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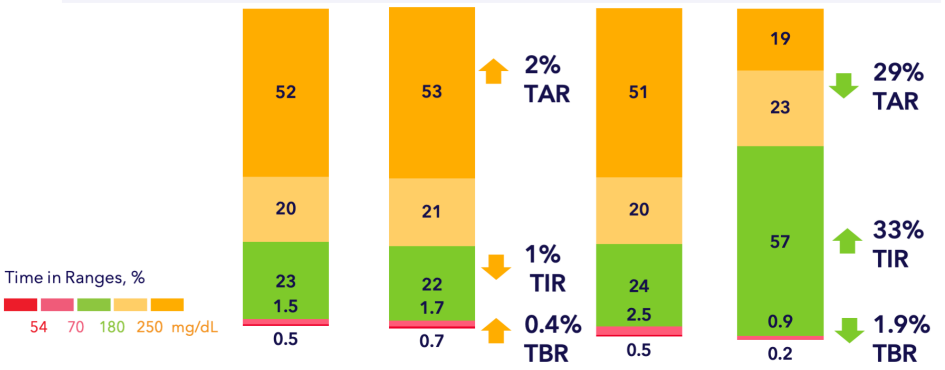
Automated insulin delivery for young people with type 1 diabetes and elevated A1C[1]

High-risk tech naïve youth previously struggling with severe hyperglycemia saw a reduction with the MiniMed™ 780G system

	Standard Care		MiniMed™ 780G system		*P*
	Baseline	13 Weeks	Baseline	13 weeks	
Participants, N	34	34	36	36	
A1C, %	10.4 ± 1.6	10.6 ± 1.8	10.5 ± 1.9	8.1 ± 1.8	<0.001



An average of 8.4 hours more hours per day spent in target glucose range (70-180 mg/dL) for those on MiniMed™ 780G system vs. those in the control group.

Mean (±SD) glycated hemoglobin decreased from 10.5±1.9% to 8.1±1.8% in the AID group but remained relatively consistent in the control group. (-14.28%) versus SIT.

29% reduction in Time Above Range with MiniMed™ 780G vs. an increase of 2% in the control group.

1.9% reduction in Time Below Range with MiniMed™ 780G vs. an increase of 0.4% in the control group.

73% of insulin was delivered automatically by the system.

Zero occurrences of diabetes-related serious adverse events compared to the control group.

Due to inherent analysis limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences.

1. Boucsein, A et al. NEJM Evid 2024;3(10) doi:10.1056/EVIDoa2400185.

Objective

The aim of this study was to evaluate the efficacy and safety of AID for children and youth with diabetes and elevated glycated hemoglobin levels.

Design

- Multicenter, open-label randomized controlled trial, patients with type 1 diabetes were assigned in a 1:1 ratio either to use an automated insulin delivery system (MiniMed 780G) or to receive usual diabetes care of multiple daily injections or non--automated pump therapy (control).[1]
- Patients were children and youth (defined as 7 to 25 years of age) with elevated glycemia (glycated hemoglobin ≥8.5% with no upper limit).
- The primary outcome was the baseline-adjusted between-group difference in glycated hemoglobin at 13 weeks.

Outcome parameters

At 13 weeks, the mean (±SD) glycated hemoglobin decreased from 10.5±1.9% to 8.1±1.8% in the automated insulin delivery group but remained relatively consistent in the control group, changing from 10.4±1.6% to 10.6±1.8% (baseline-adjusted between-group difference, -2.5 percentage points; 95% confidence interval [CI], -3.1 to -1.8; P<0.001).

Outcomes

The MiniMed™ 780G system (AID) significantly reduced glycated hemoglobin compared with usual diabetes care, without resulting in severe hypoglycemia or diabetic ketoacidosis events.

MiniMed™ 780G insulin pump system

Powered by advanced SmartGuard™ technology

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Important Safety Information for MiniMed™ 780G system with SmartGuard™ technology with Instinct sensor, Simplera Sync™ sensor, and Guardian™ 4 sensor: The MiniMed™ 780G system is intended for the continuous delivery of basal insulin at selectable rates and the administration of insulin boluses at selectable rates for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed™ 780G System includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on the continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values. The system is intended for use with connected sensors, including the Simplera Sync™ and Guardian™ 4 sensors and integrated continuous glucose monitors, including the Instinct sensor, each of which has different wear-time, form factor, insertion site, and other distinguishing characteristics that relate to sensor performance. Consult the appropriate sensor user guide when using the system. Discuss treatment decisions with your HCP.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

WARNING: Do not use the MiniMed™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G system.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a blood glucose (BG) meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. The safety of the MiniMed™ 780G system has not been studied in pregnant women or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult https://www.medtronicdiabetes.com/important-safety-information#minimed-780g-instinct and the appropriate user guide at https://www.medtronicdiabetes.com/download-library.

Important Safety Information for Extended Infusion Set: The Extended Infusion Set is indicated for up to 7 days of wear for the subcutaneous infusion of insulin from an infusion pump. It is NOT indicated for intravenous (IV) infusion or the infusion of blood or blood products. Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site. Before insertion, clean the insertion site with isopropyl alcohol. Remove the needle guard before inserting the infusion set. If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional. Do not leave air in the infusion set. Prime completely. Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication. If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin. Regularly replace the infusion set as indicated in the instructions for use, or per the insulin labeling, whichever duration is shorter. For more details, see https://www.medtronicdiabetes.com/important-safety-information.

Accu-Chek and Accu-Chek Guide Link are trademarks of Roche Diabetes Care. For detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events, please consult the device manual. For further information, contact your local Medtronic representative. DreaMed Diabetes is a trademark of DreaMed Diabetes, Ltd. The MiniMed 780G system algorithm includes technology developed by DreaMed Diabetes.

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