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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Mechanical rotational thrombectomy in long femoropopliteal artery and bypass occlusions: risk factors for periprocedural peripheral embolization

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PURPOSE
We aimed to examine lesion characteristics influencing technical outcome and periprocedural peripheral embolization (PPE) during percutaneous mechanical rotational thrombectomy (PMT) of long femoropopliteal artery and bypass occlusions.

METHODS
Retrospectively, 65 consecutive patients (43 male patients, mean age 70±12 years; Rutherford category I–III), undergoing PMT (Rotarex®, Straub Medical AG) with acutely/subacutely occluded femoropopliteal arteries/bypasses were included. Occlusions (mean length, 217±98 mm) were treated by PMT followed by percutaneous transluminal angioplasty (PTA) plus drug-coated balloon or PTA plus stenting/stentgrafting. Technical success was defined as residual stenosis <30%. Follow-up included duplex ultrasound and ankle-brachial index (ABI) after 12 months. Endpoints were technical success, complications, improvement of Rutherford category, ABI, and patency (re-stenosis <50%). The influence of lesion length, duration, and thrombus density (measured in preinterventional computed tomography angiography) on technical success and PPE was analyzed.

RESULTS
Technical success was 18% (12/65) after PMT alone, 92% (60/65) after additional means. Four patients (6%) underwent bypass surgery and one patient (2%) amputation. PPE occurred in 11% (7/65). During the 12-month follow-up, three patients (5%) were lost to follow-up. ABI increased from baseline 0.5±0.12 to 0.81±0.14 (p = 0.001) and Rutherford category increased by at least one level in 57 patients at 12-month follow-up (clinical success, 88%). At 12 months, primary patency was 57.4% (95% CI, 45.8%–68.9%) and secondary patency was 75.0% (95% CI, 59.8%–72.3%). As risk factors for PPE, we identified lesion length >200 mm (15%; 6/39; OR 4.5; 95% CI, 0.5–40; p = 0.014) and thrombus density ≤45 HU (20%; 2/10; OR 3.0; 95% CI, 0.2–38.9; p = 0.05). No significant relation between risk factors and technical success was found.

CONCLUSION
PMT followed by PTA or implantation of stent (grafts) appears to be effective and safe for revascularization of acute/subacute long occlusions. Thrombus density <45 HU and lesion length above 20 cm represent risk factors for PPE during PMT.

The Rotarex® percutaneous mechanical rotational thrombectomy (PMT) device (Straub Medical AG) has been used for almost two decades and has been proven to be safe and effective in several studies analyzing endovascular revascularization of acute and subacute iliac and femoropopliteal arteries (1–5) as well as venous and synthetic bypass graft occlusions (4, 6, 7). The combination of PMT and additional devices such as drug-coated balloons, stents, or stentgrafts has shown satisfactory long-term patency rates (3, 8, 9). Therefore, PMT has evolved to an effective endovascular alternative to vascular surgery and other minimal invasive techniques such as thrombolysis and thrombus aspiration. However, in studies with larger patient populations technical success rates vary between 90% and 97% (3–5), and the most common complication, acute periprocedural peripheral embolization (PPE), has been reported between 0% and 24% (1–3, 5). Several factors may pose risks for technical failure or acute PPE such as lesion length or duration of the lesion. Studies investigating the correlation between potential risk factors influencing technical

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success and the risk for occurrence of PPE during PMT interventions do not exist to the best of our knowledge. Therefore, the objectives of this analysis were to evaluate technical success, effectiveness, and safety of the Rotarex percutaneous mechanical rotational thrombectomy device, as well as to analyze the influence of lesion length, duration of the occlusion, and thrombus density on technical success and the occurrence of PPE.

Methods

Patients

Between February 2014 and October 2017 we retrospectively identified 65 consecutive patients (43 male, mean age 70±12 years), suffering from peripheral arterial disease (Rutherford classification for acute limb ischemia: category I–III) with an acute (start of clinical symptoms <14 days; n=55, 85%) and subacute (start of clinical symptoms ≥14 days) occlusion of the femoropopliteal vascular territory, which were revascularized by primary use of the Rotarex percutaneous mechanical rotational thrombectomy device (Straub Medical AG). Lesions were *de novo* occlusions in 26 cases (40%), bypass occlusions in 11 (17%), in-stent occlusions in 16 (25%) and stentgraft occlusions in 2 (3%). Moreover, 10 lesions (15%) were a combination of in-stent and stentgraft occlusions. The mean lesion length measured by calibration with a scaled radiopaque ruler on the angiography table was 217±98 mm (range, 40–400 mm). According to the classification of Rutherford for acute limb ischemia, 29 occlusions (45%) were category I, 28 (43%) category II, and 8 (12%) category III. Mean baseline ankle-brachial-index (ABI) was 0.5±0.12 (range, 0.3–0.7). Preinterventional imaging included computed tomography angiography (CTA) in 41 patients (63%), magnetic resonance angiography (MRA) in 4 (6%), and duplex ultrasound sonography in 20 (31%). Details of patient and lesion characteristics are illustrated in Table 1.

In all cases, the indication for an endovascular thrombectomy was decided by an interventional radiologist and a vascular surgeon. The inclusion criteria for the use of PMT were: 1) clinically driven acute or subacute vessel occlusion; 2) at least one crural outflow vessel; 3) successful intraluminal guidewire passage of the occlusion. Exclusion criteria included: 1) the lack of a patent crural outflow vessel; 2) technically not achievable intraluminal guidewire passage of the occlusion. In 55 patients (85%), an ipsilateral antegrade puncture technique of the common femoral artery was performed, while in 10 patients (15%) a crossover approach was performed. Before the intervention, informed consent was obtained from each patient. Written, informed consent for the study was not applicable, as this was a retrospective study. Local ethic review committee approval was granted (18-184A; 2018).

Percutaneous mechanical rotational thrombectomy device

The system consists of three components: the Rotarex Catheter (Straub Medical AG) which is operated using a dedicated 0.018-inch guidewire and is available in 6 F and 8 F sizes, a motor that is simultaneously used as a handle and an external electronic control unit. After the catheter is activated, it is pushed forward into the occlusion mak-

Main points

- The risk for periprocedural peripheral embolization (PPE) during mechanical rotational thrombectomy interventions is significantly higher in long occlusions than in shorter occlusions.
- The risk for PPE during mechanical rotational thrombectomy interventions is significantly higher in *de novo* occlusions with a lower thrombus density measured in preinterventional CTA than in *de novo* occlusions with a higher thrombus density.
- The duration of occlusion, occlusion length, and thrombus density showed no significant impact on technical outcome and the duration of the occlusion seems to have no influence on the risk for PPE during mechanical rotational thrombectomy interventions.

Table 1. Patient and lesion characteristics

Number of patients treated, (n)	65
Age (years), mean±SD	70±12
Sex, n (%)	
Male	43 (66)
Female	22 (34)
Baseline Rutherford category, n (%)	
I	29 (45)
II	28 (43)
III	8 (12)
Lesion length (mm), mean±SD (range)	217±98 (40–400)
Lesion age, n (%)	
Acute (<14 days)	55 (85)
Subacute (≥14 days)	10 (15)
Side treated, n (%)	
Left	35 (54)
Right	30 (46)
Type of occlusion, n (%)	
De novo	26 (40)
In-stent	16 (25)
In-stentgraft	2 (3)
Bypass	11 (17)
Stent plus stentgraft	10 (15)
Degree of vessel calcification, n (%)	
None	12 (18)
Mild	3 (5)
Moderate	29 (45)
Severe	21 (32)

ing slow back and forth movements until the target lesion is passed. The thrombotic material is broken down by the chisel-like catheter tip. The catheter should be advanced slowly to allow the detached fragments to be pushed aside against the vessel wall by the strong vortex caused by the rotating head. Those detached fragments loosen additional occlusion material on the wall without the need to touch the rotating head of the catheter. The strong vacuum aspirates mobilized fragments, which are further crushed within the head and are then transported into a collecting bag attached to the handle. The rotation of the screw and the rotating head simultaneously produce a permanent negative pressure inside the catheter, with a helix inside that rotates at 40 000 to 60 000 rpm and transmits the rotations to the catheter head. The suction performance is approximately 0.66 mL/s with the 6 F and 1.5 mL/s using the 8 F system.

Procedure details

The procedures were carried out by two interventional radiologists. A 6 F sheath was used for vessel access. Heparin 5000 IU was administered immediately after vascular access had been obtained. The occluded target lesions were intraluminally passed by a 0.035-inch (Radiofocus GuideWire M, Terumo Corp.) or 0.018-inch (V18-ControlWire, Boston Scientific) guidewire. All target lesions were then treated using the 6 F Rotarex catheter. After insertion, the Rotarex device was navigated over a dedicated 0.018-inch wire up to a few centimeters proximal to the target lesion and then turned on. Slow, back and forth motions were performed. Control angiography was performed after two passages of the target lesions. Percutaneous transluminal angioplasty (PTA) was carried out in cases of residual stenosis >30%. Additional implantation of a stent/stentgraft was performed to treat the following: remaining stenosis >30% in control angiogram, significant recoil, and/or flow limiting dissection after PTA. Figs. 1–5 illustrate a Rotarex procedure with additional PTA and secondary "spot stenting" of the proximal and distal target lesion.

Technical success of PMT alone was defined as recanalization of the entire target lesion with <30% residual stenosis on control angiogram. Technical success after the use of additional devices such as PTA or stenting was also defined as a residual stenosis <30% at the end of the procedure. Once the intervention was completed, the puncture site was closed using a percutaneous closure system (Angio-Seal, St. Jude Medical Inc.) (n=26; 40%) or manual compression (n=39; 60%). In case of PMT alone or PMT plus PTA, long-term medication with aspirin (100 mg/day) was recommended. Dual antiplatelet therapy with clopidogrel (loading dose of 300 mg followed by 75 mg/day) and aspirin (100 mg/day) was recommended for at least 3 months in case an additional stent/stentgraft had been implanted.

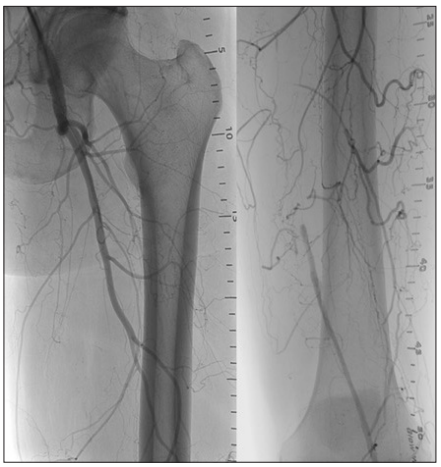

Figure 1. Initial angiogram shows total occlusion (TASC D) of the left superficial femoral artery (SFA).

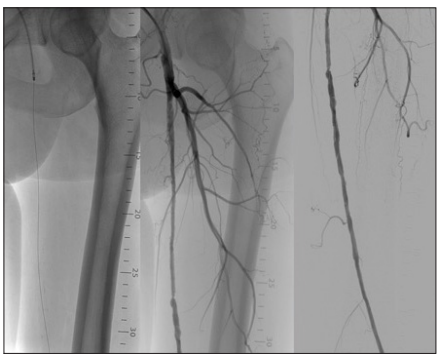

Figure 2. Rotarex thrombectomy and post percutaneous mechanical rotational thrombectomy angiogram.

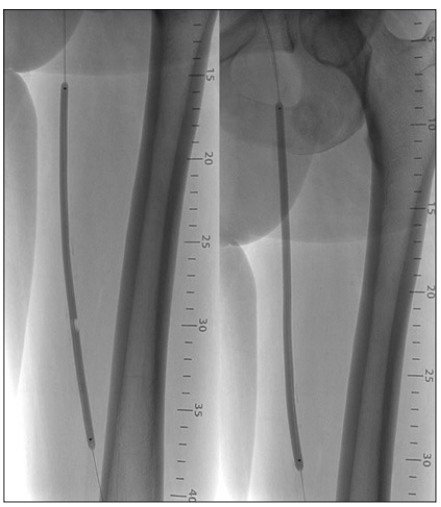

Figure 3. Percutaneous transluminal angioplasty (PTA) of extensive residual stenosis of target lesion.

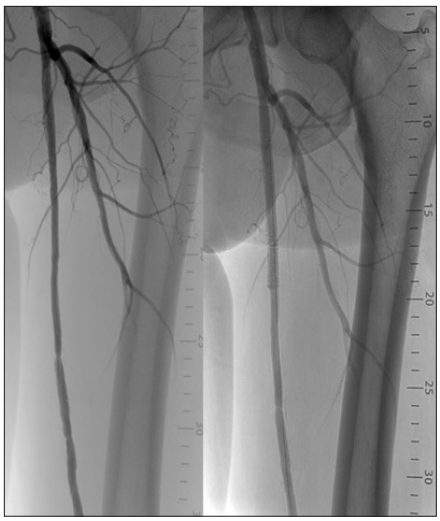

Figure 4. Post-PTA angiogram of proximal target lesion shows dissection, which is treated with stent implantation.

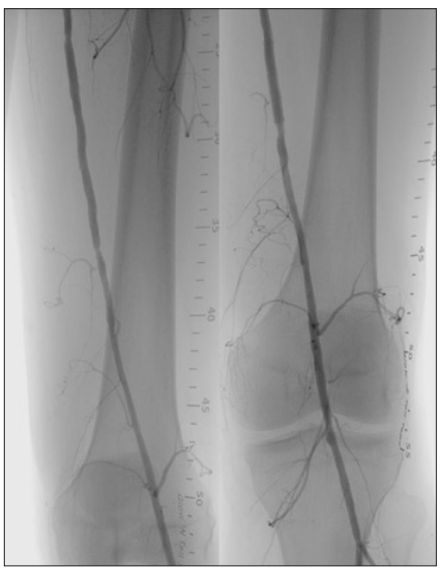

Figure 5. Post-PTA angiogram of distal target lesion shows residual stenosis, which is covered with stent implantation.

CTA image acquisition and thrombus density analysis

In 41 patients (63%), a preinterventional CTA was acquired. The CTA had a scan range extending from the costo-diaphragmatic recess to the forefoot and was conduct-

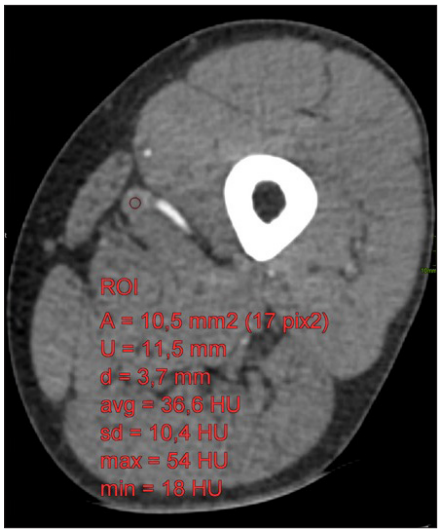

Figure 6. Region-of-interest placement in *de novo* occlusion of left SFA.

ed on a 128-slice CT scanner (Somatom Definition®, Siemens Healthcare). The CT was acquired using the following parameters: tube voltage 120 kV, reference tube current-time product 200 mAs with tube current modulation CareDose® (Siemens Healthcare), rotation time 0.3 s; collimation 0.6 mm. CTA was performed with the patient in supine position. A dose of 100 mL of Iomeprol 300 mg I/mL (Imeron 300®, Bracco), followed by a 30 mL saline flush, both at a flow rate of 4.0 mL/s, was power injected (Ct motion®, Ulrich medical) via a 20 G or larger intravenous cannula placed preferably in an antecubital vein. Arterial-phase images were obtained 15 s after bolus detection in the suprarenal aorta (threshold 150 HU, CareDose). For vascular assessment, images were first reconstructed using a medium soft kernel (B30f) with a field of view of 100/500 mm and an effective slice thickness of 1.0 mm. Then images were reconstructed with the same field of view and a slice thickness of 5.0 mm. In addition, in every patient sagittal and coronal reformations were done.

At five appropriate points of the occluded vessel segment, a circular region of interest (ROI) of approximately 10 mm^2 on a single axial slice of 1 mm thickness was drawn: one spot/point each at the proximal and distal part of the occluded lesion as well as three evenly distributed spots/points in between, depending on the length of the occlusion. Thereby the mean Hounsfield unit (HU) value for the ROI was achieved (Fig. 6). Vessel calcifications were not included in the ROI. Patients with target lesions consisting of occluded stents/stentgrafts or bypasses were excluded from this analysis owing to beam hardening artifacts, which might mislead the mean HU. In total, 23 of 65 patients (35%) had a *de novo* lesion in combination with a preinterventional CTA and were therefore included in the thrombus density measurements. Patients having a preinterventional MRA or duplex ultrasound sonography were excluded from the measurements.

Follow-up

Following the procedure patients were restricted to at least 12 hours of bed rest and were generally monitored in the hospital for at least 24 hours. The puncture site and arterial pulse were checked and duplex ultrasound was performed the day after the procedure or directly before discharge, respectively.

Routine follow-ups with physical examination, assessment of Rutherford categorization, and duplex ultrasound in outpatient clinics of patients' choice were performed every six months. Between the routine follow-ups, diagnostics such as duplex ultrasound or CTA and MRA were only carried out in case of clinical deterioration. If a significant restenosis (>50%) or a significant worsening of Rutherford category was detected, patients were scheduled for repeated angiography and treatment.

Endpoints

The primary endpoints were: 1) technical success of PMT which was defined as recanalization of the target lesion, with <30% residual stenosis on control angiogram after utilization of the Rotarex device (Straub Medical). Primary treatment success after additional PTA, stent, or stentgraft implantation (if necessary), was also defined as a residual stenosis of <30% at the end of the procedure; 2) the influence of the lesion length (in mm), occlusion-age (in days) and the thrombus density (in HU) in preinterventional CTA with regards to technical success and occurrence of PPE.

Secondary endpoints included: 1) primary and secondary patency 12 months after the procedure; 2) amputation and death as major adverse events; 3) early complication rates.

In addition to PPE, further periprocedural and early complication rates included arterial perforation, local bleeding, acute arterial closure, pseudoaneurysm, and infection.

Statistical analysis

All continuous variables were reported as mean and standard deviation (SD). Categorical data are presented as the number of patients and percentage. The Kaplan-Meier method was used to calculate patency rates for patients with all follow-up visits. Survival estimates are presented with the 95% confidence interval (CI). The Fisher's exact test and odds ratio (OR) with the 95% CI was calculated to examine the relation of occlusion length, duration of occlusion, and thrombus density to technical success and to the risk for occurrence of PPE. Because the average mean thrombus density was close to 45 HU in this study, the OR and significance was compared between patients with a mean thrombus density >45 HU, referred to as a denser thrombus, and a mean clot density ≤45 HU, as a softer thrombus. The cutoff for the duration of occlusion was set at the start of clinical symptoms ≥14 days versus start of clinical symptoms <14 days. Furthermore the cutoff for longer lesion length was >200 mm versus shorter lesions ≤200 mm, since the mean lesion length was 217 mm. Statistical significance level (p) was set to 0.05. The statistical evaluation of data was performed using dedicated statistical software (SPSS 25 for Windows, IBM Inc.).

Results

Technical success using the Rotarex device was achieved in 12 patients (18%). Besides pure PMT, the most commonly performed methods were PTA and/or the use of an additional device (n=48; 74%). Conventional PTA in combination with drug eluting PTA was carried out in 16 cases (25%) and in combination with stenting in 18 cases (28%). In 12 cases (18%), a stentgraft (Viabahn®, W.L. Gore & Associates Inc.) was implanted after conventional PTA. In 2 cases (3%) stentgrafting was performed immediately following PMT (Table 2). Self-expanding bare metal stents were implanted in case of a residual stenosis >30% after PMT and PTA in *de novo* vessel segments. Stentgrafts were implanted in case of residual in-stent stenosis >30% or flow-limiting residual thrombus after PMT. Overall technical success at the end of the procedure was achieved in 60 patients (92%). If bypass occlusions were observed separately from *de novo* and in-stent/stentgraft occlusions, technical success would be attained in 8 of 11 (72%) compared with 52 of 54 (96%). Moreover, in the remaining 5 patients (8%),

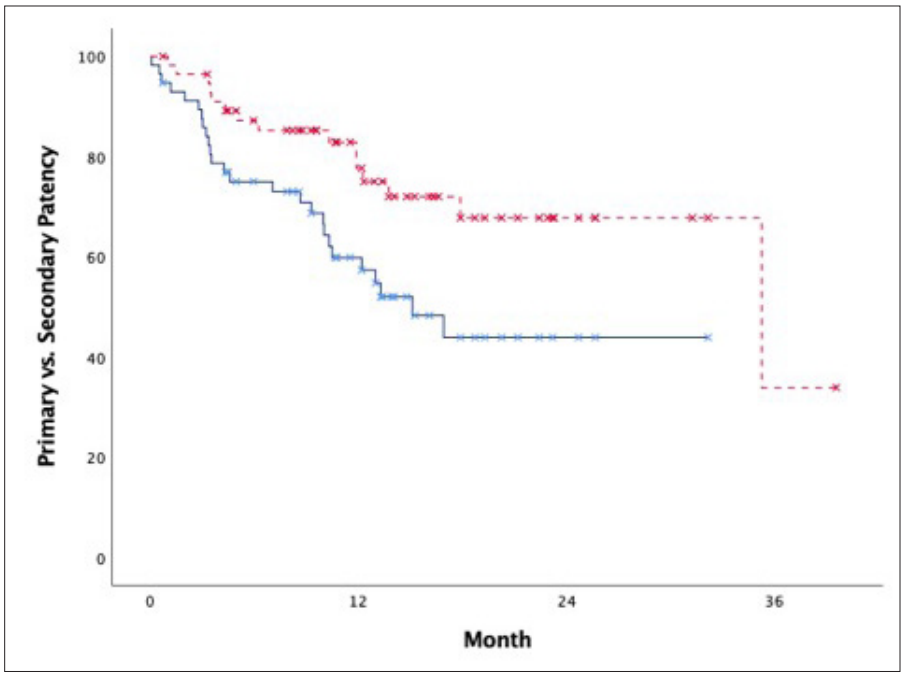

Figure 7. Overall primary vs. secondary patency: *solid lines* represent the primary patency and dotted lines the secondary patency.

Table 2. Procedure details	
Crossover, n (%)	10 (15)
6 F Rotarex catheter, n (%)	65 (100)
PMT only, n (%)	12 (18)
PMT + PTA + DCB, n (%)	16 (25)
PMT + PTA + stent, n (%)	18 (25)
PMT + PTA + stentgraft, n (%)	12 (18)
PMT + stentgraft, n (%)	2 (3)
Fluoroscopy time (min, mean±SD (range)	15±6 (6–31)
Dose area product (cGym*cm^2), mean±SD (range)	2788±2304 (435–13831)

PMT, percutaneous mechanical rotational thrombectomy; PTA, percutaneous transluminal angioplasty; DCB, drug-coated balloon; SD, standard deviation.

blood flow could not be restored even with the use of additional devices due to massive amounts of remaining thrombus that could not be effectively removed nor wall-attached by stenting: of these, three had bypass occlusion, one in-stent occlusion, and one in-stentgraft occlusion. Out of those patients, four underwent bypass surgery and one had an amputation. Comparison of baseline and final angiograms of the crural and pedal run-off showed PPE in 7 patients (11%) located in the tibial-fibular trunk (n=1), anterior tibial artery (n=3), fibular artery (n=1), posterior tibial artery (n=2). All PPE cases were successfully handled during the procedure using manual aspiration thrombectomy. During the observed timespan, an intraluminal recanalization was not achievable in 2 cases of acute and 4 cases of subacute femoropopliteal occlusion in which PMT was considered, and these patients were therefore excluded.

The mean lesion length was 217±98 mm (range, 40–400 mm). In 25 of 65 patients, the mean lesion length was ≤200 mm (126±51 mm; range, 40–200 mm), while it was >200 mm (297±45 mm; range, 210–400 mm) in the remaining 40 patients. The duration of occlusion was <14 days (1.9±1.9 days; range, 1–12 days) in 55 patients and ≥14 days (100±102 mm; range, 15–288 days) in 10 patients. Moreover, the mean density of the thrombus in preinterventional CTA was ≤45 HU (31±10 HU; range, 20–45 HU) in 10 of 23 cases and >45 HU (58±13 HU; range, 47–90 HU) in 13 cases.

Technical success in patients with a mean lesion length of ≤200 mm was 2.4 times more likely (95% CI, 0.3–23) than in patients with a mean lesion length of >200 mm (96% successful revascularization [SR], 23/24 vs. 90% SR, 37/41; $p = 0.4$). Occlusions <14 days were 1.4 times more likely (95% CI, 0.1–14) to be revascularized successfully than older occlusions of ≥14 days (93% SR, 51/55 vs. 90% SR, 9/1; $p = 0.6$). Technical success was 1.4 times more likely (95% CI, 0.2–12) in patients with a mean thrombus density of >45 HU than in patients with a lesion density ≤45 HU (85% SR, 11/13 vs. 80% SR, 8/10; $p = 0.5$).

The risk for PPE in patients with a mean lesion length >200 mm was 4.5 times greater (95% CI, 0.5–40) than in patients with lesions ≤200 mm (15% PPE, 6/39 vs. 4%, 1/26; $p = 0.014$). Patients with a duration of occlusion of <14 days faced a 1.1 times greater risk to develop a PPE (95% CI, 0.1–10.5) compared to patients with a duration of occlusion of ≥ 14 days (11% PPE, 6/55 vs. 10% PPE, 1/10; $p = 0.7$). In patients with a mean thrombus density of ≤45 HU the risk for occurrence of PPE was 3.0 times greater (95% CI, 0.2–38.9) than in patients with a mean density >45 HU (20% PPE, 2/10 vs. 8% PPE, 1/13; $p = 0.05$).

In 2 of 65 patients, a pseudoaneurysm occurred. One was treated by surgery and one was treated by percutaneous ultrasound-guided thrombin injection. Moreover, in one patient, a subcutaneous hematoma appeared at puncture site. However, this needed no further treatment. There were no other early complications reported.

The mean resting ABI significantly increased from baseline to immediate postintervention (0.5±0.12 vs. 0.89±0.12; $p = 0.001$). Postinterventionally, according to the Rutherford classification for acute limb ischemia, category increased by at least one level in 60 patients (clinical success, 92%). No amputations or procedure-related deaths were recorded during the follow-up. However, during 12 months of follow-up, 3 of 60 patients (5%) died of non-procedure-related causes and patency status was unknown. In 26 of 57 patients, a re-stenosis of >50% (n=16) or re-occlusion (n=10) was diagnosed by duplex ultrasound or CTA and successfully treated by an endovascular approach. At 12-month follow-up, clinical success was 88%, the primary patency rate was 57.4%

Table 3. Technical/clinical outcome and complications	
Technical success (<30% residual stenosis)	
Overall technical success (n=65)	60 (92)
Overall technical success after pure PMT (n=65)	12 (18)
Overall technical success after PMT plus additional means (n=65)	48 (74)
Overall technical success in *de novo* and in-stent/stentgraft occlusions (n=54)	52 (96)
After pure PMT in *de novo* and in-stent/stentgraft occlusions (n=8)	8 (100)
After PMT plus additional means in de novo and in-stent/stentgraft occlusions (n=46)	44 (96)
PTA plus DCB-PTA (n=16)	16 (100)
PTA plus stent (n=17)	15 (88)
PTA plus stentgraft (n=11)	11 (100)
Overall technical success in bypass occlusions (n=11)	8 (72)
After pure PMT in bypass occlusions (n=4)	4 (100)
After PMT plus additional means in bypass occlusions (n=7)	4 (64)
ABI (n=60), mean±SD	
Baseline	0.5±0.12
Immediate postinterventional	0.89±0.12
12-month follow-up (n=57)	0.81±0.14
Rutherford category (increase of at least one category) (n=65)	
Immediate postinterventional	60 (92)
12-month follow-up	57 (88)
Primary patency, %	57.4%
Secondary patency, %	75.0%
Target lesion revascularization	26 (40)
Restenosis	16 (24)
Reocclusion	10 (15)
Complications	
PPE	7 (11)
Pseudoaneurysm	2 (3)
Subcutaneous hematoma	1 (2)

Data are presented as n (%), unless otherwise noted.
PMT, percutaneous mechanical rotational thrombectomy; PTA, percutaneous transluminal angioplasty; DCB, drug-coated balloon; ABI, ankle-brachial-index; SD, standard deviation; PPE, periprocedural peripheral embolization.

(95% CI, 45.8%–68.9%) and the secondary patency rate was 75.0% (95% CI, 59.8%–72.3%) (Fig. 7). Results of technical/clinical outcome, additional subgroup analysis and complications are shown in Table 3.

Discussion

Our experience with the Rotarex percutaneous mechanical rotational thrombectomy device for the treatment of acute and subacute occlusions of the lower extremity in 65 peripheral arterial disease patients is reported in this study. This endovascular device is well established for the revascularization of thrombotic and embolic acute, subacute, or chronic lesions. It has proven to be of value in terms of amputation-free survival as well as low complication rates (2, 4–7, 10–16).

In our study, we used the 6 F Rotarex device for mostly acute and subacute *de novo* (40%) and in-stent occlusions (25%) of the femoropopliteal segment. Technical success was achieved in 12 patients (18%) after Rotarex passages only, which is lower compared to the studies with larger study populations, including Freitas et al. (3), Heller et al. (4), and Wissgott et al. (5) who achieved technical success rates between 27% and 68% after Rotarex alone. It should be noted that contrary to the study population of Freitas et al. (3), which mostly dealt with lesions with no or mild calcification, our study cohort had mostly moderate and severe calcifications, which may have made it more difficult to achieve a residual-stenosis-free result after primary Rotarex passage of the lesion. For PMT, intraluminal guidewire passage of the occlusion is needed, which can be more difficult in rigid and calcified lesions and furthermore might be a serious obstacle for the catheter itself to overcome. Another reason for the relatively low post-PMT technical success was our definition of technical success as residual stenosis <30%. Freitas et al. (3) defined technical success after PMT alone as the recanalization of the entire occlusion length with immediate postpassage recoil ≤50%. Nevertheless similar to Freitas et al. (3) and Wissgott et al. (5), additional implantation of a stent or stentgraft after PMT was performed in 28% and 18% of patients, respectively.

In this study, technical success (residual stenosis <30%) after PMT alone or after the use of additional devices at the end of the procedure was achieved in 60 patients (92%), which is comparable to the abovementioned large-scale studies which achieved technical success rates between 90% and 97% (3–5). Potential risk factors influencing technical success rates of Rotarex procedures have not yet been investigated. The occlusion length and duration of occlusion may have a relevant impact on technical success. In terms of lesion length, the results of Freitas et al. (3) (mean lesion length, 159 mm) and Stanek et al. (15) (n=65, mean lesion length, 100 mm) with comparably short-to-medium length occlusions and high technical success rates of 95%–97% may support the theory that shorter lesions promise better technical success rates. On the contrary, Wissgott et al. (5) achieved a comparably high technical success rate of 94% in a study population with a mean lesion length of 250 mm. The mean lesion length of our study population of 217 mm and our technical success rate of 92% are comparable to the results of Wissgott et al. (5) and not much lower than those results of Stanek et al. (15) and Freitas et al. (3). Moreover, we could not find a significant relation between technical success and the length of occlusion ($p = 0.4$). Therefore occlusion length seems to have no relevant impact on overall technical success during PMT interventions.

Concerning lesion age, the aforementioned studies solely state the numbers of acute and subacute lesions treated. The relation between the duration of an occlusion and the impact on technical success of the procedures had not been investigated. In our study, 85% were considered acute occlusions with a duration <14 days, which were 1.4 times more likely to be revascularized successfully than subacute occlusions with a duration of ≥14 days. Nevertheless, we found no significant correlation between the duration of occlusion and technical success ($p = 0.6$). Moreover, Freitas et al. (3) study, which included a more evenly distributed population with 40% acute and 60% subacute cases, also achieved an overall technical success of almost 100% (97%) suggesting that the duration of occlusion may not have a relevant impact on the technical outcome.

Thrombus density in preinterventional CTA may be another factor that influences the technical outcome of Rotarex procedures. The correlation between the thrombus density and recanalization success has been investigated in acute ischemic stroke patients so far (17, 18). Nevertheless, the few studies show varying results. Jagani et al. (18) did not find a significant relation between thrombus density in preinterventional CTA and recanalization success in stroke patients. On the contrary, in a study of 90 patients, Moftakhar et al. (17) showed that thrombus with lower HU in preinterventional CTA appears to be more resistant to mechanical thrombectomy (retriever or aspiration). In our study, we did not detect a significant difference between successful revascularization in patients with a mean thrombus density of >45 HU compared to patients having a thrombus density ≤45 HU (85%, 11/13 vs. 80%, 8/10; $p = 0.5$). Therefore, our results coincide more with Jagani et al. (18) indicating that the technical outcome of revascularization of occlusions in acute ischemic strokes and PMT interventions alike may not be influenced by thrombus density measured in preinterventional CTA.

The most common periprocedural complication in our study was PPE, which occurred in 11% of the procedures and was higher than the rates reported in the studies of Freitas et al. (3), Heller et al. (4), and Wissgott et al. (5) (5%–6%), but still comparable or lower than in other earlier studies (2). In comparison to Wissgott et al. (5) (long lesions of mean 250 mm and lower number of acute lesions, 32%) and Freitas et al. (3) (medium long lesions of mean 159 mm and lower number of acute lesions, 40%), one reason for the higher rate of thromboembolism might be the combination of long lesions (mean, 217 mm) and mostly acute occlusions not older than 14 days, in which the thrombus may still be softer than in older lesions. Regarding our study cohort, 15% of all lesions >200 mm and in 20% of all lesions with a mean thrombus density of ≤45 HU in preinterventional CTA showed PPE. Furthermore, the risk of developing PPE was significantly greater in patients with a mean lesion length >200 mm (OR, 4.5; 95% CI, 0.5–40; $p = 0.014$) and in patients with a mean thrombus density of ≤45 HU (OR, 3.0; 95% CI, 0.2–38.9; $p = 0.05$). Nonetheless, we could not find a significant correlation between the occurrence of PPE and the duration of the occlusion. Because of these results, we should be aware that PPE may occur more often in long occluded lesions with a lower thrombus density in preinterventional CTA. Therefore, the Rotarex passages should be carried out even more carefully and slowly in such cases in order to prevent distal embolization.

In our study cohort, predictive factors for PPE were longer occlusion length and a lower thrombus density compared to predictive factors of technical success, which were shorter occlusion length, shorter duration of occlusion as well as higher thrombus density. Even though the predictive factors for technical success were not statistically significant, to achieve technical success and prevent PPE during the revascularization of longer occlusions with a lower thrombus density the use of a different technical approach such as a power-aspiration-based extraction system may be more optimal. The PRISM trial showed good technical results with use of Indigo System aspiration catheters (Penumbra), especially in acute and subacute femoropopliteal occlusions (19). By power aspiration, especially in lesions with a softer thrombus, the risk for PPE may be very low and even if a distal PPE occurs it can be aspirated with the same device. Nevertheless, to our best knowledge, there is currently no data regarding power aspiration systems compared to PMT and predictive factors for technical success as well as PPE.

Immediate postinterventional clinical results and 12-month follow-up results are consistent with correlated studies (2, 3, 5, 15). The patency rates of the Wissgott et al. (5) study, which had a mean lesion length of >200 mm (54%–57% primary patency and 82%–86% secondary patency depending on acute or subacute patient group) matched our results most closely, which showed 57% primary patency and 75% secondary patency.

In line with the studies of Freitas et al. (3) and Wissgott et al. (5) we found a comparably low major amputation rate of 1.5% (n=1) owing to failed revascularization. In the period of 12-month follow-up no further amputation was reported.

In comparison to the abovementioned studies, we found a comparably low rate of minor complications such as subcutaneous hematoma or pseudoaneurysm (3, 5).

The main limitation of this study is its retrospective nature and the relatively small study population. The subgroup analysis of thrombus density in relation to technical success and PPE is particularly limited by the small sample size of these subgroups and therefore the study outcome may not be extrapolated to a greater study population. Furthermore, in our study population *de novo*, in-stent/stentgraft, and bypass occlusions were not separately examined, which might weaken the comparability of our results with the results of other studies. Nevertheless, as in the Heller et al. (4), by including all types of femoropopliteal occlusions we achieved realistic results based on a real-life patient cohort we have treated throughout a longer time-span.

In conclusion, the Rotarex percutaneous mechanical rotational thrombectomy represents an effective and safe modality for treating acute and subacute occlusions of peripheral arteries and bypasses with satisfactory immediate and long-term results. Furthermore, duration of the occlusion seems to have no influence on the risk for PPE. The duration of occlusion, occlusion length and thrombus density showed no significant impact on technical outcome. The risk for PPE in long occlusions is significantly higher than in shorter occlusions. Moreover, PPE is significantly higher in *de novo* occlusions with a lower thrombus density measured in preinterventional CTA than those with a higher thrombus density. Therefore, when treating long occlusions with a lower thrombus density, PMT should be carried out with particular care in order to prevent distal embolization.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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