ScienceDirect

Sensors and Actuators B: Chemical
Volume 286, 1 May 2019, Pages 173-180

Wearable-band type visible-near infrared optical biosensor for non-invasive blood glucose monitoring

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https://doi.org/10.1016/j.snb.2019.01.121
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Abstract

Diabetes is a worldwide-serious problem that can only be delayed or prevented by a regular monitoring of blood glucose (BG) concentration level. Continuous monitoring systems allow subjects to prepare the diabetes management strategy and prevent the long-term complications diseases. Until now, most studies utilize various biofluids such as sweat, tears and saliva that have serious unresolved setback such as expensive material, sensor stability, sensor calibration and long-settling time. Therefore, we developed a novel BG sensor which is cost efficient and highly wearable with a small data acquisition time window that allow a non-invasive, long-term continuous blood glucose monitoring (CGM) system. The novel biosensor exploits a unique information of the pulsatile to continuous components of the arterial blood volume pulsation during the change of blood glucose (BG) concentration at the wrist tissue. The reflected optical signal was measured in the combine visible-near infrared (Vis-NIR) spectroscopy. An in-vivo experiment which enclosed 12 volunteers in a two-hour modified carbohydrate-rich meals reached the average correlation coefficient (R_p) between the estimated and reference BG concentration of 0.86, with the standard prediction error (SPE) of 6.16 mg/dl. Moreover, the full-day experiment was also conducted to test the reliability of the proposed sensor. Results showed that the created model in the previous day, may estimate a full-day BG concentration which was done in next day with an adequate performance.

Introduction

Diabetes is a chronic disease that is mainly caused by the failure of the patient's body to deal with insulin [1], insulin is the hormone produced by our pancreas that plays a number of important roles in our metabolism, such as controlling glucose levels by sending signal to other organs (e.g., liver and muscle) to consume glucose from the blood, and helping glucose to move from blood into cells to provide energy. According to a previous study, global prevalence of diabetes is projected to rise from 171 million (2.8%) in 2000 to 366 million (4.4%) in 2030 for all age groups [2]. It shows that diabetes is a worldwide-serious problem that can only be delayed or prevented by a regular monitoring of blood glucose (BG) concentration level. As there is no cure, daily monitoring system can be useful in healthy subjects, to improve their quality of life and to avoid the disease. Moreover, regular monitoring of blood sugar levels allows patients to control and prepare the diabetes management strategy if it's not in the recommended range. These continuous monitoring systems are also important, as an untreated metabolic pathological condition where BG fluctuates outside the desired normal ranges, may lead to the long-term complications diseases, such as kidney problems, strokes (cerebrovascular disease), heart failure (cardiovascular disease), and ocular disease.

Traditionally, an invasive system that is painful, discontinuing, and requiring a small amount of blood sampling using finger-prick, has been being used. Sugar in the blood sample is then measured by inserting the glucose strip in a counter machine through electrochemical methods. This technique is not ideal for monitoring blood concentration changes in real time and it is considered as an expensive method since the glucose strip only can be used once. A better alternative is called minimally invasive system. This system implements an implantable sensor (e.g., microneedle patch [3]) that may measure BG continuously [4]. Some devices, based on minimally invasive technique, are already commercialized, such as Dexcom G5® (Dexcom, Inc. San Diego, CA) and FreeStyle Libre (Abbott Diabetes Care, Alameda, CA); however this technology also cannot be considered an ideal approach, since the implantable sensor itself has a limited time span, and it suffers from measurement delays and stability problems.

Noninvasive BG monitoring is a diabetes management approach that allows an in-vivo continuous blood glucose monitoring while also providing a convenient, and nonintrusive measurements technology to patients [5,6]. Several noninvasive biosensors, based on different measuring approaches such as reverse iontophoresis [7], combined reverse iontophoresis and enzyme-based amperometric biosensor [8], Raman Spectroscopy [9], and Near Infrared Spectroscopy (NIRs) [10,11], have been proposed. Thus, the direction of noninvasive technology development tends to the wearable biosensor. The wearable biosensor system is considered an answer to the deficiencies of implantable sensors. The level of this technology is still far from perfection: groups of researchers have tried to solve the problem mentioned above, and have successfully proposed several novel ideas, such as a tear-based contact lens glucose sensor [12], a salivary mouth guard biosensor [13], and a sweat-based wearable sensor array [14,15]. However, each of these proposed technology has still unresolved setbacks: for example, it is hard to isolate the inherent level of glucose in case of saliva-based biosensors, while the long settling time to collect subject's sweat is the main issue in case of sweat-based biosensors, respectively.

In this paper, a fully wearable, cost-efficient, and compact optical biosensor is proposed as a noninvasive continuous blood glucose monitoring (CGM) system. To tackle the problem of the previous method, here a combined Vis-NIR biosensor is established, to extract a useful information from a multiple Vis-NIR spectrum related to BG concentration. Our proposed system offers a small data acquisition time window, and also reliable for continuous practical application as the significance of the proposed system is on the single measurement site or sensor placement on the subject's body that is on the wrist of the subject. The main goal of our system is to be integrated to a wearable smartwatch, where it may be used for clinical monitoring application by providing a BG information. Several experiments were conducted to test the reliability and validity of the proposed biosensor signal. The first initial experiment compared the results of our proposed device with commercial devices such as an ECG and a PPG, to estimate the subject's heart rate. Subsequently, an experiment involving several subjects for BG estimation was also conducted. Finally, a full-day BG concentration change estimation was investigated, to find the possibilities of the proposed system for a long-term monitoring and a minimum calibration-time system.

Section snippets

Working principles

A combined Vis-NIR is used to determine a BG concentration continuously and noninvasively. Visible spectroscopy is a technique to determine solution concentration, using interactions of the visible light (380–720 nm) in the electromagnetic spectrum, with a chemical species. Besides that, NIR spectroscopy is a technique that corresponds to the vibrational and rotational transitions associated with the chemical bonds within molecules. It also can be used to identify molecules concentration by…

Sensor validation

Experiments were performed to validate the proposed biosensor signal. As mentioned above, the signal that was monitored in this study is PPG signal: typically it's known as the optical-based noninvasive signal that measures blood volume changes in the microvascular bed of tissue, and as the signal to estimate the subject's heart rate noninvasively. Therefore, we compared heart rate (HR) estimation results of our biosensor with a commercial ECG device AD8232 (Analog Devices Inc., USA), and PPG…

Optical wavelength selection and effect of BG on PPG signal

In term of the optical wavelength selection of the proposed biosensor, we selected our chosen LED-optical wavelength based on the conclusion of the previous study and the availability of the LEDs in the market. Earlier studies reveal that the NIR region in the first overtone region (1500–1850 nm) and the combination overtone band (2050–2392 nm) are more suitable for BG estimation [27], as the water absorption is low and the signal energy is high in these regions. However some of the studies…

Conclusions

In this work, we exhibited a wearable Vis-NIR based biosensor for noninvasive BG concentration monitoring system. The proposed novel BG biosensor considered as a cost efficient with highly wearable biosensor which allow a non-invasive, long-term continuous blood glucose monitoring (CGM) system. The proposed biosensor monitors changes of the blood volume under the microvascular bed of subject wrist tissue in different layers of skin tissue, such as dermis and subcutaneous tissue. In total, four…

Acknowledgements

This work (2016R1A2B4015) was supported by the Mid-Career Researcher Program through an NRF grant funded by MEST, Korea.…

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