

Ease of Use of Two Reusable, Half-Unit Increment Dosing Insulin Pens by Adult Caregivers of Children with Type 1 Diabetes: A Randomized, Crossover Comparison

Mayme Wong, Ph.D.,¹ Radhi Abdulnabi, Ph.D.,² and Haoda Fu, Ph.D.¹

Insulin pens deliver accurate doses, which are important for children who require low doses and are at risk for hypoglycemia.¹ Reusable insulin pens that deliver insulin in half-unit (U) increments include HumaPen® Luxura™ HD (Eli Lilly and Company, Indianapolis, IN; insulin lispro injection, 0.5 to 30 units; Pen A) and NovoPen® Junior (Novo Nordisk A/S, Bagsvaerd, Denmark; insulin aspart injection, 1 to 35 U; Pen B). The purpose of this randomized, 2-period, crossover, open-label, simulated injection study was to compare the functional usability and preference of these pens in 65 adult caregivers of children aged 3–12 years with type 1 diabetes. The caregivers' pen preferences were assessed for overall ease of use as the primary end point and for ease of changing the insulin cartridge and ease of correcting the insulin dose as the secondary end points.

All caregivers, who had no experience with reusable pens, watched a video showing the pen usability tasks and had user manuals available for reference. Each caregiver changed a cartridge, dialed and corrected a dose, injected into an injection pad at a high dose (10 U corrected to 6.5 U) and a low dose (5 U corrected to 2.5 U), and, after each dose, completed a 9-item questionnaire derived from the cognitively debriefed Insulin Device Assessment Battery.² Each item was answered on a 7-point scale (1 = strongly disagree to 7 = strongly agree), giving a total score for the low and high doses (minimum score of 2 up to a maximum score of 14). Proportions of caregivers with a pen preference (different total scores) were used to assess the primary and secondary end points. Caregivers with no preference (equal total scores) were excluded from the main frequentist analyses but were included in the total scores and the exploratory Bayesian Multinomial-Dirichlet model, which accounts for participants with no preference and informs on the relevance of the observed differences.³

The overall mean ages (\pm standard deviation) of the caregivers and children were 38.8 ± 7.9 years and 8.6 ± 2.9 years, respectively. Caregivers had previously administered insulin to children with a vial/syringe more often (56.9%) than with a prefilled delivery device (43.1%). Among caregivers with a preference (**Table 1**), the majority chose Pen A over Pen B for the three end points. Results were confirmed with the Bayesian analysis and in the total scores for all 65 caregivers (**Table 1**). In a final preference question, 80% of all 65 caregivers chose Pen A over Pen B.

These results were consistent with findings of other studies with the same or similar reusable pens.^{4–6} Pen A and Pen B use different technologies for correcting a dose and changing an insulin cartridge, which may have contributed to overall ease of use. Differences in the functionality of these pens may have been difficult to discern because some caregivers had no pen preference. Study strengths include the randomized crossover design, subjects who were naïve to

Author Affiliations: ¹Lilly Diabetes, Eli Lilly and Company, Indianapolis, Indiana; and ²i3 Data Services, Ann Arbor, Michigan

Abbreviation: (U) unit

Keywords: delivery device, insulin injection, pen, preference

Corresponding Author: Mayme Wong, Ph.D., Eli Lilly and Company, Lilly Corporate Center, Drop Code 2234, Indianapolis, IN 46285; email address wong_mayme@lilly.com

Table 1.
Analyses of the Proportions of Caregivers Preferring Pen A/B or Having No Preference

Pen attribute end point	Caregivers with a preference ^a			Caregivers with no preference ^a (n)	All caregivers (n = 65) ^a					
	Frequentist analysis				Bayesian analysis				Total score (95% CI) ^b	
	Pen A ^c n (%)	Pen B ^c n (%)	Exact 95% CI ^b		Pen A ^c n (%) ^d	Pen B ^c n (%) ^d	Difference between pens (%)	Exact 95% CrI ^d	Pen A ^c	Pen B ^c
“Overall easy to use”	36 (94.7%)	2 (5.3%)	82.3%–99.4% ^b	27	36 (54.4%)	2 (4.4%)	50.0% ^e	36.2–63.6%	13.5 (13.2–13.8)	11.6 (10.9–12.2) ^b
“Easy to change the cartridge”	32 (94.1%)	2 (5.9%)	80.3%–99.3% ^b	31	32 (48.5%)	2 (4.4%)	44.1% ^e	30.3–57.6%	13.4 (13.1–13.6)	10.8 (10.0–11.7) ^b
“Easy to correct the dose if I dial too much”	47 (94.0%)	3 (6.0%)	83.5%–98.7% ^b	15	47 (70.6%)	3 (5.9%)	64.7% ^e	50.5–78.0%	13.7 (13.5–13.9)	10.0 (7.1–10.8) ^b

CI, confidence interval; CrI, credible interval.

^a Caregivers included in the frequentist analyses had a different total score for each pen and had a pen preference. Caregivers with no preference had the same total score for both pens and were excluded from the frequentist analyses but were included in the Bayesian analyses and total score.

^b Exact 95% CI for binomial distribution. For the frequentist analysis, if the exact 95% CI did not include 50%, then the proportions of caregivers with a preference who chose one pen were statistically significant from the proportions of caregivers who chose the other pen. For the total score, if the exact 95% CI did not overlap, then the scores were statistically and significantly different between pens.

^c Pen A: HumaPen Luxura HD; Pen B: NovoPen Junior.

^d Percentage estimates based on a Bayesian model. Exact 95% CrI for the difference between pens. If the exact 95% CrI was greater than 0, then the difference between pens was statistically significant.

^e Probabilities that the difference between pens was greater than the proportion of caregivers with no preference were 76.8% for “overall easy to use,” 40.4% for “easy to change the cartridge,” and 99.8% for “easy to correct the dose if I dialed too much.”

reusable pens, and three analysis methods that confirmed the results. Study limitations included use of a nonvalidated questionnaire and simulated injections. In conclusion, Pen A is the reusable insulin pen preferred by adult caregivers over Pen B for injecting insulin in children with type 1 diabetes.

Funding:

Eli Lilly and Company sponsored this study.

Acknowledgement:

This study was performed by the contract research organization Concentrics Research, LLC, Indianapolis, IN.

Disclosures:

Drs. Wong and Fu are employees of Eli Lilly and Company and own stock in Eli Lilly and Company. Dr. Abdulnabi was paid by Eli Lilly and Company to perform the statistical analyses.

References:

1. Lteif AN, Schwenk WF. Accuracy of pen injectors versus insulin syringes in children with type 1 diabetes. *Diabetes Care*. 1999;22(1):137–40.
2. Clark PE, Valentine V, Bodie JN, Sarwat S. Ease of use and patient preference injection simulation study comparing two prefilled insulin pens. *Curr Med Res Opin*. 2010;26(7):1745–53.
3. Fu H, Qu Y, Zhu B, Huster W. A Bayesian approach to the statistical analysis of device preference studies. *Pharm Stat*. 2012;11(2):149–56.
4. Perfetti R. Reusable and disposable insulin pens for the treatment of diabetes: understanding the global differences in user preference and an evaluation of inpatient insulin pen use. *Diabetes Technol Ther*. 2010;12(Suppl 1):S79–85.
5. Penformis A. Performance of a new reusable insulin pen. *Diabetes Technol Ther*. 2011;13(3):373–9.
6. Olsen BS, Lilleore SK, Korsholm CN, Kracht T. Novopen Echo[®] for the delivery of insulin: a comparison of usability, functionality and preference among pediatric subjects, their parents, and health care professionals. *J Diabetes Sci Technol*. 2010;4(6):1468–75.