

Special Anniversary Issue

**Center for Studies of Sensory
Impairment, Aging, and Metabolism
(CeSSIAM)**

BULLETIN OF RESEARCH ABSTRACTS

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Validity and diagnostic acumen of a rapid, non-invasive, portable hemoglobin device (Haemospect®): Comparison with whole blood testing for anemia diagnosis under field conditions in rural Guatemala

Caitlin R. Crowley, Gabriela Montenegro-Bethancourt, Noel W. Solomons, and Klaus Schümann

The need for a rapid, non-invasive, cost-effective, and culturally-acceptable method for accessing hemoglobin (Hb) status has recently intensified. In the wake of the adverse events among iron-replete children receiving iron supplementation in Pemba, Tanzania, (Sazawal et al, 2006). In the wake of that occurrence, in which there was a 12% excess of the combination of hospitalizations and deaths from malaria among the groups receiving iron versus controls (Sazawal et al), a study group, convened by the World Health Organization, produced some interim directives toward the safer application of oral supplementation in populations with intense malarial transmission (Lyon Consultation Supplement, 2007). Foremost among them, from our point of view, was the call for screening of recipients of iron, to exclude those who have adequate iron status from additional exposure to oral iron.

To the end of providing a screening method, which would not only be accurate in separating the iron sufficient from the iron needy, but also be painless and non-invasive, we have explored the application of a new device (the Haemospect® from MBR Optical Systems in Wuppertal, Germany), which uses white-light laser technology to measure Hb concentration in subcutaneous capillary beds. As participants in the exploratory studies, we enrolled 40 men, living at high altitude, from the department of Totonicapán (2600 m) and 40 pregnant women, living at low-altitude in a hookworm infested region in Retalhuleu (240 m) in an effort to maximize the range of Hb values to be collected. A venous blood sample for a colorimetric Hb determination and digital readings taken at the hand and forearm, using the Haemospect®, were collected from all subjects. WHO diagnostic criteria for anemia were used to generate sensitivity, specificity, and positive and negative predictive values of non-invasive readings

versus the reference standard, a whole blood sample. Hb "registrations" were processed during a blinded reevaluation of the spectra collected in the field by an improved software version at the site of the manufacturer in Germany, due to a problem with the readouts produced by the digital device's internal software.

Hb values from whole blood samples ranged from 7.8 to 18.5 g/dL, with a mean value of 12.9±2.3 g/dL. The Haemospect® was only able to attain viable registrations from 70 of the 80 subjects on the palm, and from 60 sampled on the forearm. Mean Hb registered at both the palm and forearm sites were similar to the whole blood samples (13.2±2.1 and 12.7±1.8 g/dL, respectively) (Figure 1). Ranges were more narrowly distributed (9.1-17.5 and 8.7-15.8 g/dL, respectively). Pearson correlation coefficients between digital and blood Hb values were extremely strong at both palm and forearm sites: r=0.94 (p<0.001, n=70) and r=0.90, (p<0.001, n=60) respectively (Figure 2, Panels A and B). Furthermore, a high Lin Concordance coefficient between readings taken at the palm and forearm demonstrates the strong correlation between the two sites (r=0.84) (Figure 2, Panel C). Diagnostic discrimination was most satisfactory around the 12.0 g/dL WHO cutoff guidelines for determining anemia at sea level. Specificities were high (>90%) across the entire range of cutoff points, within the complete sample. Sensitivity was 100% at 12.0 g/dL, falling to 93% at 11.5 g/dL, and 58% at 11.0 g/dL at the forearm site.

In conclusion, the Haemospect® shows much promise for use in a field setting. It has limitations for application at sea-level (where most of the world's endemic malaria would be found), do to its still poor discrimination at the Hb cut-offs relevant to young children. With the application of fully-functioning software, however, it should offer a promising new screening technique.

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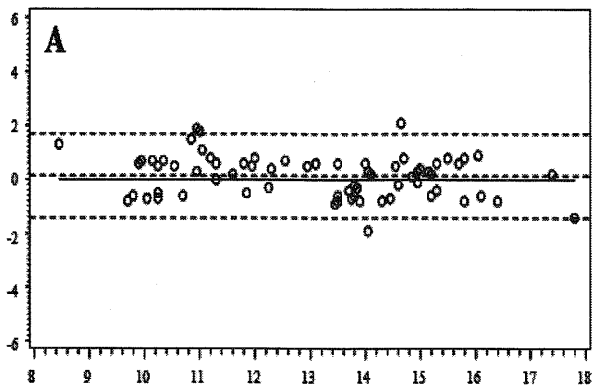
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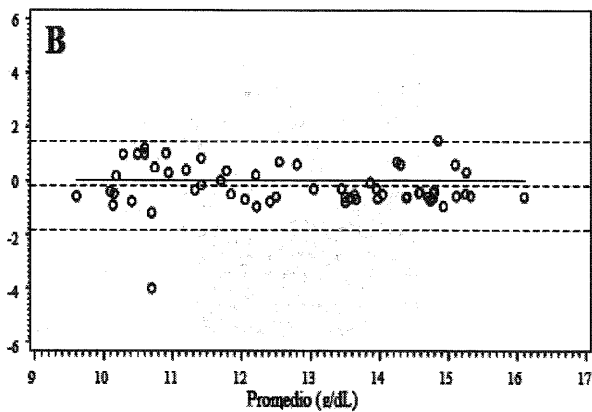


Figure 1 Bland-Altman plots of the differences between whole blood samples and both the palm (panel A) and forearm (panel B) digital readings

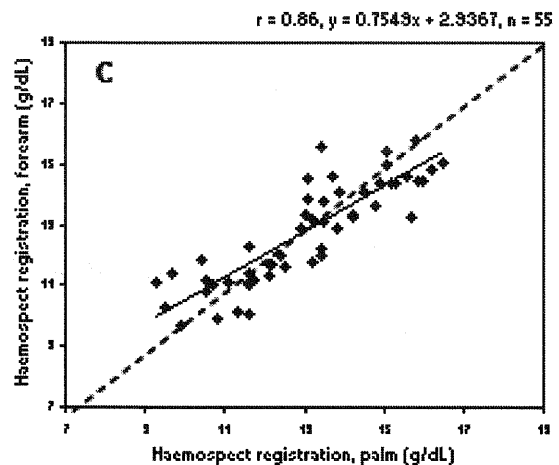
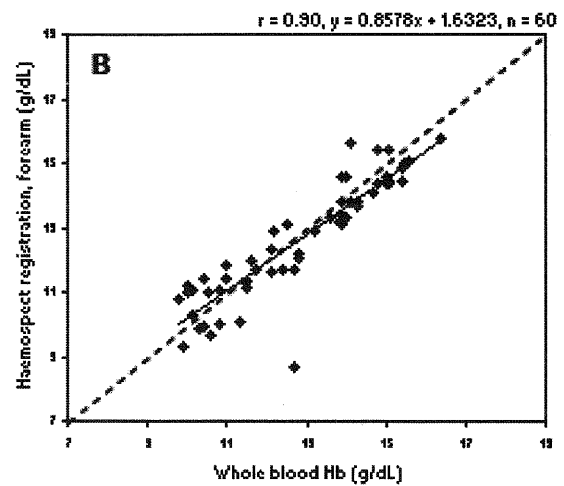
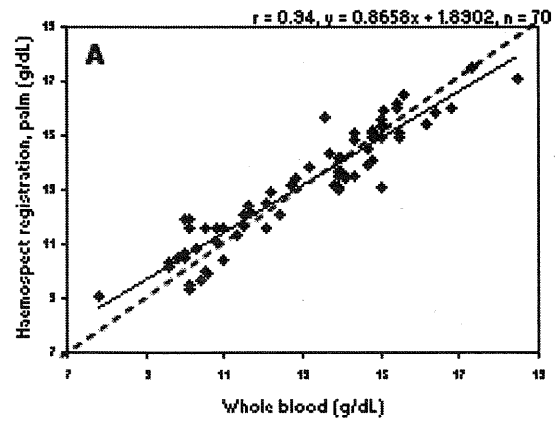


Figure 2. Panel A displays paired values of the digital registration and whole blood sample from the 70 subjects who produced a valid palm registration with the Haemospect®. Panel B displays paired values of the digital registration and whole blood sample from the 60 subjects who produced a valid forearm registration with the Haemospect®. Panel C represents paired values of registrations from the Haemospect® taken at the palm and forearm sites among the 55 subjects who provided viable readings at both sites.