Feasibility of a prototype dual function glucose sensing and insulin delivering cannula

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BACKGROUND

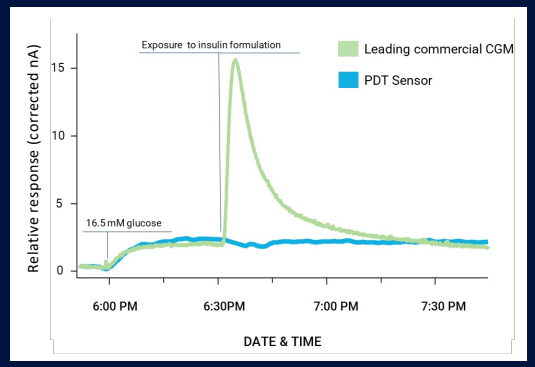

Figure 1: Artefactual glucose spike seen on commercial CGM when insulin is delivered in close proximity

- In current clinical practice, people with diabetes who are using an insulin pump in conjunction with a glucose sensor need to insert the insulin delivery cannula and glucose sensor separately.
- In previous feasibility studies which combined insulin delivery and glucose sensing components into a single insertion device, artefactual spikes were reported and hypothesized to be due to interference from the preservatives in the insulin formulation[1]

1. Graf A, McAuley SA et al. Moving Toward a Unified Platform for Insulin Deliver and Sensing of Inputs Relevant to an Artificial Pancreas. J Diabetes Sci Technol. 2017 Mar; 11(2):308-314.

AIM

To assess the feasibility of a prototype single insertion glucose-sensing and insulin delivering cannula (SynerG™) in adults with type 1 diabetes.

METHODS

- Following a 48-hour pre-study run-in using a commercial insulin cannula and study pump (Medtronic 780G), the study cannula (Figure 2) was inserted subcutaneously into the abdomen and connected to the pump.
- A standardized meal was then eaten, and an insulin bolus delivered through the study cannula. Venous glucose was then measured 15-minutely by YSI 2300 Stat Plus and by glucometer (Roche Accu Check Guide). Following two days of free living, a second meal test was performed on Day 4.
- A Dexcom G6 sensor was inserted during run-in and worn throughout the study. Insulin dosing was manually determined.
- Sensor data from the study cannula was post-processed using a preliminary algorithm to calculate glucose using a single calibration during the 30-minute warm-up.

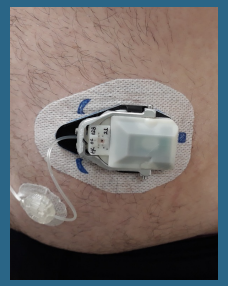

Figure 2: Prototype **SynerG™** study cannula with transmitter

RESULTS

Eight subjects (mean ± SD age 45.6 ± 12.4 years, HbA1c 7.2 ± 0.7%) have been studied to date.

GLUCOSE SENSOR RESULTS

- A total of 362 paired sensor data points with YSI as comparator have been analyzed (Table 1).
- For the four day study sensor duration, individual device **mean absolute average difference (MARD)** ranged between **11.7% to 18.6%,** compared to **YSI as benchmark** (Table 1).
- No artefactual calculated sensor glucose spikes were observed following insulin bolus (Figure 3).

	%-MARD vs. BG			*%-MARD vs. YSI*		
ID	**Dexcom G6**	**SynerG™**	**BG (n)**	**Dexcom G6**	**SynerG™**	**YSI (n)**
SV03	7.8	**14.4**	84	9.7	11.9	45
SV04	6.8	**16.3**	88	11.4	16.2	45
SV05	26.8	**15.5**	85	26.7	14.9	46
SV06	8.6	**15**	90	8.4	11.7	45
SV07	9.1	**12.7**	88	6.8	12.6	46
SV08	12.2	**13**	78	12.2	12.3	44
SV09	16.6	**11.9**	101	17	13.3	45
SV10	7.5	**19**	102	5	18.6	46
Overall	**11.9 ***	**14.7 ***	**716**	**12.2 ***	**13.9 ***	**362**

Table 1: Individual device MARD compared to BG and YSI as benchmark. *Non-weighted average of individual devices' MARD

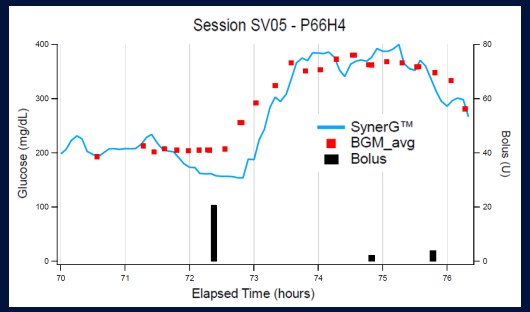

Figure 3: Participant SV05 study sensor results during a meal test

INSULIN DELIVERY RESULTS

- Comparing the run-in period to the study period (study cannula), there was no significant difference in insulin total daily dose (TDD), Dexcom G6 sensor time in range 70-180mg/dL (TIR) or mean sensor glucose (Table 2).
- These results suggest there was **no compromise in insulin delivery or glucose results while using study cannula**

	Run-in	***Study cannula* (SynerG™)**	***p-value***
TDD (units)	59 [35.9, 74.7]	66.3 [36.7, 73.6]	0.401
TIR (%)	57.3±20.7	46.4±25.1	0.440
Dexcom G6 mean sensor glucose (mg/dL)	167.4±30.6	185.4±32.4	0.476

Table 2: Comparison of TDD, TIR and mean sensor glucose between run-in vs the study cannula. Results expressed in mean± SD or median [IQR]

CONCLUSION

- Initial feasibility data supports successful function of this glucose-sensing and insulin delivering cannula. Algorithm development is underway aimed at improving sensor accuracy.