

Non-Invasive Self-Monitoring of Glucose Level by People with Pre-diabetes and T2DM

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Introduction

Pre-diabetes is one of the well-known risks for developing Type 2 diabetes mellitus (T2DM; Figure 1). Studies show that complications, accompanying pre-diabetes and T2DM, can be postponed and even prevented by maintaining tight glycemic control. Self-monitoring of glucose levels is one of the key components for achieving this goal. The positive effect of self-monitoring has also been demonstrated on pre-diabetic subjects whose state has deteriorated to T2DM (i.e. newly diagnosed T2DM individuals). Therefore, it is suggested that pre-diabetics may benefit as well from self-monitoring and a tight glycemic control. Yet, compliance with self-monitoring is limited, mainly due to the pain associated with current invasive devices. Hence, a non-invasive approach could potentially be the ideal solution for this population.

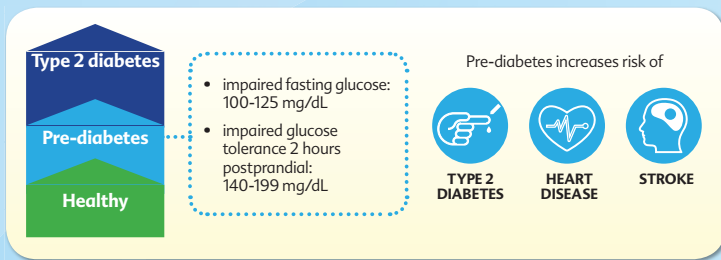


Figure 1: Pre-diabetes and its major risks (partial list)

GlucoTrack[®] is a non-invasive (NI) home-use device for self-monitoring of glucose level. The device tracks physiological changes which are correlated with glucose excursions by measuring ultrasonic, electromagnetic and thermal parameters of the earlobe tissue. The measured parameters are translated into a glucose value, based on individual calibration. GlucoTrack comprises of a Main Unit and a Personal Ear Clip (PEC; Figure 2A). Spot measurement is performed by clipping the PEC to the earlobe for the measurement duration (~1 minute length; Figure 2B).

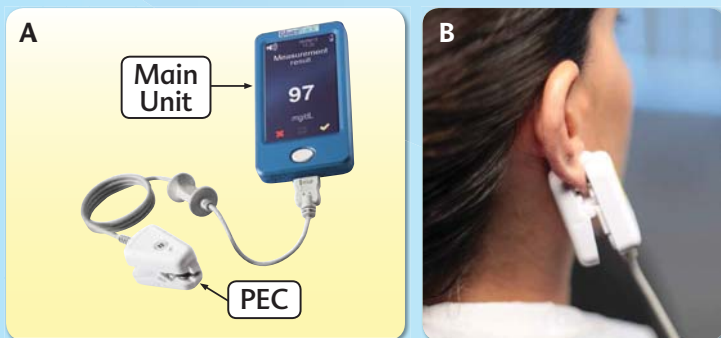


Figure 2: [A] GlucoTrack glucose monitor; [B] Conducting a glucose measurement

Caution: Investigational device. Limited by (United States) federal law to investigational use only. The device has CE certificate.

Objective

To evaluate the performance of **GlucoTrack**, a truly non-invasive glucose monitoring device, in subjects with pre-diabetes, newly diagnosed T2DM and subjects with long-duration of T2DM.

Method

Clinical trials were conducted on 32 subjects in three groups (Table 1): pre-diabetes (7 subjects), newly diagnosed T2DM (i.e. diabetes duration < 5 years; 9 subjects) and long-duration of T2DM (i.e. diabetes duration > 5 years; 16 subjects). The course of the experiment is presented in Figure 3. HemoCue[®] Glucose 201 RT system was used both for **GlucoTrack** calibration and subsequent performance evaluation.

The accuracy of the device was evaluated:

- * Clinically: using Consensus error grid (EG) analysis (type 2 version).
- * Numerically: using mean and median absolute relative differences (ARD) and mean absolute difference (MAD).

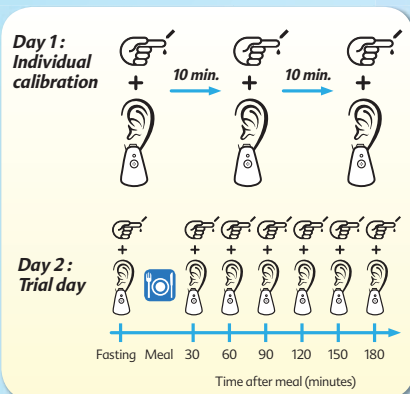


Figure 3: Clinical trial consist of two days: a day of calibration (1st day) and a day of data collection (2nd day)

Table 1: Experimental groups' properties

Group	Number of Subjects	Number of Measurements
Pre-diabetes	7	49
Newly Diagnosed (up to 5 years)	9	63
Long-duration	16	112
All	32	224

Results

- Overall, similar percentages were in the clinically accepted A and B zones of Consensus EG (Figure 4).
- All groups (pre-diabetes, newly-diagnosed, and long-duration T2DM) showed similar clinical accuracy: above 92% in the A zone of Consensus EG (Figure 4).
- Similar mean and median ARD, as well as similar MAD values were found for subjects of all groups (Figures 5A and 5B).

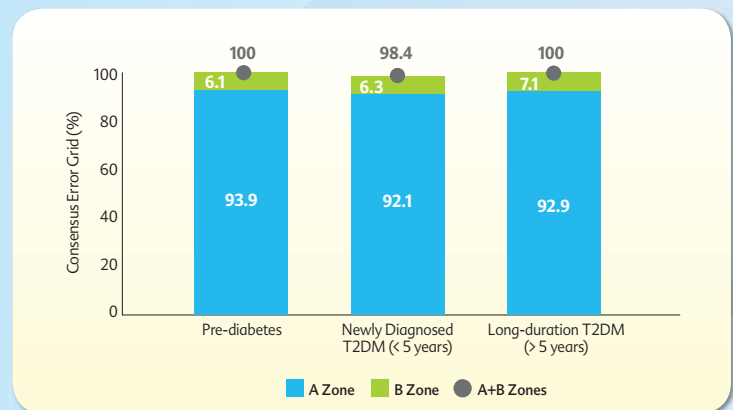


Figure 4: GlucoTrack performance evaluated by Consensus EG

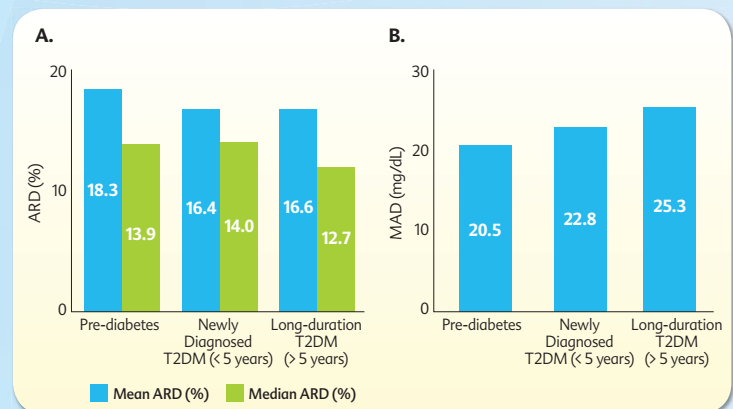


Figure 5: Device performance assessed by [A] mean and median ARD and [B] MAD values

Conclusions

- Clinical and numerical accuracies are comparable between all groups, indicating that **GlucoTrack** is suitable for both people with T2DM and pre-diabetes.
- Due to its non-invasive nature, **GlucoTrack** could potentially be the ideal solution to enhance compliance of self-monitoring of glucose and lead to tighter glycemic control in people with T2DM and pre-diabetes.