

In Vitro Evaluation of a Novel Image Processing Device to Estimate Surgical Blood Loss in Suction Canisters

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Background: Clinicians are tasked with monitoring surgical blood loss. Unfortunately, there is no reliable method available to assure an accurate result. Most blood lost during surgery ends up on surgical sponges and within suction canisters. A novel FDA-cleared device (Triton system, Gauss Surgical, Inc., Los Altos, CA) to measure the amount of blood present on sponges using computer image analysis has been previously described. This study reports on performance of a complementary FDA-cleared device (Triton Canister System, Gauss Surgical, Inc., Los Altos, CA), that uses similar image analysis to measure the amount of blood in suction canisters.

Methods: Known quantities of expired donated whole blood, packed red blood cells (PRBC), and plasma, in conjunction with various amounts of normal saline, were used to create 207 samples representing a wide range of blood dilutions commonly seen in suction canisters. Each sample was measured by the Triton device under 3 lighting conditions (Bright, Medium and Dark), resulting in a total of 621 measurements. The measured hemoglobin mass in each sample was compared

Results: The Bland-Altman bias of total Hb mass measured by Triton versus reference method was 4.1 g (95% CI 3.6 to 4.5) with the corresponding lower and upper limits of agreements of -7.8 g (95% CI -8.6 to -6.9) and 15.9g (95% CI 15.1 to 16.7), falling well within the predetermined clinically significant limits of ± 30 g.¹ Repeated measurements of the samples under the various lighting conditions were highly correlated, with intraclass correlation coefficient (ICC) of 0.995 (95% CI 0.993-0.996, $p < 0.001$). Hemoglobin mass bias was significantly associated with hemolysis level (Spearman's rho correlation coefficient -0.137, $p = 0.001$) and total canister volume (Spearman's rho correlation coefficient 0.135, $p = 0.001$), but not ambient illuminance.

Conclusion: The Triton Canister System was able to measure the Hb mass reliably with clinically acceptable accuracy in reconstituted blood samples representing a wide range of Hb concentrations, dilutions, hemolysis and ambient lighting settings.

Variable	Lighting Condition	Bias (Triton vs. Assay)	Lower Limit of Agreement	Upper Limit of Agreement
Assay Hb Mass (g)	Dark	4.7 (3.8 to 5.6)	-8.1 (-9.7 to -6.6)	17.6 (16.0 to 19.1)

	Medium	3.4 (2.6 to 4.1)	-7.4 (-8.7 to -6.1)	14.2 (12.9 to 15.5)
	Bright	4.1 (3.2 to 4.9)	-7.6 (-9.0 to -6.2)	15.7 (14.3 to 17.1)
Assay Hb Concentration (g/dl)	Dark	0.3 (0.2 to 0.3)	-0.4 (-0.5 to -0.3)	1.0 (0.9 to 1.0)
	Medium	0.2 (0.2 to 0.2)	-0.4 (-0.5 to -0.3)	0.8 (0.7 to 0.9)
	Bright	0.2 (0.2 to 0.3)	-0.4 (-0.5 to -0.3)	0.9 (0.8 to 1.0)
Assay EBL (ml)	Dark	37.8 (29.9 to 43.8)	-62.6 (-74.6 to -50.6)	136.3 (124.3 to 148.3)
	Medium	26.8 (20.9 to 32.8)	-58.7 (-69.0 to -48.4)	112.4 (102.1 to 122.7)
	Bright	32.0 (25.5 to 38.5)	-61.0 (-72.2 to -49.8)	124.9 (113.7 to 136.1)

Table: Hb mass, concentration and estimated blood loss in 207 study samples under 3 lighting conditions. The bias represents the mean difference between the Triton and Assay values. All values are provided with corresponding 95% confidence intervals.

1. Guinn NR, Broome BW, White W, Richardson W, Hill SE. Comparison of visually estimated blood loss with direct hemoglobin measurement in multilevel spine surgery. *Transfusion* 2013;53:2790-4