Critical limb ischemia (CLI) due to chronic total occlusions (CTOs) of the infrapopliteal arteries represents an advanced and often nonreconstructable pattern of disease with a high rate of associated limb loss. The Bypass Versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial has established that equivalent results can be achieved in properly selected CLI patients when treated with surgical bypass or endovascular techniques. However, although it is well established that restoration of pulsatile straight-line flow to the foot can resolve ischemic rest pain and allow ulcer healing, this can be difficult to achieve in patients with comorbidities preventing operative bypass, or in the absence of a suitable target vessel for bypass or endoluminal revascularization. Catheter-based recanalization techniques are challenging in patients with tibial CTOs, limiting the effectiveness of endovascular therapies.

Subintimal balloon angioplasty and stenting has been established as effective for patients with femoral occlusive disease and CLI but has not been as well described for patients with tibial disease. This approach provides a new course through the deep layers of the artery between the tunica intima and tunica media, making it useful in patients with extended occlusions or arterial calcification, which decrease the success rate of the more standard transluminal balloon angioplasty. Further, because subintimal balloon angioplasty does not disrupt atheroma within the native vessel lumen, the risk of embolization is potentially decreased.

**Holy Name Medical Center Experience**

**Patients**

Fifteen patients underwent subintimal angioplasty of one or more infrapopliteal arterial CTOs between January 2008 and May 2010. In all instances, the subintimal strategy was used either because of failure of traditional methods or as a planned approach due to the presence of severe calcific long-segment occlusive disease. Anatomic, device, and other procedural data and outcomes were retrospectively reviewed utilizing PACS (Picture Archiving and Communication System) analysis of the procedural angiographic images. Immediate and/or 3-month to 1-year follow-up were available for 11 of the 15 patients. Data reviewed included the occurrence of amputation, type of amputation required, concomitant procedures, need for repeat procedures, complications, anatomic success (restoration of straight line flow), and survival.

Patients included nine men (60%) and six women.
(40%). The average age of the patients during the procedure was 75 (range, 63–87 years). Before the procedure, four patients (30%) exhibited osteomyelitis, nine patients (60%) exhibited gangrene, two patients (15%) had claudication, and five patients (40%) had chronic rest pain. Indications for subintimal balloon angioplasty use included prominent and extended crural vessel occlusion, as well as calcinosis of the target vessel and/or an inability to cross the occlusion through the true lumen. Follow-up ranged from 1 week to 31 months.

Description of Technique

All procedures were performed using a coaxial 3-F Renegade STC microcatheter (Boston Scientific Corporation, Natick, MA) advanced through a 4-F angled non-tapered Glidecath (Terumo Interventional Systems, Somerset, NJ). Angled-tip (70º angle) 0.018-inch Glidewires (Terumo Interventional Systems) were used in all cases. The subsequent key technical points were used:

- After engaging the occlusion, the tip of the Glidewire was intentionally prolapsed into the target vessel (Figure 1).
- When the wire would repeatedly engage a marginal collateral, the back end of the wire was advanced for several millimeters past the collateral to secure subintimal positioning.
- The wire was prolapsed to produce a long loop configuration that was advanced in the subintimal plane. Importantly, tracking of the wire along the expected course of the target tibial vessel was used to identify subintimal positioning.
- The microcatheter was incrementally advanced over the wire. If the catheter would not advance freely or was
noted to be outside of the expected plane, a small amount of contrast was injected to confirm subintimal placement (Figures 2 through 4).

- To provide additional support, the Glidecath was advanced up to and occasionally into the tibial vessel during recanalization.
- Extraluminal recanalization paths or an intraluminal path that could not be successfully directed intraluminally were coil embolized using microcoils (Nester embolization coils [Cook Medical, Bloomington, IN]).

Results
Nine of 15 patients (60%) were successfully treated using the subintimal technique. Adjunctive transpedal access or transcollateral retrograde revascularization was utilized in four patients (Figure 11). Stents were placed in the tibial arteries of six patients. Coils were also used to redirect the path of subintimal recanalization in two patients. The success rate by target vessel is shown in Table 1.

Figure 5. Severe ischemic ulceration at the site of previous transmetatarsal amputation.

Figure 6. Angiographic images show multisegmental complex distal tibial occlusive disease (A and B).

This would allow redirection of the subintimal revascularization path to provide for another attempt at distal true lumen re-entry.

- At the point of desired re-entry as seen during initial angiography, the wire loop was reduced to 1 to 2 mm, which was then sequentially retracted and advanced for attempted re-entry.
- In cases in which no overt distal target was noted, attempted re-entry was preferentially performed in the region of the dorsalis pedis or arcuate arteries of the foot (Figures 5 through 11).
- Free distal wire passage in a straight configuration or clearly engaging pedal branches identifies successful intraluminal re-entry as confirmed by contrast injection through the microcatheter.
- A 0.014-inch exchange wire was used for subsequent angioplasty and stenting when needed. Balloon size was selected based on the expected or angiographically demonstrated diameter of the target tibial vessels.

Figure 7. Attempted posterior tibial artery recanalization results in an extraluminal course (short arrows); re-entry into the patent distal artery (curved arrows) could not be achieved (A). Subsequent subintimal passage across the anterior tibial artery (white arrow) (B).
Two patients required repeat revascularization during follow-up, and one patient required two procedures to maintain flow through the target vessel (Figures 9 and 10). An average elapsed period of 64 days was noted after the initial subintimal recanalization.

A total of eight patients underwent amputation following the procedure. Six of eight patients (75%) underwent planned digital or transmetatarsal amputations for preexisting forefoot or digital gangrene. Two patients with extensive tibial occlusive disease who failed revascularization required above-the-knee amputations. No unplanned amputations were performed in patients in whom subintimal revascularization was successful.

**DISCUSSION**

Complex tibial occlusive disease is often treated using endovascular techniques, although successful restoration of flow using an antegrade strategy can fail in up to 20% of cases. There have been various reports describing alternative endovascular approaches that may be successful when standard methods fail, including transcollateral or plantar loop recanalization and transpedal punctures.

These methods essentially provide for retrograde recanalization of the target vessel, either by direct puncture or by directing the antegrade wire across normal collaterals.

<table>
<thead>
<tr>
<th>Target Vessel</th>
<th>Success</th>
<th>Failure</th>
<th>Fisher Exact P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior tibial</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Peroneal</td>
<td>2</td>
<td>0</td>
<td>.47</td>
</tr>
<tr>
<td>Posterior tibial</td>
<td>1</td>
<td>3</td>
<td>.25</td>
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lateral pathways so that it is directed cranially across the occluded tibial vessel being treated.

Subintimal recanalization of the tibial vessels is not well described.3-7 We have found that attempted intraluminal tibial revascularization will not infrequently traverse a subintimal plane, as indicated by a loop configuration of the wire that is larger in diameter than the native vessel. Familiarity with the tools and technique for intentional subintimal recanalization and re-entry potentially allows procedural salvage when this occurs. Keys to technical success include the use of microcoils to redirect the wire from unsuccessful re-entry planes and the use of angled 0.018-inch Glidewires, which successfully and spontaneously re-engage patent distal arterial lumina.

One unique advantage of the subintimal recanalization technique is the ability to perform revascularization when there is no obvious patent distal target vessel (Figures 1 through 5). Revascularization into “blind” dorsalis pedis arteries or branches can be accomplished more easily than recanalization into occluded medial and lateral plantar arteries due to the straighter course of the subintimal path across the dorsum of the foot compared to the turns encountered in the distal posterior tibial artery around the medial malleolus. In the case where a plantar artery could not be recanalized, it may be better visualized after opening the dorsalis pedis artery.

In summary, subintimal tibial recanalization represents a potentially valuable technique in cases of complex occlusive disease and has become our preference for tibial revascularization when encountering difficulty with standard antegrade approaches. Initial experience suggests that acceptable clinical patency and limb salvage rates can be accomplished when a straight-line subintimal flow channel to the foot is achieved.

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