How accurate is SoftSpot™?

We performed two clinical studies to measure the accuracy of SoftSpot:

a. *Prospective:* for the prospective evaluation of our measurement tool, PediaMetrix compared measurements taken with the SoftSpot™ app to the measurements taken by clinicians using a standard caliper similar to the predicate device. A comparative study was performed using 25 infants (age range 3 to 12 months). Data were collected by a physical therapist in a plagiocephaly clinic at the University of Pittsburgh Children Hospital from their typical patient population. The Spearman correlation coefficient was 0.96 and 0.94 for CI and CVAI, respectively. The mean absolute error (MAE) and standard deviation (STD) were 1.48 ± 0.92 and 1.44 ± 0.85 units for CI and CVAI, respectively.

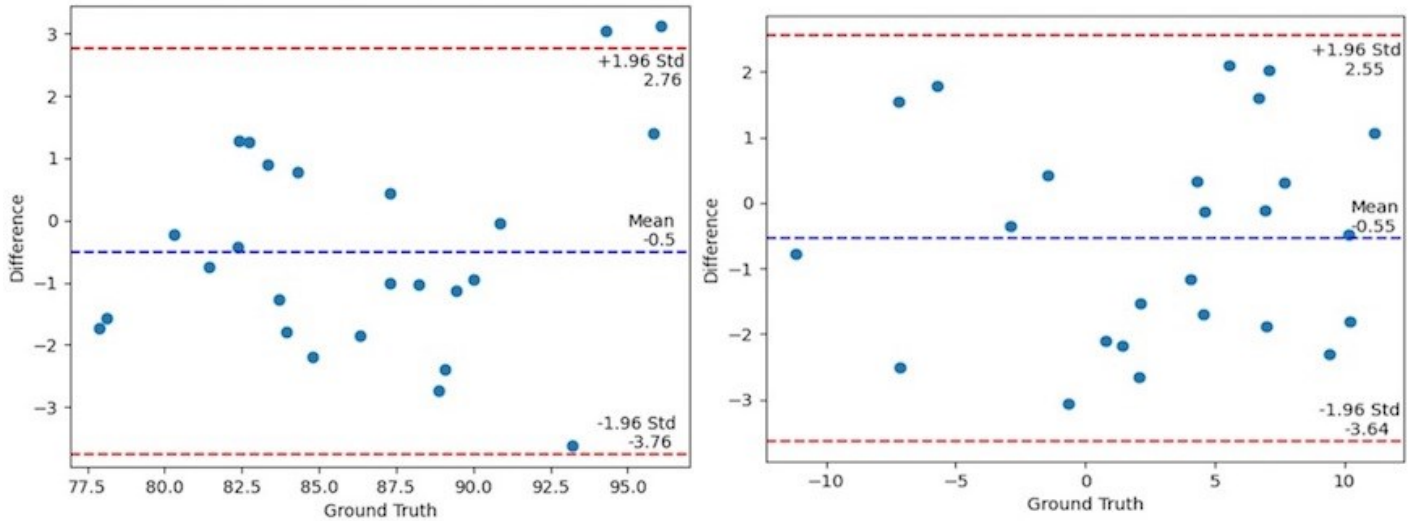| Prospective study (25 patients)	CI	CVAI
Spearman correlation test (p < 0.001)	0.96	0.94
Mean Absolute Error (MAE)	1.48	1.44
STD	0.92	0.85

Figure 1: Modified Bland-Altman comparison of measurements from 2D renders vs clinical ground truth values from caliper for CI (left) and CVAI (right).

b. _Retrospective:_ We also proposed to compare SoftSpot measurements of 2D rendered images (from 3D head scans) with direct measurements from 3D scans of the head from patients with cranial deformities in a retrospective study using 100 infants' head measurements along with their 3D scans (in .stl format). Data were collected from patients aged 3-20 months with deformational plagiocephaly and brachycephaly (DPB) in a helmet clinic at Singapore. The Spearman correlation coefficient was 0.93 and 0.94 for CI and CVAI, respectively. The mean absolute error (MAE) and standard deviation (STD) were 2.17 ± 1.53 and 1.62 ± 1.26 units for CI and CVAI, respectively.

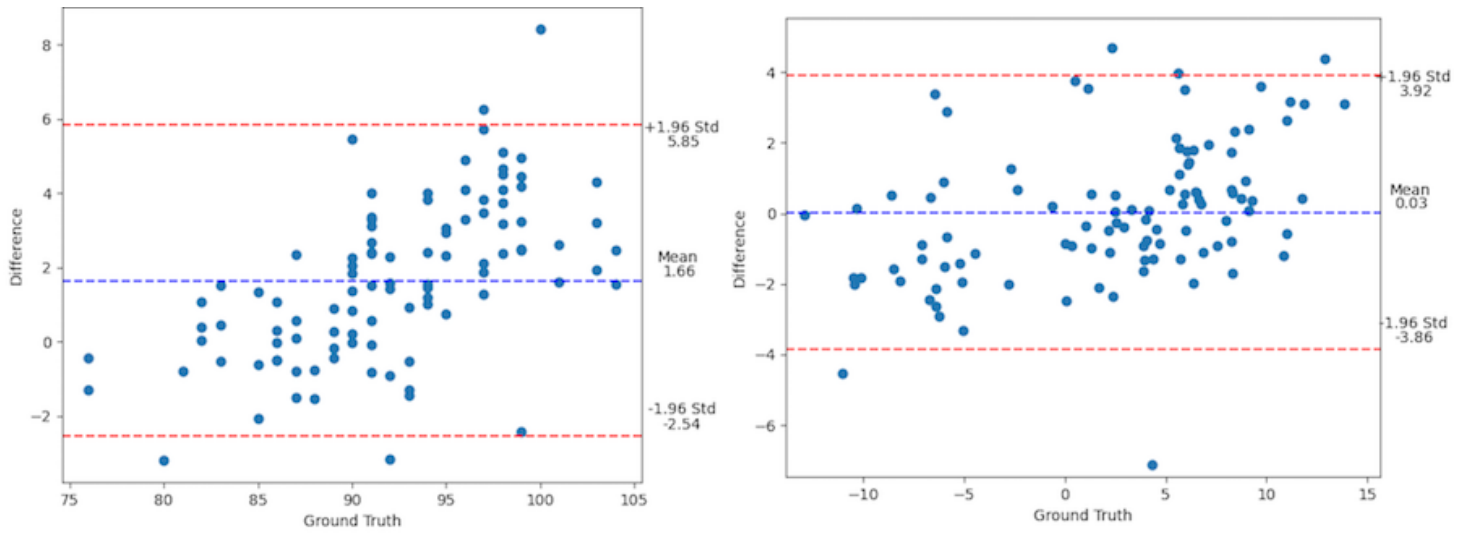| Retrospective study (100 patients)	CI	CVAI
Spearman correlation test ($p < 0.001$)	0.93	0.94
Mean Absolute Error (MAE)	2.17	1.62
STD	1.53	1.26

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Figure 2: Modified Bland-Altman comparison of measurements from 2D renders vs clinical ground truth values for CI (left) and CVAI (right).