◆ TECHNICAL NOTE ◆

Intraluminal Recanalization of Long Infrainguinal Chronic Total Occlusions Using the Crosser System

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Purpose: To assess the safety and efficacy of a device for vibrational angioplasty in the percutaneous intraluminal recanalization of long infrainguinal chronic total occlusions (CTO).
Technique: The Crosser CTO Recanalization System is a mechanical recanalization device that uses high-frequency vibrational energy to disrupt and channel through fibrocalcific plaque without harming the vessel wall, thus assisting in the recanalization of an occluded artery. In 12 diabetic patients (7 men; median age 71 years, range 58–80) with critical limb ischemia owing to long (median length 26 cm, range 21–32) infrainguinal CTOs resistant to conventional guidewire techniques, the Crosser CTO Recanalization System was successful in intraluminally crossing the occlusion in 9 (75%) patients in $<$5 minutes (mean 4:03 minutes). The safety endpoint (distal lumen guidewire position with no vessel perforation or dissection) was achieved in all successful cases.
Conclusion: In our preliminary experience, the Crosser CTO Recanalization Catheter decreased crossing time, was safe, and achieved a high rate of intraluminal recanalization of long infrainguinal CTOs.

J Endovasc Ther. 2009;16:23–27

Key words: critical limb ischemia, chronic total occlusion, percutaneous interventions, infrainguinal occlusion, intraluminal recanalization, vibrational energy

According to the TransAtlantic Inter-Society Consensus (TASC) document, the standard of care for critical limb ischemia (CLI) caused by long type D infrainguinal chronic total occlusions (CTO) is surgical bypass grafting.[1] However, this approach is not possible in all cases due to significant comorbidities or to the lack of suitable native veins for the distal bypass; in these patients, endovascular treatment is an important option.

In long, complete infrainguinal occlusions, the technical success of conventional angioplasty decreases as lesion length and degree of calcification increase because of the inability to cross the occlusion with a standard guidewire.[2–6] Among experienced interventionists, subintimal angioplasty is the most frequently used technique in the recanalization of lower extremity CTOs, but the technical challenge of this approach is significant and had led to the development of new devices for intraluminal treatment of these occlusions by less experienced operators. We report the technique for using one of these new devices in the recanalization of infrainguinal CTOs.

TECHNIQUE

Device Description

The Crosser CTO Recanalization System (FlowCardia Inc, Sunnyvale, CA, USA) is a

The authors have no commercial, proprietary, or financial interest in any products or companies described in this article.

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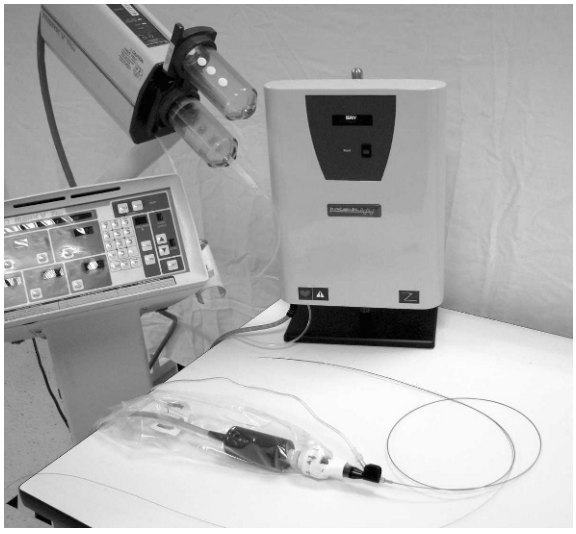

Figure 1 ◆ The Crosser device and operating equipment.

mechanical recanalization device (Fig. 1) consisting of a generator, an attached transducer, a foot switch, and a disposable Crosser catheter. The affixed transducer has piezoelectric crystals that convert the amplified alternating current supplied by the generator into high-frequency vibrational energy, which is then propagated at 21,000 cycles/s to the catheter's metal tip. The very rapid reciprocal (back and forth) stroke (depth 20 microns) disrupts and channels through fibrocalcific plaque without harming the vessel wall, thus assisting in the recanalization of an occluded artery. An irrigation line is required during device activation to guarantee a continuous chilled sterile saline flush (recommended flow rate of 18 mL/min at a back pressure of 200 psi) to cool the system and provide a medium for cavitation at the catheter tip.

Three different versions of this monorail hydrophilic catheter are available. The Crosser 14P and 14S catheters have a 1.1-mm-diameter titanium tip, are compatible with a 0.014-inch guidewire, and are delivered through a 5-F sheath. The Crosser 18 catheter has a 1.5-mm titanium tip and is delivered over a 0.018-inch guidewire via a 6-F sheath. The larger Crosser 18 catheter is suited for large-diameter, straight vessels with light to moderate calcium loads, while the more flexible designs of the Crosser 14S and 14P models accommodate to more tortuous vessels with moderate to heavy calcification. The Crosser 14S (Support) offers a balance between vibrational drilling power, flexibility, and catheter support. The Crosser 14P was designed for the most distal tibial arteries of the foot.

Device Application

After percutaneous antegrade puncture of the common femoral artery is performed, a 6-F, 10-cm-long sheath is placed. A complete lower limb diagnostic angiogram is obtained to evaluate the extent of the occlusion, its origin, and the reconstitution site. After acquiring a roadmap image, a 180-cm, 0.014-inch guidewire (PT Graphix super-support; Boston Scientific, Natick, MA, USA) is advanced to the occlusion site. The Crosser catheter is then advanced over the wire until its tip is against the face of the occlusion. The guidewire is withdrawn a few centimeters within the catheter. Cold saline irrigation is initiated and the Crosser system activated. Using gentle forward pressure on the catheter, the tip is slowly advanced through the occlusion. After an initial segment of strong resistance, the catheter navigates through sections that present variable amounts of resistance to catheter advancement. Once the catheter is close to the reconstitution site, diluted contrast is injected from the femoral sheath to evaluate the remaining length of the lesion. When the occlusion appears to be crossed, a further contrast injection is performed through the infusion lumen of the catheter, which confirms the true lumen position. The guidewire is then advanced into the patent true lumen and the Crosser catheter is removed. Once an occlusion is crossed, a prolonged (3 minutes or longer) balloon dilation is performed with 3.5-mm Amphirion Deep balloons (Invatec., Roncadelle, Italy); stents are placed in selected cases.

The Crosser CTO Recanalization Catheter was preliminarily evaluated in 12 patients (7 men; median age 71 years, range 58–80) with CLI owing to long infrainguinal CTOs after failed attempts with conventional guidewire techniques. All patients presented with TASC type D lesions (median length 26 cm, range

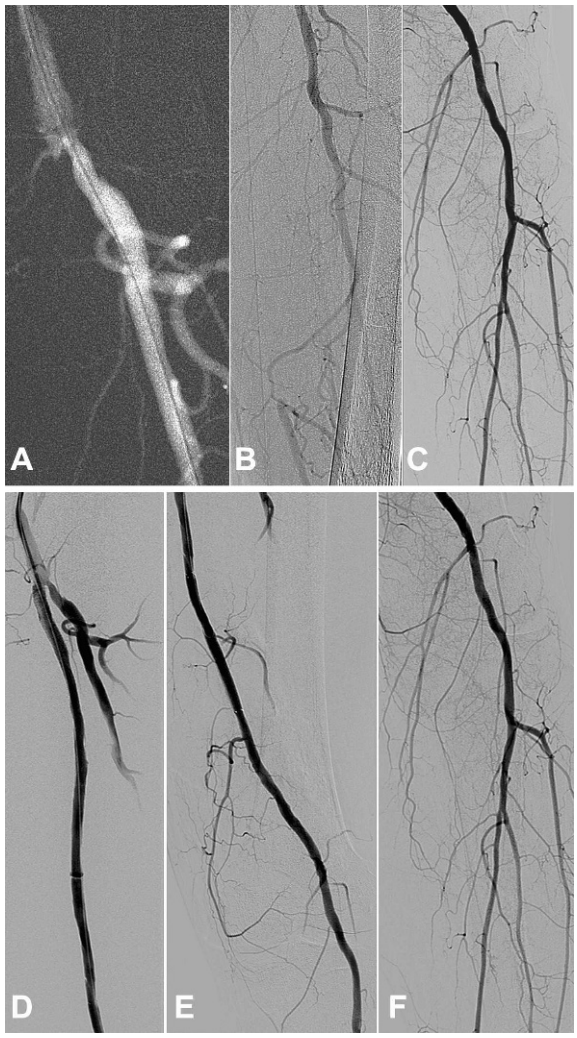

Figure 2 ◆ (**A**) Intraprocedural diagnostic angiogram depicts total occlusion of the SFA beyond a proximal stump, (**B**) with reconstitution at the distal third of the vessel, and (**C**) visualization of the 3 runoff vessels. (**D–F**) Postprocedure angiogram after stent placement demonstrating complete endoluminal recanalization of the SFA and patency of the 3 runoff vessels.

21–32) involving only the superficial femoral artery (SFA) in 5 cases (Fig. 2) and the SFA with reconstitution of the distal third of the popliteal artery in 3 cases. In 4 cases, the occlusions involved the SFA and the popliteal artery, with reconstitution of the tibioperoneal trunk (Fig. 3) in 2 cases and the peroneal artery in 2. All the patients had diabetes and Rutherford category 4 (n=2), 5 (n=7) or 6 (n=3) ischemia. All patients gave written informed consent, and the study was conducted in concordance with the local ethics committee.

Technical success, defined as complete intraluminal crossing of the occlusion with placement of the guidewire into the true distal lumen, was achieved in 9 (75%) of 12 patients. The mean activation time for complete lesion crossing was 4:03 minutes (range 3:24–4:54). In 2 cases, the device could not advance through heavy calcification at the origin of the occlusion after 5 minutes of catheter activation. The other case was unsuccessful due to the creation of a false lumen during the placement of the guide sheath. These 3 patients were treated with subintimal recanalization. The Crosser catheter caused no perforation or dissection in the recanalized vessels.

DISCUSSION

Although the standard of care for long peripheral occlusions (TASC type D) is conventional surgical bypass,[1] this approach is marred by a significant rate of early morbidity (within the first 12 months) related to wound infections and cardiovascular complications. Moreover, patients affected by life-threatening CLI, often diabetics, are typically not candidates for conventional surgical procedures; not only do they have extensive arterial wall damage that could jeopardize the distal anastomosis, but they lack veins suitable for surgical grafting, and in general, are in poor clinical condition. Additionally, the cost of managing the surgical patient is high due to the expense of the procedure itself, the hospital stay, follow-up sessions, and the health and social service resources outside the hospitals.[7] Because of these short/midterm limitations of surgery and the frequent comorbidities of this patient population, an endovascular approach should be strongly suggested.

Unfortunately, in cases of long CTOs, conventional intraluminal crossing of the lesion is often impossible, forcing the operator to switch to a technical variation, such as subintimal angioplasty (SA). The success of the SA technique, however, is influenced not only by the length of the occlusion, but also

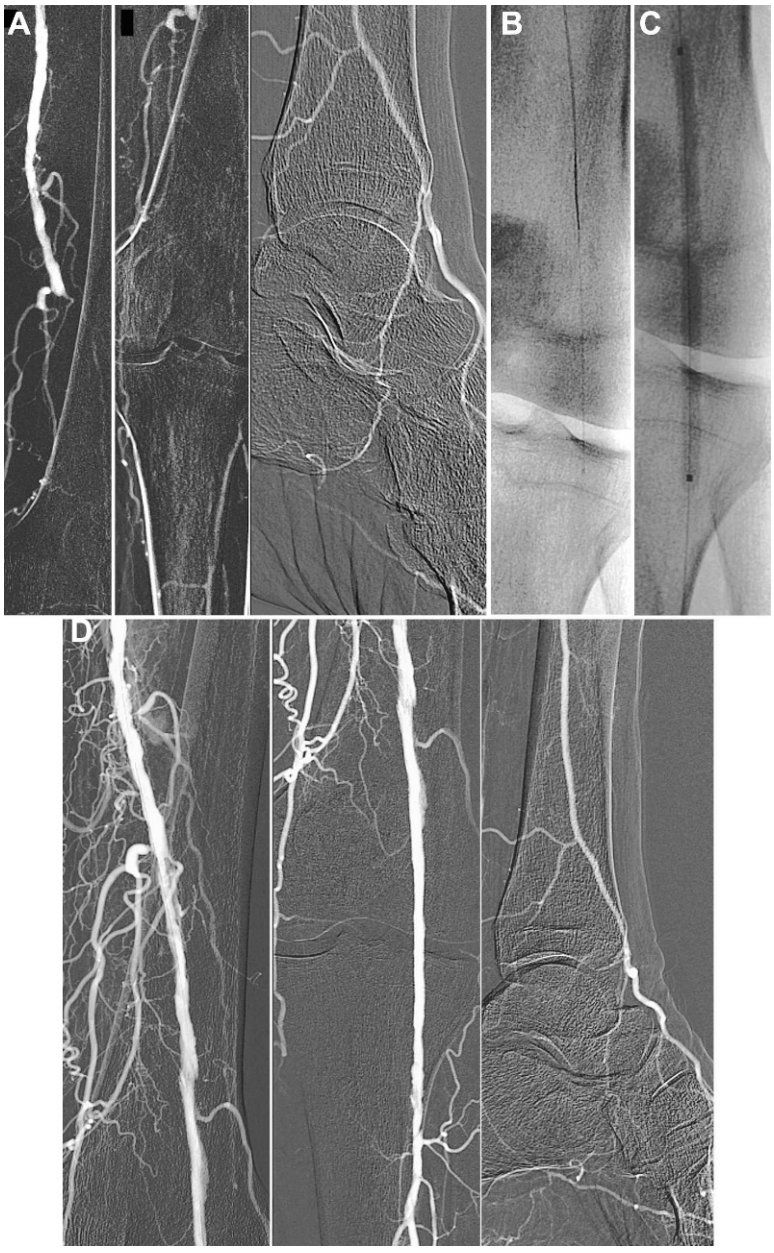

Figure 3 ◆ (**A**) An intraprocedural diagnostic angiogram evidenced a total occlusion at the distal third of the SFA and of the popliteal artery with reconstitution at the origin of the bifurcation between the posterior tibial artery and the peroneal artery, which fed a patent pedal artery through malleolar branches. (**B**) The lesion was completely crossed with the Crosser CTO Recanalization System using a PT Grafix super-support guidewire. (**C**) Multiple prolonged dilations (≥3 minutes) were performed with 3.5-mm Amphirion Deep balloons. (**D**) The completion angiogram showed complete lumen reconstitution of the femoropopliteal segment despite a small dissection at the distal third of the SFA caused by balloon dilation, promptly treated with stent deployment.

by the presence of normal vessel above and below the occlusion and on a re-entry into the true lumen. Solving the latter problem often requires the use of expensive lumen re-entry devices. Furthermore, during the attempt at re-entry, a viable collateral vessel or the main trunk to the best runoff vessel may be inadvertently occluded. In sum, the success of SA relies heavily on the operator's advanced skills and expertise; even the most experienced peripheral interventionist usually achieves a technical success rate of only ~80%, which prompts many operators to give up the treatment of CTOs in their clinical practice.[8]

Technological improvements have led to an expanded arsenal of devices (e.g., new guidewires, radiofrequency systems, and the excimer laser catheter) that facilitate crossing long infrainguinal CTOs in an intraluminal fashion. Among these devices, we selected the Crosser system mainly due to the fact that vibrational energy not only dissolves calcified lesions, but it also does not harm the vessel wall, thus avoiding the arterial perforations associated with lasers and radiofrequency systems.[9,10] On the other hand, excessively calcified lesions may lead to technical failure.

The Crosser CTO Recanalization System allowed secure intraluminal recanalization in 75% of the cases with no complications in a challenging cohort of diabetic CLI patients with lengthy CTOs resistant to conventional guidewires. This success rate is comparable to subintimal angioplasty,[8] but it is important to point out that the Crosser catheter achieved distal true lumen access in <5 minutes of catheter activation, which is shorter than previous experiences with vibrating guidewires.[11] This rapid placement of a guidewire in the distal true lumen of long, often calcified CTOs will prove valuable to interventionists looking to shorten overall CTO procedure time, which offsets the higher upfront costs associated with using a device like the Crosser catheter.

Conclusion

In our preliminary experience, the Crosser CTO Recanalization Catheters decreased CTO recanalization time, were safe, and achieved a high rate of intraluminal recanalization. Further investigation in a broader population and data from other centers are required to validate our results and demonstrate that this device may help less skilled physicians achieve recanalization in this technically challenging pathology.

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