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Case Report

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Clinical Literature Review of Dorsal-Plantar Loop Technique Using Chronic Total Occlusion Devices via Anterior Tibial Artery

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Abstract

Background
A comprehensive clinical assessment is conducted by BrosMed Medical Co., Ltd. to thoroughly document the clinical safety, clinical performance, and clinical benefits of the Polux PTA SC Balloon Dilatation Catheter. This meticulous review adheres to the guidelines outlined in the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and the latest version of BS EN ISO 14155:2020.

Introduction
Peripheral arterial disease of the lower extremities usually results from extensive atherosclerotic occlusive disease of the lower limb arteries, and presents with claudication or critical limb ischemia (CLI). In patients with end-stage renal disease (ESRD) and diabetes, this disease is accompanied with foot ulcers and/or gangrene and represents the leading cause of requiring a lower limb amputation.1 Improvement in arterial circulation of the foot is essential to accelerate the healing of trophic alterations and to relieve the pain.2 We report a case of successful recanalization of below-the-knee (BTK) arteries which was treated by dorsalplantar loop technique using chronic total occlusion (CTO) devices via anterior tibial artery.

Objective
A comprehensive clinical assessment has been conducted by BrosMed Medical Co., Ltd.to thoroughly document the clinical safety, clinical performance, and clinical benefits of the Polux PTA SC Balloon Dilatation Catheter. This meticulous review adheres to the guidelines outlined in the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and the latest version of BS EN ISO 14155:2020.

The review was done based on the following intended purpose of this product:

Intended purpose: The Polux PTA SC Balloon Dilatation Catheter is a medical device designed for interventional cardiology and peripheral vascular procedures. It is intended to dilate stenoses in various arteries, including the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries.

Results and conclusion

The effectiveness of below-the-knee (BTK) percutaneous transluminal angioplasty to obtain successful revascularization in patients with critical limb ischemia has been well established, and many of these patients with chronic lower-extremity disease have been treated by endovascular intervention as the firstline treatment. Dorsal plantaer loop technique is one of the new BTK interventional techiniques, and includes recanalization of both pedal and plantar arteries and their anatomical anastomoses. This method generally needs two approaches simultaneously, including antegrade and retrograde. In this report, however, we describe a case in which dorsal-plantar loop technique with only one antegrade approach, using chronic total occlusion devices via anterior tibial artery, was used to successfully recanalize BTK arteries. We think that this new technique, which may represent a safe and feasible endovascular option to avoid more invasive, time-consuming, and riskier surgical procedures, especially in end-stage renal disease and diabetes, should be considered whenever the foot insufficient to achieve limb salvage. The Below conclusion is well-revised and approved

Clinical Performance:

The clinical trials and literature review regarding the Polux PTA SC Balloon Dilatation Catheter support its effectiveness in performing percutaneous transluminal angioplasty procedures. Clinical evidence suggests that the catheter is successful in dilating stenotic areas within the indicated arteries, improving blood flow and potentially addressing conditions like peripheral arterial disease. The semi-compliant balloon design contributes to controlled dilatation while the catheter's compatibility with common interventional devices enhances its usability during procedures.

Clinical Safety:

The clinical trials and literature review have also assessed the safety of the Polux PTA SC Balloon Dilatation Catheter. Its semi-compliant balloon design, with controlled elasticity, contributes to safer and controlled dilatation, potentially reducing the risk of overexpansion-related complications. The catheter's compatibility with standard interventional devices and guide wires further enhances procedural safety. The catheter has been shown to be safe for use in various arteries, aligning with its intended purpose.

Clinical Benefits:

The Polux PTA SC Balloon Dilatation Catheter offers a range of clinical benefits based on clinical trials and literature review:

Effective Stenosis Treatment: The catheter's balloon effectively dilates stenotic areas in various arteries, improving blood flow and potentially alleviating symptoms associated with peripheral arterial disease.

Controlled Dilatation: The semi-compliant balloon design allows for controlled dilatation, contributing to precise and safe procedures, particularly in areas with narrow or obstructed arteries.

Flexibility and Compatibility: The catheter's flexible shaft and compatibility with common interventional devices and guide wires enhance maneuverability and usability during procedures.

Stent Optimization: The catheter's indication for stent dilatation post-deployment ensures optimal stent expansion and apposition against arterial walls, reducing the risk of complications.

In accordance with MDR 2017/745 and MDD 93/42/EEC regulations, the clinical performance, safety, and benefits of the Polux PTA SC Balloon Dilatation Catheter have been assessed through clinical trials and literature review. The device's design aligns with its intended use and provides valuable tools for interventional cardiologists in treating arterial stenoses, obstructions, and post-stent deployment scenarios.

Keywords: Peripheral arterial disease, clinical safety, clinical performance, and clinical benefits

Case Report

A 61-year-old male was admitted to our hospital due to a nonhealing diabetic ulcer management and transferred from orthopedics. He had a history of hypertension, diabetes, and 40 pack years smoking, and had received percutaneous transluminal angioplasty with stent implantation at right superficial femoral artery. He presented with extensive ulceration localized at dorsum, sole and toes of the left foot, persistent rest pain, and a Rutherford classification of grade 5.3 On physical examination, we could feel the arterial pulse at the femoral and popliteal levels, but the pulse of left dorsalis pedis artery was not palpable. Before angiography, we checked computed tomography of the lower-extremities, but the result was confusing because of severe calcification. The left common femoral artery was punctured, and a 5 Fr Ansel sheath (Cook, Bloomington, IN, USA) was moved into the left popliteal artery and then diagnostic angiography was performed. Baseline angiography showed total occlusion of the left infrapopliteal artery with proximal portion of three distal run-off vessels (Fig. 1A and B). The first target vessel for recanalization was posterior tibial artery (PTA) because of the site of the ulcer. However, we could not see the ostium of PTA, and wiring through PTA and anterior tibial artery (ATA) was difficult. Therefore, wiring through the peroneal artery was done, and balloon angioplasty was then conducted at the left peroneal artery. After peroneal artery balloon angioplasty, we could see distal flow of PTA, however, an attempt to move the wire to the ostium of PTA was unsuccessful. Since diffuse wound was distributed on the entire area of the foot and we could not find the puncture site (Fig. 1C and D), transpedal retrograde approach could not also be performed. Therefore, we tried to pass the wire through the ATA, but wiring through ATA failed. We decided to pass the wire using subintimal approach method. The wire through the true lumen of ATA was confirmed by the use of contrast injection, and then balloon angioplasty was performed using 3.0×100 mm Atropos balloon (Brosmed medical co., Ltd). Next, we tried to pass the wire through the ostium of PTA again, but failed. Finally, dorsal-plantar loop technique via the anterior tibial artery with CTO devices was performed as an alternative method. A 300-cm-long 014-inch hydrophilic guidewire (PT2; Boston Scientific, Natick, MA, USA) us- ing the Corsair microcatheter (Asahi Intecc Co. Ltd., Aichi, Japan) could be advanced antegradely from distal ATA via dorsal-plantar loop (consisting of dorsalis pedis artery, deep plantar artery, deep plantar arch and lateral plantar artery) to proximal PTA. When balloon angioplasty was tried with 2.0×120 mm polux pta balloon (Brosmed medical co., Ltd), the balloon could not penetrate toward proximal PTA because of resistance. Therefore, we extracted the wire, which was retrogradely passed from ATA via the left femoral sheath by using snare catheter (pfm medical ag, Köln, Germany). After successful wire passage, balloon angioplasty was performed with 3.0×100 mm Atropos balloon (Brosmed medical co., Ltd), penetrating from proximal to distal part of PTA (Fig. 2). Final angiography demonstrated a well visualized anterior tibial artery, dorsal-plantar loop, and posterior tibial artery with improved flow (Fig. 3). After 24 hour of observation, the patient was transferred to an orthopedics without complications, and then wound healing was achieved by surgical repair by necrotic tissue debridement and skin graft.

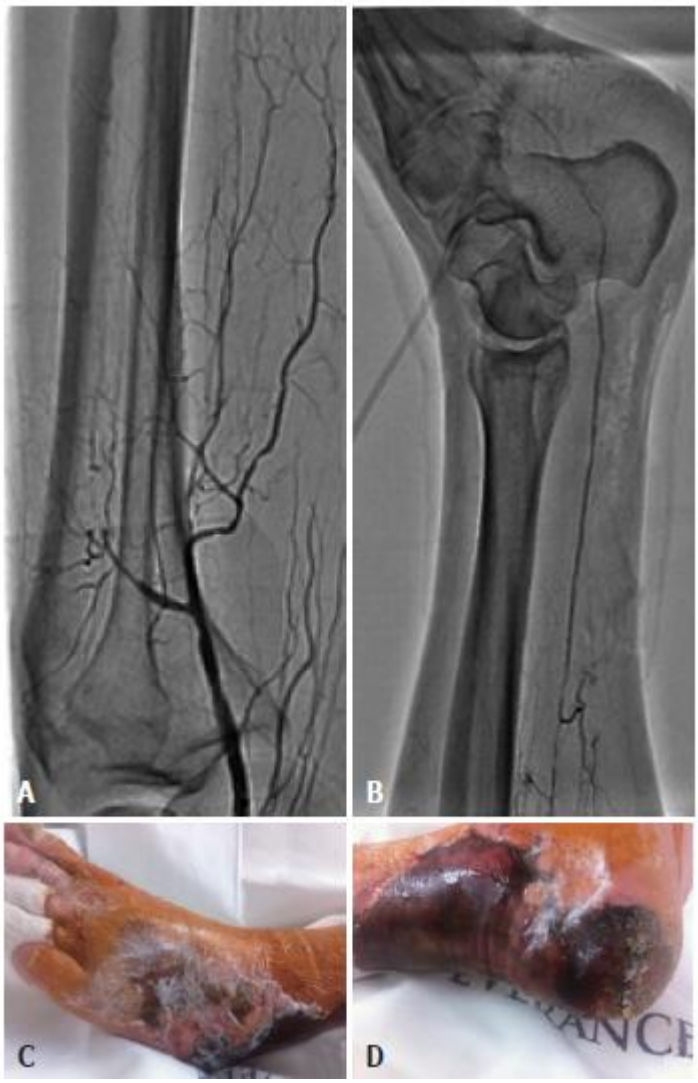

Fig. 1. Baseline peripheral angiography. (A) Baseline angiography revealed total occlusion of the left infrapopliteal artery with proximal portion of three distal run-off vessels. (B) The flow of distal posterior tibial artery and lateral plantar artery is shown. (C and D) A diffuse wound is distributed on the entire area of the foot including the transpedal puncture site.

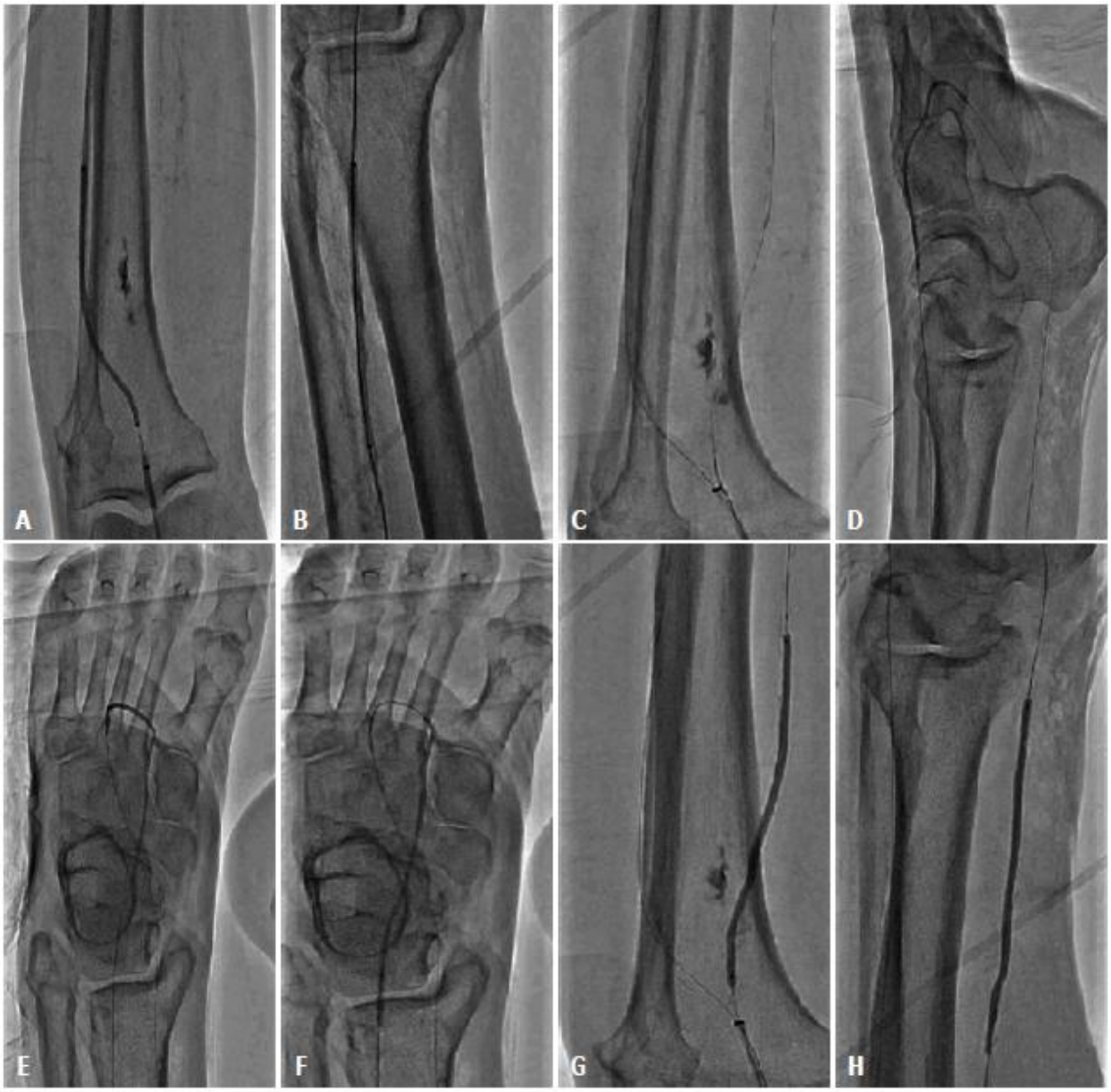

Fig. 2. Balloon angioplasty. (A and B) Balloon angioplasty of ATA using 3.0×100 mm Atropos balloon. (C) A 300-cm-long 014-inch hydrophilic guidewire was passed from ATA via a dorsal-plantar loop to PTA using the Corsair microcatheter. (D, E and F) Balloon angioplasty of dorsal-plantar loop (consisting of dorsalis pedis artery, deep plantar artery, deep plantar arch and lateral plantar artery) using 2.0×120 mm Polux balloon. (G and H) Balloon angioplasty of PTA using 3.0×100 mm Atropos balloon. ATA, anterior tibial artery; PTA, posterior tibial artery.

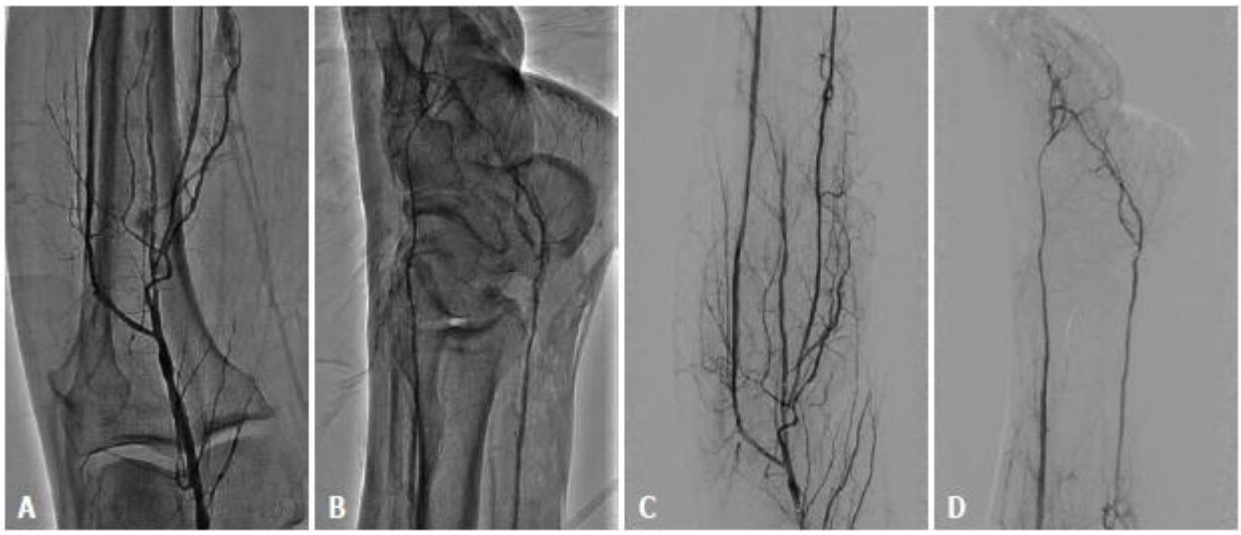

Fig. 3. (A-D) Final angiography. Final angiography reveals a well visualized anterior tibial artery, dorsal-plantar loop and posterior tibial artery with improved flow.

Discussion and Conclusion

Peripheral percutaneous transluminal angioplasty is a method for treating CLI, especially infrapopliteal level, with outcomes similar to those of bypass surgery.4,5 Ultimate aim of revascularization in patients with CLI is to prevent limb loss, including major amputation to improve patient's quality of life, and to prolong survival. However, BTK intervention may be very challenging until recently because it is of- ten necessary to treat very long occlusions of BTK vessels. The typical patient group of complex BTK lesions represents an increasing population of patients due to increasing prevalence of diabetes and ESRD. In addition to that, al- though limb salvage rates are low, the endovascular intervention have the advantage of safety and low morbidity, and might offer economical benefits, especially in patient with ESRD and diabetes. Diabetic foot ulcer occupy about 15% in patients with type 2 diabetes during their lifetime, and ap- proximately 20% of these end up with some kind of amputation.6 Therefore, multiple interventional devices and techniques available can offer patients with treatment options for diseased arterial territories that have not traditionally been amenable to treatment, especially BTK interventions.

Dorsal-plantaer loop technique is one of the new BTK interventional techniques and includes recanalization of both pedal and plantar arteries and their anatomical anastomoses, and this method generally needs two simultaneous approaches, including antegrade and retrograde.7,8 Manzi, et al.9 reported excellent results in clinical study showing 85% of acute success rate, 86% of limb salvage rate and 7.5 to 8% of repeated target vessel percutaneous transluminal angioplasty among 135 patient approached with dorsal-plan- tar loop technique. Most of diabetic ulcers are formed in distal part of the foot, and the arteries of the foot are terminal branches of ATA and PTA, dorsal and plantar arteries, respectively, and these arteries are the major source of blood supply to toes, dorsum and sole of foot.10 Therefore, revascularization of these arteries plays an important role in limb salvage and is a treatment for patients with non-healing ul- cers and possible limb loss. This patient underwent complex interventions with dorsal-plantar loop technique, which included only one antegrade approach using CTO devices via ATA, with good results.

Clinical Performance: The clinical trials and literature review regarding the Polux PTA SC Balloon Dilatation Catheter support its effectiveness in performing percutaneous transluminal angioplasty procedures.

Clinical evidence suggests that the catheter is successful in dilating stenotic areas within the indicated arteries, improving blood flow and potentially addressing conditions like peripheral arterial disease. The semi-compliant balloon design contributes to controlled dilatation while the catheter's compatibility with common interventional devices enhances its usability during procedures.

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References

1. Carmona GA, Hoffmeyer P, Herrmann FR, Vaucher J, Tschopp O, Lacraz A, et al. Major lower limb amputations in the elderly ob- served over ten years: the role of diabetes and peripheral arterial disease. Diabetes Metab 2005;31:449-54.
2. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007;45 Suppl S:S5-67.
3. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): en- dorsed by the American Association of Cardiovascular and Pulmo- nary Rehabilitation; National Heart, Lung, and Blood Institute; So- ciety for Vascular Nursing; TransAtlantic Inter- Society Consensus; and Vascular Disease Foundation. Circulation 2006;113:e463-654.

4. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet 2005;366:1925-34.
5. Söderström MI, Arvela EM, Korhonen M, Halmesmäki KH, Albäck AN, Biancari F, et al. Infrapopliteal percutaneous transluminal angioplasty versus bypass surgery as first-line strategies in critical leg ischemia: a propensity score analysis. Ann Surg 2010; 252:765-73.
6. Reiber GE. The epidemiology of diabetic foot problems. Diabet Med 1996;13 Suppl 1:S6-11.
7. Fusaro M, Dalla Paola L, Biondi-Zoccai G. Pedal-plantarloop technique for a challenging below-the-knee chronic total occlu- sion: a novel approach to percutaneous revascularization in critical lower limb ischemia. J Invasive Cardiol 2007;19:E34-7.
8. Fusaro M, Dalla Paola L, Brigato C, Marangotto M, Nicolini S, Rripay R, et al. Plantar to dorsalis pedis artery subintimal angioplasty in a patient with critical foot ischemia: a novel technique in the armamentarium of the peripheral interventionist. J Cardiovasc Med (Hagerstown) 2007; 8:977-80.
9. Manzi M, Fusaro M, Ceccacci T, Erente G, Dalla Paola L, Brocco E. Clinical results of below-the knee intervention using pedalplantar loop technique for the revascularization of foot arteries. J Cardiovasc Surg (Torino) 2009; 50:331-7.
10. Moore KL, Dalley AF. Clinically oriented anatomy. 4th ed. Philadelphia: Lippincott, Williams & Wilkins; 1999.

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