Inter-Day Reliability of Finapres® Cardiovascular Measurements During Rest and Exercise

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ABSTRACT

This study evaluated the inter-day test-retest reliability of the Finapres® finger pulse pressure measuring device during rest and exercise. Eight male participants visited the laboratory twice for evaluation of the inter-day reliability of the Finapres® finger-pulse pressure device to measure: heart rate (HR), stroke volume (SV), cardiac output (Q̇) and mean arterial pressure (MAP) at rest, and treadmill walking at 3 km/h on 1 % and 5 % inclines. There were no systematic biases for any of the variables between days. The coefficient of variation (CV %) and 95 % limits of agreement (95 % LoA) was smallest for MAP (CV % = 1.6–3.2 %; LoA total error = 4.6–12 mmHg) and HR (CV % = 3.2–3.9 %; LoA total error = 6.8–11.9 b/min), increasing with exercise intensity (gradient). The pattern of error was different for Q̇, with decreasing CV % (4.8–3.8 %) and LoA (4.2–5.7 L/min) from rest to 5 % gradient, with the larger errors occurring for resting SV (CV = 7.4 %; LoA total error = 21.5 ml). The device measures MAP and HR reliably between days; however, error increases at higher intensities. The measurement of SV is less reliable, probably owing to underlying algorithmic assumptions.

Introduction

Valid and reliable measurement of cardiovascular responses to exercise is a frequent necessity for exercise physiologists. For example, evaluations of heart rate (HR), stroke volume (SV), cardiac output (Q̇) and blood pressure (BP) are often conducted across separate days of an investigation [6, 16]. Singular measurements of these parameters, such as BP, are recorded routinely in practice using auscultatory or oscillatory methods; however, continuous measurements of BP have been developed over the past ~ 20 years [25]. These methods improve upon the traditional continuous approaches, which require invasive procedures [22]. Continuous measurements of BP are applicable to studies that aim to identify acute changes in BP across time, as well as transient fluctuations in BP that might occur during a resting or exercising bout. The most

recognizable criterion approach to measuring these variables continuously is the intra-brachial (within-artery) method, requiring an invasive cannulation of the artery, which is not always practical, safe or warranted in an exercising participant. Owing to these limitations, an alternative, non-invasive approach has been to measure finger-pulse pressure [25].

The so-called finger-clamp method has been adopted for non-invasive continuous measurements of BP [25]. This approach maintains the diameter of a measured finger artery using a small inflatable cuff. The cuff restricts any initial change in the arterial radius, identified by infrared photoplethysmography throughout each successive cardiac cycle [4]. The inevitable changes in intra-arterial pressure are counteracted, and thus inferred, from the recorded extramural tissue pressure (i. e. from the cuff) [25]. Of further in-

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terest to the exercise science community are the reconstruction of brachial arterial pressure from the finger-pulse pressure waveform and the calculation of cardiovascular parameters that are relevant to exercise performance, such as SV, HR and $\dot{Q}$ [4].

Continuous finger-pulse pressure measurements have been compared to criterion intra-arterial methods with mixed results. Collectively, research has demonstrated that non-invasive finger-pulse measurements (i. e. Finapres® device, TNO Biomedical Instrumentation, Amsterdam, Netherlands) overestimate criterion methods by between ~ 5 mmHg [17] and 20 mmHg [5, 20] but appear to be much closer based on meta-analysed datasets with a mean bias of ~ 1.6 and random error of ± 7.7 mmHg for mean arterial pressures [9]. This was within the suggested mean bias of 5 mmHg and random error of ± 8 mmHg suggested by the Association for Advancement of Medical Instrumentation (AAMI) [28]. Whilst the criterion validity of the Finapres® has been well-investigated, its reliability between laboratory visits has not been reported among healthy, normotensive participants. What is more, its reliability during light-to-moderate exercise intensities has not been evaluated, which is necessary given its application to exercising subjects [8]. Therefore, the aim of this study was to evaluate the inter-day test-retest reliability of the Finapres® finger pulse blood pressure measuring device during rest and light-moderate exercise among healthy normotensive volunteers. The a-priori analytical goal was to report mean bias and agreement between days within that suggested by the AAMI.

Methods

Participants and design

Eight recreationally active male participants (age 27 ± 4 years; body mass 74.4 ± 10.3 kg; stature 172.8 ± 6.2 cm; MAP 104.4 ± 4.4 mmHg) provided written informed consent to take part in this study, which was given institutional ethical approval. The participants visited the laboratory on three occasions at the same time of day for familiarisation (visit 1) and inter-day reliability tests over visits 2 and 3. Each visit was separated by 24 h. The participants refrained from exercise in the 48 h before any of their visits and were also instructed to abstain from caffeine, foods high in dietary nitrate and alcohol consumption during this period. A list of foods and beverages were provided to assist with this. This study was granted institutional ethical approval and was undertaken in compliance with the ethical guidelines of Harriss and Atkinson [7].

Procedure

Familiarisation

On their first visit to the laboratory, the participants completed a familiarisation trial, where they were screened for their capacity to perform moderate exercise using the Exercise and Sports Science Australia (ESSA) risk stratification procedure. This included recording of their blood pressure, both with a manual sphygmomanometer and with the Finapres® device (Finometer MIDI, TNO Biomedical Instrumentation, Amsterdam, Netherlands). All measurements were performed by an ESSA-accredited and experienced exercise physiologist. The participants were taken through the exercise trial and instrumented in the same way that they would be on their sub-
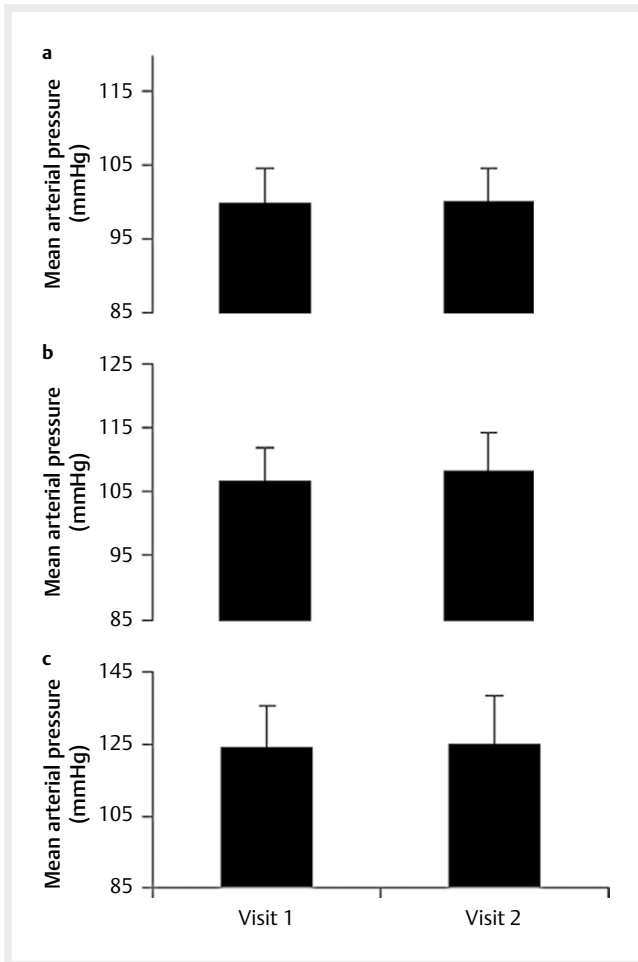
sequent visits. A food diary was completed at their familiarisation visit, which was replicated for visits 2 and 3.

Reliability trials

The two following visits were performed to evaluate the test re-test reliability of the Finapres® device during rest and 2 min of exercise at a fixed speed (3 km/h) up 1 % and 5 % gradients (in that order) on a motorised treadmill (Mercury® Med, hpcosmos sports & medical gmbh; Nussdorf-Traunstein, Germany). This mode of exercise was selected because it partially mimics stress tests performed by clinical exercise physiologists and involves minimal movement of the arms to which the device was subsequently fitted. Participants reported to the laboratory at approximately 0900 h each day, 2-h post-prandial, having consumed at least 500 ml of fluid that morning. The same fluid was consumed each day, as per their food diary. After seated rest for 20 min, the participants were asked to stand on the treadmill, where they were fitted with the Finapres® device. The laboratory was controlled at 20.0 ± 0.8 ˚C and 45 ± 10 % relative humidity.

The Finapres® device was fitted to the left arm of each participant. Specifically, the device was fitted by securing an inflatable plastic bladder (50 µm and 55 mm length) between the distal and proximal inter-phalangeal joint of the middle finger, which housed an infrared light-emitting diode (950 nm emission) and detector. This was connected to a front-end unit via an air hose. The front-end unit was attached to the left wrist using a Velcro strap. The front end is connected to the main unit and pump inside the Finometer MIDI. A height correction unit was also fitted to the front-end unit to automatically correct for hydrostatic pressure changes due to movement in the hand position relative to the heart. During the walking trials, the participants walked with a natural arm carriage, with their fingers relaxed and without holding on to the treadmill. A laptop was connected to the Finometer MIDI and the raw data were analysed using the BeatScope® software (Version 1.1, Finapres Medical Systems BV, Arnhem, Netherlands). BeatScope® software was used to reconstruct mean brachial arterial pressure from the finger-pulse pressure waveform and calculate stroke volume, heart rate and cardiac output at rest and during exercise using patented Modelflow® algorithms. In brief, the Modelflow® algorithm is used to measure SV from the integral of the pulsatile area of the systolic segment of the pressure waveform [22]. Age, gender, body mass and stature were entered into the software for each participant. The exercise comprised walking at 1 % and 5 % gradients for a period of 2 min, each separated by 5 min of standing. The Finapres® was activated 1 min prior to recording to allow for calibration. The calibration is performed automatically using the Physiocal software in the device, which was deactivated during the 2-min trials to prevent interruption of the recording. No further filtering was applied to the data.

The Finapres® device uses the finger-clamp method, whereby the diameter of the finger artery under the cuff is maintained at a constant whilst changes in intra-arterial pressure occur during the cardiac cycle [22]. Initial fluctuations in diameter are measured via an infrared photoplethysmograph, which sits within the inflatable finger cuff. The finger cuff applies the necessary counter-pressure (extramural) during monitoring via a rapid-pressure servo-control-

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► **Fig. 1** Mean 2-min arterial pressure (mmHg) (mean ± SD) during visit 1 and 2. A = rest; B = 1 % gradient; C = 5 % gradient.
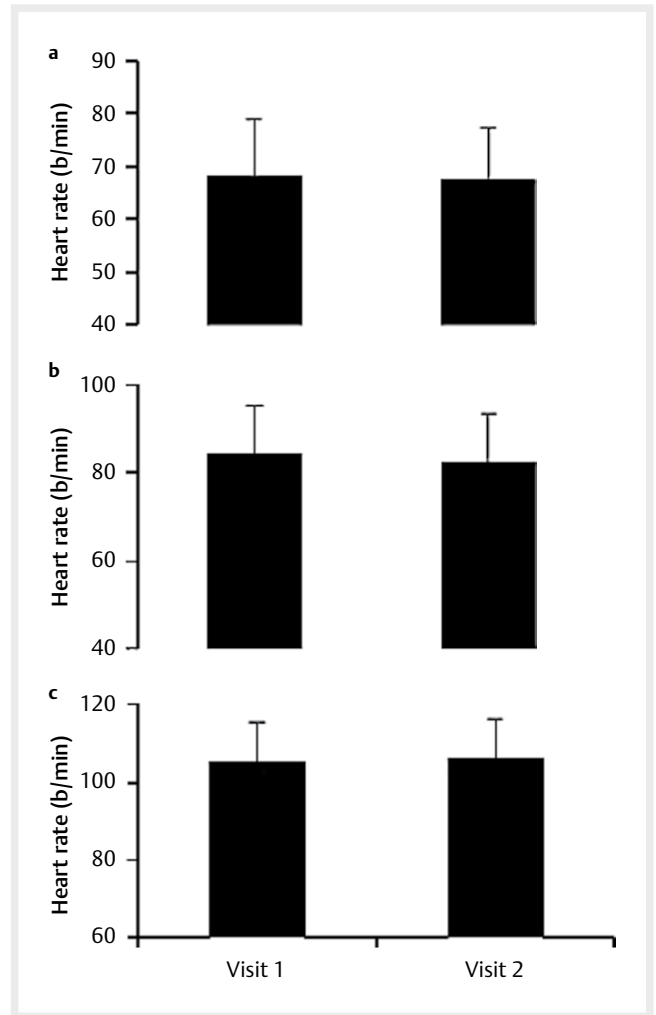
► **Fig. 2** Mean 2-min heart rate (b/min) (mean ± SD) during visit 1 and 2. A = rest; B = 1 % gradient; C = 5 % gradient.

ler system, in response to the plethysmograph signal to prevent any volume change [4]. This dynamic process alters the characteristics of the underlying artery from a pulsating, variable-sized diameter to a non-pulsating (constant) smaller state. When recorded extramural tissue pressure (i. e. from the cuff) matches intra-arterial pressure, then the transmural (difference between extramural and intra-arterial) pressure is zero [25] and finger pressure can be inferred. An in-built programme (Physiocal, Finometer Medical Systems, Amsterdam, Netherlands) acted as a calibration system, ensuring that the arterial diameter set-point remained constant [10, 11]. Left ventricular stroke volume was estimated from the integral of the arterial pressure flow-wave, with the aortic cross-section assumed and adjusted for age, gender, height and body mass of the participants [14]. Instantaneous heart rate measurements were multiplied by SV to derive Q̇.
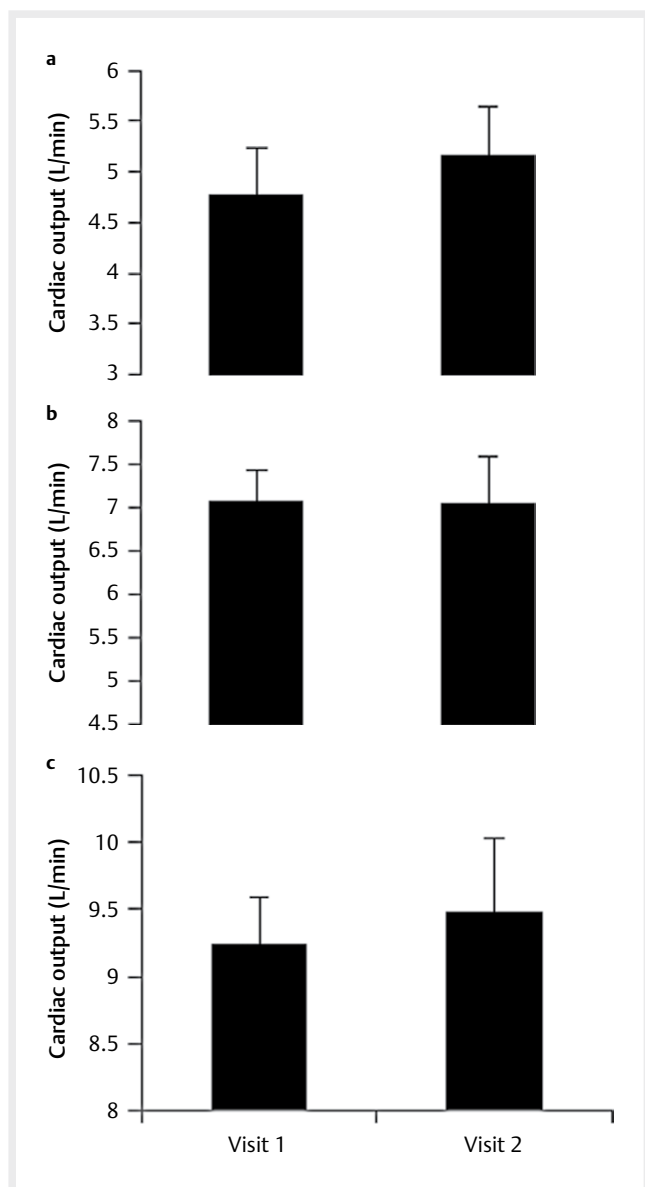
Statistical analysis

Two methods were used to evaluate the inter-day reliability of the Finapres® device for measuring MAP, HR, SV and Q̇; the 95 % limits of agreement (95 % LOA, [3]) and the coefficient of variation (CV; [1]). The ratio limits of agreement (95 % ratio LOA, [1]) were used to account for heteroscedastic errors but were reported in all cases

for comparative purposes. Data were initially checked for normality of differences using the Shapiro-Wilk test. Further checks for heteroscedastic errors were carried out using Pearson product–moment correlation (r-value). Paired samples t-tests were used to calculate differences (biases) between day 1 and day 2 of the trial. References to total error refer to the combination of the systematic and random errors calculated using the 95 % LoA technique. Statistical significance was set at $P < 0.05$. Data are reported as 2-min averages and standard deviations throughout and analysed using SPSS (v.24; SPSS Inc., Chicago, IL, USA).

Results

There were no heteroscedastic errors or systematic biases for any of the variables between visit 1 and visit 2 ($P > 0.05$) (► **Figs. 1–4**).

The CV % was smallest for MAP, ranging from 1.6–3.2 % as a function of exercise intensity (gradient). Similarly, the CV % of heart rate increased from 3.4 to 3.9 % from rest to 5 % exercising gradient. The pattern of error was different for other variables, with either decreasing Q̇ CV % from rest to 5 % gradient (4.8 to 3.8 % respectively) or larger (7.4 % CV) and less predictable errors in SV (► **Table 1**).
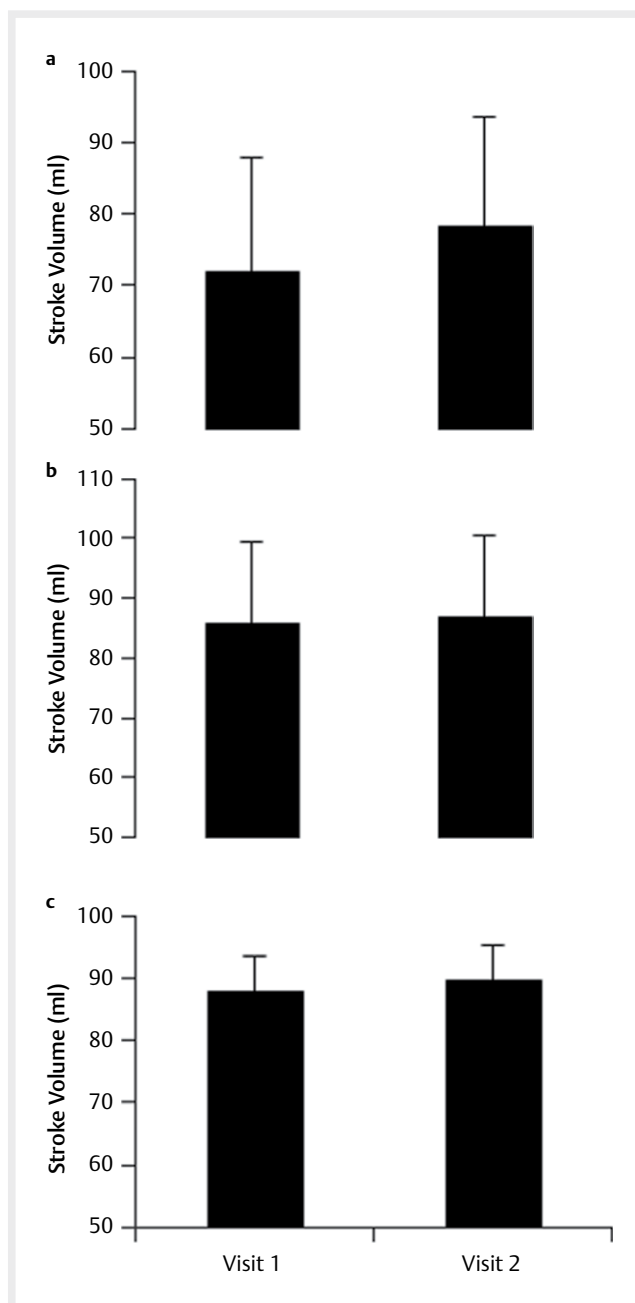
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► **Fig. 3** Mean 2-min cardiac output (L/min) (mean ± SD) during visit 1 and 2. A = rest; B = 1 % gradient; C = 5 % gradient

► **Fig. 4** Mean 2-min stroke volume (ml) (mean ± SD) during visit 1 and 2. A = rest; B = 1 % gradient; C = 5 % gradient.

The 95 % LoA confirmed the pattern of error identified with CV % but accounted for a larger portion of the sample. The largest error between days was the resting stroke volume, which was 6.1 ml higher on visit 2, with a total error of 21.5 ml. For mean arterial pressure, the mean biases were small (0.1 to 1.6 mmHg), with random error reaching 11.1 mmHg at the 5 % gradient (total error = 12 mmHg). Cardiac output demonstrated consistent total errors of ~ 1 L/min across all conditions, with the largest error occurring in the resting condition (−0.4 ± 0.7 L/min), which was explained by the larger errors in stroke volume during rest (► **Table 1**).

Discussion

The main findings of this study were that the inter-day error of the Finapres® device for measuring mean arterial brachial pressure was

within the total error range of the analytical goal (5 mmHg mean bias and 8 mmHg random error = 13 mmHg) suggested by the AAMI at rest and during treadmill walking exercise. The mean bias was below the recommended 5 mmHg in all cases but the random error was increased by the inclusion of larger biases (~ 11.1 mmHg) in the 5 % gradient condition. All of the statistical techniques used herein indicated that the MAP and HR error was increased as a function of the exercise intensity (i. e. rest through to gradients of 5 %). The more lenient CV % technique [1] agreed with this pattern, demonstrating errors of 1.6 %, 1.9 % and 3.9 % for MAP and 3.4 %, 3.5 % and 3.9 % for HR (► **Table 1**). Measurements of BP and HR are recorded in a more direct manner by the Finapres® device, either

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▶ **Table 1** The inter-day reliability of resting mean arterial pressure, heart rate, stroke volume and cardiac output during rest, walking at 1% and 5% gradients on a treadmill (n = 7).

	Resting	1% gradient	5% gradient
Mean arterial pressure			
CV % ± 95% CIs	1.6 ± 0.2	1.9 ± 0.3	3.2 ± 0.3
95% LoA (mmHg)	−0.1 ± 4.5	−1.6 ± 5.7	−0.9 ± 11.1
95% ratio LoA	1.01 × / ÷ 1.04	1.01 × / ÷ 1.1	1.01 × / ÷ 1.09
Heart rate			
CV % ± 95% CIs	3.4 ± 0.4	3.5 ± 0.4	3.9 ± 0.5
95% LoA (b/min)	0.5 ± 6.3	1.8 ± 7.8	−0.6 ± 11.3
95% ratio LoA	1.01 × / ÷ 1.10	1.02 × / ÷ 1.11	1.01 × / ÷ 1.10
Stroke volume			
CV % ± 95% CIs	7.4 ± 0.9	4.0 ± 0.5	5.8 ± 0.7
95% LoA (ml)	−6.1 ± 15.4	−1.2 ± 9.6	−1.8 ± 14.1
95% ratio LoA	1.09 × / ÷ 1.21	1.10 × / ÷ 1.1	1.02 × / ÷ 1.17
Cardiac output			
CV % ± 95% CIs	4.8 ± 0.9	3.9 ± 0.4	3.8 ± 0.4
95% LoA (L/min)	−0.4 ± 0.7	0.1 ± 0.8	−0.2 ± 1.0
95% ratio LoA	1.08 × / ÷ 1.13	1.01 × / ÷ 1.10	1.03 × / ÷ 1.10

from the cuff pressure or the pulse identification, respectively. Given that the other parameters rely on secondary calculations and a variety of assumptions, it is possible that the increases in errors of other variables, such as SV, are explained by additional factors. The largest reported CV was 7.4% (resting SV). Collectively, our findings provide encouraging evidence for the capacity of the Finapres® device to continuously measure a variety of cardiovascular responses to rest and exercise, particularly given the potential for biological variation between days.

The Modelflow® algorithm [26], used to measure SV, is a development of the original corrected impedance (cZ) method [27]. Assuming constant impedance (Z) based on age and MAP, this approach uses the systolic segment of the pressure waveform to calculate SV from the integral of the so-called pulsatile area (PSA). This was subsequently updated [26] with a 3-element Windkessel model. It was recognised that systolic flow is dependent upon arterial impedance as well as compliance and peripheral resistance [4]. Therefore, these three components are accounted for in the current Modelflow® method, dependent upon age, gender, stature and body mass [22]. These processes permit the production of a flow wave, which is integrated to compute SV and multiplied with HR to yield Q̇. Accordingly, the model makes numerous assumptions regarding the dynamics of the impedance and compliance of cardiovascular structures that are incorporated, such as the main arteries (aorta and brachial artery). For example, it assumes an 'average' aorta structure and function of connecting valves based on autopsied human tissue [14], which might not reflect the size and elastic properties of the current sample. This is particularly relevant under exercising conditions, where the pressor reflex is responsible for altering peripheral resistance via vasoconstriction of peripheral vasculature, which will consistently vary depending upon the degree of metabolic and mechanical afferent feedback [13]. Indeed, the additional mechanical movement and metabolic demand required to walk at a 5% gradient might explain the more variable MAP response compared to 1% or resting values. Modelflow® also

assumes that aortic pressure is unaffected by pulmonary hyperinflation or changes in intra-abdominal pressure [4]. These changes are typically observed in the exercising athlete and are unlikely to be consistent between trials. Lastly, the assumed aortic properties that inform the Modelflow® algorithm were based on subjects ranging from 30 to 88 years of age, which does not reflect that of the current study (27 ± 4 years). This will primarily affect the agreement with criterion SV and Q̇ measurements (see validity studies [18]) because the models outputs are based on the less compliant and elastic properties of arteries of older subjects. However, these assumptions are also likely to affect the reliability between trials. This is because Modelflow® approximates the maximal cross-sectional area of the aorta based on the same autopsy data, despite the well-known variable increases in aortic flow and pressure as a function of exercise intensity [21]. This combination of factors provides reasons for the poorer reliability of SV measurements in this study. Measurements of Q̇ appear to be salvaged by the more reliable HR recording, which is multiplied by SV to provide these data.

It has been suggested that finger pulse pressure measurements should be conducted over 'optimal' periods of time, ranging between 30 s [17] and 30 min [9]. Indeed, the 2-min period of BP recording in the current study was partly based upon these recommendations. These suggestions appear to be based on the following reasons: First, it has been reported that finger-pulse pressure measurements drift over extended periods of time (3–4 h), which is attributed to the mechanical distortion of the underlying tissues and might require participants to remove the cuff to establish baseline blood flow [19]. Secondly, periods shorter than 30 s are thought to produce erroneous data, owing to the relative contribution of anomalous data points to the entire data array across brief time periods [17]. The reasons for erroneous data points in this study are difficult to identify; however, this could be explained by the increased exercise intensity and subsequent fluctuation in centre of mass and limb movement. The Finapres® can be sensitive to sudden movement of the limb-fitted hardware on the participant,

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causing motion artefacts [23]. The type of exercise used (low-intensity incline walking) negates some of these issues, but higher intensities or the introduction of more dynamic movements may be problematic.

Other studies have reported s higher variation in the mean arterial pressure, measured via a manual brachial sphygmomanometer (CV = 4.78 %) or finger pulse pressure (13.44 %) [24]. This variation was unanticipated, given that the study was conducted on resting participants and used the same finger pulse pressure device. However, our study attempted to control for diet and hydration prior to each visit, both of which can affect haemodynamic responses. Furthermore, we did not apply any other form of occlusion to a limb during the study, whereas Wecht et al. [24] performed a concurrent manual BP measurement using a sphygmomanometer, which is also likely to inconsistently disrupt BP in the contralateral limb between visits [15]. These reasons might explain the discrepancies between studies.

Studies attempting to investigate the reliability of finger-pulse pressure devices have overlooked inter-day reliability [5, 12, 18]. In the exercise sciences, it is common to adopt within-participant crossover research designs, whereby participants are randomised into experimental conditions across days of a study. In this instance, it is imperative that researchers understand the noise associated with a device between visits to the laboratory under controlled conditions [1]. To facilitate the use of this device among researchers, we have used the nomogram of Batterham and Atkinson [2] and the reliability values reported therein to estimate sample sizes for each of the four measured variables that would be necessary to detect 5 % changes. The highest sample sizes needed would be 7 and 8 for MAP and HR, respectively, whilst SV and Q̇ would require 44 or 20 participants, respectively, to detect the same 5 % signal change. In the absence of position statements about the acceptable error for HR, SV and Q̇, we encourage users to develop a-priori analytical goals that are specific to their study and note the above sample sizes prior to using this device for research purposes.

Conclusion

The Finapres® device measures both MAP and HR reliably between consecutive visits to the laboratory, which would permit the detection of at least 5 % changes with relatively small samples of 7–8 participants. The error appeared to increase as a function of exercise intensity for HR and MAP, which might relate to the movement of the hardware. The measurement of SV and, to a lesser degree Q̇, was less reliable and would require much larger sample sizes to detect changes that might be anticipated owing to an intervention. The reason for these errors is likely to relate to the assumptions of the Modelflow® algorithm.

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Conflict of Interest

The authors declare that they have no conflict of interest

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