Measurement accuracy of a newly developed prototype system for non-invasive glucose monitoring

Stefan Pleus, Peter Wintergerst, Delia Waldenmaier, Nina Jendrike, Manuela Link, Cornelia Haug, Guido Freckmann

Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany

Background and Aims

Non-invasive glucose monitoring (NIGM) may be beneficial for people with diabetes in avoiding the need for finger pricking to obtain blood samples. The aim was to assess measurement accuracy of a prototype system for NIGM, incorporating a Raman sensor, in a mixed outpatient and in-clinic setting.

Materials and Methods

A total of 15 subjects with type 1 diabetes participated in the study which lasted for 27 days per subject. Subjects performed standard blood glucose (BG) monitoring with a Contour® next ONE meter and NIGM at the thenar with the prototype system at least 6 times per day.

Data from the first 19 to 24 days were used for calibration of the NIGM system. The data from the remaining 3 to 5 days (including 1 in-clinic day each) were used for independent validation of the calibration. In-clinic sessions, during which rapid glucose excursions with high and low glucose values were induced, took place twice (1x on a calibration day and 1x on a validation day).

For data from validation days, median absolute relative difference (MedARD) was calculated and Consensus Error Grid (CEG) analysis was performed.

Results

The median ARD was 19.2% for the out-patient days, 22.0% for the in-clinic days and 18.9% for the complete study (Table 1).
CEG analysis showed 52.9% and 40.2% of values in clinically acceptable zones A and B, respectively. The remaining values fell within zones C (6.4%) and D (0.5%). No values were found in zone E.

Table 1: Accuracy results for the outpatient days, the in-clinic day and the complete study (n = number of triplets of BG and prototype values). Median ARD (n = 15) was calculated against BG values.

	Out-patient days		In-clinic days (with glucose excursion)		Complete study	
Subject #	**Median ARD (%)**	**n**	**Median ARD (%)**	**n**	**Median ARD (%)**	**n**
1	7.8	10	26.9	14	17.5	24
2	22.5	15	15.4	14	18.9	29
3	19.2	11	22.0	19	19.8	30
4	19.5	7	32.6	22	22.1	29
5	17.4	33	12.4	16	15.7	49
6	18.3	32	18.9	11	18.6	43
7	24.6	11	19.6	27	21.4	38
8	19.9	24	17.8	9	18.8	33
9	17.4	35	26.9	21	20.2	56
10	11.6	16	26.9	15	20.5	31
11	11.4	29	26.2	14	15.3	43
12	19.7	16	18.0	25	18.0	41
13	24.4	23	27.4	28	27.3	51
14	14.1	21	12.8	30	13.5	51
15	63.1	20	37.0	26	46.1	46
Min	7.8		12.4		13.5	
Max	63.1		37.0		46.1	
Median	19.2		22.0		18.9	
Aggregated Median	18.6	303	21.9	291	19.7	594

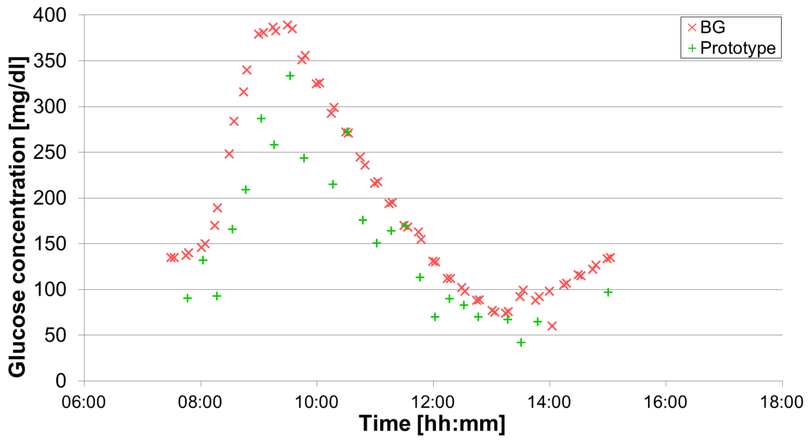

Figure 1: Example of glucose concentrations on in-clinic day (day 27). Data of subject #9.

Conclusions

Although MedARD was comparably high for the newly developed Raman-based prototype, this proof-of-concept study showed promising results. More than 93% of values were found in clinically acceptable zones of the CEG.

CEG zone	A	B	C	D	E
Out-patient performance (%)	56.1	37.6	5.9	0.3	0

CEG zone	A	B	C	D	E
In-clinic performance (%)	49.5	43.0	6.9	0.7	0

CEG zone	A	B	C	D	E
Overall performance (%)	52.9	40.2	6.4	0.5	0

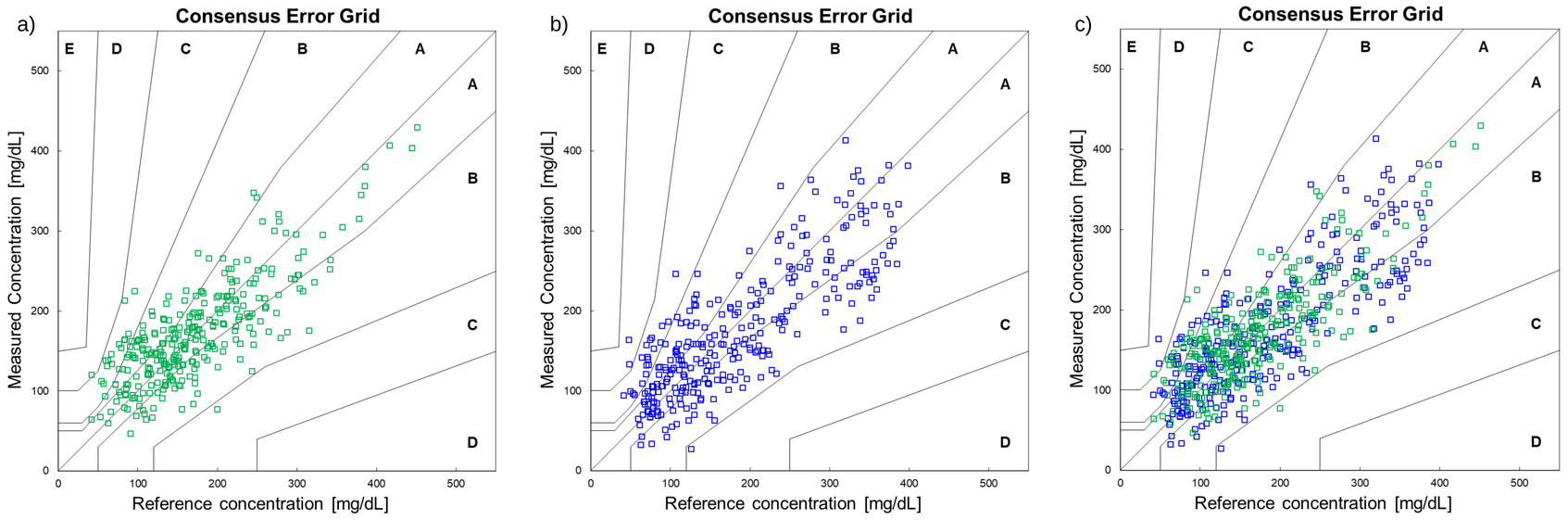

Figure 2: Consensus Error Grid distribution of paired points of out-patient (a), in-clinic (b) and overall (c) performance.

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Stefan Pleus
Institut für Diabetes-Technologie GmbH
Lise-Meitner-Str. 8/2
D-89081 Ulm, Germany
phone: +49 (0) 731 50990 0
fax: +49 (0) 731 50990 22
stefan.pleus@idt-ulm.de