# PATIENT TOLERANCE OF A LONG TERM FULLY-IMPLANTED CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM IN PEOPLE WITH TYPE 1 DIABETES

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## Background

Abundant evidence exists to support CGM as a standard of care in type 1 diabetes management, with glycaemic benefits directly related to duration of device wear[1]. All current commercially available CGM technologies however require regular patient interaction with external, body worn components; this can impact adoption or result in intermittent use[2]. In this study, attitudes of users were assessed regarding a new long-term, fully implanted continuous glucose monitoring system, incorporating a self-contained, self-powered sensor that is intended to function for up to one year without need for skin-attached or body-worn elements (Figure 1.).


Implanted Sensor

Handheld Receiver
(Glucose display for illustration purposes only.)

**Figure 1. The Model 100 ICGM Sensor with the system receiver.** The sensor is fully implantable and requires no on-the-skin or body-worn components. The handheld receiver displays blood glucose trends and provides alerts and glucose history.

## Methods

Clinical evaluation of a long-term, fully implanted (nothing worn on the skin) continuous glucose monitoring system (the Eclipse® ICGM® System, GlySens Incorporated, San Diego, CA. U.S.A.), was recently completed at St. Vincent's Hospital Fitzroy, Melbourne, AUS (CTN-02048-1). Four participants with type 1 diabetes were each implanted with the ICGM sensor for 4 months duration. Devices were implanted subcutaneously in the anterior abdomen and removed as an outpatient procedure with local anaesthesia and (optionally) conscious sedation. Participants were blinded to sensor output (receiver display inactive). All performed home SMBG 4X/day. Monthly in-clinic attendances occurred for glucose profiling with a standardized meal. At these study time-points subject surveys were administered. The monthly standardized subject surveys assessed device tolerance, yielding an "acceptance index" (AI) (-2 = strong negative, 0 = Indifferent, +2 = unaware).

## Results

### Participants

- 4 Adults with type 1 diabetes, (75% male, 25% female)
- Age: (mean ± SD) 41.4 ± 11.1 years, with disease duration >5 years
- BMI: (mean ± SD) 27.2 ± 2.6 kg/m²

Results from all subjects' AI scores, mean ± SD:

1-day = 0.5 ± 0.7,
7-days = 0.8 ± 0.7,
14-days = 0.8 ± 1.1,
1 month = 1.0 ± 0.9,
2 months = 1.2 ± 0.7,
3 months = 1.2 ± 0.7,
4 months = 1.1 ± 0.8

No significant adverse events occurred associated with the implanted sensor for the 4-month duration of the study.

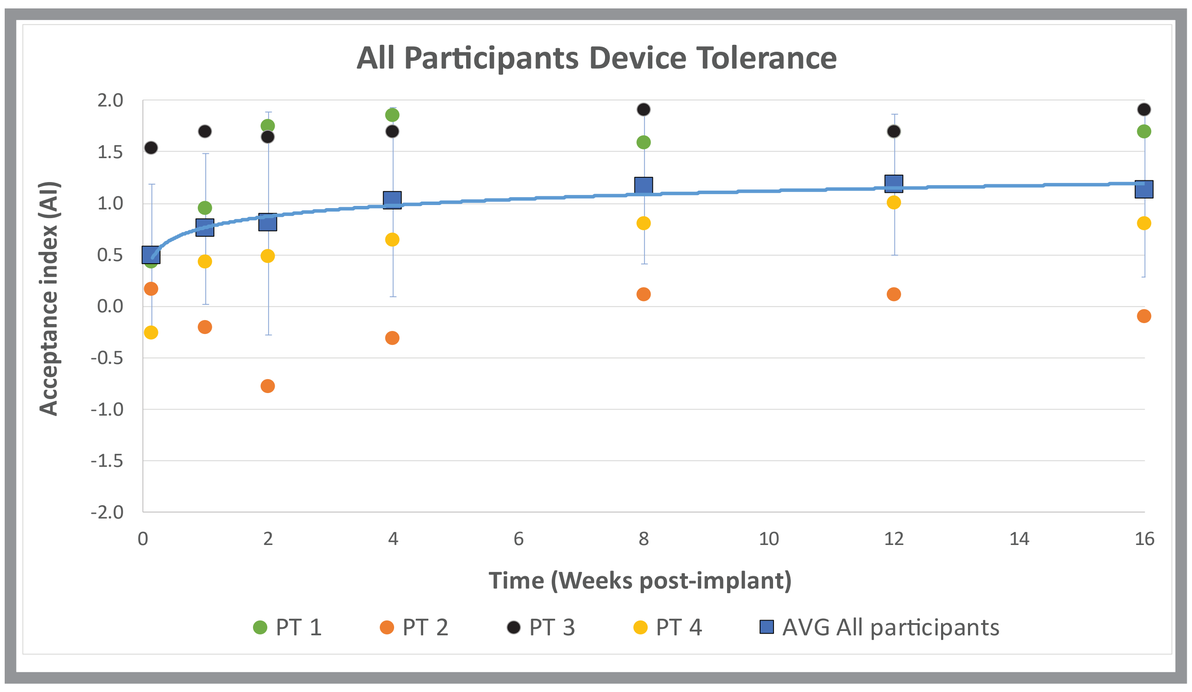


**Figure 2. Composite Device Tolerance Questionnaire over trial duration.**
+2 Unaware of sensor, 0 = Indifferent, -2 = Strong Negative.

## Conclusions

Consistent with previous clinical experience, participant responses suggest robust tolerance and acceptance of the Eclipse ICGM System which persisted for the 4-month duration of the study. A majority of participants exhibited positive attitudes and experienced no significant burden due to the implanted device. Additional studies are needed to validate device performance over an increased duration and assess changes in attitude over time.

## Acknowledgements

The Frequency Augmented Sensor Transmission Trial (FAST Trial) is an investigator initiated study, HREC/17/SVHM/99. Additional funding and supplies are provided by GlySens Incorporated.

## References

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