What role has device innovation played in your ability to treat more complex lesions?

Innovation has allowed us to treat longer and more complex lesions that otherwise were deemed not treatable. Ten years ago, it would have been a big deal to open a superficial femoral artery chronic total occlusion (CTO) and merely treat it with plain old balloon angioplasty (POBA). If there was no significant dissection, it would have been considered an optimal result. If there was a dissection, we used self-expanding bare-metal stents. Long CTOs were left alone and sent to surgery for bypass. Infrapopliteal lesions were not treated.

Today’s innovations allow operators to perform procedures in complex lesions with better devices that prepare the vessel for optimal lumen gain without the added complications that we have seen in the past. The change is unbelievable. The abundance of new technologies has enabled us to treat a full spectrum of disease both above and below the knee due to the availability of debulking devices such as atherectomy, plaque modification devices, specialty balloons, CTO crossing wires, and CTO crossing devices, to name a few.

What devices are still needed today?

We are always going to need a new device of some sort because we continue to push the limit of what we can treat. We still need better vessel prep devices that allow us to gain lumen without risk of dissection or perforation. Additionally, we need devices that provide long-term patency, especially in infrapopliteal lesions.

What balloon dilatation techniques do you use before drug-coated balloons (DCBs)?

As we have learned from the IN.PACT and LEVANT trials, well-prepped vessels respond best to DCB. Therefore, we initially do a 1:1 ratio POBA. If we can achieve proper luminal gain that can be deemed a suitable vessel prep, we proceed to DCB. In settings where POBA isn’t sufficient, we escalate our therapy to use specialty balloons (such as high-pressure balloons and scoring balloons) and/or atherectomy.

How important is vessel preparation?

I cannot emphasize enough the value of vessel prep—not just for use before DCBs, but also for acute luminal gain and stenting. Our vision toward vessel prep has become a primary element in the process of peripheral vascular intervention.

In my opinion, a good vessel prep is equivalent to reducing the lesion to < 20% residual stenosis with no flow-limiting dissections and no residual waist on the prepping balloon. Vessel preparation should be optimal despite the final therapy to be delivered. All subsequent treatments perform best if the vessel is well prepped.
What role has device innovation played in your ability to treat more complex lesions?

Our traditional approach to complex femoropopliteal lesions has been POBA and bare-metal stents, usually with nitinol self-expanding stents. This strategy produced suboptimal acute results in a significant number of complex lesions and suboptimal midterm results due to restenosis.

Device innovation has allowed improved vessel preparation with technologies including high-pressure balloons, scoring, and cutting balloons, as well as debulking strategies such as atherectomy. We have also used more novel technologies such as the Lithoplasty balloon (Shockwave Medical, Inc.) and angioplasty with the Chocolate balloon (Cordis Corporation).

Device innovation has also resulted in improved midterm durability, primarily around anti-restenosis strategies with drug-eluting stents and balloons.

What devices are still needed today?

We still need improved vessel preparation devices for complex lesions—devices that are simple to use. Before I think vessel prep was focused mainly on luminal gain. But today we are looking for devices that will give you luminal gain, minimize the severity of dissection, change vessel compliance, and prepare for drug delivery. I think these are the four essentials to help eliminate restenosis. Given the need for durability of drug administration in the femoropopliteal segment, this is becoming more meaningful. Changing vessel compliance is something we should think about, and new technologies are starting to do this. The vessel prep concept has become more sophisticated. We want to be able to achieve all of these things with our prep devices. If a device is able to do all of this at low pressure, then clearly there will be an even greater advantage.

What balloon dilatation techniques do you use before DCB?

I use high-pressure, scoring, and cutting balloons, as well as atherectomy and devices still being studied. Based on what we know, drug delivery is about the depth of penetration and particularly in allowing penetration past the calcium and into the media and adventitia. We know that calcification limits drug absorption. In the days before DCBs, vessel preparation wasn’t a concept we had at all. But now it certainly is.

How important is vessel preparation?

With the success of DCBs in vessels that respond well to angioplasty, more focus has gone on to adequate vessel preparation. We now focus on achieving technical success (minimal residual stenosis and dissection) in all patients before treatment with drug-eluting technologies.

Good vessel preparation constitutes achieving significant luminal gain with a residual stenosis $\leq 30\%$ (preferably less than this) and freedom from significant dissection (grade D or worse). In the era of drug-eluting technologies, this should also include techniques to improve drug delivery to the media and adventitia.