

MULTISENSOR CONCEPT FOR NON-INVASIVE GLUCOSE MONITORING

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Numerous reports describe the use of non invasive glucose monitoring techniques, e.g. impedance Spectroscopy (IS). These techniques were mostly tested in an in-vitro setting or under controlled in-vivo conditions. It has been shown that under daily-life conditions, additional external or physiological factors can also effect the measurement. Two experimental clinical trials (part 1 & 2) were set up to investigate the these perturbing effects and the relation to glucose changes.

The first part was designed to specify, develop, characterise and optimise an array of non-invasive sensors based around IS. The relation between changes in blood perfusion / moisture characteristics of the skin and the dielectric behaviour was investigated in 9 healthy subjects (5 male, 4 female, age 26 ± 8 years; BMI 21.5 ± 2.1 kg/m²). The dielectric properties of the skin and underlying tissue were measured in response to externally applied changes together with an optical, acceleration/pressure, temperature sensor.

The second experimental clinical part was designed to test this multisensor concept in patients with diabetes and healthy subjects. Four patients with type 1 diabetes mellitus (T1DM) age 35.8 ± 10.4 years, BMI 23.8 ± 1.6 kg/m² and HbA1c $7.0\%\pm 1.7$; three patients with T2DM age 57 ± 11.4 years, BMI 24.7 ± 3.8 kg/m², HbA1c $6.7\%\pm 0.7$; four healthy subjects age 24.5 ± 4.5 years, BMI 21.4 ± 1.6 kg/m² participated in this study. Two hyperglycemic excursions were induced using a manual glucose clamp technique.

Results Part 1: The multisensor concept was providing additional information to compensate for perturbing effects allowing to demonstrate that e.g. changes in the IS signal are due to a changes in blood perfusion or sweat.

Part 2: An empirical data modelling process based on multiple regression with variable selection was used to derive a set of tentative models for glucose prediction based on the data of the second part. The model selection was carried out on 13 runs from 4 healthy subjects and 3 T1DM patients. The resulting squared multiple correlation coefficient was $R^2=0.71$.

The multisensor concept has shown the possibility to account for and compensate the perturbing effects. From the data of the second study a global model family was derived including an individual parameter for baseline adjustment allowing glucose changes to be tracked.