

## Analysis of Insulin Pen Devices for the Treatment of Diabetes Mellitus

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### Abstract

Insulin pen devices allow for accurate, flexible, and less complicated delivery of insulin for the treatment of diabetes mellitus. These devices permit small dose administration, and can be used by patients with limited dexterity and visual impairment. These characteristics may prove beneficial when considering their usefulness. The article by Hanel *et al.* in this issue of *Journal of Diabetes Science and Technology* clearly points out that the OptiClik® reusable pen may underdose insulin early after cartridge replacement unless properly primed. Insulin pens clearly offer several advantages over traditional vials and syringes. However, patients must be well educated in their use, with continued communication between them and their health care provider to enable good glycemic control.

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### Insulin Pen Devices for the Treatment of Diabetes Mellitus

Since their introduction in 1985, insulin pens have been gaining widening popularity among diabetic patients worldwide. These devices are either disposable or reusable. Combined with simplicity, ease of use, and reliability, insulin pens offer an important tool for patients with either type 1 or type 2 diabetes mellitus. These devices can allow persons with limited manual dexterity and/or visual impairment to administer insulin with some independence. Insulin pens allow for more accurate dosing in both children<sup>1</sup> and the elderly<sup>2</sup> when compared with traditional vials and syringes.

Several considerations should be made when choosing an insulin pen for a patient. These may include lifestyle considerations, insulin regime, and dosing schedule,

as well as the ability to use such a medical device.<sup>3</sup> Characteristics that patients may find appealing, such as dose legibility, comfortable grip, audible click, as well as ease of administration, should also be kept in mind.<sup>4</sup> Insulin pens in their design are looking less like a medical device, which may alleviate a barrier to injection therapy in some patients.

In the pediatric or elderly populations, small insulin doses may be necessary. Insulin pens allow for more accurate delivery of these small doses ( $\leq 5$  IU doses).<sup>5</sup> When using traditional vial and syringe techniques, the elderly ( $>60$  years) are much more likely to experience dose error.<sup>6</sup> These errors can lead to over- or underdosing insulin, which can lead to further complications.

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Recently published data examined patient preferences and usability of various insulin pen devices.<sup>7</sup> The SoloSTAR<sup>®</sup> and FlexPen<sup>®</sup> were preferred. They also found these pens to be suitable for older patients, as they were simple to use. In another study, the SoloSTAR was shown to require less force to administer an injection than the FlexPen.<sup>8</sup> This study also presented data clearly demonstrating that the SoloSTAR administers insulin well within International Standards Organization's standards across a wide dose and temperature delivery range.

Currently available disposable and reusable insulin pens are proprietary devices. The insulins contained within are company distinct. These insulin pens are manufactured only for the specific insulin for which it was designed. The FlexPen is specific for Novo Nordisk insulins, the HumaPen<sup>®</sup> LUXURA<sup>™</sup>, pen for Eli Lilly products, and the SoloSTAR and OptiClik<sup>®</sup> for sanofi-aventis products. These insulins vary widely in their pharmacokinetics and clinical use. Until a reliable, reusable insulin pen that can contain other products is developed, insulin pens and the contained insulin will be company specific.

Disposable insulin pens and cartridges are mass produced. They are not designed to be scientific instruments. However, they must be reproducibly accurate and reliable. In a study by Hanel *et al.*<sup>9</sup>, the accuracy of popularly-available insulin pens was evaluated. While no overdosing was seen, one of the striking findings in this study was underdosing during the first attempts with a new OptiClik cartridge. This finding allowed for the authors to suggest a "system initiation" with each cartridge. My suggestions, based on these findings, would also recommend to the manufacturers of the OptiClik that a pre-use, "wasted" bolus for each cartridge change be required to avoid underdosing early in the cartridge's usage span. My concern would be that an insulin-sensitive patient, such as one in the pediatric or elderly population, requiring small doses of insulin, may be significantly underdosed early following a cartridge change without this "system initiation." This could lead to clinically important hyperglycemia and its complications in the short term.

This study and my observations mentioned earlier show the reliability and dose accuracy of the disposable FlexPen and SoloSTAR, and the reusable HumaPen LUXURA. Clearly, the OptiClik may cause inaccurate dosing early after cartridge replacement if not adequately initiated. When choosing an insulin pen, it is important to consider the type of insulin administered and its

pharmacokinetics, ease of use, and dose accuracy. Thorough training with the patient is important as well because user error can adversely affect pen action and dose administration.<sup>10</sup>

Insulin is a mainstay in our armamentarium to treat diabetes mellitus. As insulin delivery devices become less "medical looking," patients may favor the use of an insulin pen, particularly in public. Insulin pens allow for accuracy, portability, flexibility, and ease of use. Insulin pens typically do not need refrigeration, which may provide for additional patient adherence to therapy over vial and syringe therapy. Through proper device selection, training, and continued communication with the health care provider, an insulin pen can facilitate maintenance of good glycemic control.<sup>9</sup>

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