CAN WEARABLE DEVICES BRIDGE THE GAP BETWEEN PEN INJECTOR AND PUMP?

In this article, Steven Kaufman, Vice-President of Drug Delivery Systems, and Paolo Golfetto, Drug Delivery Systems Business Development Director, both of Stevanato Group, explore the potential for wearable injectors to be disruptive technologies in the drug delivery market.

As we consider the drug delivery market today, there is a convergence of trends pointing towards a demand for innovative device solutions that can administer medicine reliably, monitor compliance and improve patient quality of life. This is providing fertile ground for disruptive technologies to emerge that offer new levels of functionality and usability – even in a therapeutic area such as diabetes, that helped to pioneer the use of self-injection systems.

> "A new category of wearable products is emerging, bridging the gap between functionality and cost, while introducing improvements to patient safety and quality of life."

DIABETES GROWTH RATES

According to the International Diabetes Federation (IDF) Diabetes Atlas 2018, the global diabetic population is expected to grow by 48% per year between 2017 and 2045. Global trends show how diabetes incidence will rise much more in low- and middle-income countries than in high-income countries: India is predicted to have the highest growth in absolute values (+70 million diabetic people), moving from second in 2017 to first in 2045 in terms of diabetic population, while the North Africa region will almost double with a 106% increase, and China will move to having 119 million people with diabetes.

DEVICE LANDSCAPE

The landscape of devices used to deliver insulin has traditionally been divided into two categories: pen injectors and vials/syringes on one side, and insulin pumps on the other. Each category offers different levels of functionality and usability at a very different therapy cost.

At present, for patients who inject insulin, approximately 95% of those receiving treatment for Types 1 and 2 diabetes use a syringe or pen injector. Patients on multiple daily injection (MDI) therapies for Type 1 and Type 2 typically require 3–5 injections of insulin a day. Administration requires several, non-discreet preparation steps that can lead to patients delaying therapy to avoid injecting in public.

The frequency of injections can also be difficult to track, leading to missed doses or even double doses. Monitoring patient compliance is difficult for doctors, making it hard to make effective adjustments to treatment. These challenges are compounded when administering injections to children.

Compared with pen or syringe systems that only dispense discrete doses of insulin, pumps are intended to deliver insulin continuously at an adjustable flow rate, are therefore better suited for complex therapy

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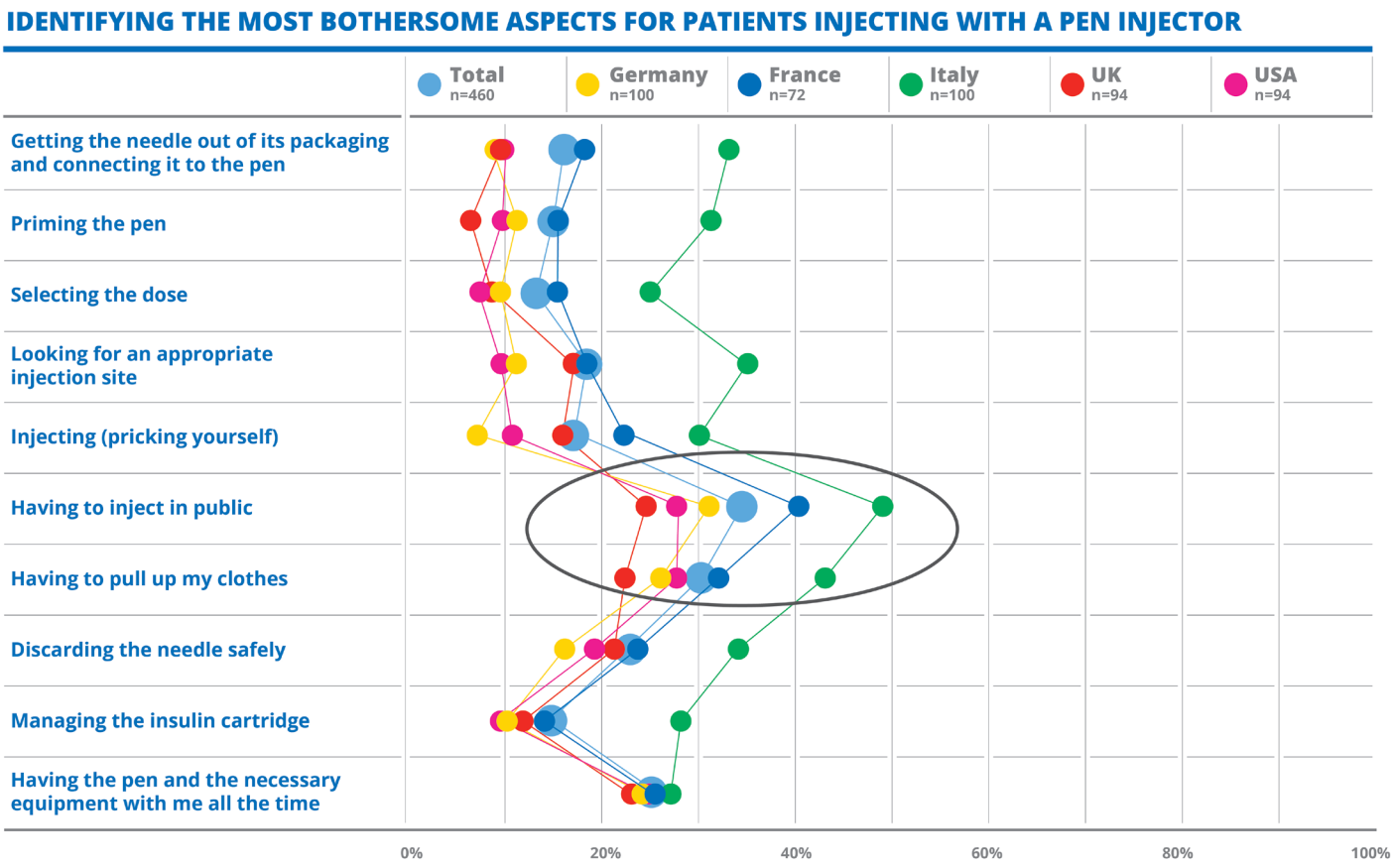

Table 1: A quantitative survey by Curth & Roth performed in 2017 for Medirio, a Stevanato Group company, shows diabetic patients using pen injectors objected most to having to inject in public and having to pull up their clothes.

regimens, and are typically adopted for Type 1 diabetes. The electronics and software architecture of the device gives patients and healthcare professionals better monitoring capabilities – and the ability to conceal the device is preferable for patient quality of life and compliance.

However, preparing the pump for use requires a more complex handling process, including programming the device correctly and transferring the drug to an internal reservoir. Ensuring the pump delivers a small and precise dose brings an increase in the device development and manufacturing costs. With an annual cost of therapy that is more than double that of a pen injector, many countries will only reimburse a pump system for Type 1 diabetes.

THE PATIENT EXPERIENCE

A quantitative internal survey was conducted in 2017 by the agency Curth & Roth for Medirio, a Stevanato Group company, involving a sample of 960 participants aged from 20 to 65. The survey was conducted in Germany, Italy, France, UK and the US – and included 460 diabetic patients and 500 professionals including nurses/educators, internists, diabetologists and endocrinologists.

The survey (Table 1) showed that insulin-dependent people who used pen injectors objected most to:

1. Having to inject in public
2. Having to pull up their clothes.

Besides discretion, other concerns included the fear of needles and of painful injections, which was reported mostly by new insulin users. Many patients expressed shock at the lifestyle changes required, continually having to carry medical supplies and ensuring that insulin doses were accurate and never missed. The feedback provided an insight into the desire of patients to be able to live with regular medicinal treatment while still having an active and social lifestyle.

WEARABLES – BRIDGING THE GAP

A new category of wearable products is emerging, bridging the gap between functionality and cost, while introducing improvements to patient safety and quality of life. One example is the cartridge-based wearable device currently under development by Stevanato Group, which received Best Innovation in Drug Delivery Device award at this year's Pharmapack event in Paris (Figure 1). The product comprises a disposable, wearable pod and an intelligent, reusable handheld controller that serves as the user interface and control unit for the pod (Figure 2).

Figure 1: Stevanato Group's cartridge-based wearable device received the Best Innovation in Drug Delivery Device award at this year's Pharmapack event in Paris.

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Figure 2: The reusable handheld controller activates the disposable pod, bridging the gap between the functionality of pump technologies and the cost of pen-injector technologies.

"The ability to track and share injection data can help to improve patient adherence and therapy outcomes."

By separating the drug delivery system's mechanical components into a disposable pod, and the electronic components for dose selection and verification into a reusable handheld controller, this new self-injection device can bridge the gap between the functionality of pump technologies and the cost of pen-injector technologies. The system has several features that have been carefully considered from an end-user perspective (Table 2).

PRODUCT HANDLING

In terms of handling the product, the user – or the healthcare provider, if used for other non-insulin therapies – first inserts the factory-sealed, sterile cartridge into the pod (Figure 3). This is designed to be intuitive, easy to use and quick. The patient then removes the backing to an adhesive sticker and places the pod on the body. This can be done earlier than required and then activated later during the day.

Once attached to the body, the user triggers the cannula insertion with the controller and the system is ready to begin injection. Then, for each dose required, the user selects the dose using the handheld controller. The user then places the controller in proximity above the pod to mechanically activate the injection. The pod unlocks and receives energy to begin the drug delivery. Injection durations can last up to 10 seconds and the pod remains attached to the skin for up to 72 hours.

ADVANCING THE INDUSTRY

Thanks to its innovative yet simple technology, this system provides new levels of comfort, convenience and discreetness that can improve patient quality of life in therapeutic areas (TAs) other than diabetes. The handheld controller uses magnetic coupling to manage the interaction with the pod and, thanks to Bluetooth connectivity, it allows injection data to be exchanged.

The ability to track and share injection data can help to improve patient adherence and therapy outcomes. Stevanato Group is currently evaluating how additional features and customisations could be integrated for different TAs, such as:

- Hormone therapy
- Pain relief
- Alzheimer's disease
- Rare/orphan drugs.

Since these TAs may require a different user interface or different ways for doctors or pharmacists to prescribe the device to

PATIENT BENEFITS OF THE STEVANATO GROUP CARTRIDGE-BASED WEARABLE DEVICE

Features		Patient Benefits
POD	Pre-filled glass cartridge	No drug transfer
	Highly tolerant adhesive	Comfortable to wear for extended periods (for a maximum of 3 days), increased wearable stability
	Light-weight	Increased comfort during travel and physical activity
	Integrated, flexible, soft canula	Minimized number of handling steps for canula insertion, minimized pain of injection and removal of needle-stick injury risk
	Flat profile, small dimensions	Discreet and easy to conceal
	Disposable	No maintenance, minimal waste of components
CONTROLLER	Activates pod through clothing	Increased discretion and convenience
	Logs injection data	Ability to track and manage therapy
	Dose selection verification	Avoid over-dose, double-injections or missed injections

Table 2: Patient benefits of the Stevanato Group cartridge-based wearable device.

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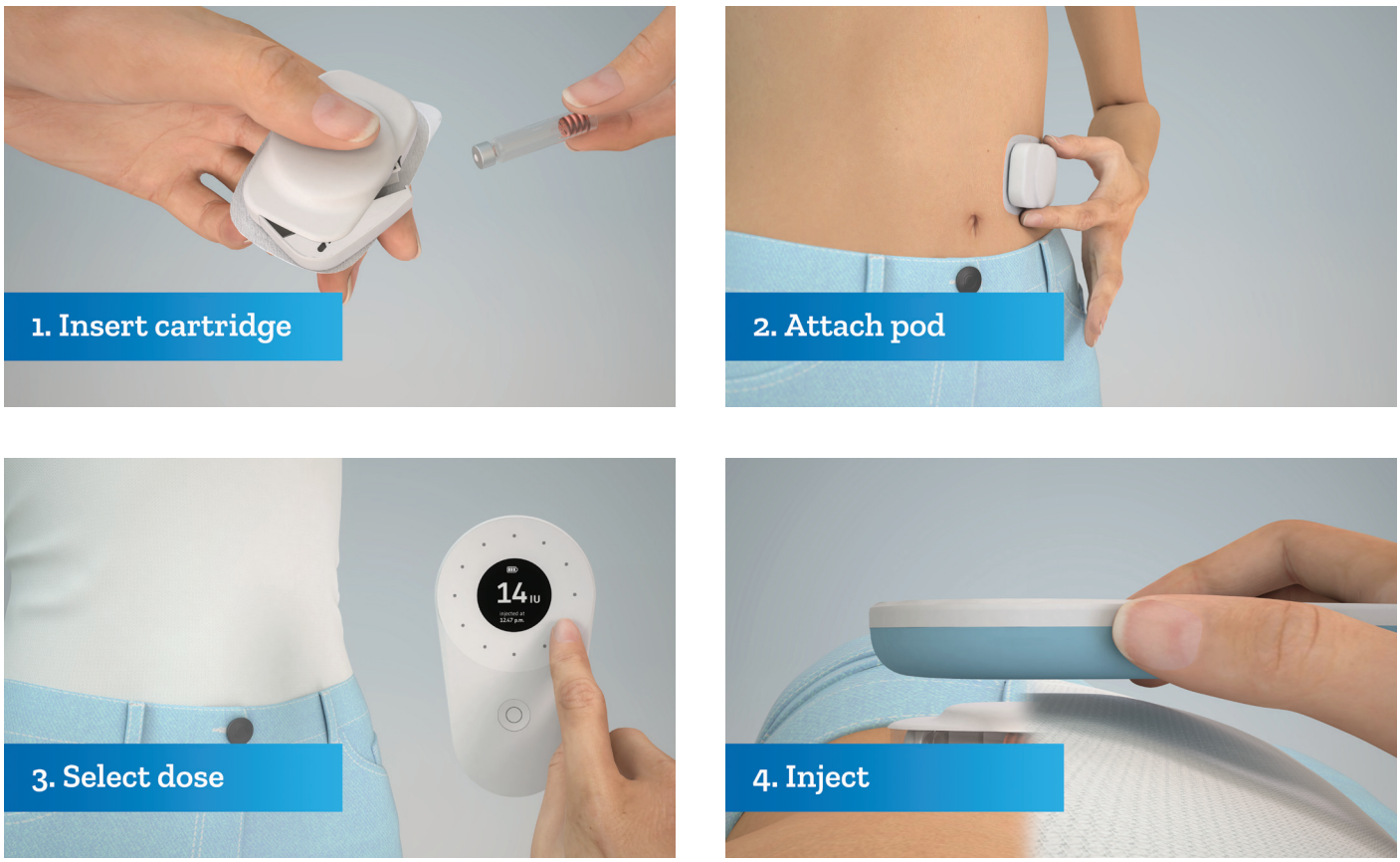

Figure 3: Steps to activate the self-injection cartridge-based wearable device by Stevanato Group.

patients, a thorough case study needs to be developed around the device, according to each different area, in co-operation with biopharma partners. Thanks to its integrated capabilities, Stevanato Group can manage the product development up to industrialisation as well as having the ability to add customisation.

DEVICE MANUFACTURING PARTNER READINESS

Bringing a device to market is complex. Biopharma companies are required to work with a range of specialty service providers in manufacturing, primary container, equipment and so on. Having one partner that can offer the required capabilities and services under one roof – from the container closure system to the assembly technology – is a key advantage to help ensure manufacturing readiness and reduced time to market.

Stevanato Group provides a range of flexible, scalable capabilities to handle device projects such as safety systems, pen injectors (Figure 4), autoinjectors, wearables and inhaler systems – whether it's done with proprietary IP developed by Stevanato Group or when Stevanato Group is acting as a contract manufacturer to produce the devices of biopharma companies.

Services range from designing, producing, testing and controlling a glass container's integrity to the integration of ready-to-use prefillable syringes and cartridges into the ever-increasing number and range of drug delivery devices. Stevanato Group provides precision injection moulding and tooling, and product development services, within an ISO13485 quality system at US FDA-audited facilities.

Flexible, modular sub-assembly and final assembly and packaging of medical devices is carried out, with inline quality control to ensure final product quality. Stevanato Group is well positioned to optimise performance of the entire system, with one point of contact and responsibility for the customer.

Figure 4: Flexible and modular assembly line developed and produced at Stevanato Group for pen injectors.

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Since the 1990s, Stevanato Group's high-performance glass primary containers – whether they're syringes, cartridges or special formats – have been used effectively in a number of devices on the market today. With the acquisition of further knowledge in injection moulding and tooling – as well as the incorporation of inspection, assembly and packaging capabilities – the company is now looking forward to bringing its wearable device and other self-injection devices to market to support the needs of biopharma customers, in co-operation with its partners.

ABOUT THE COMPANY

Established in 1949, Stevanato Group is the world's largest privately owned designer and producer of glass parenteral packaging for the pharmaceutical industry. From its outset, the group has developed its own glass converting technology to ensure the highest standards of quality throughout the production process. It comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass primary packaging with its historical brand Ompi, to high-precision plastic moulding equipment, to engineering machines and lines related to glass converting, visual inspection, assembly and packaging. The group also benefits from the SG Lab that provides technical and analytical services to study container-drug interactions and guarantee drug integrity.

ABOUT THE AUTHORS

Steven Kaufman is Vice-President of Drug Delivery Systems at Stevanato Group. He is responsible for managing the business development, proposal management and project management as well as the strategic initiatives of the drug delivery systems business. He has been active in the drug delivery device field for more than 15 years, working with leading multinational biopharmaceutical companies to provide pen injectors, autoinjectors and wearable injection systems, as well as test equipment, assembly equipment and final device assembly services. Mr Kaufman has a Master of Business Administration with an emphasis on marketing and international business.

Paolo Golfetto is the Director of Business Development, Drug Delivery Systems at Stevanato Group. In his position, he leads the development and execution of the business strategy in the drug delivery system field, supports the external technical communication of the global product platforms and manages project acquisition and transfer to the internal development structures, securing the integration of the different capabilities of the group.Before taking this position, Mr Golfetto was the Primary Packaging Development & Customer Care Director, leading new glass packaging introduction and technical support to the group's biopharmaceutical clients. Mr Golfetto is a PDA member and lecturer.

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