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

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Objective:
For many people living with diabetes and pre-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.

This presentation covers a technical feasibility study for a new method to quantify blood glucose 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.

Methods:
We use a new type of sensing device that scans through a wide band of radio frequencies and records values detected of each frequency over a period of time. In this n-of-5 study, completed between Dec-Mar 2023, participants sat in a chair and placed left and right forearms on a prototype antennae for three hours, and we monitored their BGC using a CGM while logging the readings of the sensor.

In 46 tests, we collected 92 samples–one from each forearm. Using these data, we trained a NN model to predict BGC using only RF readings and achieved repeatable results using the Dexcom as a reference device. When developing the NN model, all samples collected from a single user are held out to form the test dataset. This provides a 'blind' evaluation of model performance. The remaining samples are randomly split between a training dataset and a validation dataset and are used to provide an unbiased evaluation of model accuracy.

Results:
We observed a mean absolute relative difference (MARD) of 20.6% across the held out/test dataset and 12.5% across the training + validation dataset. We also calculated a binary measure of success, modeled after 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. 67% of values in the validation dataset and 46% of predictions on held out/test dataset were within threshold. Other studies have utilized the technology to detect Sodium Ibuprofen and Alcohol in vivo using their unique dielectric properties.

Discussion:
Though a clinically useful non-invasive BGC sensor should make 95% of predictions within threshold, we find these results encouraging given the relatively small size of the dataset. 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.

Disclosures: DK, BS, SK, and JHA are employed by Know Labs. SL, CW, and DS are service providers to Know Labs.