LETTER TO THE EDITOR

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Response to Dr. Prichep's Letter to the Editor

Dear Dr. S. W. Rothwell:

We would like to thank the BrainScope Company and Dr. Prichep for their recent letter highlighting the importance of early feedback from military personnel in the field and for their efforts toward developing technology that may improve Warfighter outcomes. Dr. Prichep is the Chief Scientific Officer of BrainScope Company and is also listed as the inventor on patents licensed by BrainScope from the New York University School of Medicine. Dr. Prichep is therefore clearly positioned to know the BrainScope One and the research conducted on the utility of the device in civilian settings extremely well. In response to Dr. Prichep, we would like to note that our recent article was focused on evaluation of the BrainScope One in the military operational (field) setting. Our independent evaluation utilized focus groups and interviews with 158 deployed medical personnel at eight bases throughout Afghanistan, Iraq, and Kuwait, and was designed to examine if and how the DoD should implement FDA-approved technology candidates (the BrainScope One and the Infrascanner 2000) for head injury assessment in far-forward medical teams. Military medicine in operational environments is quite different from medicine in civilian environments; in addition to clinical utility, operational utility requires rugged lightweight equipment that is simple to use and maintain in austere environments. Therefore, qualitative feedback from deployed medical personnel may not mirror the findings in civilian settings.

As the BrainScope One's algorithm is proprietary and the data collected for our evaluation were qualitative, not clinical, we cannot directly comment on Dr. Prichep's statements that "the most significant contributions to the [BrainScope One's] AI algorithm are EEG features" or that the BrainScope One is "an objective marker with high accuracy." Instead, our article accurately reports that providers at five of the eight facilities expressed concerns about the BrainScope One's incorporation of clinical patient information into its proprietary algorithm. Our participants also requested more information on how the BrainScope One compared with existing traumatic brain injury (TBI) screening tools such as the Military Acute Concussion Evaluation 2.

Dr. Prichep also states in her letter that some statements on the BrainScope One's proprietary algorithm reflected usage "inconsistent with intended device use." We obtained feedback after training events held in remote, far-forward locations, which do not have the capacity to hold patients. Thus, the use of healthy medical personnel pretending to suffer a head injury and providing a clinical history consistent with such an injury was the only feasible method of practical training using the BrainScope One. The training was led and supervised by an independently trained BrainScope One user. The evaluation team also verified that all medical personnel included in the evaluation were well-versed in medical TBI assessments, including TBI screening tools. Although we agree with Dr. Prichep that using the device only on injured personnel may have reduced the number of false positives that we observed, the use of healthy practice patients is a standard medical training technique, and it was accurately described in the article. The concerns raised by participants that the Brainscope One reported results consistent with TBI in normal individuals with reported TBI history and symptoms both decreased provider confidence in the objectivity of the results and raised questions among providers about the relative contributions of the algorithm versus symptoms and history.

Dr. Prichep notes that utility (as well as suitability) may be different in each role of care, which is why all 158 participants were asked about each device's utility (as well as suitability) at each role of care. Our article reports that although 55% (out of 242) of the statements about the BrainScope One's utility at one or more roles of care were negative, and 24% of the statements received were positive in regard to its potential benefits at various roles of care. Positive and negative statements about both devices were discussed in the article.

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Dr. Prichep correctly notes that the BrainScope Company was not briefed on the results. An erratum removing this misstatement is currently in press at the journal.

Overall, our original article was designed to show the value of end-user feedback in operational settings within the military medical acquisitions process and used the evaluation of BrainScope One and the Infrascanner 2000 as a case study of this methodology. This evaluation highlighted military-relevant shortcomings of the current iterations of both devices as well as areas of future promise. We look forward to assessing future TBI assessment device candidates that have the potential to improve Warfighter medical outcomes and performance in the operational environment.

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CONFLICT OF INTEREST STATEMENT

We have no conflicts of interest.

MAJ Stephen Krauss, PhD, MS, USA*

MAJ Sarah Sanjakdar, PhD, MS, USA†

Brian Dacanay, MS†

Amy Adler, PhD*

Louis Jasper, MS†

*Research Transition Office, Walter Reed Army Institute of Research, Silver Spring, MD 20910, USA
†Project Management Office, Warfighter Brain Health, US Army Medical Materiel Development Activity, Fort Detrick, MD 21702, USA