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ORIGINAL ARTICLE

First Clinical Evaluation of a New Long-Term Subconjunctival Glucose Sensor

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Abstract

Background:

To evaluate the feasibility of an implantable subconjunctival glucose monitoring system (SGMS) for glucose monitoring in humans, we investigated the *in vivo* performance of the sensor in a clinical trial with five patients.

Methods:

The new SGMS consists of an implantable ocular mini implant (OMI) and a hand-held fluorescence photometer. The implantable subconjunctival glucose sensor is composed of a fluorescence resonance energy transfer system based on Concanavalin A chemistry, embedded in a nelfilcon polymer hydrogel disk. Blood glucose changes in humans were induced by oral glucose intake and insulin injections.

Results:

The *in vivo* response of the new SGMS was tested in a first human clinical study with five diabetes patients. The OMI was well tolerated in the eyes of the patients. The SGMS exhibited high correlation coefficients (>0.88) with blood glucose changes and a good stability of the sensor response to glucose for the study period of 2 weeks. Lag times were in the range of 5–10 min. A total of 98% of all data pairs was in the clinical acceptable ranges A and B of the consensus error grid.

Conclusions:

For the first time, the possibility to measure glucose *in vivo* in the subconjunctival interstitial fluid for a period of 2 weeks was demonstrated in a human clinical trial.

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Abbreviations: (BG) blood glucose, ($C_2O_2H_3Na$) sodium acetate, ($CaCl_2$) calcium dichloride, (Con A) Concanavalin A, (K_2CO_3) dipotassium carbonate, (KCl) potassium chloride, (LED) light-emitting diode, ($MgCl_2$) magnesium dichloride, (NaCl) sodium chloride, ($NaHCO_3$) sodium hydrogencarbonate, (Na_2HPO_4) disodium hydrogenphosphate, ($NaSO_4$) sodium sulfate, (OMI) ocular mini implant, (SGMS) subconjunctival glucose monitoring system, (UV) ultraviolet

Keywords: Concanavalin A, diabetes, fluorescence, glucose monitoring, glucose sensor, long-term sensor

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