OMNA Tourniquet Efficacy Investigational Study

OMNA Inc.

Abstract:
Background: Carrying a commercial, pre-hospital tourniquet in the marine environment has been a challenging endeavor due to a variety of factors such as durability, weight, size, and integrations with existing equipment. Traditional tourniquets are not made for exposure and have been proven to have a dramatic reduction in effectiveness by as much as 40% - 50% when exposed to normal environments outside of their packaging [1]. OMNA Tourniquets (www.omnainc.com) are designed to be durable, and marine-grade for repetitive ocean exposure / training use. **Methods:** Three OMNA Tourniquets were used during the course of the study. **OMNA Amphibious Tourniquet:** 5.08 cm – 6.35 cm width x 95.25 cm length, **OMNA Marine Tourniquet:** 5.08 cm – 6.35 cm width x 95.25 cm length, **OMNA Tourniquet Leash:** 5.08 cm – 6.35 cm width x 95.25 cm length. A total of 18 volunteers were selected to participate in the study. Volunteers were given the manufacturers instructions for use to read, were allowed to familiarize themselves with the device, and then applied the tourniquet high and tight to a thigh while a registered vein technician (RVT) monitored and recorded arterial blood flow and pw wave for occlusion. **Results:** All Eighteen volunteers who applied the omna tourniquet to their thigh were able to achieve arterial occlusion pressure (AOP), with a mean application time of 29.33 seconds. **Conclusion:** OMNA tourniquets are effective at achieving the required amount of compression to achieve and sustain AOP to control hemorrhaging in adult limbs.

Keywords: tourniquet; hemorrhage; first aid; emergency treatment

Introduction:
To be considered an effective tourniquet a tourniquet must achieve AOP in 75% or greater limbs [2]. If only venous blood flow return is prevented, without arterial blood flow occlusion dangers such as increased blood loss, compartment syndrome, hypovolemic shock, or death can develop [3]. In regards, to the marine environment extremity bleeding from traumatic injuries in the water, like surfing make up roughly 50% of surf injuries, and 25% of boating injuries [4,5]. Ballas et al, 2017, concluded that the single determining factor of shark attack survival is how fast a commercial pre-hospital tourniquet can be applied to a limb [6]. However, carrying a commercial, pre-hospital tourniquet in the marine environment has been a challenging endeavor due to a variety of factors such as durability, weight, size, and lack of integration with existing marine / water sports equipment. Traditional tourniquets are not made for exposure and have been proven to have a dramatic reduction in effectiveness by as much as 40% - 50% when exposed to normal environments outside of their packaging [1]. OMNA Tourniquets (www.omnainc.com) are designed to be durable, and marine-grade for repetitive ocean exposure / training use.

Methods: All human tourniquet use was performed on volunteers who were provided study design, materials, methods, and informed consent paperwork prior to participation. In total 18 volunteers participated in the study, 11 males, and 7 females. Upon arrival volunteers were presented again with all information along with informed consents, which they completed at that time. A staff member recorded their age, sex, weight, largest thigh circumference when standing, relevant medical conditions / medical history, and took vitals via Contec cms-50d pulse oximeter and software (www.contecmed.com) before and after tourniquet application. One at a time volunteers entered the lab, and confirmed verbally that they were informed and volunteering to participate in the study. At that time the purpose of the research was explained in detail again. Each test began with the volunteer being presented with a copy of the manufacturers instructions for use and one of the three tourniquet styles. In total they were given 5-minutes of time to read the document, and familiarize them with the tourniquet function. Subsequently, they provided verbal confirmation of their understanding, and readiness to move on to the next step. Volunteers were instructed to take a seat on the floor with the tourniquet next to the RVT using a GE Doppler Ultrasound (http://www.gehealthcare.com). The RVT located posterior tibial artery in their lower leg to record the pre-test arterial blood flow / pw waveform. Once complete, RVT and volunteer verbalized their readiness, and were given a countdown of 3, 2, and 1, to apply the tourniquet. A stopwatch was started and volunteers verbalized done when they felt they had properly applied the tourniquet; at that time the stopwatch was stopped and the application time was recorded. RVT confirmed successful AOP and a second stopwatch of 60-seconds was started to determine if AOP was maintained. At the end of the 60-seconds volunteers removed the tourniquet, RVT recorded that normal blood flow and pw wave resumed, followed by a reassessment of vitals via pulse oximeter.

Results: Of the 18 tourniquet applications there were 18 successful tourniquet self-applications that achieved sufficient AOP in the thigh. Mean age of volunteers was 38 years old, mean weight was 165 lb. (75 kg), mean thigh circumference was 22.65” (57.5 cm), and mean tourniquet application time was 29.33 seconds (Figure 1).

Conclusion: OMNA Tourniquets are an effective means of controlling hemorrhage in adult limbs. See (Figure 2) for patients 1-18 doppler images.

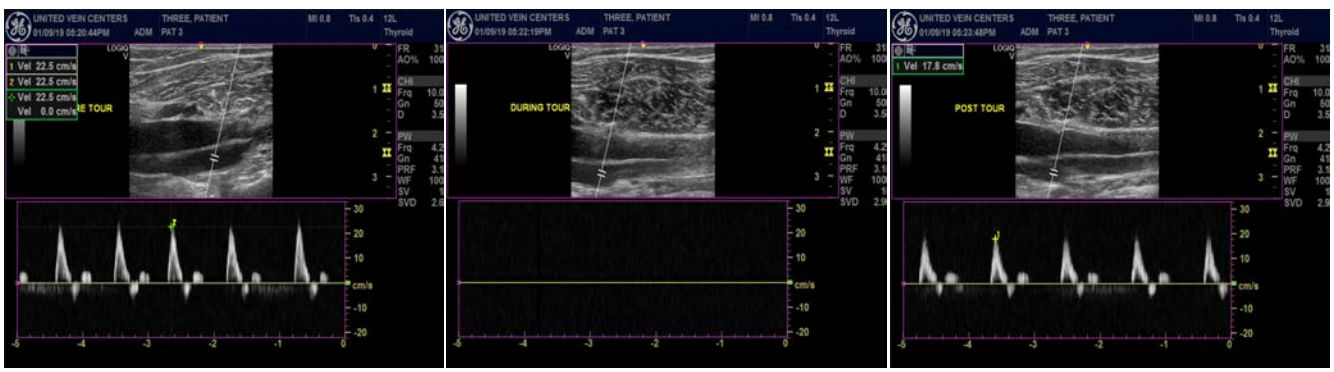
Subject #`	Age	Weight	Gender	Thigh Circumference - Largest, Standing (Inch)	Application Time	60-Sec Pass
1	70	180	Male	23.875	20	PASS
2	36	160	Male	19.25	31	PASS
3	39	148	Male	20	26	PASS
4	24	173	Male	22	29	PASS
5	35	124	Female	21.5	32	PASS
6	36	140	Female	21	28	PASS
7	59	150	Female	21.875	26	PASS
8	36	186	Male	23.5	18	PASS
9	32	143	Male	20.5	23	PASS
10	32	130	Female	22.875	49	PASS
11	57	155	Female	25.5	23	PASS
12	27	170	Male	22	58	PASS
13	38	152	Male	22.875	34	PASS
14	35	260	Male	25	20	PASS
15	36	155	Female	23	23	PASS
16	30	192	Male	25.5	38	PASS
17	30	135	Female	23	23	PASS
18	33	220	Male	24.5	28	PASS
MEAN	38.05555556	165.1666667	-	22.65277778	29.38888889	-
MODE	36	155	-	22	23	-
MEDIAN	35.5	155	-	22.875	27	-

Figure 1

Patient 1:

Patient 2:

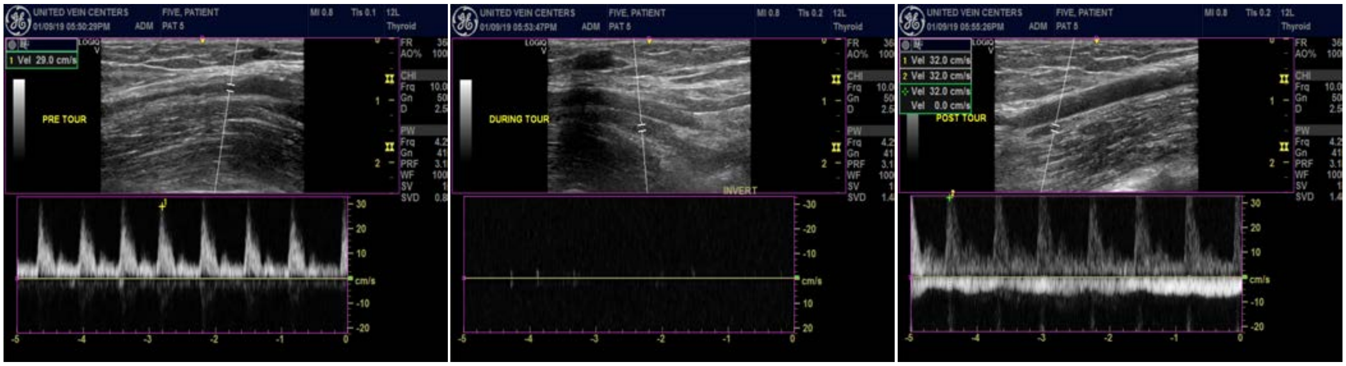
Patient 3:



Patient 4:

Figure 2

Patient 5:



Patient 6:

Patient 7:

Patient 8:

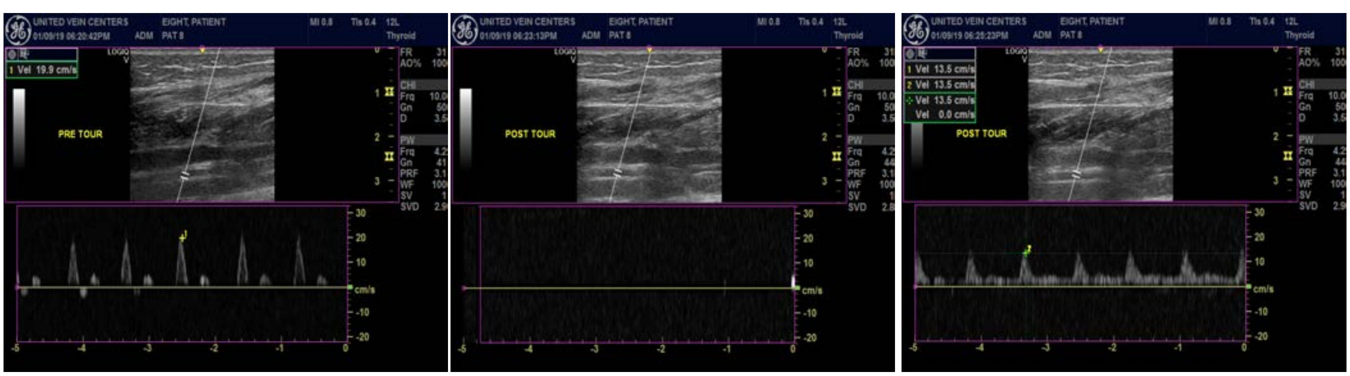
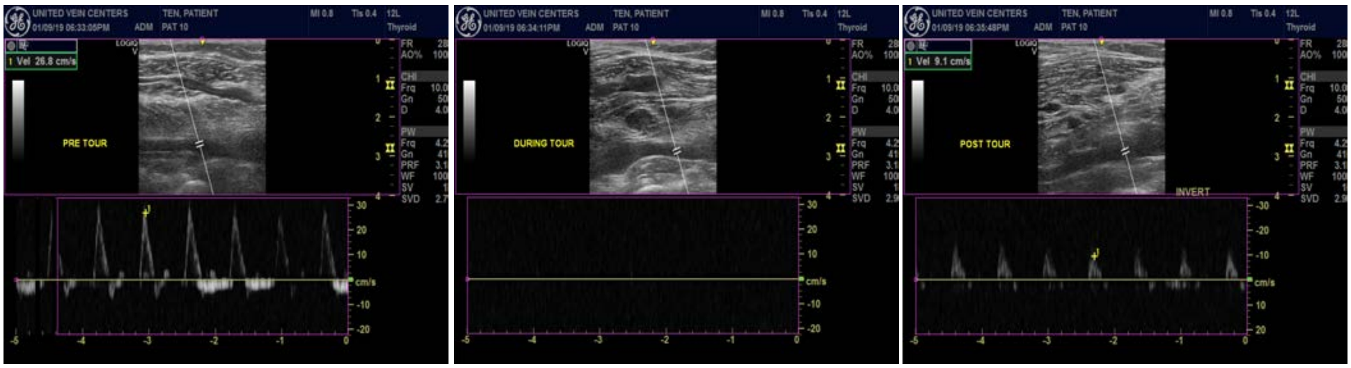


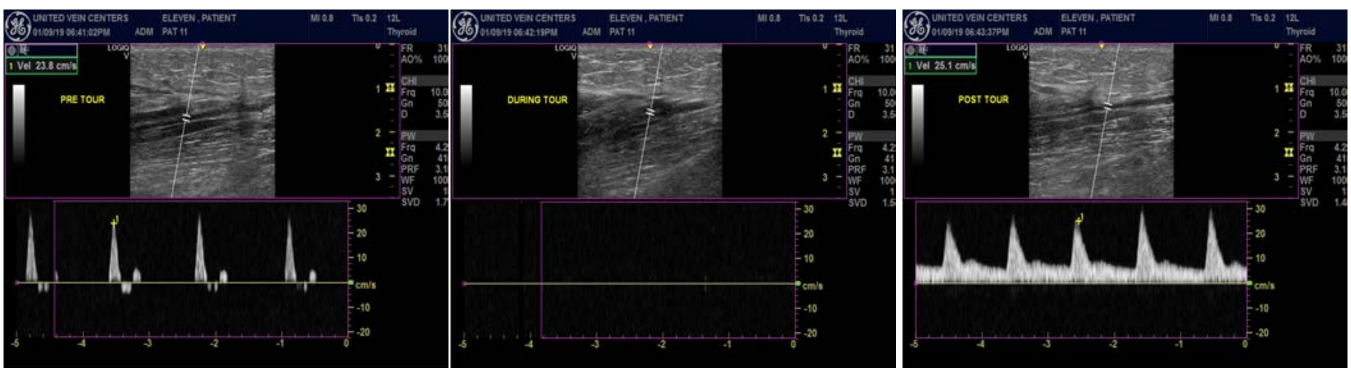
Figure 2

Patient 9:

Patient 10:



Patient 11:



Patient 12:

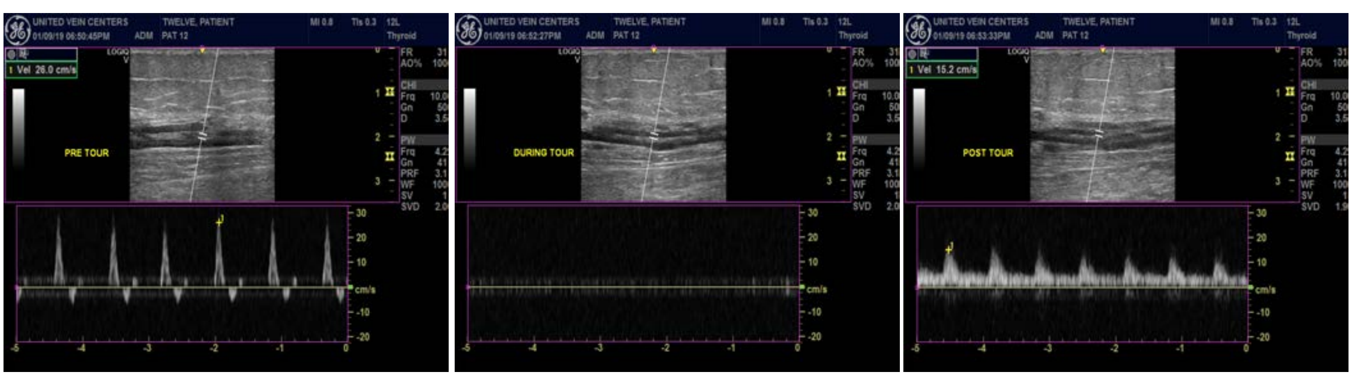
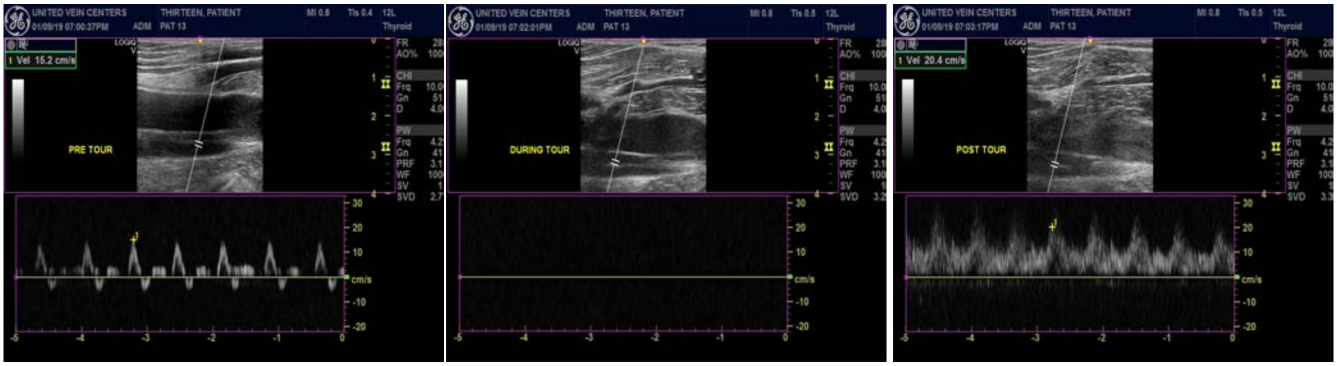


Figure 2

Patient 13:



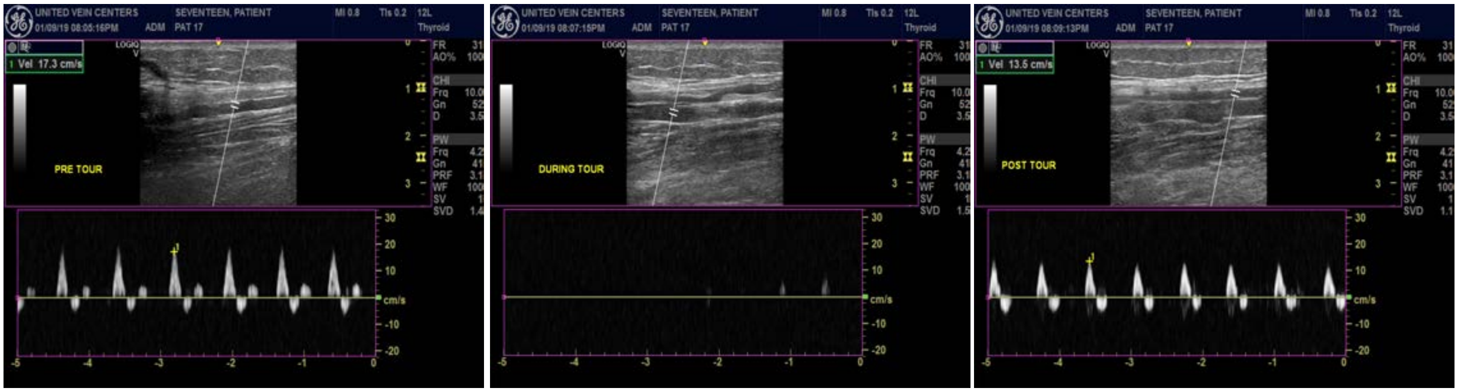
Patient 14:

Patient 15:

Patient 16:

Figure 2

Patient 17:



Patient 18:

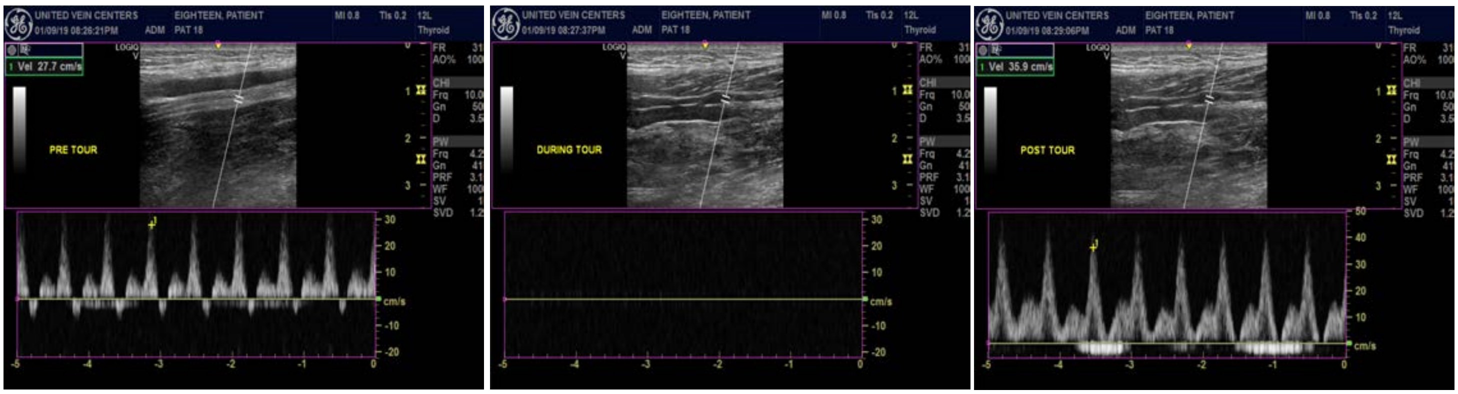


Figure 2

References:

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