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ORIGINAL RESEARCH

Where do pulse oximeter probes break?

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Abstract Pulse oximetry, a non-invasive method for accurate assessment of blood oxygen saturation (SPO2), is an important monitoring tool in health care facilities. However, it is often not available in many low-resource settings, due to expense, overly sophisticated design, a lack of organised procurement systems and inadequate medical device management and maintenance structures. Furthermore medical devices are often fragile and not designed to withstand the conditions of low-resource settings. In order to design a probe, better suited to the needs of health care facilities in low-resource settings this study aimed to document the site and nature of pulse oximeter probe breakages in a range of different probe designs in a low to middle income country. A retrospective review of job cards relating to the assessment and repair of damaged or faulty pulse oximeter probes was conducted at a medical device repair company based in Cape Town, South Africa, specializing in pulse oximeter probe repairs. 1,840 job cards relating to the assessment and repair of pulse oximeter probes were reviewed. 60.2 % of probes sent for assessment were finger-clip probes. For all probes, excluding the neonatal wrap probes, the most common point of failure was the probe wiring (>50 %). The neonatal wrap most commonly failed at the strap (51.5 %). The total cost for quoting on the broken pulse oximeter probes and for the subsequent repair of devices, excluding replacement components, amounted to an estimated ZAR 738,810 (USD $98,508). Improving the probe wiring would increase the life span of pulse oximeter probes. Increasing the life span of probes will make pulse oximetry more affordable and accessible. This is of high priority in low-resource settings where frequent repair or replacement of probes is unaffordable or impossible.

Keywords Pulse oximetry · Probes · Probe wiring · Low-resource settings

SC, GvdM, JH, DW and JL participated in the design of the study. GvdM collected data for this study and SC performed the statistical analysis. SC and DW wrote the first draft of the manuscript. All authors contributed to the writing of this paper and read and approved the final manuscript.

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1 Introduction

Hypoxaemia can be diagnosed using clinical signs, invasive blood gas analysis, or pulse oximetry and is treated with various methods of oxygen delivery. However, recognising hypoxaemia using clinical signs alone has both low sensitivity and specificity; as a result many patients who need oxygen urgently are missed and those who no longer need oxygen therapy are over treated. While invasive blood gas analysis is the gold standard for measuring the adequacy of arterial oxygenation, this method has drawbacks [1]. It is expensive and unavailable in many low-resource settings [2]. In addition, there is often a delay between blood sampling and the receipt of results from blood gas analysis which can impact negatively on patients whose condition rapidly changes [1]. Pulse oximetry has revolutionised the monitoring of oxygen therapy in most spheres of clinical medicine, especially where the need for supplementary oxygen is questioned or the adequacy of oxygen therapy is in doubt.

The use of either continuous or intermittent pulse oximetry is a simple and effective bedside means of accurately measuring arterial oxygen saturation. These methods allow changes in oxygen saturation to be identified immediately so that clinicians can take appropriate action before irreversible tissue damage occurs [1]. Furthermore, the use of pulse oximetry can guide the appropriate use of oxygen which is of particular benefit in under-resourced settings, where oxygen is expensive and often not widely available, thus minimising unnecessary oxygen use and wastage [3]. The World Health Organization, acknowledging the importance of oxygen monitoring, further mandates the use of pulse oximetry in all surgical procedures in their surgical safety checklist [4]. Although pulse oximetry can be seen to be highly beneficial and one of the most important monitoring tools in health care facilities, it is of concern that pulse oximetry is often not available in many low resource settings, especially in rural areas where the provision of good health care services is severely restricted [5].

There are numerous reasons why many modern medical devices, such as pulse oximeters, are unavailable in low-resource settings. Medical devices are often expensive and specifically designed for well-resourced countries. The overly sophisticated design can easily create information overload on poorly trained health workers. Many settings lack organised procurement systems and inadequate medical device management and maintenance structures. Furthermore medical devices are often fragile and not designed to withstand rough handling or extreme environmental conditions. Consumables, disposable equipment and accessories with a limited life span, such as oximeter probes, are a particular challenge in these circumstances.

The current literature has very little documentation on the lifespan of pulse oximeter probes and few details on the reason for, and site of, probe failures and breakages. Anecdotal evidence suggests that frequent replacement or repair of broken pulse oximeter probes further burdens health care budgets in many settings. Replacement probes provide a major revenue stream for vendors of oximetry products and therefore there is no incentive to make robust probes or ones that can be used with generic devices.

In countries with limited resources, a robust, long lasting and reusable pulse oximeter probe, designed to meet the demands of low-resource settings, would aid in ensuring that pulse oximetry is available in these settings. Single-patient- use probes are not suitable for low income settings due to supply constraints and recurrent costs. To guide the design of a new robust, long lasting probe that is well suited for use in low-resource settings the weaknesses and design failures of currently available probes need to be understood in order to be addressed.

This study forms part of a larger study aiming to develop a durable, low cost pulse oximetry probe that can be used with pulse oximeters to reduce neonatal, child and maternal mortality and morbidity rates in low-resource settings. The aim of this study was to document the site and nature of pulse oximeter probe breakages in a range of different probe designs in a low to middle income country. The objective was to identify design faults which could be addressed in order to guide the development of one or more probe designs better suited to the needs of health care facilities in low-resource settings.

1.1 Background

Reusable pulse oximeter probes are available in various designs. In general, all designs consist of active sensor components [electronics such as two light emitting diode (LEDs) and a photodiode], a protective housing that includes an attachment mechanism, an electro-magnetic shielded cable and a connector. The operation mode (reflectance or transmittance) and the intended placement of the probe direct the design of the housing. The most common transmittance probe designs for placement on digits are clips, gloves, Y-shape designs and wraps (Fig. 1). Clips are mostly used in adults. Glove designs are offered in various sizes, so that they can be used for adults and children. Loose Y-shape designs are usually attached with adhesive tape and can be used on both adult and paediatric patients. Due to the large variability in size of digits in children and neonates, easily adjustable wraps are more suitable for these patients. For the application on the ear, the clip design is most appropriate. Single patient-use probes are designed as wraps, mostly for cost reason.

2 Methods and materials

A medical device repair company based in Cape Town, South Africa, specializing in pulse oximeter probe repairs was identified as a suitable site to evaluate the pattern of pulse oximeter probe breakages. Pulse oximeter probes are sent to this company for repairs from both the public and private health care sectors in the Western Cape province of South Africa.

We hypothesized that many probes have common weaknesses and failure points. To test this hypothesis a retrospective review of job cards was conducted that related to the assessment and repair of damaged or faulty pulse oximeter probes. The review of damaged probes was conducted, by a university engineering undergraduate student, between 19th January and 10th February 2012. The recorded content of each job card included: client, manufacturer, fault, action taken, and component repaired. As part of the comprehensive evaluation of each probe by the repair company the LED and photodiode sensor were always tested for function and this too was recorded on the job card. An estimate of the average cost of repairs was made.

Data were entered into and analysed using Microsoft Excel.

3 Results

Four thousand job cards were reviewed of which 2,095 related to the assessment and repair of 1,840 pulse oximeter probes and 255 adaptor cables for the probes. Only the 1,840 job cards relating to the probe breakages will be discussed further.

Two-thirds of job cards reviewed for damaged or faulty pulse oximeter probes were for probes sent from the private health care sector in the greater Cape Town area (Table 1). Approximately one-third (31.8 %) of all probes were found to be compatible with Nellcor devices. Most (60.2 %) probes were of the finger-clip type, while less than 3 % of the probes were of the ear clip type. Of all the job cards reviewed, 97.6 % of the probes were deemed repairable and subsequently fixed, whilst the remainder (2.4 %) were considered irreparable and discarded. Information on what made the probe fault irreparable was not documented. In Table 2, a summary of the failure points of the various types of pulse oximeter probes are listed. For all probes, excluding the neonatal wrap probes, the most common point of failure was the probe wiring. In all of these probes in excess of 50 % of probe failures were due to faulty or damaged wiring. For the neonatal wrap probes the most common failure point was the strap (51.5 %) with the wiring being the second most common problem (34.1 %). Table 3 ("Appendix") details the faults by probe type.

3.1 Cost of repairs

The medical device repair company, at which this study was conducted, charged South African rand (ZAR) 90 (approximately USD $12) for an assessment and provision of a quote for the repair. On acceptance of the quote each repair was charged at ZAR 270 (USD $36); this cost excluded replacement components. These costs exclude the inevitable packing and shipping costs associated with the probe repair. Thus the total cost for quoting on the broken pulse oximeter probes and for the subsequent repair of devices, excluding replacement components, amounted to an estimated ZAR 738,810 (USD $98,508).

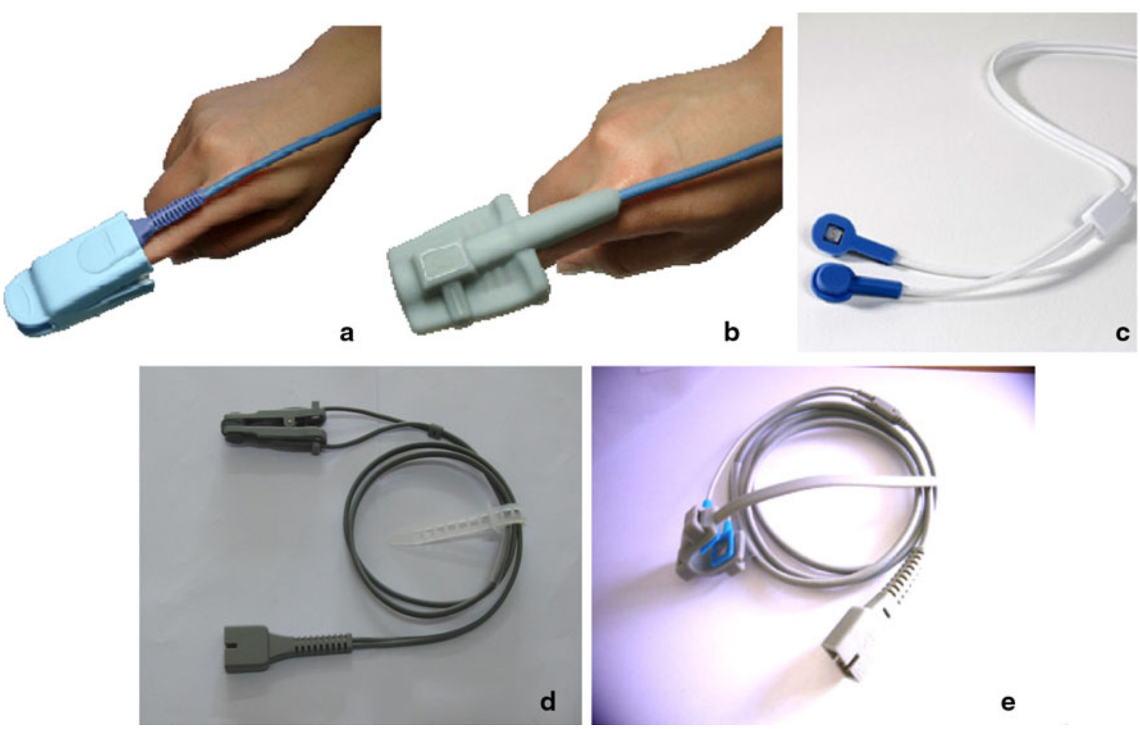

Fig. 1 Digit probe types classified by housing and adhesive design. **a** Finger clip; **b** Finger glove; **c** Multi-use 'Y' probe; **d** Ear clip; **e** Wrap

Table 1 Descriptive characteristics of job cards reviewed for broken probes (N = 1,840)

Characteristic	n	%
Client		
Private sector	1,148	62.4
Public sector	692	37.6
Compatible with		
Nellcor	586	31.8
Datex	343	18.6
Philips	169	9.2
Ohmeda	168	9.1
Trusat	144	7.8
Nihon Kohden	112	6.1
Oxytip	75	4.1
Draeger	59	3.2
Criticare	43	2.3
Novametrix	39	2.1
Masimo	32	1.7
Simed	19	1.0
Other*	51	2.8
Probe type		
Finger clip	1,108	60.2
Adult glove	312	17.0
Multi-use "Y-shape" probe	237	12.8
Neonatal wrap	88	4.8
Paediatric glove	51	2.8
Ear clip probe	44	2.4
Outcome		
Repaired	1,796	97.6
Condemned	44	2.4

4 Discussion

This study has provided new information regarding pulse oximeter probe failure points and weaknesses of existing probe designs. It has also described the associated financial burden of repairing broken probes. This information provides insight that will guide the design of a more robust pulse oximeter probe.

Nearly 98 % of all faulty or damaged probes sent for repair were repairable. It is questionable whether health care facilities in low-resource settings have the necessary finances available to fix probes. Furthermore many of these facilities may not have access to a comparable medical device repair service that is able to repair pulse oximeter probes or the shipping costs may not be affordable.

Our main finding is that across all probe types, excluding the neonatal wrap probe, the wiring is the most common point of failure. The wiring fails at many points, most often at the junction between the wire and another part of the probe. Failure in the wiring can have many causes. Fatigue of the thin wires at solder points may result in failure due to frequent and repetitive movements of the cable. Single, elevated mechanical stress on the solder points, e.g. due to improper manipulation or storage of probes, or sudden patient movements can also cause a failure at the solder point on the sensor or connector side. These observations suggest that the wiring interface is under-designed and, where applicable, the strain relief not effective. In the development of a more robust pulse oximeter probe the current weaknesses in the probe wiring should be addressed. Some probe designs, such as the gloves, have the cable moulded into the rubber boot which provides the strain relief. While this design simplifies manufacturing and reduces component costs, it might have

Table 2 Failure points by probe type. The most frequent probe failure points for each type are highlighted

Failure point	Probe type				
	Adult finger clip N = 1,108	Finger glove (adult and paediatric) N = 363	Multi-use "Y" probe N = 237	Ear clip N = 44	Neonatal wrap N = 88
Probe shell	147 (13.3 %)	N/A	N/A	2 (4.5 %)	N/A
Glove	N/A	108 (29.8 %)	N/A	N/A	N/A
Connector pins	45 (4.1 %)	28 (7.7 %)	14 (5.9 %)	1 (2.3 %)	5 (5.7 %)
Sensors	47 (4.2 %)	23 (6.3 %)	13 (5.5 %)	3 (6.8 %)	–
Swivel buttons	18 (1.6 %)	N/A	N/A	N/A	N/A
Springs	167 (15.1 %)	N/A	N/A	2 (4.5 %)	N/A
Pads	81 (7.3 %)	N/A	N/A	N/A	N/A
Wires	572 (51.6 %)	196 (54.0 %)	194 (81.9 %)	31 (70.5 %)	30 (34.1 %)
Probe cable	95 (8.6 %)	14 (3.9 %)	16 (6.8 %)	N/A	11(12.5 %)
Connector	–	9 (2.9 %)	1 (0.4 %)	5 (11.4 %)	–
Strap	–	–	–	–	45 (51.1 %)

a negative impact on robustness of the wiring inside the glove type design. In a novel more robust pulse oximeter probe design we suggest particular attention is given as to how strain relief is handled.

Results also show that the active sensor parts such as LEDs and photodiodes play a minor role in the defects. It can be concluded that the current design choice of electronic components and its protection is appropriate and does not require special attention. The attachment mechanism of the neonatal wrap requires an innovative solution.

Although the presented data provide interesting insights into weaknesses in currently available pulse oximeter probes there are limitations to this study. Firstly, this study provides an overview of probe breakages and it was not intended to provide an in-depth analysis of the exact mechanism of each breakage. Secondly, the data cannot be used to make assumptions regarding what may appear to be the most vulnerable probe or the probe most likely to break as no data are available to indicate the age of the probes at time of repair, if they were refurbished previously, what kind of use the probes have been subjected to, or the distribution of each type of probe currently being used in healthcare facilities in the greater Cape Town area. Thirdly, it is not clear if health care facilities send all broken probes for repair. It was therefore not possible to assess the nature of breakage of all probes used. To investigate probe breakages in more detail, a larger prospective study investigating faulty probes within the health care setting during their entire life cycle is required.

5 Conclusion

These data provide useful information that could guide designers and manufactures to improve the components, in particular the probe wiring and strain relief, to increase the life span of pulse oximeter probes. Increasing the life span of probes by making them more robust will make pulse oximetry more affordable in all settings irrespective of income. However in low-resource settings where frequent repair or replacement of probes is unaffordable or impossible these findings will be particularly useful. Increasing the affordability of the devices will in turn increase the accessibility of pulse oximetry for monitoring of lifesaving oxygen therapy in low-resource settings where it is often unavailable.

Conflict of interest The authors declare that they have no competing interests.

Appendix

See Table 3.

Table 3 Specific probe faults by probe type

Fault	Adult finger clip N=1108 n (%)	Finger glove[a] N=363 n (%)	Multi-use 'Y' probe N=237 n (%)	Ear clip N=44 n (%)	Wrap probe N=88 n (%)
Wires	572 (51.6%)	196 (54.0%)	194 (81.9%)	31 (70.5%)	30 (34.1%)
Wires off in cable	197 (33.0%)	33 (16.8%)	28 (14.4%)	8 (25.8%)	1 (3.3%)
Wires off at connector	134 (23.4%)	37 (18.9%)	30 (15.5%)	7 (22.6%)	3 (10.0%)
Wires off at connector	71 (12.4%)	61 (31.1%)	87 (44.9%)	10 (32.3%)	10 (33.3%)
Wires off at photodiode	67 (11.7%)	38 (35.9%)	–	5 (16.1%)	4 (13.3%)
Wires off at probe	62 (10.1%)	38 (32.5%)	113 (58.3%)	6 (19.3%)	12 (40.0%)
Wires off at LED	13 (2.3%)	1 (0.5%)	–	–	–
Wires shorting in cable Incorrect wiring	2 (0.4%)	–	–	–	–
Springs	167 (15.1%)			2 (4.5%)	
Damaged	106 (63.5%)			2 (100%)	
Missing springs	38 (22.8%)			–	
Missing spring cap	23 (13.8%)			–	
Shell	147 (13.3%)			2 (4.5%)	
Broken bottom shell	58 (39.5%)			2 (100%)	
Broken top shell	47 (32.0%)			–	
Both shells broken	36 (24.5%)			–	
Missing shell	6 (4.1%)			–	
Strap					45 (51.1%)
Torn/ damaged					27 (60.0%)

Table 3 continued

Fault	Adult finger clip N=1108 n (%)	Finger glove[a] N=363 n (%)	Multi-use 'Y' probe N=237 n (%)	Ear clip N=44 n (%)	Wrap probe N=88 n (%)
Torn bridge					18 (40.0%)
Boot (glove)		108 (29.8%)			
Torn		102 (94.4%)			
Worn		4 (3.7%)			
Loose		1 (0.9%)			
Stretched					
Cable	95 (8.6%)	14 (3.9%)	16 (6.8%)		11 (12.5%)
Broken cable	45 (47.4%)	6 (42.9%)	7 (43.8%)		–
Cable worn	26 (27.4%)	7 (50.0%)	9 (56.3%)		11 (100%)
Damaged strain relief	21 (22.1%)	1 (7.1%)	–		–
Loose strain relief	1 (1.1%)	–	–		–
Pads	81 (7.3%)				
Loose	43 (53.1%)				
One pad damaged	20 (24.7%)				
Both pads damaged	12 (14.8%)				
Missing pad	5 (6.2%)				
Sensors	47 (4.2%)	23 (6.3%)	13 (5.5%)	3 (6.8%)	
Faulty LED	28 (59.6%)	4 (17.4%)	4 (30.8%)	2 (66.7%)	
Faulty photodiode	12 (25.5%)	3 (13.0%)	2 (15.4%)	–	
Sensitivity too low	3 (6.4%)	2 (8.7%)	–	1 (33.3%)	
Missing photodiode	3 (6.4%)	1 (4.3%)	–	–	
Loose sensor	2 (4.3%)	–	–	–	
Missing LED	1 (2.1%)	3 (13.0%)	5 (38.5%)	–	
Silicone open	1 (2.1%)	–	–	–	
Damaged screen	–	9 (39.1%)	2 (15.4%)	–	
Connector pins	45 (4.1%)	28 (7.7%)	14 (5.9%)	1 (2.3%)	5 (5.7%)
Broken	27 (60.0%)	12 (42.9%)	9 (64.3%)	1(100%)	1 (20.0%)
Bent	9 (20.0%)	16 (57.1%)	5 (35.7%)		4 (80.0%)
Corroded pins	8 (17.8%)	–	–		–
Dirty pins	3 (6.7%)	–	–		–
Swivel buttons	18 (1.6%)				
Broken off	12 (66.7%)				
Missing	5 (27.8%)				
Bent	1 (5.6%)				
Connector		9 (2.5%)	1 (0.4%)	5 (11.4%)	
Damaged		9 (100%)	1 (100%)	5 (100%)	

[a] Includes both adult (n = 312) and paediatric (n = 51) glove probes

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