

Safety and Glycaemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children With Type 1 Diabetes: A Single-Arm Multicenter Clinical Trial

- **Clinical objective:** to assess the safety and efficacy of the Omnipod® 5 Automated Insulin Delivery (AID) System, the first tubeless, on-body AID system with customizable glycaemic targets, in very young children with type 1 diabetes.
- **Primary end points** were:
 - HbA1c at the end of the AID phase compared with baseline
 - Time in Range 70–180 mg/dL (3.9–10.0 mmol/L) during the AID phase compared with the ST phase
 - Incidence rates of severe hypoglycaemia or diabetic ketoacidosis (DKA).
- **Secondary end points** included percent time with glucose levels <70 mg/dL (<3.9 mmol/L) and >180 mg/dL (>10.0 mmol/L) during the AID phase compared with the ST phase.

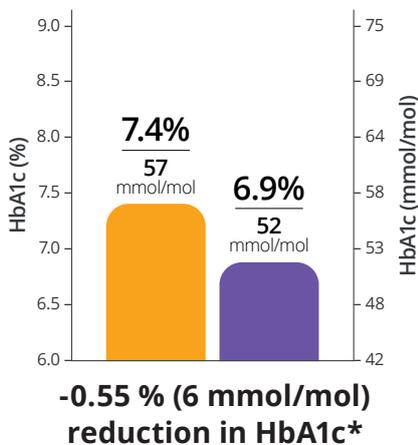
Study Design

- Multicenter, single-arm outpatient study:
 - 14-day standard therapy (ST) phase
 - 3-month AID phase with Omnipod 5 system
- No requirement for minimum body weight or total daily dose of insulin

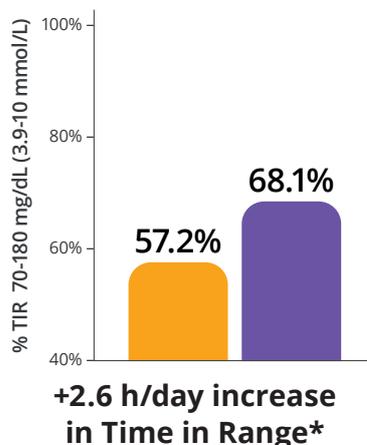
Study Participants

- 80 Children with Type 1 diabetes: Age 2.0–5.9 years, with caregiver informed consent
- HbA1c <10% (86 mmol/mol) at screening
- Prior pump or CGM use not required
- Exclusion criteria: history of DKA or severe hypoglycaemia in the past 6 months

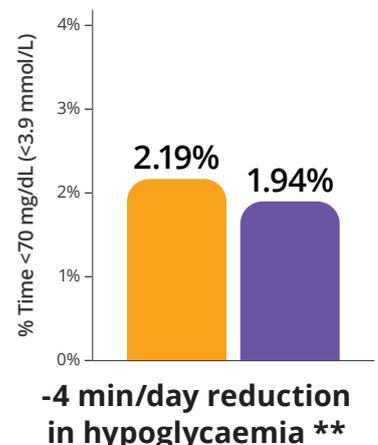
Reduction in HbA1c



Improved Time in Range (TIR)



Minimal Hypoglycaemia



● Standard Therapy phase ● Omnipod 5 System phase

* p<0.0001; ** p=0.02 Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data Shown as median for time <70 mg/dL (<3.9 mmol/L) and mean for all other outcomes.

There were no episodes of Severe Hypoglycaemia or DKA in the AID phase.

Study Highlights:

- Compared to the ST phase the Omnipod 5 System lowered HbA1c, increased Time in Range and reduced hypoglycaemia in very young children with Type 1 diabetes
- Time in Range overnight (00:00 - 06:00 h) increased from 58.2% (ST phase) to 81.0% (Omnipod 5 phase)
- There were no episodes of Severe Hypoglycaemia or DKA in the AID phase
- The proportion of children meeting consensus targets for HbA1c <7.0% (53 mmol/mol) increased from 31% with usual therapy to 54% after using the Omnipod 5 System
- The proportion of children meeting targets for >70% Time in Range increased 2.5-fold from 17.5% with usual therapy to 43.8% after using the Omnipod 5 System
- Median time in automated mode during the Omnipod 5 system phase was 97.8%
- Omnipod 5 System can be used safely and effectively in very young children with Type 1 diabetes



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This summary has been provided as part of the Omnipod Academy, an educational service provided for Healthcare Professionals by Insulet International.

References 1. Adapted from; Sherr JL, et al. Safety and Glycemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children With Type 1 Diabetes: A Single-Arm Multicenter Clinical Trial. *Diabetes Care* 2022; 45:1907-1910.

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