Published in final edited form as:

Anesth Analg. 2014 September ; 119(3): 588–594. doi:10.1213/ANE.0000000000000181.

Clinical Evaluation of a Novel System for Monitoring Surgical Hemoglobin Loss

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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.

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Attestation: Gerhardt Konig 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.

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Attestation: Vicki Ting attests to approving the final manuscript.

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

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Attestation: Bridget Philip 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.

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

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

Conflicts of Interest: Siddarth Satish holds equity in and is Director of Gauss Surgical, Inc.

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Attestation: Jonathan Waters attests to approving the final manuscript.

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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, blood lost onto laparotomy sponges during surgical cases was measured using a tablet computer programmed with a unique algorithm modeled after facial recognition technology. In this study we assessed the accuracy and performance of the system in surgical cases.

Methods—In this prospective, multicenter study, 46 patients undergoing surgery with anticipated significant blood loss contributed laparotomy sponges for hemoglobin (Hb) loss measurement using the Triton System with Feature Extraction Technology (Gauss Surgical, Inc., Los Altos, USA). The Hb loss measured by the new system was compared to Hb loss measured by manual rinsing of the sponges. Accuracy was evaluated using linear regression and Bland-Altman analysis. In addition, the new system's calculation of blood volume loss was compared with the gravimetric method of estimating blood loss from intraoperative sponge weights.

Results—A significant positive linear correlation was noted between the new system's measurements and the rinsed Hb mass ($r = 0.93$, $p < 0.0001$). Bland-Altman analysis revealed a bias of 9.0 g and narrow limits of agreement (-7.5 g to 25.5 g) between the new system's measures and the rinsed Hb mass. These limits were within the clinically relevant difference of ± 30 g, which is approximately half of the Hb content of a unit of allogeneic whole blood. Bland-Altman analysis of the estimated blood loss on sponges using the gravimetric method demonstrated a bias of 466 ml (overestimation) with limits of agreement of -171 ml and 1103 ml, due to the presence of contaminants other than blood on the laparotomy sponges.

Conclusion—The novel mobile monitoring system provides an accurate measurement of Hb mass on surgical sponges as compared with manual rinsing measurements and is significantly more accurate than the gravimetric method. Further study is warranted to assess the clinical utility of the technology.

Introduction

In determining the need for intraoperative blood product transfusion the anesthesiologist uses the patient's hemodynamic stability, cardiac status, hemoglobin (Hb) and hematocrit (Hct) levels, as well as the estimated blood loss (EBL). Hb and Hct level interpretation is

confounded by intravascular hemodilution or hemoconcentration resulting from the infusion of crystalloid or colloid solutions, blood product transfusion, third spacing, or acute hemorrhage into the surgical field.^{1,2} Blood loss estimates are usually visual estimates, and as such are difficult to standardize. The decision about whether or not to transfuse, as well as how much blood to transfuse, could be significantly improved if an accurate, real-time measure of blood loss was available alongside laboratory measures of Hb/Hct and clinical judgment based on the patient's hemodynamic stability and cardiac status.

Perioperative estimates of blood loss have relied primarily on mutual agreements of visual assessment between the surgeon and anesthesiologist.³ 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.^{4–10} 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.^{11–13} The gravimetric estimation of blood loss by weighing soaked laparotomy sponges and subtracting their known dry weight has been explored, although 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.¹⁴ Similarly, procedures for rinsing and assaying Hb content from blood-absorbing media have been described as a standard for the assessment of intraoperative blood loss in research studies,^{5,15} but are also impractical for real-time intraoperative use.

The Triton System (Gauss Surgical, Inc., Los Altos, USA) is a novel monitoring platform that combines mobile imaging with computer vision and machine learning algorithms to directly measure Hb mass (mHb) absorbed by surgical sponges. Via a camera-enabled mobile application native to the iPad 2 (Apple Inc., Cupertino, USA), the Triton system allows intraoperative scanning of surgical sponges by the circulating nurse as they are removed from the sterile surgical field, as part of the routine process of recording sponge count (Figure 1). Simultaneously, the captured images of blood-soaked sponges are encrypted and transferred wirelessly to a remote server from the mobile application via secure HTTPS protocol. Gauss Feature Extraction Technology (FET) is used by the server to parse photographic and geometric information from relevant regions of interest and compute mHb using proprietary classifiers and computational models. By design, FET includes fine-grained detection, classification, and thresholding schemes to filter out the effects of extraneous non-sanguineous fluids (e.g., saline) and to compensate for variability in intraoperative lighting conditions. A cumulative value of the mHb in sponges is returned to the mobile display within seconds. The objective of this prospective, multicenter clinical study was to assess the accuracy of the Triton system and FET in measuring mHb lost onto laparotomy sponges during surgery.

Materials and Methods

Study Population and Surgical Cases

The investigational protocol was approved by the IRBs at the University of Texas MD Anderson Cancer Center (Houston, TX), Santa Clara Valley Medical Center (San Jose, CA),

and Englewood Hospital and Medical Center (Englewood, NJ). The requirement for written informed consent was waived at all sites. The study enrolled consecutive surgical cases where many bloody laparotomy sponges were anticipated. The surgical cases enrolled included general surgery, obstetrics, orthopedics, and cardiac surgery. There were no specific enrollment criteria for procedure types. Patient preoperative Hb/Hct measurements as reported in the patient's medical record were recorded.

Hemoglobin Loss and Blood Loss Measurements

Investigators followed their standard of care for use and management of surgical sponges. At the end of each case, all laparotomy sponges were collected for measurement using the Triton System, then underwent rinsing and subsequent Hb assay. Measurements were completed within two hours of collection. The Triton System with FET technology (Version 2.0.9, Gauss Surgical Inc., Los Altos, CA) was used to capture scanned images of the sponges with resulting measurement of mHb loss (mHb_{Triton}). Sponges from each case were then weighed using a calibrated digital scale (A&D Co. Ltd., Tokyo, Japan) and the dry weight of the sponges was subtracted to yield the total fluid weight, which is equivalent to the gravimetric EBL (EBL_{Weight}). Subsequently, the Hb loss from each case was measured by manually rinsing the red blood cell (RBC) content from the sponges (mHb_{Rinse}) using methods similar to those used in recent studies.^{5,15} Sponges were soaked in heparinized normal saline and either rinsed individually using a manual compression device or rinsed in batches using a centrifuge operated at 1600 RPM for 45 seconds. After rinsing, the Hb concentration of the effluent solution (Hb_{Effluent}) was measured using a low-concentration hemoglobin analyzer (HemoCue Plasma/Low Hb, Hemocue AB, Ängelholm, Sweden). The mass of the effluent solution was measured using a digital scale, and converted to volume of effluent (V_{Effluent}) assuming a mean fluid density of 1.0 g/ml. The hemoglobin mass in the effluent was then calculated as follows: $mHb_{Effluent} = Hb_{Effluent} \times V_{Effluent}$.

Since it is not possible to recover 100% of the RBCs on sponges via rinsing, the recovery rates of the individual and batch rinse methods were independently characterized in a benchtop setting where banked blood was deposited on sponges in known quantities and mechanically extracted using the rinse methods. A linear regression analysis revealed mean mHb recovery rates of 89.5% [95% CI 86.8% to 92.1%] for individual sponges (n = 116) and 98.99% [95% CI 87.1% to 110.9%] for batches of sponges (n = 11, < 20 sponges/batch). These characteristic recovery rates were then used to adjust values of mHb_{Effluent} in the clinical study to derive a more precise measurement of Hb loss on the sponge (mHb_{Rinse}).

Statistical Analysis

A power analysis was performed to calculate a sample size necessary to detect a difference in mHb of 30 g per surgical case. This was considered a clinically relevant difference since 30 g is approximately half of the Hb content of a unit of allogeneic whole blood.¹⁵ This difference is also equivalent to a measurement difference of ± 1 g/dL in total Hb in approximately 97.5% of the population, using estimates of total blood volume ($5.65L \pm 1.41$ L) reported for a population of patients recently undergoing cardiac surgery.¹⁶ Based on data from a recent study on Hb loss¹⁵ it was estimated that 41 patients per group are required to determine a difference of ± 30 g per patient between mHb_{Triton} and mHb_{Rinse} with 90%

power and a significance level (alpha) of 0.05. As such, the study was planned for 46 patients, each with measures of mHb_{Triton} and mHb_{Rinse}. For quantitative variables, the mean, standard deviation, and range were presented. For the primary effectiveness variables, 95% confidence intervals were computed. For qualitative variables, the number, rate (percent) and 95% exact confidence limits were presented. Concordance between mHb_{Triton} and mHb_{Rinse} was tested via a Bland-Altman analysis, wherein bias (mean difference between the two measures) and limits of agreement (mean $\pm$ 1.96 x SD) were computed.¹⁷ Volumetric blood loss measures of the Triton system (EBL_{Triton}) and the gravimetric method (EBL_{Weight}) were compared with a two-sided paired t-test at a significance level of 0.05.

Results

Study Demographics

Forty-six surgical procedures between July and November 2012 contributed 758 laparotomy sponges (18 in x 18 in, from Cardinal Health, NovaPlus, and AMD Ritmed) for analysis. The preoperative Hb level (g/dl) was recorded for all but 7 subjects, or calculated from recorded Hct via the formula: Hb (in g/dl) $\approx$ Hct (%) / 3. The mean ($\pm$ SD) of preoperative Hb was 12.9 ± 1.5 g/dl. The mean ($\pm$ SD) laparotomy sponge count per case was 17 ± 10 . The mean fluid volume ($\pm$ SD) contained on sponges per case was 668 ± 455 ml. Of the 46 cases contributing sponges, 12 procedures provided measures on an individual sponge basis, which were then summed to calculate a measure of Hb loss per case. The remaining 34 cases comprised measures per batch of sponges, which were summed to yield Hb loss per case. Cases providing sponges are detailed in Table 1 by subspecialty.

Measures of Hb Mass Loss

A strong positive linear correlation between mHb_{Triton} and the mHb_{Rinse} was noted ($r = 0.93$ [95%CI 0.88–0.96], $p < 0.0001$). Figure 2 shows a plot of the association between the two measures on a per-case basis. Bland-Altman analysis revealed a bias of 9.0 g [95%CI 6.5 to 11.5 g] of Hb per case between the two measures. The corresponding lower limit of agreement was -7.5 g [95% CI -10.0 to -5.0 g] per case and the upper limit was 25.5 g [95% CI 23.0 to 28.0 g] per case (Figure 3). Bias, standard deviation of error, and the root mean-squared error were calculated and are reported in Table 2. Measures of mHb by the Triton system across individual sponges within the 12-case subset demonstrated a strong positive linear correlation with corresponding measures of mHb_{Rinse}, with $r = 0.88$ [95%CI 0.84–0.91], $p < 0.0001$. A Bland-Altman plot of the difference versus the mean of the mHb_{Triton} and mHb_{Rinse} revealed a bias of 0.7 g [95%CI 0.6 to 0.9 g] of Hb per sponge. The corresponding lower limit of agreement was -1.0 g [95% CI -1.1 to -0.9 g] and the upper limit was 2.5 g [95% CI 2.3 to 2.6 g] per sponge.

Measures of Estimated Blood Loss

To enable a comparison of the Triton system and the gravimetric measure of blood loss, values of mHb_{Triton} and mHb_{Rinse} were divided by the recorded laboratory-derived subject Hb, resulting in values of EBL_{Triton} and EBL_{Rinse}. As mentioned previously, seven cases were excluded from this analysis because subject laboratory-derived Hb level was not

available. EBL_{Triton} and EBL_{Weight} were assessed against EBL_{Rinse} as the accepted standard for both association and agreement. A significant positive linear correlation between EBL_{Triton} and EBL_{Rinse} per case was noted ($r = 0.94$ [95% CI 0.89–0.97], $p < 0.0001$) (Figure 4A). Similarly, a significant positive linear correlation was present between EBL_{Weight} and EBL_{Rinse} per case ($r = 0.92$ [95% CI 0.86–0.96], $p < 0.0001$) (Figure 4B). Bland-Altman analysis of EBL_{Triton} relative to EBL_{Rinse} revealed a bias of 88 ml [95% CI –68 to 108 ml] per case (Figure 5A). The corresponding lower and upper limits of agreement were –31 ml [95% CI –51 to –11 ml] and 207 ml [95% CI 187 to 226 ml] respectively. Although measures of EBL_{Weight} demonstrated a strong association with EBL_{Rinse} , a Bland-Altman plot of the two measures revealed a significant positive bias of 466 ml [95% CI 361 to 571 ml] per case (Figure 5B). The corresponding lower and upper limits of agreement were –171 ml [95% CI –276 to –66 ml] and 1103 ml [95% CI 998 to 1208 ml], respectively, per case. A paired t-test was used for explicit comparison of EBL_{Triton} with EBL_{Weight} . Mean EBL_{Weight} exceeded mean EBL_{Triton} by 359 ml per case (627 ml vs. 268 ml, $p < 0.0001$). Figure 6 shows a plot of the association between each of the measures EBL_{Triton} and EBL_{Weight} versus EBL_{Rinse} on a per-sponge basis for the 12-case subset. A strong positive linear correlation (**A**) between EBL_{Triton} and EBL_{Rinse} per sponge was noted ($r = 0.88$ [95% CI 0.84–0.91], $p < 0.0001$). Conversely, there was a less significant positive linear correlation (**B**) between EBL_{Weight} and EBL_{Rinse} per sponge ($r = 0.60$ [95% CI 0.49–0.69], $p < 0.0001$).

Discussion

In this study, the use of the Triton Hb loss measurement system showed a significant concordance with the direct physical measurement of Hb loss, with limits of agreement whose magnitudes were below the clinically relevant limit of ± 30 g per patient in Hb loss measurement error. The measurement bias of the Triton system in the present study (9.0 g Hb) would be equivalent to approximately 0.16 unit-equivalents of a 450-ml unit of whole blood, given the mean recorded Hb of 12.9 g/dl for our study population; or equivalent to approximately 0.20 unit-equivalents of a 250-ml packed RBC unit with a Hb of 18 g/dL. In addition, the Triton system demonstrated significantly higher measurement accuracy than the gravimetric measure of blood loss, which revealed a five-fold increase in bias and wider limits of agreement with mHb_{Rinse} when compared with those of mHb_{Triton} . A key contributor of this discrepancy with the gravimetric method is likely the absorption of the aforementioned non-sanguineous fluids, which increases the apparent blood volume absorbed by each sponge. While this observation is consistent with previous reports detailing the inaccuracy of the gravimetric method,¹⁴ its clinical significance is compounded by the labor-intensive nature of the gravimetric measurement. Indeed, a survey of anesthesiologist's blood management practices indicated that half as many anesthesiologists relied on the gravimetric measures of blood during major intraabdominal surgery in adults in 2003 compared with those in 1980 (26% vs. 48%, $p < 0.001$), whereas visual estimation of blood loss remained a widely practiced method and the use of serial Hb/Hct determinations increased.¹⁸ However, these findings are particularly relevant to current subspecialties where the practice of weighing sponges has been mandated as part of intraoperative nursing protocols. The reliance of sponge weights as a measure of blood loss in obstetric patients, for instance, may lead to an incorrect estimate of peripartum hemorrhage. Use of the Triton

system in this setting could facilitate a significantly more rapid and reliable assessment of intrapartum blood loss on laparotomy sponges and could prove valuable if extended to usage on the other blood collection reservoirs and absorbent under-buttocks drapes used in the postpartum unit.

The probable etiology of the low apparent bias of mHb_{Triton} relative to mHb_{Rinse} (Figure 2) relates to the inability to consistently recover a constant proportion of the mHb physically from each sample in the surgical setting, which was the primary limitation of this study. Since sponges were only available for collection at the conclusion of each surgical case per IRB guidelines, clot formation in some samples collected would have likely occurred before the mechanical recovery of Hb from each sample, resulting in decreased RBC recovery, an effect commonly observed during intraoperative cell salvage.¹⁹ As such, the methods used in this study to measure mHb_{Rinse} likely variably underestimated the Hb content truly present on each sponge, contributing to the apparent positive bias of mHb_{Triton} . Although the recovery method on a per-sponge and per-batch basis as an acceptable mode of mHb recovery using reconstituted blood from donor units of packed RBCs and plasma had been validated, the characterized recovery levels were likely optimistic given that the source RBCs in the validation studies had been consistently anticoagulated before their application to sponges, per standard blood banking procedures. Indeed, although the rinse method is an appropriate standard for the assessment of mHb_{Triton} and comparison of EBL_{Triton} and EBL_{Weight} , a true “gold standard” measure of blood loss has remained elusive. Moreover, there is significant variability in mechanical extraction methods, as noted by a wide variation of recovery rates (82% to 93%) reported previously for similar blood extraction and assay methods applied to donor blood deposited on cotton products.^{20,21}

The results of the present study suggest that the Triton system provides an accurate measure of the amount of Hb on laparotomy sponges from surgical cases as compared with manual rinsing of the sponges, and is significantly more accurate than the gravimetric method. Further study is warranted to assess the clinical utility of the technology.

Acknowledgments

Funding: This research was supported by a grant from the National Institutes of Health (T32GM075770). Equipment for this study was provided by Gauss Surgical, Inc., Los Altos, USA.

The authors thank Harry Lemmens (Stanford), Gregory Botz (MD Anderson), Aryeh Shander (EHMC), Tim Goodnough (Stanford), and Mazyar Javidroozi (SABM) for many helpful discussions regarding study design and for their valuable input on this manuscript. The authors further recognize the following individuals for logistical and technical support of this research: Marisa Molina and Joseph Weinberg (Gauss Surgical); Sajjad Naqvi, Mustafa Caylan, and Anna Juhl (EHMC).

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Figure 1.
Photograph demonstrating the sponge scanning and analysis process using the Triton System.

Figure 2.

Plot of mHb_{Triton} vs. the rinsed hemoglobin (Hb) mass demonstrates a strong positive linear association ($r = 0.93$ [95% CI 0.88–0.96], $p < 0.0001$).

Figure 3.

Bland and Altman plot of the concordance between mHb_{Triton} and the rinsed Hb mass per case ($n = 46$ measures). The solid blue lines represent the bias (mean difference) and the dashed lines represent the upper and the lower limits of agreement (bias ± 1.96 SD) for each plot.

Figure 4.

Accuracy comparison of Triton system as compared with gravimetric method for all cases via plot of both (A) EBL_{Triton} vs. EBL_{Rinse} ($r = 0.94$ [95% CI 0.89–0.97], $p < 0.0001$) and (B) EBL_{Weight} vs. EBL_{Rinse} ($r = 0.92$ [95% CI 0.86–0.96], $p < 0.0001$). Blue line represents 100% correlation.

Figure 5.

Bland and Altman plots of the concordance (A) between EBL_{Triton} and EBL_{Rinse} , and (B) between EBL_{Weight} and EBL_{Rinse} , per patient ($n = 39$ measures per method). The solid blue lines represent the bias (mean difference) and the dashed lines represent the upper and the lower limits of agreement (bias ± 1.96 SD) for each plot.

Figure 6.

Per-sponge accuracy comparison of Triton system as compared with gravimetric method for the 12 cases where sponges were measured individually. **(A)** Plot of EBL_{Triton} vs. EBL_{Rinse} demonstrates a strong positive linear correlation on a per-sponge basis ($r = 0.88$ [95% CI 0.84–0.91], $p < 0.0001$), whereas **(B)** plot of EBL_{Weight} vs. EBL_{Rinse} demonstrates a moderate positive linear correlation on a per-sponge basis ($r = 0.60$ [95% CI 0.49–0.69], $p < 0.0001$). Blue line represents 100% correlation.

Table 1

Procedure types contributing laparotomy sponges and corresponding sponge count and preoperative hemoglobin (Hb) (g/dl). Values are presented as number and percent or as mean and SD.

Procedure Type	Number of Cases	Average sponge count & SD	Preoperative Hb (g/dl) & SD
Obstetrics/Gynecology	27	59% 16 ± 9	12.2 ± 0.7
Orthopedics	3	7% 13 ± 6	12.8 ± 0.5
Urology	3	7% 26 ± 19	13.6 ± 1.6
General	12	26% 16 ± 12	13.9 ± 1.9
Cardiac	1	2% 13 ---	10.7 ---
Total	46	100% 17 ± 10	12.9 ± 1.5

Table 2

Performance summary of the algorithm-estimated hemoglobin (Hb) mass across the per-sponge series and per-case series. RMSE= root mean-squared error

Variable	Per-sponge series	Per-case series
Number of samples	167 sponges (12 cases)	46 cases (758 sponges)
Range (g Hb)	0 – 9	0 – 90
Correlation, r (95% CI)	0.88 (0.84 to 0.91), $p < 0.0001$	0.93 (0.88 to 0.96), $p < 0.0001$
RMSE (g Hb)	1.15	12.27
SD(error) (g Hb)	0.89	8.42
Bias (95% CI) (g Hb)	0.73 (0.60 to 0.87)	9.00 (6.50 to 11.50)
Lower limit of agreement (95% CI) (g Hb)	-1.01 (-1.14 to -0.87)	-7.51 (-10.01 to -5.01)
Upper limit of agreement (95% CI) (g Hb)	2.47 (2.34 to 2.61)	25.51 (23.01 to 28.02)