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Narrative Review of Artificial Pancreas Technologies

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ABSTRACT

The artificial pancreas (AP) represents a transformative approach in the management of type 1 diabetes mellitus, aiming to automate insulin delivery and maintain glucose homeostasis. This narrative review synthesizes current knowledge on AP technologies, including hybrid and fully closed-loop systems, sensor modalities, actuation mechanisms, control algorithms, and clinical outcomes. Historical development from early intravenous systems to modern wearable devices highlights the evolution of closed-loop insulin delivery and bihormonal approaches. Advances in continuous glucose monitoring, predictive algorithms, and personalized control strategies have demonstrated significant improvements in glycemic control, reduction of hypoglycemic events, and enhanced patient quality of life across pediatric, adolescent, and adult populations. Despite clinical successes, challenges persist in sensor accuracy, real-world usability, regulatory approval, and integration of multi-hormonal or multi-drug approaches. Ethical considerations, patient adherence, and methodological limitations in clinical evaluations further underscore the need for ongoing research. Future directions emphasize standardization of key performance metrics, enhanced interoperability, and expansion of artificial pancreas accessibility to diverse populations. Overall, AP technologies offer a promising pathway toward replicating physiological insulin regulation and improving outcomes for individuals with type 1 diabetes.

Keywords: Artificial pancreas**,** Closed-loop insulin delivery**,** Type 1 diabetes mellitus**,** Continuous glucose monitoring**, and** Hybrid and bihormonal systems.

INTRODUCTION

Insulin is a peptide hormone produced by the pancreas introducing glucose into cells and controlling blood glucose levels [2]. Type 1 diabetes mellitus is characterized by the absence of insulin from the pancreas, leading to hyperglycemia, glucosuria, ketoacidosis, and eventually the loss of life [1]. Current management requires patients to estimate the carbohydrates intake and to deliver the corresponding amount of insulin by manual means. This can be an approach for children in the early years since they rarely eat and drink at evenings. The effort to replace this manual therapy has led to the concept of an artificial pancreas (AP). Many challenges are preventing the implementation of a closed-loop artificial pancreas [2]. The research in this area is extensive and time consuming due to the different combinations of existing techniques and algorithms. The present survey reviews the principal algorithms and the three latest prototypes for an AP, that have been tested in clinical trials included in the review [5].

Historical Development of Artificial Pancreas Concepts

The concept of an artificial pancreas has gained significant research attention since the introduction of continuous glucose monitoring (CGM) in the 1990s [4]. The transition from open-loop to closed-loop control systems is an ongoing process, made possible by the development of optimal control methods based on explicit–implicit model predictive control formulations and parameter-adaptive techniques [6]. The aim of a closed-loop system is to maintain glucose concentration within a safe zone from hypoglycemia to hyperglycemia, following a metabolic disturbance. An artificial pancreas is defined as a medical device or system that can monitor and automatically adjust hormonal therapy in order to closely regulate glucose levels within a physiological range [1]. In type 1

diabetes (T1DM), the absence of β-cell function leads to loss of endogenous insulin secretion. Consequently, exogenous hormonal infusion (typically insulin) must be administered to avoid potentially severe metabolic disturbances. This control problem is particularly challenging because the effects of a bolus infusion are highly nonlinear and exhibit long and time-varying delays [5]. Early efforts focused on developing an artificial pancreas to construct a glucose-regulated insulin infusion system capable of achieving normal glucose tolerance in people with diabetes using either a single-hormone or dual-hormone approach. Although the technology continues to advance and clinical trials of hybrid and closed-loop systems become increasingly common, T1DM remains a challenging disease with no permanent cure [6]. In 2022, the first unequivocal demonstration of continuous, self-sufficient, stable, and long-term (up to 15 months) glucose control of advanced T1DM using only oral osmotic feeding with no other assistance was achieved [2].

Core Components and Architectures

Control of glucose homeostasis is essential for the wellbeing of persons with type 1 diabetes, given the potential damaging consequences of hyperglycemia or hypoglycemia [9]. Advances in artificial pancreas technology have enabled the development of closed-loop systems, which automate insulin delivery according to continuous glucose monitor (CGM) data and control algorithms [7]. These systems, however, do not yet replicate the action of the pancreatic β-cell, nor do they achieve fully closed-loop control based on the regulation of insulin alone, since other factors such as meal ingestion and variable insulin sensitivity significantly affect glucose levels [2]. Two common control strategies are therefore hybrid closed-loop systems, which combine automated insulin delivery outside the meal period with manual bolusing, and fully closed-loop systems, which aim to provide the means to fully automate insulin delivery [1]. Most systems are designed to run with commercially available pumps and CGMs, which use radio-frequency communication protocols (e.g. Bluetooth or proprietary links), while a few systems incorporate an integrated pump and transmitter. Each component thus warrants consideration when evaluating available systems [5].

Closed-Loop Insulin Delivery Systems

Closed-loop insulin delivery systems have been extensively studied since the 1970s, with numerous randomized controlled trials demonstrating their safety and efficacy in both outpatient and inpatient settings [3]. These systems have been evaluated in people with type 1 diabetes of all ages, including children younger than 6 years, pregnant and postpartum women, and individuals with coexisting conditions [2]. They can accommodate various insulin delivery methods, such as subcutaneous infusion or inhalation, and differ in components like blood glucose sensors and algorithms [5]. Most systems rely on direct continuous feedback from glucose sensors and control the insulin delivery rate [4]. In developed countries, closed-loop insulin delivery systems represent the most advanced artificial pancreas technologies [1]. The first closed-loop insulin delivery system was developed in the early 1960s by Arnold Kadish, using continuous blood glucose monitoring and intravenous pumps for insulin and glucose or glucagon, shutting off or activating pumps based on glucose levels. The first systems described as an artificial pancreas emerged in the early 1970s by Albisser and Pfeiffer, utilizing computer-controlled intravenous insulin and dextrose delivery [4]. The Pfeiffer system was commercialized in 1977 as the Biostator, which included blood withdrawal, glucose analysis, and automated insulin/dextrose infusion for research purposes. Because of its bulk and complexity, the Biostator was mainly used in hospitals to study glycemic patterns and determine insulin dosages [6]. It was extensively utilized in research throughout the 1980s and 1990s. The first wearable artificial pancreas was developed in the early 1980s by a Japanese group led by Motoaki Shichiri, featuring a sensor, microcomputer, and pumps in a portable device that used a subcutaneous glucose sensor for closed-loop insulin and glucagon delivery [8].

Hybrid versus Fully Automated Systems

Hybrid closed-loop insulin delivery systems such as the MiniMed advanced hybrid closed-loop systems have demonstrated safety and improved glycemic outcomes in adolescents and adults with type 1 diabetes [4]. Randomized controlled trials have shown that hybrid systems outperform manual insulin delivery in maintaining blood glucose levels [2]. Bihormonal fully closed-loop glucose control with artificial pancreas systems has been studied in outpatient settings, yielding promising results for glycemic management [5]. Automated insulin delivery systems also positively impact sleep and psychosocial outcomes, especially in older adults [5]. Case reports indicate the potential for hybrid systems during peritoneal dialysis [5]. All evidence suggests that hybrid and fully automated systems enhance glycemic control and patient quality of life compared to traditional methods [3].

Sensor Technologies and Signal Processing

Sensor technologies for glucose measurement are fundamental to the artificial pancreas concept and realising tight glycaemic control in type 1 diabetes [4]. Traditionally, blood sampling and laboratory laboratory analysis characterised blood glucose measurement. This was later complemented by less-invasive methods such as

interstitial fluid extraction through microdialysis but proved ineffective at the required sampling rates, prompting the advent of continuous glucose monitoring systems [1]. These typically exploit electrochemical processes in glucose biosensors, for which several implementations exist, including amperometric, potentiometric, optical, and thermistor-based sensors. Most prototypes and commercial systems employ amperometric sensors with an enzyme that catalyses the electrochemical oxidation of glucose [5]. Commercial continuous glucose monitoring performs healthily under clinical conditions but is prone to several abrupt failures, including sensor dropout and drift. Closed-loop artificial pancreas systems consequently rely on robust fault detection. Research on dual-hormone algorithms for pumps delivering both glucagon and insulin also concentrates on fault detection and effective solution strategies when only one hormone is available [6]. Algorithms enabling insulin suspension appear effective in reducing nocturnal hypoglycaemia without increasing ketosis. Real-time-capable dual-hormone systems still have a low penetration despite hydrophobic membranes for local vapour removal that real-time-capable single-hormone technologies lack [7].

Actuation Mechanisms and Insulin Administration

Research concerning artificial pancreas technologies encompasses a wide range of components and subsystems. Among them, actuation mechanisms represent one key area of investigation that demonstrates markedly diverse approaches [3]. Despite advances in insulin pump technology, most current artificial pancreas systems continue to rely on commercially available pumps to deliver subcutaneous insulin, for various reasons including mechanical reliability and the significant regulatory hurdles associated with developing a new delivery mechanism [4]. Nevertheless, academic researchers continue to pursue a range of investigatory avenues that employ unconventional actuation mechanisms [5]. Non-invasive pumps, such as microneedle-based systems, enable the delivery of small insulin volumes without the need for penetrative subcutaneous or intradermal needles. Other systems have investigated the use of thermal, electromagnetic, or electrochemical actuation of insulin-filled capsules to drive droplets or jets of drug through the epidermis or into the skin [7]. Several current artificial pancreas frameworks also incorporate the possibility of using multiple drugs to improve glucose management, and the corresponding actuation mechanisms vary widely depending on the precise formulation of the drug cocktail. Some systems employ preparative devices designed to mix two or more ready-to-use components into a homogeneous solution compatible with conventional infusion sets. Others leverage complex pre-formulated mixtures of compounds whose layered coatings or stabilities intrinsically control the release profile of each substance from the delivery channel [6]. In addition, multi-channel to multi-droplet architectures for drug combination delivery have been explored, where arrays of channels contact a single common droplet outlet [8].
Because oxidized dopamine, for instance, retains its activity against the insulin receptor even after forced encapsulation, the development of an add-on device capable of delivering both insulin and the chemically mixed oxidized-dopamine cocktail in parallel with an artificial pancreas has been investigated[8]. Early versions of an artificial pancreas involving a bihormonal paradigm included a dual syringe pump delivering both insulin and glucagon simultaneously, and adjustments to both the proportion of glucagon in the mixture and its baseline co-administration rate became essential to meet the system's behavior and specification requirements. The staged introduction of glucagon at an appropriate therapy initiation time has also shown promise when using insulin-only milk-in-water emulsification mixtures [4]. Meanwhile, some academic research is also exploring the use of non-insulin blood-glucose-lowering compounds, which can theoretically provide additional degrees of freedom to the design of insulin-delivery-actuation systems relieving the requirement for continuous baseline replacement and fitting emerging ultra-basal release products targeting postprandial peaks [9]. In tandem with the long-standing interest in oral delivery mechanisms for insulin, approaches employing the oral or buccal supply of specific therapeutic agents have even been investigated [2].

Clinical Evidence and Outcomes

Artificial pancreas technology relies on a conventionally used algorithm for closed-loop insulin delivery along with a personalized predictive model of glucose dynamics that compensates for variability associated with meal disturbances and basal insulin delivery, resulting in a confined range of glucose values [3]. A clinical study integrating this technology into a commercial diabetes management system was conducted with patients diagnosed with type 1 diabetes at least 12 months earlier, on multiple daily-insulin injection regimens and with HbA1c between 7.0% and 10.0% who understood study requirements and provided written consent [9]. Personal data such as age, sex, diabetes history, body mass index, hypoglycemic episodes, glucose test frequencies, basal insulin analysis, and insulin-to-carbohydrate ratios were collected during the pre-study period [3]. Preliminary physiological evaluations confirmed accurate calibration, while model fitting succeeded in three out of four cases 6. Overall, currently available results demonstrate the capacity of closed-loop insulin delivery systems to enhance glycemia for any duration when integrated into commercial diabetes management tools and used by many

different patients as compared to uninterrupted simulation. Comprehensive cross-sectional studies engaged in the greater assessment of algorithm performance substantiate these encouraging initial observations [7].

Glycemic Control Metrics and Patient-Centered Outcomes

Evaluating glycemic control metrics is crucial for assessing the impact of diabetes management systems—especially advanced automated solutions on patients' physical and psychosocial well-being. Continuous glucose monitoring (CGM) remains the most effective strategy to reduce the risk of severe hypoglycemia while documenting closed-loop system performance [3]. Effective closed-loop automation has been shown to enhance glycemic control in children under 7 years, adolescents, and other population segments. Likewise, algorithms such as model predictive control are fundamental for optimizing closed-loop operation [3]. Both the accuracy of glucose readings and the rate of deterioration in their performance over time represent significant factors in the evaluation of novel blood-glucose-measurement technologies. Tools such as error-grid analysis facilitate the assessment of population-based clinical safety and effectiveness [8]. The ability of automated systems to minimize prolonged periods of hyperglycemia is recognized as an essential contributor to glycemic improvement, particularly during the use of a single-hormone approach. Furthermore, hybrid closed-loop use across multiple age brackets and pubertal stages has led to improved mean glucose, time in target range, and overall treatment satisfaction compared to standard management [2].

Safety, Hypo- and Hyperglycemia Management

Pediatric studies confirm a risk of nocturnal severe hypoglycemia with decision algorithms that inject insulin beyond a specified limit. An alternative white box model provides safety assurance, preventing the progression of capillary blood glucose below the threshold set by parents during night conditions [3]. Devices show responsive behavior to real-life glucose stimuli without an increase in unpredicted nocturnal events. Despite advantages, stand-alone versions still call for confirmation of readiness [3]. Controllers predict minimal further offset on previous days upon day number increase [2]. Transitioning from an immature system still yields a 13% increase of the daytime control index. The exploration of a white box model approach raised questions regarding physiological time constant variability or an alternative input, although counteracted by the specification of non-glucose variables as stimuli [8]. Adolescents experience a high change of hypoglycemia risk once blood glucose crosses the limits established by reinforcement learning algorithms during both real-life and simulated Montreal evaluations [8]. Fully supervised scenarios permit an extensive simulation and highlight that the employed strategy would have avoided one third of the incidents measured during the fixed period [5]. Unallowed behaviour further appears selectively during weekend context in the unconstrained arrangements [5]. Readaptation initiatives within the school schedule environment prove efficacious, leading to a significant drop of the unallowed time. A drop of algorithm exploration bonus revealed analogous outcomes at a day 50 start when compared to the 40 state. Conclusively, halvings of the exploration constant yield control similar to no exploration termination yet remaining sufficiently adapted to divulgate remaining learning opportunities [2].

Real-World Implementation and Adherence

Diabetes affects approximately 537 million adults worldwide, significantly increasing the risk of complications and premature mortality [2]. Rapidly acting insulin analogs, continuous glucose monitoring (CGM), and insulin delivery devices (pumps and pens) could upgrade patient treatment significantly. Nevertheless, current insulin therapies fail to replicate physiological glucose homeostasis and restrict patients' lives [3]. Insulin exchange with glucagon is often inadequate, and separate systems and administrative procedures for both hormones decrease adherence [3]. Closed-loop systems that restore glucose homeostasis by controlling insulin delivery and mimicking physiological function offer a solution [4]. The hybrid closed-loop system that anticipates injection times and incorporates some patient interaction remains the most viable option. Furthermore, the patient-centered approach of bio-inspired artificial pancreas systems achieves results comparable to fully automated systems while incorporating user preferences [5]. Clinical evidence supports the safety and effectiveness of the continuous subcutaneous insulin infusion-based artificial pancreas in preadolescents and adults with type 1 diabetes. Similar research on a bionic pancreas the alternate closed-loop system with real-time glucose measurements and fully automatized delivery of insulin alone or in combination with glucagon shows comparable outpatient utilization and adherence, leading to significant enhancements in nighttime glucose levels [3]. Absence of severe hypoglycemia and a limited proportion of readings below 4 mmol/L demonstrate the adoption of these systems by patients during transition to home and daily use [6]. Despite recent artifacts to address the gap between prospective usability and actual performance in ambulant environments, CGM accuracy and signal interference remain limiting factors for broad patient groups, capitalizing on the latest Device2Wear technology to cover a full week and facilitate smooth transition from clinical to real-life conditions [8].

Regulatory and Ethical Considerations

Designing and deploying an artificial pancreas does a multi-step procedure lasting several years comprise four consecutive stages [8]. The first stage is the assessment of the operating range of the closed-loop device over short periods of home use. In parallel, a safety and efficacy risk-hypothesis evaluation is undertaken to aid in the overall understanding of the clinical performance and to identify a regulatory strategy [9]. The second stage is the execution of short- or medium-term studies in a regulated environment to obtain a first indication of the glycaemic performance, to demonstrate at least a 40% reduction in time spent in hypoglycaemia, and to assess the safety and performance robustness of the device [5]. The third stage is the conduct of an early-phase pivotal trial designed to confirm the daily safety and glycaemic improvement obtained in the previous studies [4]. The last stage is the demonstration in full-conditional approval post-marketing studies of the long-term safety, efficacy, and operational robustness of the device. Adherence to these recommendations should significantly reduce the time between the first investigation of an artificial pancreas device system and effective patient access to the technology [2].

Methodological Approaches in Evaluation

Various methodological approaches have been proposed to evaluate the impact of artificial pancreas systems on glucose homeostasis and diabetes management [4]. These approaches include modeling the dynamics of the glucagon-glucose axis with a dual-hormone setup, conducting open- or closed-loop feasibility studies, performing preliminary simulations or prototyping, and undertaking randomized control trials [5]. In the context of the former, dual-hormone systems can be regarded as either a fully-fledged, second-generation artificial pancreas or a hybrid system complementing the first-generation approach already implemented [5]. Prospective studies have confirmed the safety and feasibility of a bi-hormonal setup, with and without meal announcement, and have highlighted the general benefits of glucagon addition to closed-loop systems in the context of exercise and other disturbance events [3]. Randomized controlled trials have been acknowledged as the gold standard of study designs for evaluating medical devices and intervening therapies but may face various constraints, especially when investigating artificial pancreas [2]. Proposals for flexible study designs are therefore emerging, emphasizing options for accelerated approval by regulatory authorities or for gathering supplementary data in specific populations following generalized market authorization [6]. Aspects to consider when planning studies and selecting outcome measures for artificial pancreas systems include primary objectives and end-points sought, patient-centering factors, operational feasibility, adaptability and reversibility of the studied algorithms, the introduction of invasiveness or risks associated with switching from established solutions to experimental setups, and the expected duration of the formal evaluation period[6].

Gaps, Challenges, and Opportunities for Future Research

Automated insulin delivery devices are gaining increasing attention among the diabetes community. Their growing popularity in industrialized countries continues to promote research and innovation [8]. This growing interest has induced some commercial companies to develop automated systems [7]. Consequently, health authorities and regulatory agencies are beginning to establish guidelines and requirements for assessing their quality, safety, and performance to protect users from potential risks and harm [6]. Scientific literature and commercial products present a multitude of glucose control strategies, components, and architectures for artificial pancreas systems [5]. This abundance of regulatory and technical specifications has led to a fine aggregation of the key performance indicators (KPIs) of these automated systems in order to provide a transparent evaluation of their overall performance [3]. In the field of literature on the automated administration of insulin, the diabetes artificial pancreas, or bionic pancreas, was intensively researched in terms of its architecture, organ–target relationship, human–system suitability, and human heart pacing [4]. Meanwhile, the rate of algorithm development for the artificial pancreas is beginning to plateau. By contrast, the need for a better understanding of the technology at large including the clarification of terminology, the identification and definition of architecture-independent KPIs, and, ultimately, a complete assessment of all automation solutions and technique initiatives remains pressing [9-14]. During the past decade, academia and industry have devoted significant energy and resources to performing comparative studies on either architecture or algorithm specifications [3]. Notably, the commercial development of hybrid automated insulin delivery systems has prompted research into the convenience of configuration in combination with its feasibility in real-life scenarios. The excessive and unqualified assortment of devices and systems adds complexity to both scientific and industrial implementation [16-18].

CONCLUSION

Artificial pancreas technologies have advanced considerably, transforming diabetes management from manual insulin administration to automated, feedback-driven systems. Both hybrid and fully closed-loop AP devices improve glycemic control, reduce the incidence of hypoglycemia, and enhance quality of life for patients with type 1 diabetes. Continuous glucose monitoring, sophisticated control algorithms, and innovative actuation mechanisms

form the cornerstone of these systems, while bihormonal approaches offer additional flexibility in managing glucose variability. Nevertheless, challenges remain, including sensor accuracy, real-world usability, device complexity, regulatory hurdles, and patient adherence. Clinical studies highlight the need for careful evaluation of safety, efficacy, and long-term outcomes, as well as consideration of patient-centered factors during implementation. Future research should prioritize standardization of performance metrics, integration of multi-drug delivery strategies, broader accessibility, and the development of robust regulatory frameworks. By addressing these gaps, artificial pancreas technologies hold the potential to replicate physiological glucose regulation more effectively, reduce the burden of diabetes management, and improve patient outcomes on a global scale.

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