Validity of a Novel Wristband Tonometer for Measuring Central Hemodynamics and Augmentation Index

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BACKGROUND
Central hemodynamic and augmentation indices are independent predictors of cardiovascular events and all-cause mortality that can be estimated noninvasively by pulse wave analysis. The purpose of this study was to assess the reliability and validity of a newly engineered wristband tonometer for acquiring radial artery pressure waveforms.

METHODS
Radial artery pulse pressure waveforms were evaluated with an established pencil-type and a novel wristband tonometer in 31 participants (aged 30.2 ± 9.5 years) resting in a supine position. Pulse wave analysis was executed using the same validated generalized transfer function (SphygmoCor) for both tonometers.

RESULTS
A significant difference in time to data acquisition between tonometers was observed (−70.2 ± 147.7 s; P < 0.05; wristband faster). The wristband tonometer had significantly lower within-subject coefficients of variation (CV) compared with the pencil-type tonometer in aortic pulse wave height (−2.67% ± 5.51%; P < 0.05) and time to reflection (−2.26% ± 6.16%; P < 0.01). No other differences in CV were observed. Slight but statistically significant mean differences between tonometers were observed in aortic systolic blood pressure (ASBP; 0.43 ± 1.08 mm Hg; P < 0.05; wristband lower), aortic pulse pressure (APP; 0.43 ± 0.96 mm Hg; P < 0.05; wristband lower), and round-trip travel time of the reflected pressure wave (Δtp: 3.58 ± 12.86 ms; P < 0.05; wristband higher). However, ASBP, APP, and Δtp measurements were highly correlated (r = 0.9970, r = 0.9953, and r = 0.8838, respectively, P < 0.0001) between tonometers; within-subject and between tonometer significant mean differences were within clinical ranges.

CONCLUSIONS
This novel, hands-free platform may be interchangeable with the commonly used pencil-type tonometer, heralding new directions in noninvasive in vivo vascular research and clinical application.

Keywords: applanation tonometry; arterial stiffness; augmentation index; blood pressure; hypertension; pulse wave analysis.

doi:10.1093/ajh/hpt300

Central hemodynamic indices are independent predictors of future cardiovascular events and all-cause mortality.1−4 Furthermore, central blood pressures are more strongly related to vascular disease than peripheral pressures.1 Therefore, the precise measurement of central pressure, in combination with traditional clinical measurements, is crucial for the strict monitoring and titration of treatments and/or interventions.3−4 Although central aortic pressures and waveforms convey important information about cardiovascular status and risk, direct measurements are invasive and expensive.4−6 In contrast, peripheral pressures can be measured noninvasively.2,3 Importantly, these noninvasively determined indices of central pressure and pulse pressure waveforms have proven to be reliable and valid measures when compared to those achieved with invasive catheter procedures.7 The SphygmoCor system of pulse wave analysis (PWA; AtCor Medical, Inc., Sydney, New South Wales, Australia) is a U.S. Food and Drug Administration–approved device for the noninvasive measurement of central blood pressures, augmentation index (AIX), and pulse wave velocity (PWV). AIX has been shown to be a better independent predictor of future cardiovascular events than peripheral blood pressure.1 The SphygmoCor system is widely used for PWV and PWV assessment in both clinical and pharmaceutical research trials and is considered by many to be the reference standard for repeatability and validity of these assessments.8 The purpose of this study was to evaluate the validity of a newly engineered wristband tonometer for the determination of central aortic blood pressures and AIX that does not require the operator to manually manipulate the tonometer after application to the patient/participant. We sought

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Initially submitted November 7, 2013; date of first revision November 24, 2013; accepted for publication December 30, 2013; online publication February 21, 2014.
Validity of a Novel Wristband Tonometer to validate the wristband device during resting conditions, which are common to clinical practice and research trials, by comparing the primary output variables determined using the validated and widely accepted SphygmoCor system and a standard pencil-type tonometer.

METHODS

Baseline status of participants

Thirty-one participants (aged 30.2 ± 9.5 years) were enrolled from the greater Gainesville, Florida, area and evaluated for pulse pressure wave properties using both a traditional pencil-type and newly engineered wristband tonometer. Subjects with previously diagnosed cardiovascular disease were excluded from this study, and all participants maintained normal sinus rhythm throughout the testing procedures. Subjects were asked to report to the laboratory in the morning after a 12-hour fast and were instructed to abstain from the consumption of alcohol and caffeine at least 12 hours prior to testing. Additionally, participants did not exercise for at least 6 hours prior to testing. Following a 15-minute rest period in a supine position, heart rate (HR), brachial systolic (PSBP), diastolic (PDBP), and pulse blood pressure (PPP) measurements were performed at least 3 times on the left arm by oscillometric blood pressure sphygmomanometry using an automated noninvasive device (BpTRU BPM-100; VSM MedTech Ltd., Vancouver, B.C., Canada). An average of 3 HR and blood pressure measurements were used for resting values. Vascular function measurements were made in the Cardiovascular Laboratory in the Center for Exercise Science at the University of Florida. The University of Florida Institutional Review Board approved the study; written informed consent was obtained from all participants.

Pulse wave analysis

The pencil-type or wristband tonometer was randomly selected to measure the initial noninvasive radial artery pressure waveforms, and the alternate tonometer was used immediately thereafter to acquire comparison waveforms. The wristband tonometer is composed of an elastic band, a self-locking adjustable plastic clasp, ceramic pressure transducer sleeve, and a nonferrous signal transmission wire (Figure 1). Both devices use identical Millar micro-tip pressure transducers (Millar Instruments, Houston, TX). Arterial wave reflection characteristics were assessed noninvasively using the SphygmoCor Pulse Wave Analysis Px system and SCOR-2000 Version 6.31 software (AtCor Medical, Sydney, Australia), with a validated generalized mathematical transfer function to synthesize a central aortic pressure waveform and correct for pressure wave amplification in the upper limb. The generalized transfer function has been validated using both intraarterially and noninvasively obtained radial pressure waves.

Briefly, consecutive measurements were performed and the average of the first 3 high-quality recordings per participant and per tonometer were used for analysis. A trained operator with 5 years of research experience using this technique performed all measurements. Optimal recording of the pressure wave was obtained when the hold-down force

![Figure 1. Photograph of wristband tonometer.](image-url)
of the transducers on the artery was such that the resulting waveform had a stable baseline for at least 10 cardiac cycles and resulted in a quality index (QI) of >90%. QI is an internal measure derived from an algorithm that includes average pulse height variation, diastolic variation, and maximum rate of rise of the peripheral waveform and accounts for variation in tonometer hold-down pressure and waveform capture. This technique has been shown to be highly reproducible. Further, in our laboratory, reproducibility has been established in young, healthy men with a mean coefficient of variation of 6.5%, 2.1%, 2.4%, and 2.4% for aortic Alx, round-trip travel time of the reflected pressure wave (Δtp), and central systolic and diastolic blood pressure, respectively.12

The central aortic pressure wave (Ps-Pd) is composed of a forward-traveling wave with amplitude (Pi-Pd) that is returning to the ascending aorta from the periphery. The contribution or amplitude of the reflected wave to ascending aortic pulse pressure can be estimated by Alx. A detailed description of PWA parameters has been provided previously.12 Briefly, the following PWA parameters, which are related to the amplification and temporal characteristics of the reflecting wave, were used as dependent variables in the present study: central aortic SBP (ASBP), central aortic DBP (ADBP), central aortic mean arterial pressure (AMAP), end systolic pressure (ESP), ejection duration (ED), Alx, Alx normalized to an HR of 75 bpm (Alx@75), and Δtp. ED is a measure of time, in milliseconds, of the duration of each cardiac systole. MAP was obtained from an integration of the waveform. ESP is defined as the pressure at the end of systole, which is the pressure at the end of ED.11

### Statistical analysis

All values are presented as mean ± standard deviation. PWA primary and secondary variables measured using pencil-type and wristband tonometers were analyzed using Student paired t tests. Kolmogorov-Smirnov tests were used to test normality of the distributions of the variable differences. When normality was confirmed, paired t test analyses were used. When normality was not confirmed, a Wilcoxon signed rank test was performed. Additionally, linear regression by the method of ordinary least squares was used to define the correlation between pencil-type and wristband tonometer values, with goodness of fit expressed by Pearson correlation coefficient (r). Further, agreement between the pencil-type and wristband tonometers was analyzed using Bland-Altman tests for agreement of clinical measurements and defined as being within 10% of the overall mean for the studied variable as the maximal tolerated difference.14 An alpha level of P < 0.05 was required for statistical significance. All statistical analyses were performed using SPSS version 22.0 for Windows (SPSS, Chicago, IL).

### Results

Study participants (n = 31) included 22 normotensive, 7 prehypertensive, and 2 stage 1 hypertensive participants resulting in PSBP and PDBP means of 114.4 ± 12.1 mm Hg and 72.8 ± 9.4 mm Hg, respectively. Further, peripheral mean arterial pressure (PMA = 86 ± 9.78 mm Hg) ranged from 72 to 111 mm Hg. PSBP, PDBP, and PMA were not found to be significant covariates. More men than women (20 and 11, respectively) were enrolled in the study and included a wide range of ages (aged 21–60 years) and body mass indexes (13.96–36.24 kg/m²). A significant difference in time to data acquisition between the wristband and pencil-type tonometers was observed (233 ± 95 s vs. 293 ± 171 s; P = 0.013, respectively). The wristband tonometer had significantly lower within-subject coefficients of variation (CV) than the pencil-type tonometer in aortic pulse wave height and time to reflection but no other significant differences in CV were observed (Table 1).

Statistically significant mean differences were observed between the wristband and pencil-type tonometers in diastolic variation, aortic systolic blood pressure (ASBP), aortic pulse pressure, round-trip travel time of the Δtp, and time to peak pressure (Table 1). Correlation coefficients, mean differences between tonometers, and Bland-Altman agreement analyses are presented in Table 1. Highly significant correlations were observed for the commonly measured central hemodynamic parameters AMAP (r = 0.995), APP (r = 0.985), Δtp (r = 0.884), AgBP (r = 0.883), and ED (r = 0.959); P < 0.0001 for all. In addition, full agreement was observed in AMAP, APP, Δtp, AgBP, and ED (>90% of the sample is within agreement range; Table 1). Further, the clinically relevant measures of ASBP, ADBP, Alx@75, and wasted left ventricular energy were highly correlated and full agreement was observed for each (Figure 2).

### Discussion

The present study is the first to assess the validity and reliability of a newly engineered wristband tonometer for non-invasively acquiring radial artery pulse pressure waveforms. The wristband tonometer resulted in slight but significantly lower within-subject variability for two measured variables (Table 1). In addition, a shorter time to data acquisition using the wristband tonometer was observed. Some slight but significant mean differences were observed between the pencil-type and wristband tonometers (Table 1). However, upon further evaluation, these variables were highly correlated between tonometers and within-subject and between-tonometer significant mean differences were negligible, within clinical ranges, and would not be characterized as clinically significant (Figure 2; Table 1). No other differences in mean values were observed in any other variables either measured or calculated.

Blood pressure reduction is the primary determinant of the effectiveness of antihypertensive therapy. However, central blood pressures are more strongly related to vascular disease than peripheral blood pressures, and central hemodynamics and arterial stiffness are markers of target organ damage.10 Further, results from multicenter trials suggest that antihypertensive medications may improve cardiovascular outcomes beyond peripheral blood pressure reduction.16 Indeed, blood-pressure lowering drugs can have
substantially different effects on central blood pressures and hemodynamics despite reducing peripheral blood pressure similarly. Therefore, the precise measurement of central pressures is crucial for the strict monitoring and titration of treatments and interventions for the reduction of blood pressure.

Recently, Sharman and colleagues suggested that central blood pressure may be a better method of guiding hypertension management with antihypertensive treatment. Although, central aortic pressures and waveforms convey important information about cardiovascular status and risk, direct measurements are invasive and expensive. However, noninvasive and validated techniques are currently available to estimate central pressures and wave reflection characteristics via applanation tonometry. In addition, reproducibility is extremely good, and improvements would be advantageous for common use in clinical practice. The wristband tonometer essentially replaces the traditional pencil-type tonometer and reduces operator-dependent variability in the evaluation of hypertension treatment. Further, this hands-free platform potentiates simultaneous measurement of real-time central pressure waveforms and vascular images (e.g., magnetic resonance imaging) where the investigator/clinician could not otherwise be present.

The measurement of central pressure waveform indices during exercise is an important and growing area of study because a hypertensive response to exercise is an independent predictor of adverse cardiovascular outcomes and mortality. Unfortunately, traditional sphygmomanometry of the brachial artery does not reflect central blood pressures or central hemodynamic perturbations during exercise. Application tonometry, when performed during exercise, confers the advantage of providing central hemodynamic data. However, although reproducible, traditional handheld pencil-type tonometers can be cumbersome during an exercise protocol. Consequently, hemodynamic responses to exercise have been limited to upright and supine cycle ergometry. The advent of the wristband tonometer may potentiate expansion of these investigations and include additional exercise modalities (e.g., treadmill). Future evaluation of the wristband tonometer under exercising conditions is warranted.
Figure 2. Correlation coefficients and Bland-Altman plots for pencil-type and wristband measurement agreement in SphygmoCor-derived central blood pressure variables. Abbreviations: ADBP, aortic diastolic blood pressure; Alx@75, augmentation index normalized to 75 beats per minute; ASBP, aortic systolic blood pressure; LVEW, wasted left ventricular energy. *P < 0.0001.
In conclusion, we present evidence that a novel wristband tonometer may be interchangeable with the commonly used and widely accepted pencil-type tonometer. These data provide the basis for an expanded use of applanation tonometry. This novel hands-free platform may herald new directions in non-invasive in vivo vascular research by decreasing operator dependency, time to data acquisition, and variability in repeated measurement, which are essential for clinical and pharmaceutical research investigation.

The present study did not include participants with cardiovascular or chronic diseases that affect central and peripheral vascular function. Therefore, it is essential that future investigations be conducted to examine the validity and reliability of the wristband tonometer in participants with diagnosed hypertension, cardiovascular disease, and/or chronic diseases.

DISCLOSURE
The authors declared no conflict of interest.

REFERENCES