Significant Improvements in Time Above Range Using Control-IQ Technology: Real-World Insights

Harsimran Singh PhD,* Molly McElwee Malloy RN, CDCES,* Lars Mueller PhD,† Leslee Willes MS,‡ Steph Habif EdD, MS*

Introduction

Untreated hyperglycemia is a key risk factor for the development of diabetes complications. Internationally recognized consensus guidelines for time above range (TAR) recommend less than 25% of all continuous glucose monitoring (CGM) readings as a target for sensor glucose range >180 mg/dL and less than 5% of all CGM readings for sensor glucose >250mg/dL.

The t:slim X2™ insulin pump with Control-IQ™ technology is an advanced hybrid closed-loop system designed to help improve time in range (TIR) (70-180 mg/dL).§

Aim

To evaluate the effect of Control-IQ technology on TIR and TAR in people with type 1 diabetes (T1D) who were not meeting the TAR targets (i.e. <25% of sensor glucose time >180 mg/dL and <5% of sensor glucose time >250 mg/dL).

Method

This study was part of a larger project that examined glycemic data from participants with T1D at three time points:

- **Time Point 1 (T1):** 30 days pre-Control-IQ technology,
- **Time Point 2 (T2):** 3 weeks of Control-IQ technology, and
- **Time Point 3 (T3):** Additional 4 weeks of Control-IQ technology from Time Point 2.

This presentation involves study participants who, at T1, had spent ≥25% of their sensor glucose time >180 mg/dL or ≥5% of their sensor glucose time >250 mg/dL. Analysis results are presented for participants who then met TAR targets at T3 (i.e. <25% sensor glucose time >180 mg/dL [Group 1] or <5% sensor glucose time >250 mg/dL at T3 [Group 2]).

Data was captured from the t:connect™ web application from Tandem Diabetes Care (February – April 2020).

Participants' scores on the Diabetes Impact and Device Satisfaction scale (patient-reported outcome measure) were also available for T2 and T3. Outcomes are presented as mean ± standard deviation (SD) and median (IQR). Wilcoxon-signed rank tests were performed to analyze the change from T1 to T3. Data were analyzed using SAS, Version 9.4.

TABLE 1: Improvements in Glycemic Outcomes. For participants who did not meet the TAR goals (<25% of sensor glucose time >180 mg/dL for Group 1 and <5% of sensor glucose time >250 mg/dL for Group 2) at T1 but met these goals at T3 using the t:slim X2 insulin pump with Control-IQ technology.

	Group 1 (n=310)				Group 2 (n=277)			
	T1	T2	T3	Change^	T1	T2	T3	Change^
Mean TIR ± SD	63.5 ± 8.9	77.3 ± 6.3	80.2 ± 4.6	**16.8 ± 9.2**	61.4 ± 10.1	76.2 ± 7.1	78.5 ± 5.7	**17.1 ± 10.0**
Median TIR (IQR)	65.9 (59.0, 70.3)	77.3 (74.1, 81.6)	79.3 (76.8, 83.5)	**15.4 (10.3, 20.7)**	62.5 (55.7, 69.4)	76.3 (73.0, 81.3)	78.3 (74.7, 82.0)	**16.2 (10.3, 21.9)**
Mean TAR ± SD	35.0 ± 9.3	21.0 ± 6.3	18.1 ± 4.6	**-16.9 ± 9.4**	10.2 ± 5.8	3.9 ± 2.6	2.8 ± 1.3	**-7.4 ± 5.7**
Median TAR (IQR)	32.2 (28.1, 39.2)	21.0 (17.1, 24.3)	19.1 (14.7, 21.4)	**-15.5 (-21.0, -10.1)**	8.4 (6.5, 11.7)	3.3 (2.2, 5.2)	2.9 (1.7, 3.9)	**-5.9 (-8.6, -3.9)**

FIGURE 1: Box Plots for Group 1 Showing Percentage of Time in Range (■) and Time Above Range (■). Data from time points T1, T2, and T3.

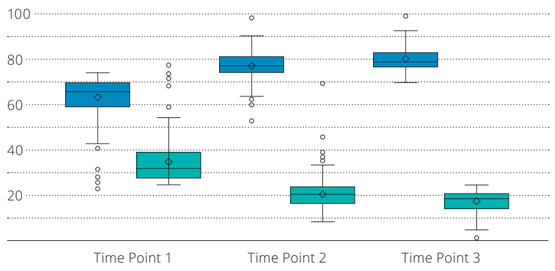
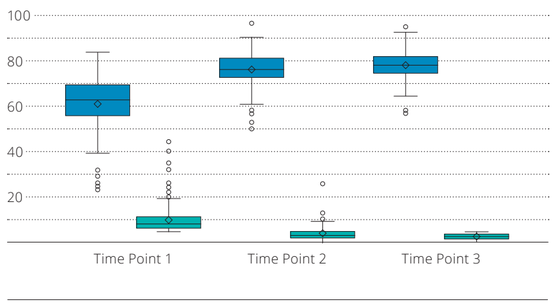


FIGURE 2: Box Plots for Group 2 Showing Percentage of Time in Range (■) and Time Above Range (■). Data from time points T1, T2, and T3.



Results

At T1, of all 1,127 participants, 658 participants spent ≥25% of their sensor glucose time at >180 mg/dL and 592 participants spent ≥5% of sensor glucose time >250 mg/dL.

GROUP 1

Glycemic Outcomes: Using Control-IQ technology, 310 of 658 participants (47.1%) met the TAR target (<25% TAR) at T3 and demonstrated a median (IQR) TIR change of +15.4% (10.3, 20.7) at T3 (79.3% [76.8, 83.5]) from T1 (65.9% [59.0, 70.3]). (Table 1, Figure 1)

Patient Reported Outcomes: Mean device satisfaction increased from 9.08 (± 0.96) to 9.23 (± 0.87) at T3 (p<.0001) and diabetes impact was reduced from 2.80 (± 1.36) to 2.65 (± 1.32) (p=0.03).

GROUP 2

Glycemic Outcomes: 277 of 592 participants (46.8%) met their TAR target (<5% TAR) at T3 and showed a median (IQR) TIR change of +16.2% (10.3, 21.9) at T3 (78.3% [74.7, 82.0]) from T1 (62.5% [55.7, 69.4]). (Table 1, Figure 2)

Patient Reported Outcomes: Device related satisfaction improved at T3 (9.21 ± 0.93) from T2 (9.08 ± 1.05) (p=0.004) and diabetes impact reduced from 2.83 (± 1.46) at T2 to 2.76 (± 1.36) at T3 (p=0.49).

Conclusions

Use of Control-IQ technology **demonstrated significant and clinically valuable improvements in hyperglycemia and TIR outcomes in T1D participants who did not previously meet guideline TAR targets.§** Glycemic improvements in participants were supported by significant reductions in diabetes-related impact and improvements in device satisfaction. These findings underline reduced burden of diabetes and high user acceptance of Control-IQ technology in study participants.

* Tandem Diabetes Care. † UC San Diego Design Lab Center for Health. ‡ Willes Consulting Group, Inc. § As measured by CGM. ^ p = <.0001 (p-value is from a Wilcoxon signed-rank test).

References: 1. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range. *Diabetes Care.* 2019;42(8):1593-1603. **2.** Marcovechhio ML. Complications of acute and chronic hyperglycemia. *US Endocrinology.* 2017;13(1):17–21. **3.** Brown SA, Kovatchev BP, Raghinaru D, et al. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Eng J Med.* 2019;381(18):1701-1717.