Material selection and an efficient development process for wearable injector drive systems

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Drive systems for wearable and automatic drug delivery devices are central to the patient outcome. Key to ensuring their value is materials specification, which helps achieve critical factors such as delivery precision, device reliability, and light weight for comfortable use. Material selection significantly impacts the industrialisation of the drive system too. Whether the design can achieve the right performance, at the right cost point, means focus on material choice is essential throughout a development project.

Portescap's Business Development Manager for medical applications, Dave Beckstoffer, explains.

In line with the increasing push from the pharmaceutical market to deliver biologics from devices that a patient can wear at home, demand is increasing on the drive systems that are powering drug delivery. While ensuring the drive systems achieve essential criteria relating to treatment efficacy, patient safety, as well as wearer comfort, the design must also optimise commercial viability. This means turning an effective concept into an industrialised product, from a CAD drawing and prototype, through to manufacturing scale.

Crucial to achieving a viable, industrial production drive system, is material selection, and the significance of the types of material used are far reaching. The selection impacts the performance of the device from the patient perspective, where competing design needs must be balanced. The material specification also depends on meeting medical device conformance, as well as ensuring effective integration with the actuation mechanism.

To optimise commercial viability, these material requirements must be carefully balanced to minimise cost. However, the materials used in the early stages of development, including prototyping, can differ significantly to those necessary for a final, production-ready design. Every iteration impacts the next, so this process must be carefully managed, avoiding deviations in material selection that can affect the delivery of the project overall, including the ability to efficiently industrialise a design. As a result, a guiding theme in drive system development is to focus on material selection at the earliest opportunity - and maintain this focus throughout.

Material selection on paper

As each drive and delivery system has its own requirements relating to factors such as drug viscosity through to the method of delivery, the design is typically customised. An overriding factor across all wearable and auto-injectors is the need for a compact form with low weight, in order to achieve patient ergonomic requirements. DC micro motors typically optimise these characteristics, such as a diameter down to just 10mm. However, the gearbox is often the larger component, especially when the design is integrated with an output drive mechanism such as a lead screw or a pump. As a result, the gear system and drive mechanism present the typical opportunity for customisation, and this includes material selection too.

In addition to size and weight requirements, the fundamental design needs, supported by material choice, include the efficacy and safety of drug delivery. This means that the drive system must ensure reliability, dependent on the required volume of delivery cycles and lifetime. Here, material choice is integral.

For example, plastic, such as polyphenylene sulphide (PPS) Ryton or Polyamide, may be a suitable material for use up to 100 hours, while applications with higher physical demands and lifecycles up to 3,000 hours would need a more durable selection. Metal, such as stainless steel, aluminium, or brass, is typically used in these instances. Dealing with day-to-day use, the delivery system must also be able to withstand accidental drops and impacts.

Designing for production

Efficacy and safety of treatment also depend on accuracy of delivery, and here too, materials are an important consideration. For continual frequency, 24/7 pump administration, moulded plastic components might be sufficient, whereas for infrequent, low volume dosing, metal machined drive components might be necessary to achieve accuracy of +/- 0.5%.

Keeping the patient at the fore also means that living with the device requires an efficient system that minimises energy use, enabling a smaller and lighter battery system. The device should also minimise audible noise, and the longer the lifecycle, the more important this is. While metal gears are typically more efficient, achieving lower friction losses, plastic gears are usually quieter, with reduced audible output during meshing.

Material demands can also impact conformance requirements, from common needs such as RoHS, REACh and Conflict Minerals, through to meeting manufacturing regulations such as ISO 13485 (Quality Management System for Medical Devices) and IEC 60601 (Medical Electrical Equipment Safety Standards).

To optimise the industrialisation of design, balancing the required criteria will help to guide material selection from a cost perspective. However, this figure doesn't just relate to the value of the raw materials, but includes the cost of the manufacturing process as well.

Design concepts and material choice

Designing the drive and delivery mechanism to achieve the best outcome for the patient, which includes specifying the ideal materials, is the right starting principle. However, the need to sequentially develop certain elements of the design, to varying schedules, means that the materials used at each phase will also likely change as the project progresses.

In real world development, a drug delivery design contractor, or the motion developer, needs to prove the concept to the pharmaceutical company. This stage will take place within a specific, and relatively short, timescale; the quicker it can be done, the faster the delivery device can be brought to market. To achieve this, initial decisions around material selection and parts design are often made based on speed and availability, rather than optimising for longer-term design objectives.
Off-the-shelf drive system designs might be used to confirm general requirements. Straight away, this means there can be a discrepancy between the materials involved in a conceptual test compared to those ultimately required for an industrialised product.

Prototyping

At this stage, 3D-printed parts are commonly introduced as well, with a short lead time a key advantage for the development of a low volume parts run. While it's possible to prototype a drive and delivery system in metal 3D print, commonly, plastic 3D printing is used because of advantages of simplicity, speed, and cost. While there will be limitations in the tolerances of 3D printed parts, material testing won't be a factor at this stage.

However, the key during the concept phase, as well as through the feasibility stage of development, is that it's important to make decisions around materials and designs that can be carried forward into industrialisation. This means that at the project's culmination, the desired material qualities, at high manufacturing scale, and at the forecasted cost point, can be achieved. If not, the deviation in material choice between design iterations can become restrictive towards meeting the final specification.

This challenge may only be realised, perhaps as late as the validation and verification stage, where the design is nearly set for confirmation. It will require either a rework of previous design steps, adding time and cost to the project overall while the design and materials are revised, or else it will mean that the final design objectives can't be met.

Moving from concept to production

The design process is complex, and there are a multitude of reasons for the industrialisation pivot point, which occurs when a design that is effective from a performance perspective fails to be commercially viable because of manufacturing capabilities or cost. Either the final part becomes prohibitively expensive to manufacture in the desired material, or else the specified material can't meet the intended tolerance.

Precision, machined metal parts may prove the concept, but may not be viable for the industrialisation of all drug delivery devices. Alternatively, plastic moulding can deliver high volume, economical manufacture, but it might not deliver the required tolerance if accuracy is vital.

Communication in design and materials specification

Key considerations include design and material changes to other components in the drive and delivery system that are made in isolation. From using metal components that could react to the motor's magnets, to the decision on whether to use plastic or metal parts in gearing and how this might integrate with the delivery system, material selections must be made in conjunction with each other. Similarly, commercial demands introduced during ongoing development could ask for a cost reduction, or for a shorter timeframe, on the procurement of specific parts. This should be met with a thorough examination of how this would impact material specifications, and the subsequent impact on other system components.

Ultimately, the only way to fully validate material selection for a given design is by testing products from the manufacturing run. Of course, in reality, this is too late, so the most effective means of achieving the right material specification is through the decisions that are made earlier on in the project.

Focus on the materials used, at every stage of development, is crucial. Supporting this, communication throughout all stages, between the pharmaceutical company, device design contractor, drive system developer, and material suppliers, is also

key. The more that the various aspects of the design process, including materials specification, are considered in parallel, the more efficient the entire process will be in achieving the optimised industrialisation of the drive system.

Image captions:

Image 1: With a design combining high power density and precious metal commutation, the 10NS61 can deliver a torque greater than 0.8 mNm continuously in a very compact package.

About Portescap

Portescap offers the broadest miniature and specialty motor products in the industry, encompassing coreless brush DC, brushless DC, stepper can stack, gearheads, digital linear actuators, and disc magnet technologies. Portescap products have been serving diverse motion control needs in wide spectrum of medical and industrial applications, lifescience, instrumentation, automation, aerospace and commercial applications, for more than 70 years.

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