

## No Effect of Insulin Pen with Memory Function on Glycemic Control in a Patient Cohort with Poorly Controlled Type 1 Diabetes: A Randomized Open-Label Study

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### Abstract

#### Background:

Injection compliance is a major problem in patients with type 1 diabetes. Increased compliance with mealtime insulin injections significantly improves metabolic control. Using an insulin pen with memory function might facilitate corrective dosing to avoid postprandial blood glucose peaks and therefore might improve overall glycemic control.

#### Methods:

This randomized, open-label, 24-week multicenter study evaluated if patients with inadequately controlled type 1 diabetes [hemoglobin A1c (HbA1c)  $\geq$  8%] who were randomized to use the HumaPen<sup>®</sup> Memoir<sup>™</sup>, an insulin pen device with memory function, for their mealtime insulin injections achieved superior glycemic control (HbA1c change from baseline) than patients who used the conventional device HumaPen Luxura<sup>™</sup>. Hemoglobin A1c, hypoglycemia, and pen acceptance were assessed at baseline and after 12 and 24 weeks.

#### Results:

Of 263 patients randomized, 257 were eligible for analysis: HumaPen Memoir 129, HumaPen Luxura 128; mean [standard deviation (SD)] baseline HbA1c 9.09% (0.99%); mean (SD) age 39.8 (16.5) years; 87.9%  $\geq$ 18 years old; and mean (SD) diabetes duration 16.0 (11.2) years. Least square mean (95% confidence interval) changes of HbA1c up to week 24 were not significantly different between the HumaPen Memoir [0.43% (-0.59%, -0.28%)] and the HumaPen Luxura group [0.48% (0.64%, 0.32%);  $p = .669$ ]. The overall incidence of hypoglycemic episodes did not differ significantly between groups ( $p = .982$ ). Average satisfaction with insulin delivery was high in both groups.

#### Conclusions:

In this patient sample, usage of a memory function pen was not associated with superior glycemic control, suggesting that adherence to mealtime injection schedules was not improved in a relevant manner. The memory function might be helpful for specific patient populations only, e.g., children or forgetful patients.

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**Abbreviations:** (ANCOVA) analysis of covariance, (CI) confidence interval, (HbA1c) hemoglobin A1c, (IDSQ) insulin delivery system questionnaire, (LS) least square, (SD) standard deviation

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