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For a select group of radial-to-peripheral pioneers, September 11-12 marked a turning point.

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Expanding the Limits of Radial-to-Peripheral Intervention

A conversation with Ramzan M. Zakir, MD.

Dr. Ramzan M. Zakir has been a radial-first operator for coronary interventions since 2009, when he trained under transradial pioneer Dr. John Coppola. Dr. Zakir developed and led the radial access program at Robert Wood Johnson University Hospital in New Jersey and has conducted hands-on radial access training for interventionalists from across the United States. Today, he serves as Director of High-Risk PCI and Research at Robert Wood Johnson while performing a large volume of peripheral cases at Cardiac and Vascular Interventions, a highly equipped office-based laboratory (OBL). We spoke with Dr. Zakir about the benefits of the radial approach and the state of the art for radial-to-peripheral procedures.

What was it like spearheading radial access for coronary interventions?

I had to overcome a lot of hurdles. At first, when I mentioned that I wanted to access the arm from the radial artery, I was told to stick to the brachial. I said, you've got to be kidding! So, we were starting from scratch. After I started the radial program and put the protocols in place, it wasn't long before everyone embraced it.

What drove adoption?

No matter how good you are at femoral access, there will still be times when the groin is just too calcified or too diseased to use that approach. Assuming the groin is available, you never know when you're going to have problems with a closure device, even if you're proficient at using them. Any obese patient, when you have that deep skin tract, will increase your chance of having issues. Then, you're left holding pressure on a fully heparinized patient. That's going to set back your whole day—your staff will be fully occupied. With radial access, you snap on a compression band and take it off in an hour. Patients are ambulatory, and they get out quickly with fewer complications.

“Having this [Sublime™] 200 cm crossing catheter is a real game-changer for radial-to-peripheral equipment.”

That difference goes a long way, especially in the OBL, where we strive for rapid turnover. You don't have to deal with groin issues late in the day, sending patients to the hospital for observation. So, if you can do radial, why not?

When did you begin performing peripheral cases from the wrist?

The turning point for us was when radial-length sheaths and atherectomy devices became available about 5 years ago. Before then, we didn't have equipment specifically designed to perform peripheral cases safely. When we would try to put in sheaths that weren't designed for radial-to-peripheral procedures, they would cause a lot of radial artery spasm. I would use radial access for some iliac occlusions, but only if there was no other option.

How do you select peripheral patients for radial access?

When I'm deciding on case selection, I think about which approach will have better long-term results for the patient. Right now, we're very well positioned to do above-the-knee cases, but still somewhat limited in the equipment we need to treat below the knee from the wrist. We have good self-expanding stents that can easily get down to the popliteal artery, but they may not be the best stents for severely calcified lesions and across the knee. We don't have drug-eluting stents, but we do have the

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"I've used Sublime™ RX Balloons in tough cases where other balloons were not able to cross, including non-radial cases."

In.Pact™ 018, 200 cm drug-coated balloon (Medtronic). You have to balance the benefits of going radial with the possibility that patients may do better in the long term with equipment that's not yet available in radial lengths.

With that in mind, I'd say that we're now able to use radial as the primary approach for the overwhelming majority of our claudicants, with tibial artery access as a backup. The number of complex CLI (critical limb ischemia) cases we can do from a purely radial approach is significantly lower. For these, we may complement radial with tibial access. Fortunately, it's just a matter of time before we see more tools. Industry is now committed to expanding the radial-to-peripheral platform.

Can you describe some of the ways you optimize success in radial-to-peripheral interventions?

Knowing the anatomy really helps. If you can get a CTA first, you know exactly what you're going after and have a game plan in place. Knowing the height of the patient and understanding

where devices will reach from the right versus left radial artery is important. Obtaining access with ultrasound leads to more efficient access and can minimize complications.

After obtaining access, there are only a few things you really have to know to get your sheath in place. I advance a pigtail and once you're in the chest, you rotate it and advance the wire down the descending aorta. With the pigtail above the iliac arteries, I like to perform a roadmap separating the internal and external iliac arteries so you don't inadvertently wire the internal iliac artery.

Once you have the stiff, angled Glidewire® (Terumo Interventional Systems) in the superficial femoral artery (SFA), you can use the radial-length sheaths we have now, which are great. The hydrophilic coating can minimize vessel damage and spasm while optimizing trackability, while the braided shaft technology can maximize kink resistance. Before you know it, you're right down in the common femoral artery if you're using a 120 cm sheath, or the SFA if you're using a 150 cm sheath. From there, you can complete the procedures very quickly and treat complex lesions from a radial approach. Then, the best thing is you're just putting a compression band on the patient's wrist and you're done.

"I think Surmodics has an advantage with the 5 Fr sheath."

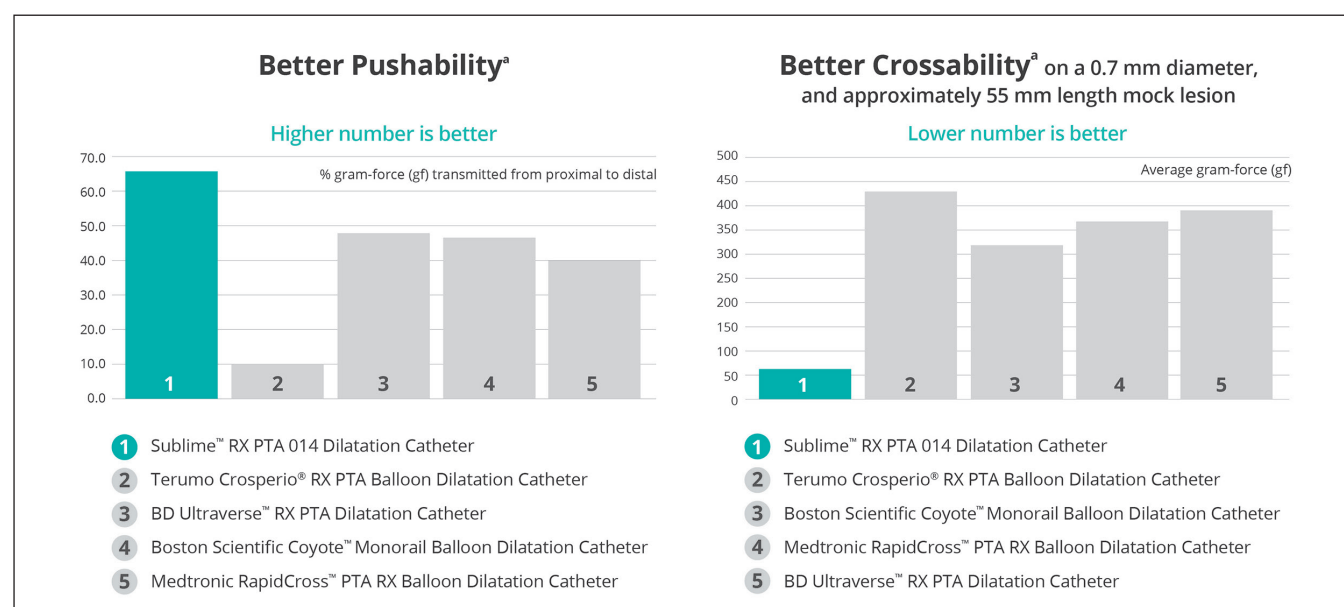


Figure 1. Sublime™ Radial Access .014 RX PTA Catheter versus competition. Third-party trademarks are property of their respective owners.

What limitations remain in the radial-to-peripheral toolkit?

I'm glad Surmodics has come out with 250 cm Sublime™ RX PTA Balloons (Surmodics, Inc.) that can reach to the foot (≤ 250 cm). But the issue remains that we don't have long enough wires that are designed to cross complex lesions and support catheters. I still do antegrade access for complicated below-the-knee cases.

Surmodics recently introduced Sublime™ .014, .018, and .035 torqueable microcatheters (≤ 200 cm) designed for the periphery. You're among the first physicians to use them. Do you think they help fill a gap in the radial-to-peripheral toolkit?

One of the limitations when using radial access to the periphery is that the tools aren't quite there. So, with that, we're excited to have a 200 cm microcatheter from Surmodics. Prior to this option, the only support catheter available was the 200 cm ViperCath™ XC (Abbott) available on a .035 platform and it's quite bulky. Having this 200 cm crossing catheter is a real game-changer for radial-to-peripheral equipment.

Can you describe your experience using other Sublime™ Radial Access products? Let's begin with Sublime™ RX Balloon Catheters.

I think these RX balloons were designed very well. They definitely have advantages. To begin with, the Sublime™ portfolio currently has the only 250 cm length available. These balloons also have a longer RX portion, which makes them perform more like a traditional over-the-wire balloon. I think their pushability and crossability is superior to other balloons (Figure 1).

I've used Sublime™ RX Balloons in tough cases where other balloons were not able to cross, including non-radial cases. I've been in up-and-over cases where it's like, "Okay, that didn't cross, let me try the Sublime™ balloon." Boom. Before you know it, the balloon has crossed the lesion into the distal areas or the pedal arch. It just tracks so well.

How about the Sublime™ Radial Guide Sheaths?

I think Surmodics has an advantage with the 5 Fr sheath. We get a lot of older patients that are frail and have thin wrists with

"We're at the start of a radial revolution in the peripherals."

small radial arteries. Having this option increases the number of patients you can treat from a radial approach, especially below the knee. The current limitation for the 5 Fr is stenting, but many cases only require percutaneous transluminal angioplasty (PTA) and atherectomy. In terms of performance, I haven't had any spasm issues with either the Sublime™ 5 or 6 Fr sheaths. They track very smoothly.

Any closing thoughts?

I think we're at the start of a radial revolution in the peripherals. As the toolbox continues to expand, we'll be able to treat more patients. This will lead to overall increased efficiency, fewer complications, happier patients, and happier hospitals and OBLs.¹ It's very exciting. ■

1. Mason PJ, Shah B, Tamis-Holland JE, et al. An update on radial artery access and best practices for transradial coronary angiography and intervention in acute coronary syndrome: a scientific statement from the American Heart Association. *Circ Cardiovasc Interv.* 2018;11:e000035. doi: 10.1161/HCI.0000000000000035



See Dr. Zakir perform a successful revascularization of the foot from the radial approach using the Sublime™ Platform.



Ramzan M. Zakir, MD

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New Brunswick, New Jersey
Disclosures: Consultant fees/honoraria/speaker's bureau for Abbott, Boston Scientific Corporation, Cardiovascular Systems, Inc., Cordis Corporation, a Johnson & Johnson company, Penumbra, Philips, Shockwave Medical, and Terumo Medical Corporation.

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CASE REPORT:

Successful Revascularization of the Foot From the Radial Approach Using the Sublime™ Platform: Guide Sheath, Microcatheter, and RX PTA Catheters

By Ramzan M. Zakir, MD

PATIENT PRESENTATION

A 75-year-old female with a medical history of diabetes, hypertension, smoking (former), and anemia presented with multiple nonhealing wounds of the left foot.

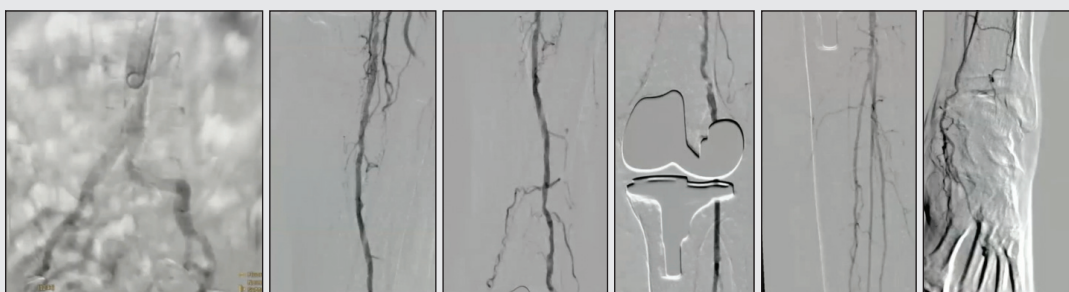


Figure 1. Angiography revealed (left to right) tortuous iliac arteries and severe multilevel disease in the SFA, popliteal artery, and AT artery.

DIAGNOSTIC FINDINGS

Diagnostic angiography of the left lower extremity revealed significant tortuosity in the iliac arteries and severe multilevel disease in the SFA, distal popliteal artery, and anterior tibial (AT) artery (Figure 1).

TREATMENT

Access was obtained through the patient's left radial artery using ultrasound guidance. A 5 Fr introducer sheath was inserted, and a radial cocktail was administered. A pigtail catheter was inserted over a guidewire and placed in the descending aorta, where the angiogram showed significant tortuosity in the left common femoral and external iliac arteries. The radial access introducer sheath was exchanged for a 6 Fr, 150 cm Sublime™ Radial Access Guide Sheath, which was advanced to the SFA. A .018, 200 cm Sublime™ Microcatheter was inserted over a .018 guidewire and advanced to the distal popliteal artery (Figure 2). The guidewire was then able to cross the distal AT occlusion and was advanced through the pedal arch. Due to heavy calcification, orbital atherectomy was performed using the Diamondback 360® system (1.75 mm; Abbott) in the SFA and popliteal artery, followed by PTA. Because of an occlusion in the distal AT artery and incomplete pedal arch, a .014, 250 cm Sublime™ RX PTA Catheter (2.0 X 150 mm) was advanced to the pedal arch and inflated, followed by inflation of a .014, 250 cm Sublime™ RX PTA Catheter (2.5 X 150 mm) in the distal AT artery (Figure 3).



Figure 2. 200 cm Sublime™ Microcatheter utilized to assist wire crossing of popliteal and AT artery lesions.



Figure 3. Sublime™ Radial Access .014 RX PTA Dilatation Catheter inflation in the pedal arch and distal AT artery.

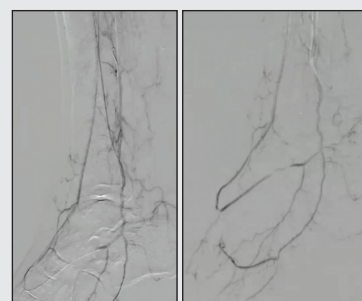


Figure 4. Arteriogram demonstrating successful revascularization of the foot.

POSTPROCEDURE OUTCOME

Following the successful intervention, arteriography showed revascularization into the pedal arch with good flow into the heel and bluish flow into the toes (Figure 4). ■

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Scaling to 70% Radial-to-Peripheral in a Hospital Setting

A conversation with Sameh Sayfo, MD.

Dr. Sameh Sayfo, an interventional cardiologist at Baylor Scott & White The Heart Hospital—Plano (Texas), earned an MBA while practicing medicine at the height of the COVID-19 pandemic. Schooled in operational efficiency, he sees radial-first vascular intervention as a major opportunity to improve patient care while optimizing hospital processes and cost containment. Today, he performs mainly peripheral interventions, most of them in patients with complex disease and multiple comorbidities. Despite this challenge, he performs about 70% of peripheral interventions from the wrist.

In general, what are your patient selection criteria for radial-to-peripheral interventions?

Anatomically, I use radial access for nearly all my subclavian, vertebral, renal, and mesenteric artery cases. For lower extremity, I use radial access for the majority of iliac artery, common femoral artery (CFA), superficial femoral artery (SFA), and popliteal artery disease. Radial access has become my standard approach, especially since Medtronic came out with their 200 cm drug-coated balloon (DCB; In.Pact™ 018).

I'll typically go radial for SFA occlusions regardless of whether the lesion is 100% calcified, short, or long. We have calcium modification tools available (orbital atherectomy and lithotripsy). If I have a chronic total occlusion (CTO) in the SFA, I'll typically use a combined radial-pedal approach. For me, that works just as well as a femoral-pedal approach. If you know how to set up the radial-pedal combination from the get-go, you'll have a higher success rate.

You've said that acceptance of radial access for peripheral interventions is at the same stage now as radial for coronary interventions was in the past. What do you see as the biggest obstacles to radial-to-peripheral adoption today?

I think it will be challenging to persuade people who have been using femoral access for 20-plus years to change to radial. If you've read about the history of percutaneous coronary intervention (PCI), people thought it was crazy to use radial

“Patient satisfaction is important. Patients hate getting a groin stick.”

access 15 years ago. Their answer was always, “I’ve been going femoral for 20 years, why would I go radial?” But now, if you do not provide your patient with a radial access for the coronary intervention, your patient will go somewhere else. Patient satisfaction is important. Patients hate getting a groin stick.

You can perform a complex intervention very well from femoral access, but the patient is not going to remember all the good work you’ve done if there’s a groin bleed. They’ll remember when the nurse put on a sandbag, or when someone pushed on their groin and it hurt a lot. We’re in the infancy of radial-to-peripheral, but more and more people graduating from fellowships are doing it. Trends are starting to change.

When do you still choose femoral over radial access for peripheral cases?

I would not go radial if I needed a stent that can’t pass through a 6 or 5 Fr sheath. Patients with certain iliac artery diameters may require femoral access due to device availability in the size they require. I’ll go femoral because I have to use a 7 or 8 Fr sheath. If I see the need for the Shockwave L6 (intravascular lithotripsy catheter, Shockwave Medical) with a vessel that’s 9, 10, or 11 mm, I’ll go femoral because, again, I need a 7 or 8 Fr sheath to accommodate the device.

I’ll usually go femoral for below-the-knee (BTK) disease, unless I cannot go femoral—for example, in patients who have undergone an endovascular aneurysm repair, aortic bifemoral bypass, or have an occluded iliac artery. I believe we’re still somewhat limited in the equipment available for BTK interventions. Having said that, I’m excited about using Sublime™ RX Balloon Catheters (Surmodics, Inc.) because they’re longer (≤ 250 cm). Hopefully I can start doing more BTK work from the radial approach now. The first time I used a Sublime™ RX Balloon Catheter (.018, 5.0 X 150 mm),

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“The first time I used a Sublime™ RX Balloon Catheter (.018, 5.0 X 150 mm), it crossed a 300 mm total occlusion in the SFA.”

it crossed a 300 mm total occlusion in the SFA (page 10). I kept expecting to feel resistance and never felt any.

One pushback against radial-to-peripheral is a perceived lack of bailout options. What’s your take?

Yes, some physician operators are worried that they can’t use a Viabahn® covered stent (Gore & Associates) for bailout if they need to. That’s understandable. Most interventionalists have used these stents for many years and love having them on hand. But right now, the sheath size and shaft length for these stents isn’t suited for radial access. So, the question is how to manage a perforation if you’re using radial access. That’s a valid concern. But if you’ve done a lot of radial cases, I believe you’ll find that radial is actually safer for a perforation than femoral access.

Let me explain. Let’s say you’re doing a common iliac or external iliac artery revascularization via radial access, you balloon and stent, and suddenly you have a perforation. The easiest thing for you to do is just inflate a balloon, stop the flow from the top, get access from the unilateral CFA with an 8 Fr sheath, and deploy your covered stent. You’ll have no problem. On the other hand, if you’re using CFA access and you perforate, you only have one access site. You’re going to have to put a balloon in distal to the perforation to stop the bleeding. The question is how to put in your Viabahn® stent.

You have two options. If you’re using a 6 Fr sheath, which is typical, you can deflate the balloon and switch to an 8 Fr sheath to put in a Viabahn® stent. But, that takes 2 to 3 minutes, and the patient could die by that time—the bleeding from an iliac artery rupture is unbelievable. The other option is to go up and over from the contralateral CFA. For me, that’s a more complicated way to manage this patient. With radial access, if you have a perforation, you just inflate the balloon in the common iliac artery, stop the flow, and the patient is stabilized.

Radial-to-peripheral skeptics also question the ability of current tools, not so much to reach lower extremity lesions, but to cross them.

I tend to disagree with that. Often, it’s just a matter of choosing the right sheath length. If you’re working on a mid-SFA

occlusion and you use a 105 cm sheath, you’re landing in the distal aorta and you have no support. If you use a 120 cm sheath, you’re in the CFA, and you’ll have the support and pushability you need. In this case, there’s really no difference between femoral or radial access in terms of pushability.

What we *have* been missing are long microcatheters. In this respect, I think Surmodics is ahead of the curve.* The only long (> 150 cm) microcatheters we have had are .035 and they don’t cross well if at all. I think the torqueability of Sublime™ .014, .018, and .035 Microcatheters (Surmodics, Inc.) will be very helpful in expanding crossability. In the case I referred to previously (page 10), I had been planning to use a pedal-radial approach, but the Sublime™ .035 Microcatheter allowed my wire to cross that long CTO. This device is different from what is currently on the market.

Admittedly, we still lack the re-entry devices that are available for femoral access because of shaft length limitations. So, whenever I have a SFA CTO or popliteal occlusion, I always prep both radial and pedal. I’ll try radial, and if I need to supplement my approach with pedal access, I have it ready. I might need to do that 10% to 20% of the time with SFA CTOs. I think that’s very similar to what you do in femoral access situations.

Your group recently completed a retrospective review comparing radial access to femoral access for iliac artery interventions.¹ Can you describe the major findings?

Certainly. We looked at 138 patients, split between radial and femoral access. Statistically, the rates of procedural success, procedure time, and contrast use were the same in each group. Three of 68 radial patients crossed over to femoral because of radial artery spasm or because we couldn’t cross the lesion. The big difference was in length of stay, which was shorter in the radial arm ($P = .044$).

Our results are consistent with what we’ve seen in the coronary intervention literature. Amin et al published a nice paper in 2017 that looked at Medicare patients who underwent PCI from either the radial or femoral approach.² There were major cost advantages for radial, mainly due to same-day discharge.

“What we have been missing are long microcatheters. In this respect, I think Surmodics is ahead of the curve.”*

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He estimated that increasing the rate of transradial access with same-day discharge by 30%, while reducing transfemoral with overnight stays by that same amount, would save hundreds of millions of dollars at the national level. The problem with radial-to-peripheral is that we don't yet have enough patients to run those numbers. I think in 5 years we will, and we'll see the same kind of strong financial benefit.

Remember, a hospital bed is the most expensive thing in the health care system, so same-day discharge is extremely important. We've seen fewer access site bleeding complications for radial versus femoral access in PCI. If a patient bleeds from the radial artery, you apply pressure and then wrap their arm and that usually solves the problem. On the other hand, a groin site bleed may lead to catastrophic consequences, which may lead to the patient going in for open surgery, require transfusion, or require thrombin injection for a pseudoaneurysm.

What has been your experience with other Sublime™ Radial Access products?

I really like the Sublime™ Radial Guide Sheath. It is very slick and goes in easily. I used it in a patient who had a lot of problems with radial spasm, and it went very well. It has an advantage over other companies' sheaths in the availability of a 5 Fr size, which is helpful in small-size arteries. I've done hundreds of radial-to-peripheral interventions and

have found that the Sublime™ Guide Sheath has two other distinct advantages. For one, even with its extremely smooth pushability, the Sublime™ Guide Sheath doesn't have the tendency to back up when crossing complex lesions. The other positive thing about the sheath is its valve. The valve on the Sublime™ Guide Sheath is amazing. I've seen zero bleed in all my cases, even with the use of a stiff wire or while inserting a microcatheter. ■

1. Sayfo S. Radial to peripheral: what is possible. Presented at: Cardiovascular Innovations Foundation (CVI) Annual Meeting; July 20-22, 2023; Austin, Texas.

2. Amin AP, Patterson M, House JA, et al. Costs associated with access site and same-day discharge among Medicare beneficiaries undergoing percutaneous coronary intervention: an evaluation of the current percutaneous coronary intervention care pathways in the United States. *JACC Cardiovasc Interv*. 2017;10:342-351. doi: 10.1016/j.jcin.2016.11.049



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Disclosures: Consultant for Boston Scientific Corporation, Imperative Care, Inari Medical, Medtronic, Penumbra, Shockwave Medical, Surmodics, and Terumo.

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CASE REPORT:

Successful Revascularization of Superficial Femoral Artery Total Occlusion Using the Sublime™ Radial Access Platform

By Sameh Sayfo, MD

PATIENT PRESENTATION

A 77-year-old male with a medical history of coronary artery disease, carotid artery disease, type 2 diabetes mellitus, hypertension, and renal artery stenosis presented with worsening right lower extremity claudication (Rutherford class 3) and an abnormal ankle-brachial index of 0.23 on the right side.

DIAGNOSTIC FINDINGS

Diagnostic angiography of the right lower extremity revealed a total occlusion of the right SFA (Figure 1).

TREATMENT

Access was achieved through the 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, which was advanced to the right iliac artery. A .035, 200 cm Sublime™ Microcatheter was

inserted over a .018 Command™ guidewire (Boston Scientific Corporation) and was advanced to the distal segment of the occluded SFA (Figure 2). The .018 guidewire was then exchanged for a .035 Glidewire Advantage® guidewire (Terumo Interventional Systems) to cross the popliteal artery. The Sublime™ Microcatheter was advanced to the popliteal artery and the .035 guidewire was exchanged for a .014, 475 cm ViperWire® guidewire (Abbott). The Sublime™ Microcatheter was removed and balloon angioplasty was performed using a 5.0 X 150 mm Sublime™ .018 RX PTA catheter (Figure 3). Subsequently, a radial-length .018, 6.0 X 150 mm In.Pact™ drug-coated balloon (DCB; Medtronic) was delivered and then inflated (Figure 4).

POSTPROCEDURE OUTCOME

A final angiogram revealed < 10% residual stenosis with a type B dissection (Figure 5). The physician elected to not stent at this point. ■



Figure 1. Diagnostic angiogram of the right lower extremity revealed a total occlusion of the right SFA.



Figure 2. Sublime™ Microcatheter advanced to the distal segment of occluded SFA.



Figure 3. Balloon angioplasty performed using 150 mm Sublime™ .018 RX PTA catheter.

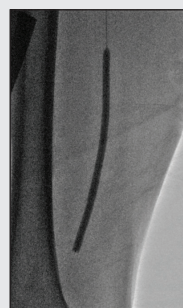


Figure 4. Inflation of radial-length .018 In.Pact™ DCB.

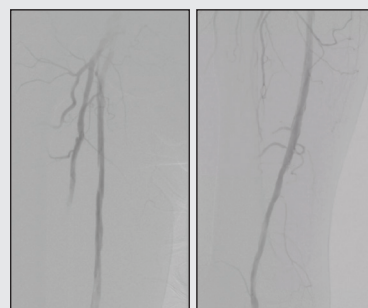


Figure 5. Final angiogram revealed < 10% residual stenosis with type B dissection.

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Reducing the Radial-to-Peripheral Gender Gap With 5 Fr Guide Sheaths

A conversation with Robert Minor, MD.

Dr. Robert Minor, an interventional cardiologist with Billings Clinic Heart and Vascular in Missoula, Montana, worked with a multidisciplinary team to launch the state's first "Limb Preservation Program." He has spent his career educating cardiologists, radiologists, and vascular surgeons in the United States and abroad on endovascular techniques. Dr. Minor can be considered a true radial-to-peripheral pioneer, having adopted the approach more than 10 years ago, before the advent of purpose-built radial-to-peripheral tools.

He and his team serve a patient population that includes many women of smaller stature with diminutive radial arteries. Although women have higher rates of bleeding and other femoral access complications than men, and transradial access (TRA) reduces this risk, women have been less likely to receive TRA.^{1,2} This may be due to an increased risk of spasm presented by their smaller radial arteries—a challenge mitigated by smaller-diameter sheaths.² The Sublime™ Radial Access Platform (Surmodics, Inc.), which includes the first 5 Fr radial-length guide sheath (Figure 1), has enabled Dr. Minor to offer radial-to-peripheral procedures to more female patients and optimize their rates of same-day discharge.³ We spoke with Dr. Minor about implementing a successful radial-to-peripheral program in his hospital.

What drove you to adopt radial access?

Beginning in 2010, my cardiology group began watching the growth of radial access closely and began speaking with others who had already embraced the technique for coronary procedures. We had a colleague come in who had radial experience to help train our team. It was a true epiphany for me. I had thought it was a marketing tool attached to a bait-and-switch, you know, "We're going to do your heart procedure through the wrist. Oh, we're sorry. It's too small. We're going to go through the groin."

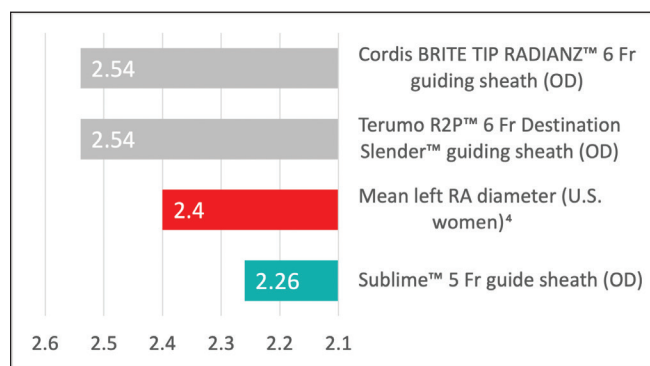


Figure 1. Smallest currently available outer diameter (OD) guide sheath in the United States (mm). RA, radial artery.

But I learned immediately that radial was much safer than femoral access. Patients really preferred it. And of course, with increasing cost-containment pressures, the growing nursing shortage, and limited inpatient beds, radial access was very attractive. I wanted to get people home the same day and began to routinely allow same-day discharge immediately after implementing radial access for my interventional procedures. It just worked out perfectly. To offer all patients these benefits, I began using radial access for both coronary and peripheral interventions at about the same time.

By 2014, I was giving presentations at meetings on my belief that all future diagnostic and interventional procedures for vascular disease would be performed using radial access. Large studies have shown significant cost savings and mortality benefits when treating heart attack patients using radial as compared with femoral access.⁵

Can you describe your use of radial access?

Our group in Missoula does more than 95% of our elective and emergent coronary interventions through radial access and occasionally ulnar access. We plan same-day hospital discharge for all patients undergoing elective cath lab procedures.

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“Until I had longer products from Surmodics, it was difficult to reach beyond the proximal SFA.”

I perform 100% of my peripheral angiograms using 5 Fr radial access, including advancement of 150 cm microcatheters selectively into each superficial femoral artery (SFA) for angiography. This allows me to complete digital subtraction imaging below the knee into the pedal arch and tibial circulation with excellent detail of disease and collateral circulation. This is an area you cannot accurately assess with standard CTA or MRA imaging. At present, catheter-based angiography is considered the gold standard for diagnosing infrapopliteal artery disease and designing endovascular treatment strategies for critical limb ischemia patients.⁶

What about radial access for peripheral interventions?

Since converting to radial access, I have treated patients with peripheral disease from a radial approach—anything I can reach. Moving from femoral to radial has been fun, rewarding, and in many cases easier technically, not to mention how beneficial it is for patients. If I plan to reach into the distal iliac and SFA from radial access, often I will go left radial instead of right radial. Left radial access reduces the distance from radial access to target lesions by 10 to 15 cm by avoiding the tortuosity of the right subclavian artery and the need to traverse the transverse thoracic aorta.

Until I had longer products from Surmodics, it was difficult to reach beyond the proximal SFA. Now we're reaching into the

“I think a 5 Fr sheath addresses a big issue with patients of smaller stature, particularly women.”

distal SFA and popliteal. I think we'll be able to reach into the tibial circulation in the near future with longer equipment and guidewires.

Do you still use femoral access for peripheral cases?

Yes, I often use combined pedal and femoral access for critical limb ischemia patients with multilevel disease, including chronic total occlusions (CTOs) and heavily calcified disease. With these procedures, which include femoral puncture, patients remain in our cath lab recovery area for 4 to 6 hours before discharge. This does slow down throughput through the lab and consumes a lot of nursing resources.

It's totally different with radial-to-peripheral procedures. These patients ambulate immediately, walking to the bathroom if they need to with their wrist compression bands on. The bands are routinely removed within 2 hours, and within an hour later these patients are being discharged. Not only is the throughput of those patients much faster, but we can also recover several of these patients with one or two nurses.

You're a strong proponent of using a 5 Fr radial access guide sheath. Why?

I think a 5 Fr sheath addresses a big issue with patients of smaller stature, particularly women. Many Native American, Asian, Hispanic, and elderly women have very small radial arteries. A lot

of operators are reluctant to advance larger 6 Fr guide sheaths through these small radial arteries. They go femoral instead. I've really enjoyed the ability to treat these types of patients from a radial approach using the 5 Fr Sublime™ Guide Sheath. Honestly, I think the Sublime™ Guide Sheath is the best on the market

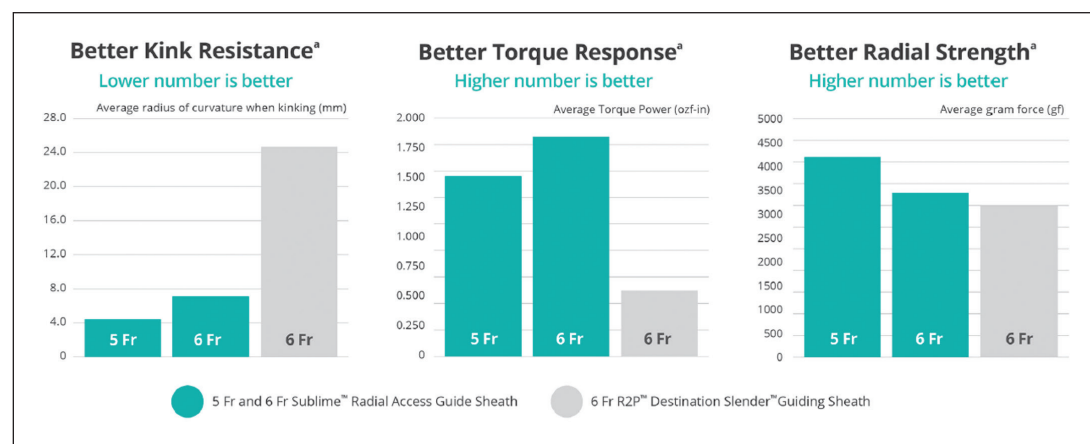


Figure 2. Sublime™ Radial Access Guide Sheath versus competition. Third-party trademarks property of their respective owners.

right now in terms of comfort and safety for these patients.* In my opinion, Sublime™ sheaths also provide the most support and backup needed for reaching through tortuous anatomy to get to more distal disease in the leg (Figure 2).

In your opinion, how big is the need for the Sublime™ 5 Fr sheath?

I think that if you are in a practice where you treat women and elderly patients who are small in stature and you want to avoid risks of femoral access, you're going to want to use the 5 Fr guide sheath in a large number of patients, I would say in a range between 25% and 40%. I'd prefer to do everything 5 Fr with the Sublime™ sheath because it's much more supportive than even the 6 Fr R2P™ Destination Slender™ guiding sheaths (Terumo Interventional Systems) (Figure 2). And I think that using 5 Fr as opposed to 6 Fr does lower radial access site complications.⁷

In addition, the Sublime™ 5 Fr Guide Sheath has a hydrophilic coating along the entire length of the sheath, which makes it very easy to slide through tortuous and calcified anatomy, and dramatically improves the comfort for the patient when you're advancing and removing the sheath.

You mentioned more support with the Sublime™ 5 Fr Guide Sheath compared with the 6 Fr R2P™ Destination Slender™ guide sheath. Can you expand on this?

In my experience, the Terumo 6 Fr R2P™ Destination Slender™ sheath is quite flexible. That makes sense—after all, you need to traverse the tortuous brachiocephalic circulation if you're doing radial to peripheral. But I've found that tortuosity can work against you, as the sheath tends to favor the greater curves of tortuous anatomy, and even accordions sometimes. That leaves you having to navigate more bends in the brachiocephalic and aortic anatomy to get to your target lesions, which takes away your pushability, your deliverability, and actually increases the length of the distance you have to traverse. The Sublime™ Guide Sheath is stiffer and provides better support through tortuous anatomy, so it tends to follow the lesser curves in tortuous aortas and iliac arteries. That's a big plus in my mind.

Do you have any experience with Sublime™ RX PTA Catheters?

I have, yes. They performed excellently. I've already used them for a case where I was treating distal popliteal disease from radial access in a shorter patient.

How do you feel about using a rapid-exchange versus an over-the-wire balloon?

As an interventional cardiologist, I'm mainly using rapid-exchange technology for everything I treat in the coronaries.

"The Sublime™ Guide Sheath is stiffer and provides better support through tortuous anatomy."

I think with the Sublime™ sheath being so supportive, the rapid exchange technology makes sense and works well. It does alleviate some of the difficulties you have with over-the-wire technology when you're going from radial access because, frankly, we just don't have long enough wires.

Do you have any tips for new radial operators?

Many operators have embraced the use of ultrasound of the wrist before making access, given the fact that it speeds time to access, reduces the number of punctures made (single puncture), and reduces risk of spasm and access site crossover.⁸ In our lab, I use ultrasound guidance for radial access in 100% of patients. I can easily image and see the diameter of both the radial and ulnar arteries. It allows identification of diffuse radial artery vascular disease or calcification, as we frequently discover in chronic dialysis patients or patients with type 1 diabetes. We can make an immediate determination from that measurement if 5 or 6 Fr size would be best for the patient.

But I'd like to add something to that. After delivering the radial cocktail through the side arm of a 5 Fr access sheath—a combination of nitroglycerin (200 µg), verapamil (2.5 mg), and heparin (5,000 units)—I immediately do a digital subtraction angiogram of the forearm with 3 to 5 mL of contrast. That's one way to make sure you know the anatomy completely. I was trained to do that, and I've continued to do that routinely for all my patients. There are three things you learn from your forearm angiogram. Number one, you confirm the size of the radial artery, as demonstrated by what your ultrasound showed you. Number two, you exclude any unusual anatomic features of the radial artery, including aberrant takeoffs and radial loops, and confirm you've got three-vessel runoff into the hand through the radial, interosseous, and ulnar arteries. And finally, if there is an access site complication, and these are extremely rare, you know the anatomy, so you know exactly what you're getting into if you have to go brachial or femoral to enter that wrist circulation to address a problem.

Any final thoughts for physicians who are holding back on transitioning to radial access?

At our practice, we always tell patients who are having femoral access procedures that there is a 10% to 15% risk of an access site complication, even with routine use of ultrasound

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guidance. It may be rebleeding, hematoma, femoral artery pseudoaneurysm, prolonged bedrest, or overnight hospital stay. And of course, there's always that very small but important risk of retroperitoneal hemorrhage and fatalities that may result. In my career, since I started doing endovascular procedures in 1992, most of the complication courses that I have attended or spoken at have featured femoral access complications leading to death or other very serious morbidity. I think that using radial access routinely for endovascular procedures really takes away the risk of the majority of access-related complications that all physicians and interventional specialists fear the most. ■

**Sublime™ sheaths feature full-length Serene™ hydrophilic coatings designed to minimize vessel damage and spasm while optimizing trackability through distal tortuosity.*

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Disclosures: Consultant for Medtronic and Surmodics.

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CASE REPORT:

5 Fr Radial Access for Bilateral Iliac Artery Stenting Using the Sublime™ 120 cm Guide Sheath

By Robert Minor, MD

PATIENT PRESENTATION

A woman in her early 60s with a medical history of smoking (former), statin intolerance, and coronary artery disease presented with severe right-greater-than-left buttock and thigh claudication and inability to walk one block. Ankle-brachial index (ABI) showed right ABI of 0.73 falling to 0.59 with exercise, and left ABI of 1.0 falling to 0.85 with exercise.

DIAGNOSTIC FINDINGS

Left radial arterial access was achieved using ultrasound guidance, confirming a small radial artery and necessitating use of 5 Fr catheters. Diagnostic angiography demonstrated isolated and severely calcified bilateral common iliac artery (CIA) disease (Figure 1).

TREATMENT

Using a .035, 300 cm Wholey™ guidewire (Medtronic) advanced into the distal abdominal aorta, the radial access sheath was exchanged for a 5 Fr, 120 cm Sublime™ Guide Sheath that was positioned above the aortoiliac bifurcation. Using a 4.3 Fr, .035, 150 cm Trailblazer™ support catheter (Medtronic), a .014, 300 cm Grand Slam® guidewire (Asahi Intecc) was advanced across the right CIA disease into the superficial femoral artery. A .014, 135 cm Viatrac™ 14 Plus RX 7 X 20 mm PTA balloon (Abbott) was used for predilation of the right CIA disease. Three overlapping .014, 135 cm Herculink Elite® RX balloon-expandable (BE) stents (Abbott; 18 X 7 mm, 18 X 7 mm, and 15 X 7 mm) were deployed to treat the right CIA disease using high pressure inflations to 14 atm (Figure 2). The .014 guidewire was then redirected across the left CIA disease, and predilation was performed with a new Viatrac™ 14 Plus RX 7 X 20 mm PTA balloon, followed by use of a 5 Fr-compatible

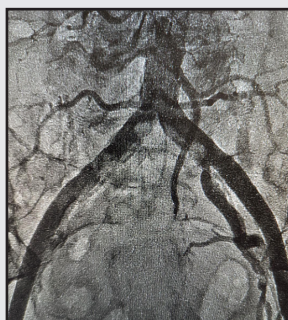


Figure 1. Abdominal aortogram demonstrating calcified bilateral CIA stenosis.

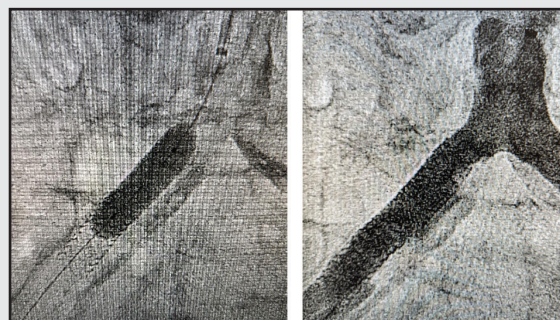


Figure 2. Deployment of overlapping right CIA Herculink Elite® RX BE stent using a .014 guidewire, with subsequent angiogram, through the 5 Fr, 120 cm Sublime™ Guide Sheath.



Figure 3. Predilatation using Viatrac™ 14 Plus RX balloon in the left CIA, with subsequent angiogram after Everflex™ with Entrust™ SE stent deployment using a .014 guidewire, through the 5 Fr, 120 cm Sublime™ Guide Sheath.

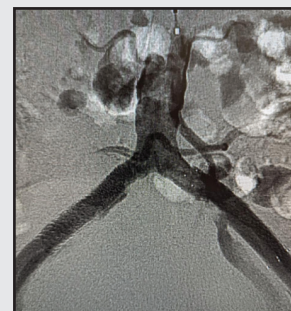


Figure 4. Completion angiogram after bilateral iliac artery stenting using 5 Fr left radial access.

.035, 150 cm OTW Everflex™ 8 X 40 mm self-expanding (SE) stent with Entrust™ delivery system (Medtronic). Final stent deployment was then performed using a Viatrac™ 14 Plus RX 7 X 40 mm PTA balloon at 14 atm (Figure 3). Completion angiography demonstrated excellent results (Figure 4).

POSTPROCEDURE OUTCOME

A TR Band® radial compression device (Terumo Interventional Systems) was used to achieve hemostasis at the radial access site. The patient was discharged 2 hours later. At 3-month follow-up, she reported resolution of claudication symptoms with the ability to walk more than 1 mile. ■

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Tackling CLTI From Alternative Access Sites

A conversation with Imraan Ansaarie, MD.

Dr. Imraan Ansaarie, an interventional cardiologist in St. Augustine, Florida, embraced radial access in 2016 after one of his femoral patients experienced a retroperitoneal bleed. This event inspired him to develop radial techniques even before the introduction of specialized tools designed for radial-to-peripheral procedures. Today, he performs > 95% of his lower extremity arterial and venous cases via radial, ulnar, pedal, or combined forearm-pedal access—an approach he has dubbed *minimal alternative access lower extremity intervention*, or MáLEI.¹ Dr. Ansaarie's passion is treating chronic limb-threatening ischemia (CLTI) while trying to reduce the risk of femoral complications associated with these challenging interventions. We spoke with him about his radial journey and the MáLEI approach.

How do you select lower extremity patients for radial, ulnar, pedal, or a combined radial-pedal approach?

I'm very comfortable doing radial or ulnar access when contrast use is of less concern and I do not have to rely upon intravascular ultrasound (IVUS) completely. However, I also treat many patients with advanced kidney disease, where contrast must be strictly limited. I use mainly IVUS imaging in these patients via pedal access because most CLTI patients need treatment at the popliteal artery or below, and IVUS does not yet reach this far from the wrist. About 30% of our cases are radial only, 35% are combined transradial and transpedal, and 35% are pedal only.

In terms of transradial access (TRA) case complexity, at this point, I've been blessed to have been allowed to perform everything from the wrist—literally. My first TRA intervention was a completely occluded, severely calcified (TASC D) superficial femoral artery (SFA) in a patient with end-stage chronic obstructive pulmonary disease.

Could you describe the hybrid radial-pedal approach?

These tend to be cases with 100% occlusions at the SFA, popliteal, or tibial levels. Let's say I come down from the radial and try to

“My first TRA intervention was a completely occluded, severely calcified (TASC D) SFA.”

cross a popliteal occlusion. The proximal cap may be less favorable to cross (CTOP type III and IV) from above with the tools currently available. I can't get through the true lumen and would like to avoid subintimal dissection at this stage of the procedure. In these cases, I upsize my 4/5 Fr Glidesheath Slender® introducer sheath (Terumo Interventional Systems) to a 5 Fr Sublime™ Radial Access Guide Sheath (Surmodics, Inc.), and then get secondary artery access in the pedal artery, again using a 4/5 Fr Glidesheath Slender® sheath. I cross the lesion from the retrograde approach, and now I'm able to floss the vessel. I can perform an intervention from either direction.

Which patients are not candidates for the radial access (MáLEI) approach?

You may not have a radial or ulnar artery (surgical resection). You could have an asymptomatic radial artery occlusion from a previous TRA procedure with single-vessel runoff to the hand. This is about 5% of our patients. In our practice, I generally avoid TRA in these patients unless the vessel is > 4.0 mm.

We also frequently do tibial-to-tibial interventions in our practice, either from one leg to the contralateral leg or in the same limb from anterior tibial artery to posterior tibial artery or any of the four combinations. One limitation is anomalous anatomy, which can preclude this approach. Like the hybrid radial technique, this approach can be done safely with 4 and 5 Fr access.

Finally, it's possible to have extreme tortuosity of the thoracic aorta or the aortic arch (right radial approach) that precludes you from coming down from above. You may have tried TRA in these situations and have been unable to cross, especially in a thickly calcified lesion that won't give, and the entire system is prolapsing in the ascending aorta. So, you may need closer contact with the chronic total occlusion (CTO), afforded by either antegrade femoral access or by using a contralateral access site.

You've integrated the Sublime™ 5 Fr Radial Access Guide Sheath into your practice. Can you describe how you use it?

When doing infrapopliteal work, I typically don't need a 6 Fr sheath because everything I need to use can go through a 5 Fr system. There's no reason to upsize and put a 6 Fr sheath into a patient. Through the retrograde approach, you can floss the vessel and place your stents if the case is complex. So, the 5 Fr Sublime™ Sheath is my go-to for most infrapopliteal work.

The 5 Fr sheath can be useful even for highly complex cases. For example, for an occlusion in the anterior tibial artery, you insert a Sublime™ 5 Fr Sheath and try to cross the lesion. If it's a heavily calcified lesion, you may want to perform an orbital atherectomy and prolonged balloon angioplasty. Even so, the result may not be desirable due to dissection or suboptimal balloon expansion. In that case, I would put in a 5 Fr sheath from the pedal access site and place a small coronary stent. Then I'm done, with two small 5 Fr holes—nothing to get upset about and very easily manageable.

Has the Sublime™ 5 Fr Radial Access Guide Sheath allowed you to expand the range of patients you feel comfortable treating from the radial approach?

Yes, absolutely. It's made things safer for my elderly female patients with smaller access sites. With every French size increase, irrespective of whether you're in the radial, pedal, or femoral artery, you're increasing the risk of a complication²—my mentors, Drs. Tanvir Bajwa and Suhail Allaqaband, always reminded me that smaller French sizes improve procedural outcomes. So, why not follow this advice if I can do all my work through a 5 Fr system?

I have many female patients who have smaller-size radial arteries. For example, instead of having a 2.7 mm radial artery, it may be 2.5 mm. In that case, I'm a little nervous about using a 6 Fr sheath. With a 5 Fr sheath, I'm not as worried. Female patients are already at a higher risk of major vascular complications.³ It is paramount to keep your access size as small as possible.

In a study you published in 2021,¹ you found considerable cost savings associated with using TRA compared with transfemoral access (TFA) in a hospital setting. What were the main drivers of those savings?

My intent with that paper was to clear up some misunderstandings that may have stood in the way of adopting the M^áLEI approach.

"The 5 Fr Sublime™ Sheath is my go-to for most infrapopliteal work."

Some felt this approach consumed more resources than the standard femoral approach or might lead to worse outcomes, either access site complications or strokes. But the most important misunderstanding was crossover, the perception that > 70% of cases needed to be changed over to femoral access.

We felt that if you manually remove a 6 Fr sheath after a TFA procedure, there are 6 hours of bed rest followed by 1 to 2 hours of ambulation before you can consider discharging the patient. In our experience, with TRA, patients walk right from the table, even after full anticoagulation, and most can be discharged within 2.5 hours.

In the study, our reported median time to discharge for TRA was longer than 3 hours, but it was still 5 hours less than for TFA (6.6 hours [IQR, 5.3-7.2 hours] vs 11.6 hours [IQR, 6.9-28.3 hours]; $P = .43$). The equipment cost was higher for TRA, but savings in total hospital duration more than made up for this. However, the most important finding was that 100% of the patients could be treated with single or dual access without femoral access. In an outpatient setting, given the need for discharge efficiency, this could be reduced to under 2.5 hours with no groin precautions. And no concern or worry about post-procedure hypotension due to femoral access complications. The peace of mind this brings is priceless.

You mentioned long discharge times for TFA patients. Don't vascular closure devices significantly reduce time to ambulation?

Yes, and we use these when we need to use femoral access in an antegrade fashion; it does help facilitate early ambulation. But it's important to remember that patients undergoing endovascular procedures typically have had prior procedures, sometimes repeatedly. Their arteries are often smaller and calcified, and there can be a lot of scar tissue and pathology in their groins. Vascular closure devices still have about an 8% to 9% risk of failure,⁴ and some of these failures can be catastrophic. You can manage these severe complications on an outpatient basis with additional procedures and resources, but at times these patients may need surgical rescue.

How do you train new operators in the M^áLEI approach?

First, I would focus on radial access instead of tibial access. For me, there's no question that if the radial or ulnar artery is appropriate, it is much easier to access and an easier procedure than tibial access. Tibial access has its nuances. Radial access is preferable to ulnar, especially if the size of the vessels is the same.

For TRA, I advise beginning with 4 Fr peripheral angiograms. First, you need to be comfortable using ultrasound for all your access—as Dr. Jihad Mustapha says, it's one of your most important tools. If the radial artery is > 2.8 mm on ultrasound assessment, you can be very comfortable doing a

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“It is paramount to keep your access size as small as possible.”

peripheral angiogram and intervention of the lower extremity. In my experience with 450 cases, the risk of sheath-related complications is under 0.5%. Then, you achieve access using ultrasound guidance, a 21 gauge needle, a .018 wire, and a short 5 Fr, 11 cm access sheath. With your sheath in, give heparin and get a radial and brachial artery angiogram. This will help you if you have an anomalous radial artery takeoff. Next, place a 4 Fr pigtail catheter over the .035 Bentson wire and go down into the descending aorta. A 125 cm catheter will get you halfway into each of the iliac arteries, and then you can image the runoff to the legs individually. About 95% of the time, these few things will get you through the first few steps of MÅLEI.

We advise people to begin by first obtaining about 30 peripheral angiograms of the lower extremity using the radial artery. Your staff will become comfortable knowing how to set up the room, how to help you get access, remove the sheath, and so on.

Peer-to-peer training is essential for getting a radial program started. An excellent example is the radial program headed by Dr. Babar Ali in Washington, DC. Dr. Ali was very interested in learning the MÅLEI technique, so 4 years ago I traveled to DC and proctored him and his staff. Today he's proficient with radial and pedal access and is a dedicated minimal-alternative-access practitioner.

How do you advise moving on to interventions?

You should start with your “chip shot” cases. For me, the chip shot would not be a long CTO (failed multiple times), calcified and long type B or C lesions, or one-vessel runoff. It's a matter of learning how to finagle your wires and catheters, which are longer than normal. We have now been fortunate enough to have completed 450 cases over 5 years, using all kinds of wires and catheters, so we have developed our own best practices.

For mid-to-distal occlusions in the SFA, particularly in a taller patient (> 6 ft 2 inches) with a very heavily calcified lesion, there's no question that there are limitations as to the tools available

today, as Dr. Craig Walker will attest. For example, due to length limitations, IVUS and certain atherectomy and laser systems cannot be used; however, you can utilize orbital atherectomy, stents, and drug-coated balloons.

Can you tell us about your experience with Sublime™ Radial Access Platform?

I'm a huge fan of the Sublime™ 5 Fr longer sheaths (120 or 150 cm). At this point, they're the only commercially available 5 Fr radial-length sheaths. I can safely use the Sublime™ 5 Fr Guide Sheath for most infrapopliteal work. If you have extreme tortuosity (ie, the aorta is tortuous and it is a difficult lesion), and you suspect you need a system with heavier body, a 6 Fr system might be necessary to give you steadier engagement, but the 5 Fr sheath works just fine most of the time. I believe a lot more patients would get treatment via TRA if the 5 Fr sheath were being used more widely and in a safe fashion.

We have also done a lot of work from the wrist using the 250 cm Sublime™ RX PTA Dilatation Catheter, especially in the dorsalis pedis and the common plantar or the lateral plantar branch. That 250 cm is a great length for me. I love it because it's long enough to reach into the foot, but it's not so long that half of the device is hanging off the back of the table. Using this balloon, I've been able to go down into the lateral or the medial plantar artery at the bottom of the foot or close to the digital branches. ■

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CASE REPORT:

Successful Three-Vessel Below-the-Knee Intervention From the Left Radial Artery Using a 5 Fr, 150 cm Sublime™ Guide Sheath

By Imraan Ansaarie, MD

PATIENT PRESENTATION

An 82-year-old female was admitted to the hospital for chronic nonhealing wounds on both heels.

DIAGNOSTIC FINDINGS

Bilateral lower extremity angiogram showed a subtotal occlusion of the tibioperoneal trunk (TPT) and a completely occluded posterior tibial (PT) artery (Figure 1).

TREATMENT

A 5 Fr introducer sheath was placed in the left radial artery using ultrasound guidance and a radial cocktail was delivered. A pigtail catheter was then inserted and advanced to the iliac bifurcation via a .035 wire. Bilateral lower extremity runoff was performed, whereupon the decision was made to treat the left lower extremity because ulceration of the left heel appeared slightly worse than on the right. Using a .035 guidewire placed in the popliteal artery, the 5 Fr introducer sheath was exchanged for a 5 Fr, 150 cm Sublime™ Guide Sheath (Figure 2), which was advanced into the left mid SFA. A .014 guidewire and a 2.5 X 150 mm PTA balloon catheter on a 200 cm shaft were used to cross the lesion in the TPT and were placed in the distal peroneal artery. Orbital atherectomy using a 1.25 mm device was performed in the TPT and peroneal artery (Figure 3), followed by balloon angioplasty. Using the same technique, the lesion was crossed in the anterior tibial (AT) artery and the PT artery, and angioplasty was performed in the proximal, mid, and mid-to-distal sections (Figure 4). The procedure required 50 minutes of fluoroscopy.

POSTPROCEDURE OUTCOME

The final arteriogram revealed 2.5-vessel runoff to the left foot with adequate perfusion of the heel (Figure 5). ■

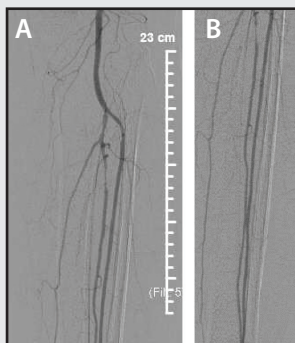


Figure 1. Diagnostic angiogram revealed subtotal occlusion of the TPT (A) and a completely occluded PT artery (B).

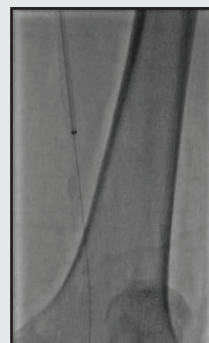


Figure 2. 5 Fr, 150 cm Sublime™ Guide Sheath.



Figure 3. Orbital atherectomy of TPT and peroneal artery.

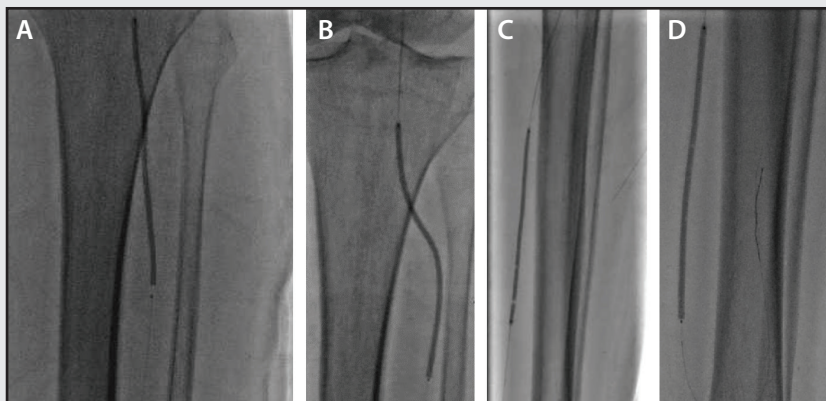


Figure 4. Balloon angioplasty of TPT and peroneal artery (A, B), AT artery (C), and PT artery (D).

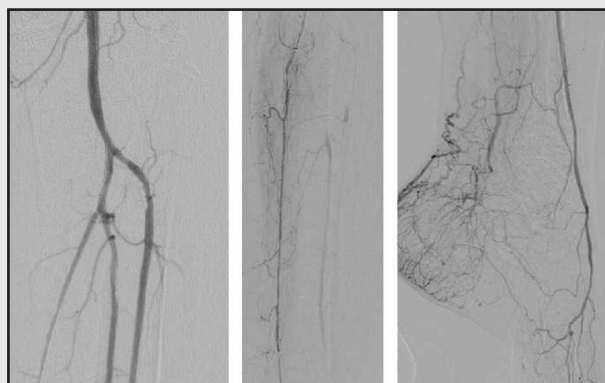


Figure 5. Final arteriogram revealed adequate perfusion of the heel.

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Drivers of Radial-to-Peripheral Adoption in Real-World Practice

A conversation with Mac Ansari, MD.

Interventional cardiologist **Dr. Mohammad (Mac) Ansari** is Vice Chair of Clinical Research and Director of the Catheter Lab and Structural Heart Program at the Texas Tech Physicians Center for Cardiovascular Health in Lubbock, a tertiary care facility with a large catchment area. As with many hospitals, the onset of the COVID-19 pandemic led to a critical shortage of beds at the Texas Tech center and severe restrictions on patient admissions. As a result, the facility was forced to halt many peripheral artery disease (PAD) cath lab procedures, even among patients requiring time-sensitive treatment for chronic limb-threatening ischemia (CLTI). To meet the crisis, Dr. Ansari and his team made a rapid pivot from transfemoral access (TFA) to transradial access (TRA) endovascular treatment for PAD. In a preliminary analysis published in the *Journal of Critical Limb Ischemia*,¹ Dr. Ansari and colleagues documented high rates of procedural success with TRA and decreased procedure time, radiation exposure, and contrast use for TRA compared with TFA. We spoke with Dr. Ansari about his experience adopting TRA for peripheral procedures.

The COVID-19 pandemic upended health care everywhere, but seemed especially disruptive for your CLTI patients. Why was that?

Our patient population is largely rural. During COVID, many of the smaller centers in our region ended up closing and all their patients were coming to us. When you have patients coming in from far-off locations, we don't discharge them on the same day if they've received a femoral access procedure—if they go back and experience a bleed, they could be in serious trouble. So, I had to come up with a strategy that would allow us to do these procedures safely without having to keep patients overnight.

"I had to come up with a strategy that would allow us to do these procedures safely without having to keep patients overnight."

Were you using TRA for peripheral procedures before the pandemic?

Yes, I was doing some radial-to-peripheral, but it really picked up during COVID. My aim was to make sure patients who most needed procedures based on their disease patterns could get basic flow restoration done quickly, with same-day discharge. From the wrist, we found we could treat iliac, common femoral, SFA (superficial femoral artery), popliteal, and even proximal-tibial segments. Radial-to-peripheral turned out to be a very safe, approachable, and feasible option that enabled me to take care of my patients in this complex situation without worrying about groin access and bleeding issues. Amazingly, it helped all those patients waiting for procedures to get their procedures done.

Undoubtedly, establishing a radial-to-peripheral program required support from your colleagues and the hospital. What benefits were you able to show them?

Fortunately, we've been collecting data on all patients who have undergone peripheral interventions via TRA at the Texas Tech University Medical Centers in our Lonestar PAD registry. So, we're able to support the safety and efficacy of the transradial approach with data. Last March, we published a pilot study of 184 TRA procedures conducted between April 2018 and October 2022 that showed that TRA decreased perioperative times, contrast use, and radiation exposure compared with TFA in peripheral interventions.¹

“Patients get mobilized quickly and are able to leave the hospital quickly.”

In the May 2023 paper, you describe the potential for cost reduction and increased hospital efficiency for peripheral procedures performed with TRA compared with TFA. How can TRA reduce cost?

From the hospital perspective, there are two ways. For one, our radial access procedures have same-day discharge, so there's cost reduction for individual patients. Patients get mobilized quickly and are able to leave the hospital quickly. But same-day discharge also frees up a bed that can be used for another patient. Same-day discharge has been the main driver of cost savings for transradial coronary interventions, and there's no reason to think this would be different for peripheral interventions.²

There's also a reduction in access site complications with TRA. This has been demonstrated repeatedly in the coronary space and is supported by data on peripheral patients.^{3,4} Beyond that, there are substantial benefits in increased patient and staff satisfaction, both of which are extremely important to hospitals, especially now. Our patient satisfaction scores have increased significantly with TRA adoption.

You mentioned staff satisfaction. How has radial-to-peripheral made a difference here?

In the past, our lab staff were typically not too happy having to do lower extremity cases because these cases took longer than the coronary cases. Similarly, the holding area staff, who are responsible for postprocedural care, disliked groin access cases—the length of recovery, need for close observation, and the inevitable complications. We've been able to reduce procedural as well as discharge time using TRA, and our employee satisfaction scores have improved.

This is very important, since staff fatigue and turnover have plagued hospitals in recent years. Every facility, including ours, really cares about staff satisfaction these days. Whenever you lose an employee it's very expensive and time-consuming to fill the position and provide training for a replacement.⁵ ■

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Disclosures: Advisory board member for Boston Scientific Corporation, Cordis, Medtronic, and Recor Medical; steering committee member for Philips; consultant for Abbott, Bard, Boston Scientific Corporation, Cordis, CSI, Edwards Lifesciences, Gore & Associates, Medtronic, Surmodics, and Terumo; conducts research trials with Abbott, Alleviant, Ancora Heart, Boston Scientific Corporation, Gore & Associates, MedAlliance, Microport, Norvartis, PQ Bypass, Recor Medical, Reflow Medical, Reva Medical, and Terumo; receives foundation grants for CH Foundation.

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CREATING A RADIAL REVOLUTION

The Sublime™ Platform brings a new level of performance to transradial peripheral interventions above and below the knee.

Sponsored by  

A Meeting of Radial Revolutionaries

For a select group of radial-to-peripheral pioneers, September 11-12 marked a turning point.

From 2007 to 2018, United States coronary procedures via radial access surged from 1% to 50%,^{1,2} driven by evidence demonstrating greater patient safety compared with the femoral approach.³ Now, devoted “radial revolutionaries,” equipped with a growing toolkit, are poised to drive rapid adoption for radial-to-peripheral procedures on behalf of their patients. But first, they need to band together and spark a movement.

That was the message from the course directors and guests at the first Radial Revolution conference, held September 11-12, 2023, in Minneapolis, Minnesota. The event, sponsored by Surmodics, brought together radialists from across the country for 2 days of case sharing (including live cases, next page) and intensive interaction on best practices.

Underlying the informal meeting was a tangible sense of urgency. “There are few technologies out there that save lives,” said Dr. Imraan Ansaarie of St. Augustine, Florida. “We all know that groin complications can result in mortality. That, to me, means the world—if one life is saved because we did a radial case rather than a groin case.”

Addressing fellow radialists, he said, “We are a community and we have to stick together.”

MAKING HISTORY

In opening remarks, Course Co-Director Dr. Paul Michael of Boynton Beach, Florida, urged physicians to make history together by taking ownership of the radial-to-peripheral movement to benefit patients and advance the field of peripheral vascular interventions.

“How many of you remember controversies in spaces like carotid, bypass, PCI, ultrasound versus fluoro guidance, to do CTO intervention or not?” Dr. Michael said. “Do you know what these controversies were really about? Not being able to have a conversation. That’s what this movement is about.”

JOIN THE MOVEMENT

Surmodics is dedicated to supporting the Radial Revolution for peripheral interventions. Visit www.radialrev.com to register for upcoming #RadRev case-presentation webinars, regional peer-to-peer training, #RadRev regional meetings, and the September 2024 Radial Revolution event. Physicians, nurses, technicians, and all others interested in learning about radial-to-peripheral advancements and best practices are encouraged to participate.

“Radial is not just an access point for us.”

—Ankur Lodha, MD,
Course Co-Director



Sparking a movement. Radial-to-peripheral revolutionaries in attendance included (back row, left to right) Dr. Imraan Ansaarie, Dr. Babar Ali, Dr. Tariq Siddiqui, Dr. Ankur Lodha, Dr. Abdul Saadi; Dr. Paul Michael, Dr. Sameh Sayfo; (front row, left to right) Bob Kelly, David Cook, Merikay Campbell, Dr. Rakesh Shah, Dr. Sneha Kolla. Not pictured: Dr. Pradeep Nair, Dr. Ramzan Zakir, Dr. Mac Ansari.



Patients have their say. The Radial Revolution event kicked off with a video of patients who had experienced femoral access advocating for the radial approach.

GOING BELOW THE KNEE—WITH CONFIDENCE

The event's live cases demonstrated the capabilities of today's radial-to-peripheral toolkit for successful treatment above and below the knee.

In the first live case, broadcast from the Cardiovascular Institute of the South (Houma, Louisiana), Course Co-Director Dr. Pradeep Nair performed a transradial case—from access to closure—involving delivery of a radial cocktail followed by revascularization of the mid-superficial femoral artery using intravascular ultrasound imaging, laser atherectomy, and balloon angioplasty.

The second, more challenging case demonstrated successful tibial revascularization from a radial-only approach. The patient was a 67-year-old woman (diabetic) with ischemic rest pain and healed foot ulceration. After experiencing femoral access for a prior coronary procedure, the patient requested that radial intervention be attempted for her lower extremity procedure.

Diagnostic imaging from the radial approach revealed patent superficial femoral, popliteal, and peroneal arteries with total occlusion of the anterior tibial (AT) artery and tight stenosis of the posterior tibial (PT) artery (Figure 1). Dr. Nair used a Sublime™ .018, 200 cm RX Microcatheter (Surmodics, Inc.) to facilitate guidewire placement through the stenosed PT to the foot (Figure 2), with subsequent PT balloon angioplasty using a Sublime™ .018, 220 cm RX Balloon Catheter (Figure 3) to restore PT blood flow (Figure 4). Dr. Nair later used a .014, 250 cm Sublime™ RX Balloon Catheter to perform angioplasty in the occluded AT artery (Figure 5). The postprocedure angiogram revealed widely patent three-vessel runoff to the foot (Figure 6).

Commenting on the case, Dr. Sameh Sayfo of Plano, Texas, said, “This patient has a complex history and the best option for this patient, or maybe the only option for this patient, was radial to peripheral.”

“The crossing catheter is a game changer,” said Dr. Babar Ali of Washington, DC. “Before we had it we couldn't do these total occlusions from above.” ■



Figure 1. Diagnostic imaging from the radial approach revealed patent superficial femoral, popliteal, and peroneal arteries with total occlusion of the AT artery and tight stenosis of the PT artery.



Figure 2. The Sublime™ .018, 200 cm RX Microcatheter facilitates guidewire placement through the stenosed PT to the foot.



Figure 3. PT balloon angioplasty using a Sublime™ .018, 220 cm RX Balloon Catheter.

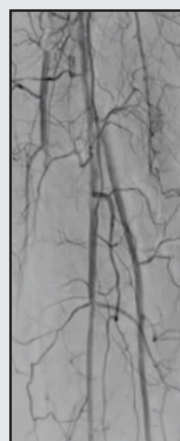


Figure 4. PT blood flow restored.



Figure 5. Angioplasty performed with a .014, 250 cm Sublime™ RX Balloon Catheter in the occluded AT artery.



Figure 6. Postprocedure angiogram revealed widely patent three-vessel runoff to the foot.

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Attend the September 2024 Radial Revolution Educational Event



#RADIALREV

The event: expert operators, live cases

Let's jump-start your radial program! We've put together an intensive course for physicians and their teams on best practices, tools, and tips for accelerating the successful adoption of radial-to-peripheral interventions. We'll review live cases and provide peer-to-peer training based on our experience with thousands of transradial peripheral procedures. By attending, you'll join a network of like-minded physicians who will support each other through the radial journey and work together to build public awareness of the benefits of this approach.

Reserve a spot now for you and your team to join us for live cases and peer-to-peer discussion at our next event in September 2024. Register now at www.radialrev.com.



Register for the September 2024 #RadialRev event at www.radialrev.com

Watch now: See what it means to be a part of this movement. qrco.de/radialrevvideo



2023 RADIAL REVOLUTION ATTENDEES

Attend a Radial Education Program

Surmodics is pleased to offer multiple education programs throughout the year. Visit sublimeradial.education to learn more and register for an event.

UPCOMING CLASSES

January 15 – 16, 2024

Pradeep Nair, MD Interventional Cardiology
Cardiovascular Institute of the South – Gray, LA

February 25 – 26, 2024

Ankur Lodha, MD Interventional Cardiology
Cardiovascular Institute of the South – Lafayette, LA

What Patients Are Saying

Meet Diane



"It's a new life"

Diane, an active church member who is constantly on the go, was delighted with the comfort of her radial-to-peripheral intervention to treat peripheral artery disease and how quickly she was able to get back to doing the things she loves.

Spreading the news about radial access

Don, a golf enthusiast and grandpa who has had previous femoral access interventions for PAD, "couldn't believe" the improved comfort of his radial access procedure to treat his peripheral artery disease.

Meet Don



Meet Richard



Getting back to woodworking

Richard, a master wood craftsman, experienced such pain from PAD that he couldn't make it out to his woodworking shop. His radial-to-peripheral procedure helped him get back to the joy of his life.

Back on the golf course

Robert, an avid golfer who has experienced multiple femoral access interventions and associated complications to treat his peripheral artery disease, was told he should consider playing cards instead of golf. A day after his radial access procedure he was back on the golf course.

Meet Robert



Disclaimer: Radial access is not for everyone, and results may vary. These testimonials are not a substitute for medical advice.

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.

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 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; RapidCross™ 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; Crosstella® 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; Crosstella® 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; Crosstella® .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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Sublime™ .014, .018, and .035 Microcatheters

INDICATIONS FOR USE

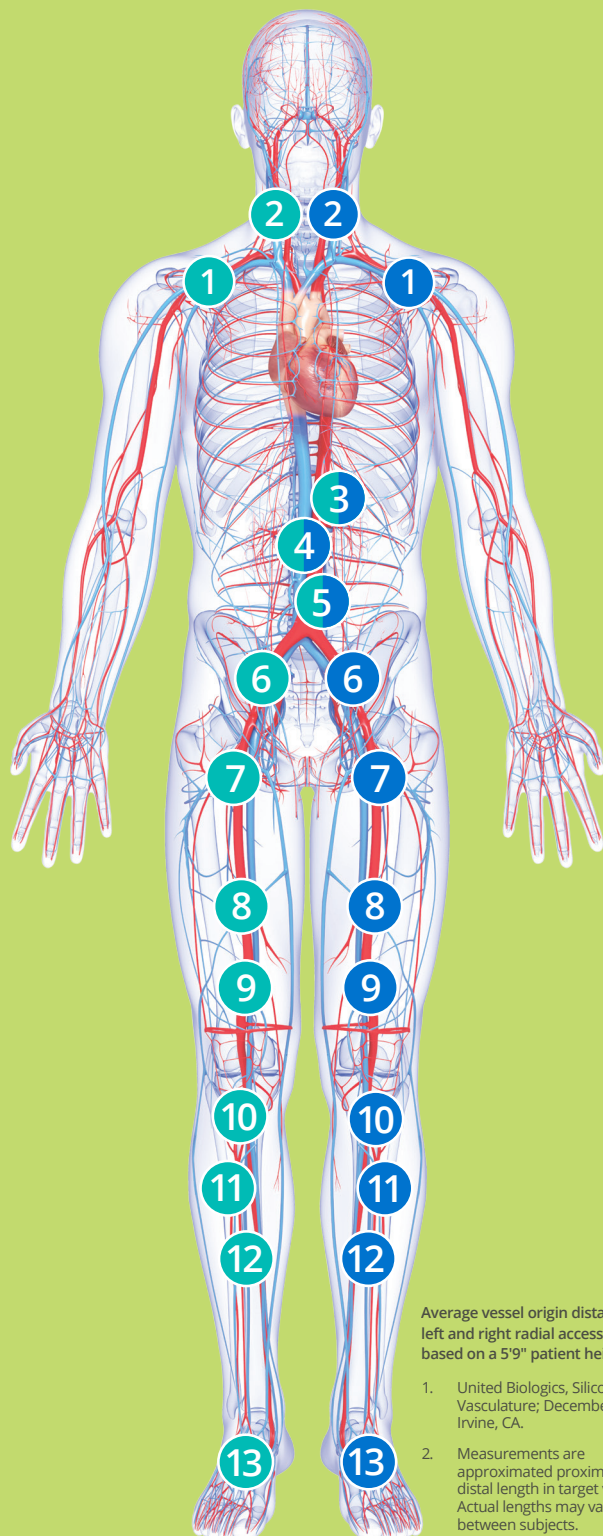
The Sublime™ Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime™ Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

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Radial Access

Artery Distance



Average vessel origin distance from left and right radial access sites based on a 5'9" patient height.^{1,2}

1. United Biologics, Silicone Vasculature; December 2022; Irvine, CA.
2. Measurements are approximated proximal-to-distal length in target vessels. Actual lengths may vary between subjects.

| RIGHT Radial Access | | LEFT Radial Access | |
|---------------------|---------------------------|---------------------------|---|
| Subclavian | | | |
| ① | 45 cm | 45 cm | ① |
| Common Carotid | | | |
| ② | 65 cm | 75 cm | ② |
| Renal | | | |
| ③ | 100 cm | 90 cm | ③ |
| Superior Mesenteric | | | |
| ④ | 92 cm | 82 cm | ④ |
| Inferior Mesenteric | | | |
| ⑤ | 105 cm | 95 cm | ⑤ |
| Common Iliac | | | |
| ⑥ | 120 cm | 110 cm | ⑥ |
| Common Femoral | | | |
| ⑦ | 135 cm | 125 cm | ⑦ |
| Superficial Femoral | | | |
| ⑧ | 140 – 160 cm ² | 130 – 150 cm ² | ⑧ |
| Popliteal | | | |
| ⑨ | 165 cm | 155 cm | ⑨ |
| Anterior Tibial | | | |
| ⑩ | 180 – 200 cm ² | 170 – 190 cm ² | ⑩ |
| Posterior Tibial | | | |
| ⑪ | 180 – 200 cm ² | 170 – 190 cm ² | ⑪ |
| Peroneal | | | |
| ⑫ | 180 – 200 cm ² | 170 – 190 cm ² | ⑫ |
| Plantar Arch | | | |
| ⑬ | 230 cm | 220 cm | ⑬ |

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