand injection just to make sure I know where I am, and I've seen some people do this with the needle. You just want to make sure your operator's hands are outside the image intensifier; you don't want your hands underneath the image. The microaccess system allows you to keep your hands out of the ionizing radiation and protect the operator in addition to the patient.

When advancing catheters or reinforced sheaths during the treatment of PAD, how often do you encounter resistance due to stenosis/plaque?

Dr. McMackin: Even though a wire or a catheter goes through easily, it doesn't necessarily mean the sheath is going to track easily. You want to have flexibility to

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MITIGATING RISK OF ACCESS SITE COMPLICATIONS

- Ultrasound can:
  - Visualize needle tip entering the vessel
  - Identify if the vessel is healthy
  - Identify spasm
- Preoperative imaging can:
  - Provide information on plaque burden
  - Determine location and length of the CFA

make turns but also stiffness. Once you are set up for success, everything is in place, and your sheath is just above your lesion, you need that stiffness so that it will not back out or push out as you're trying to push forward through the lesion.

Dr. Peña: Once you get the wire to where you want to go and you're following it with a sheath, you have to understand that tactile feel. It's common to feel some resistance. The first thing I always tell trainees is "don't push." Stop and figure out why you have resistance. Do you need a stiffer wire? Are you hitting something? Are you at an angle? Is it because of tortuosity? At that point, I stop and reassess what's going on. I might need a wire, or I might just need to back off and advance again. With experience, you learn what you can overcome with your sheath.

THE ROLE OF MULTIPLE ACCESS SITES

Is there ever a time when you plan to access multiple sites?

Dr. Peña: It is not routine to start with two or three accesses, but it is common to need two wires from both sides, and therefore you may be looking at two accesses. For instance, we may establish radial access and use that to inject and then use the pedal access for other types of manipulations. It's usually the complex cases where you have multiple access sites.

Dr. McMackin: The benefit of multiaccess is that it allows you look at it from one end and treat it from the other, and vice versa. If you are having issues tracking through a difficult lesion, sometimes having that through-and-through wire really gives you a rail that you lack when the wire is free on one side. So, you can track something across a lesion that maybe you couldn't get across before. Although you may not be intervening from both access sites, sometimes having multiple allows you to have that stiffer segment for wire if you wanted to use different treatment modalities across that lesion.

How often do you have to pivot access sites mid-case?

Dr. Peña: I think it's much more common now than it was in the past because now we have access sheaths and access devices that help us access other arteries that we wouldn't have a decade ago. We often see this in the lower extremities—being able to do a quick pedal or tibial access to get a retrograde wire that you can snare and use as a rail to help us with our therapies.

I would say this is pretty common. Sometimes we use the secondary access for a function, such as when we need to recanalize from a retrograde approach or we want to have a rail so we can bring up our devices.

Dr. McMackin: I think the more you get comfortable with multiple access, the more you see the utility in it. That first time sticking the pedal, it might take 30 minutes, and then over time, it's streamlined and it takes 90 seconds to obtain access. The more the whole team gets used to multiaccess cases, the easier the flow is for the patient. ■

Watch It Now!
Explore the full conversation.

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Real-World Data: The REALDES Registry

A look at real-world outcomes from the REALDES registry, its key clinical outcomes, and how physicians are translating these data into everyday practice.

With Koen R. Deloose, MD; Constantino S. Peña, MD; and Katherine K. McMackin, MD, MS

REALDES: CONTEXT, COMPARISON, AND KEY RESULTS

By Koen R. Deloose, MD

SETTING THE STAGE

It is a fact that drug-eluting technology in general—drug-eluting stents (DESs) specifically—significantly reduce the incidence of restenosis and reinterventions. There are two DESs on the market today: Zilver PTX (Cook Medical) and Eluvia (Boston Scientific Corporation) (Table 1).

These two devices were compared in the head-to-head randomized controlled IMPERIAL trial.[1] At 1 year, Eluvia was found to be noninferior to Zilver PTX (primary patency, 92.1% vs 81.8%). At 2 years, any statistically significant difference diminishes (83% efficacy with Eluvia vs 77.1% with Zilver PTX).[2] However, looking at the 5-year data, there was no longer any difference between the two devices in terms of target lesion revascularization (TLR), primary patency, or assisted primary patency.[3]

However, a randomized controlled trial is a strict context, and it's not completely comparable with the real-world setting. Consider the lesion characteristics in the IMPERIAL study: 8 or 8.5 cm, one-third with no calcification, one-third with moderate calcification, and one-third with severe calcification; the same was true for chronic total occlusion (CTO), with only one-third of patients with complex CTOs. Patient characteristics were also not my daily reality: 30% characterized as Rutherford classification 2, the vast majority characterized Rutherford 3, and a noticeable lack of chronic limb-threatening ischemia (CLTI) patients.

This gap between trial conditions and daily practice emphasized the importance of real-world data, ultimately leading to the launch of the REALDES study.

TABLE 1. DES CHRACTERISTICS AT A GLANCE

	Zilver PTX	Eluvia
Material used	Nitinol, polymer-free	Nitinol, polymer-coated
Drug dose density	Paclitaxel (3 µg/mm^2)	Paclitaxel (0.167 µg/mm^2)
Deployment	Self-expanding	Self-expanding
Diameter (mm)	5, 6, 7, 8	6, 7
Length (mm)	40-140	40-150

Abbreviations: DES, drug-eluting stent.

WHAT IS REALDES?

REALDES is not a randomized trial—it is a multicenter, prospective, observational study in a real-world setting where the DES (Zilver PTX or Eluvia) was chosen at the physician's discretion. The trial also distinguished itself from IMPERIAL and earlier trials by a requirement in the protocol for extensive vessel preparation. REALDES characterized restenosis by a peak systolic velocity ratio cutoff of 2.4 on duplex ultrasound. Importantly, as the REALDES study was not financially supported by industry, there was no potential for financial biases.

REALDES KEY 3-YEAR FINDINGS: SAFETY, PATENCY, AND LONG-TERM OUTCOMES

REALDES comprised 184 enrolled patients and 200 limbs. Patients were assigned to groups at the discretion of the operator, with 86 patients in the Zilver PTX group and 98 in the Eluvia group. At 36-month follow-up, there were 52 patients in the Zilver PTX group and 47 in the Eluvia group.[4]

The patient characteristics, demographics, and comorbidities clearly reflect real-world data: claudication in two-thirds of the cases, and CLTI in one-third of cases. There was no statistical difference in terms of demographics or comorbidities between the groups.

Lesion complexity reflected a real-world population:

- High PACSS (peripheral arterial calcium scoring system) score was common

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DIVING DEEPER

Were results of REALDES surprising? In my opinion, no. In the CAPSICUM registry,[5] reocclusion accounted for 71.1% of restenosis cases, 25.9% of which were due to stent thrombosis. The remaining 28.9% were due to nonocclusive restenotic disease.

The same can be said about the Zilver PTX reocclusion rate. Data at 1 year from the ZEPHYR registry point to a < 25% Tosaka 3 class in-stent reocclusion versus 75% with more restenotic disease.[6] This coincides with REALDES data.

- TASC (TransAtlantic Inter-Society Consensus) C and D lesions in 60% of cases
- Lesion length: 185.7 ± 92 mm in the Zilver PTX group versus 160 ± 98.5 mm in the Eluvia group (P = .029)
- CTO was present in half of patients
- Predilation was performed in nearly all cases, with postdilation in 100%

Comparing Zilver PTX to Eluvia, clinical outcomes up to 3 years highlight the following:

- Primary patency at 1 and 3 years: 82.5% and 70% versus 86.3% and 65.2%, respectively; there was no statistical difference between groups at 3 years (P = .7)
- Freedom from TLR at 1 and 3 years: 88.9% and 79.4% for Zilver PTX versus 90.1% and 76.3%—again with no statistical significance

The between-group difference becomes evident when you look at restenosis:

- In a univariable analysis of the 3-year risk of restenosis, there were no significant parameters or variables when looking at Zilver PTX versus Eluvia.
- In the Zilver PTX group, the rate of reocclusion was 29.2% versus 70.8% with just restenosis.
- In the Eluvia group, rate of reocclusion was 57.7% versus 42.3% with just restenosis.

Limitations

As REALDES does not have a randomized design, there are potential confounding factors and selection biases. This trial also has relatively small numbers at 3-year follow-up, and there was variation in vessel prepping methods, which may influence results. Lastly, there was no core laboratory review for duplex ultrasound or angiography. And yet, REALDES gives us very clear trends to consider in relation to these two DESs, as well as some key takeaways (see Key Takeaways Sidebar).

REALDES REGISTRY KEY TAKEAWAYS

- **Early advantage from previous trials disappears:** Statistically significant differences seen in the IMPERIAL trial at 1 year were no longer present at years 2 to 5, indicating comparable long-term performance between Eluvia and Zilver PTX.
- **Real-world performance:** REALDES showed that in real-world, complex femoropopliteal disease, Eluvia and Zilver PTX showed similar 3-year outcomes, with no significant difference in primary patency or freedom from TLR between devices.
- **A notable difference emerges:** In REALDES and similar nonrandomized studies, Eluvia showed a higher incidence of total reocclusions than Zilver PTX.

HOW DOES REALDES INFORM YOUR DAILY PRACTICE?

With Koen R. Deloose, MD; Constantino S. Peña, MD; and Katherine K. McMackin, MD, MS

What stands out to you about the REALDES study and its implications for clinical practice?

Dr. Peña: REALDES demonstrated similar patency and target lesion revascularization (TLR) rates with the two devices after the first year, which is in line with results from the IMPERIAL trial. REALDES is real-world data, with longer lesions, more occlusions, and more patients with CLTI—and outcomes are still similar among this patient population.

Also important are the morphologic differences in failure rates. Although we can't hypothesize why there

are differences in terms of reocclusions versus restenosis, we know that we need more research into the clinical relevance of this finding.

How do these findings translate to your real-world decision-making process?

Dr. McMackin: I love the idea of real-world data. It's nice to have this equipoise out to 3 years between the two stents, because not everyone has access to both. These 3-year data reinforce that either stent is a "safe choice."

Regarding reocclusion versus restenosis, once we get into the 3-year data, we're looking at very small patient numbers. Although this is not something that would currently change my practice, it is something to look out for in future databases whether this trend continues to play out in 5, 10, 15 years.

What's the main message clinicians should take from REALDES?

Dr. Deloose: To echo Drs. Peña and McMackin, we need more long-term data. Our payers want to know the long-term durability, while patients are concerned with quality of life, which is directly related to reintervention rate. Long-term data on TLR and reintervention are crucial.

The morphology of the restenotic pattern is also pivotal. Globally, we are in the days of "leave nothing behind." At least in Belgium, this remains a dream when dealing with complex lesions. I almost always end up with at least some scaffolding. It can be argued that reocclusions are then more difficult to treat if something is left behind, which is a fair point. When these findings show that one device potentially creates more in-stent reocclusions, that becomes a meaningful conversation when choosing my stent. Of course, we do want to confirm these trends in larger, more robust data sets, but this is an observation that informs my clinical decision-making.

How do these findings fit into your broader treatment algorithm?

Dr. Peña: As we refine our treatment algorithms for the superficial femoral artery, we have to ask: Where does DES fit? Even though we're talking about relatively small numbers of patients, the REALDES data give us a holistic view of how these devices perform beyond the first year. How does restenosis versus reocclusion affect our algorithm, and what does that mean when comparing the devices to other strategies, like the "leave nothing behind" approach?

It's always a balance—a long, calcified lesion may require scaffolding, but then what happens in 4 or 5 years? These decisions are where the long-term, real-world REALDES data become quite valuable.

How might this influence intraoperative decision-making today and in the future?

Dr. McMackin: It's the choices we make now that will affect our patients 5 to 10 years down the line, and it really comes down to balancing the short with the long term. For example, vessel preparation was a key component to this trial, and it points to something potentially important. I think this is worth exploring moving forward.

How do you think these data might influence clinical practice in Europe?

Dr. Deloose: Although these data are quite new, there is an increasing concern about the higher rates of in-stent reocclusion, because this is not easy to treat. I also see a slight shift toward the issue of the local toxicity of paclitaxel. Combine these concerns, and I think we will see some physicians change their mind. But importantly, I think we all agree that we need more long-term, real-world data to confirm the findings of the REALDES study. ■

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ZILVERPASS at 5 Years: Evidence Shaping Strategies for Femoropopliteal Intervention

A clinical discussion on how the long-term findings of the ZILVERPASS study inform decision-making for challenging above-the-knee femoropopliteal disease.

With Koen R. Deloose, MD; Katherine K. McMackin, MD, MS; and Constantino S. Peña, MD

ZILVERPASS STUDY: METHODS AND RESULTS

What was the objective of the ZILVERPASS study? Can you talk a little bit about its design?

Dr. Deloose: The objective of the study was to evaluate the performance of the Zilver PTX paclitaxel-eluting stent (Cook Medical) compared to prosthetic bypass surgery for the treatment of above-the-knee (ATK) femoropopliteal TASC (TransAtlantic Inter-Society Consensus) C and D lesions using the same assessment methods. It is a prospective, randomized, noninferiority, multicenter study where we randomized 220 patients in four countries and 13 clinical centers in a 1:1 fashion.

The primary endpoint of the study is very clear primary patency at 1 year, and this is quite important. In the endovascular studies, we are always looking at the absence of binary restenosis or occlusion within the treated lesion, and we do this very objectively with color flow duplex ultrasound and a peak systolic velocity ratio (PSVR) cutoff of 2.4 without target lesion revascularization (TLR) at 1 year. In the bypass surgery literature, sometimes this is analyzed differently, and it is more like an open or closed bypass or a patent or nonpatent bypass, and it is not measured on color flow duplex ultrasound. In the ZILVERPASS study, bypass results were assessed based on binary restenosis at the proximal distal anastomosis over the entire length of the bypass with the same PSVR cutoff of 2.4, and also without clinically driven TLR to restore the flow in the bypass.

Who comprised the patient population?

Dr. Deloose: Only Rutherford class 2 to 5 patients were enrolled, stenotic or reocclusive lesions, de novo lesions in the femoropopliteal area, and a minimum total lesion length of 15 cm. Exclusion criteria included any previous surgery or endovascular procedure in the target vessel, perioperative unsuccessful dilatation or treatment of the inflow, any other planned surgical intervention or procedure within 30 days, and major distal amputations in the study or nonstudy limb.

If we are looking at patient demographics, the Zilver PTX group had 70% claudicants versus 30% chronic limb-threatening ischemia (CLTI) patients, as compared with the bypass group that had more CLTI patients—45% versus 55% claudicants. This is an important difference in terms of patient demographics. Having said that, when we look at risk factors, such as smoking history, diabetes, coronary disease, cardiovascular disease, and renal insufficiency, there were no statistical differences between groups, but there was a significantly higher number of patients with hypertension, obesity, and

ZILVERPASS STUDY KEY TAKEAWAYS

- Noninferiority of Zilver PTX versus prosthetic bypass in challenging lesions with a mean lesion length of 25 cm and 95% chronic total occlusions
- Zilver PTX 5-year results: 49.3% primary patency based on objective measurements by duplex ultrasound and 63.8% freedom from TLR—not statistically significantly different compared with the prosthetic bypass
- Zilver PTX group had a significant reduction of complication rate, shorter procedural time, and shorter hospital stay
- Consistent, positive clinical status over 5 years in a very diseased population

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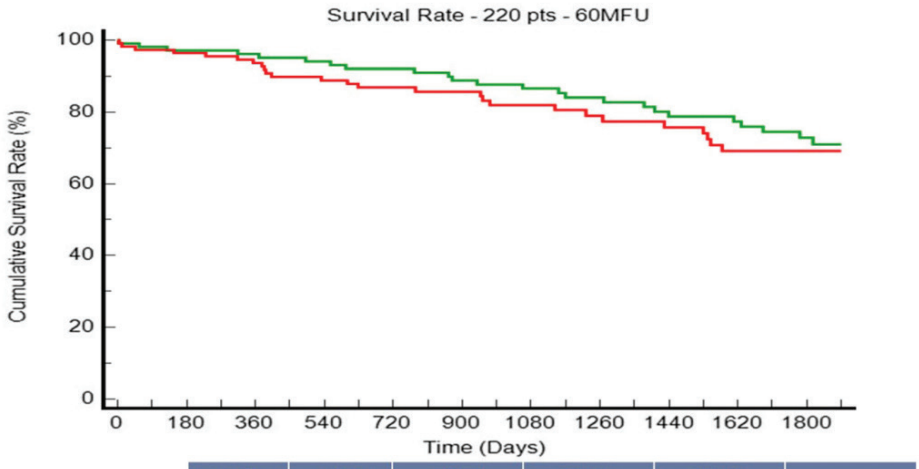
hypercholesterolemia in the bypass group compared to the Zilver PTX group.

As mentioned, the study included very complex lesions ≥ 15 cm: Mean lesion length was 25 cm in both cohorts, and the chronic total occlusion rate was 95%. There are few clinical studies available with these lesion characteristics in both cohorts.

What were some important differences in procedural characteristics and freedom from complications at 30 days?

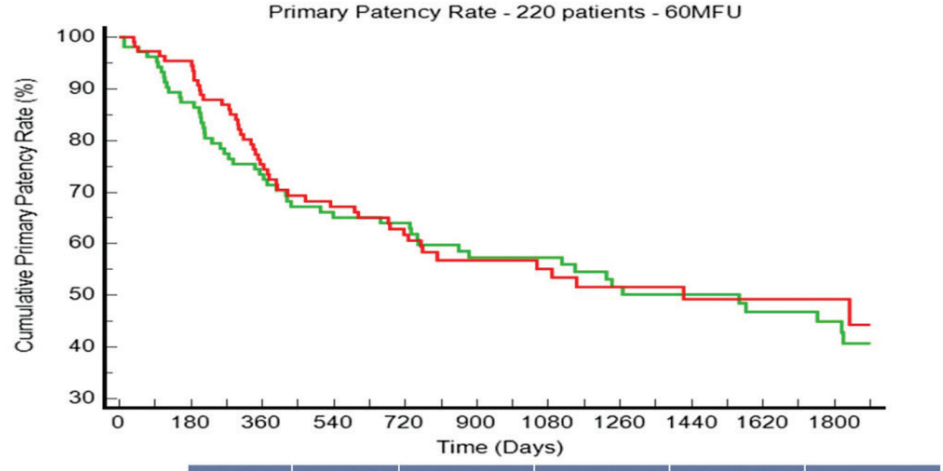
Dr. Deloose: There are two important differences when looking at the procedural characteristics. We noticed that the procedural time in the Zilver PTX group was almost half of the time compared to the open surgery group. In addition, mean hospital stay was 2.5 days in the Zilver PTX group versus 8 days in the bypass group.

The safety endpoint of freedom from complications at 30 days was 95.6% in the Zilver PTX group versus 88.7% in the bypass group. It is not surprising that there was a statistically significant difference between groups. In the bypass group, there were wound infections (most of them superficial but



		Baseline	12MFU	24MFU	36MFU	60MFU	
ZILVER PTX	Tar	113	100	84	66	36	P =0.5035
	%	100	93.6	86.90	82.00	69.10	
BYPASS	Tar	107	95	90	78	43	
	%	100	96.10	92.00	86.60	71.00	

Figure 1. Survival at 5 years. Reprinted from Bosiers MJ, De Donato G, Torsello G, et al. ZILVERPASS Study: ZILVER PTX stent versus prosthetic above-the-knee bypass surgery in femoropopliteal lesions, 5-year results. Cardiovasc Intervent Radiol. 2023;46:1348-1358. doi: 10.1007/s00270-023-03549-0



		Baseline	12MFU	24MFU	36MFU	60MFU	
ZILVER PTX	Tar	113	77	55	33	13	P = 0.6915
	%	100	74.40	60.60	53.30	49.30	
BYPASS	Tar	107	73	60	45	22	
	%	100	72.40	64.00	57.30	40.70	

Figure 2. Primary patency at 5 years. Reprinted from Bosiers MJ, De Donato G, Torsello G, et al. ZILVERPASS Study: ZILVER PTX stent versus prosthetic above-the-knee bypass surgery in femoropopliteal lesions, 5-year results. Cardiovasc Intervent Radiol. 2023;46:1348-1358. doi: 10.1007/s00270-023-03549-0

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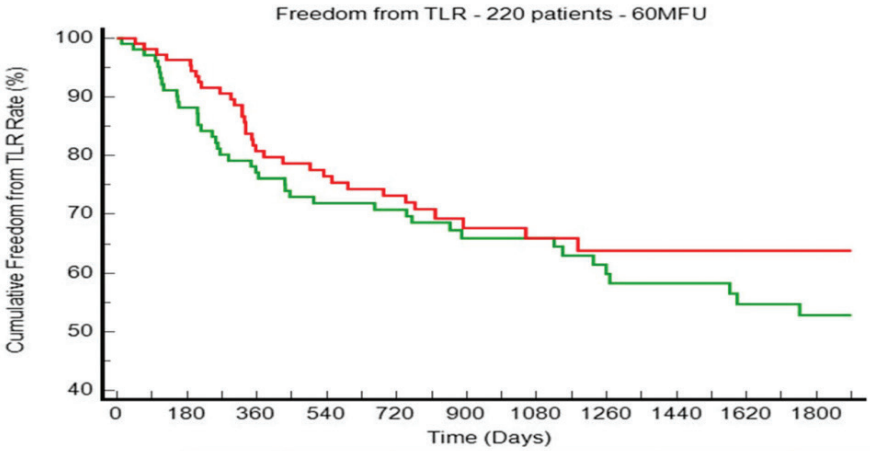
also some deep wound infections), lymph fistulas, and lymphedema. In the Zilver PTX group, there were only a few puncture side hematomas or postprocedural bleeding.

Can you elaborate on the ZILVERPASS 5-year results?

Dr. Deloose: The survival rate at 5 years between the Zilver PTX and bypass groups was similar at 69% and 71%, respectively (Figure 1). Importantly, primary patency at 5 years was 49.3% for Zilver PTX versus 40.7% for the bypass, so there was no statistically significant difference between groups with the same assessment methods (Figure 2).

Freedom from TLR at 5 years for Zilver PTX was 63.8%, and this is an amazing result—more than 6 out of 10 didn't have any reintervention after 5 years of their primary treatment. This was 52.8% in the bypass group, so there was no difference between groups (Figure 3).



		Baseline	12MFU	24MFU	36MFU	60MFU	
ZILVER PTX	Tar	113	81	64	39	17	P = 0.2637
	%	100	80.80	73.20	66.00	63.80	
BYPASS	Tar	107	76	64	49	25	
	%	100	76.10	70.80	65.90	52.80	

Figure 3. Freedom from TLR at 5 years. Reprinted from Bosiers MJ, De Donato G, Torsello G, et al. ZILVERPASS Study: ZILVER PTX stent versus prosthetic above-the-knee bypass surgery in femoropopliteal lesions, 5-year results. Cardiovasc Intervent Radiol. 2023;46:1348-1358. doi: 10.1007/s00270-023-03549-0

In terms of clinical assessment of Rutherford class, the results between groups were consistent over the years, where up to 5 years, the vast majority is a Rutherford 0 or 1 and a maximum of Rutherford 2 in both groups.

CLINICAL CONVERSATION: APPLYING THE EVIDENCE

Dr. McMackin: This study touches on all of the pieces that I think about when deciding between an endovascular or a surgical option. These are long lesions (even longer in the study than what they initially thought), very diseased, completely calcified, completely occluded. Those risks that we're always weighing all came up: access complications, infection of the prosthetic bypasses, obese patients—these are the real-world patients that we're dealing with every day. One surprising result that goes against common teaching is the reinterventions. You think if you're going with endovascular, patients are coming back again and again. However, in this study, primary patency was the same between groups, and reinterventions were actually less for TLR in the Zilver PTX group.

Dr. Peña: When you're making a decision on a long superficial femoral artery (SFA) lesion, you always consider surgery. I think we have to ask the question: If this was a vein graft, would results be different? Looking at a prosthetic versus a long-segment stenting of the SFA, these data tell us a lot; particularly in patients with CLTI and those with a lot of comorbidities, stenting is an equal option.

Dr. Deloose: Addressing the point concerning the vein or prosthesis, we had long discussions with the investigators, the committee, and the sponsor, and the rationale of the study was to stay as close as possible to the daily clinical practice, and the patient population is a clear proof of this. Also, again, we determined if our

patient population is real world, we also need to do this in our treatment modality. All 13 participating centers re-looked at our daily vascular surgery practices, and in most centers, we are using prostheses in the majority of cases for ATK bypass, and we try to save the vein for the below-the-knee bypasses.

Additionally, the prostheses that were used were the modern heparin-bonded expanded polytetrafluoroethylene bypasses, where the results to an available vein are quite close, especially in ATK settings in terms of durability and patency. This was the reason we opted for prosthesis in this particular study rather than the vein.

Dr. McMackin: Our practice is similar in this way in the United States; we have that same failing forward idea where if we can save the vein for that long distal bypass instead of using it for ATK popliteal, we will mostly use those heparin-bonded grafts for our ATK femoropopliteal as well.

Dr. Deloose: One thing that we need to discuss is that, although patients were randomized head-to-head by computer, it appeared that the bypass group had a more diseased population based on significant risk factors and the CLTI cohort. So probably, stratification was the solution. Today, I'm running another randomized controlled trial for the common femoral artery where we are comparing an endo approach versus an open approach, and with my experience in the ZILVERPASS study, I did a stratification process in advance to be 100% sure that at the time of the randomization we have equal cohorts in the open and endo groups. What do you think about this?

Dr. Peña: This is an important point as we start looking at these data and how they are going to affect practice. These study results kind of went against our dogma, and I think because of that, it's going to take a little bit more to move the needle and change practice. In the right patient, you can place a scaffold in a significant length in the SFA, and it is comparable to surgery with a prosthetic. But, the challenge is getting operators to understand and implement this going forward. These are the necessary data that we need to move forward, and it's going to be interesting to see how the practice will change over the next years and decades.

Dr. McMackin: As we look at these studies going forward, when there's a difference in the number of CLTI patients between groups, people immediately think about differences in outflow. That means we need to look beyond lesion length and consider the downstream vessels as well, whether through GLASS scoring or other scoring systems, so we understand what's happening downstream that may affect patency and the need for intervention. I think these are things we'll need to include in future studies.

Dr. Deloose: Dr. McMackin, I have a final question for you. As a vascular surgeon, you can offer both of these treatment modalities. Knowing these data, which kind of parameters will define one or the other decision, open or endo approach first?

Dr. McMackin: You definitely have to consider all of the risk factors; obesity is one of the biggest ones. Am I worried about the infection risk? Does that risk go up with one option over the other? Am I worried about surgery time or hospital stay? A long hospital stay can definitely affect a patient. For a claudicant, I think that an endovascular approach first makes perfect sense. For the CLTI patient, the decision is a little more nuanced. You still may have that endo option first, but you have to ask, what do I need to be doing first to get them more flow right now? ■

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CASE SPOTLIGHT

Recanalization of an SFA CTO: A Step-by-Step Discussion

Dr. Koen Deloose describes his algorithmic approach to treating a patient with chronic limb-threatening ischemia and a nonhealing ulcer, with discussion from Drs. Katherine McMackin and Constantino Peña on how they would approach the case and key highlights.

CASE PRESENTATION

A male patient in his late 70s presented to the diabetic foot clinic with a nonhealing, extremely painful ulcer on the left heel for a couple of months. Despite very intensive and professional wound care, there was no signal of healing. On appearance, it was a very atonic wound, not immediately infected but with a fibrinous center and no tendency to heal. He had a significant cardiovascular history, including coronary artery bypass grafting, coronary interventions, and a carotid endarterectomy on the left side for a minor stroke, from which the patient fully recovered. The patient was still a smoker and had arterial hypertension, type 2 diabetes, and hypercholesterolemia, all being treated with medication.

DR. DELOOSE'S APPROACH TO TREATMENT

Initial Imaging and Treatment Planning

This is clearly class 4 disease by WIfI (Wound, Ischemia, foot Infection) classification; the patient is at high risk for major amputation within 1 year. We performed a duplex ultrasound in our vascular lab, and there was a normal triphasic signal measured in the left common femoral artery (CFA) and weak monophasic signals at the popliteal level or the distal tibial arteries. This was a clear signal to perform CTA, which showed no problem at the level of the iliacs and CFA. However, we then saw a chronic total occlusion at the left side, almost at the level of P1, as well as some below-the-knee (BTK) disease.

My strategy was to bring the patient to the hybrid room and perform one-stage endovascular therapy via right CFA access, perform a crossover procedure, and try to recanalize the left superficial femoral artery (SFA) occlusion, prepping the lesion and determining whether it would respond to angioplasty. If so, then, I'll perform definitive treatment and subsequently do a BTK check to determine if treatment is needed there.

Access, Diagnostic Angiography, and Vessel Preparation

I started with 6-F access in the right CFA, and to make the crossover, I used a RIM catheter (Cook Medical) and a 0.035-inch, stiff, curved Glidewire (Terumo Interventional Systems). Then, I used the 6-F, 45-cm Flexor Ansel sheath (Cook Medical) in the crossover position.

Diagnostic angiography was performed, which showed a nice stump on the SFA, a long SFA occlusion on the left side, and poor collateralization out of the deep femoral artery. This explained the presence of an ulcer and the Rutherford 5 status of the patient. Looking more distal, there was a nice P2, P3 segment and a single-vessel outflow of the anterior tibial artery running all the way to the dorsalis pedis. But, remember, the ulcer of the patient was at the heel. So, there was also very poor collateralization out of the peroneal artery with a posterior branch to the posterior foot circulation, but not a real good feeling of the lateral plantar arch or the calcaneal branches.

I started with a 5-F Berenstein catheter and the 0.035-inch stiff Glidewire to get into the SFA stump. I normally

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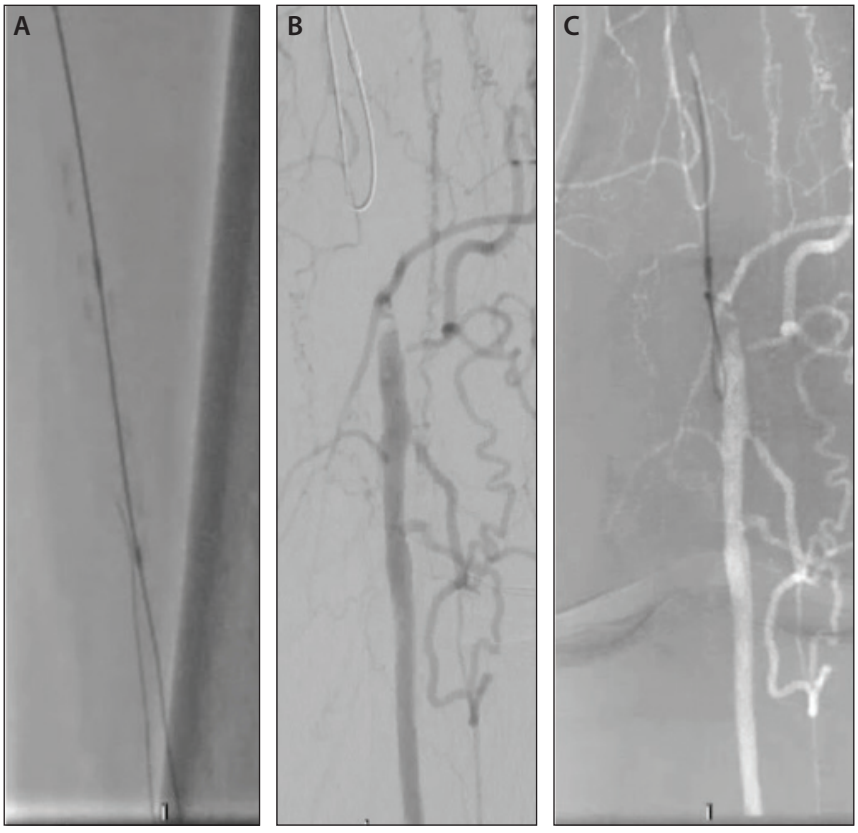

Figure 1. Approach to the left SFA occlusion. After using the subintimal Bolia technique, exchange for a low-profile, 4-F CXI support catheter (A). Reentry into the distal SFA (B, C).

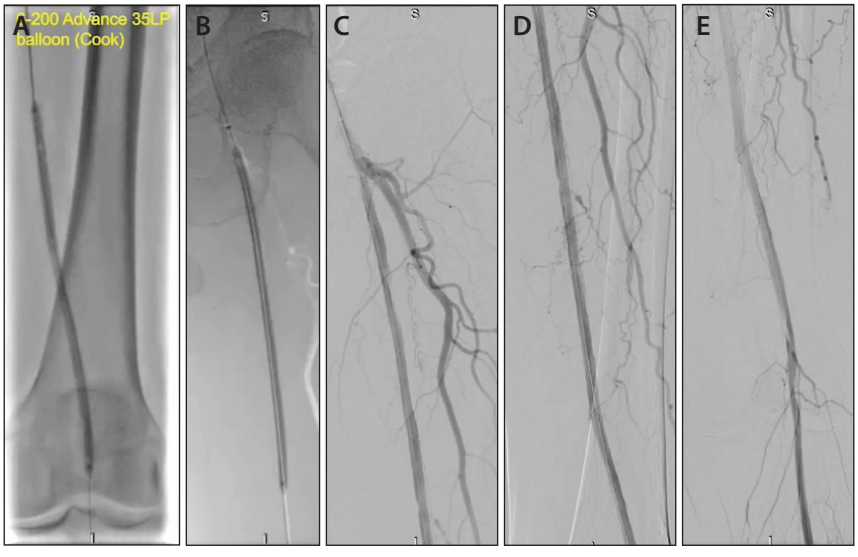

Figure 2. Lesion prep with a 6- X 200-mm Advance 35LP balloon (A). Final proximal dilatation (B). Possible dissection at the proximal lesion (C), midsection image (D), and dissection confirmed at the P1/P2 transition zone (E).

perform my recanalizations on the 0.018-inch platform, but this 0.035-inch Glidewire entered so easily that I decided to continue with the 0.035-inch platform. I made a loop, and using the subintimal Bolia technique, I was able to get through and through the wire and the loop of the wire but not the catheter. At this point, I needed to change to a supportive low-profile catheter: the 4-F CXI support catheter (Cook Medical) (Figure 1A). With this catheter, combined with the Bolia technique and the Glidewire, I was able to go all the way down quite easily.

I identified the reentry zone at the distal SFA/proximal popliteal artery, and with an atraumatic loop, I entered the distal area (Figure 1B and 1C). Vessel diameter of the proximal stump and the distal SFA/proximal popliteal artery was measured on the CT scan, and I prepped the lesion with a 6- X 200-mm Advance 35LP balloon (Cook Medical) (Figure 2A). I prepped the lesion step-by-step, atmosphere per atmosphere, inflating the balloon, and I'm not looking at the manometer, just at the lesion popping open. I stop when the lesion is completely open.

In the proximal and distal segment, I reached almost 12 to 14 atm to open the lesion, and the mid SFA opened with only 5 atm (Figure 2B). In the final proximal dilatation at the P1/P2 transition zone, there was some dissection, and this was confirmed looking distally and with another projection, with 45° difference in angulation (Figure 2C-E).

Lesion Treatment

Next, I decided to implant a 6- X 80-mm Zilver PTX drug-eluting stent (Cook Medical) in the P1/P2 segment lesion. Remember, I dilated and prepped the vessel with a 6-mm balloon, so I sized 1:1. The CT showed that the P2 segment was 5 mm, so

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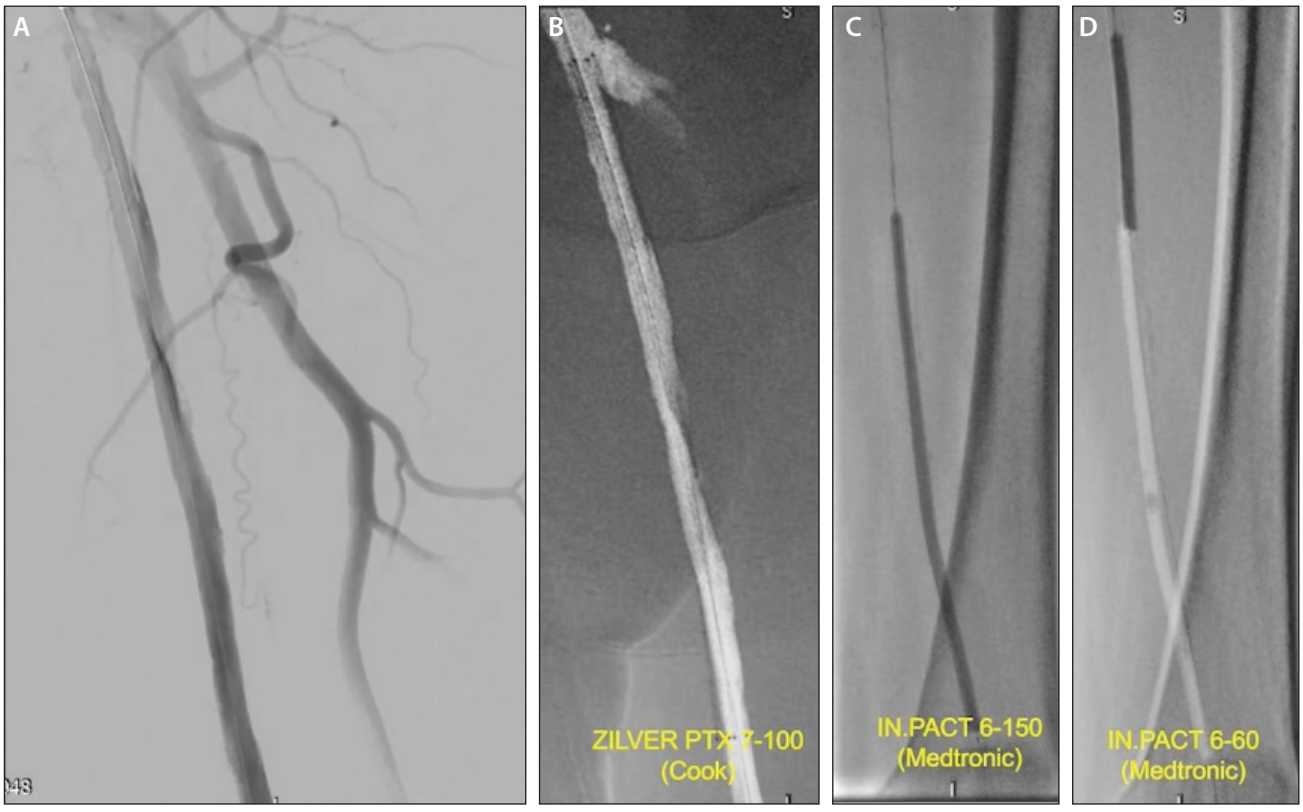

Figure 3. Angiogram showing dissection (A). Placement of a 7- X 100-mm Zilver PTX (B). Treatment with In.Pact Admiral drug-coated balloons (C, D).

it was slightly oversized distally. Figure 3A very clearly shows the proximal dissection. I implanted a 7- X 100-mm Zilver PTX based on the 6.1-mm measurement in the proximal stump (Figure 3B). Because the mid-segment responded well to angioplasty prepping, I decided not to scaffold it but rather to treat it with two In.Pact Admiral drug-coated balloons (Medtronic; 6 X 150 mm and 6 X 60 mm) (Figure 3C and 3D). I postdilated the Zilver PTX proximally and distally to have a perfect wall apposition.

Because the recanalization above the knee (ATK) was rather easy, I decided also to jump to the posterior tibial (PT) artery (Figure 4A). Once I passed the proximal two-thirds, there was a hibernating PT vessel and a lateral plantar arch with some branches toward the calcaneal area; using a 0.014-inch CXI support catheter and 0.014-inch Glidewire Advantage, it was rather easy to reach it (Figure 4B).

I injected contrast through my distal catheter and saw a nice blush at the level of the ulceration (Figure 4C). For me, this was a sign to dilate. I was not trying to recanalize the full lateral plantar arch because I was a little afraid of creating more damage than gain, and I was especially interested in bringing blood to this calcaneal branch. So, I dilated with a 0.014-inch, 3- X 220-mm Advance Serenity balloon (Cook Medical) and performed two prolonged inflations proximally and distally for 3 minutes (Figure 4D).

The final result was brisk flow through the PT artery all the way down (Figure 5). I didn't recanalize the lateral plantar arch, but there was a nice blush at the level of the ulcer. Afterward, I performed debridement of the ulcer, and there were already signs of some revascularization.

For a vascular surgeon, this is the best signal that we did an acceptable recanalization, and I think with offloading and good wound care, we can help the patient and let the wound heal.

DISCUSSION

Dr. Deloose: What do you think about my approach in this particular chronic limb-threatening ischemia (CLTI) case?

Dr. McMackin: I congratulate you on a fantastic completion—beautiful recanalization and really good decision-making throughout the entire recanalization.

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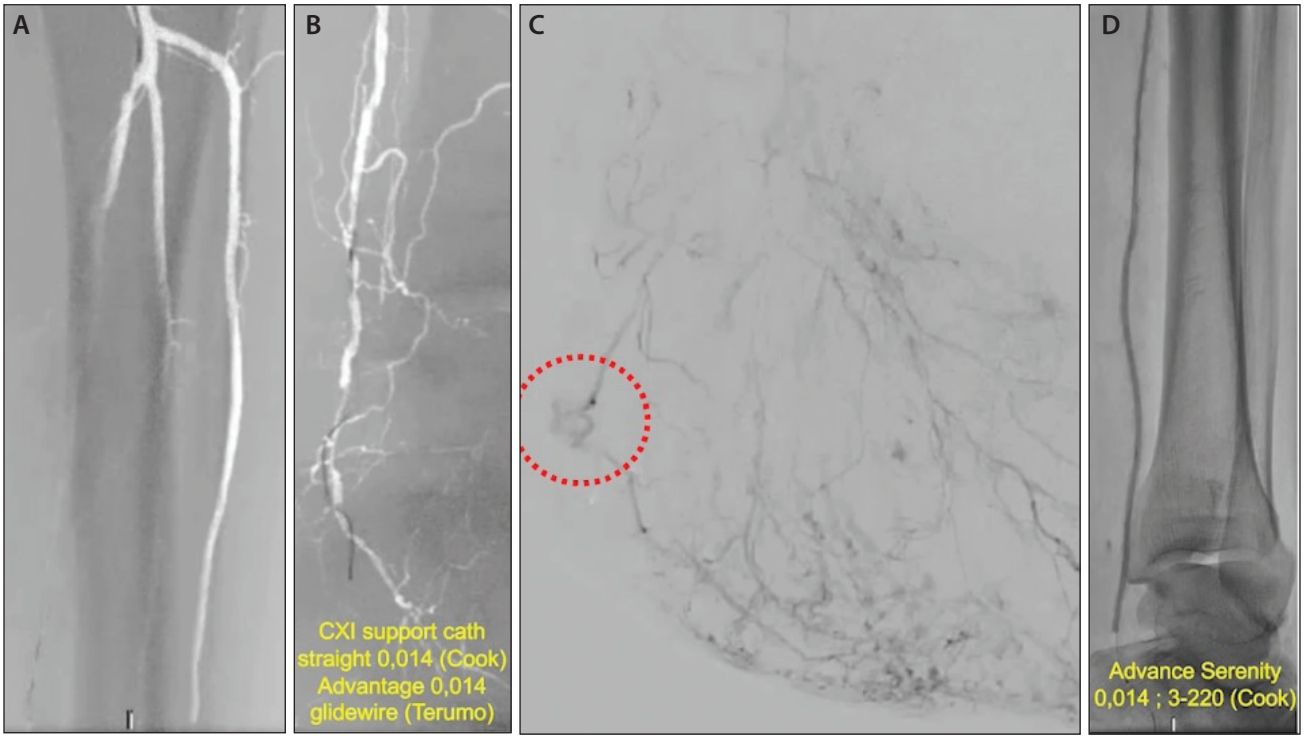

Figure 4. Approach to the PT artery (A). Use of a 0.014-inch CXI support catheter and 0.014-inch Glidewire Advantage to reach the hibernating PT vessel and lateral plantar arch (B). Blush at the level of the ulceration after contrast injection (red circle) (C). Dilatation with a 0.014-inch, 3- X 220-mm Advance Serenity balloon with prolonged inflations proximally and distally for 3 minutes (D).

I want to ask you about your preparation for that case. Did you prep in the foot ahead of time? Were you thinking that you need multiple access points to get through that PT if you couldn't get through it antegrade? How did you set yourself up for success to start this case?

Dr. Deloose: In CLTI patients, we always prep the full leg, and we do this for different reasons—for instance, if we need a second or additional access distally or if there are wounds, ulcerations, or minor amputations, we do this in the same session, and then everything is prepared.

Luckily, I didn't need an additional access in this case, and the procedure went quite well BTK. However, in my routine practice, I prefer to use ipsilateral antegrade access to have more pushability, steerability, and other possibilities to treat BTK and BTA. In this case, I started with a crossover for the SFA lesion, and I continued in a crossover for BTK disease.

Dr. Peña: I think this was a fantastic case, and it highlights all the decisions that are made during the procedure. You showed your approach to not only crossing the lesion but then also approaching the lesion and deciding what your treatment options are. You really had a good decision to place the scaffolds and why you wanted to do that. The fact that you used a drug technology to reduce restenosis is very important.

And then, again, the decision to go BTK or not. Those decisions all happen on the table—sometimes you're going to do it and sometimes you're not, depending on that clinical situation. To me, that was really the star of the procedure, because you showed how these algorithms are applied and the different tools to use.

Dr. Deloose: I agree with you, Dr. Peña. Besides this, I think we also need to look at the health economic realities. I'm working in Belgium, and for reimbursements, we are quite limited compared to the United States. So, we don't have access to reimbursement for atherectomy devices, intravascular ultrasound (IVUS), and intravascular lithotripsy (IVL). I'm a strong enthusiast of drug-eluting technologies in general and paclitaxel-eluting technologies specifically. Luckily, this technology is reimbursed in Belgium. Of course, I think when you have more devices

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available, they would be valuable here. For instance, an IVUS-guided procedure would have been useful, and instead of just prepping with the balloon angioplasty, it's possible you could use an atherectomy device.

Dr. Deloose: Can you comment on your strategy in typical cases like this?

Dr. McMackin: We have very different practices and are different specialties, so I think it highlights all of the different ways you can treat these diseases. I am a huge fan of IVL. I think it does wonders for the different vessels. I'm academic based, and I'm not in the outpatient setting. I don't use as much atherectomy, but I do think that there are ways to really open up that lumen.

You mentioned IVUS, which is a fantastic tool because the angiogram really doesn't give you the full picture. The vessel is a three-dimensional structure, and you're looking at a two-dimensional image. I applaud your decision-making, especially in the SFA, to not stent the entire thing but to selectively stent segments. I do think IVUS, especially in that segment, would have helped guide me to those decisions, hopefully leading to those same decisions that you ultimately chose.

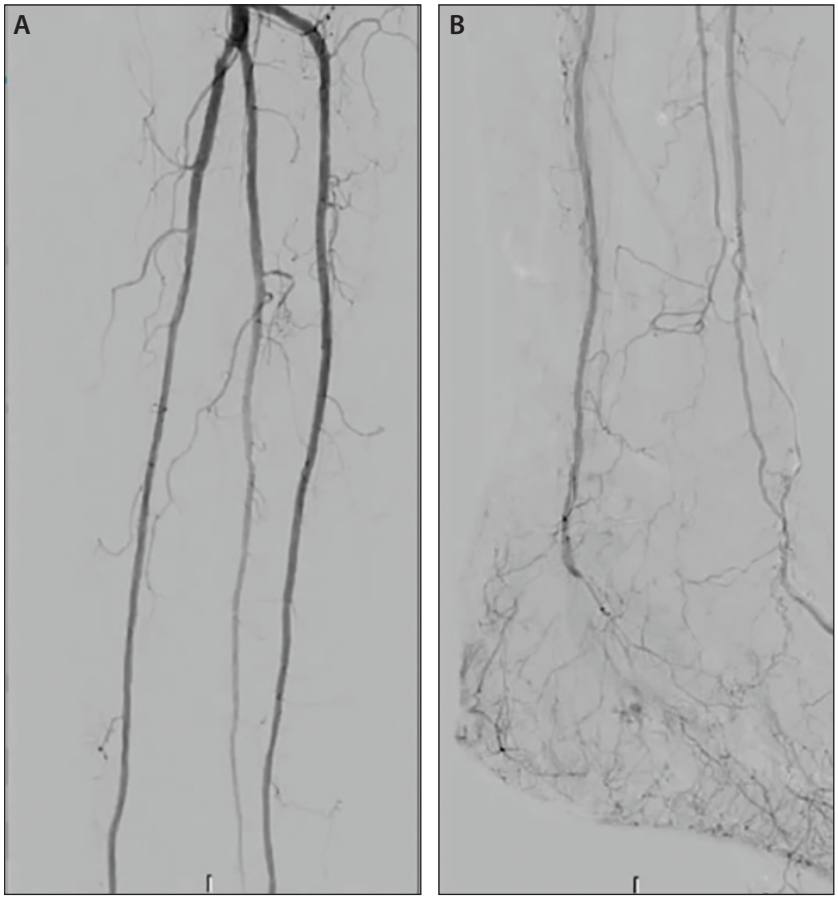

Figure 5. Final angiograms showing brisk flow from the PT artery (A) down to the foot (B).

Dr. Peña: I would second that. We're also not an institution that uses a lot of atherectomy, and we use it selectively. IVL has been involved in a lot of our decisions, but in many cases, prepping with just a balloon is helpful in a significant number of patients. Really, every patient is different. You went through the algorithm where you had a good inflation, you had an idea of what it looked like afterward, and then you decided on your treatment options.

I do think there is a role for IVUS for sizing the vessel if there's any question. If the flow isn't right, you determine whether you are going to scaffold or not. I think that's a good time to use IVUS. Generally, I'm selective in my use of IVUS. In this particular case, I think I would've done exactly what you did.

Dr. Deloose: I think the most important thing in the discussion around peripheral artery disease is to share case experiences. In this CLTI case where we treated ATK and BTK and followed a well-defined treatment algorithm, we had a good outcome, which was the most important thing for the patient. ■

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