Evaluation of a Wearable Non-Invasive Blood Glucose Monitor in Non-Clinical Environment

M.R.A. Qureshi, S. Chaudhry, B. Love, H. Kayali, C. Handy, R. Powell, J. Shillingford

Background and Aims: The rising number of patients and the complications caused by diabetes, along with the side effects of its various treatments, have given rise to a need for a next generation device: a non-invasive blood glucose monitoring system (NIGM). This paper presents the results collected by a wearable NIGM.

Methods: NIGM is based on analysing resonance shifts from an applied signal in the microwave spectrum. After improving the hardware design, the mean absolute relative difference (MARD) values have improved considerably from a previous proof of concept prototype tested in a clinical trial and presented earlier at ATTD 2020 [1]. The wearable NIGM device (Figure 1) was applied to the wrists of five volunteers for a period of eight hours in an uncontrolled non-clinical environment. Three volunteers were non-diabetics (2F, 1M) and two were Type 2 diabetics (1M, 1F). A FreeStyle Libre was applied to all the subjects as a reference device and the readings adjusted by 15-mins to correct for the time lag. Twenty-eight tests were conducted in total (data was not obtainable for one non-diabetic and one diabetic volunteer, due to the small wrist size of the volunteers). Each volunteer was tested on multiple days. A model was built and trained for each day. The model was then used to predict the blood glucose for the other days.

Figure 1 . Wearable device

Results: Interpretation of Table 1 – The columns represent the model training day, i.e. the column header Day 1 represents that the model was built using data from Day 1. The rows depict the days on which the model was applied, i.e. the cell circled in red represents that a model was built using Day 3 data and then used to predict the blood glucose on Day 2 using only data from Day 2, resulting in a MARD of 10.1%. Moving up and down the column shows the performance of the Day 3 model in predicting the blood glucose for Days 1, 3, & 4 (MARD: 10.44%, 9.91%, & 14.56% resp.). The cells in blue are effectively a self-test of the model, i.e. testing the model with the same day's data that was used to build it. Figure 2 shows the output of the model using the same data to self-predict the blood glucose, while Figure 3 shows a model built on Day 1 predicting the blood glucose on Day 2. Figure 4 shows the Surveillance Error Grid (SEG) graph for a non-diabetic volunteer.

MARD		Model training day			
		Day 1	Day 2	Day 3	Day 4
Model test day data	Day 1	9.65	9.79	10.44	9.74
	Day 2	9.51	9.72	10.1	9.65
	Day 3	10.13	9.78	9.91	9.86
	Day 4	15.41	14.91	14.56	15.04

Table 1. MARD for non-diabetic volunteer (overall MARD is 12.19%)

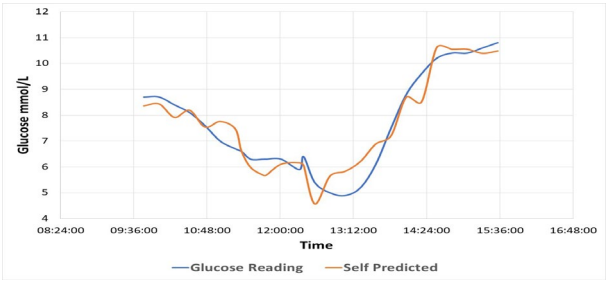

Figure 2. Model built on Day 1 and self-predicting Day 1 (Type 2 diabetic)

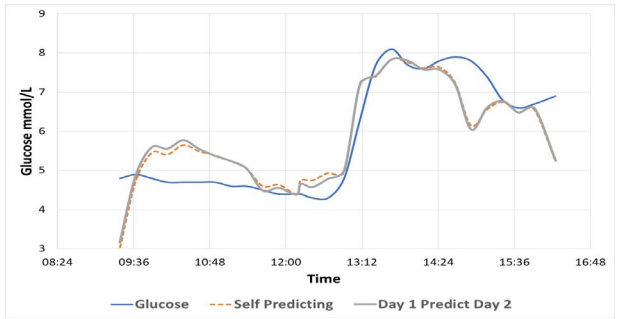

Figure 3. Model built on Day 1 predicting Day 2 (non-diabetic)

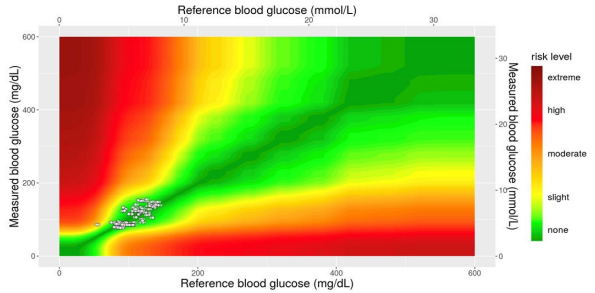

Figure 4. SEG for non-diabetic volunteer

Conclusion: We have demonstrated initial test results for a wearable, real-time, non-invasive blood glucose monitor. Although the testing has been conducted on a limited number of test subjects, in preparation for a larger clinical trial on Type 2 diabetics, an overall MARD value of c. 12% is extremely encouraging, considering the fact these experiments were conducted in an uncontrolled non-clinical environment with volunteers consuming one standard meal halfway through the test. These results demonstrate the possibility of a truly non-invasive real-time device as an alternative to the incumbent minimally invasive commercial devices.

	MARD 1st Gen	MARD Latest Gen
Abbott Freestyle Libre	11.5% - 16.6%	9.2%
Medtronic MiniMed Enlite	15.9% - 21.4%	8.7%
Dexcom	10.8% - 19%	8.2%
Afon Technology* * Fully non-invasive and real time device	22.4% (Proof of concept)	12.0%* (Wearable device) * Initial trial sample

Table 2. MARD comparison with current CGMs

[1] J.H.DeVries, M.R.A. Qureshi, et al., "A proof-of-concept study of a novel non-invasive continuous glucose monitor", Advanced Technologies & Treatments for Diabetes, Feb 2020, Madrid, Spain

Afon Technology

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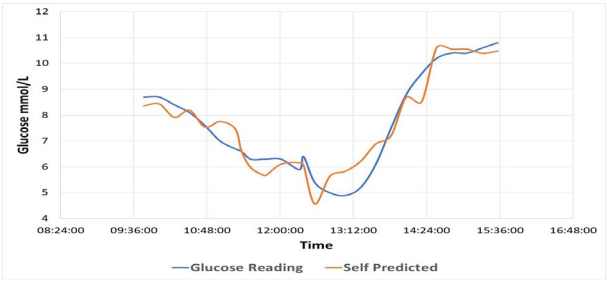

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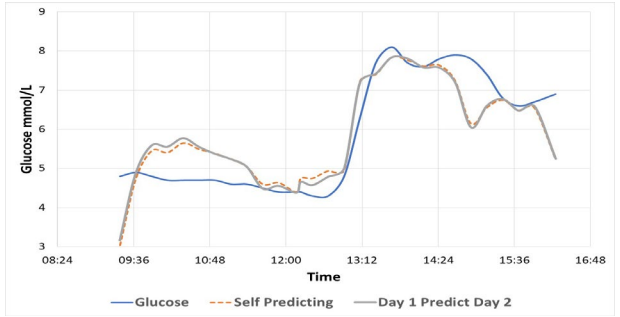
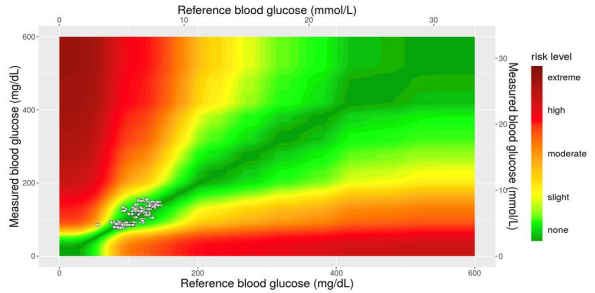


Figure 3. Model built on Day 1 predicting Day 2 (non-diabetic)



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