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Consistent efficacy and safety of automated insulin delivery in children aged 2–6 years: results from the LENNY trial continuation phase

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ABSTRACT

Objective: The LENNY randomized trial (NCT05574062) demonstrated that the MiniMed 780G system with Guardian™ 4 sensor (MM780G/G4S) is safe and effective for young children with type 1 diabetes (CwT1D). The continuation phase objective was to evaluate MM780G when used for extended time and when used with the Simplera Sync™ sensor (MM780G/SY).

Methods: CwT1D who completed the initial study phase underwent a 12–24-week period using MM780G/G4S (in Auto Mode), after which they were randomly allocated to either continue using the same set-up or switch to MM780G/SY (in Auto Mode) for 12 weeks. The primary endpoint was the between-arm difference in mean HbA1c after the 12-week period (non-inferiority).

Results: 91 CwT1D were enrolled in the continuation phase. After the initial 12–24-week period, mean ± SD HbA1c was 7.16 ± 0.59 %. After the 12-week treatment period, mean ± SD HbA1c was 7.24 ± 0.64 % for MM780G/G4S and 7.30 ± 0.53 % for MM780G/SY (estimated treatment effect = 0.14 %, 95 % CI − 0.03 to 0.31 %). Over the 12 weeks, mean ± SD time-in-range (TIR) was 68.9 ± 8.6 % for MM780G/G4S and 69.7 ± 7.7 % for MM780G/SY. Non-inferiority was confirmed for HbA1c and TIR.

Conclusion: In CwT1D aged 2–6 years and TDD ≥ 6 units, the safety and good glycemic control from MM780G were sustained for ≥ 1 year and MM780G/SY was non-inferior to MM780/G4S.

1. Introduction

In the US specifically, over the period 2001–2015, 15 % of people newly diagnosed with type 1 diabetes (T1D) were aged ≤ 9 years at diagnosis [1]. Younger age at diagnosis has been associated with worse outcomes in terms of life expectancy, as well as a high risk for many long-term complications; T1D has also been shown to negatively influence brain development and plasticity [2,3]. The management of T1D in

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the very young can be complex: young children undergo profound physiological, hormonal, and behavioral changes, which can, in turn, influence body weight, body composition, insulin sensitivity and insulin requirements as well as carbohydrate and total calorie intake. Additional factors may add to the complexity of diabetes management, such as unpredictable activity levels, periods of fussy eating, and the fact that it may be difficult for young children to adequately convey important information to caregivers, such as symptoms of hypoglycemia [4,5]. Consequently, both pediatric health care providers and caregivers must be especially vigilant in terms of modifying insulin requirements and carbohydrate entries in response to changes as the child develops. The challenges associated with the care of young children with T1D (CwT1D) may therefore also place a considerable emotional burden on caregivers [6]. Common fears in parents of young CwT1D include not detecting hypoglycemia, or hypoglycemia occurring whilst the child is asleep, as well as worries about anything happening in settings such as kindergarten/daycare [7,8].

Automated insulin delivery (AID) systems have been shown to be highly effective in the management of adults and adolescents with T1D. Technology in a more general sense has also been reported to help to alleviate some of the burden of disease management that parents/caregivers of young CwT1D experience [8]. However, the need for clinical trials of AID systems in this group has previously been highlighted, particularly given the high levels of variability in insulin requirements reported in younger versus older children; it has also been suggested that younger children may derive substantial clinical benefit from the use of such systems [9]. Indeed, in a recent open-label, single-arm study in 35 children aged 2–6 years, Pulkkinen et al. showed that, over a period of 12 weeks, with the use of the MiniMed™ 780G (MM780G) advanced hybrid closed-loop (AHCL), there was a significant improvement in HbA1c and time-in-range (TIR) while there was no significant change in time-below range (TBR) [10]. Moreover, positive treatment effects also persisted through a period of 18 months [11]. More recently, the Eva**L**uation of th**E** Mi**N**iMed 780G System i**N** **Y**oung Paediatric Subjects (LENNY) randomized crossover trial demonstrated the safety and efficacy of the MM780G, paired with the Guardian™ 4 sensor (G4S) in young children with T1D aged 2–6 years and having a total daily insulin dose (TDD) $\geq$ 6 units. LENNY was the first randomized controlled trial of MM780G to be conducted in children in this age group. The LENNY trial comprised a run-in phase and a 26-week study phase, in which study participants were randomly allocated to 12 weeks using the MM780G in Manual Mode with the suspend-before-low feature activated, followed by 12 weeks in Auto Mode, or to the alternate sequence. The results of the 26-week study phase are presented by Battelino et al. (2025) [12].

Here, we present the findings of the continuation phase of the LENNY trial, the aims of which were two-fold. The first aim was to evaluate the safety and efficacy of the MM780G system in young CwT1D aged 2–6 years and a TDD $\geq$ 6 units when the system was paired with the recently launched Simplera Sync™ sensor (SY). The new SY sensor is now commercially available in several markets, part of the rationale for the study continuation phase was therefore to assess the performance of the new sensor in this age group. The second aim was to assess long-term outcomes in young children using the MM780G with G4S. Again, the rationale was that, at the time of study conceptualization, long-term efficacy had not yet been assessed in this age group, and given the importance of sustained glycemic control, it was considered important to assess long-term safety and efficacy.

2. Methods

2.1. Study design

The LENNY study (NCT05574062; see https://www.clinicaltrials.gov/study/NCT05574062, trial record first posted on 6th October 2022) was a prospective, open-label, multicenter, randomized crossover trial conducted in young children aged 2–6 years at the time of screening. Study participants were required to be diagnosed with T1D for $\geq$ 6 months prior to screening with a HbA1c of $<$ 11 % (97 mmol/mol) at screening and a minimum insulin TDD of $\geq$ 6 units. The LENNY study consisted of a run-in phase, a study phase, and a continuation phase. For the continuation phase, the first participant visit (i.e., first participant transitioning from the study phase) was on 25 November 2023, the last visit was on 29 October 2024. The findings presented here relate exclusively to the continuation phase. Full details of the study design including inclusion and exclusion criteria and findings from the study phase have been previously published [12].

2.2. Study participants and treatments

All study participants completing the study phase were eligible for enrollment into the continuation phase. New written informed consent was obtained from the parent/legal guardian of the study participant prior to the commencement of any study-related activity pertaining to the continuation phase.

The continuation phase comprised two distinct periods. In Period 1, all enrolled participants used the MM780G with G4S (Medtronic, Northridge, USA) in Auto Mode for 18 $\pm$ 6 weeks. At the end of Period 1, participants were randomly allocated to one of two arms (Supplementary Fig. 1). In the first arm, participants were allocated to use the MM780G BLE2.0 with SY in Auto Mode for 12 weeks (MM780G/SY arm, BLE 2.0 refers to the MM780G version that can be paired to SY). In the second arm, participants continued to use the MM780G system with G4S in Auto Mode for 12 weeks (MM780G/G4S arm). Both Period 1 and 2 consisted of 2 visits. There was no recommendation to change system settings such as Glucose Target and Active Insulin Time after the LENNY study phase ended. Any further changes were done at the discretion of the investigator following the flowchart previously described [12]. Additionally, if any further care or treatment for other conditions was required the participant continued with routine care.

2.3. Continuation phase endpoints

The primary endpoint for the continuation phase was the between-arm difference in mean HbA1c at the end of Week 12 of Period 2 (non-inferiority test). HbA1c was measured at a central laboratory at the end of each period. Secondary endpoints included the between-arm difference in mean HbA1c (superiority test) and percentage of time spent in target range (TIR, 70–180 mg/dL [3.9–10.0 mmol/L], both non-inferiority and superiority test). TIR data were collected over the full 12 weeks of Period 2. Multiple exploratory endpoints were also assessed; these included time in tight range (TITR) (70–140 mg/dL [3.9–7.8 mmol/L]), time below and above range according to pump settings, insulin dosing endpoints, and system use endpoints (Table 2). Parents/guardians also completed the Pittsburgh Sleep Quality Index (PSQI) [13] and the Hypoglycemia Fear Survey Parent Version (HFS-P) [14]. In the PSQI, the total score ranges between 0 and 21, with higher scores corresponding to worse sleep quality [13]. In the HFS-P, possible scores range from 25 to 125 with a higher score corresponding to greater fear of hypoglycemia [15]. Questionnaires were collected at the end of Period 1 and Period 2. Safety endpoints including severe hypoglycemic events (SHE), diabetic ketoacidosis (DKA), serious adverse events (SAE), serious adverse device events (SADE), and unanticipated serious adverse device events (USADE) were also assessed. Study progress and safety were periodically reviewed by a data monitoring committee, and adverse events were reviewed by a clinical events committee.

2.4. Randomization

Randomization was performed via electronic case report forms using Medidata Rave (v2024.2.1, Medidata solutions, NY, USA). The study statistician generated the randomization schedule using SAS (v9.4, SAS

Institute, Chicago, USA). Investigator-blinded block randomization (study investigators did not have access to any information regarding randomization) was performed using blocks of different sizes (the order of block sizes was also selected randomly) with a 1:1 allocation within each block. Only randomization was blinded; blinding of the device was not possible, care providers and study participants could not be blinded. Randomization was performed at the study level and stratified by age (2 to 4 years, or > 4 years old).

2.5. Statistical analysis

Sample size calculations were based on assumed drop-out rates of 10 % at screening, 5 % after run-in, and 10 % during the study phase/continuation phase. Consequently, for the continuation phase, a sample size of 64 participants (32 per arm) was required to provide > 80 % power to detect non-inferiority in the mean HbA1c difference with an absolute margin of 0.4 % at a one-sided significance level of 0.025, assuming a treatment effect of 0.1 % and a standard deviation (SD) of 0.7 % for individual measurements.

For both primary and secondary endpoints, efficacy analysis was performed on an intent-to-treat (ITT) basis, with the ITT population including all randomized participants. The primary endpoint was tested for non-inferiority by using a generalized linear model, adjusted for HbA1c at time of randomization at a 0.025 (one-sided) significance level. The non-inferiority margin of 0.4 % reduction in HbA1c was chosen in agreement with Food and Drug Administration guidance [16]. The 97.5 % upper confidence limit of the between-arm difference was calculated; a value > 0.4 % allowed non-inferiority to be concluded. Analysis of secondary endpoints was performed using the same methodology, with a non-inferiority margin for TIR of 7.5 %. A gate-keeping approach was used to control for the type I error: the primary endpoint was tested first, and then secondary endpoints were tested in a hierarchical order once hypothesis of the previous endpoint was demonstrated (non-inferiority or superiority test, respectively). For sensitivity analysis, primary and secondary analyses were also conducted on two different populations: the per-protocol population (PP), which included only randomized participants without major protocol deviations, and the as-treated population (AT), which comprised all randomized participants, with treatment received used for stratification.

The White method was used to handle missing baseline covariate data (i.e., baseline HbA1c for the HbA1c endpoints). For endpoint data, no imputation was used [17].

3. Results

3.1. Participant disposition, baseline characteristics and study adherence

A total of 95 participants entered Period 1 of the continuation phase and four discontinued during this period (Fig. 1). Therefore, 91 underwent random allocation to Period 2 treatment (n = 45 to MM780G/SY, and n = 46 to MM780G/G4S) (Fig. 1). A total of 90 participants completed the continuation phase; one participant in the MM780G/SY arm was withdrawn by parent/guardian during the continuation phase. There were two protocol deviations for participants who did not use the sensor that was allocated to their treatment. One participant was randomly allocated to the MM780G/SY arm but inadvertently treated with MM780G/G4S, and to correct the randomization scheme, the next participant was allocated to MM780G/G4S but treated with MM780G/SY. As a result, the ITT population comprised a total of 91 participants, the PP population comprised 88 participants, and the AT population comprised 91 participants.

For the continuation phase, the mean ± SD age of the overall study population was 4.66 ± 1.16 years, (4.61 ± 1.15 in the MM780G/SY arm and 4.70 ± 1.18 years in the MM780G/G4S arm) and mean ± SD HbA1c at randomization was 7.51 ± 0.96 % (58.55 ± 10.46 mmol/mol) (7.41 ± 0.89 % [57.50 ± 9.73 mmol/mol] in the MM780G/SY arm and 7.60 ± 1.02 % [59.58 ± 11.14 mmol/mol in the MM780G/G4S arm) (Table 1). Overall, during Period 2 the mean ± SD amount of time spent wearing the sensor was 97.1 ± 2.27 % for the MM780G/SY arm and 96.5 ± 21.3 % for the MM780G/G4S arm, and the mean ± SD amount of time spent in Auto Mode was 95.5 ± 3.04 % for the MM780G/SY arm and 97.6 ± 2.97 % for the MM780G/G4S arm (Table 2). Sensor settings including glucose target and active insulin time are shown in Table 2.

3.2. Glycemic control

The primary outcome, mean ± SD HbA1c at the end of Period 2, was 7.30 ± 0.53 % in the MM780G/SY arm and 7.24 ± 0.64 % in the MM780G/G4S arm (Table 2). The estimate of the treatment effect in terms of HbA1c (95 % confidence interval [CI], adjusted for HbA1c at

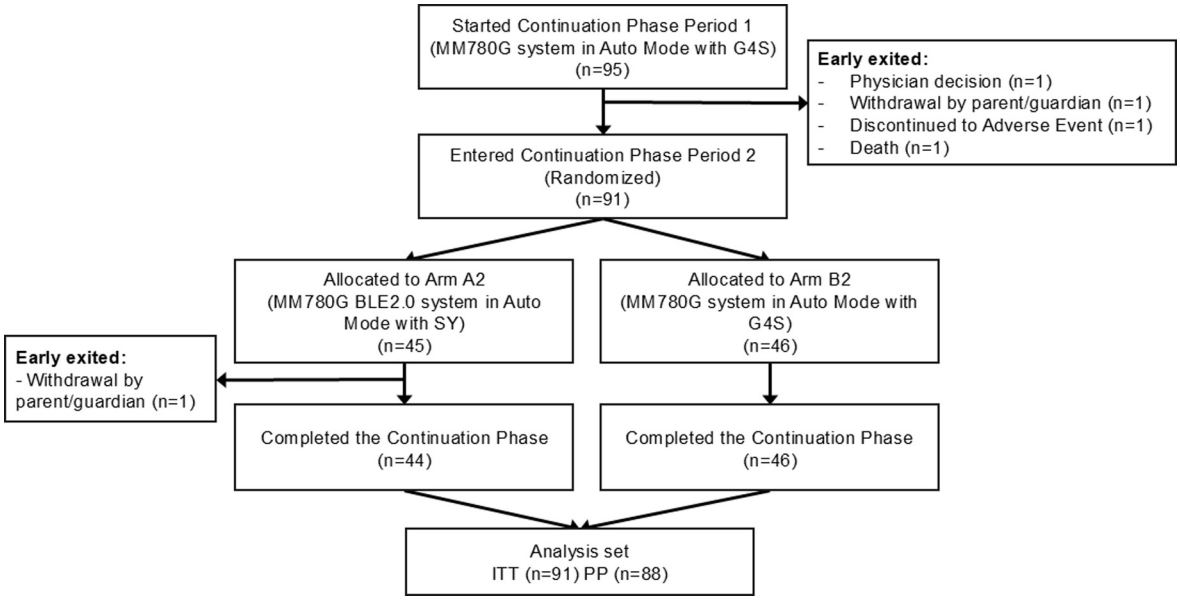

Fig. 1. Study participant disposition in the continuation phase *Three study participants were excluded from the PP analysis set: two were not treated as randomized and one participant did not complete the continuation phase.*

Table 1
Summary of baseline characteristics.

Patient characteristic	Continuation phase, All, n = 91	Continuation phase, MM780G/G4S, n = 46	Continuation phase MM780G/SY, n = 45
Age, years	4.66 (1.16)	4.70 (1.18)	4.61 (1.15)
Male, % (n/N)	49.5 (45/91)	47.8 (22/46)	51.1 (23/45)
Duration of diabetes, years	2.02 (1.17)	2.06 (1.09)	1.97 (1.26)
HbA1c, %	7.51 (0.96)	7.60 (1.02)	7.41 (0.89)
HbA1c, mmol/mol	58.55 (10.46)	59.58 (11.14)	57.50 (9.73)
DKA in 3 months before enrollment, % (n/N)	0.0 (0/91)	0.0 (0/46)	0.0 (0/45)
Insulin TDD (basal + bolus) units	13.4 (4.22)	12.8 (3.80)	14.0 (4.58)

Values are mean (standard deviation) unless otherwise stated.
DKA, diabetic ketoacidosis; G4S, Guardian 4 sensor; MM780G MiniMed™ 780G; SD, standard deviation; SY, Simplera Sync™ sensor; TDD, total daily insulin dose.

time of randomization) was 0.14 % (–0.03 to 0.31 %). As the upper confidence limit was < 0.4 %, non-inferiority was demonstrated; superiority was not demonstrated. Non-inferiority was also demonstrated in the PP and the AT populations (Supplementary Table 1).

With regard to the secondary outcomes, mean ± SD TIR during Period 2 of the continuation phase was 69.7 ± 7.73 % in the MM780G/SY arm and 68.9 ± 8.62 % in the MM780G/G4S arm (Supplementary Fig. 2 and Table 2). The estimate of the treatment effect in terms of TIR (adjusted for TIR during Period 1) was 1.17 % (−0.04 to 2.38). Non-inferiority was also demonstrated for TIR; superiority was not demonstrated (Table 2).

With regard to the other glycemic outcomes, mean ± SD TITR was 48.1 ± 6.88 % and 47.6 ± 6.72 % in the MM780G/SY and MM780G/G4S arm, respectively (Table 2). Time above range (TAR) and TBR were also assessed and are shown in Table 2. Of note, the mean ± SD percentage of time spent with glucose levels < 70 mg/dL (TBR70) was 2.87 ± 1.43 % in the MM780G/SY arm and 4.09 ± 2.29 % in the MM780G/G4S arm; mean ± SD percentage of time spent with glucose levels < 54 mg/dL (TBR54) was 0.42 ± 0.28 % and 0.82 ± 0.84 %, respectively. The mean ± SD percentage of time spent with glucose levels > 180 mg/dL (TAR180) during Period 2 was 27.47 ± 7.71 % in the MM780G/SY arm and 27.0 ± 58.03 % in the MM780G/G4S arm; similarly, the mean ± SD percentage of time spent with glucose levels > 250 mg/dL (TAR250) was 7.56 ± 4.74 % and 7.76 ± 5.92 %, respectively. Other continuous glucose monitoring (CGM) metrics including mean sensor glucose and glucose management indicator were similar between the two arms (Table 2). CGM metrics were also assessed separately for daytime and nighttime; in both treatment arms, TIR was considerably higher during nighttime than during daytime (Supplementary Table 2 and 3). For example, in the MM780G/SY arm, mean ± SD TIR was 65.54 ± 8.80 % during daytime compared with 81.80 ± 8.81 % during nighttime.

3.3. Participant reported outcomes

Parents/guardians completed the PSQI and the HFS-P (Supplementary Table 4). At the end of Period 2, PQSI and HFS-P scores were similar in both treatment arms. Despite mean nighttime TIR of 79.11 ± 10.86 % in the MM780G/G4S arm and 81.80 ± 8.81 % in the MM780G/SY arm, in terms of total sleep quality score, parents/guardians in both groups reported a mean score > 5, indicating disturbed sleep (total mean ± SD score of 5.12 ± 3.10 for the MM780G/SY arm and 5.71 ± 3.04 for the MM780G/G4S arm). Mean ± SD HFS-P total scores were 41.07 ± 12.29 for the MM780G/SY arm and 40.89 ± 15.14 for the MM780G/G4S arm.

Table 2
Primary, secondary and exploratory endpoints (ITT population).

	Continuation phase, Period 1	Continuation phase, Period 2 MM780G/G4S	Continuation phase, Period 2, MM780G/SY	Difference[a] (95 % CI)
Primary endpoint				
HbA1c, %	7.16 (0.59)	7.24 (0.64)	7.30 (0.53)	0.07 (−0.19 to 0.33)
HbA1c, mmol/mol	54.76 (6.40)	55.59 (7.03)	56.32 (5.79)	0.73 (−2.13 to 3.59)
Secondary endpoints				
TIR 70–180 mg/dL, %	68.70 (7.38)	68.86 (8.62)	69.66 (7.73)	0.79 (−2.63 to 4.22)
Exploratory endpoints				
TITR 70–140 mg/dL, %	47.86 (6.37)	47.58 (6.72)	48.11 (6.88)	0.53 (−2.32 to 3.38)
TBR 54 mg/dL, %	0.84 (0.62)	0.82 (0.84)	0.42 (0.28)	−0.18 (−0.36 to − 0.05)
TBR 70 mg/dL, %	4.44 (1.95)	4.09 (2.29)	2.87 (1.43)	−0.88 (−1.67 to − 0.19)
TAR 180 mg/dL, %	26.86 (7.05)	27.05 (8.03)	27.47 (7.71)	0.42 (−2.88 to 3.72)
TAR 250 mg/dL, %	7.56 (4.90)	7.76 (5.92)	7.56 (4.74)	0.40 (−1.67 to 2.42)
TDD insulin, units	16.53 (5.06)	16.70 (5.47)	17.39 (5.00)	
TDD per kg, units	0.78 (0.15)	0.75 (0.13)	0.76 (0.14)	
Sensor glucose mean, mg/dL	150.05 (11.85)	151.29 (13.44)	152.45 (12.12)	2.39 (−2.82 to 6.98)
Sensor glucose SD, mg/dL	61.05 (11.51)	60.56 (13.17)	58.96 (11.00)	−0.35 (−5.59 to 4.48)
Sensor glucose coefficient of variation, %	40.44 (5.10)	39.71 (5.75)	38.44 (4.88)	−1.27 (−3.50 to 0.97)
GMI, %	6.90 (0.28)	6.93 (0.32)	6.96 (0.29)	0.06 (−0.07 to 0.17)
Percentage of time spent in each glucose target setting				
100 mg/dL	13.64 (30.13)	21.55 (38.31)	12.19 (29.22)	
110 mg/dL	27.21 (36.85)	24.98 (38.82)	33.42 (42.29)	
120 mg/dL	54.54 (41.17)	48.92 (45.07)	47.35 (44.99)	
150 mg/dL	3.64 (7.04)	3.23 (6.28)	3.13 (5.84)	
Manual	0.97 (1.49)	1.22 (2.11)	3.69 (1.94)	
Unknown	0.00 (0.00)	0.10 (0.33)	0.22 (0.55)	
Percentage of time using each AIT setting				
2 h	71.73 (42.88)	78.45 (39.75)	66.95 (46.86)	
2–3 h	26.04 (41.16)	20.28 (38.09)	30.78 (45.95)	
3–4 h	2.18 (13.17)	1.26 (8.57)	2.27 (15.08)	
>4 h	0.05 (0.51)	0.00 (0.00)	0.00 (0.00)	
Sensor wear, %	96.87 (1.60)	96.54 (2.13)	97.12 (2.27)	
Time spent in Auto Mode, %	98.07 (2.28)	97.63 (2.97)	95.51 (3.04)	

[a]Note that differences between groups are actual differences and not model-based differences, which were adjusted for baseline control for the primary and secondary endpoints.
Values are mean (SD) unless otherwise stated.

AIT, active insulin time; CI, confidence interval; GMI, glucose management indicator; SD, standard deviation; TAR, time-above-range; TBR, time-below-range; TDD, total daily dose; TIR, time-in-range; TITR, time-in-tight range.

3.4. Safety

A summary of safety data is presented in Table 3. One death occurred in Period 1 of the continuation phase (prior to randomization) due to meningoencephalitis; the death was not considered to be related to study procedures or study devices. Two severe hypoglycemic events occurred during the continuation phase, both of which occurred in Period 1. There were no DKA events during the continuation phase. Overall, during the continuation phase, a total of nineteen adverse events were classified as general disorders and administration site conditions, which included a total of eight medical device site bruises, erythema, irritation, mass, rash or reaction events.

4. Discussion

The LENNY trial continuation phase was the first randomized trial to examine the efficacy and safety of MM780G over a timeframe of approximately 1 year and to assess the safety and efficacy of MM780G with the new SY sensor in children aged 2–6 years with an insulin TDD $\geq$ 6 units. The findings from this phase indicated that, overall, the treatment effects observed with the MM780G were durable, although in both the main study phase and continuation phase, mean TIR was just below the 70 % target for pre-school children recommended in the 2024 International Society for Pediatric and Adolescent Diabetes (ISPAD). [18,19] The authors of the guidelines acknowledged that the management of pre-school age children is especially challenging, and age < 16 years has previously been identified as a risk factor for lower TIR in users of MM780G [21]. Nevertheless, Battelino et al. (2025) found the MM780G performed well in the 2–6-year-old group, despite the unique characteristics of and demands associated with managing diabetes in pre-school children [4,5,12]. Of note, in this analysis, MM780G/SY users still achieved a reassuring nighttime TIR > 80 %, indicating benefits at nighttime specifically, being aligned with ISPAD targets.

The continuation phase included a randomized comparison of MM780G/G4S versus MM780G/SY, in which non-inferiority was demonstrated for HbA1c. TIR was similar in the two treatment arms and non-inferiority was confirmed for this endpoint as well. These findings were anticipated as the sensors have similar sensing chemistry with different form factor [20]. Compared to G4S, SY is a smaller, disposable all-in-one CGM that eliminates the need for overtape. Of note, TBR70 was numerically lower with MM780G/SY compared with MM780G/G4S (although not statistically tested) – it is possible to speculate that this may be partly explained by the average use of a higher glucose target in the MM780G/SY group as use of different settings has been shown to influence TIR and TBR [21]. In addition, previous work has attributed some of the glycemic improvements observed with SY versus G4S to the improved design and usability of the SY sensor, which may in turn have contributed to more time in automation and a higher likelihood of using optimal settings [22]. The 2h warm-up period of the SY, during which CGM interruptions are prevented, may have further contributed to lower TBR [23]; however, further studies on this are needed before any definitive conclusions can be drawn.

Two major protocol deviations occurred during the continuation phase, in that two participants did not follow allocated treatment. To address this, pre-specified analyses were also performed in the PP and AT populations, and non-inferiority of both HbA1c and TIR was demonstrated in both analysis sets, thereby demonstrating robustness of findings. With regard to safety, the profile of the two treatments was similar and acceptable. One death occurred in Period 1 prior to randomization; the death was due to meningoencephalitis and was not considered to be related to study procedures or study devices. Two

Table 3
Summary of safety data (full analysis set).

Event	Overall – Continuation Phase	Continuation phase Period 1	Continuation phase, Period 2 MM780G/G4S	Continuation phase, Period 2, MM780G/SY
Number of study participants with adverse events	49.5 % (47/95)	38.9 % (37/95)	37.0 % (17/46)	24.4 % (11/45)
Number of adverse events	133	78	33	22
Study exit				
Led to study exit	0.8 % (1/133)	1.3 % (1/78)	0.0 % (0/33)	0.0 % (0/22)
Did not lead to study exit	99.2 % (132/133)	98.7 % (77/78)	100.0 % (33/33)	100.0 % (22/22)
Seriousness				
Serious adverse events	5.3 % (7/133)	5.1 % (4/78)	6.1 % (2/33)	4.5 % (1/22)
Death	14.3 % (1/7)	25.0 % (1/4)	0.0 % (0/2)	0.0 % (0/1)
Non-death	85.7 % (6/7)	75.0 % (3/4)	100.0 % (2/2)	100.0 % (1/1)
Non-serious adverse events	94.7 % (126/133)	94.9 % (74/78)	93.9 % (31/33)	95.5 % (21/22)
Diagnosis				
Severe hypoglycemia	1.5 % (2/133)	2.6 % (2/78)	0.0 % (0/33)	0.0 % (0/22)
Diabetic ketoacidosis	0.0 % (0/133)	0.0 % (0/78)	0.0 % (0/33)	0.0 % (0/22)
None of the above	98.5 % (131/133)	97.4 % (76/78)	100.0 % (33/33)	100.0 % (22/22)
Study procedure- and device-relatedness				
Related to study procedure only	0.0 % (0/133)	0.0 % (0/78)	0.0 % (0/33)	0.0 % (0/22)
Related to study device only	12.0 % (16/133)	9.0 % (7/78)	9.1 % (3/33)	27.3 % (6/22)
Unanticipated adverse device effects / unanticipated serious adverse device effects	0.0 % (0/16)	0.0 % (0/7)	0.0 % (0/3)	0.0 % (0/6)
Unanticipated non-serious adverse device effects	0.0 % (0/16)	0.0 % (0/7)	0.0 % (0/3)	0.0 % (0/6)
Anticipated adverse device effects	0.0 % (0/16)	0.0 % (0/7)	0.0 % (0/3)	0.0 % (0/6)
Related to both study procedure and study device	0.0 % (0/133)	0.0 % (0/78)	0.0 % (0/33)	0.0 % (0/22)
Unanticipated adverse device effects / unanticipated serious adverse device effects	NA	NA	NA	NA
Unanticipated non-serious adverse device effects	NA	NA	NA	NA
Anticipated adverse device effects	NA	NA	NA	NA
Not related to study procedure or study device	88.0 % (117/133)	91.0 % (71/78)	90.9 % (30/33)	72.7 % (16/22)

severe hypoglycemic events (both in one participant) were reported during Period 1 and no DKA occurred.

The level of glycemic control achieved early in the course of disease, especially in those with early onset disease, has been linked with outcomes in later life, with longer duration of disease and poorer glycemic control in childhood linked with a higher likelihood of long-term complications such as retinopathy and nephropathy [24–27]. Additionally, evidence from a 2021 study showed that early initiation of pump therapy in CwT1D conveyed greater benefits compared with delayed initiation of pump therapy in terms of glycemic outcomes, hypoglycemic coma, and days in hospital due to diabetes [28]. In addition to the role in established diabetes-related complications, the role of early disease control in brain development in CwT1D is now an area of focus for many research groups. Higher HbA1c has been linked with lower volumes of white matter in some brain regions [29], and a significant relationship between hyperglycemia, glucose variability and white matter structure has also been reported in CwT1D [30]. Consequently, for young children, establishing good glycemic control early in the course of disease may have important implications in terms of brain development and complication risk in later life.

Although the LENNY trial provides the first evidence relating to the safety and efficacy of the new SY sensor in young children, two recent studies have investigated outcomes with the SY sensor in older children and adults [22,31]. For example, in a non-randomized single-arm study by Nally et al., the authors showed that MM780G with SY was safe and resulted in improved TIR compared with the study run-in period [31]. Additionally, the findings reported here largely concur with those of previous studies in children of similar ages. In particular, in a recent single-arm study in children aged 2–6 years, Pulkkinen et al. (2024) [11] reported a mean ± SD TIR of 67.0 ± 8.2 % as well as a mean ± SD TITR of 44.7 ± 7.1 % following 18 months use of the MM780G. Similarly, in the LENNY study phase, mean ± SD TIR in the run-in phase was 58.1 ± 14.3 %, compared with 68.3 % (6.9 %) in auto mode and 58.3 % (12.5 %) in manual + suspend before low feature enabled mode [12]. The findings also align with those reported in studies of other AID systems. In a 2022 single arm trial in children aged 2.0–5.9 years, the use of the Omnipod 5 system resulted in mean ± SD TIR of 68.1 ± 9.0 % (versus 57.2 ± 15.3 % at baseline) [32]. Similarly, mean ± SD TIR in a crossover trial of the CamAPS FX system in children aged 1–7 years was 71.6 ± 5.9 % [33].

The TIR values reported here and in other studies reiterate the challenges of achieving a TIR > 70 % in young children. The observation of higher TIR during nighttime, which was seen in the present study, has also been documented in previous studies with other systems. For example, in a 2022 trial of another hybrid-closed loop system in children aged 1–7 years, Ware et al. [33] reported that TIR was notably higher at nighttime than during daytime in both study periods. Such findings may offer reassurance to parents/caregivers, as fear around nocturnal hypoglycemia is a common concern among parents of young children with T1D [7]. On a related note, the present study also showed a small numerical improvement in sleep quality with the MM780G/SY relative to Period 1 of the continuation phase; however, the mean PSQI score in both groups was still above five, which is the threshold value for defining disturbed/poor sleep [13].

Additionally, a previous study using the MM780G has suggested that the greatest improvements in glucose control are seen shortly after treatment initiation and that there is only a small decline in treatment effect over time [34]. As such, studies with extended time frames of 1 year or more are especially valuable in terms of assessing the durability of treatment effects. This study shows durability of glycemic control for ≥ 1 year. In a recent long-term (2 years) study of the MM780G in children aged 7–16 years (with baseline HbA1c > 7.0 %), glycemic control improved over the first 3 months, and this was sustained through 24 months, although there was a decline in TIR (from 74.7 ± 6.5 % at 3 months to 70 ± 10.7 % at 24 months) [34]. A small decline in TIR between 3 months and 12 months (from 64.7 ± 11.8 % at 3 months to 62.0 ± 12.0 % at 12 months) was also reported in a UK-based real-world analysis of different hybrid closed-loop and AHCL systems [35].

Previous analyses of the MM780G in older patient groups have shown that outcomes are influenced by the settings used, with the use of optimized settings, in terms of active insulin time and glucose target leading to better outcomes [36,37]. For example, in a recent real-world analysis in children and adolescents aged 7–18 years based in Italy, shorter active insulin time was significantly related to better glucose control [36]. In the present study, the pump settings used were at the discretion of the investigator; outcomes according to different pump settings were assessed as exploratory outcomes and these were shown to be influential. TIR was generally higher in those with active insulin time of 2 h (data not shown); however, patient numbers across different settings were low, limiting the robustness of findings. The authors of a recent MM780G study in children and adolescents suggested that outcomes may be improved by more consistent use of optimal pump settings and also by greater attention to carbohydrate ratio settings to account for growth [34]. In this study, the majority of the time was not spent in the optimal setting, so there is room for improvement in terms of glycemic control.

The current study is associated with both strengths and limitations. Strengths include the randomized design with its high levels of adherence and very low attrition. It is also the first trial to examine the efficacy and safety of the MM780G combined with the SY in this patient group. Limitations include the fact that the study population consisted of a very homogenous population, e.g., the narrow age range of included participants (median baseline age was 4.67 [interquartile range: 3.75 to 5.67] years; and range 2.0 to 6.8 years) and the fact that participants had relatively good baseline glycemic control. The homogeneity of the cohort may have implications in terms of generalizability, and further studies in more heterogeneous groups (e.g., across different geographic regions and levels of baseline glycemic control) are needed to confirm the generalizability of the findings. However, the currently available evidence already suggests that the effect of MM780G in terms of glycemic control is consistent across regions [37–39]. Similarly, benefits of MM780G use have been observed across levels of baseline glycemic control, with larger benefits seen in people with poorer baseline glycemic control [21]. The glycemic control effect of MM780G by socioeconomic status will also need further elaboration but tentative evidence, currently available as a conference abstract, suggests that most users with the device achieve consensus glycemic targets regardless of socioeconomic status [40]. Further limitations include the fact that no data on food consumption or physical activity were collected, and quality of life (QoL), usability, and treatment satisfaction were not assessed. Further studies specifically aimed at addressing QoL and treatment satisfaction are needed to accurately determine the effect of the new sensor on these endpoints. The study size was also small for safety assessment, especially for those events that occur infrequently. In addition, heterogeneous system settings represented a limitation as system settings are known to affect glycemic outcomes so there remained some potential confounding from the use of different settings.

In conclusion, the findings of the continuation phase of the LENNY study show that, in children aged 2–6 years and a TDD of ≥ 6U, the use of MM780G/SY is non-inferior to MM780/G4S and that the safety and treatment effects observed with the MM780G are sustained for ≥ 1 year.

Disclosures

KD has received honoraria for speaking engagements from Abbott, Dexcom, Eli Lilly, Medtronic, Novo Nordisk and Pfizer and has served on advisory boards for Medtronic and Novo Nordisk. A-KT has received consultant or speaker fees from Medtronic, Nordic Infucare, Sanofi, and Ypsomed, research grants from Medtronic, and advisory board fees from Medtronic and Sanofi. IR has received consultant or speaker fees from Medtronic, advisory board fees from Sanofi, and research support from Sanofi. RA has received travel grants from Rubin Medical. RS has received consultant or speaker fees from Movi, and advisory board fees

from Sanofi. RR, BJ, FP, TH, JC and OC are employees of Medtronic.

Part of this work has been presented in abstract form at the ATTD meeting 19–22 March 2025, Amsterdam, The Netherlands.

Data availability

Study details and data, including protocol and statistical analysis plan are available from the study authors upon reasonable request.

CRediT authorship contribution statement

K. Dovc: Writing – review & editing, Investigation. **Ak. Tuomaala:** Writing – review & editing, Investigation. **S. Kuusela:** Writing – review & editing, Investigation. **A. Shetty:** Writing – review & editing, Investigation. **I. Rabbone:** Writing – review & editing, Investigation. **V. Tiberi:** Writing – review & editing, Investigation. **F. Campbell:** Writing – review & editing, Investigation. **C. Peters:** Writing – review & editing, Investigation. **R. Ahomäki:** Investigation, Writing – review & editing. **A. Zanfardino:** Writing – review & editing, Investigation. **P. Sundaram:** Writing – review & editing, Investigation. **R. Schiaffini:** Writing – review & editing, Investigation. **R. Re:** Writing – review & editing. **B. Jullian:** Writing – review & editing, Project administration, Methodology, Formal analysis, Conceptualization. **F. di Piazza:** Writing – original draft. **T. van den Heuvel:** Writing – original draft, Project administration, Methodology, Formal analysis, Conceptualization. **J. Castaneda:** Writing – review & editing, Project administration, Methodology, Formal analysis, Conceptualization. **O. Cohen:** Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of competing interest

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.

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Appendix A. Supplementary data

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