

## Analysis of Patient Satisfaction with a Prefilled Insulin Injection Device in Patients with Type 1 and Type 2 Diabetes

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### Abstract

In this issue of *Journal of Diabetes Science and Technology*, Hancu and colleagues present an observational 6–8-week Pan-European and Canadian prospective survey on patient satisfaction with a prefilled insulin injection device, the SoloSTAR pen device, in patients with type 1 and 2 diabetes ( $n = 6542$ ). The SoloSTAR pen is one of several up-to-date insulin pens of high quality and characteristics that fit many of our patients with diabetes. The mainly excellent–good votes of the participants for the SoloSTAR are not surprising, as we have seen continuous improvements with prefilled pens, such as the SoloSTAR device. Several years ago, patients as well as health care providers found considerable differences between the available pen options. Nowadays, as almost all pen providers have clearly improved their products, the differences are much smaller; we are closer to a “perfect” prefilled pen device.

Nevertheless, there is a need for more randomized controlled trials, ideally sponsored not by just one manufacturer, to be able to make clear statements toward different pen device aspects (e.g., accuracy of dosing, adherence to therapy, ease of use, and patient satisfaction). An additional handicap is the difficulty to get blinded study designs.

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Pen device development has generated several high-quality insulin pens, more and more tailored to the specific needs of patients, some even serve patient subgroups. This development has led to the situation where more and more patients are in favor of using insulin pens rather than traditional vials and syringes. From a clinical perspective, advantages of pens over syringes have been confirmed in numerous studies, including greater accuracy, ease of use, patient satisfaction, quality of life, and adherence.<sup>1,2</sup> Database analyses even indicate that improved adherence made possible by use of an insulin

pen has the potential to reduce diabetes care costs, although “pen therapy” as a first step is more expensive than vials and syringes.

Increasingly, the question asked is “which pen will I use” instead of “should I use a pen or the vial/syringe option.” Even in the United States, compared with European countries, the lower rate of insulin pen usage has continuously risen because of better informed patients and health care providers. Many patients benefit from pen devices, as they are perceived to be less intimidating,

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more portable, easier to use and handle, easier to read the scales, and more discreet when used in the public.<sup>3-5</sup>

The article by Hancu and colleagues<sup>6</sup> in this issue of *Journal of Diabetes Science and Technology* presents data from a 6–8-week multicenter ( $n = 652$ ), observational, prospective Pan-European and Canadian registry study in patients with diabetes mellitus who recently switched to or started treatment with insulin glargine and/or insulin glulisine using the insulin pen device SoloSTAR. The large number of patients, 6552 in total, including patients with type 1 and type 2 diabetes, insulin-naïve or previously receiving insulin, is a major strength of this observational study.

The aim was to investigate patient satisfaction of the SoloSTAR pen in people using insulin glargine and/or insulin glulisine in everyday clinical practice. Typical patient satisfaction 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 misdialled 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 the injection is completed or desired dose is delivered; ease of reading how much insulin is remaining in the cartridge; ease of differentiating the glargine SoloSTAR from the glulisine SoloSTAR, for patients using both; ease of learning how to use the pen; ease of use in general; overall assessment of the pen; plan to continue to use the pen (yes or no); and does the patient recommend the pen (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.

More than two-thirds of the participants had used insulin before the study; from those, again two-thirds were on reusable pens before the study. The presented results show that an overwhelming majority of patients rated the SoloSTAR to be “excellent or good” for most of the asked questions [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 the SoloSTAR pen device.

Several limitations are obvious with this study, partly addressed by the authors. First, as with any industry-sponsored trial, an obvious limitation is the funding by the manufacturer. Most of the published literature on insulin pen devices has been funded by the various manufacturers, so the interpretation of the results needs to be done with caution. Another limitation is the missing randomization and active comparison arm. Other study design aspects, especially a potential recall bias considering the comparison of the pens used before the trial compared with the “trial pen” at the final visit, need to be mentioned as well as the “unvalidated” questionnaire.

A problem we will always have with this kind of study, even with randomized trials, is the near impossibility to have a blinded study design and, not as usual, the typical open-label design.

So one could ask the question, “Who is profiting from this data primarily?” Of course, it is the manufacturer, who needs to find out the reliability, adverse events, patient acceptance, and other positive aspects of the product including potential areas of improvement for the next pen generation and, not to forget, for marketing purposes.

Nevertheless, the data of this observational study show excellent–good results and confirms a high acceptance by the patients. These results are probably repeatable when asking health care providers such as primary care physicians, endocrinologists/diabetologists, and diabetes educators instead of patients, as the actual SoloSTAR pen generation is definitely a gladly used pen.

We need insulin pens that fit our individual patients, and there is still potential for improvement, especially for those with severe visual impairments and severe manual dexterity; this applies to reusable pens as well as prefilled pens. Additionally, we should not forget environmental aspects and prefer, where possible, reusable pens.<sup>7</sup>

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Siegmund has received financial support from Berlin Chemie, Bristol Myers Squibb, Novo Nordisk, and sanofi-aventis to attend congresses. He is on the speakers bureau of Berlin Chemie, Bristol Myers Squibb, Daiichi Sankyo, Lilly, Medtronic, Merck Sharp & Dohme, Novartis, Novo Nordisk, Roche Diagnostics, and sanofi-aventis and has received honoraria for support in advisory boards for Jansen, Lilly, Merck Sharp & Dohme, Novo Nordisk, and sanofi-aventis.

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