Comparison of Usability and Patient Preference for the New Disposable Insulin Device SoloStar Versus FlexPen, Lilly Disposable Pen, and a Prototype Pen: An Open-Label Study

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ABSTRACT

Background: Patients with diabetes have been found to have a preference for insulin pens over a vial and syringe since these devices offer improvements in compliance, freedom, and flexibility.

Objective: This study assessed the usability, specific pen features, and patient preference for 4 prefilled, disposable, insulin pens: SoloStar®, Humulin®/Humalog® pen (Lilly pen), FlexPen®, and a fourth, prototype pen, Pen X, in patients with type 1 or 2 diabetes. In 1-hour interviews, patients carried out simulated use (preparing the pens, setting a dose, and injecting into a receptacle, not the body) under observation, and answered qualitative and quantitative questions. Patients were supplied with the relevant user manual. The usability (ability and time taken to carry out handling tasks) and preference (based on 14 key pen features and overall preference) of each pen were assessed without blinding for pen make/manufacturer. During the interviews, the patients prepared each pen and performed injections into a receptacle. Comparisons were made between the pens at every step. Subgroup analyses of the usability exercises were carried out based on age (11–15 years; ≥60 years), previous pen experience, and disability (visual and dexterity).

Results: In total, 510 diabetes patients (65% type 2 diabetes; 51% female; mean age, 43 years [range, 11–82 years]) from 4 countries (United States, Germany, France, and Japan) completed the study. Overall, a greater proportion of patients correctly prepared the pen and performed an injection into a receptacle with SoloStar versus all comparator pens ($P < 0.05$). Similar findings were observed in the usability subgroup analyses based on age, previous pen experience, and visual/dexterity disabilities. A significantly ($P < 0.05$) higher proportion of patients expressed overall preference for SoloStar (53%) versus FlexPen (31%) or Lilly pen (15%).

Conclusion: Of the 4 pens compared, both the SoloStar pen and FlexPen were found to have high patient usability, and the new SoloStar pen was found to have high patient preference in these patients with diabetes. (*Clin Ther*. 2007;29:650–660) Copyright © 2007 Excerpta Medica, Inc.

Key words: Insulin device, diabetes, SoloStar®, FlexPen®, Humulin®/Humalog® pen.

INTRODUCTION

It is well established that improvements in long-term glycemic control can reduce the incidence and delay the progression of diabetic complications.[1,2] Patients with type 1 diabetes require insulin from diagnosis. Patients with type 2 diabetes initially benefit from lifestyle intervention programs, for example diet and exercise,[3–5] but oral antidiabetic agents (OADs) and insulin therapy are usually required over time.[6]

It is becoming increasingly apparent that patients with type 2 diabetes benefit from the addition of insulin to their therapeutic regimen with OADs.[7–10] However, for many patients fear of injections, the inconvenience of a vial and syringe, and social acceptability can present barriers to the initiation of insulin.[11]

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Insulin pens have the potential to overcome many of the barriers to insulin initiation. Compared with a vial and syringe, insulin pens offer substantial improvements in compliance, freedom, and flexibility for all insulin-using patients.[11–13] Studies have reported a preference for pen devices versus a vial and syringe.[14,15] In addition, pens may provide more accurate dosing, which could improve blood glucose control and long-term outcomes,[12,13] and may also be associated with increased adherence and reduced therapy costs.[16]

Prefilled, disposable pens have the advantage of simplicity, with minimal training required, as patients are not required to install a new cartridge when the pen is empty. However, prefilled, disposable pens may be associated with ecological issues and cost implications.

This paper presents the results of a series of qualitative, quantitative, face-to-face interviews, during which patients with type 1 or 2 diabetes carried out simulated use exercises (injections were performed into a receptacle, not the body) under observation and answered questions about the usability and preference for a new 3.0-mL, prefilled, disposable insulin pen (SoloStar®*) compared with 2 currently available pens (FlexPen®† and Humulin®/Humalog®‡ pen [hereafter referred to as Lilly Disposable pen]) and a fourth, prototype pen (Pen X§). Pen X was an alternative pen concept that was in development but was subsequently discontinued based on various technical and user feedback data, including the results of this study. Hence, the discussion of the results presented in this paper focuses on SoloStar, the Lilly Disposable pen, and the FlexPen.

This study was carried out as part of the development program for SoloStar, which is used to deliver insulin glargine and insulin glulisine.

The objectives of this study were to assess the usability (based on simulated use), specific pen features, and patient preference of 4 disposable pens—SoloStar, FlexPen, Lilly Disposable pen, and a prototype pen, Pen X. The key features of the 4 pens are summarized in **Table I.**

PATIENTS AND METHODS

Patients

Patients with type 1 or 2 diabetes (duration, ≥2 years) were included in the study on a quota basis: insulin-naive patients with type 2 diabetes receiving OADs (quota: 50% of participants); and insulin-experienced patients with type 1 or 2 diabetes receiving insulin (quota: 50% of participants) via reusable or disposable pen. For the participants in the US arm of the study, of those using insulin, 50% were to be pen users and the remaining 50% were to be vial and syringe users. Patients' age range was set at 11 to 85 years, with an equal distribution of males and females and concomitant conditions. The study included cohorts of diabetes patients with dexterity problems and visual impairments, with quotas of 25 patients per country with dexterity problems (typically caused by rheumatoid arthritis or neuropathy) and 25 patients per country with visual impairment (typically partial blindness due to cataracts, macular degeneration, or glaucoma). Patients with hearing impairment and color blindness were also included. Impairment was determined by direct questioning of respondents during the screening phase.

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Table I. Comparison of the technical features of insulin pens.

Feature	SoloStar*	FlexPen†	Lilly Disposable‡	Pen X§
Dimensions (L × D), mm	163 × 15.5	158 × 15.5	158 × 17.5	164 × 15.9
Weight, g	25.7	24.1	30.1	29.5
Maximum single dose, U	80	60	60	80

L = length; D = diameter.
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Written informed-consent forms for participating in the study were completed by all patients. All respondents signed a confidentiality agreement before taking part in the study.

Study Design

The study was conducted in November 2004 at 24 centers in the United States (10 centers), France (5), Germany (5), and Japan (4). The study consisted of qualitative, quantitative, face-to-face 1-hour interviews with diabetes patients, carried out by independent moderators from a research agency. The research agency developed the questionnaires with input from the sponsor.

The study was divided into 2 major sections, which are described below.

Part 1: Usability

Respondents were asked to prepare each pen (SoloStar, FlexPen, Lilly Disposable pen, and Pen X) to perform injections into a receptacle. To avoid "practice bias," the order of pen use was rotated using a Latin-squares design (4 versions) to balance first placement of each pen and the number of times it followed each of the other pens. Participants were not blinded to the make/manufacturer of the pens, as pen users would most likely be able to recognize their pen according to shape and color. This was also necessary as patients were asked to compare and rank the 4 devices overall and according to specific features.

In an attempt to replicate use in clinical practice, a user's manual was present for each pen; however, respondents were not required to use this. The moderators recorded the extent to which the respondents correctly completed each individual task, plus the extent to which all tasks were completed correctly in sequence (without any assistance). Moderators did not provide assistance throughout the study but, at its conclusion, examined the pens to ensure the pens were working correctly. The independent moderators did not provide any training or guidance for the use of pens; participants were asked to rely on prior knowledge, intuition, and the relevant user manual for each pen.

The usability section consisted of the following sequential tasks:

- Getting started and removing the cap;
- Attaching a needle;
- Setting (including activation of the dose knob with the Lilly Disposable pen) and delivering a safety dose; and
- Dialing a 40-U dose and delivering that dose

Time to completion was recorded for the following groups:

- Total sample;
- Subgroup by age (11–15 years and ≥60 years);
- Subgroup by current therapy (insulin users versus OAD users [insulin naive]);
- Subgroup by previous pen use; and
- Subgroup by disability status

The second section of the study was introduced once the usability section had been completed, and is described below.

Part 2: Preference

Part 2 consisted of the preference assessment. Respondents evaluated 14 key features for each pen on a 5-point scale (1 = poor to 5 = excellent). Respondents were then asked to choose which pen was the best, second best, third, and fourth for each of those features. Again, a Latin-squares design (4 versions) was used to balance first placement of each pen and the number of times it followed each other pen, to avoid practice bias. The respondents were requested to rank the injection force of each pen by injecting 40 U into a receptacle; this task was completed for each pen in a random order. So that the respondents did not have to recall the injection force from a prior exercise, pens were injected one after another for a true comparative assessment. To conclude the interview, respondents were asked to take everything into consideration and rank the pens in order based on their overall pen preference.

Statistical Analyses

Comparisons were made between the pens at every step. Statistical tests (ie, 2-, 3- or 4-way χ^2 analysis) were performed as appropriate, with a significance level of $\alpha = 5\%$ at a power of 80%. Analyses were conducted for exploratory purposes and were not adjusted for multiple comparisons.

RESULTS

Patients

A total of 510 patients with diabetes were included in the study, 150 from the US and 120 each from

Germany, France, and Japan. Of these, 176 (35%) had type 1 diabetes and 334 (65%) had type 2 diabetes. There was an equal distribution of female (260 [51%]) and male (250 [49%]) patients, the mean age of whom was 43 years (range, 11–82 years). The mean duration of diabetes was 10 years (range, 2–54 years); 159 (31%) patients had hypertension and 137 (27%) had high cholesterol levels.

At baseline, patients were identified by questionnaire as having the following disabilities: visual impairment (98 [19%] patients); manual dexterity impairment (81 [16%]); hearing impairment (39 [8%]); and color blindness (26 [5%]).

Patient characteristics according to treatment experience at baseline are summarized in **Table II.** Of the 278 patients who used insulin, 232 (84%) were currently using or had previously used insulin pens: 47 (17%) were currently using or previously used the FlexPen and 83 (30%) were currently using or previously used the Lilly Disposable pen. A total of 209 (75%) patients used pens other than those included in this study, of whom 57 (21%) were currently using or previously used the OptiPen® (sanofi-aventis).

Part 1: Usability Assessment

The results for the usability assessment are reported for the correct completion of all steps without the safety step or attach needle step (as these were deemed independent of the device). In the overall group, a greater proportion of patients correctly completed the steps (without the safety step or attach-needle step) with SoloStar versus all comparator pens ($P < 0.05$)

Table II. Baseline demographic and clinical characteristics of the study patients.

Characteristic	OADs Only (n = 232)	Insulin Users (n = 278)
Age, mean (range), y	55 (19–82)	33 (11–80)
Sex, no. (%)		
Female	121 (52)	139 (50)
Male	111 (48)	139 (50)
Current diabetes regimen, no. (%)*		
OADs only	232 (100)	0
Insulin only	0	242 (87)
Insulin + OADs	0	36 (13)
Type of pen (ever used), no. (%)*†		
Disposable only	0	75 (27)
Reusable only	0	92 (33)
Both	0	50 (18)
Total pen use, no. (%)*	0	232 (83)
No pen used, no. (%)*	232 (100)	51 (18)
Previous experience with study pens (ever used), no. (%)*		
FlexPen‡	0	47 (17)
Lilly Disposable§	0	83 (30)
Other	0	209 (75)

OADs = oral antidiabetic drugs.
*Percentage value corresponds to proportion within treatment group.
†Four percent (n = 10) of respondents could not recall the correct name of the pen they had previously used; as such, their pen use could not be classified.
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and with FlexPen versus the Lilly Disposable pen and Pen X ($P < 0.05$) (**Figure 1A**). However, although statistically significant, the clinical relevance of a difference between SoloStar (482 [94%]) and FlexPen (457 [90%]) remains to be established. In the overall group, results including the safety step or attach-needle step found the same trend for each pen but had lower successful completion rates (**Figure 1B**), although this was expected from clinical experience, in which patients frequently omit safety tests.

The results according to age, pen use, and dexterity subgroups are shown in **Figure 2**. SoloStar and FlexPen were comparable and both pens were more usable than the Lilly Disposable or Pen X in patient groups aged ≥60 years or 11 to 15 years. In general, the younger age groups performed the steps more successfully than the older patients (**Figure 2A**), although there was a tendency for more patients in both age groups to successfully complete the steps with SoloStar and FlexPen compared with the Lilly Disposable pen or Pen X.

For pen-experienced patients, a significantly greater proportion of patients correctly completed the steps with SoloStar and FlexPen compared with the other 2 pens ($P < 0.05$) (**Figure 2B**). Significantly more insulin-naive patients correctly completed all steps with SoloStar compared with FlexPen, Lilly Disposable pen, and Pen X ($P < 0.05$ for SoloStar vs the other 3 pens) (**Figure 2C**). Overall, for the pen-experienced patients, more were able to complete the steps correctly with SoloStar and FlexPen than with the Lilly Disposable pen (**Figure 2D**). For the Lilly Disposable pen, patients who had experience with this pen were more likely to complete all of the steps than patients who had experience with either FlexPen or OptiPen.

There were no differences between dexterity- and visually impaired patients with any pen; the proportion of patients correctly completing the steps tended to be higher with SoloStar and FlexPen users compared with the Lilly Disposable pen and Pen X (**Figure 2E**).

Part 2: Preference

Pen-Feature Comparison

The evaluation of pen-feature comparisons is shown in **Table III**. Of the 4 attributes relating to the pens' design and esthetics, the SoloStar pen was rated as best significantly more often versus all other pens for tactile feel ($P < 0.05$), while the Lilly Disposable pen performed better for the "how well the cap fits the pen" question ($P < 0.05$). Of the 10 attributes relating to the pens' usability, the SoloStar pen was rated as best more frequently for 7 attributes (all, $P < 0.05$), and the Lilly Disposable pen was rated as best

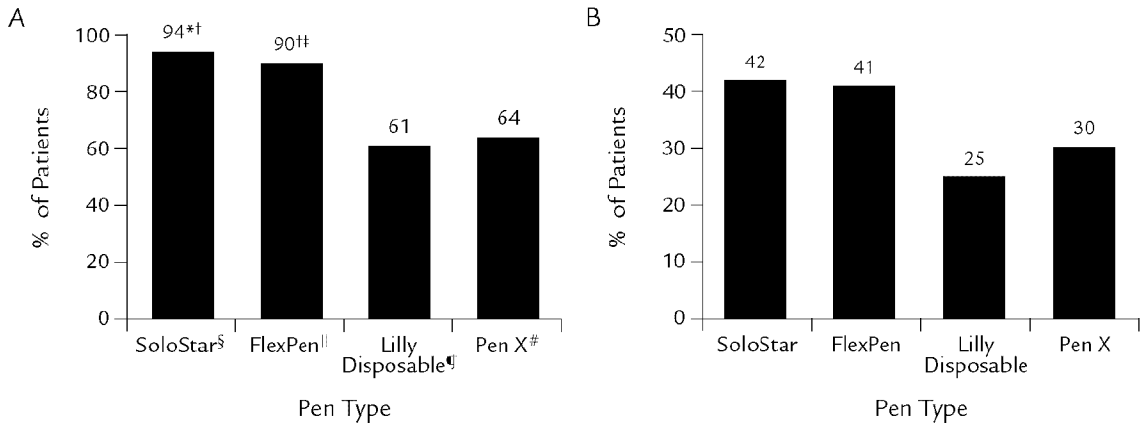

Figure 1. The proportion of patients completing: (A) steps not including the safety step or attach-needle step and (B) all steps including safety step or attach-needle step using SoloStar, FlexPen, Lilly Disposable pen, and Pen X in the total study population. *$P < 0.05$ versus FlexPen; †$P < 0.05$ versus Pen X; ‡$P < 0.05$ versus Lilly Disposable pen; §Trademark of sanofi-aventis, Paris, France; ‖Trademark of Novo Nordisk A/S, Bagsvaerd, Denmark; ¶Trademark of Eli Lilly and Company, Indianapolis, Indiana; #Produced by sanofi-aventis. (All P values were calculated without adjustment for multiple comparisons.)

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