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# Use of Topical Hemostatic Dressings in an Extended Field Care Model

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#### **ABSTRACT**

Background: We sought to test whether Celox topical hemostatic dressing (Medtrade Products) would maintain hemostasis in extended use. Methods: An anesthetized swine underwent bilateral arteriotomies and treatment with topical hemostatic dressings in line with the Kheirabadi method. The dressings were covered with standard field dressings, and these were visually inspected for bleeding every 2 hours until 8 hours, when the swine was euthanized. Results: There was no evidence of rebleeding at any point up to and including 8 hours. The Celox dressings maintained hemostasis in extended use. Conclusion: Celox topical hemostatic dressing is effective for extended use and maintains hemostasis. It should be considered for use in situations in which evacuation and definitive care may be delayed.

Keywords: hemostatic; trauma; prehospital; hemorrhage; military

# **KEY MESSAGES**

- Celox maintains hemostasis and prevents rebleeding for at least 8 hours.
- In extended use, Celox had no adverse effects, either at the wound site or systemically.
- Celox and other topical hemostatics should be considered for use when evacuation and/or definitive care may be delayed.
- In extended field care scenarios with hemorrhage, including amputation, use of topical hemostatics as an adjunct could help to increase survival.

#### Introduction

Major hemorrhage is the leading cause of death on the battlefield and in prehospital trauma in certain demographics.<sup>1-4</sup> Junctional wounds, such as those to the groin, axilla, shoulder, and neck, can be especially difficult to deal with because direct pressure and tourniquets may not arrest hemorrhage in these areas. Topical hemostatic dressings are thus a lifesaving adjunct in these instances and have been used successfully by military forces and hospital organisations for more than a decade. Numerous studies have shown the efficacy of various topical hemostatic dressings,<sup>5-12</sup> and the authors recently conducted

a review showing that the hemostatics with the greatest evidence of efficacy were Celox gauze, QuikClot Combat Gauze (Z-Medica), and HemCon (Hemcon Medical Technologies, Medline Industries). Given that Celox is the topical hemostatic currently used by the British military, it was chosen to be used in this study.

With the drawdown of operations in Iraq and Afghanistan, the US and UK militaries are focusing on contingency operations in a number of locations in the world, including the Horn of Africa and the Pacific. Operations in these locations are often remote, and any casualties may endure long delays before evacuation or definitive care. Therefore, any topical hemostatic being used to arrest a junctional hemorrhage would be required to provide wound stability for hours to days.

The aim of this study was to test whether the Celox topical hemostatic dressing would maintain hemostasis for a prolonged period, simulating a prolonged field care scenario, without rebleeding or other adverse outcome.

### Methods

A single swine was anesthetized and bilateral femoral arteriotomies were performed in line with the Kheirabadi model<sup>13</sup> for testing topical hemostatics. Standard-roll Celox gauze was used to pack the injuries, and the application was carried out by a trained Army emergency medicine physician. Because of logistical constraints, the swine had a simulated thoracic injury treated surgically prior to the bilateral femoral arteriotomies; this included injury to thoracic vasculature and resulted in minimal blood loss.

Initial hemostasis was achieved and the topical hemostatics wrapped in standard gauze dressings to secure them in place, and fluid resuscitation with Ringer's lactate solution was started. This is in keeping with both the experimental model and guidelines for clinical use. <sup>14</sup> The swine was kept alive for 8 hours using standard anesthetic sedation and fluid maintenance and then euthanized. No vasopressors or blood pressure maintenance agents were used.

The dressings were checked every 2 hours for evidence of rebleeding or leakage, and monitoring of the swine's vital signs was carried out throughout the experiment. Following

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The study has appeared in poster form at conferences in Oxford Medical School and for the British military.

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euthanasia, the external dressings were checked for evidence of any blood, then removed, and the Celox hemostatics also checked and removed. The area surrounding the wound was inspected for any evidence of adverse reaction.

#### Results

Throughout the 8-hour period, hemostasis was maintained by the dressings, with no blood soaking through to the external dressings. The animal's vital signs remained largely normal throughout the study until euthanasia, with no concerns from the veterinary anesthetist. There was some variation in blood pressure, but this was attributed to the large volumes of anesthetic agents used during the study.

On removal of the external dressings, the hemostatic dressings were still intact and the external surfaces were clean. There was no evidence of adverse reaction around the site of the wounds or in the blood vessels or the skin surrounding the wound. A rudimentary autopsy was carried out to assess for any bleeding from the previous study carried out within the animal's thoracic cavity, and no evidence of hemorrhage or other adverse effects was found.

# Discussion

To our knowledge, this is the first study to show that Celox, a first-line treatment for junctional hemorrhage,<sup>14</sup> is effective over an extended period for the maintenance of hemostasis. As NATO military forces switch from large scale to contingency operations, there is an increased chance of casualties in locations away from Role 3 hospitals with the capability to definitively treat arterial hemorrhage. Therefore, the capability of hemostatics to maintain hemostasis will be crucial to prevent exsanguination in the medium term, before and during evacuation. Some hemostatics come with suggestions for duration of use (e.g., "can be left in place for 48 hours").<sup>15</sup> It is unclear what the basis is for these recommendations, if any. There have been no adverse effects reported with the current generation of hemostatic dressings.

#### Weaknesses

This was a single experimental model on one animal with various factors that were not in keeping with simulation of the remote battlefield environment. The animal was not moved after the arteriotomy wounds were created; there were no contaminants, such as dirt or sand; and the experiment was for 8 hours' duration only. A remote field evacuation to definitive care could take considerably longer than this, but logistical constraints meant that the study was time limited. Thoracic surgery had previously been carried out on the swine, but because the hemostatic was tested in the femoral area, it is unlikely that this affected the outcome of the study. The postevacuation surgical and long-term ramifications of having the hemostatics in place for this period were also not evaluated. The lack of a control subject is another limitation that could be considered in further experimentation; here it was felt that performing the intervention bilaterally, effectively doubling the subject number of the study, was more informative than use of a control subject. Thromboelastography was not performed because of a lack of the requisite equipment, although this would have been a useful adjunct to allow monitoring of the efficiency of the animal's coagulation.

# Strengths

The aim of the study, to ascertain whether Celox topical hemostatic dressing would be effective in an extended field care model, was met in full. The strengths of the study are various. It was done using the Kheirabadi model<sup>13</sup> for testing hemostatics, which is the standard for conducting preclinical experimentation on topical hemostatics. With similarities in physiology and anatomy to human beings, as well as because of results in previous preclinical evidence on hemostatics, it is fair to say that the porcine response to hemostatics is very similar to that of humans, thus making them excellent animal test subjects. Outcomes were defined in advance, and the swine was treated in accordance with battlefield medical protocols, making the study rigorous within the confines of practicality of animal and laboratory testing. Additionally, the bilateral wounding effectively doubles the results of the study, with two separate hemorrhage sites being effectively controlled by Celox dressing.

To our knowledge this is the longest documented use of a hemostatic available in the literature and adds to the body of evidence for their effectiveness as adjuncts in the treatment of major hemorrhage. Although this study is a useful proof of principle, further research is needed to prove conclusively that hemostatics are effective in extended use, particularly in the context of remote battlefield evacuation. Large-scale controlled testing of various hemostatic agents against a gauze control, preferably with a simulated evacuation and surgical follow-up, would be the ideal method to assess this effectiveness. An analysis demonstrating how long a hemostatic would be expected, or needed, to maintain hemostasis, and then testing of this duration, would also add to the current body of evidence.

# Conclusion

This study provides preclinical evidence that topical hemostatics, specifically Celox in this instance, are effective in maintaining hemostasis over an extended period. The evidence from previous porcine studies seems to indicate that the findings may be transferable to human beings, although less-forgiving battlefield or prehospital conditions may present more of a challenge to the products used.

Further testing is needed, but in the absence of other evidence, it seems that topical hemostatics will be an effective adjunct to the maintenance of hemostasis in extended field care. Celox topical hemostatic dressing has proven to be effective in this extended field care model and should be considered for use in hemorrhage where evacuation and definitive care may be delayed.

#### **Author Contributions**

MW and JB are joint first authors; they conducted the experiment and drafted the study. AP and CW reviewed the study, made additions and corrections, and formatted the paper in a scientific style.

# **Ethical Approval Information**

The study was carried out under Institutional Animal Care and Use Committee (IACUC) certificate number 52-R-0114, approved by the University of Manchester (UK), as part of a wider body of research. It took place in a veterinary practice in Virginia, with support from a veterinarian, a veterinary

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nurse, and an anesthetist. The study was registered with the local authority, and all animals were treated appropriately and humanely.

### Disclosure

The authors have nothing to disclose.

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Winter 2021 Volume 21, Edition 4

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