Subcuject

STABILITY OF A WEARABLE INJECTOR POWERED BY OSMOSIS

Here, Jesper Roested, CEO, Subcuject, and Tomas Gundberg, Design Engineer Consultant, present engineering test data on Subcuject's wearable bolus injector, based on an osmotic drive system, demonstrating that the device presents a solution to the need for an inexpensive, mass-producible wearable injector.

THE FIELD OF WEARABLE BOLUS INJECTORS

The up-and-coming field of wearable injectors for injection volumes over 1.5–2 mL can presently be differentiated into two broad categories:

- High-end wearables that use electromechanical drive systems and commonly come with connectivity options, at the expense of relatively high complexity, high cost and large size.
- Low-end user-fillable wearables that are small and suitable for non-predefined injection volumes.

These two categories leave a clear gap in the market. Similar to the autoinjector space, the available wearable product range lacks a prefilled, simple-to-use and inexpensive wearable bolus injector designed to fill the role of a low-end product to be produced in bulk.

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Subcuject is developing such an inexpensive, prefilled wearable injector, based on osmosis as the driving force. It is now demonstrated that the base technology is indeed a feasible product, delivering consistent performance and that endures viscosities up to at least 100 cP.

THE COMPLICATIONS OF DEVELOPING A LOW COST, PREFILLED WEARABLE INJECTOR

A wearable bolus injector is characterised as a subcutaneous injection device that is attached to the body for the duration of an injection, often several minutes, during which the drug is injected at a low flow rate in order to avoid pain. The viscosity of the injected drug is often high, and one of the challenges in developing a wearable injection device is that the delivery mechanism requires quite a high amount of energy, which must be stored for the device's shelf-life. A further complication is that the energy must be released slowly and deliberately during injection. An ideal wearable injector must be acceptable to

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wear whilst attached to the body, which calls for a small size and that the product is as easy to prepare, activate and dispose of, as with a prefilled autoinjector.

In order for a wearable injector to be commercially viable in volume, it also needs to be as inexpensive as a prefilled autoinjector. Furthermore, in order not to jeopardise drug stability during shelf life, primary packaging components that come into contact with the drug must preferably be well known. Delivered dose accuracy and consistency is important, but in contrast to insulin pumps that require a very exact flow rate, the flow rate for a wearable bolus injector is less important. Thus, depending on the drug, it is less important if it takes, for example, five or seven minutes for the device to deliver the dose, as long as the injected volume is accurate.

Osmosis As A Driving Force

An actuator driven by an osmotic pump mechanism has many of the characteristics wanted for a low-cost device:

- It is inexpensive (energy is provided by means of salt and membranes)
- The energy is released slowly
- It has the ability to deliver a high pressure.

Further to these benefits, the excess water from the actuator can be used to provide a simple, compact and sophisticated hydraulic plunger pushing mechanism. However, the challenge of using osmosis as the driving force in an actuator lies in the concept being new for use in injectors and, thus, implementing the basic power concept in a practical, manufacturable solution.

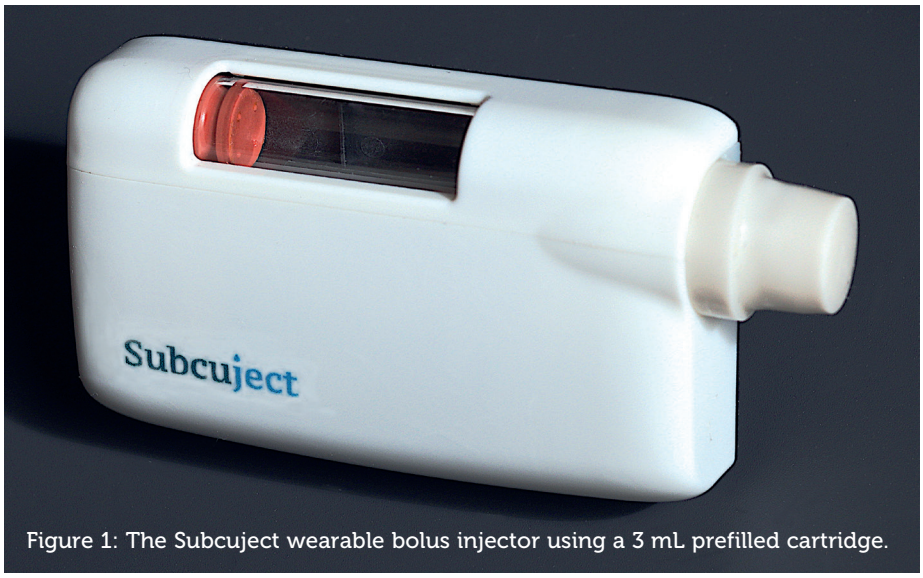

Figure 1: The Subcuject wearable bolus injector using a 3 mL prefilled cartridge.

Figure 2: The 3 mL Subcuject device attached to the body.

THE SUBCUJECT PRODUCT

The Subcuject wearable bolus injector is designed to be prefilled with drug from the manufacturer, of a small size and as simple to use as a prefilled autoinjector. Furthermore, it is designed to be low cost and to use standard primary packaging components (i.e. standard glass cartridge and a rubber stopper). The current moulded prototype shown in Figures 1 and 2 is based on a 3 mL cartridge.

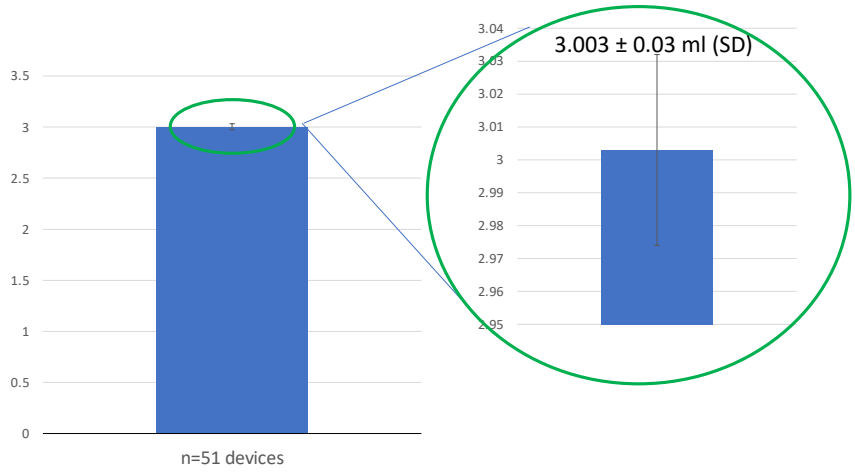

Figure 3: The Subcuject device's dose delivery consistency from a 3 mL cartridge.

Performance Consistency

The Subcuject product is currently in the late stage of concept development, and it has now been demonstrated that the product can be made repeatably as moulded single-use devices, with a very consistent delivered dose of 1% standard deviation over 3 mL (Figure 3).

The injection time is repeatable, and the injector can overcome high viscosities and high back pressures (Figure 4). The average injection time for 1 cP (water) is about four minutes, 50 cP takes five minutes and 100 cP takes about five and a half minutes.

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The time for injection against an extreme condition of 10 psi is about six minutes. These data demonstrate that the wearable injector can generate a high force and that high viscosity has limited impact on injection time.

The flow rate profile is likewise consistent during the injection. A typical flow profile of a 100 cP viscosity injection is shown in Figure 5.

As described, the results show that the base technology is powerful and consistent when implemented in a single-use device. All data on injection time discussed in this article were collected with the cartridge facing upwards, as when the device is attached to the abdomen in a standard-use position, but the dual membrane geometry used in the device ensures a similar injection time for all other possible positions. Tests with 1 cP were performed with a G30 needle and tests with higher viscosities use a G27 needle.

Outlook And Availability

The Subcuject wearable bolus injector will be ready for the first drug development combination programme in 2020, in partnership with one of the global top-tier contract development and manufacturing organisations.

The first commercial version is now being designed for a 5 mL glass cartridge.

ABOUT THE COMPANY

Subcuject develops an innovative and proprietary device platform for wearable bolus injection. The company is organised as a virtual organisation, working closely with external experts and specialist organisations. The management team and board of directors have decades of experience and a track record in medical devices, pharma and drug delivery. The company is located north of Copenhagen, Denmark and is privately held.

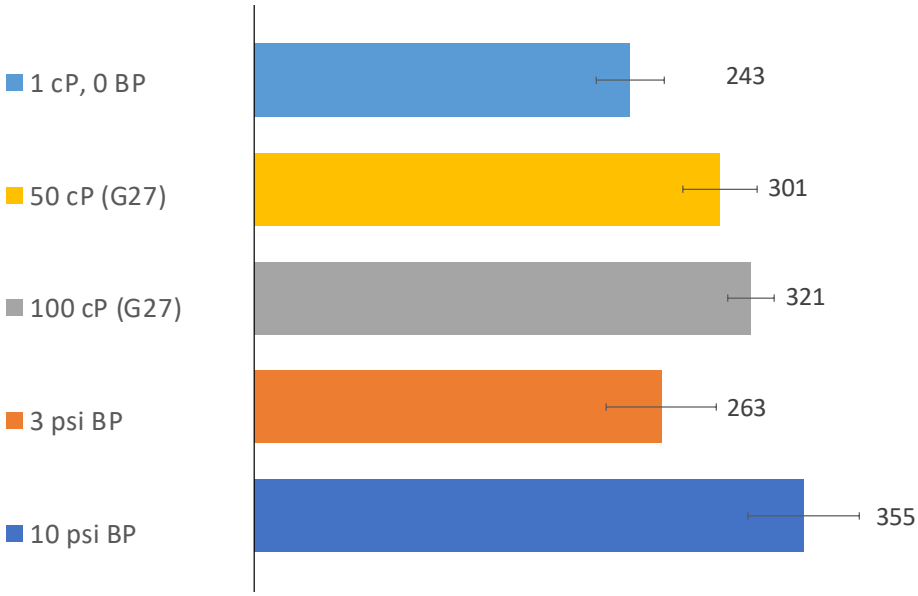

Figure 4: Total injection time (seconds) under various conditions using the Subcuject device with a 3 mL cartridge.

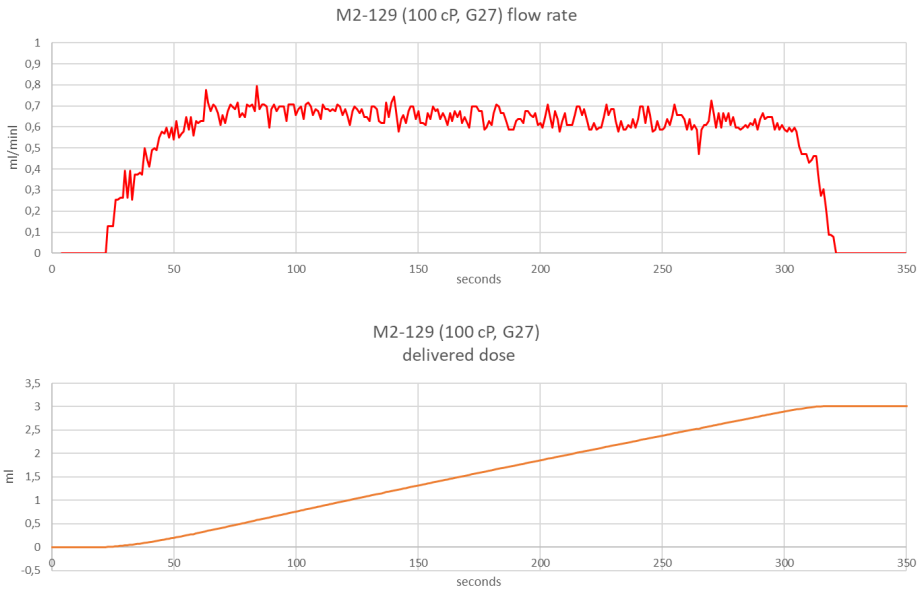

Figure 5: A typical flow rate profile of a 100 cP viscosity glycerol injection using the Subcuject device.

ABOUT THE AUTHORS

Jesper Roested holds an MSc in Medical Electronics and Physics and has 25 years of experience, most of which has been in business development and management roles in the life science industries. As part of his experience, Mr Roested spent seven years as a partner in a venture capital fund, specialising in medtech. Mr Roested has been CEO of Subcuject since 2018 and has been involved with the company since its formation in 2017.

Tomas Gundberg is an independent test and design engineer owner of the consultancy and workshop Fixit, based in Denmark. Mr Gundberg has been involved in the development of a large number of innovative medical devices with 20 years' experience in developing medical devices, of which about 12 years experience is in infusion sets and patch pumps. Mr Gundberg has been involved in the Subcuject project since 2017.