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

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

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 in a mixed outpatient and in-clinic setting.

Materials and Methods

A total of 10 subjects with type 1 diabetes participated in the study which lasted for 27 days per subject. Subjects wore a FreeStyle Libre (FL) system on the upper arm for continuous glucose monitoring, and they 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, measurement sets were performed which consisted of 1st BG meter measurement, 1st FL scan, 1st NIGM measurement, 2nd BG meter measurement, 2nd FL scan, 2nd NIGM measurement. Results from the same measurement set were averaged by device before analysis.

In-clinic sessions took place on the 6th day and on the 27th day, during which rapid glucose excursions with high and low glucose values were induced. During these sessions, measurement sets were performed every 15 minutes between 0730 and 1500.

Data from 24 / 19 days were used for calibration of the NIGM system for the first / second group of five subjects. The data from the remaining 3 / 8 days (including 1 in-clinic day each) were used for independent validation of the calibration.

For data from validation days, mean and median absolute relative differences (ARD) were calculated for FL and the NIGM prototype in comparison with the BG meter values for each subject.

Results

Outpatient mean ARD ranged from 8.0% to 26.2% for FL (mean: 16.1%) and from 9.1% to 26.9% for the prototype (mean: 20.2%), whereas in-clinic MARD ranged from 13.7% to 45.3% for FL (mean 23.3%) and from 19.8% to 36.0% for the prototype (mean: 25.5%).

Conclusions

Although mean and median ARD were somewhat higher for the NIGM prototype than for FL, this proof-of-concept study showed promising results for the newly developed NIGM prototype.

	In-clinic day (with glucose excursion)					Outpatient days				
	Mean ARD (%)		Median ARD (%)			Mean ARD (%)		Median ARD (%)		
Subject #	FL	Prototype	FL	Prototype	n	FL	Prototype	FL	Prototype	n
1	17.5	29.5	15.0	26.9	14	18.3	9.1	18.6	7.8	10
2	27.2	23.7	27.6	15.4	14	18.6	26.9	17.6	22.5	15
3	13.7	36.0	12.8	22.0	19	12.1	19.2	9.7	19.2	11
4	14.0	30.0	12.7	32.6	22	8.0	19.0	7.6	19.5	7
5	20.6	19.8	19.7	12.4	16	14.2	20.1	13.3	17.4	33
6	45.3	21.0	44.9	18.9	11	13.4	22.6	10.3	18.3	32
7	27.5	24.2	25.7	19.6	27	26.2	21.5	25.4	24.6	11
8	25.2	21.6	24.5	17.8	9	11.5	24.8	11.7	19.9	24
9	20.8	24.4	20.8	26.9	21	23.1	24.2	17.8	17.4	35
10	21.1	24.9	21.6	26.9	15	15.5	14.6	14.4	11.6	16
Min	13.7	19.8	12.7	12.4		8.0	9.1	7.6	7.8	
Mean	23.3	25.5	-	-		16.1	20.2	-	-	
Median	-	-	21.2	20.8		-	-	13.8	18.8	
Max	45.3	36.0	44.9	32.6		26.2	26.9	25.4	24.6	

Table 1: Accuracy results for the in-clinic day and the outpatient days (n = number of triplets of BG, FL, and prototype values). Mean/median ARD were calculated against BG values.

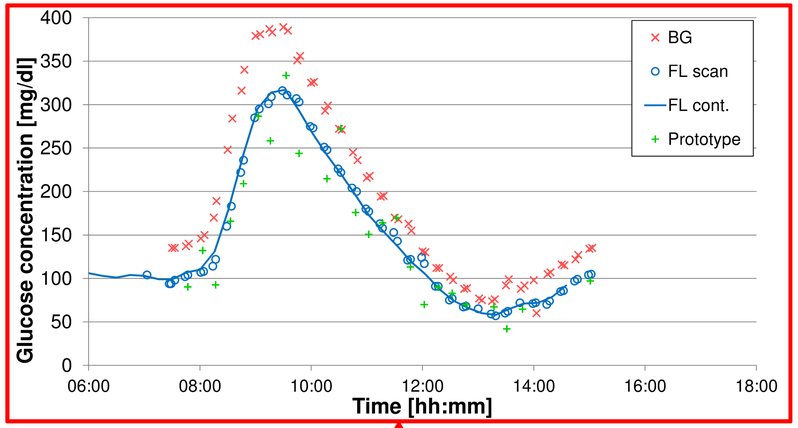

Figure 1: Example of glucose concentrations on in-clinic day (day 27). Data of subject #9.

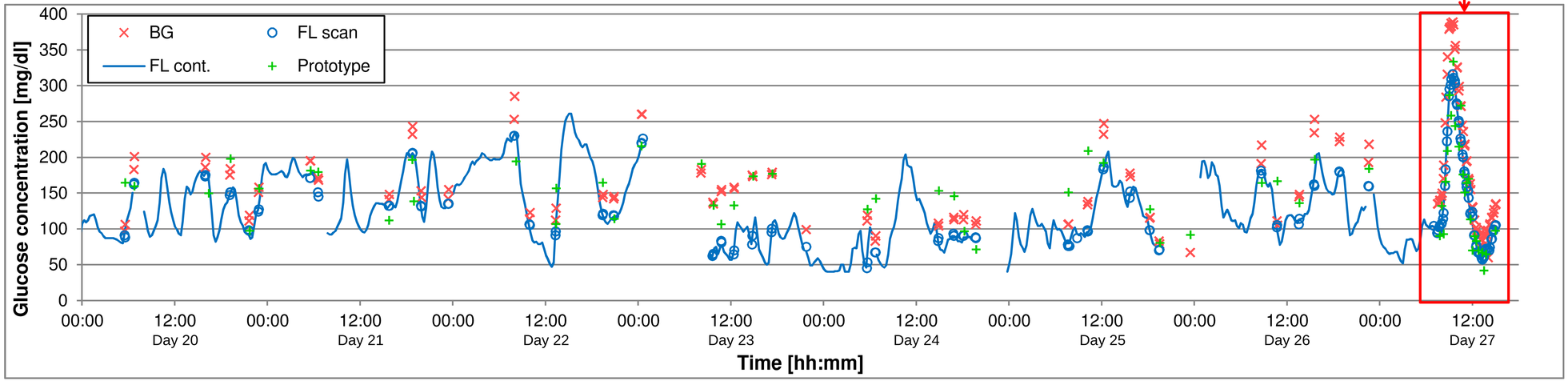

Figure 2: Example of glucose concentrations on days 20 to 27. Gaps in "FL cont." trace denote missing continuously stored FL values (e.g., FL scans performed >8h apart). Data of subject #9.

94-LB

Poster 94-LB - Category:
12-B Clinical Therapeutics/New Technology - Glucose Monitoring and Sensing
ADA 79th Scientific Sessions
San Francisco, CA, USA, June 7 – 11, 2019

This study was funded by RSP Systems A/S, Denmark

Dr. Guido Freckmann
Institut für Diabetes-Technologie GmbH
Lise-Meitner-Str. 8/2
D - 89081 Ulm
fon: +49 (0) 731 50990 0
fax: +49 (0) 731 50990 22
guido.freckmann@idt-ulm.de