Received: 12 March 2025 | Revised: 12 April 2025 | Accepted: 21 April 2025

DOI: 10.1111/dom.16436

WILEY

RESEARCH LETTER

Omnipod 5 in children and adolescents with type 1 diabetes: Improved outcomes with fewer boluses

Davide Tinti MD[1] | Valeria Castorani MD[2] | Cecilia Nobili MD[1] | Barbara Felappi MD[3] | Elena Prandi MD[3] | Barbara Piccini MD[4] | Sonia Toni MD[4] | Marta Bassi MD[5] | Nicola Minuto MD[5] | Riccardo Bonfanti MD[6] | Francesca Di Candia MD[7] | Enza Mozzillo MD[7] | Marco Marigliano MD[8] | Claudio Maffeis MD[8] | Andrea Enzo Scaramuzza MD[9] | Ivana Rabbone MD[2]

[1]Centro di Diabetologia Pediatria, A.O. "Ospedale Infantile Regina Margherita", Torino, Italy

[2]Division of Pediatrics, Department of Health Sciences, University of Piemonte Orientale, Novara, Italy

[3]Department of Pediatrics, Spedali Civili di Brescia, Brescia, Italy

[4]Endocrinology and Diabetology Unit, Meyer University Children's Hospital IRCCS, Florence, Italy

[5]Pediatric Clinic, IRCCS Giannina Gaslini, Department of Neuroscience Rehabilitation Ophthalmology Genetics, Maternal and Child Health, University of Genoa, Genoa, Italy

[6]Diabetology Unit, Ospedale San Raffaele, Diabetes Research Institute of Milan, Milan, Italy

[7]Department of Translational Medical Science, Section of Pediatrics, Università degli Studi di Napoli Federico II, Naples, Italy

[8]Department of Surgery, Dentistry, Pediatrics and Gynecology, Section of Pediatric Diabetes and Metabolism, University and Azienda Ospedaliera Universitaria Integrata of Verona, Verona, Italy

[9]Department of Pediatrics, Ospedale Maggiore, ASST Cremona, Cremona, Italy

Correspondence
Andrea Enzo Scaramuzza, Pediatric Diabetes, Endocrinology and Nutrition, Division of Pediatrics, ASST Cremona, Cremona, Italy.
Email: a.scaramuzza@gmail.com

KEYWORDS: continuous glucose monitoring, CSII, glycaemic control, insulin pump therapy

1 | BACKGROUND

Automated insulin delivery (AID) systems – which integrate an insulin pump, continuous glucose monitoring (CGM), and a sophisticated algorithm to automate insulin delivery – have revolutionized the management of type 1 diabetes (T1D). AID systems aim to improve glycaemic control and reduce the burden of manual management, and numerous clinical trials have now demonstrated their safety and efficacy in different populations with T1D.[1–6]

The Omnipod 5 (OP5) system stands out as a tubeless system that further simplifies AID. The OP5 utilizes a model predictive control algorithm embedded within the Pod, which receives real-time CGM data and calculates insulin doses based on user-customizable glucose targets from 110 to 150 mg/dL and adjustable for different times of the day.[7]

Two pivotal trials of individuals aged 2 to 70 years with T1D have demonstrated the safety and efficacy of the OP5.[8,9] After 3 months of use, time in range (TIR) increased and low (<70 mg/dL) glucose values decreased in users.[8,9] These improvements were sustained for up to 2 years in trials,[10,11] and these results have been corroborated in real-world studies.[12]

Here we further explore the performance of the OP5 algorithm by specifically evaluating adolescents transitioning from a previous version (Omnipod Dash, OPD) without the algorithm.

2 | METHODS

This was a prospective, observational study of adolescents with T1D diagnosed according to American Diabetes Association (ADA) criteria.[13] Participants were recruited from the first Italian diabetes centres to pre-launch the OP5 system. Subjects previously using OPD

Davide Tinti and Valeria Castorani equally contributed to the paper.

with continuous glucose sensing (Dexcom G6™ or G7™ or FreeStyle Libre 3) for at least 1 year were recruited consecutively, whereas children and adolescents with T1D using multiple daily injections (MDI) or any other AID system were excluded.

The study was conducted in accordance with the Helsinki Declaration, and all data were anonymized. Ethics committee approval was not required, since the General Authorization to Process Personal Data for Scientific Research Purposes (authorization 9/2014) exempts retrospective archive studies that use identifier codes preventing subject re-identification. Following standard clinical practice, participants were initiated on the OP5 system. Baseline data were collected, including anonymized demographic information and previous glycaemic control data from the previous system. Participants were instructed on how to use the OP5 system and were followed up according to their scheduled appointments.

Key parameters were assessed at baseline and 7-, 14-, 21-, and 28 days post-initiation of the OP5 using data from CGM and the OP5 system. Time below range <54 mg/dL (TBR-2), time below range 55–69 mg/dL (TBR-1), time in range (TIR), time in tight range (TITR), time above range 180–250 mg/dL (TAR-1), time above range >250 mg/dL (TAR-2), mean sensor glucose, standard deviation (SD), coefficient of variation (CV), and sensor usage CGM data were collected. For OP5 insulin delivery, we collected the total daily dose (TDD) – specifying boluses, basal units and numbers, and overridden boluses – and auto mode percentage. Serious adverse events, including severe hypoglycaemia and diabetic ketoacidosis (DKA), were evaluated during follow-up.

Statistical analysis was performed using Jamovi v2.6. Data are normally distributed and expressed as mean ± standard deviation (SD). Changes in key parameters over time were assessed using repeated measures ANOVA. Post hoc pairwise comparisons between baseline and follow-up timepoints were conducted for each metric, and *p*-values were adjusted using Holm's correction for multiple comparisons. Multivariable linear regression was performed to identify predictors of TIR values at 28 days. *p*-values <0.05 were considered significant.

3 | RESULTS

Forty-four adolescents with T1D were enrolled in this pilot program. 47.7% were female, with a mean (SD) age of 15 (2.6) years and a mean diabetes duration of 9.1 (3.5) years. The mean baseline HbA1c was 7.18 (0.64%) (55 mmol/L). All participants had previously used OPD for a mean of 3.97 (2.65) years. The majority (80%) used the Dexcom G6 CGM, with 18% using the Dexcom G7 and 2% FreeStyle Libre 3. Data were collected from shared Glooko™ accounts between December 9, 2024 and January 6, 2025. Thirty patients (68.2%) had a target of 110 mg/dL and 14 (31.8%) had a target of 120 mg/dL. No episodes of DKA nor severe hypoglycaemia were reported during the observation period.

3.1 | CGM metrics

Repeated measures ANOVA showed a significant effect of time on all key glycaemic metrics following the transition to the OP5 system (Table 1). TIR increased significantly from baseline (55.1%), reaching 67.7% after 7 days ($p < 0.001$) and remaining stable for 3 weeks before rising to 69.0% at day 28 ($p = 0.022$) (Figure 1A). TITR followed a similar trend, increasing from 33.8% to 42.5% on day 7 ($p < 0.001$) and reaching 43.1% on day 28 ($p < 0.001$, compared with baseline; Figure 1B).

TBR-2 decreased significantly from 0.9% to 0.4% within the first week ($p < 0.001$) and remained stable thereafter. TBR-1 gradually reduced from 2.9% at baseline to 1.5% at day 28 ($p < 0.001$, compared with baseline). TAR-1 decreased from 26.9% to 21.8% at day 7 ($p < 0.001$) and significantly reduced from day 14 to day 28 (20.3%, $p = 0.028$). TAR-2 decreased from 14.2% to 7.7% at day 7 ($p < 0.001$), with a non-significant increase at day 14 (9.3%, $p = 0.294$) before decreasing to 8.7% at day 28 ($p = 0.078$).

CV decreased from 39.5% to 33.7% in the first week ($p < 0.001$) before a non-significant increase at day 14 (34.8%, $p = 0.276$), remaining stable thereafter. Mean sensor glucose decreased significantly in the first week, reaching a final value of 160 mg/dL at day 28 ($p < 0.001$).

Full results of all pairwise comparisons, including Holm-corrected *p*-values, are presented in Table S1.

3.2 | Insulin delivery

TDD decreased significantly after the first 7 days ($p = 0.007$) before gradually returning to baseline values by day 28 ($p = 0.99$). The percentage of basal insulin increased by 4.4% within the first week ($p = 0.017$), remaining stable and reaching 54.3% at day 28. Conversely, bolus insulin percentages decreased, reaching 45.3% at day 28 ($p = 0.005$ compared with baseline). Boluses decreased progressively from 5.6/day at baseline to 5.0/day at day 28, although significance was reached only between day 21 and day 28 ($p = 0.038$).

3.3 | Predictors of TIR values at 28 days

Multivariable linear regression analysis was performed to identify predictors of TIR 28 days after initiating OP5. The model included baseline HbA1c, insulin basal percentage, target used, and override percentage at 28 days. HbA1c ($\beta = -4.03$, $p = 0.019$) and glucose target ($\beta = -6.806$, $p = 0.003$) were independently associated with lower TIR.

4 | DISCUSSION

This observational study demonstrates that the transition from the OPD to the OP5 significantly improves glycaemic control

TABLE 1 Mean ± SD of each glycaemic metric across five timepoints. Global *p*-values refer to repeated measures ANOVA. Detailed post hoc comparisons with Holm correction are available in Table S1.

	Baseline	Day 7	Day 14	Day 21	Day 28	*p*-value
Mean glucose (mg/dL)	173 ± 20	160 ± 18.3	163 ± 18.6	163 ± 19	160 ± 16.4	<0.001
CV	39.5 ± 5.9	33.7 ± 5.4	34.8 ± 4.1	35.9 ± 4.3	34.8 ± 4.7	<0.001
TBR-2 (%)	0.9 ± 1.2	0.4 ± 0.7	0.3 ± 0.6	0.3 ± 0.6	0.4 ± 0.6	<0.001
TBR-1 (%)	2.9 ± 2.6	3.0 ± 11.1	1.5 ± 1.5	1.6 ± 1.6	1.5 ± 1.2	<0.001
TIR (%)	55.1 ± 11.2	67.7 ± 12.9	66.4 ± 910.0	66.8 ± 9.5	69.0 ± 9.9	<0.001
TITR (%)	33.8 ± 10.0	42.5 ± 11.5	41.4 ± 11.8	40.5 ± 11.7	43.1 ± 13.4	<0.001
TAR-1 (%)	26.9 ± 6.6	21.8 ± 7.3	22.4 ± 6.4	21.2 ± 5.0	20.3 ± 6.0	<0.001
TAR-2 (%)	14.2 ± 8.1	7.7 ± 6.5	9.3 ± 6.5	10.0 ± 7.2	8.7 ± 6.0	<0.001
Sensor usage (%)	95.8 ± 3.6	94.0 ± 9.9	92.7 ± 15.6	93.2 ± 14.5	93.3 ± 12.7	0.584
TDD (IU)	50.1 ± 14.3	45.9 ± 15.5	50.8 ± 16.1	52.1 ± 16.7	50.5 ± 16.1	<0.001
Bolus per day (IU)	26.3 ± 11.5	22.1 ± 9.5	23.8 ± 8.9	23.9 ± 8.8	23.1 ± 9.0	<0.001
Bolus per day (%)	51.3 ± 12.9	47.0 ± 10.6	46.4 ± 9.7	45.7 ± 7.6	45.3 ± 8.3	<0.001
Basal per day (IU)	24.0 ± 7.9	23.8 ± 8.4	27.0 ± 9.5	28.2 ± 9.7	27.4 ± 9.2	0.001
Basal per day (%)	48.7 ± 12.9	53.1 ± 10.6	53.6 ± 9.7	54.3 ± 7.6	54.8 ± 8.3	<0.001
Auto mode (%)		97.3 ± 12.2	96.4 ± 11.3	95.5 ± 8.4	96.5 ± 6.8	0.626
Bolus overrides (%)	11.0 ± 13.5	9.6 ± 13.5	10.4 ± 14.6	8.8 ± 12.7	9.0 ± 12.8	0.221
Boluses (*n*)	5.6 ± 2.2	5.5 ± 2.3	5.6 ± 2.5	5.4 ± 2.0	5.0 ± 1.8	0.105

Abbreviations: CV, coefficient of variation; TAR-1, time above range 180–250 mg/dL; TAR-2, time above range >250 mg/dL; TBR-1, time below range 55–69 mg/dL; TBR-2, Time below range <54 mg/dL; TDD, total daily dose; TIR, time in range; TITR, time in tight range.

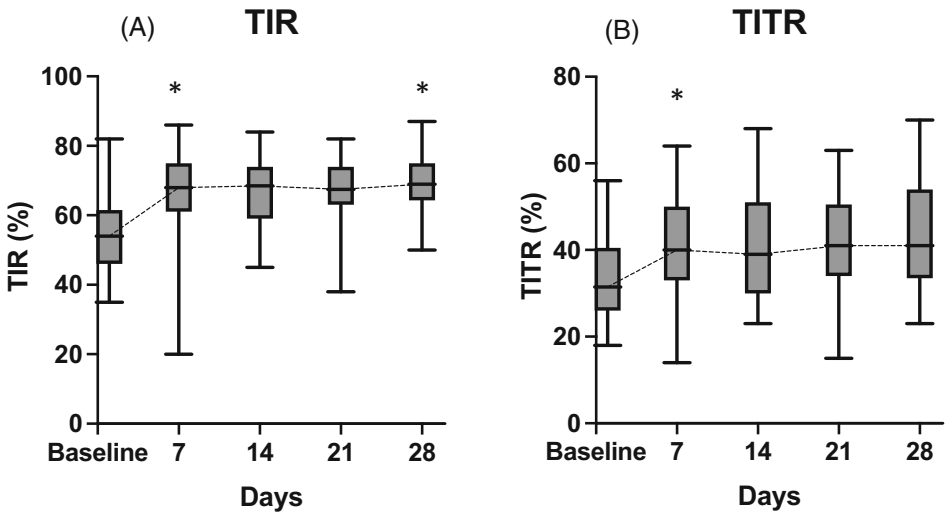

FIGURE 1 TIR (A) and TITR (B) values from baseline to week 4. Values are shown as boxplots. *$p < 0.05$ with repeated measures ANOVA.

among adolescents with T1D, despite reducing the number of user interactions (such as boluses) with the system. Notably, we observed a significant increase in TIR and TITR and reduced time spent in hypoglycaemia and hyperglycaemia. Moreover, the observed decrease in glucose variability highlights the potential of the OP5 to stabilize glucose levels and reduce the risk of glycaemic fluctuations. Most of these improvements were achieved rapidly, with significant changes observed within the first week and sustained throughout the 28-day observation period, probably related to increased automatic basal insulin delivery.

Within the limitations of this study (relatively small cohort, non-randomized), the OP5 system appears to represent a valuable tool for improving glycaemic control and simplifying diabetes management in adolescents with T1D. The observed benefits, including enhanced TIR (close to the 70% recommended in the 2019 International Consensus[14]), TITR, and reduced glucose variability despite a reduced number of boluses, highlight the potential of this system to improve clinical outcomes and quality of life in this population. Future studies with extended observation periods and larger sample sizes are warranted to evaluate the long-term effects of OP5 use and explore its impact on patient-reported outcomes.

AUTHOR CONTRIBUTIONS

IR, RB, MM, DT, and AES designed the study. CN and DT analysed the data. DT and VC wrote the first draft of the manuscript. AES critically discussed the results and wrote the final draft of the manuscript. All authors reviewed patient charts, collected data, critically revised the manuscript for important intellectual content, and approved the final version of the manuscript.

FUNDING INFORMATION

There was no formal funding to collect data or design, analyse, discuss, and write the study.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.16436.

DATA AVAILABILITY STATEMENT

Data are available upon resonable request from the corersponding author.

ORCID

Davide Tinti https://orcid.org/0000-0002-7265-9360
Valeria Castorani https://orcid.org/0000-0001-5024-0545
Cecilia Nobili https://orcid.org/0009-0001-5112-8982
Marco Marigliano https://orcid.org/0000-0002-3232-8807
Andrea Enzo Scaramuzza https://orcid.org/0000-0002-1518-8515
Ivana Rabbone https://orcid.org/0000-0003-4173-146X

REFERENCES

1. Brown SA, Kovatchev BP, Raghinaru D, et al. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Engl J Med*. 2019;381(18):1707-1717.
2. Tauschmann M, Thabit H, Bally L, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. *Lancet*. 2018;392(10155):1321-1329.
3. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA*. 2016;316(13):1407-1408.
4. Leelarathna L, Choudhary P, Wilmot EG, et al. Hybrid closed-loop therapy: where are we in 2021? *Diabetes Obes Metab*. 2021;23(3):655-660.
5. Nir J, Rachmiel M, Fraser A, et al. Open-source automated insulin delivery systems (OS-AIDs) in a pediatric population with type 1 diabetes in a real-life setting: the AWeSoMe study group experience. *Endocrine*. 2023;81(2):262-269.
6. Burnside MJ, Lewis DM, Crocket HR, et al. Open-source automated insulin delivery in type 1 diabetes. *N Engl J Med*. 2022;387(10):869-881.
7. Cobry EC, Berget C, Messer LH, Forlenza GP. Review of the Omnipod 5® automated glucose control system powered by Horizon™ for the treatment of type 1 diabetes. *Ther Deliv*. 2020;11:507-519.
8. Brown SA, Forlenza GP, Bode BW, et al. Multicenter trial of a tubeless, on-body automated insulin delivery system with customizable glycemic targets in pediatric and adult participants with type 1 diabetes. *Diabetes Care*. 2021;44(7):1630-1640.
9. Sherr JL, Bode BW, Forlenza GP, et al. Safety and glycemic outcomes with a tubeless automated insulin delivery system in very young children with type 1 diabetes: a single-arm multicentre clinical trial. *Diabetes Care*. 2022;45(8):1907-1910.
10. Criego A, Carlson AL, Brown S, et al. Two years with a tubeless AID system: a single-arm multicenter trial in children, adolescents, and adults with type 1 diabetes. *Diabetes Technol Ther*. 2024;26(1):11-23.
11. DeSalvo DJ, Bode B, Forlenza GP, et al. Glycemic outcomes persist for up to 2 years in very young children with the Omnipod® 5 automated insulin delivery system. *Diabetes Technol Ther*. 2024;26(6):383-393. doi:10.1089/dia.2023.0506
12. Forlenza GP, DeSalvo DJ, Aleppo G, et al. Real-world evidence of Omnipod® 5 automated insulin delivery system use in 69,902 people with type 1 diabetes. *Diabetes Technol Ther*. 2024;26(8):514-525. doi:10.1089/dia.2023.0578
13. American Diabetes Association Professional Practice Committee. Children and adolescents: standards of care in diabetes-2025. *Diabetes Care*. 2025;48(Supplement_1):S283-S305. doi:10.2337/dc25-S014
14. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care*. 2019;42:1593-1603.

SUPPORTING INFORMATION

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

How to cite this article: Tinti D, Castorani V, Nobili C, et al. Omnipod 5 in children and adolescents with type 1 diabetes: Improved outcomes with fewer boluses. *Diabetes Obes Metab*. 2025;27(8):4567-4570. doi:10.1111/dom.16436