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INTERVENTIONAL RADIOLOGY
ORIGINAL ARTICLE

Primary retrograde transpedal approach for revascularization of chronic total occlusions of the superficial femoral artery and re-route technique using percutaneous puncture for re-entry

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PURPOSE
We aimed to demonstrate the safety and feasibility of revascularization of chronic total occlusion of the superficial femoral artery (SFA) using the transpedal approach and describe a new technique called "re-route".

METHODS
The study included all consecutive patients who had chronic total occlusions at the level of SFA and underwent retrograde treatment through a pedal artery intervention between September 2017 and October 2019. Balloon angioplasty was applied as the first treatment option. After angioplasty, bailout stenting was performed when necessary in patients with indications. If the common femoral artery lumen could not be reached from the SFA ostium, the re-route technique was used. Technical success was defined as revascularization with residual stenosis of less than 30%.

RESULTS
Twenty-five SFAs were revascularized in 23 patients (17 males; mean age, 66±7.3 years) by angioplasty in 5 SFAs and angioplasty and stents in 20 SFAs. While the transpedal approach was applied after the failure of antegrade recanalization in three patients, it was used as the first treatment route in the remaining cases. The re-route technique was applied in 7 patients, with a 100% technical success rate. The mean follow-up was 15.3 months (range, 12–18 months). The primary patency rate was 78% at one year.

CONCLUSION
The retrograde transpedal approach is a safe and successful technique for chronic total occlusion recanalization and carries a low risk of complications. In order to increase technical success, the re-route technique can be used as an alternative re-entry method.

Lower extremity peripheral artery disease (PAD) is very common, but critical leg ischemia, which is the advanced stage of the disease, leads to high morbidity and mortality (1). In addition to the higher incidence in the elderly population, PAD is also seen at an increased frequency due to comorbidities, such as diabetes, hypertension, and obesity (2). Critical leg ischemia occurs after the multifocal and multiple vascular involvement of the lower limb and chronic total occlusion (CTO), resulting in oxygen deficiency that affects the vital functions of the tissue. The superficial femoral artery (SFA) is one of the arteries frequently affected in the lower extremity. In SFA involvement, the proximal cut and Hunter's canal are the most common locations of the disease (3). Today, although surgery is the gold standard due to its higher patency rates, the frequency of endovascular treatment is also increasing with lower procedure-related morbidity, and mortality rates that are close to surgical treatment (4).

Endovascular treatment options include balloon angioplasty, bare stents, drug-coated stents, stent grafts, atherectomy, and a combination of these treatments with or without medication. Endovascular treatment in the atherosclerotic involvement of SFA has traditionally been performed by the contralateral retrograde route (5). However, in cases where the SFA ostium is affected, technical success decreases and complication rates increase (6). In addition, due to angulation in the aortoiliac bifurcation, CTO in the iliac arteries, bypass grafts, and aneurysmatic dilatation are technically more difficult. Since the retrograde

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route is more linear, the repellency, torque and maneuverability of materials used are higher. With the development of technology and techniques and the introduction of lower-profile materials, it is now possible to perform endovascular treatment through smaller arteries (7, 8).

There are different approaches for endovascular treatment to increase the effectiveness of the procedure, such as antegrade, transcollateral, and retrograde (9). Retrograde access can be achieved through distal SFA, popliteal artery, and tibial or transpedal arteries (10). To prevent bleeding complications, retrograde puncture is often performed under the guidance of ultrasound or fluoroscopy. The most commonly associated complications are bleeding events, perforation of vessels, or damage to the vascular-nerve bundle (11). However, the retrograde approach also has certain technical difficulties, with one of the major challenges being considered as reaching the common femoral artery (CFA) bypassing SFA-level occlusion through the true lumen.

In this study, we aimed to investigate the safety and feasibility of transpedal arterial access for lesions in SFA (mostly extending to the ostium) and propose a new technique called "re-route" for re-entry from SFA to CFA.

Methods

Patient selection

This retrospective study was approved by the ethics committee of our hospital (26379996/224), and all patients were informed about the procedure before the intervention. The study included all consecutive patients who were found to have CTO of SFA and treated by a pedal artery intervention with the retrograde approach between September 2017 and October 2019. All patients had claudication (Rutherford Class 3), rest pain (Rutherford class 4), and/or tissue loss (Rutherford class 5 and 6), and some had certain conditions that could make the intervention difficult, such as obesity, distal occlusion, and excessive iliac artery angulation.

Main points

- The retrograde transpedal approach is a safe and successful technique for CTO recanalization and carries a low risk of complications.
- The re-route technique can be used as an alternative to other re-entry techniques or catheters described in the literature.
- Carbon dioxide can also be used as a contrast agent in retrograde therapy.

Procedure

All patients were informed about the possible benefits and risks of the procedure and written consent was obtained before the treatment. The patients were placed in a supine position and placed under local anesthesia (5–10 cc prilocaine). An intravascular bolus of 70 U/kg heparin was administered at the beginning of the procedure. All procedures were performed under the guidance of ultrasound and fluoroscopy using a 7 cm 21G needle. After the puncture of the pedal artery with this needle, a 0.018-inch wire (V18; Boston Scientific) was advanced directly through the needle if the artery was occluded. A 90 cm support catheter (Seeker; Bd Bard) compatible with the wire was advanced directly, and occlusion was crossed with appropriate manipulations. Only the inner part (dilator) of the micropuncture coaxial catheter system (Cook Medical) was placed if the artery undergoing intervention was not occluded. Nitroglycerin 400 µg was applied for the antispasmodic effect. Then, the recanalization process was continued with a wire and catheter. Nitroglycerin was repeated every 30 minutes. An additional 2500 U heparin was administered in cases where the procedure lasted longer than one hour.

It was first attempted to pass the occluded femoral segment with a 0.018-inch wire-support catheter system or a 0.035-inch wire-support/Bern catheter system. At this stage, when the catheterization of the true lumen is not possible, re-entry catheters are generally used. However, since re-entry catheters are not widely available in Turkey due to reimbursement problems, we applied a new method, which we called the re-route technique (Fig. 1).

When the wire reached the origin level SFA subintimally but could not be advanced to the true lumen of CFA, 18G needle puncture was performed percutaneously from the true lumen of CFA to the SFA origin or immediately distal to the SFA origin level under the guidance of ultrasound and a 0.035-inch wire of sheath was advanced to the subintimal area of SFA under fluoroscopy (Fig. 2a, 2b). This wire was slightly pulled to make it closer to the end of the needle in the vessel. Thus, a new route was obtained from the subintimal to the intimal space.

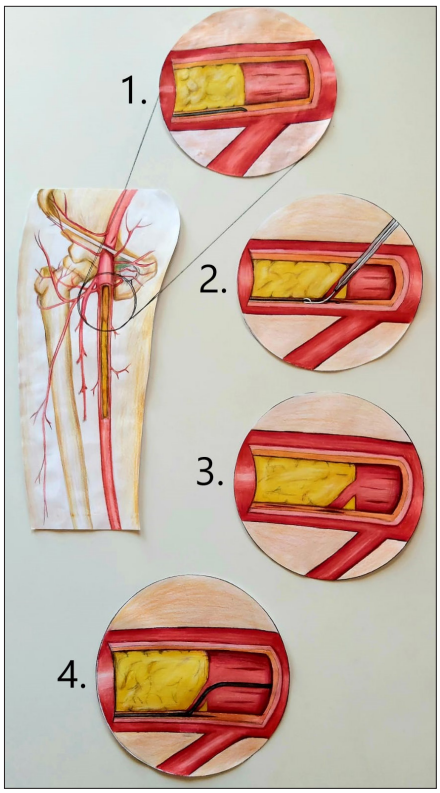

Figure 1. Illustration of the "re-route" technique: 1) Retrograde advancement of the wire in the subintimal area at the origin of superficial femoral artery (SFA); 2) A 18G needle is punctured percutaneously under ultrasound guidance from common femoral artery (CFA) to the level of SFA origin and directed toward to the subintimal area with a 0.035-inch wire; 3) As a result of advancing the wire and needle, a potential new route from the subintimal area to the lumen is shown; 4) From this new route, the wire in the subintimal area from the retrograde path is directed toward the true lumen.

Then, using a 0.035-inch standard angled wire or a 0.018-inch wire with a support or Bern catheter, the true lumen of CFA was advanced through the newly created route (Fig. 2c, 2d and ESM 1). Afterwards, angiography was performed using this catheter to verify that the wire and catheter were in the true lumen (Fig. 2e). After confirming that the wire was in the true lumen, the 18G needle was removed, and balloon angioplasty was applied for 3–5 minutes in order to achieve hemostasis and dilatation. Simultaneously, external compression was applied to the groin.

After the angioplasty procedure, bail-out stenting was applied if there was residual stenosis of more than 30% or in the presence of dissection preventing flow. If a 0.035-inch stent delivery system was planned to be used, a 6 F sheath was placed in the punctured pedal artery. If a 0.018-

Figure 2. a–e. The digital subtraction angiography image **(a)** shows that the contrast agent delivered from the catheter is in the subintimal area. Image **(b)** shows 18G needle puncture performed under ultrasound guidance and a wire sent through it. Then, the angle-tipped wire advanced through the retrograde route is directed to the new route created percutaneously **(c)**. The wire in the subintimal area is advanced toward the true lumen **(d)**. Angiography is performed to confirm that the wire and catheter are in the true lumen **(e)**.

inch stent delivery system or only balloon angioplasty was planned to be performed, the procedure was completed without a sheath to reduce the risk of acute occlusion. The patency of the pedal artery was evaluated by Doppler ultrasound after the procedure. If severe stenosis or occlusion occurred, angiography was performed by ipsilateral CFA using the antegrade route. After administering 400 µg nitroglycerin, balloon angioplasty was applied to the segment including the intervention site to remove occlusion or stenosis occurring at the pedal intervention site and to provide hemostasis. All patients were given 300 mg clopidogrel and 100 mg acetylsalicylic acid on the day of the procedure. They were discharged on the same day after appropriate monitoring.

Definitions

The lengths of the treated lesion were measured using the PACS system (Extreme PACS). Lesion lengths were measured, and the mean lesion length was calculated. The calcification degrees of the lesions on SFA were classified as none (no calcification), mild (calcified segment length <10 cm), moderate (10–20 cm), and severe (>20 cm). The pedal access sites were also evaluated to determine in terms of the presence of calcification.

The technical success of the procedure was defined as revascularization and <30% of residual stenosis. Clinical success was defined as regression in the Rutherford category. Primary patency was defined as persistent patency without any re-intervention, including angioplasty, surgical procedures of the treated lesion, and amputation. Limb salvage was defined as no requirement of major amputation, which was accepted as limb loss below or above the knee level, while minor amputation was defined as amputation at or distal to the trans-metatarsal level.

Major adverse events were assessed as death, myocardial infarction, recurrent endovascular therapy, bypass graft operation, or amputation. A major vascular complication was defined as the presence of a di-

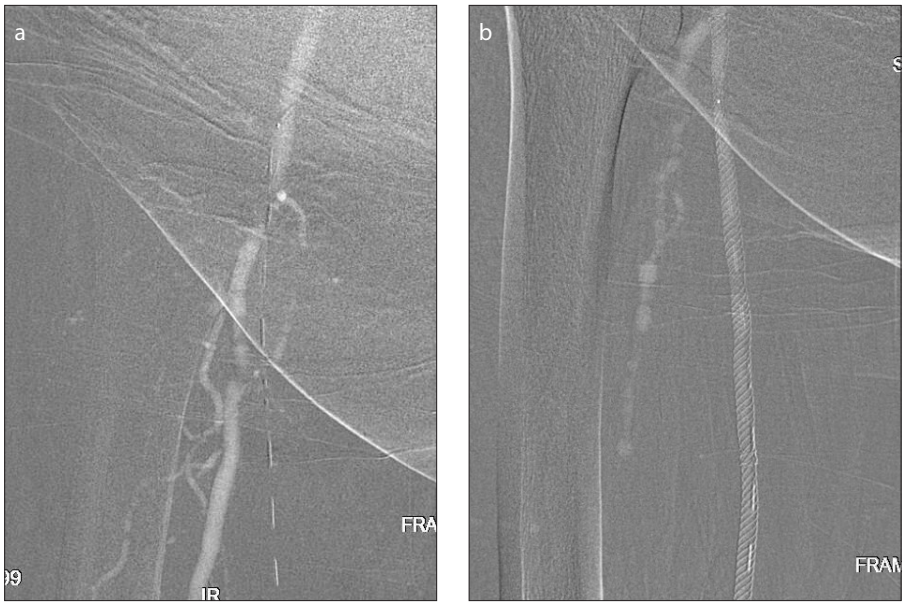

Figure 3. a, b. Carbon dioxide angiography performed with a retrograde advanced catheter showing total occlusion in SFA **(a)** and the stent placed using the PRESTO technique **(b)**.

minished or disappearing arterial pulse in the punctured or target artery, or any pseudoaneurysm or arteriovenous fistula after the procedure or during clinical follow-up. Symptomatic hematoma and bleeding requiring transfusion were defined as minor complications.

The primary endpoint was primary patency at one year after the angioplasty procedure. Secondary endpoints included complications caused by the procedure and the overall number of re-interventions.

Follow-up

After the procedure, the patients were evaluated with a physical examination (foot temperature, pulse examination) and Doppler ultrasound examination before discharge from the hospital. The patients were evaluated at the outpatient clinic at one month and 12 months after the procedure based on a clinical examination and Doppler ultrasound. We examined the clinical success, angiographic and technical data and major adverse events at one year. Late follow-up (at 18 months) was carried out by administering a telephone questionnaire to the patients or their family members.

Statistical analysis

Descriptive statistics were given as median (minimum–maximum) and mean ± standard deviation. Categorical variables were expressed as frequencies and percentages. Kaplan-Meier curves were used to estimate outcomes. MedCalc (ver. 12) was used for statistical analysis.

Results

Of the 462 cases with PAD treated during the study period, 23 (17 males) with a total of 25 occluded SFAs (bilateral in two patients) were included in the study. The average age of the patients was 66±7.3 years (range, 54–82 years). There was hypertension in 16 patients, diabetes mellitus in 14, coronary artery disease in 15, and smoking history in 16. In three patients, a retrograde intervention was applied after the failure of percutaneous antegrade recanalization, while for the remaining patients, the retrograde procedure was chosen as the first treatment method. Indications for this intervention include claudication at 200 meters or less (5 patients, Rutherford Class 3), resting pain (4 patients, Rutherford Class 4), ulcer, and pathological ischemic color changes in the finger or heel (14 patients, Rutherford Class 5-6) (Table). Two patients received femoropopliteal bypass grafts, and their native vessels were recanalized.

Technical success was achieved in all cases in which the re-route technique was used (100%). There was no major or minor amputation in any of the patients at one year. No major complication was seen in any of the patients. In 4 patients with minor complications, hematoma developed adjacent to the entrance of the pedal artery, which did not decrease arterial flow. Pseudoaneurysm was not observed in any patient. The number of major adverse events was six (five re-interventions, one bypass operation).

There were occluded segments originating from the external iliac artery in one patient (>20 cm), proximal SFA in two patients (<10 cm), distal SFA in three patients (10–20 cm), and SFA in the remaining 17 patients (>20 cm). The mean lesion length was 21.2±5.3 cm. Popliteal artery occlusions were recanalized during the retrograde procedure in three patients. The transpedal access was achieved from the posterior tibial artery in 17 legs and the anterior tibial artery in 8 legs. There were occlusions of the proximal or middle part in 8 posterior tibial arteries and 5 anterior tibial arteries. In these patients, the pedal arteries were preferred for access, and balloon angioplasty was performed during the procedure. Infrapopliteal lesions were treated to improve access to SFA lesions and increase flow. In 20 legs, stents were used for treatment after angioplasty, while balloon angioplasty was sufficient for 5 legs. In patients treated with stents, the lesions were completely covered in 11 legs and partially covered in 9 legs. The precise retrograde Supera stenting of the SFA ostium (PRESTO) technique was preferred in 4 patients (12), while a 0.035-inch over-the-wire stent delivery system (Everflex, ev3 Endovascular) was utilized in 16 legs.

While mild calcification was observed in 6 of 25 SFA regions and moderate calcification in one, there was no calcification in 18. Concerning pedal access sites, calcification was present in only three cases. In 7 legs (28%), the re-route technique was used to advance the wire to the true lumen of CFA. In three legs (12%), acute occlusion was developed at the access site after manual compression, and angioplasty was performed to maintain the pedal flow. A vascular sheath was used in two of these three patients. In two patients with diabetes mellitus and an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m^2, carbon dioxide angiography was performed due to the high risk of contrast-induced nephropathy. One of these patients was also treated using the PRESTO technique (Fig. 3).

The mean follow-up was 15.3 months (range, 12–18 months). During the follow-up, occlusion developed in 5 legs within one year. In all of these patients, the occluded segment length before the first procedure was >20 cm. Four of these patients were treated with a second inter-

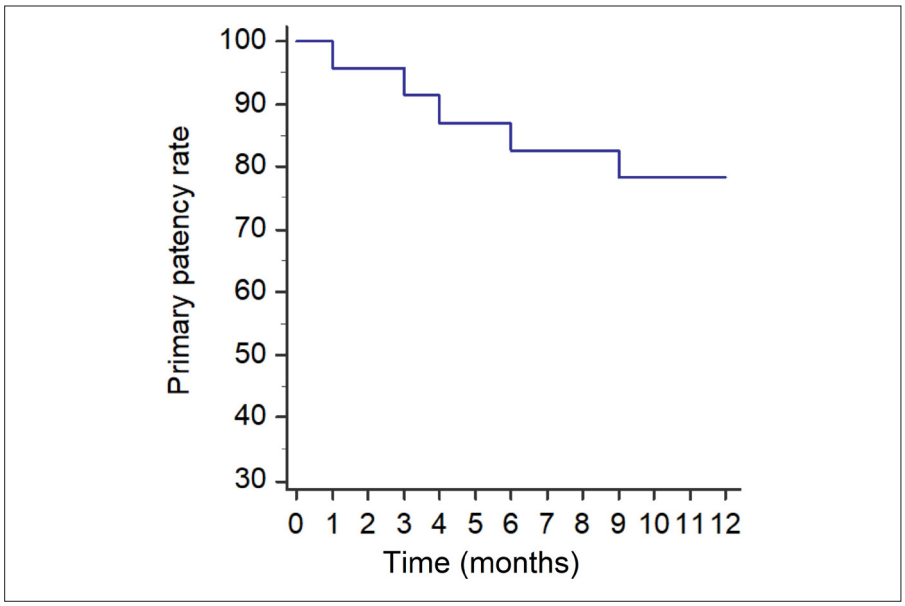

Figure 4. Kaplan-Meier primary patency rate of retrograde revascularization of the chronic total occlusions of the superficial femoral artery.

Table. Demographic data and risk factors

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Gender (F/M)	6 (26)/17 (74)
Age (years), mean±SD	66±7.3
Coronary artery disease	15 (70.5)
Hypertension	16 (70.5)
Diabetes mellitus	14 (64.7)
Smoker	16 (64.7)
Previous unsuccessful angioplasty	3 (11.7)
Rutherford category	
3	5 (21.7)
4	4 (17.4)
5-6	14 (60.9)

F/M, female/male; SD, standard deviation.

vention, but one case in which the second intervention failed also underwent bypass surgery. The median primary patency duration was 13.5 months according to the Kaplan-Meier survival analysis curve, and at the end of 12 months, the primary patency rate was 78% (Fig. 4).

Discussion

This study is important in that it primarily describes retrograde femoral artery treatment with a transpedal approach, as well as presenting a new method called re-route used when it is not possible to pass from the subintimal area to the intimal area during a retrograde intervention. In our study, the technical success of the presented technique was found to be 100%. In addition, it was shown that the transpedal approach was reliable and the rate of complications related to the intervention was low. No major vascular complication was observed; 4 patients had a hematoma adjacent to the puncture site, but it did not prevent flow.

In total SFA occlusions that do not affect the SFA ostium, ipsilateral or contralateral CFA is frequently used as a vascular access route. In cases where SFA occlusions start from the ostium or extend from CFA to the SFA ostium, contralateral CFA is preferred as the vascular access route. However, in this way, SFA catheterization can be difficult. Especially in dense calcific lesions, the guidewire cannot be directed to the origin of SFA or may progress subintimally. In the subintimal approach, re-entering the wire into the true lumen is a difficult process. In addition, regional infection in the contralateral femoral region or intense scar due to previous operation are among factors that further complicate this technique (13). In recent years, especially in cases where the antegrade procedure has failed, the retrograde treatment of SFA lesions combined with popliteal artery puncture has become increasingly common (14). However, there are some negative aspects of the retrograde popliteal approach, including the need for the patient to be placed in a prone position for the procedure, popliteal puncture being difficult to perform in obese patients, and the difficulty of controlling post-procedure bleeding at the puncture site (15).

Studies have shown the benefits of transpedal access after the failure of antegrade CTO recanalization. In a study by Amoroso et al. (16), recanalization for the CTO of SFA was performed through transpedal artery access with 100% success and no serious adverse events. Full patency was reported in all patients at the first-month follow-up. In a study by Ruzsa et al. (17), 51 patients with critical limb ischemia due to the occlusion of the vessels below the knee were treated with retrograde transpedal recanalization, and the success rate of revascularization was reported as 78.4%. In another study on this subject, Wojtasik-Bakalarz et al. (18) evaluated 17 patients after at least one failed history of percutaneous antegrade recanalization and reported the success of the procedure as 88.2%. In the same study, the mortality rate was 5.8%, primary patency was 88.2%, and secondary patency was 100% after 12 months. In the current study, there was no mortality, and at the end of 12 months, the primary patency rate was 78%.

One of the most important results of this study is that CTO including the SFA ostium was successfully treated in all patients. In a recent study by Raskin et al. (19) including 15 patients, technical success was reported to be 93%, and the limb salvage rate at one year was 83%. No complication related to the procedure was observed in any patient. In a similar study conducted with a more limited group of patients by Clark et al. (20), technical success was found to be 100%, and no complication occurred in

any patient. Patel et al. (21), who compared the transpedal and transradial methods, determined similar success rates for the two approaches. All these studies support that the transpedal approach is a successful and reliable method, which is consistent with the results in our study. However, there are also other studies in the literature reporting the success of the procedure to vary between 52% and 98% (22–24). This difference may be related to patient selection and the operator dependency of the procedure. We preferred to use the retrograde approach for obese patients, those with distal occlusion and those for whom a contralateral intervention would be difficult due to excessive iliac artery angulation. The practitioner's experience about pedal artery insertion and needle manipulation with ultrasound can affect the success of pedal insertion. In addition, pedal access site calcification can also affect the technical success. Goltz et al. (25) reported 100% technical success despite the presence of pedal access site calcification in some of the patients, as in our study. On the other hand, Mustapha et al. (26) reported that the wire was unable to be advanced due to pedal access site calcification. In our study, only three legs had pedal access site calcification, and pedal access was successful in all legs. In femoral artery treatment, longer lesions and those with a high calcification burden can decrease technical success (27). In addition, the inability to pass from the subintimal area to the intimal area reduces the technical success. According to the American guidelines, the operative success of femoral artery revascularization in PAD treatment is 75%–90% with a patency rate of 26%–80% (28).

The most important challenge in a retrograde intervention is to reach CFA by recanalizing SFA intraluminally. Since this cannot be achieved in some patients, recanalization is performed through the subintimal route. However, in such cases, the transition to the true lumen may not always be possible (14, 29). There are re-entry catheters for transition to the true lumen (30, 31). Unfortunately, in Turkey, these catheters are not available due to difficulties in reimbursement. Testi et al. (32) reported a case in which CFA could not be reached intraluminally. The authors described a new technique called FORLEE, in which the balloon was inflated in the subintimal area and puncture from CFA to this balloon was targeted percutaneously. However, inflating the balloon in the subintimal area can be very painful, and this method was only applied in one patient. In the current study, there were 7 cases in which the wire-catheter reached the SFA origin level subintimally but could not be advanced to the true lumen of CFA, and in these patients, the re-route technique provided successful results.

The high technical success of the re-route procedure indicates that transpedal access can be an important alternative in patients for whom antegrade procedures from the contralateral leg may not be successful. After the procedure, following the manual compression of the transpedal artery, three legs were found to have severe stenosis or occlusion, which is considered as the most important problem of transpedal access. In these cases, we performed angioplasty to the related artery through the antegrade route before the patients were taken off the angiography table, and full patency was achieved in the pedal artery. In a study conducted by Zachariah et al. (33), 12 patients underwent the transpedal procedure, and there was no problem in the pedal artery after the procedure. In that study, VasoStat ™ (Forge Medical) or TR Band ™ (Terumo Corporation) was used to achieve hemostasis. Using these products instead of manual compression can be effective in preventing access site occlusion, since they provide a more controlled compression. However, comparative studies with a larger patient population are needed to confirm this result.

In our study, the PRESTO technique was successfully applied in 4 patients. In this technique applied using the Supera stent, predilatation was performed with sequential balloon angioplasty to position the stent correctly and open it properly. The Supera stent was then placed precisely starting at the SFA origin level, and post-dilatation balloon angioplasty was performed (12). Due to the high radial force of the Supera stent and the less fragile structure of the stent, this approach provides advantages, especially in calcific long-segment chronic total occlusions. In addition, in the literature, first-year and 24-month patency rates have been shown to be high (34, 35).

In this study, carbon dioxide was used as a contrast agent in two patients. It is known that the risk of contrast nephropathy is high in patients with a low eGFR. Carbon dioxide angiography, which does not cause contrast-induced nephropathy and can be applied easily in these patients, has recently been preferred (36, 37). Carbon dioxide can also be used as a contrast agent in retrograde therapy. In one patient, we successfully applied carbon dioxide angiography and the PRESTO technique together.

There were some limitations to our study. First, it had a retrospective nature, and second, it had a relatively small sample size. There is a need for further large-scale studies in this area. In addition, due to the retrospective design of the study, the long-term follow-up data of some patients could not be obtained since they were not available for a telephone survey. This may have created a major bias for technical and clinical success outcomes.

In conclusion, the retrograde transpedal approach is a safe and successful technique for CTO recanalization and carries a low risk of complications. In order to increase the technical success, the re-route technique can also be used as an alternative to other re-entry techniques or catheters described in the literature.

Conflict of interest disclosure

The authors declared no conflicts of interest.

ESM 1. A video showing the 0.018-inch wire being advanced from the newly created route to the actual lumen using a support catheter under fluoroscopy guidance.

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