

Agreement and bias of three capillary blood glucose meters compared with venous plasma glucose across clinically relevant glycemic ranges in primary care: a multicenter cross-sectional study

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Abstract

Background

Capillary blood glucose meters remain widely used in diabetes management despite the increasing adoption of continuous glucose monitoring systems. Accurate glucose measurements are essential for therapeutic decision-making, particularly in patients at risk of hypoglycemia. This study aimed to evaluate the agreement and bias of three commonly used capillary blood glucose meters compared with venous plasma glucose and to assess their performance across clinically relevant glycemic ranges in a real-world primary care setting.

Methods

We conducted a multicenter cross-sectional observational study in seven primary care centers. Patients with diabetes undergoing routine blood testing were opportunistically recruited. Simultaneous glucose measurements were obtained using three capillary blood glucose meters (Contour, Glucomen, and FreeStyle) and venous plasma glucose as the clinical comparator. Agreement was assessed using Pearson's correlation coefficient, Bland–Altman analysis (mean bias and 95% limits of agreement), and mean absolute difference (MAD). An ISO-inspired tolerance criterion was calculated as ± 15 mg/dL for glucose values < 100 mg/dL and $\pm 15\%$ for values ≥ 100 mg/dL. Analyses were stratified into three glycemic ranges: < 100 , $100\text{--}180$, and ≥ 180 mg/dL.

Results

A total of 142 measurement episodes were recorded, of which 131 included complete data from all four methods. Correlations between devices and venous plasma glucose were high ($r = 0.953\text{--}0.970$). FreeStyle showed the closest agreement with venous plasma glucose, with a mean bias of -2.67 mg/dL, a MAD of 8.08 mg/dL, and 96.9% of measurements within the predefined tolerance limits. Contour and Glucomen systematically overestimated glucose values, with mean biases of $+10.73$ mg/dL and $+6.85$ mg/dL, respectively. Differences were most pronounced in the < 100 mg/dL range, where Contour showed a mean bias of $+14.10$ mg/dL and only 55.2% of measurements within tolerance, compared with 96.6% for FreeStyle.

Conclusions

High correlation between blood glucose meters does not necessarily indicate clinical interchangeability. Systematic biases were identified, particularly at lower glucose concentrations, where inaccuracies may affect hypoglycemia detection and therapeutic decisions. Consistent use of the same device should be encouraged, and caution is warranted when switching between glucose meters in clinical practice.

Trial registration

Not applicable. This study was an observational diagnostic agreement study and did not involve a healthcare intervention requiring trial registration.

Background

Diabetes mellitus is one of the most common chronic diseases managed in primary care and represents a major challenge for healthcare systems worldwide. Self-monitoring of blood glucose is a fundamental component of diabetes management because it provides immediate information that enables both patients and healthcare professionals to optimize glycemic control and reduce the risk of long-term complications (1). In individuals receiving intensive insulin therapy, the accuracy of glucose measurements is particularly important, as treatment decisions are often based directly on meter readings. Measurement errors may therefore lead to inappropriate insulin dosing and increase the risk of clinically significant hypoglycemic or hyperglycemic events (2, 3).

Although continuous glucose monitoring technologies are increasingly used and have improved diabetes self-management, capillary blood glucose meters remain widely employed in routine clinical practice. They continue to be essential for many patients who do not use continuous monitoring systems and are frequently recommended to confirm glucose values in situations where sensor accuracy may be reduced, such as rapidly changing glucose levels or extreme glycemic ranges (9). Consequently, the analytical performance of capillary glucose meters remains highly relevant for clinical decision-making in primary care.

The accuracy of blood glucose meters is currently evaluated according to international standards such as ISO 15197:2013, which requires that the majority of measurements fall within predefined limits compared with a laboratory reference method (5). However, several studies have shown that device performance under routine clinical conditions may be influenced by factors including strip lot variability, hematocrit levels, environmental conditions, endogenous substances, and medication interference (3, 5). Furthermore, concerns have been raised that manufacturer-sponsored evaluations may not fully reflect the performance achieved in everyday clinical practice because testing is often conducted under highly controlled conditions (1, 5).

An additional challenge is that differences between capillary and venous glucose measurements may vary according to physiological conditions. While fasting capillary and venous glucose concentrations are generally similar, larger discrepancies may occur in postprandial states due to glucose uptake by peripheral tissues, resulting in systematically higher capillary glucose values (6). These considerations highlight the importance of evaluating glucose meters under real-world conditions and against clinically relevant comparators.

Most previous studies have focused on regulatory compliance and analytical accuracy. However, from a clinical perspective, agreement and interchangeability between devices may be equally important. High

correlation between glucose meters does not necessarily imply that measurements can be used interchangeably, since systematic bias may produce clinically meaningful differences despite strong statistical association. This issue may be particularly relevant at lower glucose concentrations, where small deviations can affect the recognition and management of hypoglycemia (7, 8).

Methods

Study aim, design and setting

The aim of this study was to evaluate the agreement and bias of three commonly used capillary blood glucose meters compared with venous plasma glucose and to assess their performance across clinically relevant glycemic ranges in routine primary care practice.

We conducted a multicenter cross-sectional observational study in seven primary care centers belonging to Badalona Serveis Assistencials (BSA), Catalonia, Spain. Data were collected prospectively under real-world clinical conditions during routine diabetes follow-up visits. The study was designed to assess the level of agreement between different glucose measurement methods rather than to validate devices against an ISO-traceable reference method.

Participants and data collection

Patients with a previous diagnosis of diabetes mellitus who attended their scheduled routine blood testing appointments were invited to participate opportunistically. Individuals who agreed to participate provided written informed consent before inclusion.

For each participant, capillary blood glucose was measured consecutively using three commercially available blood glucose meters: Contour® (Ascensia Diabetes Care), GlucoMen® (A. Menarini Diagnostics), and FreeStyle® (Abbott Diabetes Care). Venous plasma glucose obtained from the same clinical encounter and analyzed by the reference laboratory was used as the clinical comparator.

A total of 142 measurement episodes were recorded. Complete data from all three glucose meters and venous plasma glucose were available for 131 observations, which constituted the final analytical sample. Measurements were performed under routine clinical conditions by healthcare professionals following standard procedures used in primary care practice.

Sample size estimation was based on recommendations for Bland–Altman agreement studies. Assuming a standard deviation of differences of 12 mg/dL and a desired precision of ± 5 mg/dL for the estimation of the 95% limits of agreement, a minimum of 18 paired measurements was required. The final sample of 131 complete observations provided robust estimates of bias and limits of agreement and allowed stratified analyses across glycemic ranges.

Measurements and statistical analysis

The primary variables were glucose concentrations (mg/dL) obtained from each capillary blood glucose meter and venous plasma glucose. Data were imported into a dedicated database and underwent systematic cleaning procedures, including variable standardization, verification of numerical formats, and assessment of physiologically plausible ranges. Potential outliers were identified during exploratory analyses but were retained because the objective was to compare device performance under real-world conditions.

Agreement between measurement methods was assessed using a multimethod approach. Pearson's correlation coefficient (r) was calculated to evaluate linear association between pairs of measurements. Bland–Altman analyses were performed to estimate mean bias and 95% limits of agreement (LoA), defined as the mean difference ± 1.96 standard deviations of the paired differences. Mean absolute difference (MAD) was calculated as a measure of the typical magnitude of disagreement between methods.

As an additional clinically oriented metric, we calculated the proportion of measurements meeting an ISO-inspired tolerance criterion: differences within ± 15 mg/dL when the comparator value was < 100 mg/dL and within $\pm 15\%$ when the comparator value was ≥ 100 mg/dL. This analysis was performed for comparative purposes only and should not be interpreted as formal compliance with ISO 15197 standards because an ISO-traceable reference method was not used.

To explore whether agreement varied according to glucose concentration, analyses comparing each device with venous plasma glucose were stratified into three clinically relevant glycemic ranges: < 100 mg/dL, $100\text{--}180$ mg/dL, and ≥ 180 mg/dL. Within each stratum, the number of observations, mean bias, MAD, and percentage of measurements within tolerance were calculated.

Continuous variables are presented as means, standard deviations, minimum and maximum values, and coefficients of variation where appropriate. Statistical significance of paired mean differences was assessed using paired Student's t -tests. All analyses were performed using IBM SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA).

Ethical considerations

The study was reviewed by the Research Committee of Badalona Serveis Assistencials (BSA), which determined that formal review by a Research Ethics Committee was not required because of the observational, non-interventional design of the study. All participants provided written informed consent before inclusion. Data were anonymized before analysis and handled in accordance with the Declaration of Helsinki, Regulation (EU) 2016/679 (GDPR), and applicable Spanish legislation.

Results

Study population and glucose measurements

A total of 142 measurement episodes were collected from patients with diabetes attending seven primary care centers. Complete data from the three capillary blood glucose meters and venous plasma glucose were available for 131 episodes (92.3%), which constituted the analytical sample.

Descriptive statistics for glucose measurements obtained with each method are presented in Table 1. Mean glucose values ranged from 127.9 mg/dL for FreeStyle to 141.3 mg/dL for Contour, while the mean venous plasma glucose concentration was 130.6 mg/dL. Variability was comparable across methods, with coefficients of variation ranging from 26.7% to 29.7%.

Agreement between glucose meters and venous plasma glucose

Correlation coefficients between capillary blood glucose meters and venous plasma glucose were high, ranging from 0.953 to 0.970 (Table 2). Similarly, correlations between the capillary devices themselves ranged from 0.945 to 0.959.

Despite these strong correlations, Bland–Altman analyses revealed systematic differences between devices. FreeStyle showed the closest agreement with venous plasma glucose, with a mean bias of – 2.67 mg/dL and a mean absolute difference (MAD) of 8.08 mg/dL. In contrast, Contour and GlucoMen systematically overestimated glucose concentrations, with mean biases of + 10.73 mg/dL and + 6.85 mg/dL, respectively.

The widest discrepancy between capillary devices was observed for the comparison between Contour and FreeStyle, which showed a mean bias of + 13.40 mg/dL and 95% limits of agreement ranging from – 7.69 to + 34.50 mg/dL. Comparisons between Contour and venous plasma glucose also demonstrated substantial disagreement, with limits of agreement extending from – 7.73 to + 29.20 mg/dL.

When applying the predefined tolerance criterion, FreeStyle achieved the highest overall percentage of measurements within tolerance (96.9%), followed by GlucoMen (82.4%) and Contour (80.2%). Among the pairwise comparisons between capillary devices, the lowest concordance was observed between Contour and FreeStyle, with only 71.0% of measurements meeting the tolerance criterion.

Performance across clinically relevant glycemic ranges

The agreement between capillary blood glucose meters and venous plasma glucose varied according to glucose concentration (Table 3).

In the hypoglycemia-prone range (< 100 mg/dL), FreeStyle demonstrated the closest agreement with venous plasma glucose, with a mean bias of + 3.34 mg/dL, a MAD of 6.45 mg/dL, and 96.6% of measurements within tolerance. By contrast, Contour showed a substantially larger positive bias (+

14.10 mg/dL) and only 55.2% of measurements within tolerance. GlucoMen also overestimated glucose values in this range (+ 10.83 mg/dL), with 69.0% of measurements within tolerance.

Within the intermediate glycemic range (100–180 mg/dL), FreeStyle maintained a low mean bias (– 3.73 mg/dL) and a high proportion of measurements within tolerance (96.6%). Contour and GlucoMen continued to overestimate glucose concentrations, with mean biases of + 10.14 mg/dL and + 6.89 mg/dL, respectively.

In the highest glycemic range (≥ 180 mg/dL), all devices showed relatively high percentages of measurements within tolerance. FreeStyle exhibited a mean bias of – 8.50 mg/dL, whereas Contour and GlucoMen showed mean biases of + 7.50 mg/dL and – 1.64 mg/dL, respectively.

Graphical assessment of agreement

Figure 1 shows scatter plots comparing glucose values obtained with each capillary blood glucose meter against venous plasma glucose. The plots illustrate the strong linear association between methods while also highlighting systematic deviations from the line of identity. These differences were particularly evident at lower glucose concentrations, where larger relative discrepancies between devices were observed.

Table 1

Descriptive characteristics of glucose measurements obtained using three capillary blood glucose meters and venous plasma glucose in 131 paired observations collected in routine primary care practice. Values are presented as mean, standard deviation (SD), minimum and maximum values, and coefficient of variation (CV).

Measurement method	Mean (mg/dL)	SD	Minimum (mg/dL)	Maximum (mg/dL)	CV (%)
FreeStyle®	127.88	36.66	67	308	28.67
Contour®	141.28	37.76	73	302	26.73
GlucoMen®	137.40	37.16	78	327	27.05
Venous plasma glucose	130.55	38.77	73	309	29.70

Table 2

Pairwise agreement analyses between three capillary blood glucose meters and venous plasma glucose. Agreement was assessed using mean bias, mean absolute difference (MAD), 95% limits of agreement (LoA) from Bland–Altman analyses, Pearson's correlation coefficient, and the proportion of measurements meeting an ISO-inspired tolerance criterion. Although correlations were consistently high, clinically relevant systematic biases and wide limits of agreement were observed for several device comparisons.

Comparison (A–B)	Mean bias (mg/dL)	MAD (mg/dL)	95% LoA lower	95% LoA upper	Pearson's r	Within tolerance (%)	p-value*
Contour® – GlucoMen®	3.89	10.22	-20.52	28.29	0.945	91.6	NS
Contour® – FreeStyle®	13.40	14.53	-7.69	34.50	0.959	71.0	0.004
GlucoMen® – FreeStyle®	9.52	12.82	-14.30	33.34	0.946	79.4	0.038
FreeStyle® – Venous plasma glucose	-2.67	8.08	-22.43	17.08	0.966	96.9	NS
Contour® – Venous plasma glucose	10.73	12.06	-7.73	29.20	0.970	80.2	0.024
GlucoMen® – Venous plasma glucose	6.85	11.11	-16.11	29.81	0.953	82.4	NS

*P-values were obtained using paired Student's t-tests comparing mean glucose values between methods. The tolerance criterion was defined as a difference within ± 15 mg/dL when glucose concentration was < 100 mg/dL and within $\pm 15\%$ when glucose concentration was ≥ 100 mg/dL.

Table 3

Agreement between capillary blood glucose meters and venous plasma glucose stratified by clinically relevant glycemic ranges. Agreement was assessed using mean bias, mean absolute difference (MAD), and the proportion of measurements meeting the predefined tolerance criterion. The largest discrepancies were observed in the < 100 mg/dL range, where Contour® and GlucoMen® systematically overestimated glucose concentrations and showed substantially lower percentages of measurements within tolerance than FreeStyle®. This glycemic range is particularly relevant for the identification and management of hypoglycemia.

Device	Glycemic range (venous plasma glucose, mg/dL)	n	Mean bias (mg/dL)	MAD (mg/dL)	Within tolerance (%)*
FreeStyle®	< 100	29	+ 3.34	6.45	96.6
FreeStyle®	100–180	88	-3.73	7.82	96.6
FreeStyle®	≥ 180	14	-8.50	13.07	100.0
Contour®	< 100	29	+ 14.10	15.21	55.2
Contour®	100–180	88	+ 10.14	11.27	87.5
Contour®	≥ 180	14	+ 7.50	10.50	85.7
GlucoMen®	< 100	29	+ 10.83	11.79	69.0
GlucoMen®	100–180	88	+ 6.89	10.86	84.1
GlucoMen®	≥ 180	14	-1.64	11.21	100.0

*The tolerance criterion was defined as a difference within ± 15 mg/dL when venous plasma glucose was < 100 mg/dL and within $\pm 15\%$ when venous plasma glucose was ≥ 100 mg/dL.

Figure 1. Scatter plots of capillary blood glucose meter measurements versus venous plasma glucose.

(A) FreeStyle® versus venous plasma glucose; (B) Contour® versus venous plasma glucose; (C) GlucoMen® versus venous plasma glucose. Points are coloured according to glycemic range (< 100 mg/dL, 100–180 mg/dL, and ≥ 180 mg/dL). The dashed line indicates the line of identity ($y = x$). Although all devices showed strong correlations with venous plasma glucose, systematic deviations from the identity line were observed, particularly for Contour® and GlucoMen® in the lower glycemic range.

Discussion

This multicenter study evaluated the agreement between three commonly used capillary blood glucose meters and venous plasma glucose under routine primary care conditions. Although all devices showed strong correlations with each other and with venous plasma glucose, important systematic differences were identified. The main finding was that high correlation did not translate into clinical interchangeability. FreeStyle® showed the closest agreement with venous plasma glucose, whereas Contour® and GlucoMen® tended to overestimate glucose concentrations, particularly in the lower

glycemic range (< 100 mg/dL). These findings are clinically relevant because they may influence therapeutic decisions and the recognition of hypoglycemia.

The growing adoption of continuous glucose monitoring systems has transformed diabetes care and improved patient self-management (7–9). Nevertheless, capillary blood glucose meters remain widely used in routine clinical practice and continue to play an essential role in confirming sensor readings and guiding treatment decisions, particularly in situations where continuous monitoring may be less reliable (9). Consequently, understanding the real-world performance of these devices remains highly relevant for primary care professionals.

Our results highlight the distinction between analytical association and clinical agreement. Correlation coefficients were consistently high ($r = 0.945\text{--}0.970$), indicating that all devices tracked glucose fluctuations similarly. However, Bland–Altman analyses revealed systematic bias and relatively wide limits of agreement for several device comparisons. As emphasized by Freckmann et al. (7), correlation and summary error metrics alone may provide an incomplete assessment of device performance because they do not distinguish between random imprecision and systematic bias. For this reason, agreement analyses are essential when evaluating whether measurements obtained from different devices can be used interchangeably in clinical practice.

The comparison between Contour® and FreeStyle® provides a clear example of this issue. Despite a correlation coefficient of 0.959, the mean bias reached 13.4 mg/dL and the limits of agreement extended from -7.7 to $+34.5$ mg/dL. Such differences may be clinically relevant when treatment decisions depend on specific glucose thresholds. Similar observations were reported by Zueger et al. (1), who found better performance for FreeStyle® than for Contour® in an independent clinical evaluation and reported that Contour® did not meet all accuracy requirements defined by ISO 15197:2003.

The most clinically important finding of our study concerns the lower glycemic range. In measurements below 100 mg/dL, FreeStyle® maintained a small bias and excellent agreement, whereas Contour® and GlucoMen® showed substantial positive bias. Contour® overestimated glucose values by more than 14 mg/dL on average and met the predefined tolerance criterion in only 55.2% of measurements. These results suggest that some devices may underestimate the risk of hypoglycemia by systematically reporting higher glucose values than those obtained from venous plasma glucose. This observation is consistent with previous studies indicating that accuracy in low glucose ranges is particularly important because even small measurement errors may influence clinical decisions and delay corrective actions (7, 8). The issue may be especially relevant in populations requiring tight glycemic control, such as pregnant women treated with insulin, where narrow margins of measurement error are desirable (2, 10).

From a primary care perspective, our findings support maintaining consistency in the glucose meter used for longitudinal patient follow-up. Device changes may occur because of prescribing policies, procurement processes, or patient preference; however, switching between devices may introduce clinically meaningful differences in glucose readings. A period of parallel measurements following

device replacement could facilitate interpretation and reduce the risk of inappropriate therapeutic adjustments.

Several limitations should be considered when interpreting these findings. First, venous plasma glucose was used as a clinically relevant comparator rather than as an ISO-traceable reference method; therefore, the study should not be interpreted as a formal regulatory validation of device performance. Second, measurements were obtained under routine clinical conditions, and factors such as hematocrit, medication use, environmental conditions, or strip lot variability were not systematically recorded, although these variables may influence glucose meter accuracy (3, 5). Third, the number of observations in the highest glycemic range was relatively limited, which may have reduced the precision of estimates for this subgroup. Finally, because the study was conducted within a single healthcare organization, the generalizability of the findings to other settings should be confirmed in larger multicenter studies.

Despite these limitations, the study has important strengths. Measurements were collected prospectively in real-world clinical practice, included multiple primary care centers, and were analyzed using complementary methods that assessed both statistical association and clinical agreement. In addition, stratification by clinically relevant glycemic ranges allowed identification of differences that would have been less apparent in overall analyses.

Overall, our findings indicate that capillary blood glucose meters showing similar correlations may differ substantially in agreement and clinical performance. Particular caution is warranted in the lower glycemic range, where systematic bias may affect hypoglycemia detection and patient safety.

Strengths and limitations

This study has several strengths. First, data were collected prospectively under routine primary care conditions, providing evidence that reflects real-world clinical practice rather than highly controlled experimental settings. Second, the study included seven primary care centers, increasing the diversity of clinical environments and enhancing the external validity of the findings within primary care. Third, agreement was evaluated using a comprehensive analytical approach that combined Pearson's correlation coefficients, Bland–Altman analyses, mean absolute differences, and a clinically oriented tolerance criterion. This multimethod strategy allowed assessment not only of statistical association but also of clinical agreement and potential interchangeability between devices. Finally, stratification by clinically relevant glycemic ranges enabled identification of performance differences that were particularly important in the lower glucose range, where measurement accuracy has direct implications for hypoglycemia detection and patient safety.

Several limitations should also be acknowledged. First, venous plasma glucose was used as a clinically relevant comparator rather than as an ISO-traceable reference method. Consequently, the study should not be interpreted as a formal regulatory validation of the evaluated devices and direct comparisons with studies specifically designed to assess ISO 15197 compliance should be made with caution. Second, although measurements were obtained under routine practice conditions, potentially relevant factors

known to influence glucose meter performance, such as hematocrit levels, medication use, environmental conditions, strip lot variability, and timing of sample processing, were not systematically recorded (3, 5). Third, the number of observations in the highest glycemic range (≥ 180 mg/dL) was relatively small, limiting the precision of subgroup estimates. Fourth, participants were recruited opportunistically from a single healthcare organization, which may limit the generalizability of the results to other healthcare systems, populations, or clinical settings.

An additional consideration is that capillary and venous glucose measurements are not biologically identical and may differ according to physiological conditions, particularly in non-fasting states (6). Although this reflects real-world clinical practice and was one of the reasons for selecting venous plasma glucose as a pragmatic comparator, part of the observed disagreement may be attributable to inherent physiological differences between sampling methods rather than device performance alone.

Despite these limitations, the study provides clinically relevant information regarding the agreement and potential interchangeability of blood glucose meters currently used in primary care. The findings contribute evidence from routine practice conditions and highlight the importance of considering agreement across specific glycemic ranges, particularly when evaluating devices used for the detection and management of hypoglycemia.

Conclusions

In this multicenter study conducted under routine primary care conditions, the three capillary blood glucose meters evaluated demonstrated strong correlations with venous plasma glucose and with each other. However, high statistical correlation did not translate into clinical interchangeability. Systematic biases and relatively wide limits of agreement were identified, indicating that measurements obtained from different devices cannot necessarily be considered equivalent for clinical decision-making.

Among the evaluated devices, FreeStyle® showed the closest agreement with venous plasma glucose across the overall sample and maintained consistent performance across clinically relevant glycemic ranges. In contrast, Contour® and GlucoMen® tended to overestimate glucose concentrations, particularly in the lower glycemic range. This finding is clinically important because inaccuracies at lower glucose levels may compromise the detection and management of hypoglycemia, potentially leading to delayed corrective actions or inappropriate therapeutic decisions.

The study highlights the importance of evaluating not only analytical performance but also clinical agreement when comparing blood glucose meters. From a primary care perspective, maintaining consistency in the glucose monitoring device used by an individual patient may be preferable to alternating between different systems. When a change of device is necessary, a period of parallel measurements should be considered to facilitate interpretation and reduce the risk of clinically relevant discrepancies.

Given the continued widespread use of capillary blood glucose meters, despite the growing adoption of continuous glucose monitoring technologies, understanding differences in agreement and bias between devices remains highly relevant. These findings provide real-world evidence to support safer interpretation of glucose measurements in primary care and reinforce the need to consider device-specific performance, particularly when monitoring patients at risk of hypoglycemia.

Abbreviations

BGM	
Blood glucose monitoring	
CGM	
Continuous glucose monitoring	
CV	
Coefficient of variation	
LoA	
Limits of agreement	
MAD	
Mean absolute difference	
SD	
Standard deviation	
VPG	
Venous plasma glucose	
ISO	
International Organization for Standardization	

Declarations

Ethics approval and consent to participate

The study was reviewed by the Research Committee of Badalona Serveis Assistencials (BSA), which determined, following assessment of the study characteristics at its meeting held on 12 March 2026, that submission to a Research Ethics Committee (Institutional Review Board) was not required because the project was a multicenter, observational, cross-sectional, non-interventional study conducted under routine clinical practice conditions and did not constitute interventional human subjects research under the institutional procedures applicable to this type of observational study. All participants received verbal information about the study and provided written informed consent before participation. Data were anonymized prior to analysis. The study was conducted in accordance with the Declaration of Helsinki, Regulation (EU) 2016/679 (General Data Protection Regulation), and the applicable Spanish legislation on personal data protection.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Authors' information

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Author Contribution

RPB, SAR, JCC, SLM, LMC, SMG, EMR, MJLP, MAF, AFC and XBH contributed substantially to the conception and design of the study, data acquisition, data analysis and interpretation. All authors contributed to drafting the manuscript or critically revising it for important intellectual content, approved the final version of the manuscript, and agree to be accountable for all aspects of the work.

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Data Availability

The anonymised dataset generated and analysed during the current study is available from the corresponding author on reasonable request.

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Figures

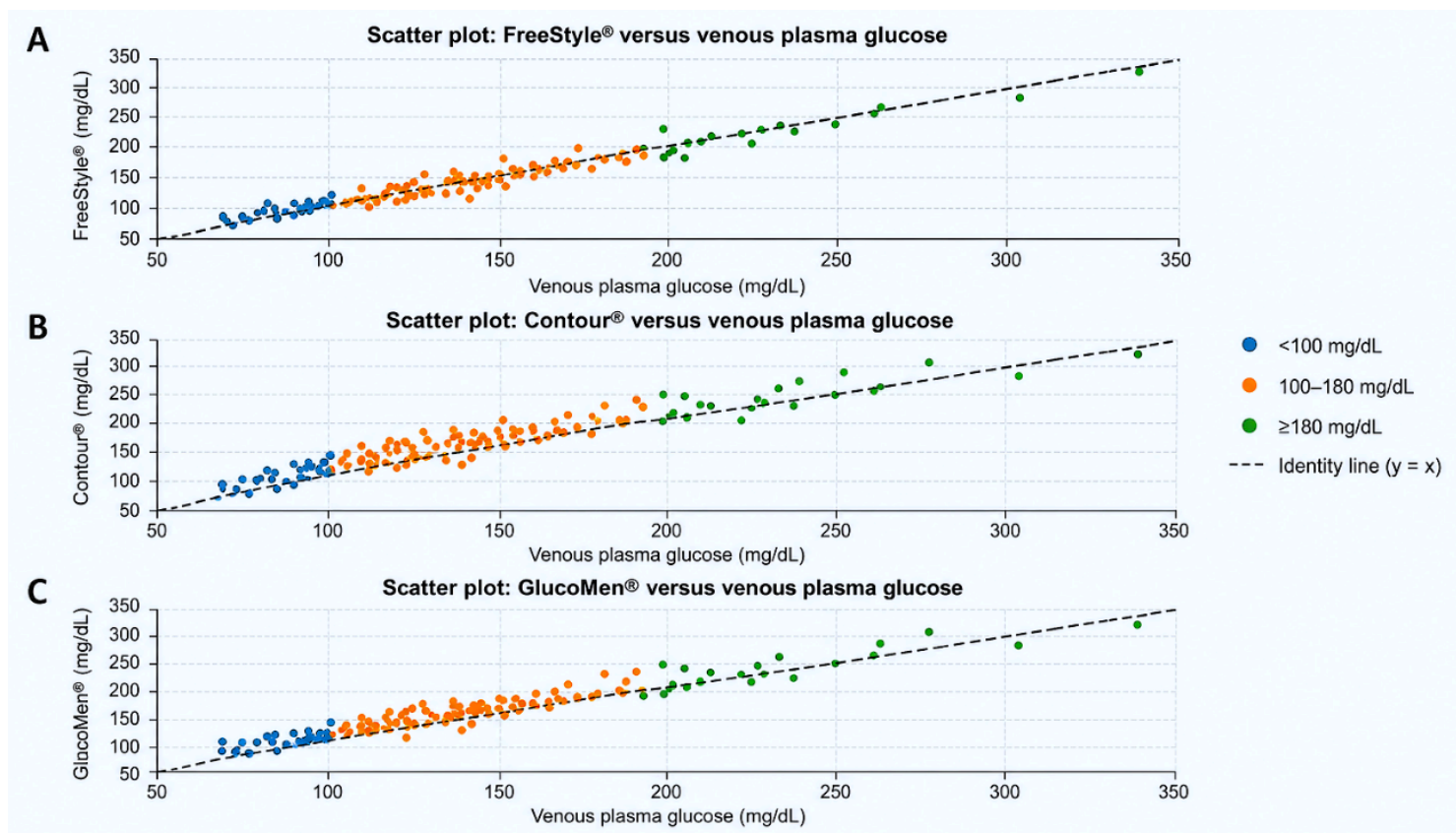


Figure 1

Scatter plots of capillary blood glucose meter measurements versus venous plasma glucose.

(A) FreeStyle® versus venous plasma glucose; (B) Contour® versus venous plasma glucose; (C) GlucoMen® versus venous plasma glucose. Points are coloured according to glycemic range (<100 mg/dL, 100–180 mg/dL, and ≥180 mg/dL). The dashed line indicates the line of identity ($y = x$). Although all devices showed strong correlations with venous plasma glucose, systematic deviations from the identity line were observed, particularly for Contour® and GlucoMen® in the lower glycemic range.