Evaluation of the use of hemostatic agents and the residual particles left in the wound

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Introduction

The development of topical hemostatic dressings has had much attention to address fatal traumatic hemorrhage wounds in both military and civilian medicine. Many dressings are available with several agents used to stop the bleeding.

Two commonly used topical hemostatic dressings, QuikClot® Combat Gauze and QuikClot® Emergency Dressing™ utilising a Kaolin fine clay and Celox™ Gauze utilising chitosan, manage the bleed by different mechanisms. One critical parameter of the dressings is to ensure that either no particles are left in the wound or any particles left in the wound are easily removed.

Celox™ Gauze has highly effective Celox™ granules bonded on to the surface of a stable gauze which will not compact under pressure.

QuikClot® Combat Gauze™ and QuikClot® Emergency Dressing™ has the active ingredient, kaolin bonded to the surface of nonwoven polyester/rayon gauze.

The aim of this study was to assess whether the hemostatic dressings released particles from the dressings and how much was released.



Celox™ Gauz

Methodology

Four in-vitro tests were performed to mimic use of the dressings in the field which allowed the assessment of the level of granule loss from the dressings.

Wound model using pork belly – A
wound was artificially created in a piece
of pork belly using a scalpel. The wound
was filled with saline solution and the
volume recorded such that each test had
the same amount applied. A 500mm
length of dressing was cut and weighed.
The dressing was then packed into the
wound site and the site covered with
backing material. The site was then



Figure 1 – Pork Belly

manipulated to mimic movement of the injured person. Following this, the product was removed from the wound site, weighed and then dried at 60°C until no further weight loss was observed. The weight loss from the bandage was recorded.

- A second in-vitro model utilising a glass beaker was used to assess granule loss. 100ml of saline solution was weighed into beaker, into which a 500mm length of dressing was placed, measure first for dry weight. The dressing was then manipulated in the fluid several times to mimic movement and use in the field. The dressing was then removed from the beaker and weighed wet to obtain absorbency. The dressing was then dried at 60°C until no further weight loss was observed. The weight loss from the bandage was recorded. This test was repeated, but on dressing removal from the beaker the dressing was allowed to drip above the beaker for 5 minutes to measure actual fluid retention in the dressing.
- A third test was utilised whereby the above in-vitro beaker test was carried out, but there was no manipulation of the dressing in the beaker. The beaker was slightly swirled 5 times in both directions (clockwise and anticlockwise) to mimic less movement of the injured person and to assess whether movement affects the level of granule loss.
- A fourth test was utilised whereby the above in-vitro beaker test as per number (2) was carried out, but there was no fluid in the beaker i.e representing weight loss in a dry state. The beaker was slightly swirled 5 times in both directions (clockwise and anticlockwise) to mimic less movement of the injured person and to assess whether movement affects the level of granule loss.

Visual assessment of the test methods was undertaken.

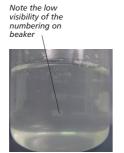


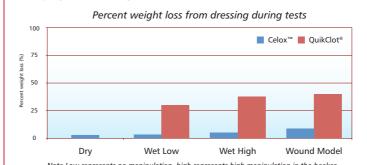
Figure 2 – Cloudy fluid in beaker following submersion of QuikClot® Combat Gauze



Figure 3 – Clear fluid in beaker following submersion of Celox™ Gauze

Results

Visual assessment of the fluid showed that the Celox™ Gauze dressing released a very small amount of larger visible particles from the dressing. This loss of particles did not discolour the saline solution. The QuikClot® Combat Gauze dressing visibly released particles resulting in a cloudy fluid within seconds of applying the dressing.



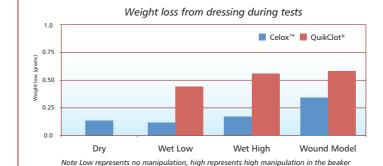




Figure 4 – Celox™ Gauze packed in wound model



Figure 5 – QuikClot® Combat Gauze packed in wound model



Figure 6 – QuikClot® Combat Gauze residual fluid in wound model – Note the milky appearance



Figure 7 – Celox™ Gauze residual fluid in wound model – Note the clear appearance

Discussion

Results from this study indicate that the Celox[™] Gauze has a lower weight loss when tested under the different parameters of the study compared with the Quikclot[®] Combat Gauze. The weight loss of the Celox[™] Gauze was between 2.2-5.8% of the dry dressing weight compared to 31-42% that for the Quikclot[®] Combat Gauze.

The visual assessment of the residual fluid for the two products in both the beaker and pork belly wound model showed that the saline solution was clear following application of the Celox™ Gauze, whilst the Quikclot® Combat Gauze turned the solution a milky colour.

The conclusion is that QuikClot® Combat Gauze has the potential to release the Kaolin particles into the wound site whilst Celox™ Gauze may release chitosan flakes.

Although both Chitosan and Kaolin are generally regarded as safe, there are differences between the two materials. Chitosan is a natural polysaccharide. Chitosan has a known metabolic pathway. That means any left in the body is broken down by the bodies normal enzymes and converted into materials normally present in the body (1).

Chitosan is digested by lysozyme, a human enzyme which is present is tears, saliva and mucus. It breaks down to give glucosamine a sugar already present in the body and helps lubricate joints. Kaolin is a clay mineral that is not easily excreted from the body unless ingested orally.

Conclusions

Based on the in-vitro studies Celox™ Gauze releases a significantly lower weight of particles into the wound models compared with the QuikClot® Combat Gauze.

Referen

1. Int. J. Biol. Macromol., 1992, Vol 14 August

2. Data on file

Celox™ is a registered trademark of Medtrade Products Ltd QuikClot® is a registerd trademark of Z-Medica Corporation

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