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Full Finger Reperfusion Time measured by pulse oximeter waveform analysis in children

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Abstract

Objectives: Capillary refill time (CRT) is a non-invasive method to assess tissue perfusion to determine shock status. CRT is defined as the time required to regain skin color after blanching pressure is applied. While common methods to measure CRT depend on clinicians' visual assessment, a new approach using a pulse oximeter waveform analysis exists, referred to as full finger reperfusion time (FFRT). We aim to evaluate reproducibility and validity of the novel FFRT measurement using clinicians' visual CRT assessment as a reference standard.

Design: Prospective observational study.

Setting: Pediatric Intensive Care Units (PICUs) and Operating Suites at a large academic children's hospital.

Patients: 99 children aged 1–12 years old with various skin color tones.

Interventions: Each child had 10 measurements, including 5 FFRT and 5 clinician CRT, alternating 2nd and 3rd digits.

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Conflict of Interest

The remaining authors have disclosed that they do not have any conflicts of interest.

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Measurements and Main Results: 18 children had prolonged CRT (>2 seconds) and 4 children with CRT >3 seconds. 485 data pairs were analyzed. Intraclass correlation coefficient (ICC) of FFRT within each patient was 0.76 (95% CI 0.68–0.83), demonstrating good reproducibility. Correlation coefficient between FFRT and clinician CRT was moderate: $r = 0.37$ ($p < 0.0001$, 95% CI 0.29–0.44) for the pairs and $r = 0.52$ ($p < 0.0001$, 95% CI 0.36–0.65) for patient average. Bland-Altman plot showed a consistent difference between FFRT and clinician CRT (FFRT 1.14 seconds longer). Weak association was found between force and FFRT ($\beta = -0.033 \pm 0.016$, 95% CI $-0.065, -0.0016$, $p = 0.04$), finger thickness ($\beta = -0.20 \pm 0.089$, 95% CI $-0.37, -0.19$, $p = 0.03$), except for color tone ($p = 0.31$). Finger temperature was associated with FFRT ($\beta = -0.18 \pm 0.041$, 95% CI $-0.26, -0.0999$, $p < 0.0001$).

Conclusions: FFRT demonstrated good reproducibility. FFRT showed moderate correlation with clinician CRT. FFRT was 1.14 seconds longer than CRT. Future studies should focus on the clinical value of FFRT as a monitoring device for hemodynamics in critically ill children.

Keywords

Capillary Refill Time; Circulation; Full Finger Reperfusion Time; Monitoring; Peripheral Perfusion; Sepsis; Shock

Introduction

Shock is defined as poor organ perfusion and is a life-threatening condition in children. Serial monitoring of circulatory status among critically ill children to detect changes in shock status is important (1,2). Time to shock reversal has been reported to be associated with outcomes in children with septic shock or after cardiac surgery (3–5).

Capillary refill time (CRT) is a simple, non-invasive assessment used to evaluate peripheral tissue perfusion (6). CRT is defined as the time required for skin to regain its color after enough pressure is applied to blanch the tissue (7). It is used to assess peripheral tissue perfusion, even when clinical resources are limited, and has been proposed as an assessment that can be performed on chronically ill patients at home by laymen caregivers (4,8). To measure CRT, manual compression is applied to the distal capillary nail bed, palm, sternum, forehead, or plantar surface of the heel (8). Historically, CRT was described as “flash”, “normal”, or “prolonged/delayed/sluggish” rather than identifying concrete numerical values to each category (7–9). Normal CRT is widely accepted as less than 2 or 3 seconds, although time varies depending on the site used for assessment (8). A prolonged CRT (greater than 3 seconds) is clinically used as a sign of shock in critically ill children, with the caveat that “flash” capillary refill may be present in children with vasodilatory shock (5,8). While convenient, clinician CRT measurement is affected by many factors unrelated to shock, including the location of measurement, applied pressure force and duration, ambient lighting and temperature (7). In addition, CRT measured by clinicians has poor inter-rater reliability despite controlling for previously mentioned external factors, yet manual assessment remains the current “gold standard” of practice (4). Standardization of CRT measurements could provide reproducible, consistent CRT to inform clinical decision-making (8,9).

The optical technology of infrared spectroscopy has been used to measure hemoglobin concentration and oxygen saturation. This technology is used in pulse oximetry which routinely traces blood in tissues (10). The pulsatile change of blood volume in tissues has been utilized to quantify peripheral tissue perfusion (6). Since CRT measures the blood refill after compressing a fingertip, this technology can also quantitatively measure the blood refill over time after the release of compression (9). Waveform analysis-based full finger reperfusion time (FFRT), also previously known as ‘Blood Refill Time’ (11), has been proposed as an alternative to traditional clinician measured CRT. This technology uses pulse oximetry light transfer through the fingertip to determine CRT based on blood leaving the digit during a standardized blanching procedure and the time it takes to return after compression is released (9,11,12).

The aim of the present study is to assess the reproducibility and accuracy of FFRT in children. The hypotheses are: 1. FFRT is reproducible in children, 2. FFRT correlates with CRT measured by clinician visual assessment (current standard), and 3. FFRT is sensitive for detection of prolonged CRT (> 3 seconds) as determined by clinician. Secondary goals include measuring the force typically applied by clinicians to measure CRT, and the effect of skin color tone, finger thickness and temperature on FFRT.

Methods

This prospective, observational study was conducted at Children’s Hospital of Philadelphia (CHOP), a large, freestanding academic children’s hospital in the United States. This study was approved by the CHOP Institutional Review Board. Written informed consent was obtained from a guardian for each participant, and assent from patients (when indicated) was also obtained.

Study participants

Children (1–12 years old) in the ICUs (PICU, Cardiac ICU), Progressive Care Unit (the unit which provides acute/subacute care or caregiver teaching for the chronically ill children with technology dependence), Operating Suites, and cardiac catheterization laboratory were recruited. We excluded children with an anatomical anomaly or disease that would prevent attachment or measurement by pulse oximeter (i.e., surgery in the proximal part of both limbs, known central venous or arterial thrombi, patients on extracorporeal membranous circulation (ECMO), or no detectable waveform in pulse oximetry due to profound shock). We *a priori* aimed to enroll a total of 30% of children with longer CRT (> 2 seconds). To evaluate the effect of skin color tone, we stratified into 9 categories defined by age (1–3 years, 4–6 years, and 7–12 years old) and Fitzpatrick skin tone scale (1 or 2, 3 or 4, and 5 or 6; Supplemental Figure A) (13).

Study measurements

The child’s index or middle finger was randomly selected and an appropriately sized pulse oximeter probe was applied (TL-272T or TL-274T, Nihon Kohden Corporation, Tokyo, Japan). The child’s hand was elevated to the level of the right atrium for blood-pressure standardization. A practicing clinician (anesthesiologist, critical care physician, or senior

respiratory therapist) performed a total 10 CRT measurements for each child: 5 pulse oximeter FFRT and 5 clinician CRT in alternating order. The order with which to begin measurement (clinician CRT or FFRT), and whether index or middle finger was used for clinician CRT were randomized by MATLAB (The MathWorks, Inc. Natick, MA). The clinician wore a glove with a force sensor for all 10 attempts (FlexiForce A201 Sensor, Tekscan, Inc., South Boston, MA) for compression force measurement. The duration of the compression for both FFRT and clinician CRT was standardized as 5 seconds using stopwatch and audio cues from a research team member, consistent with expert recommendation (5). The clinician CRT was measured using a stopwatch; clinicians verbalized when the finger capillary bed was fully refilled after the release. For FFRT, the change in the absorbed light (940 nanometer wavelength) during the release phase was measured through a commercially available pulse oximeter (OLV-3100, Nihon Kohden Corporation, Tokyo, Japan) and the time (in seconds) to return to baseline absorption was automatically measured for each compression (Figure 1). The technical details of this process have been previously published (11,12). The thickness of the child's index and middle finger was measured with calipers (Accu-Measure, AccuFitness, Denver, CO). The skin temperature at the finger and forearm on the same side were measured using an infrared thermometer (TAT-5000, Exergen, Watertown, MA). Skin color tone was assessed at the forearm on the same side using the Fitzpatrick skin tone scale (Supplemental Figure A) (13).

Sample size calculation

Sample size estimation was done based on a correlation coefficient between the time by two methods of finger reperfusion measurement (i.e., FFRT and clinician CRT) of at least 0.75. To detect a correlation coefficient of 0.75 with a two sided alpha = 0.05 and a power = 80%, 10 children would be required for each of the nine groups. In addition we planned to recruit approximately 30% of children that had clinical evidence of delayed capillary refill, clinical shock or required vasoactive infusion. For this reason, the enrollment target was increased to 102 children at 6 months after study recruitment was started.

Statistical Analysis

Counts and proportion (%) for categorical variables, and mean and standard deviation (SD) for continuous variables were reported as summary statistics. Reproducibility of the FFRT measurement was assessed by the intraclass correlation coefficient (ICC) within the patient. A correlation analyses between the FFRT (seconds) and by the clinician CRT was performed. Agreement between these two time measures were assessed by Bland-Altman plots (14). Using clinician CRT > 3 seconds as an abnormal value, we ran a receiver operating characteristic curve for FFRT and calculated the area under the curve (AUC). The optimal cutoff was identified using Youden's index (15). Regression analyses were used to determine whether compression force, finger temperature, finger thickness, and skin color tone were associated with FFRT. Two-sided p-value < 0.05 was considered statistically significant. All statistical analyses were conducted using MedCalc (MedCalc Software, Ostend, Belgium), MATLAB (The MathWorks, Inc., Natick, MA) or Stata (StataCorp, College Station, TX).

Results

One hundred and two children were enrolled in the study, Figure 2. Demographic characteristics are summarized in Table 1. Two children were excluded due to corrupt data files and 1 due to insufficient perfusion, resulting in 99 evaluable patients. Of the evaluable patients 18 children had a CRT > 2 seconds (among those children, 6 were also receiving vasoactive infusions), and 81 children had normal clinician CRT (≤ 2 seconds), Table 1. Among those children with clinician CRT ≤ 2 seconds, 8 children were receiving vasoactive infusions. Ten FFRTs were not measured: 4 corrupted, 5 algorithm failures to calculate FFRT, and 1 missed clinician CRT measurement, resulting in a total of 485 FFRT and clinician CRT measurement pairs for the analysis.

Reproducibility (Precision)

Intraclass correlation coefficient (ICC) of FFRT within each patient was 0.76 (95% CI 0.68–0.83).

Correlation between FFRT and clinician CRT

The FFRT and clinician CRT were moderately correlated: Pearson's correlation coefficient for each measurement pair was $r = 0.37$ ($p < 0.0001$), and for the averaged value for each child was $r = 0.52$ ($p < 0.0001$), Figure 3. Among the patients with clinician CRT > 2 seconds, the correlation coefficient was $r = 0.57$, $n = 84$ pairs ($p < 0.0001$), and for the averaged value for each child was $r = 0.75$, $n = 18$ patients ($p = 0.0004$). The Bland-Altman plot showed an agreement between FFRT and clinician CRT with mean difference of 1.14 ± 1.86 seconds for each measurement pair and 1.13 ± 1.24 seconds for the averaged value for each child, Figure 4.

The receiver operating area under the curve (AUC) for the FFRT to determine prolonged clinician CRT (> 3 seconds) was 0.89 (95% CI 0.86–0.92), Supplemental Figure B. The optimal cutoff for FFRT = 3.16 seconds with sensitivity 1.00 (95% CI 0.82–1.00), specificity 0.77 (95% CI 0.73–0.81), Supplemental Table C.

Effect of compression force

The average force applied to measure clinician CRT and FFRT were 10.8 ± 7.1 Newton (N) and 12.9 ± 5.2 N respectively. The mean difference within each pair of measurement was 2.1 ± 6.0 N. The applied force was significantly associated with the FFRT ($\beta = -0.033 \pm 0.016$, 95% CI $-0.065, -0.0016$, $p = 0.04$), Supplemental Figure D.

Effect of finger temperature, finger thickness and skin color tone

The finger temperature was negatively associated with the FFRT ($\beta = -0.18 \pm 0.041$, 95% CI $-0.26, -0.0999$, $p < 0.0001$), Supplemental Figure E. The finger thickness was negatively associated with the FFRT, with greater finger thickness correlating to shorter reperfusion time ($\beta = -0.20 \pm 0.089$, 95% CI $-0.37, -0.19$, $p = 0.03$), Supplemental Figure F. Skin color tone was not associated with FFRT, $p = 0.31$.

Discussion

In the present study, we demonstrated that the FFRT measured by waveform analysis algorithm was reproducible within each child. The FFRT was moderately correlated with clinician CRT, and reported on average 1.1 seconds longer than clinician CRT. The correlation between FFRT and clinician CRT was more robust when analyses were limited to children with clinician CRT >2 seconds. The discrimination ability of waveform analysis to determine prolonged CRT greater than 3 seconds was robust (AUC = 0.89), as demonstrated in ROC analysis. This study was a first step to standardize the CRT assessment using objective waveform analysis.

In pediatric practice, clinician measured CRT is commonly used in the evaluation of child at risk of hemodynamic shock in pre-hospital, emergency department, disaster, surgery, and critical care settings (8). Several clinical guidelines recommend measuring CRT as part of the assessment of ill children (1,2,16–18). However, the conventional clinical method of CRT measurement has limited reproducibility related to variability of compression force, duration, location, ambient conditions, and subjective visual assessment (19,20). Previous studies showed variable inter-observer reliability (8,19,21). In contrast to clinician CRT, FFRT by waveform analysis was reproducible (12), which has a potential to eliminate inter-observer variance in the future. Furthermore, once we develop and implement a technology to automate the compression force, we will have a robust non-invasive longitudinal monitoring device in critically ill children with ongoing circulatory condition changes (22).

The FFRT measurement used a change in the transmitted light through the fingertip, making the side (i.e., nail or palmar side) of the finger assessed as irrelevant. A compression duration of 5 seconds used in the current study is consistent with expert recommendations (5,8). A systematic review including 21 pediatric studies recommended compression on the finger for 5 seconds at an ambient air temperature of 20–25°C, and the use of abnormal CRT cutoff point at greater than 3 seconds (5).

Despite the challenges in reproducibility of CRT measurement by clinicians, CRT remains an important part of clinical practice. Recently, a multi-center randomized controlled trial investigated the impact of CRT-guided versus lactate-guided shock resuscitation in adult patients (23). The group with CRT-guided resuscitation had 34.9% mortality at 27 days compared to 43.4% in the lactate-guided resuscitation group, which did not reach statistical significance ($p = 0.06$). The CRT-guided resuscitation was significantly associated with less organ dysfunction at 72 hours ($p = 0.045$). Clinician measured CRT has been reported as a predictive factor for patient survival and is useful in the initial triage of patients with traumatic injuries and shock (17,24). Morimura *et al* showed that FFRT (they referred to as “quantitative CRT” in their paper) was statistically correlated with blood lactate levels among 23 adults in the ICU (correlation coefficient = 0.68; $p < 0.001$) (9). The cut-off value of FFRT for predicting a lactate level of ≥ 2.0 mmol/L was 6.8 seconds and for predicting a lactate level of ≥ 4.0 mmol/L was 7.3 seconds.

In addition to validating the new FFRT measurement, we were able to collect the compression force to blanch the patient’s finger for clinician CRT, which was not well

described in the literature. This information is highly valuable for future development of an automated compression device for FFRT (22). Serial measurement of peripheral perfusion on critically ill children is essential for evaluation of response to shock treatment such as fluid bolus or initiation and titration of vasoactive agents (1,2). Consistent and automated FFRT measurement is needed for this purpose (25).

The present study showed the effect of finger skin temperature on FFRT, consistent with previous studies. Gorelick *et al*/reported a significant inverse correlation between finger skin temperature and CRT in 32 children (26). Shinozaki *et al*/evaluated the effect of finger skin temperature on FFRT in 30 healthy adult patients and demonstrated strong inverse correlation between finger skin temperature and FFRT, consistent with our study finding (27). Conventional CRT by clinician visual assessment is similarly known to be affected by skin temperature (28). Since finger temperature is affected by ambient temperature as well as the peripheral perfusion condition, the CRT assessment at standard ambient temperature (20–25°C) has been recommended. In the current study, the ambient temperature was not controlled but measurement was performed in the in-patient clinical setting which eliminated a cold or hot ambient condition.

There was a weak association between the finger thickness and FFRT: For each 1 mm of additional finger thickness, the FFRT value was 0.19 seconds shorter. This may need to be taken into consideration when a FFRT measurement in a cohort of children with variety of finger sizes is performed. Also it is possible that for thicker fingers, a higher pressure to achieve blanching might be needed. The future solution for this factor is to standardize the compression pressure and time using an automated compression system.

There were no significant associations between the skin color tone and FFRT, which is supportive for the consistent reperfusion time measured by waveform analysis. This finding is also consistent with a previous study (29).

The current study has several limitations. First, we did not validate the FFRT measurement against the objective clinical values such as serum lactate level. Our study cohort only had lactate measurement in 6 subjects (6%) within 6 hours, which precluded the possibility for this secondary analysis using abnormal lactate level as a reference standard. Second, the correlation coefficient between the FFRT and clinician CRT was more modest than we initially anticipated. This may be due to the fact that the waveform-based algorithm reports a longer reperfusion time with the measurement errors between both FFRT and clinician CRT. The correlation between FFRT and CRT was more robust when we conducted a subgroup analysis in children with clinician CRT > 2 seconds, which indicates that the modest correlation may be partially due to the majority of children having normal peripheral perfusion in this study cohort. The correlation between the averaged FFRT and CRT within each patient was also substantially better than each measurement pair. This suggests that the FFRT measurement needs to be repeated for several times, ideally with standardized compression force. We did not control the ambient temperature given that data collection took place in pediatric in-patient settings. This could have affected both clinician CRT and FFRT. While we measured the compression force in both the clinician CRT and FFRT measurement, we did not control for the applied force by the clinician. The force, however,

was only weakly associated with the FFRT, therefore it is less likely that the variability in force substantially contributed to the FFRT values. Newer technology to standardize the compression force is on horizon, and the FFRT induced by this automated compression device is now called Capillary Refill Index: CRI (22).

Our study included a relatively small number of children with prolonged CRT. However, the correlation between the clinician CRT and FFRT was better among children with clinician CRT > 2 seconds in both measurement pairs and averaged measurement within each patient. Further validation of FFRT with a larger cohort of children with a higher proportion of prolonged clinician CRT is warranted in a future study.

In conclusion, the reperfusion time measured by a waveform algorithm analysis was shown to be a reproducible quantitative assessment of tissue perfusion, with a moderate correlation with the current clinical standard of clinician-assessed CRT. This study serves as an important early step in the development of an automated, full finger reperfusion time monitor in the clinical setting.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Children's Hospital of Philadelphia received a research grant from Nihon Kohden to conduct the study. Nihon Kohden employees provided technical support of their device and software for the study. The Children's Hospital of Philadelphia research team had full access to the data.

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Figure 1.

Pulse oximeter and waveform generated by compression of device.

Figure 2.
Patient enrollment flow chart.

N: number of patients.

n: number of measurement pairs.

[#] One patient was excluded due to insufficient peripheral perfusion. This patient did not have a detectable pulse oximetry waveform on digits.

[§] Patients who had fewer than 3 pairs of waveform and clinician capillary refill time data were excluded.

Figure 3.

The correlation between full finger reperfusion time (FFRT) measured by a waveform analysis and capillary refill time by clinician visual assessment.

Figure 4.
Bland-Altman plot for full finger reperfusion time (FFRT) by a waveform analysis and capillary refill time by clinician visual assessment.

Table 1.

Patient characteristics.

Patient Characteristics	N=99
Gender (count, %)	
Male	58 (58.6)
Female	41 (41.4)
Age (years, %)	
1–3	38 (38.4)
4–6	25 (25.3)
7–12	36 (36.3)
Skin Color (count, %)	
1 or 2	36 (36.4)
3 or 4	35 (35.3)
5 or 6	28 (28.3)
Finger Temperature (°C)	
Range, Mean $\pm$ SD	24.6 – 38.2, 34.67 $\pm$ 3.26
Prolonged CRT (count, %)	
> 2 seconds	18 (18.2)
> 3 seconds	4 (4.0)
Vasoactive Infusion ^a (count)	
Norepinephrine	2
Epinephrine	3
Vasopressin	1
Dopamine	1
Milrinone	8
Isoproterenol	1
None	85
Location (count, %)	
ICU ^b	42 (42.4)
OR ^c	56 (56.6)
Cardiac Catheterization Laboratory	1 (1.0)
Diagnosis (count, %)	
Acute cardiorespiratory failure	2 (2.0)

Patient Characteristics	N=99
Acute neurologic injury	2 (2.0)
Acute respiratory failure	12 (12.1)
Cardiac disease	14 (14.1)
Chronic respiratory failure	6 (6.1)
Post-operative ICU	5 (5.1)
Septic shock	2 (2.0)
Surgical/Procedural	56 (56.6)

^aTwo patients received more than one vasoactive agent.

^bICU included Pediatric, Cardiac, and Progressive care units.

^cOR included Post Anesthetic Care Unit. CRT denotes capillary refill time. SD: Standard deviation.