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**Validation of a software to perform exercise oximetry to diagnose arterial stenosis of the lower limbs**

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*To the Editor,*

We would like to congratulate Abraham et al. for their interesting review “Clinical application of transcutaneous oxygen pressure measurements during exercise”[1]. We totally agree that exercise oximetry is very useful in specific situations when patients experience exertional limb symptoms during the walk [2–4]. As mentioned in the review, the Delta from Rest Oxygen Pressure (DROP)

index used to diagnose lower extremity peripheral artery disease was validated against angiography and computed tomography angiography (CTA) [5,6]. Unfortunately, the calculation of the DROP is very complicated in clinical practice without the use of a dedicated software. Indeed, without a software, a time-consuming procedure using Excel® spreadsheets has to be performed to analyze that data from the oximeter. Therefore, the increase in the use of exercise oximetry depends on the development of dedicated available softwares. The present study assesses the correlation and the concordance of the results obtained by spreadsheets analysis to the results obtained with an in-house developed software.

## **Materials and methods**

We analyzed the data from 34 patients with exertional limb symptoms referred to our vascular clinic for exercise-TcPO<sub>2</sub> testing from 2014 to 2015. This study was conducted according to the principles outlined in the French Laws.

### *Ankle-brachial index measurement*

The measurement of the ankle-brachial index (ABI) was performed according to the AHA guidelines using a hand-held Doppler probe (8 MHz) by trained physicians[7,8].

### *Exercise-TcPO<sub>2</sub> measurement*

Measurement of TcPO<sub>2</sub> was performed using calibrated TcPO<sub>2</sub> electrodes (TCOM/TcPO<sub>2</sub>; PF 6000TcPO<sub>2</sub>/CO<sub>2</sub> Unit; Perimed®; Jarfalla, Sweden). The temperature of each electrode was set to 44°C, which allows maximal vasodilation and decreases the arterial to skin surface oxygen pressure gradient. A reference electrode (chest electrode) was placed between the scapulae to measure systemic changes in TcPO<sub>2</sub> during exercise[2,5,6]. One electrode was positioned on each buttock, 4 to 5 cm behind the bony prominence of the trochanter, and one electrode on each calf. Once the electrodes were in position, a period of 10 minutes in the standing position was required to stabilize the electrodes to obtain baseline values. Exercise was performed on a treadmill at a 10% slope and a speed of up to 2 mph [2]. Exercise was discontinued at the patient's request (or, by protocol, up to maximum

exercise duration of 20 minutes). The measurements from the TcPO<sub>2</sub> electrodes were used to calculate the Delta from Rest Oxygen Pressure (DROP) index (expressed in mmHg). The equation for the DROP index is as follows[2]:

$$\text{DROP}_{(\text{site})} = [\text{PO}_{2(\text{site})t} - \text{PO}_{2(\text{site})t_0}] - [\text{PO}_{2(\text{chest})t} - \text{PO}_{2(\text{chest})t_0}]$$

where  $\text{PO}_{2(\text{site})t}$  is the oxygen pressure at a measurement site at time  $t$ ,  $\text{PO}_{2(\text{site})t_0}$  is the mean oxygen pressure at a measurement site over the baseline resting period;  $\text{PO}_{2(\text{chest})t}$  is the oxygen pressure at a chest site at time  $t$  and  $\text{PO}_{2(\text{chest})t_0}$  is the mean oxygen pressure at a chest site over the resting period (2 min). We used the following procedure to analyze the raw data on each electrode using an excel spreadsheet. The system PF 6000 (TcPO<sub>2</sub>/CO<sub>2</sub> Unit; Perimed®; Jarfalla, Sweden) records the value at 2Hz. Moving averaging over 10 samples was performed on raw data to decrease the electronic artifacts on the signal. Then the values were averaged over 2.5-second interval. Additionally, on each 2.5-second interval, the TcPO<sub>2</sub> values in each site were corrected. For this correction, we calculated the difference between the mean TcPO<sub>2</sub> values over the 10 last seconds and over the first 2 minutes of the test. This difference was then divided by the duration of the test and the result was subtracted or added in each TcPO<sub>2</sub> values as a weighting factor. Then the DROPs at each site were calculated.

The DROPs indexes were also calculated using our in-house developed software, Oxymonitor®.

#### *Oxymonitor software*

Oxymonitor software is an in-house developed software that allows the analysis of the DROPs in real-time. The Oxymeter (TcPO<sub>2</sub>/CO<sub>2</sub> Unit; Perimed®; Jarfalla, Sweden) is plugged via USB on a laptop (Windows) where the Oxymonitor software is installed. At the beginning of the exercise test, the software begins to record the data.

#### *Statistical analysis*

The normality of the distribution was evaluated by Lilliefors goodness-of-fit test. Results are expressed as mean  $\pm$  standard deviation in case of normal distribution and as median [25<sup>th</sup>; 75<sup>th</sup>]. The correlation between the spreadsheet DROP and the OxyMonitor DROP was evaluated using Spearman test. A DROP  $\leq$  -16 mmHg was defined to detect Peripheral artery disease (i.e. arterial stenosis  $\geq$

60%)[6]. The concordance between the spreadsheet DROP and Oxymonitor DROP to diagnose PAD was calculated using the Kappa test. A  $p$  value  $<0.05$  was considered as statistically significant.

## Results

Data from 34 patients (mean age  $64 \pm 2$  years old; 74% men) were analyzed. General characteristics of the population are presented in Table 1. The right and left mean ankle-brachial indexes at rest were  $0.80 \pm 0.26$  and  $0.79 \pm 0.24$ , respectively. The median spreadsheet DROP and OxyMonitor DROP were  $-19[-29;-9]$  mmHg and  $-20[-29;-10]$  (non-significant). The correlation between the spreadsheet DROP and the OxyMonitor DROP was  $R^2 = 0.989$  ( $p < 0.05$ ; Figure 1). The Kappa concordance test between the spreadsheet DROP and the Oxymonitor DROP was equal to 1.00.

## Discussion

A near perfect correlation and concordance were found between the spreadsheet DROP and the OxyMonitor DROP. As previously reported in this population, the sensitivity, specificity and accuracy of Exercise TcPO<sub>2</sub> to diagnose arterial stenosis  $\geq 60\%$  were 80.4% [67.3–89.1], 88.2% [64.2–97.7], and 82.4% [73.3–91.4], respectively[6]. The main advantage of Exercise TcPO<sub>2</sub> is to allow measuring oxygen changes during exercise whereas other methods such as duplex or CTA can only perform a vascular assessment at rest. Although Exercise TcPO<sub>2</sub> was seemed interesting, its use in clinical practice was probably hampered by the lack of dedicated software allowing the monitoring in real-time of the cutaneous oxygen changes. Our study suggests that the OxyMonitor software can be used to perform exercise oximetry in clinical routine for PAD diagnosis. We hope that manufacturers would develop their own software to develop the technique.

## Conflict of interest

The authors declared they do not have anything to disclose regarding conflict of interest with respect to this manuscript.

## FIGURE LEGEND

FIGURE 1: Correlation between the exercise oximetry measures obtained with the spreadsheets and the Oxymonitor software.

DROP means Delta From Rest of Oxygen Pressure.

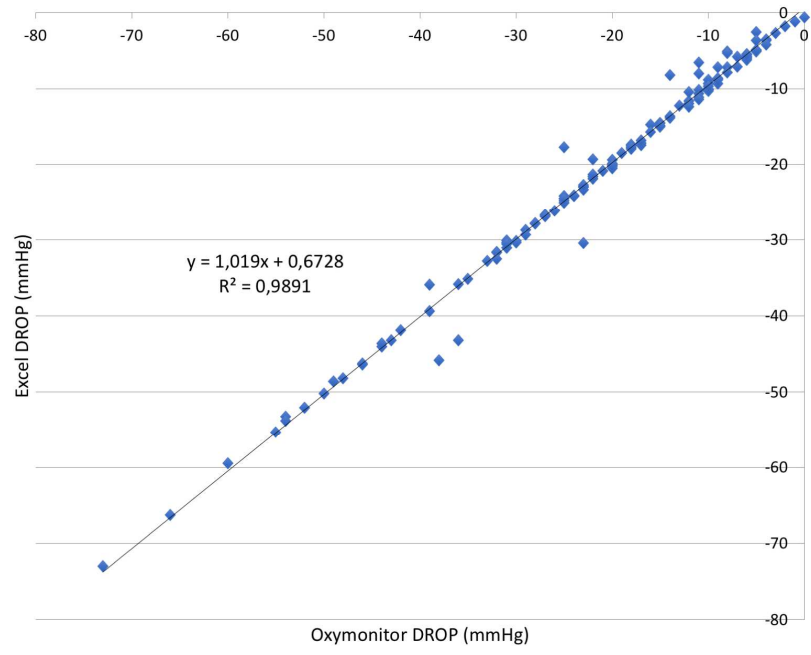
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Table 1: Characteristics of the population studied

Clinical characteristics	<i>n</i> =34
Age, years	64 ± 2
Male sex, no. (%)	25 (73.5%)
Body mass index, kg/m <sup>2</sup>	26.5 ± 5.17
Comorbidities, (history of), no. (%)	
Smoker (current or former)	12 (35%)
Hypercholesterolemia	8 (23%)
Diabetes	7 (21%)
Peripheral artery disease	11(32%)
Hypertension	24 (71%)
Current medications, no. (%)	
Statins	20 (59%)
Antiplatelet	28 (82%)
Others anticholesterolaemia	8 (23%)
Angiotensin-converting enzyme inhibitors	18 (53%)
Ankle brachial index at rest (right)	0.80 ± 0.26
Ankle brachial index at rest (left)	0.79 ± 0.24
Maximal walking distance self-reported, m	240 ± 197
Maximal treadmill walking distance, m	241 ± 236

Results are presented as mean ± standard deviation or median [25<sup>th</sup> ;75<sup>th</sup> ], or number of observation (%).



ACCEPTED MANUSCRIPT