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# Pilot Assessment of Piezoelectric Transducers as a Cost-Effective Alternative to EndoPAT

Olivia Ramraj[a] Smriti Badhwar[a] Tania J. Pereira[a] Heather Edgell[a, b]

[a]School of Kinesiology and Health Science, York University, Toronto, ON, Canada; [b]Muscle Health Research Centre, York University, Toronto, ON, Canada

**Keywords**
Non-invasive vascular assessment · Piezoelectric transducers · Vascular health · Reactive hyperemia · Microvascular function

**Abstract**
***Introduction:*** Current microvascular assessments may not be practical or accessible requiring experienced personnel and/or ongoing equipment costs. Piezoelectric transducers can reliably obtain finger blood pressure waves, similar to peripheral arterial tonometry devices; thus, they could be used to estimate microvascular function. We aimed to validate piezoelectric transducers as an alternative measure of microvascular function compared to EndoPAT. ***Methods:*** Twenty-five adults (aged 20–64 years) completed reactive hyperemia (5 min forearm circulatory occlusion and 3 min recovery) with piezoelectric transducers on the middle fingers and EndoPAT probes on the index fingers. Average area under the curve (AUC) of the pulse wave signal for the occluded and control arms was determined at baseline, every 30 s post-occlusion, and 10 s around the peak response. Microvascular function index (MFI) was calculated as the ratio of AUC post-occlusion to AUC baseline in the test arm, then normalized to the same ratio in the control arm. MFI at each time point was correlated with the reactive hyperemia index (RHI) from the EndoPAT. ***Results:*** The greatest significance was found between RHI and MFI at 10 s around the peak response (Spearman's $r = 0.67$, $p = 0.0002$; Pearson's $r = 0.76$, $p = 0.00001$). ***Conclusion:*** MFI is a reusable and user-friendly microvascular function assessment that could provide better access to vascular health screening.


## Introduction

The vascular endothelium has several crucial roles in maintaining vascular function, including regulating blood vessel tone [1]. For example, shear stress acts on the endothelium, causing vasodilation via nitric oxide release [2–4]. In chronic conditions such as diabetes and obesity, overexpression of pro-inflammatory mediators, increased oxidative stress, and disturbed arterial flow patterns can all cause endothelial dysfunction [5]. Thus, a reduction in endothelial function can be used as a screening tool for estimating cardiovascular risk.

Indeed, endothelial dysfunction has been recognized as a potential predictive and prognostic marker for cardiovascular morbidity and mortality [6–8]. Various assessments have been developed to evaluate endothelial function and the quality of an individual's

karger@karger.com
www.karger.com/jvr


Correspondence to:
Heather Edgell, edgell@yorku.ca

vascular health. The gold standard method for assessing coronary endothelial function is an invasive test involving the infusion of adenosine and/or acetylcholine into the coronary artery to induce vasodilation [9, 10]. Comparatively, flow-mediated dilation (FMD) is a non-invasive ultrasound technique that involves imaging the brachial artery to capture the post-occlusion increase in diameter in response to reactive hyperemia [11]. FMD has been shown to correlate with coronary arterial function [12]. Further, an operator-independent technique called peripheral arterial tonometry using the EndoPAT device (Itamar Medical, Israel) measures the reactive hyperemia index (RHI), where arterial pulse waves are recorded in both hands during and after reactive hyperemia. The RHI is the ratio of the pulse wave signal comparing the maximal hyperemic response to baseline while normalizing to the non-occluded hand. Several studies have established this method as a reliable measure of endothelial function [13–17], and it has been shown to correlate with FMD measurements [13]. While EndoPAT is a convenient alternative to FMD, the device still requires skilled personnel and increased equipment costs due to single use operational supplies.

In the current study, we propose using readily available reusable piezoelectric pulse transducers during reactive hyperemia as a more affordable, user-friendly method for evaluating endothelial function. The pulse transducers detect changes in force against the piezoelectric crystals, which are translated into a pulse wave signal. Foo et al. [18] found that these pulse transducers could reliably obtain pulse transit time and heart rate when placed on the radial artery at the wrist compared to commercial ECG and pulse oximetry devices. Further, Edgell et al. [19] previously used pulse transducers to determine pulse wave velocity in conjunction with the pulse wave from a Finometer Midi (Finapres Medical Systems, Netherlands) and Qananwah et al. [20] determined that there was a strong relationship and morphological similarities between piezoelectric plethysmograms and volumetric variations of blood circulation at the finger, suggesting that the pulse waves obtained from the piezoelectric pulse transducers are morphologically comparable to the waveforms recorded using the EndoPAT. Therefore, since the signal from the piezoelectric pulse transducer can be used to determine peripheral arterial stiffness and is structurally similar to the arterial tonometry signal from the EndoPAT device, we hypothesized that our new protocol, the microvascular function index (MFI), can be used in lieu of the EndoPAT to determine microvascular function.

**Table 1.** Anthropometrics and resting cardiovascular variables

| Parameter ($n$ = 25) | |
|---|---|
| Age, years | 27 (22–38) |
| Height, cm | 169±11 |
| Weight, kg | 78±22 |
| Systolic blood pressure, mm Hg | 110 (102–126) |
| Diastolic blood pressure, mm Hg | 76 (67–80) |
| Heart rate, bpm | 76±11 |

Data are presented as mean ± SD or median with IQR.

## Methods

Twenty-five adults (females, $n$ = 15; Table 1) were recruited. Inclusion criteria were adults between 18 and 75 years of age, the physical capability to transport to the testing location, and the ability to understand and give informed consent. Self-identified ethnicity was recorded: 17 Caucasian, 5 Asian/South Asian, and 3 Arab/Middle-Eastern individuals. Participants were asked to refrain from consuming caffeine, alcohol, and fatty foods at least 12 h prior to testing. Participants were not required to fast as Nardone et al. [21] observed that fasting did not impact EndoPAT score in covariate analysis. Participants were also asked to refrain from smoking and strenuously exercising for at least 12 h prior to testing.

*Reactive Hyperemia*

EndoPAT tonometry finger cuffs were placed on the left and right index fingers. As outlined in EndoPAT user manuals, participants were seated with hands and fingers in a relaxed position over the seat's armrests and palms facing down while feet were firmly planted on the ground. Piezoelectric pulse transducers (ADInstruments, Colorado Springs, USA) were wrapped around both the left and right middle fingertips such that the transducer surface was placed against the pad of the finger. Participants were asked to refrain from moving for the duration of the test to eliminate movement artifacts. A reactive hyperemia test was conducted, which consisted of 5 min of baseline, 5 min of suprasystolic circulatory occlusion to the left arm (i.e., +50 mm Hg), and 5 min of recovery following the release of occlusion. Piezoelectric signals were acquired through a PowerLab device (ADInstruments, Colorado Springs, USA) and recorded using LabChart software (ADInstruments, Colorado Springs, USA) for the duration of the reactive hyperemia test to determine the MFI. An example of the compressed waveforms of both the EndoPAT signal and the MFI signal at the time of reactive hyperemia is included as Figure 1.

*Data Analysis*

LabChart software (ADInstruments, Colorado Springs, USA) was used to determine the continuous positive area under the curve (AUC) of the pulse transducer waveform for each cardiac cycle. A standard integral of the waveform was generated and reset each heart beat. The maximal positive AUC of each heart beat was calculated and beat to beat averages were used as described below for use in the MFI calculation.

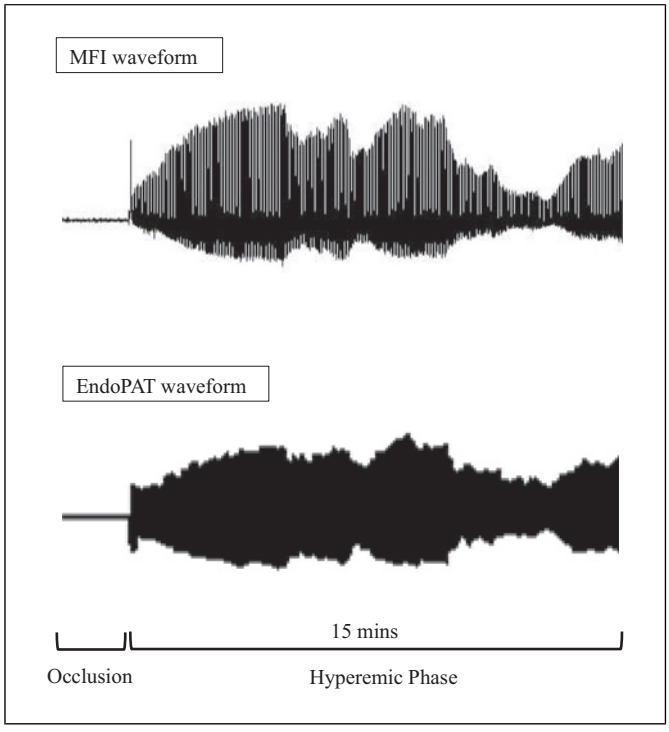


**Fig. 1.** A visual representation of compressed raw MFI waveforms (top) and EndoPAT waveforms (bottom) of the occluded hand during the hyperemic state.

In the test (occluded) and control (non-occluded) arms, the averaged AUC was calculated for 3.5 min of baseline prior to occlusion (to match the baseline analysis used by the EndoPAT [16]), 10 s around the peak response, and 30 s averages starting at cuff deflation until 3 min post-deflation. The EndoPAT algorithm uses 1 min of signal starting 1 min post-deflation [16]. For each period following the occlusion release, the MFI was calculated as the ratio of AUC post-occlusion to AUC baseline in the test arm normalized to the same ratio in the control arm:

$$\text{MFI} = \left(\text{AUC}_{\text{test}}\ \text{post-occlusion}/\text{AUC}_{\text{test}}\ \text{baseline}\right)/\left(\text{AUC}_{\text{control}}\ \text{post-occlusion}/\text{AUC}_{\text{control}}\ \text{baseline}\right)$$

The RHI was determined with proprietary software (EndoPAT, Itamar Medical, Israel) and was used as the independent variable to compare against the MFI method.

*Statistical Analysis*

Data were tested for normality using the Shapiro-Wilk test. Means and standard deviations were calculated to describe normally distributed data (e.g., height, weight, heart rate). Medians and interquartile ranges were calculated to describe variables that failed normality (e.g., age, systolic and diastolic pressure, time to peak). Univariate linear regression analysis and correlation analysis were performed between RHI (independent variable) and MFI for each time point using Pearson's test and Spearman's test using SigmaPlot software (Systat Software Inc., USA). Bland-Altman plots were constructed to compare the two methods.

**Table 2.** Correlative data and power calculations between microvascular function as measured by EndoPAT RHI versus the novel MFI method

| | 10 s around peak amplitude ratio | 0–30 s amplitude ratio | 30–60 s amplitude ratio | 60–90 s amplitude ratio | 90–120 s amplitude ratio | 120–150 s amplitude ratio | 150–180 s amplitude ratio |
|---|---|---|---|---|---|---|---|
| Spearman's *r* (*p* value) | 0.67 (0.0002) | 0.49 (0.011) | 0.57 (0.002) | 0.63 (0.0007) | 0.58 (0.002) | 0.66 (0.0002) | 0.56 (0.003) |
| Pearson's *r* (*p* value) | 0.76 (0.00001) | 0.60 (0.002) | 0.67 (0.0003) | 0.70 (0.0001) | 0.65 (0.0004) | 0.68 (0.0002) | 0.60 (0.002) |
| Coefficient of determination ($R^2$) | 0.58 | 0.37 | 0.45 | 0.49 | 0.43 | 0.47 | 0.36 |
| Power (α = 0.05) | 0.996 | 0.897 | 0.965 | 0.981 | 0.955 | 0.973 | 0.897 |

MFI, microvascular function index; RHI, reactive hyperemia index.

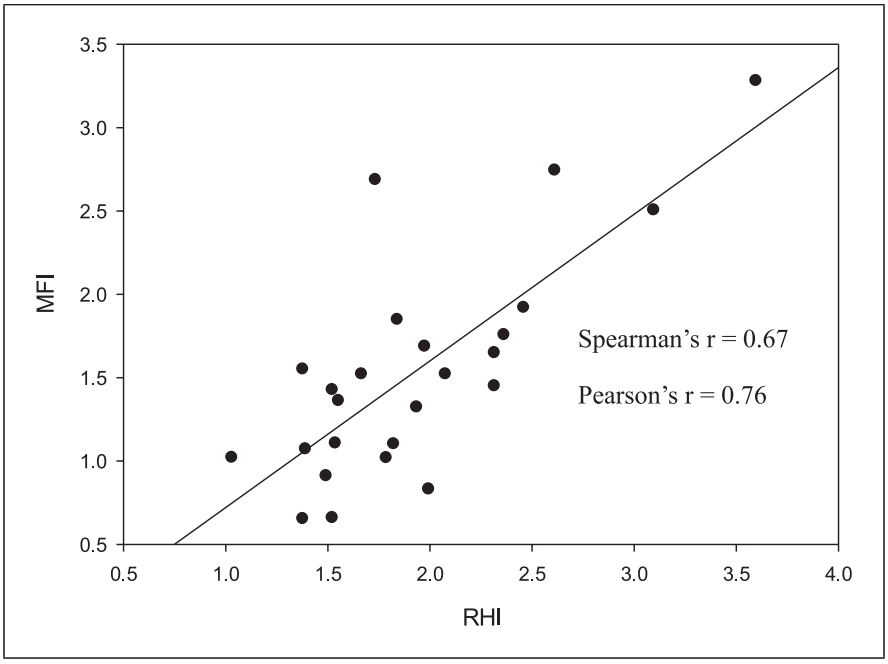


**Fig. 2.** Linear regression between EndoPAT RHI and MFI at 10 s surrounding the peak hyperemic response.

This analysis was selected as we aimed to replicate the EndoPAT algorithm such that the computer-automated process was removed. Significance was set at $p < 0.05$. Power was set to 0.80 and alpha was set to 0.05. Quartile analysis was performed by sorting individuals into quartiles based on RHI score and calculating mean and standard deviations of MFI scores falling within each quartile. A one-way ANOVA was performed on MFI quartiles and Tukey's post hoc test on quartiles found to be significantly different. SigmaPlot software (Systat Software Inc., USA) was used to generate the receiver operating characteristic (ROC) curves to determine the similarity between EndoPAT RHI and MFI. Nine participants were diagnosed with "endothelial dysfunction" by the EndoPAT and these data were used to create the ROC curves to determine preliminary MFI diagnostic threshold values in comparison to the EndoPAT. A threshold for endothelial dysfunction measured by MFI was determined by summing the sensitivity and specificity values and selecting the threshold value with the highest sum, as described by Zou et al. [22].

## Results

Participant characteristics, including resting cardiovascular variables, are described in Table 1. Participants were 27 (22–38) years old. Average height and weight were 169 ± 11 cm and 78 ± 22 kg, respectively. Systolic blood pressure was 110 (102–126) mm Hg, and diastolic blood pressure was 76 (67–80) mm Hg. Average heart rate was 76 ± 11 bpm. No participants reported having any cardiovascular conditions; however, 3 participants reported having asthma, and 1 participant reported that they were a regular smoker. For medication use, 1 participant reported using statins for preventative purposes, 1 participant used levothyroxine, 1 participant used an interleukin inhibitor, and 3 participants reported hormonal contraceptive use.

The AUC of the occluded arm increased during reactive hyperemia, where the median time to the peak AUC response was 72 s (interquartile range: 62–114 s). At this time, the AUC was significantly higher than baseline (0.014 au [0.010–0.025 au] vs. 0.010 au [0.005–0.021 au], $p < 0.001$). Compared to baseline, significant increases of the positive AUC in the test arm were observed after 90 s (0.016 au [0.010–0.025 au], $p < 0.001$), 120 s (0.017 au [0.010–0.025 au], $p < 0.001$), and 150 s (0.017 au [0.010–0.024 au], $p < 0.001$).

There were significant positive correlations between RHI and MFI at every time point analyzed; however, the highest correlation was observed at 10 s around the peak pulse amplitude in the hyperemic phase (Table 2; Fig. 2). This was supported by the Bland-Altman plot, which shows good agreement between methods using the 10 s around the peak (Fig. 3). Quartile analysis based on RHI score determined that individuals with the most impairment deemed by the lowest quartile of RHI score had the lowest MFI score (Table 3). A one-way ANOVA between quartiles determined that the fourth quartile was significantly different than the first ($p = 0.002$), second ($p = 0.042$), and third ($p = 0.018$) quartiles; however, there were no differences between the first, second, and third

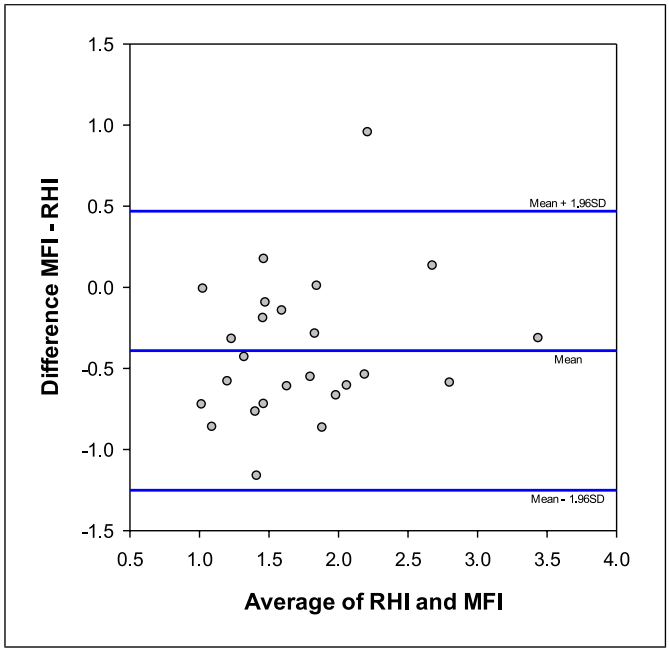


**Fig. 3.** A Bland-Altman plot demonstrating the agreement between RHI and MFI at 10 s around the peak hyperemic response. The difference between methods was plotted against the average of both methods. The outer blue lines represent the upper and lower limit of agreement; a good agreement is found between both methods since most values fall within this range.

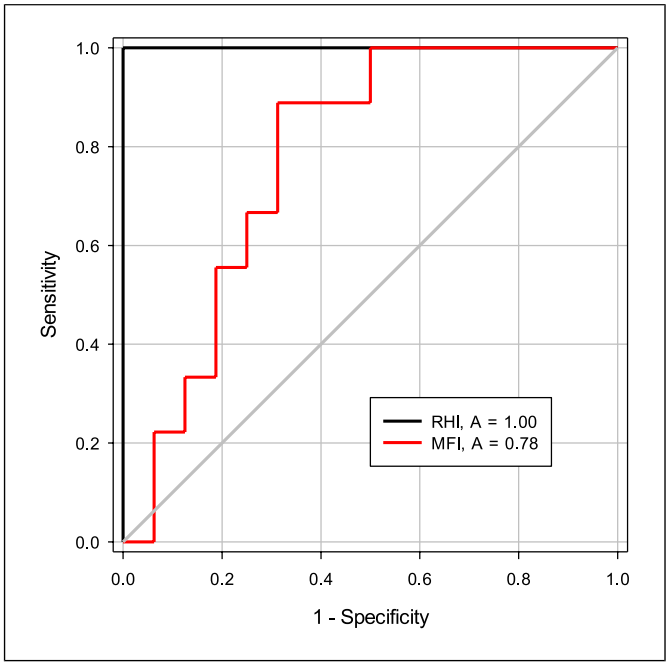


**Fig. 4.** A receiver operating characteristic (ROC) curve demonstrating sensitivity of the MFI technique in comparison to EndoPAT RHI.

**Table 3.** Quartile analysis of MFI based on RHI score

| | RHI, mean±SD | MFI, mean±SD |
|---|---|---|
| Quartile 1 | 1.39±0.17 | 1.04±0.35 |
| Quartile 2 | 1.68±0.12 | 1.42±0.52 |
| Quartile 3 | 2.02±0.16 | 1.30±0.48 |
| Quartile 4 | 2.74±0.51 | 2.28±0.69[a] |

MFI, microvascular function index; RHI, reactive hyperemia index. [a]MFI in the 4th quartile is significantly higher than all other quartiles.

quartiles ($p > 0.5$). AUC of the ROC curve was 0.78 (Fig. 4) and revealed MFI could predict low microvascular function (95% confidence interval: 0.59–0.96; $p = 0.024$). Using 1.439 as a threshold value, the sensitivity and specificity of MFI to predict low endothelial function were 89% and 69%, respectively. For 9/25 participants under the age of 30, RHI was 1.94 ± 0.45 and MFI was 1.48 ± 0.63 whereas for 16/25 participants over the age of 30, RHI was 1.96 ± 0.79 and MFI was 1.51 ± 0.78 ($p = 0.9$ for both comparisons).

## Discussion

The results of this pilot study indicate that the MFI method using piezoelectric pulse transducers could be a suitable alternative for evaluating microvascular function compared to EndoPAT. The MFI method is less expensive due to fewer operational costs and compared to vascular assessments such as cardiac catheterizations and ultrasound imaging, it does not require skilled technicians to operate the tests. It was found that MFI, calculated using a ratio of the AUC at the 10 s around the peak amplitude after cuff release to baseline and normalized to the control arm, had a strong correlation and good agreement with the RHI generated by the EndoPAT. The generation of ROC curves and threshold values further demonstrated the potential ability of MFI to detect altered hyperemic response similarly to the EndoPAT.

The EndoPAT generates its RHI score by calculating a ratio of the average pulse wave amplitude during the 60–120 s following cuff release to the 3.5 min prior to inflation in the test arm and normalizing it to the control arm [16]. The strong correlations between the two methods can be partly explained by the similar time frames utilized and the morphological similarities of

the pulse waves generated by the two methods. For example, we used a similar baseline period compared to the EndoPAT algorithm (i.e., 3.5 min average), and the time of maximal response in the current study overlapped with the previously observed time of maximum response of the EndoPAT device (60–120 s). An advantage of MFI is the use of the true peak response in its calculation, allowing for a more precise calculation of the hyperemic response. According to Black et al. [23], traditional manual FMD analysis uses arbitrary time points following cuff deflation, which can miss the true peak response. Previous studies have also observed visual similarities between the two pulse waveform types used in this study [20], suggesting comparability between methods. ROC curve analysis demonstrated the sensitivity of MFI to reactive hyperemia as intended. A threshold value was calculated, and the sensitivity and specificity values demonstrated the capability of MFI to reliably discriminate between normal microvascular function and dysfunction when compared with EndoPAT RHI.

Although we observed good agreement between the two methods, the RHI and MFI scores were not perfectly correlated. The Bland-Altman plot revealed an approximate −0.5 bias. This suggests that MFI scores are quantitatively smaller than RHI; however, the application of correction factors may resolve this in larger future studies. Potential differences could stem from the fact that the inflatable EndoPAT probes measure blood volume in the entire tip of the index finger, and the piezoelectric sensors detect changes in pressure against the ventral surface of the middle fingertip, which is a much smaller surface area. Further, the EndoPAT probes exert a counterpressure (70 mm Hg) to prevent venous pooling [13], while the piezoelectric sensors are incapable of doing so.

*Limitations*

The current study is limited by its small sample size contributing to the lack of statistical differences between quartiles 1–3 of MFI. However, the included study population was heterogeneous and included individuals of varied ages, sexes, and ethnicities. Even so, this method should be repeated in larger and more diverse populations to identify any differences associated with age, sex, ethnic group, and health status. It is important to note that despite our finding that there were no differences in RHI or MFI between age-groups, the EndoPAT may have limited value in younger participants as the Malmö Offspring Study recently found that a younger age (<30 years old) is associated with lower RHI [24]. The authors suggest that young, healthy arteries may not have the capacity to dilate as much during reactive hyperemia leading to artificial dysfunction. While equivalent methodologies should be able to detect similar responses (artificial or true dysfunction), future studies designed to evaluate the relationship between microvascular methodologies need to involve a higher proportion of older participants to capture endothelial dysfunction. Our participants were generally healthy, where none declared previously diagnosed cardiovascular disease and only 3 declared having asthma. Future studies should investigate the ability of the MFI method to detect microvascular dysfunction in unhealthy populations. It would be expected that individuals with vascular damage or endothelial dysfunction would have a delayed or blunted hyperemic response, as observed with the EndoPAT. Further, the repeatability and reliability of MFI across day-to-day measurements must be investigated as the current study conducted a single trial.

In the present study, testing was conducted in the seated position, and recent work suggests that the natural logarithm of RHI is suppressed in the upright posture [25]; thus, our RHI values may be underestimated when compared to other studies and/or population averages. Similarly, our methodologies may further underestimate RHI due to the use of forearm occlusion to induce reactive hyperemia rather than upper arm occlusion as per EndoPAT recommendations. For consistency within our laboratory, forearm occlusion was chosen to replicate a previous laboratory study that demonstrated a relationship between dobutamine-induced coronary vasodilation and the EndoPAT response [21].

Although the EndoPAT device concurrently calculates resting augmentation index, a measure of arterial stiffness, we did not investigate the potential of our method for its determination. Augmentation index is typically measured using pressure waves at conduit arteries rather than at the level of the microvasculature; however, future studies could explore whether or not our method is also capable of assessing other metrics indicative of cardiovascular health.

## Conclusion

The MFI method of evaluating microvascular function is similar to EndoPAT RHI and is advantageous as its reusability and accessibility will allow researchers, clinicians, and their patients to have better

access to vascular testing. More studies are required to determine any necessary correction factors for accuracy and/or cut-off points to detect the presence or absence of endothelial dysfunction. The devices and the associated software are easy to use and allow for more convenient analysis of the pulse wave recordings. Additionally, the simplicity of this method would provide a practical and simple demonstration of reactive hyperemia in undergraduate physiology laboratories that possess the required equipment.

## Statement of Ethics

Ethical clearance was obtained by the York University Ethics Review Board (e2021-394). Each participant gave written informed consent before starting the study.

## Conflict of Interest Statement

The authors have no conflicts to declare.


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## Author Contributions

O.R., S.B., T.P., and H.E. all (1) gave substantial contributions to the conception/design of the work or the acquisition, analysis, or interpretation of data for the work; (2) drafted or reviewed the work for important intellectual content; (3) gave final approval of the version to be published; and (4) agreed to be accountable for all aspects of the work in enduring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## Data Availability Statement

Data are not publicly available due to privacy and REB concerns; however, data are available upon reasonable request to the corresponding author with subsequent REB approval.

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