

FreeStyle® Libre™ Flash Glucose Monitoring System: A Novel Diagnostic Technique for Monitoring Diabetes

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ABSTRACT

To successfully manage diabetes, a monitoring system is needed to consistently check glucose levels. Frequent capillary blood glucose tests or self-monitoring of blood glucose (SMBG) is the traditional and one of the most effective ways to keep track of individual's blood glucose levels. With Continuous Glucose Monitoring (CGM), more detail picture of glucose levels can be obtained, which can prompt better treatment choices and better glucose control. The Abbott FreeStyle® Libre™ has come as an entirely new concept in glucose monitoring by providing much greater data than blood glucose testing. The data from the FreeStyle® Libre™ system provides a visual snapshot of a person's glucose fluctuations during a typical day. This review highlights the principle mechanism of action of FreeStyle® Libre™ system, advantages, limitations and it's amazing applications in the management of diabetes.

Key words: Diabetes, CGM, Freesyle® libre™

INTRODUCTION

Diabetes is a group of metabolic disorders that characterized by hyperglycemia due to defects in insulin secretion, insulin action, or both.¹ Diabetes is quick picking up the status of a potential epidemic in India with in excess of 62 million diabetic people as of now determined to have the diabetes.^{2,3} In 2000, India (31.7 million) beat the world with the maximum number of individuals with diabetes mellitus followed by China (20.8 million) and United States (17.7 million) in second and third place respectively. Wild et al suggested that the prevalence of diabetes anticipated to twofold all around from 171 million in 2000 to 366 million in 2030 with a most extreme increment in India.³

It is anticipated that by 2030 diabetes mellitus may harrow up to 79.4 million people in India, while China (42.3 million) and the United States (30.3 million) will likewise observe critical increments in those influenced by the disease.^{4,5}

The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels.¹ Treating diabetes needs constant monitoring and maintenance which poses a major burden for the afflicted, their communities and their families. Moreover, increasing rates of diabetes is taxing on national economies and healthcare systems. Despite the fact that the present testing strategies are entrenched, regardless they posture numerous

issues for medicinal experts and patients everywhere throughout the world. In a few societies, there might be societal strictures or taboos concerning the illustration of blood that makes it hard to secure patient compliance. Blood tests are also unstable and require refrigeration. In developing countries this can be a major issue, especially in rural regions where refrigeration and power supply won't be promptly accessible.⁶ A CGM system provides continuous insight into glucose levels throughout the day and night. The device displays information about glucose direction and rate of change providing users additional information to help with their diabetes management.⁷ The FreeStyle® Libre™ Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons with diabetes.⁸

CONTINUOUS GLUCOSE MONITORING (CGM)

Continuous glucose monitoring (CGM) provides information unattainable by intermittent capillary blood glucose, including immediate constant show of glucose level and rate of progress of glucose, cautions and alerts for real or looming hypo-and hyperglycemia, "day in and day out"

scope, and the capacity to portray glycemic fluctuation. CGM is associated with betterment of hemoglobin A1c (HbA1c) level and reduces the risk of hypoglycemia, depending upon the standard attributes of the patient populace.⁹

Continuous glucose monitoring (CGM) technology has the potential to revolutionize diabetes care in the near future because of the real-time feedback it provides about therapeutic interventions and variations in lifestyle or dietary intake. CGM represents a significant advance because it provides:

- Real-time information about current blood glucose (or, more accurately, interstitial fluid glucose) concentrations.
- Short-term feedback about the viability of diabetes mediations (eg insulin administration).
- Warnings when blood glucose concentrations become dangerously high or low.¹⁰

Beers et al evaluated the impact of continuous glucose monitoring (CGM) over glycemia and anticipation of extreme hypoglycemia contrasted and self-monitoring of blood glucose (SMBG) in high chance populace. This study supports the concept of utilizing CGM in the high - risk population.¹¹

R. Chen R compared the daily glycemic profile reflected by continuous versus self-monitoring of blood glucose in women with gestational diabetes mellitus (GDM) in Israel and California. CGM was found to be helpful for monitoring women with GDM and for adjusting diabetes therapy. CGM showed high accuracy to detect high postprandial blood glucose levels and nocturnal hypoglycemic events that may go unrecognized by intermittent blood glucose monitoring. In a study conducted by Boom et al, there were no differences in the numbers of severe hypoglycemic episodes (defined as a blood glucose < 40 mg/dL) in patients managed using continuous (with a subcutaneous monitor) or intermittent glucose monitoring.^{12,13}

Other studies have recently been completed comparing different CGM devices with intermittent sampling and the results should provide more detail regarding the effectiveness of this approach on the quality of glucose control. Importantly, CGM will be shown to have an effect on outcomes only if the monitoring data retrieved from the device are appropriately and frequently used to adjust therapy and the chosen insulin protocol is effective.^{14,15}

DIFFERENCE BETWEEN BGM AND ISF¹⁶

Blood glucose self monitoring	Interstitial fluid glucose monitoring
Measures glucose in the blood	Measures glucose in interstitial fluid of subcutaneous tissue
Finger prick needed for each reading	Simple scan collects data
Drop of blood needed	Small sensor monitors interstitial fluid
Can hurt finger tips	Most people will not feel the sensor being worn.

Each reading present one movement in time.	Continuous monitoring of glucose level by sensor.
Night time testing means waking up	Levels continues to be monitored whilst asleep.
Time consuming	One second scan.
Test “kit” requires: lancet;strips;meter.	Sensor holds 8 hours of data, Reader records 90 days of data.

FreeStyle® Libre™ Flash Glucose Monitoring System: FreeStyle® Libre™ Flash Glucose Monitoring System has two main parts:

A handheld Reader: The Reader is used to get glucose readings from your Sensor. It can store approximately 90-days of glucose history and notes enter about activities, such as taking insulin, eating food, or exercising. This information can help to understand how these activities affect glucose. (Figure:1)

A disposable Sensor

The sensor measures and stores glucose readings when it worn on body. The sensor has a little adaptable tip that is embedded simply under the skin (Figure: 2). The sensor can be worn for up to 14 days. Framework comes in Reader kit and sensor kit. (Figure:3).

Reader Kit: The Reader Kit includes:

- 1 FreeStyle®Libre™ Reader
- 1 USB Cable
- 1 Power Adapter
- User’s Manual

Sensor Kit: The Sensor Kit includes:

- 1 Sensor Pack



Figure-1: A handheld Reader



Figure-2: A disposable Sensor

- 1 Sensor Applicator
- 1 Alcohol wipe
- Product insert¹⁷

FEATURES OF SENSOR

1. Small and easy to wear: About the span of two stacked US quarters, the sensor might be scanned over dress.

2. Painless application: Painless and easy to apply. A very thin filament sits just under the skin to measure interstitial fluid.

3. Precise sensor reading: No finger stick alignments required, and the system has no obstruction with pharmaceuticals containing acetaminophen.

4. Water proof: stays on the body for up to 10 days, and can be worn while swimming, showering, or working out.⁸

FEATURES OF READER

1. Reporting capacity: Stores 90 days of glucose information. Downloading information from the Free style® Libre™ framework to the “Libre View programming” takes into consideration much more detail examination of glucose information.

2. Convenience: Compact, lightweight, and includes a built-in FreeStyle Precision Neo test strip port for blood glucose testing.

3. User-friendly: Has a backlit color touch screen for visibility in the dark.⁸

How does it work?

Interstitial liquid or ISF is basically the intracellular fluid that encompasses the cells and feeds them supplements including glucose. Glucose sensor framework measures glucose in the ISF by embedding a glucose detecting fiber into the subcutaneous tissue which sits just beneath the dermis (top layer) of the skin.

This subcutaneous tissue includes ISF which contains glucose transported from blood vessels (Figure: 4). The glucose levels in the ISF nearly take after blood glucose though with a slight time delay. The delay has been evaluated assessed at in the vicinity of 5 and 10 minutes in different studies and is in this manner far-fetched to affect routine everyday treatment choices. The delay can be more observable when a man's glucose is evolving quickly, for instance after a high

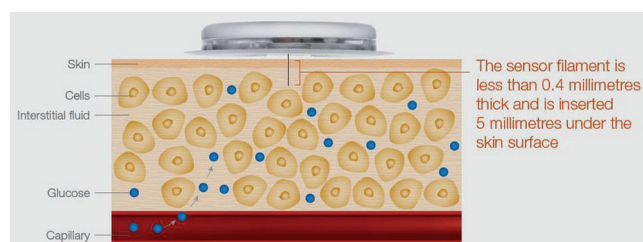


Figure-4: Placement of Glucose sensor over subcutaneous tissue.

glycaemic index meal or during exercise. To adjust for this, gadgets which measures glucose in the ISF utilize complex calculations this can make up for quickly changing glucose levels, resulting in precise glucose estimations for the end user.

The FreeStyle® Libre™ flash glucose monitoring system utilizes a sensor fiber which is embedded 5 millimeters under the skin that precisely measures glucose in the ISF. The FreeStyle® Libre™ sensors are adjusted at the processing plant.

The industrial facility alignment is intended to give sensor glucose results which are more comparable to blood glucose results. However sensor interstitial liquid outcome may not generally be the same as a blood glucose result acquired at a comparative time. Differences in glucose readings between interstitial liquid and capillary blood might be seen amid times of quick change in blood glucose, for example, in the wake of eating, dosing insulin or working out.^{18,19}

Arndis F. et al evaluated the accuracy and treatment experience of the FreeStyle® Libre™ system. 58 adults with type 1 diabetes used FreeStyle® Libre™ for 10–14 days and measured capillary blood glucose levels with the HemoCue blood glucose measurement system at least six times a day simultaneously. He concluded that the FreeStyle® Libre™ system had an overall accuracy that was similar to CGM-systems with high accuracy. The treatment experience was high. The calibration of the FreeStyle Libre system could likely be improved because it had a negative bias compared with HemoCue capillary whole blood.²⁰

By analyzing 20 subjects (8 type 1 diabetes mellitus, 12 type 2 diabetes mellitus) Fokkert MJ et al evaluated the performance of the FreeStyle® Libre™ Flash continuous glucose monitoring (FSL-CGM) system against established central laboratory methods. FSL- CGM sensor estimations (embedded in arm and stomach area) were compared and slender blood glucose outcomes analyzed with statstrip as semi gold standard. It was concluded that the FSL-CGM system can be used as a reasonably suitable adjunct in the management of diabetes, but only when used if inserted in the upper arm.²¹

Bailey T et al evaluated the performance and usability of the FreeStyle® Libre™ Flash glucose monitoring system (Abbott Diabetes Care, Alameda, CA) for interstitial glucose results compared with capillary blood glucose results. Interstitial glucose measurements with the FreeStyle® Libre™ system were found to be accurate compared with capillary BG reference values, with accuracy remaining stable over 14 days of wear and unaffected by patient characteristics.¹⁶



Figure-3: Parts of FreeStyle® Libre™ Flash Glucose Monitoring System kit.

ADVANTAGES

- Decrease the quantity of blood glucose checks during the day.
- Substantially more reasonable CGM choice.
- Provides a diagram to demonstrate to the patterns in glucose readings.
- A little sensor consequently measures and persistently stores glucose readings day and night.
- Freestyle® Libre™ system is intended to be water safe and worn while washing showering, swimming, and working out.
- Glucose readings with a painless 1 second scan even through clothing.²²

PROCEDURE

Application of Sensor

Apply sensors just on the back of upper arm. Keep away from territories with scars, moles, extend checks or protuberances. Select a zone of skin that stays flat during daily activities (no bending or collapsing). Pick a site that is no less than 2.5cm (1 inch) away from an insulin infusion site. To counteract inconvenience or skin aggravation

Clean application site with liquor wipe and allow site to dry before continuing. This enables the sensor to remain joined to body. Open the sensor pack by peeling the cover off totally. Uncover the sensor applicator and put the cover aside. Line up the dim check on the sensor applicator with the dull stamp on the sensor pack. Press immovably down on the sensor applicator until it halts. Lift the sensor applicator out of the sensor pack. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to body. Gently pull the Sensor Applicator away from body. The Sensor should now be attached to skin.

Starting of Sensor

Press the Home Button to turn on the Reader. Hold the reader within 4 cm (1.5 inches) of the Sensor to scan it. This begins Sensor. On the off chance that sounds are turned on, the Reader blares when the Sensor has been effectively initiated. The Sensor can be utilized to check glucose following an hour.

Checking for Glucose

Turn the Reader on by pressing the Home Button or touch Check Glucose from the Home Screen. Hold the Reader within 4 cm (1.5 inches) of your Sensor to scan it. Sensor wirelessly sends glucose readings to the Reader. On the off chance that sounds are turned on, the Reader blares when the Sensor has been effectively scanned. On the off chance that the Sensor isn't effectively scanned within 15 seconds, the Reader shows a prompt to scan the Sensor again. Press Ok to revert back to home screen and press Check Glucose to scan sensor. The Reader displays current glucose reading along with glucose graph and an arrow indicating the direction glucose is going.¹⁷

INDICATIONS

1. Continuous glucose monitoring (CGM)
2. Supplanting blood glucose testing and recognizing patterns and following patterns supporting in

the recognition of episodes of hyperglycemia and hypoglycemia.

3. Encouraging both acute and long term treatment changes in people (age 18 and more seasoned) with diabetes.

CONTRAINDICATIONS

1. System must be evacuated preceding Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment
2. For diagnosis or screening of diabetes.
3. In people less than 18 years of age.
4. In critically ill patients.
5. Pregnancy or persons on dialysis.
6. Person sensitive to the adhesive that keeps the Sensor attached to the skin.
7. Do not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state patients.

DISADVANTAGES

1. No programmed alarm of a hypoglycemic occasion without scanning sensor
2. System consists of small parts that might be unsafe if gulped.
3. During times of quickly evolving glucose (in excess of 2 mg/dL per minute), when interstitial fluid glucose levels as estimated by the sensor may not precisely reflect blood glucose levels.
4. NO alarms or alerts unless patient scan the sensor.
5. Sensor may become loose during intense exercise due to sweat or movement of the sensor.
6. Sensor cannot be reused.²³

FDA APPROVAL, COST AND AVAILABILITY

FreeStyle® Libre™ Flash Glucose Monitoring System is approved by U.S. Food and Drug Administration as first continuous glucose monitoring system that can be used by adult patients to make diabetes treatment decisions without calibration using a blood sample from the fingertip (often referred to as a "fingerstick").²⁴

Abbott's FreeStyle® Libre™ (real time) continuous glucose monitor (CGM) is now available in major pharmacies in the US, including CVS, Walgreens, Walmart, Rite Aid, and Kroger's/Smith's.

FreeStyle® Libre™ is the least costly at Walmart, where each 10-day sensor is \$35.99, and each reader device (one time purchase) is \$69.99. Cost may be differing at individual local pharmacy.²⁵

CONCLUSION

Management of Diabetes requires dynamic participation by the patient. Standard checking of glucose levels is particularly pivotal among patients being treated with insulin. With FreeStyle® Libre™ framework patients can acquire a superior comprehension of the effect of nourishment, exercise and particular drugs on their glucose levels because of accessibility of the information, which is essential in the

day-to-day management of diabetes and for behavioral changes towards improved diabetes control.

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