System Accuracy Assessment of the CoG Device – a Combined Invasive and Non-invasive Glucometer

PFÜTZNER
Science & Health Institute
Diabeteszentrum & Praxis

Andreas Pfützner[1,2,3], Filiz Demircik[1,2], Johannes Pfützner[1,3], Kim Kessler[3], Stephanie Strobl[1], Jan Spatz[1,2], Anke H. Pfützner[2], Alexander Lier[1] ; [1]Pfützner Science & Health Institute, Diabetes Center and Practice, Mainz, Germany; [2]Sciema UG, Mainz, Germany; [3]Technical University Bingen, Dept. of Biotechnology, Bingen, Germany

Background

The pain associated with pricking the fingertip for blood glucose self-testing is considered to be a major burden in diabetes treatment. A new glucose meter offering the option to obtain blood glucose information via the standard invasive way or to predict tissue glucose by means of an optical non-invasive technology has recently been developed (TensorTip Combo Glucometer, Cnoga Medical Ltd., Cesarea, Israel, see Fig. 1) and tested in clinical trials. This present study was performed to determine the system accuracy of the invasive device component by means of a study protocol following the ISO15197:2015 guideline. In addition, the performance of the non-invasive device component was also analyzed in accordance to the analytical procedures suggested by the ISO guideline and using a point-of-care standard capillary glucose reference method.

Methods

One hundred samples were obtained from people with type 1 and type 2 diabetes and healthy volunteers (43 female, 57 male; age: 53±16 yrs.), with glucose distribution as requested by the ISO guideline. Three strip lots were tested twice by healthcare professionals in comparison to YSI 2300 Stat Plus reference method followed by a non-invasive tissue glucose prediction (NI-CoG). Mean Absolute (Relative) Difference (MARD) was calculated and a consensus error grid analysis (CEG) was performed.

Results

The ISO system accuracy criteria were met by the invasive strip technology by 589/600 of the data points (98.2 %) and by each strip lot separately. All values (100 %) were within CEG-zone A and total MARD was calculated to be 7.1 %. With the non-invasive reading, 98 % of raw data points were in A+B. After exclusion of eight data points because of traceable errors in the calibration procedure, 100 % of the results were found in CEG-zone A and MARD was 11.9%.

Fig.1.: The TensorTip CoG device

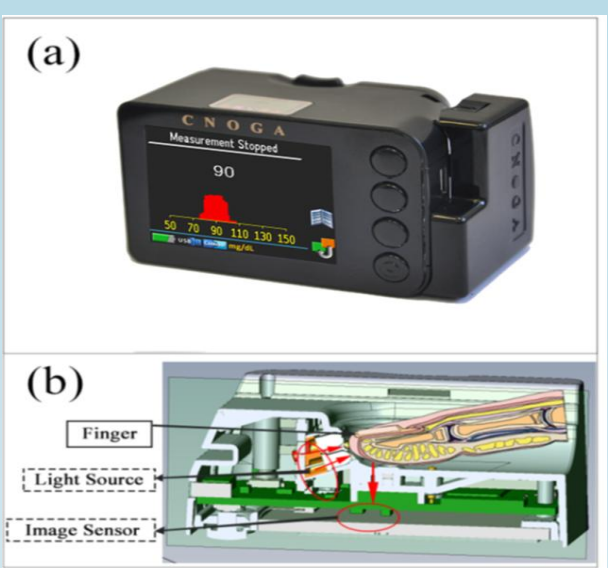


Fig. 2.: Consensus Error grid: invasive component

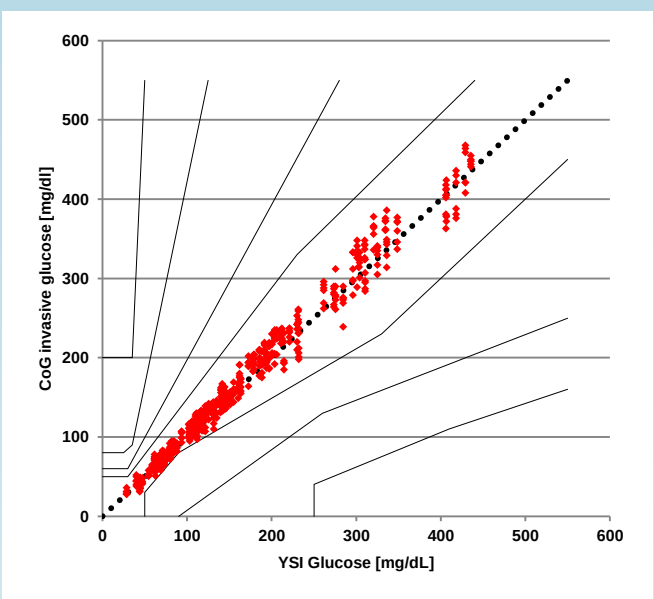
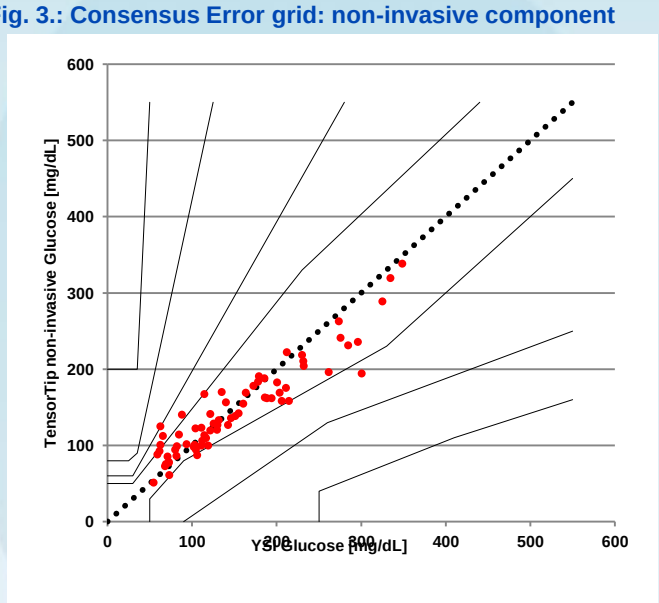


Table 1: ISO-Acceptance criteria

Strip Lot	Blood glucose	Accuracy
All lots (n=600)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	97.8 % (440/450) 99.3 % (149/150) 98.2 % (589/600)
Lot 1 (n=200)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	96.7 % (145/150) 100 % (50/50) 97.5 % (195/200)
Lot 2 (n=200)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	98.0 % (147/150) 100 % (50/50) 98.5 % (197/200)
Lot 3 (n=200)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	98.7 % (148/150) 98.0 % (49/50) 98.5 % (197/200)
non-invasive glucose prediction (raw data, n = 90)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	40.9 % (9/22) 79.4 % (54/68) 70.0 % (63/90)
Non-invasive glucose prediction (cleaned data, n = 82)	< 100 mg/dL (<5.55 mmol/L) ≥100 mg/dL (≥5.55 mol/L) Combined ISO criteria	76.9 % (9/15) 80,6 % (54/67) 76.7 % (63/82)

Fig. 3.: Consensus Error grid: non-invasive component



Conclusions

The invasive component of the CoG device was shown to be in full compliance with current ISO15197 criteria. However, good results were also obtained with the NI-CoG tissue glucose prediction. This non-invasive technology would also potentially be suitable for frequent pain-free glucose monitoring in many people with diabetes.

Pfützner Science & Health Institute, Diabetes Center and Practice, Parcusstr. 8, 55116 Mainz, Germany, Tel: +49 6131 5884640, Fax: +49 6131 5884644, www.pfuetzner-mainz.com