Diagnostics and Biomarkers

BrainScope Ahead® 300 System

Traumatic brain injury (TBI) has received increasing attention in recent years as the public is made more aware of the long-term consequences of mild TBI (mTBI) resulting from injuries sustained during military combat operations. The rapid and accurate identification and triage of head injured persons who are at-risk for having sustained structural brain injury and are in need of further clinical assessment represents a significant unmet public health need. In a project funded by the Combat Casualty Care Research Program (CCCRP), BrainScope developed the BrainScope Ahead® System. BrainScope's Ahead® technology employs an electroencephalogram (EEG), a proven electrophysiological core technology, in a portable, point-of-care, non-invasive device designed to improve early identification, staging, and optimization of treatment for patients who are suspected of a TBI. The Ahead® system incorporates sophisticated classification algorithms that enable rapid assessment of a patient's brain injury, specifically identifying those patients who are likely to have a positive finding for structural brain injury visible on a computed tomography (CT) scan of the head. Development of the next generation platform, the Ahead® 300 (Figure 1), was funded under the Army Rapid Innovation Fund Research Program and CCCRP. The primary objective of this study was to conduct a multi-center, prospective clinical trial (B-AHEAD III) in order to validate the clinical utility of the BrainScope Ahead® 300 device for the acute identification of structural brain injuries in the mTBI population. In addition, the study sought to extend findings of the B-AHEAD II Trial in a large population to replicate and extend the previous trial using the BrainScope Ahead ® 300 device. The clinical trial included 981 participants from 11 acute care emergency departments in the US. The clinical validation studies were completed in early 2016. In September 2016, the US Food and Drug Administration granted clearance of the BrainScope Ahead® 300, the first handheld medical device for assessment of the full spectrum of TBI. Having a rapid, reliable, and sensitive assessment device to aid in the triage of patients who are suspected of a traumatically induced brain injury will lead to appropriate and timely diagnosis and subsequent medical care for affected Service Members.

FIGURE 1: Combat Medics and Physician Assistants of the 1st Brigade Combat Team of the 82nd Airborne testing the Ahead® 300 system. Photographs courtesy of Michael Singer.