Article:
Lancaster, M.K., Edwards, H., Harper, D. et al. (2026) Evaluation of a New Continuous Glucose Monitoring Device. Journal of Diabetes Science and Technology. ISSN: 0103-4065

https://doi.org/10.1177/19322968261427025

Evaluation of a New Continuous Glucose Monitoring Device.

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Abbreviations: (CGM) Continuous Glucose Monitor

Keywords:

accuracy; bluetooth; continuous glucose monitor; diabetes; MARD; diabetes.

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Funding source: Urathon

Conflict of Interest:

All funding for the study was paid directly to the University of Leeds and the authors did not receive any financial incentives. At no point did Urathon have access to any data or participant information. It should be noted that ML, DH, and AU are sitting on an expert panel for Urathon.

Acknowledgments:

We would like to thank all the participants for their valuable time and contribution to the study. In addition, we would like to thank Urathon for funding the study.

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There are a number of continuous glucose monitoring (CGM) devices on the market and research has shown that they can be valuable in providing support and information to people with type 2 diabetes, improving outcomes and reducing demand on secondary care services and GP time (1-3). The purpose of this study was to evaluate the accuracy of a new CGM system, the Yuwell Anytime CT3, in participants with type 2 diabetes.

A total of n=40 participants were recruited for the 10-day study (n= 18 males and n= 22 females). Inclusion criteria were: diagnosed with type 2 diabetes; aged 21-80 years. Three failed to complete >30% of the data collection and were removed from the analysis. The final n number of 37 had a mean age (± standard deviation) of 55.9 ± 12.1 years and body mass index of 28.5 ± 6.0 $kg.m^{-2}$.

Participants were asked to record their glucose levels for 10 days using the two sampling modalities (3). The CGM was attached to the skin (upper arm) remaining in position for the duration of the study. An Accu-Chek Instant capillary blood glucose test system was used as the comparator. Participants simultaneously logged blood and CGM measurements on three occasions per day: before breakfast; before lunch; and before their evening meal. Data was maintained as pairs of readings for each of the individual participants allowing collective and inter-individual comparison of data agreement. Data were processed and statistically analysed in Microsoft Excel and GraphPad Prism 10.5 respectively.

The 37 sets of data yielded a total of 1082 paired glucose sample points ranging from 52 - 425 mg/dL (2.9-23.6 mmol/L). Pearson correlation analysis of simultaneously obtained pairs of data values from the CGM and finger-prick blood sample yielded a correlation coefficient of 0.92 ($p<0.0001$) (Figure 1) showing very strong, significant agreement between measures. The mean average relative difference (MARD) between measures was 6.9%. Analysis of age and BMI failed to identify any interactions with the MARD ($p>0.05$ by MANOVA).

For confidence it is important to consider accuracy across the physiological range (4). The majority of the data set (839 readings) fell within the range 70-180 mg/dL (3.9-10 mmol/L) with a MARD of 6.6 and Pearson's correlation of 0.74 ($p<0.0001$). As expected for people with type-2 diabetes 237 readings were greater than 180 mg/dL (10 mmol/L) with a MARD of 9.3 and Pearson's correlation of 9.3 ($p<0.0001$) across this range. Given the population studied very few (6) readings fell below 70 mg/dL (3.9 mmol/L) so a reliable indicator of accuracy in this range could not be given (Correlation = 0.57 but $p = 0.24$).

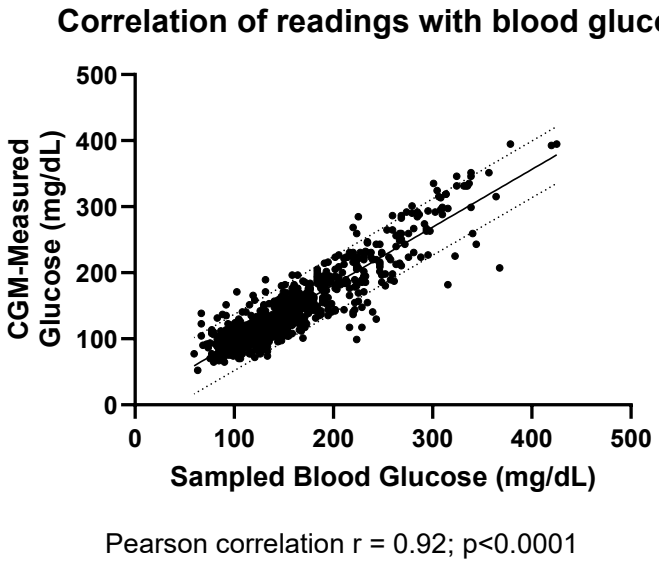

Figure 1. Linear correlation between pairs of CGM and blood measured glucose values. Solid line shows the linear regression to the data. Dashed lines show 95% confidence intervals of agreement.

The CGM measures show a significant, close correlation with blood glucose in this key patient cohort of people with type 2 diabetes. The data range is representative of that seen in other studies (5), even treated patient cohorts where desirable target ranges are 72-144 mg/dL (4-8 mmol/L) in advance of each meal (6). The CGM device as assessed offers a potential valuable tool for guiding treatment of people with diabetes.

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