Repeatability of a Non-Invasive Glucose Monitoring Device

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Introduction

According to the International Organization for Standardization (ISO) standard 15197, a repeatability test should be conducted to ensure that invasive blood glucose monitoring devices produce consistent repeatable measurements under similar conditions. Although no standard for non-invasive devices exists, good practice should also hold true for non-invasive devices. Thus, this study aims to evaluate the repeatability of ***GlucoTrack***®, a truly non-invasive (NI) glucose monitoring device for home use.

GlucoTrack 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) where sensors are located (Figure 1A). Spot measurement (~1 minute length) is performed by clipping the PEC to the earlobe for the measurement duration (Figure 1B).

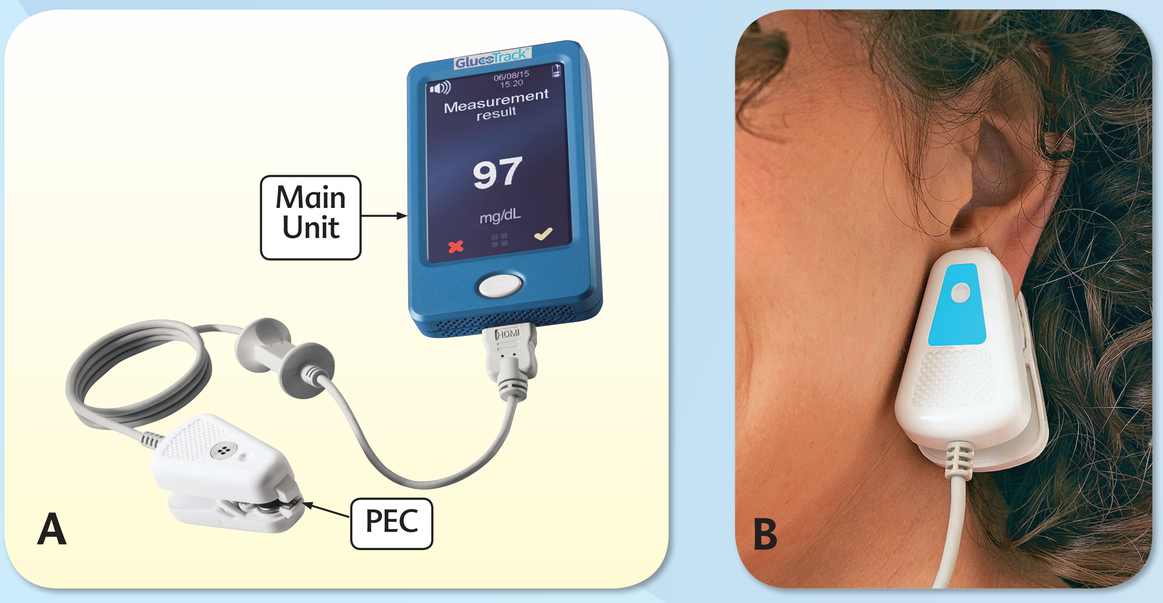

Figure 1: [A] GlucoTrack glucose monitor; [B] Performing a glucose measurement

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

Objective

To evaluate the repeatability of ***GlucoTrack***, a NI glucose monitoring device.

Methods

Two aspects of ***GlucoTrack's*** repeatability were studied:

1. Repeatability of different devices (main units and PECs) worn by the same user on different earlobes in parallel;
2. Repeatability of a specific PEC (sensors) during sequential measurements under stable glycemic conditions.

At the beginning of each trial, ***GlucoTrack*** devices were individually calibrated for a specific earlobe using HemoCue® Glucose 201 RT as reference (Figure 2). All measurements conducted in the following trials were coupled to invasive measurements as well.

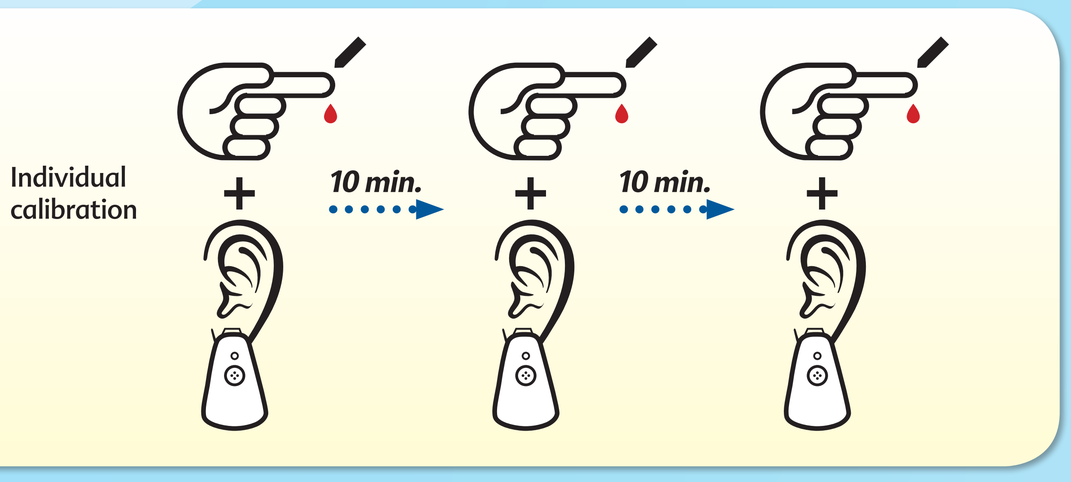

Figure 2: Calibration procedure

1. Repeatability of different devices:

- 15 Type-2 subjects performed up to 19 measurements per day, during 2-4 days, using two devices simultaneously (on both earlobes; Figure 3);
- In total, 16 main units and 20 PECs were tested during the trial;
- Repeatability between 2 different devices was assessed using precision absolute relative difference[1] (PARD; Equation 1) in different glycemic ranges and post-prandial states.

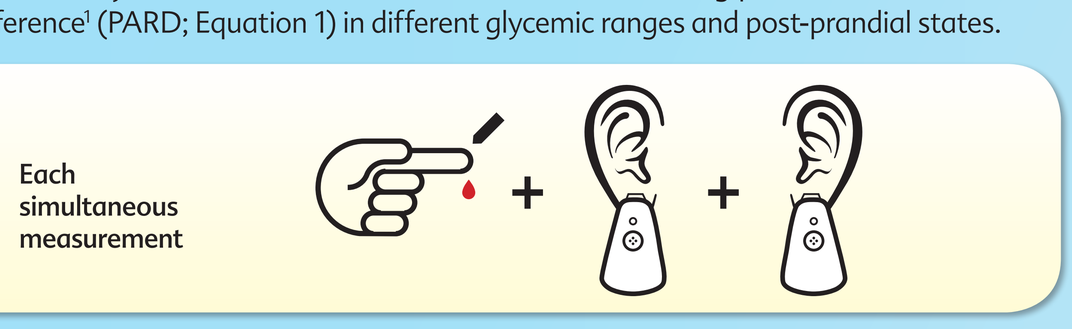

Figure 3: Simultaneous measurement conduction

[Eq. 1]

$$PARD = \frac{|\, glucose_{PEC\#1} - glucose_{PEC\#2} \,|}{mean\,(glucose_{PEC\#1}\,,\, glucose_{PEC\#2})} \cdot 100\ (\%)$$

Where $glucose_{PEC\#1}$ is a glucose reading measured by PEC placed on the right earlobe and $glucose_{PEC\#2}$ is a glucose reading measured by PEC placed on the left earlobe.

2. Sequential measurement repeatability under stable glycemic conditions:

- Relative stable glycemic condition was achieved at 2-3 hours post-prandial for 14 Type-2 subjects;
- Sequence of 4 simultaneous measurements with ***GlucoTrack*** and invasive reference were conducted every 10 minutes (Figure 4). This sequence was performed 1-2 times/day for a total of 3 days;

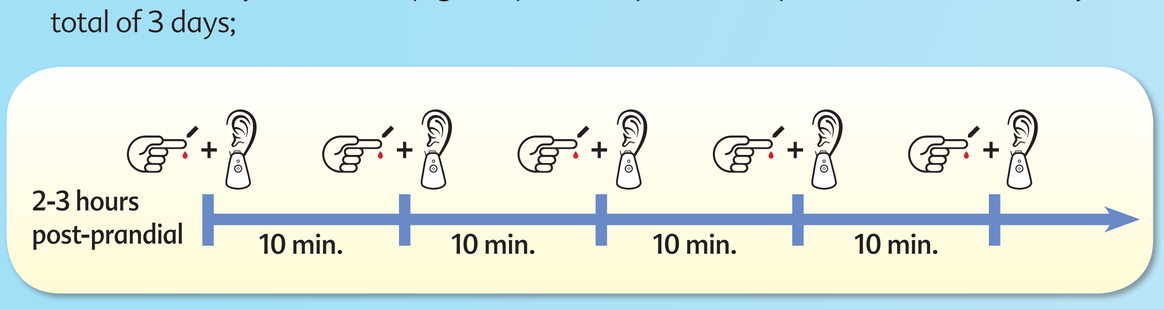

Figure 4: Trial procedure for sequential measurement repeatability test under stable glycemic conditions

- Altogether, 13 PECs were tested during the trial;
- Sequential measurement repeatability was assessed using the coefficient of variation (CV) of sequential measurements (Equation 2).

[Eq. 2]

$$CV = \frac{\sigma}{\mu} \cdot 100\ (\%)$$

Where σ is the standard deviation and μ is the mean of a measurement sequence.

Results

1. Repeatability of different devices: PARD values were calculated for 806 simultaneous ***GlucoTrack*** measurements for every pair of devices worn by the same subject (Figure 5). Table 1 displays PARD values as a function of glucose levels. Glucose levels were categorized depending on the corresponding invasive reference. Table 2 presents PARD values as a function of time elapsed from meal consumption.

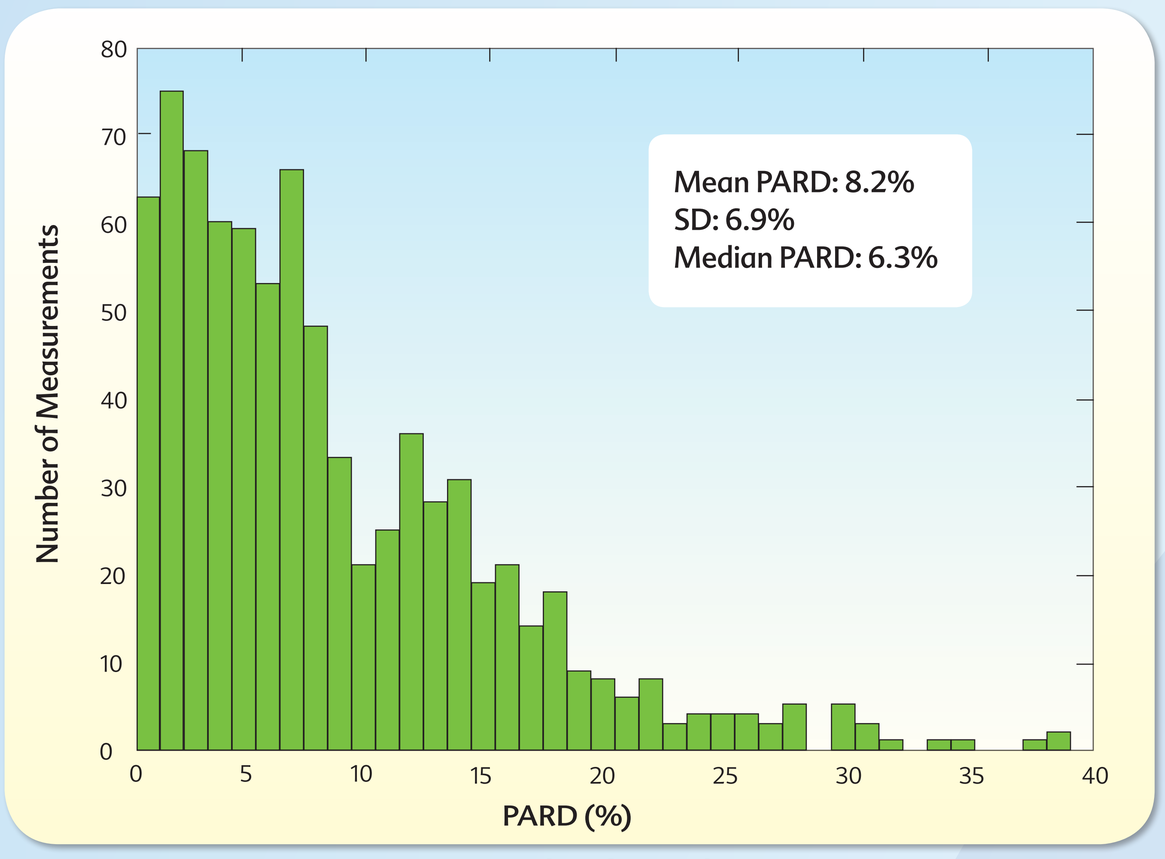

Figure 5: PARD distribution histogram

Table 1: PARD of GlucoTrack as a function of glucose range

Glucose range (mg/dL)	N	PARD (%)
70-120	198	8.8±7.7
120-240	574	8.0±6.7
>240	34	6.6±4.0

Table 2: PARD of GlucoTrack as a function of time elapsed from meal consumption

Time elapsed from meal consumption (min)	N	PARD (%)
0-30	142	8.3±7.0
30-60	230	7.6±6.2
60-90	116	7.2±5.2
90-120	195	7.8±6.6
> 120	44	9.7±8.7

2. Sequential measurement repeatability under stable glycemic conditions: The statistical values of CV and standard deviation were calculated for 54 measurement sequences (Table 3). The mean deviation in the reference values is 4.2±2.8 mg/dL.

Table 3: Statistical values for CV and standard deviation of 54 measurement sequences

	CV (%)	Standard deviation (mg/dL)
Mean	9.5	11.0
SD	7.1	7.1
Median	7.2	9.3

Conclusions

- ***GlucoTrack's*** performance shows fair repeatability between different devices on both earlobes of the same subject, as demonstrated by PARD values;
- The repeatability of different devices is similar at all glucose ranges and post-prandial periods;
- ***GlucoTrack's*** PARD values looks better than those previously reported for minimally-invasive continuous glucose monitoring devices (CGMS; Table 4);
- ***GlucoTrack's*** repeatability is constant in sequential measurements under stable glycemic values.

Table 4: GlucoTrack's PARD (mean ± SD) values compared to PARD values of popular continuous glucose monitoring devices (CGMs) [2]

Device	PARD (%)
GlucoTrack	8.2±6.9
Navigator [2]	9.6±8.2
Seven Plus [2]	16.6±16.5
Guardian [2]	18.1±18.1

References

1. Obermaier K et al. Performance evaluations of continuous glucose monitoring systems: precision absolute relative deviation is part of the assessment. *J Diabetes Sci Technol* 7, 824—832(2013).
2. Freckmann G et al. Performance evaluation of three continuous glucose monitoring systems: comparison of six sensors per subject in parallel. *J Diabetes Sci Technol.* 7(4):842-853 (2013).

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