Multimodal Assessment of Sports Concussion Using *BrainScope One*

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1.0 Introduction

Despite the prevalence of concussion in sports, there is no agreed upon gold standard for diagnosis of concussion. There is, however, consensus that concussions may have many different underlying brain pathologies, with different individual profiles of functional abnormalities present at time of injury. Recognition of the heterogeneity of concussion has fueled recommendations for comprehensive multimodal assessments. Guidelines for concussion diagnosis have advanced from reliance on subjective symptom checklists and single assessment modalities to current support for multimodal assessments, as highlighted in the consensus statement from the 5th International Conference on Concussion in Sport held in Berlin, October 2016 (McCrory, et.al 2017). The increased components in multimodal assessments allows the clinician to make more informed and confident decisions about the athlete's disposition (Elbin et.al, 2016). Pearce and Colleagues (2015) found that multimodal concussion assessments were useful as athletes may show improvements in one modality (functional area) before others and use of more than one modality of assessment can allow the clinician more precise surveillance of an athlete's recovery. The inclusion of multimodal capabilities in a concussion tool increases its sensitivity over a single modality tool (Broglio et. al, 2007). The FDA cleared *BrainScope One*[2] medical device provides clinicians an objective, multimodal head injury assessment capability to aid in the clinical diagnosis of concussion, in mild head injured patients (GCS 13-15), 18-85 years old, within 3 days of injury. It has two core electrophysiological biomarkers which are EEG based - the Structural Injury Classifier (SIC) derived and validated to indicate the likelihood of a structural brain injury visible on CT scan, and the Brain Function Index (BFI) which indicates the probability of brain function impairment. *BrainScope One* has been demonstrated to have high sensitivity (99%) for identification of the likely presence of intracranial blood ≥1 cc (SIC), and to reflect functional brain impairment (BFI) such as that seen in concussion which scales with clinical functional severity (Hanley, et.al 2017, Hanley, et.al 2018)

In addition, the device is configurable by the clinician to include two rapid neurocognitive tests which can be performed by the patient on the device, and an extensive library of digitized standard concussion assessment tools (including, for example, SCAT5, SAC, VOMS). *BrainScope One* is handheld, easy to use and integrate into patient assessment. The device provides a comprehensive summary of all tests performed which can be used to give the provider a comprehensive, multimodal panel of the patient's assessment results (Figure 1 below).

This report is based on patient data from the *BrainScope One* Registry which contains de-identified information about the initial evaluations performed at participating

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[2] *BrainScope One* device cleared as the Ahead® 300 device (K161068)

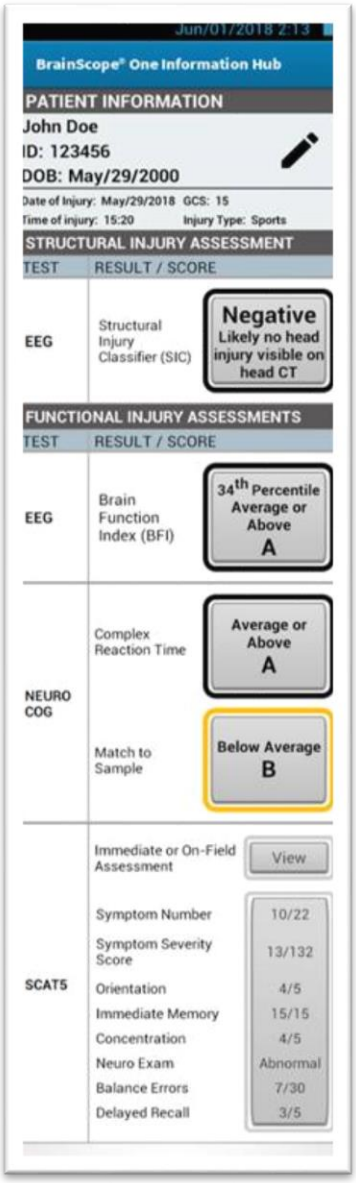
University sports sites using *BrainScope One*. Results demonstrate the clinical integration of *BrainScope One* as part of the initial evaluation using a multimodal assessment in mild head injured (mTBI/ concussion) patients in the sports environment.

2.0 Methods

2.1 Multimodal Data Collection: There are three main components to the *BrainScope One* assessment battery used:

2.2.1 EEG: *BrainScope One* collects EEG data (average ~5 minutes) from the frontal regions of the brain using a disposable headset placed on frontal and frontotemporal regions of the patient's forehead. In real-time, during data acquisition, on-line artifact algorithms identify and remove contamination (artifacts such as that caused by eye movement or muscle activity) from the data, until one to two minutes of artifact-free EEG data are obtained. This data is then used to extract features reflecting the changes in the EEG signal which are associated with structural and functional brain injuries. Results of the SIC are reported as Positive (Likely brain injury present visible on head CT; Consider further evaluation, including advanced neuroimaging or CT scan), Equivocal (consider further evaluation or observation, identifies patients close to the positive threshold, much like used in medicine today for "pre-diabetic"), and Negative (Likely no brain injury visible on head CT). Results of the BFI are reported as a percentile of the normal distribution and categorically based on significance of deviation from the mean of the normal distribution. The BFI aids in the interpretation of the likelihood of functional brain impairment compared to a non-injured population.

Figure 1: *BrainScope One* "Information Hub", summarizing findings from all modalities/assessments included in the patient evaluation (configurable by clinician). Details screens are also provided if selected.



2.2.2 Neurocogniive Tests: The *BrainScope One* device incorporates two independently normed neurocognitive tests, Procedural (or Complex) Reaction Time and Visual Match to Sample (M2S) (Vincent, et.al 2017). These performance tests allow assessment of attention, working memory, executive function, and visual spatial memory and can be performed directly on the device by the patient. As with the BFI, these results are expressed as a percentile of the normal (non-injured) distribution.

2.2.3 Signs and Symptoms: BrainScope One contains an extensive library with menu for selecting digitized concussion assessment tools to allow the user to include inventories of signs and symptoms, assessment of balance, VOMS, SAC, SCAT3/5, and others.

2.2.4 Summary of findings: The *BrainScope One* "Information Hub" presents a digital summary of all assessments performed in one place on the device, much like a blood panel. Figure 1 shows and example of the information hub screen.

3.0 Findings from Registry

3.1 Demographics: The patient population consisted of 64 patients whose clinical evaluation included *BrainScope One*, and who were entered in the *BrainScope One* Registry (between 8/8/2017 and 4/30/2018) from 8 university sports programs. All patients were student athletes who sustained a head injury. Patients were between the ages of 18 and 25 (mean 20.25 years, sd=1.29), 78% male and with a GCS ranging from 13-15 (mean 14.78) and were evaluated within 72 hours of injury (mean 19.8 hrs.). Most injuries occurred in football players (58%) and the most common mechanism of injury was head-head collisions (36%).

3.2 BrainScope One Evaluations: Ninety percent (90%,58/64) of the athletes evaluated with the Structural Injury Classifier (SIC) were found to be Negative (52/58), indicating likely no injury visible on CT, or Equivocal (6/58), indicating need for further observation and evaluation. As this report focuses on the BFI as part of the determination of concussive injury, the small number of athletes with a Positive SIC results (indicating likely structural brain injury visible on CT or advanced neuroimaging) are not reported on herein where focus is on functional brain injury such as that seen in concussion.

Of the 58 athletes, 45 (78%) were removed from play following injury evaluation. Further, in 80% (36/45) of these athletes the evaluations were multimodal – including BFI and neurocognitive tests performed on the *BrainScope One* device. Additional observations on the assessments follow:

3.2.1 Relationship between BFI and neurocognitive test findings: Concordance between the BFI score and performance on the neurocognitive tests was studied to assess the potential value of using multimodal inputs. Table 1 summarizes the relationship between the two assessment modalities for the 36 patients for whom both BFI and neurocognitive assessments were performed on the device. This table shows the mean and median BFI score for those where one or both of the two neurocognitive tests (Procedural Reaction Time (PRT) or Match to Sample (M2S)) had a percentile below 50 and for those for whom both neurocognitive tests were greater than or equal to 50. For this investigation the "throughput" output score was used for the neurocognitive assessments, as it is the measure that combines both reaction time and accuracy, and as such is considered to be more sensitive than either one alone.

Table 1 below shows a clear relationship between BFI scores and neurocognitive test

scores. The median BFI scores can be seen to be considerably lower, ~39% lower ((70-42.5)/70), in the case where either or both of the neurocognitive tests scores were below the 50th percentile (left panel) compared to the BFI score when neurocognitive test scores are above or equal to the 50th percentile (right panel).

Table 1: BFI scores (percentiles) for performance (throughput) on neurocognitive tests that were above or below the 50th percentile for the test.

	Neurocognitive Scores <50 (PRT and/or M2S)			**Neurocognitive Scores ≥ 50 (PRT and M2S)**		
BFI Score	**N**	**Mean**	**Median**	**N**	**Mean**	**Median**
	28	47.32	42.5	8	61.13	70.0

4.0 Discussion:

This report demonstrates that, in the sports environment, the *BrainScope One* multimodal capability can be incorporated into the clinical evaluation at time of injury (within 3 days), facilitating rapid multimodal evaluation at the point of care. Further, *BrainScope One* adds a novel objective biomarker of brain function impairment as an adjunct to the dimensions of injury that can be assessed in the multimodal evaluation of sports concussion.

Results demonstrate a concordance between BFI and neurocognitive scores which can strengthen the confidence of clinicians in the clinical assessment of their athletes. The BFI can add objectivity beyond the subjective report of signs and symptoms and cannot be "gamed," or influenced by test/retests learning effects. The high concordance between BFI and neurocognitive scores can add confidence to the assessment. In addition, while the numbers herein were small, it is of note that there were cases that showed a dissociation between BFI scores and neurocognitive performance (BFI<50 and neurocognitive tests were ≥50). In such cases, for example, a high BFI with low neurocognitive function can lead the clinician to consider the possibility that the neurocognitive tests were low due to factors other than concussion, for example, comorbidities, presence of drugs or alcohol, or "gaming" for secondary gain. The BFI is derived from the EEG and has been shown to be resistant to many such factors (Michelson et.al, 2018). Further study in larger numbers of subjects, with more female patients, are underway.

This data demonstrates the use of *BrainScope One's* multimodal assessment capabilities in the initial clinical evaluation of concussion, providing multimodal data to assist in the assessment of mild head injuries.

5.0 Acknowledgement:

The data presented represents the efforts of all the sports sites that participate in the *BrainScope One* Registry and whose data is included in this report.

6.0 References:

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BrainScope One is intended for patients 18-85 years of age presenting within 72 hours of mild head injury. BrainScope One is not a stand-alone diagnostic nor a replacement for CT scan. Please refer to: www.brainscope.com/products for complete indications.