Influence of medications on the accuracy of GlucoTrack® - a non-invasive glucose monitoring device

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Introduction

GlucoTrack® is a truly non-invasive glucose monitoring device that indirectly measures glucose level in the earlobe tissue. The device measures variations in ultrasonic, electromagnetic and thermal parameters, which occur due to glucose-related shifts in ion concentration, density, compressibility and hydration of the earlobe tissue. The measured parameters are translated into a glucose value based on individual calibration. Measuring tissue parameters may also be affected by factors other than glucose, such as medications (figure 1). Specifically, anti-diabetic medications cause rapid glucose excursion which may affect the glucose time lag between blood and tissue, while other medications may have an impact on the hydration status of the tissue.

Medical Condition	Probability
Blood Pressure ≥140/190 mmHg (Hypertension)	71% of adults with diabetes
Blood LDL cholesterol ≥100 mg/dl (Cholesterolemia)	65% of adults with diabetes
Blood clots formation (Thrombosis)	2 times higher than healthy adults

Figure 1: Major medical conditions associated with Diabetes Mellitus and their probability.

Objective

The current study evaluates ***GlucoTrack*** accuracy in subjects undertaking different medications.

Method

GlucoTrack is comprised of a main unit and a personal ear clip (PEC) where the sensors are located (Figure 2A). Spot measurement (~1 minute length) is performed by clipping the PEC to the earlobe for the measurement duration (Figure 2B).

Clinical trials were conducted on 172 adult subjects with type 2 diabetes, stratified to medication groups, focusing on anti-hypertension, anti-cholesterolemia, anti-thrombotic, and anti-diabetic (prolonged duration and short and mixed duration) medications (Table 1).

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.

Device accuracy was assessed:

- Clinically: using consensus error grid (EG) analysis (type 2 version);
- Numerically: using mean and median absolute relative differences (ARD).

Statistical analysis was conducted to compare the performance of ***GlucoTrack*** within medication groups using linear mixed effect models and gamma residual distribution with log link function for ARD values.

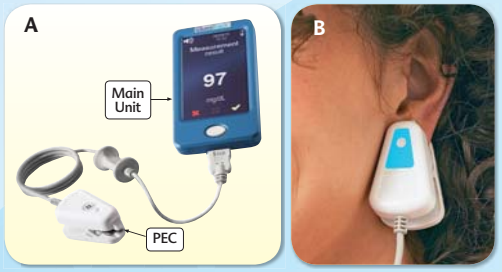
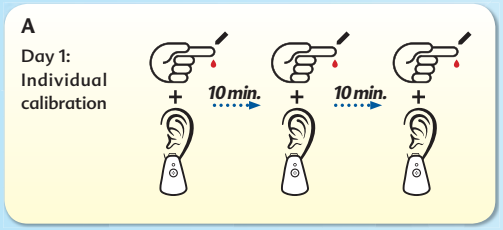


Figure 2: [A] GlucoTrack glucose monitoring device* ˆ; [B] Performing a glucose measurement.



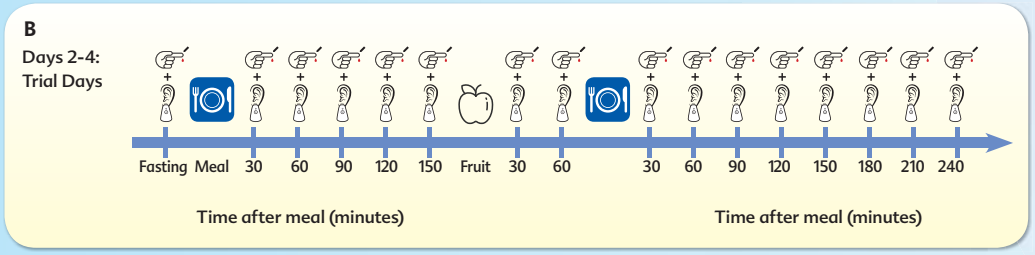


Figure 3: The clinical trial consists of several days: A. a day of calibration (1st day) and B. up to 3 days of data collection (days 2-4).

Table 1: The properties of medication groups

Medication		Number of subjects	Number of measurements
Anti-cholesterolemia	On	105	4693
	Off	67	3007
Anti-hypertension	On	117	5150
	Off	55	2550
Anti-thrombotic	On	87	3805
	Off	85	3895
Anti-diabetic: short and mixed duration	On	61	2681
	Off	111	5019
Anti-diabetic: prolonged duration	On	98	4450
	Off	74	3250
All		172	7700

Results

- Similar percentages ranging from 97.5% to 99.2% in the clinical acceptable A and B zones of Consensus EG were achieved across medication groups (Figure 4);
- All medication groups showed similar clinical accuracy: above 72.5% in the zone A of consensus EG (Figure 4);
- No statistical difference was observed in ARD values within each medication group (p>0.05; Figure 5).

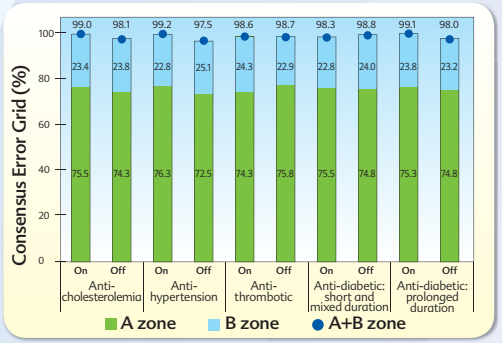


Figure 4: GlucoTrack performance as a function of medication consumption evaluated by Consensus EG.

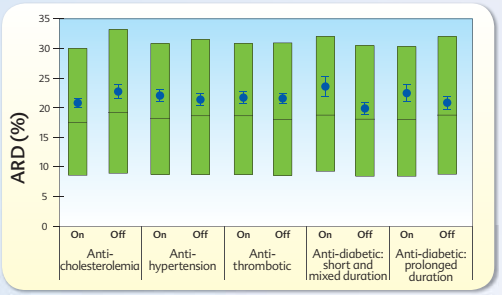


Figure 5: ARD distribution presented in a boxplot. *The lower boxplot line represents quartile 25%, the middle line represents the median, and the upper quartile 75%. The dot refers to a statistical model-based mean ARD values and their standard error.*

Conclusions

- Clinical and numerical accuracies are comparable between all subjects regardless of tested medication consumption, indicating that ***GlucoTrack*** is suitable for subjects under medication regime;
- ***GlucoTrack*** performances are maintained within each medication group, further advocating that ***GlucoTrack*** is suitable for type-2 diabetes population.

* This device has CE-mark approval.

ˆ The device is limited by United States federal law to investigational use only.

integrity applications

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