

Evaluation of the EQUANOX™, FORE-SIGHT™ and INVOS® Systems at St. Francis Hospital in Columbus, GA¹

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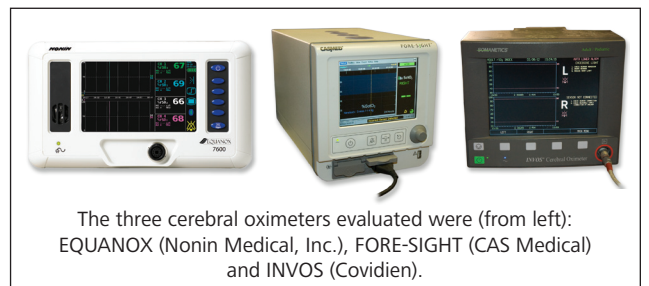
It is well understood that cerebral hypoxia can lead to neurological injuries, neuro-cognitive decline, and increased length of stay.^{2,3,4}

INTRODUCTION



Cerebral oximetry is a noninvasive monitoring technology that allows for assessment of adequacy of cerebral perfusion and is used to detect potential hypoxia during surgical procedures. It is well understood that cerebral hypoxia can lead to neurological injuries, neuro-cognitive decline, and increased length of stay.^{2,3,4} With three cerebral oximetry devices on the market it can be difficult to determine which system best meets the needs of the healthcare staff without direct comparison of the technologies. In the early part of 2010, St. Francis Hospital in Columbus, Georgia began monitoring arthroscopic shoulder repairs in the beach chair position with the Covidien INVOS NIRS technology. St. Francis experienced some challenges with the technology. Upon investigation, recent advancements

from manufacturers appeared to potentially solve some of these challenges. After reviewing commercially available systems, St. Francis decided to formally review the available technologies realizing all systems may offer some advantages, including the INVOS system, which also had the advantage of familiarity. To create an impartial view, a formal clinical evaluation was initiated at the St. Francis Hospital to assess the usability and functionality of the commercially available cerebral oximeters during real-life use experience. Not part of the formal evaluation, but a consideration in the final decision, was the cost impact to any change in devices. The three cerebral oximeters evaluated were: EQUANOX (Nonin Medical, Inc.), FORE-SIGHT (CAS Medical) and INVOS (Covidien).



METHODS

To create an impartial view, a formal clinical evaluation was initiated at the St. Francis Hospital to assess the usability and functionality of the commercially available cerebral oximeters during real-life use experience.

A total of 30 arthroscopic shoulder repair subjects were selected for use in the evaluation. It was determined to record a baseline rSO₂ value with each device across the thirty subjects; however, for usability evaluation the thirty subjects were divided into groups of ten for each device so that a single device was used during the actual procedure. The pre-operative team recorded the pre-operative rSO₂ baseline in the supine position with each device, sequentially. After the final recording a single device was selected for the remainder of the pre-operative period and until the case was completed. Sensors were applied to both the right and left cerebral hemisphere. In the instance of using the FORE-SIGHT, light-blocks were also applied to each sensor to avoid ambient light contamination and signal loss per the manufacturer's instruction.

Each device was introduced to the operating room staff and in-service training was provided by the company representative from each device manufacturer prior to initiating the study. Multiple levels of clinical users were included in the user survey, including Anesthesiologists, CRNAs, Perfusionists, and Nurses. Once the study was

complete, each clinician involved with the case and device completed a survey on the devices.

The survey consisted of a five-point LIKERT scale ranging from 1 to 5, with where 5 indicated "Superior", 4 indicated "Good", 3 indicated "Average", 2 indicated "Poor", and 1 indicated "Very Poor". There were 11 questions in three categories. The first category was the Oximetry Sensor which evaluated the device-patient interface through evaluating the sensor. This requested feedback on the sensor design for ease of use and clinical convenience; adhesion, to rate ability of the sensor to keep and maintain contact to provide a signal; and application, to rate ease of application.

The second category was evaluation of the device-clinician interface through evaluation of the monitor display. This section evaluated size as a measure of convenience in and fit into the operating theater; layout, to understand setup and mechanical configuration; visibility, to measure the ability of multiple practitioners at multiple locations viewing the device; and interface ease-of-use, to measure complexity and time-required to manage the device.

The third category evaluated the core technology. This covered the ability of the system to acquire and maintain a signal (signal acquisition) and the stability of that signal. It also covered the device's extensibility by looking at portability and battery life.

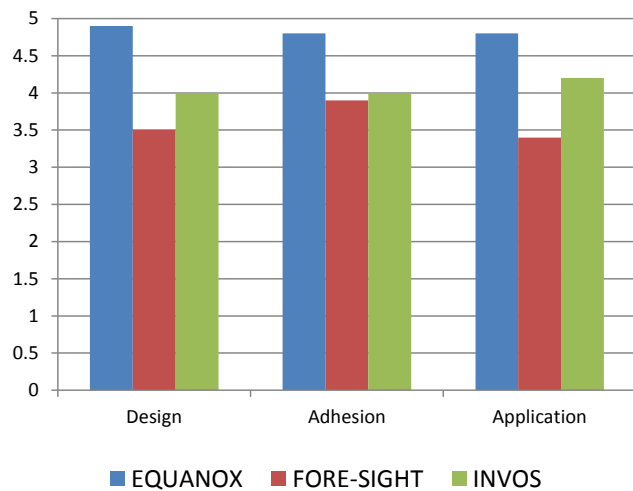
A final overall satisfaction rating was also included to cover the perception created through the holistic interaction of the device elements and the resultant net impression of each device on the clinical team.

RESULTS

There were 6 Anesthesiologists, 8 Certified Registered Nurse Anesthetists, 3 Perfusionists, 10 preoperative nurses, and 1PBMT.

In the Cerebral Sensor category, shown in Figure 1, both the EQUANOX and INVOS system scored “Good” or better with each device receiving a 4.0 or better in all categories. The EQUANOX (3-wavelength) sensor’s rating was overall scored “Superior” in this category, achieving scores ranging from 4.8 to 4.9 in the Sensor category. The next highest sensor, INVOS, scored “Good” with scores ranging from 4.0 to 4.2 while FORE-SIGHT received the lowest scores in all questions scoring from 3.4 to 4.2 in the range of “Average” to “Good”.

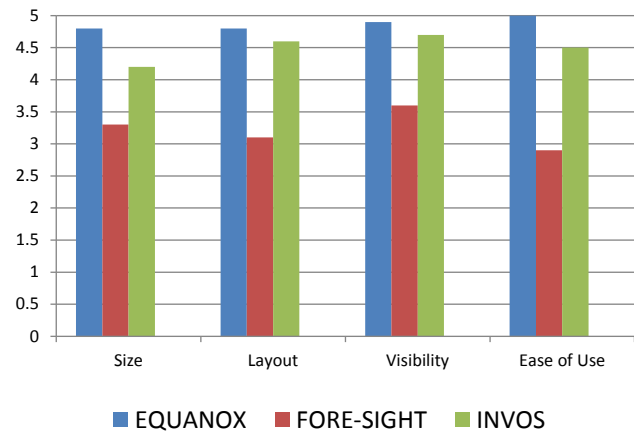
Figure 1: Cerebral Sensor Results



In the Oximetry Display category, shown in Figure 2, the EQUANOX and INVOS Systems again had satisfaction results with scores of 4.0 or greater in all categories. The EQUANOX System received the highest ratings among the three devices (Range: 4.8 to 5.0), INVOS the second highest (range: 4.2 to 4.7),

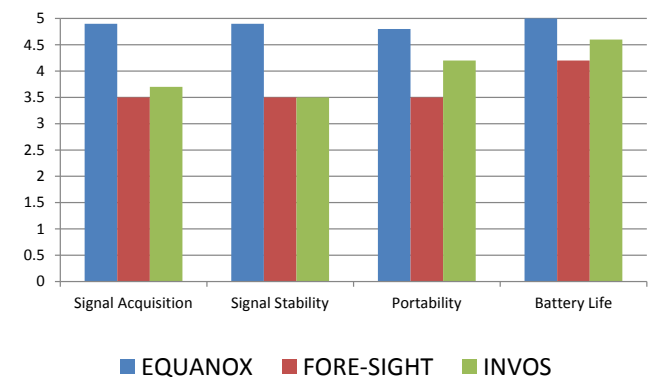
and lowest the FORE-SIGHT system (range: 2.9 to 3.6) which received marks from users rated “Poor” in the ease-of-use category dropping its score to 2.9, the lowest score in any category across all three devices.

Figure 2: Cerebral Oximeter Display Results



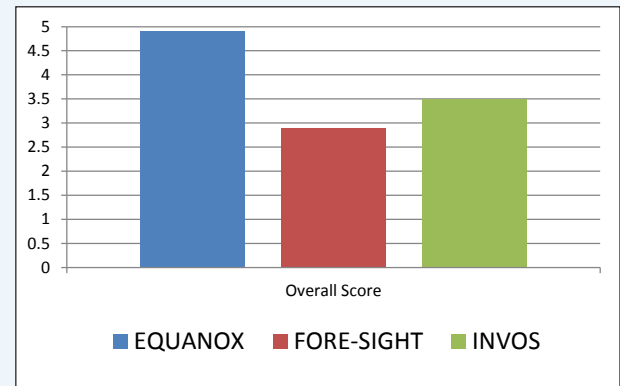
The final category looked at technology and system characteristics, as shown in Figure 3. EQUANOX maintained a “Superior” rating with scores from 4.8 to 5.0, next INVOS averaged a “Good” rating with scores from 3.5 to 4.5, and finally FORE-SIGHT scored the lowest with scores between 3.5 and 4.2, between “Average” and “Good”, having a majority of its scores below 4.

Figure 3: Core Technology Results



On final tabulation of the scores, the results revealed that the EQUANOX system scored the highest in all 3 categories compared with the other two technologies.

Figure 4: Overall Satisfaction



Consistent with the individual areas of evaluation, the overall satisfaction ranking demonstrated a marked differential between the EQUANOX System, with a score of 4.9 followed by the INVOS System at nearly a full point and a half lower. The INVOS system scored 3.5 and the FORE-SIGHT system scored the lowest, with a 2.9, indicating that a significant number of users felt some level of dissatisfaction with the device.

DISCUSSION

This usability study was undertaken independently by one institution to evaluate the three cerebral oximetry technologies currently available commercially.

Although a preferred device was determined based on the usability and functionality in our environment, each facility and user may have different criteria by which to choose a monitoring system. The evaluation scored three areas of importance: the sensor which is in contact with the patient; the monitor and user interface; and the underlying technology. The

evaluation was straight forward and easy to conduct in the clinical setting, and it demonstrated that usability requirements for the systems were different despite being seemingly comparable systems.

The facility and users surveyed had prior experience with the INVOS system which helped define our goals and focus the evaluation criteria. The previous experiences helped when considering questions on both traditional criteria, such as ease-of-use, as well as to define areas we wanted to assess for improvements, such as sensor adhesion. The familiarity with the INVOS System would obviously lend strength to any evaluation in certain areas, such as the aforementioned ease-of-use, yet it was determined to do a comparison with the newer technologies as a part of the value consideration in bringing on a new technology.

The main concern was the ability of the cerebral oximeter to be effective. Does it provide a level of accuracy and consistency which allows for

expectations to be achieved with the technology? In this instance, the question raised was whether the technology provided a stable, consistent measurement on patients. We desired the technology to limit or, preferentially, eliminate exceedingly and artificially low readings which were hampering our decision making ability on surgeries and thus eroding the value from the device. We did not clinically evaluate the precision of accuracy in this project as such an endeavor requires more complex infrastructure and research methodologies. Instead the clinical team reviewed the precision of accuracy in the manufacturer's labeling. Per the US FDA regulations, monitoring devices undergo rigorous clinical studies to establish their claims such as accuracy and furthermore are subject to subsequent FDA scrutiny to gain clearance for these claims. Manufacturers share these in their indications for use and labeling. St. Francis used the FORE-SIGHT and EQUANOX accuracy information as a prerequisite to partake in our evaluation, noting that both EQUANOX and FORE-SIGHT claimed an accuracy that purportedly solved the problem witnessed in the INVOS system with repeated artificially low readings. Based on our clinical observations, each device was effective in allowing the clinical team insights into the clinical condition of the patient to consider potential care decisions.

Our experience with Cerebral Oximetry and additional research on the devices also drove us to consider more broadly the fact that in when device does not read, a sensor comes off, or a reading cuts out repetitively on any patient there is no information valuable to clinical care, regardless of that device's purported features and benefits. Indeed, these elements also increase the cost per use comparatively

based on the cost of any disposables and the extra clinical time involved in trouble-shooting. Likewise, unstable readings, when artificial, may significantly increase the complexity of clinical decision making for potential treatments and subsequently complicate linking cause and effect of any interventions. In these areas EQUANOX scored superior which, on review, stemmed from a number of distinguishing features. The EQUANOX sensor's allowed for better adhesion and contact. These sensors also had a unique cable orientation medial to the sensor rather than lateral as the FORE-SIGHT and INVOS are structured. We found the EQUANOX sensor cable orientation ensured cabling was out of the operative field, a convenience to the surgeons. The sensor cable orientation also meant tension on the cable was far less likely to lift the sensor. We witnessed potential in the conventional sensors for tension to twist or pull the sensors away from the curvature of the skull and lift, thereby causing loss of signal and requiring a reposition or worse, replacement, of the sensor.

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The evaluators were also impressed with the EQUANOX signal stability arising, according to the manufacturer, from its unique dual LED/dual detector topology and signal processing, which allow it to interrogate a greater amount of tissue while removing signal interference from such elements as extracranial tissue and ambient light. At the other end of the spectrum, the lowest scores in these categories

were by the FORE-SIGHT system. The FORE-SIGHT system required an additional step post-sensor application on the patient. Special light blocks or shields over the sensor were required to prevent signal interference from ambient light. The FORE-SIGHT system is the only system which requires this complexity and the only system in which the sensors are apparently either extremely sensitive to ambient light and/or the FORE-SIGHT signal processing is unable to minimize signal interference. Both Covidien (including Somanetics) and Nonin have backgrounds in Oximetry spanning decades, giving them both strong histories to leverage in both Oximetry signal processing and sensor design as compared to CAS Medical, which may have allowed one or the other to avoid such limitations as the FORE-SIGHT sensors displayed.

Once the effectiveness requirements were established, usability and effectiveness focus were determined by assessing the intended, and potential, clinical settings. Because of St. Francis' frequent use of Cerebral Oximetry it was critical that our chosen system, both monitor and sensors, be highly usable, efficient to set up and use on a recurring basis by existing and new staff. The FDA has established standards and guidelines for usability in medical devices and so all devices now cleared now meet these minimum requirements; however, there are still gradients of ease-of-use between all devices. Inefficiencies in the peri-operative period create additional resource demand, increase costs, and erode the technology's value proposition. Most importantly research suggests inefficiencies and complexity in usability increase the potential for mistakes; for example, one-third of all medical device incidents reported to FDA involve use error.⁵

Beyond usability is satisfaction with the medical device. Without the support of the healthcare team, a valuable device can and will go unused. Aside from the dollars wasted on technology that is unused (or under utilized), there can be an impact on patient's care and ultimately outcomes. Cerebral Oximetry can be the key to preventing hypoxia that can lead to neurological injury, therefore a user-friendly device that fits into a surgical practice is critical.

At the end of the day, the surgical team wants to focus primarily on the procedure and patient.

Individual comments from the clinicians on the ease-of-use indicated a preference for simple set-up and avoiding data entry and initiation steps. Both the INVOS and EQUANOX system scored highly in this category, both had minimal required initial setup and both were easy to use. The monitors are quite different: EQUANOX is a solid-state electronics monitor whereas the INVOS and FORE-SIGHT are essentially desktop PC platforms. Consequently EQUANOX has a distinct advantage in size, weight, and battery life and thereby portability.

Our users slightly preferred EQUANOX's simplicity –in-use and convenient form factor over INVOS' somewhat more advanced display features, noting that the advanced features were, in our institution, seldom used in routine clinical practice. FORE-SIGHT was distinguished here with "Poor" scores, and comments, on its monitor's ease of use. The FORE-SIGHT system, through one of the two manufacturer's with claims for 'Absolute' accuracy (the other being Nonin with their EQUANOX

8004CA 4-wavelength sensor), requires specific patient set-up both on the monitor and as mentioned in the sensor. The FORE-SIGHT monitor requests entry of age, weight, and body location parameters, then selection of specific sensor size; followed by the additional step of applying special light blocks or shields. This contributed to a material amount of additional set up time per case and was confusing for some users. We have to at least pause and consider the potential in the FORE-SIGHT, both from the increased likelihood, no matter how small, of data entry error based on the number of variables to be entered, possible impact on the validity of the displayed saturation if this occurred, and any ensuing risks from this.⁶ Framing this in even another context, consider how we would view selection of pulse oximetry if its accuracy was based on entering patient specifics. Would pulse oximetry be as widely prevalent as it is today if it did?

Regardless, any savings of time in device set-up, sensor set-up, sensor management, is appreciated in the operating room when the clinical team is faced with initiating and managing a surgical case. At the end of the day, the surgical team wants to focus primarily on the procedure and patient. Ancillary monitors and sensors should contribute to patient care by taking little time away from this yet provide reliable, consistent, and actionable data. Our caregivers reflected their views on this in the final satisfaction scores; we saw lower scores in ease-of-use categories correlate with the final satisfaction scores. EQUANOX, judged the most usable in both sensor and monitor by our evaluators, had the highest satisfaction and FORE-SIGHT, judged the least usable by scores, received the lowest satisfaction.

CONCLUSION

Our users rated the EQUANOX highest throughout the test evaluation, followed second by INVOS, and lastly, FORE-SIGHT.

Cerebral Oximetry is an evolving technology where devices of varying claimed advantages offer significantly different use experiences which may impact long-term satisfaction with, and value from, the technology. The technology needs to meet accuracy thresholds for action while also being usable: easy to use, user-friendly and adaptable to the medical environment it may be used in. Our users rated the EQUANOX highest throughout the test evaluation, followed second by INVOS, and lastly, FORE-SIGHT.

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