CLINICAL EXPERIENCE
David Allie, MD
Medical Director
Louisiana Cardiovascular and Limb Salvage Center

VASCUTrak™ PTA Dilatation Catheter in Chronic Total Occlusion (CTO) of the Anterior and Posterior Tibial Arteries

Patient Overview
A 70-year-old male presents with ischemic changes to the left lower extremity. Previous history includes: smoking, hypertension, coronary artery disease with previous stenting and diabetes mellitus. Baseline angioplasty reveals total occlusion of all infrapopliteal vessels with the anterior tibial and posterior tibial filling via collaterals.

In certain cases, more than one vessel may be required for wound healing. With two vessels filling via collaterals, it was felt in this case that a more global approach to revascularization may expedite wound healing. A VASCUTrak™ PTA Dilatation Catheter allows for treatment of multiple vessels.

Keys to Success
• Size the balloon diameter 1:1 to vessel diameter
• Use a balloon length that will cover the entire diseased segment with a single inflation
• Inflate gradually, increasing 1 ATM every 30 seconds
• Do not use excessively high pressures – do not exceed rated burst pressure
• Initial studies have shown that prolonged inflation times may be beneficial

Procedural Steps
The right femoral artery was accessed and a 6F/45 cm Terumo™ sheath was advanced around the bifurcation to the level of the left common femoral artery. A CROSSER™ Recanalization Catheter 14S was used to traverse the occlusion of the anterior tibial and a 0.014" Choice™ PT guidewire was placed into the distal artery. A 2.5 mm x 120 mm VASCUTrak™ PTA Dilatation Catheter was advanced to the occlusion. One inflation was performed at 3 ATM for 3 minutes. Following balloon inflation, excellent angiographic results were noted. The CROSSER™ Recanalization Catheter 14S was then used to cross the posterior tibial artery, and the 0.014" Choice™ PT guidewire was placed in the distal vessel. The 2.5 mm x 120 mm VASCUTrak™ PTA Dilatation Catheter was advanced to this occlusion, and two inflations at 4 ATM and 3 minutes were performed. Total case time was 90 minutes.

Discussion of Results
This case illustrates the value of focused force in the treatment of multiple long infrapopliteal occlusions. By utilizing longer balloons at lower inflation pressures, areas of long total occlusion can be treated by the same balloon with a reduced risk of balloon-induced over dilatation and subsequent dissection. By not having to perform adjunctive therapies, time and contrast are saved, allowing for treatment of a second vessel if necessary.

Conclusion
• In certain cases, being able to utilize one balloon in treatment of multiple vessels not only saves time, but also cost
• The focused force of the VascuTrak™ PTA Dilatation Catheter permits low inflation pressure dilatation, thus reducing the risk of balloon-induced over-dilatation and subsequent dissection of the vessel.

VascuTrak™ PTA DILATATION CATHETER

Indications for Use: The VascuTrak™ PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications: The VascuTrak™ PTA Dilatation Catheter is contraindicated:
1) Where there is an inability to cross the target lesion with a guidewire;
2) For use in the coronary or neurovasculature.

Warnings:
1) Contents supplied sterile using ethylene oxide (EO). Non-pyrogenic. Do not use if sterile barrier is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 2) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination. 3) Do not use if severe stenosis is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 4) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination. 5) Do not use if severe stenosis is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 6) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination. 7) Do not use if severe stenosis is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 8) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination. 9) Do not use if severe stenosis is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 10) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination. 11) Do not use if severe stenosis is opened or damaged. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the “Use By” date specified on the package label. 12) This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are susceptible to cross-patient contamination.

Precautions: 1) Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. 2) The VascuTrak™ PTA Dilatation Catheter should only be used by physicians trained in the performance of percutaneous transluminal angioplasty.
3) In order to achieve the hydrophilic coating, wet the VascuTrak™ balloon and catheter with sterile saline or wipe the balloon catheter with sterile saline saturated gauze immediately prior to its insertion in the body. Do not wipe the balloon catheter with dry gauze. 4) When backloading the catheter onto the guidewire, support the catheter and ensure that the guidewire tip does not snap or come into contact with the balloon. 5) The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label. 6) Use the recommended balloon inflation medium (50% contrast medium/50% sterile saline solution). It has been shown that a 50/50% contrast/saline ratio has yielded faster balloon inflation/deflation times. Never use air or other gaseous medium to inflate the balloon. 7) VascuTrak™ PTA Dilatation Catheter should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these lesions. 8) Never attempt to move the guidewire when the balloon is inflated. 9) Fully evacuate the balloon prior to withdrawing the system. Larger sizes of VascuTrak™ balloons may exhibit slower deflation times. If the balloon does not deflate, advance a sheath or catheter over the proximal portion of the balloon to straighten out the trajectory from connection of the balloon to the inflation lumen. 10) If resistance is felt during post-procedure withdrawal of the catheter through the introducer sheath, determine if contrast medium is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon. 11) If resistance is still felt during post-procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit. 12) Do not continue to use the balloon catheter if the shaft has been bent or kinked. 13) Prior to re-insertion through the introducer sheath, re-activate the hydrophilic coating and clean the balloon catheter by wiping the balloon catheter with sterile saline saturated gauze and rinsing with sterile saline. Do not wipe the balloon catheter with dry gauze.

Potential Adverse Reactions: The complications that may result from a peripheral balloon dilatation procedure include: • Additional intervention • Allergic reaction to drugs or contrast medium • Anoxemia or pseudoxemia • Arhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Septicaemia/infection • Shock • Short-term hemodynamic deterioration • Stroke • Thrombosis • Vessel dissection, perforation, rupture or spasm.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictable for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by Bard Peripheral Vascular, Inc. for the time and effort in preparing the above case study for Bard’s further use and distribution.

Bard, Cocksring and VascuTrak are trademarks and/or registered trademarks of C. R. Bard, Inc. All other trademarks are the property of their respective owners. Copyright © 2012, C. R. Bard, Inc. All Rights Reserved.
S11799 Rev 2