Interference Test Results for an Osmotic Pressure Sensor for Interstitial Glucose Assessment

Rita Smajda, Guy Voirin, Gaëlle Andreatta, Sanja Ramljak, Rune Frisvold, Andreas Pfützner, Martha Liley
CSEM, Neufchatel, Switzerland, Sciema UG, Mainz, Germany, Lifecare AS, Bergen, Norway, Pfützner Science & Health Institute, Mainz, Germany

Background and Aims

An implantable osmotic pressure sensor for interstitial glucose assessment is currently under development by Lifecare, Bergen, Norway (Sencell). The sensor uses the binding of the plant lectin Concanvalin A to glucose and dextrose in a close chamber as core sensor technology. A working laboratory sensor prototype model has been developed, which can be used for initial optimization experiments and further developmental tasks. The purpose of this experiment was to evaluate the stability of the glucose sensor signal against a potential influence of other carbohydrates.

Methods

For each test, the sensor was equilibrated with 2 mmol/l glucose prior to addition of the potentially interfering substances in high physiological concentrations. The following carbohydrates and concentrations were tested: α-D-Mannose (100 µmol/l), xylose (1.5 mmol/l), maltose (10.5 mmol/l), fructose (120 µmol/l), transferrin (5g/L). In case of a measurable impact of the carbohydrate on the sensor signal, at least one more carbohydrate concentration below the initial concentration was to be tested.

Results

There was no impact of mannose, xylose, fructose, and transferrin in the tested concentrations on the osmotic sensor signal. A measurable interference was observed with maltose at concentrations of 10.5 mmol/l and 5 mmol/l. With 5 mmol/l maltose, the observed increase in the osmotic pressure signal amounted to ~9 % (10.5 mmol/l: ~17 %) . However, such maltose concentrations are unlikely to be seen in the interstitial fluid under physiological conditions in human subjects.

Fig.1: Drawings and pictures of the laboratory working pressure cell chamber

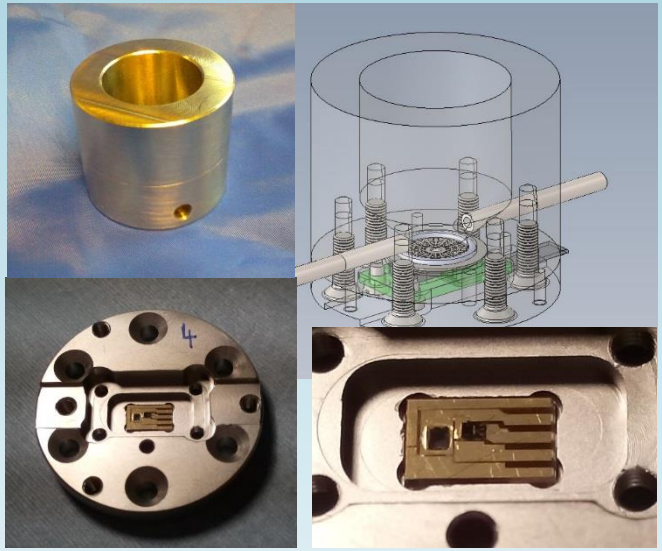


Fig.2: Addition of mannose in a concentration of 100 µM did not influence the sensor signal

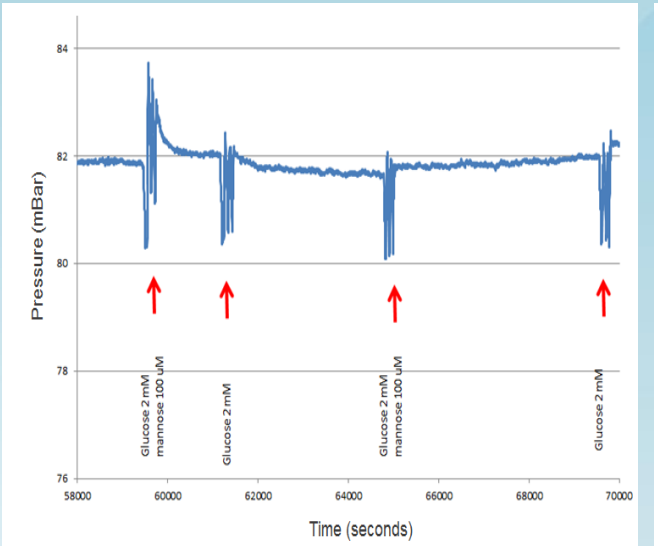
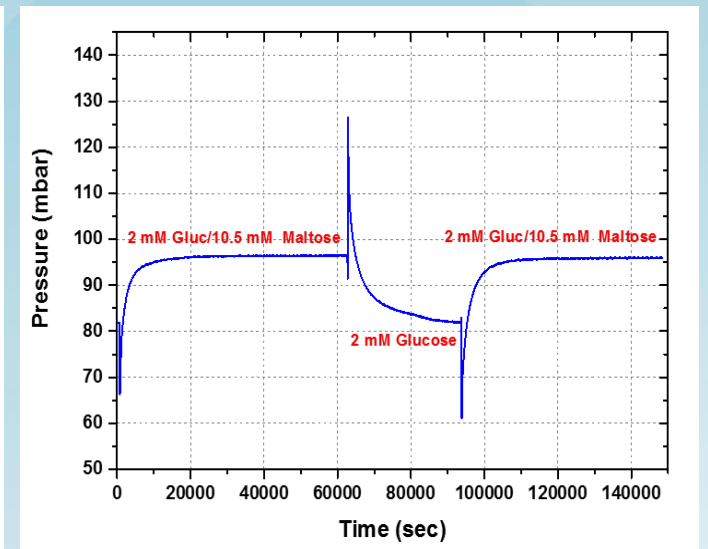


Fig.3: Addition of 10.5 mM maltose had an additive effect to glucose on the sensor signal



Conclusions

The results of our pilot experiments show that the osmotic sensor technology employing the competitive binding of glucose to Concanvalin A vs. dextrane in a core sensor chamber is not influenced by the majority of the tested potentially interfering carbohydrate molecules. The only interfering carbohydrate was maltose, which was tested in highly supra-physiological concentrations. However, the potential impact of maltose on the final product will have to be tested in an appropriately designed clinical experiment in the later development process.

Lifecare AS, Solheimsgatan 16, 5058 Bergen, Norway, www.lifecare.no