Case Report

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Crossing complex infrapopliteal lesions utilizing a front-end cutting technique: A report of two cases with a novel rotational atherectomy device

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Abstract

Critical limb ischemia represents the most severe stage of peripheral vascular disease and patients often present with complex, calcified infrapopliteal lesions. Atherectomy is an endovascular treatment modality that can be used to debulk otherwise uncrossable lesions. We performed a retrospective, single-center, case report of two patients who presented with critical limb ischemia and whose complex and calcified infrapopliteal lesions were treated with the 1.5 mm Phoenix Atherectomy System after prior failed angioplasty attempts. The 1.5 mm Phoenix Atherectomy System successfully debulked each infrapopliteal lesion, and each patient achieved thrombolysis in myocardial infarction grade 3 flow of the target lesion. There were no device-related procedural complications or deaths. These cases demonstrate that the Phoenix Atherectomy System can be used to debulk complex, calcified infrapopliteal lesions to optimize endovascular treatment and improve outcomes for patients with critical limb ischemia. Further studies are warranted to validate the long-term safety and efficacy rates of the Phoenix Atherectomy System in a larger critical limb ischemia population.

Keywords

Critical limb ischemia, infrapopliteal lesions, atherectomy, Phoenix Atherectomy System

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Introduction

Patients with critical limb ischemia (CLI) often present with infrapopliteal (IP) lesions.[1] Effective management of IP disease requires optimal revascularization strategies to restore perfusion, improve wound healing, and optimize limb salvage outcomes.[2] Endovascular therapy is often the preferred treatment modality for IP lesions,[3–6] and debulking can be employed for complex, difficult-to-cross lesions. In the context of challenging below-the-knee cases, the use of atherectomy devices is increasing as a safe and effective option both alone and as adjunctive treatment[7] and has the potential to improve outcomes for patients with CLI.

The Philips proprietary Phoenix Atherectomy System is a rotational atherectomy device designed to reduce the risks of vessel injury and distal embolization. The single insertion device has a distal tip with a front cutting metal element to directly access and cut the lesion. The various components of the device, including the blades and Archimedes screw, allow for a continuous cutting, capturing, and clearing mechanism of action. The Phoenix 1.5 mm atherectomy catheter is a second-generation tracking device within this portfolio with a lower 4 F profile for smaller lesions in the distal arteries, which are often seen in CLI patients. The device includes a cutter head with a 5-degree relief cut, which aids in the treatment of below-the-ankle lesions, in addition to creating channels in larger calcified lesions.

Here, we report details of two patients with CLI who presented with complex, calcified IP lesions that were successfully treated with the 1.5 mm Phoenix atherectomy device after prior unsuccessful crossing or angioplasty attempts.

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Table 1. Phoenix 1.5 mm case report.

Case	Age	Sex	Rutherford class	Clinical presentation	History	Access	Lesion characteristics	Procedural outcome
Case 1	66	Male	V	Nonhealing ulcer on the right fourth toe	• DM2 • ESRD on hemodialysis • Amputation of the second and third toes on right foot	• Retrograde • Right distal ATA	• 80 mm CTO with calcification • Right proximal ATA	• 0% residual stenosis* • TIMI 3 flow
Case 2	68	Male	V	Nonhealing gangrenous ulcers on the right hallux and second toe	• ESRD on hemodialysis • HTN	• Antegrade • Right CFA	• 120 mm CTO with permanent calcification • Mid segment of the right ATA	• 20%–30% residual stenosis* • TIMI 3 flow
Case 3	84	Male	IV	Nonhealing fracture of the right foot	• DM2 • HTN • HL • Smoking	• Retrograde • Right distal ATA	• 240 mm CTO with heavy calcification • Right ATA from the distal to the proximal segment	• <20% residual stenosis* • TIMI 3 flow
Case 4	64	Male	V	Right fifth toe blister that turned gangrenous	• DM2 • ESRD on hemodialysis • HTN • HL • Smoking	• Antegrade • Right CFA	• 40–50 mm CTO with severe calcification • Right proximal peroneal artery	• <20% residual stenosis* • TIMI 3 flow
Case 5	80	Male	V	Nonhealing wounds on the left lower extremity	• CKD • HTN • HL • IVC occlusion • Multiple venous ablative procedures with residual wounds	• Retrograde • Left distal PTA	• 80 mm CTO with severe calcification • Left distal PTA	• <20% residual stenosis* • TIMI 3 flow

ATA, anterior tibial artery; CFA, common femoral artery; CKD, chronic kidney disease; CTO, chronic total occlusion; DM2, type II diabetes mellitus; ESRD, end-stage renal disease; HL, hyperlipidemia; HTN, hypertension; IVC, inferior vena cava; PTA, posterior tibial artery; TIMI, thrombolysis in myocardial infarction.
*Following atherectomy and final balloon angioplasty.

Case report 1

A 66-year-old White male presented with a nonhealing ulcer on the right fourth toe consistent with Rutherford Class V disease (Table 1). The patient had a history of type II diabetes mellitus, end-stage renal disease (ESRD) on hemodialysis, and a recent amputation of the second and third toes of the right foot. An arterial duplex study showed that a long segment of the proximal posterior tibial artery was occluded with significant calcification, and the anterior tibial artery (ATA) showed monophasic flow. The patient presented with abdominal pannus, so a pedal approach was preferred in the interest of patient safety, increased chance of technical success in crossing the lesion, decreased procedural and fluoroscopy time, and simplified hemostasis with rapid discharge.

Ultrasound-guided retrograde access was obtained into the right distal ATA with a 4F RAIN sheath (Cordis). Retrograde angiography demonstrated a calcified occlusion of the proximal ATA, approximately 80 mm in length. An ASAHI Mongo wire (ASAHI INTECC) was used to cross the lesion and advanced up to the P1 segment of the popliteal artery (Figure 1(a)). A 0.035" Navicross support catheter (Terumo) was advanced over the wire but could not cross the lesion due to the severity of the circumferential calcification in the lesion. Next, a 1.5 mm × 20 mm Jade balloon (Cardiovascular Systems, Inc.) over the 0.014" wire failed to cross the lesion. Similarly, a 1.2 mm Armada XT (Abbott) balloon ruptured in the lesion when inflated. After these unsuccessful attempts to cross the lesion, the Phoenix 1.5 mm catheter was advanced into the lesion, successfully traversing it while also debulking and modifying the severe calcification (Figure 1(b)), enabling intravascular ultrasound (IVUS) imaging with a Volcano 0.014" IVUS catheter (Philips; Figure 1(c)). The lesion was then treated with

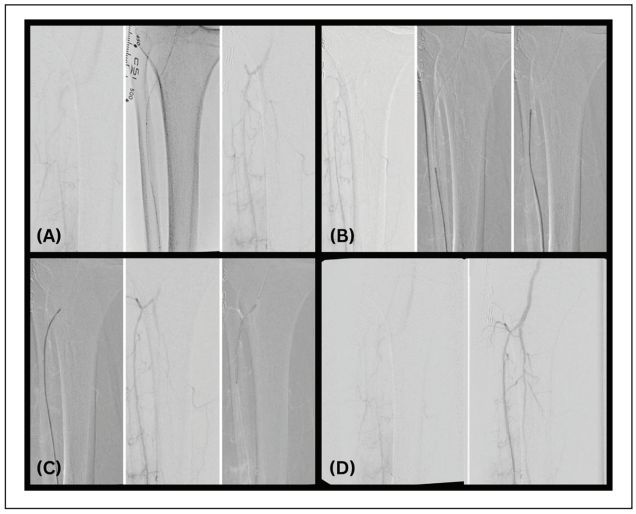

Figure 1. Case 1. (A) An ASAHI Mongo wire crosses a total occlusion of the right proximal ATA. (B) Pilot channel through the lesion created by Phoenix 1.5 mm catheter with a front-end cutting technique. (C) Post atherectomy, an IVUS catheter and an appropriately sized balloon can pass the lesion. (D) Final angiogram showing 0% residual stenosis and TIMI 3 flow as compared to the initial angiogram.
ATA, anterior tibial artery; TIMI, thrombolysis in myocardial infarction; IVUS, intravascular ultrasound.

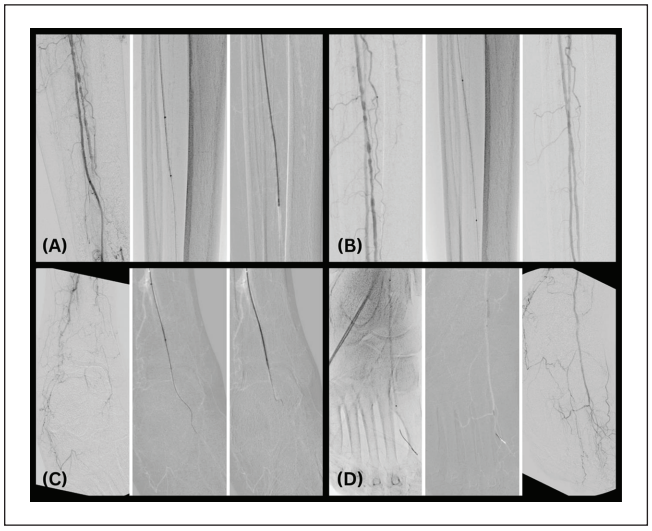

Figure 2. Case 2. (A) The Phoenix 1.5 mm catheter creates a pilot channel through an occlusion in the mid segment of the right ATA that the triaxial catheter system could not cross. (B) Final angiogram of the right ATA showing 20%–30% stenosis and TIMI 3 flow with no complications after balloon angioplasty through the pilot channel. (C) The 1.5 mm catheter debulks a focal occlusion in the proximal dorsalis pedis artery. (D) Final angiogram of the dorsalis pedis artery with TIMI 3 flow into the foot after balloon angioplasty.
ATA, anterior tibial artery; TIMI, thrombolysis in myocardial infarction

sequential balloon angioplasty using 2.0 mm × 80 mm and 2.5 mm × 80 mm Jade (Orbus Neisch) balloons at nominal pressures. After balloon angioplasty, the final angiogram showed 0% residual stenosis and TIMI 3 flow (Figure 1(d)) with no complications. Arterial duplex imaging 4 months post-procedure demonstrated patency of the revascularized right ATA segments, and the clinical exam demonstrated complete and sustained wound healing.

Case report 2

A 68-year-old African American male presented with non-healing gangrenous ulcers on the right hallux and second toe consistent with Rutherford Class V disease (Table 1). The patient had a history of hypertension and ESRD on hemodialysis. An arterial duplex study showed heavy calcific plaque in the IP vessels with flow-limiting disease. The dorsalis pedis artery was heavily calcified and the distal ATA was occluded.

Ultrasound-guided antegrade access was obtained into the right common femoral artery, and a 5 F 45 cm BriteTip sheath was placed into the right popliteal artery. Antegrade angiography demonstrated an occlusion in the mid segment of the ATA, approximately 120 mm in length. The triaxial catheter system, comprised of a 0.035" Navicross (Terumo), 0.018" Navicross, and an ASAHI Mongo wire, was able to cross up to the mid portion of the chronic total occlusion in the ATA. The wire then crossed the lesion; however, the catheters could not be advanced past the severely calcified lesion. Next, a 2.0 mm × 100 mm Jade balloon (CSI) over the 0.014" wire failed to cross the lesion. After these unsuccessful attempts to cross the lesion, the Phoenix 1.5 mm catheter was advanced into the lesion, successfully debulking and modifying the calcification (Figure 2(a)), allowing angioplasty with a 2.5 mm × 120 mm Jade balloon (CSI) to pre-dilate the lesion (Figure 2(b)). Then, the aforementioned triaxial catheter system was able to be advanced further to the level of the ankle. An ASAHI Mongo wire and a Confianza Pro wire were used to cross the lesion and advance into the dorsal metatarsal artery. Again, no catheters could be further advanced, so the Phoenix atherectomy device was used to make another channel, crossing through the distal ATA. The lesion was then treated with sequential balloon angioplasty using 1.5 mm × 40 mm, 2.0 mm × 120 mm, and 2.5 mm × 100 mm Jade balloons (CSI) at nominal pressures. Extravascular ultrasound showed a heavily calcified spot in the proximal dorsalis pedis artery, so the Phoenix atherectomy device was used a third time to debulk the lesion (Figure 2(c)). This focal lesion was then treated with balloon angioplasty using a 2.5 mm × 20 mm Jade balloon (CSI) at nominal pressures. After balloon angioplasty, the final angiogram showed residual stenosis of 20%–30% and TIMI 3 flow with no complications (Figure 2(b) and (d)). Arterial duplex imaging 6 weeks post-procedure demonstrated a patency of the revascularized right ATA with no focal occlusions.

Discussion

A common clinical scenario in patients with severe calcified IP disease is the ability to cross the culprit lesion with an interventional wire followed by inability to advance any further equipment through the intensely calcified lesions. This can result in treatment failure. This case report demonstrates the effective utilization of the Phoenix Atherectomy System in two CLI patients who presented with complex, calcified IP lesions that were challenging to cross with catheters and balloons. The 1.5 mm Phoenix catheter can be advanced to such lesions over a 0.014" workhorse wire, modifying the lesion with a "front-end cutting" technique such that subsequent therapy with balloon angioplasty can be performed. Both cases demonstrate the use of the 1.5 mm Phoenix catheter to initially create a pilot channel through calcified IP lesions and subsequently modify severely calcified plaque adequately enough to allow subsequent balloon angioplasty, otherwise not possible with traditional crossing techniques alone.

In a case series evaluating the repercussions of failed angioplasty of the superficial femoral artery, it has been found that such treatment failures incur significant consequences for patients and healthcare institutions.[8] The Phoenix Atherectomy System enables us to lower the treatment failure rate by modifying lesions and achieving optimal revascularization in previously unsuccessful lesion crossing attempts. This was seen even when a balloon could cross (as in Case 1) and was prone to rupture due to severe calcification.

Other rotational atherectomy systems such as Rotablator (Boston Scientific) and Diamondback (Abbott) are available to debulk calcified lesions prior to treatment delivery. However, the Phoenix Atherectomy System offers several advantages in the treatment of complex IP lesions. The device allows for direct access to the lesion with its front cutting metal element which cannot be crossed by conventional methods. Moreover, the system's capability to be advanced over a 0.014" workhorse wire enables targeting lesions that are too calcified to be treated with a low-profile 1.2 mm balloon, as demonstrated in Case 1. A 0.014" exchange catheter for alternative atherectomy systems may face the same constraint in crossing such lesions. This advantage holds true irrespective of access site. Also, the continuous cutting, capturing, and clearing mechanism helps to reduce the risk of vessel injury and distal embolization[9] as compared with other methods. In addition, it can be advanced to the lesion through a 4 F sheath. In comparison, larger devices like the Jetstream Atherectomy System (Boston Scientific) limit pedal access due to sheath compatibility.

Clinically, the use of the Phoenix 1.5 mm atherectomy device in these two cases suggests that it can be a valuable tool to improve perfusion, promote wound healing, and increase the likelihood of limb salvage in CLI patients, especially when used to create pilot channels while other treatment modalities are unable to cross larger calcified lesions. We have observed similar favorable results in an additional three patients with CLI and complex IP lesions (Table 1), but these cases have been excluded in the interest of conciseness.

This two-patient case report is limited by a small cohort. Of note, we observed similar outcomes in an additional three patients who were excluded from this case report in the interest of conciseness. Nonetheless, investigation is warranted in studies with a larger sample size and longer follow-up periods to confirm efficacy of the device. Additionally, appropriate patient selection is crucial to avoid vessel injury and avoid contraindications that include severe vessel tortuosity, angulation, or small caliber such as in the inframalleolar vessels. To enhance the external validity of our findings, it is also valuable in future research to evaluate the use of the 1.5 mm Phoenix atherectomy device in different patient populations, compare efficacy with other treatment modalities, investigate long-term outcomes, and determine limb salvage rates.

Conclusion

In conclusion, the 1.5 mm Phoenix atherectomy device has shown promising results in the treatment of complex, difficult-to-treat calcified IP lesions. The 1.5 mm Phoenix atherectomy device has demonstrated the potential to optimize endovascular treatment and improve outcomes for patients with CLI.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Siddhartha Rao is a paid consultant of Philips. Trisha Tarra is an employee of Philips.

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Ethical approval

Ethical approval to report this case series was obtained from WCG IRB (1-1660055-1).

Informed consent

In this single-center case report, IRB waiver was received (a waiver of informed consent and a complete HIPPAA waiver were granted) by the WCB IRB (approval number/ID: 1-1660055-1) for the anonymized information to be published in this article.

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