Chronic total occlusions occur in approximately 40% of patients with peripheral vascular disease and are a difficult lesion subset to treat by endovascular approaches. The challenge lies in the difficulty in placing a wire across the site of occlusion and remaining in an intraluminal position. Conventional percutaneous transluminal balloon angioplasty for chronic total occlusions involves advancing a stiff wire through the site of obstruction, has the chance for vessel dissection and perforation, and is associated with high rates of procedural failure. Several mechanical devices have thus been developed to treat peripheral chronic total occlusions. In this article, we provide a review of the currently available devices that may increase the procedural success of treating peripheral chronic total occlusions. (J Interven Cardiol 2012;25:395–403)

Introduction

Peripheral vascular disease (PVD) affects approximately 8 million people in the United States. Chronic total occlusions (CTO) are a common finding in patients with PVD, occurring in up to 40% (Figs. 1 and 2). CTOs are complex lesions to treat using endovascular approaches because it may be difficult to cross the site of occlusion with conventional guidewires and remain in an intraluminal position. This challenge has led to variable results in treating CTOs using standard guidewires, with procedural success rates ranging from 34% to 91%.

This review will focus on devices that have specifically been designed to treat peripheral CTOs and will summarize published data describing procedural success rates (Table 1). Although a variety of advanced endovascular techniques (balloon anchoring technique, retrograde approach, controlled antegrade and retrograde subintimal tracking [CART] technique) can also be used to effectively treat peripheral CTOs, in this review we have chosen to specifically discuss dedicated peripheral CTO devices.
is activated by depressing a footstep. The CROSSER catheter is a monorail, hydrophilic catheter with irrigation ports at the hub allowing saline and contrast injections. The catheter is available in three models: 14P, 14S, and 18. The CROSSER 14P and 14S models are 5 French (F) sheath compatible, 146 cm of working length with a 1 mm diameter tip, and are 0.014-inch guidewire compatible. The CROSSER 18 model is 6 F sheath compatible, 125 cm of working length with a 1.5 mm diameter tip, and is 0.018-inch guidewire compatible. Gandini et al. reported on the use of the CROSSER system in 12 patients with CTOs of infranigual vessels. Technical success (defined as crossing of the CTO with guidewire placement in the distal true lumen) was achieved in 75% of cases. Two cases were unsuccessful due to the CROSSER’s inability to cross the cap of the CTO, and one case was unsuccessful due to the creation of a false lumen with guidewire sheath placement. No perforations or dissections occurred with the CROSSER catheter in these 12 cases. Staniloae et al. evaluated 56 patients with 73 peripheral CTOs and found an overall primary success rate of 77%. There were no perforations related to use of the CROSSER device. Khalid et al. studied 25 consecutive patients with 27 peripheral CTOs with a success rate of 41% and 1 episode of vessel perforation.
**Table 1.** Devices Available for Crossing Peripheral Chronic Total Occlusions Include Intraluminal Devices (Crosser, Vibrational Angioplasty, Frontrunner, SafeCross, Excimer Laser, CrossBoss, Wildcat and KittyCat) and Extraluminal Devices (Pioneer, Outback, and Stingray)

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Mechanism of Action</th>
<th>Author/Year</th>
<th>n</th>
<th>Success Rate (%)</th>
<th>Complication Rate (%)</th>
<th>Ease of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crosser</td>
<td>High-frequency mechanical vibration</td>
<td>Gandini/2009</td>
<td>12</td>
<td>75%</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stanilone/2011</td>
<td>73</td>
<td>77%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Vibrational angioplasty</td>
<td>Low-frequency mechanical vibration</td>
<td>Michalis/2001</td>
<td>6</td>
<td>100%</td>
<td>0</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tsetis/2002</td>
<td>13</td>
<td>92%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Frontrunner</td>
<td>Controlled blunt microdissection</td>
<td>Mossop/2006</td>
<td>44</td>
<td>91%</td>
<td>2%</td>
<td>+</td>
</tr>
<tr>
<td>SafeCross</td>
<td>Optical coherence reflectometry</td>
<td>Kirvaitis/2004</td>
<td>75</td>
<td>75%</td>
<td>1%</td>
<td>++</td>
</tr>
<tr>
<td>Excimer Laser</td>
<td>Ultraviolet ablation</td>
<td>Steinkamp/2000</td>
<td>94</td>
<td>81%</td>
<td>23%</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laird/2006</td>
<td>145</td>
<td>86%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Pioneer</td>
<td>Intravascular ultrasound (IVUS) guided vessel reentry</td>
<td>Jacobs/2006</td>
<td>21</td>
<td>100%</td>
<td>19%</td>
<td>+++</td>
</tr>
<tr>
<td>Outback</td>
<td>Fluoroscopic guided vessel reentry</td>
<td>Setacci/2009</td>
<td>24</td>
<td>79%</td>
<td>4%</td>
<td>++</td>
</tr>
<tr>
<td>CrossBoss</td>
<td>Mechanical rotation of catheter</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>+</td>
</tr>
<tr>
<td>Stingray</td>
<td>True lumen reentry using specialized balloon and guidewire</td>
<td>Casserly/2010</td>
<td>1**</td>
<td>100%*</td>
<td>0%</td>
<td>++</td>
</tr>
<tr>
<td>Wildcat and Kittycat</td>
<td>Mechanical rotation of catheter</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>+</td>
</tr>
</tbody>
</table>

NA = no published information.

*Ease of use ranked as +++ difficult, ++ easy, and + very easy;
**Information listed is from single case report (n = 1).

**Figure 3.** Use of the CROSSER device (Bard Peripheral Vascular, Inc., Tempe, AZ, USA) to treat a right superficial femoral artery ostial occlusion. (A) Ostial occlusion (arrow) of the right superficial femoral artery. (B) Reconstitution of the distal left superficial femoral artery (arrow) via extensive collaterals (arrowheads) from the right profunda femoralis artery. (C) Crosser device (arrow) entering the proximal cap of the chronic total occlusion. (D) Distal injection via catheter (arrow head) within the popliteal artery to ensure intraluminal position (arrow) after crossing occlusion. (E) Following angioplasty and stent placement (arrows).

Peripheral Approach to Recanalization In Occluded Totals (PATRIOT) is an ongoing feasibility study evaluating the safety and efficacy of the CROSSER in peripheral CTOs.

**Vibrational Angioplasty.** Vibrational angioplasty uses mechanical vibration produced by a device to cross the cap of the CTO. Conventional 0.014-inch guidewires protruding approximately 1 to 5 mm distally from over-the-wire catheters are fluoroscopically placed at the cap of a CTO. When the device is activated, mechanical vibration is transmitted down the catheter to the end of the guidewire. The end of the guidewire vibrates laterally and distally at a frequency of 16–100 cycles/s. This vibration is used to fracture
and penetrate the cap of the occlusion. The device is activated for 1–2 minutes at a time and may be used with a large number of guidewire/catheter combinations. Michalis et al. used vibrational angioplasty in six patients each with a CTO either in the superficial femoral artery (SFA) or the popliteal artery with a success rate of 100% and no complications. Tsetis et al. studied vibrational angioplasty with infrapopliteal CTOs. A total of 13 CTOs in 12 patients were treated and 12 of the 13 CTOs were successfully crossed (success rate of 92%). The only complication was vessel perforation that resulted in an unsuccessful case. Further studies with larger patient populations are needed to determine the utility of vibrational angioplasty in peripheral CTOs.

**Frontrunner XP CTO Catheter.** The mechanism of action of the Frontrunner XP CTO catheter (Cordis Corp., Miami Lakes, FL, USA) is controlled blunt microdissection (Fig. 5). The catheter consists of a rounded distal tip with a hinged jaw, which opens and closes allowing for blunt dissection. When the operator opens the hinged jaw, the cap of the occlusion is either spread apart and fractured, or a subintimal track is made. The tip of the catheter is then closed and advanced and the process is repeated until the catheter crosses the CTO. Once across the occluded area, a guidewire may be advanced into the distal true lumen. The catheter may be integrated with a 4.5 F Micro Guide Catheter (Cordis Corp.) for additional support and guidance. Successful crossing of CTOs in coronary, mesenteric, and various peripheral vessels has been reported. Mossop et al. evaluated controlled blunt microdissection in 36 patients with 44 CTOs in the iliac, femoral, and popliteal arteries, which had failed previous conventional guidewire attempts. Procedural success, defined as recanalization with less than 30% residual stenosis, was 91%. Only one complication occurred, which was thrombosis of an iliac artery within 24 hours of the index procedure. A true lumen reentry catheter was used in 14 of the 40 successful cases. These studies suggest that the catheter is safe and effective for the treatment of peripheral CTOs, but may require a true lumen reentry device for cases of subintimal guidewire passage.

**SafeCross Radiofrequency CTO Crossing System.** The SafeCross system (Spectranetics, Colorado Springs, CO, USA) is a device that combines two technologies to cross CTOs (Fig. 6). The device uses optical coherence reflectometry (OCR) for guidance and radiofrequency ablation (RFA) for penetration through CTOs. The principles of OCR include a near-infrared light source, which is divided into a reference and sample beam. The backscattered light from the sample beam is combined with the reflected light from the reference beam in a detector, which measures interference intensity. Each type of tissue (plaque, thrombus, and intima) has a known interference intensity pattern, which allows the detector to inform the operator what type of tissue is in direct contact with the end of the catheter. RFA can also be used to penetrate through dense CTOs. Short bursts of approximately 100-ms duration of low frequency energy ranging from 250 to 500 kHz is delivered to the end of the catheter creating a 75 to 100 µm zone of ablated tissue. The SafeCross system consists of a monitor, computer unit, and disposable catheter and guidewire. The 0.014-inch guidewire contains a fiber optic cable with a 10 mm radiopaque tip. The guidewire is fluoroscopically guided to the CTO, and placed directly against the cap of the occlusion. The OCR determines the type of tissue the catheter is in contact with. The monitor will display a green bar when lumen, plaque or thrombus is detected; a red bar is displayed when intima is detected. The guidewire is advanced until the red bar appears. At that point, the guidewire is redirected until there is...
the appearance of the green bar. When the guidewire is not able to cross the occlusion, RFA can be activated, allowing further penetration of the guidewire. Kirvaitis et al. evaluated the SafeCross device as part of a prospective, multicenter registry of 72 patients with 75 peripheral CTOs that failed crossing with conventional guidewires. Clinical success, defined as placement of the SafeCross guidewire in the distal true lumen with opening of the lesion, was 75%. Only one case of vessel dissection occurred, with no cases of perforation or distal embolization.

**Excimer Laser Angioplasty.** Excimer laser angioplasty is the implementation of laser technology to ablate atherosclerotic tissue (Fig. 7). The technology consists of 2 components, the CVX-300 Excimer Laser System (Spectranetics, Colorado Springs, CO, USA) which is the module where the laser is created, and the Turbo Elite catheter (Spectranetics) which transmits the laser from the module to the tissue. The CVX-300 is a xenon-chloride (XeCl) pulsed laser system that emits a near ultraviolet (UV) B laser at a wavelength of approximately 308 nm. The UV energy is released in very short pulses at a depth of approximately 0.05 mm to break molecular bonds in a photochemical, rather than a thermal, manner. The catheters use optical fibers to transmit the UV energy to the occlusion, have a hydrophilic coating for improved tracking, and are 0.014 inch (0.9 and 1.4 mm catheters) and 0.18-inch (1.7, 2.0, 2.3, and 2.5 mm catheters) guidewire compatible.

In cases of CTOs that are resistant to conventional guidewires, a “step by step” technique is used. The catheter is placed directly adjacent to the cap of the occlusion and the guidewire is retracted into the catheter. The catheter is then advanced and activated at a rate of approximately 0.5 to 1 mm/s through approximately 1 cm of the lesion. The catheter is held in place while the guidewire is advanced in attempt to cross the lesion and confirm intraluminal placement. If unable to cross, the catheter is then reactivated and advanced. This process is repeated until the catheter crosses the occlusion. With the guidewire in the distal lumen, the catheter is removed allowing for conventional angioplasty and stenting. Success rates for excimer laser angioplasty in the treatment of peripheral CTOs range from 81% to 88%. Steinkamp et al. reported a success rate of 81% using the “step by step” technique for a series of patients that failed previous conventional guidewire attempts. The laser angioplasty in the critical limb ischemia (LACI) study included 145 patients, 155 lesions, and 141 CTOs. Twenty-six of these cases required the “step by step” technique with an overall procedural success rate of 86%. Complications occurred...
in 12% and included vessel dissection, acute thrombus formation, distal embolization, and perforation.

**CrossBoss CTO Catheter.** The CrossBoss CTO Catheter is a component of the Bridgepoint Medical System (Bridgepoint Medical, Plymouth, MN, USA) and was designed to facilitate intraluminal placement of conventional guidewires across CTOs. The CrossBoss Catheter has a 3.0 F atraumatic tip that is rotated using a ratcheting torque device. Rotation of the device advances the catheter through the proximal cap of the CTO. Following placement of the catheter across the CTO into the true lumen, conventional angioplasty and stenting can be performed. The complete Bridgepoint Medical System consists of the CrossBoss Catheter, Stingray Balloon Catheter, and Stingray Guidewire. When intraluminal advancement of the CrossBoss Catheter is not possible, the subintimal space can be entered and the Stingray Balloon Catheter and guidewire can then be used to reenter the true lumen, distal to the area of occlusion. The Stingray Balloon Catheter is a self-orienting, flat-shaped balloon that allows true lumen reentry during low-pressure (4 atm) inflation by advancing the 0.019-inch Stingray Guidewire through an exit port that is adjacent to the true lumen. The Bridgepoint system has been studied in 42 patients with coronary CTOs and achieved success rates of 67%. To date, there are 2 published case reports describing the successful use of this device for peripheral CTOs—one located within the SFA and the other within the tibial artery. The Facilitated Antegrade Steering Technique in CTO (FAST-CTO) is an ongoing multicenter study of 300 patients with peripheral CTOs refractory to conventional guidewires.

**Wildcat and Kittycat Catheters.** The Wildcat (Avinger, Inc, Redwood City, CA, USA) is a 6 F, over the wire, 0.035-inch guidewire compatible catheter with a crossing profile of 2 mm. When the proximal cap of the CTO is engaged with the catheter, the catheter is first rotated counter clockwise in what is referred to as “passive” mode. If significant resistance is encountered, the catheter is then rotated clockwise in “active” mode and the spiral edges of the catheter tip actively engage the plaque. Once the catheter is advanced across the occlusion, a guidewire can be advanced and conventional angioplasty and stenting performed. The tip of the catheter can also be deflected using a slider mechanism located at the proximal portion of the catheter. The catheter can be rotated manually or using a 3-V battery pack located at the distal portion of the catheter. The Kittycat Catheters (Kittycat, Kittycat 2) are 5 F, 0.014-inch guidewire compatible, have a smaller crossing profile (1.5 and 1.7 mm) and operate upon the same principle as the Wildcat catheter. The CTO Crossing with the Wildcat catheter (CONNECT) is a recently completed 88 patient nonrandomized study evaluating the use of the Wildcat catheter for peripheral CTOs located in the superficial femoral and popliteal arteries. To date, there are no publications describing the use of the Wildcat or Kittycat catheters for the treatment of peripheral CTOs.

**Extraluminal Devices**

The majority of the available devices for the treatment of peripheral CTOs are designed to obtain recanalization by passing through the site of vessel occlusion and attempt to maintain intraluminal device and guidewire position. However, a technique referred to as subintimal angioplasty achieves revascularization by intentionally bypassing the site of occlusion via a subintimal course. First described by Bolia et al., the technique requires deliberate advancement of the guidewire into the subintimal space, advancement of the guidewire in the subintimal track adjacent to the occlusion, and then reentry of the guidewire into the true lumen, distal to the site occlusion. With the guidewire in place, conventional angioplasty may
DEVICES TO TREAT PERIPHERAL CHRONIC TOTAL OCCLUSIONS

Figure 8. Pioneer (Medtronic Vascular, Santa Rosa, CA, USA). (A) A subintimal dissection is created using conventional guidewires. (B) The pioneer catheter is advanced within this subintimal dissection plane, to an area distal to the site of the occlusion. (C) Using ultrasound guidance on the tip of the pioneer catheter, the true vessel is localized (inset) and a needle is deployed into the true lumen of the vessel. (D) A 0.014-inch guidewire is advanced through the needle and placed into the true lumen of the vessel. (E) The pioneer catheter is removed, leaving the 0.014-inch guidewire in place, traveling from the subintimal space into the true lumen. (F) Balloon angioplasty is performed to dilate a track into the true lumen followed by stent placement (not shown).

be done to create what has been termed as “endovascular bypass.” Subintimal angioplasty is possible in the iliac, superficial femoral, popliteal, and tibial arteries with success rates ranging from 74% to 87%.27–30 The primary reason for failure of this approach is inability to reenter the true lumen distal to the area of occlusion. This difficulty may be because of either heavily calcified vessel walls resistant to penetration with a guidewire, or lack of directional control of the guidewire toward the true lumen. Devices have thus been developed to gain access to the true lumen from the subintimal space.

Pioneer Catheter. The Pioneer catheter (Medtronic Vascular, Santa Rosa, CA, USA) is a reentry device that incorporates intravascular ultrasound (IVUS) imaging (Fig. 8). A curved nitinol needle is deployed from the catheter tip just proximal to the IVUS transducer. The catheter is a monorail system that is positioned in the subintimal space just distal to the site of occlusion over a 0.014-inch guidewire. Once the catheter is in position, IVUS imaging is initiated and the true lumen of the vessel is identified. Once properly oriented, the needle is deployed under direct IVUS imaging and a second 0.014-inch guidewire is advanced through the needle into the distal true lumen. Once the guidewire is in place, then the Pioneer catheter is removed and conventional angioplasty and stenting are performed.

Jacobs et al. treated 87 CTOs, 24 of which failed reentry into the true lumen using conventional guidewire therapy and the Pioneer catheter was used in 21 of 24 cases.31 All 21 cases were successful in obtaining true lumen reentry. Four patients had bleeding at the recanalization and angioplasty sites, 2 resolved after treatment with covered stents, and 2 resolved after treatment with uncovered stents. Al-Ameri et al. reported 21 consecutive cases of peripheral CTOs involving the Pioneer catheter.32 There was a 95% success rate (defined as less than 30% residual stenosis) with a single complication. Saket et al. reported 7 cases of CTOs that failed previous guidewire therapy in which the Pioneer catheter was used.33 True lumen reentry was obtained and antegrade flow restored in all seven cases without any procedure related complications. Casserly et al. reported on 2 patients with CTOs that were successfully treated with the Pioneer catheter without complications.34

Outback Catheter. The Outback Catheter (Cordis Corp.) is another device designed to assist with reentry into the true lumen during subintimal angioplasty (Fig. 9). The device is 6 F compatible and uses fluoroscopic guidance to control reentry. A retractable nitinol needle is deployed approximately 1.5 cm proximal to the distal end of the catheter. The device is guided to the subintimal space over standard 0.014-inch guidewires. Once in the
appropriate position, the catheter is oriented so the deployable needle enters the distal true lumen. The guidewire is then advanced into the distal true lumen, the Outback catheter removed, and angioplasty and stenting performed. Several studies have evaluated the efficacy and safety of the Outback catheter and found success rates ranging from 50% to 100%.35,36 The most recent study evaluated the Outback catheter on 24 patients who had failed previous subintimal angioplasty with conventional guidewires.37 Technical success was achieved in 19 of the 24 patients, with only 1 complication which was vessel perforation that subsequently required below-the-knee surgical bypass.

Conclusions

Peripheral CTOs are a common finding in patients with PVD and pose a challenge for endovascular specialist. In recent years, there has been the addition of several new devices that improve success rates of CTO endovascular intervention. Understanding the principles and mechanisms of each these new devices will allow the endovascular specialist to choose the most appropriate device for each individual patient.

References

12. Ayers NP, Zacharias SJ, Bu-Fadel MS, et al. Successful use of blunt microdissection catheter in a chronic total

Figure 9. Outback catheter (Cordis Corp, Miami Lakes, FL, USA). (A) Subintimal dissection is created using conventional guidewires. (B) The Outback catheter is advanced within this subintimal dissection plane, to an area distal to the site of the occlusion. (C) Using fluoroscopic guidance, the true vessel is localized and a needle is deployed into the true lumen of the vessel. (D) A 0.014-inch guidewire is advance through the needle and placed into the true lumen of the vessel. (E) The Outback catheter is removed, leaving the 0.014-inch guidewire in place, traveling from the subintimal space into the true lumen. (F) Balloon angioplasty is performed to dilate a track into the true lumen followed by stent placement (not shown).


