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Workshop on Noninvasive Glucose Monitoring 2024

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Abstract

This first workshop on noninvasive glucose monitoring (NIGM) was held at the Massachusetts Institute of Technology (MIT) on October 30, 2024. Six invited speakers, representing industry, academia, and clinics, gave presentations that covered (1) an overview of the NIGM technologies, (2) the state of the art in NIGM technologies, such as near-infrared (NIR), mid-infrared (IR), photoacoustic, and Raman spectroscopies, (3) minimally invasive implantable continuous glucose monitoring (CGM) sensors, and (4) a clinician's perspective on the impact of the current CGM devices for patient care.

Keywords

accuracy, blood glucose, blood glucose meter, continuous glucose monitoring, noninvasive glucose monitoring, self-monitoring of blood glucose

Introduction

On October 30, 2024, the Massachusetts Institute of Technology (MIT) Laser Biomedical Research Center hosted its first workshop on noninvasive glucose monitoring (NIGM) that attracted more than 100 attendees from diverse backgrounds including:

Companies currently developing the next-generation glucose monitoring sensors,

Academic researchers,

Clinicians who are using the current CGM sensors for patient care,

Related biotech and consumer electronics companies,

Students and junior researchers who have an interest in this field, and

Potential investors and venture capital organizations.

Below presents the agenda for the workshop. This report summarizes the key points of each presentation.

8:00-8:45: Reception

8:45-9:00: Opening Remarks (Prof. Peter So and Dr. Jeon Woong Kang, MIT)

9:00-9:40: Noninvasive Glucose Sensing: The Challenges, Opportunities, and Progress

(Prof. Mark Arnold, University of Iowa)

9:40-10:20: Continuous Glucose Monitoring: The Current State of the Field

(Prof. Devin Steenkamp, Boston University)

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10:20-11:00: Coffee Break

11:00-11:40: Development of a Continuous Blood Glucose Sensor (CBGM)

(Dr. Mark Tapsak, GlucoTrack)

11:40-12:20: Non-invasive blood glucose measurement by mid-infrared spectroscopy: Principles and Validation

(Prof. Werner Mantele, DiaMonTech)

12:20-14:00 Lunch (Group photo)

14:00-14:40: Development of Non-Invasive Glucose Monitoring Devices Using Photoacoustic Technology: Challenges and Advances

(Dr. Yoonho Khang, HME Square)

14:40-15:20: Development of a Non-Invasive Continuous Glucose Monitoring System Using Raman Spectroscopy

(Dr. Miyeon Jue, Apollon) (Figure 1)

Noninvasive Glucose Sensing: The Challenges, Opportunities, and Progress

Mark A. Arnold, PhD (University of Iowa)

The Diabetes Control and Complications Trial (DCCT)¹ was pioneering in that it confirmed how tight-glycemic control can delay the onset of the medical complications associated with chronic hyperglycemia in people with type 1 diabetes. These findings fueled the advancement of novel glucose sensing technologies designed to guide insulin dosing, as a means to achieve euglycemia. The wide-spread use of self-monitoring blood glucose (SMBG) meters followed by continuous glucose monitoring (CGM) devices followed.

Noninvasive glucose monitoring represents an alternative approach whereby the concentration of glucose is obtained

without breaking the skin for the purpose of either collecting a sample of blood (SMBG) or inserting a biosensor (CGM). Noninvasive glucose monitoring involves passing a harmless band of electromagnetic radiation through a vascular region of the body and extracting the concentration of glucose from an analysis of the measured signal. Noninvasive glucose monitoring measurements can be either spectroscopic in nature or based on other light/matter interactions. Despite over three decades of research, no NIGM technology has been approved by the Food and Drug Administration (FDA) for clinical use. In fact, the FDA recently issued the following safety warning to consumers: “Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels.”²

This presentation will focus on the general development of NIGM systems with an eye toward common pitfalls and challenges across the various measurement platforms. An emphasis will be placed on understanding the fundamental principles that underlie the technical approach, as well as the importance of establishing a molecular-level basis for measurement selectivity. Examples from NIGM data will be presented to highlight the critical analytical issue of sensitivity, the promise and curse of machine learning methods, and the impact of data-splitting in assessing the robustness of calibration functions.

- Animal models can provide valuable insights into the biological, chemical, and physical basis for measurement selective for glucose measurements within the complex matrix of living skin.
- Background spectral variance is the principle confounding factor that limits accurate quantitation of glucose in human subjects, thereby demanding that successful calibration models capture all sources background variations within the underlying *in vivo* spectra.
- Avoid measurements dependent on the refractive index of the sample medium and challenge machine learning models with novel data assignment strategies as a means to reveal the underlying basis for chemical selectivity of the noninvasive measurement.



Figure 1. Group photo.

CGM: The Current State of the Field

Devin Steenkamp, MD (Boston University)

Continuous glucose monitoring is regarded as the standard of care for individuals living with type 1 diabetes (T1D), and type 2 diabetes (T2D) who are using insulin therapy.³ The CGM market is dominated by two manufacturers who make wearable on-body sensors that measure interstitial glucose levels. These disposable sensors are single use and have a finite lifespan of between 7 and 15 days. Continuous glucose monitoring has revolutionized the approach to intensive diabetes management through three major advancements, superseding the previous standard of intermittent self-monitoring of blood glucose via fingerstick capillary glucose measurement: (1) Allowing intensive insulin management with improved hypoglycemia mitigation; (2) providing real-time and retrospective opportunities for patients and their clinicians to review detailed glycemic data while creating opportunities to refine treatment, address behavioral concerns, and directly relate glycemic data to the lived experience of the user; (3) underpinning the increased adoption of modern automated insulin delivery systems with closed-loop control algorithms that modulate insulin delivery based on CGM glucose inputs. There is also a growing body of data supporting the value of CGM in individuals living with diabetes who are not using insulin, as well as individuals without diabetes.⁴⁻⁶ Currently, approximately 50% of individuals living with T1D in the United States are using CGM, and it is expected that CGM use will increase to over 50% of individuals living with T2D within the next 3 years.^{7,8} However, current technology is limited by the short wear-time and need for on-body adhesion, which can result in contact dermatitis and risk for sensor dislodgement.⁹ Long-term sensor applications also have a significant financial and environmental cost given that applicators and sensors are all disposable.¹⁰ Future generation CGM technology needs to improve upon these shortcomings while maintaining usability and accuracy.

- Continuous glucose monitoring is an integral part of the standard of care for all individuals living with type 1 diabetes and insulin users living with type 2 diabetes.
- Real-time and intermittently scanned, disposable, on-body transcutaneous devices dominate the current CGM market.
- Common limitations of current technology include dermatological, environmental, and financial concerns.

Development of a Continuous Blood Glucose Sensor

Mark Tapsak, PhD (GlucoTrack)

GlucoTrack, Inc. (NASDAQ: GCTK) is focused on the design, development, and commercialization of novel technologies for people with diabetes. The Company is currently developing a long-term implantable continuous blood glucose monitoring system for people living with diabetes. GlucoTrack's CBGM is a long-term, implantable system that continually measures blood glucose levels with a sensor longevity of 3+ years, no on-body wearable component and with minimal calibration. The talk will cover preclinical results from multiple ovine studies running up to 90-days. The studies demonstrate accuracy in ranges of 3 to 9% Mean Absolute Relative Difference (MARD) with a single calibration event. In silico modeling of robust sensing function out to 3 years will be shared. In addition, recently collected patient survey data that covers acceptance of an implantable sensor will be presented. Finally, results from an exploratory first of its kind implantation of a continuous glucose sensor into the epidural space in swine will be presented. For more information about GlucoTrack's CBGM, please review the downloadable posters at glucotrack.com.

- GlucoTrack's CBGM combines the best of glucose monitoring and cardiac monitoring technology into one device.
- The device uses FDA-approved materials and processes to reduce development costs, development risks, and time to market.
- Clinical trials were initiated in December of 2024 (Figure 2).

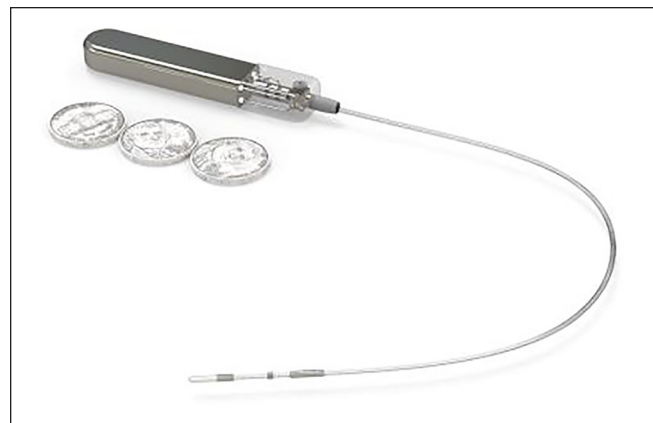


Figure 2. GlucoTrack continuous blood glucose monitor shown next to three U.S. nickels for scale.

Non-Invasive Blood Glucose Measurement by Mid-Infrared Spectroscopy: Principle and Validation

Werner Mäntele, PhD (DiaMonTech)

DiaMonTech in Berlin (Germany) founded in 2015 has introduced a technology for noninvasive glucose measurement

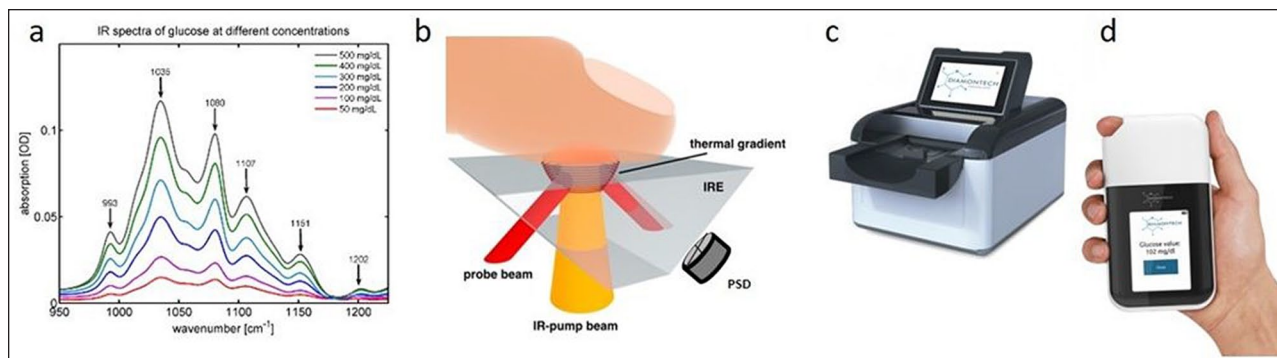


Figure 3. (a) Mid-IR spectra of glucose at concentrations relevant for blood glucose. (b) Schematic representation of photothermal detection of glucose IR absorption in skin: Yellow: MIR pump beam from QCL; Red: Red laser probe beam; PSD: Position-sensitive photodiode; IRE: Internal reflection element. (c) DiaMonTech's table top multi-user device "D-Base" used for clinical validation. (d) DiaMonTech's hand-held device "D-Pocket."

(NIGM) for diabetes patients. DiaMonTech's NIGM technology targets glucose molecules in interstitial fluid (ISF). An infrared beam from a quantum cascade laser (QCL) tuned to wavelengths between 8 and 12 μm where glucose has a highly specific fingerprint absorbance selectively excites glucose molecules in skin. Absorption results in a small amount of heat in skin detected on the surface with a proprietary photothermal deflection technique. This technology is painless, harmless, and does not require consumables. Based on previous R&D work at Frankfurt University, DiaMonTech has developed a table-top NIGM device for clinical studies ("D-Base") and currently completes a hand-held device ("D-Pocket") the size of a smartphone. DiaMonTech has started further miniaturization toward integration of the technology into a smart watch (Figure 3).

D-Base was CE certified in 2019 and validated in an initial retrospective clinical study involving 100 volunteers, where a MARD of about 12% was reached. In the consensus error diagram, 99,1 % of the noninvasive data were in Zones A and B, only 0.9 % in Zone C and no data in zones D and E, thus confirming the feasibility of NIGM based on this technology.¹¹

In a recent prospective study at the Institute for Diabetes Technology in Ulm (Germany) with 36 individuals, the time course of the NIGM was evaluated for up to 10 days after an initial calibration of the NIGM device with three invasive reference measurements, indicating a precision with a MARD of about 20%. This corresponds to the performance of early CGM systems cleared by the FDA for the use by diabetes patients and demonstrates that glucose can be reliably measured non-invasively, opening new perspectives for a better management of diabetes.

- DiaMonTech technology targets the mid-infrared signature of glucose to achieve highest possible specificity.

- A photothermal detection technology was developed for high sensitivity.
- Clinical tests of this noninvasive technology have shown a precision comparable to minimally invasive CGM devices.

Development of NIGM Devices Using Photoacoustic Technology: Challenges and Advances

Yoonho Khang PhD (HME Square)

As part of the ongoing efforts to enhance diabetes management, the development of NIGM technologies has gained significant attention. This presentation focuses on the use of photoacoustic technology in the measurement of blood glucose levels without invasive sampling. Photoacoustic methods enable precise detection of glucose concentration through the skin by analyzing the acoustic waves generated by laser-induced thermoelastic expansion.

In this workshop, we will delve into the core principles behind photoacoustic glucose sensing, highlighting the technical challenges such as signal-to-noise ratio and algorithm development. In addition, a comprehensive overview of the system design will be presented.

The presentation will also cover the practical implementation of this technology, including clinical validation steps and challenges in device commercialization. Furthermore, we will discuss regulatory requirements and market strategies necessary for transitioning from research to commercial products.

Our discussion will focus on how this innovative approach holds promise for improving the accuracy and convenience of glucose monitoring, and its potential role in transforming diabetes care through user-friendly, noninvasive devices.

Development of a Noninvasive CGM System Using Raman Spectroscopy

Miyeon Jue, PhD (Apollon)

Apollon, founded in 2021 in South Korea, is a company focused on developing health monitoring technologies. Since 2023, we have been developing a noninvasive CGM sensor to provide a convenient and accurate solution for blood glucose management without the need for invasive methods. Our CGM device leverages Raman spectroscopy to measure glucose signals from the ISF beneath the dermis. By using a near-infrared laser, we can detect glucose-specific signals from various biological signals and convert them into blood glucose concentrations.

One of the key advantages of Raman spectroscopy is its ability to selectively detect glucose signals amidst complex biochemical signals from the body. This allows us to achieve high accuracy while eliminating the discomfort of traditional finger-prick tests.

In August 2023, Apollon began collaborating with the MIT to accelerate the development of our CGM system.¹² We are currently developing the first-generation device, which is about the size of a smartphone, and are preparing for our first clinical trial on healthy individuals in the fourth quarter of this year. This marks a significant milestone in validating our NIGM technology.

Looking ahead, we are working to further miniaturize the device to make it more user-friendly and portable. By the first quarter of next year, we plan to complete the development of a second-generation device that will be one-third the size of the current model, with the goal of making the final product wearable. This will enable real-time CGM in daily life.

- Apollon is developing a noninvasive CGM device using Raman spectroscopy, enabling glucose measurement in ISF without the need for blood sampling.
- Recent in-vitro experiments using a tissue phantom demonstrated a strong correlation ($R = 0.98$) between glucose concentration and Raman signals, with a coefficient of variation (CV) of 0.04%, showcasing the device's accuracy and reproducibility.
- Future plans include miniaturizing the device to create a compact and wearable solution, making CGM more convenient and accessible for diabetic patients.

Conclusion

This report summarizes the efforts of several research groups from academia and industry on NIGM. They represent only a small fraction of the many groups working in this field. Several technologies were presented, and challenges, opportunities, and risks were discussed. The workshop's presentations covered (1) overview of the NIGM technologies, (2) state of the art NIGM technologies such near-infrared (NIR),

mid-infrared (IR), photoacoustic, Raman, (3) minimally invasive implantable CGM sensor, and (4) clinician's perspective on the current CGM device for the patients' care and future direction.

To our knowledge, it is the first time that potential competitors "on the search for the holy grail" have gathered and freely exchanged information on methodologies and results. As one outcome, a regular continuation of this workshop has been agreed.

Abbreviations

CGM, continuous glucose monitoring; DM, diabetes mellitus; FDA, Food and Drug Administration; ISO, International Organization for Standardization; NIGM, noninvasive glucose monitoring; SMBG, self-monitoring of blood glucose; YSI, Yellow Springs Instruments.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MT is a VP of Sensor Technology of GlucoTrack Inc. WM is a CSO of DiaMonTech AG. YK is a CEO of HME Square Inc. MJ is a CTO of Apollon Inc. JWK and PTCS have received research support from Apollon. DS has received research support from Abbott Diabetes Care, Tandem Diabetes Care, MannKind, and Novo Nordisk and is a consultant for Abbott Diabetes Care. MT is a VP of Sensor Technology of GlucoTrack Inc. WM is a CSO of DiaMonTech AG. YK is a CEO of HME Square Inc. MJ is a CTO of Apollon Inc.

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