Summary of Safety and Clinical Performance of the AAJT-S
The Abdominal Aortic and Junctional Tourniquet – Stabilized (AAJT-S)

The Abdominal Aortic and Junctional Tourniquet – Stabilized (AAJT-S) by Compression Works was envisioned to allow for a treatment option for massive bleeding in the junctional regions of the body and pelvis. These areas constitute a particularly difficult problem for pre-hospital providers and initial hospital providers. These injuries result in overwhelming amount of blood loss. The AAJT-S was designed to provide a solution to stop bleeding in these areas and to deliver these patients to definitive surgical care alive.

Since 2009, over 65 articles have been published related to the technology and more specifically involved the evaluation of the AAJT-S device and its capabilities. As the research progressed more areas in which the device provides benefit have been validated in both in the lab and in human prospective clinical trials.

The device was first formally studied in animals in 2009 at the Medical College of Georgia.[1] Abdominal application for 1 hour showed that the device stopped flow to femoral arteries by power and spectral doppler. Serum lactate increased 2.3 moles/l with tourniquet release ($p<0.001$). Serum potassium had no change with tourniquet release at 5 minutes and 10 minutes post release levels. Gross and histological examination revealed no significant ischemia or necrosis of the small and large intestines.

First human studies on the AAT/AAJT

Two human studies followed in 2012 by researchers at the Medical College of Georgia[2] and a larger human trial in the United Kingdom Ministry of Defense.[3] The first was published in *Journal Trauma Acute Care Surgery* and the later published in *Military Medicine*. The first study looked at 9 subjects all of which had decreased or full cessation of femoral artery flow with device application. 7/9 had full cessation of flow at 180 mm Hg bladder/tissue pressure. The second study looked at 16 healthy volunteers and showed that the device stopped all blood flow in the common femoral artery in 15/16 participants. The one unsuccessful subject was above average height, weight, body mass index and abdominal girth. Both studies showed the device to be effective in the control of blood flow in the pelvis and proximal lower limbs and potentially life saving.

First case uses published

In 2013, the device was manufactured and deployed and was quickly used to save life. The first case reports appeared in 2013 and 2014. All three were published in the *Journal of Special Operations Medicine*. The first by UK physicians treating an injured Afghanistan soldier injured by an explosive mechanism.[4,5] The casualty had wounds to the pelvis and lower extremities and was failing to improve with advanced interventions. The device was placed on and the casualty began to stabilize. Ultimately, he survived to reach definitive surgical care and lived.

The second use was to treat an upper junctional hemorrhage (axilla bleeding) in a trauma center in Birmingham, AL.[6] The patient was stabilized, bleeding was brought under control and the patient was successfully resuscitated and lived. The third published case use was for lower junctional bleeding (groin bleeding) in a patient shot through the upper left leg transecting his femoral artery.[7] This patient was also stabilized, bleeding was brought under control and the patient was successfully resuscitated and lived. The later two uses were at the time off label uses and led to the second FDA 510(k) approval to

change the name of the device from the Abdominal Aortic Tourniquet (AAT) to the Abdominal Aortic and Junctional Tourniquet (AAJT).

Human studies showing effectiveness at groin and axillary sites for lower and upper junctional hemorrhage control

In 2014, a study conducted at the Medical College of Georgia demonstrated effectiveness of the AAJT device to control axillary and femoral artery blood flow.[8] This was published in the *Annals of Emergency Medicine*. This study showed 13 of 13 healthy volunteers had cessation of blood flow in the proximal femoral artery and axillary artery. Mean bladder pressure for zero spectral Doppler flow for the proximal femoral artery over the groin was 148.5 mm Hg and mean bladder pressure for zero spectral Doppler flow in the axillary artery was 168 mm Hg.

2-hour application of AAJT

The device carries an approved recommendation for up to one hour of application at the abdominal site. It has a 4-hour recommendation for the groin and axillary placement sites. In 2017, researchers in the United States Air Force 59th Medical Wing, responsible for testing evaluation and research of medical interventions, studied the device application for 2 hours at the abdominal site.[9] Their data published in the *Journal of Surgical Research* concluded that the AAJT application in an animal model of severe shock resulted in a favorable hemodynamic profile because of afterload support. Their study did not demonstrate any adverse consequences because of caval compression, bowel injury or pulmonary dysfunction. Specifically, histological analysis of hematoxylin and eosin-stained pulmonary and bowel tissue did not demonstrate any evidence of necrosis, edema, or inflammation after 2 hours of application at the abdominal site.

First traumatic cardiac arrest study

Additionally in 2017, the researchers at the 59th Med Wing also conducted a study looking at the effect of the AAJT's abdominal site application on Traumatic Cardiac Arrest.[10] The study, published in *Military Medicine*, looked at 12 splenectomized, Yorkshire, male swine (70-90 kg) randomized into two groups: presence or absence of AAJT placement. Following 3 minutes of arrest, the animals underwent CPR using a mechanical compression device with either the presence or absence of the AAJT. Concurrently, 5 units of whole blood (2,500 ml) were delivered. Efficacy was assessed by analyzing rates of return of spontaneous circulation (ROSC) and survival. The AAJT group had an 83% survival rate.

4-hour Application of AAJT

In 2018, researchers in Stockholm, Sweden looked at a 4 hour application at the abdominal site.[11] Their study was published in the *Journal of Trauma and Acute Care Surgery*. They found no issues with 60 minutes of application. Reperfusion consequences were reversible after 60 minutes. After 240 minutes of application with reperfusion was survivable in the intensive care setting. Their study found the AAJT may be considered a rescue option in cases of hemorrhagic shock from pelvic and lower extremity bleeding if blood transfusion is not immediately available. They suggest that the AAJT should only be removed in an intensive care setting to counter the adverse reproduction effects seen at 240 minutes. No effects of 60 minutes of application at the abdominal site were demonstrated. They note that prolonged use carries substantial adverse effects, but they must be considered in relation to the indication of the device, catastrophic uncontrolled hemorrhage from which death otherwise is likely.

Postpartum hemorrhage (PPH)

In 2018 researchers looked at the efficacy of the AAJT in controlling hemorrhage in Postpartum Hemorrhage (PPH).[12] Findings published in the *Journal of the Royal Army Medical Corps*, suggested that in resource limited environments, the application of the AAJT can provide for stabilization in these patients.

Equivalency to Zone 3 REBOA

The device has been studied by the military and independent researchers as a bridging device that extends the physiologic benefits of Zone 3 Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) to the point of injury. It is capable of aiding resuscitative efforts pre-hospital to allow more patients to reach the hospital where damage control surgery or REBOA can be initiated.

The researchers at the 59th Med Wing in San Antonio, TX published a study in the *Journal of Surgical Research* demonstrating equivalency of the AAJT external application at the abdominal site with Zone 3 REBOA[13]. Dr. Rall, et al demonstrated that the AAJT group had a higher mean arterial pressure improvement than the REBOA group (59.9 vs 44.6 mm Hg, respectively; $p<0.05$). Researchers at the Institute of Surgical Research, the United States Military Medical research and testing center, also conducted studies and published a paper demonstrating equivalency between the AAJT and Zone 3 REBOA.[14] The ISR paper was published in the *Journal of Trauma and Acute Care Surgery*.

In 2019 researchers in Stockholm, Sweden further evaluated the use of the AAJT as a bridging mechanism to reach definitive care and transition to Zone 3 REBOA in a porcine class VI hemorrhage model.[15] Their study published in Journal of Trauma and Acute Care Surgery, notes that the AAJT requires low technical skills and can thus be used by nonmedical professionals. They found it was feasible to transition from the AAJT to REBOA and that it may be beneficial to do so prior to taking a patient to surgery. The transition between the AAJT and Zone 3 REBOA was also found to be effective and safe by researchers at the 59th Med Wing in a study published in Journal of Special Operations Medicine.[16] They also found that the transition between the use of AAJT initially to infra-renal REBOA is effective.

Traumatic cardiac arrest – Australian study

Researchers in Australia looked at Traumatic Cardiac Arrest[17] and published their findings in *Resuscitation*. While the length of asystole was longer than the 59th Med Wing study, their prospective trial showed that the application of the AAJT increase ROSC by 22%.

UK studies relate to bridging a patient from point of injury to REBOA at the hospital and application success rates by Combat Medical Technicians in the UK Ministry of Defense

In 2019, British researchers prepared a review of the evidence surrounding the AAJT finding it beneficial as a prehospital device in the exsanguinating patient, those in traumatic cardiac arrest, as a bridging device (to Zone 3 REBOA) and as a fluid conserving device in resource-limited environments.[18] They also compared the cost of device and training of the AAJT and REBOA as well as the sterility requirement of REBOA and its invasiveness. Their conclusions, published in the *Journal of Special Operations Medicine*,

were that the AAJT likely offers an effective, low-training-burden intervention to be applied in the prehospital environment to salvage "potential survivors" with injuries distal to the aortic bifurcation.

In 2021, British researchers looked at the effectiveness of the AAJT-S applied by UK Combat Medical Technicians.[19] They found CMTs can use the AAJT-S successfully after a 1-hour training session in the majority of applications. Application was successful in both daylight and low-light conditions.

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