Design of Wireless Intraoperative Pulse Oximeter (WiPOX) with Reticulated Pressure-sensitive Head

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Introduction

- Hand-held, real-time, wireless intra-operative tissue oxygen monitoring device
- Adapts reflectance oximetry technology - Device interprets detector signal to derive SpO₂, pulse rate and pulse waveform
- Device body- Procedure specific articulation

Clinical Use

- Surgical resections and reconstructions require restoring blood supply - Clinical trial (Phase I done, Phase II undergoing)
- Current standard of care: Surgeon’s visual inspection
- 15 – 20% of anastomoses leak - increases risk of death by 3 -fold, secondary procedures required

Limitation of First Generation WiPOX

- Inadequate control of contact angle between optical sensor and tissue
- Excessive motion artifacts due to the movement of sensor or patient
- Optimum level of pressure required to achieve adequate pulsatile optical signal
  - Too little pressure: poor SNR
  - Too much pressure: occludes blood flow, lowers SNR, and artificially lowers SpO₂ readings

Figure 1: Perspective views of Wireless Intraoperative Pulse Oximeter (WiPOX), General design layout (side view) of WiPOX (A). Front view of the WiPOX display interface (B). Schematics of the reticulated pressure sensitive head with optical sensor, pressure balloons, and swivel joint (C)

Second Generation WiPOX & Technical Solutions

Based on clinical experience gained in our trial

Balloon Pressure Sensor Array and Integrated Surgeon Display

- Incorporation of on-board contact & orientation sensor( pressure/force) behind the optical sensor that provides real-time contact feedback display

Self-correcting reticulated head

- An articulated sensor head ( swivel joint) that facilitates flat contact with the surface under minimal visibility

Improve signal processing by using systemic pulse rate as an input (PENDING)

- Use signal processing approach that relay fingertip pulse to the hand-held device
- Systemic information to improve the accuracy and response time(- 4 s) of the WiPOX SpO₂ reading
- make treatment decision & measure efficacy of therapeutic interventions in real-time

Figure 5: Integrated Patient Display on-board with the existing displays (A). Self-correcting reticulated head and the internal structure (B), and movement orientation of reticulated sensor head (C)

Conclusion

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 with FDA Investigational Device Exemption (IDE) ). Large animal and pre-clinical testing of this second generation WiPOX design is pending.

Need Statement

Redesign first generation WiPOX with:
- Swivel joint that adjusts optical sensor into a flat orientation as it is pressed against the tissue
- Pressure sensor balloons that display feedback of both consistent sensor/tissue contact and overall application pressure while providing secondary articulation and hand-motion damping

References


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