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Patch Pumps: Present and Future

An increasing number of patients with diabetes are opting for insulin pumps as a method of intensive insulin therapy. Avoiding the disadvantages of conventional pumps, such as the use of insulin infusion systems and their complications, could make insulin pump therapy even more attractive. Patch pumps, which adhere to the skin with an adhesive layer, offer several additional advantages, such as being smaller, more discreet, and easier to use. This review provides an overview of patch pumps, the clinical requirements for candidate individuals, potential failures in development, necessary clinical studies to support their use, associated costs, patient preferences (which may vary among different patient groups), and the future of patch pumps, including closed-loop systems.

INTRODUCTION AND CURRENT STATE DEVELOPMENT

An increasing number of patients with diabetes are opting for insulin pumps as a treatment method for intensive insulin therapy. However, conventional insulin pumps present barriers to their implementation (Table 1). Studies have revealed that most people with type 1 diabetes mellitus prefer insulin pumps without visible insulin infusion systems. These pumps, known as patch pumps (PP), adhere to the skin via an adhesive. The infusion systems of conventional insulin pumps represent their "Achilles' heel." Infusion sets play a crucial role in ensuring the safe infusion of insulin and must be changed every 2 to 3 days, with a considerable risk of obstruction, air bubbles, kinks in the tubing, or the Teflon catheter in the subcutaneous tissue, cumbersome management, and need for priming. Additionally, conventional pumps are visible, which affects their discretion.

A recently published article investigated the adverse effects associated with insulin infusion systems and their impact on metabolic control. Such study found that most people with diabetes follow the optimal frequency for changing the cannula and catheter within the timeframe recommended by health care professionals. However, those who change the cannula and catheter on different days tend to keep the catheter longer than recommended, which is associated with a higher frequency of related adverse effects. Accidental pulling of the catheter and kinking often occur during daily activities, while problems related to the cannula directly affect blood glucose levels. Adverse effects related to the cannula often include insulin leakage under the skin, bleeding, and skin events attributed to adhesion issues.

HISTORY OF PPS

The history of PPs is relatively recent compared with conventional insulin pumps, which have been available since the 1970s. PPs emerged as a therapeutic alternative about 15 years ago, with the development of the Omnipod system by Insulet Corporation in 2005 in the United States. This system, which was the first commercially available PP in that country, marked a milestone by offering easy-to-use, tubeless insulin delivery. Subsequently, in 2022, it became the first tubeless insulin delivery system in a closed loop, following FDA approval. Initially, the primary goal of PPs was to address a significant source of error and overcome a barrier in the treatment of conventional insulin pumps for people with type 1 diabetes mellitus. However, current advancements aim to expand their use to people with type 2 diabetes mellitus too. Although there are currently only a few PPs on the market, many companies have announced the development of new devices or reported positive results in the clinical development phase. Therefore, it is likely that more devices without infusion systems for insulin therapy in people with diabetes will emerge in the coming years. »

TABLE 1. Barriers to the Use of Conventional Insulin Pumps

Barriers to the Use of Conventional Insulin Pumps:
• **Discretion:** Concerns regarding the visibility of the device. • **Limitation of Sports Activity:** Difficulties in engaging in sports. • **Limitation of Mobility:** Restrictions on movement due to the device. • **Adverse Effects Related to the Infusion System:** Problems associated with the infusion system

TABLE 2. Advantages and Limitations of Patch Pumps

Advantages:
• No Tubes: Reduction of problems related to the insulin infusion system (catheter/needle/tube); the needle is not visible. • Reduced Risk of Insulin Obstruction: The insulin remains at a similar temperature level within the patch pump. • Complete Freedom of Movement. • Water-Resistant (not all): Some patch pumps can be used in the shower, for swimming, and during sports. • Ease of Use: Simpler handling, with design features appreciated by patients. • Simplified Training. • Placement on Different Body Parts: Provides more discretion in wearing the device. • Smaller and Lighter: Patch pumps are more compact compared with conventional insulin pumps. • Nearly Painless Application: Many patch pumps offer automatic needle insertion. • Remote Control of Insulin Infusion Rate: Some patch pumps allow for remote control. • Integrated Bolus Calculators: Some remote controls include bolus calculators.
LIMITATIONS:
• Insulin Waste: Waste from remaining unused insulin when replacing the patch pump. • Plastic Waste and Battery Disposal: Environmental impact from disposables. • Invisible Infusion Site: Infections at the infusion site may go unnoticed. • Accuracy of Insulin Infusion: Concerns about precision, especially with small doses, and the time required to infuse bolus insulin (depending on pumping technology). • Need for Additional Device: Some models require an extra device for insulin infusion control. • Cost Considerations: Costs should be lower compared to conventional pumps.

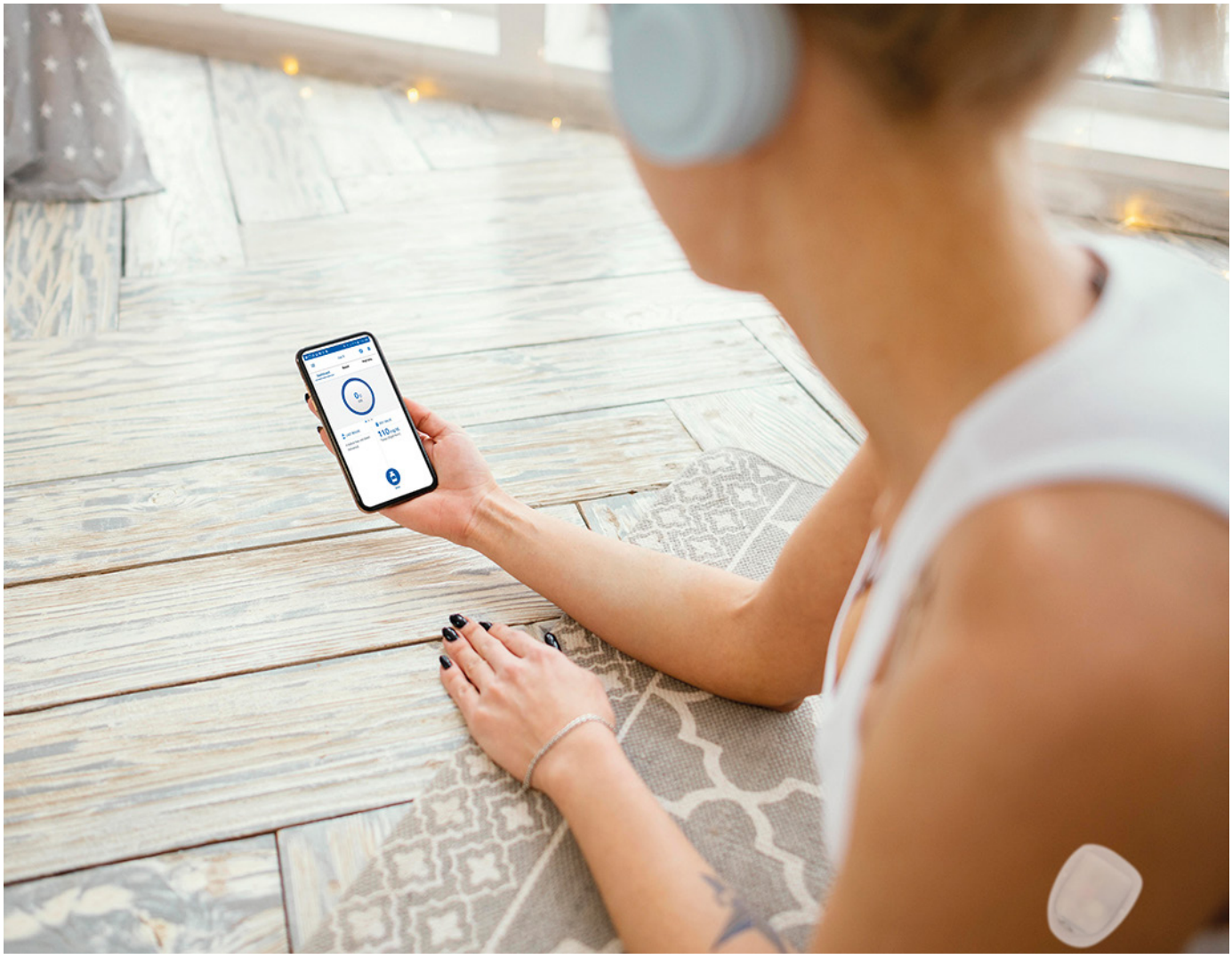
PATCH PUMPS, WHICH ADHERE TO THE SKIN THROUGH AN ADHESIVE LAYER, OFFER SEVERAL ADDITIONAL ADVANTAGES, SUCH AS BEING SMALLER, MORE DISCREET, AND EASIER TO USE

ADVANTAGES AND DISADVANTAGES OF PPS

Compared with conventional insulin pumps, PPs offer several advantages but also some limitations (see Table 2). In general, they are smaller, more discreet, easier to use, and cost-effective. However, the diversity in the basic technology for insulin delivery, availability of remote control, infusion patterns, advanced features, as well as sizes and costs, vary among the different PPs available in the market or about to be launched.

The main difference and advantage of PPs lie in the absence of infusion systems. Adverse effects related to these systems or infusion sets are a common thing. According to a survey conducted by Pickup et al. among users of conventional insulin pumps, 64% had experienced kinks in the tubing, with 12% experiencing this frequently. Additionally, 54% of users reported experiencing infusion system blockages at some point, and 10%, frequent cannula blockages. Problems at the infusion site, such as changes to the skin (e.g., lipohypertrophy) were noted by 26% of users, while 17% experienced infusion site infections on occasion. The length of the infusion set also poses risks of tangling, snagging, or pulling the tubing while moving, which can be uncomfortable in everyday situations or during physical activity.

One of the main obstacles to adopting conventional insulin pumps is their visibility, which is bothersome for many people with diabetes. According to a survey conducted among adults registered in T1D Exchange (70% insulin pump users), 47% cited barriers related to the discomfort of carrying devices, 35% disliked having diabetes devices on their body, and 26% were bothered by the look of the devices. Among the reasons for »



» discontinuing insulin pump use, the most common were physical discomfort and dislike for the look of the device. Concerns about body image due to the size and visibility of the pump were especially frequent among adolescents and women. In this context, PPs offer a useful alternative, being more comfortable to wear and discreet. Their lighter weight and ease of adherence to the skin make them ideal for individuals concerned about body image or who engage in regular physical activity. In summary, the reduced size, lightweight nature, and ease of wearing them in different parts of the body make PPs an attractive option for many diabetic patients, helping to alleviate disease-related concerns and improving quality of life.

However, there are also potential disadvantages associated with PPs (see Table 2) that certainly impact the experiences and attitudes of people with diabetes. The accuracy of insulin delivery in subcutaneous tissue depends on the technology used in the various pump models. Given the small size of PPs, achieving precise dosing poses a technical challenge, especially when it comes to dosing small amounts of insulin or maintaining low basal rates. Although some PPs may exhibit lower accuracy in these circumstances compared with conventional pumps, this aspect could be relevant for those with very low insulin requirements. However, in the largest comparative study to date on the accuracy of insulin delivery among different pumps, no significant differences were found in average bolus doses and basal rates among the 10 evaluated models.

On the other hand, in PPs, the insertion site is covered by the pump, making regular inspection impossible. This aspect could delay the detection of local skin changes such as inflammation at the insertion site. Ecological considerations and waste generation are gaining increasing importance in the choice of devices »

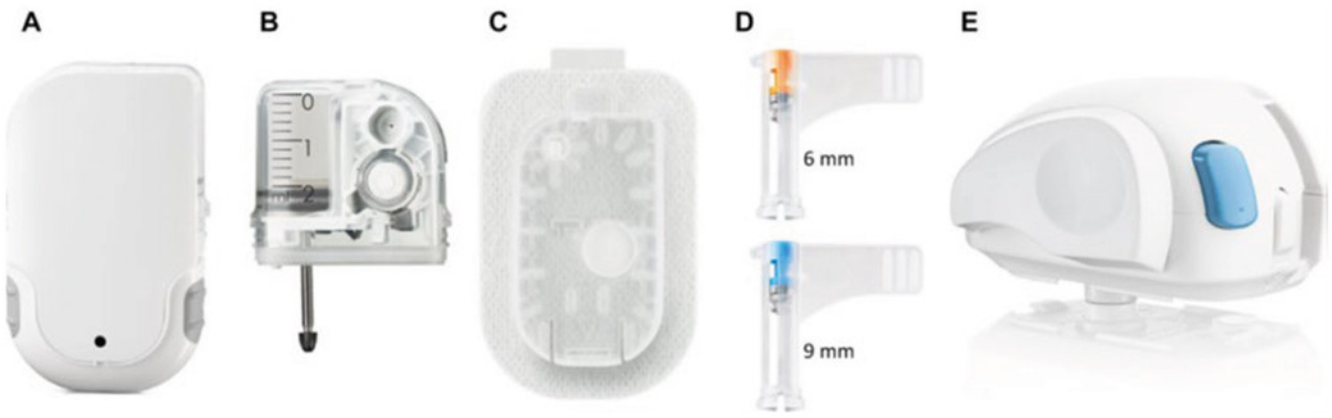


FIGURE 1. Components of the patch pump (Accucheck SOLO, Roche): (A) pump base, (B) reservoir, (C) pump support, (D) cannula with housing, and insertion device (E).

» by people with diabetes. Consequently, disposable patch pumps may be less accepted in this regard, leading most manufacturers to distinguish between recyclable and disposable components.

CATEGORIES OF PPS

The various PPs currently available present differences in their characteristics depending on the patient group they are aimed at, varying in complexity and offering suitable functionality for both type 1 and type 2 diabetes mellitus. PPs designed for patients with type 1 diabetes mellitus offer a wide range of functions with the goal of replacing conventional insulin pumps with infusion systems. In contrast, those aimed at patients with type 2 diabetes mellitus focus on providing limited features and an easy-to-use interface, intending to replace insulin pens.

Aside from the common feature of tubeless insulin delivery, the multiple PPs available or in the pipeline present significant differences: they administer only basal insulin, only bolus insulin, or both basal and bolus insulin. In general, the different PPs can be divided into 3 categories based on functionality and ease of use, the additional features of the PP, and interoperability with other devices, especially on the possibility of being part of systems for automated insulin delivery or closed loops. These differences are also particularly important for interpreting clinical trials of PPs concerning patient preferences, perceived patient satisfaction, and other patient-reported outcomes (PRO).

In general, they can be divided into the following categories:

• **Simplified:** "pen replacement." Simple forms of PPs are intended for insulin therapy for people with type 2 diabetes mellitus, with the primary goal of making them easy to handle, portable, small, and disposable. Recent advancements aim to replace insulin pen therapy with PPs that utilize relatively simple insulin dosing regimens. There are also options to administer only basal or bolus insulin through a PP to simplify insulin therapy.

• **Fully equipped:** These pumps can deliver, at least, 1 or several basal rates and individually controllable bolus insulin amounts. In most cases, advanced features similar to those of conventional pumps, such as different bolus options, information on insulin on board, a bolus calculator, or data integration from a continuous glucose monitoring (CGM) system, are also available. Examples of this category include Accuchek SOLO »

PEOPLE WITH DIABETES TEND TO PREFER PATCH PUMPS OVER THERAPY WITH MULTIPLE DOSES OF INSULIN AND CONVENTIONAL PUMP

THE MAIN DIFFERENCE AND ADVANTAGE OF PATCH PUMPS LIES IN THE ABSENCE OF INFUSION SYSTEMS

» (the only patch pump currently available in Spain, (Figure 1), Omnipod, A6 touch Care, and Glucomen day.

• **Suitable for closed-loop systems:** Since most closed-loop systems present interconnectivity among several insulin pumps, PPs represent a very attractive option due to their small size and ease of use. The prerequisite for this is the interoperability of the PP, meaning it meets FDA requirements for interaction with the CGM system and the algorithm. An example is the Omnipod 5 system. Through the control algorithm, the Omnipod can communicate directly with a Dexcom CGM system and, also with a portable device with the Omnipod 5 app implemented. With this device, the user can initiate and stop automated mode, administer boluses, change settings, and view glucose data and glucose profiles. Currently, there is no closed-loop patch pump available in Spain.

POTENTIAL CANDIDATES FOR PPS

The selection of patients eligible for PPs largely depends on the therapeutic goal, which can vary from simple substitution of multiple daily insulin doses to their use in closed-loop systems. In particular, for children with type 1 diabetes mellitus, PPs are appealing due to their small size, light weight, lower risk of interruption of insulin delivery due to the absence of tubing, ease of use, and especially the minimization of the risk of problems due to the insulin infusion set, which is a source of concern, especially in children. Young people particularly appreciate the small size of the PP and the ability to wear it discreetly on different parts of the body. For individuals with type 2 diabetes mellitus, simple PPs, designed to facilitate therapy, may represent a good alternative to traditional pen therapy. Although not as advanced in functions, these PPs would improve ease of insulin administration and enhance comfort, especially during daily activities or physical exercise. Furthermore, they could foster better adherence to insulin therapy.

FINAL CONCLUSIONS

PPs are becoming increasingly popular among people with diabetes, and it is expected that new models catering to a wide range of patient needs will enter the market in the coming future. An analysis of 12 studies (with room for methodological improvement) provides information suggesting that the use of PPs improves quality of life, treatment satisfaction, and that people with diabetes generally prefer PPs over multiple daily insulin injections and conventional pumps. In the future, the interoperability of different components of closed-loop systems can make the use of closed-loop PP possible, addressing the current most significant limitation of their use. However, there are patients with low glycemic variability, especially children and young people, patients with high insulin needs, or athletes who may currently benefit from open-loop PPs.

Looking ahead, it is important to conduct methodologically better-designed studies to obtain more scientifically robust data regarding patient experience when using PPs including randomized clinical trials with a control group design and patient-reported experiences as the primary outcome, as well as the use of representative samples from different patient groups. D

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