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Repeatability, and Intra-Observer and Interobserver Agreement of Two Dimensional Perfusion Angiography in Patients with Chronic Limb Threatening Ischaemia

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WHAT THIS PAPER ADDS

This is the first study to test the reliability of two dimensional perfusion angiography in patients with chronic limb threatening ischaemia. The results show that it is a reliable tool when using it according to standardised methods. With the results from this study, future research can be performed to investigate the relation between perfusion angiography and clinical outcomes.

Objective: Two dimensional (2D) perfusion angiography is a method that provides quantitative foot perfusion information from standard digital subtraction angiography acquisitions. The aim of this study was to test the reliability of this method in patients with chronic limb threatening ischaemia (CLTI) by investigating repeatability, and intra-observer and interobserver agreement.

Methods: Twenty patients with CLTI and a below the knee endovascular revascularisation were included in a prospective clinical study. Prior to treatment two perfusion angiography runs were acquired with a five minute interval without performing an intervention. In these recordings, regions of interest were selected and time density curves and perfusion parameters were determined. To investigate intra-observer agreement one observer performed five measurements on the same acquisition for each patient. To investigate interobserver agreement three observers performed measurements on the same acquisition for each patient. Results were presented in Bland–Altman plots and as the intraclass correlation coefficient per parameter.

Results: Two patients were excluded from repeatability analyses because of major motion artefacts. Repeatability analyses of the 18 remaining patients showed excellent correlation for every parameter ($>$ .96). Intra-observer and interobserver agreement for all 20 patients were excellent for all parameters (1.00).

Conclusion: Repeatability and intra-observer and interobserver agreement of 2D perfusion angiography in patients with CLTI were found to be excellent. It is therefore a reliable tool when used according to the standardised methods described in this study.

Keywords: 2D perfusion angiography, Chronic limb threatening ischemia, Interobserver agreement, Intra-observer agreement, Repeatability
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INTRODUCTION

Chronic limb threatening ischaemia (CLTI) is characterised by ischaemic rest pain, chronic wounds or gangrene.[1] The aim of CLTI treatment is to prevent major amputations, relieve rest pain, and achieve wound healing by means of optimisation of arterial perfusion, treatment of concomitant infection, and optimal wound care management. The clinical results of surgical and endovascular revascularisation are largely unpredictable, as demonstrated by high rates of failed or delayed wound healing, limb amputation, and repeat interventions.[2–4] In the majority of cases an endovascular revascularisation has become the first line treatment, but there is great variability in revascularisation strategies. Some interventionists select the target vessels based on the wound related artery concept according to the angiosome model; others revascularise as many arteries as possible, while some use the "best target artery approach" and choose the artery "that is the easiest to treat".[5–7]

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Technical success is often judged on experience and visual assessment of flow through the below the knee (BTK) arteries, the pedal arteries, and wound blush on digital subtraction angiography (DSA). In an attempt to predict wound healing and thereby optimise endovascular treatment of patients with CLTI, non-invasive measurements such as toe pressures, transcutaneous oxygen measurement, or near infrared spectroscopy have been investigated.[6,8] Unfortunately, these do not correlate well with wound healing and are generally not available during the procedure.

Recently, SmartPerfusion Rel. 1.0 (Philips Healthcare, Best, the Netherlands) has become available. It is a software tool that generates quantitative, functional perfusion information from standard DSA images. Several studies have demonstrated the ability of two dimensional (2D) perfusion angiography (2DPA) to quantify perfusion changes after successful revascularisation procedures (endovascular or bypass).[9–14] Another study investigated the functionality of the microcirculation in diabetic patients with 2DPA and demonstrated that a non-responsive system was a predictor of major amputation.[15] However, the results of the aforementioned studies should be interpreted with some caution because the reliability of 2DPA in patients with CLTI is unknown. Therefore, the aim of this study was to study the reliability of 2DPA for patients with CLTI by investigating repeatability, and intra- and interobserver agreement.

METHODS

Study design and population

The REPEAT study (Reproducibility and rEliability of Perfusion angiography and prEdiction of wound heAling in criTical limb ischaemia) is a prospective single centre study investigating 2DPA in patients with CLTI (Dutch trial registry: NTR6615). This study investigates the reliability of 2DPA and the correlation between perfusion changes measured with 2DPA and clinical outcomes. The reliability results are presented in this article. The correlation with clinical outcomes is ongoing and beyond the scope of this article.

The study was approved by the Medical Research Ethics Committees United, and all participants gave written informed consent before the revascularisation procedure. Included were patients diagnosed with CLTI by means of clinical examination, toe pressure measurement, duplex, or computed tomography angiography/magnetic resonance angiography imaging according to the TASC II working group document,[16,17] and who were scheduled for endovascular revascularisation. Patients who were scheduled or anticipated to have a major amputation were excluded. Other exclusion criteria were renal insufficiency (estimated glomerular filtration rate $<$ 30 mL/minute per 1.73 m^2), severe iodine based contrast medium allergy, inability or unwillingness to give written informed consent, or inability to position the foot in the footrest during the revascularisation procedure. Patients were excluded pre-procedurally for distal thrombo-embolic complications as a result of inflow treatment or when only treatment of above knee stenotic or occlusive disease was performed. In the latter case the improvement of blood flow was expected to be sufficient to obtain a satisfactory clinical outcome. In these cases, no 2DPA acquisitions were performed.

Acquisition protocol

Patients were placed in supine position with the index foot in a footrest fixed with Velcro bands (Fig. 1). A sciatic popliteal nerve block was administered when it was anticipated that major foot movements as a result of ischaemic pain or contrast administration would influence the revascularisation procedure. This was per local protocol and at the operator's discretion. After the introduction of the sheath, 5 000 U heparin was administered. Prior to and during the two acquisitions no other medications were administered. Iliac or femoral inflow lesions were treated first during the same session. After treatment of all inflow lesions, a long introducer sheath (6 Fr) was positioned at popliteal level ensuring that the tip of the sheath was 2 cm proximal to the origins of the BTK arteries. Per protocol, if the sheath caused a flow limiting obstruction it was repositioned at a more proximal level (P1 segment of the popliteal artery or distal superficial femoral artery). Contrast agents (Xenetix 300 mg I/mL (Iobitridol 658 mg/mL) or Visipaque 320 mg I/mL (Iodixanol 652 mg/mL) were heated to 37°C prior to injection and administered with a power injector (total volume 9 mL, flow rate 3 mL/second at 450 psi). Within each patient the same contrast medium was used.

For this study, two lateral projections were acquired with a five minute interval without performing any intervention, with the same table settings, sheath position, and power injector settings. 2DPA acquisitions were acquired with the SmartPerfusion Rel. 1.0 software (Philips Healthcare). Acquisitions were acquired with a frame rate of three frames per second. The duration of the acquisition was determined by the operator but was at least 20 seconds. During the procedure operators were blinded to the 2DPA results.

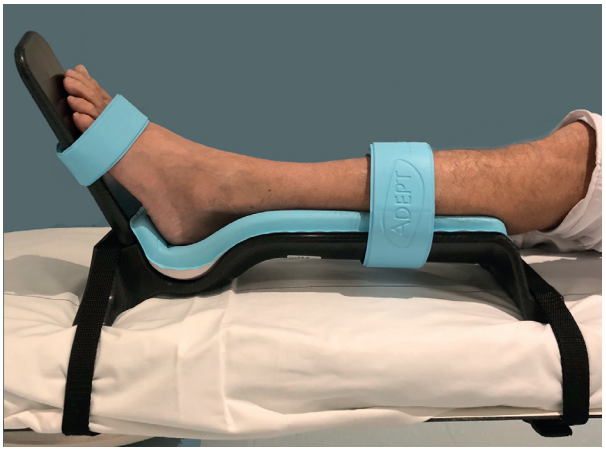

Figure 1. The index foot in a footrest fixed with Velcro bands for digital subtraction angiography imaging for the two dimensional perfusion angiography analysis.

Post-processing protocol

Post-processing was performed to prepare perfusion acquisitions for a standardised analysis. This consisted of discarding frames prior to the inflow of iodinated contrast to reduce the potential influences of the power injector. Furthermore, to minimise the potential effect of different acquisition lengths (e.g., late foot movements) the same number of frames was analysed for both acquisitions. The last frames of the longest acquisition were discarded, in order to match the length of the shorter acquisition.

Repeatability, and intra-observer and interobserver agreement

For repeatability analyses patients with severe motion artefacts on one or both acquisitions were excluded. Foot movement was visually assessed post-procedurally by one observer (J.I.). Major movements, defined as foot movements with a distorted time density curve (TDC) and colour coded image, were excluded. Movements with a representable TDC and colour coded image were considered minor and included in the analysis. To test repeatability, the two acquisitions within each patient were compared. To investigate the intra-observer agreement, one observer (J.I.) performed five measurements with the SmartPerfusion Rel. 1.0 software on the same acquisition for each patient. To minimise recall bias, the minimal time interval between measurements was 24 hours. For interobserver agreement, region of interest (ROI) measurements were performed independently by three observers (J.I., D.H., and S.H.) on the same acquisition for each patient. All measurements were performed using the same definitions for the ROI, which was through the tibiotalar joint, at the dorsal and plantar borders of the foot, and through the first tarsometatarsal joints (Fig. 2).[10] When necessary, the position of the ROI was manually adjusted to correct for translational displacement of the foot.

Functional parameters and statistical analysis

For analysis, TDCs with the following parameters were obtained from the ROIs: arrival time; area under the curve; mean transit time; peak density (PD); time to peak; width wash in rate; and wash out rate. Bland–Altman plots with mean difference and 95% limits of agreement were used to show repeatability. To test repeatability, and intra- and interobserver agreement the intraclass correlation coefficient (ICC) was calculated. The outcome was interpreted as poor for ICC < 0.50, moderate for ICC 0.50–0.75, good for ICC 0.75–0.90, and excellent for ICC > 0.90.[18] Statistical analysis was performed using SPSS version 26.0 (IBM, Armonk, NY, USA).

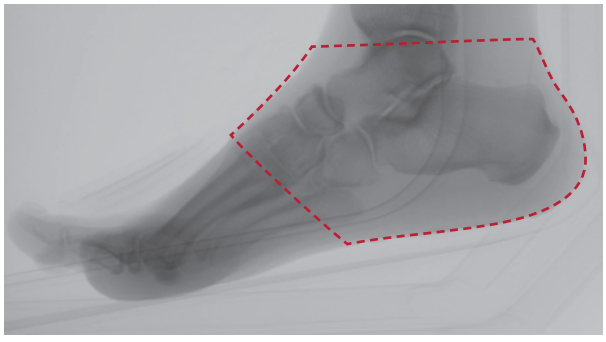

Figure 2. Example of the region of interest drawn through the tibiotalar joint, at the dorsal and plantar borders of the foot, and through the first tarsometatarsal joints for the two dimensional perfusion angiography analysis.

RESULTS

Patients characteristics

Of the 25 patients who signed informed consent, five were excluded pre-procedurally because the effect of the inflow treatment was expected to be sufficient to promote wound healing and therefore no BTK intervention was performed. Per protocol, no 2DPA acquisitions were performed in these patients. This resulted in the final inclusion of 20 patients of whom two (10%) were excluded from repeatability analyses because of motion artefacts as a result of major foot movement. An example of a measurement without movement is shown in Fig. 3(A, B), of minor movement in Fig. 3(C, D), and of major movement in Fig. 3(E, F). A flowchart of the patient inclusion process is shown in Fig. 4. The mean age of the 20 patients was 74.4 $\pm$ 8.4 years and 85% of the patients suffered from diabetes mellitus. Eighteen patients were classified as Rutherford 5 and two patients as Rutherford 6. Nine of 18 patients received a sciatic popliteal nerve block. Patient demographics are shown in Table 1.

Repeatability

Bland–Altman plots per parameter are shown in Fig. 5. Mean difference and 95% limits of agreement, as well as the ICCs of the repeatability analyses, are presented per parameter in Table 2. The ICC was > 0.90 for every parameter corresponding to excellent repeatability.

Despite excellent agreement, some outliers were observed. For example, in one patient the TDC of the first run showed a higher PD than the second run. Another patient showed a higher PD in the second run than in the first one.

Intra-observer and interobserver agreement

All 20 included patients were included for observer agreement. The ICC was 1.00 for every parameter for both intra- and interobserver measurements, indicating excellent intra- and interobserver agreement.

DISCUSSION

This study investigated the reliability of 2DPA as a foot perfusion measurement tool in patients with CLTI and demonstrated excellent repeatability, and intra- and interobserver agreement with adherence to the acquisition and the post-processing protocol described in this study.

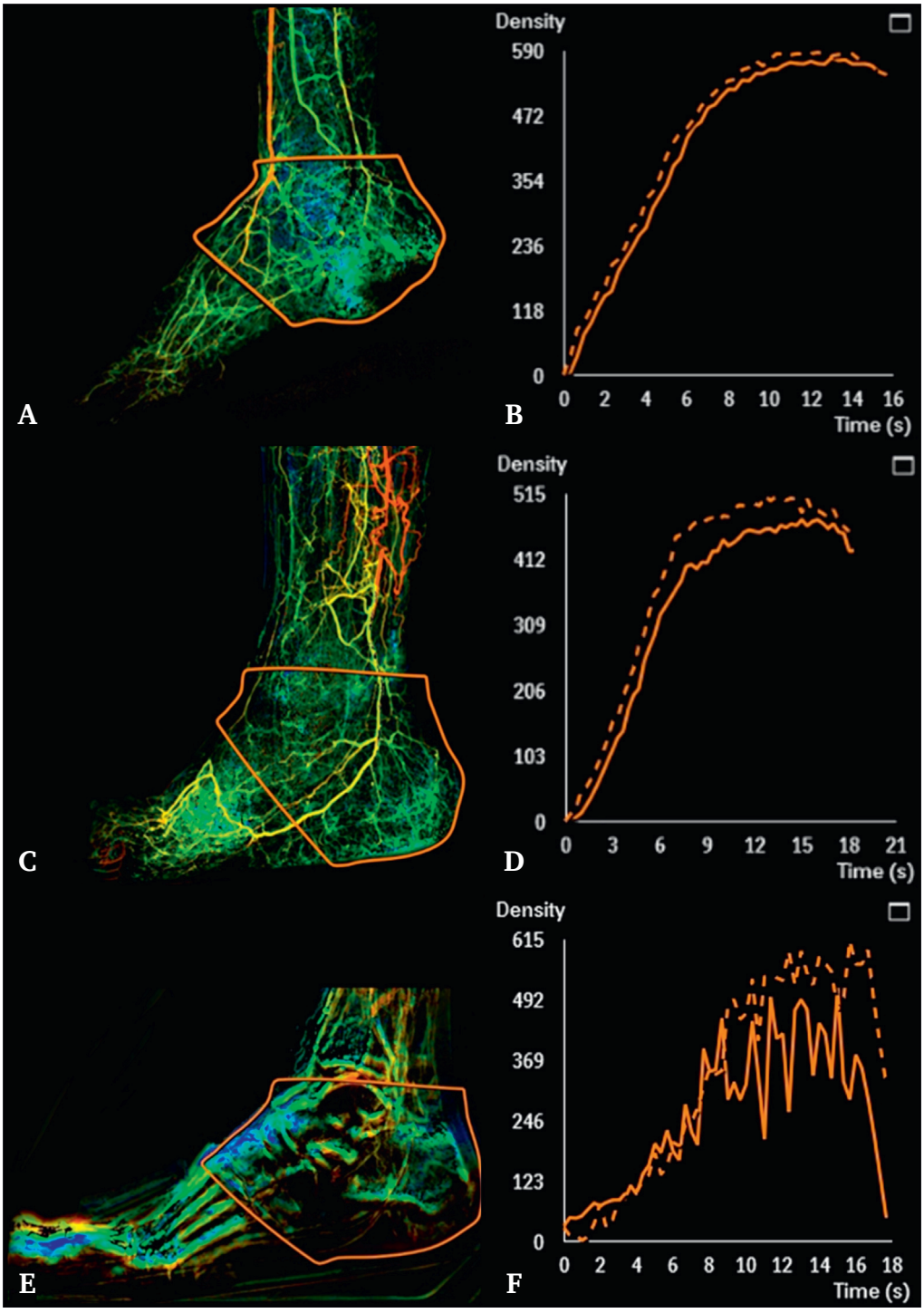

Figure 3. The (A, C, E) perfusion images and (B, D, F) time density curves on patients showing (A, B) no foot movement without any distortions, and (C, D) minor foot movements with no major distortions, and (E, F) major foot movements with major distortions in a patient who was excluded from the repeatability analysis.

Although the results are promising, there are several factors that should be kept in mind when applying perfusion angiography in clinical practice or in research.

First, it is important to use a standardised acquisition protocol. 2DPA is based on standard DSA and thus depends on contrast density to reconstruct TDCs. If the total volume of contrast or the level of contrast administration varies between runs, TDCs will be influenced and evaluation of perfusion changes may be impossible. We therefore advocate contrast administration at popliteal level with undiluted high iodine contrast media (300 — 320 mg I/mL) with a fixed volume and flow rate.

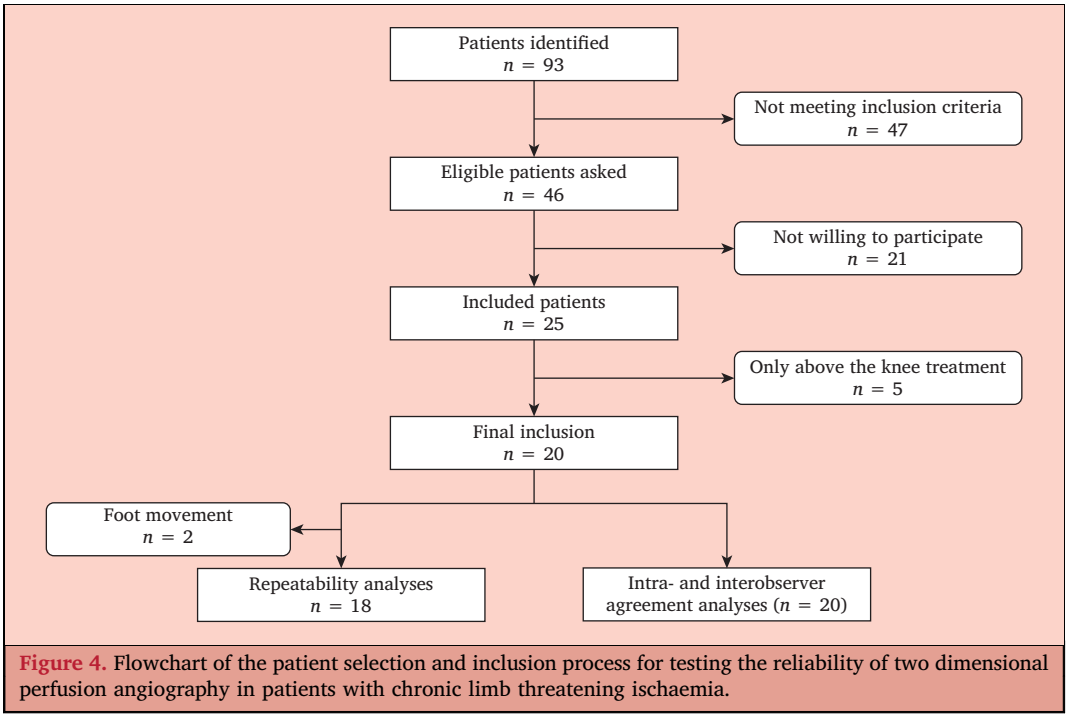

Figure 4. Flowchart of the patient selection and inclusion process for testing the reliability of two dimensional perfusion angiography in patients with chronic limb threatening ischaemia.

Second, like standard DSA, 2DPA is sensitive to foot movements. Despite immobilisation of the foot with a footrest and Velcro bands, the incidence of severe motion artefacts was 0.5% — 10% in previous studies,[10,14,19] and 10% in the current study. Minor movements, however, seemed to happen mostly at toe level, which was excluded from the ROI. Owing to the excellent results found in this study, the effect of minor movements on the 2DPA results is thought to be small. Foot movements can also be prevented by using peripheral nerve blocks, but this was not standard of care at the authors' institution.

Table 1. Baseline characteristics of the 20 included patients with chronic limb threatening ischaemia to study the reliability of two dimensional perfusion angiography

Characteristic	Patients (n = 20)
Age — y	74.4 ± 8.4
Male sex	17 (85)
Diabetes mellitus	17 (85)
Hypertension	18 (90)
Hyperlipidaemia	8 (40)
Ischaemic heart disease	7 (35)
Prior stroke	3 (15)
Smoking, current or former	11 (55)
Rutherford	
5	18 (90)
6	2 (10)
WIfI clinical stage based on one year amputation risk	
1 (very low)	5 (25)
2 (low)	6 (30)
3 (moderate)	4 (20)
4 (high)	5 (25)
Wound location — n[*]	
Digit(s)	14
Foot instep	3
Lateral malleolus	2
Medial malleolus	1
Calcaneus	1
Lower leg	2
Inflow treatment during same session	7 (35)

Data are presented as n (%) or mean ± standard deviation. WIfI = Wound, Ischemia, and foot Infection.
* Three patients had wounds on different locations.

Third, in addition to foot movements there are other factors that influence foot perfusion and could cause differences between the TDCs not related to revascularisation of the tibial arteries. Arterial spasms, for instance, resulted in a poor repeatability with decreased perfusion in one patient, while in another patient the presence of severe osteoarthritis of the tibiotalar joint with delayed enhancement of the inflammatory process resulted in an increase of perfusion as described in literature occurring in other imaging modalities.[20]

2DPA could be helpful determining procedural endpoints and predicting clinical outcome. Studies using 2DPA have already demonstrated increased perfusion after successful revascularisation procedures, but the threshold of a certain perfusion parameter to indicate good clinical outcome is unknown.[10,12,13] The current repeatability study is the first that gives an indication of the variance induced by image acquisition and post-processing by presenting 95% limits of agreement for every parameter. If the 95% limit of agreement was exceeded, the change in perfusion was statistically significant. Whether a change above this limit indicates an improved clinical outcome has yet to be established.

This study has some limitations. Although the number of patients was sufficient to show excellent repeatability results, the Bland—Altman plots show outliers that could not

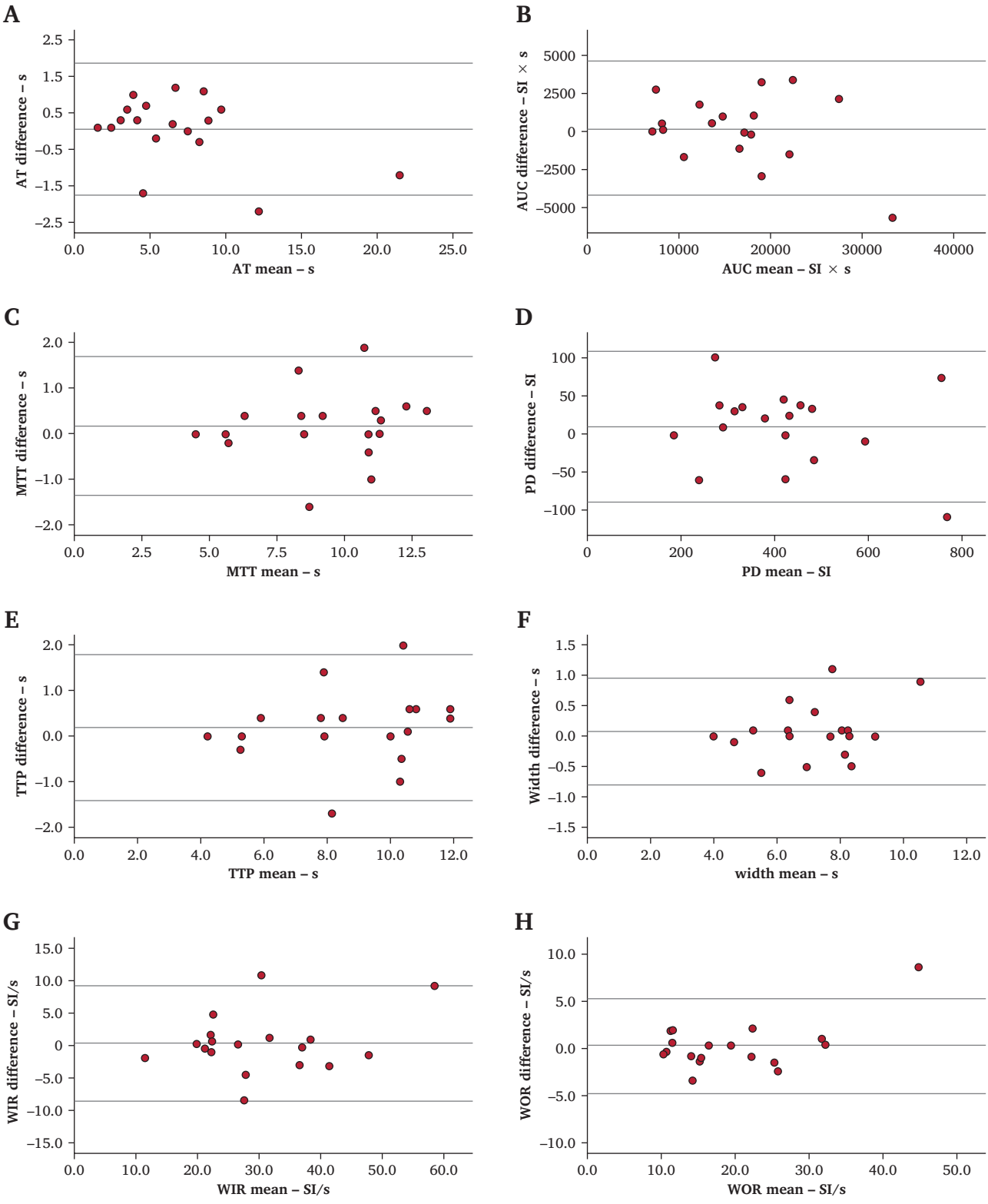

Figure 5. Bland–Altman plots of repeatability of two dimensional perfusion angiography per parameter of the 18 patients left after exclusion of two patients with major movements for (A) arrival time (AT); (B) area under the curve (AUC); (C) mean transit time (MTT); (D) peak density (PD); (E) time to peak (TTP); (F) width; (G) wash in rate (WIR); and (H) washout rate (WOR). The *x* axis represents the mean of the first and the second acquisition. The *y* axis represents the difference of the first and second acquisition. Each dot represents the result of an individual patient. Horizontal lines in the graphs represent from highest to lowest: upper limit of the 95% confidence interval (CI), mean difference, and lower limit of the 95% CI. SI = signal intensity.

Table 2. Results from the repeatability analyses of two dimensional perfusion angiography per parameter, presented as mean difference with 95% limits of agreement, and intraclass correlation coefficient (ICC)

Parameter	Mean difference (95% limits of agreement)	ICC
Area under the curve	165.5 (−4265.7 − 4596.8)	0.98
Arrival time	0.05 (−1.76 − 1.86)	0.99
Mean transit time	0.18 (−1.34 − 1.70)	0.98
Peak density	9.2 (−90.0 − 108.4)	0.98
Time to peak	0.19 (−1.41 − 1.79)	0.97
Wash in rate	0.23 (−8.65 − 9.12)	0.96
Washout rate	0.26 (−4.73 − 5.25)	0.98
Width	0.08 (−0.80 − 0.96)	0.98

be fully explained. Hopefully, with more data available in the future, there will be a better understanding of these observations.

Furthermore, current insights in CLTI are that two different macrovascular disease processes, big artery disease (BAD) and small artery disease (SAD), can be present in the same patient overlapping at foot level.[21] As described by Ferraresi *et al.*,[21] small arteries are defined as the side branches of the pedal arteries, which include the calcaneal branches, the pedal arch, and the metatarsal and digital arteries. SAD is related to disturbed blood distribution, whereas BAD is associated with disturbed transmission. In addition, it could be that SAD has a stronger correlation with microvascular disease, but this was not investigated.

Lastly, the current study only validated reliability of 2DPA. Other aspects of test validation, such as the ability to demonstrate increased blood flow after intervention (responsiveness) and the relationship with clinical outcomes (validity) were not investigated in this study but are important further research topics. Also, no attempt was made to investigate the replicability of other contrast administration protocols. Currently, only the protocol used in this study is validated and can be reliably applied in clinical practice and research correlating 2DPA with clinical outcome.

In conclusion, repeatability, and intra- and interobserver agreement of 2DPA in patients with CLTI were found to be excellent, making 2DPA a reliable tool when using it according to the standardised methods described in this study. Patient related factors, such as motion artefacts, should be taken into account when using the technique.

CONFLICTS OF INTEREST

D.A.F. van den Heuvel has received a research grant from Philips. The other authors declare no conflicts of interest.

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COUP D'OEIL

Double Check That You Are in the Endograft and Not in Front or Behind It!

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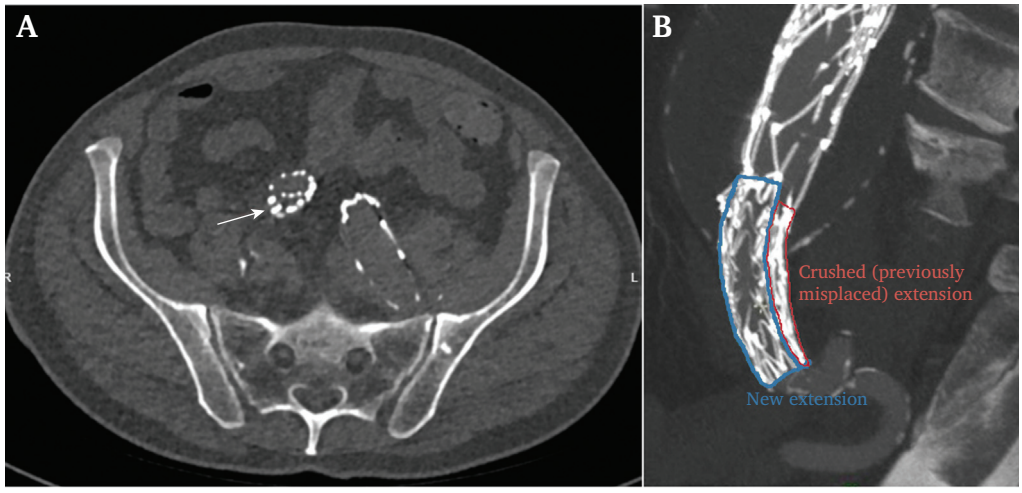

A patient who underwent treatment (elsewhere) of a type Ib endoleak by iliac extension two years after endovascular aneurysm repair, developed immediate severe right leg claudication. (A) Computed tomography angiography (CTA) showed occlusion of the endoprosthesis right limb due to compression and flow limitation by the iliac extension that was placed behind, rather than within it (arrow). A new iliac extension (Zenith Alpha Spiral-Z Iliac Leg Graft, Cook Medical, Bloomington, USA) was successfully placed next to the misplaced one ending intraluminally in the endograft, followed by 12 mm balloon dilation. (B) Patency was confirmed on two month post-operative CTA.

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