UNISAFE®: THE IMPORTANCE OF ROBUST DESIGN PREDICTIONS IN DEVICE MANUFACTURING

Here, Damian Holland, UniSafe® Design Lead at Owen Mumford, outlines how the design team went about creating a safer and user-friendly springless safety syringe – UniSafe® – which bypasses some of the problems associated with spring-based devices.

The global healthcare landscape is complex, and current changes in approach are driven primarily by the need to protect the end-user's health and safety.[1] With healthcare moving towards safety – accelerated by increased regulation scrutiny and healthcare reform – medical device manufactures are exploring new ways to protect end-users and healthcare professionals.

To respond to these conditions, advances in design and manufacturing technology are necessary. The requirement to achieve a market-ready device in an efficient and timely manner has encouraged medical device manufacturers to evolve quickly. In an increasingly competitive landscape the output achieved must meet the desired device specification, market regulations and end-user requirements all in one go.

However, in reality achieving this is not always straightforward. For medical device manufacturers and their partners, steps must be taken to simulate or predict the performance of a device ahead of production to minimise development risk.

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THE CASE FOR A NEW DEVICE

Injections have become one of the most commonplace medical procedures worldwide. Most injections are delivered by retractable and non-retractable safety syringes, which are activated through a spring component. Using a spring in safety devices has previously led to challenges. One issue is accidental activation, where a device may activate in transit; another is accidental underdosing, where it may be difficult for the user to confirm visually that the full dose has been delivered. This is common when a spring is placed at the front of the syringe barrel, obstructing the view.

The design team at Owen Mumford undertook an observation period and conducted research to identify the challenges facing healthcare providers and end-users. We responded to a requirement for an effective safety device, which the team met through the design and development of UniSafe®. The device would be springless, designed to work with existing, prefillable syringes, and offer a safe, comfortable experience to the end-user. A key design feature – the removal of the spring – would ensure that the end-user could clearly see the drug had been administered, whilst also allowing an easier view of the labelling without having to spin the syringe barrel.

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DESIGNING A NEW DEVICE

Working with an array of different materials and design specifications can present challenges, so research and analysis work is imperative in getting the device design correct. Close collaboration between project teams ensures our devices are designed for manufacture whilst still keeping end-user satisfaction in mind.

The first option explored when developing UniSafe® was to start with an existing, proven prefilled syringe and build a spring driven safety mechanism around it. This idea was quickly rejected on the basis that it may introduce other compromises to device performance. Another possibility was to design a completely new safety syringe and provide a brand new solution from scratch. However, this would mean the use of an unproven primary container, a prospect that would be considered unattractive by pharmaceutical companies. Furthermore, this idea would be difficult to integrate into existing filling lines, and would increase training requirements within the healthcare system.

It was clear that a new approach was required. To achieve a result that would meet end-user treatment needs and the requirements of the pharmaceutical industries, we had to combine forward thinking alongside data analysis to define the appropriate design.

Use of Computer-Based Simulation

The use of computer-based simulation helps any new design to be tested rigorously and ensures that a device will perform as required, both during manufacture and when received by the end-user. In the development of UniSafe®, undertaking stress analysis was a key component of this, and the use of Finite Element Analysis (FEA) allowed us to determine potential areas of stress and strain experienced by the device during use – permitting design optimisation before developing the concept further. One particular area of focus was the locking mechanism, which had to resist override forces after activation, as defined by our human factors assessments (Figure 1).

Next, we wanted to ensure that the parts required would fit together seamlessly, meeting design intent. Statistical analysis was undertaken to define the physical limitations and geometric tolerances of the components to balance device performance with process capability.

In order to determine if the design specifications would be achievable for the manufacturing process, we used known process capabilities to model and predict potential variations that could arise within the manufacturing process and thus modified the design accordingly to better accommodate these fluctuations.

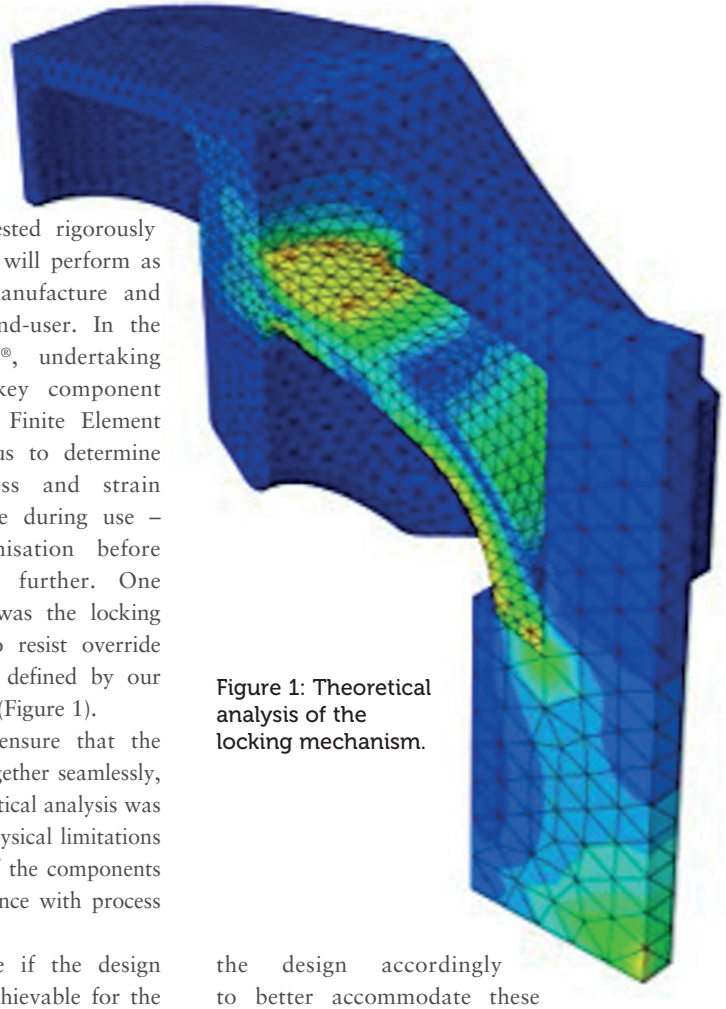


Figure 1: Theoretical analysis of the locking mechanism.

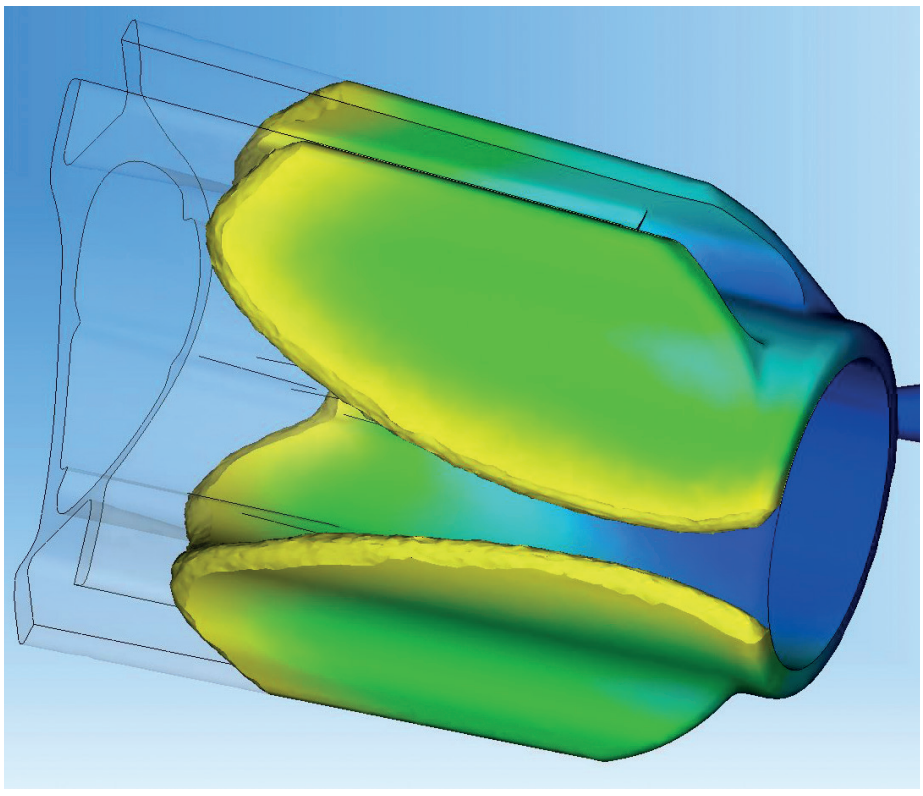


Figure 2: Computer simulation of the moulding process.

We also utilised computer-based simulations to analyse and predict the behaviour of the polymers during the injection moulding process (Figure 2). These simulations allowed us to identify how stable the component geometry would be after moulding and where any potential stress points may propagate, permitting further design iterations before placing tool orders.

However, it is vital that attempts to improve production viability do not compromise the quality of the product: an appropriate balance must always be maintained. Due to the low part count, minimal component interactions and overall simplicity of the UniSafe® design, it has been possible to achieve wide production tolerances without negatively affecting the performance of the device.

Of course, not all development work can be virtually simulated, so we also utilised our in-house 3D printing and external soft tooling capabilities to further test and iterate upon the design.

Refining the Device

Once the device's performance was deemed acceptable, the prototypes we created were used in human factors studies to identify

further improvements that could be made to better optimise UniSafe® for the end-user.

Early formative studies demonstrated that the safety plunger and finger flange did not offer enough support to the user, whilst activation needed to be improved as part of the passive safety feature mechanism. An effective design requires constant feedback, and this input fed into a further design iteration of UniSafe®. We increased the surface area of the plunger and flanges to improve comfort and a unique thread mechanism added to the passive safety feature mechanism made the activation smoother.

This rigorous prediction, testing and iteration cycle ensured that we could be confident in the device development, and that the benefits would be maximised for both pharmaceutical companies and end-users.

Building Simulation Into Product Design

The computer-based simulation techniques we use are constantly evolving. As we carry out ever more advanced simulation analysis on behalf of our manufacturing clients, we can help them to evaluate early designs and know what will and will not work in production. This phase of testing provides better guidance on potential issues in physical manufacturing ahead of committing to real-world investment.

ADVANTAGES OF UNISAFE®

UniSafe® is designed to improve patient confidence when injecting and to reduce any potential barriers to sustained treatment.

The device has a unique passive needle retraction mechanism, so the user does not need to take any additional steps to shield the needle after use. This reduces the risks associated with needle re-use and contamination, and provides additional protection for patients and healthcare professionals.

To improve comfort and user experience, UniSafe® has a larger, more ergonomic plunger head and a smoother, more integrated finger flange. This ensures that the end-user can operate the device confidently and intuitively, regardless of hand size, dexterity or condition. In addition, UniSafe® has been developed with an unobscured prefilled syringe barrel, allowing the user to view the drug and labelling without having to spin the syringe barrel, reducing the risk of underdosing.

> "The device has a unique passive needle retraction mechanism, so the user does not need to take any additional steps to shield the needle after use."

CONCLUSION

UniSafe® brings together our expertise across human factors testing, product design and manufacturing engineering to create an injection system that will help improve lives, reduce healthcare costs and deliver treatments more efficiently.

ABOUT THE COMPANY

Owen Mumford is a major medical device manufacturer that develops pioneering products for its own Owen Mumford brand and custom device solutions for major pharmaceutical and diagnostic companies. Owen Mumford's goal is to improve quality of life, encourage adherence to treatment programmes and reduce healthcare costs: making a world of difference, to a world of people.

With a history of world firsts in device solutions, Owen Mumford offers design, development and delivery services from a broad base of proven self-injection and blood sampling platform devices and intellectual property.

In business for over 65 years, Owen Mumford remains privately owned with a focus on long-term investment to deliver sustainable business growth. With a strong internal research and development capability, Owen Mumford's goal is to develop solutions that address today's healthcare demands. Through advanced research involving end-users and healthcare professionals, and extensive design and manufacturing capabilities, Owen Mumford produces class-leading medical devices that are used globally, exporting over 85% of its products to more than 60 countries worldwide.

Selected as one of The World Economic Forum's Global Growth Companies, Owen Mumford is a trusted partner to many of the world's biggest medical device, diagnostic and pharmaceutical companies and works with international organisations to support customers at a local level and provide consistent and dedicated support.

REFERENCE

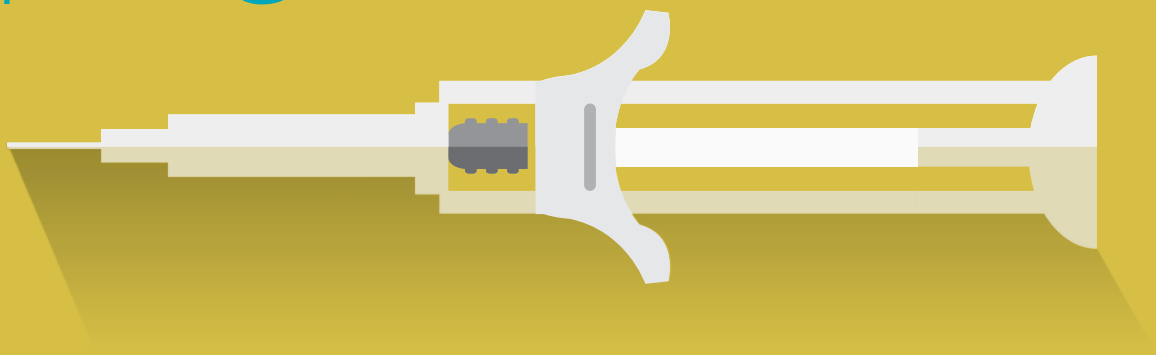
1. *Taylor K, Ronte H and Hammett S, "Healthcare and Life Sciences Predications 2020 A bold future?". Deloitte LPP, 2014. (www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-healthcare-and-life-sciences-predictions-2020.pdf)*

ABOUT THE AUTHOR

Damian Holland is is a design engineer at Owen Mumford and has worked in the medical device industry for four years. He holds a BSc in product design. His current role involves generating new device concepts and developing them through the whole product lifecycle, from initial idea to production.

UniSafe®

Safety is Springless



How can taking something away **make it more?**

Introducing the new UniSafe® springless, passive safety device

No spring means it's safe, reliable and cost effective.

Visit us at **PDA 2017, Stand X86** and take the "Assembly challenge" to be in with a chance to win an Apple Watch.

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