

Novel high-frequency vibration approach for recanalization of difficult coronary and peripheral chronic total occlusions

Chronic total occlusions (CTOs) continue to be quite prevalent and still present as some of the most challenging lesions for the coronary and/or peripheral interventionalist. Recanalization success rates have been historically low and the potential for adverse events are typically higher than the more common procedures of angioplasty and stenting. At present, there are two paths to successful CTO recanalization; the subintimal approach and the central lumen approach. The subintimal approach tracks a standard guidewire around the occlusion and through the subintimal plane, while the luminal approach attempts to recanalize the occlusion through the central lumen of the artery. After failure to stay in the true lumen, a bypass is essentially created around the occlusion through the adventitia. This may lead to adverse events. A central luminal approach may provide increased safety and more therapeutic options to the clinician and may ultimately deliver enhanced longer-term outcomes owing to the optimization of luminal therapy. In this article, we investigate the CROSSER® catheter as a device that may allow physicians to recanalize coronary and peripheral CTOs in the central lumen, thereby maximizing the therapeutic options and optimizing longer-term results.

KEYWORDS: chronic limb ischemia ■ chronic total occlusion ■ coronary artery bypass grafting ■ coronary artery disease ■ CROSSER® ■ drug-eluting stent ■ guidewire ■ major adverse cardiac event ■ peripheral artery occlusive disease ■ recanalization device ■ stent

In all of endovascular medicine, the most challenging subset of lesions to treat remains chronic total occlusions (CTOs). Treatment options for CTOs, both in the coronary and peripheral vasculature, continue to be a significant unmet clinical need and opportunity facing interventional cardiology. CTOs usually comprise of a combination of fibrocalcific and thrombotic elements that have been in existence for more than 30 days. There is inconsistency and a lack of consensus in the literature here, as some have defined CTOs anywhere from 2 weeks [1–3] to 3 months [2,4].

Chronically occluded coronary arteries account for approximately a third of patients undergoing diagnostic coronary angiography [5]. At present, there are three methods for treatment of coronary CTOs: percutaneous intervention, coronary artery bypass surgery and medical management. New-wire strategies to treat CTOs, such as the retrograde approach, appear promising [6]; however, these procedures require suitable anatomy, a specific armamentarium and are generally challenging procedures that cannot be performed in all high-volume centers. These new tools and approaches need to be used thoughtfully and in the right anatomical and clinical context.

Similar to coronary artery disease, peripheral artery occlusive disease (PAOD) – at a conservative estimate – affects between 6 and 12 million people in the USA alone and is associated with significant long-term morbidity, mortality and reduction in quality of life. Of these patients, 50% have one or more chronically occluded lower extremity arteries that cause PAOD symptoms [7]. Currently, there are four methods for treatment of lower extremity CTOs: conservative management, peripheral bypass surgery, amputation or percutaneous intervention [8].

Conservative management for PAOD, such as medical therapy, diet modification, smoking cessation and exercise, is partially efficacious, but rarely completely eliminates either the symptoms or the objective evidence of the ischemia [7]. It tends to be lifestyle-limiting and the pain that often accompanies exertional activity causes the patients to avoid exercise, which often leads to weight gain, glucose intolerance and a downward spiral to lassitude and senescence. Peripheral artery bypass surgery is effective so long as the distal target vessel is anatomically suitable for insertion of a bypass graft. The limitations of the bypass surgery are well known and include significant patient morbidity, risk of surgical mortality and significant expense, as well as

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longer patient recovery and hospital stay [7,9,10]. Amputation still occurs, despite optimized therapy, approximately 10% of the time [7].

Overview of the market

The major challenge relating to percutaneous treatment of coronary and peripheral CTOs, is the attainment of guidewire positioning distal to the occlusion that is within the true vessel lumen. Percutaneous coronary intervention is accomplished by using conventional guidewire techniques to slowly 'poke' and 'prod' through the occlusion. In order to successfully revascularize a vessel, one must first successfully traverse the occluded segment and safely enter the central lumen of the vessel beyond the occlusion. Another option is to traverse the occluded segment in the subadventitial space, alongside the occlusion, and re-enter the vessel at some point distal to the occlusion. The success rate of coronary and peripheral CTOs varies widely in the range of 40–80%, depending on the location and lesion characteristics of the CTO and on operator experience [11,12]. The main technical reason for an unsuccessful percutaneous coronary intervention for CTO is the failure to cross the occlusion with the wire. Various specialized wires or adjunctive devices have been developed over the years to improve the chances of crossing a CTO successfully or to re-enter the CTO behind the occlusion and into the distal vessel, albeit with variable success rates.

This time-intensive conventional guidewire procedure is often associated with subintimal dissection and occasional perforation of the vessel as the guidewire is extensively manipulated within the vasculature. Subintimal dissection is known to occur as the guidewire is navigated through a 'false' lumen. In recanalization of peripheral occlusions, this is most frequently achieved by using a hydrophilic wire to enter the subintimal space and then looping the wire to extend the dissection alongside the true lumen and finally re-entering at some point distal to the occlusion. Despite years of utilization, the subintimal approach to CTOs has been met with only a limited degree of adoption owing to the frequent tendency for the wire to remain in the subintimal space and fail to re-enter the distal true lumen. In coronary arteries, this subintimal approach is not favorable but is utilized in some centers for coronary occlusions [13,14]. The subintimal guidewire technique is significantly dependent on operator experience and is associated with a modest complication rate, with perforation reported up to 9.6% in peripheral CTO [15] and up to 7% in coronary CTO [16,17].

Failure to revascularize a CTO often leaves the patient with either the more invasive option of surgery (coronary or peripheral artery bypass graft) or continuing medical therapy, which may or may not control clinical symptoms. In addition, leaving a vessel occluded may also have detrimental consequences on long-term survival [18,19].

Introduction to the device

The CROSSER® catheter (CR Bard, AZ, USA) has emerged as an adjunctive therapy to facilitate the crossing of guidewire refractory CTO lesions. The CROSSER system utilizes high-frequency mechanical vibration to penetrate atherosclerotic plaque material to cross CTOs in patients and often stays intraluminal. The device has reported positive safety results with no significant clinical sequelae in published reports and presented studies.

The CROSSER CTO recanalization system is comprised of a generator, transducer, foot switch and a disposable catheter (FIGURE 1). The generator applies alternating current to the piezoelectric crystals resulting in their expansion and contraction within the transducer. The transducer then converts, amplifies and transmits this energy to the catheter, which results in vibration of the tip at a rate of 21,000 cycles/s. This vibration provides mechanical impact and cavitation effects, which aid in the recanalization of the occluded artery. The catheter is available as a monorail or over-the-wire system, is hydrophilically coated and can be mounted on a standard 0.014" guidewire. It is 1.1 mm in diameter, which makes it compatible with a 6 Fr guiding catheter, and has a blunt tip. The infusion lumen of the CROSSER is too small to aspirate blood but it is possible to inject diluted contrast to confirm true lumen position. An irrigation line is required for continuous sterile saline flush through the CROSSER during device activation, which provides cooling of the system and a medium to facilitate cavitation at the catheter tip.

The CROSSER technology allows passage of a standard guidewire to the occlusion site. The CROSSER is then advanced over the wire until it contacts the fibrous cap of the occlusion. The guidewire is then withdrawn into the body of the CROSSER. The device is activated with the foot pedal and placed in a manner that is en face to the proximal cap of the CTO. When it appears to have crossed the occlusion, its position in the true lumen is confirmed by contrast injection; the guidewire is advanced into the distal lumen and then the CROSSER is removed (FIGURE 2). In addition, one usually feels a change in tactile sensation

at the proximal and distal caps. Penetration of the caps is often also accompanied by a change in sound that is readily discernible after a few cases.

Clinical profile & postmarket findings

We reported the FlowCardia's Answer to Chronic Total Occlusion Revascularization (FACTOR) study [20] to assess the safety and effectiveness of the CR Bard CROSSER system in CTOs in the USA. The study comprised of 125 subjects enrolled at 19 US clinical investigational sites. All patients in the study had a prior or concurrent attempt with a minimum of 5 min of guidewire manipulation to recanalize their occluded artery prior to the attempt with the CROSSER system. The primary efficacy end point was the advancement of the CROSSER catheter through the occlusion and advancement of the coronary guidewire into the distal coronary lumen. The primary safety end point was defined as the occurrence of death, myocardial infarction (MI), clinical perforation or target vessel revascularization within the first 30 days; all serious sequelae of guidewire exits (GWEs). A clinically significant perforation was defined as a class II, requiring additional treatment or resulting in significant pericardial effusions, abrupt closure, MI or death, or class III, which was defined with hemodynamic evidence of tamponade or pericardial hemorrhage.

The average patient age was 62.8 years and most patients were men. A total of 54 patients (43.2%) had previously undergone at least one previous attempt to recanalize the CTO using conventional guidewires. The average total procedural fluoroscopy time was only 43.8 min. The total time with energy delivered by the CROSSER catheter averaged only 2 min 36 s. The site of occlusion was located in 50.4% of cases in the right coronary artery and in 31.2% in the left anterior descending artery (LAD), while the left circumflex artery was least likely to be involved (18.4%). The location of the total occlusion within the right coronary artery was associated with a lower rate of technical success ($p = 0.03$). The average known duration of the occlusion was 26.6 months and the average occlusion length was 23.4 mm. The age and the length of occlusions were similar for successful and unsuccessful procedures. In addition, previously described angiographic factors influencing the rate of success, such as calcification, proximal vessel tortuosity, bend greater than 45° or major branch at the site of occlusion, were often present, but had a similar distribution within successful and unsuccessful cases. There were no significant differences for successful and unsuccessful procedures regarding



Figure 1. The CROSSER® chronic total occlusion recanalization system. CROSSER chronic total occlusion recanalization system that includes the CROSSER catheter, system electronics and FlowMate injector. Reproduced with permission from Bard Peripheral Vascular, AZ, USA.

other qualitative angiographic findings, such as the shape of the total occlusion (blunt, central or eccentric) or the presence and type of collaterals.

Technical success was achieved in 76 procedures (60.8%) with advancement of a guidewire to the distal true lumen following the CROSSER device. The major adverse cardiac event rate was 8.8% (11 cases), being lower than the prespecified objective performance criteria. There were no deaths and periprocedural MIs were uncommon (4.8%). There were two angiographic perforations in the study. The first transient perforation related to the advancement of a catheter into the LAD distal to the site of successful

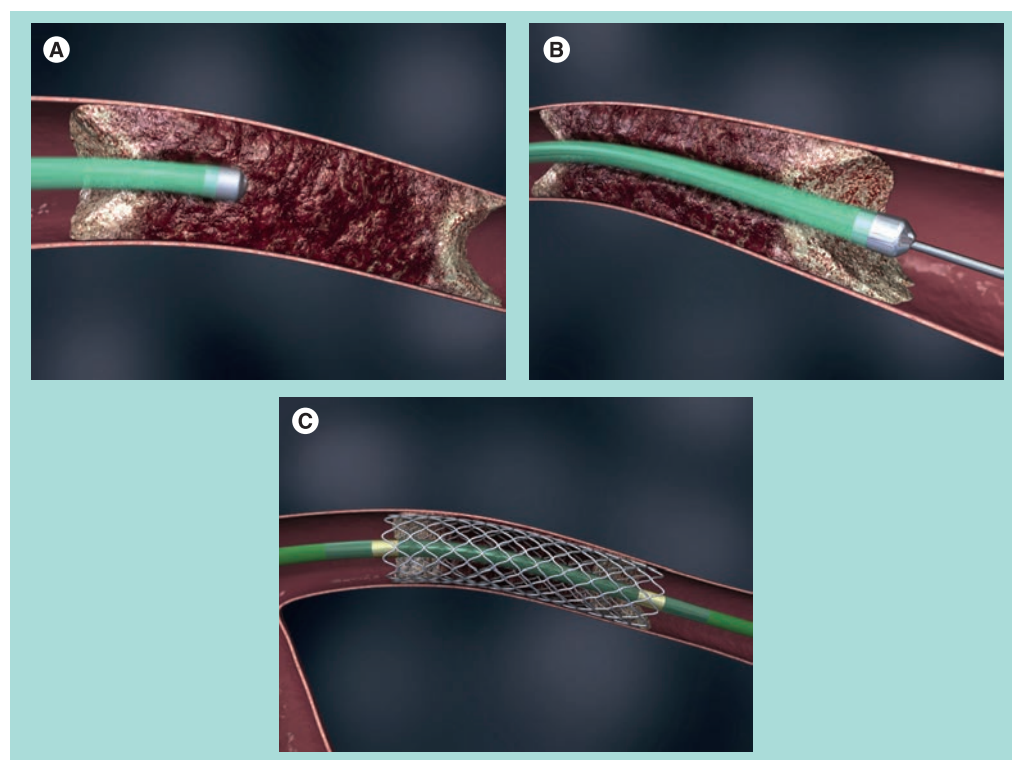


Figure 2. Procedural steps for use of the CROSSER® catheter to recanalize chronic total occlusion. (A) Advance CROSSER to the chronic total occlusion (CTO) cap and activate system. Apply gentle pressure to catheter as CROSSER advances through the CTO. (B) Once through the CTO, advance 0.014" guidewire through the lumen of CROSSER and gain access to the distal true lumen. (C) With guidewire positioned in the central lumen, complete the therapeutic option. Reproduced with permission from Bard Peripheral Vascular, AZ, USA.

CROSSER catheter use. The LAD was subsequently successfully stented and perforation was sealed, resulting in technical, procedural and clinical success. The second angiographic perforation developed following successful CROSSER catheter advancement into a ramus branch and distal wire recanalization with technical success. Following coronary stent placement, a large perforation occurred, ultimately resulting in emergency coronary artery bypass graft (CABG) surgery. As reported in the publication, neither of these perforations were directly related to CROSSER catheter use or to GWE. Six patients with procedural failure required subsequent elective CABG for angina or ischemia treatment (an expected outcome), while none of the patients with procedural success underwent elective CABG [20].

A learning curve was identified and showed a lower rate of technical success at clinical sites, with less than ten cases performed using the CROSSER (56%) compared with clinical sites that performed ten or more cases (65%). The increase in technical success was not associated with longer procedure or fluoroscopy time, but was associated with a longer use and activation of the CROSSER.

The technology was subsequently studied in the CROSSER As First Choice for Crossing Totally Occluded Coronary Arteries (CRAFT) study [21]. To better define the role of the CROSSER in the treatment of patients with CTOs, the authors studied the device as a first choice rather than after routine guidewire failure in a consecutive cohort of eligible patients who were scheduled for percutaneous recanalization of a CTO. The results were presented by A Colombo at Transcatheter Cardiovascular Therapeutics 2007. A total of 80 patients were enrolled in this prospective multicenter study of patients treated for a CTO. Despite the protocol requirement of using the CROSSER as a first attempt, 23.8% of the patients had a documented prior attempt with conventional wires and 'crossed over' to the CROSSER system. Despite this, the technical success rate was 75%, which was defined as advancement of the CROSSER system into or through an occlusion and achievement of distal vessel guidewire position with any conventional 0.014" guidewire.

By conventional coronary angiography, the length of the occlusion was 26.7 mm. Most of the occlusions were *de novo* lesions and the most

frequently treated coronary artery was the right coronary (61%). Activation of the device averaged 2 min 21 s, while procedural times and fluoroscopy times were 105 and 43 min, respectively. Multisensor computed tomography revealed moderate-to-severe calcium in 54.4% and moderate-to-severe angulation in 29.1% of the cases.

The CROSSER CTO recanalization system was cleared for commercialization by the US FDA in 2006 with an indication for intraluminal placement of guidewires beyond chronically occluded coronary arteries. The technology was subsequently studied in infrainguinal occlusions and the FDA cleared the device in 2007 for use in peripheral occlusions. The basis for the peripheral indication was the Peripheral Approach To Recanalization In Occluded Totals (PATRIOT) study [22]. This multicenter, nonrandomized, prospective study enrolled 85 guidewire refractory peripheral CTO patients. The CROSSER technical success rate was 84%, with 0% GWEs that required clinical treatment for perforation. The locations included 63.5% superficial femoral artery, 20% popliteal and 16.5% infrapopliteal CTOs. The average CTO length was 117.5 mm, the average time of occlusion was 16 months and 75% of the vessels were rated with moderate-to-severe calcification. The average CROSSER activation time was approximately 2 min 5 s, with an average fluoroscopy time of 36 min and average procedure time of 102 min. There was a 94.1% freedom from limb loss, clinical perforation and repeat revascularization during 30 days. With the ability to gain distal guidewire access, the following therapeutic therapies were completed: stenting (51.8% [44/85] with average length 196 mm); atherectomy (31.8% [27/85]); cryoplasty (23.5% [20/85]); laser (8.2% [7/85]); percutaneous transluminal angioplasty only (4.7% [4/85]); and no treatment (1.2% [1/85]).

Based on the PATRIOT results, utilizing the CROSSER catheter may also reduce procedure time, radiation and contrast exposure in this subset of difficult, historically time-consuming lesions. For many patients, this minimally invasive, endovascular approach to CTO recanalization will eliminate the need for potentially traumatic bypass surgery or amputation. The CROSSER-facilitated guidewire delivery to the distal lumen in 84% of the wire refractory CTOs with CROSSER averaged an activation time of only 2 min. No safety issues or clinical perforations occurred with GWEs with use of the device. The CROSSER system is a safe, quick and effective technology to support recanalization of infrainguinal CTOs.

The three studies discussed above all had the inclusion criteria of wire-refractory CTOs. Therefore, the reported coronary technical success rates of 60.8–75.0% and reported peripheral technical success of 84% are all after failure to cross the CTO after standard wiring techniques. Without the results of a randomized controlled trial without a crossover design, comparison of technical and clinical success between standard guidewire techniques and CROSSER is difficult.

Alternative devices

A number of devices have been used as adjuncts to conventional wires to improve recanalization rates in patients with refractory CTOs [23], but some devices, such as the laser wire, have failed to show a relevant improvement of success rates and might increase GWE complication rate [24]. The Frontrunner catheter (Cordis Endovascular, NJ, USA) contains a 0.039" cable that connects to two blunt jaws located at the tip, creating channels by blunt microdissection into and through the occluded segment. The device was approved for this application based on a registry of 107 patients with previous failure of CTO recanalization using conventional guidewires [25]. Reaching the distal lumen after using the Frontrunner device was successful in 56% of cases, with an 8% major adverse cardiac event rate, including device-related perforation in two patients (1.9%).

Another device, the Safe-Cross® radio-frequency guidewire (Spectranetics, CO, USA) combines the familiarity of a 0.014" intermediate guidewire with optical coherence reflectometry information at the guidewire tip to discern direction, with a brief radiofrequency electrical discharge to facilitate wire passage through the fibrotic and calcified elements of the occlusion [26,27]. If only amorphous plaque is ahead of the wire, the reflection falls off rapidly, but if the tip of the wire is near the vessel wall, a secondary reflection from the organized collagen fibers is observed, thereby preventing activation against the vessel wall. A color-enhanced monitor displays the position of the wire to the operator. In the Guided Radiofrequency Energy Ablation of Total Occlusion (GREAT) trial using this device, 63 out of 116 patients (54.3%) with CTOs refractory to conventional guidewire (10-min fluoroscopy time attempt) were successfully recanalized with the Safe-Cross wire. The observed major adverse cardiac event rate (including one GWE necessitating treatment of a clinical perforation) was 6.9% (eight out of 116 patients).

Other re-entry devices that have been used in conjunction to the standard guidewire and CTO devices mentioned previously have also been introduced. With peripheral indication, the Outback® catheter (Cordis Endovascular) and Pioneer® catheter (Medtronic Vascular, CA, USA) are both utilized as re-entry devices when the primary technique and approach has failed to stay within the true lumen of the occlusion. A similar re-entry technique is being evaluated by the CrossBoss® catheter and Stingray® catheter re-entry system (BridgePoint Medical, MN, USA) for coronary application.

How the technology fits into the field of medical devices

The CROSSER catheter has regulatory clearance in the USA and Europe for the treatment of coronary and peripheral CTOs. The CROSSER catheter is indicated to facilitate guidewire positioning into and beyond CTOs in the coronary and peripheral vasculature. Our investigations, as well as others, have found the device to have an established safety profile with high technical success in guidewire refractory CTOs.

Conclusion

Chronic total occlusions represent one of the last frontiers to be conquered in our quest to minimize coronary and peripheral ischemia. These procedures have classically taken more time and have a higher complication rate

when compared with similar interventions in stenosed vessels. Without having the availability of a CTO device, interventionalists refer many of these patients to cardiac and vascular surgeons for bypass graft surgery when standard guidewire therapy fails. The CROSSER CTO recanalization catheter was designed and developed to successfully and safely traverse occlusions through the central lumen of the artery. From the various reported results, the CROSSER CTO recanalization catheter was able to demonstrate device safety, a decrease in CTO recanalization time and also achieved a high rate of intraluminal recanalization [19,20,22]. Limitations of these studies include a limited number of patients involved, as well as the nonrandomized nature of the studies, and crossover failure design, which may give rise to case-selection bias.

We spend much of our time and efforts trying to prevent a total occlusion from forming; why should we be reluctant to treat an occlusion once it has formed? The CROSSER device provides practicing interventionalists a safe and efficacious modality to treat CTOs in a timeframe that is reasonable for physicians in the USA and, most importantly, for our patients.

Future perspective

Chronic total occlusion therapy over the next 5–10 years should progress dramatically. One could envisage several CTO crossing devices on

Executive summary

Clinical need

- Recanalization of coronary and peripheral chronic total occlusions (CTOs) remains a challenge, particularly when standard guidewire fails.
- The major challenge relating to percutaneous treatment of both coronary and peripheral CTOs is the attainment of guidewire positioning distal to the occlusion that is within the true vessel lumen or a guidewire exit that has no clinical sequelae.
- Despite years of utilization, the subintimal approach (controlled guidewire exit) to CTOs has been met with a moderate degree of adoption owing to the frequent tendency for the wire to remain in the subintimal space and fail to re-enter the distal true lumen after guidewire exit.

Device

- The CROSSER® system utilizes high-frequency mechanical vibration to penetrate atherosclerotic plaque material to facilitate guidewire placement beyond coronary and peripheral CTOs.
- This vibration provides mechanical impact and cavitation effects that aid in the recanalization of the occluded artery.

Efficacy

- Coronary:
 - FACTOR study – (n = 125) demonstrated a 61% procedural CTO crossing success in guidewire-refractory coronary occlusions.
 - CRAFT study – (n = 80) demonstrated a 75% procedural CTO crossing success in guidewire-refractory and *de novo* occlusions.
- Peripheral:
 - PATRIOT study (n = 85) demonstrated a 84% procedural CTO crossing success in guidewire-refractory peripheral occlusions.

Safety

- There have been no reported CROSSER catheter-related clinical perforations in the clinical studies.

Benefits

- A central luminal approach can provide more acute therapeutic options to the clinician.
- Central lumen recanalization may optimize the acute therapy and ultimately deliver enhanced longer-term outcomes versus the subintimal approach.

the market that can all safely and easily cross the majority of occlusions. Although there may not ever be a 'silver bullet' for crossing all coronary and peripheral occlusions, there may be a chance to have a portfolio of products for anatomical variation, differing plaque morphology and vessel size. With several new safe, effective and easy-to-use CTO crossing devices on the market, physicians would ideally initiate their CTO crossing procedure with one of these devices. CTO crossing devices will have the best chance of success now and into the future if the crossing devices are given a first attempt at the occlusion. Very often, if guidewires are used as a first-line therapy,

dissection planes can more easily be created, thus limiting the available options for therapy in the procedure.

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