Received: 23 February 2023 | Revised: 17 May 2023 | Accepted: 21 May 2023
DOI: 10.1111/dom.15161

RESEARCH LETTER

WILEY

Comparing the technical reliability and insulin dosing of a "do-it-yourself artificial pancreas" with a commercial hybrid closed-loop system in a "shadow-mode" scenario: An exploratory study

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Funding information
Diabetes Center Berne

KEYWORDS: CSII, insulin pump therapy, subcutaneous injection, type 1 diabetes

1 | INTRODUCTION

Do-it-yourself artificial pancreas systems (DIYAPSs) are compound devices that autonomously adjust insulin dosage in people with diabetes. Although DIYAPSs resemble commercial hybrid closed-loop systems (cHCLs), they are not approved for the treatment of diabetes. Studies investigating DIYAPSs showed glycaemic control comparable to cHCLs in different scenarios, although significant differences in study design and participant cohorts inhibit direct comparison.[1–3] The Minimed Medtronic 670G was the first cHCL available. Its glucose control algorithm, a proportional-integral-derivative algorithm, represents the most prominent class of algorithms utilized in hybrid closed-loop systems (HCLs), providing compelling evidence for its safety and efficacy.[4–7] Oref0 was the first open-source algorithm introduced for DIYAPSs; this is a "heuristic-based algorithm" that imitates the mathematical considerations of people with diabetes to calculate insulin requirements.[8]

Although both algorithms pursue similar tasks, their development history and architecture differ significantly. DIYAPSs are being increasingly utilized, especially in economically stressed countries. Although certain studies show the effectiveness and safety of DIYAPSs, a direct comparison with cHCLs remains difficult due to the aforementioned limitations. Therefore, the present study aimed to compare adaptions of basal insulin doses of a DIYAPS and a cHCL simultaneously. The study implements the "shadow-mode" principle, by which input data are handled by a newly deployed version of an existing processor without returning a response to its user.[9] The DIYAPS and the cHCL calculated the participant's insulin requirements in parallel. However, the cHCL was actually infusing insulin, while the DIYAPS' insulin pump was separated from the participant's body.

2 | METHODS

Seven participants who had no experience of using a DIYAPS but had general technical knowledge (ie, daily use of a smartphone or computer) were recruited between June and November 2019. The DIYAPS was built according to the instructions available at https://openaps.readthedocs.io/en/latest/ with the master version of the control

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TABLE 1 Technical malfunctions and alarms observed in the do-it-yourself artificial pancreas system and the commercial hybrid closed-loop system

System	Interruption of closed loop, minutes	Type of event	Number of occurrences	Resolved (by system or user)
DIYAPS	60	Loss of connection	5	Yes
DIYAPS	255	Loss of connection	1	Yes
DIYAPS	180	Loss of connection	1	Yes
DIYAPS	375	Loss of connection	1	Yes
DIYAPS	135	Loss of connection	1	Yes
DIYAPS	75	Loss of connection	2	Yes
DIYAPS	210	Loss of connection	1	Yes
DIYAPS	2485	Loosening of a screw on the Microprocessor	1	No
DIYAPS	165	Loss of connection	1	Yes
DIYAPS	60	Loss of connection	2	Yes
DIYAPS	270	Loss of connection	1	Yes
DIYAPS	105	Loss of connection	1	Yes
DIYAPS	60	Loss of connection	1	Yes
DIYAPS	120	Loss of connection	2	Yes
DIYAPS	80	Loss of connection	1	Yes
DIYAPS	3240	Malfunction of power pack	1	No
DIYAPS	90	Loss of connection	1	Yes
DIYAPS	75	Loss of connection	1	Yes
DIYAPS	6150	Malfunction of power pack	1	No
DIYAPS	240	Loss of connection	1	Yes
DIYAPS	60	Loss of connection	1	Yes
DIYAPS	600	Loosening of the charging socket on the microprocessor	1	No
DIYAPS	1200	Loosening of a screw on the Microprocessor	1	No
DIYAPS	105	Loss of connection	2	Yes
DIYAPS	120	Loss of connection	1	Yes
cHCL	4	NOTSEATED_SUSPEND	3	Yes
cHCL	21	USER_SUSPEND	1	Yes
cHCL	4	NOTSEATED_SUSPEND	2	Yes
cHCL	4	USER_SUSPEND	2	Yes

Abbreviations: cHCL, commercial hybrid closed-loop system (Minimed Medtronic 670G); DIYAPS, do-it-yourself artificial pancreas system.

algorithm (Oref0; release 0.6.3 in May 2019) installed. The treatment parameters of each participant (ie, glycaemic target, insulin used, etc.) were copied from the cHCL to the DIYAPS. Insulin infusion was performed solely by the cHCL, without study-related changes to the participants' clinical routine. The cHCL and DIYAPS received independent continuous glucose monitoring (CGM) measurements for HCL operation. The DIYAPS' insulin reservoir was filled with saline and the catheter was fixed to a gauze bandage roll. Participants kept the DIYAPS in a carrier bag within a distance of 5 m throughout the study and were instructed how to maintain its components. Bolus insulin doses and meal carbohydrates entered into the cHCL were subsequently announced to the DIYAPS. The supplementary appendix reports details of the DIYAPS composition and statistical methods. The present investigation was reviewed and approved by the Cantonal Ethics Committee Bern prior to participant recruitment (study identifier 2018-01977).

3 | RESULTS

Table 1 reports technical malfunctions observed in the DIYAPS and cHCL during the study. Figure 1 illustrates the study setup. Table S1 reports adaptions of basal insulin suggested by the DIYAPS compared with the cHCL. Figure S1 illustrates simultaneous CGM measurements and basal rate profiles of the DIYAPS compared with the cHCL.

The DIYAPSs and cHCLs were simultaneously active for 1182 hours. A total of 25 technical malfunctions were observed during DIYAPS use, interrupting HCL operations for 275.25 hours (23.3% of 1182 hours). Twenty malfunctions were either self-limiting or could be resolved by the user, while five serious hardware errors occurred using the DIYAPS, interrupting HCL operations for 227.9 hours (19% of 1182 hours). Serious malfunctions were not self-limiting, could not

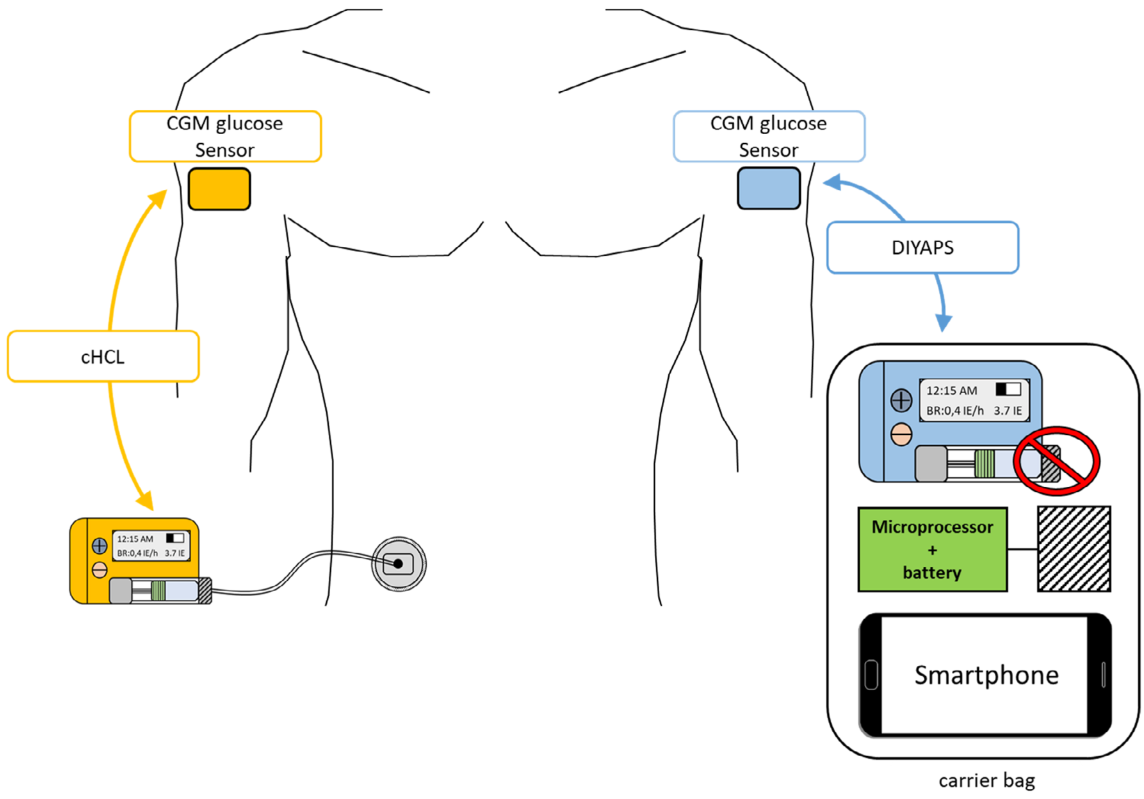

FIGURE 1 Study setup shows the implementation of the "shadow-mode" principle and the hardware components used during the study. Each participant used a commercial hybrid closed-loop system (cHCL; Minimed Medtronic 670G; insulin pump + continuous glucose monitoring [CGM] glucose sensor, left side [in yellow]) for insulin treatment. In parallel, an additional CGM glucose sensor (in blue) delivered measurements to a separate do-it-yourself artificial pancreas system (DIYAPS; insulin pump [in blue], microprocessor, ion battery pack and a smartphone) enclosed in a carrier bag

be resolved by the user, and/or required replacement or repair of the affected component. Four malfunctions were observed using cHCLs, interrupting HCL operations for 33 minutes (0.2% of 1182 hours), all of which were either self-limiting or could be resolved by the user.

In total, 546.8 hours were used for comparison of basal insulin doses. Time periods were excluded from comparison if CGM measurements were missing, if HCL operations were interrupted, or if carbohydrate or bolus insulin doses entered into the DIYAPS were divergent from those entered into the cHCL. There was a 92.6% match in CGM measurements between the DIYAPS and the cHCL. The height and shape of the CGM profiles were statistically comparable ($P = 0.987$). Decisions to increase or decrease basal insulin doses matched for 83.9% of all time points between the DIYAPSs and cHCLs. However, the DIYAPS suggested higher basal insulin doses during the daytime ($P = 0.033$), the nighttime ($P < 0.001$), euglycaemia ($P < 0.001$) and hyperglycaemia ($P = 0.002$), as compared with the cHCL. Nevertheless, suggested and delivered basal insulin doses were statistically comparable during hypoglycaemia ($P = 0.077$).

4 | DISCUSSION

The DIYAPS had a higher number of technical malfunctions compared to the cHCL and suggested higher basal insulin doses, except during hypoglycaemia. On three occasions, screws that fixed two DIYAPS components (the microprocessor and the explorer board) loosened, and on two occasions, the power bank connector was instable, causing system shutdowns. Affected participants were unable to identify the cause of the shutdown, which was further complicated by the lack of specific alarms. On all occasions, the DIYAPS reverted to the preprogrammed basal insulin rate.[10] Besides potentially harmful situations that may accompany an interruption of HCL operations, DIYAPS users cannot rely on an in-person, three-level helpdesk service, a prerequisite for commercial medical devices. Outside of a study environment, DIYAPS users must learn to resolve even more complex issues by themselves or rely on recommendations from the DIYAPS community. If serious hardware errors occur, obtaining a replacement might be particularly challenging, as many DIYAPSs rely on older, discarded insulin pumps. From an ethical point of view, it seems important to inform patients who plan to use a DIYAPS about precisely these limitations and to provide commercial alternatives. In addition, dialogue between DIYAPS users and their treating physicians should be prioritized in order to identify and discuss potential risks at an early stage.[11]

Doses of basal insulin calculated by the DIYAPS were twice as high during the daytime, the nighttime, euglycaemia and hyperglycemia versus those delivered by the cHCL. This might reflect differences between the two glucose control algorithms, with Oref0 being presumably more aggressive. In addition, the cHCL was challenged with potential injection site issues, which was not the case for the DIYAPS. If the DIYAPS had also infused insulin, the observed differences in basal insulin could be even greater if constraints in catheter function had appeared. Due to the absence of reported insulin doses, it remains difficult to assess the observed differences in relation to results from the available DIYAPS studies, which generally show satisfying glycaemic control.[1,12]

This study has the following strengths and limitations: This is the first study to implement a shadow-mode principle using a DIYAPS and a cHCL, which provides simultaneous insights in the technical reliability and adaptions of insulin doses. However, the DIYAPS was not delivering insulin, which might have caused an overcompensation of insulin adaptions if delivered insulin doses were lower than calculated by the DIYAPS. However, both technologies used the same glycaemic parameters for their calculations and CGM measurements were statistically comparable. The participants had no experience with DIYAPSs. This may have constrained the handling of malfunctions, however, it reflects the usability of DIYAPS for people outside of the DIY community more accurately. The need for delicate handling of DIYAPS components has been acknowledged by the later versions of DIYAPSs, which offer 3D-printed plastic cases to hold components in place.

In the present study serious technical malfunctions were observed when using the first-ever introduced DIYAPSs. Insulin dosing seemed more aggressive in the DIYAPS as compared to the cHCL. Despite the reports of satisfactory glycaemic control in available studies, constraints in hardware reliability and the lack of medical customer services reflect important limitations to the safe use of DIYAPSs.

ACKNOWLEDGMENT

We want to express our gratitude to all the participants in the study and the time and effort they devoted. Open access funding provided by Inselspital Universitatsspital Bern.

CONFLICT OF INTEREST STATEMENT

The authors disclose that there is no conflict of interest.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.15161.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

1. Kesavadev J, Srinivasan S, Saboo B, Krishna BM, Krishnan G. The do-it-yourself artificial pancreas: a comprehensive review. *Diabetes Ther*. 2020;11(6):1217-1235.
2. Bally L, Thabit H, Kojzar H, et al. Day-and-night glycaemic control with closed-loop insulin delivery versus conventional insulin pump therapy in free-living adults with well controlled type 1 diabetes: an open-label, randomised, crossover study. *Lancet Diabetes Endocrinol*. 2017;5(4):261-270.
3. Tauschmann M, Allen JM, Wilinska ME, et al. Day-and-night hybrid closed-loop insulin delivery in adolescents with type 1 diabetes: a free-living, Randomized Clinical Trial. *Diabetes Care*. 2016;39(7):1168-1174.
4. Hovorka R, Canonico V, Chassin LJ, et al. Nonlinear model predictive control of glucose concentration in subjects with type 1 diabetes. *Physiol Meas*. 2004;25(4):905-920.
5. Hovorka R, Chassin LJ, Wilinska ME, et al. Closing the loop: the adicol experience. *Diabetes Technol Ther*. 2004;6(3):307-318.
6. Steil GM, Rebrin K, Darwin C, Hariri F, Saad MF. Feasibility of automating insulin delivery for the treatment of type 1 diabetes. *Diabetes*. 2006;55(12):3344-3350.
7. Mauseth R, Hirsch IB, Bollyky J, et al. Use of a "fuzzy logic" controller in a closed-loop artificial pancreas. *Diabetes Technol Ther*. 2013;15(8):628-633.
8. WeAreNotWaiting OpenAPS https://openaps.org/.
9. GitHub. Shadow Testing. https://microsoft.github.io/code-with-engineering-playbook/automated-testing/shadow-testing/. Updated 25.APR.2022 Accessed 09.01., 2023.
10. OpenAPS. openaps.readthedocs.io.
11. Shaw D, Crabtree TSJ, Hammond P, McLay A, Wilmot EG. The DIY artificial pancreas system: an ethical dilemma for doctors. *Diabet Med*. 2020;37(11):1951-1953.
12. Melmer A, Zuger T, Lewis DM, Leibrand S, Stettler C, Laimer M. Glycaemic control in individuals with type 1 diabetes using an open source artificial pancreas system (OpenAPS). *Diabetes Obes Metab*. 2019;21(10):2333-2337.

SUPPORTING INFORMATION

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

How to cite this article: Künzler J, Züger T, Stettler C, Laimer MW, Melmer A. Comparing the technical reliability and insulin dosing of a "do-it-yourself artificial pancreas" with a commercial hybrid closed-loop system in a "shadow-mode" scenario: An exploratory study. *Diabetes Obes Metab*. 2023; 1-4. doi:10.1111/dom.15161