Pulse Oximeter Sensor Accuracy

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Purpose of Study.

To investigate the implications of variations in pulse oximeter sensor optical characteristics on patient safety.

Summary

Pulse oximetry is used Worldwide every day and is often influential in clinical decisions. Brave talk about leading edge medical technology gives the impression of thoroughly reliable systems, completely compliant with regulatory requirements.

This is a misleading picture. It is as if pulse oximeter sensors are an embarrassing detail that has been overlooked. Pulse oximeter system accuracy is very dependent on sensor accuracy. Sensor accuracy is dependant on the spectral properties of the sensor being the same as those used during the clinical trials. All too often this is not the case.

1008 sensors from 36 hospitals were surveyed. 30% of these sensors were a cause for concern. 17% of the sensors surveyed had wavelength errors with corresponding SATs value errors capable of compromising patient safety.

Clinical Decisions Without Foundation

Clinicians have come to rely on pulse oximeters. In good faith, judgements are based on the data they give.
The reliability of the data depends on the integrity of two very small, low cost components - Light Emitting Diodes.
If it is not known that the pulse oximeter sensor is within specification, every clinical decision made that is based on the data, is without foundation.

Introduction

In an ideal world, one would expect always to be able to go into a hospital and find that sensors of the same type, that when all tested on the same person, would all read the same. In practice this does not always happen. Particularly at patient low blood oxygen saturations (SATs), some pulse oximeter sensors will be found to read higher whilst others read lower. The operator can then be in the position of not knowing which sensor to believe. At worst clinical decisions could be made on faulty data.

When pulse oximetry was first introduced sensor error was not a major source of concern. At that time greater dependence would have been placed on blood gas analysis, and users expectations were lower. Users expectations of pulse oximetry have changed. Pulse oximetry is now being used in more demanding applications. Improvements in medicine have resulted in patients being treated at lower SATs than previously possible. Sensor errors are magnified at low SATs and previously inconspicuous errors can become a problem.

There is great concern in The USA that over 2000 babies every year have visual impairment related to ROP (Retinopathy of Prematurity), excessive oxygen is thought to be a major causative factor [(1)]. Some claim that new generation pulse oximeters can help here, but that is only if the accuracy of the sensors can be guaranteed. If the accuracy of the sensor cannot be guaranteed, it is like driving in a 30 mph speed limit, with the speedometer reading anywhere between 10 and 50 mph. There is a growing trend in the practice of spot checks, where a monitor is taken around the ward, and the SATs of each individual patient is recorded. The

value of this data depends on minimal variability between sensors. A change of sensor could result in the whole ward apparently becoming either better or worse.

Some believe that CE marking and FDA clearance are guaranties of sensor accuracy. This is not true, as historically there have been no standards that address the requirements of pulse oximeter accuracy. Even in the new International Standard on Pulse Oximeter Equipment [(2)] the issue of sensor accuracy is not clearly addressed. However the standard does state that functional testers and simulators shall not be used to validate sensor accuracy.

Pulse oximetry is a marriage of monitor and sensor technology. Monitor calibration is achieved by carrying out clinical breath down trials with a sensor of a particular specification. The results of the breath down trials are commonly referred to as the "R curve". This data is stored in the monitor in software form. The installation of software in a monitor is not a process that is particularly prone to errors, and software does not deteriorate with age. Sensor accuracy is dependant on maintaining during production the specification of the optical components, as used during the breath down trials. However unlike the installation of software in a monitor, the process of installing LEDs with the correct spectral properties in a sensor is relatively difficult to maintain in mass production. Also LEDs are prone to aging in a way that causes changes in the spectral properties of the LED s with consequent alterations in sensor accuracy. Thus in the calibration of a pulse oximeter system the sensor is the weakest link, variations in spectral properties being a major cause of variability in pulse oximeter readings.

Method.

Pulse oximeter sensors were studied from 36 hospitals. The sensors were either in use or held as spares in a variety of settings including clinical engineering departments, wards, and operating suites.

The sensors included both disposable and reusable sensors from most manufacturers including both Original Equipment Manufacturers and Third Party Manufacturers.

Each test consisted of a sensor circuit test, an optical component test, followed by a wavelength test. If

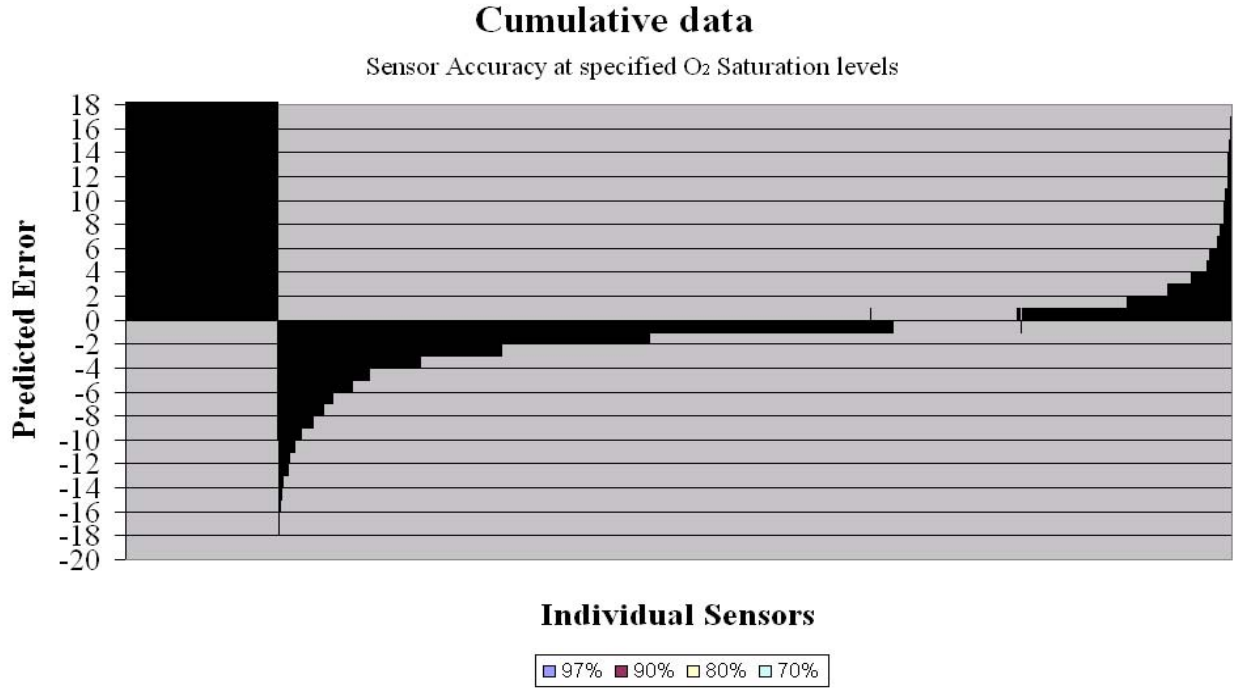


Figure 1.

circuit faults, optical component faults, or secondary emissions in the red were detected, wavelength data was not collected, and the sensors were recorded as being faulty.

Immediately prior to testing each sensor the spectrometer was calibrated against a neon argon source. Intensity correction was achieved through using a calibrated light source supplied by NPL. The light from the sensor LEDs was scattered through opal acrylic, and then passed through a quartz fibre to a spectrometer specifically designed for studying pulse oximeter sensors.

This specialised spectrometer was used to determine the wavelength errors in pulse oximeter sensors which were apparently functional. A wavelength error is defined as the difference between the expected wavelengths and the observed wavelengths. Wavelength errors for the red and infrared were treated separately and then summated. The effect of wavelength errors on the calculated SATs value that would be displayed on the monitor was calculated at patient SAT values of 97%, 90%, 80%, and 70%.

Results.

1008 sensors were studied from 36 hospitals (see Figures 1 and 2).

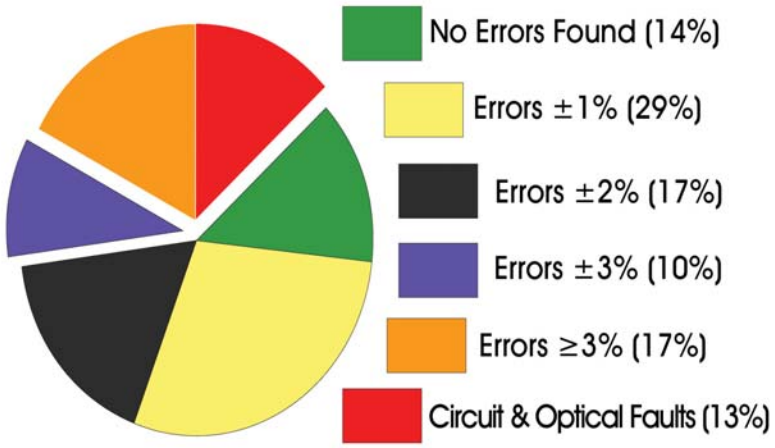


Figure 2.

Sensors with circuit faults and faulty optical components were noted, and accuracy data only taken from apparently functional sensors.

Only 14% of the sensors surveyed had no error, thus leaving 86% with errors of some sort.

Any SATs error contributable to a sensor is a systematic error additional to the component for biological variability. When the magnitude of such an error is 4% or more clinicians stated that they considered this unacceptable due to potential increased risk of an adverse incident occurring.

13% of the sensors had circuit or optical faults. Within this group there were sensors that appeared to be functional when connected to a monitor, but produced SATs values of around 80% regardless of patients SATs values. This was found to be due to conductivity of insulating material within the sensor cable.

73% of sensors that were apparently functional had SATs value errors of varying amounts. 17% of all the sensors were a cause of particular concern as they were apparently functional with SATs value errors of 4% or more.

Thus 13% of the sensors had circuit or optical faults, whilst 17% had unacceptable wavelength errors. In total 30% of the sensors surveyed were a cause for concern.

Discussion

A pulse oximeter system consists of a sensor and a monitor. The accuracy of the system is very dependant on the accuracy of the sensor. The accuracy of the sensor strongly depends on two specific wavelengths of light which come from the LEDs in the sensor. If the wrong wavelengths are used, then the wrong measurement of blood oxygen is made and hence the displayed SATs values are not correct. Errors in the wavelengths of

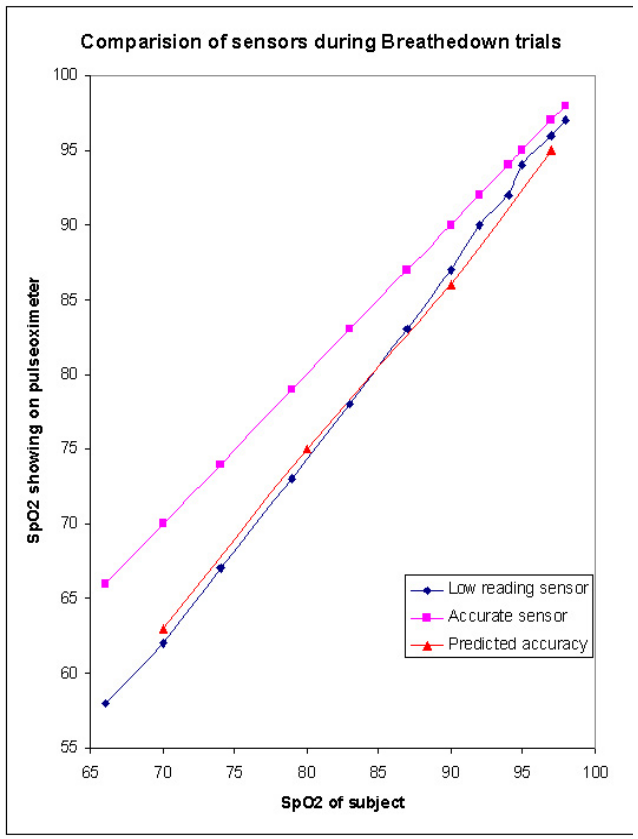


Figure 3.

the emission spectra of the LED's in a pulse oximeter result in corresponding changes in the observed oxygen saturation reading [3].

The effect of wavelength errors on the difference of readings obtained from two sensors of the same type during breathdown is illustrated in Figure 3. The two sensors used concurrently on the same person with the same type of pulse oximeter system during a breathdown trial demonstrate the effect of the wavelength error. The predicted error is shown to coincide with the error found when using the inaccurate sensor. The sensor with the correct wavelength is identified by the pink line. The breathdown data from the sensor with the incorrect wavelengths is represented by the blue line. The predicted performance of the sensor with the incorrect wavelengths is represented by the red line.

The magnification of Errors

At lower saturations the error introduced into pulse oximetry by wavelength errors is greater as the absorption of reduced haemoglobin is much more sensitive to wavelength errors [4]. So just when it is needed, a pulse oximeter sensor can become useless. This is apparent in Figure 4 where the gradient of the lines increase as saturation falls from 97% to 70%.

The Manufacturer's Dilemma

When making accuracy claims the manufacturer has to allow for not only the biological variability between patients – as noted during clinical trials - but also for any systematic errors introduced by variations in the specifications of the LED characteristics from those used for the clinical trials. Often quoted accuracy statistics seem to allow for biological variability with little room for sensor related systematic bias.

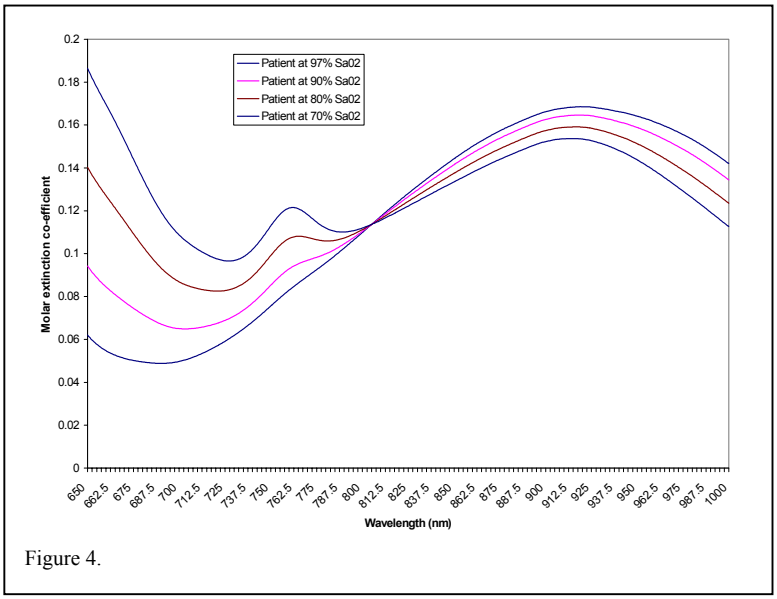


Figure 4.

Biological variability can be thought of as the variations in pulse oximeter readings that occur when the same sensor is tested on different people, even though the oxygen content of their blood is the same. Sensor variability can be thought of as the variations in pulse oximeter reading that occur when sensors with different spectral characteristics are tested on the same person.

During the original clinical trials calibration was done with a sensor of particular wavelengths. A calibration curve (R values) was compiled by comparing pulse oximeter readings with multi-wavelength measurements of oxygen saturation in arterial blood samples (SpO2) from a number of hypoxaemic volunteers [2].

The light absorption of the blood's oxygenated and, more importantly, deoxygenated haemoglobin is significantly wavelength-dependent, the relationship between R and Sp02 strongly depends on the specific emission characteristics (e.g., colour) of the sensor's LEDs [5]. Sensor accuracy depends on the value of R corresponding to the actual LED wavelengths used in the sensor.

Manufacturers take three approaches to ensuring sensor accuracy. Many sensor manufacturers purchase and screen LEDs to a narrow range of wavelengths and program into the monitor a single calibration curve that corresponds to this range. Other manufacturers use a resistor-encoding scheme in which several calibration curves are programmed into pulse oximeter monitors to span a broad range of LED wavelengths needed for high-volume sensor manufacturing. In principal these two approaches should ensure accurate sensors. However some manufacturers use a liberal range of wavelengths with a single curve, resulting in degraded accuracy performance, particularly at low oxygen saturations.

Assuming that the original trials were done correctly, the accuracy of a pulse oximeter system is largely dependant on the sensor in use having the correct wavelengths. The accuracy of the sensor is proportional to the wavelength error. Systematic errors resulting from inaccurate sensors and biological errors are cumulative, and if the cumulative sensor and biological error are greater then the manufacturers claim, then the sensor does not function as the manufacturer claims.

The data presented in Figures 1 and 2 indicates that not all the sensors in use are as accurate as might be desired. Some sensors seem to be inaccurate from new, whilst others have deteriorated with age. A view that has been further confirmed by earlier surveys of pulse oximeter sensors [6][7][8].

Consequences of Getting It Wrong

Not all sensors are the same. Sensors vary due to manufacturing tolerances and aging. Pulse oximeter systems cannot function as the manufacturers claim when sensor specifications vary from the original clinical trials.
This can lead to sensors that introduce a high reading bias and sensors that introduce a low reading bias. Any error introduced by a sensor is magnified as O_2 SATs fall (Figures 3 and 4).
High reading sensors can result in oxygen therapy being deferred or not given. Low reading sensors can result in excessive oxygen therapy being given. Inappropriate oxygen therapy can lead to outcomes ranging from metabolic disturbances to death.

30% of the sensors in our surveys do not function within clinical expectations. There are implications for patient safety. Sensors that introduce an error in SATs values can lead to inappropriate clinical decisions regarding oxygen therapy. This is a problem that can lead to cataracts, retinopathy, and strokes. We have noted that it is not unusual for sensors with circuit and/or optical faults to be kept as spares to be used in an emergency. This poses a clinical risk.

Sensors That Read High

Where a sensor introduces a high reading bias the clinician is led to believe that the patient is better oxygenated than in reality. Oxygen therapy may then be delayed, not instigated or reduced. The impact of this can be considered in the following examples.
Hypoxia - Insufficient Oxygen administered contributing to oxygen starvation leading to hypoxic damage to central nervous system and other tissue as evidenced by e.g. Confusion (such as Post op confusion), Strokes, Cerebral palsy, higher morbidity and mortality.
Sleep apnoea studies –the patient is not considered to be hypoxic and therefore a different clinical decision is made and management is not the same as would have been the case with accurate results. e.g. CPAP, surgery.

Sensors That Read Low

Low reading Sensors will lead clinicians to consider that the patient has poorer oxygen levels than is the case. Thus low reading sensor bias could lead to higher levels of oxygen administration than would

otherwise have been the case. This is a particular risk not only for premature neonates but also for those with Chronic Obstructive Pulmonary Disease (COPD / COAD) with a respiratory drive dependent on relative hypoxia.
The risk for the baby is mainly one of ROP. A causative link exists between high levels of oxygen and Retinopathy of Prematurity (ROP). The clinician is therefore trying to maintain the SpO_2 within a very specific range. There are still over 2000 cases of ROP per year in the USA and more in Europe [1].
The risk for the COPD patient is one of metabolic upset such as acid base imbalance and consequent morbidity etc. It is believed that hyperoxia can cause pulmonary toxicity. This is not just respiratory acidosis but also proinflamatory changes through to atelectasis. The risks from excess oxygen for an adult is therefore not only to those with Chronic Obstructive Pulmonary Disease (COPD) but also acutely ill patients e.g. myocardial infarct [9, 10], stroke [11], coronary bypass surgery [12], post neonatal hypoxia [13].

The additional problem for the staff is the repeated triggering of the low oxygen alarm with the frustration then engendered.

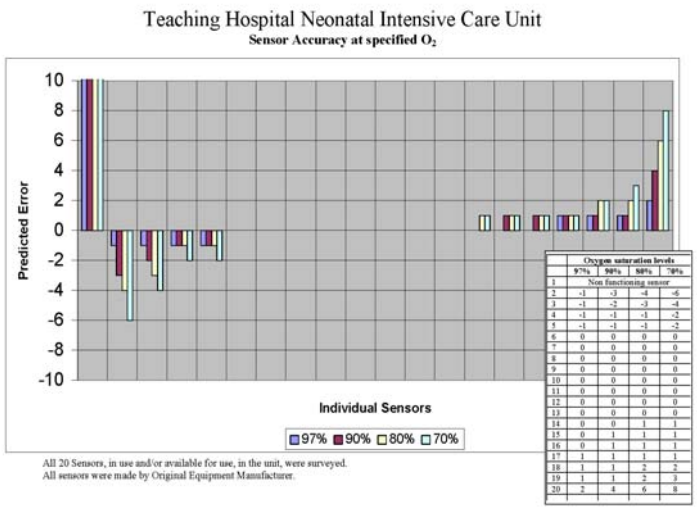
Sensors Not Working

Non-functioning sensors whilst not obviously dangerous may be a source of delay in obtaining information for clinical decisions – a risk in itself to the patient as well as frustration for staff. Many of the non-functioning sensors found are kept as 'spares' for use as and when required e.g. when the in use sensor is found to be broken. Intermittent faults and those due to internal conductivity in the insulating materials can also confuse the clinical picture.

Target Oxygen Saturation ranges

Oxygen therapy targets can only be reliably obtained if the pulse oximeter system is accurate.
Within the Special Care Baby Unit the target range for oxygen is selected to optimise survival with minimal morbidity. Hypoxia can increase the risk of e.g. cerebral palsy whereas hyperoxia increases the risks of Retinopathy of Prematurity (ROP) and chronic lung disease. The BOOST trials only allow for a minimal gap between the ranges of oxygen therapy under study. Sensor error bias could obscure any potential results.
The British Thoracic Society (BTS) guidelines [14] recommend levels for the lower levels for oxygen saturation (90%)and also upper levels (93%) for oxygen therapy. These risks of increasing the need for Intensive Care are partly related to hyperoxic respiratory acidosis [15].

Changes in users expectations are putting greater demands on pulse oximetry. Some claim that new generation pulse oximeters can help reduce the incidence of ROP, but this is only if the accuracy of the sensors can be guaranteed. More patients are being treated whilst in hypoxia, large errors at low SATs compromise patient safety. The progress of many patients is recorded by monitoring trends in SATs values by spot checks. The value of this data depends on minimal variability between sensors.



	Oxygen saturation levels			
	97%	90%	80%	70%
1	Non functioning sensor			
2	-1	-3	-4	-6
3	-1	-2	-3	-4
4	-1	-1	-1	-2
5	-1	-1	-1	-2
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
11	0	0	0	0
12	0	0	0	0
13	0	0	0	0
14	0	0	1	1
15	0	1	1	1
16	0	1	1	1
17	1	1	1	1
18	1	1	2	2
19	1	1	2	3
20	2	4	6	8

Figure 5.

One Example

A baby desaturated and the nurses were accused of turning off the low oxygen alarm on the monitor. The nurses denied this and borrowed our equipment generating the data in Figure 5. The sensor in use on the day was the high reader at the right of the graph. The nurses argued that the low oxygen alarm did not sound because a high reading sensor was responsible for causing the monitor to read high.

Some believe that CE marking and FDA clearance are guarantees of sensor

accuracy, but this belief is unfounded. In practice mismatches between sensor spectral properties and the R curve in the monitor are putting patients at risk from the perils of excessive or insufficient oxygen therapy.

Conclusion.

Pulse oximeter sensor accuracy is primarily dependent on knowing the LED wavelengths that arrive at the detector during measurement. In theory, this is done during the manufacturing phase by selecting sensor LED wavelengths in a narrow enough band to meet a desired measurement accuracy requirement. In practice due to manufacturing and aging errors, LED wavelengths arriving at the detector are not always what the manufacturer intends. Thus, it is not unusual to find pulse oximeter sensors with wavelength errors of sufficient magnitude to compromise patient safety. In other words, not all pulse oximeter sensors function as the manufacturers claim and as the user expects.

The accuracy of a pulse oximeter system is very dependant on the accuracy of the sensor. The accuracy of the sensor is largely dependant on the optical characteristics of the sensor matching the R curve in the monitor.

Not all sensors match the R curve in the monitor that they are used with. The data shows that variations in sensor spectral properties result in pulse oximeters not functioning as the manufacturers claim. Within the 36 hospitals surveyed 30% of the sensors surveyed had unacceptable faults, including 17% of sensors with SATs errors of sufficient magnitude to compromise patient safety.

Clinicians have come to rely on pulse oximeters. In good faith judgements are based on the data they give. The reliability of the data is very dependant on the accuracy of the sensor. If the accuracy of the sensor is unknown, every clinical decision made, that is based on the data is without foundation.

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