Design of Wireless Intra-Operative Pulse Oximeter With Reticulated Pressure-Sensitive Head[1]

Chris Sarantos
Department of Biomedical Engineering,
The City College of New York,
CUNY,
New York, NY 10031

Jeremy Bekritsky
Department of Biomedical Engineering,
The City College of New York,
CUNY,
New York, NY 10031;
Division of Thoracic Surgery,
Memorial Sloan-Kettering Cancer Center,
New York, NY 10065

Niranjan Khadka
Department of Biomedical Engineering,
The City College of New York,
CUNY,
New York, NY 10031

Marom Bikson
Department of Biomedical Engineering,
The City College of New York,
CUNY,
New York, NY 10031

Prasad Adusumilli
Division of Thoracic Surgery,
Memorial Sloan-Kettering Cancer Center,
New York, NY 10065

1 Background

We developed and validated a first-generation compact handheld device for real-time wireless monitoring of tissue oxygen saturation during surgical procedures termed wireless intra-operative pulse oximetry (WiPOX) [1,2]. The WiPOX provides a tool for surgeons to objectively and reliably measure tissue viability during surgery rather than rely solely on their subjective visual inspection. Routine use of such a device could help surgeons improve outcomes because the importance of adequate tissue oxygenation for healing and preventing postoperative complications is well documented [3–5]. Tissue ischemia is a major cause of wound dehiscence or anastomotic leakage resulting in significant morbidity and mortality occurring at a rate of 15% to 25% [6]. Although measurement of systemic blood oxygenation status by fingertip pulse oximetry is a mandatory requirement for every anesthetized patient, there is no standard procedure for intra-operative measurement of internal tissue oxygenation following complex resections and reconstructions. Increasingly, surgical procedures are performed by minimally invasive techniques, which add complexity to this problem because surgeons are often unable to directly touch, feel, or visualize the organs to assess oxygenation.

We successfully designed, constructed, and tested a novel WiPOX device in both preclinical and pilot clinical testing, confirming that the device provides real-time, accurate, and convenient intra-operative monitoring of tissue oxygenation. This additional input enhances the ability of surgeons to ensure tissue viability, improving surgical outcomes and decreasing mortality, patient hospitalization, and associated costs. The WiPOX is a small hand held probe that can be applied to the surface of tissue, continuously displaying oxygen saturation on a built-in display. The data can also be transferred to hospital computers for real-time monitor display or data storage. The handheld display provides both vital signs and "quality of contact" data, allowing the operator to quickly and optimally position the sensor head on the tissue.

Potential use-cases of WiPOX include over 300,000 intestinal resection surgeries performed yearly in the U.S. alone [7], as well as plastic and bariatric surgeries where tissue flap perfusion is critical [8].

Based on clinical experience gained in our trials [1,9], we present here the design of a second generation WiPOX that includes a reticulated pressure-sensitive head serving two related functions. First, the often-restricted and sensitive environment in which the device is employed constrains both the angle of approach and visibility, necessitating a self-correcting reticulated swiveling head that acts to improve the contact angle between the sensor head and the tissue. Second, because the devices are hand-held, the pressure on the tissue (often a membrane) is determined by the operator; too little pressure produces poor signal to noise ratio (SNR) while too much pressure can occlude blood flow, also reducing SNR and possibly yielding erroneously low oxygenation measurements. To address this, our sensor head includes a novel mounting for multiple "balloon" style pressure sensors that provide feedback on tissue contact pressure and contact angle. The reticulated head and pressure sensor features function in tandem to improve tissue contact and ensure reliable measurements.

2 Methods

Technical Solution 1. "Balloon" pressure sensor array and integrated surgeon display: A key technical invention is the incorporation of on-board contact and orientation sensors at the distal end of the WiPoX, alongside the existing optical pulsatile oxygen saturation (SpO_2) sensor. Positioned behind the optical sensor, multiple contact (pressure/force) sensors provide real-time feedback of contact conditions on the handheld display, allowing the surgeon to take corrective action and optimize contact. Due to the inability to observe the contact location, and the need to precisely control contact angle and pressure, this invention addresses a clinical need. Moreover, in this specific implementation, the optical sensor is mounted on four "balloon" style pressure transducers that also provide some mechanical damping of hand movements, further enhancing contact quality.

Technical Solution 2. Self-correcting reticulated shaft: Based on operating room experience, our engineering/clinical team developed a design for an articulated sensor head that facilitates flat contact with the surface under conditions of minimal visibility.

Technical Solution 3. Systemic pulse rate input to tissue oxygenation signal processing (pending): A third invention follows from recognizing that the internal tissue pulsatile signal and systematic pulse signal have the same frequency and a fixed time offset. The systemic pulse signal is readily available with high SNR from standard equipment (electrocardiogram (ECG) or a fingertip pulse oximeter). This systemic signal will be wirelessly relayed to the hand-held WiPOX as an additional input to the

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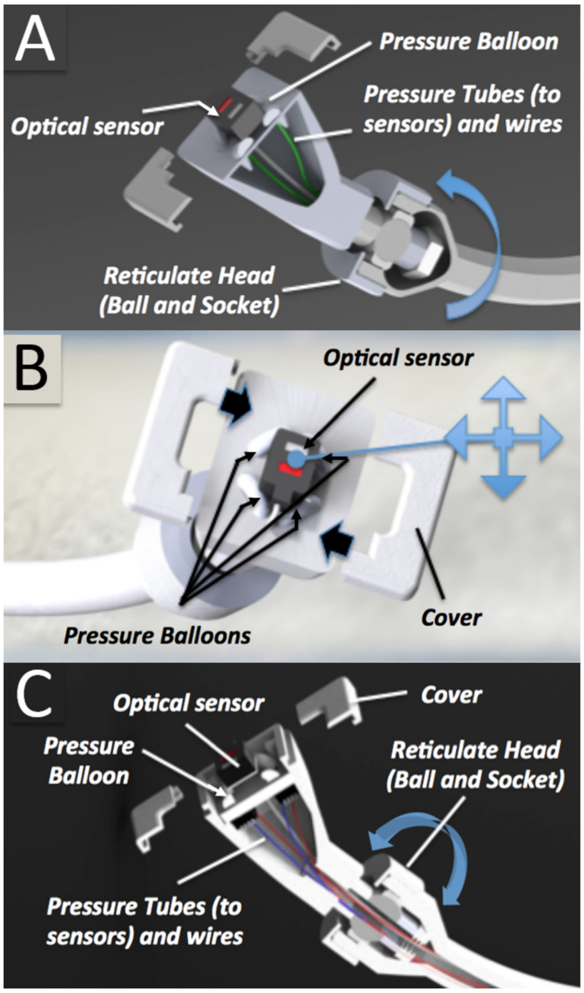

Fig. 1 Design of the novel sensor head with passive ball-and-socket reticulated head and four pressure-sensing balloons supporting a jointly packaged optical emitter and detector

signal processing algorithm. Techniques such as frequency domain filtering the lower SNR tissue waveform using the high SNR systemic pulse signal will then improve the accuracy of measurements and potentially reduce the time (number of patient heart beats) required to achieve a high-confidence tissue SpO_2 reading. This is a critical next step to enable surgeons to make treatment decisions and measure the efficacy of therapeutic interventions in real-time.

3 Results

General Design. The design includes mechanical and electronic systems allowing for a ball and socket swivel joint and multiple pressure sensors working in concert with the optoelectronic sensor. The swivel joint (Fig. 1(*a*)) naturally moves the optical sensor into a flat-on orientation as it is pressed against tissue, enhancing ease of use in minimally invasive surgeries. A pressure sensor array (Fig. 1(*b*)) will provide feedback on both the contact angle and the pressure applied. Moreover, a "balloon" sensor design provides some secondary articulation and hand-motion damping. New algorithms will process and display the contact orientation and pressure data on the handheld screen in a user-friendly form. On-board displays will warn surgeons when the contact pressure exceeds a value that would occlude blood flow, artificially lowering SpO_2 readings. The final, calibrated orientation and pressure display will allow for faster and more reliable SpO_2 measurement through a lumen without the need for visual contact with the sensor head. The head is mounted on an articulated neck that is optimized for specific surgical procedures, with embedded circuitry and leads (Fig. 1(*c*)).

The "balloon" mounted optical sensor is, to our knowledge, a novel design that provides both natural articulation (fine tilt in addition to the coarser tilt allowed by the ball and socket joint) of the sensor and meaningful tissue contact data (four pressure sensors) to the operator. Thus, once the sensor tip contacts the tissue, passive reticulation and display feedback allow the device head to swivel such that the optical sensor surface is pressed flat against the tissue.

Design Inputs for Fabrication. The target pressure in the balloons that is indicated to the operator should be high enough to allow optical coupling with the tissue, but not so high that blood flow is disrupted or displaced, leading to erroneously low SpO_2 readings. An initial guess may be obtained from fingertip readings with varying pressure. Then, large-animal and eventual clinical validations are required to determine the optimum pressure value for each specific application and tissue type (e.g., esophageal tissue).

Data from the pressure sensor array should be displayed in a manner that clearly communicates contact pressure and orientation to the operator. We have found that monochrome organic light-emoting diode displays are more readable than color displays under operating room lighting conditions. Thus, the pressure display should use bar graphs or other monochrome techniques rather than color coding. A possible design includes four bar graphs simultaneously showing pressure on all four corners of the sensor head, indicating absolute contact pressure at each corner and overall contact orientation. The display should be updated frequently by the embedded software so that there is no noticeable latency. Depending on processor speed, this may factor into the graphic design, since indicators using more pixels take longer to update.

4 Interpretation

This design has been evaluated by our surgical team and is considered to provide meaningful advantages over the existing WiPOX device (which is in ongoing human trials). Large-animal and preclinical testing of this second generation WiPOX design is pending.

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