

## Comparison of a New Forehead Reflectance Pulse Oximeter Sensor With a Conventional Digit Sensor in Pediatric Patients

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**BACKGROUND:** During conditions of poor perfusion, the accuracy of conventional extremity-based pulse oximeters may be limited. Limited evidence suggests that forehead perfusion may be better preserved during such periods, but pediatric experience with newer forehead reflectance sensors is limited. We prospectively compared the accuracy of a forehead reflectance sensor, the Max-Fast, with a new-generation digit sensor in pediatric patients. **METHODS:** Pediatric patients > 10 kg and who had arterial catheters were eligible for enrollment. Blood oxygen saturation was simultaneously measured with forehead and digit sensors, and compared to corresponding CO-oximetry-measured arterial oxygen saturation values ( $S_{aO_2}$ ) taken at the same times. We used Bland-Altman analysis to calculate the bias and precision of the forehead sensor and the digit sensor relative to the  $S_{aO_2}$  values. **RESULTS:** We obtained 116 sample sets from 28 patients. The  $S_{aO_2}$  values ranged from 84.1% to 99.2%. The bias and precision of the forehead-to- $S_{aO_2}$  difference were 0.6% and 2.7%, respectively, versus 1.4% and 2.6%, respectively, for the digit-to- $S_{aO_2}$  difference ( $p < 0.05$ ). Bias and precision were 0.7% and 2.6% versus 1.7% and 2.3% for the forehead and digit sensors, respectively, ( $p < 0.05$ ) in patients who received vasoactive medications, compared with 0.5% and 2.8% versus 1.1% and 2.8% ( $p =$  not significant), respectively, in patients who did not receive vasoactive medications. **CONCLUSIONS:** The Max-Fast sensor estimated  $S_{aO_2}$  as accurately as did a new-generation digit sensor in well-perfused pediatric patients. *Key words:* oximetry, forehead, pediatric, monitoring, oxygenation, noninvasive. [Respir Care 2006;51(7):726–731. © 2006 Daedalus Enterprises]

### Introduction

Continuous monitoring of oxygenation via pulse oximetry has become a standard of care in the critical-care environment.<sup>1,2</sup> At present, the most commonly used sensors are designed to be placed on an extremity, and their accuracy in most circumstances has been well described.<sup>3–5</sup> However, these digit-based sensors have some limitations,

the most important being sensitivity to motion artifact and consequent dropout and/or failure to provide an accurate reading. While technologies that better filter out artifacts continue to be developed, spurious signals and dropout continue to be reported.<sup>6–9</sup> Additionally, under conditions of poor perfusion, such as may occur during critical illness, the pulse amplitude in the digit may be so dampened that a pulse-oximetry-measured saturation value ( $S_{pO_2}$ ) is

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unobtainable, leaving the practitioner to rely on intermittent  $S_{pO_2}$  readings or invasive measurements via arterial-blood-gas samples. As these patients are, arguably, the ones in greatest need of both continuous and accurate monitoring, these limitations may result in less-than-optimal care.

Recently, reflectance pulse oximetry sensors have been developed that enable oximetry measurements at various

body locations, including centrally. A recently developed reflectance sensor, the Max-Fast forehead reflectance sensor (Nellcor/Tyco Healthcare, Pleasanton, California), may offer advantages over both conventional digit-based oximetry and older reflectance sensors. First, though limited, some data suggest that perfusion to the forehead region is better maintained during conditions of poor perfusion,<sup>10,11</sup> suggesting that oximeter dropout might be less with forehead oximetry. Second, sensors placed on the forehead appear to respond more rapidly to changes in oxygenation than do digit-based sensors,<sup>12</sup> which suggests that forehead oximetry may allow earlier detection of desaturation. Third, there may be less motion artifact with forehead sensor-placement, so there may be less dropout.

Preliminary data suggest that the Max-Fast forehead sensor accurately estimates oxygen saturation in critically ill, poorly perfused adults.<sup>13</sup> However, though the sensor has received approval from the Food and Drug Administration for use with patients > 10 kg, there are no published data to date regarding its accuracy with pediatric patients. The present study compares the accuracy of this sensor to that of a conventional digit-based oximetry sensor with pediatric patients, regardless of perfusion status. The primary study goal was to compare the Max-Fast sensor's ability to estimate arterial oxygen saturation (as measured via CO-oximetry [ $S_{aO_2}$ ]) to that of a conventional digit sensor. We hypothesized that this new forehead sensor would estimate  $S_{aO_2}$  as accurately as a commonly used, new-generation, digit-based transmission-type sensor in pediatric patients.

## Methods

This study was approved by the institutional review board of the University of Missouri Health Sciences Center. All pediatric patients > 10 kg, regardless of perfusion status, who were receiving care in either the pediatric intensive care unit or the operating room, and who had an indwelling arterial catheter in place, were eligible for enrollment. The need for written informed consent was waived, but we obtained verbal consent from the patient and/or his/her parent(s) prior to enrollment.  $S_{pO_2}$  was continuously measured with the Max-Fast forehead sensor and a digit sensor (Max P or Max I, Nellcor/Tyco Healthcare, Pleasanton, California).

To ensure that potential differences between the 2 monitoring sites were only sensor-related, both sensors were connected to the same pulse oximeter model (N-595, Nellcor/Tyco Healthcare, Pleasanton, California). With all the patients, the Max-Fast sensor was placed according to the manufacturer's current recommendations, which include use of a headband that holds the sensor firmly against the forehead to limit venous pooling, which causes underestimation of  $S_{pO_2}$ .<sup>14</sup> The digit sensor was placed on an up-

per-extremity digit and, unless unavoidable, on the extremity contralateral to where the arterial catheter was located.

When clinically indicated, arterial-blood-gas measurements were obtained, and the corresponding  $S_{pO_2}$  values were recorded. Because this study was designed to compare the accuracy of the forehead and digit sensors, we used only the arterial-blood-gas measurements that were obtained when the patient's  $S_{pO_2}$  reading had been stable for at least 2 min.  $S_{aO_2}$  was measured directly with a blood gas analyzer (ABL700, Radiometer, Westlake, Ohio).

The difference between the reading from the forehead sensor or digit sensor and the  $S_{aO_2}$  was calculated, and, using those values, a Bland-Altman analysis was performed.<sup>15</sup> Bias (the mean difference between the values) and precision (the standard deviation of the bias) were calculated for the forehead- $S_{pO_2}$ -versus- $S_{aO_2}$  differences, and for the digit- $S_{pO_2}$ -versus- $S_{aO_2}$  differences. Similarly, the difference between the forehead and digit  $S_{pO_2}$  values was calculated and subjected to Bland-Altman analysis to evaluate the closeness of agreement between the 2 sensors at each sample point. Using the raw data,  $S_{pO_2}$  versus  $S_{aO_2}$  differences between sensors were compared, using a paired *t* test for the entire group and for subgroups. The frequency of forehead or digit  $S_{pO_2}$  values being < 2% or > 5% different from the  $S_{aO_2}$  values was compared between sensors, using a chi-square test with a contingency table. Linear regression analysis was used to compare forehead and digit  $S_{pO_2}$  values to the  $S_{aO_2}$  values. A *p* value < 0.05 was considered significant. To avoid bias, a limit of 5 samples per patient was imposed.

## Results

We obtained 116 sample sets from 28 consecutively eligible patients (mean age  $8.4 \pm 5.6$  years, mean weight  $31.5 \pm 21.4$  kg [range 10–71 kg]). There were 16 boys and 12 girls. Underlying diagnoses included cardiac surgery ( $n = 8$ ), isolated respiratory failure ( $n = 5$ ), multiple-organ-system failure ( $n = 5$ ), trauma ( $n = 4$ ), scoliosis surgery ( $n = 3$ ), and other surgical procedures ( $n = 3$ ). No patient had a patent ductus arteriosus, which eliminated the potential for sensor-independent pre-ductal versus post-ductal  $S_{pO_2}$  differences. Data were obtained from patients under anesthesia in the operating room ( $n = 7$ ) or in the pediatric intensive care unit, either during mechanical ventilation with sedation ( $n = 12$ ) or during spontaneous ventilation without sedation ( $n = 9$ ). Eleven patients were receiving vasoactive agents during the study period, including dopamine (2–10  $\mu\text{g}/\text{kg}/\text{min}$ ,  $n = 7$ ), nesiritide (0.01–0.03  $\mu\text{g}/\text{kg}/\text{min}$ ,  $n = 4$ ), epinephrine (0.05–0.5  $\mu\text{g}/\text{kg}/\text{min}$ ,  $n = 3$ ), milrinone (0.1–0.76  $\mu\text{g}/\text{kg}/\text{min}$ ,  $n = 3$ ), and dobutamine (3  $\mu\text{g}/\text{kg}/\text{min}$ ,  $n = 1$ ).

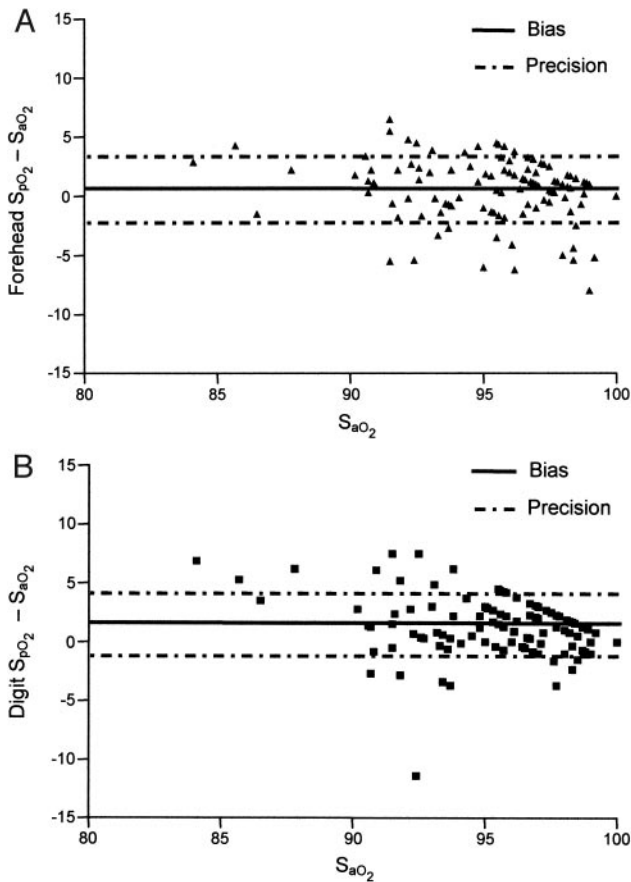


Fig. 1. A: Bland-Altman analysis of the difference between arterial oxygen saturation measurements made via CO-oximetry ( $S_{aO_2}$ ) and arterial oxygen saturation readings from a Max-Fast forehead oximetry sensor (forehead  $S_{pO_2}$ ). The values for forehead  $S_{pO_2}$  minus  $S_{aO_2}$  are plotted on the vertical axis. The  $S_{aO_2}$  values are plotted on the horizontal axis. The bias is 0.6%, and the precision is 2.7%. B: Bland-Altman analysis of the difference between  $S_{aO_2}$  and arterial oxygen saturation readings from a digit oximetry sensor (digit  $S_{pO_2}$ ). The values for digit  $S_{pO_2}$  minus  $S_{aO_2}$  are plotted on the vertical axis. The  $S_{aO_2}$  values are plotted on the horizontal axis. The bias is 1.4%, and the precision is 2.6%.

The  $S_{aO_2}$  values ranged from 84.1% to 99.2%. Bland-Altman analysis (Fig. 1) revealed a bias of 0.6% and precision of 2.7% when comparing the forehead- $S_{pO_2}$  with the  $S_{aO_2}$ . This compares with a bias of 1.4% and precision of 2.6% when comparing the digit- $S_{pO_2}$  with the  $S_{aO_2}$  ( $p = 0.011$ ). In 55/115 measurements the forehead sensor more closely estimated  $S_{aO_2}$  than did the digit sensor. In 38/115 measurements the digit sensor was more accurate than the forehead sensor. In 22/115 measurements the sensors provided equivalent estimations.

Recently, Branson et al reported that patients with hypotension requiring vasoactive medications may be more likely to benefit from reflectance oximetry.<sup>13</sup> Therefore, we also performed Bland-Altman analyses on the subgroups of patients who received or did not receive vaso-

Table 1. Bias and Precision of a Digit Oximetry Sensor Versus a Forehead Oximetry Sensor in Patients Receiving and Not Receiving Vasoactive Medications

	Entire Group (n = 116)		Received Vasoactive Agents (n = 53)		Received No Vasoactive Agents (n = 63)	
	Digit	Forehead	Digit	Forehead	Digit	Forehead
Bias %	1.4	0.6*	1.7	0.7*	1.1	0.5
Precision %	2.6	2.7	2.3	2.6	2.8	2.8

\* $p < 0.05$ , compared to the digit-based sensor.

active agents. For the subgroup of patients who received vasoactive medications, the forehead sensor more accurately estimated  $S_{aO_2}$  than did the digit sensor, with bias and precision values of 0.7% and 2.6% versus 1.7% and 2.3%, respectively ( $p < 0.05$ , Table 1). For the subgroup of patients who received no vasoactive medications, bias and precision were similar between the 2 sensors: 0.5% and 2.8% versus 1.1% and 2.8% (see Table 1).

Bland-Altman analysis to compare the forehead to digit sensor values revealed a bias of 0.8% and a precision of 2.9%, which suggests that the digit sensor gave  $S_{pO_2}$  values slightly higher than those from the forehead sensor (Fig. 2). In 73/116 measurements (63%), the difference between the 2 sensors was  $\leq 2\%$ . In 9/116 measurements (8.6%), the difference between the 2 sensors was  $> 5\%$ .

To assess the clinical relevance of the discrepancies between the forehead and digit sensor values and the  $S_{aO_2}$

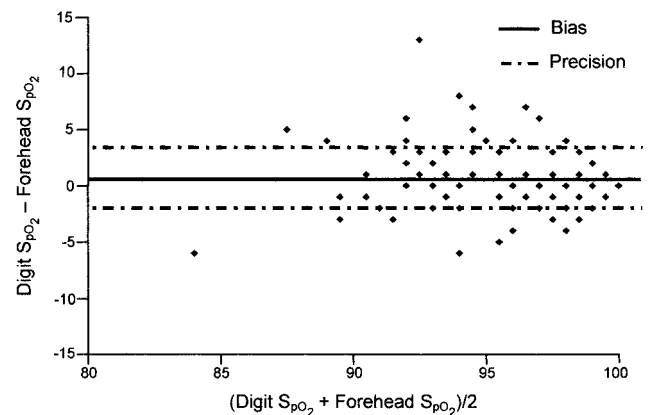


Fig. 2. Bland-Altman analysis of the difference between arterial oxygen saturation readings from a Max-Fast forehead oximetry sensor (forehead  $S_{pO_2}$ ) and readings from a digit oximetry sensor (digit  $S_{pO_2}$ ). The values for digit  $S_{pO_2}$  minus forehead  $S_{pO_2}$  are plotted on the vertical axis. The averages of the 2 sensor  $S_{pO_2}$  values are plotted on the horizontal axis. The bias is 0.8%, and the precision is 2.9%. We obtained 116 sample sets, but on this graph there are fewer than 116 data points, because of repetition of numerous digit- $S_{pO_2}$ -minus-forehead- $S_{pO_2}$  combinations.

values, we calculated the frequency with which  $S_{pO_2}$  values deviated from  $S_{aO_2}$  values by  $< 2\%$  (the manufacturer's stated accuracy for both devices, defined as  $\pm 1$  standard deviation of the  $S_{pO_2}$ -to- $S_{aO_2}$  difference obtained from preclinical studies), and by  $> 5\%$ . The latter value was chosen based on the study by Van De Louw et al, who reported a  $\pm 2$ -standard-deviation variability of almost 5% with conventional digit pulse oximetry in intensive-care patients.<sup>2</sup> The forehead- $S_{pO_2}$ -versus- $S_{aO_2}$  difference was  $< 2\%$  in 66/116 measurements (57%) and  $> 5\%$  in 10/116 (8.6%) measurements, whereas the digit- $S_{pO_2}$ -versus- $S_{aO_2}$  difference was  $< 2\%$  in 64/116 measurements (55%) and  $> 5\%$  in 9/116 (7.7%) measurements ( $p =$  not significant).

Linear-regression analysis of forehead  $S_{pO_2}$  versus- $S_{aO_2}$  values revealed a slope of 0.81 and an  $r^2$  value of 0.45. Regression analysis of the digit- $S_{pO_2}$ -versus- $S_{aO_2}$  values revealed a slope of 0.76 and an  $r^2$  value of 0.46.

### Discussion

The present study suggests that, over a range of clinically common  $S_{aO_2}$  values, the Max-Fast forehead reflectance sensor estimates  $S_{aO_2}$  as accurately as does a currently used new-generation, digit-based transmittance pulse oximetry sensor, in pediatric patients. The forehead sensor consistently overestimated  $S_{aO_2}$  an average of 0.6%, compared to a 1.4% average overestimation with the digit sensor, whereas the sensors had a similar dispersion (2.6% and 2.7%). Clinically, this suggests that for a patient with an  $S_{aO_2}$  of 90%, the forehead sensor would read  $90.6 \pm 2.7\%$ , and the digit sensor would read  $91.4 \pm 2.6\%$ . Though the difference between the 2 sensors is statistically significant, in most situations this difference (0.8%) is likely to be of little clinical importance.

To the best of our knowledge, this is the first study to compare the accuracy of these 2 types of sensors in the pediatric population. Our data are consistent with data from adult patients, which also showed good agreement between the Max-Fast sensor's readings and  $S_{aO_2}$ .<sup>13</sup>

Reflectance oximetry differs slightly from the transmission oximetry used in extremity-based (ie, digit, nasal septum, and earlobe) oximetry sensors. With transmission oximetry, the tissue is transilluminated by 2 wavelengths of light in the red and infrared ranges, and saturation is estimated from the relative absorption of these 2 wavelengths across the tissue, with nonarterial interference being filtered out by internal oximeter algorithms. With reflectance oximetry, saturation is estimated from light that is backscattered, rather than transmitted. This allows the sensor to be placed on many body locations.<sup>16</sup> The sensor has only one side, which contains both the transmission and reception components. The incentive for the development of this type of sensor is the clinical observation that, due to decreases in extremity pulse amplitude, transmission-based oximeters may fail to function un-

der conditions of poor perfusion, such as hypothermia, hypotension, or shock.<sup>17</sup>

It was recognized some time ago that the forehead may be a good location at which to perform reflectance oximetry. In 1942, Hertzman and Roth used photoelectric plethysmography and found both a rich arterial blood supply to the forehead and a lack of vasoreactivity of this vascular bed to a cold-pressor test.<sup>11</sup> Recently, Bebout and Mannheim found maintenance of both forehead perfusion and pulse amplitude with the Max-Fast sensor during cold-induced peripheral vasoconstriction,<sup>10</sup> confirming the potential viability of both the site and new sensor.

Clinical applications of reflectance sensors have been limited, and the few studies published to date have reported mixed results. Palve reported that a forehead reflectance sensor he studied provided accurate estimation of  $S_{aO_2}$  and earlier readings than did a digit-based transmittance sensor, following cardiopulmonary bypass in adults.<sup>18</sup> However, Clayton et al reported a consistent underestimation of  $S_{aO_2}$  with a different forehead reflectance sensor, with 120 adults following cardiopulmonary bypass.<sup>19</sup> Similarly, Cheng and colleagues reported that forehead reflectance oximetry accurately estimated  $S_{aO_2}$  in healthy patients but was less accurate in patients who were critically ill, particularly if they were moving and/or perspiring.<sup>20</sup> A criticism of these latter studies is that the forehead sensor appears to have been only loosely secured, creating the possibility of venous pooling and consequent underestimation of  $S_{aO_2}$ .<sup>21</sup>

The Max-Fast sensor was designed to address some of the problems with earlier-generation forehead reflectance sensors. New design aspects include improved algorithms to optimize sensor function during suboptimal signal characteristics<sup>22</sup> and the manufacturer's consequent recommendation to routinely use a headband in addition to the sensor's own adhesive for securing the sensor in place, to decrease or avoid venous pooling.<sup>14</sup>

Though published data regarding the Max-Fast sensor remain limited, they suggest that it has better functioning and accuracy than did previous reflectance oximetry sensors. Sugino et al found that this sensor detected induced desaturation episodes more quickly than did a digit-based sensor, under conditions of simulated poor perfusion in healthy adults,<sup>23</sup> whereas Nuhr and colleagues reported significantly (62%) fewer oximeter-malfunction alerts with the Max-Fast sensor than with a new, digit-based sensor, during emergency pre-hospital transport of adults with mild hypothermia and poor peripheral perfusion.<sup>24</sup>

Branson et al reported the first comparison of  $S_{aO_2}$  measurements and  $S_{pO_2}$  readings with the Max-Fast sensor. In a convenience sample of 20 mechanically ventilated adults, they reported good functioning of the sensor compared to a digit-based sensor.<sup>25</sup> In a follow-up study with 20 poorly perfused adults, following surgical procedures, they con-

firmed those findings; they reported a mean  $S_{pO_2}$ -to- $S_{aO_2}$  difference of  $0.1 \pm 1.5\%$  with the forehead sensor, versus  $1.5 \pm 2.2\%$  with the digit sensor.<sup>13</sup> Also there was a 2.5-fold greater duration of oximeter-failure time with the digit sensor than with the Max-Fast. These data compare favorably with the findings of the present study, and these are the only reports to date that have compared the Max-Fast sensor's  $S_{pO_2}$  readings to  $S_{aO_2}$  values. The fact that neither of these studies report a consistent underestimation of  $S_{aO_2}$  further suggests that the provisions designed to decrease venous pooling are effective.

The present study has some limitations. First, though the forehead sensor was designed to be useful in patients with poor perfusion, the majority of our patients were well-perfused during the monitoring period. We intentionally included these patients, as our primary objective was to study the sensor's accuracy with children. Our cohort did include one patient in whom peripheral perfusion was markedly decreased on study entry. That patient was an 8-year-old boy with neurogenic pulmonary edema and hypotension following a closed head injury. With this patient the forehead sensor was the only one to record an  $S_{pO_2}$  value during the approximately 3 hours while resuscitation was ongoing, and it accurately estimated  $S_{aO_2}$  values. However, because of the absence of a paired digit-sensor value, these data are not included. We are currently conducting studies on the functioning of this sensor with poorly perfused children.

This study is further limited in that it only evaluated the sensor's ability to estimate  $S_{aO_2}$  (ie, sensor accuracy). We did not evaluate oximeter-dropout rate (ie, sensor reliability). As pulse oximetry should be both accurate and reliable and since dropout remains an issue, even with the new motion-resistant oximeters,<sup>6-9</sup> further evaluation of dropout rates with this sensor would be useful. These studies are underway.

From a practical standpoint, 2 observations bear discussion. First, though the sensor and headband appeared to be well tolerated, including in awake, spontaneously breathing patients, in 2 patients who had prolonged (> 24 h) use of the sensor we observed small areas of redness on the skin where the sensor had been. These reddened areas were limited to the site of sensor contact, which sits slightly elevated from the adhesive pad of the sensor. The redness cleared rapidly, and there was no skin-breakdown, but we suggest that the sensor site be assessed and the sensor moved every 12 hours, in accordance with the manufacturer's recommendations, to prevent skin-breakdown. As the sensor is designed with multiple adhesive strips, this can be easily done without substantially increasing the number of sensors used.

In addition, on some occasions when the forehead sensor reading was less than that of the digit sensor, we found that slightly tightening the headband brought the forehead-

sensor reading closer to that of the digit sensor, which suggests that venous pooling was causing the difference. This probably also explains an observation from Figure 1, in which several data points show a forehead  $S_{pO_2}$ -to- $S_{aO_2}$  difference of negative 5–10%. Therefore, with the Max-Fast sensor we suggest that the headband tension be checked periodically and when  $S_{pO_2}$  values are unexpectedly low.

## Conclusion

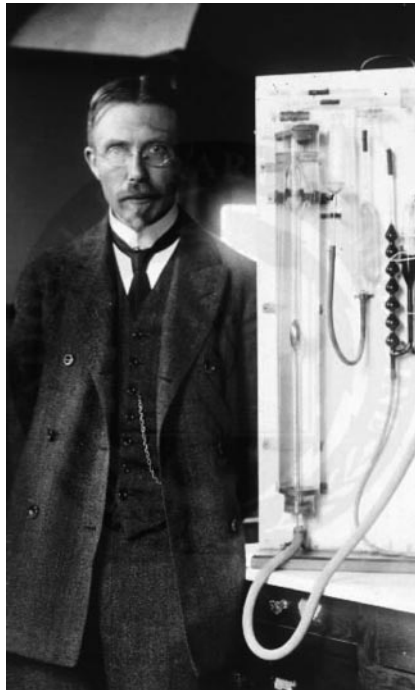
The present study is the first to evaluate the accuracy of the Max-Fast sensor in the pediatric population. In well-perfused children, this sensor provided as accurate an estimation of  $S_{aO_2}$  as did a commonly used new-generation, digit-based transmittance sensor. Though conventional digit-based oximetry works well for the majority of patients, these data suggest that reflectance oximetry adds a viable alternative monitoring site when access to patient extremities is limited, such as in patients with extremity burns, and under conditions of poor perfusion, such as during shock or hypothermia, when digit-based oximetry may not function adequately, although further evaluation of that setting is necessary.

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Physiologist and Nobel Prize winner August Krogh with Dr Carpenter's blood gas analysis apparatus, 1922  
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