

Using Distributional Data Analysis Tool to Investigate the Sensor Collected Glucose Density (GD%) Distribution of the Daily Mean Glucose (eAG), Fasting Plasma Glucose (FPG), and Postprandial Plasma Glucose (PPG) Collected from a Continuous Glucose Monitoring Sensor Device of a Long-Term Type 2 Diabetes Patient Over a Period of 3.33 Years Based on GH-Method: Math-Physical Medicine (No. 509)

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Abstract

Recently, the author have made two further improvements on his glucose data analysis with his collected big data of sensor glucoses via a continuous glucose monitoring sensor device (CGM).

First, in addition to using the HbA1C, which is the mean value of the past 115 days of red blood cell's glucoses, of a patient as the golden standard in evaluating diabetes conditions. He investigates the glucose fluctuation or GF (glucose excursion or glycemic variability) and then transforms the GF values from a wave's time-space into an energy's frequency-space via Fourier transform operations. Using this analytic approach, he can then guesstimate the degree of damage caused on internal organs by the energies associated with various glucose fluctuations. Although the GF research is one step deeper compared to the study of mean value of glucoses, such as HbA1C, it is still not deep enough in order to dig out more detailed and useful information hidden inside of the glucose waves.

Second, he realized that the average values or mean values of glucoses defined by the American Diabetes Association (ADA) such as the HbA1C or Time in Range (average glucose within a range) can only provide partial views of diabetes conditions. However, these basic biomarkers are still missing some hidden internal turmoil, i.e. glucose vibrations or stimulations, within certain timeframe due to all types of external and/or internal stimulators. Therefore, he defined another term known as the glucose density (GD) in order to discover different hidden information within the glucose data and their waveforms. GD% is defined as the occurrence frequency at a specific glucose value, for example 2.1% occurrence rate at 110 mg/dL glucose value over a selected time period of collected sensor glucoses. In this way, he can then calculate and examine each glucose value's occurrence rate within a glucose range that is suitable to a specific patient. In this article, the author's possible covering range of his sensor glucose vibration is 221 is between 40 mg/dL and 261 mg/dL over the past 3.33 years. This glucose examination method, if accepted by the medical community, would be an extremely beneficial tool for doctors to truly understand their diabetes patient's conditions. The author has also programmed his algorithm into an iPhone APP software. Through the combination of his published papers and medical books along with a widely distributed APP for patient's use in the future, he believes that worldwide T2D patients can benefit from his research work.

As part of his follow-on research tasks, he plans to further examine his glucose density % resulted from certain food/diet nutritional types and exercise intensity levels. Hopefully, in this way, his research papers would not be limited within the scope of a "descriptive style using 26 alphabets" but instead as a "quantitative style

using 10 digits". Numbers do not lie as long as we don't use fake, unorganized, and/or uncleaned data. Statistics is a tricky tool to use because it has the characteristics related to "garbage in and garbage out (GIGO)". It is important to know that by using statistics with different selected time-windows will result into varying

conclusions.

This part of the introduction assists the author to organize and summarize his thoughts and forces him to express the abstract ideas and theoretical concepts by writing on paper, which has helped him before. Actually, there is nothing fancy about the above-mentioned density analysis approach; however, he would like to re-iterate what he has learned in the past and apply all of available and useful mathematical tools to interpret interesting biophysical phenomena or solving different biomedical challenges.

The author has read an article recently, "Glucodensities: a new representation of glucose profiles using distributional data analysis," dated August 19, 2020, from arxiv.org (see Reference 1). He has decided to perform a series of research tasks using the Glucodensity (GD) concept but with his own developed algorithm & APP software with his collected CGM sensor glucose data over a longer period of 3.33 years from 5/8/2018 through 9/8/2021.

In summary, for most of clinical practices, medical doctors use HbA1C as the golden standard to evaluate the conditions of their type 2 diabetes (T2D) patients. The HbA1C value represents the average glucose value of all glucoses over the past 90 to 120 days or perhaps 115 days based on the red blood cell's lifespan; however, the HbA1C alone cannot tell doctors additional information other than the mean value. In fact, many other glucose information are hidden within. Biomarkers such as the glucose variability (GV) or the glucose fluctuation (GF) can provide some more information regarding the damage of a patient's internal organs via glucose excursion which causes many diabetic complications, including both micro-vascular and macro-vascular diseases. Furthermore, the American Diabetes Association (ADA) has issued certain guidelines on time in range (TIR), time above range (TAR), and time below range (TBR) which can offer a general idea of how glucoses are distributed in three different ranges: TIR for normal conditions, TAR for hyperglycemic conditions, and TBR for hypoglycemic conditions. However, they are still using the mean values within each range, e.g. <70, 70-180, >180.

Therefore, these three biomarkers, HbA1C, GF, and Time in/above/below Range (i.e. TxR), are still missing the needed ability to provide more detailed glucose variations. Even the GV or GF are still dealing with another kind of mean values. Based on these observed shortcomings, glucose density or (GD) can indeed fill in certain gaps of "missing information" from these three biomarkers, HbA1C, GF, and TxR.

By using the author's collected CGM sensor glucoses, including FPG, PPG, eAG, and his developed APP software program on iPhone, he can calculate his GD% data and GD% curves for 3 CGM sensor collected glucoses such as FPG, PPG, eAG separately. Through a combination of these three GD% curves, he can then describe his key conclusive observation at below:

His GD% peak-lumps of "densely populated glucoses" or "majority of glucoses" are listed here:

FPG = 2.0% within 85-110 mg/dL, PPG = 1.6% within 100-130 mg/dL, eAG = 1.6% within 97-125 mg/dL.

In general, these findings are matching with his 2 approximated equations of eAG used in the past.

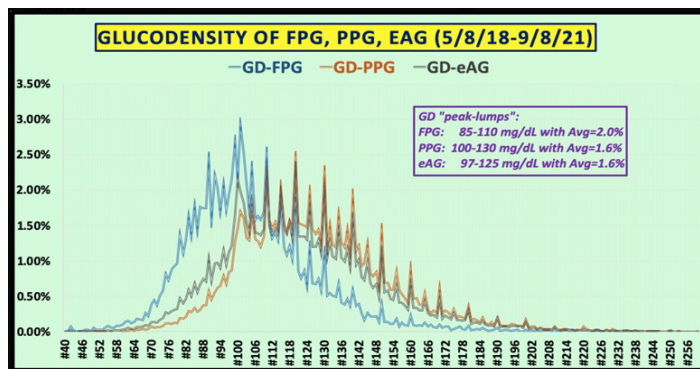
$$\text{Finger eAG} = \text{FPG} * 0.25 + \text{PPG} * 0.75$$

$$\text{Sensor eAG} = \text{FPG} * 0.29 + \text{PPG} * 0.71$$

However, the obviously higher GD% (2.0%) associated with FPG's lower glucose range (85-110 mg/dL) has shown the importance of influential factors of his body weight and his sleep/stress conditions on his FPG. It should also be pointed out that the key influential factors of PPG, diet and exercise, are not associated with FPG.

The GD% analysis can identify more detailed information regarding glucose variance and T2D conditions than the traditional biomarkers such as HbA1C and TxR. It should be noted here that GF can offer some additional insights regarding the risk probabilities of developing various diabetic complications. Similarly, GD can also provide other useful indications regarding various diabetic complications.

Furthermore, his own sensor GD% waveforms of FPG, PPG, and eAG are extremely **similar in shape** with the GD waveforms from the paper of Reference 1, except for *his peak GD percentages are within 1% to 3% (with only one T2D patient, himself) while the peak GD percentages in Reference 1 are within 2% to 6% (with many more severe T2D patients but over relatively shorter time-frames).*



Introduction

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Methods

MPM Background

To learn more about his developed GH-Method: math-physical medicine (MPM) methodology, readers can read the following three papers selected from his ~500 published medical papers.

The first paper, No. 386 describes his MPM methodology in a general conceptual format. The second paper, No. 387 outlines the history of his personalized diabetes research, various application tools, and the differences between biochemical medicine (BCM) approach versus the MPM approach. The third paper, No. 397 depicts a general flow diagram containing ~10 key MPM research methods and different tools.

In particular, his paper No. 453 illustrates his GH-Method: math-physical medicine in great details, "Using Topology concept of mathematics and Finite Element method of engineering to develop a mathematical model of Metabolism in medicine in order to control various chronic diseases and their complications via overall health conditions improvement".

The Author'S Case of Diabetes and Complications

The author has been a severe T2D patient since 1996. He weighed 220 lb. (100 kg, BMI 32.5) at that time. By 2010, he still weighed 198 lb. (BMI 29.2) with an average daily glucose of 250 mg/dL (HbA1C of 10%). During that year, his triglycerides reached to 1161 (diabetic retinopathy or DR) and albumin-creatinine ratio (ACR) at 116 (chronic kidney disease or CKD). He also suffered from five cardiac episodes within a decade. In 2010, three independent physicians warned him regarding his needs of kidney dialysis treatment and future high risk of dying from severe diabetic complications. Other than cerebrovascular disease (stroke), he has suffered most known diabetic complications, including both macro-vascular and micro-vascular complications.

In 2010, he decided to launch his self-study on endocrinology, diabetes, and food nutrition in order to save his own life. During 2015 and 2016, he developed four prediction models related to diabetes conditions: weight, PPG, fasting plasma glucose (FPG), and A1C. As a result, from using his developed mathematical metabolism index (MI) model in 2014 and the four prediction tools, by end of 2016, his weight was reduced from 220 lbs. (100 kg, BMI 32.5) to 176 lbs. (89 kg, BMI 26.0), waistline from 44 inches (112 cm, nonalcoholic fatty liver disease /NAFLD) to 33 inches (84 cm), average finger glucose reading from 250 mg/dL to 120 mg/dL, and lab-tested A1C from 10% to ~6.5%. One of his major accomplishments is that he no longer takes any diabetes medications since 12/8/2015.

In 2017, he has achieved excellent results on all fronts, especially his glucose control. However, during the pre-COVID period of 2018 and 2019, he traveled to approximately 50+ international cities to attend 65+ medical conferences and made ~120 oral presentations. This hectic schedule inflicted damage to his diabetes control, through dinning out frequently, post-meal exercise disruption, jet lag, and along with the overall metabolism impact due to his irregular life patterns through a busy travel schedule; therefore,

his glucose control and overall metabolism state were somewhat affected during this two-year heavier traveling period.

During 2020 with a COVID-19 quarantined lifestyle, not only has he published ~400 medical papers in 100+ journals, but he has also reached his best health conditions for the past 26 years. By the beginning of 2021, his weight was further reduced to 165 lbs. (BMI 24.4) along with a 6.1% A1C value (daily average glucose at 105 mg/dL), without having any medication interventions or insulin injections. These good results are due to his non-traveling, low-stress, and regular daily life routines. Due to his knowledge of chronic diseases, practical lifestyle management experiences, and developed various high-tech tools contribute to his excellent health status since 1/19/2020, which is the start date of being self-quarantined.

On 5/5/2018, he applied a CGM sensor device on his upper arm and checks glucose measurements every 5 minutes for a total of ~288 times each day. He has maintained the same measurement pattern to present day. In his research work, he uses the CGM sensor glucose at time-interval of 15 minutes (96 data per day). By the way, the difference of average sensor glucoses between 5-minute intervals and 15-minute intervals is only 0.4% (*average glucose of 114.81 mg/dL for 5-minutes and average glucose of 114.35 mg/dL for 15-minutes with a correlation of 93% between these two sensor glucose curves*) during the period from 2/19/20- to 8/13/21.

Therefore, over the past 11 years, he could study and analyze the collected 2+ million data regarding his health status, medical conditions, and lifestyle details. He applies his knowledge, models, and tools from mathematics, physics, engineering, and computer science to conduct his medical research work. His medical research work is based on the aims of achieving both “high precision” with “quantitative proof” in the medical findings.

The following timetable provides a rough sketch of the emphasis of his medical research during each stage:

- 2000-2013: Self-study diabetes and food nutrition, developing a data collection and analysis software.
- 2014: Develop a mathematical model of metabolism, using engineering modeling and advanced mathematics.
- 2015: Weight & FPG prediction models, using neuroscience.
- 2016: PPG & HbA1C prediction models, using optical physics, artificial intelligence (AI), and neuroscience.
- 2017: Complications due to macro-vascular research such as cardiovascular disease (CVD), coronary heart disease (CHD) and stroke, using pattern analysis and segmentation analysis.
- 2018: Complications due to micro-vascular research such as chronic kidney disease (CKD), bladder, foot, and eye issues such as diabetic retinopathy (DR).
- 2019: CGM big data analysis, using wave theory, energy theory, frequency domain analysis, quantum mechanics, and AI.
- 2020: Cancer, dementia, longevity, geriatrics, DR, hypothyroidism, diabetic foot, diabetic fungal infection, linkage between metabolism and immunity, and learning about certain infectious diseases such as COVID-19.
- 2021: Applications of linear elastic glucose theory (LEGT)

and perturbation theory from quantum mechanics on medical research subjects, such as chronic diseases and their complications, cancer, and dementia. Using metabolism and immunity.it’s as the base, he expands his research into cancers, semantic, and COVID-19.

To date, he has collected more than two million data regarding his medical conditions and lifestyle details. In addition, he has written 498 medical papers and published 400+ articles in 100+ various medical journals, including 6 special editions with selected 20-25 papers for each edition. Moreover, he has given ~120 presentations at ~65 international medical conferences. He has continuously dedicated time and effort on medical research work and shared his findings and learnings with other patients worldwide.

Glucose Density (GD%)

The author took the following photo directly from the beginning part of Section 3 in the Glucodensities’ paper (Reference 1), because he is not familiar with writing English articles with LATEX math symbols using Page application on iPad.

3 Definition and Estimation of the Glucodensity

For patient i , denote the gathered glucose monitoring data by pairs (t_{ij}, X_{ij}) , $j = 1, \dots, m_i$, where the t_{ij} represent recording times that are typically equally spaced across the observation interval, and X_{ij} is the glucose level at time $t_{ij} \in [0, T_i]$. Note that the number of records m_i , the spacing between them, and the overall observation length T_i can vary by patient. One can think of these data as discrete observations of a continuous latent process $Y_i(t)$, with $X_{ij} = Y_i(t_{ij})$. The glucodensity for this patient is defined in terms of this latent process as $f_i(x) = F_i'(x)$, where

$$F_i(x) = \frac{1}{T_i} \int_0^{T_i} \mathbf{1}(Y_i(t) \leq x) dt \quad \text{for} \quad \inf_{t \in [0, T_i]} Y_i(t) \leq x \leq \sup_{t \in [0, T_i]} Y_i(t)$$

is the proportion of the observation interval in which the glucose levels remain below x . Since F_i are increasing from 0 to 1, the data to be modeled are a set of probability density functions f_i , $i = 1, \dots, n$.

Of course, neither F_i nor the glucodensity f_i is observed in practice, but one can construct an approximation through a density estimate $\hat{f}_i(\cdot)$ obtained from the observed sample. In this case of CGM data, the glucodensities may have different support and shape. Therefore, we suggest using a non-parametric approach to estimate each density function. For example, using a kernel-type estimator, we have

$$\hat{f}_i(x) = \frac{1}{m_i} \sum_{j=1}^{m_i} K_{h_i}(x - X_{ij}),$$

where $h_i > 0$ is the smoothing parameter and $K_{h_i}(s) = \frac{1}{h_i} K(\frac{s}{h_i})$. The choice of K does not have a big impact on the efficiency of the estimator, but the value of h_i is crucial.

For the case of one patient of himself ($i = 1$), he can then ignore the index i and only use $j = 1, \dots, T$, where T is the overall observation length of glucoses. *For his case in this article, the total T is 245 (from 40 mg/dL to 285 mg/dL).*

His gathered CGM glucose data by pairs (t_j, X_j) , $j=1, \dots, T$, where the $X_j = Y(t_j) =$ CGM glucose and the t_j represents recording times (every 15 minutes for 96 times each day). Therefore, he can simplify the above equation in the photo further into a simplified equation for one patient only. The GD for himself can be defined in terms of a **continuous format** as follows:

$$GD(x) = \frac{\int_{x_1}^{x_2} Y(t) dt}{T}$$

with $x_1 < Y(t) < x_2$
 where x_1 and x_2 are \lceil boundaries of his selected glucose range.

The **glucose density % (GD%) equation** for one patient, such as himself, can also be defined in terms of a **discrete format** as follows:

$$GD(x) = \frac{\sum Y(t_j)}{T}$$

$j=1$

with $x1 < Y(t) < x2$

where $x1$ and $x2$ are boundaries of his selected glucose range.

He uses the above equations to develop his APP software program on iPhone device to calculate three GD% values of FPG, PPG, and eAG then draw the three associated GD% curves.

Results

Figure 1 shows his glucose density (GD%) curves for FPG, PPG, and eAG for a period of 3.33 years from 5/8/2018 to 9/8/2021.

In Figure 1, there are 3 distinctive glucose ranges:

FPG: 39 (x1) to 281 (x2)

PPG: 53 (x1) to 288 (x2)

eAG: 39 (x1) to 300 (x2)

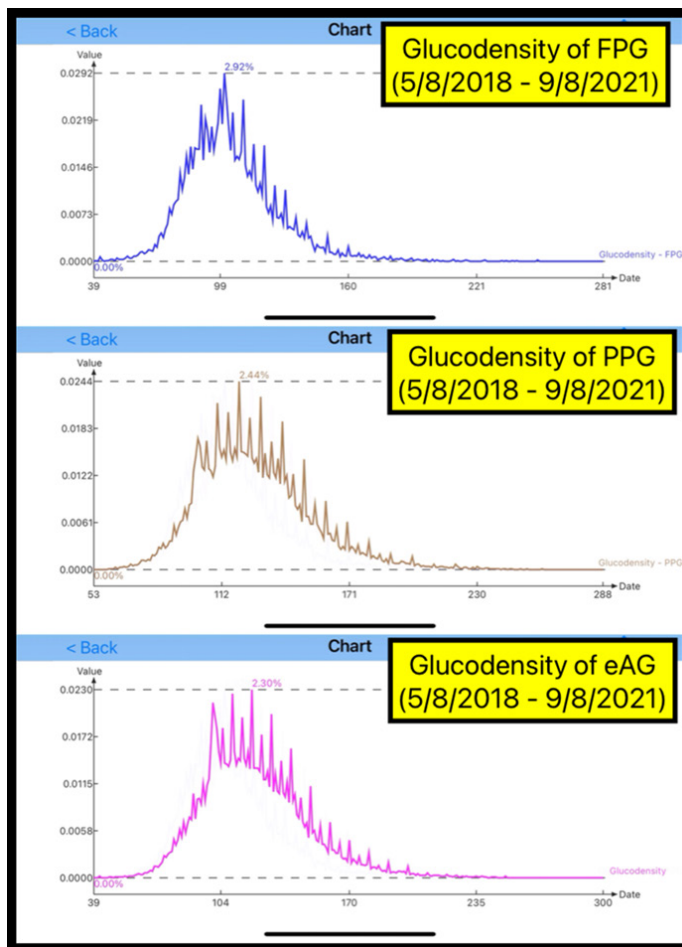


Figure 1: Glucodensity (GD) curves of FPG, PPG, eAG (5/8/2018-9/8/2019)

However, most of the GD% values are near the glucose data $x1$ (39-53 mg/dL) and the glucose data $x2$ (281-300 mg/dL) in having 0% of GD% values. Therefore, the author has truncated off the 0% GD values near $x1$ and $x2$, and then re-summarized these 3 GD%

curves into one diagram with identical glucose ranges from 40 mg/dL ($x1$) to 260 mg/dL ($x2$) which has a total glucose range value of 221, i.e. $T = 221$.

Figure 2 depicts the conclusive diagram of this study. The top diagram demonstrates the combined three GD% curves of FPG, PPG, and eAG. His GD% peak-lumps of “densely populated glucoses” or “majority of glucoses” are listed below:

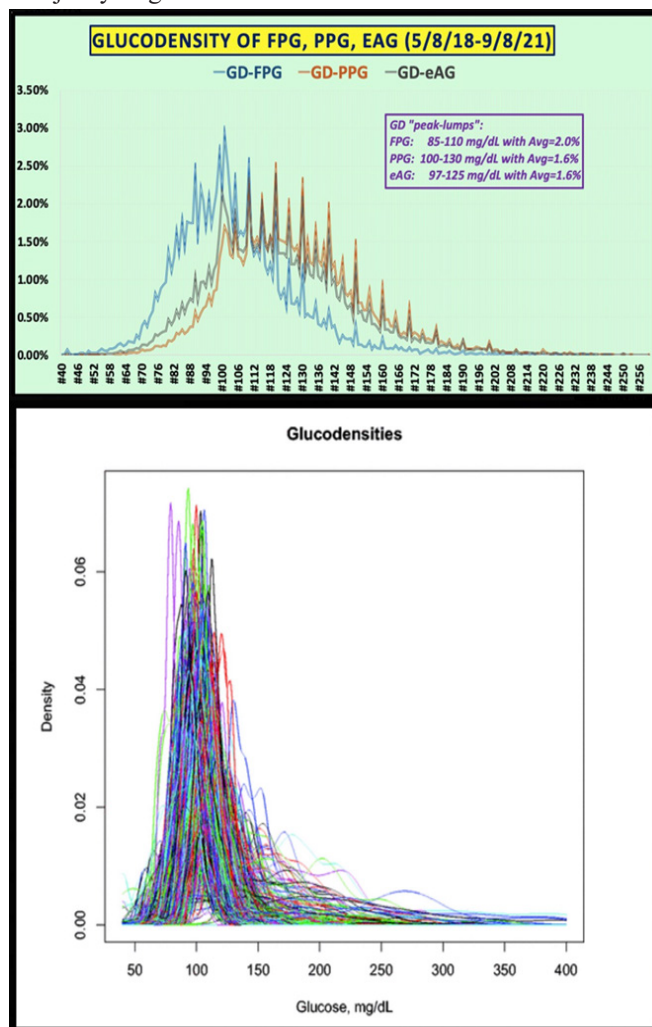


Figure 2: The author’s combined 3 GD% curves of FPG, PPG, eAG, and Reference 1’s GD% curve

FPG = 2.0% within 85-110 mg/dL, PPG = 1.6% within 100-130 mg/dL, eAG = 1.6% within 97-125 mg/dL.

However, in comparison with the PPG and eAG, the obvious higher GD% peak-lumps (2.0%) with lower glucose range (85-110 mg/dL) of FPG have shown the importance of influential factors of his body weight and his sleep/stress conditions. It should also be pointed out that key influential factors of PPG, diet and exercise, are not associated with FPG. On the other hand, these findings of relationships among FPG, PG, and eAG are matching with his 2 approximated equations of eAG expressed and used in the past.

Finger eAG
= FPG*0.25 + PPG*0.75

Sensor eAG
= FPG*0.29 + PPG*0.71

Finally, the lower diagram in Figure 2 illustrates that his own GD% waveforms of FPG, PPG, and eAG are extremely *similar in shape* with the GD% waveforms from the paper in Reference 1, except for *his peak-lumps of GD percentages are within 1% to 3% (with only one T2D patient, himself) while the peak-lumps GD percentages in Reference 1 are within 2% to 6% (with many more severe T2D patients but over relatively shorter timeframes).*

Conclusions

In summary, for most of clinical practices, medical doctors use HbA1C as the golden standard to evaluate the conditions of their type 2 diabetes (T2D) patients. The HbA1C value represents the average glucose value of all glucoses over the past 90 to 120 days or perhaps 115 days based on the red blood cell's lifespan; however, the HbA1C alone cannot tell doctors additional information other than the mean value. In fact, many other glucose information are hidden within. Biomarkers such as the glucose variability (GV) or the glucose fluctuation (GF) can provide some more information regarding the damage of a patient's internal organs via glucose excursion which causes many diabetic complications, including both micro-vascular and macro-vascular diseases. Furthermore, the American Diabetes Association (ADA) has issued certain guidelines on time in range (TIR), time above range (TAR), and time below range (TBR) which can offer a general idea of how glucoses are distributed in three different ranges: TIR for normal conditions, TAR for hyperglycemic conditions, and TBR for hypoglycemic conditions. However, they are still using the mean values within each range, e.g. <70, 70-180, >180.

Therefore, these three biomarkers, HbA1C, GF, and Time in/above/below Range (i.e. TxR), are still missing the needed ability to provide more detailed glucose variations. Even the GV or GF are still dealing with another kind of mean values. Based on these observed shortcomings, glucose density or (GD) can indeed fill in certain gaps of "missing information" from these three biomarkers, HbA1C, GF, and TxR.

By using the author's collected CGM sensor glucoses, including FPG, PPG, eAG, and his developed APP software program on iPhone, he can calculate his GD% data and GD% curves for 3 CGM sensor collected glucoses such as FPG, PPG, eAG separately. Through a combination of these three GD% curves, he can then describe his key conclusive observation at below:

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However, the obviously higher GD% (2.0%) associated with FPG's lower glucose range (85-110 mg/dL) has shown the importance of influential factors of his body weight and his sleep/stress conditions on his FPG. It should also be pointed out that the key influential factors of PPG, diet and exercise, are not associated with FPG.

The GD% analysis can identify more detailed information regarding glucose variance and T2D conditions than the traditional biomarkers such as HbA1C and TxR. It should be noted here that GF can offer some additional insights regarding the risk probabilities of developing various diabetic complications. Similarly, GD can also provide other useful indications regarding various diabetic complications.

Furthermore, his own sensor GD% waveforms of FPG, PPG, and eAG are extremely similar in shape with the GD waveforms from the paper of Reference 1, except for his peak GD percentages are within 1% to 3% (with only one T2D patient, himself) while the peak GD percentages in Reference 1 are within 2% to 6% (with many more severe T2D patients but over relatively shorter timeframes).

References

For editing purposes, majority of the references in this paper, which are self-references, have been removed for this article. Only references from other authors' published sources remain. The bibliography of the author's original self-references can be viewed at www.eclaircmd.com.

Readers may use this article as long as the work is properly cited, and their use is educational and not for profit, and the author's original work is not altered.

1. Marcos Matabuena¹, Alexander Petersen, Juan C Vidal, Francisco Gude (2020) Glucodensities: a new representation of glucose profiles using distributional data analysis <https://arxiv.org/pdf/2008.07840.pdf>

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