

Comparison of Quantra™ vs ROTEM Delta and Routine Coagulation Tests in Cardiac Surgery

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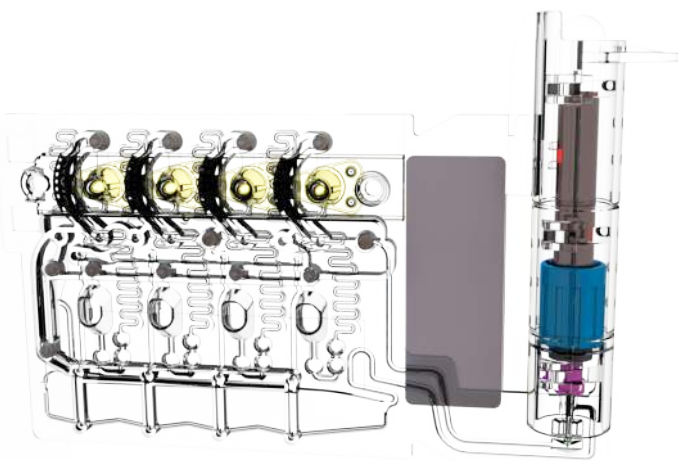
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Background

Coagulation testing is often performed in cardiac surgery and other major procedures to aid in the management of perioperative bleeding. The Quantra™ Hemostasis Analyzer (HemoSonics) is a novel cartridge-based viscoelastic analyzer that measures changes in clot stiffness during coagulation using ultrasound detection of resonance. The Quantra provides results not currently available in other viscoelastic analyzers and can be operated at the point of care (POC). The goal of this pilot study* was to compare, when applicable, results obtained with the Quantra to the ROTEM® delta (TEM International) and lab-based assays in cardiac surgery patients.



Quantra System



Data Acquisition

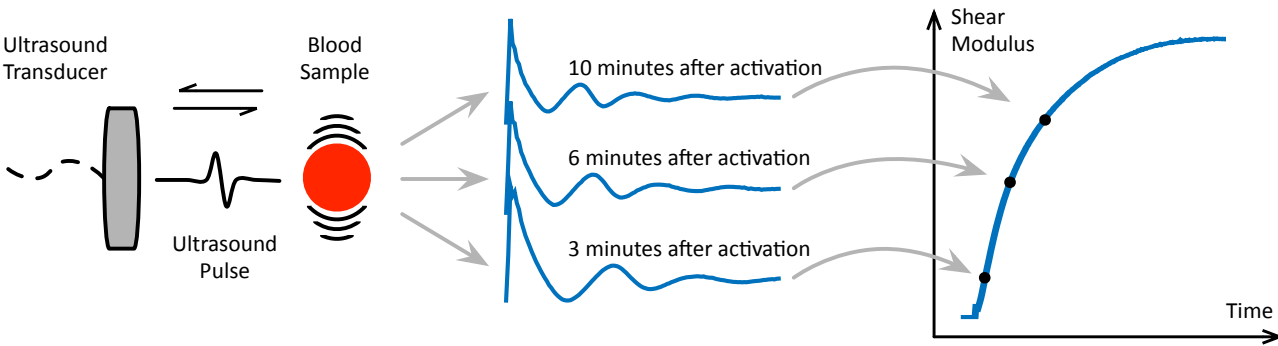
An ultrasound pulse is sent into the blood sample to generate a shear wave, causing the sample to resonate.

Displacement Estimation

As the clot vibrates during resonance, ultrasound "tracking" pulses are used to estimate the sample motion.

Shear Modulus Estimation

The shear modulus of the sample at a specific time point is calculated by analyzing the sample motion pattern.



The Quantra System

The Quantra is a fully automated in vitro diagnostic (IVD) device that performs whole blood coagulation tests. The Quantra sensing mechanism is based on the estimation of shear modulus during clot formation using ultrasound detection of resonance. This patented approach is termed SEER Sonorheometry. Clot time and clot stiffness values are estimated from a curve depicting the dynamic changes of shear modulus vs time.

The Quantra Surgical Cartridge was designed to provide complete information to rapidly assess perioperative bleeding. The cartridge consists of four channels having different lyophilized reagents and which perform four SEER measurements in parallel. Clot times and clot stiffness values obtained from each channel are combined to form six test results that depict the functional status of the patient's coagulation system.

Quantra Surgical Cartridge Test Results

Quantra Test Result	Units	Description
Clot Time (CT)	sec	Clot time measured with kaolin activation
Heparinase Clot Time (CTH)	sec	Clot time measured with kaolin activation and with heparinase I
Clot Stiffness (CS)	hPa	Clot stiffness measured with thromboplastin activation and with polybrene
Fibrinogen Contribution (FCS)	hPa	Clot stiffness measured with thromboplastin activation and with polybrene and abciximab
Platelet Contribution (PCS)	hPa	Calculated from subtracting FCS from CS [Unique to Quantra; not clinically available in other devices]
Clot Time Ratio (CTR)	N/A	Calculated ratio of CT over CTH [Unique to Quantra; not clinically available in other devices]

References

FS Corey et al. Ann of Biomed Eng 2016; 44.5:1405-1424.
EA Ferrante et al. Anesth Analg. 2016;123(6):1372-1379.
JL Huffmyer et al. Anesth Analg. 2016;123(6):1390-1399.
BI Naik et al. Anesth Analg. 2016;123(6):1380-1389.
PS Reynolds et al. Anesth Analg. 2016;123(6):1400-1407.

Disclosure

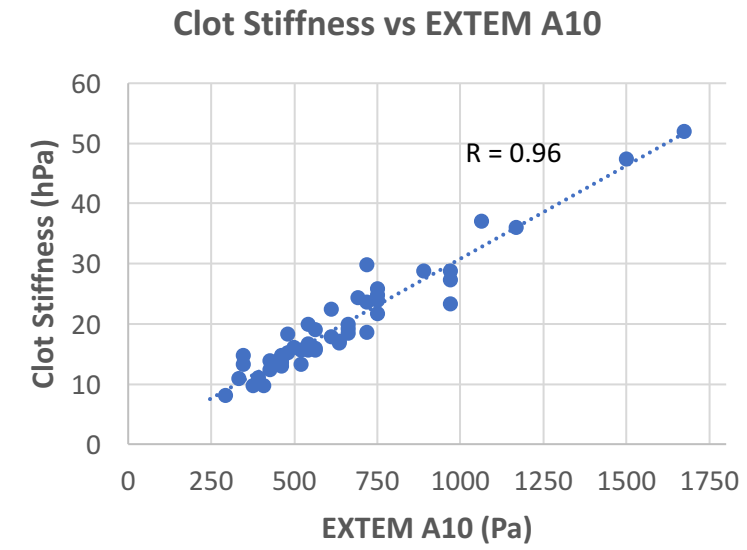
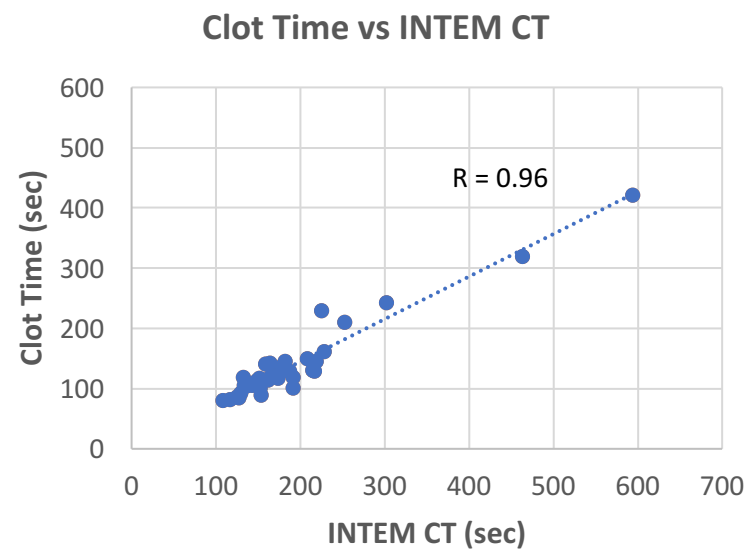
F Viola and DA Winegar have an ownership interest in HemoSonics LLC, a medical device company commercializing the Quantra System.

*clinicaltrials.gov #: NCT02978872

Materials and Methods

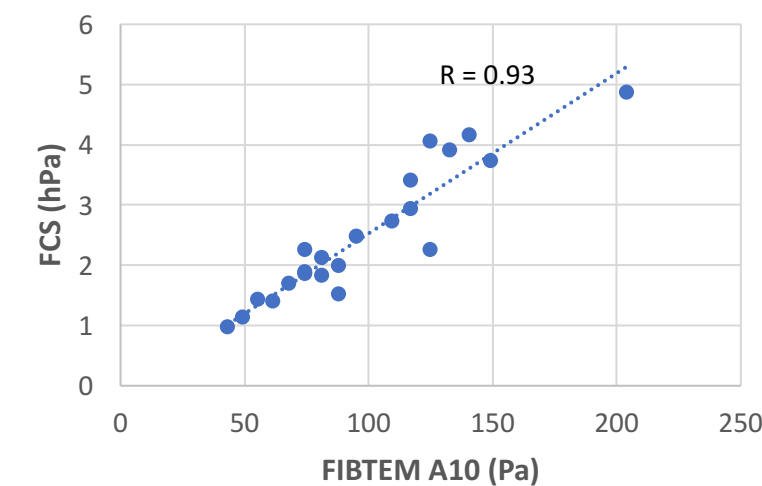
A cohort of 25 patients undergoing elective cardiac surgery with cardiopulmonary bypass were enrolled in this pilot study. The Quantra was operated near patient by the anesthesia staff whereas the ROTEM was placed in the hospital blood bank and operated by trained technicians. For each enrolled patient, citrated whole blood samples were obtained at two of three possible time points: (A) baseline, (B) during cardiac bypass, or (C) after protamine administration. Measurements were performed on a Research Use Only (RUO) version of the Quantra.

Results – Quantra vs ROTEM delta

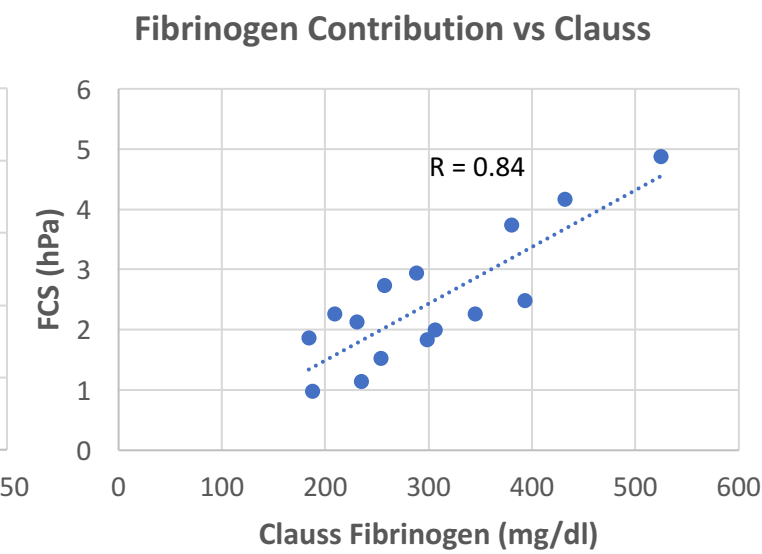
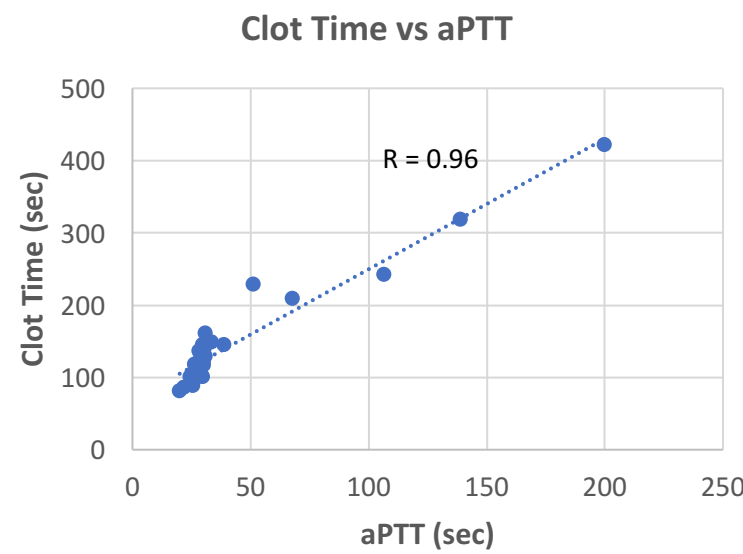


Scatter plots showing correlation between Quantra test results and the corresponding ROTEM assays. EXTEM A10 and FIBTEM A10 parameters were transformed from mm to Pascal using published transformations (T Lang et al. Anesth Analg 2009). PCS is not shown in these figures since a platelet parameter is not clinically available with the ROTEM delta.

Fibrinogen Contribution vs FIBTEM A10

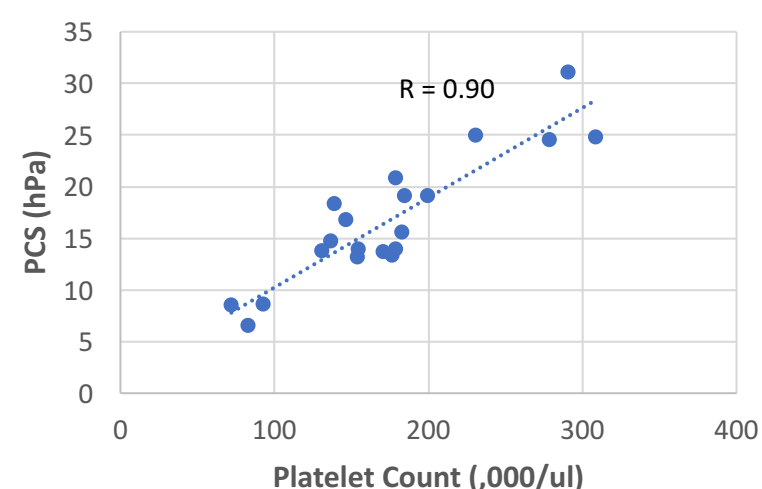


Results – Quantra vs Central Lab Assays



Scatter plots showing correlation between a series of Quantra test results and corresponding central lab coagulation assays.

Platelet Contribution vs Platelet Count



Conclusions

- Results from the Quantra demonstrated strong correlation with viscoelastic device as well as conventional laboratory assessment of coagulation.
- The Quantra was successfully operated at the point of care with no specialized laboratory operator required.
- The Quantra provided complete results within 15 minutes of test initiation.
- The Quantra provided a functional measurement of platelet contribution to clot stiffness (unique to this platform).

