

Analysis of Comparison of Patient Preference for Two Insulin Injection Pen Devices in Relation to Patient Dexterity Skills

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Abstract

Insulin therapy is the cornerstone of medical treatment for many patients with diabetes. Self-administration of this life-saving medication is no longer limited to the traditional vial and syringe. Instead, more and more patients worldwide are using prefilled insulin pen devices. Ease of use, convenience, confidence in dosing accuracy, and improved quality of life are just a few of their advantages. As with any medical technology, safe and proper use is vital. Many studies have examined pen device preference and usability. Until now, no study has included patients with both visual and dexterity impairments. To ensure safe and simple self-administration of insulin for all patients, it is time for the special needs of patients with diabetes to be considered not only during product development, but during postmarketing studies as well.

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The first insulin pen was introduced in the United States in 1985.¹ Pens were durable devices with prefilled exchangeable cartridges at that time. Newer pens are disposable, prefilled, all-in-one devices. Originally, only a few types of insulin were available in pen form. Now, not only do all manufacturers include pens in their product line, but almost all insulins are available in pen form. Dialing the dose has become a smoother process over the years, and fewer steps are involved. Number displays or dosing windows have become larger to improve dosing visibility. Injection force has also improved and permits virtually effortless administration. The first durable pen device on the market required a two-handed procedure to correct a misdialled dose without wasting any insulin. Now, all pens, durable and disposable, permit dose adjustment by simply dialing forward or

backward. Durable devices continue to require manual manipulation of the piston rod when changing the cartridge, a task never required with disposable pens.

Improvements in pen technology over the years have influenced their growing popularity. Today, nearly 30 years later, pen devices are becoming the standard method of insulin administration worldwide.² It is estimated that more than half of the 100 million people in the world who use insulin use a pen device.³ There are many reasons for this. From the patient perspective, these reasons include less fear of injection, ease and convenience of use, portability, social acceptability, confidence in dosing accuracy, improved glycemic control, and overall quality of life.⁴⁻¹⁶ From a health care provider perspective, reasons for prescribing pen devices include patient acceptance, ease

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of teaching how to use, improved medication compliance, decreased emergency room and physician office visits, decreased hypoglycemia events, improved glycemic control, and lower health care costs.^{8–10,13,15–18} Improved insurance coverage of pen devices has also made an impact on pen use. Now, most pens have excellent formulary coverage, making them more affordable than in the past.⁵

All patients with diabetes should be able to take advantage of insulin pen technology and its benefits.

Unfortunately, this is not always possible. Patients with special needs, such as those who are blind, have poor vision, and/or limited manual dexterity may not be able to easily or safely use pens. Some believe that the audible click heard with each unit dialed on most pen devices can help with preparing a correct dose. This feature, if accurate, can benefit those with visual deficits. However, manufacturers discourage this practice. Moreover, user guides include a disclaimer specifically discouraging pen use by those who are blind or visually impaired without the assistance of a sighted person.^{19–20} Two studies evaluated the potential benefit of the audible clicks.^{21–22} Both concluded that this feature may be able to assist patients with visual impairments to confidently and accurately dial a dose of insulin.

A closer look at the demographics of the diabetes population further emphasizes the importance of addressing product deficiencies for those with special needs. Currently, almost 19% of adults diagnosed with diabetes in the United States have some form of visual impairment.²³ It is estimated that “74% of people who have had diabetes for 10 years or more will develop some form of diabetic retinopathy.”²⁴ Worldwide, 2.5 million people are affected by this microvascular complication, and it is the leading cause of vision loss in adults.²⁴ Also important to consider is the aging of the diabetes population as a whole. Today, the largest age group affected by diabetes is between the ages of 40 and 59, but by the year 2030, the largest group will be the 60–79 year age group.²⁵ The natural aging process itself impacts vision and fine motor skills and adds to the visual deficiency plight. Altogether, the significance of considering patients with vision and dexterity limitations during product development and postmarketing studies is evident and key to ensuring safe insulin administration.

A study that specifically evaluated patient limitations and their impact on pen preference and usability is presented in this issue of *Journal of Diabetes Science and Technology* by Pfützner and colleagues.²⁶ The investigators’

primary objective was to determine if patient preference is influenced by dexterity skills, with and without visual limitations. The secondary objectives included the impact of dexterity and cognitive function on ability to use the devices correctly. Both type 1 and type 2 diabetes patients were included in the study. The two devices used in the study, InnoLet[®] and FlexTouch[®], are both manufactured by Novo Nordisk A/S, Bagsvaerd, Denmark.

Although the InnoLet is categorized as a pen device in this study, it is not a pen by design. Instead, it resembles a traditional kitchen timer with a “handle”. The handle houses two compartments: the insulin reservoir and needle compartment. The InnoLet, described by the manufacturer as an “easy-to-use-doser,” was designed with a large ergonomic dial and black numbers on an off-white background specifically to assist those with poor vision and limited manual dexterity.²⁷ No other insulin device makes this claim.

The FlexTouch, on the other hand, is the newest pen innovation by Novo Nordisk. This second-generation disposable pen incorporates a built-in spring extension injection mechanism that eliminates the push button extension seen with other pens.²⁸ Regardless of dose, the injection process involves only light touch to deliver the insulin. With this design, the injection force is driven by the spring rather than the patients’ thumb, a feature that can help those with dexterity challenges. With all other pens on the market, the larger the dose of insulin, the higher the extension of the push button. This causes larger doses to be difficult to perform for those with limited hand dexterity.

While it is commendable that the authors specifically focused their study on patients with special needs, neither product evaluated is currently available in the United States. The InnoLet was retired from Novo Nordisk’s product line in December 2009 due to low usage. On the other hand, the FlexTouch has yet to be introduced in the U.S. market. A comparison of the FlexTouch against another device with a true pen design and one that is available in the U.S. market would provide more meaningful practice implications for health care professionals and patients once it is available.

It is refreshing to review a study aimed specifically at understanding the impact of visual and dexterity impairment on pen preference and usability. Knowing that the InnoLet was designed for this patient population, the authors anticipated that it would be the device of choice. However, this did not happen. The FlexTouch

was preferred in all subgroups, including the visual impairment group. This leads to the question of how vision was assessed and what constituted visual impairment in the study. These details were not discussed and could provide additional insight into the results. This is especially true when a closer look at the results identify the few that did prefer the InnoLet as those with the greatest visual and dexterity impairments.

Regardless of preference, a patient's ability to administer a dose of insulin safely and accurately is imperative. Acknowledging this, the investigators also assessed injection technique by having subjects complete mock injections. The results showed a considerable amount of errors (more than 1/3 of patients) with both devices in all groups. This demonstrates the importance of proper patient training and ongoing reassessment of injection technique to ensure safe and accurate medication administration.

In summary, the study completed by Pfützner and colleagues²⁶ is one of the first to investigate preference and usability of pen devices in patients with visual and dexterity limitations. Future studies of diabetes technology should follow suit, as they provide health care professionals with a better understanding of how to best care for patients with these special needs.

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