

UltraClot® Gauze v. Combat Gauze® Comparative Performance Study Data in a Transected Femoral Artery Wound Model

	Animal number	Animal weight (Kg)	Estimated blood volume (gm-ml) ¹	Hemostatic agent ²	Attempts at hemostasis ³	Dry gauze @ start (gm)	Unused dry gauze @ end (gm)	Total gauze used (gm)	Wet gauze @ end (gm)	Agent weight (gm)	Empty plastic bag (gm)	Total blood loss per animal (gm-ml)	Total blood loss per animal (%)	Wound temp pre-treatment C°	Wound temp +1 min post-treatment C°	Survival at 60 min post application	Survival at 180 min post application
	1	66.36	5309	C	2	416	154	262	860	6	12	580	10.92	35.6	36.5	Yes	Yes
	2	73.18	5855	U	1	432	216	216	560	100	12	232	3.96	37.6	38.4	Yes	Yes
	3	70.00	5600	C	2	414	114	300	1152	6	12	834	14.89	37.1	37.9	Yes	Yes
	4	70.00	5600	C	1	436	187	249	856	6	12	589	10.52	36.7	37.5	Yes	Yes
	5	78.18	6255	U	2	414	252	162	738	100	12	464	7.42	36.9	37.7	Yes	Yes
	6	70.90	5673	U	1	412	222	190	716	100	12	414	7.30	37.2	37.9	Yes	Yes
	7	72.27	5782	C	2	432	166	266	1126	6	12	842	14.56	36.0	36.8	Yes	Yes
	8	64.09	5127	C	1	426	290	136	560	6	12	406	7.92	37.2	37.9	Yes	Yes
	9	74.09	5927	U	1	442	240	202	606	100	12	292	4.93	36.2	37.0	Yes	Yes
	10	74.54	5964	U	1	416	314	102	360	100	12	146	2.45	36.8	37.4	Yes	Yes
	11	79.54	6364	U	1	412	148	264	700	100	12	324	5.09	35.1	35.6	Yes	Yes
	12	59.09	4727	C	2	416	218	198	944	6	12	728	15.40	35.4	36.0	Yes	Yes
	13	68.18	5455	C	1	412	148	264	712	6	12	430	7.88	35.6	36.5	Yes	Yes
	14	77.27	6182	C	3	822	364	458	1882	12	12	1400	22.65	35.8	38.0	No	No
	15	70.45	5636	U	1	414	140	274	760	100	12	374	6.64	35.4	36.1	Yes	Yes
	16	70.00	5600	C	3	816	284	532	2120	12	12	1564	27.93	36.1	37.5	No	No
	17	73.63	5891	U	1	412	244	168	584	100	12	304	5.16	36.3	37.0	Yes	Yes
	18	66.81	5345	U	1	414	192	222	658	100	12	324	6.06	36.8	37.4	Yes	Yes
	19	65.00	5200	U	2	410	125	285	790	100	12	393	7.56	35.6	36.5	Yes	Yes
	20	68.18	5455	C	3	838	312	526	1930	12	12	1380	25.30	35.9	36.9	No	No
Total U	10	726.32	58110		12	4178	2093	2085	6472	1000	120	3267					
Total C	10	685.44	54837		20	5428	2237	3191	12142	78	120	8753					
Avg U		72.63	5811		1.20	418	209	209	647	100	12	326.70	5.66	36.41	37.1		
Avg C		68.54	5484		2.00	543	224	319	1214	8	12	875.30	15.80	36.13	37.2		
Totals		1411.76	112947		32	9606	4330	5276	18614			12020	214.53				
Averages		70.59	5647		1.6	480	216.5	263.8	930.7			601	10.73	36.27	37.13		

Hemostatic Agent	Total blood loss per group (gm-ml)	N	Avg blood loss per animal (gm-ml)	Avg blood loss per animal (%)	Wound temp +1 min post-treatment C°
UltraClot® Gauze	3267	10	326.70	5.66	37.1
Combat Gauze®	8753	10	875.30	15.80	37.2

UltraClot® Gauze Attempts	1,1,1,1,1,1,1,1,2,2	1.20 average
Combat Gauze® Attempts ³	1,1,1,2,2,2,2,3,3,3	2.00 average

Survival Rate	
UltraClot® Gauze	100%
Combat Gauze®	70%

- Notes:
- Blood volume in ml = Animal weight (Kg) X .08
 - U=UltraClot® Gauze, C=Combat Gauze®
 - Third application (using 2nd package) required of Combat Gauze®

Study performed by Deployment Medicine International under the auspices of Dr. John Hagmann, M.D., PhD., Lt. Col. U.S. Army, Ret.



Evaluation of UltraClot® Gauze

The protocol chosen is based upon actual combat practice of hemorrhage control. This is a comparison of a new hemostatic agent UltraClot Gauze® to Combat Gauze®, a proven agent presently in use since 2007. Combat Gauze® has been well documented and has demonstrated effective hemostasis in field use applied to wounds sustained in combat. Combat Gauze®, a kaolin powder in an absorbent gauze, has been approved by the US Food and Drug Administration and is recommended for use on the battlefield by the Committee on Tactical Combat Casualty Care.

Twenty animals were selected for this evaluation. The swine *porcus scrotus* was chosen as the appropriate model that best replicates injuries demonstrating severe bleeding. Hemostatic agents (HA) have been shown to be effective in animal models of severe bleeding.

UltraClot® is a hectorite, 200 micron clay, designed to be applied directly into an exsanguating wound where a tourniquet cannot be applied or hemostasis cannot be otherwise controlled. The material is inert, does not chemically interact with live tissue and does not generate an exothermic reaction. The hectorite clay is embedded in a Kerlix® type gauze. The clay material interacts with blood creating a physical barrier that can be held on or directed toward the source of bleeding. Pressure is applied over the material within the wound until hemostasis is achieved.

Abstract;

A number of hemostatic agents designed to aid in the management of uncontrolled bleeding on the battlefield have been developed and are currently in use. The agents best supported by data from ongoing studies at this time (Alam 2003, Pusateri 2003, Sondeen Hemostatic Dressings 2003, Alam 2004, and Pusateri 2004) as being able to stop massive hemorrhage were reviewed by the Committee on Tactical Combat Casualty Care. The kaolin based Combat Gauze has been judged to be effective based on study findings to date. UltraClot Gauze® application, performance and results are compared to Combat Gauze® in a side-by-side evaluation.

Purpose;

To present for US Food and Drug Administration approval a study to evaluate the efficacy of the hemostatic agent UltraClot Gauze® using Combat Gauze® as a comparison.

Methods and Materials;

Twenty animals were weighed and prepped in the usual fashion; sedation was achieved following DMI Veterinary protocol. Two Acme Heavy Duty Game scales, 0-300 lbs. marked in 5lb increments were used to measure weights. The sedated animals were laid across a Raven Litter and a combination of the readings was added minus the litter weight. Intubation was accomplished by direct laryngoscopy. The external jugular vein was cannulated and the cannula was secured with two ligatures distal and two ligatures proximal. The incision was closed using simple-interrupted sutures of braided polyglycol.

The right femoral artery was exposed, using a template, through a 4 in. linear incision along the inguinal crease. A single operator performed the wounding by transecting the vessel with a knife. This operator was blinded to the selection of hemostatic agent (HA). Another operator immediately applied digital pressure to the wound. This was held for 30 seconds at which time the HA, standard packaged unit-dose (3" x 4 yds), was introduced into the wound. A limited number of operators were involved with applying HA to maintain consistency with technical aspects of application. Sufficient gauze, standard 4"x 4", was placed over the HA and held firmly in place with continued manual pressure. A limited number of operators were involved to maintain consistency in applying pressure. Pressure was slowly released at 2 minutes and a one liter bag of IV fluid was rolled into place only maintaining gentle pressure to hold the gauze in place. Success was measured by 2 elements. First; hemostasis of the wound. If additional pressure was needed due to uncontrolled hemorrhage, this was continued and re-evaluated at 5 minute intervals. Evaluations are recorded as 1 attempt for 2 min of pressure, 2 attempts for 5 min of pressure and 3 attempts for 10 min of pressure required for complete hemostasis. Second; the animals were viable and monitored for at least 3 hours post application for any evidence of re-bleeding. Several of the animals survived 5-6 hours post wounding and upon termination of the study were sacrificed to retrieve the HA.

Every attempt was made to capture all the hemorrhage with gauze. A plastic bag was placed beneath the animal and gloves of the operators were wiped clean. All gauze was collected and weighed for blood and agent.

Results;

The average weight of the animals was 70.59 kg. with a range of 59.09 kg to 79.54 kg. Eight percent of the animal's weight represents total circulating blood volume. The estimated average blood volume was 5.65 liters per animal, range 4.73 L to 6.36 L. Total blood loss was calculated weighing the wet gauze, subtracting the HA. Total blood loss averaged 601cc or 10.73%, ranging 146cc to 1564cc.

Ten animals were selected for Combat Gauze® and ten for UltraClot Gauze®. Average blood loss per animal group was 875.30cc or 15.80% for Combat Gauze® and 326.70cc or 5.66% for UltraClot Gauze®. Average number of attempts for success of hemostasis using Combat Gauze® was 2.00 compared to 1.20 for UltraClot Gauze®.

Additionally, the operators could detect no exothermic reaction with the UltraClot® material.

Discussion;

The average blood loss per animal was lower in the UltraClot® group. The number of attempts to achieve hemostasis was greater, 1-3 attempts, when using Combat Gauze as compared to UltraClot Gauze, 1-2 attempts. Given these results of a limited study, UltraClot® demonstrated to be at least as efficacious as Combat Gauze® in controlling massive exsanguination in the porcine model.



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