CAMBRIDGE DESIGN PARTNERSHIP

Accurately Estimating Blood Loss

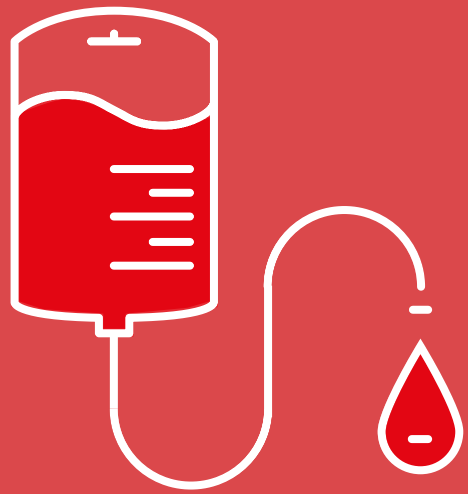
Navigating Design Challenges and Pioneering Future Solutions

By Brian Chang and Michael McKnight

Why is estimating blood loss accurately **still a challenge?**

Significant advancements in surgery, such as the emergence of surgical robotics and augmented reality (AR)-assisted instrument navigation, have revolutionized patient care. Despite these innovations, there are still critical needs that technology has yet to fully address. One such need is the accurate and easy estimation of blood loss during surgery. The lack of a comprehensive solution for real-time monitoring of blood loss poses serious risks to patient outcomes.

In this article, we will explore the challenges of estimating blood loss (EBL), evaluate the advantages and disadvantages of various novel solutions, and discuss the key factors necessary for achieving more accurate, timely, and insightful monitoring.



Visual estimation techniques currently **underestimate blood loss by 30%,**[1, 2] regardless of the clinician's experience.

Such inaccuracies can lead to incorrect treatment decisions and unresolved major bleeds.

What happens if we **estimate blood loss inaccurately?**

Accurate measurement of blood loss is critical in various surgical procedures, including cardiothoracic, orthopedic, obstetric, gynecologic, and trauma surgeries. These surgeries often span several hours, making the accurate and timely management of blood essential for success.

Overestimation of blood loss can lead to unnecessary blood transfusions, increasing the risk of infections and hemolytic (destruction of red blood cells) and nonhemolytic (fever) reactions. This not only prolongs hospital stays but also impacts overall patient recovery. Moreover, consistent overestimation of blood loss within a hospital strains resources, raises costs, and reduces blood product availability for other patients.

Conversely, underestimating blood loss may result in the patient not receiving a necessary blood transfusion, leading to serious complications like hypovolemic shock. This critical condition prevents the heart from pumping enough blood through the body, potentially causing organ damage or failure. Additionally, delayed recognition of complications due to inadequate tissue oxygenation can hinder timely intervention and treatment, increasing the risk of adverse outcomes and extended hospital stays.[3]

Why is measuring blood loss **so difficult?**

There is a complex trade-off between accuracy and time in estimating blood loss during surgery. The oldest method, visual estimation, likely predates the first human blood transfusion in the 1800s.[4, 5] This quick and easy method involves counting the number of sponges or gauze pads used, but is notoriously inaccurate due to variability in absorption levels and the types of fluids being absorbed.

The gravimetric method, which calculates the difference in weight between dry (pre-procedure) and soaked (post procedure) surgical gauzes, offers improved accuracy. However, it still falls short by not accounting for other liquids, such as amniotic fluid, rinse liquid, and urine, particularly during obstetric surgery.

Attempts to develop a mathematical framework, like the Moore formula,[2, 6] have consistently overestimated blood loss, even when accounting for height, weight, and sex. These methods aim for quick estimations, but they are widely recognized for being inaccurate.

Running blood tests for hemoglobin and hematocrit levels can accurately determine if a patient needs a blood transfusion. Low levels during surgery can indicate significant blood loss. The process involves extracting blood, sending the sample to a lab, and waiting for the results, which can take from 20 minutes to several hours depending on lab availability. While highly accurate and dependable, this method sacrifices time and valuable blood during lengthy surgeries and poses a risk of hypoxia. Moreover, such readings during surgery are intermittent and do not reflect the patient's real-time status, potentially leading to delayed responses to complications. Only two or three data points would be available during an hour-long surgery, which is insufficient for making well-informed decisions.

On the next page, we summarize known methods for EBL and evaluate each for their accuracy, speed, cost, usability, and space in the operating room. No options perform well across all metrics, however in the research and development stage, doppler ultrasound and pulse CO-oximetry show promise. We discuss these technologies further on page 9.

There is a complex trade-off between **accuracy and time** in estimating blood loss during surgery.

Technologies and techniques for estimating blood loss

TECHNIQUE	ACCURACY	SPEED	COST	USABILITY	SPACE	NOTES
LAB TEST	HIGH	SLOW	EXPENSIVE	UNFRIENDLY	N/A	Uncommon during surgery
GRAVIMETRIC	LOW	MEDIUM	CHEAP	MODERATE	LOW	Widely used
VISUAL	LOW	MEDIUM	CHEAP	FRIENDLY	NONE	Least accurate, widely used
VOLUMETRIC	LOW	MEDIUM	CHEAP	MODERATE	LOW	Widely used
MATHEMATICAL MODEL	LOW	SLOW	CHEAP	FRIENDLY	NONE	Uncommon during surgery
COLORIMETRY	HIGH	MEDIUM	MEDIUM	MODERATE	LARGE	Not widely used
DOPPLER ULTRASOUND	PROMISING BUT UNPROVEN	FAST	MEDIUM	FRIENDLY	LOW	R&D stage
PULSE CO-OXIMETRY	PROMISING BUT UNPROVEN	FAST	MEDIUM	FRIENDLY	LOW	R&D stage
PULSE OXIMETRY	LOW	FAST	CHEAP	FRIENDLY	LOW	R&D stage
fNIRS	UNPROVEN	FAST	MEDIUM	MODERATE	LOW	R&D stage

Key considerations for advanced EBL technology

ACCURACY VS. SPEED

Most common techniques for measuring blood loss during surgery face a significant tradeoff: they are either fast but inaccurate or accurate but slow. Operating room personnel will likely prioritize speed over accuracy due to the critical need for immediate data to make timely decisions. Newer technologies show promise in providing accurate, real-time qualification of blood loss. However, these technologies require more due diligence for long-term reliability and usability, given conflicting clinical evidence regarding their effectiveness.[2] Ideally, new solutions for EBL should balance accuracy and speed, but currently, few technologies achieve this. Therefore, the primary focus should be improving accuracy, with speed as a secondary consideration.

USABILITY

Usability is a driving factor for the widespread adoption of medical devices. Accurate blood loss measurements depend on the proper handling of devices, software, and consumables. This includes appropriate and frequent calibration and maintenance to ensure optimal device performance. Enhancing the user experience through human factors engineering can significantly improve the success of these products.

SPACE

Optimizing space in a busy operating room is challenging. New technologies that rely on cameras need considerable space to capture the specific field of view necessary for accurate measurements. Any obstructions in the line of sight can cause problems, making efficient use of space a critical consideration.

COST

The financial barrier to adopting new EBL technologies can be significant, especially when other equipment may take priority. These advanced technologies often involve substantial development costs, making them more costly than traditional methods. Software-heavy solutions might require a subscription service, while hardware-heavy systems entail higher upfront costs. Additionally, the use of custom consumables calibrated specifically for these systems increases long-term expenses, ultimately impacting patient costs.

Paving the way with **promising technologies**

One of the latest blood loss measurement technologies is **Stryker's Triton platform**, a system which leverages colorimetry. This requires a clinician to soak blood using a custom-designed gauze pad, hold it within the system camera's field of view to record, and then discard the used gauze. The camera captures both color and infrared images, which are then processed by a computer vision algorithm. The algorithm determines the amount of blood in the soaked gauze based on the coloration and shape of the stain. A key benefit of this method is its ability to differentiate between the hemoglobin in blood and other fluids such as urine, fecal matter, amniotic fluid, and saline.

The Triton system also includes the gravimetric approach, using a scale for weight measurements and a canister for direct liquid volume measurements when gauze is not suitable. Its ease of use during operations facilitates quick and continuous monitoring of blood loss. The overall system has demonstrated promising accuracy across a range of measurements.[7, 8] We look forward to observing the rate of adoption by hospitals considering all key factors such as accuracy, cost, usability, and space requirements.

IMAGE: Stryker's Triton platform

Colorimetry requires clinicians to soak blood in a custom designed gauze pad and hold it up to the system camera's field of view to record. The **computer vision algorithm** then determines the amount of blood in the soaked gauze.

Candidate Technologies

Pulse CO-Oximetry is capable of non-invasively and continuously monitoring hemoglobin levels in a patient. It comprises of a light source and a detector. As light passes through the patient's skin, it is absorbed and scattered by various components, most notably hemoglobin. By comparing light absorption at different wavelengths, algorithms can calculate parameters such as spectrophotometric hemoglobin levels and oxygen saturation. Traditional pulse oximeters use two wavelengths, whereas pulse CO-oximeters use up to a dozen, providing concentration metrics on other molecules in the body.

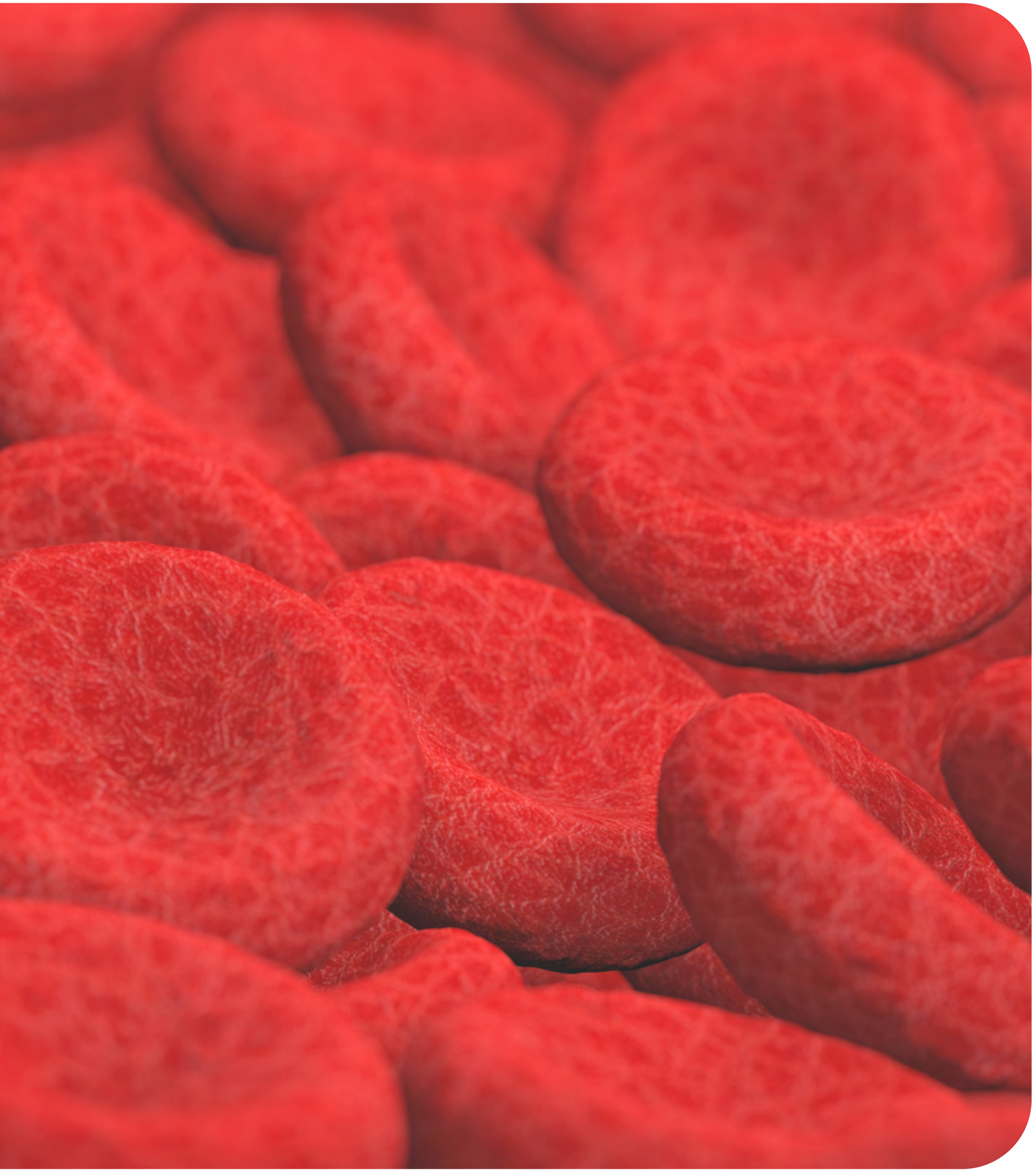
While measuring hemoglobin concentration does not directly estimate blood loss, it indicates oxygen levels in the blood, which may suggest a substantial bleed (e.g. low hemoglobin count due to insufficient blood). Ongoing research has identified spectrophotometric hemoglobin monitoring as a potentially viable technique for measuring blood loss during surgery, though clinical results are currently mixed.[9, 10] Factors such as movement, breathing rate, and patient health all influence the device's efficacy. Additionally, the need for user involvement to monitor trends and gain insights in an already busy operating room could make this device less appealing.

Doppler Ultrasound is a technique that measures blood flow through blood vessels in real time. A sensor placed on the patient's skin emits high-frequency sound waves through the tissue, which bounce back from the moving red blood cells in the blood vessels. The reflected sound waves are picked up by a receiver and analyzed. The "Doppler" part refers to the frequency difference between the emitted and received sound waves, allowing calculations of the corrected carotid flow time (ccFT). The ccFT, essentially the systolic time interval in the carotid artery, correlates with stroke volume.[11]

A decrease in blood volume might indicate a reduced amount of blood available for the heart to pump, or a decreased stroke volume, suggesting blood loss. Recent studies have shown potential for accurate blood loss volume estimations by detecting decreasing stroke volumes that may lead to hypovolemic shock, although these findings are based on highly controlled settings.[12] More research is needed to address the limitations such as the use of the lower body negative pressure model, uncertainties around digital vasoconstriction measurements, and the idealized controlled environment.

Functional Near Infrared Spectroscopy (fNIRS) is an optical brain monitoring method that has enticing indirect applications in estimating blood loss during surgery. To use fNIRS for EBL applications, a patient wears a head cap equipped with multiple electrodes. Similar to pulse oximetry, fNIRS uses light at different wavelengths to detect changes in molecular concentrations in cerebral blood non-invasively. This allows for the continuous and rapid assessment of the hemodynamic cortical response.

From a usability perspective, fNIRS is portable and requires minimal space. While cable management may be an issue, developments in wireless technology could address this concern. Although fNIRS lacks clinical evidence as a viable technique for EBL, it continues to find applications in intraoperative brain monitoring, particularlyin pain management.[13]



What's on the horizon for **innovation in EBL?**

The limitations of current blood loss estimation technologies are significantly impacting their adoption in intraoperative procedures. One characteristic of current solutions is that data input is typically done in a single modality. This only provides one of several indicators of blood loss, like hemoglobin measurements, contributing to inaccuracy or delays in information.

Losing blood triggers a range of physiological effects, from immediate change in heart rate to prolonged changes in blood pressure.[14] The sympathetic nervous system responds by diverting blood away from non-critical organs to the heart and brain, potentially causing organ failure. For effective real-time blood loss estimation, it is essential to use all available information.

To address these challenges, we are likely to see the development of more integrated multimodal solutions over time. These would monitor several physiological parameters, such as oxygenation, volumes, and pressure changes to provide a more accurate estimation of blood loss. This is where mathematical modeling, data analytics, and artificial intelligence (AI) can play a crucial role.

Translating real-time measurements into **real-time insights**

Quantifying physiological fluids in real time is challenging, yet critical for improving patient outcomes. Current approaches typically rely on a single modality to estimate blood loss, such as calculating the volume of blood soaked gauze or measuring hemoglobin content noninvasively. While some of the technologies previously mentioned show promise, they need to address key criteria like accuracy, speed, cost, continuous monitoring, and usability for wider adoption.

A multimodal approach could overcome these limitations by leveraging existing monitoring instruments available in the operating room and harnessing their data to estimate blood loss. Utilizing the vast knowledge in physiological biofluid mathematical modeling and AI can transform real-time measurements into real-time insights.

This integration can offer clinicians a virtual assistant that streamlines the operating room workflow by collating information from multiple modalities and managing blood loss promptly. In the age of data, modeling, and AI, we have the tools to improve patient safety and surgical outcomes significantly.

An integrated solution for estimating blood loss will pave the way for the next generation of technologies and patient-centric blood management, **ensuring that every drop counts**.

Ready to take EBL technology **to the next level?**

We have discussed how EBL technologies need to be multi-modal and implement cutting-edge approaches such as mathematical modeling and artificial intelligence. With experts in medical therapies, digital technologies, and biological systems, Cambridge Design Partnership can help implement these approaches while ensuring you retain control and intellectual property of your technology.

At CDP, we integrate seamlessly with your team to accelerate your project's development. To discuss how we can help you, get in touch.

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References

1. Olofsson, B. (2019). Accuracy of visually estimated blood loss in surgical sponges by members of the surgical team. AANA journal, 87(4), 277.
2. Gerdessen, L. et al. (2021). Comparison of common perioperative blood loss estimation techniques: a systematic review and meta-analysis. Journal of Clinical Monitoring and Computing, 35(2), 245-258.
3. English, E. M., Bell, S., Kamdar, N. S., Swenson, C. W., Wiese, H., & Morgan, D. M. (2019). Importance of Estimated Blood Loss in Resource Utilization and Complications of Benign Hysterectomy. Obstetrics and gynecology, 133(4), 650.
4. Thompson, P., & Strandenes, G. (2020). The history of fluid resuscitation for bleeding. Damage Control Resuscitation: Identification and Treatment of Life-Threatening Hemorrhage, 3-29.
5. Zimmerman, L. M., & Howell, K. M. (1932). History of blood transfusion. Annals of Medical History, 4(5), 415.
6. Lopez-Picado, A., Albinarrate, A., & Barrachina, B. (2017). Determination of perioperative blood loss: accuracy or approximation?. Anesthesia & Analgesia, 125(1), 280-286.
7. Konig, G., Waters, J. H., Hsieh, E., Philip, B., Ting, V., Abbi, G., ... & Adams, G. (2018). In vitro evaluation of a novel image processing device to estimate surgical blood loss in suction canisters. Anesthesia and analgesia, 126(2), 621.
8. Doctorvaladan, S. V., Jelks, A. T., Hsieh, E. W., Thurer, R. L., Zakowski, M. I., & Lagrew, D. C. (2017). Accuracy of blood loss measurement during cesarean delivery. American Journal of Perinatology Reports, 7(02), e93-e100.
9. Beleta, M. I. et al. (2022). Noninvasive continuous hemoglobin monitoring of blood transfusion in obstetric procedures. Egyptian Journal of Anaesthesia, 38(1), 701-708.
10. Barker, S. J., Shander, A., & Ramsay, M. A. (2016). Continuous noninvasive hemoglobin monitoring: a measured response to a critical review. Anesthesia and analgesia, 122(2), 565.
11. Jon-Émile S. Kenny, Christine Horner, Mai Elfarnawany, Andrew M. Eibl, Joseph K. Eibl. Carotid Artery Corrected Flow Time Measured by Wearable Doppler Ultrasound Accurately Detects Changing Stroke Volume During the Passive Leg Raise in Ambulatory Volunteers. Front. Biosci. (Elite Ed) 2023, 15(2), 12. https://doi.org/10.31083/j.fbe1502012
12. Kenny, J. É. S., Elfarnawany, M., Yang, Z., Eibl, A. M., Eibl, J. K., Kim, C. H., & Johnson, B. D. (2022). A wireless ultrasound patch detects mild-to-moderate central hypovolemia during lower body negative pressure. The Journal of Trauma and Acute Care Surgery, 93(2), S35.
13. Karunakaran, K. D., Peng, K., Green, S., Sieberg, C. B., Mizrahi-Arnaud, A., Gomez-Morad, A., ... & Borsook, D. (2023). Can pain under anesthesia be measured? Pain-related brain function using functional near-infrared spectroscopy during knee surgery. Neurophotonics, 10(2), 025014-025014.
14. Hooper N, Armstrong TJ. Hemorrhagic Shock. [Updated 2022 Sep 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470382/

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