IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Comparative Analysis Of Invasive And Non-Invasive Methods For Blood Sugar Measurement

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ABSTRACT: A study was conducted to investigate the prevalence of diabetes among individuals in countries such as India and abroad. The research focused on examining the traditional approach to measuring blood sugar levels. In order to address the challenges and complexities associated with this process, a novel non-invasive method for blood sugar measurement is suggested in this research paper. However, the development of reliable non-invasive blood sugar measurement devices faces significant challenges. Interference from other substances in the body, variability in skin properties, and the need for calibration against traditional blood tests are key hurdles that must be overcome. Additionally, the accuracy and reliability of non-invasive methods must be rigorously validated against invasive techniques to ensure clinical utility and regulatory approval. This review provides an overview of current non-invasive and invasive methods of blood sugar measurement, highlighting their respective advantages, limitations, and future prospects. While non-invasive techniques hold great promise for improving patient care and quality of life.

Key Words: Non-invasive, Invasive, Diabetes, Sensors

1. INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease, of inadequate control of blood glucose levels. Diabetes is characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves.[1][2] The body's primary source of energy is glucose which comes from the food that we eat. The body breaks down most of that food into glucose and releases it into the bloodstream. When the blood glucose goes up, it signals the pancreas to release insulin. Insulin is considered to be the main anabolic hormone of the body produced by beta cells of the pancreatic islets encoded in humans by the insulin (*INS)* gene.

In case a body cannot produce enough insulin or cannot consume the insulin produced effectively, type 1 diabetes (T1DM) and type 2 diabetes (T2DM) occur respectively [3-6]. The average concentration of fasting blood glucose (FBG) levels must be 70 mmol-100 mg/dl (3.9-5.6 mmol/L) and two hours after having a meal, the blood glucose (BG) level must be <140 mg/dl (7.8mmol/L). An individual with low fasting blood glucose concentration or increased fasting blood glucose concentration than the normal range of blood glucose is reflected as Hyperglycemia and Hypoglycemia [7].

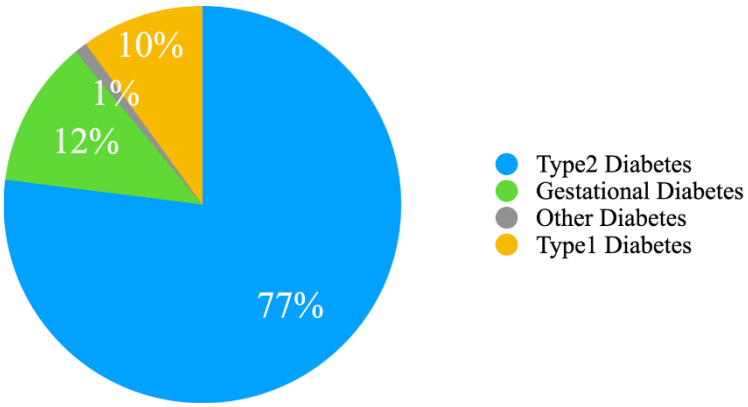

Figure 1. Types of Diabetes

According to the estimates released by the Lancets medical journal, more than 1.3 billion people worldwide will have diabetes at the half-century mark, up from 529 million in 2021. The vast majority of patients will have type 2 diabetes. According to the World Health Organization (WHO), currently there are around 450 million cases of diabetes in the world, and the number could potentially reach 700 million by 2045, with an increase to 39.7 million by 2030 and 60.6 million in 2060 in the United States alone. The focus on preventing diabetes has increased in many countries, particularly in developed nations, due to the substantial number of undiagnosed individuals and those at high risk. This has led to diabetes diagnosis and treatment becoming an area of great practical importance and economic advantage.

2. LITERATURE REVIEW

This literature review aims to provide an overview of various techniques used for blood sugar measurement, both invasive and non-invasive, highlighting their principles, advantages, limitations, and potential applications.

The classification of glucose measurement primarily depends on the degree of invasiveness exhibited by the sensing devices, which are typically categorized as either invasive (devices that are implanted or invade the body to extract a blood sample), minimally invasive (devices that non-painfully invade a small portion of the body, such as the skin, to collect a minimal sample like sweat, tears, saliva), or non-invasive devices (devices that do not invade the body).[8]

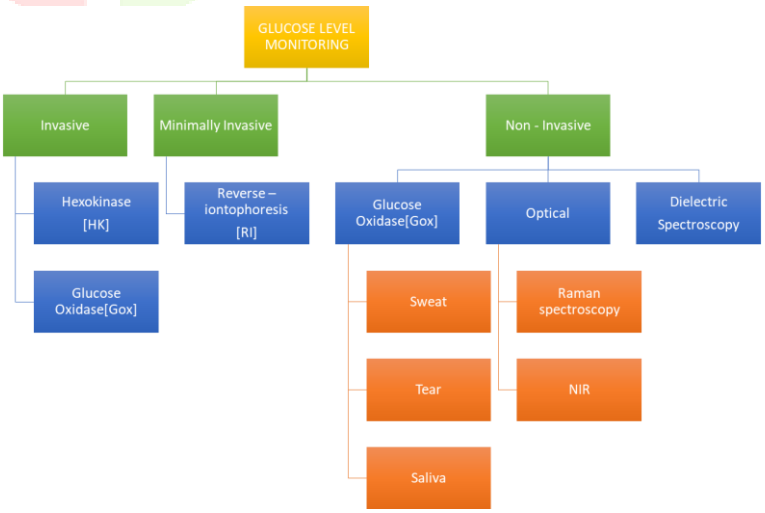

Figure 2. Overview of Glucose Monitoring Techniques

2.1. Invasive Blood Glucose Monitoring

Currently, the prevailing practice involves the utilization of invasive methods to measure blood glucose levels. The invasive methods require collecting blood from diabetic patients. However, the amount of blood collected relies on the monitoring technique. the clinical laboratory tests (wet chemistry) require 1-3 ml of blood sample to analyse the glucose levels, utilizing hexokinase method as a reference standard to diagnose diabetes.[9] Within hospital settings, individuals are required to provide a fasting blood sample in the morning, which is then analysed to determine the concentration of glucose. The automatic biochemical analyser provides precise measurements, making it a valuable tool for diagnosing diabetes.

However, its limitations, such as the time-consuming process, lengthy detection time, and the need for a significant amount of venous blood extraction, make it unsuitable for continuous monitoring of diabetic patients. The act of monitoring blood glucose levels, known as self-monitoring of blood glucose (SMBG), shown in the figure 3, involves checking the concentration of glucose in the blood at a particular moment. This is typically accomplished using a personal electronic glucose meter at home. However, glucose meters commonly found in households utilize glucose oxidase biosensors and require a disposable strip of paper to collect a blood sample from the fingertip. The concentration of blood glucose is then determined by measuring the chemical reaction current of the strip.[10] These devices offer notable benefits such as ease of use, simplicity, and cost-effectiveness.

Figure 3. Self-monitoring of blood glucose (SMBG)

2.1.1. Filter Photometry

The functioning of a biochemistry analyser is based on the principle of filter photometry, which involves the utilization of a light source, typically a halogen lamp. The light emitted from the lamp is directed through a convex lens to ensure that the light rays converge into a singular beam. This concentrated beam of light is then transmitted through the sample, which is placed within the flow cell of the chemistry analyser. The light energy is selectively absorbed by the sample, while the remaining light is filtered through an interference filter, known as a colour filter screen, to convert it into a narrow bandwidth or single wavelength. Once this filtered light reaches the photodetector, it is transformed into electrical energy that can be utilized by the microprocessor.

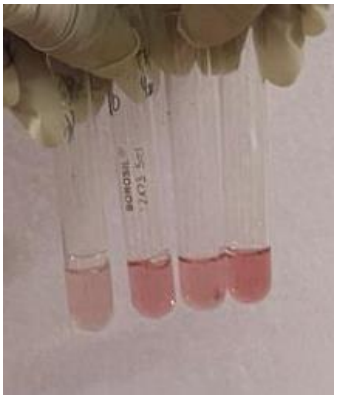

Figure 4. Samples for Diabetes

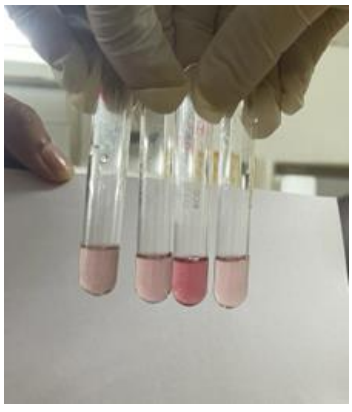

Figure 5. Samples for Cholesterol

2.2. Non-Invasive Blood Glucose Monitoring

Non-invasive blood glucose monitoring, refers to the detection of human blood glucose without causing damage to human tissues. The inconvenience of invasive glucose methods has invited the attention of scientists to develop minimally invasive and non- invasive techniques for continuous glucose monitoring (CGM). Figure 6 shows continuous glucose monitoring (CGM). Cells are surrounded by interstitial fluid (ISF) which provides them with nutrients such as glucose, amino acids, hormones, salts, potassium, calcium, magnesium, enzymes and coenzyme. [11] Further glucose can noninvasively be measured in other bio-fluids like saliva, tears, sweat. Raman spectroscopy, Near-infra-red spectroscopy (NIRS), polarised optical rotation, ultraviolet-visible (UV-VIS) spectrophotometry are some of the non-invasive glucose measurement methods. Monitoring glucose in alternative bio-fluids reduces the pain and inconvenience to patients.[9]

Numerous research studies have consistently demonstrated that there is a time-lag phenomenon between the glucose levels in interstitial fluid (ISF) and blood glucose. In other words, the change in blood glucose is reflected in ISF with a certain delay, typically ranging from approximately 4 to 10 minutes.[12] Moreover, the lag and low glucose levels of body fluids may decrease the accuracy of CGM and other alternative methods.

Figure 6. Continuous glucose monitoring (CGM)

2.2.1. Near-infrared spectroscopy (NIRS)

Biochemicals in fluids and human tissues have various light absorption abilities regarding wavelength, frequency and energy level. Penetrating the body may be destructive, which makes the extraction of BG information challenging. The infra-red spectrum (700 nm to 1 mm) has relatively ideal non-destructive detection spectra. The principle of NIR glucose monitoring is based on the transmission, reflection, and interaction of components with the NIR light. Water is the most abundant substance in plasma (up to 90%, having two IR absorption peaks of 1350-1520 nm and 1790-2000 mm, which are in the range of NIR. In comparison, only 0.07-0.1% of plasma is made of glucose. In order to minimise water interference, NIR short wavelengths are more effective. However, water is not the only interfering substance in glucose monitoring. Besides, the biofluids such as saliva samples, have also been studied through non-invasive NIR glucose measurement. Therefore, the range of NIR needs, to be chosen with reference, to glucose NIR absorption, Although NIR glucose sensors are non-invasive, cost-efficient, accessible, and skin pigmentation free, highly scattering levels low glucose concentration, and tissue complexity makes this method unreliable as other non-invasive methods.

3. METHODOLOGY

NON-INVASIVE METHOD: Non-invasive methods utilize various technologies such as optical spectroscopy, electrochemical sensors, microneedle arrays, thermal techniques, ultrasound, and spectroscopy to measure blood glucose levels without the need for blood samples. These techniques offer the potential for continuous monitoring, reducing patient discomfort and improving compliance with monitoring regimens.

The method works by directing a light beam onto the surface of the skin, which effectively penetrates beneath the skin's surface and interacts with the glucose molecules present in the bloodstream. These glucose molecules readily absorb a portion of the light, leading to a change in the light's wavelength. The modified wavelength is then captured and analysed by the photosensor, allowing for the determination of the individual's blood glucose level.

The block diagram of the proposed methodology is shown in Figure 5.

[A] BLOCK DIAGRAM

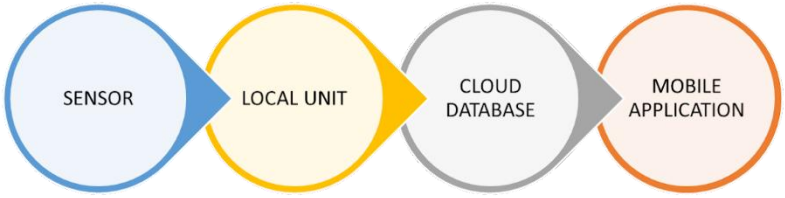

Figure 5. Block Diagram

[B] ENCLOSURE DESIGN

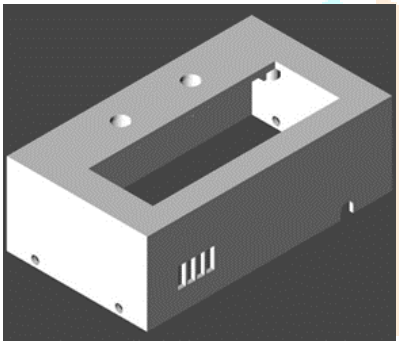

Figure 6. Casing

Dimensions: Length 95mm

Width 54mm

Height 32mm

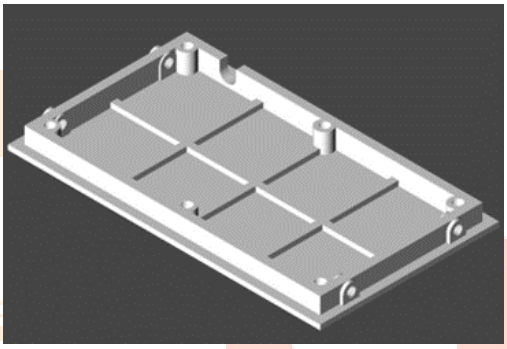

Figure 7. Base Plate

Dimensions: Length 95mm

Width 54mm

6 mounting points evenly distributed

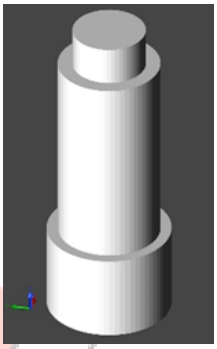

Figure 8. Button

For the casing, ventilation is provided and provision for adding buttons is given. The material used is PLA. While the material used for the base plate is ABS.

B. 1. PLA: Polylactic acid, also known as PLA, is a thermoplastic monomer derived from renewable, organic sources such as corn starch or sugar cane. The sugar in these renewable materials are fermented and turned into lactic acid, which is then made into polylactic acid, or PLA. The material properties of PLA makes it suitable for the manufacture of plastic film, bottles and biodegradable medical devices, including screws, pins, plates and rods that are designed to biodegrade within 6 to 12 months). PLA can be used as a shrink-wrap material since it constricts under heat. This ease of melting also makes polylactic acid suitable for 3D printing applications.[13]

B. 2. ABS: ABS or Acrylonitrile butadiene styrene is a common thermoplastic polymer. ABS is made up of three monomers: acrylonitrile, butadiene, and styrene.[14]. ABS is typically used for injection moulding applications. This engineering plastic is popular due to its low production cost and the ease with which the material is machined by plastic manufacturers. Better yet, its natural benefits of affordability and machinability do not hinder the ABS material's desired properties:

- Excellent High and Low Temperature Performance
- Great Electrical Insulation Properties
- Impact Resistance
- Chemical Resistance
- Structural Strength and Stiffness

- Easy to Paint and Glue [15]

[C] SENSORS

C. 1. MAX30102 is a sensor that combines a pulse oximeter and a heart rate monitor. MAX30102 includes internal LEDs, photodetectors, optical elements, and low-noise electronics with ambient light rejection. It's an optical sensor that measures the absorbance of pulsating blood through a photodetector after emitting two wavelengths of light from two LEDs - a red and an infrared one. This particular LED colour combination is designed to allow data to be read with the tip of one's finger [16-21].

C. 1.1. WORKING PRINCIPLE: The MAX30102 works by shining both lights onto the finger or earlobe (or essentially anywhere where the skin isn't too thick, so both lights can easily penetrate the tissue) and measuring the amount of reflected light using a photodetector. This method of pulse detection through light is called Photoplethysmogram [22-26].

C. 1.2. SPECIFICATIONS:

- LED peak wavelength: 660nm/880nm
- LED power supply voltage: 3.3~5V
- -40°C to +85°C operating temperature range
- Detection signal type: light reflection signal (PPG)
- Output signal interface: I2C interface
- Communication interface voltage: 1.8~3.3V~5V (optional)
- Board reserved assembly hole size: 0.5 x 8.5mm
- Tiny 5.6mm x 3.3mm x 1.55mm 14-pin optical module
- Integrated cover glass for optimal, robust performance
- Low-power heart rate monitor (<1mW)
- Ultra-low shutdown current (0.7µA Type.)
- High SNR [27]

C. 2. MLX90614 is a contactless temperature sensor used to measure temperature without touching the target object using Infrared Rays. It is built from 2 chips developed and manufactured by Melexis: The first is the MLX81101, an infrared thermopile detector responsible for detecting thermal radiation and the second chip, the MLX90302, is an application-specific signal conditioning device designed specifically to process the output of the IR sensor. The MLX90614 infrared temperature sensor has 4 pins which are VIN, GND, SCL and SDA. The VIN and GND are connected to the 5V power supply and ground of the circuit respectively. The SDA is the Serial Data Pin and SCL is the Serial Clock pin which are used for the I2C communication.[28]

C. 2.1. WORKING PRINCIPLE: MLX90614 works by transforming the infrared radiation signal collected from objects and bodies into electrical signals, sends the electrical signal into converter after noise amplification processing by amplifier, then the electrical signal is converted to digital signals and store the processed signals into the internal memory, finally sending the signals into the SCM control system for further processing.[28]

C. 2.2. SPECIFICATIONS:

- Operating Voltage: 3.6V to 5V
- Supply Current: 1.5mA
- Object Temperature Range: -70° C to 382.2°C
- Ambient Temperature Range: -40° C to 125°C
- Accuracy: 0.5°C
- Distance between object and sensor: 2cm-5cm (approx.)

4. CONCLUSION

The utilization of non-invasive techniques is advantageous and should be prioritized to prevent testing delays and complications associated with invasive procedures. This approach is suitable for both initial testing and ongoing monitoring purposes.

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