The effect of Celox™ Vascular in a Vascular Access Model

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Introduction

The Celox™ Vascular product range takes the Celox™ technology from the battlefield into the hospital setting to help medical professionals with their patients bleeding problems. The Celox™ Vascular product comes as an easy to use 2.5cm x 2.5cm pad.

When mixed with blood, Celox™ Vascular forms a gel like clot in 30 seconds. This clotting action is independent of the bodies normal clotting processes. Celox™ Vascular s' clotting ability has been proven to work in the presence of common anti-coagulants such as warfarin and heparin. It also works on hypothermic (cold) blood.

Celox™ Vascular does NOT use non degrading minerals or nano particles, which will remain in the body indefinitely unless completely removed. Celox™ Vascular is made with chitosan, a natural polysaccharide. Chitosan is broken down in the body by lysozyme, a human enzyme, to leave glucosamine, a sugar which is normally found in the body.

The objective of this study is to assess the efficacy of topical hemostat pad, Celox™ Vascular and both negative and positive controls, in a vascular access wound model, to obtain and maintain hemostasis over a period of over 1 hour.

Methodology

Wounds

All swine models were fully heparinised with 10,000 units / animal.

Treatment sites had papaverine (arterial dilator) topically applied to them.

Access holes to models arteries were made using PIKA kits with both 12 French and 16 French introducers. Once the required hole size was obtained then the inducer was left in place for a minimum of 10 minutes.

Access sites to the femoral, carotid and brachial were attempted. Access was difficult because of the model's thick skin and strong spasms. Access was impossible in some cases. Up to 6 access sites per model were accepted.

Test Wounds

The test wounds had Celox Vascular hemostatic pads applied. To start a test the inducer was withdrawn and free bleeding allowed for approximately 30 seconds. The site was then be covered with the test pad and heavy compression applied for 5 minutes. At the end of 5 minutes the pressure was slowly released. Pressure was then applied for a further 5 minutes if required. A product which stopped bleeding within 5 + 5 minutes was counted as successful. No crossovers were required with this test group. At least 1 hour (as the schedule allowed) after treatment the wound was assessed for bleeding. Before a model was finally put down the test product was removed. Any bleeding at this point was recorded as well as the time after treatment.

Control Wounds

Negative Control. Standard Gauze. STERILE NAR S-Rolled Gauze - 4.5" x 4.1 yds.

Positive Control. D-Stat Dry. Vascular Solutions. STERILE hemostatic bandage with thrombin.

The controls were used in an identical way to the test materials. If after 5 + 5 minutes compression there was still bleeding then a crossover treatment to the test product Celox Vascular was attempted in order to stabilize the model. 5 minutes compression was then applied.

Crossovers

If either the control or test wound was bleeding after 5 + 5 minutes compression then a crossover was performed.

Assessment of Product Efficacy

Visual Assessment: Included environmental conditions for subject, time of assessment, position and type of wound, condition of subject.

Blood pressure: Measured using a VetSpec VSM 7.

Body temperature: Measured using the VetSpec VSM 7. Heart rate: Measured using a VetSpec VSM 7.

Assessment of hemostasis: Made by visual assessment by the data collection officers and confirmed with one of the surgeons. A wound which is not hemo-stable (bleeding) after both 5 minutes compression and a further 5 min minutes compression will count as a product 'failure'.

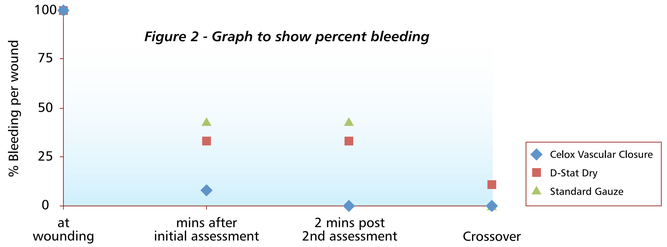
Statistical Analysis

Hemostatic efficacy was assessed by the Data Collection Officers in collaboration with the Surgeon. The hemostatic data collected was binary (pass/fail) and had no confidence limits. The vital sign data was assessed to give averages and confidence limits. There were no detrimental statistically significant changes in vitals signs to a level of 0.05.

	Prior	Treatment	5 mins	1+ hours
Visual assessment	X		X	X
Measure blood pressure, etc	X		X	X
Make wound. Leave for 30 mins. Withdraw inducer		X		
Apply hemostat		X		
Compression		X		
Video Treatment		X		
Assess hemostats		X	X	X

Study Flow Chart

Results



Discussion

The CELOX Vascular test product was used to treat n=12 varying sites. It gave 100% hemostasis after 2nd compression, at 1+ hour and after final pad removal. During the very first test the Celox Vascular pad was used with only 2 minutes compression to confirm that the expected 5 minutes compression was required. There was some minor bleeding after this initial 2 minutes compression. It is believed that if this initial test had used 5 minutes compression then the product would have given hemostasis at first attempt.

The negative control, standard gauze, was used to treat n=7 wounds. It gave 57% hemostasis after initial compression and 57% hemostasis after any secondary compression. If the initial compression did not achieve hemostasis then no further improvements was obtained by a further 5 minutes compression. The negative control crossovers after product failure were treated with Celox products and all stopped bleeding.

The positive control D-Stat Dry, was used to treat n= 9 wounds. It gave 67% hemostasis after initial compression and 67% hemostasis after any secondary compression. If the initial compression did not achieve hemostasis then a further 5 minutes compression seemed to consistently reduce but not stop further bleeding.

The positive control crossovers after product failure were treated with Celox Vascular and 2 out of 3 stopped bleeding with 5 minutes further compression.

With all products, once hemostasis was obtained with this model then it was maintained out to the end of the test.

Celox Vascular maintained hemostasis at all measured timepoints. Timepoints ranged from 1.51 hours to 5.01 hours.

All models vital signs were stable and consistent with this type of study. There were no adverse reactions to any product.

The crossover studies confirmed the efficacy of Celox Vascular in this wound model. It achieved hemostasis in 80% of attempted crossovers (from any control product) within 5 minutes.

Conclusions

Celox™ Vascular gave very good results with 100% haemostasis following 5 minutes compression. It performed considerably better than both the standard gauze negative control (57% n=7) and the D-Stat Dry positive control (67% n=9).

Figure 1 - Celox Vascular

References

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- Data on File

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