

Introduction

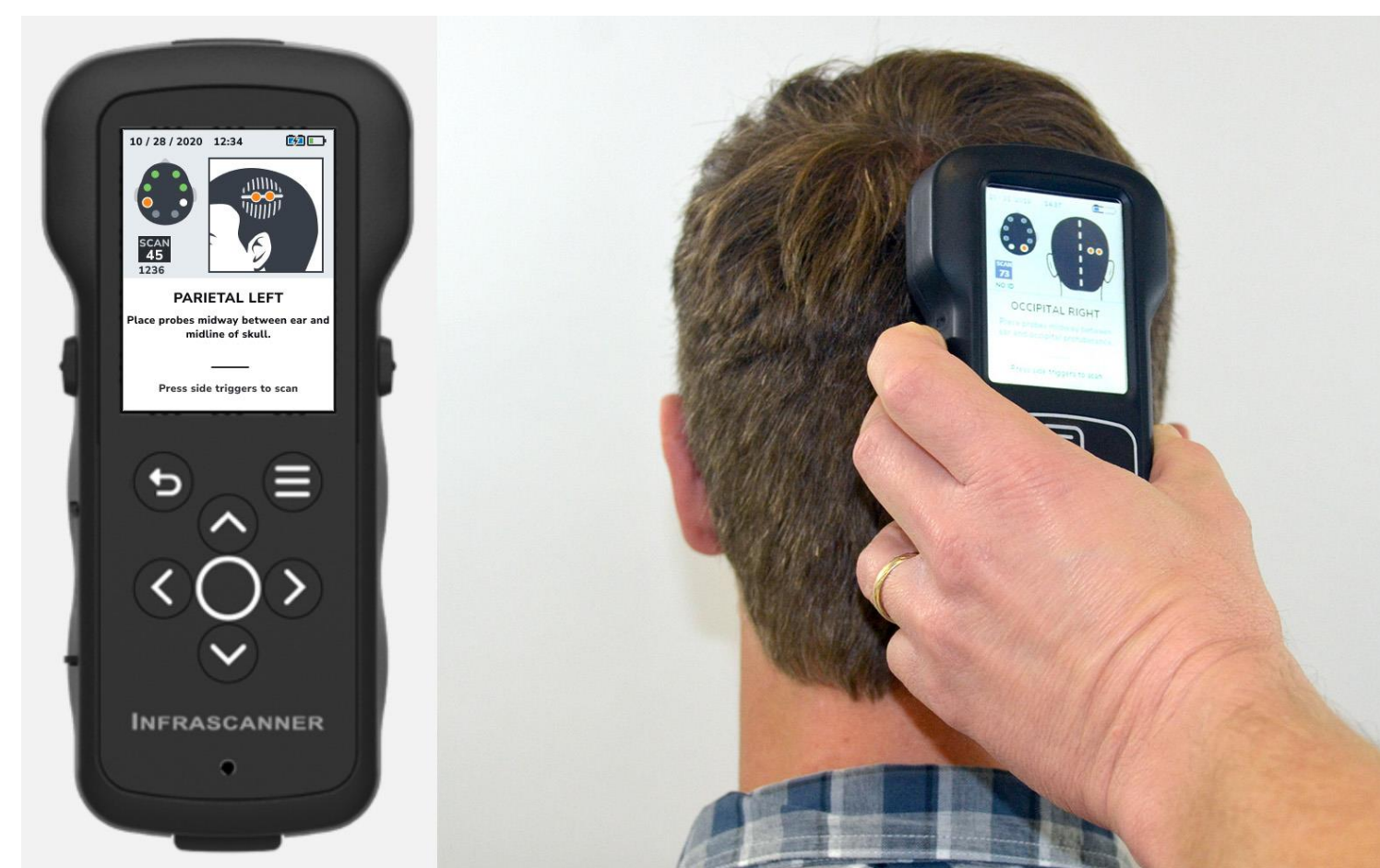
Intracranial hematomas are an important, treatable cause of secondary brain injury in patients with head trauma. Timing of the intervention for traumatic intracranial hematomas is critical for good outcomes, specifically since expansion of the hemorrhage can result in debilitating, and sometimes fatal, outcomes. A first generation, handheld brain hematoma detector for early triage and diagnosis of traumatic brain injury (TBI) project was supported initially by the Office of Naval Research (ONR) and later by the Marine Corps Systems Command (MARCORSYSCOM). After obtaining De Novo FDA clearance, over two hundred Infrascanner Model 2000 systems were deployed in Marine Battalion Aid Stations (BAS) around the world.

In 2017 U.S. Army Medical Materiel Development Activity (USAMMDA) funded development of the vastly improved, Infrascanner Model 2500 which was FDA cleared in 2020. This technologically advanced Model 2500 is currently in final stages of development

Capability Description

The Infrascanner 2500 was developed to provide a rapid evaluation of head trauma patients with suspected intracranial hemorrhage. The near infrared (NIR) based technology is portable and noninvasive, allowing for repeated use without concern for radiation dose. The principle used in detecting intracranial hematomas with the Infrascanner is that extravascular blood absorbs NIR light more than intravascular blood. This is because there is a greater (usually 10-fold) concentration of hemoglobin in an acute hematoma than in normal brain tissue where blood is contained within vessels. The Infrascanner compares the left and right side of the brain in four different brain areas. The absorbance of NIR light is greater (and therefore the reflected light less) on the side of the brain containing a hematoma, than on the uninjured side. **In a recently published study from Duke Neurosurgery, a total of 500 TBI patients were evaluated. There were 104 intracranial hematomas, confirmed by a CT scan completed on all subjects within 30 minutes of the Infrascanner test. For bleeds within the detection capabilities of Infrascanner (bleeds of more than 3.5 mL), the sensitivity was 94% and the specificity 96%. In those patients who required surgical intervention, the device demonstrated 100% sensitivity**

Methods



An advanced prototype of Infrascanner Model 2500 completed a Military Users' Evaluation (MUE) in October of 2022 with 51 clinicians at 5 different sites. The sites were: Ft. Detrick, Maryland; University of Alabama at Birmingham; Brooke Army Medical Center, Joint Base San Antonio-Fort Sam Houston, Texas; Lackland Air Force Base, Texas; and Marine Corps Base Quantico, Virginia. The clinicians included: 28 medics, 11 physicians and others (nurses, biomedical technicians, etc.). Following short training the clinicians operated the Infrascanner in a simulated scan. Following the hands-on evaluation, the users rated the Infrascanner in a questionnaire that included 49 questions on different aspects of device usage. There were 46 comments covering a wide range of topics.

Results

Overall, the average results of the MUE were 95% positive response to 49 questions. By comparison, in the MUE conducted by Marines at Camp Pendleton, California in 2017, the Infrascanner Model 2000 demonstrated 85% positive response.

Impact to the Warfighter / Significance

- The Infrascanner is a clinically effective screening solution for head trauma patients in pre-hospital settings where timely triage is critical.
- It is intended to be used as an adjunct to the standard diagnostic workup to aid in the decision of choosing evacuation destination (a regional trauma center or the nearest hospital), evacuation urgency (air or ground) and in prioritizing patients with suspected hematomas for urgent CT scans and surgical interventions.
- Infrascanner was field tested at the Fallujah Level 2 Shock Trauma Platoon (STP) of Combat Logistics Battalion 1 commencing February 2008 under special permit from Marine Corps Lt. Gen. John Kelly. That evaluation demonstrated the impact of the device's high sensitivity: "The Infrascanner located in Fallujah provided immediate information that was not available by any other means and offered life-saving prioritization of patients who required immediate surgical intervention." (CDR Dr. Luis Becerra)
- In 2012, 2nd Battalion, 4th Marine Regiment performed a field evaluation during combat operations in Helmand Province, Afghanistan of four prototypes of Infrascanner Model 2000. That evaluation demonstrated the impact of the device's high specificity: "The Infrascanner has proven to be an exceedingly valuable asset this deployment, both in finding problems and a lack of problems (therefore preventing air medical evacuation, saving tens of thousands of dollars, preserving limited assets and reducing lost man power)." (Lt. Dr. Victor Jourdain).

Applicability to Medical Roles of Care

Rapid triage, diagnosis and treatment are critical in minimizing the adverse consequences of the more serious TBI cases. Since many TBI cases occur in clusters and are part of complex, extensive trauma to the individual victim, the challenges presented to on-site medical personnel are significant. For patients with moderate-to-severe TBI in particular, diagnosis within the first (the "golden") hour of the traumatic event is critical as intracranial hematomas can result in death or significant neurological impairment. Current SOP involves an immediate clinical evaluation and neurological examination. Delayed hematomas also occur in significant numbers and may not be diagnosed until significant neurological impairment occurs. A CT scan is the definitive diagnostic modality. A rapid diagnosis, followed by immediate evacuation to a location which has CT and neurosurgical intervention capability, is paramount to maximizing survivability and minimizing irreversible neurological impairment. The Infrascanner is aimed for Role/Level 1 in a Battalion Aid Stations as primary use. A similar application is in military ambulances and Role/Level 2 installations.

Developmental Status of the Technology

The MUE completed the development phase of the Infrascanner advanced model 2500. The design is transitioning now from engineering to production and in 2024 the U.S. military will begin fielding the system.

Acknowledgment

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