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Concurrent Validity of a Continuous Glucose-Monitoring System at Rest and During and Following a High-Intensity Interval Training Session

Pauline Clavel, Marina Fabre, Cédric Leduc, Eve Tiollier, Mathieu Lacome,
Martin Buchheit

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2 following a high-intensity interval training session.

3

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5 *Authors:* Clavel P^{1,2}, Tiollier E², Leduc C^{1,3}, Fabre M^{1,2}, Lacomme M^{1,2}, Buchheit M^{2,4,5,6}

6 ¹ Performance Department, Paris Saint-Germain FC, Saint-Germain-en-Laye, France

7 ² French National Institute of Sport (INSEP), Laboratory of Sport, Expertise and Performance
8 (EA 7370), Paris, France

9 ³ Carnegie Applied Rugby Research (CARR) centre, Institute for Sport, Physical Activity and
10 Leisure, Carnegie School of Sport, Leeds Beckett University, Leeds, United Kingdom

11 ⁴ HIITScience, Revelstoke, BC, Canada

12 ⁵ Institute for Health and Sport, Victoria University, Melbourne, VIC, Australia

13 ⁶ Kitman Labs, Performance Research Intelligence Initiative, Dublin, Ireland

14

15 *Contact details:*

16 Mathieu Lacomme

17 Paris Saint-Germain FC, Saint-Germain-en-Laye, France

18 Email: mlacomme@psg.fr

19 Mobile: +33 6 09 42 78 33

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28

29 **Abstract**

30 **Purpose:** To assess the concurrent validity of a continuous blood glucose monitoring system
31 (CGM) Post-Breakfast, Pre-exercise, Exercise and Post-exercise, while assessing the impact
32 of two different breakfasts on the observed level of validity. **Methods:** Eight non-diabetic
33 recreational athletes (age: 30.8 ± 9.5 years; height: 173.6 ± 6.6 cm; body mass: 70.3 ± 8.1 kg)
34 took part in the study. Blood glucose concentration was monitored every 10 min using both a
35 CGM (FreeStyle Libre, Abbott, France) and finger-prick blood glucose measurements
36 (FreeStyle Optimum, Abbott, France) over 4 different periods (Post-Breakfast, Pre-Exercise,
37 Exercise and Post-Exercise). Two different breakfasts (carbohydrates- [CHO] and protein-
38 [PROT] oriented) over two days (2x2 days in total) were used. Statistical analyses included
39 the Bland-Altman method, standardized mean bias (expressed in standardized unit), median
40 absolute relative difference (MARD) and the Clarke Error Grid (EGA). **Results:** Overall,
41 mean bias was trivial-to-small at Post-Breakfast (effect size \pm 90% confidence limits: -
42 0.12 ± 0.08), Pre-Exercise (-0.08 ± 0.08) and Post-Exercise (0.25 ± 0.14), while moderate during
43 Exercise (0.66 ± 0.09). Higher MARD was observed during Exercise (13.6% vs 7 to 9.5% for
44 the other conditions). While there was no effect of the breakfast type on the MARD results,
45 EGA revealed higher value in Zone D (*i.e.* clinically unsafe zone) during Exercise for CHO
46 (10.5%) compared with PROT (1.6%). **Conclusion:** The CGM device examined in this study
47 can only be validly used at rest, after both a CHO and PROT-rich breakfast. Using CGM to
48 monitor blood glucose concentration during exercise is not recommended. Moreover, the
49 accuracy decreased when carbohydrates are consumed before exercise.

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59 **Introduction**

60 Regulation of blood glucose has first been widely studied from a health perspective.
61 Hyperglycemia for example, is believed to be an independent risk factor for the development
62 of several diseases such as type II diabetes mellitus¹ and cardiovascular disease.² More
63 recently, the monitoring of blood glucose concentration has also elicited great interest in
64 sport, as hypoglycaemia influences both physical and cognitive performances.³

65 In particular, it is known that at the beginning of exercise or after half-time in team sports,
66 athletes experience transient hypoglycemia, which may affect physical and cognitive
67 performance.⁴ Moreover, it has then been shown that a large glycemic variability exists
68 among individuals in the general population.⁵ Additionally, similar results have been shown
69 in sub-elite athletes,⁶ suggesting that providing more individualized guidelines to regulate
70 blood glucose would be beneficial for both health and performance goals.

71 The emergence of new technologies such as continuous glucose monitoring (CGM) devices
72 has allowed blood glucose concentration dynamics to be captured more frequently and less
73 invasively than traditional measures such as finger pricks. Indeed, as CGM devices only need
74 to be placed once (usually on the back of the arm), it can be used for several days without
75 disturbing sport practices. So far, these devices have been mainly used by diabetic populations
76 but as the technology becomes more accurate, less invasive, and less expensive, their use has
77 increased in other populations and especially in healthy individuals. Therefore, the inclusion
78 of CGM in sport nutritionists' monitoring tool box could help to optimize nutritional
79 strategies before and during exercise, and in turn, improve athletes' performance by
80 preventing hypoglycemia. However, to date, the validity of these new systems at rest or
81 during exercise has been only assessed in diabetics patients and showed promising results.⁷
82 Evidence regarding its relevance with an athletic population is still lacking. Moreover, the
83 ability of such devices to detect potential glucose fluctuations due to different nutritional
84 intakes need to be confirmed.

85 Therefore, the aim of this study was to assess the concurrent validity of a new CGM device
86 during different periods, *i.e.* pre, during and after exercise, while assessing the potential
87 impact of different nutritional intakes in the observed level of validity.

88

89 **Methodology**

90 **Study Population**

91 Eight non-diabetic recreational athletes (5 females, 3 males) (age: 30.8 ± 9.5 years; height:
92 173.6 ± 6.6 cm; body mass: 70.3 ± 8.1 kg) who regularly participate in running and
93 resistance-based training (8 ± 2 hours per week) were included in the study. An a priori power
94 analysis was conducted using the package *pwr* from R software (Version 4.0.0) for t-tests for
95 non-parametric data with a significance level alpha of 0.05 a power of 0.8 and add a non-
96 parametric correction of 15%. Result showed a minimal sample of 310 paired observations for
97 8 participants were necessary. Alcohol intake was prohibited during the study period.
98 Regarding female participants, we ensured they were all within the same menstrual phase
99 during the study period.

100 Participants provided informed consent prior to starting the study. Ethics approval was
101 granted before any data collection was undertaken and the recommendations of the
102 Declaration of Helsinki were respected.

103

104

105 **Design**

106 A concurrent validity design was employed to assess the validity of a CGM system against
107 finger prick measures which was considered as the reference method. Over 2 consecutive
108 weeks, participants took part in 4 nonconsecutive standardized days. Each standardized day
109 was broken-down into 4 distinct periods: 1) Post-Breakfast which corresponded to the first
110 hour after the end of the Breakfast 2) Pre-Exercise which corresponded to the first hour
111 following the Post-Breakfast, 3) Exercise, which started 2 hours after the end of the breakfast
112 and lasted from the beginning of the warm up to the end of the workout and 4) Post-exercise,
113 which started immediately at the end of the workout, and up to 30 min later. A detailed
114 outline of the standardized day structure is provided in Figure 1. Nutritional intake during
115 breakfast was manipulated in order to provide either a high carbohydrate (CHO) or protein
116 (PROT) breakfast, to induce different levels of resting and pre-exercise glycemia. Each typical
117 breakfast was repeated twice. Over those standardized days, blood glucose was measured
118 continuously with a CGM, while finger prick measures were taken every 10 minutes and. Day
119 1 was used for each participant to familiarize with the CGM and ensure calibration (as per
120 manufacturer recommendations) before the experimentation could start. Between day 2 and

121 13, participants undertook at their convenience the 4 standardized days. They were also
122 instructed to have at least one full day of recovery between each experimental day.

123

124 **Insert Figure 1**

125

126 **Methodology**

127 *Continuous glucose monitoring.* Each participant was provided with a CGM system
128 (FreeStyle Libre, Abbott, France) over the full duration of the study. Each participant inserted
129 a sensor (FreeStyle Libre, Abbott, France) in their non-dominant upper arm (*i.e.* back the
130 triceps brachialis) one day before the beginning of the study. Glucose concentration was
131 recorded in the interstitial fluid every minute.

132 *Finger prick blood glucose.* Finger prick (FreeStyle Optium, Abbott, France) measures were
133 collected following the procedure described by Gomez.⁸ Each sample was immediately
134 analysed using the FreeStyle Libre reader (FreeStyle Libre Reader, Abbott, France) (The
135 validity and reliability of this device has been previously confirmed.⁹

136 *Breakfast.* Two typical breakfasts were employed. The CHO breakfast contained a high
137 proportion of carbohydrates (CHO) with 1 gKg⁻¹ of body mass with a ceiling set at 70g of
138 carbohydrates per breakfast (*e.g.* breakfast contained a mix of orange juice, bread and
139 jam).The macronutrients and energy were as follow: 65±7g of carbohydrates, 9±1g of
140 proteins and 1±0g of fat for a total of 311±31 Kcal. The protein (PROT) breakfast was
141 isoenergetic compared with CHO (*e.g.* breakfast contained a mix of eggs, ham and cheese).
142 The macronutrients and energy were as follow: 1±0g of carbohydrates, 30±0g of proteins and
143 23±0g of fat for a total of 311±31 Kcal.

144 *Standardized exercise.* Participants completed the 30-15 Intermittent Fitness Test (30-15_{IFT})
145 as described by Buchheit et al.¹⁰ prior the beginning of the study. The speed (km·hr⁻¹)
146 achieved by each participant during the last successfully completed stage of the test was
147 recorded (V_{IFT}) in order to prescribe exercise intensity. The standardized exercise started with
148 a 10-min low-intensity run (30 to 40% of V_{IFT}) and was followed by a high-intensity
149 intermittent training exercise performed outdoor. The trials consisted of six reps of 3-min
150 running intervals interspersed with 2 min of passive recovery. Reps 1 and 2 were performed at

151 75% V_{IFT} , reps 3 and 4 at 80% V_{IFT} and reps 5 and 6 at 85% V_{IFT} . The session was ended with
152 a 10-min walk.

153 *Data processing.* Each time point within a specific period was averaged as described above to
154 perform the concurrent validity analysis for each method (CGM and finger prick) and per
155 specific period (Figure 1). Each standardized day was analyzed first without (overall) and
156 then as a function of breakfast type (CHO and PROT).

157 **Statistical Analysis**

158 Bland-Altman method for repeated measures and standardized mean bias were first applied
159 to assess the agreement between CGM and finger prick measures at each specific period.¹¹
160 The following thresholds were applied to rate the magnitude of the bias as follow: >0.2
161 (small), >0.6 (moderate), >1.2 (large) and >2 (very large).¹²

162 Additionally, analysis of the median average relative difference (MARD)¹³ and the Clarke
163 Error Grid Analysis (EGA)¹⁴ were conducted. Regarding MARD, further comparisons
164 between the different periods were performed using Wilcoxon test and/or Kruskal-Wallis
165 tests. Level of statistical significance was set at $P < 0.05$. Results were further analyzed while
166 calculating standardized differences, *i.e.* Wilcoxon effect sizes. The thresholds to rate the
167 magnitude of the effects were the same than those used for mean bias. Regarding EGA,
168 results were divided into 5 zones (A, B, C, D, E). Each zone denotes a degree of clinical
169 implications of blood glucose concentration measures. Zones A and B were considered
170 clinically acceptable while zone C, D and E (erroneous treatment) were deemed possibly
171 unsafe.¹⁴

172

173 **Results**

174 The Bland-Altman analysis for the 4 periods is presented in Figure 2 and reported as mean
175 bias (standard error). Irrespectively of the breakfast content, mean biases were trivial-to-small
176 for Post-Breakfast (-2.99 [17.75] mg/dL), Pre-Exercise (-1.67 [10.95] mg/dL), Post-Exercise
177 (4.18 [17.88] mg/dL) and moderate during Exercise (12.25 [13.86] mg/dL). Regarding CHO
178 breakfast, mean biases were trivial-to-small for Post-Breakfast (-1.43 [25.98] mg/dL), Pre-
179 Exercise (-4.29 [11.66] mg/dL), Post-Exercise (3.32 [18.18] mg/dL) and moderate during
180 Exercise (14.06 [13.81] mg/dL). For PROT Breakfast, trivial mean bias was observed for Pre-
181 Exercise (0.91 [8.98] mg/dL), Post-Breakfast (-4.51 [8.31] mg/dL) and Post-Exercise (5.13

182 [15.98] mg/dL), while moderate mean biases were observed for Exercise (10.47 [13.19]
183 mg/dL).

184

185 **Insert Figure 2**

186 **Insert Figure 3**

187 The results of the MARD analysis between the different periods are presented in Table 1 and
188 2.

189

190 **Insert Table 1 and 2**

191

192 Results regarding EGA are presented in Table 3. Irrespectively of the breakfast content, Post-
193 Breakfast, Pre-Exercise, and Post-Exercise periods fell into Zone A (accurate) and B (benign
194 errors) (100%). However, during Exercise, 94% of the values fell into A (70.4%) and B
195 (23.6%), and 6% in Zone D (failure to treat errors). For CHO breakfast, 10.5% of data fell
196 into Zone D for Exercise, while the other periods fell into Zone A and B. Similarly, for PROT
197 breakfast, 1.6% fell into Zone D during the Exercise period.

198

199 **Insert Table 3**

200 **Discussion**

201 The aim of this study was 1) to investigate the concurrent validity of a new CGM device in
202 recreational athletes at Post-Breakfast, Pre-exercise, Exercise and Post-exercise, and 2) to
203 assess the potential impact of either a CHO-rich or protein-rich breakfast on the observed
204 level of validity. The main results highlighted that, while the validity of CGM was acceptable
205 at rest (*i.e.* Post-Breakfast, Pre-Exercise and Post-Exercise), it was lower during Exercise and
206 especially after the CHO breakfast.

207 The first results demonstrated trivial-to-small mean bias during all the non-exercise periods,
208 irrespectively of nutritional intake. Moreover, all results from EGA fell into the “clinically
209 safe zone” (A and B), albeit during Exercise. These results are similar to those shown
210 previously in non-athletic diabetic populations.¹⁵ Indeed, the present results suggest that

211 assessing glucose dynamics at rest is feasible with this CGM device. This could open the door
212 to a better individualization of nutritional strategies.⁵

213 Yet, we observed a higher bias during Exercise compared with the other periods, confirming
214 previous studies in a non-athletic diabetic population.¹⁶ Reasons that may contribute to the
215 reduced validity of the CGM device in this context include microcirculation perturbations as a
216 as a result of movements around or within the insertion area, increases in body temperature
217 and rapid fluxes in glucose levels during exercise.¹⁷ Regarding the likely physiological time
218 lag of glucose transport between blood and interstitial fluid compartments (see Figure 3,
219 finger pricks measures changed faster Post-Breakfast than that of the CGM device), it should
220 be noted that it might not have accounted for the observed difference in accuracy as the
221 pattern is not only delayed but it varies with time and conditions. Indeed, while a clear
222 hypoglycemia was observed with finger prick measures immediately at the start of exercise
223 (which was the expected physiological response), the CGM showed an increased blood
224 glucose response (Figure 2). Nonetheless, this discrepancy indicates that the CGM device was
225 unable to detect a potential hypoglycemia observed at the onset of exercise, and could
226 therefore not be used to assess strategies aiming at preventing this phenomenon in practice. It
227 is worth mentioning that a trend for a better agreement was observed toward the end of the
228 exercise periods (Figure 2). If the duration of the exercise also affects the accuracy of CGM, it
229 means that while the device may not be suitable for sport including short and intermittent
230 exercise durations, its use could perhaps be considered during longer event such as cycling,
231 trail or triathlon. This potential better accuracy toward longer exercise duration highlights the
232 need to conduct further research involving 1) longer exercise duration, 2) nutritional intake
233 during long endurance race 3) various exercise modalities and 4) different intensities.

234 To examine the potential effect of the absolute levels of glycemia on the validity of the CGM
235 device, different breakfasts were proposed (CHO and PRO). Similar MARD and EGA results
236 were observed, suggesting that the CGM validity was not affected by the breakfast content
237 during non-exercise periods (*i.e.* Post-Breakfast, Pre-Exercise, Post-Exercise). Specific pre-
238 competition nutritional strategies can have a positive influence on both the acute running
239 performance among rugby league players¹⁸ or endurance athletes,¹⁹ and the chronic training
240 adaptations to training.²⁰ Consequently, the use of this CGM device could be considered by
241 practitioners willing to monitor glycemic responses before and after competition or training,
242 to ensure the efficacy of the nutritional strategies employed.

243 However, during the Exercise period, the CGM accuracy was modulated by breakfast content.
244 Indeed, a 10 times higher value in Zone D of the EGA (*i.e.* clinically unsafe) was observed
245 post CHO (10.5%) compared with post PROT (1.6%) breakfast. In our study, zone D
246 corresponds to the situation where finger prick measures indicate an hypoglycemic state
247 whereas CGM measures are within the normal range¹⁴ suggesting that CGM failed to detect
248 the hypoglycemia occurring during exercise after the CHO-rich breakfast. It is well known
249 there is a rapid drop of blood glucose concentration at the onset of exercise, due to an
250 increased glucose uptake by exercising muscles.²¹ This physiological mechanism could
251 explain why the sensor lacks sensitivity to rapid changes in glucose concentration, as
252 observed in the present study. As it stands, if practitioners want to monitor blood glucose
253 during high-intensity intermittent exercise, they need to consider other devices than CGM
254 (e.g. finger prick).

255

256 **Practical applications**

257

- 258 - The present CGM system provided valid measures at rest. Therefore, the use of such a
259 system may allow for a better individualization of nutritional strategies before or after
260 competition.
- 261
- 262 - The level of validity was lower during high-intensity intermittent training and was in
263 addition influenced by the type of breakfast consumed (*i.e.* high carbohydrates or high
264 protein). Consequently, practitioners should avoid using this device during intermittent
265 exercise.

266

267 **Conclusion**

268 Daily monitoring of blood glucose is of importance in athletes given the likely impact of
269 glycemia on performance and the individualized nutritional recommendations that can be
270 made with CGM. Our results highlighted that the CGM device examined in the present study
271 presented only trivial-to-small bias when compared with a traditional fingerpick device at rest,
272 suggesting that it could be used confidently during this specific period. The CGM device is
273 not valid enough to monitor glucose during intermittent exercise. Further analyses should
274 however evaluate the validity of this device over longer exercise duration.

275

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- 342

Table and figure caption

Figure 1. Schematic representation of the study design.

Figure 2. Bland-Altman analysis between the continuous glucose monitoring device (CGM) and finger prick measures (FPBG). Dash lines represent the limits of agreements.

Figure 3. Continuous glucose monitoring (CGM) and finger prick measures during each standardized condition, when ingesting a carbohydrate- (upper) and protein- (lower) oriented breakfasts, with the 2 days of each breakfast condition pooled for each participant ($n = 2 \times 8$ for each curve). Data are presented as mean (SE).

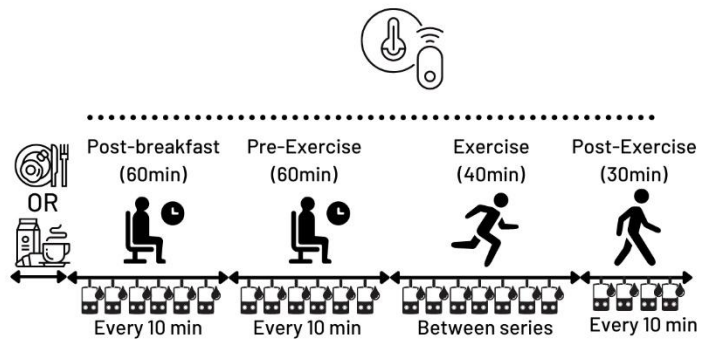
Table 1. Median Absolute Relative Difference between the continuous glucose monitoring device (CGM) and finger prick measures. Data are median (interquartile range) and expressed in percentage. *: significantly different from Post-Breakfast. #: significantly different from Pre-Exercise. †: significantly different from Exercise. Comparisons between period are presented as effect size with 90% confidence interval.

Table 2. Comparisons between period are presented as effect size for Wilcoxon test with 90% confidence interval.

Table 3. Clark Error Grid Analysis between the continuous glucose monitoring device (CGM) and finger prick measures. Zone A represents a clinically accurate measure. Zone B stands for benign errors. Zone C represents overcorrection errors. Zone D and E represent failure to treat errors and erroneous treatment errors respectively. For more details see Clarke et al. (1987).

Figures

Figure 1



Legend:



Protein Breakfast



Carbohydrate Breakfast



Continuous glucose monitoring



Finger prick blood glucose

Figure 2

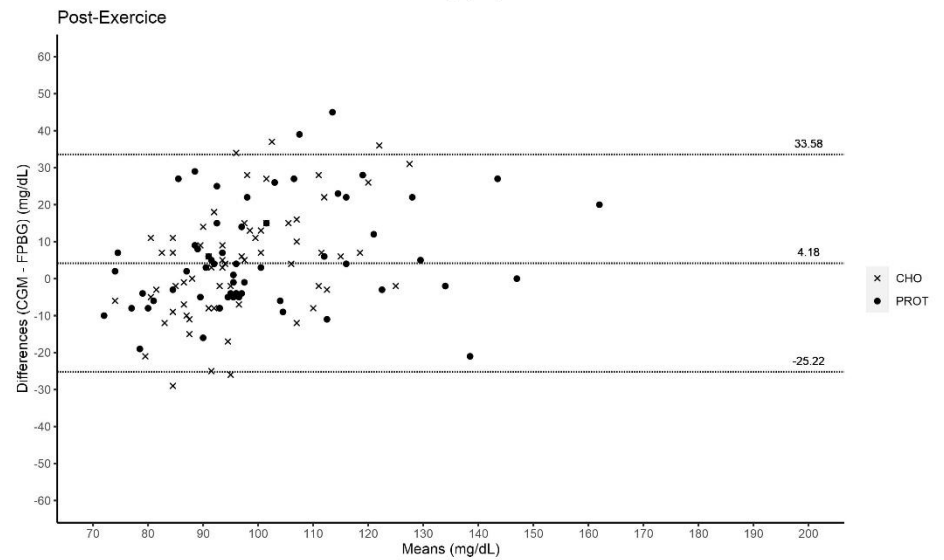
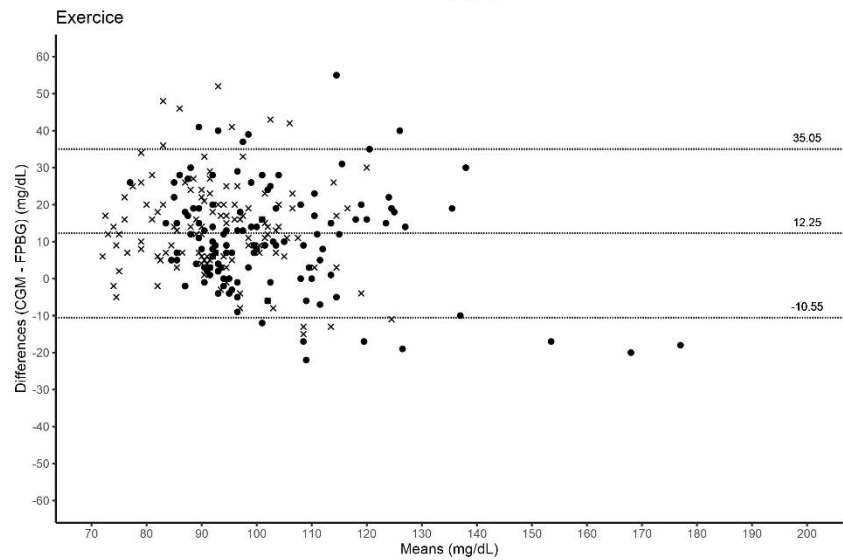
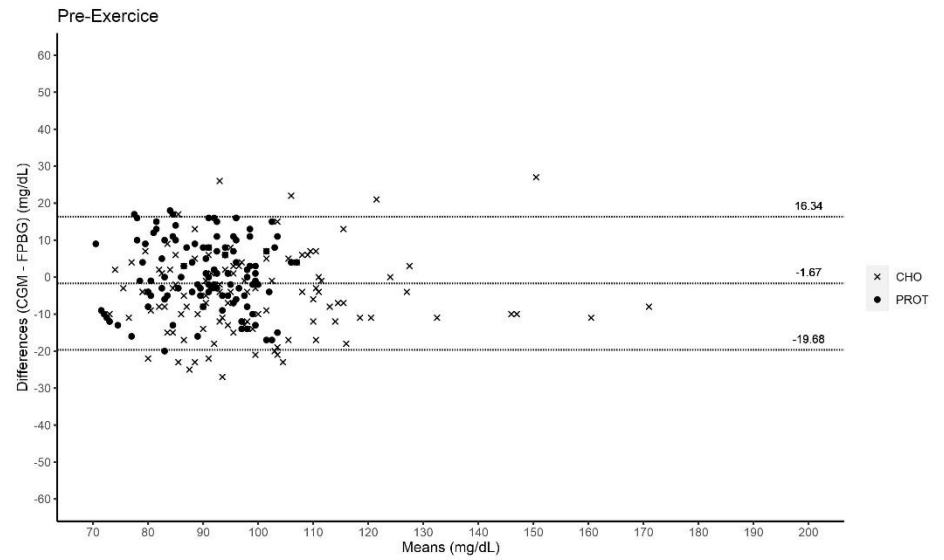
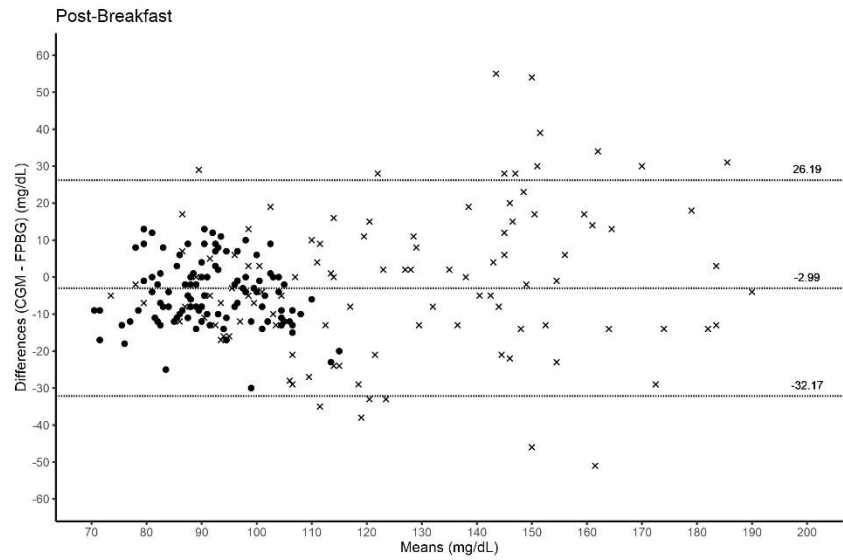
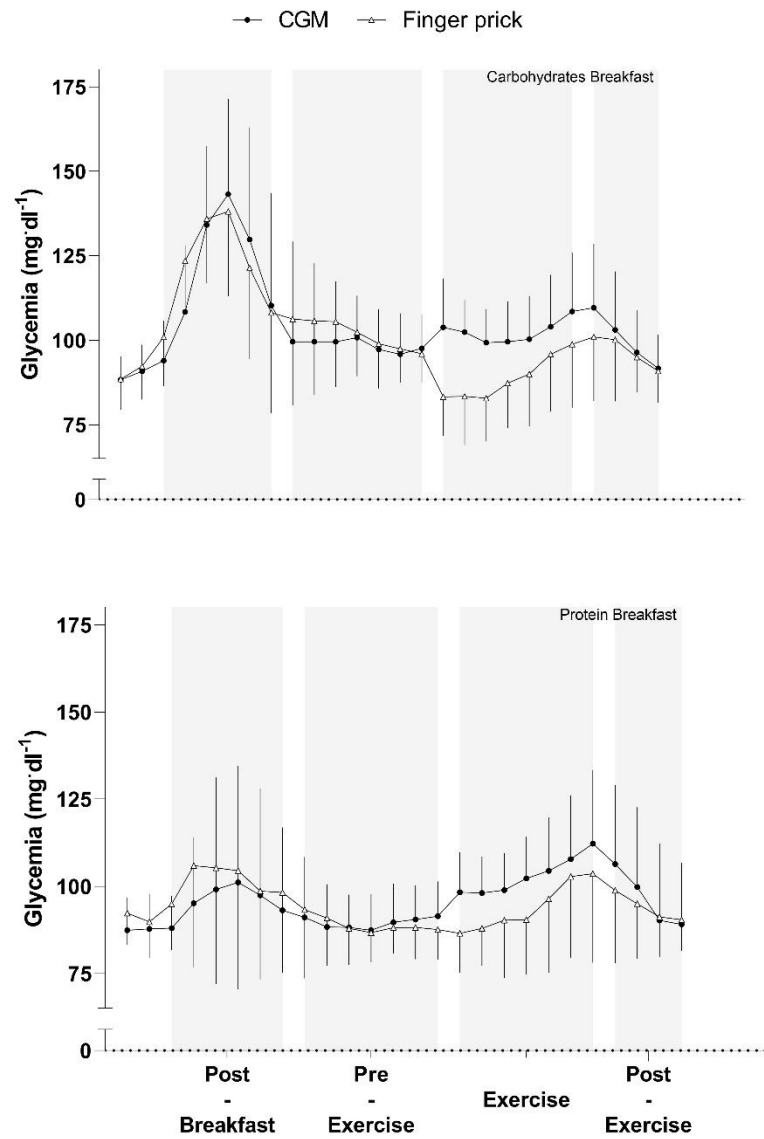


Figure 3



Tables

Table 1

	Post- Breakfast	Pre- Exercise	Exercise	Post- Exercise
Overall	9.1 (4.6-13.8)	7.1 (3.6-13.4) #	13.6 (6.8-23.2) *	9.4 (5.0-17.3) #†
CHO	9.4 (5.3-16.8)	7.1 (3.9-13.2) *	16.2 (7.4-25.6) *#	10.1 (6.1-16.9) #†
PROT	8.8 (4-11.9)	7.0 (3.4-13.4)	11.3 (6-19.7) *#	8.2 (4.1-17.3)

Table 2

	Post-Breakfast	Post-Breakfast	Pre-Exercise	Pre-Exercise	Exercise
	vs.	vs.	vs.	vs.	vs.
	Exercise	Post-Exercise	Exercise	Post-Exercise	Post Exercise
Overall	0.24 (0.17 to 0.31)	0.07 (0.01 to 0.16)	0.31 (0.24 to 0.38)	0.16 (0.07 to 0.24)	0.15 (0.06 to 0.23)
CHO	0.24 (0.13 to 0.34)	0.06 (0.01 to 0.18)	0.37 (0.27 to 0.46)	0.19 (0.07 to 0.31)	0.18 (0.07 to 0.28)
PROT	0.24 (0.14 to 0.34)	0.08 (0.01 to 0.2)	0.26 (0.16 to 0.36)	0.18 (0.01 to 0.24)	0.12 (0.02 to 0.24)

Zone	Post-Breakfast	Pre-Exercise	Exercise	Post-Exercise
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Table 3

Overall	A (Accurate)	189 (88.3%)	213 (93.4%)	176 (70.4%)	100 (76.3%)
	B (Benign errors)	25 (11.7%)	14 (6.1%)	59 (23.6%)	31 (23.7%)
	D (Failure to treat errors)	/	1 (0.5%)	15 (6.0%)	/
CHO	A (Accurate)	85 (80.2%)	104 (92.0%)	81 (65.3%)	52 (75.4%)
	B (Benign errors)	21 (19.8%)	9 (8.0%)	30 (24.2%)	17 (24.7%)
	D (Failure to treat errors)	/	/	13 (10.5%)	/
PROT	A (Accurate)	104 (96.3%)	109 (94.8%)	95 (75.4%)	48 (77.4%)
	B (Benign errors)	4 (3.7%)	5 (4.3%)	29 (23.0%)	14 (22.6%)
	D (Failure to treat errors)	/	1 (0.9%)	2 (1.6%)	/