Original Article

Percutaneous mechanical atherothrombectomy using the Rotarex®S device in peripheral artery in-stent restenosis or occlusion: a French retrospective multicenter study on 128 patients

Romaric Loffroy[1], Nizam Edriss[2], Gilles Goyault[3], Alain Chabanier[4], Jean-Marc Pernes[5], Antoine Sauguet[6], Mehdi Touil[2], Bernard Woerly[3], Dionyssios Pongas[5], Olivier Chevallier[1], Nicolas Falvo[1], Christophe Galland[1], Marco Midulla[1], Nathalie Garnier[7], Marie-Pierre Guenfoudi[7], Mathieu Boulin[7], Serge Aho-Gléglé[8], Stéphanie Bost[7]

[1]Department of Vascular and Interventional Radiology, Centre Hospitalier Universitaire François-Mitterrand, Dijon, France; [2]Department of Vascular Surgery, Centre Hospitalier Artois-Ternois, Arras, France; [3]Department of Vascular and Interventional Radiology, Clinique de l'Orangerie, Strasbourg, France; [4]Department of Interventional Cardiology, Centre Hospitalier de la Côte Basque, Bayonne, France; [5]Department of Interventional Radiology and Cardiology, Hôpital Privé d'Antony, Paris, France; [6]Department of Interventional Cardiology, Clinique Pasteur, Toulouse, France; [7]Department of Pharmacy, [8]Department of Epidemiology, Statistics and Clinical Research, Centre Hospitalier Universitaire François-Mitterrand, Dijon, France

Correspondence to: Prof. Romaric Loffroy, MD, PhD, FCIRSE. Department of Vascular and Interventional Radiology, Image-Guided Therapy Center, François-Mitterrand University Hospital, 14 Rue Paul Gaffarel, BP 77908, 21079 Dijon Cedex, France. Email: romaric.loffroy@chu-dijon.fr.

Background: To ascertain the safety and mid-term outcomes of Rotarex®S rotational atherectomy plus thrombectomy device (Straub Medical AG, Wangs, Switzerland) with or without adjunctive treatment (e.g., percutaneous transluminal angioplasty, PTA/drug-coated balloon, DCB/stenting) in patients with in-stent restenosis (ISR) or occlusion in the iliac and/or infrainguinal arteries.

Methods: French multicenter retrospective study of all patients treated by in-stent percutaneous mechanical debulking (PMD) of the lower limbs with Rotarex®S device between January 2013 and November 2018.

Results: The cohort consisted of 128 patients (88 men and 40 women), aged 39–94 years (mean, 66.7±12 years). All patients presented with cardio-vascular risk factors. Overall, 51.5% of patients had critical limb ischemia. The study demonstrated a technical success of 96.9% in the population with PMD and adjunctive PTA (95/128, 74.2%) or adjunctive DCB (16/128, 12.5%) or both (13/128, 10.2%). At 12-months follow-up, the primary clinical success/patency rate was 92.3% and the secondary clinical success/patency rate was 91.4%. Rate of limb salvage was 93.7%. Overall 32 (25%) reinterventions were reported with mean time from Rotarex®S treatment to reintervention of 7.1±8.2 months. Target lesion revascularization (TLR) was 19.5% (25/128). Seven (5.5%) patients developed distal embolism that responded to endovascular treatment. At mean follow-up, major adverse events (MAE) observed were death (18/128, 14.1%), myocardial infarction (MI) (9/128, 7.0%), stroke (2/128, 1.6%) and renal failure (3/128, 2.3%).

Conclusions: Recanalization with Rotarex®S rotational atherectomy plus thrombectomy device is a practical choice for arterial ISR/occlusions of the iliac and/or infrainguinal arteries, regardless of the age of the thrombus, with satisfying TLR. Only adjunctive PTA is often necessary to further improve the recanalization.

Keywords: Lower limb ischemia; in-stent restenosis (ISR); in-stent occlusion; rotational atherectomy angioplasty; drug-coated balloon (DCB)

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Introduction

In-stent restenosis (ISR) of the lower limb arteries is a significant issue that occurs in up to 40% to 50% of cases after percutaneous transluminal angioplasty (PTA) or stenting. It frequently occurs following treatment of long, complex and diffuse lesions. According to the literature, in-stent thrombosis may occur in up to 4.3% of patients, and in a half of these cases it is a consequence of late or very late thrombosis (1). Chronic total re-occlusions are localized, most often in the popliteal artery (PA) and superficial femoral artery (SFA) (1,2). Because of the difficulty with ongoing management, ISR after peripheral angioplasty constitutes a growing therapeutic challenge (2). The incidence of ISR generally ranges from 15–42% at one year (but is documented at up to 73%) (3). Bare metal stents showed a higher rate of ISR and re-occlusion in patients with peripheral arterial disease (PAD). This has led to the development of new stents, including drug-coated stents (DCS). After the DCS, drug-coated balloon (DCB) angioplasty was used as a strategic treatment to reduce ISR in patients with SFA and PA lesions. However, one study showed that approximately 30% of patients treated with DCB angioplasty required an additional stent (4). There is currently no widely-accepted standard treatment for ISR. Percutaneous mechanical debulking (PMD) treatment, has been attempted to lessen restenotic tissue burden and improve patency while reducing target lesion revascularization (TLR). The debulking of the restenotic stent may potentially improve DCB treatment effects by reducing the thickness of thrombus and hyperplastic tissue and increasing drug dosage transit to the intima. However, only few studies have reported results of debulking devices in such a setting. Furthermore, all were monocentric including small number of patients.

In this context, we therefore undertook a retrospective multicentre study to ascertain the safety and mid-term outcomes of Rotarex®S rotational atherectomy plus thrombectomy (Straub Medical AG, Wangs, Switzerland) with or without adjunctive treatment (PTA/DCB/stenting) in patients with ISR or reocclusion in the iliac and/or infrainguinal arteries.

Methods

From January 15, 2013, till November 19, 2018, we retrospectively analysed 128 treatments for lower limb ISR by PMD.

Patient cohort

There were 128 symptomatic patients (88 men and 40 women) with ISR thrombosis of a previously implanted stent who underwent PMD treatment. The mean age was 66.7±12 years (median, 65 years) ranging from 39 to 94 years. Risk factors and co-morbidities of patients such as high blood pressure, diabetes, smoking, dyslipidemia, heart disease and chronic renal failure were collected (*Table 1*). Patients with an acute (<14 days), subacute (<3 months) or chronic (>3 months) onset of ischemia were included who showed either a stenosis (50 events, 39.1%) or an occlusion (76 events, 59.4%) in-stent lesion. They were categorized according to the Rutherford-Becker classification (RBC). Patients presented with limb ischemia Rutherford category II–III (moderate to severe claudication) in 62 cases (48.4%), Rutherford category IV (ischemic rest pain) in 44 instances (34.4%) and Rutherford V–VI (minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia to major tissue loss-extending above transmetatarsal level, functional foot no longer salvageable) in 22 cases (17.2%). Thus the cohort included 51.5% CLI patients. The main inclusion endpoints were acute, subacute or chronic ISR (>50%) or CTO, Rutherford category 2 to 6 in the target limb, iliac and/or infrainguinal arteries and successful intraluminal guidewire crossing of target lesions. The exclusion criteria were below-the-knee (BTK) lesions.

Due to the retrospective nature of this study, our Ethics Committee waived the requirement for informed patient consent.

Lesion characteristics and procedural details

Patients were classified by the location of their occlusion (*Table 2*) as iliac arteries (IA), SFA and PA. The PMD

Table 1 Patient demographics and clinical characteristics of 128 patients of the study

Variable	Values
Age (years)	66.7±12
Gender	
Male	88 (68.8)
Female	40 (31.2)
Comorbidities	
Smoker	87 (68.0)
Arterial hypertension	80 (62.5)
Diabetes	40 (31.2)
Dyslipidemia	78 (60.9)
Coronary vascular disease	14 (10.9)
Chronic renal impairment	14 (10.9)
Cardiopathy	38 (29.7)

Values are means ± SD or numbers (%) of observations.

Table 2 Baseline Rutherford class of patients at admission

Rutherford class	Patients with events, n (%)
2–3	62 (48.4)
4	44 (34.4)
5–6	22 (17.2)

device used was the Rotarex®S System (Straub Medical, Wangs, Switzerland), with 6-, 8- or 10-French (Fr) sheath compatible devices, depending on the vessel diameter to be treated. The length of the lesions was visually estimated on digital subtraction angiography.

The approaches performed during the interventions included common femoral ipsilateral, common femoral contralateral or brachial access. The Rotarex®S device was inserted over a 0.018-inch guidewire until a few centimetres proximal to the lesion. Several passes were necessary to eliminate the thrombus. In case of a persistent underlying severe stenosis or residual prominent thrombus, certain adjunctive treatments such as the PTA, DCB or both were utilised (*Figures 1,2*). Mean runtime was 5.1±2.3 minutes with the Rotarex®S device. A stent was implanted if residual stenosis diameter was >50%. The new stent was positioned either in the same place as the previous one, or at another location or both. An appropriate closure device was used to obtain hemostasis in case of complications. Post-interventional medication included anticoagulation therapy as a curative or preventive measure. After the procedure, an antiplatelet therapy single or dual (aspirin 150 mg/day and clopidogrel 75 mg/day) was recommended for at least 12 weeks to avoid thrombotic events.

Study device

The catheter head is made up of two overlying metal cylinders, with two side openings. The outer cylinder is connected to the rotating helix, and the inner cylinder to the catheter shaft. The helix and the catheter head rotate at approximately 40,000–60,000 rpm depending on the model, by means of a gear box in the catheter housing and a motor contained within the catheter handle driven by the Drive System. The rotating outer cylinder is fitted with facets at its foremost tip which when rotating, serve to abrade occluding material lying in front of it.

When in operation, both the helix and the outer catheter head, rotate and are advanced along the guidewire toward an arterial occlusion. When an occlusion is met, the rotating head, with its small, blunt facets in its forward aspect, breaks down the occlusive material. Concomitantly, the rotation of the catheter head creates a vortex in the blood which assists to further erode occluding material from the vessel lumen. The rotating helix produces a negative pressure inside the catheter tube and acts as a conveyor screw upon which the ablated material is transported. The detached particles are drawn into the catheter through side windows in the head where they are further broken down and drawn out of the body and into the attached collecting bag under continuous aspiration. At no time is it necessary for the catheter or rotating head to come into contact with the vessel wall in order to be effective. The catheter is designed in such a manner that when used as directed, over a guidewire and with adequate proximal blood flow, no wall damage would result if contact with a vessel wall should unintentionally occur. There are different catheter sizes: 6-, 8- and 10-Fr.

Three lengths are useful depending on the size of the lesion: 85, 110 and 135 cm. They are free of phthalates and latex. They are composed of three parts: cutting-head, helix and side window, respectively (*Figure 3*). The suction performance is about 0.66 mL/s with the 6-Fr system and

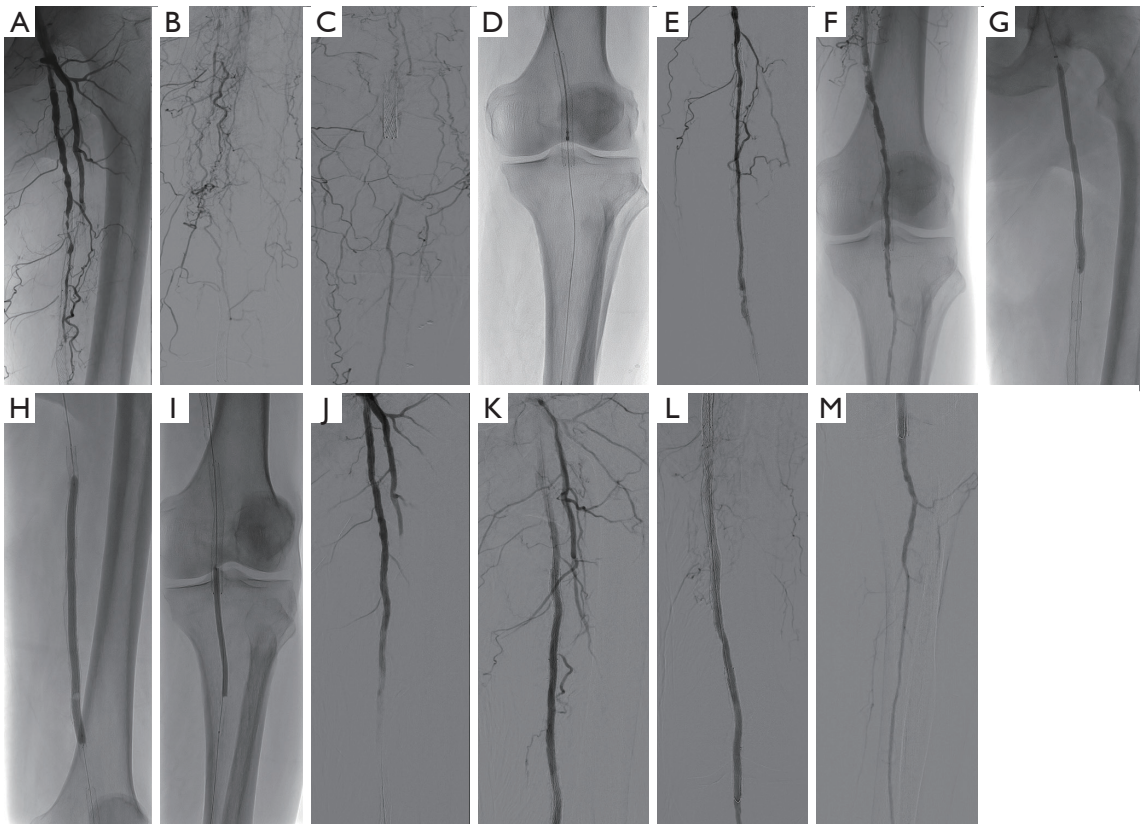

Figure 1 Subacute arterial in-stent occlusion in a 69-year-old limping male. (A,B,C) Complete in-stent occlusion at the left femoro-popliteal artery level with only one run BTK vessel; (D) use of a 6-Fr Rotarex®S catheter on a 0.018-inch guidewire for in-stent debulking; (E,F) angiogram after 2 runs of atherothrombectomy showing reopening vessel; (G,H,I) in-stent PTA+DCB angioplasty; (J,K,L,M) final angiogram showing excellent results after combined debulking and adjunctive therapy, with normal in-stent flow.

1.5 mL/s with the 8-Fr system (5).

Data collection

Success

Technical success was defined as successful completion of the procedure and recanalization of the entire occlusion length with ≤30% diameter residual stenosis.

Clinical success for patients with claudication (Rutherford 2) was defined as clinical improvement of at least one clinical category and for patients with rest pain (Rutherford 3) or CLI (Rutherford 4-5-6) was defined as the resolution of ischemic rest pain and the healing of ischemic ulcers.

TLR was defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion.

Follow-up and endpoints

All patients were routinely scheduled to return for ambulatory follow-up visits at 30 days and then at 3, 6 and 12 months. The key endpoints included safety, technical success, clinical success, patency rates of the in-stent lesion, limb salvage and survival at 1, 3, 6 and 12 months. Other outcome measures are, rate of major adverse events (MAE) defined as death, myocardial infarction (MI), stroke, renal failure and major complications (requiring hospitalization and/or reintervention) including dissection, perforation, bleeding, thrombosis, embolization, false aneurysm and infection between 30-day and 12-month follow-up period.

Statistical analysis

Categorical variables are summarized as percentages and proportions and compared using the Chi-square test or

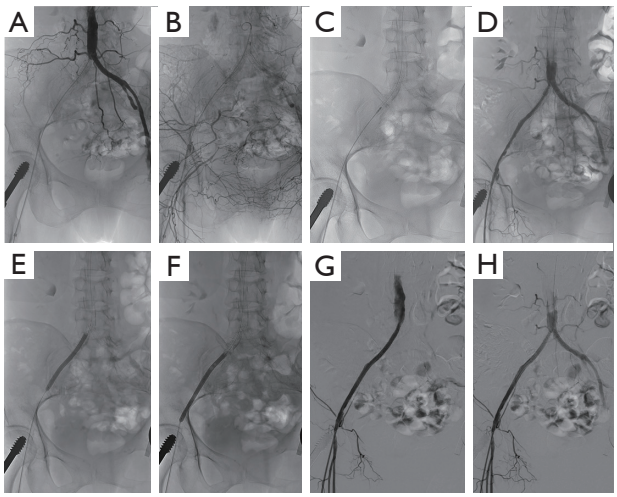

Figure 2 Acute painful symptoms after common iliac artery stenting in a 59-year-old female. (A,B) Extensive right iliofemoral artery thrombosis and in-stent thrombosis at the common iliac artery level; (C) use of a 8-Fr Rotarex®S catheter on a 0.018-inch guidewire for in-stent thrombectomy; (D) angiogram after 2 runs of debulking showing reopening stented vessel; (E,F) in-stent PTA alone; (G,H) final angiogram showing normal in-stent flow and excellent recalibration.

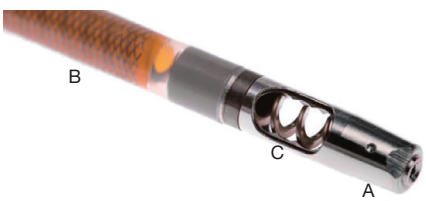

Figure 3 Rotarex®S device. (A) Cutting-head; (B) Helix; (C) side window.

Fisher exact test, as appropriate. Continuous variables are presented as mean ± standard deviation or as median with range. Kaplan-Meier survival analysis and the log-rank test were performed to assess primary and secondary patency rates after different procedures. Statistical significance was defined as $P<0.05$.

Results

A total of 128 patients (88 men and 40 women) were included in this study. *Table 1* highlights patient demographics and clinical characteristics as well as cardiovascular risks factors. Over 50% of our patients had a Rutherford score of 4–6 (i.e., CLI). *Table 2* shows lesions Rutherford classification.

In the majority of patients (n=66; 51.6%), the in-stent lesion length was between 5 and 10 cm with SFA alone (n=56; 43.8%) and iliac (n=31; 24.2%) vessels segments as the mostly treated. The majority of patients presented with an in-stent occlusion (n=76; 59.4%) and the age of lesion observed were acute or subacute lesion. The median time of the interventional procedure was 57.2±32 min but the runtime of Rotarex®S lasted a mere 5.1±2.3 min. We used Rotarex®S device alone only in 4 (3.1%) cases. Others cases all have an adjunctive treatment (PTA, DCB or PTA + DCB). In 75% of the patients, we used post-interventional medication preventatively. A contralateral approach was used in more than 80 interventions, i.e., 67.2% of the time. During the intervention, a stent-in-stent was performed in 85 patients, either in the same or another location. Operative details and overall angiographic data are outlined in *Table 3*.

In 124 of 128 cases, a primary technical success (residual stenosis ≤50%) of 96.9% was obtained with a complete recanalization of the previous stented lesions. At one-month follow-up, clinical success was of 94.5% and at 12 months 92.3% of the evaluable population. At a mean follow-up of 7 months (range of 1–60), the secondary reintervention rate was 25% (32 patients). Among them, 40.6% (13 patients) were treated by Rotarex®S alone or 34.4% (11 patients) with bypass and 25% (8 patients) have undergone an amputation. TLR was 19.5% (25 patients). Limb salvage at mean follow-up was 93.8%.

Table 4 shows procedure success of the study. The overall primary clinical success rate at three-month follow-up was 88.8%. Primary patency/clinical success at 30 days was 94.5%. At mean follow-up, 90% of patients evaluable (*Figure 4*). Kaplan-Meier curve (*Figure 5*) showed that freedom from any reintervention was over 50% at 41.5 months.

At one-month follow-up, there were acute complications requiring hospitalization and/or reintervention. Among other things, we observed 3 perforations (2.3%), 1 device defect (0.8%) and 7 embolizations (5.5%). One (0.8%) patient died and 1 (0.8%) patient had suffered a major amputation. Detailed data on major complications and MAE during follow-up are described in *Table 5*. Overall MAE, at mean follow-up showed a mortality rate of 14.1%. Others MAE are outlined in *Table 6*.

Kaplan-Meier curve (*Figure 6*) showed a survival rate of 68% at 60 months. In our study, 32 reinterventions

Table 3 Overall angiographic and procedural data on stented arteries

Variables	Values
Arterial level	
Iliac	31 (24.2)
SFA	56 (43.8)
Popliteal	14 (10.9)
SFA + popliteal	27 (21.0)
In-stent lesion length (cm)	
<5	32 (25.0)
5–10	66 (51.6)
>10	30 (23.4)
In-stent lesion type	
Stenosis	50 (39.1)
Occlusion	76 (59.4)
Other	2 (1.5)
Age of lesion	
Acute (<14 days)	48 (37.5)
Subacute (<3 months)	55 (43.0)
Chronic (>3 months)	25 (19.5)
Operative details	
Procedure time (min)	
Rotarex run time	5.1±2.3
Total time	57.2±32
Rotarex size	
6-French	73 (57.0)
8-French	53 (41.4)
10-French	2 (1.6)
Approach	
Ipsilateral	40 (31.3)
Contralateral	86 (67.2)
Brachial	2 (1.6)
Use of closure device	
Yes	117 (91.4)
No	11 (8.6)
Intraoperative adjunctive procedure	
No (Rotarex alone)	4 (3.1)
PTA	95 (74.2)
DCB	16 (12.5)
PTA + DCB	13 (10.2)
Additional stenting	
Yes	85 (66.4)
Same location	50 (58.8)
Other location	30 (35.3)
Both	5 (5.9)
No	43 (33.6)
Post-interventional medication	
Anticoagulant therapy	
Preventive	96 (75.0)
Curative	32 (25.0)
Antiplatelet therapy	
Single	51 (39.8)
Double	77 (60.2)

Values are means ± SD or numbers (%) of observations. SFA, superficial femoral artery; PTA, percutaneous transluminal angioplasty; DCB, drug-coated balloon.

were performed. Of these 32 reinterventions, 10 (13%) of 77 patients had double antiplatelet therapy. The other 22 (43.1%) were on single antiplatelet therapy. Reintervention rate was lower in patients under antiplatelet therapy *vs.* single antiplatelet therapy (P<0.05). There was no impact of lesion type (length, degree, age) on patency/reintervention/survival rates (P>0.05).

Discussion

In recent years, ISR following peripheral angioplasty or stenting has become a major therapeutic challenge driving the development of new innovative medical devices. Recent studies and case reports have shown the high technical success rates of Rotarex®S in the treatment of stenosis and occlusion of native peripheral arteries (6-8). However, few studies have evaluated the success of this safe and effective technique in the treatment of ISR in the lower limbs.

Table 4 Procedural success and outcomes

Variables	Values
Technical success	124/128 (96.9)
Additional thrombolysis for outflow occlusion	6/128 (4.7)
Primary clinical success/patency rate	
At 1 month	121/128 (94.5)
At 3 months	103/116 (88.8)
At 6 months	80/88 (90.9)
At 12 months	51/55 (92.7)
Mean follow-up in months [range]	7 [1–60]
Secondary clinical success/patency rate at mean follow-up	117/128 (91.4)
Failure at mean follow-up	
Rate of reintervention	32/128 (25.0)
Mean time from Rotarex treatment to reintervention (months)	7.1±8.2
Type of reintervention	
Rotarex alone	13/32 (40.6)
Bypass	11/32 (34.4)
Amputation	8/32 (25.0)
Target lesion revascularization (TLR)	25/128 (19.5)
Type of amputation	
Major amputation	4/32 (12.5)
Minor amputation	4/32 (12.5)
Rotarex or bypass + minor or major amputation	3/32 (9.4)
Limb salvage at mean follow-up	120/128 (93.8)

*, percentage of patients who are known to have good patency at 12 months. The others are either lost to follow-up or not evaluable. Values are means ± SD or numbers (%) of observations.

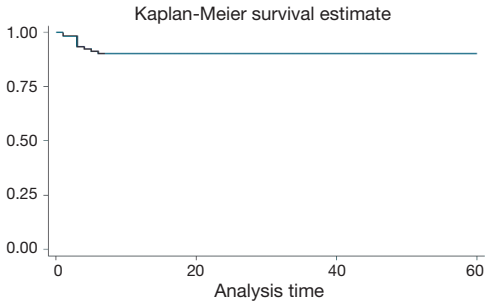

Figure 4 Kaplan-Meier curve representing patency rate at mean follow-up (analysis time in months).

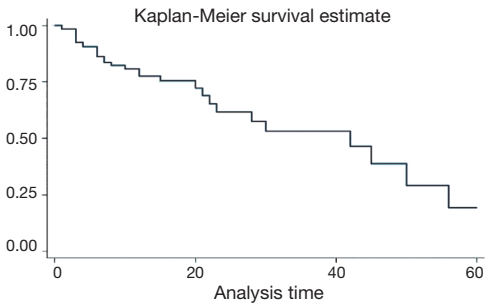

Figure 5 Kaplan-Meier curve representing freedom from-reintervention rate (analysis time in months).

This article presents a 5-year study whose main objective was to evaluate the technical and clinical success of revascularization of the stented peripheral arteries with PMD by the Rotarex®S medical device. In our study this treatment was combined with either PTA or with the DCB or both. In our series, we achieved a primary patency rate of 92.3% at 12 months all techniques combined. Secondary clinical success at mean follow-up was 117/128 (91.4%) after reinterventions. The overall reintervention rate observed was 25%. The TLR was 25/128 (19.5%). The dissection rate at 30 days was 2.3% and perforation rate of 2.3%. The risk of vessel perforation or dissection is mainly dependent on the safe, intraluminal position of the guidewire. Calcified arteries were at high risk to be perforated. Moreover, lesion type (length, degree, age) did not influence the patency, reintervention or survival rates (P>0.05). Milnerowicz *et al.* made the same observation (2).

Several devices and techniques can be used to treat femoropopliteal artery disease. Bare metal stents implantation is commonly used. Stents resolve the problems of elastic recoil, residual stenosis and dissection but ISR stay high with an incidence of 15% to 32% in 12 months (3,9). Dick *et al.* showed the ISR treatment with angioplasty resulted in a restenosis recurrence rate with up to 73% (10). Cutting balloon angioplasty has proven to be more successful but the restenosis recurrence rate showed it was not statistically significant (65% *vs.* 73%) (10). Zeller *et al.* had obtained better results with implantation of paclitaxel-coated stents. The primary patency rate at one

Table 5 Complications within 30 days

Variables	Values
Major (requiring hospitalization and/or reintervention)	
Perforation	3/128 (2.3)
Dissection	3/128 (2.3)
Device defect	1/128 (0.8)
Thrombosis	2/128 (1.6)
Embolization	7/128 (5.5)
Bleeding	6/128 (4.7)
False aneurysm	5/128 (3.9)
Infection	3/128 (2.4)
Major adverse events (MAE)	
Death	1/128 (0.8)
Myocardial infarction	2/128 (1.6)
Stroke	0/128 (0)
Major amputation	1/128 (0.8)
Renal failure	2/128 (1.6)

Values are numbers (%) of observations.

Table 6 Major adverse events (MAE) at mean follow-up

Variables	Values
Death	18/128 (14.1)
Myocardial infarction	9/128 (7.0)
Stroke	2/128 (1.6)
Major amputation	8/128 (6.3)
Renal failure	3/128 (2.3)

Values are numbers (%) of observations.

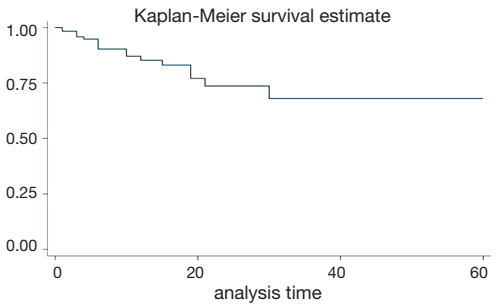

Figure 6 Kaplan-Meier curve showing the survival after intervention at mean follow-up (analysis time in months).

Table 7 Comparison of published results following endovascular treatment of femoropopliteal in-stent restenosis

Study	Devices	Follow-up, months	Lesions	Freedom from TLR, %	Primary patency, %
FAIR (12)	DCB	12	62	90.8	70.5
PACUBA (13)	DCB	12	74	49.0	40.7
PLAISIR (14)	DCB	12	55	90.2	83.7
EXCITE ISR (15)	Laser atherectomy + PTA	6	169	73.5	/
PATENT (16)	Excimer laser + Turbo-Booster	12	90	64.4	37.8
Current study	Rotational atherectomy ± adjunctive therapy	7	128	80.5	90.9

DCB, drug-coated balloon; PTA, percutaneous angioplasty; TLR, target lesion revascularization.

year was 78.8% of the lesion with mean lesion length of 133±91.7 mm and occlusion rate of 30% (11).

Table 7 shows the outcomes of several treatment techniques for femoropopliteal ISR. Several studies have documented positive outcomes of hybrid treatment for restenotic lesions combining atherectomy (laser, directional) with DCB angioplasty (2). The EXCITE ISR trial is the first large, randomized and prospective study to demonstrate superiority of laser atherectomy + PTA versus PTA alone. The first group had shown a better procedural success (93.5% *vs.* 82.7%, P=0.01) with few complications. At six months, the freedom from TLR was 73.5% versus 51.8% (P<0.005) (15).

The Rotarex®S system is a purely mechanical endovascular atherectomy plus thrombectomy device (17). It was reported by Freitas *et al.* that 6-Fr Rotarex®S device is used in the treatment of acute mesenteric ischemia or acute limb ischemia with no mortality, few complications and great outcomes (18). The main advantage of this technique is safe, rapid and effective removal of large thrombus volume (19). Kronlage *et al.* conducted a comparative study of two intervention methods, PMD

and local thrombolysis for the treatment of acute and subacute ischemia of limbs in thrombotic occlusions of peripheral limbs. Their results show a primary patency success of more than 98% for both techniques used. At 12 months follow-up, primary and secondary patency after PMD alone was significantly better compared to local thrombolysis or Rotarex®S and lysis (63% and 85%, P<0.05). Overall survival 12 months after surgery was 96% in patients without critical illness and survival without amputation was 94.3%. Direct comparison between the different intervention techniques in this study showed that the rate of major bleeding was significantly lower in patients treated with Rotarex®S than in patients receiving thrombolysis (20). Stanek *et al.* showed immediate successful recanalization in 69 interventions performed (95%) in 65 patients with acute and subacute occlusion in the peripheral arteries, in an evaluation of the immediate and long-term outcomes of the Rotarex®S catheter. Peripheral embolization was the most common transient complication (6%). Thus, the Rotarex®S system provided fast and effective treatment of peripheral arterial thromboembolic occlusions. It is a safe tool for the treatment of in-stent acute and subacute arterial thromboembolic occlusions or even chronic peripheral thromboembolic occlusions. According to the authors, it can be used for short or long occlusions with the same success, provided that the obstruction is not strongly calcified and that a guidewire has been safely passed through the obstruction (21). It has been shown by other authors too (22,23).

Our study included 128 patients with ISR in femoropopliteal arteries and iliac arteries with cardiovascular co-morbidities. It is the largest multicentre series published to date despite limitations. First, this was a non-randomized, retrospective study with a modestly-sized cohort with absence of control group. Furthermore, we had heterogeneous population with different target vessels (iliac *vs.* SFA *vs.* PA *vs.* combined), different stent occlusions like restenosis *vs.* occlusion, acute thrombosis *vs.* chronic thrombosis vs combined and the use of different techniques (debulking alone *vs.* debulking + PTA *vs.* debulking + DCB *vs.* combined). The outcomes need to be confirmed in a larger study or randomized controlled trial with longer follow-up.

In conclusion, this study showed that Rotarex®S rotational debulking device alone or associated with PTA or/and DCB angioplasty is safe, quick and effective in patients with in-stent occlusion or restenosis in iliac and infrainguinal arteries. Mechanical thrombectomy and atherectomy are efficient methods of arterial debulking to achieve recanalization when used in the treatment of acute, subacute or even chronic occlusion or stenosis of peripheral arteries. It is also safe when performed by less experienced operators. It may produce satisfactory outcomes in patients with in-stent occlusion in peripheral arteries in terms of primary patency rate. This is the largest and only multicentre study that has analysed the outcomes of such a hybrid intervention in the treatment of in-stent occlusion. Its results justify further research in the application of the therapy to determine cost/benefit.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This retrospective study was performed in compliance with the requirements of the institutional review board and approved by the institution ethical committee. Informed consent was waived.

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