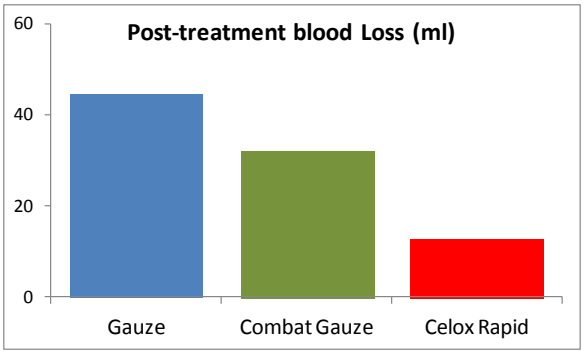
Published studies on Celox™ Rapid Haemostatic Gauze.

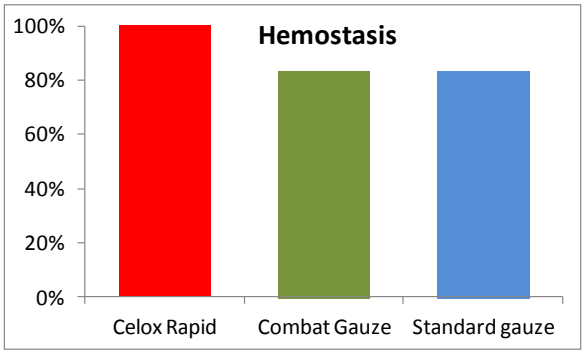
This document briefly summarises the available published test data on Celox Rapid Haemostatic Gauze.

Study 1: Chitosan based haemostatic dressing is associated with decreased blood loss in a swine uncontrolled haemorrhage model. Kunio N, Riha G, Differding J, Watson K, Kremenevskiy I, Schreiber M, Watters J. In Press, American Journal of Surgery, 2013.

Method: The study consisted of a randomized, controlled, blinded trial of lethal femoral arteriotomy injury utilizing thirty-six swine. The injuries were treated with either standard gauze (SG), Combat Gauze[1] (CG), or Celox Rapid Gauze (XG). After packing there was no further compression applied. Animals were followed for 120-minutes after injury or until death.

Results: All animals survived to study end. Physiologic parameters were similar between groups throughout the study. Dressing success rates were XG:12/12, CG: 10/12, SG: 10/12 (p=0.14). Post treatment blood loss was significantly less with XG (12.8 ml [8.8, 39.7]) compared to SG (44.7 ml [17.8, 85.3]) (p=0.02) and CG (31.9 ml [18.6, 69.1]) (p=0.05). Packing time was also significantly shorter with XG (37.1 ± 6.2 seconds) compared to both SG (45.2 ± 6.0)(p<0.01) and CG (43.5 ± 5.6)(p=0.01).





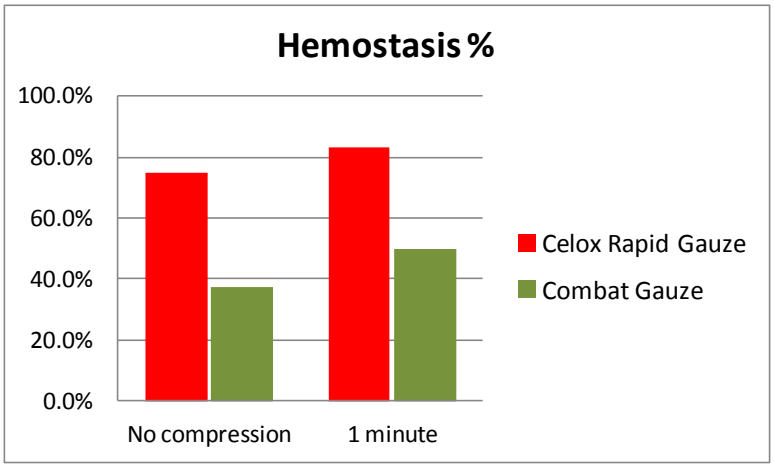
Discussion:

- **Celox Rapid had shorter application time than Combat Gauze/Quikclot or plain gauze.**
- **Celox Rapid decreased secondary blood loss compared to standard gauze and Combat Gauze/Quikclot.**
- **Celox Rapid had a trend to higher haemostasis.**

Study 2: Testing a new gauze haemostat with reduced treatment time.
Hoggarth A, Hardy C, Millner R, Lyon A.
Presented at ATACCC, FL, August 2012.

Method: The test consisted of a lethal 6 mm punch arteriotomy to the femoral artery of Yorkshire swine. Treatment was with Celox Rapid (n=12) or Combat Gauze (8). Haemostasis was assessed after no compression and (where needed) after one minute compression. Additional tests were carried out with Celox Rapid and three minute compression to test equivalence to previous generation products.

Results: Celox Rapid had 75 % haemostasis with no compression, compared to 38 % for Combat Gauze. After one minute compression the results were 83 and 50 % respectively. Celox Rapid with 3 minutes' compression had 75 5 haemostasis. Initial haemostasis was sustained to study end. Celox Rapid was removed intact with no tissue damage.



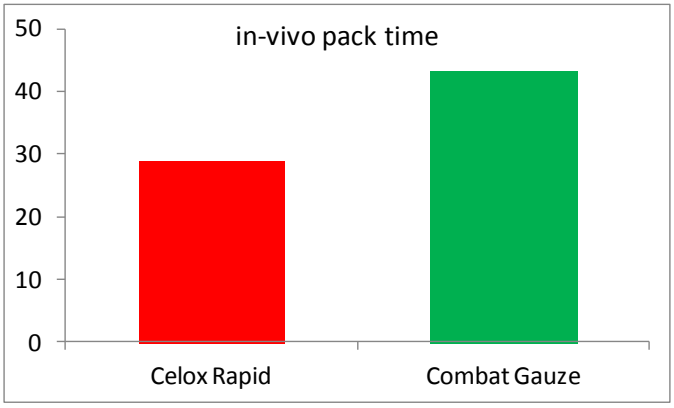
Discusion:

- The test deliberately used short treatment time to test the effect of application in emergency or high-stress situation.
- The packing process (around 45 seconds) probably contributed a compression effect.
- **Celox Rapid achieved haemostasis reliably with short compression or zero compression time.**

Study 3: Reduced application time with a rapid packing gauze haemostat.
Hoggarth A, Hardy C, Eason G, Marsden C.
Presented at ATACCC, FL, August 2012.

Method: Haemostatic gauze was packed wounds and the pack time measured. This was done first in a simulated wound cavity in pork belly, 10 repeats, then in field tests on a swine femoral artery sever model (n=5 for each product). The products all were capable of filling the same wound cavity size.

Results: Packing times in the laboratory were: Celox Rapid 12.8 seconds, Combat Gauze 28.3, Chitogauze[2] 30.6. Field packing times were longer: Celox Rapid 28.8 seconds, Combat Gauze 43.2 seconds.



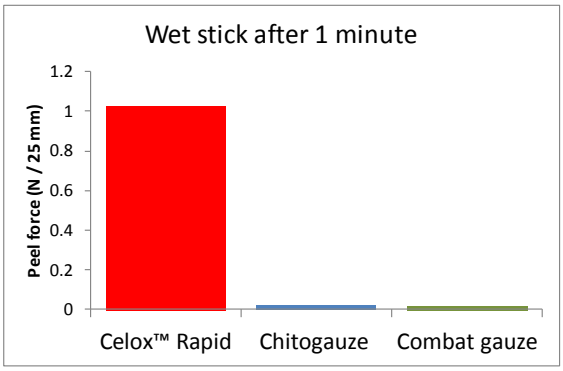
Discussion:

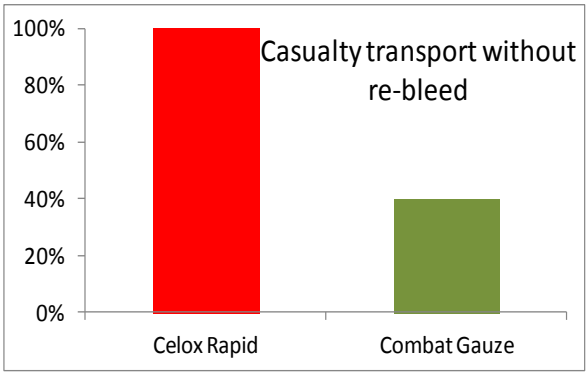
- **Celox Rapid was faster to pack than the other products in both tests.**
- Celox Rapid is a shorter, denser bandage than the other products (5 feet as opposed to 12 feet).
- The difference is consistent having to pack less length of bandage to fill the wound.

Study 4: Mechanism of action of rapid-action gauze haemostat.
Hoggrth A, Hardy C, Eason G, Lyon A, Marsden C.
Presented at ATACCC, FL, August 2012.

Method: Celox Rapid haemostatic gauze is designed to stick to wet tissue. Two tests were carried out to evaluate the effectiveness of the "wet-stick". First, strips of gauze haemostats were pressed on to pork belly and the force to remove was measured using a tensiometer after 1, 3 or 20 minutes. Secondly, swine femoral artery injury models were treated and then the models were driven over rough ground for approximately five minutes to simulate a casualty movement, before being examined for evidence of re-bleeding.

Results: The force to remove Celox Rapid from pork belly was 1.02 N/25 mm after one minute and consistent up to the end of test. Other products recorded forces <0.1 N/25 mm, below the validated limit of the gage. In the transport test, Celox Rapid had zero (0/5) bleeding after transport, Combat gauze showed evidence of re-bleeding in 60 % (3/5) models.





Discussion:

- **Celox Rapid adhered to wet tissue significantly more than other haemostatic gauze.**
- **After haemostasis is achieved, Celox Rapid was able to maintain haemostasis in a model of casualty transport without re-bleeding.**