

Continuous Noninvasive Glucose Monitoring Technology Based on "Occlusion Spectroscopy"

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Abstract

Background:

A truly noninvasive glucose-sensing device could revolutionize diabetes treatment by leading to improved compliance with recommended glucose levels, thus reducing the long-term complications and cost of diabetes. Herein, we present the technology and evaluate the efficacy of a truly noninvasive device for continuous blood glucose monitoring, the NBM (OrSense Ltd.).

Methods:

In vitro analysis was used to validate the technology and algorithms. A clinical study was performed to quantify the *in vivo* performance of the NBM device. A total of 23 patients with type 1 ($n = 12$) and type 2 ($n = 11$) diabetes were enrolled in the clinical study and participated in 111 sessions. Accuracy was assessed by comparing NBM data with paired self-monitoring of blood glucose meter readings.

Results:

In vitro experiments showed a strong correlation between calculated and actual glucose concentrations. The clinical trial produced a total of 1690 paired glucose values (NBM vs reference). In the paired data set, the reference glucose range was 40–496 mg/dl. No systematic bias was found at any of the glucose levels examined (70, 100, 150, and 200 mg/dl). The mean relative absolute difference was 17.2%, and a Clarke error grid analysis showed that 95.5% of the measurements fall within the clinically acceptable A&B regions (zone A, 69.7%; and zone B, 25.7%).

Conclusions:

This study indicates the potential use of OrSense's NBM device as a noninvasive sensor for continuous blood glucose evaluation. The device was safe and well tolerated.

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Abbreviations: (CGM) continuous glucose monitoring, (CSID) continuous subcutaneous insulin delivery, (EGA) error grid analysis, (MDI) multiple daily injections, (NBM) noninvasive blood monitor, (RAD) relative absolute difference, (RBC) red blood cells, (RNIR) red/near infrared, (SMBG) self-monitoring of blood glucose

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