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Patch Pumps: Are They All the Same?

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Abstract

Insulin pumps are used by a steadily increasing number of patients with diabetes. Avoiding certain disadvantages of conventional pumps (ie, the insulin infusion set) might make pump therapy even more attractive. Patch pumps are usually attached by means of an adhesive layer to the skin and have several additional advantages (smaller, more discrete, easier to use, and cheaper than conventional insulin pumps). This review provides a general overview of patch pumps, the technologies used, basic clinical requirements, why a number of developments failed, which clinical studies are needed to provide sufficient evidence for their usage, which costs are associated, what the patient preferences are (which might differ between certain patient groups), and what is the future of patch pumps (ie, artificial pancreas systems).

Keywords

insulin pumps, infusion sets, patch pumps, insulin therapy

Surveys have demonstrated that most patients with type 1 diabetes (T1D) prefer insulin pumps without visible insulin infusion sets (IISs) for continuous subcutaneous insulin infusion (CSII) therapy.[1,2] Such pumps are called patch pumps, as they are usually attached to the skin by means of an adhesive. IISs represent the Achilles heel of conventional insulin pumps.[3] Not only do they have to be replaced every 2-3 days, there is also a considerable risk of clogging (mainly by insulin inside the tubing), air bubbles impairing pumping, kinking of the tubing or the Teflon catheter in the subcutaneous tissue, cumbersome handling, and the need for priming.[4] Furthermore, they represent an expensive part of the CSII therapy. The long tubing also makes conventional pumps prone to handling issues (being pulled out while playing, etc) and are visible, that is, it does not allow the insulin pump to be discrete.

In general, patch pumps are smaller, more discrete, easier to use, and often cheaper than conventional insulin pumps.[2,5] The patch pumps that are already on the market or will soon come to the market, share a long list of similarities; however, at the same time they are diverse in the

- Basic technology used to pump the insulin (Table 1)
- Availability of remote control
- Choice of infusion patterns available (only continuous/flexible basal infusion rate, with or without bolus insulin delivery, only bolus insulin delivery)
- Advanced functions (eg, integrated blood glucose monitoring system [BGM] or continuous glucose monitoring [CGM] and remote control)
- Size, costs, etc
- Target audience (patients type 1 replacement for conventional insulin pumps with IIS versus patients type 2 diabetes replacement of insulin pens)
- Manufacturing: accurate insulin delivery at low costs is demanding—patch pumps should meet the same standards as conventional insulin pumps but there are no specific standards for patch pumps

Table 1. Technologies Used by Patch Pumps for Insulin Delivery.

Current
• Nitinol wire (OmniPod)
• Step motor (Accu-Chek Solo)
• Piezoelectric crystal
• Spring
• Bladder
• Manual pumping chamber
Potential
• Iontophoresis (need to remove epidermis)
• Ultrasonic
• ElectroOsmosis

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Table 2. Advantages (a) and Limitations (b) of Patch Pumps: Some of the Advantages/Disadvantages Are Present in Patch Pumps, but the Respective Design Defines What Is Actually Applicable.

a.
- Tubeless, eg, reduction of problems with the insulin infusion set (IIS) (catheter/needle/tube), needle is not visible
- IIS is inside the pump or within the base part of the patch pump
- Reduced risk of clogging of the insulin in the IIS, insulin remains at similar temperature level inside the patch pump
- Full freedom of movement
- Water resistant; some patch pumps can also be used under the shower, for swimming and sport
- Ease of use, simpler handling, design features that are appreciated by patients
- Simplified training, fewer steps to initiate CSII
- Many parts of the body can be used to attach patch pumps, ie, they provide more discretion
- Patch pumps are smaller and lighter than conventional insulin pumps
- Their application is almost pain-free; many patch pumps provide an automatic insertion of the needle
- Many patch pumps enable control of insulin infusion rate by a remote control (like a number of conventional pumps as well)
- At least in some patch pumps bolus calculators are integrated in the remote control

b.
- Waste of insulin when patch pumps are replaced but the remaining insulin was not used
- Waste of plastic material, batteries
- Infusion site is not visible, ie, an infection could not be seen
- Accuracy with which the insulin is infused varies between patch pumps, also the time required to infuse a given bolus varies depending on the pumping technology used
- Need for an additional device to control insulin infusion (not via smartphone), ie, the patch pumps themselves are smaller, etc; however, need to have another charger for the remote control, etc
- Patch pumps look quite similar, but their properties differ massively; need for adequate training; not easy to switch
- Costs should be lower compared with conventional pumps

In comparison to conventional insulin pumps, patch pumps offer a number of advantages, but also some limitations (Table 2).

Due to the small number of publications about patch pumps that could be identified by a literature search (PubMed, search terms "diabetes," "pumps," and "patch pumps"), this is not a conventional review of the published evidence, but a brief introduction to the basic approaches used for patch pumps, the existing evidence for their usage, and discussion of open questions with respect to clinical usage of patch pumps.

Design Factors of Patch Pumps

Conventional insulin pumps (those with an IIS) all look similar. This is driven not by the limited creativity of the developer but by technical reasons, mainly by the format insulin cartridges have today (inflexible, round, and lengthy). The development of flexible insulin reservoirs of different shapes enables construction of patch pumps that look different from conventional insulin pumps.

Pumping of the insulin requires energy. Thus, appropriate batteries become more of a problem with the smaller electrically driven patch pumps. While the energy requirements for the basal infusion rate, with small amounts of liquid infused over time, are low current, but over a long time, the boluses require much higher current over shorter periods. Overall, the energy requirements for each are similar. In addition, the time needed to infuse prandial insulin boluses vary largely between conventional insulin pumps and among patch pumps.

The heterogeneity of patch pumps makes it somewhat difficult to compare them; some are replacements for insulin pens, others are high-end replacements for conventional insulin pumps. Most patch pumps require filling of insulin reservoirs by the patients themselves, only a few have the option of using prefilled cartridges.

Patch pumps come in a variety of shapes, sizes and technologies (Table 3). This is also a reflection of varying patient requirements, especially depending on the type of diabetes. There are two tasks in insulin delivery: basal rate and bolus.

One can decide if the pump should allow only one or both, depending on the target group:

- Simple pumps may provide basal rate or bolus only
- Simple basal pumps may have a fixed infusion rate determined by the infuser used
- In more sophisticated devices, basal rates may be programmable
- Boluses may be fixed size, programmable, and fixed shape or complex (extended/box, multiwave/dual) depending on sophistication level

Simple, mechanical patch pumps may provide only bolus insulin (insulin pen replacement). These patients inject a long-acting basal insulin with an additional insulin pen. Others may provide fixed rate basal and mechanical boluses. The latter type of patch pumps usually infuses the insulin with a constant infusion rate and the infusion rate in each device is preset. To get a different rate the patient must choose a different model of the infuser.

Table 3. Overview of Patch Pumps.

Name	Accu-Chek Solo micropump system	Cellnovo	JewelPump	OmniPod	OneTouch Via (formerly Calibra Finesse)	PAQ	V-Go
Manufacturer	Roche	Cellnovo	Debiotec	Insulet Corp	LifeScan	CeQur	Valeritas
Intended for	The micropump system is intended to be used by insulin-dependent persons with diabetes mellitus	Insulin Dependent	Types 1+2	Types 1+2	—	Type 2	Type 2
Approval	FDA (predecessor from Medingo; CE mark is expected end of 2018)	(Pending) + CE		FDA + CE	FDA, not yet released	CE, not yet released	FDA, CE, available in US
Components	Cradle with inserter, detachable 2 part minipump (reservoir + pump base), remote controller	Disposable insulin cartridge + reusable electronics + handset	Disposable reservoir/ pumping mechanism/ battery + reusable electronics + remote controller (touch)	Pod + PDM	Disposable pump	Disposable insulin reservoir + reusable electronic messenger	100% disposable
Principle	Piston driven by step motor	Paraffin wax micro-actuator; intelligent delivery system	Micro electro mechanical system, volumetric membrane pump	Microprocessor control, shape memory allow wire assembly	Manual piston, volume displacement by pressing button, non–electrically powered	Elastomer bladder drives basal flow, capillary flow restrictors control basal rate	Nonelectronic spring-force drive with flow restrictor
Insertion	Soft cannula 6 or 9 mm, reusable insertion device	Soft/steel cannula + minitubing (priming required)	Auto-inserted infusion cannula (can be changed every 3 days, reattached to patch)	Integrated soft cannula, inserted automatically	Inserter, flexible cannula	Inserter, flexible cannula	"Floating" steel needle, push needle button
Functions	5 basal rate profiles with up to 24 segments, temporary basal (0-250%), different bolus types	20 basal rate profiles with hourly segments, temporary basal, different bolus types	5 editable basal profiles, temporary basal, different bolus types	7 basal rate programs with 24 segments, temporary basal, different bolus types	Only 2 U boluses, no basal	7 preset basal rates (16, 20, 24, 32, 40, 50, 60 U/d), 2 U manual bolus on demand	Preset basal rates (20, 30, 40 U/d), 2 U manual bolus on demand
Size	68 × 40 × 15 mm, 32 g	54 × 35 × 14 mm, 32 g	70 × 40 × 12 mm, 25 g	1.6 × 2.4 × 0.7 inches, 34 g	51 × 25 × 6.4mm	50 × 70 × 17 mm, 32 g	61 × 33 × 13 mm, 20-50 g
Insulin reservoir	80-200 U	150 U	500 U	200 U	200 U	330 U	20 option, 30 option, 40 option, +36 U for meals
Wearing time	Reservoir up to 4 days and cannula 2-3 days, pump base 90 120 days	3 days	7 days	3 days	3 days	3 days	24 hours
Further	Integrated BGM, bolus advice, flight mode, bolusing remotely and directly on pump	Cloud-based, integrated BGM, activity monitor	Integrated BGM, additional bolus buttons on pump	Integrated BGM	Dose count card	Message card	—
References	25-26	8, 25-27	Homepaage, 11, 25, 26	23-27	25-26	25, 26, 28	Manual, 25, 26, 29

The pumps are sorted in alphabetical order and not into "simple" or mechanical-driven devices and electrically driven pumps. The latter have the full features of traditional pumps (high upfront costs and training time) and those that are simpler to use, but with less basal and bolus dosing options. Not all information for all pumps was available.

Other, more complex electronic patch pumps allow coverage of basal and prandial insulin requirements; different boluses types are possible. Offering different therapeutic options comes along with more complex design requirements to pump technology and additional cost.

These different requirements are handled by different developers/manufacturers by using a variety of innovative technologies: mechanical versus electrical, monolithic versus modular, and so on. The latter is important, as it allows reuse of some components. Thus, the insulin reservoir can be replaced/filled without having the need to replace the electronic part (this most often contains also the battery). Other patch pumps do not need electronic parts at all, that is, they are purely mechanical. Some patch pumps have a cradle that is attached to the skin with an adhesive and not the patch pump itself. The patch pump itself is clicked into this holding device. An additional handheld device to control the function of the pump itself is used by most patch pumps; however, some patch pumps can also be used without such an additional device, that is, a bolus can be applied via a button on the pump itself when needed. In the future, usage of more concentrated forms of insulin (U200, U300, or even U500) might allow reducing the size of the patch pumps even further (but highly precise pumping mechanisms are needed as the delivered volume decreases further, which is the limiting factor for accuracy).

Patch pumps have no external IIS; however, there has to be an internal tubing transferring the insulin from its reservoir to the needle. This tubing is short and has a small volume; nevertheless, it requires some priming in the same way as an IIS with conventional pumps. It can also lead to an "aging effect" at the infusion site, in which insulin delivery characteristics change with increasing wear time.

History of Patch Pumps

The idea to develop smaller and easier to use insulin pumps is not new and a number of different approaches were pursued over time, many without success. Indeed, several announcements of new patch pumps can be found in the internet, with no products to follow. As with other medical products, a good idea and innovative technological concepts are not enough to develop a successful patch pump that can be manufactured in large quantities with a sufficient accuracy and reliability at an acceptable price and in regulatory compliance. It appears as if the challenges the production process present are not taken seriously enough early in the development process. This is also reflected by the fact that the time required to develop patch pumps into products took a much longer time than initially announced. It becomes obvious that development of reliable patch pumps products is more difficult, cost and time intensive than one would expect with such "simple tools." The first patch pump that came to the market is the OmniPod (Table 3). The basic technology was developed more than 10 years ago, and their third generation is described in this section.

Performance of Patch Pumps/Accuracy of Insulin Infusion

In view of the quite different technological concepts used by patch pumps to infuse insulin, it is not of surprise that the accuracy with which the patch pumps deliver insulin differs; however, the number of adequately performed clinical experimental and clinical studies is very limited. A useful standard procedure would be to perform such studies as head-to-head studies.[6-10] Measuring the tiny flow rates of a patch pump (as low as 0.5 μL/min) is challenging, and a 10% error would only be ±50 nL/minute. These measurements are susceptible to errors and normative measurements may yield indicators that have only limited use. Currently we are lacking both the optimal experimental and analytical tools to evaluate the performance of patch pumps. One also wonders about the interpump differences from the same manufacturer when it comes to accuracy of insulin application (might it be infusion of basal rate of insulin bolus). On the same line of thinking, how good is the accuracy of a conventional insulin pump over time?

In the last years a number of comparison studies were published, evaluating the accuracy of insulin infusion over time with different pumps; however, most often conventional pumps were studied under the same experimental conditions (at least this was the aim). To establish an experimental setup that enables reliable estimation of pumping properties of patch pumps (and also of conventional pumps) is very difficult; no good standard experimental setup has been agreed upon thus far.[6,8,10-12]

In view of its market share and success, it is understandable that in most of these studies the OmniPod patch pump was studied. In most such studies, accuracy of this patch pump was inferior to that of conventional pumps.[11] Relevant differences in accuracy are mainly becoming evident with smaller infusion rate, that is, with a basal infusion rate of 0.1 U/hour the differences are pronounced; but with 1.0 U/hour the differences are small. It is also a matter of debate if such differences are clinically meaningful or not. A topic that also might be of relevance is that the accuracy of a given patch pump might differ between manufacturing batches; small differences in the manufacturing process (especially the form and size of the pumping chamber) might lead to significant differences in the amount of insulin pumped.

Another issue of patch pumps is/or can be that they are most often applied to the same skin area over and over again. The adhesives used can induce skin reactions, which can range from more or less harmless red skin to severe allergic reactions.[13] Such allergic reactions are most probably induced by certain acrylates in the adhesives; however, these are also prevalent in the plastic material used for the patch pump itself.[14] As in the future patients might have different systems attached to their body for prolonged periods of time (eg, CGM systems and patch pumps), such allergic reactions might impair or even block usage of such systems.[15]

Current Evidence for Patch Pumps and the Need for Clinical Studies

All medical devices that are used for treatment of patients with diabetes should receive adequate scientific study. The benefit of their usage should also be studied in adequately designed clinical studies. Such studies generate the evidence that is needed to convince payers to cover the costs for patch pumps.

Despite the widespread usage of one patch pump (the OmniPod) and the number of other patch pumps that are expected to come to the market in the near future, the number of publications that report the results from clinical trials with patch pumps found by a respective PubMed search was small (eg, Layne et al[16,17]). In addition, most of these studies appear to be of mediocre quality when it comes to study design, sample size, and study duration. However, a number of observational data were published.[18] A certain reluctance of payers toward reimbursement of patch pumps based on the limited evidence for their usage is therefore understandable.

An appropriate clinical outcome study using parallel groups should include conventional insulin pumps, patch pumps, and insulin pens, all using intensive insulin therapy to be conclusive; the study should include a sufficient number of patients (per group $>$100 patients), different patient groups (eg, children, type 1 and 2, elderly, vision impaired), and clinically relevant endpoints. This would also enable an economic analysis and patient-reported outcomes. The study would help us understand if the different therapeutic options are equally safe and effective, if they are robust enough for daily life. Safety aspects should also include skin reactions to the adhesives used and/or substances in the plastic used for the patch pumps. Another safety aspect can be interferences between the patch pumps and medical examinations.[19]

Costs of Patch Pumps

In view of the different technologies and concepts used by the different patch pumps, their costs vary considerably. From a payer point of view the advantages of patch pumps are that low upfront costs are required (in comparison to conventional insulin pumps). When it comes to CSII, considerable differences exist between countries. For example, in the different countries in the EU—to the extent insulin pumps are used at all—there is wide variation in their reimbursement. Some patch pumps are intended to be used in patients with type 2 diabetes who previously used insulin pens. Such patch pumps compete on prices with pens and not with conventional insulin pumps. It is of interest to note that patch pumps are not a hot topic at scientific meetings. In contrast the interest of patients in such products is high, which is understandable in view of the many advantages they offer for daily diabetes therapy.

Patient Preference

It appears as if the relatively high market share of patch pumps is mainly a patient-driven decision. This is of interest, not only from a clinical point of view, but also for the manufacturer. This might also be the driving force behind the clinical studies that only focus on patient preference (=patient-reported outcomes).[20] As most of these studies were uncontrolled, it is not of surprise that patients and also physicians reported enthusiastic about patch pumps.[21] Subsequently also the reported benefit in terms of glycemic control should be taken with caution.

Concept of "Micropumps"

In addition to conventional insulin pumps and patch pumps, a third insulin pump category was established recently: micropumps.[11] Such pumps are named for the quality of their insulin delivery due to the high manufacturing quality, tight specifications, and modular design. They are very similar to conventional insulin pumps in accuracy of delivery and in features. But like patch pumps, they are worn on the body. The first micropump will be introduced into the marketplace in the near future. It will represent a key part of a technology platform the manufacturer of this pump is developing. Nevertheless, the strong presence of the patch pumps concept in the marketplace might represent a barrier for the acceptance of a new class of pumps at this point of time.

Patch Pumps in Special Patient Groups

Different types of patch pumps are likely to appeal to different segments of the diabetes population. There is a need to differentiate groups like

- Children and adolescents
- Adult patients with type 1 or type 2 diabetes
- Geriatric patients
- Pregnant women with T1D or gestational diabetes
- Patients with psychosocial problems

For each of these groups the considerable variability in patch pump design and available features will enable a choice of selecting the pump model that best suits the patient's needs in the future. The simplified training and usability are of help to patients and professionals and might be a great advantage. This should be associated with increased adherence in most patients groups and better glycemic control and quality of life. For patients the important factors are the near pain-free usage, the discrete handling (patch pumps can be applied at nearly invisible sites), and that changes of infusion rate can be done via a remote control or an insulin bolus can be applied more discretely without having to handle an insulin pen. Appropriately designed clinical trials are needed to demonstrate the potential advantages of patch pumps in different patient groups.

Patch Pumps and Automated Insulin Delivery

Currently the first Automated Insulin Delivery (AID) systems are in late stages of clinical development; a hybrid AID system is already on the market in the United States. Such systems are based on a concept of combining for continuous glucose monitoring (CGM), a small computer with the necessary algorithm(s), and an insulin pump. An advanced version of an AID system will use an advanced CGM system and a patch pump, linked via Bluetooth to a smartphone. From a patient point of view, this is an attractive version of an AP system, at least from a discretion point of view. The first data from clinical trials with AID systems using a patch pump became available recently.[22]

In such a system, patch pumps are connected to other devices through the cloud. This connectivity also means that they can be hacked. Like with conventional insulin pumps, this in principle represents a certain risk and the manufacturer will have to take measures to prevent this. Additional concerns are the following: What happens if the steering device or the connection fails? How is the patch pump operated (no display, bolus buttons)? How easy is it to go back to normal pump mode (basal rate, etc) in case of an AID failure.

Summary and Outlook

From our point of view, patch pumps and similar concepts (micropumps) represent an attractive and modern option for insulin administration. They come along with a number of convincing properties paired with a probably attractive cost situation; however, the latter might differ between countries.

Clearly more patch pumps will come to the market in the next years. In view of the advantages patch pumps offer, they will be used by a considerable number of patients of different groups. The future success of patch pumps, that is, their market success, will depend—beside their price and the reimbursement situation—very much on how attractive patients (groups) will find these and if they use them instead of an insulin pen or a conventional insulin pump. Clearly, patch pumps represent an important enhancement of the treatment portfolio for patients with diabetes. In view of the rapid increase of connected devices, patch pumps will transfer relevant information (how much insulin was applied when) to the cloud or other systems to enhance diabetes management together with other information such as glucose values, and so on. In a "connected world" patch pumps might play a highly integrated and important role. However, we also see the need to investigate a number of open questions, like frequency of cannula clogging, malfunctions, infusion site issues, quality of life, adherence to pump procedures, and accuracy of insulin infusion in daily life. Such aspects might differ considerably between the different patch pumps.

Abbreviations

AID, automated insulin delivery; BGM, blood glucose monitoring; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; IIS, insulin infusion set.

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