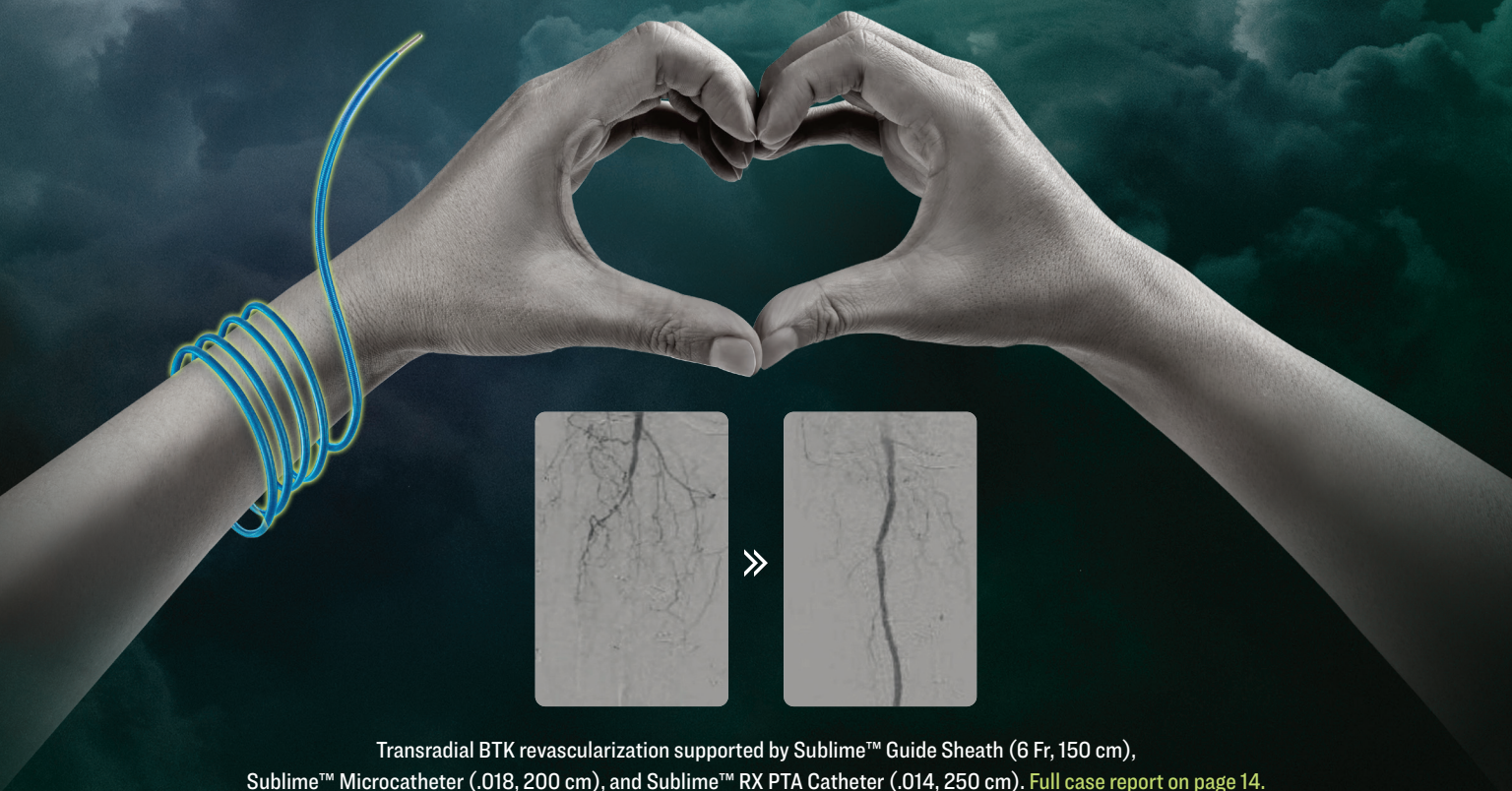


Endovascular TODAY

FULFILLING THE RADIAL PROMISE FOR PAD PATIENTS

Top centers are going radial-first for a wide range of peripheral interventions.
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Transradial BTK revascularization supported by Sublime™ Guide Sheath (6 Fr, 150 cm), Sublime™ Microcatheter (.018, 200 cm), and Sublime™ RX PTA Catheter (.014, 250 cm). [Full case report on page 14.](#)



Sameh Safyo, MD



Eleanor Huff, RN



Morgan Weems, RCIS

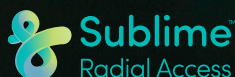


Ankit A. Patel, MD



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Sublime™ Guide Sheath

INDICATIONS FOR USE

The Guide Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neurovasculature.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters

INDICATIONS FOR USE

The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS

The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are contraindicated for use in the coronary arteries and the neurovasculature.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ .014, .018, and .035 Microcatheters

INDICATIONS FOR USE

The Sublime™ Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime™ Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CAUTION: Federal (US) law restricts these devices to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

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Building a Radial-First Peripheral Intervention Program at Baylor Scott & White The Heart Hospital—Plano

A conversation with Sameh Sayfo, MD, MBA, FSCAI, FACC; Eleanor Huff, MSN, RN, FACC; and Morgan Weems, RCIS.

In 2023, Baylor Scott & White The Heart Hospital—Plano, in Plano, Texas, became one of the first four hospitals nationwide to be verified as part of the Vascular Verification Program (Vascular-VP), a quality program launched by the American College of Surgeons with the Society for Vascular Surgery.¹ The hospital has a long-standing commitment to radial access as a quality metric for percutaneous coronary interventions (PCIs); today, 67% of its PCI cases are performed from the wrist. In the recent years, the team at Heart Hospital has adopted radial access for peripheral procedures, driven by the improved safety and patient satisfaction of the radial approach amply demonstrated in the medical literature.²⁻⁴

In close partnership with hospital administration and staff, interventional cardiologist **Sameh Sayfo, MD**, has led the facility's radial-to-peripheral initiative. Dr. Sayfo, who is Endovascular Fellowship Program Director at the hospital, now performs 63% of peripheral procedures via radial access, with an annual infrainguinal case volume of approximately 150. We spoke with Dr. Sayfo; registered cardiovascular invasive specialist, **Morgan Weems**; and Vice President of Cardiovascular Service Line Operations, **Ellie Huff**, about radial-to-peripheral adoption at Baylor Scott & White The Heart Hospital—Plano and its impact on patient care.

KEY TAKEAWAYS*

- New tools allow for more routine use of radial access for peripheral interventions (page 4)
- Partnering with administration can facilitate radial-peripheral adoption (page 6)
- Evidence challenges traditional objections to the radial-peripheral approach (page 8)
- The Sublime™ Radial Access Platform includes Sublime™ 5 Fr radial-length guide sheaths, ≤ 200 cm Sublime™ torqueable microcatheters, and Sublime™ PTA catheters suitable for BTK treatment (page 10)

* Based on current practice and clinical experience of Sameh Sayfo, MD.

DRIVERS OF RADIAL-PERIPHERAL ADOPTION

As an interventional cardiologist, what led you to focus on peripheral procedures?

Dr. Sayfo: I was trained at Brown University under one of the best endovascular interventionalists there is, Dr. Peter Soukas. Since then, I've had a strong interest in endovascular peripheral therapy. I feel as though patients with peripheral artery disease (PAD) in the United States don't get the high quality of care they deserve, especially compared with the care given to coronary artery disease patients. A lot of people with PAD aren't being diagnosed or offered therapy.⁵ Because of that, many are living in pain or lose



Baylor Scott & White The Heart Hospital—Plano.

Courtesy of Baylor Scott & White The Heart Hospital—Plano.



A radial-to-peripheral procedure underway at Baylor Scott & White The Heart Hospital—Plano. From left: M. Kasim Malik, DO, general cardiology fellow; Sameh Sayfo, MD, interventional cardiologist; and Usman Sarwar, MD, endovascular fellow.

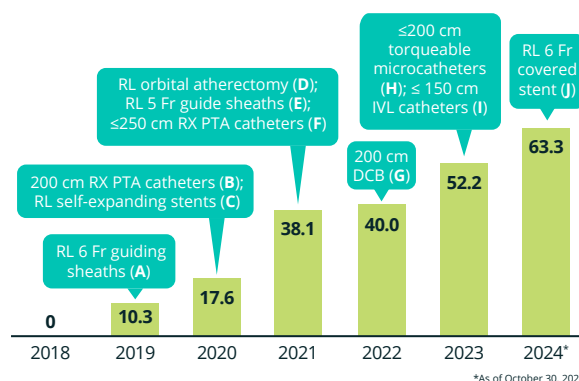
their limbs. The data for amputation in the United States are very concerning. Many people who end up getting an amputation have never had a prior arterial examination and given the increased mortality rate in patients with amputation,⁶ PAD management has become a passion of mine.

Regarding radial-to-peripheral procedures, our interest really picked up in 2020, during the COVID era. We didn't have enough beds to accommodate the huge influx of patients. Patients didn't want to stay in hospitals because they didn't consider them safe. Radial access helped us get them home safely sooner, with fewer overnight stays.

How would you describe the patient population you serve?

Dr. Sayfo: Since I began my practice, I've seen increasing numbers of older patients coming in with more complicated disease. Many have had prior procedures such as aortobifemoral bypass or endovascular aneurysm repair (EVAR). The more complex the patient, the more likely they have had multiple groin access procedures and groin complications, and they're often very hesitant to have another groin access procedure. They might be afraid to even see a doctor. With obesity in the United

"The more complex the patient, the more likely they have had multiple groin access procedures and groin complications, and they're often very hesitant to have another groin access procedure."



(A) 6 Fr, 119/149 cm guide sheaths (Terumo); (B) .018, .035, 200 cm RX PTA catheters (Terumo); (C) .035, 200 cm self-expanding peripheral stent (Terumo); (D) 200 cm, 1.5mm crown orbital atherectomy catheter (Abbott); (E) 5 Fr 120/150 cm guide sheath (Surmodics); (F) .014 (250 cm), .018 (220 cm) RX PTA catheters (Surmodics); (G) 5, 6 Fr, 200 cm OTW DCB (Medtronic); (H) .014, .018, .035, ≤200 cm microcatheters (Surmodics); (I) 135, 150 cm IVL catheter (Shockwave); (J) 6 Fr covered stent (Gore).

DCB, drug-coated balloon; IVL, intravascular lithotripsy; OTW, over the wire; PTA, percutaneous transluminal angioplasty; RL, radial-peripheral length (≥119 cm); RX, rapid exchange.

Figure 1. Progression of radial access utilization for peripheral interventions (%) with high-impact product adoptions by Sameh Sayfo, MD.

States reaching 40% recently,⁷ we are seeing more patients with body mass index (BMI) > 35 kg/m², and we know that higher BMI equates to higher risk of groin access complications.⁸

Why are some patients so put off by groin access?

Ms. Weems: Groin access can involve a fair amount of discomfort and pain for patients.⁹ We use a local anesthetic during groin procedures, but local anesthesia is not always sufficient to manage the pain. When we deploy a vascular closure device, we have to give patients a warning and give them more pain medication, because it often hurts. When we need to apply manual compression, that takes 20 minutes even if things go well. If there's any track ooze or if we have to give lidocaine-epinephrine to the groin, the patient is lying on their back a lot longer, dealing with the pressure we're holding on their groin and the associated pain, which is worse if they have existing back pain.

I've seen patients with bruising all over their groins from previous cases. Some people have said their groin was very sore for a week after their femoral access procedure. Older patients who are on blood thinners or have fragile skin may have some bruising on their wrist from radial access, but it's nothing compared with groin bruising.

How does recovery differ for femoral versus radial access?

Ms. Weems: With groin access, patients have to lie with their heads flat on the pillow for 2 to 3 hours with both legs straight. They want to be able to lift their heads, but we have to tell them that doing so applies pressure to the groin and they shouldn't do it. If we go radial access, we just wake up the patient and their

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"I'm now doing 63% or more peripheral cases with radial access."

bed is ready right next to them. They just scoot over, and they can sit up right away. That makes a big difference to them.

When did you begin doing radial-to-peripheral procedures at the Heart Hospital?

Dr. Sayfo: Before 2019, we didn't use radial access because we lacked radial-to-peripheral sheaths. For alternative access we'd sometimes use brachial or axillary, but I stayed away from them unless they were absolutely necessary because of complication risk.^{10,11} For alternative access we mainly used pedal access, which has advantages and disadvantages.¹² In my opinion, the main disadvantage is if there is a superficial femoral artery (SFA) occlusion, the only angiogram being performed is distal to the occlusion, which prevents you from recognizing the complexity and length of the occlusion. So, you're flying blind, trying to fix something based on a CT scan or ultrasound.

When Terumo Interventional Systems came out with radial-to-peripheral sheaths, I started tackling simple cases or cases that absolutely required radial access. Back then, I was doing about 10% of peripheral cases radially. But over the years, my volume of radial-to-peripheral cases has risen significantly as more equipment has become available. I'm now doing 63% or more peripheral cases with radial access (Figure 1). The percentage would be higher if I excluded cases in clinical trials that require groin access.

What other products have helped you increase the rate of peripheral interventions you perform from the radial approach?

Dr. Sayfo: The introduction of orbital and, later, laser atherectomy has been very helpful, specifically the Diamondback 360[®] orbital atherectomy system (Abbott) and Aurion[™] atherectomy system (AngioDynamics, Inc.). The same with the IN.PACT[™] 018, 200 cm drug-coated balloon (DCB; Medtronic). In the past, we needed to treat some younger patients via femoral access because we didn't have radial-peripheral-length DCBs. In my opinion, it's not fair to just balloon and stent given the great data we have with DCBs.¹³

Over the past few years, Surmodics has also introduced products that have made a huge impact on my practice. With the Sublime[™] .014 and .018 RX PTA catheters [250 cm and 220 cm working lengths, respectively] (Surmodics, Inc.), we were able to do below-the-knee (BTK) work. Surmodics also introduced the Sublime[™] microcatheters in 2023. That really changed the game, because now we have 200 cm microcatheters in .014, .018, and .035, and we're able to navigate complicated cases such as chronic total occlusions (CTOs) in the SFA, popliteal artery, or BTK lesions. The Sublime[™] 5 Fr guide sheath has also been very useful for patients with small arteries, especially older,

thinner females. All of these products have made us comfortable treating more challenging cases.

Morgan, from your point of view as a scrub tech, has radial access impacted your workflow or the complexity of cases?

Ms. Weems: Not really. Even though radial access might involve learning an extra step or two, with repetition you get it down and it becomes second nature. There are technical differences, such as prepping pedal access as backup when we're going radial access. But overall, radial procedures are now faster for us to perform than femoral procedures and allow for faster turnover. This potentially allows us to do more cases in a room per day.

"Over the past few years, Surmodics has introduced products that have made a huge impact on my practice."

Dr. Sayfo, as a physician with a master's in business administration, what are your thoughts on the economics of radial versus femoral access for PAD?

Dr. Sayfo: Data from the coronary side show you can eliminate a tremendous amount of cost for patients, hospitals, and health care systems by increasing rates of same-day discharge with radial access.¹⁴ We just published a retrospective study of 143 radial-peripheral patients we treated between 2020 and 2022.¹⁵ Our rate of same-day discharge was 97%. And remember, we didn't have a lot of the equipment back then that we have now, such as radial-peripheral-length DCBs or laser atherectomy. That's what we're trying to achieve—to send patients home the same day, safely. Same-day discharge is a driver of patient satisfaction. People always want to sleep in their own beds—nobody likes staying in a hospital.

We also need to combat the biggest risk associated with interventions: access site bleeding. Population trends are making this even more important. Age, BMI, comorbidities, and case complexity increase bleeding risk.^{8,16} Women have higher access site bleeding complications than men.¹⁷ You can minimize these risks by going radial access.¹⁸⁻²⁰

Reducing complications with radial access also results in cost savings.²¹ With radial, even if you have an access site complication, you rarely need to take the patient to surgery to repair it.²² For groin access procedure complications, it's not uncommon to have to resort to open surgery, blood transfusion, vasopressors, or thrombin injections, things requiring intensive care unit admission.²³ There are so many things that can go wrong.

What advice would you offer physicians seeking to implement the radial-to-peripheral approach?

Dr. Sayfo: There are two partnerships you need to develop. The first is with your staff, and the second is with your administration. Let's start with the staff.

If the staff has never done a radial case before, you're going to meet resistance. They're going to assume the procedures will take longer. You need to explain to the staff why you're taking this approach and make them part of the solution. Educate them on the technology and what is expected of them. For example, if you're going to use ultrasound every time—well, almost every vascular interventionalist uses ultrasound for groin access, so it's not going to be an issue. Our staff has reached the point where they will text me before each case "radial, yes? Or radial/pedal?" When I reply "femoral," their response is "really?" Radial has become the norm.

Morgan, any tips for staff who are new to radial-to-peripheral procedures?

Ms. Weems: It's really important to make sure all the sheaths remain wet right up to the moment they're inserted; otherwise, they can be painful for the patient. I always keep wet 4 X 4 inch sterile gauze pads over the sheaths until they're needed, to keep them hydrophilic. I'll also flush and prep the small sheath after it's been used at the beginning of the procedure just in case it needs to be used again.

What kind of partnership do you need to develop with administration?

Dr. Sayfo: Well, at a basic level you're going to need administration to support you in getting the equipment you'll need. You can start with diagnostic procedures, which are easy to do with the equipment you already have. This applies to simple iliac cases using, say, 150 cm balloons, DCBs, or stents. But when you move on to SFA, popliteal, BTK, or complex cases, you really need to partner with someone in administration.

"There are two partnerships you need to develop. The first is with your staff, and the second is with your administration."

I've been extremely fortunate to be able to partner with Ellie and the rest of the administration for this.

Ms. Huff: The key to successfully launching a new approach or program is for a physician, like Dr. Sayfo, to collaborate with someone like me in administration to develop an adoption strategy. We need to determine how to communicate the message and secure investment for the proposed program. This collaboration, which we call a dyad between an executive partner and a physician leader, is the secret sauce for success.

How does this collaboration work?

Ms. Huff: Physicians often lack the time to create detailed presentations or may not have training in change management. When introducing a new concept, you'll inevitably encounter resistance. Therefore, you need a strategy to promote the idea, implement it, and monitor progress over time. An administrator typically has the time for these tasks, whereas physicians are usually occupied with patient care. Although physicians may have access to the latest approaches, tools, and innovations, they might not have the time to navigate the organization's processes for acceptance and procurement.

Challenges can arise with supply chain management, but if you've already prepared a pitch deck with your administrator that outlines the implications and value proposition, you're better equipped to handle them. Not everyone will be on board initially, but I've found that if I partner with early adopters and have a passionate physician leading the change, we're more likely to succeed.

RADIAL-PERIPHERAL PRO TIPS

What's your top tip for new radial operators?

Dr. Sayfo: As basic as it sounds, you really need to attend a course on radial access. After that, start with simple cases and make sure you have all the equipment you need—don't go ad hoc (Figure 2). There's nothing worse than being surprised without the right tools. I have a rule of four: (1) know your equipment, (2) know your staff, (3) know your skills, and (4) know your patients. The more experience you get with radial-to-peripheral, the more comfortable you become doing complex cases.

How often do you perform peripheral cases solely from the wrist, without additional access?

Dr. Sayfo: Most of my cases are radial alone. Of course, the groin is always prepped just in case, but our crossover rate to femoral is $\leq 3\%$.¹⁵ Whenever I have a patient with complex SFA anatomy, a CTO, or a previous stent that clearly looks undersized, I also prep pedal access. Sometimes I might want to complement a radial case with just a wire and snare from pedal access to get an arterial railway or go pedal with a sheath for combined radial/pedal therapy.

As with any other intervention, the more complicated the case, the more likely you are to need dual access. Surprisingly enough,

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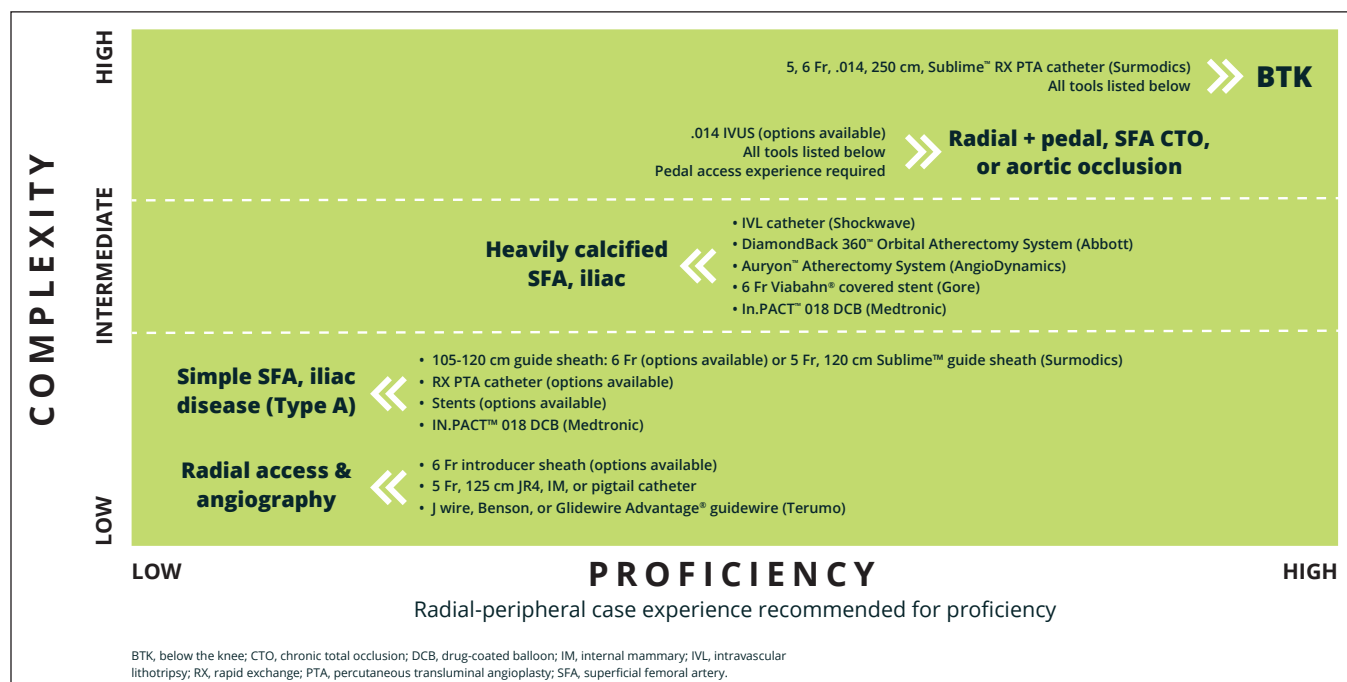


Figure 2. Radial-to-peripheral learning curve and recommended toolkit. Based on current practice and clinical experience of Sameh Sayfo, MD.

I think one of the most complicated cases is aortoiliac occlusion, and I've done many of these cases with dual-radial or -ulnar access, no groin or pedal stick (page 13).

Do you prefer left or right radial?

Dr. Sayfo: I prefer right radial, mainly because our rooms are set up with the physician on the right side of the table. For a very small percentage of patients, I'll choose the left radial when I expect navigation of the arch will be difficult or the patient is very tall, but most of the time that's not a problem. The moment I have a long sheath where I want it, right or left doesn't matter as much as it did in the past. The devices are much longer now, which reduces the need to go left radial to obtain more length.

Tell us a little more about how you set up for radial.

Dr. Sayfo: How you set up the table can be important. If you go left radial, and the patient's arm is extended and you have two long tables, then the radiation protection is only protecting you. That's one of the reasons I don't choose the left radial. When I go with right radial, the staff can't feel the difference between going femoral or radial. The monitors in your room may also be set up for working from the right side of the patient, making it uncomfortable to keep an eye on the monitors if you choose the left radial. So, the room should be set up in a way that's comfortable for you, comfortable for the patient, and avoids you getting in the way of the staff.

For example, if you put a long table on the left side, you're taking up a lot of the space in a cath lab. That's the side where the nurses are standing, where the medications are for the nurses to

administer, and where the devices and equipment are. The nurses won't have enough room to bring you devices and you're going to be in the way. Even when I go left radial, I don't put in a long table or extend the patient's arm—I just move the arm up and over, so I can work from the right side, or I stay on the left side but I move the arm to the side of the left groin and continue the case as if I had left groin access.

How do you obtain radial access?

Dr. Sayfo: I now use ultrasound to size the vessel 100% of the time. If the vessel is too small for a 6 Fr guide sheath, I might use the Sublime™ 5 Fr guide sheath. Alternatively, I might use the ulnar artery on the same [right] arm or the left radial artery if either of those are bigger.

Ultrasound-guided access is really important, especially for a physician who does not do a lot of radial cases. Ultrasound access saves time and reduces the number of times you have to do a stick—that's clearly demonstrated in the literature.²⁴ Using ultrasound guidance, we obtain radial access and insert a 6 F short sheath. We use a Terumo system, but there are others. Next, we always give a mixture of nitroglycerin and verapamil to help vasodilate the radial artery.

What is your radial cocktail?

Dr. Sayfo: We combine 400 µg nitroglycerin with 5 mg verapamil. Usually, I administer half the dose at the beginning of diagnostics, then we give about 50 U/kg of heparin through the peripheral intravenous line. Some operators mix heparin with the vasodilation cocktail, but we usually give it intravenously.

Which catheter do you use for imaging?

Dr. Sayfo: I usually use a JR4 5 Fr catheter for diagnostics—I like the small profile and long length. Sometimes we have patients who have had an EVAR or aortobifemoral bypass, which can take up length. A 125 cm JR4 catheter can get you anywhere you need for your diagnostic picture, no matter the patient's height or anatomy. Also, since I usually go right radial, the JR4 curve helps me navigate the arch.

My number two choice is a 5 Fr, 125 cm internal mammary catheter, and my number three choice is a pigtail catheter. A pigtail catheter takes a little finesse to use, but it works well because you can flip it to the arch. If you're going left radial with a pigtail, you just go over the wire; there's not much need for manipulation. Some operators like a pigtail because it can be positioned to visualize the aortobifemoral bifurcation and aortic runoff, but I usually don't perform a distal aortic angiogram unless I'm dealing with an aortobiiliac occlusion. If I'm dealing with SFA or any selective disease, I do selective pictures. This saves you contrast and reduces radiation.

What about wire selection?

Dr. Sayfo: I start with a table J wire. If that doesn't cross the arch, then I switch to a Benson or a soft Glidewire® guidewire (Terumo Interventional Systems). When you're using a Glidewire® guidewire, it's very important to always keep an eye on the tip of the wire, because if you're not paying attention it can go into the superior mesenteric or renal arteries and perforate. If that happens, you have a big problem on your hands before you've even started your case. I deliver my JR4 catheter into the common iliac or external iliac artery as distal as possible and we start with selective angiograms.

Next, if you're going to convert to intervention, you'll need to switch out your diagnostic catheter and sheath to a long radial-to-peripheral sheath, and for that it will be better to utilize a stiff wire like a Supra Core™ guidewire (Abbott).

How do you select your interventional sheath?

Dr. Sayfo: If I'm going to work on a common iliac or aortobiiliac occlusion, I'll typically use a 105 cm radial-to-peripheral sheath. For the external iliac, SFA, or popliteal arteries in an average-size patient, I usually use a 119 or 120 cm sheath. If the patient is 6 ft or taller or has had an aortobifemoral bypass

or an EVAR, I might switch to a longer sheath, especially if I'm dealing with distal SFA, popliteal, or BTK disease.

How do you deliver the sheath?

Dr. Sayfo: For sheath delivery, I replace my J wire with a stiff wire through the JR4 catheter. As I said, my preference is a Supra Core™ guidewire, though some operators prefer Amplatz or Glidewire® guidewires. But again, if you use a Glidewire®, you need to keep an eye on the tip to avoid complication. After I place the stiff wire, I take out the JR4 and give my second dose of radial cocktail, heparin 50 U/kg, to reach full heparinization. My goal is an activated clotting time (ACT) of 250 seconds. Then I take out my radial access sheath and deliver the long sheath.

No matter what product you're using, the sheath should be wetted with saline to activate the hydrophilic layer of the sheath. For successful delivery of the sheath, you need to ensure you have a nice rail with the stiff wire and make sure to just keep advancing the sheath—don't pause halfway—until you get to the external iliac or wherever you want to land it. Otherwise, you might run into a spasm, and that makes it hard to push the sheath. Now I have the sheath in place, I have heparinization, and a couple minutes later I'm going to get an ACT.

What comes next?

Dr. Sayfo: That depends on the disease and how I plan to treat it. If I'm going to treat the common femoral, SFA, popliteal, or BTK arteries—really, anything but an iliac case—I'll deliver a microcatheter as deep as possible and switch to a ViperWire Advance™ 475 cm guidewire (Abbott), which is the only long wire we have. I put it all the way into the foot, and now I can do whatever else I need to do: orbital atherectomy, laser atherectomy, intravascular lithotripsy (IVL), DCB, or just a regular balloon and stent.

When I'm finished with treatment, it's time to remove the sheath. We used to do this by putting the dilator back, removing the .014 wire, putting in a .035 wire, removing the sheath, and closing with either a TR Band® (Terumo Interventional Systems) or other vascular band. More recently, I've simply been removing the sheath and putting the short sheath back in (the one we used at the beginning). You can only do this if the patient is heavily sedated, and you can't do this over an .035 wire.

ANSWERS TO COMMON RADIAL-PERIPHERAL OBJECTIONS

One objection you hear to the radial-peripheral approach is the lack of a bailout option. How do you feel about that?

Dr. Sayfo: Yes, a lot of operators will not do an iliac case with radial access because of the risk of iliac perforations, which can be fatal, and the concern of not being able to deliver a bailout device via a 6 F sheath. I actually love to have that conversation, because I think that iliac perforations are easier to manage from the radial compared with the femoral approach.

If you're going femoral, you're usually up and over with a 6 Fr system. You balloon the contralateral external iliac artery, and boom, you have a rupture. In this situation, the first thing you do is inflate the balloon to tamponade the bleeding and try to get contralateral access. That's easy.

If you're treating from the ipsilateral side, after you tamponade the perforation you cannot safely change to an 8 Fr covered stent system from that same access site. So, operators go up and over from the other side, but now you need to get your wire through

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the balloon that's already there. The contralateral side may also be occluded or severely diseased. You're working as fast as you can, because the patient's hemodynamics can deteriorate very quickly during an iliac perforation, and blood pressure can drop 100 mm Hg within a few minutes. It just becomes a hard situation.

With radial access, regardless of left or right radial, you just reinflate the balloon. Now you have all the time you need to get groin access with an 8 Fr system. Next, you can easily put the wire through, deflate the tamponade balloon, deploy the covered stent, and you're done.

We've had two perforations in iliac cases, and I was much less stressed handling those via radial access than I would have been with femoral access. Granted, you're not going to be able to deploy an 8 Fr covered stent from radial access, but you can easily tamponade with the balloon from radial access. That gives you all the time you need, all the safety margin, to get 8 Fr groin access when the patient's stable. Alternatively, Gore & Associates now offers a 6 Fr compatible, balloon-expandable covered stent (VIABAHN® VBX balloon expandable endoprosthesis) that can be delivered via radial access.

What are some other common objections to radial-to-peripheral and your take on those?

Dr. Sayfo: Common objections include:

- **Risk of stroke.** There has been concern about the risk of stroke with radial access in general because you're crossing the aortic arch. As others have reported,²⁵ I don't think the data support this concern. Our single-center study showed a < 1% stroke rate among 143 radial-peripheral patients.¹⁵ Another paper came out last year on the first prospective, multicenter registry on radial access for PAD.²⁶ There were no reports of stroke among more than 100 patients. Remember, with radial access, the moment you have your catheter and stiff wire in and you place your sheath, you have a tube that's delivering all the devices. There's not a lot of motion in the arch while you're working.
- **Long learning curve.** The idea that radial access requires a long learning curve depends on your background and the complexity of radial-peripheral procedures you want to do. It's easy to teach a cardiologist to get started with radial-to-peripheral because they've already learned the access part of it, which is what matters the most. Good interventional radiologists have been using radial or brachial access for a long time for prostate artery embolization and gastrointestinal bleeds.

Even if you've never learned radial access, with ultrasound, radial access is not hard—it's sometimes easier than femoral access. After you learn access, the main thing is learning navigation of the arch. If you start with diagnostics and simple iliac and SFA cases, it takes you about 10 to 30 cases to become comfortable. Doing diagnostic angiograms with radial access is faster and safer from radial compared with femoral access—no groin stick, no downtime, and the patient can go in for surgery the same day. After you're comfortable doing that, you can move on to more complex iliac and SFA cases (Figure 2).

“Another myth is that there are not enough radial-to-peripheral devices. I don't think that's accurate; a lot of operators simply don't know what's available.”

High-complexity cases involve SFA CTOs, distal aortic occlusions and, at the most complex level, BTK occlusions. For these you need to understand pedal access. Unfortunately, a lot of good operators either don't do any pedal cases or very few, and you need experience to become proficient. Intravascular ultrasound (IVUS) is also extremely important in aortic occlusion cases because you need to know where you can reenter. You can use some reentry devices from the radial approach for the iliacs, but you need to understand how long they are and what sheath to use for them. For example, you cannot use anything longer than a 120 sheath because the reentry device has a 120 cm shaft length (Pioneer Plus™ IVUS-guided reentry catheter, Philips). Aside from that, in my view, when tackling a BTK lesion you really need to familiarize yourself with radial-to-peripheral length laser atherectomy and the Sublime™ 250 cm .014 RX PTA balloon.

- **Longer procedure/fluoroscopy time.** The data do not support prolonged procedure time and more radiation exposure for radial versus femoral access. We published an abstract at TCT 2023 that retrospectively compared iliac intervention via femoral access (n = 72) versus radial access (n = 72).²⁷ There was no difference between the two groups in procedure time or volume of contrast media. In fact, the only difference between the groups was shorter length of stay for radial versus femoral (1.0 vs 1.3 days, respectively; $P = .044$) and a trend toward lower 1-year mortality for radial versus femoral (3% vs 11.1%; $P = .067$). Similar data have been published in the coronary literature.²⁸

- **Lack of devices.** Another myth is that there are not enough radial-to-peripheral devices. I don't think that's accurate; a lot of operators simply don't know what's available (Figure 1). For example, many physicians don't know there's a 200 cm DCB (IN.PACT™ 018) or radial-to-peripheral length orbital and laser atherectomy devices (Diamondback 360® peripheral orbital atherectomy system and Auryon™ XL catheter, respectively). They also don't know about the Sublime™ 200 cm microcatheter, which is a game-changer, and the Sublime™ 220 cm and 250 cm RX PTA balloons (.018 and .014 profiles, respectively). There are still some gaps, but they don't prevent me from doing most of my peripheral cases from radial access.

What do you see as the principal remaining gaps in the radial-to-peripheral toolkit?

Dr. Sayfo: The Achilles' heel for radial-to-peripheral has been lack of a long wire. We use the ViperWire Advance™ 475 cm guidewire (Abbott), but I'm not satisfied with the support it provides. Having said that, we just did a case involving an old, occluded stent from the popliteal down to the tibioperoneal trunk (TPT) and peroneal artery. We crossed it with the Sublime™ microcatheter and wire escalation, put in the 475 cm wire, performed laser atherectomy, ballooned, and used the DCB. That's exactly what everybody else would have done from femoral access (page 14).

Lack of radial-peripheral-length IVUS remains a limitation, and there's a limitation for bioresorbable stents. The Esprit™ BTK resorbable scaffold system (Abbott) is now commercially available, but that's a 145 cm working length. So those are challenges for BTK.

I would also like to see more stent options. We have stents from Terumo Interventional Systems (R2P™ MISAGO® RX

“At this point I use a Sublime™ microcatheter for most of my cases.”

self-expanding peripheral stent) and Cordis (SMART Radianz™ vascular stent system). I really like the stent from Terumo Interventional Systems, but it's a .035 system. Sometimes I'll already be working with an .014 wire, so it can be challenging to deliver an .035 stent on an .014 system. But the balloon catheters, microcatheter, and guide sheaths that Surmodics offers are the most important things. We just need a good radial-length wire, more stent options, and IVUS to complete the package.

EXPERIENCE WITH SUBLIME™ RADIAL ACCESS PRODUCTS

Let's dig a little deeper into your experience with the Sublime™ Radial Access Platform, beginning with the guide sheaths.

Dr. Sayfo: The fact that Surmodics offers the Sublime™ guide sheath in 5 Fr as well as 6 Fr has been very helpful for patients with small arteries. This sheath is very trackable and deliverable, which is great, because you're always worried about tracking a stiff wire through the tortuosity of the brachiocephalic artery and the aortic arch. This sheath tracks a stiff wire very easily, and when the sheath is settled down where you want it, let's say in the common or external iliac artery, you don't have to worry about it moving. This gives you the stability you need to take care of the patient without worrying about the sheath pulling back and losing that support.

Do you see advantages in using Sublime™ PTA catheters?

Dr. Sayfo: The balloons have been great, and they have different advantages. For one, they have a variety of profiles. The .014 has a working length of 250 cm, which allows you to reach the BTK arteries. Their performance is also important. The first case

I performed with a Sublime™ PTA catheter was a complete SFA CTO, and I was worried the balloon was not going to cross, but it crossed very easily. The rapid-exchange design of these catheters makes handling them much easier. For example, if I cross with a .018 and I want to use just a balloon, I don't have to switch to a long wire.

How about the Sublime™ microcatheters?

Dr. Sayfo: The 200 cm length of these microcatheters is extremely important, but the design is also very good. These microcatheters are very torqueable and deliverable. Most of the time I use an angled tip, which is very important in CTO cases, where there is a higher chance you'll need to perform a dissection reentry technique. An angled tip catheter allows you to get back to the true lumen distally.

It's also useful to have the Sublime™ .014, .018, and .035 microcatheters. Sometimes in a calcified or tortuous artery, or a distal artery, I like to use either the .018 or .014 microcatheters with their smaller profiles so I can cross farther. These are also very, very slippery catheters. I can deliver these through a 100% occlusion without any issues.

What kinds of procedures do Sublime™ microcatheters help enable?

Dr. Sayfo: It can be really hard to deliver a .014 wire, such as the 475 cm ViperWire Advance® (Abbott) guidewire, through a lesion unless it's only, for example, a 70% occlusion that anything can cross. If you have a highly calcified, tortuous lesion or a CTO, you're going to have to cross with a hydrophilic wire, such as a Glidewire® or Hi-Torque Command™ (Abbott) guidewire. Then, after you cross

“The fact that Surmodics offers the Sublime™ guide sheath in 5 Fr as well as 6 Fr has been very helpful for patients with small arteries.”

FULFILLING THE RADIAL PROMISE FOR PAD PATIENTS

Top centers are going radial-first for a wide range of peripheral interventions

with that, you want the microcatheter to track through that wire and serve as a delivery vehicle that allows you to put the 475 cm ViperWire Advance® guidewire where you want it.

At this point I use a Sublime™ microcatheter for most of my cases, unless I'm dealing with a proximal iliac that doesn't require the 200 cm length or a 70%-type lesion where I can cross with the ViperWire Advance® guidewire by itself. ■

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CASE REPORT

Successful Revascularization of SFA Stenosis Via Radial Access

By Sameh Sayfo, MD, MBA, FSCAI, FACC

PATIENT PRESENTATION

A woman in her early 70s with a medical history of diabetes, hypertension, and hyperlipidemia presented to the hospital with worsening left lower extremity claudication (Rutherford class 3).

DIAGNOSTIC FINDINGS

Arterial ultrasound and CTA showed a heavily calcified proximal left superficial femoral artery (SFA) stenosis. The plan was to revascularize this vessel utilizing a radial approach.

TREATMENT

Access was achieved through the patient's right radial artery using ultrasound guidance and a radial cocktail was delivered. The radial access introducer sheath was exchanged for a 6 Fr, 120 cm Sublime™ guide sheath (Surmodics, Inc.), which was navigated to the stenosis. An angiogram confirmed that the patient had a heavily calcified proximal left SFA stenosis (Figure 1). A Hi-Torque Command™ 18 guidewire (Abbott) and 150 cm Navicross® support catheter (Terumo Interventional Systems) were used in conjunction to cross the lesion. The Hi-Torque Command™ 18 guidewire was swapped out for a .014, 475 cm ViperWire™ guidewire (Abbott).

Orbital atherectomy was performed using the Diamondback 360® peripheral orbital atherectomy system (Abbott) with a 1.75 mm solid crown (Figure 2). Following the atherectomy passes, a 5 X 60 mm IN.PACT™ 018 drug-coated balloon (Medtronic) was dilated across the lesion. The final angiogram showed 0% residual stenosis, patent flow, and no dissections (Figure 3).

POSTPROCEDURE OUTCOME

The patient was discharged the same day with a complete resolution of her symptoms. ■



Figure 1. Initial angiogram displaying calcified left SFA stenosis.

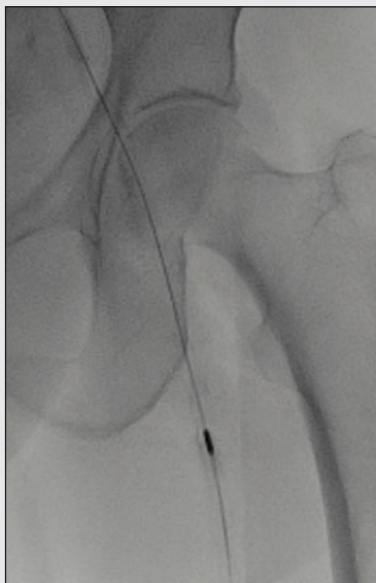


Figure 2. Orbital atherectomy was performed using the Diamondback 360® peripheral orbital atherectomy system with a 1.75 mm solid crown.

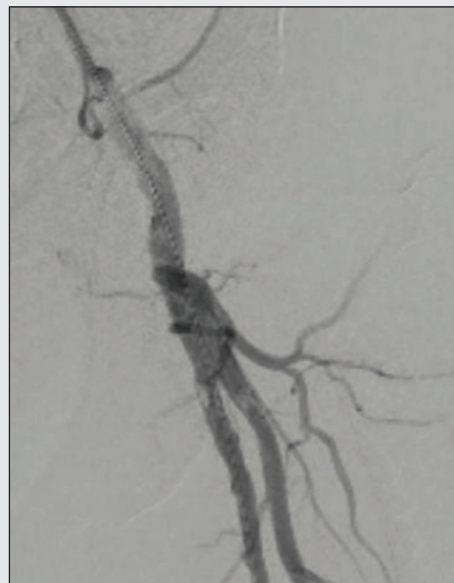


Figure 3. Final angiogram showed 0% residual stenosis, patent flow, and no dissections.

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FULFILLING THE RADIAL PROMISE FOR PAD PATIENTS

Top centers are going radial-first for a wide range of peripheral interventions

CASE REPORT

Successful Revascularization of Aortoiliac Stenosis Via Radial Access

By Sameh Sayfo, MD, MBA, FSCAI, FACC

PATIENT PRESENTATION

A woman in her mid 50s with a medical history of coronary artery disease, coronary artery bypass grafting, and diabetes presented with severe bilateral hip claudication.

DIAGNOSTIC FINDINGS

Preprocedure ankle-brachial index (ABI) showed abnormality with readings of 0.23 on the right leg and 0.37 on the left leg (Figure 1). Follow-up CTA showed a distal aorta and bilateral common iliac artery occlusion (Figure 2).

TREATMENT

Bilateral ulnar access was obtained using ultrasound guidance and radial cocktails were delivered. Follow-up angiography confirmed the prior CTA results. The two introducer sheaths were exchanged for two 6 Fr, 120 cm Sublime™ guide sheaths (Surmodics, Inc.), which were advanced to the distal aorta and into each occluded common iliac artery. Utilizing an .018 Glidewire Advantage® peripheral guidewire (Terumo Interventional Systems) and .035, 135 cm Navicross® support catheter through both sheaths, both lesions were successfully crossed. A 6 X 60 mm Shockwave™ M5+ intravascular lithotripsy catheter (Shockwave Medical) was used in both common iliac arteries to debulk the calcium. Two 8 X 80 mm R2P™ Misago® RX self-expanding peripheral stents (Terumo Interventional Systems) were deployed into each vessel, starting from the external iliac artery down to the distal common iliac artery. Additionally, two 7 X 39 mm RX AccuLink™ carotid stent system stents (Abbott) were deployed from common iliac to the distal aorta. The final angiogram showed complete resolution of the lesion, and the patient's pain was also observed to be completely resolved the same day (Figure 3).

POSTPROCEDURE OUTCOME

The patient was discharged hours after the intervention. ■

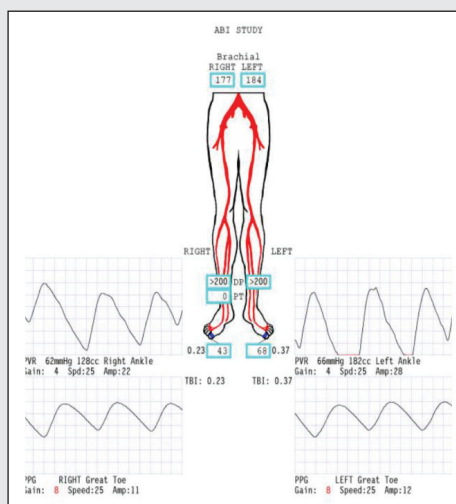


Figure 1. The patient's initial ABI measurements.

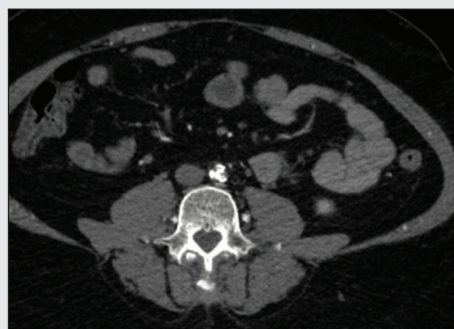


Figure 2. CTA showed a distal aorta and bilateral common iliac artery occlusion.



Figure 3. The final angiogram showed complete resolution of the lesion.

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CASE REPORT

Successful Revascularization of BTK In-Stent Restenosis Via Radial Access

By Sameh Sayfo, MD, MBA, FSCAI, FACC

PATIENT PRESENTATION

A man in his early 80s with extensive previous peripheral artery disease presented with resting pain. He had a previously placed stent extending from the peroneal artery to the distal popliteal artery. The patient had experienced contralateral groin access complications (pseudoaneurysm) in the past requiring thrombin injection.

DIAGNOSTIC FINDINGS

Right radial access was achieved and a radial cocktail was delivered. The introducer sheath was exchanged for a 6 Fr, 150 cm Sublime™ guide sheath (Surmodics, Inc.). An initial angiogram showed an occluded distal popliteal and peroneal arteries with 100% restenosis of the previously deployed stent (Figure 1).

TREATMENT

The Sublime™ guide sheath was advanced further into the vasculature. A 200 cm Sublime™ .018 microcatheter (Surmodics, Inc.) was introduced over the already placed .018 Glidewire Advantage® peripheral guidewire (Terumo Interventional Systems). The .018 Glidewire Advantage® guidewire was then swapped out for an .014 Astato® XS 20 guidewire (Abbott), and the lesion was then crossed. The Sublime™ microcatheter was removed, and the Astato® XS 20 guidewire was swapped out for a .014, 475 cm ViperWire Advance™ guidewire (Abbott).

Laser atherectomy using the Auryon™ 1.5 XL laser (AngioDynamics, Inc.) was performed throughout the stenotic segment. Next, an IN.PACT™ 018 drug-coated balloon (DCB; Medtronic) was dilated inside the stent (Figure 2). The DCB was removed, and a 2.5 X 100 mm, 250 cm, .014 Sublime™ Radial Access RX PTA catheter was advanced and dilated in the distal portion of the vessel for a final dilation.

A final angiogram showed single-vessel runoff to the plantar arch (Figure 3).

POSTPROCEDURE OUTCOME

The patient was sent home the same day. At his 2-week follow-up, he had no pain. ■

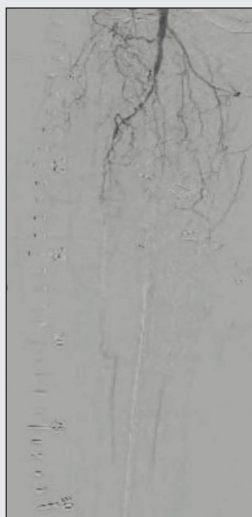


Figure 1. Initial angiogram showed occluded distal popliteal and peroneal arteries with 100% restenosis of the previously deployed stent.



Figure 2. An IN.PACT™ 018 DCB dilated inside the stent.

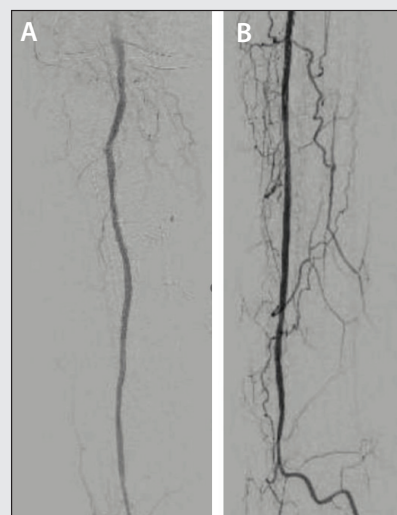


Figure 3. Final angiogram showed single-vessel runoff from distal popliteal artery (A) to the plantar arch (B).

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Approaching 90% Radial-to-Peripheral for Complex CLI Interventions

A conversation with Ankit A. Patel, MD, FSCAI, FACC, RPVI.

Dr. Ankit A. Patel, an interventional cardiologist with the Northside Hospital health care system in greater Atlanta, Georgia, specializes in performing complex coronary and peripheral interventions from the radial approach. By his own account, he will do “anything to avoid femoral access”—including tackling long chronic total occlusions (CTOs)—to reduce patient risk with wrist access. Dr. Patel has participated as a site investigator for multiple clinical trials and has been actively involved in medical executive, credentialing, peer review, and technology steering committees. We spoke with Dr. Patel about the state of the art for radial-peripheral interventions.

What types of patients do you typically see?

Almost 80% of my peripheral interventions are Rutherford class 4 to 6. I like to treat rest pain, people we can help improve dramatically overnight. Many are no-option patients, people with very complex disease who have prohibitive surgical risks or very elderly patients with nonhealing wounds. These patients are in pain, they're miserable, and their families don't know what to do. It's satisfying to be able to open their blood flow and see them get better.

How would you describe your transition to radial access for peripheral interventions?

During my early career, I was content with doing straightforward, less complex peripheral interventions. With time and experience, I became very comfortable doing transfemoral CTOs and atherectomy. These were 100% femoral access because of equipment limitations.

When radial-length sheaths and orbital atherectomy became available around 2019, I began doing about 20% of peripheral cases with radial access; most were less complex TASC (TransAtlantic Inter-Society Consensus) A or B lesions. I'm now very close to 90% radial-to-peripheral. About 60% of these cases are radial only, and 40% are radial and pedal for very complicated critical limb ischemia (CLI) with tight CTOs. We do a lot of CLI below-the-knee (BTK) work and CTOs of the iliacs or superficial femoral artery.

“The Sublime™ 5 Fr guide sheath helps with patients who have very small radial arteries—for example, elderly, petite female patients—that aren't suitable for a 6 Fr system.”

In a nutshell, why do you prefer the radial approach?

It's much safer for the patient.¹ Recovery is also faster, so you don't hold up the bed—the patient can be out of the hospital in 2 hours.² My staff has become very comfortable with radial access. For me, doing a radial-peripheral intervention is as fast as a femoral intervention.

When do you still select femoral access?

Lack of radial pulse, arteriovenous fistula, or a CTO case where I feel I need directional atherectomy. Of course, you also need to exclude patients with radial arteries too small for available equipment. The Sublime™ 5 Fr guide sheath (Surmodics, Inc.) helps with patients who have very small radial arteries—for example, elderly, petite female patients—that aren't suitable for a 6 Fr system (see case on page 17). I would prefer to use the 5 Fr system for these patients to reduce the risk of losing their radial pulse for future interventions. To be successful as radialists, we need to maintain the option for radial access.

“Surmodics has filled a big gap we faced in trying to go BTK.”

What other equipment limitations do you feel the Sublime™ Radial Access Platform has helped to address?

At times, I've had to bail out to femoral access because we couldn't cross highly calcified distal CTOs—we've lacked support catheters longer than 150 cm. The only one we had was the ViperCath™ XC catheter (Abbott), which is .035 and, in my experience, will not cross a CTO segment. Surmodics has filled a big gap we faced in trying to go BTK. Since we've added Sublime™ PTA catheters and the Sublime™ 200 cm support catheters in the last few months, I have successfully opened three or four CTOs that I would not have been able to do transradial without using combined pedal access (see case on page 18). I don't like to use pedal access unless it is absolutely necessary.

One of the drawbacks to radial-peripheral has been having to go left radial for interventions to get that extra 10 or 15 cm of length, which is precious for us. It's prudent to use right radial access if possible—in my experience, it helps reduce radiation exposure for the patient, provider, and staff. I think the Sublime™ platform fills that void with the 220 cm (.018) and 250 cm (.014) PTA catheters. They have long rapid-exchange segments (45 and 50 cm for the .014 and .018 platforms, respectively), which gives you support, pushability, and crossability.

Do you have practical tips for new radialists for avoiding radial artery spasm?

The number one tip is to do an ultrasound of your radial artery, whether it's left or right, and make sure you are not setting yourself up for failure. If you know the radial artery is big enough, then you know you can be comfortable doing the procedure. Number two is to heavily sedate these patients, numb them very well. You don't want to have a wide-awake patient go into the procedure anxious—that can just kill your access. The third thing is that you can always test for radial spasm with smaller catheters. When you do your diagnostic angiogram with a 5 Fr multipurpose catheter or a pigtail, you can observe how the patient reacts. If that goes smoothly, the chance of them having spasm with a 6 Fr is very low.

In terms of spasm, your dilator is your best friend. They help reduce risk of radial spasm as the sheaths advance. Even if you're new to radial access, avoiding spasm is not that difficult—you may have to do five cases to be comfortable. You just need someone like me you can call and say, "OK, I'm stuck in this situation, what do I do?"

"Since we've added Sublime™ PTA catheters and the Sublime™ 200 cm support catheters in the last few months, I have successfully opened three or four CTOs that I would not have been able to do transradial without using combined pedal access."

What is the key to getting radial-peripheral adopted in hospitals?

You need experienced endovascular specialists in a program who can train new radial fellows, or even just talk to them, support them. I think endovascular specialists—whether they're surgeons, radiologists, or cardiologists—owe it to colleagues to train them on how to do the right thing for the patient. When you have this, radial-peripheral will amplify very quickly, just as it did for coronary interventions after the trials came out that showed mortality benefit from using radial instead of femoral access.¹ Radial access procedures result in less bleeding, less risk of retroperitoneal hematoma, and reduce the risk of patient death. ■

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FULFILLING THE RADIAL PROMISE FOR PAD PATIENTS

Top centers are going radial-first for a wide range of peripheral interventions

CASE REPORT

Successful Below-the-Knee Revascularization Via Radial Access With Sublime™ Guide Sheath

By Ankit A. Patel, MD, FSCAI, FACC, RPVI

PATIENT PRESENTATION

A woman in her early 60s with a history of diabetes, hypertension, hyperlipidemia, and peripheral artery disease presented with a nonhealing wound in her right lower leg.

DIAGNOSTIC FINDINGS

An initial angiogram displayed severe runoff disease, a completely occluded anterior tibial (AT) artery, a 90% calcified stenosis in the tibioperoneal trunk (TPT) and posterior tibial (PT) artery, and a peroneal stenosis (Figure 1A). Overall flow was sluggish, and the patient complained of leg numbness.

The patient reported having a poor experience with a prior femoral access intervention due to bleeding and was pleased that a transradial procedure could be attempted.

TREATMENT

Left radial access was obtained using a 5 Fr, 150 cm Sublime™ guide sheath (Surmodics, Inc.). The guide sheath was advanced into the right superficial femoral artery. A guidewire was maneuvered into the AT artery, and a 2.0 X 100 mm Sublime™ .014 RX PTA catheter (Surmodics, Inc.) was used to open flow to the artery (Figure 1B). After the AT artery was revascularized, attention was given to the TPT. Due to the highly calcific nature of the TPT stenosis, the .014 guidewire and Sublime™ .014 RX PTA catheter would not cross. The Sublime™ PTA catheter was swapped out for a .018, 200 cm Sublime™ microcatheter (Surmodics, Inc.). With application of both push and torque, the microcatheter crossed the TPT stenosis.

Atherectomy was then used to debulk calcium in the TPT. After a few passes of the atherectomy system, the PT artery was wired and further atherectomy was conducted in the vessel to debulk more of the highly calcific stenosis. The atherectomy system was removed, and a 2.0 X 100 mm Sublime™ .014 RX PTA Catheter was dilated in the PT artery. After dilating the PT artery, a final angiogram showed good two-vessel runoff, a blush foot, and no further disease to the distal foot (Figure 1C and 1D). A TR Band® radial compression device (Terumo Interventional Systems) was placed on the patient's left wrist.

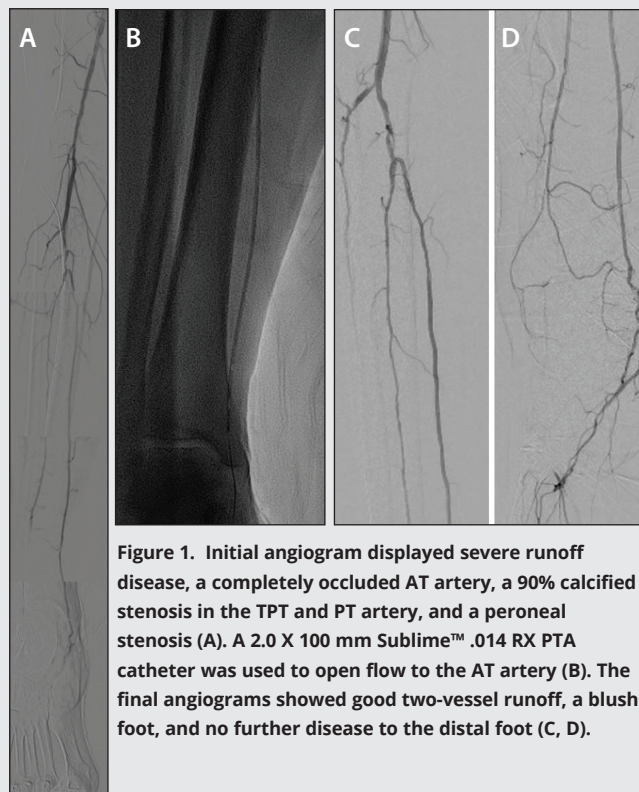


Figure 1. Initial angiogram displayed severe runoff disease, a completely occluded AT artery, a 90% calcified stenosis in the TPT and PT artery, and a peroneal stenosis (A). A 2.0 X 100 mm Sublime™ .014 RX PTA catheter was used to open flow to the AT artery (B). The final angiograms showed good two-vessel runoff, a blush foot, and no further disease to the distal foot (C, D).

POSTPROCEDURE OUTCOME

The patient was discharged 2 hours after the intervention on dual antiplatelet therapy.

PHYSICIAN OBSERVATIONS

Due to the small stature of the female patient, a 5 Fr guide sheath was needed to maintain access and make the procedure as comfortable for her as possible. The .018, 200 cm Sublime™ microcatheter facilitated crossing of highly calcified below-the-knee stenoses, leading to same-day discharge without the need for femoral access. ■

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CASE REPORT

Successful Revascularization of Distal AT and DP Via the Radial Approach

By Ankit A. Patel, MD, FSCAI, FACC, RPVI

PATIENT PRESENTATION

A woman in her mid 80s presented with a nonhealing wound on the lateral aspect of her left foot. Although she had been receiving wound care at an outside location, the wound resisted healing, and she reported pain in the foot. After ultrasound confirmation of diseased vessels in the foot, and with her TBI (toe-brachial index) in the range of 0.5 to 0.6, she was referred in for further diagnosis and potential treatment.

DIAGNOSTIC FINDINGS

The patient was confirmed to have nonpalpable dorsalis pedis (DP) artery pulses, with palpable posterior tibial (PT) artery pulses. Right radial access was obtained, and a 5 Fr, 150 cm Sublime™ guide sheath (Surmodics, Inc.) was placed to facilitate diagnostics. An initial angiogram confirmed that the DP and distal AT arteries were 100% occluded, while the PT artery was patent (Figure 1A and 1B).

TREATMENT

A .014 Regalia® XS 1.0 (Asahi Intecc) guidewire and a 2.0 X 100 mm Sublime™ .014 RX PTA catheter (Surmodics, Inc.) were advanced through the 5 Fr Sublime™ guide sheath but were unable to cross the occlusion. The guidewire was swapped out for a Hi-Torque Whisper™ MS guidewire (Abbott). The occlusion still could not be crossed using an antegrade approach, so a retrograde approach was conducted via the PT artery around the pedal arch. The curvature of the pedal arch made crossing difficult. The Hi-Torque Whisper™ MS guidewire was then knuckled and used to cross into the DP and distal AT arteries. A further dilatation in the DP and distal AT arteries was conducted using the 2.0 X 100 mm Sublime™ .014 RX PTA catheter (Figure 1C). After the dilation, a Doppler pulse was observed in the DP artery. The final angiogram showed spasm in the distal tibial vessels, but after a brief period the spasm resolved, and the patient was observed to have bounding DP arterial pulses and patent flow (Figure 1D).

POSTPROCEDURE OUTCOME

The patient was discharged 2 hours after the intervention. At 1-week follow-up, her wound had observably improved. ■

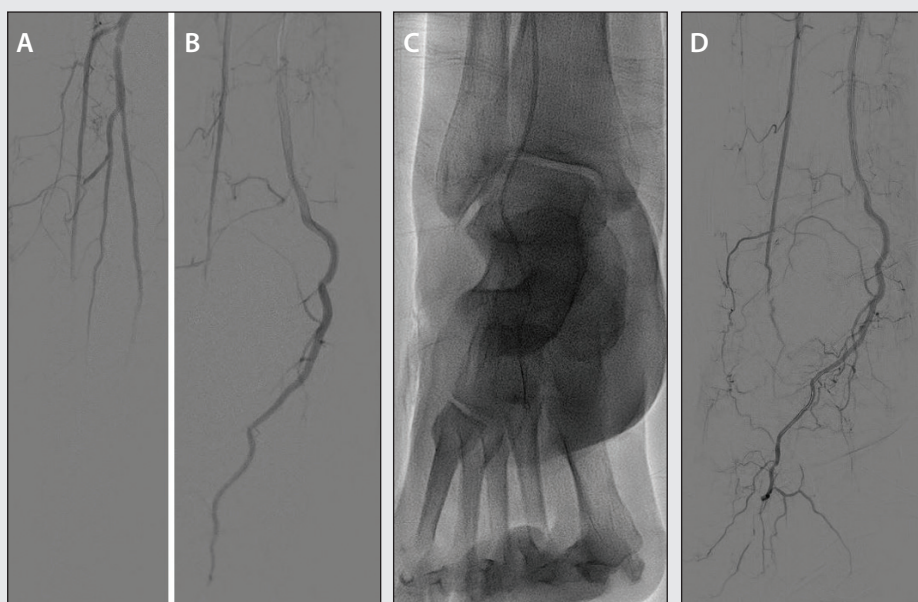


Figure 1. An initial angiogram confirmed that the DP and distal AT arteries were 100% occluded, while the PT artery was patent (A, B). The Hi-Torque Whisper™ MS guidewire was knuckled and used to cross into the DP and distal AT arteries. A further dilatation in the DP and distal AT arteries was conducted using the 2.0 X 100 mm Sublime™ .014 RX PTA catheter (C). Postintervention angiogram showing flow to the DP artery (D).

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A Passion for the Radial-to-Peripheral Approach

A conversation with Matthew C. Hann, MD.

Throughout his career, interventional cardiologist **Dr. Matthew C. Hann** has demonstrated a strong commitment to medical education, receiving multiple teaching awards and serving as a clinical professor. His career also includes distinguished service in the United States Air Force, with deployment to Afghanistan during Operation Enduring Freedom.

Today, Dr. Hann serves patients at Singing River Cardiology on the Mississippi Gulf Coast. Board certified in cardiovascular disease as well as interventional cardiology, Dr. Hann has extensive experience treating complex coronary and peripheral artery disease from the radial approach. We spoke with Dr. Hann about his approach to radial-to-peripheral interventions and his experience with the Sublime™ Radial Access Platform (Surmodics, Inc.).

What inspired you to adopt radial access?

I trained at Duke University Medical Center with Dr. Sunil Rao as one of my mentors. He is a strong proponent of radial access for coronary procedures and emphasized an unwavering commitment to the approach to improve patient outcomes and satisfaction. I took that to heart and have been passionate about this approach ever since. Naturally, I was a very early adopter of the radial approach for peripheral interventions once the technology became available.

From a patient perspective, it's absolutely the best approach. When I'm able to use radial instead of femoral access, patient flow and recovery is so much more efficient—patients can sit in a chair and eat a sandwich instead of lying flat in bed for hours after their procedures, often requiring more nursing support.¹⁻⁴ I also sleep better at night knowing I don't have to worry about a retroperitoneal bleed or groin complication for these patients.^{3,5,6} I get very frustrated when I hear femoral operators say they can't do radial access for peripheral procedures because the tools are not available. The technology has gotten so much better; with current wire and crossing catheter technology, I rarely struggle to cross lesions the way I used to, even compared to a femoral approach. The current radial-to-peripheral sheaths provide remarkable support. Once you do a few cases, you see that radial-to-peripheral works very well for the vast majority of patients.

"I also sleep better at night knowing I don't have to worry about a retroperitoneal bleed or groin complication for these patients."

What types of radial-peripheral cases do you perform?

My bread-and-butter cases are superficial femoral artery (SFA) occlusions. I deal with a lot of those. I'll also treat iliac arteries, and occasionally disease below the knee for limb salvage situations. Rarely, I run into equipment-length issues with below-the-knee cases, but I'll at least start radial in a "radial-first approach," given the very low complication risk with radial access.⁶ A working knowledge of balloon and shaft length along with sheath length is required to make "off-the-shelf supplies" work.

One thing I love about the radial-to-peripheral approach is being able to fix bilateral SFA occlusions at the same time. This often allows a patient to come in and get everything treated at once as opposed to having a staged procedure, which minimizes supply usage and further streamlines cath lab flow with only one preoperative visit, one moderate sedation period, and one recovery period. From the femoral approach, you're typically obligated to work in stages for these types of procedures with at least two separate cath lab procedures, frequently requiring patients to take more time away from work. As physicians, we need to put ourselves in our patients' shoes.

When do you still use femoral access for peripheral procedures?

After I take images from the radial approach, if I see that there is bilateral iliac disease, I'll sometimes obtain femoral access to allow kissing stents. However, if one iliac artery is affected, I may use a hybrid approach with radial access and single femoral access. For example, if I only need to treat the right iliac, I will place my radial wire down the left iliac for protection and then obtain right femoral access. Unfortunately, the technology has not advanced to the point of allowing large stents to be placed via a 6 Fr system. Additionally, shaft length becomes a limiting

"I find the Sublime™ sheaths to be very deliverable and the support I get from them is outstanding."

factor. Simple math would dictate that minimizing femoral access to a single side instead of bilateral access reduces femoral complications by 50%.

One objection to radial-peripheral is a perceived lack of bailout options. What are your thoughts?

I've found the risk of having complications that require you to bailout and put in a stent are very low if you're careful and have some patience.

For example, when I'm treating a SFA lesion, my practice is to perform atherectomy and then do very long balloon inflations to reduce the risk of dissection and the subsequent need for bailout stenting.⁷ I'll frequently do a 5-minute inflation, and I usually just go up to whatever pressure expands the balloon. I'm not doing nominal pressure, going to 10 atm on every SFA lesion. If 4 atm expands the balloon and there is no waist in the balloon, I stop there. In any case, stents are not the ideal way of treating SFA disease. I think that's clearly demonstrated now in the literature.⁸

Admittedly, unless the patient is a poor surgical candidate, I usually steer clear of treating common femoral stenoses via radial access, because that's an area where I don't ever want to have to bailout with a stent. Additionally, compromising the profunda can lead to severe complications. In any case, it is a fairly straightforward procedure for a vascular surgeon to make a small incision and perform an endarterectomy in the common femoral artery. A team approach and knowing technological limitations always lead to better outcomes.

What has been your experience with Sublime™ Radial Access devices?

I find the Sublime™ sheaths to be very deliverable and the support I get from them is outstanding. The Sublime™ RX PTA

"The Sublime™ RX PTA .014 and .018 catheters (250 and 220 cm working lengths, respectively) are very deliverable and track through lesions exceptionally well."

.014 and .018 catheters (250 and 220 cm working lengths, respectively) are very deliverable and track through lesions exceptionally well. Our facility recently gained access to the Sublime™ microcatheters (.014, .018, and .035 inch; ≤ 200 cm working lengths) and I have used them only a few times. My experience so far is that they are very pushable and cross very well, especially with the angled tip. ■

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FULFILLING THE RADIAL PROMISE FOR PAD PATIENTS

Top centers are going radial-first for a wide range of peripheral interventions

CASE REPORT

Successful Revascularization of Near-Total Peroneal Artery Occlusion Via Radial Access

By Matthew C. Hann, MD

PATIENT PRESENTATION

A man in his mid 70s with a nonhealing ulcer on his right great toe (Figure 1) was referred by his podiatrist to interventional care for revascularization of his right leg. The patient had a history of hypertension, hyperlipidemia, chronic kidney disease, diastolic heart failure, coronary artery disease, and diabetes. He had been followed by wound care for his nonhealing toe ulcer for several months prior to presentation for interventional care. A previous Doppler study performed by the podiatrist suggested a distal superficial femoral artery (SFA) stenosis. A CT scan that had been performed several months prior had shown occlusion of all below-the-knee (BTK) vessels, but the patient had not had a nonhealing wound at that time and conservative treatment was recommended.

DIAGNOSTIC FINDINGS

Access was achieved in the left radial artery using a 6 Fr Slender™ sheath (Terumo Interventional Systems). The radial cocktail was administered, and a 400 cm Glidewire® Baby-J™ hydrophilic-coated guidewire (Terumo Interventional Systems) was used to place a 4 Fr pigtail catheter in the right common femoral artery. Angiography showed that the right distal SFA was not occluded, but rather that all three BTK vessels on the right side had occlusions (Figure 2). The anterior tibial (AT) and posterior tibial (PT) arteries had long, total occlusions, and the peroneal artery had a near-total occlusion in the proximal segment.

TREATMENT

The 400 cm Glidewire® guidewire was placed in the SFA and the short sheath was exchanged for a 150 cm Sublime™ 6 Fr sheath (Surmodics, Inc.). The peroneal stenosis was crossed using the Glidewire® Baby-J™ guidewire and an angled, 200 cm, .035 Sublime™ microcatheter (Surmodics, Inc.). True lumen crossing was confirmed by injecting a small amount of contrast through the microcatheter. The guidewire was then exchanged for the 475 cm ViperWire Advance™ peripheral guidewire (Abbott) and four orbital atherectomy passes were performed. After atherectomy, balloon angioplasty was performed.

Final angiography showed single-vessel runoff to the foot (Figure 3). Revascularization of the AT and PT arteries was not attempted due to the patient complaining of persistent back pain. Nonetheless, given brisk, single-vessel runoff to the foot, the procedure was deemed successful. A TR Band® radial compression device (Terumo Interventional Systems) was used for hemostasis. Total procedure time from access to closure was 58 minutes.

POSTPROCEDURE OUTCOME

The patient was discharged 4 hours after the intervention with a plan to continue his aspirin and clopidogrel therapy. This radial-first approach allowed for same-day patient discharge without the need for femoral access in a patient with chronic back pain and difficulty lying on his back for extended periods. ■

Courtesy of Dr. Matthew C. Hann.



Figure 1. Nonhealing right great toe ulcer.



Figure 2. Near-total occlusion of the right peroneal artery.



Figure 3. Patent peroneal artery with single-vessel runoff to the foot.

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The Sublime™ Radial Access Platform

Sublime™ Guide Sheath

5 Fr and 6 Fr, 120 cm and 150 cm working lengths



Reliable Access and Delivery

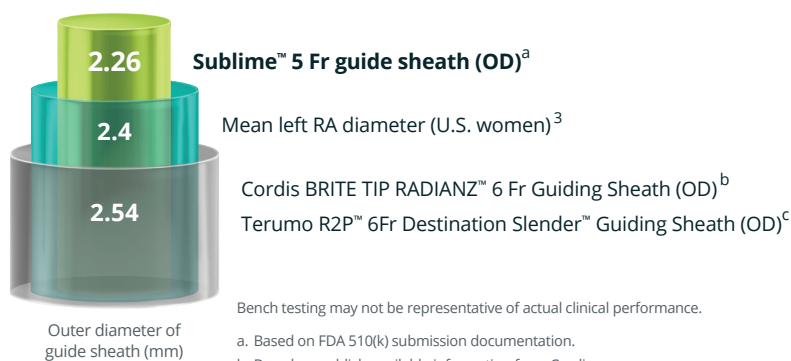
The Sublime™ Guide Sheath is constructed with a proprietary braided shaft technology that combines the performance features of traditional coil and braid structures in a thin-walled profile.

The Impact of 5 Fr: Expanding radial access for women

Today, fewer women than men receive radial access, due in part to a lack of tools that can accommodate their smaller radial arteries.^{1,2}

ACCOMMODATING SMALL RADIAL ARTERIES

The Sublime 5 Fr Radial Access Guide Sheath has an outer diameter narrower than 2.4 mm, the average diameter of the left radial artery in women.³



Bench testing may not be representative of actual clinical performance.

a. Based on FDA 510(k) submission documentation.

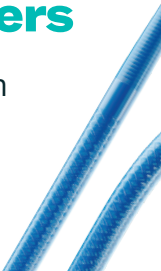
b. Based on publicly available information from Cordis.

c. Based on publicly available information on FDA 510(k) database.

Sublime™ Microcatheters

.014 & .018, 65-200 cm working lengths

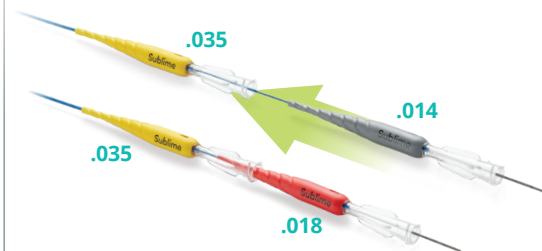
.035, 90-200 cm working lengths



Torqueable Peripheral Microcatheters

Applying rotation (torque) to a microcatheter can help cross heavily calcified lesions or CTOs.⁴

Cross with confidence



SUBLIME MICROCATHETERS VERSUS COMPETITION

Competitive bench testing demonstrates the Sublime microcatheter outperforms two leading competitors for pushability and torque response.⁵

- Sublime™ Microcatheter (200 cm)
- Cook CXI® Support Catheter (150 cm)
- Terumo NaviCross® Support Catheter (150 cm)

Bench testing may not be representative of actual clinical performance

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Sublime™ RX PTA Catheters

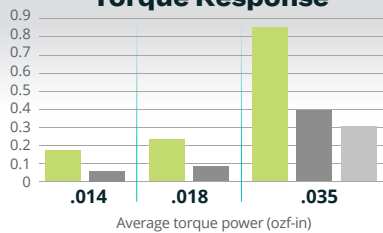
.014, 250 cm working length

.018, 220 cm working length

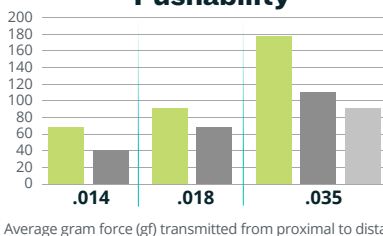
Sublime™ Microcatheters are designed to cross tough lesions while maintaining the flexibility to navigate extremity tortuosity.

The .014 and .018 microcatheters can be telescoped through the .035 microcatheter to provide additional back up support and deliverability when traversing heavily stenosed lesions or tortuous anatomy.

Torque Response



Pushability

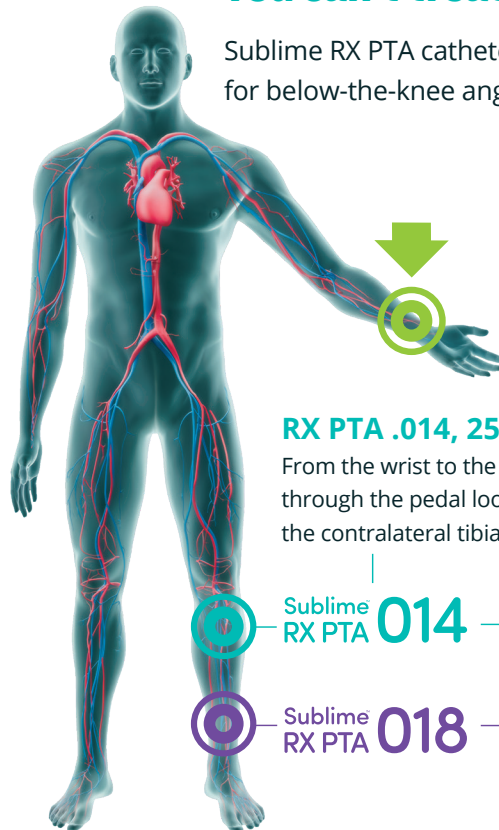


A Breakthrough for Below-the-Knee Treatment

Sublime™ Radial Access .014 (250 cm working length) and .018 (220 cm working length) RX PTA Catheters are suitable for treatment above or below the knee—and even through the pedal loop. For added pushability, their rapid-exchange segments are fully 45 cm and 50 cm for the .014 and .018 platforms, respectively.

You can't treat what you can't reach.

Sublime RX PTA catheters extend the treatment zone for below-the-knee angioplasty.

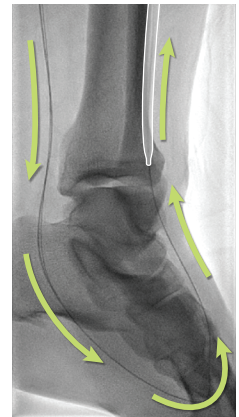


RX PTA .014, 250 cm

From the wrist to the foot, through the pedal loop and **UP** the contralateral tibial artery.

Sublime™ RX PTA **.014** — 250 cm

Sublime™ RX PTA **.018** — 220 cm



Average vessel origin distance from left radial access site based on 5' 9" patient.⁶ Actual lengths may vary between subjects.



Be a **#radialfirst** hero for PAD patients

Fulfilling the radial-peripheral promise begins
with **peer-to-peer education**. Learn state-of-
the-art approaches to transradial peripheral
intervention through expert **live-case training**.



sublimeradial.education

Scan this code to learn more about
the program and register for a course.

Space is limited!



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