

Abdominal Aortic and Junctional Tourniquet – AAJT™

The AAJT 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 as well as the axilla and upper extremities. These areas are where the torso meets the extremities and neck and they are referred to as the junctional regions of the body when discussing hemorrhage control. Junctional hemorrhage is 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 AAJT™ is capable of this, and animal and human studies have demonstrated its safety and efficacy.

The AAJT™ is the only device indicated for pelvic hemorrhage (blunt or penetrating), which is very common in causes of lower junctional hemorrhage. The AAJT™ treats both pelvic hemorrhage and severe bilateral lower junctional hemorrhage by application at its original abdominal placement. This periumbilical placement provides a rapid application of pneumatic compression at the bifurcation of the aorta, at the abdominal-pelvic junction, to occlude all blood flow into the pelvis. This includes the common iliac and inguinal arteries bilaterally. If only one inguinal area is affected the AAJT™ is placed over that region and inflated to stop the flow of blood through the arteries of the effected side. Additionally the AAJT™ carries an indication for bleeding in the axilla. At this placement site the device applies focused pressure to stop flow in the subclavian and axillary arteries.

Each of these approved placement sites have animal and live human studies showing the AAJT™ to be effective and safe. In fact the AAJT™ remains the only device to have live human studies showing safety and efficacy at each of the placement sites. The device can be applied in about 45 seconds. Wounds to the pelvis, inguinal and axilla region are now preventable causes of death.

The AAJT™ is a circumferential device that utilizes a belt, windlass and pneumatic pressure to compress the indicated regions of the body. 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 region of application and preventing flow. In essence the AAJT™ acts as a valve to figuratively 'turn the faucet off' and prevent the further flow of blood out of wounds distal to it's application site.

When applied to the groin, the AAJT™ is effective using less pressure than that required for the Combat Ready Clamp (CRoC), Junctional Emergency Treatment Tool (JETT) or the SAM Junctional Tourniquet to work. The large bladder of the AAJT™ applies pressure over a larger surface area allowing for lower overall tissue pressures. This allows for a reduced risk of tissue and nerve injury than other devices. The CRoC has been found to

exert tissue pressures as high as 800 mm Hg and the SAM has been found to also exert tissue pressures as high as 790 mm Hg, while the AAJT™ is effective below 230 mm Hg.

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 AAJT™ is the only FDA approved solution for the prevention of shock in the casualty injured in the pelvis, and it is the most effective solution for managing casualties injured in the lower or upper junctional regions of the body. It remains the only device to have actually saved human life in both upper and lower junctional hemorrhage.

Collateral flow is a unique problem in treatment of junctional hemorrhage. Swan et al found that application of focused pressure over the proximal femoral artery did stop arterial blood flow at the level of the popliteal artery but only temporarily. In their study the mean time to return of arterial flow even with effective proximal inguinal pressure was 41 seconds. Return of collateral flow is also a problem with some junctional devices. The AAJT™ is the only junctional tourniquet that does not demonstrate return of collateral arterial flow in 60 seconds. In fact the application of the device in the axilla on an individual found to have lost 6 cm of his axillary artery showed no collateral flow return in over 20 minutes between time of application and removal during surgery. Further investigation of all the devices with regard to collateral flow is warranted. Early results from an ISR study recently concluded showed failure rates as high as 20-27% of correct applications of the other devices at 60 seconds but 0% failure at 60 seconds with the AAJT™.

Impact on ventilation has been of interest with an abdominal application. In a soon to be published study the application of the AAJT™ minimally impacts airway resistance in ventilated patients. Increases peak inspiratory pressures (PIP) were measured in paralyzed sedated and ventilated animals. Early findings show the increase in PIP measured from a baseline of 20 cm H₂O/L/second on average.

Primary Advantages of the AAJT™

- The AAJT™ is the only device to have an approved indication for bleeding in the pelvis which is a common complication in lower junctional trauma
- Pelvic hemorrhage, whether blunt or penetrating, is a common cause of morbidity and mortality in multiple settings
- Pelvic stabilization alone has not been found effective to decrease pelvic hemorrhage in penetrating trauma.
- It is the only device to not show the return of arterial flow through collateral blood flow within 60 seconds.
- It is the only device to have actually saved human life in upper and lower junctional bleeding to date
- It is the only device with human research that supports its safety and efficacy at each of its applications sites. Why use any device that has not been tested on live humans for safety and efficacy?
- It is the only device with independent international validation of its effectiveness and safety
- Speed of application (mean time of application 45 sec, faster than a single CAT application)
- Its is the only device simple enough to be applied by non-medical providers, since its application doesn't require knowledge of the vascular anatomy.
- It provides definitive cessation of arterial blood flow below the umbilicus, at the groin or in the axilla by stopping proximal arterial flow.
- Lower tissue pressures for increased comfort and decreased risk of secondary tissue and nerve injury. The ISR presented data in 2013 that the CRoC produced both muscular necrosis and nerve injury due to their high tissue pressures.
- The AAJT™ 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 AAJT™ is the only device found to remain on a patient and effective at hemorrhage control during confined space rescue maneuvers.
- The AAJT™ 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.
- The AAJT™ has only a minimal effect on diaphragm movement and airway resistance during application. Increases in PIP and airway resistance were not significant.
- It can be applied to one inguinal region for one sided inguinal or leg injuries with pressures far lower than the CRoC, JETT or SAM JT
- 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 ($3.6 \text{ mmol/L} \pm .95$) and after tourniquet release 65 minutes ($5.9 \text{ mmol/L} \pm .87$) ($p < 0.001$). 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. Their study is the most substantial study of a junctional device on human volunteers.

The Naval Medical Research and Development Unit San Antonio (NMRU-SA) Expeditionary Medicine Division conducted an altitude and pressure 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. NMRU-SA also validated that the manometer on the device accurately measured pressures applied to the casualty. The data from both of the above mentioned studies were presented at the Special Operations Medical Association conference in December 2012.

GHSU once again studies the device in 2013 for application to the groin and axilla and found that 13 out of 13 human subjects had full cessation of blood flow with single groin application and that the axilla application also had 100% efficacy in completely stopping all arterial flow in the upper extremity. The mean pressures required for the cessation of blood flow in axilla application were 168 mm Hg. For reference the SAM Junctional Tourniquet required over 790 mm Hg pressure to stop flow in a study preformed by Dr. Johnson at Wake Forrest University. In the individual groin arm of the study it was 100%

effective with the mean pressure required being 148.5 mm Hg. Again for reference the Institute for Surgical Research found that point mechanical compression devices (such as the CRoC and JETT) required pressures of 800 mm Hg to work effectively and were very position specific.

GRU just concluded a study in a hemicorporectomy animal model showed the AAJT™ to be 100% effective at keeping animals alive for one hour. This DoD funded study looked at a worse case scenario and found the AAJT™ to be extremely effective.

FDA Approval

Compression Works received FDA clearance for the AAT™ on October 22, 2011. On December 10, 2013 the FDA cleared the AAJT™ with new indications and capabilities. The AAJT is a Class II medical Device. The AAJT™ is made in the USA. 510(k) approval available upon request.

CE Mark Approval

Compression Works received CE mark approval on May 9, 2012. It is currently in use in Europe, Asia, Africa, North and South America.

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. It is available through GSA Schedule by Speer Operational Technologies. Other international distributors can be accessed through Compression Works.

NSN: 6515-01-616-4999



HEMORRHAGE STOPS HERE™