The in vivo assessment of an unusual new hemostat technology

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Introduction

Bleeding is a universal issue which affects many aspects of woundcare. Blood clotting is impaired by many conditions, diseases and disorders as well as by some medicines.

Patients with impaired clotting suffer from abnormal bleeding, sometimes with considerably prolonged clotting times. Prolonged clotting times are inconvenient at best and can extend the time and risks of medical treatments. They can also become life threatening in the case of significant surgical procedures and accidents which cause major wounds.

A new emergency granular hemostat (CX) is being used by the military & other first responders to stop bleeding during major trauma.

This poster shows the results from the in vivo assessment of the ability of CX to stop bleeding in two different wound models.

1. Severed artery – a lethal wound model

This wound model is used to assess the ability of a product to stop a higher pressure life threatening bleed from a major artery such as may result from a battlefield wound or a medical emergency. The test is based on the method described by Alam, NB et al, Journal Trauma, June 04. The femoral artery is exposed and then severed. The wound is allowed to bleed for 90 seconds to simulate a time period before treatment. The product is then applied to the wound bowl, packed with gauze and compressed for 5 minutes. After 15 minutes the subjects are resuscitated with 500ml of Hespan given over a 30 min period. The results are given below in Figure 2.

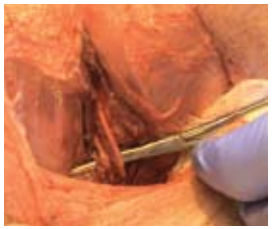

Fig. 2: Clots at 20 minutes

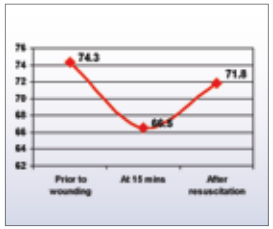

Fig. 3: Mean arterial pressure (MAP) following the...

	At 15 mins post wounding	After resuscitation	After severe agitation
Survival	100%	100%	100%
Re-bleeds	None	None	None
MAP	66.5%	71.8%	Not measured
N=	6	6	6

Fig. 2: Clots at 20 minutes

The new agent was exceptionally effective and stopped bleeding in 100% of cases and all subjects survived. After resuscitation mean arterial pressure returned to normal levels with no incidents of rebleeding, see (fig. 3).

2. Vascular Closure Site.

In this wound model a 16 gauge needle was used to puncture the femoral artery of subjects similar to those in part 1. This wound model is used to simulate vascular closure. The CX agent was presented as a sheet (Fig. 4).

Fig. 4

The puncture wound was left to bleed for 10 seconds before the sheet was applied. Two different application methods were used. In the first the sheet was applied using a gloved hand and held in place for 180 seconds using finger tip pressure. In the second the sheet was applied using tweezers and held in place with minimal pressure for 45 seconds.
In both cases the bleeding stopped. Figure 5 shows a sheet in place.

Fig. 5

The sheets were left in place for 10 minutes with no rebleeding. After 10 mins the sheet were slowly peeled away from the wounds, again with no rebleeding. The wounds were monitored for 1 hour. No rebleeding occurred. Figure 6 shows the wound following dressing removal.

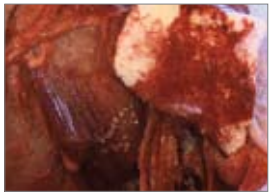

Fig. 6

Conclusions

The new CX agent has been assessed in two in vivo wound models and has proven to be surprisingly effective in both stopping major arterial bleeds and in sealing simulated vascular closure sites.

Previous laboratory work has also shown that the clotting ability of this agent is largely unaffected by the presence of heparin or sodium warfarin in blood. With this profile, the new clotting agent is believed to work independently of the bodies normal clotting mechanisms.

CX shows great potential to assist clinicians in both emergency arterial bleeding and in vascular closure. It already has a FDA 510k and warrants further clinical assessment.

References:

Agent CX *– Agent CX is Celox granular hemostat. www.celoxmedical.com*

From the 21st Annual Symposium on Advanced Wound Care and the Wound Healing Society. *April 24th – 27th 2008 San Diego*

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