Clinical Testing Protocol for Recon Medical GEN 4 Trauma Tourniquet for Use in Injury To Human Extremity

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Purpose
This documentation will outline a clinical study performed by Recon Medical to prove its GEN 4 trauma tourniquet, for use in the event of an injury to human extremity outside of the hospital, can successfully occlude blood flow.

Background
The Recon Medical GEN 4 trauma tourniquet is a newly developed product therefore there is a lack of documentation on whether the product can cope with the requirements of a product such as a tourniquet for use in the event of injury on the extremities outside the hospital. Recon Medical has documented 16 lives that have been saved by the GEN 4 trauma tourniquet, but there has yet to be a clinical study performed to test the ability of Recon Medical GEN 4 trauma tourniquet to occlude blow flow.

This clinical study will provide evidence that the GEN 4 trauma tourniquet can occlude blood flow to an injury to human extremity, whether it is an upper or lower, by human volunteers applying a tourniquet to upper arm and upper thigh and testing for pulse using a Vascular Doppler.

There are already several comparable trauma tourniquet products on the market. A study was completed by the U.S. military titled, "*Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers"* by Thomas J. Walters, Ph. D, in which similar tourniquet products were tested for efficacy in blood occlusion. This military study was used to create the methodology for the Recon Medical GEN 4 tourniquet clinical study.

Testing Methodology
A non-biased, unpaid, non-employee will facilitate the clinical study to ensure there is no conflict of interest. The facilitator is a retired Navy corpsman with experience in operating tourniquets and finding a pulse. A total of 10 volunteers will be involved in this study. Data will be recorded for each volunteer such as height, weight, etc. Each volunteer will be seated during the study. Using an Ultrasonic Pocket Vascular Doppler, the facilitator will locate a pulse on the wrist of the volunteer. A tourniquet is then applied to the same arm. The tourniquet should be located in an area between the shoulder and the peak of the bicep. The tourniquet is then tightly secured using single-component hook and loop fastener and turning the windlass. Once it is believed that blood flow is occluded, the facilitator will check for a pulse using the Vascular Doppler. If there is no pulse, then the tourniquet has successfully occluded blood flow to the extremity. If the pulse is still present, an additional turn should be given to the windlass and then the pulse checked again.

The same process will be used for the leg by applying tourniquet to the upper thigh and a pulse will be measured for at the base of the leg near the ankle bone, on the inside of the leg.

The circumference at each tourniquet application site will also be measured for each volunteer. This same methodology will be repeated for each individual volunteer. It is important to note that a brand-new tourniquet shall be used for each volunteer. This concludes the testing methodology.

Equipment

Ultrasonic Pocket Vascular Doppler by SONOTRAX
Ultrasound Transmission Gel
QTY (10) Recon Medical GEN 4 trauma tourniquet, black

Figure 1: Vascular Doppler

Figure 2: Transmission Gel

Volunteer Criteria

Since both sexes exist in military, both sexes must be represented in this evaluation, and the age restriction must reflect the representative age group of the military in combat. It is expected that the volunteer test subjects are healthy, according to their own knowledge, in such a way that they could be active in the military. The following data will be collected from each volunteer.

- Height
- Weight
- Age
- Sex
- Circumference of the upper arm
- Circumference of thighs

Success Criteria

- All tourniquets occlude blood flow to arm and leg as confirmed by Vascular Doppler reading taken by facilitator.
- All tourniquets withstand tensile force enacted upon it by application to extremity, both on the upper arm and upper thigh, in the form of the strap, buckle or hook and loop fastener not failing.

Procedure:

Procedure has been outlined in detail in the results publication.

Results

The results obtained during the clinical study can be viewed by request of relevant authority or institution.

Clinical Study Location:

The evaluation shall take place at:
Recon Medical, LLC.
1872 Buenaventura Blvd Suite 1
Redding, CA 96001

Rights

All data and results collected belong to Recon Medical, LLC.

Ethical

All participants are volunteers, and they can opt out at any time if they do not wish to participate. Everyone participates anonymously in the evaluation and therefore does not need to provide their name or other data that is not attributable.

Consent

Participants will be asked orally if they are willing to participate in this study. They will be fully informed about the intentions, methodology and the discomfort associated with the study. The volunteer may choose to stop and withdraw from study at any point in time if they are uncomfortable or discomfort from tourniquet application is unbearable. For this evaluation it has been considered that it is enough to obtain an oral consent from the volunteer to participate.

Data

Data is entered in an Excel spreadsheet. Data is stored on Recon Medical property, accessible only to Recon Medical personnel.

Economy

All costs associated with this evaluation will be borne by Recon Medical, LLC.

Recon Medical GEN 4 Trauma Tourniquet

Clinical Study Results

Purpose

This documentation will outline the results of a clinical study performed by Recon Medical to prove its GEN 4 trauma tourniquet can successfully occlude blood flow.

Equipment

Ultrasonic Pocket Vascular Doppler by SONOTRAX
Ultrasound Transmission Gel
QTY (10) Recon Medical GEN 4 trauma tourniquet, black

Figure 1: Vascular Doppler

Figure 1: Transmission Gel

Procedure

A non-biased individual facilitated the clinical study to ensure there was no conflict of interest. The facilitator is a retired Navy corpsman with experience in operating tourniquets and finding a pulse. A total of 10 volunteers were involved in this study. Data was recorded for each volunteer such as height, weight, etc. Each volunteer was seated during the study.

Step 1: Using an Ultrasonic Pocket Vascular Doppler, the facilitator located a pulse on the wrist of the volunteer. The ultrasound transmission gel was used to aid in finding a pulse.
Step 2: A tourniquet was then applied to the same arm where the pulse was located. The tourniquet was positioned in an area between the shoulder and the peak of the bicep. The tourniquet was then tightly secured using the single-component hook and loop fastener strap and further tightened by then turning the windlass and securing the windlass in the windlass retainer clip.
Step 3: Once it is believed that blood flow was occluded, the facilitator checked for a pulse using the Vascular Doppler.
Step 4: If there was no pulse, then the tourniquet successfully occluded blood flow to the extremity. If the pulse was still present, an additional turn was given to the windlass and then the pulse checked again.

The same process was then used for the leg.
Step 5: Using an Ultrasonic Pocket Vascular Doppler, the facilitator located a pulse at the base of the leg near the ankle bone, on the inside of the leg.
Step 6: A tourniquet was then applied to the upper thigh of the same leg. The tourniquet was positioned in an area between the hip socket and the peak of the thigh. The tourniquet was then tightly secured using the single-component hook and loop fastener strap and further tightened by then turning the windlass and securing the windlass in the windlass retainer clip.
Step 7: Once it was believed that blood flow was occluded, the facilitator checked for a pulse using the Vascular Doppler.
Step 8: If there was no pulse, then the tourniquet successfully occluded blood flow to the extremity. If the pulse was still present, an additional turn was given to the windlass and then the pulse checked again.
Step 9: Data Collection - the circumference at each tourniquet application site was then measured and recorded for each volunteer.

This concludes the testing procedure.

Volunteer Data Collection

7 male volunteers, 3 female volunteers
Average height – 68.3 inches
Average weight – 183.8 pounds
Average age – 30.7 years
Upper arm circumference:

- Average – 14.3 inches
- Smallest – 11 inches
- Largest – 17 inches

Upper thigh circumference

- Average – 23.8 inches
- Smallest – 21 inches
- Largest – 27.6 inches

Results

All tourniquet applications successfully occluded blood flow to both arm and leg extremity in all volunteers as confirmed by Vascular Doppler reading taken by nonbiased facilitator.
All tourniquets withstood tensile force enacted upon it by application to extremity, both on the upper arm and upper thigh, in the form of the strap, buckle or hook and loop fastener not failing.

Discussion

The tourniquet performed exactly as expected with 100% blood occlusion in the arm and leg in all 10 volunteers, regardless of sex, age, weight, or extremity circumference.
Opportunities for improvement to study include future clinical studies involving the GEN 4 tourniquet performed by 3rd party to replicate the study and verify results are consistent. Additionally, regarding test methodology, it would be appropriate and recommended to maintain vascular doppler reading on pulse and slowly release pressure on extremity by removing tourniquet. The doppler should read the return of blood flow and therefore furthering the accuracy of the study. Lastly, a greater number of volunteers and a greater variance in age and arm and thigh circumference may also be recommended in future studies.

Conclusion

To conclude, the Recon Medical GEN 4 trauma tourniquet has been clinically proven to occlude blood flow in human extremity. This is a massive result as there was previously no clinical study available to prove GEN 4 tourniquet efficacy. Further studies may be necessary to strengthen this claim but for now the result is clear and should instill confidence and peace of mind that the Recon Medical GEN 4 trauma tourniquet is able to stop the bleed and save lives when called into action!