Next generation viscoelastic haemostatic assays and platelets function testing

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ROTEM® sigma
fully-automated thromboelastometry system
ROTEM® *sigma* – Fully automated.

- Fully automated system for the POC area
  - fully automated, no pipetting and test preparation
  - no sample preparation or handling
  - automated functionality checks before every measurement
ROTEM® sigma cartridge 1 (APTEM C, INTEM C, EXTEM C, FIBTEM C)
Scatter plots and linear regression ROTEM® \textit{sigma} vs. ROTEM® \textit{delta}, EXTEM A5, A10, A20, MCF
Scatter plots and linear regression ROTEM® $\sigma$ vs. ROTEM® $\Delta$, FIBTEM A5, A10, A20, MCF
TEG 6s
TEG 5000

- Concentric cylinders, 360uL sample
- Outer cylinder moves, motion of the inner is resisted by a spring
- Clotting increases shear modulus, opposing spring force and resulting in the well-known tracing
- Amplitude increases with clot strength
- Downsides are large sample volume and sensitivity to vibration
TEG 6s the same physical properties measured with resonance frequency technique

- Test cell 20ul
- Different sample geometry
  - Single cylinder (ring); no pin
  - Blood held in place by surface tension
- Different measurement technique
- **Same physical property measured (shear modulus)**
TEG 6s Technology Innovation

**Measurement Technique**
- Resonant Measurement of Viscoelastic hemostasis.
- The TEG 6s measure the same viscoelastic properties as the TEG 5000.
- New measurement technique

**Automatic Sample Preparation**
- Microfluidics cartridge with prepackage reagents.
- Removes user variability, and simplifies operation.
- Up to 4 assays in one cartridge.

**Software**
- Analyzers networked and accessed anywhere within the hospital/institute network allowing for remote access to test results and administration of devices.

**Software**
- TEG Manager
STUDY DESIGN

- **3 sites**
  - Mayo Clinic, Rochester, MN
  - Sinai Hospital, Baltimore, MD
  - University of Pittsburgh Medical Center, Pittsburgh, PA

**Patients Undergoing Open Heart Surgery** (n=264)
- Pre-OP GH (n=98) and PLM (n=99)
- During Procedure/ Post Heparin GH (n=20)
- Post Procedure/ 30 min Post-Protamine GH (n=80) and PLM (n=93)
- ICU GH (n=98) and PLM (n=101)

**Patients Undergoing PCI** (n=36)
- Pre-Procedure GH (n=19) and PLM (n=18)
- Post-Procedure GH (n=18) and PLM (n=18)

**Healthy Volunteers** (n=165)
- Citrate (n=165) PLM (n=165)

- **~5100 tests**

- Inter and Intra-Assay Comparison

- Establish Normal Ranges
Correlation between TEG 5000 vs TEG 6s

**R Parameter**

![R Parameter Graph](image1)

**MA Parameter**

![MA Parameter Graph](image2)

**LY30 Parameter**

![LY30 Parameter Graph](image3)
## Agreement between TEG 5000 and TEG 6s

<table>
<thead>
<tr>
<th></th>
<th>Number of samples</th>
<th>PA (95% CI)</th>
<th>PPA (95% CI)</th>
<th>NPA (95% CI)</th>
<th>TEG 5000 Cut-off</th>
<th>TEG 6s Cut-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADP Aggregation</td>
<td>261</td>
<td>72 (67, 78)</td>
<td>66 (60, 73)</td>
<td>90 (82, 97)</td>
<td>&lt;80</td>
<td>&lt;83</td>
</tr>
<tr>
<td>ADP Inhibition</td>
<td>261</td>
<td>72 (67, 78)</td>
<td>66 (60, 73)</td>
<td>90 (82, 97)</td>
<td>≥20</td>
<td>≥17</td>
</tr>
<tr>
<td>AA Aggregation</td>
<td>267</td>
<td>90 (86, 94)</td>
<td>91 (87, 95)</td>
<td>91 (87, 95)</td>
<td>&lt;80</td>
<td>&lt;89</td>
</tr>
<tr>
<td>AA Inhibition</td>
<td>267</td>
<td>90 (86, 94)</td>
<td>91 (87, 95)</td>
<td>91 (87, 95)</td>
<td>≥20</td>
<td>≥11</td>
</tr>
</tbody>
</table>

CI, confidence interval; NPA, negative percentage agreement; PA, overall percentage agreement; PPA, positive percentage agreement.
HemoSonics' Quantra™ Platform
HemoSonics' Quantra™ Platform

POC instrument using novel SEER ultrasound technology to measure hemostasis

- Tabletop instrument designed for POC
- Uses self-contained cartridges for ease of use
- Rapid results
- Comprehensive hemostasis measurement
- Vibration resistant

For research or investigational use only. Not for use in diagnostic procedures. The performance characteristics of this product have not been established. This device has not been cleared or approved for use by the U.S. FDA or other regulatory authorities.
• A strong ultrasound pulse causes the sample to vibrate.
• This vibration is measured by ultrasound.
• Clot stiffness is determined from vibration characteristics.
Four Channel Cartridge Provides Comprehensive and Actionable Information

**Clot Formation**

1. **Clot Time**
   Activation of coagulation

2. **Heparinase Clot Time**
   Activation of coagulation with heparin neutralizer

Channels 1 and 2 assess ability of coagulation system to initiate clot formation with and without a heparin neutralizer.

**Clot Stiffness**

3. **Overall Clot Stiffness**
   Strong activation of coagulation

4. **Fibrinogen Contribution to Clot Stiffness**
   Strong activation of coagulation with platelet inhibition

Channels 3 and 4 measure overall clot stiffness and the contribution of fibrinogen platelet to clot stiffness.
Quantra Data

*The Quantra can measure the functional role of various components of the coagulation system*

**Quantra Time to Clot Against Varying LMWH Concentrations**

**Quantra Clot Stiffness Against Varying Reopro Concentrations**

**Quantra Fibrinogen Correlation with Clauss Fibrinogen (Stago STart4)**

R values between 0.98 and 0.99
Ongoing External Clinical Studies & Publications

Clinical Studies of the Quantra platform are underway at multiple sites:

- University of Virginia Cardiac Surgery
- University of Virginia Spine Surgery
- Virginia Commonwealth University Cardiac Surgery

Abstracts were presented recently at:

**International Society on Thrombosis and Haemostasis (ISTH)**
- Development and Validation of An Assay for Intra-Surgical (or Peri-Operative) Management of Bleeding
- Assessment of a Test for Functional Fibrinogen in Whole Blood Using Ultrasound Technology Compared to Clauss Fibrinogen in Plasma

**American Association for Clinical Chemistry (AACC)**
- Development of A Novel Device to Assess Hemostatic Function from Whole Blood
Thank you!!

"Pull out Betty! Pull out!!......You´ve hit an ARTERY"