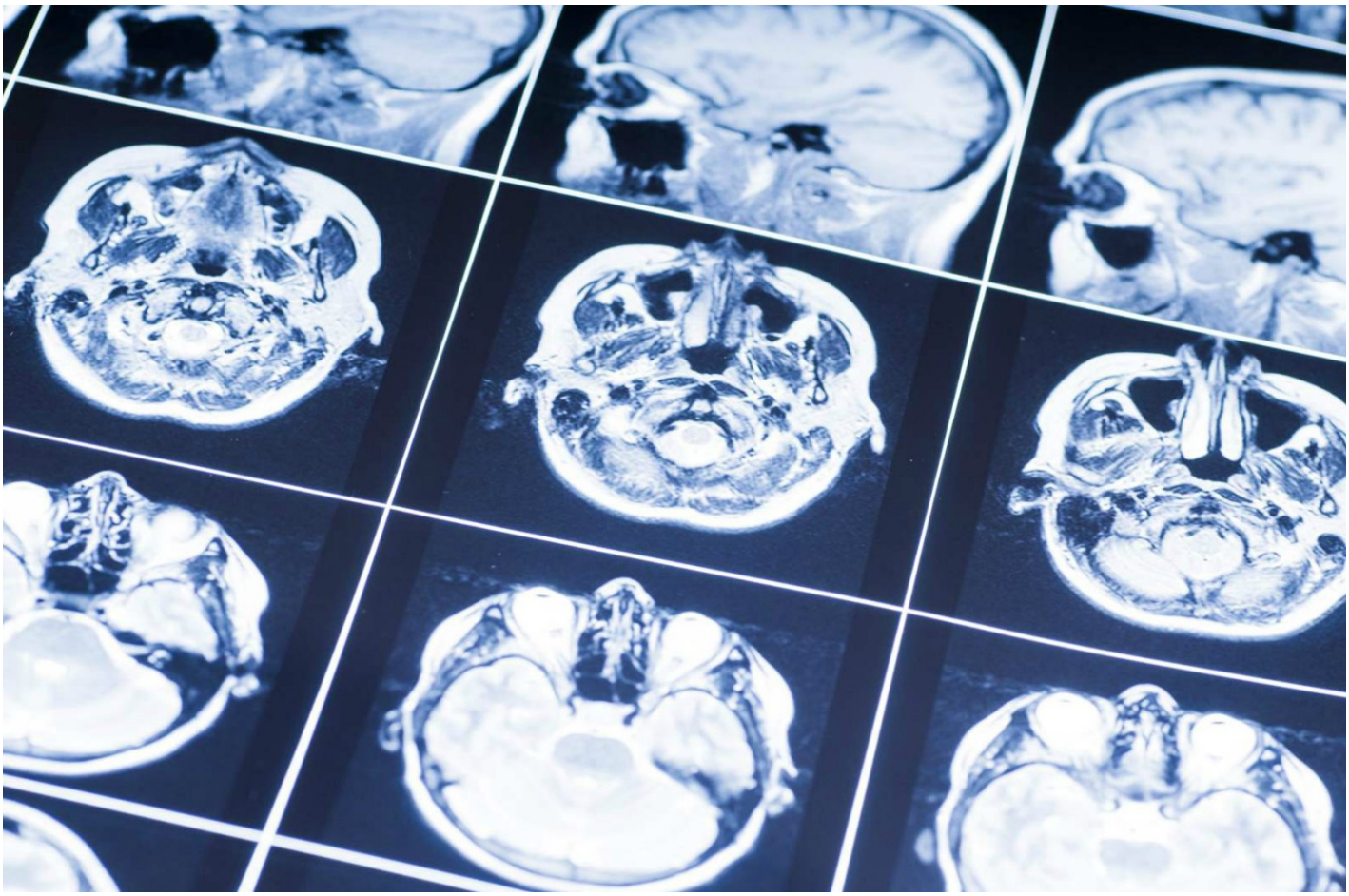
Scanning For Survival: Portable Head Scanner Makes Time-Critical Injury Diagnosis Possible

Baylor College of Medicine
Drexel University
Infrascan
University of Pennsylvania



About 25 years ago, Alok Sharma, M.D., watched an episode of the "Star Trek" science fiction television series that featured a USS Enterprise crew member having his injured head examined with a hand-held device. Sharma thought this concept was interesting, but not something that would ever evolve beyond the science fiction realm. But Sharma was wrong: He was recently involved in a trial of such equipment at Lokmanya Tilak Medical General Hospital (Sion Hospital) in Mumbai, India, where he serves as chief neurosurgeon.

Known as the Infrascanner™, the device tested by Sharma and his team detects intracranial hematomas-blood clots on the brain's surface that result from traumatic brain injury. Computeraided tomography (CAT) scanners are viewed as

state-of-the-art technology for diagnosing brain hematomas, yet many hospitals-particularly in developing countries-do not have this equipment in place. Other facilities have only a limited number of units, and, in turn, delayed diagnosis of some patients. However, time is of the essence in intracranial hematoma cases, as outcomes have been found to be significantly better if treatment begins within one hour after head trauma has occurred. Left undetected or detected too late, intracranial hematomas can expand, compressing the brain and resulting in death. Even if death does not occur, brain function can be compromised by an intracranial hematoma of any size.

Wanted: Non-Invasive Diagnosis

Development of the Infrascanner™ began as a collaborative effort by Britton Chance, Ph.D., Sc.D. (Cantab.), M.D. (Hon), a professor emeritus of biophysics, physical chemistry and radiologic physics at the University of Pennsylvania, and Claudia S. Robertson, M.D., a leading neurosurgeon in the Department of Neurology at Baylor College of Medicine, Houston. Robertson was seeking a noninvasive means of identifying brain hematomas.

> *Based on his own extensive research, Chance proposed that beaming near-infrared light at the brain via a hand-held instrument, and subsequently analyzing the light reflected back at the device, could indeed reveal the presence of intracranial hematomas.*

"Dr. Chance had a number of workable patents, and Dr. Robertson was the neurologist with the right application," says Stewart Davis, assistant director of Baylor Licensing Group, Baylor College of Medicine's technology transfer arm.

Robertson and her colleagues conducted clinical trials of the device over a period of several months, utilizing it on more than 300 patients. Their study indicated that it could facilitate the detection of hematomas in and around the brain by measuring the differential absorption of near infrared light in brain tissue and/or the three layers of membranes between the brain and the spinal cord.

Scratching an Entrepreneurial Itch

In 2002, Chance was approached by Baruch Ben Dor, Sc.D., a medical optics specialist and acquaintance who had worked as a CEO and was anxious to start a company of his own. Ben Dor spent several learning about Chance's technologies to determine which of the professor's intellectual properties he might develop into a commercial product. "I chose the brain scanner because I saw it as the most mature option in terms of its ability to get to market, and also because it had strong potential to address the need for a cost-effective, efficient means of closing the neurological window in brain injury cases-particularly in environments where a CAT scan isn't even an option," Ben Dor explains. He adds that the latter include not only health care facilities, but ambulances and battlefields, among others.

As Chance had formally retired from University of Pennsylvania when the device was developed and tested, he and Robertson licensed the technology to InfraScan, the Philadelphia-based company Ben Dor had formed, solely through Baylor Licensing Group. "It seemed like an extremely good fit given Dr. Ben Dor's area of expertise and the potential for multiple commercial applications," notes Davis.

Then came Ben Dor's first obstacle: raising capital for his venture. He wrote a business plan in 2003, but failed to generate the necessary monies. Undeterred, he reviewed the feedback he had received and followed critics' suggestions that he improve the plan and increase the size of his team. To handle the former, he called upon two business students at the University of Pennsylvania's Wharton School, Sandeep Naik and Samonnoi Banerjee. Naik and Banerjee entered the plan in the 2004 Wharton Business Plan competition and won the $20,000 prize. "They got the money, and I got an excellent business plan along with credibility for investors," Ben Dor says. Meanwhile, to

develop the technology further, Ben Dor partnered with Banu Onaral, Ph.D., director of the School of Biomedical Engineering, Science & Health Systems at Drexel University, and her colleagues. Onaral specializes in biomedical signal processing and imaging.

Funded in part by a Phase I Small Business Innovation Research (SBIR) grant from the U.S. Navy, the group embarked on several modifications to the device. Most importantly, Ben Dor explains, the original unit "was scientific, rather than medical," and required the use of "knobs and dials" to manually measure light reflection. "We developed a prototype that runs proprietary software," he continues. "The software does the measuring and automatically adjusts measurements according to an algorithm we devised." The Infrascanner™ unit itself comprises a sensor and an off-the-shelf, hand-held personal digital assistant (PDA) that runs the proprietary software and operates on the Windows Mobile platform. Like the device developed in Chance's laboratory, the device relies on the differential light absorption of the injured versus the non-injured part of the brain.

A healthy, normal brain displays light absorption that is symmetrical in the right and left hemispheres. However, when there is internal bleeding, the higher concentration of hemoglobin present results in a greater absorbance of light and commensurate reduction in the reflected component. This difference is detected by the unit's sensor component, which is placed symmetrically on the skull lobes.

By using the principle of diffused optical tomography, the Infrascanner™, via the proprietary software, converts the differential optical data into interpretable results. Communication between the sensor and PDA components occurs via the BluetoothTM wireless protocol.

Three months after Naik and Banerjee won the business plan competition in April 2004, InfraScan incorporated and before the summer was over, the team received a $50,000 pilot investment from BioAdvance, the biotechnology greenhouse of Southeastern Pennsylvania, to fund the conduction of due diligence on InfraScan's business plan.

In January 2005, BioAdvance awarded InfraScan, Inc. an additional $450,000. The U.S. Navy and Army have also recognized the relevance of deploying Infrascanner™ technology in combat operations, providing $1.1 million in grants. InfraScan has since received several other grants, including $100,000 from a U.S. Army SBIR and $150,000 from the National Institutes of Health (NIH), and has secured additional investments from Ben Franklin Technology Partners of Southeastern Pennsylvania and the Philadelphia Industrial Development Corp. A number of studies of the Infrascanner™ have since been conducted. A pilot human clinical study conducted on 305 patients at the Baylor College of Medicine demonstrated high sensitivity for detecting bleeding in the brain and for rapidly identifying the onset of delayed hematomas. Equally positive outcomes have been revealed in a subsequent 400-patient multi-hospital study, as well as a limited study by the U.S. Army and a trial of the device by Sharma at Lokmanya Tilak Medical General Hospital.

In late 2008, InfraScan received the CE Mark, or European marketing clearance, for the device, certifying that it meets European Union health, safety and environmental requirements. The company has since signed its first distributors in the United Kingdom, Spain, Israel, India and Africa. Ben Dor is now awaiting FDA clearance to market the device in the U.S.

"Meanwhile, we are leveraging the fact that we can sell the device not just in Europe, but in undeveloped countries, where other scanning methods are not readily available," Ben Dor concludes. "The market need and the benefits are clear."

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