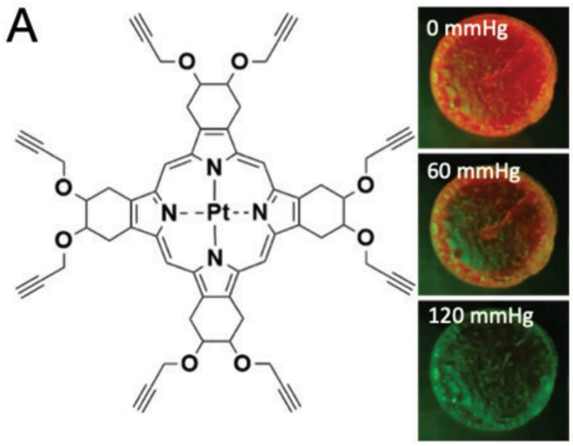


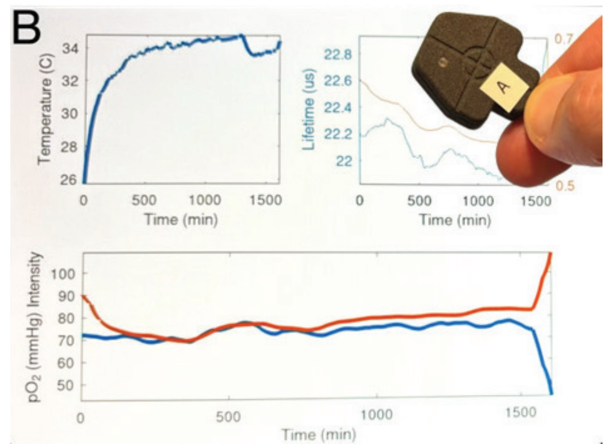
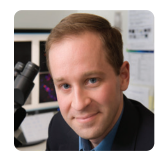


Figure A: The core technology is based on a highly sensitive, brightly-emitted porphyrin molecule that can be enmeshed or conjugated into a host of materials. When paired with a green emitter like fluorescein, this allows for simple "traffic light" oxygen-sensitive, color-changing materials that can be read out by-eye or by a simple camera.

Figure B: The extreme brightness of the porphyrin allows it to be excited by LEDs and read out by photodiodes to build small quarter- and dime-sized sensors based on inexpensive, commodity electronics, such as the one shown here that has been validated in human studies.



Simple, Lightweight, and Accurate Oxygen Concentration Sensing Platform Technology

Conor Evans, PhD
Principal Investigator, Wellman Center for Photomedicine, Mass General Brigham; Associate Professor, Harvard Medical School
evans.conor@mgh.harvard.edu

A central challenge in the clinical care of patients is the measurement of tissue oxygen. The majority of devices currently in use for tissue oxygen monitoring measure SpO2 or StO2, the oxygen saturation of hemoglobin. While adequate for measuring systemic oxygenation, these metrics rely on normal oxygen delivery to tissues and provide only indirect information regarding local tissue oxygen concentration. These tools importantly can fail to report meaningful information when blood flow is compromised, such as in injured, ischemic tissues. Transcutaneous oxygen measurement (TCOM, or TcpO2), on the other hand, is a noninvasive technique used in wound care and surgical settings to record the oxygen concentration, or partial pressure of oxygen (pO2), at the skin surface. Standard-of-care TCOM devices, however, require precise placement in controlled environments, as much as 20 minutes of bedside calibration, heating of tissue to 45°C, and a well-trained operator. Despite the need for the information they provide, current TCOM devices have significant limitations that prevent their use in crucial applications including post-surgical monitoring, ICU, and NICU settings.

To address this important gap in patient care, we have developed a platform technology that rapidly, accurately, and directly reports tissue oxygen concentration. The core technology employs phosphores that emit red light in response to oxygen levels; this highly sensitive chemistry is based on ultrabright oxygen-sensitive phosphores known as Clickaphores. Their glow is so bright it can be seen by eye even in sunlight, enabling oxygen sensing films, bandages, dressings, wearable sensors, needles, and catheters. Films, bandages, and dressings allow by-eye or simple camera-based imaging of oxygen across tissue for simple, red-light/green-light mapping of pO2. We have miniaturized the sensors, developing low-cost, self-contained, and quarter-sized devices weighing a few grams. These wearable sensors enable continuous, unobtrusive measurement of tissue oxygen without the need for heating or wires. We have validated these materials and devices across numerous animal and human studies, including first-in-human clinical testing in patients undergoing breast reconstruction surgery.

We are seeking partners or financing to further advance this technology. Plastic surgery is the planned beachhead market as there are predicate devices for a 510k pathway and existing CPT codes.