TANDEM Diabetes Care

AMERICAN DIABETES ASSOCIATION'S 2023 ANNUAL MEETING

Mobile Bolus Feature Improves Bolus Behavior in Control-IQ Technology Users who Bolus <3 Times/Day

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positively different

Photography Allowed

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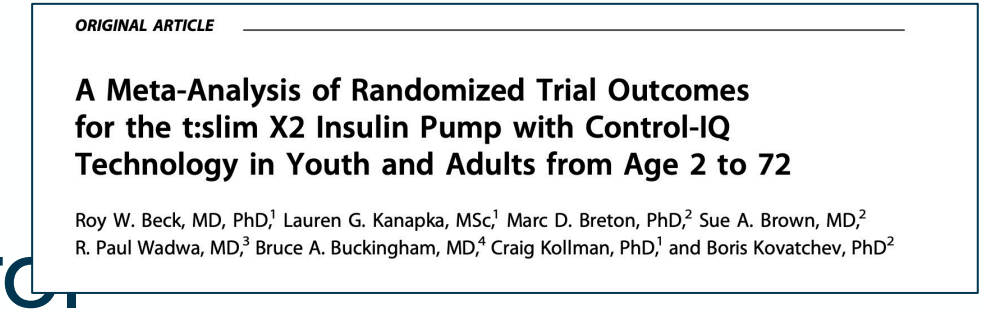
Disclosures

Employee and Shareholder of Tandem Diabetes Care

BACKGROUND

Control-IQ technology improves glycemic control in clinical trials …



ORIGINAL ARTICLE

A Meta-Analysis of Randomized Trial Outcomes for the t:slim X2 Insulin Pump with Control-IQ Technology in Youth and Adults from Age 2 to 72

Roy W. Beck, MD, PhD,[1] Lauren G. Kanapka, MSc,[1] Marc D. Breton, PhD,[2] Sue A. Brown, MD,[2] R. Paul Wadwa, MD,[3] Bruce A. Buckingham, MD,[4] Craig Kollman, PhD,[1] and Boris Kovatchev, PhD[2]

- **Meta-analysis** of 3 RCTs for PWD ages 2-75 years old:
  - Time in range (TIR) increased mean adjusted group difference of +11.5% (95% CI +9.7-+13.2%)
  - Across all age ranges, race-ethnicities, household income, pre-study insulin method
  - Participants with higher baseline A1c showed the greatest improvements

… and has been used for 125 million* patient days in the real world!

*Data on file as of 05/2023, Tandem Diabetes Care

Beck RW, Kanapka LG, Breton MD, et al. A Meta-Analysis of Randomized Trial Outcomes for the t:slim X2 Insulin Pump with Control-IQ technology in Youth and Adults from Age 2 to 72. *Diabetes Technol Ther*. 2023;25(5):329-342. doi: 10.1089/dia.2022.0558

Control-IQ technology is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. It is for single-patient use and use with U-100 insulin only.

BACKGROUND

t:slim X2 pump with Control-IQ technology: advanced hybrid closed loop

- Automatically adjusts basal insulin based on 30-minute predicted glucose every five minutes
- Two types of boluses:
  - Automatic correction boluses – automatically delivered up to once/hour when glucose predicted to be >180 mg/dL in 30 minutes
  - User-given boluses:
    - For carbohydrate consumption
    - For high glucose correction

BACKGROUND

Bolus behavior impacts glucose outcomes

Study with real-world Control-IQ technology users (n=30)

- Participants divided into those who gave a **larger, medium, and lower proportion** of user-initiated boluses
- TIR improved across all three group
- PWD with low bolus frequency improved TIR with Control-IQ technology use, they still had the lowest overall TIR …

… meaning that bolus behavior still matters

ORIGINAL ARTICLE

Efficacy and Safety of Tandem Control IQ Without User-Initiated Boluses in Adults with Uncontrolled Type 1 Diabetes

Halis Kaan Akturk, MD, Janet Snell-Bergeon, PhD, and Viral N. Shah, MD

TANDEM CONTROL IQ WITHOUT USER-INITIATED BOLUSES 781

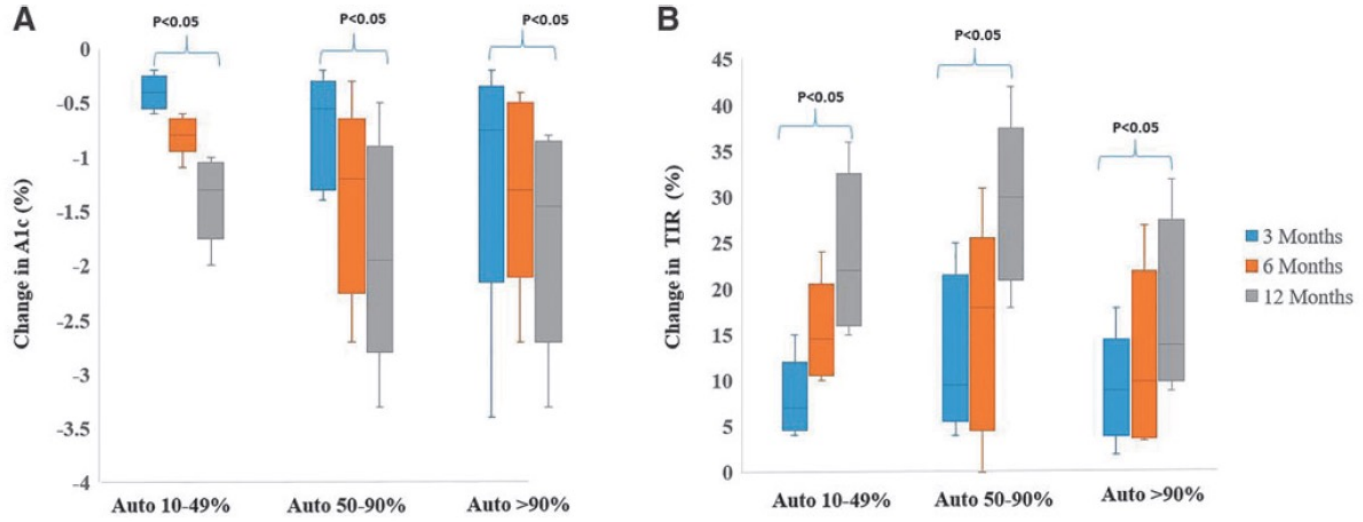


FIG. 1. Change in A1c **(A)** and percent TIR (70–180 mg/dL) **(B)** over 12 months between high bolusing (auto 10%–49%), intermediate bolusing (auto 50%–90%), and nonbolusing (auto >90%) group. TIR, time in target range.

Akturk HK, Snell-Bergeon J, Shah VN. Efficacy and Safety of Tandem Control IQ Without User-Initiated Boluses in Adults with Uncontrolled Type 1 Diabetes. *Diabetes Technol Ther*. 2022;24(10):779-783. doi: 10.1089/dia.2022.0162

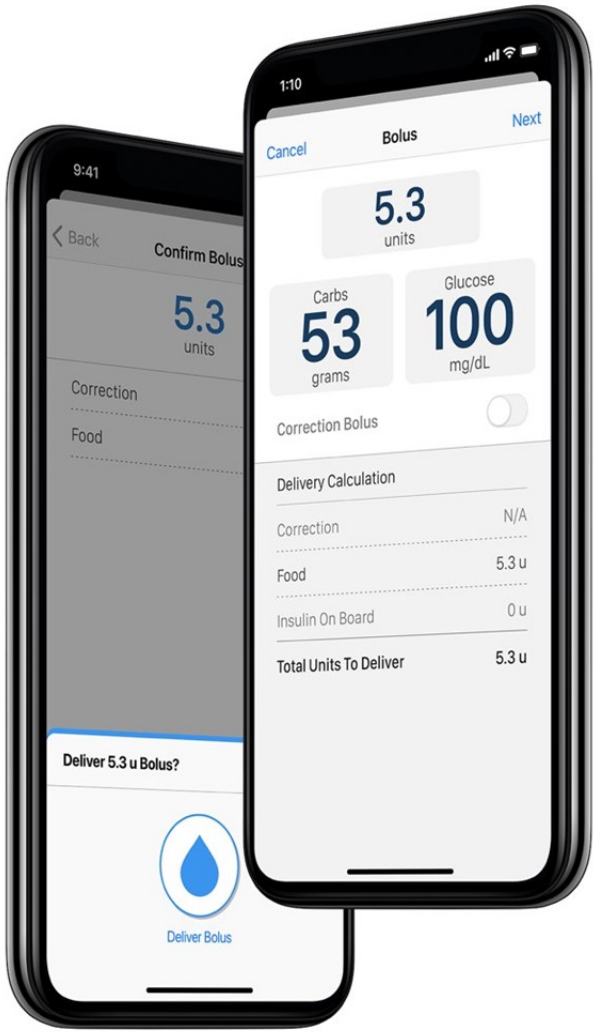
BACKGROUND

Can design affect bolus behavior?

Summer 2021: Smartphone application for the t:slim X2 pump with Control-IQ technology became available

- Secondary display of glucose information
- mobile uploading to t:connect software

Summer 2022: Mobile bolus feature introduced with software update*

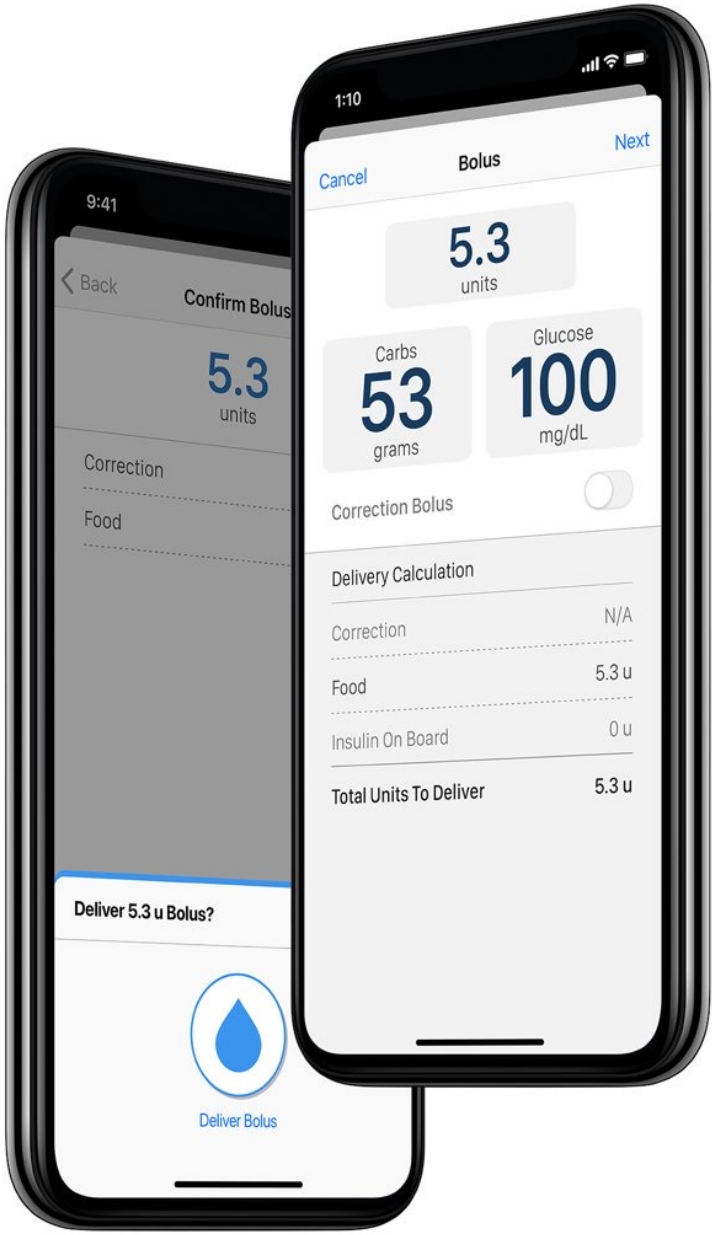


* Bolus delivery from the t:connect mobile app requires a compatible smartphone model and operating system, an app update, a remote software update on the t:slim X2 insulin pump and additional training. Only available to customers who reside in the United States.

t:connect mobile app

- Discreet **secondary display** of the pump
- **View pump data:** Basal and bolus events, insulin on board, carbs, current settings, and both pump and sensor status directly on the phone
- **Wirelessly uploads** pump data to the cloud-based t:connect web application
- No need to plug in pump during office visits
- More than 40 available smartphones for both iOS and Android

* Bolus delivery from the t:connect mobile app requires a compatible smartphone model and operating system, an app update, a remote software update on the t:slim X2 insulin pump and additional training. Only available to customers who reside in the United States.



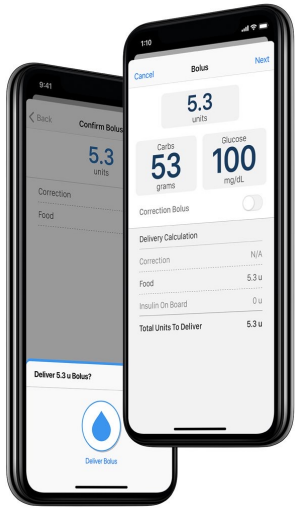
ADDITION OF MOBILE BOLUS:

+ Ability to request and cancel a bolus
+ App Guide

Study Aim

+ How does a mobile bolus (MB) option affect bolus behaviors in users of Control-IQ technology?

+ Does mobile bolus feature impact the bolus frequency in individuals with low bolus frequency?



METHODS

Study methods

+ Retrospective analysis of de-identified Control-IQ technology users from the Tandem t:connect web application

+ Selection criteria:
  - **Greater than** 21 days with 70% CGM data PRIOR to updating smartphone app to MB
  - **Greater than** 21 days with 70% CGM data AFTER to updating smartphone app to MB
  - **Fewer than** three user-initiated boluses/day at baseline

METHODS

Analysis

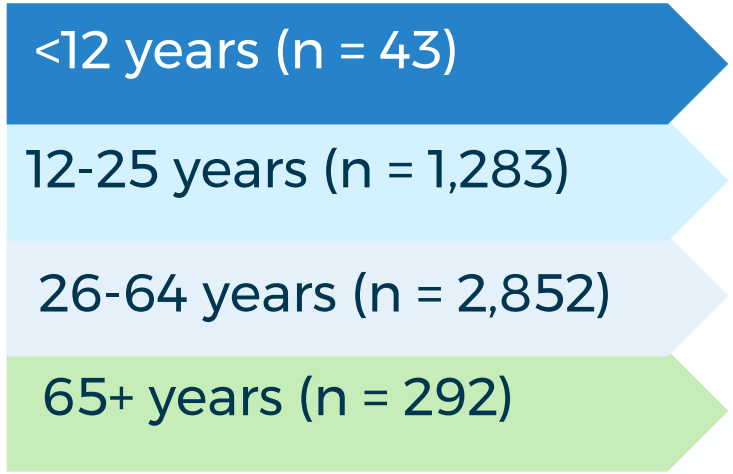
+ Stratified by age group

+ Pre-post analysis:
  - Number of user-given boluses
  - % of bolus insulin given by user-initiated boluses vs. automatic correction bolus
  - TIR 70-180 mg/dL, user satisfaction scores

Control-IQ technology is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. It is for single-patient use and use with U-100 insulin only.

Results: Demographics

- N=4,470
- Average age 37.4 ± 16.3 (range 3 to 89 years)



- 56.6% female
- 89.7% type 1 diabetes

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Results:
Did MB increase number of boluses?

Yes.

Results:
Low bolusers increased bolusing with MB feature

	User-given boluses (Median [IQR])	
	Pre-MB	**Post-MB**
Overall	2.2 (1.6-2.6)	
<12 years (n = 43)	2.5 (2.1-2.9)	
12-25 years (n = 1,283)	2.1 (1.5-2.6)	
26-64 years (n = 2,852)	2.2 (1.6-2.6)	
65+ years (n = 292)	2.4 (1.8-2.7)	

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Results:
Low bolusers increased bolusing with MB feature

User-given boluses (Median [IQR])

	Pre-MB	Post-MB
Overall	2.2 (1.6-2.6)	2.7 (2.0-3.3)
<12 years (n = 43)	2.5 (2.1-2.9)	3.0 (2.4-3.7)
12-25 years (n = 1,283)	2.1 (1.5-2.6)	2.6 (1.9-3.3)
26-64 years (n = 2,852)	2.2 (1.6-2.6)	2.7 (2.0-3.4)
65+ years (n = 292)	2.4 (1.8-2.7)	2.9 (2.3-3.4)

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Results:
Low bolusers increased bolusing with MB feature

	User-given boluses (Median [IQR])		Change in user-given boluses	
	Pre-MB	**Post-MB**	**Δ**	**% Δ**
Overall	2.2 (1.6-2.6)	2.7 (2.0-3.3)	0.48***	22.1%
<12 years (n = 43)	2.5 (2.1-2.9)	3.0 (2.4-3.7)	0.45***	17.9%
12-25 years (n = 1,283)	2.1 (1.5-2.6)	2.6 (1.9-3.3)	0.47***	22.2%
26-64 years (n = 2,852)	2.2 (1.6-2.6)	2.7 (2.0-3.4)	0.52***	23.5%
65+ years (n = 292)	2.4 (1.8-2.7)	2.9 (2.3-3.4)	0.53***	22.6%

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Results:

How many of those boluses were given by the smartphone app?

Results:
Approx 1 bolus/day delivered by MB

Overall	1.0 (0.4-1.7) bolus/day
<12 years (n = 43)	0.7 (0.3-1.6) boluses/day
12-25 years (n = 1,283)	1.0 (0.5-1.8) bolus/day
26-64 years (n = 2,852)	0.9 (0.4-1.7) boluses/day
65+ years (n = 292)	1.1 (0.3-2.0) boluses/day

Control-IQ technology is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. It is for single-patient use and use with U-100 insulin only.

Results:
TIR and user satisfaction?

+ Trend toward increased TIR:
  - Children <12 years old experienced 38 more minutes/day in range

+ User satisfaction:
  - 87% reported satisfaction or high satisfaction with the MB feature

Control-IQ technology is intended for the management of type 1 diabetes mellitus in persons six years of age and greater. It is for single-patient use and use with U-100 insulin only.

Conclusion/Summary

- The addition of the MB feature **increased the number of boluses/day in those with low bolus frequency**
- While ~1 bolus/day given by MB, perhaps over time this number will increase as new muscle memory and automatic behaviors form
- Behavioral design strategies like mobile bolus can help lower burden of diabetes care for PWD
- **Further directions:** Explore how to leverage this to meaningfully increase glycemic outcomes in people with diabetes

RESPONSIBLE USE OF CONTROL-IQ TECHNOLOGY

Control-IQ technology does not prevent all highs and lows. Users must still bolus for meals and actively manage their diabetes. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

Important Safety Information: RX ONLY. The t:slim X2 pump and Control-IQ technology are intended for single patient use. The t:slim X2 pump and Control-IQ technology are indicated for use with U-100 insulin only. t:slim X2 insulin pump: The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The t:slim X2 pump is indicated for use in individuals six years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (iCGM, sold separately) and ACE pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons six years of age and greater.

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 55 pounds.

Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and Control-IQ technology must: use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump, and the CGM transmitter and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

t:connect mobile app: The feature set available within the t:connect mobile app is dependent on the pump software version and the compatible smartphone's model and operating system (OS).

- The **Display and Data Upload** feature set provides a secondary display of pump and continuous glucose monitoring (CGM) information, including display of your pump alerts and alarms, and enables wireless uploading of pump and CGM data to the Tandem cloud through an internet or wireless data connection. Standard carrier data rates may apply.
- The **Bolus Delivery plus Display and Data Upload** feature set additionally allows users to request, stop, and cancel a bolus on the pump from the t:connect mobile app. At least one smartphone security setting must be enabled to utilize the Bolus Delivery feature of the t:connect mobile app.
- **WARNING**: Always rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.
- **PRECAUTIONS**: Always rely on your pump to make therapy decisions if using a smartphone that is incompatible, the smartphone is lost or damaged, or the smartphone loses *Bluetooth®* connectivity with your pump. Important pump alerts and alarms are only received as app notifications when enabled and the app is either active or running in the background.