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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

A novel technique of percutaneous intraluminal cracking using a puncture needle for severe calcified lesions of below-the-knee and below-the-ankle arteries

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PURPOSE
Endovascular therapy has recently become acceptable for the reconstruction of below-the-knee (BTK) and below-the-ankle (BTA) arterial lesions. However, we have sometimes experienced BTK or BTA lesions with calcifications that are too severe for balloon catheters to cross or expand despite successful guidewire passage. In this study, we assessed the feasibility and safety of the novel inner PIERCE technique for breaking down the calcium burden of BTK and BTA arterial lesions.

METHODS
We retrospectively reviewed the records of patients who had undergone endovascular therapy between August 2018 and December 2019. The inner PIERCE technique was performed in those cases where low-profile balloon catheters were unable to pass through the target lesions or balloon indentation did not disappear beyond the rated burst pressure. An externalized guidewire system was established in 8 cases via bidirectional approaches, and a 20-gauge needle was directly inserted through the guidewires from the distal puncture site. In 10 cases of successful antegrade wiring, the tibial or pedal arteries distal to the lesion site were punctured for a retrograde guidewire approach to the lesion. The needle was slowly rotated and advanced across the lesion.

RESULTS
We found that all lesions were severely calcified and 83.3% had chronic total occlusion. The inner PIERCE procedure allowed successful passage of the needle and subsequent low-profile balloon catheters in all cases. Optimal balloon dilatation was achieved in 94.4% of the cases using this technique. No procedure-related adverse events were observed.

CONCLUSION
The novel inner PIERCE technique is a safe and feasible method for disrupting calcified BTK and BTA lesions.

Chronic limb-threatening ischemia (CLTI) is associated with major amputation and severely limits blood flow to the foot due to multilevel arterial occlusions. CLTI includes severe below-the-knee (BTK) and/or below-the-ankle (BTA) arterial disease (1). To salvage ischemic limbs, the establishment of a straight line of flow to the foot is essential. Revascularization of arteries in BTK and/or BTA arterial disease plays a pivotal role in the treatment of CLTI because most patients with CLTI suffer from diabetes and chronic kidney disease and frequently have long total occlusions and/or severely calcified lesions in the BTK arteries (2–6).

Recently, endovascular therapy was reported to be acceptable for the reconstruction of arteries in BTK disease due to operators' experience, technical improvements, and the development of angioplasty instruments (7, 8). The success rate of endovascular therapy is approximately 90% for long total occlusion of BTK arteries using bidirectional approaches and current devices like fine guidewires (9–12). However, we have witnessed BTK and BTA lesions with calcifications too severe for balloon catheters to cross or expand despite successful passage of a guidewire. Rotational atherectomy devices may be effective in removing or reducing the calcium burden in the plaque that disturbs the passage of the catheter but pose potential risk for procedural complications such as burr entrapment, dissection, and perforation. Furthermore, the BTK and BTA arteries are small, distal vessels, and most of the critical ischemic limbs have

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poor vascular beds (13). Therefore, the rotational atherectomy device may cause distal embolisms, leading to major adverse events.

Nakama et al. (14) reported a novel inner PIERCE technique in which a needle is inserted directly into the calcified lesions to break down the calcium burden in a vessel. However, the feasibility and safety of this technique are still unclear because only one case has been reported. We evaluated the efficacy of the inner PIERCE technique in patients who had experienced dilatation failure using conventional approaches, due to calcified lesions. In this work, we aimed to assess the feasibility and safety of the novel inner PIERCE endovascular technique for breaking down the calcium burden of BTK and BTA arterial lesions.

Methods

Subjects

Between August 2018 and December 2019, we performed 278 sessions of BTK/BTA angioplasty because of CLTI that included re-intervention in 187 limbs of 154 patients. Fifteen of these patients underwent the inner PIERCE procedure because balloon catheters were unable to pass through the calcified lesions despite the successful crossing of a guidewire. The feasibility and safety of the inner PIERCE technique were retrospectively assessed. This study was conducted in accordance with the Declaration of Helsinki. All patients agreed to the treatment and gave written consent. This study was approved by the institutional review board (No. CR-20-07).

Main points

- Chronic limb-threatening ischemia (CLTI), including severe below-the-knee (BTK) and below-the-ankle (BTA) arterial disease, severely limits blood flow to the foot due to multilevel arterial occlusions. Ischemic limbs are salvaged via establishing a straight line of blood flow to the foot.
- Endovascular treatment by guidewires is used to reconstruct arteries in BTK disease with a 90% success rate. In cases where calcifications are too severe, rotational atherectomy may be effective in addressing the calcium burden in the plaque, but this technique may cause distal embolisms and major adverse events.
- We assessed the feasibility and safety of a novel inner PIERCE technique that can disrupt calcified BTK and BTA lesions. This technique involves the direct insertion of a needle into the calcified lesions to break down the calcium burden in the vessels.
- The efficacy of the inner PIERCE technique was evaluated, and promising technical and procedural success rates of 94.4% were achieved.

Endovascular therapy procedure

All sessions of endovascular therapy were initially performed via the antegrade ipsilateral femoral approach using 5 French (F), 60 cm long sheath or 6 F, 55 cm guide catheters. All endovascular therapy manners were executed with 0.014-inch diameter guidewires and balloon systems. If conventional antegrade wiring failed, retrograde tibial or pedal approaches were added to provide bidirectional wiring. The inner PIERCE technique was performed if 1.0–1.5 mm low-profile balloon catheters were unable to pass the target lesions or balloon indentation did not disappear at the rated burst pressure. A schematic diagram of the inner PIERCE technique is presented in Fig. 1. The externalized guidewire system was already established in 8 cases via bidirectional approaches, and the 20-gauge, 105 mm long puncture needle (MEDIKIT) or the 20-gauge, 310 mm long biopsy needle (NIPRO) was directly inserted through the guidewires from the distal puncture site. The length of the needle was dependent on the distance from the puncture site to the target lesion. In 10 cases of successful antegrade wiring, the tibial or pedal arteries that were distal to the lesion site were punctured to allow the retrograde guidewire to cross the lesion. The needle was slowly rotated and advanced across the lesion that had caused the failure in balloon passage. During this procedure, guidewire tension was maintained by pulling the externalized guidewire or the retrograde wire that was anchored with antegrade balloon catheters. Polymer jacket guidewires should not be used for inner PIERCE because the polymer gets peeled off by the tip of needle. After the needle was passed through the lesion several times, the passage and expansion of the balloon catheter were re-attempted. The needle was removed and exchanged for a 22-gauge plastic canula to prevent bleeding from the puncture site after the balloon catheters had passed the target lesions. Hemostasis of the distal puncture site was accomplished by a long inflation period using an optimally sized balloon and compression using an elastic tourniquet.

Assessment of inner PIERCE

Patient characteristics, target lesion morphology, procedure indications, and technical and procedural success were investigated in all patients who underwent the inner PIERCE procedure. The technical success was defined as successful balloon passage through the vessel or full balloon expansion after inner PIERCE. The procedural success was defined as a residual stenosis <30% without any adverse events.

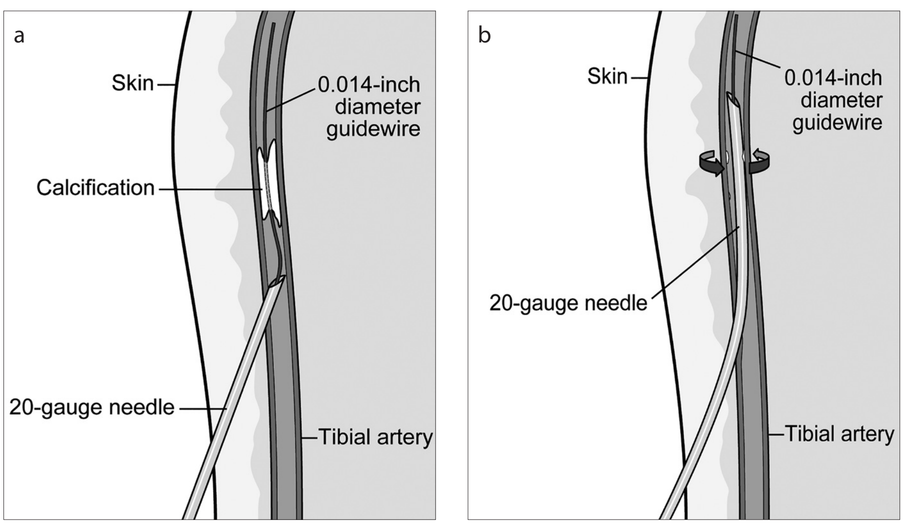

Figure 1. a, b. Schematic of the inner PIERCE technique. In panel **(a)**, bidirectional approaches with distal BTK or BTA puncture are performed by establishing wire externalization between the antegrade approach site and the distal puncture site, or a retrograde wire is anchored by an antegrade balloon catheter at a more proximal part of the calcified lesions. In panel **(b)**, a 20-gauge needle is inserted into the artery through the guidewire from the distal puncture site; the 20-gauge needle is carefully advanced with rotation through the calcified lesions several times.

Statistical analysis

The data were analyzed using IBM SPSS version 22 (IBM Corp). Values in Table 1 are presented as means ± standard deviations or numbers (percentage). Values in Table 2 are presented as medians (interquartile range, IQR) or numbers (percentage).

Results

The inner PIERCE technique was performed in 18 limbs of 15 patients who presented with CLTI. The mean age of the patients was 73.4±7.6 years, and 14 of them were male. Fourteen patients (93.3%) were undergoing maintenance hemodialysis. All patients had non-healing ulcers and/or gangrene of the feet with 7 of the 18 limbs (37.9%) belonging to category 6 of the Rutherford classification system. The inner PIERCE technique was used for target lesions located in the anterior tibial (4 limbs), posterior tibial (10 limbs), and dorsal (4 limbs) arteries. According to lesion morphology, all lesions were severely calcified, and 83.3% of the affected arteries had chronic total occlusion. The patient characteristics and lesion morphology are shown in Table 1.

We did not experience adverse events, such as vascular rupture or perforation, bleeding, or guidewire fracture, related to the inner PIERCE technique. With respect to the indications for using the inner PIERCE technique, 83.3% and 16.7% of the cases were due to a failure in the passage of low-profile balloon catheters and inability of balloon dilatation, respectively (Table 2). In 17 lesions, the 105 mm long puncture needle was used. Only one lesion required the use of the 310 mm long biopsy needle. The median distance from the distal puncture site to the target lesion was 12.5 mm (IQR, 10.0–21.3). The minimum and maximum distances were 10 mm and 160 mm, respectively. The passage of the needle and subsequent passage of the balloon catheters were successful for all 18 lesions after the inner PIERCE procedure. Optimal balloon dilatation was achieved in 94.4% of the cases after the inner PIERCE technique. Only one lesion was extremely difficult to

Table 1. Patient characteristics and lesion morphology

Patient	n=15
Age (years), mean±SD	73.4±7.6
Male, n (%)	14 (93.3)
Hypertension, n (%)	11 (73.3)
Diabetes mellitus, n (%)	8 (53.3)
Dyslipidemia, n (%)	7 (46.7)
Smoking history, n (%)	10 (66.7)
Maintenance hemodialysis, n (%)	14 (93.3)
CAD, n (%)	7 (46.7)
Previous endovascular therapy or distal bypass surgery, n (%)	11 (73.3)
Lesion	n=18
Rutherford classification, n (%)	
Category 5	11 (61.1)
Category 6	7 (38.9)
Target, n (%)	
ATA	4 (22.2)
PTA	10 (55.6)
Dorsal artery	4 (22.2)
Severe calcification, n (%)	18 (100)
Chronic total occlusion, n (%)	15 (83.3)
Stenosis, n (%)	3 (16.7)

CAD, coronary artery disease; ATA, anterior tibial artery; PTA, posterior tibial artery.

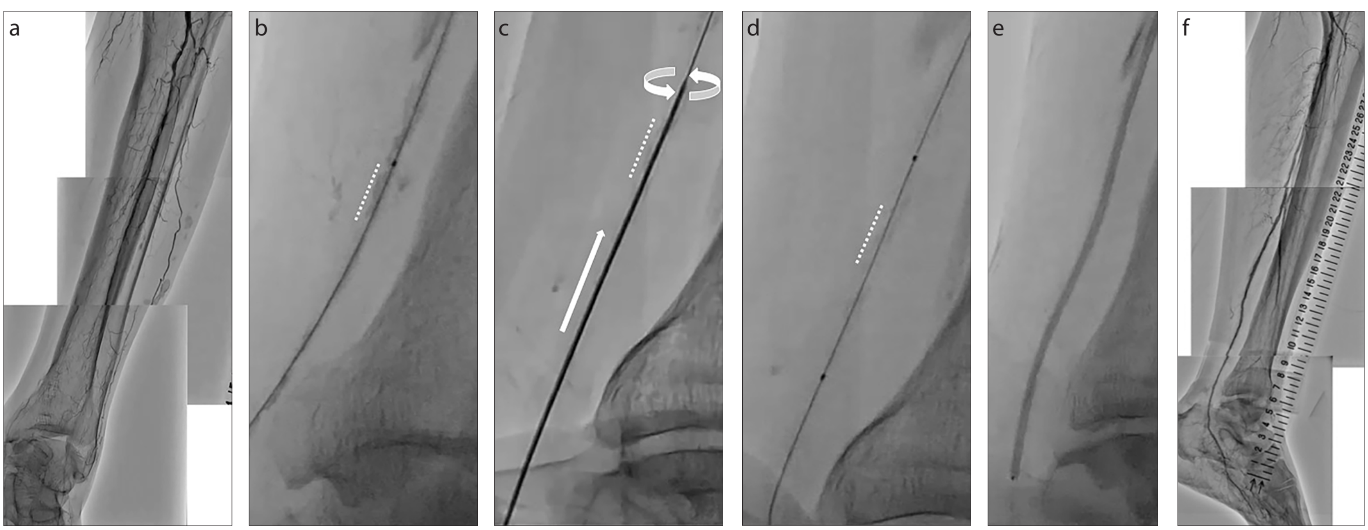

Figure 2. a–f. A representative case for difficulty in device delivery. Preprocedural angiogram **(a)** shows long chronic total occlusion (CTO) of the posterior tibial artery (PTA). In panel **(b)**, retrograde wire from the distal PTA crosses the CTO lesion and is externalized. The low-profile balloon catheter is unable to cross the calcified lesion *(dotted line)*. Panel **(c)** shows the inner PIERCE technique. Panel **(d)** shows a low-profile balloon crossing and dilating the calcified lesion. In panel **(e)**, sufficient lesion dilatation is achieved via the long balloon catheter. Final angiogram **(f)** shows successful revascularization of the PTA.

Table 2. Outcome of the inner PIERCE technique (n=18)

	n (%)
Indication	
Difficulty of balloon catheter delivery	12 (66.6)
Difficulty of microcatheter delivery	3 (16.7)
Difficulty of sufficient lesion dilatation	3 (16.7)
Distance from the distal puncture site to the target lesion	
Distance (mm), median (range)	12.5 (10.0–21.3)
≤20	14 (77.8)
21–50	2 (11.1)
≥51	2 (11.1)
Success rate of the inner PIERCE technique	
Successful 20-gauge needle crossing	18 (100)
Successful device delivery	18 (100)
Successful sufficient lesion dilatation	17 (94.4)
Technical success rate	17 (94.4)
Procedural success rate	17 (94.4)
Complication	
Vascular rupture	0 (0)
Guidewire rupture	0 (0)
Puncture site trouble	0 (0)

dilate completely using a high-pressure balloon catheter at 30 atm. Therefore, the technical and procedural success rates for inner PIERCE were 94.4%. Fig. 2 shows a representative case where the inner PIERCE technique was performed because no device could pass through the lesion despite attempts at using the Crosser and FORcible Manner (BADFORM) techniques (15).

Discussion

In this study, we assessed the feasibility and safety of our novel inner PIERCE endovascular technique in breaking down the calcium burden of BTK and BTA arterial lesions. We concluded that this technique is a safe and feasible method for disrupting calcified lesions located below the knee or ankle. Recently, the success rate for endovascular therapy in BTK and BTA occlusive diseases has increased notably because of technical improvements that include bidirectional approaches using distal tibial or pedal punctures and the development of new devices like fine guidewires and low-profile balloon catheters (16–18). However, we sometimes encounter hardened calcified plaques that prevent dilatation devices from passing through the vessel. The concept of the inner PIERCE is that cracking the superficial calcified plaque using a needle enables the passage of balloon catheters. The PIERCE technique that was reported by Ichihashi et al. (19) has a concept similar to that of the inner PIERCE technique but is a method of cracking calcified plaques with a needle from the outside of the vessel. Compared to the PIERCE technique, the inner PIERCE technique has several advantages. The inner PIERCE technique is an intraluminal needle method that creates linear fissures in superficially calcified plaques and can create channels with a minimum diameter of 0.9 mm diameter after a 20-gauge needle is passed through the lesion. Specific points in the lesions can be definitively treated by needle passage using the guidewire. In fact, balloon catheters could successfully pass through the vessels in all the above cases after the inner PIERCE technique. Moreover, multiple needle punctures were not needed after the establishment of bidirectional approaches. In the PIERCE technique, we frequently experienced difficulties in accurately puncturing the target lesions due to dense calcification in the vessel walls. The PIERCE technique can only crack one point of the calcified plaque using one needle puncture and frequently requires multiple needle punctures for successful device passage even when an accurate puncture is performed.

However, the inner PIERCE technique has some limitations. Bidirectional approaches are essential for this technique. The pull-through wire or anchored retrograde wire system under bidirectional approaches is required to maintain the wire tension so that the needle can advance to the lesion. When target lesions are present in the distal pedal arteries, it is difficult to puncture the vessels that are distal to the target lesions. We were able to perform the inner PIERCE procedure in three patients with dorsal arterial lesions, who had undergone a retrograde digital puncture. However, no patient with a plantar arterial lesion could undergo the inner PIERCE technique due to our inability to puncture the distal plantar artery. The inner PIERCE technique can only be performed for lesions within the range of the distal puncture site that can be reached by the needle. In one of the lesions treated via the inner PIERCE procedure, balloon indentation did not completely disappear after dilatation with over 30 atm. Therefore, the effectiveness of the inner PIERCE technique may be limited by deep calcification in the vascular wall that limits balloon expansion.

With respect to the safety of the inner PIERCE technique, we were concerned about vascular injury due to rupture, perforation or dissection, guidewire fracture, and bleeding at the distal puncture site. However, we experienced no adverse events related to it. The tibial arteries are relatively straight, and maintenance of wire tension may have attenuated the bias of needle tracking, reducing vascular complications and guidewire fracture. Furthermore, most of the lesions were located within 5 cm from the distal puncture site.

In conclusion, the inner PIERCE technique is a safe and feasible method for disrupting calcified tibial and pedal lesions that disturb the passage or expansion of balloon catheters in patients with CLTI.

Conflict of interest disclosure

The authors declared no conflicts of interest.

References

1. Iida O, Soga Y, Yamauchi Y, et al. Clinical efficacy of endovascular therapy for patients with critical limb ischemia attributable to pure isolated infrapopliteal lesions. J Vasc Surg 2013; 57:974–981.e1. [Crossref]
2. Kawarada O, Fujihara M, Higashimori A, Yokoi Y, Honda Y, Fitzgerald PJ. Predictors of adverse clinical outcomes after successful infrapopliteal intervention. Catheter Cardiovasc Interv 2012; 80:861–871. [Crossref]

3. Higashimori A, Iida O, Yamauchi Y, et al. Outcomes of One straight-line flow with and without pedal arch in patients with critical limb ischemia. Catheter Cardiovasc Interv 2016; 87:129–133. [Crossref]
4. Nakama T, Watanabe N, Kimura T, et al. Clinical implications of additional pedal artery angioplasty in critical limb ischemia patients with infrapopliteal and pedal artery disease. J Endovasc Ther 2016; 23:83–91. [Crossref]
5. Mustapha JA, Diaz-Sandoval LJ, Saab F. Infrapopliteal calcification patterns in critical limb ischemia: diagnostic, pathologic and therapeutic implications in the search for the endovascular holy grail. J Cardiovasc Surg (Torino) 2017; 58:383–401.
6. Ohtake T, Oka M, Ikee R, et al. Impact of lower limbs' arterial calcification on the prevalence and severity of PAD in patients on hemodialysis. J Vasc Surg 2011; 53:676–683. [Crossref]
7. Meyer A, Schilling A, Kott M, Rother U, Lang W, Regus S. Open versus endovascular revascularization of below-knee arteries in patients with end-stage renal disease and critical limb ischemia. Vasc Endovascular Surg 2019; 52:613–620. [Crossref]
8. Janko PJ, Nebojsa BB, Andrej PV. Endovascular procedures in treatment of infrapopliteal arterial occlusive disease: single center experience with 69 infrapopliteal procedures. Arch Iran Med 2018; 21:118–121.
9. Kawarada O, Sakamoto S, Harada K, Ishihara M, Yasuda S, Ogawa H. Contemporary crossing techniques for infrapopliteal chronic total occlusions. J Endovasc Ther 2014; 21:266–280. [Crossref]
10. Chou HH, Huang HL, Hsieh CA, et al. Outcomes of endovascular therapy with the controlled antegrade retrograde subintimal tracking (CART) or reverse CART technique for long infrainguinal occlusions. J Endovasc Ther 2016; 23:330–338. [Crossref]
11. Biagioni RB, Biagioni LC, Nasser F, et al. Infrapopliteal angioplasty of one or more than one artery for critical limb ischemia: a randomised clinical trial. Eur J Vasc Endovasc Surg 2018; 55:518–527. [Crossref]
12. Park SW, Kim JS, Yun IJ, et al. Clinical outcomes of endovascular treatments for critical limb ischemia with chronic total occlusive lesions limited to below-the-knee arteries. Acta Radiol 2013; 54:785–789. [Crossref]
13. Katsanos K, Spiliopoulos S, Reppas L, Karnabatidis D. Debulking atherectomy in the peripheral arteries: is there a role and what is the evidence? Cardiovasc Intervent Radiol 2017; 40:964–977. [Crossref]
14. Nakama T, Muraishi M, Obunai K, Watanabe H. Efficacy of the novel inner PIERCE technique for severely calcified below-the-knee occlusions in apatient with chronic limb-threatening ischemia. Catheter Cardiovasc Interv 2020; 1–6. [Crossref]
15. Nakabayashi K, Ando H, Kaneko N, et al. A novel lesion crossing technique: Balloon deployment using FORcible Manner (BADFORM) technique. Catheter Cardiovasc Interv 2017; 90:1161–1165. [Crossref]
16. Nakama T, Ando H, Watanabe N, Ogata K, Takei T, Shibata Y. Novel retrograde puncture technique for infrapopliteal artery revascularization: transplantar retrograde access. Cardiovasc Interv Ther 2017; 32:287–293. [Crossref]
17. Rogers RK, Dattilo PB, Garcia JA, Tsai T, Casserly IP. Retrograde approach to recanalization of complex tibial disease. Catheter Cardiovasc Interv 2011; 77:915–925. [Crossref]
18. Fusaro M, Agostoni P, Biondi-Zoccai G. "Trans-collateral" angioplasty for a challenging chronic total occlusion of the tibial vessels: a novel approach to percutaneous revascularization in critical lower limb ischemia. Catheter Cardiovasc Interv 2008; 71:268–272. [Crossref]
19. Ichihashi S, Sato T, Iwakoshi S, Itoh H, Kichikawa K. Technique of percutaneous direct needle puncture of calcified plaque in the superficial femoral artery or tibial artery to facilitate balloon catheter passage and balloon dilation of calcified lesions. J Vasc Interv Radiol 2014; 25:784–788. [Crossref]