



# Endovascular — TODAY —

## FROM WRIST TO FOOT: The Sublime™ Radial Access Platform and its impact on patients and practices.



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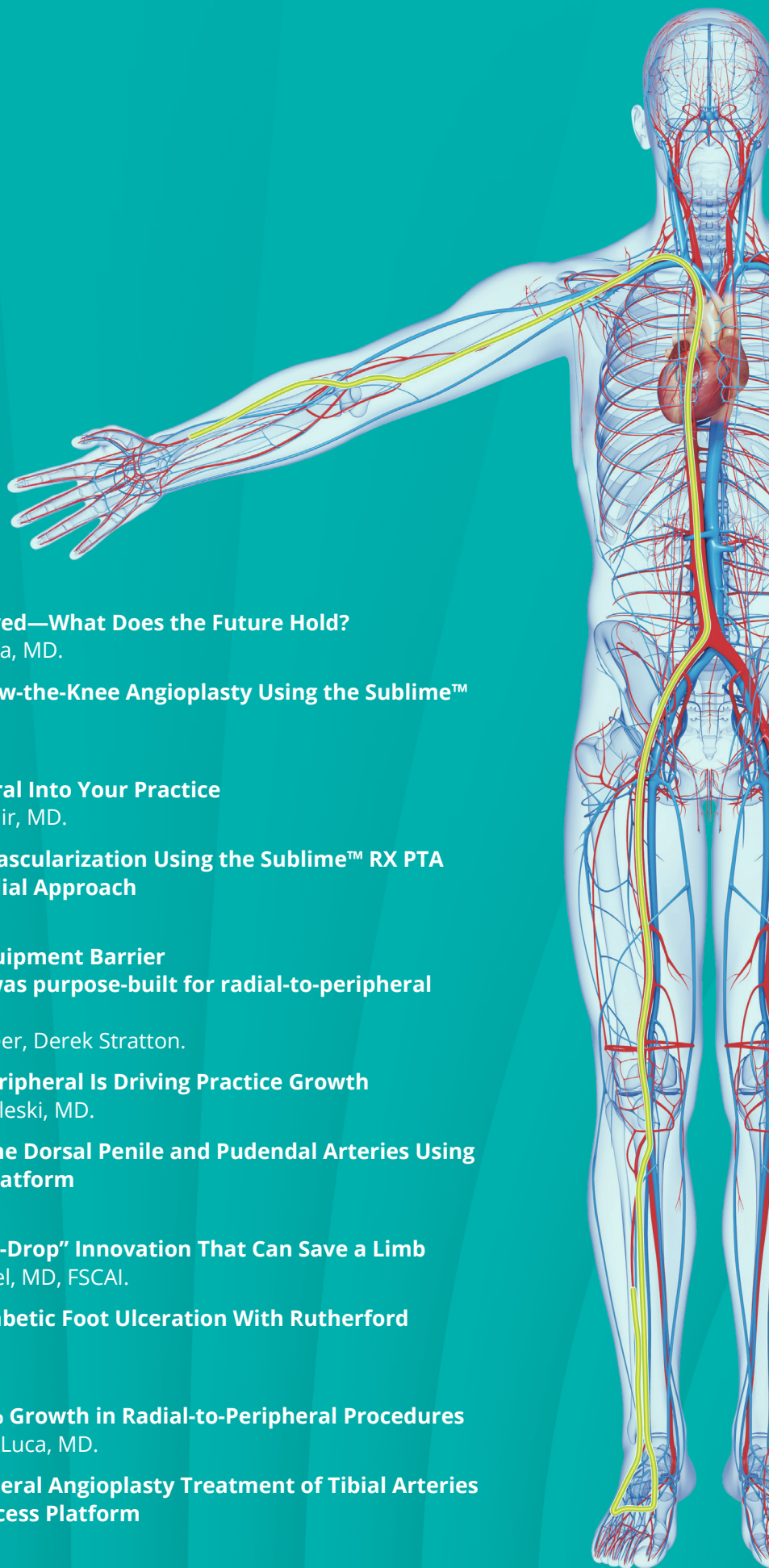


Paul Michael, MD



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# Radial-to-Peripheral Has Arrived—What Does the Future Hold?

A conversation with Ankur Lodha, MD.

**Dr. Ankur Lodha** is an interventional cardiologist with Cardiovascular Institute of the South in Lafayette, Louisiana. He has served as a reviewer for prominent medical journals and has published numerous articles and abstracts in the field of endovascular medicine.

## You've been a passionate advocate of radial-to-peripheral intervention. What inspired you to begin using and championing this approach?

We came across patients who were in a great deal of pain but were avoiding having a procedure because of the negative experience they had with groin access and manual closure. Patients would put off procedures until they literally couldn't take the pain any longer. Some of the patients had serious complications in the groin and had to go in for surgery, and one of the patients died. Those experiences made a deep impression on me.

As an interventional cardiologist, I was familiar with performing coronary interventions through the radial approach and knew how convenient, comfortable, and safe it is for those patients. So, when I came to Louisiana in 2014 and we started building up a peripheral artery disease (PAD) practice, I wondered why we were still using the femoral approach—why not make these procedures safer with radial? But very few physicians were doing radial-to-peripheral procedures at the time, and there was no dedicated equipment available.

## What has changed since then?

Everything is dependent on the level of confidence you have in your tools. One of the reasons radial-to-peripheral interventions did not take off initially was that we did not have the equipment available that was long enough to reach and cross distal lesions. We now have a wide array of tools that make radial-to-peripheral possible and these tools work very well.

"OBLs need to make the transition to radial now."

## You've said that radial access performed in office-based labs (OBLs) will transform how PAD patients are treated in the United States. Why is that?

I firmly believe that OBLs are here to stay and that most patients will eventually undergo interventions in OBLs. Hospitals are overloaded—they don't have enough beds or enough staff. Furthermore, patients don't want to go to the hospital, especially after the COVID-19 pandemic. They prefer procedures with safer access that can get them on their feet quickly and are less expensive. As taxpayers, we want procedures to be done in a way that can significantly reduce health care expense.

To make this happen, we must concentrate on reducing complications in OBLs. Most complications happen with access, and the case is now closed that radial access reduces complications and improves patient satisfaction compared with femoral access. OBLs need to make the transition to radial now, not only because it's better for patients, but because OBL payments will eventually be tied to patient outcomes and satisfaction. This has already started to happen in hospitals, and OBLs will be next.

Radial access makes great business sense for OBLs. Since adopting radial access, we've been able to perform at least two more cases per day because our patients can be discharged early.

## Patient comfort and safety aside, what types of clinical situations did you encounter that made radial access preferable to femoral access?

There were many. To give one example, if we have a high and steep aortic bifurcation of the aorta, it can be nearly impossible to take a sheath up and around that anatomy from a femoral access

# FROM WRIST TO FOOT

## The Sublime™ Radial Access Platform and its impact on patients and practices

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“Since adopting radial access, we’ve been able to perform at least two more cases per day.”

site. Some patients have tortuous bifurcations, and therefore, catheters lose trackability, pushability, and torqueability to cross the lesions (Figure 1). It’s like driving a car in the Grand Prix. This requires more contrast and radiation in those patients, which is not safe. Radial access allows the operator to enter either artery from above rather than going up and over from the femoral artery. This approach also enables the physician to treat lesions in both legs in one procedure.

Another example is with obese patients—not only can achieving femoral access with obese patients be extremely difficult, these patients are also at an increased risk for groin complications. Radial access is the preferred approach for this patient population.

### When you started doing radial-to-peripheral cases 6 years ago, what types of cases were not possible because you lacked suitable equipment?

We were quite motivated, but there were still some cases we had to do from the femoral approach, such as complicated superficial femoral artery (SFA) occlusions, critical limb ischemia due to infrapopliteal disease, and complex iliac artery disease. The access complications that resulted from these cases made us even more determined to go radial and to work with industry to develop the right new tools.

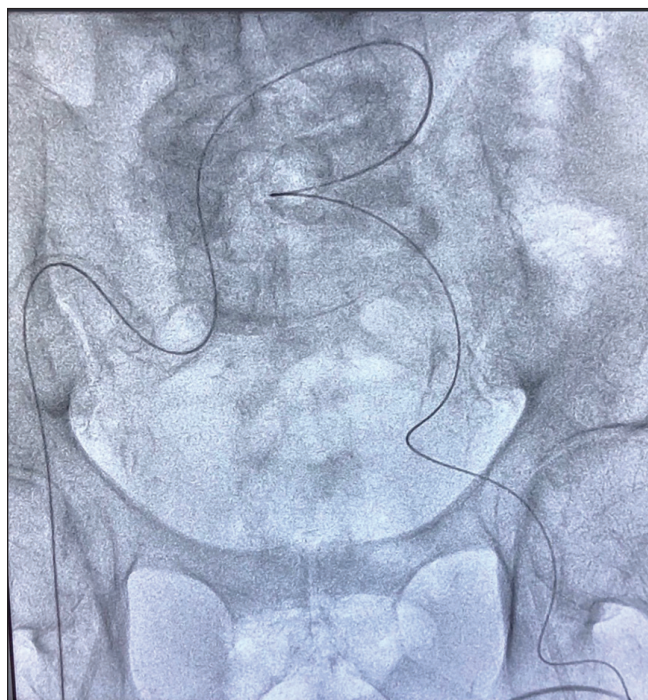
### Where are we now in terms of radial-to-peripheral tools?

I think to start, we are very well placed in terms of access sheaths, balloons, and wires. What we lack is imaging—we don’t have a dedicated 200 or 220 cm intravascular ultrasound system. That’s a problem. We also need drug-coated balloons and drug-eluting stents.

Having said that, I think 80% of the cases done in an OBL today can easily be done radially with the current equipment. It helps that OBLs by nature do less complicated cases. If you select patients correctly, you will rarely need to cross over from radial to femoral access. Today, our crossover rate is < 2%.

### What has been your experience with the Sublime™ Radial Access Guide Sheath and Sublime™ balloon catheters?

We’ve been using these products since they first came out and they’re very good. First and foremost, the Sublime™ Radial Access Platform includes new sizes and working lengths that allow us to provide radial access to many more patients than were possible before.



**Figure 1. Complex tortuosity of the aortic bifurcation in a patient receiving arterial intervention via the femoral approach.**

Regarding the Sublime™ Radial Access Guide Sheath (Figure 2), it’s great there is a 6 Fr size; however, the availability of 5 Fr allows us to perform radial interventions on patients with smaller arteries—older female patients, for example—who otherwise would require femoral access. The 5 Fr size can be used in infrapopliteal lesions when we know we’re not going to need a stent. In my opinion, the 5 Fr guide sheath is a complete game changer.

The Sublime™ Radial Access Balloon Catheters (Figure 3) deserve special mention. They’re the longest shaft length, radial dedicated balloons on the market. At 220 and 250 cm (.018 and .014, respectively), they allow us to go all the way to the infrapopliteal, cross the pedal loop, and even go back to the other infrapopliteal vessels. We’re able to do this very easily now, and this was not possible with the shorter lengths previously available. I think it’s game changing. We need products that can reach

“The Sublime™ Radial Access Platform includes new sizes and working lengths that allow us to provide radial access to many more patients.”

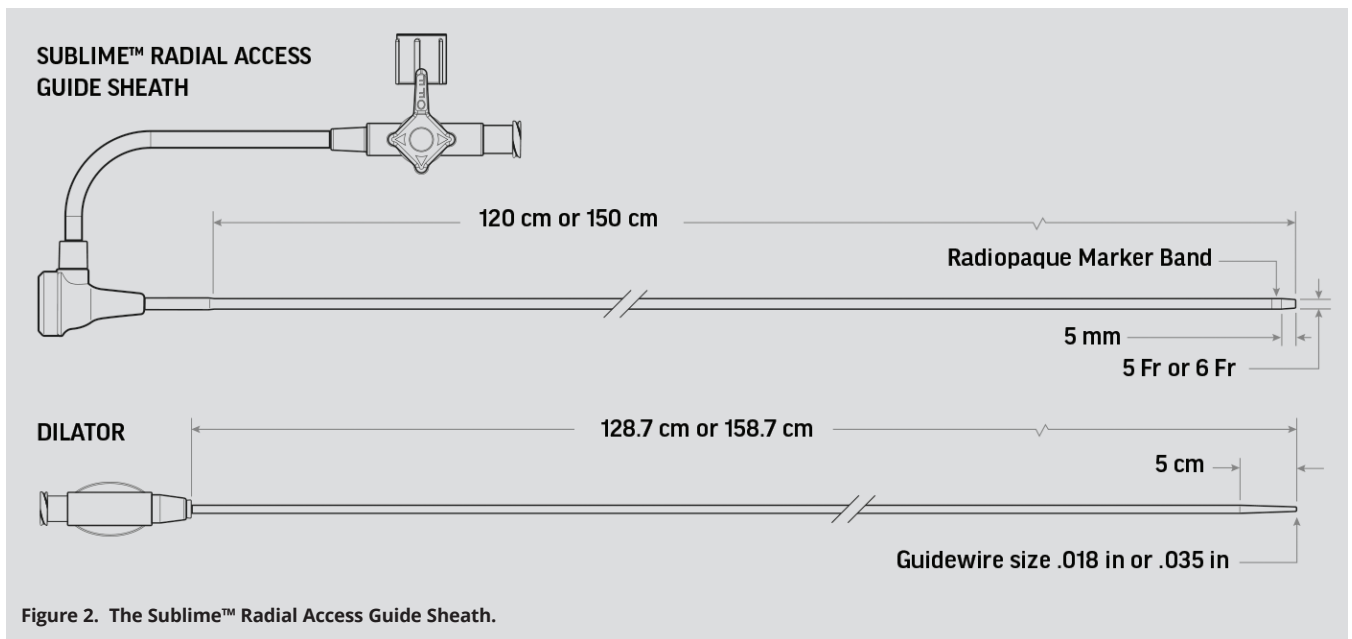


Figure 2. The Sublime™ Radial Access Guide Sheath.

lesions anywhere in the peripheral anatomy, and Sublime™ Radial Access devices have helped us fill a lot of these gaps.

### Physicians may assume you lose pushability with a rapid exchange (RX) platform. What's been your experience with the deliverability of the Sublime™ RX Balloon Catheters?

The pushability of an RX balloon is dependent on the RX length. The RX length of the Sublime™ RX PTA Balloon Catheters is the longest on the market (45 cm for the .014 and 50 cm for the .018), and this makes these balloons behave pretty much like over-the-wire balloons. In addition, the Sublime™ balloon catheters are constructed with a hypotube that transitions from being very stiff and supportive on the proximal end to very flexible at the distal end of the device. This combination of the shaft design with the longer RX length gives us a tremendous amount of pushability with a low profile that's also very trackable. These devices work very well for the distal lesions we treat.

### What kinds of cases are straightforward to perform via radial access, which require some experience, and which are best left to femoral?

Straightforward cases include simple SFA lesions of < 100%, short chronic total occlusions of the SFA, and infrapopliteal diseases that are not long occlusions. These can easily be done via a transradial approach. Once your team has done about 20 or 25 of these cases, you should easily be able to perform slightly more complex procedures such as infrapopliteal long occlusions, SFA long occlusions, or calcified lesions. For more complicated cases, you can consider a hybrid radial-pedal approach.

Cases that still require a femoral approach include those that involve a covered stent being delivered in an iliac artery occlusion. You need a 7 Fr sheath for that. But we do perform radial-assisted iliac occlusion procedures, where we cross the iliac artery from the radial approach but deliver stents through the femoral artery.

### Radial artery occlusion (RAO) has been called the Achilles' heel of radial access. What are your thoughts?

RAO does happen, but the incidence is very low. Overall, I don't think RAO is much of a concern. It's clinically silent. Radial arteries recanalize, and you can still access occluded radial arteries for future procedures using ultrasound guidance. These occlusions are short and easily reaccessed. We have done this often.

### What would you say the learning curve is for transitioning to radial access in an OBL?

The perception that radial is hard to learn has slowed adoption in OBLs because OBLs are built on patient turnover. Taking the time to learn a new approach can initially delay procedures. But I would like to use this opportunity to tell people that the learning

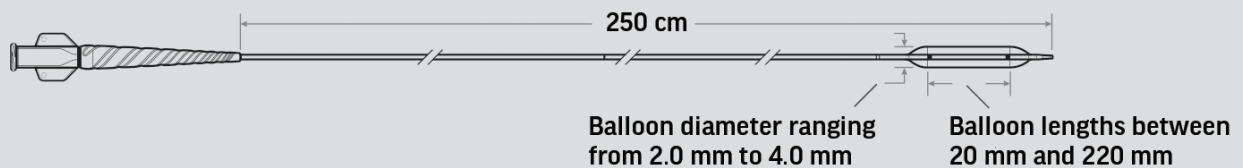
*"When you offer the radial approach, your patients become your biggest advocates."*

# FROM WRIST TO FOOT

## The Sublime™ Radial Access Platform and its impact on patients and practices

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### SUBLIME™ RADIAL ACCESS .014 RX PTA BALLOON CATHETER



### SUBLIME™ RADIAL ACCESS .018 RX PTA BALLOON CATHETER

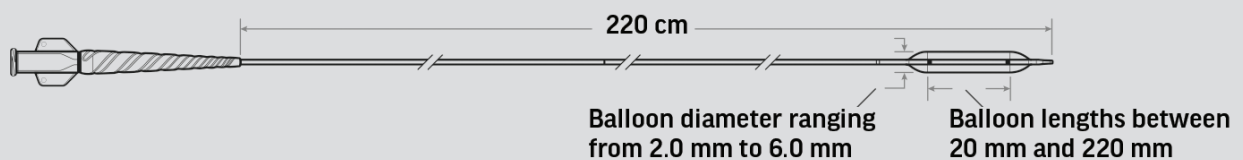


Figure 3. The Sublime™ Radial Access .014 (top) and .018 (bottom) RX PTA Balloon Catheters.

curve for physicians is not that hard—it's really just five to 10 cases. And once you get trained in radial procedures, you can safely discharge these patients early.

### What's the best way to get radial access adopted in a new facility?

You need to have one person who champions radial access in a group. This person trains the staff, and then the staff trains the other doctors. That's precisely what happened in my practice. Our scrub techs were very well trained after a few cases so they could troubleshoot and help other physicians. The nurses also became strong advocates because they could see the patient benefits firsthand. Our techs and nurses would point out cases that were ideal for radial and push the physicians to do them. Later, the physicians realized this was a great call and began doing radial cases routinely.

### Let's switch gears and focus on how radial access has helped you build your OBL business. Has radial access helped to grow your referral network?

Big time. Patients overwhelmingly prefer wrist access over groin access. When you offer the radial approach, your patients become your biggest advocates. Patients talk to friends who have similar peripheral issues and tell them how easy their wrist access procedure was compared with the groin procedure they had before. Many patients get repeat procedures due to the nature of the disease, and once they experience the ease of recovery and greater comfort of radial access they would never prefer the femoral access. They remember the experience

of having to lie flat on their backs for hours after a femoral access procedure, which can be very uncomfortable and even painful. These patients will go back to their primary care doctors and say, "Wow, Dr. Lodha did this procedure from my wrist that everybody else does from the groin." That kind of patient satisfaction drives referrals.

### Can you describe how you leverage radial access in community outreach and marketing?

We use a variety of approaches aimed directly at patients. Our message is, if you need a procedure, ask your doctor about radial access because it's safer, easier, more comfortable, and more convenient.

Like many practices, we're active on social media, but the most effective way we've found to reach the community is through television. We talk to news people, who are very interested these days in medical procedures and available devices. This gets us into the main morning and evening news segments and helps us gain recognition. We also focus on print media. We've been featured in articles in a variety of local magazines. Finally, we do community outreach in nursing homes and make direct contact with primary care physicians.

"The question will not be, 'why radial?' It will be, 'why not radial?'"

**Radial access equipment is generally more expensive than equipment for femoral access. Can you speak to any direct cost savings that may mitigate this expense?**

It's not surprising that radial equipment is somewhat more expensive. Not only does it come in longer lengths, but more research has gone into making the equipment perform well at these lengths. But, aside from the patient satisfaction radial brings, there are direct cost savings.

One obvious example is elimination of the need for femoral closure devices, which are far more expensive than the simple closure devices used in radial cases. But there's also reduction in OBL staff time. Radial access reduces the acuity of postoperative care. In femoral cases, nurses have to check the groin every 10 or 15 minutes for postoperative recovery, and during sheath pull you need two dedicated nurses next to the patient. For radial access cases, that is not needed and postoperative recovery is very safe and uneventful.

**Do you envision a day when femoral access for peripheral cases is the exception rather than the norm?**

100%. The question will not be, "why radial?" It will be, "why not radial?" Radial access is going to make procedures for our patients safer and much more comfortable. I don't see any other way. ■



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*Disclosures: Consultant for Boston Scientific, Cardiovascular Systems, Inc., Cordis, Penumbra, Philips, Surmodics, and Terumo.*

**Caution:** Federal (US) law restricts the Sublime™ Radial Access Guide Sheath and the Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters to sale by or on the order of a physician. Please refer to each product's Instructions for Use for indications, contraindications, warnings, and precautions.

### CASE REPORT:

## Successful Below-the-Knee Angioplasty Using the Sublime™ Radial Access Platform

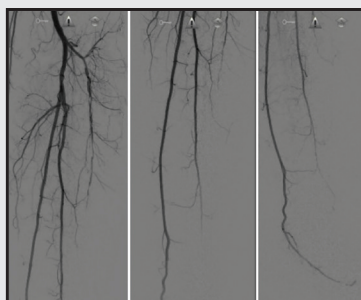
By Ankur Lodha, MD

### Patient Presentation

A 52-year-old male presented with discomfort to his left calf and had pregangrenous changes of nonhealing wounds on the toes of his left foot.

### Diagnostic Findings

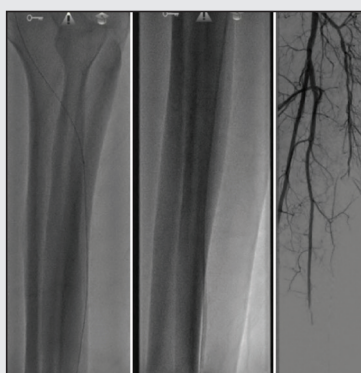
Diagnostic angiogram of the left lower extremity revealed a 100% occluded left anterior tibial (AT) artery, which was most likely the cause of the patient's bluish discoloration (Figure 1).



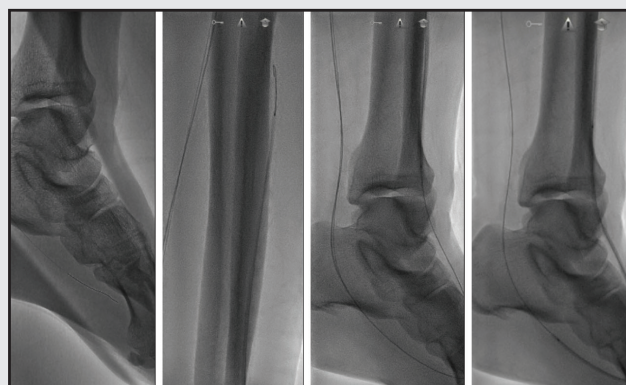
**Figure 1. Angiogram revealed a 100% occluded left AT artery.**

### Treatment

Access was achieved via the left radial artery using ultrasound guidance. A pigtail catheter was inserted over a guidewire and placed in the distal abdominal aorta so an abdominal aortography and a left femoral artery angiography could be performed. Once completed, a 5 Fr, 150 cm Sublime™ Radial Access Guide Sheath was inserted and a guidewire and 2.0 X 220 mm Sublime™ Radial Access RX PTA Catheter were advanced to cross the lesion in the AT artery. The balloon was inflated in an attempt to open the lesion; however, the guidewire was not able to cross (Figure 2). The guidewire was then repositioned in the posterior tibial artery where it crossed the pedal loop and was advanced retrograde to the AT artery. A 2.0 X 220 mm Sublime™ Radial Access .014 RX PTA Dilatation



**Figure 2. Guidewire and PTA Catheter attempt to cross the lesion.**



**Figure 3. Sublime™ Radial Access .014 RX PTA Dilatation Catheter inflation.**

Catheter was then advanced to the lesion in the left AT artery where it tracked through the pedal loop. The balloon was inflated and removed after deflation. A 3.0 X 220 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter was then inserted, advanced to the lesion in the left AT artery, and was inflated and removed (Figure 3).



**Figure 4. Arteriogram demonstrating 100% recanalization of the affected artery.**

### Post Procedure Outcome

The patient underwent balloon angioplasty of the left AT artery. Following the successful intervention, the patient's angiography revealed 100% recanalization of the affected artery (Figure 4). ■



SCAN FOR ADDITIONAL CASE EXAMPLES.

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# Integrating Radial-to-Peripheral Into Your Practice

A conversation with Pradeep Nair, MD.

**Dr. Pradeep Nair** is an interventional cardiologist with Cardiovascular Institute of the South in Houma, Louisiana. An avid researcher, he has frequently published in peer-reviewed journals and textbooks. He serves as the Director of the Vein Program at the Cardiovascular Institute of the South and is Vice-Chairman of the annual New Cardiovascular Horizons Meeting in New Orleans, Louisiana.

“I average around three to four radial-to-peripheral cases a day.”

these last 5 years. Today, I average around three to four radial-to-peripheral cases a day when I'm in the lab.

## Your experience with radial access dates to 2006. How did you get started?

I started with femoral cases almost universally during my training in coronary interventions. We had one attending, however, who was a firm believer in radial intervention for coronaries. We didn't have the best devices or sheaths for radial intervention back then, so we had a lot of issues and learning curves dealing with radial spasm, loops, and I even remember a case where we inadvertently pulled out a radial artery on the sheath—the dreaded “radial on a stick.” Yet, despite these setbacks he still believed in it and pushed it forward because he thought the approach would be best and safest for his patients. Groin complications, after all, can be very serious and potentially life-threatening. That stuck with me. Fast forward a few years, and the American College of Cardiology meetings began encouraging physicians to look at the benefits of radial access for coronary intervention. Then, you had RIVAL, RIFLE, and other clinical trials that clearly showed the safety of the radial approach. Today, radial-first is the preferred percutaneous coronary intervention strategy in both the United States and Europe.

## When did you begin doing radial-to-peripheral cases?

I began doing radial-to-peripheral cases about 5 years ago, and the number of other physicians doing the same has been climbing ever since. As an interventional cardiologist, it was a natural transition for me because radial interventions for the coronaries are the preferred strategy. By now, our center has vast experience performing thousands of radial-to-peripheral procedures over

## What are the biggest concerns new operators have with the radial-to-peripheral approach?

I'd say one of the primary concerns of operators remains radial artery occlusion (RAO). In the past, reported rates of RAO ranged to as high as 10%. Those numbers, in my opinion, are a gross overestimate of the actual RAO rates we see today. Recent data from the DISCO trial showed a .6% RAO rate, which is the lowest rate seen to date. Another concern of operators includes the perceived inability to tackle complex lesions safely or efficiently. As our toolbox for radial-to-peripheral interventions grow, this concern should continue to diminish.

## What do you do to prevent RAO?

Always ultrasound the radial artery. Coronary interventionalists don't always do this because of the nature of the procedure and a desire to move quickly, but I think it's mandatory for radial-to-peripheral cases. You need to assess the size of the vessel to ensure the radial artery is at least 2 mm before you can safely consider doing the procedure with a radial approach. With the Sublime™ Radial Access 5 Fr Guide Sheath, which has a .089" outer diameter and a .076" inner diameter, you can push this a little bit. I've used this sheath without issue in patients with marginally sub-2 mm vessels—1.7 or 1.8 mm—because these patients didn't have great conduits for access in the groin. The Sublime™ Radial Access 5 Fr Sheaths make a huge difference for treating patients with smaller radial arteries.

But again, when you're getting into the < 2 mm range, that's where you're going to have potential complications. You should try to avoid placing a 6 Fr sheath into a < 2 mm vessel.

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### What other precautions do you take to prevent RAO?

You want to ensure there is good palmar flow around the arch. You can check this with an Allen test. Ultrasound can also be used to determine whether the patient has good radial and ulnar pulses. In my opinion, ultrasound preaccess should absolutely be used for radial interventions to avoid complications. Once you have decided on radial access, you can administer local lidocaine and mixed with 50 to 100 µg of nitroglycerin in the syringe to help with localized vasodilation. Then, when you gain access, a radial cocktail (typically verapamil, nitroglycerin, and heparin) can be given through the sheath as per normal protocol. To begin my angiogram, I'll typically start with a small-profile, 4 or 5 Fr access sheath to give the vasodilator time to work and to first assess the distal vasculature that will be intervened upon. Sometimes after the initial diagnostic angiogram, a lesion may be encountered that you may not want to tackle via a radial approach. In these instances, keeping the sheath small makes sense. These are some small tips that may be helpful to new operators.

### Is there anything different about the way you use anticoagulation in radial access cases?

One of the benefits of radial procedures is that I'm not as concerned with major bleeding unless the patient has high-risk issues, for example, prior intracranial bleeding. I'm able to provide more anticoagulation up front, and I think that helps reduce RAO post procedure. I keep my activated clotting times a little higher, close to 300 seconds, and I am comfortable doing so because of lessened bleeding complications from the radial access compared to femoral. I also feel comfortable using glycoprotein IIb/IIIa inhibitors during these procedures to help mitigate adverse effects for the same reason, as most of the bleeding risk with this drug is related to groin access. So, your anticoagulation strategy can be a bit more liberal.

### What about avoiding complications when you withdraw the sheath?

I think it's always important that the patient is sedated at that time because pain response is a very potent stimulator for vasospasm. You need to feel for any resistance or spasm. The moment you start to hear the patient respond to any pain, sedate them a little bit more, and maybe give them a little bit of lidocaine infiltration with nitroglycerin in that area. Put the dilator in when you're pulling the sheath out. Sometimes a stiff wire can help if you're having a lot of resistance when pulling out, because there is some tortuosity coming around the subclavian. However, most of the time you won't have these issues if ultrasound is used on the radial artery up front.

### What about compression?

Patent hemostasis is the key. You don't want to just compress and occlude the vessel. Ideally, some flow should be going down into the hand. You want just enough compression to prevent

"I've been using the Sublime™ Radial Access Guide Sheath predominantly now, primarily because I like the rigidity, the balance between stiffness and support."

bleeding. Our interventional ultrasound technologists go to the patient's bedside before the patients leave to ensure they still see good flow in the radial artery. Not everybody has the staff to do this, but most labs today have a portable ultrasound that they can take to the bedside before patients leave the facility. It doesn't require a sonographer to perform. You can also simply check a Doppler pulse. Radial artery complications are much rarer now if you just follow simple steps such as the ones I've described here.

### What practical advice could you provide to physicians who are new to radial-to-peripheral?

Identifying appropriate patients for radial access is a major part of the learning curve in the current era. Again, you need to perform an ultrasound of the vessel from the get-go because you don't want to inadvertently access a diseased or small radial artery with poor flow. If you do that, you're setting yourself up for a potential procedural complication.

You should also begin with easier cases. A good starting point is claudicants, Rutherford class 3 patients with non-chronic total occlusion (CTO) disease in the superficial femoral artery (SFA) or popliteal artery. If your goal is to avoid stenting, it's important to remember the physics of balloon angioplasty, namely utilizing long and slow inflations to the minimal pressure necessary to reduce the risk of tearing or dissections in the vessel. This is very important. During this initial phase of the learning curve, the cath lab staff can get comfortable with the room set up and procedural details.

During the next phase, try tackling some short CTOs—ones that can easily be crossed from the radial approach. Once you have this experience under your belt, I think it is realistic to tackle some proximal tibials. Orbital atherectomy devices are now available that can reach that far. In other words, take a stepwise approach. Try to avoid making your first case a long SFA CTO with a poor runoff. Long SFA CTOs can be done via a radial approach, but oftentimes require a hybrid approach with concomitant pedal access. The radial-to-peripheral toolbox still has significant room for growth in these types of more complex lesional subtypes.

When you're starting out, understanding the working lengths of available devices is very important because you're dealing with some limitations. With the Sublime™ Radial Access Platform, a lot of that has gone away. We're able to go with a rapid exchange (RX) device and use a wire of our choice, but with some devices you'll be disappointed if you open it up and then find out it's not able to get you from point A to point B.

### Can you describe how you position patients for radial access?

I go from the left, but every lab is different. I like left radial because you get that extra length of 10 cm, which can sometimes make the difference of reaching your target lesion with a device. Right radial is a viable option for therapy delivery, but aside from the loss of approximately 10 cm of length, there can sometimes be challenges with type 2 and 3 aortic arches where the angulation can lead to a loss of pushability through challenging downstream lesions. In this scenario, pushing distally in a vessel can sometimes lead to sheath prolapse into the aortic root, but in my experience, the support of the Sublime™ guide sheaths has made this less of a concern. I'll typically go right radial if the left radial artery isn't anatomically suitable, if there's a diseased or previously stented left subclavian artery, or if the patient has an arteriovenous fistula or lymph node dissections in that arm.

Some physicians access the left arm with the arm lying over the patient, but I've never had to do that. If you work from the left side, you can set up your lab so there are two tables. They don't have to be large tables, but just long enough to accommodate the longer working lengths of the devices, specifically the wire. If your lab isn't big enough for this, there are workarounds. Training is important, not just for the physician but for the cath lab staff as well. They should be in attendance to see how they can most efficiently set up their lab for radial-to-peripheral procedures (Figure 1).

“The biggest positive with the balloons is the length (220 cm for the .018 and 250 cm for the .014 versions).”

### Do you prep other access sites when you're taking the radial approach?

We typically have one groin access site prepped in the event it is needed at some point during the procedure in an emergent situation. Perforations are rare, but distal embolization is a concern especially when dealing with longer, more complex lesions with suboptimal outflow. My crossover rate to a femoral access is < 1%, but I still think it is wise to be prepared for any potential complications. If I encounter a complex lesion that likely will require a certain atherectomy/thrombectomy tool, stent, or balloon technology that is currently unavailable in working lengths suitable for primary radial access, I may choose a different strategy. This may be a femoral approach or potentially direct pedal access if the groin is inaccessible. If you select patients correctly, you will rarely need to cross over from radial to femoral access.

### What's been your experience with the Sublime™ Radial product portfolio? Let's begin with the guide sheath.

I've been using the Sublime™ Radial Access Guide Sheath predominantly now, primarily because I like the rigidity, the balance between stiffness and support. It easily enters the vessels and goes through tortuous anatomy, but I also have enhanced support with this device. The support aspect is key—it gives me a little bit more pushability through lesions. The availability of a 5 Fr size is also important for me.

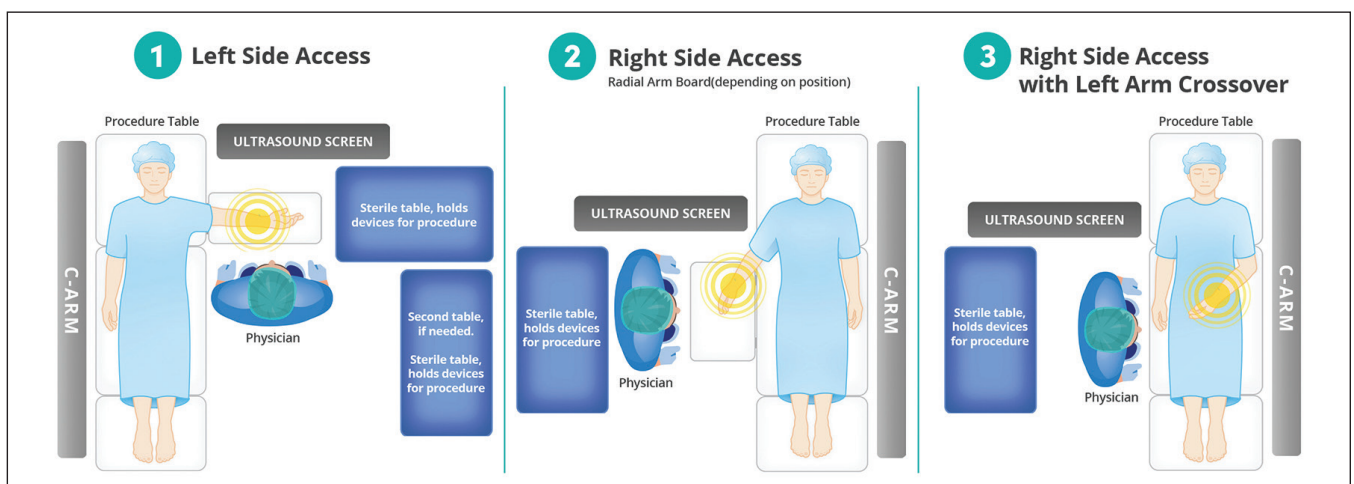


Figure 1. Variations in patient positioning and lab setup for radial-to-peripheral procedures.

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### Are you able to treat more patients with radial access using the Sublime™ Radial Access 5 Fr Guide Sheath?

Yes, I would say 5% to 10% more, because with 5 Fr I can treat radial arteries 2 mm in size and have even gone as small as 1.6 mm. I've always advocated using the smallest size device available that can get the job done. Smaller is better whenever it makes sense, and an efficacious smaller profile device is available. Many of our leg cases, as I have experienced, can be treated with the 5 Fr Sublime™ Guide Sheath. It is not advised for complex lesions where stents will likely be required because this would require a 6 Fr sheath. Again, meticulous balloon angioplasty is required where we inflate balloons slowly for as long as 4 to 5 minutes in some cases.

### How do you feel about the Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters?

The biggest positive with the balloons is the length (220 cm for the .018 and 250 cm for the .014 versions). That can be game-changing when treating critical limb ischemia where below-the-knee disease is quite prevalent. I also think the long RX lengths, 45 cm (.014 version) and 50 cm (.018 version), are valuable because they enhance our pushability through vessels. I've used it to aid in crossing lesions, too. I don't currently have crossing catheters that reach these lengths, so I've used the long monorail as my support catheter as I'm advancing through lesions. Does that always work? No, but now I can reach the foot from a radial approach. You must always be ready to go to the foot, especially when treating critical limb ischemia.

### Why do you always need to be ready to go to the foot?

Aside from critical limb ischemia where below-the-knee or below-the-ankle disease is prevalent, when you perform a peripheral intervention, you must be prepared to treat complications. For example, if you have distal emboli that travels down to the pedal arch and you're in the radial position, these balloons allow us to get down there. If you're able to cross with a wire, the balloons track easily.

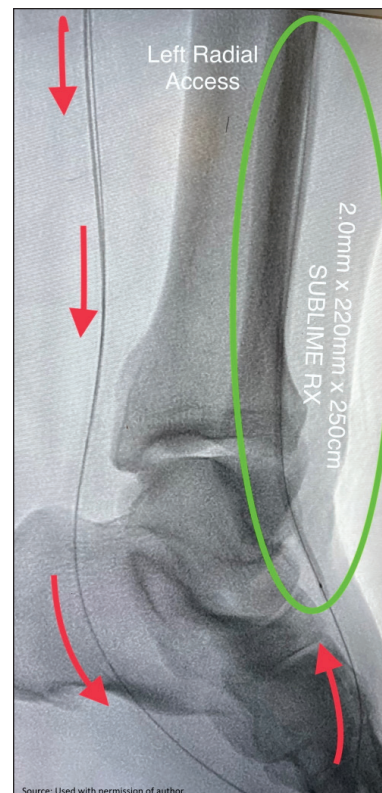
### Can you provide any examples of cases that are enabled by the unique length of Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters?

I've used them to treat infrapopliteal disease in critical limb ischemia using a contralateral approach. Let's say you have an occluded posterior tibial artery. My preferred strategy is still generally femoral access using an antegrade approach because it provides a lot of strength to cross tough lesions. The problem is that not every patient is a great candidate for this approach—patients with obesity, prior endovascular aneurysm repairs, or bypass conduits are some

examples. For these patients, I favor using a radial approach. I have had success crossing occluded tibials from the radial approach. With the Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters, I'm able to cross into the pedal loop to dilate and recanalize (Figure 2). The Sublime™ balloons have crossed the pedal loop seamlessly and are the only devices that can accommodate this from a radial approach.

### Radial-to-peripheral is a relatively new technique. Why should interventionalists take this on now?

I think physicians are going to find that if they start with a stepwise approach, beginning with the easier cases, patients are going to be very appreciative. In my experience, some of the happiest patients are those who can now be treated radially. That's great for your practice, because you're going to be known as the physician who can do a procedure through the wrist to fix the leg, and not everybody's doing it right now. If you start now, as more tools become available, you're going to be ahead of the game. This is a train that's not going to stop and it's moving fast! ■



**Figure 2. Crossing the pedal loop with the 250 cm Sublime™ Radial Access .014 RX PTA Dilatation Catheter.**



#### Pradeep Nair, MD

Interventional Cardiologist  
Cardiovascular Institute of the South  
Houma, Louisiana

*Disclosures: Speaker and consultant for BD Bard, Boston Scientific, CardioFlow, Cardiovascular Systems, Inc., Philips, and Surmodics, Inc.*

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## CASE REPORT:

# Pedal Loop Revascularization Using the Sublime™ RX PTA Dilatation Catheters via a Radial Approach

By Pradeep Nair, MD

### Patient Presentation

A man in his early 70s with a past medical history of coronary artery disease, peripheral artery disease, and hypertension presented to the clinic with gangrenous changes to the fifth digit (Rutherford category 5; Figure 1). The patient had previous right femoral endarterectomies leading to dense scar tissue at the prior access sites.



Figure 1. Gangrenous changes to the fifth digit.

### Diagnostic Findings

A diagnostic angiogram was taken of the right lower extremity, which revealed occlusion in the proximal anterior tibial (AT) artery and the dorsalis pedis (DP) artery (Figure 2).

### Treatment

The left common femoral artery was accessible, but the tortuous iliac anatomy indicated that a contralateral approach would be challenging. Given that past contralateral attempts had



Figure 2. Angiogram revealed occlusion in the proximal AT artery (A) and DP artery (B).

failed, radial access was chosen to revascularize the pedal loop by crossing the occluded AT artery into the dorsal-plantar loop. The 2.0 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter was advanced to the AT artery and inflated. The balloon was then advanced to the dorsal-plantar loop and inflated to revascularize (Figure 3).

### Post Procedure Outcome

Balloon angioplasty was performed and flow was restored to the AT artery and the pedal arch (Figure 4).

The Sublime™ Radial Access .014 RX PTA Dilatation Catheter allowed for treatment of a patient with extensive scar tissue at the femoral access site. A radial approach was used to provide a safer option for balloon angioplasty, restoring flow to the pedal loop in a patient where femoral access was not an option. ■



Figure 3. The 2 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter.

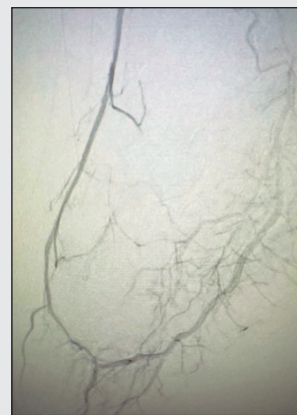


Figure 4. Arteriogram demonstrating restored flow through the AT artery and the pedal arch.

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SCAN FOR ADDITIONAL CASE EXAMPLES.

# Tackling the Radial Access Equipment Barrier

**How the Sublime™ Platform was purpose-built for radial-to-peripheral interventions.**

A conversation with R&D Engineer, Derek Stratton.

**T**ransradial access (TRA) has become a preferred approach for percutaneous coronary interventions, providing significant improvements in bleeding, access site complications, ambulation, same-day discharge, and patient satisfaction when compared to femoral access.<sup>1-5</sup> However, adoption of transradial access for peripheral vascular interventions has lagged, largely due to lack of equipment of suitable length, profile, and performance.

To meet this challenge, Surmodics developed the Sublime™ Radial Access Platform, a purpose-built suite of endovascular devices designed to facilitate treatment in above- and below-the-knee arteries using a transradial approach. The product lineup currently includes the Sublime™ Radial Access Guide Sheath, available in 5 or 6 Fr and in lengths of 120 or 150 cm; and the Sublime™ .014 and .018 RX PTA Dilatation Catheters. Both the .014 and .018 RX PTA catheters provide the industry's longest

“Surmodics has developed a platform of radial access devices that includes a 5 Fr, 150 cm guide sheath and .014 and .018 RX PTA Dilatation Catheters in the industry's longest working lengths.”

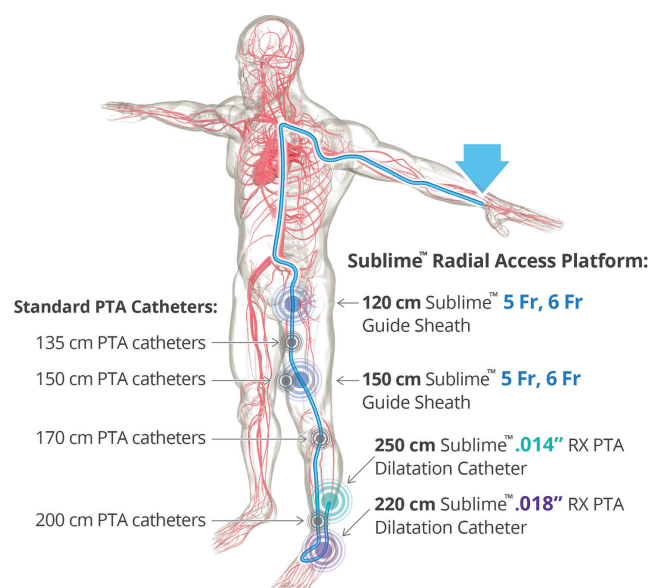
working lengths at 250 and 220 cm, respectively (Figures 1 and 2). To reinforce its leadership in the transradial-to-peripheral space, Surmodics intends to expand its Sublime™ Radial Access Platform. Most recently, Surmodics received FDA 510(k) clearance for the Sublime™ Microcatheter, a high performance crossing catheter, which will be available in working lengths up to 200 cm.

Engineering effective radial access devices for use in the periphery involves far more than adding length. We spoke with Derek Stratton, research and development engineer for the Sublime™ Radial Access Platform, about the challenges the team had to overcome when developing transradial devices that perform effectively from wrist to foot.

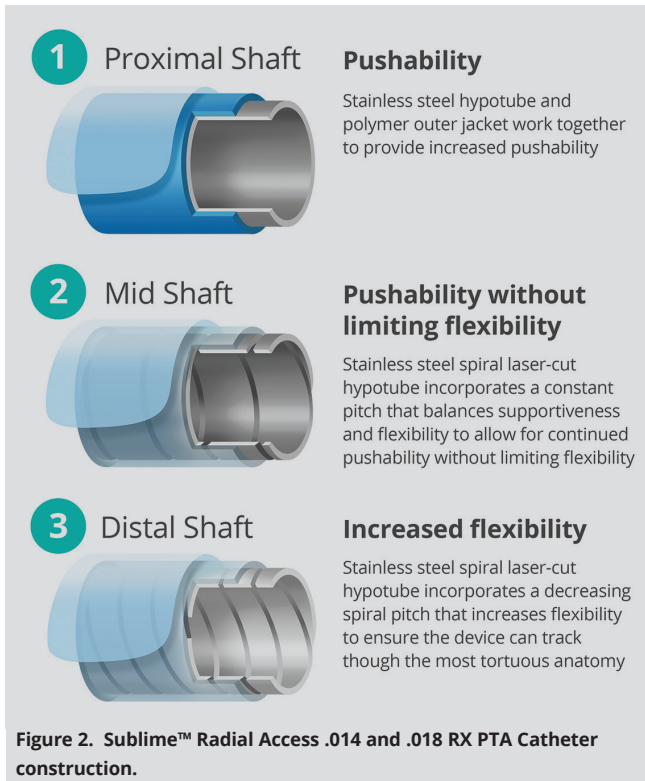
## What performance characteristics are most important in radial access devices used in the periphery, and how has Surmodics managed to achieve them?

It may seem simple, but in truth it's anything but. Medical device companies use words such as flexibility, trackability, kink resistance, radial strength, torque, and so on to describe device performance, but none of these things matter by themselves if the device can't reach the treatment site or isn't highly responsive when it gets there.

The proprietary catheter and shaft construction behind the Sublime™ Radial Access Platform devices is intended to offer



**Figure 1. The Sublime™ Radial Access Platform is purpose-designed to meet the specific demands of TRA to the periphery, including the distance and tortuosity encountered to reach the lower periphery and the smaller diameter of the radial artery.**



differentiated performance in pushability and flexibility to aid physicians in successfully delivering the devices.

With the Sublime™ Radial Access Guide Sheath, our goal is to provide the “highway” that allows physicians to deliver the necessary tools from the wrist (or their choice of access site) to

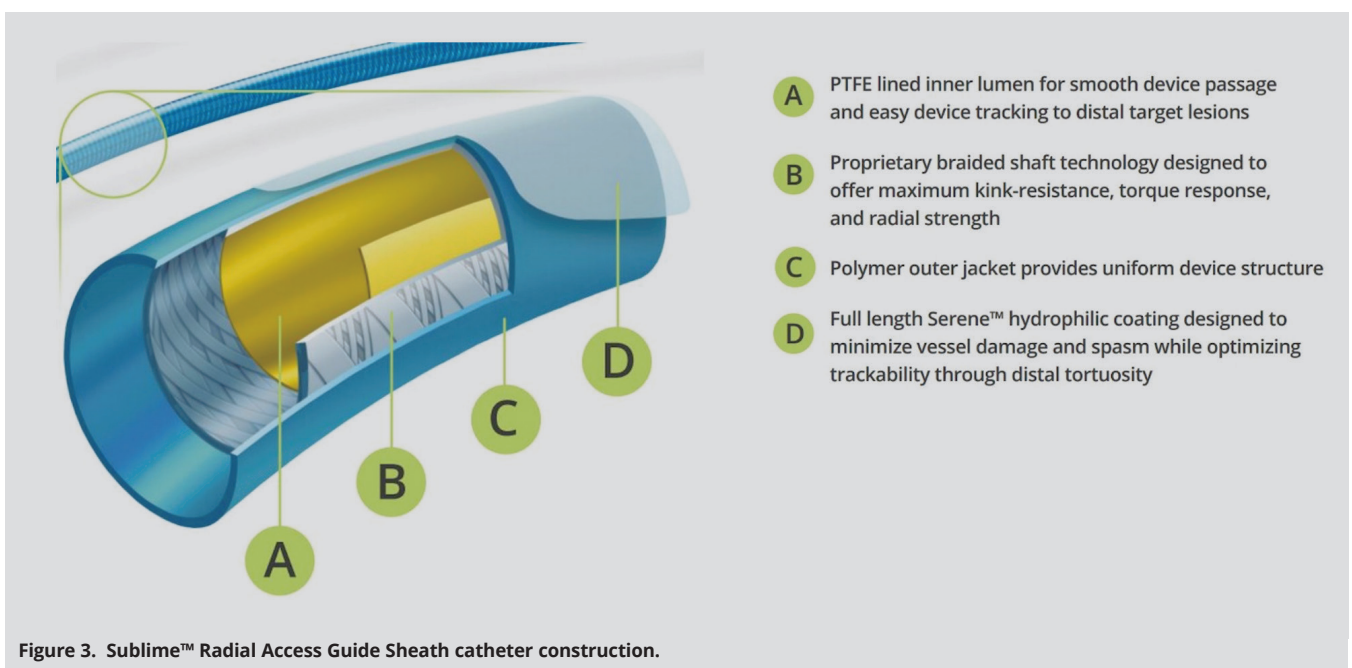
the periphery so they can successfully treat patients. With the Sublime™ .014 and .018 RX PTA Dilatation Catheters, we want physicians to be able to confidently deliver the Sublime™ balloons from the wrist to below the knee (with the .018 device) or even down to the foot. We love it when physicians tell us they can do this thanks to the Sublime™ Radial Access Platform.

Now, from a product design standpoint, these goals get exponentially harder to achieve the longer you make a device and the more tortuous the vessel pathway. It's the combination that matters. For example, in our Sublime™ .014 and .018 RX PTA Dilatation Catheters shaft designs, we have differentiated engineering built into portions of the shaft, including a more supportive proximal segment, a more flexible distal segment, and a mid-shaft segment to transition from supportive to flexible (Figure 2).

### In engineering terms, what differentiates Sublime™ Radial Access devices from others available on the market?

It's the proprietary technology that makes up the construction of these catheters, but the difference is really in the details. To give just one example, our Sublime™ Guide Sheath is constructed using a proprietary braid technology that marries the best performance features of both a traditional coil structure and a traditional braid structure while maintaining a thin-walled profile (Figure 3). This provides best-in-class kink resistance, torque, and radial strength (Figure 4). In my opinion, some companies struggle with long devices because there is a lack of sufficient support structure to ensure their devices can be delivered.

Another key differentiator is the coatings on these devices. With all endovascular devices—including those intended for peripheral



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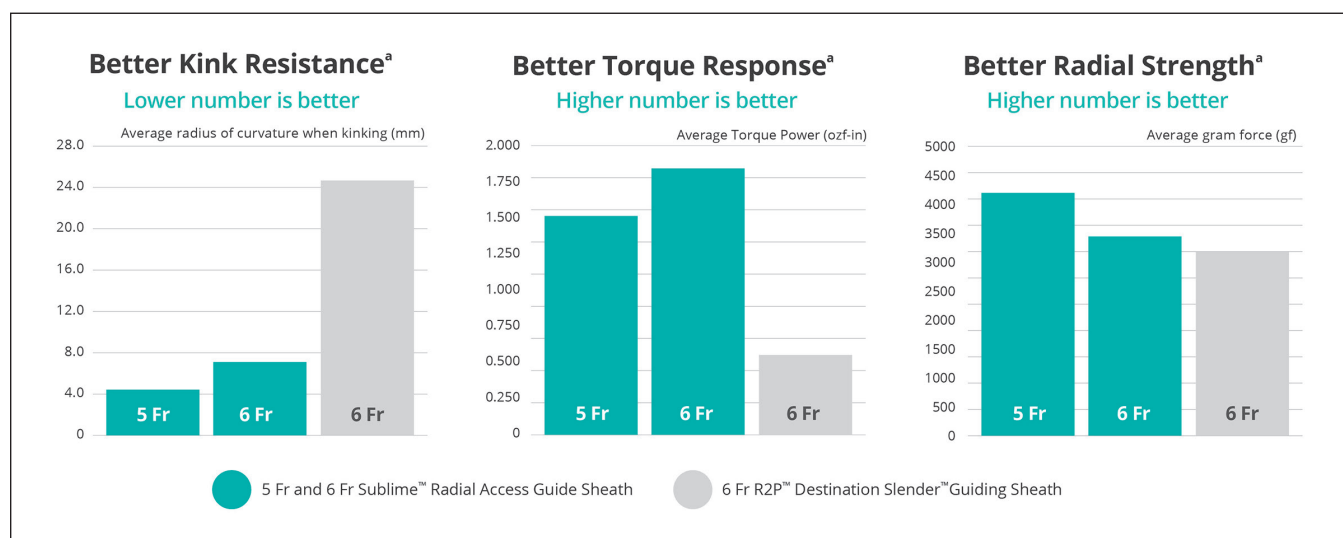


Figure 4. Sublime™ Radial Access Guide Sheath versus competition. Third-party trademarks property of their respective owners.

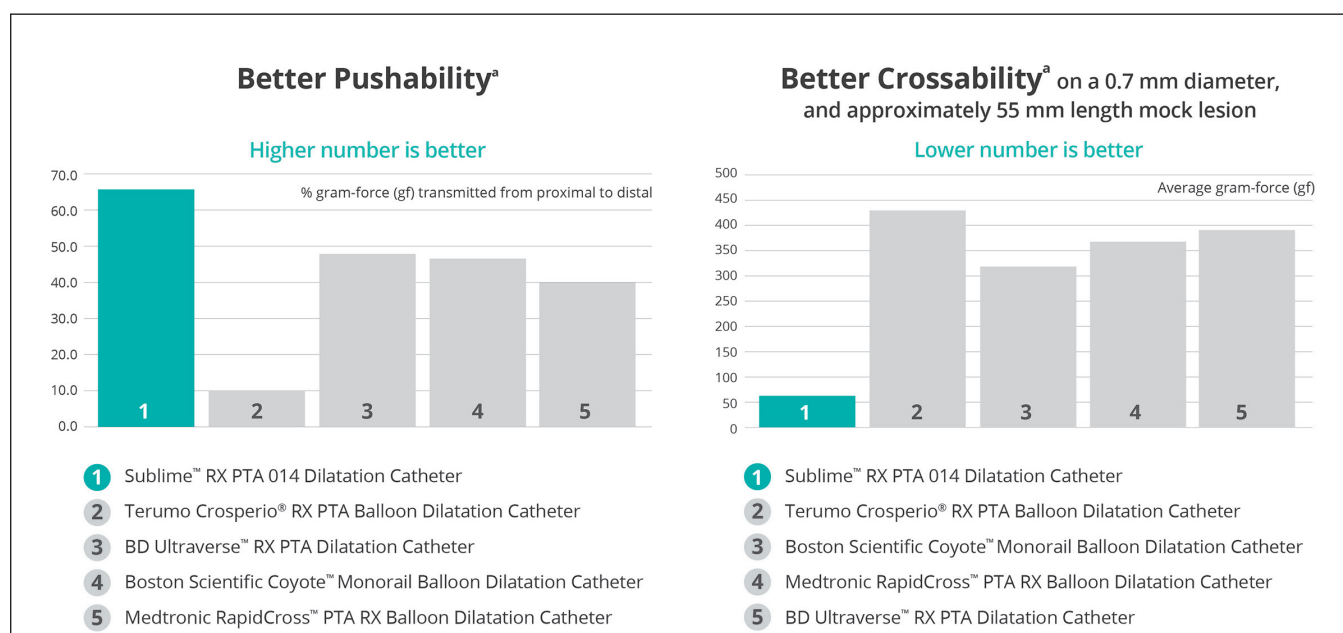


Figure 5. Sublime™ Radial Access .014 RX PTA Catheter versus competition. Third-party trademarks property of their respective owners.

use—minimizing vessel trauma and optimizing trackability with the right coating is important. Within the industry, Surmodics is known as a global leader in hydrophilic coatings. The coatings on our Sublime™ devices helps set them apart.

**Regarding the Sublime™ Radial Access RX PTA Catheters, how did Surmodics achieve deliverability of a 250 cm device without an over-the-wire design?**

Because there is a lack of guidewire options in long working lengths, we decided to deliver much-needed balloons with a

“With all endovascular devices—including those intended for peripheral use—minimizing vessel trauma and optimizing trackability with the right coating is important.”

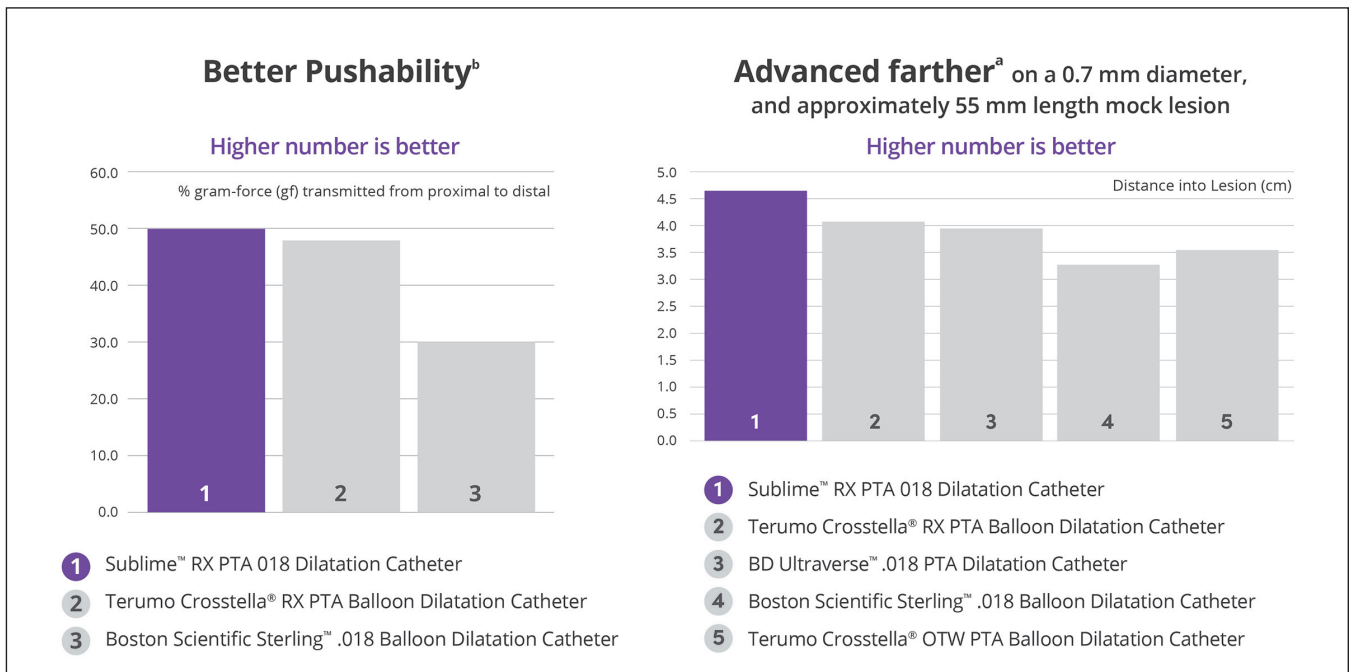


Figure 6. Sublime™ Radial Access .018 RX PTA Catheter versus competition. Third-party trademarks property of their respective owners.

rapid exchange (RX) design. Again, the answer to the challenge of delivering such a long RX balloon catheter lies in our shaft technology. These catheters feature a laser-cut hypotube that transitions from a highly supportive proximal segment to a more flexible distal segment to provide the support and deliverability expected from a more traditional over-the-wire design. This construction, combined with the Serene™ hydrophilic coating (Surmodics, Inc.), ensures that we get the exceptional pushability, trackability, and crossability. For added pushability, the RX length of these catheters is also the industry's longest at 45 cm and 50 cm for .014 and .018 version catheters, respectively (Figures 5 and 6). The feedback from users has been extremely positive. ■

For references, see page 27.



#### Derek Stratton

R&D Engineer  
Surmodics, Inc.  
Eden Prairie, Minnesota  
*Disclosures: Research & Development  
Engineer at Surmodics, Inc.*

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#### PRACTICE PROFILE

# At ECCO Medical, Radial-to-Peripheral Is Driving Practice Growth

A conversation with Aaron Kovaleski, MD.

**Dr. Aaron Kovaleski**, physician-owner at ECCO Medical in Denver, Colorado, received his formal training in interventional radiology but learned business on the job. After joining a large radiology practice early in his career, he took on business development of the group's office-based lab (OBL), from evaluating the financial health of the OBL to procedural selection for optimizing revenue generation.

He has put that experience to good use. In 2020, Dr. Kovaleski opened his own endovascular OBL in Denver, ECCO Medical, with partner Dr. Charles Nutting. Their practice has thrived on an intense dedication to patient satisfaction, disciplined business management, and energetic marketing. From humble beginnings, the practice now employs 11 full-time staff, with a focus on minimally invasive, image-guided treatment of arterial and venous disease, cancer, pelvic conditions, and much more. This fall, they will build out another procedure room with a fixed C-arm. We spoke with Dr. Kovaleski about the lessons he's learned along the way.

#### What's the first thing you'd say to a physician looking to open an OBL?

You don't need the Taj Mahal. Procedures pay the same in a 2,200 sq ft space with a mobile C-arm as they do in a 20,000 sq ft palace with a \$2 million C-arm. You need to manage your overhead. We opened with a small place and a small staff, and we were profitable within 5 months, without taking out a loan. Later, we built out the Taj Mahal (laughs).

#### Your practice does a lot of marketing. What works best?

Securing referrals. This begins in the clinic. Many patients have had procedures before, and if you can provide patients with a superior experience, they will tell their referring doctors. However,

"If you can provide patients with a superior experience, they will tell their referring doctors."

you also have to go out and generate referrals, especially when you're starting out. When we opened, if things were slow, we would drive around visiting clinics. After the pandemic hit, we cold-called clinics to set up online appointments and sent in lunch. This type of marketing never ends.

#### Your practice began doing radial-to-peripheral procedures in January 2022. Do you promote this capability with your referral base?

Absolutely. We live in a world where referring physicians really don't know the nuances of what my field does. I'll take the time to tell them about access points and explain why this is so important for patients. It looks bad for them if they refer their patients to someone who doesn't deliver a positive experience. Radial access is a lower-risk access site, which is priceless. And it's much easier on patients—they can move around in recovery without any worries about popping a femoral stick. If they feel good 30 minutes after the procedure, they can get up and go. That really resonates with referring physicians.

#### Why did you wait until this year to begin doing radial-to-peripheral procedures?

I'd known about radial access for years, but until recently, I just didn't think we had the right equipment. That changed last January when I was able to try out the Sublime™ Radial Access Guide Sheath and the Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters.

“I just didn’t think we had the right equipment. That changed last January when I was able to try out the Sublime™ Radial Access Guide Sheath and the Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters.”

**What do you like about the Sublime™ Radial Access Guide Sheath?**

The sheath is very hydrophilic. Whenever you have something that long that also has good support, you’re going to be concerned about it making that turn into the aorta. That has not been a problem. The sheath tracks very well, especially when making that difficult turn. Once you place the guide sheath, it doesn’t back out. As far as patients are concerned, I haven’t had any complaints of pain when I have put this guide sheath through the wrist. I think that speaks to the coating. It’s just able to sail through.

**What are your impressions of the Sublime™ Radial Access .014 and .018 Balloon Catheters?**

The shaft construction on those balloons—there’s so much support, it’s nice and steady, and it gets through lesions very well. With that nice, tapered tip, I’m able to sail through a lot of lesions I would otherwise be struggling with if I were using other balloons. Even coming from a femoral approach, those balloons have become a real asset in the procedure room, especially with the more complex patients.

**How about the level of pushability, given these balloons are rapid exchange (RX) and not over the wire?**

The company did a lot of things right with the design of the RX balloons. Even though they’re RX, the RX portion is quite long and provides over-the-wire support, which gives you a lot more pushability and torqueability to get through lesions or around turns. In my opinion, the push on the catheter itself has a lot of support, certainly more than anything else on the market. There’s nothing even close. With other balloon catheters, when you’re pushing through a lesion or through the iliac bifurcation, you often end up prolapsing the push portion of the catheter where

it connects to the over-the-wire portion; you’re having to push so hard that it will bend. You just don’t have that sort of issue with the Sublime™ balloons.

**What kinds of cases do you perform using the Sublime™ Radial Access devices?**

In addition to treating peripheral artery disease (PAD), I use these products for pelvic angiograms, prostate interventions, and some iliac interventions. For example, if you’re going to do prostate artery embolization, some of these patients are going to have very tortuous aortas and iliac arteries. You need a support sheath to get down deep to relieve the tension on your microcatheter through all those turns. The support we get from Sublime™ products enables us to get through challenging cases that would be nearly impossible using a femoral stick.

We also do pelvic artery revascularization for erectile dysfunction. In these cases, we’re probably using atherectomy devices and we’re certainly using balloons, so it’s essentially a PAD case, just in the pelvis. So, a good support sheath is very useful for the same reasons it’s useful in PAD. Some of these patients are also very tall. If you’re treating a man who is 6 ft, 6 inches from the radial approach, you’re almost using the whole of length of the sheath just to get into the pelvis. In any case, angles are so much easier from the radial approach, because vessels come off their origins in the direction of blood flow. Coming in from above makes it easier to direct the wire to the appropriate vessel.

**How has the ability to perform radial-to-peripheral procedures impacted your bottom line?**

It has a substantial impact, because your two premiums in an OBL are space and time. If you have two recovery bays and you’ve done two procedures, you can’t do another procedure until those people are out. We all know how long femoral access patients can take in recovery, especially if the closure doesn’t take. With radial access, with a typical 30-minute recovery time, even a small practice can probably add an extra procedure per day. Between

“The support we get from Sublime™ products enables us to get through challenging cases that would be nearly impossible using a femoral stick.”

# FROM WRIST TO FOOT

## The Sublime™ Radial Access Platform and its impact on patients and practices

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that and the nursing time you save in recovery, you more than make up for any marginal added expense from using purpose-built radial access devices. Add to that the money you save on femoral closure devices, which cost us around \$150 compared with the \$10 we spend for radial bands. With radial access, you're coming out quite a bit ahead given the way these procedures are reimbursed. ■



### Aaron Kovaleski, MD

Interventional Radiologist  
ECCO Medical  
Denver, Colorado

*Disclosures: Consultant for AngioDynamics, Sirtex, and Surmodics, Inc.*

## CASE REPORT:

# Treatment of the Dorsal Penile and Pudendal Arteries Using the Sublime™ Radial Access Platform

By Aaron Kovaleski, MD

## Patient Presentation/Baseline

A 57-year-old male presented to the clinic with longstanding erectile dysfunction and was unresponsive to prescription medications. The patient also had a past medical history of diabetes, hyperlipidemia, hypertension, and atrial fibrillation.

## Treatment

Access was obtained via the radial artery using ultrasound guidance and an introducer sheath was exchanged for a 6 Fr Sublime™ Radial Access Guide Sheath, which was advanced and delivered to the common iliac artery. A 3.0 X 100 mm Sublime™ Radial Access RX PTA Dilatation Catheter was inserted and advanced to the dorsal penile artery where prolonged balloon

angioplasty was performed. The balloon was then advanced to the internal pudendal artery where prolonged balloon angioplasty was once again performed before the balloon was removed (Figure 1).

## Post Procedure Outcome

The procedure was technically successful with improved flow through the dorsal penile artery and increased blush of the spongiosum (Figure 2). The Sublime™ Radial Access Guide Sheath and Sublime™ Radial Access RX PTA Dilatation Catheter provided the deliverability required to successfully reduce erectile dysfunction symptoms and improve erectile function for this patient, thereby improving his quality of life. ■

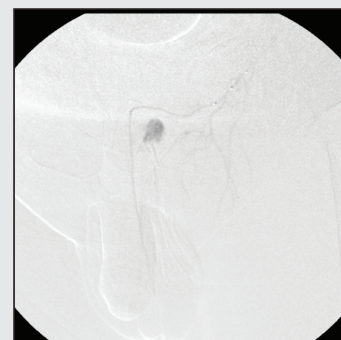


Figure 2. Completion arteriogram.

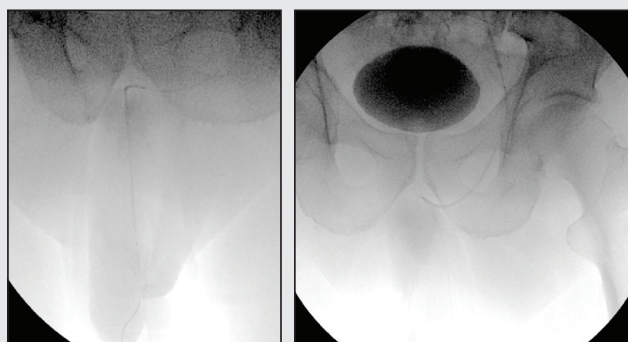


Figure 1. A 3.0 X 100 mm Sublime™ Radial Access RX PTA Dilatation Catheter was used to treat the stenoses.

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## PRACTICE PROFILE

# Radial-to-Pedal Access: A “Mic-Drop” Innovation That Can Save a Limb

A conversation with Paul Michael, MD, FSCAI.

**Dr. Paul Michael** began his medical education at age 10, helping his father, a Miami veterinarian, in the operating room. By age 12, he was assisting with veterinary surgery, general anesthesia, and placing IVs—a challenge in dehydrated cats—and receiving on-the-job training in catheters and devices. The joy of “using your hands to transform medical outcomes” in his father’s practice planted the seeds of his career as an interventional cardiologist.

Today, as the Medical Director of Palm Beach Heart & Vascular, in Boynton Beach, Florida, he is passionately dedicated to providing what he calls “transformational outcomes” in the field of limb salvage. He built out his practice as a care continuum wheel, with a clinic, a vascular lab, an interventional suite, and a recovery area. “We’re in the wound-closing business,” he says. “To close wounds, you need to be able to revascularize as well as treat the ‘whole’ person, not just the ‘hole’ in the person.” A frequent speaker at international congresses, Dr. Michael is renowned for applying advanced coronary revascularization techniques to the lower extremity, including opening blood vessels down to the foot using a radial access approach. His zeal for radial access dates to the mentors who encouraged him to explore outside-the-box solutions before dedicated equipment was available. “We used to build our own guide catheters,” he says. “It was no different from what my dad used to do.” Doing the right thing at the right time for the right reason meant having to frequently “MacGyver” equipment when purpose-built tools were not available.

We asked Dr. Michael about lessons he’s learned in using radial access for treatments aimed at preventing amputation and relieving critical limb ischemia (CLI) and the current state of dedicated radial-to-peripheral equipment.

**As someone focused on limb salvage, why do you think it’s important to have endovascular equipment capable of reaching all the way to the foot from a radial access point?**

With CLI, or end-stage peripheral artery disease (PAD), we’re often talking about multivessel, multisegment disease. That’s why radial to pedal access is extremely beneficial. Adding another meaningful access option that favors a particular vascular anatomy is always a benefit in complex cases. If you have a patient with disease in the inframalleolar vessels and corresponding wound anatomy, you need to reconstruct the foot vessels. Aortoiliac, femoropopliteal, and tibial disease can all be looked at as “inflow” vessels when foot vessels are diseased, and these can be treated with many approaches. Being able to perform pedal revascularization from the radial access has advantages, such as maintaining a single access point in multivessel, multisegment disease; minimal to no sedation usage; less recovery time; patient comfort; procedural mobility for elderly patients with lumbosacral disease; internal balloon tamponade for retrograde tibial access; less equipment usage per case; as well as economic advantages related to all of the aforementioned benefits in the outpatient and inpatient setting.

I’ll give you an example. Not long ago, I had a diabetic patient who had already had one leg amputated. After he developed ulcers on his remaining leg, his surgeon told him the leg would need to be amputated as well. They didn’t give him another option. The patient fortunately sought a second opinion and found his way to us. Using coronary interventional techniques through radial artery access, we were able to successfully take devices all the way down to his foot and restore flow. He spent 2 hours in recovery and went home. After that, it’s all about wound management and follow-up.

**Your passion is delivering exceptional patient outcomes, but your practice is also a business. What are the economics of performing radial access procedures?**

Economics is important and radial access is a money saver. First, there is the recovery time involved in a procedure. If you can shorten your recovery time by adopting radial, you’ve already offset any added costs with these devices. Why? (1) You don’t have

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to pay a nurse to sit and watch the patient as long during recovery; (2) you don't have to use a femoral closure device; and (3) you can reduce complications. And remember, complications are not just a financial cost. There's a psychologic, physical, and emotional cost to a complication, both for the patient and the operator.

### When you're teaching or mentoring people who are new to radial access, where do you begin?

I teach them how to do diagnostic angiograms via radial access because that's low-hanging fruit. All my diagnostics are done with a radial approach. We put an introducer sheath in, and I use a 150 cm flush catheter to perform low-contrast abdominal and terminal aortography, if necessary, followed by subselective unilateral runoffs. I can subselect each leg and keep contrast volumes low by using CO<sub>2</sub> angiography and diluted contrast. Plus, navigating the ascending and descending aorta can be tricky for those with no experience, so this is a great place to build confidence. Being able to manage difficult anatomy is important because you don't want to get stuck spending too much time on that during an intervention. The best way to learn is to spend time watching an experienced operator, then being supervised by a supportive mentor or partner.

### You began using the Sublime™ Radial Access Platform earlier this year. What do you think is different about the Sublime™ Guide Sheath and Balloon Catheters?

First is the lower profile of the 5 Fr radial guide sheath, which didn't exist before. You can do a lot of nifty things with a 5 Fr, 150 cm sheath. Surmodics also has the longest balloons on the market, and they're highly deliverable. The first case I did with Sublime™ Radial Access devices was a pedal loop reconstruction from the wrist. This can't be done with other equipment. To me, that's a mic-drop, and we don't have many of those with devices these days.

### Aside from pedal reconstruction, what other types of cases lend themselves to requiring a longer radial platform?

"The first case I did with Sublime™ Radial Access devices was a pedal loop reconstruction from the wrist. This can't be done with other equipment. To me, that's a mic-drop, and we don't have many of those with devices these days."

This platform shines for combined iliac and tibial disease or similar types of complex cases. I've also found that longer equipment is useful for treating bypass grafts. We did an axillobifemoral bypass that could not have been done cleanly without the Sublime™ Radial Access devices. Other examples could include morbid obesity hostile to groin access when you want to get down to the legs and you need ipsilateral antegrade access. You can use a radial approach instead of having to do a direct superficial femoral artery (SFA) stick. Or if there's proximal SFA disease, and groin access is not a good option. ■



#### Paul Michael, MD, FSCAI

Medical Director  
Palm Beach Heart & Vascular  
Boynton Beach, Florida

*Disclosures: Consultant for Abbott, ASAHI, Boston Scientific, Immertec, Medtronic, and Surmodics, Inc.*

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## CASE REPORT:

# Left Plantar Diabetic Foot Ulceration With Rutherford Category 6 CLI

By Paul Michael, MD, FSCAI

### Patient Presentation/Baseline

A 72-year-old male with type 2 diabetes mellitus, coronary artery disease, hypertension, and a history of PAD with left axillofemoral bypass and sequential femoral-tibial bypass grafting presented with large nonhealing diabetic foot ulceration and severe rest pain of his left leg. He was referred for a second opinion regarding amputation prevention.

### Diagnostic Findings

With known occlusion of distal aorta and femorofemoral graft, the diagnostic angiogram revealed a subtotal occlusion of the patient's left profunda artery to the anterior tibial (AT) artery bypass graft and chronic total occlusions of the left peroneal and posterior tibial artery (Figure 1).



**Figure 1.** Diagnostic angiogram revealed subtotal occlusion of the left profunda artery to the AT artery bypass graft.

### Treatment

With the patient awake under local anesthesia, ultrasound-guided left radial artery access was achieved, followed by insertion of a 5 Fr, 120 cm Sublime™ Radial Access Guide Sheath through the axillofemoral graft,



**Figure 2.** Sequential balloon angioplasty using Sublime™ Radial Access .014 PTA Balloon Catheters (2.5 X 220 mm, 3.0 X 220 mm, 4.0 X 220 mm).

terminating in the left profunda artery. The graft lesion was crossed with a 300 cm, .014 guidewire, which was parked in the left AT, followed by sequential balloon angioplasty using 250 cm Sublime™ Radial Access .014 PTA Balloon Catheters (sized 2.5 X 220 mm, 3.0 X 220 mm, and 4.0 X 220 mm; Figure 2). PTA was followed by immediate on-table debridement of the diabetic foot ulcer.

### Post Procedure Outcome

The revascularized foot received the necessary perfusion and driving pressure for successful debridement (Figure 3). The patient is currently ambulatory and completely healed 6 months into CLI follow-up with patent PTA results assessed by ultrasound surveillance.



**Figure 3.** The revascularized foot received the necessary perfusion and driving pressure for successful debridement.

The dedicated, purpose-built Sublime™ Radial Access Guide Sheath and Sublime™ Radial Access RX PTA Balloon Catheters were successful in restoring flow of the left femoral-tibial graft through an axillofemoral graft (Figure 4), providing a meaningful outcome in a diabetic patient facing amputation with Rutherford category 6 CLI disease. ■



**Figure 4.** The Sublime™ Radial Access Guide Sheath and Sublime™ Radial Access RX PTA Balloon Catheters were successful in restoring flow.

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SCAN FOR ADDITIONAL CASE EXAMPLES.

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### PRACTICE PROFILE

# Longer Equipment Means 50% Growth in Radial-to-Peripheral Procedures

A conversation with Michael De Luca, MD.

**Dr. Michael De Luca**, an interventional cardiologist with El Paso Cardiology Associates in El Paso, Texas, performs femoral access procedures about 1% of the time—for the rest, he prefers the radial approach, both for coronary and peripheral cases.

Dr. De Luca didn't begin this way. As a fellow, he learned about the radial approach but was frustrated by the available tools, noting that the sheaths kept getting stuck in the radial artery. He began doing radial-to-peripheral procedures when radial sheaths became available, but he was still limited by the lengths of balloon catheters. That changed earlier this year, when he started using Sublime™ Radial Access Balloon Catheters, which are available in 250 cm (.014) and 220 cm (.018) working lengths.

"With the longer balloons, I can do 50% more cases without having to do a femoral stick," he says. Together with the 150 cm Sublime™ Radial Access Guide Sheath, available in 5 or 6 Fr, he uses Sublime™ balloon catheters to treat everything from routine superficial femoral artery (SFA) cases to pedal reconstructions and chronic total occlusions below the knee.

We spoke with Dr. De Luca about lessons he's learned from adopting a radial-first strategy for peripheral procedures.

### When and why did you first take up the radial-to-peripheral approach?

I started using the radial-to-peripheral approach about 8 years ago. We started having problems with high bleeding rates from performing access through the groin. Unless I pulled a sheath and held manual pressure myself, probably 40% of my patients were getting hematomas. Patients were also getting pseudoaneurysms and I was having to control them.

### What was your approach to patient selection for your radial cases?

"With the longer balloons, I can do 50% more cases without having to do a femoral stick."

I started with patients I knew were not good candidates for femoral access. Some were patients I knew were never going to remain still in recovery, so they were going to bleed for sure. Other patients were obese, so I was never going to get a good access site in the groin. Nobody was going to be able to hold pressure, and even if we used a closure device, it wasn't likely going to work.

### What were the equipment limitations back then?

Most balloons were only 135 or 150 cm long at best. You could only go down to the iliacs, femoral, or the proximal SFA, but that was mainly in women. With men, it was even harder. Later, a 200 cm rapid-exchange balloon came out and I could get down farther. The problem was I didn't have a sheath long enough to travel down to support the wire when I was pulling the balloon back. If you weren't careful, once you got the rapid-exchange balloon down to the tibial arteries, the wire would bend on the balloon when you pulled it back. There wasn't enough support for the catheter way down there.

The other problem was that no company followed suit with atherectomy devices or intravascular ultrasound that could reach that far. This is still an issue, but I've had extremely good results with balloon angioplasty alone in the SFA and popliteal and tibial arteries with the Sublime™ Radial Access products.

### What are your impressions of the Sublime™ Radial Access Platform? Let's start with the guide sheath.

With the 120 and 150 cm sheaths, I can get down far and I don't have to worry about delivering a balloon. The guide sheath is firm, and it travels easily to the locations I want to reach. When I extract it, I don't have issues with it getting stuck in the radial arteries and causing spasms. It's also flexible enough to go through the brachiocephalic arch, which can be difficult if you're taking a right radial approach. Compared with other guide sheaths I've used, the Sublime™ Radial Access Guide Sheath is just a grade ahead.

With the Sublime™ Radial Access .014 and .018 RX PTA Balloon Catheters, the added length is clearly a big deal. But it's not just the overall length—the rapid-exchange mechanism is also longer, so you can pass it, you can pull it, and you don't have to worry about it folding on your wire and then having to go through a different vessel. These balloons travel easily, I can get them to where I want them to go, and when I deflate them, they come out easily. That's why I use them.

### What practical advice would you give physicians who are just starting with the radial approach to the periphery?

Number one, use ultrasound to access the radial artery. I've seen people struggle with getting radial access, and if it takes them too long, they're not going to do it. It's easy with ultrasound. I'd also advise people to start with left arm access, which is easier than using the right arm. When you work from the right side, you need to cross the brachiocephalic arch, which creates a little extra level of difficulty.

Another thing has to do with passing wires. Traditionally, as cardiologists, we've been trained to put a catheter over a wire. But my experience with radial is that you should not do that. The radial arteries have little branches, and the wire we use for access (the J wire) is designed for a femoral artery. In the radial,

“Compared with other guide sheaths I've used, the Sublime™ Radial Access Guide Sheath is just a grade ahead.”

the wire doesn't “J,” it stays pointing out. If you advance the wire yourself, without a catheter, you can feel where it's going. If you push with a catheter, you lose that feel, and the wire may go down a little branch and cause a hematoma. But even if that happens, a hematoma in the arm is much easier to control than one in the groin.

### Do you think radial-to-peripheral is ready for prime time?

Definitely. People just need to break the habit of going femoral. With a little training, you can become very comfortable with radial access. If you use ultrasound and left arm access, it's fairly easy to get started. ■



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*Disclosures: None.*

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### CASE REPORT:

## Successful Bilateral Angioplasty Treatment of Tibial Arteries Using the Sublime™ Radial Access Platform

By Michael De Luca, MD

### Patient Presentation

A woman in her early 80s with a history of peripheral artery disease and intermittent claudication in both legs presented with symptoms of pain and numbness to the lower extremities.

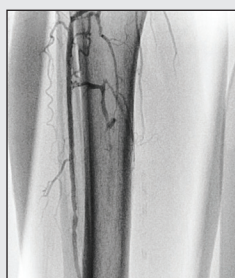
### Diagnostic Findings

A diagnostic angiogram of the right lower extremity revealed 90% occlusion in the mid-section of the anterior tibial (AT) artery, which provided collaterals to the peroneal artery (Figure 1). The peroneal artery had collaterals to the distal posterior tibial (PT) artery. No areas of occlusion could be accessed into the peroneal or PT arteries.

A diagnostic angiogram of the left lower extremity revealed total occlusion of the distal section of the PT artery. The AT artery had a collateral over to the distal PT artery.

### Treatment

Radial access was achieved via the right upper extremity and an access guidewire was inserted and advanced under fluoroscopy. After the initial angiogram, a 6 Fr, 150 cm Sublime™ Radial Access Guide Sheath was inserted and advanced to the right superficial femoral artery. A guidewire was inserted, advanced to the right AT artery, and successfully crossed the occlusion. A 2.5 X 40 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter was advanced to the AT artery, inflated twice for 2 minutes per inflation, and then removed (Figure 2).



**Figure 1. Angiogram revealed 90% occlusion of the AT artery and a total occlusion of the PT artery.**



**Figure 2. 2.5 X 40 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter used to treat the stenosis.**

With flow restored to the right AT artery, the Sublime™ Radial Access Guide Sheath was pulled back and was rerouted to the left superficial femoral artery. The guidewire was advanced through the occlusion in the left PT artery and down to the ankle. A 2.0 X 220 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter was advanced down the leg and inflated in a stepwise fashion to reach the distal PT artery. Once in the occlusion, the balloon was inflated multiple times for 2 minutes per inflation to restore flow (Figure 3).

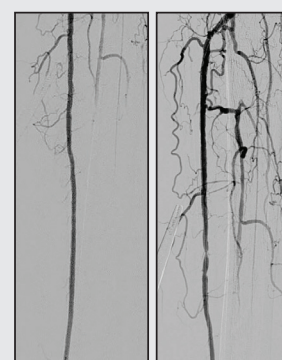


**Figure 3. 2.0 X 220 mm Sublime™ Radial Access .014 RX PTA Dilatation Catheter used to treat the stenosis.**

### Post Procedure Outcome

A final arteriogram was obtained and showed reduction from 90% occlusion in the right AT artery to 20% to 30% residual stenosis (Figure 4). Also confirmed was reduction from 100% occlusion in the left distal PT artery to < 30% residual stenosis.

The Sublime™ Radial Access Guide Sheath and Sublime™ Radial Access RX PTA Dilatation Catheters were instrumental in delivering bilateral angioplasty to the patient in a single procedure and restoring flow to the extremities. Utilizing a radial approach allowed both legs to be treated during a single procedure. ■



**Figure 4. Arteriogram demonstrating reduced stenoses.**



SCAN FOR ADDITIONAL CASE EXAMPLES.

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## SUBLIME™ RADIAL ACCESS GUIDE SHEATH

### INDICATIONS FOR USE

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

### COMPARISON TESTING

a. Average measurements from bench testing by Surmodics, Inc. R2P™ Destination Slender™ Guiding Sheath, 6 Fr (Terumo Medical Corp.) N = 5; Sublime™ Radial Access Guide Sheath, 5 Fr (Surmodics, Inc.) N = 5; Sublime™ Radial Access Guide Sheath, 6 Fr (Surmodics, Inc.) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

**TEST METHOD for Kink-resistance:** Each test device was made into a loop and placed into a kink resistance test fixture mandrel. Visual inspection of kink was administered. If no kink occurred, the devices were made into a smaller loop and placed in the mandrel. This was continued until a kink was visually observed on the test device and the mandrel radius at which the kink occurred was recorded.

**TEST METHOD for Torque:** Each test device was placed into calibrated torque test instrument. Devices were clamped into the torque test instrument on the distal end and rotated via the proximal hub. Devices were rotated clockwise one full rotation and maximum torque force on torque sensor was recorded.

**TEST METHOD for Radial Strength:** Each test device was compressed between two flat plates. Force was measured at a fixed percent compression of the shaft diameter.

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## Sublime™ Radial Access .014 RX PTA Dilatation Catheter

### 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.

### COMPARISON TESTING

a. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .014 RX PTA Dilatation Catheter (Surmodics, Inc.) N = 5; Crosperio® RX (0.014) PTA Dilatation Catheter (Terumo Medical Corp.) N = 5; Ultraverse™ RX PTA Dilatation Catheter (Becton, Dickinson and Company) N = 5; Coyote™ Monorail Balloon Dilatation Catheter (Boston Scientific) N = 5; Rapid-Cross™ PTA RX Balloon Dilatation Catheter (Medtronic, Inc.) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

**TEST METHOD for Crossability:** Each device was tested using a lesion containment fixture and MSI™ track tester water heater with water temperature of  $37^{\circ} \pm 2^{\circ}\text{C}$ . A guidewire was used to cross the mock lesion. Each device was tracked through the track tester where the catheter tip was proximal to the lesion. The catheter was then advanced through the lesion and maximum force (gf) and average force (gf) was measured.

**TEST METHOD for Pushability:** Each device was tested using an MSI™ track tester water heater with water temperature of  $37^{\circ} \pm 2^{\circ}\text{C}$ . Each device was advanced through the track tester into a distal load cell and the maximum proximal and distal forces were measured and a percentage difference between the proximal and distal force was calculated.

**TEST METHOD for Track Force:** Each device was tested using a radial track model and MSI™ track tester water heater with water temperature of  $37^{\circ} \pm 2^{\circ}\text{C}$ . Each device was advanced through the radial track model and the average force in grams was measured.

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## Sublime™ Radial Access .018 RX PTA Dilatation Catheter

### 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.

### COMPARISON TESTING

a. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .018 RX PTA Dilatation Catheter (Surmodics, Inc.) N = 5; Crostella® RX (0.018) PTA Dilatation Catheter (Terumo Medical Corp.) N = 5; Ultraverse™ RX PTA Dilatation Catheter (Becton, Dickinson and Company) N = 5; Sterling™ .018 Balloon Dilatation Catheter (Boston Scientific) N = 5; Crostella® OTW (0.018) PTA Dilatation Catheter (Terumo Medical Corp.) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

b. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .018 RX PTA Dilatation Catheter (Surmodics, Inc.) N = 5; Cross-tella® .018 RX PTA Balloon Dilatation Catheter (Terumo) N = 5; Sterling™ .018 Balloon Dilatation Catheter (Boston Scientific) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

**TEST METHOD for Crossability:** Each device was tested using a lesion containment fixture and MSI™ track tester water heater with water temperature of  $37^{\circ} \pm 2^{\circ}\text{C}$ . A guidewire was used to cross the mock lesion. Each device was tracked through the track tester where the catheter tip was proximal to the lesion. The catheter was then advanced through the lesion and maximum force (gf) and average force (gf) was measured.

**TEST METHOD for Pushability:** Each device was tested using an MSI™ track tester water heater with water temperature of  $37^{\circ} \pm 2^{\circ}\text{C}$ . Each device was advanced through the track tester into a distal load cell and the maximum proximal and distal forces were measured and a percentage difference between the proximal and distal force was calculated.

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