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RESEARCH ARTICLE

Treatment

Impact of Simplera Sync™ sensors and Extended™ Wear Infusion Sets on glycaemia and system performance of the MiniMed™ 780G system in children and young adults with previously high HbA1c

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Abstract

Aims: The MiniMed™ 780G improves glycaemia and reduces burden in type 1 diabetes. We investigated how new all-in-one "Simplera Sync™" sensors and 7-day Extended™ Wear Infusion Sets (EIS) affect glycaemia and system performance in young people with previously elevated HbA1c levels (≥69 mmol/mol [≥8%]) after transitioning from 780G with Guardian 4™ sensors and 3-day infusion sets.

Methods: We conducted an extension phase analysis in 75 participants (aged 7–25 years) initially enrolled in the CO-PILOT randomised controlled trial. For this analysis, baseline was defined as the period following the use of 780G with Guardian 4™ sensors and 3-day infusion sets. Participants then transitioned to 780G with Simplera Sync™ and EIS. We compared glycaemic and system performance outcomes from baseline to those after the transition to 780G with Simplera Sync™ and EIS.

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Results: Baseline HbA1c was 66.1 mmol/mol ± 14.2 mmol/mol and remained stable at 66.7 mmol/mol ± 11.2 mmol/mol after the transition ($p = 0.38$). Time in range (3.9–10.0 mmol/L [70–180 mg/dL]) at baseline was 58.5% ± 14.9% and 60.4% ± 15.7% after transition ($p = 0.09$). Time in tight range (3.9–7.8 mmol/L [70–140 mg/dL]) increased from 38.1% ± 13.1% at baseline to 40.5% ± 13.6% after the transition ($p = 0.04$). While using 780G with Simplera Sync™ and EIS, automation time increased from baseline 79.2% ± 25.9% to 85.8% ± 21.8% ($p = 0.007$), and sensor wear time from 80.7% ± 22.4% at baseline to 88.4% ± 17.2% ($p < 0001$).

Conclusions: Simplera Sync™ and EIS improved time in automation and sensor wear time when using 780G AHCL in this high-risk young population. This was associated with incremental improvement in time in tight range despite the challenges of this population.

KEYWORDS

advanced hybrid closed loop, artificial pancreas, glycaemia, system performance, type 1 diabetes, youth

1 | INTRODUCTION

Diabetes technology is continuously evolving to improve glycaemia and psychosocial outcomes for people with type 1 diabetes (T1D). Advanced hybrid closed-loop (AHCL) systems, also known as automated insulin delivery or artificial pancreas, have revolutionised T1D management.[1] The MiniMed™ 780G AHCL system (Medtronic, Northridge, California) has been extensively tested in people with T1D, showing substantial improvements in glycaemia, even for those who are seen as "high risk" for technology failure.[1,2] With the goal of improving outcomes and burden in users of this system, more recently the all-in-one continuous glucose monitoring system (CGM) Simplera Sync™ and a 7-day Extended™ Wear Infusion Set (EIS) have become available.

Participant-reported benefits were noted during the transition from previous calibration requiring calibration-free sensors while using this AHCL system.[3] However, there are limited data comparing outcomes following the transition from Guardian 4™ sensors and traditional 3-day infusion sets to the next-generation options of Simplera Sync™ sensors and EIS.[4] More research is required in larger studies to investigate glycaemic and system performance outcomes following the implementation of Simplera Sync™ and EIS, particularly in more complex populations.

Therefore, we conducted an analysis during the extension phase of the recently published CO-PILOT trial, where participants transitioned from 780G with Guardian 4™ and 3-day infusion sets to 780G with Simplera Sync™ and EIS.[1]

What is already known?

- Automated insulin delivery (AID) systems improve glycaemia in young people with type 1 diabetes, but benefits often plateau or deteriorate after 3–6 months.
- Newer AID technology aims to improve glycaemic outcomes while reducing the burden of diabetes care.
- Limited data comparing outcomes following the transition from Guardian 4™ sensors and traditional 3-day infusion sets to Simplera Sync™ sensors and EIS exists.

What this study has found?

- Transitioning participants to an investigative AID system led to significant increases in time in automation and sensor wear (≥6.5 percentage points). These gains further improved glycaemia, including more time in the tight range (3.9–7.8 mmol/L) and reduced hyperglycaemia.

What are the implications of the study?

- Our study suggests that transitioning to upgraded AID sensor and infusion set technology may overcome the typical decline in glycaemic outcomes observed with prolonged AID use.

2 | MATERIALS AND METHODS

2.1 | Trial design

The protocol and primary outcomes of the CO-PILOT trial have been previously published.[1,5] In brief, CO-PILOT was a randomised controlled trial where 80 AID-naive children and young adults with elevated glycaemia (mean HbA1c 10.5%; 91 mmol/mol) were assigned 1:1 to either their usual diabetes care (84% on multiple daily injections; 16% on CGM) or to MiniMed™ 780G AHCL with Guardian 4™ and 3-day infusion sets. Participants were followed up for 13 weeks in the RCT, and all then continued for an additional extension study phase of 9 months. At 13 weeks, intervention participants stayed on AHCL while control participants were transitioned to AHCL. In the extension study, participants remained on the MiniMed™ 780G AHCL system (Medtronic, San Francisco, CA) for a further 3 months after the RCT phase before being transitioned to a MiniMed™ 780G AHCL system compatible with all-in-one (integrated transmitter and smaller size) Simplera Sync™ sensors and EIS. The Southern Health and Disability Ethics Committee (Wellington, New Zealand) approved this trial (2022 FULL 13508). Locality approvals including consultation with Māori (indigenous New Zealanders) research consultation committees were undertaken at each study site.

2.2 | Participants

Participants from the CO-PILOT trial participated in this extension trial. Eighty original participants were recruited from four diabetes centres spanning New Zealand between March and August 2023. Eligible participants for the CO-PILOT RCT were of any gender, diagnosed with T1D as per ADA guidelines for at least one year, had a pre-enrolment glycated haemoglobin (HbA1c) ≥69 mmol/mol (8.5%), and a daily insulin requirement of ≥8 units/day. Exclusion criteria encompassed the following: previous use of closed-loop technology; current or planned pregnancy; the use of medications indicative of moderate or severe diabetes complications; administration of systemic glucocorticoids within two weeks of the CO-PILOT baseline visit; a diagnosis or history of a severe psychiatric disorder, uncontrolled seizure disorder, renal impairment or cardiovascular disease; and the presence of moderate or severe diabetic retinopathy.

2.3 | Devices

The key features of the studied devices are as follows. Guardian 4™ and the all-in-one Simplera Sync™ are both calibration-free and share the same 7-day sensor wear period. However, the key differences are that Simplera Sync™ is a disposable, all-in-one CGM sensor requiring no overtape (Guardian 4™ has a reusable transmitter that requires charging between changes and overtape to hold in place). It also features an improved user experience with a simpler, faster two-step insertion process. The form factor for Simplera Sync™ is also half the size of the Guardian 4™ sensor system. With regard to the infusion set, prior to using 780G with EIS, participants used 3-day infusion sets. While the form factor is largely comparable, EIS can last up to 7 days, thus requiring fewer site changes.

2.4 | Outcomes

For this extension study, we compare glycaemic and system performance outcomes between the MiniMed™ 780G AHCL with Guardian 4™ sensors and 3-day infusion sets, and the MiniMed™ 780G AHCL system with Simplera Sync™ sensors and EIS. The primary objective was to describe the change in time in each glycaemic range between baseline and study end. Secondary objectives included change in HbA1c, changes in system performance metrics, and adverse events. Time in range and system performance data were collected during the 14-day period prior to the transition and again for the last 14 days of the 3 months period following the transition, while HbA1c was collected during each study visit. System performance metric data collected included percentage of time in automation, sensor wear time, carbohydrate and meal announcements, active insulin time and set-point glycaemic targets. Adverse events data were collected throughout the duration of the study. Per protocol analysis was conducted for those spending ≥80% time in automation.[5]

2.5 | Statistical methods

Standard descriptive statistics were used to describe the data and are presented as means ± standard deviations, and ranges and frequencies and percentages as appropriate. For time below glycaemic range (TBR), due to these data usually being skewed, medians and the 25th and 75th percentiles are reported, as well as mean change. Wilcoxon signed-rank tests were used to calculate statistical significance. Statistical analyses were performed using GraphPad Prism 9 (© 1994–2022 GraphPad Software, LLC) and StataSE 18.0 (© 1996–2023 StataCorp LLC).

3 | RESULTS

Data from 75 out of 76 participants who transitioned to the AHCL system with Simplera Sync™ and EIS were available for analysis during this extension study (one who transitioned did not have outcome data available). Baseline demographics and diabetes characteristics are displayed in Table 1. The duration of time on 780G with Guardian 4™ and 3-day infusion sets prior to transitioning to 780G with Simplera Sync™ and EIS varied based on initial RCT study arm allocation (i.e. intervention versus control). Therefore, of 75 participants, 39 participants (52%) had approximately 3 months on the 780G system with Guardian™ 4 and 3-day infusion sets, while 34 out of 75 participants (45%) used this system for approximately 6 months, and 2 out of 75 participants (3%) used it for 9 months.

3.1 | Glycaemic outcomes

Baseline HbA1c on 780G with Guardian™ 4 and 3-day infusion sets was 66.1 mmol/mol ± 14.2 mmol/mol (8.2% ± 1.3%) and stayed stable at 66.7 mmol/mol ± 11.2 mmol/mol (8.3% ± 1.0%) at study end ($p = 0.38$). Individual changes in HbA1c are displayed in Figure 1 alongside means for participants who adhered to protocol use of >80% of time in automation at various timepoints. CGM derived glycaemic metrics are displayed in Table 2 and illustrated in Figure 2. Overall, time in range (TIR) (3.9–10.0 mmol/L [70–180 mg/dL]) was 58.5% ± 14.9% at baseline and 60.4% ± 15.7% at study end (mean change = 1.9; SD = 11.2; $p = 0.09$). Time spent in the tight glycaemic range (3.9–7.8 mmol/L [70–140 mg/dL]) increased from 38.1% ± 13.1% at baseline to 40.5% ± 13.6% at study end (mean change = 2.5; SD = 10.0; $p = 0.04$). Glycaemic metrics for participants with per protocol analysis time in automation ≥80% at study end are displayed in Table 3.

3.2 | System performance and insulin delivery distribution

System performance and insulin delivery distribution outcomes from baseline and at study end are seen in Table 2. Following the introduction of Simplera Sync™, the percentage of time spent in automation (also known as SmartGuard™) improved from 79.2% ± 25.9% at baseline to 85.8% ± 21.8% at study end (mean change = 6.5; SD = 25.6; $p = 0.007$). Likewise, the sensor wear percentage of time increased from 80.7% ± 22.4% at baseline to 88.4% ± 17.2% at study end (mean change = 7.7; SD = 23.0; $p < 0.001$).

TABLE 1 Baseline demographics and diabetes characteristics of participants.

	Participants ($n = 75$)
Demographics	
Age, mean (SD), years	17.3 (4.2)
Gender, *n* (%)	
Male	30 (40)
Female	44 (59)
Non-binary	1 (1)
Ethnicity[a], *n* (%)	
Māori[b]	13 (17)
Pacific[c]	16 (21)
New Zealand European and others[d]	58 (77)
Area-level deprivation[e], *n* (%)	
Low (score 1–3)	23 (31)
Medium (score 4–7)	31 (41)
High (score 8–10)	21 (28)
Diabetes characteristics	
Time since diagnosis, median (25th, 75th percentile), years	7.4 (4.3, 10.4)
Months using 780G AHCL at baseline, *n* (%)	
3 months	39 (52)
6 months	34 (45)
9 months	2 (3)
HbA1c at baseline[f]	
mmol/mol	66.1 (14.2)
%	8.2 (1.3)

Note: Mean HbA1c pre-AHCL in this cohort was 91.6 mmol/mol (10.5%).

[a]Total response ethnicity is reported, so percentages for all ethnicities may be more than 100%. This is because participants could identify with more than one ethnic group.

[b]Māori are the indigenous people of New Zealand.

[c]The Pacific ethnic group included Samoan ($n = 12$), Cook Island Māori ($n = 4$) and Tokelauan ($n = 1$).

[d]Other ethnicities included Indian ($n = 1$) and European ($n = 1$).

[e]New Zealand index of socioeconomic deprivation 2018, in which 1 represents the least and 10 the most socioeconomic deprivation.[6]

[f]HbA1c, glycated haemoglobin, mean (SD).

The number of participants reaching per-protocol percentages of time in automation (≥80%) and sensor wear increased from 48/75 (64%) and 51/75 (68%) to 55/75 (73%) and 62/75 (83%), respectively. Carbohydrates and meals entered into the system were stable between 780G with Guardian 4™ sensors and 3-day infusion sets and 780G with Simplera Sync™ and EIS; carbohydrates entered into the system were 109.2 ± 94.5 g at baseline and 101.3 ± 95.3 g at study end (mean change = −7.9; SD = 62.8; $p = 0.54$). Likewise, the number of meals entered per day was 2.7 ± 2.0 and 2.5 ± 2.0 at baseline and study end, respectively (mean change = −0.1;

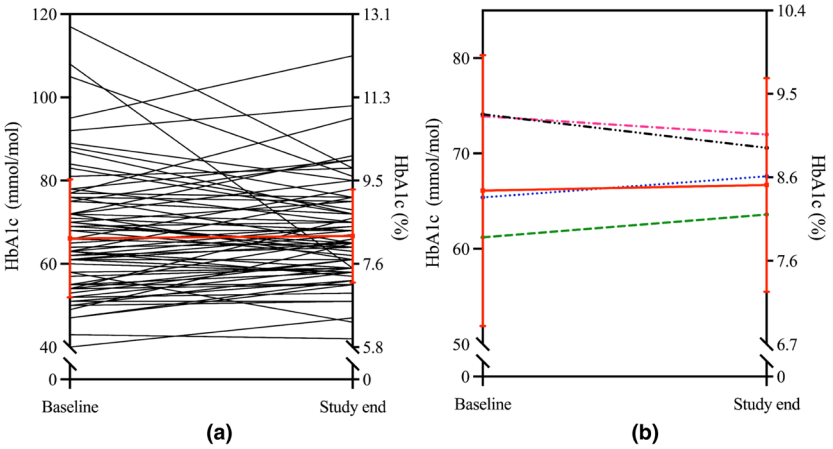

FIGURE 1 HbA1c at baseline and study end. (a) displays each individual shown in black, with the mean and standard deviation displayed in red. (b) shows means for the following groups: green (dash line) represents each participant who had time in automation ≥80% at both baseline and study end ($n = 38$), blue (dot line) represents those with automation time ≥80% at baseline but not at study end ($n = 5$), pink (dash-dot-dash line) represents participants who had automation time ≥80% at study end but not at baseline ($n = 13$), and black (dash-dot-dot-dash line) represents those who did not have automation time ≥80% at either timepoint ($n = 11$), mean and standard deviation for the entire cohort ($n = 67$) is shown in red (solid line). The figure illustrates group means without measures of variability.

SD = 1.3; $p = 0.26$). With increased CGM data, it became possible to safely titrate the algorithm's set-point target, something that had not been achievable during several months of using 780G with Guardian 4™ sensors and 3-day infusion sets due to glycaemic variability. For 9 participants, set-point targets of 6.7 mmol/L (120 mg/dL) or 6.1 mmol/L (110 mg/dL) were optimised to 5.5 mmol/L (100 mg/dL) during 780G with Simplera Sync™ and EIS use, while 3 participants adjusted from 6.7 mmol/L (120 mg/dL) to 6.1 mmol/L (110 mg/dL). Conversely, optimal set-point settings were lost for two participants during 780G with Simplera Sync™ and EIS use. Optimal 780G AHCL settings—active insulin time at 2 h and a set-point target of 5.5 mmol/L (100 mg/dL)—were initially set for 35/75 (47%) participants at baseline, increasing to 49 of 75 (65%) participants by extension-end.

3.3 | Adverse events

Throughout the time participants were using 780G with Guardian 4™ sensors and 3-day infusion sets, one participant had severe hypoglycaemia (event rate = 0.03 per patient-year) and four were hospitalised for diabetic ketoacidosis (DKA) (rate = 0.14 per patient-year). In the 3 months following the transition to the 780G with Simplera Sync™ and EIS, no participants had severe hypoglycaemia and two were hospitalised for DKA (rate = 0.11 per patient-year). In the 12 months prior to entering the original CO-PILOT RCT and first use of automation, the DKA rate was 0.43 per patient-year, and the severe hypoglycaemia rate was 0.15 per patient-year. All adverse events resolved without sequelae.

4 | DISCUSSION

This extension study investigated the additive impacts of incorporating the all-in-one Simplera Sync™ sensor and Extended™ Wear Infusion Set to the MiniMed™ 780G system. We show that after this transition from 780G with Guardian 4™ sensors and 3-day infusion sets, both time in automation and sensor wear showed clinically important increases of ≥6.5 percentage points. These improved system performance outcomes sustained improvements in all glycaemic metrics, further improving time spent in the tight glucose range (3.9–7.8 mmol/L [70–140 mg/dL]) by 2.5 percentage points and reducing time in the hyperglycaemic range. This improved stability also allowed for increased use of "optimal settings".[7] No safety concerns were seen in either AHCL phase, with the DKA and hypoglycaemia rates lower than before institution of automation.

This improvement in time in automation is important, as in young people with very high HbA1c, we often see either a deterioration[2] or a plateau[8–10] of these metrics from 3 to 12 months of automation use. We can therefore suggest that the design changes potentially decreased the burden for these young people already struggling with their diabetes, which has been suggested previously.[4] The improvements we found in this trial mirror and increase the impacts seen when participants transitioned from Guardian 3™ to calibration-free Guardian 4™ sensors.[11] We are additionally exploring the psychosocial impact of this new AHCL system in a qualitative study yet to be published.

Improvements in automation and sensor wear time paralleled small increases to time in healthy glycaemic

TABLE 2 Glycaemic and system performance outcomes at baseline and study end.

	n	Baseline[a]	Study end[b]	Mean change	*p* value
Time in automation, %	75	79.2 (25.9)	85.8 (21.8)	6.5 (25.6)	0.007
Participants with automation ≥80%, *n* (%)		48 (64)	55 (73)	7 (9)	
Sensor wear, %	75	80.7 (22.4)	88.4 (17.2)	7.7 (23.0)	<0.001
Participants with sensor wear ≥80%, *n* (%)		51 (68)	62 (83)	11 (15)	
Participants on optimal settings[c], *n* (%)	75	35 (47)	49 (65)	14 (19)	
Active insulin time, *h* (*n*)	75	2.0 (49); 2.0–3.0 (24); >3.0 (2)	2.0 (62); 2.0–3.0 (12); >3.0 (1)		
Set-point, *n* (%)	75				
5.5 mmol/L (100 mg/dL)		51 (68)	58 (77)		
6.1 mmol/L (110 mg/dL)		15 (20)	11 (15)		
6.7 mmol/L (120 mg/dL)		9 (12)	6 (8)		
Carbohydrates per day, g	75	109.2 (94.5)	101.3 (95.3)	−7.9 (62.8)	0.54
Meals per day, *n*	75	2.7 (2.0)	2.5 (2.0)	−0.1 (1.3)	0.26
HbA1c[d]	67				
mmol/mol		66.1 (14.2)	66.7 (11.2)	0.6 (9.2)	0.38
%		8.2 (1.3)	8.3 (1.0)	0.1 (0.8)	0.39
Time in glycaemic range[e], %	73				
>13.9 mmol/L (>250 mg/dL)		16.9 (13.2)	16.4 (14.0)	−0.5 (11.0)	0.48
10.0–13.9 mmol/L (180–250 mg/dL)		23.1 (6.0)	22.0 (5.8)	−1.1 (4.5)	0.04
3.9–10.0 mmol/L (70–180 mg/dL)		58.5 (14.9)	60.4 (15.7)	1.9 (11.2)	0.09
3.9–7.8 mmol/L (70–140 mg/dL)		38.1 (13.1)	40.5 (13.6)	2.5 (10.0)	0.04
3.0–3.9 mmol/L (54–70 mg/dL)[f]		0.8 (0.2, 1.7)	0.7 (0.3, 1.3)	−0.2 (0.9)	0.16
<3.0 mmol/L (<54 mg/dL)[f]		0.1 (0.0, 0.4)	0.03 (0.0, 0.3)	−0.1 (0.4)	0.13
Mean sensor glucose	73				
mmol/L		9.9 (1.9)	9.8 (1.8)	−0.1 (1.6)	0.23
mg/dL		179.2 (30.9)	176.5 (32.7)	−2.7 (29.3)	0.23

[a]Data from participants during the 14 days preceding transition to 780G with Simplera Sync™ and EIS from 780G with Guardian 4™ and 3-day infusion sets.

[b]Data collected during the 14 days prior to participants being on 780G with Simplera Sync™ and EIS system for 3 months.

[c]Optimal settings are an active insulin time of 2.0 hours and a set-point of 5.5 mmol/L.

[d]Glycated haemoglobin (HbA1c). Data loss for 7 participants: 5 participants had missing HbA1c data at baseline and 2 participants had missing HbA1c data at study end.

[e]Time in glycaemic range data missing for 2 participants who had 0% sensor wear time: 1 participant at baseline and 1 participant at study end.

[f]Due to hypoglycaemic ranges being skewed, medians and the 25th and 75th percentiles were reported. Changes between baseline and study end are reported as means (SD), in line with all other variables.

ranges and reduced time in the hyperglycaemic range of 10.0–13.9 mmol/L (180–250 mg/dL), with stability in time spent in hyperglycaemia >13.9 mmol/L (>250 mg/dL) and hypoglycaemia, and stable HbA1c levels. In contrast to our results, Matejko et al. found no changes in time in range after switching from Guardian 3™ to Guardian 4™, but they did see a 0.4 percentage-point improvement in HbA1c.[11] Notably, their sensor wear time exceeded 99%,[11] much higher than in most of our young participants, who have persistently struggled to meet glycaemic targets prior to this trial. The improvement in time in the tight glycaemia range (3.9–7.8 mmol/L [70–140 mg/dL]) in our cohort also occurred in the context of small decreases in carbohydrate quantity and meal entries per day after 3 months of 780G with Simplera Sync™ and EIS use. Despite fewer carbohydrate entries, system performance and glycaemic outcomes still improved. As previously noted, strict accuracy in carbohydrate counting does not appear to be a barrier to using 780G in this population, and accessing and maintaining automation is the key to improved health outcomes for these young people.[1,12]

The incremental improvement in glycaemia was not necessarily expected, due to the similarity of the two sensors' chemistry. Therefore, we attribute the glycaemic improvements to be due to the improved design

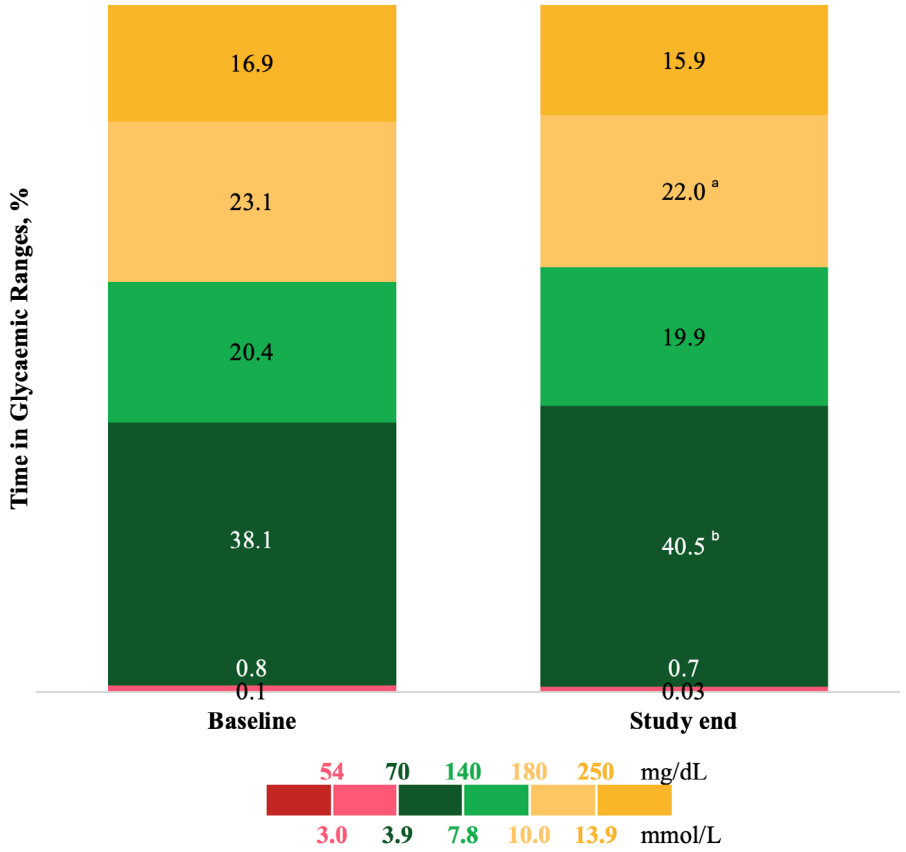

FIGURE 2 Glycaemic outcomes for participants at baseline and study end. [a]*p* value = 0.04 for change in time in the glycaemic range of 10.0–13.9 mmol/L; [b]*p* value = 0.04 for change in time in the glycaemic range of 3.9–7.8 mmol/L; No other TIR changes were statistically significant. The figure illustrates group means without measures of variability. Additionally, the variables for time in glycaemic ranges are mixed; some are normally distributed while others have skewed distribution. For these reasons, this figure is for illustrative purposes only.

TABLE 3 Time in glycaemic ranges at baseline and study end for participants with per-protocol time in automation ≥80% at study end.

	n	Baseline[a]	Study end[b]	Mean change	*p* value
Time in glycaemic range[c], %	54				
>13.9 mmol/L (>250 mg/dL)		15.1 (10.5)	12.5 (8.7)	−2.5 (8.4)	0.05
10.0–13.9 mmol/L (180–250 mg/dL)		22.8 (5.8)	21.9 (5.6)	−0.9 (4.2)	0.08
3.9–10.0 mmol/L (70–180 mg/dL)		60.7 (12.3)	64.4 (11.5)	3.7 (9.6)	0.007
3.9–7.8 mmol/L (70–140 mg/dL)		39.6 (11.5)	43.3 (10.5)	3.7 (8.9)	0.005
3.0–3.9 mmol/L (54–70 mg/dL)[d]		0.8 (0.2, 1.7)	0.7 (0.3, 1.3)	−0.2 (0.9)	0.25
<3.0 mmol/L (<54 mg/dL)[d]		0.1 (0.0, 0.4)	0.03 (0.0, 0.3)	−0.1 (0.4)	0.22
Mean sensor glucose, mmol/L	54	9.8 (1.7)	9.4 (1.2)	−0.42 (1.4)	0.02

[a]Data from participants during the 14 days preceding transition to 780G with Simplera Sync™ and EIS from 780G with Guardian™ and 3-day infusion sets;
[b]Data collected during the 14 days prior to participants being on 780G with Simplera Sync™ and EIS for 3 months;
[c]Time in range data are for participants who had per protocol time in automation of ≥80% at study end. Data are missing for 1 participant who had 0% sensor wear at baseline but met per protocol automation time at study end;
[d]Due to hypoglycaemic ranges being skewed, medians and 25th and 75th percentiles were reported. Changes between baseline and study end are reported as mean (SD), in line with all other variables.

of the sensor, with improved usability potentially contributing to higher use in automation and the ability to increase participants on optimal settings. Our observed improvements in glycaemia are also likely to be a result of the increase in the number of participants using recommended optimal 780G settings from 35/75 to 49/75 participants,[7] noting these were only able to be safely optimised due to the increased CGM use and subsequent time in automation seen during the use of 780G with Simplera Sync™ and EIS.

Reassuringly, DKA and severe hypoglycaemia rates declined throughout the trial, particularly when compared to pre-AHCL, where the DKA rate was 0.43 per patient-year and the severe hypoglycaemia rate was 0.15 per patient-year in this cohort. While using 780G with Guardian 4™ sensors and 3-day infusion sets, the DKA rate was 0.14 per patient-year, and the severe hypoglycaemia rate was 0.03 per patient-year. After switching to 780G with Simplera Sync™ and EIS, the DKA rate was 0.11 per patient-year, with no severe hypoglycaemia events. Again, this provides reassurance around the safety of this technology in a complex population of young people.

The strengths of this extension phase trial include the study population choice, targeting those struggling with the elevated pre-AHCL HbA1c, child and young adults age group, and the socioeconomic and ethnic diversity, reflecting the broader T1D population. The large sample size and high follow-up rate, with minimal participant withdrawal, also add to its robustness. The trial's design allowed for direct comparison between two systems in the same population. However, the lack of a comparator group is a limitation, though ethically necessary due to AHCL's clear health benefits. The shorter follow-up after transition to 780G with Simplera Sync™ and EIS was also a limitation but necessary as two participants transitioned to AHCL at their 9-month study visit (of the whole CO-PILOT trial), with the trial ending at 12 months. Another limitation was the simultaneous change of sensors and infusion sets, making it difficult to distinguish the effects of each technology on glycaemia. A final limitation is that user satisfaction and experience are not further presented. This work is ongoing with a qualitative investigation underway.

5 | CONCLUSION

Our data provide initial evidence that in young people with previously high HbA1c, when Simplera Sync™ and EIS are combined, improvements in 780G automation (Smartguard™), sensor wear time, and achievement of optimal settings are seen. Small gains in glycaemic metrics were also observed, countering the typical plateaus or deteriorations usually seen in this population.

AUTHOR CONTRIBUTIONS

B.J.W. conceptualised this sub-study and acquired funding. A.B., Y.Z., V.R.M., A.S.W., S.D.J., A.P.S., E.W., C.A.J., M.I.d.B., and B.J.W. researched data. V.R.M. conducted formal data analysis. V.R.M. and B.J.W. wrote the first draft of the manuscript. All authors contributed to and approved the final manuscript. B.J.W. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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CONFLICT OF INTEREST STATEMENT

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ETHICS APPROVAL

This trial has been approved by the Southern Health and Disability Ethics Committee (2022 FULL 13508).

INFORMED CONSENT

Informed consent/assent to participate in this study was obtained from all patients as per the requirements of ISO 14155:2011 and Good Clinical Practices.

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REFERENCES

1. Boucsein A, Zhou Y, Michaels V, et al. Automated insulin delivery for young people with type 1 diabetes and elevated A1c. *NEJM Evid*. 2024;3(10):EVIDoa2400185. doi:10.1056/EVIDoa2400185
2. Michaels VR, Boucsein A, Watson AS, et al. Glucose and psychosocial outcomes 12-months following transition from multiple daily injections to advanced hybrid closed loop in youth with type 1 diabetes and suboptimal glycemia. *Diabetes Technol Ther*. 2024;26(1):40-48. doi:10.1089/dia.2023.0334
3. Sehgal S, De Bock M, Jones S, Frewen C, Wheeler BJ. User experiences during the transition to calibration-free sensors with remote monitoring while using automated insulin delivery—a qualitative study. *Front Endocrinol*. 2023;14:1214975.
4. Yuan CY, Kong YW, Amoore T, et al. Improved satisfaction while maintaining safety and high time in range (TIR) with a Medtronic investigational enhanced advanced hybrid closed-loop (e-AHCL) system. *Diabetes Care*. 2024;47(4):747-755.
5. Boucsein A, Zhou Y, Haszard JJ, et al. Protocol for a prospective, multicenter, parallel-group, open-label randomized controlled trial comparing standard care with closed lOoP in chiLdren and yOuth with type 1 diabetes and high-risk glycemic control: the CO-PILOT trial. *J Diabetes Metab Disord*. 2024;23:1397-1407.
6. Atkinson J, Salmond C, Crampton P. *NZDep2018 Index of Deprivation Final Research Report*; 2019. Wellington: University of Otago.
7. Castañeda J, Mathieu C, Aanstoot H-J, et al. Predictors of time in target glucose range in real-world users of the MiniMed 780G system. *Diabetes Obes Metab*. 2022;24(11):2212-2221.
8. Passanisi S, Salzano G, Bombaci B, et al. Sustained effectiveness of an advanced hybrid closed-loop system in a cohort of children and adolescents with type 1 diabetes: a 1-year real-world study. *Diabetes Care*. 2024;47(6):1084-1091.
9. Nigi L, Iraci Sareri G, Cataldo D, Dotta F. 12-month efficacy of advanced hybrid closed-loop system in adult type 1 diabetes patients. *Diabetes Technol Ther*. 2023;26(2):130-135.
10. Breton MD, Kovatchev BP. One year real-world use of the control-IQ advanced hybrid closed-loop technology. *Diabetes Technol Ther*. 2021;23(9):601-608.
11. Matejko B, Juza A, Kieć-Wilk B, et al. One-year follow-up of advanced hybrid closed-loop system in adults with type 1 diabetes previously naive to diabetes technology: the effect of switching to a calibration-free sensor. *Diabetes Technol Ther*. 2023;25(8):554-558.
12. Petrovski G, Campbell J, Pasha M, et al. Simplified meal announcement versus precise carbohydrate counting in adolescents with type 1 diabetes using the MiniMed 780G advanced hybrid closed loop system: a randomized controlled trial comparing glucose control. *Diabetes Care*. 2023;46(3):544-550.

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