Transcutaneous oximetry measurements of the leg: comparing different measuring equipment and establishing values in healthy young adults

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Abstract
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Introduction: Transcutaneous oximetry measurement (TCOM) is a non-invasive method of determining oxygen tension at the skin level using heated electrodes.
Aim: To compare TCOM values generated by different machines and to establish lower limb TCOM values in a cohort of healthy individuals younger than 40 years of age.
Method: Sixteen healthy, non-smoking volunteers aged 18 to 39 years were recruited. TCOM was obtained at six locations on the lower leg and foot using three different Radiometer machines. Measurements were taken with subjects lying supine, breathing air.
Results: Except for one sensor site, there were no statistical differences in measurements obtained by the different TCOM machines. There was no statistical difference in measurements comparing left and right legs. Room air TCOM values for the different lower leg sites were (mean (SD) in mmHg): lateral leg 61.5 (9.2); lateral ankle 61.1 (9.7); medial ankle 59.1 (10.8); foot, first and second toe 63.4 (10.6); foot, fifth toe 59.9 (13.2) and plantar foot 74.1 (8.8). The overall mean TCOM value for the lower limb was 61 (10.8; 95% confidence intervals 60.05–62.0) mmHg.
Conclusion: Lower-leg TCOM measurements using different Radiometer TCOM machines were comparable. Hypoxia has been defined as lower-leg TCOM values of less than 40 mmHg in non-diabetic patients and this is supported by our measurements. The majority (96.9%) of the lower leg TCOM values in healthy young adults are above the hypoxic threshold.

Key words
Patient monitoring; Standards; Wounds; Hyperbaric oxygen therapy

Introduction

Transcutaneous oximetry measurement (TCOM) is a technique used for recording oxygen (O_2) partial pressure at the skin level ($P_{tc}O_2$). The diffusion of extracellular O_2 into heated electrodes at the skin surface is non-invasively quantified, serving as a surrogate for tissue oxygenation. In hyperbaric medicine, TCOM has become an important assessment tool used to identify peri-wound hypoxia, monitor tissue responsiveness to oxygenation and help distinguish macro- from microvascular disease.[1] Hyperbaric oxygen treatment (HBOT) is likely to be beneficial in patients with chronic wounds who demonstrate hypoxia in the surrounding tissues and who show response to O_2 administration. An algorithm incorporating TCOM has been developed to identify patients who may respond to or are suitable for HBOT and to guide further management.[1]

The majority of chronic wounds arise in the lower limbs and the interpretation of TCOM data in this area is based on previous studies defining a normoxic range in a healthy population.[2–5] According to these data, a mean value of 67 (SD 10) mmHg can be considered normoxic. Based on this, hypoxia of the lower limbs was defined as a $PtcO_2$ of less than 40 mmHg in non-diabetic patients.[1,6] A recent study reported TCOM values lower than those previously reported and raised the question as to whether the use of different measurement equipment influences obtained TCOM data. That study has now been retracted after discovering an instrumentation error that renders the measurements from the study unreliable.[7]

This study was undertaken to compare TCOM values generated by three different machines. As a secondary endpoint, we establish TCOM values in a cohort of healthy

Figure 1

TCOM leg sensor placement: sensor 1 – 10 cm distal to the lateral femoral epicondyle; sensor 2 – 5 cm proximal to the anterior aspect of the lateral malleolus; sensor 3 – 5 cm proximal from the centre of the medial malleolus; sensor 4 – dorsum of the foot between the first and second metatarsal heads away from any obvious veins; sensor 5 – dorsum of the foot proximal to the head of the fifth metatarsal; sensor 6 – plantar first metatarsal area (proximal to the fat pad at the base of the great toe)

individuals younger than 40 years of age. This age range was chosen with the aim of selecting a population without age-related physiological changes.[8]

Methods

The Human Research Ethics Committee of the Townsville Hospital and Health Service granted ethics approval for the study (HREC/15/QTHS/111) and the Centre for the Advancement of Clinical Research of the Royal Brisbane and Women's Hospital and Metro North Hospital and Health Service granted site-specific approval.

Sixteen healthy volunteers (eight males, eight females) were recruited to participate in the study. Exclusion criteria included subjects younger than 18 and older than 39 years of age; disorders that could impair diffusion of O_2 through the skin; any significant medical history, especially underlying cardiovascular and respiratory disease; and current or past smoking. All participants were provided with written information at the time of recruitment, questions were answered and informed written consent was obtained. The subjects were de-identified by allocating a study number to ensure confidentiality.

Basic demographic data were collected including age, sex, weight and height. All participants were asked a series of standardized questions to determine their overall health status including medical and surgical history, confirmation of non-smoking status, medication/drug use and allergies. Heart rate and rhythm, blood pressures (on upper arm and lower leg) and O_2 saturation were measured and recorded. Dorsalis pedis (DP) and posterior tibial (PT) pulses were palpated and graded according to quality (palpable/detectable by Doppler/absent). Any abnormalities in these observations or in the detectability of pulses would have led to exclusion from the study. The participants refrained from consuming caffeine, eating a heavy meal and performing heavy exercise for two hours prior to the measurements.

Subjects were placed in a supine position on an examination bed with the head slightly raised on one pillow for the duration of the study. A blanket was offered for comfort and to limit any vasoconstrictive effects from being cold. The room temperature (between 22.5°C and 24.5°C) and humidity (between 52% and 62%) were monitored.

The study compared $P_{tc}O_2$ measurements obtained by five TCOM machines of three types, using the same type of electrodes and membranes:

- 1 x Radiometer TCM400, 6 channels; Software Version 4.2 (v4.2); E5250 tc electrodes
- 1 x Radiometer TCM400, 6 channels; Software Version 5.01 (v5.01); E5250 tc electrodes
- 3 x Radiometer TCM30, 1 channel; E5250 tc electrodes

The TCM400 machines have six electrodes and can record $P_{tc}O_2$ data at all six sensor sites simultaneously. The TCM30 machine only has one electrode, therefore three TCM30 machines were used to allow for simultaneous measurement at three sensor sites. The electrode temperatures were pre-set to 44°C, a temperature that allows maximal vasodilation but limits the risk of burn injury at the sensor site.[9,10] Prior to commencement of the study, new membranes (D826 – $tcpO_2$) were applied to all sensors. The accuracy of the sensors at low and high O_2 values was checked by calibrating the sensors with atmospheric air and by performing a sensor zero-current check with CAL2 standard calibration gas (10% carbon dioxide, 90% nitrogen). The sensors were re-membraned halfway through the study.

Table 1

Demographics and baseline characteristics of 16 healthy subjects (eight male, eight female) < 39 years old; mean (SD) or * median and interquartile range ((IQR))

Variable (n = 16)	Mean or median*	SD or IQR*
Age (years)	33.6	(3.7)
Height (cm)	172.8	(6.8)
Weight (kg)	72.2	(13.1)
BMI ($kg{\cdot}m^{-2}$)	24.1	(3.6)
Systolic BP (left) (mmHg)	113.2	(11.1)
Diastolic BP (left) (mmHg)*	70	(61.0–71.5)
Heart rate ($beats{\cdot}min^{-1}$)	67.6	(6.6)
Ankle brachial index (L and R)	1.2	(0.1)
SpO_2 (L and R) (%)*	100	(99.0–100)

For the TCM400 machines, a 'humidity correction factor' was calculated from the saturated water vapour pressure (according to the room temperature) and relative humidity and input into the machine according to the operator's manual.[11] The TCM30 machines do not provide the option of inserting a humidity correction factor. Therefore, a pO_2 calibration value was calculated from the barometric pressure, the relative humidity and the saturated vapour water pressure (according to the room temperature) and programmed into the machines according to the operator's manual.[12] The participants lay quietly for 20 minutes (min) while the TCOM machines were zeroed and calibrated to room air and the sensors were applied (Figure 1).

The sensor sites were prepared by shaving hair, if necessary, wiping clean, rubbing with an alcohol swab and drying with gauze. The order of the TCOM machines for each leg was randomized, right or left leg for TCM30 first then randomized order for the TCM400 machines. Two researchers (TT and DY) placed three sensors of the TCM30 machines to leg 1 (sensor positions 1–3) and six sensors of the first TCM400 machine to leg 2 (sensor positions 1–6). The leads were secured in place by tape to prevent pull on the sensors and an air leak occurring. Subjects were requested to keep talking to a minimum during the study.

After at least 20 min and stabilization of the values, the measurements were recorded and the sensors removed while the fixation rings remained in place. After a 10-min break, the three sensors of the TCM30 were re-attached to leg 1 (sensor positions 4–6) and the sensors of the second TCM400 machine were attached to leg 2. Measurements were again recorded after 20 min. After another 10 min break, the measurement procedure was repeated on the opposite leg: first TCM400 to leg 1 (sensor positions 1–6) and TCM30 to leg 2 (sensor positions 1–3). Then the second TCM400 was applied to leg 1 and TCM30 to leg 2 (sensor positions 4–6).

Table 2

Medial ankle $P_{tc}O_2$ values (mmHG) among the three oximetry devices (n = number of observations); one way ANOVA $P = 0.01$; post hoc Bonferroni test adjusted for multiple comparisons:
* $P = 0.03$ for TCM400 (v4.2) vs. TCM30;
† $P = 0.04$ for TCM400 (v5.01) vs. TCM30

	Transcutaneous oxygen (mmHg)		
Device	Mean	SD	95% CIs
TCOM400 (v4.2)*	57.3	11.4	51.2–63.3
TCM400 (v5.01)†	57.7	5.5	54.7–60.7
TCM30	65.8	8.9	61.1–70.6

At the end of the measurements, the sensors were removed and all sites were inspected for any thermal injury.

DATA ANALYSIS

The primary outcome of this study was to compare the tissue oxygen levels in the lower leg and foot of healthy volunteer participants recorded by the two different models of TCOM machines, TCM400 and TCM30, and different TCOM machines of the same model, TCM400, but using different software versions. Based on the premise that the true difference between the machines is 10 mmHg, our sample size of 16 measurements provided 80% power (with $\alpha = 0.05$) to be able to reject the null hypothesis using a two-sided Student t-test.

Demographic characteristics of the subjects are presented as median and inter-quartile range (IQR) or mean and standard deviation (SD) based on outcome of normality testing. Descriptive statistics are reported for TCOM readings at each of the six sensor sites: mean (standard deviation SD) for normally distributed data; median (IQR) for non-parametric data. Differences between TCOM measurements for each machine were compared using one way ANOVA followed by a Bonferroni post hoc test adjusted for multiple comparisons; P values which can be compared directly to 0.05 have been reported (for an explanation see <http://imaging.mrc-cbu.cam.ac.uk/statswiki/FAQ/SpssBonferroni>). All data were entered into the Statistical Package of Social Sciences version 22 (SPSS, IBM USA, Armonk) for analysis. A P value of < 0.05 was considered statistically significant.

Results

Demographic and baseline data are shown in Table 1. The subjects were all less than 40 years old. There were equal numbers of females and males. All DP and PT pulses were palpable or easily detected by Doppler. Baseline measures of perfusion were clinically unremarkable in all subjects. There were no missing data.

The TCOM readings for all sensor sites were normally distributed. There was no statistical difference between the TCM400 (v4.2) and TCM400 (v5.01) machines at any sensor site or between the right and left leg sensor sites for

Table 3

$P_{tc}O_2$ (mmHg) for each site for the three transcutaneous oximetry devices (n = 16); mean (SD) and range shown; ** One way ANOVA P = 0.01; post-hoc test: Bonferroni adjustment for multiple comparisons: * P = 0.03 for TCM400 (v4.2) vs. TCM30; † P = 0.04 for TCM400 (v5.01) vs. TCM30; ‡ P = 0.05 for TCM400 (v4.2) vs. TCM30; § P = 0.02 for TCM400 (v5.01) vs. TCM30

Anatomical site	**TCM400 (v4.2)**			**TCM400 (v5.01)**			**TCM30**		
Right lateral leg	60.2	(9.1)	40–73	60.4	(9.9)	42–78	61.3	(7.9)	42–72
Right lateral ankle	64.4	(9.0)	43–80	62.6	(11.8)	35–80	58.9	(10.3)	42–74
Right medial ankle**	57.3	(11.4)*	29–77	57.8	(5.6)†	50–66	65.9	(9.0)	46–83
Right foot, 1st/2nd toe	65.6	(11.2)	37–79	61.7	(10.2)	41–75	58.8	(12.7)	34–76
Right foot, 5th toe	60.0	(15.3)	16–80	61.9	(13.8)	27–78	52.7	(14.3)	13–71
Right plantar foot	74.6	(8.2)	54–86	72.9	(9.9)	49–91	73.1	(11.3)	41–90
Left lateral leg	60.4	(12.8)	30–79	64.1	(7.7)	53–78	62.4	(7.8)	52–76
Left lateral ankle	61.3	(7.0)	51–75	61.6	(9.0)	41–78	57.8	(10.1)	37–72
Left medial ankle**	55.1	(13.6)‡	34–92	53.8	(9.5)§	39–67	64.7	(9.3)	43–77
Left foot, 1st/2nd toe	65.5	(12.0)	39–86	64.7	(8.7)	44–86	64.1	(7.8)	49–76
Left foot, 5th toe	59.9	(11.2)	39–78	65.6	(12.3)	40–96	59.6	(10.5)	29–75
Left plantar foot	74.8	(8.1)	61–94	74.9	(8.3)	58–95	74.1	(7.3)	59–85

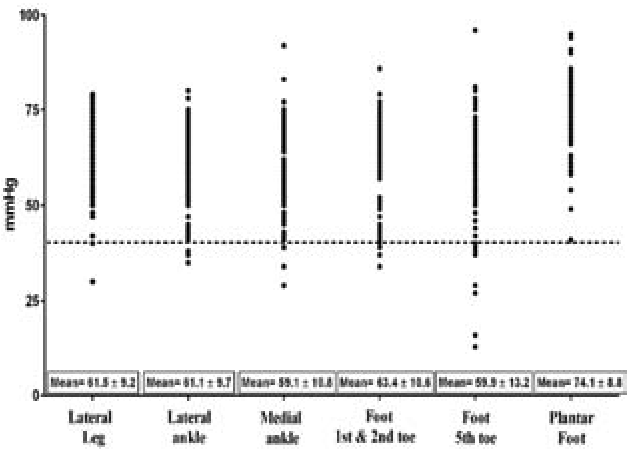
Table 4

Lower limb transcutaneous oxygen values (mmHg) in 16 healthy subjects < 39 years old

	Transcutaneous oxygen (mmHg)		
Anatomical site	Mean	(SD)	95 % CI
Lateral leg	61.5	(9.2)	59.6–63.3
Lateral ankle	61.1	(9.7)	59.1–63.0
Medial ankle	59.1	(10.8)	56.8–61.2
Foot, 1st/2nd toe	63.4	(10.6)	61.2–65.5
Foot, 5th toe	59.9	(13.2)	61.2–65.5
Plantar foot	74.1	(8.8)	57.2–62.6
Averaged lower leg	61.0	(10.8)	60.1–62.0

Figure 2

Combined TCOM readings for all three models of oximetry devices at each monitoring site on the lower leg of 16 healthy subjects < 39 years old; dotted line = 40 mmHg



each machine. There was a statistical difference between the two TCM400 machines and the TCM30 machine at two out of 12 sensor sites: right medial ankle and left medial ankle (Table 2). Figure 2 displays graphically the combined TCOM readings for all three machines at each site. The majority of measurements show readings above 40 mmHg – by definition non-hypoxic for a healthy population. The means of TCOM values of the lower limbs (mmHg) of a healthy population less than 40 years old are displayed in Table 3 and the combined means are shown in Table 4. The overall mean TCOM value for the lower limb can be calculated as 61.0 (10.8) mmHg; 95% CI 60.05–62.0 (Table 4).

False positives for hypoxia with measurements of less than 40 mmHg were seen in 18 out of 576 measurements (3.1%). These occurred at five out of the six sensor sites: sensor 5 (dorsum of the foot proximal to the head of the fifth metatarsal) 7/18; sensor 3 (5 cm proximal from the centre of the medial malleolus) 4/18; sensor 2 (5 cm proximal to the anterior aspect of the lateral malleolus) 3/18; sensor 4 (dorsum of foot between first and second metatarsal heads) 3/18; sensor 1 (10 cm distal to the lateral femoral epicondyle) 1/18. Hypoxic readings were found with all machines: TCM400 (v4.2): 7/192 (3.65%); TCM400 (v5.01): 4/192 (2%); TCM30: 7/192 (3.65%).

Discussion

Transcutaneous oximetry measures tissue O_2 tension noninvasively and is a useful tool in determining patient who are unlikely to respond to HBOT. Hypoxic wounds that improve with a 100% O_2 challenge are potentially amenable to HBOT whilst non-responding and normoxic wounds are usually excluded from treatment. To define hypoxic TCOM readings in lower limbs, it is important to establish the normoxic range in a young population without underlying medical disease or age-related vascular changes. Even though there have been studies to determine TCOM readings in a normal population,[2–4] there have not been any that define lower limb TCOM readings in healthy, non-smoking subjects younger than 40 years of age by using a standardized measurement method.

Two earlier studies reported TCOM values for both the upper and lower limbs of healthy subjects, but an instrumentation error was identified that rendered these measurements unreliable and the papers have been retracted. The present study was undertaken in part to redress this problem.

Most of the studies that laid the foundation of defining hypoxia and normoxia in a healthy population are from the 1980s and 1990s. The equipment used was of older technology and presumably less sophisticated compared to newer generation TCOM machines. Despite technological advances, we could not find a statistical difference comparing an older generation machine (TCM30) with newer generation machines (TCM400) for 10 out of 12 sensor sites. This result is expected considering that the measuring sensors of the different generation TCOM Machines are all based on Clark electrodes and are similar in construction. The differences at the left and right medial ankle sensor sites between the TCM30 and both the TCM400 (v4.2) and TCM400 (v5.01) models were statistically significant. The causes for the consistently higher reading with TCM30 at the medial ankle sites are unknown. Our measurements confirm the reproducibility of results, despite the technological advances with the passage of time.

Hypoxia is defined as a $P_{tc}O_2 < 40$ mmHg in patients without underlying diabetes mellitus and as a $P_{tc}O_2 < 50$ mmHg in patients with diabetes mellitus and in those with renal failure.[1,13–15] The majority of the readings were non-hypoxic by definition and consistent with current guidelines. Only 3.1% of the readings were < 40 mmHg, i.e., the hypoxic range. Hypoxic readings were found with all the machines and were not specific to any measuring site.* Isolated low readings in a healthy population are to be expected and can be explained by underlying low-perfused structures (e.g., tendons, bones). It is often difficult to place fixation rings in peri-wound areas but away from these low-perfused structures especially near the base of the fifth toe. The decision to treat should not be influenced by an isolated, single low reading.

There were no statistical differences between the right and left lower limb sensor sites of the same patient, measured by the same TCOM machine. Historically, the contralateral limb was used to determine an individual patient's baseline values. Some hyperbaric units still use this technique and apply sensor/sensors to the contralateral (non-diseased) leg and use it as a reference point in the context of wound assessments. Given our data this may be an acceptable practice.

The plantar foot site has traditionally not been used for TCOM measurements due to a presumed thicker stratum corneum with a subsequent increased diffusion distance. Contrary to expectations, we measured consistently high values at this site. The mean difference between the plantar foot site and the other sensor sites was 10.7 mmHg to 15 mmHg (Table 3). The sole has adapted to deal with high local compression forces by developing a system of pressure chambers, composed of fibro-fatty tissue covered by external collagen. The internal walls of these chambers are permeated by numerous blood vessels, making the sole of the foot one of the most vascularised regions of the human body.

LIMITATIONS

The five TCOM machines of three model types used in the study were all manufactured by Radiometer Medical, Denmark, using the same type of electrodes and membranes. Comparing the reproducibility of data obtained by TCOM machines from different manufacturers, and also with different electrodes and membranes, would be an area of further research. All the subjects in the study were younger than 40 years old without any significant medical problems and without age-related changes. The obtained data might not be generalizable to a different population.

Conclusions

Lower limb TCOM measurements obtained using Radiometer TCM30 machines and same generation Radiometer TCM400 machines using different software versions were comparable except for the medial ankle site. Only 18 out of 576 observations (3.1%) were below the hypoxic threshold. This appeared to be random rather than related to a specific measuring site. The overall mean $P_{tc}O_2$ value for the lower limb was 61 mmHg (SD 10.8; 95% confidence intervals 60.05–62.0).

References

1 Smart DR, Bennett MH, Mitchell SJ. Transcutaneous oximetry, problems and hyperbaric oxygen therapy. *Diving Hyperb Med.* 2006;36:72-86.

2 Dowd GSE, Linge K, Bentley. Measurement of transcutaneous oxygen pressure in normal and ischemic skin. *J Bone Joint Surg*. 1983;65–B(1):79-83.

3 Dowd GSE, Linge B, Bentley G. The effect of age and sex of normal volunteers upon the transcutaneous oxygen tension in the lower limb. *Clin Phys Physiol Meas*. 1983;4:65-8.

4 Hauser CJ, Shoemaker WC. Use of a transcutaneous PO_2 regional perfusion index to quantify tissue perfusion in peripheral vascular disease. *Ann Surg*. 1983;197:337-43.

5 Dooley J, King G, Slade B. Establishment of reference pressure of transcutaneous oxygen for the comparative evaluation of problem wounds. *Undersea Hyper Med*. 1997;24:235-44.

6 Fife CE, Smart DR, Sheffield PJ, Hopf HW, Hawkins G, Clarke D. Transcutaneous oximetry in clinical practice: consensus statements from an expert panel based on evidence. *Undersea Hyperb Med*. 2009;36:43-53.

7 Blake DF, Young DA, Brown LH. Retraction of two papers

* **Footnote:** Separate data plots for each machine at each anatomical monitoring site are available from the authors or the journal office <editorialassist@dhmjournal.com>.

investigating transcutaneous oxygen tensions in healthy volunteers. *Diving Hyperb Med*. 2016;46:54.

8 Ogrin R, Darzins P, Khalil Z. Age-related changes in microvascular blood flow and transcutaneous oxygen tension under basal and stimulated conditions. *J Ger*. 2005;60A:200-6.

9 Moritz AR, Henriques FC Jr. Studies of thermal injury II. The relative importance of time and surface temperature in the causation of cutaneous burns. *Am J Path*. 1947;23:695-720.

10 Sheffield PJ. Measuring tissue oxygen tension: a review. *Undersea Hyperb Med*. 1998;25:179-88.

11 Radiometer Medical ApS. *TCM400 transcutaneous pO_2 monitoring system. Operator's manual*. Bronshoj, Denmark: Radiometer; 2005.

12 Radiometer Medical ApS. *TCM30 Transcutaneous pO_2 Monitoring System. Operator's manual*. Bronshoj, Denmark: Radiometer; 1997.

13 Wyss CR, Matsen FA, Simmons CW, Burgess EM. Transcutaneous oxygen measurements on limbs of diabetic and non-diabetic patients with arterial vascular disease. *Surgery*. 1984;95:339-45.

14 Padberg FT, Back TL, Thompson PN, Hobson RW 2nd. Transcutaneous oxygen ($TcPO_2$) estimates probability of healing in the ischaemic extremity. *J Surg Res*. 1996;60;365-9.

15 White RA, Nolan L, Harley D, Long J, Klein S, et al. Non-invasive evaluation of peripheral vascular disease using transcutaneous oxygen tension. *AM J Surg*. 1982;144;68-75.

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