SCA40
Validation of the Next Generation FORE-SIGHT Elite Tissue Oximeter for Adult Cerebral Tissue Oxygen Saturation.

MacLeod D; Ikeda K; Cheng C; Shaw A;
Duke University Medical Center, Durham, NC, USA;
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Introduction

The accuracy of NIRS cerebral oximeters is measured by comparing the NIRS-derived cerebral tissue oxygen saturation (StO_2) with the independently measured co-oximeter derived cerebral tissue oxygen saturation (Ref CX) value over the range of SpO_2 70 - 100% in healthy volunteers in accordance with ISO 80601-2-61 (2011). In this study we measured the accuracy of FORE-SIGHT® Elite Tissue Oximeter (FS2, CAS Medical Systems, Inc. Branford CT USA) and compared it with the first generation FORE-SIGHT monitor (FS1).

Methods

With IRB approval & written informed consent, healthy ASA 1 volunteers were recruited. Radial arterial & right jugular bulb (JB) catheters were inserted. A FS2 Large sensor was placed on one side of the forehead and a FS1 Large sensor on the opposite side, with left & right positions alternating between subjects. An initial measurement was taken with the subject breathing room air before a tight fitting mask was placed on the subject's face. The administration of combinations of $O_2/N_2/CO_2$ by Sequential Gas Delivery system allowed control of end-tidal CO_2 of 40 mmHg with variable end-tidal O_2 between 100 - 40 mmHg during step-down protocol from SpO_2 100 to 70% in 5% increments. Once each SpO_2 plateau was considered stable a pair of arterial & JB blood samples were taken and immediately analyzed with blood gas analyzer.

FS2 & FS1 StO_2 readings were compared to the established weighted co-oximetry reference (Ref CX) via the following equation:

Ref CX = (0.7 x $SjvO_2$) + (0.3 x SaO_2)

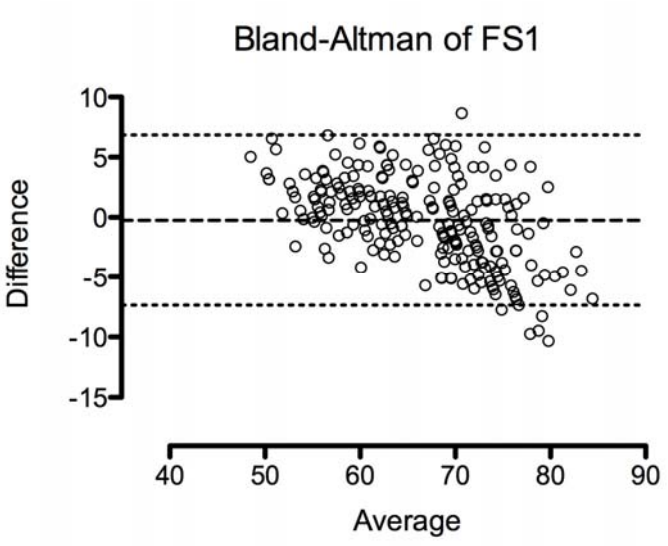
Where: $SjvO_2$ and SaO_2 are the functional oxygen saturations from the blood samples drawn simultaneously from the jugular bulb & systemic arterial catheters, respectively.

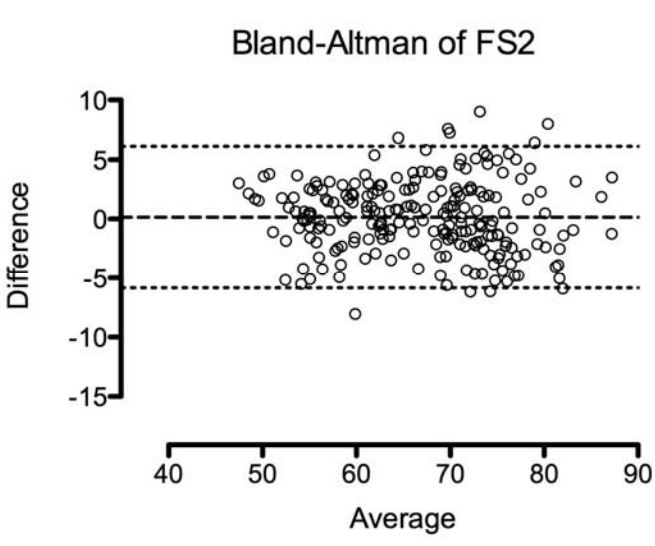
Results

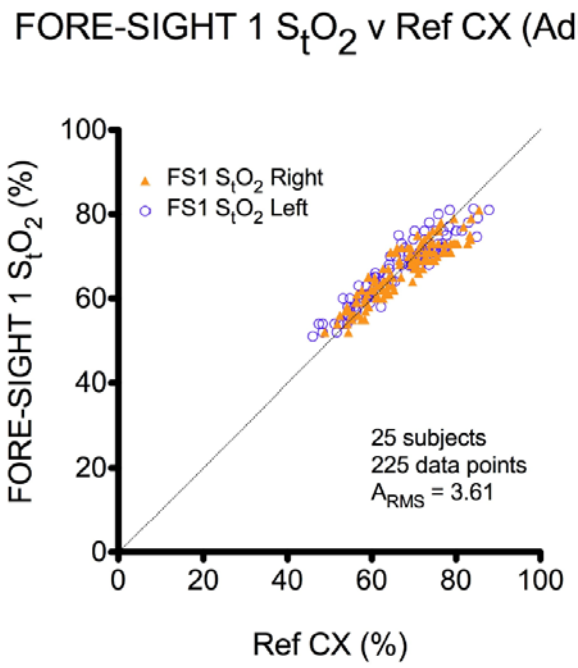
25 Subjects: 12 M / 13 F; 15 Cauc, 5 AA, 4 Asian and 1 Hispanic; Wt: 44.6 - 108.9 kg; Age: 19.4 - 41.7 yr. Scatterplots of FS2 & FS1 StO_2 saturations against Ref CX are shown in Figs 1 & 2. FS2 RIGHT & LEFT forehead measurements exhibited bias ± precision of 0.03 ± 3.00% (12 subjects RIGHT) & -0.30 ± 3.11% (13 subjects LEFT), demonstrating equivalent agreement from both cerebral hemispheres. Bland-Altman plots are shown in Fig 3.

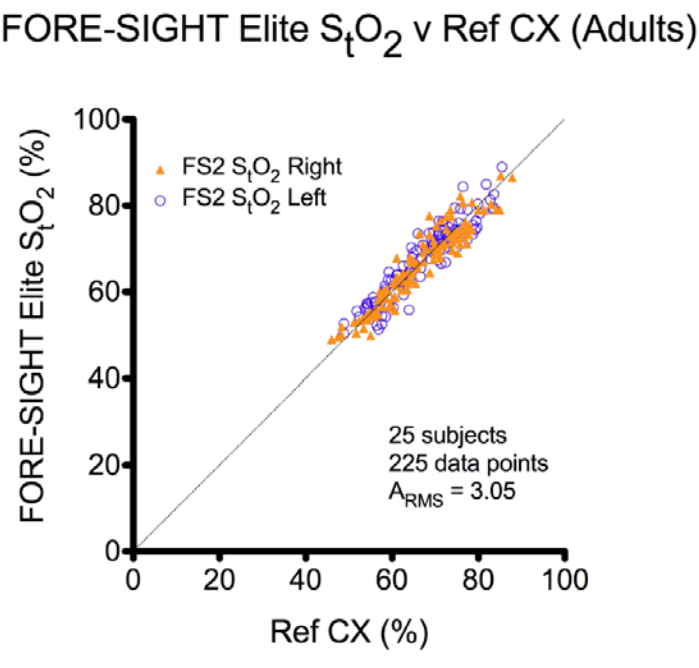
Discussion and Conclusions

The next generation FORE-SIGHT Elite tissue oximeter demonstrated a high level of accuracy for measuring cerebral tissue StO_2 in adult subjects, with greater accuracy than FS1.


Bland-Altman of FS1
Difference
10
5
0
-5
-10
-15
40
50
60
70
80
90
Average


Bland-Altman of FS2
Difference
10
5
0
-5
-10
-15
40
50
60
70
80
90
Average


FORE-SIGHT 1 StO2 v Ref CX (Adults)
FORE-SIGHT 1 StO2 (%)
FS1 StO2 Right
FS1 StO2 Left
25 subjects
225 data points
ARMS = 3.61
0
20
40
60
80
100
Ref CX (%)


FORE-SIGHT Elite StO2 v Ref CX (Adults)
FORE-SIGHT Elite StO2 (%)
FS2 StO2 Right
FS2 StO2 Left
25 subjects
225 data points
ARMS = 3.05
0
20
40
60
80
100
Ref CX (%)