omnipod 5 automated insulin delivery system

Multicentre Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes

- **Clinical objective:** to evaluate the safety and efficacy of the Omnipod® 5 Automated Insulin Delivery (AID) System, the first tubeless, on-body AID system with customizable glycemic targets.
- **Primary endpoints** were changed in HbA1c at the end of the AID phase compared with baseline and Time in Range (TIR) 3.9–10.0 mmol/L during the AID phase compared with the Standard Therapy (ST) phase. Primary safety outcomes were incidence of severe hypoglycemia and diabetic ketoacidosis (DKA).
- **Secondary endpoints** included percent time with glucose levels <3.9 mmol/L, >10.0 mmol/L, and <3.0 mmol/L during the AID phase compared with the ST phase.
- **Significant improvements** in HbA1c and glycemic measures, with a low rate of hypoglycemia in a heterogeneous participant group with varied age, baseline glycemia, and prior insulin delivery regimen.

Study Design

- Prospective, multicentre, single-arm outpatient study:
  - 14-day ST phase
  - 3-month AID phase with Omnipod 5 system
- 240 children, adolescents, and adults enrolled at 17 institutions across the US
- User-selected target glucose ranges from 6.1–8.3 mmol/L
- Unrestricted diet and exercise throughout

Study Participants

- 112 Children: Age 6 to <14 years
- 128 Adolescents and Adults: Age 14 to 70 years
- All participants:
  - Type 1 diabetes for ≥6 months
  - HbA1c <10.0% (<86 mmol/mol)
  - Any prior insulin therapy (MDI or CSII)

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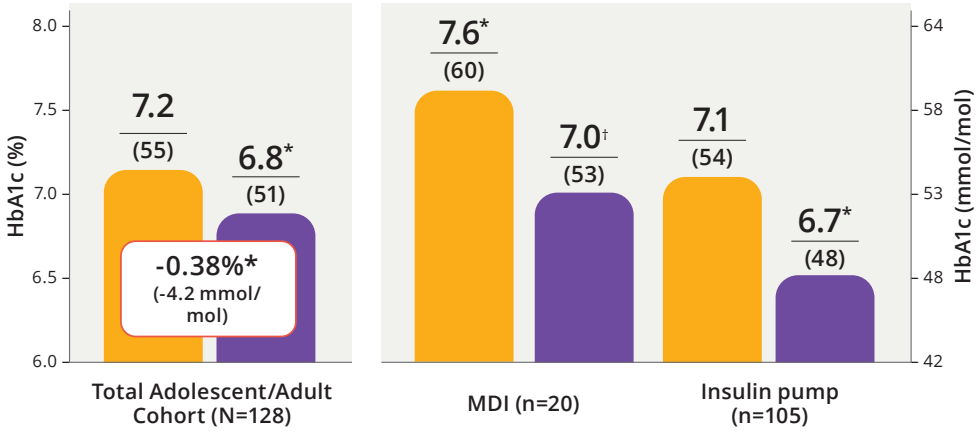
Omnipod 5 System reduced HbA1c

HbA1c is reduced by 0.38% (4.2 mmol/mol) in Adolescents and Adults[1]



ST phase Omnipod 5 System phase

Participant endorsement of the system was evident, with 95% enrolling in the extension phase.

*p<0.0001.

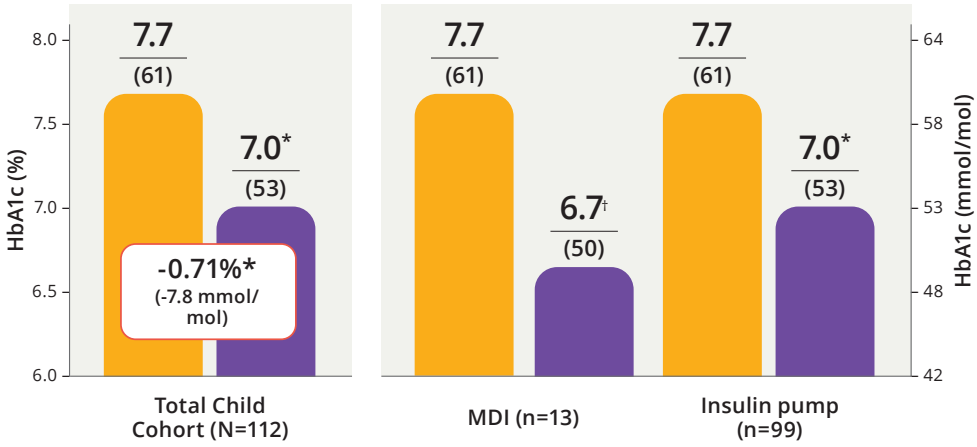
†p=0.046.

Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data shown as mean HbA1c.

MDI, multiple daily injections with insulin.

HbA1c is reduced by 0.71% (7.8 mmol/mol) in Children[1]



ST phase Omnipod 5 System phase

Connectivity of the on-body devices was excellent, allowing use of automated insulin delivery for median 96.4% of possible time for children.

*p<0.0001.

†p<0.0005.

Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data shown as mean HbA1c.

MDI, multiple daily injections with insulin.

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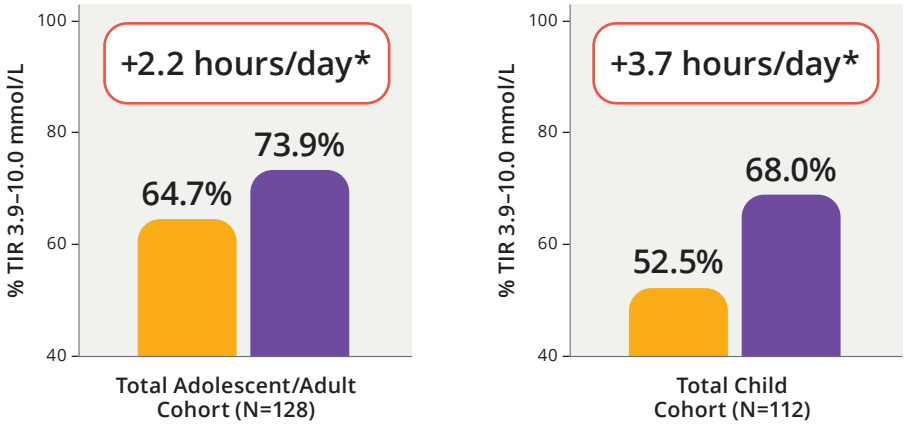
Omnipod 5 System increased TIR

- TIR is improved by 2.2 hours/day (9.3%) in Adolescents and Adults[1]
- TIR is improved by 3.7 hours/day (15.6%) in Children[1]



Children spent median 96.4% and adults/ adolescents spent median 96.7% of total study time in automated mode.

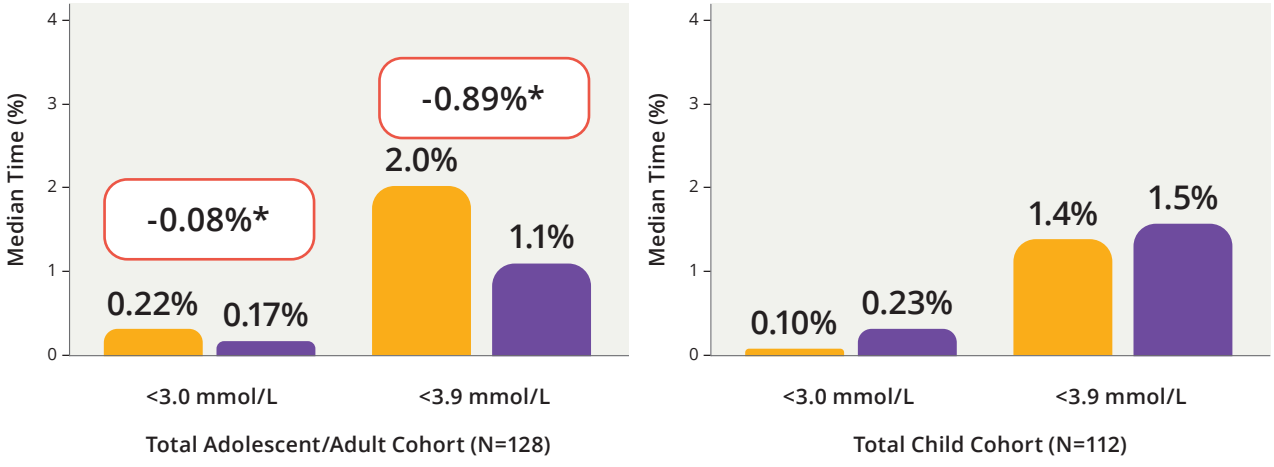
ST phase Omnipod 5 System phase

*p<0.0001.

Data shown as mean % TIR.

Time spent in hypoglycemia was reduced in adolescents and adults while remaining low in children

- Time in hypoglycemia was reduced by 46% in Adolescents and Adults[1]
- Time in hypoglycemia remained low in Children



ST phase Omnipod 5 System phase

*p<0.0001.

Data shown as median % Time Below Ranges <3.0 mmol/L and <3.9 mmol/L.

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Study Highlights[1]:

Reduced HbA1c

- Omnipod 5 System lowered HbA1c by 0.38% (4.2 mmol/mol) in Adolescents/Adults and by 0.71% (7.8 mmol/mol) in Children
- 66% of Adolescents/Adults and 53% of Children achieved the ADA recommended HbA1c target of <7.0% (<53 mmol/mol)

Increased TIR

- Improved TIR by 2.2 hours/day (9.3%) in Adolescents/Adults and by 3.7 hours/day (15.6%) in Children
- 69% of Adolescents/Adults and 82% of Children met consensus clinical targets for TIR
- All age groups demonstrated 78% TIR overnight (00:00–06:00 h) during the study

Low time in hypoglycemia

- Omnipod 5 System reduced time in hypoglycemia by 46% in Adolescents/Adults, including a 60% reduction in nocturnal hypoglycemia (00:00–06:00 h)
- Time in hypoglycemia remained low throughout the study in Children

System use

- Adolescents/Adults spent a median of 96.7% and Children spent a median of 96.4% of total study time in automated mode
- 3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) were reported in participants during Omnipod 5 System use. These cases were not related to automated insulin delivery malfunction
- The incidence of severe hypoglycemia and DKA were below reported rates in the US T1D Exchange Registry

Scan code to view published study

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

References 1. Adapted from; Brown SA, et al. Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes. *Diabetes Care* 2022; 44:1630-1640.

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