

**The Novel Insulin Patch Pen Device.****\*Sasmita Biswal**

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**Abstract**

Diabetes is a chronic, life-threatening disease caused by failure of the body to produce sufficient insulin or to utilize it correctly to control blood glucose levels. Insulin is the main stay for treatment of virtually all IDDM and many NIDDM patients. More than 98% of the 30 million people in the world who self-administer insulin use syringes and pens. However, many are challenged to overcome the difficulties and social stigma associated with delivering mealtime insulin multiple times every day with these devices. As a result, many fail to adhere to their dosing regimen, which leads to complications due to poor glycaemic control, such as nerve damage, blindness, heart disease and kidney disease. Most patients want to eliminate the social embarrassment, elaborate preparation before each dose and the many daily needle sticks required by syringes and insulin pens. On the other hand in order for insulin to have a clinical effect; it must be administered in the amounts and at the times prescribed by the physician. Patients often find syringes, insulin pens and other insulin delivery devices inconvenient and socially challenging, making it difficult for them to take insulin when they should. In a recent study led by researchers at Loyola University Maryland, 20% of patients with diabetes admitted to regularly skipping doses of insulin, 60% admitted to occasionally skipping doses, and 33% admitted to feeling "dread" before dosing<sup>1</sup>. A number of new insulin delivery devices have been tried over the years to improve the ease, accuracy and glycaemic control with insulin. Some of them are Insulin syringes, Pen devices, Insulin pumps, Implantable pumps etc. The most promising amongst them is Finesse, a novel device, currently in development that combines the advantage of a patch, pump and an insulin pen. Finesse, is an insulin patch-pen designed to improve care for diabetic patients by simplifying insulin delivery, thereby improving patient adherence to their physician's treatment recommendations resulting in improved glycaemic control. In July 27, 2010, The US Food and Drug Administration (FDA) granted Calibra Medical, Inc, a private medical device company, based in Redwood City, California, clearance to market an insulin patch-pen (*Finesse*; Calibra Medical, Inc) for up to 3 days' use with rapid-acting insulin aspart.

**Key Words**

Bolus meal time doses, Calibra, Diabetes, Finesse, FDA, Insulin patch pen, Lispro,

**Introduction**

Diabetes or Diabetes Mellitus is a condition where a person's body is unable to regulate the glucose level in blood. These glucose levels are controlled by a hormone called insulin. The disturbance in the level of insulin leads to an increase in glucose levels in blood, resulting in Diabetes mellitus. Even though there are many different medications available for treating diabetes, Insulin is the primary medication used. The Diabetes Control and Complications Trials (American Diabetes Association 1993)<sup>2</sup> reveals that normalizing plasma glucose prevents many of the complications associated with diabetes. Here a mean blood glucose concentration of 2.8mmol/l in the intensely managed group had a substantial reduction in the occurrence and progression of retinopathy,

nephropathy and neuropathy over a period of 4-9 years. Amongst the various regimens of insulin, the commonest one for type 1 patients is a combination of short and intermediate acting insulin twice daily, before breakfast and before evening meal. Other intensified regimens employed for control of blood glucose include multiple daily injections or continuous subcutaneous infusion of soluble insulin through a pump. Most modern pumps provide a constant basal infusion of insulin and have the option of different infusion rates during the day and night to help avoid the dawn phenomenon and bolus injections as per the size and nature of a meal. In spite of all the above facts there is no well-documented advantages of pump therapy over other conventional regimens<sup>3</sup>. Moreover, cost, strict adherence to diet, exercise, care of device and cannula, risk of pump failure, infection at the site weighs a huge burden on the patient. Therefore, the

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search for new user friendly devices for insulin is still going on.

### **Insulin Patch Pen Device**

A "patch pen" is a device that adheres to the skin, contains insulin and can deliver the drug over a period of time, either transdermally, or via an integrated subcutaneous mini-catheter inserted discreetly and painlessly into the skin. These devices need to be reapplied on a frequent basis, such as every-three-days. It's like a cross between a pen and a patch. It is a small, plastic device designed to be worn on the skin like a bandage. Measuring roughly two inches long, one-inch wide and one-quarter inch thick it contains a mini reservoir of 200-unit of insulin aspart. The device delivers insulin through a tiny, flexible plastic tube (the cannula) which can be painlessly inserted into the skin after the device is filled. Usually applied over the anterior abdominal wall, It can be operated discreetly through a user's clothing by squeezing together two buttons on either side of the device at the same time, and the insulin is dispensed in one or two units. Depending on the requirement, it can provide mealtime, snack time, and correction bolus of insulin in seconds. From start to finish, delivery of each dose takes seconds to complete. Unlike syringes or insulin pens, no preparations are ever needed, it takes only a few seconds to dose, and no one will ever see. It is truly that simple! When the reservoir of insulin aspart is exhausted, usually in a 3- daytime, refilling of the device has to be done. For which one just has to insert a needle of a standard syringe (a regular 2cc or 3cc syringe) into the port and fill it, there is no necessity of a cartridge or anything. This patch is so designed to remain securely adhered to the body during daily activities like showering, exercising and sleeping. This innovative device dispenses rapid acting-insulin for up to three days and needs no batteries, electronics or infusion sets for its functioning. It can hold up to 200 units of insulin and can be used as a bolus-only device. That means that there is still the need to inject long-acting insulin's. But it could virtually eliminate injections at meals and snacks, which many people with type 1 are uncomfortable doing in social situations. Like expensive insulin pumps, Finesse provides fast, discreet, needle-free dosing with the simplicity, safety and affordability of

syringes or insulin pens, thereby justifying its name as insulin patch pen device.

### **Target User Groups**

It is targeted at both type 1 and type 2 patients of diabetes currently on insulin, as a much easier and more discrete way to deliver mealtime, snack, and correction boluses. It is much, much smaller than any other insulin devices. That's why a type 1 diabetic would prefer it which is a lot more convenient than a pen or syringe and vial over multiple daily injections, for sure, but not over a full-featured pump. The dosing is set differently for each group: 1 unit per squeeze of the buttons for type 1 patients, and 2 units per squeeze for type 2 patients.

### **Advantages**

With such a device people will find daily self-administration of multiple doses of insulin far easier, with less disruption and increased potential for better diabetic control, simplifying insulin delivery, thereby improving patient adherence to their physician's treatment recommendations. This combines the mealtime therapy-adherence benefits of insulin pumps with the simplicity and affordability of syringes and pens with its fast, discreet and needle-free dosing. Designed so, people with diabetes can now avoid the inconvenience and the occasional social challenges of daily mealtime injections with needles.

### **Disadvantages**

On the other hand, it does not deliver basal insulin at all. It is designed to deliver only bolus doses in set amounts when the sides of the patch are squeezed together. Thus it won't be a replacement for a pump. Furthermore, it does not have any of the advantages of a pump in terms of flexible basal delivery, extended bolus options, memory, small increment dosing, or bolus calculators. It can be used for short-term quick-acting insulin therapy, and does not replace the requirement for long-term basal insulin injections or basal pumped-in insulin. However, it may probably be more expensive than insulin pens.

### **Conclusions**

Over the last two decades, the evidence that better glycemic control i.e., keeping blood glucose and HbA1c levels as close to normal as possible reduces the rates of many complications of diabetes has

become overwhelming. As a result, diabetes specialists have expended increasing effort to help most people with diabetes to achieve blood glucose levels as close to normal as achievable with a traditional two or three injection regimen. Frequent glucose monitoring, attention to timing and amounts of meals is a standard care for most patients. Nevertheless, with such simple novel devices like insulin patch pen, one can live with small mismatches like having a snack before bed. Diabetics are now getting close to usable, affordable devices that can not only improve their quality of lives, but also reduce the long term medical costs of complications arising out of improper glycaemic control. However, the post marketing surveillance of such devices can only suggest their reliability.

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**The Device attached to Body**



**To Release the Insulin Press Buttons**



**The Insulin Patch Pen**

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