Measuring Transcutaneous Oxygenation to Validate the Duration Required to Achieve Electrode Equilibration

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ABSTRACT

OBJECTIVE: The transcutaneous oxygenation measurement (TCOM) system is useful in assessing tissue viability. There are no clear recommendations regarding the duration required for the electrode to equilibrate and reliably evaluate tissue oxygenation values. The objective of this study was to validate the duration required to achieve electrode equilibration in a clinical setting.

METHODS: Minute-by-minute recordings using TCOM (TCOM3; Radiometer Medical ApS, Brønshøj, Copenhagen) were obtained for 82 limbs in 50 participants. Twenty-five limbs were in patients with peripheral vascular disease; 30 were in patients with no known peripheral vascular disease; and 27 were in healthy volunteers. Transcutaneous partial pressure of oxygen and carbon dioxide ($TcPo_2$ and $TcPco_2$) were recorded over a 15-minute period.

RESULTS: Participants' $TcPo_2$ decreased and $TcPco_2$ increased over time. Both changed in a nonlinear fashion, eventually settling at an "equilibrium" where the measurements became stable. The difference in proportional change of $TcPo_2$ between minutes 14 and 15 was 0.8%, and for $TcPco_2$was 2.9%. Changes in TCOM measurements over time were similar among the 3 groups.

CONCLUSIONS: This is the first study to target minute-by-minute variation in $TcPo_2$ and $TcPco_2$ measurements. Recording for a minimum of 15 minutes allows a reliable period for the TCOM electrode to equilibrate to record absolute values and determine wound healing potential.

KEYWORDS: electrode equilibration, peripheral vascular disease, tissue oxygenation, tissue viability, transcutaneous oximetry, transcutaneous partial pressure of carbon dioxide, transcutaneous partial pressure of oxygen

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INTRODUCTION

Transcutaneous oxygenation measurement (TCOM) is a useful tool for assessing peripheral circulation. This method measures oxygen tension on the skin surface and assesses both transcutaneous partial pressure of oxygen ($TcPo_2$) and transcutaneous partial pressure of carbon dioxide ($TcPco_2$).[1] Transcutaneous oxygenation measurement estimates tissue oxygenation by measuring the diffusion of extracellular oxygen and carbon dioxide into a heated electrode on the skin.[2] It is used to determine tissue viability and wound healing potential.

Tissue hypoxia ($TcPo_2$ <40 mm Hg) disrupts all phases of wound healing, leading to anaerobic metabolism.[3,4] Wounds with a $TcPo_2$ greater than 40 mm Hg generally heal.[5–7] This predictive index has a sensitivity and specificity of 85% and 92%, respectively.[7] Patients with diabetes and renal failure may require a higher $TcPo_2$ over 50 mm Hg for successful healing.[8,9] An improvement in $TcPo_2$ beyond 40 mm Hg after revascularization is indicative of significant improvement.[10] Similarly, a $TcPo_2$ of less than 30 mm Hg despite breathing 100% normobaric oxygen is consistent with critical limb ischemia that would not respond to hyperbaric oxygen therapy.[11]

Guidelines have been published for the use of TCOM. Landmark articles on TCOM by Fife et al,[3] Restrepo et al,[12] and Wimberley et al[13] have provided comprehensive literature reviews of its use, reference ranges for normal and diseased individuals, and previous research findings, such as its value for predicting amputation and wound healing. However, there are no precise recommendations regarding the length of time that the electrode should be in contact with the skin to achieve reliable and accurate measurements. One reason this is important is that TCOM typically is used to obtain continuous measurements of tissue oxygenation instead of performing regular invasive arterial blood gases in such settings as pediatric intensive care, respiratory care, and sleep medicine.

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Some authors described recording measurements at periods "between 10 and 20 minutes," whereas others took recordings only when measurements ceased to fluctuate. The manual for the device used in this study (TCOM3; Radiometer Medical ApS, Brønshøj, Copenhagen) recommends 10 to 17 minutes of continuous measurements to obtain reliable $TcPO_2$ and 3 to 7 minutes for $TcPCO_2$.[14] According to Sheffield,[15] equilibration of the electrode occurs within 10 to 15 minutes for subjects with normal circulation and 15 to 20 minutes for compromised circulation. This was referenced by a "personal communication" with Vesterager.[16] These suggestions are crude and not objective. Shah et al[17] attempted to demonstrate that 20 minutes was ideal to achieve an accurate reading of the foot; however, this study involved only 2 time points, at 10 and 20 minutes.

METHODS

Ethics approval for this study was secured from the local ethics committee (NTY/08/08/082).

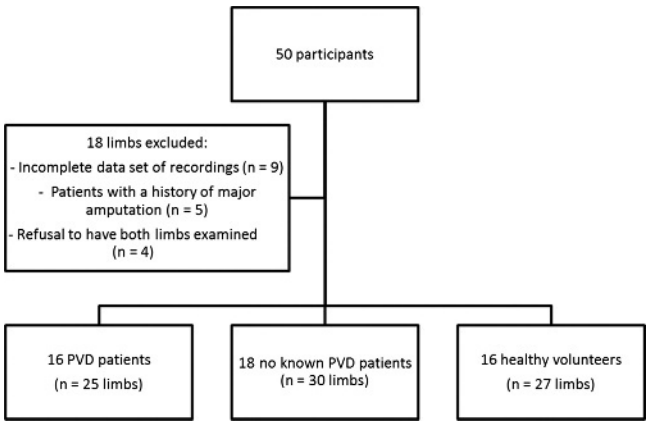
Participants

Fifty participants were recruited by responding to an advertisement placed in the vascular ward at Waikato Hospital (Hamilton, New Zealand) over a 3-month period in 2009 (Figure 1). Patients with preexisting vascular disease were identified through their medical history and presenting complaint if they were concurrently admitted to hospital. Of the 50 participants, 16 were healthy volunteers (ie, hospital staff with no known cardiovascular history) who were recruited to act as the control group for analysis.

Only 82 of the study's 100 lower extremities were studied. Reasons for excluding 18 limbs included an incomplete data set of recordings, patients with a history of major amputation, and refusal to have both limbs examined. Participants younger than 18 years; those with cellulitis; those who had ulcers or calluses on the plantar skin overlying the first metatarsal head; and those with a history of lymphedema, severe dementia, or methicillin-resistant *Staphylococcus aureus* were also excluded. Participants were required to abstain from nicotine and caffeine intake for at least 60 minutes prior to examination.

Of the 82 recordings analyzed, 25 limbs were from 16 inpatients admitted to hospital with known peripheral vascular disease (PVD) of the lower limb, 30 were from 18 patients hospitalized within the vascular or cardiothoracic subspecialties with no known PVD but with clinical risk factors, and 27 were from 16 healthy volunteers (ie, medical and nursing staff or students).

Figure 1.
RECRUITMENT FLOWCHART



Abbreviation: PVD, peripheral vascular disease.

Procedure

Minute-by-minute TCOM readings of $TcPO_2$ and $TcPCO_2$ were recorded using the plantar surface of the first metatarsal head over a 15-minute period. This region was chosen because of its extensive arteriovenous anastomoses that make it sensitive to changes in tissue oxygenation. Operation of the TCOM3 system is described in the manufacturer's manual and in the literature.[10,13,15] The TCOM was operated by 2 experienced operators who had conducted other TCOM research studies.

Participants were rested in a supine position for 15 minutes in a small quiet room with room temperature set at 20° C to 23° C prior to placing the electrode onto the fixation ring. The electrode was calibrated prior to each application at 158 mm Hg for $TcPO_2$ and 40 mm Hg for $TcPCO_2$ at 44° C and atmospheric pressure.[15,18] The skin around the first metatarsal head was prepared with alcoholic wipes prior to testing, and patients were required to uncover the entire lower extremity. Electrode membranes were replaced after every 5 participants or 7 days, or if the readings suggested significant electrode drift. Basic demographics and ankle-brachial index (ABI) were also recorded.

Statistical Analysis

Statistical analyses were performed using SPSS version 22 software (IBM Corporation, Armonk, New York). A type I error of 5% ($P \leq .05$, 2-tailed) was considered statistically significant.

Descriptive statistics were described in terms of the range, mean, or median and SD. When comparing the means of 3 groups of continuous variables, analysis of variance was used; χ^2 and Fisher exact tests were applied depending on the size of the sample.

RESULTS

Demographics

Basic demographics for the 3 groups are shown in the Table. The volunteers (control group) on average were younger and had higher ABI compared with the other participants.

Table.

BASIC DEMOGRAPHICS OF THE 3 PATIENT GROUPS

	Known PVD	No Known PVD	Volunteers	*P*
No. of participants	16	18	16	
Limbs analyzed	25	30	27	
Age, mean (SD), y	70 (10)	52 (11)	36 (9)	.01
Male, n (%)	10 (63)	10 (56)	6 (38)	.34
White, n (%)	13 (81)	15 (83)	9 (56)	.16
Active smoker, n	3	4	4	.91
Diabetes mellitus, n	4	4	0	.10
ABI, mean (SD)	0.62 (0.19)	0.82 (0.09)	1.0 (0.05)	.01

Abbreviations: ABI, ankle brachial index; PVD, peripheral vascular disease.

Changes in Measurements over Time

The mean values of $TcPo_2$ and $TcPco_2$ obtained over the 15-minute period of readings were plotted against time (Figure 2). There were 2 curves, showing that the measurements reached a plateau during the latter phase of the measurements. Note the mean (SD) for $TcPo_2$ at minute 15 is approximately 79.2 (16.2) mm Hg, and for $TcPco_2$ is approximately 26.7 (9.6) mm Hg.

The proportional change in value over time for $TcPo_2$ and $TcPco_2$ is demonstrated in Figures 3 and 4, respectively. Proportional change for $TcPo_2$ was calculated by dividing the absolute $TcPo_2$ value in that minute by $TcPo_2$ at baseline (ie, value at calibration at 158 mm Hg), whereas the proportional change for $TcPco_2$ was determined by dividing the $TcPco_2$ of that minute by the $TcPco_2$ at the end of the reading for that patient (ie, at 15 minutes). The variation was less than 3% between minutes 14 and 15 for both measurements. The change was seen to a lesser degree in the $TcPo_2$ measurements at 0.8% between minutes 14 and 15 and less than 5% between minutes 11 and 15. Although a variation of 3% for $TcPco_2$ between minutes 14 and 15 might appear substantial, 3% of the mean $TcPco_2$ value of 26.7 mm Hg is insignificant.

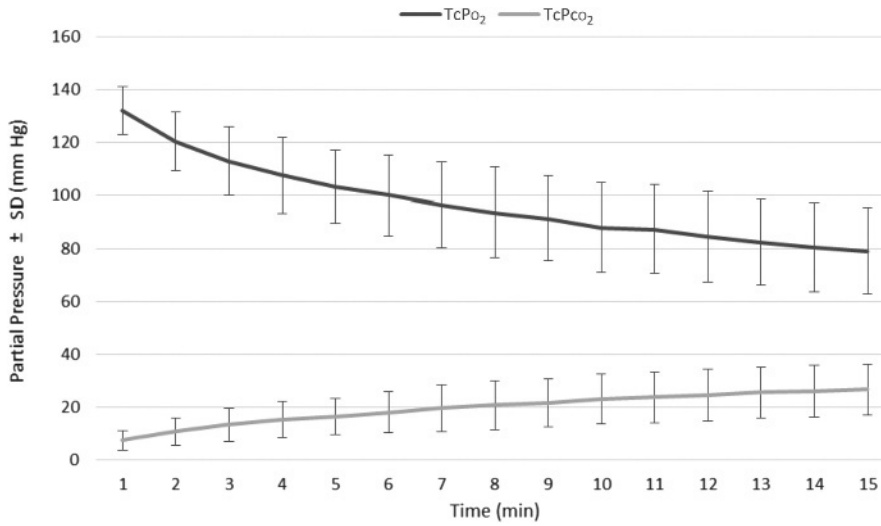
Recordings were subdivided for the 3 groups: those with PVD of the lower limb (PVD group), hospitalized patients without documented PVD of the lower limb (non-PVD group), and healthy volunteers (volunteer group). Variations of less than 4% between minutes 14 and 15 were detected in $TcPo_2$ and $TcPco_2$, and these were not different among the 3 groups (Figures 5 and 6). Even when the symptomatic limbs of the 16 patients with PVD were analyzed separately, variations between 14 and 15 minutes were less than 2% (Figure 7).

DISCUSSION

This study is the first that targets minute-to-minute variation in $TcPo_2$ and $TcPco_2$ measurements obtained using the TCOM device. Previous research used the recommendations of Sheffield[15] regarding the duration needed for the electrodes to reach equilibrium. However, these were based on experience rather than evidence-based findings. This study showed that after 15 minutes of monitoring, the $TcPo_2$ and $TcPco_2$ readings obtained had less

Figure 2.

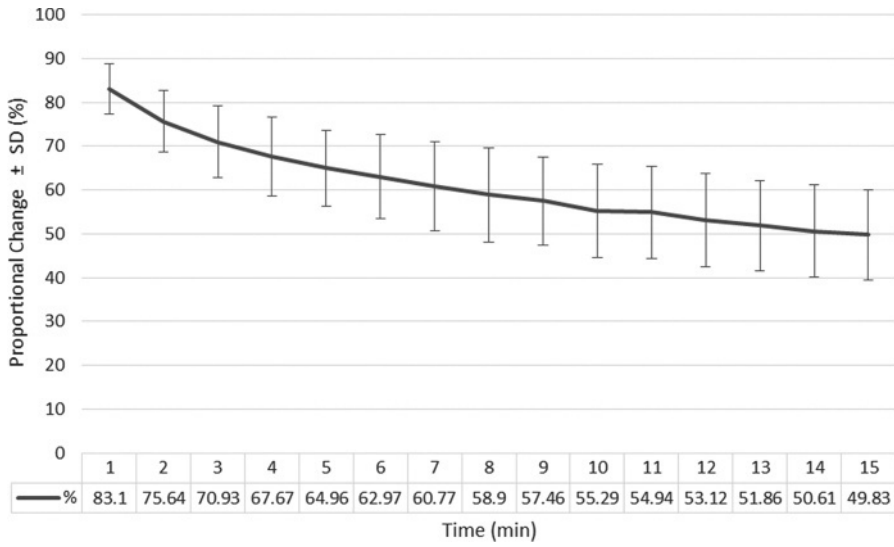
LINE GRAPH SHOWING MEAN (SD) VARIATION IN $TCPo_2$ AND $TCPco_2$ OVER TIME



Abbreviations: $TcPo_2$, transcutaneous partial pressure of oxygen; $TcPco_2$, transcutaneous partial pressure of carbon dioxide. Note: All 3 groups are pooled together.

Figure 3.

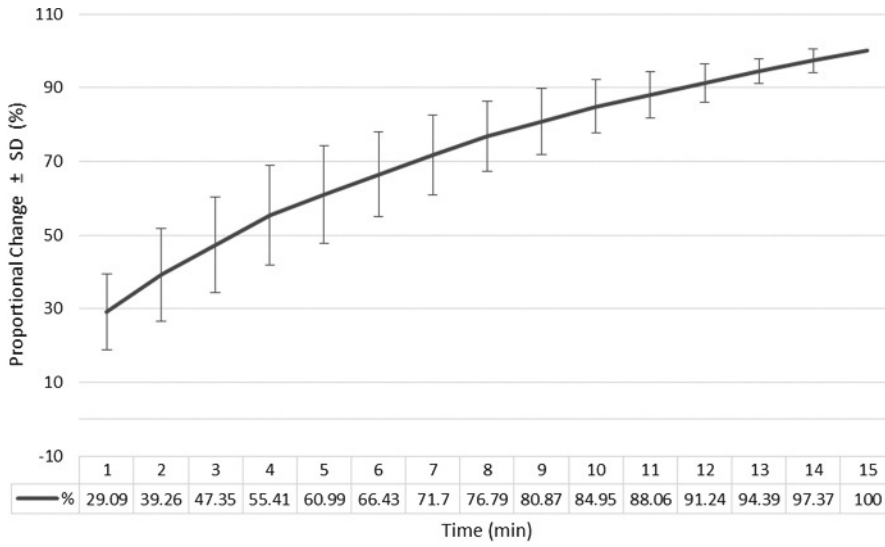
LINE GRAPH SHOWING PROPORTIONAL CHANGE (SD) IN $TCPo_2$ OVER TIME



Abbreviation: $TcPo_2$, transcutaneous partial pressure of oxygen. Note: All 3 groups are pooled together.

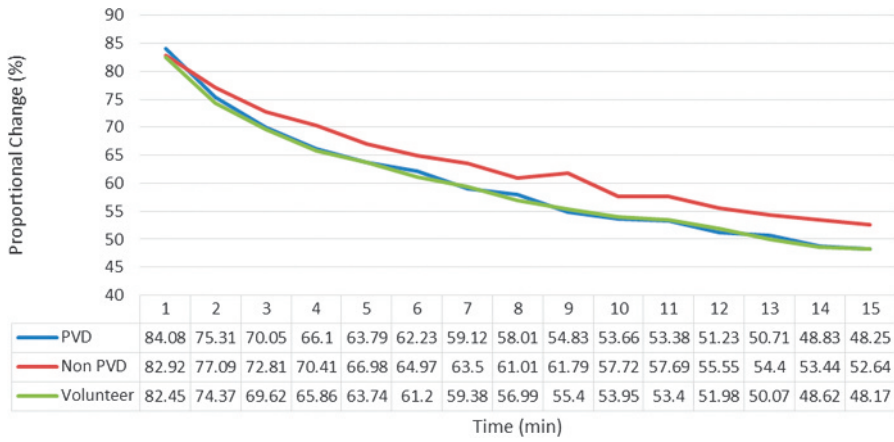
Figure 4.

LINE GRAPH SHOWING PROPORTIONAL CHANGE (SD) IN $TCPco_2$ OVER TIME



Abbreviation: $TcPco_2$, transcutaneous partial pressure of carbon dioxide. Note: All 3 groups are pooled together.

Figure 5.
LINE GRAPH SHOWING THE PROPORTIONAL CHANGE IN $TCPo_2$ IN SUBGROUPS OVER TIME



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PVD	84.08	75.31	70.05	66.1	63.79	62.23	59.12	58.01	54.83	53.66	53.38	51.23	50.71	48.83	48.25
Non PVD	82.92	77.09	72.81	70.41	66.98	64.97	63.5	61.01	61.79	57.72	57.69	55.55	54.4	53.44	52.64
Volunteer	82.45	74.37	69.62	65.86	63.74	61.2	59.38	56.99	55.4	53.95	53.4	51.98	50.07	48.62	48.17

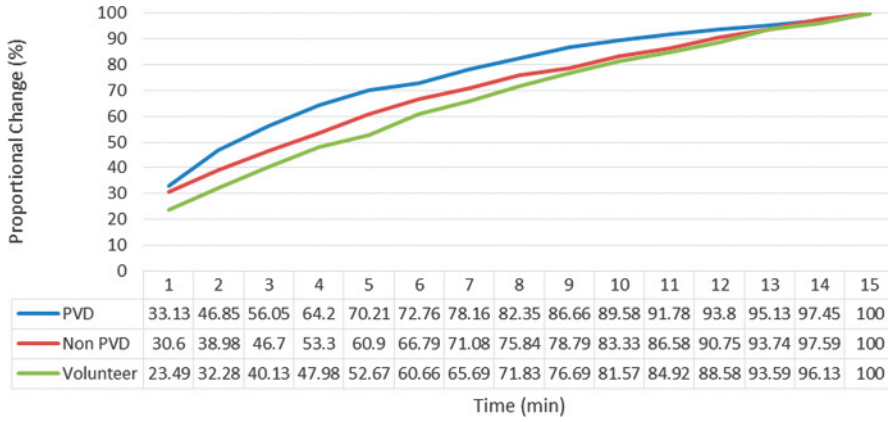
Abbreviations: PVD, peripheral vascular disease; $TcPo_2$, transcutaneous partial pressure of oxygen.

than 1% and 3% variation, respectively, which are clinically insignificant, irrespective of the PVD status.

Research studies on $TcPco_2$ are scarce, and little is known about the relevance of $TcPco_2$ in vascular surgery in patients with PVD. One of the author's recent publications interrogated the clinical use of a hyperspectral TCOM device.[19] Its recordings correlated with the severity of PVD, skin temperature, and ABI. They were also more sensitive to $TcPco_2$ than $TcPo_2$. Perhaps measurement of $TcPco_2$ has a vital role to play in screening for PVD in clinical practice.

Interpreting TCOM values prematurely can result in up to 10% variation based on this study. Given the mean values of $TcPo_2$ and $TcPco_2$ at 15 minutes, this could lead to significant deviation of 79.2 ± 8 and 26.7 ± 3 mm Hg, respectively. In addition, the intraoperator variability in TCOM was found to be 10% for $TcPo_2$ and 5% for $TcPco_2$.[3,10] Several factors can influence readings, including Pao_2 (or $Paco_2$), capillary blood flow in the skin under the electrode, oxygen consumption and carbon dioxide production by the skin, oxygen consumption by

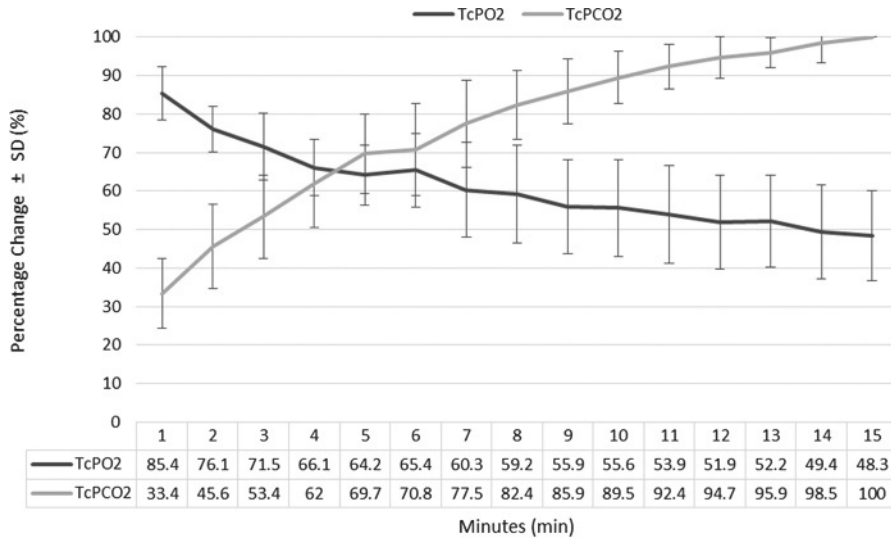
Figure 6.
LINE GRAPH SHOWING THE PROPORTIONAL CHANGE IN $TCPco_2$ IN SUBGROUPS OVER TIME



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PVD	33.13	46.85	56.05	64.2	70.21	72.76	78.16	82.35	86.66	89.58	91.78	93.8	95.13	97.45	100
Non PVD	30.6	38.98	46.7	53.3	60.9	66.79	71.08	75.84	78.79	83.33	86.58	90.75	93.74	97.59	100
Volunteer	23.49	32.28	40.13	47.98	52.67	60.66	65.69	71.83	76.69	81.57	84.92	88.58	93.59	96.13	100

Abbreviations: PVD, peripheral vascular disease; $TcPco_2$, transcutaneous partial pressure of carbon dioxide.

Figure 7.
PROPORTIONAL CHANGE IN $TCPo_2$ AND $TCPco_2$ OVER TIME IN LIMBS WITH PERIPHERAL VASCULAR DISEASE



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
TcPO2	85.4	76.1	71.5	66.1	64.2	65.4	60.3	59.2	55.9	55.6	53.9	51.9	52.2	49.4	48.3
TcPCO2	33.4	45.6	53.4	62	69.7	70.8	77.5	82.4	85.9	89.5	92.4	94.7	95.9	98.5	100

Abbreviations: $TcPco_2$, transcutaneous partial pressure of carbon dioxide; $TcPo_2$, transcutaneous partial pressure of oxygen.

the electrode, temperature gradients in the skin, and structural and diffusive properties of the skin (eg, skin thickness, edema, and inflammation). Imprecision of TCOM values may also be from "electrode drift" caused by wear and tear of the electrode membrane, variations in pressure on the electrode (such as direct pressure on the electrode), and skin properties.[3]

Recordings for this study in patients with or without PVD sometimes included the contralateral limb with potential undiagnosed PVD; however, the heterogeneity is unlikely to have had a significant impact on the findings because the aim of the study was to determine the time required to achieve equilibration of the TCOM device irrespective of participants' preexisting disease burden. Comparative studies of $TcPO_2$ and $TcPCO_2$ measurements in various subgroups have been described previously, for example, in normal individuals, claudicants, those with critical limb ischemia, smokers, and patients with diabetes.[10] The "healthy volunteer" group served as a control group to prevent selection bias and establish whether there was any variation in the time required for electrode equilibration depending on clinical history or the presence of PVD.

Vesterager[16] and Vesterager and Jensen[20] previously described the relationship between $TcPO_2$ and the time taken to reach equilibrium of the electrode. A typical dip in measurements at approximately 8 minutes was described, where $TcPO_2$ reached the lowest value and subsequently rebounded to equilibrium at approximately 15 minutes. Shah et al[17] also showed $TcPO_2$ values of the foot were 2.5 mm Hg higher at 20 minutes compared with 10 minutes. The significance of this was not tested. While electrode drifts and minute-by-minute variations to reflect local tissue demands could be anticipated, this study did not demonstrate an increase in $TcPO_2$ of the foot in any phase of the recordings. Other anatomical locations may behave differently.

Limitations

This study has several limitations. Only 1 target point was chosen for analysis, at the plantar aspect of the head of the first metatarsophalangeal joint. The average $TcPO_2$ values from 2 or more adjacent sites of an area are better predictors of healing potential than single site values.[3] The plantar angiosome chosen at the head of the first metatarsal bone is covered by glabrous skin that is rich in arteriovenous anastomoses. This skin tissue has more oxygenation and is more reactive to changes in oxygenation than skin on other parts of the body. However, the skin in this area can be thick. In some individuals, this skin can be pathologically hypertrophic, taking the form of calluses or corns, which are common in patients with diabetic neuropathy. Electrode equilibration could be expected to take longer.

In addition, the study did not stratify participants in relation to their smoking history or background of chronic obstructive pulmonary disease and vasculitic diseases.

Going forward, a comparative study should be conducted to correlate the readings at 15 minutes and those taken when the

electrode readings "ceased to fluctuate." This would allow identification of a definitive time point for TCOM measurements. While previous studies including Shah et al[17] obtained measurements at 10 and 20 minutes, they did not analyze minute-by-minute variations, which were the focus of this study.

CONCLUSIONS

Assessing TCOM can be time consuming, especially when measurements at multiple sites and various positions are required. This study suggests that TCOM readings can be reliably measured at 15 minutes when recording readings of the foot. This provides evidence for a more standardized and robust protocol in the use for TCOM in determining absolute values of $TcPO_2$ and $TcPCO_2$, which would eliminate operator bias and avoid wasting valuable time and resources. ●

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