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.

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.