Assessing traumatic head injuries in the field

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A near-IR-based portable device can identify and localize suspected brain bleeding in trauma patients.

Every year 1.5 million Americans incur head injuries, which represents only a fraction of the head injuries observed annually worldwide. While there are many aspects of a head injury that must be addressed by a physician, the most urgent of these is brain bleeding or intracranial hematoma. Failure to detect and treat such injuries within the first hour significantly increases the possibility of severe neurological deficits and even death. Patients with intracranial hematomas often require surgery and therefore must be transported to a trauma center that has neurosurgical coverage. This requirement highlights the need for rapid and accurate field diagnosis of such injuries.

In rural and underdeveloped areas of the world, as well as on a battlefield, timely identification of patients who require surgery can be difficult. Methods for identifying patients with hematomas in these settings primarily include a neurological exam and, when available, x-rays. However, both of these modalities are notably unreliable. The computed axial tomography (CT) scan is the gold standard for identification and localization of traumatic intracranial hematomas; however, its high cost and limited availability restricts its use in many areas of the world. As such, a low-cost portable system that could achieve high levels of diagnostic accuracy would be a welcome innovation.

To address this need we formed a small company, InfraScan, with the hope of fundamentally changing the way head injuries are evaluated. This effort was spearheaded by Britton Chance from the University of Pennsylvania, Claudia Robertson from the Baylor College of Medicine, and an entrepreneurial team from Drexel University. Together we developed the Infrascanner, a handheld, battery-operated, noninvasive brain-hematoma detector that uses near-IR (NIR) technology to assay the differential light absorption of the left versus right brain. Under normal circumstances, the brain’s absorption should be symmetrical. However, when additional underlying extravascular blood is present, there is a greater local concentration of hemoglobin; consequently, the light absorbance is significantly greater and the reflected component is commensurately less. This differential is detectable via sources and detectors placed on symmetrical lobes of the skull.

The system is depicted in Figure 1 and consists of two components: the sensor and a personal digital assistant (PDA). The sensor consists of an 808nm diode laser located 4cm from a silicon light detector, which is covered by a NIR optical filter. The laser delivers NIR light to the tissue under the sensor via an optical fiber, and the detector receives the signal via a separate optical fiber after the light has interacted with the tissue. The 4cm separation between the light source and the detector allows measurement of NIR absorbance in a volume of tissue approximately 2cm wide by 2–3cm deep. The detector signal is then digitized.
and transmitted via a Bluetooth wireless link to the PDA. Using this setup, a full head scan can be acquired in less than 2min.

Because this system allows for rapid diagnosis in situations where CT is not available, the Infrascanner can significantly improve the way our health system identifies patients who need neurosurgical intervention. Furthermore, it can also function as an adjunct tool, in combination with a CT scanner, for regular monitoring of patients within hospitals and intensive care units.

The Infrascanner completed multicenter clinical trials in the USA and abroad, and the results were submitted to the US Food and Drug Administration in November of 2008, with expected clearance in early 2009. We have also completed field evaluations in collaboration with the US Navy and Marines stationed in Iraq. By achieving these landmark trials, we hope for a US launch sometime in 2009.

NIR diffuse spectroscopy is a very active field of research, and the Infrascanner is one of the first products of this technology that has completed the path from lab bench to bedside. In addition to its use in detecting brain hematomas, future applications for this technology include the monitoring of patients with strokes and other blood-flow disorders.

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Baruch Ben Dor is the founder and CEO of InfraScan. In 2004 he won the Wharton business plan competition and won second place in a global business plan competition in Singapore. Previously he was the general manager of Medibell Ltd., specializing in ophthalmic digital photography, and also served as the director of marketing for CMT Medical with a focus on digital x-ray technologies.

References

3. Premarket notification to the FDA, 510k application number K080377.