

Usability Feedback of the 90-Day Implantable Glucose Sensor in the PRECISE Study

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INTRODUCTION

A new CGM system consisting of a fluorescence-based glucose sensor, smart transmitter and smartphone app has been developed. Unlike existing CGM systems, this new system utilizes a fully implantable sensor that can provide continuous glucose readings for up to 90 days before replacing. The insertion procedure takes approximately 5 minutes to perform in a clinic office setting. Besides demonstrating safety and efficacy of the CGM system, the PRECISE Study (A Prospective, Multicenter Evaluation of the Accuracy of a Novel Continuous Implanted Glucose Sensor) also gathered direct feedback from participants on use of the long-term sensor.



The Eversense[®] Continuous Glucose Monitoring System (Senseonics, Inc., Maryland USA) consists of an implanted glucose sensor, body-worn smart transmitter and smartphone app. The small cylindrical sensor is inserted subcutaneously in the upper arm to provide 90 days of continuous glucose measurements. The smart transmitter wirelessly communicates with the smartphone app to display real-time glucose readings, trends, and alarms to the user.



IMPLANTABLE CGM SYSTEM

STUDY DETAILS AND RESULTS

Demographics

Participants surveyed	50 (UK = 10, Germany = 40)
Diabetes type	T1 = 45, T2 = 5
Age	20-68 years
Insulin therapy	Pump = 25; MDI = 25
CGM use	New = 28; Experienced = 22

Methods

The PRECISE study duration was for continuous 180 days with the first 90 days used for interim analysis.

A study-specific quantitative and qualitative psychosocial and attitudinal questionnaire was administered to participants approximately 90 days after sensor insertion.

Results

Level of Agreement to Statement	Pump	MDI
The CGM system was easy to use	100%	100%
The CGM system was convenient to use	100%	92%
The app was easy to use	100%	100%
The calibration process was easy	83%	88%
The transmitter was comfortable to wear	71%	88%
The transmitter was comfortable to wear during sleep	67%	83%
I was able to wear the transmitter in my everyday setting	92%	88%
I don't feel the sensor during wear	83%	92%
The sensor insertion was painless	75%	96%
I did not experience pain or discomfort when using the sensor	83%	100%
The alarm warned me of low/high glucose	83%	96%
The alarm helped me avoid low/high glucose	83%	88%
The vibratory alarms from the transmitter provided reassurance	79%	92%
I was able to feel the vibratory alarms on the transmitter	88%	92%
I was able to hear the alarms from the iPod at night	58%	63%
The transmitter adhesive was comfortable to use and wear	63%	79%
The transmitter adhesive did not cause skin irritation	67%	83%
I would want to be inserted with a sensor again	75%	92%
The CGM helped me gain more confidence about my diabetes	79%	92%
Using the system helped minimize the burden of diabetes in my life	88%	92%
I'd like to use the system everyday to help me manage my diabetes more effectively	79%	92%

Percent on pump or MDI who agree, somewhat agree, or strongly agree with the statement.

- Overall participants scored the CGM system very highly on ease of use, convenience, and comfort.
- Participants were able to wear the transmitter in everyday setting through 90 days of wear; most would want to be inserted again.

Likeability of Product Features	Pump	MDI
90-day sensor life	6.6	6.2
Ability to remove and replace transmitter	8.2	8.9
Alarms/alerts on iPod	7.8	8.0
Alarms/alerts on transmitter	7.7	8.0
Ability of display glucose readings on iPod	9.3	9.9
Hypo/hyperglycemia alarm detection	8.3	9.5
Projected hypo/hyperglycemia alarm detection	7.7	9.0
Implanted sensor	7.5	8.9

Mean likeability score (1= don't like as much, 10= like very much) of various product features.

- Both groups scored mobile device display very high on likeability scale along with alarm detection and ability to remove and replace the transmitter.

"It was very interesting to participate in the trial - it is something for the future; adhesive patch is superb." – Subject 05022

"A good feeling to directly see your glucose levels. The handling is very easy, it enormously simplifies the daily routine to coordinate your diabetes." – Subject 06015

Post study HbA1c levels across all subjects reduced from 7.51 to 7.05 (p<.0001)

Variable	HbA1c (%) Mean (SD)	HbA1c (%) 95% CI (Lower - Upper)	p-value
Day 0	7.5 (1.1)	(7.2 - 7.8)	--
Day 90	7.0 (0.9)	(6.8 - 7.3)	<.0001

Conclusion

The implantable CGM system was acceptable to participants and using the system was associated with gaining more confidence about, and minimizing burden of, their diabetes. Study data showed significant reduction in HbA1c levels within a short period of time. There are nuanced differences in scores between participants on pump therapy vs MDIs that may be due to level of experience that would be important to explore further. The results from this study demonstrate a strong promise for this new and first ever implantable CGM system.

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