PANEL DISCUSSION

Must-Haves and Wishlists for BTK Devices

Experts weigh in on device limitations, imaging gaps, and the future of innovation in the below-the-knee space.

With Marianne Brodmann, MD; Yann Gouëffic, MD, PhD; and Michael C. Siah, MD

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When you have a device-related shortcoming (ie, less than a failure), in which phase of a case does it most commonly occur—access, crossing, vessel prep, or primary therapy deployment?

Prof. Gouëffic:

- **Access:** Thanks to the use of duplex ultrasound–guided puncture, technical success in access is high and failures are rare. In routine practice, I prefer an ipsilateral access via the common femoral or superficial femoral artery.
- **Crossing:** Crossing failures can be related to either the guidewire or catheter. Sometimes, the guidewire can cross the lesion, but the catheter cannot. In such cases, various techniques can be used to enable catheter crossing, such as the PIERCE technique, atherectomy, or laser. However, the most common issue remains guidewire crossing failure. Today, many guidewires are available for below-the-knee (BTK) procedures, increasing the chances of successfully crossing lesions. Additionally, the retrograde approach offers another opportunity for success.
- **Vessel preparation/definitive treatment:** Plain old balloon angioplasty is usually sufficient for good vessel preparation and definitive treatment, but shortcomings still occur, such as thrombosis, dissection, residual stenosis, embolism, or spasm. Recently, I encountered a spasm after percutaneous transluminal angioplasty of the fibular artery for a long chronic total occlusion. In this case, no additional device was needed, just a vasodilator (verapamil hydrochloride) and time to achieve a good result. In other cases, bailout stenting may be required to address flow-limiting dissection or acute thrombosis. To answer the initial question, I would say that the most critical phase remains vessel preparation/definitive treatment, both in terms of intraoperative results and long-term outcomes.

Prof. Brodmann: The most common scenario of a device-related shortcoming in BTK disease is the vessel prep scenario. Vessel recoil in these small-caliber, extensively diseased arteries is so common and very often underdiagnosed. Another issue is that dissections are not recognized. New innovations in this field are much needed.

Dr. Siah: Fortunately, I don't really come across this problem often, but when it arises, I think the Achilles heel of all endovascular interventions is the ability to deliver the technology across the lesion. Often, factors like tortuosity and calcium are the biggest barriers to therapeutic device delivery. These new technologies are well engi-

neered—they are hydrophilic, and shaft lengths are long enough and small enough to overcome most anatomic challenges we face. Despite this, we all have been in the scenario where we've crossed a lesion with a wire, but nothing else will go! We often rely on less elegant solutions to overcome this, like using small coronary balloons to sequentially dilate from a top-down approach, externalizing our wires and pulling really hard, or even using needles to pierce the plaque in an attempt to disrupt the lesion to facilitate balloon crossing. While these can work, and ultimately lead to definitive treatment, they can cause problems that directly affect procedural outcomes.

What are your biggest wishlist items when you think of imaging capabilities?

Dr. Siah: When I compare my pre- and intraprocedural use of imaging to my partners who do a lot of aortic surgery, I would definitely say that they use imaging in a much more sophisticated way than I do. They extensively plan their procedures long before the patient gets to the operating room—they pick their devices, plan how they may fabricate them, identify potential intraprocedural challenges, and plan accordingly. In the operating room, they use on-table image overlays and FORS (Fiber Optic RealShape, Philips) routinely. This imaging-based strategy has been shown to decrease procedure time and radiation exposure, which ultimately has really changed the way they practice. When it comes to my chronic limb-threatening ischemia (CLTI) interventions, these patients generally have worse kidney function, so I do not routinely obtain cross-sectional imaging with contrast and rely almost exclusively on my physical exam and arterial noninvasive testing. Ultimately, my angiographic findings and intravascular ultrasound (IVUS), coupled with wound location information, inform how I treat my patients. The use of IVUS can certainly affect my treatment decisions as well, but ultimately, I would love for imaging to not only provide anatomic information but also inform me on which devices I should use. Will this lesion respond well to a certain type of atherectomy, will drug-coated technologies work well, am I at risk of embolization, and how long will this lesion remain patent? I think if we had granular outcome-related expectations based upon imaging, it would revolutionize the way we all approach CLTI patients.

Prof. Brodmann: In the preoperative phase, I'd want really good, advanced CT or MRI, ideally with artificial intelligence support, so I can fully understand the vessel anatomy and what the lesion is made of. Then during the procedure, I would want to rely on imaging to help guide me in real time, so I can navigate confidently and clearly see what still needs to be done.

Prof. Gouëffic: The primary goal of imaging is to assess intraoperative technical success. This can be done by evaluating lumen narrowing using various imaging modalities, such as near-infrared light (optical coherence tomography) or IVUS. Imaging can also assess flow using fractional flow reserve or quantitative flow ratio. However, intraoperative imaging should not be limited to technical success. Many other factors can influence patient outcomes, including major amputation, survival, and target limb reintervention. Imaging could also help determine which arteries to treat and how many. Currently, intraoperative imaging support is lacking.

How would you view the current state of innovation in the BTK setting? Are we in a time of advancement or somewhat stalled on meaningful breakthroughs?

Prof. Gouëffic: In terms of devices, there are many innovations in drug and scaffolding technologies. Robust data have been published on bioresorbable scaffolds (BRS) for simple lesions, but these should also be evaluated for more complex lesions (eg, calcified or longer). Limus-based devices have already been investigated or are currently under investigation. It is important to note that limus-eluting, balloon-expandable stents have shown superiority in terms of patency and reintervention rates compared to bare-metal stents for short BTK lesions.[1-3] Currently, some limus-coated balloons are being studied for patients with BTK disease.

Innovative alternatives to direct revascularization have also been developed. Although gene or cell therapy has not shown favorable outcomes, percutaneous deep vein arterialization (DVA) has shown promising results. However, there is still room for improvement in determining the quality of revascularization during the procedure. Various modalities exist to monitor intraoperative tissue oxygen levels, such as injectable tissue-integrated biosensors or two-dimensional (2D) perfusion angiography. So far, the evidence is limited and does not support routine use of these devices in daily practice.

Prof. Brodmann: In my opinion, this is really where the focus of innovation is right now. Even though we're dealing with the most challenging patients (CLTI) and the most difficult vessel territory (BTK), we're still seeing meaningful progress, which is encouraging and moving us in the right direction. I think one misconception we still hold onto is expecting the same kind of large trials and outcomes we're used to from the femoropopliteal and intermittent claudication space. In reality, we should appreciate the progress we're seeing in smaller studies, because they are pointing us in a promising direction.

Dr. Siah: It is an incredible time to be a CLTI interventionalist. There are so many devices and tools that have become available or are on the near horizon; it feels like we are in a moment of rapid advancement in our ability

to deliver better care to our patients. The success of the LIFE-BTK trial has certainly been fantastic, not only for our patients but also for emerging technologies in the BTK space. We finally have, in the BTK space, the highest level of evidence demonstrating that percutaneous transluminal angioplasty is no longer the gold standard, and apart from the results of that trial, we are more aware of the limitations of this standard angioplasty, primarily related to poor medium- to long-term outcomes due to dissection and recoil.[4] I'm excited for all the new tools.

What do you view as the biggest hurdles in BTK device innovation, getting from concept to case-ready?

Dr. Siah: What we've seen historically is that innovating in the BTK space is incredibly challenging. There have been a variety of failed device trials aiming at improving outcomes for these lesions. I think that's a product of the nature of BTK, which often is home to long lesions of tapering diameters, as well as the fact that these trials are conducted in CLTI patients with a host of comorbidities that inherently increase mortality. Separating the device and outcomes related to the intervention in patients with advanced chronic kidney disease, end-stage renal disease, coronary artery disease, or congestive heart failure presents unique challenges not necessarily seen in patients with aortic disease or less severe types of peripheral artery disease.

Another great example of a fantastic concept in the BTK space that stumbled after commercialization was the Tack endovascular system (Philips). I remain a huge fan of the device—a purpose-built tool with adaptable sizing to address dissections! But despite great data, some users found its deployment to be challenging, so much so that it eventually was removed from the market. So, beyond the challenges that innovators and companies have to overcome to bring a technology to market, this is a great reminder that even fantastic technologies still need to be overwhelmingly user-friendly to remain available.

Prof. Gouëffic: These questions might be better answered by engineers! From a physician's perspective, the main challenges include the amount of calcification, the length of lesions, and the small, variable diameters of the vessels. Assessment is also difficult due to patient comorbidities (infection, diabetes, renal failure).

Prof. Brodmann: The biggest hurdle is that we evaluate new devices for BTK interventions with the same endpoints we used for claudicants and the above-the-knee space. BTK arteries are different, and so is the CLTI patient cohort.

When facing severe BTK calcification, what is the most significant unmet need in your armamentarium?

Prof. Brodmann: I would love to have the ultimate best vessel preparation tool for highly calcified, small vessels.

Prof. Gouëffic: Calcification can certainly compromise the quality of vessel preparation, but perhaps the most frustrating situation is when the guidewire crosses the lesion but the catheter cannot. Techniques like the PIERCE technique or laser can be used in such cases, but further progress is needed to address this issue effectively.

Dr. Siah: The factor that makes BTK calcification challenging is that you cannot consistently predict when calcium will make a case more challenging. There are scenarios where you anticipate a very tough case, such as a small patient with long-standing, poorly controlled diabetes and end-stage renal disease with extensive tissue loss and cross-sectional imaging where it looks like the entire length of all the BTK vessels are stented. But sometimes you get into the case and lesion traversal is easy, device delivery happens without any problems, and you blast through the case without any hiccups. Other times, you encounter a short, seemingly straightforward calcified lesion and it doesn't matter what you do, what tools you use, which direction you come from; you simply can't cross, or even if you are able to, you cannot deliver a therapy across the lesion. I think, if there was a way to consistently predict which lesions are going to be uncrossable or impossible to delivery therapy through, that would be fantastic for both patients and operators.

What are your "must-haves" in a BTK scaffold? What are your "would-love-to-haves"?

Prof. Gouëffic: Since BRS are not yet available in France, coronary drug-eluting stents are currently the "must-haves." Although they are used sparingly, they remain essential for treating short, proximal BTK residual stenosis, dissection, or occlusion. The arrival of BRS is highly anticipated.

Dr. Siah: It's funny, we only recently have gotten our hands on a BTK scaffold, but almost immediately, we've identified its shortcoming, which is primarily scaffold length. Oftentimes, I'm treating tibial lesions 20 to 35 cm in length, and these vessels often taper from 4 to 2 mm in diameter. Given these long lesions with tapering anatomies, no single scaffold is going to be able to address this. That being said, I would love longer scaffolds that have the ability to adaptively size to the tapering nature of BTK vasculature, while at the same time maintain flexibility and crush resistance to handle the natural motions of the vessels during normal activity. Another must-have is visibility. For the most part, a lot of the scaffolds and stents we have available today are very challenging to see! It would be nice if in the future, they are more visible so they can be appreciated during procedures, as well as during follow-up on duplex imaging.

Prof. Brodmann: Long BRS are definitely a must-have for me.

If cost and enrollment were no issue, what BTK trial would you most like to see?

Prof. Brodmann: I'd really like to see a comparative analysis of Spur stent (Reflow Medical) alone versus Spur stent plus paclitaxel drug-coated balloon (DCB) versus Spur stent plus limus DCB.

Dr. Siah: That's a really tough question! There are a lot of things I would like to see in a prospective, randomized fashion. We need more randomized data in a larger subset of patients, especially when it pertains to CLTI and BTK disease. The shortcoming of a lot of device trials is primarily related to the inclusion criteria of these studies. We often exclude patients with lesions longer than 15 to 20 cm in length or those with disease that extends across the ankle joint. As a result, it is hard to extrapolate data from trials to our real-world populations. Additionally, the utilization of intravascular imaging to corroborate our angiographic findings, as well as provide more insight into the lesions we're treating, would provide additional data, not only on sizing and plaque morphology but also what happens after we treat these types of lesions, with a specific focus on procedural data and also outcomes.

Beyond that, I would like to have more subgroup analyses directly looking at treatments and recoil acutely and also the natural history of recoil after BTK treatment and its real outcome effect. Basically, I want head-to-head randomized controlled trials looking at all the tools we use and including longer lesions that extend into the below-the-ankle space, with mandatory IVUS pre- and postinterventional imaging, as well as waiting 15 minutes after the intervention to assess for recoil with patient follow-up to see the results.

Prof. Gouëffic: Percutaneous DVA is a very promising treatment for patients with CLTI and a "desert foot." Some evidence already supports this technique, but no head-to-head comparison has been conducted. For such a trial, the choice of control group would be crucial. Currently, the standard treatment for patients with no revascularization options is major amputation or conservative care. Major amputation can relieve pain and allow patients to walk again with a prosthesis, but it remains a significant trauma for both the patient and their family. To establish percutaneous DVA as a viable option when no revascularization is possible, it should be compared to major amputation/conservative treatment, which is currently the gold standard.

If you could help advise a company on how to eliminate one problem you face in BTK interventions, what would it be?

Dr. Siah: Honestly, I would love for a purpose-built device that can be used to treat dissections along the entirety of the BTK space. I think that despite all the tools we currently have, dissections still occur and can occur in locations where we hesitate to place balloon-expandable scaffolds, irrespective of whether or not the body can resorb them. I think dissections happen more than we really can appreciate, especially if you don't routinely use IVUS or extravascular ultrasound after your interventions, and we also know that they have adverse effects on our outcomes. We cannot forget about them, nor should we tolerate them, especially as more scaffolds enter the market. Additionally, these scaffolds were not and are not being studied to be dissection repair or bailout tools; they are being studied as primary therapies, and as a result, extrapolating their outcomes for dissection treatment may miss the point.

Prof. Gouëffic: BTK procedures are costly and time-consuming. Interventionalists invest a lot of effort into achieving revascularization, yet some patients may not improve and may still require major amputation. It is crucial to determine, preoperatively and/or intraoperatively, the quality of revascularization to ensure a successful procedure. Intraoperative monitoring of tissue oxygen levels could influence the procedure in terms of target vessel selection (location and number) and outcomes. Various modalities, such as injectable tissue-integrated biosensors or 2D perfusion angiography, could be useful for vascular interventionalists.

Prof. Brodmann: I would love a whole package of devices/tools that I need to manage BTK patients. That would really help save on costs! ■

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