Brief Communication

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Evolution of Delivery Devices

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Introduction

To overcome some of the problems of vial and syringe use and to facilitate patient acceptance of, and adherence with, multiple intensive injection regimens, a variety of pen injection devices have been developed. The world's first such insulin pen was NovoPen®, which was introduced in 1985 and has helped to revolutionize the treatment by making everyday therapy more convenient, simpler, and more painless with increasingly thin pen needles. Since the introduction of NovoPen®, other durable insulin pens have been developed by various manufacturers, including the NovoPen® family of insulin pens, the most recent of which are NovoPen® 4 and NovoPen Echo®.

A range of prefilled insulin pens are also available for diabetes management. The world's first prefilled insulin pen to be launched was NovoLet® in 1989, and more modern prefilled devices, such as Next Generation FlexPen® and FlexTouch®, have since been developed.

Despite the advantages of pens over vials and syringes, there are many issues that can reduce the ease of pen use and that may affect adherence to regimens. These include the need to reduce injection-site bruising, injection force, and the length of the push-button extension on pens, which may make it difficult to inject with or manipulate among people with small or weak hands. This may also reduce the flexibility of the user, as they must depress the push-button with their thumb and usually with their dominant hand. Other factors that may hinder pen use among some patients are a lack of awareness, perceived cost, and reduced confidence in the device.

FlexTouch® is the latest developed prefilled insulin pen and has distinct advantages over existing prefilled devices: i) It has no push-button extension, ii) it has an easy-touch button, iii) the dial resets to zero, and the patient may hear or feel a click, iv) which improves patient confidence in full dose delivery, v) accurate and consistent dosing from 1–160 units, and vi) it is available with NovoTwist®, NovoFine®, and NovoFinePlus®, which permit easy and simple needle attachment.

Novo Nordisk Device History

The development of our devices for insulin delivery therapy has been a long and innovative journey (Fig. 1). It began with the companies Novo and Nordisk Gentofte, which merged to become Novo Nordisk in 1989.

The importance of the delivery device as a means of connecting insulin with the patient has been acknowledged by Novo Nordisk for many years.

As seen below, the overall device evolution has been driven by the continuous improvement of earlier devices, as well as research and development and customer feedback. Below is a timeline of the major milestones of the device business.

People with diabetes that require insulin injections have a significant responsibility for managing their own treatment. Even excluding any concomitant oral therapies, the process of injecting insulin involves a number of tasks, such as measuring the blood glucose level, assessing the timing of insulin injections relative to meals, and performing the insulin injection itself. The insulin injection involves several steps from attaching the needle to detaching the needle, and these steps must be performed correctly to ensure the proper delivery of insulin tens of thousands of times

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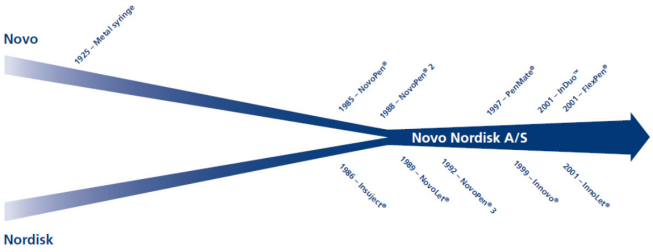

Fig. 1. Novo Nordisk Device History.

Fig. 2. Various pen devices of Novo Nordisk.

in a lifespan.

The pharmaceutical industry has developed numerous delivery devices to help patients with diabetes manage their disease. To date, the most popular and successful method remains subcutaneous injection. However, the way in which patients can deliver this injection has been the focus of much innovation and development.

Pen devices simplify insulin administration, making the injection procedure easier and quicker and dosing more accurate; other advantages include reliability, durability, convenience, discretion, and improved flexibility (Fig. 2). Pens are also more portable and less conspicuous, and so they may improve the social acceptability of insulin injection for some patients compared with conventional vials and syringes.

Insulin pens are compatible with NovoFine® needles, which are short, thin, and coated to reduce pain on injection, and they may reduce bleeding and bruising relative to longer and thicker needles. The introduction of NovoTwist® has offered greater ease of use with its just-twist attachment.

Development Goals

1. Convenience – Easier to use
2. Safety – More discreet and accurate
3. Adherence

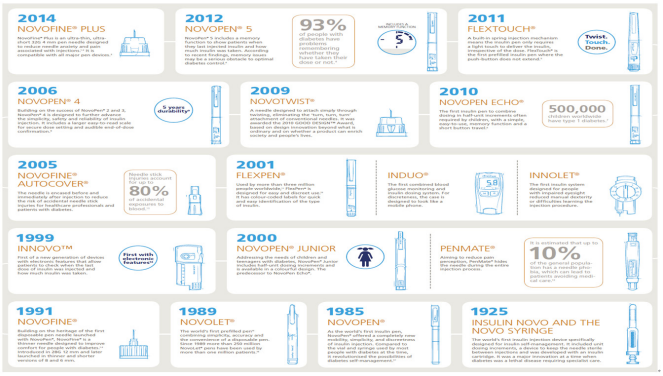

Fig. 3. Advenced in injection devices.

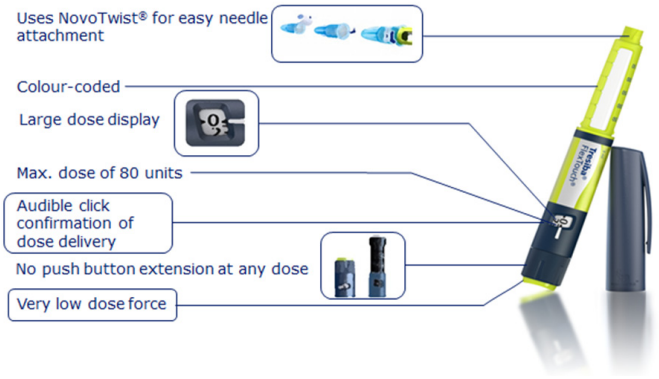

Fig. 4. FlexTouch®.

We Continuously Develop Ideas to Create New Devices as Follows

1. Idea
2. Developing the concept
3. Plan and investment decision
4. Engineering and prototyping
5. Pilot production and clinical trials
6. Marketing plan
7. Ready for launch

Advances in Injection Devices (Fig. 3)

FlexTouch® is a novel prefilled insulin delivery pen, which is the latest innovation, with the following features (Fig. 4):

1. Only a prefilled insulin pen with no push-button extension.
2. Easy-touch button.
3. The dial resets to zero, and the patient may hear or feel a click, which improves patient confidence in full dose delivery.
4. Accurate and consistent dosing from 1–80 units with U 100

and 1-160 units with U 200.

5. Available with NovoTwist® and NovoFine®, which permit easy and simple needle attachment.

The Future of Pen Devices

1. Dosing
   - Precision
   - Automatic
2. Handling
   - Ease-of-use
   - Activation force
3. Size and look
   - Accommodated to market needs
4. Quality of life
   - Lighter and more seamless

Conclusion

There has been an ever-changing paradigm shift in diabetes management. Innovation is the key at every stage for subjects to adhere to definite therapy in diabetes management. Patient-centered development goals boost the evolution of disease management.