Technical Feasibility of a Novel Sensor for Non-Invasive Blood Glucose Monitoring Compared to Dexcom G6®

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BACKGROUND & AIM

For the over 537M people living with diabetes, current methods of testing blood glucose concentration (BGC) come with drawbacks, whether they use traditional blood draws and test strips or more modern continuous glucose monitors (CGMs): the pain of finger-sticks or CGM probe insertion; the recurring cost of test strips or one-time use probes; and the environmental impact of both.

Know Labs has developed a novel electromagnetic platform technology - the Bio-RFID™ platform - to non-invasively capture data from individual radio frequencies and convert those data into physiologically meaningful information and insights.

We investigated the technical feasibility for this new method **to quantify blood glucose in vivo non-invasively using RF** by means of training a neural network (NN) model to predict readings of the Dexcom G6® as a proxy for BGC.

METHOD

- In a series of **46 tests (92 samples)**, five participants placed forearms on the Bio-RFID sensor and consumed 37.5 grams of liquid D-Glucose.
- **We monitored their BGC for three hours using the Dexcom G6® as reference device, while logging the readings of the sensor.**
- Data were collected on a continuous basis, **using sweeps across the 500 MHz – 1500 MHz range at 0.1 MHz** intervals, collecting values at 10,001 frequencies per sweep.
- **Using the data captured with the Bio-RFID sensor, we trained a NN model to predict BGC readings of the Dexcom G6® reference device.**

RESULTS

In aggregate, across the five individual participants and 92 samples, **we observed a mean absolute relative difference (MARD) of 20.6%.** In accordance to FDA limits for accuracy for new blood glucose monitors a prediction is "within threshold" of the observed reference value if either: A) the prediction is within 15% of the reference value for blood sugars over 70 mg/dL; or B) the prediction is within 15 mg/dL for blood sugars below 70 mg/dL. **46% of the Bio-RFID predictions were within threshold.**

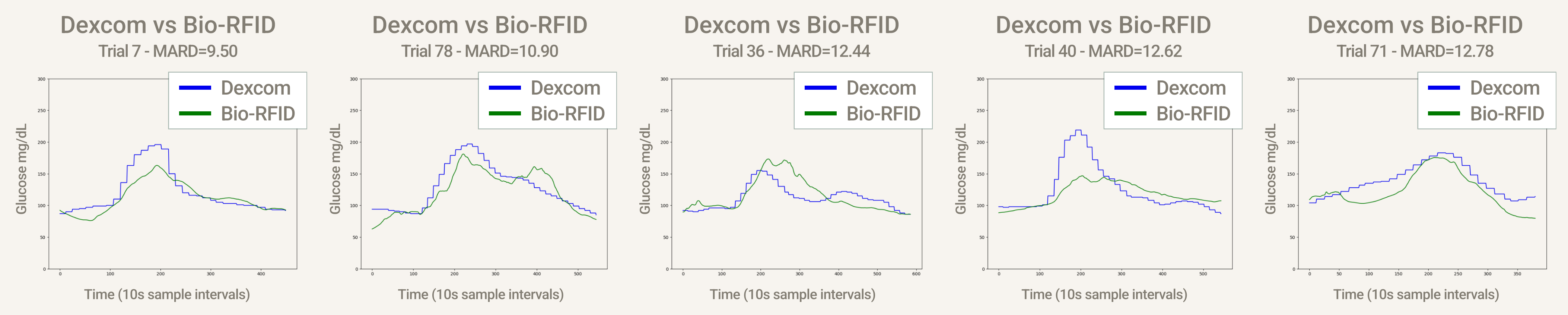

***FIG.1** Select results predicted by the NN model, plotted with the Dexcom G6® readings across time.*

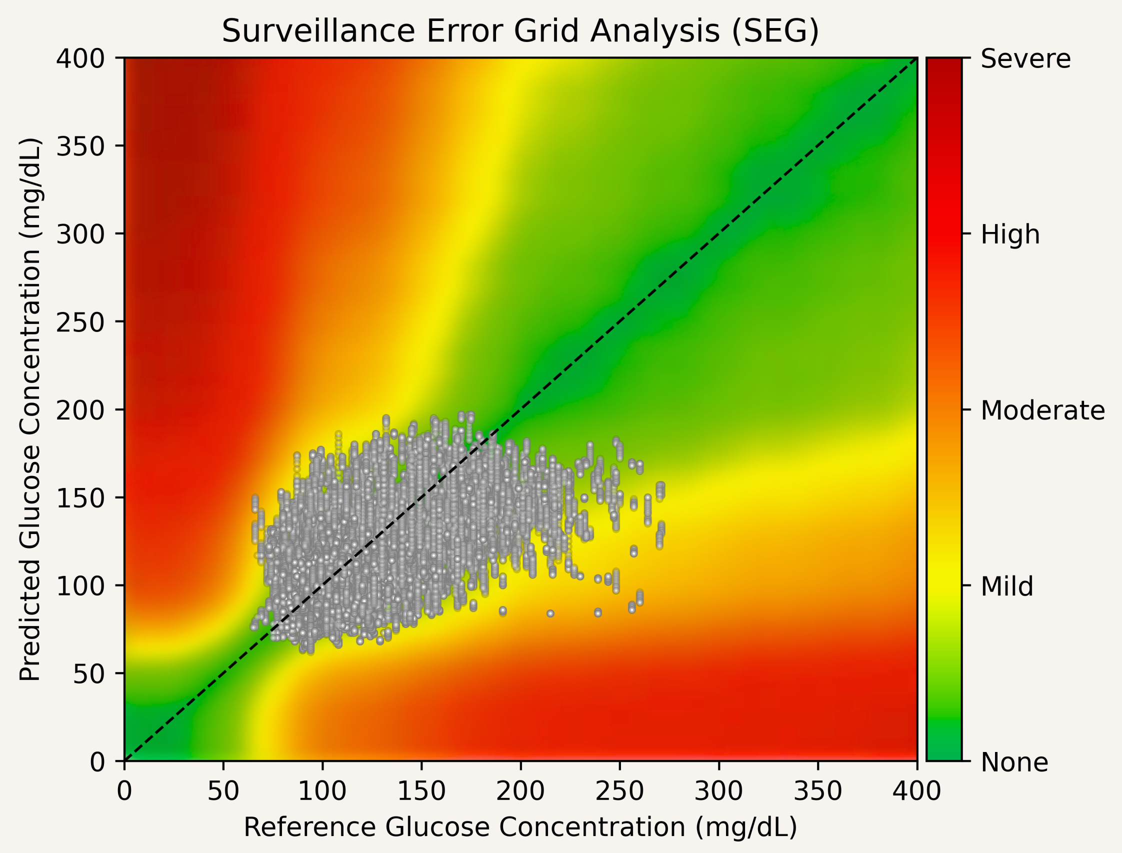

***FIG.2** SEG for prediction of the held out/test dataset.*

Risk Grade	Number of Pairs	Percent	Risk Factor Range
A	26785	67%	0 - 0.5
B	13075	32.7%	> 0.5 - 1.5
C	111	0.3%	> 1.5 - 2.5
D	NA	NA	> 2.5 - 3.5
E	NA	NA	> 3.5

SEG Risk Level	SEG Risk Category	Number of Pairs	Percent
1	None	26785	67%
2	Slight, Lower	11213	28.1%
3	Slight, Higher	1862	4.7%
4	Moderate, Lower	111	0.3%
5	Moderate, Higher	NA	NA
6	Severe, Lower	NA	NA
7	Severe, Upper	NA	NA
8	Extreme	NA	NA

***FIG.3** Risk Table for SEG plot.*

CONCLUSIONS

Though a clinically useful non-invasive BGC monitor should make 95% of predictions within threshold, we find these results encouraging given the relatively small size of the dataset. This study validated Bio-RFID as stable to deliver repeatable results, and as infrastructure for future data collection. Because a truly non-invasive CGM would be a powerful tool in diagnosing, managing, and treating diabetes and pre-diabetes, more research is underway to continue refining and developing these algorithms.

Know Labs Generation One Device*

**Imagery not representative of final product design.*

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