PREDICTION OF THE GLUCOSE LEVEL IN BLOOD USING NEAR INFRARED SPECTROMETER

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ABSTRACT

Diabetes is a medical condition caused by high glucose level in blood. A good control of glucose level is essential for diabetes patients as negligence of management could lead to severe health conditions such as obesity, blindness, stroke or heart attack. A conventional glucose level assessment uses an invasive glucometer device that is widely used in clinical practice. However, this practice is unfavourable for some patients since pricking fingers multiple times per day can be tiresome and painful, besides causing calluses, and not preferred by individuals with dexterity limitation, algophobia or anxiety problems. Therefore, prediction system of glucose level using non-invasive method is widely investigated. This thesis presents development of a non-invasive prediction system of glucose level in blood using near infrared spectrometer (NIRs), combined with predictive linear and non-linear models. This research focuses on the capability of spectrum to penetrate the skin, as well as the correlation between skin depth, location of human blood vessel and length of NIR spectrum. The data utilized are acquired from three groups: the existing diabetic patients, the non-diabetic persons, and a group of persons with no prior diagnosis. The existing diabetic patients are under medical treatment from Hospital Universiti Sains Malaysia (HUSM), while the non-diabetic persons are subjects who had their medical check-up in less than one year prior. Meanwhile, the control group consists of subjects who never had their medical check-up in the last 2 years. The glucometer is treated as reference data, and both glucometer and NIR spectral readings were obtained from all subjects (1000nm-2000nm). From the wavelength, regions that show significant information of glucose and water are between 1440 nm – 1460 nm and 1940 nm – 1960 nm. Results from pre-processing stage imply that data pre-processed by Savitzky-Golay (SG) filter with optimal parameter setting achieved the best accuracy. To establish correlation between the reference data and the NIR spectrum, two linear models, Autoregressive with Exogenous (ARX) and Autoregressive Moving Average Exogenous (ARMAX) models were implemented, and the combination of ARX and ARMAX with Artificial Neural Network (ANN) were utilized as non-linear models. The unregularized and regularized models for both ARX and ARMAX show unsatisfying results, where unregularized ARX is only at 24.82%, regularized ARX at 36.40%, unregularized ARMAX at 53.89% and regularized ARMAX shows accuracy of 78.57%. The results from regularized ARX and ARMAX are then used to combine with the ANN models. The ARMAX-ANN result shows a significant improvement at 89.45% respectively. The Clarke Error Grid Analysis (CEG) was used as a method to validate the new system with the reference established method in clinical practice. The CEG analysis reveals that the distribution of samples lies in region A and region B, where region A is within 20% of the reference sensor and region B is outside of 20% but would not lead to an inappropriate treatment for patients. From the results obtained, it is concluded that the selection of NIR regions and non-linear ARMAX-ANN model is proven as a promising method in predicting the glucose level in blood and future works can be executed in enhancing system accuracy.

ABSTRAK

Diabetes ialah keadaan kesihatan yang disebabkan oleh kandungan glukosa yang tinggi dalam darah. Kawalan glukosa yang baik penting untuk pesakit diabetes kerana pengabaian dalam pengurusan boleh membawa kepada keadaan kesihatan yang serius seperti obesiti, buta, strok atau serangan jantung. Kaedah saringan paras glukosa konvensional adalah menggunakan glukometer invasif yang digunakan secara meluas dalam amalan klinikal. Tetapi, kaedah ini kurang digemari oleh sesetengah pesakit kerana menusuk jari beberapa kali sehari menimbulkan kelelahan dan kesakitan, selain mengakibatkan kalus, dan tidak digemari oleh individu yang mempunyai had ketangkasan, algofobia, atau masalah kegelisahan. Maka, sistem ramalan tahap glukosa menggunakan kaedah tidak invasif diselidik secara meluas. Tesis ini menampilkan pembangunan sistem ramalan paras glukosa dalam darah secara tidak invasif menggunakan spektroskopi inframerah (NIRs), digabungkan bersama model ramalan linear dan tidak linear. Kajian ini mengfokus kepada keupayaan spektrum untuk menembusi kulit manusia, dan korelasi antara kedalaman kulit, lokasi pembuluh darah dan kepanjangan spektrum inframerah. Data diperolehi daripada tiga kumpulan: pesakit kencing manis tersedia, kumpulan bukan pesakit kencing manis dan mereka yang belum pernah didiagnosis. Kumpulan pesakit kencing manis tersedia adalah di bawah rawatan kesihatan di Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian, manakala kumpulan bukan pesakit kencing manis adalah subjek yang telah mendapatkan laporan perubatan mereka dalam masa setahun sebelumnya. Sementara itu, kumpulan kawalan adalah subjek yang tidak pernah mendapatkan laporan perubatan dalam masa 2 tahun sebelumnya. Bacaan glukometer dijadikan sebagai data panduan, dan kedua-dua bacaan glukometer dan spektra inframerah (1000nm-2000nm) diambil dari setiap subjek. Daripada panjang gelombang, kawasan yang menunjukkkan informasi ketara glukosa dan air adalah antara 1440 nm – 1460 nm dan 1940 nm – 1960 nm. Keputusan dari pra-pemprosesan menunjukan data yang diproses menggunakan penapisan Savitzky-Golay (SG) dengan tetapan parameter yang optimum memberi ketepatan terbaik. Untuk menghasilkan korelasi antara data rujukan dan spektra inframerah, dua model linear iaitu *Autoregressive with Exogenous* (ARX) dan *Autoregressive Moving Average Exogenous* (ARMAX) digunakan manakala gabungan ARX dan ARMAX bersama *Artificial Neural Network* (ANN) digunakan sebagai model tidak linear. Model tidak teratur dan teratur bagi kedua-dua ARX dan ARMAX menunjukkan keputusan kurang memberangsangkan di mana ARX tidak teratur adalah pada 24.82%, ARX teratur pada 36.40%, ARMAX tidak teratur pada 53.89%, dan ARMAX teratur pada 78.57%. Keputusan dari ARX dan ARMAX teratur kemudian diguna dan digabungkan bersama model ANN. Keputusan ARMAX-ANN menunjukkan peningkatan memberangsangkan pada 89.45%. Analisa Clarke Error Grid (CEG) digunakan sabagai kaedah untuk mengesahkan sistem terbaru dengan kaedah rujukan yang terdahulu digunakan. Analisa CEG didapati menunjukkan taburan sampel terdapat pada kawasan A dan kawasan B di mana kawasan A dalam 20% dari sensor rujukan dan kawasan B di luar 20% tetapi tidak ke arah rawatan yang tidak sesuai. Mengikut keputusan yang diperolehi, dapat disimpulkan bahawa model tidak linear ARMAX-ANN terbukti berpotensi sebagai kaedah untuk meramal tahap glukosa dalam darah dan kajian pada masa hadapan boleh dijalankan bagi meningkatkan ketepatan sistem.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATION

ANN	-	Artificial Neural Network
ARMAX	-	Autoregressive Moving Average Exogenous
ARMAX - ANN	-	Autoregressive Moving Average Exogenous – Artificial Neural Network
ARX	-	Autoregressive with Exogenous
C	-	Carbon
CEG	-	Clarke Error Grid
DM	-	Diabetes Mellitus
DM Type I	-	Diabetes Mellitus Type I
DM Type II	-	Diabetes Mellitus Type II
DO	-	Derivative Order
FBG	-	Fasting Blood Glucose
FDA	-	The Food and Drug Administration
FFT	-	Fast Fourier Transform
FL	-	Filter Length
FTIRs	-	Fourier Transform Infrared spectroscopes
GA	-	Genetic Algorithm
GBP	-	Glucose Binding Protein
GDM	-	Gestational Diabetes Mellitus
GP	-	Genetic Programming
H	-	Hydrogen
	-	Hemoglobin
	-	Glycated Hemoglobin
HDL	-	High-Density Lipoprotein
HUSM	-	Hospital Universiti Sains Malaysia
iPLS	-	Interval Partial Least Square
ISO	-	International Standardization of Organization
KS	-	Kennard-Stone
LED	-	Light Emitting Diode
LM	-	Levenberg - Marquardt

MARE	-	Mean Absolute Relative Error
MIR	-	Mid Infrared
MLPNN	-	Multilayer Perceptron Neural Network
MSC	-	Multiplicative Scatter Correction
MWPLS	-	Moving Window Partial Least Square
Ni-NTA	-	Nickel-Nitrilotriacetic Acid
NIR	-	Near Infrared
NIR-CGM	-	NIR-Continuous Glucose Monitoring
NIRs	-	Near Infrared Spectroscopy
O	-	Oxygen
OGT	-	Oral Glucose Tolerance
OLS	-	Orthogonal Least Square
OPD	-	Outpatient Department
PBS	-	Physiological Buffer Solution
PCA	-	Principle Component Analysis
PCCA	-	Polymerized *Crystalline Colloidal Arrays*
PLS	-	Partial Least Square
PLSR	-	Partial Least Square Regression
PO	-	Polynomial Order
PRESS	-	Predicted Residuals Error Sums of Squares
PSO	-	Particle Swarm Optimization
QCL	-	Quantum Cascade Laser
RMSECV	-	Root Mean Square Error of Cross Validation
RMSEP	-	Root Mean Square Error of Prediction
ROC	-	Receiver Operating Characteristics
SG	-	Savitzky - Golay
SI	-	System Identification
SPA	-	Successive Projections Algorithm
SPSS	-	Statistical Package for the Social Sciences
UTM	-	Universiti Teknologi Malaysia
VPBF	-	Volterra Polynomial Basis Function
WT	-	Wavelet Transform
ANN	-	Artificial Neural Network
GA	-	Genetic Algorithm

PSO	-	Particle Swarm Optimization
MTS	-	Mahalanobis Taguchi System
MD	-	Mahalanobis Distance
TM	-	Taguchi Method
UTM	-	Universiti Teknologi Malaysia
XML	-	Extensible Markup Language
ANN	-	Artificial Neural Network
GA	-	Genetic Algorithm
PSO	-	Particle Swarm Optimization

LIST OF SYMBOLS

	-	Stretching Vibration
	-	Bending Vibration
s	-	Symmetric
as	-	Asymmetric
	-	Correlation of Determination
R	-	Correlation of Coefficient
	-	Binding Constant
V	-	Voltage
C_i	-	Convolution Coefficient
t	-	Time
	-	System Unit Impulse Response
	-	Filters of Finite Order
	-	Function of Parameter Vector
	-	Parameter Vector
	-	White Noise
	-	Estimated Parameter
	-	Input Lags
	-	Output Lags
θ	-	Parameter Vector
	-	Total Number of Regressor
d	-	Number of Estimated Parameters
N	-	Number of Value in Estimation Dataset
Δ	-	Weight

LIST OF APPENDICES

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes Mellitus (DM) or commonly referred to as diabetes, is a chronic disease that occur when the body are not able to properly utilize the glucose content in blood [1], over a prolong period of time and occurred either when the pancreas does not produce enough insulin or when the body cannot effectively utilize natural insulin. Insulin in human is a hormone that regulates blood glucose [2]. The World Health Organization (WHO) stated that the number of people with diabetes rose from 108 million in 1980 to 422 million in 2014. The prevalence of this disease has been rising rapidly especially in low and middle-income countries, compared to the high-income countries. The organization estimated in 2019 that 1.5 million deaths were directly caused by diabetes and another 2.2 million deaths were attributable to high blood glucose in 2012 [2].

Three common types of diabetes are Diabetes Mellitus Type I (Type I DM), Diabetes Mellitus Type II (Type II DM) and Gestational Diabetes Mellitus (GDM) [3]. Type I DM is developed in the early age of an individual where natural insulin is not produced in the body and this condition usually occurs since birth. This type of DM is an insulin-dependent diabetes, categorized as a chronic condition which is caused by autoimmune reaction. Once the symptom appears, it could lead to severe condition [4]. Guidelines published by the Ministry of Health (MOH), Malaysia suggest a Self-Monitoring Blood Glucose (SMBG) test as frequent as four to six times per day where the regularity depends on an individual condition [5].

Meanwhile, Type II DM happens when the natural insulin does not work or is not well-produced, which commonly occurs among the elderlies. The cells do not respond well to the natural insulin, and this condition is known as insulin-resistance

[6]. In general, Type II DM is more common among diabetic patients, with risk of complications as severe as Type I DM. Thus, it requires a proper management. The SMBG test for the patients with Type II DM is depending on an individual condition. Pre-diabetes is defined as a stage where symptoms of diabetes begin to emerge and yield warning sign to the individual to take precautions, avoiding the occurrence of Type II DM. The glucose level at this stage is higher than normal, but not high enough to be considered as diabetic. Early precautions could prevent progression towards Type II DM.

The third type of diabetes, i.e. GDM, occurs during pregnancy. In gestational diabetes, a pregnant woman without diabetes develops high blood glucose levels which upsurge to abnormal level. This condition is caused by reaction of pregnancy hormone. However, the glucose level will subside after labour. A proper management for GDM is essential as the disease is associated with risk to the woman and the developing fetus as complications that can arise such as pre-eclampsia, major birth defects, premature birth or stillbirth. The screening of GDM is based on risk factors like family history and previous pregnancy history. The guidelines published by MOH suggest the implementation of SMBG and the frequency should be individualised based on the mode of treatment and glycaemic control of patients [7].

Statistics reported by MOH through National Diabetes Registry Report (NDR) indicate that there were more than 1.6 million diabetics recorded by the end of 2019. From this number, 99.29% were patients who suffered from Type II DM, 0.62% suffered from Type I DM and 0.09% suffered from other types of DM [8]. The statistics also show that 42.9% were males and 57.1% females and from this, Malay ethnicity contributed 59.15%, Chinese with 19.62%, Indian with 13.17% and the remaining 8.05% represented other minor ethnicities. The NDR reports on the statistics of complication and co-morbidities that occurred on diabetic patients indicate that hypertension, dyslipidaemia, retinopathy, ischaemic heart disease, cerebrovascular disease, diabetic foot ulcer, amputation and erectile dysfunction are among the highest complications experienced by correspondents [8]. The complication rate shows an increment over the years, thus suggesting the need for better glucose management by the patients.

The management of the disease is unlike other chronic diseases, where it is managed mostly by patients, with the help from medical practitioners. Thus, the patients are responsible in managing their glucose levels and need to be equipped with knowledge and tools that are comfortable to be operated. The SMBG is widely agreeable as a method in clinical practice guidelines and should be easily accessible to patients as part of their diabetes management. Real-time data of a patient's glucose level reflects the influence of dietary and physical activity, thus helping in understanding the impact of lifestyle on glycaemic control [9].

It is important for the glucose level in blood to stay within healthy range and healthy people are encouraged to perform the glucose level test in order to maintain them and to identify any abnormalities presence. The glucometer is a standard clinical practice to observe glucose level at one particular time, typically used as a screening tool. On the other hand, a standard diagnosis of diabetes is performed using H_bA1_c test, a standard clinical test to determine the average glucose level in a blood sample for a period of three to six months [10], [11]. The H_bA1_c test typically performed post to the glucometer test, if the abnormality in glucose level of a person's blood is identified. The other method used is oral tolerance test (OTT) that is commonly conducted on pregnant women to discover GDM [7].

The established glucose level tests in clinical practice are invasive tests, where a certain amount of blood is drawn from patients, to be sampled using an analyser machine. Even though there is enormous research on the development of non-invasive technique, the implementation and commercialization of this technique is far from reality. The following Table 1.1 shows glucose range for classes of diabetes, pre-diabetes and normal according to the different glucose tests.

Table 1.1 The glucose range for diabetes, pre-diabetes and normal range for different type of glucose test.

Stages	H_bA1_c	Fasting Test (mmol/L)	Oral Tolerance Test (mmol/L)
Diabetes	≥ 6.5	≥ 7.0	≥ 11.0
Pre-diabetes	5.7 – 6.4	5.4 – 6.9	7.7 – 10.9
Normal	~ 5.0	< 5.4	< 7.7

Near-infrared spectroscopy (NIRs) technology is proven to be a reliable non-invasive technique used in various fields and biomedical is among them [12]–[20]. Wavelength range of NIR could provide various information for numerous types of experimental subjects, thus the NIR application has generated interest of many researchers. The ability of NIR in identifying substances such as carbon, oxygen and hydrogen has further strengthened the opinion of NIR application in determining glucose level in blood. Some studies show that the correlation of glucometer reading and sensory attributes to be unsatisfactory with more that 20% - 30% error [21], [22]. Improvement on the correlation of these characteristics is required and by implementing non-linear models such as neural network, the validity of predictive system could be increased.

1.2 Problem Statement

The statistics of the diabetic patients show an increment over the years, and according to NDR, the total number of diabetic patients enrolled in the registry as at the end of 2019 were more than 1.6 million patients. However, this is contrary to the survey that was also made by MOH through National Health and Morbidity Survey 2019 [23] indicating about 3.9 million people aged 18 and above suffered from diabetes. This number shows that nearly one of five Malaysian adults has diabetes and may also suffer from other complications. This survey also discovered increment in percentage of individuals who are diagnosed with diabetes and people who are not aware that they have the disease. The difference in numbers from both reports suggests that besides patients who are getting treatments from government medical care, about twice the number of individuals either receiving treatment from private practice or solely ignoring the fact that they are suffering from the disease. There are numerous qualitative studies investigating the SMBG practice among the patients, and these studies show low utilization of the practice [24]–[27].

The low utilization of SMBG does not only occur in Malaysia, but also in advanced countries like Australia and Korea. The main factors discovered by these studies that contributed to this circumstance are fear of testing and pain, cost of the glucometer strips and lack of awareness on the importance of SMBG [28], [29]. In routine clinical practices, blood glucose test is performed through a quick prick of needle on finger and the blood is tested using glucometer. In this conventional method, for close monitoring of severe diabetic patients, the glucose level needs to be tested several times per day or per week, depending on individual needs [5], [7]. According to the previous studies conducted, it is not surprising that this practice is not favoured since pricking fingers multiple times a day can be tiresome, painful and impacting the mental health of patients, hence this becomes a dreadful ordeal to many diabetics. On top of the dreadful experience, besides causing some calluses and forming sensitive fingers, the conventional technique is not preferred by patients with dexterity limitation, algophobia or anxiety problems. If coerced, this can lead to a situation of total avoidance or negligence by these patients, and therefore, proper treatment is not received [30], [31].

Resulting from this situation, further experiments of the non-invasive techniques were explored such as ultrasonic sensor implementation [32], multisensory systems [33]–[36], and the absorbance of transmittance photometry [37], [38]. Other interesting approaches include bio-impedance [39]–[41], voltage intensity [42] and thermography [43]. These approaches show promising results, but never been developed as clinical practice. Thus, the search for a novel, fast and reliable test for non-invasive routine clinical application continues.

The implementation of near infrared (NIR) as a non-invasive medium in estimating the glucose level has received numerous attentions. Due to the characteristic of NIR that offers distinct advantage in speed while identifying and quantifying degradation products, its application in various fields is quite extensive, in addition to the fact that the technique is a non-destructive technique [44]. Although numerous researches conducted related to investigating the ability of NIR for glucose level detection, researchers tend to use very small sample size [45], [46] and some of the studies were only focusing on healthy subjects, or only on diabetic patients [47]. Certain number of researches focussed on NIR ability in estimating glucose concentration on glucose solution and cell specimens [48], [49] without further implementation on human subjects. This research attempts to overcome the limitation of previous studies. The subjects used in this research include diabetic patients and healthy persons, with different groups of age, races and gender.

A progression was made by researchers in order to analyse the data from NIR spectroscopy (NIRs) using various analysing models. The various approaches executed use either linear models or non-linear models. The application of linear and non-linear models generally depends on the form of NIR data. Linear regression model follows a very particular form while the non-linear model can fit an enormous variety of information. The subjects of experiment influence the result of the models; thus selection of models is a crucial part of the research. For instance, the NIR data from subjects with single or a few information may require linear model in data analysing process.

However, the data that tend to offer overlapped information may require complicated analysing compared to a simple singular information. In this particular research, the information that could be extracted from human skin possibly contains various information, not limited to glucose concentration in blood. The human skin contains numerous substances and the penetration of NIRs that surpasses many layers of skin may contribute to complex analysing process. So, the pre-processing phase is essential to determine beneficial information to be analysed. In this research, the implementation of near-infrared spectrum in detecting the substance of glucose in blood and predicting the glucose level by using both the linear and non-linear system identification models will be executed. The outcome in terms of accuracy and performance from both linear and non-linear models will be calculated and compared. The combination of appropriate pre-processing of NIR information and the non-linear models, the accuracy of the glucose level estimation can possibly be enhanced for optimum result. Hence, this provides a harmless and highly coveted non-invasive glucose level test technique for clinical use.

1.3 Objectives of study

The main objective of this study is to develop a non-invasive method in measuring the glucose level in blood using NIR spectrometer. In addition to the main objective, the other objectives are as below:

(a) To investigate the practicality of NIR wavelength and a suitable data range as input of the system in determining the glucose level in blood.

(b) To develop algorithm in analysing the blood glucose level using NIR spectrum signals range

(c) To evaluate and validate the effectiveness of the implemented linear and non-linear models in the system

1.4 Scope

The scope of this project comprises designing of linear and non-linear models using NIR spectral data in estimating glucose level in blood. The data acquisition process in this study is divided into two, which are obtained from the near-infrared spectrometer (spectral data) and data obtained from the conventional glucometer (reference data). These data were obtained from Hospital Universiti Sains Malaysia (HUSM) in Kubang Kerian and Universiti Teknologi Malaysia (UTM). The data acquisition process is divided into three groups: individuals diagnosed with diabetes who are currently undergoing treatment at HUSM, individuals without diabetes who had their medical check-up within one year, and individuals with no prior history of diabetes and never undergone medical check-up for the last two years. The system is for a single sample monitoring (one-at-a time) particularly, with no continuous monitoring system.

The diffuse reflectance of the NIR measuring mode is used to measure the wavelength depending on the absorption and scattering characteristics. Spectroscopy measured the data from 200 nm until 3500 nm. The contents of water and glucose substances in blood are analysed as the main factors in determining the glucose level. To analyse the obtained data, linear and non-linear models of system identification (SI) and combination artificial neural network (ANN) were used and the performances were compared. To validate the results obtained, Clarke Error Grid Analysis (CEG), an established method in medical field was used to compare the newly developed system with the reference value.

1.5 Thesis Outline

In chapter 1, introduction of the project and overview of the whole research are presented. The chapter starts by introducing the problem background of the project, continuing with problem statement, and objectives on why conducting the research, followed by scope of the research. This chapter also states the contribution of this study.

Chapter 2 focuses on reviewing the previous and existing work or researches made on the field of diabetes disease, concerning with the development of invasive and non-invasive techniques to determine glucose level in blood. This chapter elaborates more on the efforts made previously in developing non-invasive technique in glucose determination using an in-vitro, in-vivo or both methods in experimental process. This chapter also describes and enlightens the theoretical aspects of pre-processing technique implemented on the data set.

In Chapter 3, the methodology or flow of the research is elaborated. Beginning with explanation of the data collection stage of subjects, continuing with the pre-processing of the data set process. This chapter explains more on the implementation of system identification (SI) and artificial neural network (ANN) models, both linear and non-linear models and comparison for both types of methods and their usage. The next stage after the model implementation is model validation. This chapter gives details on the Clarke Error Grid (CEG) analysis method that is effectively used in the medical field as a reference in diabetes related devices.

Chapter 4 presents the results for each process run and method used from the very first stage of research. It also presents the final accuracy result of each linear and non-linear model implemented in the research. In addition, this chapter discusses the performance of models based on accuracy result of the estimation and validation process.

Chapter 5 concludes the overall performance of research with some recommended future works. This provides a better idea on how the system can help for further improvements. This chapter presents the advantages, disadvantages, limitations and affecting factors that occur during research.

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