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

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Abstract body:
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.

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 absolute relative differences (MARD) were calculated for FL and the NIGM prototype in comparison with the BG meter values for each subject.

Outpatient MARD 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%).

Although MARD was somewhat higher for the NIGM prototype than for FL, this proof-of-concept study showed promising results for the newly developed NIGM prototype.

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