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ORIGINAL ARTICLE

Continuous Glucose Monitoring in the Subcutaneous Tissue over a 14-Day Sensor Wear Period

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Abstract

Background:

Glucose monitoring systems using subcutaneously inserted sensors are currently labeled for up to 7 days of wear. In this study, we evaluated the feasibility of a 14-day wear duration using a modified version of the sensor found in the Freestyle Navigator™ continuous glucose monitoring system.

Methods:

Sixty-two subjects with diabetes were enrolled in the study. One sensor per subject was inserted on the arm for a wear time of 14 days. Two different calibration algorithms were applied retrospectively, one that uses periodic sensor recalibrations and one without recalibrations. Sensor *in vivo* stability was determined by least square regression analysis using capillary blood glucose. Mean absolute relative difference (MARD) and mean relative difference were calculated. Consensus error grid analysis was performed by day and over the 14-day wear period to evaluate accuracy of both systems. The sensor insertion sites were inspected after sensor removal for skin reactions.

Results:

Sensor data from 55 subjects were used for the analysis. The accuracy metrics for the system with recalibration were calculated to MARD = 13.9% and 84.0% in zone A (error grid analysis). The system without recalibration performed significantly better, resulting in MARD of 12.2% and 88.0% in zone A ($p < .0001$). The maximum change of *in vivo* sensor sensitivity over the 14-day wear period was 2% per day. Two subjects reported pain during the first 5 days of sensor wear, and 1 subject reported itching at the sensor site. No further skin reactions were noticed.

Conclusions:

The study shows that a 14-day sensor wear period is achievable. Moreover, sensors using "wired enzyme" technology showed excellent *in vivo* stability, with no significant sensitivity loss over the 14-day wear period.

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Abbreviations: (BG) blood glucose, (MARD) mean absolute relative difference, (MRD) mean relative difference

Keywords: diabetes, glucose monitoring, sensor wear duration, subcutaneous

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