It seems intuitive that accurate vessel size assessment would be integral to all peripheral vascular interventions (PVI), similar to what interventional cardiologists have done for years during percutaneous coronary interventions (PCI). Multiple PCI reports have correlated acute and long-term stent patency with outcomes of post-PCI precise apposition of the stent to the vessel wall and minimal lumen diameters (MLD).1-7 Various reports have also described the benefits of intravascular ultrasound (IVUS) during PCI as related to overall PCI outcomes.1,4,8,9 IVUS is considered the clinical gold standard for precise circumferential three-dimensional vascular luminal analysis for MLD, cross-sectional area, and/or volume.

Despite the results seen with IVUS in the coronaries, many peripheral interventions continue to be done without using this or another means of vessel sizing. Furthermore, many peripheral vascular interventionists have not been trained in the use of IVUS; therefore, the highest clinical standard for optimizing PCI results is rarely offered to the PVI patient by comparison. Considering that the overall acute and long-term outcomes post-PCI are better than post-PVI results, it raises the question of whether IVUS or an IVUS equivalent should be used more frequently during PVI than PCI due to:

- Severe vascular inflow disease and a high incidence of chronic total occlusions (CTOs) (>50% in CLI).
- Poor imaging quality or technique.
- Frequent underfilling of vessels with contrast due to severe disease, PVI technical complexity, and a need for procedures with lower volume contrast than PCI (the typical PVI patient, especially in CLI, is at a much higher risk for contrast-induced nephropathy [CIN] versus PCI patients, due to a higher incidence of diabetes, pre-existing renal insufficiency, and more advanced age).
- Frequent vessel size mismatches in PVI versus PCI, including the natural vessel tapering (popliteal to infrapopliteal), poststenotic dilation (celiac and mesenteric), and bypass graft-native vessel mismatch.

It is logical that every reason optimal sizing has been deemed beneficial during PCI would also apply biologically and clinically to PVI, and the overall inferior results during PVI versus PCI should justify any strategy aimed to improve outcomes. Additionally, accurate vessel imaging and sizing can be much more challenging during PVI than PCI due to:

WHY OPTIMAL SIZING MATTERS IN PVI

In an effort to optimize our PVI strategies and results, we began to utilize the Metricath (MC) System (Neovasc,
Inc., Richmond, BC, Canada) in a wide range of PVI cases in August 2006. The MC is a novel system consisting of a low-pressure balloon catheter and an external, computerized console that calculates vessel luminal diameters and cross-sectional areas to the nearest hundredth of a millimeter for measurements of fluid volume and pressure with the balloon (Figure 1A). Fluid inflates the compliant balloon catheter to 250 mm Hg or 1/3 atm. The MC balloon is available in two sizes, including a 1.8- to 4-mm-diameter X 7-mm-length version that is useful in popliteal and infrapopliteal arteries. A 4- to 8-mm-diameter X 10-mm-length version is also available and is useful in larger vessels including renal, femoral, subclavian, mesenteric, and bypass grafts. The MC balloon catheter is rapid exchange and has a triluminal design with lumens for measuring balloon fluid infusion and pressure, as well as for a .014-inch guidewire. Proximal and distal radiopaque balloon markers facilitate precise balloon positioning. The MC console is small and composite, consisting of a pressure transmitter, printer, syringe pump, display screen, computer, and related software and hardware (Figure 1B).

The MC balloon is calibrated ex vivo first; the balloon pressure and volume are recorded in an unconstrained environment, and a calibrated pressure-volume curve (P-VC) is calculated. The balloon is advanced to the target site over either a .014- or .018-inch wire using standard interventional techniques. The balloon has proximal and distal opaque markers that facilitate precise balloon positioning. The balloon is automatically inflated, at which point it conforms to the size and shape of the vessel lumen. The MC console software uses the volume of fluid and the balloon pressure to calculate an in vivo P-VC, which is compared to the calibration P-VC. The MC software then calculates the balloon’s cross-sectional area and average luminal diameter to the hundredth millimeter, and both figures are displayed digitally on the console screen and stored. The MC system allows for multiple inflations with the same balloon within the same or additional vessels. Therefore, multiple vessels can be size-mapped during a single PVI. The current cost of the console is $5,000, and the MC balloon is $400. Vessel sizing using the MC system is not reimbursed at this time. Similarly, peripheral IVUS is not reimbursed in most states.

The MC balloon is not a treatment catheter; therefore, inflation within a lesion should be avoided. Unlike IVUS, the MC gives no morphological information regarding a vessel or lesion. The balloon is low profile, and its wings collapse after deflation, facilitating trackability through critical or complex lesions. We have found clinical benefit in PVI cases in which multiple tapering vessels of different sizes are diseased, such as the popliteal artery, tibioperoneal trunk (TPT), and infrapopliteal arteries. Ideally, the balloon is inflated both proximally and distally to a lesion in an effort to identify an accurate vessel size to facilitate the definitive clinical treatment. The MC can also be inflated in a stent postdeployment to evaluate stent expansion and MLD, as is common in PCI. The following are two illustrative cases.

**CASE 1**

A 79-year-old CLI patient presented with a recurrent ischemic ulcer 1 year after undergoing PTA and stenting of the anterior tibial artery (ATA) (Figure 2A). Angiography revealed 100% ATA stent occlusion and 95% proximal TPT stenosis (Figure 2B). The ATA was crossed, and the MC measurement was 2.48 mm in proximal ATA, distal to the stent, where contrast poorly filled the ATA (Figure 2C). A 2.5- X 20-mm AngioSculpt balloon (AngioScore, Inc., Fremont, CA) was utilized in the ATA, and the MC measured the TPT at 2.98 mm (Figure 2D and E). A 3- x 20-mm AngioSculpt was kissed with the 2.5-mm AngioSculpt for excellent definitive results (Figure 2F and G). The limb was salvaged with aggressive wound care after revascularization. The MC Libra balloon catheter facilitated the clinical decision-making, and optimal results were achieved in the case.

**CASE 2**

A 69-year-old CLI patient presented for limb salvage with failed bypass, no conduit, and osteomyelitis of the
Foot after digital amputation (Figure 3A). Angiography revealed single-vessel ATA runoff with a short, distal CTO and poor pedal vessel filling, making ATA sizing and distal lesion identification difficult (Figure 3B and C). The ATA was crossed, and the MC’s measurement was 2.14 mm just distal to the CTO and 2.31 mm proximally (Figure 3D). A long 2- X 100-mm balloon was inflated for 5 minutes with excellent results (Figure 3E). A 2.5-mm angioplasty balloon had been initially chosen using initial angiographic assessment of the more proximal ATA. A 2.5-mm balloon would have oversized the vessel and increased the risk of dissection, in contrast to the excellent results facilitated by clinical decision-making in optimal vessel sizing (Figure 3F).

**PUBLISHED METRICATH DATA**

Several recent publications have assessed the use of the MC system during PCI and renal PTA/stenting.10,11 Van der Giessen et al compared MC and IVUS in the Coronary Angioplasty Metricath vs. Ultrasound (CAMUS) trial.10 This MC/IVUS validation trial also used quantitative coronary angiography and independent core labs to validate MC/IVUS equivalency in 22 PCI patients. The MC system was noted to be accurate, reproducible, rapid, and easy to use during the trial, and the conclusion advocated that the MC system should be further studied as an alternative to evaluate vessel size and stent expansion.10

Renal artery PTA/stenting has been found to be superior to renal PTA, but the incidence of renal in-stent restenosis remains high and has been associated with vessel size and stent diameters.12-17 Aquel et al recently reported their results using the MC system in accessing optimal renal stent deployment in 16 patients (20 lesions) undergoing renal PVI.11 MC guidance resulted in adjunctive intervention in 90% of the lesions, with an increase of MLD from 4.4±0.77 mm before adjunctive PVI to 5.17±0.82 mm (P<.001) after it. The MC MLD to reference vessel diameter increased from 77.4±15.2% to 91.2±17.5% (P<.001), and the MC MLD to nominal stent diameter increased from 76.2±7.1% to 90±9.4% (P<.001). The conclusion of the Aquel report identified a large pro-

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**Figure 2. CLI case 1. Recurrent CLI ulcer (A). Angiogram demonstrating critical TPT lesion and occluded ATA stent (B). MC measures 2.48 mm in the ATA (arrow); note the TPT size appears larger (arrow) (C). AngioSculp 2.5 mm in the ATA stent (D). TPT measures 2.98 mm, facilitating the choice of a larger AngioSculp (3 mm) for definitive treatment (E). Kissing AngioSculp balloons rebuild the TPT-ATA bifurcation (F). Final results facilitated with optimal vessel sizing avoids an additional stent (G). If another infrapopliteal stent had been necessary, optimal stent sizing and decision making was provided by MC sizing.**

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portion of underdeployed renal stents, despite optimal operator visual and quantitative angiographic analysis. These underdeployed renal stents were identified by MC, therefore potentially optimizing the renal PVI.

At the Transcatheter Cardiovascular Therapeutics (TCT) 2008 symposium, we reported our safety and feasibility results utilizing the MC system in a variety of PVI scenarios and especially in treating CLI.\textsuperscript{18} From August 1, 2006, to June 1, 2008, we used the MC Libra system (1.8- to 4-mm sizes) for infrapopliteal artery sizing in 69 vessels during 55 PVIs for CLI. The vessels analyzed included 29 posterior tibial arteries, 21 anterior tibial arteries, 15 peroneal arteries, and four popliteal arteries. All vessels were first angiographically analyzed with two opinions of vessel sizing recorded (primary operator [PO] and primary tech) and the best primary treatment estimated (including infrapopliteal stent sizing) before MC analysis. MC analysis included vessel sizing above and below the predicted treatment site and the best predicted normal segment. Treatments predicted before MC analysis included laser/percutaneous transluminal angioplasty (PTA) (40), long PTA (15), cutting/scoring PTA (eight), and PTA/stent (six). There were no device-related complications, and the system demonstrated ease and rapidity. Using a threshold of ±0.5 mm for vessel sizing, the PO-predicted vessel diameter was within ±0.5 mm in 31/69 (44.9%) of the cases. The PO-predicted vessel diameter was >0.5 mm versus MC value in 24/69 (34.7%) of the cases and <0.5 mm in 14/69 (20.2%) of the cases. Final treatment analysis resulted in laser/PTA (28), long PTA (six), cutting/scoring PTA (17), and PTA/stent (±laser) (18). The MC system was found to be safe and feasible during our infrapopliteal PVIs for CLI. During our analysis, the PO over/underestimated the MC-determined vessel size by ±0.5 mm in >50% of cases, and the final treatment frequently changed with a marked increase in infrapopliteal PTA/stenting.

**DISCUSSION**

CLI is responsible for >220,000 amputations annually in the US and Europe, and a large portion of CLI patients suffer from severe infrapopliteal artery disease.\textsuperscript{19-22} The results of PVI have been much poorer than in PCI, especially in the treatment of infrapopliteal artery disease, in which only in the last few years has it even been considered feasible to treat complex CLI. Multiple dedicated PVI tools are now available, including low-profile treatment strategies, such as infrapopliteal artery stents, which hold great promise in treating infrapopliteal artery disease. Unfortunately, most interventionists receive sparse formal

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**Figure 3.** CLI case 2. CLI of the right foot (A). Single-vessel (ATA) runoff with a distal CTO and poor distal vessel visualization (B and C). MC inflated during contrast injection measuring at ATA 2.14 mm just distal to the CTO (D). Final results facilitated by optimal vessel sizing (E and F).
PVI training in treating infrapopliteal artery disease, and an overall unfamiliarity of treating this challenging vascular territory persists, even including such a basic principle as precise vessel sizing.

Since the arrival of the MC system in our laboratory, our selections of peripheral balloons, specialty balloons, laser catheters, atherectomy devices, and infrapopliteal stents have been made with precise vessel sizing information. Prior to the MC system arrival, we rarely if ever used the balloon compliance chart or balloon-expandable stent sizing charts that accompany all balloons and stents, which, like the MC system, are also calibrated to the hundredth millimeter. The risks of stent oversizing (rupture, dissection, stretch injury, and aggressive in-stent restenosis) and undersizing (stent-vessel malposition/undersizing, in-stent restenosis, and stent thrombosis) are associated with poorer acute and long-term outcomes.

Today, our routine during a CLI case is to obtain precise infrapopliteal vessel sizing before treatment and choose the definitive therapy, especially with specialty balloon-based PTA or balloon-expandable stents, based on the MC system-guided vessel size.

CONCLUSION

We have found that the MC system has provided important clinical information facilitating our PVI treatment decisions and is an example of a more sophisticated and precise way of treating PAD, CLI, and especially infrapopliteal vessels. The MC system will not only allow ment decisions and is an example of a more sophisticated

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21. Yost, ML. Peripheral arterial disease: a report by The Sage Group. 2004;Vol. II.