

# Intraluminal Versus Subintimal Approach to Chronic Total Occlusions

The pros and cons of each approach for challenging femoropopliteal crossing.

BY JOHN P. PIGOTT, MD, FACS

**A**n increasing percentage of interventionists treat patients with symptomatic femoropopliteal occlusive disease with a “percutaneous intervention-first” approach. This is particularly so in patients deemed to be at high risk for surgical procedures<sup>1</sup> and is based on the results of recent reports showing reduced morbidity and mortality with an intraluminal or subintimal endovascular approach to these lesions.<sup>2,3</sup> These patients generally have an increased risk of cerebral and cardiovascular comorbidities. Many patients also prefer endovascular treatment because of reduced cost and shorter hospital stay.

The BASIL trial substantiated essentially no difference in long-term outcomes between percutaneous and surgical revascularization in patients suitable for either form of treatment.<sup>4</sup> If the patient’s arterial occlusion cannot be crossed by percutaneous techniques, the patient will necessarily be relegated to a surgical procedure or, worse, amputation, depending on the arterial anatomy and patient comorbidities. Currently, there is evidence that even the most extensive TASC II D femoropopliteal lesions can be approached percutaneously with a reasonable expectation of hemodynamic and limb salvage success.<sup>3,5</sup> Although the observation has been made that all femoropopliteal lesions can be safely and effectively managed with endovascular therapy, the more complex lesions have a lower primary and primary-assisted patency rate.<sup>6</sup>

Crossing femoropopliteal chronic total occlusions (CTOs) remains a particularly challenging endeavor for the interventionist. Generally accepted factors that contribute to procedural success can be divided into

patient-specific and lesion-specific criteria. Worsening degrees of critical limb ischemia, such as rest pain or tissue loss, are generally associated with poor outcomes. Patients with symptomatic infrainguinal atherosclerosis on hemodialysis are identified as a particularly high-risk subset for procedural failure and limb loss.

Lesion characteristics associated with unsuccessful or limited patency rates include: (1) increasing lesion length, (2) more advanced TASC II classification, (3) increasing severity of calcification noted on fluoroscopy, and (4) flush occlusions at the superficial femoral artery origin. Most studies also show that at least one tibial vessel needs to be patent for long-term procedural success. It is generally accepted that the greater the number of tibial runoff vessels present, the greater the opportunity for long-term patency due to increased flow rates across the intervened segment.<sup>7</sup>

The most common way to address CTOs currently is to choose either an intraluminal (IL) or subintimal (SI) approach. Until the recent introduction of crossing catheters, the fallback position for failed initial guidewire crossing of the CTO by IL technique was SI angioplasty. This technique was first popularized by Bolia et al.<sup>8</sup> Others have subsequently validated this technique in published reports, with or without adjunct stent placement.

Both IL and SI techniques have their proponents. Generally, the enthusiasm for a particular technique is based on training and personal experience. A review of the literature reveals very little comparative data of SI versus IL lesion crossing. Comparative trials of these two procedures for procedural success and long-term paten-

TABLE 1. IL TECHNIQUE: PROS AND CONS

Pros	Cons
Easily acquired and familiar skill set	Not uniformly successful
Low-cost procedure	May require conversion to SI if crossing is difficult
Frequently combined with low-cost balloon angioplasty	Difficult to know if wire remains in true lumen along entire CTO course
	Adjunct therapy may be required to debulk or modify plaque (atherectomy, scoring balloon)

cy are indicated. Unfortunately, in cases of long CTOs, conventional IL crossing may be impossible, and the interventionist may need to switch to an SI approach to achieve technical success. Moreover, it is certainly possible that with the IL approach to long CTOs, wire passage through some segments of the recanalized channel are located extraluminally. The only way to accurately discern this, however, would be with real-time imaging of the crossing with either intravascular ultrasound or optical coherence tomography.

Both IL and SI procedures can provide effective CTO crossing with acceptable technical success rates.<sup>9</sup> The most common postcrossing procedure remains balloon angioplasty to develop the flow lumen.<sup>10</sup> It does appear that technical adjuncts, such as stents and atherectomy, contribute to technical success and procedural durability, but they may be required in cases of flow-limiting stenosis, recoil, or dissection. Characteristically, primary patency rates over time do not match the high initial technical success rates, and reintervention is not uncommon. In a meta-analysis of studies involving critical limb ischemia patients and successful CTO crossing, long-term limb salvage remains fairly high (> 80%–90%) in many series.

### TECHNICAL DESCRIPTION

Crossing femoropopliteal CTOs involves wire passage of three segments: (1) the proximal cap, (2) the lengthy CTO, and (3) the distal reentry site. The proximal cap generally has a meniscus shape and may be particularly difficult to penetrate if it is fibrotic or a flush occlusion. Immediately adjacent collateral vessels may also be challenging because the guidewire preferentially deflects into them. The middle portion of the CTO, which has varying segments of plaque and organized thrombus, may be soft or fibrotic and may also contain a degree of associated calcification. Cap penetration into the obliterated true lumen immediately distal to the proximal cap is essential for continued progress through the lesion until reaching the distal reconstituted target vessel.

The specific composition and characteristics of the occluded lumen are really what guides the wire. Soft plaque or IL thrombus generally allow for IL wire passage, whereas more fibrotic or calcific plaque tend to cause a more difficult central channel crossing. This may necessitate an SI approach as the wire progress is impeded and then deflected to a less resistant SI channel.

If an IL position can be maintained throughout the length of the CTO, the guidewire typically exits into the true lumen. If an SI approach has been employed, the looped guidewire will likely reenter spontaneously through the thin dissection flap near the reentry point. Reentry devices, such as Outback (Cordis Corporation, Bridgewater, NJ) or Pioneer (Medtronic, Inc., Minneapolis, MN), are required in 10% to 15% of SI CTO crossings to regain distal true lumen. Care needs to be taken not to propagate the SI dissection flap too far distally to preserve collaterals as well as possible distal targets for bypass if required later.

### INTRALUMINAL TECHNIQUE

The IL technique is the classic approach used by most interventionists to cross CTOs. A 0.014-, 0.018-, or 0.035-inch hydrophilic wire is frequently used in combination with a support catheter. Much of this technique relies on tactile feedback as well as operator perception as to the course of the vessel. In addition to support catheters, a balloon catheter can be sequentially advanced with the wire and inflated in an attempt to stay in the true lumen. Angioplasty of the proximal segments can also decrease catheter friction that is sometimes experienced with a “tight” CTO. Some proponents also use laser ablation and sequentially advance the laser catheter along the wire to ablate IL debris for this same purpose.

### SUBINTIMAL TECHNIQUE

The SI technique creates a neolumen between the intimal and adventitial layers of the arterial wall, displacing the atheromatous and calcified intimal and medial layers to the contralateral side of the vessel lumen and produc-

TABLE 2. SI TECHNIQUE: PROS AND CONS

Pros	Cons
Low-cost device and procedure	Advanced interventional skill set required
High technical success rate	Steep learning curve
High limb salvage rate in critical limb ischemia	10% to 15% need for reentry device
Does not preclude or jeopardize surgical bypass options	Substantial need for adjunctive stenting

ing a relatively smooth flow lumen. Generally, a 0.035-inch hydrophilic guidewire is advanced with a hydrophilic support catheter to the CTO origin. The guidewire tip is directed toward the arterial wall at the site of the occlusion. There is generally little resistance after entering the SI space. A wire loop is formed and the SI space dissected. Caution should be taken to maintain a relatively narrow wire loop, which perforates spontaneously back into the true lumen in the majority of cases.

#### PROS AND CONS OF INTRALUMINAL TECHNIQUE

IL CTO crossing is an easily acquired skilled set and is the most commonly used CTO crossing method (Table 1). It is an easy transition from crossing highly stenotic lesions and a well-understood translation for the interventionist. Furthermore, the procedural costs are quite low and limited to a standard guidewire and crossing catheter. Problems associated with the IL technique are that it is not uniformly successful and may require conversion to SI angioplasty to achieve a technically successful crossing. Without concurrent imaging, it is also difficult to know whether CTO crossing remains truly IL and that the guidewire does not veer off segmentally into SI channels. Because of the amount of IL material, there is a frequent need to add adjunctive therapy other than a standard angioplasty balloon. This may require the addition of atherectomy devices or scoring balloons to debulk or modify the plaque. Stents may also be required to maintain an adequate flow channel.

#### PROS AND CONS OF SUBINTIMAL TECHNIQUE

The SI technique is also a low-cost procedure in that it only requires a guidewire and hydrophilic support catheter, and multiple studies have documented its high technical procedural success rate (Table 2). Limb salvage rates are substantial in patients who present with critical limb ischemia.<sup>11</sup> The technique, however, is somewhat difficult to assimilate, with a steeper learning curve compared to IL techniques. There remains a 10% to 15% need for reentry devices. Many investigators will

not use atherectomy in an SI space for the concern of vessel perforation of the thin subadventitial layer. It appears that technical success and patency rates are positively affected with stenting. Some proponents of SI techniques routinely line the channel with stents, especially to ensure luminal gain at the proximal cap and distal reentry sites.<sup>12</sup>

Complications common to either the SI or IL technique include vessel perforation, distal embolization, or occlusion of collateral vessels. Rarely, however, do these complications lead to the need for emergent open repair, and they can usually be managed with percutaneous techniques. Prolonged balloon inflation at lower dilation pressures as well as covered stents are typically effective at managing complications of vessel perforation.

#### RECENT TRIALS AND FUTURE DIRECTION

Despite high procedural success crossing rates with both IL and SI techniques, the outcomes are not uniformly successful. The medical device industry continues to attempt to address this problem with different device types. The corporate rationale behind these efforts is to improve crossing rates that allow for subsequent delivery of therapeutic devices (angioplasty balloons, atherectomy catheters, cryoplasty, lasers) to the target lesion. Other goals include decrease in crossing times and allowing for more consistent distal reentry.

Devices such as the Crosser (Bard Peripheral Vascular, Tempe, AZ) and Wildcat (Avinger, Redwood City, CA) CTO catheters validate the clinical need for a device that consistently crosses through the true lumen. The recently completed CONNECT (Chronic Total Occlusion Crossing with the Wildcat Catheter) study is a prospective, multicenter, nonrandomized trial documenting the safety and efficacy profile of the Wildcat catheter in crossing femoropopliteal CTOs. The catheter demonstrated an 89% crossing rate with minimal associated morbidity.<sup>13</sup> This trial was the basis for US Food and Drug Administration clearance of the Wildcat as a CTO crossing catheter in August 2011.

It is still unclear as to whether procedural patency and limb salvage rates are affected by the specific technique used for CTO crossing. A comparative trial of these techniques appears warranted to better define any advantages of IL versus SI CTO crossing. An important part of such a trial would necessitate the use of high-quality intravascular ultrasound or optical coherence tomography to ensure that crossing was through an SI or true IL channel. Until a clear advantage of one technique over the other is established, it is likely that interventionists will continue to use the technique they consider most efficacious based on their experience. ■

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