



# Safety of Real-life Usage of Advanced Hybrid Closed-Loop System MiniMed 780G in Children With Type 1 Diabetes Younger Than 7 Years Old

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Glycemic control in young children is challenging, mainly due to unpredictable meals and activities, fear of hypoglycemia by families, and minimal insulin doses. Although the hybrid closed-loop (HCL) systems have dramatically changed the management of type 1 diabetes and might offer a chance to improve glycemic control in these children, most of the devices available on the market are currently approved with minimum age and insulin daily dose limits.

We conducted a retrospective analysis of all children <7 years of age with type 1 diabetes followed at the Institute for Maternal and Child Health (IRCCS) “Burlo Garofolo” diabetes clinic who were on the Medtronic MiniMed 780G system for at least 6 months with SmartGuard feature (Auto Mode). The family agreed on the use of the algorithm, although it is currently only approved in children above the age of 7 years with a minimum daily insulin dose of 8 units. Sensor-specific measures of glycemic control were extracted from reports generated with CareLink Personal software with observation time frames of 2 weeks. Ethics committee approval was not requested, since the General Authorization to Process Personal Data for Scientific Research Purposes (authorization no. 9/2014) declared that retrospective archive studies that use identifier codes, preventing the data from being traced back directly to the data subject, do not need ethics approval. Data are presented as median and interquartile range

(IQR) for continuous variables and absolute frequency and percentage for categorical variables. We performed the Wilcoxon signed rank test to check whether the differences between paired data were statistically significant. A *P* value <0.05 was considered statistically significant.

Twelve children (5 female) were included in the study. Sensor-specific measures of glycemic control, adherence to advanced HCL (a-HCL) use, insulin dose and basal-to-bolus ratio, meals and carbohydrate (CHO) intake, and a-HCL settings are reported in Table 1.

Median age at diabetes onset was 3.8 years (IQR 2.3; 5.3). Subjects started using a-HCL in Manual Mode at a median age of 4.7 years (IQR 2.5; 6.2 [minimum 2.1; maximum 6.7]): in seven cases, a-HCL was started within 2 months after diabetes onset (median duration of diabetes 49 days [IQR 18; 341 [minimum 1; maximum 609]]). The Auto Mode was started after a median of 12 days (IQR 9; 32 [minimum 4; maximum 79]) in Manual Mode.

No episodes of ketoacidosis or severe hypoglycemia were recorded during the study period. At the beginning of Auto Mode, there was a significant increase in time in range (TIR) (70–180 mg/dL) (*P* < 0.01) and a significant decrease in time above range (TAR) (>180 mg/dL) (*P* = 0.02) and time below range (<70 mg/dL) (*P* = 0.01). Differences in TAR and TIR remained also at 6 and 9 months but not at 3 months. The minimum reported daily dose was 4 units; even when the total

daily dose was <8 units, the system was steadily running in Auto Mode (median 97.5% [IQR 95.8; 99.0]). While at the beginning target glucose was set at 120 mg/dL for the majority of children, after 3 months most of them used a target of 110 or 100 mg/dL, with a reduction in median active insulin time.

To our knowledge, this is the first study entirely conducted in children below the age of 7 years to report that the use of an a-HCL system MiniMed 780G is safe also with a total daily insulin dose <8 units and soon after diagnosis. Our data are in line with a recent prospective study conducted for 3 months in 35 children between 2 and 6 years of age (1); however, children with a total daily dose of <8 units per day and with a diagnosis ≤6 months old were excluded from that study (1). In a previous article investigators reported the case of a 9-year-old boy who started using MiniMed 780G with a total daily dose of 8.5 units that has dropped down to 5.7 units, with Auto Mode still running almost 100% of the time (2).

These results are relevant, considering that type 1 diabetes diagnoses at a younger age were associated with a detectable reduction in brain volumes and cognitive scores over time, mostly associated with hyperglycemia (3,4). On the other hand, good glycemic control in the first months after onset can have an important role in preventing the

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**Table 1—Sensor-specific measures of glycemic control, adherence to advanced hybrid closed loop (a-HCL) use, insulin dose and basal-to-bolus ratio, meals and CHO intake, and a-HCL settings\***

n	Manual		Auto Start		Auto 3M		Auto 6M		Auto 9M		Auto 12M		P <sub>Manual vs. Auto 12M</sub>
	12	12	12	12	12	12	12	10	8	10	8		
% TAR	39.0 (35.0; 40.8)	33.0 (25.0; 39.8)	0.02	28.0 (19.3; 48.3)	NS	32.5 (26.3; 38.0)	0.01	34.5 (26.3; 37.5)	0.02	30.5 (25.5; 40.3)	<0.01		
>250 mg/dL	12.0 (10.0; 16.8)	8.0 (5.0; 9.8)	0.01	7.0 (2.8; 15.8)	NS	9.5 (4.0; 11.0)	0.02	8.0 (4.8; 12.3)	NS	8.5 (3.3; 14.8)	0.01		
180–250 mg/dL	25.0 (23.0; 29.5)	26.0 (20.0; 26.0)	NS	21.5 (16.0; 26.5)	NS	23.5 (21.3; 26.3)	0.01	22.5 (20.5; 25.0)	NS	23.0 (19.5; 26.8)	0.01		
% TIR	57.0 (51.0; 62.8)	65.5 (58.3; 71.3)	<0.01	67.0 (49.3; 76.5)	NS	63.5 (58.8; 68.0)	<0.01	63.5 (60.0; 70.8)	0.02	66.5 (57.3; 70.5)	<0.01		
% TBR	4.0 (2.3; 5.0)	2.5 (2.0; 3.8)	0.01	4.0 (1.3; 4.8)	NS	3.0 (1.0; 6.5)	NS	3.0 (0.8; 4.3)	NS	3.5 (1.3; 4.0)	0.04		
54–70 mg/dL	3.0 (2.3; 4.0)	2.0 (2.0; 3.0)	0.04	3.0 (1.3; 3.8)	NS	3.0 (1.0; 4.8)	NS	2.0 (0.8; 3.0)	0.04	2.5 (1.3; 3.0)	0.01		
<54 mg/dL	1.0 (0.0; 1.0)	0.0 (0.0; 1.0)	NS	1.0 (0.0; 1.0)	NS	0.5 (0.0; 1.8)	NS	0.5 (0.0; 1.0)	NS	0.5 (0.0; 1.8)	NS		
% time in Auto Mode		98 (96; 100)		99 (97; 100)		100 (98; 100)		100 (97; 100)		99 (98; 100)			
% time of sensor wear	94 (73; 98)	98 (95; 98)	0.03	96 (93; 98)	NS	95 (93; 97)	NS	95 (94; 97)	NS	96 (93; 97)	NS		
Mean glucose sensor (mg/dL)	166 (163; 173)	160 (145; 166)	0.02	151 (140; 185)	NS	159 (149; 169)	0.02	162 (146; 169)	NS	159 (145; 174)	0.02		
SD glucose sensor (mg/dL)	68 (63; 77)	58 (56; 62)	<0.01	58 (51; 65)	NS	59 (54; 67)	0.01	60 (53; 68)	0.03	62 (52; 70)	<0.01		
CV (%)	38.9 (32.5; 43.3)	37.4 (35.4; 38.6)	0.03	37.5 (33.5; 40.2)	0.01	38.0 (35.2; 41.0)	NS	38.6 (35.9; 41.2)	NS	40.1 (36.0; 41.0)	NS		
GMI (%)	7.3 (6.6; 7.7)	7.1 (6.8; 7.3)	NS	7.0 (6.7; 7.8)	NS	7.1 (6.8; 7.4)	NS	7.2 (6.8; 7.3)	NS	7.1 (6.8; 7.5)	NS		
Total daily dose (units/day)	8.9 (6.0; 10.7)	8.7 (6.6; 11.6)	NS	12.3 (7.2; 18.1)	NS	13.7 (7.7; 20.0)	0.03	16.7 (7.5; 21.3)	0.03	17.8 (11.5; 23.9)	<0.01		
Total daily dose (units/kg/day)	0.60 (0.38; 0.78)	0.54 (0.43; 0.64)	NS	0.65 (0.50; 0.77)	NS	0.68 (0.49; 0.94)	NS	0.78 (0.48; 0.93)	NS	0.85 (0.61; 1.14)	NS		
Bolus (%)	50 (43; 58)	57 (53; 61)	0.03	62 (56; 64)	<0.01	60 (52; 62)	0.04	57 (54; 60)	NS	58 (54; 62)	NS		
Correction (%)		30 (19; 37)		32 (14; 53)		32 (19; 47)		35 (19; 48)		38 (28; 49)			
Basal (%)	50 (42; 57)	44 (39; 47)	0.03	39 (36; 44)	<0.01	41 (38; 48)	0.04	43 (40; 46)	NS	43 (38; 46)	NS		
Meals per day	3.4 (3.0; 3.9)	3.9 (3.5; 4.5)	NS	4.3(4.0; 5.6)	NS	4.9 (3.7; 5.5)	NS	5.0 (3.5; 5.8)	NS	4.8 (4.4; 5.6)	<0.01		
CHO (g/day)	119 (80; 139)	131 (82; 160)	0.03	116 (99; 160)	NS	127 (98; 160)	NS	122 (90; 140)	NS	124 (97; 164)	0.01		
SD CHO (g/day)	26 (19; 33)	20 (12; 24)	0.03	28 (18; 33)	NS	28 (22; 46)	NS	30 (21; 45)	NS	27 (17; 41)	NS		
CHO (g/kg/day)	6.40 (5.50; 7.98)	6.35 (5.48; 7.95)	NS	6.95 (5.75; 7.40)	NS	6.45 (5.95; 7.93)	NS	6.70 (5.15; 7.23)	NS	6.40 (5.00; 7.40)	NS		
Glycemic target (mg/dL)		120 (103; 120)		120 (110; 120)		115 (110; 120)		110 (100; 120)		110 (100; 120)			
120 mg/dL		67%		58%		17%		30%		37%			
110 mg/dL		8%		25%		33%		40%		25%			
100 mg/dL		25%		17%		50%		30%		37%			
AIT (h)		3.0 (2.6; 4.0)		3.0 (2.5; 3.0)		3.0 (2.5; 3.4)		2.5 (2.0; 3.1)		2.3 (2.0; 2.5)			

AIT, active insulin time; CHO, carbohydrates; CV, coefficient of variation; GMI, glucose management indicator; NS, not significant; SD, standard deviation; TAR, time above range; TIR, time in range; TBR, time below range. \*From reports generated with CareLink Personal software with observation time frames of 2 weeks, at insulin pump start in Manual Mode (Manual), at the beginning of Auto Mode (Auto Start), and after 3 months (Auto 3M), 6 months (Auto 6M), 9 months (Auto 9M), and 12 months (Auto 12M) of treatment.

development of microvascular complications in early childhood (5).

We, therefore, believe that where available an a-HCL system, such as MiniMed 780G, should be considered a good therapeutic option for children age <7 years from the onset of type 1 diabetes, also with a total insulin daily dose <8 units, as with low body weights and in the remission phase.

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**Author Contributions.** G.To. designed research, analyzed data or performed statistical analysis, and took responsibility for the contents of the article. M.A.L. and G.Ta. collected data and wrote the first draft of the manuscript, C.C., E.B., and E.F. contributed to the discussion and reviewed the manuscript. All authors read and approved the final manuscript. G.To. 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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