

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 results** from a prospective multicenter, single-arm, outpatient study in 80 pre-school children with Type 1 diabetes.
- **The 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.

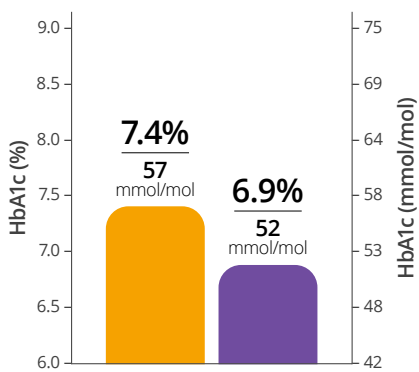
Study Design

- 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
- Unrestricted diet and exercise throughout

Study Participants

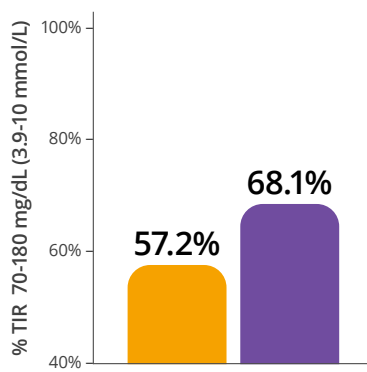
- 80 Children with Type 1 diabetes: Age 2.0–5.9 years, with caregiver informed consent
- HbA1c <10% (86 mmol/mol) at screening
- Prior pump or CGM use not required
- Exclusion criteria: history of DKA or severe hypoglycemia in the past 6 months

Reduction in HbA1c



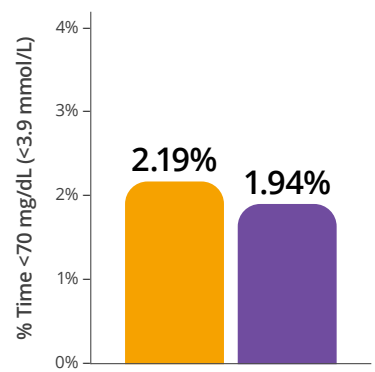
-0.55 % (6 mmol/mol) reduction in HbA1c*

Improved Time in Range (TIR)



+2.6 h/day increase in Time in Range*

Minimal Hypoglycaemia



-4 min/day reduction in hypoglycaemia **

● ST 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 ST 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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Omnipod® System
Availability guide



Please contact Geffen
Medical representative
for more information

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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