‘Smart Devices’ vs. ‘Smart Design’:

Demonstrating the value of polymeric PDC technology upon user-centric autoinjector design.

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Over the past 20 years, there has been a shift in pharmaceutical pipelines towards the development of biologics, which currently make up a large percentage of drugs in development. Biologics now offer more targeted therapy with improved efficacy and safety, bringing a greater number of diverse user needs to the autoinjector market. Typically, the use of glass-based Primary Drug Container (PDC) technology presents challenges to achieving devices which fully address these diverse user needs. In recent years, smart technology has been used to alleviate the design freedom restrictions imposed by glass-based systems through supplementing the usability of autoinjector user interfaces. Below, we discuss how the polymeric PDC technology can support the development of user-centric devices which are more intuitive, minimise use errors and reduce the requirement for additional smart technology.

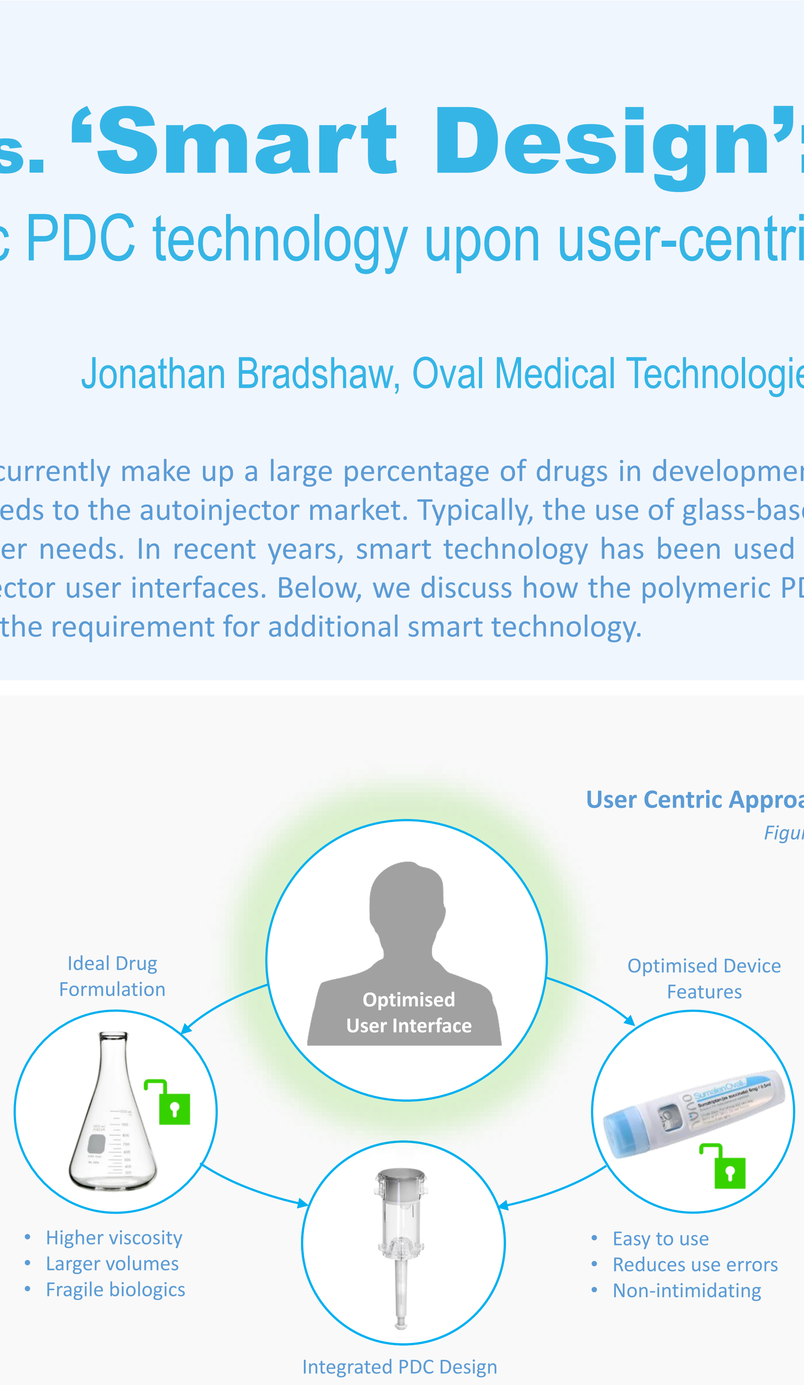
A truly user-centric approach

Today autoinjectors are used to deliver a variety of drugs to a wide range of patient populations, with innovations in biologics and long-acting injectables (LAIs) further broadening access. The differences between user populations can be vast and the needs per group unique. Patients with migraine may experience aura, causing visual impairment which hinders their ability to identify device features or text, whereas patients suffering from anaphylaxis may require administration from a user with good vision, but who are naïve with respect to autoinjector use. These diverse, and often conflicting user needs require full integration early in the development process to ensure the design of truly user-centric devices which promote correct, safe and efficacious use (Figure 1). A key component of this is being able to achieve an intuitive and well-considered user interface.

Currently, the use of glass-based autoinjector technology can limit the design freedoms available when developing a user interface (Figure 2). These restrictions can lead to compromises in device size, form and/or simplistic use steps, and an interface that is prevented from fully meeting the needs of its users.

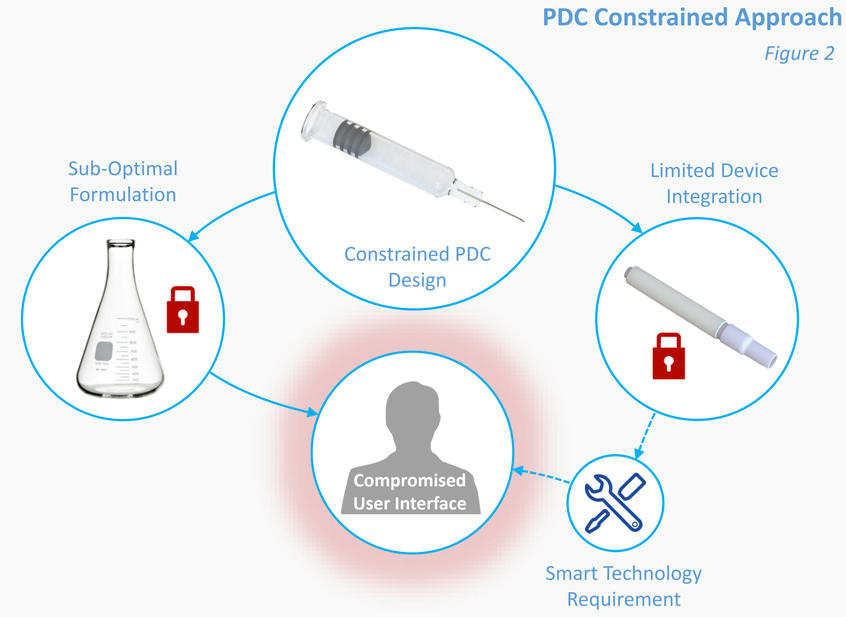
User Centric Approach

Figure 1



PDC Constrained Approach

Figure 2



Using Smart Technology Effectively

The integration of smart technology (ST) into medical devices offers significant opportunities for the holistic management of patient treatment, however there are many challenges to overcome before these opportunities become fully viable (e.g. patient confidentiality, IT infrastructure development and suitable feedback mechanisms). With the potential for significantly improved healthcare outcomes, and a consumer desire for ‘high-tech’ solutions, there exists a temptation to apply ST without first clearly defining a patient need that only ST can address.

For maximum effect, ST should complement a good design (e.g. as part of a data-driven personalised healthcare system). However, ST should not be used to compensate for any shortcomings in the design of a device (e.g. including electronic user guidance to avoid known use errors arising from a poor user interface). The application of ST can be categorised as follows:

1) Developed from the concept stage to meet a user need (e.g. the collection and analysis of patient data presenting the opportunity to better manage health outcomes), or;

2) Applied within the development process to compensate for design deficiencies (e.g. device guidance and support which reduces the impact of lay time for devices delivering LAIs).

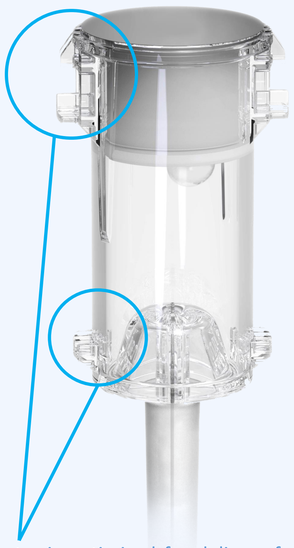
Although using ST for device guidance has certain useful applications (e.g. for crisis medications whereby naïve users may require additional support), use in other non-crisis delivery contexts could be better approached through intuitive user interface design. The input to a ‘Smart Design’ is a thorough understanding of user needs; the solution is fully integrated to ensure that the drug formulation and user interface are optimised for the user, and not constrained by predetermined technologies. This could include the implementation of ST where it has the potential to provide real value to the patient and other stakeholders.

Unlocking Design Freedoms

Polymeric PDC technology unlocks some of the constraints of glass-based PDC systems through facilitating an integrated approach to device design. The increased design freedoms provide the opportunity to overcome user interface weaknesses typically observed within glass-based PDC autoinjectors, creating a more intuitive, easy to use device with real value to the user.

Other benefits include:

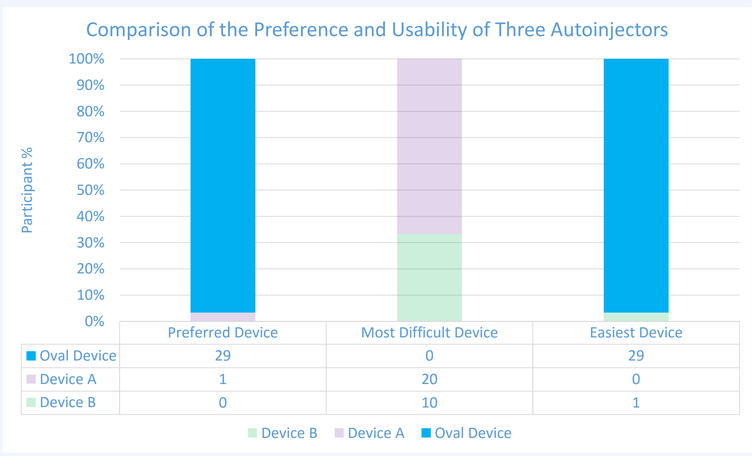
- Delivery speed consistency (reducing the risk of wet injections).
- Shorter injection times for viscous biologic formulations, without the risk of glass breakage.
- Improved user experience through smaller gauge needles.
- Needle depth consistency, optimising therapeutic outcomes.



PDC geometry is optimised for delivery forces and management of key device mechanisms and tolerances. This enables a simple user interface with a full range of features.

User Interface Validation

A comparative usability study evaluated the Oval device against two marketed autoinjectors (A & B). 30 participants performed a sub-set of tasks with the three devices using only the IFU. The errors they made, the time they took and their preferences were compared for the different devices. The results indicated that 96% of participants preferred the Oval device and operated it with fewer use errors. 77% of these noted that it was easier to use than the other devices. 67% of participants rated Device A and 33% rated Device B as the most difficult to use. Participants averaged 59 seconds to use the Oval device, compared with 2 mins 27 secs for Device A and 1 min 48 secs for Device B. 96% of participants believed the Oval device was the easiest to use with the best interface.



Optimising User Interface Design

PDC components can be moulded with features that directly interact with device mechanisms which can overcome issues such as device recoil, variable use forces and injection speed. This reduces the impact on the user, whilst ensuring all required user interface features are present (e.g. automatic needle insertion, end of delivery feedback and passive needle safety) without compromise to overall device size or usability.

The increased design freedoms available offer the opportunity to ‘tune’ a user interface to the needs of an individual patient population. Ultimately this leads to a device which is sympathetic to the needs of its users, whilst offering a full range of features.

Decoupling Drug and User Requirements

An important step towards producing a truly user-centric device is understanding the requirements of both the drug and user and integrating these early on within the development process. Drug and user requirements often conflict; the drug can require high forces for delivery, whereas users can require low force for activation. Using moulded PDC features, Oval’s subcutaneous platform actively decouples the drug delivery challenges from those of the user interface. The use of separate springs for needle insertion and for drug delivery reduces the risk of recoil and excessive force on the patient, whilst retaining the ability to deliver challenging formulations.