

Expert Opinion

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Ease of use and preference of a new versus widely available prefilled insulin pen assessed by people with diabetes, physicians and nurses

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Objective: FlexTouch[®] (FT; Novo Nordisk A/S, Bagsvaerd, Denmark) is a new prefilled insulin pen that has no push-button extension and low injection force. This multi-centre, crossover usability study evaluated the perceptions of, and preference for, FT versus another widely used prefilled pen, SoloStar[®] (SS; Sanofi, Paris, France), by people with diabetes and healthcare professionals.

Research design and methods: Following instruction, participants performed injections into a foam cushion, randomly alternating between doses of 20, 40 and 80 international units (IU). Participants then answered questions on usability and preference.

Results: In all, 59 people with diabetes and 61 healthcare professionals (30 physicians and 31 nurses) took part. Overall, significantly more respondents preferred to use FT than SS (83 vs 10%, respectively), found FT easier to use (83 vs 9%) and would recommend FT to others (83 vs 8%; $p < 0.001$ for all). More respondents found it 'very/fairly easy' to reach the push-button and to inject 20, 40 and 80 IU with FT (93, 90 and 88% to inject, respectively) than with SS (73, 43 and 15% to inject, respectively; $p < 0.001$ for all). Most respondents chose FT as giving them the most confidence in correct and complete insulin delivery (76 vs 6%; $p < 0.001$) and considerably more were 'very/rather confident' in managing their daily insulin injections with FT than with SS (88 vs 58%).

Conclusions: Most participants rated FT as easier to use and to inject with, were more confident in its accuracy of insulin delivery and preferred it to SS.

Keywords: confidence, diabetes, insulin, preference, prefilled injection pen, usability

Expert Opin. Drug Deliv. (2011) 8(10):1259-1269

1. Introduction

Adhering to insulin treatment regimens for diabetes can be challenging and inconvenient, and many patients lack confidence in their ability to self-inject [1-4]. Patient participation in treatment choice is a key factor that leads to better disease management through greater adherence to treatment [5,6].

Insulin pens and pen needles, first introduced > 25 years ago [7], are continually being enhanced with features aimed at improving the injection experience and removing some of the barriers to good treatment adherence, such as needle anxiety and pain associated with injection, handling of cumbersome vial and syringe systems that are often indiscreet for use in public, and confidence in correct insulin delivery [4,5,8-18]. Insulin pens can contribute to diabetes patients leading more flexible and less restricted lives, which can improve quality of life [19,20]. Insulin pens have also been shown to provide more accurate delivery of insulin doses than vials and syringes [21-23], which

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in turn may improve glycaemic control. However, despite continued improvements in the design of insulin pens, some people with diabetes may still struggle with certain aspects of their use, such as the force required to depress the extended push-button when injecting (injection force).

Insulin pens can be durable (re-usable) or prefilled (disposable). FlexTouch® (FT; Novo Nordisk A/S, Bagsvaerd, Denmark) is a new prefilled insulin pen that was designed to improve ease of use and insulin administration by incorporating features such as a push-button that does not extend at any set dose and a unique spring-loaded mechanism, in which the injection is driven by a torque spring rather than the user's thumb pressure. The torque spring is loaded during dose-setting and the spring energy is activated by depressing the push-button. As a consequence, the injection force of FT is significantly lower than in other widely used prefilled pens [24]. Insulin pens with relatively low injection force have previously been rated as easier and more comfortable to use by people with diabetes [25], and this may be especially important for the many people with diabetes who suffer from reduced hand strength or impaired manual dexterity [13,26-28]. Technical data also show that FT provides accurate and consistent dosing at low, medium and high doses [29]. FT has colour-coded pens designed for easier identification of different insulin types and is designed to have a clearer dose display.

The purpose of this study was to evaluate user perceptions of, and preference for, FT versus the widely available prefilled pen SoloStar® (SS; Sanofi, Paris, France), both of which have a maximum dose of 80 international units (IU). Participants comprised people with diabetes, physicians and nurses. Healthcare professionals were included in the sample because their perceptions of the insulin pen may influence patient uptake of the pens [30,31].

2. Patients and methods

2.1 Study design and participants

This was a multi-centre, open-label, usability study in people with type 1 or 2 diabetes (out-patients) and in physicians and nurses who had a minimum of 2 years of experience in diabetes management. The test evaluated FT and SS in a crossover design. The test was managed, conducted and analysed by an independent clinical research organisation in June 2010. The test was conducted in the US, UK and Spain (at the participant's home, place of work or other suitable venue) in accordance with the Declaration of Helsinki Ethical Principles for Medical Research involving Human Subjects 2000, with amendments 2002, 2004 and 2008, and ISO/IEC 62366:2008, 'Medical Devices. Application of usability engineering to medical devices'. Necessary institutional review board approval was obtained for the research.

Participants were recruited via either healthcare professional databases, fieldwork agency databases, or via nurses and physicians and were pre-screened by telephone before the visit. The databases were independent of one another and the identity of all participants and their responses were confidential.

In line with good medical practice procedures, informed consent and confidentiality agreements regarding test products were obtained before any test-related activities were initiated.

2.2 Inclusion criteria

Male or female people with type 1 or 2 diabetes who were ≥ 18 years of age were eligible. Participants taking oral anti-diabetes agents for at least 2 years or using an insulin pen for > 6 months were suitable for inclusion. The study enrolled pen-experienced and pen-naïve patients in an approximate 1:1 ratio. No more than 50% of enrolled pen-experienced patients could be current SS or FlexPen® (FP; Novo Nordisk A/S) users. A minimum of 10% of people with diabetes were to be left-handed in order to represent the estimated 10% of the global population who are left-handed [32]; 25% were to have a body mass index $> 30 \text{ kg/m}^2$ and 25% were to have manual dexterity impairment (based on self-assessment) to represent the weight and dexterity issues that are often seen among people with diabetes. Healthcare professionals with a minimum of 2 years of experience in diabetes management were included. There was an approximate 1:1 ratio of physicians:nurses.

2.3 Exclusion criteria

People with diabetes who had mental or physical incapacity, or showed unwillingness to co-operate, or had language barriers precluding adequate understanding were excluded from the study. Individuals who had any disease or condition that might interfere with the test were also excluded. People with diabetes with any personal or family ties to a pharmaceutical or market research company and people who had previously tested FT were also ineligible.

2.4 Materials and procedures

Each participant was randomly assigned to start with either FT or SS (batch number 40C712) and then repeated the procedure described below with the other pen. Following instructions on how to operate the pen by a trained interviewer from the independent clinical research organisation, the participant performed several injections with the pen into a foam cushion, randomly alternating between doses of 20, 40 and 80 IU. Instruction manuals for the devices were available to the participants if required. NovoFine® 32G Tip extra thin wall 6 mm needles, which are compatible with all widely used insulin pens including SS [33], were used for all tests. Participants then answered written questions in relation to device handling and operation. Questions were based on the questionnaire used by Niskanen *et al.* [34]. Currently, there is no regulatory authority-validated questionnaire for assessing medical devices, and so the questions were devised to target the usability of, and preference for, the features of insulin pens known to be important to users.

After testing both pens, the participants answered written questions on preference. Questions on usability and

Table 1. Characteristics of respondents.

People with diabetes		n = 59
Variable		%
Type 1 diabetes		19
Type 2 diabetes		81
Male		39
Age		
< 25 years		5
25 – 34 years		3
35 – 44 years		7
45 – 54 years		27
55 – 64 years		31
≥ 65 years		27
Right handed		80
BMI > 30 kg/m ²		47
Manual dexterity impairment		39
Length of time taking insulin (± oral anti-diabetes drugs)		n = 30
Variable		%
< 2 years		23
2 – 3 years		13
4 – 6 years		20
7 – 9 years		3
10 – 15 years		17
16 – 20 years		7
> 20 years		17
Insulin pen used		n = 30
Variable		%
FlexPen [®]		50
SoloStar [®]		47
NovoPen [®]		10
HumaPen [®] /KwikPen [®]		10
OptiSet [®]		3
Healthcare professionals		
	Physicians (n = 30)	Nurses (n = 31)
Variable	%	%
Number of years treating/managing diabetes		
≤ 10 years	27	29
11 – 15 years	30	26
16 – 20 years	17	23
> 20 years	23	16
Right handed	87	97
Visual impairment	27	26
Hearing impairment	3	0
Injection devices that nurses train patients on		
SoloStar [®]		93
FlexPen [®]		90
HumaPen/KwikPen [®]		67
NovoPen [®]		53
InnoLet [®]		33
OptiClik [®]		33
AutoPen [®]		30
OptiPen [®]		13
PenMate [®]		13
OptiSet [®]		7

BMI: Body mass index.

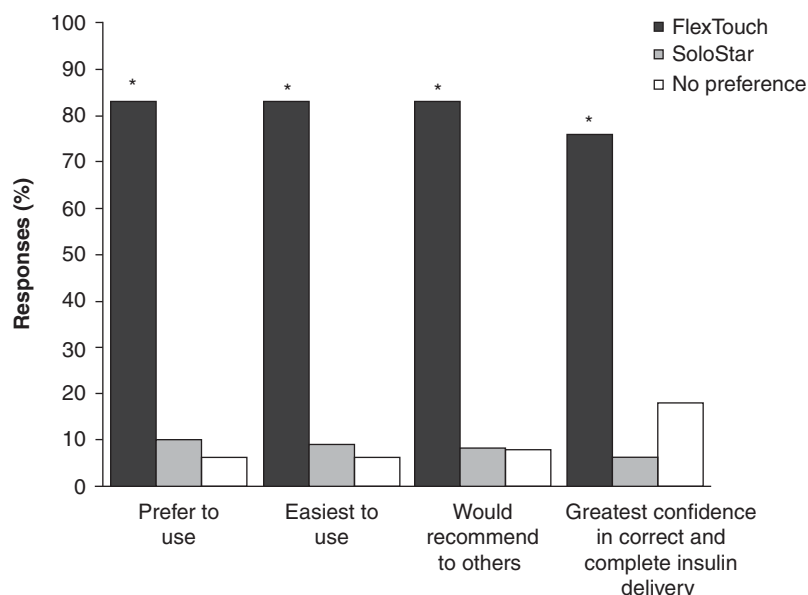


Figure 1. Overall preference, preference for ease of use, preference for recommendation, and confidence in correct and complete insulin delivery for FlexTouch versus SoloStar among respondents (n = 120).

*Significant difference ($p < 0.001$) between number of respondents choosing FlexTouch vs SoloStar.

confidence were answered on a 5-point rating scale (e.g., from 1 = very difficult to 5 = very easy). Questions on preference were answered as 'test pen A', 'test pen B' or 'either/neither'. The interview lasted ~ 60 min.

2.5 Statistical analysis

The primary end point of the study was the overall preference for FT versus SS, which was evaluated by a single question. This was tested by the use of a one-sample binomial test using an exact method. The null hypothesis was that the preference for FT was equal to 50%, against the hypothesis that it was different to 50%.

Secondary end points included perceptions of pen operation, which were assessed on a 5-point scale. The null hypothesis was that there was no difference in the ratings of answers between SS and FT, and this was tested by Wilcoxon signed rank (WSR) tests [35]. The frequencies of ratings in the two most favourable categories combined (the 'very' and 'fairly/rather' categories corresponding respectively to '5' and '4' on the rating scale) were of interest and these were compared between FT and SS. The frequencies of ratings in the best category (the 'very' category corresponding to '5' on the rating scale) were also of interest and were compared between the pens. Additional preference questions were also secondary end points, and these were analysed by the same method as the primary end point. A question concerning whether respondents experienced any problems using the pen (Yes/No) was analysed using McNemar's test [36].

For the preference questions, a sample size of 120 participants gave a power of 89% to show a difference by a

one-sample binomial test in preference for FT given the assumption that 65% of participants prefer FT. The statistical significance level used throughout the statistical analyses was 5%. Significance was calculated with adjustment for multiple testing (Bonferroni adjustment). All tests were conducted as two-sided tests. The statistical tests were performed using Proc Univariate in SAS.

3. Results

A total of 120 individuals took part in the study (Table 1), 59 people with diabetes and 61 healthcare professionals (30 physicians and 31 nurses). Of the people with diabetes, 30 had experience using insulin pens and, of these, 14 had experience using SS. The US sample comprised 60 participants (30 people with diabetes, 15 physicians and 15 nurses), the UK sample comprised 30 participants (14 people with diabetes, 7 physicians and 9 nurses) and the Spanish sample comprised 30 participants (15 people with diabetes, 8 physicians and 7 nurses).

3.1 Preference

The vast majority of people with diabetes and healthcare professionals (respondents) preferred to use FT overall ($n = 99$, 83%) rather than SS ($n = 12$, 10%). This difference was significant ($p < 0.001$ one-sample binomial test) and, therefore, the primary end point was met. Considerably more respondents chose FT ($n = 100$, 83%) as the easier to use than chose SS ($n = 11$, 9%), and considerably more would recommend FT ($n = 100$, 83%) to others than would recommend SS ($n = 10$, 8%), and these differences were

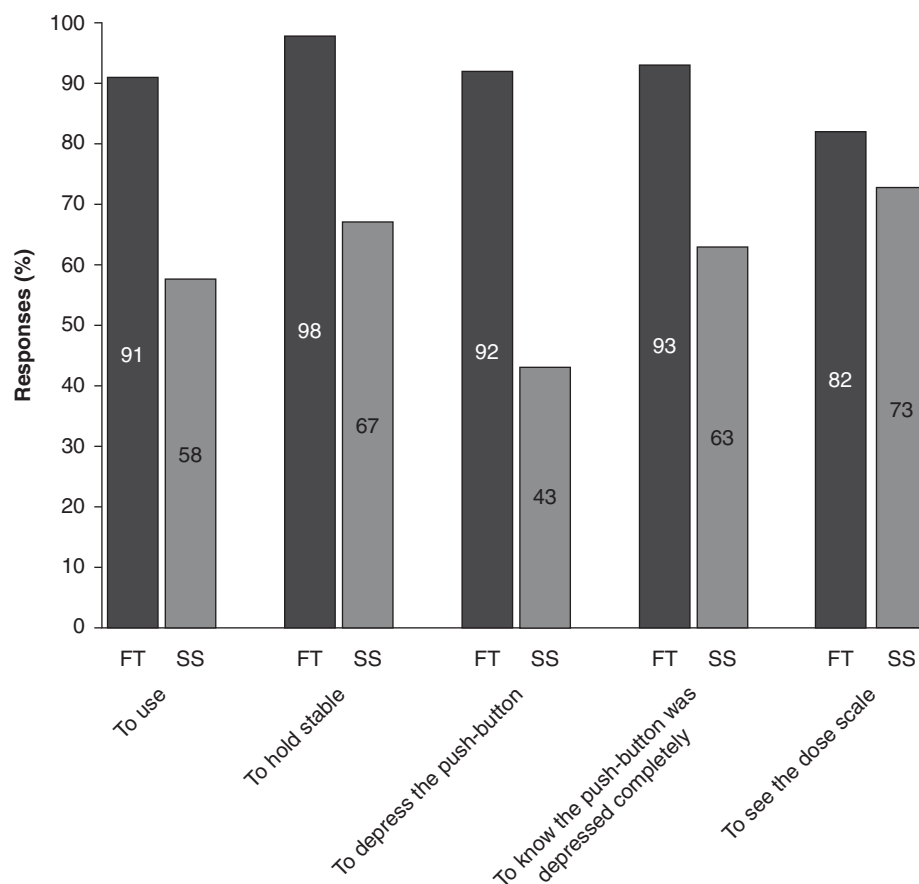


Figure 2. Percentage of respondents giving scores of 5 ('very easy') or 4 ('fairly easy') on the 5-point rating scale (the two most favourable answers combined), after handling FlexTouch and SoloStar (n = 120).

FT: FlexTouch; SS: SoloStar.

statistically significant (all $p < 0.001$ one-sample binomial test; Figure 1).

3.2 Ease of use

Scores on the 5-point scale for ease of use were significantly higher for FT than for SS ($p < 0.001$ WSR test) and substantially more respondents ($n = 109$, 91%) rated FT 'very easy' or 'fairly easy' to use compared with SS ($n = 70$, 58%; Figure 2). Similarly, FT scored significantly higher on the 5-point scale for ease of holding the pen stable when injecting than SS ($p < 0.001$ WSR test) and more respondents rated this aspect of the pen as 'very easy' or 'fairly easy' with FT ($n = 117$, 98%) than with SS ($n = 80$, 67%; Figure 2).

FT scored significantly higher than SS on the 5-point scale for ease of depressing the push-button and ease of knowing that the push-button was completely depressed ($p < 0.001$ for both, WSR tests). More respondents evaluated depressing the push-button as 'very easy' or 'fairly easy' with FT ($n = 110$, 92%) than with SS ($n = 51$, 43%; Figure 2), and 'knowing that the push-button was depressed completely' was rated as 'very easy' or 'fairly easy' by more respondents for FT ($n = 111$, 93%)

than for SS ($n = 75$, 63%; Figure 2). FT also scored significantly higher on the 5-point scale for ease of seeing the dose scale when injecting ($p < 0.001$, WSR test) and more respondents found it 'very easy' or 'fairly easy' to see the dose scale on FT ($n = 98$, 82%) than on SS ($n = 87$, 73%; Figure 2).

Ratings on the 5-point scale for FT were significantly higher than for SS for ease of identifying/differentiating between the type of insulin by looking at the cartridge holder ($p < 0.001$, WSR test), and the majority of respondents found this 'very easy' or 'fairly easy' with FT ($n = 101$, 84%) versus SS ($n = 51$, 43%). Similarly, ratings were significantly higher on the 5-point scale for FT than for SS for identifying the types of insulin during injection ($p < 0.001$, WSR test) and substantially more respondents found this 'very easy' or 'fairly easy' with FT ($n = 102$, 85%) than with SS ($n = 63$, 53%).

Questions relating to performing test injections at each of the three doses showed that considerably more respondents found it 'very easy' or 'fairly easy' to reach the push-button, depress the push-button and inject the dose, when injecting 20, 40 or 80 IU with FT than with SS (Figure 3). Similar observations were made for ratings of suitability of length of

Ease of use and preference of a new versus widely available prefilled insulin pen

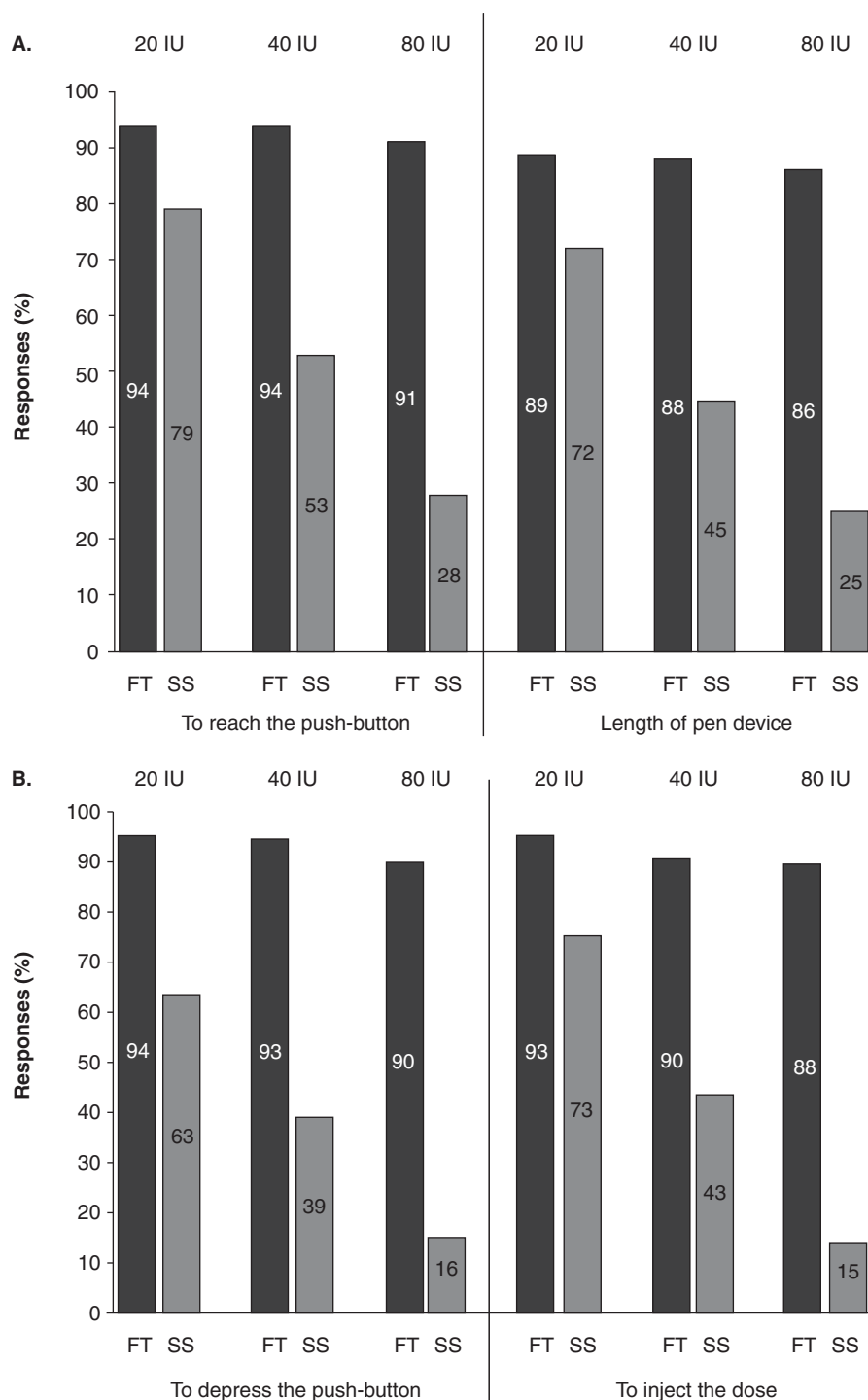


Figure 3. Percentage of respondents giving scores of 5 ('very easy/suitable') or 4 ('fairly easy/rather suitable') on the 5-point rating scale (the two most favourable answers combined), after performing test injections at three doses with FlexTouch and SoloStar (n = 120) for: **A)** ease of reaching the push-button and suitability of pen length and **B)** ease of depressing the push-button and injecting the dose.

FT: FlexTouch; IU: International units; SS: SoloStar.

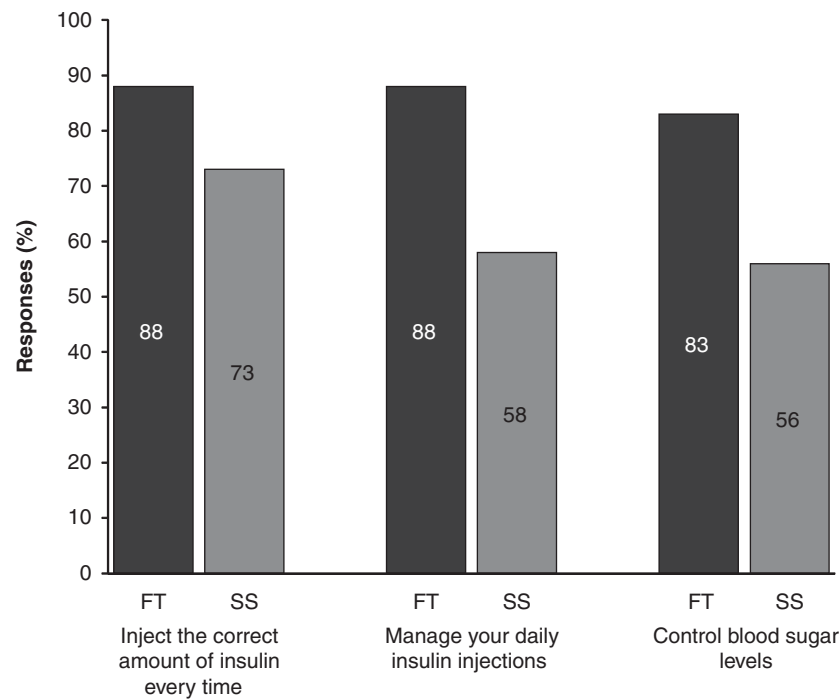


Figure 4. Percentage of respondents giving scores of 5 ('very confident') or 4 ('rather confident') on the 5-point rating scale (the two most favourable answers combined), after handling FlexTouch and SoloStar (n = 120).

FT: FlexTouch; SS: SoloStar.

delivery device at the three doses (Figure 3). FT scored significantly higher than SS on the 5-point scale for all four of these measures at each dose ($p < 0.001$ for all, WSR tests). The difference in positive responses for these questions was greater at higher doses than lower doses, due to large declines in positive ratings with SS as the dose set/delivered increased, but little change with FT (Figure 3).

Overall, 88% ($n = 105$) of respondents reported no problems when handling FT and 58% ($n = 69$) reported no problems when handling SS ($p < 0.001$, McNemar's test).

3.3 Confidence

Most respondents chose FT ($n = 91$, 76%) as the pen that gave them more confidence in correct and complete insulin delivery than SS ($n = 7$, 6%; $p < 0.001$, one-sample binomial test; Figure 1). In addition, many more respondents stated that they would be 'very confident' or 'rather confident' that they/their patient would inject the correct type of insulin if they were using different types of insulin (at different times of the day) using FT ($n = 102$, 85%) than using SS ($n = 67$, 56%). More respondents were also 'very confident' or 'rather confident' that they injected the correct amount of insulin every time with FT ($n = 105$, 88%) than with SS ($n = 88$, 73%; Figure 4) and more would be 'very confident' or 'rather

confident' that they/their patient could manage their daily insulin injections using FT ($n = 105$, 88%) than using SS ($n = 69$, 58%; Figure 4). Similarly, more respondents would be 'very confident' or 'rather confident' that they/their patient would control blood sugar levels using FT ($n = 100$, 83%) than using SS ($n = 67$, 56%; Figure 4). Ratings for FT were also significantly higher than for SS on the 5-point scale for these four measures ($p < 0.001$ for all, WSR tests).

The percentages of respondents giving the highest ratings (very easy/very suitable/very confident) for each question confirmed the pattern of results described above, and these are shown in Table 2. The results showed that many more respondents gave ratings of 'very easy', 'very suitable' or 'very confident' for FT than for SS.

4. Discussion

On a range of assessments relating to ease of use and confidence, FT was rated significantly higher than SS. A significantly greater proportion of respondents also preferred FT overall, for ease of use and confidence in correct insulin delivery, and significantly more would recommend it to others. The patients in this study who showed a preference for FT included pen-naïve patients, pen-experienced patients and manual dexterity impaired patients and,

Table 2. Percentage of respondents giving scores of '5' (very easy/very confident/very suitable) for FlexTouch and SoloStar for each pen operation (n = 120).

Pen operation	Score of 5 ('very')	
	FlexTouch	SoloStar
<i>Easy</i>		
Using the pen	67%	19%
Seeing the dose scale when injecting	58%	31%
Identifying/differentiating the insulin type using cartridge holder	58%	19%
Identifying the insulin type during injection	58%	24%
Holding the pen stable when injecting	74%	23%
Depressing the push-button	73%	11%
Knowing if the push-button has been completely depressed	70%	29%
Depressing the push-button when injecting 20 IU	82%	26%
Depressing the push-button when injecting 40 IU	76%	8%
Depressing the push-button when injecting 80 IU	64%	5%
Injecting the dose of 20 IU	77%	30%
Injecting the dose of 40 IU	76%	12%
Injecting the dose of 80 IU	63%	3%
Reaching the push-button when injecting the dose of 20 IU	78%	40%
Reaching the push-button when injecting the dose of 40 IU	77%	25%
Reaching the push-button when injecting the dose of 80 IU	70%	13%
<i>Suitable</i>		
Length of the pen device when injecting 20 IU	73%	38%
Length of the pen device when injecting 40 IU	73%	22%
Length of the pen device when injecting 80 IU	70%	15%
<i>Confident</i>		
Injecting the correct amount of insulin every time	62%	44%
Managing your daily insulin injections using this pen	60%	30%
Controlling your blood sugar levels using this pen	53%	25%
Using different types of insulin at different times of the day and injecting the correct type	59%	28%

IU: International unit.

therefore, included the range of patients who may typically use insulin pens to inject insulin. The findings of this study are particularly impressive given that 47% of the patients who had previously injected insulin were already users of SS and nearly all the nurses in this study regularly trained patients on the use of SS.

FT is currently the only prefilled insulin pen with no push-button extension at any set dose. In this usability study, actions such as reaching the push-button, injecting and depressing the push-button while injecting 20, 40 or 80 IU were judged by participants to be easier to perform with FT than with SS. The length of FT was also rated more suitable than SS when injecting at the three doses. With SS, the proportion of people rating these actions or attributes as 'very/fairly easy' or 'very/rather suitable' dropped substantially when the delivered dose increased from 20 to 40 IU and from 40 to 80 IU. In contrast, the ratings remained relatively constant with FT at all doses. The findings for SS suggest that typically, users of insulin

pens with push-button extension find them more difficult to use as the set/delivered dose of insulin is increased. The lack of push-button extension on FT may also make the pen easier to hold stable while injecting as users do not need to stretch their thumb so far in order to reach the push-button. This should be of value to users, particularly those who have manual dexterity impairment, weak hand strength (as seen in the elderly) or smaller hands (as seen in young people with diabetes). The difficulty of using pens with push-button extension, such as SS, at higher doses may also add to the psychosocial barrier of injecting high doses of insulin [37]: FT may overcome this barrier, as perceptions of ease of injecting higher doses were only slightly lower than perceptions of injecting low doses of insulin.

There was a large difference between the number of participants who chose FT (76%) and the number who chose SS (6%) as the pen that gave them the most overall confidence, and participants had more confidence in FT

for the correct and complete delivery of insulin with every injection. While the clinical implications of these findings can only be speculated, increased confidence and preference for FT could improve patient trust and have important implications for adherence across all patient groups. The findings here also show that participants were more confident in their/their patient's ability to identify/differentiate the insulin type from the cartridge using FT than SS. This is at odds with recent suggestions from a market research study, of greater confidence in identifying insulin types with SS compared with FP [38], a prefilled insulin pen that uses similar labelling to FT. However, in that study, participants were not asked to simulate a real-life injection, which would include removal of the pen cap and make the colour-coded cartridge holders on FP more apparent. This may have further improved participants' ability to correctly identify the insulin type. Fewer problems while using the pen were also reported with FT (88% reported no problems) than with SS (58% reported no problems) in the current study. This question did not relate to pen malfunctions (none were reported), but was a general question relating to problems of usage, and the better perceptions of FT may further enhance confidence in the device and potentially patients' ability to manage their diabetes.

A limitation of this usability study is that the questionnaires used did not assess the factors that influence preference. Further analyses of the data using multivariate regression analysis may prove useful in determining the impact that specific attributes of FT had on user preference. In addition, further analyses of these results among particular subgroups of participants (such as among pen-experienced versus pen-naïve patients, or among the elderly) may help further elucidate the features of this prefilled pen that appeal to different patients. The validity of any questionnaire-based usability study for everyday clinical use can only be speculated, but the diverse nature of the population assessed here would suggest that a wide range of people with diabetes and healthcare professionals may share similar perceptions of the insulin pens.

5. Conclusions

People with diabetes and healthcare professionals rated FT as easier to use and as instilling more confidence than SS. Participants also preferred FT to SS. The features of FT include a push-button that does not extend at any set dose and a low injection force due to a unique spring-loaded mechanism for dose delivery. These features, among other attributes of FT, could potentially enhance the insulin injection experience and decrease the treatment burden for a wide range of people with diabetes.

Acknowledgements

The authors thank R Rubin and M Peyrot for their input into the outline of this manuscript.

Declaration of interest

This study and the preparation of this article were funded by Novo Nordisk A/S (Bagsvaerd, Denmark). D Oyer has received compensation for speaking from Advanced Health Media, Astra-Zeneca, Eli Lilly and Co., Forest Pharmaceuticals, Inc. (a subsidiary of Forest Laboratories, Inc.), KnowledgePoint360 Group, Medicus Resource Group, Inc., Meetings and Events International, Merck & Co., Inc., Novo Nordisk A/S, PamLab (Pan American Laboratories), SCS Healthcare Marketing, Inc., Sanofi-Aventis US LLC, and Young & Rubicam, Inc. D Oyer has received compensation for advisory board consultation from Novo Nordisk A/S. D Nadeau is on the speaker bureau for Novo Nordisk, Inc., Eli Lilly, Abbott, and Warner Chilcott, Inc. and has been on an advisory board for Novo Nordisk, Inc. P Narendran has received compensation for advisory board consultation from Novo Nordisk A/S, and support for attendance at scientific meetings from Sanofi-Aventis. M Qvist and M Niemeyer are employees of Novo Nordisk A/S. Editorial support for this article was provided by J Clarke and N Meinel of ESP Bioscience (Crowthorne, UK), funded by Novo Nordisk A/S. The study was managed and performed, and the data analysed, by Aequus Research (London, UK), funded by Novo Nordisk A/S.

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