Results of ECAT EQA programme on ROTEM and TEG

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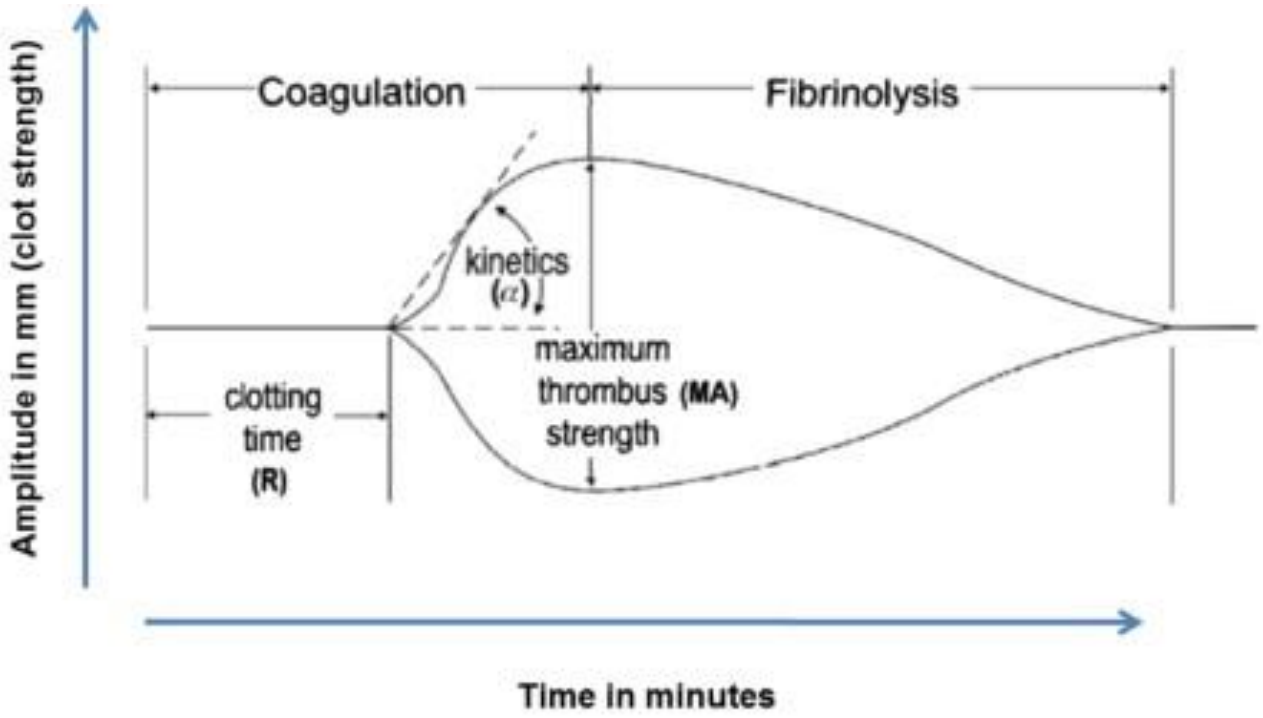
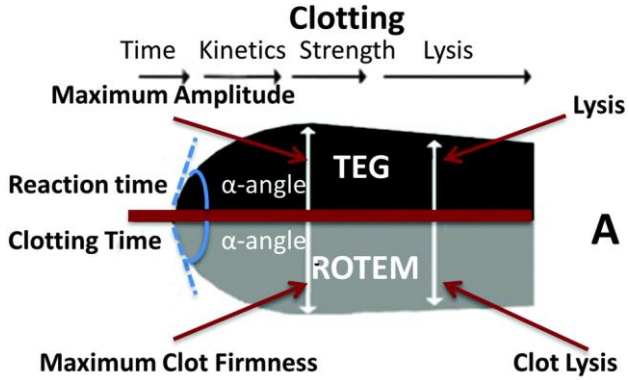
ROTEM

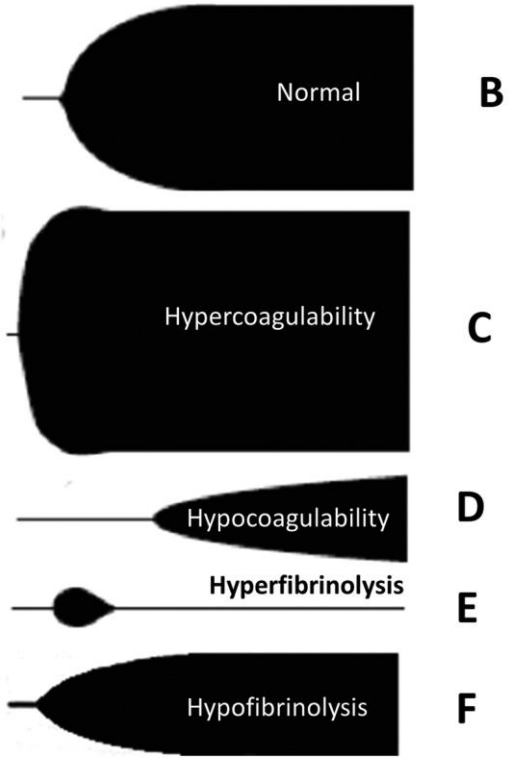
CLOTSCANNER

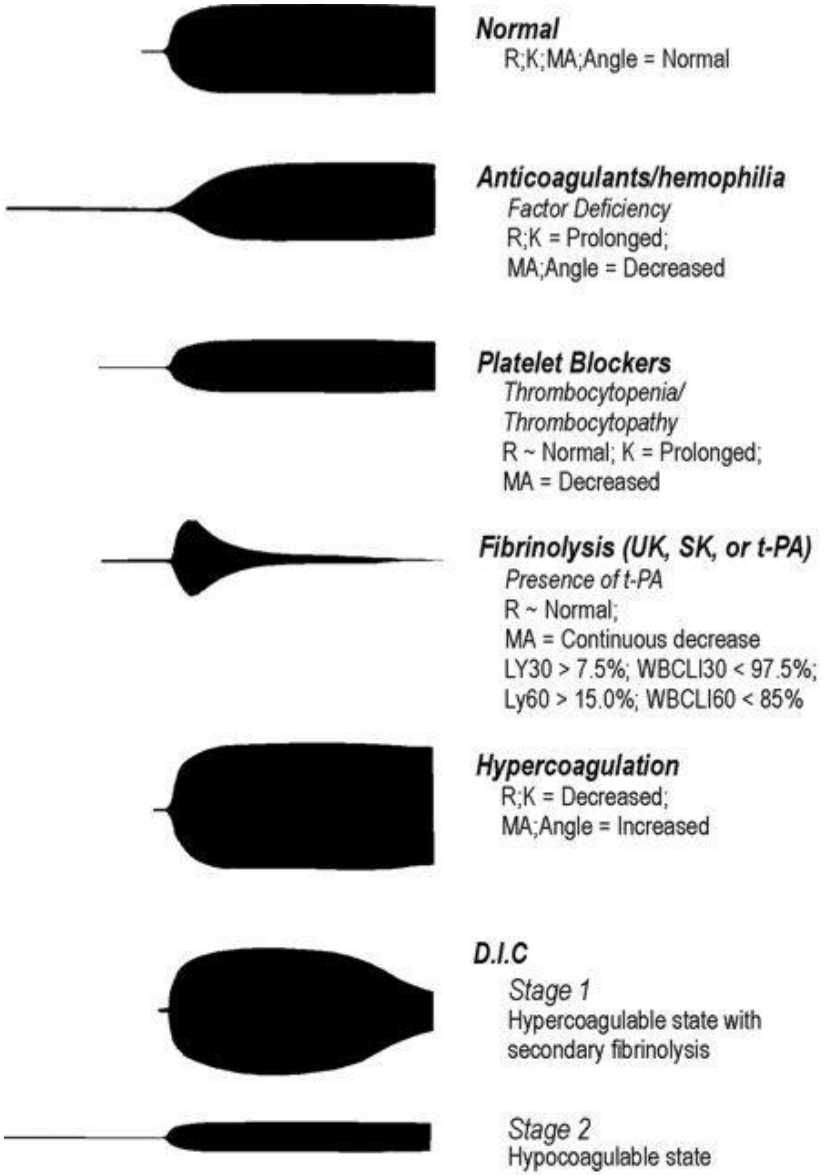
TEG



Key: **R** (minutes) = Reaction time, time from start of test to initial clot formation. **K** (minutes) = Kinetics of clot i.e. time taken to achieve a certain level of clot strength (amplitude of 20 mm). **Alpha angle** (degrees) = measure of the speed at which fibrin build up and cross-linking occurs, assessing clot formation. **MA** (mm) = measure of the ultimate strength of the fibrin clot. **LY30** (%) = percentage decrease in amplitude at 30 minutes after MA, a measure of the degree of fibrinolysis.


Clotting
Time
Kinetics
Strength
Lysis
Maximum Amplitude
Lysis
Reaction time
α-angle
TEG
Clotting Time
α-angle
ROTEM
A
Maximum Clot Firmness
Clot Lysis


Normal
B
Hypercoagulability
C
Hypocoagulability
D
Hyperfibrinolysis
E
Hypofibrinolysis
F


Normal
R;K;MA;Angle = Normal
Anticoagulants/hemophilia
Factor Deficiency
R;K = Prolonged;
MA;Angle = Decreased
Platelet Blockers
Thrombocytopenia/
Thrombocytopathy
R ~ Normal; K = Prolonged;
MA = Decreased
Fibrinolysis (UK, SK, or t-PA)
Presence of t-PA
R ~ Normal;
MA = Continuous decrease
LY30 > 7.5%; WBCLI30 < 97.5%;
Ly60 > 15.0%; WBCLI60 < 85%
Hypercoagulation
R;K = Decreased;
MA;Angle = Increased
D.I.C
Stage 1
Hypercoagulable state with
secondary fibrinolysis
Stage 2
Hypocoagulable state

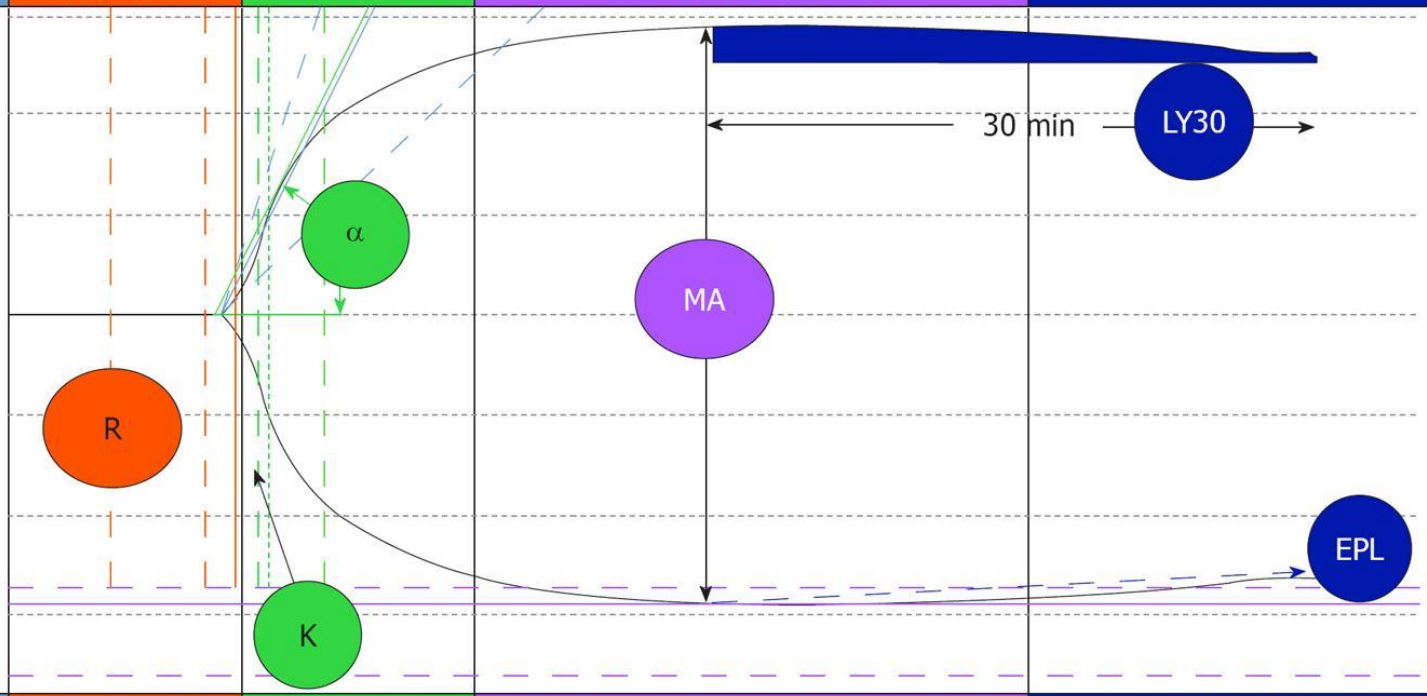
ROTEM tests

Intem	Mildly activates the contact phase of hemostasis, high heparin sensitivity, screening test
Extem	Mildly activates hemostasis via the physiological activator tissue factor, moderate heparin sensitivity, screening test
Fibtem	EXTEM based assay for measuring fibrinogen. Cytochalasin D inhibits platelet contribution of clot formation
Heptem	Neutralisation of heparin --> measures coagulation without heparin (comparable with Intem)
Aptem	inhibits fibrinolysis --> detection of hyper fibrinolysis (comparable with Extem)

TEG tests

Kaolin TEG	An intrinsic pathway activated assay.
Kaolin TEG with Heparinase	Eliminates the effect of heparin in the test sample.
RapidTEG	An intrinsic and extrinsic pathway activated assay speeds the coagulation process to more rapidly assess coagulation properties.
TEG Functional Fibrinogen	An extrinsic pathway activated assay uses a potent GPIIb/IIIa platelet inhibitor to restrict platelet function to isolate fibrin contribution to clot strength.
TEG Platelet Mapping	Includes a thrombin generated tracing and platelet receptor specific tracing(s) (ADP/AA). Identifies the level of platelet inhibition and Aggregation.

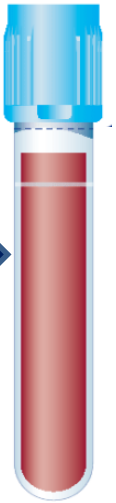
Parameter	Clot time	Clot rate	Maximum clot strength	Clot stability
Hemostatic activity	Ila generation fibrin formation	Fibrin X-linking fibrin←→platelet	Platelet-fibrin(ogen) interactions	Reduction in clot strength
Hemostatic component	Coagulation pathways	Fibrinogen, ila, platelets	Platelets (80%) Fibrin[ogen (20%)]	Fibrinolysis



Dysfunction				
Hypo-coagulable	↑ R (min)	↑ K (min) ↓ α (deg)	↓ MA	LY30 > 7.5% EPL > 15%
Hyper-coagulable	↓ R (min)	↓ K (min) ↑ α (deg)	↑ MA	n/a

Performance Assessment ROTEM / TEG

Real life application



Performance Assessment

Performance Assessment ROTEM / TEG

Limitations in External Quality Assessment

ROTEM :	**CT**	**MCF**
TEG :	**R**	**MA**

Performance Assessment ROTEM

NORMAL PLASMA

EXTEM (CT) sec	N	Mean	Range	CV (%)
All	85	55.8	38 – 117	16.2
Delta: Single-use	32	52.3	39 – 117	19.8
Delta: Liquid	39	58.2	38 – 86	12.2
Sigma	14	56.8	42 – 72	7.6

EXTEM (CT) sec	N	Mean	Range	CV (%)
All	80	49.1	37 - 80	13.0
Delta: Single-use	22	42.9	37 - 50	10.7
Delta: Liquid	41	50.2	45 - 78	7.3
Sigma	17	56.4	42 - 80	18.3

Performance Assessment ROTEM

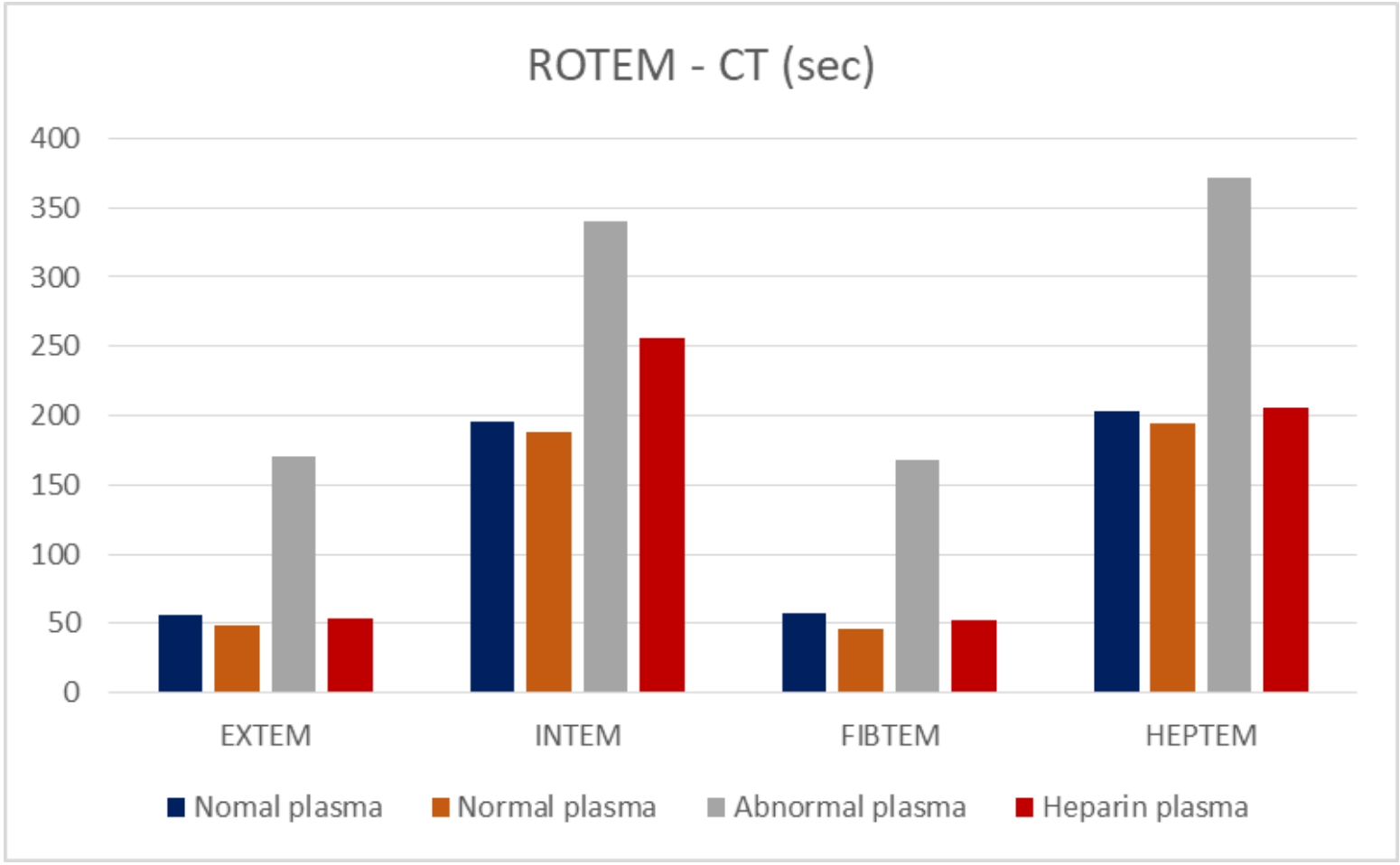
UNFRACTIONATED HEPARIN PLASMA

EXTEM (CT) sec	N	Mean	Range	CV (%)
All	80	54.1	40 – 146	8.6
Delta: Single-use	22	52.6	47 - 60	6.4
Delta: Liquid	41	54.2	45 - 146	7.8
Sigma	17	61.3	40 - 103	27.3

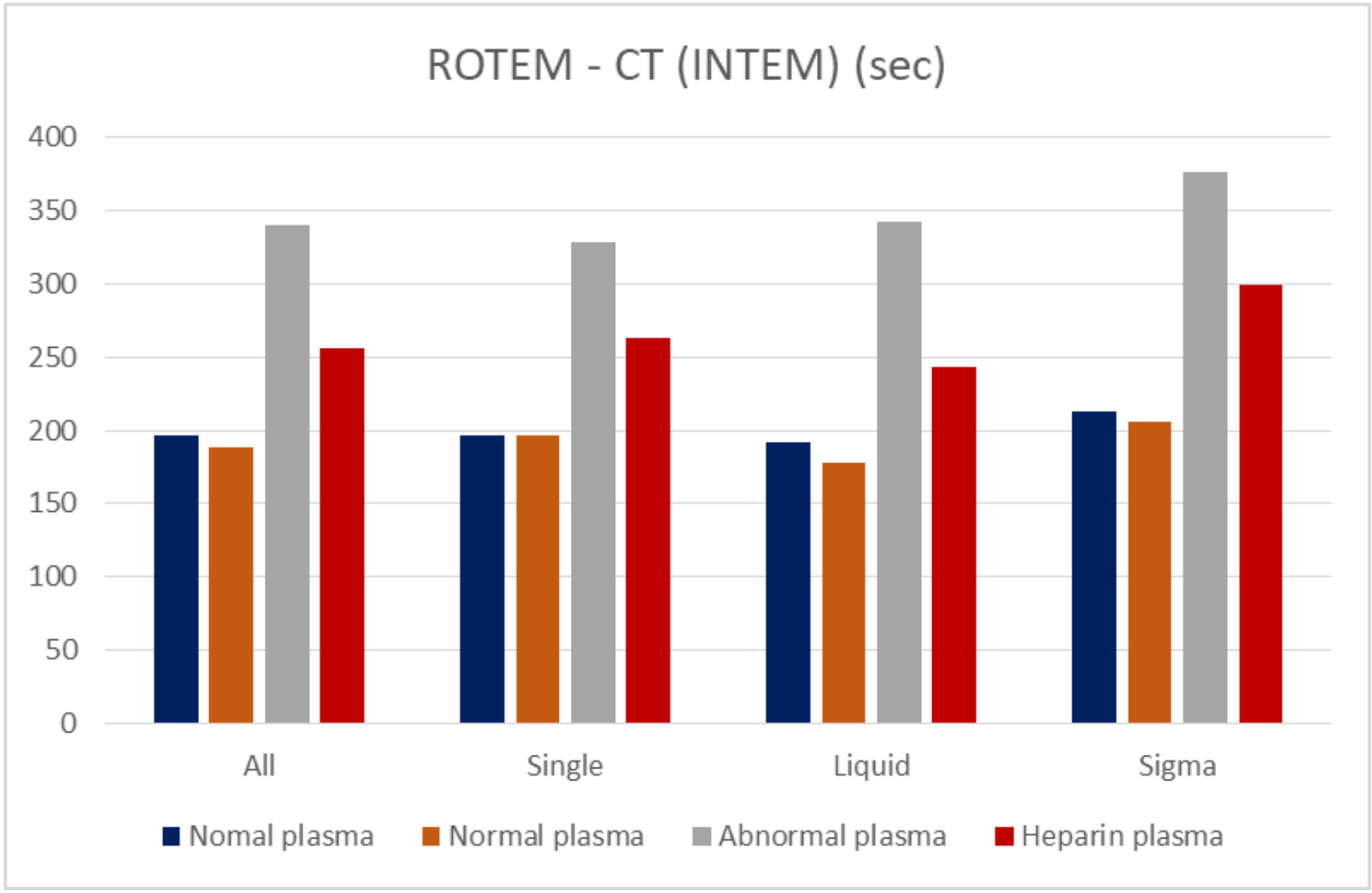
LOW COAGULATION FACTOR PLASMA

EXTEM (CT) sec	N	Mean	Range	CV (%)
All	86	170.8	86 – 790	29.5
Delta: Single-use	31	139.7	86 – 656	41.4
Delta: Liquid	41	180.4	118 – 220	11.0
Sigma	14	239.0	145 - 790	41.7

Performance Assessment ROTEM



Performance Assessment ROTEM



Performance Assessment ROTEM

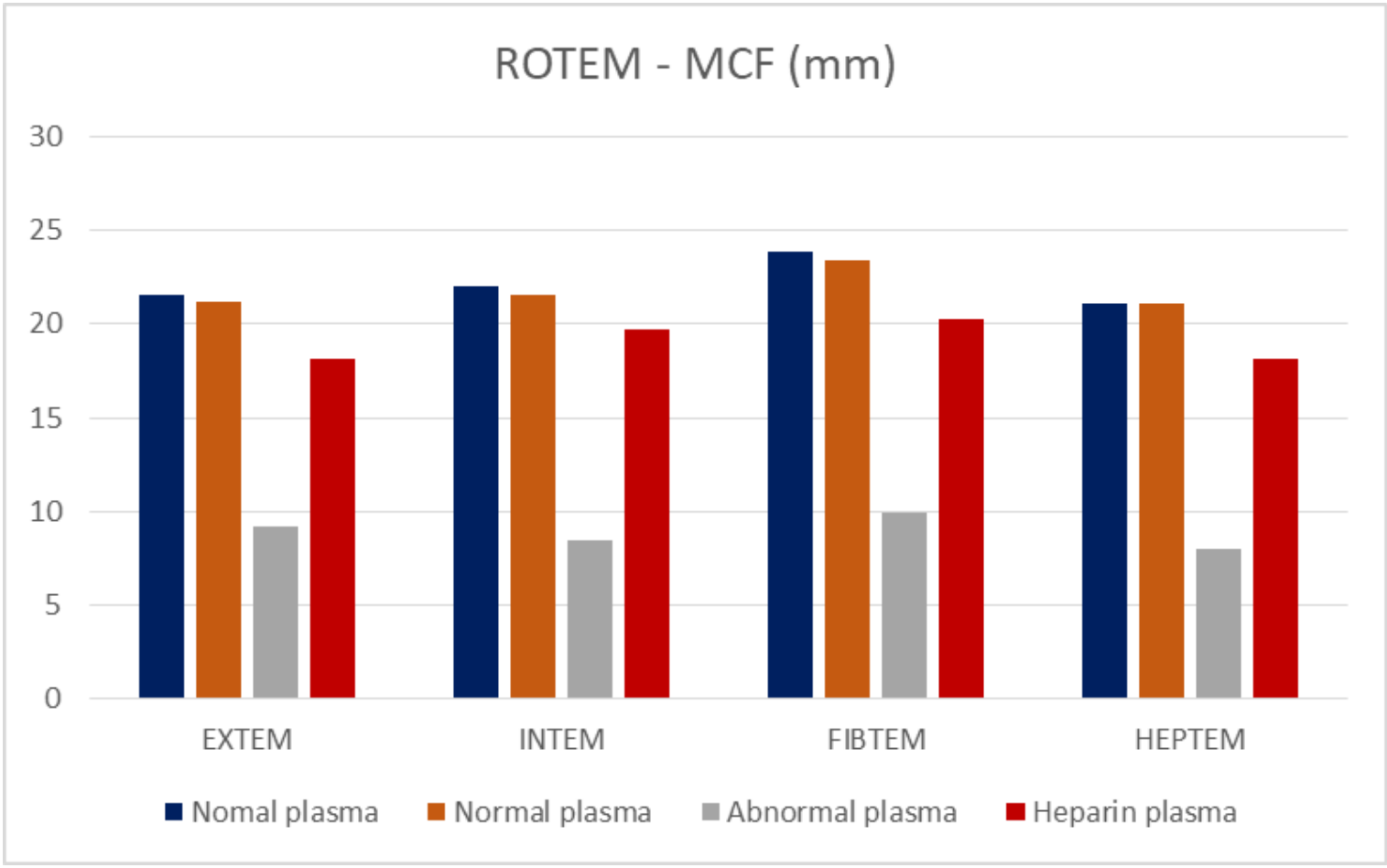
NORMAL PLASMA

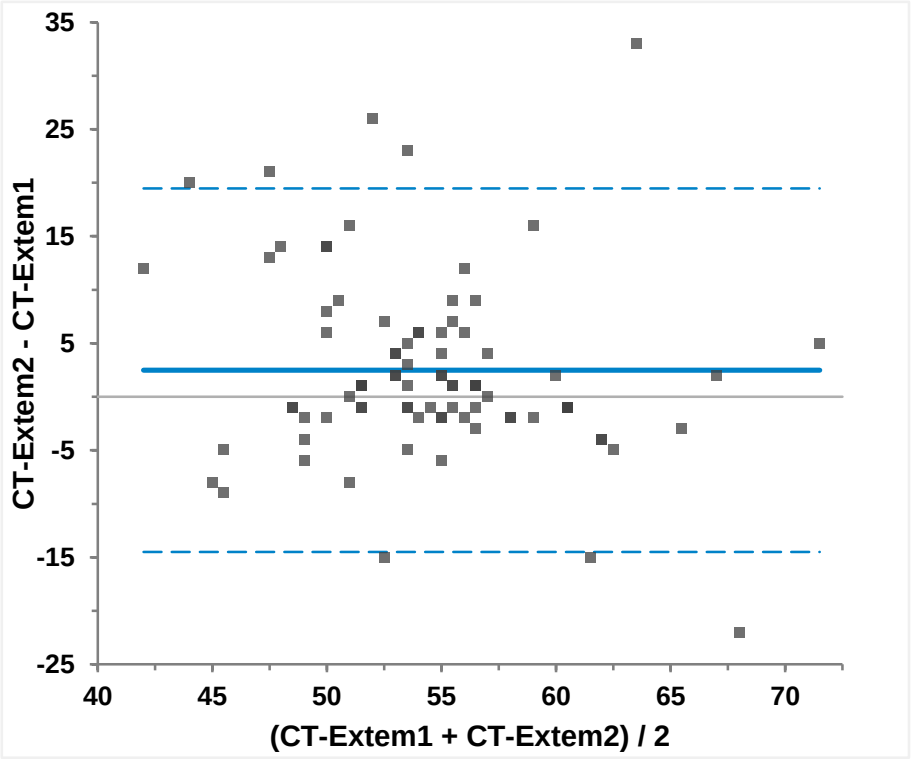
CT CV (%)	EXTEM	INTEM	FIBTEM	HEPTEM
All	16.2	6.5	14.0	9.9
Delta: Single-use	19.8	3.0	13.9	9.4
Delta: Liquid	12.2	6.5	15.5	10.1
Sigma	7.6	17.1	12.8	-

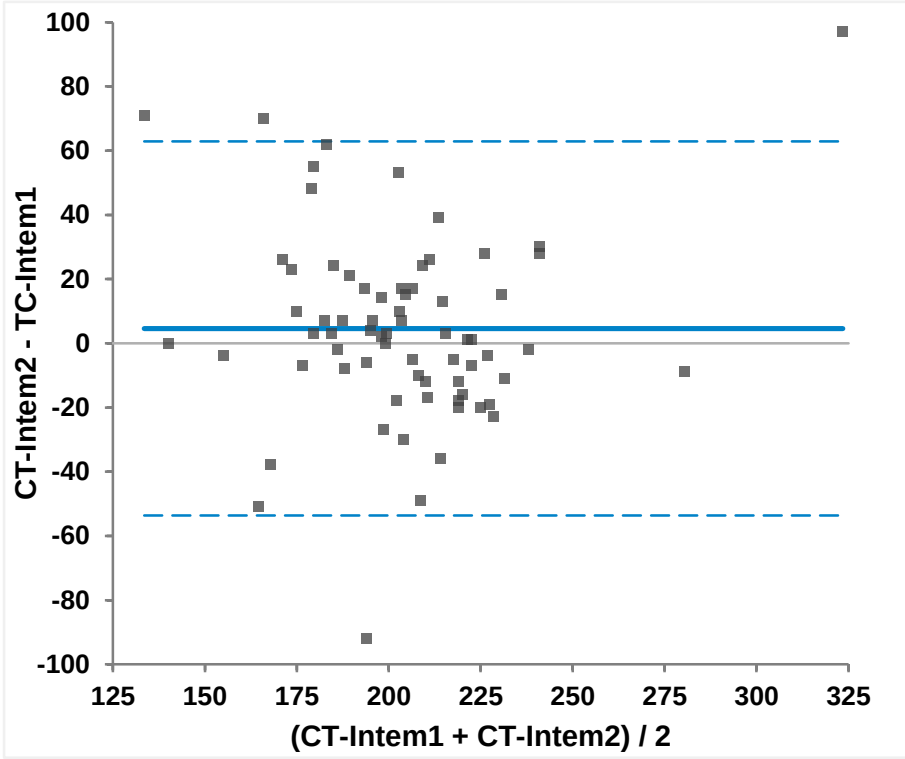
LOW COAGULATION FACTOR PLASMA

CT CV (%)	EXTEM	INTEM	FIBTEM	HEPTEM
All	29.5	10.0	16.0	12.8
Delta: Single-use	41.4	6.8	19.7	10.8
Delta: Liquid	11.0	9.0	12.3	11.0
Sigma	41.7	22.9	34.9	-

Performance Assessment ROTEM




35
25
15
5
-5
-15
-25
CT-Extem2 - CT-Extem1
40
45
50
55
60
65
70
(CT-Extem1 + CT-Extem2) / 2


100
80
60
40
20
0
-20
-40
-60
-80
-100
CT-Intem2 - TC-Intem1
125
150
175
200
225
250
275
300
325
(CT-Intem1 + CT-Intem2) / 2

Performance Assessment TEG

NORMAL PLASMA

R (min)	N	Mean	Range	CV (%)
Plain cup	20	15.6	10.1 – 34.9	32.3
Heparinased cup	13	24.3	15.5 – 37.2	36.6

UNFRACTIONATED HEPARIN PLASMA

R (min)	N	Mean	Range	CV (%)
Plain cup	17	332	25.4 - 800	122
Heparinased cup	17	25.2	16.2 – 47.2	31.9

LOW COAGULATION FACTOR PLASMA

R (min)	N	Mean	Range	CV (%)
Plain cup	17	57.5	7.9 - 120	72.9
Heparinased cup	8	120.0	30.8 - 120	-

Performance Assessment TEG

NORMAL PLASMA

MA (mm)	N	Mean	Range	CV (%)
Plain cup	20	28.6	25.3 – 46.5	7.9
Heparinased cup	12	24.4	14.9 – 29.5	15.1

UNFRACTIONATED HEPARIN PLASMA

MA (mm)	N	Mean	Range	CV (%)
Plain cup	5	-	-	-
Heparinased cup	17	23.6	19.5 – 31.2	14.0

LOW COAGULATION FACTOR PLASMA

MA (mm)	N	Mean	Range	CV (%)
Plain cup	8	14.0	11.3 – 70.0	-
Heparinased cup	2	44.5	10.4 – 78.6	-

Concluding Remarks

- For external quality assessment for ROTEM and TEG we have to compromise with the use of plasma. This makes the evaluation of only a limited number of parameters possible.
- EQA for TEG is more difficult because of the sensitivity for abnormalities.
- Although the sometimes relative high between-monitor CV most participants are able to properly discriminate between normal and abnormal samples.
- The within-monitor variation isng the same sample in different surveys can also be considerable.