

A validation method for near-infrared spectroscopy based tissue oximeters for cerebral and somatic tissue oxygen saturation measurements

Benni P et al. J Clin Monit Comput. 2018.

Objective

The goal of this study was to **evaluate the performance of ForeSight Elite tissue oximeter** for cerebral and somatic tissue oxygen saturation (StO₂) measurements for adult subjects.

Patients

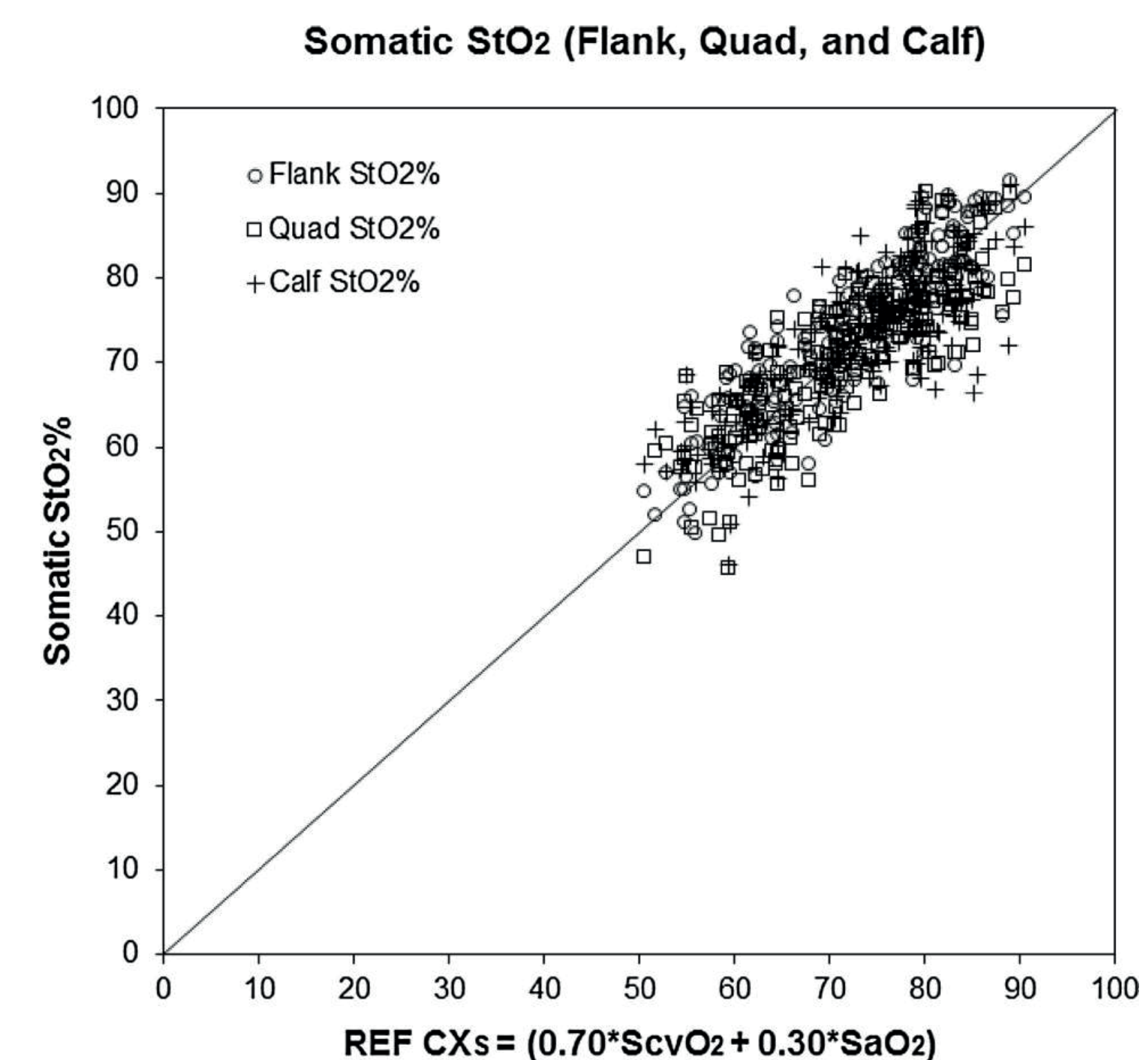
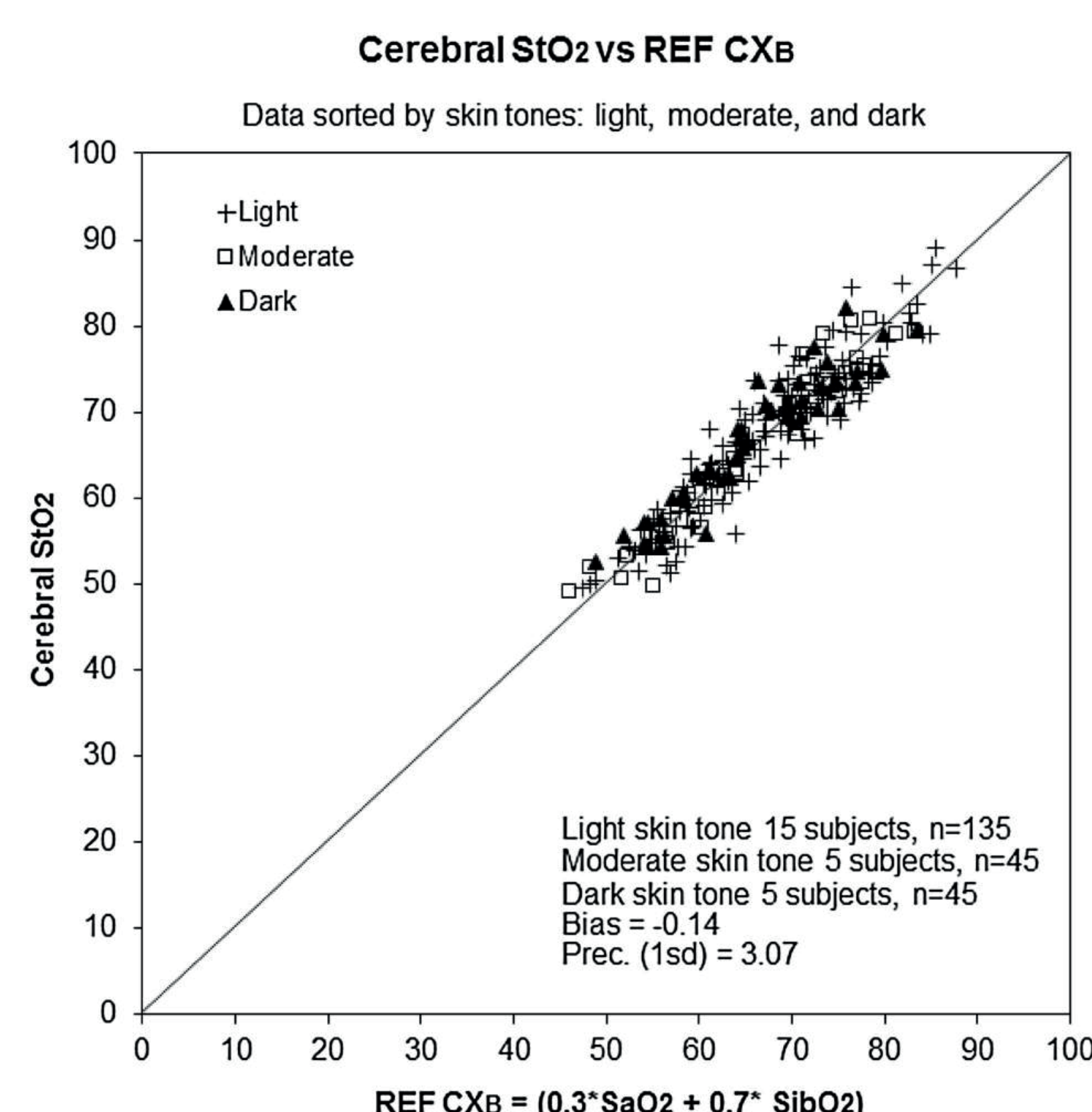
25 subjects successfully completed the cerebral validation study. 24 subjects successfully completed the somatic validation study.

Protocol

Subjects were enrolled in either the cerebral or somatic cohort as venous catheter placement could only be in one location. For cerebral, a catheter was placed in the right jugular bulb for blood sampling, with location verified by X-ray. For somatic, a catheter was placed for blood sampling in the superior vena cava outside of the right atrium. The level of oxygen within the blood was reduced in a controlled manner by altering the inspired oxygen concentration.

Results

25 subjects **successfully completed the cerebral validation** study with the following demographics: 15 White, 5 Black, 4 Asian, and 1 Hispanic subject, with 12 Males and 13 Females. Weight range was 44.6–108.9 kg; and age range was: 19.4–41.7 years.



The monitor's StO₂ measurements from the right forehead sensor demonstrated an overall bias ± precision (1 SD) of 0.03 ± 3.02%, while the left forehead sensor demonstrated an overall bias ± precision (1 SD) of -0.30 ± 3.13%. **Cerebral StO₂ accuracy of both cerebral hemispheres was similar**, even though jugular bulb catheterization was always on the right side.

24 subjects **successfully completed the somatic validation** study with the following demographics: 8 White, 14 Black, and 2 Asian.

Conclusions of the authors

*"We believe that a cerebral tissue oximeter validated using a controlled fixed V:A blood volume ratio **reliably provides clinicians real time information of the effect of both adverse and beneficial changes in cerebral vasoreactivity and V:A blood volume ratio shifts.**"*

Pubmed Link: <https://www.ncbi.nlm.nih.gov/pubmed/28374103>

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Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

ForeSight Elite tissue oximetry system is manufactured by CAS Medical, Inc., a subsidiary of Edwards Lifesciences.

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