Early Feasibility Study to Evaluate an Intravascular Continuous Blood Glucose Monitor in Adults With Diabetes Mellitus

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Background

This first-in-human trial aims to evaluate the safety, feasibility, and initial performance of the Glucotrack System, a novel continuous blood glucose monitor (CBGM) designed for long-term use in adults with diabetes. The commercial Glucotrack system is fully implantable with no external on-body wearable, consisting of a sensor lead placed in the subclavian vein and connected to subcutaneous electronics that communicate with a mobile application. In this study, the commercial CBGM sensor lead was placed intravascularly and connected to a prototype electronics component that was placed on the skin. Fingerstick blood glucose measurement, venous glucose measurement, and interstitial glucose measurement using commercial CGMs were included.

Objectives

Primary endpoint:

- Absence of procedure or device-related serious adverse events from sensor insertion through 7 days post-removal

Secondary endpoints:

- Validation of surgical procedures
- Device performance metrics compared with BG measurements

Methods

This study was conducted in the catheterization lab at InCor Hospital in São Paulo, Brazil, between December 13, 2024 and January 31, 2025. 10 participants were enrolled and 8 were inserted. Of the 8 participants (6 female; 2 male) the average duration of diabetes was 22 ±12.57 years; 6 participants have T1D and 2 participants have T2D, all on intensive insulin therapy.

Percutaneous insertion of the sensor lead was performed by interventional cardiologists, followed by a 4-day inpatient observation period. During this time, frequent blood sampling and glucose tolerance tests were conducted to assess device performance. Safety was evaluated through a follow-up visit to confirm no post-removal adverse events occurred, ensuring participants exited the study safely. Sensor data were analyzed using the OneTwo Analytics' AI platform.

BGM=blood glucose monitor; CGM=continuous glucose monitor; FST=frequent sample testing; InCor=The Heart Institute, University of São Paulo; MARD=mean absolute relative difference; T1D=type 1 diabetes; T2D=type 2 diabetes.

Results

Primary endpoint:

- No procedure- or device-related serious adverse events occurred

Surgical validation:

- Sensor lead insertion and removal were successfully performed using standard percutaneous techniques, with fluoroscopic confirmation and no complications

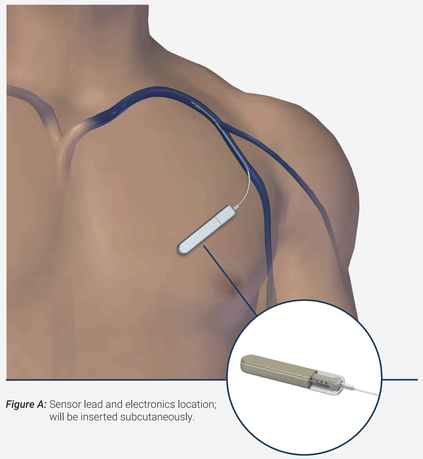


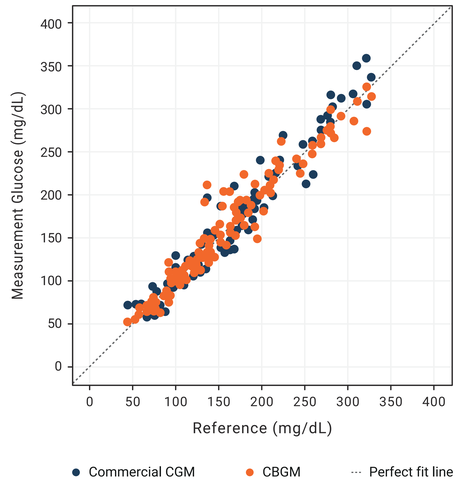
Figure A: Sensor lead and electronics location; will be inserted subcutaneously.

Figure B: Intended commercial device.

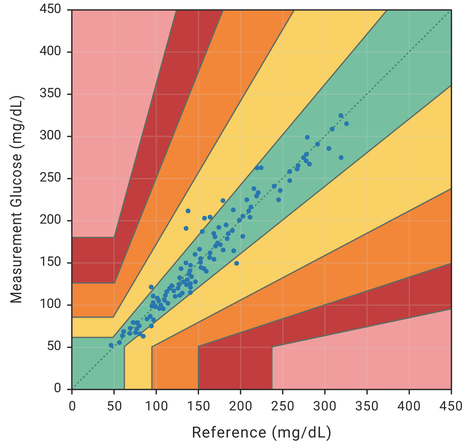
Device performance:

- Sensor lead & the prototype electronics performed as expected
- The prototype system accurately captured and stored sensor data throughout the insertion period, achieving a 99% data capture rate
- Average MARD was 7.7% across 122 matched pairs (BGM-CBGM)

Continuous Measurements vs Reference



DTS Error Grid CBGM Including Calibration Points



- 113 (91.62%) within green boundaries
- 9 (8.38%) within yellow boundaries
- 0 (0.00%) within orange, red, pink boundaries

Discussion

- The primary endpoint was met with no procedure- or device-related serious adverse events, and the insertion and removal were successfully performed
- The CBGM measurements lie closer to the perfect reference line for low values than the CGM and the spread of the CBGM measurements is similar to the CGM
- 100% of points in the green zone and yellow zone, indicating high clinical accuracy. This supports the CBGM's potential feasibility and safety in guiding glucose-related treatment decisions

Conclusion

Findings confirm high clinical performance of the continuous blood glucose monitor. The CBGM demonstrated promising accuracy that is comparable to commercial CGMs, thus supporting its transition to long-term clinical evaluation as an alternative approach for continuous glucose monitoring in diabetes management.

Learn more about Glucotrack

CBGM shown; system under development.