ORIGINAL ARTICLE

Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator

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Abstract

Background: This study assessed the accuracy of a factory-calibrated 10-day real-time continuous glucose monitoring (CGM) system (G6), which includes an automated sensor applicator.

Methods: Seventy-six participants with insulin-treated diabetes were enrolled at four U.S. sites as part of a larger study of G6 system performance. In-clinic visits for frequent comparative blood glucose measurements using a reference instrument (YSI) were conducted on days 1, 4–5, 7, and/or 10 of system use. Accuracy evaluation included the proportion of CGM values that were within $\pm 20\%$ of YSI reference value for glucose levels >100 mg/dL and ± 20 mg/dL for YSI glucose levels ≤ 100 mg/dL ($\%20/20$), the analogous $\%15/15$ and $\%30/30$, and the mean absolute relative difference (MARD) between temporally matched CGM and YSI values. Participants calibrated the systems once daily. Raw sensor data were reprocessed using assigned sensor codes and a factory-calibration algorithm.

Results: Reprocessed data from 62 participants (25 adults and 37 children and adolescents of ages 6–17 years; 3532 YSI–CGM pairs) were analyzed. The G6 system's overall $\%20/20$ was 93.9% (adults, 92.5%; children and adolescents, 96.2%), its $\%15/15$ was 83.3% (adults, 78.3%; children and adolescents, 91.1%), and its MARD was 9.0% (adults, 9.8%; children and adolescents, 7.7%). Overall day-1 $\%20/20$ accuracy was 92.2%, $\%15/15$ was 81.5%, and MARD was 9.3%. Accuracy was maintained across 10 days of use and various glucose concentration ranges in both adults and children and adolescents.

Conclusions: The G6 system utilizing an automated sensor applicator provides accurate glucose readings in adults and children and adolescents throughout the 10-day sensor life.

Keywords: Glucose sensor performance, Clinical accuracy, MARD, Continuous glucose monitoring, Advanced algorithm, Factory-calibrated.

Introduction

CLINICAL OUTCOME TRIALS evaluating continuous glucose monitoring (CGM) systems have shown that CGM use is associated with improved glycemic control and reduction in hypoglycemia in patients with type 1 diabetes (T1D) and insulin-treated type 2 diabetes (T2D) across age, gender, and education levels.^{1–6} Moreover, a small pilot study showed improvement in glycemic control when CGM was initiated as early as 6 months after the diagnosis of T1D.⁷

Despite the benefits of CGM, $<30\%$ of patients with T1D⁸ and a minority of patients with T2D in the United States use CGM. There are many explanations for this low penetrance

besides cost and inadequate insurance coverage, including device deficiencies related to human factors and usability.⁹ Early devices faced challenges of CGM inaccuracy, painful sensor insertions, and the need for frequent calibrations, which have contributed to the reduced adoption and durability of CGM use.^{9,10} Optimization of CGM human factors and performance characteristics is, therefore, critical for increased uptake and sustained use of the technology.

A sixth-generation factory-calibrated real-time CGM (rtCGM) system (G6) was developed to improve upon the performance and usability of currently marketed rtCGM systems and to reduce barriers to CGM adoption. In addition to extending each sensor's functional life and eliminating the

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requirement for user calibrations, the G6 system includes a sensor with a permselective membrane to limit the interference effect of acetaminophen¹¹ and an automated sensor applicator¹² to simplify insertion.

Three related studies were performed to assess G6 system performance. A large pivotal study assessed the accuracy of the system when sensors were deployed with a manual applicator (NCT02880267). An ancillary study assessed system performance after acetaminophen dosing (NCT03087877).¹¹ The study reported here examined the system accuracy and user preference using the automated sensor applicator. This system, utilizing the automated sensor applicator, received clearance by the FDA in March, 2018.¹³

Methods

Study design

The G6 rtCGM system (Dexcom, Inc., San Diego, CA) was evaluated in a prospective multicenter single-arm study involving both adults (ages 18 and older) and children and adolescents (ages 6–17) with T1D or insulin-requiring T2D at four U.S. sites. Inclusion criteria comprised use of intensive insulin therapy (either multiple daily injections or insulin pump therapy) and willingness to perform at least seven self-monitored blood glucose (SMBG) tests per day during home use with the study-assigned blood glucose meter (Contour NEXT ONE Blood Glucose Meter; Ascensia Diabetes Care, Parsippany, NJ) for once-daily calibration, diabetes management, alert verification, and comparative purposes. Exclusion criteria comprised the presence of extensive skin abnormalities at the sensor insertion site, pregnancy, or hematocrit values outside the normal range.

Study procedures and data collection

Participants received training on the system using prepared training materials; all sensor insertions were performed at the clinic by participants and/or guardians using the automated sensor applicator. The applicator measures 65.7 × 115.8 × 49.8 mm (H × W × L) and features a single button that deploys the sensor and retracts the introducer needle when pressed. All participants used the G6 system for one 10-day wear period (up to 240 h). Adult participants wore the sensor on the abdomen. Children and adolescents could choose to wear the sensor on the abdomen or upper buttocks. Sensors that failed within the first 12 h after insertion were replaced.

Participants returned to the clinic for one or two sessions of varying duration on days 1, 4–5, 7, and/or 10 of system use. Adults returned for two 12-h clinic sessions, participants of ages 13–17 years returned for one 12-h clinic session, and participants of ages 6–12 years returned for one 6-h clinic session for comparison of CGM readings with venous glucose concentrations using a laboratory reference method (YSI). Participants had venous blood drawn once every 15 ± 5 min for the duration of each clinic session for reference glucose measurement. A heating pad was applied around the intravenous site to “arterialize” the venous sample, allowing a closer match between venous and capillary glucose concentrations. The CGM data were masked to participants and clinic staff for the duration of the clinic session. SMBG measurements were obtained as needed for diabetes man-

agement. No glucose manipulations were performed in this study. The study was reviewed by the FDA through the Investigational Device Exemption process and registered at ClinicalTrials.gov (NCT02880267).

Methods of data analysis

Raw sensor data were reprocessed using assigned sensor codes and a factory-calibration algorithm. The sensor code accounts for intersensor variation and was developed for each sensor individually during manufacturing based on the unique performance characteristics of each sensor.

Each YSI value was paired with the CGM value that immediately followed (within 5 min); these matched pairs formed the analysis data set. CGM–YSI matched pairs within the CGM reportable range of 40–400 mg/dL were evaluated. The CGM–YSI matched pair data available from clinic-session participants were included in the analysis; no matched pair data were excluded.

Accuracy metrics included the proportion of the CGM system values that were within ±20% of paired YSI values >100 mg/dL or ±20 mg/dL of YSI values ≤100 mg/dL (hereafter referred to as %20/20), as well the analogous %15/15 and %30/30. The overall mean absolute relative difference (MARD) was determined as the average relative difference between the CGM and YSI values in each of the paired points and is expressed as a percentage. The MARD was also assessed for each sensor and plotted as a histogram. The mean absolute difference (in mg/dL) was calculated for YSI values <70 mg/dL. Clarke error grid (CEG) analysis and surveillance error grid analysis¹⁴ were used to quantify the clinical risks resulting from CGM inaccuracies compared with the reference YSI measurement. The number and percentage of points in various risk zones of the surveillance error grid were determined with software from the Diabetes Technology Society as described.¹⁵

To estimate time lag, CGM measurements were interpolated to provide values at 1-min intervals. Each of the measured and interpolated CGM values was associated with a delay time between it and the most recently preceding YSI value. The absolute relative difference (ARD) between each CGM value and its associated YSI value was calculated. The delay time associated with the CGM value having the lowest ARD was taken as the time lag for that subject. Summary statistics for subjects' delay times were calculated.

System safety was characterized descriptively by device-related adverse events (AEs). Skin irritation resulting from CGM sensor use was tabulated after each sensor removal and categorized by needle insertion site or adhesive area. Any edema and/or erythema observed at the sensor insertion site or adhesive area were evaluated according to the Draize's scale.¹⁶ All enrolled participants were asked to complete questionnaires on the comfort and ease of use of the G6 system's automated sensor applicator. All analyses were performed using SAS[®] software, version 9.3 (SAS Institute, Inc., Cary, NC).

Results

Study population

Seventy-six participants enrolled in the study, 96% had T1D and 4% had T2D, all with T2D were adults, 61% were

TABLE 1. OVERALL CONTINUOUS GLUCOSE MONITORING PERFORMANCE, BY SUBJECT AGE GROUP

Population	Participants (n)	Matched pairs (n)	%15/15 (%; 95% LB)	%20/20 (%; 95% LB)	%30/30 (%; 95% LB)	MARD (%; 95% UB)
Overall	62	3532	83.3 (77.8)	93.9 (90.5)	99.4 (99.0)	9.0 (10.1)
Ages 18+ years	25	2145	78.3 (69.7)	92.5 (87.3)	99.3 (98.7)	9.8 (11.5)
Ages 6–17 years	37	1387	91.1 (86.8)	96.2 (92.7)	99.6 (99.2)	7.7 (8.8)

95% LB, lower bound of the one-sided 95% CI; 95% UB, upper bound of the one-sided 95% CI.
CI, confidence interval; MARD, mean absolute relative difference.

female. The mean age (standard deviation [SD]) of the study sample was 25.5 years (18.6). The majority (89%) of participants identified themselves as non-Hispanic white. Most adults (59%) were overweight or obese (body mass index [BMI] ≥ 25.0 kg/m²), whereas 41% had a normal BMI (18.5–24.9 kg/m²). Most children and adolescents (65.3%) had a normal BMI (BMI 5th–<85th percentile for age and gender), 26.5% were overweight (≥ 85 th BMI percentile), and the remainder (8.2%) were underweight (<5th BMI percentile). The mean (SD) A1C was 8.2% (2.0%) for adults and 8.1% (1.1%) for children and adolescents; mean (SD) duration of insulin use was 26.3 years (16.1) for adults and 5.9 years (3.9) for children and adolescents. All participants were using intensive insulin therapy; more children and adolescents than adults were using pump therapy (84% vs. 52%, respectively).

Fourteen participants were excluded from the CGM–YSI accuracy analysis: two withdrew from the study voluntarily after sensor insertion, six had a sensor or adhesive failure before the clinic session, and six inadvertently ended their study participation before a clinic session (accidental sensor dislodgement or unintentional session termination).

Therefore, 62 participants were analyzed for accuracy analysis. However, all 76 participants answered the questionnaire about comfort and ease of use of automated sensor applicator. Three participants experienced technical difficulties within 12 h of sensor insertion and had their sensors replaced.

CGM performance with reprocessed factory calibration

Overall MARD. There were 3532 CGM readings that had a temporally matched YSI reading and were used for analysis. The overall MARD between CGM and YSI values was 9.0% for all participants, 9.8% for adults, and 7.7% for children and adolescents (Table 1). Table 1 also gives the upper boundaries of the 95% confidence intervals [CIs] for these estimates.

Individual sensor MARD. The performance of individual sensors is shown in Figure 1. The mean per-sensor MARD was 8%, with an SD of 5%. The majority of sensors (75%)

FIG. 1. Distribution of per-sensor MARD (%): histogram and log-normal density curve. MARD, mean absolute relative difference.

TABLE 2. CONTINUOUS GLUCOSE MONITORING PERFORMANCE ACROSS GLUCOSE RANGES

CGM glucose (mg/dL)	Matched pairs (n)	%15/15 (%)	%20/20 (%)	%30/30 (%)	MAD (mg/dL)	MARD (%)
<70	185	80.0	90.8	96.8	9.5	NA
70–180	2718	83.4	94.3	99.5	NA	8.8
181–250	551	82.6	92.9	99.6	NA	8.9
>250	78	92.3	96.2	100.0	NA	6.3

CGM, continuous glucose monitoring; MAD, mean absolute difference; NA, non-applicable.

had MARD of 10% or less, 50% of sensors had MARD of 7% or less, and <5% of sensors had MARDs >18%.

Percentage accuracy overall, across glucose ranges, and across days of wear. The G6 system showed an overall %20/20 accuracy of 93.9%. The %20/20 accuracy was 92.5% for adults and 96.2% for children and adolescents (Table 1). The analogous %15/15 and %30/30 accuracies along with the lower boundaries of the 95% CIs are also given in Table 1. Accuracy in children adolescents was similar whether they wore the sensor on their abdomen (%20/20=97.6%) or on their upper buttocks (%20/20=94.2%).

The %20/20 of the G6 system was 90.8% for CGM values <70 mg/dL, 94.3% for CGM values 70–180 mg/dL, 92.9% for CGM values 181–250 mg/dL, and 96.2% for CGM values >250 mg/dL (Table 2). The analogous %15/15 and %30/30 accuracies are also given in Table 2.

The G6 system's accuracy across days of wear was evaluated using percentage accuracy (Table 3). The %20/20 and %15/15 on the first day of wear were 92.2% and 81.5%, respectively. Accuracy remained consistent throughout the 10-day wear period: the %20/20 and %15/15 on day 10 were 92.5% and 82.4%, respectively.

Clarke error grid and surveillance error grid analysis. CEG analysis on data from adults showed that 91.9% of points fell in the clinically accurate A zone, whereas only one point (0.05%) fell in the higher risk C, D, or E zones (Fig. 2A). For children and adolescents, 95.7% of points fell in the clinically accurate A zone, whereas only three points (0.2%) fell in the C, D, or E zones (Fig. 2B). Surveillance Error Grid analysis of the combined adult and pediatric data showed that 3176 points (89.9%) fell in the “No Risk” zone, 332 points (9.4%) were in the “Slight, Lower” risk zone, 23 points were in the “Slight, Higher” risk zone, and only 1 point was in the “Moderate, Lower” risk zone.

TABLE 3. CONTINUOUS GLUCOSE MONITORING PERFORMANCE ACROSS DAYS OF SENSOR WEAR

Clinic session day	Matched pairs (n)	%15/15 (%)	%20/20 (%)	%30/30 (%)	MARD (%)
Day 1	719	81.5	92.2	99.0	9.3
Day 2	664	84.0	92.3	100.0	8.4
Days 4–5	880	85.8	95.5	99.2	9.4
Day 7	588	82.1	97.3	99.8	8.7
Day 10	681	82.4	92.5	99.1	9.0

Lag. The overall time lag was 4 min, whether calculated using %20/20 or MARD. The mean $\pm$ SD time lag of the 62 individually analyzed sensors was 3.7 ± 3.1 min, and the median (IQR) was 4 min (1–6). Fourteen (23%) of the sensors had estimated time lags of <1 min.

Patient-reported outcomes and safety

Sixty-four of 76 participants (84%) reported “no pain” or “mild pain” with the autoapplicator insertion process. All 76 participants rated the autoapplicator as either “somewhat” or

FIG. 2. Clarke error grid analysis for (A) adults and (B) children. Green, zone A; yellow, zone B; red, zones C, D, or E.

“very” easy to use, and all rated the instructions for use as either “somewhat” or “very” easy to understand.

Two nonserious AEs were reported. One was potentially device related: a child (6 years old) reported pain from the autoapplicator. The second occurred in an adult who became nauseated and had emesis during the clinic session (thought by the investigator to be a vasovagal reaction); however, it was not related to the device. Qualitative assessment (Draize’s scale) of 79 sensor insertion sites and adhesive areas revealed 8 (10.1%) instances of well-defined erythema (5 of which were at the sensor insertion site and 3 of which were at the adhesive site) and 1 (1.3%) instance of well-defined edema at the sensor insertion site. No infections occurred at the sensor insertion site and no significant medical adhesive-related skin injuries occurred.

Discussion

This study demonstrated that the G6 system, utilizing an automated sensor applicator designed to produce more consistent sensor insertion, has consistent accuracy in adults and children and adolescents, across various glucose ranges, at different wear sites, and across days of wear. All participants reported that the new sensor applicator was easy to use and nearly all reported that sensor deployment using this applicator was painless or nearly painless.

The design and performance of rtCGM systems have improved markedly over the past decade.¹⁷ More accurate glucose measurements, reliable alarms, flexibility of display devices, and increased sensor wear time have been fundamental to regulatory approval and increased patient adoption. Although more comprehensive insurance coverage will likely have a significant effect on uptake of CGM technologies, other improvements in factors affecting CGM usability by patients, such as automation of insertion and calibration-free use, will likely promote device uptake as well as consistency and durability of use. The G6 rtCGM system was developed to improve upon the performance and usability of currently marketed rtCGM systems by increasing wear time to 10 days, eliminating acetaminophen interference, reducing the complexity of sensor insertion, and eliminating the need for daily calibrations. In the Diamond study, a CGM system with twice-daily calibrations and a 7-day expected sensor lifespan was found to be cost-effective at a willingness-to-pay threshold of \$100,000 per quality-adjusted life year.¹⁸ Elimination of the calibration requirement and a 10-day expected sensor lifespan suggest favorable implications for the cost-effectiveness of the G6 system.

The benefits of rtCGM use compared with SMBG testing have been well established. Numerous studies have established that rtCGM use is associated with reduced A1C, reduced hyperglycemia and hypoglycemia, and improved quality of life compared with SMBG testing.^{1–5,19,20} Despite these benefits, a minority of people with T1D and few people with T2D are currently using CGM. The G6 system described here incorporates multiple improvements over past rtCGM systems. It eliminates the need to calibrate, is not susceptible to acetaminophen interference,¹¹ and extends wear time to 10 days. Moreover, the automatic sensor applicator simplifies sensor insertion, affords nearly painless sensor insertion, and provides consistent sensor deployment that may contribute to improved day-1 performance.

This was an FDA-regulated study, required for premarket submission, which evaluated the accuracy, safety, and ease of use of the new G6 system. Strengths of the study include the large number of enrolled patients and analyzed data points and its inclusion of children, adolescents, and adults. The study was not designed to assess sustained use of the system or clinical endpoints such as change in A1C or incidence of hypoglycemia.

In conclusion, the 10-day G6 rtCGM system eliminates the need for fingersticks, either for calibration or diabetes management, decreasing patient burden while maintaining a high level of performance. The accuracy and usability demonstrated here should provide users with high device confidence and facilitate persistent use. Patient adherence to CGM is required for glycemic benefit.^{1,21,22}

Participating Clinical Sites

The number of randomized participants is noted in parentheses preceded by the site location and site name. Personnel listed are study investigators. AMCR Institute, Inc. (Escondido, CA) (18), Timothy Bailey; Atlanta Diabetes Associates (Atlanta, GA) (18), Bruce Bode; Joslin Diabetes Center (Boston, MA) (21), Lori Laffel; Diablo Clinical Research Center (Walnut Creek, CA) (19), Mark Christiansen.

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