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ORIGINAL ARTICLE

Performance of the DIDGET Blood Glucose Monitoring System in Children, Teens, and Young Adults

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Abstract

Background:

This study evaluated the performance of the DIDGET® blood glucose monitoring system (BGMS) in the hands of its intended users: children, teens, and young adults with diabetes.

Methods:

Finger stick capillary blood samples were tested in duplicate by subjects (with parent/guardian assistance, if needed) and health care professionals using the DIDGET BGMS, and results were compared with those obtained using a Yellow Springs Instruments (YSI) glucose analyzer. Modified venous blood samples (i.e., glycolyzed or spiked with glucose) were used to analyze meter performance under extreme glucose concentrations. Accuracy was assessed using International Organization for Standardization (ISO) 15197:2003 guidelines (i.e., 95% of meter results within ±15 mg/dl or ±20% of reference values).

Results:

A total of 123 subjects aged 4 to 24 years with type 1 or type 2 diabetes were enrolled. The DIDGET meter achieved accuracy according to ISO 15197:2003 criteria: >97% of meter results were within ±15 mg/dl or ±20% of reference values. Regression analyses showed a high degree of correlation between meter and YSI results: coefficient of determination (R^2) = 98.2% for all samples combined and 97.2% for capillary samples only. Clinical accuracy for combined samples was demonstrated by Parkes consensus error grid analyses; 100% of meter results were in zone A (98.5%) or zone B (1.5%). There was no difference in performance or accuracy across age subsets. Hematocrit values did not affect meter blood glucose results.

Conclusion:

The DIDGET BGMS provided accurate test results across all age ranges in children, teens, and young adults with diabetes.

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Abbreviations: (BGMS) blood glucose monitoring system, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (YSI) Yellow Springs Instruments

Keywords: blood glucose monitoring, children with diabetes, diabetes management, health-related video game technology, motivational tools for self-monitoring of blood glucose, self-monitoring of blood glucose

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Introduction

Diabetes in children is becoming an increasing problem in the United States, with an estimated 15,000 children newly diagnosed with type 1 diabetes each year.[1] Worldwide, the incidence of type 1 diabetes is increasing at a rate of approximately 3% per year.[2] Although type 1 diabetes remains the most common form of diabetes in children, the incidence of type 2 diabetes is also rising with the increasing prevalence of childhood obesity; a large, standardized registry study estimated that approximately 3700 children in the United States are diagnosed annually with type 2 diabetes.[1]

Self-monitoring of blood glucose (SMBG) is an integral component of diabetes management.[3–5] Parents of children with diabetes and health care professionals (HCPs) who manage their diabetes care may benefit from novel methods for encouraging children, teens, and young adults to test their blood glucose as recommended. Advances in technology may serve as motivational tools to encourage SMBG in children with diabetes. In particular, video game technology has increasingly been used for applications outside of entertainment, such as health care management.[6] While the majority of these technologies to date have focused primarily on patient education and self-care relating to pediatric diabetes management,[7–10] gaming systems designed to motivate SMBG may be of particular interest for this patient population. In one randomized clinical trial (N = 40) evaluating the use of a motivational game to assist with outpatient diabetes management, the frequency of blood glucose monitoring was significantly increased in children and adolescents who used the game compared with those who did not ($p < .0001$).[11]

DIDGET® (Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY) is a novel blood glucose monitoring system (BGMS) that was developed with the goal of improving SMBG habits in children, adolescents, and young adults through the use of positive rewards for consistent blood glucose testing. The DIDGET system, an adaptation of the CONTOUR® blood glucose meter, interfaces with Nintendo® game systems, including Nintendo DS® and Nintendo DS Lite. Users of the BGMS receive reward points for positive testing behaviors (i.e., frequency and consistency of testing habits over time), which can then be used in a video game to access different levels of play as well as mini games. A prototype blood glucose meter was tested and found to be precise and clinically accurate in the hands of pediatric subjects and young adults with type 1 diabetes.[12] There was high subject satisfaction with the BGMS, and most subjects found it easy to use and motivating and indicated that it could be helpful for building good blood glucose monitoring habits. Modifications were subsequently made to the blood glucose meter. The current study further evaluated the performance of the final version of the DIDGET system in the hands of its intended users—children, teens, and young adults with diabetes—in accordance with International Organization for Standardization (ISO) 15197:2003 criteria.[13]

Methods

Subjects

Eligible subjects were between the ages of 4 and 24 years with type 1 or type 2 diabetes who regularly performed SMBG at home. Subjects were excluded from participation if they were pregnant, had hemophilia or other bleeding disorder, were taking prescription anticoagulants (with the exception of clopidogrel or daily aspirin) or had clotting problems that could prolong bleeding, or had an infection with a blood-borne pathogen. Subjects or subjects' parent or legal guardian completed the informed consent process, which included assent for subjects aged 7 to 17 years, prior to participation in the study. Subjects aged 17 years or younger were accompanied by a parent/guardian who assisted or performed the testing, as usually done for the subject's routine SMBG. The protocol, informed consent forms, case report forms, advertising materials, and DIDGET labeling materials were approved by an institutional review board before study initiation.

Study Design

This study was conducted at two clinical sites in the United States (The Pediatric Endocrinology Office of Larry C. Deeb, Tallahassee, FL, and AMCR Institute, Escondido, CA) from September 2009 to October 2009. Subjects completed one clinic visit, which was conducted by a HCP. During the clinic visit, subjects were trained how to use the DIDGET meter based on the user guide and quick reference guide, and the HCP demonstrated to subjects how to put a test strip into the meter and run a normal control solution test. The HCP performed a deep finger stick on the subject using a Tenderlett® (International Technidyne Corporation, Edison, NJ), or similar, lancing device, and the finger stick blood was

tested in duplicate by each subject (or parent/guardian) and HCP using the DIDGET system. From the same finger stick (or an additional finger stick if needed), blood was collected for testing on the Yellow Spring Instruments (YSI) blood glucose analyzer (YSI Life Sciences, Inc., Yellow Springs, OH). Hematocrit was measured on the CritSpin Reader (Iris Sample Processing, Westwood, MA). After these finger stick tests, a venipuncture was performed on consenting subjects; this blood was modified (i.e., glycolyzed or spiked with glucose) and tested to assess performance across the entire blood glucose range, including very high and very low glucose levels that could not be achieved directly from the subjects without compromising their safety. The modified blood samples were tested on both the DIDGET system and the YSI analyzer by the HCP.

Precision and accuracy of the YSI analyzers were demonstrated by assaying six traceability control sera that spanned the range from 20 to 600 mg/dl. Target glucose levels for the controls had previously been determined using a reference method traceable to the National Institute of Standards and Technology Standard Reference Material 965a Glucose in Frozen Human Serum (aqueous New England Reagent Laboratory glucose standards). Controls were assayed in duplicate on the YSI analyzer for at least three runs prior to the assay of subject samples over at least 3 days and at the beginning and end of each day during the study that the YSI analyzer was used.

Assessments and Analyses

The primary outcome measure of the study was to evaluate the accuracy of the DIDGET system in the hands of its intended users. Accuracy was assessed using the ISO 15197:2003 criteria[13] and defined as at least 95% of subject-generated meter results and results from modified blood samples that were within ±15 mg/dl of the reference value for blood glucose values less than 75 mg/dl or within ±20% of the reference value for blood glucose values of 75 mg/dl or higher. Each individual subject meter result (two per subject) was compared with the average of duplicate subject YSI results, and each modified blood sample was tested on meters (two per sample) by the HCP and compared with the mean YSI result. Accuracy was also evaluated by least squares regression analysis to compare YSI results with subject meter results (capillary only and combined capillary/modified). Parkes consensus error grid analyses[14] were used to determine clinical accuracy, comparing subject meter results with YSI results for all samples. Percentage of difference between each subject result and YSI result was plotted against the corresponding hematocrit value for each blood sample to determine the effect on meter results.

Results

Subjects

A total of 123 subjects aged 4 to 24 years with type 1 or type 2 diabetes participated in the study (**Table 1**). Three age groups were represented: children aged 4 to 12 years (33.3%), teens aged 13 to 17 years (24.4%), and young adults aged 18 to 24 years (42.3%). Nine subjects between the ages of 4 and 7 years had their parent/guardian assist with or perform the testing in a manner consistent with what they do at home; all other subjects

Table 1.
Subject Demographic and Clinical Characteristics

Characteristic	Subjects, *n* (%) (*N* = 123)
Age	
4–12 years	41 (33.3)
13–17 years	30 (24.4)
18–24 years	52 (42.3)
Gender	
Female	69 (56.1)
Male	54 (43.9)
Ethnicity	
Caucasian	100 (81.3)
Black/African American	13 (10.6)
Asian	2 (1.6)
Other	8 (6.5)
Type of diabetes	
Type 1	118 (95.9)
Type 2	5 (4.1)
Length of time with diabetes[a]	
1–3 months	2 (1.6)
3–6 months	0
6–12 months	2 (1.6)
1–2 years	19 (15.4)
3–5 years	30 (24.4)
5–10 years	44 (35.8)
>10 years	26 (21.1)

[a] Percentages may not total 100% due to rounding.

performed their own testing. Two subjects did not have a YSI reference result; thus 121 subjects were included in assessments of accuracy and regression. With duplicate testing for each subject, there were a total of 242 subject capillary results used for accuracy and regression analysis, along with 94 modified sample results for a total of 336 blood sample results for overall assessment of accuracy and regression. Health care provider capillary results were not included in these analyses. Glucose distribution of unmodified capillary samples ranged from 53.7 to 463.5 mg/dl, and glucose distribution of the combined capillary and modified samples ranged from 25.7 to 563.5 mg/dl.

Accuracy

Table 2 shows that the DIDGET meter exceeded ISO 15197:2003 criteria. For both capillary samples and capillary and modified samples combined, more than 97% of blood samples were within ±15 mg/dl or ±20% of the YSI value. Regression analyses showed a high degree of correlation between meter results and YSI reference results: coefficient of determination (R^2) = 98.2% for all samples combined (**Figure 1A**) and 97.2% for capillary samples only (**Figure 1B**). The within-subject coefficient of variation was approximately 6.4%, and a modified Bland–Altman plot with 95% confidence limits is shown in **Figure 2**.

Clinical accuracy was demonstrated by Parkes consensus error grid analyses, which compared meter results to YSI results for all samples. As shown in **Figure 3**, 100% of results for all analyses were in zone A or zone B. For combined samples (capillary and modified), 98.5% of subject results were in zone A and 1.5% were in zone B. For capillary samples only, 97.9% of samples were in zone A and 2.1% were in zone B. There were no results in zones C, D, or E.

There was no difference in performance or clinical accuracy across age subsets. Average hematocrit values ranged from 21% to 61% for all subject samples and did not affect meter results (data not shown).

Table 2.
Percentage of Meter Results as per ISO 15197:2003 Criteria for Accuracy

Sample type	*N*	Percentage of meter results within ±15 mg/dl or ±20% of YSI values
Capillary and modified	336	97.9
Capillary only	242	97.1

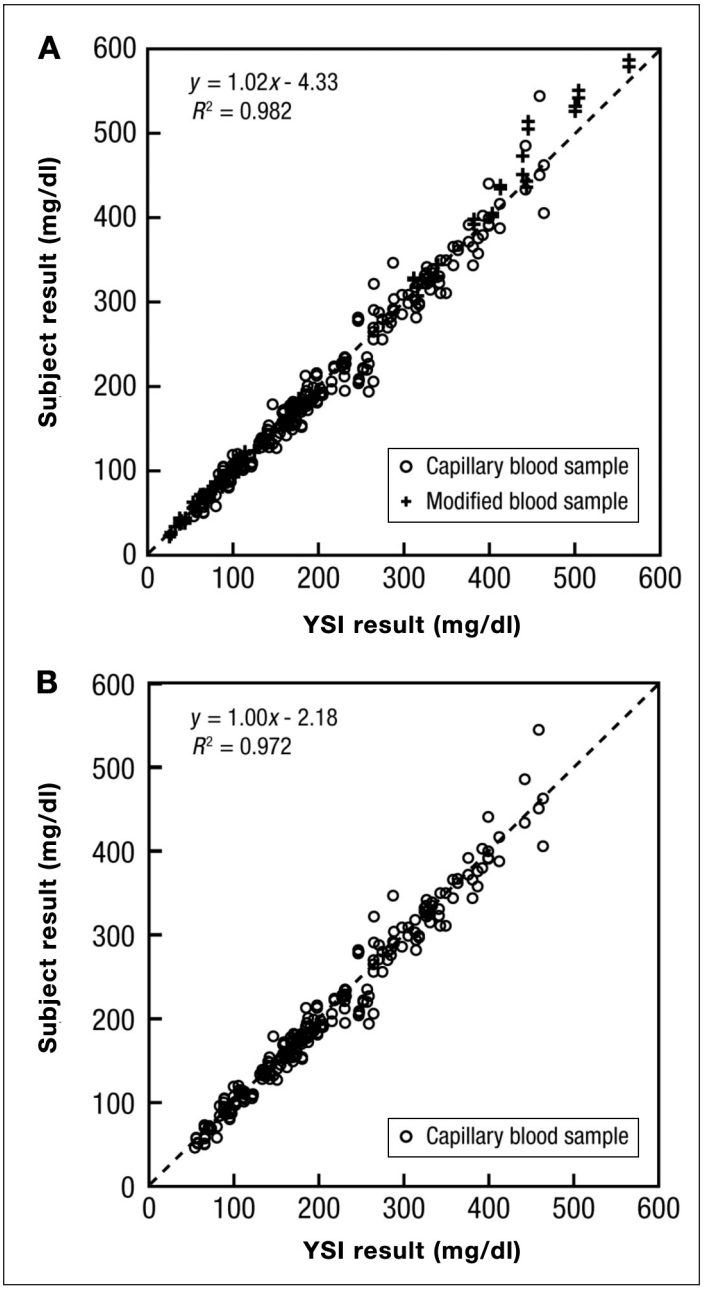

Figure 1. System accuracy regression analysis of subject meter results for **(A)** capillary and modified samples combined or **(B)** capillary samples only versus YSI reference results.

Adverse Events

There was one non-serious, non-device-related adverse event (mild hypoglycemic event) reported during the study. The event was anticipated and was completely resolved prior to the subject leaving the clinical site.

Discussion

The increasing prevalence of diabetes among children poses a significant burden to patients as well as their

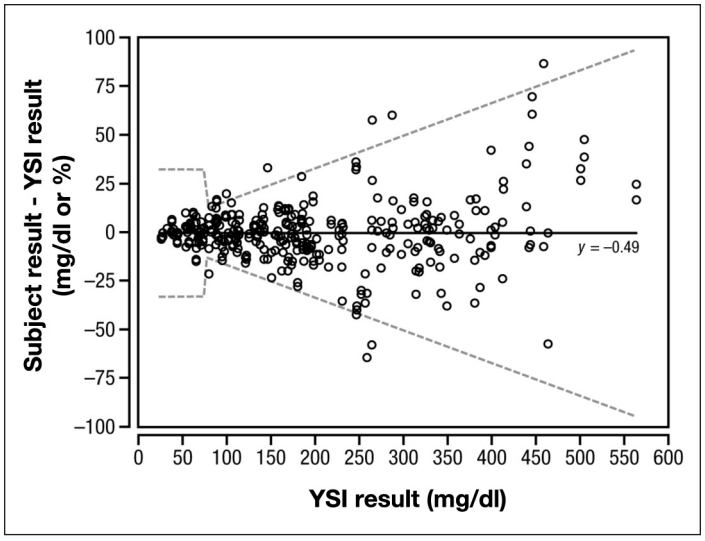

Figure 2. Modified Bland–Altman plot of subject meter results for capillary and modified samples combined. The dashed lines are based on the ISO 15197:2003 accuracy criteria (i.e., ±15 mg/dl for blood glucose values <75 mg/dl and ±20% for blood glucose values ≥75 mg/dl).

families.[1] Evidence suggests that regular SMBG among children and young adults is associated with improved glycemic control,[3,15–20] and developing good blood glucose testing habits at an early age may benefit these patients over the long term. Parents and HCPs who care for children with diabetes may be able to take advantage of new technologies that encourage positive SMBG habits.

Incorporation of video gaming systems that address diabetes management[7–10] may be particularly useful in motivating SMBG in children, teens, and young adults with diabetes.[11] Video game use among children and teens has dramatically increased in recent years; 87% of children ages 8 to 18 years in the United States have a video game console in their home.[21] Studies have also suggested that educational video games are well received by children[9] and can have a significant positive impact on disease management.[10,11]

The DIDGET system combines SMBG with video game technology, with the goal of motivating children and adolescents to regularly perform SMBG. The DIDGET system is an adaptation of the CONTOUR BGMS that allows for connection of the blood glucose meter to a Nintendo DS or Nintendo DS Lite gaming system. Based on the frequency and timing of SMBG, as well as the results of blood glucose tests, users can receive reward points that can be used to access different levels of the game or additional mini games; bonus reward points can also be earned for consistent, long-term testing habits.

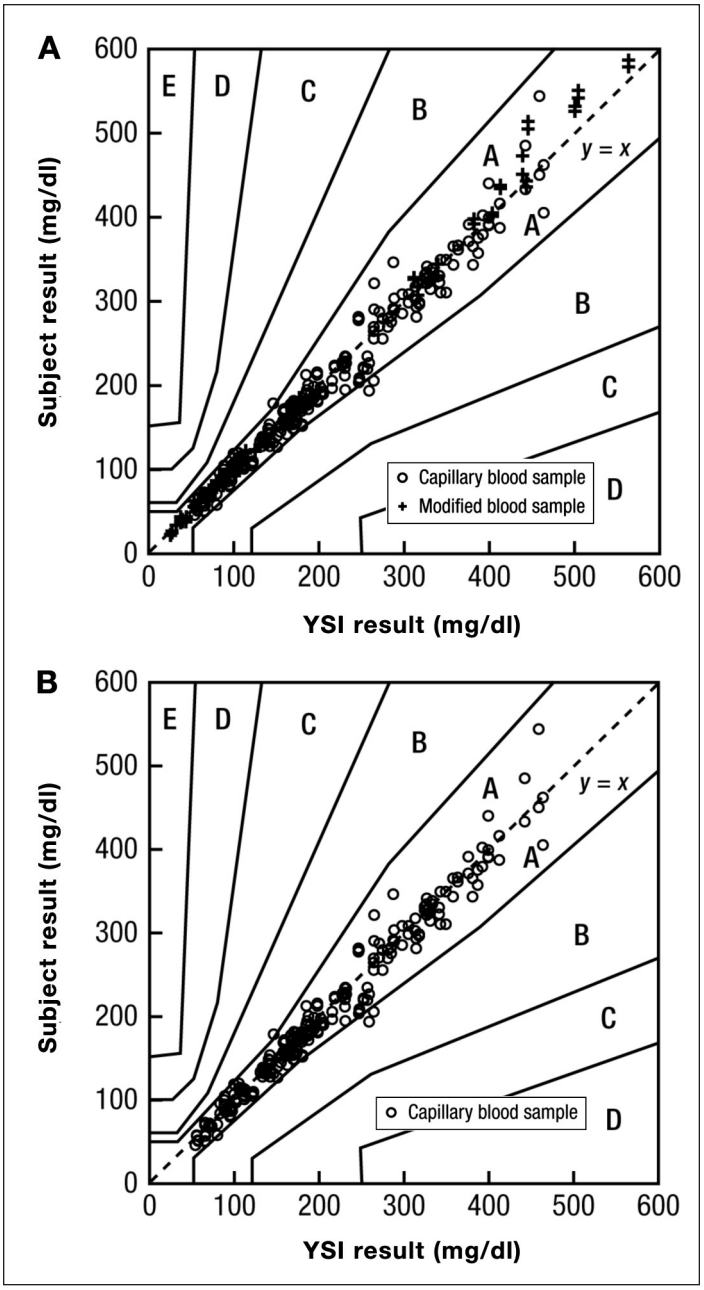

Figure 3. Clinical accuracy comparisons (Parkes consensus error grid analyses) of subject meter results for **(A)** capillary and modified samples combined or **(B)** capillary samples only versus YSI reference results.

In this study, the DIDGET system was shown to be accurate in the hands of children, teens, and young adults with diabetes based on the ISO 15197:2003 criteria; 97.1% of meter results from capillary samples and 97.9% of meter results from combined capillary and modified samples were within ±15 mg/dl or ±20% of the YSI value. Regression analyses showed a high degree of correlation between meter results and YSI reference results: the coefficient of determination (R^2) was 98.2% for all

samples combined and 97.2% for capillary samples only. Clinical accuracy was demonstrated by Parkes consensus error grid analysis, with 100% of results in zone A or zone B (i.e., no effect or minimal effect on clinical action, respectively). Meter results were shown to be accurate over the wide range of hematocrit levels tested in this study. Additionally, there were no differences in system performance or clinical accuracy of the DIDGET system across age groups.

The results of the current study evaluating the adapted DIDGET system in the hands of its intended users complement and further reinforce those from the previous study of an earlier prototype,[12] which additionally showed high rates of both subject satisfaction and comprehension of instructional materials. In that study, most HCPs felt that the DIDGET system would fulfill a need in diabetes management.

Conclusions

Findings from this study demonstrate a high degree of correlation between subject and YSI reference results and show that the DIDGET BGMS exceeded the ISO 15197:2003 criteria for accuracy. These data indicate that use of the DIDGET BGMS provides accurate blood glucose test results across all age ranges in children, adolescents, and young adults with diabetes.

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Disclosures:

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