



Tandem Diabetes Care Announces NEJM Publication of Study Demonstrating Increased Time in Range in Young Children with Type 1 Diabetes Using the t:slim X2 Insulin Pump with Control-IQ Technology

March 15, 2023

SAN DIEGO--(BUSINESS WIRE)--Mar. 15, 2023-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced publication of results from the Pediatric Artificial Pancreas (PEDAP) Clinical Trial by the *New England Journal of Medicine* showing an approximate 3-hour per day increase in time in range* in children ages 2-5 years old using the t:slim X2 insulin pump with Control-IQ advanced hybrid closed-loop technology** compared to those on a standard insulin pump or multiple daily injections. All participants were using a Dexcom G6 Continuous Glucose Monitoring (CGM) System.

Results observed in this randomized, controlled trial for subjects using Control-IQ technology, an automated insulin delivery (AID) system, were immediate, sustained, and observed across the spectrum of patient characteristics including race-ethnicity, parental education, family income, baseline glycated hemoglobin level, virtual vs. in-person training format, and pre-study insulin delivery method. Subjects with higher baseline hemoglobin A1c values (A1c) experienced greater improvements in time in range and A1c during the study.

"The safety and efficacy outcomes observed in this study support using Control-IQ technology for young children with type 1 diabetes to enhance quality of life and minimize the risk of long-term complications," said Dr. R. Paul Wadwa, Professor of Pediatrics at the Barbara Davis Center for Diabetes, University of Colorado Anschutz Medical Campus and protocol chair for the PEDAP Clinical Trial. "Studies using Control-IQ technology have shown impressive results in different age groups, now in a sequence of randomized controlled trials published by the New England Journal of Medicine, demonstrating more time in range with low risk of hypoglycemia."

"After the resounding success of Control-IQ technology in people ages six and up, it is very rewarding to see our youngest patients, and often the most challenging patients to help, benefit as well," said Dr. Marc Breton, the Associate Director for Research of The Center for Diabetes Technology at the University of Virginia, and the Principal Investigator of the PEDAP study. "With these results, we have now accumulated years of clinical validation of this system across all age groups and look forward to seeing this life changing technology made available to the broadest possible population."

"Use of the t:slim X2 insulin pump with Control-IQ technology demonstrated substantial improvements in glucose control, particularly overnight, with no increase in hypoglycemia in young children," said Jordan Pinsker, MD, Vice President and Medical Director at Tandem Diabetes Care. "Initiating pump therapy with automated insulin delivery can be very daunting for parents. A system offering these clinical benefits that is simple enough to start with virtual training makes the t:slim X2 insulin pump an excellent therapeutic option for this population."

Key Data Highlights

Glycemic Control Over 13 Weeks

- Mean time in range with Control-IQ technology increased from 57 percent at baseline to 69 percent during follow-up compared to 55 percent to 56 percent in the control group, for a mean adjusted difference of 12.4 percent.
- Hemoglobin A1c decreased 0.5 percent from baseline with Control-IQ technology, a median improvement of 0.42 percent compared to the control group.
- Time spent in hyperglycemia (>250 mg per deciliter) was 5.4 percentage points less with Control-IQ technology than the control group.
- Time spent in hypoglycemia (<70 mg per deciliter) was low but not significantly different between groups.
- Results with Control-IQ technology were immediate (evident within 1 day of initiation) and sustained.
- Nighttime mean time in range was 74 percent with Control-IQ technology versus 56 percent in the control group and daytime was 67 percent versus 56 percent, respectively.
- Total daily insulin dose and weight change appeared similar between the Control-IQ technology and standard care groups.

System Performance and Useability

- The median time the system was in active closed loop was 94 percent.
- Results were observed regardless of pre-study experience with an insulin pump.
- The 13-week trial was completed by all but one patient (101 of 102 enrolled.)

This was a 13-week randomized, multi-center trial, featuring 101 children age 2 to <6 years old with type 1 diabetes. Patients previously using a hybrid closed-loop system were excluded. Participants were assigned two to one to Closed Loop Control (N=68) or Standard Care (N=34) which included either an insulin pump or multiple daily injections of insulin plus a CGM. Baseline glycated A1c levels ranged from 5.2 percent to 11.5 percent. Clinical training was virtual for 81 percent of the participants using Control-IQ technology and follow-up visits were 91 percent virtual.

This study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through grant [U01DK127551](#). Product support was provided by Tandem Diabetes Care and Dexcom, Inc.

These data will be published in the March 16, 2023 issue of *The New England Journal of Medicine*.

Study Reference:

Wadwa RP, Reed ZW, Buckingham BA, et al. Trial of Hybrid Closed-Loop Control in Young Children with Type 1 Diabetes. *N Engl J Med*. 2023;388:991-1001. DOI: 10.1056/NEJMoa2210834

Results from the Protocol 3 study (DCLP3) of the International Diabetes Closed Loop (iDCL) trial evaluating the use of Control-IQ technology in ages 14 and up, and from the Protocol 5 study (DCLP5) of the iDCL trial studying use in ages 6 to 13 were published by the *New England Journal of Medicine* in [October 2019](#) and [August 2020](#) respectively.

* Time in range is defined as 70-180 mg/dL and is measured by CGM.

** The algorithm used in this study was identical to the commercial version of Control-IQ technology, except for the ability to enter a lower body weight and total daily insulin value at system initialization.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc., a global insulin delivery and diabetes technology company based in San Diego, California, creates new possibilities for people living with diabetes, their loved ones, and healthcare providers through a positively different experience. The company's human-centered approach to design, development, and support delivers innovative products and services for people who use insulin. Tandem manufactures and sells the t:slim X2 insulin pump with Control-IQ technology. For more information, visit [tandemdiabetes.com](#).

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #t:slimX2, and #TandemDiabetes.

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Forward-looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements relate to, among other things, our goal to establish that Control-IQ technology could be a powerful management solution for therapy needs of children age 2 to <6 years old with type 1 diabetes. These forward-looking statements are subject to numerous risks and uncertainties, including risks associated with the research and development process generally, such as the design, testing and validation of products and related systems in compliance with applicable regulatory and legal requirements in the markets that we serve, the real-world clinical benefits from use of Control-IQ technology may not match the results reported in the study and the level of customer satisfaction from the use of our products and features may be different from what we expect, our ability to develop, scale and maintain systems, personnel and infrastructure to support customers across diverse geographies and market segments, as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and other documents that we file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Actual results could differ materially from those anticipated or projected in the forward-looking statements. Tandem undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

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.

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