Open Source Artificial Pancreas Systems are safe and effective when supported in-clinic: outcomes in 248 consecutive T1 patients.

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Competing interests: TE received CGM trade samples and honoraria from Dexcom Inc. and Abbott Diabetes Canada Inc.

Abstract

Background

This paper reports safety, glycemia and quality of life outcomes associated with in-clinic installation and management of DIY Artificial Pancreas Systems (APS) in Type 1 diabetes (T1D) using three Automated Insulin Delivery (AID) apps. In this paper clinic-supported DIYAPS is termed supported open source APS (SOSAPS).

Methods

SOSAPS was offered as an alternative to MDI and retail APS to T1Ds at a Canadian privately-owned publicly funded diabetes centre. SOSAPS hardware included an Omnipod pod (either Eros or Dash, no PDM required), Dexcom G6 CGM, intermediary radio-frequency device (for users of Eros pump) and smartphone (iPhone or Android phone). All TID clinic patients using CGM for 3+ months who expressed interest in SOSAPS, deemed tech savvy and good communicators were invited to participate. All provided informed consent and waiver. All 3 SOSAPS algorithms were built by clinic software engineers and installed and configured by clinic staff. Android phone users (n=26) were assigned to AndroidAPS (AAPS); iPhone users were assigned to either Loop (n=108) or iPhoneAPS (iAPS, n=114) based on personal preference, age and tech skills. patients were prepared and trained over 3 appointments: after APS installation patients were offered daily fine-tuning visits for up to 3 weeks followed by support as needed including online non-clinic channels. Primary outcomes were safety (incidence of severe hypoglycemia and diabetic ketoacidosis), % time spent with glucose 4·0–10·0 mM (time in range, TIR) and % time below 4·0 mM (TBR). Secondary outcomes were change in A1c, and Quality of Life measures: Diabetes Distress Score (DDS), Fear of Hypoglycemia Score (FHS) and Insomnia Index (II).

Results

A total of 248 subjects (131 M, 117 F) had SOSAPS installed with mean age 37 (range 2-78) years and diabetes duration 21 (range 1-67) years. Three episodes of severe hypoglycemia and no episodes of ketoacidosis were reported. Average TIR (n=248) rose from 64% to 81% (p<0.0001), TBR 4·0 mM fell from 3.5% to 2.5% (p=0·001) and A1c (n=184) fell from 7·2% to 6·7% (p<0·0001). Almost identical changes in TIR and A1c were seen with Loop and iAPS; AAPS users started with lower A1c and higher TIR and demonstrated smaller improvements. Quality of Life (DDS, FHS and ISI) scores were healthy pre and improved further post SOSAPS. Of the entire clinic T1D cohort (n=1130) the average "most recent A1c" was 7.5%. By insulin treatment strategy the highest A1c was 7.8 with MDI (n=560). Of APS strategies Medtronic was 7.2 (n=24), Tandem was 6.9 (n=48) and SOSAPS 6.8 (n=253).

Conclusions

In a publicly funded diabetes centre with requisite technical expertise and support infrastructure, and T1D patients selected primarily by tech skills and ability to afford Omnipod pods, the use of SOSAPS and medical care provided at no cost to the patient was safe, improved TIR, A1c and quality of life and provided superior A1c compared with conventional treatment with MDI and retail pump systems.

Paper Proper

Introduction

Do-it-yourself artificial pancreas systems (DIYAPS), hereafter open-source APS (OSAPS), have been in use by people living with Type 1 Diabetes (TIDs) since at least 2014 (Lewis 2018). Best estimates suggest that 30,000 TIDs are now using OSAPS (Lucas 2022).

A growing body of evidence supports OSAPS as both safe and effective: Lum et al (2021) described the self-reported outcomes of 558 users of the “Loop” OSAPS: including a tenfold reduction in the incidence of severe hypoglycemia, improvement in Time in Range (TIR) for CGM glucose 4·0-10·0 mM from 67% to 73% and reduction in A1c from 6·8% to 6·5%. Gawrecki et al (2021) showed similar results in 12 adults supported by a single Polish clinic using open source AndroidAPS (AAPS): 44 patients in a New Zealand study randomized to a modified version of AAPS by Burnside et al (2022) had a TIR 14% higher than 54 controls randomized to sensor-augmented pump.

As yet no single OSAPS algorithm has received regulatory approval though “Loop” was submitted to the FDA by the non-profit Tidepool in 2021-Jan.

The widespread use of OSAPS has prompted increased interest in the TID medical community. The 2022-Jan review by Braune et al included an international consensus statement and practical guidance for health-care professionals.

Perceived advantages of OSAPS over retail APS, in Canada represented by Tandem and Medtronic systems, include 1) support of the tubeless Omnipod patch pump controlled by smartphone alone without requirement for omnipod PDM 2) reduced up-front costs - no need to purchase tubed pump hardware or Omnipod PDM 3) app agility - rapidly evolving, more flexible algorithms contributed to by thousands of OSAPS users/programers worldwide.

In our clinic's jurisdiction (British Columbia, Canada), a fourth OSAPS advantage pertained: subject to a deductible, the hardware and consumables for our default OSAPS (Omnipod pods and Dexcom G6) were covered by the public purse while only partially covered for retail APS (Medtronic and Tandem).

Obstacles to the implementation of OSAPS in a diabetes clinic are many. These include the technical challenges of building, maintaining, installing and configuring the necessary open-source apps, developing the expertise and confidence to adjust app settings and physician liability concerns in the absence of regulatory approval.

In this paper the authors report outcomes for 248 clinic patients started on supported OSAPS (hereafter SOSAPS) during the period 2020-Jul-01 - 2022-Nov-22 and for comparison provide A1c outcomes for the remainder of the clinic’s T1D population (n=882) by insulin strategy.

This retrospective chart review was approved by Advarra Center for IRB Intelligence.

Materials and methods

Clinic logistics

Background: BCDiabetes is a privately-owned, publicly-funded full service pediatric and adult diabetes centre in Vancouver, Canada with a staff of 17 including 3 endocrinologists and 8 full-time case managers (nurses and unlicensed foreign medical graduate-physician assistants). All client appointments are provided at no cost to the client through fee-for-service by the Medical Services Plan of British Columbia. Standard practice is to recommend CGM for all individuals with TID and to only prescribe insulin pump therapy to those using a CGM. In the prior 12 months 94% of TID patients had used a CGM for at least 10 days.

SOSAPS Apps: In late 2019, with the support of volunteers in the local open-source software diabetes community the clinic developed the necessary infrastructure to build, maintain and distribute OSAPS algorithms to Patients. These apps included two iPhone apps: Loop and iPhoneAPS (previously known as freeAPSX NexGen, hereafter iAPS distributed through our clinic’s account on Apple’s TestFlight’s beta testing utility) and AndroidAPS (AAPS) distributed from the clinic’s cloud storage. By default, apps were updated from the latest open-source code every 80 days or fewer. Apps were shared at no charge to Patients.

Consent and Waiver to use SOSAPS: Consent and waiver forms for the use of non-Health Canada approved SOSAPS for adults and minors were developed organically and improved iteratively with the input of legal advice.

CGM connectivity: The clinic employs a cloud instance of Nightscout interfaced with the clinic's custom electronic medical record system providing for both immediate deployment of Nightscout accounts and within EMR access to real-time CGM data and analytics.

Diabetes Technologist: In December 2019 the clinic hired a dedicated diabetes technology lead (a foreign medical graduate and Orthopedic Surgeon) who over the course of many months developed high-level diabetes clinical skills including expertise in all 3 apps. In October 2022 the clinic hired a second diabetes technologist..

Client logistical requirements

Hardware (all items listed below were provided by client at client's expense).

Insulin pump: Omnipod Eros or Dash pods (Omnipod PDM not required for OSAPS)

CGM: Dexcom G6

Smartphone: iPhone 6S (or later) or Android phone OS 9 (or later)

(Orangelink or Rileylink): Required only for Omnipod Eros pods - not required for Omnipod Dash users. The Orangelink and Rileylink are intermediary radiofrequency communication devices that translate communication between phones and Omnipod Eros pods (C$200 one time expense, bought from getrileylink.org).

Inclusion criteria: T1D, compatible smartphone with data plan, actively using CGM for 3+ months, ability to afford the additional cost of Omnipod pods (C$0-10/day depending on deductible), and willingness to sign informed consent and waiver.

Exclusion criteria: Inadequate tech skills (eg: inability to install CGM software easily, unawareness of Apple ID and/or password), significant communication barrier).

SOSAPS installation, training and follow-up

Client awareness: As part of routine clinical care, all TIDs were informed of the existence of APS including retail options and the clinic's SOSAPS program. Patients who indicated a desire to pursue SOSAPS treatment and who met the eligibility criteria were provided this information handout.

Client preparation: patients were booked for three appointments with the diabetes technologist. At the first appointment of 30 minutes, a general discussion about SOSAPS and suitability for SOSAPS were confirmed (only 2 potential patients were excluded at this visit) and for iPhone users, a decision made re app: Loop vs iAPS - by default patients <12 years of age and individuals with tech skills considered no better than moderate were offered Loop while the others offered iAPS). At the second appointment, also of 30 minutes, a Nightscout account was deployed (if necessary), a Nightscout and insulin adjustment tutorial given and consent and waiver obtained. Requisition for A1c, if not done in the last month was also provided. At the third appointment (90 minutes) the APS app was installed and configured. From January 2022, between the second and third appointments, patients were asked to complete Quality of Life (QoL) questionnaires for Diabetes Distress Score (DDS), Fear of Hypoglycemia (HFS-II) and Insomnia Severity Index (ISI).

App installation and configuration visit: By default this visit was in person: approximately 90% of installations were performed in-person, the rest by Zoom. Several two-client and two three-client simultaneous installations were performed. Time In Range (TIR) for the previous 14 days was calculated via Nightscout. This TIR was used to reflect "before" SOSAPS.

Post installation fine-tuning: After initial installation and configuration patients were offered daily (Monday to Friday) virtual post-installation follow-up visits for fine tuning. Most patients required 5 or fewer visits (the mode number of visits was 3; no client required more than 10 fine-tuning visits). These appointments were typically of 5-10 minutes duration.

App troubleshooting and after-hours care: After completion of the fine-tuning visits patients were encouraged to join the clinic's no-charge volunteer-run online Slack channel support group.

Three weeks post installation visit: TIR for the previous 7 days was calculated from Nightscout for users of Loop and iAPS and used as the measure of TIR "after" SOSAPS.

Three month post installation visit: For users of AAPS, TIR for the previous 7 days was calculated from Nightscout and used as the measure of TIR "after" SOSAPS (see Discussion for rationale). Patients were asked to go for an A1c. Repeat QoL questionnaire completion was sought and responses were considered to reflect "after" SOSAPS status.

Change in A1c with SOSAPS

Because of the COVID pandemic, for the period March 2020 - December 2022 the expectation of routine external laboratory quarterly A1c measurement was suspended: this period encompassed the entire duration of this chart review. For the purposes of this chart review the following definitions were applied: Pre-SOSAPS A1c was the A1c obtained closest to SOSAPS installation providing it was obtained <52 weeks pre and <2 weeks post SOSAPS. Post-SOSAPS A1c was the A1c obtained closest to 3 months post SOSAPS installation providing it was drawn < 52 weeks and > 10 weeks post SOSAPS.

Most recent A1c

The clinic runs a monthly quality improvement database query for various parameters including A1c. The "most recent A1c" measure for each clinic patient was taken from the December 2022 query. For the "most recent" A1c value to qualify as being representative for a patient it had to have been obtained after October 2019.

Statistical methods

Data were subjected to the Shapiro-Wilks test and found to be normally distributed. P values shown in the results section were based on two-tailed paired Student's T-tests.

Results

The first SOSAPS installation occurred on 2020-Aug-1. The table below shows demographic data for the 248 BCDiabetes patients with T1D on whom pre- and post-SOSAPS installation TIR data were available as of 2023-Jan-06.

	Loop (n=108)	iAPS (n=114)	AAPS (n=26)	Total (n=248)
Sex				
Male	57 (53%)	58 (51%)	16 (62%)	131 (53%)
Female	51 (47%)	56 (49%)	10 (38%)	117 (47%)
Age (yrs)	34 (13-56)	36 (21-51)	43 (30-56)	36 (18-54)
age <18	36 (33%)	18 (16%)		54 (22%)
T1 Duration (yrs)	21 (5-37)	20 (7-32)	23 (9-36)	20 (6-35)

Table 1: Demographics Data are shown as counts (percent of sample) or means (+/-SD),

The youngest client started on SOSAPS was 2: 20 were under the ages of 10 and 9 patients were older than 70 years.

Thirty-six patients switched SOSAPS algorithms during the period of observation. Their outcomes were counted once only and attributed to the first SOSAPS installed. All 36 started with Loop and migrated to iAPS; 10 of the 36 then moved back from iAPS to Loop.

Three episodes of severe hypoglycemia were reported: two in the same iAPS patient and one with an AAPS patient. No episodes of DKA were reported. Two patients stopped using SOSAPS: both reported the expense of replacing a lost or damaged Orangelink to be the factor preventing resumption.

The table below shows change in TIR and TBR target 4·0-10·0 mmol/L before and after SOSAPS.

	Loop (n=108)	iAPS (n=114)	AAPS (n=26)	Total (n=248)
TIR				
Before	64%	63%	69%	64%
After	81%	79%	81%	80%
Change	17%	16%	12%	16%
p value	<0.0001	<0.0001	0.004	<0.0001
TBR				
Before	3.9%	3.1%	3.5%	3.5%
After	2.3%	2.6%	3.2%	2.5%
Change	-1.6%	-0.5%	-0.3%	-1.0%
p value	0.0003	0.242	0.717	0.001

Table 2: Change in TIR and TBR

The table below shows change in A1c before and after SOSAPS.

	Loop (n=83)	iAPS (n=87)	AAPS (n=14)	Total (n=184)
Before	7.1	7.3	6.6	7.2
After	6.7	6.7	6.4	6.7
Change	-0.4	-0.6	-0.2	-0.5
p-value	0.0001	0.0002	0.65	<0.0001

Table 3: Change in A1C

In the A1c change table above n = 184, 64 fewer than the n = 248 reported in the change in TIR change table above. Of the 64 patients without a pair of pre and post A1c values, 38 had no qualifying A1c pre SOSAPS and 26 had no qualifying A1c post SOSAPS. Of those 26, half were less than 3 months post SOSAPS.

Diabetes Distress outcomes are shown below. Diabetes distress levels are defined as follows: low-mild 1·0-1·9, moderate 2·0-2·9 and high 3·0-4·0.

	Loop (n=23)	iAPS (n=34)	AAPS (n=9)	Total (n=66)
DDS				
Before	1.9	2.2	1.8	2.0
After	1.2	1.1	1.2	1.2
Change	-0.6	-1.0	-0.7	-0.8
p value	0.001	<0.0001	0.05	<0.0001

Table 4: Change in Diabetes Distress Score

Levels of Diabetes distress were low-mid before SOSAPS and low on SOSAPS.

Fear of Hypoglycemia outcomes are shown below. Fear of Hypoglycemia is defined as present at values > 54.

	Loop (n=23)	**iAPS (n=33)**	**AAPS (n=9)**	**Total (n=65)**
HFS				
Before	45.7	36.8	35.2	39.7
After	31.3	28.6	22.9	28.8
Change	-14.4	-8.2	-12.3	-11.0
p value	0.005	0.095	0.100	0.001

Table 5: Change in Hypoglycemia Fear Score

Fear of Hypoglycemia scores were low pre and lower still on SOSAPS.

Insomnia Severity Index outcomes are shown below. Insomnia severity is defined as follows: absent 0–7, sub-threshold 8–14, moderate 15–21; and severe 22–28.

	Loop (n=16)	**iAPS (n=31)**	**AAPS (n=7)**	**Total (n=54)**
ISI				
Before	10.4	10.1	10.4	10.3
After	7.3	7.6	8.1	7.6
Change	-3.1	-2.5	-2.3	-2.7
p value	0.166	0.093	0.506	0.021

Table 6: Change in Insomnia Severity Index

Insomnia index levels were in the sub-threshold range pre SOSAPS and were in the absent range on SOSAPS.

Discussion

Our clinic developed the logistic capability for SOSAPS because excellent outcomes were observed in patients using self-installed OSAPS, because these same patients offered to support the necessary process, and because SOSAPS supported a setup that was less expensive than retail APS. To facilitate the process our systems engineer developed a cloud instance of Nightscout with the capacity to deploy Nightscout accounts instantly and to interface with our electronic medical record system remotely allowing clinic patient CGM (including SOSAPS patients) to be followed in real time.

Three OSAPS apps were offered: Loop and iAPS for iPhone users and AAPS for Android users.

Loop offers an experience similar to that of sensor-enhanced pumps but with added layers of automation. It has a simple highly appealing interface that against a background of manual carb inputs and user-assigned basal rates, ICFs and ISFs uses a primarily predictive algorithm that automatically adjusts basal rates and provides additional corrective insulin via micro boluses every 5 minutes. The same code is embedded in the Tidepool version of the Loop app submitted to the FDA in 2021 - our clinic's version of the Loop app is little changed compared to Tidepool's. Because of the development of more advanced algorithms such as oref0/oref1 (see below) the Loop app is considered unlikely to further evolve.

Both iAPS and AAPS utilize algorithms known as oref0 and oref1 - these demand more complex user interfaces than Loop. The oref1 algorithm is undergoing daily iterative development by the OpenAPS community. With the combination of the two algorithms, insulin dosage is handled in a more physiologic manner, by reacting primarily to changes in glucose rather than to where glucose is predicted to be in say 30 minutes (=oref0). The oref0 algorithm is similar to that on which Tidepool's Loop is based: it utilizes temp changes in basal rate to react to small changes in glucose; oref1 extends oref0 by adding the ability to autonomously react to larger changes in glucose, most often a result of the consumption of carbs. It also employs predictive logic based on user input of carbs but unlike oref0 it relies primarily on reactive logic. Reactive logic protects against excessive prandial insulin dosing (only a portion of the calculated bolus from user inputted carbs is given initially; the balance is given only when the algorithm sees a risk in sugar) and allows for user configured controls to automate micro bolusing for “unannounced meals” (food consumed without user input of carbs) and for dynamic ISF (providing higher ISFs with higher sugar). See this document for more on the comparison of oref0 and oref1.

The AAPS app includes a self teaching tool that enforces the completion of 10 “Objectives”, before starting full closed-loop, the point at which all oref1 features are available. The earliest an AAPS user could start the fully closed-loop is at 6 weeks post installation. For this reason TIR for AAPS users was calculated for the last seven days prior to the 3 month post SOSAPS visit.

Retail APS algorithm source code is proprietary, not accessible to the public and unknown to the authors. With respect to the clinical use of retail APS, the authors have worked extensively with Medtronic and Tandem systems but neither Omnipod 5 nor CamAPS. The authors believe that the current Medtronic, Tandem and Omnipod 5 algorithms are similar to oref0 and include some features of oref1. The authors believe that the future of APS lies in further development of oref1 and related algorithms. Open source favours such a development path because it allows for frequent iterative changes and has the ability to test proposed changes and receive feedback from hundreds of users within days.

We chose to support the Omnipod patch pump and Dexcom G6 CGM because both were covered by our Provincial reimbursement program and both had stable mature implementations with the three SOSAPS apps.

We chose initially to have one diabetes technologist installing, configuring and fine-tuning the three OSAPS algorithms allowing for uniformity and a high level of expertise. Our clinic trained an additional diabetes technologist as backup and will train more as volume demands.

There was a high degree of interest in SOSAPS at our clinic - all those expressing interest were reminded that SOSAPS were unregulated and unapproved by Health Canada. Retail APS options were encouraged for patients who expressed a preference for retail APS or any who voiced regulatory concerns.

Three episodes of severe hypoglycemia was seen with SOSAPS over 2.5 years (=6.2 hundred patient years of exposure) representing an incidence of 0·5 episodes per hundred-person years. By contrast Lum and colleagues in their 2021 study of 553 self-installed Loop users, reported an incidence of severe hypoglycemia of 18·7 per hundred-person years (this incidence itself one tenth the severe hypoglycemia rate for the cohort pre-Loop). With respect to retail APS, no episodes of severe hypoglycemia were reported by Bergenstal et al in 2016 in 0·3 hundred-patient years experience with Tandem Control-IQ, and by Brown et al in 2019 in 0·6 hundred-patient years experience with the Medtronic 670G system. Brown et al in 2021 reported 3 episodes of severe hypoglycemia with the Omnipod 5 system for an incidence of 0·8 per hundred-patient years. At our clinic during the same 2.5 year time period as the SOSAPS experience described in this report, 882 non-SOSAPS TIDs were followed, representing 18 hundred-patient years, during which a total of 30 episodes of severe hypoglycemia were reported for an incidence of 1.4 episodes per 100-patient years.

Two patients stopped using SOSAPS - one in his 30s and the other in his 70s; both attributed their stopping SOSAPS to having lost their Orangelink and being unwilling to incur further expenditure. Several patients took a rest from SOSAPS but all resumed SOSAPS thereafter.

Overall 22% of SOSAPS patients were under age 18 (and 15% under 14 years) - the < 18 age group was more likely to use the Loop app (33%) than iAPS(16%) or AAPS (0%). Compared to the 2022 study of Lum et al which examined the reported use of the Loop app only, a similar proportion of participants were of pediatric age. Our study exhibited a slight preponderance of male (53%) over female (47%) participants, the opposite of what was observed in the Lum study which described 57% of participants as female.

Time below range pre SOSAPS averaged 3.5% (optimal <4.0%) and fell by an average 1.0% to 2.5% on SOSAPS consistent with no signal hypoglycemia concern.

All three SOSAPS apps were associated with improved Time in Range (TIR). On average the TIR was 64% pre SOSAPS and 80% post SOSAPS, an absolute increase of 16% and relative increase of 25%. Lower starting TIRs were seen with Loop and iAPS than with AAPS however similar TIR post SOSAPS were seen for all 3 algorithms.

All three SOSAPS apps were associated with a lowering of A1c averaging 0.5 from a pre SOSAPS value of 7.2. Greater lowering of A1c was shown with Loop and iAPS than with AAPS though starting A1c was lower for AAPS.

With respect to published results of glycemia with retail APS, the rise in TIR of 16% and the lowering of A1c of 0·5 to 6·7 with SOSAPS in our clinic compares favorably to the absolute rise in TIR of 12% and reduction in A1c of 0·5 to 6·9 achieved in 3 months in the Omnipod 5 study of Brown et al in 2021, to the absolute rise in TIR of 11% and reduction of A1c of 0·3 to 7·1 achieved in 6 months in the Medtronic 670G study of Brown et al in 2020, and to the absolute rise in TIR of 6% and the reduction in A1c of 0·5 to 6·9 achieved in 3 months in the Tandem study of Bergenstal et al in 2016.

The table below shows the average "most recent A1c" in our clinic for all TIDs by insulin regime.

Insulin delivery regime	Age (yrs)	T1 Duration (yrs)	Most recent A1c
MDI (n=560)	46 (29-63)	22 (6-38)	7.8
Medtronic non-APS (n=90)	41 (24-58)	25 (10-40)	7.8
Omnipod non-APS (n=155)	34 (15-53)	17 (3-30)	7.7
Medtronic APS (n=24)	48 (33-63)	29 (16-42)	7.3
Tandem APS (n=48)	31 (16-46)	19 (4-34)	6.9
Omnipod SOS (n=253)	37 (19-55)	20 (6-34)	6.8
Total (n=1130)	**41**	**21**	**7.5**

Table 7: most recent A1c by T1D insulin regime

The most recent A1c for SOSAPS of 6.8 compared to the post SOSAPS A1c of 6.7, drawn nominally at 3 months post SASAPS, argues that improvement in glycemic control with SOSAPS is durable. The most recent A1c with SOSAPS compares favorably with retail APS. The n for SOSAPS of 253 exceeds the 248 installations described in this report for two reasons: our clinic supported a number of OSAPS users who set up their own OSAPS and some A1c values are from SOSAPS users whose post A1c value did not qualify for inclusion in the report proper because it was more than 52 weeks post SOSAPS Installation.

Quality of Life (QoL) questionnaires indicated low levels of diabetes distress, fear of hypoglycemia and insomnia pre SOSAPS and lower levels still on SOSAPS. This is consistent with the findings of Schipp et al 2022 who with a swath of nine QoL questionnaires (including the 3 used in this report), showed that adults with T1D using OSAPS report significantly better psychosocial outcomes than non-users on OSAPS

The authors are aware that better QoL tools are required for the study of TID APS users - to that end a questionnaire designed to quantitate the benefits of APS with what they have termed the "freedom from diabetes" index is being validated. It is hoped that this index will capture reported benefits of APS that include reduced burden of TID vigilance, improved trust in technology, of not having to manually bolus for meals and an overall reduction in time spent conscious of living with T1D.

The most important finding of this study is that when supported by a suitably trained and equipped clinic, SOSAPS is at least as safe as retail APS and as efficacious. A further benefit is lower cost - the incremental cost of running SOSAPS with Omnipod and Dexcom over MDI with Dexcom is the expense of an Omnipod pod alone, C$10/day.

With respect to the limitations of this study the authors acknowledge that the logistical requirements for an SOSAPS service are beyond those available at most diabetes clinics.

The authors acknowledge the huge contribution of the open source APS community and in the same spirit offer to share their expertise and resources, including access to SOSAPS apps and Nightscout build capability, with any physician who wishes to develop a local SOSAPS capability.

Author attribution of work

Praveen Samuel - SOSAPS primary patient for SOSAPS app trainer including installation, configuration and trouble-shooting.
Nabeel Khan - Loop app builder, data analyst, secondary patient trainer on SOSAPS apps
Gerri Klein - Omnipod pump trainer
Sergey Skobkarev - directed all software development including EMR development, built Nightscout cloud generator, built Nightscout-EMR interface
Benjamin Mammon - secondary writer & data analyst, built Loop app, contributed to Nightscout development
Marc Fournier - active contributor to iAPS code base, iAPS app builder, online iAPS support channel moderator
Arthur Weissinger - secondary writer, scientific oversight, prepared paper for submission
Tom Elliott - primary writer, clinic owner, originator & driver of SOSAPS service concept

Research in Context

Evidence before this study

The reader is directed to the following literature review paragraphs in the manuscript's introduction

> A growing body of evidence supports OSAPS as both safe and effective: Lum et al (2021) described the self-reported outcomes of 558 users of the "Loop" OSAPS: including a tenfold reduction in the incidence of severe hypoglycemia, improvement in Time in Range (TIR) for CGM glucose 4·0-10·0 mM from 67% to 73% and reduction in A1c from 6·8% to 6·5%. Gawrecki et al (2021) showed similar results in 12 adults supported by a single Polish clinic using open source AndroidAPS (AAPS): 44 patients in a New Zealand study randomized to a modified version of AAPS by Burnside et al (2022) had a TIR 14% higher than 54 controls randomized to sensor-augmented pump.
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> As yet no single OSAPS algorithm has received regulatory approval though "Loop" was submitted to the FDA by the non-profit Tidepool in 2021-Jan.
>
> The widespread use of OSAPS has prompted increased interest in the TID medical community. The 2022-Jan review by Braune et al included an international consensus statement and practical guidance for health-care professionals.

Google scholar searches in 2022-Oct1 and 2023-Jan-18 using the search terms "DIY APS RCT", "DIY APS clinic" "Open-source automated insulin delivery RCT" and "Open-source automated insulin delivery clinic" revealed no other reported studies with more than 10 subjects.

Added value of this study

The current paper describes results with DIY/open source APS/Automated insulin delivery in single clinic cohort of 248 consecutively treated subjects (5 times the size of previously reported studies). The results indicate safety and efficacy efficacy equivalent or better than retail APS, and the potential for considerable cost-savings.

Implications of all the available evidence

Clinic-supported DIY/open source APS/Automated insulin delivery, with the necessary training and access to SOSAPS apps and Nightscout accounts, is feasible. In the final paragraph of the manuscript the authors offer to collaborate with the world using the same open source tools.

> The authors acknowledge the huge contribution of the open source Loop community and in the same spirit offer to share their expertise and resources, including access to SOSAPS apps and Nightscout build capability, with any physician who wishes to develop a local SOSAPS capability.

Citation for # OSAPS users worldwide

Personal communication with Jeremy Lucas, CEO of getrileylink.org who declared total # Riley/Orangelink customers as of 2022-Jun-26 = 17118. At annual growth rate of 20% as of 2023-Jan-18 it is estimated there are 19112 Riley/Orangelink customers. It is estimated the number of androidAPS users to be half the number of iPhone APS users. Thus estimated total = 1.5*19112 = 28673..

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