Letter to the Editor

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Inaccuracies in the Article "Quickly Evaluating an Emerging Medical Technology Using Feedback From the Field: A Case Study of the BrainScope One and Infrascanner 2000 User Evaluation"

Dear Dr. S. W. Rothwell,

As Chief Scientific Officer of BrainScope, I read with interest the article entitled, "Quickly Evaluating an Emerging Medical Technology Using Feedback From the Field: A Case Study of the BrainScope One and Infrascanner 2000 User Evaluation."

The article focuses on the importance of using methods for early feedback from the field use of medical devices in informing acquisition and as such is dependent on use of the device being evaluated according to appropriate indications for use. Seeking feedback from the field is important; however, it is noteworthy to point out that there are several inaccuracies or limitations to the review.

First, some statements made about the BrainScope FDA cleared (510(k) #K190815) medical device are inconsistent with the intended device use and are inaccurate regarding algorithm components such that they may be misleading as to the device's utility and potential value. For example, (1) Assumptions about the device's "reliance on patient summary information" is inaccurate. Although multivariate, the most significant contributions to the artificial intelligence (AI) algorithm are EEG features, with minor contribution by specific clinical factors. Importantly, the clinical features by themselves do not lead to the accurate prediction of CT findings or outcome but only serve as a component of the "profile" identified by the algorithm; (2) The statement that BrainScope requires "normal state of mind" is not accurate. The device was developed in Emergency Department (ED) trauma centers, and algorithms take into account factors that will likely be encountered in such trauma environments (e.g., fatigue, anxiety, pain, altered mental status, etc.) in the derivation of the algorithms.

Second, it is of note that this evaluation was done in far-forward environments and included roles 1-3, which might represent very different criteria for utility in each. If, at role 1, the standing rules require, as noted, anyone in the vicinity of an improvised explosive device blast be evacuated, the BrainScope evaluation may add little immediate value in that environment. However, in an environment where evacuation is problematic, the value of avoiding a risky evacuation or a need to conserve the force locally, then such a tool would offer considerable value. Such potential value has been suggested in a recent publication in this Journal.[2] Furthermore, in role 2 or higher, BrainScope could be employed as a decision support tool, providing objective data for assessment of both structural brain injury and functional or concussive injury.

Third, the reliance on noted responses about satisfaction with existing clinical decision tools, and confidence about knowing when someone needs a CT, does not take into consideration the potential added value of an objective marker with high accuracy in the assessment process. While I have respect for the clinical judgment, it is worth noting that there was no follow-up regarding CT evaluation after evacuation to validate the clinical judgments with or without BrainScope. Further, study of the integration of BrainScope and comparisons to CT scan results when they are obtained would be required before conclusions on false positive and negatives could be considered.

Clinical experience in the civilian world, in what would be considered equivalent to a role 3 environment, 30.8% decrease in CTs have been reported[1] when BrainScope was integrated in clinical ED triage. The potential of reducing unnecessary CT scans by integrating BrainScope with standard care protocols could help reduce evacuations and conserve fighting strength.

Lastly, in the article it was stated that "These results have been communicated to the respective manufacturers…." BrainScope has received no such feedback, although fundamental to the intent of the process.

I would like to again thank the authors for highlighting the importance of early in-field feedback and hope that the clarifications herein help in the evaluation of the potential

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contribution of the BrainScope device. References are available from the author.

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CONFLICT OF INTEREST STATEMENT

The author is the Chief Scientific Officer of BrainScope Company and inventor on patents licensed by BrainScope from New York University School of Medicine.

REFERENCES

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