

# Alternative Subintimal Recanalization Technique Using Fluoroscopy-Guided Direct Puncture at the Level of the Common Femoral Artery

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## Abstract

**Objective:** To present a clinical case of subintimal angioplasty of the popliteal femoral territory using an alternative technique of re-entry into the lumen after failure with traditional re-entry methods.

**Material and Methods:** This case involves a patient with a history of infrapopliteal femoro-popliteal bypass with a previous inverted internal saphenous vein by-pass (2021), admitted for angioplasty to maintain primary patency assisted by a stenosis in it, but showing total occlusion of the by-pass during intraoperative arteriography. Due to the intense symptoms, with risk of limb loss, endovascular femoral recanalization was performed, without success in performing intraluminal recanalization by antegrade and retrograde routes. Subintimal recanalization was performed, using an alternative salvage technique to allow re-entry into the true lumen, described in this article.

**Results:** Retrograde subintimal recanalization was performed with intraluminal re-entry into the proximal superficial femoral artery via fluoroscopy-guided puncture in an intraluminal balloon implanted in a retrograde direction, with implantation of 3 stents. No residual femoropopliteal stenosis was observed, with good inflow and outflow.

**Conclusion:** The subintimal recanalization technique in itself is already a salvage technique, and with the aid of fluoroscopy-guided intraluminal balloon puncture by distal retrograde puncture, we were able to break through the dissection flap and re-enter the lumen proximally, enabling dilation and implantation of subintimal stents with technical success.

## 1. Introduction

With the increase in the average age of the world's population, there has been an increase in the number of people with PAD (peripheral arterial disease) of the lower limbs, which is considered to be the leading cause of lower limb amputation in developed countries [1]. Symptomatic disease is twice as common in men as in women, possibly due to greater muscle mass and activity levels, but when looking at population studies using ABI screening, no difference is observed between the sexes. Asymptomatic chronic limb ischemia (CLI) accounts for more than 50% of cases and BMT (Best Medical Treatment) should be prioritized. In symptomatic patients, 70% present with intermittent claudication. Patients with peripheral arterial obstructive disease at the level of the femoral popliteal territory commonly have heavily calcified lesions related to the chronic atherosclerosis process. Chronic limb-threatening ischemia (CLTI) is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration [2].

Endovascular techniques and materials have evolved, and materials such as bare metal stents made from nitinol, drug-eluting stents (DES), covered stents, drug-coated balloons (DCB) and novel stents specifically to superficial femoral artery like supra® have emerged with the aim of improving long-term patency outcomes following angioplasty of the femoral and popliteal arteries. Today, we treat patients in categories TASK A to D, because in many of these patients, due to their age and comorbidities, as well as technical aspects such as the lack of veins to bypass, endovascular revascularizations are successful in increasingly challenging lesions [3]. Peripheral obstructive artery disease (POAD) affected more than 200 million people worldwide in 2010, and data shows that the trend is increasing, partly due to the ageing of the population. (ref) Epidemiological studies show variations of between 3% and 10%, increasing from 15% to 20% in people over 70 [4, 5].

Diagnosis begins with an assessment of the patient's history and physical examination, noting previous myocardial infarctions, ischemic stroke, history of smoking, and observing

arterial pulses [2]. The prevalence of comorbid coronary and cerebrovascular disease in the PAD population exceeds 50% [6]. ABI(Ankle brachial index) is used as a primary screening test, along with Doppler ultrasound. In some cases, angiotomography or magnetic resonance angiography is used. Arteriography is the gold standard, but because it is invasive, it is now used in the perioperative period. The risk factors for POAD are smoking, DM, hypertension, cardiovascular disease and age, and chronic kidney disease is a risk factor for amputation in POAD, especially if associated with DM. O'Hare et al. showed that patients with moderate to severe chronic kidney disease are more likely to develop PAD [7]. The ABI is considered a primary screening tool, along with the patient's complaints and physical examination.

In the ABI's assessment, we have:

1 - 1.4 - normal

0.9 to 0.99 - borderline

< 0.9 - obstructive disease

>1.4 - severe parietal calcification

You can also subanalyze the ABI values as:

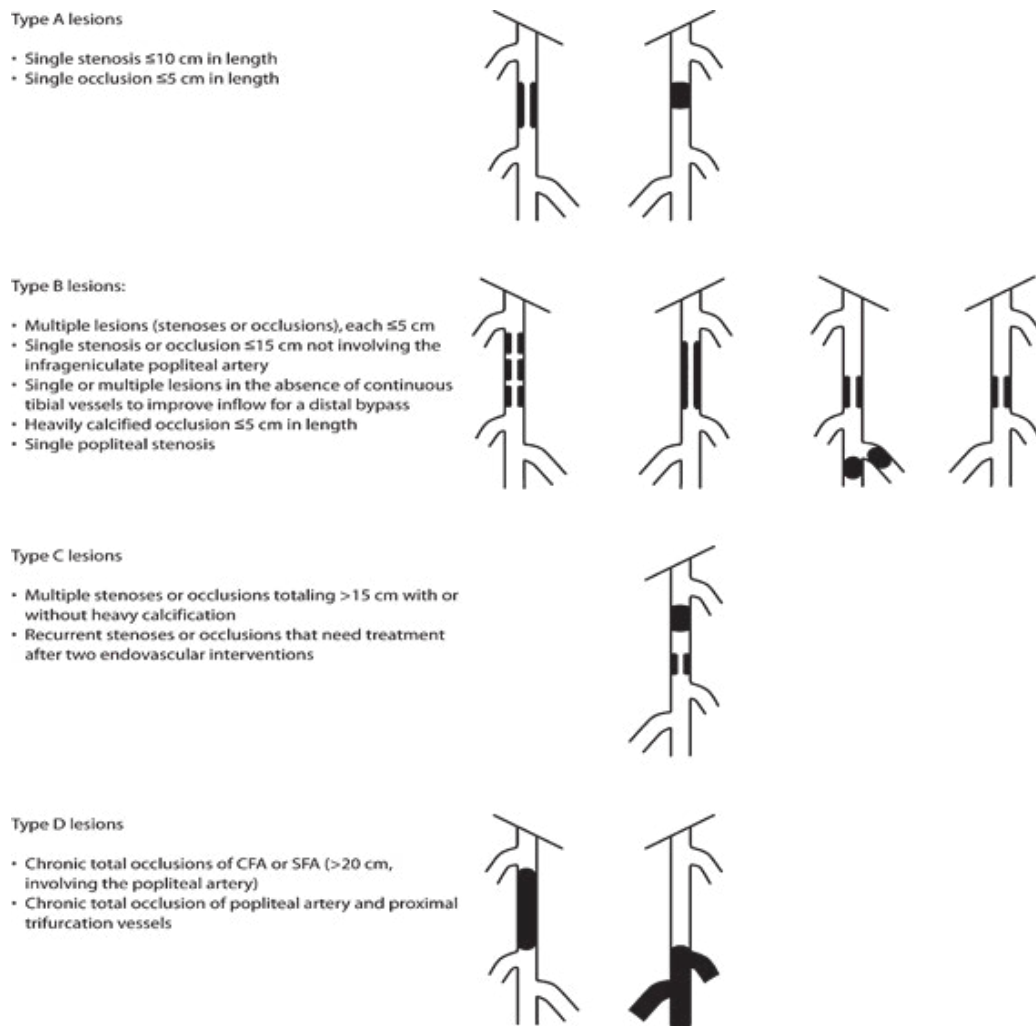
Normal 1.11 +/- 0.10

Intermittent claudication 0.6 +/- 0.15

Ischemic pain at rest 0.26 +/- 0.13

Gangrene 0.05 +/- 0.08 [8]

According to TASK 2, the concept of limb salvage after revascularization is the preservation of part or all of the foot. The attempt at a foot salvage procedure should take place after a revascularization procedure, if possible. A waiting period of at least 3 days has been suggested, which allows sufficient time for the restoration of perfusion and the demarcation of viable areas. The goals of treatment should include increasing the distance walked, especially in the case of people whose work requires them to walk long distances, improving pain, healing wounds, controlling infections and reducing the level of amputation, when this is unavoidable. Surgical treatment is generally more durable, but has a higher initial morbidity and mortality rate and should be performed on patients who preferably have a life expectancy of more than 2 years, a good venous conduit and an acceptable surgical risk [9]. TASK 2 is an anatomical classification used as a reference for therapeutic decisions. It divides the severity of lesions according to their extent and areas of involvement, suggesting the best method between endovascular or surgical revascularization for each case. Generally, in TASK A and TASK B lesions, endovascular techniques are suggested as the first choice, in TASK C lesions, endovascular or surgical techniques can be used and in TASK D lesions, surgical techniques are preferred.



**Figure 1:** Task 2 scheme for femoro-popliteal injuries

## Task 2 Recommendation 37 for Treatment of femoral popliteal lesions

**1.1. Task A and D lesions:** Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions.

**1.2. Task B and C lesions:** Endovascular treatment is the preferred treatment for type B lesions and surgery is the preferred treatment for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions

With the development of new devices for endovascular revascularization, combined with the technical refinement of the teams, better results are being obtained in lesions previously only treated by surgery. For example, we have support catheters, guide wires with heavy-duty tips for recanalization, mechanical thrombectomy catheters and new high-strength and flexible stents for reconstruction of the femoropopliteal sector [10]. In the superficial femoral artery, biomimetic stents promise better results because they better withstand the stresses to which this arterial segment is subjected.

In patients with successive failures of by-pass, prosthetic or autologous grafts, endovascular revascularization may be the

second or only possible therapeutic option. The superficial femoral artery is one of the most affected by obstructive atherosclerosis. It serves as a direct conduit between the common femoral artery and the popliteal artery, carrying blood to the legs.

Failure of the infra-articular femoropopliteal bypass, especially in patients with long and complex atherosclerotic lesions, is traditionally associated with the development of critical ischemia, with a high rate of amputation<sup>1</sup>. In patients without the possibility of revascularization, the overall annual mortality rate can reach 50% [11]. The subintimal recanalization technique was first described by Bolia et al. as a way of saving ischemic limbs where the intraluminal technique could not be performed. Bolia et al. described the successful recanalization of an occluded femoral artery in a patient (index case), unintentionally passing into the subintimal space and back into the true lumen distal to the occlusion. The angioplasty balloon was inflated inside the subintimal space along the entire length of the lesion, and a good result was obtained without complications. We then moved on to intentional subintimal passage for the treatment of long occlusions of the femoral and popliteal arteries. In the index case and all subsequent patients, 7F catheters and 0.035-inch guidewires were used. Details of the technique and its results in 71 occlusions of the femoro-popliteal segment with an average length of 11.4 cm were described. Primary technical success was achieved in 54 (76%) cases, with complications occurring in 4 (5.6%).

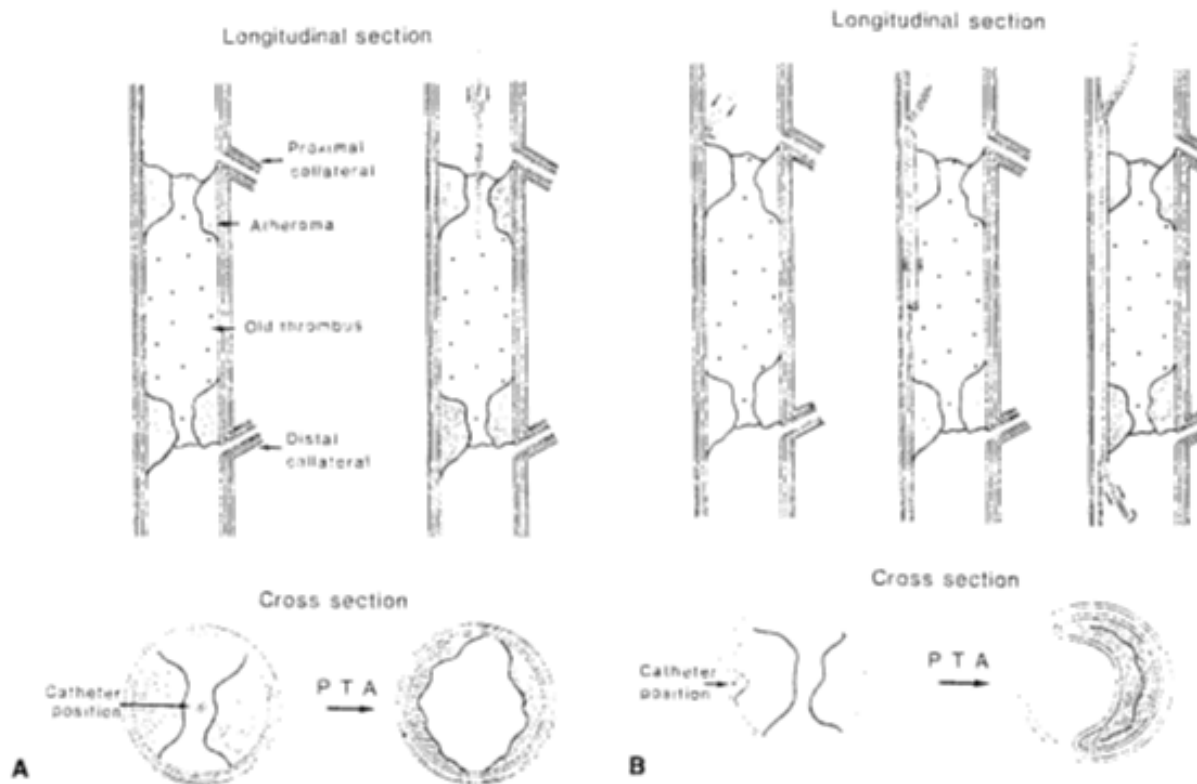


Figure 3: From Bolia, et al.

After that, Bolia, et al. described their results in 71 patients with femoropopliteal occlusion by intentionally entering the subintimal space with a guide wire from an antegrade approach, creating a loop in the lead portion of the guide wire and advancing the guidewire distally in the subintimal space until it reentered the true lumen beyond the occlusion [1]. The technical success rate was (76%), the complication rate was (5.6%), and clinical success was noted after a technically successful procedure in most (84%) patients at 6-month follow-up [12]. Despite advances in materials, there are still situations in which the intraluminal technique is not possible, and in these cases the subintimal technique is used, although re-entry into the lumen can be very difficult. Ideally, re-entry should be done soon after the end of the occlusive plaque, preferably in the popliteal region above the joint interline, and if this cannot be done conventionally, there are various materials available today for this purpose and techniques aimed at penetrating the arterial lumen. Re-entry devices should be available whenever possible to help salvage the procedure.

One way of attempting intraluminal re-entry would be retrograde popliteal puncture, with the aim of breaking the rigid cap that exists on the proximal surface, facilitating intraluminal recanalization [13]. However, even with retrograde puncture, sometimes an intraluminal path is not achieved and the subintimal space is re-entered. Another technique described is CART, where subintimal recanalization is done in antegrade and retrograde directions and two balloons are inflated simultaneously in parallel in order to break the dissection cap, allowing the guide wire to re-enter the true lumen. A variant of this is SAFARI, where a Snare is used to capture the guide intraluminally.

There is a risk of losing collaterals and damaging a possible distal bed for future by-pass when trying to progress through the subintimal space far beyond the obstruction. In this case report, we will demonstrate a way of re-entering the true lumen that used the basic materials of any angioplasty, achieving success and saving the procedure.

## 2. Case Description

The following clinical case involves a 78-year-old male patient with a history of previous lower limb ischemia, treated with a femoro-popliteal by-pass with a reverse saphenous vein in 2021, where after 6 months the pain at rest returned, even with better medical treatment.

Functional capacity around 4 METS, SAH / DM/ Left carotid stent (2021) 2018/ Post-surgery for right and left cataract.

**2.1. Taking:** Metformin 500mg one tablet a day, Losartan 50mg two tablets a day, Nebivolol 5mg one tablet a day, Lixiana 60mg per day, Rosuvastatin 10mg per day, aspirin 100mg per day, clopidogrel 75mg per day and chlorthalidone 25mg.

**2.2. ECG 07/06/21:** Atrial fibrillatory rhythm, HR: 158bpm, left bundle branch block.

Transthoracic echocardiography 18/06/21: Ao 30 LA 37 RV 23 LV 54X37 SIV 8 LVPP 8 EF 59% Mild AoI and MI.

**2.3. Carotid echo:** CE - CIE calcified plaque 60% // CD - 40% bifurcation. Vertebral - left vertebral without flow;

Task 2 type C

Assessment of the risk of amputation must take into account, in addition to the degree of ischemia, the presence of a wound and infection according to the WIFI classification, which is a system based on the presence and severity of 3 independent risk factors, W - Extent of the wound

I - Degree of ischemia

Fi- Foot Infection

Grading each from 0 to 3 [14]

This patient was at grade w1i3f0 or medium risk of amputation and the treatment took into account the pain at rest and the low ITB 3, leading to a significant drop in quality of life.

On 31/08/2023 he was seen with a trophic lesion in hallux wound 1, pain at rest, and urgent arteriography was requested. Patient Fontaine 4 rutherford 5

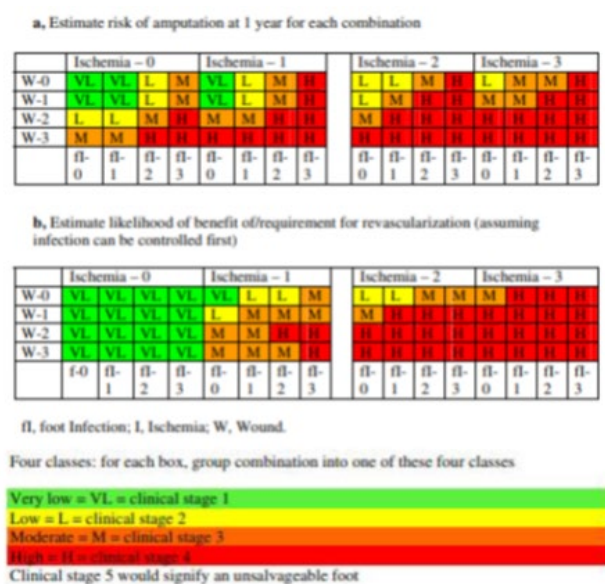


Figure 4: WIFI classification scheme

A new anatomical classification for CLI (chronic ischemia with threatened limb) aims to assess the possibility of restoring linear pulsatile flow to the area of critical ischemia, preferably aiming to revascularize the corresponding angiosome region up to the foot. The GLASS classification has incorporated two important concepts, the target arterial path (TAP) and the estimated limb patency (LBP). LBP makes it possible to compare results between revascularization strategies. Work by Bandik et al. already demonstrated the importance of a favorable flow rate for the patency of lower limb by-passes, scoring the flow rate according to the number of patent arteries below the distal anastomosis of the by-pass [15]. The ideal of all revascularization is to bring pulsatile flow to the site of the tissue lesion, according to the concept of TAP (Target arterial path), which would be the ideal way to restore direct flow to the target foot or angiosome. Angiosome-guided revascularization can be important when planning endovascular intervention for lesions in the midfoot and calcaneus, but for lesions in the forefoot, smaller lesions and ischemic pain at rest there is little advantage in looking for a specific angiosome [16, 17].

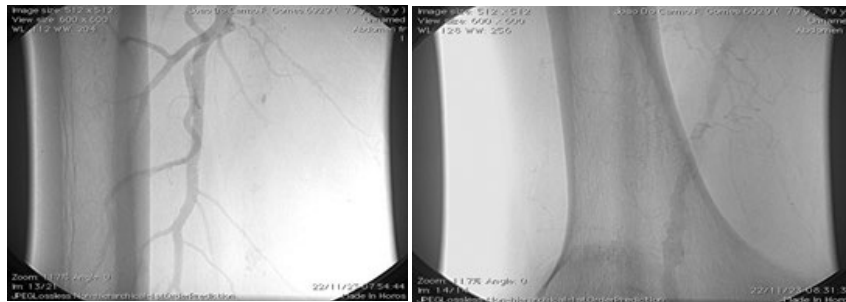
The GLASS classification individualizes lesions in the femoro-popliteal and infra-popliteal segments on a scale of 0 to 4, and is combined into 3 generic GLASS stages 1 to 3 for the limb [18].

Specific material was requested for the treatment of stenosis in a previous by-pass, according to a previous examination. Only with guide wire, introducer, contralateral sheath and angioplasty balloons. On the day of the procedure, we observed total occlusion of the by-pass and therefore opted to perform angioplasty with stent implantation.

After several attempts to bypass the lesion intraluminally by contralateral catheterization with a 6fr sheath, we observed subintimal dissection.

We used 0.035 hydrophilic stiff guide wires, an IMA catheter, Vert, and finally a 0.035 Trailblazer® support catheter.

#### 2.4. Arteriography Images of the Procedure



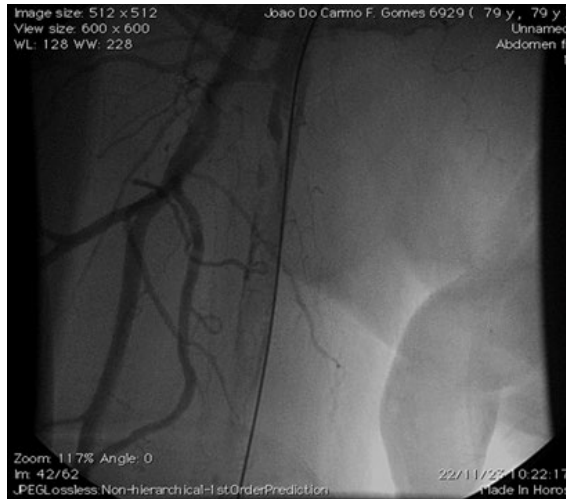
Pre-procedure arteriography showing total occlusion of the previous by-pass and occlusion at the origin of the SFA. Distal refilling of the suprapatellar popliteal artery is observed.



This arteriography shows the guidewire in an anterograde direction in the subintimal space at popliteal level, we can see the retrograde puncture of the infrapatellar popliteal aiming at retrograde intraluminal recanalization.



In this image we can see the retrograde intraluminal guide wire and the antegrade subintimal guide wire, with attempts to re-enter the true lumen. We can see balloon inflation in the proximal subintimal segment and the distal guide wire in the subintimal space, also after unsuccessful attempts at retrograde intraluminal recanalization.



In this image, recanalization has already been achieved in the antegrade direction after direct puncture with an 18g needle of the balloon located intraluminally in the retrograde direction, with purposeful rupture of the balloon and passage of the guide wire distally.



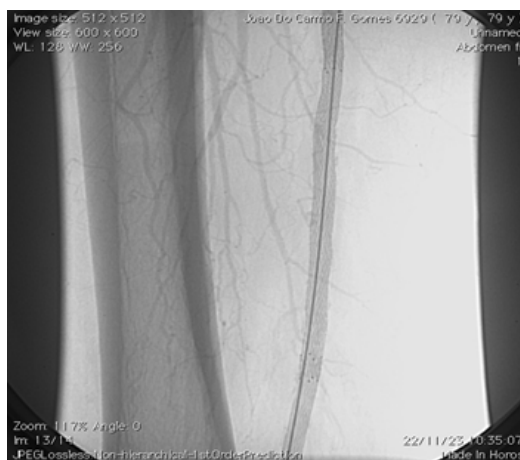
In this image we see the two guide wires, retrograde and antegrade intraluminally, then we perform the clothesline maneuver to support stent implantation by capturing the distal guide through the contralateral sheath.



Image showing post-dilation after stent implantation.

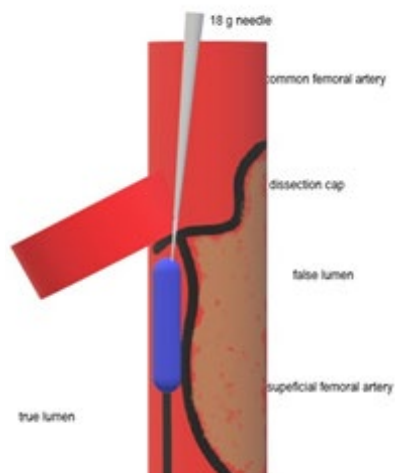


Proximal control images show stent patency with good contrast delivery.



We opted to attempt antegrade subintimal recanalization, but after several attempts with the material we had, we were unsuccessful in re-entering the true lumen. We then performed retrograde popliteal puncture by roadmapping, achieving initial entry into the true lumen, but in the proximal third of the superficial femoral artery there was again entry into the false lumen. We tried several times with balloons and catheters without success.

Finally, we opted for a rescue technique for this situation, which had not been described until then, which consisted of puncturing the balloon located just before the bifurcation with an 18-gauge needle in order to break through the dissection flap with the needle puncturing the balloon by fluoroscopy, and after puncturing the balloon, passing the guide wire antegradely now through the true lumen, and proceeding with stent implantation retrogradely using 5 and 6 mm balloons and 5 x 150 and 6 x 150 stents.



**Figure 5:** Schematic of the technique used, where we inflated a 5 x 80 balloon in the true lumen in a retrograde direction to the closest possible location to the bifurcation and punctured it under fluoroscopy using an antegrade puncture through the common femoral artery with an 18g needle.

In practically all cases of recanalization of the popliteal femoral segment, the first attempt is made by the antegrade route, either by contralateral or ipsilateral access. If the lesion cannot be overcome by the antegrade route, the popliteal retrograde route is attempted, guided by fluoroscopy, ultrasound or road mapping. The subintimal technique was first described by Bolia, et al., transforming a negative aspect of the procedure into a potential limb-saving method with reported success rates of 80-90% at 1 year. It has lower patency but can serve as a bridge to a later procedure. A potential advantage of opting for this recanalization method is the preservation of a possible distal bed for a future by-pass by avoiding excessive manipulation of the infrapatellar popliteal area, through the progression of the loop guide wire characteristic of the subintimal technique over long stretches below the occlusion area. Ideally, a re-entry catheter such as the Outback® or Fronrunner® should be used, but these materials are not always available, so this would be a rescue technique for extreme situations.

### 2.5. Comments

Acute lower limb ischemia, as presented in the TASC II (TransAtlantic Inter-Society Consensus II) guidelines, has an associated 30-day amputation rate of up to 30%. In addition, around half of patients with acute obliterating peripheral artery disease without the possibility of revascularization have a life expectancy of less than one year after the onset of critical ischemia. The ideal in any endovascular revascularization procedure is to try the intraluminal technique first, with materials in the operating room to rescue the procedure if the subintimal technique is needed, such as re-entry catheters. However, the reality in many developing countries means that such materials are not always available, and here we present a rescue technique that uses easily accessible materials used in any angioplasty.

### 3. Conclusion

The gold standard technique for revascularizing severe femoro-popliteal lesions is still by-pass with autologous grafts, but endovascular techniques with stent implantation have gained prominence, often being used as the first option. However, in many cases the lesions are long and calcified, making intraluminal recanalization impossible, so the subintimal technique can be used for limb salvage. The technique described here proved to be feasible with commonly used materials and without major technical difficulties, and can be a means of rescue in selected cases.

### Ethical Responsibilities

Protection of people and animals. The authors declare that no experiments were carried out on humans and/or animals for this research.

Confidentiality of data. The authors declare that no patient data appears in this article.

Right to privacy and written consent. The authors declare that no patient data appears in this article.

### Conflict of Interest

The authors declare no conflict of interest.

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