Evaluation of hemostatic performance of SpeedM® Emergency Hemostatic Dressing under hypothermic conditions

Dr. Matthes Kenning, Dr. Bernd Hehmke, Institut für Diabetes Karlsburg GmbH, Brandteichstraße 20, 17489 Greifswald, Germany

Correspondence:
Speed Care Mineral GmbH, science@speedcaremineral.de

Background

The trauma triad of death is a medical term describing the combination of hypothermia, acidosis, and coagulopathy [1]. This combination is commonly seen in patients who have sustained severe traumatic injuries and results in a significant rise in the mortality rate [2]. In a recent analysis of seriously injured patients, almost half (43%) were hypothermic upon admission to the hospital, with an average admission temperature of only about 35°C. A study from the emergency room reports that 39% of seriously injured patients were already hypothermic upon arrival [3, 4].
This hypothermia impairs coagulation: the blood clots more slowly, stable clots form later, and bleeding lasts longer. In an intensive care study, the risk of death approximately doubled when patients arrived at the intensive care unit hypothermic.

Objective

This study assessed the thermal stability of the hemostatic performance of SpeedM® Emergency Hemostatic Dressing, a mineral-impregnated textile wound dressing, to determine the clotting time in human citrated plasma under hypothermic conditions.

Material & methods

To assess the performance of the wound dressings on clotting time, test samples were cut into 0.25 cm² sections and placed into transparent plastic test tubes containing 0.5 mL citrated plasma. For each test lot, four replicates were tested simultaneously to ensure statistical consistency. For a baseline and control two additional groups were included: a negative control consisting of plasma only and a reference-standard using a designated reference lot. Following equilibration in a water bath for 10 minutes at the respective test temperature (28°C to 37°C in 2°C increments), coagulation was initiated by recalcification through the addition of 0.25 mL 25 mmol/L $CaCl_2$ solution. During incubation, samples were gently stirred at 10-second intervals. Clotting time was measured using a stopwatch and defined as the time point at which visible clot formation with plug development occurred. All recorded clotting times are reported as decimal values. To ensure accurate timing, no more than four test tubes were processed simultaneously. This study focused exclusively on characterizing and recording the clotting times under various hypothermic conditions to establish a performance profile. The standard deviation for clotting time measurements was 0.15 minutes, resulting in a total variability range of ±0.30 minutes. All data were evaluated within this predefined variability framework to ensure the reliability of the recorded values and to facilitate a comparative analysis between the test samples, the reference and control.

Environmental conditions were continuously monitored and automatically logged. The ambient temperature averaged 20.9°C with a relative humidity of 46.6% rH, complying with protocol requirements.

Results

Clotting times of test lots, reference and control for different temperatures are illustrated in Fig. 1.

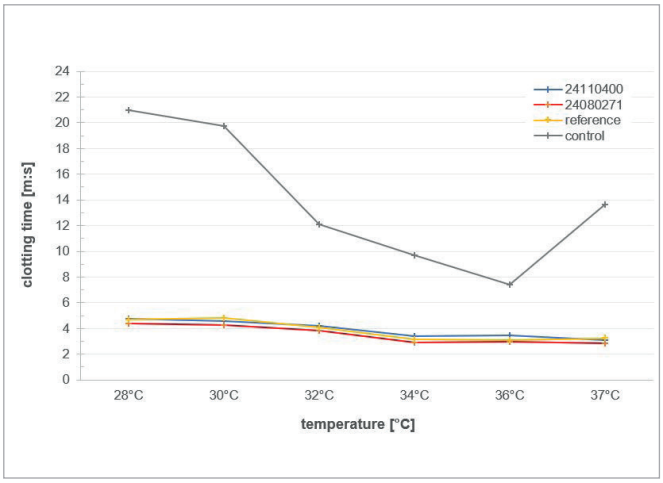

Fig.1: Clotting times of tests, reference and control

All test samples and the reference demonstrated substantially shorter clotting times versus the control group at all temperatures.

Conclusion

In vitro studies with recalcified citrate plasma show that SpeedM® significantly shortens clotting times compared to the control over a hypothermia-simulating temperature range of 28–37 °C.

References

1. Rotondo, Michael F.; Zonies, David H. (Aug 1997), „The damage control sequence and underlying logic“, Surgical Clinics of North America, 44 (7): 761–777, doi:10.1016/S0039-6109(05)70582-X, PMID 9291979

2. Lewis, Anne Marie (Mar 2000), „Trauma triad of death emergency“, Nursing, 30 (3): 62–4, doi:10.1097/00152193-200030030-00028, PMID 11000823

3. Struck MF, Nündel A, Kirsten H, Kaiser F, Zimmermann S, Thriemer N, Werdehausen R, Keß A, Kleber C, Hempel G. Admission Hypothermia in Trauma Patients Undergoing Prehospital Tracheal Intubation: 15-Year Review of a Level-1 Trauma Center. Prehosp Emerg Care. 2025 Sep 24:1-10. doi: 10.1080/10903127.2025.2558865. Epub ahead of print. PMID: 40932762.

4. Akena P, Kiweewa R, Olum R, Basenero A, Nabulya R, Nabawanuka A, Mugisa D. Factors associated with hypothermia and its response to resuscitation among major trauma patients at St Francis Hospital Nsambya: a prospective observational study. BMC Emerg Med. 2025 Jul 1;25(1):104. doi: 10.1186/s12873-025-01254-4. PMID: 40596816; PMCID: PMC12219614

SCM2026001 RevO0 01/2026