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Reduced Diabetes Burden Over Glycemic Gains With the Dexcom G7 Upgrade in Youth on Automated Insulin Delivery System

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1 | Introduction

Automated insulin delivery (AID) systems play a crucial role in achieving tight blood sugar control. The Dexcom G7 continuous glucose monitor (CGM) is smaller, more accurate, faster to warm up, and provides a 12-h grace period compared to the G6 [1, 2]. In early 2024, the G7 was integrated with the Tandem t:slim X2 insulin pump with Control-IQ algorithm. It is important to note that the Dexcom G7 is also compatible with other automated insulin delivery systems, such as the Omnipod 5, which is also approved for paediatric use.

While the technical advantages of the G7 are well-documented in previous studies [1, 2], their translation into measurable real-world benefits for paediatric AID users remains largely unquantified. For youth already achieving good glycemic control

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(defined here as HbA1c < 7.0%) [3], improvements in user experience and reduced burden of care may be more important than incremental glycemic gains.

We hypothesized that the G7's features (shorter warm-up and grace period) would increase the time spent in closed loop (TCL) by reducing system downtime, thereby improving glycemic control and reducing the burden of care [4]. TCL is a particularly sensitive metric in paediatric AID users, as even small increases in system uptime can significantly impact overall algorithm efficacy and reduce daily management burden by ensuring continuous automated insulin delivery, thereby reducing glycemic variability and improving outcomes. The primary aim of this study was to compare TCL, glucometrics, and patient-reported outcomes (PROs) in children and adolescents switching from Dexcom G6 to G7, with a specific focus on understanding the drivers of user satisfaction in this high-performing cohort.

2 | Methods

The study was conducted in accordance with the Helsinki Declaration. This was a non-interventional study using paired fully anonymized and aggregated data extracted from the Glooko data management platform. In compliance with the Italian General Authorization to Process Personal Data for Scientific Research Purposes (authorization 9/2014), which governs studies based on such anonymized real-world data, formal ethics committee approval and separate informed consent were not required beyond the initial consent provided by users for the collection and use of their anonymized data on the platform. We enrolled children and adolescents (aged 7–17 years) with type 1 diabetes (diagnosed by ISPAD criteria) for at least 1 year who had been using the Tandem Control-IQ system for at least 6 months. Exclusion criteria included severe hypoglycemia or diabetic ketoacidosis in the prior month. This age range was chosen to ensure consistency across participating paediatric diabetes centers, although Control-IQ is approved for use from 6 years of age. Participants were recruited consecutively from multiple specialized paediatric diabetes centers across Italy. While we aimed for broad inclusion within our criteria, the observed baseline HbA1c of 6.43% indicates that the enrolled cohort demonstrated excellent glycemic control prior to the study, thus characterizing them as a 'high-performing' group in terms of metabolic management.

The primary outcome was the change in percentage TCL between 3 weeks of Dexcom G6 use and the subsequent 3 weeks of Dexcom G7 use. A 3-week observation window was chosen as a pragmatic approach to capture the immediate impact of the sensor transition while maintaining feasibility in a multi-centre real-world study; this duration is common in similar short-term CGM comparative studies. Secondary outcomes were changes in time in range (TIR, 70–180 mg/dL), time in tight range (TITR, 70–140 mg/dL), time above range (TAR, > 180 mg/dL), time below range (TBR, < 70 mg/dL), coefficient of variation (%CV), and glucose management indicator (GMI).

PROs were assessed using the Italian-validated CGM Satisfaction (CGM-SAT) scale, a 44-item questionnaire (0–5 Likert scale) measuring hassles, benefits, and overall satisfaction [5]. We selected this instrument specifically for its focus on sensor-related experiences, which was central to evaluating the impact of switching from Dexcom G6 to G7. Versions for both youths and parents were administered at the end of each 3-week period.

A sample size calculation indicated that 34 participants would be sufficient to detect a clinically meaningful 5% difference [6] in TIR (e.g., from 70% to 75%), referencing similar studies in paediatric populations using AID systems. This calculation was based on a paired-sample design with a power of 0.8 and alpha of 0.05, assuming a standard deviation of the differences of 10%, consistent with similar real-world evaluations of AID technology transitions in paediatric cohorts [7, 8]. Although TCL was a primary outcome, an established minimally clinically important difference for TCL is not widely available in the literature. Given the strong correlation between TCL and TIR in AID users, and the well-defined clinical benchmarks for TIR, the sample-size calculation was based on TIR. Our final sample of 36 participants was therefore considered adequately powered. Statistical analysis was performed using the non-parametric Wilcoxon signed-rank test for paired data, and effect sizes (mean differences with 95% confidence intervals for normally distributed data, or median differences for non-normally distributed data) are reported alongside p values. To explore the drivers of change in PROs, multiple linear regression analyses were conducted. Changes in the 'hassles' and 'benefits' subscale scores were set as dependent variables, while changes in key glycemic and system metrics served as independent variables, adjusted for baseline characteristics. A p value of ≤ 0.05 was considered statistically significant.

3 | Results

Between February and April 2024, 36 participants were enrolled, aged 7–17 years (median 11.4, IQR 10.6–13.3). The majority of the cohort was thus younger, with fewer participants in the older adolescent range. 45.5% were female, and median diabetes duration was 6.9 years (IQR 4.2–8.7). No participants discontinued G7 during the study. At baseline, median BMI was 18.6 (IQR 17.5–21.6) and HbA1c was 6.43% (47 mmol/mol) (IQR 6.2%–6.8%).

3.1 | Glycemic and System Outcomes

The primary outcome, mean TCL, increased modestly but significantly from 97.9% ± 1.4% (Dexcom G6) to 98.7% ± 1.1% (Dexcom G7) (mean increase 0.8%, 95% CI 0.3–1.3; $p = 0.0018$, Cohen's $d = 0.63$). Glycemic outcomes improved significantly after the switch as shown in Table 1. Median TIR increased from 73.5% to 76.0% ($p = 0.034$, $d = 0.38$), and TITR increased from 47.5% to 52.5% ($p = 0.05$). Time spent in hyperglycemia decreased significantly, with time > 180 mg/dL falling from 24.0% to 18.0% ($p < 0.001$). No significant changes were observed in TBR. GMI improved from 7.2% to 6.8% ($p = 0.001$) and %CV decreased from 36% to 33% ($p = 0.001$). Baseline GMI (7.2%) was higher than HbA1c, likely reflecting the 3-week assessment window vs. 3-month average. No severe adverse events were reported. Notably, there were no discontinuations of G7 use or reversions to G6 during the study observation period.

TABLE 1 | Glycemic and system metrics before and after switching from Dexcom G6 to G7 ($n = 36$).

Metric	Dexcom G6	Dexcom G7	*p*
Time in closed loop (%)[a]	97.9 ± 1.4	98.7 ± 1.1	**0.0018**
Time in range (70–180 mg/dL, %)	73.5 (64.7; 71.2)	76.0 (65.5; 81.0)	**0.034**
Time in tight range (70–140 mg/dL, %)	47.5 (44.0; 58.0)	52.5 (44.5; 60.2)	**0.05**
Time above range (> 180 mg/dL, %)	24.0 (20.0; 28.0)	18.0 (14.0; 22.0)	**< 0.001**
Time in high hyperglycemia (> 250 mg/dL, %)	9.0 (4.0; 13.0)	4.0 (2.0; 6.0)	**< 0.001**
Time below range (54–70 mg/dL, %)	2.0 (1.0; 3.0)	2.0 (1.0; 4.0)	0.296
Time in low hypoglycemi a (< 54 mg/dL, %)	1.0 (0.0; 1.0)	1.0 (0.0; 1.0)	0.581
GMI (%)	7.2 (6.9; 7.4)	6.8 (6.6; 7.0)	**0.0062**
%CV	36.0 (33.0; 39.0)	33.0 (31.0; 36.0)	**0.001**

Note: All data are presented as median (IQR) unless otherwise noted. Bold values are the significant ones.
[a]Data for time in closed loop are presented as mean ± SD.GMI, glucose management indicator; %CV, coefficient of variation.

TABLE 2 | CGM satisfaction (CGM-SAT) subscale scores for youths and parents ($n = 35$).

Group	Subscale	G6 Score (Mean ± SD)	G7 Score (Mean ± SD)	*p*
Youths	Overall Score	4.36 ± 0.42	4.42 ± 0.39	0.61
	Benefits Score	4.42 ± 0.42	4.33 ± 0.43	0.08
	Hassles Score	4.29 ± 0.54	4.45 ± 0.52	**0.043**
Parents	Overall Score	4.39 ± 0.36	4.46 ± 0.29	0.28
	Benefits Score	4.48 ± 0.34	4.46 ± 0.37	0.77
	Hassles Score	4.30 ± 0.53	4.51 ± 0.40	**0.042**

Note: A higher score on the 'Hassles' subscale indicates fewer perceived hassles and a more positive outcome. Bold values are the significant ones.

3.2 | Patient-Reported Outcomes

The switch to Dexcom G7 significantly reduced perceived daily hassles for both youths ($p = 0.043$) and parents ($p = 0.042$) on the CGM-SAT questionnaire (Table 2). No significant changes were observed in the overall or benefits scores.

3.3 | Predictors of Improved User Experience

Regression analyses were performed to understand the drivers of improved user experience. For the 'hassles' subscale, the most significant predictor of improvement was the change in TITR ($\beta = 0.03$, $p = 0.007$), indicating that greater stability was associated with a reduction in perceived daily burden. Baseline hassles score and younger age also significantly predicted hassle reduction. For the 'benefits' subscale, the only significant predictor of improvement was the change in TCL ($\beta = 0.29$, $p = 0.045$), suggesting that individual increases in perceived benefits were associated with improvements in system uptime.

4 | Discussion

In this real-world study of high-performing children and adolescents, switching from Dexcom G6 to G7 was observed with a modest but statistically significant increase in TCL, which translated into tangible glycemic benefits without increasing hypoglycemia. The observed glycemic changes were modest in absolute terms, likely due to a ceiling effect in this highly optimized cohort. Therefore, the primary clinical value of the upgrade appears to be the significant reduction in user- and parent-reported hassles. This improvement is likely attributable to the G7's 30-min warm-up period and the 12-h grace period providing flexibility to change sensors without interrupting AID [1, 2, 6]. Even small increases in TCL can enhance AID algorithm efficacy. It is important to acknowledge, however, that some of the observed improvements in glycemic metrics, particularly the modest shift from the > 140 mg/dL range to below 140 mg/dL, could partly reflect inherent differences in how the two sensors measure and report glucose values, rather than solely indicating a true physiological improvement attributable to the system's performance with the Dexcom G7. This is a recognized limitation in studies comparing different CGM generations, even from the same manufacturer.

Our findings contrast with Akturk et al. who reported no significant changes in outcomes for adults transitioning to G7 [9]. This difference likely reflects those practical benefits of the G7's rapid warm-up and grace period are more pronounced in a paediatric population, whose unpredictable schedules and frequent sensor replacements make system downtime more disruptive. Crucially, clinical improvements were accompanied by a markedly enhanced user experience [10]. Our regression analyses provide insights into the mechanisms underlying the disconnect between modest objective glycemic gains and the

more pronounced subjective improvements. The improvement in 'hassles' was associated with increased stable glycemic profile (TITR). This suggests that perceived burden diminishes most when the system delivers more stable control, likely resulting in fewer alarms and less cognitive effort. The increase in perceived 'benefits' was associated with increased TCL, reflecting trust that the system is actively managing diabetes. This dual finding—that stable glycemic outcomes drive hassle reduction, while increased automation (higher TCL) drives benefit perception—is critical for understanding user satisfaction. It is important to note, however, that the effect sizes (beta coefficients of 0.03 for ΔTITR predicting ΔHassles and 0.29 for ΔTCL predicting ΔBenefits) are relatively small in magnitude, suggesting that while statistically significant, these factors contribute modestly to the overall change in perceived burden and benefits. This implies that other unmeasured variables may also play a substantial role in influencing user experience. It reinforces the idea that for a population already achieving high TCL, the primary value of an upgrade lies in making diabetes management less intrusive and more effectively stable [11]. While not presented as individual items, qualitative feedback and trends within the 'hassles' subscale suggested reduced perceptions of pain and technical interruptions among youths. For parents, the reduction in time is powerful, suggesting technology is becoming less intrusive, allowing families to reclaim time and mental energy [12]. The reduction in familial conflicts highlights how a less burdensome device can impact family dynamics [13]. It is noteworthy that the model for change in benefits had modest explanatory power ($R^2 = 0.25$), suggesting that unmeasured factors (e.g., aesthetics and reduced parental anxiety) likely contribute to the perception of benefits.

Limitations include the pre-post observational design (susceptible to Hawthorne and novelty effects) and lack of a control group. Furthermore, the short 3-week follow-up period does not assess long-term sustainability, as well as the sample size ($n = 36$), while statistically sufficient to detect the hypothesized glycemic changes in a paired analysis, is relatively small and may limit the broader generalizability of our patient-reported outcome findings. Potential confounders during this short period, such as seasonal effects, intercurrent illness, variations in physical activity, or school schedule changes, were not controlled for, and their impact cannot be fully excluded. Furthermore, it is important to note the potential mismatch between the CGM-SAT's validated 6-month recall period and our study's 3-week assessment window, which might affect the precise interpretation of satisfaction and burden scores, especially for capturing acute changes. Finally, our small sample of well-controlled participants limits generalizability due to the observed ceiling effect. These results should therefore be considered exploratory.

In conclusion, switching from Dexcom G6 to G7 in high-performing youth using the Tandem Control-IQ system is observed with modest but significant improvements in both system usability and glycemic outcomes, associated with increased TCL. Importantly, these technological benefits were associated with a markedly improved user experience. Our findings suggest that the primary value of this upgrade lies in reducing the daily burden of diabetes management, highlighting the critical importance of user-centric design in paediatric diabetes technology.

Author Contributions

A.E.S., I.R., R.B., MarM, and V.C. conceived the study, collected data, supervised data collection, and critically discussed the results. A.E.S. drafted the report. R.F. collected and analysed CGM-SAT questionnaire. E.G. performed statistical analysis of collected data and contributed to discussion. M.B., M.G.B., C.C., F.D.C., D.I., F.L., D.L.P., MadM, G.M., C.M., N.M., E.M., B.P., S.P., E.P., B.P., A.R., C.R., S.S., R.S., D.T., S.T., and A.Z. collected data, critically discussed the findings, revised the first draft, and approved the final draft of the manuscript. A.E.S. and I.R. wrote the final version of the report.

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The authors have nothing to report.

Conflicts of Interest

A.E.S. is on the advisory board of Abbott, Medtronic, Movi, Sanofi, Theras and University Bocconi; has received travel grants from Ypsomed and Abbott. I.R. has received grants to the author or organization from Sanofi and Medtronic, and personal fees (e.g., honoraria, consulting fees, lecture fees) from Sanofi, Theras, Menarini, and Movi. RF has received travel grants from Movi. M.B. has a master service agreement with Medtronic, received honoraria to speak at congress from Theras, and has been supported for attending meetings from Movi, Theras, Medtronic and Ypsomed. R.B. is on the advisory board for Metronic, Movi, Theras, Abbott, and Sanofi and received travel grants from Movi, Abbott, Theras, and Sanofi. F.L. has been supported for attending meetings from Movi and Ypsomed and is on an advisory board for Sanofi. MadM has been supported for attending meetings from Movi, Medtronic, Sanofi and received speaker's honoraria from Sanofi. MarM has received honoraria for lectures from Theras, Novo Nordisk, Ypsomed, and Medtronic, has been supported for attending meetings from Movi and Abbott, and has participated in data monitoring for Movi. E.M. has received payment to her department for educational events from Medtronic; travel grants from Movi, Abbott and Theras; and an advisory board from Sanofi. S.P. received travel grant and speaking honoraria from Movi. B.P. has received travel grant from Movi and speaker's honoraria from Movi. A.R. has received honoraria from Movi, Abbott, Eli Lilly, Medtronic, Theras, and Ypsomed for travel, attendance and for speaking at symposiums and conferences. C.R. is on the advisory board for Sanofi and received speaker's honoraria from Theras. R.S. is on the advisory board for Sanofi and received speaker's honoraria from Theras. E.G., M.G.B., C.C., F.D.C., D.I., D.L.P., G.M., C.M., N.M., B.P., E.P., S.S., D.T., S.T., A.Z., V.C. have no conflicts of interest to declare. All authors declare they have no conflict-of-interest to disclose related to the present study, its data collection, analysis, and presentation.

Peer Review

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