Performance Evaluation of a New Non-Invasive Glucose Monitoring Device in Different Patient Subtypes During Standardized Meal Experiments

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Background

Patients with insulin-treated diabetes mellitus have to perform regular blood glucose self-testing several times a day. Capillary blood samples are obtained by pricking the fingertip, which is considered to be the most painful procedure during daily routine. This study was undertaken to evaluate the meal-related performance of TensorTip CoG, a non-invasive glucose monitoring device (NI-CoG) with an additional built-in invasive glucose meter (Inv-CoG) in different patient populations during a standardized meal experiment.

Methods

The study was performed in 15 healthy volunteers (HV: age, gender, HbA1c), 6 patients with type 1 diabetes (T1D: age, gender, HbA1c), and 15 patients with type 2 diabetes (T2D: age, gender, HbA1c). The participants ingested a standardized meal and blood glucose was assessed by means of NI-CoG, and from capillary blood samples by means of Inv-CoG, YSI Stat 2300 plus, and Ascensia Contour Next, at time-points -30, 0, 15, 30, 45, 60, 75, 90, 120, 150, and 180 min. Mean Absolute (Relative) Differences (MA(R)D) was calculated and a consensus error grid analysis (CGA) was performed in comparison to YSI for statistical analysis.

Results

Similar results were obtained with each individual device in all three study cohorts. MARD (for values >100 mg/dL) with NI-CoG was determined to be 11.1 % (HV), 13.2% (T1D), and 13.6% (T2D), respectively (NI-CoG MAD for values≤100 mg/dL: 20.0mg/dL/18.8mg/dL/20.0mg/dL, Inv-Cog: MARD: 8.9%/7.6%/8.0% and MAD: 11.5mg/dL/13.4mg/dL/14.2mgdL, Contour: MARD: 4.4%/4.1%/3.9% and MAD: 4.3mg/dL/2.6mg/dL/4.9mgdL). All data pairs were seen in CGA zones A+B with all devices (NI-CoG: 83%+17%, Inv-CoG: 100%+0%, Contour: 100%+0%).

Fig.1.: The TensorTip CoG device

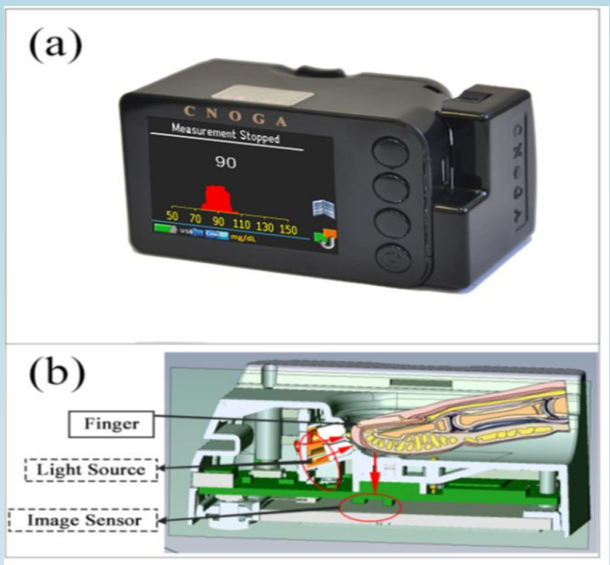
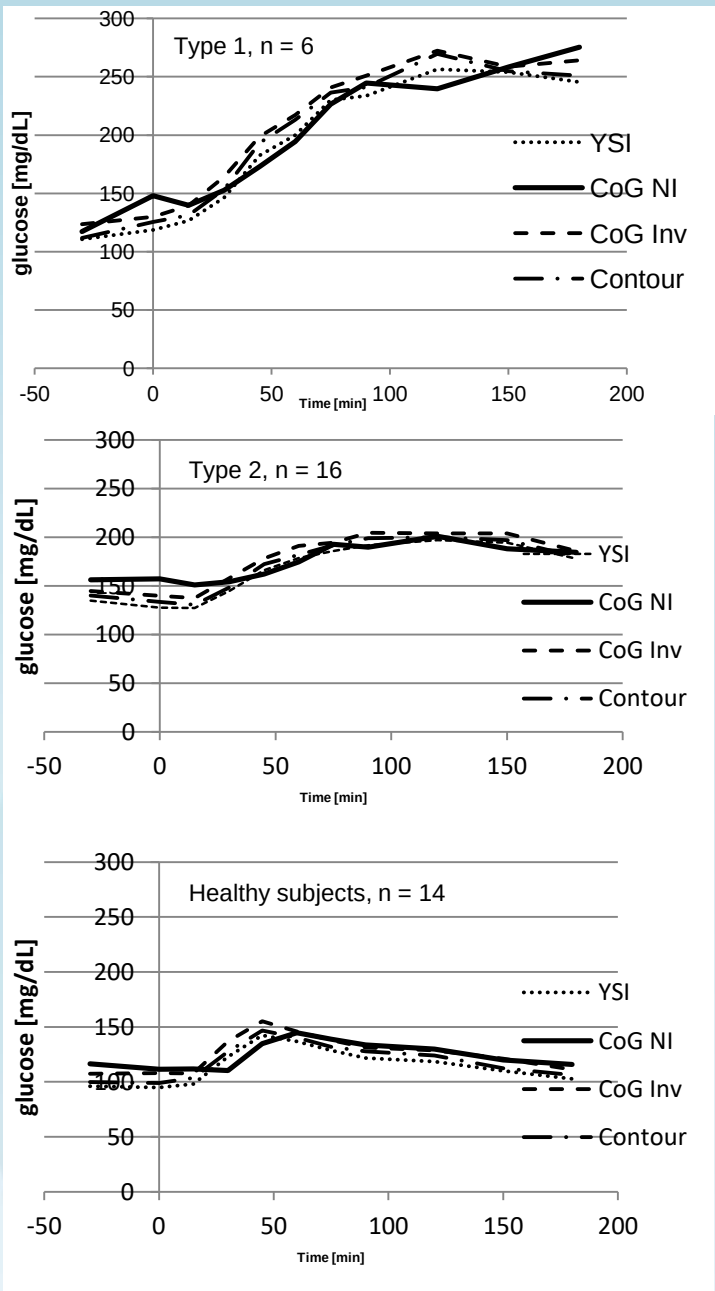


Table 1: ISO-Acceptance criteria

Parameter	Type 1 diabetes	Type 2 diabetes	Healthy subjects
N	6	16	14
Non-invasive CoG component			
MARD (59 – 317 mg/dL)	15.2 %	14.1 %	14.4 %
MAD (≤ 100 mg/dL)	18.8 mg/dL	20.0 mg/dL	20.0 mg/dL
MARD (> 100 mg/dL)	13.2 %	13.6 %	11.1 %
Consensus Error Grid			
Zone A	83.7 %	97.7 %	96.7 %
Zone B	16.7 %	2.3 %	3,3 %
Zone C – E	0 %	0 %	0 %
Invasive CoG component			
MARD (59 – 317 mg/dL)	9.3 %	8.5 %	10.0 %
MAD (≤ 100 mg/dL)	13.4 mg/dL	14.2 mg/dL	11.5 mg/dL
MARD (> 100 mg/dL)	7.6 %	8.0 %	8.9 %
Consensus Error Grid			
Zone A	100 %	100 %	100 %
Zone B	0 %	0 %	0 %
Zone C – E	0 %	0 %	0 %
Ascensia Contour Next			
MARD (59 – 317 mg/dL)	4.0 %	4.0 %	4.5 %
MAD (≤ 100 mg/dL)	2.6 mg/dL	4.9 mg/dL	4.3 mg/dL
MARD (> 100 mg/dL)	4.1 %	3.9 %	4.4 %
Consensus Error Grid			
Zone A	100 %	100 %	100 %
Zone B	0 %	0 %	0 %
Zone C – E	0 %	0 %	0 %

Fig. 2.: Consensus Error grid: invasive component



Conclusions

In this pilot study, the NI-CoG technology was shown to reliably track meal related glucose excursions in all three patient populations with a similar and acceptable performance as compared to common needle sensor methods. This non-invasive technology may therefore be suitable for pain-free glucose monitoring in subjects at diabetes risk but also in all diabetes patient populations.

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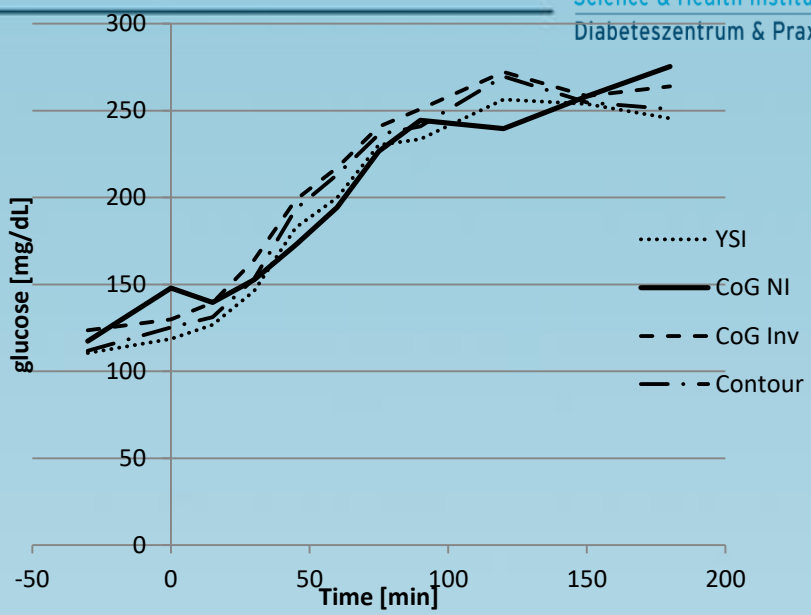
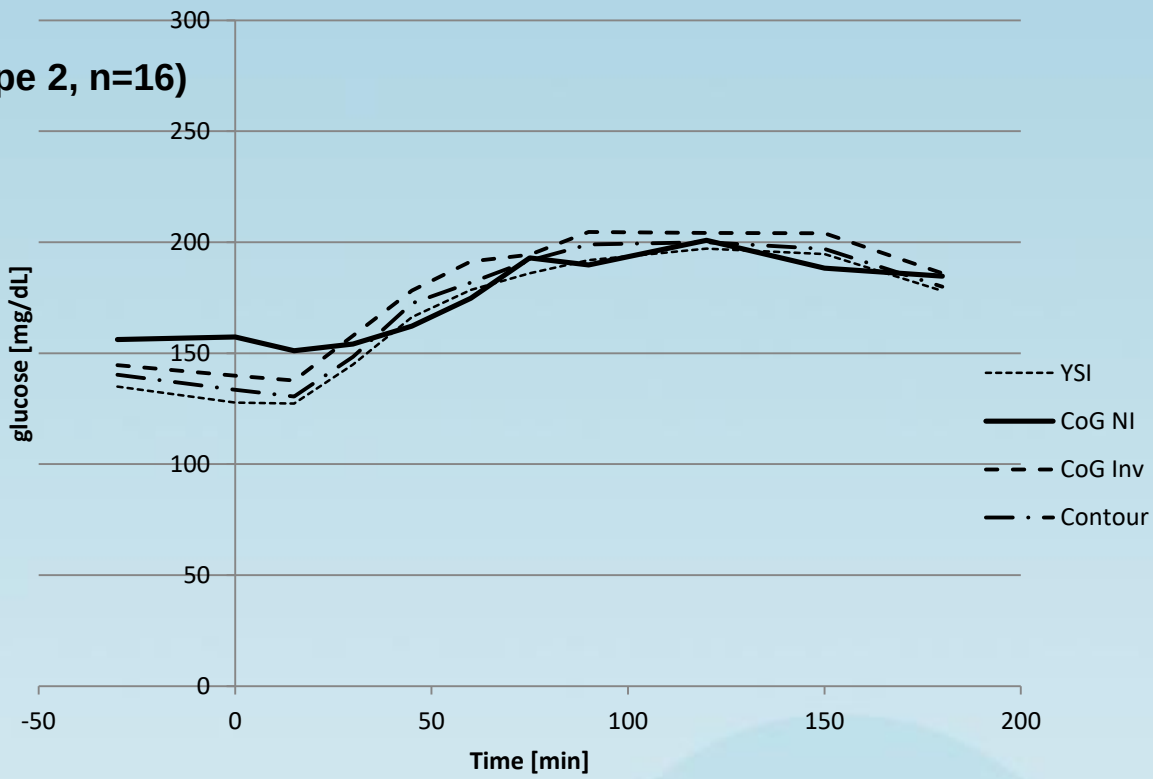
1A (type 1, n=6)



1B (type 2, n=16)



1C (healthy, n=14)