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In Vitro Evaluation of a Novel System for Monitoring Surgical Hemoglobin Loss

Gerhardt Konig, MD,

Department of Anesthesiology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

Allen A. Holmes, MD,

Department of Anesthesiology and Perioperative Medicine, MD Anderson Cancer Center, Houston, Texas

Rosario Garcia, MD,

Department of Anesthesia, Stanford University School of Medicine, Palo Alto, California

Corresponding Author: Gerhardt Konig, MD, Department of Anesthesiology, University of Pittsburgh School of Medicine, UPMC Department of Anesthesiology, Kaufmann Bldg. Suite 910, 3471 Fifth Avenue, Pittsburgh, PA 15213, Phone: 412-692-4540, Fax: 412-692-4515, konigg@upmc.edu.

DISCLOSURES:

Name: Gerhardt Konig, MD

Contribution: manuscript preparation, data analysis

Attestation: Gerhardt Konig attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

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Name: Allen A. Holmes, MD

Contribution: manuscript preparation, data analysis

Attestation: Allen A. Holmes attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

Name: Rosario Garcia, MD

Contribution: study design, data collection and analysis, manuscript preparation

Attestation: Rosario Garcia attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

Name: Julianne M. Mendoza, MD

Contribution: study design, data collection and analysis, manuscript preparation

Attestation: Julianne Mendoza attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

Name: Mazyar Javidroozi, MD, PhD

Contribution: study design, statistical analysis, manuscript preparation

Attestation: Mazyar Javidroozi attests to approving the final manuscript and to the integrity of the statistical analysis reported in this manuscript.

Conflicts of Interest: Mazyar Javidroozi is a consultant for Gauss Surgical, Inc.

Name: Siddarth Satish, MS

Contribution: study design, data analysis, manuscript preparation

Attestation: Siddarth Satish attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

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Name: Jonathan H. Waters, MD

Contribution: manuscript preparation.

Attestation: Jonathan Waters attests to approving the final manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

This manuscript was handled by: Maxime Cannesson, MD, PhD

Reprints will not be available from the authors.

Julianne M. Mendoza, MD,

Department of Anesthesia, Stanford University School of Medicine, Palo Alto, California

Mazyar Javidroozi, MD, PhD,

Department of Anesthesiology, Critical Care and Hyperbaric Medicine, Englewood Hospital and Medical Center, Englewood, New Jersey

Siddarth Satish, MS, and

Division of Research & Development, Gauss Surgical, Inc., Palo Alto, California

Jonathan H. Waters, MD

Departments of Anesthesiology and Bioengineering, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; McGowan Institute for Regenerative Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania

Abstract

Background—Accurate measurement of intraoperative blood loss is an important clinical variable in managing fluid resuscitation and avoiding unnecessary transfusion of blood products. In this study, we measured surgical blood loss using a tablet computer programmed with a unique algorithm modeled after facial recognition technology. The aim of the study was to assess the accuracy and performance of the system on surgical laparotomy sponges *in vitro*.

Study Design and Methods—Whole blood samples of pre-measured hemoglobin (Hb) and volume were reconstituted from units of human packed red blood cells and plasma and distributed across surgical laparotomy sponges. Normal saline was added to simulate the presence of varying levels of hemodilution and/or irrigation use. Soaked sponges from four different manufacturers were scanned using the Triton System with Feature Extraction Technology (Gauss Surgical, Inc., Palo Alto, USA) under three different ambient light conditions in an operating room. Accuracy of Hb loss measurement was evaluated relative to the pre-measured values using linear regression and Bland-Altman analysis. Correlations between studied variables and measurement bias were analyzed using nonparametric tests.

Results—The overall mean percent error for measure of Hb loss for the Triton System was 12.3% [95% CI 8.2 to 16.4%]. A strong positive linear correlation between the pre-measured and actual Hb masses was noted across the full range of intraoperative lighting conditions, including (A) high ($r = 0.95$ [95% CI 0.93–0.96]), (B) medium ($r = 0.94$ [95% CI 0.93–0.96]), and (C) low ($r = 0.90$ [95% CI 0.87–0.93]) mean ambient light intensity. Bland-Altman analysis revealed a bias of 0.01 g [95% CI –0.03 to 0.06 g] of Hb per sponge between the two measures. The corresponding lower and upper limits of agreement were –1.16 g [95% CI –1.21 to –1.12 g] per sponge and 1.19 g [95% CI 1.15 to 1.24 g] per sponge, respectively. Measurement bias of estimated blood loss and Hb mass using the new system were not associated with the volume of saline used to reconstitute the samples ($p = 0.506$ and $p = 0.469$, respectively), suggesting that the system is robust under a wide range of sponge saturation conditions.

Conclusion—Mobile blood loss monitoring using the Triton system is accurate in assessing Hb mass on surgical sponges across a range of ambient light conditions, sponge saturation, saline contamination, and initial blood Hb. Utilization of this tool could significantly improve the accuracy of blood loss estimates.

Introduction

Intraoperative blood loss is very common but difficult to objectively measure and track in real time. Patient blood is vacuum-suctioned from the surgical field, absorbed into laparotomy sponges and drapes, and on occasion may accidentally spill onto the floor. There is no standard method to determine the amount of blood or hemoglobin (Hb) contained within blood-soaked sponges. Gravimetric estimation can be performed by subtracting the dry weight of the sponge from the wet weight, although this method is time consuming and insensitive due to the presence of confounding, non-sanguineous fluids and other substances on the sponges (e.g., saline, ascites, amniotic fluid, other tissues).¹ This method also relies on the assumption that the Hb of the blood the patient is bleeding remains constant, which is a poor assumption given that the patient's blood becomes increasingly dilute from IV fluids. Measuring Hb concentrations from all blood-containing media is a more accurate method and has been described as a standard to assess intraoperative blood loss in research studies,^{2,3} but this method is impractical for real-time intraoperative use. An efficient and accurate method to objectively measure Hb contained within blood-soaked laparotomy sponges would improve intraoperative blood loss estimates.

The Triton system (Gauss Surgical, Inc., Palo Alto, CA) is a novel mobile monitoring platform that combines mobile computing with Gauss Feature Extraction Technology (FET) to directly assess Hb mass (mHb) absorbed by surgical sponges from an image.⁴ Gauss FET uses computer vision and machine-learning algorithms to automatically filter out the effects of non-sanguineous components absorbed and, as such, may provide a robust measurement of blood loss in real time. The objective of this *in vitro* study was to assess the accuracy of the Triton system in measuring different amounts of mHb on a variety of laparotomy sponges in a variety of lighting conditions.

Materials and Methods

This study protocol was approved by the Stanford University School of Medicine IRB (Protocol ID 22078). Blood samples of known Hb concentrations and volumes were reconstituted from outdated units of human packed red blood cells and plasma obtained from the Stanford Blood Center. The blood was reconstituted in a range of Hb concentrations (5.0–17.0 g/dL) and a range of volumes (2.5–50.0mL). The Hb range was selected to represent the clinical range of Hb values.⁵ To account for different sponge saturation levels that occur routinely during surgery, known blood volumes were mixed with known normal saline volumes (range 0–35 mL), and poured onto a single sponge. This known mHb constituted the control for each sponge (mHb_{Assay}). The total fluid volumes used per sponge in this *in vitro* study (mean volume = 33.5 ml [95% CI 28.4 – 38.7 ml] per sample) were similar to volumes of fluid per sponge found in a previous clinical study (mean volume = 31.7 ml [95% CI 27.4 – 35.9 ml] per sponge). Four different 18" x 18" 12-ply laparotomy sponge brands (Cardinal Allegiance, RFDetect, AMD Ritmed, and Novaplus) were used in this study. For each sponge sample created, the Triton System with FET technology (Version 2.0.9, Gauss Surgical Inc., Palo Alto, USA) was used to capture scanned images of the sponges and obtain measurements of mHb loss (mHb_{Triton}). To test for changes in accuracy due to different lighting conditions that may be present in different operating

rooms, image capturing was performed under three different ambient lighting conditions. Ambient lighting ranged from dark ambient settings to bright ambient settings, modulated by changes in the overhead light levels. Representative pictures of the different lighting conditions, including corresponding measures of brightness, are shown in Figure 1.

Statistical Analysis

A measurable difference in blood Hb concentration of ± 1 g/dL is commonly described as an acceptable tolerance in measuring Hb-related indicators and laboratory tests. For the purposes of this study, we converted that clinically significant blood Hb concentration error to a clinically significant absolute mHb error per laparotomy sponge. Using mean patient estimated blood volumes from the surgical population as previously reported,⁶ and the mean sponge count of 21 sponges for inpatient surgical procedures,⁷ we converted the ± 1 g/dL blood Hb concentration acceptable error to an absolute ± 1.99 g Hb per sponge error. Based on pilot data, power analysis revealed that 32 samples would be required per sponge brand to be 95% certain that the limits of a two-sided 95% confidence interval will exclude an absolute difference of more than 1.99 g per sponge between mHb_{Triton} and mHb_{Assay} if there is truly no difference between the two methods. To improve the precision of this estimate, a minimum of 50 sponges was sampled for each of the four sponge brands used in the study. To provide for a wide range of saline content on sponges as observed during surgery, approximately 20% of the sponges were soaked with blood only, whereas the remaining sponges were soaked with both blood and normal saline. As the 50 sponges sampled per cohort of sponges were each scanned across the three ambient light settings, a minimum of 150 scans was captured per sponge brand, resulting in 621 measures in total. Statistical analyses were performed with SPSS (Chicago, USA) and MATLAB (Palo Alto, USA). For quantitative variables, the mean, standard deviation (SD), and range were presented. For the primary effectiveness variables (mean difference, mean percent error), 95% confidence intervals (CI) were computed using SPSS, based on alpha of 0.05 and sample size of 621 (for all measures) or the corresponding number of samples within an analysis subgroup. In each case, the skewness and kurtosis of the distribution of differences were calculated and considered, alongside the sample size and visual inspection of the distribution of the differences, which confirmed that they followed a normal distribution. For qualitative variables, the number, rate (percent), and 95% CI were presented. Concordance between mHb_{Triton} and mHb_{Rinse} was tested via a Bland-Altman analysis,⁸ wherein bias (mean difference between the two measures) and limits of agreement (mean $\pm 1.96 \times$ SD) were computed. To assess the consistency of agreement between measures across the different ambient light settings, the intraclass correlation coefficients (ICC) for single measures across the three ambient light groups and ICC for the average measure were calculated using the Reliability Analysis function of SPSS and a Two-way Mixed Effects model with a consistency definition and CI of 95%. Finally, a covariate analysis of the effects of ambient light conditions, sponge saturation, saline contamination level, and initial blood Hb, was performed. Given the non-normal distribution of these covariables, nonparametric tests (Kruskal Wallis test and Spearman's rho [ρ] tests) were used to evaluate the correlations between the studied covariables and bias (Hb and estimated blood loss [EBL]), defined as the difference between the actual and algorithm-predicted values of mHb and EBL (positive

bias being indicative of predicted values being smaller than the actual number; numbers provided as median $\pm$ interquartile range).

Results

A strong positive linear correlation between mHb_{Triton} and the mHb_{Assay} was noted ($r = 0.92$ [95% CI 0.91–0.93], $p < 0.0001$) across all sponges over the range of intraoperative ambient light conditions tested. Figure 2 shows a plot of the correlation between the two measures across all sponges under the three ambient lighting conditions. Figure 3 depicts a distribution of the differences between the two measures, showing that the error of the new method followed a normal distribution centered around a low bias. Overall, Bland-Altman analysis revealed a bias of 0.01 g [95% CI –0.03 to 0.06 g] of Hb per sponge between the two measures. The corresponding lower limit of agreement was –1.16 g [95% CI –1.21 to –1.12 g] per sponge and the upper limit was 1.19 g [95% CI 1.15 to 1.24 g] per sponge. The Bland-Altman plot for all measures under each ambient light setting is depicted in Figure 4. Bias, SD of error, and the root mean-squared error (RMSE) were calculated and are presented in Table 1 for each sponge type. The overall mean percent error for measure of Hb loss for the Triton System was 12.3% [95% CI 8.2 to 16.4%].

To assess the consistency of agreement between measures across the different ambient light settings, the ICC for single measures across the three ambient light groups and ICC for the average measure were calculated using the Reliability Analysis function of SPSS and a Two-way Mixed Effects model with a consistency definition and CI of 95%. The ICC for single measures was 0.944 (95% CI 0.930–0.956, $p < 0.001$) and the ICC for the average measure was 0.981 (95% CI 0.975–0.985, $p < 0.001$). Both ICC values indicated a very high level of consistency among the results obtained across all three ambient light conditions. The average coefficient of variation (CV) for measurements across all three light conditions was 20.7% and the CV was 6.6% between measures captured under the bright and medium ambient light settings. Figure 5 depicts the association of bias in mHb measures with sponge type and ambient light condition. Bias of mHb measures differed significantly according to the brand of sponge (overall $p = 0.008$; Cardinal Allegiance, 0.167 ± 0.857 ; AMD Ritmed, 0.055 ± 0.627 ; Novaplus, 0.042 ± 0.508 ; and RFDetect, 0.001 ± 0.661 g) and ambient light status ($p < 0.001$; medium, 0.180 ± 0.573 ; bright, 0.112 ± 0.631 ; and dark, -0.126 ± 0.710 mL). mHb bias correlated with index of samples (Spearman correlation coefficient [ρ] 0.104, $p = 0.010$), initial Hb ($\rho -0.234$, $p < 0.001$), and volume of blood ($\rho -0.206$, $p < 0.001$). Hb bias was not associated with volume of saline used to reconstitute the samples ($p = 0.469$). Similarly, EBL bias differed significantly according to the brand of sponge (overall $p = 0.003$; Cardinal Allegiance, 1.337 ± 7.500 ; AMD Ritmed, 0.445 ± 4.780 ; Novaplus, 0.518 ± 5.159 ; and RFDetect, 0.012 ± 5.483 mL) and ambient light status ($p < 0.001$; medium, 1.541 ± 4.989 ; bright, 1.005 ± 5.113 ; and dark, 1.005 ± 5.648 mL). EBL bias was correlated with index of samples ($\rho 0.121$, $p = 0.003$), initial Hb ($\rho -0.274$, $p < 0.001$), and volume of blood ($\rho -0.207$, $p < 0.001$). However, EBL bias was not associated with the volume of saline used to reconstitute the samples ($p = 0.506$).

Discussion

The primary objective of this *in vitro* study was to evaluate the accuracy of the Triton Hb loss measurement algorithm in measuring Hb loss in surgical sponges. First, the system's performance was characterized via analysis of correlation between algorithm-predicted and pre-measured mHb values per sponge. The results showed a strong positive linear correlation. Next, Bland-Altman analysis was performed to investigate concordance between the two measures, revealing significant concordance with the direct physical measurement of Hb loss. Limits of agreement had magnitudes below the clinically relevant difference of ± 1.99 g per sponge in Hb loss measurement error across a total of 621 measures, including four sponge brands, three ambient light settings, and systematic variations in saturation levels and starting Hb concentrations. Measures of Hb loss using the new system displayed a mean percent error of 12%. The 95% limits of agreement between the Triton system and the pre-measured mHb were approximately ± 1.2 g per sponge following a normal distribution, whereas the bias was negligible (0.01 g Hb), indicating an increasing level of total accuracy as more sponges are used during a surgical procedure. The Triton system tended to underestimate Hb loss on sponges with higher levels of Hb loss under dark ambient light settings. The likely cause of this bias is that incremental changes in Hb absorption are not as perceptible via photographic features when scene illumination is diminished. Although such statistically significant differences were noted in the bias across different sponge types and ambient light settings, these differences remain clinically insignificant given the low bias and narrow limits of agreement demonstrated within each sponge type (per the Bland-Altman approach) and ambient light setting. In practice, we have found a single 18" x 18" laparotomy sponge to be able to absorb up to 100mL of blood. When one considers that two or three dozen sponges are used routinely in large blood loss cases, it becomes clear that a significant portion of the total blood shed by the patient may be contained within surgical sponges. In addition to considering blood in suction canisters and on the surgical field and floor, accurate measurement of Hb loss in sponges is therefore necessary to accurately estimate total blood lost by the patient.

Current methods of estimating blood lost onto surgical sponges include the gravimetric method (where sponges are weighed, subtracting their dry weight), and visual estimations. Visual estimations are notoriously inaccurate and inconsistent.^{2,9-14} Simulations and didactic training have been shown to improve visual estimations, but there are still poor associations between experience level and accuracy, and a significant decay in blood loss estimation skills over time.¹⁵⁻¹⁷ The gravimetric method is inaccurate, overestimating blood loss due to the presence of contaminants other than blood on the laparotomy sponges.¹ It is also impractical in the setting of a high blood loss surgical case due to being very labor intensive and time consuming.^{2,3}

The Triton system may also be useful in blood salvage. Intraoperative blood salvage is typically only 40–60% efficient at returning blood lost back to the patient.¹⁸ If this efficiency can be improved, a patient can sustain much greater blood loss before requiring allogeneic blood transfusions. It is thought that a significant contributor to the diminished efficiency of blood salvage is the exclusion of blood-soaked surgical sponges.¹⁹ The Triton

system may be used as a decision-making tool to determine which sponges should be diverted and rinsed into the cell salvage machine before being discarded.

Limitations of the study include the use of banked blood, and statistically significant differences in the bias of different sponge brands. The use of banked blood soaked into surgical sponges in pre-measured volumes, saturation levels, and Hb is only an approximation of how the device will be used clinically when measuring amounts of blood absorbed into sponges. Further, the limitations of the *in vitro* study included the anticoagulated nature of the blood used on sponges, and the absence of platelets in the reconstituted sample. Even though these factors were unlikely to affect Hb measures using the new method or the Hb assay, further study of the device's accuracy in real-time use during actual major blood loss procedures with blood that forms clots and in which various non-sanguineous, pigmented fluids (e.g., bile, administered dyes, or pigments such as indigocarmine, methylene blue) are also absorbed in the lap sponges, are warranted.

The results of this *in vitro* study suggest that the Triton system is able to measure the amount of Hb on laparotomy sponges across a range of lighting conditions, sponge brands, and starting Hb concentrations of shed blood. It may provide a rapid and useful means of augmenting the traditional methods of assessing blood loss in real time including blood aspirated into suction canisters and visible blood on the surgical field, drapes, and floor.

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Figure 1.

Representative scans of sponges captured by the Triton System under ambient light settings (A1) bright lighting conditions, (B1) medium lighting conditions, and (C1) dark lighting conditions and corresponding (A2–C2) distributions of image Brightness (Bv), in $\log_2(\text{cd}/\text{cm}^2)$, over all scans.

Figure 2.

Plot of hemoglobin mass (mHb)_{Triton} vs. pre-measured mHb (mHb_{Assay}) demonstrates a strong positive linear correlation between the two measures across a range of intraoperative ambient lighting conditions.

Figure 3. Distributions of the differences between hemoglobin mass (mHb)_{Triton} and the pre-measured mHb per sponge across three ambient lighting conditions.

Figure 4. Bland-Altman plot of the concordance between hemoglobin mass (mHb)_{Triton} and the pre-measured value of mHb per sponge. The solid blue line represents the bias (mean difference) and the dashed lines represent the upper and the lower limits of agreement (bias $\pm$ 1.96 SD).

Figure 5.
Association of bias ($\text{mHb}_{\text{Triton}} - \text{mHb}_{\text{Assay}}$) with sponge type and ambient light setting.

Table 1

Detailed performance summary of the Triton system, by sponge type. Values are presented as number or as mean [95% CI].

	AMD Ritmed	RF Detect	Cardinal Allegiance	NovaPlus
Number of samples	50	50	50	57
Range (g Hb)	0 – 6	0 – 6	0 – 6	0 – 6
Mean fluid volume [95% CI] (ml)	35.3 [31.9 to 38.6]	33.5 [28.4 to 38.7]	33.5 [28.4 to 38.7]	29.5 [24.9 to 34.1]
Correlation, R [95% CI]	0.94 [0.89 to 0.96]	0.94 [0.92 to 0.96]	0.92 [0.89 to 0.94]	0.93 [0.91 to 0.95]
RMSE (g Hb)	0.58	0.52	0.68	0.52
Bias [95% CI] (g Hb)	−0.22 [−0.38 to −0.07]	−0.03 [−0.11 to 0.05]	0.15 [0.04 to 0.26]	0.08 [0.00 to 0.16]
Lower limit of agreement [95% CI] (g Hb)	−1.28 [−1.43 to −1.13]	−1.04 [−1.12 to −0.96]	−1.15 [−1.26 to −1.05]	−0.92 [−1.00 to −0.84]
Upper limit of agreement [95% CI] (g Hb)	0.84 [0.68 to 0.99]	0.98 [0.90 to 1.06]	1.45 [1.34 to 1.56]	1.08 [1.01 to 1.16]