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EXPERT OPINION

The importance of patient compliance with insulin pens: how can a new user-friendly pen help?

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FlexTouch® (FT) is a new prefilled insulin pen with the unique characteristic of no extendable push button at any dose setting and consequently a low activation force. Its technical features along with health care professionals' and patients' preferences in comparison to other traditionally used devices for insulin delivery have already been investigated. Recently, a study of injection force and accuracy using FT in the delivery of new basal insulin has compared FT with the insulin pens KwikPen® and SoloStar® and has shown that FT exhibits preciseness in insulin delivery of all insulin formulations and a significantly lower activation force than the other two insulin injectors. Despite the very promising characteristics of this new device, important questions remain to be answered, mainly the possible promotion of treatment adherence and the notion of confidence in self-administration of insulin. Moreover, an analysis of patients' perception on injecting higher doses with FT in comparison to other insulin injectors would be useful.

Keywords: compliance, devices, diabetes mellitus, insulin pens, treatment

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In 2011, 12% of adults with either type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) were using insulin [1]. To deliver the latter, a number of options are available, such as syringes, jet injectors, insulin pumps, artificial pancreas and, most importantly, insulin pens [2]. Syringes have the advantage of low cost, but they are larger, less easily portable and relatively cumbersome to use [1,2]. The advantage of jet injectors is the absence of needles, but they are complex to use and their precision in administering insulin dosage has been questioned [1,2]. The advantage of insulin pumps is that patients do not have to inject, while the main disadvantage is that they need to carry a device on their body all the time [1,2]. The artificial pancreas is for limited use by young well-trained type 1 diabetic patients. Insulin pens are by far the most widely used devices: they are easy to use, small and light enough to be easily portable, facilitating frequent insulin injections when appropriate.

Ideally, choice of the appropriate device for insulin administration should be discussed with the individual patient, in line with the modern patient-centred approach [3]. Relevant to this choice is also the fact that there may be diabetes-induced somatic limitations, such as impaired visual acuity [1], limited joint mobility in the hands, reduced motor dexterity and carpal tunnel syndrome [4]. In an endeavour to overcome such practical difficulties, new insulin pens are being launched, for instance the FlexTouch® (FT) (Novo Nordisk A/S, Bagsværd, Denmark), a prefilled insulin pen injector [5].

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All current available prefilled insulin pens are characterised by an extendable push button: the higher the insulin dose, the more pronounced this button extension. Consecutively, patients need to manually depress the button, in order to administer insulin [6]. FT is a new prefilled insulin pen with the unique characteristic of no extendable push button at any dose setting, which results in low activation force [7]. Insulin is delivered by a novel internal torque spring mechanism. The latter is loaded when the dose is set and is activated by pressing down the push button. As a result, determination of activation force depends on the push button spring and not on the thumb pressure of the user [6]. Other features of FT are the audible clicks heard after each adjustment and in the end of insulin administration, the clear dose display, as well as the different colours of each insulin type and a maximum 80 U dose [6,8]. Studies have already looked at technical features of FT [7] along with health care professionals' and patients' preferences [8,9], in comparison to other traditionally used devices. Compared to vial and syringe use by T1DM/T2DM patients, physicians and nurses, FT was preferred for insulin delivery and it emerged as easier to use, to hold steady, to depress the plunger and to read the dosing scale [8]. Confident use of FT was unchanged even at high doses, while it diminished with increasing doses for vial and syringes [8]. The vast majority of participants felt more confidence in glycaemic control with FT [8]. Moreover, the majority of physicians and all nurses preferred FT as a device to show to patients by virtue of its easiness to use and demonstrate [9].

Two more works have assessed perceptions of FT manipulation in comparison to KwikPen® (KP) (Eli Lilly & Co., Indianapolis, USA) and SoloStar® (SS) (Sanofi Aventis, Paris, France) among health care professionals and diabetic patients [10,11]. It was demonstrated that insulin was easier to inject with FT than with KP or SS, particularly at the maximum dose, and FT was rated by the majority as providing greater confidence in managing their daily insulin injections than the other pens [10,11]. Nonetheless, we need more information on factors influencing patient preferences, given that usability questionnaires in aforementioned studies did not provide this analysis [8,10]. When FT and Innolet® (Novo Nordisc A/S, Bagsværd, Denmark) were used by subjects with T1DM/T2DM, with/without visual or dexterity impairment, the vast majority preferred FT [12]. Indeed, this pen has consistently exhibited precision in delivery of insulin detemir and aspart [12-14]. Of particular note, this held true for all doses (minimum, midpoint and maximum) [13,14].

More recently, a study of injection force and the accuracy in the delivery of a new basal insulin using FT has been published in this journal [7]. In this work, FT was filled with three insulin formulations: insulin degludec 100 units of insulin per ml (U/ml), insulin degludec 200 U/ml and insulin degludec/insulin aspart 100 U/ml. This was compared to SS, which was filled with insulin glargine 100 U/ml and KP with insulin lispro mix 75/25 100 U/ml [7]. Outcome measures were accuracy and consistency in delivery of insulin dose, based on measurements of mean values and standard deviation [7]. For determination of dose accuracy, 30 pens of each type were used to deliver each dose (minimum, midpoint and maximum) twice for each experiment. To evaluate injection force, each pen provided 25 measurements for each dose level, which was set to maximum dose for each pen [7]. For FT, thanks to the torque spring mechanism, insulin dose delivered was independent of the speed at which the push button was compressed and the force at the activation point [7]. The inner diameter of all needles used was very similar, and all testing was conducted in accordance with ISO recommendations [7]. For FT, there was no difference in the delivery of all the three insulin formulations and at all three dosages. Insulin delivery was within ISO limits for all pens, except for some doses delivered by SS [7]. Injection force of FT did not differ between the three insulin formulations [7]. Importantly, mean injection force at all speeds of plunger decompression was significantly lower for FT, as compared with the other two insulin pens [7].

The strengths of this report are threefold. First, technical characteristics of FT were compared with those of other insulin pens; second, three insulin formulations and three dose levels were tested; third, experienced personnel and detailed analysis were employed [7]. Two limitations may apply. First, ISO guidelines were used, but these are designed to set a technical minimum for precision, which is not always reflective of accepted dosing accuracy in clinical practice, and second, examined parameters were assessed in an *in vitro* environment [7].

1. Conclusion

FT consistently delivers insulin degludec 100 units of insulin per ml (U/ml), insulin degludec 200 U/ml and insulin degludec/insulin aspart 100 U/ml at minimum, midpoint and maximum doses with precision, while it exhibits a significantly lower injection force than SS and KP [7]. Although important questions remain to be answered, this new insulin pen might facilitate insulin injections, promote compliance with insulin regimens and certainly merits further consideration in clinical practice.

2. Expert opinion

The major practical implication of the recent new study published in this journal is that FT retains dose accuracy and low injection force (lower than other commercially available insulin pens), independent of the insulin formulation delivered [6]. While low injection force may be appreciated by all patients who inject insulin, a number of issues await further clarification.

The first relates to the perception of handling FT when injecting higher doses, in comparison to other insulin injectors. Second, it would be extremely useful to know whether FT might prove more efficacious for use in public. Indeed, the absence of a push button extension might facilitate injection

in public places, thereby, possibly, reducing social stigma. Interestingly, social embarrassment has been identified as a risk factor for omission of insulin doses [1,5]. In this context, compliance with treatment is influenced by the device used. Indeed, it has already been shown that public use of vials and syringes was less probable than use of insulin pens [6]. Accordingly, easiness of use for FT might promote treatment adherence, although it is currently premature to assume this beneficial effect. However, it should be underlined that it has already been proven that insulin pens, compared to vials and syringes, promote patients' adherence to insulin regimens [1,2,5]. This is probably due to increased convenience and due to the pens' superior accuracy and consistency in insulin delivery, particularly at low doses. Of relevance, minimising variability of delivered dose is considered of great importance contributing to higher confidence in pen use [6].

Third, we should appreciate more fully the advantages provided by the absence of a push button for subjects with impaired manual dexterity, elderly subjects with diminished hand strength [4] and, perhaps, those with small hands or small thumb. In addition to the low injection force, the absence of extendable push button may facilitate injection by improving stability during the procedure and reducing the likelihood of injection-induced bruises. Of note, patients with inability to reach the extended push button may need to adopt an extreme angle position to administer insulin. However, this may increase injection force, rendering the pen less stable during injection and increasing the chance of bruises.

Furthermore, FT has been identified as easier to teach [9,10], and so a detailed analysis of any reduction in training time for health care professionals would be desirable. Last but not the least, FT is easier to learn, and an analysis of patients' confidence in self-injecting is highly welcome.

Overall, it is particularly patients with impaired hand dexterity, those who receive high insulin doses and those with lower treatment compliance who will, most probably, benefit from the aforementioned unique technical advantages of the FT. The authors believe that this new pen is in harmony with Hippocrates' advice that a physician should sometimes cure, often treat, but always relieve.

Declaration of interest

N Papanas has been an advisory board member of TrigoCare International; has participated in sponsored studies by Novo Nordisk and Novartis; has received honoraria as a speaker for Astra-Zeneca, Eli-Lilly, Novo Nordisk and Pfizer; and attended conferences sponsored by TrigoCare International, Novo Nordisk, Sanofi-Aventis and Pfizer.

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