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A Preliminary Evaluation of a Novel System for Monitoring Blood Loss in Clinical Settings.

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Abstract

Background Real-time measurement of blood loss is of high importance in fluid management and for ensuring optimal patient outcomes, specifically during surgical treatment and trauma. The current ''standard of care'' for monitoring blood loss is via visual estimation and is highly inaccurate. As such, new and more accurate methods are needed for fluid management. This study describes a preliminary evaluation of a novel, non-invasive blood volume monitor: The Zynex® Blood Volume Monitor (CM-1500). Designed to detect a slight change in blood volume, the CM-1500 signals blood loss by monitoring a collection of variables associated with blood loss: 1) an increase in bio-impedance, 2) increase in heart rate, 3) decrease in peripheral blood flow, 4-5) decrease in skin temperature and increase in skin humidity. Based on the parameters measured, the BVM sets an individual's Blood Volume Index (BVI) at a baseline of 100. With ongoing real-time monitoring, a built-in algorithmic processor alerts clinical staff of changes in the Index relative to the baseline, indicative of a hemorrhagic event.

Purpose The purpose of this study was to perform a preliminary evaluation of the effectiveness of the BVM in detecting acute blood loss among healthy adults during a controlled blood draw.

Methods Eight participants underwent a manual blood draw of 470 mL. The blood draw was performed during a routine blood drive at a local blood bank in Colorado. During the blood draw participants' fluid volume was monitored using the BVM. Monitoring was started after a needle had been inserted and at the beginning of a blood draw for each individual. Monitoring was ended at 5-10 minutes after blood draw had been completed. The total duration of monitoring for each participant ranged between 12-18 minutes.

Results During the 470 mL blood draw the BVI went consistently down for all participants. The average low after blood draw had been completed was 96.6 (range = 93.6 – 98.0) as compared with the baseline value of 100.

Conclusion The outcomes from this preliminary evaluation of the Zynex® Blood Volume Monitor lend support to the hypothesis that measuring a collection of physiological variables (bio-impedance, heart rate, peripheral blood flow, skin temperature and skin humidity) provides easy monitoring of blood loss. Further evaluation is needed to assess the clinical utility of the CM-1500.

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Introduction

Hemorrhagic shock is a leading cause of death in trauma (1). Blood loss monitoring in clinical settings, specifically during surgical treatment and trauma, is critical for appropriate hemodynamic management and for preventing adverse patient outcomes. The decision about the need for blood product transfusion could be significantly improved by the ability to continuously and non-invasively detect changes in central blood volume and blood loss during events at high risk for acute blood loss. Through early detection and improved hemodynamic monitoring, optimization of fluid balance, anesthesia titration, and augmenting other acute care management requirements, a clinician would be able to improve overall patient stability, minimize complications, diminish surgical trauma and reduce in- and out-patient recovery time.

Thus far perioperative estimates of blood loss have relied primarily on visual assessment (2). Such visual estimates of blood loss have been shown to be highly inaccurate, with clinicians tending to underestimate at high blood loss volumes and overestimate at low volumes, most likely resulting in under- or over- transfusion (3). Although simulations and didactic training to improve providers' blood loss estimation skills have been proposed, the long-term retention of these skills has been shown to decay. There is also a lack of association between experience level and providers' estimation accuracy (4). A gravimetric estimation of blood loss by weighing soaked laparotomy sponges and subtracting their known dry weight has been explored but this method is impractical for real-time intraoperative use and highly sensitive to the presence of confounding non-sanguineous fluids (e.g., saline, ascites, amniotic fluid) on absorbent media (5). Other procedures for rinsing and assaying hemoglobin (Hb) content from blood-absorbing media have been described as a standard for the assessment of intraoperative blood loss in research studies (6). Those procedures however, are also impractical for real-time intraoperative use.

The Zynex® Blood Volume Monitor (CM-1500) is a novel non-invasive monitoring device. It is designed to detect and monitor blood volume changes in pre-, intra- and post-operative environments. Blood volume changes are calculated by the device using real-time data from several physiological measures, including bio-electrical impedance, heart rate, electrocardiogram (ECG) amplitude, photoplethysmogram (PPG) amplitude, skin humidity, and skin temperature, all previously shown to be associated with fluid status and blood loss (7-13). However, as individual parameters often remain stable despite fluid loss, and thus on their own may not provide information for performing necessary early intervention to prevent negative patient outcomes (1, 14), the device combines information from multiple parameters. Using a complex algorithm, taking into account artifacts (patient movement, etc.) and weighting each parameter by its hypothesized relative importance, the CM-1500 calculates and establishes a baseline that is displayed on the monitor's screen as an index (Blood Volume Index = BVI). Ongoing, relative changes in the parameters as compared to baseline are reflected by the BVI, indicating a patient's blood volume status at any given time.

The objective of this preliminary study was to assess the ability of the CM-1500 to detect blood loss in healthy adults during a controlled blood draw.

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Materials and Methods

Study Population and Blood Loss Measurements

This study was performed in February, 2016 . No investigational approval was required for this preliminary, non-invasive study. Participants provided their verbal consent but no written informed consent was obtained. The study enrolled participant volunteers from a routine local blood draw hosted by Zynex, Inc. but performed by staff from a mobile blood bank (Penrose-St. Francis Hospital, Colorado Springs, Co.). Eight adults agreed to have their blood drawn and the Zynex® CM-1500 attached to them for monitoring vital signs during the blood draw. Normal blood bank enrollment criteria were employed. During the blood draw, changes in participants' blood volume were monitored via the Blood Volume Index, the primary outcome from the CM-1500 (see Figure 1 for a description of study activities).

Study Activities	
	Performed
Screening for inclusion/exclusion criteria by blood bank staff	
Obtain participants' consent	
Participant placed in a supine position	
Place electrode pads on participant's left arm and pulse ox glove on middle finger	
Complete venipuncture and cannulation	
Start the BVM	
Whole blood draw of 470mL	
Remove IV cannulation	
Participant remains supine for a minimum of 5 minutes post-blood draw with BVM still attached and streaming data.	
Evaluate participant for adverse events occurring throughout visit and make notes on data recording sheet	
Stop monitoring and detach electrodes and pulse ox glove from subject.	

Figure 1. Study Activities.

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Data Analysis

Data was visually analyzed for each individual by graphing changes in the Blood Volume Index for the duration of monitoring. Data was summarized across participants and a mean BVI drop was calculated. As the number of participants was small (n=8) and because of the nature of this study (a preliminary study) no formal hypothesis testing was performed.

Results

The participants were healthy adults in the age range of 30-65 years. Three males and five females took part in the study (n=8). Figures 2-9 show changes in the Blood Volume Index for individual participants over the course of the blood draw. Monitoring time ranged between 12-18 minutes.

As shown in the graphs from Figures 2-9 the Index went down from the baseline value of 100 for all participants after blood draw had been completed. The average low for the BVI was 96.6 (range = 93.6 – 98.7) and occurred between 1-8 minutes after blood draw had been completed. Table 1 demonstrates time and Index and blood draw completion, time and Index when the Index was at its lowest point and time and Index at the end of the monitoring session.

Table 1. Individual results (see changes in Index over time for each participant in Figures 2-9).

Participant (no.)	**Blood draw completion**		**Index low point**		**End of monitoring**	
	Time (min.)	**Index**	**Time (min.)**	**Index**	**Time (min.)**	**Index**
1	05:30	99.5	10:23	98.0	13:24	98.8
2	09:22	96.8	12:23	93.6	15:24	96.5
3	11:23	98.8	15:09	97.6	17:40	99.7
4	09:02	100.1	13:44	96.4	17:04	100.5
5	06:02	99.2	13:24	96.6	13:47	96.7
6	06:15	97.2	09:17	96.1	12:13	97.9
7	05:10	99.2	08:20	98.7	12:03	99.4
8	06:21	98.5	08:23	95.9	12:48	96.7

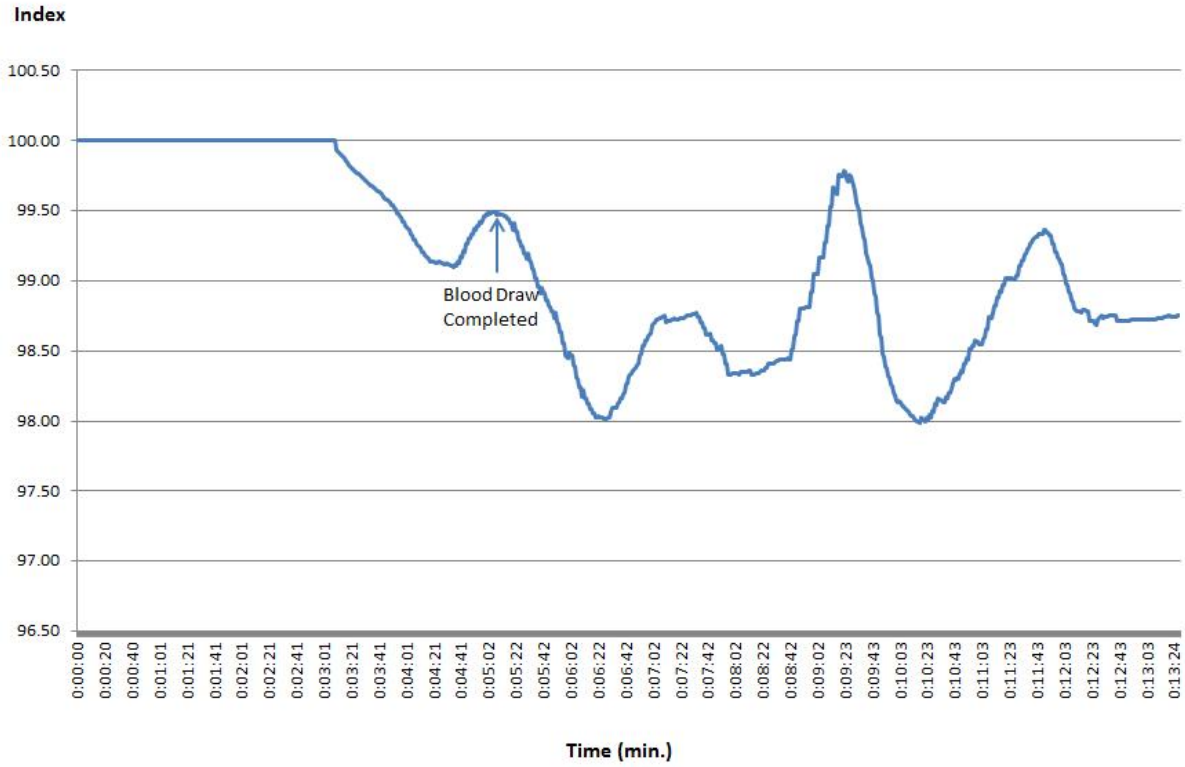

Figure 2. Changes in the Blood Volume Index for Participant 1**.**

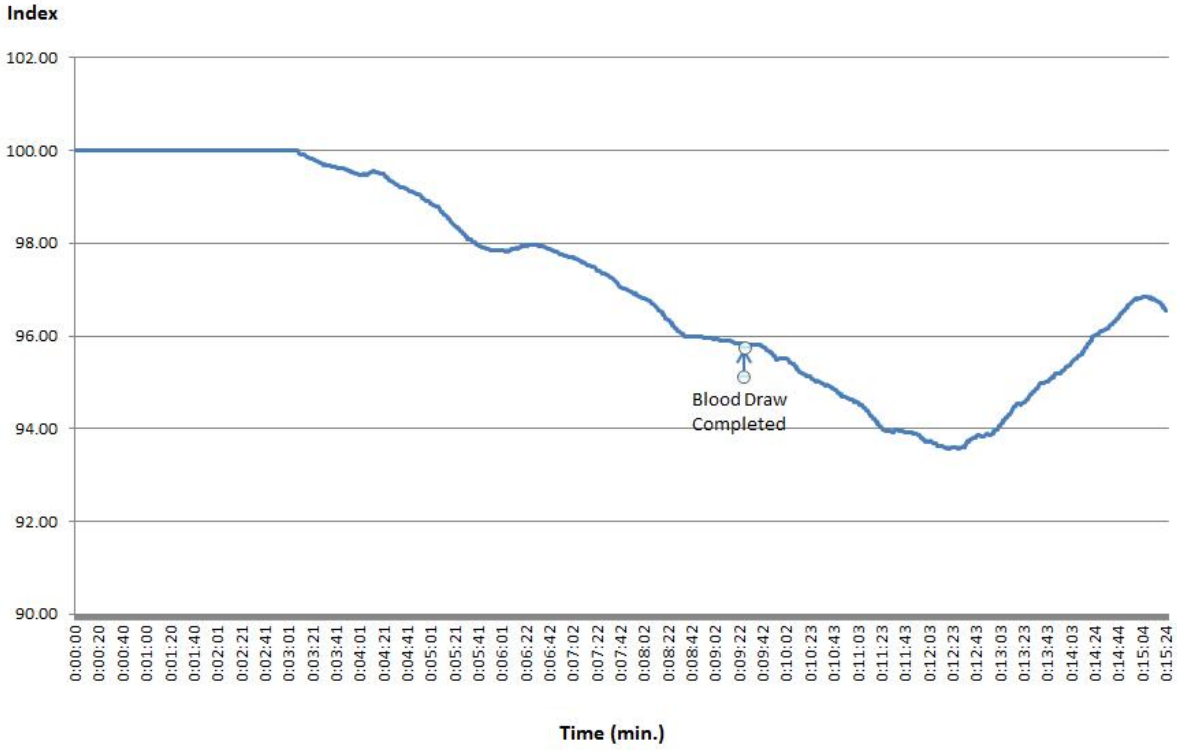

Figure 3. Changes in the Blood Volume Index for Participant 2**.**

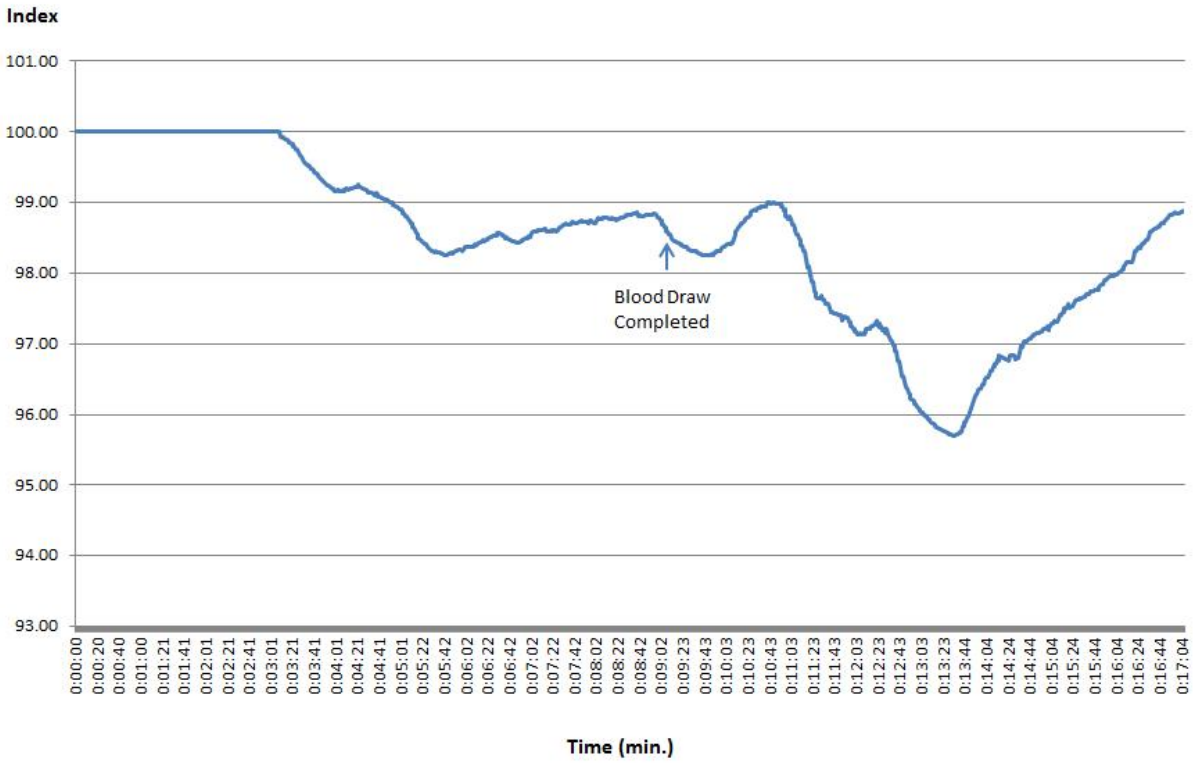

Figure 4. Changes in the Blood Volume Index for Participant 3**.**

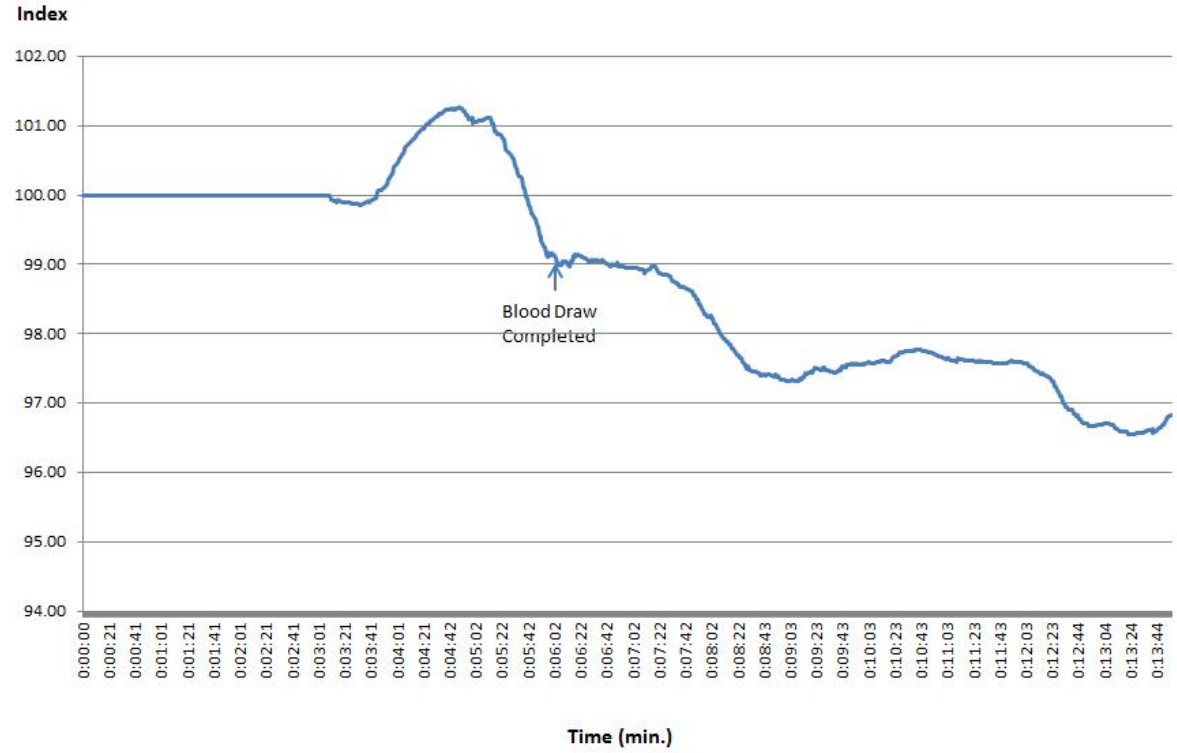

Figure 5. Changes in the Blood Volume Index for Participant 4**.**

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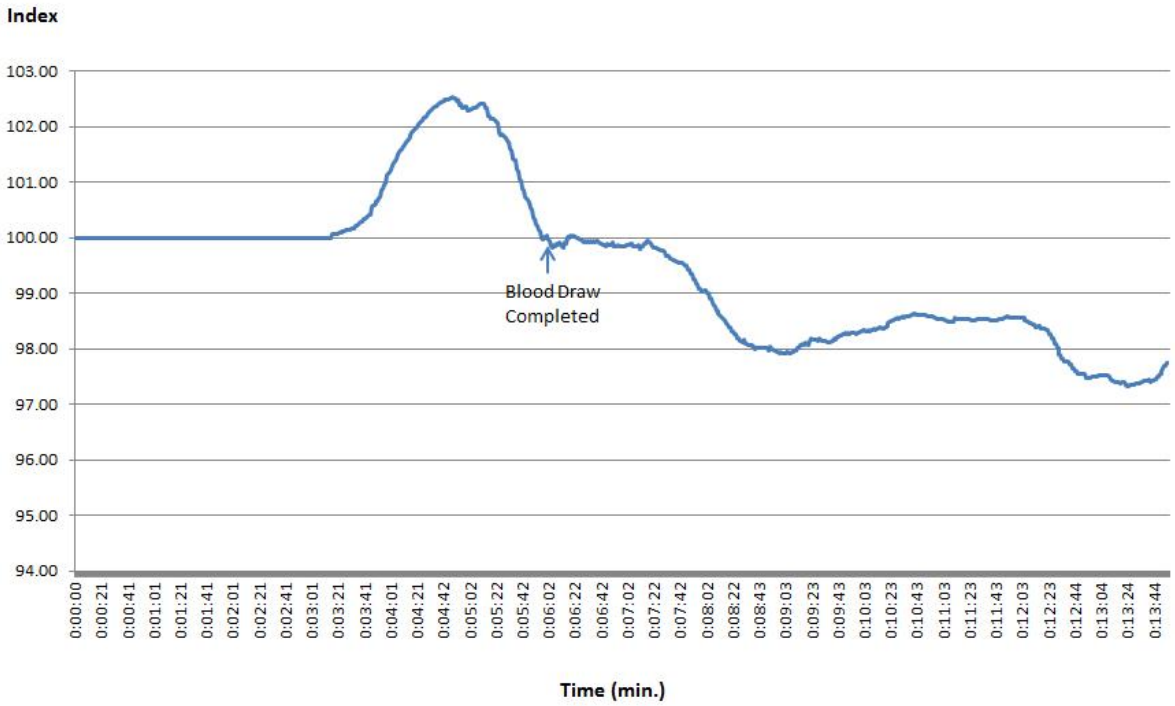

Figure 6. Changes in the Blood Volume Index for Participant 5**.**

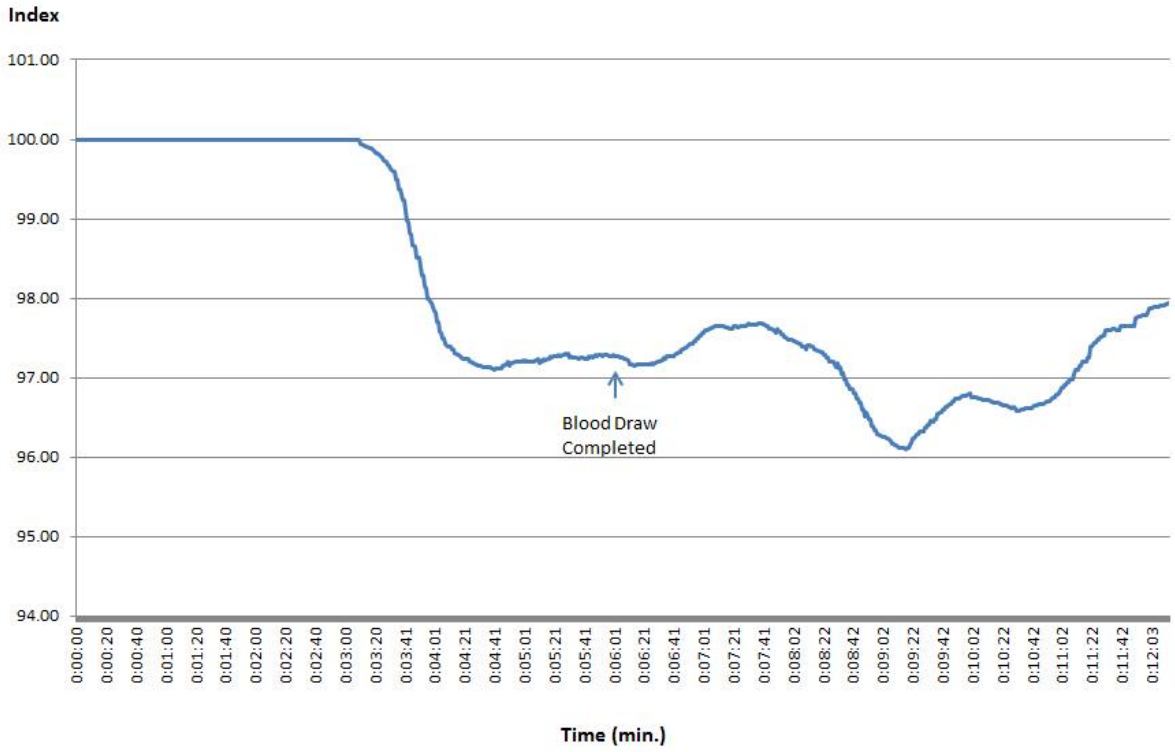

Figure 7. Changes in the Blood Volume Index for Participant 6**.**

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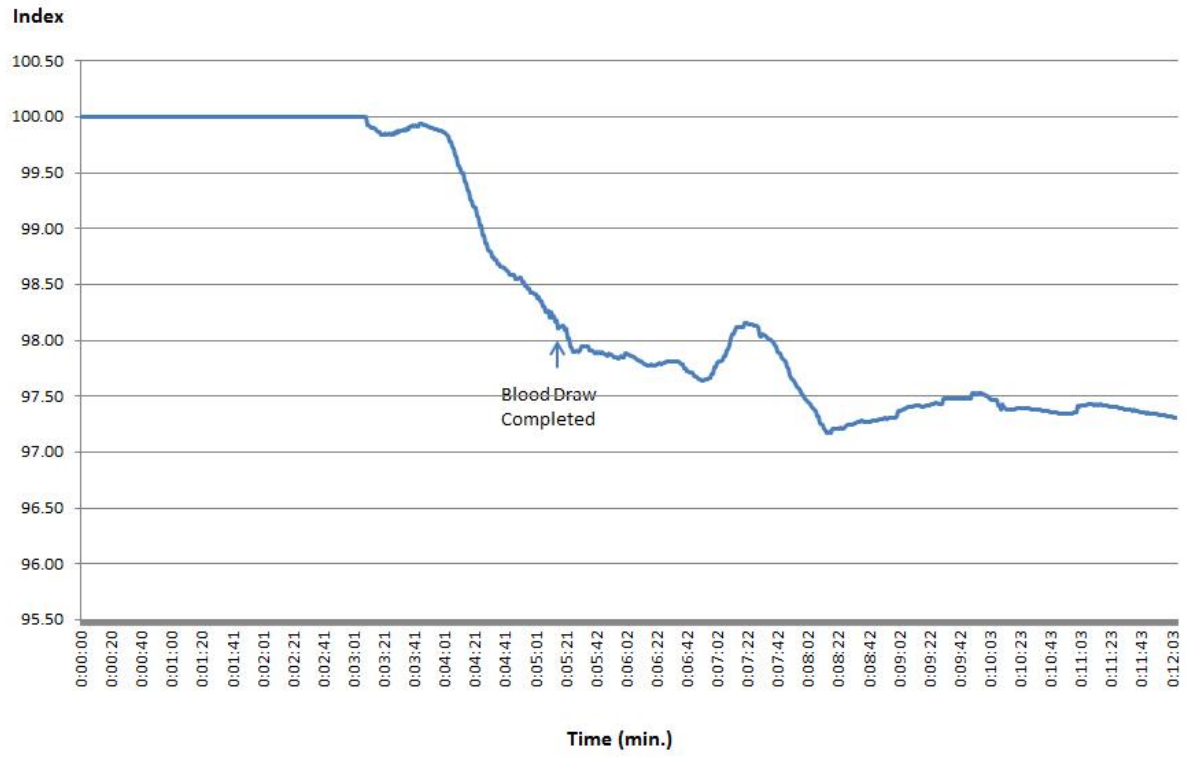

Figure 8. Changes in the Blood Volume Index for Participant 7**.**

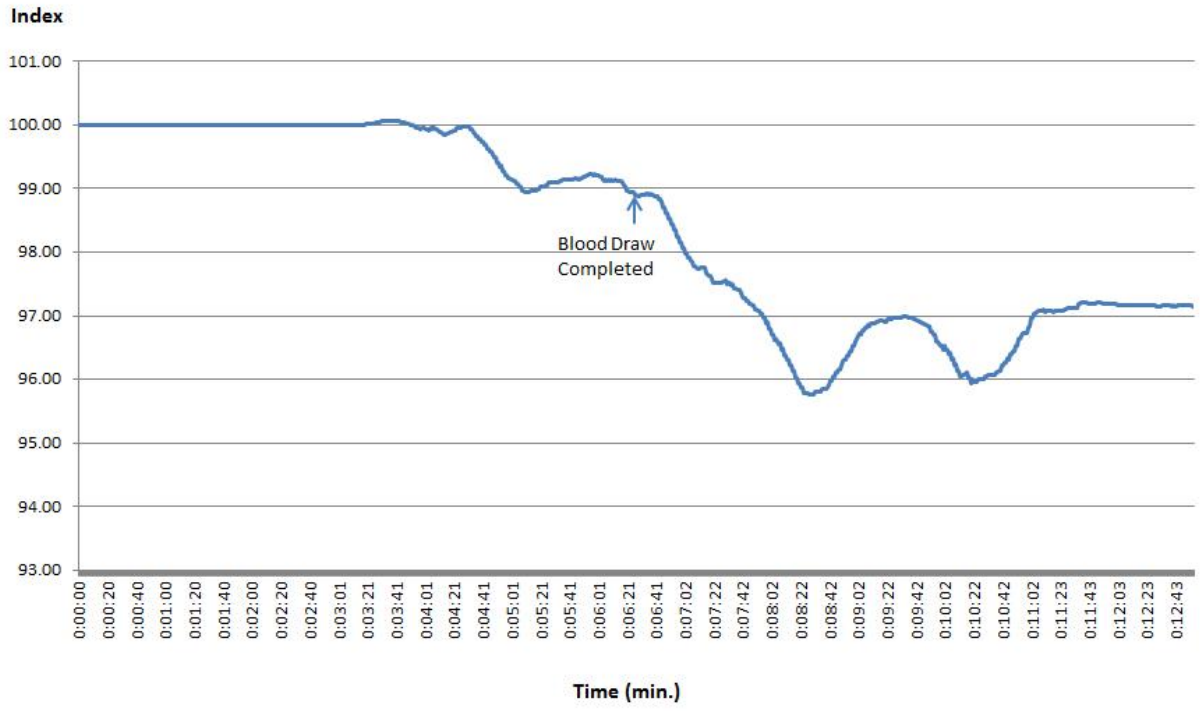

Figure 9. Changes in the Blood Volume Index for Participant 8**.**

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Discussion

In this study, the use of the Zynex® Blood Volume Monitor (CM-1500) showed a correlation with blood loss among all participants during a manual blood draw of 470 mL. Thus, by using several physiological parameters and combining them through a complex algorithm into an Index, the CM-1500 seems to be effective in detecting blood loss in healthy adults during a controlled blood draw. Nevertheless, the clinical utility of this device requires further testing but the potential usefulness of a non-invasive device such as the CM-1500 in blood management is of great importance. The inaccuracy, potential invasive and labor-intensive nature of some of the other methods currently used in blood management (5) provides ample reason for further development and refining of this novel product. Indeed, a survey of anesthesiologist's blood management practices indicated an increased reliance on gravimetric measures of blood among anesthesiologists during major intra-abdominal surgery in adults in 2003 compared with 1980. Visual estimation of blood loss has also remained a widely practiced method (15). The reliance on these inaccurate measures of blood loss may lead to an incorrect estimate of a potential hemorrhagic event and may as such pose undue risk for patients. Therefore, as the findings from this preliminary study are promising, further testing of the device should be undertaken as some limitations exist to these current findings. Some of the current limitations concern the variability in delay time for Index drop during blood loss and also the variable amount of Index drop among individuals. The body's ability to compensate for fluid loss is impressive (1) and varies depending on the individual and his or her characteristics such as fitness levels and basal state of health (16). Therefore, whether or rather how delay in detection time as well as amount of Index drop is related to an individual's age, sex, height and weight and/or BMI, as well as their basal health status and current fitness levels warrants study. Further studying the effects of blood loss and its subsequent correlation with the Index will help in refining the complex algorithm behind the Index. Also, further study and refining of the formula may facilitate the Index being able to demonstrate an accurate percentage (%) change in blood volume for a specific individual. Thus, continued work is required to adjust the complex formula behind the Index for taking into account patient movement and other artifacts not related to blood loss. Nevertheless, despite some current limitations, the results of the present study suggest that the Zynex® Blood Volume Monitor (CM-1500) provides an effective, low-risk and non-invasive method for monitoring blood loss, which is what its intended to do. The clinical utility of the device remains to be tested but it may provide a simple and effective method for monitoring of blood loss in clinical settings. Further study is warranted to assess the clinical utility of this novel technology.

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