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CGM Technology Brings Health: A StudyThrough Freestyle Libre Flash Glucose Monitoring System

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Abstract

Diabetes mellitus also called diabetes is an incurable disease in which the body does not produce enough insulin, causing blood sugar (glucose) levels to be abnormally high. Which resulting from an insufficiency of insulin in the body.Continuous Glucose Monitoring (CGM) is an advanced way for people living with diabetes to check glucose readings in real-time or monitor glucose readings over a period of time.FreeStyle Libre was considered as the first ever non-blood calibration **CGM** system by the FDA(US Food and Drug Administration)in 2017.

Keywords

CGM ,Diabetes mellitus ,biosensor, FreeStyle Libre System,Flash Glucose Monitoring

Introduction

In just a few short years, wearable technology has a spike in popularity . wearables have the potential to change our lives and society.These wearables have only one sole purpose,to improve our lives. measuring the physical activity is necessary to evaluate both healthy people and patients in order to plan their needs for wellbeing.There are a number of new and innovative types of wearable technologies, especially in the health care industry .where they're looking to take a step beyond fitness trackers to create health care trackers. These health care trackers helps to monitor blood pressure, vital signs, or blood sugar levels for diabetics and so on.

More than 425 million people around the world have diabetes.Diabetics have to test their blood sugar usually by pricking their finger with a lancet. This can be uncomfortable and painful .A continuous glucose monitor or CGM for short is a small device with glucose sensors that are injected just under the skin (usually into the abdominal wall or arm). The insertion is quick, just likea shot, and is not painful.

Abbreviations

CGM-Continuous Glucose Monitoring FDA(US Food and Drug Administration)

Diabetes mellitus

Glucose is an important source of energy for the cells that make up your muscles and tissues. It's also your brain's main source of fuel.In a normal case when we eat a carbohydrate, our body turns them in to a sugar called glucose and sends that to our bloodstream. Our pancreas releases insulin, a hormone that helps move glucose from our blood into the cells.

But when we have diabetes and don't get treatment, our pancreas doesn't make enough insulin or pancreas makes insulin but our body's cells don't respond to it and can't use it as it normally should. If glucose can't get into our body's cells, it stays in your bloodstream and our blood glucose level rises. This condition usually called

high blood sugar, can cause health problemsthat may be serious or even life-threatening.

There's no cure for diabetes. But with treatment and lifestyle changes, can live a long, healthy life.

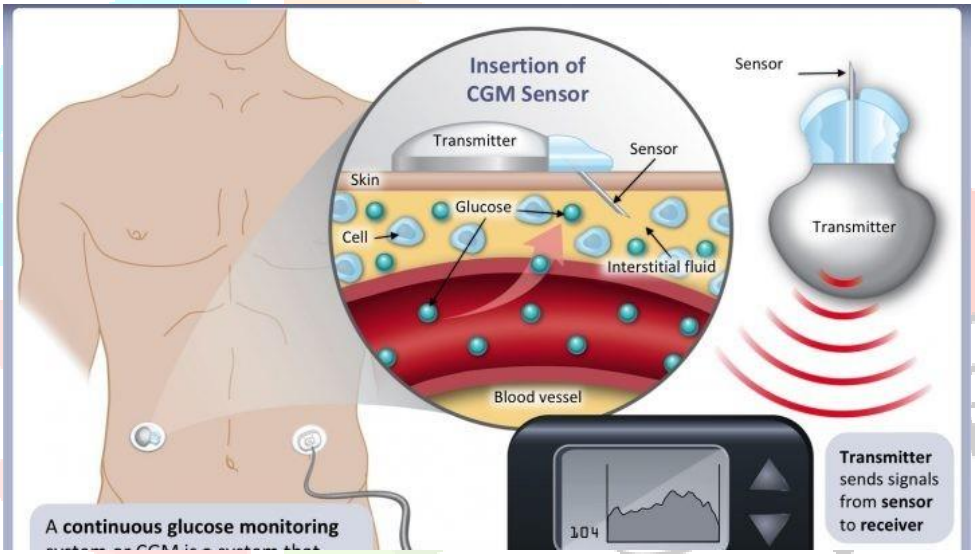
Continuous Glucose Monitoring

A CGM is a compact medical system,which measures the amount of glucose in the fluid inside our body. People with diabetes need to keep their blood glucose levels in a healthy range.Seeing glucose levels in real time can help to make more informed decisions throughout the day about how to balance food, physical activity, and medicines.its also possible to review glucose changes in our body over a few hours or days to see trends. CGMs can essentially eliminate the need for those regular fingerstick tests.

Working of CGM

A CGM works through a tiny sensor inserted under the skin, usually on belly or arm. The sensor measures interstitial glucose level, which is the glucose found in the fluid between the cells. The sensor tests glucose every few minutes. A transmitter wirelessly sends the information to a monitor.

The monitor may be part of an insulin pump or a separate device, which you might carry in a pocket or purse. Some CGMs send information directly to a smartphone or tablet



The FreeStyle Libre is a CGM system which works by having a small round sensor applied to your arm,about 5mm high and 35mm diameter. The sensor is applied to the skin with a painless applicator but some users experience mild skin irritation.The FreeStyle Libre allowed users to wear it for up to 14 days.Within the 14 days of usage, the sensor scan the sugar levels and sends data to your sugar levels over the previous 8 hours to the Libre system's handset.

Instead of checking your glucose several times a day with a finger stick, you wave the monitor above the sensor in your skin to check your levels anytime you wish.

When used over time, this monitor can also help you see patterns in your blood sugar levels. For example, you may notice they're stabilizing, or perhaps trending upward or downward. Such information is crucial to share with your doctor to help determine your diabetes treatment plan.

Some studies about FreeStyle Libre's point out that it reduces the risk of diabetes complications.

A 2020 study found a 52 percent decrease in hospital visits for ketoacidosis in people with type 1 diabetes, as well as a 47 percent decrease in those with type 2 diabetes-according to the study titled *"Dramatic Drop in Ketoacidosis Rate after FreeStyle Libre System Initiation in Type 1 and Type 2 Diabetes in France, Especially in People with Low Self-Monitoring of Blood Glucose (SMBG): A Nationwide Study,"* -presented at the American Diabetes Association's® (ADA's) 80th Virtual Scientific Sessions.

CGMs require three basic parts:

1. **Sensor**

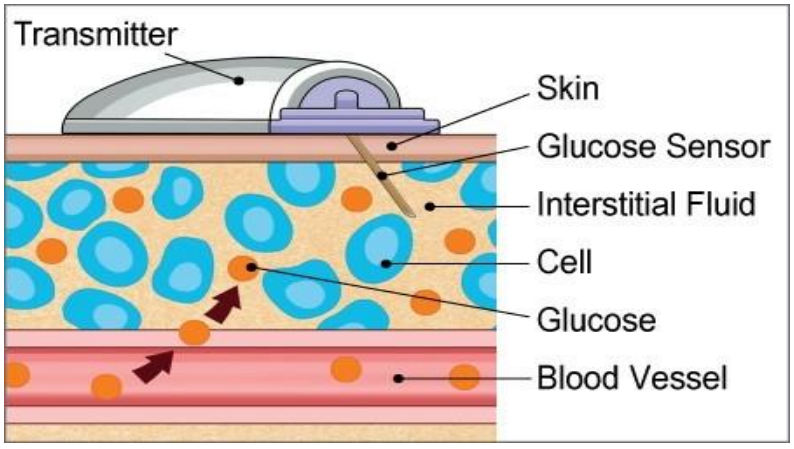
Glucose sensors are biosensors designed to detect glucose levels, which is vital to managing diabetes. According to the Oxford Dictionary: "A biosensor is a device that uses a living organism or biological molecules, especially enzymes or antibodies, to detect the presence of chemicals."

In order to maintain normal blood glucose levels, **biosensors** began to be increasingly used for continuous monitoring of the level of glucose in the blood.

There are many other applications for biosensors, most commonly used in health care system. Because of their ability to be highly selective, sensitive, and relatively easy to use, biosensors can rapidly recognize and measure key biometrics in bodily fluids to aid in health monitoring. These are some examples of commercially available biosensors.

- At-home pregnancy tests
- Blood glucose meters
- Continuous glucose monitors
- Cholesterol meters

Glucose sensors are a small, thin metallic filament that is inserted just below the skin using a mechanical insertion device or called applicator. Sensors in CGM are normally worn for 7-14 days, depending on the system. . An adhesive patch covering keeps the sensor securely in place. The sensor contains a chemical that reacts with the glucose in the "interstitial fluid" (fluid between the fat cells below the skin surface), triggering a tiny electric current.



FreeStyle Libre System Sensor measures the interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. Some features of FreeStyle Libre System Sensor is given below

- **Painless, Easy to Apply:**-Using the supplied disposable applicator, the FreeStyle Libre sensor can be easily applied and stays on the back of your upper arm for up 14 days.
- **Water-resistant**-The FreeStyle Libre sensor can even be worn while you shower, swim, bathe or exercise, so it fits seamlessly into your lifestyle.
- **Factory Calibrated-**FreeStyle Libre is the only factory-calibrated glucose monitoring system. You don't need to recalibrate it again and again with painful fingerpricks.
- **Accurate Sensor Readings-**The FreeStyle Libre system is accurate, stable and consistent over 14 days without need for finger prick calibrations.

Technical specifications (sensors)

- Memory: 8 hours (32 readings)
- Sensor life: Up to 14 days
- Battery: 1 silver oxide battery (lasts the life of the sensor)
- Dimensions: 35 mm diameter and 5 mm height
- Weight: 5 g

Operating and storage ranges

- Operating temperature: 10° to 45°C
- Storage temperature: 4° to 30°C
- Relative humidity: 10-90% (non-condensing)
- Altitude: -381 m (-1,250 ft) to 3048 m (10,000 ft)
- Water resistance: IP27: Can withstand immersion into 1m (3 ft) of water for up to 30 mins

Product Specifications and Features:

- The sensor has been tested to withstand immersion into one metre (3 ft) of water for up to 30minutes
- It is also protected against the insertion of objects >12mm diameter (IP27)
- It stores up to 90 days of data
- Trend arrow indicates if glucose levels have increased, decreased or are staying steady

2. Transmitter

The transmitter is small, flat and waterproof ,sits on top of the sensor ,which receives the tiny electric current from the sensor and sends out a short-range radio signal.It contains its own battery that is either permanent, replaced as needed, or recharged periodically. In the case of FreeStyle Libre, there is no reusable transmitter; each sensor is fully disposed after 14 days and a new one isput on.

3. Smartphone app or receiver

The signal from the transmitter is received by this handheld device that displays the glucose measurement.In addition it displays whether blood glucose is trending up or down, and glucose history. Most CGMs offer smartphone apps for viewing data. Abbott and Dexcom are other examples of CGM,which offer handheld devices for people that don't use a smartphone. The receiver can be customized to alert the user of glucose values that exceed certain high or low levels. Some receivers are integrated into insulin pumps, where the pump's screen serves as the display.

FreeStyle Libre Reader/reciever specifications are given below

Technical specifications (reader)

- Radio frequency: 13.56 MHz

- Data port: Micro USB
- Blood glucose measurement range: 1.1 to 27.8 mmol/L
- Blood ketone measurement range: 0.0 to 8.0 mmol/L
- Battery: 1 lithium-ion rechargeable battery
- Battery life: 7 days typical usage between charging
- Service life: 3 years of typical use
- Dimensions: 95 x 60 x 16 mm
- Weight: 65 g

Difference between Blood Glucose Monitoring and Flash Glucose Monitoring

Flash Glucose Monitoring enables to test glucose levels without pricking your finger. The small sensor automatically measures and continuously stores glucose readings day and night.Finger prick blood glucose readings and sensor glucose reading won't always match and in fact are likely to be different.There is a 5 to 10 minute delay in ISF glucose response to changes in blood glucose.

Blood Glucose	**Interstitial fluid glucose(in CGM)**
one of the oldest and most common methods for testing glucose	CGM technologies automatically detects and measures glucose levels in interstitial fluid.
Measures glucose in the blood	Measures glucose in the interstitial fluid of the subcutaneous tissue
Finger prick needed for each reading	Simple scan collects data they are embedded below the skin
Drop of blood needed	Small sensor monitors interstitial fluid
Each reading represents one moment intime	CGM sensor can be used continuously for several days or weeks — the exact duration will vary by manufacturer.
Night time testing means waking up	levels continue to be monitored whilst asleep
Time consuming	scan simply anywhere
Test kit requires:lancet,strips,meter enzyme-coated test strips with a precise amount of specific enzymes that can only react to one blood sample test strips are intended for single use and cannot be reused.	one second scan uses a filament coated in glucose sensing enzymes The sensor works with a transmitter that sits above the skin to send data to a receiver or smart device
May be unpleasant to take a reading in some situations or in public	Most people will not feel the sensor being worn
Affordable cost	More expensive

Special Features of a CGM

CGM sensors continuosly measure glucose as you go about your normal activities, including eating, sleeping, exercising, showering, etc. Many CGMs are capable of finding additional featuresfrom the glucose readings like

- By sounding an alarm when blood sugar levels become too high or too low,
- Easily see how physical activity and the food you eat, impact blood sugar. And thus begin to analyze your metabolic fitness.
- The information about glucose trends can download to a computer or smart device which helps us and doctor to make the best plan for managing our diabetes.
- its also possible to send information right away to a second person's smartphone—perhaps a parent, partner. For example, if a child's glucose drops dangerously low overnight, the CGM could be set to wake a parent in the next room.

Benefits of a CGM

Compared with a standard blood glucose meter, using a CGM system can help you in many ways.FreeStyle Libre provides a number of benefits to us.

- monitor glucose levels every day via an app you download after purchasing the system .
- Helping to clarify the effect of diet and exercise on blood sugar levels
- Eliminating the need for numerous finger pricks, which may be painful and difficult to manage frequently
- painless sensor application process
- convenient for travel, work, and other instances when you're on the go
- more affordable than other glucose monitors
- waterproof sensor for short periods of swimming and bathing in a few feet of water

Over time, good management of glucose greatly helps people with diabetes stay healthy and prevent complications of the disease.

The FreeStyle Libre system provides three critical pieces of data with each scan:

- A real-time glucose result.
- An eight-hour historical trend.
- A directional trend arrow showing where glucose levels are headed.

Limits of a CGM

Researchers are working to make CGMs more accurate and easier to use.

limitations

- Need a finger-stick glucose test twice a day to check the accuracy of your CGM against a standard blood glucose meter.
- CGM devices takes about five to 25 minutes longer to show a rise in glucose readings as compared to blood glucose.
- CGM system is more expensive than using a standard glucose meter.
- There can be periods when the system is "down" or the reading is not accurate.(symptoms of high and low glucose should not be ignored just because the CGM reading says glucose is in range.Thus do regular blood glucose checking is necessary if the sensor glucose readings do not fit with your symptoms)

Apart from these general limitations of a CGM , FreeStyle Libre has some other important cautionsand limitations.

- Since the FreeStyle Libre doesn't have any automatic alerts when your blood glucose is at dangerous levels(going low or high glucose level.),
- The possibility of blood glucose issues during sleep, in which the system won't alert you (unless you're using the Libre 2) .it's important to set reminders to help you remember to check your monitor regularly. while the other

CGMS such as Dexcom and Medtronic do.
You should check your levels at least every 8 hours.

- The Freestyle Libre sensor can't be "restarted", once the time period is up, then it's finished. The flash monitoring system does not integrate with insulin pump devices like some CGM devices can.
- It's not completely waterproof. It is water resistant for up to one meter for around 30 minutes. However, FreeStyle Libre Abbot has stated that "intense activities whereby a user is continually moving or repeatedly in and out of the water, may reduce the sensor wear
time".

Warning

Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the sensor glucose reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your healthcare professional.

Limitations of Use

Abbot website warning us some limitations about Freestyle Libre Pro and Freestyle Libre .They are not approved in children less than 18 years of age or the patients who are pregnant, on dialysis,or critically ill. Patients who are dehydrated or have high levels of vitamin C or salicylic acid maynot get accurate readings with the system

Other glucose monitors

Another popular non-finger-stick CGM on the market is the Dexcom G6. The sensors for Dexcom s lasts 10 days, but it is more costly than the FreeStyle Libre. Another key difference is that the monitor continuously sends glucose data to your smartphone every 5 minutes.

Conclusion

CGM is an important tool for monitoring diabetes that has been shown to improve outcomes in patients with diabetes mellitus. This study of CGM based on FreeStyle Libre system lead us to conclude that Seeing glucose levels in real time can help youto make more informed decisions throughout the day about how to balance your food, physical activity, and medicines.

Overall, users satisfied with the functionality and ease of use of the FreeStyle Libre. However, there have been reports of unusual fluctuations in glucose readings, especially during the last day of the sensor's life. Abbot free style studies shows that 97% of users, ages between 4 to 12 , say the FreeStyle Libre system is easier to use than finger prick testing.

According to a study published inThe Lancet, people using the FreeStyle Libre system spent 38 percent less time within hypoglycemia (low blood sugar,)as compared with those who managed their glucose with traditional self-monitoring glucose system.

A CGM is life-changing in the best possible way.A CGM may give you a better quality of life .It teaches you about your diabetes,help you to be more active and the piece of mind may make you amore chill person.

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