

Study Objective:

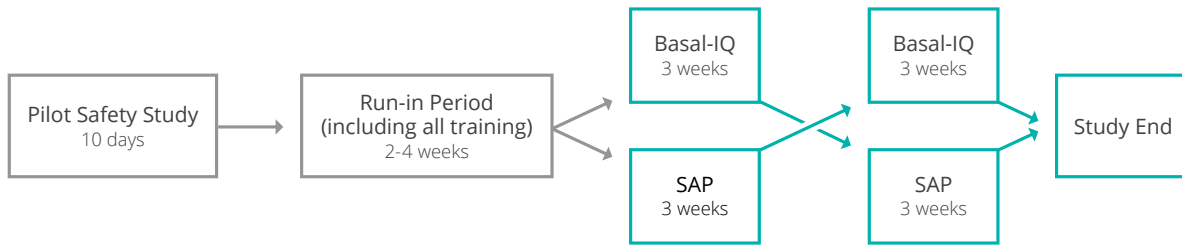
Determine the safety and efficacy of a predictive low glucose suspend algorithm (**Basal-IQ™ Technology**) integrated with the t:slim X2™ Insulin Pump to minimize hypoglycemia using automatic insulin suspension when sensor glucose is predicted to be less than 80 mg/dL within 30 minutes and resuming when sensor glucose rises.

Inclusion Criteria:

- Diagnosis of Type 1 for at least one year
- Age ≥ 6
- Insulin pump or multiple daily injections
- CGM user or naïve
- **No HbA1C restrictions**

Study Methods:

Randomized, cross-over trial of 102 patients assigned to use either the Basal-IQ pump or a sensor-augmented pump (SAP) at home for three weeks. After the first three weeks, participants were switched to the other therapy.

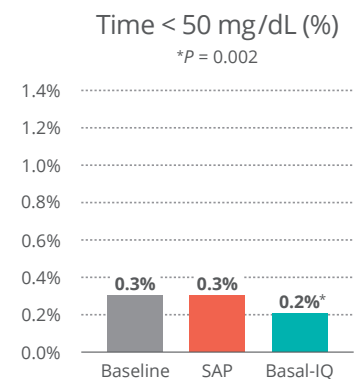
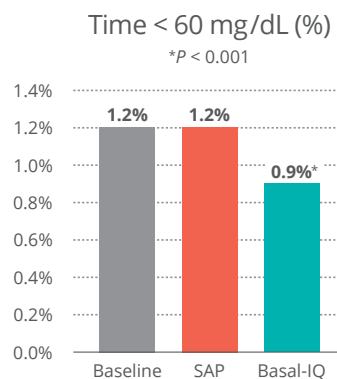
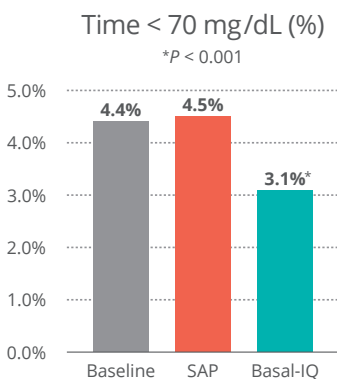


Results

Reduced Rates of Hypoglycemia

Results showed a 31% relative reduction overall in sensor time below 70 mg/dL in the Basal-IQ arm. There was a 40% relative reduction in sensor time below 70 mg/dL in those who experienced more hypoglycemia during the run-in period (baseline). Reductions in hypoglycemia were observed in all subgroups analyzed, regardless of previous pump and/or CGM therapy.

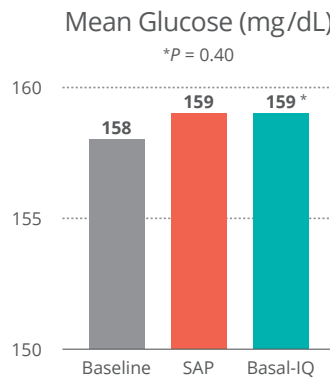
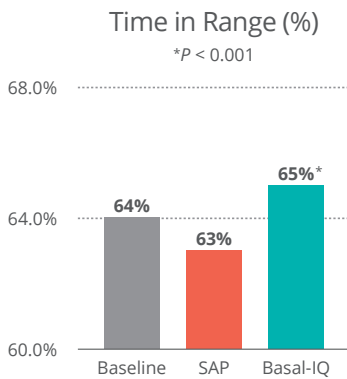
31%
Reduction
in sensor time
below 70 mg/dL



Results (Continued)

Improved Glycemic Control

Mean time in range (70-180 mg/dL) improved in the Basal-IQ arm by 2%, which equates to 30 more minutes per day of time spent in the target range. Additionally, there was no difference in the mean glucose concentration between the Basal-IQ and SAP arms. These findings are in contrast to several published studies on PLGS systems^{2,3} that found an increased mean glucose and a decreased time in range and reflect the lack of rebound hyperglycemia observed during use of the Basal-IQ system.



No Evidence of Rebound Hyperglycemia

Simple to Learn and Use

At the conclusion of the study, participants completed a System Usability Questionnaire,⁴ a highly validated tool for measuring ease of use. The system was found to be exceptionally easy to use.



Confidence

Participants felt very confident using the system.

93%

thought they would like to use the system frequently.

91%

thought the system was easy to use.

90%

did not feel they had to learn a lot before getting started with the system.

95%

did not think they would need the support of a technical person to use the system.



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1. Forlenza GP, Li Z, Buckingham BA, Pinsky JE, et al. Predictive low glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial. *Diabetes Care*. 2018 [In Press]. 2. Zhong A, Choudhary P, McMahon C, et al. Effectiveness of Automated Insulin Management Features of the MiniMed® 640G Sensor-Augmented Insulin Pump. 2016;18:657-663. 3. Choudhary P, Olsen BS, Conget I, et al. Hypoglycemia Prevention and User Acceptance of an Insulin Pump System with Predictive Low Glucose Management. 2016;18:288-291. 4. Pinsky JE, et al. Exceptional Usability of Tandem t:slim X2 Insulin Pump with Basal-IQ Predictive Low Glucose Suspend (PLGS): The PROLOG Study. Poster presented at: American Diabetes Association 78th Scientific Sessions; June 22-26, 2018; Orlando, FL.

RX ONLY. The t:slim X2 Insulin Pump with Basal-IQ Technology (the system) consists of the t:slim X2 Insulin Pump which contains the Basal-IQ technology, and a continuous glucose monitor (CGM). The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the t:slim X2 Insulin Pump with Basal-IQ Technology system. When the System is used with a compatible iCGM, the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings. Interpretation of the System results should be based on the trends and patterns seen with several sequential readings over time. CGM also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Compatible iCGM systems are intended for single patient use and require a prescription. The System is indicated for use in individuals 6 years of age and greater. The System is intended for single patient use and requires a prescription. The System is indicated for use with NovoLog or Humalog U-100 insulin. For detailed indications for use and safety information, call Tandem Toll-Free at (877) 801-6901 or visit www.tandemdiabetes.com/safetyinfo.