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**Validation of the FORE-SIGHT<sup>®</sup> Tissue Oximeter for Measurement of Somatic Oxygenation in Children**

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**Introduction:** Despite FDA approval for clinical use of near infrared spectroscopy (NIRS) to measure somatic tissue oxygen saturation, human validation studies have not been reported. In neonatal piglets, renal blood flow was found to contribute at least 50% to the tissue oxygen saturation signal measured by NIRS from a sensor placed over the paravertebral T12-L2 region<sup>1</sup>. The aim of this study is to validate the FORE-SIGHT<sup>®</sup> NIRS tissue oximeter (CASMED, Branford, CT) for measurement of somatic tissue oxygen saturation (StO<sub>2</sub>) in pediatric subjects.

**Methods:** With IRB approval and written informed consent, 65 pediatric subjects (0.2-16.0 yrs.; 3.9-49.5 kg) with congenital heart disease undergoing elective cardiac catheterization were enrolled. A FORE-SIGHT<sup>®</sup> medium sensor (source-detector separation 12 and 40 mm) was placed on the flank in the paravertebral region just below the 12<sup>th</sup> rib to measure StO<sub>2</sub>. Reference blood samples were obtained simultaneously from arterial (SaO<sub>2</sub>) and central venous (ScvO<sub>2</sub>) catheters and analyzed by co-oximetry. As the venous system contains about 70% of the blood volume, a reference for StO<sub>2</sub> was determined as  $REF\ StO_2 = (0.3 \cdot SaO_2) + (0.7 \cdot ScvO_2)$ <sup>2</sup>. NIRS StO<sub>2</sub> was compared to REF StO<sub>2</sub> by the FDA-favored Deming regression, with determination of bias (REF StO<sub>2</sub> - NIRS StO<sub>2</sub>) and precision (1SD), and by concordance correlation coefficient (CCC) analysis. Measurements were performed at a single time point for each subject.

**Results:** Complete data was obtained from all subjects (n=65). Mean  $\pm$  SD SaO<sub>2</sub> was  $92.1 \pm 6.9\%$ , ScvO<sub>2</sub>  $66.5 \pm 7.7\%$ , REF StO<sub>2</sub>  $74.2 \pm 6.7\%$  and NIRS StO<sub>2</sub>  $74.6 \pm 7.4\%$ . By Deming regression, the bias was -0.45 and precision (1SD) 5.17%, with a concordance correlation coefficient of 0.73 (95% CI: 0.60-0.83) (Figure). As abdominal wall thickness correlates better with patient weight rather than age<sup>3</sup>, data according to patient weight are shown in the table.

**Discussion:** This study demonstrates that the FORE-SIGHT<sup>®</sup> NIRS tissue oximeter accurately measures somatic tissue oxygen saturation in patients weighing 3.9-49.5 kg. In addition, the findings question the extent of renal tissue interrogated in subjects < 20 kg when using a similar surface anatomic landmark and NIRS sensor with a source-detector separation of 40 mm<sup>3</sup>, since a bias influence of the higher renal venous oxygen saturation and hence NIRS StO<sub>2</sub> compared to the REF StO<sub>2</sub> would have been the result. As no significant bias was found even in smaller subjects weighing 3.9-9.9 kg, we conclude that the major contribution to the NIRS measurement with the sensor placed on the flank is from skeletal muscle rather than kidney.

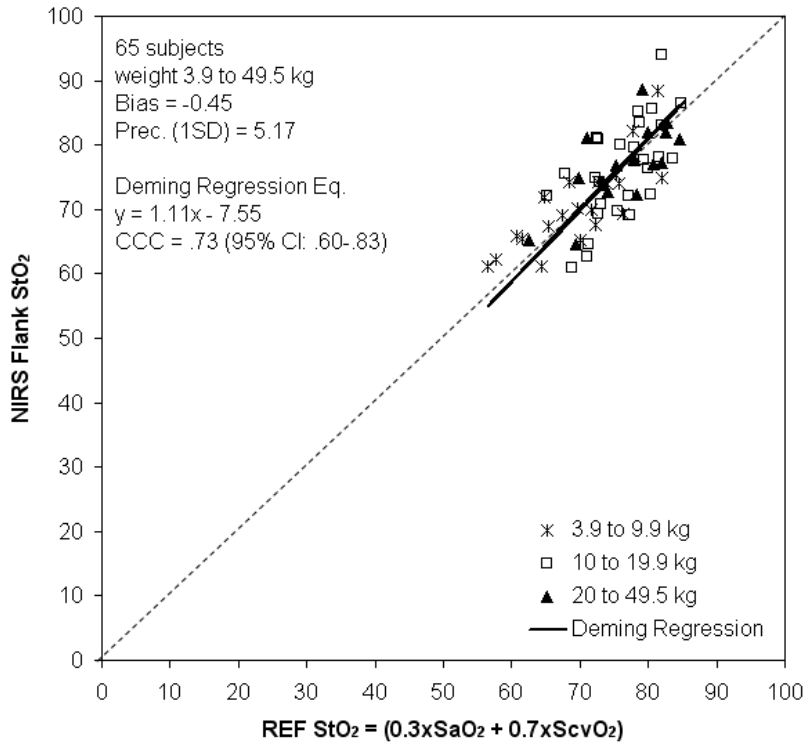
<sup>1</sup>Anesthesiology 2008; 109 A272.

<sup>2</sup>Pang CC, J Pharmacol Toxicol Methods. 2000;44(2):341-60.

<sup>3</sup>Balaguru, et al, Pediatr Crit Care Med. 2011 May;12(3):e145-8.

**Figure 1**

**FORE-SIGHT Flank StO<sub>2</sub> vs REF StO<sub>2</sub> (0.3 x SaO<sub>2</sub> + 0.7 x ScvO<sub>2</sub>)**



**Figure 2**

Data According to Patient Weight

Weight Range (kg)	3.9 - 9.9 (n = 22)	10 - 19.9 (n = 27)	20 - 49.5 (n = 16)
SaO <sub>2</sub> (%)	90.2 ± 7.8	93.3 ± 6.8	92.8 ± 5.7
ScvO <sub>2</sub> (%)	61.6 ± 7.8	68.8 ± 6.1	69.5 ± 6.8
REF StO <sub>2</sub> (%)	70.2 ± 7.3	76.1 ± 5.1	76.5 ± 6.1
NIRS StO <sub>2</sub> (%)	71.0 ± 6.7	76.2 ± 7.7	76.9 ± 6.4
Bias	-0.88	-0.10	-0.44
Precision (1SD)	4.32	6.11	4.80

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