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Safety and Efficacy of the Omnipod 5 Automated Insulin Delivery System in Adults With Type 2 Diabetes: From Injections to Hybrid Closed-Loop Therapy

Georgia M. Davis, Anne L. Peters, Bruce W. Bode, Anders L. Carlson, Bonnie Dumais, Todd E. Vienneau, Lauren M. Huyett, and Trang T. Ly

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POPULATION

24 patients with type 2 diabetes, mean age 61 years, & baseline HbA_{1c} ≥8%

Basal-bolus insulin users n=12

Basal-only insulin users n=12

STUDY DESIGN

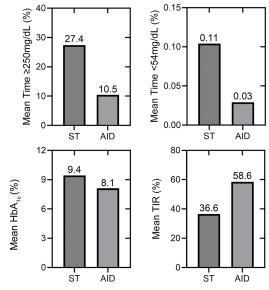
8-week single-arm outpatient study of automated insulin delivery

OUTCOMES

Primary: time with sensor glucose ≥250mg/dL and <54mg/dL

Secondary: HbA_{1c}, time in target range (70-180mg/dL)

RESULTS



Abbreviations: AID, automated insulin delivery; ST, standard therapy; TIR, time in range. Median Time <54mg/dL was 0.0% in ST and AID.

Results from this study in people with type 2 diabetes show that the use of the Omnipod 5 AID System in this population is not only possible, but that it is associated with improvement in key glycemic metrics.

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ARTICLE HIGHLIGHTS

- Automated insulin delivery (AID) has been studied extensively in people with type 1 diabetes, but few data exist on its use for type 2 diabetes.
- We tested the feasibility of the Omnipod 5 AID System in people with type 2 diabetes in a multicenter outpatient trial.
- Results showed that use of the AID system in this population is possible, and it is associated with remarkable improvement in key glycemic metrics.
- These preliminary results justify further evaluation of AID in type 2 diabetes, particularly for patients not meeting treatment goals or who are unsatisfied with their current insulin therapy.

Safety and Efficacy of the Omnipod 5 Automated Insulin Delivery System in Adults With Type 2 Diabetes: From Injections to Hybrid Closed-Loop Therapy

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ORIGINAL ARTICLE

OBJECTIVE

Automated insulin delivery (AID) has rarely been studied in adults with type 2 diabetes. We tested the feasibility of using AID for type 2 diabetes with the Omnipod 5 System in a multicenter outpatient trial.

RESEARCH DESIGN AND METHODS

Participants previously were using either basal-only or basal-bolus insulin injections, with or without the use of a continuous glucose monitor (CGM), and had a baseline HbA_{1c} ≥8% (≥64 mmol/mol). Participants completed 2 weeks of CGM sensor data collection (blinded for those not previously using CGM) with their standard therapy (ST), then transitioned to 8 weeks of AID. Participants who previously used basal-only injections used the AID system in manual mode for 2 weeks before starting AID. Antihyperglycemic agents were continued at clinician discretion. Primary safety outcomes were percentage of time with sensor glucose ≥250 mg/dL and <54 mg/dL during AID. Additional outcomes included HbA_{1c} and time in target range (TIR) (70–180 mg/dL).

RESULTS

Participants (*N* = 24) had a mean (± SD) age of 61 ± 8 years, baseline HbA_{1c} of 9.4% ± 0.9% (79 ± 10 mmol/mol), and diabetes duration of 19 ± 9 years. Percentage of time with sensor glucose ≥250 mg/dL decreased with AID by 16.9% ± 16.2% ($P < 0.0001$), whereas percentage of time at <54 mg/dL remained low during both ST and AID (median [interquartile range] 0.0% [0.00%, 0.06%] vs. 0.00% [0.00%, 0.03%]; $P = 0.4543$). HbA_{1c} (± SD) decreased by 1.3% ± 0.7% (14 ± 8 mmol/mol; $P < 0.0001$) and TIR increased by 21.9% ± 15.2% ($P < 0.0001$) without a significant change in total daily insulin or BMI with AID.

CONCLUSIONS

Findings from this feasibility trial of AID in adults with type 2 diabetes with suboptimal glycemic outcomes justify further evaluation of this technology in this population.

The management of type 2 diabetes has undergone a paradigm shift during the past decade, with treatment preferences moving toward increased use of noninsulin agents carrying additional benefits for the prevention of cardiorenal disease and promotion of weight loss (1–3). Despite the glycemic and nonglycemic benefits of these noninsulin

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agents, many people continue to require insulin injection therapy and still may not achieve the level of glycemic outcomes necessary to avoid diabetes-related complications and promote long-term health and quality of life (3–8).

Diabetes technology devices have been developed that can enable better and safer insulin therapy and glycemic management; however, their use has centered on the management of type 1 diabetes, with little data on use in type 2 diabetes despite a heavy disease burden (9–12). One of the recent advances in diabetes technology is automated insulin delivery (AID), the result of progressive integration of a continuous glucose monitor (CGM) and insulin pump therapy into algorithm-based systems capable of dynamic insulin infusion based on CGM values and trends. Many studies have shown efficacy and safety of AID in type 1 diabetes (13–16), but limited data exist on its use in type 2 diabetes. Nearly all trials to date in people with type 2 diabetes have focused on inpatient use of a fully closed loop AID system (no meal boluses needed) (17–21), with one short outpatient trial showing promising results with this system (22). Still, it is currently unknown whether AID will be safe or more effective than other therapies in this population, especially for those receiving less intensive insulin regimens. As management strategies evolve and adoption of technology increases among people with type 2 diabetes, there is a need to understand the potential role for AID in this setting.

The Omnipod 5 AID System is cleared by the U.S. Food and Drug Administration and has a CE (Conformite Européenne [European Conformity]) mark for people aged 2 years or older with type 1 diabetes. This system includes a tubeless, on-body device (Pod) that modulates insulin delivery every 5 min in response to sensor glucose values. This system is not currently cleared for use in type 2 diabetes and had never been tested in this population. Accordingly, we conducted an 8-week outpatient assessment of AID use with the Omnipod 5 System in a diverse population of adults with type 2 diabetes with suboptimal glycemic outcomes on either basal-bolus or basal-only insulin injections.

RESEARCH DESIGN AND METHODS

This was a single-arm, multicenter feasibility study conducted in the U.S. across four clinical sites between November 2020 and July 2021. The protocol was approved by a central institutional review board and relevant local review boards. The U.S. Food and Drug Administration approved an investigational device exemption. An independent medical monitor provided study oversight. The trial was registered at ClinicalTrials.gov (identifier NCT04617795).

Study Participants

Participants were recruited from the clinic populations of the four study sites to reflect general community endocrinology practice. Key eligibility criteria were as follows: aged 18–75 years old, diagnosed with type 2 diabetes, using insulin therapy by injection via either a basal-bolus or basal-only regimen, had no insulin pump use within 3 months of screening, and had an HbA_{1c} of 8.0–12.0% (64–108 mmol/mol). Recruitment was targeted to include an equal number of prior CGM users and those who were CGM-naive, and an equal number of basal-bolus and basal-only users, to ensure a more diverse and representative patient population. A key exclusion criterion was a history of severe hypoglycemia or diabetic ketoacidosis in the past 6 months (a complete list of criteria is given in Supplementary Table 1).

Study Design

This outpatient study consisted of a standard therapy phase followed by phases in which participants used the investigational device, which included a tubeless insulin pump with an embedded proprietary AID algorithm (Omnipod 5; Insulet Corporation, Acton, MA), an interoperable CGM (Dexcom G6; Dexcom Inc., San Diego, CA), and a mobile application (Omnipod 5 app) on a locked-down Android phone (23,24). The device can be used in either manual mode, during which it functions as a conventional insulin pump with preprogrammed basal rates, or automated mode, during which the algorithm delivers microboluses of insulin every 5 min using the current and predicted glucose values and the programmed target glucose value (from 110 mg/dL to 150 mg/dL in 10 mg/dL increments).

Participants were separated into two groups: group A (prior basal-bolus insulin injection users) or group B (prior basal-only insulin injection users). Some study procedures differed between the two groups, as outlined by the study flow diagram in Supplementary Fig. 1. First, both groups completed 2 weeks of their usual therapy (standard therapy phase), with data collection via the study CGM (Dexcom G6), which participants were fully trained to use. The study CGM was blinded during this phase for participants not already using Dexcom G6 for their diabetes management, although these participants could continue using their other glucose sensor during this time, if applicable. Data were collected until the sufficiency criteria were met (i.e., $>$80% CGM use during any consecutive 14 days in the past 30 days, with $\geq$2,016 CGM values during the 14 days). Participants already using Dexcom G6 before the trial could provide data meeting the sufficiency criteria from the previous month in lieu of wearing a blinded CGM. During the standard therapy phase, participants kept a 3-day diary of their insulin injections to determine average basal and bolus insulin amounts delivered per day and average number of injections, as applicable.

After the standard therapy phase, participants were fully trained on the use of the investigational device, with follow-up device support provided throughout the study as needed. Group A then immediately transitioned to 8 weeks of investigational device use in automated mode (the AID phase). Group B first completed 2 weeks using the investigational device in manual mode (i.e., fixed basal rate, no bolus, unblinded CGM not connected to investigational device) before transitioning to 8 weeks of use in automated mode. The target glucose level was determined in consultation between the participant and the clinician, with a recommended initial value of 120 mg/dL. Adjustments could be made throughout the study as needed (e.g., lowering or raising the target for those experiencing hyperglycemia or hypoglycemia, respectively [4]).

As part of this study, system performance was assessed without mandatory meal boluses and with a simplified meal-bolus approach. At the initiation visit, the investigational device was programmed so the user could select simplified boluses using three meal-size presets (i.e., small, medium, and large) tailored to each participant by investigator discretion depending on the usual number of carbohydrates

in their meals. Participants were advised to use these customized presets, in addition to the "Use CGM" option in the bolus calculator, which automatically added a correction bolus based on the current CGM reading. For the first 4 weeks of the AID phase, participants in both groups were advised that meal boluses were optional (optional bolus phase). For the second 4 weeks of the AID phase, group A participants were advised to bolus for all meals (simplified bolus phase). Any group B participants not achieving desired glycemic outcomes during the first 4 weeks of the AID phase (time in target range [TIR] of 70–180 mg/dL ≤50%) were also advised to bolus for all meals during the second 4 weeks of the AID phase; the remainder of participants could continue with the optional bolus strategy. For both groups, the meal-size presets and insulin to carbohydrate ratios could be adjusted throughout the study at investigator discretion.

Data on medical history, demographics, concomitant medications, height, weight, insulin doses, adverse events, device uploads, and other parameters were collected at various points throughout the study when participants attended screening and follow-up visits either online or over the phone. The HbA_{1c} value was collected at baseline and end of study via point-of-care or local laboratory testing. The complete visit schedule is shown in Supplementary Table 2. Reportable glycemia-related adverse events included severe hypoglycemic events (i.e., required assistance of another person, because of altered consciousness, to actively administer carbohydrate, glucagon, or other resuscitative actions, or otherwise resulted in a serious adverse event), hyperglycemic or ketotic events (involved diabetic ketoacidosis, treatment was sought from a health care provider or the clinical site, or otherwise resulted in a serious adverse event), and prolonged hyperglycemia (blood glucometer reading ≥300 mg/dL after CGM >300 mg/dL for 1 h or >250 mg/dL for 2 h). Additional safety procedures are included in Supplementary Material. At study completion, participants could elect to continue in an optional 6-month extension phase.

Participant satisfaction with the system was assessed at screening (in reference to their usual therapy) and after 8 weeks of AID via the Insulin Device Satisfaction Survey – Type 2 Diabetes (IDSS-T2D). The IDSS-T2D is used to understand patient satisfaction with the device and its impact on quality of life (25). The survey consists of 12 items categorized into three subscales: difficulty, usefulness, and freeing. A higher score indicates greater satisfaction for all measures except the difficulty subscale.

Outcomes

The primary objective was to evaluate system safety, assessed by the percentage of time with sensor glucose ≥250 mg/dL (level 2 hyperglycemia) and <54 mg/dL (level 2 hypoglycemia) during the 8-week AID phase (2). The secondary objective was to evaluate system efficacy by comparing various metrics during the AID phase with those during the standard therapy phase: percentage of time in glucose ranges <54 mg/dL, <70 mg/dL, 70–180 mg/dL, >180 mg/dL, and ≥250 mg/dL; mean, SD, and coefficient of variation of sensor glucose; and total daily dose of insulin. HbA_{1c}, BMI, and IDSS-T2D scores at the end of study were compared with baseline. System-use metrics were also assessed.

Statistical Methods

The sample size for the study was not hypothesis driven and was chosen to gather adequate safety and clinical performance data of the device algorithm in people with type 2 diabetes. The intent was to enroll up to 36 participants to obtain approximately 24 evaluable participants. Analyses were performed on a modified intention-to-treat data set of participants who entered the Omnipod 5 System–use phase of the study.

Continuous variables were summarized using descriptive statistics and frequencies, and percentages summarized categorical variables. Outcomes are summarized as mean and SD or as median and interquartile range (IQR) as appropriate, based on the observed distribution of the data. End points were stratified by study phase (standard therapy and AID phase) and by group (A and B). Safety and efficacy variables were compared between the standard therapy phase or baseline and the AID phase or end of study using paired *t* tests or Wilcoxon signed-rank tests for small sample sizes ($n < 10$) or if Shapiro-Wilk tests of normality were significant ($P < 0.05$). Statistical comparisons were conducted at a two-sided significance level of 5%.

RESULTS

Participants

The Consolidated Standards of Reporting Trials flow diagram is included in Supplementary Figure 2. Thirty-six participants consented, 11 did not meet eligibility criteria, and 25 were enrolled and completed the standard therapy phase. One participant was lost to follow-up after standard therapy. The other 24 entered the Omnipod 5–use phase and were included in the modified intention-to-treat data set. All 24 participants completed the study, and 22 (92%) elected to continue in the optional extension phase.

Characteristics of the participants at baseline are reported in Table 1. Participants were a mean age of 61 years, with mean diabetes duration of 19 years. Notably, most participants (96%) had never used an insulin pump previously, and about half (54%) had never used CGM. Most (92%) were taking at least one other diabetes medication, with half (54%) taking more than one (Supplementary Table 3). The study population was diverse in terms of race and ethnicity: less than half of participants (46%) were non-Hispanic White, 17% were Hispanic White, 33% were Black or African American, and 4% were Asian.

Glycemic Outcomes

Glycemic outcomes are displayed in Table 2. Percentage of time with sensor glucose ≥250 mg/dL decreased by a mean ± SD of 12.2% ± 13.3% and 21.6% ± 17.9% in group A and group B, respectively ($P = 0.0089$ and $P = 0.0015$). This decrease corresponds to 2.9 and 5.2 fewer hours in this range per day, respectively. Percentage of time with sensor glucose <54 mg/dL was low during both the standard therapy and AID phases: median (IQR) 0.03% (0.00%, 0.11%) with standard therapy vs. 0.02% (0.00%, 0.07%) with AID for group A ($P = 0.4922$), and 0.00% (0.00%, 0.00%) with standard therapy vs. 0.00% (0.00%, 0.01%) with AID for group B ($P = 1.0000$). Individual results for the primary safety outcomes are shown in Supplementary Fig. 3.

HbA_{1c} decreased significantly from baseline to the end of the 8-week AID phase, from a mean ± SD of 9.4% ± 0.9% (79 ± 10 mmol/mol) to 8.1% ± 0.7% (65 ± 8 mmol/mol; $P < 0.0001$). Group A had a mean ± SD decrease of 1.2% ± 0.7% (13 ± 8 mmol/mol; $P =$

Table 1—Characteristics at baseline of the study participants in the modified intention-to-treat data set

Characteristic	Group A (basal-bolus injection)	Group B (basal injection)	Overall
N	12	12	24
Age (years)†	61.8 ± 8.9	59.4 ± 7.5	60.6 ± 8.1
Duration of diabetes (years)	20 ± 10	18 ± 8	19 ± 9
BMI (kg/m^2)	35.2 ± 4.5	31.9 ± 3.8	33.5 ± 4.4
Female sex, *n* (%)	6 (50)	6 (50)	12 (50)
Race/ethnicity, *n* (%)§			
White	6 (50)	9 (75)	15 (63)
Hispanic or Latino	2 (17)	2 (17)	4 (17)
Not Hispanic or Latino	4 (33)	7 (58)	11 (46)
Black or African American	5 (42)	3 (25)	8 (33)
Asian	1 (8)	0 (0)	1 (4)
HbA_{1c} (%)	9.4 ± 1.0	9.5 ± 0.8	9.4 ± 0.9
HbA_{1c} (mmol/mol)	79 ± 11	80 ± 9	79 ± 10
Daily insulin dose (units/day)‖	92.4 ± 44.0	30.6 ± 21.9	61.5 ± 46.4
Short-acting insulin boluses per day, *n*	2.9 ± 0.7	0.0 ± 0.0	1.6 ± 1.5
No previous¶ or current continuous glucose monitor use, *n* (%)	6 (50)	7 (58)	13 (54)
No previous¶ or current pump use, *n* (%)	11 (92)	12 (100)	23 (96)

Data are reported as mean ± SD unless otherwise indicated. †Age was determined at the date of informed consent. §Race and ethnicity were reported by the participants and are displayed exactly as reported. ‖Baseline total daily insulin dose was determined from 3 days of data collected during the standard therapy phase. ¶Previous use is defined as having used the device for any duration in the past.

0.0001), whereas group B had a decrease of 1.4% ± 0.7% (15 ± 8 mmol/mol; $P <$ 0.0001). Nearly all participants experienced a decrease in HbA_{1c} (Fig. 1 and Supplementary Fig. 4). Mean TIR ± SD increased from 36.6% ± 19.6% to 58.6% ± 15.9% ($P < 0.0001$), corresponding to an additional 5.3 h/day in target range. Group A had a mean ± SD increase of 17.8% ± 15.2% ($P = 0.0019$), whereas group B had an increase of 26.1% ± 14.6% ($P <$ 0.0001). Similar to HbA_{1c}, nearly all participants experienced an increase in TIR during the AID phase (Fig. 1).

The increase in TIR was achieved primarily through a reduction of time in hyperglycemia >180 mg/dL, which decreased by a mean ± SD of 17.0% ± 15.5% ($P = 0.0030$) for group A and 25.9% ± 14.6% ($P < 0.0001$) for group B. Time in hypoglycemia <70 mg/dL decreased in group A by a median of 0.27% ($P = 0.0210$) and remained low in group B (median 0.01% vs. 0.04% in standard therapy vs. AID; $P = 0.5693$). In particular, two participants in group A and one in group B had >1% time at <70 mg/dL with their prior therapy; all three saw substantial decreases with AID (Fig. 1). Glycemic outcomes stratified between daytime (0600–2400 h) and overnight (0000–0600 h) periods are included in Supplementary Table 4. Figure 1 shows the median glucose profile over the 24-h period, illustrating the decrease in mean glucose level that was experienced with AID both during the daytime and overnight hours.

Glycemic outcomes stratified by concurrent use of sodium-glucose cotransporter-2 (SGLT-2) inhibitors and/or glucagon-like peptide 1 receptor agonists (GLP-1 RAs) during the AID phase are presented in Supplementary Table 5. For those using these medications ($n = 14$), HbA_{1c} decreased by a mean ± SD of 1.5% ± 0.7% (16 ± 8 mmol/mol), from 9.4% ± 1.0% (79 ± 11 mmol/mol) to 7.9% ± 0.8% (63 ± 9 mmol/mol; $P < 0.0001$), and TIR increased by 24.5% ± 14.9%, from 37.8% ± 21.6% to 62.3% ± 17.6% ($P < 0.0001$). For those not using these medications ($n = 10$), HbA_{1c} decreased by a mean ± SD of 1.1% ± 0.8% (12 ± 9 mmol/mol), from 9.5% ± 0.7% (80 ± 8 mmol/mol) to 8.4% ± 0.5% (68 ± 6 mmol/mol; $P =$ 0.0016), and TIR increased by 18.3% ± 15.5%, from 35.0% ± 17.4% to 53.3% ± 11.9% ($P = 0.0047$).

Glycemic outcomes stratified by previous CGM experience are presented in Supplementary Table 6. For those with ($n = 11$) and without ($n = 13$) prior CGM experience, HbA_{1c} decreased by a mean ± SD of 1.3% ± 0.8% (14 ± 9 mmol/mol; $P = 0.0002$) and 1.3% ± 0.7% (14 ± 8 mmol/mol; $P < 0.0001$), and TIR increased by a mean ± SD of 21.6% ± 15.7% ($P = 0.0010$) and 22.2% ± 15.4% ($P = 0.0002$), respectively.

To facilitate comparison of system use between those with type 1 and type 2 diabetes, select outcomes from adults (aged ≥18 years) with type 1 diabetes with baseline HbA_{1c} ≥8% (≥64 mmol/mol) using the same AID algorithm in a 3-month outpatient trial (16) are presented in Supplementary Table 7.

Weight Change and Insulin Use

Insulin use and weight outcomes are included in Table 2. BMI was unchanged from baseline to end of study for both groups ($P \geq 0.05$). For group A, insulin use decreased with AID by a mean ± SD 29.3 ± 26.9 units/day ($P = 0.0030$), corresponding to a 32% decrease. For group B, the mean change in insulin use was strongly affected by a single outlier; thus, it is most appropriate to refer to the median (IQR) change of −0.1 units/day (−7.5, 17.2; $P = 0.5693$), showing no clear pattern of increase or decrease of insulin dose with AID. The amount of insulin used during the AID phase spanned a wide range, from 5.4 to 127.9 units/day. Insulin

Table 2—Primary and secondary safety and efficacy outcomes (*N* = 24)

	ST‡ (2 weeks)	AID (8 weeks)	Change	*P* value
Primary outcomes				
Percentage of time in ranges				
<54 mg/dL glucose				
Group A	0.03 [0.00, 0.11]	0.02 [0.00, 0.07]	0.00 [−0.11, 0.01]	0.4922‖
Group B	0.00 [0.00, 0.00]	0.00 [0.00, 0.01]	0.00 [0.00, 0.01]	1.0000‖
Overall	0.00 [0.00, 0.06]	0.00 [0.00, 0.03]	0.00 [−0.02, 0.01]	0.4543‖
≥250 mg/dL glucose				
Group A	21.5 ± 16.8	9.3 ± 5.6	**−12.2 ± 13.3**	**0.0089**§
Group B	33.3 ± 23.8	11.7 ± 11.3	**−21.6 ± 17.9**	**0.0015**§
Overall	27.4 ± 21.0	10.5 ± 8.8	**−16.9 ± 16.2**	**<0.0001**‖
Secondary outcomes				
HbA_{1c} (%)				
Group A	9.4 ± 1.0	8.1 ± 0.8	**−1.2 ± 0.7**	**0.0001**§
Group B	9.5 ± 0.8	8.1 ± 0.6	**−1.4 ± 0.7**	**<0.0001**§
Overall	9.4 ± 0.9	8.1 ± 0.7	**−1.3 ± 0.7**	**<0.0001**§
HbA_{1c} (mmol/mol)				
Group A	79 ± 11	65 ± 9	**−13 ± 8**	**0.0001**§
Group B	80 ± 9	65 ± 7	**−15 ± 8**	**<0.0001**§
Overall	79 ± 10	65 ± 8	**−14 ± 8**	**<0.0001**§
Mean sensor glucose (mg/dL)				
Group A	199 ± 33	176 ± 17	**−24 ± 26**	**0.0085**§
Group B	225 ± 41	182 ± 25	**−43 ± 32**	**0.0008**§
Overall	212 ± 38	179 ± 21	**−33 ± 30**	**<0.0001**§
SD of sensor glucose (mg/dL)				
Group A	58 ± 18	48 ± 9	**−10 ± 12**	**0.0005**‖
Group B	61 ± 16	50 ± 14	**−12 ± 18**	**0.0456**§
Overall	60 ± 17	49 ± 11	**−11 ± 15**	**<0.0001**‖
CV of sensor glucose (%)†				
Group A	29 ± 7	27 ± 4	−2 ± 5	0.2040§
Group B	28 ± 7	27 ± 5	−1 ± 7	0.7668§
Overall	28 ± 7	27 ± 4	−1 ± 6	0.2981§
Percentage of time in ranges				
<70 mg/dL glucose				
Group A	0.31 [0.06, 0.66]	0.10 [0.03, 0.29]	**−0.27 [−0.47, −0.05]**	**0.0210**‖
Group B	0.01 [0.00, 0.24]	0.04 [0.02, 0.07]	0.01 [−0.18, 0.03]	0.5693‖
Overall	0.13 [0.00, 0.51]	0.06 [0.02, 0.15]	**−0.08 [−0.41, 0.02]**	**0.0142**‖
70–180 mg/dL glucose				
Group A	42.8 ± 20.4	60.5 ± 14.3	**17.8 ± 15.2**	**0.0019**§
Group B	30.5 ± 17.4	56.6 ± 17.7	**26.1 ± 14.6**	**<0.0001**§
Overall	36.6 ± 19.6	58.6 ± 15.9	**21.9 ± 15.2**	**<0.0001**§
>180 mg/dL glucose				
Group A	56.3 ± 20.6	39.3 ± 14.3	**−17.0 ± 15.5**	**0.0030**§
Group B	69.2 ± 17.6	43.3 ± 17.7	**−25.9 ± 14.6**	**<0.0001**§
Overall	62.8 ± 19.9	41.3 ± 15.9	**−21.4 ± 15.4**	**<0.0001**§
≥300 mg/dL glucose				
Group A	8.8 ± 9.1	2.2 ± 1.8	**−6.6 ± 7.8**	**0.0138**§
Group B	16.0 ± 17.3	4.3 ± 5.9	**−11.7 ± 14.0**	**0.0015**‖
Overall	12.4 ± 14.0	3.2 ± 4.4	**−9.2 ± 11.4**	**<0.0001**‖
Insulin use (units)				
Group A	92.4 ± 44.0; 89.5 [55.0, 118.2]	63.1 ± 26.4; 72.3 [37.9, 86.7]	**−29.3 ± 26.9; −26.3 [−35.0, −16.1]**	**0.0030**§
Group B	30.6 ± 21.9; 25.0 [17.5, 34.0]	42.1 ± 38.4; 29.5 [14.5, 66.4]	11.5 ± 33.4; −0.1 [−7.5, 17.2]	0.5693‖
Overall	61.5 ± 46.4; 49.2 [25.0, 90.0]	52.6 ± 34.0; 42.2 [23.7, 86.6]	−8.9 ± 36.2; −8.8 [−26.3, 3.9]	0.0708‖
BMI (kg/m^2)				
Group A	35.2 ± 4.5	35.5 ± 4.6	0.3 ± 0.9	0.2795§
Group B	31.9 ± 3.8	32.4 ± 3.6	0.5 ± 1.7	0.3260§
Overall	33.5 ± 4.4	33.9 ± 4.3	0.4 ± 1.3	0.1487‖

Data reported as mean ± SD and median [IQR]. To convert the values for glucose to mmol/L, multiply by 0.05551. Values that are statistically significant are highlighted in bold. CV, coefficient of variation; ST, standard therapy. †The coefficient of variation of sensor glucose is calculated as SD divided by the mean. ‡Baseline and follow-up data were used for the outcome of HbA_{1c}; the remaining outcomes are described for the ST phase and the AID phase. §Unadjusted *P* value was determined using two-sided paired *t* tests. ‖Unadjusted *P* value was determined using two-sided Wilcoxon signed-rank tests.

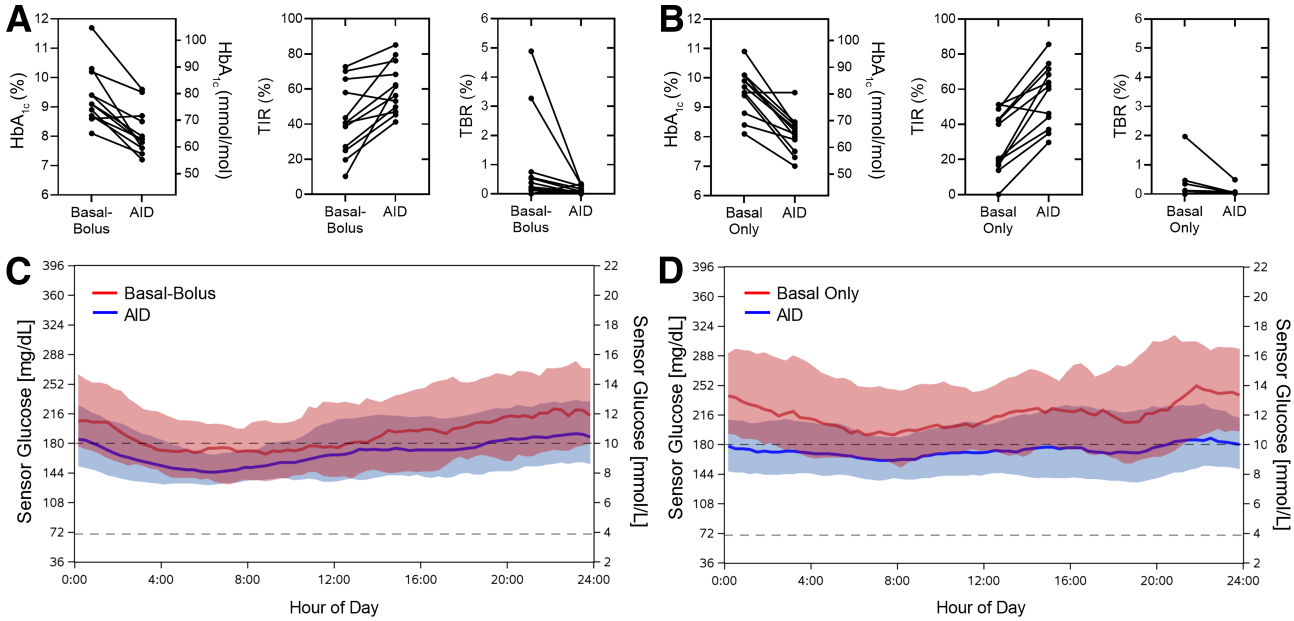

Figure 1—Individual level and group level glycemic response to AID by baseline insulin regimen. *A* and *B:* Individual efficacy outcomes showing HbA_{1c} (left), percentage TIR 70–180 mg/dL (middle), and percentage time below range (TBR) (<70 mg/dL) (right) for prior basal-bolus injection users ($n = 12$) (*A*) and prior basal-only injection users ($n = 12$) (*B*). Each set of circles connected by a line indicates the results of a single person with their prior therapy and with 8 weeks of the Omnipod 5 AID System. *C* and *D*: Median sensor glucose measurements across participants in group A ($n = 12$) (*C*) and group B ($n = 12$) (*D*) by time of day during the AID phase (blue line) and the standard therapy phase (red line), with blue and red shaded areas indicating the IQR for each phase. The target range (70–180 mg/dL) is indicated by black dashed lines. Measurements represent a 24-h period from midnight to midnight.

use outcomes divided between basal (algorithm-directed) and bolus (user-directed) delivery are included in Supplementary Table 8. When compared with a similar group of users with type 1 diabetes (Supplementary Table 7), the algorithm-directed insulin delivery (excluding user-initiated boluses) was similar: 30.1 units/day (18.7, 47.5) over 8 weeks of use in adults with type 2 diabetes, compared with 32.4 units/day (22.0, 39.8) over 3 months in adults with type 1 diabetes.

In group A, participants delivered a mean ± SD of 3.1 ± 1.1 boluses/day during the optional bolus phase ($n = 12$) (Supplementary Fig. 1) and 3.2 ± 1.3 boluses/day during the simplified bolus phase ($n = 12$). In group B, participants delivered a mean ± SD of 1.9 ± 1.6 boluses/day during the optional bolus phase ($n = 12$) and 2.1 ± 1.3 boluses/day during the simplified bolus phase ($n = 6$). Of note, three participants in group B did not deliver any boluses throughout the entire study. Because there was not a clinically meaningful difference in the number of boluses delivered in the optional bolus phase versus the simplified bolus phase, results were not compared between the two phases.

Psychosocial Outcomes

The results of the IDSS-T2D questionnaire are shown in Table 3. The overall score increased by 0.68 (± 0.82 SD), from 3.53 ± 0.67 to 4.20 ± 0.63 ($P = 0.0005$), corresponding to an effect size of 0.83, indicating a significant improvement in insulin delivery satisfaction for participants with AID. Participants also saw a significant improvement in the three subscales overall (difficult, $P = 0.0200$; useful, $P = 0.0025$; freeing, $P = 0.0011$). Similar trends were observed when stratifying by group, except group B did not have a significant improvement in the difficult subscale.

Safety Outcomes

There were no serious adverse events related to the study device or procedures during use of the Omnipod 5 System (Supplementary Table 9). There was one episode of hyperglycemia during which the participant contacted the site for guidance and three episodes of prolonged hyperglycemia. There was one unrelated serious adverse event (cardiovascular disorder resulting in hospitalization) and one other adverse event (a positive COVID-19 diagnosis).

System Use

The system was in automated mode for a median (IQR) of 96.0% (88.8, 97.6) of time for group A, 92.4% (79.4, 95.8) of time for group B, and 94.4% (87.9, 96.7) of time overall. The 110 mg/dL, 120 mg/dL, and 130 mg/dL targets were used for 57%, 21%, and 21% of cumulative study time for group A and 51%, 37%, and 9% for group B, respectively. There were 37 device deficiencies (e.g., occlusion alert, unable to pair Pod, sensor or transmitter failure): 15 related to the Pod, 5 related to the handheld device, 12 related to the CGM transmitter, and 5 related to the CGM sensor.

CONCLUSIONS

Results from this outpatient feasibility study in a diverse group of people with type 2 diabetes show that use of the Omnipod 5 AID System in this population not only was possible but that it was associated with remarkable improvement in key glycemic metrics. Importantly, this study included people using basal-only injections as well as those using basal-bolus injections, with continuation of other relevant noninsulin medications for type 2 diabetes. Participants in both groups experienced significant improvements in TIR and spent less time with glucose values ≥250 mg/dL, with an overall reduction in HbA_{1c} by 1.3% (14 mmol/mol) without an increase in the incidence of hypoglycemia <54 mg/dL. In fact, the prior basal-bolus injection group experienced less

Table 3—IDSS-T2D version results

Questionnaire	*N*	Score range (optimal score)	Baseline	8 weeks of AID	Change	*P* value	Cohen *d* value*
Combined A+B							
IDSS, overall	24	1 to (5)	3.53 ± 0.67; 3.50 [3.04, 3.92]	4.20 ± 0.63; 4.38 [3.71, 4.71]	**0.68 ± 0.82; 0.46 [0.13, 1.21]**	**0.0005**†	0.83
Difficult	24	(1) to 5	2.20 ± 0.69	1.76 ± 0.79	**−0.44 ± 0.86**	**0.0200**†	0.51
Useful	24	1 to (5)	3.56 ± 0.78	4.32 ± 0.70	**0.76 ± 1.10**	**0.0025**†	0.69
Freeing	24	1 to (5)	3.22 ± 0.89	4.05 ± 0.68	**0.83 ± 1.09**	**0.0011**†	0.76
Group A							
IDSS, overall	12	1 to (5)	3.48 ± 0.68; 3.50 [2.92, 3.92]	4.33 ± 0.65; 4.63 [3.92, 4.71]	**0.85 ± 1.00; 0.88 [0.17, 1.58]**	**0.0134**†	0.85
Difficult	12	(1) to 5	2.29 ± 0.72	1.48 ± 0.66	**−0.81 ± 0.75**	**0.0033**†	1.08
Useful	12	1 to (5)	3.50 ± 0.80	4.35 ± 0.81	**0.85 ± 1.29**	**0.0419**†	0.66
Freeing	12	1 to (5)	3.23 ± 0.97	4.10 ± 0.71	**0.88 ± 1.37**	**0.0492**†	0.64
Group B							
IDSS, overall	12	1 to (5)	3.58 ± 0.68; 3.50 [3.08, 3.83]	4.08 ± 0.60; 4.00 [3.71, 4.58]	**0.51 ± 0.60; 0.25 [0.13, 0.92]**	**0.0141**†	0.85
Difficult	12	(1) to 5	2.10 ± 0.68	2.04 ± 0.84	−0.06 ± 0.81	0.7949†	0.07
Useful	12	1 to (5)	3.63 ± 0.80	4.29 ± 0.60	**0.67 ± 0.92**	**0.0288**†	0.73
Freeing	12	1 to (5)	3.21 ± 0.84	4.00 ± 0.68	**0.79 ± 0.78**	**0.0010**‡	1.01

Data are reported as mean ± SD or median [IQR]. Values that are statistically significant are highlighted in bold. *Cohen *d* value is calculated as the mean change divided by the SD of the change. †*P* value determined using unadjusted two-sided paired *t* tests, unless otherwise specified. ‡Two-sided Wilcoxon signed rank tests were used for IDSS Freeing subscale for group B.

time in hypoglycemia <70 mg/dL with AID. These improvements were achieved alongside lower insulin requirements for prior basal-bolus injection users, and BMI did not increase in either group.

Despite the availability of an increasing number of noninsulin medications for type 2 diabetes, many people will eventually require insulin therapy to achieve adequate glycemic control and promote long-term health (1). The initiation and intensification of insulin therapy can be cumbersome and may result in limited adherence or the use of fixed insulin dosing for regimen simplification. This type of insulin delivery can be imprecise for any given situation and not easily adjusted for changes in routine, such as exercise, that may significantly affect glycemia, which may explain the observed decrease in insulin requirements with AID for prior basal-bolus injection users in this study (3).

AID has the potential to allow for intensification of therapy to drive improvements in glycemia without a compensatory increase in hypoglycemia or weight gain. This technology combines the benefits of CGM, which allows users to gain a better understanding of their daily glucose levels (26), with continuous insulin delivery that is automatically tailored to the current situation using real-time glucose data and insulin delivery history. Several studies have demonstrated the feasibility of a fully closed-loop AID system for people with type 2 diabetes in the inpatient environment (17–21), with one outpatient trial with 26 patients undergoing hemodialysis showing that use of the system over 20 days significantly reduced time in hypoglycemia and severe hyperglycemia (22).

Our study expands knowledge of AID use in the outpatient setting in patients with insulin-requiring type 2 diabetes with diverse backgrounds and limited previous device exposure who were not achieving adequate glycemic outcomes. The benefits of this AID system have been demonstrated in adults with type 1 diabetes (16); yet, whether the same AID algorithm could extend to the type 2 diabetes population is of interest. Results from this feasibility study show that the glycemic outcomes achieved were nearly indistinguishable from those achieved in a comparable group of adults with type 1 diabetes. Algorithm-directed insulin delivery was also similar between the two groups. These results suggest that not only can the same algorithm be safely used in both populations but also that the AID system can deliver the same level of success in type 2 diabetes that health care providers have come to expect for those with type 1 diabetes. Additionally, insulin delivery satisfaction increased and most participants (92%) opted to continue device use during an extension phase, suggesting that benefits of AID include psychosocial components beyond improvements in glycemic outcomes. User satisfaction is a critical metric because even the most effective treatment will not be continued if it is too difficult for the user to incorporate into their daily life.

Unlike in type 1 diabetes, candidates for AID with type 2 diabetes may often be using other glucose-lowering medications. GLP-1 RAs and SGLT-2 inhibitors have shown compelling results; thus, it is of interest to know whether those medications can be used in combination with AID and whether AID would provide any additional benefit in those already using these medications. Our results showed that those using these medications experienced significant benefits, including a reduction in mean HbA_{1c} to 7.9% (63 mmol/mol) and an increase in mean TIR to 62.3%. Although those not using these medications also experienced substantial improvements, these results suggest that those using AID in conjunction with GLP-1 RAs and/or SGLT-2 inhibitors may experience greater benefit than those not using these medications; however, additional research is needed to confirm whether this trend is reproducible. These outcomes are not surprising; several studies have already investigated the use of GLP-1 RAs and SGLT-2 inhibitors

alongside AID in people with type 1 diabetes, with promising results reported (27–29).

Limitations of this feasibility study include a small sample size and the lack of a control group to assess the impact of AID under research conditions. Further evaluation of how this AID system functions in a real-world setting with a usual frequency of health care provider interactions is also needed. Although these preliminary results demonstrated that initiation of this AID system improved glycemia without a significant increase in weight, larger and longer-term studies are required to assess the durability of these benefits. Lastly, given the short intervention time of this study, HbA_{1c} results could be underestimated and should be interpreted with caution.

A particular strength of this study was the inclusion of participants using either basal-bolus or basal-only injection therapy, most without prior pump experience, and allowing the continuation of other antihyperglycemic agents, thus increasing the anticipated generalizability of our results. Still, additional study is required to understand how results may differ in groups not included in our study. Because similar improvements in glycemic outcomes were seen in participants with or without previous CGM experience, the benefits seen were likely not just due to CGM initiation but rather were due to the added insulin automation. However, these results should be interpreted with caution because of the small sample sizes. Lastly, an important strength was the inclusion of a diverse population in terms of race and ethnicity despite it being a small study. This inclusion is critical given the disproportionate impact of type 2 diabetes on minority populations in the U.S. and the racial and ethnic disparities that exist in treatment outcomes as well as in representation in clinical research of therapies that may improve outcomes (30).

The use of the Omnipod 5 System among people with type 2 diabetes from diverse backgrounds, with variable device exposure and widely varying insulin requirements, was safe and effective. The preliminary estimates generated from this study justify further evaluation of this approach in type 2 diabetes, particularly in those not meeting treatment goals or who are unsatisfied with their current insulin therapy.

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