Abdominal Aortic Tourniquet – AAT™

The AAT is focused at a significant capability gap identified by the Institute of Surgical Research for care on the battlefield: how to address uncompressible hemorrhage that is not treatable by a tourniquet in the leg, groin, inguinal region and pelvis. This significant capability gap focuses on treatment for a class of preventable deaths not previously treatable. The solution to this problem must be stable, easy to apply and completely stop the loss of blood. The AAT™ is capable of this, and animal and human studies have demonstrated its safety and efficacy.

The AAT™ provides a rapid application of pneumatic compression to the aorta at the abdominal-pelvic junction to occlude blood flow in the common iliac and inguinal arteries. The target of the compression is the aortic bifurcation, which has historically been identified in relation to the umbilicus or the superior margin of the iliac crests. Compression at this level is effective and safe and approved by the FDA. The device can be applied in about 45 seconds.

Difficult bleeds in the inguinal region continue to be a significant source of morbidity and mortality on the battlefield. Providing solutions for treating these wounds have direct life saving results. Wounds to the pelvis and inguinal region are now preventable causes of death.

The AAT™ is a circumferential device that utilizes a belt, windlass and pneumatic pressure to compress the aorta. The belt and windlass together greatly increase the stability of the compression. The pneumatic wedge shaped bladder provides focused pressure to squeeze the blood vessels passing through the lower abdomen and preventing flow. The research referenced below demonstrates the safety and effectiveness in non-invasively cross-clamping the aorta or fully stopping all blood flow to the pelvis and lower extremities. In essence the AAT™ acts as a valve to figuratively 'turn the faucet off' and prevent the further flow of blood out of wounds below its application site.

When applied to the groin, it can be applied longer with less risk of tissue and nerve injury than any other junctional device. The larger bladder of the AAT allows for lower overall pressures applied. The AAT is effective using less than $1/8^{th}$ the pressure required for the CRoC and JETT to work.

Blood is the vital component to surviving blunt or penetrating trauma in the golden hour. It allows oxygen to be carried to the heart, brain and kidneys. Every drop of blood lost impacts survival. The AAT is the best solution for the prevention of shock in the casualty injured below the waist, or in the upper junctional regions of the body.

Primary Advantages of the AAT

- Speed of application (mean time of application 45 sec, faster than a single CAT application)
- Definitive cessation of arterial blood flow below the umbilicus or subclavian flow at or near the sternal clavicular junction
- Lower tissue pressures for increased comfort and decreased risk of secondary tissue and nerve injury
- The AAT is the most stable junctional device during patient movement due to not using a mechanical fulcrum that pulls away from the body during application
- The AAT is the only device to stop bleeding in interpelvic injuries which is a common complication in lower junctional trauma
- The AAT provides the capability to be used as a triage and assessment tool. First application allows a blood free field to identify wounds and apply appropriate interventions.
- No effect on diaphragm movement during application
- It is the only device to show effectiveness when used in upper junctinoal bleeding in humans
- It can be applied effectively to the axilla to effectively stop proximal subclavian arterial flow at or near the sternal clavicular junction
- It can also be applied to one inguinal region for one sided inguinal or leg injuries
- It has a larger volume and more physiologically focused bladder design than any other pneumatic device.
- It is one device for all junctional bleeding

Research

Georgia Health Sciences University (formerly the Medical College of Georgia) has conducted research on the device using a swine model in 2009. Flow was undetectable in the femoral catheter during the tourniquet application. For hemodynamic variables, there were no significant differences in MAP or CVP measurements among animals. However, using one way repeated measures analysis of variance, there was a significant difference in MAP ($P = 0.008$) between 0 and 55 minutes for each subject. Serum potassium did not reach clinically significant numbers. However, serum lactate was significantly different between times 55 minutes (3.6 mmol/L +/- .95) and after tourniquet release 65 minutes 5.9 mmol/L +/- .87) ($p < 0.001$). Gross and histological examination revealed no signs of significant ischemia or necrosis of the small and large intestine. These data were presented at the Advanced Technology Applications for Combat Casualty Care conference in August 2009 and the American College of Emergency Physicians Scientific Assembly in 2009.

Application of the device was studied on humans in 2011 again at the Georgia Health Sciences University and found to be safe and effective during the protocol. The Common Femoral Artery (CFA) was reduced to a no flow state by applying an average of 191 mm Hg. The device was associated with moderate discomfort that resolved completely with device removal. These data were presented at the Advanced Technology Applications for Combat Casualty Care conference in August 2011.

The device was further tested on human subjects in October 2012 in the United Kingdom by the Ministry of Defense. They had a 94% success rate of full occlusion and successful application. This research extended the experience and data on human subjects with the AAT to over 15 times that of it's closest competitor, the Combat Ready Clamp.

The Naval Medical Research and Development Unit's Expeditionary Medicine Division conducted an altitude study in the fall of 2012, which showed no variance in intra-abdominal pressure on ascent up to 15,000 feet due to ambient low barometric pressures. This independently validated that the 300 mm Hg relief valve operated as designed. The data from both of the above mentioned studies were presented at the Special Operations Medical Association conference in December 2012.

FDA Approval

Compression Works received FDA approval for the AAT™ on October 22, 2011. The AAT™ is made in the USA. 510(k) approval available upon request.

Continuing Research

Georgia Health Science University is conducting research on a pelvic junctional injury animal model comparing the AAT to current hemostatic dressings. Additional research in the use of the device in EMS for blunt trauma and cardiac arrest also began in 2012 by American Heart Association researchers. Application of the device may increase coronary perfusion pressures during CPR as well as quicken time to steady state concentrations of cardioaffective medications.

CE Mark Approval

Compression Works received CE mark approval on May 9,2012 and is currently the only junctional device with that approval. It is currently in use in Europe.

Availability

The AAT is currently available in the US from Speer Operational Technologies (www.speeroptech.com) and in the EU from Fenton Pharmaceuticals. It has an NSN issued by USAMMA.

NSN: 6515-01-616-4999

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