Proof-of-Concept Study Results with a New Osmotic-Pressure Based Continuous Glucose Sensor

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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 blood glucose meter) during repeated meal experiments with observation periods between 2 h and up to 72 days. 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, (Fig 3.).

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

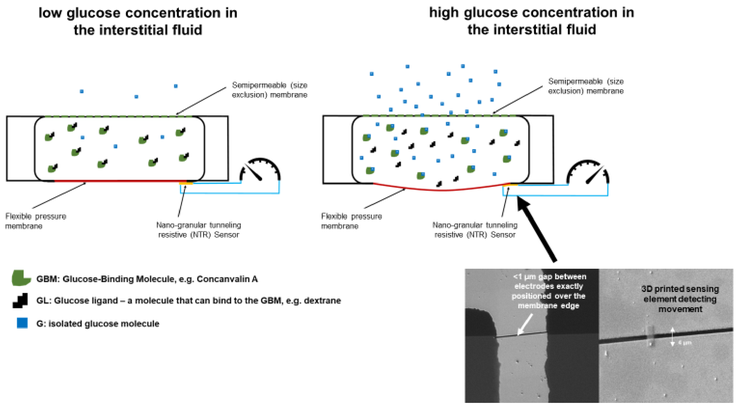


Fig.2: Examples for individual patient results

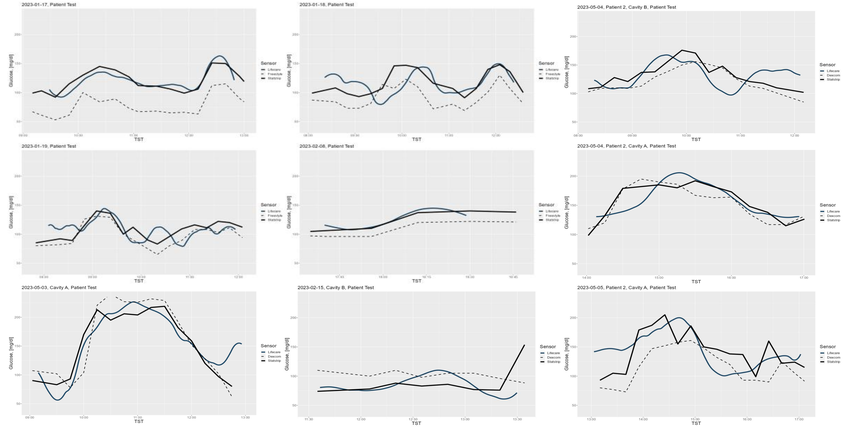
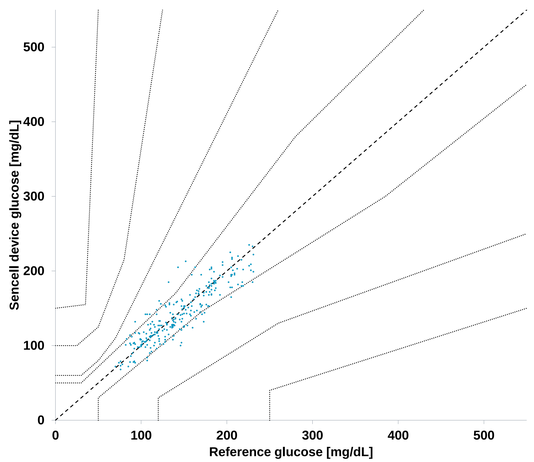


Fig.3: Retrospective consensus error-grid analysis



N = 261

Zone A: 237 (90.8%)
Zone B: 24 (9.2%)
Zone C: 0 (0.0%)
Zone D: 0 (0.0%)
Zone E: 0 (0.0%)

MARD: 9.6%

Conclusion:

In this first human proof-of-concept study, the osmotic-pressure based continuous glucose sensor was shown to track s.c. glucose concentrations in a comparable manner as the Libre 2 or Dexcom G7 needle sensors. The clinical performance characteristics of the first wired prototypes provide an encouraging perspective for the upcoming next development steps.

FORGET DIABETES

Acknowledgements: This project received financial support from the European Union's Horizon 2020 research and innovation program under grant agreement No 951933 (ForgetDiabetes) and also from Lifecare AS, Bergen, Norway

References: Pfützner A, Jensch H, Cardinal C, Srikanthamoorthy G, Riehn E, Thomé N. Laboratory Protocol and Pilot Results for Dynamic Interference Testing of Continuous Glucose Monitoring Sensors. J Diabetes Sci Technol. 2022:19322968221095573. (epub ahead of print) doi: 10.1177/19322968221095573. PMID: 35549522.

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