The Burden of CLI and CROSSER® Catheter Recanalization Strategies
The Burden of CLI
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The signs and symptoms of peripheral vascular disease are most commonly nothing at all or atypical symptoms that people do not recognize. Patients often attribute typical calf claudication when walking to arthritis or simply getting old. Critical limb ischemia represents advanced peripheral vascular disease and is characterized by true ischemic rest pain (Rutherford-Becker 4), ischemic ulceration (Rutherford-Becker 5), and gangrene (Rutherford-Becker 6).1 “Critical limb ischemia” (CLI) was so named because if you had these vascular symptoms and your leg was not revascularized, there was a very high chance that amputation would be required within a year. Due to recent advancements, our treatment for these patients is far more effective now when compared to the early days of vascular intervention and surgery, and in many cases, amputation can be avoided.

There is a global epidemic of CLI. The most rapidly growing segment of the US population is octogenarians. In addition, there is a worldwide epidemic of diabetes mellitus. Some epidemiologists believe if current trends continue by 2020, 50% of Americans will either be overtly diabetic or glucose intolerant. Advanced age and diabetes are the most important risk factors for developing CLI.

CLI is usually caused by atherosclerotic obstruction of infrapopliteal arteries with or without associated inflow disease. It should not be confused with acute limb ischemia typically caused by acute thrombus or emboli.

Despite reported limb salvage rates of greater than 85% with advanced interventional and surgical techniques, major amputation is still frequently the first recommendation given to patients presenting with CLI without any vascular assessment. While amputation may be life saving, it should be the last rather than the first recommendation.

One of my patients had five bypass surgical procedures to restore blood flow to his left leg. He had lost his other leg, and was caring for an invalid wife and two invalid children.
Figure 5. Severely ischemic foot with ulcer.

Figure 6. SFA occluded at origin.

Figure 7. Occluded SFA, popliteal, and IP vessels.

Figure 8. Wire in faintly filling distal posterior tibial artery.
He said he would prefer dying than losing his other leg. His vascular surgeon had previously told him that if he developed recurrent ischemia his only option would be amputation. His leg became ischemic and this progressed to the point of gangrenous changes (Figure 1). He asked if we would try intervention. He had total occlusions of all his infrapopliteal vessels (Figure 2). An excimer laser was used with a step-by-step technique to cross and open the peroneal artery (Figure 3). Subsequent percutaneous transluminal angioplasty (PTA) resulted in a widely patent vessel to the foot. The patient had subsequent transmetatarsal amputation and skin grafting (Figures 4). This patient remained ambulatory and capable of caring for his family for 12 years before he died. I think this case is illustrative of what can be achieved with advanced intervention.

**Morbidity, Mortality, and Cost-Effectiveness**

About 70% of patients with CLI are ultimately going to need amputation if not revascularized.\(^2\) Thirty-day perioperative mortality after amputation can range from 4%-30% and morbidity from 20%-37%. Amputations are not benign. There is no endovascular intervention that carries 4%-30% mortality but practitioners who perform interventions in CLI are often referred to as aggressive and those who amputate first as conservative. I strongly disagree with that assessment.

Within 18-24 months of successful limb salvage intervention, 20%-30% of patients will require re-intervention. A third will require intervention in the other leg because this disease is often bilateral. In comparison, within 3-5 years of unilateral
limb loss, a third of all patients are going to lose the other leg. Only about 50% of amputees are alive 3-4 years after amputation so this type of treatment clearly affects mortality.\textsuperscript{2}

Using amputation as the primary treatment for CLI is also profoundly expensive. Due to higher mortality, higher morbidity, and higher cost, it is surprising that amputation is still called conservative. There are associated costs to consider such as the yearly costs of follow-up for the 75%-80% of patients who go home post-amputation. The other 15%-20% of amputations ultimately will result in permanent nursing home placement. Average annual cost is $100,000 per year just for the nursing home. There are many articles that state angioplasty is cheaper than bypass surgery but if you look at the results, there is a wealth of data proving vascular surgery and interventional therapies are less expensive than primary amputation in addition to saving the leg and avoiding high morbidity.\textsuperscript{2,3,4}

**Current Practice**

In the United States, primary amputations are still the most common treatment ordered for CLI. In 2001, 67% of CLI patients had amputations in the United States as their primary treatment, according to the Medicare database. These patients were not informed about revascularization or alternative therapies prior to amputation. In one study of CLI patients that assessed diagnostic work ups:\textsuperscript{2}

- Only 26% of patients had a cardiology consultation
- Only 21% of patients had a vascular surgical consultation
- Among patients who had primary amputations:
  - Only 35% had an ankle brachial index prior to amputation
  - Only 16% had angiography prior to amputation

\textbf{Figure 12. Right side initial angio showing occluded distal SFA, popliteal, and IP vessels.}

\textbf{Figure 13. Magnified view of CTO segment.}

\textbf{Figure 14. Treatment tools.}
Physicians cannot know if a patient has an easy lesion to treat or has advanced disease without some form of assessment.2

Case Report
Most people think that CLI affects elderly patients but in this case, a 27-year-old single mother/nurse developed a dorsal ulcer and rest pain. At age 21, she had her first bypass surgery at a well-known institution. She had multiple surgeries on both legs over the ensuing years, but was never asymptomatic. She ultimately developed a dorsal foot ulcer (Figure 5), went back to the hospital where she had undergone surgery, and was told that she needed amputation. She sought a second opinion at another institution where she was advised to have bilateral amputation. She was referred for psychological evaluation prior to amputation, but she ultimately decided against amputation. She returned home and resumed her routine where she worked on her feet all day before going home to play with her child and put him to sleep. She would then take pain medications and sleep only to repeat this ritual daily. She had progression of pain and the ulcer enlarged. She sought a third opinion from another institution. That physician referred her to me for possible intervention.

Angiography showed that the superficial femoral artery was occluded at its origin (Figure 6). There was faint reconstitution of the posterior tibial artery at the ankle. The entire long segment occlusion was crossed with a guidewire (Figures 7 and 8). Prolonged balloon inflations were then performed with suboptimal results. The patient was treated with chemical thrombolitics overnight, establishing faint flow. The entire segment was then stented with brisk straight-line flow established to the foot (Figures 9 and 10). A month later, the ulcer was healed (Figure 11) and she was pain free in her left leg for the first time since age 21. The SFA and popliteal were widely patent by arterial duplex. The patient desired intervention on her still symptomatic right leg. Angiography disclosed that the distal SFA and the entire popliteal artery were occluded with distal reconstitution of the peroneal artery (Figures 12 and 13). This lesion could not be crossed with a guidewire despite very aggressive attempts. The occlusion was subsequently crossed utilizing the Crosser® Catheter recanalization device. The occluded segment was then dilated and stented with excellent final result (Figures 14 and 15). The patient has been totally asymptomatic since that time.

Figure 15. Final result right leg.
**CROSSER® Catheter Recanalization Strategies**

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Advancements in endovascular technologies are making it possible to aggressively treat advanced CLI cases. Some of the data that we take for granted is that 25% of CLI patients will undergo a major amputation after they have been diagnosed. You might see it as 25% but that is 1 out of 4 patients that will have a major amputation. Another 25% will die. So, if you have 4 siblings with CLI, one of your siblings is going to die within a year.\(^2\)

Within 18 months of successful limb salvage, 33% will need some re-salvage procedure or re-intervention, but this is normal and it gives the patient more opportunities than they would if they had an amputated limb.\(^2\) An excellent example is Dr. Walker’s patient walking through the zoo with her son, which would not have happened if she had lost both legs.

In patients with advanced peripheral vascular disease, revascularization should be performed sooner rather than later because as these patients come in later, they present with a more advanced disease stage ulcer, gangrene, and occlusions. If you have a patient with moderate disease or moderate to severe disease, treat them and do not wait until it gets worse as it becomes harder to recanalize. In our lab, the CROSSER® Catheter has been a critical tool for treating CTOs and advancing limb salvage.

**Case Report**

A 46-year-old patient was scheduled for an above the knee amputation when he came to us. After assessing the critical limb, we proceeded with ipsilateral antegrade access in combination with ipsilateral retrograde tibial access (Figure 16 and 17). We usually refer to this approach as ipsilateral antegrade retrograde access. Due to the severity of the tibial disease, we proceeded with using the CROSSER® Catheter from the tibial access and a CROSSER® Catheter from the antegrade common femoral artery access to cross his CTO (Figure 18). This dual antegrade/retrograde CROSSER® Catheter method is reserved for patients with severe tibial runoff or no runoff as in this patient. We used ultrasound to map the tibial arteries (Figure 19). We found a short patent segment in the posterior tibial, which we used to place a retrograde sheath. We were able to cross two vessels in less than five minutes and delivered the antegrade CROSSER® Catheter past the retrograde CROSSER® Catheter (Figure 20). We were in two different vessels, which was exactly what we needed and once we did that, we secured our wires.

We placed a wire from the retrograde approach and a wire from an antegrade approach into two separate vessels that were not visualized pre-crossing. We performed kissing balloon angioplasty from the posterior tibial retrograde wire and from the antegrade common femoral artery wire. Post-procedure, there was excellent popliteal and two-vessel runoff to the foot. Technology and ultrasound-guided access made the difference here. The CROSSER® Catheter played a major role as it was advanced blindly in both antegrade and retrograde directions. It found the path to the two previously occluded tibial arteries. The low profile of the CROSSER® Catheter made this complex procedure feasible.

The CROSSER® Generator converts AC power into vibrational energy to cross CTOs. The device is used in conjunction with the FlowMate® Saline Injector and activated using a foot pedal. The CROSSER® Catheter creates a channel through the CTO via atherectomy utilizing mechanical impact and cavitation. The treatment is delivered throughout the entire length of the blockage until it crosses through the end of the other side and blood flow can be restored.

A key tip for success using the CROSSER® Catheter is to keep the shaft as straight as possible. If the shaft is pushed too hard, it will form an arch. When in this situation, simply stop pushing, pull back the shaft until it is straight, and then re-advance until resistance is felt. Then activate and wait.

**CROSSER® Device Variations**

There are three catheter design options for the CROSSER® System: 14S, 14P, and S6. The 14S and 14P are available as...
over-the-wire or rapid exchange and are utilized with a 0.014”
guidewire. The wire-compatible systems are great when using
a contralateral approach as you can exchange wires for support
and they give you the additional ability to push by simply
exchanging the guide wire to a stiffer one. This can be helpful
especially if you are going for ribio-pedal CTO from a contra-
lateral access. The 14S and 14P catheters can be used with a
specially designed catheter to support the Crosser® Catheter
It is available in straight, angled, tapered, and non-tapered
configurations. The tapered support catheter helps when
you go into the tibial vessels and the non-tapered is better
utilized supratibial in the popliteal artery. In my experience,
the angled support catheter is phenomenal when utilized in
a long CTO as it has capabilities to maneuver the Crosser®
Catheter around the calcified CTO segments and facilitates
crossibility and energy delivery to the CTO cap.

The S6 catheter has the same amount of energy that is
created for the 14S and 14P with a smaller tip and cross sec-
tional area making the device drill more efficiently due to the
fact that the energy source is now concentrated and focused
into a smaller cross sectional area. Therefore, it is more effec-
tive in severely calcified CTOs. The S6 has a unique support
sheath called the Usher® Support Catheter. It is available in
straight and angled configurations and both are tapered.

The PATRIOT study showed 83.5% crossing rate with the
Crosser® Catheter with no Crosser® Catheter clinical
perforations. In our experience, the Crosser® Catheter has
higher crossing success rate due to our better understand-
ing of the device, the addition of the support catheters,
and our increased skill level due to our experience with the de-
vice. In our institution, the crossing rate of complex CTOs
is 96%.

Conclusion
Using the Crosser® Catheter in the absence of target vessels
was really a revelation for us. I sought out many vascular sur-
geons for the opportunity to have one chance on their patients
with advanced CLI. We found 32 patients whose angiograms
did not show tibial arterial reconstitution distally. At the time of
this study, we were not using ultrasound or retrograde access so
we used the Crosser® Catheter blindly, taking it to the CTO
cap and activating it. The Crosser® Catheter went down into
a tibial artery, which we then revascularized. The challenge was
to cross an occlusion at the level of the foot or into the pedal
circulation. We had a 92% success rate on our first attempt in
crossing the first tibial artery. For the 8% that failed, we in-
tentionally directed our therapy toward a second tibial artery
until we were able to cross a CTO segment into a patent distal
tibial or pedal arterial segment. The time to fix the case was
long, about 3 hours on average, but the crossing time with the
Crosser® Catheter took an average of 3.8 minutes.

When treating patients with advanced CLI, we do every-
thing we can with the endovascular tools we have to preserve
their limbs because many of these patients have already lost
something. Some patients have already had a contralateral am-
putation or tranmetatarsal amputation. I believe aggressive en-
dovascular treatment is worthwhile for these patients. For one
patient, it was important to save that little bit of stump on the
right leg because she already learned how to transfer and walk
with that. She still has her leg today.

Additional Case Reports
Case Report 1. A patient presented with
two CTO segments in the popliteal artery,
one proximal and one distal. Between the
CTO caps lies a hibernating arterial seg-
ment. This was recognized during the
CTO crossing and post-Crosser® Cath-
eter angiogram. The target proximal and
distal plaque was treated with directional
atherectomy followed with scoring balloon
angioplasty utilizing the VascuTrak® PTA
Catheter with excellent results. Final distal
angiogram showed patent two-vessel runoff
to the foot.

Case Report 2. A 57-year-old male pre-

Figure 18. Sheathless retrograde Crosser® Catheter 14S over-the-
wire advanced through left retrograde posterior tibial access.

Figure 19. Simultaneous visualization of the retrograde Crosser® 14S with ultrasound
and fluoroscopy. A technique used in complex tibial CTO revascularization.
ABI .71, no palpable pulses, and a monophasic Doppler pulse. The initial angiogram showed a proximal superficial femoral artery (SFA) CTO and reconstituted in the popliteal with a single vessel runoff to the foot. The 14S Crosser® Catheter penetrated the CTO cap after two minutes. At the distal CTO cap, a secondary resistance was met to which the Crosser® Catheter was kept activated with slight forward motion until it was visualized penetrating the distal CTO cap. The distal CTO cap was watched carefully as we could not afford to lose any of the popliteal patent segment due to the fact that the patient only had single vessel runoff to the foot. A VascuTrak® PTA Catheter followed and stenting was performed with excellent results.

**Case Report 3.** A 67-year-old patient presented with Rutherford III claudication. After a diagnostic angiogram, we proceeded with treating this patient’s CTO with the following step-by-step approach. The Crosser® Catheter and support catheter were advanced to the lesion and across the proximal cap. The guidewire was then advanced past the Crosser® Catheter tip until resistance was met. At this point, we pulled the wire back about 4 mm and activated the Crosser® Catheter. Once across the proximal and distal CTO caps, this lesion was treated with a VascuTrak® PTA Balloon.

**Case Report 4.** A 58-year-old female with a recent history of bypass surgery presented with a cold foot. An angiogram showed the graft was occluded. The CTO cap and segment were evaluated. We created projections of vectors and planned a path for the Crosser® Catheter. We crossed the CFA with the Crosser® 14S, which was chosen for its ability to deliver force and flexibility. We were unable to visualize where the bypass graft reconstituted. Therefore, a blind advancement of the Crosser® 14S was performed. The proximal CTO cap was crossed easily. A second resistance was met below the knee at the level of the P3 segment of the popliteal. The support catheter was advanced to the P3 popliteal and the Crosser® Catheter was activated until it crossed the CTO cap at the graft/popliteal anastomosis. Post-crossing, the distal angiogram showed two patent tibial arteries. The graft and the proximal and distal CTO segments were treated with balloon angioplasty and stents with excellent final angiogram and brisk flow to the foot.

**Case Report 5.** A 48-year-old male had a severe aneurysmal popliteal artery and presented with a cold foot. An attempt for two hours to cross the popliteal CTO via catheter/wire technique failed. After discussing the patient’s options with our team (surgical versus endovascular), we proceeded with an endovascular approach utilizing the Crosser® Catheter. An angled support catheter was positioned at the CTO cap. We activated the Crosser® Catheter and crossed the lesion in less than 30 seconds. Once this CTO was crossed, we treated it with a covered stent due to the aneurysmal nature of the popliteal. The distal runoff showed a tibio-pedal CTO of the posterior tibial artery. Given the brisk flow to the foot and the absence of ischemic skin break down, we decided not to treat the distal CTO.

**References**

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