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ORIGINAL ARTICLE

A Pan-European and Canadian Prospective Survey to Evaluate Patient Satisfaction with the SoloSTAR Insulin Injection Device in Type 1 and Type 2 Diabetes

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Abstract

Objective:

This study evaluated patient satisfaction with SoloSTAR® (sanofi-aventis), a prefilled insulin pen device for injection of insulin glargine or insulin glulisine.

Methods:

This was a 6–8-week multicenter (n = 652), observational, prospective Pan-European and Canadian registry study in patients with diabetes mellitus (n = 6542) who recently switched to or started treatment with insulin glargine and/or insulin glulisine using SoloSTAR or were insulin naïve. At the baseline visit, patients were asked to evaluate their satisfaction with their previous device, if applicable. After 6–8 weeks of SoloSTAR use, patients were asked to rate their satisfaction.

Results:

Overall, 6481 patients (mean age 54 years, 48.7% male, 72% type 2 diabetes) were analyzed in this study. Of these, 4995 (77.1%) patients had used insulin before the study and 1641 (32.9%) and 3395 (68.0%) patients had previously used prefilled and/or reusable pens, respectively. During the study, SoloSTAR was used to administer insulin glargine and/or insulin glulisine by 97.3% and 36.0% of patients, respectively (both: 27.0%). Most patients rated SoloSTAR as "excellent/good" for ease of use (97.9%), learning to use (98.3%), selecting the dose (97.6%), and reading the dose (95.1%). Most patients rated ease of use (88.4%) and injecting a dose (84.5%) with SoloSTAR as "much easier/easier" versus their previous pen. Overall, 98% planned to continue using SoloSTAR. No safety concerns were reported.

Conclusion:

This European and Canadian survey shows that SoloSTAR was well accepted in this large patient population. Most patients preferred SoloSTAR to their previous pen and planned to continue SoloSTAR use.

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Abbreviations: (SD) standard deviation, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus, (TEAE) treatment-emergent adverse event

Keywords: European, insulin glargine, insulin glulisine, insulin pen device, patient satisfaction, SoloSTAR

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Introduction

Insulin pen devices are generally perceived by patients as being more convenient, flexible, and socially acceptable methods for administering insulin compared with traditional vial and syringe systems.[1–4] As a result, prefilled and disposable pens are now the predominant method for injecting insulin in many countries among patients with type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM). Nevertheless, the use of the vial and syringe still prevails in countries such as Brazil, India, and the United States[5] due, in part, to the perceived cost of using insulin pens relative to the vial and syringe. This is despite evidence showing that the overall treatment costs incurred by patients using insulin pens are lower than in those who use the vial and syringe, as a consequence of the lower rate of hypoglycemia associated with insulin pen use[3,6] and the higher rates of adherence to treatment that are achieved with insulin pens.[7]

In addition to the perceived convenience, flexibility, and social acceptability, insulin pens are able to accurately administer the required doses of insulin, as demonstrated in studies performed by trained research staff and by patients after receiving appropriate training for the device.[8–12] However, there are some additional features that could further improve these devices for patients. Practical aspects of insulin injection pen devices for people with diabetes include the ability to hear and feel clicks when dialing a dose, easy dialing and delivery, ease of performing safety tests, and overall ease of use and cartridge replacement in reusable pens. Specific features that may be attractive to pen users include insulin pens with higher maximum doses to reduce the need for split-dose injections (most pens have a dose limit of 60 U), reduced injection force and dial extension, and improved device differentiation, since most of the existing devices have little scope for differentiating between the different types of insulin to be injected, aside from the product label. Both reduced manual dexterity and visual impairments are common in people with diabetes, with up to 58% of people with diabetes having limited hand joint mobility[13] and 16 million people with diabetes in the United States predicted to have diabetic retinopathy by 2050.[14] In the United States, retinopathy accounts for approximately half of all cases of visual impairment among people with diabetes older than 50 years.[15] Visual impairment in people with diabetes is also frequently associated with other advanced age-related conditions, including macular degeneration, glaucoma, and cataracts.[16]

SoloSTAR® is a novel insulin device approved for the administration of the long-acting insulin, insulin glargine (LANTUS®), or the rapid-acting insulin, insulin glulisine (Apidra®), all manufactured by sanofi-aventis for the treatment of T1DM or T2DM. SoloSTAR offers a higher maximum dose than many of the other insulin pens already available (80 U) and offers product differentiation by the use of different body colors for insulin glargine and insulin glulisine. This should be beneficial for patients with T1DM who are likely to use a basal and a bolus insulin as well as for the increasing number of patients with T2DM who are on basal–bolus regimens. Previous studies have demonstrated the dose accuracy,[10,11] low injection force,[8] and patient preference for SoloSTAR versus other prefilled insulin pen devices.[17] The clinical acceptance of SoloSTAR with insulin glargine has been examined in an observational survey in Australia,[18] showing that health care professionals consider it easy to educate people with diabetes on the use of the pen and consider the pen easy for people with diabetes to use. However, the clinical acceptance and patient satisfaction with SoloSTAR using insulin glargine and/or insulin glulisine have been examined only in Australian patients with diabetes,[19] not yet in European or North American patients. Therefore, in this study, the authors investigated acceptance and patient satisfaction with SoloSTAR in Canada and 12 European countries.

Methods

Study Objectives

The objective of this study was to investigate patient satisfaction with SoloSTAR in people using insulin glargine and/or insulin glulisine in everyday clinical practice.

Study Design

This was a 6–8-week, multinational (Austria, Canada, Denmark, Greece, Hungary, Latvia, The Netherlands, Poland, Romania, Slovenia, Slovakia, Sweden, and the United Kingdom), multicenter (n = 645), open, prospective, observational product/device registry study performed between January 14, 2008, and April 4, 2009. The study was performed in accordance with the principles and all subsequent amendments of the declaration of Helsinki, in compliance with the guidelines for good

epidemiological practice and in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.[20] All patients provided informed consent to participate in the study.

Study Population

Patients with T1DM or T2DM aged >18 years were enrolled. Subjects were eligible if they were current insulin users with prior disposable or reusable pen experience, or were insulin-naïve subjects on oral medications who were considered by their health care provider to be candidates for starting injectable insulin therapy. Exclusion criteria were current addiction to or abuse of alcohol and/or drugs, diagnosis of dementia, severe visual or dexterity impairment, or a mental condition rendering subjects unable to understand the nature, scope, and possible consequences of the study. Also excluded from the study were subjects who were considered to be uncooperative by the investigators and unlikely either to comply with the study or to reply honestly to the questionnaire or who had a concomitant disease or concomitant medication that may have interfered with their ability to participate in the study.

Study Protocol

The study consisted of two visits. At the initial registry visit (visit 1), patients were switched to, or started on, insulin therapy with LANTUS SoloSTAR for insulin glargine and/or Apidra SoloSTAR for insulin glulisine. For regulatory reasons, patients in Greece and Romania could be treated with SoloSTAR for no more than 15 days before the study to be considered eligible. All patients in Sweden were to be using SoloSTAR before inclusion. All treatment decisions were made in accordance with local clinical practice, and it was entirely at the physician's discretion whether to use insulin glargine, insulin glulisine, or both.

At visit 1, patients completed a questionnaire surveying their prior experience with insulin pens, if applicable, and their demographic and clinical characteristics were also assessed. After 6–8 weeks of SoloSTAR use as part of everyday clinical practice, patients completed a second questionnaire (visit 2) to document their experience and determine their acceptance of SoloSTAR. For patients who used an insulin pen before inclusion, acceptance of SoloSTAR was compared to the pen used before the study. In addition, the following information was collected: person who gave the insulin injection; use of other insulin pen before SoloSTAR; type of insulin currently used; number of injection devices currently used; start of SoloSTAR use the day patient received the supply; if patient did not start using SoloSTAR the day he or she received it, number of days after; whether patient was still using SoloSTAR; if patient was not still using SoloSTAR, number of days since he/she stopped; number of SoloSTAR pens used; disability or other restrictions; frequency of use of a new needle; frequency of safety test; brand of needles with SoloSTAR; face-to-face training on the use of SoloSTAR; confidence in the use of the pen after the training; and number of days to be confident in the use of SoloSTAR.

Treatment-emergent adverse events (TEAEs), possibly related TEAEs, and serious TEAEs were analyzed. Treatment-emergent adverse events are adverse events beginning between the first use of the SoloSTAR pen and the last use of SoloSTAR pen plus 7 days for SoloSTAR with insulin glargine and plus 2 days for SoloSTAR with insulin glulisine. For patients who were treated with SoloSTAR before inclusion in the study, TEAEs were counted from date of inclusion.

Study End Points

The primary end point was patient evaluation of the SoloSTAR pen. The following items (answered with excellent, good, acceptable, poor, or very poor) were described to evaluate the SoloSTAR pen: ease of selecting the dose; ease of correcting a misdialed dose; ease of reading the insulin dose; ease of feeling and hearing dialing clicks; force or effort needed to inject insulin; smoothness or gentleness of injection; ease of knowing that injection was completed or desired dose was delivered; ease of reading how much insulin remained in the cartridge; ease of differentiating the LANTUS SoloSTAR from the Apidra SoloSTAR, for patients using both; ease of learning how to use SoloSTAR; ease of use of SoloSTAR in general; overall assessment of SoloSTAR pen; plan to continue to use SoloSTAR (yes or no); and whether the patient would recommend SoloSTAR (yes or no).

Secondary end points were acceptance of individual pen features; insulin daily dose injected; number of daily injections; confidence in managing the pen or condition; occurrence of pen defects spontaneously reported by users; satisfaction with the previous pen, if appropriate, and comparison between SoloSTAR and the previous pen; and adverse events, including hypoglycemia (adverse events were recorded and coded using MedDRA version 8).

Statistical Analysis

There was no formal sample size calculation for this observational study; however, the authors planned to recruit approximately 6900 patients across 645 centers distributed in 13 countries. The primary outcomes were evaluated using chi-squared tests for the overall population and for subgroups of patients according to age, diabetes type, prior history of using insulin and insulin pens, and whether the patient performed safety tests. Logistic regression was also performed to identify factors predicting satisfaction with SoloSTAR. Secondary outcomes and adverse events were assessed using appropriate summary statistics, with means ± standard deviation (SD) for continuous variables and *n* (%) for categorical variables. Factors recorded by questionnaire at visits 1 and 2 were analyzed by McNemar's test to evaluate change in these factors over the course of using the SoloSTAR pen.

Results

Baseline Characteristics

A total of 6542 patients were enrolled in this registry (6528 eligible; 14 excluded owing to missing age or that they did not have T1DM or T2DM). Of these, 6364 were included in the assessment of patient satisfaction and 6481 were included in the safety population (**Figure 1**): mean ± SD age of 54.3 ± 14.5 years, 48.7% were male, and 72.0% had T2DM. Overall, 164 patients were excluded from the patient satisfaction population for the following reasons: no insulin injections with SoloSTAR (*n* = 47),

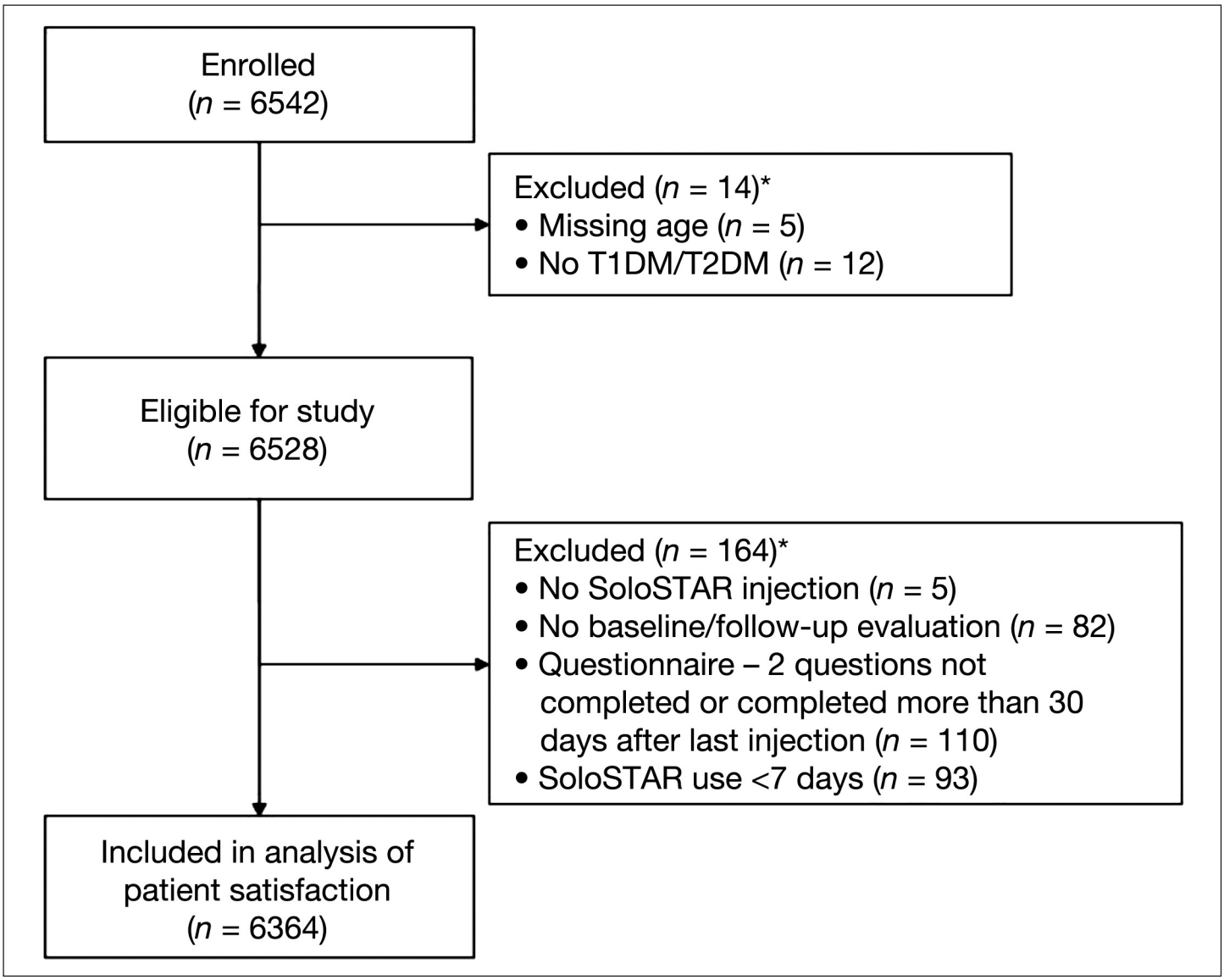

Figure 1. Participant disposition. The safety population (*n* = 6481) included all eligible patients excluding those who did not inject SoloSTAR (*n* = 47). *Patients may have more than one reason for exclusion.

nonparticipation at baseline or follow-up (n = 82), or follow-up questionnaire was missing or completed more than 30 days after the last injection (n = 110; patients were allowed more than one reason for exclusion). The characteristics of the eligible patients are shown in **Table 1**.

Prior Insulin Treatment

Most patients (77.1%) had previously received insulin (**Table 1**), and the majority were using basal or rapid-acting insulin, with similar proportions of patients using analog or human insulins; doses of insulin prior to the study are presented in **Table 1**. The majority of patients

Table 1.
Baseline Characteristics and Prior Insulin Therapy[a]

Characteristic	T1DM	T2DM	Total population
N	1817	4664	6481
Age (years)	40.4 ± 13.8	59.7 ± 10.6	54.3 ± 14.5
18–35	715 (39.4)	65 (1.4)	780 (12.0)
35–60	939 (51.7)	2458 (52.7)	3397 (52.4)
60–70	136 (7.5)	1383 (29.7)	1519 (23.4)
70–80	22 (1.2)	656 (14.1)	678 (10.5)
>80	5 (0.3)	102 (2.2)	107 (1.7)
Sex			
Male	948 (52.2)	2209 (47.4)	3157 (48.7)
Female	869 (47.8)	2455 (52.6)	3324 (51.3)
Weight (kg)	73.8 ± 15.2	86.8 ± 17.4	83.1 ± 17.8
Height (cm)	171.0 ± 9.4	168.4 ± 9.0	169.1 ± 9.2
Body mass index (kg/m^2)	25.2 ± 4.5	30.6 ± 5.6	29.1 ± 5.9
<25	1014 (56.2)	677 (14.7)	1691 (26.3)
25–30	570 (31.6)	1673 (36.2)	2243 (34.9)
≥30	219 (12.1)	2270 (49.1)	2489 (38.8)
Prior insulin therapy			
Yes	1736 (95.5)	3259 (69.9)	4995 (77.1)
Prior analog insulin (U)			
Basal insulin	26 ± 13 (n = 909)	36 ± 23 (n = 1160)	31 ± 20 (n = 2069)
Rapid-acting insulin	29 ± 13 (n = 1113)	37 ± 21 (n = 952)	33 ± 17 (n = 2065)
Premixed insulin	40 ± 21 (n = 79)	53 ± 31 (n = 291)	50 ± 30 (n = 370)
Prior human insulin (U)			
Basal insulin	25 ± 13 (n = 671)	30 ± 19 (n = 1412)	29 ± 17 (n = 2083)
Rapid-acting insulin	29 ± 15 (n = 493)	37 ± 19 (n = 933)	34 ± 18 (n = 1426)
Premixed insulin	33 ± 16 (n = 93)	47 ± 23 (n = 279)	43 ± 22 (n = 372)
Use of an insulin pen before inclusion[b]			
Yes	1717 (98.9)	3092 (94.9)	4809 (96.3)
Prefilled	538 (31.0)	1103 (33.8)	1641 (32.9)
Reusable	1313 (75.6)	2082 (63.9)	3395 (68.0)
LANTUS SoloSTAR	337 (19.3)	1491 (32.9)	1828 (29.2)
Apidra SoloSTAR	547 (38.1)	1382 (35.2)	1929 (36.0)

[a] Values are mean ± SD or n (%).
[b] Only patients using insulin before inclusion.

who used insulin were using insulin pens, with use of reusable pens (68%) predominating over prefilled pens (32%). The most commonly used devices were NovoPen® 3 (Novo Nordisk; 21.6%), HumaPen® Ergo (Eli Lilly; 19.3%), FlexPen® (Novo Nordisk; 12.4%), OptiPen Pro® (sanofi-aventis; 11.7%), and NovoPen® 4 (Novo Nordisk; 9.3%). Of the 97.3% (n = 6305) of patients that used SoloSTAR with insulin glargine during the study, 29.2% (n = 1828) were using SoloSTAR with insulin glargine prior to the study. Of the 36% (n = 1929) that used SoloSTAR with insulin glulisine during the study, 23.7% (n = 454) were using SoloSTAR with insulin glulisine prior to the study. Before inclusion, 30.5% (n = 1975) of patients were using SoloSTAR with both insulin glargine and insulin glulisine, and 27.0% (n = 1753) used SoloSTAR with both insulin glargine and insulin glulisine during the study. A total of 655 patients (17.6%) were insulin-naïve prior to inclusion in this study, of which 81 patients were newly diagnosed with T1DM and initiated insulin therapy at the start of the study.

Insulin Therapy During the Study

During the study, most patients (97.3%, n = 6305) started SoloSTAR with insulin glargine with a mean daily dose of 26 ± 17 U [T1DM, n = 1749 (96.3%), 24 ± 12 U; T2DM, n = 4556 (97.7%), 27 ± 18 U]. In addition, 36% (n = 1929) of patients started SoloSTAR with insulin glulisine, with a mean daily dose of 31 ± 16 U [T1DM, n = 547 (38.1%), 29 ± 14 U; T2DM, n = 1382 (35.2%), 32 ± 17 U]. The median number of insulin glulisine doses per day was three (range 1–8 doses).

Evaluation of SoloSTAR

A total of 3569 patients completed the questionnaire documenting prior insulin and insulin pen use at baseline, and 6364 completed the follow-up questionnaire documenting their use of SoloSTAR during the study. Patients' perceptions of their previous pen (n = 3569) and of SoloSTAR (n = 6364) are summarized in **Figure 2**. Previously used pen devices were generally perceived as excellent or good by similar proportions of participants for each of the factors recorded. However, the SoloSTAR pen was perceived extremely positively, as shown by the majority of patients who rated SoloSTAR as excellent across all eight factors. In particular, the ease of selecting the dose (prior pen, 38.1%; SoloSTAR, 76.3%) and the ease of correcting a misdialed dose (prior pen, 32%; SoloSTAR, 73.4%) were rated very highly for SoloSTAR by the total study population, compared with those documenting prior pen use. Less than 2% of patients rated SoloSTAR as poor or very poor for all eight factors, while 1.5–10.3% of the patients rated their previous device as poor or very poor.

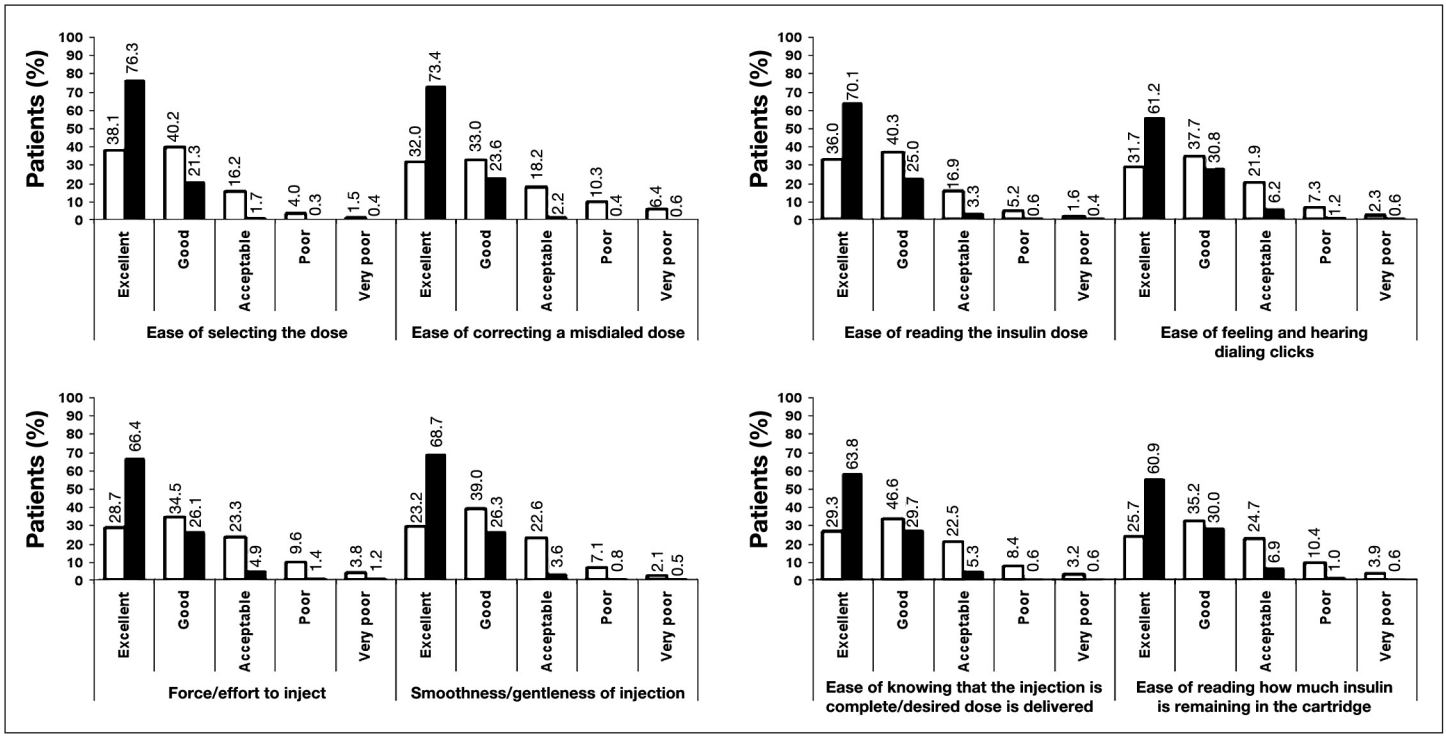

Figure 2. Patient acceptance of SoloSTAR and the acceptance of a previously used device. Open bars, previous device (n = 3569) reported at visit 1; closed bars, SoloSTAR (n = 6364, reported at follow-up visit).

The final follow-up questionnaire also asked patients to directly compare SoloSTAR with their previously used pen. In total, 55.5% (2588/4660) rated SoloSTAR as much easier to use, 32.9 (1531) as easier, 9.9% (460) as the same, and 1.7% (79) as more difficult or much more difficult to use compared with the previously used device. In terms of ease of injecting the insulin dose, 54.7% (2538/4644) rated SoloSTAR as much easier, 29.8% (1386) as easier, 13.3% (618) as the same, and 2.2% (102) as more difficult or much more difficult to use. Of 1703 patients who compared ease of differentiation between SoloSTAR with insulin glargine and SoloSTAR with insulin glulisine, 72.7% of patients rated this factor as excellent, 22.2% as good, 3.8% as acceptable, 0.9% as poor, and 0.4% as very poor.

Overall, 87.7% (4092/4668) of patients stated that they preferred SoloSTAR to their previous pen, while 3.4% (160) preferred their previous pen and 8.9% (414) had no preference. The majority of patients were planning to continue to use SoloSTAR (98.2%; n = 6059) and would recommend SoloSTAR (98.8%; n = 6078). Additional data collected from the final follow-up questionnaire is reported in **Table 2**.

Ease of Learning and Ease of Use

In the population of patients who were included in the assessment of patient satisfaction (n = 6364), the ease of learning and ease of use of SoloSTAR was rated as excellent (80.7% and 78.9%, respectively) or good (17.6% and 19%, respectively; **Figure 3**).

Overall Assessment of SoloSTAR

In the overall assessment of SoloSTAR (n = 6364), the device was rated as excellent by 75.8% of patients, good by 21.4%, acceptable by 2.0%, and poor or very poor by 0.7% (**Figure 4**). Most patients planned to continue using SoloSTAR (98.2%) and would recommend SoloSTAR to

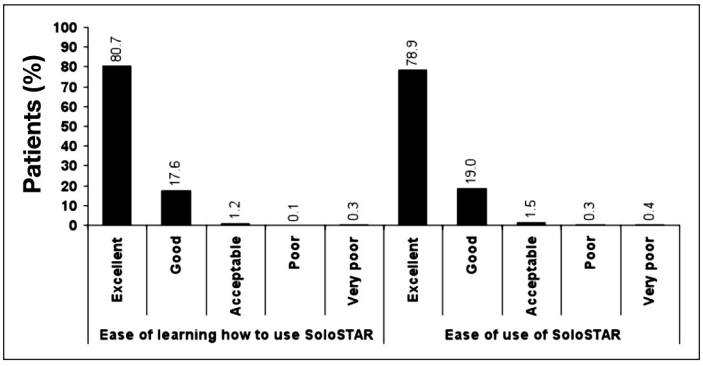

Figure 3. Acceptance of SoloSTAR in terms of use and ease of training.

Table 2.
Responses to the Follow-Up Questionnaire: Patient Satisfaction Population

	n/N (%) (*N* = 6364)
Patient filled in questionnaire 2	
Yes	6364/6364 (100.0)
Person who gave the insulin injection	
Self	6188/6355 (97.4)
Parent	11/6355 (0.2)
Spouse	73/6355 (1.1)
Nurse/carer	39/6355 (0.6)
Other	44/6355 (0.7)
Missing (*n*)	9
Use of other insulin pen before SoloSTAR	
One other	2463/6330 (38.9)
Two others	1804/6330 (28.5)
Three or more	442/6330 (7.0)
Never	1621/6330 (25.6)
Missing (*n*)	34
Type of insulin currently used	
Insulin glargine only	2036/6228 (32.7)
Insulin glulisine only	39/6228 (0.6)
Insulin glargine and apidra	2157/6228 (34.6)
Insulin glargine + one other insulin	1870/6228 (30.0)
Insulin glargine + two other insulins	26/6228 (0.4)
Insulin glargine + three other insulins	15/6228 (0.2)
Insulin glulisine + one other insulin	83/6228 (1.3)
Insulin glulisine + two other insulins	1/6228 (0.0)
Insulin glulisin + three other insulins	1/6228 (0.0)
Missing (*n*)	136
Number of injection devices currently used	
SolorSTAR only	4110/6310 (65.1)
SolorSTAR + one other	2180/6310 (34.5)
SolorSTAR + two others	20/6310 (0.3)
Missing (*n*)	54
Start of SoloSTAR use the day patient received the supply	
Yes	5018/6333 (79.2)
No, 1 day later	683/6333 (10.8)
No, 2 days later No, 3 days later	199/6333 (3.1)
No, 4 days later	113/6333 (1.8)
Yes/no, 2 days later	318/6333 (5.0)
Yes/no 3 days later	1/6333 (0.0)
Missing (*n*)	1/6333 (0.0)
	31
Patient was still using SoloSTAR	
Yes	6245/6291 (99.3)
No, stopped 1–6 days ago	22/6291 (0.3)
No, stopped 1–2 weeks ago	10/6291 (0.2)
No, stopped 3–4 weeks ago	9/6291 (0.1)
No, stopped 5–6 weeks ago	5/6291 (0.1)
Missing (*n*)	73
Number of SoloSTAR pens used	
1–7 pens	4070/5941 (68.5)
8–14 pens	1362/5941 (22.9)
15–21 pens	352/5941 (5.9)
>21 pens	157/5941 (2.6)
Missing (*n*)	423
Mean number of pens used (SD)	7 (6.0)
Median number of pens used (Q1, Q3)	5 (3, 9)

(*continued*) →

Table 2. Continued

	n/N (%) (*N* = 6364)
Disability or other restrictions	
None	5151/5151 (100.0)
Missing (*n*)	1213
If patient has disability or other restrictions	
Poor eyesight not corrected by glasses/ contact lenses	
Mild	447/828 (54.0)
Moderate	317/828 (38.3)
Severe	64/828 (7.7)
Missing (*n*)	482
Manual dexterity problems	
Mild	379/731 (51.8)
Moderate	283/731 (38.7)
Severe	69/731 (9.4)
Missing (*n*)	482
Other type of disability	
Mild	153/322 (47.5)
Moderate	126/322 (39.1)
Severe	43/322 (13.4)
Missing (*n*)	891
Frequency of using a new needle	
Before every injection	1488/6327 (23.5)
Every second day	976/6327 (15.4)
Every third day	1061/6327 (16.8)
Between 4–5 days	1059/6327 (16.7)
Between 6–7 days	822/6327 (13.0)
>7 days	921/6327 (14.6)
Missing (*n*)	37
Frequency of safety test	
Before every injection	2337/6283 (37.2)
Every second day	686/6283 (10.9)
Once a week	893/6283 (14.2)
With each new pen	1843/6283 (29.3)
Only when there are air bubbles in the reservoir	232/6283 (3.7)
Never	292/6283 (4.6)
Missing (*n*)	81
Brand of needle used with SoloSTAR[a]	
BD	3224/6201 (52.0)
Novo Nordisk	1713/6201 (27.6)
Ypsomed	576/6201 (9.3)
Braun	66/6201 (1.1)
Other	484/6201 (7.8)
BD/Novo Nordisk	77/6201 (1.2)
BD/Ypsomed	18/6201 (0.3)
BD/Braun *n/N*	2/6201 (0.0)
BD/other *n/N*	9/6201 (0.1)
Novo Nordisk/Ypsomed	3/6201 (0.0)
Novo Nordisk/other	6/6201 (0.1)
Ypsomed/Braun	2/6201 (0.0)
Braun/other	2/6201 (0.0)
BD/Novo Nordisk/Ypsomed	9/6201 (0.1)
BD/Novo Nordisk/Braun	1/6201 (0.0)
BD/Novo Nordisk/other	4/6201 (0.1)
BD/Ypsomed/Braun	3/6201 (0.0)
BD/Ypsomed/other	1/6201 (0.0)
BD/Novo Nordisk/Ypsomed/Braun	1/6201 (0.0)
Missing	163
Face-to-face training on the use of SoloSTAR	
Yes	6101/6344 (96.2)
No	243/6344 (3.8)
Missing (*n*)	20
Confidence in the use of the pen after the training	
Yes	5905/6228 (94.8)
No	323/6228 (5.2)
Missing	136
Number of days to be confident in the use of SoloSTAR	
0 days	767/6098 (12.6)
1 day	3515/6098 (57.6)
2 days	826/6098 (13.5)
3 days	436/6098 (7.1)
4–8 days	446/6098 (7.3)
>8 days	108/6098 (1.8)
Missing	266
Mean number of days (SD)	2 (2.3)
Median (Q1, Q3)	1 (1,2)

[a] BD: Becton, Dickinson & Co.

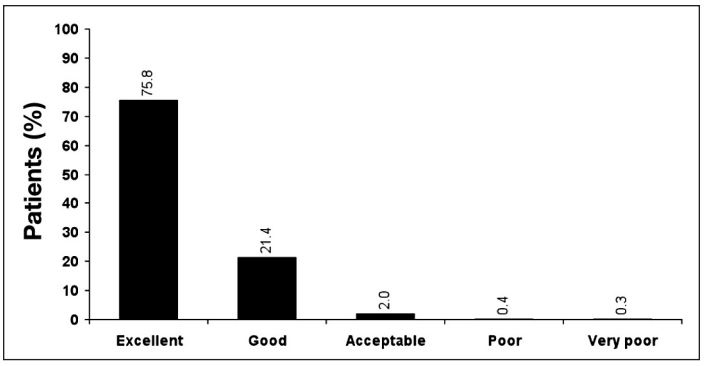

Figure 4. Overall assessment of SoloSTAR.

others (98.8%). The overall assessment of SoloSTAR was comparable between age groups, type of diabetes, and prior use of insulin in patients with T2DM.

Safety

A total of 353 TEAEs were reported by 192 patients, of which 238 events in 105 patients were episodes of hypoglycemia (**Table 3**). Ten events corresponding to injection-site conditions were reported by 10 patients, including four episodes of injection site pain, three of injection site discomfort, and one each of cyst and injection site erythema. Thirty patients experienced a serious TEAE, of which three were considered by the investigator to be possibly related to insulin glargine treatment. One patient experienced moderate hypoglycemia due to an overdose of insulin glargine and was involved in a car accident. This occurred 4 days after the study start, and the patient recovered after 1 day. One patient experienced severe hypoglycemia due to an overdose of insulin glargine approximately 1 month after the study start. Recovery occurred on the same day. One patient experienced unconsciousness due to severe hypoglycemia following insulin glargine use. This occurred approximately 1 month after study start, and the patient recovered the same day.

Table 3.
Treatment-Emergent Adverse Events

	Insulin glargine or insulin glargine plus insulin glulisine (*n* = 6305)			Insulin glulisine (*n* = 176)			All patients (*n* = 6481)		
	Events	Patients		Events	Patients		Events	Patients	
		n	%		*n*	%		*n*	%
All	352	191	3.03	1	1	0.57	353	192	2.96
Metabolism and nutrition disorders	250	116	1.84				250	116	1.79
Infections and infestations	21	20	0.32	1	1	0.57	22	21	0.32
General disorders and administration site conditions	20	19	0.3				20	19	0.29
Nervous system disorders	9	9	0.14				9	9	0.14
Cardiac disorders	9	8	0.13				9	8	0.12
Injury, poisoning, and procedural complications	8	8	0.13				8	8	0.12
Skin and subcutaneous tissue disorders	7	7	0.11				7	7	0.11
Musculoskeletal and connective tissue disorders	6	6	0.1				6	6	0.09
Gastrointestinal disorders	6	5	0.08				6	5	0.08
Respiratory, thoracic, and mediastinal disorders	4	4	0.06				4	4	0.06
Vascular disorders	5	4	0.06				5	4	0.06
Surgical and medical procedures	2	2	0.03				2	2	0.03

Discussion

This European and Canadian study shows that SoloSTAR was well accepted in this large patient population. Overall, the results obtained in this study are consistent with those reported in a similar observational survey of Australian patients.[18] Indeed, most of the patients in both studies rated SoloSTAR as "excellent or good" for ease of use and learning, despite only 23% of patients in this study having not had prior insulin therapy, suggesting that, despite major changes in their therapy, patients accepted the new treatment and administration methods well. Furthermore, 15.5% of participants of the observational study had visual impairments and 16.3% had manual dexterity problems; however, compared with those who had no such impairments, they reported a similar level of satisfaction using SoloSTAR (mostly "satisfied" or "very satisfied").[19] The majority of patients also preferred SoloSTAR versus their previous pen, rating SoloSTAR as easier to use, and planned to continue using SoloSTAR as part of their treatment regimen. In this study, insulin delivery with SoloSTAR was well tolerated, with relatively few TEAEs reported. Most adverse events were considered to be associated with the use of insulin glargine or insulin glulisine, rather than the use of the SoloSTAR device to inject the insulin. This observation, in combination with the accuracy of SoloSTAR previously demonstrated in simulated clinical settings,[9,21,22] should provide reassurance to patients and physicians alike that SoloSTAR could be appropriate for many patients, with low risk of patient errors in use.

The findings of this study must be weighed against a number of limitations. First, this study was performed in a nonrandomized patient population, and only half of the patients completed the questionnaire at visit 1, limiting the validity of the comparison between pens. However, because the patients completed the questionnaire regarding their prior pen at the initial visit, this should overcome any potential recall bias for this analysis. It must be acknowledged that patients with pen use experience were asked to compare SoloSTAR with their previous pen at visit 2, and this comparison may be subject to recall bias. However, the majority rated SoloSTAR as easier to use and inject and preferred SoloSTAR versus the previous pen. Second, a number

of patients had already used SoloSTAR with insulin glargine or insulin glulisine or both prior to visit 1, and these patients were included in the analysis of the initial questionnaire, which should be considered when interpreting comparisons between SoloSTAR and prior pens. Third, almost one-third of patients who previously used insulin pens did not complete the questionnaire at the initial visit, although they did complete the questionnaire at the follow-up visit. Accordingly, the perceptions of the previous device should not be directly compared with that of SoloSTAR, because these patients did not provide feedback on their previously used pen. Additionally, it is possible that not all adverse events were reported, possibly as a result of patient recall. Lastly, this study did not specifically evaluate the use of SoloSTAR in people with either severe visual or dexterity impairments. As these impairments are common among people with diabetes, future studies should assess the use of SoloSTAR in people with severe visual or dexterity impairments. Preliminary evidence suggests that visually impaired people are just as capable as those without impairment at self-administering insulin using pen devices.[23]

Conclusion

Taken together, the results of this study confirm those reported elsewhere[17,19] that SoloSTAR is perceived by patients to be easy to use, particularly in comparison with previously used insulin pens, and is associated with high levels of user satisfaction among patients with diabetes worldwide. Future randomized controlled trials to compare the clinical utility of SoloSTAR versus the vial and syringe would be valuable, both in terms of assessing overall effects on patient satisfaction and glycemic control and in terms of risk of hypoglycemia and overall treatment costs.

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References:

1. Davis EM, Bebee A, Crawford L, Destache C. Nurse satisfaction using insulin pens in hospitalized patients. Diabetes Educ. 2009;35(5):799–809.
2. Korytkowski M. When oral agents fail: practical barriers to starting insulin. Int J Obes Relat Metab Disord. 2002;26 Suppl 3:S18–24.
3. Lee WC, Balu S, Cobden D, Joshi AV, Pashos CL. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. Clin Ther. 2006;28(10):1710–25.
4. Robertson KE, Glazer NB, Campbell RK. The latest developments in insulin injection devices. Diabetes Educ. 2000;26(1):135–8, 141–6, 149–52.
5. IMS Health. IMS MidasTM June 2009 insulin sales volume.
6. Pawaskar MD, Camacho FT, Anderson RT, Cobden D, Joshi AV, Balkrishnan R. Health care costs and medication adherence associated with initiation of insulin pen therapy in medicaid-enrolled patients with type 2 diabetes: a retrospective database analysis. Clin Ther. 2007;29 Spec No:1294–305.
7. Asche CV, Shane-McWhorter L, Raparla S. Health economics and compliance of vials/syringes versus pen devices: a review of the evidence. Diabetes Technol Ther. 2010;12 Suppl 1:S101–8.
8. Clarke A, Spollett G. Dose accuracy and injection force dynamics of a novel disposable insulin pen. Expert Opin Drug Deliv. 2007;4(2):165–74.
9. Friedrichs A. Dose accuracy of SoloSTAR and FlexPen as assessed in a clinical setting. Diabetes Technol Ther. 2009;11(9):609–13.
10. Hermanns N, Kulzer B, Haak T. Dosing accuracy with a novel pen device (SoloSTAR) as performed by patients with diabetes in a clinical setting. Diabetes Technol Ther. 2008;10(4):322–7.
11. Penfornis A, Horvat K. Dose accuracy comparison between SoloSTAR and FlexPen at three different dose levels. Diabetes Technol Ther. 2008;10(5):359–62.
12. Pfützner A, Asakura T, Sommavilla B, Lee W. Insulin delivery with FlexPen: dose accuracy, patient preference and adherence. Expert Opin Drug Deliv. 2008;5(8):915–25.
13. Papanas N, Maltezos E. The diabetic hand: a forgotten complication? J Diabetes Complications. 2010;24(3):154–62.
14. Saaddine JB, Honeycutt AA, Narayan KM, Zhang X, Klein R, Boyle JP. Projection of diabetic retinopathy and other major eye diseases among people with diabetes mellitus: United States, 2005-2050. Arch Ophthalmol. 2008;126(12):1740–7.
15. Centers for Disease Control and Prevention. Prevalence of visual impairment and selected eye diseases among persons aged ≥50 years with and without diabetes---United States, 2002. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5345a3.htm. Accessed January 29, 2011.
16. Williams A. Diabetes and visual impairment - identifying needs, ensuring full accessibility. Diabetes Voice. 2008;53(3).
17. Haak T, Edelman S, Walter C, Lecointre B, Spollett G. 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. Clin Ther. 2007;29(4):650–60.
18. Carter J, Roberts A. Usability of a pre-filled insulin injection device in a 3-month observational survey of everyday clinical practice in Australia. Curr Med Res Opin. 2008;24(10):2741–9.

19. Carter J, Beilin J, Morton A, De Luise M. Usability, participant acceptance, and safety of a prefilled insulin injection device in a 3-month observational survey in everyday clinical practice in Australia. J Diabetes Sci Technol. 2009;3(6):1425–38.

20. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344–9.

21. Krzywon M, Abdel-Tawab M, van der Burg T, Fuhr U, Schubert-Zsilavecz M. Dosing accuracy of commonly used disposable insulin pens. Curr Med Res Opin. 2010;26(4):901–5.

22. Weise A, Pfützner JW, Borig J, Pfützner AM, Safinowski M, Hänel H, Musholt PB, Pfützner A. Comparison of the dose accuracy of prefilled insulin pens. J Diabetes Sci Technol. 2009;3(1):149–53.

23. Williams AS, Schnarrenberger PA. A comparison of dosing accuracy: visually impaired and sighted people using insulin pens. J Diabetes Sci Technol. 2010;4(3):514–21.