

Efficacy and safety of different hybrid closed loop systems for automated insulin delivery in people with type 1 diabetes¹

Given the lack of head-to-head studies across HCL systems, this meta-analysis aimed to compare the performance of various HCL systems in people with diabetes against subcutaneous insulin therapy without CGM (SIT).

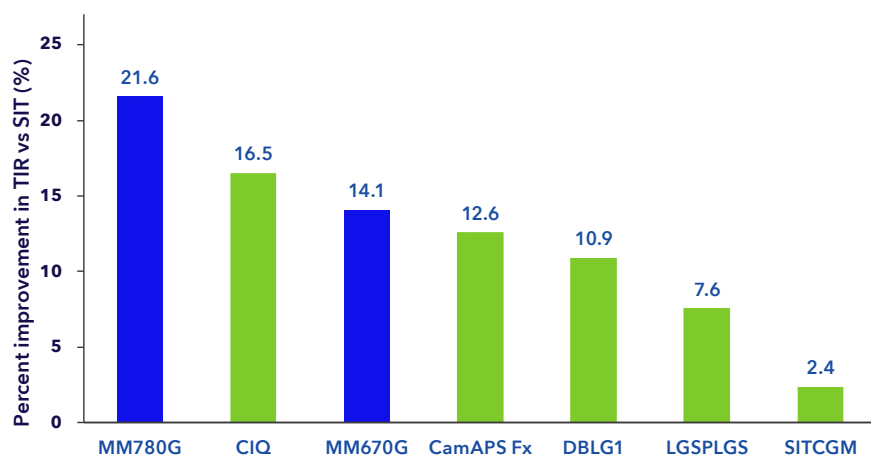


Figure 1. Percent improvement in TIR compared to subcutaneous insulin therapy without CGM (SIT), MiniMed™ 670G (670G), Minimed™ 780G (780G), T:slim X2 with Control-IQ technology (CIQ), CamAPS Fx, Diabeloop Generation 1 (DBLG1), LGSPLGS: low glucose suspension (LGS), predictive low glucose suspension (PLGS), subcutaneous insulin therapy with CGM (SITCGM).



Largest improvement in Time in Range (21.5%) with MiniMed™ 780G compared to other HCL systems, followed by Control-IQ, MiniMed™ 670G, CamAPS Fx, and Diabeloop Generation 1 (Figure 1).



Largest reduction in Time Above Range with MiniMed™ 780G (-18.82%) and Control-IQ (-14.28%) versus SIT.



Largest reductions in Time Below Range were reported for Diabeloop Generation 1 (-3.69%), followed by MiniMed™ 670G (-2.9%), and MiniMed™ 780G (-2.79%) versus SIT.



Serious adverse events were low in all HCL systems, including severe hypoglycemia and DKA.

In the absence of direct comparisons, the analysis revealed that available HCL systems show a hierarchy of efficacy in achieving glycemic control and that differences may exist in specific subgroups of patients. The certainty of the evidence was low for many comparisons; hence, the results of this network meta-analysis should not be regarded as conclusive.

1. Di Molfetta et al. Diabetes Metab Res Rev. 2024;40(6):e3842.

Objective

To compare the safety and efficacy of different HCL systems in people living with diabetes.

Design

- A network meta-analysis is a statistical technique that compares multiple interventions across a network of studies, allowing for indirect comparisons between treatments even if they haven't been directly tested against each other.¹
- It was performed independently and following the Cochrane guidelines for systematic review.
- 28 randomized controlled trials were included, comprising a total of 2,446 PwT1D.

Outcome parameters

Comparison of HCL systems versus subcutaneous insulin therapy without CGM (SIT) in safety and glycemic outcomes: Time in Range (TIR): 70-180 mg/dL, Time Above Range (TAR): > 180 mg/dL, Time below Range (TBR): < 70 mg/dL, mean sensor glucose, coefficient of variation of mean glucose (CV), severe adverse events, patients' satisfaction, and quality of life.

Outcomes

In this analysis including 28 RCTs and several HCL systems, MiniMed™ 780G was shown to achieve the largest improvements in glycemic control (TIR, TAR, mean sensor glucose) vs. subcutaneous insulin therapy, when compared to other HCL systems.

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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>.

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