

# TRANSDERMAL GLUCOSE MONITORING SYSTEM: COMPARISON BETWEEN PATIENT SPECIFIC & UNIVERSAL CALIBRATION DURING EXTREMES OF HYPO- & HYPERGLYCEMIA

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## INTRODUCTION

Glucose monitoring is essential to achieve tight glycaemic control, especially in patients taking insulin. Compliance with glucose testing is hampered by pain and lack of social acceptability.

A new noninvasive transdermal glucose monitoring system (TDG-MS) developed by TCPI utilizes a small transdermal patch and a wand-type electronic meter. The completely bloodless and pain free TDG-MS extracts glucose from the skin and measures the reflectance generated from the glucose oxidase/peroxidase enzymatic reaction. These readings are translated into the corresponding glucose concentrations.

The TDG-MS was tested at the extremes of hyper- and hypoglycemia, and the results compared with Yellow Springs Instrument (YSI) and One Touch<sup>®</sup> Profile<sup>™</sup> measurements.

## OBJECTIVE

The objectives of this study were to investigate the degree of inter-patient variation, the need for patient calibration and the potential for developing a calibration-free method validated at blood glucose extremes.

## METHODS

After giving informed consent, 13 adults with diabetes were admitted to the GCRC, IV lines were placed for infusion of insulin and/or D20W as needed and for venous sampling.

Venous blood glucose was measured by YSI and capillary blood glucose by One Touch<sup>®</sup> Profile<sup>™</sup> every 5 – 15 minutes during hyperglycemia (induced by caloric intake and supplemental D20W) to approximately 30 mmol/mL and hypoglycemia (induced by insulin infusion with physician present) to 2 mmol/mL. Parallel measurements were performed using the TDG-MS.

The patches were applied for 5 minutes to the patient's volar forearm and then read with an electronic meter.

Each patient was individually calibrated. A simple 2-parameter correlation model was developed for the translation of the meter's mV readings into the corresponding blood glucose values.

Figure 1: Patch and electronic meter



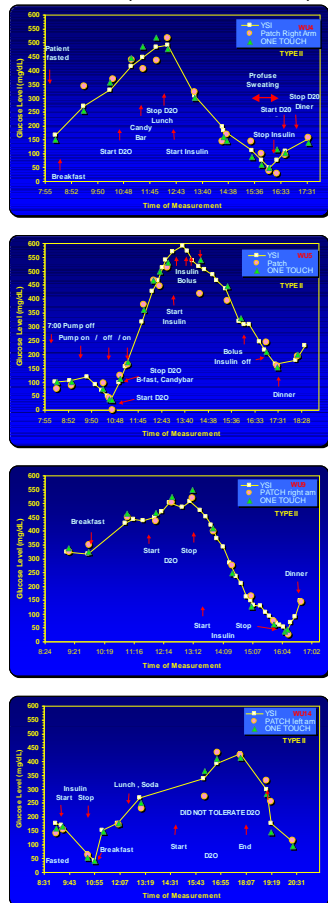
## RESULTS

### Glucose Concentration Profiles

TDG-MS parallels venous and capillary measurements. The patch data track the venous and the fingerstick results into the hypo- as well as the hyperglycemic concentration range very well.

Figure 2 a-d:

Representative samples of concentration profiles

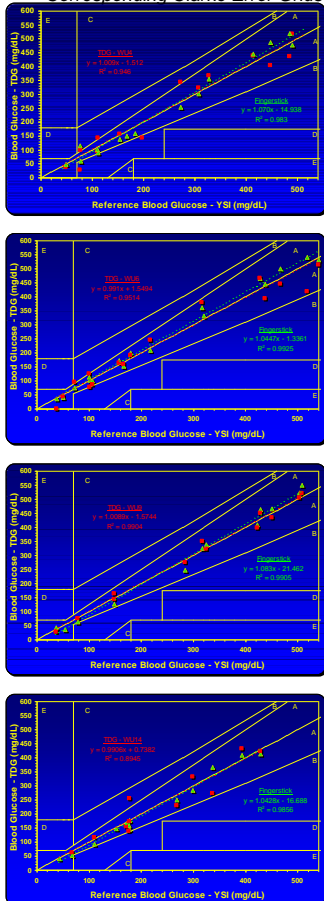


### Clarke Error Grid Analysis

Clarke Error Grid analysis shows clustering of the TDG-MS data in the A & B grid regions:

Figure 3 a-d:

Corresponding Clarke Error Grids



## DISCUSSION

Individual patient calibration results in excellent prediction/correlation; however, model correlation parameters vary from patient-to-patient:

Table 1:

Patient specific algorithm parameters (A & B) incl. their average values

PARAMETER	A	B
1	915	3.4
2	798	4.5
3	798	5.2
4	793	5
5	902	4.4
6	796	5.3
7	905	5
8	793	6.6
9	798	5
10	794	6.7
11	908	4.8
12	908	5.4
13	902	6.7
AVG	801	5.2
STD	0	0.0
CV	0.0%	10%

Figure 4a-b: All Patients INDIVIDUALLY calibrated  
a: YSI-reference b: Fingerstick reference

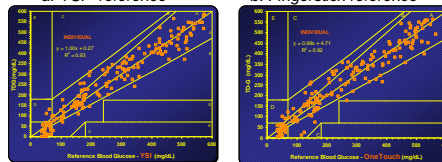
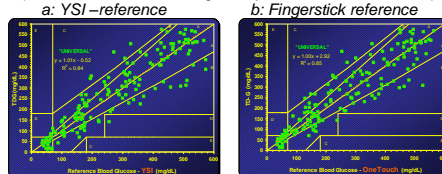


Figure 5a-b: All Patients UNIVERSALLY calibrated  
(All data recalculated using AVG parameters from Table 1)  
a: YSI-reference b: Fingerstick reference



TDG-MS data correlate very well with both reference methods. At this stage of the development it appears that individual patient calibration generates a better overall correlation.

Table 2: Correlation Coefficients

	Venous	Capillary
Individual	93%	92%
Universal	84%	85%

### Other Observations:

- Profuse sweating can interfere with measurement. Excess sweat needs to be removed before patch application.
- Cosmetics (oily lotions) should not be used
- Dehydration may affect results

## CONCLUSIONS

Pain free glucose monitoring using the TDG-MS is possible with accuracy comparable to capillary blood glucose measured with One Touch<sup>®</sup> Profile<sup>™</sup>. Individual calibration increases the accuracy of the system.

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