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COMMENTARY

United States Patient Preference and Usability for the New Disposable Insulin Device Solostar® versus Other Disposable Pens

Jerome S. Fischer, M.D.,[1] Steven V. Edelman, M.D.,[2] and Sherwyn L. Schwartz, M.D., P.A.[1]

Abstract

The uptake of insulin pen use has been slow in the United States, despite their advantages over the vial/syringe. We present results of a United States subset of 150 patients with type 1/type 2 diabetes, who were enrolled in an open-label study, that assessed usability, pen features, and patient preferences for four prefilled insulin pens: SoloSTAR®, FlexPen®, Lilly disposable pen, and a prototype, Pen X. Overall, the SoloSTAR and FlexPen were more user-friendly; 95 and 88% of patients, respectively, completed the steps correctly (without safety/attach-needle step—deemed independent of device) versus the Lilly disposable pen (60%) and Pen X (61%; all $p < 0.05$). The SoloSTAR was rated highest most frequently for pen feature comparisons. Results suggest that the SoloSTAR and FlexPen could potentially facilitate insulin use in the United States.

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Commentary

In the United States, the prevalence of diabetes has been estimated at 7% of the population (20.8 million individuals) and the majority have type 2 diabetes mellitus (T2DM).[1]

Insulin pens have the potential to enhance initiation and acceptance of insulin use among patients with diabetes. Compared with vial and syringes, insulin pens offer substantial improvements in compliance, freedom, and flexibility for all insulin-using patients.[2] Insulin pens may also provide more accurate dosing, which could improve blood glucose control and long-term outcomes,[3] along with increased adherence and reduced therapy costs.[4] Furthermore, compared with vial and syringes, a clear preference for pen devices has been shown[5–7]; in addition, prefilled, disposable insulin pens offer the advantage of simplicity, require minimal training, and do not necessitate the installation of new cartridges. Insulin pens may also provide greater protection from the heat and light, with fewer units of insulin being exposed to the environment compared with a vial and syringe. Despite these advantages, the uptake of insulin pen devices in the United States has been slow.[8]

A recent multinational trial involving 510 patients in France, Germany, Japan, and the United States, investigated patient acceptability of a new 3.0-ml prefilled, disposable insulin pen [SoloSTAR® (sanofi-aventis, Paris, France)]

Author Affiliations: [1]Diabetes and Glandular Disease Research Associates, Inc., San Antonio, Texas, and [2]University of California, San Diego Veterans Affairs Medical Center, San Diego, California

Abbreviations: (OAD) oral antidiabetic drug, (SD) standard deviation, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

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Corresponding Author: Sherwyn L. Schwartz, M.D., P.A., Diabetes and Glandular Disease Research Associates, Inc., 5107 Medical Drive, San Antonio, TX 78229-4801; email address slschwartz@dgdclinic.com

compared with two currently available prefilled pens [Novolog® FlexPen® (Novo Nordisk A/S, Bagsvaerd, Denmark) and Lilly disposable pen (Eli Lilly and Company, Indianapolis, IN)] and a prototype-prefilled pen (Pen X) in patients with type 1 diabetes mellitus (T1DM) or T2DM.[9] Pen X was an alternative pen concept that was in development, but was subsequently discontinued based on technical and user feedback, including the results of this study. The study was conducted as part of the sanofi-aventis development program for SoloSTAR, which is used to deliver insulin glargine (LANTUS®; sanofi-aventis, Paris, France) and insulin glulisine (Apidra®; sanofi-aventis, Paris, France). This article presents results from the United States subset of patients enrolled in this study, which assessed the usability, specific pen features, and patient preferences for the SoloSTAR, FlexPen, Lilly disposable pen, and Pen X.

Patients with T1DM/T2DM (duration ≥2 years) were included in the study: insulin-naive patients with T2DM receiving oral antidiabetic drugs (OADs) and insulin-experienced patients with T1DM/T2DM receiving insulin via a reusable or disposable pen, or a vial and syringe. Patients were aged between 11 and 85 years with a similar distribution of males and females. The study also included cohorts of patients with diabetes with dexterity problems and visual impairments.

The trial consisted of qualitative, quantitative, face-to-face, 1-hour interviews conducted in patients with diabetes, which were carried out by independent moderators, as described in more detail elsewhere.[9] Respondents were asked to prepare each pen (SoloSTAR, FlexPen, Lilly disposable pen, and Pen X) for injection and inject into a receptacle; independent moderators recorded the extent to which the respondents completed each step correctly. A user's manual was present for each pen; however, respondents were not required to use this; this was to mimic everyday practice, in that the patient was able to choose if he/she wanted to read the manual. Moderators did not provide assistance or training throughout the study and no other training materials were made available. Respondents were not blinded to the make/manufacturer of the pens, but were not informed of who sponsored the study. All respondents provided written, informed consent and signed a confidentiality agreement before taking part in the study. Respondents were recruited locally using research databases at each study site.

The study was divided into two sections; the first section examined the usability of the pens with the following steps: getting started and removing the cap; attaching a needle; activating the dose-knob setting; setting and delivering a safety dose; dialing a 40-unit dose; and delivering that dose. Subanalyses were also performed for the following groups of patients: age (11–15 years and ≥60 years), current therapy (insulin users versus OAD users), previous pen use, and self-reported disability status (visual disorders not fully corrected by glasses; any problems with manual dexterity). The second section consisted of a competitive assessment and respondents evaluated 14 key features (**Table 1**) using a five-point scale. Respondents were asked to rank the pens in order based on their overall pen preference. For both sections, a Latin-square design (four versions) was used to balance the order in which pens were given to the patients. Significance testing among the pens was conducted by two-, three-, and four-way χ^2 analysis on the patient population as a whole; no significance testing was performed on the subanalysis groups, such as elderly patients or patients with manual or visual impairments.

Of the 510 patients included in the study, 150 were from the United States (across 10 centers), of whom 45% had T1DM and 55% had T2DM. There was an equal distribution of male (47%) and female (53%) patients, the mean [standard deviation (SD)] age was 42 (21) years, and the mean (SD) duration of diabetes was 10 (9) years. Regarding the usability assessment, in the overall group, a greater proportion of patients completed the steps correctly (without the safety step or attach-needle step, which were deemed independent of the device) with the SoloSTAR (95%; $p < 0.05$) and FlexPen (88%; $p < 0.05$) versus both the Lilly disposable pen (60%) and Pen X (61%).

In the subanalysis of patients aged ≥60 years ($n = 41$), the SoloSTAR and FlexPen demonstrated similar usability (proportion of patients completing the steps correctly without the safety or attach-needle step), with a trend for greater usability with the SoloSTAR (98% vs 83%, respectively), and greater usability versus the Lilly disposable pen (46%) or Pen X (44%). In patients aged 11–15 years ($n = 35$), a similar trend was observed (SoloSTAR: 97%; FlexPen: 89%; Lilly disposable pen: 63%; Pen X: 66%). With regard to younger patients, the lower insulin doses used typically in children are measured more easily with pen devices.[3] The fact that the majority of older and younger patients in our study completed the steps correctly with both the SoloSTAR and the FlexPen suggests that these difficult-to-treat age groups would benefit from either device in terms of increased accuracy of insulin dosing. Furthermore, the ease of use of these insulin pens could reduce the social impact and the many challenges of diabetes in young patients.[3]

In diabetes patients with visual impairments [n = 27; including glaucoma (8), cataracts (6), retinopathy (6), macular degeneration (4), another reason (4)] or dexterity impairments (n = 22; including neuropathy (7), rheumatoid arthritis (4), osteoarthritis (4), another reason (9)], the proportion of patients completing the assessed steps again correctly demonstrated a trend similar to that observed in the other subgroups: SoloSTAR: 96 and 91%; FlexPen: 85 and 77%; Lilly disposable pen: 52 and 46%; and Pen X: 48 and 46%; for visual and dexterity impairment, respectively. The fact that the vast majority of both visually and dexterity-impaired patients were able to complete all steps correctly using the SoloSTAR and FlexPen is important; self-management can prove difficult and, as such, injection devices with easily readable dose scales and easy-to-handle dose selectors are preferred for those patients in whom coordination or vision is compromised.

As expected, pen-experienced patients found all pens easier to operate compared with pen-naive patients, with the SoloSTAR (98% vs 89%, respectively) and FlexPen (93% vs 82%, respectively) being very usable in both groups.

SoloSTAR was rated "best" most frequently by the patients for pen feature comparisons, including 3 out of 4 attributes relating to the design and esthetics of the pen and 9 out of 10 attributes relating to the usability of the pen (**Table 1**).

Regarding injection performance, the SoloSTAR was preferred by a significantly greater number of patients as their first choice (65%) compared with the other pens assessed (FlexPen: 15%; Lilly disposable pen: 15%; Pen X: 5%; $p < 0.05$). A significantly higher proportion of patients expressed an overall preference for the SoloSTAR (55%) versus the FlexPen (28%; $p < 0.05$) and the Lilly disposable pen (17%; $p < 0.05$).

The results of this study, obtained in patients from the United States, demonstrate that, as observed in the multinational trial,[9] the SoloSTAR and FlexPen were associated with comparable usability. Importantly, the findings also demonstrate the suitability of both the SoloSTAR and the FlexPen in a wide range of patients with diabetes, including both elderly and younger patients and those with visual and dexterity impairments. Of note, if reading of the pen user manual had been mandatory, the percentage of patients completing the steps correctly may have been different; however, lack of providing training and allowing patients to choose whether or not to read the manual was to stimulate real life.

Table 1.
Evaluation of Four Prefilled Insulin Pen Devices by Patients with Type 1 or Type 2 Diabetes Mellitus[a]

Evaluation of pen features: percentage of time rated as "best"	SoloSTAR® A	FlexPen® B	Lilly[b] C	Pen X D
Design/esthetics				
Exterior design and styling	41[C,D]	34[D]	25	13
Size and portability	47[C,D]	36[D]	28	15
How well the cap fits onto the pen	45[D]	35	49[D]	23
Tactile feel	47[B,C,D]	23	13	22
Usability				
Easy/intuitive to figure out	60[B,C,D]	25	18	11
Easy to set dose	57[B,C,D]	26	15	16
Easy to read that you have set the exact dose	48[B,C,D]	23	21	19
Easy to correct dose if overdialed	55[B,C,D]	31[C]	20	24
Auditory feedback	40[C,D]	39[C,D]	12	15
Requires low numbers of turns to set 40 units	46[B,D]	27	32[D]	12
How far the dose button sticks out (40 units)	39[B,D]	19	47[B,D]	9
Effort it takes to inject 40 units	63[B,C,D]	17	17	3
Easy to determine the entire dose delivery	55[B,C,D]	27	27	15
Easy to determine the amount left in the cartridge	49[B,D]	26	35	19

[a] Pen feature comparison: percentage of time that the pens were rated as "best" by patients using the SoloSTAR, FlexPen, Lilly disposable pen, and Pen X (n = 150). Letters denote statistical significance versus the corresponding letter, at $p < 0.05$. Respondents selected the one pen they considered "best" on each attribute. Row percentages may add to >100%, as some respondents could not select one pen as "best," but instead opted for "ties."
[b] Lilly disposable pen.

Given that the obstacles of initiation of insulin therapy include the fear of self-injection[2] and that, compared with a vial and syringe, a clear preference for pens has been shown across all age groups,[5–7] advances in diabetes therapy should be aimed at providing diabetes patients with the most efficient, convenient, and adaptable treatment. Accordingly, a well-accepted insulin device will likely improve compliance and, consequently, result in better adherence to treatment,[4] improved glycemic control, and a reduced risk of long-term diabetes-associated complications,[3,8] in addition to reducing therapy costs.[4] Acceptance of, and adherence to, insulin

treatment regimens is more likely to occur if pen devices are easy to use and offer effective delivery of insulin with minimal discomfort.[6] In many patients, particularly those who have visual and/or dexterity impairments[7] or are young[10,11] or elderly,[7,12,13] insulin devices have been demonstrated to improve the accuracy of insulin administration and adherence compared with the vial and syringe. In the elderly population, who are very susceptible to the debilitating effects of hypoglycemia,[14,15] along with the greater prevalence of comorbidities, such as visual and/or manual disorders,[7,12,13] making insulin administration easier and simpler will likely promote self-care in this population, as advocated by the American Diabetes Association.[16]

Overall, our findings provide evidence that the SoloSTAR was preferred by more patients in this study and that the SoloSTAR and FlexPen are particularly user-friendly and acceptable prefilled insulin pen devices that offer promising alternatives to the vial and syringe for the initiation and administration of insulin in the treatment of diabetes in the United States. Further studies comparing the SoloSTAR with other commercially available pens on the market, such as the Humalog KwikPen™, would be of interest.

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