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Real world hybrid closed-loop discontinuation: Predictors and perceptions of youth discontinuing the 670G system in the first 6 months

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Abstract

Objective: To describe predictors of hybrid closed loop (HCL) discontinuation and perceived barriers to use in youth with type 1 diabetes.

Subjects: Youth with type 1 diabetes (eligible age 2–25 y; recruited age 8–25 y) who initiated the Minimed 670G HCL system were followed prospectively for 6 mo in an observational study.

Research Design and Methods: Demographic, glycemic (time-in-range, HbA1c), and psychosocial variables [Hypoglycemia Fear Survey (HFS); Problem Areas in Diabetes (PAID)] were collected for all participants. Participants who discontinued HCL (<10% HCL use at clinical visit) completed a questionnaire on perceived barriers to HCL use.

Results: Ninety-two youth (15.7 ± 3.6 y, HbA1c $8.8 \pm 1.3\%$, 50% female) initiated HCL, and 28 (30%) discontinued HCL, with the majority (64%) discontinuing between 3 and 6 mo after HCL start. Baseline HbA1c predicted discontinuation ($P = .026$) with the odds of discontinuing 2.7 times higher (95% CI: 1.123, 6.283) for each 1% increase in baseline HbA1c. Youth who discontinued HCL rated difficulty with calibrations, number of alarms, and too much time needed to make the system work as the most problematic aspects of HCL. Qualitatively derived themes included technological difficulties (error alerts, not working correctly), too much work (calibrations, fingersticks), alarms, disappointment in glycemic control, and expense (cited by parents).

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AUTHOR CONTRIBUTIONS

L.H.M. designed the study, researched data and wrote the manuscript. C.B. designed the study, researched data, contributed to introduction and discussion and reviewed/edited the manuscript. T.V. completed statistical analysis, contributed to the methods and reviewed/edited the manuscript. L.P. completed statistical analysis and reviewed/edited the manuscript. C.G. assisted with the qualitative data analysis, contributed to the methods and reviewed/edited the manuscript. R.P.W. reviewed/edited the manuscript. K.A.D. designed the study, and reviewed/edited the manuscript. G.F.P. designed the study, contributed to the discussion and reviewed/edited the manuscript. L.H.M. is the guarantor of this work.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

Conclusions: Youth with higher HbA1c are at greater risk for discontinuing HCL than youth with lower HbA1c, and should be the target of new interventions to support device use. The primary reasons for discontinuing HCL relate to the workload required to use HCL.

Keywords

artificial pancreas; continuous glucose monitor; insulin pump; hybrid closed loop; pediatrics; type 1 diabetes

1 | INTRODUCTION

Type 1 diabetes (T1D), typically diagnosed in childhood^{1,2} requires lifelong replacement of exogenous insulin, and monitoring of glucose levels to minimize hypoglycemia and hyperglycemia.³ Long-term consequences of suboptimal glycemic control include both microvascular and macrovascular complications that increase morbidity and mortality for individuals with T1D.³ Sub-optimal glycemic control also increases risk of emergent complications such as hypoglycemic seizures and loss of consciousness, and diabetic ketoacidosis or diabetic coma.^{4,5} The T1D Exchange Registry recently showed that in the United States only 21% of adults and 17% of youth with T1D meet hemoglobin A1c (HbA1c) goals set forth by the American Diabetes Association, signifying the need for improvements in treatment and care of T1D.⁶

Technological advancements have aided in the management of T1D in the past 25 y, with continuous subcutaneous insulin infusion (CSII), or insulin pump, and continuous glucose monitoring (CGM) becoming mainstays of treatment for many individuals in the United States.^{7–9} During 2016–2018, 63% of individuals in the T1D Exchange Registry reported using an insulin pump, and 30% reported using CGM. Combining these technologies has led to the development of sensor augmented pump systems,^{10,11} low glucose and predicted low glucose suspend systems,^{12–14} and the first commercially available hybrid closed loop (HCL) system, the Minimed 670G (Northridge, CA).^{15,16}

The Minimed 670G HCL system consists of the 670G insulin pump and Guardian 3 CGM. The system uses the CGM sensor glucose levels and a proprietary algorithm¹⁷ to calculate basal insulin delivery that is automatically delivered without the user having to program or approve the dose. Discrete boluses of insulin for carbohydrate consumption or hyperglycemia are still administered by the user. The 670G is considered a “hybrid” closed loop, since the user is responsible for meal time insulin dosing, in contrast to a “fully” closed-loop system that does not require any user intervention to deliver insulin. The system is able to function as a HCL in “Auto Mode”, and also as a traditional insulin pump, with or without CGM, called “Manual Mode”.¹⁸

To maintain the system in Auto Mode, the user must wear the CGM consistently, calibrate the CGM sensor at least twice per day, and respond to alerts in a timely manner. Users are exited from Auto Mode to Manual Mode if: (1) there is prolonged hyperglycemia (ie, sensor glucose >250 mg/dL for 3 h or >300 mg/dL for 1 h); (2) the pump has delivered a minimum insulin delivery rate for 2.5 h or maximum insulin rate for 4 h; or (3) sensor glucose data are missing or inaccurate. A “BG required” alert, requiring a blood glucose (BG) value to be

entered into the pump to return to Auto Mode, may occur for any issue with the system and will require intervention by the user.

Although non-randomized 3-mo studies have demonstrated the safety of the 670G HCL system and its ability to improve glycemic control in the short term,^{15,16,19} data from real-world 670G use indicate that many individuals have difficulty sustaining the use of the system over time. Data from our group's observational study presented elsewhere indicate that Auto Mode use and sensor wear decreased over the first 6 mo of use, and 30% of the youth discontinued HCL altogether.²⁰ In addition, other prospective observational studies have reported 35%²¹ and 38% of patients discontinuing Auto Mode use in the first 9–12 mo of system use.²² The reasons for HCL discontinuation are not well documented, with one report indicating sensor issues and difficulty obtaining supplies as primary reasons.²¹ Other general diabetes technology barriers also likely apply, such as the hassle of wearing devices and too many alerts.^{23,24} Research is needed to identify risk factors for HCL discontinuation and to understand the reasons for its discontinuation to better inform prescribing practices and clinician support. Therefore, the purpose of this observational study is to identify predictors of HCL discontinuation, and describe reasons for discontinuation in a sub-sample of youth who discontinued HCL within the first 6 mo of use during a prospective real-world observational study.

2 | RESEARCH DESIGN AND METHODS

2.1 | Study design

Patients from an academic, pediatric clinical center were enrolled in a longitudinal observational study upon starting the 670G system for their routine T1D care. The goal of the observational study was to describe the adherence to the HCL system and the impact of HCL on glycemic and psychosocial outcomes after 6 mo of use. The participants and their caregivers were trained on the 670G per the Barbara Davis Center's routine clinical process.²⁵ Training consisted of Manual Mode training (using the 670G without the automated features), Auto Mode training 1–2 wks later (using and maintaining the HCL feature), and 2–3 phone calls to review device downloads and provide additional education and support during the first month after Auto Mode training. Data collection occurred simultaneously with routine clinical care, at baseline (before starting Auto Mode), 1 mo after starting Auto Mode, and during routine clinic visits, approximately 3 and 6 mo after starting Auto Mode. This study was approved by the University of Colorado Multiple Institutional Review Board.

2.2 | Participants

Participants were recruited for the observational study who were ages 2–25 years old with T1D, who were prescribed the 670G HCL system as part of their routine clinical care and the parent who identified as the primary caregiver for participants <18 years old. While the on-label age approval was initially 14 y, it decreased to 7 y mid-way through the data collection period. Off-label prescribing of the device to any patients on at least 8 units of insulin per day was common at our practice, and thus enrollment was allowed for patients using the device off-label. Participants were excluded if they did not read or speak English as questionnaires were only validated in the English language. Participants 7–17 years old

provided assent for the study, and adult participants or caregivers >18 years old provided informed consent for participation.

For the current analysis, participants in the observational study were stratified after 6 mo of follow-up into “HCL continuers” and “HCL discontinuers”. HCL discontinuers were defined as participants who had <10% HCL use at any visit in the first 6 mo after starting Auto Mode, as identified by device downloads (described next).

2.3 | Measures

2.3.1 | Full cohort measures—Participants’ age, sex, race/ethnicity, T1D duration, insurance status, HbA1c, and history of insulin pump and CGM use were collected via the electronic medical record at study enrollment. Participant use of the 670G system and Auto Mode were collected via the commercially available CareLink™ software at baseline (up to 14 days using Manual Mode prior to starting Auto Mode), 1 mo after starting Auto Mode, and during clinic visits after starting Auto Mode, approximately 3 and 6 mo after starting Auto Mode. System metrics included percent of time using Auto Mode, percent time using CGM, number of Auto Mode exits per day, and number of blood glucose checks per day.

Participants and caregivers also completed two self-report questionnaires at baseline and again approximately 3 and 6 mo after starting Auto Mode: (a) Hypoglycemia Fear Survey (HFS; Worry sub-scale); and (b) Problem Areas in Diabetes (PAID). The HFS Worry sub-scale assesses worry related to hypoglycemia and its negative consequences,^{26,27} and validated versions were administered to caregivers (PHFS, Cronbach’s alphas = 0.87–0.92), children <18 y (CHFS, Cronbach’s alphas = 0.83–0.87), and young adults ≥18 y (HFS-II, Cronbach’s alphas not calculated due to sample size). The PAID assesses emotional distress and psychosocial burden associated with T1D management, and validated versions were used for caregivers (PAID-PR, Cronbach’s alphas = 0.87–0.92), children <18 y (PAID-Peds, Cronbach’s alphas = 0.91–0.94), and young adults ≥18 y (PAID, Cronbach’s alphas not calculated due to sample size).^{28–31}

2.3.2 | Discontinuer specific measures—An additional questionnaire was developed for and administered via email survey link to participants who discontinued HCL and their caregivers, which was comprised of both qualitative and quantitative measures to describe reasons for discontinuing HCL and barriers to HCL use and was completed on-line via REDCap.³² (Appendix A).

The qualitative data collection for discontinuers consisted of an open ended, free text response to the following prompt: “Please describe in your own words why you stopped using Auto Mode/HCL. Please provide as much detail as you can. You may wish to discuss: Features of the device itself; experience with your diabetes; aspects of your life at school or work or home; relationships with friends, family, or with your diabetes care team; your health and well-being; what you feel or what others feel; any other aspects of the device that you would like to mention”. There was no character limit to answer the question.

Participants then completed the quantitative portion, which consisted of 22 equally weighted possible burdens or problems with diabetes technology that the users and parents rated on a

visual analog scale (VAS) developed by the study team. The scale included burdens described from the literature on device barriers^{23,24} with additional content added based on the study group's clinical experience and specific concerns with HCL. The survey prompt stated: "For the following questions, move the slider to indicate how much of a burden or problem the following have been for you when using the HCL device. The left side (0) means it has not been a problem. The right side (100) means it has been a major problem." The item list included general device concerns such as "cost of supplies/device", "hassle of wearing devices all the time" and other concerns more specific to 670G HCL, such as "difficulty calibrating the sensor" and "too many error alerts". VAS scores were ranked for each individual, then mean rank across the cohort was computed for each survey item. In addition to mean rank score, median VAS score was calculated to determine the magnitude of each burden across all subjects.

2.4 | Analysis

Quantitative variables were assessed for normality using the Kolmogorov-Smirnov test. Continuous variables were compared using *t* tests or Kruskal-Wallis Rank Sum tests, and chi-squared or Fisher's exact tests were used for categorical variables. Logistic regression was used to examine associations between baseline characteristics and discontinuation. The logistic regression model included baseline HbA1c, age, T1D duration, insurance category, PAID score, HFS Worry scores, and 1 mo % Auto Mode time, 1 mo % Sensor wear, 1 mo % Auto Mode Exits, and 1 mo number of blood glucose checks. A second logistic regression model was run with 1 mo Time-In-range (TIR) substituted for HbA1c as well.

Qualitative thematic analysis of survey data was conducted by a behavioral scientist with qualitative expertise (C.G.) and two certified diabetes educators with qualitative experience who are also pediatric registered nurses (L.H.M. and C.B.). A priori categories of themes and topics were assigned to the raw data to help substantiate the coding process. Survey responses were independently coded by the three coders and reviewed for agreement on initial themes. Coders then independently assigned codes to all responses, met a final time to resolve any conflict in scoring, and finalized the descriptions of each code.

3 | RESULTS

Description of the full cohort enrolled in the observational study ($N = 92$) as well as those who continued HCL ($n = 64$) vs those who discontinued HCL ($n = 28$) are found in Table 1. The age range of participants at baseline was 8–25 years old. When comparing HCL continuers to HCL discontinuers in the first 6 mo, significant differences were found in baseline HbA1c, with continuers having a mean HbA1c of $8.3\% \pm 1.3\%$ compared to $10.0\% \pm 2.2\%$ for discontinuers ($P < 0.001$). Further, use of Auto Mode, CGM wear, and number of blood glucose checks at month 1 after starting HCL were significantly different for continuers and discontinuers, excluding individuals who had already discontinued HCL before month 1 ($n = 2$). There were no other significant differences between groups in univariate analysis.

Overall, 28 (30%) youth in the observational study discontinued HCL within the first 6 months of use. Of these discontinuers, two individuals discontinued HCL by month 1

(7.1%), eight more discontinued by month 3 (28.6%), and the majority (18 individuals) discontinued between months 3 and 6 (64.3%). Among discontinuers, there was no significant difference between the PAID and HFS Worry scores at baseline and post-discontinuation.

3.1 | Predictors of discontinuation

With all of the predictors included in the logistic regression model, only baseline HbA1c significantly predicted HCL discontinuation ($P = 0.026$). On average, the odds of discontinuing HCL were 2.7 times higher (95% CI: 1.1, 6.3) for each 1% increase in baseline HbA1c. No other predictors were significantly associated with HCL discontinuation. TIR at 1 mo was also not predictive of device discontinuation.

3.2 | Qualitative data thematic analysis

Ten participants who discontinued HCL and 13 caregivers of youth (9 dyads) who discontinued HCL entered free text responses for why they discontinued HCL (50% of discontinuers represented by either a caregiver or subject). The median number of words for each participants was 25 (range: 3, 125) overall, 26.5 (6–68) for youth, and 30 (3–125) for parents. The qualitative coders reached consensus on five prominent qualitative themes (Table 2).

The three most common themes reported by HCL discontinuers were: (a) technical issues/problems; (b) too much work to maintain HCL; and (c) alarms. The majority of participants (80%) reported “Technical issues/problems” as a primary reason for discontinuation; namely, they frequently perceived the system to not be working correctly as indicated by poor CGM accuracy, failed sensor calibrations, sensor errors, trouble staying in Auto Mode, and transmitters or sensors not working. The second most common theme of “Too much work to maintain HCL” was reported by 60% of participants and included comments related to needing to enter excessive blood glucose values for calibrations and “BG Required” alerts, and also the hassle of replacing sensors. One participant noted it was easier to take care of his T1D by himself without the HCL. The third most common theme, “Alarms”, was reported by 40% of participants, and related to the frequency and inconvenience of alerts and alarms by the system. Two participants noted that alerts affected their ability to sleep well at night, and others described ignoring the alarms because they occurred so regularly.

The four most common themes expressed by caregivers included: (a) technical issues/problems; (b) too much work to maintain HCL; (c) expense/reimbursement; and (d) alarms. Caregiver themes closely mirrored participant themes as described previously, with the addition of expense/reimbursement being noted by 23% of caregivers, and included comments related to having difficulty with insurance reimbursement of sensors, and the cost of sensors. In addition, one participant and one caregiver reported “Glycemic control” as a reason for HCL discontinuation. The full list of themes, descriptions, and example comments are found in Table 2.

3.3 | Perceptions of HCL barriers reported by HCL discontinuers and caregivers

Twelve youth who discontinued HCL and 13 caregivers of youth who discontinued HCL (57% of discontinuers represented by either a caregiver or subject) completed the VAS scale asking how much of a problem they considered different aspects of HCL use, with a score of 0 indicating “not a problem” and 100 indicating “major problem”. For HCL discontinuers, the top five ranked items were (1) difficulty calibrating; (2) too many alarms; (3) too much time to make work; (4) too many error alerts, and (5) hassle of wearing devices (Table 3). For caregivers of HCL discontinuers, the top five ranked items were (1) difficulty calibrating; (2) too many fingersticks; (3) taking too much time to make the system work; (4) not having remote monitoring; and (5) too many alerts/alarms. Table 3 shows the full list of items ranked by HCL discontinuers and parents.

The median VAS scores for each item are displayed in Figure 1 (HCL discontinuers) and Figure 2 (caregivers of HCL discontinuers). Magnitude of burden for discontinuers was related to difficulty with calibrations (median score = 96/100), too many alarms (92.5/100), too many error alerts (79.5/100), too much time to make the system work (71.5/100), and too many fingersticks (71/100). Caregivers of discontinuers likewise reported the highest magnitude of burden for difficulty calibrating (91/100), followed by too many fingersticks (83/100), too many error alerts (75/100), Auto Mode not helping with blood sugars (68/100), and too much time to make work (63/100).

4 | CONCLUSIONS

This is the first study to evaluate predictors of HCL discontinuation in a clinical sample of youth using a commercially available HCL system, the Minimed 670G. Additionally, this is one of first studies to identify reasons youth discontinue HCL. There is substantial evidence that HCL systems have potential to improve overall glycemic control, with many controlled trials reporting increased time in target range and reduction in hyperglycemia and hypoglycemia.^{33,34} However, individuals need to use HCL consistently to realize these benefits, and emerging observational data of 670G HCL use in the real-world suggests a high risk for HCL discontinuation²² as well as attrition in time spent in HCL for those who continue using it.²⁰

In this study, higher baseline HbA1c was the only baseline factor to predict HCL discontinuation, with greater than 2-fold increase in odds of discontinuation for each 1% increase in HbA1c. This presents a challenging paradox for clinicians, as youth with higher HbA1c have been reported to benefit the most from HCL. As reported by Berget and colleagues from this same clinical observation trial, youth in the highest tertile of HbA1c prior to starting HCL (HbA1c > 9.0%) experienced a mean decrease in HbA1c of 1.7% after 6 mo of HCL use ($P = .001$), whereas youth in the middle HbA1c tertile (HbA1c 7.6–8.9% prior to starting HCL) and low HbA1c tertile (< 7.5% prior to starting HCL) did not experience a significant change in HbA1c after 6 mo on HCL (Berget, in press). Additional clinical insight will be needed to determine how to best support youth with higher HbA1c to maintain HCL therapy.

Other factors in addition to baseline HbA1c may also predict HCL discontinuation but were not detected in this current study. Diabetes distress, for example, has been shown previously to be associated with poorer T1D self-management practices and glycemic control in youth with T1D,^{24,35} and should be further considered in light of the workload and alert fatigue described by HCL discontinuers. Other psychological factors may yield further insight into discontinuation of HCL, including self-efficacy for diabetes care,³⁶ or perceptions and expectations of HCL systems.³⁷ Fear of hypoglycemia, while important to overall glycemic control, may not be the most likely indicator for understanding who will discontinue HCL. Overall, further inquiry into psychological factors related to HCL systems will help clarify attributes of individuals who discontinue device use over time.

The greatest barriers to HCL use reported in both the qualitative and quantitative responses related to the work required to maintain system use, either due to errors or system requirements. This workload included frequent blood glucose checks, responding and troubleshooting alarms, and difficulties calibrating the sensor. This is similar to data presented by Goodwin and colleagues²² from 38 youth who discontinued HCL, who primarily cited frustrations related to forced exits from HCL, frequent alarms, sensor issues, and skin issues. It is also consistent with data from Lal and colleagues who reported sensor issues being the primary reason for discontinuation.²¹ Youth may be especially sensitive to alarms and persistent attention to diabetes tasks, as they are developmentally absorbed in the cognitive and emotional challenges of childhood and adolescence.^{38–40} Diabetes devices that require less attention from the user may be better used by youth. Clinicians can employ a variety of strategies to help decrease technical challenges for children and adolescents. These can include re-education in the timing of sensor calibrations (to avoid failed calibrations), support in how to best respond (or not respond) to system alerts to minimize error messages, and carefully setting alerts to reduce the number of nuisance alarms.¹⁹

In addition to mitigating workload with education and device optimization, there is an essential need to design easy-to-use diabetes devices to improve sustainability of use across time. The 670G is a first generation HCL system, and it is likely that future devices will improve upon this current technology. One major frustration with the 670G is the need for multiple calibrations each day, and the work of mitigating failed calibrations. Future HCL systems will ideally be designed with factory calibrated sensors, reducing the burden of providing multiple BG values to keep the sensor reading accurately. Another significant frustration with the 670G is the difficulty keeping it operating in Auto Mode. This is often due to system conditions that must be satisfied in order to maintain HCL status (eg, maximum and minimum insulin delivery parameters, internal sensor accuracy calculations). As ongoing research cements the safety record of HCL systems, future system iterations should reduce the conditions that must be met to maintain HCL, minimizing user burden. It is imperative for future systems to increase the ease of use by minimizing alarms, eliminating the need for blood glucose checks, and reducing overall interaction with the device.

This is the first study reporting on both qualitative and quantitative measures to identify barriers to HCL use and reasons for HCL discontinuation, which is a significant strength of this study. It further elucidates the importance of HbA1c as an important predictor of HCL

discontinuation. The findings are generalizable to many youth populations, as these data were gathered in a real world observational setting and not in the context of a clinical trial. It is also important to consider the limitations of this study. Due to the observational nature of the study design, a sample size could not be determined a priori, and therefore, it is possible that there are other predictors of discontinuation that were not detected. Additionally, data on reasons for device discontinuation were collected up to several months after many individuals discontinued HCL devices, and it is thus possible their recollection of barriers differs from the barriers they perceived at the time of discontinuation. The questionnaire was completed by 57% of the total discontinuer families and there may be a selection bias in the respondents, where non-respondent discontinuers may report different barriers than the respondents. Further, some of the qualitative responses are brief, and do not provide extensive understanding of the user experience with the device. Beyond insurance status which was extracted from the medical records, we did not obtain other data on household income or other markers of socioeconomic status. In future studies, we will ask this in a manner similar to the type 1 diabetes exchange. While HbA1c provides some data on diabetes comorbidity, no data on previous hospitalizations, mental health status or other comorbidities was obtained. Nonetheless, this study provides valuable insight into risk factors for HCL discontinuation, although more research should be done. Future research should evaluate the perceptions of barriers and benefits to HCL use for both HCL discontinuers and HCL continuers, to identify important differences and potential intervention strategies.

Overall, data on HCL use and discontinuation is vital for understanding who may succeed on advanced diabetes technologies and who will need further support. Interventions are needed to help individuals sustain the use of devices that improve glycemic control. Developers of future systems can increase uptake and sustainable use of their devices by increasing the ease of use for individuals living with diabetes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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REFERENCES

1. EURODIAB ACE Study Group. Variation and trends in incidence of childhood diabetes in Europe, EURODIAB ACE Study Group. *Lancet*. 2000;355:873–876. [PubMed: 10752702]

2. Harjutsalo V, Sjoberg L, Tuomilehto J. Time trends in the incidence of type 1 diabetes in Finnish children: a cohort study. *Lancet*. 2008;371: 1777–1782. [PubMed: 18502302]
3. American Diabetes Association. Glycemic targets: standards of medical care in diabetes 2019. *Diabetes Care*. 2019;42:S61–S70. [PubMed: 30559232]
4. Secrest AM, Becker DJ, Kelsey SF, Laporte RE, Orchard TJ. Cause-specific mortality trends in a large population-based cohort with longstanding childhood-onset type 1 diabetes. *Diabetes*. 2010;59:3216–3222. [PubMed: 20739685]
5. Maahs DM, West NA, Lawrence JM, Mayer-Davis EJ. Epidemiology of type 1 diabetes. *Endocrinol Metab Clin North Am*. 2010;39:481–497. [PubMed: 20723815]
6. Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes Technol Ther*. 2019; 21(2):66–72. [PubMed: 30657336]
7. American Diabetes Association. Diabetes technology: standards of medical care in diabetes 2019. *Diabetes Care*. 2019;42:S71–S80. [PubMed: 30559233]
8. Rodbard D Continuous glucose monitoring: a review of successes, challenges, and opportunities. *Diabetes Technol Ther*. 2016;18(suppl 2):S3–S13.
9. Wong JC, Dolan LM, Yang TT, Hood KK. Insulin pump use and glycemic control in adolescents with type 1 diabetes: predictors of change in method of insulin delivery across two years. *Pediatr Diabetes*. 2015; 16:592–599. [PubMed: 25387433]
10. Bergenstal RM, Tamborlane WV, Ahmann A, et al. Sensor-augmented pump therapy for A1C reduction (STAR 3) study: results from the 6-month continuation phase. *Diabetes Care*. 2011; 34:2403–2405. [PubMed: 21933908]
11. Slover RH, Welsh JB, Criego A, et al. Effectiveness of sensor-augmented pump therapy in children and adolescents with type 1 diabetes in the STAR 3 study. *Pediatr Diabetes*. 2012;13:6–11. [PubMed: 21722284]
12. Weiss R, Garg SK, Bode BW, et al. Hypoglycemia reduction and changes in hemoglobin A1c in the ASPIRE in-home study. *Diabetes Technol Ther*. 2015;17:542–547. [PubMed: 26237308]
13. Choudhary P, Olsen BS, Conget I, Welsh JB, Vorrink L, Shin JJ. Hypoglycemia prevention and user acceptance of an insulin pump system with predictive low glucose management. *Diabetes Technol Ther*. 2016;18:288–291. [PubMed: 26907513]
14. Forlenza GP, Li Z, Buckingham BA, et al. Predictive low-glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: results of the PROLOG trial. *Diabetes Care*. 2018;41:2155–2161. [PubMed: 30089663]
15. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *Jama*. 2016;316:1407–1408. [PubMed: 27629148]
16. Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes. *Diabetes Technol Ther*. 2017;19(3):155–163. [PubMed: 28134564]
17. Grosman B, Ilany J, Roy A, et al. Hybrid closed-loop insulin delivery in type 1 diabetes during supervised outpatient conditions. *J Diabetes Sci Technol*. 2016;10:708–713. [PubMed: 26880389]
18. Messer LH, Berget C, Forlenza GP. A clinical guide to advanced diabetes devices and closed-loop systems using the CARES paradigm. *Diabetes Technol Ther*. 2019;21:462–469. [PubMed: 31140878]
19. Messer LH, Forlenza GP, Sherr JL, et al. Optimizing hybrid closed-loop therapy in adolescents and emerging adults using the MiniMed 670G system. *Diabetes Care*. 2018;41:789–796. [PubMed: 29444895]
20. Berget C, Messer LH, Vigers T, et al. Hybrid closed loop therapy in the real world: 6 month clinical observation of youth with type 1 diabetes. *Diabetes Technol Ther*. 2019;(suppl 1):21.
21. Lal RA, Basina M, Maahs DM, Hood K, Buckingham B, Wilson DM. One year clinical experience of the first commercial hybrid closed-loop. *Diabetes care*. 2019;42(12):2190–2196. [PubMed: 31548247]
22. Goodwin G, Waldman G, Lyons J, Oladunjoye A, Steil G. OR 14–5: Challenges in implementing hybrid closed loop insulin pump therapy (Medtronic 670G) in a ‘Real World’ clinical setting. 101st Annual Meeting of the Endocrine Society New Orleans, Louisiana, 2019.

23. Tanenbaum ML, Hanes SJ, Miller KM, Naranjo D, Bensen R, Hood KK. Diabetes device use in adults with type 1 diabetes: barriers to uptake and potential intervention targets. *Diabetes Care*. 2017;40: 181–187. [PubMed: 27899489]
24. Forlenza GP, Messer LH, Berget C, Wadwa RP, Driscoll KA. Biopsy-chosocial factors associated with satisfaction and sustained use of artificial pancreas technology and its components: a call to the technology field. *Curr Diab Rep*. 2018;18:114. [PubMed: 30259309]
25. Berget C, Thomas S, Messer LH, et al. A clinical training program for hybrid closed-loop therapy in a pediatric diabetes clinic. *Diabetes*. 2019 10.1177/1932296819835183.
26. Gonder-Frederick L, Nyer M, Shepard JA, Vajda K, Clarke W. Assessing fear of hypoglycemia in children with Type 1 diabetes and their parents. *Diabetes Manag (London, England)*. 2011;1:627–639.
27. Gonder-Frederick LA, Schmidt KM, Vajda KA, et al. Psychometric properties of the hypoglycemia fear survey-ii for adults with type 1 diabetes. *Diabetes Care*. 2011;34:801–806. [PubMed: 21346182]
28. Welch G, Weinger K, Anderson B, Polonsky WH. Responsiveness of the problem areas in diabetes (PAID) questionnaire. *Diabetes Med*. 2003;20:69–72.
29. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes Care*. 2005;28:626–631. [PubMed: 15735199]
30. Markowitz JT, Volkening LK, Butler DA, Antisdel-Lomaglio J, Anderson BJ, Laffel LM. Re-examining a measure of diabetes-related burden in parents of young people with Type 1 diabetes: the Problem Areas in Diabetes Survey - Parent Revised version (PAID-PR). *Diabet Med*. 2012;29:526–530. [PubMed: 21883443]
31. Markowitz JT, Volkening LK, Butler DA, Laffel LM. Youth-perceived burden of type 1 diabetes: problem areas in diabetes survey-pediatric version (PAID-Peds). *J Diabetes Sci Technol*. 2015;9:1080–1085. [PubMed: 25910541]
32. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap): a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42:377–381. [PubMed: 18929686]
33. Dai X, Luo ZC, Zhai L, Zhao WP, Huang F. Artificial pancreas as an effective and safe alternative in patients with type 1 diabetes mellitus: a systematic review and meta-analysis. *Diabetes therapy: research, treatment and education of diabetes and related disorders*. 2018;9:1269–1277.
34. Weisman A, Bai JW, Cardinez M, Kramer CK, Perkins BA. Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials. *Lancet Diabetes Endocrinol*. 2017;5:501–512. [PubMed: 28533136]
35. Hilliard ME, Wu YP, Rausch J, Dolan LM, Hood KK. Predictors of deteriorations in diabetes management and control in adolescents with type 1 diabetes. *J Adolesc Health*. 2013;52:28–34. [PubMed: 23260831]
36. Iannotti RJ, Schneider S, Nansel TR, et al. Self-efficacy, outcome expectations, and diabetes self-management in adolescents with type 1 diabetes. *J Dev Behav Pediatr*. 2006;27:98–105. [PubMed: 16682872]
37. Weissberg-Benchell J, Shapiro JB, Hood K, et al. Assessing patient-reported outcomes for automated insulin delivery systems: the psychometric properties of the INSPIRE measures. *Diabetes Med*. 2019;36:644–652.
38. Casey BJ, Getz S, Galvan A. The adolescent brain. *Dev Rev*. 2008;28: 62–77. [PubMed: 18688292]
39. Sanders RA. Adolescent psychosocial, social, and cognitive development. *Pediatr Rev*. 2013;34:354–358. quiz 8–9. [PubMed: 23908362]
40. Chiang JL, Kirkman MS, Laffel LM, Peters AL, Authors TDS. Type 1 diabetes through the life span: a position statement of the American Diabetes Association. *Diabetes Care*. 2014;37:2034–2054. [PubMed: 24935775]

FIGURE 1.

Visual analog scale results for burdens perceived by HCL discontinuers (median with IQR bars)

FIGURE 2.

Visual analog scale results for burden perceived by parents of HCL discontinuers (median with IQR bars)

TABLE 1

Description of total cohort and comparison of HCL discontinuers and continuers

	Overall	Continuers	Discontinuers	P value*
N	92	64	28	
Baseline HbA1c	8.8% ± 1.8	8.3% ± 1.3	10.0% ± 2.2	<.001
T1D Duration (years)	6.8 [4.6, 9.8]	6.7 [4.6, 9.1]	7.4 [3.8, 10.6]	.78
Age (years)	15.7 ± 3.6	15.5 ± 3.9	16.3 ± 2.8	.30
PAID Score (baseline)	33.8 [17.8, 57.5]	31.3 [12.5, 56.3]	41.3 [27.5, 57.5]	0.14
Worry Z-Score (baseline)	0.04 ± 1.05	0.01 ± 0.98	0.10 ± 1.24	.74
Month 1 Auto Mode Time (%)	73.5 [55.0, 86.8]	82.0 [68.5, 88.5]	46.0 [31.0, 63.0]	<.001
Month 1 Sensor Wear (%)	84.0 [68.5, 92.0]	89.0 [80.5, 93.0]	63.0 [47.5, 75.5]	<.001
Month 1 Auto Mode Exits per Day	0.87 ± 0.37	0.86 ± 0.37	0.90 ± 0.38	.675
Month 1 BG Checks per Day	5.5 [4.3, 7.4]	6.3 [4.5, 7.5]	4.4 [3.1, 5.2]	.004
Race/ethnicity (N, %) White Non-Hispanic	71 (77.2%)	52 (81.2%)	19 (67.9%)	.255
Female (N, %)	46 (50.0%)	33 (51.6%)	13 (46.4%)	.821
Insurance (N, %)				.611
Public	14 (15.4%)	9 (14.1%)	5 (18.5%)	
Private	72 (79.1%)	52 (81.2%)	20 (74.1%)	
Other ^a	5 (5.5%)	3 (4.7%)	2 (7.4%)	
Pump use > 1 y (N(%))	73 (83.0%)	50 (82.0%)	23 (85.2%)	.950
CGM use > 1 y (N(%))	55 (61.1%)	40 (64.5%)	15 (53.6%)	.452

Note: Statistics are reported as either Mean ± SD or (median [IQR]) or counts (% of sample).

^aInsurance status of “other” were individuals who had combination of public and private insurance or military insurance (Tricare).

* P-value represents difference between continuers and discontinuers.

TABLE 2
Description of qualitative themes reported by caregivers and participants who discontinued HCL

Theme	Description	Quote
Technical issues/problems (described by 80% of discontinuers and 54% of parents)	• Perceptions of system not working correctly	• "We have been through four transmitters, each which stopped working" (parent of 13-year-old male)
	• Error messages	• "The sensor took hours to charge and would die quickly" (16-year-old female)
	• Faulty or broken equipment	• "I stopped using the CGM simply because it would only last 3-4 days. With my being so lean I really don't have many places to put it. With it only a few days it was tearing up the spots I could use." (22-year-old male)
Too much work to maintain HCL (described by 60% of discontinuers and 38% of parents)	• Work required by system to stay in auto mode	• "Keeping myself in the closed loop was too much work. I had to check my blood sugar even more than I did when I wasn't wearing a sensor. The sensors were always wrong, and calibrating them to try and make them more accurate always kicked me out of closed loop and caused sensor errors. It was just too much work to try and make the whole system work." (19-year-old male)
	• Calibrations, poking fingers, responding to alerts	• "Kept kicking out of auto mode at night and waking me up, and requiring too many bg updates even though I calibrate when I'm supposed to" (16-year-old male)
		• "...it was too much work to get it into auto mode. He spent more time poking his finger and wrangling it into automode than not. He was frustrated which meant the entire house heard about it. It was daily and constant. He was poking his finger more than without the CGM cause it would not take a calibration even though the number was super close to the CGM number." (parent of 18-year-old male)
Alarms (described by 40% of discontinuers and 15% of parents)	• Perception/irritation from too many alarms	• "I got so many alarms, alerts and calibrations that I started ignoring the alarms." (20-year-old female)
	• Alarms negatively impacting sleep	• "It woke me up multiple times in the middle of the night to enter my blood sugar. It woke me up around three times per night and I was not able to go to sleep afterwards. I was in a bad mood most days because of lack of sleep..." (15-year-old female)
		• "Cost of sensors" (parent of 19-year-old female)
Expense/reimbursement (described by 23% of parents)	• Too expensive to afford	• "Having problems getting sensors through insurance. Am working on this and will start wearing again once this is figured out..." (parent of 20-year-old male)
	• Problem with insurance coverage	
		• "The target blood sugar for auto mode is higher than we are comfortable with. It was worsening my son's A1c." (parent of 14-year-old female)
Glycemic control (described by 10% of discontinuers and 8% of parents)	• Not achieving desired glycemic control	• "I felt as though it made controlling my blood sugar more difficult." (19-year-old female)
	• More difficult to control glucose level	

TABLE 3

Mean rank of burdens by HCL discontinuers and parents of HCL discontinuers

HCL discontinuers (<i>n</i> = 12)	Rank	Parents of HCL discontinuer (<i>n</i> = 13)
Difficulty calibrating the sensor	1	Difficulty calibrating the sensor
Too many alarms/alerts	2	Needing to check my blood sugar (fingerstick) too much
Takes too much time to make it work	3	Too many error alerts
Too many error alerts	4	Not having remote monitoring
Hassle of wearing devices all of the time	5	Too many alarms/alerts
Needing to check my blood sugar (fingerstick) too much	6	Takes too much time to make it work
Feeling like the device interferes with my daily life	7	Feeling like there are better devices for handling my diabetes
Feeling like the device is interfering with a good night's sleep	8	Feeling like the device is not helping with my glucose levels
Feeling like the device is not helping with my glucose levels	9	Feeling like the device is interfering with a good night's sleep
How diabetes device feel on my body	10	Causes stress and fighting with my family
Causes stress and fighting with my family	11	Feeling like I can't control my insulin settings
Feeling like there are better devices for handling my diabetes	12	Feeling nervous that the device might not work
Not having remote monitoring	13	Feeling like the device interferes with my daily life
Too busy to use the device	14	Not understanding what to do with the information or features of the device
Feeling nervous that the device might not work	15	How diabetes device feel on my body
Feeling like I can't control my insulin settings	16	Cost of supplies/device
How diabetes devices look on my body	17	Hassle of wearing devices all of the time
Not understanding what to do with the information or features of the device	18	Not enough support from my diabetes care team for using the device
Cost of supplies/device	19	Too busy to use the device
Do not want to have more information about my diabetes	20	Do not want to have more information about my diabetes
Not enough support from my diabetes care team for using the device	21	How diabetes devices look on my body
Worried about what other will think of me	22	Worried about what other will think of me