

Limb Salvage with the CROSSER[®] Catheter and Diamondback 360[®] in the Absence of Target Vessel Reconstitution

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Category: Critical Limb Ischemia

Background

- Limb salvage is often associated with multiple chronic total occlusions (CTOs) without clear vessel reconstitution
 - Patients with these lesion characteristics have traditionally had little hope of restoring flow
 - Amputation of the foot or lower leg frequently results
 - More than 160,000 amputations occur in the US each year

Methods

- Retrospective study of 32 diabetic patients with CLI
 - Below-the-knee occlusions in all 3 runoff vessels to the foot
 - Previously scheduled for amputation
- Attempted treatment in each tibial until one successfully recanalized
- CROSSER Catheter (FlowCardia, Inc.) used to pass CTOs
 - Safely finds the true distal lumen, allowing for subsequent therapy
- Diamondback 360° Orbital Atherectomy System used to modify plaque and restore flow to distal vessels

Initial Angiographic Findings

- 34% No significant vessel reconstitution distal to CTO
- 48% Faint and significantly delayed filling of possible vessel reconstitution
- 18% Vessel reconstitutions with moderate delayed filling

100% Recanalization Rate

- CROSSER passed through first attempted lesion in 92% of cases
- Remaining 8% of patients were successfully recanalized in a second tibial vessel
- Average of 3.8 minutes of activation time with CROSSER

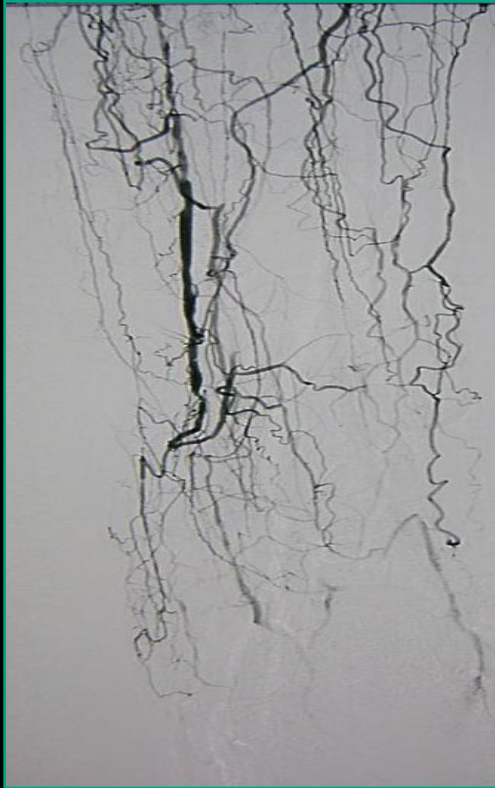
Blood Flow Restored

- Diamondback 360° used to establish straight-line blood flow
 - Low-pressure balloon angioplasty used adjunctively to “touch up”
- All patients left the cath lab with palpable or Doppler pulse
- Xx patients angiographically followed six weeks post procedure if scheduled for a second procedure
 - Patency maintained in all xx

Case Study

- 82-year-old male with PVD, HTN, CAD, DM
- Smoker
- Right foot pain, but declined an angiogram
 - Returned 7 months later with gangrenous 1st and 2nd toes
 - Conclusion of initial evaluation was that patient had no options; amputation offered
- Second opinion sought; angiogram found no-vessel runoff
- Heavily calcified AT with a CTO of distal AT

No-Vessel Runoff



Heavily Calcified AT; CTO in Distal AT

Debulk Proximal AT

- 1.25 mm Diamondback Classic Crown
- 3 minutes

Cross Distal CTO

- CROSSER
- 3 minutes

Debulk Distal AT

- 1.25 mm Diamondback Classic Crown
- 3 minutes

Return to Proximal AT to Create Larger Lumen

- 1.5 mm Diamondback Classic Crown
- 3 minutes

Final Balloon Touch-Up

- 2.0/2.5 Amphirion x 210
- Low-pressure: 4 atm

Flow Restored to Foot



Limb Saved!

Conclusions

- Limbs once scheduled for amputation can be saved using recently available endovascular devices
 - CROSSER catheter uses high-frequency vibration to quickly cross CTOs
 - Diamondback 360° Orbital Atherectomy System uses a unique orbital mechanism of action that effectively sands calcified plaque
- Blood flow can be restored even in the absence of target vessel reconstitution
- Patients currently scheduled for amputation should receive evaluation from a physician qualified in endovascular therapy with these devices