

## Blood Glucose Self-Monitoring with a Long-Term Subconjunctival Glucose Sensor

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### Abstract

#### Background:

To evaluate the feasibility of an implantable subconjunctival glucose monitoring system (SGMS) for long-term glucose monitoring, we investigated the *in vivo* performance of the system.

#### Method:

The SGMS consists of an implantable ocular mini implant (OMI) and a handheld fluorescence photometer. A clinical study was performed on 47 diabetes patients split into two cohorts. Two different types of OMI were used, with and without a biocompatible surface coating. Duration of the study was 1 year. Correlation between capillary blood glucose and SGMS-derived interstitial fluid glucose was investigated during the first 6 months of the study.

#### Results:

Both OMI types were tolerated well in the eyes of the patients. At the beginning of the study, the SGMS of both cohorts revealed a high accuracy with mean absolute relative difference (MARD) values of 7–12%. The performance of the uncoated OMIs deteriorated within 3 months of wearing time, exhibiting a MARD value of 20%. The performance of the surface-coated OMIs was preserved longer. Glucose correlation measurement with reasonable results (MARD of 14%) could be performed for up to 6 months of wear.

#### Conclusions:

The biocompatible surface coating on the OMIs enabled a longer duration of action of up to 6 months compared with 3 months for uncoated implants in a clinical trial.

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**Abbreviations:** (BG) blood glucose, (Con A) concanavalin A, (FBR) foreign body response, (MARD) mean absolute relative difference, (OCT) optical coherence tomography, (OMI) ocular mini implant, (SGMS) subconjunctival glucose monitoring system

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

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