

Point-of-Care Complete Blood Count for Pre-Hospital and Prolonged Field Care

Application following Polytrauma Managed with ECLS

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Introduction

- Complete blood count (CBC) is the most commonly ordered first-line test for patient screening and management, providing information on cell counts and morphology, hemoglobin concentration, hematocrit, and white blood cell (WBC) differential
- Availability of CBC in prolonged field care (PFC) settings would improve patient management; however, standard automated CBC systems remain limited to hospital laboratories due to large, cumbersome, and sensitive instrumentation
- A miniaturized, battery-operated point-of-care CBC device (20 × 10 × 15 cm; 0.5 kg), Hilab Lens, was developed for use outside the hospital laboratory (**Figure 1**). The device has regulatory approval in Brazil (National Health Surveillance Agency [ANVISA] registration no. 880583710047)
- Lens uses a 40-μL blood sample applied to a cartridge to perform automated chromatography and microscopy-based classification of cell morphology (4-part leukocyte differential) and cell counts using artificial intelligence (AI) and machine learning (**Figure 2**)
- Lens previously demonstrated accuracy compared with standard laboratory CBC in healthy volunteers (Gasparin et al., *Scientific Reports*, 2022) and in an oncology setting (Gasparin et al., *Diagnostics*, 2023)
- We conducted the first comparative evaluation of Lens in a swine model of trauma and simulated prolonged field care

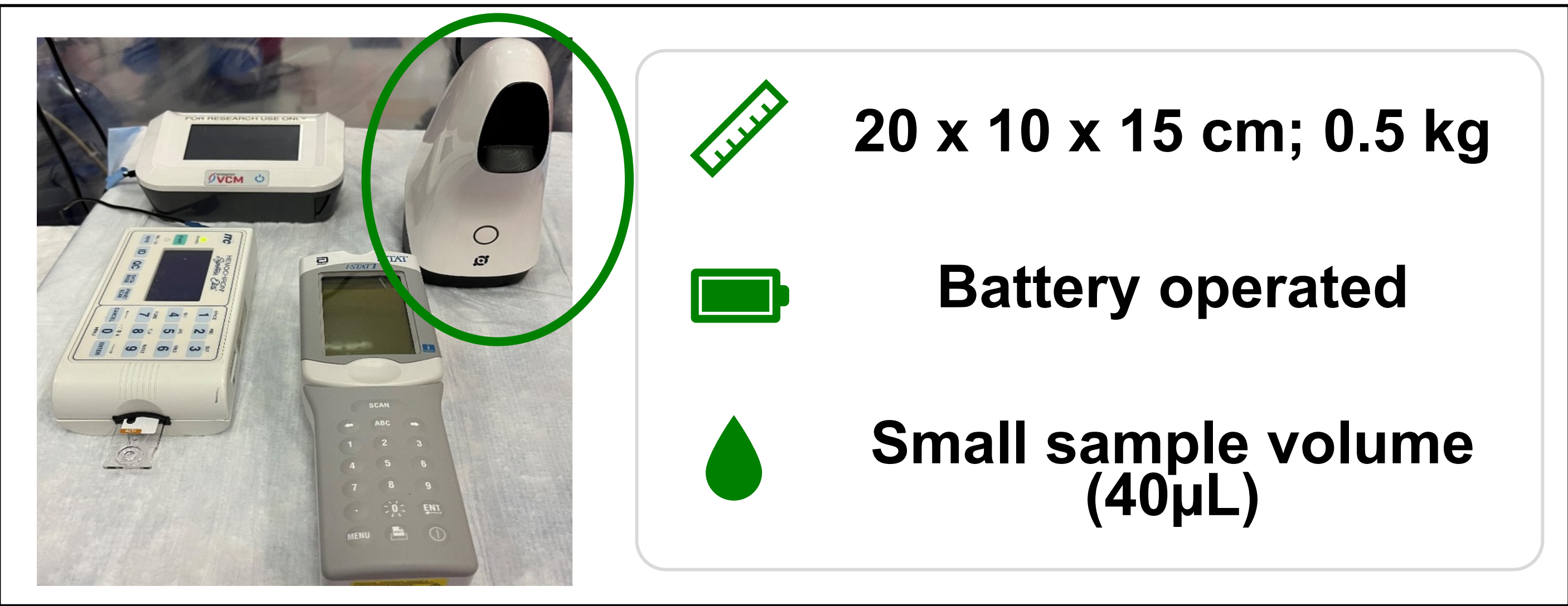


Figure 1. Lens CBC in ICU with suite of POC devices



Figure 2. Schematic of Lens sample processing

Objective and Hypothesis

Objective: Assess feasibility of Lens CBC at POC in translational polytrauma swine model with extracorporeal life support (ECLS) and simulated ground and high-altitude aeromedical evacuation

Hypothesis: Lens strongly correlates with standard of care laboratory CBC through 72-hours polytrauma management; and is not affected by systemic anticoagulation with heparin

Methods

- Anesthetized, mechanically ventilated swine (n=10, 45-60 kg) received polytrauma (pulmonary contusion, traumatic brain injury, and/or hemorrhage) followed by veno-venous ECLS with systemic heparin administration
- Blood was collected at 10 key timepoints (**Figure 3**) for paired analysis by Lens CBC at POC and by laboratory CBC (Siemens ADVIA 2120; Siemens, Germany)
- Mean difference between analyzers, concordance correlation, and Deming regression were conducted to evaluate agreement between Lens versus reference CBC

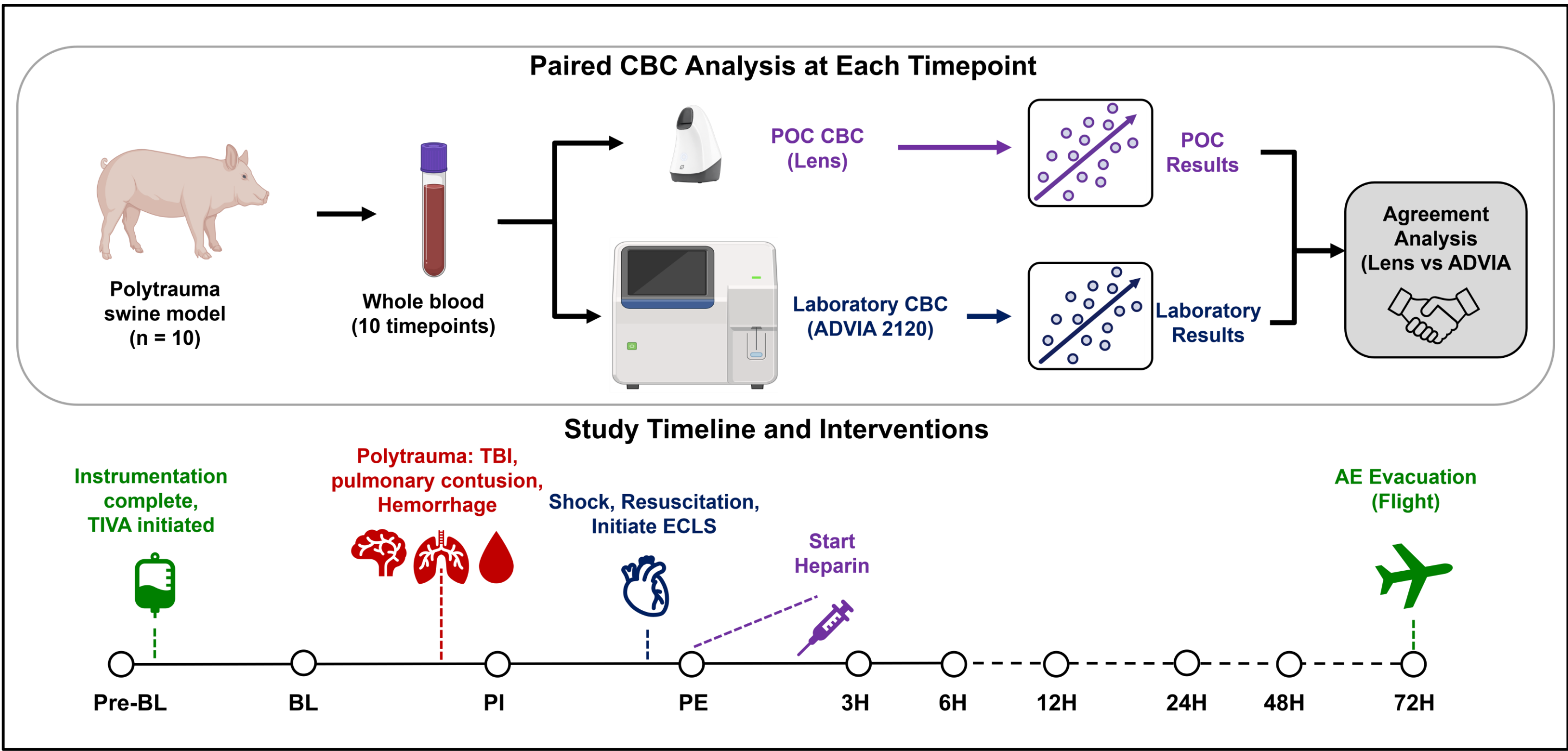


Figure 3. Schematic of timepoints and interventions

Results

- Mean difference between analyzers was minimal (**Table 1**)
- Lens showed strong agreement ($r > 0.75$) with SOC (**Figure 4** and **Table 1**), with comparable agreement across timepoints
- Time to results was ~30 min. No samples were lost to operational error

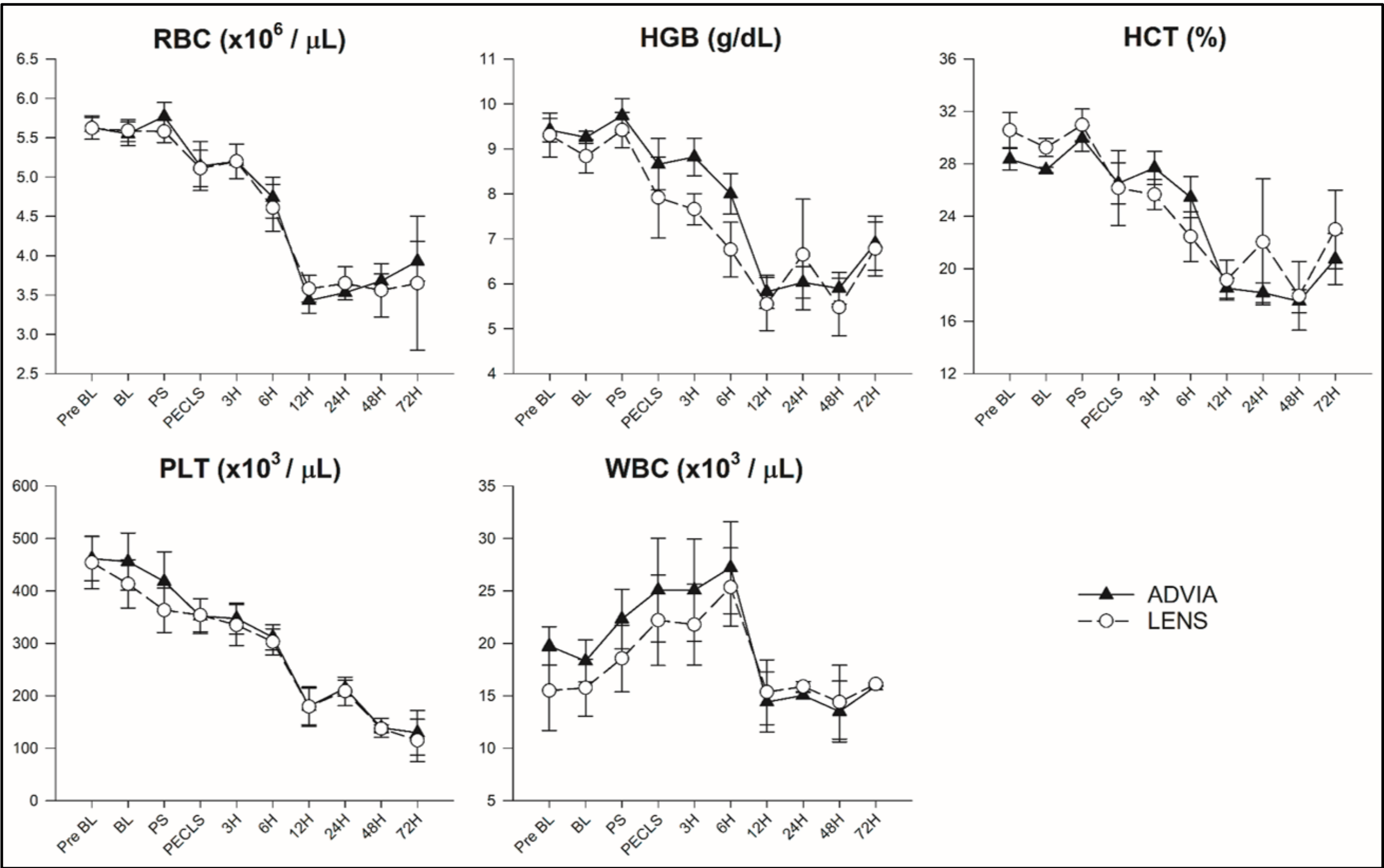


Figure 4. Mean ± std. err Lens CBC versus ADVIA results over time.

Results

Variable	Correlation	Mean Difference (Advia – Lens) ± st err		
		All Timepoints	Pre BL	48 Hours
RBC	0.951	0.03 ± 0.05	0.01 ± 0.09	0.12 ± 0.38
HGB	0.819	0.49 ± 0.14	0.11 ± 0.65	0.42 ± 0.32
HCT	0.798	-0.43 ± 0.52	-2.2 ± 1.4	-0.39 ± 1.75
PLT	0.959	16 ± 5	7 ± 27	2 ± 11
WBC	0.875	1.9 ± 0.5	4.3 ± 2.5	1.1 ± 0.7

Table 1. Spearman correlation and mean difference in ADVIA and Lens CBC

- Presence of unfractionated heparin in sample due to systemic anticoagulation did not affect device agreement (**Figure 5**)
- Leukocyte aggregates flagged by Lens not detected by ADVIA

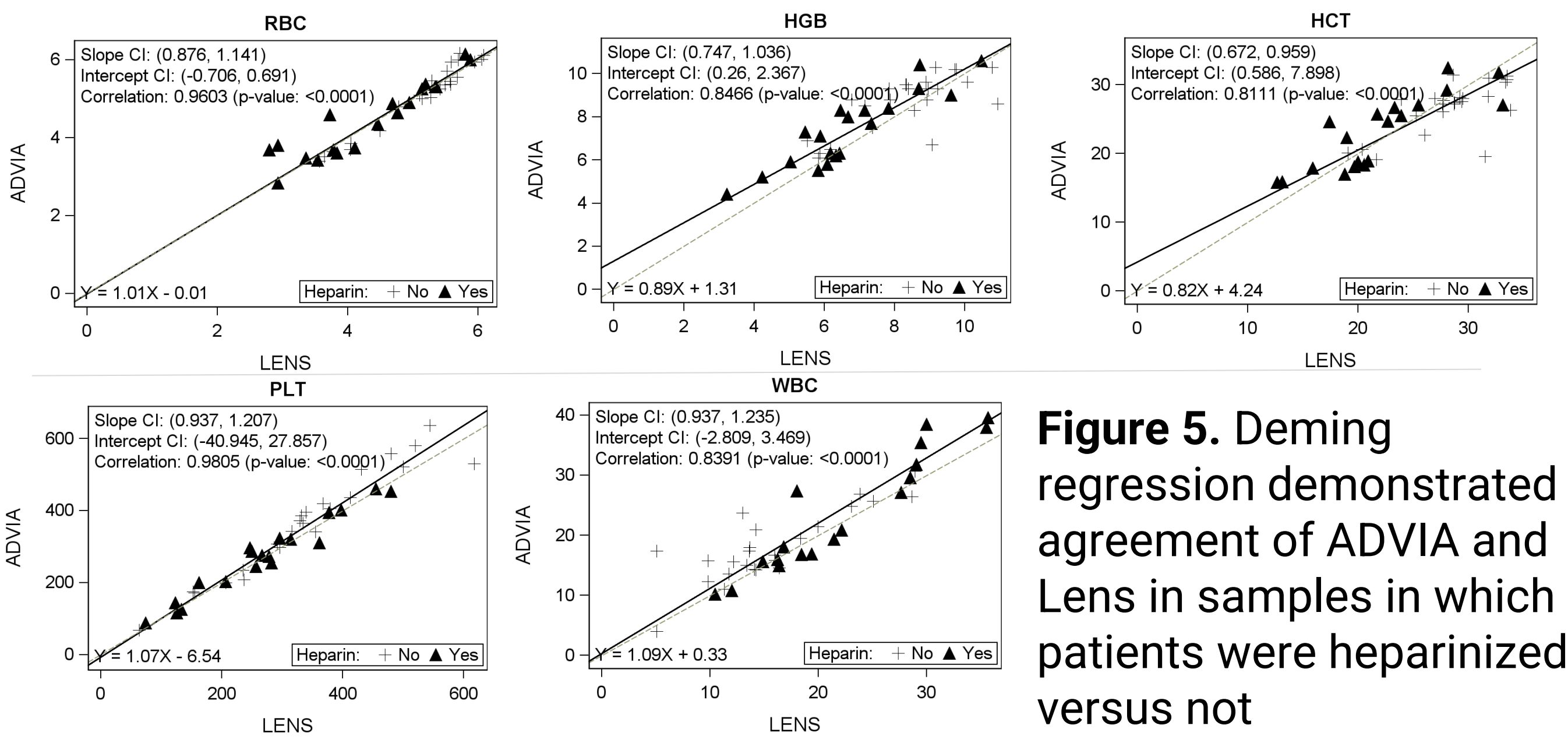


Figure 5. Deming regression demonstrated agreement of ADVIA and Lens in samples in which patients were heparinized versus not

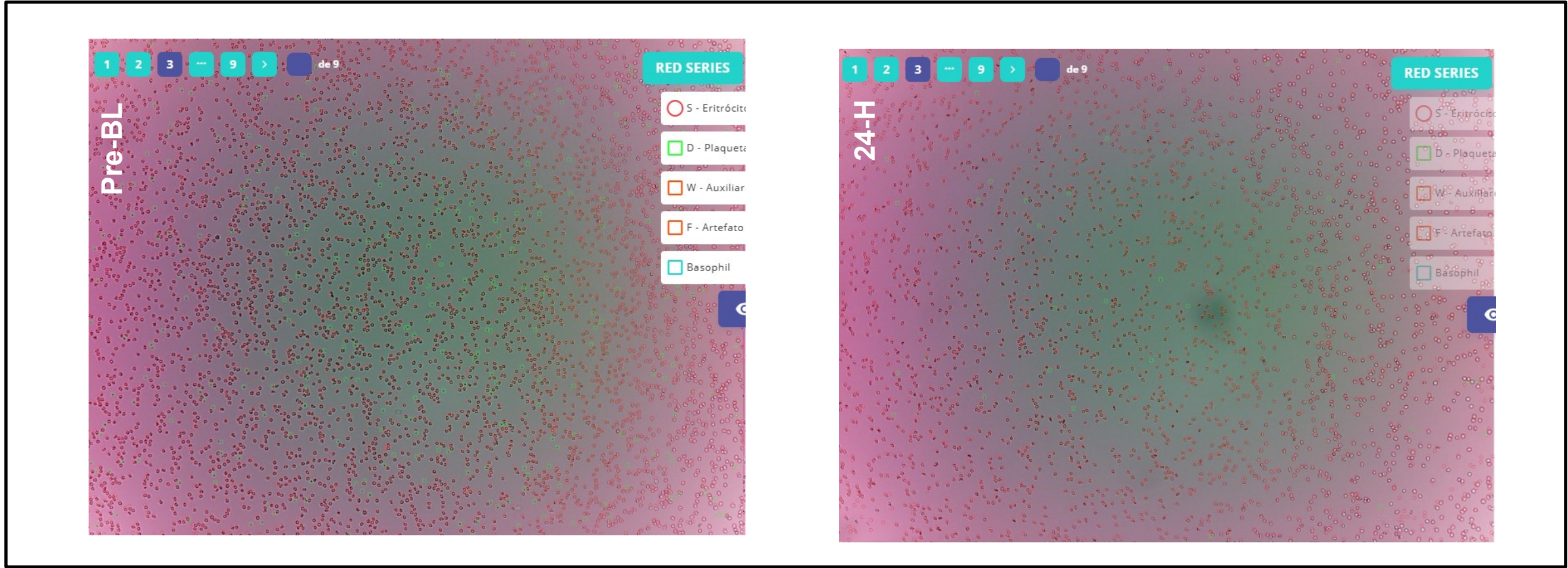


Figure 6. Example images acquired at Pre-BL versus 24-H timepoint

Conclusions

- Lens showed strong correlation with standard hospital-grade CBC in translational model of trauma and PFC
- Follow-on studies in EMS and pre-hospital setting are warranted to further assess utility and feasibility

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