

Dosing Accuracy and Insulin Flow Rate Characteristics of a New Disposable Insulin Pen, FlexTouch, Compared with SoloSTAR

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Abstract

Background:

The introduction of the FlexTouch® (FT; Novo Nordisk; insulin aspart), a prefilled insulin pen with a spring-loaded mechanism, has created more insulin pen options. The present study compared the dosing accuracy of the FT with that of the manually operated SoloSTAR® (SS; Sanofi; insulin glulisine). The volumetric flow rate of insulin delivery with the FT was also evaluated.

Methods:

Thirty unused pens from one batch of each pen type were used to test dosing accuracy at minimum (1 U), mid (40 U), and maximum dose (80 U). Statistical analysis was performed using Student's *t*-test. Insulin flow was determined with 20 FT pens ejecting 80 U three times per pen using a mass flow meter.

Results:

Both insulin pens revealed excellent dosing accuracy, delivering all doses within the limits set by ISO 11608-1:2000. The average relative deviation of the actual dose from the target dose was +6.86% and +3.87% at the minimum, -0.72% and -1.01% at the mid, and -0.68% and -1.06% at the maximum dose for the SS and FT, respectively. The difference at maximum dose was statistically significant ($p = .006$) in favor of the SS. The FT showed a mean maximum flow rate of 15.61 U/s, with 80.52% of the total dose delivered at an injection speed exceeding 10 U/s.

Conclusions:

This study demonstrated excellent dosing accuracy for the SS and FT at all tested dosage levels. The average maximum injection speed of the FT was considerably higher than the usual range of 6–10 U/s assumed for a smooth and painless injection. Further investigations should confirm the clinical relevance.

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Abbreviations: (FT) FlexTouch, (ISO) International Organization for Standardization, (SS) SoloSTAR

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