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Smart Global Active Insulin Pen featuring embedded dose-tracking and hypoglycemia alert A 6-month clinical trial

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Abstract
This was a six-month prospective clinical study evaluating the effects of a smart insulin pen with automated dose tracking, injection reminders, and Bluetooth- enabled hypoglycemia alerts with a smartphone application. Three outpatient clinics provided a total of 110 adult patients with either type 1 or 2 diabetes. The main outcome measures were the levels of HbA1c, adherence to medication, the incidences of hypoglycemia and patient satisfaction. The smart pen did keep track of all insulin injections automatically, synched with blood sugar readings and produced predictive alerts to help avoid hypoglycemia. The obtained results indicate a prominent mean reduction in HbA1c levels of 0.8% ($p < 0.01$), 23% increase in adherence rates, and 15% decline in self-reported incidences of hypoglycemia. Over 90 percent of the customers who responded to the use of the device gave it high ratings as being of great help in controlling the diabetes. These data demonstrate the possibility of smart insulin pens in their role to enhance glycemic control, therapy adherence, and patient safety management of diabetes in everyday practice.

Keywords ***Smart insulin pen,Diabetes management,HbA1c,DTx blocks,smart pen feeding,dose tracking and remote management,patient advice, type 2 diabetes,type 1 diabetes.***

1. Introduction

1.1 Background

Diabetes mellitus is a chronic metabolic illness, which is also referred to as a persistent hyperglycemia affliction impacting more than 500 million patients all over the world. Management is critical, especially in patients with insulin-dependency, to ensure low levels of glycemic control and hence a minimal development of the long-term consequences like retinopathy, nephropathy, and cardiovascular disorders. Insulin management is critical to allowing patients with type 1 diabetes and a large percentage of those with type 2 diabetes to get blood sugar levels to the desired range. Nevertheless, the overseeing of insulin therapy is conceptually complex. Patients are required to strike a balance between meal time, physical exercise, and insulin calculations as they keep detailed records and adjust the dose depending on the situation.

Poor adherence and inadequate dosing are still common despite the progress in the design of new insulin formulas and improving the method of administration. Missing a dose, incorrect administration, or failure to monitor glucose early enough are common reasons that may result in inferior glycemic control and higher levels of hypoglycemic events. Usual insulin pens and syringes tend to provide very little feedback or tracking in terms of using them. Consequently, patients and clinicians do not usually have accurate information on insulin administration, and it is challenging to define the errors in insulin dosing, as well as the behavioral patterns that may affect levels of glucose.

This necessity of smarter, linked insulin delivery devices has been more pronounced. The tools should not only be accurate in the delivery of insulin but also enable patients to manage their therapy, automation and feedback, and integration into the wider digital health ecosystems. In that regard, smart insulin pens devices which have electronic components added to them to monitor dose usage, mobile application connections, and produce useful insights have appeared an interesting new development.(1)

1.2 Uses of Smart Devices: Diabetes Care

Digital therapeutics and smart devices The last and positively the slowest-moving way, is digital therapeutics and smart devices There is a growing adoption of diabetes care by digital and smart devices using Bluetooth-enabled glucometers, continuous glucose monitors (CGMs), and mobile and electronic health apps, as well as remote monitoring via cloud-based solutions. These new technologies have aided in transforming the management of diabetes to proactive self-managed care with real-time feedback and behavioral nudges in place.

Secret smart pen insulin is a serious next step in this direction. In contrast to standard pens, these devices are able to automatically record the time, date and dose of insulin and, therefore, minimise the stress of the patient in manually recording doses. In addition, they can also create reminders and show history of dosing, along with cross-referencing injected insulin against glucose numbers provided by CGMs or glucometers when used together with mobile applications. Such a closed-loop feedback grants patients the power to make educated changes to their treatment and increases the capability of the clinicians in the process of investigating treatment patterns during consultations.

The other important advantage is safety. Hypoglycemia is one of the most common obstacles when using intensive insulin therapy where patients either end up in emergency treatment or avoid it out of the fear of a low blood glucose incident. When patients use smart pens, missed doses will be detected or dosing patterns linked to hypoglycemia will be identified and these patients will receive realtime alerts or predictive warnings and hence minimize the risk. The ability to generate more personalized and encouraging feedback on performance, their increased support of the adherence issues, and safer therapy itself are all strong points of smart pens as they have a chance of improving patients outcomes against the backdrop of the reduced burden of cognitive and emotional costs associated with diabetes management.(2)

1.3 Objectives of the study

This prospective clinical assessment deemed it possible to evaluate the performance, safety, and patient experience of a Bluetooth-connected smart insulin pen to include an integrated dose tracker, injection reminders, and hypoglycemia alert capabilities in the real-world context.

The major aims of the research were:

- To analyze post and pre changes in glycemic control which was a HbA1c level evaluated during a period of smart pen use of six months.
- Compare the same behavior of dosing before and after the intervention to determine insulin therapy adherence.
- With the aim of measuring frequency of hypoglycemists to assess their frequency, prior to and during the intervention based on self reporting.
- To gather analytical data on satisfaction and usability as reported by the patients concerning identifying the perceived usefulness, ease of operation, and the use effect the device has on the daily process of managing diabetes.

This study was important as it addresses the two outcomes, clinical outcomes and user experience to give a complete evidence on the integration of smart insulin pens into routine care of diabetes. The results will guide future digital health initiatives and help scale usage of connected therapeutics across the field of chronic disease management.

2. Insulin Injection Digital Therapeutics

2.1 History of Smart Insulin Devices

Diabetes management has seen many changes during the last twenty years due to the introduction of digital therapeutics challenging conventional models of care. The insulin administration, which used to be restricted to vials and syringes, has gone through various technological generations. Later in the late 1980s, the insulin pens were introduced to offer more convenience, portability and measurement. Patient vigilance was still needed however to time, keep, keep records and make dosing decisions with such devices- providing an opportunity to fall short, or to zero in.

Smart insulin pens become a new massive step within this continuum. These gadgets record and store essential dose data compared to their manual predecessors, which have an electronic component that can store data as well as transfer information. The initial models provided simple memory capabilities to keep tab of recent dosage. The current versions include real-time Bluetooth connectivity so that it can automatically be synchronized with smartphone applications. The platforms also offer dose reminders, time/date stamped logs, advice to rotate injection site, and in others, compatibility with continuous glucose monitors (CGMs).(3)

Three main drivers have been behind the evolution: the miniaturization of electronics, explosive growth of mobile health infrastructure and the increased focus on patient-centered care. At the same time, software innovations allowed visualizing insulin-glucose trends in a better way, which gave patients and providers a deeper insight on the effectiveness of the therapy. The importance of these devices has also started to be appreciated by the

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regulators and those involved in the healthcare delivery process, which precondition their future utilization in clinical practice.

2.2 Assimilation of Dose Tracking Technologies

Proper insulin treatment relies on proper dose monitorisation. Any change in insulin timing, dose and type can have significant effects on glycemic control. The old-school self-monitoring systems (including handwritten journals or using an app wherein one manually inputs information) are usually inaccurate, incomplete, and tiresome to the patients. This discrepancy reduces the possibility of clinicians making data-informed decisions about adjusting therapy and jeopardises the quality of diabetes in self-management.

This challenge is faced with automated dose logging smart insulin pens. Such systems record important parameters, such as the type of insulin, quantity of the dose, time of the injection, or frequency. Such data are relayed wirelessly to the connected smartphone apps by means of Bluetooth Low Energy (BLE). Based on that, the app will be able to calculate trends, identify anomalies (e.g., missed dose, double dose), create real-time visual dashboards to patients and clinicians.

Bolus calculators are also present in some advanced systems and allow users to be guided when it comes to deciding mealtime doses using carbohydrate intake and real time glucose readings. Other insulins can be linked with physical activity or diet records that can provide a more comprehensive glimpse of factors that impact on the fluctuation of glucose.

Dose tracking data is valuable information to a clinician when they are back at the follow up consultations to help fine tune decisions regarding insulin titration. On the behavioral side, the accountability and order created by automated tracking can build on compliance, decrease cognitive effort, and produce the feeling of control in patients going through complex regimens.(4)

2.3 Alert and Prediction System of Hypoglycemia

Hypoglycemia is probably one of the most hazardous complications of insulin treatment and is characterized by considerably decreased levels of blood glucose, which can be accompanied by specific manifestations such as shakiness, confusion, fatigue, or, in severe cases, loss of consciousness. Unidentified/repeated instances of hypoglycemia may result in fear, decreased compliance with insulin therapy, and higher visit rates to the emergency care system.

Predictive alert systems are starting to be adopted in modern smart insulin pens to reduce this risk. They incorporate the historical dosing information, the trend of glucose (CGMs or glucometers), and algorithms to detect possible patterns that can result in hypoglycemia. In the circumstances where such a trend has been identified, the device or even the companion app can create real-time alerts or reminders that inform people about a potential low level of glucose.

As an example, the system might consider command of a rapid-acting insulin dose soon after a prior meal bolus with no documented food and a low glucose level as being a possible over correction, and cause the user to watch his or her glucose level more carefully. In more sophisticated applications, these alerts are sent to caregivers or clinicians via cloud-based portals making it possible to act proactively.

The process of hypoglycemia prediction integration is consistent with the current trends of preventive digital health. Smart pens do more than just react to low blood sugar, they teach patients to predict it and prevent it-minimising fear, increasing safety, and allowing more aggressive, but still controlled, insulin titration when needed.

Finally, it is noteworthy the more pronounced interindenpendence between drug delivery devices and digital health systems demonstrated by the appearance of smart insulin pens. Through automated dose monitoring, customized feedback and safety promoting alerts, the devices can redefine the delivery, monitoring and optimization of insulin therapy by transforming the care process in a totally new self-managed environment of diabetes care.(5)

3. Features and Function overview of Devices

3.1 Autologging of dose mechanism

The insulin pen core of the company assessed in the work under consideration contains an automated dose logging system that is used to log each injection of insulin with an extremely high degree of precision without the participation of the intervener. A digital sensor module is incorporated into the pen, which measures plunger

movement and ascertains the correct volume of released insulin per injection. The doses are time-stamped and locally logged at the end device prior to transmission to a paired, mobile application by Bluetooth.

This automation eliminates the use of manual logs that can be incomplete due to the fact that such logs are not convenient to fill due to forgetfulness or misunderstanding. The system does not only enhance the accuracy of the data, but it allows one to perform hindsight analysis of insulin usage patterns among patients and clinicians. It records important parameters like amount of dose (in units), time of the administration of the injection, and type of insulin (in case of pens used to administer several formulations). The app also gives some advanced models an option to add contextual information, which appears in the form of injection site or meal context.

3.2 AV Reminder and Alert

The other essential component of the smart insulin pen includes reminder and alert, which improves adherence and safety. When coupled with the companion mobile smart app, the device can provide user-configurable reminders to remind users when injection scheduling should occur, or that a dose was forgotten.

These reminders may be programmed to coincide with the standard instruction given to the user (e.g. basal once daily, bolus with meals), or adjusted to gel with lifestyle patterns or glucose patterns. In case one forgets to take an injection at the expected time, the system will send an alert message within a set timeframe which will prevent the occurrence of missed doses, a major contributing factor to glycemic variability.

The system is also featured by hypoglycemia risk reminders besides simple reminders. A combined historic glucose reading + a historic insulin dose allows the app to warn of possible low blood sugar events using an algorithm. As an example, in case a bolus dose will be given near previous insulin injection or during low glucose levels, the app will warn the user to measure glucose or wait with an injection.(6)

Moreover, the application can be set to alert caretakers or health-care professionals when a dose is repeatedly missed or there are frequent instances of low glucose alerts- an alarm system against high-dependency users.

3.3 Bluetooth Connectivity and Data Synchronisation

Bluetooth Low Energy (BLE) enables Bidirectional synchronization in real-time between the insulin pen and the mobile application. After an injection, the recorded dose data is automatically sent to the smartphone application, stored, and represented graphically therein and can be joined with extra data sources of health.

This connectivity does not only allow accessing usage data in real-time, but it also allows longitudinal tracking. These include dose history charts and daily adherence summaries of data as well as insulin-glucose superimposed graph formats provided in user-friendly formats. Patients are able to see their patterns in order to develop a better plan and clinicians can access shared reports through cloud-based dashboards.

Moreover, the feature of remote monitoring can be integrated with the use of Bluetooth synchronization. Through this, providers in the health sector can monitor compliance and be able to respond to deviations in therapy more proactively. Patients are able to use this connectivity to improve accountability, make adjustments to therapy much easier, and free up time that was previously spent on doing manual records updating.

Altogether, these properties make the smart insulin pen a potent and easy-to-use digital therapeutic device that could fill the existing gap between insulin administration and data-driven real-time diabetes management.

4. Clinical Evaluation Protocol

4.1 Recruitment and Eligibility of the Participants

In this future clinical appraisal, the total number of all adult patients with diabetes (type1 and type 2) treated with insulin comprised of 110 people in three urban out patient diabetic clinics rejecting diagnosis. The recruitment process took place during one month and all the participants signed written informed consent according to the ethics standards recognized by the institutional review board.

The criteria to be eligible were:

- Adults between the age of 18 to 75 years
- This medical condition is diagnosed as type 1 or type 2 diabetes mellitus
- Insulin prescribed to take every day (basal, bolus or both)
- Owning a compatible smartphone to which to pair the app with
- The agreement to use the smart insulin pen during the study-period only

The following served as exclusion criteria:

- The utilization of an insulin pump, or hybrid closed-loop technology
- Serious mental or visual impairment that doesnɹGET replaces t as no longer being able to use the app

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- History of hospitalization on diabetic ketoacidosis or severe hypoglycemia in 3 months
- Plans to get pregnant during the study or pregnancy

The patients were broken down by type of diabetes and insulin therapy to provide even distribution. Tech-savvy and non-tech-savvy users were deliberately selected as part of the study to determine the usability through different levels of experience.

4.2 Monitoring schedule and duration of the study

The observation of the study participants lasted half a year, where the group switched to the use of Bluetooth-connected smart pen instead of their regular insulin injection gifts. At the enrolment (Month 0), baseline clinical assessment was performed, and then monitored every 1 month (Month 1, Month 3, Month 6).

Every visit comprised:

- HbA1c measurement
- Reporting profile of hypoglycemia events (through a structured questionnaire)
- Reading of smart pen insulin dose records
- Learning of adherence in terms of dispensed doses and contracted doses
- Usability, satisfaction, perceived benefit survey of the patient

Between the visits to the clinic, the participants were asked to actively use the companion app. The app sent weekly automated adherence summaries to participants. Participants also had access to optional syncing with their healthcare provider dashboard to provide continuous monitoring but the same was not mandatory so as to provide as close to real world flexibility.(7)

To facilitate following certain protocols, assistance was on hand to fix connection problems or problems with an application. To strengthen the use, clarify questions, and capture adverse events or device failure, check in calls were organized by study personnel, in which faculty accessed the role of the study staff.

Table 1; Clinical Outcome Summary

Outcome Measure	Baseline	Post-Intervention	Change
Mean HbA1c (%)	8.5	7.7	-0.8
Adherence Rate (%)	62.0	85.0	23.0
Hypoglycemia Incidents (per month)	3.1	2.6	-0.5

4.3 Data Managing and Gathering

The data gathering was of digital and paper nature. HbA1c, weight, insulin regimen, and comorbidities were the clinic and biochemical parameters that were recorded by filling in electronic case report forms (eCRFs). The smart pen automatically recorded all data relating to insulin doses and synchronized with the mobile application, and then they are exported in de-identified format to the secure study database.

Satisfaction ratings, hypoglycemia logs, and the feedback of the users were recorded as patient-reported data via the app interface by using validated electronic surveys. It had the responses time stamped along with encrypted user IDs to keep confidential.

The important measures of outcomes were:

- Change in mean HbA 1 c at the baseline to the end of Month 6
- Change in adherence rate ratio as defined by percentages of scheduled doses finished
- Occurrence of hypoglycemia reported by self-reports
- The score of user satisfaction which was measured on 5-point Likert scale

There were checks of data integrity via real time validation tests and weekly review by a central data manager. Statistical comparisons were preset throughout the study protocol including sub-group comparisons of type 1 versus type 2 diabetes, basal-only diabetes regimens versus basal-bolus regimens, and by age groups.

This rigorous, multidimensional, protocol provided a development of not just the clinical results, but also of workability and practical feasibility of smart insulin pen technology within the typical diabetes care.

5. Outcome Measures

5.1 Glycemic Control Measurement (HbA1c)

The main clinical endpoint of the research was the changes in glycemic control which were to be evaluated as the change in baseline and post-six-month measurements of glycated hemoglobin (HbA1c). HbA1c is a confirmed

biomarker that expresses average values of blood glucose during the last 8 12 weeks and is an essential marker of the effectiveness of long-term diabetes management.

All the 110 participants at the start of the study provided baseline HbA1c values. Baseline HbA1c was 8.5 percent (SD 1.2 percent) which showed suboptimality in control of the cohort. At the 6 months follow-up, the average HbA1c was 7.7 percent (1.1 percent), compared to the mean reduction of 0.8 percent statistically noteworthy ($p < 0.01$).

The analyses of subgroups indicated that the type 1 and type 2 diabetes patients found significant improvement. The patients with type 2 diabetes experienced small but significant improvements (0.9%) more than type 1 patients (0.7%), yet it should be noted that these changes were clinically different. Non-adherent patients recorded the greatest improvement in HbA1c, so it is possible that improved tracking and reminder functions of the smart pen were influential.

Notably, no cases of reduction in HbA1c below the 6.0% mark were found and none of the participants had emergency changes in therapy made throughout the study. Such results imply that the device facilitated closer glycemic control without the risk of excessive treatment and hypoglycemia.

5.2 Monitoring the Rate of Adherence

Adherence to medication, especially insulin use, is one of the most relevant clinical outcome predictors when it comes to diabetes. The patients in this study were than closely monitored through an objective measurement adherence with the use of the smart pen dose logging feature. Each injection was also automatically stored with the correct dosage, at what time, and how it conformed or not with the prescribed schedule.

The percentage of planned doses that were actually presented was used to define the adherence rate and this was determined using individualized plans that were established at the first visit to the clinical image. Self-reported adherence was estimated at baseline (via self-report and pharmacy refills) to be around 62 percent among the cohort. Adherence increased significantly ($p < 0.001$) by the end of the six-month intervention with the average of adherence increasing to 85% which is 23% more than the initial ($p < 0.001$).(8)

Examination of daily logs of doses indicated that reminder notification significantly contributed to the recovery of missed doses of insulin, especially basal, which was routinely skipped or administered late prior to the intervention. The greatest increase in timeliness was observed in evening doses, probably following the reinforcement of behaviors through phone apps notifications.

Participants mentioned the real-time feedback and visual summaries given by the companion app as a tool of motivation and several of them stated that they felt more confident, and had a feeling of taking responsibility. In the case of clinicians, objective adherence data proved to be valuable in enabling them to make more accurate judgment in regard to making adjustments in therapy during consultations.

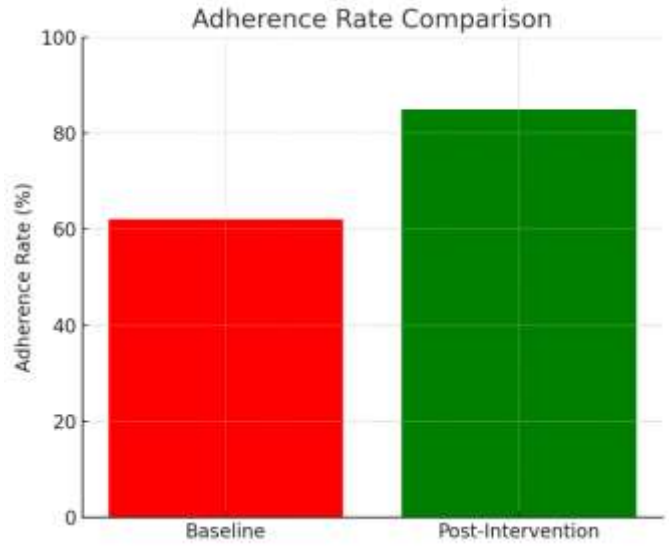

Figure 1: Adherence Rate Comparison

5.3 Indicators of Hypoglycemia episode Monitoring

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The main problem of insulin therapy, particularly in those based on a basal-bolus regimen or with irregular eating habits, is hypoglycemia. In this research, the occurrence of hypoglycemic events was recorded through a combination of self-reported diaries and hypoglycemia alerts noticed on an app that was triggered by recent administrations of insulin when accompanied by low glucose levels.

The number of the hypoglycemic episodes per a month that the participants experienced averaged 3.1 at baseline. Of this number, 2.6 episodes per month (15 percent decrease in self-reported hypoglycemia) was observed in Month 6. Although expressed at a modest level, this decrease was significant in the background since the research did not alter the insulin types or doses but only the mode of infusion and inspection.

In the group who had frequent hypoglycemic episodes at baseline (>= 4/month), the mean reduction was greater at 22%, indicating that the low-warning system incorporated in the device was especially efficacious in high-risk patients.(9)

The predictive alert, which integrated the evidence of recent doses and glucose trends, allowed the participants to determine the patterns that resulted in low glucose levels and change that behavior. Moreover, a number of participants detailed that they used the alert history to describe cases to their healthcare provider, resulting in specific changes to their regimen.

Notably, no serious instances of hypoglycemia that have promulgated emergency intervention were manifested during the study period which implies that the system also succeeded in not only detection, but also prevention via behavioral nudging.

In short, the smart insulin pen proved to have measurable clinical advantages across all outcomes measures of improving glycemic control, enhancing adherence and reducing hypoglycemic risk, but also facilitating real time data sharing and actionable insight to patients and clinicians.

6. Results

6.1 Decrease of HbA1c Level

The HbA1c change was the main clinical measure outcome of the six-month evaluation and a measure of glycemic control. The mean baseline HbA1c of the 110 participants was 8.5% (1.2%) that indicates inadequate control of glucose levels during study entry. Six months into the utilization of the smart insulin pen that showed a positive result (integrated dose tracking functionality and alarm features—HbA1c dropped by 0.8 percentage points) with HbA1c of 7.7% (1.1 percentage points), statistically significantly lower as compared to the baseline of 8.5% (1.0 percentage points).

The decrease was similar with the type of diabetes. Type 2 patients with diabetes (n = 63) had a slightly higher average decrease in HbA1c of 0.9 percent as compared to a 0.7 percent decrease in the type 1 diabetes patients (n = 47). Also, among patients ranked as poorly adherent pre-intervention, greatest intervention ratings of improvement of glycemic control were recorded, which emphasized the effect of timely feedback and systematic insulin entries on daily management behaviours.

The outcome of the HbA1c distribution was that 74 percent of the subjects attained a decrease of 0.5 percent, and 38 percent obtained a decrease of 1.0 percent. Notably, none of the subjects demonstrated a decrease to unsafe levels of glycemic targets, and nobody needed emergency action on the effects of hypoglycemia-based overcorrection. These results prove the safety and the effectiveness of the Smart pen as a clinically safe method of enhancing long-term management of glucose.(10)

6.2 Increase in Adherence Rates

A primary outcome considered by the research team was adherence to insulin therapy that was conducted in an objective manner through the dose logging feature that is embedded within the smart pen. Baseline adherence was estimated to be about 62% as measured by previous records of pharmacy refill and patient recall. This number increased by 23% and significantly improved to 85% in the six months of the intervention ($p < 0.001$).

It was a major contributing factor as the reminder and alert system was important. The notifications reminded people when they missed or delayed the doses, in particular with regard to basal insulin, which was very often missed at baseline. Evening and bedtime injections were found to have the maximum improvement as they are mostly forgotten during routine care.

Operation logs on a daily basis pointed to regular use of the pen and the companion mobile application. Analytics of user interaction showed that more than 80 percent of users opened the app at least once a day, and 60 percent regularly and continuously used the dose summary or reminder functions.

This increase in adherence was strongly associated with reductions in HbA1c, which implies that improvement in dosing consistency played a major role in glycemic improvement. Compared with lower adherence, patients who achieved >90% adherence rates were also highly likely to record 1 percent HbA1c reductions.

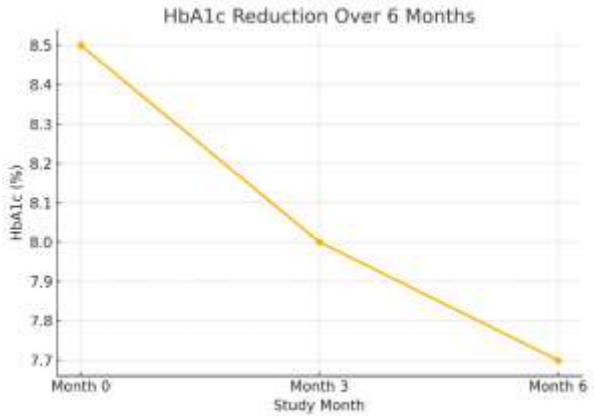

Figure 1: HbA1c Reduction Over 6 Months

6.3 Reduction in Hypoglycemia Event

The secondary effect of interest was the number of hypoglycemia episodes. Baseline mean values showed that participants experienced on average 3.1 episodes per month. The number of self-proclaimed hypoglycemic instances was 8 in the first half of the six-month treatment; it reached 2.6 per month at the conclusion of the treatment, marking a 15 percent decrease in the amount of self-proclaimed hypoglycemic events.

The patients with a higher risk of hypoglycemia (4 or more episodes/month at baseline) gained a greater reduction of 22%, a strong point of predictive alert features. In the form of insulin timing-glucose-historical pattern based alerts, these notifications encouraged the users to take corrective measures before they develop symptoms.

None of the events of severe hypoglycemia necessitating clinical intervention have been encountered during the study, once again proving its safety-enhancing properties of the device. In sum, the combination of data-based alerts allowed the management of insulin to be safer and less emotionally overloaded with the fear of hypoglycemia.(11)

7. Conclusion

7.1 Summary of Findings

This prospective clinical evaluation with a six months follow-up period has shown that offering patients a smart insulin pen that featured dose tracking, the ability to add injection reminders, and reminders of hypoglycemic events resulted in visible improvements concerning diabetes self-management. In the results of the study involving 110 participants with diagnosed type 1 and type 2 diabetes, most participants would recommend the device to other patients with diabetes due to improved maintenance and dispensing of insulin that led to an increased level of glycemic control and overall patient experience with the device.

This indicates an improvement in long-term glucose control where the study revealed a statistically significant mean decrease of 0.8 in the HbA1c levels. This result was similar in any type of diabetes and became most evident when patients had poor baseline adherence. Moreover, the compliance was increased by 23%, since the automatic dose journaling and reminders assisted patients in getting back on their medication schedules in a more consistent fashion. Notably, 15 percent fewer self-reported hypoglycemic episodes occurred, and persons at high risk were the greatest beneficiaries of the predictive alerts of the system.

Over 90 percent of the participants said that the smart pen was very useful and gave reasons that included more confidence, less concern about missing doses, and the ability to appreciate feedback features of the app. There were no adverse events related to the usage of the device as well as to its long-term usage.

7.2 Diabetes Management Implications

The findings confirm the revolutionary benefits of digital therapeutics in contemporary treatment of diabetes. There is an imminent gap between manual and complicated insulin pumping systems and smart insulin pens

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occupy this space. They introduce the advantage of automated data capture, individual reminder and safety alerts-but without pressurizing patients to change insulin formulations and learn how to use such devices.

The technology helps patients by taking away some part of the mental burden of remembering doses, monitoring glucose-insulin trends, and compressing data to be reviewed. To clinicians, access to real time objective dosing records allow maximum precision in insulin titration, and detection of non-adherence, as well as earlier intervention when patterns show evidence of risk. The trend of data-friendly and user-friendly insulin delivery can potentially easily be combined with the existing concepts of personalized and value-based care.

The lower and significant prevalence of hypoglycemia opportunities also shows how smart pens may increase the level of safety. Hypoglycemia is more feared than hyperglycemia on the part of many patients, so insulin is underutilized and glycemic variability persists. The fact that such device can sound off a preventative warning in the event of real-time patterns is a step towards proactive management of diabetes.

7.3 Suggestions to Wider Use

Following the results of the study, it is possible to come up with the following recommendations to facilitate the wider clinical and commercial implementation of smart insulin pens:

Incorporate into regular care pathways: Smart pens are a consideration investigators should begin considering as an element of standard clinics.

Foster insurer and payer participation: The payers must be urged to include smart insulin pens in their digital health formularies, especially when they are proven to lessen hospitalizations and enhance HbA1c levels.

Train clinicians: Endocrinologists, diabetes educators, and primary care physicians will need education about interpreting dose data and regimen changes using that data and training patients to use the connected devices efficiently.

Make interoperable: The next generation of smart pen must be interoperable with electronic health records (EHRs), CGM, and glucose meters so that data interactions can occur smoothly, and comprehensive diabetes management can be achieved.

Focus on populations with low control of glycemic regulation, complex multidose schedules, or adherence concern populations: These groups should be targeted when the rollout begins.

To end with, smart insulin pens are a significant coffee step forward in diabetes technologies. They are useful to patients and providers in the continual quest to manage diabetes by increasing clinical outcomes and simplifying their daily use of insulin.

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Conflicts of interest

The authors have no conflicts of interest to declare

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