

Functional stability of the TEG 6s hemostasis analyzer under stress

Michael Adam Meledeo, PhD, Grantham C. Peltier, MS, Colby S. McIntosh, Chet R. Voelker, James A. Bynum, PhD, and Andrew P. Cap, MD, PhD, Fort Sam Houston, Texas

BACKGROUND:	Viscoelastic measurements of coagulation provide much needed information, including guidance for triage and insight into bleeding disorders. The current clinical standards for these devices are the thromboelastogram (TEG) 5000 and the rotational thromboelastometer (ROTEM) delta, but a new product, the TEG 6s, has recently come to market, designed to simplify the user experience, reduce the required blood volume, and conduct multiple assays simultaneously. This study compares the performance of these three devices and examines the resiliency of the TEG 6s under various stresses.
METHODS:	The variances of coagulation metrics obtained by the TEG 6s (prototype and production models), TEG 5000, and ROTEM delta were compared using manufacturers' reagents and citrate-collected blood from healthy donors. Variability between devices was examined, and their performances under various motion and temperature stresses were compared by placing one unit on a linear or orbital shaker, in the cold, or in the heat while a counterpart remained stationary at room temperature.
RESULTS:	Although most comparable parameters had low degrees of variance, there were small but significantly increased variances found in some ROTEM delta and TEG 5000 parameters versus comparable TEG 6s parameters. Orbital rotation of the TEG 6s had no effect on means of any parameter but resulted in increased variance of 2 parameters, but linear motion with sudden striking had no observed impact on results. Similarly, 7-day exposure to heat (45°C) or cold (4°C) only resulted in minor deviations within normal ranges of the TEG 6s.
DISCUSSION:	The TEG 6s provides several improvements over other coagulation analyzers: it is easier to use and robustly resilient against motion and temperature stresses. These features suggest that it may be capable of deployment not only in the clinical laboratory but also to a variety of austere settings. (<i>J Trauma Acute Care Surg.</i> 2018;84: S83–S88. Copyright © 2018 Wolters Kluwer Health, Inc. All rights reserved.)
LEVEL OF EVIDENCE:	Diagnostic test, level III.
KEY WORDS:	Thromboelastography; motion artifact; temperature sensitivity.

Because hemorrhage remains a leading cause of preventable death, and optimization of resuscitation strategies is critical to reducing morbidity and mortality in trauma and hemorrhage,^{1,2} new techniques and assays continue to be a focus for triage and diagnosis in bleeding disorders. Whereas the clinical standard of care for identifying coagulopathies has been prothrombin time,³ more recently, clinical assays that are capable of describing many different clot parameters have emerged. Viscoelastic assays like thromboelastography (TEG) and rotational thromboelastometry (ROTEM) have proven to be more informative, allowing for a variety of therapeutic options to be considered.⁴

The rapid assessment of multiple parameters provides guidance to transfusion requirements in traumatic or surgical hemorrhage. Because of the technical nature of operation, the reagent requirements, and the sensitivity to motion-induced artifacts,⁵ usage of currently available models of these devices in the United States (namely, Haemonetics' TEG 5000 and Instrumentation Laboratory's ROTEM delta) is typically restricted to (and effectively used in) operating theaters and clinical laboratories,^{6,7} although at least one study has shown the feasibility of using the ROTEM delta in the austere conditions of a Norwegian naval vessel at sea.⁸ Expanding the availability of this type of technology represents a potential next step in patient transfusion management even in a myriad of technologically hostile environments, from accidents in the most rural locales to the wounded on battlefields.

The TEG 5000 operates by the principle of rotating a cup containing the blood sample over a small arc (4.75 degrees) at a consistent oscillating rate. As a clot forms within this cup, the pin inserted into the sample begins to oscillate as well with the torque increasing as clot strength increases. This torque is transduced into the TEG signal via a torsion spring affixed to the top of the pin. The ROTEM delta operates by a similar but reversed principle: blood in a cup (stationary) forms a clot, and the pin inserted into the cup oscillates over a small arc (also 4.75 degrees). As the clot forms, this rotation is impeded, increasing torque and obstructing movement of a small mirror at the top of the rotating vertical axis. This is transduced into the ROTEM delta signal by

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From the United States Army Institute of Surgical Research (M.A.M., G.C.P., C.S.M., C.R.V., J.A.B., A.P.C.), Joint Base San Antonio, Fort Sam Houston, Texas.

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Address for reprints: Michael Adam Meledeo, PhD, United States Army Institute of Surgical Research, 3650 Chambers Pass, Bldg 3610, Joint Base San Antonio, Fort Sam Houston, TX 78234; email: michael.a.meledeo.civ@mail.mil.

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light-emitting diode directed to the mirror, which then reflects to a sensor. Software on both devices converts these transduced signals into the coagulation curves and calculated parameters, which are displayed on their respective monitors.

Whereas these viscoelastic analyzers have been described as point-of-care instruments for humans and other animals,^{4,7,9,10} Haemonetics has developed a new coagulation analyzer, the TEG 6s, which seeks to improve upon the TEG 5000 by reducing sample volume, eliminating the need for a separate computer, and incorporating four assays' reagents into a single cartridge (which also reduces the introduction of operator errors).^{11,12} The functional principle of the TEG 6s has been described in detail elsewhere,¹² but in brief, a blood sample in the TEG 6s is directed through microfluidics channels into a chamber, forming a meniscus, which oscillates vertically at a frequency between 20 and 500 Hz, and the motion of the sample is detected as it blocks a beam of light through these vibrations. Fast Fourier transform calculations are used to identify resonant frequencies in the sample, which increase during clot formation, and these calculations are used to produce the TEG curves for visualization on the monitor.

However, a recent study demonstrated that an early production model in Australia experienced artifacts under a motion stress.¹³ Because resistance to motion-induced artifacts is a key requirement for operation aboard emergency transport (ambulance, helicopter, ship, or airplane) or in certain austere environments, this current research sought to evaluate the response of the most recently manufactured TEG 6s models to determine if these measurement artifacts had been remedied. The effects of temperature challenges were also examined. In addition, this study compared the performance of the TEG 6s with that of the aforementioned viscoelastic hemostasis analyzers (TEG 5000 and ROTEM delta).

PATIENTS AND METHODS

Donor Blood

Fresh blood was collected in citrate vacutainers from healthy donors according to an approved institutional standard operating procedure at the US Army Institute of Surgical Research Blood Bank. Three separate donors were collected on three different days for initial comparison studies. Two vacutainer tubes were collected from each donor and allowed to rest on a rocker for a period of 15 minutes before initial tests.

TEG 6s Units

Four TEG 6s units were provided by Haemonetics (Braintree, MA). Two of these were preproduction prototype units, and 2 were full production models intended for commercial sale (although labeled "research use only"). In addition, cartridges produced for use with citrate anticoagulated blood containing reagents for the following four tests were provided: (1) kaolin, (2) RapidTEG (kaolin and tissue factor), (3) kaolin with heparinase, and (4) functional fibrinogen (FF). Because no heparin was used in collection and no donor was on heparin therapy, the results of assay (3) were generally ignored, as they provided no additional information over the kaolin-only test (1)—results between (1) and (3) were not statistically different. The cartridge requires approximately 300 μ L of blood to run all four tests simultaneously.

Comparisons Against Viscoelastometers

With the TEG 5000 (Haemonetics), standard kaolin and RapidTEG assays were performed, whereas in the ROTEM delta (Instrumentation Laboratory, Bedford, MA), the EXTEM, INTEM, and FIBTEM assays were conducted. All were performed using manufacturer's specifications, each test requiring 300 μ L of blood for an individual test and specific reagents (including calcium to counteract the citrate). Although the reagent compositions are not identical, the various tests on TEG and ROTEM are designed to evoke similar responses through activation of different coagulation pathways. On the ROTEM, the EXTEM assay consists of tissue factor and phospholipid activation, similar to RapidTEG (which additionally contains kaolin, a contact activator); the primary differences between EXTEM and RapidTEG are found in expected range of clot initiation times. In addition, the ROTEM's INTEM test is comparable with the kaolin assay of the TEG, as both assays activate coagulation through contact activation pathways. The ROTEM's FIBTEM assay is also similar to the TEG 6s FF test, as both use inhibitors of platelet function to examine the plasma fibrinogen contribution to clot formation. The distinction between these assays is found in the inhibitor used: cytochalasin D in the FIBTEM and ReoPro (abciximab) in the TEG FF. Both FIBTEM and TEG FF use tissue factor activation of coagulation, although the TEG adds kaolin as well, leading to a more rapid initiation of clot time.

Because of the differences in absolute values produced in the different devices and their tests,¹⁴ variances in outcomes were selected for comparison between TEG 6s, TEG 5000, and ROTEM delta instead. One donor blood sample tube was tested immediately after the 15-minute resting period on a rocker, and a second tube was tested (only on the TEG 6s) after an additional hour of resting to determine what effects, if any, would result from delayed sample testing.

Stress Testing

Performance of the coagulation analyzers under stress was evaluated with several challenge conditions. First, a TEG 6s, TEG 5000, or ROTEM delta unit was placed on a MaxQ 2508 orbital shaker (ThermoFisher Scientific, Waltham, MA) at high velocity (246 rpm). Second, a unit was placed on a PF 15i linear motion platelet shaker (at a rate of 72 cycles/min; Helmer Scientific, Noblesville, IN). Third, units were struck with nondamaging force during a run to observe if artifacts appeared. Finally, only using the TEG 6s, a device was placed in a low humidity refrigerated room (4°C) whereas another was placed in a low humidity heated incubator (45°C), each for 1 week; after this, samples were run immediately and then again after the units were allowed to return to room temperature 21°C to 22°C over a period of 2 hours. In all of these scenarios, results were compared with a stationary room temperature-maintained TEG 6s, TEG 5000, or ROTEM delta unit using identical blood samples.

Statistical Analysis

Data collection, aggregation, and statistical analyses were performed in Microsoft Excel 2010 and GraphPad PRISM 7.01. Repeated measures one-way analysis of variance tests were performed to determine intergroup differences against the null hypothesis for studies comparing ROTEM delta, TEG 5000, TEG 6s, TEG 6s on orbital shaker, and TEG 6s with blood

sample held for one additional hour. The *F* test of equal variances was used to determine differences in the variances of individual parameters on each platform, and, as described above, this measurement was used as the ultimate comparison between parameters on different devices. Absolute values of parameters were only used when comparing TEG 6s results under different stress conditions. Because of limited supply of TEG 6s cartridges, samples tested with the linear motion platelet shaker and in extreme temperatures were only conducted once each and compared with the normal ranges obtained in prior studies.

RESULTS

Device/Assay Variance Comparisons

Differences between comparable coagulation parameters of the different platforms indicated that there were only small differences in variance for most. Although two of each type of unit were used for these tests, no intraunit variability was observed for the duplicated devices of each type (ie, both ROTEM units gave equivalent results etc), and thus, these duplicate devices' results were grouped together for data analysis.

Comparisons of TEG 5000, TEG 6s, and ROTEM delta were made by examining the outcomes of assays that use similar modalities: kaolin versus INTEM, RapidTEG versus EXTEM, and FF versus FIBTEM (Table 1). However, using the absolute values of these raw data as the comparison did not give insight into performance distinctions because each test has different reference ranges. Thus, coefficients of variance were used as comparators. Although most parameters had low and equivalent variances, there were some that showed a higher degree of variability.

In kaolin/INTEM tests, variability of the equivalent reaction time (R) and clotting time (CT) parameters in TEG 5000 (15.54%) and ROTEM delta (17.11%) both showed greater variability than the TEG 6s (4.88%). The α angle, a

measure of rate of clotting, was also more highly variable in the ROTEM delta (8.25%) versus the TEG 6s (2.24%).

For RapidTEG/EXTEM comparisons, the ROTEM delta had greater variability in the CT (16.97%) and maximum clot firmness (MCF, 4.01%) parameters versus TEG 6s R (11.13%) and maximum amplitude (MA, 1.50%) values, respectively. The degree of lysis at 30 minutes was not measurable in the ROTEM delta (0.00%), and as such had much lower variance than TEG 6s or TEG 5000 measurements of lysis.

With the FF/FIBTEM assays, the TEG 6s production models had no variability in R parameters (0.00%), although the prototype did show some variability (14.92%). The TEG 5000 and ROTEM delta both had a higher degree of variance (7.04% and 11.05%, respectively) for R/CT. The TEG 6s and TEG 5000 showed no demonstrable degree of lysis, whereas a small lysis measurement was observed in the ROTEM delta, resulting in a greater degree of variance (131.90% vs 0.00% for all TEGs).

Stress Challenges

When blood samples were allowed to rest for an additional hour after the initial TEG 6s testing, no statistically significant differences were observed in any parameter (Table 2). However, the delayed sample had a larger coefficient of variance in the kaolin test R time and the RapidTEG MA.

When the TEG 6s was subjected to high motion/vibration produced by an orbital rotator, no parameters were significantly changed when compared with a stationary unit running simultaneously. Samples ran to completion, producing TEG curves that appeared normal. However, some increases in coefficient of variance were observed in comparison to the stationary TEG 6s (Table 2), specifically the kaolin R time and RapidTEG MA. Attempts were made to evaluate the TEG 5000 and ROTEM delta performances on the orbital rotator, but neither was capable of functioning under this condition. The TEG 5000 reported an out-of-range error (attributed to misloaded disposables),

TABLE 1. Variance Comparisons between Devices Using Normal Blood Samples

		TEG 6s (Production)	TEG 6s (Prototype)	TEG 5000	ROTEM Delta
Kaolin or INTEM	R/CT, min	6.43 ± 0.31 (4.88%)	6.45 ± 0.77 (11.96%)	7.07 ± 1.10 (15.54%)*	3.71 ± 0.63 (17.11%)*
	K/CFT, min	1.57 ± 0.12 (7.73%)	1.62 ± 0.21 (13.22%)	2.25 ± 0.19 (8.31%)	1.85 ± 0.55 (29.57%)*
	MA/MCF, mm	57.47 ± 2.18 (2.43%)	57.57 ± 1.40 (3.80%)	62.18 ± 2.41 (3.87%)	57.17 ± 1.47 (2.57%)
	α , degree	69.6 ± 1.56 (2.24%)	70.05 ± 2.37 (3.39%)	58.17 ± 2.66 (4.57%)	68.5 ± 5.65 (8.25%)*
	LY30/LI30, %	0.77 ± 0.60 (77.68%)	0.72 ± 0.40 (55.41%)	0.12 ± 0.18 (157.27%)	0.33 ± 0.52 (154.92%)
RapidTEG or EXTEM	R/CT, min	0.73 ± 0.08 (11.13%)	0.72 ± 0.08 (10.50%)	0.85 ± 0.05 (6.44%)	1.34 ± 0.23 (16.97%)*
	K/CFT, min	1.95 ± 0.08 (4.29%)	2.07 ± 0.10 (5.00%)	1.62 ± 0.10 (6.08%)	1.74 ± 0.16 (8.92%)
	MA/MCF, mm	58.55 ± 0.88 (1.50%)	58.18 ± 1.54 (2.64%)	64.60 ± 1.48 (2.30%)	59.83 ± 2.40 (4.01%)*
	α , degree	66.03 ± 0.95 (1.44%)	65.53 ± 0.62 (0.95%)	71.32 ± 0.89 (1.25%)	69.00 ± 1.79 (2.59%)
	LY30/LI30, %	0.52 ± 0.37 (71.81%)	0.40 ± 0.32 (80.62%)	0.38 ± 0.29 (74.55%)	0.00 ± 0.00 (0.00%)**
FF or FIBTEM	R/CT, min	0.70 ± 0.00 (0.00%)	0.78 ± 0.12 (14.92%)*	0.73 ± 0.05 (7.04%)*	1.26 ± 0.14 (11.05%)*
	MA/MCF, mm	16.25 ± 1.62 (9.96%)	16.90 ± 1.18 (6.97%)	16.83 ± 1.17 (6.95%)	11.33 ± 1.03 (9.11%)
	α , degree	55.53 ± 2.53 (4.56%)	52.40 ± 3.79 (7.23%)	54.92 ± 2.12 (3.86%)	58.00 ± 4.24 (7.31%)
	LY30/LI30, %	0.00 ± 0.00 (0.00%)	0.00 ± 0.00 (0.00%)	0.00 ± 0.00 (0.00%)	2.17 ± 2.86 (131.90%)*

*Higher variances.

**Lower variances.

Data are means ± standard deviations coefficients of variance in parentheses from n = 3 samples run side-by-side on duplicate devices and averaged before statistical analysis. Significant (*p* < 0.05 by *F* test for equal variances) higher or lower variances versus same/similar parameter in the TEG 6s production model are indicated. Kaolin, RapidTEG, and FF tests were conducted in TEG 6s and TEG 5000, whereas INTEM, EXTEM, and FIBTEM were used in the ROTEM delta. K, kinetics value; CFT, clot formation time; LY30, lysis after 30 min; LI30, lysis index after 30 min.

TABLE 2. Impact of Delayed Sample Analysis and Motion Stress on TEG 6s Performance

		TEG 6s (Production)	TEG 6s (Sample Delay)	TEG 6s (Motion)
Kaolin	R, min	6.43 ± 0.31 (4.88%)	6.08 ± 0.90 (14.75%)*	6.33 ± 0.94 (14.80%)*
	K, min	1.57 ± 0.12 (7.73%)	1.65 ± 0.21 (12.57%)	1.67 ± 0.15 (9.03%)
	MA, mm	57.47 ± 2.18 (2.43%)	55.7 ± 3.27 (5.87%)	55.58 ± 2.67 (4.79%)
	α, degree	69.6 ± 1.56 (2.24%)	70.57 ± 2.44 (3.46%)	69.68 ± 2.20 (3.16%)
	LY30, %	0.77 ± 0.60 (77.68%)	0.78 ± 0.65 (82.90%)	0.87 ± 0.74 (85.93%)
RapidTEG	R, min	0.73 ± 0.08 (11.13%)	0.68 ± 0.08 (11.02%)	0.72 ± 0.04 (5.70%)
	K, min	1.95 ± 0.08 (4.29%)	2.12 ± 0.16 (7.57%)	2.07 ± 0.15 (7.28%)
	MA, mm	58.55 ± 0.88 (1.50%)	55.92 ± 3.05 (5.45%)*	56.00 ± 2.50 (4.47%)*
	α, degree	66.03 ± 0.95 (1.44%)	65.38 ± 1.36 (2.07%)	66.13 ± 0.61 (0.92%)
	LY30, %	0.52 ± 0.37 (71.81%)	0.43 ± 0.34 (78.14%)	0.55 ± 0.48 (88.14%)
FF	R, min	0.70 ± 0.00 (0.00%)	0.70 ± 0.00 (0.00%)	0.70 ± 0.00 (0.00%)
	MA, mm	16.25 ± 1.62 (9.96%)	16.42 ± 1.46 (8.87%)	16.43 ± 1.47 (8.97%)
	α, degree	55.53 ± 2.53 (4.56%)	55.02 ± 1.23 (2.24%)	54.95 ± 1.12 (2.03%)
	LY30, %	0.00 ± 0.00 (0.00%)	0.00 ± 0.00 (0.00%)	0.00 ± 0.00 (0.00%)

**p* < 0.05 by *F* test for equal variances.

Means and standard deviations are shown. No significant differences in means were measured, but increased coefficients of variance were seen in select parameters.

and the ROTEM delta warning indicator came on, giving no viscoelastic curve. In a second test, the ROTEM delta service module was used to observe that oscillation of the axis was greatly disturbed by the motion (see Supplemental Digital Content 1–3, <http://links.lww.com/TA/B73>, <http://links.lww.com/TA/B74>, and <http://links.lww.com/TA/B75>, for photos and videos illustrating TEG 5000 and ROTEM delta failure under motion stress).

In limited tests, a TEG 6s unit was also placed on a horizontal platelet shaker (in both parallel- and perpendicular-facing configurations, separately), and the results of these tests also aligned with stationary sample evaluation (Table 3; see Supplemental Digital Content 4 for outcome screenshots, <http://links.lww.com/TA/B76>). During one of these tests, the TEG 6s unit was stricken by hand two times to observe if a sudden jarring motion would cause any artifacts to develop in the curve; none were seen (see video in Supplemental Digital Content 5, <http://links.lww.com/TA/B77>). Striking tests against the TEG 5000 resulted in drastic artifacts, whereas the ROTEM was more resilient to this type of assault, producing only minor deviations in the curve, which apparently did not affect any parameters (see Supplemental Digital Contents 6–8, <http://links.lww.com/TA/B78>, <http://links.lww.com/TA/B79>, and <http://links.lww.com/TA/B80>).

The temperature stress testing showed that placing one TEG 6s unit in the cold (4°C) or in the heat (45°C) for a week had no impact on a blood sample tested; all results collected immediately before temperature exposure, immediately after 7-day exposure, or after a 2-hour room temperature recovery period were within the previously observed normal ranges (Table 4). Only minor deviations were observed in R time of RapidTEG and FF tests, and these were contained to the day 0 (pretemperature exposure) samples and were within normal ranges.

DISCUSSION

The three devices compared in this study, TEG 6s, TEG 5000, and ROTEM delta, do not have directly comparable results for many parameters. All three devices were comparable

in their repeatability in most functional outcomes (as determined by comparing coefficients of variance for similar test results), although a few exceptions were noted.

There are several benefits unique to the TEG 6s, not the least of which is its simplified operation. The operator of a TEG 6s is required to sample blood from a citrate tube with a disposable transfer pipette (provided in the cartridges' box) and eject blood into a loaded cartridge until the volume reaches the indicator line. Identifying information is entered through a touch screen on the unit, and resultant data can be viewed directly on the screen, exported, or directly printed on thermal paper. In comparison, both the TEG 5000 and ROTEM delta require precise loading of pin and cup combinations (poorly seated cups

TABLE 3. Stress Testing of TEG 6s on Linear Motion Shaker

		TEG 6s (Production)	TEG 6s (Parallel)	TEG 6s (Perpendicular)
Kaolin	R, min	7.2	7.1	6.7
	K, min	1.5	1.6	1.7
	Angle, degree	71.1	70.7	69.4
	MA, mm	55.5	55.0	54.2
	LY30, %	1.1	0.6	0.1
RapidTEG	R, min	0.7	0.7	0.7
	K, min	1.8	1.7	2.1
	Angle, degree	70.3	70.4	68.6
	MA, mm	57.8	57.3	54.3
	LY30, %	0.6	0.5	0.1
FF	R, min	0.7	0.6	0.7
	Angle, degree	61.6	62.7	63.2
	MA, mm	16.5	16.7	17.6
	LY30, %	0.0	0.0	0.0

Results from the TEG 6s on the linear shaker oriented parallel or perpendicular to the direction of motion were compared with a stationary unit using the same blood sample. During the perpendicular test, the unit was stricken by hand twice consecutively to observe if a sudden violent motion would cause any artifacts to develop in the curve (see video in Supplemental Digital Content 5).

TABLE 4. Temperature Stress Testing of TEG 6s

		Day 0			Day 7			Day 7 + 2 h		
		22°C	4°C	45°C	22°C	4°C	45°C	22°C	4°C	45°C
Kaolin	R, min	7.2	7.2	6.7	6.5	6.2	5.7	6.2	6.4	6.2
	K, min	6.2	6.4	6.2	1.4	1.5	1.5	1.5	1.6	1.4
	Angle, degree	71.6	72.8	74.0	72.7	70.7	70.7	71.7	69.1	72.6
	MA, mm	60.6	61.7	59.7	57.8	56.6	57.2	56.7	57.2	56.4
	LY30, %	1.3	0.6	1.4	0.7	0.7	1.0	0.4	0.4	0.8
RapidTEG	R, min	0.5	0.9	0.2	0.7	0.7	0.5	0.7	0.7	0.7
	K, min	1.3	1.3	1.1	1.8	1.7	1.6	1.6	1.6	1.6
	Angle, degree	75.0	74.1	76.6	68.7	70.5	71.1	71.0	71.2	70.2
	MA, mm	62.8	63.4	63.4	59.3	58.4	59.7	59.2	59.2	58.5
	LY30, %	0.4	0.1	0.5	0.1	0.4	0.3	0.1	0.4	0.3
FF	R, min	0.4	0.7	0.2	0.6	0.7	0.4	0.6	0.6	0.6
	Angle, degree	72.0	72.4	72.9	62.7	63.4	64.2	62.1	65.9	61.9
	MA, mm	20.7	21.0	21.8	17.5	16.8	17.9	17.1	18.1	17.4
	LY30, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

No significant impact on results was observed when collected immediately before temperature exposure, immediately after 7-day exposure, or after 7-day exposure with a 2-hour room temperature recovery period. Only minor deviations within normal ranges were observed in R time of RapidTEG and FF tests.

will give aberrant results), use of a micropipetter to accurately load activating reagent and blood volume (although the ROTEM delta has streamlined this process through the addition of an automatic pipette), and handling of moving parts to set the loaded sample into the test configuration. The TEG 5000 also requires an external computer to enter patient identifiers and record data. Because test configuration, reagent loading, and computer operation have been eliminated with the TEG 6s, a user is able to obtain results with very little training and very little handling during clinical trauma management. In addition, only 300 μ L of blood are required to run all four tests in the TEG 6s versus the same volume required to run a single test in the other two devices, making it particularly appealing in cases where sample collection is limited (eg, pediatrics cases).

Tem Innovations GmbH is in the process of manufacturing a new device (ROTEM sigma) that seeks to provide fully automated point-of-care features.¹⁵ This device is not yet available in the United States and was unavailable for these tests. The trade-off between the TEG 6s and the ROTEM sigma is that the TEG 6s uses only a small volume of blood but requires use of a transfer pipette to load the sample, whereas the ROTEM sigma requires the user to load a full blood tube into the machine but needs no pipetting.

The stability of the TEG 6s units under moderate velocity oscillation indicates that they may be more useful in transportation, including aboard ambulances, ships, and even aircraft. This feature is of greatest import when considering deployment of coagulation analyzers into austere environments such as combat support hospitals. Temperature resiliency is also significant, although the limited tests performed here may not accurately reflect the long term functionality of the TEG 6s when exposed to consistently high or low temperatures.

Further evaluation will be required to determine the ramifications of long-term exposure to these various stresses on unit performance. However, the TEG 6s has shown over the intermediate term that it can perform while under rapid

oscillation, shaking, and vibration, even withstanding a sudden violent strike, and temperature exposures of 4°C and 45°C for a week did not impact performance in limited testing. Although a previous study showed measurement artifacts when the TEG 6s was subjected to motion,¹³ the software and hardware updates that Haemonetics has made appear to have corrected these issues.

AUTHORSHIP

M.A.M. designed the study, collected, analyzed, and interpreted data, and wrote the article. G.C.P. collected, analyzed, and interpreted data. C.S.M. collected and analyzed data. C.R.V. collected data. J.A.B. interpreted data and provided a critical revision of the article. A.P.C. designed the study, interpreted data, and provided a critical revision of the article.

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DISCLOSURE

The authors declare no conflicts of interest.

REFERENCES

- Eastridge BJ, Mabry RL, Seguin P, Cantrell J, Tops T, Uribe P, Mallett O, Zubko T, Oetjen-Gerdes L, Rasmussen TE, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg.* 2012;73(6 Suppl 5):S431–S437.
- Bellamy RF. The causes of death in conventional land warfare: implications for combat casualty care research. *Mil Med.* 1984;149(2):55–62.
- Brohi K, Cohen MJ, Davenport RA. Acute coagulopathy of trauma: mechanism, identification and effect. *Curr Opin Crit Care.* 2007;13(6): 680–685.
- da Luz LT, Nascimento B, Rizoli S. Thrombelastography (TEG®): practical considerations on its clinical use in trauma resuscitation. *Scand J Trauma Resusc Emerg Med.* 2013;21:29.
- Karon BS. Why is everyone so excited about thromboelastography (TEG)? *Clin Chim Acta.* 2014;436:143–148.

6. Whiting D, DiNardo JA. TEG and ROTEM: technology and clinical applications. *Am J Hematol*. 2014;89(2):228–232.
7. Whiting P, Al M, Westwood M, Ramos IC, Ryder S, Armstrong N, Misso K, Ross J, Severens J, Kleijnen J. Viscoelastic point-of-care testing to assist with the diagnosis, management and monitoring of haemostasis: a systematic review and cost-effectiveness analysis. *Health Technol Assess*. 2015; 19(58):1–228. v-vi.
8. Strandenes G, Austlid I, Apelseh TO, Hervig TA, Sommerfelt-Pettersen J, Herzig MC, Cap AP, Pidcoke HF, Kristoffersen EK. Coagulation function of stored whole blood is preserved for 14 days in austere conditions: a ROTEM feasibility study during a Norwegian antipiracy mission and comparison to equal ratio reconstituted blood. *J Trauma Acute Care Surg*. 2015; 78(6 Suppl 1):S31–S38.
9. McMichael MA, Smith SA. Viscoelastic coagulation testing: technology, applications, and limitations. *Vet Clin Pathol*. 2011;40(2):140–153.
10. Hyatt CE, Brainard BM. Point of care assessment of coagulation. *Top Companion Anim Med*. 2016;31(1):11–17.
11. Gurbel PA, Bliden KP, Tantry US, Monroe AL, Muresan AA, Brunner NE, Lopez-Espina CG, Delmenico PR, Cohen E, Raviv G, et al. First report of the point-of-care TEG: a technical validation study of the TEG-6S system. *Platelets*. 2016;27(7):642–649.
12. Dias JD, Haney EI, Mathew BA, Lopez-Espina CG, Orr AW, Popovsky MA. New-generation thromboelastography: comprehensive evaluation of citrated and heparinized blood sample storage effect on clot-forming variables. *Arch Pathol Lab Med*. 2017;141(4):569–577.
13. Gill M. The TEG®6s on shaky ground? A novel assessment of the TEG®6s performance under a challenging condition. *J Extra Corpor Technol*. 2017; 49(1):26–29.
14. Sankarankutty A, Nascimento B, Teodoro da Luz L, Rizoli S. TEG® and ROTEM® in trauma: similar test but different results? *World J Emerg Surg*. 2012;7(Suppl 1):S3.
15. Tem International GmbH. ROTEM(r) sigma: Combining Innovation with Experience. Available at: <https://rotem.de/en/products/rotem-sigma/>. Accessed November 7, 2017.