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Immediate changes of microperfusion during angioplasty of the lower limb arteries

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Abstract

The success of lower-limb revascularization in peripheral artery disease (PAD) is usually assessed by vessel patency, while tissue-level perfusion is not routinely monitored during the procedure. We examined whether continuous microcirculatory monitoring could detect immediate perfusion changes during angioplasty. In this prospective single-center observational study, 25 patients with symptomatic PAD undergoing technically successful percutaneous revascularization were evaluated. Microvascular blood flow (Flow), postcapillary oxygen saturation (SO_2), and relative hemoglobin content (rHb) were continuously measured at the forefoot using combined laser Doppler flowmetry and white-light spectrophotometry (O2C). All three parameters peaked during reactive hyperemia after balloon deflation ($P < 0.001$ for changes over time). Flow and SO_2 remained significantly elevated at the end of the procedure, while rHb returned to baseline. By the next day, all three parameters were comparable to baseline despite a significantly improved ankle–brachial index ($P < 0.001$), patent treated lesions, and improved Rutherford category on follow-up ($P < 0.001$). Successful revascularization was thus associated with immediate but transient changes in resting, supine microcirculatory measurements. Continuous O2C monitoring captures transient intraprocedural microcirculatory responses that complement conventional postprocedural assessments of vessel patency and macrocirculatory hemodynamics. Larger studies are needed to determine whether these dynamic responses can guide revascularization or predict clinical outcomes.

Introduction

Angioplasty of the lower limb arteries is a common procedure to restore blood flow in patients with peripheral artery disease (PAD). Although the prevalence of cardiovascular diseases and the number of catheter-based revascularization procedures for PAD are increasing worldwide [1,2], procedural success is typically assessed by morphological criteria, such as vessel patency or residual stenosis, without consideration of real-time functional perfusion data. However, microcirculation and oxygenation within the tissue are essential for clinical improvement and limb salvage.

While angiographic and hemodynamic parameters such as the ankle-brachial index (ABI) and angiographic patency are commonly used to evaluate the success of angioplasty procedures, these parameters provide only indirect insight into microcirculatory tissue-level perfusion. At the same time, microcirculatory integrity is a crucial determinant of wound healing and limb salvage, particularly in patients with chronic limb-threatening ischemia (CLTI) [3–5]. Previous studies have shown that macrovascular improvement does not always correlate with restored microvascular function or clinical benefit. Gerken et al. demonstrated significant improvements in microcirculatory oxygenation and blood flow after peripheral revascularization assessed by the laser Doppler spectrophotometry device oxygen-to-see (O2C), suggesting its potential as a more sensitive surrogate marker [6]. Despite these insights, most studies assess microcirculation only at pre- and postprocedural timepoints, leaving a gap regarding standardized real-time intraoperative perfusion monitoring [7].

Addressing this gap, a systematic review by Wermelink et al. (2021) [7] identified ten intraoperative techniques for assessing microcirculation. These techniques included laser speckle contrast imaging (LSCI), microlightguide spectrometry, magnetic resonance imaging perfusion and laser Doppler flowmetry, but highlighted methodological limitations. These included heterogeneous study designs, inconsistent measurement time points, and insufficient validation against clinical outcomes. Similarly, Wermelink et al. (2022) [8] explored intraoperative microcirculatory monitoring using LSCI in patients with critical limb-threatening ischemia. Although LSCI proved technically feasible and reproducible, no significant correlation with clinical outcomes was found. This may be due to methodological limitations, such as anesthetic effects, lack of baseline control, or population heterogeneity. Complementing this perspective, Boezeman et al. (2016) [9] provided additional evidence for the feasibility and safety of intraoperative microcirculatory monitoring using near-infrared spectroscopy (NIRS) during endovascular lower limb revascularization in CLTI patients. In their prospective observational study, they successfully obtained, real-time measurements of tissue oxygen saturation (StO_2) at two foot-level sites. While single NIRS measurements of StO_2 significantly increased four weeks after endovascular revascularization, indicating improved microcirculatory perfusion, continuous intraoperative StO_2 monitoring did not reveal consistent changes during the procedure itself. Moreover, the microvascular StO_2 showed no significant correlation with traditional macrocirculatory parameters such as the ankle-brachial index (ABI) and toe-brachial index (TBI), which were significantly elevated postinterventionally. These findings not only highlight a dissociation between macro- and microcirculatory improvements but also expose key limitations of angiographic and hemodynamic assessment tools, such as digital subtraction angiography (DSA), ABI, and TBI, which primarily reflect large-vessel patency while failing to capture perfusion status at the level of the ischemic target tissue. A recently published prospective study by Kluckner et al. [10] investigated the benefit of pre- and post-interventional fluorescence imaging (FI) with indocyanine green (ICG) in comparison with transcutaneous oxygen pressure ($TcPO_2$). The authors concluded that FI was not reliable for detecting perfusion improvements or predicting clinical outcomes.

In summary, there is currently no validated standard for real-time intraoperative monitoring of microcirculatory oxygenation, reinforcing the need for more sensitive, tissue-level perfusion assessment tools in patients with CLTI that extend beyond morphological criteria alone. The continuous intraoperative assessment of microcirculatory changes remains rare and poorly standardized. Despite its potential to guide decision-making and improve the prediction of clinical outcomes, continuous O2C-based microperfusion monitoring has not yet been validated as a prognostic tool. Whether these dynamic measurements can reliably predict procedural success or patient outcomes remains an open question and a potential opportunity to improve intraoperative decision-making in peripheral revascularization, particularly for patients at high risk of limb loss.

This study proposes that assessing O2C microcirculatory parameters, measured directly and continuously during angioplasty, reveals immediate, procedure-associated hemodynamic changes. The objective of this study is to investigate, whether effective restoration of macrocirculatory blood flow is

directly reflected in improved microcirculatory perfusion of the affected limb, and whether these quantitative parameters can serve as intraprocedural predictors of both clinical and technical outcomes.

Methods

Study design, patient selection and revascularization procedure

This prospective, single-center observational study was conducted at the Interdisciplinary Vascular Center of the University Medical Center Mannheim, Germany between May and September 2024. Patients over the age of 18 years with symptomatic PAD undergoing PTA of lower limbs were consecutively enrolled. Inclusion criteria comprised Rutherford clinical category 2–5 with clinical indications for intervention. Exclusion criteria encompassed acute systemic or foot infection, severe heart failure and limb edema. The study protocol was approved by the responsible Medical Ethics Commitee II of the Medical Faculty Mannheim (ID 2024 – 566), adhered to the declaration of Helsinki, and was and registered at DRKS (DRKS00039358, date of registration: 2026-02-17, https://drks.de/search/de/trial/DRKS00039358). Written informed consent was obtained from each patient included in the study.

Current recommendations, technical strategies, and antithrombotic therapy recommendations were the basis for percutaneous revascularization. Following antegrade, retrograde, and crossover femoral approaches, both uncoated and coated balloons and stents were used.

A one-time one-minute balloon inflation time was intended but could be repeated or extended to up to two minutes in individual cases according to the interventionalist's decision. No significant residual stenoses of the iliac and FP arteries were noted in the final angiographies.

Microvascular assessment

Microcirculatory parameters were recorded using the spectrophotometry device oxygen-to-see version III (O2C, LEA Medizintechnik GmbH, Giessen, Germany), which combines white light spectrometry (500–630 nm) and laser Doppler flowmetry (830 nm)[11].

Briefly, in the latter, a laser beam is directed onto the tissue. Moving blood cells within the blood vessel cause a frequency shift (Doppler effect) of the reflected light, providing information on the microvascular blood flow ("Flow", arbitrary units). In white light spectrometry, the absorption of light by the tissue at different wavelengths is measured. This allows for the determination of post-capillary hemoglobin oxygen saturation (SO2, %), and relative microvascular hemoglobin content (rHb, in arbitrary units).

At the beginning of the intervention, the LFX-29 O2C probe (LEA Medizintechnik GmbH, Giessen, Germany) was securely attached at the dorsum of the forefoot near the big toe using double-sided

adhesive tape (LTDT-001; LEA Medizintechnik GmbH, Giessen, Germany). All measurements were carried out following a standardized protocol, after at least ten minutes of rest in the supine position with the leg positioned horizontally. The complete sterile covering of both limbs and the darkened measuring probe environment also prevented measurement interference from ambient light.

The microcirculatory parameters (Flow, SO2, and rHb) were measured continuously, allowing real-time detection of perfusion changes. The measurements from three predefined time points were included in the analysis: PRE (before the revascularization procedure); MAX (at the time of intraprocedural maximum values, which was expected in the phase of reactive hyperemia after balloon angioplasty); PERI (at the end of the revascularization procedure and before removing the catheter sheath). In addition, the measurement was repeated on the first post-procedural day under similar conditions: POST (at the same site with the probe covered after a resting time of at least 10 minutes and the limb in the horizontal position).

Macrovascular assessment

The ankle-brachial index (ABI) was measured pre- and post-intervention (on the first post-procedural day) using Doppler ultrasound. Both minimal and maximal ABI values of the treated limb were documented to assess macrocirculatory improvement. The ABI was calculated as the ratio of the highest systolic ankle pressure to the highest systolic arm pressure, as recommended by recent guidelines[12]. Moreover, the patency of the treated lesions was determined with duplex ultrasonography (defined as peak velocity ratio smaller than 2.4 at the target lesion) the day after the procedure.

Endpoints and Follow-up

The study focused on immediate and early post-procedural changes in microcirculatory parameters. The primary endpoints were the intraprocedural microcirculatory parameter SO2, Flow and rHb at maximum, at the end of the procedure and the next day compared to baseline. Secondary endpoints were the ABI shift and the Rutherford category shift (difference between follow-up as compared to baseline). Follow-up times were set at 1–3 months for patients with IC and 3–6 months for patients with CLTI.

A percutaneous revascularization procedure was defined as technically successful if angioplasty was possible and no flow-limiting residual occlusion, stenosis, or dissection of the target lesions were noted in the completion angiograms. Hemodynamically successful revascularization was defined as a significant improvement in the post-interventional ankle–brachial index (POST ABI) compared with the pre-interventional value (PRE ABI). Clinically successful revascularization was defined as a decrease in Rutherford category in patients presenting with intermittent claudication or rest pain.

Statistical analysis

Categorical data are presented as counts and percentages, continuous variables as means ±standard deviations (SD) or as medians with interquartile ranges, depending on their distribution (assessed by the Shapiro-Wilk test). The sample size was calculated prior to our analysis. The outcomes were changes of intra- or early postinterventional microcirculatory parameters, changes of ABI values, and changes of the Rutherford category at follow-up compared to baseline. Assuming a medium effect (Cohen's D = 0.6), a sample size of 24 was required to detect statistically significant differences (alpha = 0.05, power = 0.8, 2-sided paired t-test). To analyze the effect of revascularization on the ABI, a paired t-test was used. To analyze the change in Rutherford category from PRE to follow-up, the Wilcoxon signed-rank test was used. For analyses involving multiple time points (PRE-MAX-PERI-POST), repeated measures analysis of variance (ANOVA) was conducted. In cases where significant effects were observed, post hoc comparisons were conducted using the Bonferroni test to identify specific differences between time points. A p-value < 0.05 was considered statistically significant. Data analysis, graph generation, and statistics were performed using Excel and PowerPoint (Microsoft Corporation, USA), numiqo (numiqo, Austria), and SPSS Statistics 23 (SPSS Inc., USA).

Results

A total of 32 people were examined, five of whom were excluded due to severe mediasclerosis with incompressible arteries. A total of 27 patients with symptomatic PAD underwent percutaneous interventions. In two patients, percutaneous recanalization attempts failed, and the data were excluded from subsequent analysis. Figure 1 shows representative continuous recordings of microcirculatory parameters during a technically successful revascularization and a failed recanalization attempt.

Clinical characteristics

A total of 25 patients (16 patients with IC and 9 patients with CLTI) with technically successful revascularization were included in the subsequent analysis. Baseline demographic and clinical characteristics are summarized in Table 1.

Table 1
Baseline characteristics of the patients with symptomatic peripheral arterial disease (n = 25)

Patients	**Number (%)**
Age, years	71.8 ± 10.0
Male	16 (64)
Peripheral arterial disease	
Rutherford category	
2	1 (4)
3	15 (60)
4	4 (16)
5	5 (20)
Prior percutaneous or open-surgical revascularization	
yes	13 (52)
no	12 (48)
ABI[a]	
Lower ABI	0.57 ± 0.26
Higher ABI	0.83 ± 0.19
Crural-vessel runoff	
0	4 (16)
1	8 (32)
2	3 (12)
3	10 (40)
Cardiovascular comorbidities and risk factors	
Cerebral vascular disease[b]	8 (32)
Coronary artery disease[c]	10 (40)
Chronic kidney disease[d]	13 (52)
Tobacco smoking history	19 (76)
Diabetes mellitus	11 (44)
Arterial Hypertension	24 (96)

Patients	Number (%)
Dyslipidemia	23 (92)

Data presented as mean ± standard deviation or absolute numbers and proportions (%).

[a]The ankle-brachial index (ABI) of the clinically most affected (and revascularized) side is indicated.

[b]History of transient ischemic attacks or stroke, present (sonographically ≥ 50% stenosis) or previously revascularized carotid stenosis.

[c]Invasive angiographically proven coronary artery disease

[d]defined as chronically decreased calculated glomerular filtration rate < 60 mL/min/1.73m^2

In Table 2, the intraprocedural characteristics of the percutaneous interventions are summarized.

Table 2
Procedural characteristics

Parameter	Number (%)
Side of revascularization	
left	14 (56)
right	11 (44)
Site of revascularization[a]	
iliac	7 (28)
femoropopliteal	19 (76)
cruropedal	3 (12)
Postprocedural crural-vessel runoff	5 (20)
0[b]	1 (4)
1	11 (44)
2	3 (12)
3	10 (40)
[a]multiple mentions possible	

[b]Due to sufficient collateral distal runoff, the interventionalist decided against additional cruropedal recanalization of native arteries.

Microcirculatory parameters

One-way analyses of variance with repeated measures showed that there were significant differences between the microcirculatory flow, SO2 and rHb at different time points (each $p < 0.001$).

Pairwise Bonferroni post-hoc analysis revealed significant higher MAX and PERI Flow (Fig. 2a) and SO2 (Fig. 2b) values, while POST values were similar compared to baseline.

The median values of Flow and SO2 at baseline were 34 AU and 30%, respectively, each without significant differences between the IC and CLTI subgroups.

Post-hoc analysis showed significantly higher MAX rHb values (Fig. 3) compared to baseline. In contrast to Flow and SO2, the PERI rHb did not significant differ from PRE values.

Ankle-brachial and Rutherford category changes

The ABI values measured the day after the revascularization procedure (POST), were significantly higher than the PRE values (paired t test; $p < 0.001$; Fig. 4a). The effect size (1.0529) indicated a large effect. Rutherford category decreased significantly from PRE to follow-up, with a median Rutherford category of 3 at PRE versus 0 at follow-up (Wilcoxon signed-rank test; $p < 0.001$; Fig. 4b). In 20 of 25 patients the category improved, five remained unchanged, and none worsened.

Discussion

In this prospective study, we examined real-time changes in hemodynamic microcirculatory perfusion parameters during and after percutaneous revascularization in patients with PAD Rutherford categories 2–5. The results show measurable/significant immediate (temporarily detectable) changes of microcirculation and tissue oxygenation in the horizontal position after technically and clinically successful macrocirculatory percutaneous revascularization:

1) Immediately after iliac or femoropopliteal balloon inflation, the three microcirculation parameters Flow, SO2 and rHb reached their maximum value.

2) The increase of Flow and SO2 was prolonged until the end of the procedure (before sheath removal and manual compression of the puncture site), while rHb immediately returned to baseline level.

3) One day after the intervention, no more microcirculatory changes were detectable compared to the initial value in the horizontal leg position at rest, although Doppler ultrasound, ABI measurement, and clinical follow-up confirmed successful recanalization of the target vessels.

The results support our hypothesis that effective revascularization of lower limb arteries is directly reflected in improved tissue perfusion of the foot. Based on these findings, we propose three distinct phases of microcirculatory change: reactive hyperemia, reperfusion, and microcirculatory adaptation.

Reactive hyperemic brachial flow is as well-known indicator of vascular function and cardiovascular risk [13], also in patients with PAD undergoing vascular surgery [14]. Moreover, it provides information on endothelial function or collateral circulation [15], while its role in intraprocedural guidance is currently unclear. A previous publication by Jarm et al. [16] demonstrated that the microcirculatory flow pattern of reactive hyperemia differed between patients with PAD and healthy subjects. As reflected in LDF and NIRS, microcirculatory flow over time increased more slowly and had a lower amplitude during postocclusive hyperemia, depending on the severity of PAD and the duration of occlusion, confirming the results of Matsubara et al. [17] The $TcPO_2$ method, however, could not detect these early postocclusion differences in the phase of reactive hyperemia. Additionally, continuous intraprocedural NIRS monitoring was not suitable for reflecting hemodynamic changes during balloon inflation and deflation.

The advantage of O2C spectrophotometry over alternative methods, is that it enables the noninvasive assessment of three dimensions of microcirculation using a single probe noninvasively. Over the last two decades, the device has been constantly improved for clinical application. Measurements can be performed continuously or at a standardized predefined point in time. The presented continuous intraprocedural measurements show that all three O2C microcirculatory parameters of microcirculation (Flow, SO2 and rHb) reached their maximum in the phase of reactive hyperemia after standardized (occlusive) balloon angioplasty/deflation and subsequent restoration of the blood flow in the target arterial segment with “unrestricted” inflow of blood in the peripheral tissue. As clearly observable in Fig. 1, there were no relevant changes in failed attempts of percutaneous recanalization. While rHb values had already decreased by the end of the intervention, all microcirculation parameters were back to the initial level the following day, when measured in the horizontal limb position at rest during microcirculatory adaptation. Therefore, the diagnostic window in which the peripheral microcirculation reflects the success of macrocirculatory revascularization appears to be limited. However, this could be the “window of opportunity” for non-invasive hemodynamic monitoring and intraprocedural guidance of revascularization procedures.

As far as postinterventional measurements in the phase of adaptation are concerned, Woo et al., identified a threshold of 40mmHg TCPO to predict wound healing in CLTI patients after revascularization [18]. For SO2, a threshold of 30% has been associated with successful wound healing [5]. Kluckner et al. found that oxygen pressure measured by TcPO2 postinterventionally is a more suitable predictor of the outcomes of revascularization compared to FI with ICG [10]. Therefore, TcPO2 and SO2 seem to be more suitable methods to reflect the improvement of skin perfusion postinterventionally during the period of microcirculatory adaptation. In our study, mean SO_2 increased from 34% at baseline to 39% at the postinterventional measurement, although this difference did not reach statistical significance. Rother et al. performed pre- and postinterventional O2C measurements after angioplasty of below-the-knee arteries. In congruence with our results, a significant improvement of global SO2 and Flow was observed immediately after the intervention in the phase of reperfusion in a cohort of 30 CLTI patients [19] (Rother 2017). In the present study, the median values of Flow and SO2 at baseline (34 AU and 30%, respectively) were rather low within a wide range of baseline values. Previous studies revealed median SO2 values of

57% in patients with IC and mean values of 46–51% in patients with CLTI [6,20]. This is partially in line with a study published by Gerken et al., which showed that microvascular flow improved immediately after successful open or endovascular revascularization, but SO2 was significantly improved in the elevated position at follow-up compared to the preoperative status. The variance of baseline values could be explained by probe position, measurement conditions and positioning. Additionally, local anesthesia was found to influence O2C values in arteriovenous fistula creation [21].

Limitations

Although we were able to demonstrate significant effects of the intervention on intraprocedural O2C values of microperfusion, the validity of this primary study is limited due to the small number of patients included. In general, it appears that the O2C spectrophotometry device is a sensible method to depict intraprocedural changes. However, further research is necessary to define threshold values for intraoperative guidance. As already mentioned, the absolute values presented here should be interpreted with caution, as there seems to be a large variance of baseline values among different publications. Relative changes should be calculated in addition to absolute values in future investigations. Therefore, it is crucial to assess baseline values before the intervention. Furthermore, the characteristics of patients with diabetes should be captured in more detail. A distinction between type 1 and 2 diabetes, insulin dependence, or further complications of diabetes could explain more causal relationships between microcirculation and PAD with coexisting diseases altering the quality of microperfusion. A subgroup analysis was not feasible in this trial. Further prospective studies should be carried out to confirm the preliminary findings of this study and improve the homogeneity of data.

Conclusions

In conclusion, successful percutaneous interventions led to a significant improvement of hemodynamic microcirculatory perfusion parameters, which was detectable only for a limited period congruent with postocclusive reactive hyperemia. The results indicate the importance of the optimal time frame for periprocedural monitoring to ensure valid interpretations. Further investigation is warranted to evaluate the predictive value of O2C spectrophotometry and its potential for intraprocedural guidance of the extent of revascularization procedures.

Declarations

Data availability: The research data are available from the corresponding author upon request.

Author contributions statement:

Conceptualization, Martin Sigl and Loïs Eissele.; methodology, Martin Sigl and Andreas L.H. Gerken; investigation, Martin Sigl and Loïs Eissele.; data curation, Loïs Eissele; writing—original draft preparation, Loïs Eissele, Yasmin Zeidan, Laurin Gerdes and Andreas L.H.- Gerken; writing—review and editing, Christoph Reißfelder and Kay Schwenke; funding acquisition, none.

Additional Information:

Competing interests statement: The authors declare no competing interests.

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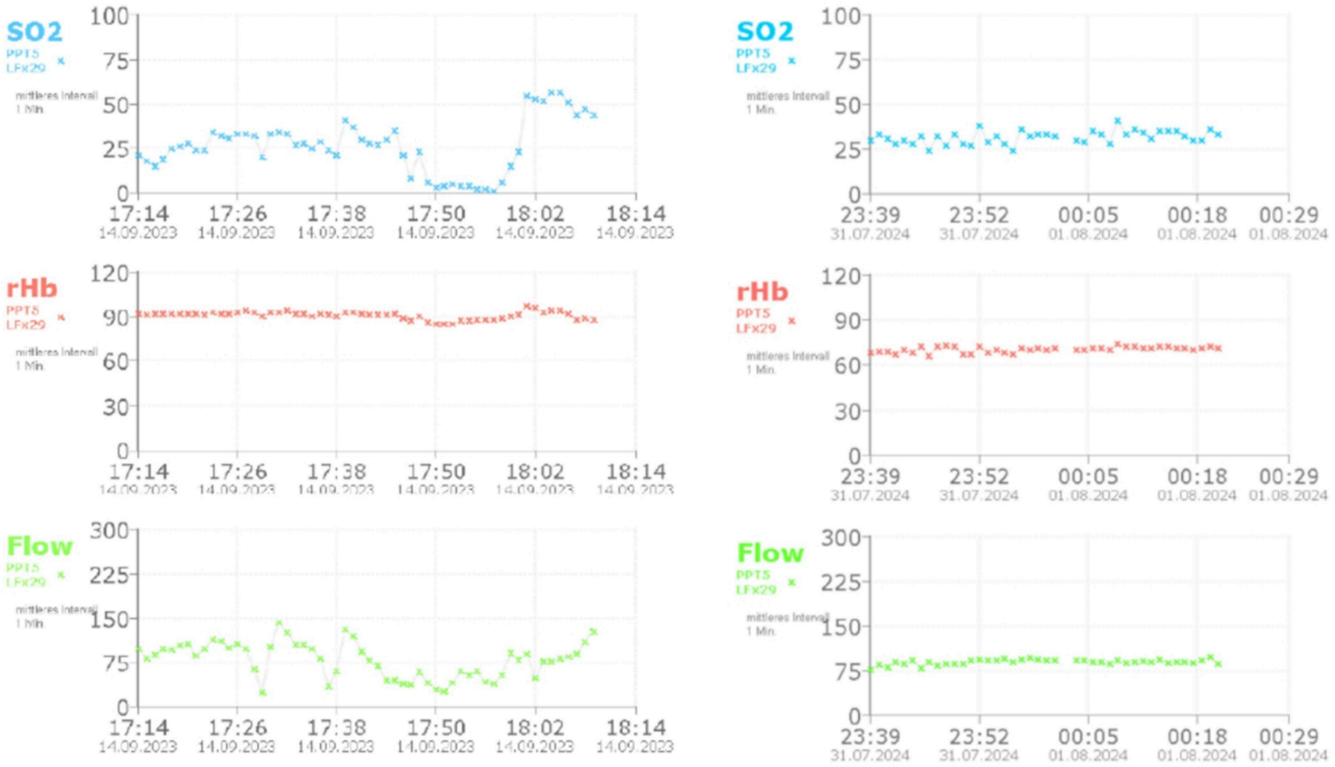
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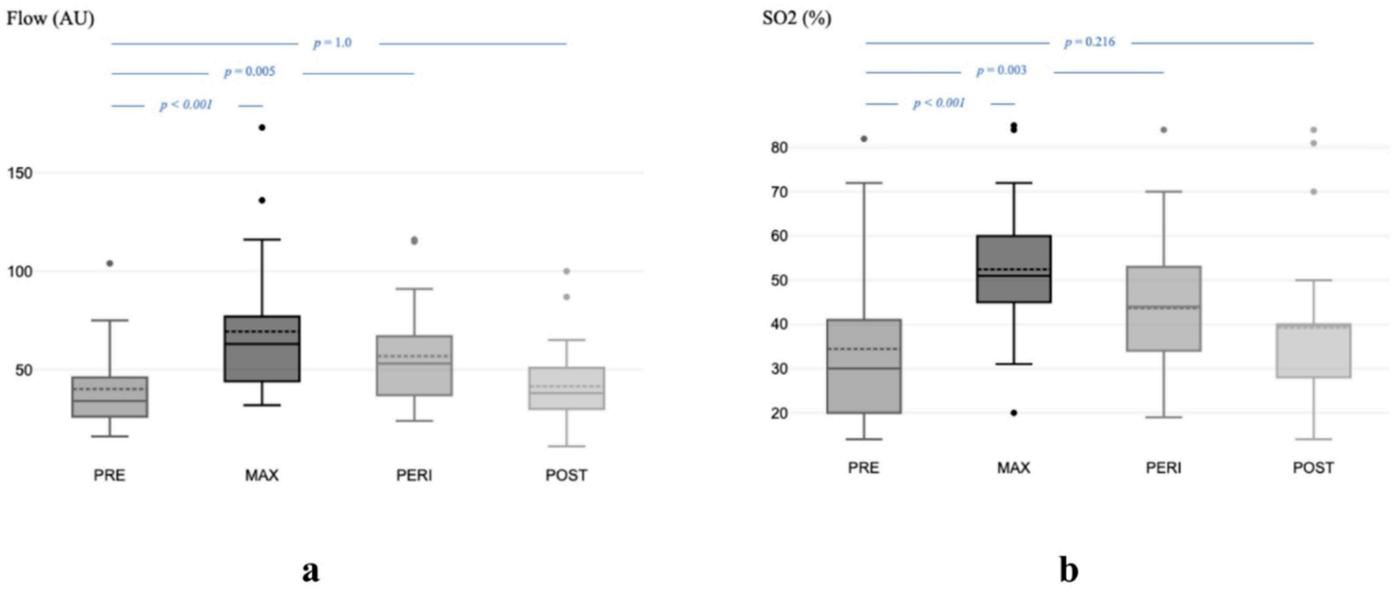
Figures



a b

Figure 1

Continuous recording of microcirculatory parameters during percutaneous angioplasty of the lower limb arteries demonstrating the difference between hemodynamically successful (a) and failed (b) recanalization attempts.



a b

Figure 2

Microvascular blood flow (Flow) (a) and oxygen saturation (SO2) (b) at sequential time-points during the percutaneous revascularization procedure: preinterventional (PRE), at the time of the maximal flow or SO2 (MAX), respectively, at the end of the intervention (PERI), and the following day (POST). A one-way analysis of variance with repeated measures revealed significant difference between the variables ($p < 0.001$); p values for pair-wise comparison are indicated (Bonferroni Post-hoc-Test). AU: arbitrary units

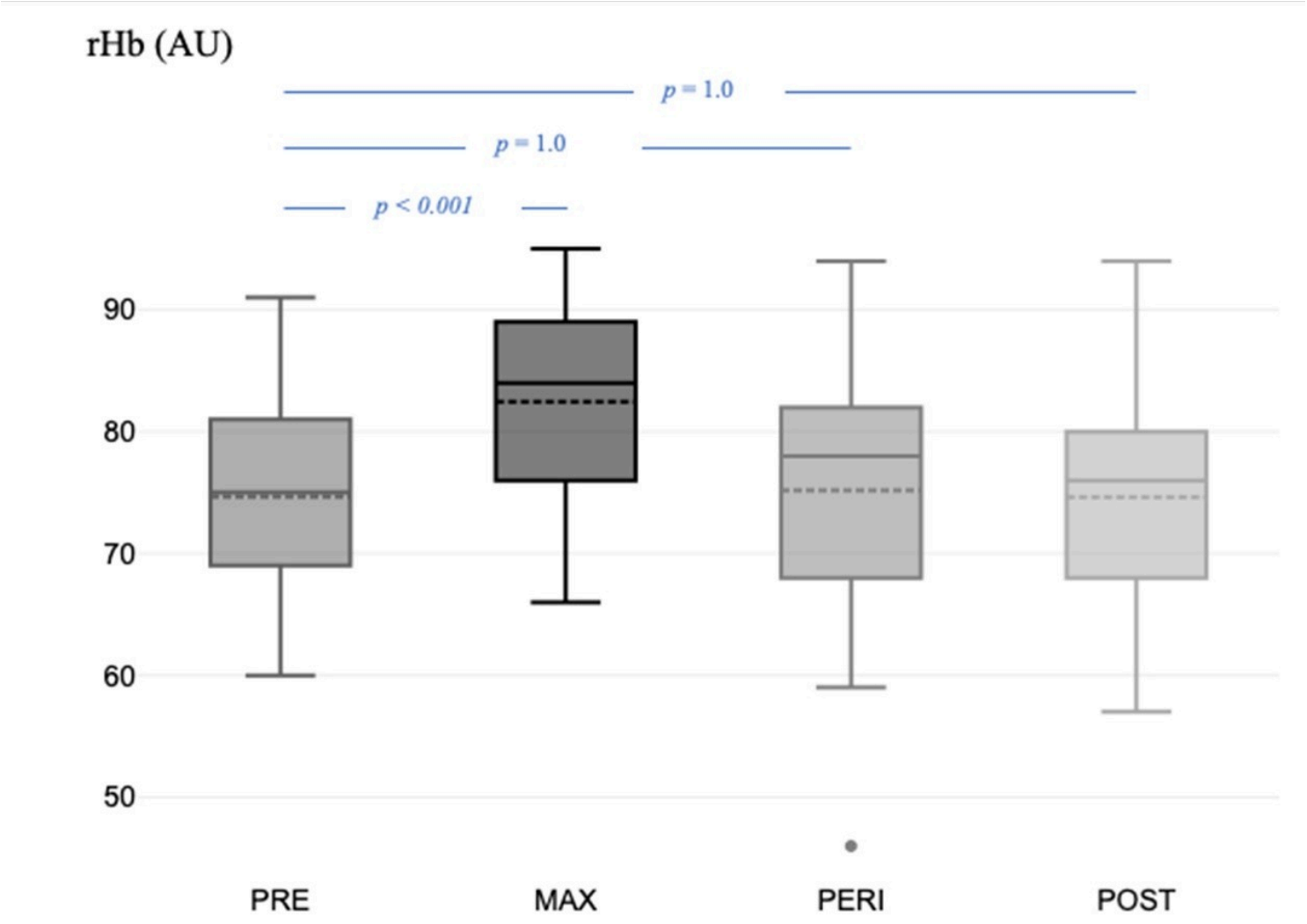


Figure 3

Microvascular relative hemoglobin content (“rHb”) at sequential time-points during the percutaneous revascularization procedure: preinterventional (PRE), at the time of the maximal rHb (MAX), at the end of the intervention (PERI) and after 24h (POST). A one-way analysis of variance with repeated measures ($p < 0.001$) followed by pair-wise comparison revealed significantly higher rHb values only for the MAX values compared to baseline. AU: arbitrary units

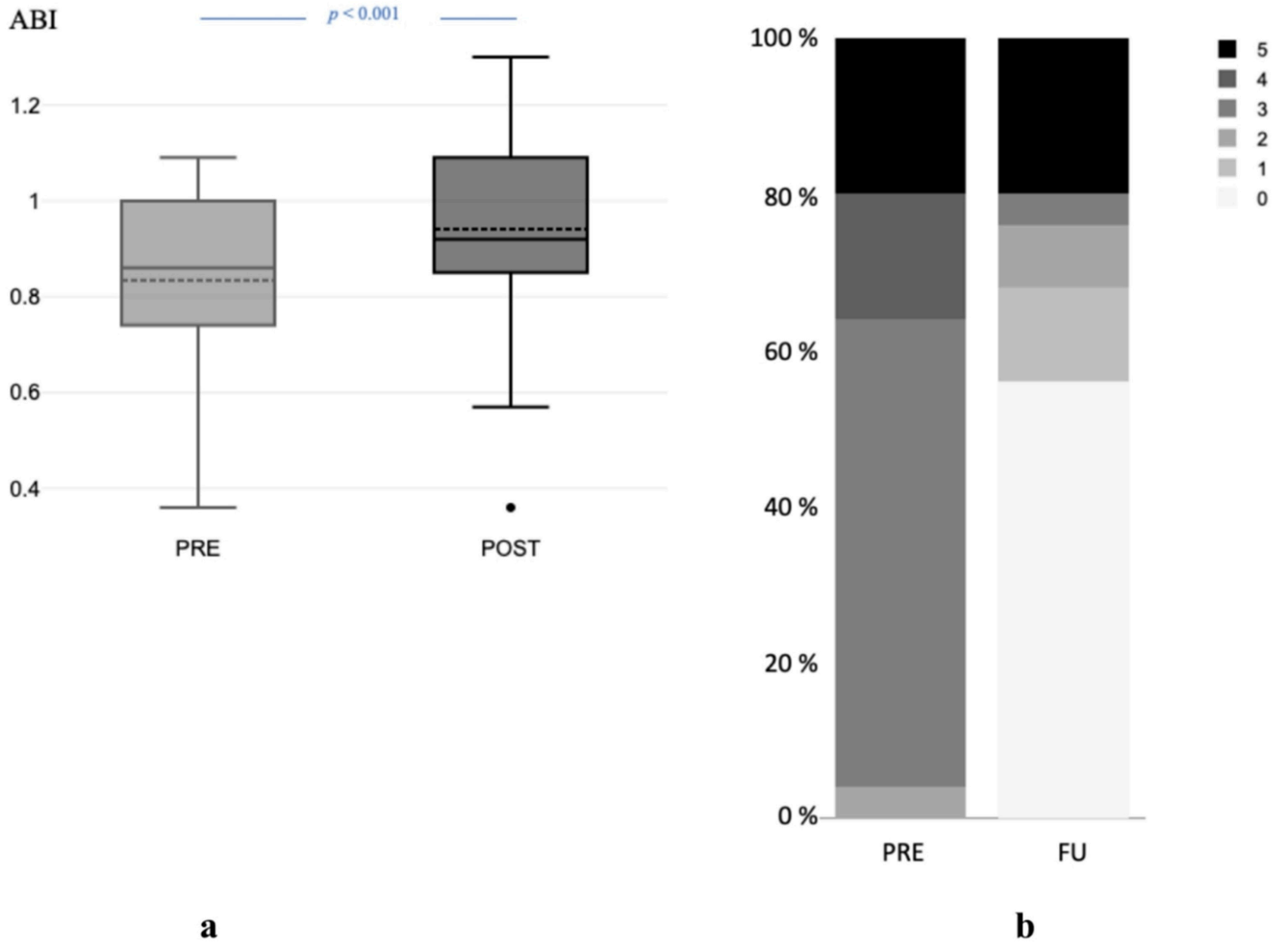


Figure 4

Changes in the higher ankle–brachial index (ABI) of the treated limb from baseline (PRE) to the day after the procedure (POST) (a), and Rutherford category shift from baseline to follow-up (FU) (b). ABI increased significantly from PRE to POST (paired t test; $p < 0.001$), and Rutherford category decreased significantly from PRE to FU (Wilcoxon signed-rank test; $p < 0.001$).