

GWave: a Novel Noninvasive Blood Glucose Monitoring Radio Wave Base Technology

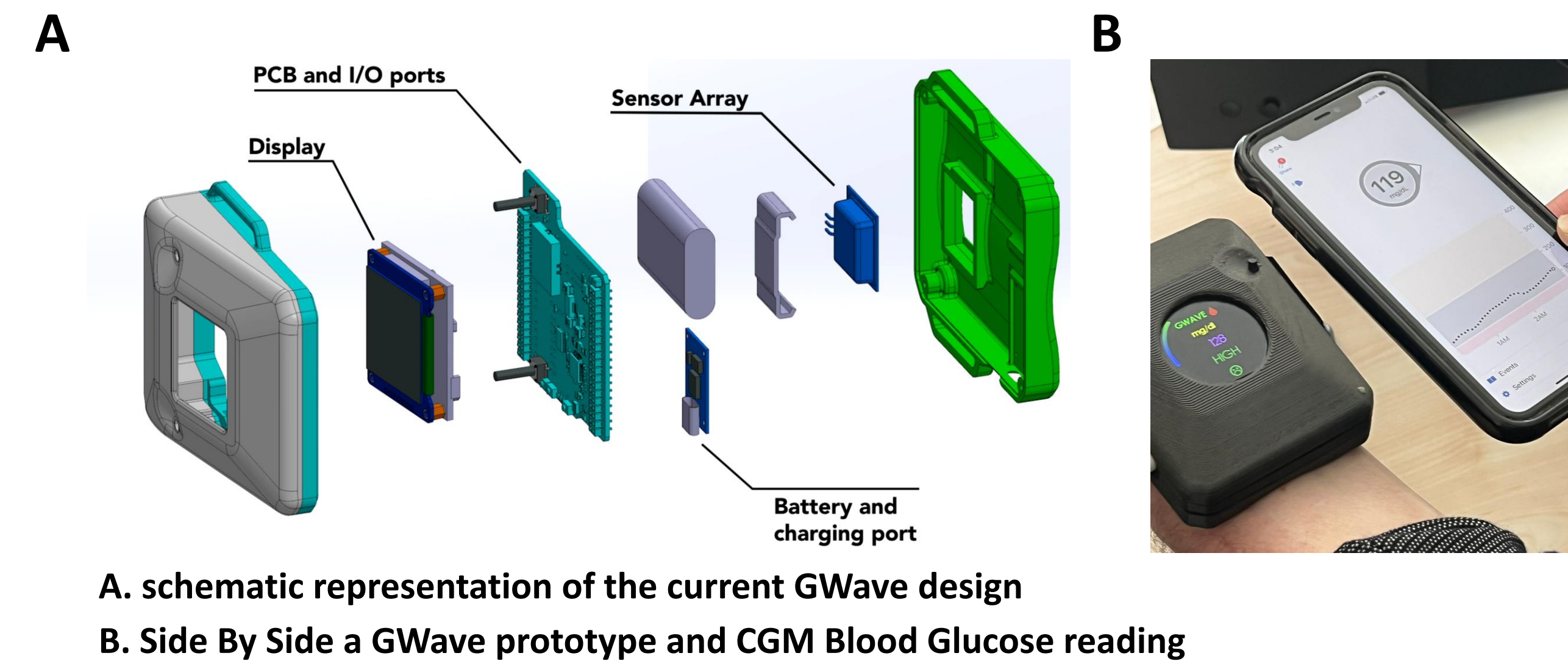
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Introduction

Truly noninvasive CGM has been a challenge for decades and to date has not been successful. Our current CGMs require skin puncture and measure interstitial fluid glucose, which can have a 5-to-15-minute lag time with blood glucose. Our current sensors have poor accuracy on the first day (after the puncture of the skin) and may entail local discomfort and irritation.

GWave (Hagar, Haifa Israel) is a non-invasive glucose monitor which by filtering out “white noise” and using radiofrequency (RF) through the skin can noninvasively measure venous blood glucose concentrations in the physiological range. Calibrations are not required. Previously, we had shown excellent accuracy with a prototype device and chip. In this study, the objective is to provide accuracy data with a second-generation chip which can be mass produced for commercial use.

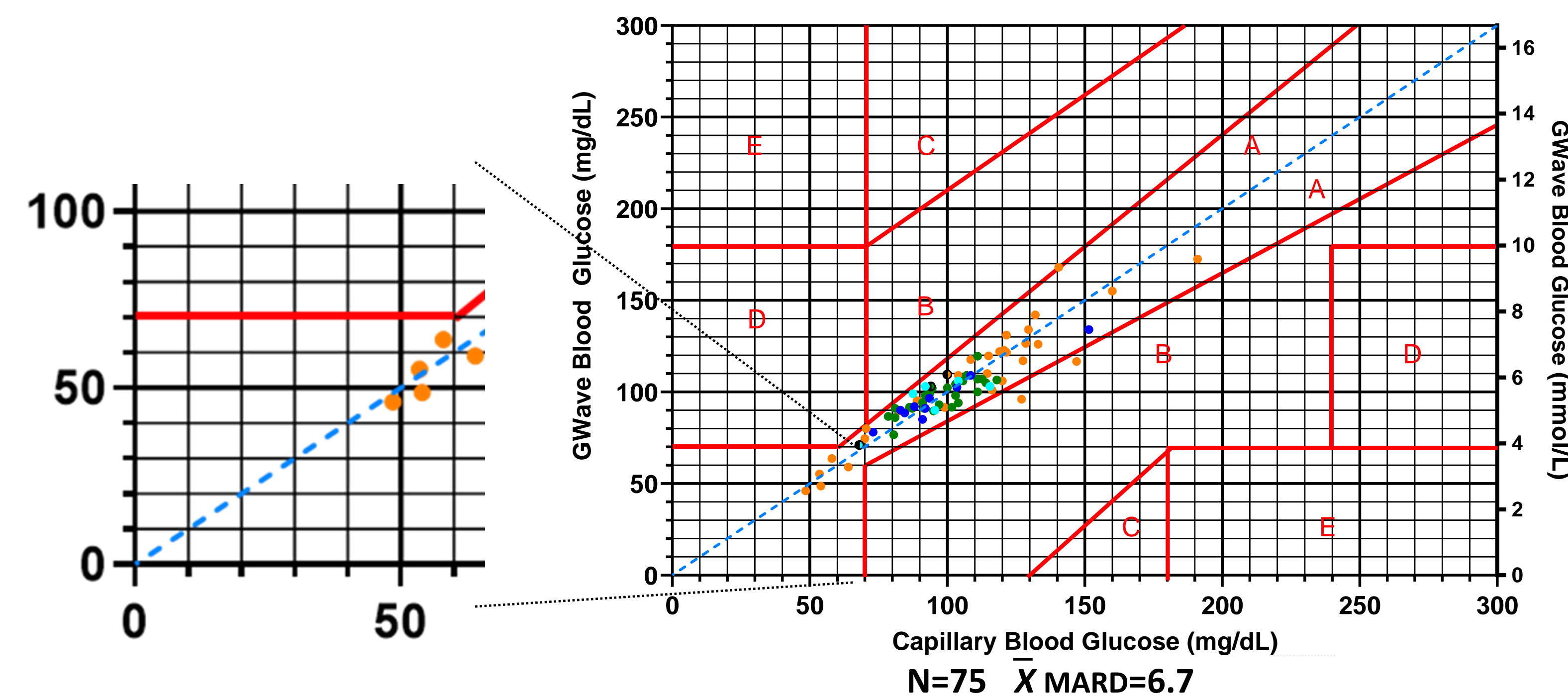


Methods

Noninvasive glucose monitoring was performed on the bottom of the wrist with the GWave device in subjects both with and without diabetes. Following the GWave glucose measurement, a fingerstick was performed to obtain 3 blood samples for capillary glucose monitoring with a Freestyle Lite Blood Glucose Monitor (Abbott Diabetes Care, Alameda, CA). The average of the 3 blood tests is the comparator for the average of 3 GWave blood glucose tests. Several patients with diabetes were wearing their personal CGMs and comparisons were also made to the CGMs readout.

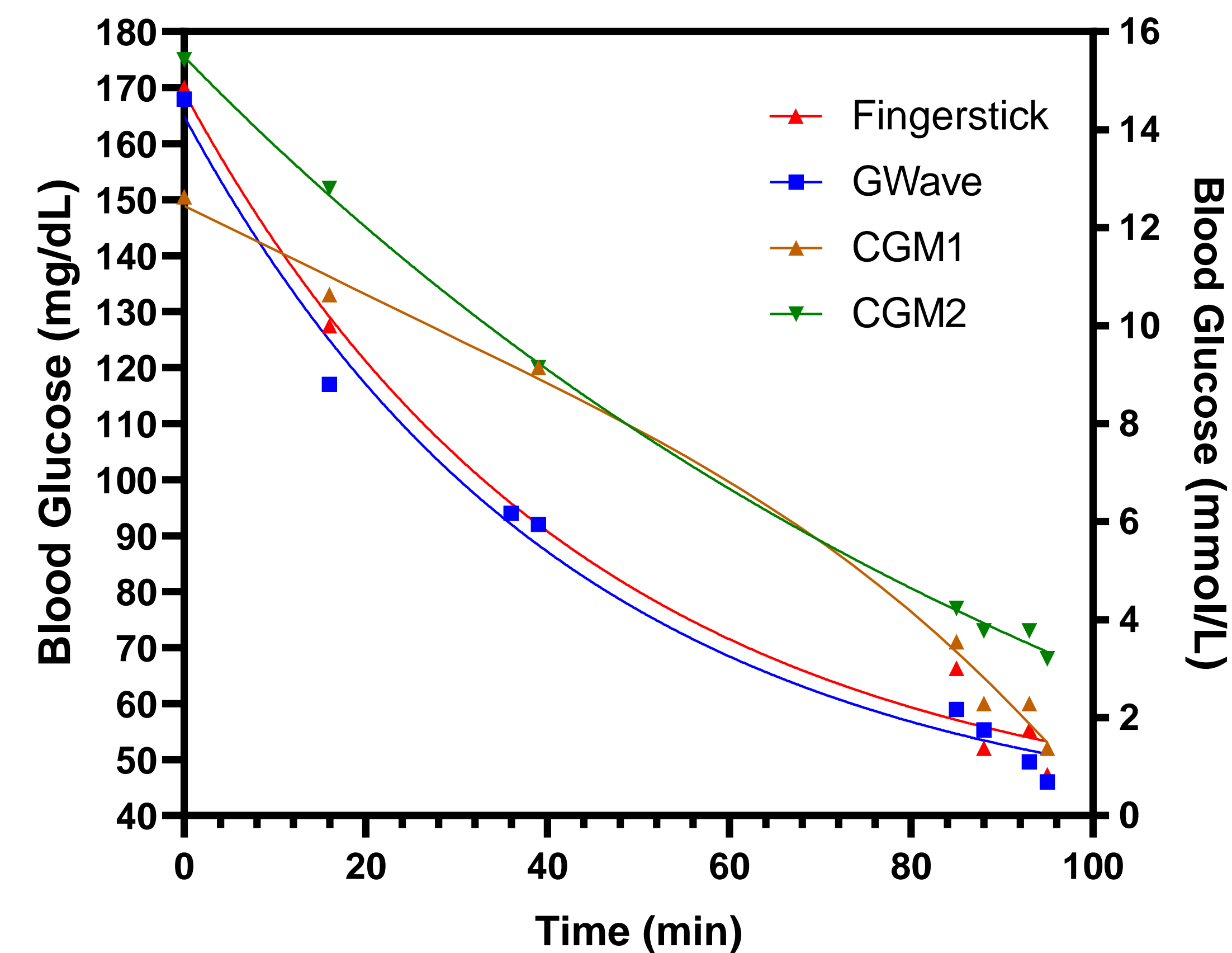
Statistical analysis: Each measurement (handheld pricking devices, as well as GWave) was performed in triplicates to allow statistical analysis of both the correlation between the different measurement modalities, as well as the MARDs.

GWave Capillary Blood Glucose Correlation

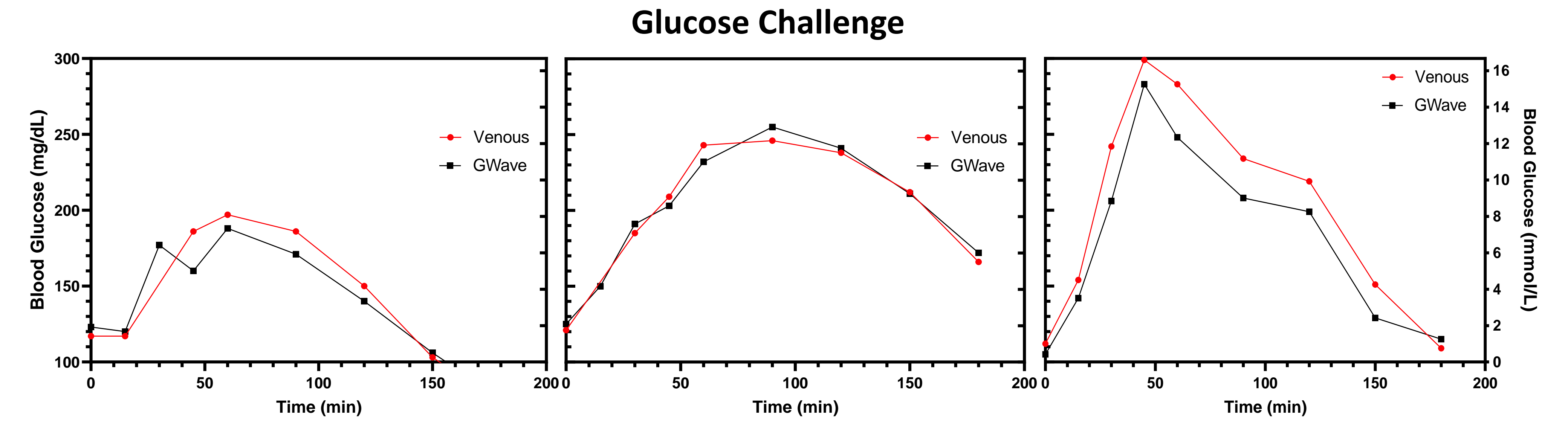


GWave glucose readings were compared to a fingerstick (FreeStyle Lite) glucose reading. 75 individuals were tested, 34 diabetic individuals (●), 28 type 1 and six type 2; 10 diabetic pregnant women (●) and 31 nondiabetic individuals (●) of which 5 were 15 years old or younger (●) and five were dark-skinned (●). The correlation between GWave measured blood glucose and capillary blood glucose is overlaid on a Clarke Error Grid (N=75, 97% in zone A, 3% in zone B). The dashed blue line represents perfect correlation.

CGM's are Trailing in the Detection of Insulin-Induced Hypoglycemia



A demonstration of GWave ability to follow blood glucose in real-time. Insulin was administered to induce blood glucose decrease from 170 mg/dL to about 45 mg/dL over a period of about 95 minutes. Blood glucose levels were measured by fingerstick (▲), GWave (■) or two types of CGMs (▲ and ▼). While GWave tightly followed the fingerstick pattern, in contrast, the CGMs readout converged with the capillary blood values only after 90min (N=1).

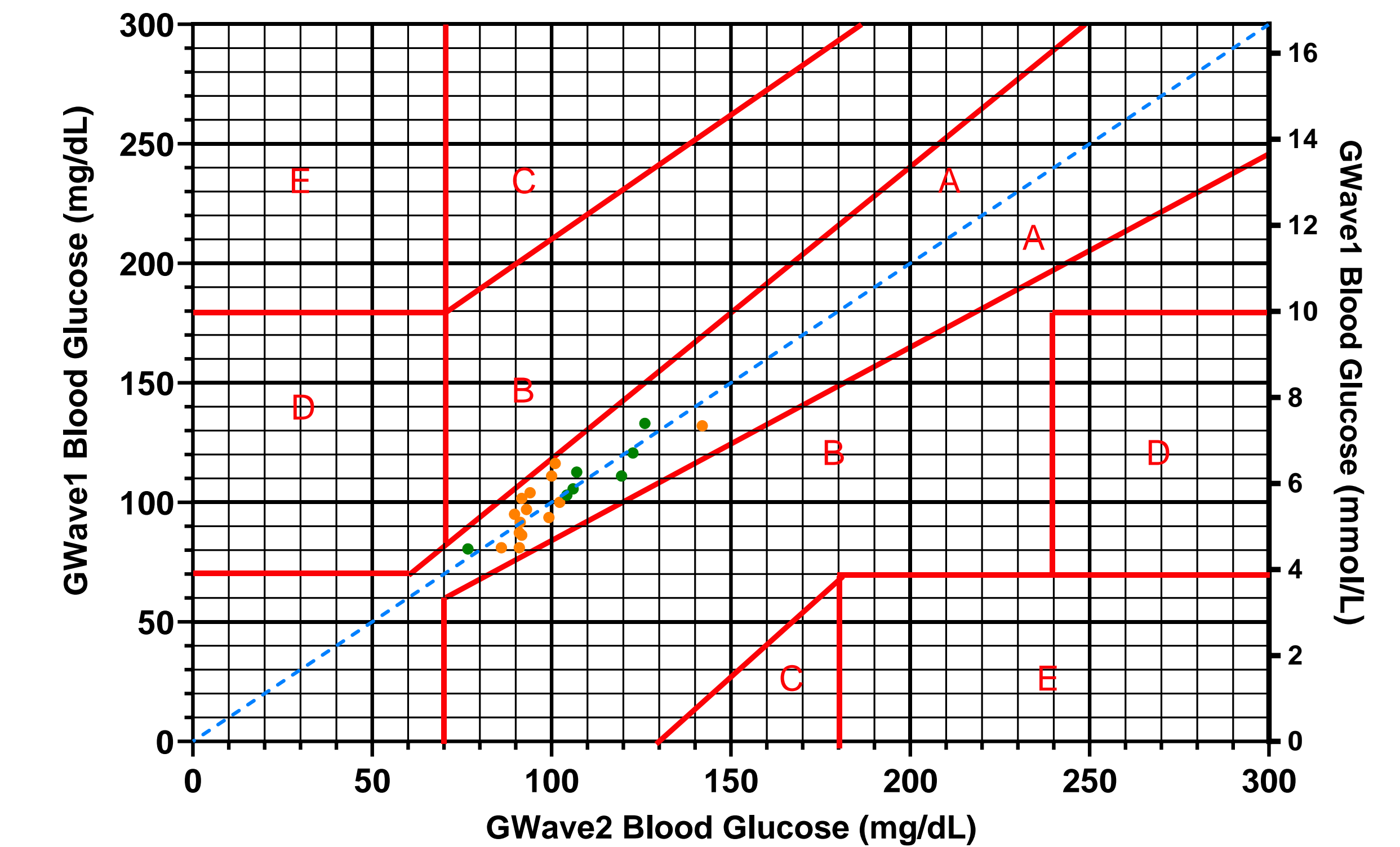


GWave accurately detects glucose levels along a glucose tolerance test.

Study Procedure:

A 75 g oral glucose tolerance test (OGTT) was conducted. Blood glucose levels were measured at pre-defined time points (0, 15, 30, 45, 60, 90, 120, 150 and 180 minutes) simultaneously by the GWave glucose meter, Sheba Medical Center core laboratory and hand-held glucose meters (Abbott FreeStyle®). These findings were obtained in a study that was performed in the Sheba Medical Center¹.

Correlation Between two GWave Devices Demonstrates Reproducibility



Blood Glucose levels of 13 diabetic individuals (●) and of 7 nondiabetic individuals (●) were measured by two independent GWave devices demonstrating the reproducibility between GWave instruments.

Discussion

- The GWave non-invasive radiofrequency glucose meter can accurately measure blood glucose (not interstitial fluid) with an MARD well below 10%.
- In 75 people 97% were in Clark Error Grid A (CEG) and 3% in CEG B with a range of capillary glucose of 45 to 180 mg/dL.
- For insulin-induced hypoglycemia, there was no lag time compared to CGM, as glucose levels dropped to 45 mg/dL.
- During an OGTT, GWave spiked at same rate as Venous glucose to a level of about 300 mg/dL.

Conclusion

Current results from the GWave glucose monitor show promise as the first noninvasive technology.

Future studies will focus on larger numbers and diversity of people in all glucose ranges.

References:

1. Schwarz Y, Konvalina N, Tiros A. A Pilot Trial to Evaluate the Accuracy of a Novel Non-Invasive Glucose Meter. Sensors (Basel). 2021 Oct 9;21(20):6704. doi: 10.3390/s21206704.

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