omnipod 5 automated insulin delivery system

Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customisable Glycaemic Targets in Paediatric 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 customisable glycaemic targets.
- **Primary end points** were change in HbA1c at the end of the AID phase compared with baseline and Time in Range 3.9-10.0 mmol/L during the AID phase compared with the Standard Therapy (ST) phase. Primary safety outcomes were incidence of severe hypoglycaemia and diabetic ketoacidosis (DKA).
- **Secondary end points** 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 glycaemic measures, with a low rate of hypoglycaemia in a heterogeneous participant group with varied age, baseline glycaemia and prior insulin delivery regimen.

Study Design

- Prospective, multicenter, single-arm outpatient study:
  - 14-day standard therapy 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%
  - Any prior insulin therapy (MDI or CSII)

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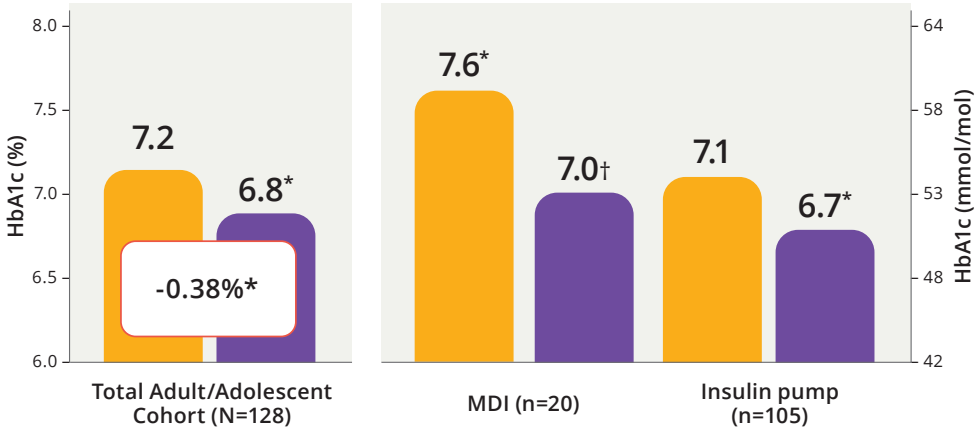
Omnipod 5 System reduced HbA1c

HbA1c is reduced by 0.38% in Adolescents and Adults[1]

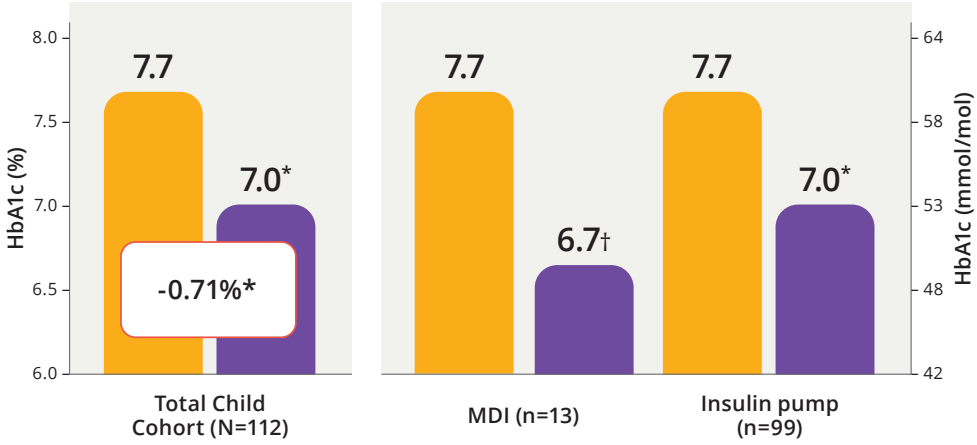


Participant endorsement of the system was evident, with 95% enrolling in the extension phase.

Standard Therapy phase Omnipod 5 System 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% in Children[1]



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

Standard Therapy phase Omnipod 5 System phase

* 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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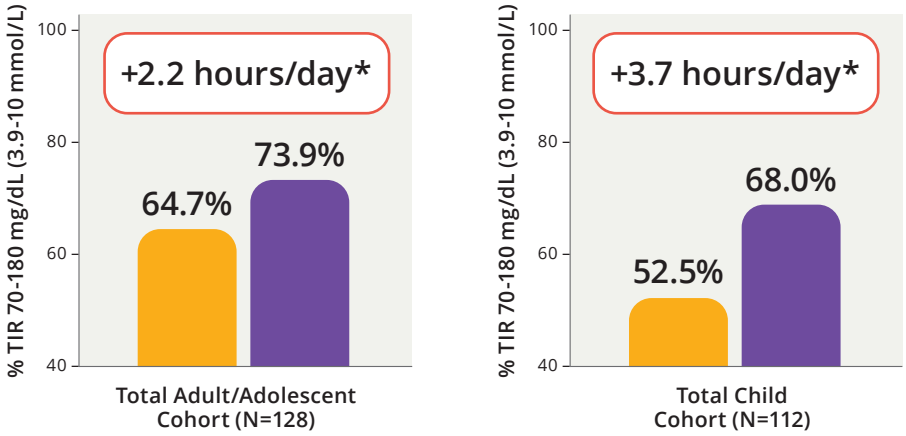
Omnipod 5 System increased Time in Range (TIR)

- 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]



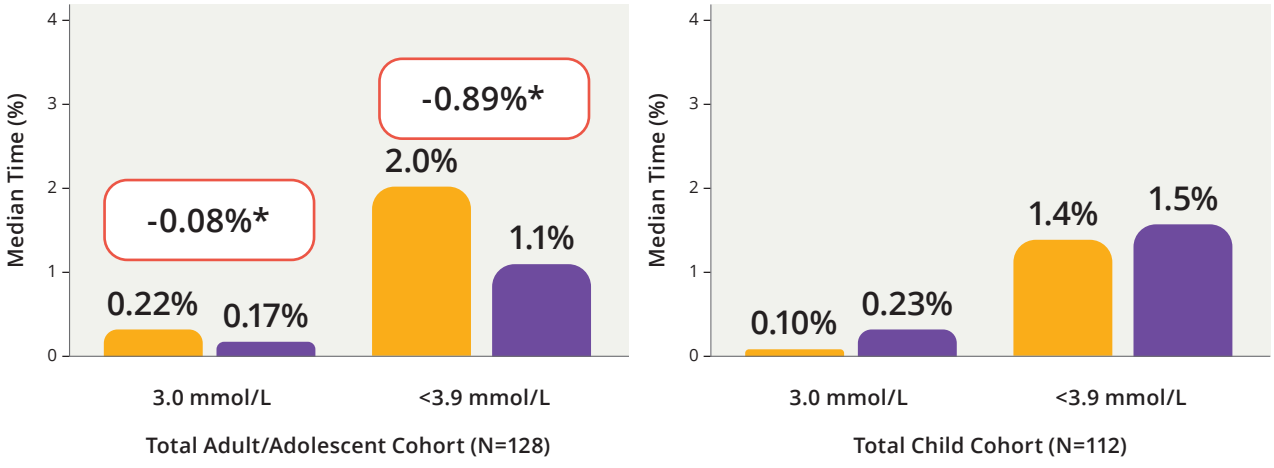
Children spent median 96.4% and adults/ adolescents spent median 96.7% of total study time in automated mode.

Standard Therapy phase Omnipod 5 System phase

* p<0.0001. Data shown as mean %TIR

Reduced time in hypoglycaemia in adolescents and adults, while time in hypoglyaemia remained low in children.

- Time in hypoglycaemia is reduced by 46% in Adolescents and Adults[1]
- Time in hypoglycaemia remains low in children



Standard Therapy phase Omnipod 5 System phase

* p<0.0001. Data shown as median %Time Below Ranges <3.9 mmol/L and <3.0 mmol/L.

3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) were reported in participants aged 6-70 years durin Omnipod® 5 System use. These cases were not related to automated insulin delivery malfunction.

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Study Highlights:[1]

Reduced HbA1c

- Omnipod 5 System lowered HbA1c by 0.38% in Adolescents/Adults, and by 0.71% in Children
- 66% of Adults/Adolescents and 53% of Children achieved the ADA recommended HbA1c target of <7.0%

Increased Time in Range (TIR)

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

Low time in hypoglycaemia

- Omnipod 5 System reduced time in hypoglycaemia by 46% in Adults and Adolescents, including a 60% reduction in nocturnal hypoglycaemia[2] (00:00–06:00 h)
- Time in hypoglycaemia remained low throughout the study in Children

System use

- Children spent median 96.4% and Adults/Adolescents spent median 96.7% of total study time in automated mode
- Incidence of severe hypoglycaemia and DKA were below reported rates in the US T1D Exchange Registry and were not attributable to AID malfunction

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 International.

References:

1. Brown S A et al. Diabetes Care. 2021;44(7):1630-1640. Multicenter trial of a tubeless, on-body automated insulin delivery system with customisable glycaemic targets in paediatric and adult participants with type 1 diabetes. Study funded by Insulet.
2. Brown S A et al. Diabetes Care. 2021;44:1630-1640. Prospective pivotal trial in 240 participants with T1D, including 128 participants aged 14-70 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop (HCL) phase. Mean time in hypoglycaemic range (<3.9 mmol/L as measured by CGM; 12AM - < 6AM) as measured by CGM: ST: 2.07% vs. Omnipod 5: 0.82%, P<0.0001 Comparison is a relative change.

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