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REPORT OF RESULTS

Clotting test of Soluble Hemostatic Gauze *WoundClot™ Advanced Bleeding Control™*

MATERIALS AND METHODS

Test items: Core Scientific Creations: Soluble Hemostatic Gauze

Number	Lot Number	Name of the item
1	1640001	WoundClot™ Advanced Bleeding Control™ (10 cm x 10 cm, sterile)

Size: 0,5 x 2 cm

Test-system: Dynamic Rotation model using an orbital shaker (Polymax 1040, Heidolph, Schwabach, Germany) at 20 rpm.

Timing: 30 min incubation in the model.

Random Tests: The experiment consisted out of a baseline measurement from freshly drawn blood, one control tube without test item and five tubes with test item samples incubated with blood containing different heparin concentrations.

Blood donor: One healthy volunteer (age: 26 years). The quality of the blood used for this experiment is of decisive importance. Therefore, following exclusion criteria for the blood donator must be strictly fulfilled: smokers, drug intake within the last 2 weeks, especially hemostasis affecting agents like acetylsalicylic acid, oral contraceptives, non-steroidal antiphlogistics.

Blood Drawing: Without stasis, careful venipuncture with butterfly needle (0,9 mm) directly and sterile in pre-anticoagulated containers.

Anticoagulation: 1.0 - 5.0 IU/mL Heparin-Natrium 25000 (Ratiopharm GmbH, Ulm, Germany)

Blood volume: 9 ml for each test tube

Temperature: 37°C

**Macroscopic
clot formation
observation:**

Clot formation was observed by quickly pouring the blood onto a towel after incubation. The blood stains were captured via photo documentation.

**Thrombin-anti-
thrombin III
(TAT):**

TAT quantification was performed by using test blood-derived citrate plasma in an enzyme-linked immunosorbent assay (ELISA) kit (Siemens Healthcare, Marburg, Germany)

RESULTS

1. Macroscopic clot formation:

Number	Sample
1	Test tube: blood only (5 IU heparin/ mL blood)
2	Test tube: WoundClot™ Advanced Bleeding Control™ (1 IU heparin/ mL blood)
3	Test tube: WoundClot™ Advanced Bleeding Control™ (2 IU heparin/ mL blood)
4	Test tube: WoundClot™ Advanced Bleeding Control™ (3 IU heparin/ mL blood)
5	Test tube: WoundClot™ Advanced Bleeding Control™ (4 IU heparin/ mL blood)
6	Test tube: WoundClot™ Advanced Bleeding Control™ (5 IU heparin/ mL blood)

1.



2.



3.



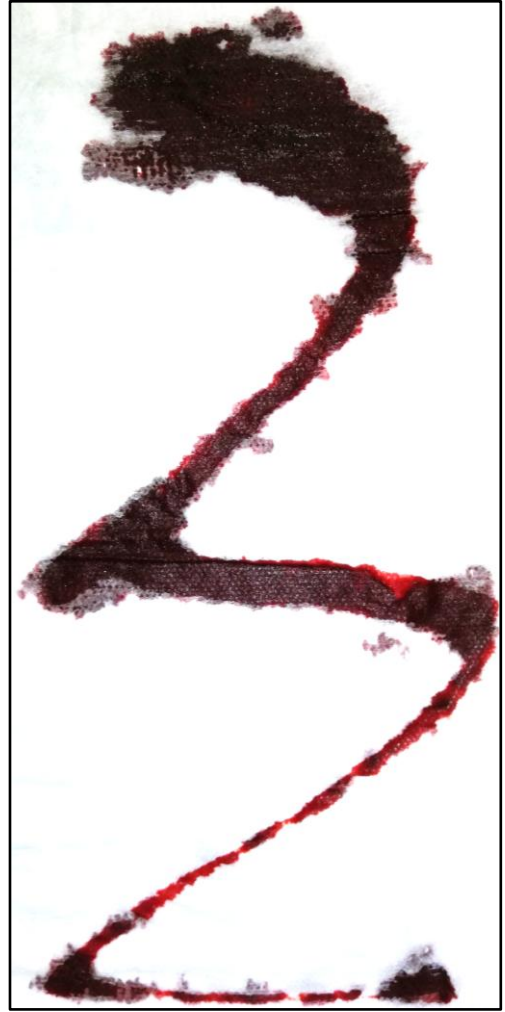
4.



5.



6.



Result:

Blood clot formation occurred in the presence of WoundClot™ Advanced Bleeding Control™ when the blood contained 1.0-4.0 IU/ mL heparin. When the heparin concentration was increased to 5.0 IU/ mL no clot formation could be observed.

2. Thrombin-anti-thrombin III (TAT) quantification

Number	Sample	TAT [$\mu\text{g/L}$]
0	Baseline: Freshly drawn blood (5 IU heparin/ mL blood)	70.66
1	Control: Test tube: blood only (5 IU heparin/ mL blood)	71.24
2	Test tube: WoundClot™ Advanced Bleeding Control™ (1 IU heparin/ mL blood)	5903.20
3	Test tube: WoundClot™ Advanced Bleeding Control™ (2 IU heparin/ mL blood)	135.93
4	Test tube: WoundClot™ Advanced Bleeding Control™ (3 IU heparin/ mL blood)	214.86
5	Test tube: WoundClot™ Advanced Bleeding Control™ (4 IU heparin/ mL blood)	123.92
6	Test tube: WoundClot™ Advanced Bleeding Control™ (5 IU heparin/ mL blood)	30.31

Result:

Thrombin-antithrombin-III-complexes are an indirect measure of coagulation activation since antithrombin is bound to thrombin when clotting is activated. The TAT quantification reflects and confirms the results of the macroscopic blood investigation: The presence of WoundClot™ Advanced Bleeding Control™ activates the clotting process in blood containing 1.0-4.0 IU heparin / mL. The strongest activation of blood clotting is seen when the tested blood contains 1 IU heparin / mL. With increasing heparinization, the TAT-level and thus the coagulation activation decreases. If the tested blood contains 5 IU heparin / mL, there is no measurable coagulation activation and the TAT content is lower or comparable to the freshly collected blood.

Discussion & Summary:

The soluble hemostatic gauze *WoundClot™ Advanced Bleeding Control™* (10 cm x 10 cm, sterile; LOT: 1640001) was tested in order to investigate its coagulation-activating potency by using a dynamic rotation with fresh human whole blood. The test was run under different anticoagulation ranging between 1.0 – 5.0 IU heparin per mL of blood from 1 healthy donor.

The macroscopic observations showed that the soluble hemostatic gauze induces the formation of blood clots during the 30 min incubation period. The coagulation-activating effect was detectable both macroscopically and by quantification of the TAT level up to a heparin concentration of 3 to 4 IU/ mL blood.

These findings show that the soluble hemostatic gauze *WoundClot™ Advanced Bleeding Control™* has strong coagulation-activating potential and can reliably trigger the coagulation process in human whole blood which is anticoagulated with up to 3 to 4 IU heparin/ mL

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