Application of a Multisensor Device for Continuous Glucose Monitoring under Home Use Conditions

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For continuous non invasive glucose monitoring (NIGM) a novel Multisensor has been developed. The Multisensor yields signals from skin-surface sensors for impedance, dielectric, optical, temperature, blood perfusion and hydration measurements. The first block of data was used to build a multivariate model relating blood glucose (BG) changes to multiple signal variations and the rest, to predict BG in patients with type 1 diabetes mellitus (T1DM) during daily life.

Sixteen T1 DM patients (age 39±12 y; BMI 23.8±2.7 kg/m^2, duration of diabetes 20±13 y; HbA1c 6.8±0.8%) wore the Multisensor, attached to the upper arm via an elastic band, on average 9 h per day over a period of 4 months of normal life conditions. A total of 380 study days were collected. The Multisensor recorded a measurement from each sensor every 20 sec. and the patients collected 11 capillary blood glucose (cBG) measurements on average during each study day. The study was split into two blocks, of 160 non consecutive and 220 consecutive days, respectively. The Multisensor and the cBG measurements from the first block were used for selecting and training a linear regression model. The model was then prospectively applied on the second block of data, and the glucose estimations were compared to the cBG measurements.

The regression model selected consisted of seven sensor signals for which coefficients were adjusted to the individual patient. When applied to the second block of data, it yielded glucose predictions with an average medium absolute relative difference (MARD) of 29%, and a mean absolute difference MAD of 32.6 mg/dL - in spite of the fact that the data were collected during daily life and across climatic conditions, ranging from hot summer to colder autumn (average temperature 20±10 °C).

Usage of the Multisensor allows for NIGM in T1DM patients in daily life like conditions with an acceptable measurement quality. With appropriate training patients can easily use and attach the Multisensor, allowing stable measurements. Only a few issues with skin reddishness were observed. Further developments in calibration to individuals and increase of precision are under way.