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ORIGINAL ARTICLE

Comparison of new generation motion-resistant pulse oximeters

Jennifer Townshend,[1] Barry J Taylor,[1] Barbara Galland[1] and Sheila Williams[2]

Departments of [1]Women's and Children's Health and [2]Preventive and Social Medicine, Dunedin School of Medicine, University of Otago, Dunedin, New Zealand

Aim: To compare the performance of pulse oximeters during movement and brachial artery occlusion.

Methods: Three machines (MasimoSET, using MasimoSET LNOP Pdt paediatric sensor, Mars 2001 using Novametrix paediatric sensor no. 6455 and Nellcor 595 using Nellcor 595 Oximax-P paediatric sensor and Nellcor 595 MAX-FAST adhesive forehead reflectance sensor) were used simultaneously on the left hand and forehead. The subjects were 18 healthy children aged 6–10 years. Interventions were 20 sequential 90° body turns from mimicking normal movements while asleep followed by step increases in brachial artery occlusion. Mean heart rate (HR) from the four machines was compared with ECG HR. Haemoglobin O_2 saturation was compared with a baseline saturation and the proportion of epochs with false (low) saturation values.

Results: The mean difference from ECG HR was not clinically significantly different for any machine but the limits of agreement were such that the Mars Model 2001 and Nellcor 595 (forehead) could have clinically important differences from ECG-derived HR (–20.04–15.00 and –14.95–14.04, respectively). Only the Nellcor 595 with finger probe had limits of agreement within the *a priori* set value of 4%. The prevalence of epochs with an haemoglobin O_2 saturation of greater than 4% below baseline values was lowest for the Nellcor 595 finger probe (1.59%) and highest for the Nellcor forehead probe (20.45%). During brachial artery occlusion, all machines performed well up to within 20 mmHg of total occlusion.

Conclusion: Current motion-resistant pulse oximeters performed well but only the Nellcor 595 with finger probe achieved our *a priori* set standards.

Key words: Masimo; movement artifact; Nelcor; Novametrix; pulse oximeter.

Pulse oximetry is now the standard non-invasive method of measuring blood oxygenation in both children and neonates. Accurate and reliable measurements are important both in acute and chronic settings, to aid the clinician in diagnosis as well as for ensuring that the delivery of treatment is effective.

Although most models of pulse oximeter have been proven to be reliable in still, well-perfused patients,[1] inaccuracies during movement and poor perfusion have been inherent in the design of all traditional pulse oximeters.[2] Despite recent attempts to minimise this, false alarm rates of 7.8% have been reported in poorly perfused compared with 1% in well-perfused subjects.[3] Other studies have shown that voluntary movements can cause false desaturation and false alarms, with as many as 71% of all alarms being false.[2,3] This high false alarm rate can lead to 'true' alarms being ignored during continuous monitoring.

In the early 1990s, new analysis algorithms were developed specifically with the aim of reducing artefacts related to motion and poor signal without increasing the number of false negatives (true episodes of desaturation not recorded by the machine). The new technology employed by the MasimoSET has been shown to be overwhelmingly superior to other models tested in both accuracy and reliability during motion.[4,5]

Several new models incorporating new technology have recently been developed and are being marketed with claims of being more accurate during motion. In trying to decide which model our hospital should use in both children's sleep studies and the newborn intensive care unit, we could not find any published studies comparing the MasimoSET with the recently available Nellcor 595 and Novametrix Mars Model 2001 in either the adult or paediatric age groups. The aims of this study were therefore to compare each model's recorded heart rate (HR) with an ECG-derived HR and to compare each model's recorded oxygen saturation with a baseline recorded saturation both during movement and poor perfusion in a sample of school-aged children. The number of epochs of false desaturation were also calculated.

Key Points

1. New generation pulse oximeters have been developed in an attempt to decrease high false alarm rates reported during movement and poor perfusion.
2. All new generation pulse oximeters tested performed well to within 20 mmHg of total brachial artery occlusion, mimicking poor perfusion.
3. Only the Nellcor 595 (finger sensor) met all predefined criteria for accuracy during movement.

Correspondence: Professor Barry J Taylor, Department of Women's and Children's Health, Dunedin School of Medicine, University of Otago, PO Box 913, Dunedin, New Zealand. Fax: +64 3 474 7817; email: barry.taylor@stonebow.otago.ac.nz

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Methods

Study Population

The sample comprised 20 healthy volunteers, 14 boys and six girls from a local primary school in the Dunedin area. Their mean age was 8.2 years with an age range 6–10 years. Informed written consent was obtained from both parents and participants. Ethical approval was obtained from the Otago District Health Board Human Ethics Committee (ref no. 03/05/040).

Study Design

Information sheets and consent forms were sent to the parents of 50 randomly selected children aged between 5 and 10 years. The first 20 children who returned signed consent forms were recruited into the study. Each child was monitored with three models of pulse oximeter (MasimoSET, Nellcor 595 and Novametrix Mars model 2001). The three finger sensors (MasimoSET LNOP Pdt paediatric sensor, Nellcor OXIMAX-P paediatric sensor and Novametrix paediatric sensor no. 6455) were allocated sequentially in rotation between consecutive subjects to either the index, middle of ring finger on the left hand such that each finger was used an equal number of times over the whole study for each type of probe. The fourth probe, a Nellcor 595 MAX-FAST adhesive forehead reflectance sensor was used in each child. The advantages of the forehead sensor are said to be a faster response time and immunity to the effects of vasoconstriction.[6] All sensors were disposable adhesive sensors and were shielded from one another to minimise cross-talk. Signal quality from each pulse oximeter was checked at the start of each volunteer experiment. The forehead sensor was secured using the foam head-band provided. The numeric pulse rate and saturation of each oximeter was digitised at a sampling frequency of 40 Hz using PowerLab hardware (ADInstruments, Castle Hill, NSW, Australia) and viewed and analysed using PowerLab Chart 4.6 software. The high sampling rate was used as we were also digitising the plethysmograph signal and our system required equal sampling speeds on each channel. Signal quality from each pulse oximeter was checked at the start of each volunteer experiment. A standard 3 lead ECG was recorded at the 400 Hz sampling frequency using the same hardware and software. The hardware model, software version and averaging time used for each machine was:

- Novametrix Mars model 2001 software version 22, averaging time 2 s
- MASIMO RADICAL software version 3.1.1.2, averaging time 2 s
- Nellcor 595; Oxismart software, variable average time, usually 5–7 s but depending on signal quality can extend to a maximum of 40 s

Each child was instructed to lie still in the supine position for 2 min while baseline recordings were taken. They were then asked to turn onto their left side for 1 min, then back to supine for 1 min and then to the right side for 1 min before completing the sequence by turning supine. This was repeated further four times giving 20 total turns per child. This sequence was chosen to mimic normal movements while asleep.

Finally, the child was asked to sit on the end of the bed with their arm supported from below with a pillow and their systolic blood pressure was taken using a mercury sphygmomanometer with a cuff covering at least two-thirds of the left upper arm. After a period of 1 min the cuff was re-inflated to 40 mmHg and the pressure was increased in increments of 10 mmHg every 20 s until 10 mmHg above the child's previously measured systolic blood pressure.

Measurements

Analysis during turns

The data from the last 50 s of baseline recording and the first 50 s following each turn were analysed.

Analysis during incremental increase in cuff pressure

The 20 s after each increase in cuff pressure was analysed in the blood pressure studies.

For each of these epochs mean, maximum and minimum saturation and HR were extracted and recorded on an excel spreadsheet. Theses were compared with either ECG-derived HR or the baseline saturation recording. We also extracted for each interval the percentage time that the saturation was below 4% of the baseline reading.

We defined agreement as a difference of HR from ECG HR of less than 10 beats per minute[7] or a drop of saturation reading of greater than 4% of the baseline reading, as used in previous studies comparing models of pulse-oximeter.[8] Machine saturations during movement were compared with baseline mean saturation as it was assumed that a healthy child would not desaturate during turns or cuff occlusion.

Statistical Analysis

Power studies were based on contours to assess reliability or agreement provided by Donner and Eliasziw.[9] Five measurements on 20 children, using 5% level of significance meant that the study had an 80% chance of showing that the reliability or agreement was 0.8 (substantial) rather than 0.6 moderate. Because we were also interested in body position (supine and either left or right side) 20 rather than five measurements were made so that comparisons between each could be performed.

The differences between mean machine derived-HR and mean ECG-derived HR per interval analysed were analysed using Bland–Altman plots.[10] The differences between movement or occlusion-related mean saturation and mean baseline saturation were also analysed in this way. Because multiple measures were obtained for each child, 95% confidence intervals for the differences were corrected.[11] These methods were also used to compare saturation readings with baseline values as well as and HR readings with ECG-derived HR for each increase in cuff pressure. Adjusted limits of agreement are presented.

The results are presented as differences and 95% confidence intervals. Generalised estimating equations were used to compare the number of epochs with a false low saturation reading (4% drop below baseline).

Results

All 20 children recruited completed the study. Two children were excluded from the final analysis; one because of previously undiagnosed bigeminal heart rhythm that made HR analysis difficult, the other due to computer technical faults at the time of data collection.

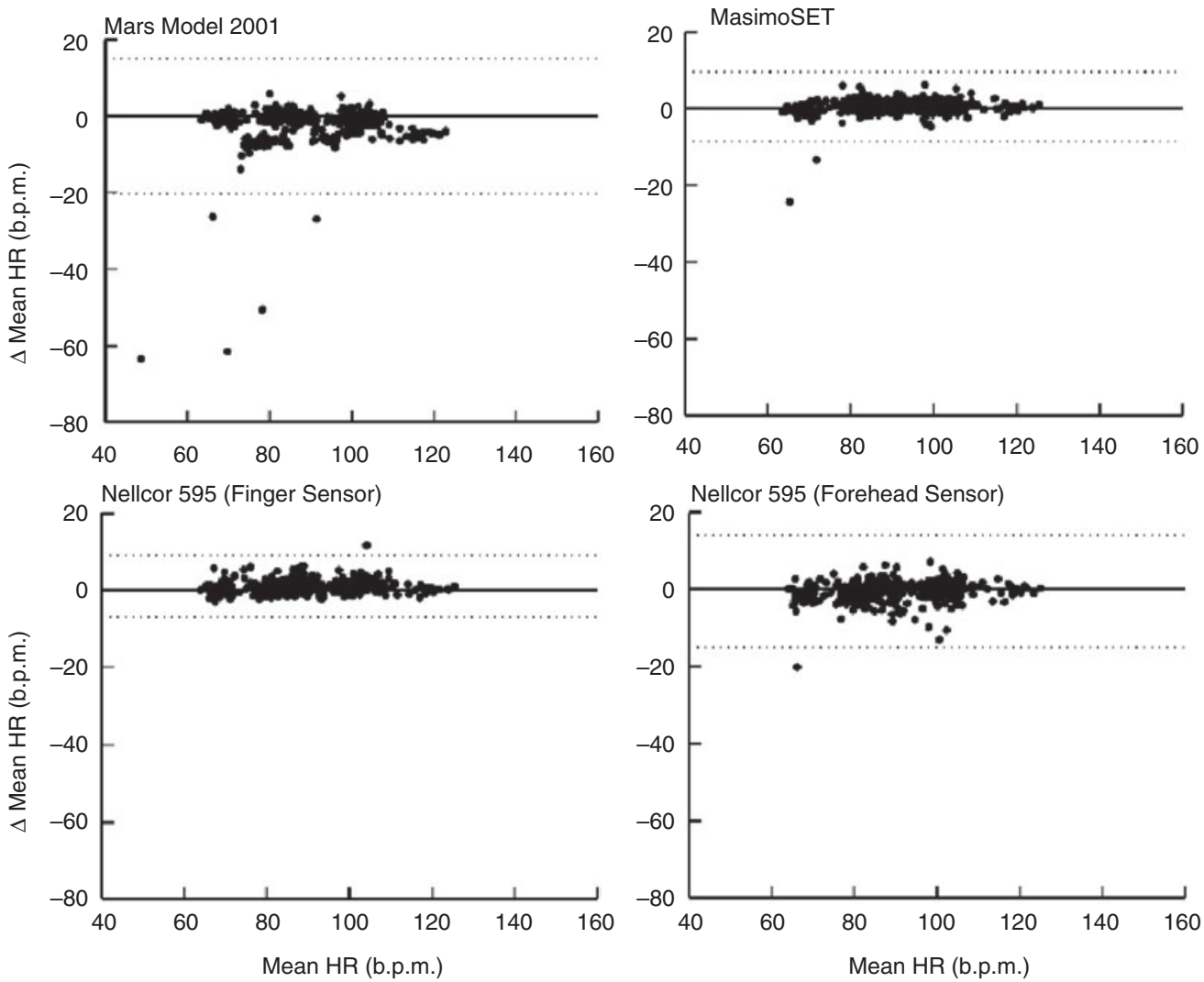

Fig. 1 Bland–Altman plots comparing turn heart rates with ECG-derived heart rates.

Table 1 Comparison of mean difference in recorded heart rate and saturation after turning plus limits of agreement between machines

	Δ† (b.p.m./%)	Limits of agreement	
		Lower limit	Upper limit
Heart rate (b.p.m.)			
Mars (2001)	–2.52	–20.04	15.00
MasimoSET	0.53	–8.54	9.59
Nellcor595 (finger)	1.11	–6.88	9.10
Nellcor595 (forehead)	–0.46	–14.95	14.04
Saturation (%)			
Mars (2001)	–0.84	–12.96	11.26
MasimoSET	–0.04	–4.46	4.37
Nellcor595 (finger)	0.07	–1.84	1.99
Nellcor595 (forehead)	–0.74	–5.30	3.83

†A value of 0 means no mean difference in comparisons.

Measurement of ECG Agreement

The agreement between machines and ECG gold standard (for each machine) are shown as Bland–Altman plots in Figure 1. As also shown in Table 1 the limits of agreement are within 10 beats on both the MasimoSET and the Nellcor 595 (finger). The mean difference from ECG-derived HR was not clinically different for any machine but the 95% limits of agreement around these differences were such that the Mars Model 2001 and Nellcor 595 (forehead) could have clinically important differences from ECG-derived HR. The tendency of the Mars Model 2001 to record a value of 0 during situations of poor signal quality resulted in a small number of outliers and wider 95% confidence intervals.

Measurement of Saturation Agreement

For oxygenation, Figure 2 shows similar plots comparing baseline and turn saturations. The limits of agreement are within 4% saturation of the recorded baseline reading for the Nellcor 595 (finger) only

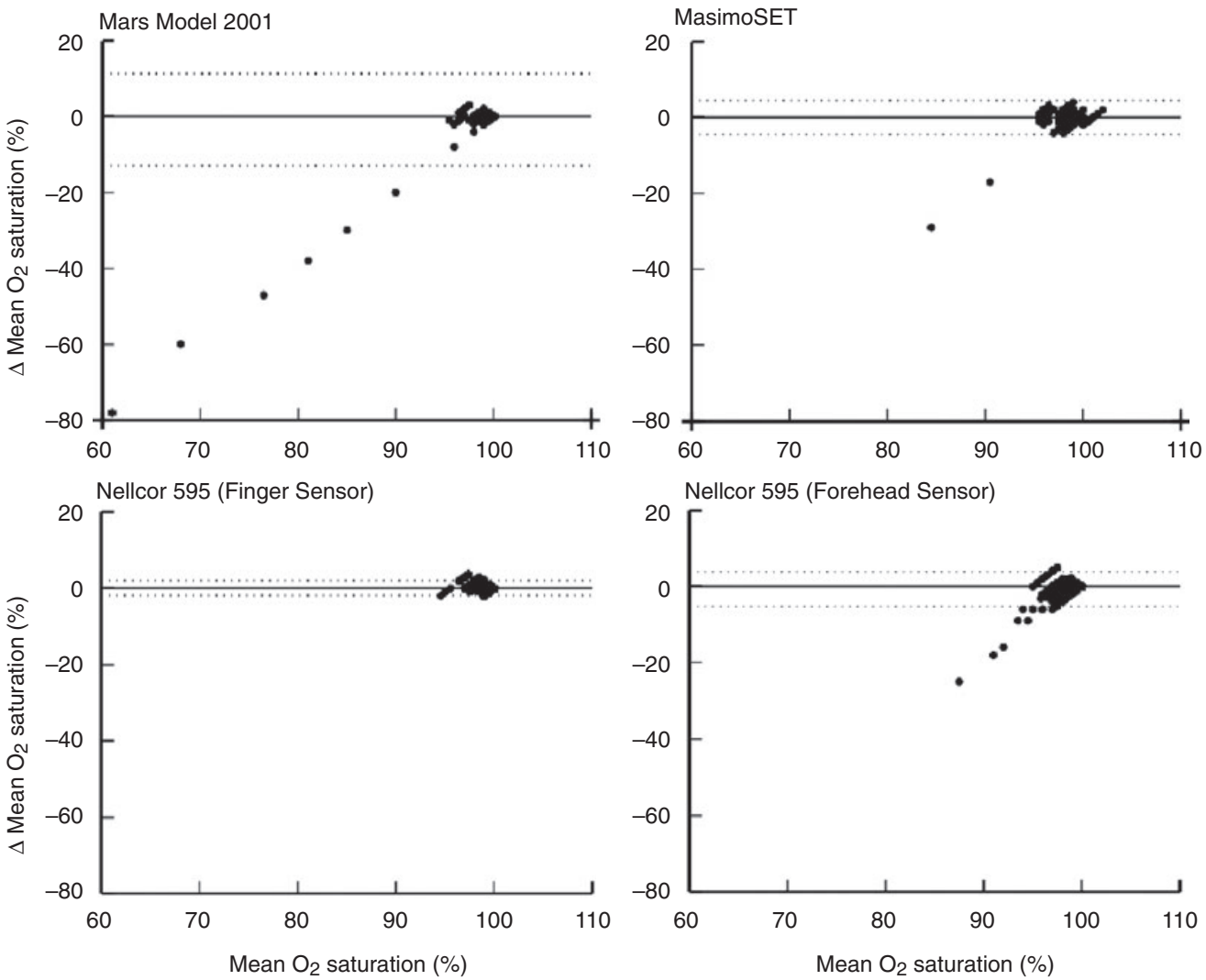

Fig. 2 Bland–Altman plots comparing turn saturations with baseline saturations.

(Table 1). The mean difference in saturations compared with baseline was less than 4% and thus not clinically significant in any of the machines.

Measurement of Epochs

Table 2 gives the proportion of epochs with a presumed false low saturation reading (4% drop below baseline) as a per cent of the 360 observation epochs during turns per machine. The Nellcor 595 (finger) had the lowest prevalence of presumed false values with the other machines being between three (Mars) and 20 times (Nellcor 595 (forehead)) more likely to have epochs with presumed falsely low results.

Table 2 Prevalence of epochs with a false low saturation recording during turns

	Prevalence of epochs with a saturation >4% below baseline %
Nellcor finger probe	1.59
Mars	4.78
MasimoSET	8.22
Nellcor forehead probe	20.45

Measurement of the Effect of Brachial Artery Pressure

Tables 3 and 4 demonstrate the effect of reducing peripheral perfusion on HR and saturation readings. Patient numbers appear reduced at the highest values from total cuff occlusion as the older children had higher systolic blood pressures and recordings were always initiated from 40 mmHg. MasimoSET recorded accurate HRs up to presumed total occlusion of brachial artery (cuff pressure up to previously measured systolic blood pressure) with the exception of an inaccurate recording at 70 mmHg below total cuff occlusion.

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Table 3 Effect of increasing cuff pressure on heart rate

Cuff pressure (mmHg)†	*n*	Mean Δ between machine and ECG-derived heart rate (limits of agreement)			
		Mars2001	MasimoSET	Nellcor595 (finger)	Nellcor595 (forehead)
–70	5	1.9 (–2.3–6.1)	11.3 (–30.3–52.9)	–0.3 (–4.3–3.7)	0.7 (–4.0–5.4)
–60	11	3.6 (–3.1–10.2)	1.0 (–10.0–7.9)	1.0 (–10.0–7.9)	1.0 (–8.9–10.9)
–50	16	2.2 (–6.2–10.5)	–0.2 (–8.0–7.7)	–1.4 (–8.4–5.7)	0.2 (–6.4–6.7)
–40	18	3.4 (–9.0–14.9)	2.1 (–7.3–11.4)	0.3 (–5.1–5.7)	1.2 (–6.7–9.2)
–30	18	2.3 (–4.4–8.9)	–0.4 (–8.0–7.2)	–0.7 (–5.7–4.3)	0.1 (–6.0–6.1)
–20	18	3.4 (–9.0–15.9)	0.7 (–9.8–11.1)	0.0 (–10.5–10.6)	1.5 (–11.2–14.3)
–10	18	2.1 (–6.3–10.6)	0.4 (–6.8–7.6)	–0.9 (–7.8–6.0)	0.7 (–6.7–8.0)
0	18	7.1 (–34.9–49.2)	1.0 (–6.4–8.4)	–0.8 (–7.6–6.0)	0.1 (–5.4–5.7)
10	18	6.63 (–28.9–42.2)	11.4 (–32.3–55.3)	0.9 (–10.0–11.7)	0.4 (–6.0–6.8)

†As mmHg above or below the measured systolic pressure of each child.

Table 4 Effect of increasing cuff pressure on saturation recording (Δ and 95% level of agreement)

Cuff pressure (mmHg)†	*n*	Mean Δ between machine and ECG-derived heart rate (limits of agreement)			
		Mars2001	MasimoSET	Nellcor595 (finger)	Nellcor595 (forehead)
–70	5	–0.2 (–2.8–2.4)	–12.4 (–70.4–45.6)	–0.4 (–2.2–1.4)	1.2 (–3.4–5.8)
–60	11	–0.2 (–1.9–1.6)	0.5 (–3.5–4.6)	0.1 (2.0–2.2)	0.5 (–2.8–3.9)
–50	16	–0.3 (–2.5–1.9)	0.4 (–2.8–3.7)	–0.1 (–2.4–2.3)	0.4 (–2.3–3.0)
–40	18	–0.4 (–3.1–2.3)	0.4 (–3.3–4.0)	–0.2 (–2.9–2.6)	0.2 (–2.5–3.0)
–30	18	–0.7 (–3.4–2.0)	0.6 (–2.9–4.1)	0.4 (–2.7–2.0)	0.5 (–2.2–3.1)
–20	18	–1.0 (–4.1–2.1)	0.3 (–3.3–3.9)	–0.6 (–3.2–2.1)	0.4 (–2.5–3.3)
–10	18	–1.4 (–5.0–2.2)	0.1 (–3.4–3.5)	0.9 (–4.1–2.3)	0.2 (–2.7–3.0)
0	18	–7.9 (–54.1–38.4)	–0.7 (–5.3–3.9)	–2.7 (–9.5–4.2)	0.3 (–2.6–3.2)
10	18	–7.0 (–43.3–29.3)	–9.1 (–61.3–43.0)	–3.4 (–11.2–4.5)	0.2 (–2.9–3.3)

†As mmHg above or below the recorded systolic blood pressure of each child.

It recorded accurate saturations up to within 10 mmHg of presumed total occlusion. Nellcor 595 (finger) recorded accurate HRs up to presumed total occlusion and accurate saturation up to 20 mmHg below presumed total occlusion. Mars Model 2001 gave inconsistent HR recordings when within 40 mmHg of presumed total occlusion and recorded accurate saturations up to within 20 mmHg of presumed total occlusion. The mean HRs and saturations recorded for each machine at differing degrees of impaired perfusion are shown in Figures 3 and 4.

No clinically significant difference was found in HR and saturation recording according to which finger was chosen for sensor application or body position (Table 5).

Discussion

This is one of the first published studies to directly compare the current generation of 'motion-resistant' pulse oximeters. All previous studies that we were able to find compared MasimoSET with 'outdated' models from other companies.[3,4,7,12–14] Our results suggest

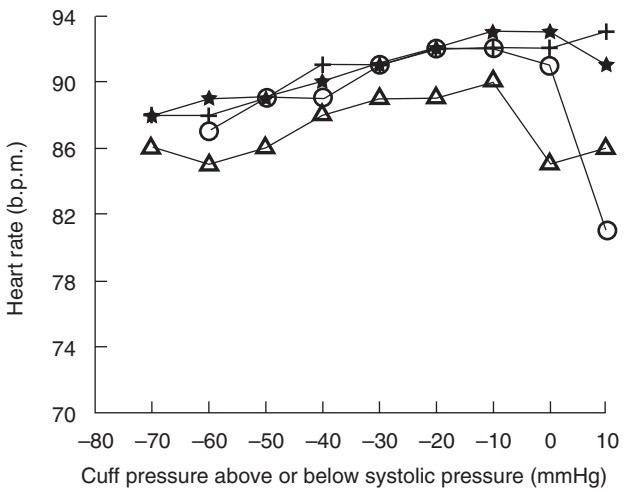

Fig. 3 Average heart rate at increasing cuff inflation for each pulse oximeter. (–△–) Mars; (–○–) Masimo; (–★–) Nellcor 595; (–+–) ECG-derived.

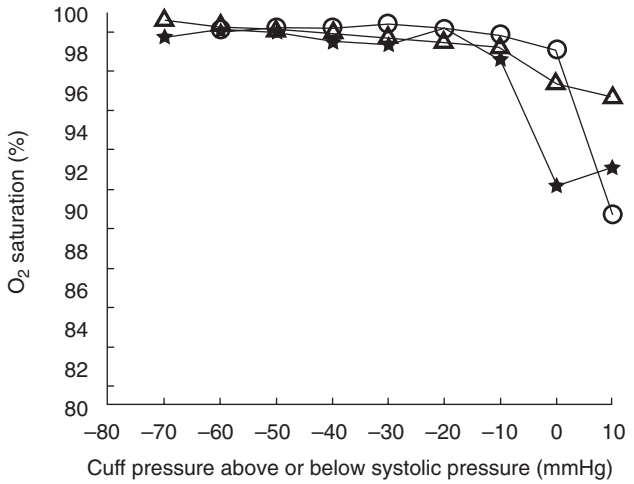

Fig. 4 Average saturation at increasing cuff inflation for each pulse oximeter. (–△–) Mars; (–○–) Masimo; (–★–) Nellcor 595.

Table 5 Inter-turn comparison of heart rate and saturation recordings (NB probe on left hand)

Turn direction	Coefficient	Limits of agreement	
		Lower	Upper
Heart rate (b.p.m.)			
Sensor down versus neutral	0.22	–0.23	0.67
Sensor down versus up	–0.46	–0.97	0.62
Sensor up versus neutral	–0.67	–1.12	–0.23
Saturation (%)			
Sensor down versus neutral	–0.77	–1.23	–0.32
Sensor down versus up	–0.25	–0.77	0.28
Sensor up versus neutral	0.53	0.78	0.98

that both the Nellcor 595 (finger) and MasimoSET machines are equally good at reporting HR but that the Nellcor 595 is superior with regard to saturation. The limits of agreement for saturation for the Nellcor 595 are within the *a priori* set clinically important limits of ±4%. Comparing machines by assessing the proportion of epochs where there were false low saturation events also suggested significant superiority of the Nellcor 595 finger probe. The MasimoSET and Nellcor 595 machines approach the removal of motion artefact differently, with the Nellcor 595 in particular, having a variable averaging time determined by the quality of the signal. The increasing averaging time during movement is likely to explain the much lower rate of false low saturations shown with this machine. Nellcor technical support suggests that the response time can be set to a 'fast-mode' that will provide a faster response time of 2–3 s compared with the normal 5–7 s, but it too will dynamically adjust up to a maximum 40 s averaging time if the signal quality is simply not sufficient to make an accurate fast-response measurement of saturation. Unfortunately, this feature was not documented in the supplied user manual and was thus not tested in this study. However, it is likely to be the preferred mode in sleep studies. We have subsequently discovered that a new motherboard is currently marketed with this feature.

Nellcor have promoted the forehead sensor for clinical use, but our results suggest that estimates of HR and saturation should not be relied on. We however, found that the band holding the forehead sensor in place was responsible for changes in sensor position that affected the readings.

The Novametrix Mars model 2001 has wide limits of agreement for both HR and saturation when compared with both the Masimo and Nellcor finger probes. The tendency of the Mars Model 2001 to give a reading of 0 because of a poor signal may, however, help explain the machine's relatively poor performance. This, although a disadvantage in this study, could be of benefit in the clinical setting as an indicator of a false alarm. The analysis may have benefited from the possibility of including a 'missing signal' value rather than including the numeric value of 0.

We were impressed with the ability of these machines to detect a pulse waveform when the brachial artery was occluded. Although there must have been a significant element of venous engorgement during this exercise, the MasimoSET was able to give accurate results up to presumed occlusion pressure. The Nellcor 595 (finger) was equally good up to within 10 mmHg of occlusion pressure. The ability of these machines to detect a wave-form at levels of presumed total cuff occlusion may be, in part, explained by the mild discomfort in increasing cuff pressure over a period of time leading to an overall increase in systolic blood pressure above our baseline measured systolic blood pressure. In addition, the size of the cuff covering two-thirds or greater of their upper arm would have resulted in underestimations of the true systolic pressure.[15] Ideally we should have determined cuff width as 40% of the measured upper arm circumference.

The results also show that neither finger nor body position affect the results in a clinically or statistically significant way. We note that most manufacturers recommend use of the index finger.

The strengths of this study are in the fact that no manufacturer sponsored the research but each manufacturer supplied both machines and probes free of charge. The number of children and the number of tests per child were determined by power studies beforehand to give maximum information for minimal number of subjects. We designed the testing to mimic the natural situation during sleep with children turning from one side to the other. At least one other study uses a motorised finger tapping movement to compare machines – an unlikely movement in most clinical situations.[3] The use of blood pressure cuff to increasingly occlude the brachial artery is somewhat artificial as this produces significant venous pooling – not seen in the clinical situation of hypotension due to hypovolaemia or septic shock. Despite this, the ability of modern machines to track HR and saturation was impressive.

One problem with a study like this is to continuously measure a 'gold standard' for haemoglobin oxygen saturation. We assumed that there was unlikely to be any real drop in saturation during body turns in healthy children and that during brachial occlusion, any arteriolar blood should still be oxygenated at the same level as the rest of the body. However, we were unable to fully exclude the possibility that true desaturations were missed by the machines, or that recorded desaturations that we interpreted as false may in fact have been true values. One study in 2002 looked at the ability of oximeters in newborn intensive care to detect hypoxic episodes defined with transcutaneous partial pressure of oxygen.[16] This study suggested that the Nelcor hardware used (Nelcor N-3000)/software

(oxismart) was less good at detecting hypoxic or bradycardic episodes than the MasimoSET technology. The results of our study suggest that the current hardware software combination of Nelcor N595/Oxismart software need to be evaluated again in such a study, ideally in both the neonatal, child and adult population.

In conclusion, this study has shown that current generation of Nellcor oximeters (N595) matches and may even slightly improve on the advances made with MasimoSET oximeters with regard to accurate tracking of HR and saturation during movement and decreased perfusion in healthy children. Some of the difference between machines may simply be because of the difference in averaging technique used during movement artefact. Their use should result in accurate and reliable monitoring of oxygenation and HR as well as lower levels of false alarms in the sleep laboratory setting. Further testing of current models is needed in settings of acute hypoxia.

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