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ORIGINAL ARTICLE

Making Life Easier for Insulin Users: One Step Forward with Incremental Advances in Insulin Delivery Systems

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Abstract

More than five million Americans use insulin every day for glucose control. The great majority use traditional vials and syringes containing different insulin preparations. The adoption of insulin pens and cartridges in the United States remains disproportionately low in contrast to Europe and Japan. Hopefully, incremental advances in delivery technology of prefilled insulin pens such as the new FlexTouch may help reduce the gap. The article by Wielandt and colleagues in this issue of *Journal of Diabetes Science and Technology* describes performance and accuracy of the FlexTouch insulin delivery system as well as some user-friendly features of the new prefilled pen.

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In this issue of *Journal of Diabetes Science and Technology*, Wielandt and coauthors[1] describe the evaluation of the new FlexTouch prefilled insulin pen. The study assessed dose accuracy of three prefilled insulin pens, FlexTouch, KwikPen, and SoloSTAR. The latter two Food and Drug Administration-approved pen systems enjoy wide clinical usage in the United States, and the European Commission has approved FlexTouch for patient care in Europe.

The study was designed to investigate the accuracy and reproducibility of FlexTouch pens filled with insulin detemir and FlexTouch pens filled with insulin aspart when dosing insulin at minimum, medium, and high doses and to compare the performance measures with the dosing accuracy of industry-accepted pen devices, SoloSTAR filled with insulin glargine and KwikPen filled with insulin lispro.

Each pen from all four prefilled pen types contained 3 ml of respective insulin, and each pen was fitted with the manufacturers' recommended pen tip. Thirty pen samples of each pen type were chosen from two different production lots, and dosage sampling was conducted in duplicate for each pen. Sixty measurements from each dose level of all four prefilled pen groups were performed.

The primary study objective was accuracy of insulin dose delivery. Pens were tested for dosing accuracy repeatedly for low, medium, and maximum doses of each pen type, i.e., 1, 40, and 80 U for FlexTouch and SoloSTAR and 1, 30, and 60 U for KwikPen. Insulin preparations used in testing were maintained at strict temperature and humidity conditions in accordance with International Organization for Standardization (ISO) 11608-1.[2] This study condition is important because measuring the weight of delivered

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Abbreviations: (ISO) International Organization for Standardization

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dose and then correcting for the specific density of the insulin formulation determines the amount of insulin actually delivered with each use of a pen.

The authors report that the new prefilled FlexTouch delivered insulin accurately and consistently at low, medium, and high doses. Superiority over competitors was not the intended goal of the study. In fact, all three pen systems delivered doses of insulin that were well within accepted limits of the ISO standard. FlexTouch showed similar accuracy to KwikPen at 1 U dose trials. The reader should note, however, that the ISO standard allows variance of delivered insulin from 0 to 2 U at the intended 1 U dose of insulin. All three manufacturers' types of prefilled pens tested in the study demonstrated levels of accuracy superior to allowable variance from the standard. The accuracy of insulin delivery for FlexTouch at 1 U was sharp with a range of 0.72 to 1.18 U as was KwikPen with a range of 0.8 to 1.3 U.

Clinicians and patients should be mindful that some variation in delivered insulin dose in relation to intended dose is generally present with all insulin delivery devices. Variation or error is usually quite small with prefilled mechanical pen devices.[3] Degree of error may increase when vials and syringes are used for administration of insulin.[4] The potential for variation may become more pronounced when the insulin user suffers some medical impairment such as tremor or neuropathy of hands or has limited vision. In addition, potential for error in accuracy assessment studies may also increase when the persons testing the delivery device are patients with diabetes naïve to insulin injection.

Clinicians should be aware that this small study is an *in vitro* or bench study and was conducted with trained laboratory professionals. The article by Wielandt and colleagues[1] makes no mention of device accuracy when patients with diabetes recruited from real-life community medical settings inject insulin with these devices.

Dose accuracy of the delivery devices at minimal (1 U) dosing ranges can be very important clinically to physicians and other health providers who treat small children or lean adults who may be ill with impaired ability to produce counter-regulatory hormones to insulin. Even small doses of insulin administered to these patients can result in big changes in blood sugar levels, especially when their ambient glucose levels approach near-hypoglycemia ranges. Minimal variation in dosing from the standard thus has more clinical relevance in this setting than absolute dosing accuracy in maximal (80 U) dose ranges in overweight adults with varying degrees of insulin resistance and global hyperglycemia.

According to the authors, the technical advance behind the FlexTouch insulin pen is the spring-loaded release innovation that removes the need to continually apply pressure to the push button atop existing prefilled pens when administering insulin. The degree to which the newly designed pen potentially improves the insulin delivery process for persons who inject insulin remains to be determined. My personal bias is that the technical innovations described by Wielandt and colleagues[1] are an incremental step forward in making life easier for people with diabetes. My additional belief is that FlexTouch offers possible advantage in treating patients with diabetes who are burdened with significant dexterity and neuropathy issues, such as interosseous muscle atrophy of hands.

Our diabetes educators instruct all persons who use prefilled insulin pens with the practical mnemonic "prime to two, dial to dose, and hold to ten." Clinicians and insulin users still need to prime the pen when applying a new pen needle. However, the authors' understated description of end-of-dose click that is built in to the FlexTouch pen may be an additional innovation for persons who use prefilled pens. Many persons who are transitioning from vials and syringes to prefilled pens express some uneasiness as to whether the insulin dose that they dialed on their pen was actually delivered into their body. The end-of-dose click may be reassuring in this matter.

The real importance of the study reaches far beyond reporting on accuracy of a new delivery device. The authors and their research team have taken an incremental step forward, making it easier for people who take insulin to manage their chronic illness. It is hoped that the innovations presented in this journal serve as a sort of medical epiphany to help make prefilled insulin pens more available to all those persons with diabetes living in the United States who could benefit from the accuracy, convenience, and ease of use of prefilled insulin pens.

References:

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