Acta Diabetologica (2022) 59:31–37
https://doi.org/10.1007/s00592-021-01789-5

ORIGINAL ARTICLE

Improved technology satisfaction and sleep quality with Medtronic MiniMed® Advanced Hybrid Closed-Loop delivery compared to predictive low glucose suspend in people with Type 1 Diabetes in a randomized crossover trial

Benjamin J. Wheeler[1,2] · Olivia J. Collyns[3] · Renee A. Meier[4] · Zara L. Betts[4] · Chris Frampton[5] · Carla M. Frewen[2] · Barbara Galland[2] · Niranjala M. Hewapathirana[1] · Shirley D. Jones[2] · Denis S. H. Chan[3] · Anirban Roy[6] · Benyamin Grosman[6] · Natalie Kurtz[6] · John Shin[6] · Robert A. Vigersky[6] · Martin I. de Bock[3,5,7]

Received: 5 July 2021 / Accepted: 15 August 2021 / Published online: 27 August 2021

Abstract

Background Automated insulin delivery aims to lower treatment burden and improve quality of life as well as glycemic outcomes.

Methods We present sub-study data from a dual-center, randomized, open-label, two-sequence crossover study in automated insulin delivery naïve users, comparing Medtronic MiniMed® Advanced Hybrid Closed-Loop (AHCL) to Sensor Augmented Pump therapy with Predictive Low Glucose Management (SAP + PLGM). At the end of each 4-week intervention, impacts on quality of life, sleep and treatment satisfaction were compared using seven age-appropriate validated questionnaires given to patients or caregivers.

Results 59/60 people completed the study (mean age 23.3 ± 14.4yrs). Statistically significant differences favoring AHCL were demonstrated in several scales (data shown as mean ± SE). In adults (≥ 18yrs), technology satisfaction favored AHCL over PLGM as shown by a higher score in the DTSQs during AHCL ($n = 28$) vs SAP + PLGM ($n = 29$) (30.9 ± 0.7 vs 27.9 ± 0.7, $p = 0.004$) and DTSQc AHCL ($n = 29$) vs SAP + PLGM ($n = 30$) (11.7 ± 0.9 vs 9.2 ± 0.8, $p = 0.032$). Adolescents (aged 13–17yrs) also showed a higher DTSQc score during AHCL ($n = 16$) versus SAP + PLGM ($n = 15$) (14.8 ± 0.7 vs 12.1 ± 0.8, $p = 0.024$). The DTQ "change" score ($n = 59$) favored AHCL over SAP + PLGM (3.5 ± 0.0 vs 3.3 ± 0.0, $p < 0.001$). PSQI was completed in those > 16 years ($n = 36$) and demonstrated improved sleep quality during AHCL vs SAP + PLGM (4.8 ± 0.3 vs 5.7 ± 0.3, $p = 0.048$) with a total score > 5 indicating poor quality sleep.

Conclusion These data suggest that AHCL compared to SAP + PLGM mode has the potential to increase treatment satisfaction and improve subjective sleep quality in adolescents and adults with T1D.

Keywords Automated insulin delivery · Psychosocial · Type 1 · Diabetes · Children · Adolescents · Sleep

Abbreviations

AHCL	Advanced hybrid closed-loop
SAP + PLGM	Sensor augmented pump therapy with predictive low glucose management
DTSQs and DTSQc	Diabetes treatment satisfaction questionnaire status and change
DTQ	Diabetes technology questionnaire
PSQI	Pittsburgh sleep quality index
WHO-5	World health organization-five well-being index
HFS-II	Hypoglycemic fear survey
HCS	Hypoglycemia confidence scale
AID	Automated insulin delivery
HCL	Hybrid closed-loop
CGM	Continuous glucose monitor

Managed by Massimo Porta.

Benjamin J Wheeler and Olivia J Collyns : Joint-First authors.

✉ Martin I. de Bock
Martin.debock@otago.ac.nz

Extended author information available on the last page of the article

Introduction

Worldwide, there is rapidly increasing interest in the therapeutic potential of automated insulin delivery (AID) for Type 1 Diabetes (T1D). While not fully automated yet, recently published technology demonstrates the efficacy of hybrid closed-loop (HCL) systems, pairing an insulin pump with a control algorithm that adjusts insulin delivery based on sensor glucose from a continuous glucose monitor (CGM). These systems have consistently shown improvement in glycemic metrics, including increased time in target glucose range (TIR, 70–180 mg/dl [3.9–10 mmol/L]) and reduced hypoglycemia [1–5].

The Medtronic 670G was the first commercial HCL device approved and to become widely available. The data to date have been largely very positive, including users converting from both multiple daily injections and traditional insulin pump therapy to HCL [6–8]. While gains in both HbA1c [7] and TIR in randomized trials of up to 15% have been reported for 670G [7] (and beyond in some single arm and real-world data [6, 8]), AID has the potential to more widely improve the lives of people with diabetes, including impacting quality of life, diabetes treatment satisfaction, and reduce treatment burden. These additional benefits have been reported for the 670G [7, 8] and more widely from earlier generation HCL systems in recent systematic reviews which highlight improvements in treatment satisfaction, well-being and sleep [9, 10]. However, some recent observational real-world data on use of the 670G have revealed a minority of users discontinue HCL, often due to burdens related to calibrations, alarms, and difficulties staying in automode [11, 12].

These real-world first-generation HCL data highlight the importance of exploring user experience and psychosocial factors during development and trials of newer HCL systems [13]. With positive glycemic results of next-generation AHCL systems now available [2, 3], the purpose of this sub-study [2] is to present treatment satisfaction, fear of hypoglycemia, general well-being, and subjective sleep quality data from a recent randomized crossover trial comparing the MiniMed™ Advanced Hybrid Closed-Loop system (AHCL) to Sensor Augmented Pump therapy with Predictive Low Glucose Management (SAP + PLGM).

Methods

The study was a dual-center (Christchurch and Dunedin, New Zealand), randomized, two-sequence crossover study, comparing AHCL to SAP + PLGM in users naïve to automated insulin delivery. The study was conducted in compliance with the International Organization for Standardization ISO14155: 2011, the ethical principles that have their origin in the Declaration of Helsinki, and all applicable regulatory requirements. The study was approved by the Southern Health and Disability Ethics Committee and registered at ANZCTR (#12,619,000,007,134) and ClinicalTrials.gov (NCT04073576). The trial sponsor was the Christchurch Clinical Studies Trust. Additional study details focusing on safety and glycemic data have previously been published [2].

The key inclusion criteria were as follows: T1D for ≥ 1 year; age 7–80 years; and prior insulin pump use for ≥ 6 months. The primary exclusion criteria were a mean HbA1c of > 10% (86 mmol/mol), within 6 months prior to Study Day 1 (minimum of one test required). The study was conducted under free-living conditions and consisted of a 2–4 week run-in phase with two 4-week intervention phases (Either 4 weeks of AHCL followed by 4 weeks of SAP + PLGM or vice versa). The two intervention phases were separated by a 2-week washout (SAP + suspend on low). In brief, the investigational AHCL system included the automated basal insulin delivery of the commercial MiniMed 670G with the addition of: a choice of target set points of 5.6 mmol/L (100 mg/dL) or 6.7 mmol/L (120 mg/dL); and an automated correction bolus feature delivered up to every 5 min, correcting to 6.7 mmol/L (120 mg/dl). These investigational features have subsequently been made commercially available within the MiniMed 780G system. The control arm used traditional SAP + PLGM as previously described [14].

Self (or caregiver)-reported age-appropriate questionnaires were administered at baseline and after each intervention phase including Diabetes Treatment Satisfaction Questionnaire status (DTSQs), Diabetes Treatment Satisfaction Questionnaire change (DTSQc), Diabetes Technology Questionnaire (DTQ), Pittsburgh Sleep Quality Index (PSQI), World Health Organization-Five Well-Being Index (WHO-5), Hypoglycemia Confidence Scale (HCS) and Hypoglycemia Fear Survey– short-form (HFS-II).

The DTSQ is a validated and widely used questionnaire investigating treatment satisfaction [15]. The treatment satisfaction score of the DTSQ has 6–10 items depending on the age of the respondent, rated 0–6 for the DTSQs and – 3–3 for the DTSQc with a higher score indicating greater satisfaction. Mean scores are calculated and then multiplied by 6. The DTSQc is used to overcome potential ceiling effects seen with the DTSQs if baseline scores are already high. The age bands used were ≥ 18 years for the adult version, 13–17 years for the teen version, and parent version for children aged 7–12 years.

The DTQ includes a 30 item measure which assesses the impact and satisfaction of technology [16]. The DTQ provides two separate scores one for the baseline or the current status,

with the other one measuring change. The DTQ was completed by all subjects with parents answering for the children aged 7–13 years. Each item is scored on a 5-point scale: 1 (very much a problem) to 5 (not at all a problem) for current subscale; and for change subscale 1 (much worse) to 5 (much better). The mean score was calculated with higher scores indicating more positive attitude or change.

The PSQI has been used in multiple prior technology trials and is a validated 19 item questionnaire for evaluating subjective sleep quality and quantity [17]. PSQI was only completed by those aged over 16 years, with use down to this age validated in teenagers [18]. The PSQI generates 7 domains for subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, sleep medication, and daytime dysfunction, with each component score ranging from 0 to 3, and summed to produce a global score. A global score > 5 suggests a "poor sleeper" with significant sleep complaints.

WHO-5 is a 5-item questionnaire assessing general psychological health and was completed by those aged 8 and over. Assessed on 6-point Likert scale from 0 (= not present) to 5 (= constantly present). Scores are summated, with raw score ranging from 0 to 25. Then, the scores are transformed to 0–100 by multiplying by 4, with higher scores meaning greater well-being [19].

The HFS-II is designed to measure the worry associated with anticipated hypoglycemia [20]. Worry and behavior mean subscale score are calculated with higher scores indicating greater fear of hypoglycemia. Subjects aged 7–17 years completed the 25-item child/teen version in addition to their parent completing the 26-item parent version. Subjects aged 18 years or older completed the adult version (11 items). Finally, the HCS is a 9 item validated measure with high scores indicating confidence. It was completed by those aged 16 and over [21].

Standard descriptive statistics were used to describe the presenting features of the participants, these included means, standard deviations, and ranges and frequencies and percentages as appropriate. The comparisons between the two interventions were tested using a repeated measures ANOVA. These models included intervention sequence as a between subjects factor and tested the interaction between sequence and intervention to determine whether there were any carryover effects influencing the effects of the interventions. A two-tailed p value < 0.05 was taken to indicate statistical significance, and all analyses were undertaken using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA).

Results

59/60 participants completed the primary study. One participant withdrew during the run-in phase due to sensor burden. Baseline demographic data are shown in Table 1. Mean age was 23.5 years (range 7–65; 16 subjects. aged 7–12 years, 14 aged 13–17 years; and 29 subjects aged 18–65 years). Mean baseline HbA1c was 7.6% (60 mmol/mol). Less than a quarter (23%) had real-time CGM experience, and no participant had previously used automated insulin delivery.

Table 1 Baseline demographics ($n = 60$)

Age, years (range)	23.5 (7.0–65)
Female sex	35 (58%)
Ethnicity	
New Zealand European	41 (68%)
Maori	11 (18%)
Other ethnicity	8 (13%)
Prior primary glucose monitoring method	
Capillary glucose testing, *n* (%)	26 (44%)
Freestyle Libre, *n* (%)	20 (33%)
RT-CGM, *n* (%)	14 (23%)
Body Mass Index, mean ± SD	24.1 ± 5.8 kg/m^2
Years since diagnosis, mean ± SD	13.2 ± 10.2
Years on insulin pump, mean ± SD	6.3 ± 4.2
Baseline HbA1c%(mmol/mol), mean ± SD	7.6 ± 0.9% (59.9 ± 9.8)

Data are presented as *n* (%), mean ± SD, or as indicated otherwise. RT-CGM, real-time continuous glucose monitoring

Statistically significant differences favoring AHCL were demonstrated in several scales, specifically those examining diabetes technology and treatment satisfaction, and the PSQI examining subjective sleep. Complete questionnaire data are presented in Table 2.

Discussion

Currently, few randomized studies have investigated psychosocial factors comparing AID to SAP + PLGM. This sub-study examines a next-generation AID system, with the AHCL algorithm used now commercially available in the MiniMed™ 780G. Our main findings highlight an increased treatment satisfaction and subjective sleep quality with MiniMed™ AHCL system in free-living conditions compared to SAP + PLGM. Interestingly, despite these positive impacts, including to glycemic control as previously described [2], no changes in well-being index nor hypoglycemia fear/confidence were seen.

Our findings of improved diabetes treatment satisfaction for AHCL are consistent with one prospective longitudinal study comparing the 670G HCL to SAP + PLGS [22], and with the improved diabetes related quality of life, and diabetes-specific positive well-being seen with randomized studies of the 670G [7]. In contrast, other studies investigating HCL systems while reporting favorable psychosocial and/or treatment satisfaction, either did not compare data to

Table 2 Comparison of psychosocial outcomes between AHCL and SAP + PLGM

Questionnaire	AHCL	SAP + PLGM	*P* value
DTSQs			
Adults (≥ 18 yrs, *n* = 29)	30.9 ± 0.7	27.9 ± 0.7	0.004
Adolescents, (13–17 yrs, *n* = 16)	38.8 ± 0.9	38.3 ± 0.9	0.681
Parent (of child 7–12 yrs, *n* = 14)	47.2 ± 1.2	45.1 ± 1.2	0.258
DTSQc			
Adults (≥ 18 yrs, *n* = 29)	11.7 ± 0.8	9.2 ± 0.9	0.032
Adolescents, (13–17 yrs, *n* = 16)	14.8 ± 0.7	12.1 ± 0.8	0.024
Parent (of child 7–12 yrs, *n* = 14)	17.9 ± 1.5	13.4 ± 1.6	0.064
DTQ change (all participants, *n* = 59)	3.5 ± 0.0	3.3 ± 0.0	< 0.001
PSQI (Aged > 16 years, *n* = 36)	4.8 ± 0.3	5.7 ± 0.3	0.048
HFS-II Adult (≥ 18 yrs, *n* = 28)			
Behavior subscale	1.13 ± 0.08	1.26 ± 0.08	0.189
Worry subscale	1.01 ± 0.11	1.1 ± 0.11	0.572
HFS-II Child (7–17yrs, *n* = 29)			
Behavior subscale	2.09 ± 0.06	2.02 ± 0.06	0.452
Worry subscale	1.07 ± 0.05	1.14 ± 0.05	0.331
HFS-II Parent (of child 7–17yrs, *n* = 28)			
Behavior subscale	2.02 ± 0.08	1.94 ± 0.08	0.527
Worry subscale	1.35 ± 0.06	1.28 ± 0.06	0.510
HCS (≥ 16yrs, *n* = 35)	3.3 ± 0.1	3.2 ± 0.1	0.229
WHO-5 (≥ 8yrs, *n* = 53)	69.5 ± 1.3	68.1 ± 1.4	0.365

Data presented are model estimates using repeated measures ANOVA and are mean (SE) unless otherwise stated. AHCL, Advanced Hybrid Closed-Loop; SAP + PLGM, Sensor Augmented Pump therapy with Predictive Low Glucose Management; DTSQs, Diabetes treatment satisfaction questionnaire status; DTSQc, Diabetes treatment satisfaction questionnaire change; DTQ, Diabetes Technology Questionnaire; PSQI, Pittsburgh Sleep Quality Index; HFS-II, Hypoglycemia Fear Survey; HCS, hypoglycemia confidence scale WHO-5, World Health Organization Well-Being Index

DTSQs—higher scores indicate higher treatment satisfaction; DTSQc—higher positive scores indicate improved treatment satisfaction; negative scores indicate a worsening of treatment satisfaction; DTQ status and change—The mean score was calculated with higher scores indicating more positive attitude or change; PSQI—A global score > 5 suggests a "poor sleeper" with significant sleep complaints; HFS-II Behavior subscale mean item scores range from 0 to 4; higher scores indicate a greater tendency to avoid hypoglycemia. HFS-II Worry subscale mean item scores range from 0 to 4; higher scores indicate more worry concerning episodes of hypoglycemia and its consequences. HCS higher scores indicate increased confidence. WHO-5 higher scores indicate greater well-being

baseline data [23], or show significant comparative advantage [24, 25]. The FLAIR study [3] using the same of AHCL algorithm as this study supports a potential small benefit for 780G AHCL over 670G, finding greater satisfaction using the glucose monitoring satisfaction score in AHCL compared to HCL (2.8 vs 2.65, p 0.003). Given the incrementally improving AHCL stability we have demonstrated, as evidenced by improvements in time in automode from 87.2% in HCL [26] to 96.4% in AHCL (with Auto Mode interruption of only 1.2 events/week) [2], these improvements in treatment satisfaction may suggest burden reduction. This is highlighted in the improved diabetes treatment satisfaction seen in other diabetes burden reducing technologies such as intermittently scanned CGM [27].

These benefits to psychosocial outcomes are seen spanning adolescent and adult ages. In the primary study, the greatest glycemic benefits were also seen in the adolescent/young adult population [2], a population group experiencing considerable diabetes challenges [28]. This may suggest that next-generation AHCL may be improving patient experience and burden, areas identified in real-world studies as needing improvement with the first-generation 670G [11]. The fact that no changes in hypoglycemia fear nor confidence were seen likely reflects the strength of comparator group which was predictive low glucose suspend. This makes sense given that for the previously published primary outcome data TIR improved with AHCL by 12.5% over SAP + PLGM without any deterioration in time spent below target [2].

Subjective sleep as measured by PSQI also showed a small but statistically significant improvement with AHCL, and a mean score of < 5, while those on SAP-PLGM demonstrated mean global sleep scores > 5 suggestive of

considerably disrupted sleep. This is the first next-generation AID study to demonstrate subjective sleep improvements. Sleep is a major contributor to quality of life and well-being for those impacted by diabetes [29], as well as those without diabetes. Interestingly, sleep, including both objective and subjective measures, has also been demonstrated to have a bidirectional relationship with glycemic control [30]. Previous data on earlier AID systems have been mixed with some studies supportive for improvements in sleep [22] and others inconclusive [7, 31, 32]. Clearly, further trials exploring the impact of next-generation AID systems are needed, with exploration of both objective as well as subjective aspects.

This study's main strengths are the multicenter randomized crossover design in free-living conditions. The comparison of AHCL to a strong comparator such as SAP + PLGM is another strength. The patient population also had a high proportion of sensor naïve participants, and all participants were AID naïve. The main limitation is the study's relatively short duration. A longer study would confirm if these improvements in treatment satisfaction and subjective sleep quality are sustained. In addition, we did not undertake objective sleep measurements nor qualitative interviews or focus groups, which would have allowed for more consumer-focused feedback and richer data about the lived experience. A consensus guideline regarding the preferred psychosocial measures to use in AID clinical trials would be a useful future development to allow greater consistency.

Conclusion

In this sub-study presenting secondary outcomes of a randomized crossover trial, AHCL demonstrates increased treatment satisfaction and improved subjective sleep quality in adolescents and adults with T1D compared to SAP + PLGM. These findings highlight the rapidly developing and improving nature of next-generation AHCL systems and their ability to improve not only glycemic but also potentially reduce burden and improve psychosocial outcomes as well. Clearly, investigation of user experience and psychosocial outcomes is essential when exploring and communicating future AHCL studies, as well as to provide a richer understanding of AHCLs impact on well-being and burden for patients living with this chronic health condition.

Acknowledgements The authors thank the participants and families for taking part in the study.

Author contributions RAM, AR, BG, NK, JS, RAV, BJW, and MIdB designed the study protocol. OJC, RAM, ZLB, DSHC, CMF, NMH, SDJ, BJW, and MIdB were involved with recruitment and data collection. BJW, OJC, and MIdB wrote the manuscript. RAM edited the manuscript. CF conducted the statistical analyses. MIdB is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Funding The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was financially supported by Medtronic.

Availability of data and material De-identified data are available from the authors on request.

Declarations

Conflict of interest B.J.W. and M.I.d.B. are financially supported by Otago University. N.M.H. received honoraria from Sanofi. A.R., B.G., N.K., J.S., and R.A.V. are employees of Medtronic. M.I.d.B. received honoraria from Medtronic. B.J.W. and M.I.d.B have received research funding from Medtronic. No other potential conflicts of interest relevant to this article were reported.

Ethics approval This study was conducted in compliance with the International Organization for Standardization ISO14155: 2011, and conforms to the provisions of the Declaration of Helsinki. The study was approved by the Southern Health and Disability Ethics Committee and registered at ANZCTR (#12619000007134) and ClinicalTrials.gov (NCT04073576).

Informed consent to participate and publish Informed consent was obtained from all participants for inclusion in the study.

References

1. Bekiari E, Kitsios K, Thabit H, Tauschmann M, Athanasiadou E, Karagiannis T et al (2018) Artificial pancreas treatment for outpatients with Type 1 Diabetes: systematic review and meta-analysis. BMJ 361:k1310
2. Collyns OJ, Meier RA, Betts ZL, Chan DSH, Frampton C, Frewen CM et al (2021) Improved glycemic outcomes with medtronic minimed Advanced Hybrid Closed-Loop delivery: results from a randomized crossover trial comparing automated insulin delivery with predictive low glucose suspend in people with Type 1 Diabetes. Diabetes Care 44(4):969–975
3. Bergenstal RM, Nimri R, Beck RW, Criego A, Laffel L, Schatz D et al (2021) A comparison of two hybrid closed-loop systems in adolescents and young adults with type 1 diabetes (FLAIR): a multicentre, randomised, crossover trial. Lancet 397(10270):208–219
4. Breton MD, Kanapka LG, Beck RW, Ekhlaspour L, Forlenza GP, Cengiz E et al (2020) A randomized trial of closed-loop control in children with Type 1 Diabetes. N Engl J Med 383(9):836–845
5. Kanapka LG, Wadwa RP, Breton MD, Ruedy KJ, Ekhlaspour L, Forlenza GP et al (2021) Extended use of the control-IQ closed-loop control system in children with Type 1 Diabetes. Diabetes Care 44(2):473–478
6. Petrovski G, Al Khalaf F, Campbell J, Umer F, Almajaly D, Hamdan M et al (2021) One-year experience of hybrid closed-loop system in children and adolescents with Type 1 Diabetes previously treated with multiple daily injections: drivers to successful outcomes. Acta Diabetol 58(2):207–213
7. McAuley SA, Lee MH, Paldus B, Vogrin S, de Bock MI, Abraham MB et al (2020) Six months of hybrid closed-loop versus manual insulin delivery with fingerprick blood glucose monitoring in

adults with Type 1 Diabetes: a randomized. Control Trial Diabetes Care 43(12):3024–3033
8. Horowitz ME, Kaye WA, Pepper GM, Reynolds KE, Patel SR, Knudson KC et al (2021) An analysis of Medtronic MiniMed 670G insulin pump use in clinical practice and the impact on glycemic control, quality of life, and compliance. Diabetes Res Clin Pract 177:108876
9. Farrington C (2018) Psychosocial impacts of hybrid closed-loop systems in the management of diabetes: a review. Diabet Med 35(4):436–449
10. Munoz-Velandia O, Guyatt G, Devji T, Zhang Y, Li SA, Alexander PE et al (2019) Patient values and preferences regarding continuous subcutaneous insulin infusion and artificial pancreas in adults with Type 1 Diabetes: a systematic review of quantitative and qualitative data. Diabetes Technol Ther 21(4):183–200
11. Messer LH, Berget C, Vigers T, Pyle L, Geno C, Wadwa RP et al (2020) Real world hybrid closed-loop discontinuation: Predictors and perceptions of youth discontinuing the 670G system in the first 6 months. Pediatr Diabetes 21(2):319–327
12. Lal RA, Basina M, Maahs DM, Hood K, Buckingham B, Wilson DM (2019) One year clinical experience of the first commercial hybrid closed-loop system. Diabetes Care 42(12):2190–2196
13. Russell SJ, Beck RW (2016) Design considerations for artificial pancreas pivotal studies. Diabetes Care 39(7):1161–1167
14. Battelino T, Nimri R, Dovc K, Phillip M, Bratina N (2017) Prevention of hypoglycemia with predictive low glucose insulin suspension in children with Type 1 Diabetes: a randomized controlled trial. Diabetes Care 40(6):764–770
15. Bradley C (1994) The diabetes treatment satisfaction questionnaire (DTSQ). In: Bradley C (ed) Handbook of psychology and diabetes: a guide to psychological measurement in diabetes research and practice. Harwood Academic Publishers, Switzerland, pp 111–132
16. Wysocki T, Reeves G, Kummer M, Ross J, Yu M (2015) Psychometric validation of the Diabetes technology questionnaire. Diabetes 64:A633-A
17. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ (1989) The pittsburgh sleep quality index—a new instrument for psychiatric practice and research. Psychiat Res 28(2):193–213
18. Raniti MB, Waloszek JM, Schwartz O, Allen NB (2018) Trinder J (2018) Factor structure and psychometric properties of the Pittsburgh Sleep Quality Index in community-based adolescents. Sleep 41(6):zsy066
19. Topp CW, Ostergaard SD, Sondergaard S, Bech P (2015) The WHO-5 well-being index: a systematic review of the literature. Psychother Psychosom 84(3):167–176
20. Gonder-Frederick LA, Schmidt KM, Vajda KA, Greear ML, Singh H, Shepard JA et al (2011) Psychometric properties of the hypoglycemia fear survey-II for adults with Type 1 Diabetes. Diabetes Care 34(4):801–806
21. Polonsky WH, Fisher L, Hessler D, Edelman SV (2017) Investigating hypoglycemic confidence in Type 1 and Type 2 Diabetes. Diabetes Technol The 19(2):131–136
22. Beato-Vibora PI, Gallego-Gamero F, Lazaro-Martin L, Romero-Perez MDM, Arroyo-Diez FJ (2020) Prospective analysis of the impact of commercialized hybrid closed-loop system on glycemic control, glycemic variability, and patient-related outcomes in children and adults: a focus on superiority over predictive low-glucose suspend technology. Diabetes Technol Ther 22(12):912–919
23. Pinsker JE, Muller L, Constantin A, Leas S, Manning M, McElwee Malloy M et al (2021) Real-world patient-reported outcomes and glycemic results with initiation of control-IQ technology. Diabetes Technol Ther 23(2):120–127
24. Barnard KD, Wysocki T, Ully V, Mader JK, Pieber TR, Thabit H et al (2017) Closing the loop in adults, children and adolescents with suboptimally controlled Type 1 Diabetes under free living conditions: a psychosocial substudy. J Diabetes Sci Technol 11(6):1080–1088
25. Kropff J, DeJong J, Del Favero S, Place J, Messori M, Coestier B et al (2017) Psychological outcomes of evening and night closed-loop insulin delivery under free living conditions in people with Type 1 Diabetes: a 2-month randomized crossover trial. Diabet Med 34(2):262–271
26. Bergenstal RM, Garg S, Weinzimer SA, Buckingham BA, Bode BW, Tamborlane WV et al (2016) Safety of a hybrid closed-loop insulin delivery system in patients with Type 1 Diabetes. JAMA 316(13):1407–1408
27. Boucher SE, Gray AR, Wiltshire EJ, de Bock MI, Galland BC, Tomlinson PA et al (2020) Effect of 6 months of flash glucose monitoring in youth with Type 1 Diabetes and high-risk glycemic control: a randomized controlled trial. Diabetes Care 43(10):2388–2395
28. Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA et al (2019) State of Type 1 Diabetes management and outcomes from the T1D exchange in 2016–2018. Diabetes Technol Ther 21(2):66–72
29. Macaulay GC, Boucher SE, Yogarajah A, Galland BC, Wheeler BJ (2020) Sleep and night-time caregiving in parents of children and adolescents with Type 1 Diabetes mellitus—a qualitative study. Behav Sleep Med 18(5):622–636
30. Macaulay GC, Galland BC, Boucher SE, Wiltshire EJ, Haszard JJ, Campbell AJ et al (2020) Impact of Type 1 Diabetes mellitus, glucose levels, and glycemic control on sleep in children and adolescents: a case-control study. Sleep 43(2):zsz226
31. Cobry EC, Hamburger E, Jaser SS (2020) Impact of the hybrid closed-loop system on sleep and quality of life in youth with Type 1 Diabetes and their parents. Diabetes Technol The 22(11):794–800
32. Bisio A, Gonder-Frederick L, McFadden R, Chernavvsky D, Voelmle M, Pajewski M et al (2021) The impact of a recently approved automated insulin delivery system on glycemic, sleep, and psychosocial outcomes in older adults with Type 1 Diabetes: a pilot study. J Diabetes Sci Technol. https://doi.org/10.1177/19322968820986879

Authors and Affiliations

Benjamin J. Wheeler[1,2] · Olivia J. Collyns[3] · Renee A. Meier[4] · Zara L. Betts[4] · Chris Frampton[5] · Carla M. Frewen[2] · Barbara Galland[2] · Niranjala M. Hewapathirana[1] · Shirley D. Jones[2] · Denis S. H. Chan[3] · Anirban Roy[6] · Benyamin Grosman[6] · Natalie Kurtz[6] · John Shin[6] · Robert A. Vigersky[6] · Martin I. de Bock[3,5,7]

Benjamin J. Wheeler
ben.wheeler@otago.ac.nz

Olivia J. Collyns
Olivia.Collyns@cdhb.health.nz

Renee A. Meier
renee.meier@otago.ac.nz

Chris Frampton
chris.frampton@otago.ac.nz

Carla M. Frewen
carla.frewen@otago.ac.nz

Barbara Galland
Barbara.galland@otago.ac.nz

Niranjala M. Hewapathirana
Niranjala.Hewapathirana@cdhb.health.nz

Shirley D. Jones
shirley.jones@otago.ac.nz

Denis S. H. Chan
Dennis.Chan@cdhb.health.nz

Anirban Roy
anirban.roy@medtronic.com

Benyamin Grosman
Barbara.galland@otago.ac.nz

Natalie Kurtz
Natalie.Kurtz@medtronic.com

John Shin
john.shin@medtronic.com

Robert A. Vigersky
robert.a.vigersky@medtronic.com

1 Southern District Health Board, 201 Great King Street, Dunedin 9016, New Zealand

2 Department of Women's and Children's Health, Dunedin School of Medicine, University of Otago, 201 Great King Street, Dunedin 9016, New Zealand

3 Canterbury District Health Board, 2 Riccarton Avenue, Christchurch Central City, Christchurch 8011, New Zealand

4 Christchurch Clinical Studies Trust, Level 4/264 Antigua Street, Christchurch Central City, Christchurch 8011, New Zealand

5 Departent Paediatrics, University of Otago, Terrace House, 4 Oxford Terrace, Christchurch 8011, New Zealand

6 Medtronic, 18000 Devonshire Street, Northridge, CA 91325, USA

7 Christchurch Hospital, 2 Riccarton Ave, P.O. Box 3245, Christchurch 8140, New Zealand