# Feasibility and Outcome of Endovascular Recanalization of Flush Superficial Femoral Artery Occlusions

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## ABSTARCT

*Superficial femoral artery (SFA) chronic total occlusions (CTOs), especially in the ostial location, present the greatest operator challenge. The aim of this study is to evaluate the different techniques of crossing the superficial femoral artery flush occlusion in patients with critical limb ischaemia regarding the feasibility, patency, clinical success, limb salvage rates and complications.* ***Patients and Methods:*** *This retrospective study included patients with flush SFA occlusion and having critical limb ischemia for whom endovascular revascularization was performed, between January 2013 and January 2015.* ***Result:*** *The study included 94 patients with a mean age of 63 years, and male:female ratio 70:24. Technical success was achieved in 84%. After one year primary patency was 63%, secondary patency was 67%, and limb salvage rate was 81%. Subintimal angioplasty was used in 67 cases (71%), while the intraluminal route was used in 27 cases (29%). Stents were used in 43 patients. Retrograde popliteal or pedal access was used in 11 cases.* ***Conclusion:*** *Endovascular management of flush SFA occlusion is feasible with comparable midterm outcome. Retrograde access is a well-established and safe technique when antegrade recanalization fails.*

*Keywords: Flush occlusion - superficial femoral artery - endovascular – retrograde*

## INTRODUCTION

Chronic total occlusions (CTO) of the femoropopliteal segments or infrapopliteal vessels are encountered more frequently with increasing patient longevity. Surgical revascularization has been well documented for achieving limb salvage; however, the morbidity and mortality rate in such patients can be significant. Endovascular therapy has been shown to be equivalent to surgical revascularization in achieving limb salvage with a favorable patient survival[1].

Flush occlusions of the superficial femoral artery (SFA) often preclude endovascular interventions. From a technical standpoint, the absence of an SFA stump can preclude successful wire access of the SFA. Furthermore, angioplasty at the SFA origin can risk compromising the profunda femoris artery ostium. Finally, stenting at the groin crease is not advisable because of risk of stent fracture and occlusion[2]. This study aims to evaluate the feasibility and outcome of endovascular recanalization of SFA CTOs.

## PATIENTS AND METHODS

This is a retrospective study of consecutive patients presenting with flush SFA CTOs and indicated for endovascular recanalization at the vascular departments in Kasr Alainy Hospital and the National Institute of Diabetes and Endocrinology between January 2013 and January 2015.

All patients presented with CLI, Rutherford categories (RC) 4, 5 or 6. All patients had flush SFA occlusion (no stump or stump < 3 mm). Bypass surgery was not feasible as a first choice either due to unfitness, poor distal run off, distal infection or refusal by the patient himself to undergo surgery.

patients were consented for the risks of the intervention. All treatment options were discussed. The study obtained the approval of the ethical committee of Kasr Alainy General Sugery department.

Patients' demographic data were collected including age, sex, and risk factors. The patients were evaluated by history and examination for their presentation and degree of ischemia. Arterial

imaging was obtained by duplex and/or CT angiography.

We followed a standard endovascular technique through a contralateral femoral access followed by the administration of a bolus of 5000IU of unfractionated heparin. Brachial access was used if the contralateral iliac/common femoral arteries had lesions precluding their use as an access. The occlusion was first tackled from above using a 0.035" hydrophilic wire supported by a 4F angled glide catheter. The wire negotiated the lesion intraluminally trying to find its way through one of the microchannels in the atherosclerotic fibrous cap, but if this failed it was pushed in a subintimal plane as a loop to cross the lesion. If there was failure to complete the crossing or failure of reentry to the true lumen a retrograde access (popliteal or pedal) was used to continue the procedure. After crossing, the lesions were dilated by a 4-6mm diameter balloons (according to the size of the artery, 6-12 atmospheres of pressure for a duration of 120 seconds. Self-expanding Nitinol stents were deployed if there was a flow-limiting dissection or residual stenosis >30%. If the profunda femoris ostium was found to be endangered by the dilatation of the proximal SFA, a body wire technique was used, where a second wire is parked inside the profunda to protect it during SFA dilatation (Fig.1).

**Figure 1: Body wire protecting profunda femoris artery**

Technical angiographic success was defined as having patent revascularization with less than 30% residual stenosis measured at the narrowest point of arterial lumen and no flow-limiting lesions. Immediate clinical success was considered if there was regaining of pulses, revascularization warmness, and/or disappearance of rest pain.

Patients were followed up at one, three, six, and twelve months after the procedure for palpable pulses (popliteal and pedal), clinical status, complications, and restenosis or occlusion by duplex.

Primary patency was defined as the absence of restenosis or occlusion in the treated arterial segment. Loss of primary patency is considered to have occurred with vessel occlusion, or when a 50% or greater restenosis at the previous site of angioplasty and/or stenting was noted whether or not intervention was undertaken. Secondary patency was achieved utilizing secondary procedures which involved recanalizing occluded arterial segments. Limb salvage was defined as absence of any major amputations above foot level.

**Statistical analysis:**

Results were expressed as means ± standard deviation of the means or number (%). Comparison between different parameters was performed using unpaired t-test. Comparison between categorical data was performed using Chi square test. Statistical Package for Social Sciences (SPSS) computer program (version 19 windows) was used for data analysis. P value ≤ 0.05 was considered significant.

## RESULTS

During the study time 732 patients were managed in both study centers for infrainguinal PAD. Of these 94 patients fulfilled the inclusion criteria and were enrolled in the study. There were 70 males and 24 females with a mean age of 63.1 ± 7.60 years. Distribution of risk factors showed that diabetes mellitus (77%) and hypertension (79%) are the most common risk factors. This is followed by smoking (60%) and coronary artery disease (48%), end stage renal disease (ESRD) 8.5% , and finally hyperlipidaemia which represents 6.3%. Cerebrovascular events were present in 12% of patients. Table 1 shows patients' data.

**Table 1:** Demographic data and risk factors

| | ***Number (%)*** |
|---|---|
| Males | 70 (74%) |
| Females | 24 (26%) |
| Diabetes mellitus | 72 (77%) |
| Hypertension | 74 (79%) |
| Smoking | 56 (60%) |
| Hyperlipidaemia | 6 (6.3%) |
| ESRD | 8 (8.5%) |
| coronary artery disease | 45 (48%) |
| Cerebrovascular events | 11 (12%) |

The main clinical presentation was minor tissue loss in 40 patients, followed by major tissue loss in 36 patients, then ischaemic rest pain in 18 patients. The angiographic data showed that 49 cases had flush SFA occlusion only (52%), 40 cases had additional tibial disease (43%), 2 cases had additional popliteal disease (2%), and 3 cases had additional iliac disease (3%) (Fig.2).

The majority of patients had TASC D lesions (n=88; 94%). The extensive nature of the disease mandated the use of multidetector CT angiography in addition to duplex in 35 patients (37%).

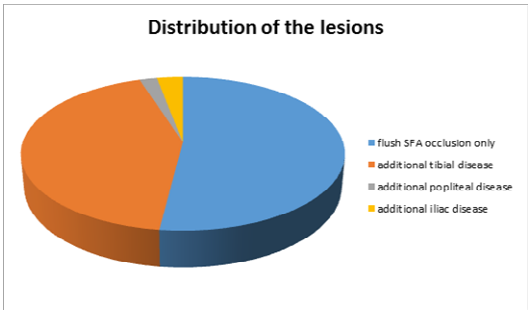


**Figure 2: Distribution of the lesions**

The contralateral femoral (crossover) approach was the only approach used in 79 cases (84%). Contralateral femoral and popliteal approach was used in 10 cases (11%). Contralateral femoral and posterior tibial approach was used in one case. A brachial access was used in one case and an ipsilateral femoral approach was used in 3 patients. One case was as part of a hybrid procedure at which the patient had an 80% common femoral artery stenosis. Under local anaesthesia open femoral endartrectomy was performed and then a short femoral sheath was inserted and angioplasty of the SFA done. In the other two cases a high antegrade femoral access was used.

Subintimal recanalization was the main technique used (Fig.3) ; 67 out of the 94 cases (71%), while the intraluminal route was used in the remaining 27 cases (29%). Self expandable Nitinol stents 6mm in diameter were deployed in 43 patients. Technical success was achieved in 79 patients (84%); and 15 patients (16%) showed primary failure. These failures were managed by a femoro-popliteal bypass (n=8), above knee amputation (n=6), and conservative treatment (n=1). Only two of the cases converted to open surgery were associated with limb salvage. The case managed conservatively was also amputated after 6 months of treatment.

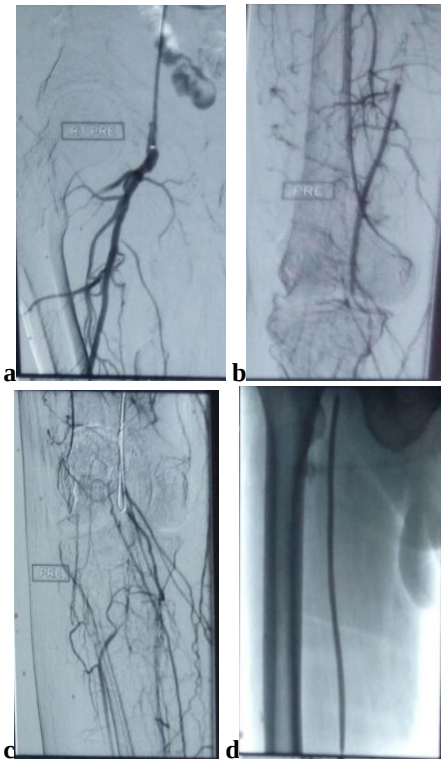

**Figure 3: Subintimal Recanalization of SFA**

After exclusion of the 15 cases of primary failure the primary patency at 12 months was 63% (50 patients). Three patients had occluded vessels and were recanalized in secondary procedures raising the secondary patency to 67% (53 patients) at 12 months. Limb salvage at 12 months was achieved in of patients in 81% of patients (n=64).

The following complications were reported: Vessel perforation by the wire occurred in 3 cases (5.9%) which were managed by 3 minutes balloon inflation to seal the perforation. Arterial wall dissection occured in 32 patients and was managed by prolonged balloon inflation or stenting. One case (2%) was complicated by a femoral artery psudoaneurysm at the puncture site that was later repaired.

Subanalysis of the outcome of patients who were managed through the intraluminal versus subintimal passage route revealed a slight better outcome following subintimal angioplasty but this didn't reach statistical significance (Table 2 ).

**Table 2:** Comparison of 1ry patency, 2ry patency and limb salvage after 12 months following subintimal and intraluminal passage

| | ***1ry patency P=.567*** | ***2ry patency P=.440*** | ***Limb salvage P=.315*** |
|---|---|---|---|
| subintimal | 63% | 69% | 83% |
| intraluminal | 64% | 64% | 76% |

Comparison of the outcome of stented and non-stented patients showed few minor differences (Table 3) which were not statistically significant.

**Table 3:** Comparison of 1ry patency, 2ry patency and limb salvage after 12 months following stenting versus no stenting

| | ***1ry patency P=.583*** | ***2ry patency P=.499*** | ***Limb salvage P=.434*** |
|---|---|---|---|
| Stented patients | 63% | 66% | 83% |
| Patients with no stents | 63% | 68% | 79% |

Sub analysis of the patients according to the direction or recanalization (antegrade versus retrograde popliteal) revealed that all patients who were successfully managed through a retrograde popliteal approach remained patent and amputation-free till the end of the 12 months. Though this is a better outcome than patients managed through the femoral access, the results did not reach statistical significance.

**Figure 4: Retrograde popliteal access used to recanalize the SFA**

**Table 4:** Comparison of 1ry patency, 2ry patency and limb salvage after 12 months following antegrade versus retrograde recanalization

| | ***1ry patency P=.209*** | ***2ry patency P=.293*** | ***Limb salvage P=.105*** |
|---|---|---|---|
| Antegrade recanalization | 61% | 65% | 78% |
| Retrograde recanalization | 80% | 80% | 100% |

## DISCUSSION

Endovascular management of lower extremity peripheral arterial disease (PAD) is rapidly gaining popularity and acceptance. Goodney et al reported that endovascular interventions for PAD more than tripled between 1996 and 2006, whereas surgical bypasses for the same period decreased by 42%, suggesting that endovascular therapies are not only replacing surgery for many patients with PAD, but are also expanding the total number of patients with PAD who undergo intervention[1]. Improved vascular imaging techniques, expanding skill level of many endovascular specialists across multiple disciplines, and dissemination of these skills, have contributed significantly to this shift in treatment strategy[3].

This rapid shift in clinical practice is presumably not related to a change in the patterns or natural history of arterial disease in the lower extremities. Rather, it appears to be due to the continued evolution of technology available for the endovascular treatment of PAD, including sheaths, catheters, wires, re-entry devices, balloons, stents, drug-device combinations, and debulking tools[3].

The most famous randomized trial, published in 2005, comparing infrainguinal saphenous vein bypass to the above-knee or below-knee segment with PTA (BASIL trial) found that endovascular therapy equaled the results with surgery based on amputation-free survival at 6 months. Endovascular therapy was a less morbid procedure with equivalent quality of life outcomes and was significantly less costly than surgery[4]. It should be noted at the time the BASIL trial was performed, the angioplasty group did not include stents or other adjunctive procedures; as such, the primary comparison between surgery and angioplasty may not reflect modern endovascular strategies.

In a meta-analysis of observational studies, reviewing the literature from 1995 to 2012, no differences were found between endovascular and open surgical revascularization regarding all-cause mortality, amputation, or amputation-free survival at 2 years[5].

Flush occlusion of the SFA origin was usually considered a contraindication to endovascular intervention[6]. This study was performed to evaluate the feasibility and outcome of endovascular management of flush SFA occlusions as regarding technical success, patency rate and limb salvage rates, and it proved that flush SFA occlusions can be successfully managed by endovascular techniques with satisfactory outcome.

To the best of our knowledge no large series in the literature reported the outcome in flush SFA lesions. So, we could only compare our results with studies of SFA CTOs or small series describing a certain technique in ostial SFA lesions. The immediate technical success was achieved in 79 (84%) cases, and was comparable to the 85.7% rate achieved by Faglia et al in a study examining the endovascular management of TASC II D femoropopliteal occlusions[7], and even comparable to the technical success rate of Antusevas et al (84%) who studied all types of SFA lesions[8]. However, the primary and secondary patency in Faglia et al are higher than ours (78.6% and 97.1% respectively)[7]. This could be explained by their lesions morphology which showed many stenoses. Their limb salvage rate (91.6%) was also higher than ours[7].

But when compared to a small series of 14 flush SFA occlusions (Hayes et al, 2011)[2], our results showed better patency rates. Antusevas et al showed similar primary patency of 43-68% at 12 months[8].

A meta-analysis comparing the outcome of open bypasses versus Endovascular intervention in any femoropopliteal lesion revealed that endovascular management in the examined studies was associated with a technical success rate of 91% (85% in randomized trials), a primary patency at 1 year of 62% , and a limb salvage rate of 88%[9].

Subintimal angioplasty (SA) was the main recanalization technique used in this study ; 67 cases (71%). But there was no significant difference in the outcome when compared to patient managed by the intraluminal route. Limb salvage was slightly higher in SA but this didn't reach statistical significance. In contrast; Antusevas et al operated upon 146 patients, where 71 were performed by SA route and 75 by the intraluminal route. The technical success rate of SA was higher than for intraluminal route (87.7% versus 81.3%). Primary patency rate in the SA group at 12 months was 68.5%, close to our rate of 63%; while in the intraluminal group it was much lower (42.7 %)[8]. Thus they concluded that SA gives better results which we could not proof in our study. In 2011 Bolia and his colleagues described the continuing experience of the subintimal technique they invented 20 years earlier. In their hands and with their experience SA was associated with a patency rate of 71% and a 100% limb salvage rate at 12 months[10].

We did not establish any differences in the outcome between stented and non stented lesions. The limb salvage rate was slightly higher in the stented group (83% versus 79% for non stented group), but this didn't reach statistical significance. So, we still recommend a policy of bailout stenting in the SFA. Primary patency rate in stented SFA lesions was 75% in Cvetanovski et al[11] and 68% in Krankenberg et al[12].

Our standard technique of management involved the contralateral femoral access in almost every case as it was convenient providing adequate room and length for the tools. on the other hand brachial access mandated the use of tools with longer shafts to be able to recanalize the whole SFA. Ispsilateral femoral access was used once as part of a hybrid procedure, and two times in the form of a high antegrade femoral access. The technique used in this case was similar to that adopted by Hayes et al[2]. An Italian study demonstrated that the antegrade ispilateral route was feasible in 43 out of 64 ostial SFA lesions. Technical success was achieved in 38/45 (84%) of their patients, but they did not mention later (follow-up) results[13].

In 11 patients we opted to the use of a retrograde popliteal or pedal access after failure of antegrade crossing. The outcome in these patients seemed to be better than patients managed in the antegrade direction but this was not statistically significant. Spreen et al managed similar lesions by a retrograde popliteal access and achieved technical success in 84% with a restenosis/occlusion rate of 50% and 0% amputation[14]. Younis et al reported the same technique in 16 patients with a primary patency of 66 ± 9%, assisted patency 81 ± 9%, and secondary patency 87 ± 8% at 2 years. Limb salvage was 100%[15]. Our results confirm the results of previous studies which recommend the use of retrograde access after failed antegrade crossing.

In our study we did not use any of the new devices known for their potential use in CTO lesions as atherectomy devices or re-entry devices, as we believe that they do not show evidence of superiority in the outcome. Literature has emerged regarding the role of primary atherectomy for femoropopliteal disease. Despite the different types of atherectomy devices (laser, directional, orbital)[16-18] there remain concerns regarding the risk of distal embolic debris and restenosis with this strategy. Publications of larger prospective multicenter trials are needed to highlight the role of atherectomy in femoropopliteal arterial disease[19]. Charalambous et al used the Frontrunner recanalization catheter and Outback reentry device for management of long SFA occlusions with an overall technical success of 88%[20], close to our rate of 84%.

In view of our results and the current literature we believe that endovascular management of flush SFA lesions is feasible and safe. In practical terms, although the level of evidence is low, the initial revascularization strategy for femoropopliteal disease is commonly an endovascular approach. Depending on numerous factors, namely lesion complexity, availability of autologous conduit, patient condition, and center

experience, hybrid procedures may reduce the surgical trauma, while bypass surgery is commonly reserved for complex, extensive lesions, provided that the patient's health status suggests 2-year survival[3]. This is supported by the meta-analysis of Antoniou et al addressing endovascular versus surgical revascularization for femoropopliteal disease. In this analysis, only 10 published randomized controlled trials (RCT)s were included, with only one considered high quality. Accepting these limitations, an endovascular-first strategy was suggested by the authors, particularly for those patients with limited life expectancy[9].

An update on TASC II reported in 2015 that except for the BASIL trial, there is an absence of adequate data comparing surgical to endovascular strategies for key outcomes, such as limb viability, wound healing, quality of life, survival, and costs in patients with CLI[3]. The available evidence for treatment of patients with CLI is limited by few RCTs that provide direct comparisons of revascularization treatment options. There is apparently no significant differences in mortality or limb outcomes between endovascular and surgical revascularization in CLI patients. However, these data are derived from very few RCTs and many observational studies, and the presence of clinical heterogeneity of these results makes conclusions for clinical outcomes uncertain and highlights the need for further research[5].

Surgery could be indicated in patients with low surgical risk, good run-off in the foot, and good saphenous vein, but endovascular treatment, when easily feasible, remains the first choice for revascularization because of the known advantages (no contraindications even when an infection of the foot is present, low hard complication rate, little stress, and short hospital stay[7].

The TASC II classification provided an anatomic and morphologic description of the complexity of the lesions. But it lacks additional considerations to determine specific revascularization approaches as the hemodynamic condition in the limb, the overall health of the patient and the desired outcome, limb preservation and symptom relief in CLI, and improved limb function in all patients with PAD, which is a 'patient-limb-lesion' approach[3]. Thus the current TASC II classification cannot be used strictly to decide the choice of revascularization in the modern era.

This study is limited by the lack of long-term follow up, but it included a large number of patients with this specific morphology, derived from two high-volume centers. Moreover, patients were managed by standard wires, balloons and stents, demonstrating that centers concerned with reducing the costs of intervention can achieve good results with less budget if adequate skill and proper technique were followed.

## CONCLUSION

Endovascular management of flush SFA occlusion is feasible with comparable midterm outcome. Retrograde access is a well established technique when antegrade recanalization fails.

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