

Dialogue

Innovations in insulin pen devices: *The introduction of NovoRapid® FlexTouch® (insulin aspart)*

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I don't have diabetes. I do, however, carry out quite a few "dummy" injections on myself. All in the aid of education. I don't believe that we should be asking people with diabetes to self-inject without knowing what it feels like ourselves.

I also do finger-prick tests on myself during educational workshops. Have you tried it? If, like me, you have done both, I can guess which you find least comfortable. Finger pricking, probably because we have a lesser concentration of nerves in our abdomens than in our finger tips.

So, while noting that the injection is normally fairly easy and acceptable, how can we strive to make it more so?

Device advances

Long gone are the days when people with diabetes needed to use needles and syringes. Portable devices have revolutionised how insulin is delivered. The first pen on the market was the NovoPen®, launched way back in 1985. It has steadily been upgraded over the years and we are now on NovoPen® 4. The first disposable prefilled pen, NovoLet®, was introduced in 1989. It further simplified the injection process by eliminating the cartridge-loading step. In disposable devices, we now have the FlexPen® amongst others from other companies. But more innovations are taking place, including Novo Nordisk's most recent advance, the FlexTouch® pen.

This supplement was sponsored by Novo Nordisk.
The content was approved by the sponsoring
company and the author prior to publication.

www.novonordisk.co.uk

Prescribing information can be found on page 4.



Published by SB Communications Group on behalf of Novo Nordisk. For enquiries regarding distribution of Dialogue please contact Novo Nordisk Customer Care Centre on 0845 600 5055 (calls charged at local rate and may be monitored for training purposes)

The plunger: Much more than a trifling matter

It might, on first thought, seem a trifling matter that most pens rely on the user to depress a plunger, which in turn pushes down a rubber bung delivering the user's set dose of insulin. Unless the individual has poor manual dexterity, this should be easy enough, although the strength of the user is the only control over the force of the injection.

However, it is possible for the plunger not to be depressed fully – thus failing to deliver the full dose – without the user being aware of it. This is of significance to all insulin users, but is



The FlexTouch[®] pen uses a completely different, and unique, mechanism to deliver its insulin.



particularly important in older people, and those with impaired vision, arthritis, or poor coordination (Bohannon, 1999). Simplicity is what we want.

Benefits of FlexTouch[®]

The FlexTouch[®] pen uses a completely different, and unique, mechanism to deliver its insulin. Instead of relying on pressure

on the plunger, the FlexTouch[®] has a neat spring-loaded button which, when pressed, easily delivers the chosen dose. Simple! Not only that but it also gives an audible click to let the user know that the full dose has been administered, without the need to gaze down at the pen-dose window during the injection.

The FlexTouch[®] (demonstrated in *Animation 1*) has three features that particularly appeal to me:

- There is no push-button extension when the pen is dialled up, unlike with conventional pens, such as the FlexPen[®].
- There are audible clicks on turning the dose selector.
- There is the ability to turn back the dose selector without losing any insulin.

In addition, the device prevents the user choosing a dose that amounts to more than the contents of the device.

Studies have also shown that the FlexTouch[®] injections are accurate and consistent at minimum, half-maximum and maximum doses (Bailey and Campos, 2012).

NovoRapid[®] (insulin aspart) is now available in the FlexTouch[®] pen and, in common with other Novo Nordisk insulins, is colour coded to assist people with diabetes in ensuring that they get the correct insulin. This is especially useful in those using more than one insulin daily. The orange colouring of NovoRapid[®] is highly visible along the body of the pen and in the packaging, allowing ease of identification even when stored in the fridge. Other features that enhance its ease of use include a large window for viewing the chosen dose of insulin and an ability to dial up to 80 units in one go. I do acknowledge that many people using NovoRapid[®] insulin are unlikely to need to dial up 80 units for one injection, but in the future hopefully basal insulins will utilise the FlexTouch[®] pen. It will be a boon to those requiring higher doses.

Animation 1. A demonstration of the FlexTouch[®] pen's features.



I like the FlexTouch® for its ease of use and the simplicity with which it can be taught to people starting or progressing on insulin. I find that people with diabetes appreciate the simplicity of the action and the fact that they can just touch the delivery button with their thumb rather than having to extend it to reach the plunger. Currently, TREND-UK (Training, Research and Education for Nurses in Diabetes-UK) advises that a tip for making injections less painful is to use needles that are of shorter length and smaller diameter (TREND-UK, 2011). When FlexTouch® is combined with NovoTwist® needles the whole procedure becomes very slick indeed in terms of preparing the device.

But what do those who use it think? Recent studies have found that when a selection of people with diabetes and healthcare professionals were surveyed, approximately 80% of them preferred FlexTouch® over the SoloStar® and KwikPen™ disposable pens (Oyer et al, 2011; Bailey et al, 2011). The rationale for their preference was not investigated, but the people I see in practice identify the ease of use as an important benefit. Like the people I see, those responding to a questionnaire in the studies found that FlexTouch® gave more confidence in correct and complete insulin delivery and was easier to use than SoloStar® and KwikPen™ (Oyer et al, 2011; Bailey et al, 2011).

The importance of individual choice

We know that individual choice can be a key factor leading to better self-management of diabetes (Nair et al, 2007; Karter et al, 2010).

Choosing the device that suits the individual should be part of the consultation and be built into our education plans. ■

Bailey T, Campos C (2012) *Expert Rev Med Devices* [Epub ahead of print] doi: 10.1586/ERD.12.13
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SoloStar® is a registered trademark of Sanofi.
 KwikPen™ is a trademark of Eli Lilly and Company.

There are no basal insulins currently available for use with FlexTouch®

Study summary

Bailey T, Thurman J, Niemeyer M, Schmeisl G (2011) Usability and preference evaluation of a prefilled insulin pen with a novel injection mechanism by people with diabetes and healthcare professionals. *Curr Med Res Opin* 27: 2043–52

1 This was an open-label, multi-centre study in people with type 1 or type 2 diabetes and healthcare professionals. People with diabetes had to be ≥18 years of age and to have been taking oral antidiabetes agents for ≥2 years or using an insulin pen for >6 months. Healthcare professionals needed ≥2 years' experience in managing diabetes.

2 The study involved a single face-to-face interview of approximately 1 hour's duration in which FlexTouch® and KwikPen™ were tested by injecting into a foam cushion. Each participant was randomly assigned to start with either FlexTouch® or KwikPen™ and questionnaires were completed in a cross-over fashion.

3 Questions on ease of use and confidence were answered on a 5-point rating scale, while questions on preference could be answered as "test pen A", "test pen B" or "either/neither". The primary endpoint of the study was the overall preference for FlexTouch® versus KwikPen™.

4 A total of 160 individuals participated in the study, comprising 79 people with diabetes and 81 healthcare professionals (40 physicians and 41 nurses).

5 Overall, 86% (n=137) of respondents preferred FlexTouch®, whereas 7% preferred KwikPen™ (P<0.001 for difference). The majority of respondents (85% [n=136]) found FlexTouch® to be the easier pen to use; the corresponding value for KwikPen™ was 4% (P<0.001 for difference). A greater proportion of respondents would recommend FlexTouch® (88% [n=140]) than would recommend KwikPen™ (6%; P<0.001).

6 Ratings were also higher for FlexTouch® than KwikPen™ on questions regarding the injection process, including ease of injecting at three doses (20, 40 and 60 IU; P<0.001 for all). More respondents (73% [n=117]) chose FlexTouch® as the pen that gave them most confidence in correct and complete insulin delivery (compared with 6% for KwikPen™; P<0.001).

KwikPen™ is a trademark of Eli Lilly and Company.

Study summary

Oyer D, Narendran P, Qvist M et al (2011) Ease of use and preference of a new versus widely available prefilled insulin pen assessed by people with diabetes, physicians and nurses. *Expert Opin Drug Deliv* 8: 1259–69

1 This was an open-label, multi-centre study in people with type 1 or type 2 diabetes and healthcare professionals. People with diabetes had to be ≥ 18 years of age and to have been taking oral antidiabetes agents for ≥ 2 years or using an insulin pen for >6 months. Healthcare professionals needed ≥ 2 years' experience in managing diabetes.

2 The study involved a single interview of approximately 21 hour's duration in which FlexTouch[®] and SoloStar[®] were tested by injecting into a foam cushion. Each participant was randomly assigned to start with either FlexTouch[®] or SoloStar[®] and questionnaires were completed in a cross-over fashion.

3 Questions on ease of use and confidence were answered on a 5-point rating scale, while questions on preference could be answered as "test pen A", "test pen B" or "either/neither". The primary endpoint of the study was the overall preference for FlexTouch[®] versus SoloStar[®].

4 A total of 120 individuals participated in the study, comprising 59 people with diabetes and 61 healthcare professionals (30 physicians and 31 nurses).

5 A greater proportion of participants preferred to use FlexTouch[®] overall (83% [$n=99$]) rather than SoloStar[®] (10%; $P<0.001$ for difference). There were also greater proportions of respondents who chose FlexTouch[®] as the easier pen to use (83% [$n=100$], compared with 9% for SoloStar[®]; $P<0.001$) and who would recommend FlexTouch[®] (83% [$n=100$], compared with 8% for SoloStar[®]; $P<0.001$).

6 FlexTouch[®] was also rated more highly than SoloStar[®] on questions regarding the injection process, including ease of injecting at three doses (20, 40 and 80 IU; $P<0.001$ for all) and confidence in correct and complete insulin delivery ($P<0.001$).

SoloStar[®] is a trademark of Sanofi.

UK/NR/0512/0024a. Date of preparation: June 2012

NovoRapid[®] Insulin aspart.

NovoRapid[®] 10 ml vial
NovoRapid[®] Penfill[®]
NovoRapid[®] FlexPen[®]
NovoRapid[®] FlexTouch[®]

All presentations contain insulin aspart 100 U/ml

Prescribing information

All available in a strength of 100 U/ml; each device contains 3 ml. NovoRapid[®] FlexPen[®] and NovoRapid[®] FlexTouch[®] are disposable pre-filled pens able to deliver 1-60 units and 1-80 units respectively, in increments of 1 unit. NovoRapid[®] FlexPen[®], NovoRapid[®] FlexTouch[®] and Penfill[®] are colour coded.

Indication: Treatment of diabetes mellitus in adults and adolescents and children aged 2 to 17 years. **Posology and administration:** Individual by subcutaneous injection. It should normally be used in combination with intermediate or long-acting insulin given at least once a day. NovoRapid[®] has a faster onset and a shorter duration of action than soluble human insulin and should generally be given immediately before a meal. When necessary NovoRapid[®] can be given soon after a meal. Blood glucose monitoring and dose adjustments are recommended to achieve optimal glycaemic control. In elderly patients, patients with renal or hepatic impairment, glucose monitoring should be intensified and insulin aspart dosage adjusted on an individual basis. No studies in children under the age of 2 years; should only be used in this age group under careful medical supervision. Can be used in children in preference to soluble insulin when a fast onset of action might be beneficial. Transfer from other insulin products, may require adjustment of the NovoRapid[®] or basal dose. May also be used in a suitable pump system for continuous subcutaneous insulin infusion. If necessary may be administered intravenously by healthcare professional. Penfill[®] designed to be used with Novo Nordisk insulin delivery systems. Penfill[®] and FlexPen[®] are designed to be used with NovoFine[®] and NovoTwist[®] needles. **Contraindications:** Hypersensitivity to active substance or excipients. **Special warnings and precautions for use:** Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis, which is potentially lethal. Travelling between time zones may require change in the applied insulin regimen. Omission of a meal, unplanned strenuous physical exercise or too high a dose in relation to insulin requirements may lead to hypoglycaemia. Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia. Usual warning symptoms may disappear in patients with longstanding diabetes. If hypoglycaemia occurs, it may occur earlier after an injection compared with soluble human insulin. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. The fast onset of action should be considered in patients where a delayed absorption of food might be expected. Transferring to another type or brand of insulin should be done under strict medical supervision. Patients transferred to NovoRapid[®] from another type of insulin may require an increased number of daily injections or a change in dosage. Injection site reactions, usually transitory, may occur; rotation of injection sites within an area may help reduce or prevent these reactions. Rarely injection site reactions may require discontinuation of NovoRapid[®]. Hypoglycaemia may constitute a risk when driving or operating machinery. NovoRapid[®] must not be mixed with other medicinal products except for NPH (Neutral Protamine Hagedorn) insulin and some infusion fluids. Cases of cardiac failure were reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination of pioglitazone and NovoRapid[®] is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. **Fertility, pregnancy and lactation:** NovoRapid[®] can be used in pregnancy. No restrictions on use during breast-feeding. **Undesirable effects:** Very common ($\geq 1/10$); common ($\geq 1/100$ to $<1/10$); uncommon ($\geq 1/1,000$ to $\leq 1/100$); rare ($\geq 1/10,000$ to $\leq 1/1,000$); very rare ($\leq 1/10,000$), not known (cannot be estimated from the available data). Common: Hypoglycaemia; Uncommon: Refraction anomalies on instituting therapy, diabetic retinopathy with intensification may result in temporary worsening, lipodystrophy, oedema and urticaria, rash and eruptions, local hypersensitivity reactions which are usually transient and disappear during continued treatment; Rare: Peripheral neuropathy – acute painful neuropathy, usually reversible, may occur with rapid improvement in glycaemic control; Very rare: Anaphylactic reactions - Generalised hypersensitivity reactions are potentially life-threatening. The Summary of Product Characteristics should be consulted for a full list of side effects.

MA numbers:

NovoRapid [®] 10 ml vial	EU/1/99/119/001
NovoRapid [®] Penfill [®]	EU/1/99/119/003
NovoRapid [®] FlexPen [®]	EU/1/99/119/009
NovoRapid [®] FlexTouch [®]	EU/1/99/119/020

Legal category: POM.

Basic NHS price:

1 x 10 ml vial	£16.28
5 x 3 ml Penfill [®]	£28.31
5 x 3 ml FlexPen [®]	£30.60
5 x 3 ml FlexTouch [®]	£32.13

Full prescribing information can be obtained from:

Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.

Date created/last revised: March 2012

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.

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