

# Optimising the CamAPS FX automated insulin delivery system for exercise and complex meals in adolescents with type 1 diabetes: A prospective interventional study in a camp setting

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## 1 | INTRODUCTION

Automated insulin delivery (AID) systems have revolutionised type 1 diabetes management.<sup>1-3</sup> Nevertheless, physical activity (PA) and complex meals challenge effective AID,<sup>4,5</sup> as they often cause

glycemic variability. While advanced features can address these challenges, there is little evidence-based guidance for their optimal use.<sup>6</sup> This study aimed to compare specific, user-driven, and recommendation-consistent strategies within the CamAPS FX AID system<sup>7</sup> to optimise glycemia during PA and complex meals in a real-world, supervised camp setting.<sup>6</sup>

## 2 | METHODS

### 2.1 | Participants

This was a prospective, interventional study of a cohort of adolescents with type 1 diabetes attending a supervised camp (Figure S1, Supporting Information). All participants were existing CamAPS FX system (FreeStyle Libre 3 Plus sensor) users. Twenty-six adolescents [14 males, median (IQR) age 14.8 years (13.7–15.8); diabetes duration 7.3 years (range 3.3–10.0); HbA1c 6.7% (6.5–7.1), weight 60.5 kg (54.1–68.9)] participated. The study received ethics committee approval, and informed consent was obtained.

### 2.2 | Physical activity and exercise challenge

Over two consecutive days, each participant undertook bouts of exercise (see Methods section in Data S1). For PA, participants were randomly assigned to undertake two of the three dose-adjustment strategies in a balanced, incomplete block design. The strategies, activated 2 h before exercise, were consistent with consensus recommendations to allow for sufficient reduction of insulin on board (IOB): Group A: Ease-Off function activated with a personal standard glucose target (GT) of 104 mg/dL (5.8 mmol/L) ( $N = 17$ ); Group B: Ease-Off function activated with a personal GT of 120 mg/dL (6.7 mmol/L) ( $N = 17$ ); and Group C: Personal GT set to 150 mg/dL (8.3 mmol/L) without activating the Ease-Off function ( $N = 18$ ). “Ease-Off” temporarily modifies the AID algorithm for less aggressive insulin delivery. All exercise sessions were conducted  $\geq 2$  h after eating.

To contextualise glycemic outcomes, exercise effort was quantified using heart rate and caloric expenditure data collected using a high-precision heart rate sensor (Polar H10, Polar Electro, Kempele, Finland). Since no maximal exercise test was performed, the % maximum heart rate was calculated using the age-predicted formula  $220 - \text{age}$ . A proactive protocol was used to prevent exercise-induced hypoglycemia (see Methods section in Data S1). The primary efficacy outcome was CGM-derived time in range (TIR; 70–180 mg/dL), analysed for the entire period from setting activation until 2 h post-exercise.

### 2.3 | Complex meal challenge

On the evening of Day 2, after a rest afternoon, participants were randomised in a parallel-group design to one of three bolus strategies for

a standardised complex dinner of spinach and ricotta pie, lasagna, bread, and a berry mousse (~700 kcal; 90 g carbohydrates, 34 g fat, 29 g protein) designed to represent a challenging, high-fat/protein meal often consumed by adolescents. There were no significant baseline differences in age, diabetes duration, or HbA1c between meal groups ( $p > 0.05$  for all). The groups were: Group D: 100% of the calculated dose as a standard bolus ( $N = 8$ ); Group E: 50% of the dose as a standard bolus and 50% as a “slowly absorbed meal” bolus delivered over 2 h ( $N = 8$ ); and Group F: 70% of the dose as a standard bolus and 30% as a “slowly absorbed meal” bolus delivered over 2 h ( $N = 10$ ). The “slowly absorbed meal” function allows users to split a meal bolus, delivering a portion upfront and the remainder over a user-defined period. Glycemic outcomes were analysed for a 5-h postprandial window.

### 2.4 | Statistical analysis

Data are presented as median and interquartile range (IQR) (not normally distributed, Shapiro–Wilk test). Outcomes for the randomised PA and meal modules were treated as independent observations per strategy and compared using the Kruskal–Wallis  $H$  test, with Dunn's test for post hoc comparisons. A  $p$ -value  $< 0.05$  was considered significant.

## 3 | RESULTS

### 3.1 | Overall system performance

Despite the glycemic challenges of the camp, median TIR remained stable across periods (pre-camp: 68.0%, during-camp: 68.0%, post-camp: 69.0%;  $p = 0.841$ ) (Table S1). Increased physical activity during the camp was associated with improved glycemic variability (CV decreasing from 37.0% to 34.8%,  $p = 0.012$ ) and reduced total daily insulin dose (TDD) (47.9–41.5 U/day,  $p < 0.001$ ) with fewer daily boluses ( $p < 0.001$ ) (Table S1).

### 3.2 | Physical activity and exercise challenges

Participants in Group C (150 mg/dL GT) exerted significantly higher physical effort compared to Groups A and B ( $p < 0.01$ ) (Table S2). The median (IQR) caloric expenditure was higher in Group C at 8.0 (6.8–9.2) kcal/min compared to 4.8 (4.1–5.5) kcal/min for Group A and 5.6 (5.0–6.1) kcal/min for Group B.

Despite this higher physiological demand, the Group C strategy was most effective in preventing hypoglycemia, resulting in the lowest TBR  $< 70$  mg/dL ( $p < 0.001$ ) (Table 1) but at the cost of more time in hyperglycemia (TAR  $> 180$  mg/dL: median 30.0% vs. 24.0% for Group B;  $p < 0.05$ ). In contrast, combining “Ease-Off” with a 120 mg/dL target (Group B) offered the best balance, achieving acceptable TIR (median 73.0%), while mitigating hypoglycemia without excessive

**TABLE 1** Glycemic outcomes during physical activity by randomised strategy.

Metric	Group A (Ease-Off, 104 mg/dL)	Group B (Ease-Off, 120 mg/dL)	Group C (No Ease-Off, 150 mg/dL)	p-value (Overall)
Time in range, %	69.0 (61.0–77.0)	73.0 (67.0–81.0)	69.0 (63.0–75.0)	0.285
Time below range (<70 mg/dL), %	3.5 (2.0–5.3) <sup>a</sup>	2.5 (1.8–4.0) <sup>a</sup>	1.0 (0.8–2.0) <sup>b</sup>	<b>&lt;0.001</b>
Time (<54 mg/dL), %	0.5 (0.0–1.0) <sup>a</sup>	0.5 (0.0–1.0) <sup>a</sup>	0.0 (0.0–0.3) <sup>a</sup>	<b>&lt;0.01</b>
Time above range (>180 mg/dL), %	27.0 (21.0–33.0) <sup>a,b</sup>	24.0 (18.0–29.0) <sup>a</sup>	30.0 (25.0–36.0) <sup>b</sup>	<b>&lt;0.05</b>
Time (>250 mg/dL), %	5.5 (3.0–8.0) <sup>a</sup>	4.5 (2.0–7.0) <sup>a</sup>	9.0 (6.0–13.0) <sup>b</sup>	<b>&lt;0.01</b>
Mean glucose (mg/dL)	152.0 (146.0–159.0) <sup>a,b</sup>	147.0 (141.0–155.0) <sup>a</sup>	158.0 (150.0–168.0) <sup>b</sup>	<b>&lt;0.05</b>
CHO corrections (n)	8.1 (6.8–9.7) <sup>a</sup>	4.5 (3.7–5.5) <sup>b</sup>	4.1 (3.3–5.0) <sup>b</sup>	<b>&lt;0.001</b>

Note: Data are presented as median (interquartile range). p-value from Kruskal–Wallis test. Values in the same row with different superscript letters (a, b) differ significantly ( $p < 0.05$ ) in Dunn's post hoc pairwise comparisons. Group sizes for this analysis were  $N = 17$  (Group A),  $N = 17$  (Group B), and  $N = 18$  (Group C). The bold values are the one significant.

**TABLE 2** Postprandial glycemic control following a complex meal by bolus strategy.

	Group D (100% Standard)	Group E (50/50 Split)	Group F (70/30 Split)	p-value (Overall)
Time in range, %	68.0 (60.0–75.0) <sup>b</sup>	80.0 (76.0–87.0) <sup>a</sup>	71.0 (65.0–78.0) <sup>b</sup>	<b>&lt;0.001</b>
Time below range (<70 mg/dL), %	1.5 (0.5–2.5)	1.0 (0.2–2.0)	1.2 (0.4–2.2)	0.650
Time (<54 mg/dL), %	0.4 (0.0–0.9)	0.2 (0.0–0.6)	0.3 (0.0–0.7)	0.710
Time above range (>180 mg/dL), %	30.0 (24.0–36.0) <sup>b</sup>	18.0 (14.0–23.0) <sup>a</sup>	28.0 (22.0–34.0) <sup>b</sup>	<b>&lt;0.001</b>
Time (>250 mg/dL), %	10.0 (7.0–14.0) <sup>b</sup>	4.0 (1.0–6.0) <sup>a</sup>	6.0 (3.0–9.0) <sup>a,b</sup>	<b>&lt;0.01</b>
Mean glucose, mg/dL	167.0 (158.0–176.0) <sup>c</sup>	140.0 (134.0–146.0) <sup>a</sup>	152.0 (145.0–160.0) <sup>b</sup>	<b>&lt;0.001</b>
Peak postprandial glucose (mg/dL)	239.0 (210.0–256.0) <sup>b</sup>	198.0 (178.0–209.0) <sup>a</sup>	201.0 (185.0–228.0) <sup>a</sup>	<b>&lt;0.01</b>

Note: Data are presented as median (interquartile range). p-value from Kruskal–Wallis test. Values in the same row with different superscript letters (a, b, c) differ significantly ( $p < 0.05$ ) in Dunn's post hoc pairwise comparisons. Group sizes for this parallel-group analysis were  $N = 8$  (Group D),  $N = 8$  (Group E), and  $N = 10$  (Group F). The bold values are the one significant.

hyperglycemia. Group B also required significantly fewer carbohydrate corrections than Group A ( $p < 0.001$ ) (Table 1).

### 3.3 | Complex meal challenge

The 50/50 bolus strategy (Group E) was superior for managing postprandial glucose (Table 2). This strategy was associated with a significantly higher TIR of 80.0%, compared to 68.0% (Group D,  $p < 0.001$ ) and 71.0% (Group F,  $p < 0.001$ ). Consequently, TAR >180 mg/dL was lowest in Group E (median 18.0%) compared with Group D (30.0%,  $p < 0.001$ ) and Group F (28.0%,  $p < 0.001$ ). Group E also achieved the lowest mean glucose and peak postprandial glucose ( $p < 0.01$  vs. Group D).

## 4 | DISCUSSION

This exploratory study suggests that proactive, user-driven adjustments can significantly enhance glycemic outcomes of the CamAPS FX AID system during PA and complex meals. For complex, high-fat meals, a standard bolus is inadequate.<sup>8,9</sup> A 50/50 split between a standard and “slowly absorbed meal” bolus provided a robust

strategy, as previously,<sup>10–14</sup> improving TIR by 12% over a standard bolus alone, providing a robust starting point for patients managing meals with a significant macronutrient mix when using the CamAPS FX system.

For PA, combining the “Ease-Off” feature with a moderate temporary target of 120 mg/dL best balanced mitigating hypoglycemia and avoiding excessive hyperglycemia, extending consensus statements<sup>6,15</sup> but providing new information on the interplay between energy expenditure and system settings.<sup>16</sup> The frequency of carbohydrate corrections, though different between groups, highlights the inherent challenge of preventing hypoglycemia during varied exercise, even with proactive AID adjustments. However, the results highlight that how an exercise setting is configured is as crucial as simply activating it.<sup>17</sup> Our findings, demonstrating the benefit of user-initiated adjustments, are consistent with observational data from other AID systems like the Tandem Control-IQ, where manual interventions were often necessary to prevent hypoglycemia during exercise.<sup>18</sup>

The primary strength of this study is its prospective design with randomisation of interventions in a supervised setting, which minimises many real-world variabilities. However, it also has limitations. First, a key limitation is the small sample size for the parallel-group meal challenge and the use of an incomplete block design for the physical activity module, which limits statistical power compared to a

full crossover design and prevents within-subject comparisons. Second, the study was conducted in a camp setting, which may not reflect daily life. Third, although standardising effort across participants, using an estimated maximum heart rate rather than direct measurement was a limitation, as was not assessing baseline fitness. The significant difference in exertion levels between the exercise strategy groups is a major confounder that prevents isolating the effect of the AID setting alone. The higher intensity in Group C likely contributed to stress-induced hyperglycemia, which, combined with the elevated GT, mitigated hypoglycemia but at the cost of significant TAR. While this finding raises the hypothesis that a higher pre-exercise glucose target may reduce fear of hypoglycemia, enabling greater physical exertion, this remains speculative. Finally, our analysis focused on the periprocedural period, and longer-term, 24-h glycemic effects were not assessed. Translating these short-term strategies into long-term, real-world conditions now warrants further investigation.

In conclusion, our findings suggest that using an automated insulin reduction feature (Ease-Off) with a temporary 120 mg/dL glucose target is a promising strategy for managing moderate-to-intense PA, while a 50/50 split bolus is highly effective for managing complex meals in the CamAPS FX system. These results provide evidence to empower users as active partners in their care, reinforcing AID therapy as a collaborative partnership between the user and the technology.<sup>1,19,20</sup> Future studies should examine strategy effectiveness for different exercise modalities.

#### AUTHOR CONTRIBUTIONS

Andrea E. Scaramuzza, Marco Marigliano, Othmar Moser, Riccardo Bonfanti, and Ivana Rabbone conceptualised the study, developed the methodology, and supervised the project. Andrea E. Scaramuzza was involved in data curation and formal analysis. Federico Abate Daga and Davide Tinti performed heart rate monitoring and analysed data. Bruno Bombaci, Roberto Franceschi, Donatella Lo Presti, Barbara Predieri, Carlo Moretti, Enza Mozzillo, Gianluca Musolino, Valentina Tiberi, Sonia Toni, and all collaborators in the study group contributed to the investigation and data discussion. Andrea E. Scaramuzza wrote the original draft. All authors reviewed, discussed, and edited the manuscript and approved the final version.

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#### CONFLICT OF INTEREST STATEMENT

A.E.S. is on the advisory board of Abbott, Medtronic, Movi, Sanofi, Theras and University Bocconi; has received travel grants from Ypsomed and Abbott. M.M. has received honoraria for lectures from Theras, Novo Nordisk, Ypsomed, and Medtronic, has been supported for attending meetings from Movi and Abbott, and has participated in data monitoring for Movi. O.M. has received clinical trial support: Sêr Cymru II COFUND, Fellowship/European Union, Novo Nordisk A/S, Novo Nordisk AT, Abbott Diabetes Care, Sanofi,

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#### PEER REVIEW

The peer review history for this article is available at <https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.70295>.

#### DATA AVAILABILITY STATEMENT

Andrea E. Scaramuzza 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. Data are available upon reasonable request made by email to the corresponding author with the aim of the request.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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