Continuous Glucose Monitoring with an Osmotic-Pressure Based Continuous Glucose Sensor – Human and Veterinarian Study Results

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Background

The Sencell sensor (Lifecare AS, Bergen, Norway) uses glucose induced changes in an osmotic pressure chamber for continuous measurement of glucose concentrations in the subcutaneous tissue (see Fig. 1). A close to linear correlation between the raw sensor signal and the glucose concentration and a very long duration of use (of up to 6-12 months or longer) are theoretically to be expected. The final device is planned to have the size of a grain of rice and to be implanted employing wireless energy and data transfer.

Methods

For a first clinical proof of concept study in humans, a wired version of the core sensing technology was embedded into a 4 mm diameter needle and inserted into the abdominal subcutaneous tissue of healthy volunteers and a type 1 patient. The study was conducted to collect first human proof-of-concept performance data for algorithm development during meal experiments and for further device optimization. The raw data was analyzed after one-point calibration and minor trend correction in comparison to the Statstrip blood glucose meter and the Freestyle Libre 2 or Dexcom G7 glucose sensor.

Results

Nine participants (6 female, 3 male, age: 49±11 years) delivered a total of 261 direct comparator data-points (vs. Statstrip) with meal experiments (observation periods: 2 h - 72 h). The osmotic-pressure sensor followed glucose changes similar to the FreeStyle Libre 2 or Dexcom G7 device (Fig. 2) and reached an overall MARD of 9.6% in comparison to StatStrip. In the retrospective analysis with the newly developed algorithm, 90.8 % and 9.2 % of the datapoints were lying in zones A and B of the consensus error grid, respectively. A dog study has been initiated to investigate long-term efficacy.

Fig.1: Mode of action principle of the Sencell device

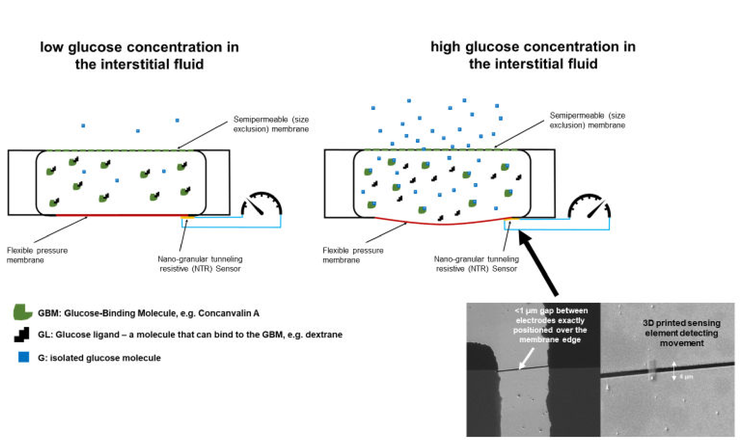

Fig.2: Examples for individual patient results

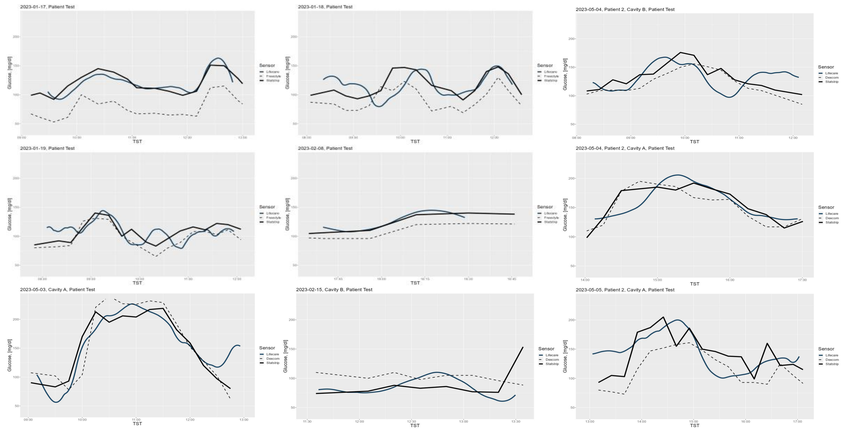

Fig.3: Currently ongoing veterinary longevity study

Conclusions and Next Steps:

After development of a first algorithm to translate sensor signals into a glucose concentration, the osmotic-pressure based continuous glucose sensor was shown to track s.c. glucose concentrations in a comparable manner as commercially available needle sensors. In consequence, a next development step was initiated to integrate suitable electronics and energy sources for wireless data and energy transfer. First prototypes have been manufactured and are currently investigated for their longevity of use in a veterinary study with dogs with a minimum duration of use of 3 months (Fig. 3).