

Performance of three different continuous glucose monitoring systems in children with type 1 diabetes during a diabetes summer camp

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Abstract

The aim of this study was to assess accuracy of the three most commonly used continuous glucose monitoring (CGM) systems in almost real-life situation during a diabetes camp in children with type 1 diabetes (T1D) aged 9–14 years. Data was gathered during a 2-week summer camp under physicians' supervision. Out of 38 participating children with T1D (aged: 11.0 [9.9; 12.1] years; 57% girls, mean HbA1c 7.2 [6.9; 7.7] %), 37 wore a CGM system (either Abbott FreeStyle Libre (FSL), Dexcom G6 (DEX) or Medtronic Enlite (ENL)) throughout the camp. All concomitantly available data pairs of capillary glucose measurements and sensor values were used for the analysis. Mean absolute relative difference (MARD) was calculated and Parkes Error Grid analyses were done for all three systems used. In total 2079 data pairs were available for analysis. The overall MARDs of CGM systems used at the camp was FSL: 13.3% (6.7;21.6). DEX: 10.3% (5.8; 16.7) and ENL 8.5% (3.6; 15.6). During eu-, hypo- and hyperglycemia MARDs were lowest in ENL. Highest MARDs were seen in hypoglycemia, where all three systems exhibited MARDs above 15%. Overnight MARDs of all systems was higher than during daytime. All sensors performed worst in hypoglycemia. Performance of the adequately calibrated Medtronic system outperformed the factory-calibrated sensors. For clinical practice, it is important to adequately train children with T1D and families in the correct procedures for sensors that require calibrations.

KEYWORDS

accuracy, calibration, CGM, children, sensor, type 1 diabetes

Abbreviations: BMI, body-mass-index; CGM, continuous glucose monitoring; CSII, continuous insulin infusion; DEX, Dexcom G6; ENL, Medtronic Enlite 2; FSL, Abbott FreeStyle Libre; isCGM, intermittently scanned continuous glucose monitoring; MARD, mean absolute relative differences; OEDV, Österreichische Diabetikervereinigung = Austrian Diabetes Union; PEG, Parkes Error Grid; SD, standard deviation; T1D, type 1 diabetes; TIR, time in range.

1 | INTRODUCTION

Continuous subcutaneous glucose monitoring (CGM) is commonly used in pediatric diabetes care and has facilitated diabetes management for children, adolescents with T1D and their caregivers.^{1,2}

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As a result of ongoing development, the accuracy of CGM systems is comparable to that of capillary blood glucose monitoring devices.³⁻⁶ Consequently, usage of CGM systems has increased substantially in the last years and might soon exceed usage of continuous subcutaneous insulin infusion (CSII) devices in children with type 1 diabetes (T1D).^{7,8} Furthermore, it has been shown that the use of CGM systems⁹ might be a main driver of improvement in terms of glycemic control and that the method of insulin delivery (pen vs. CSII) might be of lesser importance in all age groups.^{10,11} As part of a future development, for the implementation of hybrid closed-loop systems, both compartments – sensor and pump are a must.¹²

CGM systems support children with T1D and caregivers to manage every day diabetes issues, such as insulin dosing, carbohydrate intake and exercise, but also improve hypoglycemia-related confidence in social situations¹³ and thereby help to improve glycemic control.^{7,14,15} Remaining problems of CGM systems are the high frequency of alarms, false alarms and inaccuracy, which can also be aggravated by incorrect calibrations or issues related to sensor insertion or signal delay. Previously, glucose values derived from CGM systems were only considered adjunctive and capillary fingerstick measurements were required prior to make treatment decisions. With the newest sensor generations, sensor values can be used for insulin titration. Children with T1D and caregivers are instructed to perform capillary glucose measurements only in case there is uncertainty of sensor accuracy or a capillary glucose value is required for sensor calibration. Recently developed, factory-calibrated systems, such as Abbott FreeStyle Libre and Dexcom G6 overcome calibration-related issues. For commercially marketed predictive low glucose suspend and hybrid closed-loop systems (Medtronic MiniMed 640G and 670G) that automatically adjust the basal rate depending on sensor glucose, calibrations via capillary fingerstick measurements are still required.

For all currently available sensor systems, there are concerns with regard to sensor accuracy especially in periods of hypo- and hyperglycemia. Several pediatric studies have investigated the accuracy of modern sensor systems in individuals with T1D.⁶ They have shown encouraging results for both user- and factory-calibrated real-time continuous glucose monitoring systems such as the Guardian Sensor 3,⁶ the Dexcom G6^{16,17} and for the intermittently scanned continuous glucose monitoring (isCGM) system FreeStyle Libre.¹⁸ To the best of our knowledge, no study so far has compared the three sensor systems that are approved in pediatric diabetes care in parallel under real-world conditions in a standardized way in children with type 1 diabetes (T1D).

We compared the performance of the three commercially available CGM systems, namely, Medtronic Enlite (ENL), Dexcom G6 (DEX) and Abbott FreeStyle Libre (FSL) in standardized real-life conditions at a diabetes summer camp in children with T1D.

2 | METHODS

Data was gathered during a 2-week summer camp for diabetes education and recreation in July 2019, which was organized by the Austrian Diabetes Union (Österreichische Diabetikervereinigung [ÖDV]), a

diabetes support group. In general, the ÖDV diabetes camp is open for all children with T1D aged 8 to 12 years and the camp has taken place annually for more than 50 years. The aims of the camp are to connect children with T1D and to improve self-confidence and independence in the handling of insulin therapy.

Children attending the camp originate from all regions of Austria and are seen regularly at different pediatric diabetes care facilities/outpatient clinics across Austria. The number of participants is limited to ensure adequate care. The 14-days camp takes place in a youth hostel at a lake-site near Salzburg, Austria. The team of supervisors consists of diabetologists, nurses, medical students, dieticians, and pedagogical staff who are constantly present. Participation in the camp is fee-based. In many cases, however, health insurance companies refund a partial amount of the costs and for socially and financially disadvantaged children, there is the possibility to receive funding for the total amount of the camp costs from charity organizations.

The investigations on sensor accuracy are part of the main study “Diabetes Knowledge and Skills in Children with Type 1 Diabetes before and after participation in a diabetes camp”. The main study was registered and approved by the ethics board of the Medical University of Vienna (EK-Nr. 1394/2018, Reg.Nr. DRKS00020415). The main inclusion criteria were diagnosis of T1D for at least 3 months and willingness to participate in the study. After the approval to attend the summer camp 2019, children with T1D and their parents were invited to participate in the study and information about the study was sent to the families, so that families had enough time to decide whether they agreed to participate in the study as well. Participation in the study was not a prerequisite for participating in the camp or linked to it. On the first day of camp parents and children were again invited to take part in the study and informed consent was obtained from children and parents. All 38 families decided to participate in the main study and consent was signed by parents/guardians and acknowledged by each child prior to any study-related procedures. Before parents left, camp physicians collected data on children's insulin home regimens, device settings, and medical history.

The children continued to use the insulin regimen and glucose monitoring system they had already been using at home and had been trained on by their diabetes teams prior to the camp. All but three children were experienced in the use of CGM or isCGM. Two children started to use a CGM system (FSL) at camp and were trained in its use by the camp personnel. One child was not routinely using a CGM system, did not want to try CGM during camp and thus did not participate in the sub-analysis concerning sensor accuracy.

Camp staff was thoroughly trained on diabetes management in general and on all devices used by the camp participants (CGM/isCGM systems, blood glucose meters, insulin pumps, insulin pens) before the camp started. The following CGM/isCGM systems were used at the camp: Abbott FreeStyle Libre (FSL; Abbott Diabetes Care, Alameda, USA), Dexcom G6 (DEX; Dexcom Inc, San Diego USA) and Medtronic Enlite 2 in combination with MiniMed 640G (ENL; Medtronic Diabetes, Northridge, USA).

All families were instructed to insert a new sensor on the first day of the camp under supervision of the parents. FSL was inserted into

the arms, for ENL and DEX different insertion sites (arm, thigh, bottom, abdomen) were used. In case of using stand-alone CGM/isCGM systems – namely DEX and FSL – families were asked to start the new sensor using the dedicated reader instead of using the smartphone app.

With the start of the camp, all children routinely performed capillary blood glucose measurements several times a day under the supervision of medical personnel after a thorough cleaning of the fingertip: before meals (i.e. 07:00–08:00, 11:00–12:00 and 17:00–18:00), before bedtime (21:00–22:00), in case of signs of hyper- or hypoglycemia or signal loss. In line with camp safety regulations, additional fingerprick measurements were performed in case sensor values were > 250 mg/dL (13.9 mmol/L) or < 80 mg/dL (4.4 mmol/L), as sensor accuracy is reported to be lower in the low glycaemic range and during rapidly changing blood glucose concentrations.⁵

All children used the glucometers they had been using at home. The following glucometers were used (Bayer Contour next link 2.4 (39%), Freestyle lite (5%), Freestyle precision (53%), and One Touch Verio Flex (3%). In the respective trials ISO 15197:2013 criteria were met by 98.6%,¹⁹ 95–100%,²⁰ 86%–96%,²¹ 100%–99.5%.²²

CGM was routinely performed throughout the camp. During the night (22:00–07:00), sensor readings were checked twice (at 01:00–02:00 and 04:00–05:00 AM) by medical staff and capillary blood glucose measurements were carried out according to camp safety regulations. Calibrations of ENL was performed at least twice daily when glycaemia was stable represented by horizontal trend arrows on the display under supervision of medical staff.

Insulin doses were adjusted on a regular basis, depending on observed blood glucose values, carbohydrate intake and physical activity under the oversight and supervision of the camp physicians. All obtained blood glucose values, insulin dosages and carbohydrate units were documented.

HbA1c values of all children were obtained during the second week of the diabetes camp on-site (DCA-Vantage, Siemens, Germany).

During the last 2 days of the camp, all data of the two camp weeks was downloaded from all devices for later analysis.

2.1 | Data analysis

For data analysis, sensor glucose values were matched with the corresponding capillary blood glucose values. All concomitantly available data pairs were used for the analysis. Overall accuracy and accuracy during hypoglycemia (<70 mg/dL [<3.9 mmol/L]), euglycemia (70–180 mg/dL [3.9 – 10 mmol/L]) and hyperglycemia (>180 mg/dL [10 mmol/L]) were assessed by calculating the mean absolute relative difference (MARD) between sensor and capillary glucose measurements. Daytime, as well as night-time, were analyzed separately. Night-time was defined as the period when children were supposed to be in bed (10.00 PM until 7.00 AM).

Overall sensor accuracy was determined using ISO 15197:2013 (percentage of sensor values that are within ± 15 mg/dL (0.8 mmol/L) of the reference value at glucose concentrations <100 mg/dL (5.6 mmol/L)

and within $\pm 15\%$ at glucose concentrations ≥ 100 mg/dL (5.6 mmol/L)). The clinical relevance of discrepancies between blood glucose values and CGM values was illustrated by Parkes Error Grid (PEG) analysis.²³ The most commonly used analysis methods for accuracy analysis of CGM, among those Parkes error grid (PEG) was used. By using PEG analysis we aim to illustrate the clinical relevance of discrepancies between blood glucose and CGM values. The grid is divided into zones illustrating the degree of risk caused by erroneous measurements: zone A means no effect on clinical action; zone B represents altered clinical action—small or no significant effect on clinical outcome; zone C represents altered clinical action—likely to affect clinical outcome; zone D means altered clinical action—could have significant medical risk; and zone E represents altered clinical action—could have dangerous consequences.²³

For FSL, DEX and ENL sensor and reference glucose values were also compared using Bland–Altman analysis. The mean difference of reference glucose values – CGM values \pm standard deviation (SD) are given and 95% limits of agreement were calculated as average difference ± 1.96 times the SD of the difference.

Camp Time in range (TIR) (70–180 mg/dL [3.9 – 10 mmol/L])⁹ was calculated for each individual separately, using sensor readings and is given as percentage.

Body mass index (BMI) was calculated as: weight in kilograms divided by squared height in meters. In order to adjust for age and sex, BMI SD score (BMI-SDS) values were derived applying the least mean square method (Box-Cox-Transformation by Cole et al.)²⁴ using age- and sex-specific BMI-reference values based on the World Health Organization (WHO) growth reference for school-aged children and adolescents.²⁵

Baseline characteristics and MARD values are given as median (25th,75th percentile) or percentages. Baseline characteristics and MARD were calculated using Microsoft Office Excel 2019. Parkes Error Grid, Bland Altman plots and ISO 15197:2013 criteria calculation was performed using Python 3.

3 | RESULTS

Baseline characteristics are displayed in Table 1. Out of 38 children, 37 wore an isCGM or CGM system (either FSL, DEX or ENL) while

TABLE 1 Baseline characteristics of the children with T1D participating at the diabetes camp

	a	b
Age (years)	11.0 (9.9; 12.1)	8.5–13.4
Female (%)	60	
Diabetes duration (years)	3.8 (2.7; 6.6)	0.3–12.5
HbA1c (%)	7.2 (6.9; 7.7)	5.4–9.0
HbA1c (mmol/mol)	55.2 (51.0; 60.7)	35.5–74.9
BMI-SDS	0.04 (–0.58; 0.59)	–2.05 - 2.52

Note: a denotes values are given as median (25th,75th percentile) or percentages and b denotes values are given as range from minimum to maximum.

TABLE 2 MARD of the three investigated sensor systems - overall, separately for day- and night-time as well as for hypo-, eu- and hyperglycemia. As no hypoglycemic episode in Dexcom users occurred, no MARD data are available

	FSL (overall)	FSL (day)	FSL (night)	DEX (overall)	DEX (day)	DEX (night)	ENL (overall)	ENL (day)	ENL (night)
All Glycemic Ranges	13.3 (6.7; 21.6) n = 1166	13.3 (6.8; 21.6) n = 1048	13.5 (5.7; 21.8) n = 118	10.3 (5.8; 16.7) n = 242	10.1 (5.9; 16.3) n = 225	16.0 (4.9; 28.9) n = 17	8.5 (3.6; 15.6) n = 671	8.1 (3.4; 14.9) n = 600	12.6 (4.6; 19.8) n = 71
<70 mg/dL(<3.9 mmol/L)	17.9 (9.4; 27.5) n = 224	18.6 (9.9; 27.7) n = 198	15.2 (5.6; 21.8) n = 26	18.7 (10.1; 23.5) n = 21	18.7 (10.1; 23.5) n = 21	- n = 0	14.1 (9.5; 28.2) n = 69	12.8 (9.6; 26.3) n = 58	18.6 (12.7; 40.5) n = 11
70-180 mg/dL(3.9-10 mmol/L)	13.0 (6.7; 21.3) n = 678	12.8 (6.5; 20.8) n = 639	20.8 (12.6; 39.7) n = 39	9.8 (5.9; 15.4) n = 178	9.6 (5.8; 14.6) n = 165	21.3 (6.9; 37.5) n = 13	7.6 (3.2; 14.5) n = 412	7.5 (3.1; 14.4) n = 398	12.2 (6.1; 61.8) n = 14
>180 mg/dL(>10 mmol/L)	11.0 (5.4; 17.6) n = 264	11.7 (5.9; 18.8) n = 211	8.4 (4.0; 14.6) n = 53	11.1 (4.7; 17.0) n = 43	11.1 (5.0; 17.0) n = 39	9.6 (4.2; 15.7) n = 4	8.6 (3.9; 14.9) n = 190	8.6 (4.1; 13.9) n = 144	8.8 (3.9; 16.2) n = 46

Note: Values are given as median (25th, 75th percentile). There were no nighttime hypoglycemic events in DEX users.

participating at the camp. Sensor distribution was 51% FSL, 35% ENL, and 14% DEX. Insulin pumps (Medtronic 640G, Omnipod and AccuChek insight) were used by 68% of children; all other children were on multiple daily insulin injections. The combination of pump and sensor was used in 63%, while 100% of children wore at least a pump or a sensor. A sensor-pump combination with a predicted-low-glucose-suspend mode (Medtronic 640G + Enlite with smart guard) was worn in 39% of children. All children were educated to carb counting and adjusted their insulin dosages under supervision accordingly.

On average, sensor readings of all camp participants showed a mean time in range (TIR) of $66.7\% \pm 9.8\%$ SD. During the camp no severe hypoglycemia, no ketoacidosis or any other intercurrent illness requiring medication or treatment at a hospital occurred.

A total of 1166, 242, and 671 sensor-reference pairs for FSL, DEX and ENL, were available, respectively. Overall the sensors met ISO15197:2013 criteria in 56.9% (FSL), 60.6% (DEX) and 74.4% (ENL). For glucose <100 mg/dL ISO 15197:2013 criteria were met in 56.7% (FSL), 69.4% (DEX) and 76.6% (ENL) and for ≥ 100 mg/dL 57.0% (FSL), 75.5% (DEX) and 77.7% (ENL).

Sensor accuracy data assessed by MARD are displayed in Table 2. ENL showed best overall performance in terms of MARD, in particular in the hypoglycemic range, ENL exhibited the lowest MARD (14.1%) compared to the other systems used. MARDs in the hyperglycemic range were comparable for the three CGM systems. ENL but also DEX showed the best MARDs in the normoglycemic range, whereas the MARD of FSL was better in the hyperglycemic range than in hypo- or normoglycemic ranges.

MARD in the various glycaemic ranges were also calculated for day- and night-time separately. Overall, in all glycaemic ranges, CGM systems performed worse during night-time. Nighttime MARD, independent of glycaemic range, was lowest for ENL. For all three tested systems, MARDs were lowest during hyperglycemia.

The results of Parkes Error Grid (PEG) analyses are depicted in Figure 1. Clinical sensor performance yielded the following percentages per sensor and zone. For FSL (Figure 1.1) 98.9% of values were located in the clinically benign zones A and B (A: 79.4%, B: 19.5%). 1.1% of values were located in zone C. No value was in zones D or E. For DEX (Figure 1.2) 98.8% of values were located in the clinically benign zones A and B (A: 90.1%, B: 8.7%). 1.2% of values were located in zone C. No value was in zones D or E. For ENL (Figure 1.3) 98.5% of values were located in the clinically benign zones A and B (A: 86.9%, B: 11.6%). 1.3% of values were located in zone C. One value was located in zone D and no value was in zone E.

Bland-Altman analyses (Figure 2) showed that both the FSL (Figure 2.1) and DEX (Figure 2.2) system tended to underestimate blood glucose, as reference values were on average 13.9 ± 26.5 mg/dL (0.8 ± 1.5 mmol/L) and 5.9 ± 24.0 mg/dL (0.3 ± 1.3 mmol/L) higher than sensor values. The mean difference between values reported by ENL (Figure 2.3) and fingerprick measurements was 1.2 ± 25.6 mg/dL (0.1 ± 1.4 mmol/L).

The PEG analyses and Bland-Altman Plots for day- and night-time separately are given as Supplement Figure S1 and Figure S2.

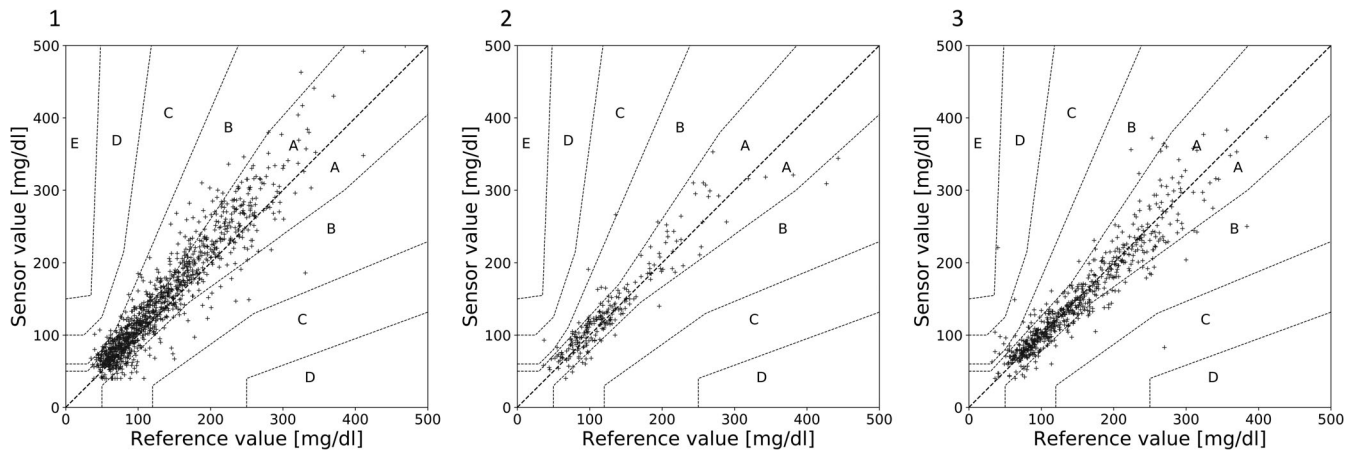


FIGURE 1 Parkes error grid (PEG) for the individual systems. 1) FSL, 2) DEX, 3) ENL. The x-axis displays reference blood glucose values (mg/dl), y-axis presents the corresponding values measured by sensors (mg/dl)

4 | DISCUSSION

Several studies have assessed the accuracy of the most frequently used sensor systems.^{4-6,16-18} Some have compared different sensor systems simultaneously in a head-to-head comparison under hospital conditions in adults with T1D.^{5,26} In children with T1D only few data concerning sensor accuracy are available.^{6,17,18} This is the first comparison of performance and accuracy of the three currently most widely used sensor systems in children and adolescents with T1D in a quasi-real-life situation, at a diabetes camp.

Sensor performance of the user-calibrated ENL system outperformed the factory-calibrated sensors. Similar to what has been reported in other studies,^{4,5,17} all sensors performed worse in hypoglycemia.

Moreover, during night, performance of all three CGM systems decreased notably. While night-MARDs in hyperglycemia tended to be even better than overall-MARDS, in the eu- and hypoglycemic areas in particular, CGM-performance was worst at night. Therefore, the marked decrease in accuracy at night might be attributed to artifacts caused by pressure on the CGM insertion sites during sleep,²⁷ since compression at the sensor site can lead to false negative hypoglycemic measurements.²⁸ In comparison to daytime, at night, less blood glucose measurements were taken. This led to fewer nighttime reference pairs and a broader MARD-range. During night, however, in the hyperglycemic area MARDs were consistently below 10% in all three tested systems and thus show very satisfactory results. Only five children used DEX at camp. By chance, no nighttime hypoglycemia occurred in this group during the camp. Therefore, no statement can be made about MARD of DEX in the hypoglycemic range during night.

Large studies have already demonstrated the safety of nonadjunctive use of the sensors systems used in our study.^{29,30} Nevertheless, a lower susceptibility to position-related pressure artifacts²⁷ and thus improved accuracy during night and especially in case of nighttime hypoglycemia would be desirable.

MARD is a widely used and simple to calculate parameter to assess CGM accuracy. However, it has to be taken into account that

MARD, as a method of describing CGM performance, has its limitations.²⁸ Those inherent limitations might be responsible for the large differences in MARD results in the same CGM systems seen in different investigations.²⁸ For example, MARD does not differentiate between a positive or negative bias, does not take into account number of data pairs, only covers a part of CGM data and is also positively related to the extent of fluctuations in glycemia.²⁸

The advantage of this camp study compared to other studies is the heterogeneity and random composition of the group, as well as a setting that included meals and physical activity, and therefore comes very close to a home application study.

The daily routines and program during the camp varied daily so that despite professional medical care and comprehensive support and monitoring, there were marked blood glucose fluctuations, which made it possible to investigate the performance of the sensors in spontaneous hypo- or hyperglycemia under quasi-real-life conditions. In contrast to an at-home study, the conditions regarding daily diabetes care, daily structure, and support for technology-related issues such as sensor insertions and calibrations were the same for all participating children.

Compared to other studies, CGM systems, used by camp-participants in our study, performed well or comparable in terms of their accuracy. Recent evaluations of FSL in children and adolescents showed slightly higher MARD (16.7%¹⁸ and 18.3%³¹) than our study. Accuracy of the DEX system was comparable to results of other studies in children and adults with T1D.^{17,32} In most studies^{5,26,33} examining the accuracy of the ENL system, MARDs were higher than in our study.

In our study, a relatively large proportion of sensor-reference pairs are located outside the normoglycemic range. This is attributable to camp safety policy which made fingerprick tests mandatory when sensor values were below or above the target range. Thus, values in these areas are overrepresented as compared to glycemic control seen during the camp. This procedure of checking out-of-range values reflects real-life conditions, as children with T1D and care givers are likely to recheck these glucose values by fingerprick before they prompt action.

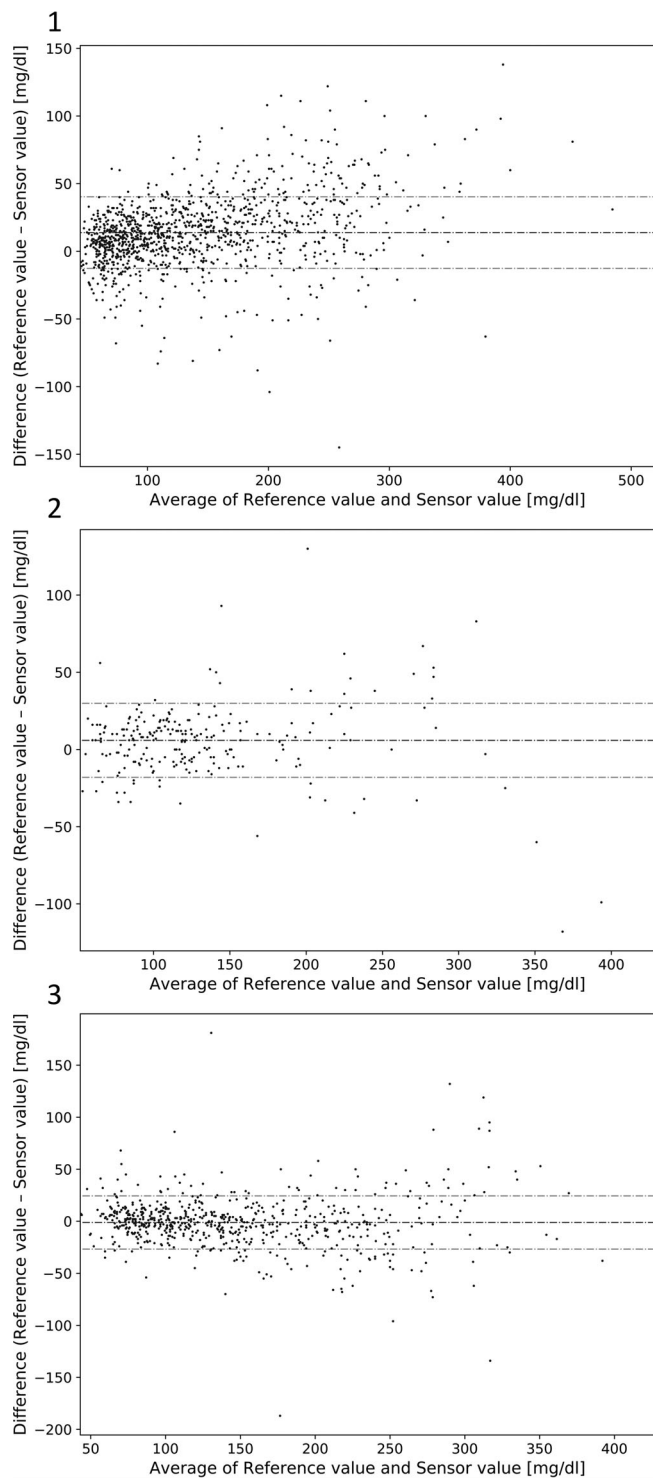


FIGURE 2 Bland-Altman plots for FSL, DEX, and ENL: x-axis represents the average of blood glucose reference and sensor glucose values, y-axis represents the difference between sensor glucose and reference glucose reference. The black dashed line indicates the mean difference; the gray dashed lines indicate 95% limits of agreement (average difference \pm 1.96 times the SD of the difference). 1) FSL: mean: 13.9 mg/dL (0.8 mmol/L), SD: 26.5 mg/dL (1.5 mmol/L); 2) DEX: mean: 5.9 mg/dL (0.3 mmol/L), SD: 24.0 mg/dL (1.3 mmol/L); 3) ENL: mean: -1.2 mg/dL (-0.1 mmol/L), SD: 25.6 mg/dL (1.4 mmol/L)

Also due to camp policies, during night-time fingerprick measurements of blood glucose were only performed when children's CGM/isCGM systems showed values outside of the target area, or when hypo- or hyperglycemia was clinically suspected. This resulted in fewer sensor-reference pairs during normoglycemia overnight.

Another result of this study is that almost 100% of randomly selected children with T1D, who took part in a diabetes training camp in Austria in 2019 were already using modern diabetes technologies, either pump, sensor or the combination of both. This is also possible thanks to insurance policies in Austria refunding the costs for sensors and pumps on a broad scale, especially in the pediatric population. Even more common than the use of insulin pumps was the use of sensors. Most children, however, used isCGM using FLS.

With a median HbA1c of 7.2 (6.9;7.7)%, diabetes control within the 3 months before camp in was good and is comparable with the glycemic control in this age-group registered by the Prospective Diabetes Follow-up registry, the DPV,^{15,34} which covers an estimated 80% of children with T1D in Germany, Austria and Luxembourg.³⁵

In general, Austrian children with T1D have a very high proportion of CSII / CGM systems usage, when compared internationally.⁸ This is also reflected in the camp participants. However, not all of the children who attended the camp were highly motivated about their diabetes therapy or came from a supportive environment. One could possibly assume that especially children with parents who actively take care of diabetes management also take part in a fee-based education camp for diabetes. Nonetheless, there were also children from socially weaker classes attending the camp, for whom special funding programs covered costs. Through the influence of the peer group, the camp most likely had a motivating effect on the children, which is also the strength and benefit of diabetes camps in general.³⁶

The comparatively good results of the CGM systems, and in particular the superior results of the ENL system, may be attributable to the supportive influence of medical staff on the children. Especially support with regard to technological tasks, such as proper calibrations and easy to implement but maybe sometimes neglected tasks such as proper washing of hands before finger-prick measurements, might have had a positive impact on CGM accuracy. Equipped with a sufficient number of well-trained supervisors, the camp offered a 24/7 monitoring and support. Calibrations were carried out when needed, at any time of the day or night. Correct calibrations are essential for a good CGM performance but may not be easy for families to do in everyday life, especially during the night and could reduce the performance of diabetes technology.

A strength of our study are close monitored sensor-reference pairs in a quasi-real-life situation with controlled conditions. Moreover, our study covers a broad spectrum of glycaemia in girls and boys during a camp-setting, also depicting phases of meals, exercise and sleep. Reflecting a real-life situation, all children used glucometers, which they had also been using at home. Consequently, many different glucometers were used, and which is a limitation of our study. However, all glucometers used at the camp had good accuracy results in the respective clinical trials.¹⁹⁻²²

Overall, our study shows very satisfactory results in terms of the accuracy and performance of the sensor systems used at a diabetes summer camp. Regarding their clinical applicability, the three systems are comparable, as was shown in the PEG analyses. For the clinical practice, it is important to adequately train children with T1D and their families in the correct calibration procedures for sensors that require calibrations.

ACKNOWLEDGMENTS

The authors thank the OEDV and especially all participating children and their families and numerous people involved in the OEDV diabetes camp 2019. There was no commercial sponsor involved in the study.

CONFLICT OF INTEREST

KN has no conflict of interest. GB has no conflict of interest. JKM is a member in the advisory board of Becton-Dickinson, Boehringer Ingelheim, Eli Lilly, Medtronic, Prediktor SA and Sanofi, and received speaker honoraria from Abbott Diabetes Care, Astra Zeneca, Eli Lilly, Dexcom, Medtronic, Novo Nordisk, Roche Diabetes Care, Sanofi, Servier, and Takeda. BRM has received speaker honoraria from Eli Lilly, Medtronic, Novo Nordisk, Roche Diabetes Care, Sanofi and Menarini and has been on the advisory boards of Roche Diabetes Care and Abbott Diabetes Care. FA received speaker honoraria from Eli Lilly, Merck Sharp & Dome, Boehringer Ingelheim, Astra Zeneca and travel grants from Sanofi, Novo Nordisk, Takeda, Merck Sharp & Dome and Amgen. The remaining authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Katrin Nagl, Gabriele Berger, Felix Aberer, Haris Ziko, Katharina Weimann, Ina Bozic, Birgit Rami-Merhar and Julia K. Mader designed and performed the study, interpreted data and contributed to discussions. Katrin Nagl and Julia K. Mader drafted the manuscript. Katrin Nagl, Julia K. Mader, Felix Aberer, Ina Bozic and Haris Ziko designed the study and performed statistical analysis. Birgit Rami-Merhar, Gabriele Berger, Katharina Weimann and Julia K. Mader performed the study. Felix Aberer, Ina Bozic and Haris Ziko interpreted data and contributed to discussions. Julia K. Mader and Birgit Rami-Merhar supervised the project. All authors critically revised the article and approved the final version of the manuscript.

PEER REVIEW

The peer review history for this article is available at <https://publons.com/publon/10.1111/pedi.13160>.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Nagl K, Berger G, Aberer F, et al. Performance of three different continuous glucose monitoring systems in children with type 1 diabetes during a diabetes summer camp. *Pediatr Diabetes*. 2021;22:271-278. <https://doi.org/10.1111/pedi.13160>