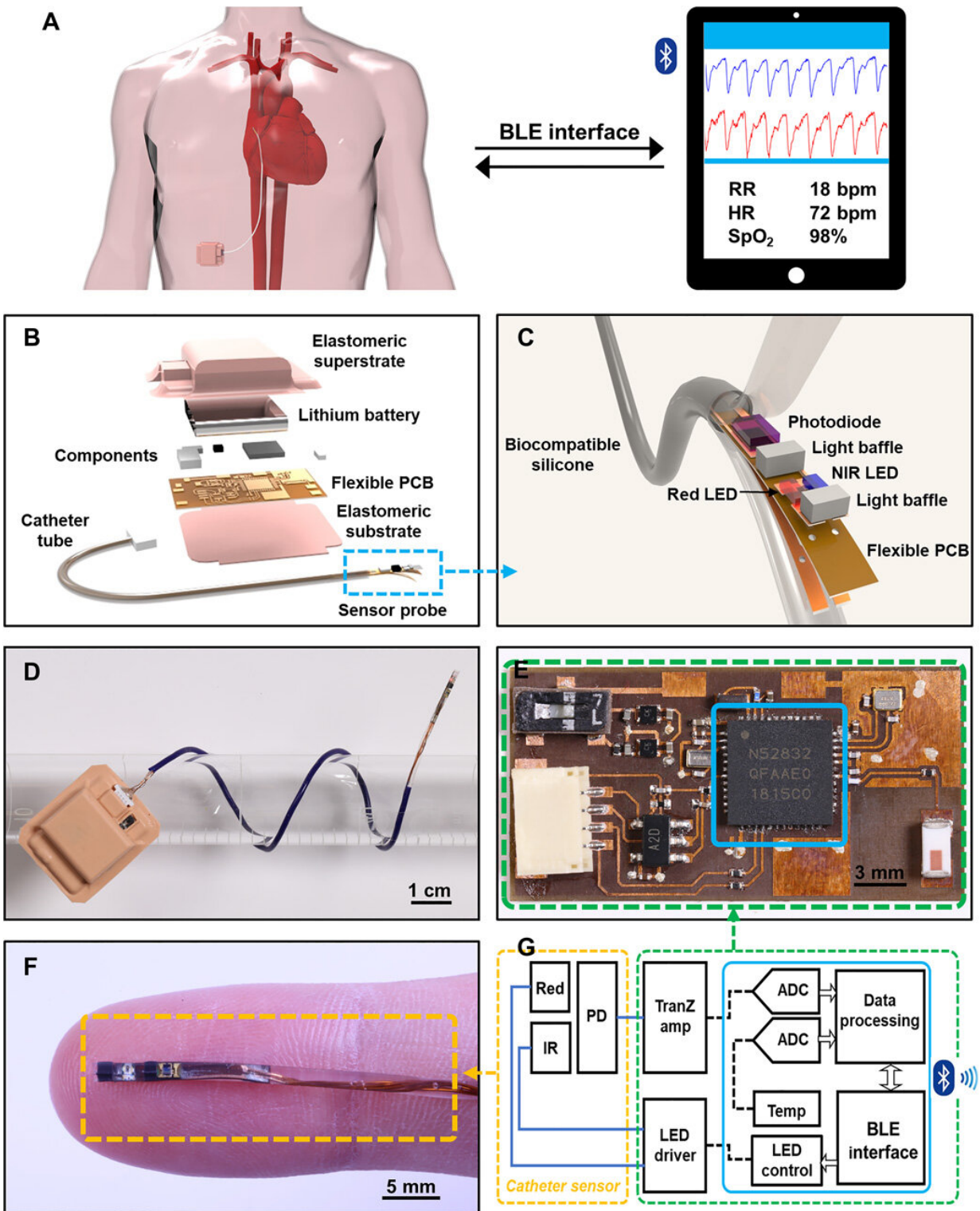


Wireless, implantable catheter-type oximeter designed for cardiac oxygen saturation

February 25 2021, by Thamarasee Jeewandara



Implantable, wireless catheter oximeter for real-time monitoring of cardiac physiology in the context of surgical procedures. (A) Schematic illustration of

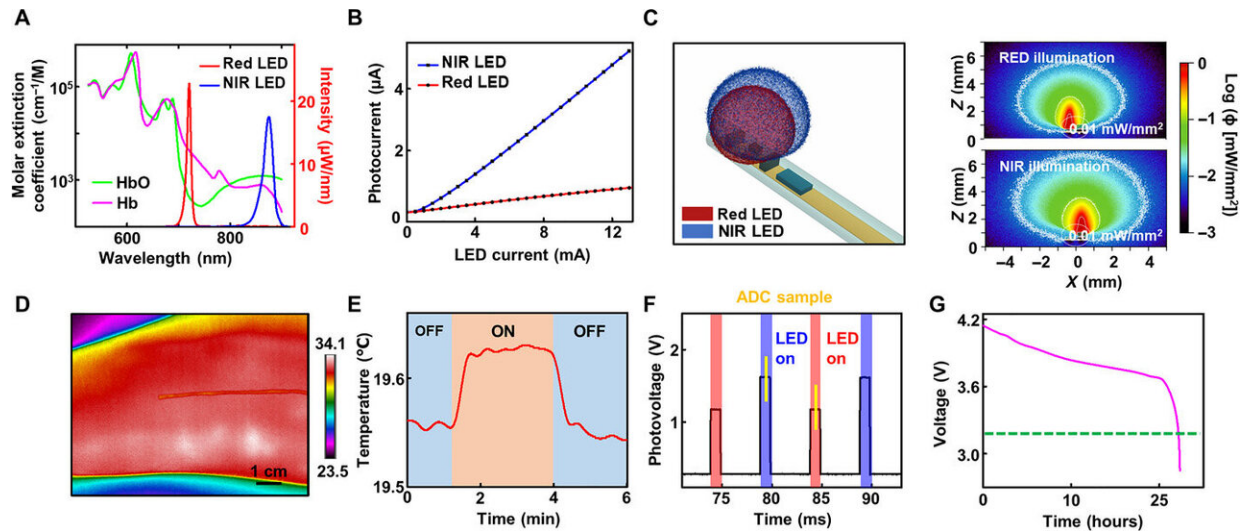
the use of an implanted device for wireless blood oximetry near the cardiac surface. The system consists of a catheter-type oximeter with sensing tip sutured onto the surface of the heart, interfaced to an electronic module that attaches to the skin for signal collection and wireless data transmission through Bluetooth protocols. A custom GUI displays and records the data on a computer and serves as a control interface to the device. (B and C) Exploded view schematic illustration of the device design. (B) The electronic module contains five layers: a bottom elastomeric substrate, a flexible PCB, a collection of electronic components, a lithium ion battery, and a top elastomeric encapsulation. (C) The enlarged image shows the sensor probe, which consists of a flexible PCB, optical stimulation and sensing components, and optical blocking modules. The probe has a diameter of 1.5 mm and is fully encapsulated with transparent, biocompatible silicone. (D) Image of a catheter oximeter wrapped around a glass rod. (E) Image of an electronic module without encapsulation. (F) Image of a catheter-type oximetry sensor. (G) Schematic block diagram of the system. Photo credit: Wei Lu and Wubin Bai, Northwestern University. Credit: Science Advances, doi: 10.1126/sciadv.abe0579

The real-time monitoring of intravascular oxygen levels is important to accurately track the cardiopulmonary health of patients after cardiothoracic surgery. Existing methods use intravascular placement of [glass fiber-optic catheters](#) that pose risks of blood vessel damage, thrombosis and infection. Physical tethers to power supply systems can limit freedom of movement in the intensive care unit. In a new report now on *Science Advances*, Wei Lu and a team of international researchers in multidisciplinary research across the U.S., China, the Republic of Korea and Italy introduced a wireless, miniaturized and implantable optoelectronic catheter system. The device included optical components on the probe, encapsulated by soft biocompatible materials. The flexible, biocompatible construction of the probe represented key defining features to form a high-performance, patient-friendly oximeter that could monitor localized tissue oxygen, heart rate and respiratory activity in real time. The platform offered measurement accuracy and

precision similarity to existing chemical standards.

The cardiovascular system

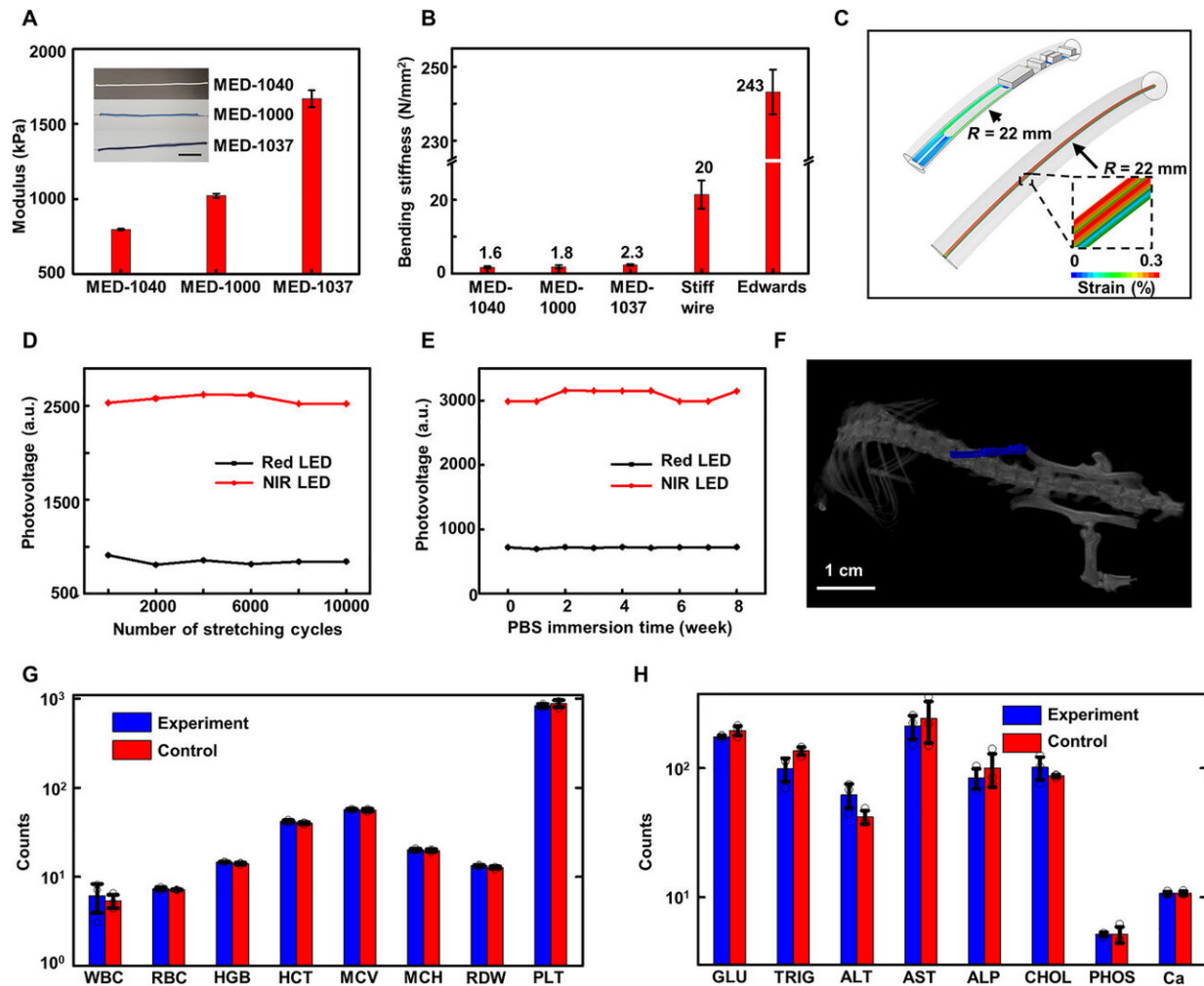
The cardiovascular system [delivers oxygen and nutrients](#) to tissues and cells in the body and maintains an adequate balance between oxygen delivery and consumption for [cellular physiological function](#). The accurate and real-time monitoring process of specific intracardial and major vascular saturations after open-heart surgery is critical to treat patients suffering from [cyanotic congenital heart defects](#). Wearable oximeters and clinical pulse oximeters can capture global oxygenation of the body. In the intensive care unit (ICU) setting, the fiber-optic oximetric catheter can be used to monitor blood oxygen saturation levels continuously. With existing fiber-optic catheter oximetry, clinicians incorporate hard glass fiber waveguides to connect to a [light source](#) and sensing module to deliver light from an external source to the blood at the tip of the catheter in order to transmit some fractions of the backscattered light back to an external unit for detection. The apparatus can be connected to an additional interface containing a [display monitor and controlling software](#). The platform introduced in this work contained a thin, flexible catheter-type [optoelectronic probe](#) connecting to a small, wearable electronic module for wireless and continuous real-time measurements of intravascular oxygen with clinical-grade accuracy.



Design features

The probe tip of the device contained high-performance, miniaturized light-emitting diodes (LEDs) and photodiode (PD) fully encapsulated with a medical-grade, soft, transparent silicone elastomer. The electronic module supported rechargeable powering, circuit control and wireless data communication via Bluetooth protocols. A graphical user interface (GUI) deployed on a smartphone or tablet computer of ICU monitoring display allowed real-time visualization storage and analysis of measurement data. The results represented important advances in wireless optoelectronic technologies in cardiology. The platform was fully encapsulated with a medical-grade silicone layer and contained three main components:

- A low modulus flexible catheter with an optoelectronic sensor that contained two light-emitting diodes with emission wavelengths of 645 and 950 nm and one silicone photodiode.
- A bendable, miniaturized Bluetooth electronic module for gentle mounting on the skin
- A custom GUI deployed on a [handheld device](#) to support real-time visualization storage and data analysis and provide a control interface for the illumination parameters for LEDs.



Mechanical encapsulation and biocompatibility characteristics. (A) Measured Young's moduli for three catheter probes (inset images; scale bar, 2 cm) encapsulated with three different biocompatible silicone elastomers (labeled: MED-1040, MED-1000, and MED-1037, respectively). The Young's moduli of the three catheter probes range from 800 to 1700 kPa. (B) Measured bending stiffnesses for the three catheter probes in (A), a catheter probe fabricated from relatively stiff copper wire encapsulated with MED-1000, and a commercial fiber-optic catheter (Swan Ganz 777F8, Edwards LifeSciences Inc.). The bending stiffnesses are 1.6, 1.8, 2.3, 20, and 243 N/mm², respectively. (C) Finite element modeling of the sensor probe and catheter subjected to a bending radius of 22 and 27 mm, respectively. (D) Measured photovoltage from the catheter probe as a function of cycles of compression and bending. Experimental details appear in figs. S7 and S8. The photovoltage generated from the photodetector

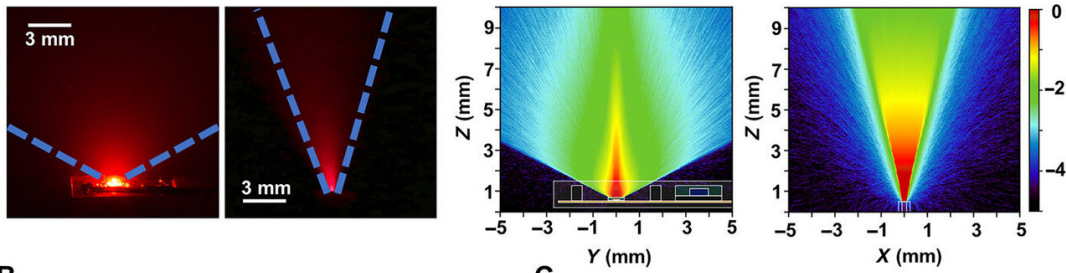
corresponds to operation of the two LEDs (peak wavelengths of 645 and 950 nm, respectively) at the tip of the catheter probe. a.u., arbitrary units. (E) Measured photovoltage as a function of immersion time in PBS solution at 37°C. Experimental details appear in figs. S10 and S11. The data indicate negligible change in performance over 8 weeks. (F) CT image of the catheter sensor after 2 weeks of implantation. (G and H) Analysis of complete blood count (G) and blood chemistry (H) for mice with an oximetry probe implanted subcutaneously for 30 days (labeled as Experiment) and for mice without device implantation (labeled as Control). Credit: Science Advances, doi: 10.1126/sciadv.abe0579

The team then wirelessly transferred data to a personal computer using Bluetooth protocols.

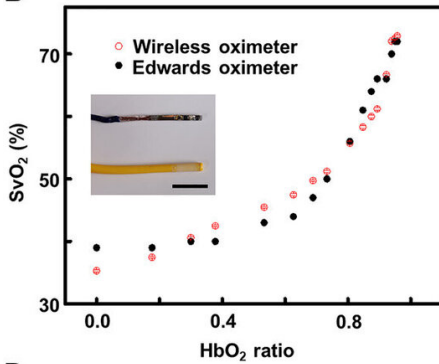
Optical, thermal and electrical characterization

The scientists provided effective estimates of blood oxygen saturation using well-known optical approaches to define the fraction of oxyhemoglobin (HbO_2) relative to total hemoglobin ($\text{HbO}_2 + \text{deoxyhemoglobin—Hb}$) by comparing the absorption spectra of oxyhemoglobin and deoxyhemoglobin in the visible and near-infrared spectral range. Using the large differences at 645 nm and 950 nm, the scientists established the basis of optical measurements of blood oxygenation. Lu et al. measured the physics of light transport in biological tissues using the [Monte Carlo method](#). The results provided quantitative insights into the illumination distribution around the LEDs and into aspects of light detection by the photodiode based on the optical properties of human cardiac muscle tissue [found in literature](#). While the device functioned when pressed against the skin of the fingertips, Lu et al. obtained thermal images with an IR camera, which did not show apparent increase in temperature in the region. The scientists performed measurements every five minutes for a duration of five seconds.

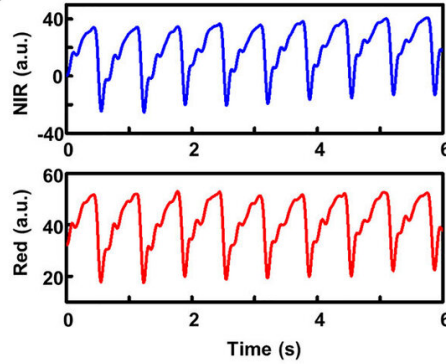
A



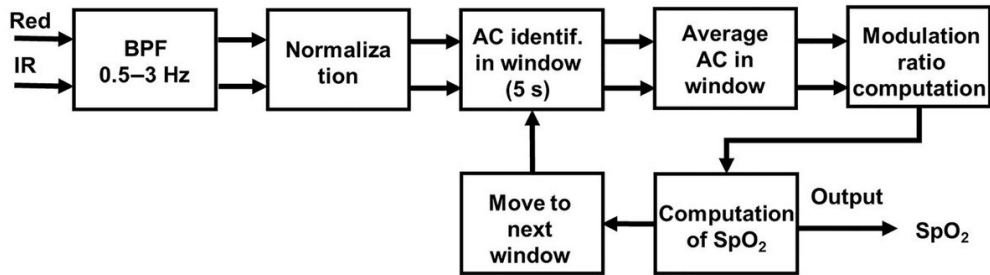
B



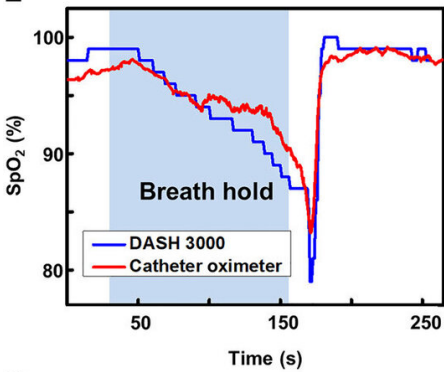
C



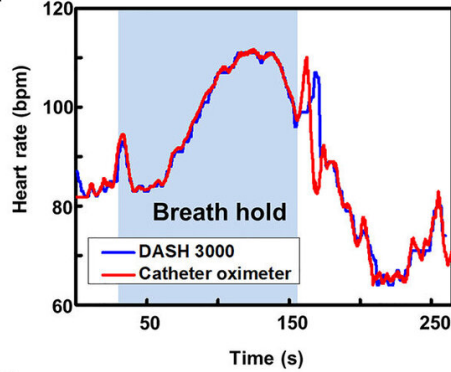
D



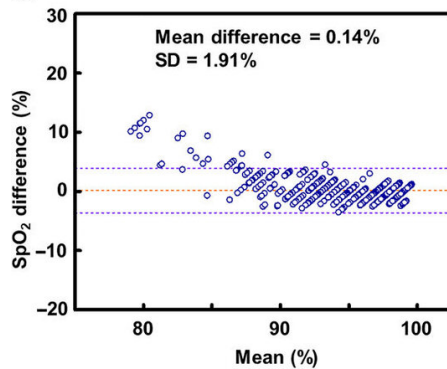
E



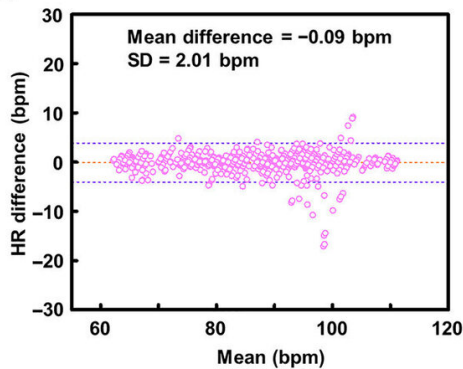
F



G



H



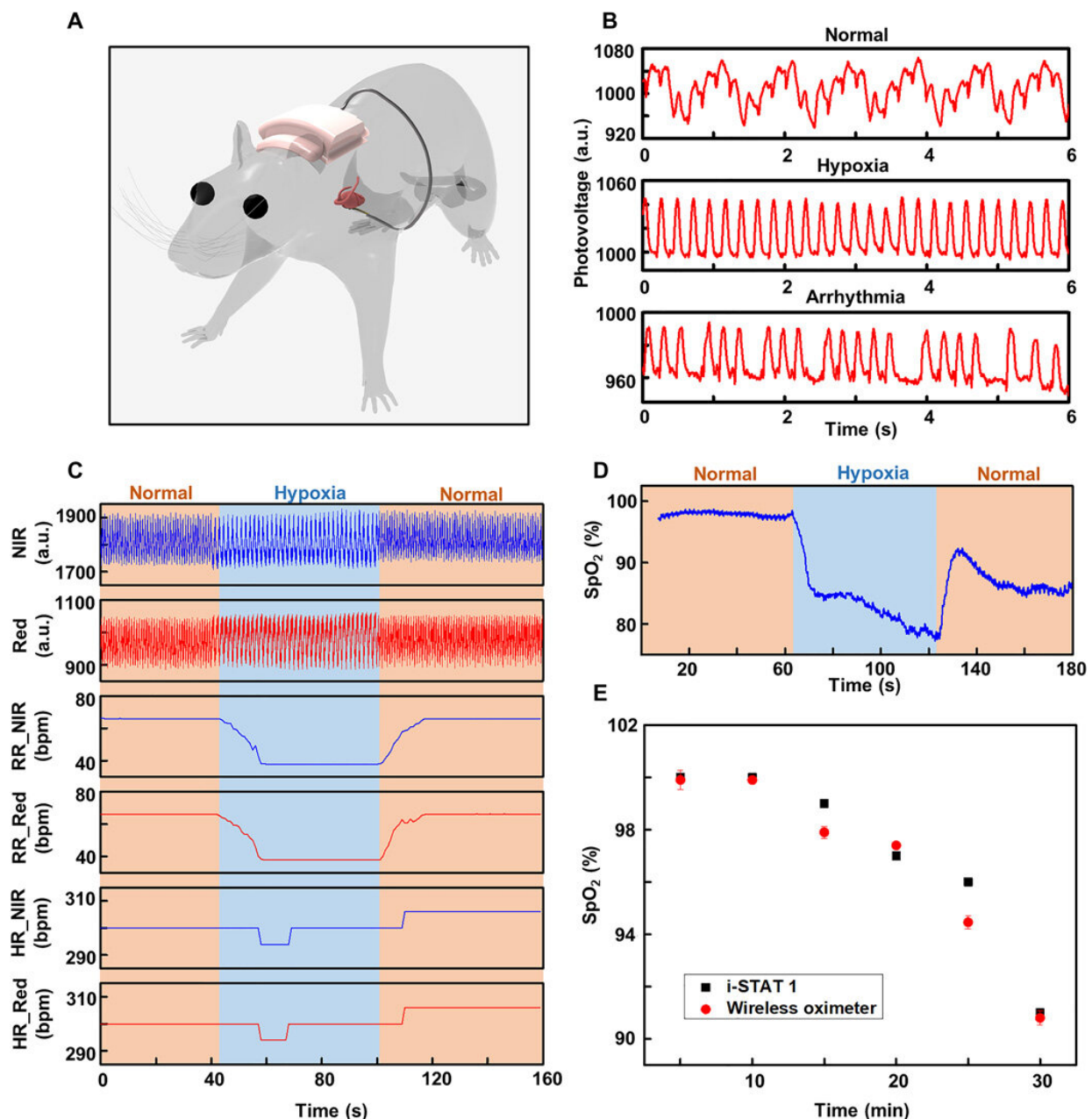
Performance characteristics for oximetry measurements. (A) Comparisons of light emission profiles of a commercial catheter oximeter (Swan Ganz 777F8, Edwards LifeSciences Inc.) and the device introduced here. (B) Comparisons of the commercial catheter oximeter and the device introduced here in measuring the oxygen saturation in blood solutions with different ratios of HbO₂ and Hb. The inset image shows a comparison of the wireless catheter probe and a commercial fiber-optic catheter (scale bar, 1 cm). (C) Measured pulse signals from the device placed on the index finger of an adult. (D) Algorithm flow chart of the calculation of pulse oximetry based on photovoltage signals. (E and F) Measured SpO₂ (E) and HR (F) during a period of rest followed by a breath hold and then another period of rest. The results match those obtained with a commercial oximeter (General Electronic Inc). The results of additional experiments appear in fig. S17. (G and H) Bland-Altman plots. (G) SpO₂ from finger (four subjects, 801 points). (H) HR from finger (4 subjects, 801 points). Credit: Science Advances, doi: 10.1126/sciadv.abe0579

Mechanical characterization and encapsulation performance

The mechanical properties of the device minimized the mechanical forces on adjacent biological tissues for improved biocompatibility. Human skin typically maintains a [Young's modulus](#) or stiffness between 400 and 800 kPa and human cardiac tissue muscles have a Young's modulus approximating 100 kPa. The Bluetooth module contained a biocompatible silicone for encapsulation with a Young's modulus in the range of human skin. The team used three catheter oximeter probes with biocompatible silicone with diverse Young's modulus values. The resulting bending stiffness of the construct was 50 times greater than that of the probe. The probe could easily and conformally deform with the heart muscle with negligible mechanical load and without associated damage to the heart, although its modulus was greater. Lu et al.

implanted the device subdermally on the back near the spine of a mouse model and conducted [computed tomography](#) two weeks later. The team then obtained complete blood count and blood chemistry for mice with implants for 30 days to indicate no evidence of organ damage or injury and without detrimental effects on electrolyte or enzyme balance.

Bench tests and in vivo studies



In vivo demonstration of real-time monitoring of cardiac physiology in a rodent model. (A) 3D schematic illustration of the placement of the catheter oximeter around the heart of a rat with the wireless module placed on the back. (B) Signal waveform captured with this system. Modifying the settings associated with the ventilator that supports respiration provides access to different cardiac conditions (labeled as Normal, Hypoxia, and Arrhythmia). (C) Measurements of cardiac activity (beating patterns, HR, and RR). (D) Measured oxygenation of the heart. Induced changes in cardiac pulse oximetry (SpO₂) match well with the changes on the ventilator machine. (E) Measured cardiac oxygenation using the wireless catheter oximeter and using a commercial blood gas analyzer. The analyzer measures blood sampled from the left ventricle, while the wireless catheter oximeter measures the oxygen saturation from the heart surface immediately after collecting blood samples. Credit: Science Advances, doi: 10.1126/sciadv.abe0579

Major cardiac surgeries rely on the monitoring of [venous oxygen saturation](#) (SvO₂) and [central venous oxygen saturation](#) (ScvO₂) measured using fiber-optic oximeters to guide care. Such devices can be implanted transvenously to support the optical transmission from external sources across to sense with detectors in a patient tethered to a bedside apparatus. The team conducted in-lab tests using horse blood at various oxygen levels and compared those with commercial systems. The results showed measurement capabilities of SvO₂ and ScvO₂ across relevant ranges. The method can be implemented in pediatric cardiac surgery and recovery to monitor oxygen saturation levels within vessels during early and critical post-operative period in real time. Lu et al. conducted experiments on rat models and the device captured changes in HR, respiration rate (RR), ischemia and arrhythmia. The team also measured the [heart rate](#) and respiration rate during the experiments. The high degree of correlation demonstrated that the device offered

sufficient sensitivity and precision in real-time oxygenation monitoring.

Outlook

In this way, Wei Lu and colleagues used a flexible, thin, catheter-type oximeter to accurately monitor venous and cardiac oxygenation levels in real time. The results demonstrated a wireless optoelectronic platform at the millimeter-scale to detect cardiac oxygenation saturation in rats during open-heart surgery. They explored the potential of the device to monitor oxygen levels in main vessels and expect to conduct further studies on the efficiency and reliability of oxygen saturation detection in large animal models to mimic open heart surgery of patients.

More information: Liu W. et al. Wireless, implantable catheter-type oximeter designed for cardiac oxygen saturation, *Science Advances*, DOI: [10.1126/sciadv.abe0579](https://doi.org/10.1126/sciadv.abe0579)

McGee D. C. et al. Preventing complications of central venous catheterization. *New England Journal of Medicine*.
10.1056/NEJMra011883

Lee K. et al. Mechano-acoustic sensing of physiological processes and body motions via a soft wireless device placed at the suprasternal notch, *Nature Biomedical Engineering*, doi.org/10.1038/s41551-019-0480-6

© 2021 Science X Network

Citation: Wireless, implantable catheter-type oximeter designed for cardiac oxygen saturation (2021, February 25) retrieved 20 March 2024 from <https://medicalxpress.com/news/2021-02-wireless-implantable-catheter-type-oximeter-cardiac.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.