Medtronic
Engineering the extraordinary

Diabetes Clinical Summaries

MiniMed™ 780G System
Simplified Meal Announcement

Study rationale

- The MiniMed™ 780G System has shown to be safe and to significantly improve glycaemic control, compared to baseline or control treatment group in clinical trials and in real life[1-3].
- Carb counting is an essential component of diabetes management in both adults and children and associated with lower HbA1c and is still very important in automatic insulin delivery systems as per system design.
- Carb counting is very burdensome, and frequently done inconsistently and with poor accuracy especially in adolescents.

About the MiniMed™ 780G system

- The MiniMed™ 780G system contains an advanced hybrid closed loop (AHCL) algorithm that automates the delivery of both basal and correction insulin boluses every 5 minutes based on sensor glucose values, adapting to the individual's unique insulin needs.
- The AHCL algorithm targets a glucose level which can be adjusted by the user to be 5.5, 6.1or 6.7 mmol/L, based on individuals' needs.

Study objectives

- To compare glucose control in adolescents with Type 1 Diabetes (T1D) on MiniMed™ 780G system who used simplified meal announcement to those who used precise carbohydrate counting.

Get in touch to learn more about how the MiniMed™ 780G system can improve patient outcomes.

Get in touch

Key points

- 6.8% TIR difference in favor of the flex group
- No difference in the other glycaemic metrics
- Double the proportion of autocorrection boluses in fix group
- Simplified meal announcement is a valuable alternative

Study type

- Randomised Controlled Trial
- Fix meal vs Flex meal announcements
- 12 weeks
- 36 subjects:
  - Type 1 diabetes ≥ 12 months
  - Aged 12-18
  - MDI or pump therapy

Parameters assessed

- Time spent in the glycaemic ranges
- HbA1c
- Insulin use

References

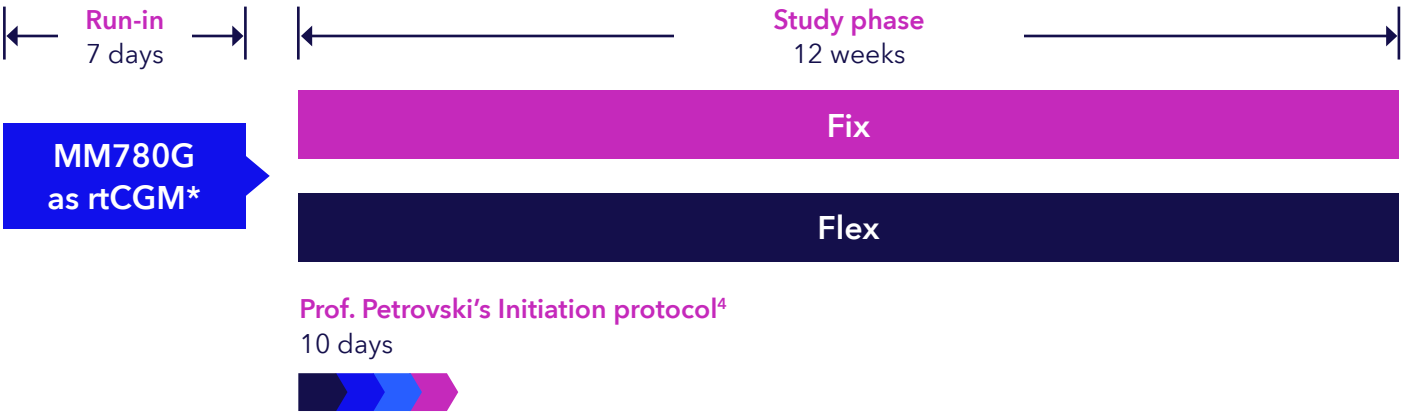
Petrovski G, et al. Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control. Diabetes Care 2023 doi: 10.2337/dc22-1692.

Access article online

Study design and methods

- This is a randomised controlled trial at 1 site, Sidra Medicine, Qatar, enrolling patients aged 12-18 years, with T1D duration ≥1 year and using multiple daily injections (MDI) or pump therapy.
- The study consists of a 7-day run-in period to assess carb counting skills and carb intake using a food diary. After randomisation, the subjects of both groups followed a 10-day initiation protocol[4] on the MiniMed™ 780G system and continued with a 12-week study phase. (Figure 1)
- Subjects were randomly assigned to the Fix group (simplified meal announcement by preset of 3 personalised fixed carbohydrate amounts) or the Flex group (precise carbohydrate counting).
- The 3 fixed-carbohydrate amounts were set as follows and personalised based on the 7-day run-in food diary:
  - regular meal at 40 to 70 grams
  - large meal at 60 to 90 grams
  - snack at 15 to 20 grams
- The primary endpoint was the between-group difference in TIR 3.9-10.0 mmol/L in the 12-week study phase. Secondary endpoints were between-group differences in HbA1c, other CGM derived metrics for glycaemic control, metrics for meal announcement and insulin use, metrics for system settings, and safety.

Figure 1: Study design



* no insulin delivered by the MiniMed™ 780G system

Study results

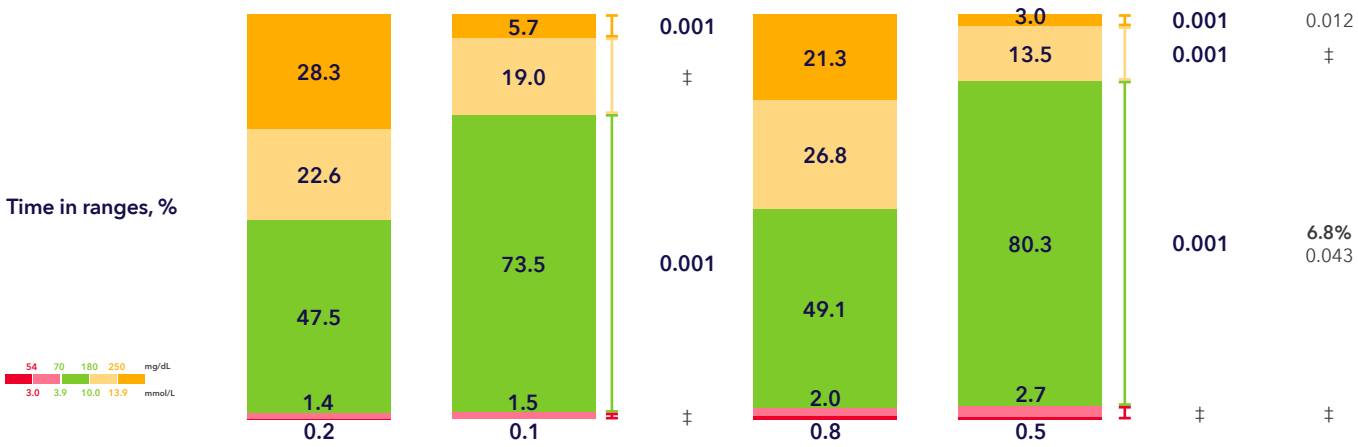
- Subjects were recruited between November 2021 and February 2022, and 34 subjects were randomly allocated to either the Fix group (N=17) or the Flex Group (N=17); all subjects completed the 12-week study period.

Glycaemic control

- Subjects in both groups spent a significantly greater proportion of time in range during the study phase compared to baseline (run-in phase), with a significant 6.8% TIR difference in favour of the flex group during the study phase (TIR: 80.3% and 73.5%, respectively, P<0.043, 95% CI 4.1-9.2) (Figure 2).
- No difference was shown between groups in the other glycaemic parameters except for time above 13.9 mmol/L. (Figure 2)
- HbA1c decreased in both groups compared to baseline; from 8.0 ± 2.1% to 6.8 ± 0.3% in the Fix group and from 7.9 ± 1.5%to 6.6 ± 0.5% in the Flex group, without a group difference (P=0.168).
- In the Fix group and in the Flex group, most of the subjects achieved the glycaemic targets of HbA1c <7% (70% vs 75%, respectively), of TIR >70% (67% vs 72%, respectively), and of TBR <4% (82% vs 86%, respectively).

Figure 2: Glycaemic control outcomes

	Fix group		p	Flex group		p	Group Δ p
	Baseline	Study		Baseline	Study		
Mean SG, mg/dL	174 ± 26	147 ± 23	0.002	168 ± 29	145 ± 18	0.005	‡
Mean SG, mmol/L	9.7 ± 1.4	8.2 ± 1.3	0.002	9.3 ± 1.6	8.1 ± 1	0.005	‡



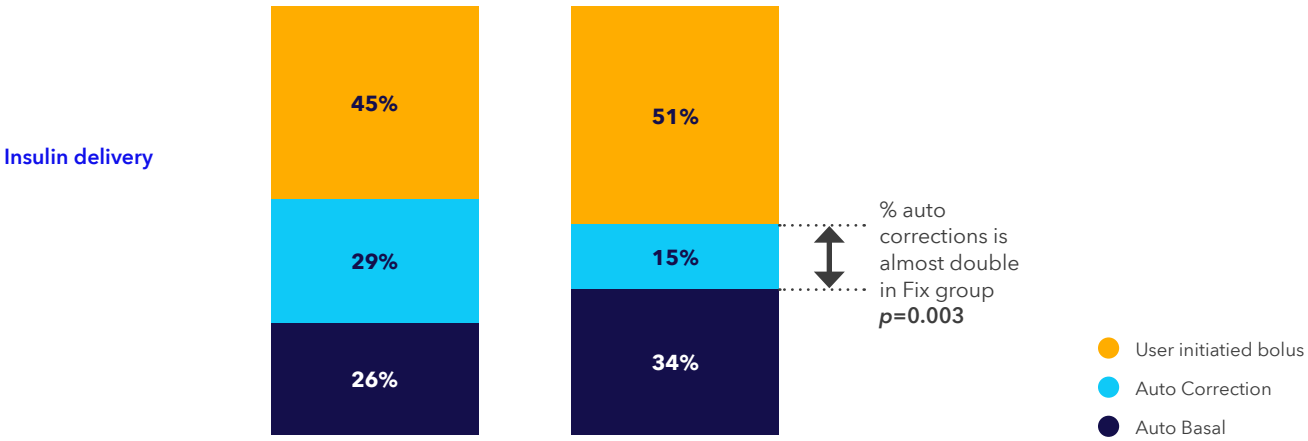
‡ non-significant

Insulin delivery

- Subjects in the Fix group announced fewer meals per day compared with the Flex group (P=0.003), but the total daily announced carbohydrates did not differ between the groups. (Figure 3)
- While the total daily insulin dose did not differ, the proportion of insulin delivered by autocorrection was doubled in the Fix group versus the Flex group (P = 0.003). (Figure 3)

Figure 3: Insulin delivery outcomes

	Fix Weeks 9-12	Flex Weeks 9-12	Group Δ p
Meals, n per day	3.7 ± 0.9	5.1 ± 1.1	0.003
Carbs, g/day	165 ± 66	178 ± 65	0.566
TDD, u/day	60.8 ± 10.2	60.1 ± 8.8	0.813



System use

- No group difference was observed in the sensor and pump use nor in the number of exits.
- The optimal settings, active insulin time of 2 hours and glucose target of 5.5 mmol/L, were both used by 94% of the subjects

Safety

- No episodes of severe hypoglycaemia nor DKA were reported in either group.

Conclusion

- Precise carbohydrate counting reaches better TIR in adolescents using the MiniMed™ 780G system users when compared to simplified meal announcement, but HbA1c and mean SG were comparable.
- Simplified meal announcement on average reached the international target criteria and is therefore a valuable alternative in those adolescents that cannot or do not want to count carbohydrates.
- Lower precision in carb counting is overcome by increased automated insulin delivery.
- Meal management with precise carbohydrate counting further improves outcomes, and thus carbohydrate estimation skills remain important.

Additional References

[1] Carlson AL, et al. Safety and Glycemic Outcomes During the MiniMed Advanced Hybrid Closed-Loop System Pivotal Trial in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther. 2022;24(3):178-189

[2] Arrieta A, et al. Comparison of MiniMed 780G system performance in users aged below and above 15 years: Evidence from 12,870 real-world users. Diabetes, Obesity and Metabolism 2022;24(7):1370-1379.

[3] Choudhary P, et al. Advanced Hybrid Closed Loop Study In An Adult Population With Type 1 Diabetes (Adapt): A Randomized Controlled Study. Lancet Diabetes Endocrinol. 2022;10(10):720-731.

[4] Petrovski G, et al. Successful transitioning children and adolescents with type 1 diabetes from multiple daily injections to advanced hybrid closed-loop system in 10 days: a prospective intervention study on MiniMed 780G system. Acta Diabetol. 2022;59(5):743-6.

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For detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events, please consult the device manual. For further information, contact your local Medtronic representative.

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