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# PERIPHERAL VASCULAR DISEASE

## *Original Studies*

# Controlled Blunt Microdissection for Percutaneous Recanalization of Lower Limb Arterial Chronic Total Occlusions: A Single Center Experience

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**Background: Percutaneous techniques for the revascularization of symptomatic lower limb arterial chronic total occlusions (CTOs) remain suboptimal due to difficulty in safely and reliably crossing these heavily calcified lesions using standard guidewire and balloon technology. Objectives: The objective of this prospective study was to evaluate the technical success and safety of controlled blunt microdissection (CMD) for the treatment of resistant peripheral CTOs. Methods: This series enrolled 36 patients (26 men; mean age 67 ± 12 years), with 44 symptomatic CTOs (2 terminal aortic, 24 iliac, 16 femoral, and 2 popliteal), which had previously failed conventional percutaneous revascularization. CMD was carried out using a specialized prototype catheter. Actuation of the hinged jaws of this CMD catheter created a channel within the occluded arterial segment for guidewire passage, and subsequent angioplasty and stenting using standard procedures. The problem of subintimal CMD catheter passage, creating an eccentric channel, was addressed using a second novel device, the true-lumen reentry (LRE) catheter, which allowed reentry into the downstream lumen. Results: Procedural success, evaluated angiographically, was achieved in 40 (91%) of the 44 CTOs. Fourteen (35%) of these 40 successful recanalizations required guidewire redirection, using the LRE catheter for lesion traversal. There were no complications related to CMD *per se*; although one patient experienced acute in-stent thrombosis, managed successfully with intra-arterial thrombolysis. Conclusions: We therefore conclude that CMD can be used safely and successfully to facilitate recanalization of resistant CTOs in the pelvic and lower limb arteries.** © 2006 Wiley-Liss, Inc.

**Key words: iliac; femoral; stent; atherosclerosis; peripheral arterial disease; arterial occlusion; angioplasty; percutaneous revascularization**

## INTRODUCTION

Chronic atherosclerotic disease of the pelvic and lower limb arteries, leading to lower extremity ischaemia, is a significant cause of morbidity and mortality, affecting about 8–10 million in the United States alone [1,2]. Clinical manifestations of intermittent claudication and rest pain, with or without tissue loss, reflect a pathological continuum from moderate degrees of fixed stenosis through to total occlusion.

Percutaneous catheter-based techniques have emerged as the preferred first line method of revascularization when conservative medical management fails, entailing shorter periods of hospitalization and associated with lower morbidity and mortality as compared with surgical bypass [3,4]. However, percutaneous methods have been

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**TABLE I. Patient Characteristics**

| | |
|---|---|
| Demographics | |
| Age | 67 ± 12 (47–89) |
| Males | 26 (72%) |
| Females | 10 (28%) |
| Risk factors and comorbidities | |
| Diabetes mellitus | 10 (28%) |
| Smoker/ex-smoker | 16 (44%) |
| Hypertension | 25 (69%) |
| Hypercholesterolaemia | 27 (75%) |
| Ischemic heart disease | 18 (50%) |
| Clinical presentation of ischemia | |
| Mild claudication (>500 m) | 0 |
| Moderate claudication (40–500 m) | 23 |
| Severe claudication (<40 m) | 8 |
| Ischemic rest pain or minor tissue loss | 6 |
| Major tissue loss/impending limb loss | 7 |

**TABLE II. Inclusion and Exclusion Criteris for Participation in the Study**

| |
|---|
| Inclusion criteria |
| CTO in the terminal aorta, iliacfemoral or popliteal arteries |
| Prior unsuccessful attempt at percutaneous recanalization |
| Patent calf vessels |
| Symptoms of leg ischaemia |
| Exclusion criteria |
| Subtotal occlusion |
| Lesion <3 months old (determined on review of old angiograms) |
| Occluded crural vessels |
| Pregnancy |
| Coagulopathy |
| Terminal malignancy |

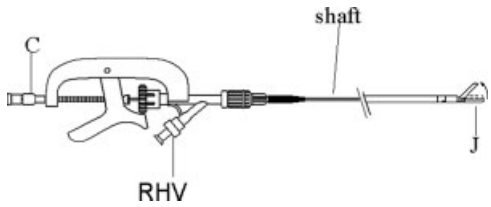


**Fig. 1. Manufacturer's schematic diagram of the prototype controlled blunt microdissection catheter used in this study (not drawn to scale). Using the distal control knob (C), the hinged jaws (J) of the catheter distal assembly were advanced, rotated and repeatedly actuated to create a channel through the occlusive plaque, permitting guidewire passage. The rotating haemostatic valve (RHV) allowed flushing of the guidewire and pull-wire lumina with heparinized saline.**

suboptimal in the treatment of pelvic and lower limb chronic total occlusions [5–8]. Attempted recanalization fails in approximately 20% of these peripheral arterial chronic total occlusions (CTOs) because of difficulty in safely and reliably crossing heavily calcified lesions, using standard guidewire and balloon technology [5–8]. Surgical bypass of the occluded segment is then necessary for restoring flow to the ischemic leg.

We have previously approached the problem of recanalizing difficult peripheral CTOs with the novel technique of controlled blunt microdissection (CMD), reporting its successful use in two patients [9]. However, there has been no previous study of the use of CMD in peripheral CTO recanalization. In this prospective series, the aim was to determine whether CMD can be safely and successfully applied to a larger sample of 36 patients with resistant CTOs. A further problem commonly encountered during CTO recanalization, subintimal catheter passage resulting in inability to reenter the downstream true lumen, was addressed using a specialized reentry catheter (LRE catheter). This novel device was used to redirect the guidewire into the arterial true lumen.

## MATERIALS AND METHODS

### Study Design and Patient Characteristics

This prospective, nonrandomized, single-center study enrolled 36 patients (26 male; mean age 67 ± 12 years) with 44 angiographically demonstrated native artery total occlusions (2 terminal aortic, 24 iliac, 16 femoral, and 2 popliteal). These occlusions were at least 3 months old, as determined on the basis of duration of symptoms and/or angiographic findings. The patients were referred to our institution, a tertiary referral centre, for management of leg ischemia refractory to medical therapy. All had failed attempts at percutaneous recanalization of the culprit lesion using conventional guidewire and catheter-based techniques, six of these during a prior admission and the rest during the index admission. The two patients whose successful lower limb revascularization using CMD has reported previously [9] were also included in this study.

Eligible patients underwent evaluation, which included a thorough medical history, physical examination, and review of diagnostic angiograms and treatment records.

Patient characteristics, including the severity of ischemia, are listed in Table I, and the inclusion and exclusion criteria in Table II. All patients had patent crural vessels ipsilateral to the CTO.

Each patient was required to sign an informed consent document prior to enrolment in the study, which was approved by our hospital's Human Research Ethics Committee.

### Catheter Design

Two novel devices were used in this study to facilitate guidewire traversal of the refractory CTOs. Both are single-use, over the wire devices with a shaft length of 80 cm, compatible with a 0.018″ guidewire.

The prototype CMD catheter consisted of a flexible braided shaft, with an outside diameter of 5.4 Fr, termi-

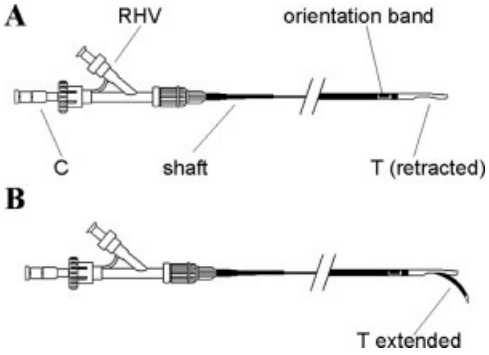


**Fig. 2. Manufacturer's schematic diagram of the prototype true lumen reentry (LRE) catheter used in this study (not drawn to scale). The sharp, curved, radio-opaque distal cannula tip could be retracted (A) and extended (B), enabling guidewire reorientation and puncture of overlying plaque, in turn permitting guidewire reentry centered in the downstream true-lumen.**

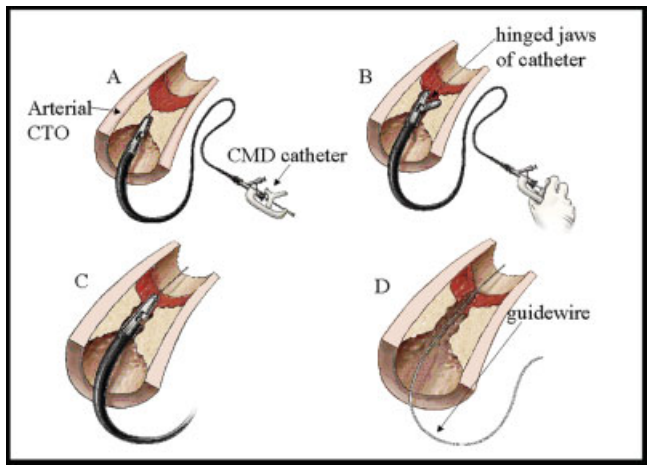


**Fig. 3. Schematic diagram of the process of CMD. (A) The CMD catheter is advanced to the chronic total occlusion. (B, C) Actuation of the hinged jaws of the catheter distal assembly creates a passage within the occluded arterial segment. (D) This in turn permits guidewire traversal of the lesion, enabling recanalization by angioplasty and stenting. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]**

nating in a 7.1 Fr radio-opaque blunt distal assembly (Fig. 1). This articulated nitinol dissecting assembly, with one fixed and one hinged jaw, is attached to a coaxial guidewire conduit and pull-wire. The jaws can be opened, rotated, and advanced using the distal control knob to displace, separate, and fracture atheromatous plaque in the occluded segment. This process of blunt microdissection permits advancement of a guidewire beyond the diseased segment by creating a passage in either the true vessel lumen or the subintimal plane.

In cases of subintimal CMD catheter passage, the LRE catheter (Fig. 2) was used. Its sharp, curved, radio-opaque distal cannula tip enabled guidewire reorientation, permitting reentry centered in the downstream true-lumen. The outside diameter of the LRE catheter is 4.2 Fr at the distal tip, and 3.2 Fr at the shaft.

Approval was obtained for the use of the prototype CMD and LRE catheters from both the hospital's ethics committee and our state's health department.

## Treatment Procedure and Medications

All 44 procedures were performed within a 25-month period (December 2001 to January 2004) by the same interventional team.

Primary access was obtained either via an anterograde transfemoral or a retrograde popliteal approach in all cases. Imaging was performed using a Philips Integris V3000 diagnostic angiocatheter system (Philips Medical Systems, The Netherlands). Screening angiography was used to assess the position and length of CTOs, the degree of calcification, and distal vessel runoff. Plaque calcification was graded as 0 (no visible calcification) 1 (mild), 2 (moderate), or 3 (severe).

Attempts were made, for 10–20 minutes, to coaxially cross the lesions with two or more of the following conventional guidewires, in combination with balloon support: ACS HiTorque Balance and Steelcore 18 (Guidant, MN, USA); Hi-Torque Flex T Steerable (Malinckrodt, Germany); Crosswire and Hydrophilic 0.035″ angle Tip Glidewires (Terumo Medical, Tokyo, Japan); V18 Control Wire (Boston Scientific, MA, USA); and Amplatz and Bentson (Cook, IN, USA). A straight Glidewire (Terumo Medical, Tokyo, Japan) was used in all cases before conventional techniques were abandoned.

After repeated failure of wire passage across the lesion, the prototype CMD catheter (Lumend Inc., Redwood City, CA) was deployed. Under fluoroscopic guidance, the occluded arterial segment was microdissected with multiple actuations of the distal assembly of the device, creating a channel within the CTO (Fig. 3). This enabled subsequent guidewire passage across the lesion. In cases where the passage was subintimal, the LRE catheter was used to facilitate true lumen reentry. Following guidewire traversal of the lesions, predilatation to 3mm was performed. Subsequent stent implantation within the recanalized segment was performed in 34 cases, with approximately 1–2 mm oversizing of the stent relative to the diameter of the adjacent native vessel. In 25 successfully recanalized lesions, self-expanding nitinol Memotherm (Bard, Murray Hill, NJ, USA) and SMART (Cordis, Warren NJ, USA) stents were used. In nine iliac lesions, balloon expandable stents, either an XT Stent (Bard, Murray Hill, NJ, USA) or a Corinthian (Cordis Corp, FL, USA), were used. The choice of stent type was made on

**TABLE III. Results of Percutaneous Recanalization Using Controlled Blunt Microdissection**

| Characteristics of CTO | Procedural outcome | | |
|---|---|---|---|
| | Successful recanalization | Failed recanalization | Total |
| Location of CTO | | | |
| Iliac | 21 | 3 | 24 |
| CFA | 1 | 0 | 1 |
| SFA | 14 | 1 | 15 |
| Popliteal | 2 | 0 | 2 |
| Terminal aorta | 2 | 0 | 2 |
| Total | 40 | 4 | 44 |
| Length (cm) | 9 ± 7 | 14 ± 6 | 9.5 ± 7 |
| Calcification grade | 1.8 ± 0.1 | 2.3 ± 0.5 | 1.9 ± 0.9 |

the basis of lesion characteristics, with balloon expandable stents being favored for shorter, less tortuous, more calcific iliac lesions with osteal involvement. Self-expanding stents were used for all other lesions. In six of the shorter, minimally calcific lesions, which were successfully recanalized using CMD, balloon angioplasty alone was used. In these cases, there was excellent vessel reconstitution, with negligible residual stenosis. In all cases, completion angiography was performed to evaluate the success of recanalization.

All patients received loading doses of aspirin (300 mg orally, 1 hr preprocedure). Intravenous unfractionated sodium heparin maintained an activated clotting time of >300 sec during the procedure. Participants were discharged home on lifelong low-dose aspirin, and those who had received stents were continued on either ticlopidine (250 mg orally, twice daily) or clopidogrel (75 mg orally, daily) for 1 month.

### End-points

The primary end-point of this study was procedural success, defined as recanalization, with restoration of lower limb perfusion. This was demonstrated on completion of angiography by opacification of the previously occluded segment, with less than 30% residual stenosis of the arterial lumen, and downstream contrast flow. Immediate clinical success, evaluated on the first day postprocedure, was defined as the presence of the femoral, the popliteal, and at least one pedal pulse in the treated limb, to palpation and/or Doppler ultrasound assessment.

### Data Analysis

Data are presented as a mean ± standard deviation. All p values were determined using two-tailed tests, statistical significance being defined as $p < 0.05$. Data analysis was performed using SPSS 10.0 (SPSS Inc., Chicago, IL).

## RESULTS

Immediate outcomes are summarized in Table III. Successful recanalization was achieved in 40 (91%) of the 44 CTOs treated using CMD. In all cases, residual stenosis was found to be less than 30% on completion angiography (Fig. 4). Angioplasty alone was employed in six, while stents were deployed in 34 (85%) of successful recanalizations. A total of 44 stents were implanted, either one or two per lesion (mean 1.3).

The time from the introduction of the guidewire to its removal or successful placement across the CTO was 22 ± 24 (2–130) min. In 30 (68%) of the 44 CTOs treated, 2 or 3 crural vessels were shown to be patent angiographically. In the remaining 14 (32 %), only one calf artery was patent; however, this vessel was of good caliber in all of these cases.

The LRE catheter was used in 14 (35%) of the 40 successful recanalizations. In 9 (22.5%) of these, the LRE catheter was used to reorient a guidewire that had passed eccentrically through the lesion. In the other 5 (12.5%) cases, subintimal passage of the guidewire necessitated use of the LRE catheter for reentry into the vessel lumen distal to the CTO. The four procedural failures arose from inability to access an iliac CTO due to excessive vessel tortuosity.

The mean occlusion length was 9.5 ± 7 (2-45) cm for all CTOs treated, 9.05 ± 7 (2–45) cm for successful recanalizations, and 14 ± 6(8–20) cm for failed recanalizations. This difference in occlusion length was not statistically significant ($p = 0.18$).

Either mild or no calcification was observed in 20 (45 %) of lesions, while 24 (55%) were moderately or severely calcified. The mean calcification index was 1.9 ± 0.9 for all treated lesions, 1.8 ± 0.1 for the 40 successfully traversed lesions and 2.3 ± 0.5 for the four lesions that could not be recanalized using CMD. Again, although uncrossed lesions were more calcified on average, this difference was not statistically significant ($p = 0.38$).

Only one complication was encountered. In-stent thrombosis occurred within 24 hr of iliac recanalization in one patient; however, this was managed successfully with intraarterial urokinase therapy. There were no complications, namely distal embolization, arterial dissection, or perforation, related to the blunt microdissection procedure *per se*.

In all 40 angiographically successful revascularizations, immediate clinical success was evidenced by the restoration of one or both pedal pulses on palpation.

No deaths resulted from the procedure, or during the immediate postprocedure period. One patient did, however, die of an aggressive lung carcinoma 2 months after revascularization; however, this condition had not been diagnosed at the time of percutaneous intervention.

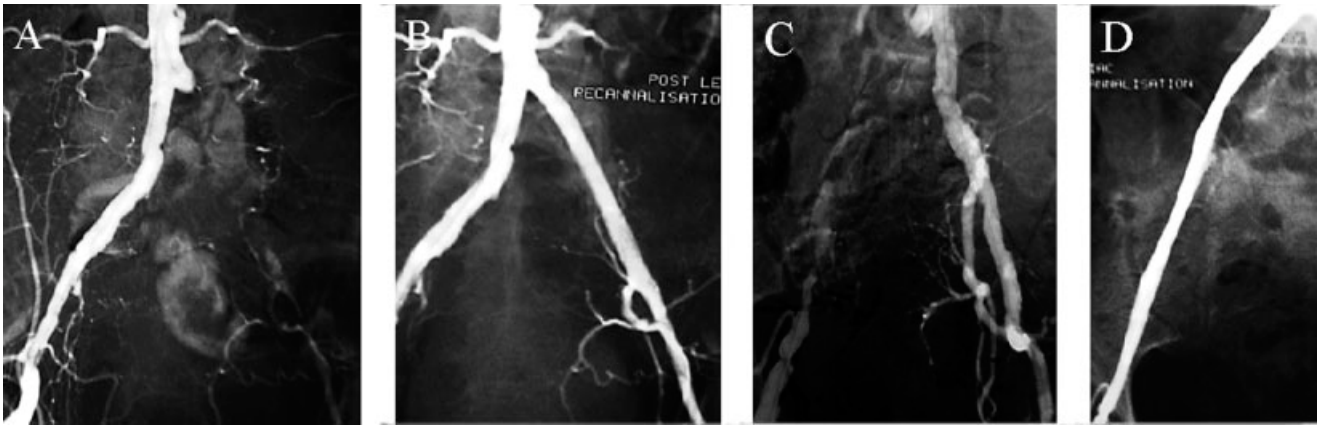


**Fig. 4. Digital subtraction angiograms illustrating two cases of successful CMD-facilitated recanalization. (A, B) Angioplasty and stenting of a totally occluded left common iliac artery was carried out successfully following CMD-facilitated guidewire traversal of the lesion, with excellent angiographic result. (C, D) A chronically occluded right common iliac artery was similarly successfully recanalized.**

## DISCUSSION

Chronic total occlusions remain the Achilles heel of the percutaneous treatment of peripheral vascular disease. Catheter-based techniques are now established as the preferred means of revascularizing chronically ischemic lower limbs, owing to the lower morbidity and mortality rates and shorter hospital stays when compared with surgical bypass [3–5].

However, chronic occlusions pose an obstacle to endoluminal therapy, as breaching and traversing these lesions with guidewires is rendered difficult by their fibrous cap and heavy calcification [5,8]. Reported technical success rates for the recanalization of pelvic and lower limb CTOs using conventional guidewires are of the order of 80%, ranging from 26% to 100% [5–18]. In contrast, the crossing rate for subtotal occlusions and stenoses was greater than 95% in most series [5]. Although failure usually resulted from inability to safely pass a guidewire across the CTO, successful revascularization was prevented in some cases by subintimal wire passage, with eccentric reentry through the vessel wall [10]. Apart from the degree of calcification, success was also influenced by the length of the CTO, longer lesions having a lower recanalization rate [11].

Patients with peripheral CTOs who fail conventional methods of percutaneous revascularization require surgical bypass or atherectomy of the culprit CTO, to address the ongoing ischemia. However, this carries a significant risk in vascular patients, who have a high rate of comorbid cerebrovascular and ischemic heart disease.

Consequently, there has been much interest in the development of new devices and techniques for the percutaneous recanalization of these resistant CTOs. These include lysis therapy (intra-arterial thrombolysis through an indwelling catheter) and laser angioplasty [10,19–23]. Lysis therapy, usually as a precursor to guidewire placement, has not been shown to be uniformly effective for recanalizing CTOs [10]. Likewise, the reported technical success rates for reopening CTOs with percutaneous laser angioplasty, in combination with conventional angioplasty, ranged from 73% to 85%. The relatively high failure rate was attributed to the inability to cross heavily calcified CTOs using laser-induced vaporization, and the limited maneuverability of laser fibers, which restricted their use to straight vessel segments [19].

Given these limitations, there is still a need for the development and evaluation of alternative methods of percutaneously managing resistant peripheral CTOs to address the needs of those patients who are poor surgical candidates, have inoperable lesions or fail surgical bypass.

### Controlled Blunt Microdissection

Having previously demonstrated the success of CMD for recanalizing difficult lower limb CTOs in two patients, we applied the same technique to a larger sample of patients in the present series [9]. Despite each lesion previously resisting standard techniques of endoluminal recanalization, technical success was achieved in 91% with the use of the CMD and LRE catheters.

The prototype CMD catheter was used to microdissect atheromatous plaque. Its shaft possessed significant column strength and moderate flexibility; therefore, little guide support was required to engage and breach the fibrous cap of the CTO with the jaws of the device.

Actuation of the jaws then enabled propagation of a dissection plane within the occlusive plaque, providing a passage for crossing and advancement of a standard guidewire beyond the diseased segment. Access to the downstream true lumen facilitated stent-supported balloon angioplasty, with good angiographic and clinical outcome. In cases where the CMD catheter created a subintimal channel in the occluded segment, the LRE catheter was used to access downstream true lumen.

We did not detect a statistically significant difference in occlusion length and degree of calcification between successfully traversed lesions and CTOs resistant to recanalization using CMD, although the average occlusion length and average calcification index were higher for the four cases where CMD failed. However, due to the small number of procedural failures, no conclusion can be drawn from these finding. Further, the four procedural failures arose from inability deliver the CMD catheter to the CTO, due to excessive iliac artery tortuosity; therefore, recanalization using the process of blunt microdissection could not be attempted in these cases.

### Complications of CTO Recanalization

Although the morbidity associated with percutaneous revascularization is low, persistent efforts to navigate CTOs with guidewires may engender intraprocedural complications of vessel dissection, perforation, and distal embolization [10]. In fact, a higher rate of major complications, ranging from 4% to 20%, has been reported for the recanalization of CTOs than for subtotal occlusions and stenoses [10–12,16]. The most commonly encountered of these is distal embolization, occurring more often with recanalization of long occlusions, with reported rates of up to 20% [16]. Vessel wall injury is less common; however, this complication was reported to occur in 9% with the use of laser angioplasty [19].

In this study, neither vessel damage nor distal embolization was encountered. Trauma to the vessel wall appeared to be minimized by the directed and controlled nature of microdissection, and by the blunt shape of the leading edge of the CMD catheter. In addition, the LRE catheter permitted reorientation of the guidewire in cases of eccentric passage, further minimizing the risk of vessel perforation.

The complication rate of 3%, with one patient experiencing in-stent thrombosis, was well within the reported range of complication rates for percutaneous lower limb revascularization. Further, this recognized complication of stent placement does not pertain to the process of CMD *per se*.

### Study Limitations

This was a single center, prospective study, enrolling a relatively small number of patients. Further, no comparison was made of the efficacy of CMD with that of other techniques for percutaneously recanalizing CTOs. This would require a larger series, with randomization or matching for lesion and clinical characteristics.

There was no analysis of intermediate and long-term clinical outcomes in this study, as our aim was to assess the technical success of the procedure of CMD. Following CMD-facilitated guidewire traversal of the CTOs, angioplasty and stenting followed standard protocols. The clinical outcomes of angioplasty and stenting for lower limb revascularization are well established. There is a high correspondence of angiographic outcome to clinical outcome in published studies, with most patients displaying clinical improvement after successful percutaneous revascularization [5]. The use of stents has been shown to increase the durability of clinical improvement and angiographic patency of recanalized lower limb arteries, and it has also been hypothesized that the degree of plaque fracture and debulking during angioplasty influences patency [5,19,24,25]. As blunt microdissection does not significantly remove atherosclerotic plaque, we do not expect the long-term patency to be significantly altered by the use of CMD to facilitate conventional angioplasty and stenting. It may be argued that, by causing some injury to the vessel wall, for instance during subintimal passage, CMD may adversely influence long-term patency. It should, however, be kept in mind that, even using conventional guidewire techniques, traversal of CTOs may result in vessel wall injury during subintimal passage. Of course, the validation of these assumptions regarding the effects of CMD does require long-term follow up.

### Device Limitations

Limitations of CMD include the cumbersome nature of the two prototype catheters used, and the necessity for switching between devices. Despite this, the procedure was not excessively time consuming, making its use feasible in standard interventional practice.

The prototype CMD and LRE catheters used in this study are now obsolete; however, newer versions are now available in the United States. Despite availability, these devices remain expensive. We did not evaluate the cost-effectiveness of their use in comparison to the use of conventional techniques for CTO recanalization. The rationalization for this is that these devices were employed after the failure of, rather than as an alternative to, standard guidewires. A comparison of the costs of the CMD and LRE catheters to bypass surgery as well as alternative devices for percutane-

ously recanalizing CTOs is warranted, although we did not obtain this data.

In conclusion, the technique of CMD is safe and effective for recanalizing resistant peripheral CTOs, of varying length, location, and degree of calcification, with a high procedural success rate. This provides an attractive solution to the problem posed by symptomatic CTOs that are refractory to revascularization with conventional endoluminal techniques, obviating the need for bypass surgery in these patients.

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