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Portal Instruments

Needle-free: solving challenges with viscous biologic self-injections

Portal Instruments' needle-free and digitally controlled device can help improve the patient tolerability and adherence of self-injections via a 'smart' needle-free drug delivery system.

The challenge with biologics

The advent of large-protein biologics enabled the creation of breakthrough treatments for many chronic conditions, and this represents a multi-billion-dollar market. However, challenges exist with the delivery of biologics: to be effective, these biologics often need to be delivered at high doses, but regulatory bodies impose limits on the injectable volumes of drug formulations. The result is high-viscosity drug solutions. High viscosity solutions, however, pose new challenges both at the technical level—for example, with respect to needle size and the force needed to administer the injection—and at the patient-comfort level, owing to increased pain, anxiety about 'doing it right', and potentially the need for repeated injections to achieve an effective therapeutic dose.

The challenge with needles

Patient adherence and persistence with injection-based chronic therapy regimes are notoriously low owing to, among other factors, needle anxiety and injection-related pain. Needle phobia, a condition officially recognized by the American Psychiatric Association in its *Diagnostic and Statistical Manual of Mental Disorders*, affects up to 10% of the population and is associated with a spectrum of mild to severe symptoms of distress. Because the condition is triggered by the presence of a needle, no easy solution to the problem exists beyond helping patients relax or avoiding injections altogether.

The Portal platform: a simple and 'smart' solution

Portal Instruments, founded in 2012, can solve some of these challenges with its needle-free, connected drug delivery device. The technology, currently being developed under a global licensing agreement with the Massachusetts Institute of Technology (MIT), allows for comfortable, fast and safe medication administration, including high-concentration and high-viscosity biologics (**Fig.1**).

The device also allows data related to drug, dosage, injection frequency and other relevant parameters to be collected automatically by the device and shared (as desired) with physicians or other health care providers and stakeholders. Insights into patient adherence and symptom progression will enable health care providers to more accurately assess the effectiveness of the medication and, if needed, make changes more quickly. The Portal solution gives clinicians the confidence to modify treatment, as they will have current and relevant insights into their patients' medication patterns.

Figure 1: Portal's connected, handheld, needle-free drug delivery device. This device is designed to deliver high-viscosity drugs quickly and precisely.

Cutting-edge technology

To allow the delivery of precise amounts of drug subcutaneously, the Portal platform leverages a unique intellectual property portfolio of patents for a jet-injector-based technology developed at MIT over the past ten years.

The Portal platform consists of an electromagnetic actuator controlled by a computer that generates a jet of liquid with a diameter that is about 1/3 that of a 27 gauge hypodermic needle, which is approximately the diameter of a human hair. It is this jet of liquid, which contains the drug of interest, that pierces the skin to reach the desired subcutaneous space, without the intervention of any physical component to puncture the skin. The effect for the patient is less pain sensation than experienced with a traditional needle and syringe.

The actuator enables precise control of the speed of the pressurized jet of liquid, thus resulting in accurate targeting of the desired subcutaneous space with the exact amount of drug needed. The high adaptability of the system further allows the jet-injection device to accommodate the delivery of low to very high liquid viscosities and drug concentrations without any changes to the device. The design of the device currently supports the subcutaneous administration of up to 1 ml of drug preparation in 0.4 s.

"The unique technology from MIT allows full control of the jet via a computer-controlled feedback mechanism, thus decreasing sensation when compared with needle and syringe," said Patrick Anquetil, CEO of Portal Instruments.

In collaboration with Sanofi, one of Portal's main corporate investors and development partners, Portal has developed a pipeline of proof-of-concept applications with various monoclonal antibodies (mAbs). In animal studies carried out with Genzyme, a subsidiary of Sanofi, comparison of pharmacokinetic (PK) and pharmacodynamic (PD) parameters for these mAbs—administered via traditional syringe-based delivery or the Portal platform—showed no significant differences in maximum concentrations recorded (C_{max}), time to reach C_{max} (t_{max}) and other PK parameters, or in clinical effect as determined by PD analysis.

"The Portal Instruments drug delivery system solves a problem often overlooked in the past, which is how to increase the patient tolerability of injection-based therapies, especially for chronic diseases," said Anquetil.

Partnering ahead

Portal's jet drug delivery platform provides a unique opportunity for large and small companies advancing their therapeutic biologic pipelines to achieve maximum differentiation through optimized delivery of their products.

Portal's model is to grant partner companies exclusive access to its platform for a specific combination of drug, target and therapeutic indication. The deals are structured in a three-tiered manner: up-front and milestone payments, R&D monies, and royalties on final drug sales.

Portal is looking to develop strong partnerships with all major biologics players seeking to gain an edge by offering their therapeutics fully integrated with an optimum delivery system.

According to Anquetil, "Portal's goal is to partner with leading biopharmaceutical companies to enable them to deliver their biologics in a way that is tolerable and easy to use for the patient. We believe that our game-changing approach will enable our partners to better differentiate, provide insights to physicians and increase the adherence rate of their patient population, ultimately driving better outcomes."

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