

First Clinical Evaluation of a New Percutaneous Optical Fiber Glucose Sensor for Continuous Glucose Monitoring in Diabetes

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Abstract

Background:

This article describes a new fiber-coupled, percutaneous fluorescent continuous glucose monitoring (CGM) system that has shown 14 days of functionality in a human clinical trial.

Method:

The new optical CGM system (FiberSense) consists of a transdermal polymer optical fiber containing a biochemical glucose sensor and a small fluorescence photometer optically coupled to the fiber. The glucose-sensitive optical fiber was implanted in abdominal and upper-arm subcutaneous tissue of six diabetes patients and remained there for up to 14 days. The performance of the system was monitored during six visits to the study center during the trial. Blood glucose changes were induced by oral carbohydrate intake and insulin injections, and capillary blood glucose samples were obtained from the finger tip. The data were analyzed using linear regression and the consensus error grid analysis.

Results:

The FiberSense worn at the upper arm exhibited excellent results during 14 wearing days, with an overall mean absolute relative difference (MARD) of 8.3% and 94.6% of the data in zone A of the consensus error grid. At the abdominal application site, FiberSense resulted in a MARD of 11.4 %, with 93.8% of the data in zone A.

Conclusions:

The FiberSense CGM system provided consistent, reliable measurements of subcutaneous glucose levels in human clinical trial patients with diabetes for up to 14 days.

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Abbreviations: (ARD) absolute relative difference, (CGM) continuous glucose monitoring, (Con A) concanavalin A, (FRET) fluorescence resonance energy transfer, (MARD) mean absolute relative difference

Keywords: concanavalin A, continuous glucose monitoring, diabetes, fluorescence, glucose sensor

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