

Blunt Microdissection of Chronic Total Occlusions

The Frontrunner CTO Catheter facilitates placement of guidewires across coronary and peripheral CTOs.

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Stenotic lesions in both the coronary and peripheral vasculature are routinely treated with an effective array of minimally invasive percutaneous techniques, including balloon angioplasty (PTCA) and stenting.¹⁻³ With a guidewire placed across a target lesion, these proven catheter-based techniques work well and excellent revascularization is typically achieved.⁴⁻⁷ The availability of drug-eluting stents is expected to further solidify percutaneous treatment of vascular stenosis as the standard of care in both coronary and peripheral vascular disease.⁸⁻¹⁰ In the case of chronic total occlusions (CTOs), however, conventional guidewires cannot be consistently and reliably placed across the lesion. It is currently estimated that CTOs are present in up to one third of patients with coronary disease diagnosed by angiography, and they remain the primary reason for surgical referral. When percutaneous intervention is attempted in these patients, inability to place a guidewire across the occlusion is the leading cause of failure.¹¹

CTOs are typically composed of a hard fibrotic and sometimes calcified proximal cap. This cap is followed by a segment of poorly organized fibrous and calcified plaque ending with a firm distal cap. These mature lesions are commonly located in tortuous areas of the vasculature that have varying degrees of vascular wall remodeling. They are refractory to conventional floppy guidewires with which insufficient axial force can be applied to achieve reliable advancement [AU: please clarify the previous sentence]. The use of stiffer and more aggressive hydrophilic guidewires is often also insufficient and suffers from an attendant increase in risk of perforation.

Novel catheter technology has recently been developed

that allows for facilitated recanalization of many previously intractable CTOs through a process of "blunt microdissection."^{12,13} The Frontrunner [AU: X39?] CTO Catheter (LuMend, Inc., Redwood City, CA) (Figure 1) is a third-generation, single-use, disposable, 3.1-F catheter consisting of an articulating, distal tip assembly manually actuated by means of a proximal rocker handle.

The Frontrunner X39 CTO Catheter is most commonly used in combination with the Frontrunner Micro Guide Catheter (MGC). The MGC provides additional support for the X39 when needed, and acts as a conduit for a more rapid wire exchange after the X39 has crossed the CTO. The system is specifically designed for facilitating placement of conventional guidewires safely across CTOs in both the coronary and peripheral vasculature. This is achieved by steering the distal tip of the device to the occlusion site, and then remotely actuating the tip to facilitate blunt microdis-



Figure 1. The Frontrunner X39 with Micro Guide Catheter.

TABLE 1. PERIPHERAL CTO CROSSING SUCCESS RATE

Location of CTO	Success Rate
Iliac	5 / 6 (83%)
SFA	27 / 28 (96%)
Subclavian	3 / 4 (75%)
Overall peripheral	38 / 41 (93%)

TABLE 2. CORONARY CTO CROSSING SUCCESS RATE

Location of CTO	Success Rate
LAD	39 / 56 (70%)
LCX	19 / 27 (70%)
RCA	92 / 161 (57%)
Overall Coronary	150 / 244 (62%)

TABLE 3. PERIPHERAL CTO CROSSING SUCCESS RATES AS A FUNCTION OF LESION LENGTH

Location of CTO	Success Rate
<100 mm	20 / 21 (95%)
100 mm to 200 mm	11 / 12 (92%)
>200 mm	3 / 3 (100%)

TABLE 4. CORONARY CTO CROSSING SUCCESS RATES AS A FUNCTION OF LESION LENGTH

Location of CTO	Success Rate
<15 mm	16 / 23 (70%)
15 mm to 30 mm	97 / 158 (61%)
>30 mm	30 / 45 (67%)

TABLE 5. FAILURE MODES - PERIPHERAL AND CORONARY

Failure Mode	Percentage of Total Cases	
	Peripheral	Coronary
Subintimal	2%	16%
Engagement	0%	6%
Engaged, did not cross	2%	8%
Fronrunner-related complication	0%	1%
Procedure-related complication	0%	2%
Other	3%	4%

TABLE 6. STENT PLACEMENT - PERIPHERAL AND CORONARY

Manufacturer	Percentage of Total Cases	
	Peripheral	Coronary
Cordis	57%	52%
Guidant	23%	22%
Boston Scientific	3%	12%
Medtronic	5%	11%
Bard	4%	-
Other	8%	3%

section of the plaque (Figure 2). The distal assembly of the Fronrunner can be cycled repeatedly as required in various planes to microdissect and separate tissue in the target vessel segment. In this way, the technique provides a space for crossing and advancing guidewires beyond the CTO.

Originally designed for use in coronary arteries, the Fronrunner CTO Catheter has been increasingly used to facilitate placement of guidewires across peripheral CTOs (Figure 3). Atherosclerotic peripheral arterial disease is the leading cause of occlusive disease of the extremities. The primary sites of involvement are the abdominal aorta and iliac arteries (30% of symptomatic patients), the femoral and popliteal arteries (80% to 90% of patients), and the more

distal vessels, including the tibial and peroneal arteries (40% to 50% of patients).¹⁴

RESULTS

Various versions of the Fronrunner device have now been documented in more than 1,000 procedures in both peripheral and cardiovascular applications. Data have been collected using the current version of the device, the X39 in combination with the MGC, in almost 300 cases. With success defined as placement of a guidewire across the CTO lesion, the X39 (0.039-inch diameter) and MGC have been successfully used in 38 of 41 peripheral procedures (iliac, subclavian, and SFA arteries) for a 93% success rate (Table 1).

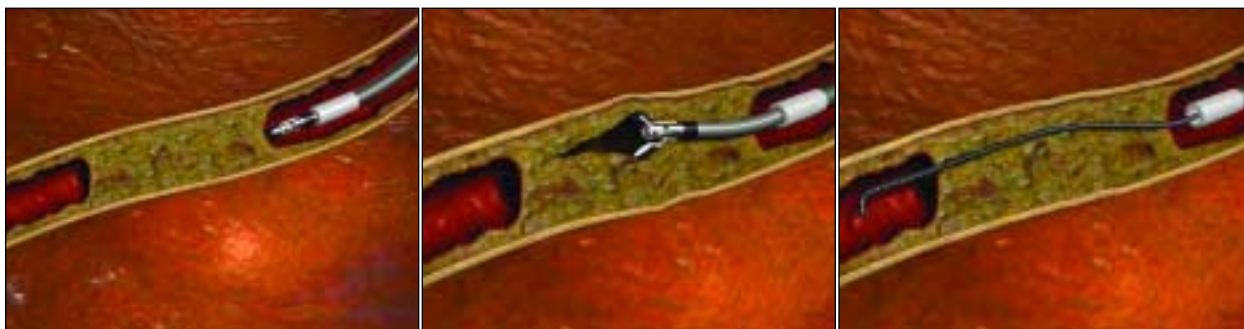


Figure 2. Schematic of Fronrunner controlled blunt microdissection.

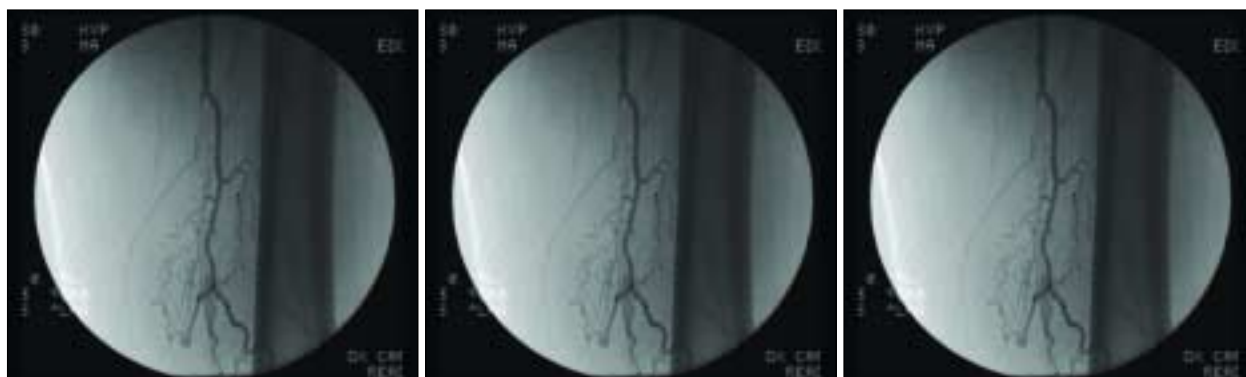


Figure 3. Cine of superficial femoral artery with CTO (A), with the Frorunner actuating and working through occlusion (B); the final result (C).

The same combination of Frorunner and MGC has been successful in 150 of 244 (62%) of coronary procedures (Table 2).

Initial peripheral vasculature experience to date appears to be relatively insensitive to CTO location. Coronary success rates, however, are somewhat variable depending on location, ranging from a low of 57% in the RCA to [AU: a high of?] 70% in the left coronary anatomy. This variability in the coronaries is thought to be primarily due to vessel tortuosity and the right coronary artery's size and predisposition to dissection. Generally, higher success rates in the periphery may be due to straighter, less complex vessel anatomy. Success rates in both peripheral and coronary applications appear to be relatively insensitive to lesion length (Tables 3 and 4).

Blunt microdissection of CTOs with the Frorunner catheter has also demonstrated a significant reduction in crossing times versus conventional guidewires. Approximately 30% of all coronary cases and 50% of all peripheral cases are crossed in less than 10 minutes with the Frorunner device. Furthermore, 70% of both coronary and peripheral cases are crossed in less than 20 minutes.

Failure modes can be summarized into six categories: (1) subintimal advancement with inability to re-enter the true lumen, (2) failure to engage the lesion, (3) failure to dissect through the lesion after successful engagement, (4) Frorunner-related complication, (5) procedure-related complication, or (6) other (Table 5).

Subsequent to successful guidewire placement, an average of two stents per patient are placed in both coronary and peripheral vessels. An analysis of stents currently being placed is shown in Table 6. This distribution is likely to change as drug-eluting products become more readily available. Nonetheless, it is encouraging to see revascularization complete in patients [AU: please clarify "revascularization complete in patients"] who would otherwise be referred to surgery or be relegated to medical therapy.

SUMMARY

The use of a blunt microdissection technique to safely fracture and separate stenotic material and form a pathway through CTOs for the purpose of placing conventional guidewires and subsequent PTCA and stent therapy is proving to be a very safe and effective method of treating these previously recalcitrant lesions. The blunt distal tip of the LuMend Frorunner device appears to significantly reduce the risk of perforation. The optional use of the recently developed Micro Guide Catheter provides additional support for the Frorunner X39 CTO Catheter, further enhancing its effectiveness. Successful minimally invasive treatment of peripheral and coronary CTOs clearly benefits patients who have historically required referral to surgery. ⁿ

[AU: For each reference, please provide names for the first three authors of each. Also, there are 14 call-outs in the text, but only thirteen references. Please send the 14th and indicate where in the list it should appear.]

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