A first clinical verification of a radio frequency-based spectroscopy sensor intended for glucose detection in interstitial fluid

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Background and Aims

Conventional self-monitoring methods of blood glucose measurement are inconvenient, painful, and cause trauma to the skin and underlying tissues. Ultimately, this can result in low compliance to frequent testing of blood glucose levels and thus poor treatment among diabetics.

A novel, minimal invasive chipset that combines several hundred hollow micro needles designed to collect dermal interstitial fluid (ISF) and a radio frequency spectroscopy glucose sensor, is under development. ISF has previously been proven to be a good indicator of blood glucose levels. A convenient way of accessing ISF in a study situation is by emptying burn blisters.

This poster presents the first clinical verification of the sensor element within the chipset using fluid from burn blisters as substitute for ISF.

Methods

Burn blister fluid was collected from 25 consecutive acute burn patients at the Burn Center, Uppsala University Hospital, Sweden. Measurements were conducted on unfiltered and non-centrifuged blister fluid. Each sample was divided into two parts. Glucose content was measured in one portion using the radio frequency spectroscopy sensor where the complex permittivity of the liquid was analyzed using a cavity perturbation resonator. The sensing resonator had a normal resonance frequency at approximately 9 GHz and was used in a setup where the resonance frequency shifted proportionally to the glucose concentration within the sample. The second portion of blister fluid was used as reference and analysis of glucose content was made with a clinical chemistry analyzer (Architect Plus C16000, Abbott Diagnostics, Illinois, USA). Two different teams conducted the measurements separately. The measurements were subsequently organized in pairs and compared using an accuracy plot.

Results

Sixty-eight percent of the measurements obtained from the specroscopy sensor under test, had an error less than 15 mg/dl below concentrations of 100 mg/dl and an error less than 15 % above 100 mg/dl, when compared with reference measurements. Using the Parkes Error Grid for type 1 diabetes, 88 % of the measurements from the sensor under test are within zone A. The remaining 12 % are within zone B.

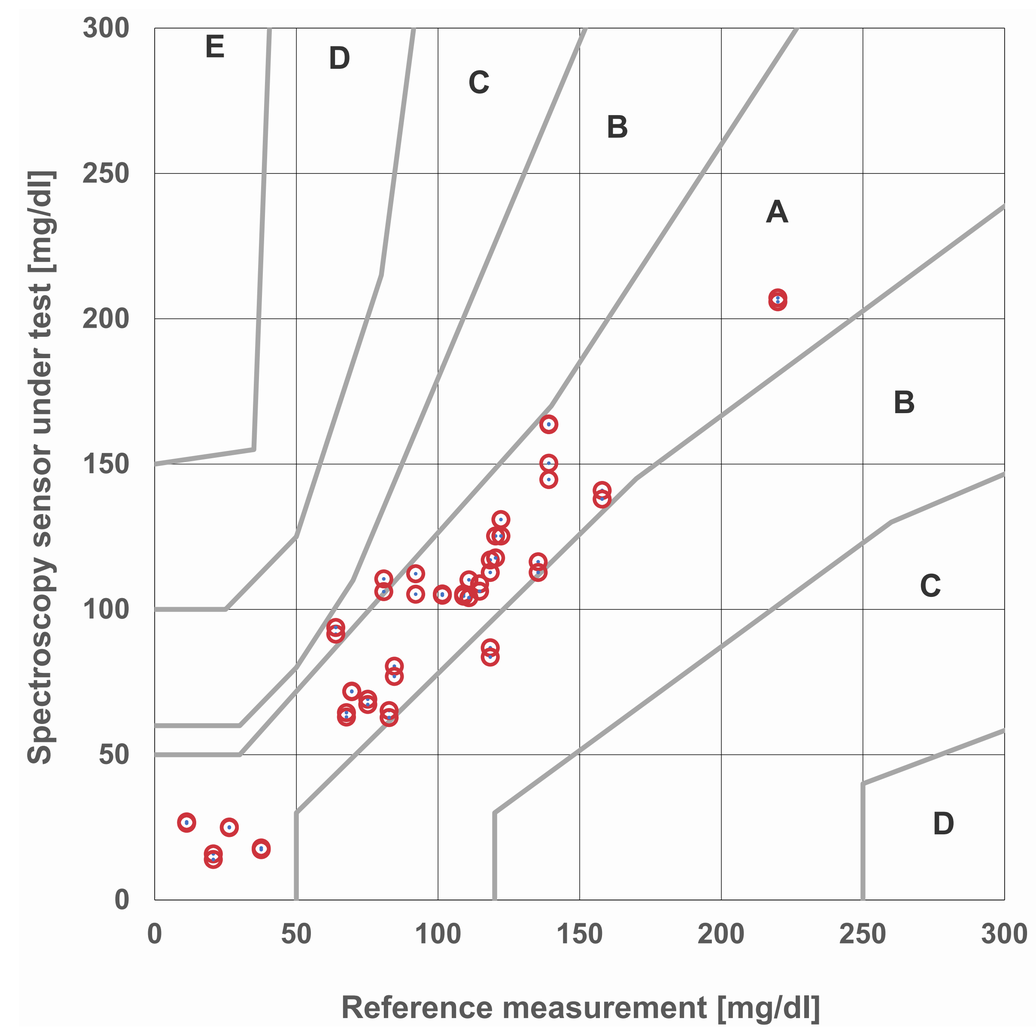

Photo: Burn blisters.

Figure: Clinical data from 25 patients where glucose in burn blister fluid was measured using the radio frequency-based spectroscopy sensor under test, presented in a Parkes Error Grid.

Conclusions

Glucose measurements on ISF substitute (burn blister fluid) using the radio frequency-based spectroscopy sensor under test, fulfill the consensus error grid requirements for type 1 diabetes. The study demonstrates that the sensor could be a reliable, pain-free, and cost-effective method for glucose measurements. This system may serve to improve patient compliance with regard to selfmonitoring and thus improved glucose control. Further studies are, however, needed in order to properly evaluate the clinical value of this novel principle.

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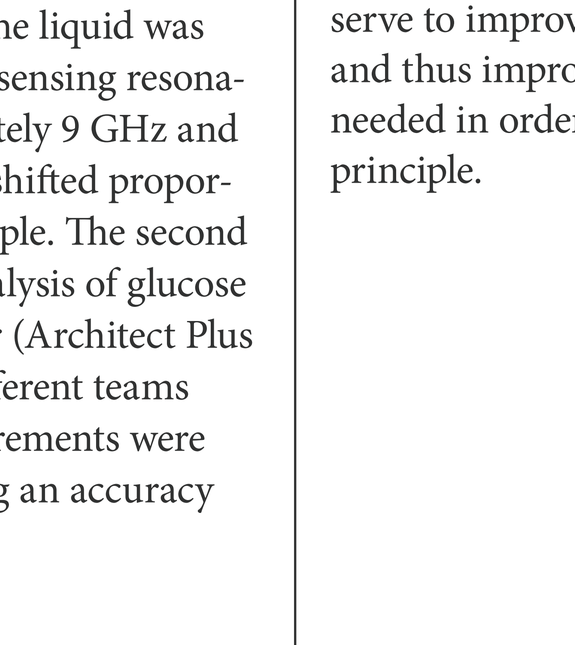

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