Accuracy Assessment for a Long Term Implantable CGM System with One per Day Calibration in the PRECISE II Study

Mark P Christiansen[1], Leslie J Klaff[2], Ron Brazg[2], Anna R Chang[3], Carol J Levy[4], David Lam[4], Douglas S Denham[5], George Atiee[6], Bruce W Bode[7], Xiaoxiao Chen[8], Timothy S Bailey[9]

[1]Diablo Clinical Research, Inc.; [2]Rainier Clinical Research Center, Inc.; [3]John Muir Physician Network Clinical Research Center; [4]Mount Sinai Diabetes Center; [5]Clinical Trials of Texas, Inc.; [6]Worldwide Clinical Trials; [7]Atlanta Diabetes Associates; [8]Senseonics Incorporated; [9]AMCR Institute, Inc.

Introduction

The PRECISE II pivotal trial was a blinded, single-arm, 90 day prospective multi-center U.S. study of the fully implantable sensor based Eversense CGM System. Subjects used the system per the manufacturer's instruction by performing two per day calibration. The impact of one per day calibration on sensor accuracy was evaluated with the 82 subjects in the Primary Effectiveness Analysis Population.

Eversense CGM System

The Eversense CGM System utilizes a long-term implantable glucose sensor powered by an external, wearable smart transmitter through a wireless inductive link. The sensor is fluorescence-based and developed for subcutaneous insertion in the upper arm. The smart transmitter wirelessly communicates with the mobile app to display real-time glucose readings, trends, and alerts.

Sensor

- Sensor lasts up to 90 days
- Five minute insertion procedure
- No weekly sensor insertion
- No open wound

Smart Transmitter

- Removable and rechargeable
- On-body vibration alerts
- Gentle-on-skin adhesive
- Wireless, secure, encrypted BLE communication with smartphone

Mobile App

- View real-time glucose readings
- Use your own smartphone - no extra device to carry
- iOS and Android compatible
- Customizable alert settings and reports

Study Details

Study Design

Population	82 adults
Diabetes Type	55 (67%) T1DM and 27 T2DM
Gender	48 (59%) males and 34 females
Age	Mean 44.9 years, SD 16.5 years
Insulin Pump Use	39 (48%)

Methods

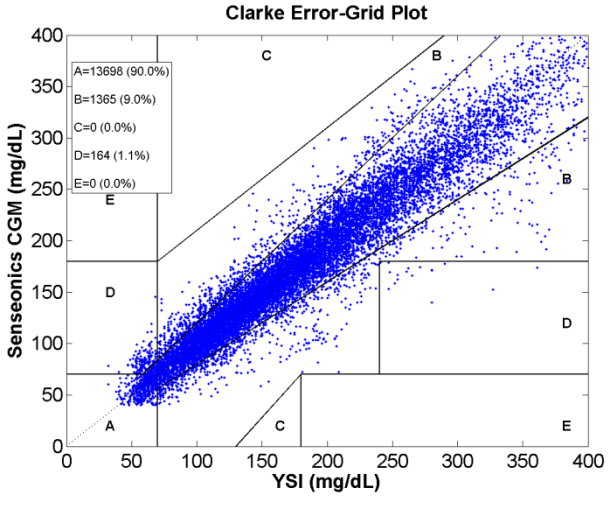
Subjects were enrolled at 8 clinical sites and implanted with the CGM. Subjects were asked to wear the transmitter over the sensor at all times and follow a calibration procedure twice daily. Subjects used the system at home and in-clinic during 4 in-clinic visits (8h, 14h & 15h) where venous reference glucose measurements were taken (YSI 2300 STAT PLUS) to compare with the glucose measurements from the Eversense CGM. For the analysis of one per day calibration, only one of the two calibrations was used to assess the calibration stability throughout 24 hrs. When possible, the SMBG measurement taken the night before a next day in-clinic visit was used to enable accuracy assessment.

Results

Calibration Regimen	Mean Absolute Relative Difference (%)	Percent of System Readings within 20/20% YSI	Percent of System Readings within 30/30% YSI	Percent of System Readings within 40/40% YSI
Two per Day Calibration	8.8% (SD 8.6%)	93.3%	98.1%	99.4%
One per Day Calibration	**9.5% (SD 9.3%)**	**90.5%**	**97.1%**	**99.0%**

One per Day Calibration

Clarke Error-Grid Plot



Calibration Stability

Time from Calibration	Percent within 20/20% Reference	Percent within 30/30% Reference	Percent within 40/40% Reference
0-2 hours	90.0%	96.6%	99.0%
2-4 hours	91.9%	98.0%	99.7%
4-6 hours	91.5%	98.2%	99.5%
6-8 hours	93.9%	98.8%	99.5%
8-10 hours	92.5%	97.6%	99.4%
10-12 hours	91.7%	95.3%	98.0%
12-14 hours	89.8%	96.8%	98.7%
14-16 hours	90.2%	95.7%	97.9%
16-18 hours	88.2%	96.8%	99.2%
18-20 hours	88.1%	97.4%	99.1%
20-22 hours	89.2%	97.6%	98.6%
22-24 hours	89.7%	97.1%	99.4%

Conclusions

One per day calibration maintained system accuracy throughout the 90 day period for the Eversense CGM system, which is equal to or better than the current two per day calibration CGM systems. The Eversense CGM system provides the benefit of a long term implantable that is accurate while having the potential to lessen the burden of daily diabetes management.

Contact Information:
Mark P Christiansen Mchristiansen@Diabloclinical.com
Xiaoxiao (Oliver) Chen oliver.chen@senseonics.com