Feasibility of PT, aPTT, and Fibrinogen on a Multifunctional Digital Microfluidic Cartridge

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BACKGROUND

- Measurement of multiple coagulation parameters quickly is vital to correcting coagulopathy and improving outcomes in severe trauma patients.
- There are no rapid, near-patient technologies that can perform multiple coagulation assays simultaneously on a single consumable.
- We are developing a rapid (<15 minutes), point-of-care multifunctional digital microfluidic (DMF) platform to test critical coagulation markers - prothrombin time (PT), activated partial thromboplastin time (aPTT), and fibrinogen – using low volume samples (<50 µL).

METHODS

- 10 µL samples are loaded onto a DMF cartridge and then dispensed to combine with PT, aPTT, or fibrinogen reagents.
- Reaction droplets are then shuttled within the cartridge where the droplet motion is monitored through electrical impedance to measure the rate of change in viscosity of each reaction. Droplet viscosity changes at a rate proportional to the amount of coagulation precursors present, allowing for the calculation of clotting time and activity.
- To determine accuracy of the PT and aPTT assays, five proficiency testing plasma samples (College of American Pathologists [CAP], Northfield, IL) with known values for normal, mid-level abnormal, and high-level abnormal clotting were tested on the DMF platform.
- For method comparison studies, contrived plasma samples containing K2 EDTA and unfractionated heparin to simulate prolonged time were tested on the DMF platform for PT and aPTT assays respectively and compared to results from an FDA-cleared comparator method. CAP and patient plasma samples (LabCorp, NC) were tested on the DMF platform and an FDA-cleared comparator for the fibrinogen assay.

Figure 1. Baebies' point-of-care platform for rapid coagulation testing

RESULTS

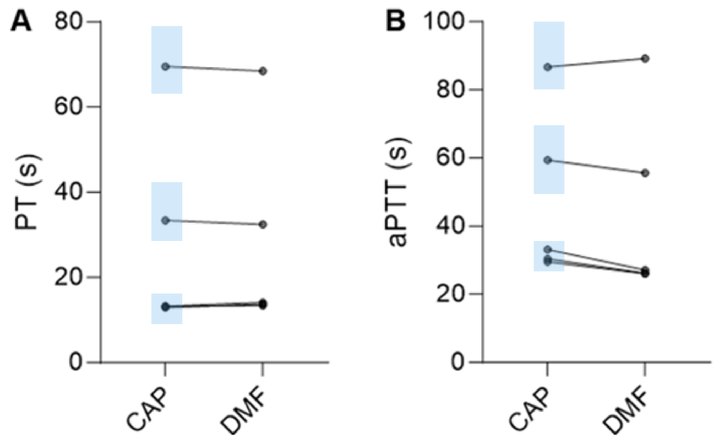

Figure 2. Paired comparison of CAP sample values with DMF values for **(A)** prothrombin time and **(B)** activated partial thromboplastin time. Shaded rectangles represent the minimum and maximum times reported from the comparator method in the CAP survey.

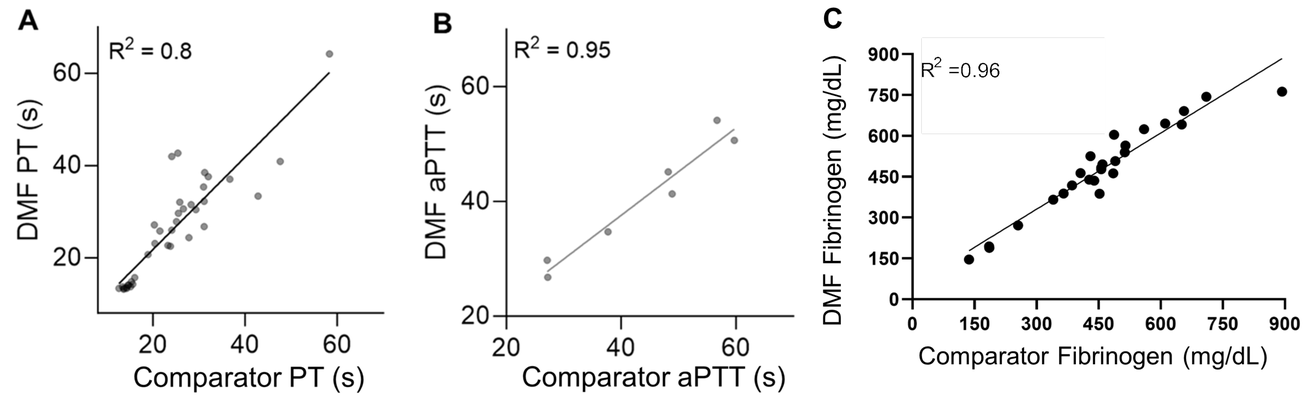

Figure 3. Method comparison studies against FDA-cleared comparators using **A)** contrived plasma for PT (n=37), **B)** contrived plasma for aPTT (n=7), and **C)** CAP and patient plasma samples for fibrinogen (n=26). The DMF PT, aPTT, and fibrinogen assays correlated to the comparator method with R^2 values of 0.80, 0.95, and 0.96, respectively.

CONCLUSIONS

- **PT, aPTT, and fibrinogen results correlated well with comparator testing in plasma samples, and we are currently adapting the assays for use on whole blood samples.**
- **DMF coagulation testing with a rapid turnaround time can aid in guiding hemostatic resuscitation in severe trauma patients.**

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These assays are not available at this time for sale or use in any territory