

# Long-term Results of the Combined Use of Rotational Atherectomy and Drug-Coated Balloon in Isolated Total Occlusion of the Superficial Femoral Artery

Yüzeyel Femoral Arterin İzole Total Oklüzyonunda Rotasyonel Aterektomi ve İlaç Kaplı Balon Kombine Kullanımının Uzun Dönem Sonuçları

## Abstract

**Aim:** In this study, we aimed to evaluate the long-term results of combined treatment with rotational atherectomy (RA) and drug-coated balloon (DCB) in isolated total occlusion of the superficial femoral artery (SFA).

**Materials and Methods:** The retrospective study was conducted between February 2016 and January 2018 and included a total of 23 limbs of 20 patients with isolated total occlusion of the SFA. Patient data on demographic and clinical characteristics were obtained from the hospital records. The stage of the disease was classified according to the Rutherford classification. The ankle-brachial index was measured pre- and postoperatively.

**Results:** Of the patients, 19 (95%) were male and one (5%) was female. The mean patient age was 67.40±7.50 (49–77) years. According to the preoperative Rutherford classification, there were 4 (17.40%) limbs with stage 5 disease, 8 (34.80%) limbs with stage 4 disease, and 11 (47.80%) limbs with stage 3 disease. The rates of one- and two-year freedom from target lesion revascularization were 82.61% and 69.57%, respectively.

**Discussion and Conclusion:** Our study results showed that combined treatment with RA and DCB was an effective method in SFA lesions with a high calcified plaque burden, providing high rates of primary patency and freedom from target lesion revascularization as well as low rates of complication.

**Keywords:** angioplasty; atherectomy; peripheral arterial disease

## Öz

**Amaç:** Bu çalışmada yüzeyel femoral arterin (YFA) izole total oklüzyonunda rotasyonel aterektomi (RA) ve ilaç kaplı balon (İKB) ile kombine tedavinin uzun dönem sonuçlarını değerlendirmek amaçlanmıştır.

**Gereç ve Yöntemler:** Retrospektif çalışmamız Şubat 2016–Ocak 2018 döneminde gerçekleştirildi ve izole total YFA oklüzyonu olan 20 hastanın toplam 23 uzvunu içerdi. Demografik ve klinik özelliklere dair hasta verileri hastane kayıtlarından elde edildi. Hastalığın evresi Rutherford sınıflamasına göre sınıflandırıldı. Ayak bileği–kol indeksi müdahaleden önce ve sonra ölçüldü.

**Bulgular:** Hastaların 19'u (%95) erkek, 1'i (%5) kadındı. Ortalama hasta yaşı 67,40±7,50 (49–77) yılı idi. Preoperatif Rutherford sınıflamasına göre, 4 (%17,40) uzuvda evre 5, 8 (%34,80) uzuvda evre 4, 11 (%47,80) uzuvda evre 3 hastalık mevcuttu. Bir yıllık ve iki yıllık hedef lezyon revaskülarizasyonundan kurtulma oranları sırasıyla %82,61 ve %69,57 idi.

**Tartışma ve Sonuç:** Çalışma sonuçlarımız RA ve İKB ile kombine tedavinin kalsifik plak yükü fazla olan YFA lezyonlarında gerek yüksek primer açıklık ve yüksek hedef lezyon revaskülarizasyonundan kurtulma oranları gerekse düşük komplikasyon oranları ile etkili bir yöntem olduğunu göstermektedir.

**Anahtar Sözcükler:** anjiyoplasti; aterektomi; periferik arteriyel hastalık

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## INTRODUCTION

Atherosclerotic peripheral vascular disease is a chronic, progressive disease associated with a high burden on the healthcare system (1). Currently, the main treatment options include surgical and endovascular procedures. Endovascular treatment has been shown to be associated with an increased risk of dissection and need for stenting during balloon angioplasty in lesions with a high calcific burden (2). In such cases, atherectomy reduces the calcified plaque burden, thereby decreasing the need for stenting with a lower dissection risk (3). In addition, the decrease in the calcific burden through atherectomy before drug-coated balloon (DCB) use enables a higher penetration of the drug into the vessel wall (4).

The literature contains a limited number of studies investigating the long-term results of combined treatment with atherectomy and DCB. Accordingly, the present study aimed to evaluate the long-term results of combined use of these two procedures in the treatment of isolated total occlusion of the superficial femoral artery (SFA, <25 cm).

## MATERIALS AND METHODS

### Study design and study population

The single-center retrospective study was conducted at the Department of Cardiovascular Surgery of the Istanbul Medeniyet University Goztepe Education and Research Hospital between February 2016 and January 2018. A total of 168 patients who underwent endovascular peripheral intervention due to critical lower limb ischemia or claudication limiting daily living activities were screened. From this population, 42 limbs of 36 patients with occlusion or stenosis of the SFA were treated with combined rotational atherectomy (RA) and DCB. We excluded patients with missing postoperative follow-up records (n=4), those undergoing stent implantation due to flow-limiting dissection (n=4), those who underwent prior endovascular or surgical treatment for SFA lesions (n=3), those without partial occlusion (n=4) or in whom intraluminal passing failed (n=2), and those with severe distal peripheral artery disease (n=2). Finally, a total of 23 limbs of 20 patients with isolated total occlusion of the SFA were included in the study. Patient data on demo-

graphic and clinical characteristics were obtained from the hospital records. The stage of the disease was classified according to the Rutherford classification, and the ankle-brachial index (ABI) was measured before and after the intervention in the outpatient setting.

### Study ethics

Written informed consent was obtained from each patient. The study protocol was approved by the Ethics Committee of the Istanbul Medeniyet University Goztepe Education and Research Hospital (24.6.2020-0409). The study was conducted in accordance with the principles of the Declaration of Helsinki.

### Operative technique

The standard antithrombotic regimen before the procedures consisted of acetylsalicylic acid and  $\geq 5$  days of clopidogrel use. Patients who were not on clopidogrel received a loading dose of 300 mg before the procedure. Postprocedurally, all patients were prescribed 6 months of clopidogrel treatment and lifelong use of aspirin.

The patients were hydrated preoperatively. All procedures were performed percutaneously and under local anesthesia. Arterial puncture was carried out using a 7-Fr short sheath through the contralateral femoral artery and a 7-Fr long sheath was then introduced. Initially, 70 to 100 IU/kg heparin was given to keep an activated clotting time (ACT) of >250 sec and additional doses were given afterwards. Following diagnostic imaging studies, the lesion was passed through a 0.018" or 0.035" guidewire and a 0.014" guidewire was then used. When atherectomy device was unable to be advanced through the lesion, low-profile balloon angioplasty was performed before atherectomy. All recanalizations were performed using the intraluminal technique. In all lesions, lumen patency was achieved through RA (JetStream™, Boston Scientific Inc., MA, USA). Following RA, plain balloon angioplasty was performed at 12 to 18 atm for 60 sec. The DCB was applied in patients with <30% stenosis as evidenced by postoperative imaging studies (8 to 12 atm, 180 sec). Control imaging studies were carried out. The long sheath was replaced with the short sheath. The sheath was removed 4 hours after the intervention. Manual compression was applied to the entry site.

**Table 1.** Demographic and clinical characteristics of the 20 patients

Preoperative	n	%	Mean±SD	Min.–max.
Total number of limbs	23	100	-	-
Patient age (years)	-	-	67.40±7.50	49–77
Sex	-	-	-	-
Male limbs	22	95.60	-	-
Female limbs	1	4.40	-	-
Diabetes mellitus	12	52.20	-	-
Hypertension	19	82.70	-	-
Hyperlipidemia	2	8.70	-	-
Coronary artery disease	10	43.50	-	-
Renal dysfunction (GFR<30 ml/min)	5	21.70	-	-
Dialysis	2	8.70	-	-
Smoking	-	-	-	-
Current	9	39.10	-	-
Previous	11	47.80	-	-
Rutherford category	-	-	-	-
(3) Severe claudication	11	47.80	-	-
(4) Rest pain	8	34.80	-	-
(5) Minor ischemic ulceration	4	17.40	-	-
Lesion length (cm)	-	-	17.70±6.90	5–25

GFR: glomerular filtration rate; max.: maximum; min.: minimum; SD: standard deviation

**Table 2.** Preoperative and postoperative ankle-brachial index

	Mean±SD	Min.–max.
Preoperative (total number of limbs=23)	0.65±0.16	0.40–0.90
1. month (total number of limbs=23)	1.03±0.09	0.90–1.20
1. year (total number of limbs=19)	0.99±0.07	0.90–1.10
2. year (total number of limbs=16)	0.98±0.06	0.90–1.10

max.: maximum; min.: minimum; SD: standard deviation

Follow-ups were scheduled for 30 days and 6, 12 and 24 months after the operations. Arterial color Doppler ultrasonography was planned for the patients with reduced ABI and worsening disease according to the Rutherford classification.

### Statistical analysis

All statistical analyses were performed using the SSPS (v. 23.0) software (SPSS, Chicago, IL). Categorical variables were presented as counts and frequencies while continuous variables were expressed in mean±standard deviation or median (interquartile range). Event-free survival curves were shown with Kaplan-Meier graphs and life-tables. Changes in the patient Rutherford class were presented with a box-plot chart. p<0.05 was considered statistically significant.

## RESULTS

A total of 23 limbs of 20 patients with isolated total occlusion of the SFA were included in the study. In three patients, both limbs were treated with RA and DCB with one-month interval. Of the patients, 19 (95%) were male and one (5%) was female. The mean patient age was 67.40±7.50 (range: 49–77) years. According to the preoperative Rutherford classification, there were 4 (17.40%) limbs with stage 5 disease, 8 (34.80%) limbs with stage 4 disease, and 11 (47.80%) limbs with stage 3 disease.

The success rate of the procedure (<30% stenosis postoperatively) was 100%. None of the patients had procedure-related bleeding, entry site infection, or pseudoaneurysm. The mean length of treated lesions was 17.70±6.90 (5–25) cm. Symptoms were relieved in the early postoperative period in all patients.

The mean follow-up was 19.78±7.17 (2–24) months. Four patients (17.30%) at one year and three patients (13%) at two years of follow-up developed an increasing number of complaints and underwent ultrasonography and conventional angiography, which

revealed stenosis or occlusion requiring intervention to the target lesion (>70% stenosis). Both limbs were treated in two of these patients at different time points. Endovascular treatment was re-administered in five of the seven patients, while the remaining two underwent femoropopliteal bypass grafting.

During the follow-up period, one patient (4.30%) underwent amputation and two patients (8.60%) underwent minor amputation to accelerate the wound healing. All three of these patients had restenosis. No major complications were observed in any of the patients.

The one- and two-year rates of freedom from target lesion revascularization (fTLR) were 82.61% and 69.57%, respectively (Figure 1). The ABI and disease stage data were excluded from the analysis in patients who required target lesion revascularization (TLR). The patient clinical scores based on the Rutherford classification during the postoperative follow-up visits were recorded (Figure 2). Accordingly, the mean preoperative ABI was  $0.65 \pm 0.16$  (range: 0.40–0.90) while the mean postoperative ABI was  $0.99 \pm 0.07$  (0.90–1.10) at one year and  $0.98 \pm 0.06$  (0.90–1.10) at two years (Table 2).

**DISCUSSION AND CONCLUSION**

In the present study, our results showed that the combined use of RA and DCB was a feasible approach with a high success rate and low TLR rate in the treatment of isolated total occlusion of the SFA.

Owing to its favorable properties, including reduced proliferation in the vessel wall and acceptable patency rates, DCB has become widely used in recent years. Several studies have demonstrated that DCB increases the primary patency rate and decreases the TLR rate in the treatment of femoropopliteal artery disease (5,6). In the Drug-Coated Balloon versus Standard Percutaneous Transluminal Angioplasty for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease trial (IN.PACT SFA), DCB treatment without atherectomy and plain balloon angioplasty were compared (5). In this study, the primary patency rates were 82.20% and 52.40% in the DCB arm and the plain balloon angioplasty arm, respectively ( $p < 0.001$ ). In the Trial of a Paclitaxel-Coated Balloon

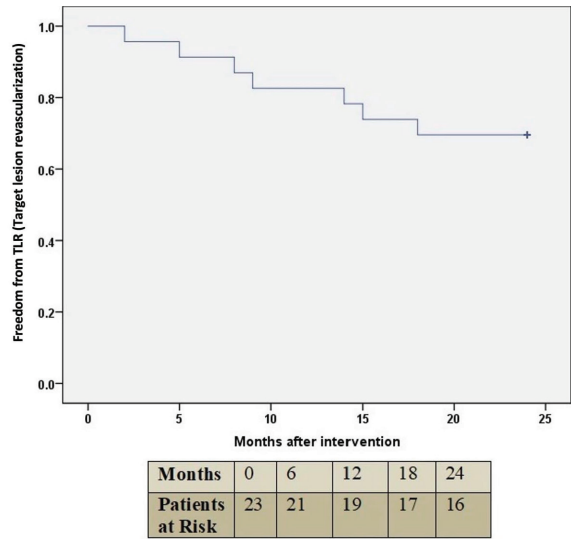


Figure 1. Freedom from target lesion revascularization during follow-up

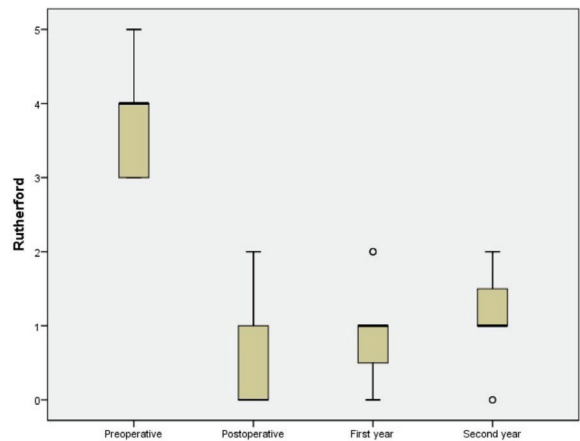


Figure 2. Patient postoperative clinical scores based on the Rutherford classification

for Femoropopliteal Artery Disease (LEVANT II), the primary patency rates were 65.20% and 52.60% in the DCB arm and plain balloon angioplasty arm, respectively ( $p = 0.02$ ) (6). However, in the presence of lesions with a high calcific burden and long lesions or chronic total occlusion, DCB angioplasty increases the dissection and rescue stenting rates (7,8). In addition, some authors have stated that severe calcification in the vessel wall decreases the absorption of paclitaxel, leading to poor DCB results (9,10). In their study, Fanelli et al. (10) reported that the high calcium burden in the SFA was significantly associated with a higher late lumen loss rate and a lower patency rate in patients undergoing DCB treatment. Similarly, Tepe et al. (9) found that

severe calcification was associated with a higher late lumen loss rate in patients treated with DCB at the end of the follow-up.

The utilization of atherectomy prepares the vessel wall for balloon angioplasty and, thus, reduces the calcific burden in patients with a high calcified plaque burden. As a result, the rates of dissection and rescue stenting decrease during balloon angioplasty (11). In a preclinical study, Tzafirri et al. (12) investigated the effects of atherectomy on radiolabeled paclitaxel delivery in cadaveric human peripheral arteries with substantial calcified plaque. In the atherectomy-treated segments, the mean paclitaxel concentration increased by 50%, compared to the non-treated segments. This finding was also supported by further studies showing higher patency rates in patients treated with atherectomy, followed by DCB (10,13–15). Furthermore, in the Directional Atherectomy Followed by a Paclitaxel-coated Balloon to Inhibit Restenosis and Maintain Vessel Patency study, the early procedural success rate was found to be higher in the atherectomy+DCB arm, compared to the DCB use alone (89.60% vs. 64.20%, respectively;  $p=0.004$ ) (10). In addition, the rate of dissection was significantly higher in the DCB alone group (19% vs. 2%, respectively;  $p=0.01$ ). In another study, Cioppa et al. (13) reported that one-year patency and fTLR rates were respectively 90% and 90% in patients with calcified femoropopliteal artery disease treated with combined DCB and atherectomy. In addition, Aydin (14) assessed the results of the combined use of atherectomy and DCB in femoropopliteal artery disease. Thirty-nine patients received additional DCB and six patients underwent stenting due to dissection after atherectomy. The one-year fTLR rate was 86.70%. In another study including 75 patients with femoropopliteal lesions, Shammas et al. (15) compared DCB and plain balloon angioplasty following atherectomy, and observed a significantly higher ABI during one-year follow-up in patients undergoing adjunctive DCB (1.10 vs. 0.80, respectively;  $p=0.013$ ). Furthermore, the fTLR rate was higher in the patients with *de novo* lesions and all patients undergoing combined treatment with atherectomy and DCB, compared to that with atherectomy with adjunctive plain balloon angioplasty. Similarly, in our study the mean postoperative ABI was  $0.99\pm 0.07$  at one year and  $0.98\pm 0.06$  at two

years. The one- and two-year fTLR rates were 82.61% and 69.57%, respectively, which is consistent with the previous findings.

Finally, it should be noted that our study has several limitations, the main of which is its single-center, retrospective design with a small sample size. Accordingly, further large-scale, prospective, randomized studies are needed to confirm our findings. In conclusion, our study results indicate that the combined use of RA and DCB is an effective method with high rates of primary patency and fTLR and low rates of complication in the treatment of SFA lesions, particularly those with a high calcified plaque burden.

### Conflict-of-Interest and Financial Disclosure

The authors declare that they have no conflict of interest to disclose. The authors also declare that they did not receive any financial support for the study.

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